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061604 17864 U.S. PTO

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	30207-710.201
First Inventor	Ulrich R. Haug
Title	Everting Heart Valve
Express Mail Label No.	EV 334638890 US

17548 10/870340 U.S. PTO 061604

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

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1. ☐ Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original, and a duplicate for fee processing)*
2. ☒ Applicant claims small entity status. See 37 CFR 1.27.
3. ☒ Specification *[Total Pages 41]*
   (preferred arrangement set forth below)
   - Descriptive title of the invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R&D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Detailed Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. ☒ Drawing(s) (35 U.S.C. 113) *[Total Sheets 63]*
5. ☐ Oath or Declaration *[Total Pages ___]*
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   b. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional with Box 18 completed)*
      i. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76
7. ☐ CD-Rom or CD-R in duplicate, large table or Computer Program *(Appendix)*
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ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney *(when there is an assignee)*
11. ☐ English Translation Document *(if applicable)*
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
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☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No. _____

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PATENT APPLICATION

EVERTING HEART VALVE

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EVERTING HEART VALVE

BACKGROUND OF THE INVENTION

[0001] The present invention relates to methods and apparatus for endovascularly replacing a heart valve. More particularly, the present invention relates to methods and apparatus for endovascularly replacing a heart valve with a replacement valve and an expandable and retrievable anchor. The replacement valve preferably is not connected to the expandable anchor and may be wrapped about an end of the anchor, for example, by everting during endovascular deployment.

[0002] Heart valve surgery is used to repair or replace diseased heart valves. Valve surgery is an open-heart procedure conducted under general anesthesia. An incision is made through the patient's sternum (sternotomy), and the patient's heart is stopped while blood flow is rerouted through a heart-lung bypass machine.

[0003] Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates. When replacing the valve, the native valve is excised and replaced with either a biologic or a mechanical valve. Mechanical valves require lifelong anticoagulant medication to prevent blood clot formation, and clicking of the valve often may be heard through the chest. Biologic tissue valves typically do not require such medication. Tissue valves may be obtained from cadavers or may be porcine or bovine, and are commonly attached to synthetic rings that are secured to the patient's heart.

[0004] Valve replacement surgery is a highly invasive operation with significant concomitant risk. Risks include bleeding, infection, stroke, heart attack, arrhythmia, renal failure, adverse reactions to the anesthesia medications, as well as sudden death. 2-5% of patients die during surgery.

[0005] Post-surgery, patients temporarily may be confused due to emboli and other factors associated with the heart-lung machine. The first 2-3 days following surgery are spent in an intensive care unit where heart functions can be closely monitored. The average hospital stay is between 1 to 2 weeks, with several more weeks to months required for complete recovery.

[0006] In recent years, advancements in minimally invasive surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of

the aortic heart valve. See, e.g., U.S. Pat. No. 6,168,614. In many of these procedures, the replacement valve is deployed across the native diseased valve to permanently hold the valve open, thereby alleviating a need to excise the native valve and to position the replacement valve in place of the native valve.

[0007] In the endovascular aortic valve replacement procedure, accurate placement of aortic valves relative to coronary ostia and the mitral valve is critical. Standard self-expanding systems have very poor accuracy in deployment, however. Often the proximal end of the stent is not released from the delivery system until accurate placement is verified by fluoroscopy, and the stent typically jumps once released. It is therefore often impossible to know where the ends of the stent will be with respect to the native valve, the coronary ostia and the mitral valve.

[0008] Also, visualization of the way the new valve is functioning prior to final deployment is very desirable. Visualization prior to final and irreversible deployment cannot be done with standard self-expanding systems, however, and the replacement valve is often not fully functional before final deployment.

[0009] Another drawback of prior art self-expanding replacement heart valve systems is their lack of radial strength. In order for self-expanding systems to be easily delivered through a delivery sheath, the metal needs to flex and bend inside the delivery catheter without being plastically deformed. In arterial stents, this is not a challenge, and there are many commercial arterial stent systems that apply adequate radial force against the vessel wall and yet can collapse to a small enough of a diameter to fit inside a delivery catheter without plastic deformation. However when the stent has a valve fastened inside it, as is the case in aortic valve replacement, the anchoring of the stent to vessel walls is significantly challenged during diastole. The force to hold back arterial pressure and prevent blood from going back inside the ventricle during diastole will be directly transferred to the stent/vessel wall interface. Therefore, the amount of radial force required to keep the self-expanding stent/valve in contact with the vessel wall and not sliding will be much higher than in stents that do not have valves inside of them. Moreover, a self-expanding stent without sufficient radial force will end up dilating and contracting with each heartbeat, thereby distorting the valve, affecting its function and possibly migrating and dislodging completely. Simply increasing strut thickness of the

self-expanding stent is not a practical solution as it runs the risk of larger profile and/or plastic deformation of the self-expanding stent.

[0010] In view of drawbacks associated with previously known techniques for endovascularly replacing a heart valve, it would be desirable to provide methods and apparatus that overcome those drawbacks.

SUMMARY OF THE INVENTION

[0011] One aspect of the present invention provides apparatus for endovascularly replacing a patient's heart valve, the apparatus including: a replacement valve; and an expandable anchor, wherein the replacement valve and expandable anchor are configured for endovascular delivery to the vicinity of the heart valve, and wherein at least a portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

[0012] Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; everting at least a portion of the replacement valve about the anchor; and expanding the anchor to a deployed configuration.

[0013] Yet another aspect of the invention provides apparatus for endovascularly replacing a patient's heart valve including: an anchor comprising a lip region and a skirt region; and a replacement valve, wherein at least a portion of the replacement valve is configured to evert about the anchor during endovascular deployment, and wherein the lip region and skirt region are configured for percutaneous expansion to engage the patient's heart valve.

[0014] Still another aspect of the present invention provides a method for endovascularly replacing a patient's heart valve, the method including: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve, endovascularly wrapping at least a portion of the replacement valve about the anchor, and expanding the anchor to a deployed configuration.

[0015] Another aspect of the present invention provides apparatus for endovascularly replacing a patient's heart valve, the apparatus including: a replacement valve, and an expandable anchor, wherein the replacement valve and the anchor are configured for

endovascular delivery to a vicinity of the patient's heart valve, and wherein at least a portion of the replacement valve is wrapped about an end of the anchor in a deployed configuration.

INCORPORATION BY REFERENCE

[0016] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0018] Figures 1A-B are elevational views of a replacement heart valve and anchor according to one embodiment of the invention.

[0019] Figures 2A-B are sectional views of the anchor and valve of Figures 1.

[0020] Figures 3A-B show delivery and deployment of a replacement heart valve and anchor, such as the anchor and valve of Figures 1 and 2.

[0021] Figures 4A-F also show delivery and deployment of a replacement heart valve and anchor, such as the anchor and valve of Figures 1 and 2.

[0022] Figures 5A-F show the use of a replacement heart valve and anchor to replace an aortic valve.

[0023] Figures 6A-F show the use of a replacement heart valve and anchor with a positive registration feature to replace an aortic valve.

[0024] Figure 7 shows the use of a replacement heart valve and anchor with an alternative positive registration feature to replace an aortic valve.

[0025] Figures 8A-C show another embodiment of a replacement heart valve and anchor according to the invention.

[0026] Figures 9A-H show delivery and deployment of the replacement heart valve and anchor of Figures 8.

[0027] Figure 10 is a cross-sectional drawing of the delivery system used with the method and apparatus of Figures 8 and 9.

[0028] Figures 11A-C show alternative locks for use with replacement heart valves and anchors of this invention.

[0029] Figures 12A-C show a vessel wall engaging lock for use with replacement heart valves and anchors of this invention.

[0030] Figure 13 demonstrates paravalvular leaking around a replacement heart valve and anchor.

[0031] Figure 14 shows a seal for use with a replacement heart valve and anchor of this invention.

[0032] Figures 15A-E show alternative arrangements of seals on a replacement heart valve and anchor.

[0033] Figures 16A-C show alternative seal designs for use with replacement heart valves and anchors.

[0034] Figures 17 show an alternative anchor lock embodiment in an unlocked configuration.

[0035] Figures 18A-B show the anchor lock of Figure 17 in a locked configuration.

[0036] Figure 19 shows an alternative anchor deployment tool attachment and release mechanism for use with the invention.

[0037] Figure 20 shows the attachment and release mechanism of Figure 19 in the process of being released.

[0038] Figure 21 shows the attachment and release mechanism of Figures 19 and 20 in a released condition.

[0039] Figure 22 shows an alternative embodiment of a replacement heart valve and anchor and a deployment tool according to the invention in an undeployed configuration.

[0040] Figure 23 shows the replacement heart valve and anchor of Figure 22 in a partially deployed configuration.

[0041] Figure 24 shows the replacement heart valve and anchor of Figures 22 and 23 in a more fully deployed configuration but with the deployment tool still attached.

[0042] Figure 25 shows yet another embodiment of the delivery and deployment apparatus of the invention in use with a replacement heart valve and anchor.

[0043] Figure 26 shows the delivery and deployment apparatus of Figure 25 in the process of deploying a replacement heart valve and anchor.

[0044] Figure 27 shows an embodiment of the invention employing seals at the interface of the replacement heart valve and anchor and the patient's tissue.

[0045] Figure 28 is a longitudinal cross-sectional view of the seal shown in Figure 27 in compressed form.

[0046] Figure 29 is a transverse cross-sectional view of the seal shown in Figure 28.

[0047] Figure 30 is a longitudinal cross-sectional view of the seal shown in Figure 27 in expanded form.

[0048] Figure 31 is a transverse cross-sectional view of the seal shown in Figure 30.

[0049] Figure 32 shows yet another embodiment of the replacement heart valve and anchor of this invention in an undeployed configuration.

[0050] Figure 33 shows the replacement heart valve and anchor of Figure 32 in a deployed configuration.

[0051] Figure 34 shows the replacement heart valve and anchor of Figures 32 and 33 deployed in a patient's heart valve.

[0052] Figures 35A-H show yet another embodiment of a replacement heart valve, anchor and deployment system according to this invention.

[0053] Figures 36A-E show more detail of the anchor of the embodiment shown in Figures 35A-H.

[0054] Figures 37A-B show other embodiments of the replacement heart valve and anchor of the invention.

[0055] Figures 38A-C illustrate a method for endovascularly replacing a patient's diseased heart valve.

[0056] Figures 39A-G are side views, partially in section, as well as an isometric view, illustrating a method for endovascularly replacing a patient's diseased heart valve with an embodiment of the present invention comprising a replacement valve that is not connected to the expandable anchor, the replacement valve wrapped about the anchor, illustratively by everting during deployment.

[0057] Figures 40A-D are side views, partially in section, illustrating a method for endovascularly replacing a patient's diseased heart valve with another everting embodiment of the present invention.

[0058] Figures 41A-E are side views, partially in section, illustrating a method for endovascularly replacing a patient's diseased heart valve with yet another everting embodiment of the present invention, wherein the replacement valve and the anchor are telescoped relative to one another during endovascular delivery.

[0059] Figures 42A-B are side-sectional views of alternative everting apparatus comprising everting valve leaflets.

[0060] Figures 43A-B, are side-sectional views of further alternative everting apparatus comprising a locking mechanism coupled to the everting segment.

[0061] Figures 44A-B are side-sectional views of telescoping embodiments of the present invention comprising U-shaped valve frames.

DETAILED DESCRIPTION OF THE INVENTION

[0062] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. For example, for the two-part locking mechanisms described hereinafter, it will be apparent that the locations of the male and female elements may be reversed. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

[0063] With reference now to Figures 1-4, a first embodiment of replacement heart valve apparatus in accordance with the present invention is described, including a method of actively foreshortening and expanding the apparatus from a delivery configuration and to a deployed configuration. Apparatus 10 comprises replacement valve 20 disposed within and coupled to anchor 30. Figures 1 schematically illustrate individual cells of anchor 30 of apparatus 10, and should be viewed as if the cylindrical anchor has been cut open and

laid flat. Figures 2 schematically illustrate a detail portion of apparatus 10 in side-section.

[0064] Anchor 30 has a lip region 32, a skirt region 34 and a body region 36. First, second and third posts 38a, 38b and 38c, respectively, are coupled to skirt region 34 and extend within lumen 31 of anchor 30. Posts 38 preferably are spaced 120° apart from one another about the circumference of anchor 30.

[0065] Anchor 30 preferably is fabricated by using self-expanding patterns (laser cut or chemically milled), braids and materials, such as a stainless steel, nickel-titanium ("Nitinol") or cobalt chromium, but alternatively may be fabricated using balloon-expandable patterns where the anchor is designed to plastically deform to its final shape by means of balloon expansion. Replacement valve 20 is preferably made from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues or human cadaver tissue. Alternatively, it can be made from tissue engineered materials (such as extracellular matrix material from Small Intestinal Submucosa (SIS)) or may be prosthetic and made from an elastomeric polymer or silicone, Nitinol or stainless steel mesh or pattern (sputtered, chemically milled or laser cut). The leaflet may also be made of a composite of the elastomeric or silicone materials and metal alloys or other fibers such Kevlar or carbon. Annular base 22 of replacement valve 20 preferably is coupled to skirt region 34 of anchor 30, while commissures 24 of replacement valve leaflets 26 are coupled to and supported by posts 38.

[0066] Anchor 30 may be actuated using external non-hydraulic or non-pneumatic force to actively foreshorten in order to increase its radial strength. As shown below, the proximal and distal end regions of anchor 30 may be actuated independently. The anchor and valve may be placed and expanded in order to visualize their location with respect to the native valve and other anatomical features and to visualize operation of the valve. The anchor and valve may thereafter be repositioned and even retrieved into the delivery sheath or catheter. The apparatus may be delivered to the vicinity of the patient's aortic valve in a retrograde approach in a catheter having a diameter no more than 23 french, preferably no more than 21 french, more preferably no more than 19 french, or more preferably no more than 17 french. Upon deployment the anchor and replacement valve

capture the native valve leaflets and positively lock to maintain configuration and position.

[0067] A deployment tool is used to actuate, reposition, lock and/or retrieve anchor 30. In order to avoid delivery of anchor 30 on a balloon for balloon expansion, a non-hydraulic or non-pneumatic anchor actuator is used. In this embodiment, the actuator is a deployment tool that includes distal region control wires 50, control rods or tubes 60 and proximal region control wires 62. Locks 40 include posts or arms 38 preferably with male interlocking elements 44 extending from skirt region 34 and mating female interlocking elements 42 in lip region 32. Male interlocking elements 44 have eyelets 45. Control wires 50 pass from a delivery system for apparatus 10 through female interlocking elements 42, through eyelets 45 of male interlocking elements 44, and back through female interlocking elements 42, such that a double strand of wire 50 passes through each female interlocking element 42 for manipulation by a medical practitioner external to the patient to actuate and control the anchor by changing the anchor's shape. Control wires 50 may comprise, for example, strands of suture.

[0068] Tubes 60 are reversibly coupled to apparatus 10 and may be used in conjunction with wires 50 to actuate anchor 30, e.g., to foreshorten and lock apparatus 10 in the fully deployed configuration. Tubes 60 also facilitate repositioning and retrieval of apparatus 10, as described hereinafter. For example, anchor 30 may be foreshortened and radially expanded by applying a distally directed force on tubes 60 while proximally retracting wires 50. As seen in Figures 3, control wires 62 pass through interior lumens 61 of tubes 60. This ensures that tubes 60 are aligned properly with apparatus 10 during deployment and foreshortening. Control wires 62 can also actuate anchor 60; proximally directed forces on control wires 62 contacts the proximal lip region 32 of anchor 30. Wires 62 also act to couple and decouple tubes 60 from apparatus 10. Wires 62 may comprise, for example, strands of suture.

[0069] Figures 1A and 2A illustrate anchor 30 in a delivery configuration or in a partially deployed configuration (e.g., after dynamic self-expansion from a constrained delivery configuration within a delivery sheath). Anchor 30 has a relatively long length and a relatively small width in the delivery or partially deployed configuration, as compared to the foreshortened and fully deployed configuration of Figures 1B and 2B.

[0070] In Figures 1A and 2A, replacement valve 20 is collapsed within lumen 31 of anchor 30. Retraction of wires 50 relative to tubes 60 foreshortens anchor 30, which increases the anchor's width while decreasing its length. Such foreshortening also properly seats replacement valve 20 within lumen 31 of anchor 30. Imposed foreshortening will enhance radial force applied by apparatus 10 to surrounding tissue over at least a portion of anchor 30. In some embodiments, the anchor is capable of exerting an outward radial force on surrounding tissue to engage the tissue in such way to prevent migration of anchor. This outward radial force is preferably greater than 2 psi, more preferably greater than 4 psi, more preferably greater than 6 psi, more preferably greater than 8 psi, more preferably greater than 10 psi, more preferably greater than 20 psi, or more preferably greater than 30 psi. Enhanced radial force of the anchor is also important for enhanced crush resistance of the anchor against the surrounding tissue due to the healing response (fibrosis and contraction of annulus over a longer period of time) or to dynamic changes of pressure and flow at each heart beat. In an alternative embodiment, the anchor pattern or braid is designed to have gaps or areas where the native tissue is allowed to protrude through the anchor slightly (not shown) and, as the foreshortening is applied, the tissue and anchor become intertwined and immobilized. This feature would provide additional means to prevent anchor migration and enhance long-term stability of the device.

[0071] Deployment of apparatus 10 is fully reversible until lock 40 has been locked via mating of male interlocking elements 44 with female interlocking elements 42. Deployment is then completed by decoupling tubes 60 from lip section 32 of anchor 30 by retracting one end of each wire 62 relative to the other end of the wire, and by retracting one end of each wire 50 relative to the other end of the wire until each wire has been removed from eyelet 45 of its corresponding male interlocking element 44.

[0072] As best seen in Figure 2B, body region 36 of anchor 30 optionally may comprise barb elements 37 that protrude from anchor 30 in the fully deployed configuration, for example, for engagement of a patient's native valve leaflets and to preclude migration of the apparatus.

[0073] With reference now to Figures 3, a delivery and deployment system for a self-expanding embodiment of apparatus 10 including a sheath 110 having a lumen 112. Self-

expanding anchor 30 is collapsible to a delivery configuration within lumen 112 of sheath 110, such that apparatus 10 may be delivered via delivery system 100. As seen in Figure 3A, apparatus 10 may be deployed from lumen 112 by retracting sheath 110 relative to apparatus 10, control wires 50 and tubes 60, which causes anchor 30 to dynamically self-expand to a partially deployed configuration. Control wires 50 then are retracted relative to apparatus 10 and tubes 60 to impose foreshortening upon anchor 30, as seen in Figure 3B.

[0074] During foreshortening, tubes 60 push against lip region 32 of anchor 30, while wires 50 pull on posts 38 of the anchor. Wires 62 may be retracted along with wires 50 to enhance the distally directed pushing force applied by tubes 60 to lip region 32. Continued retraction of wires 50 relative to tubes 60 would lock locks 40 and fully deploy apparatus 10 with replacement valve 20 properly seated within anchor 30, as in Figures 1B and 2B. Apparatus 10 comprises enhanced radial strength in the fully deployed configuration as compared to the partially deployed configuration of Figure 3A. Once apparatus 10 has been fully deployed, wires 50 and 62 may be removed from apparatus 10, thereby separating delivery system 100 and tubes 60 from the apparatus.

[0075] Deployment of apparatus 10 is fully reversible until locks 40 have been actuated. For example, just prior to locking the position of the anchor and valve and the operation of the valve may be observed under fluoroscopy. If the position needs to be changed, by alternately relaxing and reapplying the proximally directed forces exerted by control wires 50 and/or control wires 62 and the distally directed forces exerted by tubes 60, expansion and contraction of the lip and skirt regions of anchor 30 may be independently controlled so that the anchor and valve can be moved to, e.g., avoid blocking the coronary ostia or impinging on the mitral valve. Apparatus 10 may also be completely retrieved within lumen 112 of sheath 110 by simultaneously proximally retracting wires 50 and tubes 60/wires 62 relative to sheath 110. Apparatus 10 then may be removed from the patient or repositioned for subsequent redeployment.

[0076] Referring now to Figures 4, step-by-step deployment of apparatus 10 via delivery system 100 is described. In Figure 4A, sheath 110 is retracted relative to apparatus 10, wires 50 and tubes 60, thereby causing self-expandable anchor 30 to dynamically self-expand apparatus 10 from the collapsed delivery configuration within lumen 112 of

sheath 110 to the partially deployed configuration. Apparatus 10 may then be dynamically repositioned via tubes 60 to properly orient the apparatus, e.g. relative to a patient's native valve leaflets.

[0077] In Figure 4B, control wires 50 are retracted while tubes 60 are advanced, thereby urging lip region 32 of anchor 30 in a distal direction while urging posts 38 of the anchor in a proximal direction. This foreshortens apparatus 10, as seen in Figure 4C. Deployment of apparatus 10 is fully reversible even after foreshortening has been initiated and has advanced to the point illustrated in Figure 4C.

[0078] In Figure 4D, continued foreshortening causes male interlocking elements 44 of locks 40 to engage female interlocking elements 42. The male elements mate with the female elements, thereby locking apparatus 10 in the foreshortened configuration, as seen in Figure 4E. Wires 50 are then pulled through eyelets 45 of male elements 44 to remove the wires from apparatus 10, and wires 62 are pulled through the proximal end of anchor 30 to uncouple tubes 60 from the apparatus, thereby separating delivery system 100 from apparatus 10. Fully deployed apparatus 10 is shown in Figure 4F.

[0079] Referring to Figures 5, a method of endovascularly replacing a patient's diseased aortic valve with apparatus 10 and delivery system 100 is described. As seen in Figure 5A, sheath 110 of delivery system 100, having apparatus 10 disposed therein, is endovascularly advanced over guide wire **G**, preferably in a retrograde fashion (although an antegrade or hybrid approach alternatively may be used), through a patient's aorta **A** to the patient's diseased aortic valve **AV**. A nosecone 102 precedes sheath 110 in a known manner. In Figure 5B, sheath 110 is positioned such that its distal region is disposed within left ventricle **LV** of the patient's heart **H**.

[0080] Apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance, such that anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration, as in Figure 5C. Advantageously, apparatus 10 may be retracted within lumen 112 of sheath 110 via wires 50 - even after anchor 30 has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition apparatus 10 or delivery system 100. As yet another advantage, apparatus 10 may be dynamically repositioned, e.g. via sheath 110 and/or tubes 60, in order to properly align the apparatus relative to anatomical landmarks, such

as the patient's coronary ostia or the patient's native valve leaflets **L**. When properly aligned, skirt region 34 of anchor 30 preferably is disposed distal of the leaflets, while body region 36 is disposed across the leaflets and lip region 32 is disposed proximal of the leaflets.

[0081] Once properly aligned, wires 50 are retracted relative to tubes 60 to impose foreshortening upon anchor 30 and expand apparatus 10 to the fully deployed configuration, as in Figure 5D. Foreshortening increases the radial strength of anchor 30 to ensure prolonged patency of valve annulus **An**, as well as to provide a better seal for apparatus 10 that reduces paravalvular regurgitation. As seen in Figure 5E, locks 40 maintain imposed foreshortening. Replacement valve 20 is properly seated within anchor 30, and normal blood flow between left ventricle **LV** and aorta **A** is thereafter regulated by apparatus 10. Deployment of apparatus 10 advantageously is fully reversible until locks 40 have been actuated.

[0082] As seen in Figure 5F, wires 50 are pulled from eyelets 45 of male elements 44 of locks 40, tubes 60 are decoupled from anchor 30, e.g. via wires 62, and delivery system 100 is removed from the patient, thereby completing deployment of apparatus 10. Optional barb elements 37 engage the patient's native valve leaflets, e.g. to preclude migration of the apparatus and/or reduce paravalvular regurgitation.

[0083] With reference now to Figures 6, a method of endovascularly replacing a patient's diseased aortic valve with apparatus 10 is provided, wherein proper positioning of the apparatus is ensured via positive registration of a modified delivery system to the patient's native valve leaflets. In Figure 6A, modified delivery system 100' delivers apparatus 10 to diseased aortic valve **AV** within sheath 110. As seen in Figures 6B and 6C, apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance, such that anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration. As when deployed via delivery system 100, deployment of apparatus 10 via delivery system 100' is fully reversible until locks 40 have been actuated.

[0084] Delivery system 100' comprises leaflet engagement element 120, which preferably self-expands along with anchor 30. Engagement element 120 is disposed between tubes 60 of delivery system 100' and lip region 32 of anchor 30. Element 120

releasably engages the anchor. As seen in Figure 6C, the element is initially deployed proximal of the patient's native valve leaflets **L**. Apparatus 10 and element 120 then may be advanced/dynamically repositioned until the engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus 10. Also, delivery system 100' includes filter structure 61A (e.g., filter membrane or braid) as part of push tubes 60 to act as an embolic protection element. Emboli can be generated during manipulation and placement of anchor, from either diseased native leaflet or surrounding aortic tissue, and can cause blockage. Arrows 61B in Figure 6E show blood flow through filter structure 61A where blood is allowed to flow but emboli is trapped in the delivery system and removed with it at the end of the procedure.

[0085] Alternatively, foreshortening may be imposed upon anchor 30 while element 120 is disposed proximal of the leaflets, as in Figure 6D. Upon positive registration of element 120 against leaflets **L**, element 120 precludes further distal migration of apparatus 10 during additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. Figure 6E details engagement of element 120 against the native leaflets. As seen in Figure 6F, once apparatus 10 is fully deployed, element 120, wires 50 and tubes 60 are decoupled from the apparatus, and delivery system 100' is removed from the patient, thereby completing the procedure.

[0086] With reference to Figure 7, an alternative embodiment of the apparatus of Figures 6 is described, wherein leaflet engagement element 120 is coupled to anchor 30 of apparatus 10', rather than to delivery system 100. Engagement element 120 remains implanted in the patient post-deployment of apparatus 10'. Leaflets **L** are sandwiched between lip region 32 of anchor 30 and element 120 in the fully deployed configuration. In this manner, element 120 positively registers apparatus 10' relative to the leaflets and precludes distal migration of the apparatus over time.

[0087] Referring now to Figures 8, an alternative delivery system adapted for use with a balloon expandable embodiment of the present invention is described. In Figure 8A, apparatus 10'' comprises anchor 30' that may be fabricated from balloon-expandable materials. Delivery system 100'' comprises inflatable member 130 disposed in a deflated configuration within lumen 31 of anchor 30'. In Figure 8B, optional outer sheath 110 is retracted, and inflatable member 130 is inflated to expand anchor 30' to the fully

deployed configuration. As inflatable member 130 is being deflated, as in earlier embodiments, wires 50 and 62 and tubes 60 may be used to assist deployment of anchor 30' and actuation of locks 40, as well as to provide reversibility and retrievability of apparatus 10'' prior to actuation of locks 40. Next, wires 50 and 62 and tubes 60 are removed from apparatus 10'', and delivery system 100'' is removed, as seen in Figure 8C.

[0088] As an alternative delivery method, anchor 30' may be partially deployed via partial expansion of inflatable member 130. The inflatable member would then be advanced within replacement valve 20 prior to inflation of inflatable member 130 and full deployment of apparatus 10''. Inflation pressures used will range from about 3 to 6 atm, or more preferably from about 4 to 5 atm, though higher and lower atm pressures may also be used (e.g., greater than 3 atm, more preferably greater than 4 atm, more preferably greater than 5 atm, or more preferably greater than 6 atm). Advantageously, separation of inflatable member 130 from replacement valve 20, until partial deployment of apparatus 10'' at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This profile reduction may facilitate retrograde delivery and deployment of apparatus 10'', even when anchor 30' is balloon-expandable.

[0089] Although anchor 30' has illustratively been described as fabricated from balloon-expandable materials, it should be understood that anchor 30' alternatively may be fabricated from self-expanding materials whose expansion optionally may be balloon-assisted. In such a configuration, anchor 30' would expand to a partially deployed configuration upon removal of outer sheath 110. If required, inflatable member 130 then would be advanced within replacement valve 20 prior to inflation. Inflatable member 130 would assist full deployment of apparatus 10'', for example, when the radial force required to overcome resistance from impinging tissue were too great to be overcome simply by manipulation of wires 50 and tubes 60. Advantageously, optional placement of inflatable member 130 within replacement valve 20, only after dynamic self-expansion of apparatus 10'' to the partially deployed configuration at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This reduction may facilitate retrograde delivery and deployment of apparatus 10''.

[0090] With reference to Figures 9 and 10, methods and apparatus for a balloon-assisted embodiment of the present invention are described in greater detail. Figures 9 and 10 illustratively show apparatus 10' of Figures 7 used in combination with delivery system 100'' of Figures 8. Figure 10 illustrates a sectional view of delivery system 100''. Inner shaft 132 of inflatable member 130 preferably is about 4 Fr in diameter, and comprises lumen 133 configured for passage of guidewire **G**, having a diameter of about 0.035", therethrough. Push tubes 60 and pull wires 50 pass through guidetube 140, which preferably has a diameter of about 15 Fr or smaller. Guide tube 140 is disposed within lumen 112 of outer sheath 110, which preferably has a diameter of about 17 Fr or smaller.

[0091] In Figure 9A, apparatus 10' is delivered to diseased aortic valve **AV** within lumen 112 of sheath 110. In Figure 9B, sheath 110 is retracted relative to apparatus 10' to dynamically self-expand the apparatus to the partially deployed configuration. Also retracted and removed is nosecone 102, which is attached to a pre-slit lumen (not shown) that facilitates its removal prior to loading and advancing of a regular angioplasty balloon catheter over guidewire and inside delivery system 110.

[0092] In Figure 9C, pull wires 50 and push tubes 60 are manipulated from external to the patient to foreshorten anchor 30 and sufficiently expand lumen 31 of the anchor to facilitate advancement of inflatable member 130 within replacement valve 20. Also shown is the tip of an angioplasty catheter 130 being advanced through delivery system 110.

[0093] The angioplasty balloon catheter or inflatable member 130 then is advanced within the replacement valve, as in Figure 9D, and additional foreshortening is imposed upon anchor 30 to actuate locks 40, as in Figure 9E. The inflatable member is inflated to further displace the patient's native valve leaflets **L** and ensure adequate blood flow through, and long-term patency of, replacement valve 20, as in Figure 9F. Inflatable member 130 then is deflated and removed from the patient, as in Figure 9G. A different size angioplasty balloon catheter could be used repeat the same step if deemed necessary by the user. Push tubes 60 optionally may be used to further set leaflet engagement element 120, or optional barbs **B** along posts 38, more deeply within leaflets **L**, as in Figure 9H. Then, delivery system 100'' is removed from the patient, thereby completing percutaneous heart valve replacement.

[0094] As will be apparent to those of skill in the art, the order of imposed foreshortening and balloon expansion described in Figures 9 and 10 is only provided for the sake of illustration. The actual order may vary according to the needs of a given patient and/or the preferences of a given medical practitioner. Furthermore, balloon-assist may not be required in all instances, and the inflatable member may act merely as a safety precaution employed selectively in challenging clinical cases.

[0095] Referring now to Figures 11, alternative locks for use with apparatus of the present invention are described. In Figure 11A, lock 40' comprises male interlocking element 44 as described previously. However, female interlocking element 42' illustratively comprises a triangular shape, as compared to the round shape of interlocking element 42 described previously. The triangular shape of female interlocking element 42' may facilitate mating of male interlocking element 44 with the female interlocking element without necessitating deformation of the male interlocking element.

[0096] In Figure 11B, lock 40'' comprises alternative male interlocking element 44' having multiple in-line arrowheads 46 along posts 38. Each arrowhead comprises resiliently deformable appendages 48 to facilitate passage through female interlocking element 42. Appendages 48 optionally comprise eyelets 49, such that control wire 50 or a secondary wire may pass therethrough to constrain the appendages in the deformed configuration. To actuate lock 40'', one or more arrowheads 46 of male interlocking element 44' are drawn through female interlocking element 42, and the wire is removed from eyelets 49, thereby causing appendages 48 to resiliently expand and actuate lock 40''.

[0097] Advantageously, providing multiple arrowheads 46 along posts 38 yields a ratchet that facilitates *in-vivo* determination of a degree of foreshortening imposed upon apparatus of the present invention. Furthermore, optionally constraining appendages 48 of arrowheads 46 via eyelets 49 prevents actuation of lock 40'' (and thus deployment of apparatus of the present invention) even after male element 44' has been advanced through female element 42. Only after a medical practitioner has removed the wire constraining appendages 48 is lock 40'' fully engaged and deployment no longer reversible.

[0098] Lock 40''' of Figure 11C is similar to lock 40'' of Figure 11B, except that optional eyelets 49 on appendages 48 have been replaced by optional overtube 47. Overtube 47 serves a similar function to eyelets 49 by constraining appendages 48 to prevent locking until a medical practitioner has determined that apparatus of the present invention has been foreshortened and positioned adequately at a treatment site. Overtube 47 is then removed, which causes the appendages to resiliently expand, thereby fully actuating lock 40'''.

[0099] With reference to Figures 12, an alternative locking mechanism is described that is configured to engage the patient's aorta. Male interlocking elements 44'' of locks 40'''' comprise arrowheads 46' having sharpened appendages 48'. Upon expansion from the delivery configuration of Figure 12A to the foreshortened configuration of Figure 12B, apparatus 10 positions sharpened appendages 48' adjacent the patient's aorta **A**. Appendages 48' engage the aortic wall and reduce a risk of device migration over time.

[00100] With reference now to Figure 13, a risk of paravalvular leakage or regurgitation around apparatus of the present invention is described. In Figure 13, apparatus 10 has been implanted at the site of diseased aortic valve **AV**, for example, using techniques described hereinabove. The surface of native valve leaflets **L** is irregular, and interface **I** between leaflets **L** and anchor 30 may comprise gaps where blood **B** may seep through. Such leakage poses a risk of blood clot formation or insufficient blood flow.

[00101] Referring to Figure 14, optional elements for reducing regurgitation or leakage are described. Compliant sacs 200 may be disposed about the exterior of anchor 30 to provide a more efficient seal along irregular interface **I**. Sacs 200 may be filled with an appropriate material, for example, water, blood, foam or a hydrogel. Alternative fill materials will be apparent.

[00102] With reference to Figures 15, illustrative arrangements for sacs 200 are provided. In Figure 15A, sacs 200 are provided as discrete sacs at different positions along the height of anchor 30. In Figure 15B, the sacs are provided as continuous cylinders at various heights. In Figure 15C, a single sac is provided with a cylindrical shape that spans multiple heights. The sacs of Figure 15D are discrete, smaller and provided in larger quantities. Figure 15E provides a spiral sac. Alternative sac configurations will be apparent to those of skill in the art.

[00103] With reference to Figures 16, exemplary techniques for fabricating sacs 200 are provided. In Figure 16A, sacs 200 comprise 'fish-scale' slots 202 that may be back-filled, for example, with ambient blood passing through replacement valve 20. In Figure 16B, the sacs comprise pores 204 that may be used to fill the sacs. In Figure 16C, the sacs open to lumen 31 of anchor 30 and are filled by blood washing past the sacs as the blood moves through apparatus 10.

[00104] Figures 17 and 18 show yet another alternative embodiment of the anchor lock. Anchor 300 has a plurality of male interlocking elements 302 having eyelets 304 formed therein. Male interlocking elements are connected to braided structure 300 by inter-weaving elements 302 (and 308) or alternatively suturing, soldering, welding, or connecting with adhesive. Valve commissures 24 are connected to male interlocking elements 302 along their length. Replacement valve 20 annular base 22 is connected to the distal end 34 of anchor 300 (or 30) as is illustrated in figures 1A and 1B. Male interlocking elements 302 also include holes 306 that mate with tabs 310 extending into holes 312 in female interlocking elements 308. To lock, control wires 314 passing through eyelets 304 and holes 312 are pulled proximally with respect to the proximal end of braided anchor 300 to draw the male interlocking elements through holes 312 so that tabs 310 engage holes 306 in male interlocking elements 302. Also shown is release wires 314B that pass through eyelet 304B in female interlocking element 308. If needed, during the procedure, the user may pull on release wires 314B, thereby reversing orientation of tabs 310, releasing the anchor and allowing for repositioning of the device or its removal from the patient. Only when finally positioned as desired by the operating physician, would release wire 314B and control wire 314 be cut and removed from the patient with the delivery system.

[00105] Figures 19-21 show an alternative way of releasing the connection between the anchor and its actuating tubes and control wires. Control wires 62 extend through tubes 60 from outside the patient, loop through the proximal region of anchor 30 and extend partially back into tube 60. The doubled up portion of control wire 62 creates a force fit within tube 60 that maintains the control wire's position with respect to tube 60 when all control wires 62 are pulled proximally to place a proximally directed force on anchor 30. When a single control wire 62 is pulled proximally, however, the frictional fit between

that control wire and the tube in which it is disposed is overcome, enabling the end 63 of control wire 62 to pull free of the tube, as shown in Figure 21, thereby releasing anchor 30.

[00106] Figures 22-24 show an alternative embodiment of the anchor. Anchor 350 is made of a metal braid, such as Nitinol or stainless steel. A replacement valve 354 is disposed within anchor 350 and supported by a replacement valve support, such as the posts described in earlier embodiments. Anchor 350 preferably is fabricated from a single strand of metal wire wound into the braid. It is expected that fabricating anchor 350 from a single strand of wire will facilitate deployment of the anchor, as well as retrieval of the anchor, by more evenly distributing forces applied to the anchor. Fabrication from a single strand is also expected to facilitate coupling of replacement valve 354 to the anchor, as well as coupling and decoupling of control wires (not shown) and tubes 352 thereto. Anchor 350 is actuated in substantially the same way as anchor 30 of Figures 1-4 through the application of proximally and distally directed forces from control wires and tubes 352 and may be locked in its expanded deployed configuration, as described above. The employed configuration of anchor 354 may have the shape and anchoring characteristics described with respect to other embodiments as well.

[00107] The braid forming anchor 350 (as well as that forming previously described anchor 30) optionally may be locally increased in diameter, e.g. via dipping in silicone or a hydrogel, in order to provide a better or complete seal against the patient's anatomy. An improved seal is expected to reduce paravalvular leakage, as well as migration of the anchor over time. The local increase in diameter of the braid may, for example, be provided over a full radial segment of anchor 350.

[00108] Figures 25 and 26 show yet another embodiment of the delivery and deployment apparatus of the invention. As an alternative to the balloon expansion method described with respect to Figures 8, in this embodiment the nosecone (e.g., element 102 of Figures 5) is replaced by an angioplasty balloon catheter 360. Thus, angioplasty balloon catheter 360 precedes sheath 110 on guidewire G. When anchor 30 and valve 20 are expanded through the operation of tubes 60 and the control wires (not shown) as described above, balloon catheter 360 is retracted proximally within the expanded anchor and valve and expanded further as described above with respect to Figures 8.

[00109] As an alternative, or in addition, to further expansion of balloon catheter 360 within valve 20 and expanded anchor 30 to further expand the anchor, the balloon may be deflated prior to proximal retraction within and past the valve and anchor. In this manner, balloon catheter 360 may act as an atraumatic nosecone during delivery of valve 20 and anchor 30, but then may be deflated to provide a reduced profile, as compared to a standard nosecone, during retrieval of the balloon catheter through the deployed valve. It is expected that a smaller balloon catheter 360 may be provided when the catheter is utilized merely in place of a nosecone than when the catheter is also utilized to complete expansion of anchor 30.

[00110] Figures 27-31 show seals 370 that expand over time to seal the interface between the anchor and valve and the patient's tissue. Seals 370 are preferably formed from Nitinol wire surrounded by an expandable foam. As shown in cross-section in Figures 28 and 29, at the time of deployment, the foam 372 is compressed about the wire 374 and held in the compressed form by a time-released coating 376. After deployment, coating 376 dissolves in vivo to allow foam 372 to expand, as shown in Figures 30 and 31.

[00111] Figures 32-34 show another way to seal the replacement valve against leakage. A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. When deployed, as shown in Figures 33 and 34, fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve.

[00112] Figures 35A-H show another embodiment of a replacement heart valve apparatus in accordance with the present invention. Apparatus 450 comprises replacement valve 460 (see Figures 37B and 38C) disposed within and coupled to anchor 470. Replacement valve 460 is preferably biologic, e.g. porcine, but alternatively may be synthetic. Anchor 470 preferably is fabricated from self-expanding materials, such as a stainless steel wire mesh or a nickel-titanium alloy ("Nitinol"), and comprises lip region 472, skirt region 474, and body regions 476a, 476b and 476c. Replacement valve 460 preferably is coupled to skirt region 474, but alternatively may be coupled to other regions of the anchor. As described hereinbelow, lip region 472 and skirt region 474 are configured to

expand and engage/capture a patient's native valve leaflets, thereby providing positive registration, reducing paravalvular regurgitation, reducing device migration, etc.

[00113] As seen in Figure 35A, apparatus 450 is collapsible to a delivery configuration, wherein the apparatus may be delivered via delivery system 410. Delivery system 410 comprises sheath 420 having lumen 422, as well as wires 424a and 424b seen in Figures 35D-35G. Wires 424a are configured to expand skirt region 474 of anchor 470, as well as replacement valve 460 coupled thereto, while wires 424b are configured to expand lip region 472.

[00114] As seen in Figure 35B, apparatus 450 may be delivered and deployed from lumen 422 of catheter 420 while the apparatus is disposed in the collapsed delivery configuration. As seen in Figures 35B-35D, catheter 420 is retracted relative to apparatus 450, which causes anchor 470 to dynamically self-expand to a partially deployed configuration. Wires 424a are then retracted to expand skirt region 474, as seen in Figures 35E and 35F. Preferably, such expansion may be maintained via locking features described hereinafter.

[00115] In Figure 35G, wires 424b are retracted to expand lip region 472 and fully deploy apparatus 450. As with skirt region 474, expansion of lip region 472 preferably may be maintained via locking features. After both lip region 472 and skirt region 474 have been expanded, wires 424 may be removed from apparatus 450, thereby separating delivery system 410 from the apparatus. Delivery system 410 then may be removed, as seen in Figure 35H.

[00116] As will be apparent to those of skill in the art, lip region 472 optionally may be expanded prior to expansion of skirt region 474. As yet another alternative, lip region 472 and skirt region 474 optionally may be expanded simultaneously, in parallel, in a step-wise fashion or sequentially. Advantageously, delivery of apparatus 450 is fully reversible until lip region 472 or skirt region 474 has been locked in the expanded configuration.

[00117] With reference now to Figures 36A-E, individual cells of anchor 470 of apparatus 450 are described to detail deployment and expansion of the apparatus. In Figure 36A, individual cells of lip region 472, skirt region 474 and body regions 476a, 476b and 476c are shown in the collapsed delivery configuration, as they would appear while disposed

within lumen 422 of sheath 420 of delivery system 410 of Figures 35. A portion of the cells forming body regions 476, for example, every 'nth' row of cells, comprises locking features.

[00118] Body region 476a comprises male interlocking element 482 of lip lock 480, while body region 476b comprises female interlocking element 484 of lip lock 480. Male element 482 comprises eyelet 483. Wire 424b passes from female interlocking element 484 through eyelet 483 and back through female interlocking element 484, such that there is a double strand of wire 424b that passes through lumen 422 of catheter 420 for manipulation by a medical practitioner external to the patient. Body region 476b further comprises male interlocking element 492 of skirt lock 490, while body region 476c comprises female interlocking element 494 of the skirt lock. Wire 424a passes from female interlocking element 494 through eyelet 493 of male interlocking element 492, and back through female interlocking element 494. Lip lock 480 is configured to maintain expansion of lip region 472, while skirt lock 490 is configured to maintain expansion of skirt region 474.

[00119] In Figure 36B, anchor 470 is shown in the partially deployed configuration, e.g., after deployment from lumen 422 of sheath 420. Body regions 476, as well as lip region 472 and skirt region 474, self-expand to the partially deployed configuration. Full deployment is then achieved by retracting wires 424 relative to anchor 470, and expanding lip region 472 and skirt region 474 outward, as seen in Figures 36C and 36D. As seen in Figure 36E, expansion continues until the male elements engage the female interlocking elements of lip lock 480 and skirt lock 490, thereby maintaining such expansion (lip lock 480 shown in Figure 36E). Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated.

[00120] With reference to Figures 37A-B, isometric views, partially in section, further illustrate apparatus 450 in the fully deployed and expanded configuration. Figure 37A illustrates the wireframe structure of anchor 470, while Figure 37B illustrates an embodiment of anchor 470 covered in a biocompatible material **B**. Placement of replacement valve 460 within apparatus 450 may be seen in Figure 37B. The patient's native valve is captured between lip region 472 and skirt region 474 of anchor 470 in the fully deployed configuration (see Figure 38B).

[00121] Referring to Figures 38A-C, in conjunction with Figures 35 and 36, a method for endovascularly replacing a patient's diseased aortic valve with apparatus 450 is described. Delivery system 410, having apparatus 450 disposed therein, is endovascularly advanced, preferably in a retrograde fashion, through a patient's aorta **A** to the patient's diseased aortic valve **AV**. Sheath 420 is positioned such that its distal end is disposed within left ventricle **LV** of the patient's heart **H**. As described with respect to Figures 35, apparatus 450 is deployed from lumen 422 of sheath 420, for example, under fluoroscopic guidance, such that skirt section 474 is disposed within left ventricle **LV**, body section 476b is disposed across the patient's native valve leaflets **L**, and lip section 472 is disposed within the patient's aorta **A**. Advantageously, apparatus 450 may be dynamically repositioned to obtain proper alignment with the anatomical landmarks. Furthermore, apparatus 450 may be retracted within lumen 422 of sheath 420 via wires 424, even after anchor 470 has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition sheath 420.

[00122] Once properly positioned, wires 424a are retracted to expand skirt region 474 of anchor 470 within left ventricle **LV**. Skirt region 474 is locked in the expanded configuration via skirt lock 490, as previously described with respect to Figures 36. In Figure 38A, skirt region 474 is maneuvered such that it engages the patient's valve annulus **An** and/or native valve leaflets **L**, thereby providing positive registration of apparatus 450 relative to the anatomical landmarks.

[00123] Wires 424b are then actuated external to the patient in order to expand lip region 472, as previously described in Figures 35. Lip region 472 is locked in the expanded configuration via lip lock 480. Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated. Wires 424 are pulled from eyelets 483 and 493, and delivery system 410 is removed from the patient. As will be apparent, the order of expansion of lip region 472 and skirt region 474 may be reversed, concurrent, etc.

[00124] As seen in Figure 38B, lip region 472 engages the patient's native valve leaflets **L**, thereby providing additional positive registration and reducing a risk of lip region 472 blocking the patient's coronary ostia **O**. Figure 38C illustrates the same in cross-sectional view, while also showing the position of replacement valve 460. The patient's

native leaflets are engaged and/or captured between lip region 472 and skirt region 474. Advantageously, lip region 472 precludes distal migration of apparatus 450, while skirt region 474 precludes proximal migration. It is expected that lip region 472 and skirt region 474 also will reduce paravalvular regurgitation.

[00125] Referring now to Figures 39, an embodiment of apparatus in accordance with the present invention is described, wherein the replacement valve is not connected to the expandable portion of the anchor. Rather, the replacement valve is wrapped about an end of the anchor. Such wrapping may be achieved, for example, by everting the valve during endovascular deployment.

[00126] In Figures 39, apparatus 500 comprises expandable anchor 30' and everting replacement valve 520, as well as delivery system 100' for endoluminally delivering and deploying the expandable anchor and everting valve. Expandable anchor 30' illustratively is described as substantially the same as previously described anchor 30 of Figures 1-4; however, it should be understood that anchor 30' alternatively may be substantially the same as anchor 300 of Figures 17 and 18, anchor 350 of Figures 24-26, or anchor 470 of Figures 35. As with anchor 30, anchor 30' comprises posts 38 and locks (comprised of elements 523 and 532). Alternative locks may be provided, such as locks 40', 40'', 40''' or 40'''' of Figures 11 and 12, or the reversible lock of anchor 300 described with respect to Figures 17 and 18.

[00127] Everting valve 520 is similar to previously described valve 20, in that commissures 524 of replacement valve leaflets 526 are coupled to and supported by posts 38 of anchor 30'. However, annular base 522 of replacement valve 520 is not coupled to anchor 30'. Rather, annular base 522 is coupled to everting segment 528 of everting replacement valve 520. Everting segment 528 is disposed distal of anchor 30' in the delivery configuration and is configured to wrap about the distal end of the anchor during deployment, such as by everting, thereby holding (such as by friction locking) replacement valve 520 between the anchor and the patient's tissue, thereby creating a seal between the anchor and the patient's tissue. In this manner, replacement valve 520 is entirely disconnected from the expandable/collapsible portion of anchor 30', and a delivery profile of apparatus 500 is reduced, as compared to previously described apparatus 10.

[00128] Everting segment 528 of valve 520 may be fabricated from the same material as valve leaflets 526, e.g., a biologic tissue or a polymeric material. Alternatively, the segment may comprise a fabric, such as a permeable or impermeable fabric, a fabric that promotes or retards tissue ingrowth, a sealing foam, etc. Additional materials will be apparent.

[00129] Delivery system 100' for use with anchor 30' and replacement valve 520, is similar to previously described delivery system 100. The delivery system comprises sheath 110' having lumen 112', in which anchor 30' may be collapsed for delivery. Control wires 50, tubes 60 and control wires 62 have been provided to deploy, foreshorten, retrieve, etc., anchor 30', as discussed previously, and optional balloon catheter 360 has been provided as a collapsible nosecone (see Figure 25). In delivery system 100', the posts are connected to the distal end of the anchor and the everting valve is connected to the posts. Delivery system 100' differs from system 100 in that it further comprises eversion control wires 550, which may, for example, be fabricated from suture.

[00130] Control wires 550 are coupled to a distal region of everting segment 528 of valve 520, and then pass proximally out of the patient external to anchor 30' for manipulation by a medical practitioner. Control wires 550 preferably are kept taut to keep everting segment 528 in tension. Upon retraction of sheath 110' relative to anchor 30' and valve 520 (or advancement of the anchor and valve relative to the sheath), the tension applied to segment 528 by wires 550 causes the segment to evert and wrap about the distal end of anchor 30'. Anchor 30' then may be expanded and deployed as described previously, thereby friction locking everting segment 528 between the anchor and the patient's anatomy.

[00131] Figures 39 illustrate a device and method for endovascularly replacing a patient's diseased aortic valve utilizing apparatus 500. In Figure 39A, sheath 110' of delivery system 100', having expandable anchor 30' and everting valve 520 disposed therein within lumen 112', is endovascularly advanced over guide wire **G**, preferably in a retrograde fashion (although an antegrade or hybrid approach alternatively may be used), through a patient's aorta **A** to the patient's diseased aortic valve **AV**. Balloon catheter nosecone 360 precedes sheath 110'. Sheath 110' is positioned such that its distal region is disposed within left ventricle **LV** of the patient's heart **H.** In Figure 39A, wires 550

pass from segment 528 and lumen 112' to the exterior of sheath 110' via through-holes 111a', and then more proximally pass back into the interior of sheath 110' via through-holes 111b', which are disposed proximal of anchor 30'.

[00132] Figure 39B is a blow-up of the intersection of tubes 60, wires 62 and anchor 30'.

[00133] Figure 39C illustrates the beginning of the everting process wherein everting segment 528 is being pulled proximally over the exterior of anchor 30'. As seen in Figure 39C, which provides and isometric view of the device, the inflatable element of balloon catheter 360 is deflated and further distally advanced within left ventricle **LV** along guide wire **G** relative to sheath 110'. Anchor 30' and replacement valve 520 then are advanced relative to the sheath via tubes 60 and control wires 62, thereby deploying everting segment 528 of valve 520, as well as a distal region of anchor 30', from the distal end of lumen 112'. Tension applied to everting segment 528 via control wires 550 connected through eyelets 529 causes the segment to wrap about the distal region of anchor 30' by everting.

[00134] In Figure 39C, wires 550 may pass distally from everting segment 528 out the distal end of lumen 112' of sheath 110', then proximally along the interior surface of the sheath all the way out of the patient. Optional through-holes 111b' allow wires 550 to be disposed within lumen 112' along a majority of their length. Wires 550 may also pass back into multi-lumen sheath 180.

[00135] Figure 39D provides a cross sectional view of apparatus 500 after replacement valve 520 has everted about anchor 30'. This and other cross sectional figures portray a 120° view of the apparatus herein. Sheath 110' is then retracted relative to anchor 30' and valve 520, which deploys a remainder of the anchor and the replacement valve from lumen 112' of the sheath. Such deployment may be conducted, for example, under fluoroscopic guidance. Anchor 30' dynamically self-expands to a partially deployed configuration.

[00136] Advantageously, anchor 30' and replacement valve 520 may be retrieved and retracted within the lumen of sheath 110' via retraction of multi-lumen catheter 180 to which tubes 60 are attached and release of wires 50. Such retrieval of apparatus 500 may be achieved even after segment 528 has been wrapped about anchor 30', and even after anchor 30' has dynamically expanded to the partially deployed configuration. Retrieval

of apparatus 500 may be utilized, for example, to abort the procedure or to reposition the apparatus. As yet another advantage, anchor 30' and valve 520 may be dynamically repositioned, e.g. via proximal retraction of multi-lumen catheter 180 and/or release of wires 50, in order to properly align the apparatus relative to anatomical landmarks, such as the patient's coronary ostia **O** or the patient's native valve leaflets **L**.

[00137] Once properly aligned sheath 110', tubes 60 and wires 62 are advanced relative to wires 50 and 550 to impose foreshortening upon anchor 30', thereby expanding the anchor to the fully deployed configuration, as in Figure 39G. Foreshortening friction locks everting segment 528 of valve 520 between anchor 30' and annulus **An**/leaflets **L** of the patient's diseased valve, thus properly seating the valve within the anchor while providing an improved seal between the replacement and native valves that is expected to reduce paravalvular regurgitation. Foreshortening also increases a radial strength of anchor 30', which is expected to prolong patency of valve annulus **An**. Furthermore, foreshortening actuates the anchor's locks, which maintain such imposed foreshortening.

[00138] Deployment of anchor 30' and replacement valve 520 advantageously is fully reversible until the anchor locks have been actuated. Furthermore, if the anchor's locks are reversible locks or buckles, such as those described in conjunction with anchor 300 of Figures 17 and 18, deployment of the anchor and valve may be fully reversible even after actuation of the locks/buckles, right up until delivery system 100' is decoupled from the replacement apparatus.

[00139] As seen in Figure 39G, in order to complete deployment of anchor 30' and replacement valve 520, wires 50 of delivery system 100' are decoupled from posts 38 of anchor 30', tubes 60 are decoupled from anchor 30', e.g. via wires 62, and wires 550 are decoupled from friction-locked everting segment 528 of replacement valve 520. Figure 39E illustrates how wires 50 are associated with posts 38. In one example, wires 50 are decoupled from posts 38 by pulling on one of the wires. Decoupling of the wires and tubes may also be achieved, for example, via eyelets (see Figures 4E, 19-21 and 39E) or via cutting of the wires. Delivery system 100' then is removed from the patient, as are deflated balloon catheter 360 and guide wire **G**, both of which are retracted proximally across the replacement valve and anchor. Normal blood flow between left ventricle **LV** and aorta **A** thereafter is regulated by replacement valve 520. Figure 39F is a blow up

illustration of replacement valves 526 which are connected to everting segment 528, wherein everting segment 528 has been everted around anchor 30'.

[00140] Referring now to Figures 40, an alternative embodiment of everting apparatus in accordance with the present invention is described, wherein the posts are connected and the everting valve is disposed within the anchor to the proximal end of the anchor in the delivery configuration. In Figures 40, apparatus 600 comprises everting replacement valve 620 and anchor 630, as well as previously described delivery system 100'. Replacement valve 620 and anchor 630 are substantially the same as valve 520 and anchor 30' of Figures 39, except that valve 620 is initially seated more proximally within anchor 630, such that everting segment 628 of valve 620 is initially disposed within the anchor. Locking mechanisms as described previously may be implemented at the distal end of the post and anchor or proximal end of everted segment and anchor.

[00141] As with replacement valve 520, everting segment 628 of valve 620 is configured to wrap about the distal end of anchor 630 by everting during deployment, thereby friction locking the replacement valve between the anchor and the patient's anatomy. Furthermore, replacement valve 620 is entirely disconnected from the expandable/collapsible portion of anchor 630. In the delivery configuration, since only a single circumferential layer of valve 620 is present along any cross section of apparatus 600, a delivery profile of the apparatus is reduced, as compared to previously described apparatus 10. With apparatus 10, two circumferential layers of valve 20 are present in the cross section where annular base 22 of the valve is coupled to the expandable anchor 30.

[00142] Figures 40 illustrate a method of endovascularly replacing a patient's diseased aortic valve utilizing apparatus 600. In Figure 40A, apparatus 600 is endovascularly advanced into position with valve 620 and anchor 630 disposed within lumen 112' of sheath 110' of delivery system 100'. As seen in Figure 40B, the valve and anchor are advanced relative to the sheath and/or the sheath is retracted relative to the valve and anchor, which deploys everting segment 628 of the valve, as well as a distal region of the anchor. Tension applied to the everting segment via control wires 550 causes the segment to evert and wrap about the distal region of anchor 630. Control wires 550 may enter the multi-lumen catheter at the distal end of the catheter or more proximally as is

illustrated in 40C. Further retraction of sheath 110' deploys a remainder of replacement valve 620 and anchor 630 from lumen 112' of the sheath. Such deployment may be conducted, for example, under fluoroscopic guidance. Anchor 630 dynamically self-expands to a partially deployed configuration.

[00143] Once the anchor and valve have been properly aligned in relation to anatomical landmarks, foreshortening is imposed upon anchor 630 to expand the anchor to the fully deployed configuration, as in Figure 40C. At this point, Locks may be actuated as previously described. Foreshortening friction locks everting segment 628 of valve 620 between anchor 630 and annulus **An**/leaflets **L** of the patient's diseased valve, thus properly seating the valve within the anchor while providing an improved seal between the replacement and native valves. Foreshortening also increases a radial strength of anchor 630, which is expected to prolong patency of valve annulus **An**. Deployed valve 620 and anchor 630 then are decoupled from delivery system 100', as in Figure 40D, thereby completing deployment of apparatus 600. Thereafter, normal blood flow between left ventricle **LV** and aorta **A** is regulated by replacement valve 620.

[00144] As with apparatus 500, apparatus 600 may be dynamically repositioned during deployment, for example, in order to properly align the apparatus relative to anatomical landmarks. Furthermore, apparatus 600 advantageously may be retrieved at any point at least up until actuation of optimal locks maintaining foreshortening. When the optional locks are reversible, retrieval may be achieved until valve 620 and anchor 630 are separated from delivery system 100'.

[00145] Figures 41 illustrate an alternative embodiment of the present invention wherein the everting valve is distal to the anchor and the posts are not connected to the braid in the delivery configuration. As is illustrated in Figure 41A, apparatus 700 comprises everting valve 720 and expandable anchor 730, as well as delivery system 750. Delivery system 750 includes multi-lumen catheter 180. Anchor 730 is fabricated from an expandable braid and comprises female/male element 732 of a locking mechanism, which is preferably reversible. Everting valve 720 comprises valve leaflets 726 and everting segment 728. Everting valve 720 further comprises posts 722 to which valve leaflets 726 are attached to provide commissure support. Posts 722, which are non-expandable and non-collapsible, comprise opposite male/female elements 723 of locking mechanism

comprising eyelets. In the delivery configuration of Figure 41A, anchor 730 may extend distally far enough to just overlap the proximal-most section of valve 720.

[00146] Delivery system 750 is similar to previously described delivery system 100' and includes multi-lumen catheter 180. As with previous embodiments, delivery system 750 facilitates dynamic repositioning and/or retrieval of apparatus 700 after partial or full deployment of the apparatus, e.g., right up until the apparatus is separated from the delivery system.

[00147] As seen in Figure 41A, wires 50 pass from the multi-lumen catheter 180 through the female/male locking mechanism 732, which is associated with anchor 730. Wires 50 then further pass through female/male locking mechanism 723, which is at the proximal end of posts 722. Preferably, a double strand of each wire 50 is provided to facilitate decoupling of wires 50 from valve 720 and anchor 730 in the manner described previously. When wires 50 are pulled proximally into the multi lumen catheter 180, posts 722 move proximally within anchor 730, and the female/male element 723 interacts with female/male element 732 of anchor 730. In this embodiment, when element 723 is male, then element 732 is female, and vice versa.

[00148] Thus, valve 720 and anchor 730 are entirely decoupled from one another in the delivery configuration. Wires 50 are configured to approximate the telescoped valve and anchor, as well as to actuate locking mechanism 740 and contribute to foreshortening of anchor 730. By separating valve 720 and anchor 730 within lumen 112' of sheath 110', a delivery profile of apparatus 700 may be reduced.

[00149] In Figure 41A, apparatus 700 is endovascularly advanced into position with valve 720 and anchor 730 spaced from one another within lumen 112' of sheath 110' of delivery system 750. Substantially all of valve 720 and its supporting posts 722 are disposed distal to the anchor during delivery. As seen in Figure 41B, to evert valve 720, sheath 110' is pulled proximally around anchor 730.

[00150] Next, in Figure 41C, to approximate anchor 730 and valve 720, the elongated braid of anchor 730 is pushed distally to the base of posts 722 using tubes 60 maintained in association with anchor 730 by wire 62. Anchor 730 will engage with the distal end of posts 722 - an anchor engagement feature 729. In some embodiments, as illustrated in

Figure 41C, wires 550 re-enter sheath 110' proximal to the distal end of the multi-lumen catheter 180.

[00151] In Figure 41D, the multi-lumen catheter 180 is held steady, while wires 50 are pulled proximally. This allows the foreshortening of anchor 730 and the engagement of the male and female elements of locking mechanism of 740. Foreshortening friction locks segment 728 of valve 720 against valve annulus **An**/leaflets **L**, thereby properly seating the valve within anchor 730. Foreshortening also completes expansion of anchor 730 and actuates locking mechanism 740, which maintains such expansion of the anchor. Delivery system 750 then may be decoupled from valve 720 and anchor 730, thereby completing deployment of apparatus 700. Normal blood flow between left ventricle **LV** and aorta **A** thereafter is regulated by replacement valve 720.

[00152] With reference now to Figures 42, yet another alternative embodiment of everting apparatus in accordance with the present invention is described, wherein the replacement valve leaflets evert and wrap about the distal region of the anchor. Apparatus 800 comprises everting replacement valve 820 and expandable anchor 830. Valve 820 comprises posts 822, to which valve leaflets 826 are attached. The valve further comprises everting segment 828. Proximal regions 823 of posts 822 are rotatably coupled to a distal region of anchor 830, while distal regions 824 of the posts are coupled to control wires 50.

[00153] In the delivery configuration of Figure 42A, posts 822 (and, thus, valve leaflets 826) and everting segment 828 of replacement valve 820 are disposed distal of anchor 830. Figure 42B illustrates deployment of apparatus 800, whereby tubes 60/wires 62 (see, e.g., Figures 41) are actuated in conjunction with control wires 50 to actively foreshorten anchor 830 and rotate posts 822 into position within the lumen of anchor 830, thereby everting valve leaflets 826 into position within the anchor. Furthermore, eversion wires 550 are actuated to evert segment 828 and wrap the segment about the exterior of anchor 830. Locks 840 maintain expansion and foreshortening of anchor 830.

[00154] Referring to Figures 43, an everting embodiment of the present invention is described wherein a portion of the locking mechanism configured to maintain expansion of the anchor is coupled to the everting segment of the replacement valve instead of, or in addition to, the anchor posts and anchor posts P are only loosely associated with the

anchor 930. Apparatus 900 comprises replacement valve 920 and anchor 930. Everting segment 928 of the replacement valve comprises male elements 942 of locks 940, while anchor 930 comprises female elements 944 of locks 940. Upon deployment of apparatus 900 from the delivery configuration of Figure 43A to the deployed configuration of Figure 43B, segment 928 of replacement valve 920 everts to wrap about the exterior of anchor 930, which is actively foreshortened during expansion. Locks 940 maintain anchor expansion.

[00155] With reference to Figures 44, another telescoping embodiment of the present invention is described wherein the replacement valve comprises a U-shaped frame configured to receive the anchor. Optionally, the valve may comprise an everting segment that everts about the frame and/or the anchor during deployment. Apparatus 1000 comprises replacement valve 1020 and expandable anchor 1030. Replacement valve 1020 comprises frame 1022, leaflets 1026 and optional everting segment 1028.

[00156] Valve 1020 and anchor 1030 are configured for relative movement, such that the valve and anchor may be telescoped and spaced apart during delivery, thereby reducing a delivery profile of apparatus 1000, but may be approximated during deployment. Everting segment 1028 of valve 1020 optionally may be disposed distal of valve frame 1022 during delivery, thereby further reducing a delivery profile of apparatus 1000, then everted during deployment.

[00157] As seen in Figure 44A, the U-shape of valve frame 1022 preferably tilts leaflets 1026 of replacement valve 1020 slightly inward relative to blood flow through apparatus 1000. As seen in Figure 44B, valve frame 1022 optionally may comprise a symmetric U-shape, which captures anchor 1030 on both sides in the deployed configuration. Frame 1022 may comprise lock 1040 that closes the frame's U-shape into an elliptical shape in the deployed configuration, thereby maintaining expansion of anchor 1030.

[00158] Prior to implantation of one of the replacement valves described above, it may be desirable to perform a valvuloplasty on the diseased valve by inserting a balloon into the valve and expanding it using saline mixed with a contrast agent. In addition to preparing the valve site for implant, fluoroscopic viewing of the valvuloplasty will help determine the appropriate size of replacement valve implant to use.

WHAT IS CLAIMED IS:

1. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the expandable anchor are configured for endovascular delivery to a vicinity of the patient's heart valve, and

wherein at least an everting portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

2. The apparatus of claim 1, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

3. The apparatus of claim 1, wherein the replacement valve is adapted to be held between the anchor and patient tissue upon eversion of the everting portion of the replacement valve about the anchor and expansion of the anchor.

4. The apparatus of claim 1 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

5. The apparatus of claim 4 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

6. The apparatus of claim 1 further comprising a delivery system configured to endovascularly deliver the replacement valve and the anchor.

7. The apparatus of claim 6, wherein the delivery system is configured to evert the replacement valve.

8. The apparatus of claim 6, wherein the delivery system is configured to change the anchor's shape.

9. The apparatus of claim 8, wherein the delivery system is configured to actively foreshorten the anchor.

10. The apparatus of claim 1, wherein the anchor and the replacement valve are telescoped relative to one another during endovascular delivery.

11. The apparatus of claim 1 further comprising a lock configured to maintain anchor expansion.

12. The apparatus of claim 1, wherein the anchor further comprises lip and skirt regions configured to expand and engage the patient's heart valve.

13. The apparatus of claim 1, wherein the anchor further comprises a braid fabricated from a single strand of wire.

14. The apparatus of claim 1, wherein the replacement valve further comprises valve leaflets.

15. The apparatus of claim 14, wherein the everting segment comprises a material chosen from the group consisting of biologic materials, polymeric materials, fabric materials, permeable materials, impermeable materials, materials that promote tissue ingrowth, materials that retard tissue ingrowth, foam materials, sealing materials, and combinations thereof.

16. The apparatus of claim 1, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

17. The apparatus of claim 16, further comprising a supporting connection between the replacement valve and the replacement valve support.

18. The apparatus of claim 17, wherein the supporting connection is adapted to support replacement valve commissures.

19. The apparatus of claim 16, wherein the replacement valve support and at least a portion of the anchor are adapted to move with respect to each other during endovascular deployment of the anchor and replacement valve.

20. The apparatus of claim 16, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

21. A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor; and

expanding the anchor to a deployed configuration.

22. The method of claim 21, further comprising using the everting portion of the replacement valve as a seal between the anchor and patient tissue.

23. The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises holding the replacement valve between the anchor and patient tissue.

24. The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

25. The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises expanding lip and skirt regions of the anchor into engagement with the patient's heart valve.

26. The method of claim 21, further comprising approximating the anchor and the replacement valve.

27. The method of claim 21, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

28. The method of claim 27, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

29. The method of claim 21, further comprising locking the anchor in the deployed configuration.

30. The method of claim 21, further comprising repositioning the replacement valve and the anchor.

31. The method of claim 21, further comprising retrieving the replacement valve and the anchor.

32. The method of claim 21, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

33. The method of claim 32, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

34. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor having a lip region and a skirt region; and

a replacement valve,

wherein at least an everting portion of the replacement valve is configured to evert about the skirt region of the anchor during endovascular deployment, and

wherein the lip and skirt regions of the anchor are configured for percutaneous expansion to engage the patient's heart valve.

35. The apparatus of claim 34, wherein percutaneous expansion of the skirt region is configured to hold the everting portion of the replacement valve between the skirt region and the patient's heart valve.

36. The apparatus of claim 34, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

37. The apparatus of claim 34, wherein the anchor further comprises a braid fabricated from a single strand of wire.

38. A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor; and

expanding the anchor to a deployed configuration.

39. The method of claim 38, further comprising using the wrapping portion of the replacement valve as a seal between the anchor and patient tissue.

40. The method of claim 38, wherein expanding the anchor to the deployed configuration further comprises holding the wrapping portion of the replacement valve between the anchor and patient tissue.

41. The method of claim 38, wherein wrapping at least a portion of the replacement valve about the anchor further comprises everting at least a portion of the replacement valve about the anchor.

42. The method of claim 38 wherein endovascularly delivering the replacement valve and anchor further comprises delivering and deploying the valve and anchor without connecting the valve to expandable portions of the anchor.

43. The method of claim 38, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

44. The method of claim 43, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

45. The method of claim 39, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

46. The method of claim 45, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

47. The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

48. The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises approximating the anchor and the replacement valve.

49. The method of claim 39 further comprising locking the anchor in the deployed configuration.

50. The method of claim 39 further comprising repositioning the replacement valve and the anchor.

51. The method of claim 39 further comprising retrieving the replacement valve and the anchor.

52. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the anchor are configured for endovascular delivery to a vicinity of the patient's heart valve with no portion of the replacement valve being wrapped about the anchor, and

wherein at least a wrapping portion of the replacement valve is configured to be wrapped about an end of the anchor in a deployed configuration.

53. The apparatus of claim 52, wherein the wrapping portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

54. The apparatus of claim 52 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

55. The apparatus of claim 54 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

56. The apparatus of claim 52, wherein the replacement valve is not connected to the expandable anchor.

57. The apparatus of claim 52, wherein at least a portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

58. The apparatus of claim 52, wherein the wrapped portion of the replacement valve is configured to be held between the anchor and the patient tissue upon endovascular deployment.

59. The apparatus of claim 52, wherein the expandable anchor is configured for active foreshortening during endovascular deployment.

60. The apparatus of claim 52 further comprising a lock configured to maintain expansion of the anchor.

61. The apparatus of claim 52, wherein the lock is reversible.

62. The apparatus of claim 52, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

63. The apparatus of claim 62, further comprising a supporting connection between the replacement valve and the replacement valve support.

64. The apparatus of claim 63, wherein the supporting connection is adapted to support replacement valve commissures.

65. The apparatus of claim 62, wherein the replacement valve support is adapted to move with respect to the anchor during endovascular deployment of the anchor and replacement valve.

66. The apparatus of claim 62, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

67. The apparatus of claim 62, wherein the anchor comprises a braid fabricated from a single strand of wire.

EVERTING HEART VALVE
ABSTRACT OF THE DISCLOSURE

The present invention provides methods and apparatus for endovascularly replacing a patient's heart valve. The apparatus includes a replacement valve and an expandable anchor configured for endovascular delivery to a vicinity of the patient's heart valve. In some embodiments, the replacement valve is adapted to wrap about the anchor, for example, by everting during endovascular deployment. In some embodiments, the replacement valve is not connected to expandable portions of the anchor. In some embodiments, the anchor is configured for active foreshortening during endovascular deployment. In some embodiments, the anchor includes expandable lip and skirt regions for engaging the patient's heart valve during deployment. In some embodiments, the anchor comprises a braid fabricated from a single strand of wire. In some embodiments, the apparatus includes a lock configured to maintain anchor expansion. The invention also includes methods for endovascularly replacing a patient's heart valve. In some embodiments, the method includes the steps of endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve, wrapping at least a portion of the replacement valve about the anchor, and expanding the anchor to a deployed configuration.

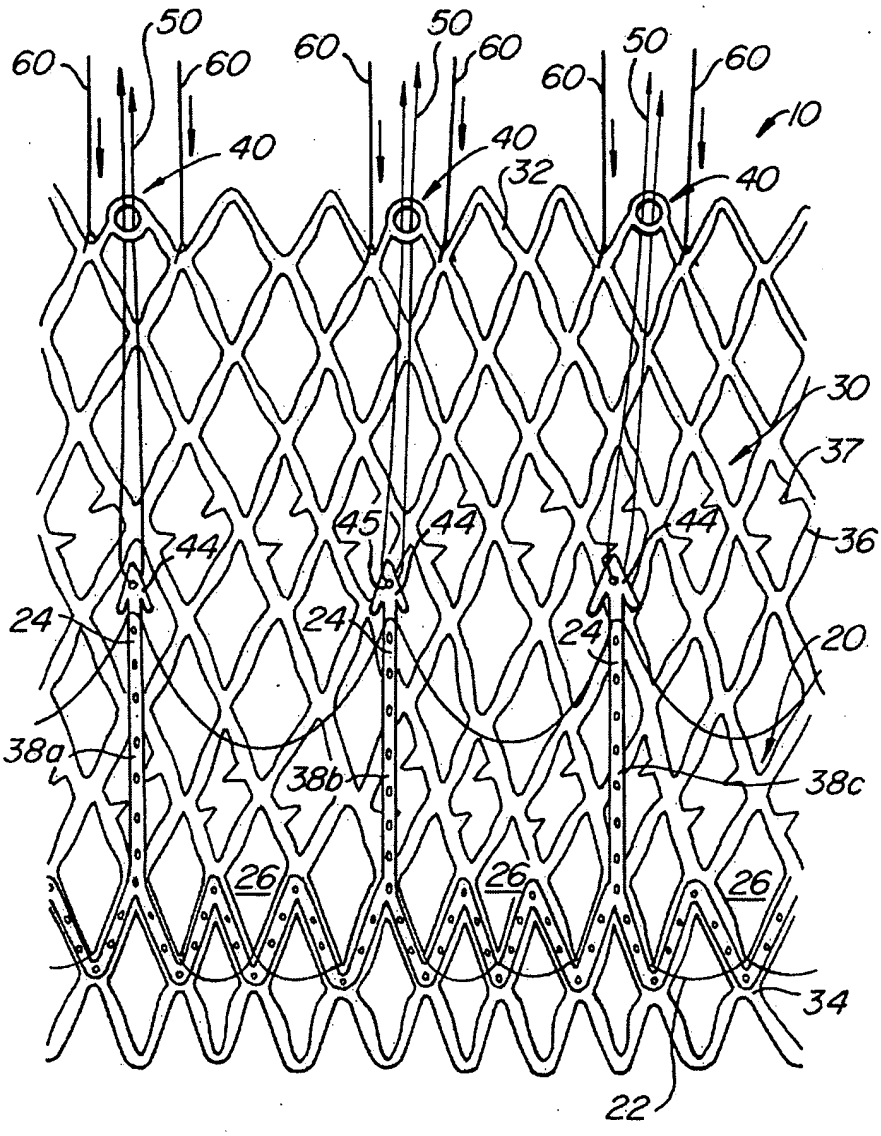
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FIG. 1A

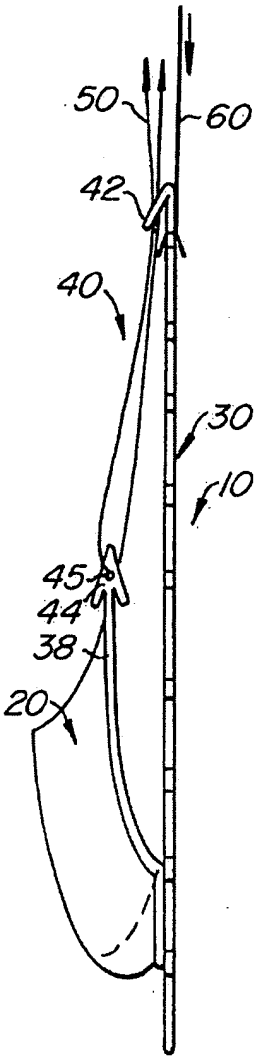
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FIG. 2A

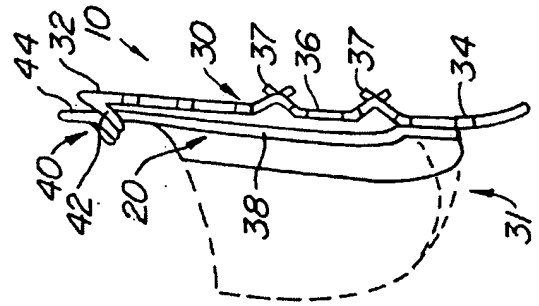
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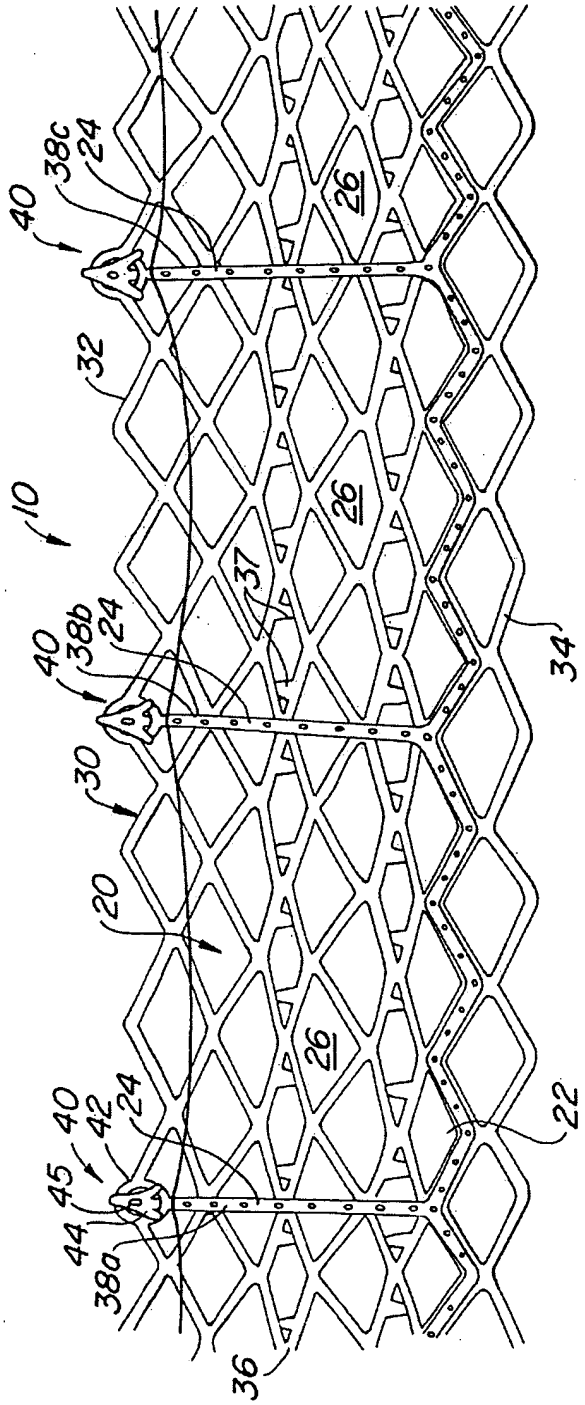
FIG. 2B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38a
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FIG. 1B

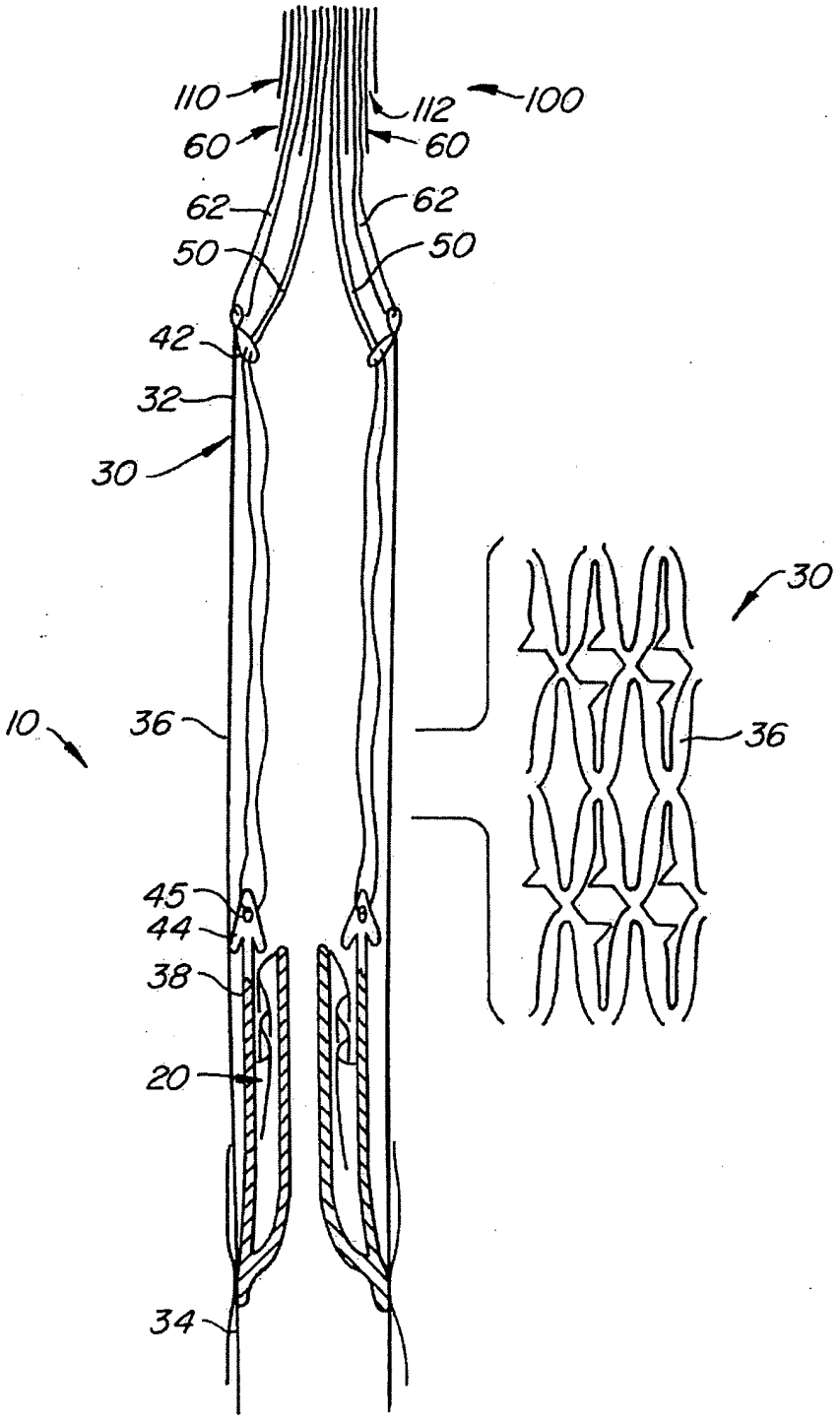

FIG. 3A

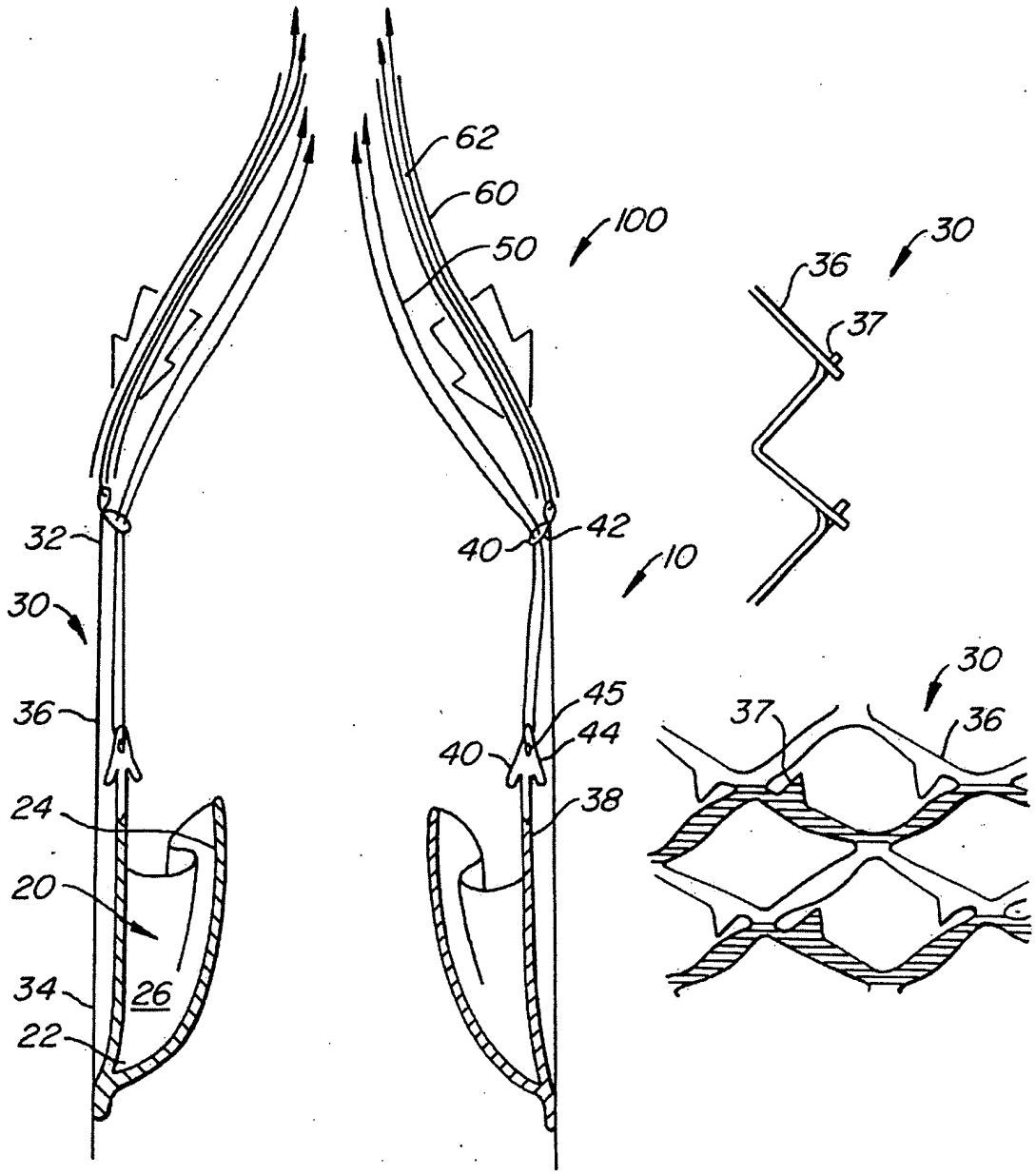
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FIG. 3B

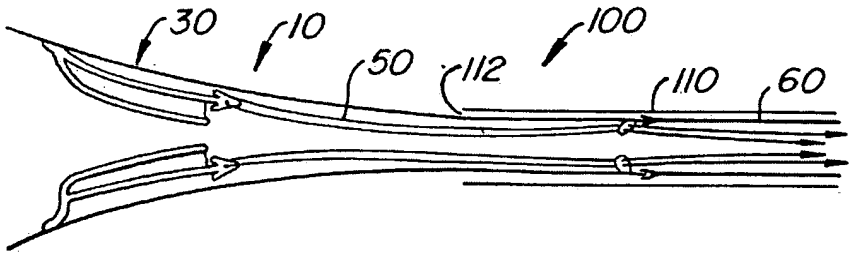

FIG. 4A

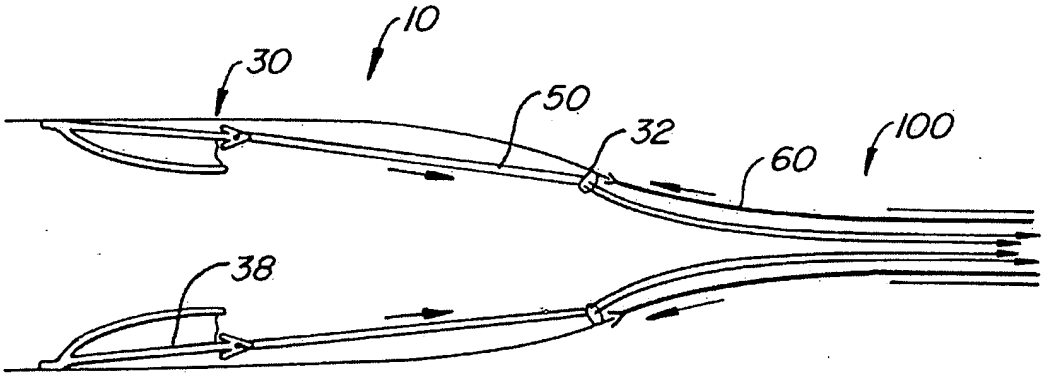

FIG. 4B

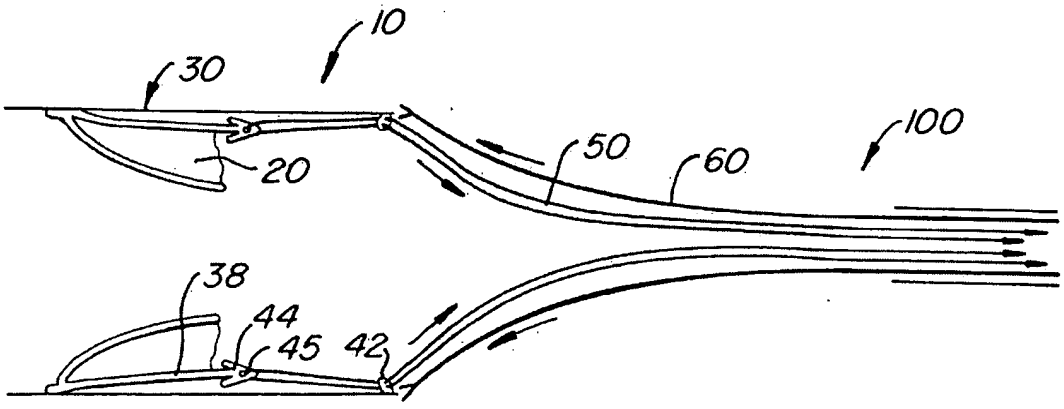

FIG. 4C

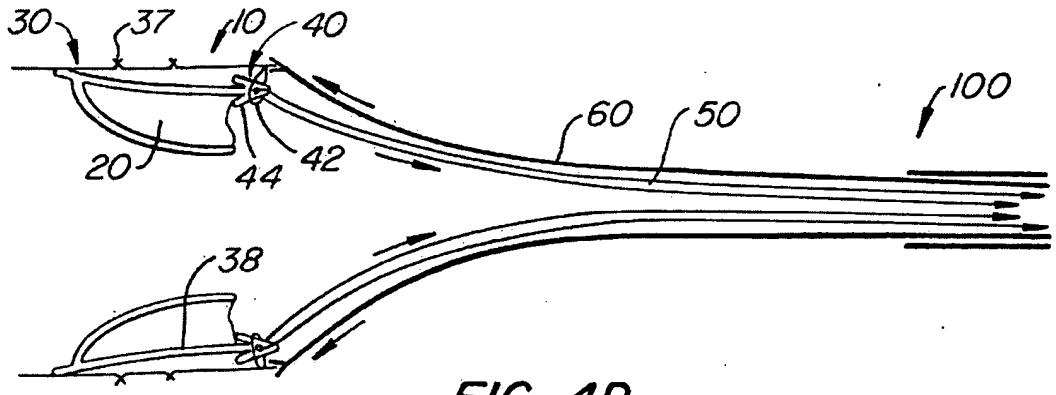

FIG. 4D

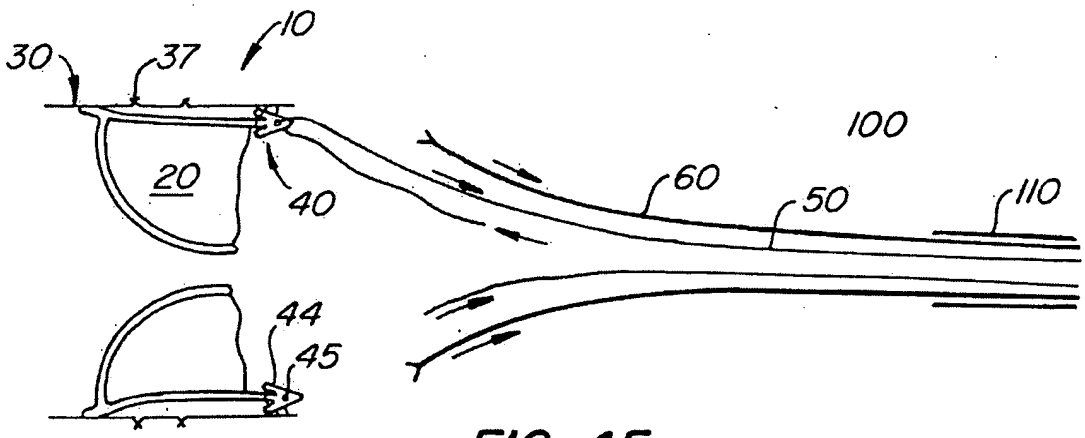

FIG. 4E

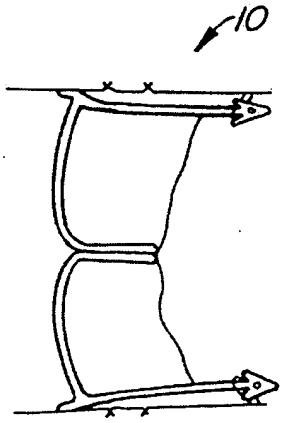

FIG. 4F

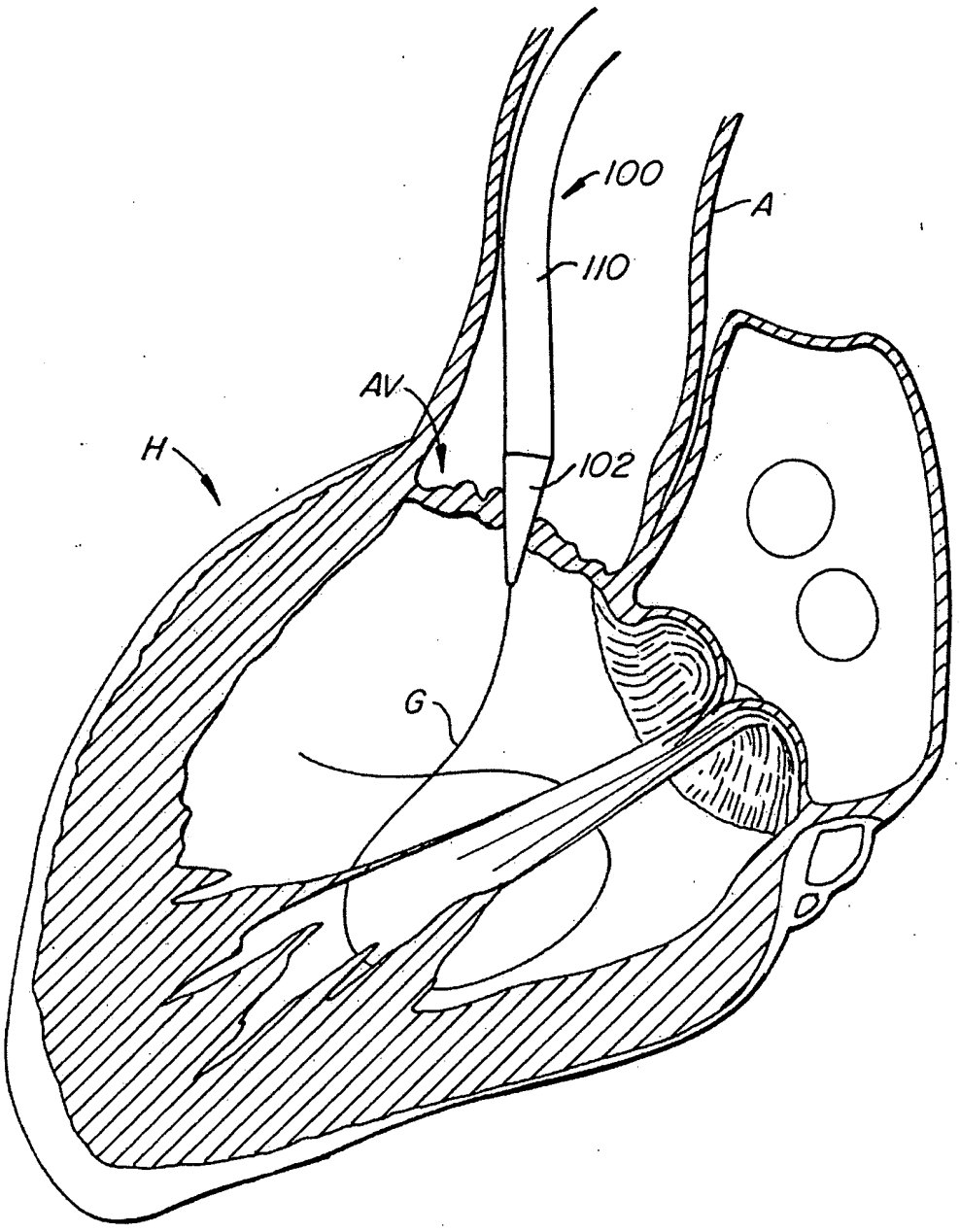

FIG. 5A

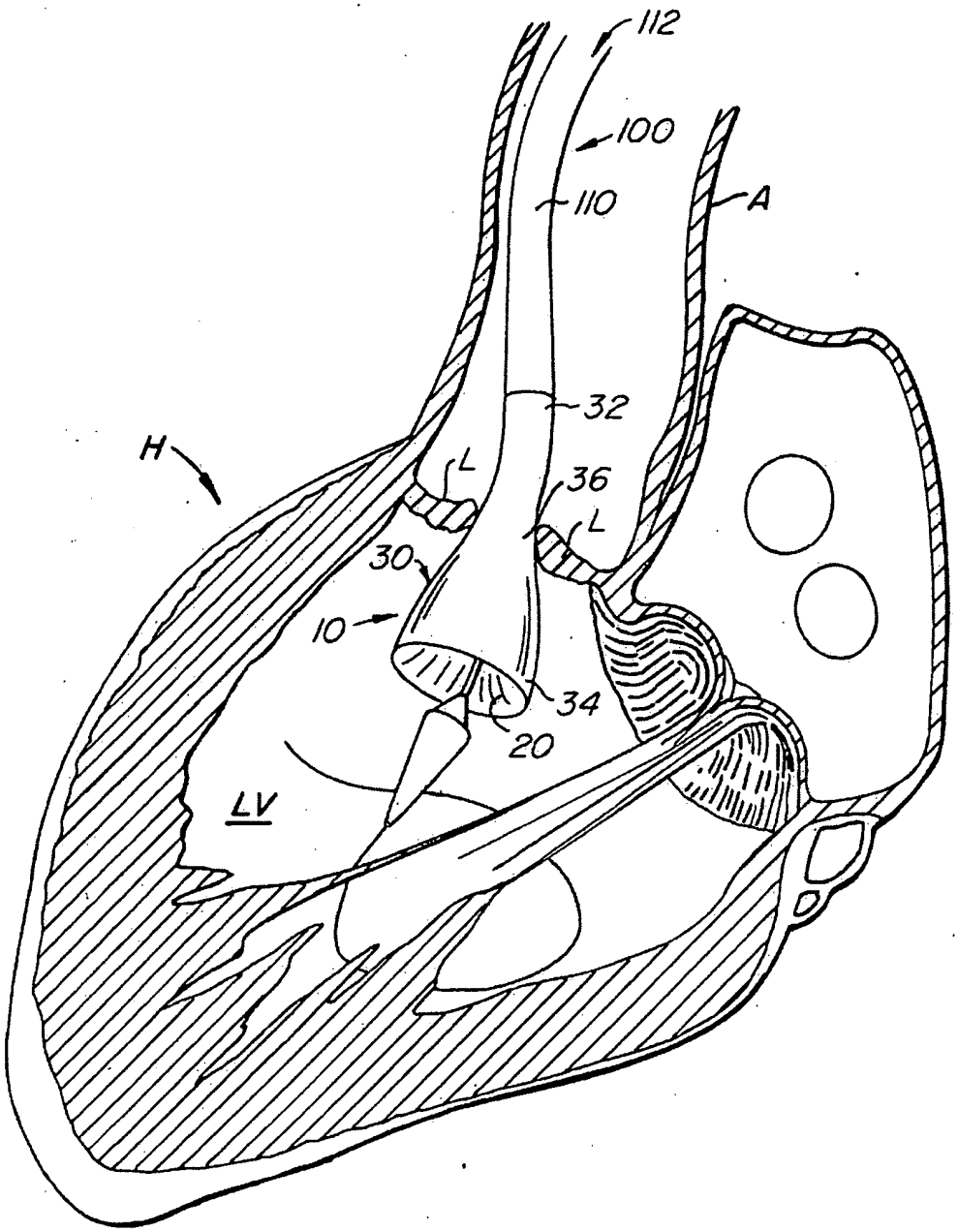

FIG. 5B

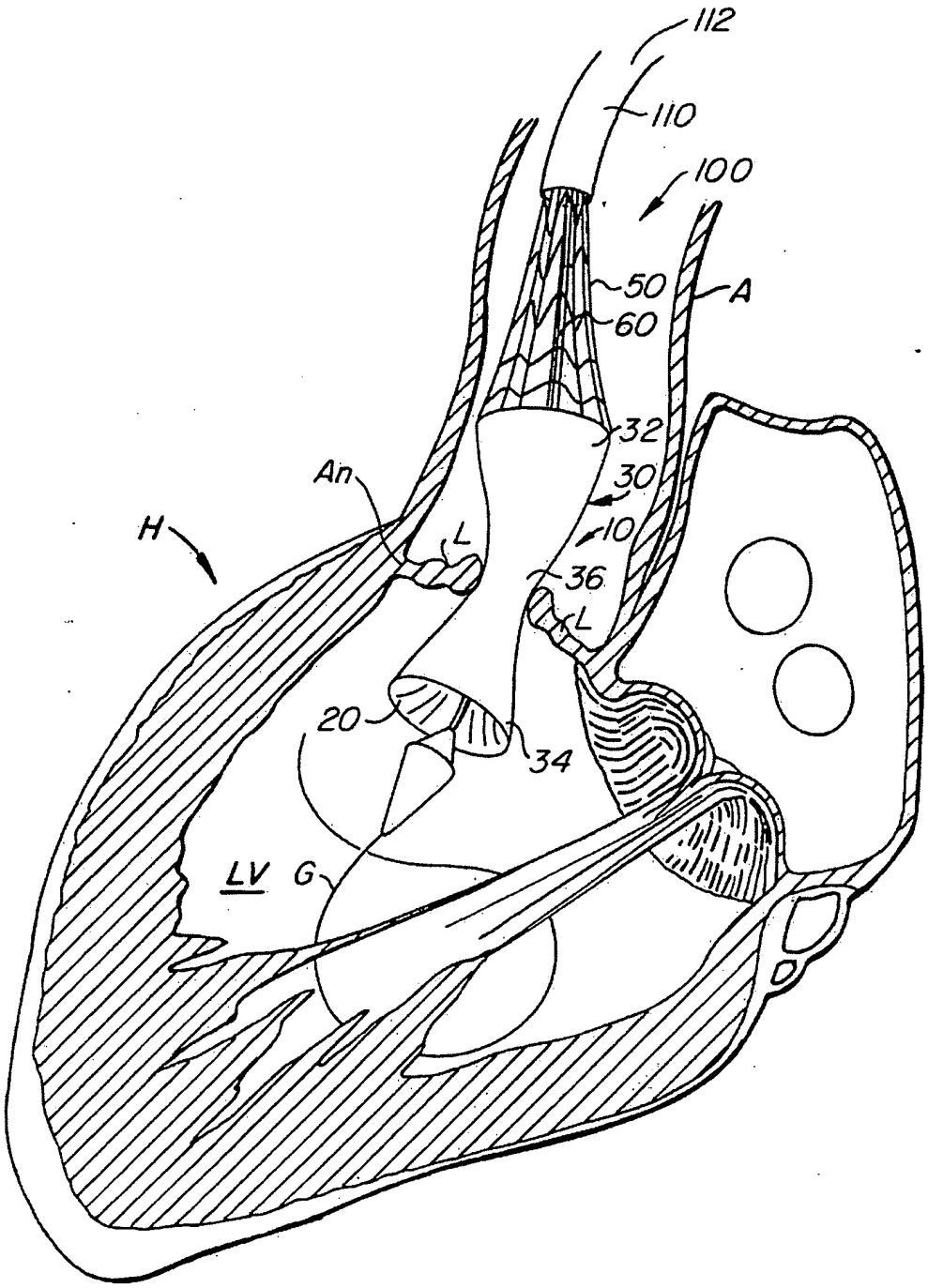

FIG. 5C

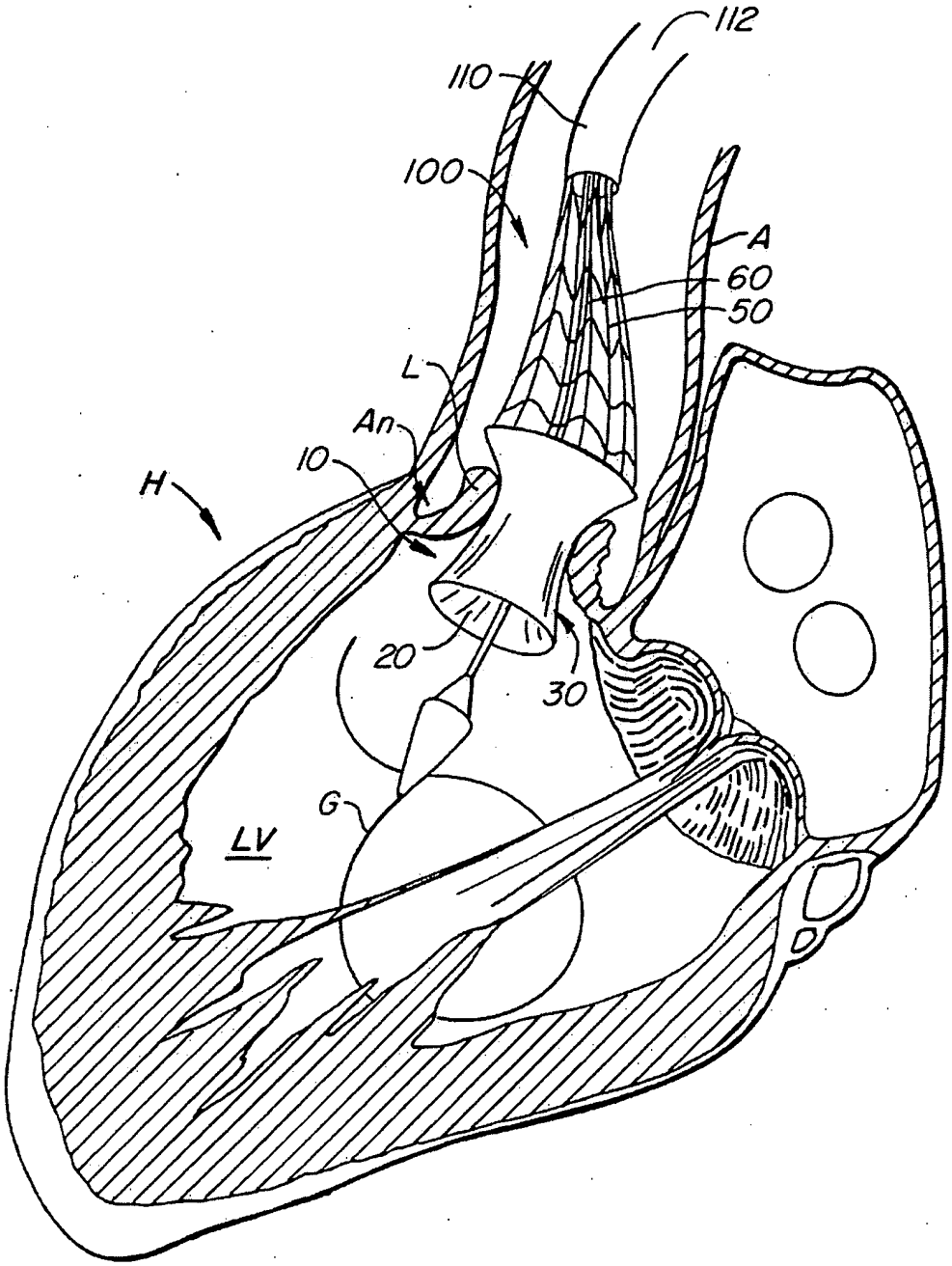

FIG. 5D

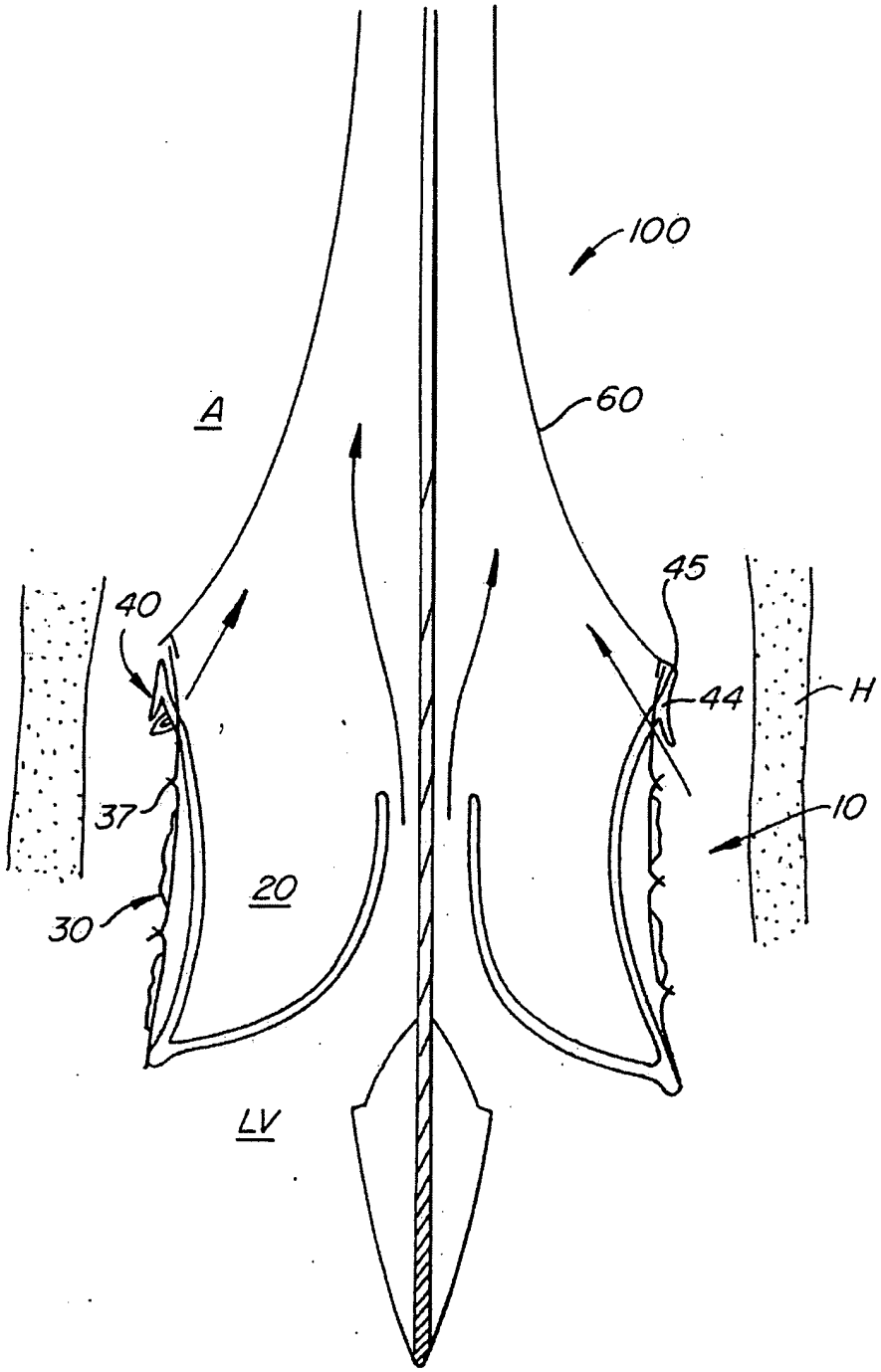

FIG. 5E

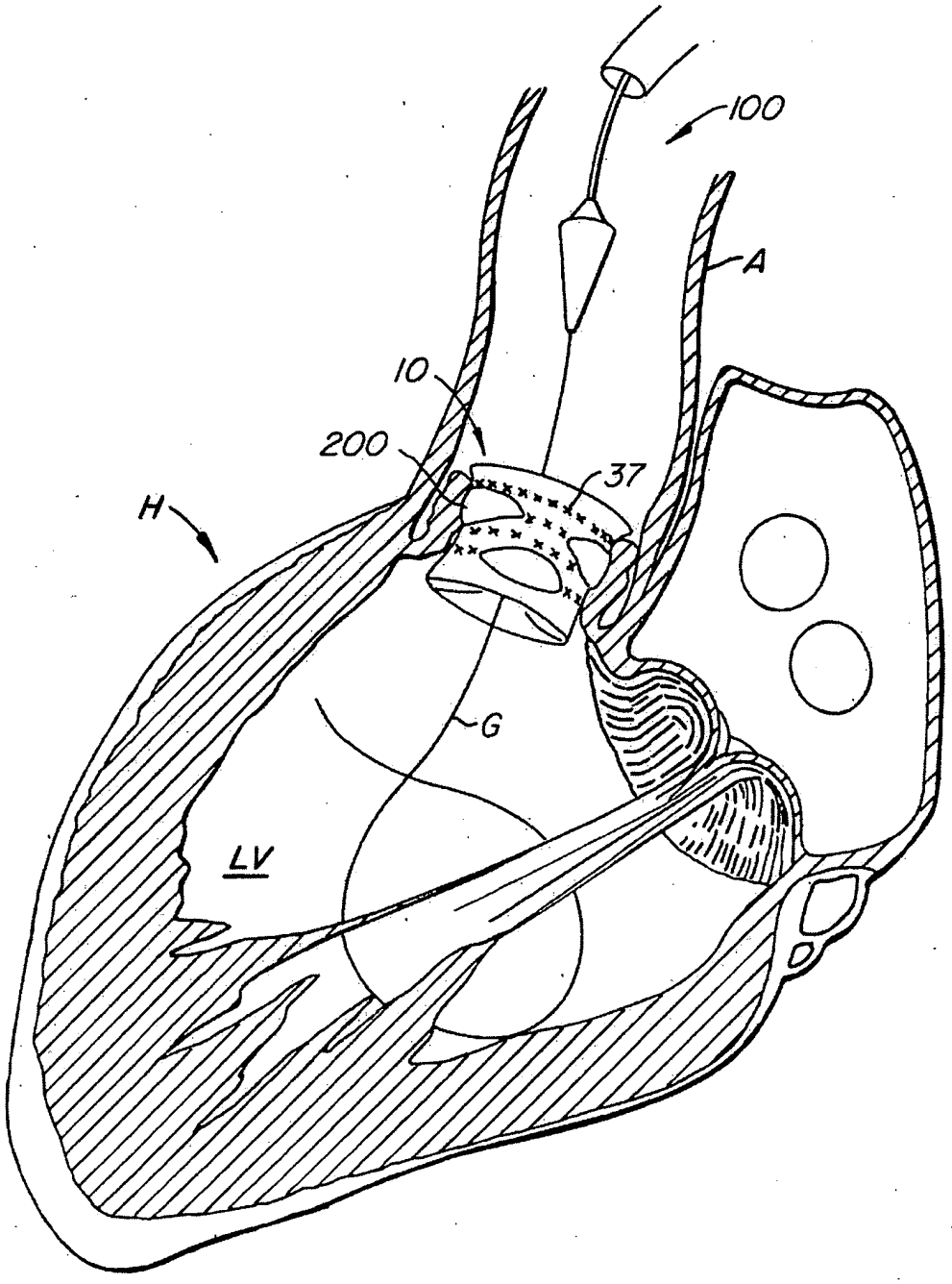

FIG. 5F

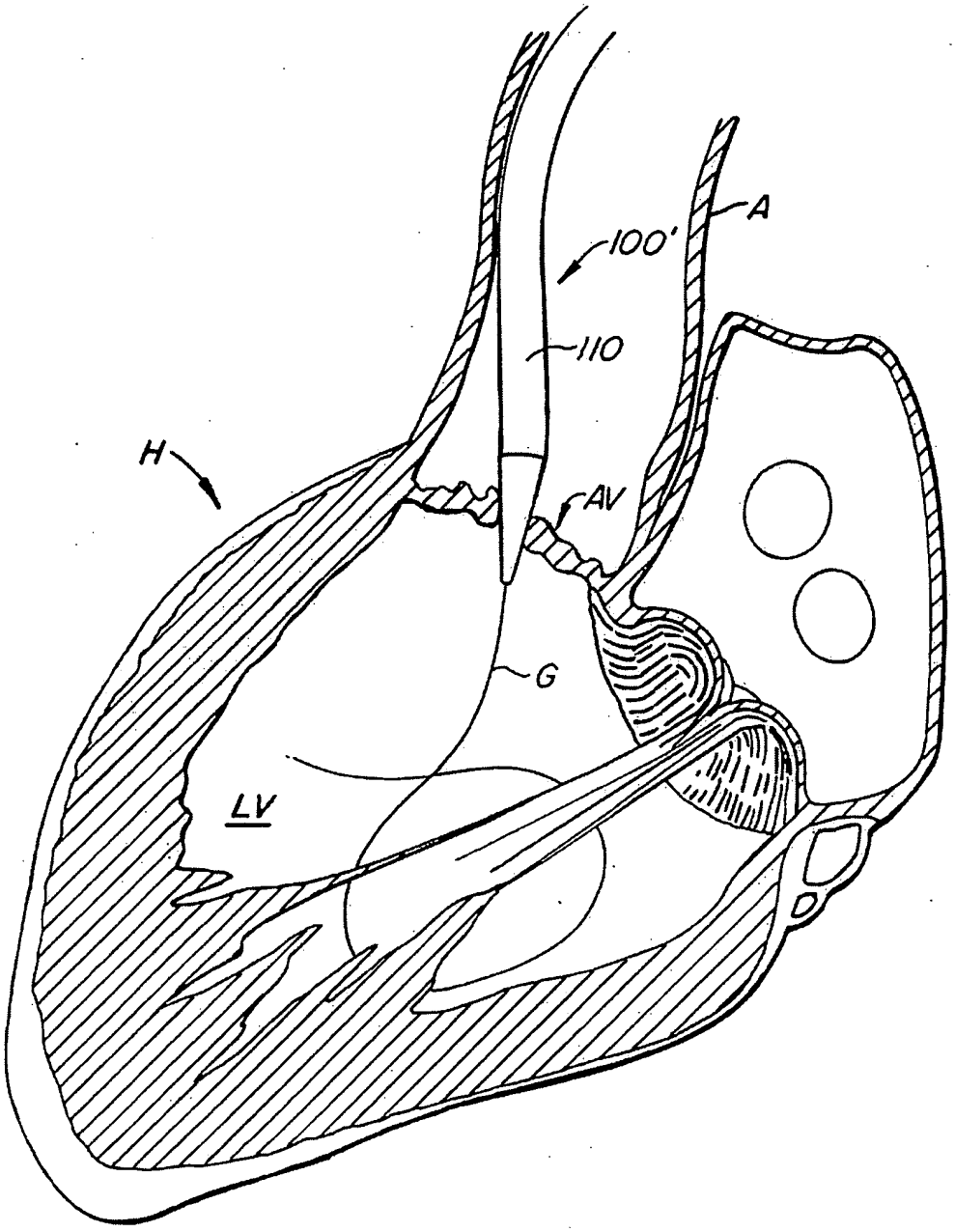

FIG. 6A

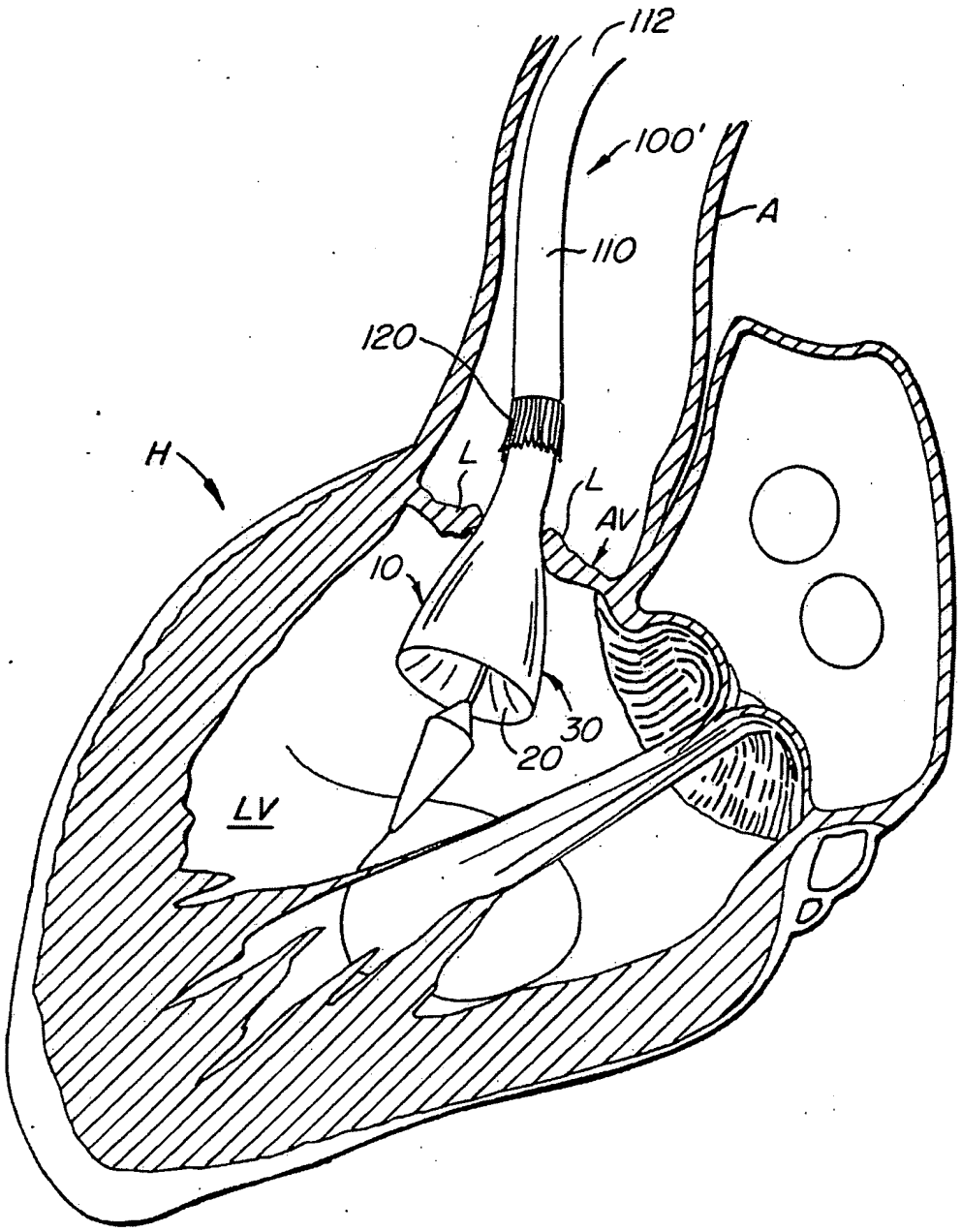

FIG. 6B

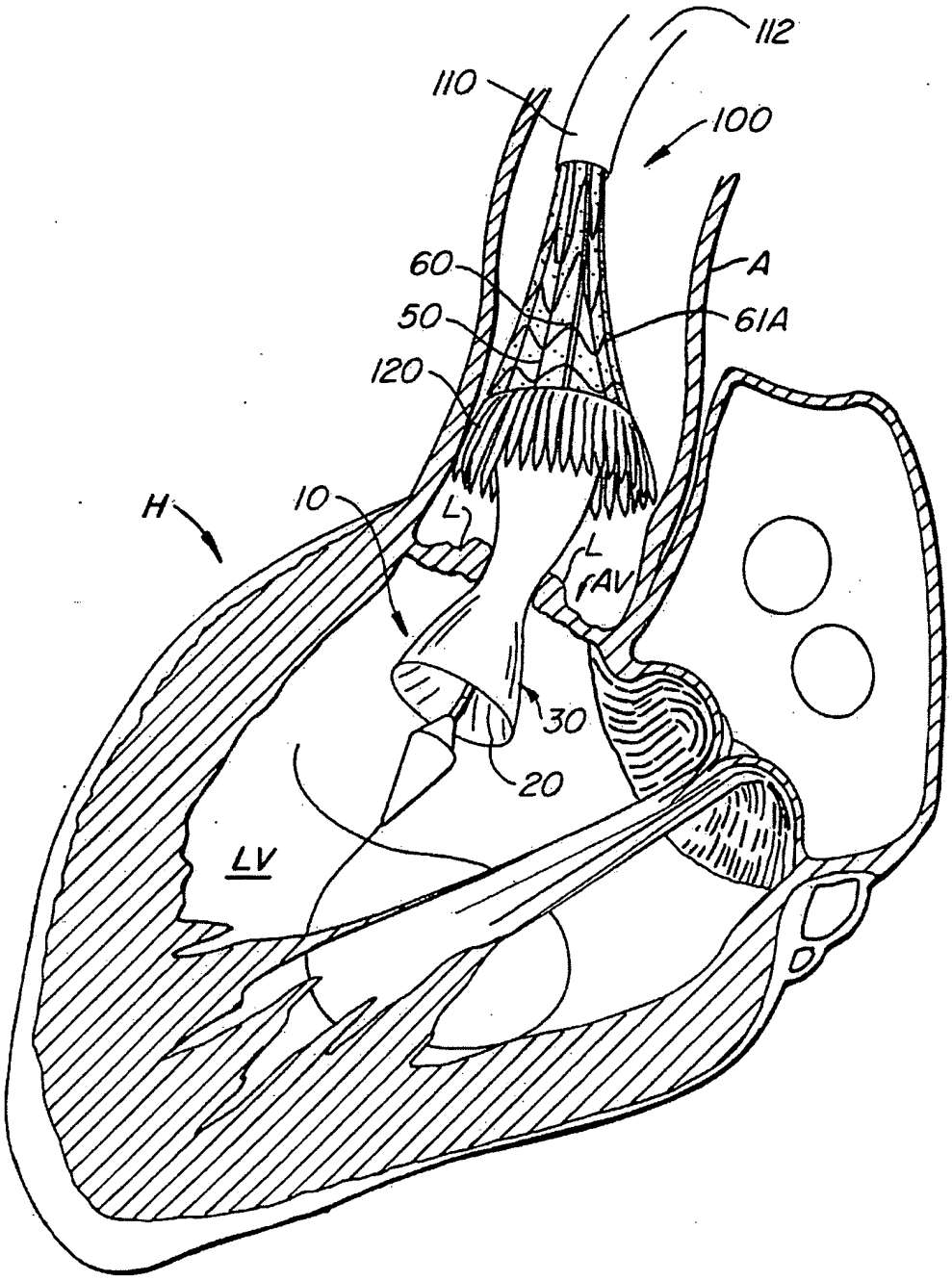

FIG. 6C

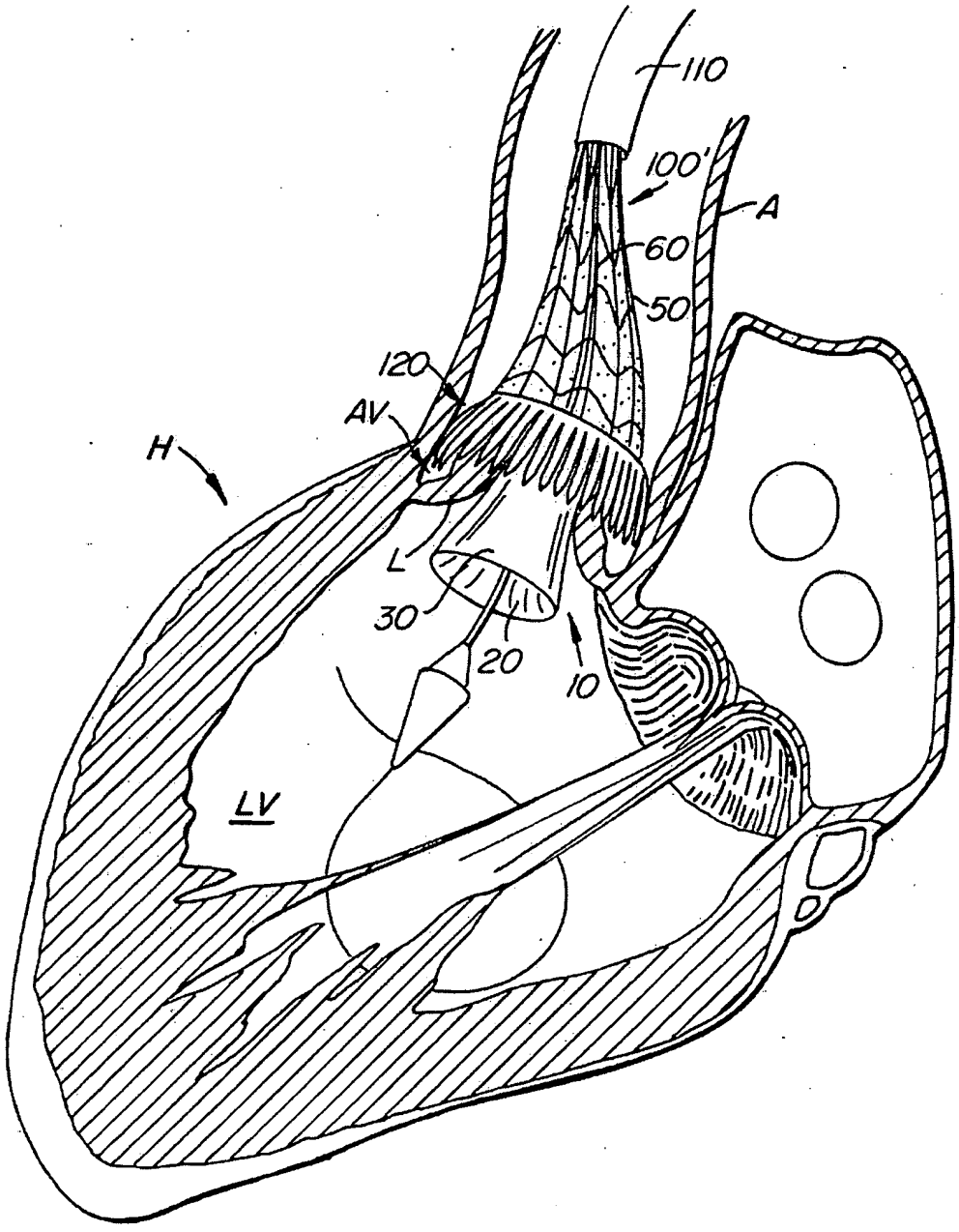

FIG. 6D

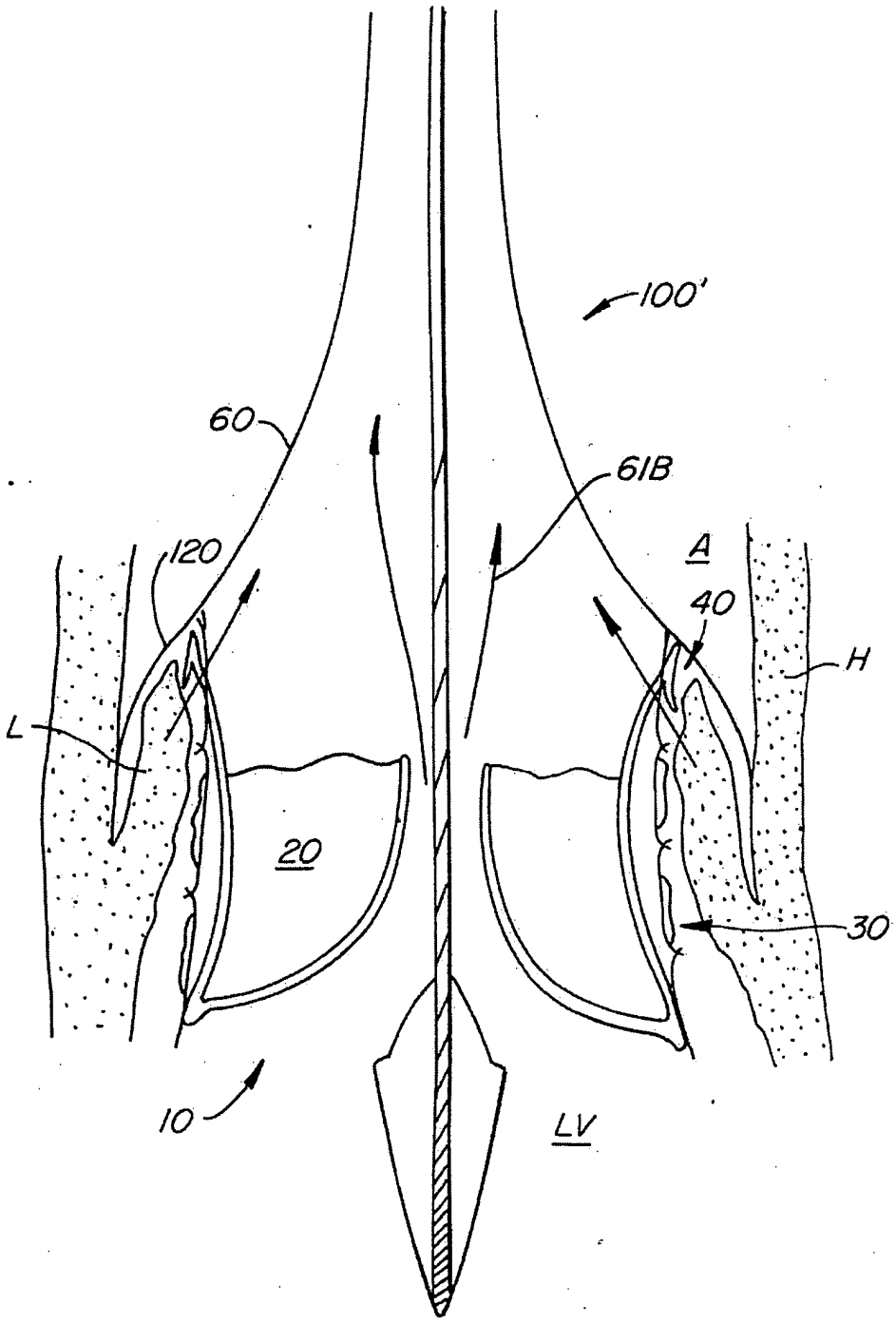

FIG. 6E

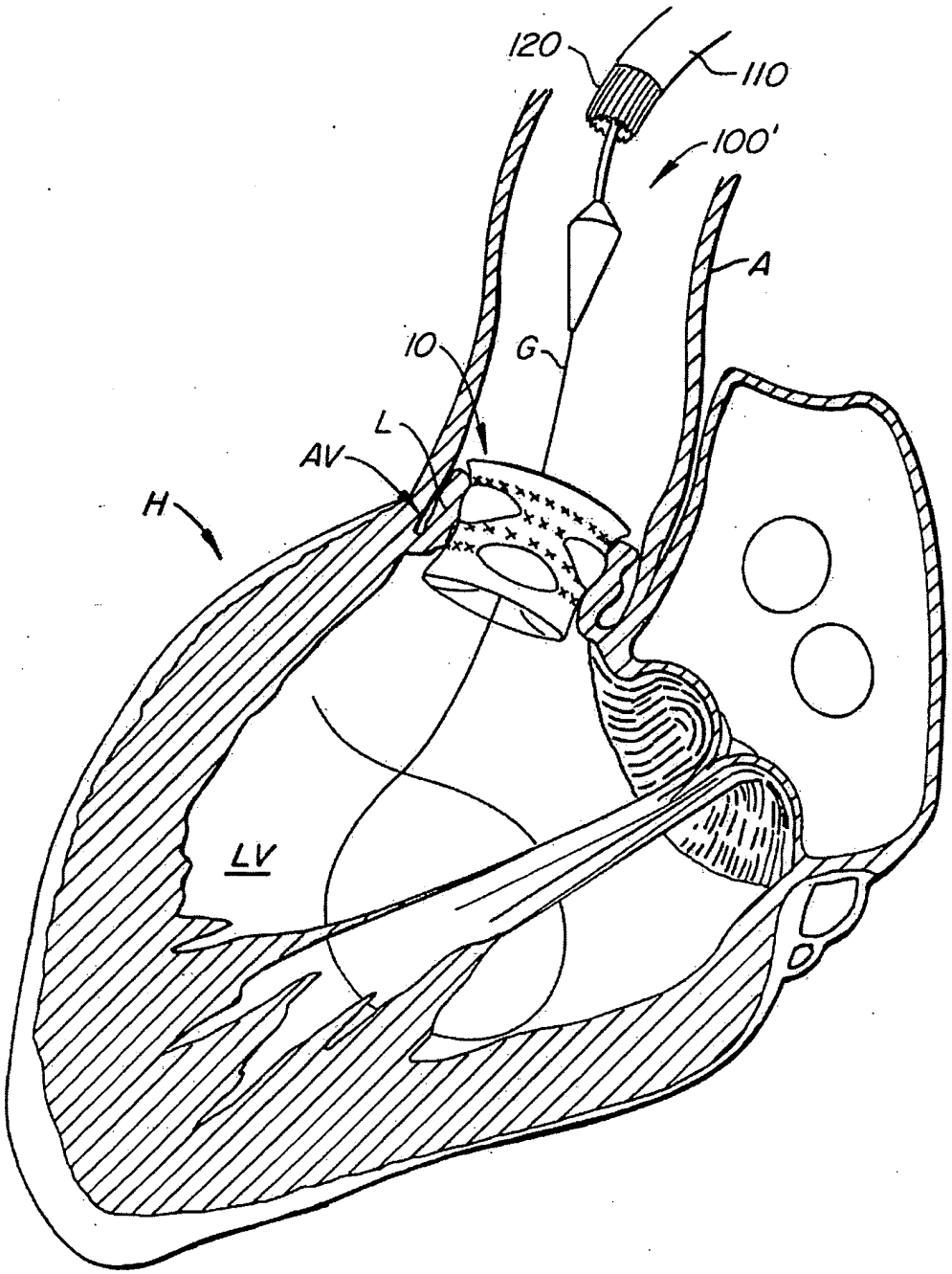

FIG. 6F

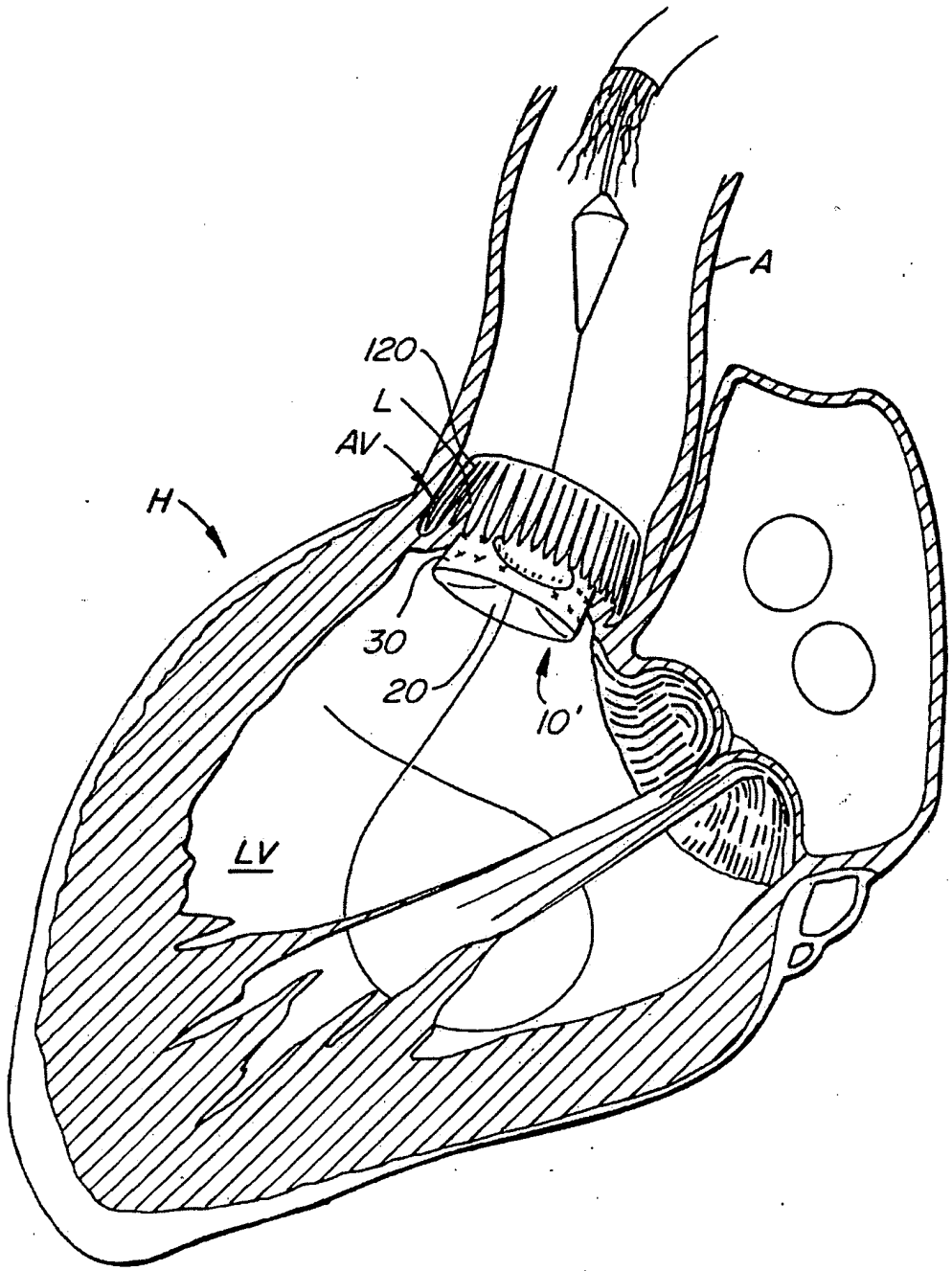

FIG. 7

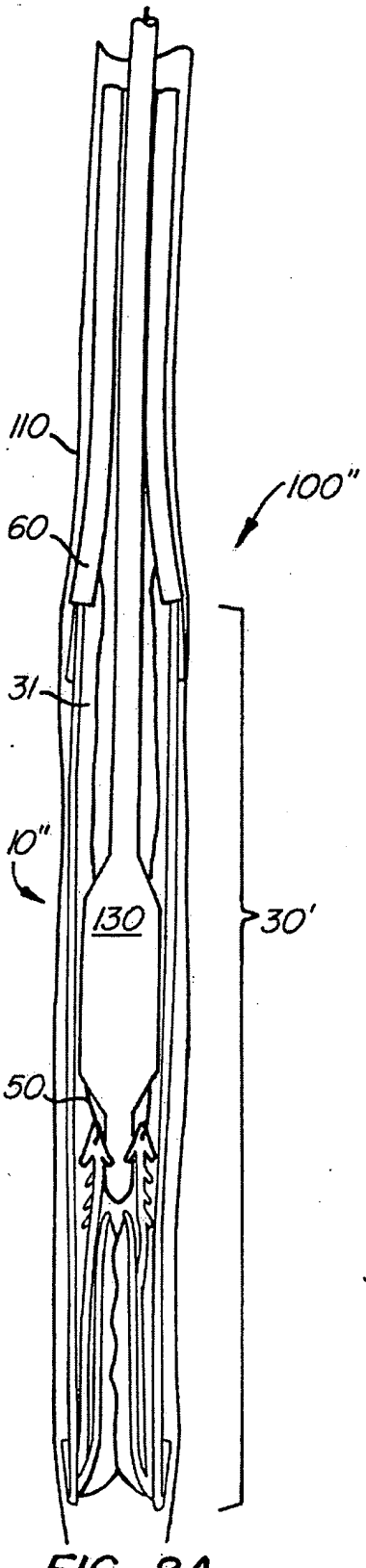

FIG. 8A

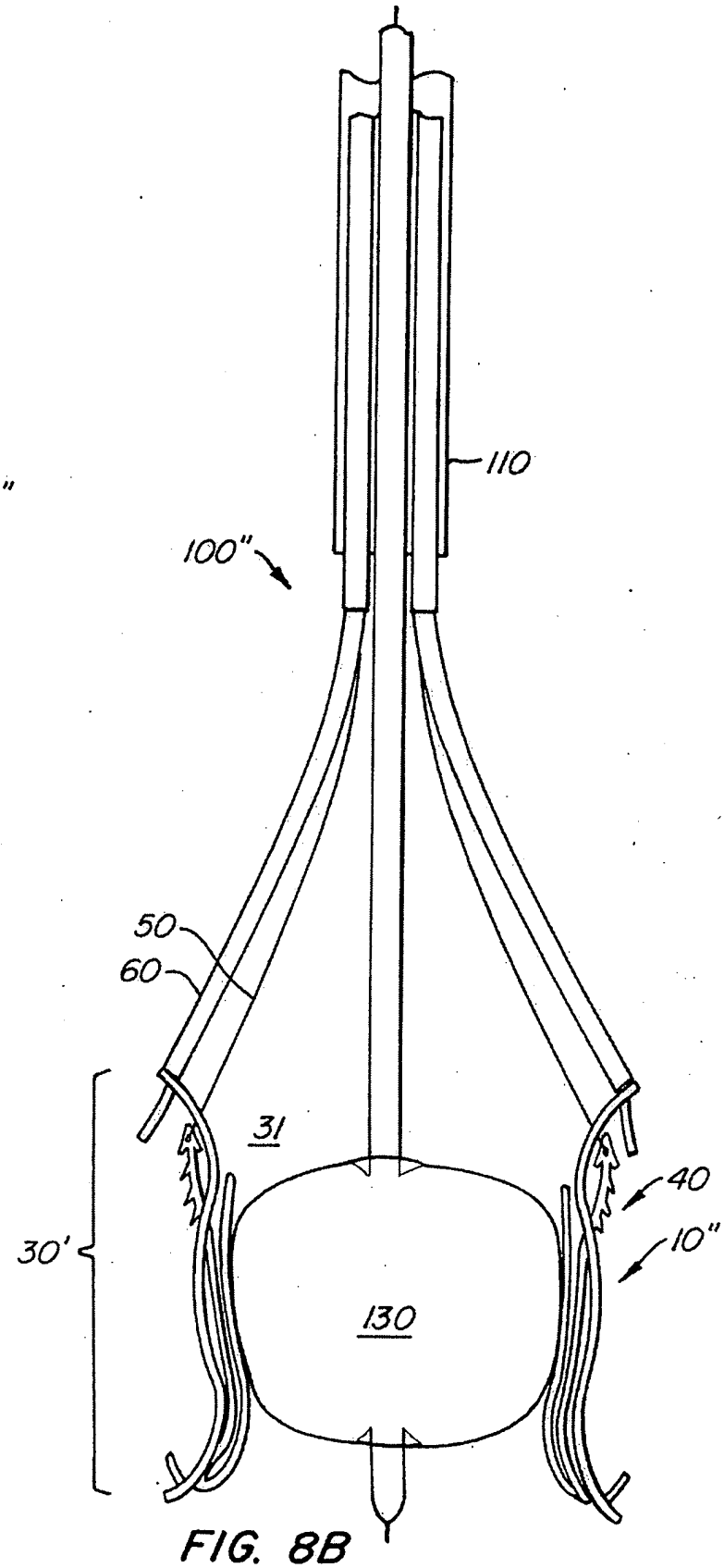

FIG. 8B

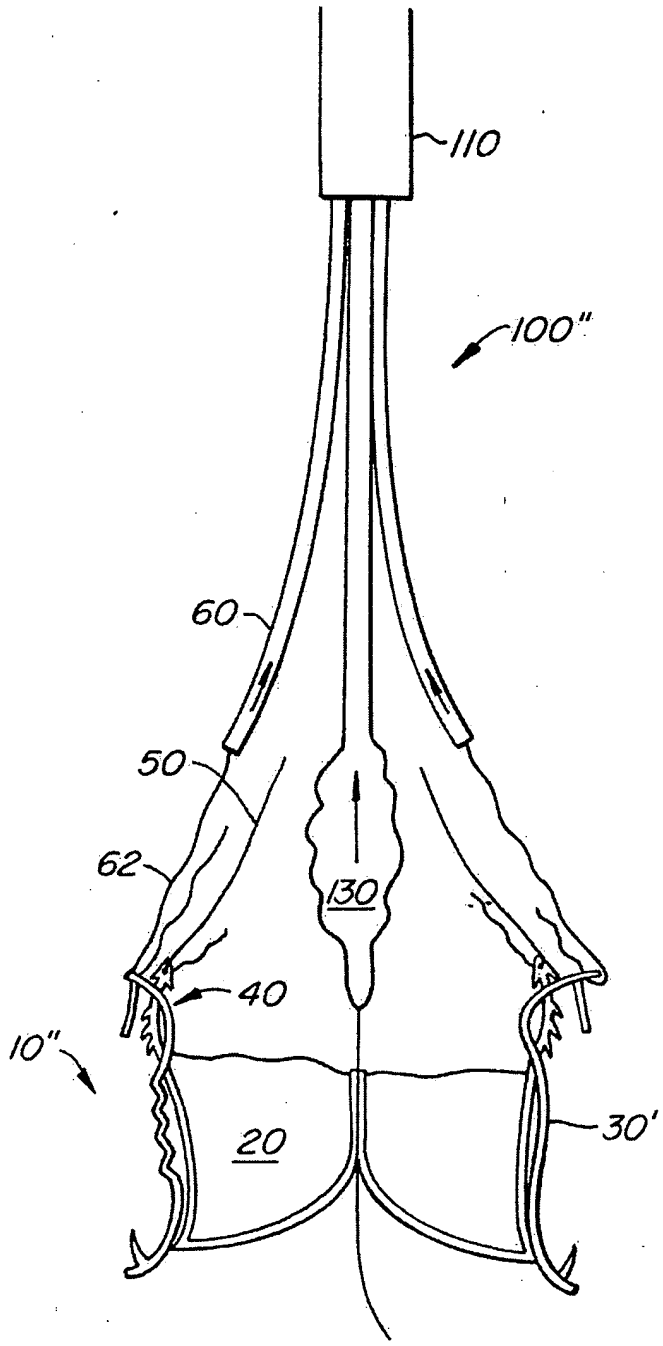

FIG. 8C

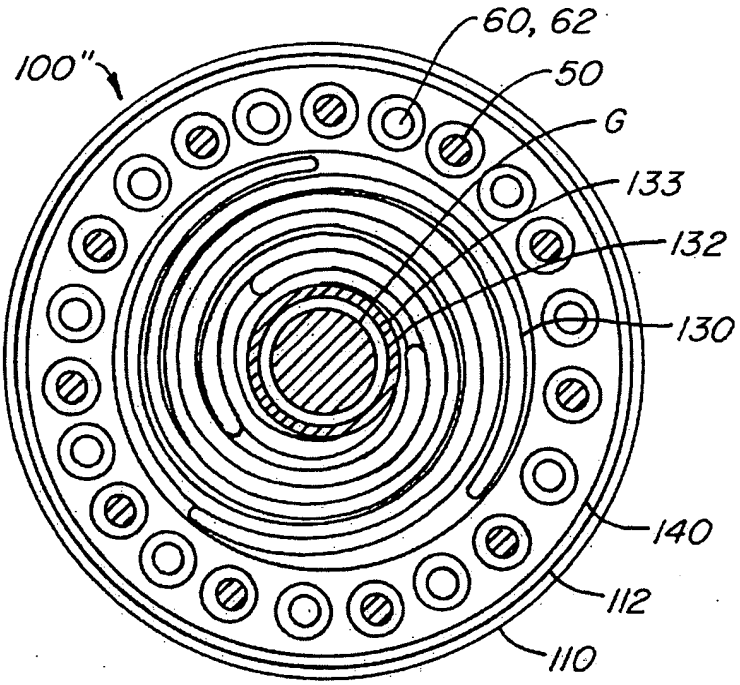

FIG. 10

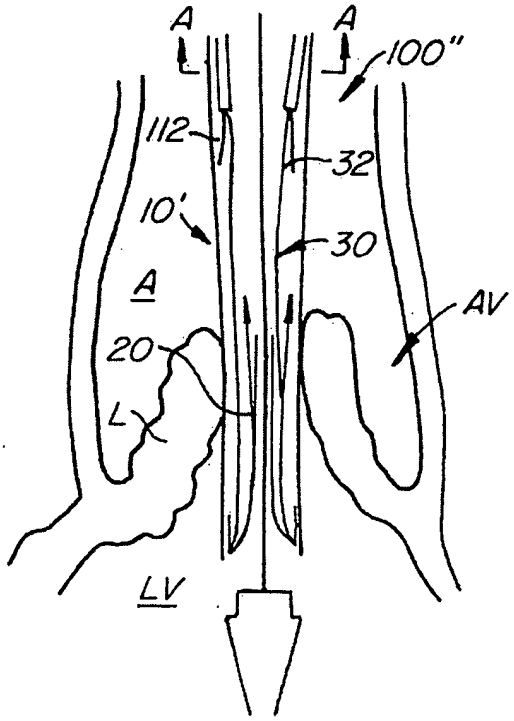

FIG. 9A

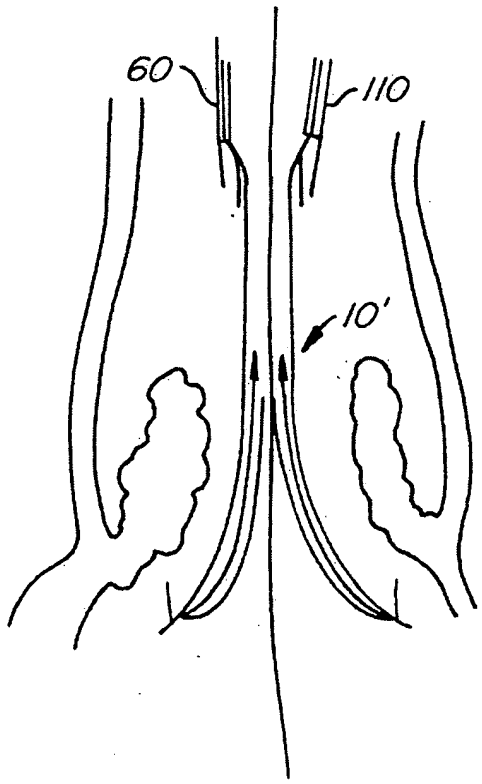

FIG. 9B

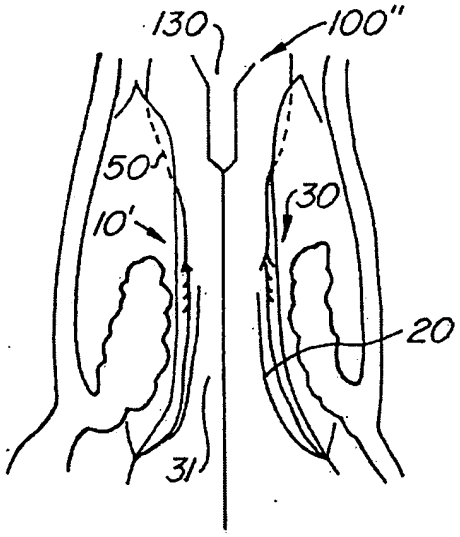

FIG. 9C

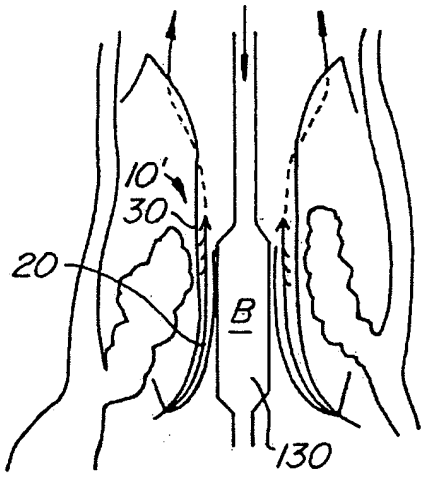

FIG. 9D

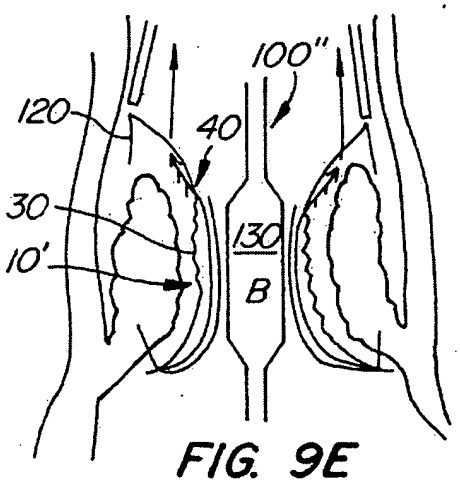

FIG. 9E

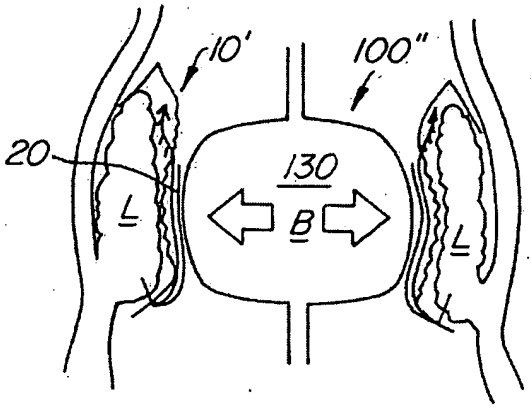

FIG. 9F

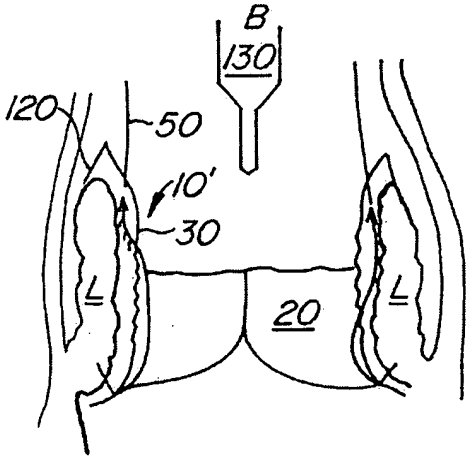

FIG. 9G

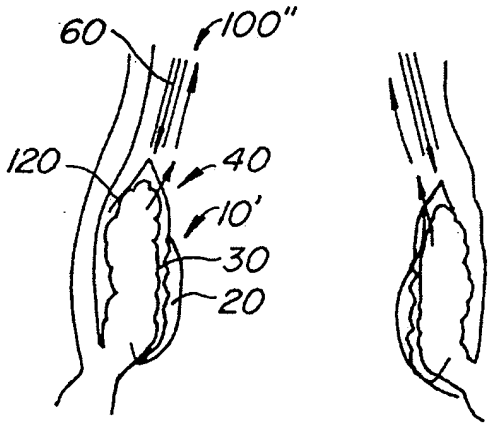

FIG. 9H

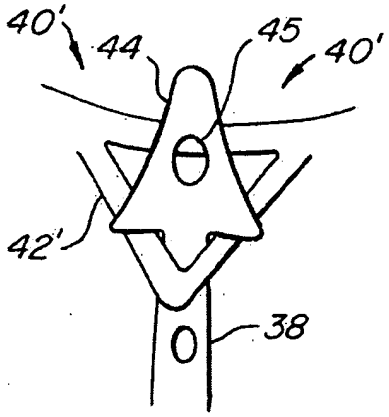

FIG. IIA

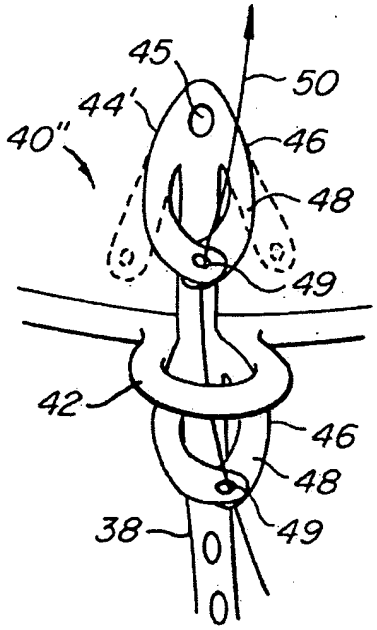

FIG. IIB

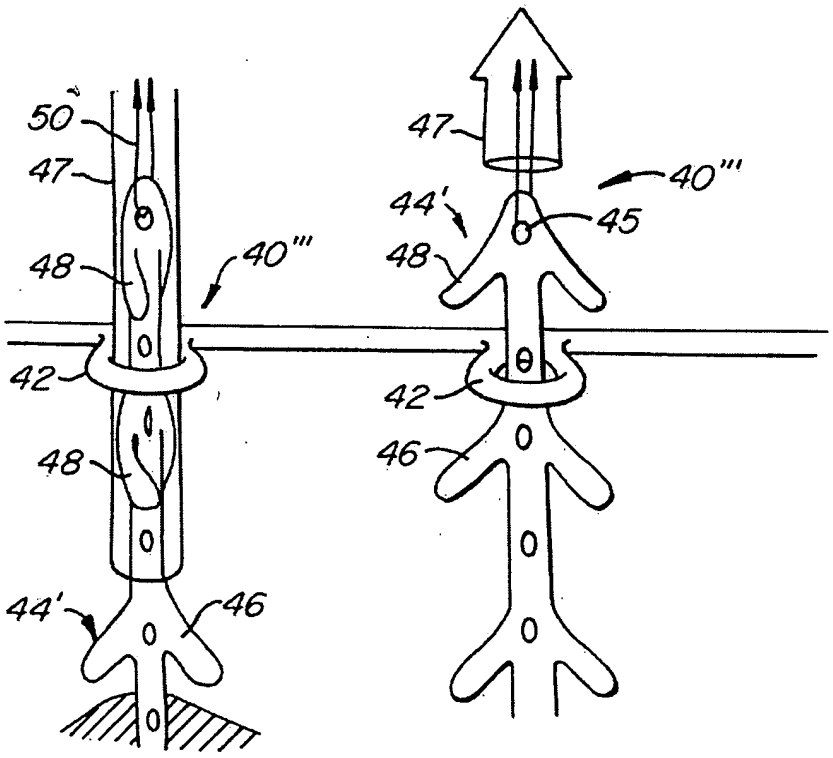

FIG. IIC

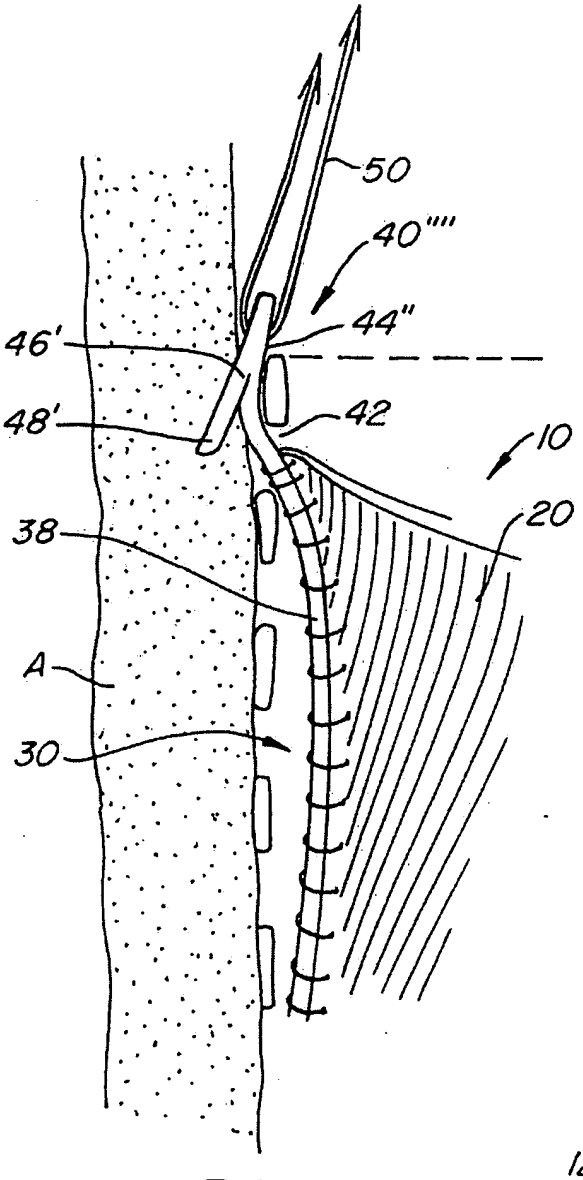

FIG. 12C

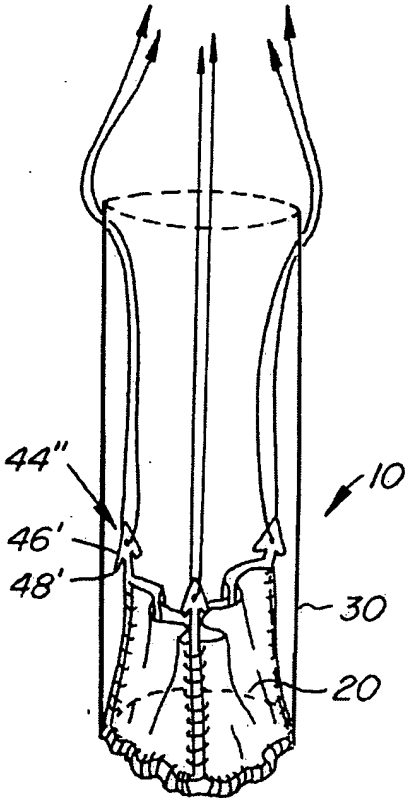

FIG. 12A

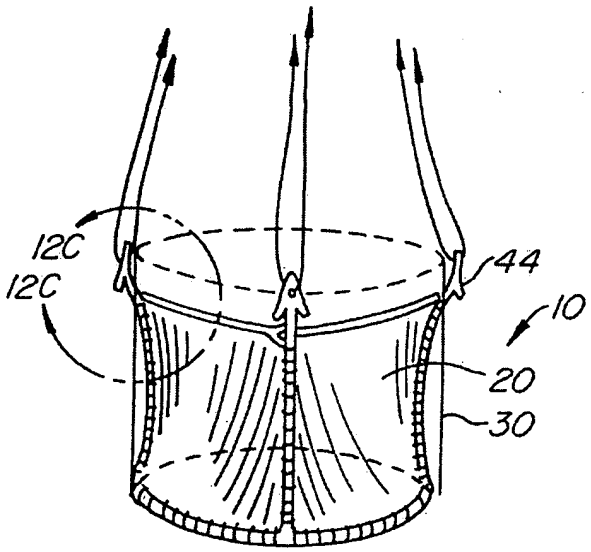

FIG. 12B

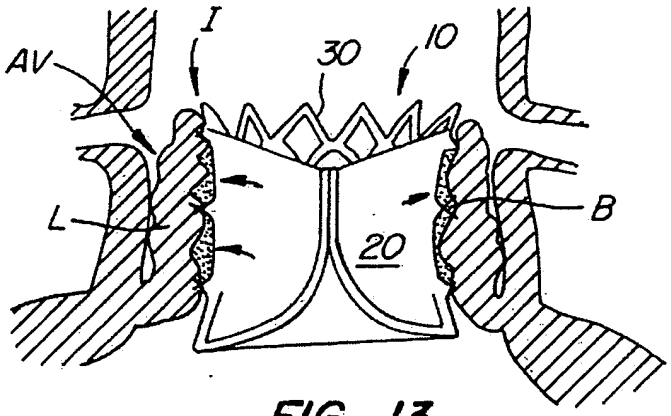

FIG. 13

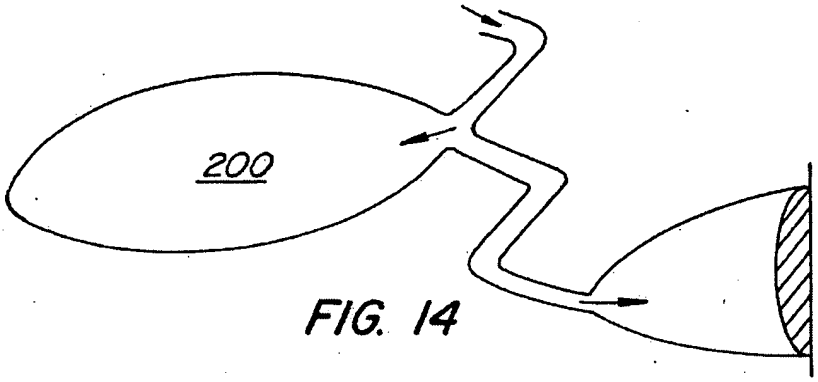

FIG. 14

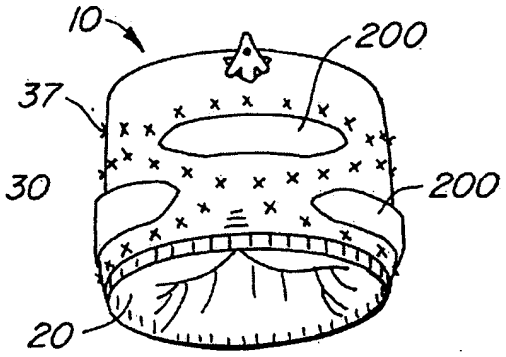

FIG. 15A

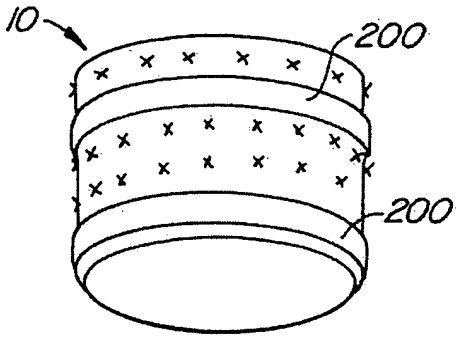

FIG. 15B

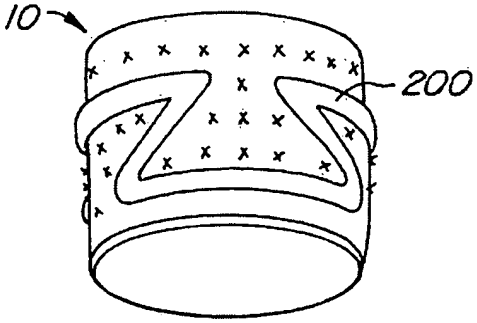

FIG. 15C

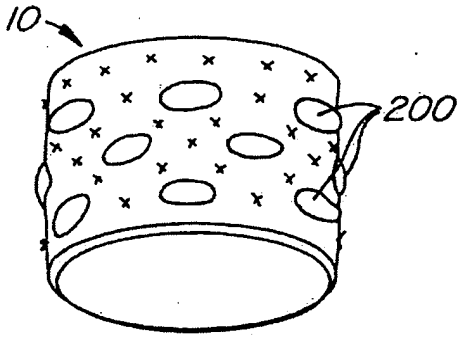

FIG. 15D

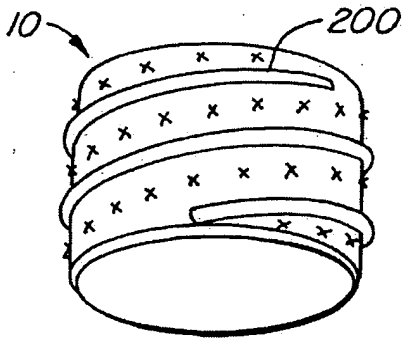

FIG. 15E

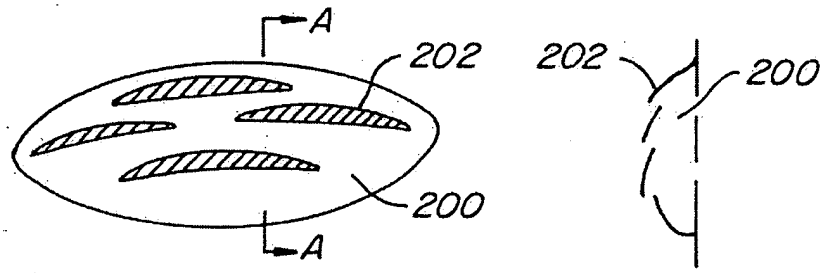

FIG. 16A

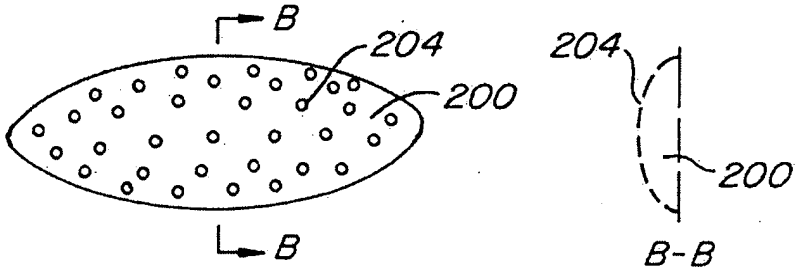

FIG. 16B

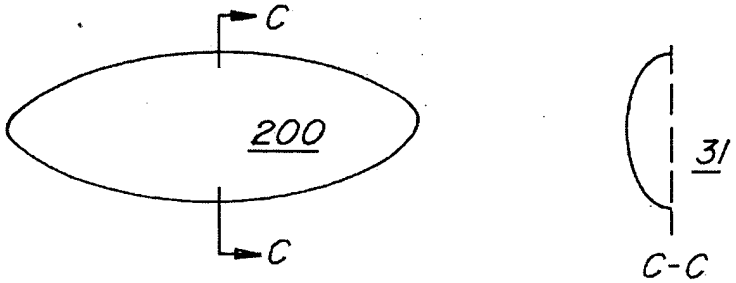

FIG. 16C

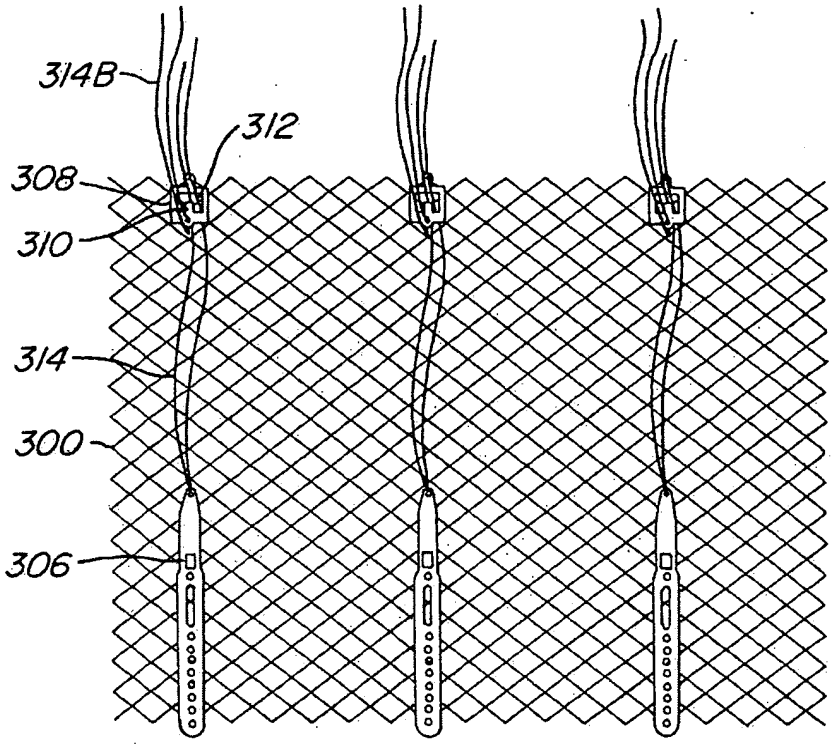

FIG. 17A

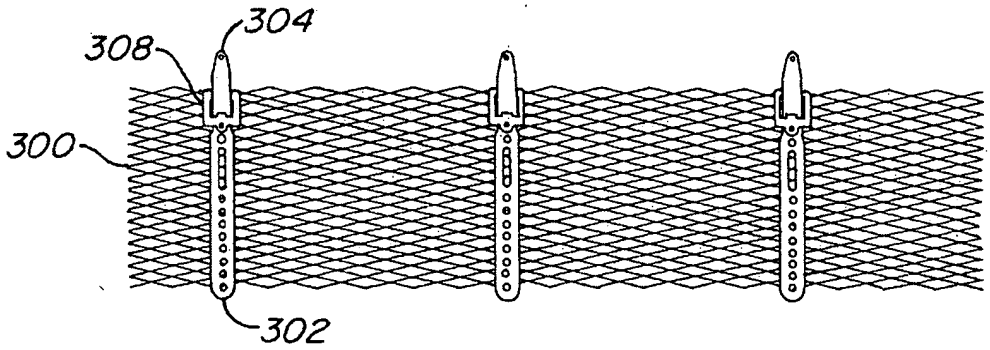

FIG. 18A

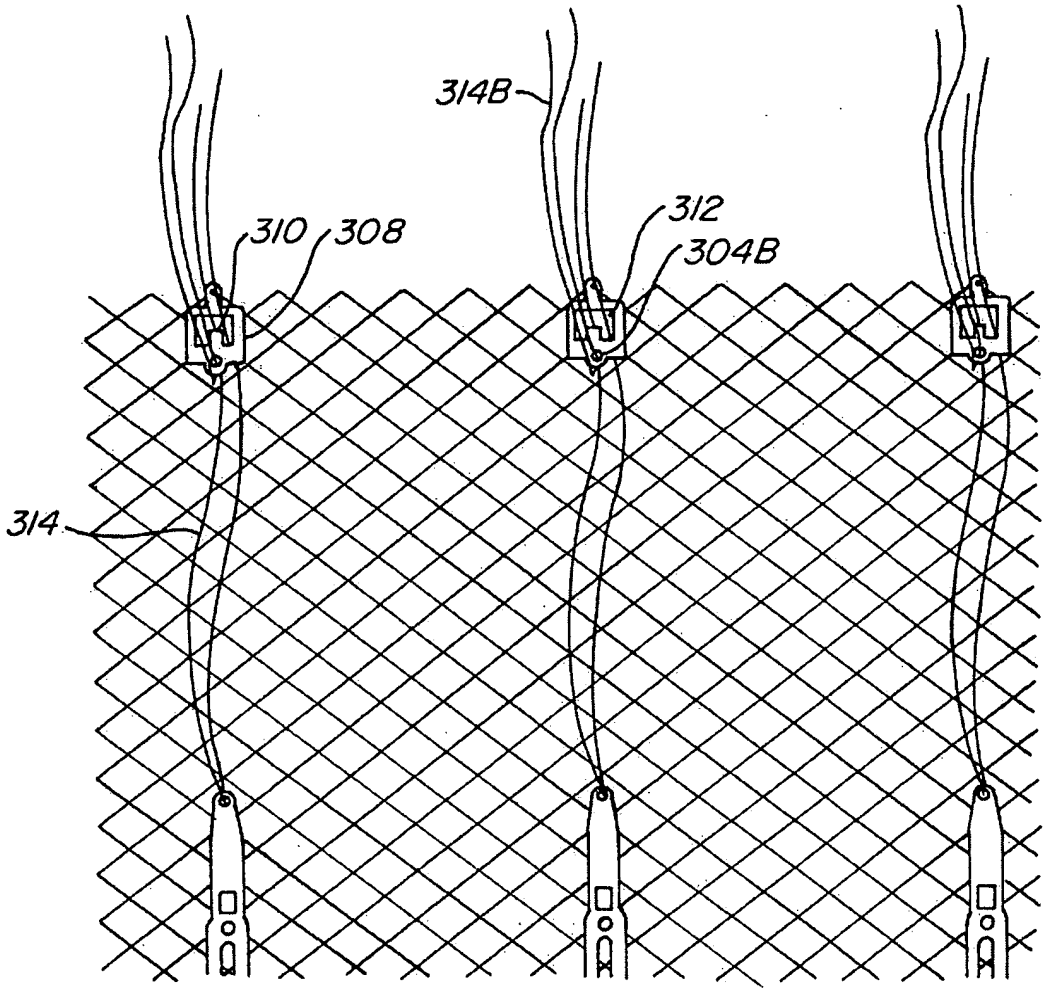

FIG. 17B

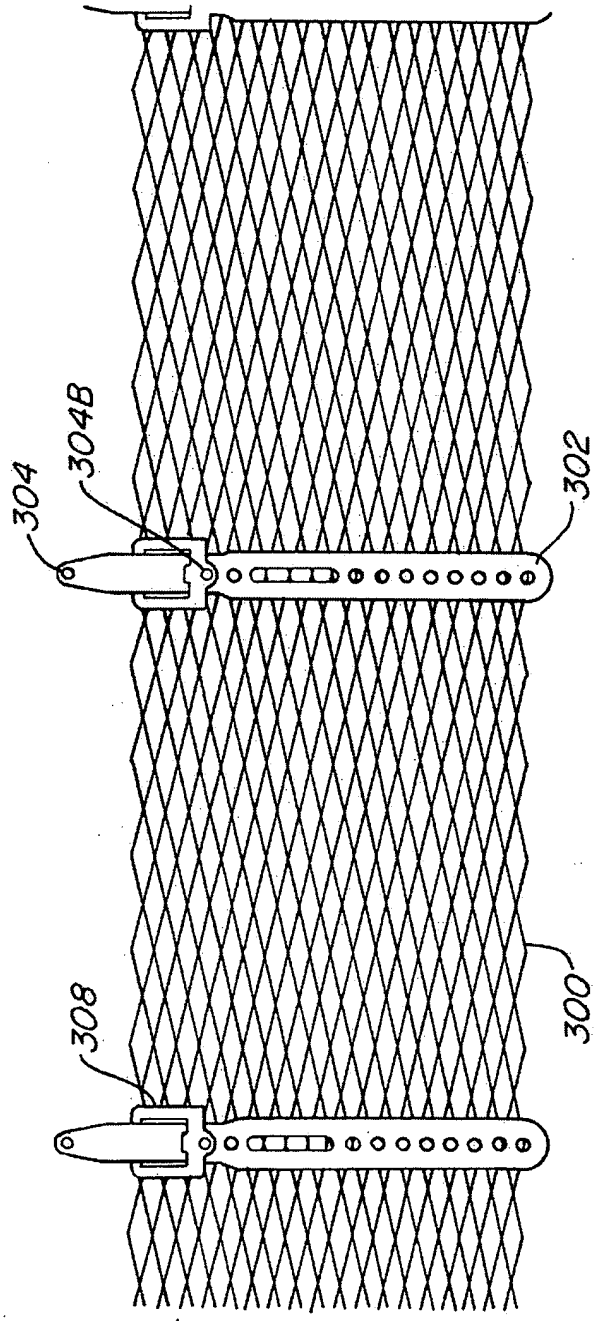

FIG. 18B

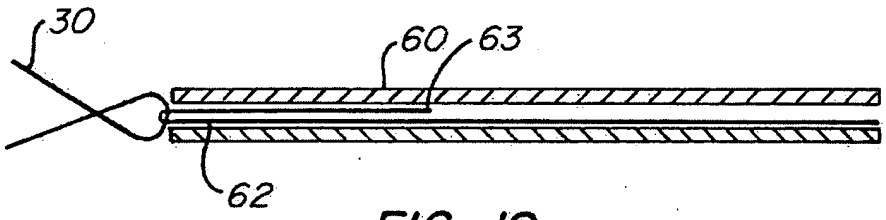

FIG. 19

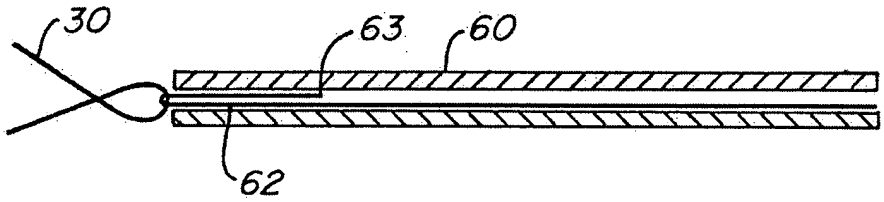

FIG. 20

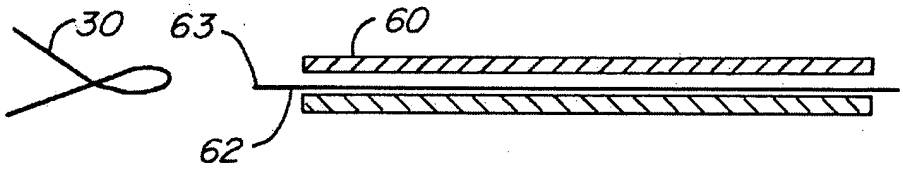

FIG. 21

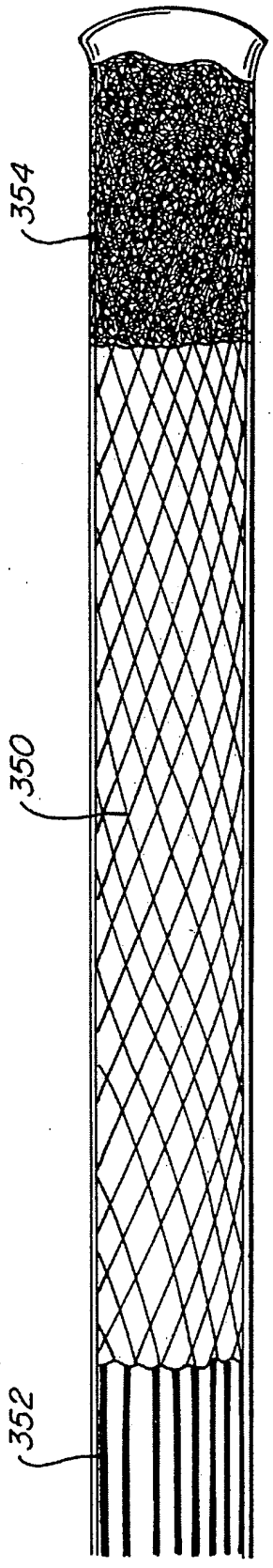

FIG. 22

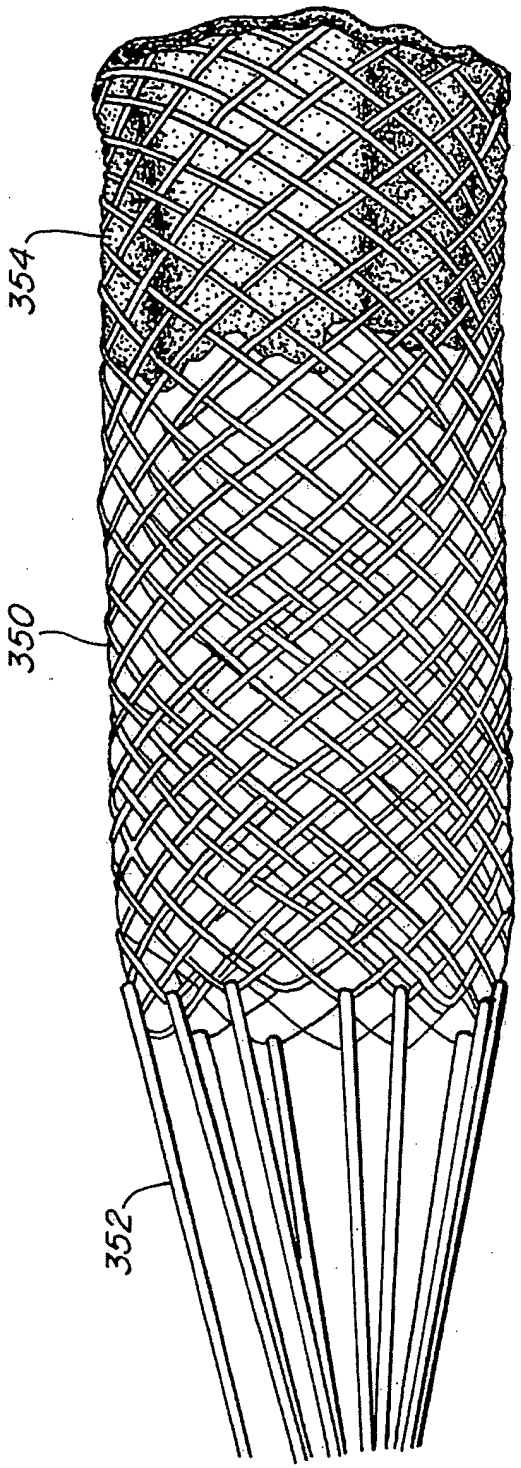

FIG. 23

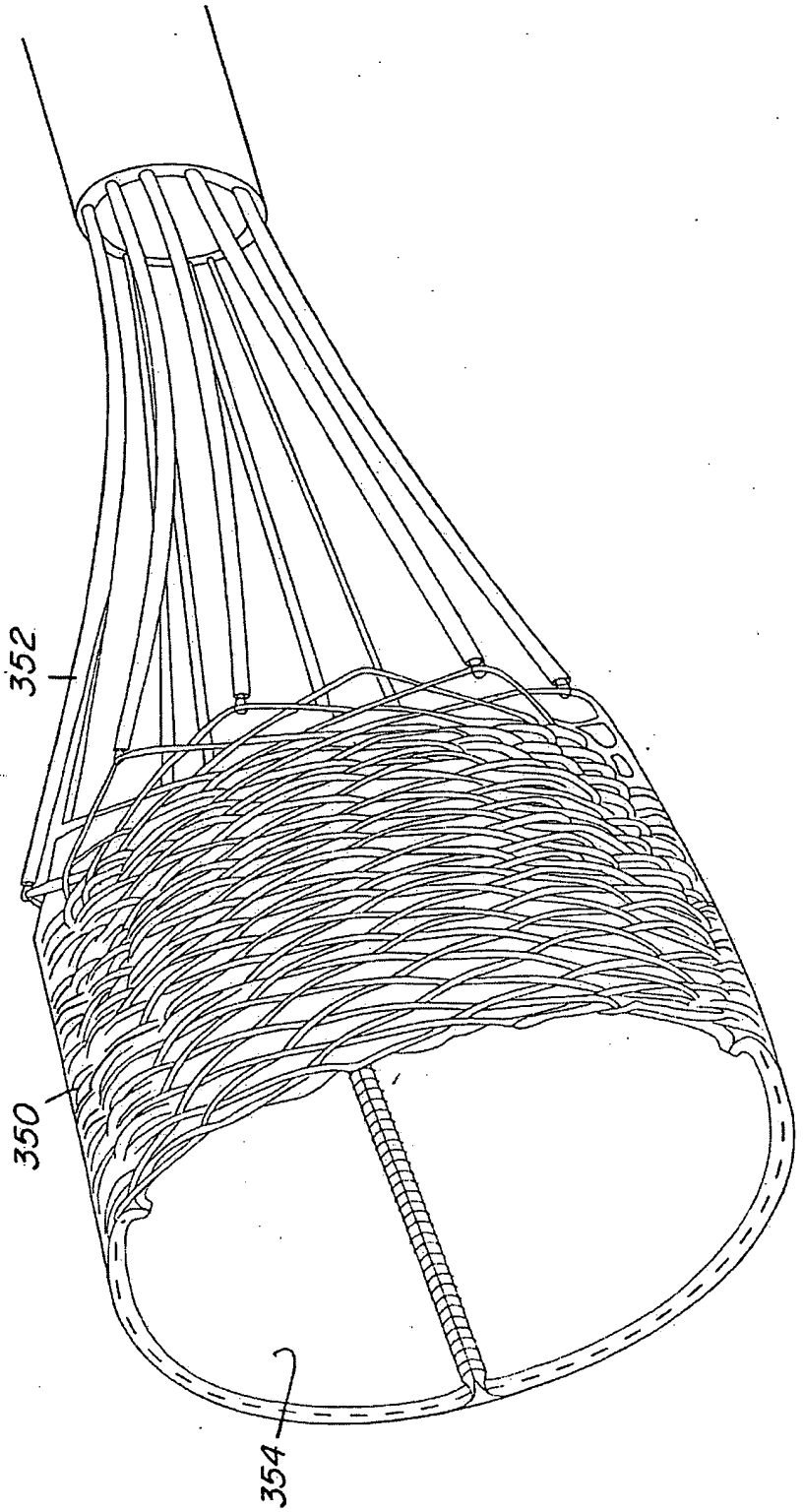

FIG. 24

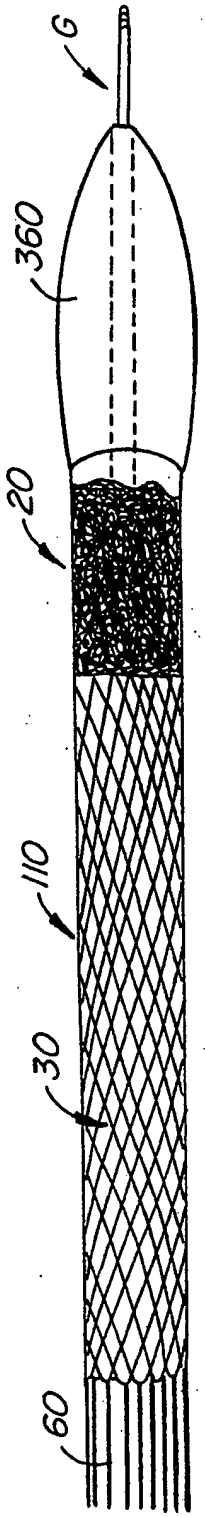

FIG. 25

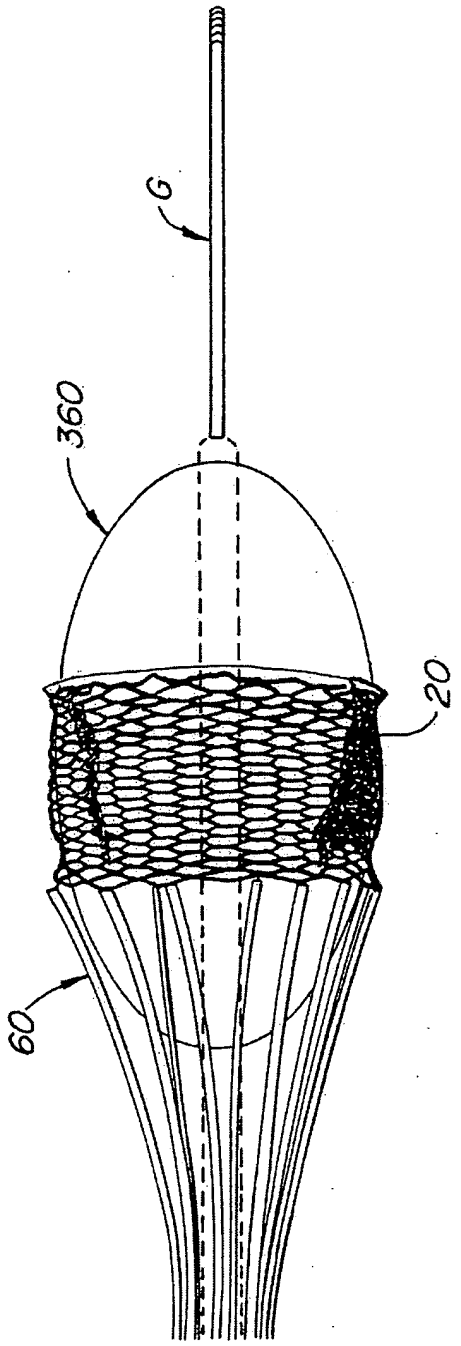

FIG. 26

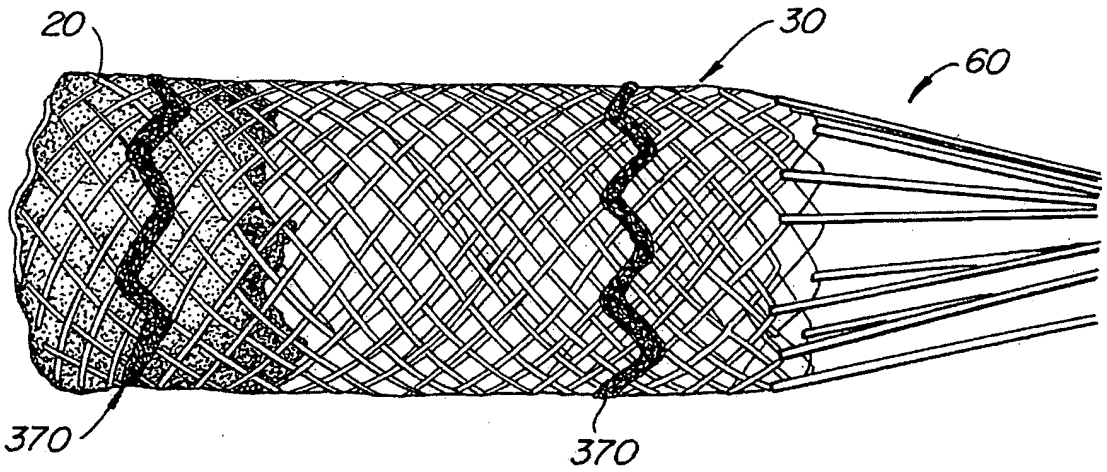

FIG. 27

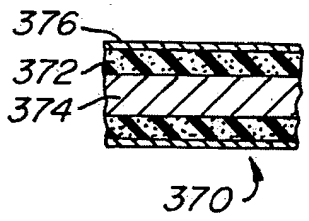

FIG. 28

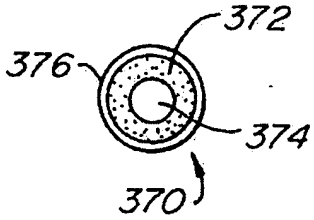

FIG. 29

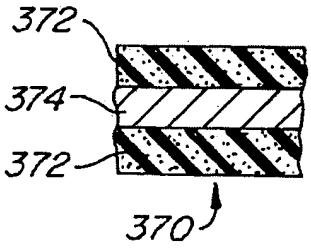

FIG. 30

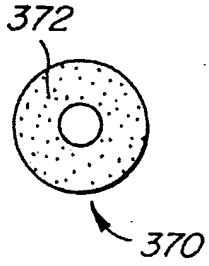

FIG. 31

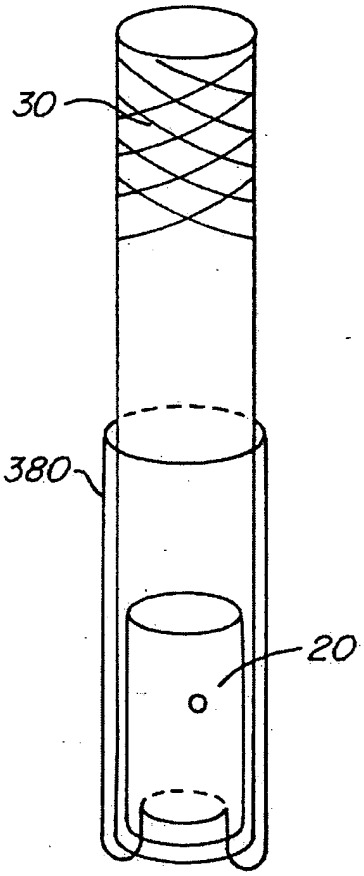

FIG. 32

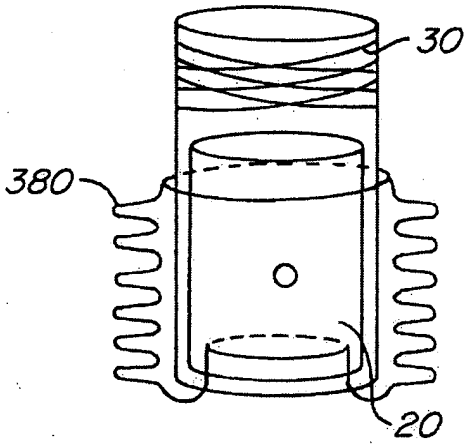

FIG. 33

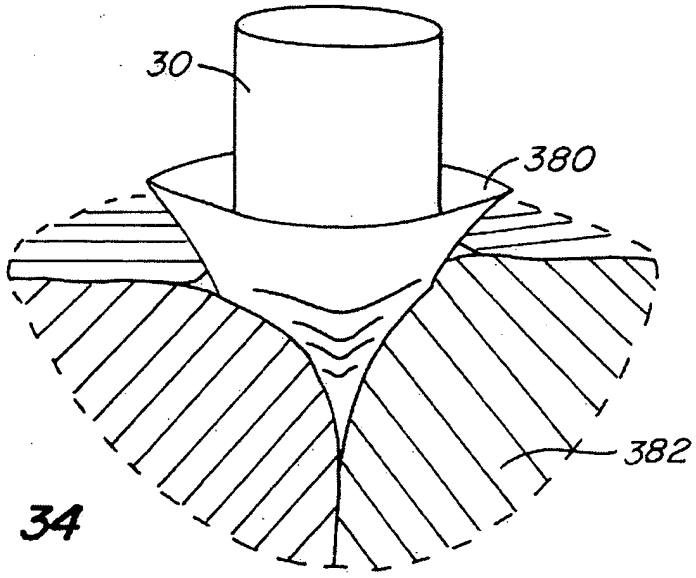

FIG. 34

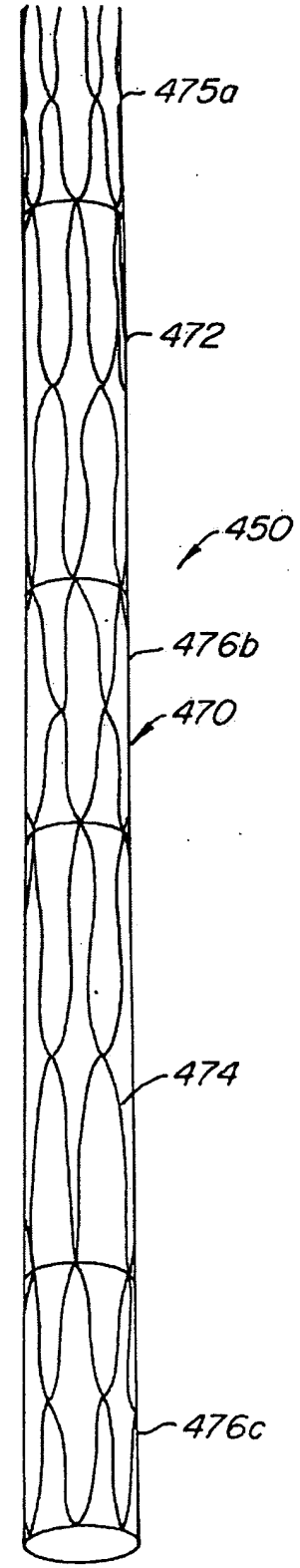

FIG. 35A

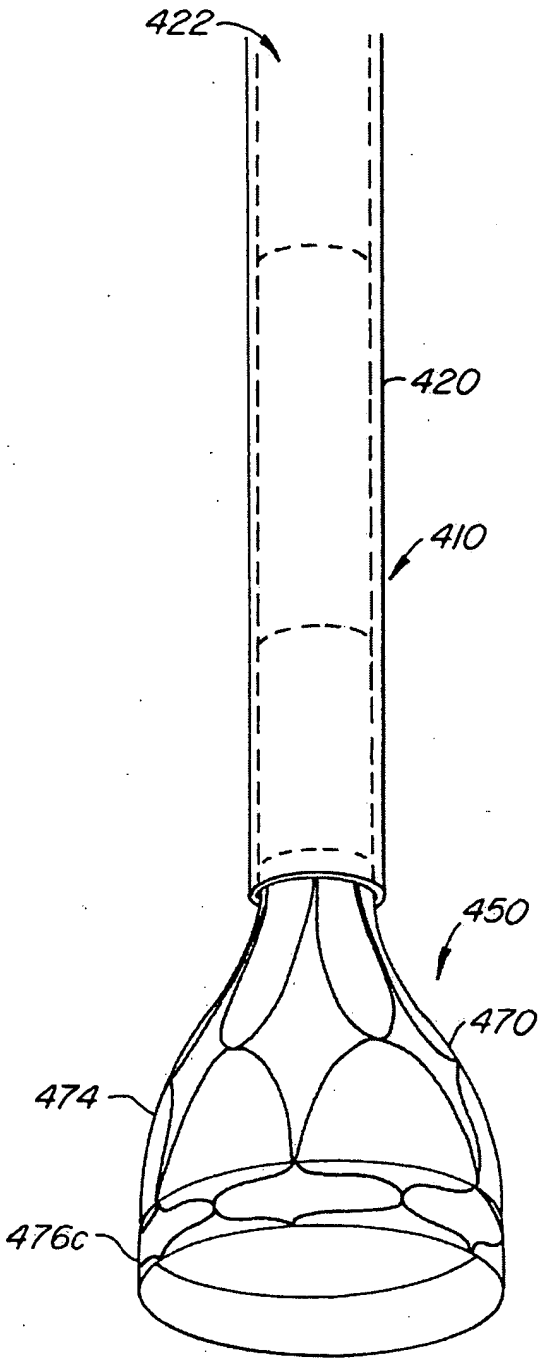

FIG. 35B

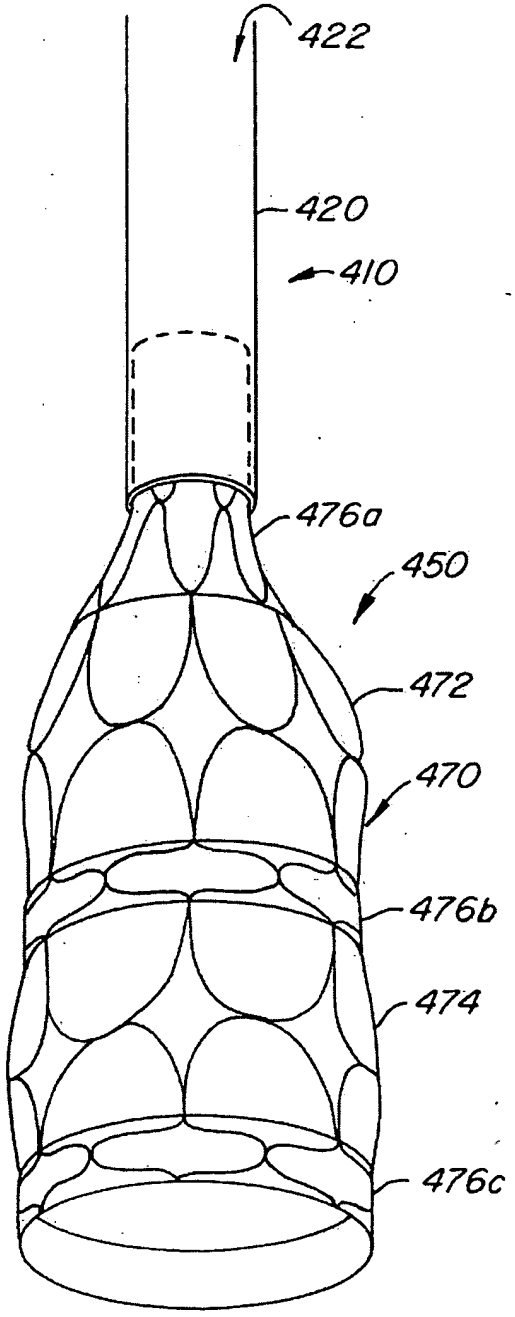

FIG. 35C

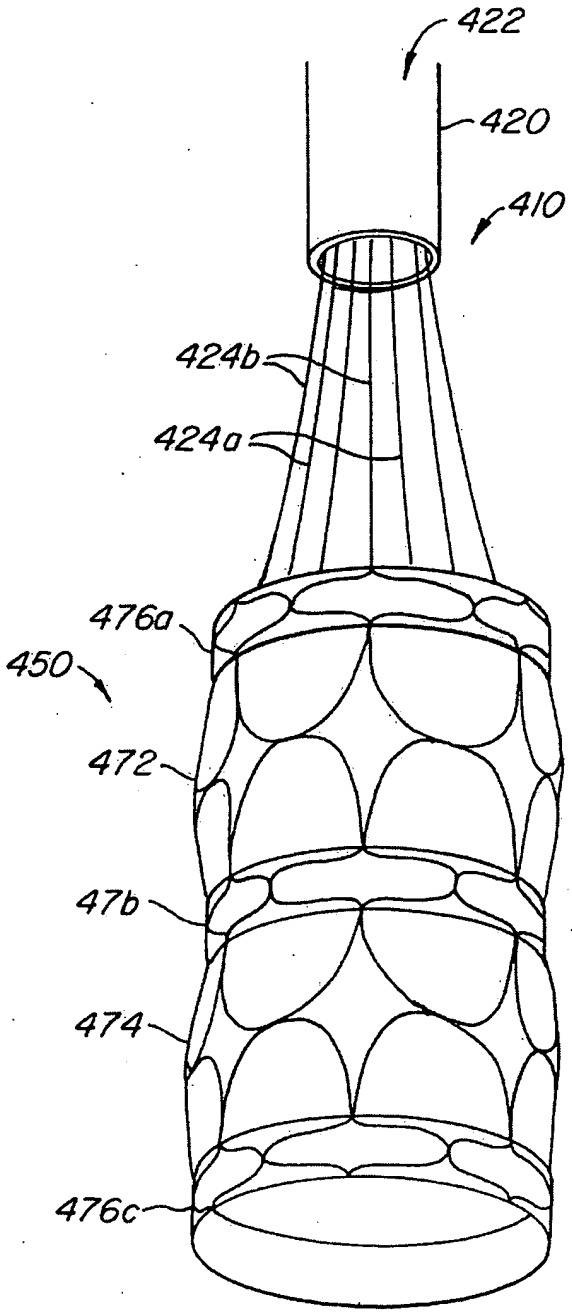

FIG. 35D

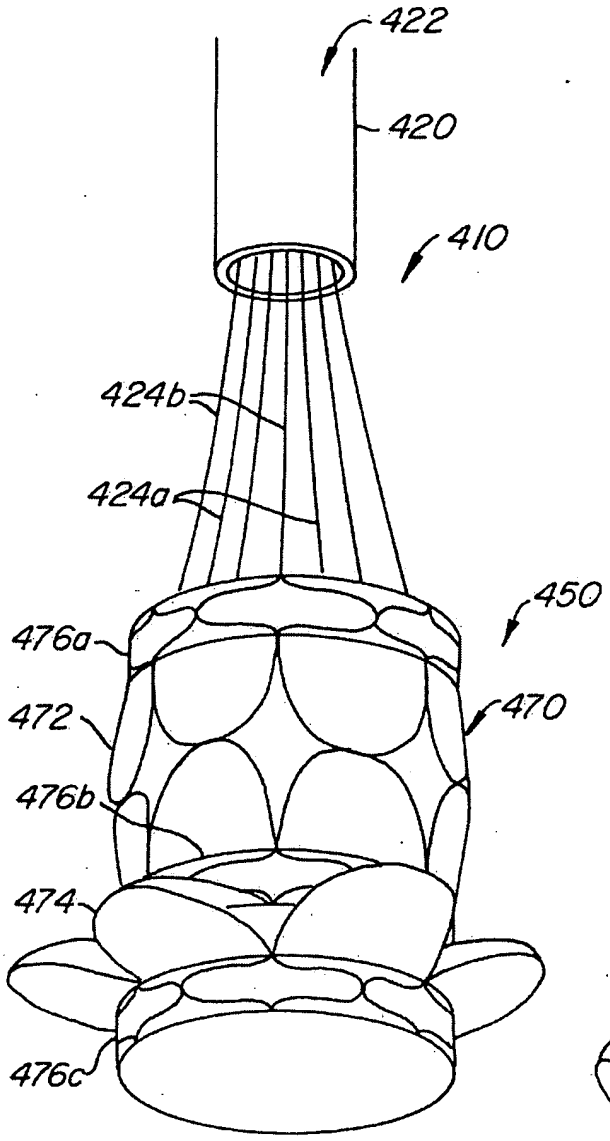

FIG. 35E

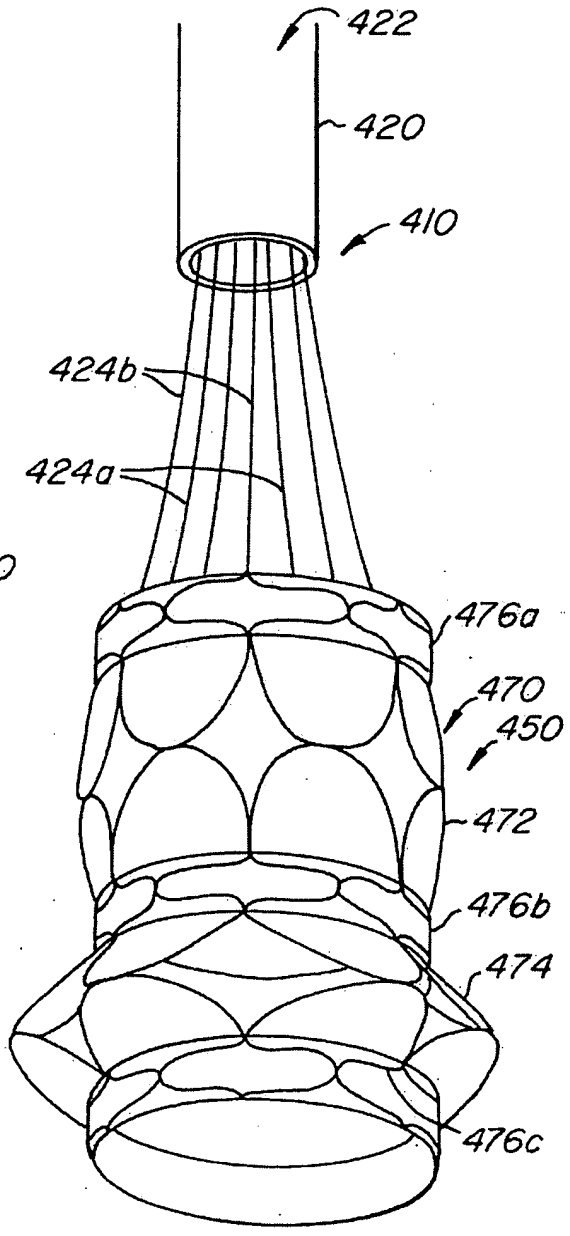

FIG. 35F

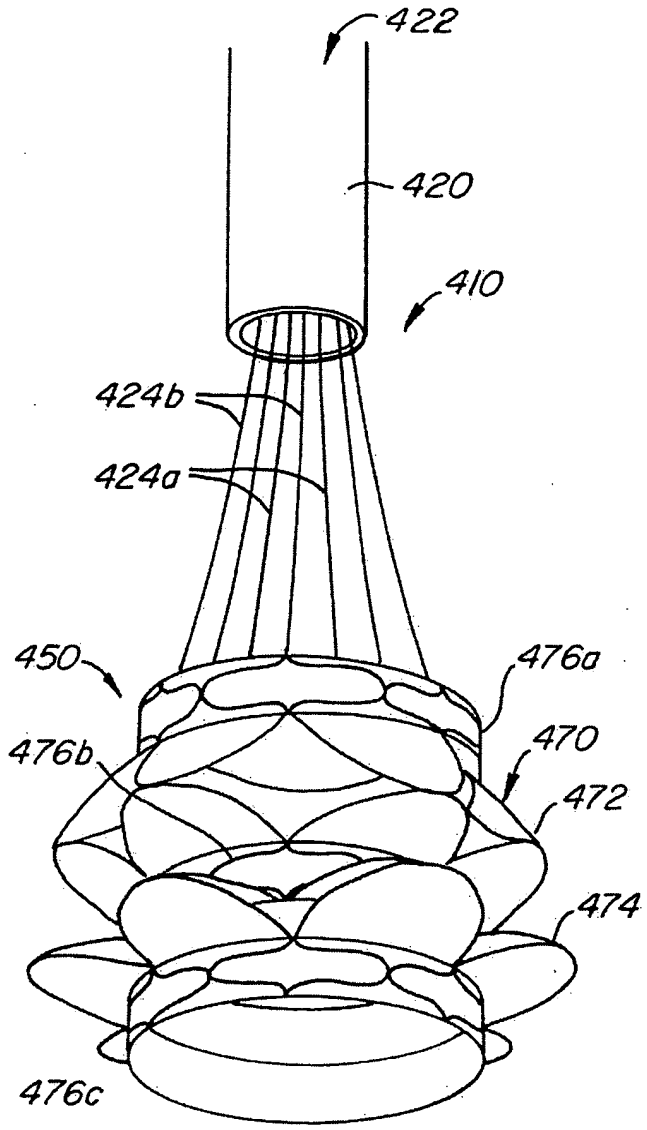

FIG. 35G

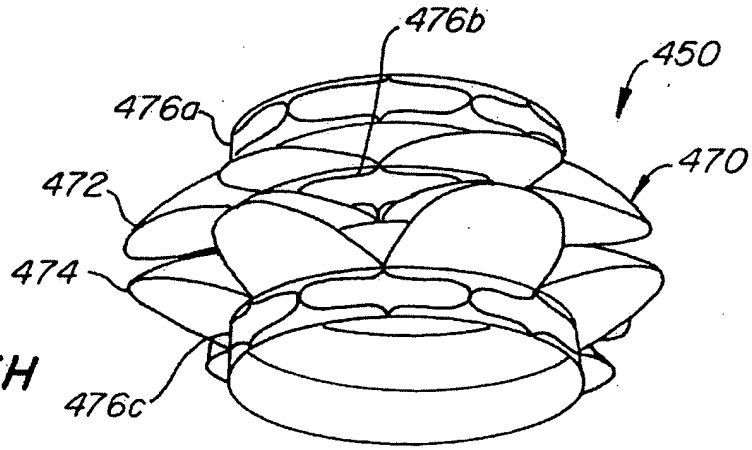

FIG. 35H

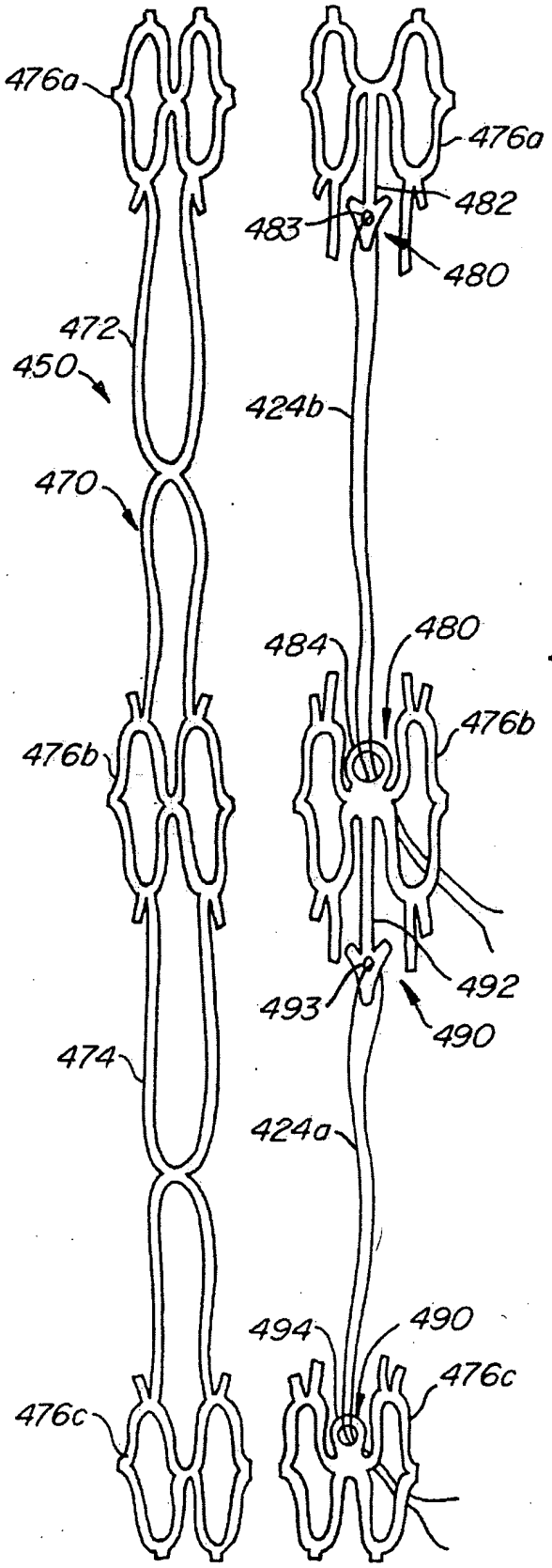

FIG. 36A

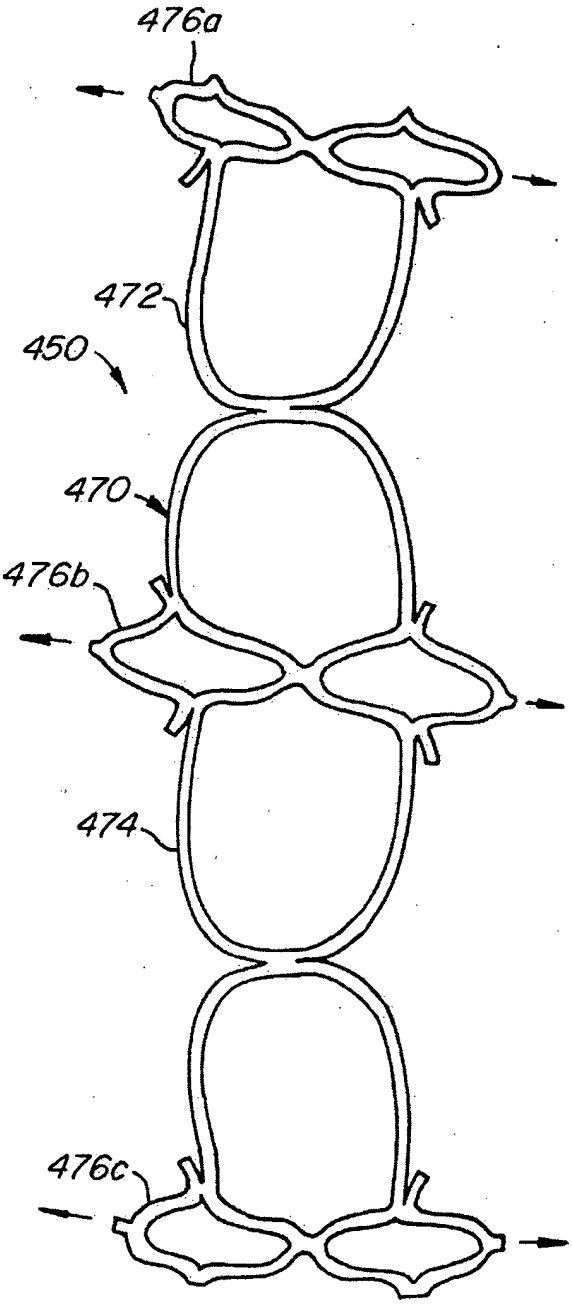

FIG. 36B

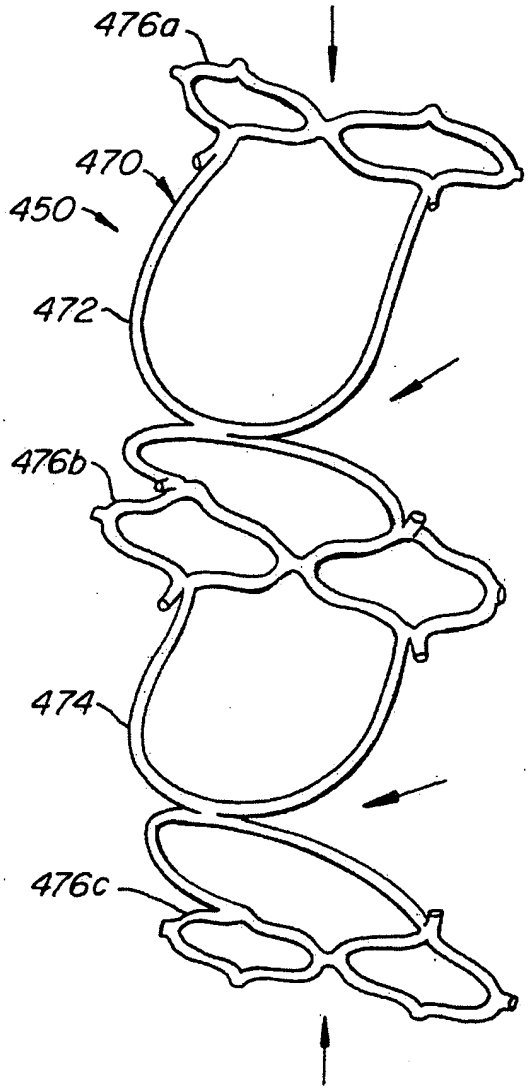

FIG. 36C

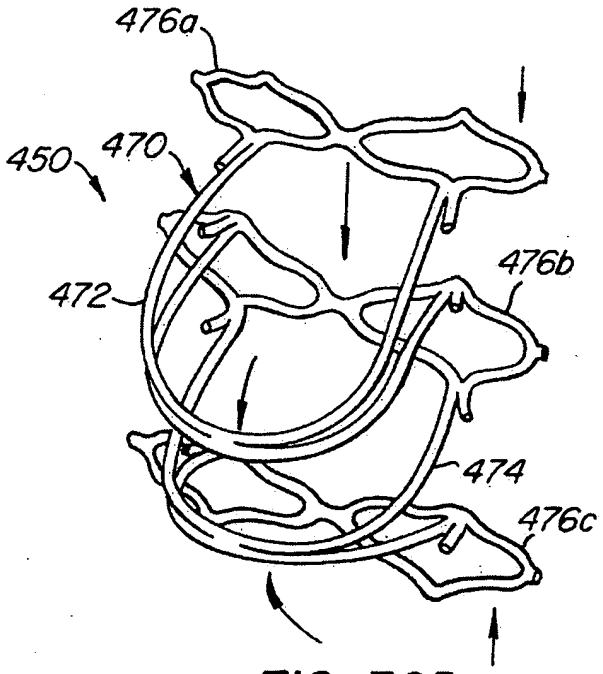

FIG. 36D

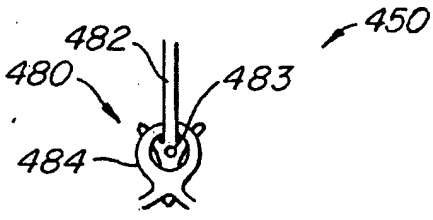

FIG. 36E

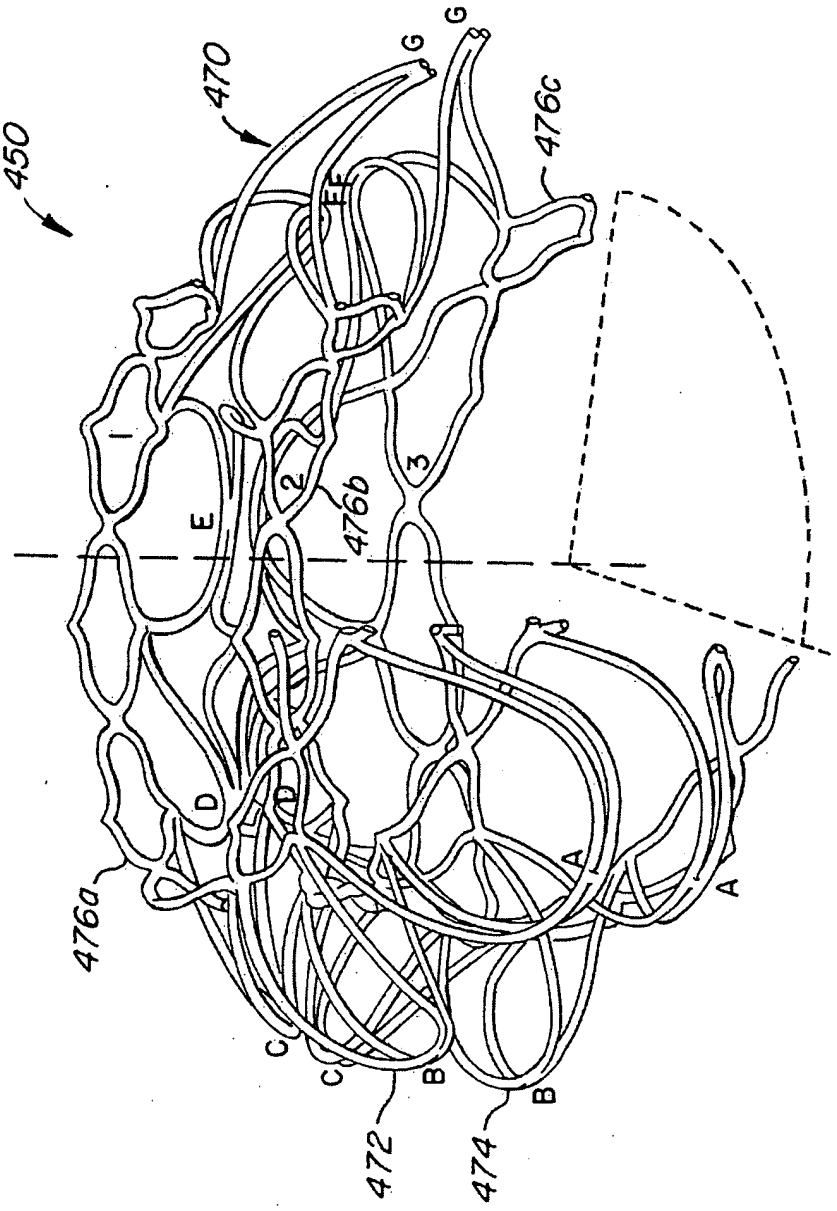

FIG. 37A

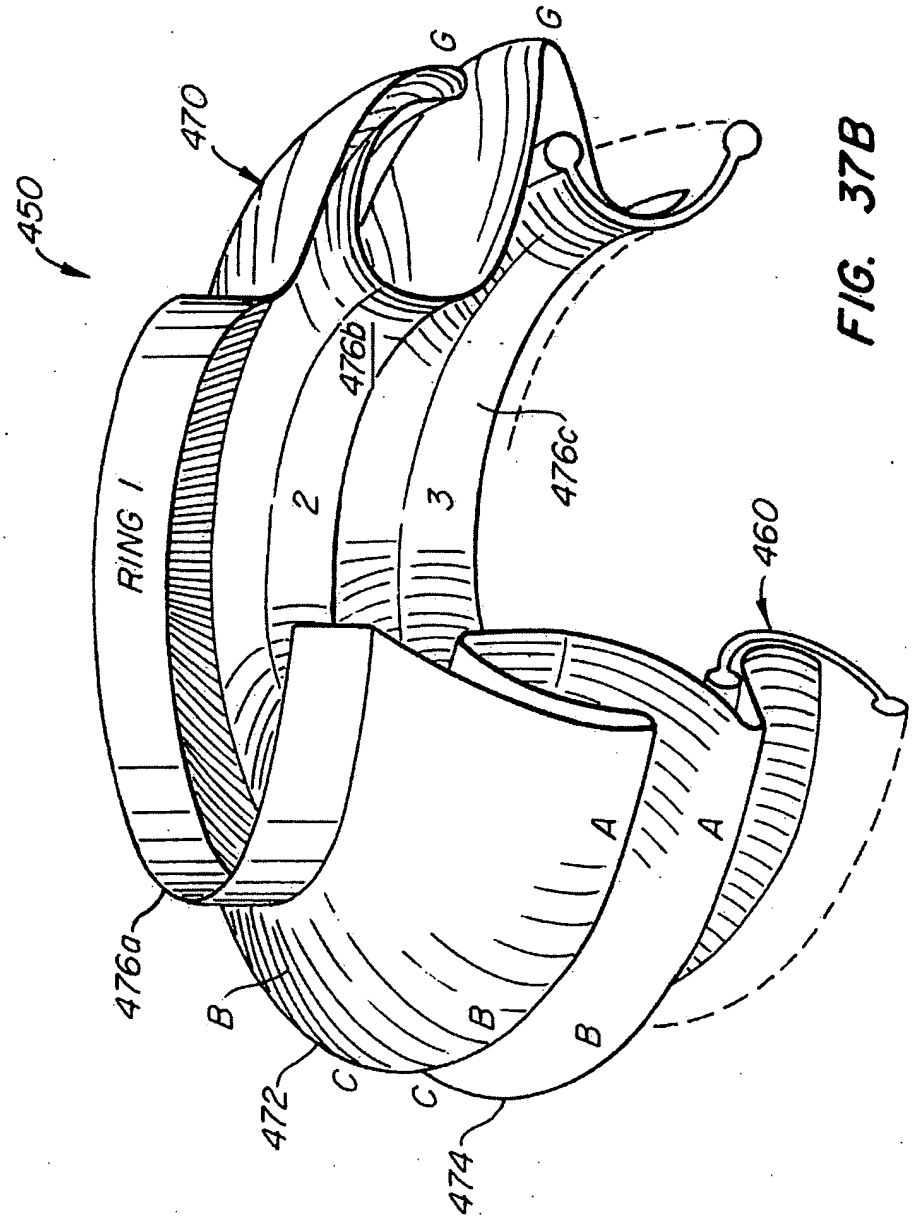

FIG. 37B

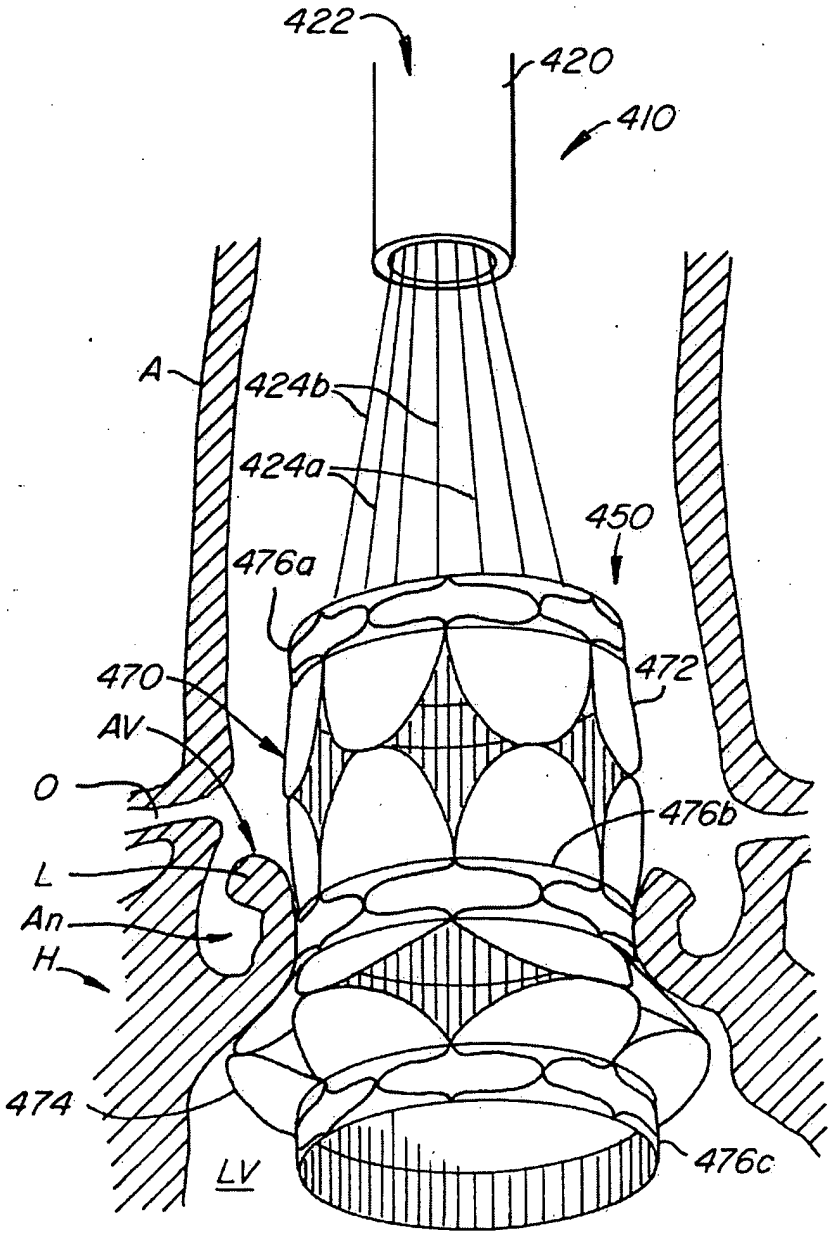
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FIG. 38A

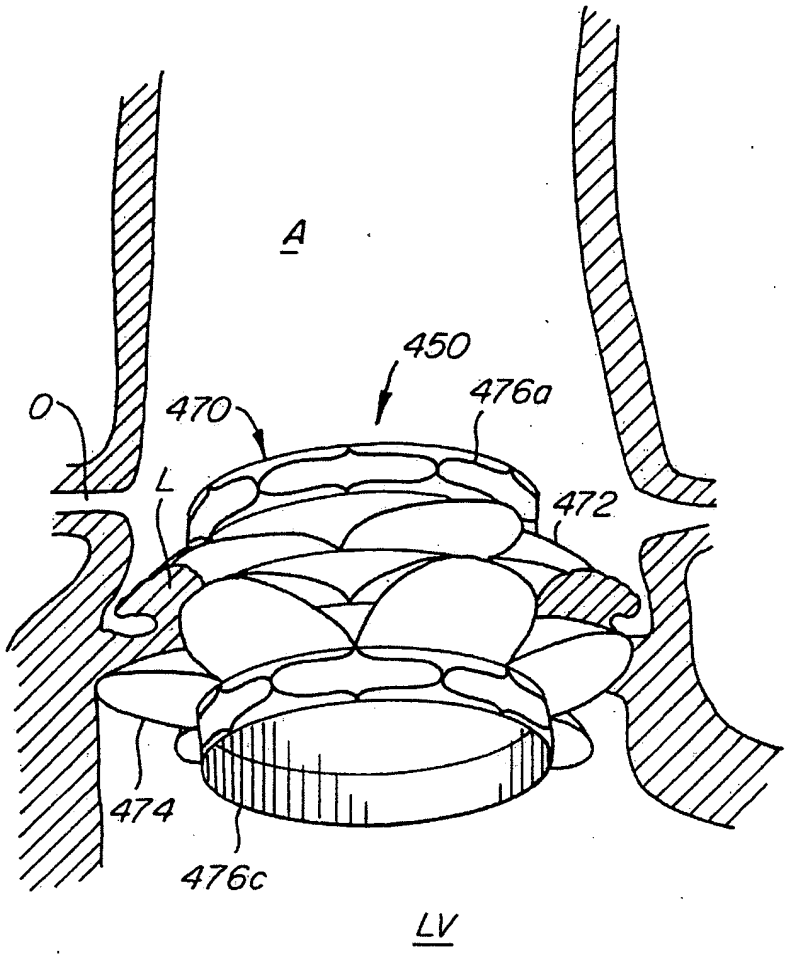

FIG. 38B

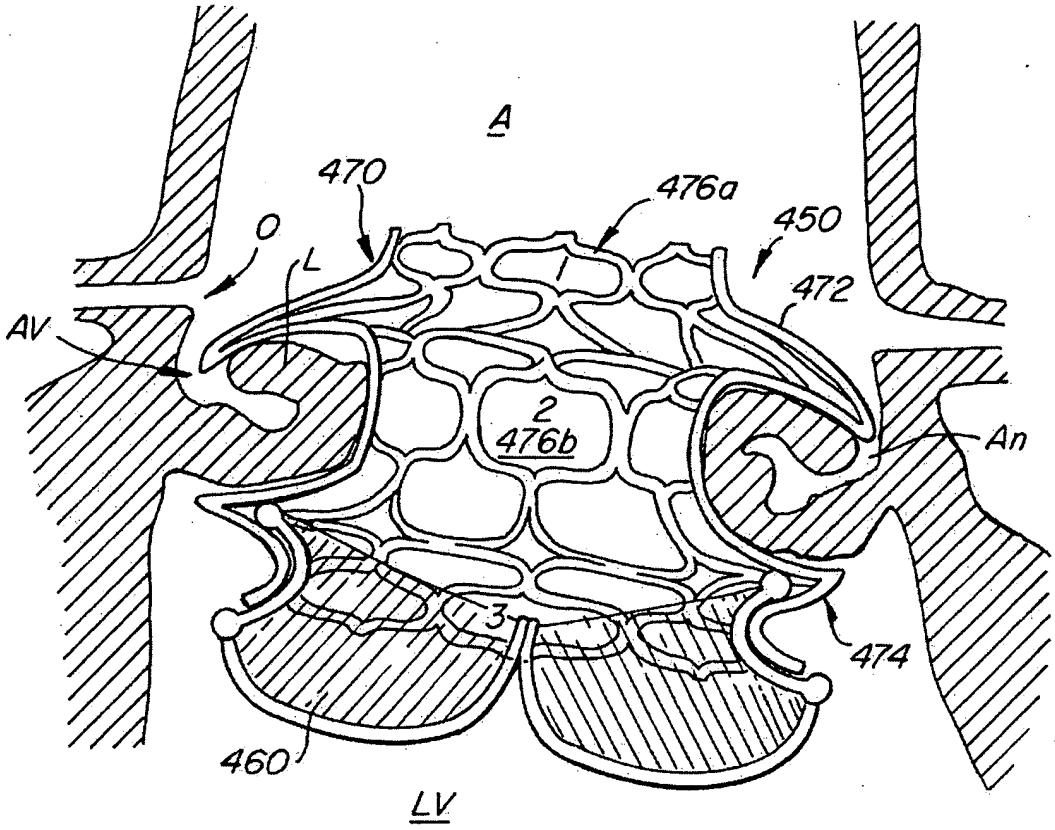

FIG. 38C

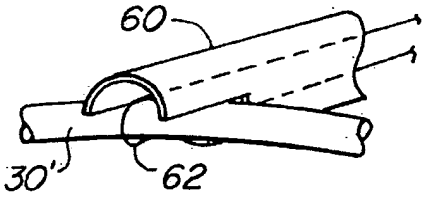

FIG. 39B

FIG. 39A

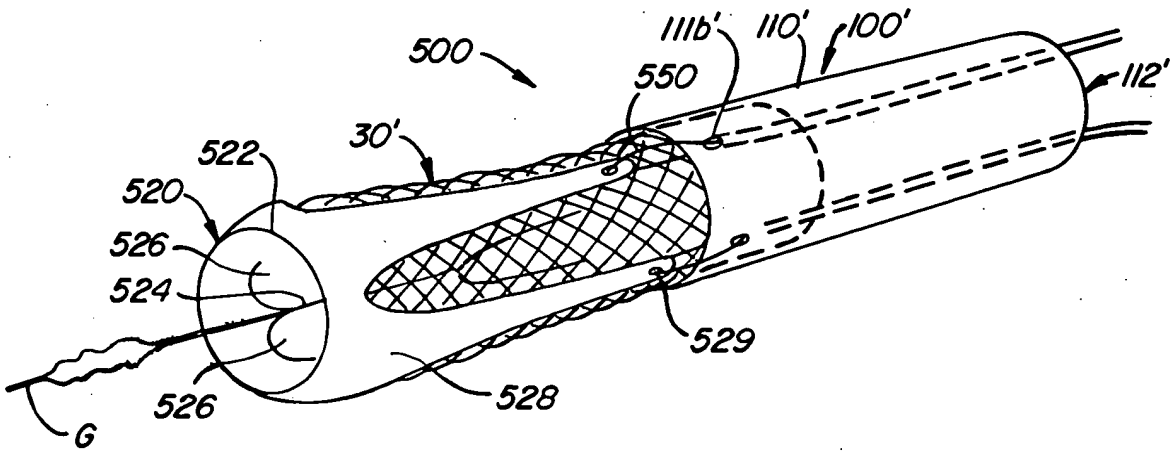

FIG. 39C

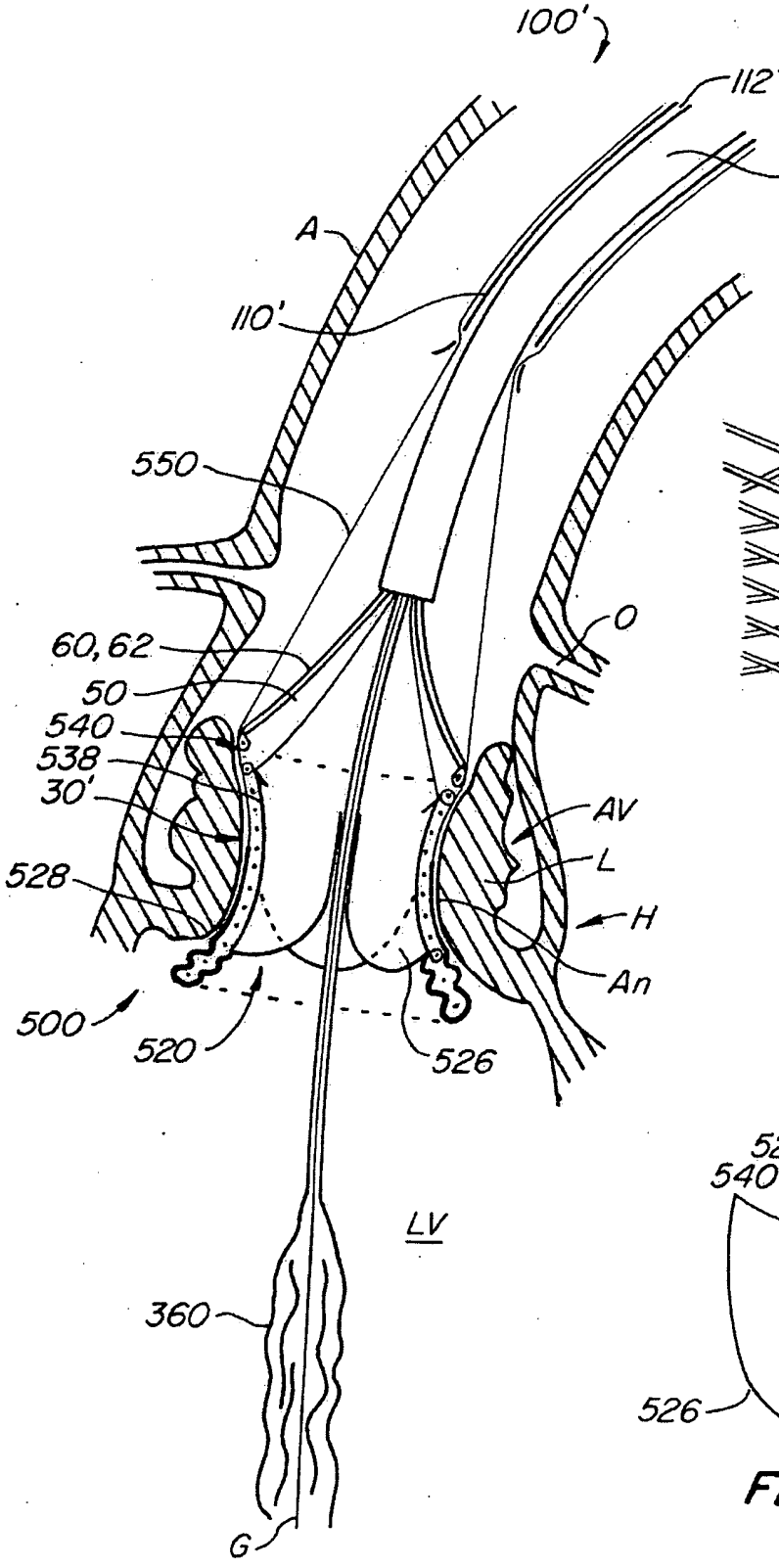

FIG. 39D

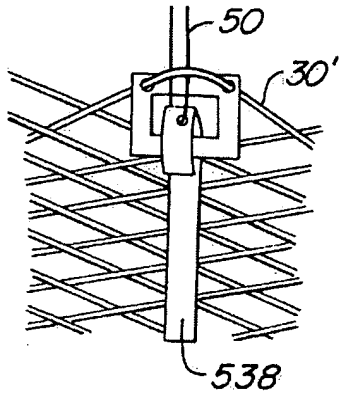

FIG. 39E

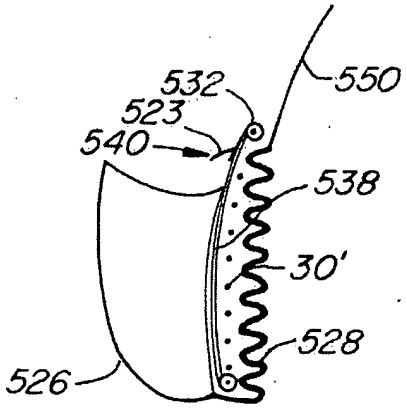

FIG. 39F

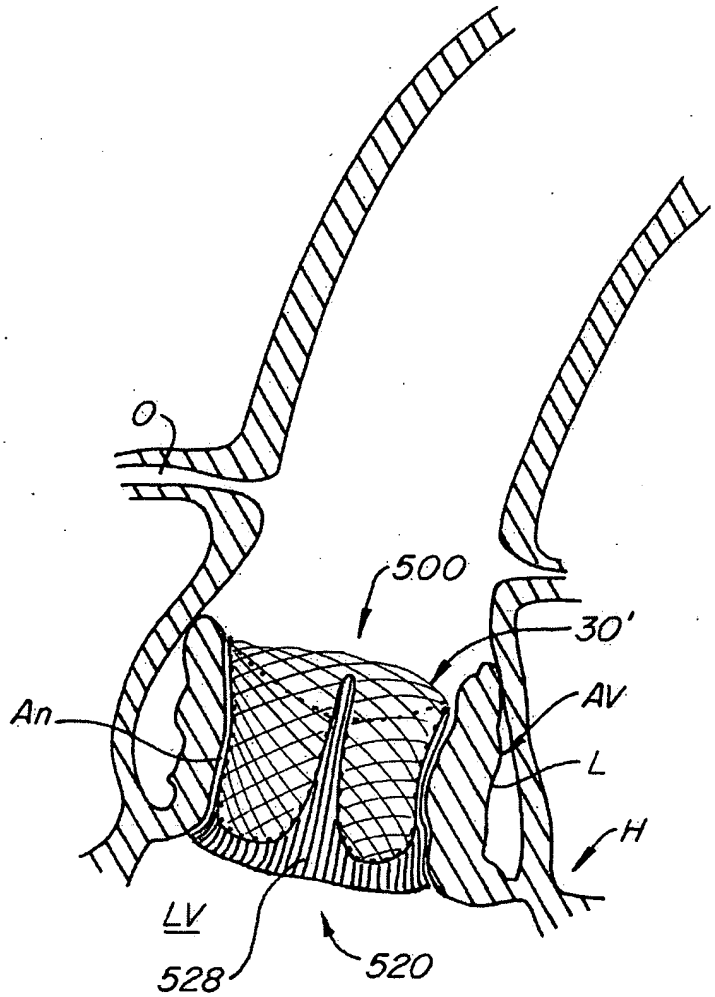

FIG. 39G

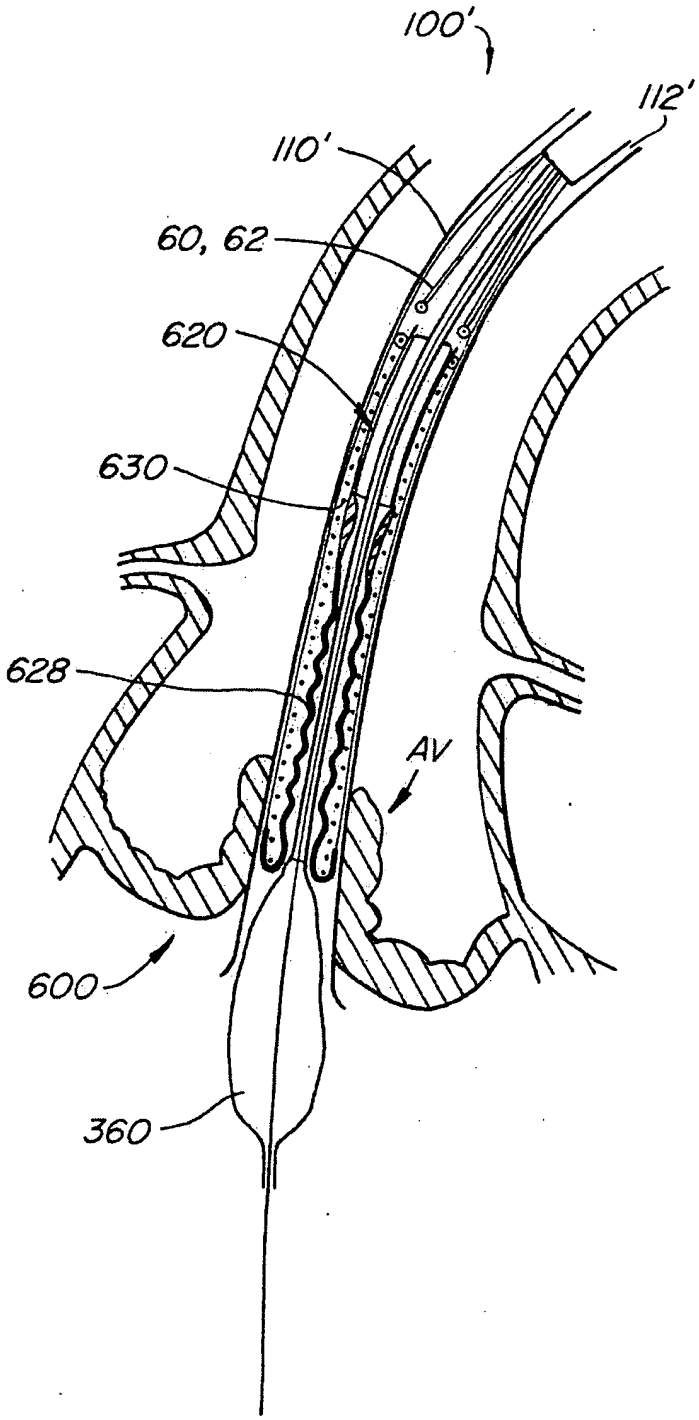

FIG. 40A

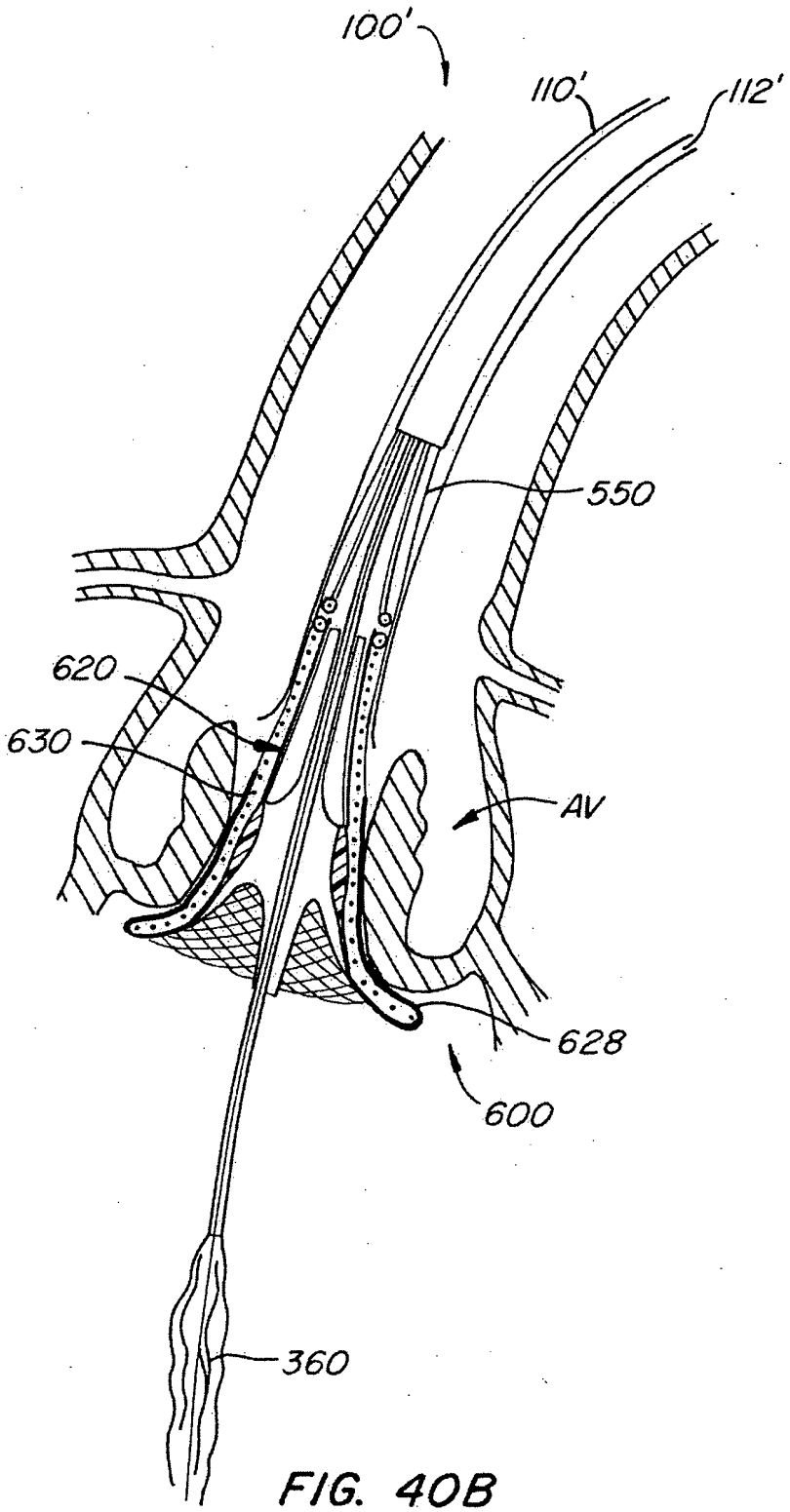

FIG. 40B

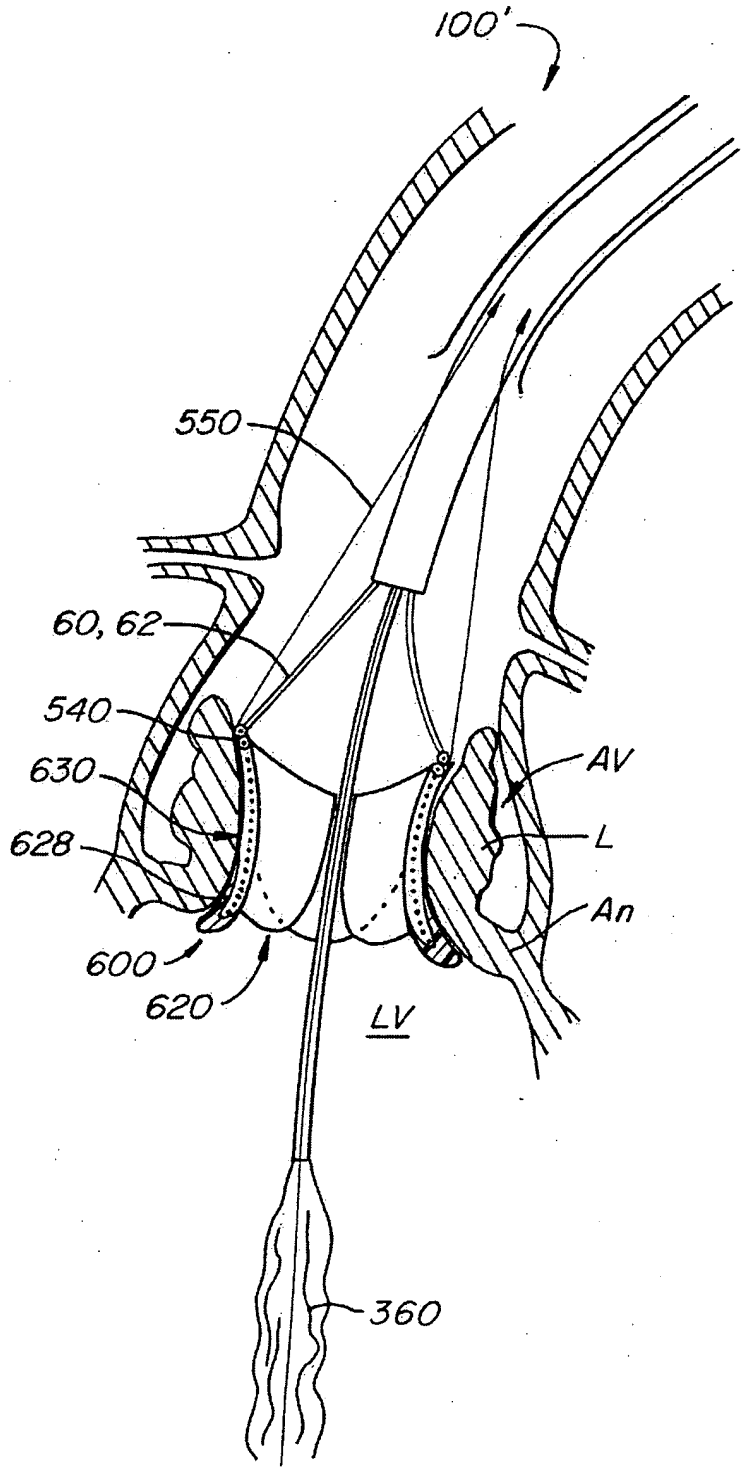

FIG. 40C

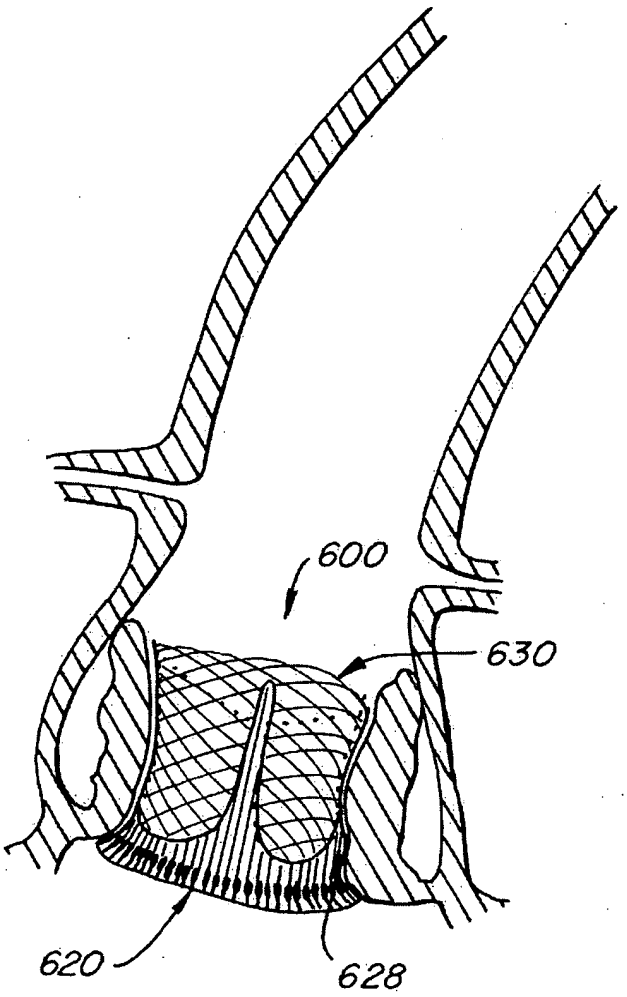

FIG. 40D

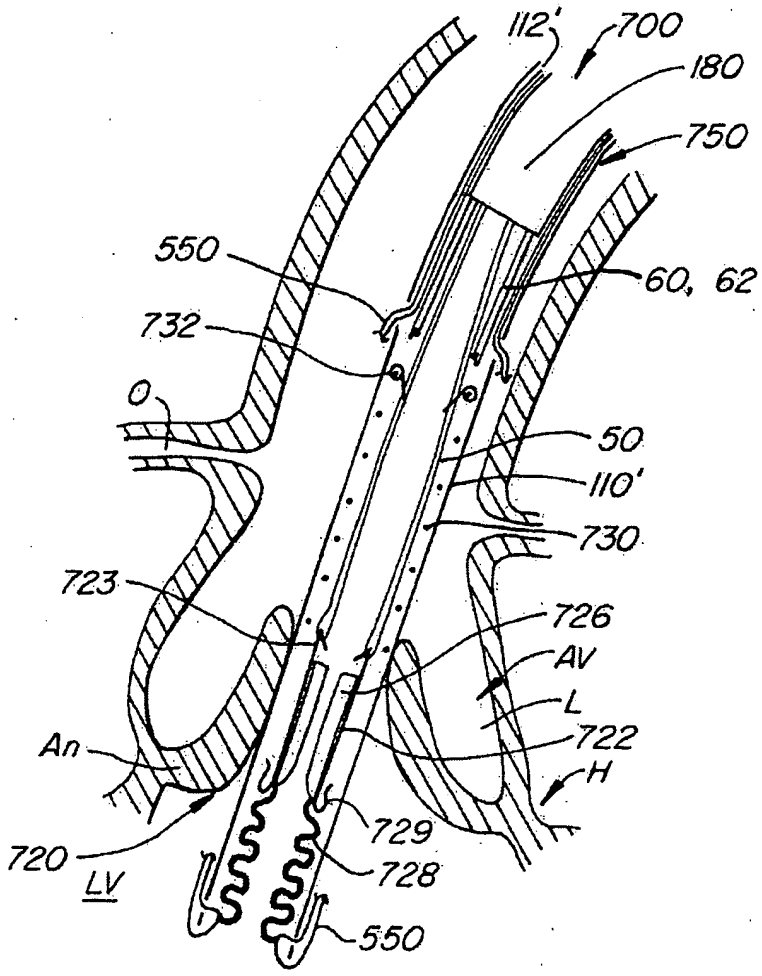
112'
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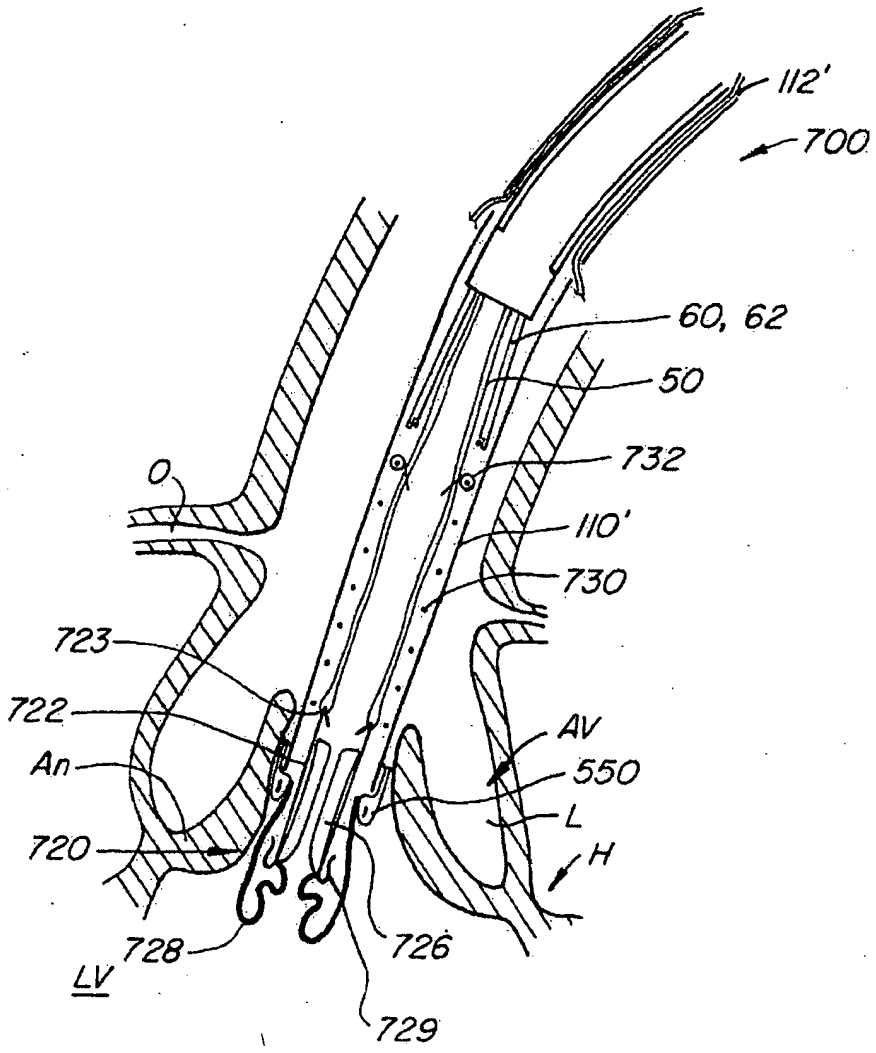
FIG. 41A


112'
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An
720
728
LV
726
729
AV
550
L
H

FIG. 41B

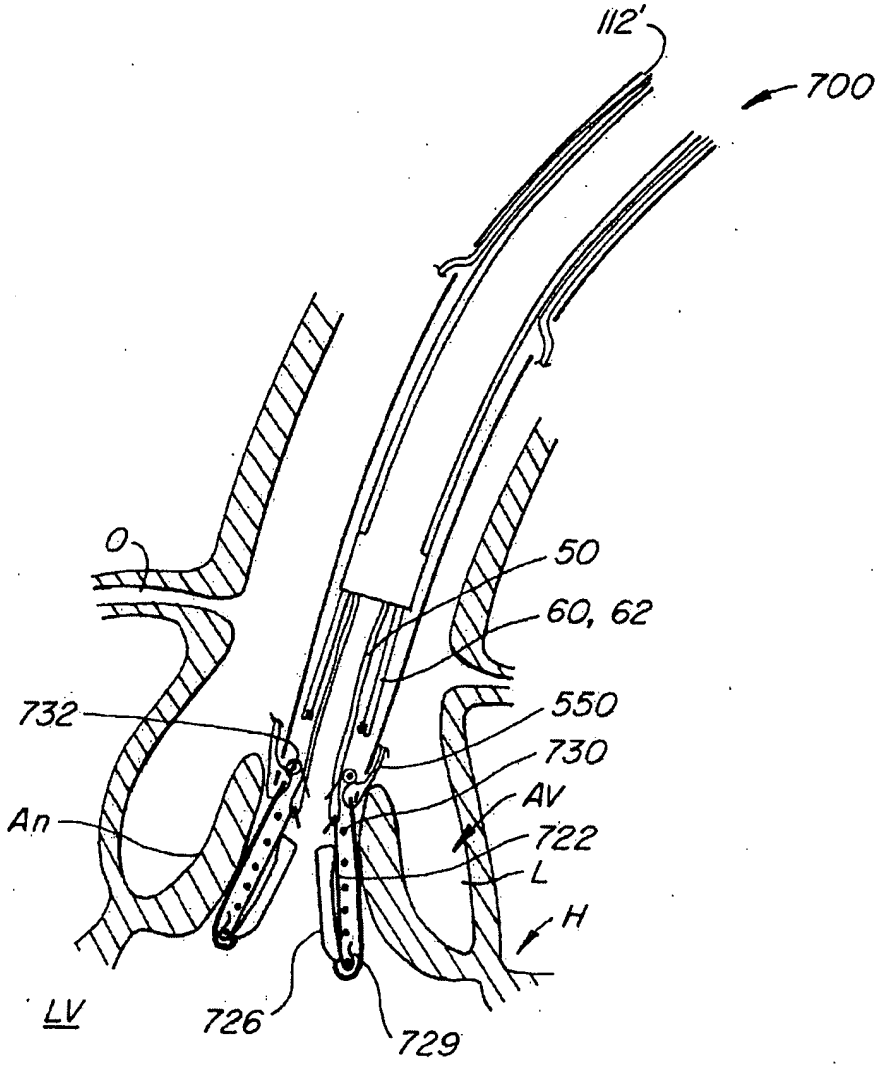

FIG. 41C

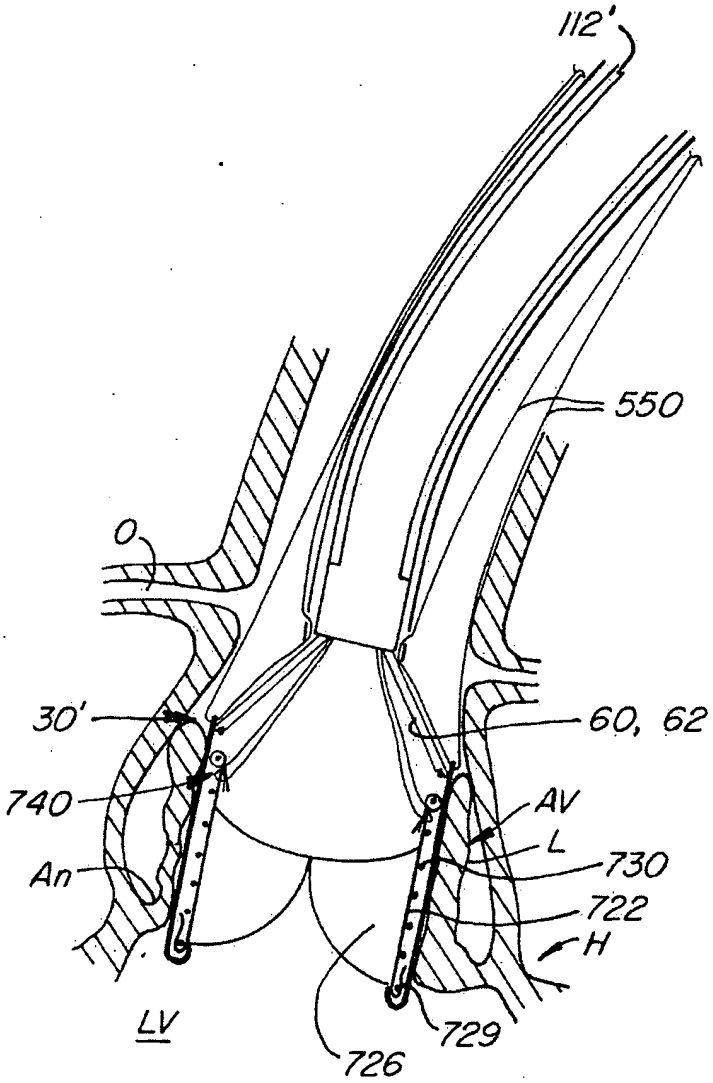

FIG. 41D

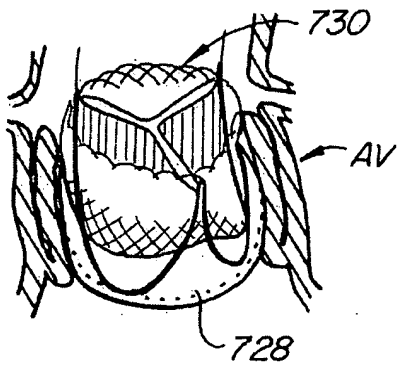

FIG. 41E

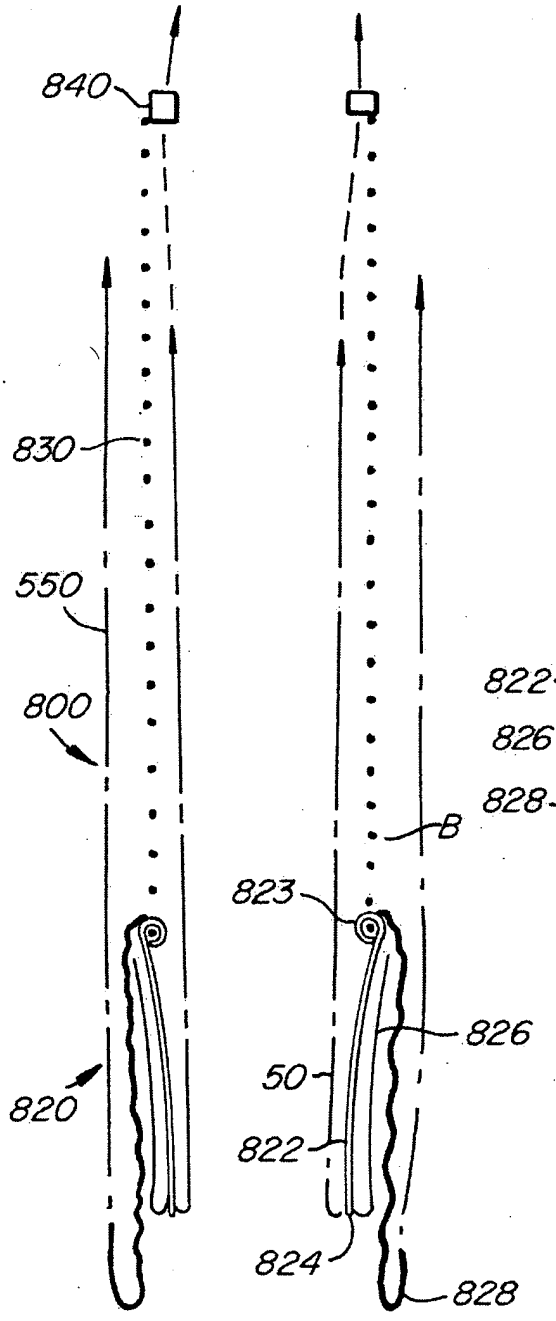

FIG. 42A

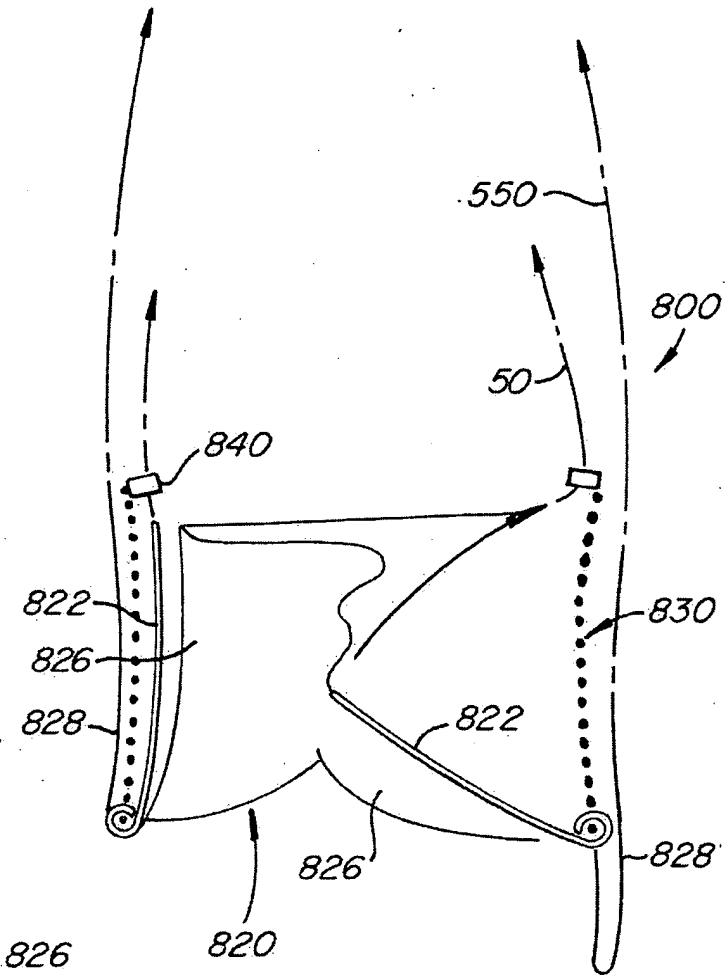

FIG. 42B

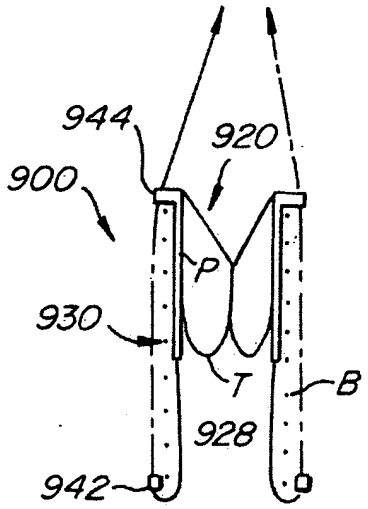

FIG. 43A

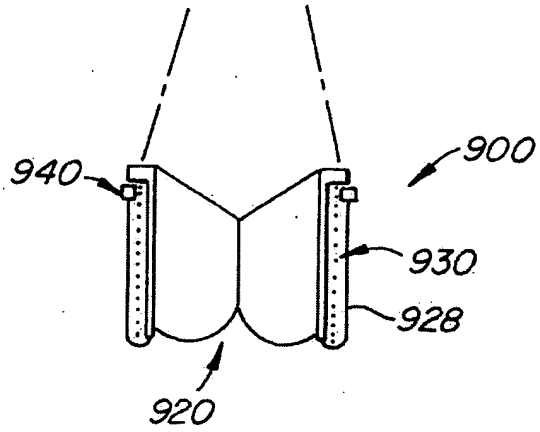

FIG. 43B

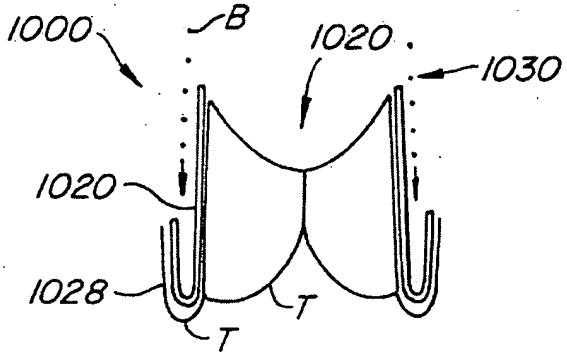

FIG. 44A

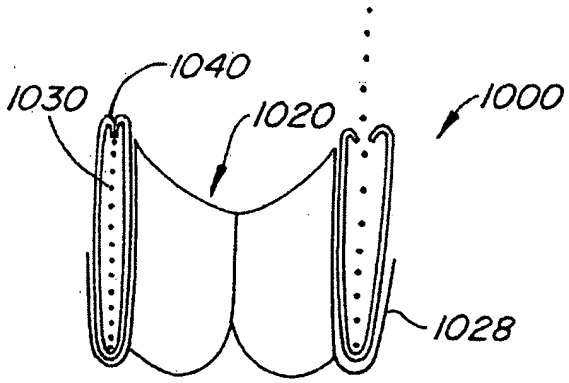

FIG. 44B

PATENT APPLICATION FEE DETERMINATION RECORD
Effective October 1, 2003

Application or Docket Number: 10870340

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	67	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	67 minus 20=	* 47
INDEPENDENT CLAIMS	5 minus 3 =	* 2
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	385.00	OR	BASIC FEE	770.00
XS 9=	423	OR	X$18=	
X43=	86	OR	X86=	
+145=		OR	+290=	
TOTAL	894	OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X43=		OR	X86=	
+145=		OR	+290=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X43=		OR	X86=	
+145=		OR	+290=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X43=		OR	X86=	
+145=		OR	+290=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
***If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/870,340	06/16/2004	Ulrich R. Haug	30207-710.201

CONFIRMATION NO. 7111

021971
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 943041050

FORMALITIES LETTER

OC000000013434322

Date Mailed: 08/04/2004

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  Applicant must submit $ **385** *to complete the basic filing fee for a small entity.*
- The oath or declaration is missing.
  A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **$509** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$959** for a Small Entity

- **$385** Statutory basic filing fee.
- **$65** Late oath or declaration Surcharge.

- Total additional claim fee(s) for this application is **$509**

- **$86** for **2** independent claims over 3.
- **$423** for **47** total claims over 20.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY

PATENT

Attorney Docket No. 30207.710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	PATENT APPLICATION
Inventor(s): Ulrich R. HAUG et al.	Art Unit: 3738
Application No.: 10/870,340	Examiner: Not yet assigned
Filed: June 16, 2004	Confirmation No.: 7111
Title: Everting heart valve	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ This statement qualifies under *37 C.F.R. §1.97*, subsection (b) because:

☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)

-- OR --

☐ (2) It is being filed within 3 months of entry of a national stage

-- OR --

☒ (3) It is being filed before the mail date of the first Office Action on the merits

-- OR --

☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

☐ *37 C.F.R. §1.97(c)*. If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:

☐ a certification as specified in §1.97(e) is provided below; **or**

☐ a fee of $180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ *37 C.F.R. §1.97(d)*. If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:

A. a certification as specified in §1.97(e) is completed below; and

B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**

C. a fee of $130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

☒ Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.), copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are provided in PDF format on the attached CD ROM, clearly titled by publication number or author, in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).

☐ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).

☐ Attached are the following non-published pending patent applications which may be deemed relevant.

☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.710.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 11-22-04

By: Maya Skubatch, Reg. No. 52,505

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 12

Complete if Known	
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2001/0025196	09/27/2001	Chinn et al.	
		US-2001/0032013	10/18/2001	Marton	
		US-2001/0039450	11/08/2001	Pavcnik et al.	
		US-2001/0041928	11/15/2001	Pavcnik et al.	
		US-2002/0032480	03/14/2002	Spence et al.	
		US-2002/0052651	05/02/2002	Myers et al.	
		US-2002/0058995	05/16/2002	Stevens	
		US-2002/0077696	06/20/2002	Zadno-Azizi et al.	
		US-2002/0095209	07/18/2002	Zadno-Azizi et al.	
		US-2002/0111674	08/15/2002	Chouinard et al.	
		US-2002/0151970	10/17/2002	Garrison et al.	
		US-2002/0161392	10/31/2002	Dubrul	
		US-2002/0161394	10/31/2002	Macoviak et al.	
		US-2002/0193871	12/19/2002	Beyersdorf et al.	
		US-2003/0014104	01/16/2003	Cribier	
		US-2003/0023303	01/30/2003	Palmaz et al.	
		US-2003/0028247	02/06/2003	Cali	
		US-2003/0036791	02/20/2003	Philipp et al.	
		US-2003/0040771	02/27/2003	Hyodoh et al.	
		US-2003/0040772	02/27/2003	Hyodoh et al.	
		US-2003/0055495	03/20/2003	Pease et al.	
		US-2003/0109924	06/12/2003	Cribier	
		US-2003/0125795	07/03/2003	Pavcnik et al.	
		US-2003/0149476	07/08/2003	Damm et al.	
		US-2003/0130729	07/10/2003	Paniagua et al.	
		US-2003/0149475	08/07/2003	Hyodoh et al.	
		US-2003/0149478	08/07/2003	Figulla et al.	
		US-2003/0153974	08/14/2003	Spenser et al.	
		US-2003/0181850	09/25/2003	Diamond et al.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	10/870,340
				Filing Date	06/16/2004
				First Named Inventor	Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	2	of	12	Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2003/0199913	10/23/2003	Dubrul et al.	
		US-2003/0199971	10/23/2003	Tower et al.	
		US-2003/0199972	10/23/2003	Zadno-Azizi et al.	
		US-2003/0212452	11/13/2003	Zadno-Azizi et al.	
		US-2003/0212454	11/13/2003	Scott et al.	
		US-2004/0034411	02/19/2004	Quijano et al.	
		US-2004/0039436	02/26/2004	Spenser et al.	
		US-2004/0049224	03/11/2004	Buehlmann et al.	
		US-2004/0049262	03/11/2004	Obermiller et al.	
		US-2004/0049266	03/11/2004	Anduiza et al.	
		US-2004/0082904	04/29/2004	Houde et al.	
		US-2004/0088045	05/06/2004	Cox	
		US-2004/0098112	05/20/2004	DiMatteo et al.	
		US-2004/0111096	06/10/2004	Tu et al.	
		US-2004/0116951	06/17/2004	Rosengart	
		US-2004/0117004	06/17/2004	Osborne et al.	
		US-2004/0122468	06/24/2004	Yodfat et al.	
		US-2004/0127979	07/01/2004	Wilson et al.	
		US-2004/0138742	07/15/2004	Myers et al.	
		US-2004/0138743	07/15/2004	Myers et al.	
		US-2004/0215339	10/28/2004	Drasler et al.	
		US-3,334,629	08/08/1967	Cohn	
		US-3,540,431	11/17/1970	Mobin-Uddin	
		US-3,628,535	12/21/1971	Ostrowsky et al.	
		US-3,642,004	02/15/1972	Osthagen et al.	
		US-3,671,979	06/27/1972	Moulopoulos	
		US-3,795,246	03/05/1974	Sturgeon	
		US-3,839,741	10/08/1974	Haller	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	3	of	12

Complete if Known	
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-3,868,956	03/04/1975	Alfidi et al.	
		US-3,874,388	04/01/1975	King et al.	
		US-4,056,854	11/08/1977	Boretos et al.	
		US-4,106,129	08/15/1978	Carpentier et al.	
		US-4,233,690	11/18/1980	Akins	
		US-4,291,420	09/29/1981	Reul	
		US-4,425,908	01/17/1984	Simon	
		US-4,501,030	02/26/1985	Lane	
		US-4,580,568	04/08/1986	Gianturco	
		US-4,610,688	09/09/1986	Silvestrini et al.	
		US-4,647,283	03/03/1987	Carpentier et al.	
		US-4,648,881	03/10/1987	Carpentier et al.	
		US-4,655,771	04/07/1987	Wallsten	
		US-4,662,885	05/05/1987	DiPisa, Jr.	
		US-4,665,906	05/19/1987	Jervis	
		US-4,710,192	12/01/1987	Liotta et al.	
		US-4,733,665	03/29/1988	Palmaz	
		US-4,819,751	04/11/1989	Shimada et al.	
		US-4,834,755	05/30/1989	Silvestrini et al.	
		US-4,856,516	08/15/1989	Hillstead	
		US-4,872,874	10/10/1989	Taheri	
		US-4,909,252	03/20/1990	Goldberger	
		US-4,917,102	04/17/1990	Miller et al.	
		US-4,954,126	09/04/1990	Wallsten	
		US-4,994,077	02/19/1991	Dobben	
		US-5,002,559	03/26/1991	Tower	
		US-5,161,547	11/10/1992	Tower	
		US-5,163,953	11/17/1992	Vince	

Examiner Signature		Date Considered	

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PTO/SB/08A (08-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	10/870,340
				Filing Date	06/16/2004
				First Named Inventor	Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	4	of	12	Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,217,483	07/08/1993	Tower	
		US-5,217,483	07/08/1993	Tower	
		US-5,332,402	07/26/1994	Teitelbaum et al.	
		US-5,350,398	09/27/1994	Pavcnik et al.	
		US-5,370,685	12/16/1994	Stevens	
		US-5,389,106	02/14/1995	Tower	
		US-5,397,351	03/14/1995	Pavcnik et al.	
		US-5,411,552	05/02/1995	Andersen et al.	
		US-5,431,676	07/11/1995	Dubrul et al.	
		US-5,507,767	04/16/1996	Maeda et al.	
		US-5,545,211	08/13/1996	An et al.	
		US-5,575,818	11/19/1996	Pinchuk	
		US-5,645,559	07/08/1997	Hachtman et al.	
		US-5,674,277	10/07/1997	Freitag	
		US-5,695,498	12/09/1997	Tower	
		US-5,713,953	02/03/1998	Vallana et al.	
		US-5,800,456	09/01/1998	Maeda et al.	
		US-5,817,126	10/06/1998	Imran	
		US-5,824,043	10/20/1998	Cottone Jr.	
		US-5,824,053	10/20/1998	Khosravi et al.	
		US-5,824,056	10/20/1998	Rosenberg	
		US-5,824,064	10/20/1998	Taheri	
		US-5,840,081	11/24/1998	Andersen et al.	
		US-5,855,597	01/05/1999	Jayaraman	
		US-5,855,601	01/05/1999	Bessler et al.	
		US-5,860,996	01/19/1999	Tower	
		US-5,861,028	01/19/1999	Angell	
		US-5,868,783	02/09/1999	Tower	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	10/870,340
				Filing Date	06/16/2004
				First Named Inventor	Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	5	of	12	Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,876,448	03/02/1999	Thompson et al.	
		US-5,888,201	03/30/1999	Stinson et al.	
		US-5,891,191	04/06/1999	Stinson	
		US-5,907,893	06/01/1999	Zadno-Azizi et al.	
		US-5,925,063	07/20/1999	Khosravi	
		US-5,944,738	08/31/1999	Amplatz et al.	
		US-5,954,766	09/21/1999	Zadno-Azizi et al.	
		US-5,957,949	09/28/1999	Leonhardt et al.	
		US-5,984,957	11/16/1999	Laptewicz, Jr. et al.	
		US-6,022,370	02/08/2000	Tower	
		US-6,027,525	02/22/2000	Suh et al.	
		US-6,042,598	03/28/2000	Tsugita et al.	
		US-6,051,104	04/18/2000	Jang	
		US-6,123,723	09/26/2000	Konya et al.	
		US-6,146,366	11/14/2000	Schachar	
		US-6,162,245	12/19/2000	Jayaraman	
		US-6,168,614	01/02/2001	Andersen et al.	
		US-6,200,336	03/13/2001	Pavcnik et al.	
		US-6,221,006	04/24/2001	Dubrul et al.	
		US-6,221,091	04/24/2001	Khosravi	
		US-6,241,757	06/05/2001	An et al.	
		US-6,245,102	06/12/2001	Jayaraman	
		US-6,258,114	07/10/2001	Konya et al.	
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		US-6,258,120	07/10/2001	McKenzie et al.	
		US-6,277,555	08/21/2001	Duran et al.	
		US-6,309,417	10/30/2001	Spence et al.	
		US-6,319,281	11/20/2001	Patel	

Examiner Signature		Date Considered	

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Substitute for form 1449/PTO	*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*	Application Number	10/870,340
	Filing Date	06/16/2004
	First Named Inventor	Haug
	Art Unit	3738
	Examiner Name	Not yet assigned
Sheet 6 of 12	Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,327,772	12/11/2001	Zadno-Azizi et al.	
		US-6,338,735	01/15/2002	Stevens	
		US-6,348,063	02/19/2002	Yassour et al.	
		US-6,352,708	03/05/2002	Duran et al.	
		US-6,371,970	04/16/2002	Khosravi et al.	
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		US-6,379,383	04/30/2002	Palmaz et al.	
		US-6,398,807	06/04/2002	Chouinard et al.	
		US-6,409,750	06/25/2002	Hyodoh et al.	
		US-6,425,916	07/30/2002	Garrison et al.	
		US-6,440,164	08/27/2002	DiMatteo et al.	
		US-6,458,153	10/01/2002	Bailey et al.	
		US-6,468,303	10/22/2002	Amplatz et al.	
		US-6,475,239	11/05/2002	Campbell et al.	
		US-6,482,228	11/19/2002	Norred	
		US-6,494,909	12/17/2002	Greenhalgh	
		US-6,503,272	01/07/2003	Duerig et al.	
		US-6,508,833	01/21/2003	Pavcnik et al.	
		US-6,527,800	03/04/2003	McGuckin, Jr. et al.	
		US-6,530,949	03/11/2003	Konya et al.	
		US-6,562,058	05/13/2003	Seguin et al.	
		US-6,592,546	07/15/2003	Barbut et al.	
		US-6,622,604	09/23/2003	Chouinard et al.	
		US-6,632,243	10/14/2003	Zadno-Azizi et al.	
		US-6,635,068	10/21/2003	Dubrul et al.	
		US-6,652,571	11/25/2003	White et al.	
		US-6,652,578	11/25/2003	Bailey et al.	
		US-6,663,663	12/16/2003	Kim et al.	

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	Examiner Name	Not yet assigned
Sheet 7 of 12	Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

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		US-6,669,724	12/30/2003	Park et al.	
		US-6,673,089	01/06/2004	Yassour et al.	
		US-6,673,109	01/06/2004	Cox	
		US-6,682,558	01/27/2004	Tu et al.	
		US-6,682,559	01/27/2004	Myers et al.	
		US-6,685,739	02/03/2004	DiMatteo et al.	
		US-6,689,144	02/10/2004	Gerberding	
		US-6,689,164	02/10/2004	Seguin	
		US-6,692,512	02/17/2004	Jang	
		US-6,702,851	03/09/2004	Chinn et al.	
		US-6,719,789	04/13/2004	Cox	
		US-6,730,118	05/04/2004	Spenser et al.	
		US-6,730,377	05/04/2004	Wang	
		US-6,733,525	05/11/2004	Yang et al.	
		US-6,736,846	05/18/2004	Cox	
		US-6,752,828	06/22/2004	Thornton	
		US-6,758,855	07/06/2004	Fulton, III et al.	

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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	Filing Date	06/16/2004
	First Named Inventor	Haug
	Art Unit	3738
	Examiner Name	Not yet assigned
Sheet 8 of 12	Attorney Docket Number	30207.710.201

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] – Number[4] – Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP 1057459	12/06/2000	Numed, Inc.		
		EP 1057460	12/06/2000	Numed, Inc.		
		EP 1340473	09/09/2003	3F Therapeutics, Inc.		
		EP 1356793	10/29/2003	Numed, Inc.		
		EP 0937439B1	09/17/2003	Heartport, Inc.		
		EP 0819013	06/23/2004	Heartport, Inc.		
		WO 93/15693	08/19/1993	Vince Medical Company Limited		
		WO 95/04556	02/16/1995	Active Control Experts, Inc.		
		WO 95/29640	11/09/1995	Aesculap AG		X
		WO 96/14032	05/17/1996	Duran, Carlos		
		WO 98/36790	08/27/1998	Conado Medical Devices Corporation		
		WO 00/09059	02/24/2000	Prodesco, Inc.		
		WO 00/44308	08/03/2000	Board of Regents, The University of Texas System		
		WO 00/44313	08/03/2000	Viacor Inc.		
		WO 00/67661	11/16/2000	Ortiz, Mark		
		WO 01/05331	01/25/2001	Biocompatibles Ltd.		
		WO 01/35870	05/25/2001	Seguin, Jacques		X
		WO 01/64137	09/07/2001	Fraunhofer-Gesellschaft Zur Forderung Der Angewandten Forschung E.V.		X
		WO 02/36048	05/10/2002	Seguin, Jacques		X
		WO 02/100297	12/19/2002	Rex Medical, L. P.		

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Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	10/870,340
				Filing Date	06/16/2004
				First Named Inventor	Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	9	of	12	Attorney Docket Number	30207.710.201

FOREIGN PATENT DOCUMENTS

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		WO 03/003943	01/16/2003	Advanced Bio Prosthetic Surfaces, Ltd.		
		WO 03/003949	01/16/2003	Seguin, Jacques		X
		WO 03/011195	02/13/2003	Seguin, Jacques		X
		WO 03/015851	11/27/2003	Scimed Life Systems, Inc.		
		WO 2004/019811	03/11/2004	Heart Leaflet Technologies		
		WO 2004/023980	03/25/2004	3F Therapeutics, Inc.		
		WO 2004/041126	05/21/2004	Seguin, Jacques		
		WO 2004/047681	06/10/2004	Boudjemline Younes		X

Examiner Signature		Date Considered	

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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets os necessary)*				***Complete if Known***	
				Application Number	10/870,340
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				Examiner Name	Not yet assigned
Sheet	10	of	12	Attorney Docket Number	30207.710.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		ANDERSEN, H.R. et al., "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs". Euro. Heart J. (1992) 13:704-708.	
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		BODNAR, E. et al., Replacement Cardiac Valves, Pergamon Publishing Corporation, New York, (1991), 307-322.	
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		BOUDJEMLINE, Y. et al., "Percutaneous Pulmonary Valve Replacement in a Large Right Ventricular Outflow Tract". J. of Am. College of Cardio. (2004) 43:6, 1082-1087.	
		BOUDJEMLINE, Y. et al., "Percutaneous valve insertion: A new approach?" J. of Thoracic and Cardio. Surg. (2003) 125:3, 741-743.	
		BOUDJEMLINE, Y. et al., "Steps Toward Percutaneous Aortic Valve Replacement." Circulation (2002) 775-778.	
		CRIBIER, A. et al., "Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis". J. or Am. Coll. of Cardio. (2004) 43:4, 698-703.	
		CRIBIER, A., et al., "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description," Circulation (2002) 3006-3008.	
		CRIBIER, A., et al., "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case". Percutaneous Valve Technologies, Inc. (2002).	

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				Filing Date	06/16/2004
				First Named Inventor	Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	11	of	12	Attorney Docket Number	30207.710.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		FERRARI, M. et al., "Percutaneous transvascular aortic valve replacement with self expanding stent-valve device". Poster from the presentation given at SMIT 2000, 12th International Conference (September 5, 2000).	
		HIJAZI, Z.M., "Transcatheter Valve Replacement: A New Era of Percutaneous Cardiac Intervention Begins". J. of Am. College of Cardio. (2004) 43:6, 1088-1089.	
		HUBER, C.H. et al., "Do valved stents compromise coronary flow?" European Journal of Cardio-thoracic Surgery, (2004) 25:754-759.	
		KNUDSEN, L. L. et al., "Catheter-implanted prosthetic heart valves". Int'l J. of Art. Organs, (1993) 16:5, 253-263	
		KORT, S. et al., "Minimally invasive aortic valve replacement: Echocardiographic and clinical results". Am. Heart J. (2001) 142:3, 476-481.	
		LOVE, C. et al., The Autogenous Tissue Heart Valve: Current Status, Journal of Caridac Surgery, (1991) 6:4, 499-507.	
		LUTTER, G. et al., "Percutaneous aortic valve replacement: An experimental study. I. Studies on implantation," J. of Thoracic and Cardio. Surg. (2002) 123:4, 768-776.	
		MOULOPOULOS, S. D. et al., "Catheter-Mounted Aortic Valves," Annals of Thoracic Surg. (1971) 11:5, 423-430.	
		PANIAGUA, D. et al., "Percutaneous heart valve in the chronic in vitro testing model". Circulation (2002), 106:e51-e52, American heart Association, Inc.	
		PANIAGUA, D. et al., Heart Watch (2004), Spring, 2004 Edition, Texas Heart Institute	

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		PAVCNIK, D. et al., "Percutaneous bioprosthetic venous valve: A long-term study in sheep". J. of Vascular Surg. (2002) 35:3, 598-603.	
		PHILLIPS, S. J. at al., "A Temporary Catheter-Tip Aortic Valve: Hemodynamic Effects on Experimental Acute Aortic Insufficiency". Annals of Thoracic Surg. (1976) 21:2, 134-136.	
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		ZHOU, J. Q. et al., "Self-expandable valved stent of large size: off-bypass implantation in pulmonary position". Eur. J. Cardiothorac. (2003) 24, 212-216	

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[ ] Other, description: _____
Doc Code: Artifact Artifact Type Code: Z

Practitioner's Docket No. 30207-710.201 *PATENT*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ulrich R. Haug
Serial No.: 10/870,340
Filed: June 16, 2004
For: Everting Heart Valve

Group No.: 3738
Examiner: Unassigned
Confirmation No.: 7111

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMPLETION OF FILING REQUIREMENTS-NONPROVISIONAL APPLICATION

I. This replies to the Notice TO File Missing Parts of Application (PTO-1533) mailed **August 4, 2004**. A copy of the Notice to File Missing Parts of Application –Filing Date Granted (Form PTO-1533) is enclosed.

DECLARATION

II. No declaration or oath was filed. Enclosed is the original declaration or oath for this application.

POWER OF ATTORNEY

III. Enclosed is an original Power of Attorney by Assignee to Exclusion of Inventor.

SMALL ENTITY STATUS

IV. Applicant claims small entity status. See 37 CFR 1.27.

COMPLETION FEES

1.	Filing Fee: Original patent application (37 C.F.R. 1.16(a))	$395.00
2.	Fee for Claims: Each claim in excess of 20 (37 C.F.R. 1.16(c))	$423.00
3.	Fee for Claims: Each independent claim in excess of 3 (37 C.F.R. 1.16(b))	$ 88.00
4.	Surcharge Fee: Late payment of filing fee (37 C.F.R. 1.116(e))	$ 65.00
	Total Completion Fees	**$971.00**

REQUEST FOR EXTENSION OF TIME

V. This is a request under the provisions under 37 CFR 1.136(a) to extend the period for filing a reply in the above-referenced patent application two month(s). The Extension fee is: $215.00

TOTAL FEE DUE

VI. The total fee due is: Completion fees: **TOTAL FEE DUE $1,186.00**

PAYMENT OF FEES

VII. Charge Deposit Account No. 23-2415 (30207-710.201) in the amount of $1,186.00.
The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (30207-710.201).

Date: 12-2-04

Maya Skubatch, Reg. No. 52,505

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
(650) 849-3330
Customer No. 021971

12/07/2004 EAREGAY1 00000020 232415 10070340
05 FC:2252 215.00 DA

12-06-04

IFW

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/870,340	06/16/2004	Ulrich R. Haug	30207-710.201

CONFIRMATION NO. 7111

021971
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 943041050

FORMALITIES LETTER

OC000000013434322

Date Mailed: 08/04/2004

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

12/07/2004 EAREGAY1 00000020 232415 10870340

01 FC:2001 395.00 DA
02 FC:2051 65.00 DA
03 FC:2201 88.00 DA
04 FC:2202 423.00 DA

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  Applicant must submit $ **385** *to complete the basic filing fee for a small entity.*
- The oath or declaration is missing.
  A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **$509** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$959** for a Small Entity

- **$385** Statutory basic filing fee.
- **$65** Late oath or declaration Surcharge.

- Total additional claim fee(s) for this application is **$509**

- **$86** for **2** independent claims over 3.
- **$423** for **47** total claims over 20.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202
PART 2 - COPY TO BE RETURNED WITH RESPONSE

Please type a plus sign (+) inside this box → [+]

PTO/SB/01 (12-97)
Approved for use through 9/30/00.OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e)) required)

Attorney Docket Number	30207-710.201
First Named Inventor	Ulrich R. Haug
COMPLETE IF KNOWN	
Application Number	10/870,340
Filing Date	June 16, 2004
Group Art Unit	3738
Examiner Name	Unassigned

As a below named Inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

EVERTING HEART VALVE

(Title of the Invention)

the specification of which
☐ is attached hereto
OR
☒ was filed on (MM/DD/YYYY) 06/16/2004 as United States Application Number or PCT International Application Number 10/870,340 and was amended on (MM/DD/YYYY) ☐ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/028 attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(h) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
		☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/028 attached hereto.

Please Type a plus sign (+) inside this box → [+]

PTO/SB/01 (12-97)
Approved for use through 9/30/00.OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of the application is not designated in the prior United States or PCT international application in the manner provided by the first paragraph of 31 U.S.C. 112. I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number *(if applicable)*

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/028 attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☒ Customer Number 021971 → *Place Customer Number Bar Code Label here*

OR

☐ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] OR ☒ Correspondence address below

Name	Maya Skubatch						
Address	Wilson Sonsini Goodrich & Rosati						
Address	650 Page Mill Road						
City	Palo Alto			State	CA	ZIP	94304
Country	U.S.	Telephone	650-493-9300			Fax	650-493-6811

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any)	Family Name or Surname
Ulrich R.	Haug

Inventor's Signature					Date	10/06/04	
Residence: City	Campbell	State	CA	Country	USA	Citizenship	Germany
Post Office Address	2479 Twyla Court, Campbell, CA 95008						
Post Office Address							
City	Campbell	State	CA	ZIP	95008	Country	USA

☒ Additional inventors are being named on the 2 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto:

C:\NrPortbl\PALIB1\DH1\2520926_1.DOC (8499)

Please Type a plus sign (+) inside this box → [+]

PTO/SB/02A (3-97)
Approved for use through 9/30/98,OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 2

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle (if any)			Family Name or Surname				
Hans F.			Valencia				
Inventor's Signature	H Valencia					Date	10/08/04
City	Berkeley	State	CA	Country	USA	Citizenship	Peru
Post Office Address	1609 La Vereda Road, Berkeley, Ca 94709						
Post Office Address							
City	Berkeley	State	CA	ZIP	94709	Country	USA

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle (if any)			Family Name or Surname				
Robert A.			Geshlider				
Inventor's Signature	Robert Geshlider					Date	10/8/04
Residence: City	San Francisco	State	CA	Country	USA	Citizenship	USA
Post Office Address	233 27th Street, San Francisco, CA 94131						
Post Office Address							
City	San Francisco	State	CA	ZIP	94131	Country	USA

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle (if any)			Family Name or Surname				
Tom			Saul				
Inventor's Signature	Tom Saul					Date	10/6/04
City	El Granada	State	CA	Country	USA	Citizenship	USA
Post Office Address	151 Madrid Avenue, El Granada, CA 94018						
Post Office Address							
City	El Granada	State	CA	ZIP	94018	Country	USA

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Please Type a plus sign (+) inside this box → [+]

PTO/SB/02A (3-97)
Approved for use through 9/30/98,OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet Page 2 of 2

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle (if any)			Family Name or Surname				
Amr			Salahieh				
Inventor's Signature						Date	10/8/04
City	Saratoga	State	CA	Country	USA	Citizenship	USA
Post Office Address	18729 Metler Court, Saratoga, CA 95070						
Post Office Address							
City	Saratoga	State	CA	ZIP	95070	Country	USA

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle (if any)			Family Name or Surname				
Dwight P.			Morejohn				
Inventor's Signature	Dwight P. Morejohn					Date	10-20-04
Residence: City	Davis	State	CA	Country	USA	Citizenship	USA
Post Office Address	731 N. Campus Way, Davis, CA 95616						
Post Office Address							
City	San Francisco	State	CA	ZIP	95616	Country	USA

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle (if any)			Family Name or Surname				
Kenneth J.			Michlitsch				
Inventor's Signature						Date	11/11/04
City	Livermore	State	CA	Country	USA	Citizenship	USA
Post Office Address	822 South M Street, Livermore, CA 94550						
Post Office Address							
City	Livermore	State	CA	ZIP	94550	Country	USA

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

PTO/SB/21 (02-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Ulrich r. Haug
Art Unit	3738
Examiner Name	Unassigned
Total Number of Pages in This Submission: 6	Attorney Docket Number: 30207-710.201

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☒ Power of Attorney by Assignee
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)
- ☐ After Allowance communication to Technology Center (TC)
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below):
  Copy of assignment, PTO 1595 form and notice of recordation of assignment document

Remarks

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual name	Maya Skubatch, Reg. No. 52,505, WILSON SONSINI GOODRICH & ROSATI
Signature	Maya Skubatch
Date	December 7, 2004

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Donna L. Hengst		
Signature	Donna L. Hengst	Date	December 7, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Practitioner's Docket No.: 30207-710.201 *PATENT*

POWER OF ATTORNEY BY ASSIGNEE TO EXCLUSION OF INVENTOR UNDER 37 C.F.R. § 3.71 WITH REVOCATION OF PRIOR POWERS

The undersigned ASSIGNEE of the entire interest in:

☐ U.S. Patent No.
☒ U.S. application no. 10/870,340, filed on June 16, 2004

hereby appoints all Wilson Sonsini Goodrich & Rosati attorneys registered to practice before the United States Patent and Trademark Office, as associated with Customer No. 021971, to prosecute this application and transact all business in the United States Patent and Trademark Office in connection therewith and hereby revokes all prior powers of attorney; said appointment to be to the exclusion of the inventors and the inventors' attorneys in accordance with the provisions of 37 C.F.R. § 3.71.

The following evidentiary documents establish a chain of title from the original owner to the Assignee:

(complete one of the following)

☒ a copy of an Assignment attached hereto, which Assignment the Application has been (or is herewith) forwarded to the Patent and Trademark Office for recording; or

☐ the Assignment recorded on ___ at reel ___, frames ___-___.

Pursuant to 37 C.F.R. § 3.73(b) the undersigned Assignee hereby states that evidentiary documents have been reviewed and hereby certifies that, to the best of ASSIGNEE's knowledge and belief, title is in the identified ASSIGNEE.

CHANGE OF CORRESPONDENCE ADDRESS

Direct all correspondence and telephone calls to:

Name	Maya Skubatch					
Address	Wilson Sonsini Goodrich and Rosati					
Address	650 Page Mill Road					
City	Palo Alto	State	CA	Zip	94304	Customer No.: 021971
Country	USA	Telephone	(650) 493-9300	Fax	(650) 493-6811	

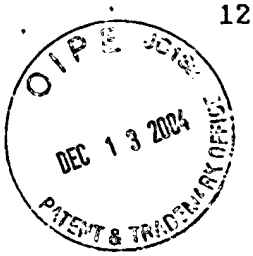
ASSIGNEE: SADRA MEDICAL, INC.

Name: AMR SALAHIEH
Print

Signature

Title: President/CEO

Date: 12/6/04



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ASSISTANT SECRETARY AND COMMISSIONER
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Washington, D.C. 20231

700135380A

DECEMBER 07, 2004

PTAS

WILSON SONSINI GOODRICH & ROSATI
MAYA SKUBATCH
650 PAGE MILL RD.
PALO ALTO, CA 94304-1050

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 12/02/2004 REEL/FRAME: 015421/0038
NUMBER OF PAGES: 2

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
HAUG, ULIRCH R. DOC DATE: 10/06/2004

ASSIGNOR:
VALENCIA, HANS F. DOC DATE: 10/08/2004

ASSIGNOR:
GESHLIDER, ROBERT A. DOC DATE: 10/20/2004

ASSIGNOR:
MICHLITSCH, KENNETH DOC DATE: 11/11/2004

ASSIGNEE:
SADRA MEDICAL, INC.
1717 DELL AVENUE
CAMPBELL, CALIFORNIA 95008

015421/0038 PAGE 2

SERIAL NUMBER: 10870340
PATENT NUMBER:
TITLE: EVERTING HEART VALVE

FILING DATE: 06/16/2004
ISSUE DATE:

PAULA MCCRAY, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

12/02/2004
700135380

FORM PTO-1595 (Rev. 06/04)
OMB No. 0651-0027 (exp. 6/30/2005)

U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

RECORDATION FORM COVER SHEET

PATENTS ONLY

To the Director of the U.S. Patents and Trademark Office: Please record the attached documents or the new address(es) below.

1. **Name of conveying party(ies)/Execution Date(s):**
Ulirch R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth Michiltsch

Execution Date(s) October 6, 2004, October 8, 2004, October 20, 2004 and November 11, 2004

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

2. **Name and address of receiving party(ies):**
Name: Sadra Medical, Inc.
Street Address: 1717 Dell Avenue
City: Campbell
State: CA
Country USA Zip 95008
Additional name(s) & address(es) attached? ☐ Yes ☒ No

3. **Nature of conveyance:**
☒ Assignment ☐ Merger
☐ Security Agreement ☐ Change of Name
☐ Government Interest Assignment
☐ Executive Order 9424, Confirmatory License
Other

4. **Application number(s) or patent number(s):** ☐ This document is being filed together with a new application.
A. Patent Application No.(s) 10/870,340
B. Patent No.(s):
Additional numbers attached? ☐ Yes ☒ No

5. **Name and address to whom correspondence concerning document should be mailed:**
Name: Maya Skubatch
Internal Address: Wilson Sonsini Goodrich & Rosati
Street Address: 650 Page Mill Road
City: Palo Alto
State: CA Zip: 94304-1050
Phone Number: (650) 493-9300
Fax Number: (650) 493-6811
Email Address: mskubatch@wsgr.com

6. **Total number of applications and patents involved:** 1

7. **Total fee** (37 CFR 1.21(h) & 3.41) $40.00
☐ Authorized to be charged by credit card
☒ Authorized to be charged to deposit account
☐ Enclosed
☐ None required (government interest not affecting title)

8. **Payment Information**
a. Credit Card Last 4 Numbers
Expiration Date
B. Deposit account number: 23-2415 (Attorney Docket No. 30207-710.201)
Authorized User Name Wilson Sonsini Goodrich & Rosati

9. **Signature.**
Signature
December 2, 2004
Date

Maya Skubatch, Reg. No. 52,505
Name of Person Signing

Total number of pages including cover sheet, attachments, and documents: 2

Documents to be recorded (including cover sheet) should be faxed to (703) 308-5835, or mailed to:
Mail Stop Assignment Recordation Services, Director of USPTO, P.O.Box 1450, Alexandria, V.A. 22313-1450

C:\NrPortb\PALIB1\DH1\2569624_1.DOC

ASSIGNMENT OF APPLICATION	Docket Number 30207-710.201

Whereas, the undersigned:

1. HAUG, Ulrich R. Campbell, CA
2. VALENCIA, Hans F. Berkeley, CA
3. GESHLIDER, Robert A. San Francisco, CA
4. SAUL, Tom El Granada, CA
5. SALAHIEH, Amr Saratoga, CA
6. MOREJOHN, Dwight P. Davis, CA
7. MICHLITSCH, Kenneth Livermore, CA

hereinafter termed "Inventors", have invented certain new and useful improvements in

EVERTING HEART VALVE

for which an application for United States Patent was filed on June 16, 2004, Application No. 10/870,340.

WHEREAS, Sadra Medical, Inc., a corporation of the State of Delaware, having a place of business at 1717 Dell Avenue, Campbell, CA 95008, (hereinafter termed "Assignee"), is desirous of acquiring the entire right, title and interest in and to said application and the invention disclosed therein, and in and to all embodiments of the invention, heretofore conceived, made or discovered jointly or severally by said Inventors (all collectively hereinafter termed "said invention"), and in and to any and all patents, inventor's certificates and other forms of protection (hereinafter termed "patents") thereon granted in the United States and foreign countries.

NOW, THEREFORE, in consideration of good and valuable consideration acknowledged by said Inventors to have been received in full from said Assignee:

1. Said Inventors do hereby sell, assign, transfer and convey unto said Assignee the entire right, title and interest (a) in and to said application and said invention; (b) in and to all rights to apply for foreign patents on said invention pursuant to the International Convention for the Protection of Industrial Property or otherwise; (c) in and to any and all applications filed and any and all patents granted on said invention in the United States or any foreign country, including each and every application filed and each and every patent granted on any application which is a divisional, substitution, continuation, or continuation-in-part of any of said applications; and (d) in and to each and every reissue or extensions of any of said patents.

2. Said Inventors hereby jointly and severally covenant and agree to cooperate with said Assignee to enable said Assignee to enjoy to the fullest extent the right, title and interest herein conveyed in the United States and foreign countries. Such cooperation by said Inventors shall include prompt production of pertinent facts and documents, giving of testimony, execution of petitions, oaths, specifications, declarations or other papers, and other assistance all to the extent deemed necessary or desirable by said Assignee (a) for perfecting in said Assignee the right, title and interest herein conveyed; (b) for prosecuting any of said applications; (c) for filing and prosecuting substitute, divisional, continuing or additional applications covering said invention; (d) for filing and prosecuting applications for reissuance of any said patents; (e) for interference or other priority proceedings involving said invention; and (f) for legal proceedings involving said invention and any applications therefor and any patents granted thereon, including without limitation reissues and reexaminations, opposition proceedings, cancellation proceedings, priority contests, public use proceedings, infringement actions and court actions; provided, however, that the expense incurred by said Inventors in providing such cooperation shall be paid for by said Assignee.

3. The terms and covenants of this assignment shall inure to the benefit of said Assignee, its successors, assigns and other legal representatives, and shall be binding upon said Inventors, their respective heirs, legal representatives and assigns.

4. Said Inventors hereby jointly and severally warrant and represent that they have not entered and will not enter into any assignment, contract, or understanding in conflict herewith.

IN WITNESS WHEREOF, said Inventors have executed and delivered this instrument to said Assignee as of the dates written below:

Date: 10/06/04 — Ulrich R. Haug

Date: 10/08/04 — Hans F. Valencia

Date: 10/8/04 — Robert A. Geshlider

Date: 10/06/04 — Tom Saul

Date: 10/8/04 — Amr Salahieh

Date: 10-20-04 — Dwight Morejohn

Date: 11/1/04 — Kenneth J. Michlitsch

IPW

PATENT

Attorney Docket No. 30207.710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	PATENT APPLICATION
Inventor(s): Ulrich R. HAUG et al.	Art Unit: 3738
Application No.: 10/870,340	Examiner: Not yet assigned
Filed: June 16, 2004	Confirmation No.: 7111
Title: Everting heart valve	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

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This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ This statement qualifies under *37 C.F.R. §1.97*, subsection (b) because:

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-- OR --

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-- OR --

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☐ a certification as specified in §1.97(e) is provided below; **or**

☐ a fee of $180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

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B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**

C. a fee of $130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

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Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 2/16/05

By: _____
James R. Shay, Reg. No. 32,062

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2004/0186563	09/23/2004	Lobbi	
		US-5,554,185	09/10/1996	Block et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] – Number[4] – Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP 1000590A1	05/17/2000	Cordis Corporation		

Examiner Signature		Date Considered	

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Please forward to Group Art Unit 3738

Amended Compact Discs

EXAMINER NOTE: THIS PAPER IS AN INTERNAL WORKSHEET ONLY. DO NOT ENCLOSE WITH ANY COMMUNICATION TO THE APPLICANT. ITS PURPOSE IS ONLY THAT OF AN AID IN HIGHLIGHTING A PARTICULAR PROBLEM IN A COMPACT DISC.

THE ATTACHED CD (COPY 1) HAS BEEN REVIEWED BY OIPE FOR COMPLIANCE WITH 37 CFR 1.52(E). ***Please match this CD with the application listed below.***

Date: 3/11/2005
Serial No./Control No. 10/870340
Reviewed By: K. SMITH Phone: 3089210 ext. 118

☐ The compact discs are readable and acceptable.

☐ Copy 1 and Copy 2 of the compact discs are not the same.

☐ The compact discs are unreadable.

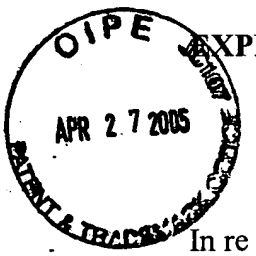
☑ The files on the compact discs are not in ASCII.

☐ The compact discs contain at least one virus.

☑ Other ONE CD SUBMITTED - NOT PROPER SUBJECT MATTER

4-29-05

IFW



EXPRESS MAIL LABEL NO.: EV 518896079 US

PATENT

Attorney Docket No. 30207.710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	PATENT APPLICATION
Inventor(s): Ulrich R. HAUG et al.	Art Unit: 3738
Application No.: 10/870,340	Examiner: Cheryl L. Miller
Filed: June 16, 2004	Confirmation No.: 7111
Title: Everting heart valve	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

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☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.710.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 4/27/05

By: _____
Maya Skubatch, Reg. No. 52,505

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

	Complete if Known
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Miller
Attorney Docket Number	30207.710.201

Sheet 1 of 2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		SALAHIEH, A. et al. US Patent Application No. 10/746,280 entitled "Repositionable heart valve and method", filed 12/23/2003 (Docket No. 30207.701.201).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,131 entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (Docket No. 30207.701.501).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,151, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.502).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,143, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.503).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,142, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.504).	
		SALAHIEH, A. et al. US Patent Application No. 10/920,736, entitled "Apparatus and methods for protecting against embolization during endovascular heart replacement", filed 08/17/2004 (30207.701.505).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,240, entitled "Heart valve anchor and method", filed 12/23/2003 (30207.702.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/972,287, entitled "Leaflet engagement elements and methods for use thereof", filed 10/21/2004 (30207.702.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/971,535, entitled "Leaflet engagement elements and methods for use thereof", filed 10/21/2004 (30207.702.502).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,120, entitled "Externally expandable heart valve anchor and method", filed 12/23/2003 (30207.703.201).	

Examiner signature		Date Considered	

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[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	10/870,340
				Filing Date	06/16/2004
				First Named Inventor	Haug
				Art Unit	3738
				Examiner Name	Miller
Sheet	2	of	2	Attorney Docket Number	30207.710.201

NON PATENT LITERATURE DOCUMENTS

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		SALAHIEH, A. et al., US Patent Application No. 10/982,388, entitled "Methods and apparatus for endovascularly replacing a heart valve", filed 11/05/2004 (30207.703.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,285, entitled "Retrievable heart valve anchor and method", filed 12/23/2003 (30207.704.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/982,692, entitled "Retrievable heart valve anchor and method", filed 11/05/2004 (30207.704.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,887, entitled "Low profile heart valve and delivery system", filed 12/23/2003 (30207.705.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,872, entitled "Locking heart valve anchor", filed 12/23/2003 (30207.706.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/911,059, entitled "Replacement valve and anchor", filed 08/03/2004 (30207.706.301).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,942, entitled "Two-piece heart valve and anchor", filed 12/23/2003 (30207.707.201).	

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This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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10/870 840 UB.

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[1] CD(s) containing:
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450 Alexandria, VA 22313-1450, on 6/27/05

Mi Kyong Shin

PATENT

Attorney Docket No. 30207.710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	PATENT APPLICATION
Inventor(s): Amr SALAHIEH et al.	Art Unit: 3738
Application No.: 10/870,340	Examiner: Cheryl L. Miller
Filed: June 16, 2004	Confirmation No.: 7111
Title: Everting heart valve	

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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WILSON SONSINI GOODRICH & ROSATI

Dated: 6/27/05

By: _____
James R. Shay, Reg. No. 32,062

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Customer No. 021971

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Sheet 1 of 1

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First Named Inventor	Salahieh et al.
Art Unit	3738
Examiner Name	Miller
Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2005/0085841	04/21/2005	Eversull et al.	
		US-2005/0085842	04/21/2005	Eversull et al.	
		US-2005/0085843	04/21/2005	Opolski et al.	
		US-2005/0085890	04/21/2005	Rasmussen et al.	
		US-2005/0096692	05/05/2005	Linder et al.	
		US-2005/0096734	05/05/2005	Majercak et al.	
		US-2005/0096735	05/05/2005	Hojeibane et al.	
		US-2005/0096738	05/05/2005	Cali et al.	
		US-2005/0100580	05/12/2005	Osborne et al.	
		US-5,667,523	09/16/1997	Bynon et al.	
		US-6,887,266	05/03/2005	Williams et al.	
		US-			
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] – Number[4] – Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP 1229864 B1	04/27/2005	Boston Scientific Limited		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

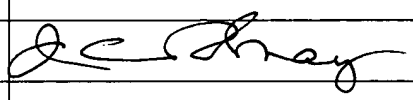
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Ulrich R. Haug
Group/Art Unit	3738
Confirmation No.	7111
Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission: 4	Attorney Docket Number: 30207-710.201

ENCLOSURES *(check all that apply)*

- ☒ Petition Fee Under 37 CFR 1.17(f), (g) & (h) Transmittal
- ☒ Petition To Correct Inventorship Order (37 C.F.R. § 1.182 (MPEP 605.04(f)))
- ☒ Return Post Card
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers (2) *(for an Application)*
- ☐ Drawing(s)
- ☐ Declaration For Utility or Design Application
- ☐ Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney By Assignee
- ☐ Terminal Disclaimer
- ☐ Sequence Listing/Diskette
- ☐ Request for Refund
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Additional Enclosure(s) *(please identify below):*

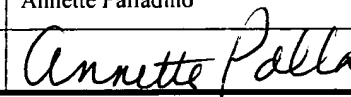
Remarks

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm *or* Individual name	James R. Shay Reg. No. 32,062, WILSON SONSINI GOODRICH & ROSATI		
Signature			
Date	September 29, 2005	Customer Number:	021971

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated below and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: September 29 2005 Express Mail Label EV 578 084 885 US

Typed or printed name	Annette Palladino		
Signature		Date	September 29, 2005

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/17p (11-04)
Approved for use through 7/31/2007 OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FEE
Under 37 CFR 1.17(f), (g) & (h)
TRANSMITTAL

(Fees are subject to annual revisions)

Send completed form to: Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Ulrich R. Haug
Art Unit	3738
Examiner Name	Not Yet Assigned
Attorney Docket Number	30207-710.201

Enclosed is a petition filed under 37 CFR 1.182 that requires a processing fee (37 CFR 1.17(f), (g), or (h). Payment of $400.00 is enclosed.

This form should be included with the above-mentioned petition and faxed or mailed to the Office using the appropriate Mail Stop (e.g., Mail Stop Petition), if applicable. *For transmittal of petition fees under 37 CFR 1.17(i), see form PTO/SB/17i.*

Payment of Fees (small entity amounts are NOT available for the petition fees)

☒ The Commissioner is hereby authorized to charge the following fees to Deposit Account No. 23-2415:

☒ petition fee under CFR 1.17(f), (g) or (h) ☒ any deficiency of fees and credit of any overpayments
Enclose a duplicative copy of this form for fee processing.

☐ Check in the amount of $___ is enclosed.

☐ Payment by credit card (Form PTO-2038 or equivalent enclosed). Do not provide credit card information on this form.

Petition Fees under 37 CFR 1.17(f): **Fee $400** **Fee Code 1462**
For petitions filed under:
§ 1.53(e) – to accord a filing date.
§ 1.57(a) – to accord a filing date.
§ 1.182 – for decision on a question not specifically provided for.
§ 1.183 – to suspend the rules.
§ 1.378(e) – for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.
§ 1.741(b) – to accord a filing date to an application under § 1.740 for extension of a patent term.

Petition Fees under 37 CFR 1.17(g): **Fee $200** **Fee Code 1463**
For petitions filed under:
§ 1.12 – for access to an assignment record.
§ 1.14 – for access to an application.
§ 1.47 – for filing by other than all the inventors or a person not the inventor.
§ 1.59 – for expungement of information.
§ 1.103(a) – to suspend action in an application.
§ 1.136(b) – for review of a request for extension of time when the provisions of section 1.136(a) are not available.
§ 1.295 – for review of refusal to publish a statutory invention registration.
§ 1.296 – to withdraw a request for publication of a statutory invention registration filed on or after the date the notice of intent to publish issued.
§ 1.377 – for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.
§ 1.550(c) – for patent owner requests for extension of time in ex parte reexamination proceedings.
§ 1.956 – for patent owner requests for extension of time in inter partes reexamination proceedings.
§ 5.12 – for expedited handling of a foreign filing license.
§ 5.15 – for changing the scope of a license.
§ 5.25 – for retroactive license.

Petition Fees under 37 CFR 1.17(h): **Fee $130** **Fee Code 1464**
For petitions filed under:
§ 1.19(g) – to request documents in a form other than that provided in this part.
§ 1.84 – for accepting color drawings or photographs.
§ 1.91 – for entry of a model or exhibit.
§ 1.102(d) – to make an application special.
§ 1.138(c) – to expressly abandon an application to avoid publication.
§ 1.313 – to withdraw an application from issue.
§ 1.314 – to defer issuance of a patent.

Signature — Date: 9/29/05

James R. Shay — Typed or printed name

32,062 — Registration No., if applicable

10-03-05

DAC
TFW

PATENT
Attorney Docket No. 30207-710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	Confirmation No.: 7111
Ulrich R. Haug et al.	)	Group Art Unit: 3738
Application No.: 10/870,340	)	Examiner: Not Yet Assigned
Filed: June 16, 2004	)	Customer No.: 021971
For: Everting Heart Valve	)	

PETITION TO CORRECT INVENTOR ORDER
(37 C.F.R. § 1.182 (MPEP 605.04(f)))

Commissioner for Patents
Mail Stop: Petition
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 1.182 and MPEP 605.04(f), Applicants hereby petition the Commissioner to change the order of listed inventors in the official record for the above-identified application.

REMARKS

The present application was filed June 16, 2004 in the names of co-inventors: Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch, and an executed Declaration in compliance with 37 CFR 1.63 was duly filed on December 2, 2004, with Ulrich R. Haug named as "Sole or First Inventor" and Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch named as "Additional Joint Inventors". Currently, all application papers including the official filing receipt list the inventors as indicated above.

10/04/2005 TBESHAH1 00000045 232415 10870340
01 FC:1462 400.00 DA

C:\NrPortbl\PALIB1\AG2\2734082_1.DOC

Applicants respectfully request that the order of inventors in the present application be corrected to the following:

Amr Salahieh

Ulrich R. Haug

Hans F. Valencia

Robert A. Geshlider

Tom Saul

Dwight P. Morejohn

Kenneth J. Michlitsch

Favorable action on this petition is respectfully solicited.

Please charge the Petition fee of $400.00 under 37 C.F.R. 1.17(f) to Deposit Account No. 23-2415 (Docket No. 30207-710.201).

The Commissioner is hereby authorized to charge any additional fees that may be required by this paper, including Petition Fees and extension of time fees, and to credit any overpayment, to Deposit Account No. 23-2415 (Docket No. 30207-710.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

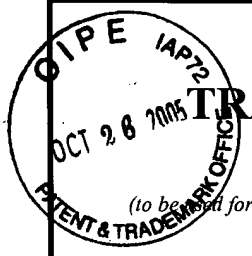
Date: 9/29/05

By: _____
James R. Shay, Reg. No. 32,062

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No.: 021971

IFW

PTO/SB/21 (02-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Ulrich R. Haug
Art Unit	3738
Examiner Name	Not yet assigned
Total Number of Pages in This Submission	Attorney Docket Number: 30207-710.201

ENCLOSURES ***(Check all that apply)***

☐ Fee Transmittal Form	☐ Drawing(s)	☐ After Allowance communication to Technology Center (TC)
☐ Fee Attached	☐ Licensing-related Papers	☐ Appeal Communication to Board of Appeals and Interferences
☐ Amendment/Reply	☐ Petition	☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
☐ After Final	☐ Petition to Convert to a Provisional Application	☐ Proprietary Information
☐ Affidavits/declaration(s)	☐ Power of Attorney, Revocation Change of Correspondence Address	☐ Status Letter
☐ Extension of Time Request	☐ Terminal Disclaimer	☒ Other Enclosure(s) (please identify below): return receipt postcard
☐ Express Abandonment Request	☐ Request for Refund	
☒ Information Disclosure Statement	☐ CD, Number of CD(s)	
☐ Certified Copy of Priority Document(s)	Remarks	
☐ Response to Missing Parts/ Incomplete Application		
☐ Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual name	Maya Skubatch, Reg. No. 52,505, WILSON SONSINI GOODRICH & ROSATI
Signature	Maya S
Date	October 24, 2005

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Frank Chen		
Signature		Date	October 24, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Ulrich R. HAUG, et al.	Group Art Unit: 3738
Serial Number: 10/870,340	Examiner: Not yet assigned
Filing Date: June 16, 2004	**CONFIRMATION NO:** 7111
Title: EVERTING HEART VALVE	

Certificate of Mailing or Transmission
37 CFR §1.8

I hereby certify that this paper is being: ☒ deposited with the U.S. Postal Service with sufficient postage as first class mail and addressed to Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450; or ☐ transmitted by facsimile to the Patent and Trademark Office in accordance with §1.6(d) to facsimile number on October 24, 2005.

Signature

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08A. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further requests that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ *37 CFR §1.97(b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);

-- OR --

☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;

-- OR --

☒ (3) It is being filed before the mailing date of the first Office Action on the merits;

-- OR --

☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

☐ *37 CFR §1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a certification as specified in §1.97(e) provided concurrently herewith;

-- OR --

☐ a fee of $180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ *37 CFR §1.97(d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

A. a certification as specified in §1.97(e); and

B. a fee of $180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

☐ *37 CFR §1.97(e).* A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).

☒ *37 CFR §1.98(a)(2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

☒ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☒ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

EP 1562515 A1 (WO 2004/047681) was published in French. The English language abstract and the drawings are sufficient to convey the scope of its disclosure.

Should the Examiner believe that a complete translation of any of the above mentioned publications is necessary to understand its disclosure, Applicant(s) will endeavor to provide such translations at the Examiner's request.

☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith.

☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).

☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 30207-710.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: October 24, 2005

By: _____
Maya Skubatch, Reg. No. 52,505

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

PTO/SB/08A (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 5

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Ulrich R. Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207-710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 2001/0044634	11/22/2001	Don Michael et al.	
		US 2002/0010489 A1	1/24/2002	Grayzel, et al.	
		US 2002/0095173	07/18/2002	Mazzocchi et al.	
		US 2003/0060844	03/27/2003	Borillo et al.	
		US 2003/0176884	09/18/2003	Berrada et al.	
		US 2003/0187495	10/02/2003	Cully et al.	
		US 2003/0208224	11/06/2003	Broome	
		US 2003/0216774	11/20/2003	Larson	
		US 2004/0073198	04/15/2004	Gilson et al.	
		US 2004/0082967	04/29/2004	Broome et al.	
		US 2004/0093016	05/13/2004	Root et al.	
		US 2004/0138694	07/15/2004	Tran et al.	
		US 2004/0158277	08/12/2004	Lowe et al.	
		US 2004/0167565	08/26/2004	Beulke et al.	
		US 2004/0204755 A1	10/14/2004	Robin	
		US 2004/0225321	11/11/2004	Krolik et al.	
		US 2004/0254636 A1	12/16/2004	Flagle, et al.	
		US 2005/0075662 A1	4/7/2005	Pedersen, et al.	
		US 2005/0090846 A1	4/28/2005	Pedersen, et al.	
		US 2005/0096736 A1	5/5/2005	Osse, et al.	
		US 2005/0113910 A1	5/26/2005	Paniagua, et al.	
		US 2005/0165352 A1	7/28/2005	Henry, et al.	
		US 2005/0165477 A1	7/28/2005	Anduiza, et al.	
		US 2005/0197695A1	9/8/2005	Stacchino, et al.	
		US 2005/0203614A1	9/15/2005	Forster	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	10/870,340
				Filing Date	June 16, 2004
				First Named Inventor	Ulrich R. Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	2	of	5	Attorney Docket Number	30207-710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 2005/0203615A1	9/15/2005	Forster	
		US 2005/0203616 A1	9/15/2005	Cribier	
		US 2005/0203617 A1	9/15/2005	Forster, et al.	
		US 4,796,629	1/10/1989	Grayzel	
		US 4,986,830	1/22/1991	Owens, et al.	
		US 5,209,741	5/11/1993	Spaeth	
		US 5,258,042	11/2/1993	Mehta	
		US 5,425,762	6/20/1995	Muller	
		US 5,443,495	8/22/1995	Buscemi, et al.	
		US 5,545,133	8/13/1996	Burns, et al.	
		US 5,843,158	12/1/1998	Lenker, et al.	
		US 5,910,154	06/08/1999	Tsugita et al.	
		US 5,911,734	06/15/1999	Tsugita et al.	
		US 5,968,070	10/19/1999	Bley, et al.	
		US 6,027,520	02/22/2000	Tsugita et al.	
		US 6,143,987	11/07/2000	Tsugita	
		US 6,165,200	12/26/2000	Tsugita et al.	
		US 6,168,579	01/02/2001	Tsugita	
		US 6,171,327	01/09/2001	Daniel et al.	
		US 6,179,859	01/30/2001	Bates	
		US 6,270,513	08/07/2001	Tsugita et al.	
		US 6,336,934	01/08/2002	Gilson et al.	
		US 6,537,297	03/25/2003	Tsuigita et al.	
		US 6,540,768	04/01/2003	Diaz et al.	
		US 6,592,614	7/15/2003	Lenker, et al.	
		US 6,676,698	01/13/2004	McGuckin, Jr. et al.	
		US 6,695,864	02/24/2004	Macoviak et al.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	10/870,340
				Filing Date	June 16, 2004
				First Named Inventor	Ulrich R. Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	3	of	5	Attorney Docket Number	30207-710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 6,695,865	02/24/2004	Boyle et al.	
		US 6,773,454	08/10/2004	Wholey, et al.	
		US 6,890,340	05/10/2005	Duane	
		US 6,905,743	6/14/2005	Chen, et al.	
		US 6,911,036	6/28/2005	Douk, et al.	
		US 6,936,067	8/30/2005	Buchanan	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08A (07-05)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 5

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Ulrich R. Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207-710.201

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] – Number[4] – Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP 1042045 BI	05/19/2004	Domnick Hunter Ltd.		
		EP 1059894 BI (WO 99/44540)	7/20/2005	Scimed Life Systems, Inc.		
		EP 1078610 BI	8/10/2005	Cordis Corp.		
		EP 1430853 A3	6/8/2005	M. I. Tech Co., Ltd.		
		EP 1551274 A2 (WO 04/026117)	7/13/2005	3F Therapeutics, Inc.		
		EP 1551336 AI(WO 04/014256)	7/13/2005	Abbott Laboratories Vascular Enterprises		
		EP 1562515 A1 (WO 2004/047681)	8/17/2005	Boudjemline		√
		WO 98/50103 AI	11/12/1998	Embol-X, Inc.		
		WO 99/44542 A2	09/10/1999	Scimed Life Systems, Inc.		
		WO 00/49970 A1	08/31/2000	Scimed Life Systems, Inc.		
		WO 01/08596 AI	02/08/2001	Scimed Life Systems, Inc.		
		WO 01/10320 AI	02/15/2001	Scimed Life Systems, Inc.		
		WO 01/10343 A1	02/15/2001	Scimed Life Systems, Inc.		
		WO 2005/084595 A1	9/15/2005	Cardiacmd, Inc.		

Examiner Signature		Date Considered	

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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	10/870,340
				Filing Date	June 16, 2004
				First Named Inventor	Ulrich R. Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	5	of	5	Attorney Docket Number	30207-710.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		BOUDJEMLINE, Y. et al. Percutaneious implantation of a biological valve in the aorta to treat aortic valve insufficiency - a sheep study. *Med Sci.Monit.* (2002) Vol. 8, No. 4, pages BR113-116	

Examiner signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
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www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/870,340	06/16/2004	3738	971	30207-710.201	63	67	5

CONFIRMATION NO. 7111
CORRECTED FILING RECEIPT
OC000000018061255
OC000000018061255

021971
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

Date Mailed: 02/15/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Amr Salahieh, Saratoga, CA;
Ulrich R. Haug, Campbell, CA;
Hans F. Valencia, Berkeley, CA;
Robert A. Geshlider, San Francisco, CA;
Tom Saul, El Granada, CA;
Dwight P. Morejohn, Davis, CA;
Kenneth J. Michlitsch, Livermore, CA;

Power of Attorney: The patent practitioners associated with Customer Number **021971**.

Domestic Priority data as claimed by applicant

Foreign Applications

If Required, Foreign Filing License Granted: 08/03/2004

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/870,340

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Everting heart valve

Preliminary Class

623

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted

under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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FEB 16 2006

OFFICE OF PETITIONS

In re Application of :
Arm Salahieh et al :
Application No. 10/870,340 : ON PETITION
Filed: June 16, 2004 :
Attorney Docket No. 30207-710.201 :

This is a decision on the petition under 37 CFR 1.182, filed September 29, 2005, to change the order of the names of the inventors.

The petition is **Granted**.

A corrected Filing Receipt with the desired order of the names of the inventors accompanies this decision on petition.

Telephone inquiries regarding the above matter should be directed to the undersigned at (571)272-3208.

This matter is being referred to Technology Center AU 3738.

Karen Creasy

Karen Creasy
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

ATTACHMENT: CORRECTED FILING RECEIPT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Amr SALAHIEH, et al.	Group Art Unit: 3738
Serial Number: 10/870,340	Examiner: Cheryl L. Miller
Filing Date: June 16, 2004	**CONFIRMATION NO: 7111**
Title: EVERTING HEART VALVE	

FILED ELECTRONICALLY ON: Aprit 12 , 2006

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

A. ☒ *37 CFR §1.97(b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;

-- OR --

☒ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

B. ☐ *37 CFR §1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR §1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97(e) provided concurrently herewith;

-- OR --

☐ a fee of $180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☐ *37 CFR §1.97(d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in §1.97(e);

-- AND --

ii. a fee of $180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☐ *37 CFR §1.97(e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);

-- AND/OR --

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98(a)(2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☒ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G. ☒ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☒ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

EP 1469797 was published in German. The English language title, the claims and the drawings are sufficient to convey the scope of its disclosure. Should the Examiner believe that a complete translation of the above mentioned publication is necessary to understand its disclosure, Applicants will endeavor to provide such translation at the Examiner's request.

H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207-710.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: April 12, 2006

By: _____
Maya Skubatch, Reg. No. 52,505

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

PTO/SB/08 (07/05)
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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	10/870,340
				Filing Date	June 16, 2004
				First Named Inventor	Amr Salahieb
				Art Unit	3738
				Examiner Name	Cheryl L. Miller
Sheet	1	Of	3	Attorney Docket Number	30207-710.201

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		US 2005/0137695	06/23/2005	Salahieh et al.	
		US 2005/0209580 A1	09/22/2005	Freyman	
		US 2005/0228472 A1	10/13/2005	Case et al.	
		US 2005/0251250	11/10/2005	Verhoeven et al.	
		US 2005/0251251	11/10/2005	Cribier	
		US 2005/0261759 A1	11/24/2005	Lambrecht et al.	
		US 2005/0267560 A1	12/1/2005	Bates	
		US 2005/0283962	12/29/2005	Boudjemline	
		US 2006/0004439	01/05/2006	Spenser et al.	
		US 2006/0004442	01/05/2006	Spenser et al.	
		US 2006/0015168	01/19/2006	Gunderson	
		US 6,042,607	03/28/2000	Williamson, IV et al.	
		US 6,953,332	10/11/2005	Kurk et al.	
		US 6,96,4673	11/15/2005	Tsugita et al.	
		US 6,974,464	12/13/2005	Quijano et al.	
		US 6,974,474	12/13/2005	Pavcnik et al.	
		US 6,974,476	12/23/2005	McGuckin, Jr. et al.	
		US 6,979,350	12/27/2005	Moll et al.	
		US 6,984,242	01/10/2006	Campbell et al.	

Examiner Signature		Date Considered	

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				Filing Date	June 16, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Cheryl L. Miller
Sheet	2	Of	3	Attorney Docket Number	30207-710.201

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		EP 1156757 B1	12/07/2005	Board of Regents, The University of Texas System		
		EP 1469797 (in German with English Claims)	11/02/2005	Figulla, Hans-Reiner		
		EP 1576937 A2	09/21/2005	Board of Regents, The University of Texas System		
		EP 1582178 A2	510/5/2005	Board of Regents, The University of Texas System		
		EP 1582179 A2	10/05/2005	Board of Regents, The University of Texas System		
		EP 1589902 (WO 2004/066876)	08/12/2004	Ave Connaught		
		EP 1600121A1	11/30/2005	William Cook Europe ApS		
		EP 1605871 (WO 2004/082536 A1)	09/30/2004	Aortech International PLC		
		EP 1616531	01/18/2006	Boston Scientific Limited		
		WO 2005/087140 A1	09/22/2005	Percutaneous Cardiovascular Solutions PTY Ltd.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	10/870,340
				Filing Date	June 16, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Cheryl L. Miller
Sheet	3	Of	3	Attorney Docket Number	30207-710.201

UNPUBLISHED PATENT APPLICATIONS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
		FAWZI, et al., U.S. Patent Application No 11/155309, entitled "Apparatus and methods for intravascular embolic protection," filed 06/16/2005 (WSGR Reference No. 30207-719.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/232441, entitled "Methods and apparatus for endovascular heart valve replacement comprising tissue grasping elements," filed 09/20/2005 (WSGR Reference No. 30207-702.503)	
		SALAHIEH, et al., U.S. Patent Application No 11/232444, entitled "Methods and apparatus for endovascular heart valve replacement comprising tissue grasping elements," filed 09/20/2005 (WSGR Reference No. 30207-702.504)	
		SALAHIEH, et al., U.S. Patent Application No 11/274889, entitled "Medical implant deployment tool," filed 11/14/2005 (WSGR Reference No. 30207- 718.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/314183, entitled "Medical Device Delivery," filed 12/20/2005 (WSGR Reference No. 30207-725.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/314969, entitled "Methods And Apparatus For Performing Valvuloplasty," filed 12/20/2005 (WSGR Reference No. 30207-727.201)	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	1022359
Application Number:	10870340
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor:	Amr Salahieh
Customer Number:	21971
Filer:	Vernon A. Norviel/Frank Chen (VN/MSK/fc)
Filer Authorized By:	Vernon A. Norviel
Attorney Docket Number:	30207-710.201
Receipt Date:	12-APR-2006
Filing Date:	16-JUN-2004
Time Stamp:	20:17:05
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1	Foreign Reference	1.pdf	757288	no	85

Warnings:					
Information:					
2	Foreign Reference	2.pdf	455304	no	29
Warnings:					
Information:					
3	Foreign Reference	3.pdf	876476	no	88
Warnings:					
Information:					
4	Foreign Reference	4.pdf	878362	no	88
Warnings:					
Information:					
5	Foreign Reference	5.pdf	859808	no	88
Warnings:					
Information:					
6	Foreign Reference	6.pdf	832582	no	20
Warnings:					
Information:					
7	Foreign Reference	7.pdf	5287563	no	96
Warnings:					
Information:					
8	Foreign Reference	8.pdf	240497	no	11
Warnings:					
Information:					
9	Foreign Reference	9.PDF	280722	no	16
Warnings:					
Information:					
10	Foreign Reference	10.PDF	2056394	no	42

Warnings:					
Information:					
11	Information Disclosure Statement (IDS) Filed	IDS-30207-710-201-04-12-06.pdf	343439	no	7
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
12	NPL Documents	US30207-719-201.pdf	1852786	no	54
Warnings:					
Information:					
13	NPL Documents	US30207-702-503.pdf	4673537	no	64
Warnings:					
Information:					
14	NPL Documents	US30207-702-504.pdf	5800562	no	66
Warnings:					
Information:					
15	NPL Documents	US30207-718-201.pdf	2074084	no	42
Warnings:					
Information:					
16	NPL Documents	US30207-725-201.pdf	1868947	no	40
Warnings:					
Information:					
17	NPL Documents	US30207-727-201.pdf	1695717	no	38
Warnings:					
Information:					
Total Files Size (in bytes):			30834068		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Amr SALAHIEH, et al.	Group Art Unit: 3738
Serial Number: 10/870,340	Examiner: Thomas C. Barrett
Filing Date: June 16, 2004	**CONFIRMATION NO: 7111**
Title: EVERTING HEART VALVE	

FILED ELECTRONICALLY ON: July 13, 2006

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

A. ☒ *37 CFR §1.97(b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;

-- OR --

☒ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

B. ☐ *37 CFR §1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR §1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97(e) provided concurrently herewith;

-- OR --

☐ a fee of $180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☐ *37 CFR §1.97(d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in §1.97(e);

-- AND --

ii. a fee of $180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☐ *37 CFR §1.97(e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);

-- AND/OR --

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98(a)(2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☒ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G. ☒ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☒ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

WO 96/24306 A1 was published in French. The English language abstract and the drawings are sufficient to convey the scope of its disclosure. Should the Examiner believe that a complete translation of the above mentioned publication is necessary to understand its disclosure, Applicants will endeavor to provide such translation at the Examiner's request.

H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207-710.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: July 12, 2006

By: _____
Maya Skubatch, Reg. No. 52,505

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

PTO/SB/08 (07/05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 Of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	Thomas C. Barrett
Attorney Docket Number	30207-710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 3,657,744	04/25/1972	Ersek	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] – Number[4] – Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		EP 0409929 B1	04/23/1997	Boston Scientific Corp.		
		WO 96/24306 A1 (in French with English abstract)	08/15/1996	De Fays, Robert		
		WO 98/57599 A2	12/23/1998	Camilli, Sante		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08 (07/05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	10/870,340
				Filing Date	June 16, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Thomas C. Barrett
Sheet	2	Of	2	Attorney Docket Number	30207-710.201

UNPUBLISHED PATENT APPLICATIONS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
		SALAHIEH, et al., U.S. Patent Application No. 11/275,912, entitled "Medical Implant Delivery and Deployment Tool," filed 02/02/2006 (WSGR Reference No. 30207-722.501)	
		SALAHIEH, et al., U.S. Patent Application No. 11/275,913, entitled "Two-Part Package for Medical Implant," filed 02/02/2006 (WSGR Reference No. 30207-723.201)	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Electronic Acknowledgement Receipt

EFS ID:	1112323
Application Number:	10870340
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor:	Amr Salahieh
Customer Number:	21971
Filer:	Vernon A. Norviel/Frank Chen (VN/MSK/FC)
Filer Authorized By:	Vernon A. Norviel
Attorney Docket Number:	30207-710.201
Receipt Date:	13-JUL-2006
Filing Date:	16-JUN-2004
Time Stamp:	16:52:31
Application Type:	Utility
International Application Number:	

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1	Information Disclosure Statement (IDS) Filed	IDS30207-710-201-07-13-06.pdf	269379	no	6

Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	EP04.PDF	1025699	no	15
Warnings:					
Information:					
3	Foreign Reference	WO96.PDF	1127284	no	34
Warnings:					
Information:					
4	Foreign Reference	WO98.PDF	885222	no	24
Warnings:					
Information:					
5	NPL Documents	722-501.PDF	2359623	no	36
Warnings:					
Information:					
6	NPL Documents	723-201.PDF	1332786	no	33
Warnings:					
Information:					
		Total Files Size (in bytes):	6999993		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

02-01-07

IPW

PATENT
WSGR Docket No. 30207-710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:			
Inventor:	Amr Salahieh	Confirmation No.:	7111
Application No.:	10/870,340	Examiner:	Thomas C. Barrett
Filed:	June 16, 2004	Group Art Unit:	3738
Title:	EVERTING HEART VALVE	Customer No.	021971

REVOCATION OF POWER OF ATTORNEY WITH NEW POWER OF ATTORNEY CHANGE OF CORRESPONDENCE ADDRESS AND 3.73 STATEMENT

I hereby revoke all previous powers of attorney given in the above-identified application.

☒ I hereby appoint the practitioners associated with Customer Number: **66854**

☒ Please change the correspondence address for the above-identifies application to:

☒ The address associated with Customer Number: **66854**

STATEMENT UNDER 37 CFR 3.73(b)

Sadra Medical, Inc. (Name of Assignee) a Delaware corporation (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.) states that it is: the assignee of the entire right, title and interest; in the patent application/patent identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 015421, Frame 0038, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To: _____
   The document was recorded in the United States Patent and Trademark Office at Reel ___, Frame ___, or for which a copy thereof is attached.
2. From: _____ To: _____
   The document was recorded in the United States Patent and Trademark Office at Reel ___, Frame ___, or for which a copy thereof is attached.
3. From: _____ To: _____
   The document was recorded in the United States Patent and Trademark Office at Reel ___, Frame ___, or for which a copy thereof is attached.

I am an authorized representative of the:

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is incorporated herein.

SIGNATURE of Assignee of Record

Signature _____

Name/Title Amr Salahieh, CEO

Date 1/29/2007 Telephone No. (408) 370-1550

3036554_1.DOC

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/870,340	06/16/2004	Amr Salahieh	30207-710.201

CONFIRMATION NO. 7111

OC000000022467973

66854
SHAY LAW GROUP, LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

Date Mailed: 02/12/2007

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/30/2007.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

SYED AREEBUDDIN
PTOSS (703) 308-9150 EXT 148

OFFICE COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/870,340	06/16/2004	Amr Salahieh	30207-710.201

CONFIRMATION NO. 7111

OC000000022467911

21971
WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

Date Mailed: 02/12/2007

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/30/2007.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

SYED AREEBUDDIN
PTOSS (703) 308-9150 EXT 148

OFFICE COPY

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	6

Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	Thomas C. Barrett
Attorney Docket Number	10012-710.201

ENCLOSURES ***(check all that apply)***

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) ____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) *(please identify below)*:

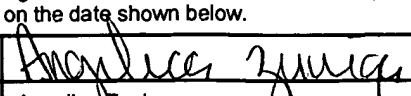
Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm	Shay Law Group LLP		
Signature			
Printed Name	Thomas Zlogar		
Date	3/26/07	Reg. No.	55,760

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Signature			
Typed or printed name	Angelica Zuniga	Date	03/26/07

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: 10/870,340
Inventors: Amr Salahieh
Filed: June 16, 2004
Title: **EVERTING HEART VALVE**

Confirmation No.: **7111**
Examiner: Thomas C. Barrett
Group Art Unit: 3738

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d),

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491,

☒ **3).** Before the mail date of a first Office Action on the merits,

☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application,

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application,

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of the earlier of a Final Office action or a Notice of Allowance under § 1.311, but before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii) U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☒ **37 CFR §1.98 (a)(2)(iii) Pending unpublished U.S. applications cited**

A copy of each application specification including the claim(s)s, and any drawing of the application, or that portion of the application that caused it to be listed, including any claims directed to that portion, is attached.

☐ **37 CFR §1.98 (a)(2)(iii) English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **37 CFR §1.98 (a)(2)(i) Foreign patent(s) in English cited**

A legible copy of each foreign patent is attached.

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) Foreign patent(s) or other foreign documents not in English cited**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached,

--AND--

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of the translation of a written English-language translation, or portion thereof, is readily available and is attached.

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 3/26/07

By: _____
Thomas Zlogar Reg. # 55760

Shay Law Group
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08A (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	Thomas C. Barrett
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	366	US- 2003/0233117-A1	12/18/2003	Adams et al.	
	364	US- 2004/0153094-A1	08/05/2004	Dunfee et al.	
	367	US- 2005/0107822-A1	05/19/2005	WasDyke, Joel	
	368	US- 6,610,077	08/26/2003	Hancock et al.	
	369	US- 6,790,229	09/14/2004	Berreklouw, Eric	
	365	US- 6,969,395	11/29/2005	Eskuri et al.	
	363	US- 6,361,545	03/26/2002	Macoviak et al.	
	142	US- 5,064,435	11/12/1991	Porter	
	262	US- 6,712,843	03/30/2004	Elliott	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Peges, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	Thomas C. Barrett
Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	305	SALAHIEH, et al., U.S. Patent App.11/531,980, "Externally expandable heart valve anchor and method," filed 09/14/2006 SLG Ref 10012-703.301(formerly 30207-703.301)	
	306	SALAHIEH, et al., U.S. Patent App.11/532,019, "Methods and apparatus for endovascularly replacing heart valve," filed 09/14/2006SLG Ref 10012-703.302(formerly 30207-703.302)	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	5

Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	Schillinger, Ann M
Attorney Docket Number	10012-710.201

ENCLOSURES ***(check all that apply)***

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:

Postcard

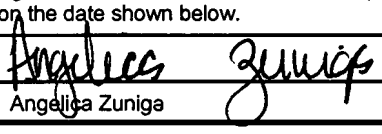
Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm	Shay Law Group LLP		
Signature			
Printed Name	Thomas Zlogar		
Date	5/24/07	Reg. No.	55,760

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Signature			
Typed or printed name	Angelica Zuniga	Date	05/24/07

Docket No. 10012-710.201

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

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05/24/07 Angelica Zuniga
Date Angelica Zuniga

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: 10/870,340
Inventors: Amr Salahieh
Filed: June 16, 2004
Title: **EVERTING HEART VALVE**

Confirmation No.: **7111**
Examiner: Schillinger, Ann M
Group Art Unit: 3738

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**
This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:
☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d),
☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491,
☒ **3).** Before the mail date of a first Office Action on the merits,
☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☐ **37 CFR § 1.97(c)**
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☐ **1).** Three months beyond the filing date of a national application,
☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application,
☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
☐ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement
☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**
This statement is being filed after the mailing date of the earlier of a Final Office action or a Notice of Allowance under § 1.311, but before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement
--AND--
B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☐ **37 CFR §1.98 (a)(2)(ii) U.S. patents or patent application publication(s) cited**
☐ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☒ **37 CFR §1.98 (a)(2)(iii) Pending unpublished U.S. applications cited**
A copy of each application specification including the claim(s)s, and any drawing of the application, or that portion of the application that caused it to be listed, including any claims directed to that portion, is attached.

☐ **37 CFR §1.98 (a)(2)(iii) English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**
A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **37 CFR §1.98 (a)(2)(i) Foreign patent(s) in English cited**
A legible copy of each foreign patent is attached.

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) Foreign patent(s) or other foreign documents not in English cited**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached,

--AND--

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of the translation of a written English-language translation, or portion thereof, is readily available and is attached.

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 5/24/07

By: _____

Thomas Zlogar Reg. # 55760

Shay Law Group
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08B (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	Schillinger, Ann M
Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	374	Haug, et al; U.S. Pat App. # 11/716,123, entitled "Methods and apparatus for endovascularly replacing a heart valve," filed 3/9/2007 (SLG #10012-701.301).	
	372	SALAHIEH, et al; U.S. Pat App. # 11/706,549, entitled "Systems and Methods for Delivering a Medical Implant," filed 2/14/2007 (SLG #10012-732.201).	
	373	Salahieh, et al; U.S. Pat App. # 11/732,906 entitled "Assessing the location and performance of replacement heart valves," filed 4/4/2007 (SLG #10012-702.505).	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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PTO/SB/21 (04-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 5

Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Shaw Law Group LLP		
Signature			
Printed name	Thomas Zlogar		
Date	7/12/07	Reg. No.	55,760

CERTIFICATE OF TRANSMISSION/MAILING

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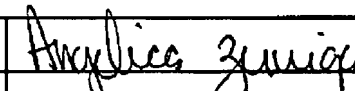
Signature			
Typed or printed name	Angelica Zuniga	Date	07/12/07

Docket No.10012-710.201

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at Fax No. 571.273.8300 on

07/12/07 Angelica Zuniga
Date Angelica Zuniga

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: 10/870,340
Inventors: Amr Salahieh
Filed: June 16, 2004
Title: EVERTING HEART VALVE

Confirmation No.: 7111
Examiner: SCHILLINGER, ANN M
Group Art Unit: 3738

Commissioner for Patents
P.O. Box 1450
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JUL 12 2007

Docket No.10012-710.201

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☐ **37 CFR § 1.97(c)**
This statement is being filed after the latest of:
☐ **1).** Three months beyond the filing date of a national application, or
☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or
☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
☐ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or
☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**
This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement
--AND--
B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**
☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**
☐ **1).** A copy of each application specification including the claim(s)s, and any drawing of the application, or that portion of the application that caused it to be listed, including any claims directed to that portion, is attached.
☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**
☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.
☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

Docket No.10012-710.201

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ 1). A legible copy of each foreign patent is attached.

☐ 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND--**

☐ 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ 2b). A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ 2c). An English language copy of a foreign search report is submitted.

--OR--

☐ 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 7/12/07

By: _____
Thomas Zlogar Reg. # 55760

Shay Law Group
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	375	US- US 5,824,041 A	10/20/1998	Lenker, et al.	
	376	US- US 6,863,668	03/08/2005	Gillespie et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-788-9199) and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahich	30207-710.201	7111

66854 7590 07/16/2007

SHAY LAW GROUP LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
07/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/870,340	SALAHIEH ET AL.	
	Examiner	Art Unit	
	Ann Schillinger	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Stetement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, 34-37, and 52-67, drawn to an apparatus to replace a heart valve, classified in class 623, subclass 1.1.

II. Claims 21-33 and 38-51, drawn to a method to replace a heart valve, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product. For example, it may be implanted using a catheter.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER

Ann Schillinger
July 5, 2007

FILED VIA EFS ON AUGUST 15, 2007

Attorney Docket No. 10012-710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Amr SALAHIEH et al.	Group Art Unit: 3738
Application No. 10/870,340	Examiner: Ann M. SCHILLINGER
Filing Date: June 16, 2004	Confirmation No. 7111
Title: **Everting Heart Valve**	**CUSTOMER NO. 66854**

RESPONSE TO RESTRICTION REQUIREMENT

MailStop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

This communication is in response to the Office Action dated July 16, 2007, for which a reply is due August 16, 2007.

Prior to reconsidering this application on the merits, please amend the application as follows:

Amendments to the Specification are not being made.

Amendments to the Claims / Claim Listing begin on page 2 of this paper.

Remarks /Arguments begin on page 5 of this paper.

Amendments to the Claims / Claim Listing

A complete listing of the claims follows:

1. (withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the expandable anchor are configured for endovascular delivery to a vicinity of the patient's heart valve, and

wherein at least an everting portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

2. (withdrawn) The apparatus of claim 1, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

3. (withdrawn) The apparatus of claim 1, wherein the replacement valve is adapted to be held between the anchor and patient tissue upon eversion of the everting portion of the replacement valve about the anchor and expansion of the anchor.

4. (withdrawn) The apparatus of claim 1 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

5. (withdrawn) The apparatus of claim 4 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

6. (withdrawn) The apparatus of claim 1 further comprising a delivery system configured to endovascularly deliver the replacement valve and the anchor.

7. (withdrawn) The apparatus of claim 6, wherein the delivery system is configured to evert the replacement valve.

8. (withdrawn) The apparatus of claim 6, wherein the delivery system is configured to change the anchor's shape.

9. (withdrawn) The apparatus of claim 8, wherein the delivery system is configured to actively foreshorten the anchor.

10. (withdrawn) The apparatus of claim 1, wherein the anchor and the replacement valve are telescoped relative to one another during endovascular delivery.

11. (withdrawn) The apparatus of claim 1 further comprising a lock configured to maintain anchor expansion.

12. (withdrawn) The apparatus of claim 1, wherein the anchor further comprises lip and skirt regions configured to expand and engage the patient's heart valve.

13. (withdrawn) The apparatus of claim 1, wherein the anchor further comprises a braid fabricated from a single strand of wire.

14. (withdrawn) The apparatus of claim 1, wherein the replacement valve further comprises valve leaflets.

15. (withdrawn) The apparatus of claim 14, wherein the everting segment comprises a material chosen from the group consisting of biologic materials, polymeric materials, fabric materials, permeable materials, impermeable materials, materials that promote tissue ingrowth, materials that retard tissue ingrowth, foam materials, sealing materials, and combinations thereof.

16. (withdrawn) The apparatus of claim 1, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

17. (withdrawn) The apparatus of claim 16, further comprising a supporting connection between the replacement valve and the replacement valve support.

18. (withdrawn) The apparatus of claim 17, wherein the supporting connection is adapted to support replacement valve commissures.

19. (withdrawn) The apparatus of claim 16, wherein the replacement valve support and at least a portion of the anchor are adapted to move with respect to each other during endovascular deployment of the anchor and replacement valve.

20. (withdrawn) The apparatus of claim 16, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

21. (original) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor; and

expanding the anchor to a deployed configuration.

22. (original) The method of claim 21, further comprising using the everting portion of the replacement valve as a seal between the anchor and patient tissue.

23. (original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises holding the replacement valve between the anchor and patient tissue.

24. (original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

25. (original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises expanding lip and skirt regions of the anchor into engagement with the patient's heart valve.

26. (original) The method of claim 21, further comprising approximating the anchor and the replacement valve.

27. (original) The method of claim 21, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

28. (original) The method of claim 27, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

29. (original) The method of claim 21, further comprising locking the anchor in the deployed configuration.

30. (original) The method of claim 21, further comprising repositioning the replacement valve and the anchor.

31. (original) The method of claim 21, further comprising retrieving the replacement valve and the anchor.

32. (original) The method of claim 21, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

33. (original) The method of claim 32, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

34. (withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor having a lip region and a skirt region; and

a replacement valve,

wherein at least an everting portion of the replacement valve is configured to evert about the skirt region of the anchor during endovascular deployment, and

wherein the lip and skirt regions of the anchor are configured for percutaneous expansion to engage the patient's heart valve.

35. (withdrawn) The apparatus of claim 34, wherein percutaneous expansion of the skirt region is configured to hold the everting portion of the replacement valve between the skirt region and the patient's heart valve.

36. (withdrawn) The apparatus of claim 34, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

37. (withdrawn) The apparatus of claim 34, wherein the anchor further comprises a braid fabricated from a single strand of wire.

38. (original) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor; and

expanding the anchor to a deployed configuration.

39. (original) The method of claim 38, further comprising using the wrapping portion of the replacement valve as a seal between the anchor and patient tissue.

40. (original) The method of claim 38, wherein expanding the anchor to the deployed configuration further comprises holding the wrapping portion of the replacement valve between the anchor and patient tissue.

41. (original) The method of claim 38, wherein wrapping at least a portion of the replacement valve about the anchor further comprises everting at least a portion of the replacement valve about the anchor.

42. (original) The method of claim 38 wherein endovascularly delivering the replacement valve and anchor further comprises delivering and deploying the valve and anchor without connecting the valve to expandable portions of the anchor.

43. (original) The method of claim 38, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

44. (original) The method of claim 43, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

45. (original) The method of claim 39, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

46. (original) The method of claim 45, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

47. (original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

48. (original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises approximating the anchor and the replacement valve.

49. (original) The method of claim 39 further comprising locking the anchor in the deployed configuration.

50. (original) The method of claim 39 further comprising repositioning the replacement valve and the anchor.

51. (original) The method of claim 39 further comprising retrieving the replacement valve and the anchor.

52. (withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the anchor are configured for endovascular delivery to a vicinity of the patient's heart valve with no portion of the replacement valve being wrapped about the anchor, and

wherein at least a wrapping portion of the replacement valve is configured to be wrapped about an end of the anchor in a deployed configuration.

53. (withdrawn) The apparatus of claim 52, wherein the wrapping portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

54. (withdrawn) The apparatus of claim 52 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

55. (withdrawn) The apparatus of claim 54 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

56. (withdrawn) The apparatus of claim 52, wherein the replacement valve is not connected to the expandable anchor.

57. (withdrawn) The apparatus of claim 52, wherein at least a portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

58. (withdrawn) The apparatus of claim 52, wherein the wrapped portion of the replacement valve is configured to be held between the anchor and the patient tissue upon endovascular deployment.

59. (withdrawn) The apparatus of claim 52, wherein the expandable anchor is configured for active foreshortening during endovascular deployment.

60. (withdrawn) The apparatus of claim 52 further comprising a lock configured to maintain expansion of the anchor.

61. (withdrawn) The apparatus of claim 52, wherein the lock is reversible.

62. (withdrawn) The apparatus of claim 52, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

63. (withdrawn) The apparatus of claim 62, further comprising a supporting connection between the replacement valve and the replacement valve support.

64. (withdrawn) The apparatus of claim 63, wherein the supporting connection is adapted to support replacement valve commissures.

65. (withdrawn) he apparatus of claim 62, wherein the replacement valve support is adapted to move with respect to the anchor during endovascular deployment of the anchor and replacement valve.

66. (withdrawn) The apparatus of claim 62, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

67. (withdrawn) The apparatus of claim 62, wherein the anchor comprises a braid fabricated from a single strand of wire.

REMARKS

Summary of Claims

Claims 1-67 are pending. Claims 1-20, 34-37 and 52-67 have been withdrawn. Claims 21-33 and 38-51 remain in this application for further prosecution. Reconsideration is respectfully requested in light of the election below.

Restriction Requirement

The Examiner has restricted Applicants' claims to one of the following allegedly distinct inventions:

I. Claims 1-20, 34-37, and 52-67, drawn to an apparatus to replace a heart valve, classified in class 623, subclass 1.1.

II. Claims 21-33 and 38-51, drawn to a method to replace a heart valve, classified in class 128, subclass 898.

Applicants elect Group II, claims 21-33 and 38-51. Applicants reserve the right pursuant to 35 U.S.C. § 121 to file one or more divisional applications directed to the non-elected invention during the pendency of the present application.

Please charge any fees due to Deposit Account No. 50-4050.

CONCLUSION

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Date: August 15, 2007 By: _____

Thomas Zlogar, Reg. No. 55,760

SHAY LAW GROUP LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

Electronic Acknowledgement Receipt

EFS ID:	2087432
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	James R. Shay/Sue Bromaghim (TZ)
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10012-710.201
Receipt Date:	15-AUG-2007
Filing Date:	16-JUN-2004
Time Stamp:	17:05:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710-201-RespRestriction.pdf	820690 51f7907cf6abb675555e5850c0fb01c74a8bb189	yes	11

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response to Election / Restriction Filed	1	1
	Claims	2	10
	Applicant Arguments/Remarks Made in an Amendment	11	11
Warnings:			
Information:			
	Total Files Size (in bytes):	820690	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (12-04)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 10870340

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))							
SEARCH FEE (37 CFR 1.16(k), (l), or (m))							
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))							
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*					
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
			X =		OR	X =	
			X =		OR	X =	
			TOTAL			TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

8/16/07

APPLICATION AS AMENDED – PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 67	Minus	** 61	6	X 25 =	150			
Independent (37 CFR 1.16(h))	* 5	Minus	*** 3	2	X 100 =	200	OR	X 50 =	
Application Size Fee (37 CFR 1.16(s))							OR	X 200 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=					
Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
Application Size Fee (37 CFR 1.16(s))					X =		OR	X =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

66854 7590 09/14/2007

SHAYGLENN LLP
2755 CAMPUS DRIVE
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SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
09/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/870,340	SALAHIEH ET AL.	
	Examiner	Art Unit	
	Ann Schillinger	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) *1-20,34-37 and 52-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33 and 38-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Data. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/26/04, 2/22/05, 4/27/05, 6/30/05, 10/26/05, 4/12/06, 7/13/06, 3/28/07, 5/29/07, 7/12/07.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, 34-37, and 52-67, drawn to an apparatus for replacing a heart valve classified in class 623, subclass 1.26.

II. Claims 21-33 and 38-51, drawn to a method of replacing a heart valve, classified in class 128, subclass 898.

Applicant's election of Invention II in the reply filed on 8/15/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-20, 34-37, and 52-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention I, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/15/2007.

This application contains claims 1-20, 34-37, and 52-67 drawn to an invention nonelected in the reply filed on 8/15/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-23, 25-33, 38-41, 43-46, and 48-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey et al. (US Pub. No. 2001/0021872). Bailey et al. discloses the following of claim 21: a method for endovascularly replacing a patient's heart valve, the method comprising: endovascularly delivering a replacement valve (26) and an expandable anchor (12, 22) to a vicinity of the heart valve (paragraphs 0002, 0021); everting at least an everting portion (11a, 11b) of the replacement valve about the anchor (paragraph 0049); and expanding the anchor to a deployed configuration (paragraph 0022).

Bailey et al. discloses the limitations of claims 22 and 39 as shown in Figure 4.

Bailey et al. discloses the limitations of claims 23, 25, 32, 33, 40, 43, and 44 as shown in Figures 6A and 6B.

Bailey et al. discloses the limitations of claims 26 and 48 in paragraph 0046.

Bailey et al. discloses the limitations of claims 27-30, 45, 46, 49, and 50 in paragraph 0069.

Bailey et al. discloses the limitations of claims 31 and 51 in paragraph 0019.

Bailey et al. discloses the following of claim 38: a method for endovascularly replacing a patient's heart valve, the method comprising: endovascularly delivering a replacement valve (26) and an expandable anchor (12, 22) to a vicinity of the heart valve (paragraphs 0002, 0021);

endovascularly wrapping at least a wrapping portion (11a, 11b) of the replacement valve about the anchor (paragraph 0049); and expanding the anchor to a deployed configuration (paragraph 0022).

Bailey et al. discloses the limitations of claim 41 in paragraph 0049.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of Gifford, III et al. (US Pat. No. 6,712,842). Bailey et al. discloses the invention substantially as claimed, however, Bailey et al. does not disclose shortening the anchor of the apparatus. Gifford, III et al. teaches shortening the anchor in col. 15, lines 39-54 for the purpose of reducing interference with branch vessels during insertion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shorten the anchor in order to reduce interference with branch vessels during insertion.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of Chew et al. (US Pub. No. 2004/0215331). Bailey et al. discloses the invention substantially as claimed, however, Bailey et al. does not disclose not connecting the valve to expansion portion of the anchor. Chew et al. teaches not connecting the valve to expansion portion of the anchor in paragraphs 0016, 0058, 0118, and 0119 for the purpose of separating

expandable from non-expandable parts so that the anchor may be more accurately deployed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to not connect the valve to expansion portion of the anchor in order to separate expandable from non-expandable parts so that the anchor may be more accurately deployed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A. Stewart

Ann Schillinger
September 11, 2007

ALVIN J. STEWART
PRIMARY EXAMINER

PTO/SB/08A (08-03)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 12

Complete if Known	
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AS		US-2001/0025196	09/27/2001	Chinn et al.	
		US-2001/0032013	10/18/2001	Marton	
		US-2001/0039450	11/08/2001	Pavcnik et al.	
		US-2001/0041928	11/15/2001	Pavcnik et al.	
		US-2002/0032480	03/14/2002	Spence et al.	
		US-2002/0052651	05/02/2002	Myers et al.	
		US-2002/0058995	05/16/2002	Stevens	
		US-2002/0077696	06/20/2002	Zadno-Azizi et al.	
		US-2002/0095209	07/18/2002	Zadno-Azizi et al.	
		US-2002/0111674	08/15/2002	Chouinard et al.	
		US-2002/0151970	10/17/2002	Garrison et al.	
		US-2002/0161392	10/31/2002	Dubrul	
		US-2002/0161394	10/31/2002	Macoviak et al.	
		US-2002/0193871	12/19/2002	Beyersdorf et al.	
		US-2003/0014104	01/16/2003	Cribier	
		US-2003/0023303	01/30/2003	Palmaz et al.	
		US-2003/0028247	02/06/2003	Cali	
		US-2003/0036791	02/20/2003	Philipp et al.	
		US-2003/0040771	02/27/2003	Hyodoh et al.	
		US-2003/0040772	02/27/2003	Hyodoh et al.	
		US-2003/0055495	03/20/2003	Pease et al.	
		US-2003/0109924	06/12/2003	Cribier	
		US-2003/0125795	07/03/2003	Pavcnik et al.	
		US-2003/0149476	07/08/2003	Damm et al.	
		US-2003/0130729	07/10/2003	Paniagua et al.	
		US-2003/0149475	08/07/2003	Hyodoh et al.	
		US-2003/0149478	08/07/2003	Figulla et al.	
		US-2003/0153974	08/14/2003	Spenser et al.	
AS		US-2003/0181850	09/25/2003	Diamond et al.	

Examiner Signature	AS	Date Considered	9/11/07

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Sheet 2 of 12

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AS		US-2003/0199913	10/23/2003	Dubrul et al.	
		US-2003/0199971	10/23/2003	Tower et al.	
		US-2003/0199972	10/23/2003	Zadno-Azizi et al.	
		US-2003/0212452	11/13/2003	Zadno-Azizi et al.	
		US-2003/0212454	11/13/2003	Scott et al.	
		US-2004/0034411	02/19/2004	Quijano et al.	
		US-2004/0039436	02/26/2004	Spenser et al.	
		US-2004/0049224	03/11/2004	Buehlmann et al.	
		US-2004/0049262	03/11/2004	Obermiller et al.	
		US-2004/0049266	03/11/2004	Anduiza et al.	
		US-2004/0082904	04/29/2004	Houde et al.	
		US-2004/0088045	05/06/2004	Cox	
		US-2004/0098112	05/20/2004	DiMatteo et al.	
		US-2004/0111096	06/10/2004	Tu et al.	
		US-2004/0116951	06/17/2004	Rosengart	
		US-2004/0117004	06/17/2004	Osborne et al.	
		US-2004/0122468	06/24/2004	Yodfat et al.	
		US-2004/0127979	07/01/2004	Wilson et al.	
		US-2004/0138742	07/15/2004	Myers et al.	
		US-2004/0138743	07/15/2004	Myers et al.	
		US-2004/0215339	10/28/2004	Drasler et al.	
		US-3,334,629	08/08/1967	Cohn	
		US-3,540,431	11/17/1970	Mobin-Uddin	
		US-3,628,535	12/21/1971	Ostrowsky et al.	
		US-3,642,004	02/15/1972	Osthagen et al.	
		US-3,671,979	06/27/1972	Moulopoulos	
		US-3,795,246	03/05/1974	Sturgeon	
AS		US-3,839,741	10/08/1974	Haller	

Examiner Signature	AS	Date Considered	9/11/07

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				*Complete if Known*	
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				First Named Inventor	Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	3	of	12	Attorney Docket Number	30207.710.201

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AS		US-3,868,956	03/04/1975	Alfidi et al.	
		US-3,874,388	04/01/1975	King et al.	
		US-4,056,854	11/08/1977	Boretos et al.	
		US-4,106,129	08/15/1978	Carpentier et al.	
		US-4,233,690	11/18/1980	Akins	
		US-4,291,420	09/29/1981	Reul	
		US-4,425,908	01/17/1984	Simon	
		US-4,501,030	02/26/1985	Lane	
		US-4,580,568	04/08/1986	Gianturco	
		US-4,610,688	09/09/1986	Silvestrini et al.	
		US-4,647,283	03/03/1987	Carpentier et al.	
		US-4,648,881	03/10/1987	Carpentier et al.	
		US-4,655,771	04/07/1987	Wallsten	
		US-4,662,885	05/05/1987	DiPisa, Jr.	
		US-4,665,906	05/19/1987	Jervis	
		US-4,710,192	12/01/1987	Liotta et al.	
		US-4,733,665	03/29/1988	Palmaz	
		US-4,819,751	04/11/1989	Shimada et al.	
		US-4,834,755	05/30/1989	Silvestrini et al.	
		US-4,856,516	08/15/1989	Hillstead	
		US-4,872,874	10/10/1989	Taheri	
		US-4,909,252	03/20/1990	Goldberger	
		US-4,917,102	04/17/1990	Miller et al.	
		US-4,954,126	09/04/1990	Wallsten	
		US-4,994,077	02/19/1991	Dobben	
		US-5,002,559	03/26/1991	Tower	
		US-5,161,547	11/10/1992	Tower	
AS		US-5,163,953	11/17/1992	Vince	

Examiner Signature	AS	Date Considered	9/11/07

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

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Sheet 4 of 12

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First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AS		US-5,217,483	07/08/1993	Tower	
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		US-5,332,402	07/26/1994	Teitelbaum et al.	
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Sheet 5 of 12

Complete if Known	
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
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AS		US-5,876,448	03/02/1999	Thompson et al.	
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AS		US-6,327,772	12/11/2001	Zadno-Azizi et al.	
		US-6,338,735	01/15/2002	Stevens	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[2] - Number[3] - Kind Code[4] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[5]
AS		EP 1057459	12/06/2000	Numed, Inc.		
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		WO 01/35870	05/25/2001	Seguin, Jacques		X
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		WO 02/36048	05/10/2002	Seguin, Jacques		X
AS		WO 02/100297	12/19/2002	Rex Medical, L. P.		

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AS		WO 03/003943	01/16/2003	Advanced Bio Prosthetic Surfaces, Ltd.		
		WO 03/003949	01/16/2003	Seguin, Jacques		X
		WO 03/011195	02/13/2003	Seguin, Jacques		X
		WO 03/015851	11/27/2003	Scimed Life Systems, Inc.		
		WO 2004/019811	03/11/2004	Heart Leaflet Technologies		
		WO 2004/023980	03/25/2004	3F Therapeutics, Inc.		
		WO 2004/041126	05/21/2004	Seguin, Jacques		
AS		WO 2004/047681	06/10/2004	Boudjemline Younes		X

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				Examiner Name	Not yet assigned
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
AB		ANDERSEN, H.R. et al., "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs". Euro. Heart J. (1992) 13:704-708.	
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Examiner signature	AB	Date Considered	9/11/07

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AB		FERRARI, M. et al., "Percutaneous transvascular aortic valve replacement with self expanding stent-valve device". Poster from the presentation given at SMIT 2000, 12th International Conference (September 5, 2000).	
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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	10/870,340
				Filing Date	06/16/2004
				First Named Inventor	Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	12	of	12	Attorney Docket Number	30207.710.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
AB		PAVCNIK, D. et al., "Percutaneous bioprosthetic venous valve: A long-term study in sheep". J. of Vascular Surg. (2002) 35:3, 598-603.	
		PHILLIPS, S. J. at al., "A Temporary Catheter-Tip Aortic Valve: Hemodynamic Effects on Experimental Acute Aortic Insufficiency". Annals of Thoracic Surg. (1976) 21:2, 134-136.	
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AB		ZHOU, J. Q. et al., "Self-expandable valved stent of large size: off-bypass implantation in pulmonary position". Eur. J. Cardiothorac. (2003) 24, 212-216	

Examiner signature	AB	Date Considered	9/11/07

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Sheet	1	of	1	Attorney Docket Number	30207.710.201

Complete if Known	
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AB		US-2004/0186563	09/23/2004	Lobbi	
AB		US-5,554,185	09/10/1996	Block et al.	1

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] – Number[4] – Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
AB		EP 1000590A1	05/17/2000	Cordis Corporation	1	

Examiner Signature	AB	Date Considered	9/11/07

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Examiner Name	Miller
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Sheet 1 of 2

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AS		SALAHIEH, A. et al. US Patent Application No. 10/746,280 entitled "Repositionable heart valve and method", filed 12/23/2003 (Docket No. 30207.701.201).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,131 entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (Docket No. 30207.701.501).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,151, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.502).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,143, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.503).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,142, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.504).	
		SALAHIEH, A. et al. US Patent Application No. 10/920,736, entitled "Apparatus and methods for protecting against embolization during endovascular heart replacement", filed 08/17/2004 (30207.701.505).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,240, entitled "Heart valve anchor and method", filed 12/23/2003 (30207.702.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/972,287, entitled "Leaflet engagement elements and methods for use thereof", filed 10/21/2004 (30207.702.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/971,535, entitled "Leaflet engagement elements and methods for use thereof", filed 10/21/2004 (30207.702.502).	
AS		SALAHIEH, A. et al., US Patent Application No. 10/746,120, entitled "Externally expandable heart valve anchor and method", filed 12/23/2003 (30207.703.201).	

Examiner signature	AS	Date Considered	9/11/07

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				Filing Date	06/16/2004
				First Named Inventor	Haug
				Art Unit	3738
				Examiner Name	Miller
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AS		SALAHIEH, A. et al., US Patent Application No. 10/982,388, entitled "Methods and apparatus for endovascularly replacing a heart valve", filed 11/05/2004 (30207.703.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,285, entitled "Retrievable heart valve anchor and method", filed 12/23/2003 (30207.704.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/982,692, entitled "Retrievable heart valve anchor and method", filed 11/05/2004 (30207.704.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,887, entitled "Low profile heart valve and delivery system", filed 12/23/2003 (30207.705.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,872, entitled "Locking heart valve anchor", filed 12/23/2003 (30207.706.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/911,059, entitled "Replacement valve and anchor", filed 08/03/2004 (30207.706.301).	
AS		SALAHIEH, A. et al., US Patent Application No. 10/746,942, entitled "Two-piece heart valve and anchor", filed 12/23/2003 (30207.707.201).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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				Complete if Known	
				Application Number	10/870,340
				Filing Date	06/16/2004
				First Named Inventor	Salahieh et al.
				Art Unit	3738
				Examiner Name	Miller
Sheet	1	of	1	Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

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AB		US-2005/0085841	04/21/2005	Eversull et al.	
		US-2005/0085842	04/21/2005	Eversull et al.	
		US-2005/0085843	04/21/2005	Opolski et al.	
		US-2005/0085890	04/21/2005	Rasmussen et al.	
		US-2005/0096692	05/05/2005	Linder et al.	
		US-2005/0096734	05/05/2005	Majercak et al.	
		US-2005/0096735	05/05/2005	Hojeibane et al.	
		US-2005/0096738	05/05/2005	Cali et al.	
		US-2005/0100580	05/12/2005	Osborne et al.	
		US-5,667,523	09/16/1997	Bynon et al.	
AB		US-6,887,266	05/03/2005	Williams et al.	
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AB		EP 1229864 B1	04/27/2005	Boston Scientific Limited		

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Sheet 1 of 5

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Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Ulrich R. Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207-710.201

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AS		US 2001/0044634	11/22/2001	Don Michael et al.	
		US 2002/0010489 A1	1/24/2002	Grayzel, et al.	
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AS		US 2005/0203614A1	9/15/2005	Forster	

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	Filing Date	June 16, 2004
	First Named Inventor	Ulrich R. Haug
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AS		US 2005/0203615A1	9/15/2005	Forster	
		US 2005/0203616 A1	9/15/2005	Cribier	
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		US 4,986,830	1/22/1991	Owens, et al.	
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		US 5,258,042	11/2/1993	Mehta	
		US 5,425,762	6/20/1995	Muller	
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		US 5,545,133	8/13/1996	Burns, et al.	
		US 5,843,158	12/1/1998	Lenker, et al.	
		US 5,910,154	06/08/1999	Tsugita et al.	
		US 5,911,734	06/15/1999	Tsugita et al.	
		US 5,968,070	10/19/1999	Bley, et al.	
		US 6,027,520	02/22/2000	Tsugita et al.	
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		US 6,336,934	01/08/2002	Gilson et al.	
		US 6,537,297	03/25/2003	Tsuigita et al.	
		US 6,540,768	04/01/2003	Diaz et al.	
		US 6,592,614	7/15/2003	Lenker, et al.	
		US 6,676,698	01/13/2004	McGuckin, Jr. et al.	
AS		US 6,695,864	02/24/2004	Macoviak et al.	

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Art Unit	3738
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AS		US 6,695,865	02/24/2004	Boyle et al.	
		US 6,773,454	08/10/2004	Wholey, et al.	
		US 6,890,340	05/10/2005	Duane	
		US 6,905,743	6/14/2005	Chen, et al.	
		US 6,911,036	6/28/2005	Douk, et al.	
AS		US 6,936,067	8/30/2005	Buchanan	

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	10/870,340
				Filing Date	June 16, 2004
				First Named Inventor	Ulrich R. Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	4	of	5	Attorney Docket Number	30207-710.201

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document — Country Code[2] – Number[3] – Kind Code[4] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
AS		EP 1042045 B1	05/19/2004	Domnick Hunter Ltd.		
		EP 1059894 B1 (WO 99/44540)	7/20/2005	Scimed Life Systems, Inc.		
		EP 1078610 B1	8/10/2005	Cordis Corp.		
		EP 1430853 A3	6/8/2005	M. I. Tech Co., Ltd.		
		EP 1551274 A2 (WO 04/026117)	7/13/2005	3F Therapeutics, Inc.		
		EP 1551336 A1(WO 04/014256)	7/13/2005	Abbott Laboratories Vascular Enterprises		
		EP 1562515 A1 (WO 2004/047681)	8/17/2005	Boudjemline		√
		WO 98/50103 A1	11/12/1998	Embol-X, Inc.		
		WO 99/44542 A2	09/10/1999	Scimed Life Systems, Inc.		
		WO 00/49970 A1	08/31/2000	Scimed Life Systems, Inc.		
		WO 01/08596 A1	02/08/2001	Scimed Life Systems, Inc.		
		WO 01/10320 A1	02/15/2001	Scimed Life Systems, Inc.		
		WO 01/10343 A1	02/15/2001	Scimed Life Systems, Inc.		
AS		WO 2005/084595 A1	9/15/2005	Cardiacmd, Inc.		

Examiner Signature	AS	Date Considered	9/11/07

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				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	5	of	5	Attorney Docket Number	30207-710.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
AS		BOUDJEMLINE, Y. et al. Percutaneious implantation of a biological valve in the aorta to treat aortic valve insufficiency - a sheep study. *Med Sci.Monit.* (2002) Vol. 8, No. 4, pages BR113-116	

Examiner signature	AS	Date Considered	9/11/07

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				Application Number	10/870,340
				Filing Date	June 16, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Cheryl L. Miller
Sheet	1	Of	3	Attorney Docket Number	30207-710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AS		US 2005/0137695	06/23/2005	Salahieh et al.	
		US 2005/0209580 A1	09/22/2005	Freyman	
		US 2005/0228472 A1	10/13/2005	Case et al.	
		US 2005/0251250	11/10/2005	Verhoeven et al.	
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		US 2005/0267560 A1	12/1/2005	Bates	
		US 2005/0283962	12/29/2005	Boudjemline	
		US 2006/0004439	01/05/2006	Spenser et al.	
		US 2006/0004442	01/05/2006	Spenser et al.	
		US 2006/0015168	01/19/2006	Gunderson	
		US 6,042,607	03/28/2000	Williamson, IV et al.	
		US 6,953,332	10/11/2005	Kurk et al.	
		US 6,96,4673	11/15/2005	Tsugita et al.	
		US 6,974,464	12/13/2005	Quijano et al.	
		US 6,974,474	12/13/2005	Pavcnik et al.	
		US 6,974,476	12/23/2005	McGuckin, Jr. et al.	
		US 6,979,350	12/27/2005	Moll et al.	
AS		US 6,984,242	01/10/2006	Campbell et al.	

Examiner Signature	AS	Date Considered	9/11/07

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AS		EP 1156757 B1	12/07/2005	Board of Regents, The University of Texas System		
		EP 1469797 (in German with English Claims)	11/02/2005	Figulla, Hans-Reiner		
		EP 1576937 A2	09/21/2005	Board of Regents, The University of Texas System		
		EP 1582178 A2	510/5/2005	Board of Regents, The University of Texas System		
		EP 1582179 A2	10/05/2005	Board of Regents, The University of Texas System		
		EP 1589902 (WO 2004/066876)	08/12/2004	Ave Connaught		
		EP 1600121A1	11/30/2005	William Cook Europe ApS		
		EP 1605871 (WO 2004/082536 A1)	09/30/2004	Aortech International PLC		
		EP 1616531	01/18/2006	Boston Scientific Limited		
AS		WO 2005/087140 A1	09/22/2005	Percutaneous Cardiovascular Solutions PTY Ltd.		

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				Art Unit	3738
				Examiner Name	Cheryl L. Miller
Sheet	3	Of	3	Attorney Docket Number	30207-710.201

UNPUBLISHED PATENT APPLICATIONS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
AS		FAWZI, et al., U.S. Patent Application No 11/155309, entitled "Apparatus and methods for intravascular embolic protection," filed 06/16/2005 (WSGR Reference No. 30207-719.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/232441, entitled "Methods and apparatus for endovascular heart valve replacement comprising tissue grasping elements," filed 09/20/2005 (WSGR Reference No. 30207-702.503)	
		SALAHIEH, et al., U.S. Patent Application No 11/232444, entitled "Methods and apparatus for endovascular heart valve replacement comprising tissue grasping elements," filed 09/20/2005 (WSGR Reference No. 30207-702.504)	
		SALAHIEH, et al., U.S. Patent Application No 11/274889, entitled "Medical implant deployment tool," filed 11/14/2005 (WSGR Reference No. 30207- 718.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/314183, entitled "Medical Device Delivery," filed 12/20/2005 (WSGR Reference No. 30207-725.201)	
AS		SALAHIEH, et al., U.S. Patent Application No 11/314969, entitled "Methods And Apparatus For Performing Valvuloplasty," filed 12/20/2005 (WSGR Reference No. 30207-727.201)	

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				Filing Date	June 16, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Thomas C. Barrett
Sheet	1	Of	2	Attorney Docket Number	30207-710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AS		US 3,657,744	04/25/1972	Ersek	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] – Number[4] – Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
AS		EP 0409929 B1	04/23/1997	Boston Scientific Corp.		
AS		WO 96/24306 A1 (in French with English abstract)	08/15/1996	De Fays, Robert		
AS		WO 98/57599 A2	12/23/1998	Camilli, Sante		

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				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Thomas C. Barrett
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UNPUBLISHED PATENT APPLICATIONS			
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AS		SALAHIEH, et al., U.S. Patent Application No. 11/275,912, entitled "Medical Implant Delivery and Deployment Tool," filed 02/02/2006 (WSGR Reference No. 30207-722.501)	
AS		SALAHIEH, et al., U.S. Patent Application No. 11/275,913, entitled "Two-Part Package for Medical Implant," filed 02/02/2006 (WSGR Reference No. 30207-723.201)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	Thomas C. Barrett
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

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	366	US- 2003/0233117-A1	12/18/2003	Adams et al.	
	364	US- 2004/0153094-A1	08/05/2004	Dunfee et al.	
	367	US- 2005/0107822-A1	05/19/2005	WasDyke, Joel	
	368	US- 6,610,077	08/26/2003	Hancock et al.	
	369	US- 6,790,229	09/14/2004	Berreklouw, Eric	
	365	US- 6,969,395	11/29/2005	Eskuri et al.	
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	142	US- 5,064,435	11/12/1991	Porter	
	262	US- 6,712,843	03/30/2004	Elliott	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

Complete if Known	
Application Number	10/870,340
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First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	Thomas C. Barrett
Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

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AS	305	SALAHIEH, et al., U.S. Patent App.11/531,980, "Externally expandable heart valve anchor and method," filed 09/14/2006 SLG Ref 10012-703.301(formerly 30207-703.301)	
AS	306	SALAHIEH, et al., U.S. Patent App.11/532,019, "Methods and apparatus for endovascularly replacing heart valve," filed 09/14/2006SLG Ref 10012-703.302(formerly 30207-703.302)	

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Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	Schillinger, Ann M
Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

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AS	374	Heug, et al; U.S. Pat App. # 11/716,123, entitled "Methods and epparetus for endovascularly replacing a heart valve," filed 3/9/2007 (SLG #10012-701.301).	
AS	372	SALAHIEH, et al; U.S. Pat App. # 11/706,549, entitled "Systems and Methods for Delivering a Medical Implant," filed 2/14/2007 (SLG #10012-732.201).	
AS	373	Salahieh, et al; U.S. Pat App. # 11/732,906 entitled "Assessing the location and performance of replacement heart valves," filed 4/4/2007 (SLG #10012-702.505).	

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Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	June 18, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

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AS	375	US- US 5,824,041 A	10/20/1998	Lenker, et al.	
AS	376	US- US 6,863,668	03/08/2005	Gillespie et al.	
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Notice of References Cited	Application/Control No. 10/870,340	Applicant(s)/Patent Under Reexamination SALAHIEH ET AL.	
	Examiner Ann Schillinger	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2001/0021872	09-2001	Bailey et al.	623/1.24
*	B	US-6,712,842	03-2004	Gifford et al.	623/1.13
*	C	US-2004/0215331	10-2004	Chew et al.	623/001.21
	D	US-			
	E	US-			
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	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes

Application/Control No.	Applicant(s)/Patent under Reexamination	
10/870,340	SALAHIEH ET AL.	
Examiner	**Art Unit**	
Ann Schillinger	3738	

SEARCHED			
Class	Subclass	Date	Examiner
623	1.1-2.1	9/11/2007	AS
128	898	9/11/2007	AS

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR

UNITED STATES PATENT AND TRADEMARK OFFICE

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Bib Data Sheet

CONFIRMATION NO. 7111

SERIAL NUMBER	FILING OR 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
10/870,340	06/16/2004 RULE	623	3738	30207-710.201

APPLICANTS

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** CONTINUING DATA ********** AB

** FOREIGN APPLICATIONS ********** AB

IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** SMALL ENTITY **
** 08/03/2004

Foreign Priority claimed	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ yes ☑ no	CA	63	67	5

35 USC 119 (a-d) conditions met: ☐ yes ☑ no ☐ Met after Allowance

Verified and Acknowledged: _____ Examiner's Signature _____ Initials

ADDRESS
66854

TITLE
Everting heart valve

FILING FEE RECEIVED	FEES: Authority has been given in Paper
971	No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:

☐ All Fees
☐ 1.16 Fees (Filing)
☐ 1.17 Fees (Processing Ext. of time)
☐ 1.18 Fees (Issue)
☐ Other _____
☐ Credit

PTO/SB/21 (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 5

Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  Postcard

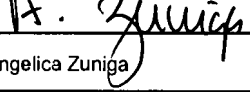
Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Shay Glenn LLP		
Signature			
Printed name	Thomas Zloger		
Date	11/16/07	Reg. No.	55,760

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Angelica Zuniga	Date	11/16/07

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: MailStop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

11/16/07 — A. Zuniga
Date: Angelica Zuniga

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/870,340	Confirmation No.: 7111
Applicant(s):	Amr Salahieh	
Filed:	June 16, 2004	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

11/20/2007 CCHAU1 00000028 504050 10870340
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FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☒ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s)s, and any drawing of the application, or that portion of the application that caused it to be listed, including any claims directed to that portion, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 11/16/07

By: _____

Thomas Zlogar Reg. # 55760

Shay Law Group LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	380	US- 5,720,391 A	2/24/1998	Dohm et al.	
	377	US- 6,712,842	3/30/2004	Gifford et al.	
	384	US- 7,018,406	3/28/2006	Seguin et al.	
	381	US- 2001/0044656 A1	11/22/2001	Williamson et al.	
	382	US- 2002/0032481 A1	3/14/2002	Gabbay, Shlomo	
	379	US- 2002/0120328 A1	8/29/2002	Pathak et al.	
	378	US- 2004/0215331	10/28/2004	Chew et al.	
	383	US- 2006/0259134 A1	11/16/2006	Schwammenthal et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	385	WO 02/0041789 A2	5/30/2002	Rex Medical, L. P.		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

FILED VIA EFS ON DECEMBER 14, 2007

Attorney Docket No. 10012-710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/870,340	Confirmation No.:	7111
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	June 16, 2004		
Title	:	Everting Heart Valve		
Group Art Unit	:	3738		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.201		
Customer No.	:	66854		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

AMENDMENT IN RESPONSE TO OFFICE ACTION

Introductory Comments:

This Amendment is responsive to the non-final Office Action mailed September 14, 2007, for which a response is due December 14, 2007. Please enter the amendments and consider the remarks as follows.

Amendments to the Specification are not being made at this time.

Amendments to the Claims begin on page 2.

Remarks/Arguments begin on page 11 of this paper.

Amendments to the Claims / Claim Listing

A complete listing of the claims follows:

1. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the expandable anchor are configured for endovascular delivery to a vicinity of the patient's heart valve, and

wherein at least an everting portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

2. (Withdrawn) The apparatus of claim 1, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

3. (Withdrawn) The apparatus of claim 1, wherein the replacement valve is adapted to be held between the anchor and patient tissue upon eversion of the everting portion of the replacement valve about the anchor and expansion of the anchor.

4. (Withdrawn) The apparatus of claim 1 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

5. (Withdrawn) The apparatus of claim 4 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

6. (Withdrawn) The apparatus of claim 1 further comprising a delivery system configured to endovascularly deliver the replacement valve and the anchor.

7. (Withdrawn) The apparatus of claim 6, wherein the delivery system is configured to evert the replacement valve.

8. (Withdrawn) The apparatus of claim 6, wherein the delivery system is configured to change the anchor's shape.

9. (Withdrawn) The apparatus of claim 8, wherein the delivery system is configured to actively foreshorten the anchor.

10. (Withdrawn) The apparatus of claim 1, wherein the anchor and the replacement valve are telescoped relative to one another during endovascular delivery.

11. (Withdrawn) The apparatus of claim 1 further comprising a lock configured to maintain anchor expansion.

12. (Withdrawn) The apparatus of claim 1, wherein the anchor further comprises lip and skirt regions configured to expand and engage the patient's heart valve.

13. (Withdrawn) The apparatus of claim 1, wherein the anchor further comprises a braid fabricated from a single strand of wire.

14. (Withdrawn) The apparatus of claim 1, wherein the replacement valve further comprises valve leaflets.

15. (Withdrawn) The apparatus of claim 14, wherein the everting segment comprises a material chosen from the group consisting of biologic materials, polymeric materials, fabric materials, permeable materials, impermeable materials, materials that promote tissue ingrowth, materials that retard tissue ingrowth, foam materials, sealing materials, and combinations thereof.

16. (Withdrawn) The apparatus of claim 1, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

17. (Withdrawn) The apparatus of claim 16, further comprising a supporting connection between the replacement valve and the replacement valve support.

18. (Withdrawn) The apparatus of claim 17, wherein the supporting connection is adapted to support replacement valve commissures.

19. (Withdrawn) The apparatus of claim 16, wherein the replacement valve support and at least a portion of the anchor are adapted to move with respect to each other during endovascular deployment of the anchor and replacement valve.

20. (Withdrawn) The apparatus of claim 16, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

21. (Currently Amended) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor; and

expanding the anchor to a deployed configuration.

22. (Original) The method of claim 21, further comprising using the everting portion of the replacement valve as a seal between the anchor and patient tissue.

23. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises holding the replacement valve between the anchor and patient tissue.

24. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

25. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises expanding lip and skirt regions of the anchor into engagement with the patient's heart valve.

26. (Original) The method of claim 21, further comprising approximating the anchor and the replacement valve.

27. (Original) The method of claim 21, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

28. (Original) The method of claim 27, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

29. (Original) The method of claim 21, further comprising locking the anchor in the deployed configuration.

30. (Original) The method of claim 21, further comprising repositioning the replacement valve and the anchor.

31. (Original) The method of claim 21, further comprising retrieving the replacement valve and the anchor.

32. (Original) The method of claim 21, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

33. (Original) The method of claim 32, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

34. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor having a lip region and a skirt region; and

a replacement valve,

wherein at least an everting portion of the replacement valve is configured to evert about the skirt region of the anchor during endovascular deployment, and

wherein the lip and skirt regions of the anchor are configured for percutaneous expansion to engage the patient's heart valve.

35. (Withdrawn) The apparatus of claim 34, wherein percutaneous expansion of the skirt region is configured to hold the everting portion of the replacement valve between the skirt region and the patient's heart valve.

36. (Withdrawn) The apparatus of claim 34, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

37. (Withdrawn) The apparatus of claim 34, wherein the anchor further comprises a braid fabricated from a single strand of wire.

38. (Currently Amended) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor; and

expanding the anchor to a deployed configuration.

39. (Original) The method of claim 38, further comprising using the wrapping portion of the replacement valve as a seal between the anchor and patient tissue.

40. (Original) The method of claim 38, wherein expanding the anchor to the deployed configuration further comprises holding the wrapping portion of the replacement valve between the anchor and patient tissue.

41. (Original) The method of claim 38, wherein wrapping at least a portion of the replacement valve about the anchor further comprises everting at least a portion of the replacement valve about the anchor.

42. (Original) The method of claim 38 wherein endovascularly delivering the replacement valve and anchor further comprises delivering and deploying the valve and anchor without connecting the valve to expandable portions of the anchor.

43. (Original) The method of claim 38, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

44. (Original) The method of claim 43, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

45. (Original) The method of claim 39, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

46. (Original) The method of claim 45, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

47. (Original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

48. (Original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises approximating the anchor and the replacement valve.

49. (Original) The method of claim 39 further comprising locking the anchor in the deployed configuration.

50. (Original) The method of claim 39 further comprising repositioning the replacement valve and the anchor.

51. (Original) The method of claim 39 further comprising retrieving the replacement valve and the anchor.

52. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the anchor are configured for endovascular delivery to a vicinity of the patient's heart valve with no portion of the replacement valve being wrapped about the anchor, and

wherein at least a wrapping portion of the replacement valve is configured to be wrapped about an end of the anchor in a deployed configuration.

53. (Withdrawn) The apparatus of claim 52, wherein the wrapping portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

54. (Withdrawn) The apparatus of claim 52 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

55. (Withdrawn) The apparatus of claim 54 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

56. (Withdrawn) The apparatus of claim 52, wherein the replacement valve is not connected to the expandable anchor.

57. (Withdrawn) The apparatus of claim 52, wherein at least a portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

58. (Withdrawn) The apparatus of claim 52, wherein the wrapped portion of the replacement valve is configured to be held between the anchor and the patient tissue upon endovascular deployment.

59. (Withdrawn) The apparatus of claim 52, wherein the expandable anchor is configured for active foreshortening during endovascular deployment.

60. (Withdrawn) The apparatus of claim 52 further comprising a lock configured to maintain expansion of the anchor.

61. (Withdrawn) The apparatus of claim 52, wherein the lock is reversible.

62. (Withdrawn) The apparatus of claim 52, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

63. (Withdrawn) The apparatus of claim 62, further comprising a supporting connection between the replacement valve and the replacement valve support.

64. (Withdrawn) The apparatus of claim 63, wherein the supporting connection is adapted to support replacement valve commissures.

65. (Withdrawn) he apparatus of claim 62, wherein the replacement valve support is adapted to move with respect to the anchor during endovascular deployment of the anchor and replacement valve.

66. (Withdrawn) The apparatus of claim 62, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

67. (Withdrawn) The apparatus of claim 62, wherein the anchor comprises a braid fabricated from a single strand of wire.

68. (New) The method of claim 21 wherein everting at least an everting portion of the replacement valve about the anchor comprises everting at least an everting portion of the replacement valve about the distal end of the anchor.

69. (New) The method of claim 38 wherein endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor comprises wrapping at least a wrapping portion of the replacement valve about the distal end of the anchor.

REMARKS

Summary of Claims

Claims 1-67 were pending in this application prior to entry of this amendment. Claims 1-20, 34-37 and 52-67 have been withdrawn from consideration in view of a restriction requirement. Claims 21 and 38 are amended herein, and claims 68-69 are newly presented.

Claim Rejections under 35 USC 102

Claims 21-23, 25-33, 38-41, 43-46, and 48-51 stand rejected under 35 USC 102 (e) as allegedly being anticipated by Bailey et al. (2001/0021872).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

Independent claim 21 is a method claim, and is currently amended to recite, in part, a method for endovascularly replacing a patient's heart valve, comprising endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; everting at least an everting portion of the replacement valve about the anchor **during the deployment of the anchor**; and expanding the anchor to a deployed configuration. Support for the claim 1 method, including the amendment thereto, can be found in, for example, paragraphs [00127] and [00141] of Applicants' specification as filed.

Bailey does not anticipate independent claim 21 because Bailey does not disclose each and every method step in claim 21. For example, Bailey does not describe everting at least an everting portion of the replacement valve about the anchor **during the deployment of the anchor.**

Bailey states, in reference to Figures 1-5, "portions of the outer graft member 11a may be passed through to the lumenal surface of the stent body member 12, thereby becoming the inner graft member 11b and everted to form the valve body 26." (Bailey, [0049]). Here, Bailey is merely describing the structure of the prosthesis, and does not describe "everting at least an everting portion of the replacement valve about the anchor **during the deployment of the anchor**," as required by claim 1. Furthermore, in Bailey's description of the delivery sequence of the stent valve (*see* [0073]), there is no mention of the "everting at least an everting portion of the replacement valve about the anchor **during the deployment of the anchor**." As such, Bailey does not describe each and every limitation of currently amended independent claim 21

and therefore does not anticipate claim 21. Claims 22-23, 25-33 depend from claim 21 and are therefore not anticipated by Bailey for at least the same reasons set forth above.

Independent claim 38 is currently amended to recite, in part, a method for endovascularly replacing a patient's heart valve, comprising endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor **during the deployment of the anchor**; and expanding the anchor to a deployed configuration.

The same limitation that was added to claim 21 has been added to claim 38, and at least the same arguments apply. As such, Bailey does not describe each and every limitation of currently amended independent claim 38 and therefore does not anticipate claim 38. Claims 39-41, 43-46, and 48-51 depend from claim 38 and are therefore not anticipated by Bailey for at least the same reasons set forth above.

Claim Rejections under 35 USC 103

Claims 24 and 47 stand rejected under 35 USC 103 (a) as being allegedly unpatentable over Bailey in view of Gifford et al. (USP 6,712,842). Claim 24 depends from currently amended claim 21 and claim 47 depends from currently amended claim 38.

As discussed above, Bailey does not disclose each and every limitation of claim 24. For example, Bailey does not describe everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor. Bailey also does not describe each and every limitation of claim 38. For example, Bailey does not describe endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor. Gifford does not overcome these deficiencies of Bailey. As such, claims 24 and 47 are not unpatentable over Bailey in view of Gifford.

Claim 42 stands rejected under 35 USC 103 (a) as being allegedly unpatentable over Bailey in view of Chew et al. (2004/0215331). Claim 42 depends from claim 38.

As discussed above, Bailey does not describe each and every limitation of claim 38. For example, Bailey does not describe endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor. Chew does not overcome this deficiency of Bailey. As such, claim 42 is not unpatentable over Bailey in view of Chew.

New Claims

To more fully claim the invention, Applicants have added new claims 68 and 69, which depend from currently amended independent claims 21 and 38, respectively. Support for the limitation "about the distal end of the anchor" recited in each of claims 68 and 69 can be found in, for example, paragraphs [00127] and [00141] of Applicants' specification as filed.

CONCLUSION

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Date: December 14, 2007 By: _____

Thomas Zlogar, Reg. No. 55,760

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Walter B. Glenn/Sue Bromaghim (TZ)
Attorney Docket Number:	10012-710.201

Filed as Small Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	2202	2	25	50
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	50

Electronic Acknowledgement Receipt

EFS ID:	2596024
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Walter B. Glenn/Sue Bromaghim (TZ)
Filer Authorized By:	Walter B. Glenn
Attorney Docket Number:	10012-710.201
Receipt Date:	14-DEC-2007
Filing Date:	16-JUN-2004
Time Stamp:	19:21:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$50
RAM confirmation Number	3385
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710-201-Response.pdf	1173132 03e7d75ab8d09c76ee9a193e9b32b7a72a8d8fb5	yes	13

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment - After Non-Final Rejection	1	1
Claims	2	10
Applicant Arguments/Remarks Made in an Amendment	11	13

Warnings:

Information:

2	Fee Worksheet (PTO-06)	fee-info.pdf	8128 b112974fe79886421623fab2f432fe4c993132c2	no	2

Warnings:

Information:

Total Files Size (in bytes):	1181260

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
10/870,340	06/16/2004	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 12/14/2007	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 69	Minus	** 67	= 2	X $25 =	50	OR	X $ =	
Independent (37 CFR 1.16(h))	* 4	Minus	***5	= 0	X $105 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	50	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
Lorraine E. Walden

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	394	US- 5,443,499	08/22/1995	Schmitt, Peter	
	395	US- 5,824,055	10/20/1998	Spiridigliozzi et al.	
	396	US- 6,893,459 B1	05/17/2005	Macoviak, John	
		US-			
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Thomas M. Zlogar/Angelica Zuniga
Attorney Docket Number:	10012-710.201

Filed as Large Entity

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	2863654
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Angelica Zuniga
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.201
Receipt Date:	14-FEB-2008
Filing Date:	16-JUN-2004
Time Stamp:	18:38:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	3610
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710201.pdf	224062 66eba29389da98481ddc0544f9b82730a625513e	yes	4

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Information Disclosure Statement Letter	1	3
Information Disclosure Statement (IDS) Filed	4	4

Warnings:

Information:

2	Fee Worksheet (PTO-06)	fee-info.pdf	8149 c817210e7a6b8d02eab6796de470bdf8552c1fd2	no	2

Warnings:

Information:

Total Files Size (in bytes):	232211

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/870,340	Confirmation No.: 7111
Applicant(s):	Amr Salahieh	
Filed:	June 16, 2004	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☒ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 2/14/08

By: _____

Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

66854 7590 03/17/2008

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/870,340	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *1-20,34-37 and 52-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33,38-51,68 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/07, 2/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-23, 25-33, 38-41, 43-46, 48-51, 68, and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey et al. (US Pub. No. 2001/0021872). Bailey et al. discloses the following of claim 21: a method for endovascularly replacing a patient's heart valve, the method comprising: endovascularly delivering a replacement valve (26) and an expandable anchor (12, 22, 42, 44) to a vicinity of the heart valve (paragraphs 0002, 0021); everting at least an everting portion (11a, 11b) of the replacement valve about the anchor during the deployment of the anchor (paragraphs 0048, 0049, 0058, 0059); and expanding the anchor to a deployed configuration (paragraph 0022).

Bailey et al. discloses the limitations of claims 22, 39, 68, and 69 as shown in Figures 4 and 7-10.

Bailey et al. discloses the limitations of claims 23, 25, 32, 33, 40, 43, and 44 as shown in Figures 6A and 6B.

Bailey et al. discloses the limitations of claims 26 and 48 in paragraph 0046.

Bailey et al. discloses the limitations of claims 27-30, 45, 46, 49, and 50 in paragraph 0069.

Bailey et al. discloses the limitations of claims 31 and 51 in paragraph 0019.

Bailey et al. discloses the following of claim 38: a method for endovascularly replacing a patient's heart valve, the method comprising: endovascularly delivering a replacement valve (26) and an expandable anchor (12, 22, 42, 44) to a vicinity of the heart valve (paragraphs 0002, 0021); endovascularly wrapping at least a wrapping portion (11a, 11b) of the replacement valve about the anchor during the deployment of the anchor (paragraphs 0048, 0049, 0058, 0059); and expanding the anchor to a deployed configuration (paragraph 0022).

Bailey et al. discloses the limitations of claim 41 in paragraph 0049.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of Gifford, III et al. (US Pat. No. 6,712,842). Bailey et al. discloses the invention substantially as claimed, however, Bailey et al. does not disclose shortening the anchor of the apparatus. Gifford, III et al. teaches endovascular repair methods and devices that shorten the anchor in col. 15, lines 39-54 for the purpose of reducing interference with branch vessels during insertion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to shorten the anchor in order to reduce interference with branch vessels during insertion.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of Chew et al. (US Pub. No. 2004/0215331). Bailey et al. discloses the invention substantially as claimed, however, Bailey et al. does not disclose not connecting the valve to expansion portion of the anchor. Chew et al. teaches endovascular delivery methods that do not connect the valve to expansion portion of the anchor in paragraphs 0016, 0058, 0118, and 0119 for the purpose of separating expandable from non-expandable parts so that the anchor may be more accurately deployed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to not connect the valve to expansion portion of the anchor in order to separate expandable from non-expandable parts so that the anchor may be more accurately deployed.

Response to Arguments

Applicant's arguments with respect to claims 21-33, 38-51, 68, and 69 have been considered but are moot in view of the new ground(s) of rejection. The Bailey et al. reference has been re-interpreted to include the distal and proximal flange anchors which are directly connected to the cited everting portions of the Bailey reference. Therefore, the everting portions will move simultaneously with the anchors as indicated by the citations given above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Schillinger/
Examiner, Art Unit 3774

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738

Notice of References Cited	Application/Control No. 10/870,340	Applicant(s)/Patent Under Reexamination SALAHIEH ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2001/0021872	09-2001	Bailey et al.	623/1.24
*	B	US-6,714,842	03-2004	Ito, Hiroshi	700/302
*	C	US-2004/0215331	10-2004	Chew et al.	623/001.21
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	394	US- 5,443,499	08/22/1995	Schmitt, Peter	
	395	US- 5,824,055	10/20/1998	Spiridigliozzi et al.	
	396	US- 6,893,459 B1	05/17/2005	Macoviak, John	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Ann Schillinger/	Date Considered	02/29/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AS/

PTO/SB/08A (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	380	US- 5,720,391 A	2/24/1998	Dohm et al.	
	377	US- 6,712,842	3/30/2004	Gifford et al.	
	384	US- 7,018,406	3/28/2006	Seguin et al.	
	381	US- 2001/0044656 A1	11/22/2001	Williamson et al.	
	382	US- 2002/0032481 A1	3/14/2002	Gabbay, Shlomo	
	379	US- 2002/0120328 A1	8/29/2002	Pathak et al.	
	378	US- 2004/0215331	10/28/2004	Chew et al.	
	383	US- 2006/0259134 A1	11/16/2006	Schwammenthal et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	385	WO 02/0041789 A2	5/30/2002	Rex Medical, L. P.		

Examiner Signature	/Ann Schillinger/	Date Considered	02/29/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AS/

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10870340	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

SEARCHED

Class	Subclass	Date	Examiner
623	2.11-2.42	2/29/2008	AS

SEARCH NOTES

Search Notes	Date	Examiner

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

~~PTO/SB/31 (07-06)~~
Approved for use through 09/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES	Docket Number (Optional) 10012-710.201

FILED VIA EFS

JULY 10, 2008

In re Application of	
Amr SALAHIEH et al.	
Application Number: 10/870,340	Filed: June 16, 2004
For **EVERTING HEART VALVE**	
Art Unit: 3774	Examiner: Ann M. SCHILLINGER

Applicant hereby **appeals** to the Board of Patent Appeals and Interferences from the decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 510

☒ **Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is:** **$ 255**

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ **The Director is authorized to charge fees in this application to a Deposit Account. – BY EFS**

☒ **The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 50-4050.**

☒ A petition for an extension of time under 37 CFR 1.136(a) is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 32,062

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34. ____

Signature

JAMES R. SHAY
Typed or printed name

650.212.1700
Telephone number

JULY 10, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	James R. Shay/Sue Bromaghim
Attorney Docket Number:	10012-710.201
Filed as Small Entity	

Utility Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Notice of appeal	2401	1	255	255
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	2251	1	60	60
Miscellaneous:				
			Total in USD ($)	**315**

Electronic Acknowledgement Receipt

EFS ID:	3599305
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	James R. Shay/Sue Bromaghim
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10012-710.201
Receipt Date:	10-JUL-2008
Filing Date:	16-JUN-2004
Time Stamp:	19:11:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$315
RAM confirmation Number	3808
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) / Message Digest	Multi Part /.zip	Pages (if appl.)

1		10012-710-201-NoticeAppeal.pdf	233353 337f4df894a6e14e50fed348abafee2d34bb76f4	yes	2

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Extension of Time	1	1
Notice of Appeal Filed	2	2

Warnings:

Information:

2	Fee Worksheet (PTO-06)	fee-info.pdf	8280 98e95ba2d427fc6644e9640c75dc0ae80e630d21	no	2

Warnings:

Information:

Total Files Size (in bytes):	241633

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

FILED VIA EFS ON JULY 10, 2008

Attorney Docket No. 10012-710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 10/870,340	Confirmation No.: 7111
Applicant(s)	: Amr SALAHIEH et al.	
Filed	: June 16, 2004	
Art Unit	: 3774	
Examiner	: Ann M. SCHILLINGER	
Title	: **Everting Heart Valve**	
Customer No.	: 66854	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

TRANSMITTAL OF NOTICE OF APPEAL
AND REQUEST FOR EXTENSION OF TIME

Transmitted herewith are the following documents in the above-identified application:

(1) Notice of Appeal from the Examiner to the BPAI.

▶ Request is hereby made for a one (1) month extension of time to file this document, up to and including **July 17, 2008**.

▶ The notice of appeal filing fee of $255, and the extension fee (one month / small entity) of $60 are being paid via EFS. Please deduct from or credit to Deposit Account No 50-4050 any other fees attendant with this matter.

Respectfully submitted,

Date: July 10, 2008

By: _____
James R. Shay, Reg. No. 32,062

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

FILED VIA EFS ON SEPTEMBER 10, 2008

Attorney Docket No. 10012-710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/870,340	Confirmation No.:	7111
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	June 16, 2004		
Title	:	Everting Heart Valve		
Group Art Unit	:	3774		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.201		
Customer No.	:	66854		

APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 41.37

MailStop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

Appellants submit this brief in accordance with the provisions of 37 C.F.R. § 41.37 in response to the Final Rejection mailed March 17, 2008. Appellants' Notice of Appeal was filed July 10, 2008. This Appeal Brief is therefore timely filed.

The filing fee for this document is being paid via EFS. Please charge any deficit in these fees to Deposit Account No. 50-4050.

I. REAL PARTY IN INTEREST

The real party in interest herein is Sadra Medical, Inc. (Assignee) by virtue of an assignment executed by the inventors (Appellants) to Sadra Medical, Inc. The assignment was recorded by the Assignment Branch of the U.S. Patent and Trademark Office on December 2, 2004 at Reel / Frame 015421 / 0038.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

In the current application under appeal, claims 1-69 are pending, and claims 1-20, 34-37 and 52-67 are withdrawn from consideration. The rejection of claims 21-33, 38-51, 68 and 69 is appealed herein.

IV. STATUS OF AMENDMENTS

Appellants have submitted no amendments after the final rejection. All amendments prior to the close of prosecution on the merits have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 21 recites a method for endovascularly replacing a patient's heart valve, the method comprising: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor; and expanding the anchor to a deployed configuration. Support for this claim can be found at least at ¶¶ 125-154 and Figures 39-43 of Appellants' specification.

Independent claim 38 recites a method for endovascularly replacing a patient's heart valve, the method comprising: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor; and expanding the

anchor to a deployed configuration. Support for this claim can be found at least at ¶¶ 125-154 and Figures 39-43 of Appellants' specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants respectfully request the Board of Patent Appeals and Interferences to review the following grounds of rejection on appeal:

1. Whether claims 21-23, 25-33, 38-41, 43-46, 48-51, 68 and 69 are patentable over Bailey et al. US 2001/0021872 ("Bailey") under 35 U.S.C. § 102(e).

2. Whether claims 24 and 47 are patentable over Bailey in view of Gifford et al. US 6,712,842 ("Gifford") under 35 U.S.C. § 103(a).

VII. ARGUMENTS

Appellants respectfully submit that claims 21-33, 38-51, 68 and 69 are in proper form and are patentable over the prior art of record.

1. Rejections Under § 102(e)

The Examiner rejected claims 21-23, 25-33, 38-41, 43-46, 48-51, 68 and 69 under 35 U.S.C. § 102(e) as being anticipated by Bailey. The Examiner's rejection of these claims should be overturned for at least the reasons discussed below.

a. Rejection Of Claim 21 Over Bailey

The Examiner asserts that Bailey anticipates claim 21 under 35 U.S.C. § 102(e). Bailey describes a prosthetic valve that can be supported within an expandable stent and endovascularly delivered to a patient's heart. Bailey describes two alternative methods of manufacture of one embodiment of the valve at ¶ 49. As shown in Bailey Figs. 1-5, an outer graft member 11a is placed around the outside of the stent, and an inner graft member 11b is placed on the inside of the stent. The outside and inside graft members 11a and 11b may be coupled through the interstices of the stent body. The valve body 26 is then formed by everting the inner graft member 11b toward the central longitudinal axis of the stent body member to form the valve flaps 28. As an alternative, Bailey states that "portions of the outer graft member 11a may be passed through to the lumenal surface of the stent body 21, thereby becoming the inner graft member 11b and everted to form the valve body 26." (Bailey ¶ 49) Bailey shows a second

embodiment in Figs. 7-11. In this embodiment as well, the valve flaps are formed by everting the lumenal (inner) graft member 11b inwardly toward the central longitudinal axis of the stent. (Bailey ¶ 59)

The invention of method claim 21 defines over Bailey for at least two reasons. First, claim 21 recites the step of everting a portion of the of the replacement valve *about* the anchor. Bailey, on the other hand, everts the graft material forming the valve *away* from the anchor, *i.e.*, toward the centerline of the anchor. Second, claim 21 requires that the everting step be performed during deployment of the anchor. Bailey, on the other hand, everts the graft material during manufacture of the prosthesis, not during deployment. Bailey deploys the valve stent with the valve already everted and formed within the anchor. (See Bailey ¶¶ 49, 59 and 73)

Because Bailey fails to disclose at least two explicit limitations of claim 21, Bailey cannot anticipate claim 21. Claim 21, and claims 22-33 and 68 depending from it, are patentable over Bailey under § 102(e).

b. Rejection Of Claim 22 Over Bailey

Claim 22 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above with respect to claim 21. In addition, claim 22 adds the step of using the everting portion of the replacement valve as a seal between the anchor and patient tissue. As discussed above, the everting portion of the Bailey valve forms the valve flaps on the interior of the anchor. The valve flaps function as a valve within the anchor, not as a seal between the anchor and patient tissue. Bailey therefore fails to anticipate claim 22 for this reason as well.

c. Rejection Of Claim 27 Over Bailey

Claim 27 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 27 further limits claim 21 by reciting that the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve. As described above, Bailey assembles his valve within his stent prior to deployment. During deployment, Bailey delivers a fully supported valve and does not perform the step of moving a valve support and a portion of

the anchor with respect to each other during deployment. Bailey therefore fails to anticipate claim 27 for his reason as well.

d. Rejection Of Claim 28 Over Bailey

Claim 28 depends from claim 27 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 28 recites the additional step of using the replacement valve support to lock the anchor in the deployed configuration. Bailey does not disclose any manner of locking the anchor in its deployed configuration and certainly does not recite the step of using a valve support to lock the anchor. Claim 28 is therefore patentable over Bailey for this reason as well.

e. Rejection Of Claim 29 Over Bailey

Claim 29 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 29 adds the step of locking the anchor in the deployed configuration. As indicated above, Bailey does not disclose any manner of locking of his stent in a deployed configuration. Claim 29 is therefore patentable over Bailey for this reason as well.

f. Rejection Of Claim 30 Over Bailey

Claim 30 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 30 adds the step of repositioning the replacement valve and the anchor. Bailey does not disclose any repositioning of the valve and anchor. Claim 30 is therefore patentable over Bailey for this reason as well.

g. Rejection Of Claim 31 Over Bailey

Claim 31 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 31 adds the step of retrieving the replacement valve and the anchor. Bailey does not disclose any retrieval of the valve and anchor. Claim 31 is therefore patentable over Bailey for this reason as well.

h. Rejection Of Claims 32 and 33 Over Bailey

Claim 32 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 32 further limits the delivering step by reciting the endovascular deliver of at least a portion of the replacement valve distal to the anchor. Claim 33 depends from

claim 32 and recites endovascular delivery of the entire replacement valve distal to the anchor. Bailey, on the other hand, has the entire valve disposed within the anchor—not distal to it—during endovascular delivery of the prosthesis. Bailey therefore cannot anticipate either claim 32 or claim 33 for this reason as well.

i. Rejection Of Claim 38 Over Bailey

Independent method claim 38 defines over Bailey for at least two reasons. First, claim 38 recites the step of endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor. Bailey does not perform any endovascular wrapping of any portion of the valve about the stent. Second, Bailey does not wrap any portion of the valve about the stent during the deployment of the anchor. For at least these reasons, Bailey cannot anticipate claim 38. Claim 38, and claims 39-51 and 69 depending from it, are patentable over Bailey under § 102(e).

j. Rejection Of Claim 41 Over Bailey

Claim 41 depends from claim 38 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 41 recites that the step of wrapping at least a portion of the replacement valve about the anchor further comprises everting at least a portion of the replacement valve about the anchor. As discussed above, Bailey everts his graft material away from the anchor, not about the anchor. Claim 41 is therefore patentable over Bailey for this reason as well.

k. Rejection Of Claim 42 Over Bailey

Claim 42 depends from claim 38 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 42 recites that the step of endovascularly delivering the replacement valve and anchor further comprises delivering and deploying the valve and anchor without connecting the valve to expandable portions of the anchor. Bailey, on the other hand, supports the valve solely with the expandable stent. Claim 42 is therefore patentable over Bailey for this reason as well.

l. Rejection Of Claims 43 and 44 Over Bailey

Claim 43 depends from claim 38 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 43 further limits the delivering step by reciting the endovascular

deliver of at least a portion of the replacement valve distal to the anchor. Claim 44 depends from claim 43 and recites endovascular delivery of the entire replacement valve distal to the anchor. As discussed above, Bailey has the entire valve disposed within the anchor—not distal to it—during endovascular delivery of the prosthesis. Bailey therefore cannot anticipate either claim 43 or claim 44 for this reason as well.

m. Rejection Of Claim 45 Over Bailey

Claim 45 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 45 further limits claim 39 by reciting that the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve. As described above, Bailey assembles his valve within his stent prior to deployment. During deployment, Bailey delivers a fully supported valve and does not perform the step of moving a valve support and a portion of the anchor with respect to each other during deployment. Bailey therefore fails to anticipate claim 45 for his reason as well.

n. Rejection Of Claim 46 Over Bailey

Claim 46 depends from claim 45 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 46 recites the additional step of using the replacement valve support to lock the anchor in the deployed configuration. Bailey does not disclose any manner of locking the anchor in its deployed configuration and certainly does not recite the step of using a valve support to lock the anchor. Claim 46 is therefore patentable over Bailey for this reason as well.

o. Rejection Of Claim 48 Over Bailey

Claim 48 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 48 states that the step of expanding the anchor to the deployed configuration further comprises approximating the anchor and the replacement valve. Bailey's anchor expansion step does not include the approximation of the valve and anchor. Claim 48 is therefore patentable over Bailey for this reason as well.

p. Rejection Of Claim 49 Over Bailey

Claim 49 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 49 recites the additional step of locking the anchor in the deployed configuration. As indicated above, Bailey does not disclose any manner of locking of his stent in a deployed configuration. Claim 49 is therefore patentable over Bailey for this reason as well.

q. Rejection Of Claim 50 Over Bailey

Claim 50 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 50 adds the step of repositioning the replacement valve and the anchor. Bailey does not disclose any repositioning of the valve and anchor. Claim 50 is therefore patentable over Bailey for this reason as well.

r. Rejection Of Claim 51 Over Bailey

Claim 51 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 51 adds the step of retrieving the replacement valve and the anchor. Bailey does not disclose any retrieval of the valve and anchor. Claim 51 is therefore patentable over Bailey for this reason as well.

2. Rejections Under § 103(a)

The Examiner rejected claims 24 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Bailey in view of Gifford. The Examiner's rejection of these claims should be overturned for at least the reasons discussed below.

a. Rejection Of Claim 24 Over Bailey And Gifford

Claim 24 depends from claim 21 and states that the step of expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor. This method step is neither disclosed nor suggested by either Bailey or Gifford. In Bailey, the anchor is described as self-expanding after emerging from the delivery sheath. (Bailey ¶ 73). Likewise, Gifford fails to describe any anchor or stent that expands through active foreshortening. For example, the portion of Gifford relied upon by the Examiner in the Final Rejection describes a stent that is shorter than a conventional stent, not a stent that actively foreshortens during expansion. (Gifford col. 15, lines 39-54). Since the combination of Bailey and Gifford fails to disclose

every element recited by claim 24, claim 24 is patentable over Bailey and Gifford under § 103(a).

b. Rejection Of Claim 47 Over Bailey And Gifford

Claim 47 depends from claim 39 and, like claim 24, states that the step of expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor. As described above with respect to claim 24, neither Bailey nor Gifford describes this explicit claim limitation. Claim 47 is therefore patentable over Bailey and Gifford under § 103(a).

CONCLUSION

For the reasons stated above, claims 21-33, 38-51, 68 and 69 are patentable over the prior art of record, and the rejections of those claims under 35 U.S.C. §§ 102 and/or 103 are improper and should be overturned. Appellants respectfully ask the Board to overturn the Examiner's rejection with instructions to allow the claims.

Respectfully submitted,

Date: September 10, 2008 By: _____

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VIII. CLAIMS APPENDIX

1. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the expandable anchor are configured for endovascular delivery to a vicinity of the patient's heart valve, and

wherein at least an everting portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

2. (Withdrawn) The apparatus of claim 1, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

3. (Withdrawn) The apparatus of claim 1, wherein the replacement valve is adapted to be held between the anchor and patient tissue upon eversion of the everting portion of the replacement valve about the anchor and expansion of the anchor.

4. (Withdrawn) The apparatus of claim 1 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

5. (Withdrawn) The apparatus of claim 4 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

6. (Withdrawn) The apparatus of claim 1 further comprising a delivery system configured to endovascularly deliver the replacement valve and the anchor.

7. (Withdrawn) The apparatus of claim 6, wherein the delivery system is configured to evert the replacement valve.

8. (Withdrawn) The apparatus of claim 6, wherein the delivery system is configured to change the anchor's shape.

9. (Withdrawn) The apparatus of claim 8, wherein the delivery system is configured to actively foreshorten the anchor.

10. (Withdrawn) The apparatus of claim 1, wherein the anchor and the replacement valve are telescoped relative to one another during endovascular delivery.

11. (Withdrawn) The apparatus of claim 1 further comprising a lock configured to maintain anchor expansion.

12. (Withdrawn) The apparatus of claim 1, wherein the anchor further comprises lip and skirt regions configured to expand and engage the patient's heart valve.

13. (Withdrawn) The apparatus of claim 1, wherein the anchor further comprises a braid fabricated from a single strand of wire.

14. (Withdrawn) The apparatus of claim 1, wherein the replacement valve further comprises valve leaflets.

15. (Withdrawn) The apparatus of claim 14, wherein the everting segment comprises a material chosen from the group consisting of biologic materials, polymeric materials, fabric materials, permeable materials, impermeable materials, materials that promote tissue ingrowth, materials that retard tissue ingrowth, foam materials, sealing materials, and combinations thereof.

16. (Withdrawn) The apparatus of claim 1, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

17. (Withdrawn) The apparatus of claim 16, further comprising a supporting connection between the replacement valve and the replacement valve support.

18. (Withdrawn) The apparatus of claim 17, wherein the supporting connection is adapted to support replacement valve commissures.

19. (Withdrawn) The apparatus of claim 16, wherein the replacement valve support and at least a portion of the anchor are adapted to move with respect to each other during endovascular deployment of the anchor and replacement valve.

20. (Withdrawn) The apparatus of claim 16, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

21. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor; and

expanding the anchor to a deployed configuration.

22. (Original) The method of claim 21, further comprising using the everting portion of the replacement valve as a seal between the anchor and patient tissue.

23. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises holding the replacement valve between the anchor and patient tissue.

24. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

25. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises expanding lip and skirt regions of the anchor into engagement with the patient's heart valve.

26. (Original) The method of claim 21, further comprising approximating the anchor and the replacement valve.

27. (Original) The method of claim 21, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

28. (Original) The method of claim 27, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

29. (Original) The method of claim 21, further comprising locking the anchor in the deployed configuration.

30. (Original) The method of claim 21, further comprising repositioning the replacement valve and the anchor.

31. (Original) The method of claim 21, further comprising retrieving the replacement valve and the anchor.

32. (Original) The method of claim 21, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

33. (Original) The method of claim 32, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

34. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor having a lip region and a skirt region; and

a replacement valve,

wherein at least an everting portion of the replacement valve is configured to evert about the skirt region of the anchor during endovascular deployment, and

wherein the lip and skirt regions of the anchor are configured for percutaneous expansion to engage the patient's heart valve.

35. (Withdrawn) The apparatus of claim 34, wherein percutaneous expansion of the skirt region is configured to hold the everting portion of the replacement valve between the skirt region and the patient's heart valve.

36. (Withdrawn) The apparatus of claim 34, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

37. (Withdrawn) The apparatus of claim 34, wherein the anchor further comprises a braid fabricated from a single strand of wire.

38. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor; and

expanding the anchor to a deployed configuration.

39. (Original) The method of claim 38, further comprising using the wrapping portion of the replacement valve as a seal between the anchor and patient tissue.

40. (Original) The method of claim 38, wherein expanding the anchor to the deployed configuration further comprises holding the wrapping portion of the replacement valve between the anchor and patient tissue.

41. (Original) The method of claim 38, wherein wrapping at least a portion of the replacement valve about the anchor further comprises everting at least a portion of the replacement valve about the anchor.

42. (Original) The method of claim 38 wherein endovascularly delivering the replacement valve and anchor further comprises delivering and deploying the valve and anchor without connecting the valve to expandable portions of the anchor.

43. (Original) The method of claim 38, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

44. (Original) The method of claim 43, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

45. (Original) The method of claim 39, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

46. (Original) The method of claim 45, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

47. (Original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

48. (Original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises approximating the anchor and the replacement valve.

49. (Original) The method of claim 39 further comprising locking the anchor in the deployed configuration.

50. (Original) The method of claim 39 further comprising repositioning the replacement valve and the anchor.

51. (Original) The method of claim 39 further comprising retrieving the replacement valve and the anchor.

52. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the anchor are configured for endovascular delivery to a vicinity of the patient's heart valve with no portion of the replacement valve being wrapped about the anchor, and

wherein at least a wrapping portion of the replacement valve is configured to be wrapped about an end of the anchor in a deployed configuration.

53. (Withdrawn) The apparatus of claim 52, wherein the wrapping portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

54. (Withdrawn) The apparatus of claim 52 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

55. (Withdrawn) The apparatus of claim 54 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

56. (Withdrawn) The apparatus of claim 52, wherein the replacement valve is not connected to the expandable anchor.

57. (Withdrawn) The apparatus of claim 52, wherein at least a portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

58. (Withdrawn) The apparatus of claim 52, wherein the wrapped portion of the replacement valve is configured to be held between the anchor and the patient tissue upon endovascular deployment.

59. (Withdrawn) The apparatus of claim 52, wherein the expandable anchor is configured for active foreshortening during endovascular deployment.

60. (Withdrawn) The apparatus of claim 52 further comprising a lock configured to maintain expansion of the anchor.

61. (Withdrawn) The apparatus of claim 52, wherein the lock is reversible.

62. (Withdrawn) The apparatus of claim 52, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

63. (Withdrawn) The apparatus of claim 62, further comprising a supporting connection between the replacement valve and the replacement valve support.

64. (Withdrawn) The apparatus of claim 63, wherein the supporting connection is adapted to support replacement valve commissures.

65. (Withdrawn) he apparatus of claim 62, wherein the replacement valve support is adapted to move with respect to the anchor during endovascular deployment of the anchor and replacement valve.

66. (Withdrawn) The apparatus of claim 62, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

67. (Withdrawn) The apparatus of claim 62, wherein the anchor comprises a braid fabricated from a single strand of wire.

68. (Previously Presented) The method of claim 21 wherein everting at least an everting portion of the replacement valve about the anchor comprises everting at least an everting portion of the replacement valve about the distal end of the anchor.

69. (Previously Presented) The method of claim 38 wherein endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor comprises wrapping at least a wrapping portion of the replacement valve about the distal end of the anchor.

IX. EVIDENCE APPENDIX

Bailey et al. US 2001/0021872 cited by the Examiner in an Office Action dated 9/14/07.

Gifford et al. US 6,712,842 cited by the Examiner in an Office Action dated 9/14/07.

X. RELATED PROCEEDINGS APPENDIX

None.

US 20010021872A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2001/0021872 A1**

Bailey et al. (43) **Pub. Date: Sep. 13, 2001**

(54) **ENDOLUMINAL CARDIAC AND VENOUS VALVE PROSTHESES AND METHODS OF MANUFACTURE AND DELIVERY THEREOF**

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(21) Appl. No.: **09/854,002**

(22) Filed: **May 11, 2001**

Related U.S. Application Data

(62) Division of application No. 09/477,120, filed on Dec. 31, 1999.

(30) **Foreign Application Priority Data**

Dec. 18, 2000 (US)..... PCT/US00/34591

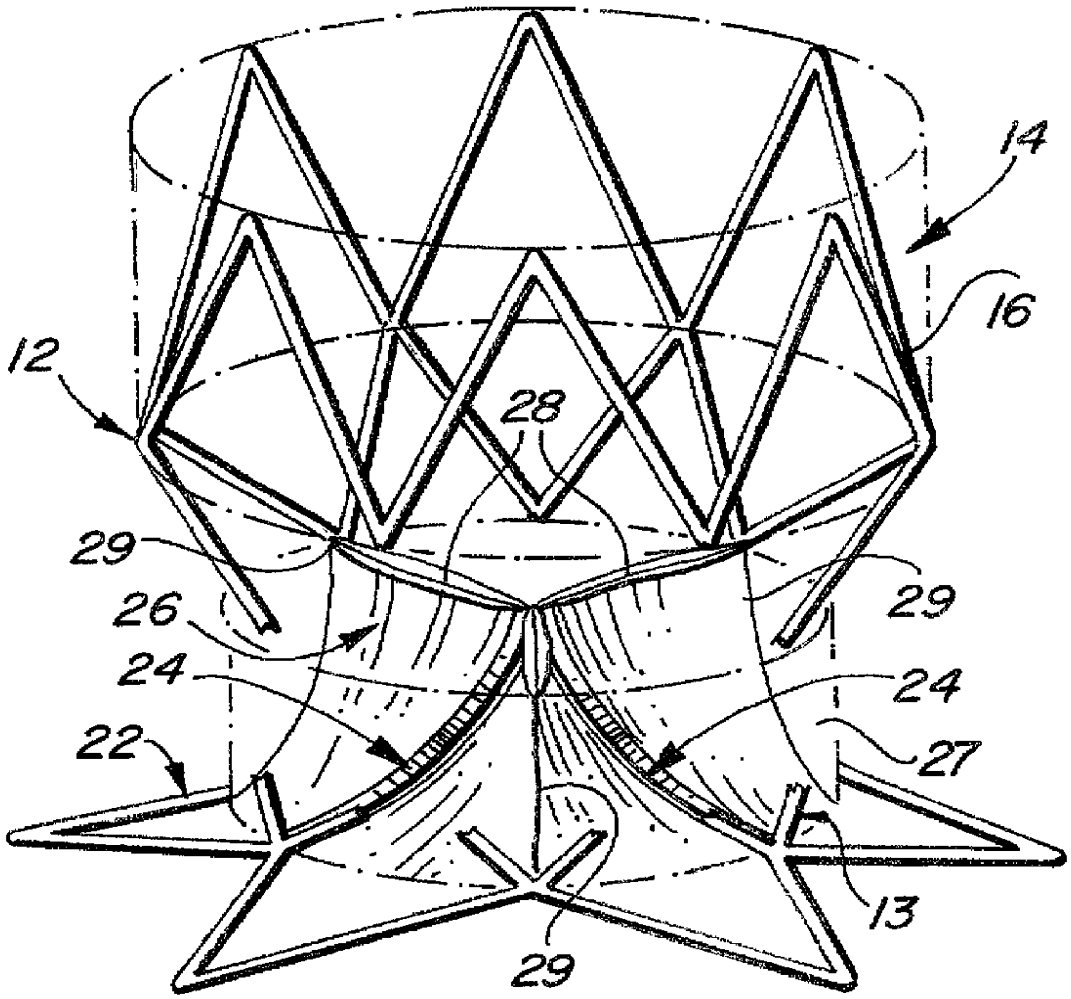
Publication Classification

(51) **Int. Cl.**[7] **A61F 2/06**; A61F 2/24

(52) **U.S. Cl.** **623/1.24**; 623/2.18

(57) **ABSTRACT**

This invention relates to prosthetic cardiac and venous valves and a single catheter device and minimally invasive techniques for percutaneous and transluminal valvuloplasty and prosthetic valve implantation.



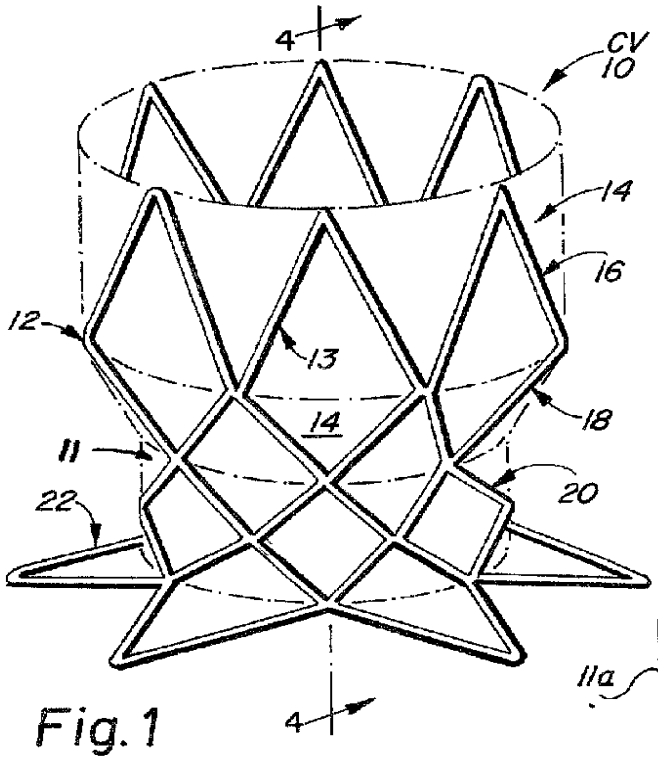


Fig. 1

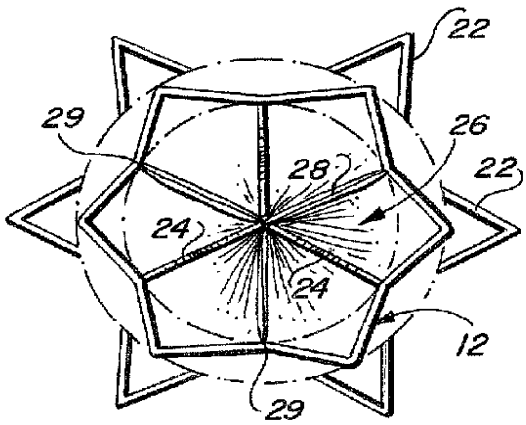


Fig. 3

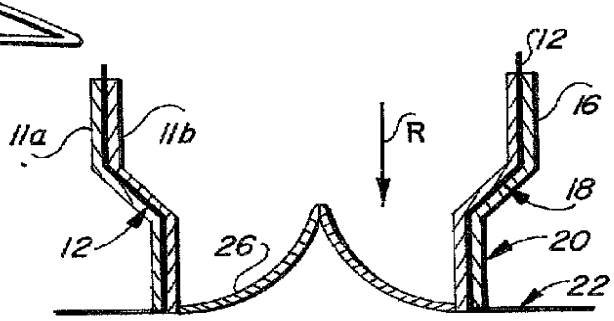


Fig. 4

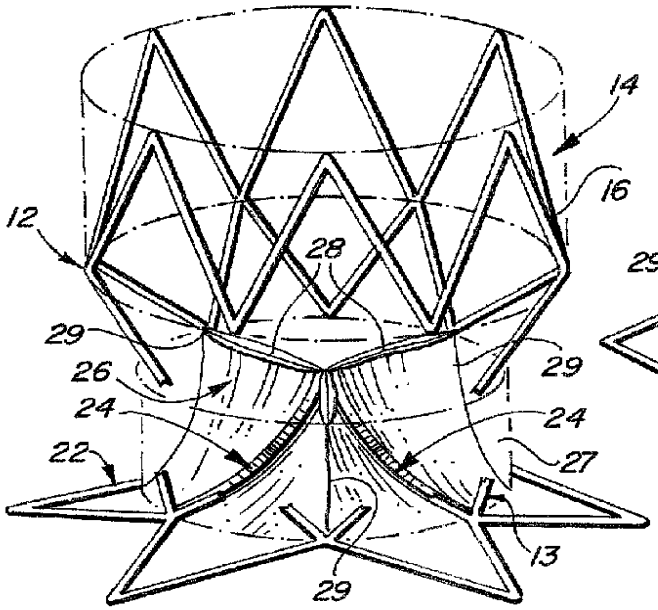


Fig. 2

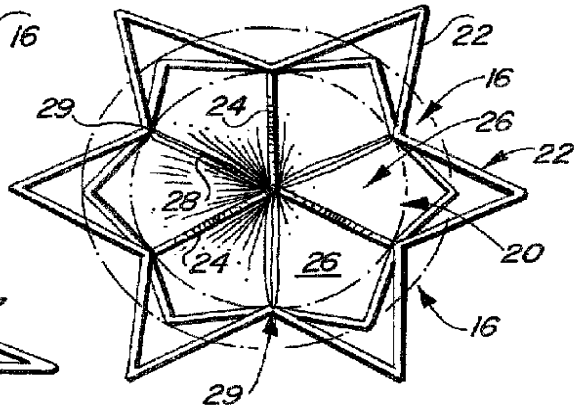


Fig. 5

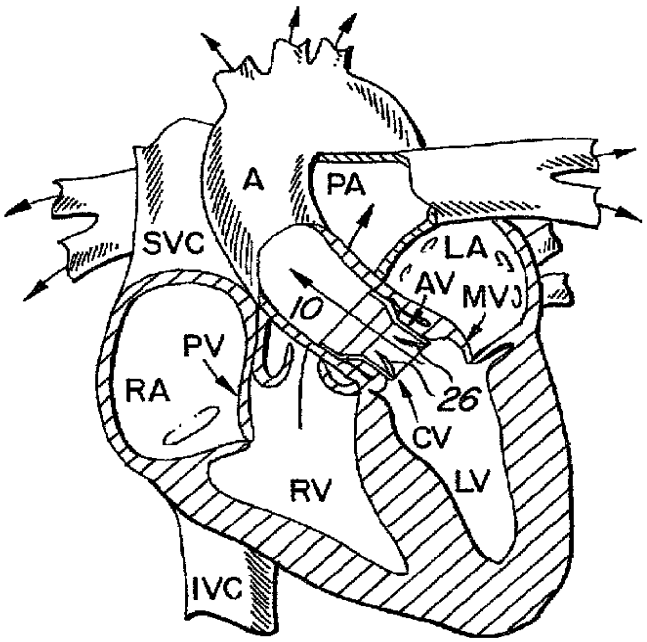


Fig. 6A

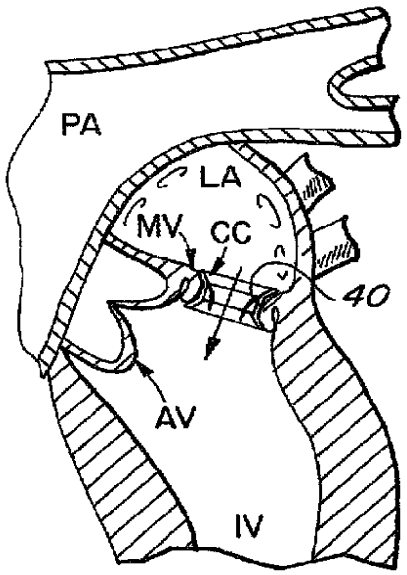


Fig. 12A

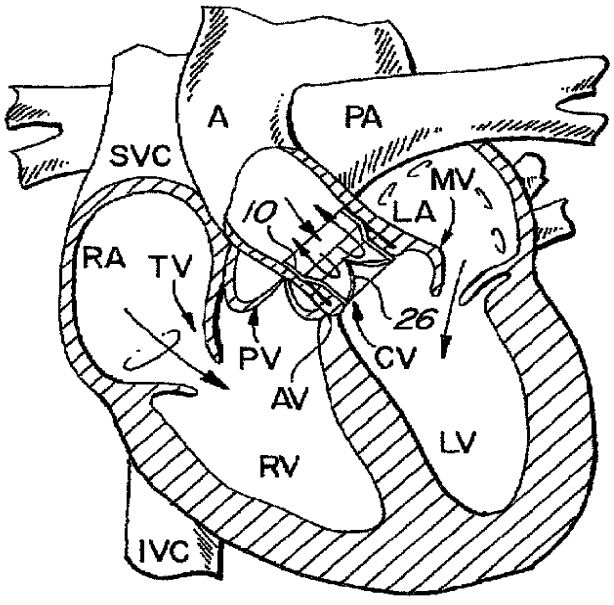


Fig. 6B

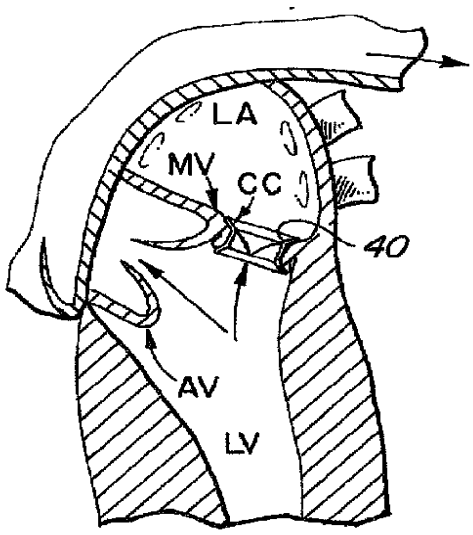


Fig. 12B

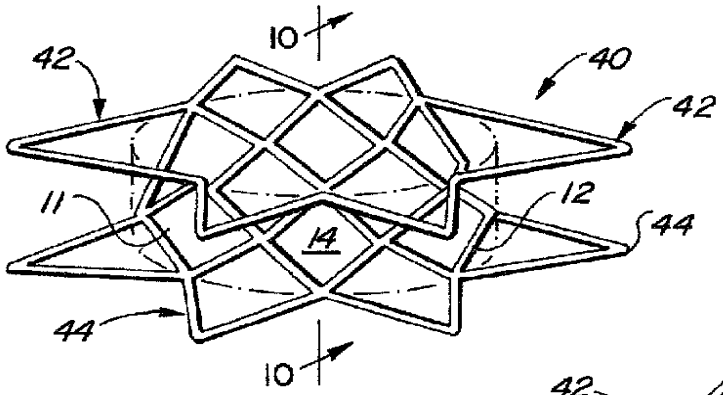


Fig. 7

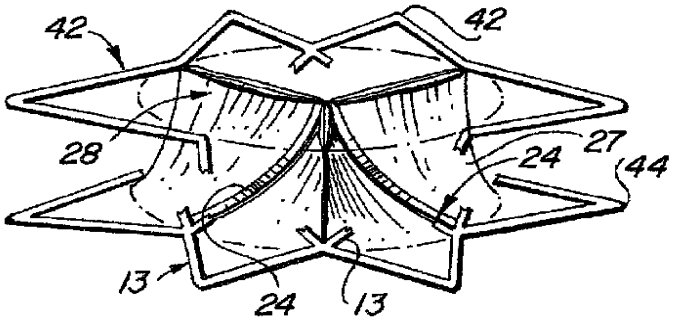


Fig. 8

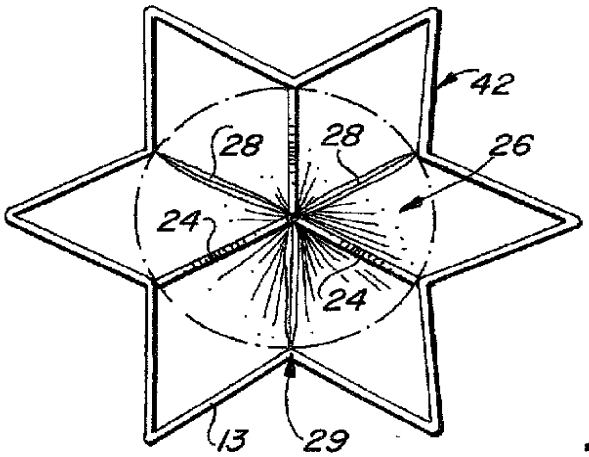


Fig. 9

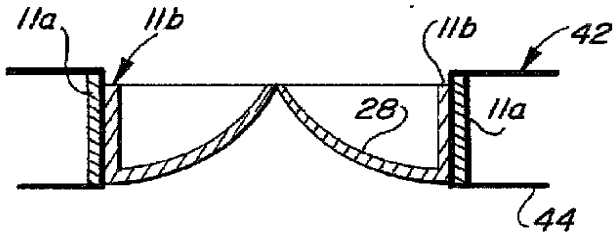


Fig. 10

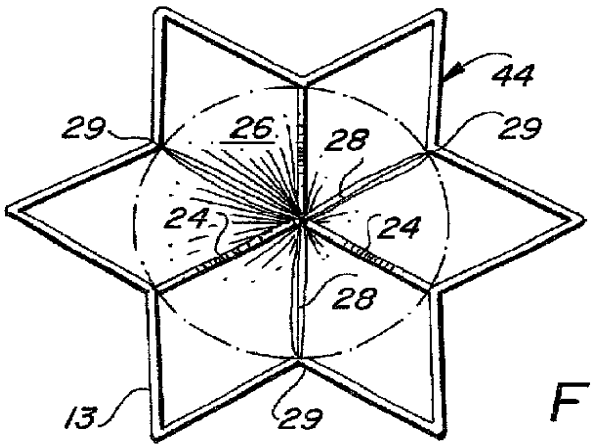


Fig. 11

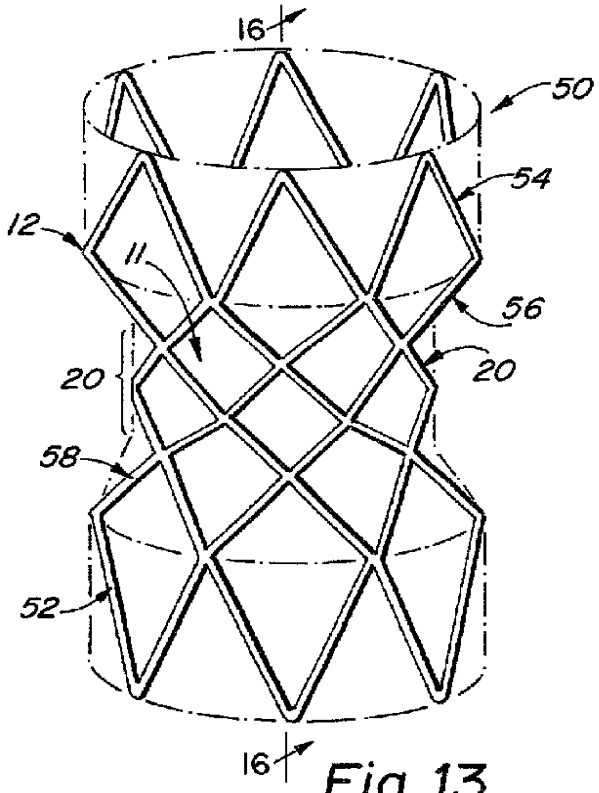


Fig. 13

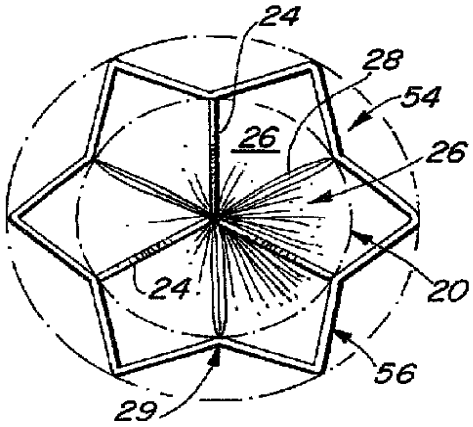


Fig. 15

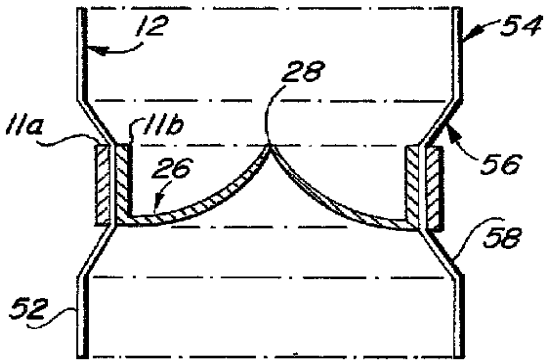


Fig. 16

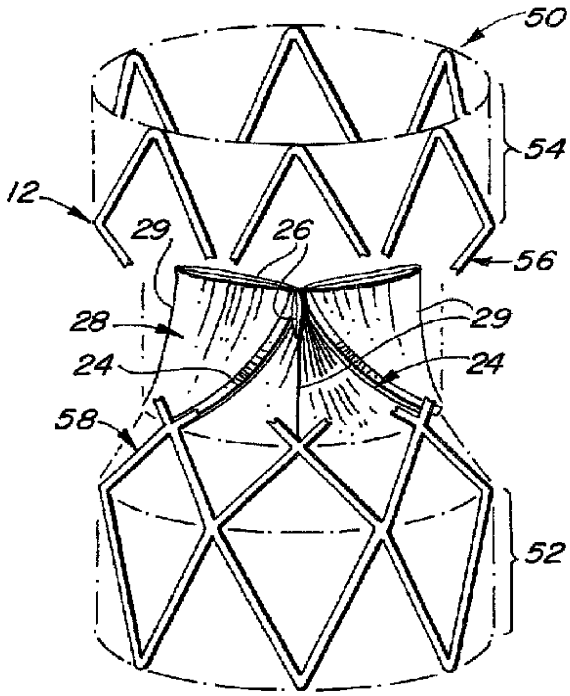


Fig. 14

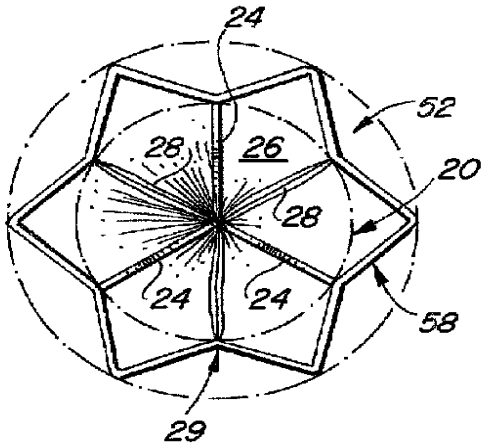


Fig. 17

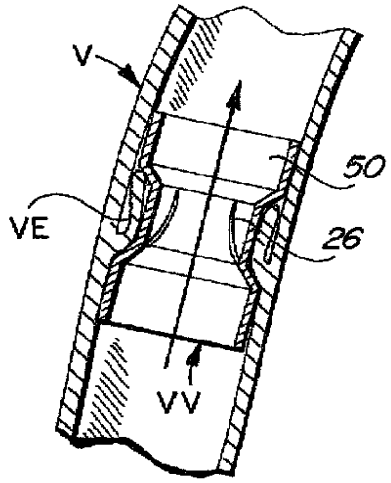


Fig. 18A

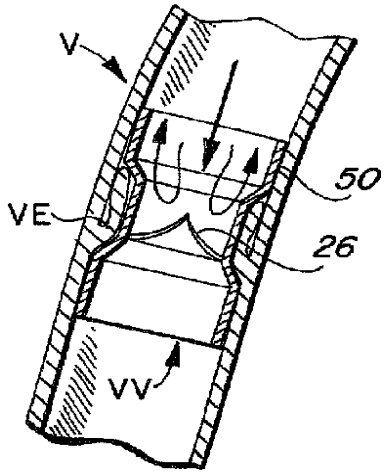


Fig. 18B

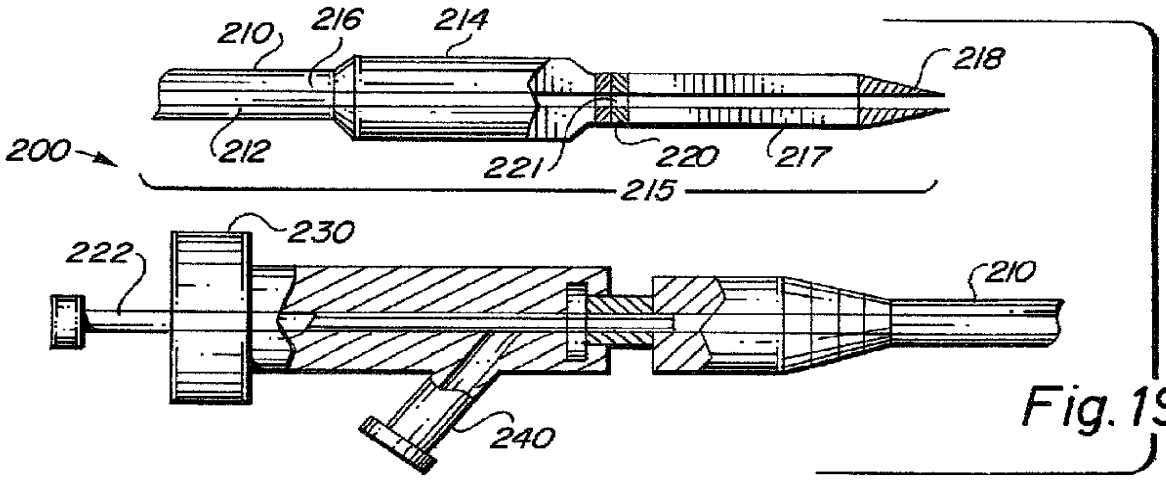


Fig. 19

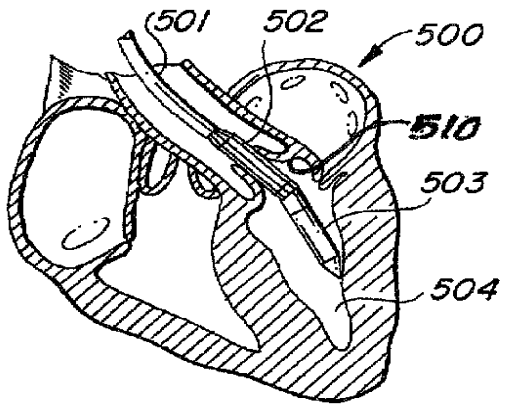


Fig. 20A

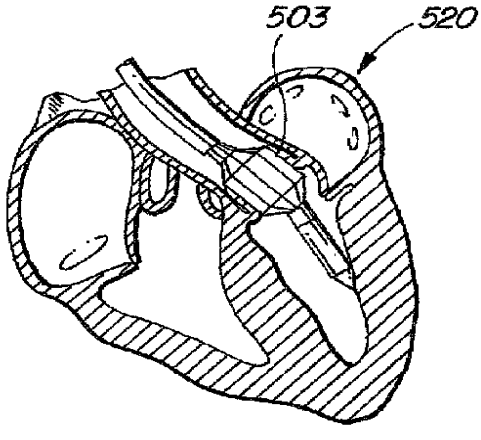


Fig. 20B

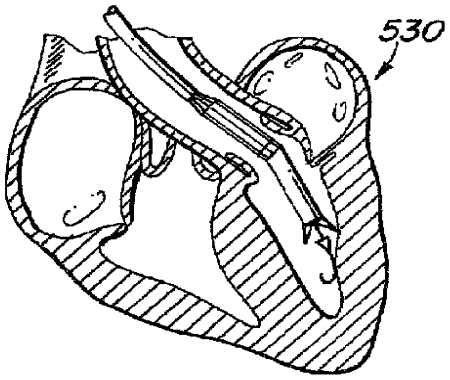


Fig. 20C

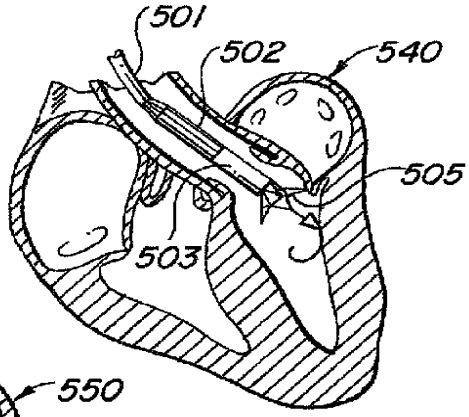


Fig. 20D

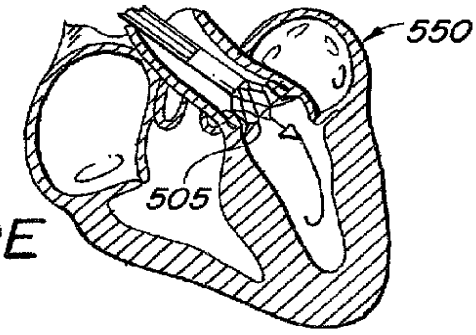


Fig. 20E

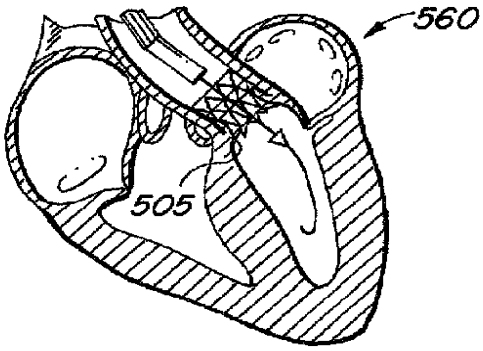


Fig. 20F

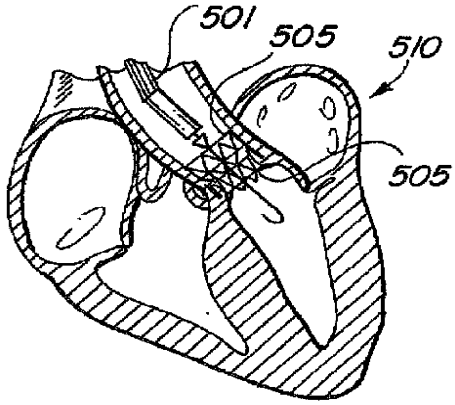


Fig. 20G

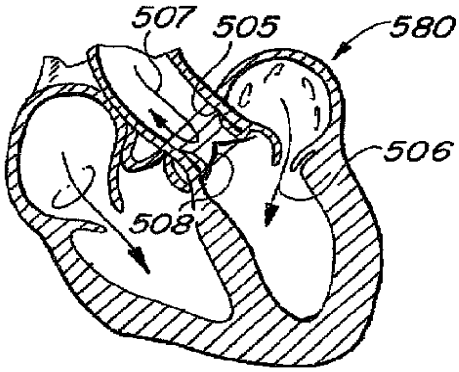


Fig. 20H

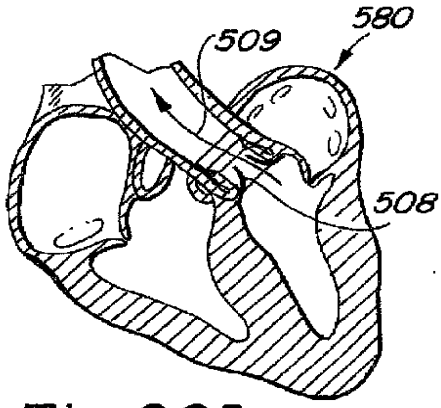


Fig. 20I

ENDOLUMINAL CARDIAC AND VENOUS VALVE PROSTHESES AND METHODS OF MANUFACTURE AND DELIVERY THEREOF

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application corresponds to and claims priority of pending U.S. utility patent application, Ser. No. 09/477,120, filed Dec. 31, 1999 and PCT International Application, Ser. No. PCT/US00/34591, filed Dec. 18, 2000.

BACKGROUND OF THE INVENTION

[0002] The present invention relates generally to implantable prosthetic cardiac and venous valves. More particularly, the present invention pertains to prosthetic cardiac and venous valve implants which are capable of being delivered using endovascular techniques and being implanted at an intracardiac or intravenous site without the need for anatomic valve removal. The prosthetic valves of the present invention are well-suited for cardiac delivery via a femoral or subclavian artery approach using a delivery catheter, and, depending upon the specific configuration selected, may be deployed within the heart to repair valve defects or disease or septal defects or disease. According to one embodiment of the invention, there is provided a chamber-to-vessel (CV) configuration which is particularly well-suited as an aortic valve prosthesis to facilitate blood flow from the left ventricle to the aorta. In a second embodiment, there is provided a prosthetic valve in a chamber-to-chamber (CC) configuration which is particularly well-adapted for mitral valve replacement or repair of septal defects. Finally, a third embodiment is provided in a vessel-to-vessel (VV) configuration, which is well suited for venous valve exclusion and replacement.

[0003] Common to each of the CV, CC and VV embodiments of the present invention are a stent support member, a graft member which covers at least a portion of either or both the lumenal and ablumenal surfaces of the stent, valve flaps which are formed either by biological xenograft valves, synthetic valves formed from either the same material or a different material as the graft member, the valve flaps being coupled to the stent in a manner which biases the valve flaps so they close upon a zero pressure differential across the valve region.

[0004] It is important for the present invention to provide orientational definitions. For purposes of the present invention, references to positional aspects of the present invention will be defined relative to the directional flow vector of blood flow through the implantable device. Thus, the term "proximal" is intended to mean on the inflow or upstream flow side of the device, while "distal" is intended to mean on the outflow or downstream flow side of the device. With respect to the catheter delivery system described herein, the term "proximal" is intended to mean toward the operator end of the catheter, while the term "distal" is intended to mean toward the terminal end or device-carrying end of the catheter.

SUMMARY OF PRIOR ART

[0005] The prior art discloses certain common device segments inherently required by a percutaneous prosthetic valve: an expandable stent segment, an anchoring segment and a flow-regulation segment.

[0006] Prior art percutaneous prosthetic valve devices include the Dobben valve, U.S. Pat. No. 4,994,077, the Vince valve, U.S. Pat. No. 5,163,953, the Teitelbaum valve, U.S. Pat. No. 5,332,402, the Stevens valve, U.S. Pat. No. 5,370,685, the Pavcnik valve, U.S. Pat. No. 5,397,351, the Taheri valve, U.S. Pat. No. 5,824,064, the Anderson valves, U.S. Pat. Nos. **5,411,552 & 5,840,081,** the Jayaraman valve, U.S. Pat. No. 5,855,597, the Besseler valve, U.S. Pat. No. 5,855,601, the Khosravi valve, U.S. Pat. No. 5,925,063, the Zadano-Azizi valve, U.S. Pat. No. 5,954,766, and the Leonhardt valve, U.S. Pat. No. 5,957,949. Each of these pre-existing stent valve designs has certain disadvantages which are resolved by the present invention.

[0007] The Dobben valve has a disk shaped flap threaded on a wire bent like a safety pin to engage the vessel wall and anchor the valve. A second embodiment uses a stent of a cylindrical or crown shape that is made by bending wire into a zigzag shape to anchor the device and attach the flow regulator flap. The device presents significant hemodynamic, delivery, fatigue and stability disadvantages.

[0008] The Vince valve has a stent comprised of a toroidal body formed of a flexible coil of wire and a flow-regulation mechanism consisting of a flap of biologic material. Numerous longitudinal extensions within the stent are provided as attachment posts to mount the flow-regulation mechanism. The device requires balloon expansion to deliver to the body orifice. The main shortcoming of this design is delivery profile. Specifically, the device and method put forth will require a 20+ French size catheter (approximately 9 French sizes to accommodate the balloon and 14+ French sizes to accommodate the compressed device) making the device clinically ineffective as a minimally invasive technique. Additionally, the device does not adequately address hemodynamic, stability and anchoring concerns.

[0009] The Teitelbaum valve is made of shape memory nitinol and consists of two components. The first component is stent-like and comprised of a meshwork or braiding of nitinol wire similar to that described by Wallsten, U.S. Pat. No. 4,655,771, with trumpet like distal a proximal flares. The purpose of the stent is to maintain a semi-ridged patent channel through the diseased cardiac valve after initial balloon dilation. The flared ends are intended to maintain the position of the stent component across the valve thereby anchoring the device. Embodiments for the flow-regulation mechanism include a sliding obturator and a caged ball both which are delivered secondary to the stent portion. The disadvantages of the device are the flow regulators reduce the effective valve orifice and generate sub-optimal hemodynamic characteristics; fatigue concerns arise from the separate nature of the stent and flow-regulation components; the high metal and exposed metal content raises thrombogenesis, valvular stenosis and chronic anticoagulation concerns; and the separate delivery requirements (although addressing the need for small delivery profile) in addition to any initial valvuloplasty performed increases the time, costs, risks, difficulty and trauma associated with the percutaneous procedure.

[0010] The Pavcnik valve is a self-expanding percutaneous device comprised of a poppet, a stent and a restraining element. The valve stent has barbed means to anchor to the

internal passageway. The device includes a self-expanding stent of a zigzag configuration in conjunction with a cage mechanism comprised of a multiplicity of crisscrossed wires and a valve seat. The disadvantages of the device include large delivery profile, reduced effective valvular orifice, possible perivalvular leakage, trauma-inducing turbulent flow generated by the cage occlusive apparatus and valve seat, thrombogenesis, valvular stenosis, chronic anticoagulation, problematic physiological and procedural concerns due to the barb anchors and complex delivery procedure that includes inflation of occlusive member after initial implantation.

[0011] Stevens discloses a percutaneous valve replacement system for the endovascular removal of a malfunctioning valve followed by replacement with a prosthetic valve. The valve replacement system may include a prosthetic valve device comprised of a stent and cusps for flow-regulation such as a fixed porcine aortic valve, a valve introducer, an intraluminal procedure device, a procedure device capsule and a tissue cutter. The devices disclosed indicate a long and complex procedure requiring large diameter catheters. The valve device disclosed will require a large delivery catheter and does not address the key mechanisms required of a functioning valve. Additionally, the device requires intraluminal-securing means such as suturing to anchor the device at the desired location.

[0012] The Taheri valve describes an aortic valve replacement combined with an aortic arch graft. The devices and percutaneous methods described require puncture of the chest cavity.

[0013] Anderson has disclosed various balloon expandable percutaneous prosthetic valves. The latest discloses a valve prosthesis comprised of a stent made from an expandable cylindrical structure made of several spaced apices and an elastically collapsible valve mounted to the stent with the commissural points of the valve mounted to the apices. The device is placed at the desired location by balloon expanding the stent and valve. The main disadvantage to this design is the 20+ French size delivery requirement. Other problems include anchoring stability, perivalvular leakage, difficult manufacture and suspect valve performance.

[0014] The Jayaraman valve includes a star-shaped stent and a replacement valve and/or replacement graft for use in repairing a damaged cardiac valve. The device is comprised of a chain of interconnected star-shaped stent segments in the center of which sits a replacement valve. The flow-regulation mechanism consists of three flaps cut into a flat piece of graft material that is rolled to form a conduit in which the three flaps may be folded inwardly in an overlapping manner. An additional flow-regulation mechanism is disclosed in which a patch (or multiple patches) is sutured to the outside of a conduit which is then pulled inside out or inverted such that the patch(s) reside on the fully inverted conduit. A balloon catheter is required to assist expansion during delivery. The disadvantages of this design include lack of sufficient anchoring mechanism; problematic interference concerns with adjacent tissues and anatomical structures; fatigue concerns associated with the multiplicity of segments, connections and sutures; lack of an adequately controlled and biased flow-regulation mechanism; uncertain effective valve orifice, difficult manufacture; balloon dilation requirement; complex, difficult and inaccurate delivery and large delivery profile.

[0015] The Besseler valve discloses methods and devices for the endovascular removal of a defective heart valve and the replacement with a percutaneous cardiac valve. The device is comprised of a self-expanding stent member with a flexible valve disposed within. The stent member is of a self-expanding cylindrical shape made from a closed wire in formed in a zigzag configuration that can be a single piece, stamped or extruded or formed by welding the free ends together. The flow-regulation mechanism is comprised of an arcuate portion which contains a slit (or slits) to form leaflets and a cuff portion which is sutured to and encloses the stent. The preferred flow regulator is a porcine pericardium with three cusps. An additional flow regulator is described in which the graft material that comprises the leaflets (no additional mechanisms for flow-regulation) extends to form the outer cuff portion and is attached to the stent portion with sutures. The anchoring segment is provided by a plurality of barbs carried by the stent (and therefor penetrating the cuff-graft segment). Delivery requires endoluminal removal of the natural valve because the barb anchors will malfunction if they are orthotopically secured to the native leaflets instead of the more rigid tissue at the native annulus or vessel wall. Delivery involves a catheter within which the device and a pusher rod are disposed. The disadvantages of the device are lack of a well defined and biased flow-regulation mechanism, anatomic valve removal is required thereby lengthening the procedure time, increasing difficulty and reducing clinical practicality, trauma-inducing barbs as described above and the device is unstable and prone to migration if barbs are omitted.

[0016] The Khosravi valve discloses a percutaneous prosthetic valve comprised of a coiled sheet stent similar to that described by Derbyshire, U.S. Pat. No. 5,007,926, to which a plurality of flaps are mounted on the interior surface to form a flow-regulation mechanism that may be comprised of a biocompatible material. The disadvantages of this design include problematic interactions between the stent and flaps in the delivery state, lack of clinical data on coiled stent performance, the lack of a detailed mechanism to ensure that the flaps will create a competent one-directional valve, lack of appropriate anchoring means, and the design requirements imposed by surrounding anatomical structures are ignored.

[0017] The Zadno-Azizi valve discloses a device in which flow-regulation is provided by a flap disposed within a frame structure capable of taking an insertion state and an expanded state. The preferred embodiment of the flow-regulation mechanism is defined by a longitudinal valve body made of a sufficiently resilient material with a slit(s) that extends longitudinally through the valve body. Increased sub-valvular pressure is said to cause the valve body to expand thereby opening the slit and allowing fluid flow there through. The valve body extends into the into the lumen of the body passage such that increased supra-valvular pressure will prevent the slit from opening thereby effecting one-directional flow. The device includes embedding the frame within the seal or graft material through injection molding, blow molding and insertion molding. The disadvantages of the device include the flow-regulation mechanism provides a small effective valve orifice, the turbidity caused by the multiple slit mechanisms, the large delivery profile required by the disclosed embodiments and the lack of acute anchoring means.

[0018] Finally, the Leonhardt valve is comprised of a tubular graft having radially compressible annular spring portions and a flow regulator, which is preferably a biological valve disposed within. In addition to oversizing the spring stent by 30%, anchoring means is provided by a light-activated biocompatible tissue adhesive is located on the outside of the tubular graft and seals to the living tissue. The stent section is comprised of a single piece of super-elastic wire formed into a zigzag shape and connected together by crimping tubes, adhesives or welds. A malleable thin-walled, biocompatible, flexible, expandable, woven fabric graft material is connected to the outside of the stent that is in turn connected to the biological flow regulator. Disadvantages of this device include those profile concerns associated with biological valves and unsupported graft-leaflet regulators, a large diameter complex delivery system and method which requires multiple anchoring balloons and the use of a light activated tissue adhesive in addition to any prior valvuloplasty performed, interference with surrounding anatomy and the questionable clinical utility and feasibility of the light actuated anchoring means.

SUMMARY OF THE INVENTION

[0019] With the shortcomings of the prior art devices, there remains a need for a clinically effective endoluminally deliverable prosthetic valve that is capable of orthotopic delivery, provides a mechanically defined, biased and hemodynamically sound flow-regulation mechanism, provides sufficient force to maintain a large acute effective valvular orifice dimension which expands to a known larger effective orifice dimension, compliant with adjacent dynamic anatomical structures, does not require valve removal, does not require chronic anticoagulation treatment, meets regulatory fatigue requirements for cardiac valve prostheses, provides a low-metal high-strength stent-annulus, is surgically explantable or endoluminally removable, in addition to being able to deploy multiple valves orthotopically, provides a delivery profile which does not exceed the 12 French size suitable for peripheral vascular endoluminal delivery, combines anatomic valve exclusion and prosthetic valve delivery via a single catheter delivery system and with short duration atraumatic procedure which is easy to complete and beneficial to very sick patients.

[0020] It is, therefore, a primary of the present invention to provide a prosthetic endoluminally-deliverable unidirectional valve. The invention has multiple configurations to treat malfunctioning anatomical valves including heart and venous valves. Prosthetic cardiac valve configurations include the chamber-to-vessel for orthotopic placement at the valvular junction between a heart chamber and a vessel, and the chamber-to-chamber for orthotopic placement at the valvular junction between two heart chambers or for septal defect repair where a septal occluding member is substituted for the flow regulator valve flaps. Prosthetic venous valve configurations include the vessel-to-vessel for orthotopic or non-orthotopic placement at a valvular junction within a vessel.

[0021] The invention consists generally of a stent body member, a graft, and valve flaps. The stent body member may be fashioned by laser cutting a hypotube or by weaving wires into a tubular structure, and is preferably made from shape memory or super-elastic materials, such as nickel-titanium alloys known as NITINOL, but may be made of balloon expandable stainless steel or other plastically deformable stent materials as are known in the art, such as titanium or tantalum, or may be self-expanding such as by weaving stainless steel wire into a stressed-tubular configuration in order to impart elastic strain to the wire. The graft is preferably a biocompatible, fatigue-resistant membrane which is capable of endothelialization, and is attached to the stent body member on at least portions of either or both the lumenal and ablumenal surfaces of the stent body member by suturing to or encapsulating stent struts. The valve leaflets are preferably formed by sections of the graft material attached to the stent body member.

[0022] The stent body member is shaped to include the following stent sections: proximal and distal anchors, a intermediate annular stent section, and at least one valve arm or blood flow regulator struts. The proximal and distal anchor sections are present at opposing ends of the prosthesis and subtend either an acute, right or obtuse angle with a central longitudinal axis that defines the cylindrical prosthesis. In either the CV or CC configurations, the proximal anchor is configured to assume approximately a right angle radiating outward from the central longitudinal axis of the prosthesis in a manner which provides an anchoring flange. When being delivered from a delivery catheter, the proximal anchor is deployed first and engages the native tissue and anatomical structures just proximal to the anatomic valve, such as the left ventricle wall in the case of retrograde orthotopic delivery at the aortic valve. Deployment of the proximal anchor permits the intermediate annular stent section to be deployed an reside within the native valve annular space and the ablumenal surface of the intermediate annular stent section to abut and outwardly radially compress the anatomic valve leaflets against the vascular wall. The distal anchor is then deployed and radially expands to contact the vascular wall and retain the prostbesis in position, thereby excluding the anatomic valve leaflets from the bloodflow and replacing them with the prosthetic valve leaflets.

[0023] Flow regulation in the inventive stent valve prosthesis is provided by the combination of the prostbetic valve leaflets and the valve arms and is biased closed in a manner similar manner to that described for a surgically implanted replacement heart valve by Boretos, U.S. Pat. No. 4,222,126. The valve regulator-struts are preferably configured to be positioned to radiate inward from the stent body member toward the central longitudinal axis of the prosthesis. The graft-leaflet bas the appearance of a partially-everted tube where the innermost layer, on the lumenal surface of the stent body member, forms the leaflets and the outer-most layer, on the ablumenal surface of the stent body member, forms a sealing graft which contacts and excludes the immobilized anatomical valve leaflets. The struts of the stent are encapsulated by the outer graft-membrane. The valve regulator-struts are encapsulated by the inner leaflet-membrane and serve to bias the valve to tbe closed position. The regulator-struts also prevent inversion or prolapse of the otherwise unsupported leaflet-membrane during increased supra-valvular pressure. The inner leaflet-membrane may also be attached to the outer graft-membrane at points equidistant from the valve strut-arms in a manner analogous to that described for a surgically implanted replacement heart valve by Cox, U.S. Pat. No. 5,824,063. The combination of the thin walled properties of the leaflet-membrane, the one-sided open lumen support of the intermediate annu-

lar stent section, the free ends of the valve leaflets, the biasing and support provided by the valve regulator-struts and the attachment points all work to provide a prosthetic valvular device capable of endoluminal delivery which simulates the hemodynamic properties of a healthy anatomical cardiac or venous valve.

BRIEF DESCRIPTION OF FIGURES

[0024] **FIG. 1** is a perspective view of the inventive valve stent chamber-to-vessel embodiment in its fully deployed state.

[0025] **FIG. 2** is a perspective view of the inventive valve stent chamber-to-vessel embodiment in its fully deployed state with the outermost graft layer and stent layer partially removed to show an embodiment of the valve apparatus.

[0026] **FIG. 3** is a top view of the inventive valve stent chamber-to-vessel embodiment in its fully deployed state.

[0027] **FIG. 4** shows the cross-sectional taken along line **4—4** of **FIG. 1**.

[0028] **FIG. 5** is a bottom view of the inventive valve stent chamber-to-vessel embodiment in its fully deployed state.

[0029] **FIG. 6A** illustrates a cross-sectional view of a human heart during systole with the inventive valve stent chamber-to-vessel embodiment implanted in the aortic valve and illustrating a blood flow vector of an ejection fraction leaving the left ventricle and passing through the inventive valve stent.

[0030] **FIG. 6B** illustrates a cross-sectional view of a human heart during diastole with the inventive valve stent chamber-to-vessel embodiment implanted in the aortic valve and illustrating a blood flow vector of blood passing from the left atrium, through the mitral valve and into the left ventricle during and a retrograde blood flow vector blocked by the inventive valve stent in the aorta.

[0031] **FIG. 7** is a perspective view of the inventive valve stent chamber-to-chamber embodiment in its fully deployed state.

[0032] **FIG. 8** is a is a perspective view of the inventive valve stent chamber-to-chamber embodiment in its fully deployed state with the outermost graft layer and stent layer partially removed to show an embodiment of the valve apparatus.

[0033] **FIG. 9** is a top view of the inventive valve stent chamber-to-chamber embodiment in its fully deployed state.

[0034] **FIG. 10** shows the cross sectional view taken along line **10—10** of **FIG. 7**.

[0035] **FIG. 11** is a bottom view of inventive valve stent chamber-to-chamber embodiment in its fully deployed state.

[0036] **FIG. 12A** illustrates a cross-sectional view of a human heart during atrial systole with the inventive valve stent chamber-to-chamber embodiment implanted at the site of the mitral valve and illustrating a blood flow vector of a filling fraction leaving the left atrium and entering the left ventricle.

[0037] **FIG. 12B** illustrates a cross-sectional view of a human heart during atrial diastole with the inventive valve stent chamber-to-chamber embodiment implanted at the site of the mitral valve and illustrating a blood flow vector of an ejection fraction from the left ventricle to the aorta and the back pressure against the implanted mitral valve prosthesis.

[0038] **FIG. 13** is a perspective view of the chamber-to-vessel configuration in the fully deployed state.

[0039] **FIG. 14** is a perspective view of the same configuration in the fully deployed state with the outermost graft layer and stent layer partially removed to show an embodiment of the valve apparatus.

[0040] **FIG. 15** is a top view of the same configuration.

[0041] **FIG. 16** shows the cross sectional view of the same configuration for the deployed state.

[0042] **FIG. 17** is a bottom view of the same configuration.

[0043] **FIG. 18A and 18B** show cross-sectional views of a vein and venous valve illustrating the inventive prosthetic venous valve in the open and closed state.

[0044] FIGS. **19** is a cross-sectional diagrammatic view of a valvuloplasty and stent valve delivery catheter in accordance with the present invention.

[0045] **FIG. 20A-20I** are diagrammatic cross-sectional views illustrating single catheter valvuloplasty, inventive stent valve delivery and stent valve operation in situ in accordance with the method of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0046] The present invention consists generally of three preferred embodiments, each embodiment corresponding to a prosthetic stent valve configuration adapted for either heart chamber to blood vessel communication, chamber to chamber communication or vessel to vessel, or intravascular configuration. Certain elements are common to each of the preferred embodiments of the invention, specifically, each embodiment includes a stent body member which defines a central annular opening along the longitudinal axis of the stent body member, a graft member which covers at least a portion of the stent body member along either the lumenal or ablumenal surfaces of the stent body member, at least one biasing arm is provided and projects from the stent body member and into the central annular opening of the stent body member, and at least one valve flap member which is coupled to each biasing arm such that the biasing arm biases the valve flap member to occlude the central annular opening of the stent body member under conditions of a zero pressure differential across the prosthesis. The stent body member is preferably made of a shape memory material or superelastic material, such as NITINOL, but also be fabricated from either plastically deformable materials or spring-elastic materials such as is well known in the art. Additionally, the stent body member has three main operable sections, a proximal anchor section, a distal anchor section and an intermediate annular section which is intermediate the proximal and distal anchor sections. Depending upon the specific inventive embodiment, the distal and proximal anchor sections may be either a diametrically enlarged section or may be a flanged section. The intermediate annular section defines a valve exclusion region and primary blood flow channel of the inventive valve stent. The intermediate annular section defines a lumenal opening through

which blood flow is established. The transverse cross-section of the lumenal opening may be circular, elliptical, ovular, triangular or quadralinear, depending upon the specific application for which the valve stent is being employed. Thus, for example, where a tricuspid valve is particularly stenosed, it may be preferable to employ a valve stent with a lumenal opening in the intermediate annular section which has a triangular transverse cross-sectional dimension.

[0047] Chamber-to-Vessel Configuration

[0048] An implantable prosthesis or prosthetic valve in accordance with certain embodiments of the chamber-to-vessel CV configuration of the present invention is illustrated generally in FIGS. **1-5**. The chamber-to-vessel valve stent **10** consists of an expandable stent body member **12** and graft member **11**. The stent body member **12** is preferably made from a shape memory and/or superelastic NITINOL material, or thermomechanically similar materials, but may be made of plastically deformable or elastically compliant materials such as stainless steel, titanium or tantalum. The graft member **11** is preferably made of biologically-derived membranes or biocompatible synthetic materials such as DACRON or expanded polytetrafluoroethylene. The stent body member **12** is configured to have three functional sections: a proximal anchor flange **22**, an intermediate annular section **20** and a distal anchor section **16**. The stent body member **12**, as with conventional stents is formed of a plurality of stent struts **13** which define interstices **14** between adjacent stent struts **13**. The stent body member preferably also includes a transitional section **18** which interconnects the intermediate annular section **20** and the distal anchor section **16**, which together define a valve exclusion region of the inventive stent valve **10** to exclude the anatomic valve after implantation. The proximal anchor flange **22**, the intermediate annular section **20** and the distal anchor section **16** are each formed during the formation of the stent body member and are formed from the same material as the stent body member and comprise stent struts **13** and intervening interstices **14** between adjacent pairs of stent struts **13**. The anchor flange **22**, for example, consists of a plurality of stent struts and a plurality of stent interstices, which project radially outwardly away from the central longitudinal axis of the stent body member. Thus, the different sections of the stent body member **12** are defined by the positional orientation of the stent struts and interstices relative to the central longitudinal axis of the stent body member **12**.

[0049] With reference to **FIG. 2**, there is shown in greater detail the valve body **26** and valve arms or flow regulator struts **24** coupled to the stent body member **12**. The valve body **26** subtends the central annular opening of the stent valve **10** and is illustrated in its closed position. In accordance with one embodiment of the present invention, the graft member **11** consists of an outer or ablumenal graft member **11***a* and an inner or lumenal graft member **11***b*. The outer graft member **11***a* encloses at least a portion of the ablumenal surface of the intermediate annular section **20** of the stent body member, while the inner graft member **11***b* is coupled, on the lumenal surface of the intermediate annular section **20** of the stent body member **12**, to the outer graft member **11***a* through the interstices **14** of the stent body member. The valve body **26** is formed by everting the inner graft member **11***b* toward the central longitudinal axis of the stent body member **12** such that free ends or valve flap portions **28** of the inner graft member **11***b* are oriented toward the distal anchor section **16** of the stent body member **12** and a pocket or envelope **27** is formed at the eversion point of the inner graft member **11***b* adjacent the junction between the intermediate annular section **20** and the proximal anchor flange **22** of the stent body member **12**. Alternatively, portions of the outer graft member **11***a* may be passed through to the lumenal surface of the stent body member **12**, thereby becoming the inner graft member **11***b* and everted to form the valve body **26**.

[0050] Valve arms or regulator struts **24** are coupled or formed integral with the stent body member **12** and are positioned adjacent the junction point between intermediate annular section and the proximal anchor flange **22** of the stent body member **12**. The valve arms **24** are oriented radially inward toward the central longitudinal axis of the stent body member **12** when in their zero strain state. The valve arms **24** are attached or coupled to the valve flap portions **28** of the inner graft member leaflets to bias the valve flap portions **28** to the closed position when under zero pressure differential across the stent valve **10**.

[0051] The zero strain position of the valve arms **24** is radially inward and orthogonal to the central longitudinal axis of the stent valve **10**. Valve arms **24** have a length which is preferably longer than the radius of the lumenal diameter of the stent valve **10**, and they extent distally into the lumen of the stent valve **10** such that, in conjunction with the action of the valve leaflets **28**, the valve arms **24** are prevented from achieving their zero strain configuration thereby biasing the valve closed. As shown in **FIG. 4**, the valve arms **24** force the valve leaflets **28** to collapse into the center of the lumen of the stent valve **10**, thus biasing the valve to its closed position.

[0052] It is preferable to couple sections of the valve flaps **28**, along a longitudinal seam **29**, to the inner graft member **11***b* and the outer graft member **11***a* at points equidistant from the valve arms **24** in order to impart a more cusp-like structure to the valve flaps **28**. It should be appreciated, that the graft member **11** should cover at least a portion of the ablumenal surface of the stent body member **12** in order to exclude the anatomic valves, but may also cover portions or all of the stent valve member **12**, including the distal anchor section **16**, the intermediate annular section **20**, the transition section **18** and/or the proximal anchor flange **22**, on either or both of the lumenal and ablumenal surfaces of the stent body member.

[0053] In accordance with a particularly preferred embodiment of the CV valve stent **10**, the proximal anchor flange **22**, which consists of a plurality of stent struts and stent interstices which project radially outward away from the central longitudinal axis of the valve stent **10**, is configured to have one or more stent struts eliminated from the proximal anchor flange **22** to define an open region which is positioned in such a manner as to prevent the CV valve stent **10** from interfering with or impinging upon an adjacent anatomic structure. For example, where the CV valve stent **10** is to be an aortic valve prosthesis, it is known that the mitral valve is immediately adjacent the aortic valve, and the mitral valve flaps deflect toward the left ventricle. Thus, placing the CV valve stent **10** such that the proximal anchor flange **22** is adjacent the mitral valve might, depending upon the particular patient anatomy, interfere with normal open-

ing of the mitral valve flaps. By eliminating one or more of the stent struts in the proximal anchor flange **22**, an opening is created which permits the mitral valve flaps to deflect ventricularly without impinging upon the proximal anchor flange **22** of the CV valve stent **10**.

[0054] Similarly, the stent struts of the CV valve stent **10** may be oriented in such a manner as to create interstices of greater or smaller area between adjacent struts, to accommodate a particular patient anatomy. For example, where the stent struts in the distal anchor section **16** would overly an artery branching from the aorta, such as tbe coronary ostreum arteries, it may be desirable to either eliminate certain stent struts, or to configure certain stent struts to define a greater interstitial area to accommodate greater blood flow into the coronary ostreum.

[0055] In the case of providing an oriented opening in the proximal anchor flange, or an oriented opening in the interstitial spaces of the distal anchor, it is desirable to provide radiopaque markers on the stent body member **12** to permit the CV valve stent to be oriented correctly relative to the anatomic structures.

[0056] **F1GS. 6A and 6B** illustrate the inventive CV stent valve **10** implanted in the position of the aortic valve and excluding the anatomic aortic valve AV. **FIG. 6A** illustrates the heart during systole in which a positive pressure is applied to the prosthetic aortic valve by contraction of the left ventricle LV and the ejection fraction represented by the arrow. The systolic pressure overcomes the bias exerted by the valve arms **24** and causes the valve leaflets **26** to open and release the ejection fraction into the aorta. **F1G. 6B** illustrates that the presence of a negative pressure head across the stent valve **10**, i.e. such as that during diastole, causes the biased valve leaflets **26** which are already closed, to further close, and prevent regurgitation from the aorta into the left ventricle.

[0057] Chamber-to-Chamber Configuration

[0058] FIGS. **7-11** illustrate the inventive stent valve in the chamber-to-chamber (CC) configuration **40**. The CC valve stent **40** is constructed in a manner which is virtually identical to that of the CV valve stent **10** described above, except that the distal anchor section **16** of the CV valve stent **10** is not present in the CC valve stent **40**, but is substituted by a distal anchor flange **42** in the CC stent valve. Thus, like the CV valve stent **10**, described above, the CC valve stent **40** if formed of a stent body member **12** and a graft member **11**, with the graft member having lumenal **11***b* and ablumenal **11***a* portions which cover at least portions of the lumenal and ablumenal surfaces of the stent body member **12**, respectively. The CC valve stent **40** has both a proximal anchor flange **44** and a distal anchor flange **42** which are formed of sections of the stent body member **12** which project radially outward away from tbe central longitudinal axis of the CC valve stent **40** at opposing ends of the stent body member **12**.

[0059] Like the CV valve stent **10**, the lumenal graft portion **11***b* is everted inwardly toward the central longitudinal axis of the valve stent **40** and free ends **28** of the lumenal graft portion **11***b* to form valve flaps **26** which project distally toward distal anchor flange **42**. Flow regulation struts **24** are coupled to or integral with the proximal anchor flange **44** and intermediate annular section **20** and project radially inward toward the central longitudinal axis of the CC valve stent **40**. The valve flaps **26** are coupled to the flow regulation struts **24** and the flow regulation struts **24** bias the valve flaps **26** to a closed position under a zero strain load.

[0060] Like with the CV stent valve **10**, it is preferable to couple sections of the valve flaps **28**, along a longitudinal seam **29**, to the inner graft member **11***b* and the outer graft member **11***a* at points equidistant from the valve arms **24** in order to impart a more cusp-like structure to the valve flaps **28**.

[0061] Turning to **F1GS. 12A and B** there is illustrated the inventive CC stent valve **40** implanted in the position of the mitral valve and excluding the anatomic mitral valve MV. **F1G. 12A** illustrates the heart during atrial systole in whicb a positive pressure is applied to the prosthetic mitral valve by contraction of the left atrium LA and the pressure exerted by the blood flow represented by the arrow. The atrial systolic pressure overcomes the bias exerted by the valve arms **24** onto the valve leaflets **26**, and causes the valve leaflets **26** to open and release the atrial ejection fraction into the left ventricle. **F1G. 12B** illustrates that the presence of a negative pressure head across the stent valve **40**, i.e. such as that during atrial diastole, causes the biased valve leaflets **26** which are already closed, to further close, and prevent backflow from the left ventricle into the left atrium.

[0062] In accordance with another preferred embodiment of the invention, the CC configuration may be adapted for use in repairing septal defects. By simply substituting a membrane for the valve leaflets **26**, the lumen of the stent body member **12** is occluded. The CC stent valve **40** may be delivered endoluminally and placed into a position to subtend a septal defect and deployed to occlude the septal defect.

[0063] Vessel-to-Vessel Configuration

[0064] Turning now to FIGS. **13-17**, there is illustrated the inventive stent valve in its vessel-to-vessel (VV) valve stent configuration **50**. The VV valve stent **50** is constructed in a manner which is virtually identical to that of the CV valve stent **10** described above, except that the proximal anchor flange **22** of the CV valve stent **10** is not present in the VV valve stent **50**, but is substituted by a proximal anchor section **52** in the VV stent valve. Thus, like the CV valve stent **10**, described above, the VV valve stent **50** is formed of a stent body member **12** and a graft member **11**, with the graft member having lumenal **11***b* and ablumenal **11***a* portions which cover at least portions of the lumenal and ablumenal surfaces of the stent body member **12**, respectively. The VV valve stent **50** has both a proximal anchor section **52** and a distal anchor section **54** which are formed of sections of the stent body member **12** which are diametrically greater than tbe intermediate annular section **20** of the VV valve stent **50**. Transition sections **56** and **58** taper outwardly away from the central longitudinal axis of the VV valve stent **50** and interconnect the intermediate annular section **20** to each of the distal anchor section **54** and the proximal anchor section **52**, respectively.

[0065] Like the CV valve stent **10**, in the VV valve stent **50**, the graft member **11**, particularly the lumenal graft portion **11***b* or the ablumenal graft portion **11***a*, or both, is everted inwardly toward the central longitudinal axis of the

valve stent **40** and free ends **28** of the lumenal graft portion **11***b* to form valve flaps **26** which project distally toward distal anchor flange **42**. Flow regulation struts **24** are coupled to or integral with the stent body member at the proximal transition section **58** and project radially inward toward the central longitudinal axis of the VV valve stent **50**. The valve flaps **26** are coupled to the flow regulation struts **24** and the flow regulation struts **24** bias the valve flaps **26** to a closed position under a zero strain load. Like with the CV stent valve **10** and the CC stent valve **40**, it is preferable to couple sections of the valve flaps **28**, along a longitudinal seam **29**, to the inner graft member **11***b* and the outer graft member **11***a* at points equidistant from the valve arms **24** in order to impart a more cusp-like structure to the valve flaps **28**.

[0066] Turning to **FIGS. 18A and B** there is illustrated the inventive VV stent valve **50** implanted in the position of a venous valve and excluding the anatomic venous valve flaps VE. **FIG. 18A** illustrates the vein under systolic blood pressure in which a positive pressure is applied to the prosthetic venous valve and the pressure exerted by the blood flow represented by the arrow. The systolic pressure overcomes the bias exerted by the valve arms **24** onto the valve leaflets **26**, and causes the valve leaflets **26** to open and permit blood flow through the prosthesis. **FIG. 18B** illustrates that the presence of a negative pressure head across the VV stent valve **50**, i.e. such as which exists at physiological diastolic pressures, causes the biased valve leaflets **26** which are already closed, to further close, and prevent backflow from the left ventricle into the left atrium.

[0067] The purpose of the proximal **54** and distal **52** anchor sections of the stent body member **12** is to anchor the prosthesis at the anatomic vessel-vessel junction, such as a venous valve, while causing minimal interference with adjacent tissue. The intermediate annular section **20** of the VV stent valve **50** excludes diseased anatomic leaflets and surrounding tissue from the flow field. The flare angle of the transition sections **56, 58** between the intermediate annular section **20** and each of the proximal and distal anchor sections **54, 52**, respectively, may be an acute angle, a right angle or an obtuse angle, depending upon the anatomical physiological requirements of the implantation site. Alternatively, the transition sections **56, 58** may be coplanar with the proximal and distal anchor section **52, 54**, respectively, thereby, eliminating any transition flare angle, depending upon the anatomical and physiological requirements of the delivery site.

[0068] Single Catheter Valvuloplasty Stent Valve Delivery System and Method of Delivery

[0069] In accordance with the present invention, there is also provide a single catheter valvuloplasty and valve stent delivery system **200** illustrated in **FIG. 19**. The objective of the single catheter delivery system **200** is to permit the surgeon or interventionalist to percutaneously deliver and deploy the inventive valve stent **10, 40** or **50** at the desired anatomical site and to perform valvuloplasty with a single catheter. In accordance with the preferred embodiment of the single catheter delivery system **200** of the present invention, there is provided a catheter body **210** having dual lumens **212, 216**. A first lumen **212** is provided as a guidewire lumen and is defined by a guidewire shaft **222** which traverses the length of the catheter body **210**. A second lumen is an inflation lumen **216** for communicating an inflation fluid, such as saline, from an external source, through an inflation port **240** at the operator end of the catheter **210**, to an inflatable balloon **214** located at or near the distal end of the catheter body **210**. The inflation lumen **216** is defined by an annular space between the lumenal surface of the catheter body **210** and the ablumenal surface of the guidewire shaft **222**. A capture sheath **217** is provided at the distal end **215** of the catheter body **210** and is positioned adjacent and distal the balloon **214**. The capture sheath **217** defines an annular space about the guidewire lumen **212** and the capture sheath **217** into which the stent valve **10, 40** or **50** is positioned and retained during delivery. An annular plug member **220** is within the inflation lumen **216** distal the balloon **214** and terminates the inflation lumen **216** in a fluid tight manner. Annular plug member **220** has a central annular opening **221** through which the guidewire shaft **222** passes. The annular plug member **220** is coupled to the guidewire shaft **222** and is moveable axially along the central longitudinal axis of the catheter **200** by moving the guidewire shaft **222**. The annular plug member **220** also serves to abut the stent valve **10, 40** and **50** when the stent valve **10, 40** and **50** is positioned within the capture sheath **217**. The guidewire shaft **222** passes through the capture sheath **217** and terminates with an atraumatic tip **218** which facilitates endoluminal delivery without injuring the native tissue encountered during delivery. With this configuration, the stent valve is exposed by proximally withdrawing the catheter body **210**, while the guidewire shaft **222** is maintained in a fixed position, such that the annular plug member **220** retains the position of the stent valve as it is uncovered by capture sheath **217** as the capture sheath **217** is being proximally withdrawn with the catheter body **210**.

[0070] In many cases the anatomic valve will be significantly stenosed, and the valve flaps of the anatomic valve will be significantly non-compliant. The stenosed valves may be incapable of complete closure permitting blood regurgitation across the anatomic valve. Thus, it may be desirable to configure the inflatable balloon **214** to assume an inflation profile which is modeled to maximally engage and dilatate the anatomic valves. For example, a tricuspid valve, such as the aortic valve may stenose to an opening which has a generally triangular configuration. In order to maximally dilatate this triangular opening, it may be desirable to employ a balloon profile which assumes a triangular inflation profile. Alternatively, it may be advantageous to configure the balloon such that it does not fully occlude the anatomic lumen when inflated, but permits a quantum of blood flow to pass around the balloon in its inflated state. This may be accomplished by providing channels or ridges on the ablumenal surface of the balloon. Additionally, irregular inflation profiles of the balloon may facilitate continuous blood flow about the inflated balloon. Furthermore, it may be desirable to configure the balloon to have an hour-glass inflation profile to prevent migration or slippage of the balloon in the anatomic valve during valvuloplasty.

[0071] In accordance with the present invention, it is preferable that the capture sheath **217** be made of a material which is sufficiently strong so as prevent the stent valve **10, 40, 50** from impinging upon and seating into the capture sheath **217** due to the expansive pressure exerted by the stent valve **10, 40, 50** against the capture sheath. Alternatively, the capture sheath **217** may be lined with a lubricious material, such as polytetrafluoroethylene, which will prevent the capture sheath **217** from exerting drag or frictional forces against the stent valve during deployment of the stent valve.

[0072] In accordance with the present invention, it is also contemplated that the position of the balloon **214** and the capture sheath **217** may be reversed, such that the balloon

214 is distal the capture sheath **217**. In this configuration, the anatomic valve may be radially enlarged by dilatating the balloon **214**, then the catheter moved distally to position the capture sheath **217** at the anatomic valve and deployed in the manner described above. This would also allow for post-deployment balloon expansion of the deployed stent valve without the need to traverse the prosthetic valve in a retrograde fashion. Alternatively, the catheter **200** of the present invention may be provided without a balloon **214** in those cases where valvuloplasty is not required, e.g., where a stenotic valve does not need to be opened such as with a regurgitating valve, and the catheter **200** is terminated at its distal end with only a capture sheath **217**, and deployment occurs as described above.

[0073] Turning now to FIGS. **20A-20I** there is illustrated the sequence of steps in delivery of the stent valve of the present invention, valvuloplasty of the aortic valve and deployment of the stent valve at the position of the aortic valve. The single catheter delivery system **501** having a distal balloon **502** and a capture sheath **503** covering the valve stent **10** (not shown in FIGS. **20A-B**), is delivered percutaneously either through a femoral or subclavian artery approach, and traverses the aorta and is passed through the aortic valve **510** such that the balloon **503** on the distal end of catheter **501** is adjacent the aortic valve **510** and the capture sheath **503** is within the left ventricle **504**. A valvuloplasty step **520** is performed by inflating balloon **503** to dilate the aortic valve and deform the aortic valve flaps against the aorta wall adjacent the aortic valve. After the valvuloplasty step **520**, delivery of the valve stent **505** is initiated by stabilizing the guidewire shaft (not shown) while the catheter body is withdrawn antegrade relative to the blood flow until the proximal anchor flange section of the valve stent **505** is exposed by the withdrawal of the capture sheath **503**. The distal anchor flange of the valve stent **505** is then positioned at the junction between the aortic valve and the left ventricle at step **540**, such that the distal anchor flange engages the ventricular surface of the aortic valve. The valve stent is fully deployed at step **550** by retrograde withdrawal of the catheter body **501** which continues to uncover the intermediate annular section of the valve stent and release the aortic valve stent **505**. at the aortic valve site **510**. In step **560**, the valve stent **505** is completely deployed from the catheter **501** and the capture sheath **503**. The distal anchor section of the valve stent **505** expands and contacts the lumenal wall of the aorta, immediately distal the aortic valve, thereby excluding the aortic valve flaps from the lumen of the prosthetic aortic valve stent **505**. In step **570**, the atraumatic tip and guidewire are retracted by retrograde movement of the guidewire shaft of the catheter, and the catheter **501** is withdrawn from the patient. **FIGS. 20H and 201** depict the implanted valve stent **505** during diastole and systole, respectively. During ventricular diastole **580**, the left ventricle expands to draw blood flow **506** from the left atrium into the left ventricle. A resultant negative pressure gradient is exerted across the valve stent **505**, and the valve arms and valve flaps **506** of the valve stent **505** are biased to the closed position to prevent a regurgitation flow **507** from passing through the valve stent **505** and into the left ventricle **504**. During ventricular systole **590**, the left ventricle contracts and exerts a positive pressure across the valve stent **505**, which overcomes the bias of the valve arms and valve flaps, which open **508** against the lumenal wall of the intermediate annular section of the valve stent and permit the ejection fraction **509** to be ejected from the left ventricle and into the aorta.

[0074] The method for delivery of the CC valve stent **40** or the VV valve stent **50** is identical to that of the CV stent **10** depicted in FIGS. **20A-20I**, except that the anatomical location where delivery and deployment of the valve stent occurs is, of course, different.

[0075] Thus, while the present invention, including the different embodiments of the valve stent, the delivery and deployment method and the single catheter valvuloplasty and delivery system, have been described with reference to their preferred embodiments, those of ordinary skill in the art will understand and appreciate that the present invention is limited in scope only by the claims appended hereto.

What is claimed is:

1. A catheter, comprising:

a. a catheter body defining a central longitudinal lumen;

b. an inflatable balloon positioned proximate the distal end of the catheter body and in fluid flow communication with the central longitudinal lumen;

c. a sheath positioned proximate the distal end of the catheter, distal the inflatable balloon and fixedly coupled to the catheter body and distally extensible therefrom;

d. a guidewire shaft positioned co-axially within the central longitudinal lumen of the catheter body and passing through an entire longitudinal length of the catheter body; and

e. an annular plug member concentrically coupled to the guidewire shaft and positioned distal the inflatable balloon and proximal the sheath, the annular plug member terminating the central longitudinal lumen of the catheter body in a fluid tight manner and being moveable therein.

2. The catheter of claim 1, further comprising a valve stent member, in a reduced diametric state, positioned within the sheath and concentrically about the guidewire shaft and distal the annular plug member.

3. A method of endoluminally delivering a valve stent within an anatomic passageway, comprising the steps of:

a. percutaneously passing a catheter endoluminally through an anatomic passageway to a valved anatomic situs within a body;

b. dilatating an inflatable balloon section of the catheter to dilatate anatomic valves at the anatomic situs within the body;

c. withdrawing the catheter from the dilatated valves at the anatomic situs and positioning a proximal end of a valve stent residing on the catheter;

d. positionally stabilizing the proximal end of the valve stent within the anatomic situs and withdrawing the catheter, inflatable balloon and sheath in a retrograde fashion thereby deploying the valve stent within the anatomic situs.

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US006712842B1

(12) **United States Patent**
Gifford, III et al.

(10) **Patent No.: US 6,712,842 B1**
(45) **Date of Patent: *Mar. 30, 2004**

(54) **METHODS AND DEVICES FOR LINING A BLOOD VESSEL AND OPENING A NARROWED REGION OF A BLOOD VESSEL**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/522,316**

(22) Filed: **Mar. 9, 2000**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/416,309, filed on Oct. 12, 1999.

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/1.13**; 623/1.23
(58) **Field of Search** 623/1.13, 1.23, 623/1.36, 1.2; 604/506–509, 96.01; 606/108, 151–158, 198, 194

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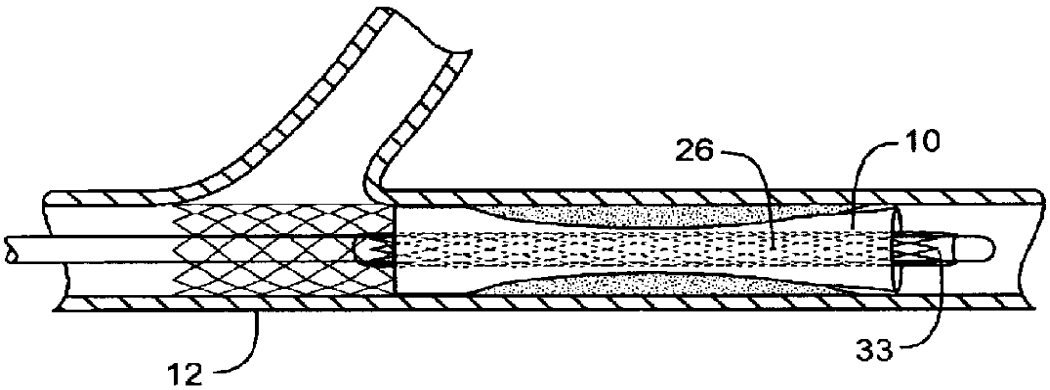
Assistant Examiner—Jason R Baxter
(74) *Attorney, Agent, or Firm*—Jens E. Hoekendijk; Hoekendijk & Lynch, LLP

(57) **ABSTRACT**

A liner is advanced through a narrowed region in a vessel such as the internal carotid artery. The liner is advanced through the narrowed region in a collapsed position. A stent is then advanced through the liner and expanded to open the narrowed region. The liner may also have an anchor which expands an end of the liner before the stent is introduced.

88 Claims, 36 Drawing Sheets



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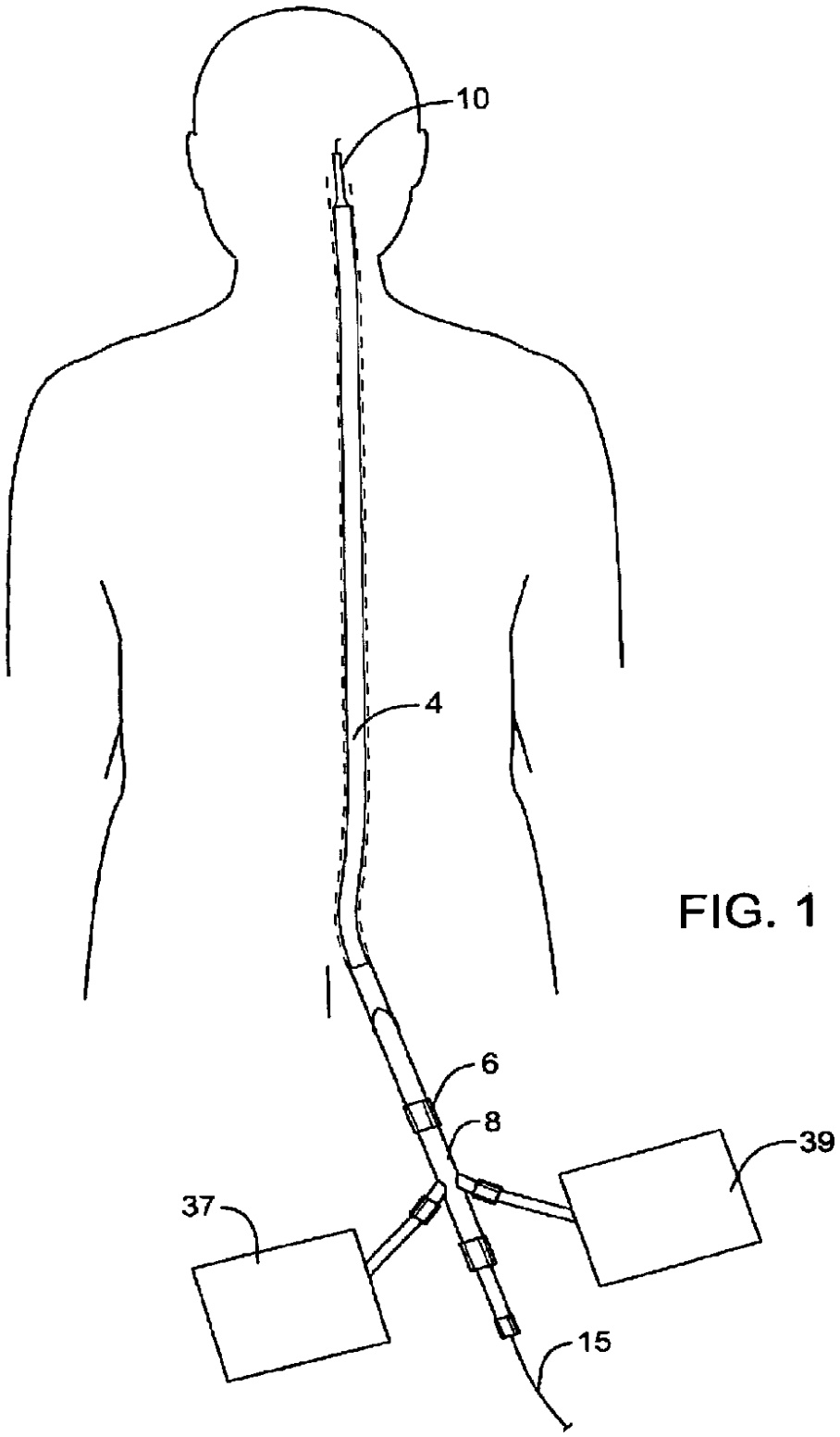


FIG. 1

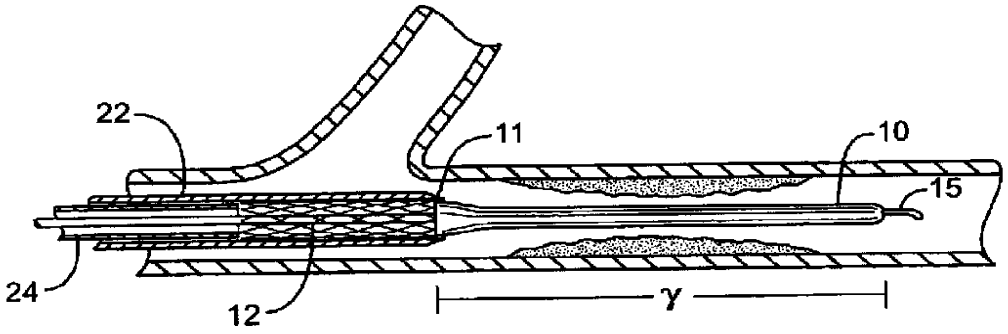


FIG. 2

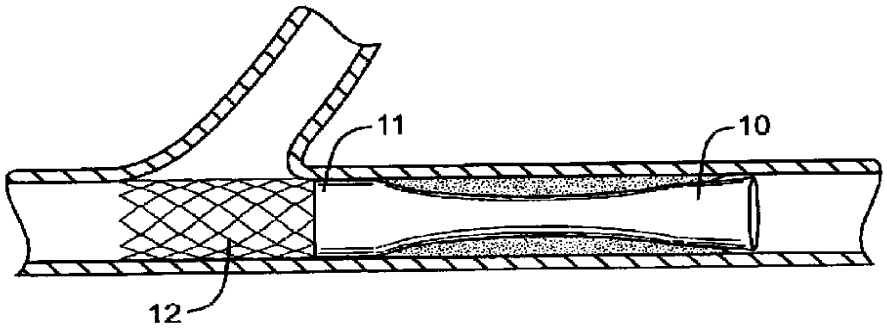


FIG. 3

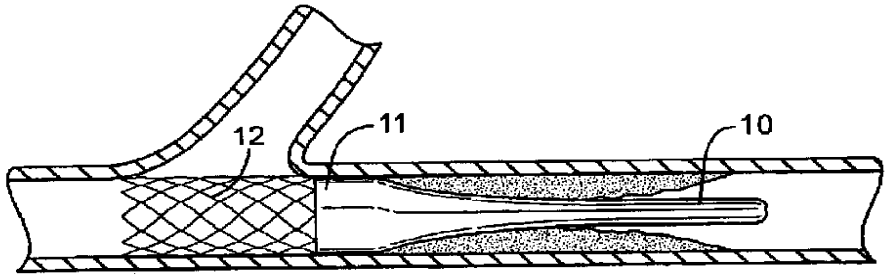


FIG. 4

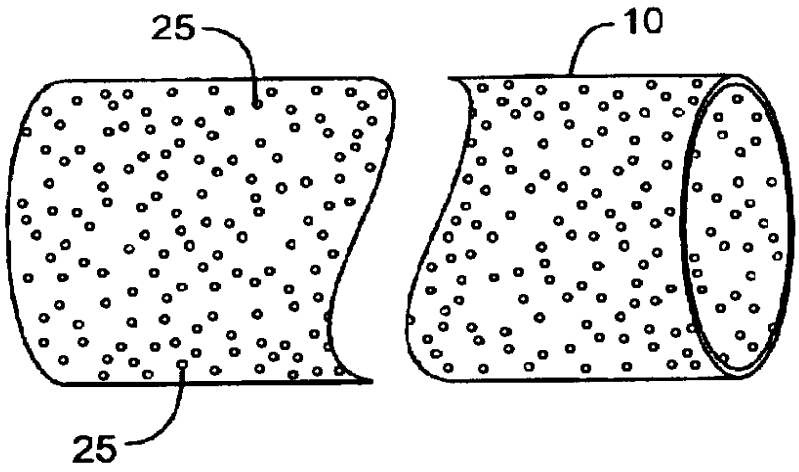
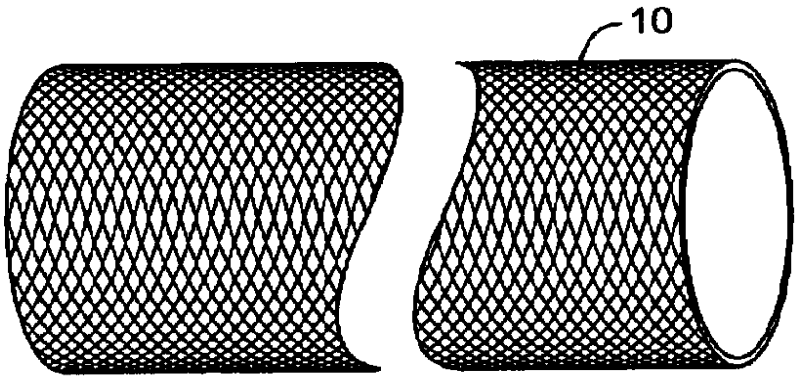


FIG. 6A



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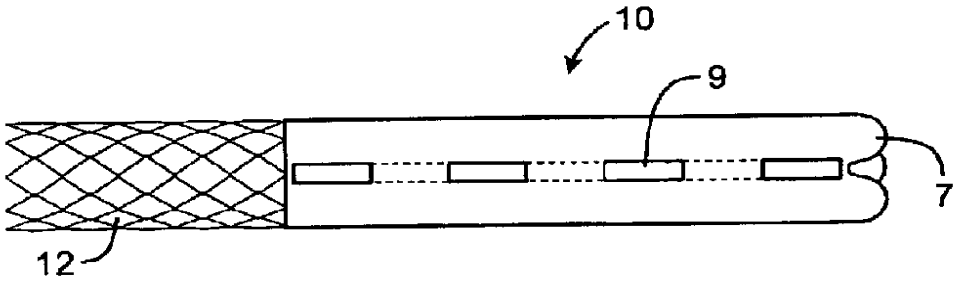
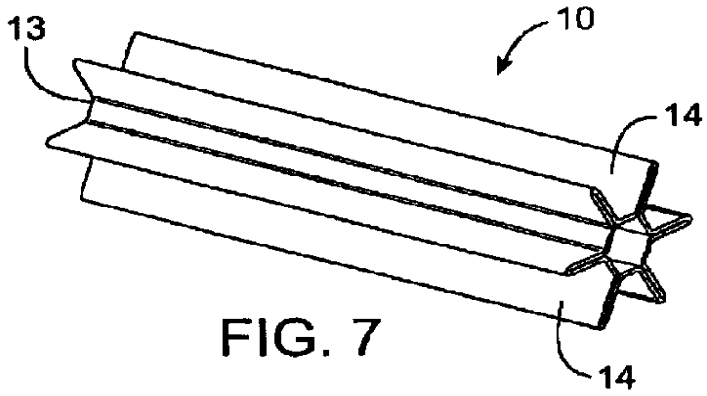


FIG. 6B



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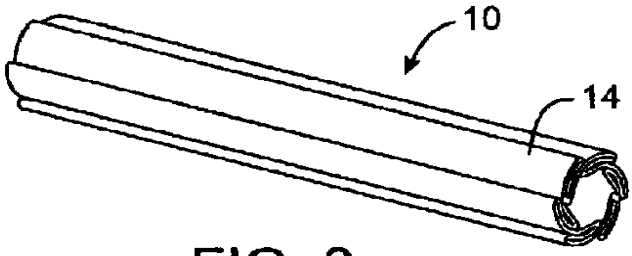

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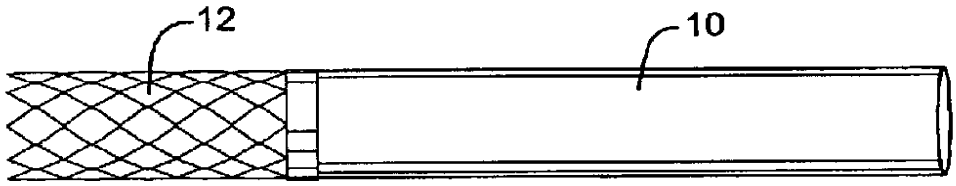

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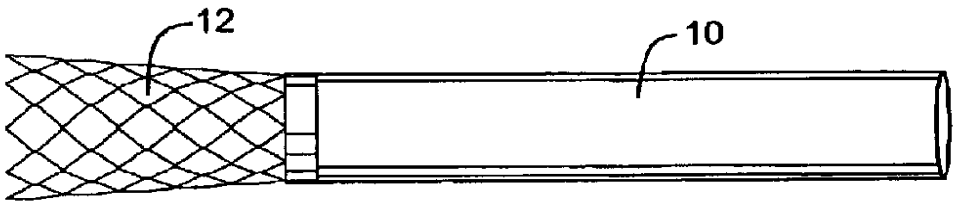
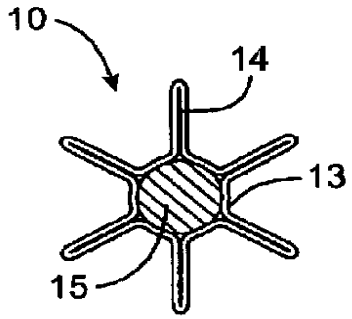


FIG. 20



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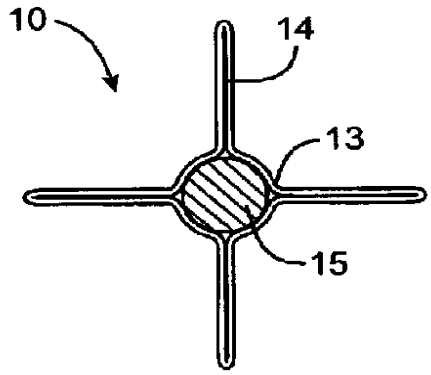

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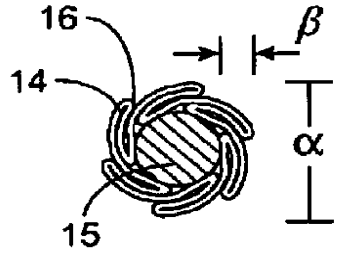


FIG. 10

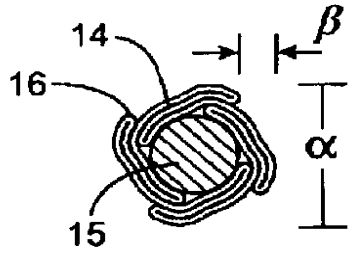


FIG. 12

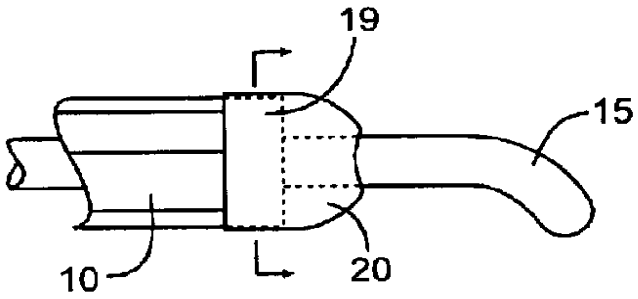


FIG. 13

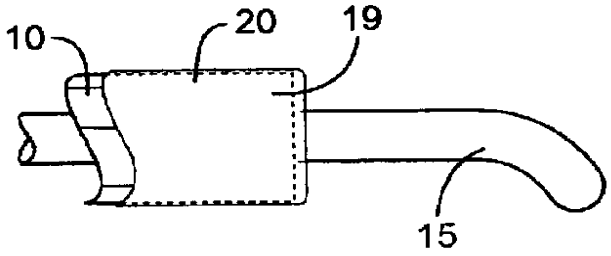


FIG. 14

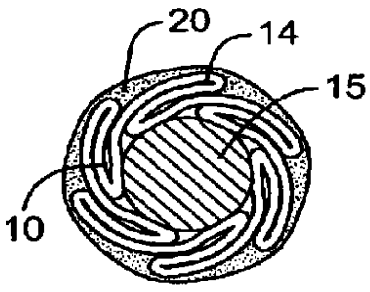
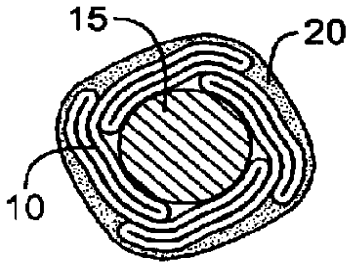


FIG. 15



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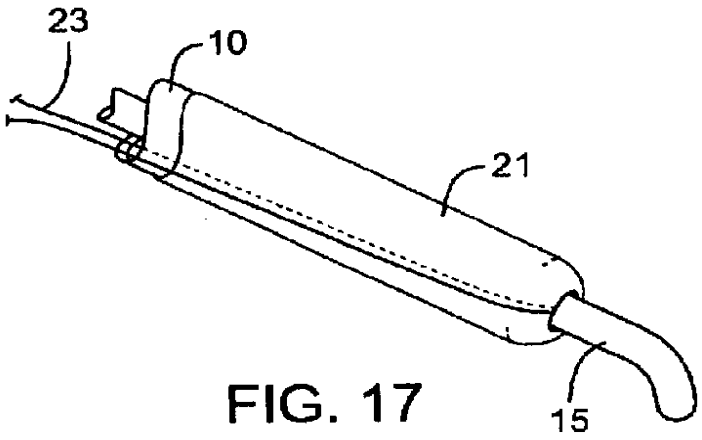

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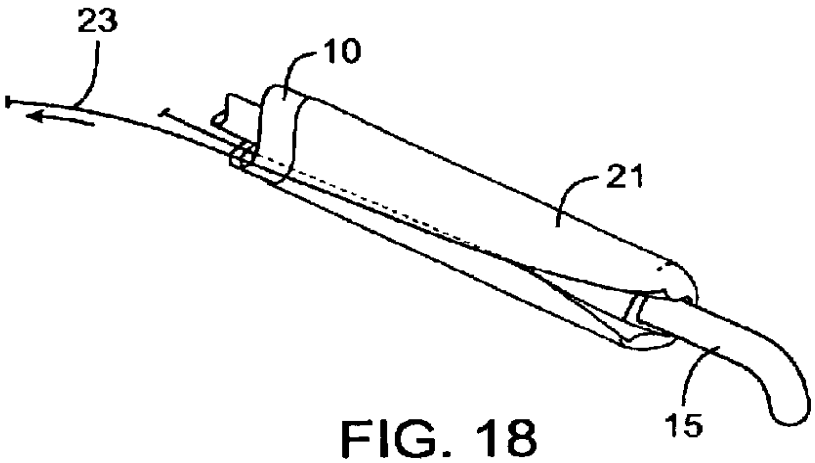

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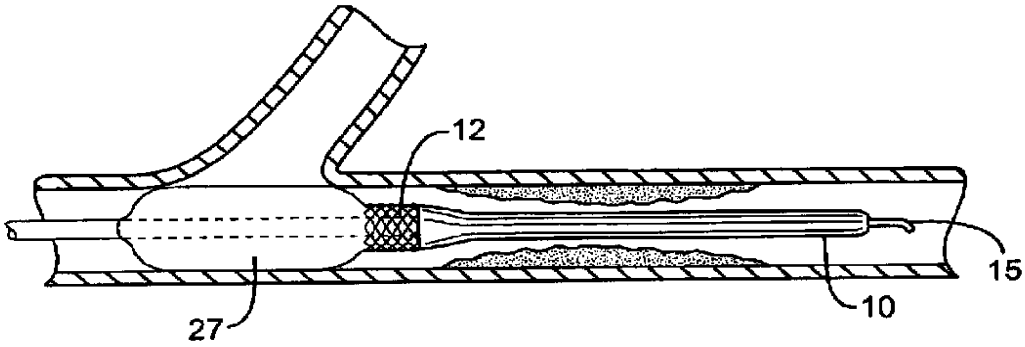

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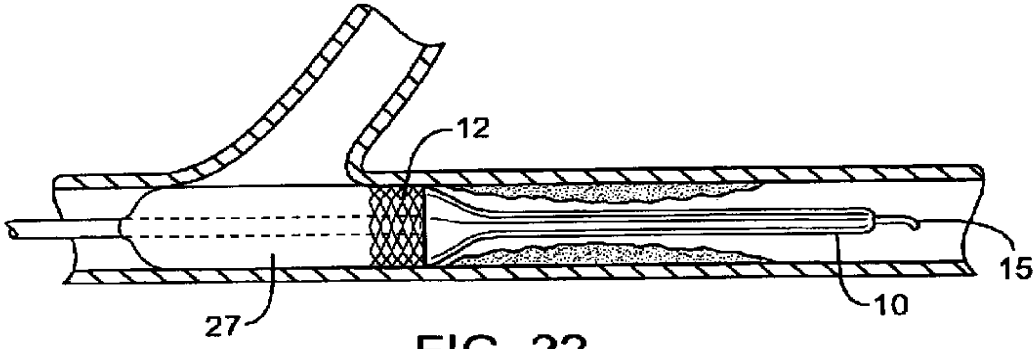

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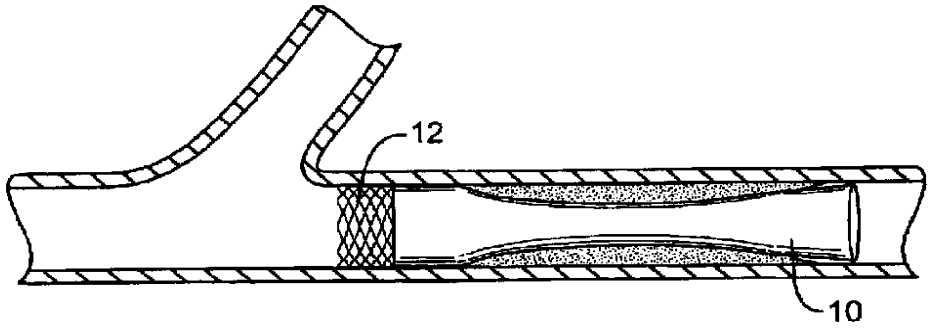

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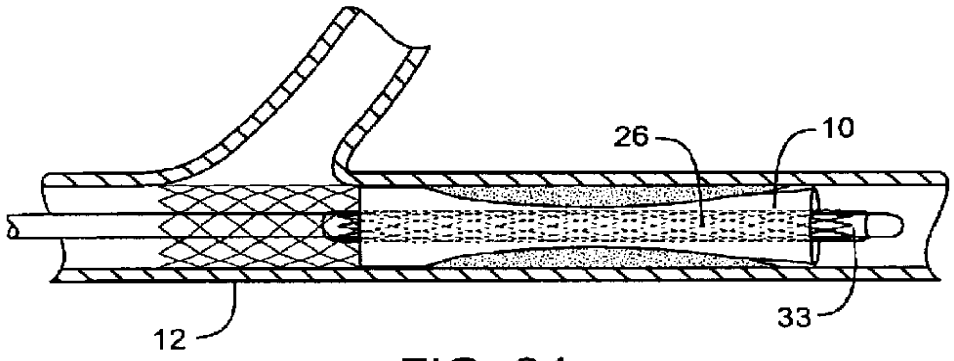

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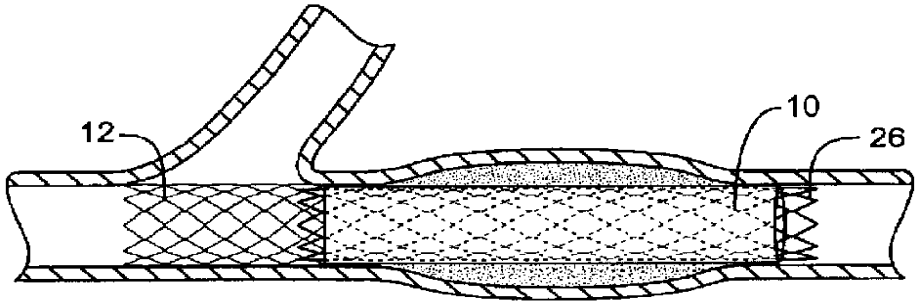

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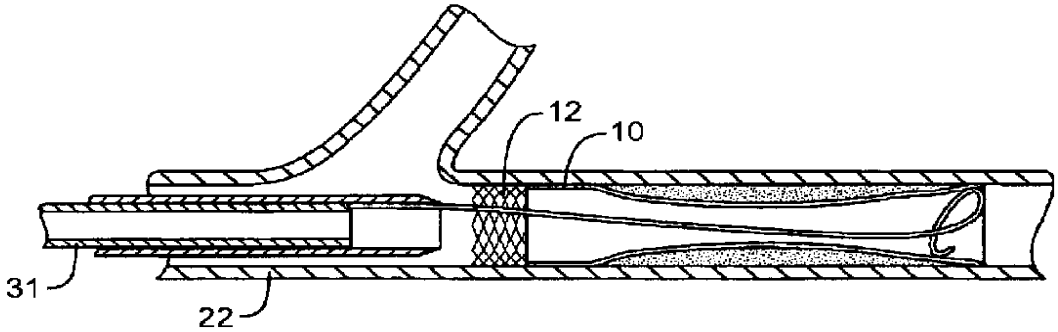
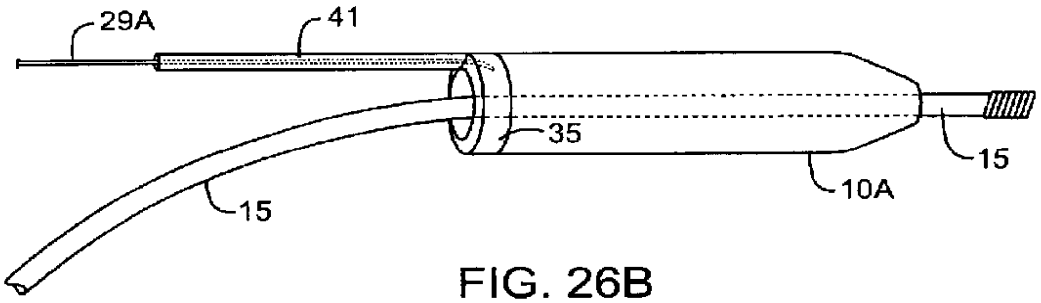


FIG. 26A



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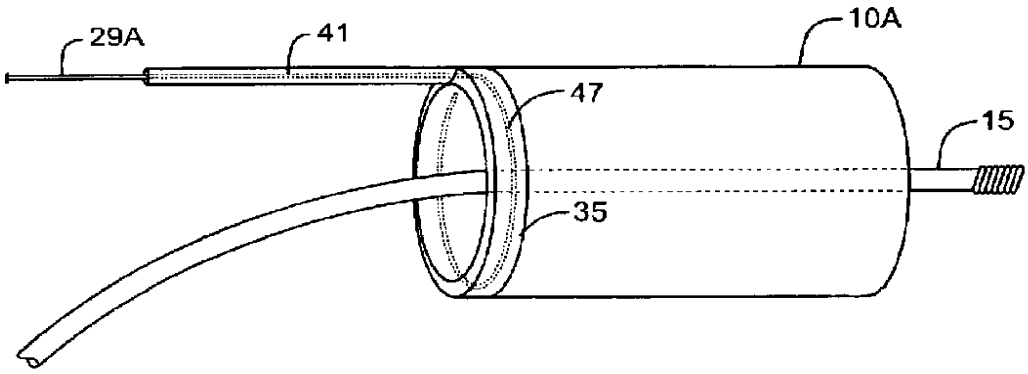

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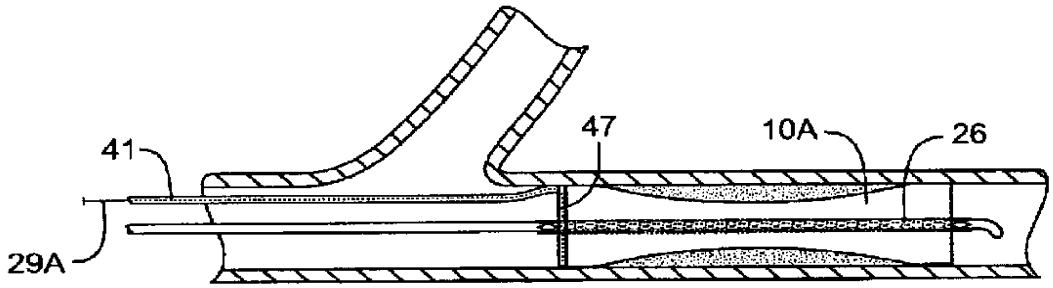

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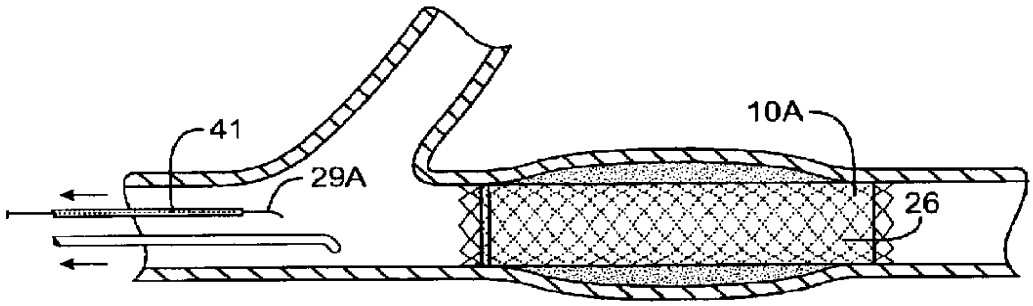

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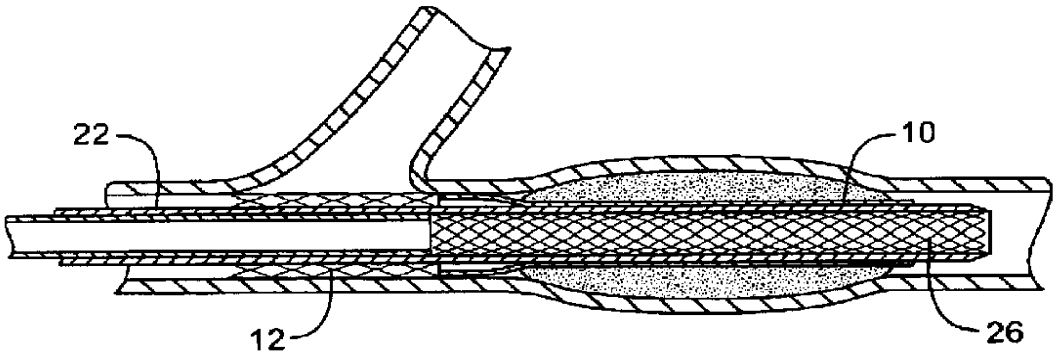

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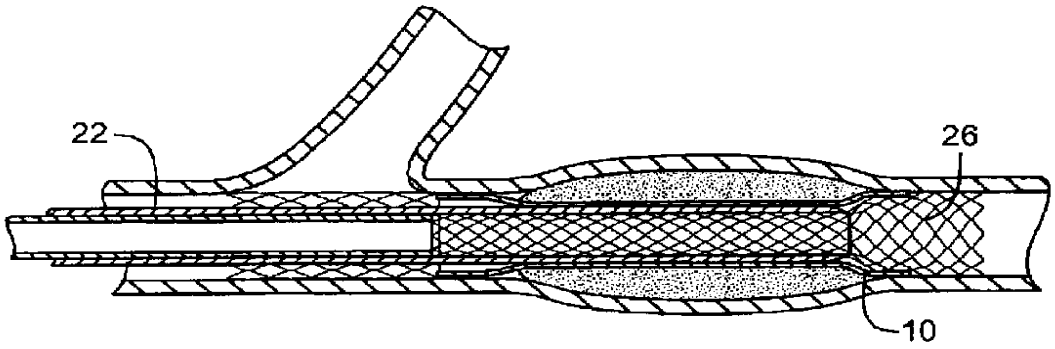

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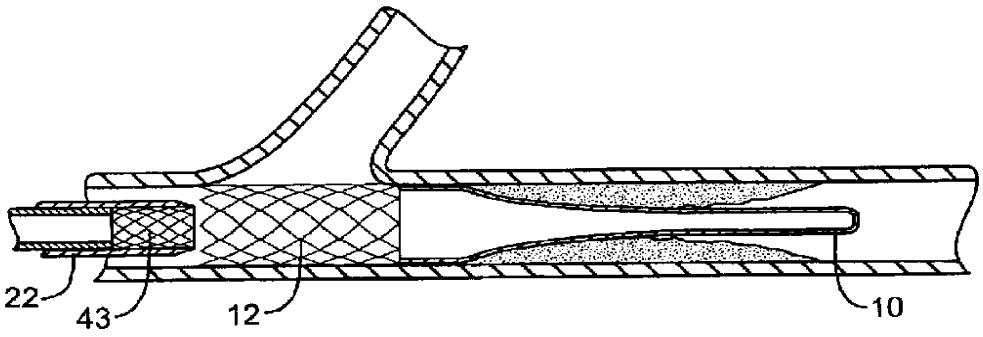

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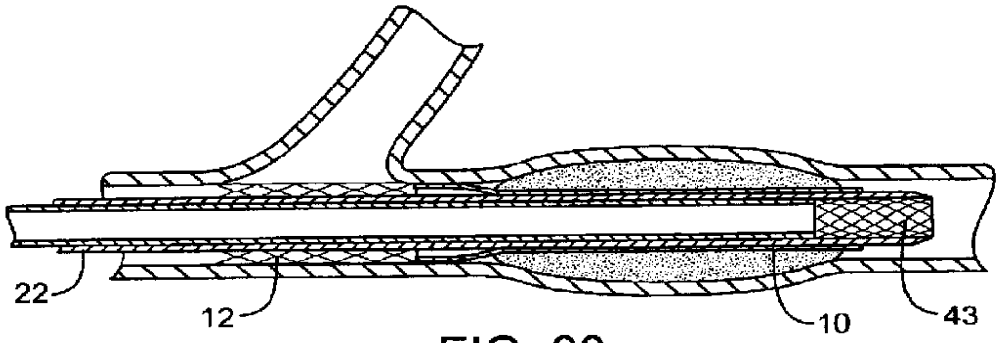

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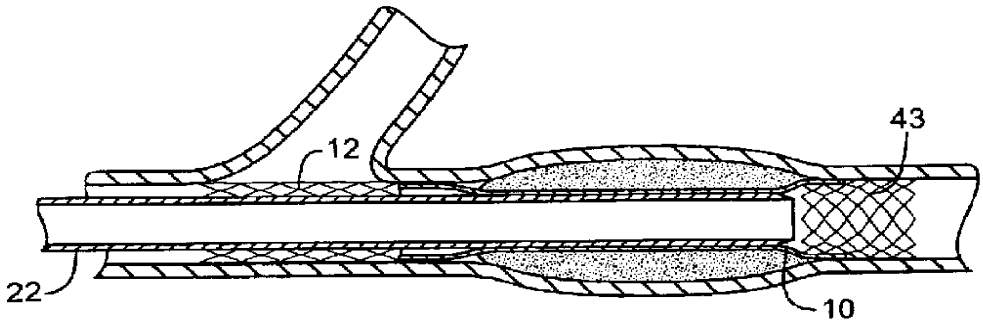


FIG. 31

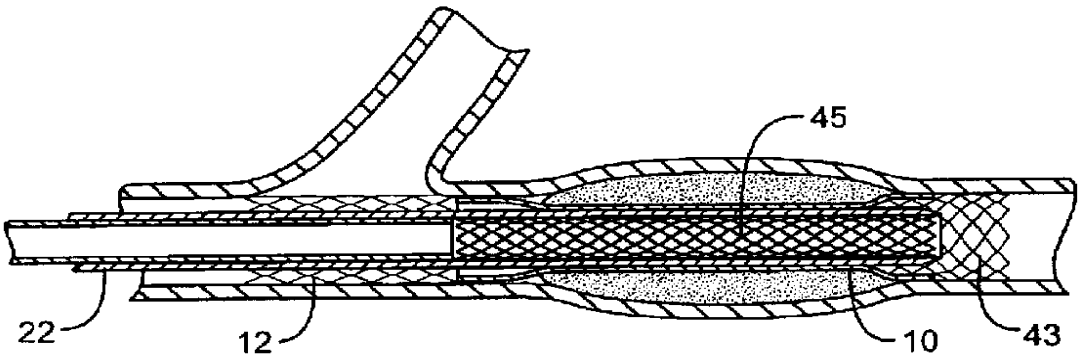


FIG. 32

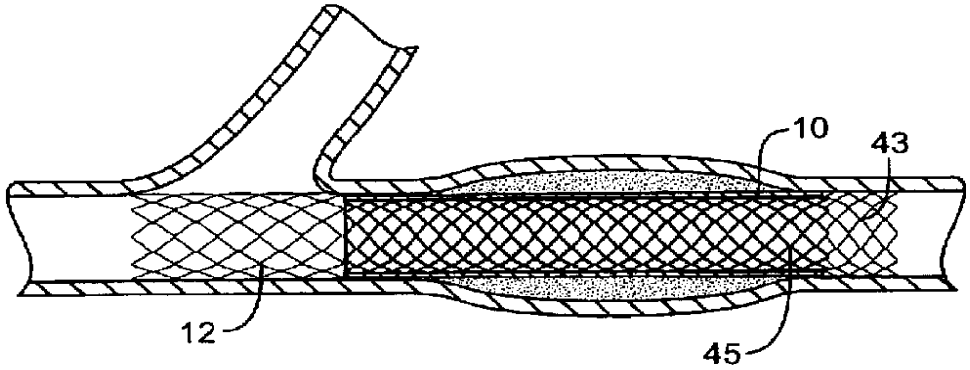


FIG. 33

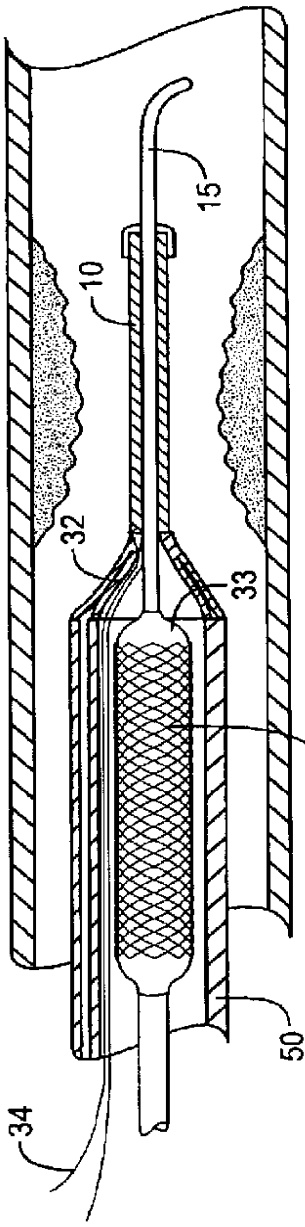


FIG. 34

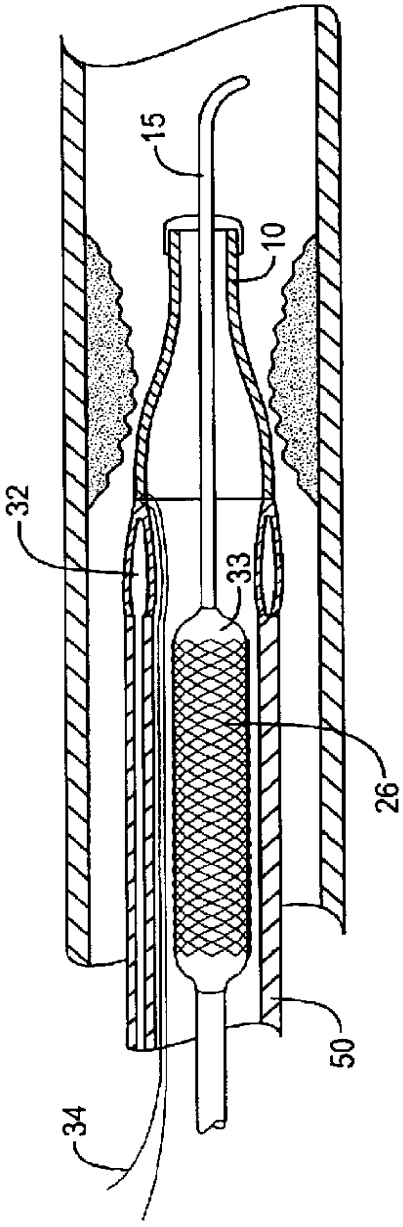


FIG. 35

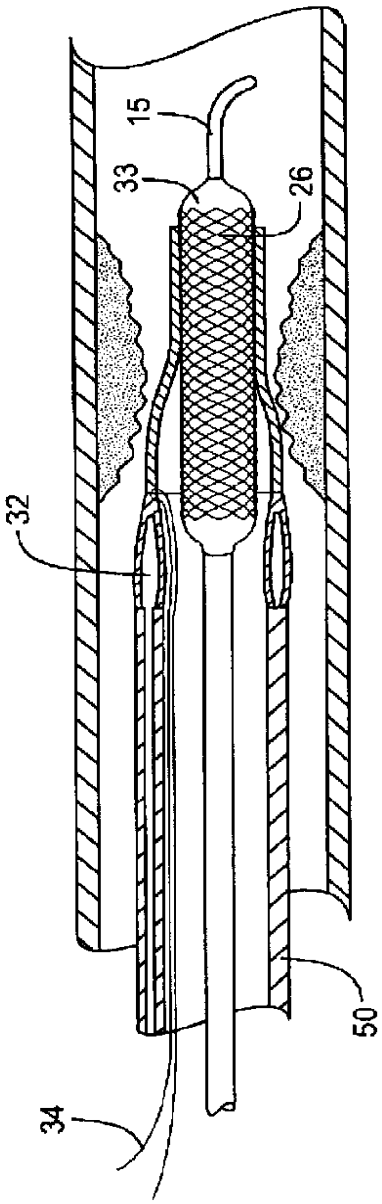


FIG. 36

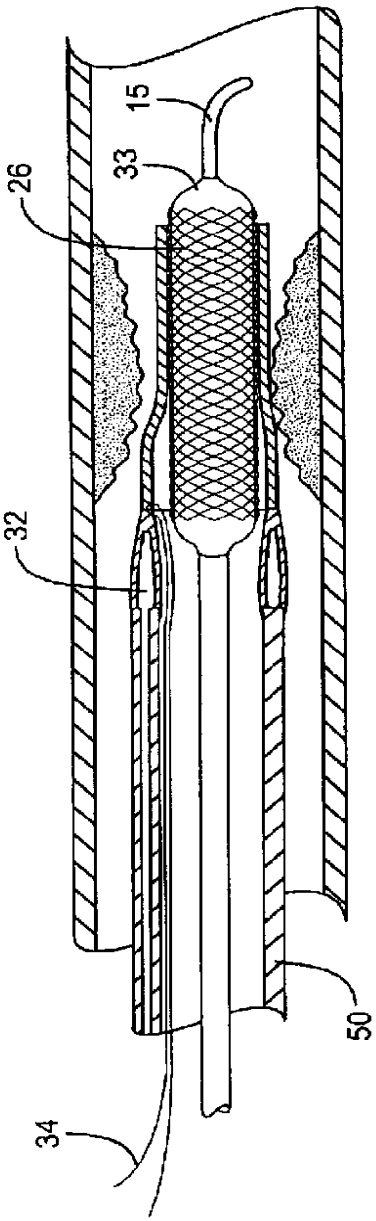


FIG. 37

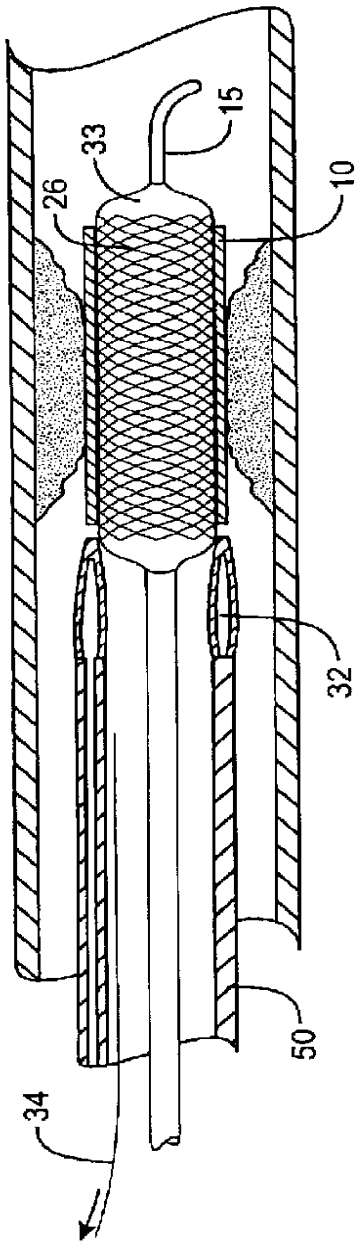


FIG. 38

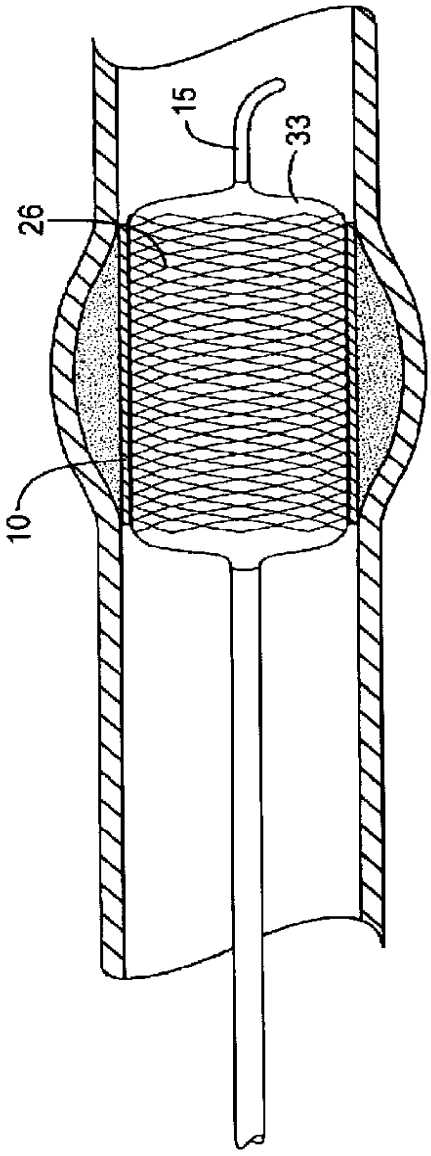


FIG. 39

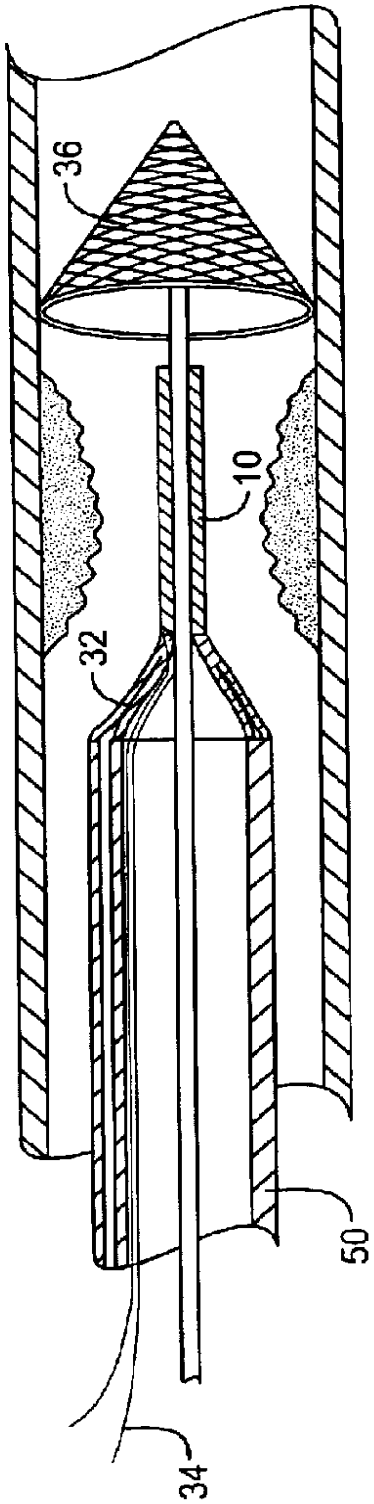


FIG. 40

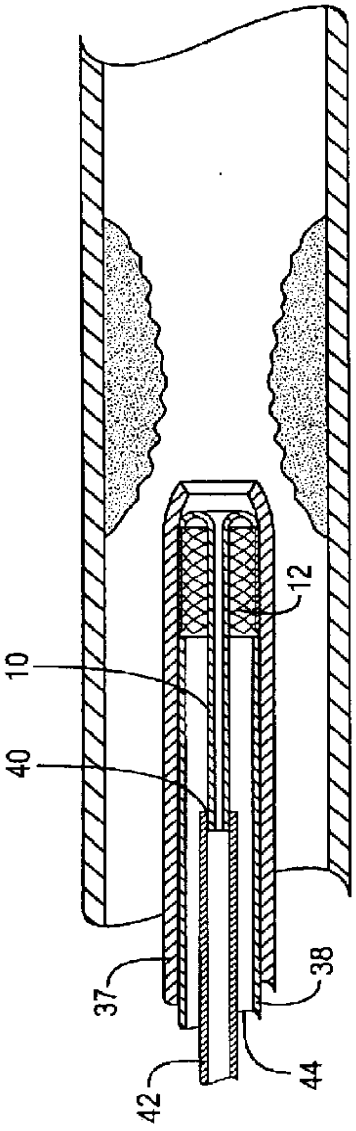


FIG. 41

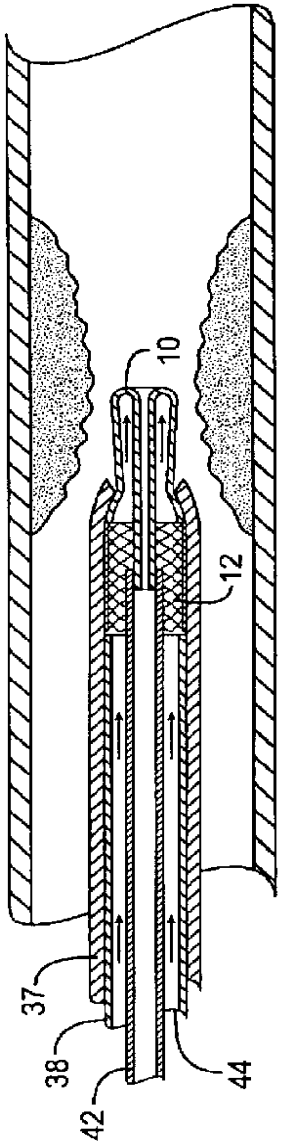


FIG. 42

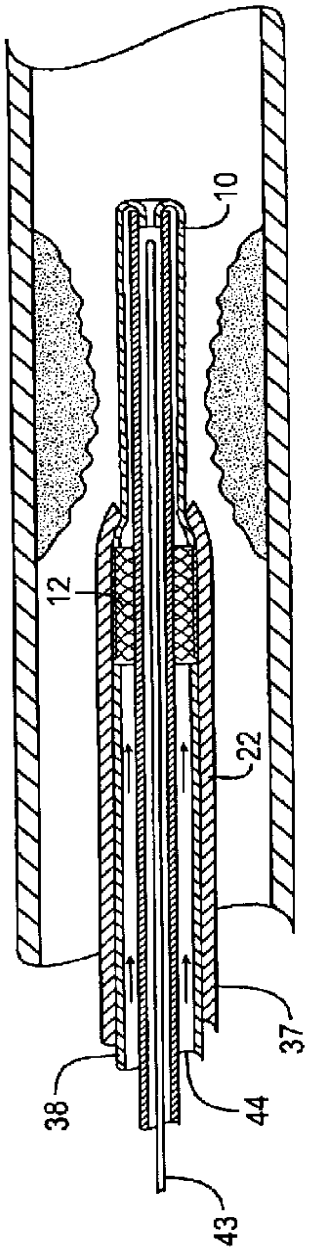


FIG. 43

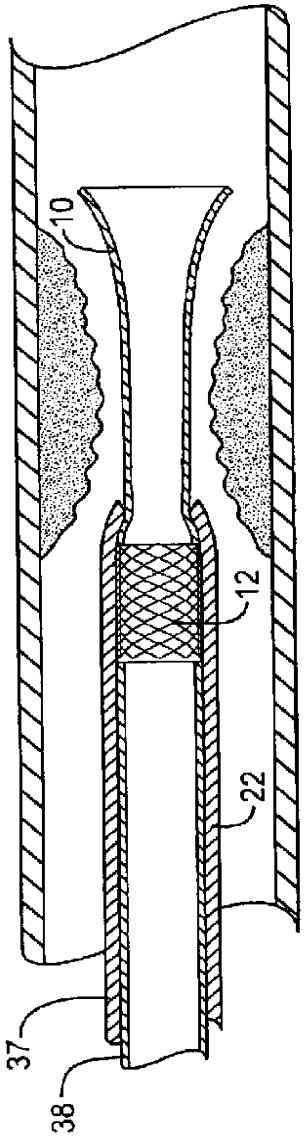


FIG. 44

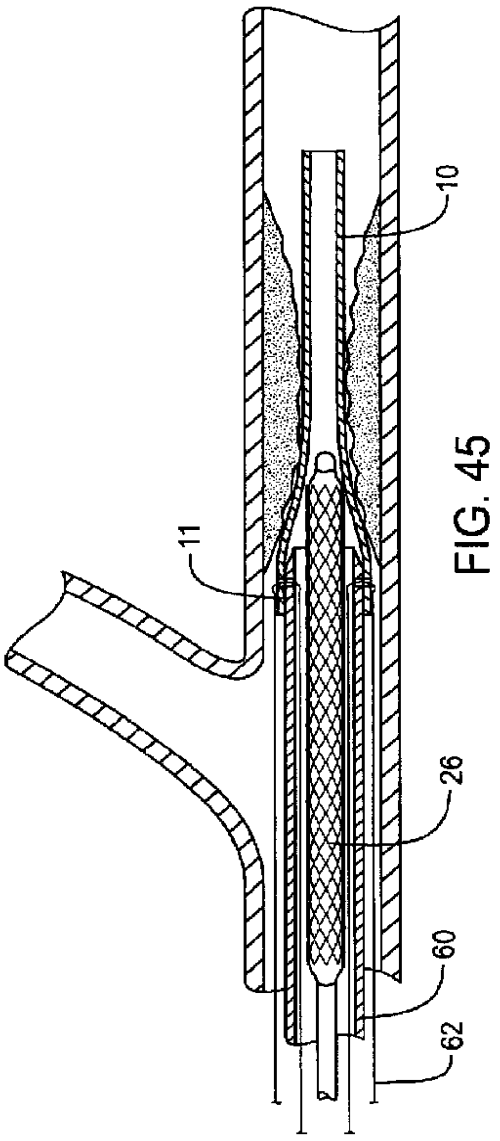


FIG. 45

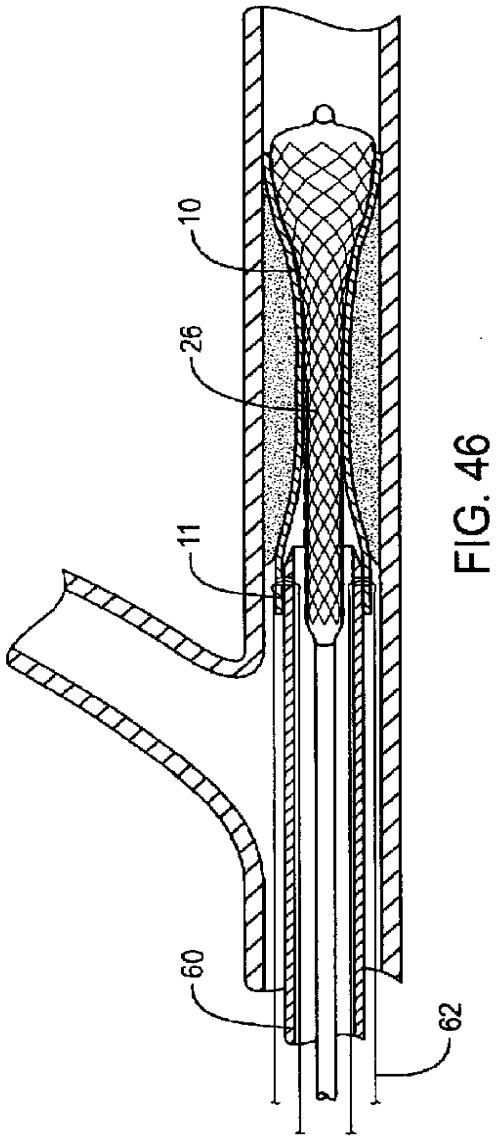


FIG. 46

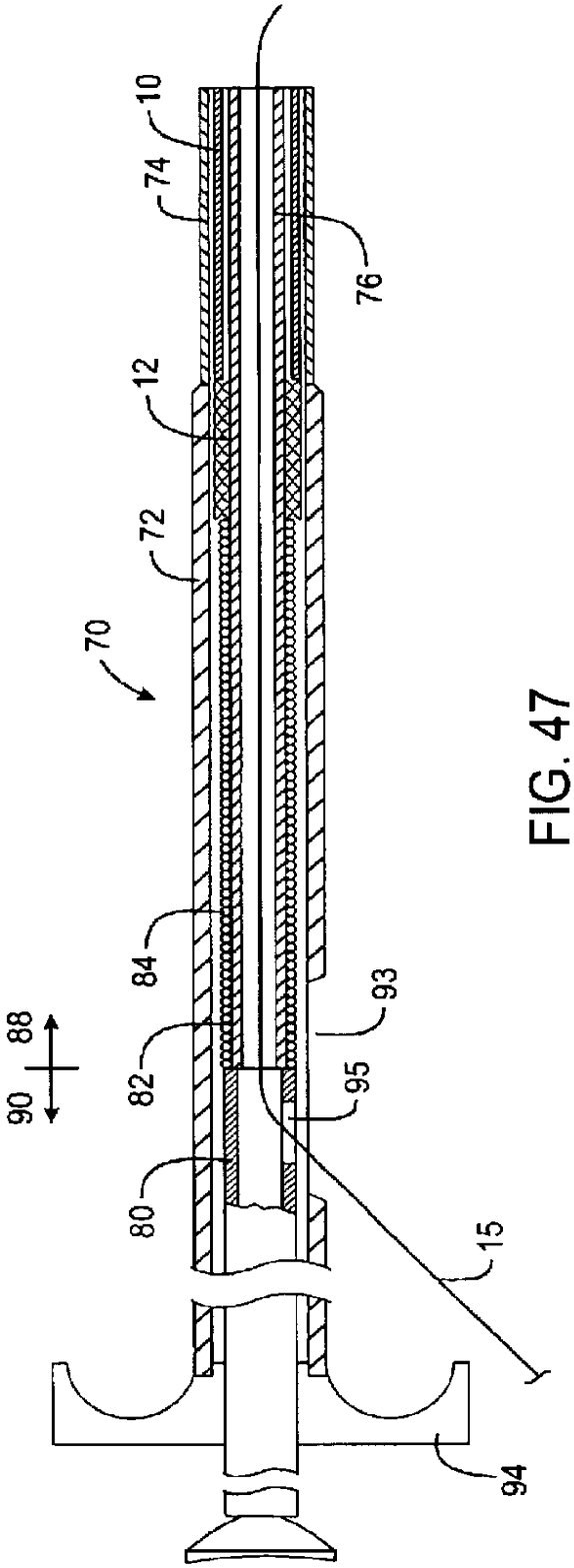


FIG. 47

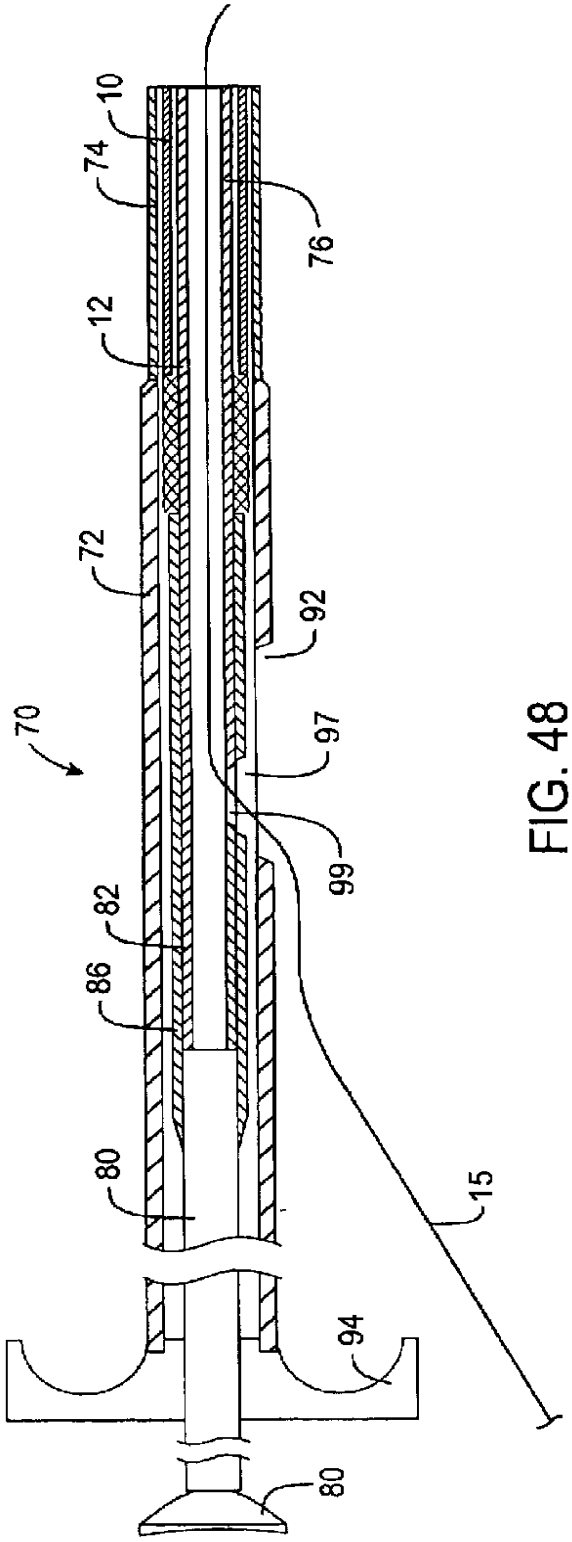
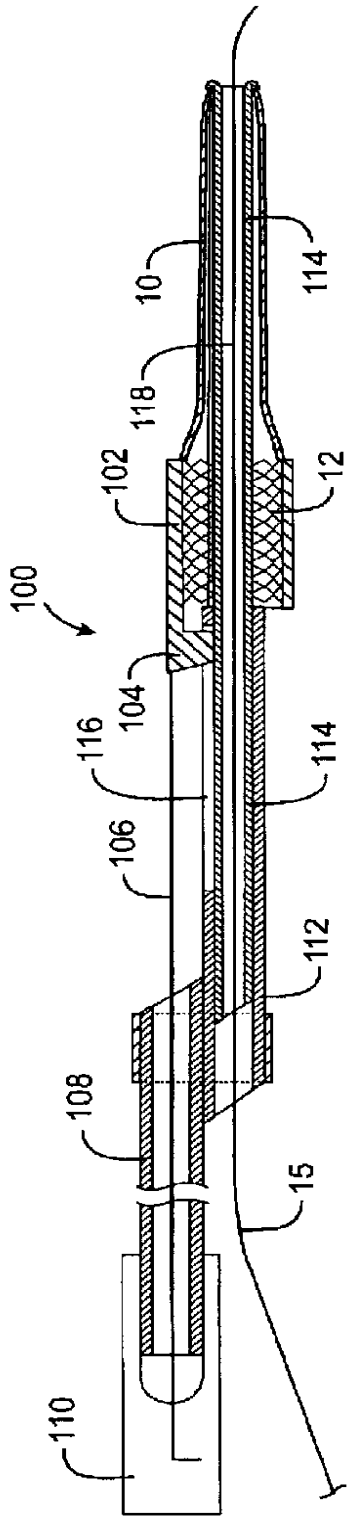


FIG. 48


100
10
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12
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116
114
106
112
108
15
110

FIG. 49

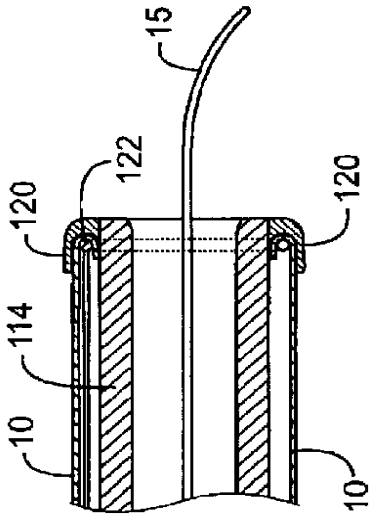
15
122
120
120
114
10
10

FIG. 50

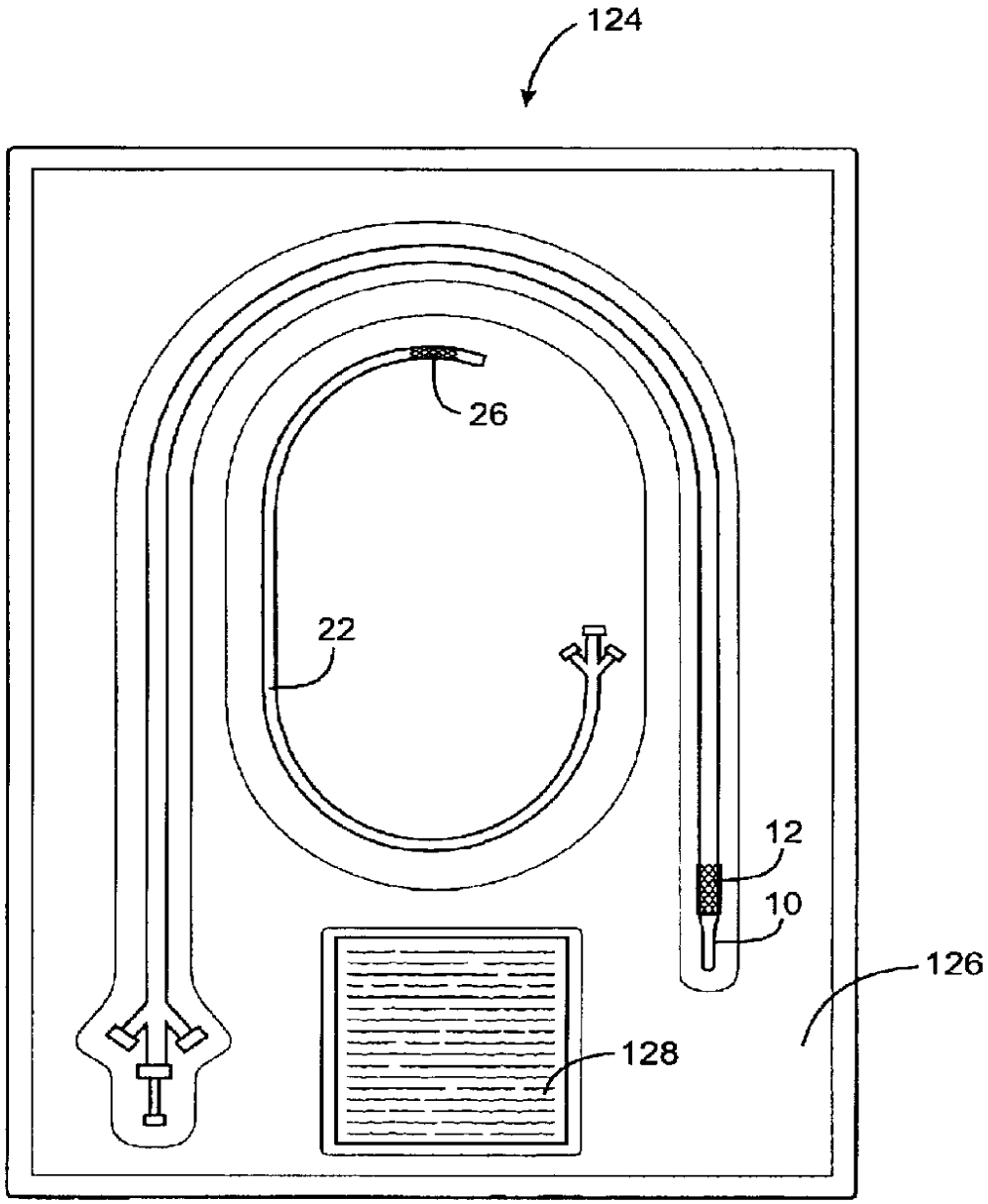

FIG. 51

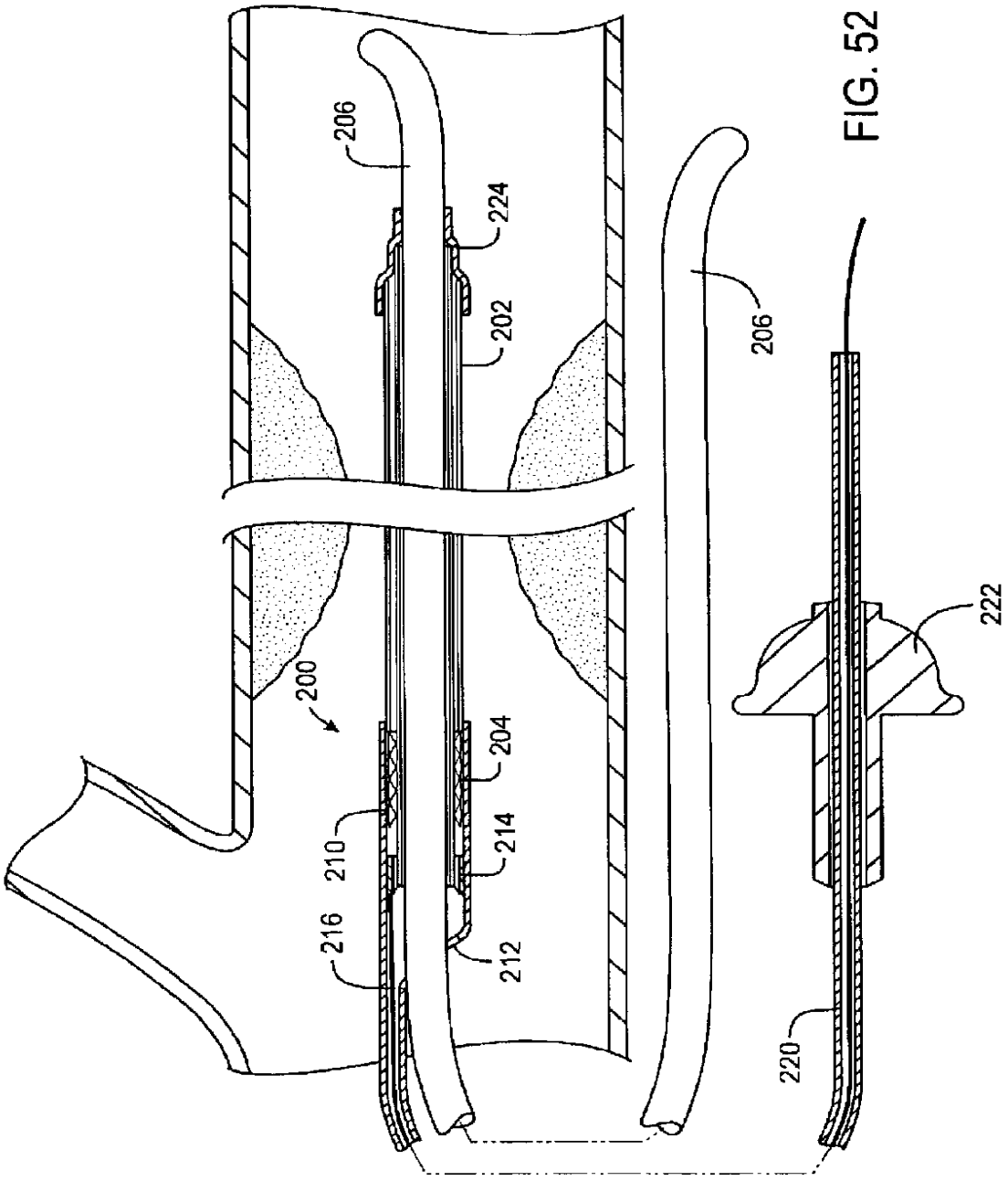

FIG. 52

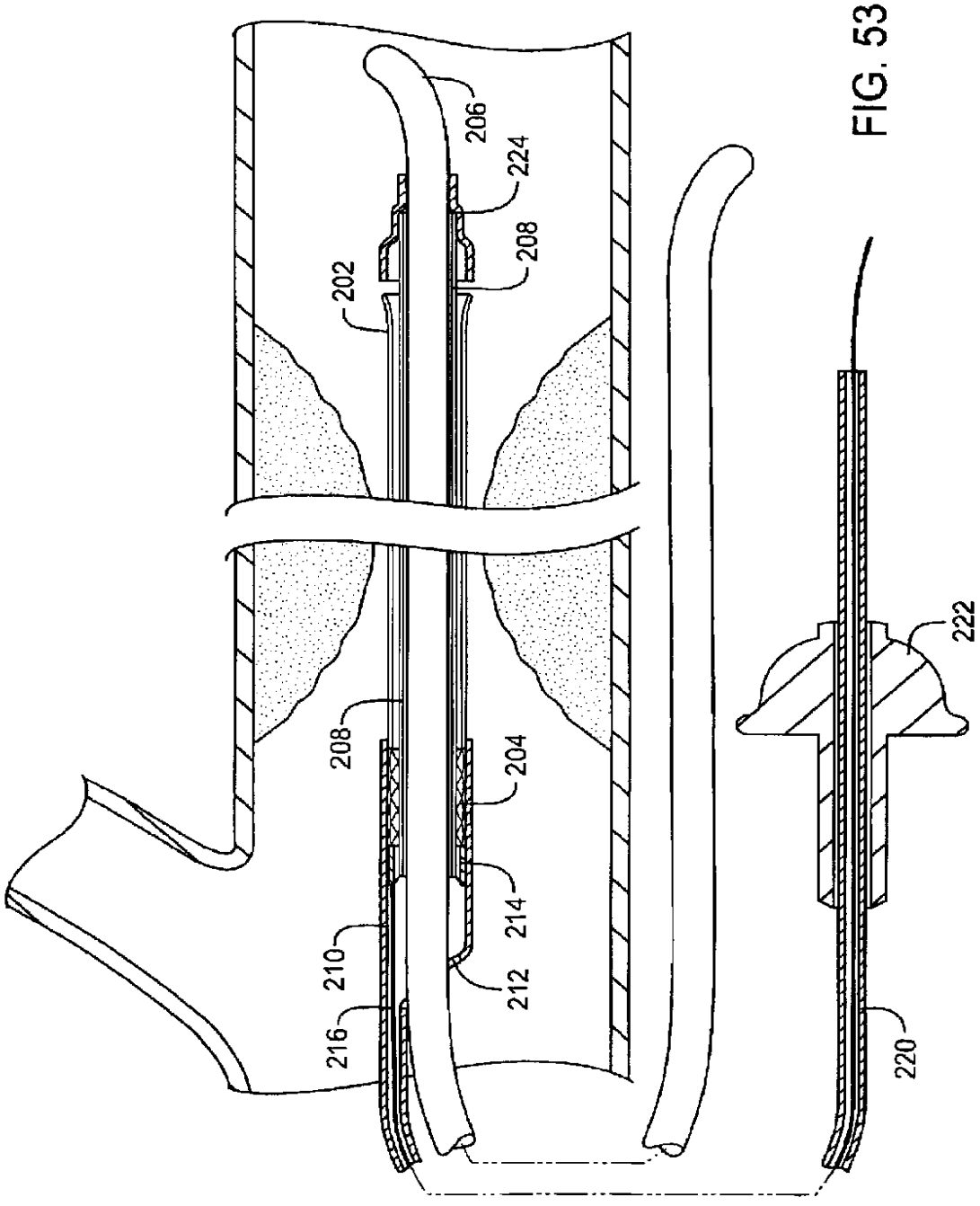

FIG. 53

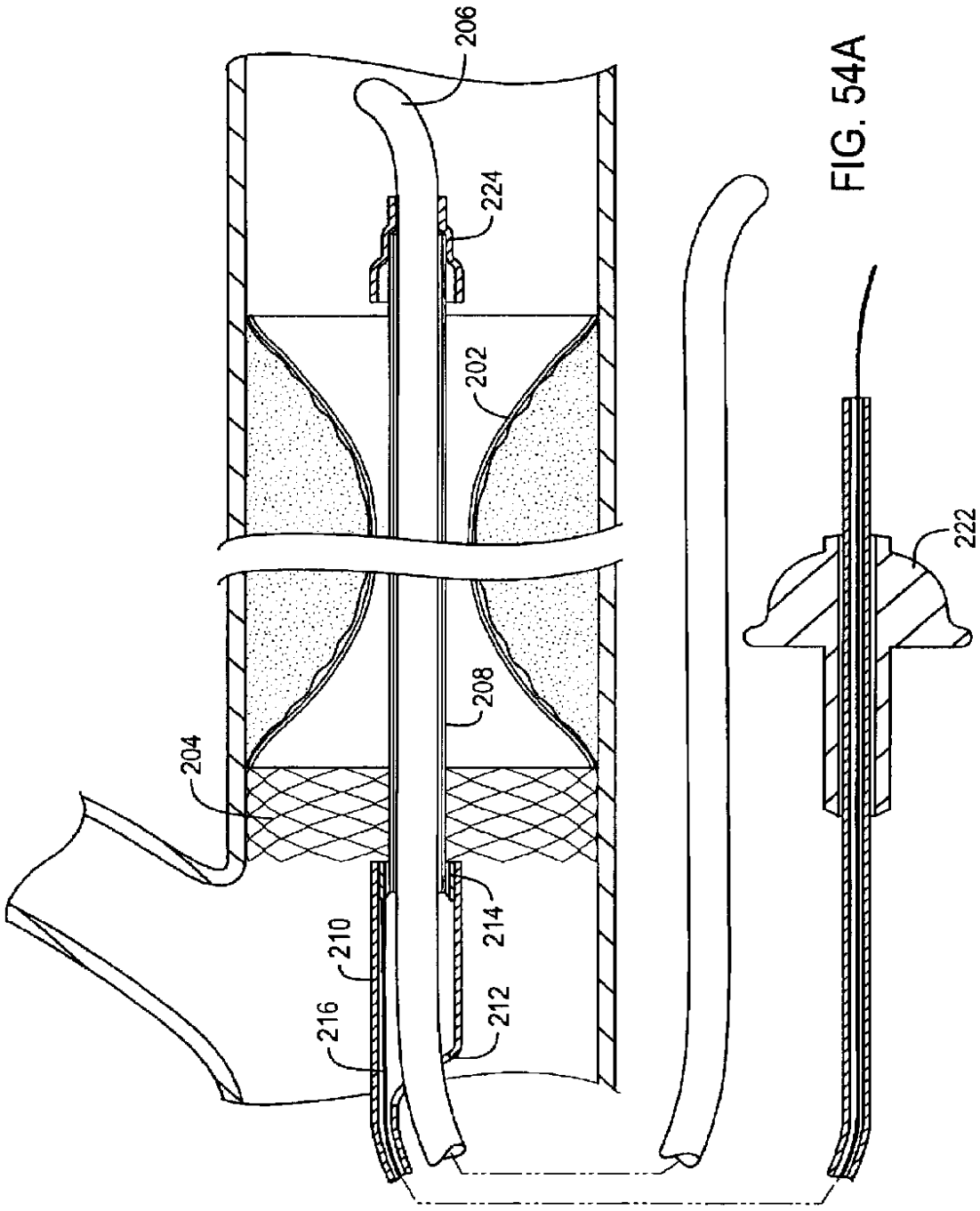

FIG. 54A

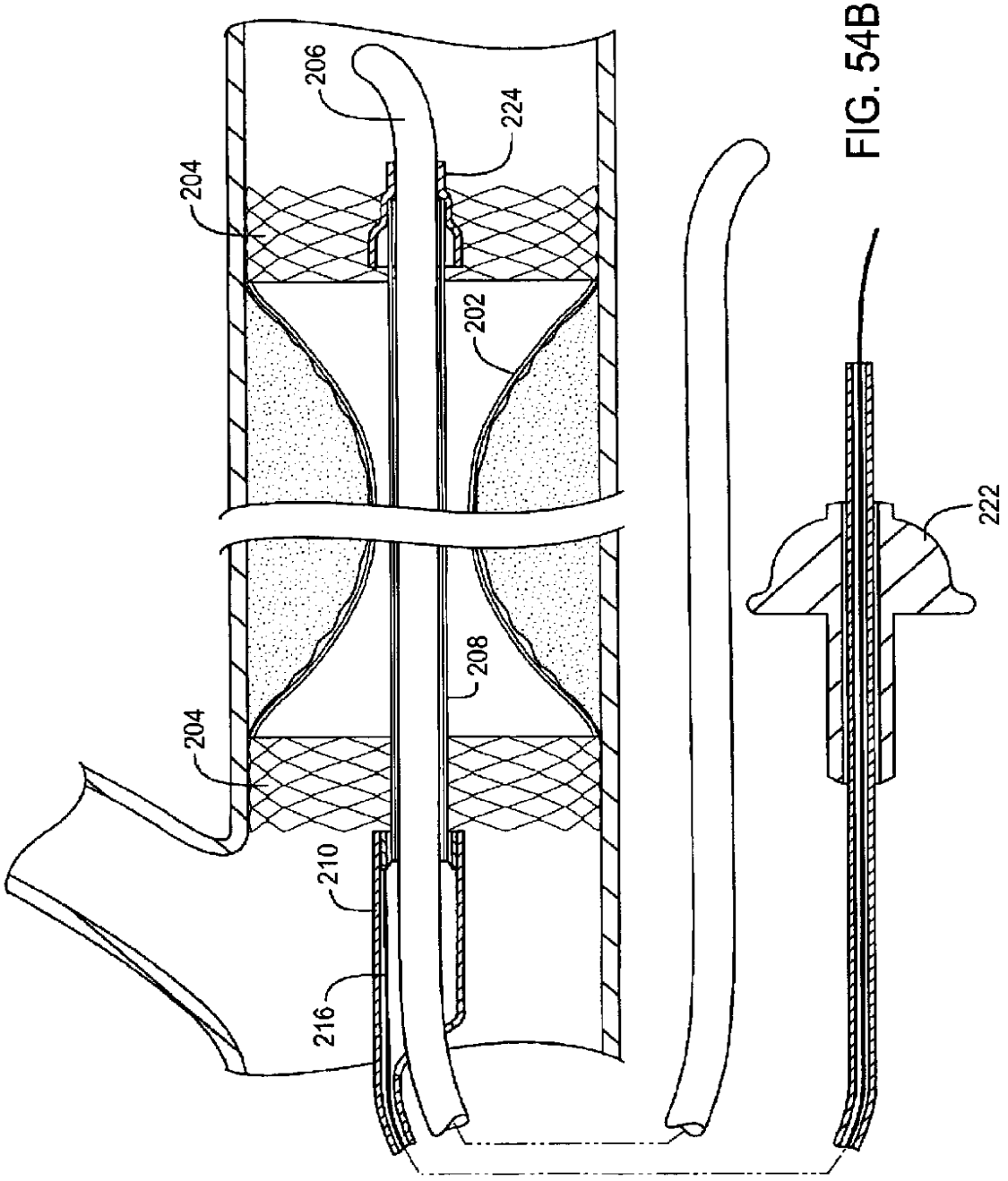

FIG. 54B

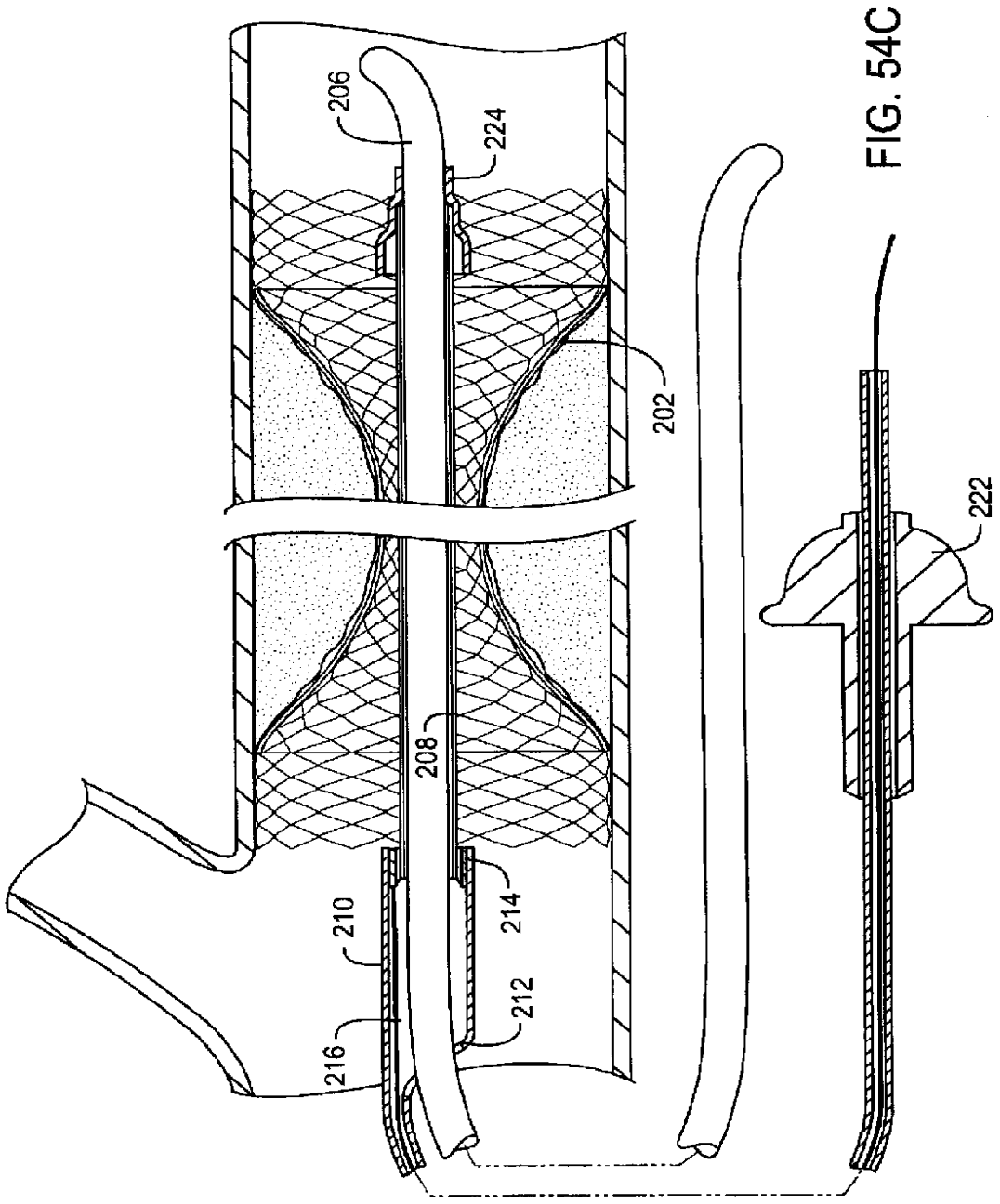

FIG. 54C

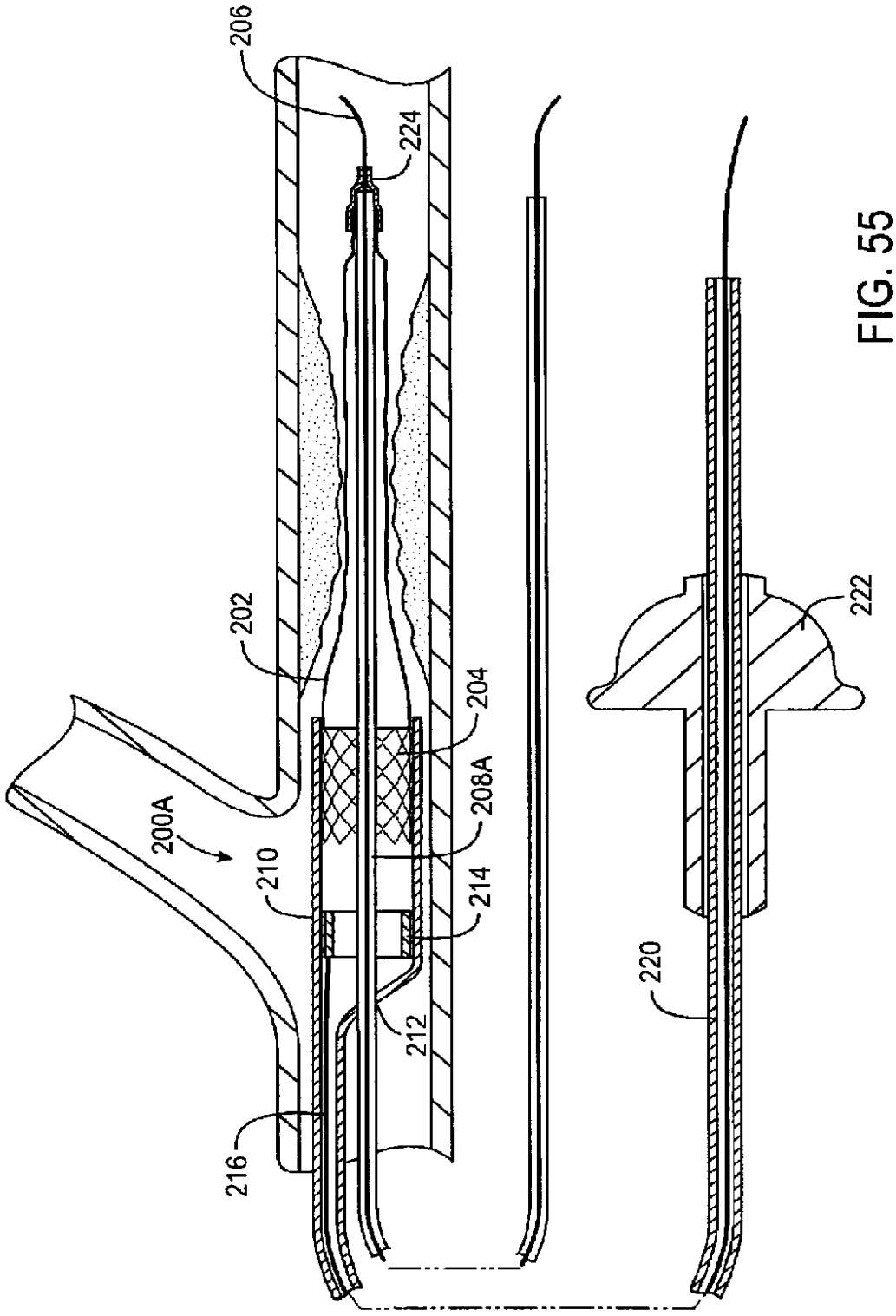

FIG. 55

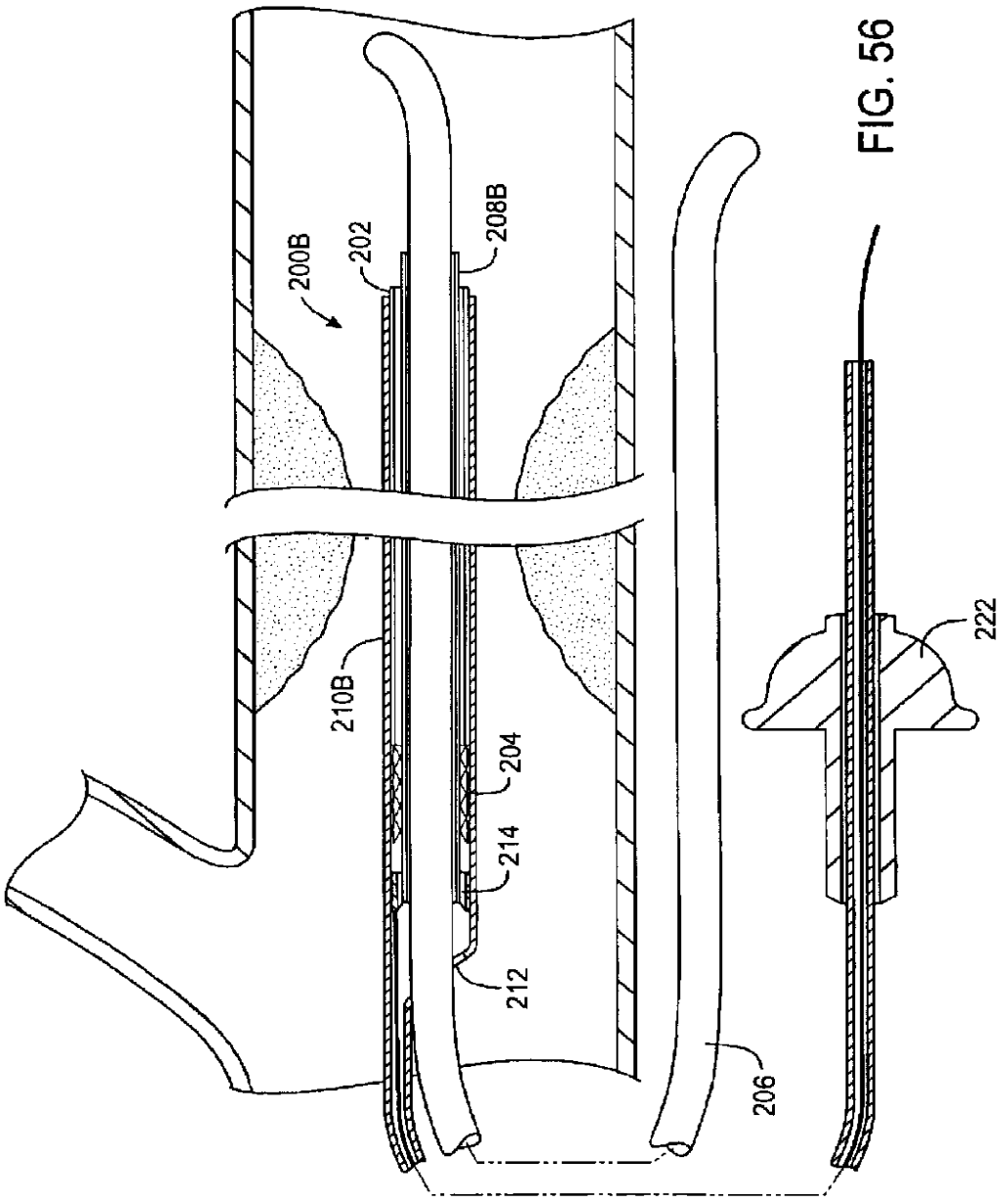

FIG. 56

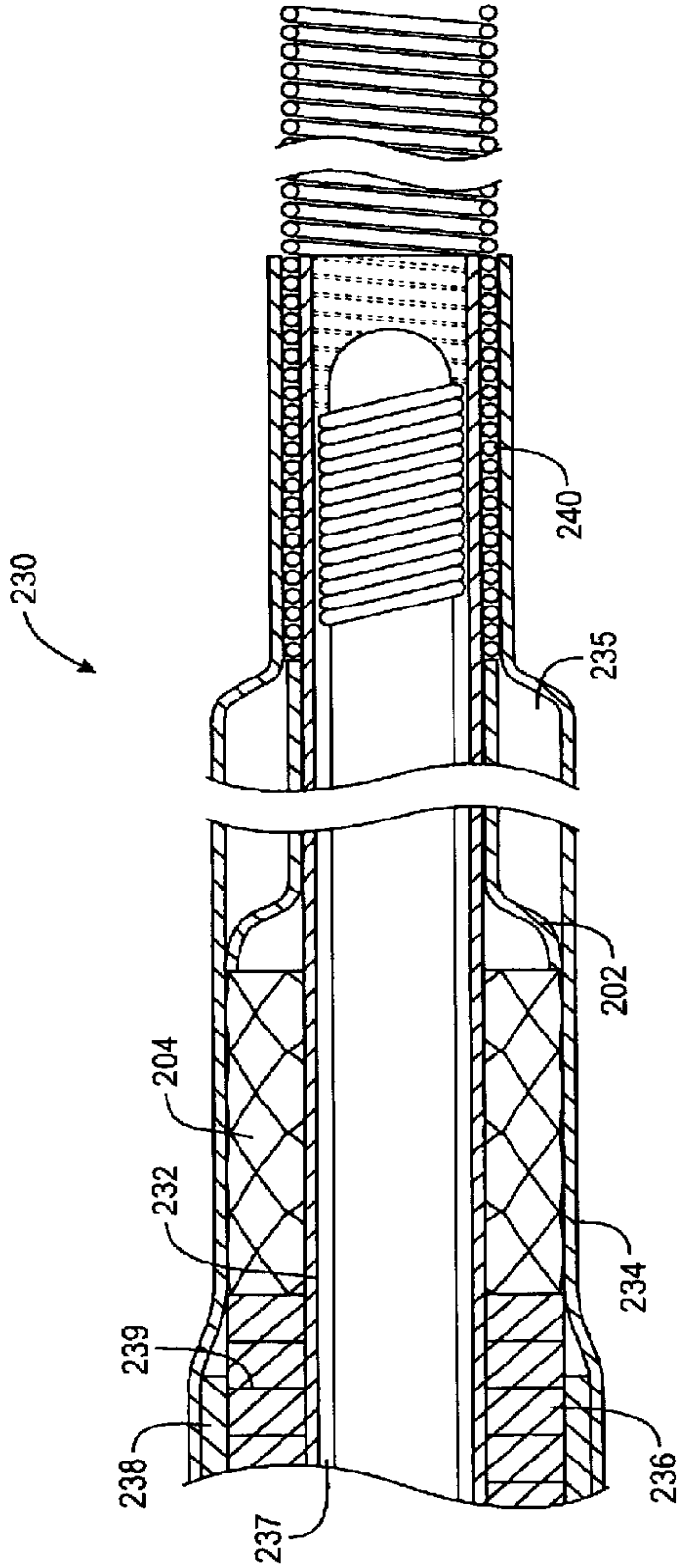

FIG. 57

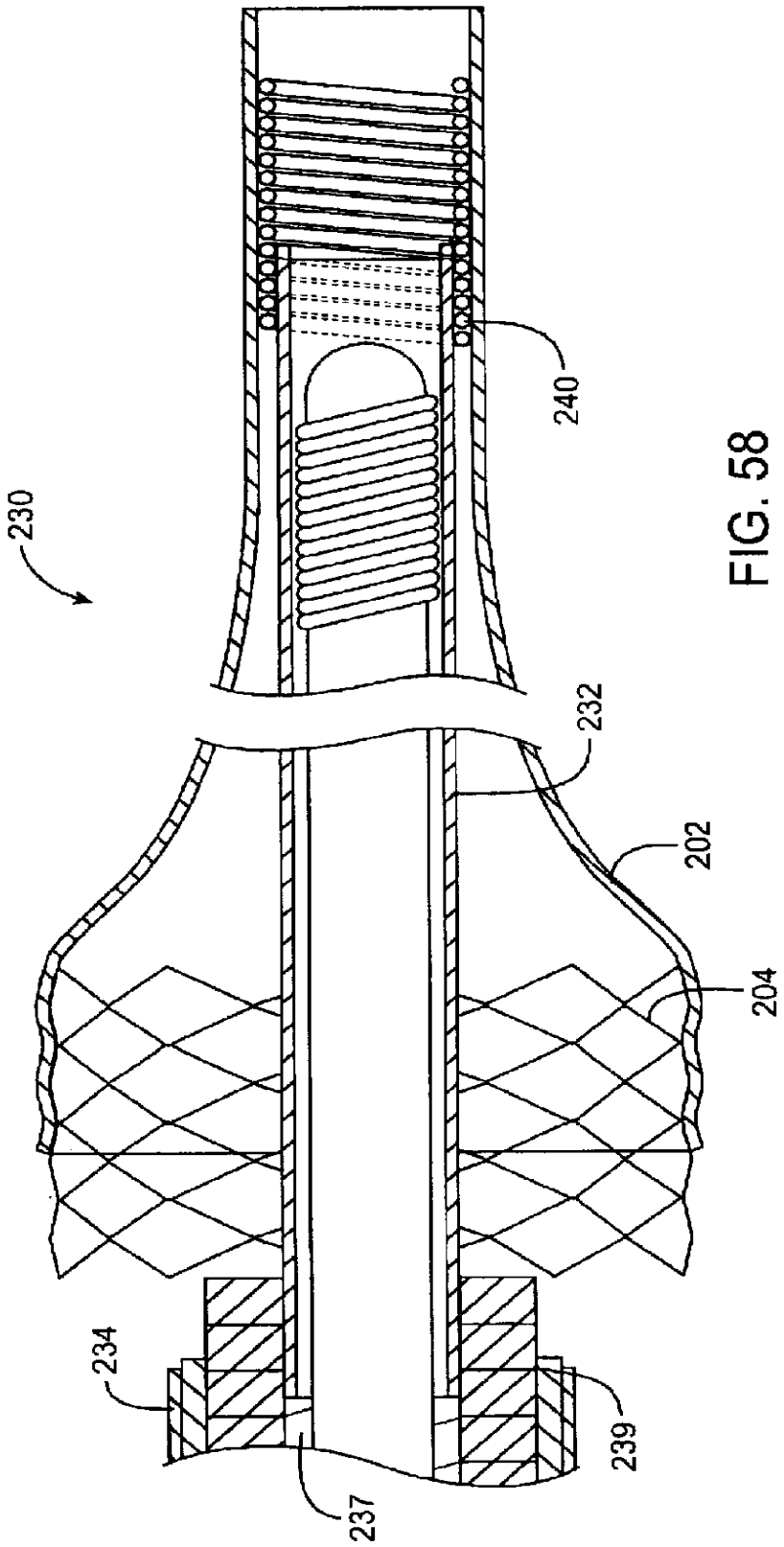

FIG. 58

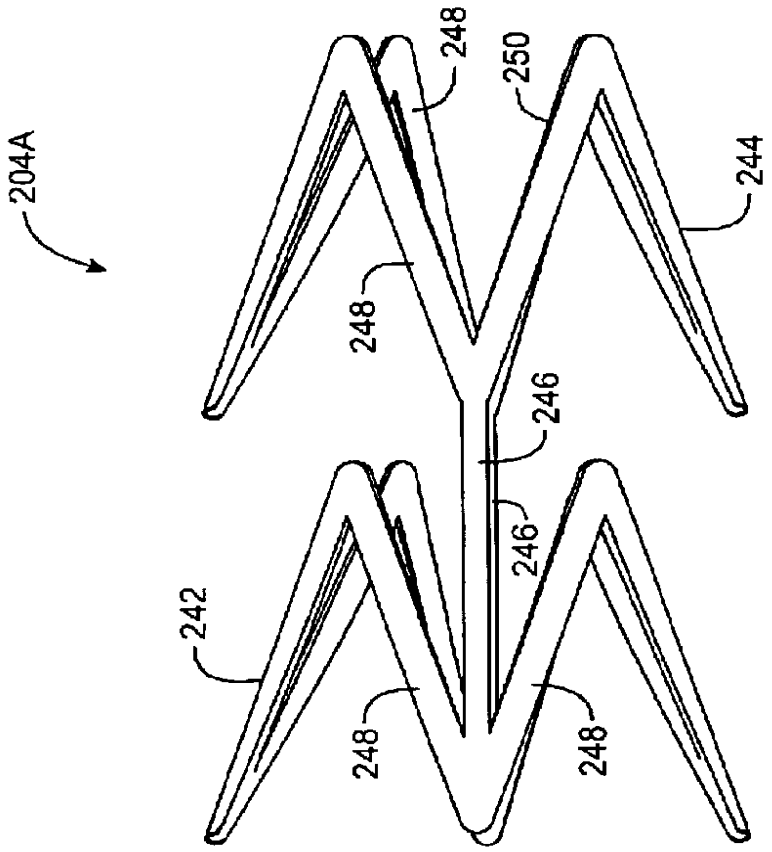

FIG. 59

METHODS AND DEVICES FOR LINING A BLOOD VESSEL AND OPENING A NARROWED REGION OF A BLOOD VESSEL

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of 09/416,309, filed Oct. 12, 1999, which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention is directed to methods and devices for protecting a passageway in a body when advancing devices through the passageway. A specific application of the present invention is for treatment of blood vessels although the invention may be used in any part of the body. For example, the present invention is used to protect blood vessels during intravascular procedures for treating aneurysms, arteriovenous malformations, and atherosclerotic disease of vessels. A particular application of the present invention is for atherosclerotic disease of the carotid arteries or saphenous vein grafts. Carotid artery atherosclerotic occlusive disease contributes to hundreds of thousands of strokes annually in the United States. Atherosclerotic disease of the internal carotid artery is particularly problematic since plaque from the internal carotid artery leads directly to the cerebral vasculature.

A conventional method of treating carotid artery occlusive disease is by surgical removal of the plaque (carotid endarterectomy). The carotid artery is opened surgically, the plaque is removed and the carotid artery is then closed. Carotid endarterectomies have demonstrated significant clinical benefit over conservative treatment with medication by reducing strokes over the next five years. Although carotid endarteretomy reduces strokes over a period of time after the procedure, the procedure still has a 6% risk of death or stroke.

Another method of treating carotid artery disease is to use interventional devices such as stents. A problem with treating carotid artery occlusive disease with stents is that the user is wary of dislodging plaque when advancing the stent through the carotid artery. Any plaque which breaks free during introduction of the stent travels directly to the patient's brain and can cause a stroke or death.

Yet another method of treating carotid artery occlusive disease is to introduce a filter through the carotid artery to trap emboli released during subsequent deployment of a stent or angioplasty balloon. This method suffers the same drawback in that advancement of the filter itself may dislodge plaque. Moreover, exchange of various therapeutic catheters over the filter element result in undesirable movement of the filter with attendant risk of losing filtered emboli or damaging the vessel wall with the filter.

The present invention is directed to improved methods of protecting a body passageway when advancing devices through the body passageway. The present invention is also directed to improved methods of treating atherosclerotic vessels and, in particular, occlusive disease of the internal carotid artery.

SUMMARY OF THE INVENTION

In accordance with the objects of the invention, a liner is provided to protect a body passageway during introduction of other devices into the passageway. In a specific application, the methods and devices of the present invention are used to protect blood vessels, such as the internal carotid artery, during intravascular procedures. It is understood that use of the present invention for protection of blood vessels is discussed as an example of how the present invention may be used, however, the invention may be used in any other part of the body without departing from the scope of the invention. The liner is collapsed for introduction into the patient and advanced to a narrowed region of a blood vessel. The liner is passed through a region of the blood vessel in the collapsed condition and an intravascular device, such as a stent or filter, is then introduced into the liner. The liner may be used to protect vessels from any type of problem including atherosclerotic disease, perforation, aneurysm or AVM.

The liner protects the vessel as the intravascular device is passed through the region to prevent the device from dislodging plaque. When the device is a stent, the stent is preferably expanded within the liner to trap the liner between the stent and the vessel. The liner may be expanded by the stent or may be partially or fully expanded before introduction of the stent. The devices and methods of the present invention are particularly useful for treating occlusive disease of the internal carotid artery. The liner may be any suitable material and suitable materials include expanded PTFE, woven dacron, nylon, low durometer silicone, or thin-walled polyethylene.

The liner is preferably mounted to a delivery catheter and is advanced over a guidewire. The liner may have an anchor at a proximal end which is used to open the proximal end of the liner. The anchor may be self-expanding or balloon expandable. Once the proximal end of the liner is opened, the liner can be designed so that blood pressure opens the liner. Alternatively, the liner may open automatically or may be opened with a separate device, the delivery catheter or the stent itself. When treating occlusive disease of the internal carotid artery, the anchor may be positioned completely in the internal carotid artery or may extend from the common carotid artery across the bifurcation of the internal and external carotid arteries and into the internal common carotid. The anchor preferably has an open structure which permits blood flow into the external carotid artery.

The liner may be an elastic liner or may be folded into a collapsed position. The liner may be collapsed in any suitable manner and preferably has a number of folded sections which are wrapped around one another. The folded sections are preferably adhered to one another to hold the liner in the collapsed position. The folded sections may be adhered together by application of heat or with an adhesive or coating. The distal end of the liner may be coated to form a curved surface which covers the ends of the folded sections. Alternatively, the ends of the liner may be scalloped or contoured so that when folded the edge tapers down more cleanly.

The liner may also be designed to evert when expanding. The everting liner reduces sliding between the liner and vessel so that plaque is not dislodged when introducing the liner. An end of the everting liner may be releasably attached to the delivery catheter.

The proximal end of the liner may also be opened with an expandable device, such as a balloon, on the delivery catheter rather than with an anchor attached to the liner. Once the proximal end is open, the stent or other device is advanced through the liner.

In yet another aspect of the invention, the catheter holds the proximal end partially open. The stent or other device is then advanced through the open proximal end. The liner can be released when using a stent or may be removed after use.

These and other features and advantages of the invention will become evident from the following description of the preferred embodiments.

The present invention is also directed to a device for lining a vessel which has an expandable anchor movable from a collapsed shape to an expanded shape. The liner attached to the anchor and extends from an end of the anchor. The liner is held between thin, flexible inner and outer layers which are preferably shrink tubing. The outer layer is retracted to expose and free the liner. The outer layer may also hold the anchor in the collapsed position.

The inner and outer layers preferably have a thickness of 0.0005–0.002 inch. The outer layer stretches over a tapered portion and is preferably flexible enough to stretch over the tapered portion as it passes over the tapered portion. The outer layer has a diameter of no more than 0.055 inch, and more preferably no more than 0.050 inch, when in the collapsed position. A radiopaque coil may also be provided which extends beyond the distal end of the liner and between the inner and outer layers. The inner layer is preferably attached to an inner element and the outer layer is preferably attached to an outer element.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a system for advancing devices through a narrowed region of a blood vessel such as the internal carotid artery.

FIG. **2** shows a liner advanced through the narrowed region in a collapsed position.

FIG. **3** shows the liner detached from the delivery catheter and expanded.

FIG. **4** shows only the proximal end of the liner expanded with an anchor.

FIG. **5** shows the liner having openings or perforations.

FIG. **6**A shows the liner having a woven or braided configuration.

FIG. **6**B shows the liner having a radiopaque maker and a scalloped distal end.

FIG. **7** shows the liner folded into six folded sections.

FIG. **8** shows the folded sections wrapped around one another.

FIG. **9** shows an end view of the liner of FIG. **7**.

FIG. **10** shows an end view of the liner of FIG. **8** with the liner wrapped around a guidewire.

FIG. **11** shows the liner having four folded sections.

FIG. **12** shows the liner of FIG. **11** with the folds wrapped around one another.

FIG. **13** shows a coating over a distal end of the liner.

FIG. **14** shows the coating extending over the length of the liner.

FIG. **15** is a cross-sectional view of the liner and coating with four folded sections.

FIG. **16** is a cross-sectional view of the liner and coating with six folded sections.

FIG. **17** shows a sheath covering the liner in the collapsed condition.

FIG. **18** shows a filament tearing a distal end of the sheath.

FIG. **19** shows the liner attached to the anchor.

FIG. **20** shows the liner attached to a tapered anchor.

FIG. **21** shows an anchor contained entirely within the internal carotid artery.

FIG. **22** shows the balloon expanding the anchor and blocking blood flow into the internal carotid artery.

FIG. **23** shows the liner and anchor of FIG. **22** deployed.

FIG. **24** shows a balloon-expandable stent introduced into the liner.

FIG. **25** shows the stent expanded.

FIG. **26**A shows an elongate element which opens the distal end of the liner.

FIG. **26**B shows the elongate element contained within a tube during delivery the liner.

FIG. **26**C shows the elongate element of FIG. **26**B advanced into a pocket of the liner to open the proximal end of the liner.

FIG. **26**D shows the stent introduced into the liner of FIG. **26**C.

FIG. **27** shows the delivery catheter for the anchor used to deliver a stent into the liner.

FIG. **28** shows the distal end of the stent of FIG. **27** expanded to trap plaque behind the liner.

FIG. **29** shows the delivery catheter for the anchor used to deliver a distal anchor.

FIG. **30** show the delivery catheter in position for delivering the distal anchor.

FIG. **31** shows the distal anchor deployed so that the proximal and distal ends of the liner are expanded.

FIG. **32** shows another stent delivered between the proximal and distal anchors.

FIG. **33** shows the stent of FIG. **32** expanded.

FIG. **34** shows a delivery catheter having an expandable section for opening the proximal end of the liner.

FIG. **35** shows the proximal end of the liner opened with the expandable section.

FIG. **36** shows the stent advanced through the liner.

FIG. **37** shows the stent partially expanded.

FIG. **38** shows the stent expanded into contact with the vessel wall and the liner released from the delivery catheter.

FIG. **39** shows the stent fully expanded.

FIG. **40** show a filter passed through the liner.

FIG. **41** shows the liner everting when deployed.

FIG. **42** shows the liner partially everted.

FIG. **43** shows the liner almost completely everted and the distal end released.

FIG. **44** shows the liner released from the delivery catheter.

FIG. **45** shows another delivery catheter which holds the proximal end of the liner open.

FIG. **46** shows the stent advanced through the liner of FIG. **45**.

FIG. **47** shows another delivery catheter for the liner.

FIG. **48** shows still another delivery catheter for the liner.

FIG. **49** shows yet another delivery catheter for the liner.

FIG. **50** shows a distal end of the liner trapped in a fold.

FIG. **51** shows a kit having devices and instructions for use in accordance with the present invention.

FIG. **52** shows still another liner in accordance with the present invention.

FIG. **53** shows the liner of FIG. **52** with a bumper advanced adjacent to the anchor.

FIG. **54**A shows the retention element retracted to expose the anchor and permit the anchor to expand.

FIG. **54**B shows the liner having anchors at both ends.

FIG. **54**C shows the liner having the anchor extending the length of the liner.

FIG. **55** shows an alternative embodiment of the device of FIG. **52**.

FIG. **56** shows another alternative embodiment of the device of FIG. **52**.

FIG. **57** shows yet another liner in accordance with the present invention.

FIG. **58** shows the device of FIG. **57** with the anchor expanded and the liner released.

FIG. **59** shows a preferred anchor in an expanded position.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A system **2** for protecting vessels during intravascular procedures is shown in FIGS. **1–4**. Although the present invention is described in relation to treatment of atherosclerotic disease of the internal carotid artery and the particular problems encountered when working in the carotid arteries, the liner may be used in other vessels such as saphenous vein grafts of coronary bypass procedures, iliac and coronary arteries. A guide catheter **4** is introduced through the femoral artery and advanced to the common carotid artery in the conventional manner. The guide catheter **4** has a hemostasis valve **6** which receives a liner delivery catheter **8**. The guide catheter **4** may be omitted without departing from the scope of the invention.

A liner **10** is used to protect the body passageway when passing other devices through the body passageway. For example, the liner **10** may be used to protect the carotid artery to prevent plaque from being dislodged when passing other devices through the carotid artery. A proximal end **11** of the liner **10** may be attached to an anchor **12** which expands and opens the liner **10** and holds the liner **10** against the vessel wall to reduce or eliminate flow around the liner. The liner is preferably non-metallic and is relatively flexible to conform to the body passageway. The anchor **12**, as will be discussed below, is mounted to one end of the liner **10** while the other end of the liner **10** is preferably free. Of course, the anchor **12** may be provided at both ends or throughout the liner **10** without departing from the scope of various aspects of the present invention. The liner **10** is advanced through the vessel in the collapsed condition of FIG. **2** so that the liner **10** can be advanced through small or highly stenosed vessels. After the liner **10** is in position, other devices, such as a stent **26** (FIG. **25**) or filter (FIG. **40**), may be passed through the liner **10** so that the liner **10** prevents contact between the device and the vessel wall. The liner **10** may also be used to protect the vessel when advancing other devices such as angioplasty balloons, drug delivery catheters, laser catheters or ultrasound catheters. FIG. **3** shows both ends of the liner **10** opened to trap plaque behind the liner **10** so that loose plaque cannot flow downstream. The liner **10** is preferably delivered over a conventional guidewire **15** which has a 0.010–0.018 inch diameter but may be of any other suitable size depending upon the vascular site.

The liner **10** is preferably made of expanded PTFE having a thickness of 0.006 to 0.0005 inch, more preferably 0.001 to 0.002 inch and most preferably about 0.001+/–0.0005 inch although any other suitable material may be used. For example, the liner **10** may have a woven construction such as silk or polyester as shown in FIG. **5**. The liner **10** may also have small openings **25** or perforations which act similar to a filter in that they permit blood to flow through but prevent large emboli from escaping (FIG. **6A**). The openings **25** also may promote tissue growth. The liner **10** is also preferably thin enough and has a porosity sufficient to allow tissue throughgrowth. Referring to FIG. **6B**, the liner **10** may also have a scalloped distal end **7** to form a smoother transition at the distal end when collapsed. The liner **10** may also have a radiopaque marker **9**, such as a 0.002 inch by 0.008 inch platinum ribbon, embedded, sewn, or folded into the liner **10**. The liner **10** may have the markers **9** extending longitudinally (FIG. **6B**) or circumferentially. When the markers **9** extend longitudinally, three markers **9** are preferably provided 120 degrees apart.

The liner **10** may also be elastic so that the liner **10** remains substantially cylindrical and without folds in the collapsed and expanded positions. When using an elastic liner **10**, the liner **10** is preferably a tube of low durometer silicone, latex or natural rubber, thermoplastic elastomers such as Kraton or hydrogenated thermoplastic isoprenes having a thickness of 0.001 to 0.0005 inch. Alternatively, the liner **10** could be made of an inelastic but plastically deformable material. Initially the liner **10** would be sized to allow easy passage of the devices such as the balloons, stents and filters described herein. The liner **10** is then plastically deformed by the devices which pass therethrough. For example, a pre-dilatation balloon may be introduced to dilate the liner **10**. The stent **27** can then be advanced into the dilated liner **10** and expanded to open the narrowed vessel. Expansion of the stent continues plastic deformation of the liner **10** to a final size. Any of the liners **10** described herein may be substituted for any of the other liners **10** without departing from the scope of the invention.

FIGS. **7–12** show a preferred method of collapsing the liner **10**. The liner **10** is folded longitudinally along creases **13** to create at least 2 and preferably 4–6 folded sections **14**. Four folded sections **14** are shown in FIG. **11** and six folded sections **14** are shown in FIG. **7** and **9**. The folds **14** are then wrapped as shown in FIGS. **8**, **10** and **12**. The liner **10** may, of course, be wrapped in any other manner. For example, the liner **10** may be spiral wrapped or randomly compressed and set with high pressure and/or heat. The folded sections **14** may be adhered to one another by application of heat which holds the folded sections **14** together without melting and fusing the sections **14** together. Another method of holding the liner **10** in the collapsed position is to apply an adhesive **16** such as medical grade glue, cyanoacrylates, epoxies, ultraviolet activated adhesives, low molecular weight polyvinyl alcohol polymer, gelatin and sucrose. The liner **10** may also be partially or completely covered with a coating **20** which dissolves in blood such as sugar (FIGS. **13–16**). In particular, the distal end **19** of the liner **10** may be covered with the coating **20** to form a smooth, atraumatic end as shown in FIG. **13**. The coating **20** may extend along the length of the liner **10** as shown in FIG. **14** or may be only at the distal end or intermittent as shown in FIG. **13**.

The liner **10** may also be covered by a removable sheath **21** as shown in FIGS. **17** and **18**. The sheath may be removed in any manner such as tearing along perforations or with a chemical, thermal or electrolytically severable bond. A filament **23** may also be used to tear the sheath **21** as shown in FIGS. **17** and **18**. The filament **23** may have both ends extending through the catheter rather than having one end extend out of the catheter. The filament **23** is shown separated from the sheath **21** for clarity but would either pass inside the sheath **21** or would be partially embedded in the sheath **21**. The sheath **21** can also be a simple retractable sheath **21** as is known in the art.

Referring again to FIGS. **10** and **12**, the liner **10** is collapsed onto the guidewire **15** so that the liner **10** has an outer diameter α of no more than 0.065 inch, more prefer-

ably no more than 0.040 inch, and most preferably no more than 0.026 inch. Stated another way, the thickness β of the liner **10** is preferably no more than 0.015 inch, more preferably no more than 0.012 inch, and most preferably no more than 0.008 inch when measured in a radial direction. For a guidewire **15** having a 0.014 inch diameter, the liner **10** is preferably collapsed so that the outer diameter α is 0.020 to 0.032 inch, preferably about 0.026 inch, and the thickness β of the liner **10** is 0.004 to 0.008 inch, preferably about 0.006 inch. For a guidewire **15** having a 0.018 inch diameter, the liner **10** is preferably collapsed so that the outer diameter α is still about 0.020 to 0.032 inch, preferably about 0.026 inch, and the thickness β of the liner **10** is 0.003 to 0.006 inch, preferably about 0.004 inch. The liner **10** also has a high ratio of collapsed cross-sectional area to expanded circumference in the range of 1:10 to 1:30 and preferably at least 1:20.

The relatively small size of the liner **10** advantageously permits the liner **10** to be introduced through small and heavily stenosed vessels. The carotid artery is often occluded 95 to 98% and may have diameters as small as 0.020 inch or even 0.010 inch before surgical or interventional procedures are performed. Conventional stents used in the internal carotid artery have a collapsed diameter of about 0.065 to 0.092 inch and, thus, must often displace the plaque to pass through the vessel. It is believed that some strokes which occur when using stents in the carotid artery are caused by plaque which is dislodged when the stent is advanced through and expanded within highly stenosed regions. The liner **10** of the present invention protects the vessel as the stent or other device is passed through the vessel. The liner **10** preferably has a length γ of at least 2 cm and preferably 2–10 cm (FIG. **2**). The liner **10** and anchor **12** have a diameter of 4–10 mm in the expanded condition with the specific size selected depending upon the size of the vessel being treated. The relative dimensions shown in the drawing have been exaggerated to illustrate the features of the invention. In fact, the liner **10** has a length to width ratio (γ to α) in the collapsed position of at least 20 to 1, 50 to 1, 80 to 1, and even up to 200 to 1 depending upon the particular application. The liner **10** preferably increases in outer diameter at least 5, more preferably at least 6 and most preferably at least 8 times when moving from the collapsed to expanded positions.

Referring again to FIGS. **3** and **4**, the anchor **12** may be attached to the proximal end **11** of the liner **10** to expand the end **11** of the liner **10**, hold the liner **10** in position and reduce flow around the liner **10**. The anchor **12** may be any suitable device including a commercially available nitinol or stainless steel stent such as the MULTILINK manufactured by ACS and the NIR manufactured by Scimed. The liner **10** is attached to a portion of the anchor **12** with an adhesive, mechanical interconnection, thermal bond, suture or the like, or fused or soldered with radiopaque wire or ribbon. The liner **10** may, of course, be attached in any other manner. The liner **10** may also be encapsulated between layers of expanded PTFE.

The anchor **12** and liner **10** may form a continuous, cylindrical shape in the expanded position (FIG. **19**) or the anchor **12** may have a tapered shape, (FIG. **20**). The tapered shape of the anchor **12** may be useful when used in the carotid arteries with the small end positioned in the internal carotid artery and the large end in the common carotid. A method of forming the expanded shape of FIG. **20** is for the anchor **12** to have a larger diameter than the liner **10** so that the liner **10** holds an end of the anchor **12** at a smaller diameter. For example, the anchor **12** may be a stent having an 8 mm diameter with the liner **10** having a 6 mm expanded diameter so that the liner **10** holds the end **11** of the anchor **12** to about 6 mm. Alternatively, the anchor **12** could be designed to expand to different predetermined diameters at different points along its length by varying strut lengths along its length.

The anchor **12** is positioned within an anchor retention catheter **22** (FIG. **2**). The anchor **12** is naturally biased to the expanded condition of FIG. **3** and is held in the collapsed position by the retention catheter **22**. The anchor **12** is deployed by retracting the catheter **22** while an inner element **24** holds the anchor **12** at the desired location in the vessel. The liner **10** is advanced over the guidewire **15** which is advanced ahead of the catheter **22**.

The anchor **12** may be deployed to extend into the common carotid artery at the bifurcation of the external and internal carotid arteries (FIG. **2**) or may be contained entirely within the internal carotid artery (FIGS. **21–23**). The anchor **12** may also be deployed by inflating a balloon **27** as shown in FIG. **21** or may be a shape memory material which is heat activated. When using a balloon **27** to expand the anchor **12**, the anchor **12** is preferably a conventional nitinol or stainless steel stent although any suitable stent or device may be used. The balloon **27** is preferably compliant so that a proximal portion of the balloon **27** expands to occlude the vessel as shown in FIG. **21** before expansion of the anchor **12**. Alternatively, the balloon could be non-compliant but designed to inflate at a lower pressure than that required to expand the stent. By occluding the vessel, blood flow through the vessel is stopped so that even if plaque is released the plaque will not flow downstream. Further inflation of the balloon **27** (using inflation source **39**) expands the anchor **12** into engagement with the vessel wall (FIG. **22**). Any of the embodiments of the liner **10** described herein may be used with balloon or self-expanding anchors **12** and stents **26**.

After the anchor **12** has been expanded, the liner **10** can be configured to automatically open with blood pressure (FIG. **3**). Alternatively, the catheter **22** may be advanced through the liner **10** to partially open the liner **10**. The device, such as the stent **26**, may also be advanced through the liner **10** to open the liner **10**. The liner **10** protects the vessel to prevent intravascular devices from dislodging plaque when passing through the vessel. The distal end of the liner **10** may also be opened with an elongate element **29**, such as a nitinol wire, advanced into the liner **10** to open the liner **10** as shown in FIG. **26A**. The element **29** may be advanced and retracted independently with an inner actuator **31**.

Referring to FIGS. **26B** and **26C**, the elongate element **29A** may also be advanced into a pocket **35** in liner **10A**. The pocket **35** is preferably formed by simply inverting or everting the end of the liner **10A** and attaching the end to another part of the liner **10A** to form the pocket **35**. The elongate element **29A** passes through a tube **41**, preferably a hypotube, polymer tube or composite tube, which is releasably attached to the pocket **35**. The tube **41** is preferably released by heat, electrolytic detachment, mechanical detachment, dissolution of a bond by blood, or retraction of a retention cord although any suitable method may be used.

The elongate element **29A** is preferably made of a superelastic material, such as nitinol, which forms a loop **47** in the expanded position. The elongate element **29A** is contained within the tube **41** when the liner **10A** is advanced through the vasculature. The liner **10A** is advanced over the guidewire **15** by pushing the tube **41**. When the user is ready

to expand the proximal end of the liner **10A**, the element **29A** is advanced into the pocket **35** so that the loop **47** opens the liner **10A** as shown in FIGS. **26C** and **26D**. After opening the proximal end of the liner **10A**, the liner **10** may be used in any manner described herein. For example, the stent **26** may be advanced into the liner **10A** to open the narrowed region of the blood vessel as described in further detail below and shown in FIGS. **26D** and **26E**.

When the device introduced into the liner **10** is the stent **26**, the stent **26** is preferably expanded to open the narrowed portion of the vessel as shown in FIG. **25**. The stent **26** is mounted to a balloon **33** which is coupled to an inflation source **37** (FIG. 1) for inflating the balloon **33**. The stent **26** is preferably a conventional nitinol or stainless steel stent. The delivery catheter **22** is preferably introduced into the liner **10** as shown in FIG. **27** with the distal end of the catheter **22** positioned beyond the end of the liner **10**. The catheter **22** is then retracted to expose the distal end of the stent **26**. The distal end of the stent **26** is preferably opened first so that plaque is trapped between the anchor **12** and stent **26** when expanding the rest of the stent **26**. The liner **10** may have the openings **25** (FIG. **5**) which effectively filter blood trapped behind the liner **10** and help to equalize pressure on opposite sides of the liner as the stent **26** is expanded. The catheter **22** may also be used to deliver a distal anchor **43** which holds the distal end of the liner **10** open as shown in FIGS. **29–31**. Of course, the distal anchor **43** may be already attached to the liner **10** before introduction without departing from the scope of the invention. Another stent **45** can then be delivered to expand the liner **10** between the anchor and distal anchor **43** (FIGS. **32** and **33**).

Referring to FIGS. **34–39**, the proximal end of the liner **10** may be expanded by delivery catheter **50** and then released so that the anchor **12** is not required. The catheter **50** has an expanding section **32** which is preferably inflatable but may also be mechanically actuated. The expanding section **32** is coupled to a lumen for inflating Ad the expanding section **32**. The liner **10** is attached to the expanding section **32** with any suitable connection such as glue, suture, or soldered with radiopaque wire or ribbon. The liner **10** is preferably attached to the expanding section **32** with a thread **34** which passes through the liner **10** and expanding section **32**. An end of the thread **34** is pulled to release the liner **10**.

The expanding section **32** is inflated to expand the proximal end of the liner **10** as shown in FIG. **35**. The stent **26** or other device may then be passed through the liner **10** to open the liner **10** further as shown in FIG. **35**. Referring to FIG. **38**, the stent **26** is partially expanded so that the liner **10** is held firmly in place by the stent. The liner **10** is then detached by pulling the thread **34** and the stent **26** is fully expanded. Referring to FIG. **40**, the device may also be a filter **36** which is advanced through the liner **10** to trap dislodged plaque during an angioplasty, stent or other procedure. The liner **10** may then be removed before removing the filter **36** or may be used to line the vessel when deploying the stent **26**.

Referring to FIGS. **41–44**, the liner **10** may also be everted when moving from the collapsed to expanded positions. The liner **10** has the anchor **12** which is self-expanding and held in the collapsed position by retention catheter **37**. Pusher element **38** holds the anchor **12** in place while retracting the retention catheter **37**. A proximal end **40** of the liner **10** is releasably attached to an inner member **42**. The liner **10** is pressurized, preferably with saline, using lumen **44** in the pusher element **38**. Once the liner **10** is pressurized, the inner member **42** is advanced so that the liner **10** everts and moves through the vessel as shown in FIGS. **42–43**. An advantage of the everting liner **10** is that sliding forces between the liner **10** and the vessel wall are reduced when advancing the liner **10**.

After the liner **10** has been fully everted, the retention catheter **37** is retracted so that the anchor **12** expands and holds the proximal end of the liner **10** open. The liner **10** is then detached from the inner member **42**. The liner **10** may have a mechanical connection which is released with a push rod or guidewire **43**. The liner **10** may also have a severable bond with the inner member **42** such as a thermally, chemically or electrolytically severable bond using the guidewire **43**. The device, such as the stent **26**, is then delivered through the liner **10**.

Referring now to FIGS. **45** and **46**, the liner **10** may also be held open slightly at the proximal end **11** by delivery catheter **60**. The proximal end **11** of the liner is preferably held open to a diameter of 6 mm to 8 mm or 4 Fr to 7 Fr. One or more filaments **62** hold the liner to the catheter **60**. The liner **10** extends over the distal end of the catheter **60** but may also be mounted inside the catheter **60**. The filaments are shown separated from the body of the catheter **60** for clarity but would, of course, either pass through the catheter or be held close to the catheter **60**. The distal end of the stent **26** is inflated first to trap the plaque behind the liner **10** and reduce flow around the liner **10**. The rest of the stent **26** is then expanded in the conventional manner.

Referring to FIG. **47**, another catheter **70** for delivering the liner **10** is shown wherein the same or similar reference numbers refer to the same or similar structure. The catheter **70** operates similar to catheter **22** described above in that the liner **10** is mounted to the self-expanding anchor **12**. The anchor **12** is held in the collapsed position of FIG. **47** by an outer wall **72** of the catheter **70**. The outer wall **72** is retracted to expose the anchor **12** and permit the anchor **12** to expand.

The liner **10** is positioned between a flexible sheath **74** and an inner tube **76**. The sheath **74** and inner tube **76** prevent the liner **10** from contacting the walls of the vessel and guidewire **15** when the liner **10** is advanced through the vasculature. The sheath **74** and tube **76** also hold the liner **10** in the collapsed position although the liner **10** may be collapsed without requiring the sheath **74** and tube **76**. The sheath **74** is attached to the outer wall **72** and is retracted together with the outer wall **72**.

A shaft **80** extends through the catheter **70** and a flexible shaft extension **82** extends from the shaft **80**. The shaft extension **82** and inner tube **76** provide a relatively flexible distal portion to navigate tortuous vessels such as the cerebral vasculature. The flexible shaft extension **82** may be a coil **84** as shown in FIG. **47** or may be a tube **86** of material as shown in FIG. **48**. A distal portion **88** of the catheter **70**, which extends from the distal end of the shaft **80**, is preferably more flexible than a proximal portion **90** which terminates at the end of the shaft **80**.

Referring to FIG. **47**, the guidewire **15** passes through slots **93**, **95** in the outer wall **72** and shaft **80** for loading the device on the guidewire **15**. Referring to FIG. **48**, the guidewire **15** may also pass through slots **92**, **97**, **99** in the outer wall **72**, inner tube **76** and shaft extension **82**. The catheter **70** may, of course, have a continuous lumen which extends to the proximal end of the catheter **70**. Referring again to FIG. **47**, a handle **94** is attached to the outer wall **72** and is pulled relative to the shaft **80** to retract the sheath **74** and outer wall **72**. The outer wall **72** is preferably made of high density polyethylene having a thickness of about 0.005 inch and an outer diameter of 0.040 to 0.070 inch, preferably

about 0.055 inch. The outer wall **72** preferably has a length of 110 to 150 cm and preferably about 135 cm. The sheath **74** is preferably made of linear low density polyethylene having a wall thickness of about 0.002 inch and an outer diameter of about 0.049 inch. The inner tube **76** is preferably made of polyimide having a wall thickness of 0.0005 to 0.001 inch and an outer diameter of 0.014 to 0.026 inch, more preferably 0.018 to 0.024 inch and most preferably about 0.022 inch. The liner **10** is collapsed to have a diameter, length, thickness and length to thickness ratios as described above when mounted to the tube **76**. The shaft **80** is preferably a 0.022 inch diameter stainless steel mandrel and the shaft extension **82** is preferably a stainless steel coil. The shaft extension is fused to the inner tube **76** (FIG. **47**). The extension **82** may also be a tube of linear low density polyethylene which is extruded and then irradiated with 25/30 Mrads to an outer diameter of about 0.040 and a wall thickness of about 0.018 inch (FIG. **48**). Any other suitable materials may be used without departing from the scope of the invention.

The catheter **70** and liner **10** are used in substantially the same manner as the catheters and liners **10** described above and the discussion above is equally applicable here. The liner **10** is advanced over the guidewire **15** to a narrowed region of a blood In vessel such as the internal carotid artery. The liner **10** and catheter have a small profile, as discussed above and incorporated here, so that the liner **10** may be advanced into the narrowed region without dislodging plaque. When the liner **10** is at the desired location, the handle **94** and shaft **80** are manipulated to retract the sheath **74** and the outer wall **72**. When the outer wall **72** and sheath **74** are retracted, the anchor **12** is free to expand. The liner **10** may then be used in the manner described above. For example, the stent **26** or filter **36** may be advanced into the liner **10**.

Referring to FIG. **49**, another catheter **100** for delivering the liner **10** is shown. The catheter **100** has the self-expanding anchor **12** which is held in the collapsed position by a collar **102**. An arm **104** is attached to the collar **102** which in turn is attached to a first core-wire **106**. The first core wire **106** passes through a shaft **108** which has a handle **110** mounted to the proximal end. The handle **110** is retracted to pull the core wire **106**, first arm **104** and collar **102** for releasing the self-expanding anchor **12**.

A tube **112** is fused to the shaft **108** and an inner tube **114** is attached to the tube **114**. The arm **104** travels in a slot **116** in the tube **114** to stabilize retraction of the collar **102**. The tube **112** and inner tube **114** form a lumen **118** through which the guidewire **15** passes.

Referring to FIG. **50**, the distal end of the liner **10** is locked into a fold **120** at the end of the inner tube **114**. A wire loop **122** holds the liner **10** in the fold **120**. The wire loop **122** is preferably attached to the collar **102** with a wire **124** embedded in the collar **102**. The wire loop **122** is retracted together with the collar **102** so that the distal end of the liner **10** is released as the collar **102** is retracted. The wire loop **122** is preferably a 0.005 inch diameter stainless steel wire. The fold **120** is preferably made of silicone although other suitable materials may be used. The shaft **108** is preferably made of stainless steel hypotube having a wall thickness of about 0.005 inch and an outer diameter of about 0.024 inch. The tube **112** is preferably made of linear low density polyethylene having a wall thickness of about 0.004 inch and an outer diameter of about 0.040 inch. The inner tube **114** is preferably made of polyimide having a thickness of 0.0005 inch and an outer diameter of about 0.022 inch. The liner **10** is deployed and used in substantially the same manner as described above and the discussion above is applicable here.

Referring to FIG. **52**, yet another device **200** is shown. The device has a liner **202** and an anchor **204** which may be any liner or anchor described herein or any other suitable anchor or liner. The anchor **204** is attached to the proximal end of the liner **200** in any suitable manner such as with an adhesive such as a UV curable polyurethane. As with any of the liners described herein, the liner **200** and anchor **204** may have any of the dimensions and features described herein and may be used in any manner described herein without departing from the scope of the invention. The device **200** is advanced over a guidewire **206** which preferably has a diameter of 0.018 inch but may be any size. The guidewire **206** passes through a guidewire tube **208** which is preferably a polyimide tube having an inner diameter of 0.020 inch and a wall thickness of about 0.001 inch.

The anchor **204** is held in the collapsed position of FIG. **52** by a retention element **210** which has a size of about 4–8 French and preferably about 6 Fr. The retention element **210** has a length of 0.1–1.0 inch and more preferably 0.200–0.600 inch. A proximal end of the retention collar **210** has an opening **212** to receive the guidewire **208**.

A bumper **214** is contained within the retention element **210** and is used to release the anchor **204** from the retention element **210** in the manner described below. An elongate element **216**, such as a cable **218**, is coupled to the bumper **214** for manipulating the bumper **214**. The elongate element **216** passes through an actuator tube **220** coupled to the retention element **210**. The actuator tube **220** is relatively small and has a size of no more than 0.030 inch and preferably no more than 0.025 inch. The elongate element **216** and actuator tube **220** are coupled to an actuator **222** for manipulating the bumper **214**. The actuator **222** is shown schematically and can be formed in any suitable manner to provide relative movement as is known in the art. The bumper **214** is attached to the guidewire tube **208** so that the guidewire tube **208** moves with the bumper **214** in the manner described below. The bumper **214** is preferably a section of hypotube having an outer diameter suitable to slide within the retention element **210**.

The distal end of the liner **200** is trapped by a tip cover **224** which is preferably made of isoprene such as CHRONOPRENE sold by CardioTech. Of course, any other suitable material may be used. The tip cover **224** has an inner diameter which is somewhat smaller, preferably about 0.0005–0.002 inch smaller, than the outer diameter of the guidewire tube **208**. In this manner, the tip cover **224** applies a modest compressive force to the distal end of the liner **202** to hold the liner **202** in the collapsed position. The tip cover **224** lies partially over the guidewire tube **208** and partially over the liner **202**. The tip cover **224** may be bonded to the distal end of the guidewire tube **208** to prevent release of the tip cover **224**. Although the tip cover **2224** is preferred, any other mechanism for holding the sleeve in the collapsed position may be used including those described herein.

Use of the device **200** is now described with reference to FIGS. **52**–**54A**. The liner **202** is advanced over the guidewire **206** to a treatment site such as the internal carotid artery. The treatment site may require any treatment described herein including opening of a narrowed portion of a blood vessel as shown in FIG. **52**. Once the device **200** is in position, the bumper **214** is advanced adjacent to the anchor **204** as shown in FIG. **53** by manipulating the elongate element **216** with the actuator **222**. As the bumper **214** is advanced, the tip cover **224** is moved distally out of engagement with the liner

202 to release the distal end of the liner 202. The retention element 210 is then withdrawn while holding the bumper 214 in the same position to expose the anchor 204 and permit the anchor to expand as shown in FIG. 54A. The liner 202 is now in position to receive another medical device as described above. For example, a balloon could be advanced into the liner 202 and expanded to open the narrowed region. Alternatively, or in addition to use of the balloon, a stent may be advanced into the liner 202 and expanded for opening the narrowed portion of the vessel.

As mentioned above, any of the liners described herein may have the anchor at both ends (FIG. 54B) or throughout the liner (FIG. 54C) without departing from various aspects of the present invention. The anchor preferably has a relatively low opening force and does not significantly open the narrowed portion of the vessel (FIG. 54C). It is believe that barotrauma, or pressure-induced trauma, may contribute to restenosis when using conventional devices. The present invention provides low opening force thereby reducing barotrauma as compared to conventional methods and devices.

Referring to FIG. 55, another device 200A is shown wherein the same or similar reference numbers refer to the same or similar structure. The guidewire 206 has been reduced in size for clarity. The device 200A has the liner 202 and the anchor 204 which may be any liner or anchor described herein and all features, dimensions, methods of use and advantages of the liners and anchors described herein are equally applicable here. The device 200A is similar in structure and use to the device 200 except that the guidewire tube 208A is not attached to the bumper 214. The guidewire tube 208A is separate from the bumper 214 so that bumper 214 can be moved independent of release of the distal end of the liner 202 with the tip cover 224.

The device 200A is used in substantially the same manner as the device 200 except that the guidewire lumen 208A and the retention element 210 are advanced together to the target site. The user may then advance the bumper 214 adjacent to the anchor 204 before releasing the distal end of the liner 202. The anchor is then released by withdrawing the retention element 210. The distal end of the liner 200A is then released by simply advancing the guidewire tube 208A. Alternatively, the user may release the distal end of the liner 200A before advancing the bumper 214.

Referring now to FIG. 56, still another device 200B is shown wherein the same or similar reference numbers refer to the same or similar structure. The device 200B has the liner 202 and the anchor 204 which may be any liner or anchor described herein. The device 200B is similar in structure and use to the device 200 except that a retention element 210B extends over the liner 202 to hold the liner 202 in the collapsed position. The device 200B is used in the same manner as the device 200.

Referring now to FIG. 57, the distal end of another device 230 is shown. The device 230 has the liner 202 and the anchor 204 which may be any liner or anchor described herein and all features, dimensions and advantages of the liners and anchors described herein are equally applicable here. The liner 202 is trapped between an inner layer 232 and an outer layer 234. The liner 202 occupies a space 235 between the inner and outer layers 232, 234 and the manner in which the liner 202 is collapsed is not shown for clarity. The liner 202 is preferably collapsed in the manner described above or another suitable method.

The inner and outer layers 232, 234 are relatively thin and flexible. Specifically, the inner and outer layers 232, 234 have a thickness of no more than 0.002 inch and more preferably no more than 0.001 inch. The inner layer 232 is preferably a shrink tube having a thickness of about 0.0005–0.002 inch, preferably about 0.0005 inch, and an outer diameter of 0.021 inch. The outer layer 234 is preferably a PET shrink tube having a 0.001 inch thickness and an outer diameter of 0.0047 inch. The outer layer 234 preferably applies a modest compressive force to the liner 202 to hold the liner 202 in the collapsed position. To provide such a force, the outer layer 234 is sized about 0.0005–0.002 inch smaller than the collapsed diameter of the liner. The outer layer 234 preferably bas an outer diameter of less than 0.050 inch and more preferably less than 0.045 inch and most preferably about 0.043 inch. The inner and outer layers 232, 234 preferably extend to the proximal end of the device. The inner and outer layers 232, 234 advantageously hold the liner 202 in the collapsed position of FIG. 57 while still maintaining sufficient flexibility to pass through small, tortuous vessels.

The liner 202 may be collapsed in any manner described herein. For example, the liner 202 may have the folds 14 (FIGS. 7–12) which are wrapped around one another. The folds 14 may be formed in any suitable manner and a preferred manner is to tension the liner 202 to naturally create the folds 14. When the liner 202 is tensioned, the liner 202 naturally forms about 10–20 folds 14 which are then wrapped to collapse the liner 202 in the manner shown in FIGS. 7–12. The liner 202 is collapsed to the preferred dimensions described above, for example, tbe liner may have the length, collapsed length, thickness, and expanded sizes described above.

The inner layer 232 is preferably bonded to an inner element 236 and the outer layer 234 is preferably bonded to an outer element 238. The inner and outer elements 236, 238 are preferably tubes but may take other suitable shapes and configurations. The inner and outer elements 236, 238 can be moved relative to one another to retract the outer layer 234 and release the anchor 204 and liner 202 as described below. The outer element 238 may be made of any suitable material and a preferred material is a polyimide tube having a thickness of about 0.003 inch and an outer diameter of about 0.039 inch. Although it is preferred to provide the outer element 238, the device may also be practiced without the outer element 236 and only the outer layer 234 without departing from the scope of the invention.

The inner element 236 provides a lumen 237 for receiving the guidewire. The lumen 237 preferably has a diameter of 0.010–0.030 inch, more preferably 0.015–0.025 inch and most preferably about 0.017 inch. The inner element 236 is preferably polyetherether ketone having a thickness of about 0.007 inch and an outer diameter of about 0.035 inch. The guidewire 206 may have any suitable size and s preferably a 0.014 inch guidewire. The inner element 236 preferably has a spiral cut 39 near the distal end to enhance flexibility and prevent kinking. The spiral cut 239 forms sections having a length of about 0.003–0.004 inch.

As mentioned above, the device, and in particular the liner 202 and the anchors 204, may take any of the dimensions, features and advantages of the other liners and anchors described herein. The device may also have the following dimensions. The diameter of the outer layer extending over the liner and anchor is preferably no more than 0.055 inch, more preferably no more than 0.050 inch and most preferably no more than 0.040 inch. The outer layer 232, liner 202 and inner layer 234 together form a relatively small radial thickness, preferably about 0.007–0.015 and more preferably 0.007–0.013 inch.

The inner and outer layers **232, 234** preferably continue beyond the distal end of the liner and a radiopaque coil **240**, such as a platinum coil, extends between and beyond the layers **232, 234**. The coil **240** preferably has a diameter of 0.003 inch and is wound to a diameter of about 0.018 inch. The coil **240** extends for a total length of about 0.300 inch with an exposed length beyond the inner and outer layers **232, 234** of about 0.250 inch. The outer layer **234** tapers down distal to the liner **202** to a diameter of less than 0.035, more preferably less than 0.030 and most preferably about 0.024 inch.

Use of the device **230** is now described. The device **230** is advanced through the vasculature to a treatment site. The outer layer **238** is then retracted while holding the inner element **236** to expose the liner **202** and anchor **204** thereby permitting the anchor **204** to expand as shown in FIG. **58**. As the anchor **204** expands, the liner **202** is released and expands together with the anchor **204**. After deployment of the liner **202**, any medical device described herein, including a device to open a narrowed region of a blood vessel such as a stent, may be advanced into or through the liner **202**.

Referring to FIG. **59**, a preferred anchor **204A** is shown in an expanded and position. As mentioned herein, any of the anchors may be used with any of the liners without departing from the scope of the invention. The anchor **204A** is formed by laser cutting or etching a tube which is preferably made of a superelastic material such as nitinol. As an example, the anchor **204A** may have an outer diameter of about 0.060 inch and a wall thickness of about 0.006 inch. The tube is cut or etched to form first and second sections **242, 244** connected by longitudinal connecting elements **246**. Each section **242, 244** is formed by struts **248** connected end to end in a zig-zag pattern to form a closed loop **250**. As mentioned above, the anchor **204A** may be similar to a stent or any other suitable device for holding the liner **202** at the desired location. The preferred anchor **204A** of the present invention does, however, differ from conventional stents as described below.

The preferred anchor **204A** of FIG. **59** is shorter than conventional stents to provide reduced interference with branch vessels. The anchor **204A** has a length of less than 15 mm, more preferably less than 10 mm when expanded. The relatively small length provides flexibility to access small, tortuous vessels. The anchor **204A** can be somewhat short since the anchor **204A** is simply holding the liner in place during introduction of other devices, such as the stent, into the liner **202**. The anchor **204A** also preferably has a relatively low opening force since the anchor **204A** is not intended to provide significant opening of the vessel. Although the anchor **204A** is shorter and has a lower opening force than a conventional stent, the anchor **204A** may differ from conventional stents in more or fewer ways without departing from various aspects of the present invention.

The present invention is also directed to kits **124** which include various assemblies as described above. For example, the kit **124** may include the liner **10**, delivery catheter **22** and instructions for use **128** setting forth any of the methods described herein as shown in FIG. **51**. The kits may, of course, also include the stent(s) **26**, anchors **12** and stent delivery catheter(s) **22** and/or the filter **36** as well. The kits **124** will usually include a container **126**, such as a pouch, tray, box, tube, or the like, which contains the devices as well as the instructions for use **128**. The instructions for use **128** may be set forth on a separate instructional sheet within the package or printed in whole or in part on the packaging itself. Optionally, other system components useful for performing the methods of the present invention could be provided within the kit **124**, including guidewires, introductory sheaths, guiding catheters, and the like. Any of the devices described herein may form a kit with instructions setting forth a method of the present invention.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims. For example, any of the delivery catheters may have a balloon for occluding the vessel while delivering the liner or advancing the device through the liner and any of the liners may have perforations to filter blood or may be made of a tightly woven material. Furthermore, the preferred dimensions described herein with respect to any of the embodiments is equally applicable to other embodiments. Finally, all aspects of the present invention may also be practiced with the delivery of drugs, radiation and drugs for anti-restenosis and anti-platelet adhesion.

What is claimed is:

1. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer;

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer; and

a radiopaque coil extending beyond the distal end of the liner and the inner and outer layers, the radiopague coil also being positioned at least partially between the inner and outer layers.

2. The device of claim **1** wherein:

the outer layer holds the anchor in the collapsed position.

3. The device of claim **1** wherein:

the outer layer has a thickness of 0.0005–0.002 inch.

4. The device of claim **1** wherein:

the outer layer stretches over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer.

5. The device of claim **1** further comprising:

an inner element positioned beneath the liner and the anchor, the inner layer being attached to the inner element.

6. The device of claim **5**, wherein:

the inner layer has a thickness of 0.0005–0.002 inch.

7. The device of claim **1** wherein:

the outer layer has a diameter of no more than 0.055 inch when in the collapsed position.

8. The device of claim **1** wherein:

the outer layer has a diameter of no more than 0.050 inch when in the collapsed position.

9. The device of claim **1** wherein:

the outer layer applies a compressive force to the liner to hold the liner in the collapsed position.

10. The device of claim **1** wherein:

the outer layer lies directly over the anchor and holds the anchor in the collapsed position, the outer layer being retracted by an outer element to expose the anchor and permit the anchor to move to the expanded position.

11. The device of claim 1 wherein:

the liner is collapsed by forming a number of folds.

12. The device of claim 1 wherein:

the liner is made of expanded PTFE.

13. The device of claim 1 wherein:

the inner and outer layers extend beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer.

14. The device of claim 1 wherein:

the inner liner is attached to an inner element, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer.

15. The device of claim 14, wherein:

the inner element is spiral cut at a distal end.

16. The device of claim 15, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

17. The device of claim 1 wherein:

the anchor has a length of less than 15 mm when collapsed.

18. A method of lining a vessel, comprising the steps of:

providing an expandable anchor, a liner, an inner layer, and an outer layer, the anchor and liner being movable from a collapsed shape to an expanded shape, the liner being attached to the anchor and extending from an end of the anchor, the outer layer being slidable relative to the inner layer, the outer layer extending over the liner and the anchor in the collapsed position, the radiopaque coil extending beyond the distal end of the liner and the inner and outer layers, the radiopaque coil being positioned at least partially between the inner and outer layers;

advancing a medical device to a treatment site;

retracting the outer layer to expose the liner and the anchor to permit the anchor to expand; and

advancing the medical device into the liner after the retracting step.

19. The method of claim 18 wherein:

the providing step is carried out with the outer layer holding the anchor and the liner in the collapsed position.

20. The method of claim 18 wherein:

the providing step is carried out with the outer layer having a thickness of 0.0005–0.002 inch.

21. The method of claim 18 wherein:

the providing step is carried out with the outer layer having a tapered portion when the anchor is in the collapsed position; and

the retracting step is carried out with the outer layer stretching over the tapered portion as it passes over the tapered portion.

22. The method of claim 21, wherein:

the providing step is carried out with the inner layer having a thickness of 0.0005–0.002 inch.

23. The method of claim 18 wherein:

the providing step is carried out with the outer layer having a diameter of no more than 0.050 inch when in the collapsed position.

24. The method of claim 18 wherein:

the providing step is carried out with the outer layer having a diameter of no more than 0.045 inch when in the collapsed position.

25. The method of claim 18 wherein:

the providing step is carried out with the outer layer lying directly over the anchor to hold the anchor in the collapsed position;

the retracting step being carried out so that the outer layer is retracted to expose the anchor and permit the anchor to expand.

26. The method of claim 18 wherein:

the providing step is carried out with the liner collapsed by forming a number of folds which are folded around one another.

27. The method of claim 18 wherein:

the providing step is carried out with the liner being made of expanded PTFE.

28. The method of claim 18, wherein:

the advancing step is carried out with the medical device being a medical device selected from the group consisting of a stent, an angioplasty balloon, a filter, a drug delivery device, and an atherectomy device.

29. The method of claim 18 wherein:

the providing step is carried out with the inner layer being attached to an inner element; and

the retracting step is carried out with the inner element contacting the anchor to hold the anchor in place while retracting the outer layer.

30. The method of claim 29, wherein:

the providing step is carried out with the inner element having a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

31. The method of claim 18 wherein:

the providing step is carried out with the outer layer attached to an outer element; and

the retracting step is carried out with the outer element being retracted with the outer layer.

32. The method of claim 18 wherein:

the providing step is carried out with the anchor having a length of less than 15 mm when collapsed.

33. A method of opening a narrowed region in a blood vessel, comprising the steps of:

providing a liner movable from a collapsed condition to an expanded condition;

advancing the liner to a narrowed region of a blood vessel with the liner in the collapsed position;

passing at least a portion of the liner through the narrowed region of the blood vessel in the collapsed position;

moving a stent into the liner after the passing step so that the stent is also positioned in the narrowed region of the blood vessel; and

expanding the stent after the moving step so that the stent expands the liner and opens the narrowed region of the vessel.

34. The method of claim 33, wherein:

the advancing and passing steps are carried out with the blood vessel being a vessel selected from the group comprising the internal carotid artery and saphenous vein graft.

35. The method of claim 33, further comprising the step of:

expanding at least part of the liner before expanding the stent.

36. A device for lining a vessel, comprising:

An expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer; and

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer, the outer layer stretching over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer;

wherein the inner layer is attached to an inner element, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer, the inner element being spiral cut at a distal end.

37. The device of claim **36** wherein:

the outer layer holds the anchor in the collapsed position.

38. The device of claim **36** wherein:

the outer layer has a thickness of 0.0005–0.002 inch.

39. The device of claim **36** further comprising:

an inner element positioned beneath the liner and the anchor, the inner layer being attached to the inner element.

40. The device of claim **39** wherein:

the inner layer has a thickness of 0.0005–0.002 inch.

41. The device of claim **36** wherein:

the outer layer has a diameter of no more than 0.055 inch when in the collapsed position.

42. The device of claim **36** wherein:

the outer layer has a diameter of no more than 0.050 inch when in the collapsed position.

43. The device of claim **36** wherein:

the outer layer applies a compressive force to the liner to hold the liner in the collapsed position.

44. The device of claim **36** wherein:

the outer layer lies directly over the anchor and holds the anchor in the collapsed position, the outer layer being retracted by an outer element to expose the anchor and permit the anchor to move to the expanded position.

45. The device of claim **36** wherein:

the liner is collapsed by forming a number of folds.

46. The device of claim **36** wherein:

the liner is made of expanded PTFE.

47. The device of claim **36** further comprising:

radiopaque coil extending beyond the distal end of the liner and being positioned at least partially between the inner and outer layers.

48. The device of claim **47**, wherein:

the radiopaque coil extends beyond the distal end of the inner and outer layers.

49. The device of claim **36**, wherein:

the inner and outer layers extend beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer.

50. The device of claim **36**, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

51. The device of claim **36**, wherein:

the anchor has a length of less than 15 mm when collapsed.

52. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer; and

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer, the inner and outer layers extending beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer;

wherein the inner layer is attached to an inner element, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer, the inner element being spiral cut at a distal end.

53. The device of claim **52**, wherein:

the outer layer holds the anchor in the collapsed position.

54. The device of claim **52**, wherein:

the outer layer has a thickness of 0.0005–0.002 inch.

55. The device of claim **52**, wherein:

the outer layer stretches over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer.

56. The device of claim **52**, further comprising:

an inner element positioned beneath the liner and the anchor, the inner layer being attached to the inner element.

57. The device of claim **56**, wherein:

the inner layer has a thickness of 0.0005–0.002 inch.

58. The device of claim **52**, wherein:

the outer layer has a diameter of no more than 0.055 inch when in the collapsed position.

59. The device of claim **52**, wherein:

the outer layer has a diameter of no more than 0.050 inch when in the collapsed position.

60. The device of claim **52**, wherein:

the outer layer applies a compressive force to the liner to hold the liner in the collapsed position.

61. The device of claim **52**, wherein:

the outer layer lies directly over the anchor and holds the anchor in the collapsed position, the outer layer being retracted by an outer element to expose the anchor and permit the anchor to move to the expanded position.

62. The device of claim **52**, wherein:

the liner is collapsed by forming a number of folds.

63. The device of claim **52**, wherein:

the liner is made of expanded PTFE.

64. The device of claim **52**, further comprising:

a radiopaque coil extending beyond the distal end of the liner and being positioned at least partially between the inner and outer layers.

65. The device of claim **64**, wherein:

the radiopaque coil extends beyond the distal end of the inner and outer layers.

66. The device of claim **52**, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

67. The device of claim **52**, wherein:

the anchor has a length of less than 15 mm when collapsed.

68. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer;

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer; and

an inner element attached to the inner layer, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer, the inner element being spiral cut at a distal end.

69. The device of claim **68**, wherein:

the outer layer holds the anchor in the collapsed position.

70. The device of claim **68**, wherein:

the outer layer has a thickness of 0.0005–0.002 inch.

71. The device of claim **68**, wherein:

the outer layer stretches over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer.

72. The device of claim **68**, wherein:

the inner layer has a thickness of 0.0005–0.002 inch.

73. The device of claim **68**, wherein:

the outer layer has a diameter of no more than 0.055 inch when in the collapsed position.

74. The device of claim **68**, wherein:

the outer layer has a diameter of no more than 0.050 inch when in the collapsed position.

75. The device of claim **68**, wherein:

the outer layer applies a compressive force to the liner to hold the liner in the collapsed position.

76. The device of claim **68**, wherein:

the outer layer lies directly over the anchor and holds the anchor in the collapsed position, the outer layer being retracted by an outer element to expose the anchor and permit the anchor to move to the expanded position.

77. The device of claim **68**, wherein:

the liner is collapsed by forming a number of folds.

78. The device of claim **68**, wherein:

the liner is made of expanded PTFE.

79. The device of claim **68**, further comprising:

a radiopaque coil extending beyond the distal end of the liner and being positioned at least partially between the inner and outer layers.

80. The device of claim **79**, wherein:

the radiopaque coil extends beyond the distal end of the inner and outer layers.

81. The device of claim **68**, wherein:

the inner and outer layers extend beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer.

82. The device of claim **68**, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

83. The device of claim **68**, wherein:

the anchor has a length of less than 15 mm when collapsed.

84. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer;

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer; and

a radiopaque coil extending beyond the distal end of the liner and also being positioned at least partially between the inner and outer layers,

wherein the inner liner is attached to an inner element, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer, the inner element being spiral cut at a distal end.

85. The device of claim **84**, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

86. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer;

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer, the outer layer stretching over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer; and

a radiopaque coil extending beyond the distal end of the liner and being positioned at least partially between the inner and outer layers.

87. The device of claim **86**, wherein:

the radiopaque coil extends beyond the distal end of the inner and outer layers.

88. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer, the inner element being spiral cut at a distal end; and

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer, the inner and outer layers extending beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer.

* * * * *

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	James R. Shay/Sue Bromaghim
Attorney Docket Number:	10012-710.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Filing a brief in support of an appeal	2402	1	255	255
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**255**

Electronic Acknowledgement Receipt

EFS ID:	3922373
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	James R. Shay/Sue Bromaghim
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10012-710.201
Receipt Date:	10-SEP-2008
Filing Date:	16-JUN-2004
Time Stamp:	19:30:03
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$255
RAM confirmation Number	4140
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Appeal Brief Filed	10012-710-201-AppealBrief.pdf	1929424 bc26ebd93362bc7a533986e7fe615ab176e6dd45	no	20
Warnings:					
Information:					
2	Appeal Brief Filed	Bailey_US20010021872.pdf	344324 6ac45d4b673f05cbb7d1be49651d530f54073612	no	15
Warnings:					
Information:					
3	Appeal Brief Filed	Gifford_US6712842.pdf	720302 795a9259f80d65effd16c5cb6b00f62b942a5a08	no	49
Warnings:					
Information:					
4	Fee Worksheet (PTO-06)	fee-info.pdf	29464 c687185ba0c509c1127605f8828c250070fc3166	no	2
Warnings:					
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		Total Files Size (in bytes):	3023514		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

66854 7590 09/22/2008

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 09/22/2008

Please find below and/or attached an Office communication concerning this application or proceeding.

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No.	Applicant(s)	
	10/870,340	SALAHIEH ET AL.	
	Examiner	Art Unit	
	Ann Schillinger	3774	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on *10 September 2008* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☐ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☒ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☐ Other (including any explanation in support of the above items):

1.) The grounds of rejection to be reviewed on appeal; fails to list the examiner's 103(a) rejection of claim 42 over Bailey in view of Chew 2004/0215331 .

/Timothy Cole/
T.Cole
Patent Appeal Specialist

FILED VIA EFS ON OCTOBER 21, 2008

Attorney Docket No. 10012-710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/870,340	Confirmation No.:	7111
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	June 16, 2004		
Title	:	Everting Heart Valve		
Group Art Unit	:	3774		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.201		
Customer No.	:	66854		

APPELLANTS' AMENDED BRIEF PURSUANT TO 37 C.F.R. § 41.37

MailStop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

Appellants submit this amended brief in accordance with the provisions of 37 C.F.R. § 41.37 in response to the Final Rejection mailed March 17, 2008. Appellants' Notice of Appeal was filed July 10, 2008. This Appeal Brief is therefore timely filed.

The filing fee for this document was paid via EFS on September 10, 2008. Please charge any deficit in these fees to Deposit Account No. 50-4050.

I. REAL PARTY IN INTEREST

The real party in interest herein is Sadra Medical, Inc. (Assignee) by virtue of an assignment executed by the inventors (Appellants) to Sadra Medical, Inc. The assignment was recorded by the Assignment Branch of the U.S. Patent and Trademark Office on December 2, 2004 at Reel / Frame 015421 / 0038.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

In the current application under appeal, claims 1-69 are pending, and claims 1-20, 34-37 and 52-67 are withdrawn from consideration. The rejection of claims 21-33, 38-51, 68 and 69 is appealed herein.

IV. STATUS OF AMENDMENTS

Appellants have submitted no amendments after the final rejection. All amendments prior to the close of prosecution on the merits have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 21 recites a method for endovascularly replacing a patient's heart valve, the method comprising: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor; and expanding the anchor to a deployed configuration. Support for this claim can be found at least at ¶¶ 125-154 and Figures 39-43 of Appellants' specification.

Independent claim 38 recites a method for endovascularly replacing a patient's heart valve, the method comprising: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor; and expanding the

anchor to a deployed configuration. Support for this claim can be found at least at ¶¶ 125-154 and Figures 39-43 of Appellants' specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants respectfully request the Board of Patent Appeals and Interferences to review the following grounds of rejection on appeal:

1. Whether claims 21-23, 25-33, 38-41, 43-46, 48-51, 68 and 69 are patentable over Bailey et al. US 2001/0021872 ("Bailey") under 35 U.S.C. § 102(e).

2. Whether claims 24 and 47 are patentable over Bailey in view of Gifford et al. US 6,712,842 ("Gifford") under 35 U.S.C. § 103(a).

3. Whether claim 42 is patentable over Bailey in view of Chew 2004/0215331 ("Chew") under 35 U.S.C. § 103(a).

VII. ARGUMENTS

Appellants respectfully submit that claims 21-33, 38-51, 68 and 69 are in proper form and are patentable over the prior art of record.

1. Rejections Under § 102(e)

The Examiner rejected claims 21-23, 25-33, 38-41, 43-46, 48-51, 68 and 69 under 35 U.S.C. § 102(e) as being anticipated by Bailey. The Examiner's rejection of these claims should be overturned for at least the reasons discussed below.

a. Rejection Of Claim 21 Over Bailey

The Examiner asserts that Bailey anticipates claim 21 under 35 U.S.C. § 102(e). Bailey describes a prosthetic valve that can be supported within an expandable stent and endovascularly delivered to a patient's heart. Bailey describes two alternative methods of manufacture of one embodiment of the valve at ¶ 49. As shown in Bailey Figs. 1-5, an outer graft member 11a is placed around the outside of the stent, and an inner graft member 11b is placed on the inside of the stent. The outside and inside graft members 11a and 11b may be coupled through the interstices of the stent body. The valve body 26 is then formed by everting the inner graft member 11b toward the central longitudinal axis of the stent body member to form the valve flaps 28. As an alternative, Bailey states that "portions of the outer graft member 11a may be

passed through to the lumenal surface of the stent body 21, thereby becoming the inner graft member 11b and everted to form the valve body 26." (Bailey ¶ 49). Bailey shows a second embodiment in Figs. 7-11. In this embodiment as well, the valve flaps are formed by everting the lumenal (inner) graft member 11b inwardly toward the central longitudinal axis of the stent. (Bailey ¶ 59).

The invention of method claim 21 defines over Bailey for at least two reasons. First, claim 21 recites the step of everting a portion of the replacement valve *about* the anchor. Bailey, on the other hand, everts the graft material forming the valve *away* from the anchor, *i.e.*, toward the centerline of the anchor. Second, claim 21 requires that the everting step be performed during deployment of the anchor. Bailey, on the other hand, everts the graft material during manufacture of the prosthesis, not during deployment. Bailey deploys the valve stent with the valve already everted and formed within the anchor. (See Bailey ¶¶ 49, 59 and 73).

Because Bailey fails to disclose at least two explicit limitations of claim 21, Bailey cannot anticipate claim 21. Claim 21, and claims 22-33 and 68 depending from it, are patentable over Bailey under § 102(e).

b. Rejection Of Claim 22 Over Bailey

Claim 22 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above with respect to claim 21. In addition, claim 22 adds the step of using the everting portion of the replacement valve as a seal between the anchor and patient tissue. As discussed above, the everting portion of the Bailey valve forms the valve flaps on the interior of the anchor. The valve flaps function as a valve within the anchor, not as a seal between the anchor and patient tissue. Bailey therefore fails to anticipate claim 22 for this reason as well.

c. Rejection Of Claim 27 Over Bailey

Claim 27 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 27 further limits claim 21 by reciting that the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve. As described above, Bailey assembles his valve within his stent prior to deployment. During deployment, Bailey delivers a

fully supported valve and does not perform the step of moving a valve support and a portion of the anchor with respect to each other during deployment. Bailey therefore fails to anticipate claim 27 for his reason as well.

d. Rejection Of Claim 28 Over Bailey

Claim 28 depends from claim 27 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 28 recites the additional step of using the replacement valve support to lock the anchor in the deployed configuration. Bailey does not disclose any manner of locking the anchor in its deployed configuration and certainly does not recite the step of using a valve support to lock the anchor. Claim 28 is therefore patentable over Bailey for this reason as well.

e. Rejection Of Claim 29 Over Bailey

Claim 29 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 29 adds the step of locking the anchor in the deployed configuration. As indicated above, Bailey does not disclose any manner of locking of his stent in a deployed configuration. Claim 29 is therefore patentable over Bailey for this reason as well.

f. Rejection Of Claim 30 Over Bailey

Claim 30 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 30 adds the step of repositioning the replacement valve and the anchor. Bailey does not disclose any repositioning of the valve and anchor. Claim 30 is therefore patentable over Bailey for this reason as well.

g. Rejection Of Claim 31 Over Bailey

Claim 31 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 31 adds the step of retrieving the replacement valve and the anchor. Bailey does not disclose any retrieval of the valve and anchor. Claim 31 is therefore patentable over Bailey for this reason as well.

h. Rejection Of Claims 32 and 33 Over Bailey

Claim 32 depends from claim 21 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 32 further limits the delivering step by reciting the endovascular

deliver of at least a portion of the replacement valve distal to the anchor. Claim 33 depends from claim 32 and recites endovascular delivery of the entire replacement valve distal to the anchor. Bailey, on the other hand, has the entire valve disposed within the anchor—not distal to it—during endovascular delivery of the prosthesis. Bailey therefore cannot anticipate either claim 32 or claim 33 for this reason as well.

i. Rejection Of Claim 38 Over Bailey

Independent method claim 38 defines over Bailey for at least two reasons. First, claim 38 recites the step of endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor. Bailey does not perform any endovascular wrapping of any portion of the valve about the stent. Second, Bailey does not wrap any portion of the valve about the stent during the deployment of the anchor. For at least these reasons, Bailey cannot anticipate claim 38. Claim 38, and claims 39-51 and 69 depending from it, are patentable over Bailey under § 102(e).

j. Rejection Of Claim 41 Over Bailey

Claim 41 depends from claim 38 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 41 recites that the step of wrapping at least a portion of the replacement valve about the anchor further comprises everting at least a portion of the replacement valve about the anchor. As discussed above, Bailey everts his graft material away from the anchor, not about the anchor. Claim 41 is therefore patentable over Bailey for this reason as well.

k. Rejection Of Claim 42 Over Bailey

Claim 42 depends from claim 38 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 42 recites that the step of endovascularly delivering the replacement valve and anchor further comprises delivering and deploying the valve and anchor without connecting the valve to expandable portions of the anchor. Bailey, on the other hand, supports the valve solely with the expandable stent. Claim 42 is therefore patentable over Bailey for this reason as well.

l. Rejection Of Claims 43 and 44 Over Bailey

Claim 43 depends from claim 38 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 43 further limits the delivering step by reciting the endovascular deliver of at least a portion of the replacement valve distal to the anchor. Claim 44 depends from claim 43 and recites endovascular delivery of the entire replacement valve distal to the anchor. As discussed above, Bailey has the entire valve disposed within the anchor—not distal to it—during endovascular delivery of the prosthesis. Bailey therefore cannot anticipate either claim 43 or claim 44 for this reason as well.

m. Rejection Of Claim 45 Over Bailey

Claim 45 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 45 further limits claim 39 by reciting that the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve. As described above, Bailey assembles his valve within his stent prior to deployment. During deployment, Bailey delivers a fully supported valve and does not perform the step of moving a valve support and a portion of the anchor with respect to each other during deployment. Bailey therefore fails to anticipate claim 45 for his reason as well.

n. Rejection Of Claim 46 Over Bailey

Claim 46 depends from claim 45 and is therefore patentable over Bailey for the reasons stated above. In addition, claim 46 recites the additional step of using the replacement valve support to lock the anchor in the deployed configuration. Bailey does not disclose any manner of locking the anchor in its deployed configuration and certainly does not recite the step of using a valve support to lock the anchor. Claim 46 is therefore patentable over Bailey for this reason as well.

o. Rejection Of Claim 48 Over Bailey

Claim 48 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 48 states that the step of expanding the anchor to the deployed configuration further comprises approximating the anchor

and the replacement valve. Bailey's anchor expansion step does not include the approximation of the valve and anchor. Claim 48 is therefore patentable over Bailey for this reason as well.

p. Rejection Of Claim 49 Over Bailey

Claim 49 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 49 recites the additional step of locking the anchor in the deployed configuration. As indicated above, Bailey does not disclose any manner of locking of his stent in a deployed configuration. Claim 49 is therefore patentable over Bailey for this reason as well.

q. Rejection Of Claim 50 Over Bailey

Claim 50 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 50 adds the step of repositioning the replacement valve and the anchor. Bailey does not disclose any repositioning of the valve and anchor. Claim 50 is therefore patentable over Bailey for this reason as well.

r. Rejection Of Claim 51 Over Bailey

Claim 51 depends from claim 39 (which depends from claim 38) and is therefore patentable over Bailey for the reasons stated above. In addition, claim 51 adds the step of retrieving the replacement valve and the anchor. Bailey does not disclose any retrieval of the valve and anchor. Claim 51 is therefore patentable over Bailey for this reason as well.

2. Rejections Under § 103(a)

The Examiner rejected claims 24 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Bailey in view of Gifford. The Examiner's rejection of these claims should be overturned for at least the reasons discussed below.

a. Rejection Of Claim 24 Over Bailey And Gifford

Claim 24 depends from claim 21 and states that the step of expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor. This method step is neither disclosed nor suggested by either Bailey or Gifford. In Bailey, the anchor is described as self-expanding after emerging from the delivery sheath. (Bailey ¶ 73). Likewise, Gifford fails to describe any anchor or stent that expands through active foreshortening. For example, the

portion of Gifford relied upon by the Examiner in the Final Rejection describes a stent that is shorter than a conventional stent, not a stent that actively foreshortens during expansion. (Gifford col. 15, lines 39-54). Since the combination of Bailey and Gifford fails to disclose every element recited by claim 24, claim 24 is patentable over Bailey and Gifford under § 103(a).

b. Rejection Of Claim 47 Over Bailey And Gifford

Claim 47 depends from claim 39 and, like claim 24, states that the step of expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor. As described above with respect to claim 24, neither Bailey nor Gifford describes this explicit claim limitation. Claim 47 is therefore patentable over Bailey and Gifford under § 103(a).

The Examiner rejected claim 42 under 35 U.S.C. § 103(a) as being unpatentable over Bailey in view of Chew. The Examiner's rejection of these claims should be overturned for at least the reasons discussed below.

a. Rejection Of Claim 42 Over Bailey And Chew

Claim 42 depends from independent claim 38 and therefore includes the limitation of endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor. Neither Bailey nor Chew describes this explicit claim limitation. Claim 42 is therefore patentable over Bailey and Chew under § 103(a).

CONCLUSION

For the reasons stated above, claims 21-33, 38-51, 68 and 69 are patentable over the prior art of record, and the rejections of those claims under 35 U.S.C. §§ 102 and/or 103 are improper and should be overturned. Appellants respectfully ask the Board to overturn the Examiner's rejection with instructions to allow the claims.

Respectfully submitted,

Date: October 21, 2008 By: _____

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VIII. CLAIMS APPENDIX

1. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the expandable anchor are configured for endovascular delivery to a vicinity of the patient's heart valve, and

wherein at least an everting portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

2. (Withdrawn) The apparatus of claim 1, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

3. (Withdrawn) The apparatus of claim 1, wherein the replacement valve is adapted to be held between the anchor and patient tissue upon eversion of the everting portion of the replacement valve about the anchor and expansion of the anchor.

4. (Withdrawn) The apparatus of claim 1 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

5. (Withdrawn) The apparatus of claim 4 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

6. (Withdrawn) The apparatus of claim 1 further comprising a delivery system configured to endovascularly deliver the replacement valve and the anchor.

7. (Withdrawn) The apparatus of claim 6, wherein the delivery system is configured to evert the replacement valve.

8. (Withdrawn) The apparatus of claim 6, wherein the delivery system is configured to change the anchor's shape.

9. (Withdrawn) The apparatus of claim 8, wherein the delivery system is configured to actively foreshorten the anchor.

10. (Withdrawn) The apparatus of claim 1, wherein the anchor and the replacement valve are telescoped relative to one another during endovascular delivery.

11. (Withdrawn) The apparatus of claim 1 further comprising a lock configured to maintain anchor expansion.

12. (Withdrawn) The apparatus of claim 1, wherein the anchor further comprises lip and skirt regions configured to expand and engage the patient's heart valve.

13. (Withdrawn) The apparatus of claim 1, wherein the anchor further comprises a braid fabricated from a single strand of wire.

14. (Withdrawn) The apparatus of claim 1, wherein the replacement valve further comprises valve leaflets.

15. (Withdrawn) The apparatus of claim 14, wherein the everting segment comprises a material chosen from the group consisting of biologic materials, polymeric materials, fabric materials, permeable materials, impermeable materials, materials that promote tissue ingrowth, materials that retard tissue ingrowth, foam materials, sealing materials, and combinations thereof.

16. (Withdrawn) The apparatus of claim 1, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

17. (Withdrawn) The apparatus of claim 16, further comprising a supporting connection between the replacement valve and the replacement valve support.

18. (Withdrawn) The apparatus of claim 17, wherein the supporting connection is adapted to support replacement valve commissures.

19. (Withdrawn) The apparatus of claim 16, wherein the replacement valve support and at least a portion of the anchor are adapted to move with respect to each other during endovascular deployment of the anchor and replacement valve.

20. (Withdrawn) The apparatus of claim 16, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

21. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor; and

expanding the anchor to a deployed configuration.

22. (Original) The method of claim 21, further comprising using the everting portion of the replacement valve as a seal between the anchor and patient tissue.

23. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises holding the replacement valve between the anchor and patient tissue.

24. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

25. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises expanding lip and skirt regions of the anchor into engagement with the patient's heart valve.

26. (Original) The method of claim 21, further comprising approximating the anchor and the replacement valve.

27. (Original) The method of claim 21, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

28. (Original) The method of claim 27, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

29. (Original) The method of claim 21, further comprising locking the anchor in the deployed configuration.

30. (Original) The method of claim 21, further comprising repositioning the replacement valve and the anchor.

31. (Original) The method of claim 21, further comprising retrieving the replacement valve and the anchor.

32. (Original) The method of claim 21, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

33. (Original) The method of claim 32, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

34. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

an anchor having a lip region and a skirt region; and

a replacement valve,

wherein at least an everting portion of the replacement valve is configured to evert about the skirt region of the anchor during endovascular deployment, and

wherein the lip and skirt regions of the anchor are configured for percutaneous expansion to engage the patient's heart valve.

35. (Withdrawn) The apparatus of claim 34, wherein percutaneous expansion of the skirt region is configured to hold the everting portion of the replacement valve between the skirt region and the patient's heart valve.

36. (Withdrawn) The apparatus of claim 34, wherein the everting portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

37. (Withdrawn) The apparatus of claim 34, wherein the anchor further comprises a braid fabricated from a single strand of wire.

38. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor; and

expanding the anchor to a deployed configuration.

39. (Original) The method of claim 38, further comprising using the wrapping portion of the replacement valve as a seal between the anchor and patient tissue.

40. (Original) The method of claim 38, wherein expanding the anchor to the deployed configuration further comprises holding the wrapping portion of the replacement valve between the anchor and patient tissue.

41. (Original) The method of claim 38, wherein wrapping at least a portion of the replacement valve about the anchor further comprises everting at least a portion of the replacement valve about the anchor.

42. (Original) The method of claim 38 wherein endovascularly delivering the replacement valve and anchor further comprises delivering and deploying the valve and anchor without connecting the valve to expandable portions of the anchor.

43. (Original) The method of claim 38, wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

44. (Original) The method of claim 43, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

45. (Original) The method of claim 39, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

46. (Original) The method of claim 45, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

47. (Original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

48. (Original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises approximating the anchor and the replacement valve.

49. (Original) The method of claim 39 further comprising locking the anchor in the deployed configuration.

50. (Original) The method of claim 39 further comprising repositioning the replacement valve and the anchor.

51. (Original) The method of claim 39 further comprising retrieving the replacement valve and the anchor.

52. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising:

a replacement valve; and

an expandable anchor,

wherein the replacement valve and the anchor are configured for endovascular delivery to a vicinity of the patient's heart valve with no portion of the replacement valve being wrapped about the anchor, and

wherein at least a wrapping portion of the replacement valve is configured to be wrapped about an end of the anchor in a deployed configuration.

53. (Withdrawn) The apparatus of claim 52, wherein the wrapping portion of the replacement valve is configured to create a seal between the anchor and patient tissue.

54. (Withdrawn) The apparatus of claim 52 wherein at least a portion of the replacement valve is configured to be endovascularly delivered distal to the anchor.

55. (Withdrawn) The apparatus of claim 54 wherein substantially the entire replacement valve is configured to be endovascularly delivered distal to the anchor.

56. (Withdrawn) The apparatus of claim 52, wherein the replacement valve is not connected to the expandable anchor.

57. (Withdrawn) The apparatus of claim 52, wherein at least a portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

58. (Withdrawn) The apparatus of claim 52, wherein the wrapped portion of the replacement valve is configured to be held between the anchor and the patient tissue upon endovascular deployment.

59. (Withdrawn) The apparatus of claim 52, wherein the expandable anchor is configured for active foreshortening during endovascular deployment.

60. (Withdrawn) The apparatus of claim 52 further comprising a lock configured to maintain expansion of the anchor.

61. (Withdrawn) The apparatus of claim 52, wherein the lock is reversible.

62. (Withdrawn) The apparatus of claim 52, further comprising a replacement valve support adapted to support the replacement valve in a deployed configuration.

63. (Withdrawn) The apparatus of claim 62, further comprising a supporting connection between the replacement valve and the replacement valve support.

64. (Withdrawn) The apparatus of claim 63, wherein the supporting connection is adapted to support replacement valve commissures.

65. (Withdrawn) he apparatus of claim 62, wherein the replacement valve support is adapted to move with respect to the anchor during endovascular deployment of the anchor and replacement valve.

66. (Withdrawn) The apparatus of claim 62, wherein the replacement valve support comprises a lock adapted to lock configured to maintain anchor expansion.

67. (Withdrawn) The apparatus of claim 62, wherein the anchor comprises a braid fabricated from a single strand of wire.

68. (Previously Presented) The method of claim 21 wherein everting at least an everting portion of the replacement valve about the anchor comprises everting at least an everting portion of the replacement valve about the distal end of the anchor.

69. (Previously Presented) The method of claim 38 wherein endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor comprises wrapping at least a wrapping portion of the replacement valve about the distal end of the anchor.

IX. EVIDENCE APPENDIX

Bailey et al. US 2001/0021872 cited by the Examiner in an Office Action dated 9/14/07.

Gifford et al. US 6,712,842 cited by the Examiner in an Office Action dated 9/14/07.

Chew US 2004/0215331 cited by the Examiner in an Office Action dated 3/17/08.

X. RELATED PROCEEDINGS APPENDIX

None.

US 20010021872A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2001/0021872 A1**

Bailey et al. (43) **Pub. Date: Sep. 13, 2001**

(54) **ENDOLUMINAL CARDIAC AND VENOUS VALVE PROSTHESES AND METHODS OF MANUFACTURE AND DELIVERY THEREOF**

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(21) Appl. No.: **09/854,002**

(22) Filed: **May 11, 2001**

Related U.S. Application Data

(62) Division of application No. 09/477,120, filed on Dec. 31, 1999.

(30) **Foreign Application Priority Data**

Dec. 18, 2000 (US)..... PCT/US00/34591

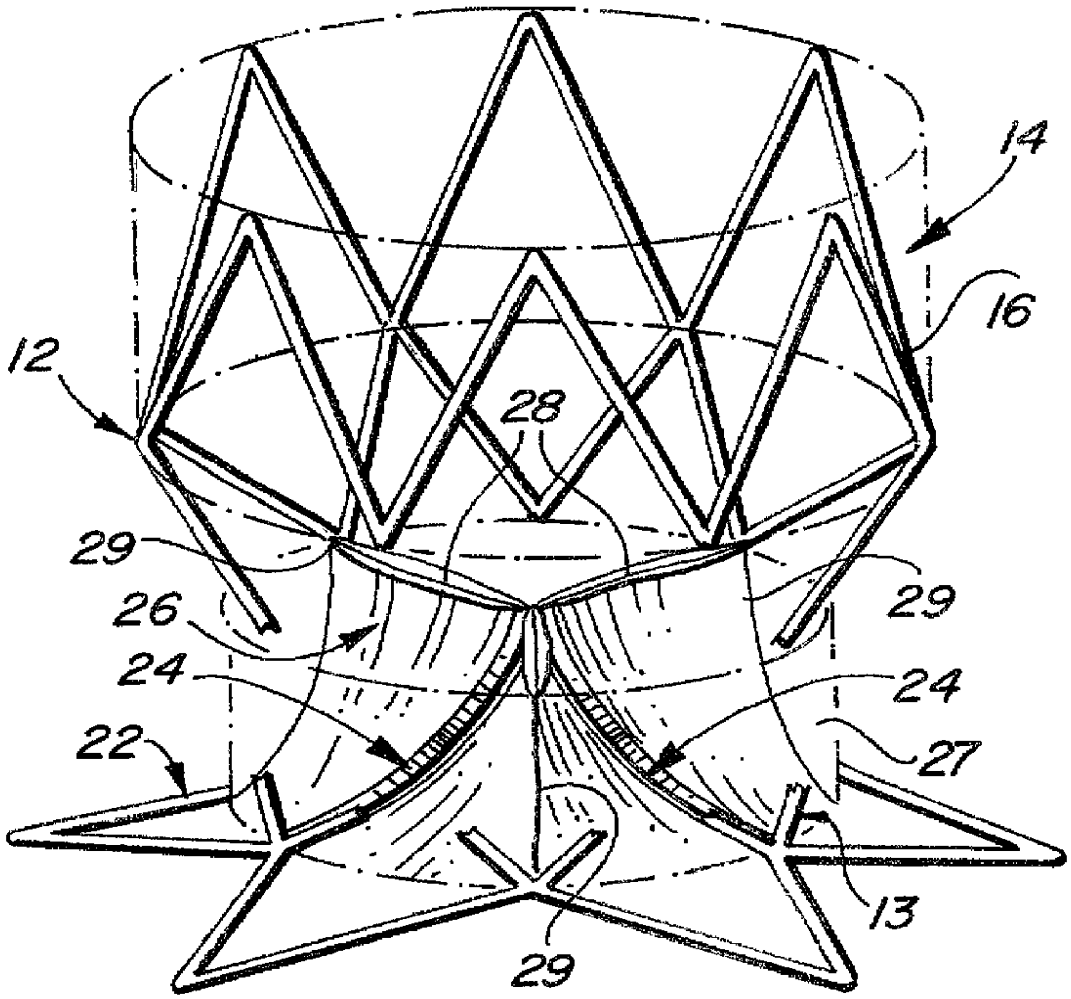
Publication Classification

(51) **Int. Cl.**[7] **A61F 2/06**; A61F 2/24

(52) **U.S. Cl.** **623/1.24**; 623/2.18

(57) **ABSTRACT**

This invention relates to prosthetic cardiac and venous valves and a single catheter device and minimally invasive techniques for percutaneous and transluminal valvuloplasty and prosthetic valve implantation.



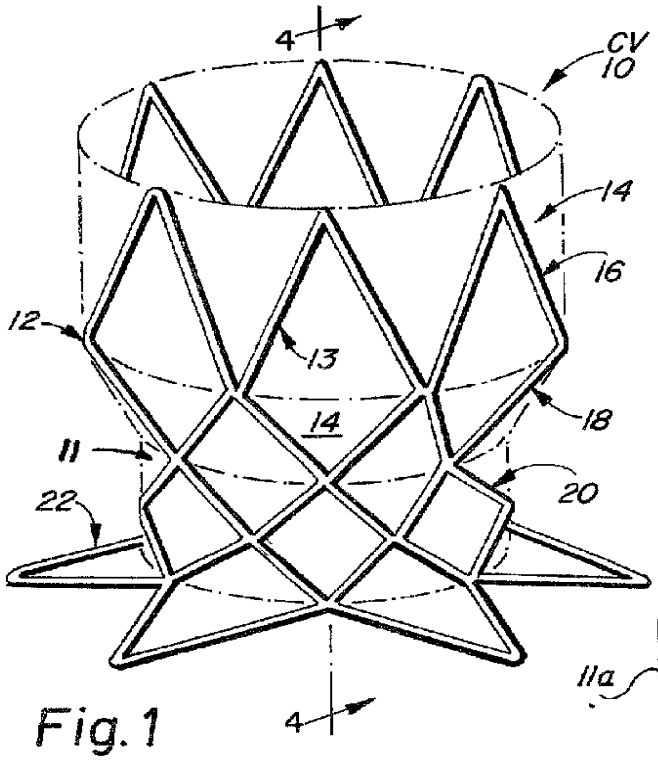


Fig. 1

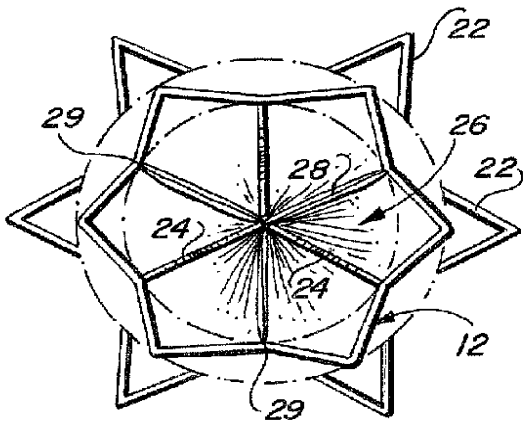


Fig. 3

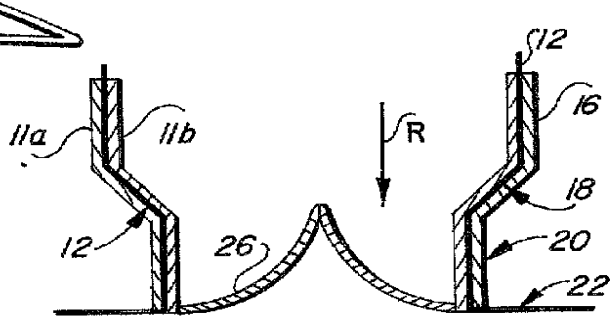


Fig. 4

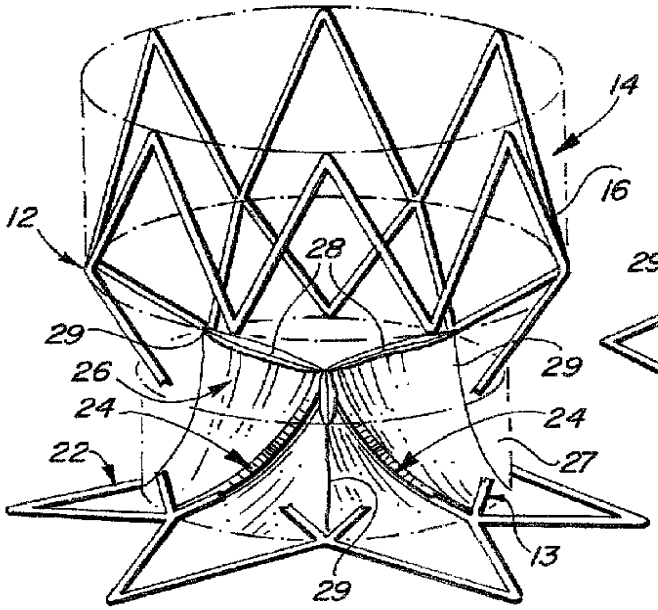


Fig. 2

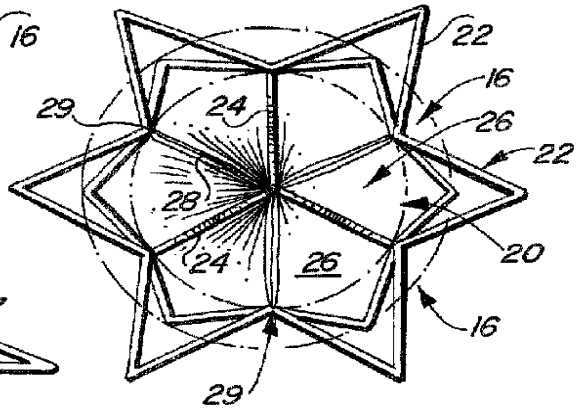


Fig. 5

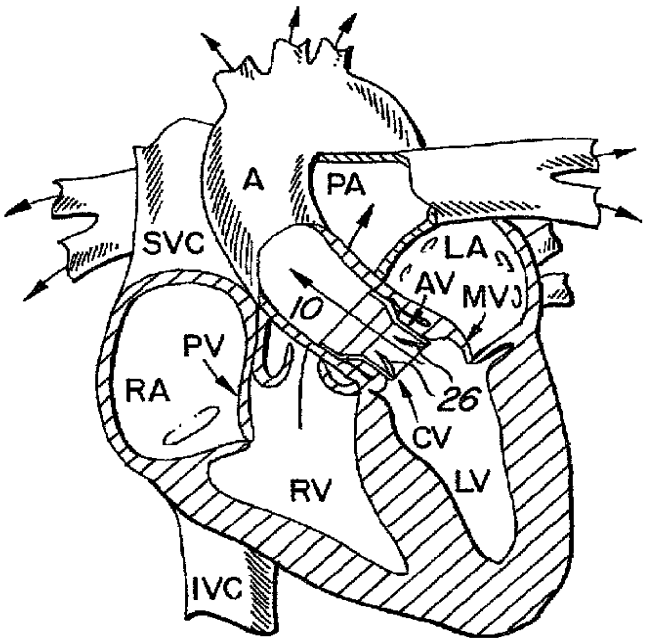


Fig. 6A

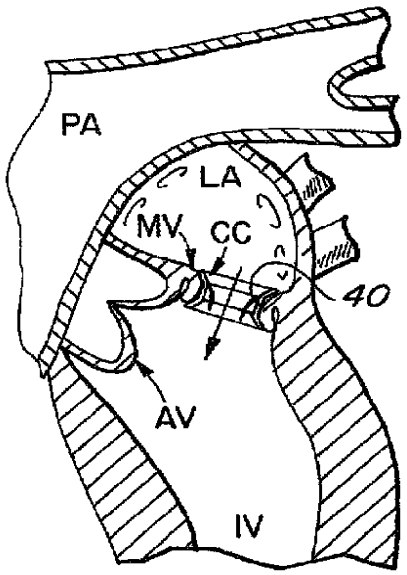


Fig. 12A

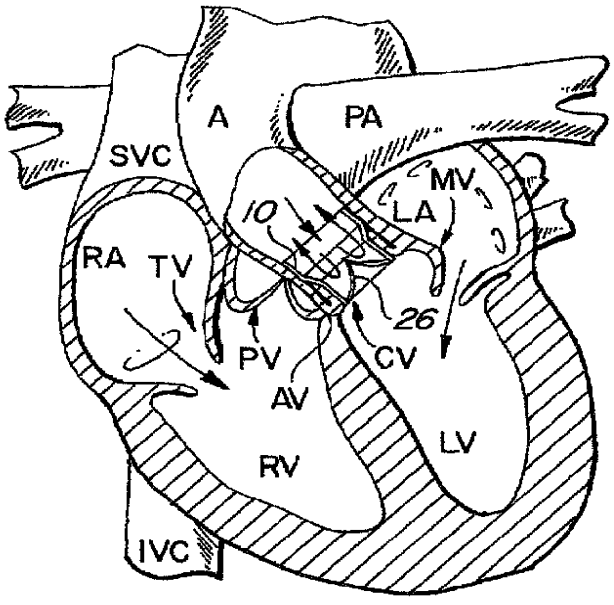


Fig. 6B

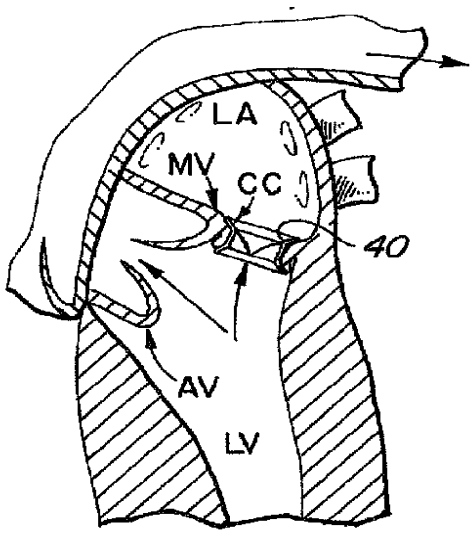


Fig. 12B

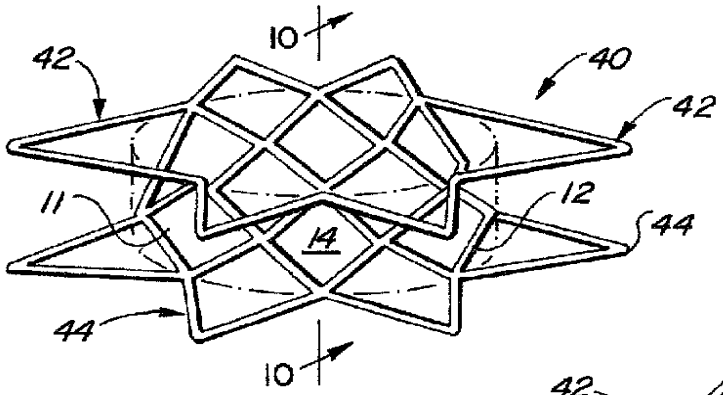


Fig. 7

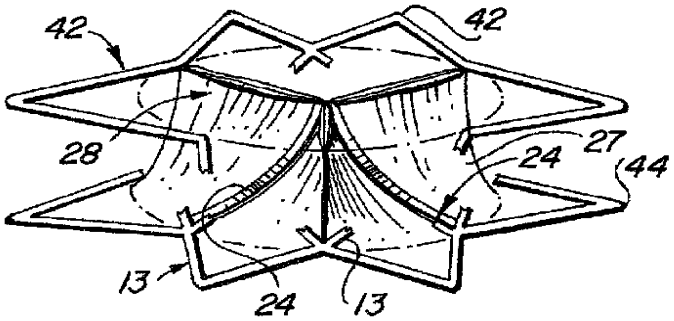


Fig. 8

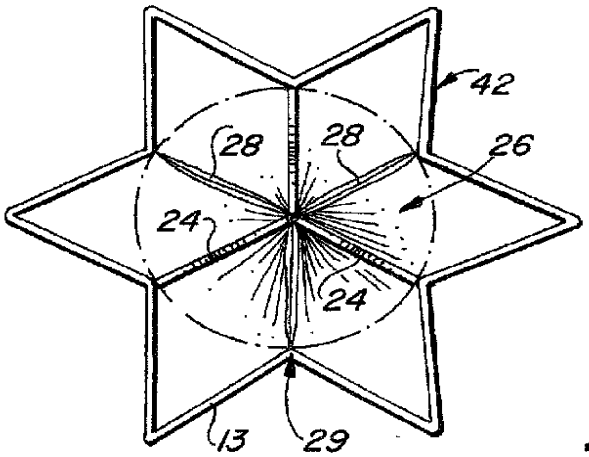


Fig. 9

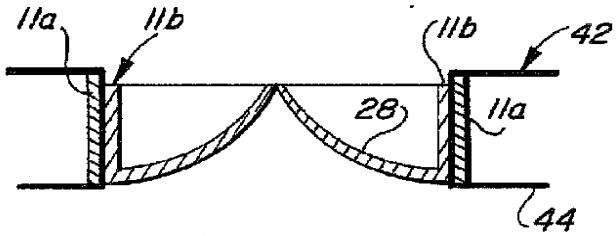


Fig. 10

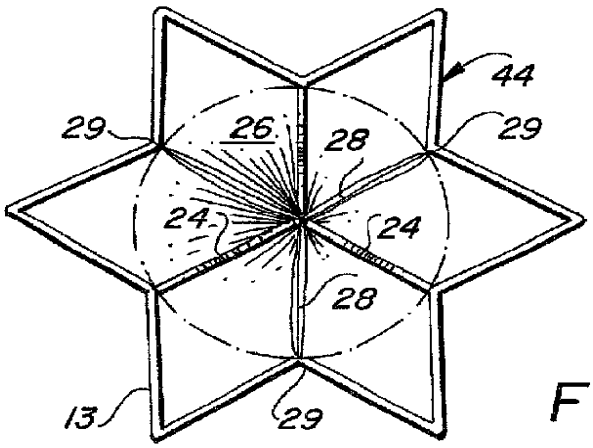


Fig. 11

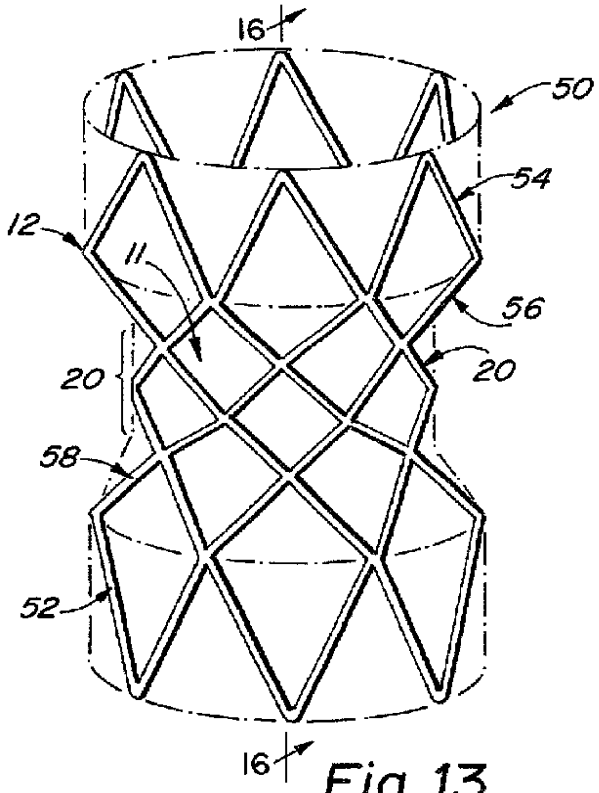


Fig. 13

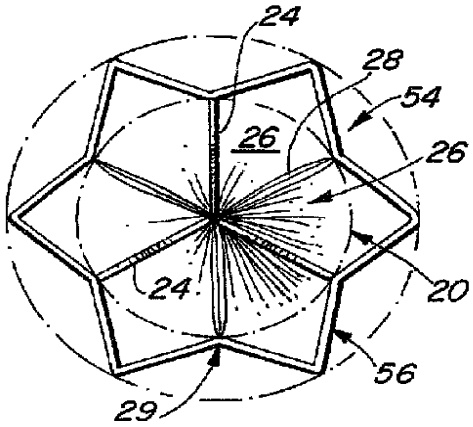


Fig. 15

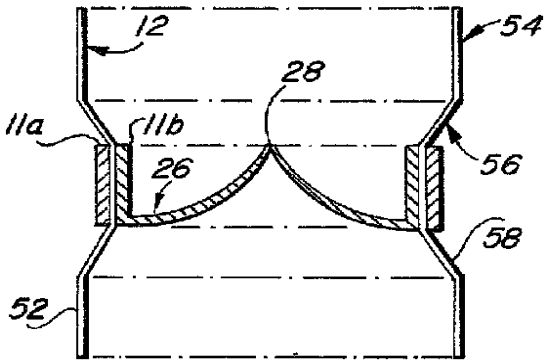


Fig. 16

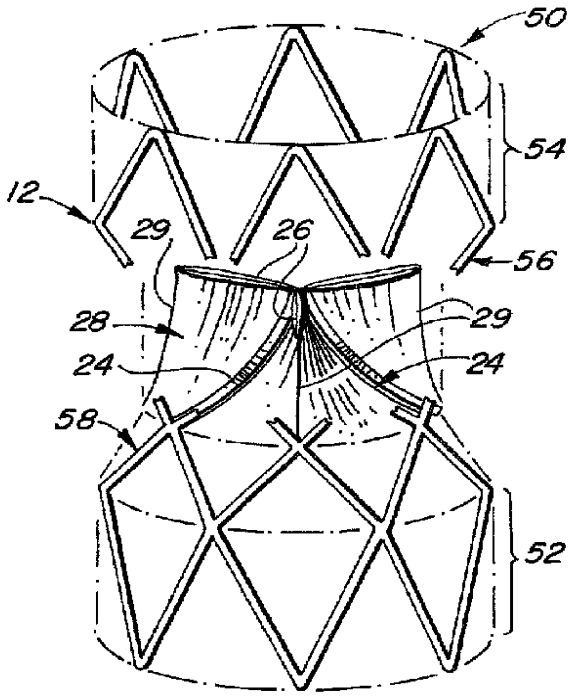


Fig. 14

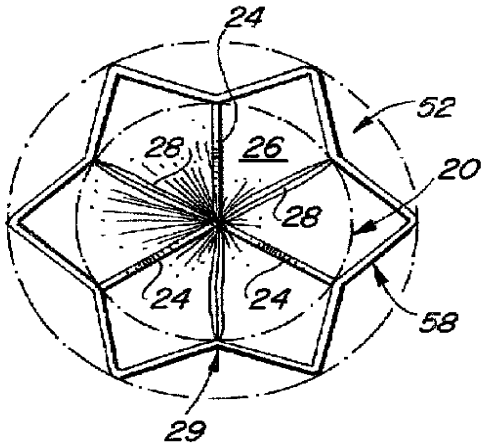


Fig. 17

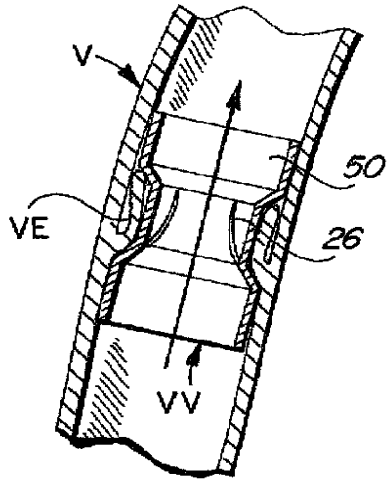


Fig. 18A

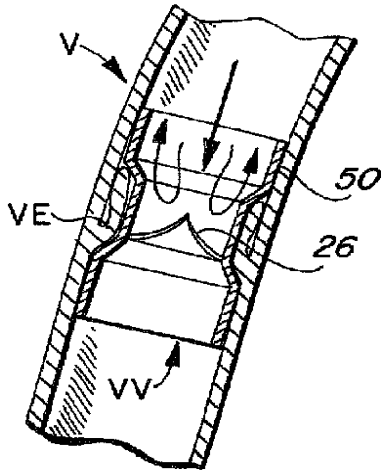


Fig. 18B

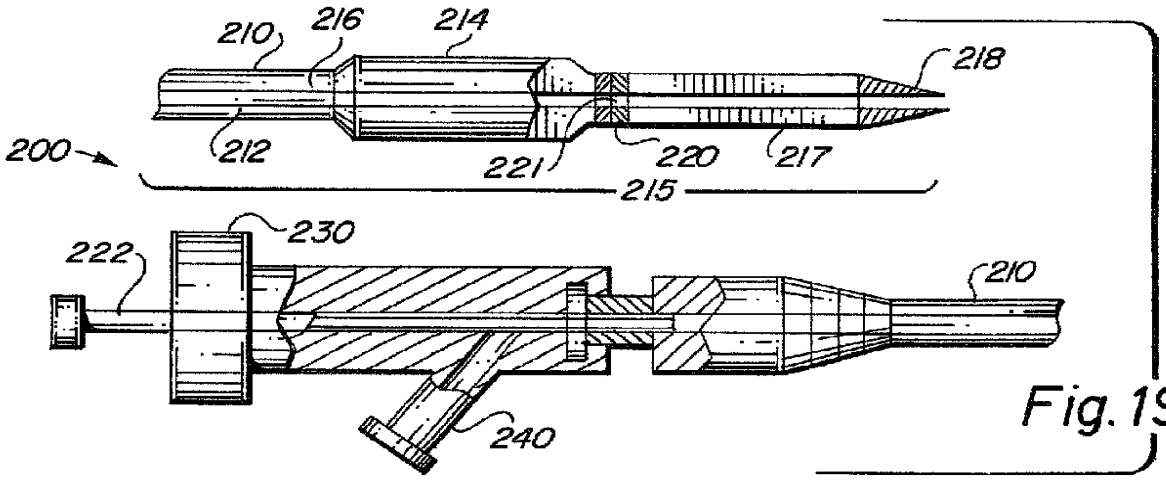


Fig. 19

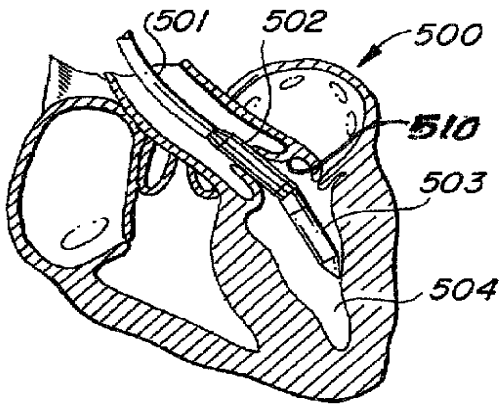


Fig. 20A

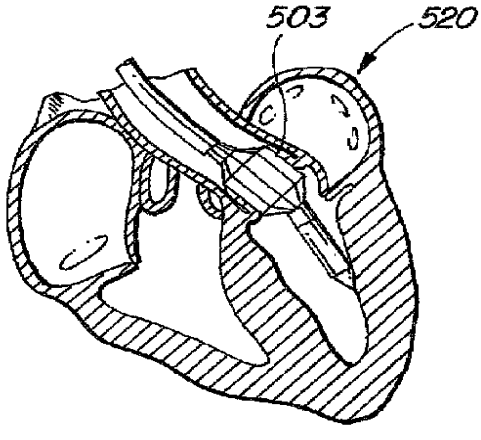


Fig. 20B

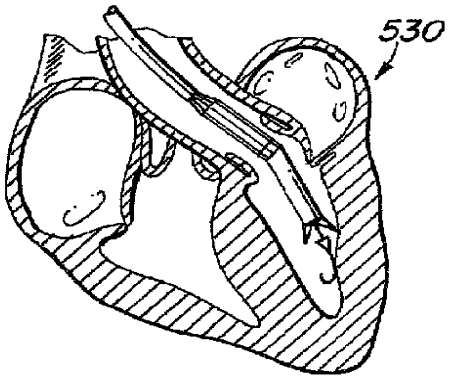


Fig. 20C

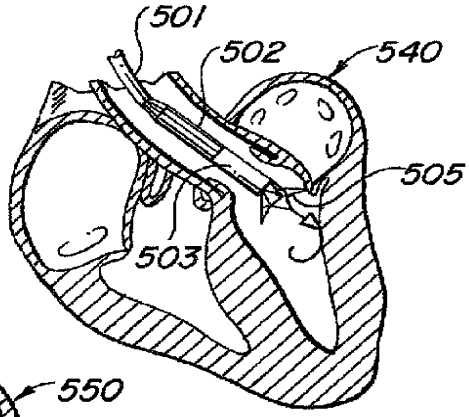


Fig. 20D

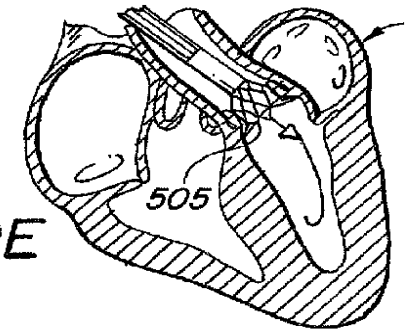


Fig. 20E

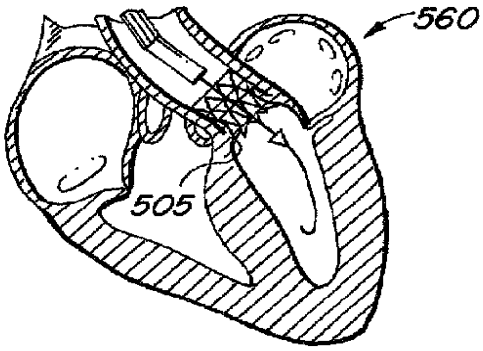


Fig. 20F

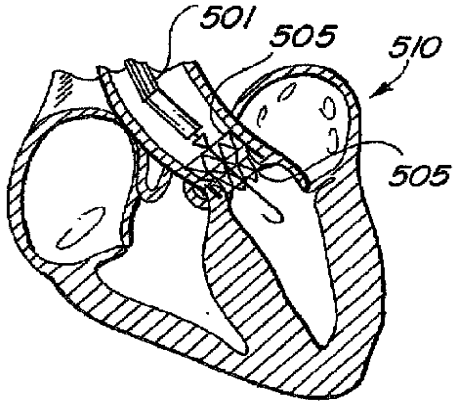


Fig. 20G

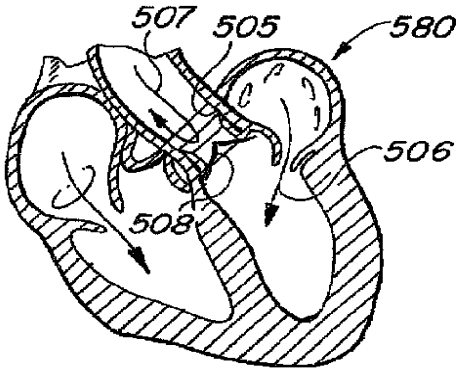


Fig. 20H

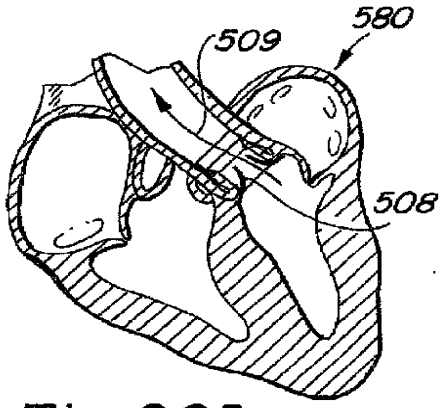


Fig. 20I

ENDOLUMINAL CARDIAC AND VENOUS VALVE PROSTHESES AND METHODS OF MANUFACTURE AND DELIVERY THEREOF

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application corresponds to and claims priority of pending U.S. utility patent application, Ser. No. 09/477,120, filed Dec. 31, 1999 and PCT International Application, Ser. No. PCT/US00/34591, filed Dec. 18, 2000.

BACKGROUND OF THE INVENTION

[0002] The present invention relates generally to implantable prosthetic cardiac and venous valves. More particularly, the present invention pertains to prosthetic cardiac and venous valve implants which are capable of being delivered using endovascular techniques and being implanted at an intracardiac or intravenous site without the need for anatomic valve removal. The prosthetic valves of the present invention are well-suited for cardiac delivery via a femoral or subclavian artery approach using a delivery catheter, and, depending upon the specific configuration selected, may be deployed within the heart to repair valve defects or disease or septal defects or disease. According to one embodiment of the invention, there is provided a chamber-to-vessel (CV) configuration which is particularly well-suited as an aortic valve prosthesis to facilitate blood flow from the left ventricle to the aorta. In a second embodiment, there is provided a prosthetic valve in a chamber-to-chamber (CC) configuration which is particularly well-adapted for mitral valve replacement or repair of septal defects. Finally, a third embodiment is provided in a vessel-to-vessel (VV) configuration, which is well suited for venous valve exclusion and replacement.

[0003] Common to each of the CV, CC and VV embodiments of the present invention are a stent support member, a graft member which covers at least a portion of either or both the lumenal and ablumenal surfaces of the stent, valve flaps which are formed either by biological xenograft valves, synthetic valves formed from either the same material or a different material as the graft member, the valve flaps being coupled to the stent in a manner which biases the valve flaps so they close upon a zero pressure differential across the valve region.

[0004] It is important for the present invention to provide orientational definitions. For purposes of the present invention, references to positional aspects of the present invention will be defined relative to the directional flow vector of blood flow through the implantable device. Thus, the term "proximal" is intended to mean on the inflow or upstream flow side of the device, while "distal" is intended to mean on the outflow or downstream flow side of the device. With respect to the catheter delivery system described herein, the term "proximal" is intended to mean toward the operator end of the catheter, while the term "distal" is intended to mean toward the terminal end or device-carrying end of the catheter.

SUMMARY OF PRIOR ART

[0005] The prior art discloses certain common device segments inherently required by a percutaneous prosthetic valve: an expandable stent segment, an anchoring segment and a flow-regulation segment.

[0006] Prior art percutaneous prosthetic valve devices include the Dobben valve, U.S. Pat. No. 4,994,077, the Vince valve, U.S. Pat. No. 5,163,953, the Teitelbaum valve, U.S. Pat. No. 5,332,402, the Stevens valve, U.S. Pat. No. 5,370,685, the Pavcnik valve, U.S. Pat. No. 5,397,351, the Taheri valve, U.S. Pat. No. 5,824,064, the Anderson valves, U.S. Pat. Nos. **5,411,552 & 5,840,081,** the Jayaraman valve, U.S. Pat. No. 5,855,597, the Besseler valve, U.S. Pat. No. 5,855,601, the Khosravi valve, U.S. Pat. No. 5,925,063, the Zadano-Azizi valve, U.S. Pat. No. 5,954,766, and the Leonhardt valve, U.S. Pat. No. 5,957,949. Each of these pre-existing stent valve designs has certain disadvantages which are resolved by the present invention.

[0007] The Dobben valve has a disk shaped flap threaded on a wire bent like a safety pin to engage the vessel wall and anchor the valve. A second embodiment uses a stent of a cylindrical or crown shape that is made by bending wire into a zigzag shape to anchor the device and attach the flow regulator flap. The device presents significant hemodynamic, delivery, fatigue and stability disadvantages.

[0008] The Vince valve has a stent comprised of a toroidal body formed of a flexible coil of wire and a flow-regulation mechanism consisting of a flap of biologic material. Numerous longitudinal extensions within the stent are provided as attachment posts to mount the flow-regulation mechanism. The device requires balloon expansion to deliver to the body orifice. The main shortcoming of this design is delivery profile. Specifically, the device and method put forth will require a 20+ French size catheter (approximately 9 French sizes to accommodate the balloon and 14+ French sizes to accommodate the compressed device) making the device clinically ineffective as a minimally invasive technique. Additionally, the device does not adequately address hemodynamic, stability and anchoring concerns.

[0009] The Teitelbaum valve is made of shape memory nitinol and consists of two components. The first component is stent-like and comprised of a meshwork or braiding of nitinol wire similar to that described by Wallsten, U.S. Pat. No. 4,655,771, with trumpet like distal a proximal flares. The purpose of the stent is to maintain a semi-ridged patent channel through the diseased cardiac valve after initial balloon dilation. The flared ends are intended to maintain the position of the stent component across the valve thereby anchoring the device. Embodiments for the flow-regulation mechanism include a sliding obturator and a caged ball both which are delivered secondary to the stent portion. The disadvantages of the device are the flow regulators reduce the effective valve orifice and generate sub-optimal hemodynamic characteristics; fatigue concerns arise from the separate nature of the stent and flow-regulation components; the high metal and exposed metal content raises thrombogenesis, valvular stenosis and chronic anticoagulation concerns; and the separate delivery requirements (although addressing the need for small delivery profile) in addition to any initial valvuloplasty performed increases the time, costs, risks, difficulty and trauma associated with the percutaneous procedure.

[0010] The Pavcnik valve is a self-expanding percutaneous device comprised of a poppet, a stent and a restraining element. The valve stent has barbed means to anchor to the

internal passageway. The device includes a self-expanding stent of a zigzag configuration in conjunction with a cage mechanism comprised of a multiplicity of crisscrossed wires and a valve seat. The disadvantages of the device include large delivery profile, reduced effective valvular orifice, possible perivalvular leakage, trauma-inducing turbulent flow generated by the cage occlusive apparatus and valve seat, thrombogenesis, valvular stenosis, chronic anticoagulation, problematic physiological and procedural concerns due to the barb anchors and complex delivery procedure that includes inflation of occlusive member after initial implantation.

[0011] Stevens discloses a percutaneous valve replacement system for the endovascular removal of a malfunctioning valve followed by replacement with a prosthetic valve. The valve replacement system may include a prosthetic valve device comprised of a stent and cusps for flow-regulation such as a fixed porcine aortic valve, a valve introducer, an intraluminal procedure device, a procedure device capsule and a tissue cutter. The devices disclosed indicate a long and complex procedure requiring large diameter catheters. The valve device disclosed will require a large delivery catheter and does not address the key mechanisms required of a functioning valve. Additionally, the device requires intraluminal-securing means such as suturing to anchor the device at the desired location.

[0012] The Taheri valve describes an aortic valve replacement combined with an aortic arch graft. The devices and percutaneous methods described require puncture of the chest cavity.

[0013] Anderson has disclosed various balloon expandable percutaneous prosthetic valves. The latest discloses a valve prosthesis comprised of a stent made from an expandable cylindrical structure made of several spaced apices and an elastically collapsible valve mounted to the stent with the commissural points of the valve mounted to the apices. The device is placed at the desired location by balloon expanding the stent and valve. The main disadvantage to this design is the 20+ French size delivery requirement. Other problems include anchoring stability, perivalvular leakage, difficult manufacture and suspect valve performance.

[0014] The Jayaraman valve includes a star-shaped stent and a replacement valve and/or replacement graft for use in repairing a damaged cardiac valve. The device is comprised of a chain of interconnected star-shaped stent segments in the center of which sits a replacement valve. The flow-regulation mechanism consists of three flaps cut into a flat piece of graft material that is rolled to form a conduit in which the three flaps may be folded inwardly in an overlapping manner. An additional flow-regulation mechanism is disclosed in which a patch (or multiple patches) is sutured to the outside of a conduit which is then pulled inside out or inverted such that the patch(s) reside on the fully inverted conduit. A balloon catheter is required to assist expansion during delivery. The disadvantages of this design include lack of sufficient anchoring mechanism; problematic interference concerns with adjacent tissues and anatomical structures; fatigue concerns associated with the multiplicity of segments, connections and sutures; lack of an adequately controlled and biased flow-regulation mechanism; uncertain effective valve orifice, difficult manufacture; balloon dilation requirement; complex, difficult and inaccurate delivery and large delivery profile.

[0015] The Besseler valve discloses methods and devices for the endovascular removal of a defective heart valve and the replacement with a percutaneous cardiac valve. The device is comprised of a self-expanding stent member with a flexible valve disposed within. The stent member is of a self-expanding cylindrical shape made from a closed wire in formed in a zigzag configuration that can be a single piece, stamped or extruded or formed by welding the free ends together. The flow-regulation mechanism is comprised of an arcuate portion which contains a slit (or slits) to form leaflets and a cuff portion which is sutured to and encloses the stent. The preferred flow regulator is a porcine pericardium with three cusps. An additional flow regulator is described in which the graft material that comprises the leaflets (no additional mechanisms for flow-regulation) extends to form the outer cuff portion and is attached to the stent portion with sutures. The anchoring segment is provided by a plurality of barbs carried by the stent (and therefor penetrating the cuff-graft segment). Delivery requires endoluminal removal of the natural valve because the barb anchors will malfunction if they are orthotopically secured to the native leaflets instead of the more rigid tissue at the native annulus or vessel wall. Delivery involves a catheter within which the device and a pusher rod are disposed. The disadvantages of the device are lack of a well defined and biased flow-regulation mechanism, anatomic valve removal is required thereby lengthening the procedure time, increasing difficulty and reducing clinical practicality, trauma-inducing barbs as described above and the device is unstable and prone to migration if barbs are omitted.

[0016] The Khosravi valve discloses a percutaneous prosthetic valve comprised of a coiled sheet stent similar to that described by Derbyshire, U.S. Pat. No. 5,007,926, to which a plurality of flaps are mounted on the interior surface to form a flow-regulation mechanism that may be comprised of a biocompatible material. The disadvantages of this design include problematic interactions between the stent and flaps in the delivery state, lack of clinical data on coiled stent performance, the lack of a detailed mechanism to ensure that the flaps will create a competent one-directional valve, lack of appropriate anchoring means, and the design requirements imposed by surrounding anatomical structures are ignored.

[0017] The Zadno-Azizi valve discloses a device in which flow-regulation is provided by a flap disposed within a frame structure capable of taking an insertion state and an expanded state. The preferred embodiment of the flow-regulation mechanism is defined by a longitudinal valve body made of a sufficiently resilient material with a slit(s) that extends longitudinally through the valve body. Increased sub-valvular pressure is said to cause the valve body to expand thereby opening the slit and allowing fluid flow there through. The valve body extends into the into the lumen of the body passage such that increased supra-valvular pressure will prevent the slit from opening thereby effecting one-directional flow. The device includes embedding the frame within the seal or graft material through injection molding, blow molding and insertion molding. The disadvantages of the device include the flow-regulation mechanism provides a small effective valve orifice, the turbidity caused by the multiple slit mechanisms, the large delivery profile required by the disclosed embodiments and the lack of acute anchoring means.

[0018] Finally, the Leonhardt valve is comprised of a tubular graft having radially compressible annular spring portions and a flow regulator, which is preferably a biological valve disposed within. In addition to oversizing the spring stent by 30%, anchoring means is provided by a light-activated biocompatible tissue adhesive is located on the outside of the tubular graft and seals to the living tissue. The stent section is comprised of a single piece of super-elastic wire formed into a zigzag shape and connected together by crimping tubes, adhesives or welds. A malleable thin-walled, biocompatible, flexible, expandable, woven fabric graft material is connected to the outside of the stent that is in turn connected to the biological flow regulator. Disadvantages of this device include those profile concerns associated with biological valves and unsupported graft-leaflet regulators, a large diameter complex delivery system and method which requires multiple anchoring balloons and the use of a light activated tissue adhesive in addition to any prior valvuloplasty performed, interference with surrounding anatomy and the questionable clinical utility and feasibility of the light actuated anchoring means.

SUMMARY OF THE INVENTION

[0019] With the shortcomings of the prior art devices, there remains a need for a clinically effective endoluminally deliverable prosthetic valve that is capable of orthotopic delivery, provides a mechanically defined, biased and hemodynamically sound flow-regulation mechanism, provides sufficient force to maintain a large acute effective valvular orifice dimension which expands to a known larger effective orifice dimension, compliant with adjacent dynamic anatomical structures, does not require valve removal, does not require chronic anticoagulation treatment, meets regulatory fatigue requirements for cardiac valve prostheses, provides a low-metal high-strength stent-annulus, is surgically explantable or endoluminally removable, in addition to being able to deploy multiple valves orthotopically, provides a delivery profile which does not exceed the 12 French size suitable for peripheral vascular endoluminal delivery, combines anatomic valve exclusion and prosthetic valve delivery via a single catheter delivery system and with short duration atraumatic procedure which is easy to complete and beneficial to very sick patients.

[0020] It is, therefore, a primary of the present invention to provide a prosthetic endoluminally-deliverable unidirectional valve. The invention has multiple configurations to treat malfunctioning anatomical valves including heart and venous valves. Prosthetic cardiac valve configurations include the chamber-to-vessel for orthotopic placement at the valvular junction between a heart chamber and a vessel, and the chamber-to-chamber for orthotopic placement at the valvular junction between two heart chambers or for septal defect repair where a septal occluding member is substituted for the flow regulator valve flaps. Prosthetic venous valve configurations include the vessel-to-vessel for orthotopic or non-orthotopic placement at a valvular junction within a vessel.

[0021] The invention consists generally of a stent body member, a graft, and valve flaps. The stent body member may be fashioned by laser cutting a hypotube or by weaving wires into a tubular structure, and is preferably made from shape memory or super-elastic materials, such as nickel-titanium alloys known as NITINOL, but may be made of balloon expandable stainless steel or other plastically deformable stent materials as are known in the art, such as titanium or tantalum, or may be self-expanding such as by weaving stainless steel wire into a stressed-tubular configuration in order to impart elastic strain to the wire. The graft is preferably a biocompatible, fatigue-resistant membrane which is capable of endothelialization, and is attached to the stent body member on at least portions of either or both the lumenal and ablumenal surfaces of the stent body member by suturing to or encapsulating stent struts. The valve leaflets are preferably formed by sections of the graft material attached to the stent body member.

[0022] The stent body member is shaped to include the following stent sections: proximal and distal anchors, a intermediate annular stent section, and at least one valve arm or blood flow regulator struts. The proximal and distal anchor sections are present at opposing ends of the prosthesis and subtend either an acute, right or obtuse angle with a central longitudinal axis that defines the cylindrical prosthesis. In either the CV or CC configurations, the proximal anchor is configured to assume approximately a right angle radiating outward from the central longitudinal axis of the prosthesis in a manner which provides an anchoring flange. When being delivered from a delivery catheter, the proximal anchor is deployed first and engages the native tissue and anatomical structures just proximal to the anatomic valve, such as the left ventricle wall in the case of retrograde orthotopic delivery at the aortic valve. Deployment of the proximal anchor permits the intermediate annular stent section to be deployed an reside within the native valve annular space and the ablumenal surface of the intermediate annular stent section to abut and outwardly radially compress the anatomic valve leaflets against the vascular wall. The distal anchor is then deployed and radially expands to contact the vascular wall and retain the prostbesis in position, thereby excluding the anatomic valve leaflets from the bloodflow and replacing them with the prosthetic valve leaflets.

[0023] Flow regulation in the inventive stent valve prosthesis is provided by the combination of the prostbetic valve leaflets and the valve arms and is biased closed in a manner similar manner to that described for a surgically implanted replacement heart valve by Boretos, U.S. Pat. No. 4,222,126. The valve regulator-struts are preferably configured to be positioned to radiate inward from the stent body member toward the central longitudinal axis of the prosthesis. The graft-leaflet bas the appearance of a partially-everted tube where the innermost layer, on the lumenal surface of the stent body member, forms the leaflets and the outer-most layer, on the ablumenal surface of the stent body member, forms a sealing graft which contacts and excludes the immobilized anatomical valve leaflets. The struts of the stent are encapsulated by the outer graft-membrane. The valve regulator-struts are encapsulated by the inner leaflet-membrane and serve to bias the valve to tbe closed position. The regulator-struts also prevent inversion or prolapse of the otherwise unsupported leaflet-membrane during increased supra-valvular pressure. The inner leaflet-membrane may also be attached to the outer graft-membrane at points equidistant from the valve strut-arms in a manner analogous to that described for a surgically implanted replacement heart valve by Cox, U.S. Pat. No. 5,824,063. The combination of the thin walled properties of the leaflet-membrane, the one-sided open lumen support of the intermediate annu-

lar stent section, the free ends of the valve leaflets, the biasing and support provided by the valve regulator-struts and the attachment points all work to provide a prosthetic valvular device capable of endoluminal delivery which simulates the hemodynamic properties of a healthy anatomical cardiac or venous valve.

BRIEF DESCRIPTION OF FIGURES

[0024] **FIG. 1** is a perspective view of the inventive valve stent chamber-to-vessel embodiment in its fully deployed state.

[0025] **FIG. 2** is a perspective view of the inventive valve stent chamber-to-vessel embodiment in its fully deployed state with the outermost graft layer and stent layer partially removed to show an embodiment of the valve apparatus.

[0026] **FIG. 3** is a top view of the inventive valve stent chamber-to-vessel embodiment in its fully deployed state.

[0027] **FIG. 4** shows the cross-sectional taken along line **4—4** of **FIG. 1**.

[0028] **FIG. 5** is a bottom view of the inventive valve stent chamber-to-vessel embodiment in its fully deployed state.

[0029] **FIG. 6A** illustrates a cross-sectional view of a human heart during systole with the inventive valve stent chamber-to-vessel embodiment implanted in the aortic valve and illustrating a blood flow vector of an ejection fraction leaving the left ventricle and passing through the inventive valve stent.

[0030] **FIG. 6B** illustrates a cross-sectional view of a human heart during diastole with the inventive valve stent chamber-to-vessel embodiment implanted in the aortic valve and illustrating a blood flow vector of blood passing from the left atrium, through the mitral valve and into the left ventricle during and a retrograde blood flow vector blocked by the inventive valve stent in the aorta.

[0031] **FIG. 7** is a perspective view of the inventive valve stent chamber-to-chamber embodiment in its fully deployed state.

[0032] **FIG. 8** is a is a perspective view of the inventive valve stent chamber-to-chamber embodiment in its fully deployed state with the outermost graft layer and stent layer partially removed to show an embodiment of the valve apparatus.

[0033] **FIG. 9** is a top view of the inventive valve stent chamber-to-chamber embodiment in its fully deployed state.

[0034] **FIG. 10** shows the cross sectional view taken along line **10—10** of **FIG. 7**.

[0035] **FIG. 11** is a bottom view of inventive valve stent chamber-to-chamber embodiment in its fully deployed state.

[0036] **FIG. 12A** illustrates a cross-sectional view of a human heart during atrial systole with the inventive valve stent chamber-to-chamber embodiment implanted at the site of the mitral valve and illustrating a blood flow vector of a filling fraction leaving the left atrium and entering the left ventricle.

[0037] **FIG. 12B** illustrates a cross-sectional view of a human heart during atrial diastole with the inventive valve stent chamber-to-chamber embodiment implanted at the site of the mitral valve and illustrating a blood flow vector of an ejection fraction from the left ventricle to the aorta and the back pressure against the implanted mitral valve prosthesis.

[0038] **FIG. 13** is a perspective view of the chamber-to-vessel configuration in the fully deployed state.

[0039] **FIG. 14** is a perspective view of the same configuration in the fully deployed state with the outermost graft layer and stent layer partially removed to show an embodiment of the valve apparatus.

[0040] **FIG. 15** is a top view of the same configuration.

[0041] **FIG. 16** shows the cross sectional view of the same configuration for the deployed state.

[0042] **FIG. 17** is a bottom view of the same configuration.

[0043] **FIG. 18A and 18B** show cross-sectional views of a vein and venous valve illustrating the inventive prosthetic venous valve in the open and closed state.

[0044] FIGS. **19** is a cross-sectional diagrammatic view of a valvuloplasty and stent valve delivery catheter in accordance with the present invention.

[0045] **FIG. 20A-20I** are diagrammatic cross-sectional views illustrating single catheter valvuloplasty, inventive stent valve delivery and stent valve operation in situ in accordance with the method of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0046] The present invention consists generally of three preferred embodiments, each embodiment corresponding to a prosthetic stent valve configuration adapted for either heart chamber to blood vessel communication, chamber to chamber communication or vessel to vessel, or intravascular configuration. Certain elements are common to each of the preferred embodiments of the invention, specifically, each embodiment includes a stent body member which defines a central annular opening along the longitudinal axis of the stent body member, a graft member which covers at least a portion of the stent body member along either the lumenal or ablumenal surfaces of the stent body member, at least one biasing arm is provided and projects from the stent body member and into the central annular opening of the stent body member, and at least one valve flap member which is coupled to each biasing arm such that the biasing arm biases the valve flap member to occlude the central annular opening of the stent body member under conditions of a zero pressure differential across the prosthesis. The stent body member is preferably made of a shape memory material or superelastic material, such as NITINOL, but also be fabricated from either plastically deformable materials or spring-elastic materials such as is well known in the art. Additionally, the stent body member has three main operable sections, a proximal anchor section, a distal anchor section and an intermediate annular section which is intermediate the proximal and distal anchor sections. Depending upon the specific inventive embodiment, the distal and proximal anchor sections may be either a diametrically enlarged section or may be a flanged section. The intermediate annular section defines a valve exclusion region and primary blood flow channel of the inventive valve stent. The intermediate annular section defines a lumenal opening through

which blood flow is established. The transverse cross-section of the lumenal opening may be circular, elliptical, ovular, triangular or quadralinear, depending upon the specific application for which the valve stent is being employed. Thus, for example, where a tricuspid valve is particularly stenosed, it may be preferable to employ a valve stent with a lumenal opening in the intermediate annular section which has a triangular transverse cross-sectional dimension.

[0047] Chamber-to-Vessel Configuration

[0048] An implantable prosthesis or prosthetic valve in accordance with certain embodiments of the chamber-to-vessel CV configuration of the present invention is illustrated generally in FIGS. **1-5**. The chamber-to-vessel valve stent **10** consists of an expandable stent body member **12** and graft member **11**. The stent body member **12** is preferably made from a shape memory and/or superelastic NITINOL material, or thermomechanically similar materials, but may be made of plastically deformable or elastically compliant materials such as stainless steel, titanium or tantalum. The graft member **11** is preferably made of biologically-derived membranes or biocompatible synthetic materials such as DACRON or expanded polytetrafluoroethylene. The stent body member **12** is configured to have three functional sections: a proximal anchor flange **22**, an intermediate annular section **20** and a distal anchor section **16**. The stent body member **12**, as with conventional stents is formed of a plurality of stent struts **13** which define interstices **14** between adjacent stent struts **13**. The stent body member preferably also includes a transitional section **18** which interconnects the intermediate annular section **20** and the distal anchor section **16**, which together define a valve exclusion region of the inventive stent valve **10** to exclude the anatomic valve after implantation. The proximal anchor flange **22**, the intermediate annular section **20** and the distal anchor section **16** are each formed during the formation of the stent body member and are formed from the same material as the stent body member and comprise stent struts **13** and intervening interstices **14** between adjacent pairs of stent struts **13**. The anchor flange **22**, for example, consists of a plurality of stent struts and a plurality of stent interstices, which project radially outwardly away from the central longitudinal axis of the stent body member. Thus, the different sections of the stent body member **12** are defined by the positional orientation of the stent struts and interstices relative to the central longitudinal axis of the stent body member **12**.

[0049] With reference to **FIG. 2**, there is shown in greater detail the valve body **26** and valve arms or flow regulator struts **24** coupled to the stent body member **12**. The valve body **26** subtends the central annular opening of the stent valve **10** and is illustrated in its closed position. In accordance with one embodiment of the present invention, the graft member **11** consists of an outer or ablumenal graft member **11***a* and an inner or lumenal graft member **11***b*. The outer graft member **11***a* encloses at least a portion of the ablumenal surface of the intermediate annular section **20** of the stent body member, while the inner graft member **11***b* is coupled, on the lumenal surface of the intermediate annular section **20** of the stent body member **12**, to the outer graft member **11***a* through the interstices **14** of the stent body member. The valve body **26** is formed by everting the inner graft member **11***b* toward the central longitudinal axis of the stent body member **12** such that free ends or valve flap portions **28** of the inner graft member **11***b* are oriented toward the distal anchor section **16** of the stent body member **12** and a pocket or envelope **27** is formed at the eversion point of the inner graft member **11***b* adjacent the junction between the intermediate annular section **20** and the proximal anchor flange **22** of the stent body member **12**. Alternatively, portions of the outer graft member **11***a* may be passed through to the lumenal surface of the stent body member **12**, thereby becoming the inner graft member **11***b* and everted to form the valve body **26**.

[0050] Valve arms or regulator struts **24** are coupled or formed integral with the stent body member **12** and are positioned adjacent the junction point between intermediate annular section and the proximal anchor flange **22** of the stent body member **12**. The valve arms **24** are oriented radially inward toward the central longitudinal axis of the stent body member **12** when in their zero strain state. The valve arms **24** are attached or coupled to the valve flap portions **28** of the inner graft member leaflets to bias the valve flap portions **28** to the closed position when under zero pressure differential across the stent valve **10**.

[0051] The zero strain position of the valve arms **24** is radially inward and orthogonal to the central longitudinal axis of the stent valve **10**. Valve arms **24** have a length which is preferably longer than the radius of the lumenal diameter of the stent valve **10**, and they extent distally into the lumen of the stent valve **10** such that, in conjunction with the action of the valve leaflets **28**, the valve arms **24** are prevented from achieving their zero strain configuration thereby biasing the valve closed. As shown in **FIG. 4**, the valve arms **24** force the valve leaflets **28** to collapse into the center of the lumen of the stent valve **10**, thus biasing the valve to its closed position.

[0052] It is preferable to couple sections of the valve flaps **28**, along a longitudinal seam **29**, to the inner graft member **11***b* and the outer graft member **11***a* at points equidistant from the valve arms **24** in order to impart a more cusp-like structure to the valve flaps **28**. It should be appreciated, that the graft member **11** should cover at least a portion of the ablumenal surface of the stent body member **12** in order to exclude the anatomic valves, but may also cover portions or all of the stent valve member **12**, including the distal anchor section **16**, the intermediate annular section **20**, the transition section **18** and/or the proximal anchor flange **22**, on either or both of the lumenal and ablumenal surfaces of the stent body member.

[0053] In accordance with a particularly preferred embodiment of the CV valve stent **10**, the proximal anchor flange **22**, which consists of a plurality of stent struts and stent interstices which project radially outward away from the central longitudinal axis of the valve stent **10**, is configured to have one or more stent struts eliminated from the proximal anchor flange **22** to define an open region which is positioned in such a manner as to prevent the CV valve stent **10** from interfering with or impinging upon an adjacent anatomic structure. For example, where the CV valve stent **10** is to be an aortic valve prosthesis, it is known that the mitral valve is immediately adjacent the aortic valve, and the mitral valve flaps deflect toward the left ventricle. Thus, placing the CV valve stent **10** such that the proximal anchor flange **22** is adjacent the mitral valve might, depending upon the particular patient anatomy, interfere with normal open-

ing of the mitral valve flaps. By eliminating one or more of the stent struts in the proximal anchor flange **22**, an opening is created which permits the mitral valve flaps to deflect ventricularly without impinging upon the proximal anchor flange **22** of the CV valve stent **10**.

[0054] Similarly, the stent struts of the CV valve stent **10** may be oriented in such a manner as to create interstices of greater or smaller area between adjacent struts, to accommodate a particular patient anatomy. For example, where the stent struts in the distal anchor section **16** would overly an artery branching from the aorta, such as tbe coronary ostreum arteries, it may be desirable to either eliminate certain stent struts, or to configure certain stent struts to define a greater interstitial area to accommodate greater blood flow into the coronary ostreum.

[0055] In the case of providing an oriented opening in the proximal anchor flange, or an oriented opening in the interstitial spaces of the distal anchor, it is desirable to provide radiopaque markers on the stent body member **12** to permit the CV valve stent to be oriented correctly relative to the anatomic structures.

[0056] **F1GS. 6A and 6B** illustrate the inventive CV stent valve **10** implanted in the position of the aortic valve and excluding the anatomic aortic valve AV. **FIG. 6A** illustrates the heart during systole in which a positive pressure is applied to the prosthetic aortic valve by contraction of the left ventricle LV and the ejection fraction represented by the arrow. The systolic pressure overcomes the bias exerted by the valve arms **24** and causes the valve leaflets **26** to open and release the ejection fraction into the aorta. **F1G. 6B** illustrates that the presence of a negative pressure head across the stent valve **10**, i.e. such as that during diastole, causes the biased valve leaflets **26** which are already closed, to further close, and prevent regurgitation from the aorta into the left ventricle.

[0057] Chamber-to-Chamber Configuration

[0058] FIGS. **7-11** illustrate the inventive stent valve in the chamber-to-chamber (CC) configuration **40**. The CC valve stent **40** is constructed in a manner which is virtually identical to that of the CV valve stent **10** described above, except that the distal anchor section **16** of the CV valve stent **10** is not present in the CC valve stent **40**, but is substituted by a distal anchor flange **42** in the CC stent valve. Thus, like the CV valve stent **10**, described above, the CC valve stent **40** if formed of a stent body member **12** and a graft member **11**, with the graft member having lumenal **11***b* and ablumenal **11***a* portions which cover at least portions of the lumenal and ablumenal surfaces of the stent body member **12**, respectively. The CC valve stent **40** has both a proximal anchor flange **44** and a distal anchor flange **42** which are formed of sections of the stent body member **12** which project radially outward away from tbe central longitudinal axis of the CC valve stent **40** at opposing ends of the stent body member **12**.

[0059] Like the CV valve stent **10**, the lumenal graft portion **11***b* is everted inwardly toward the central longitudinal axis of the valve stent **40** and free ends **28** of the lumenal graft portion **11***b* to form valve flaps **26** which project distally toward distal anchor flange **42**. Flow regulation struts **24** are coupled to or integral with the proximal anchor flange **44** and intermediate annular section **20** and project radially inward toward the central longitudinal axis of the CC valve stent **40**. The valve flaps **26** are coupled to the flow regulation struts **24** and the flow regulation struts **24** bias the valve flaps **26** to a closed position under a zero strain load.

[0060] Like with the CV stent valve **10**, it is preferable to couple sections of the valve flaps **28**, along a longitudinal seam **29**, to the inner graft member **11***b* and the outer graft member **11***a* at points equidistant from the valve arms **24** in order to impart a more cusp-like structure to the valve flaps **28**.

[0061] Turning to **F1GS. 12A and B** there is illustrated the inventive CC stent valve **40** implanted in the position of the mitral valve and excluding the anatomic mitral valve MV. **F1G. 12A** illustrates the heart during atrial systole in whicb a positive pressure is applied to the prosthetic mitral valve by contraction of the left atrium LA and the pressure exerted by the blood flow represented by the arrow. The atrial systolic pressure overcomes the bias exerted by the valve arms **24** onto the valve leaflets **26**, and causes the valve leaflets **26** to open and release the atrial ejection fraction into the left ventricle. **F1G. 12B** illustrates that the presence of a negative pressure head across the stent valve **40**, i.e. such as that during atrial diastole, causes the biased valve leaflets **26** which are already closed, to further close, and prevent backflow from the left ventricle into the left atrium.

[0062] In accordance with another preferred embodiment of the invention, the CC configuration may be adapted for use in repairing septal defects. By simply substituting a membrane for the valve leaflets **26**, the lumen of the stent body member **12** is occluded. The CC stent valve **40** may be delivered endoluminally and placed into a position to subtend a septal defect and deployed to occlude the septal defect.

[0063] Vessel-to-Vessel Configuration

[0064] Turning now to FIGS. **13-17**, there is illustrated the inventive stent valve in its vessel-to-vessel (VV) valve stent configuration **50**. The VV valve stent **50** is constructed in a manner which is virtually identical to that of the CV valve stent **10** described above, except that the proximal anchor flange **22** of the CV valve stent **10** is not present in the VV valve stent **50**, but is substituted by a proximal anchor section **52** in the VV stent valve. Thus, like the CV valve stent **10**, described above, the VV valve stent **50** is formed of a stent body member **12** and a graft member **11**, with the graft member having lumenal **11***b* and ablumenal **11***a* portions which cover at least portions of the lumenal and ablumenal surfaces of the stent body member **12**, respectively. The VV valve stent **50** has both a proximal anchor section **52** and a distal anchor section **54** which are formed of sections of the stent body member **12** which are diametrically greater than tbe intermediate annular section **20** of the VV valve stent **50**. Transition sections **56** and **58** taper outwardly away from the central longitudinal axis of the VV valve stent **50** and interconnect the intermediate annular section **20** to each of the distal anchor section **54** and the proximal anchor section **52**, respectively.

[0065] Like the CV valve stent **10**, in the VV valve stent **50**, the graft member **11**, particularly the lumenal graft portion **11***b* or the ablumenal graft portion **11***a*, or both, is everted inwardly toward the central longitudinal axis of the

valve stent **40** and free ends **28** of the lumenal graft portion **11***b* to form valve flaps **26** which project distally toward distal anchor flange **42**. Flow regulation struts **24** are coupled to or integral with the stent body member at the proximal transition section **58** and project radially inward toward the central longitudinal axis of the VV valve stent **50**. The valve flaps **26** are coupled to the flow regulation struts **24** and the flow regulation struts **24** bias the valve flaps **26** to a closed position under a zero strain load. Like with the CV stent valve **10** and the CC stent valve **40**, it is preferable to couple sections of the valve flaps **28**, along a longitudinal seam **29**, to the inner graft member **11***b* and the outer graft member **11***a* at points equidistant from the valve arms **24** in order to impart a more cusp-like structure to the valve flaps **28**.

[0066] Turning to **FIGS. 18A and B** there is illustrated the inventive VV stent valve **50** implanted in the position of a venous valve and excluding the anatomic venous valve flaps VE. **FIG. 18A** illustrates the vein under systolic blood pressure in which a positive pressure is applied to the prosthetic venous valve and the pressure exerted by the blood flow represented by the arrow. The systolic pressure overcomes the bias exerted by the valve arms **24** onto the valve leaflets **26**, and causes the valve leaflets **26** to open and permit blood flow through the prosthesis. **FIG. 18B** illustrates that the presence of a negative pressure head across the VV stent valve **50**, i.e. such as which exists at physiological diastolic pressures, causes the biased valve leaflets **26** which are already closed, to further close, and prevent backflow from the left ventricle into the left atrium.

[0067] The purpose of the proximal **54** and distal **52** anchor sections of the stent body member **12** is to anchor the prosthesis at the anatomic vessel-vessel junction, such as a venous valve, while causing minimal interference with adjacent tissue. The intermediate annular section **20** of the VV stent valve **50** excludes diseased anatomic leaflets and surrounding tissue from the flow field. The flare angle of the transition sections **56, 58** between the intermediate annular section **20** and each of the proximal and distal anchor sections **54, 52**, respectively, may be an acute angle, a right angle or an obtuse angle, depending upon the anatomical physiological requirements of the implantation site. Alternatively, the transition sections **56, 58** may be coplanar with the proximal and distal anchor section **52, 54**, respectively, thereby, eliminating any transition flare angle, depending upon the anatomical and physiological requirements of the delivery site.

[0068] Single Catheter Valvuloplasty Stent Valve Delivery System and Method of Delivery

[0069] In accordance with the present invention, there is also provide a single catheter valvuloplasty and valve stent delivery system **200** illustrated in **FIG. 19**. The objective of the single catheter delivery system **200** is to permit the surgeon or interventionalist to percutaneously deliver and deploy the inventive valve stent **10, 40** or **50** at the desired anatomical site and to perform valvuloplasty with a single catheter. In accordance with the preferred embodiment of the single catheter delivery system **200** of the present invention, there is provided a catheter body **210** having dual lumens **212, 216**. A first lumen **212** is provided as a guidewire lumen and is defined by a guidewire shaft **222** which traverses the length of the catheter body **210**. A second lumen is an inflation lumen **216** for communicating an inflation fluid, such as saline, from an external source, through an inflation port **240** at the operator end of the catheter **210**, to an inflatable balloon **214** located at or near the distal end of the catheter body **210**. The inflation lumen **216** is defined by an annular space between the lumenal surface of the catheter body **210** and the ablumenal surface of the guidewire shaft **222**. A capture sheath **217** is provided at the distal end **215** of the catheter body **210** and is positioned adjacent and distal the balloon **214**. The capture sheath **217** defines an annular space about the guidewire lumen **212** and the capture sheath **217** into which the stent valve **10, 40** or **50** is positioned and retained during delivery. An annular plug member **220** is within the inflation lumen **216** distal the balloon **214** and terminates the inflation lumen **216** in a fluid tight manner. Annular plug member **220** has a central annular opening **221** through which the guidewire shaft **222** passes. The annular plug member **220** is coupled to the guidewire shaft **222** and is moveable axially along the central longitudinal axis of the catheter **200** by moving the guidewire shaft **222**. The annular plug member **220** also serves to abut the stent valve **10, 40** and **50** when the stent valve **10, 40** and **50** is positioned within the capture sheath **217**. The guidewire shaft **222** passes through the capture sheath **217** and terminates with an atraumatic tip **218** which facilitates endoluminal delivery without injuring the native tissue encountered during delivery. With this configuration, the stent valve is exposed by proximally withdrawing the catheter body **210**, while the guidewire shaft **222** is maintained in a fixed position, such that the annular plug member **220** retains the position of the stent valve as it is uncovered by capture sheath **217** as the capture sheath **217** is being proximally withdrawn with the catheter body **210**.

[0070] In many cases the anatomic valve will be significantly stenosed, and the valve flaps of the anatomic valve will be significantly non-compliant. The stenosed valves may be incapable of complete closure permitting blood regurgitation across the anatomic valve. Thus, it may be desirable to configure the inflatable balloon **214** to assume an inflation profile which is modeled to maximally engage and dilatate the anatomic valves. For example, a tricuspid valve, such as the aortic valve may stenose to an opening which has a generally triangular configuration. In order to maximally dilatate this triangular opening, it may be desirable to employ a balloon profile which assumes a triangular inflation profile. Alternatively, it may be advantageous to configure the balloon such that it does not fully occlude the anatomic lumen when inflated, but permits a quantum of blood flow to pass around the balloon in its inflated state. This may be accomplished by providing channels or ridges on the ablumenal surface of the balloon. Additionally, irregular inflation profiles of the balloon may facilitate continuous blood flow about the inflated balloon. Furthermore, it may be desirable to configure the balloon to have an hour-glass inflation profile to prevent migration or slippage of the balloon in the anatomic valve during valvuloplasty.

[0071] In accordance with the present invention, it is preferable that the capture sheath **217** be made of a material which is sufficiently strong so as prevent the stent valve **10, 40, 50** from impinging upon and seating into the capture sheath **217** due to the expansive pressure exerted by the stent valve **10, 40, 50** against the capture sheath. Alternatively, the capture sheath **217** may be lined with a lubricious material, such as polytetrafluoroethylene, which will prevent the capture sheath **217** from exerting drag or frictional forces against the stent valve during deployment of the stent valve.

[0072] In accordance with the present invention, it is also contemplated that the position of the balloon **214** and the capture sheath **217** may be reversed, such that the balloon

214 is distal the capture sheath **217**. In this configuration, the anatomic valve may be radially enlarged by dilatating the balloon **214**, then the catheter moved distally to position the capture sheath **217** at the anatomic valve and deployed in the manner described above. This would also allow for post-deployment balloon expansion of the deployed stent valve without the need to traverse the prosthetic valve in a retrograde fashion. Alternatively, the catheter **200** of the present invention may be provided without a balloon **214** in those cases where valvuloplasty is not required, e.g., where a stenotic valve does not need to be opened such as with a regurgitating valve, and the catheter **200** is terminated at its distal end with only a capture sheath **217**, and deployment occurs as described above.

[0073] Turning now to FIGS. **20A-20I** there is illustrated the sequence of steps in delivery of the stent valve of the present invention, valvuloplasty of the aortic valve and deployment of the stent valve at the position of the aortic valve. The single catheter delivery system **501** having a distal balloon **502** and a capture sheath **503** covering the valve stent **10** (not shown in FIGS. **20A-B**), is delivered percutaneously either through a femoral or subclavian artery approach, and traverses the aorta and is passed through the aortic valve **510** such that the balloon **503** on the distal end of catheter **501** is adjacent the aortic valve **510** and the capture sheath **503** is within the left ventricle **504**. A valvuloplasty step **520** is performed by inflating balloon **503** to dilate the aortic valve and deform the aortic valve flaps against the aorta wall adjacent the aortic valve. After the valvuloplasty step **520**, delivery of the valve stent **505** is initiated by stabilizing the guidewire shaft (not shown) while the catheter body is withdrawn antegrade relative to the blood flow until the proximal anchor flange section of the valve stent **505** is exposed by the withdrawal of the capture sheath **503**. The distal anchor flange of the valve stent **505** is then positioned at the junction between the aortic valve and the left ventricle at step **540**, such that the distal anchor flange engages the ventricular surface of the aortic valve. The valve stent is fully deployed at step **550** by retrograde withdrawal of the catheter body **501** which continues to uncover the intermediate annular section of the valve stent and release the aortic valve stent **505**. at the aortic valve site **510**. In step **560**, the valve stent **505** is completely deployed from the catheter **501** and the capture sheath **503**. The distal anchor section of the valve stent **505** expands and contacts the lumenal wall of the aorta, immediately distal the aortic valve, thereby excluding the aortic valve flaps from the lumen of the prosthetic aortic valve stent **505**. In step **570**, the atraumatic tip and guidewire are retracted by retrograde movement of the guidewire shaft of the catheter, and the catheter **501** is withdrawn from the patient. **FIGS. 20H and 20I** depict the implanted valve stent **505** during diastole and systole, respectively. During ventricular diastole **580**, the left ventricle expands to draw blood flow **506** from the left atrium into the left ventricle. A resultant negative pressure gradient is exerted across the valve stent **505**, and the valve arms and valve flaps **506** of the valve stent **505** are biased to the closed position to prevent a regurgitation flow **507** from passing through the valve stent **505** and into the left ventricle **504**. During ventricular systole **590**, the left ventricle contracts and exerts a positive pressure across the valve stent **505**, which overcomes the bias of the valve arms and valve flaps, which open **508** against the lumenal wall of the intermediate annular section of the valve stent and permit the ejection fraction **509** to be ejected from the left ventricle and into the aorta.

[0074] The method for delivery of the CC valve stent **40** or the VV valve stent **50** is identical to that of the CV stent **10** depicted in FIGS. **20A-20I**, except that the anatomical location where delivery and deployment of the valve stent occurs is, of course, different.

[0075] Thus, while the present invention, including the different embodiments of the valve stent, the delivery and deployment method and the single catheter valvuloplasty and delivery system, have been described with reference to their preferred embodiments, those of ordinary skill in the art will understand and appreciate that the present invention is limited in scope only by the claims appended hereto.

What is claimed is:

1. A catheter, comprising:

a. a catheter body defining a central longitudinal lumen;

b. an inflatable balloon positioned proximate the distal end of the catheter body and in fluid flow communication with the central longitudinal lumen;

c. a sheath positioned proximate the distal end of the catheter, distal the inflatable balloon and fixedly coupled to the catheter body and distally extensible therefrom;

d. a guidewire shaft positioned co-axially within the central longitudinal lumen of the catheter body and passing through an entire longitudinal length of the catheter body; and

e. an annular plug member concentrically coupled to the guidewire shaft and positioned distal the inflatable balloon and proximal the sheath, the annular plug member terminating the central longitudinal lumen of the catheter body in a fluid tight manner and being moveable therein.

2. The catheter of claim 1, further comprising a valve stent member, in a reduced diametric state, positioned within the sheath and concentrically about the guidewire shaft and distal the annular plug member.

3. A method of endoluminally delivering a valve stent within an anatomic passageway, comprising the steps of:

a. percutaneously passing a catheter endoluminally through an anatomic passageway to a valved anatomic situs within a body;

b. dilatating an inflatable balloon section of the catheter to dilatate anatomic valves at the anatomic situs within the body;

c. withdrawing the catheter from the dilatated valves at the anatomic situs and positioning a proximal end of a valve stent residing on the catheter;

d. positionally stabilizing the proximal end of the valve stent within the anatomic situs and withdrawing the catheter, inflatable balloon and sheath in a retrograde fashion thereby deploying the valve stent within the anatomic situs.

* * * * *

US006712842B1

(12) **United States Patent**
Gifford, III et al.

(10) **Patent No.: US 6,712,842 B1**
(45) **Date of Patent: *Mar. 30, 2004**

(54) **METHODS AND DEVICES FOR LINING A BLOOD VESSEL AND OPENING A NARROWED REGION OF A BLOOD VESSEL**

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(73) Assignee: **Allan Will**, Atherton, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/522,316**

(22) Filed: **Mar. 9, 2000**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/416,309, filed on Oct. 12, 1999.

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/1.13**; 623/1.23
(58) **Field of Search** 623/1.13, 1.23, 623/1.36, 1.2; 604/506–509, 96.01; 606/108, 151–158, 198, 194

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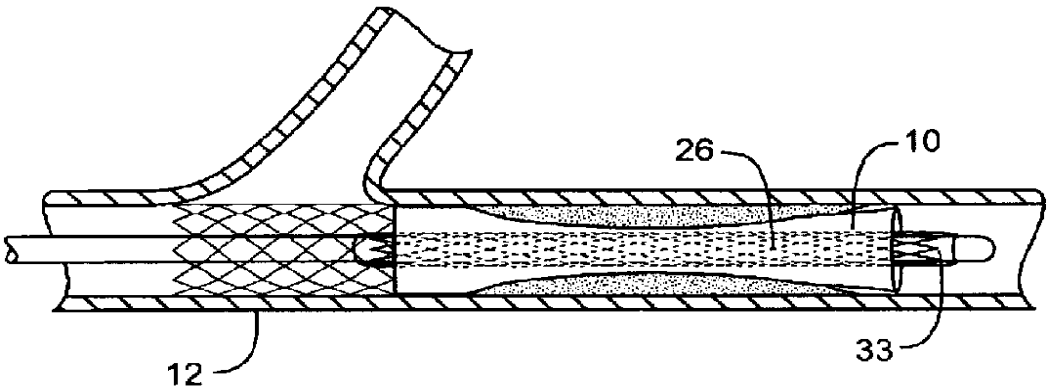
Primary Examiner—Michael J. Milano
Assistant Examiner—Jason R Baxter
(74) *Attorney, Agent, or Firm*—Jens E. Hoekendijk; Hoekendijk & Lynch, LLP

(57) **ABSTRACT**

A liner is advanced through a narrowed region in a vessel such as the internal carotid artery. The liner is advanced through the narrowed region in a collapsed position. A stent is then advanced through the liner and expanded to open the narrowed region. The liner may also have an anchor which expands an end of the liner before the stent is introduced.

88 Claims, 36 Drawing Sheets



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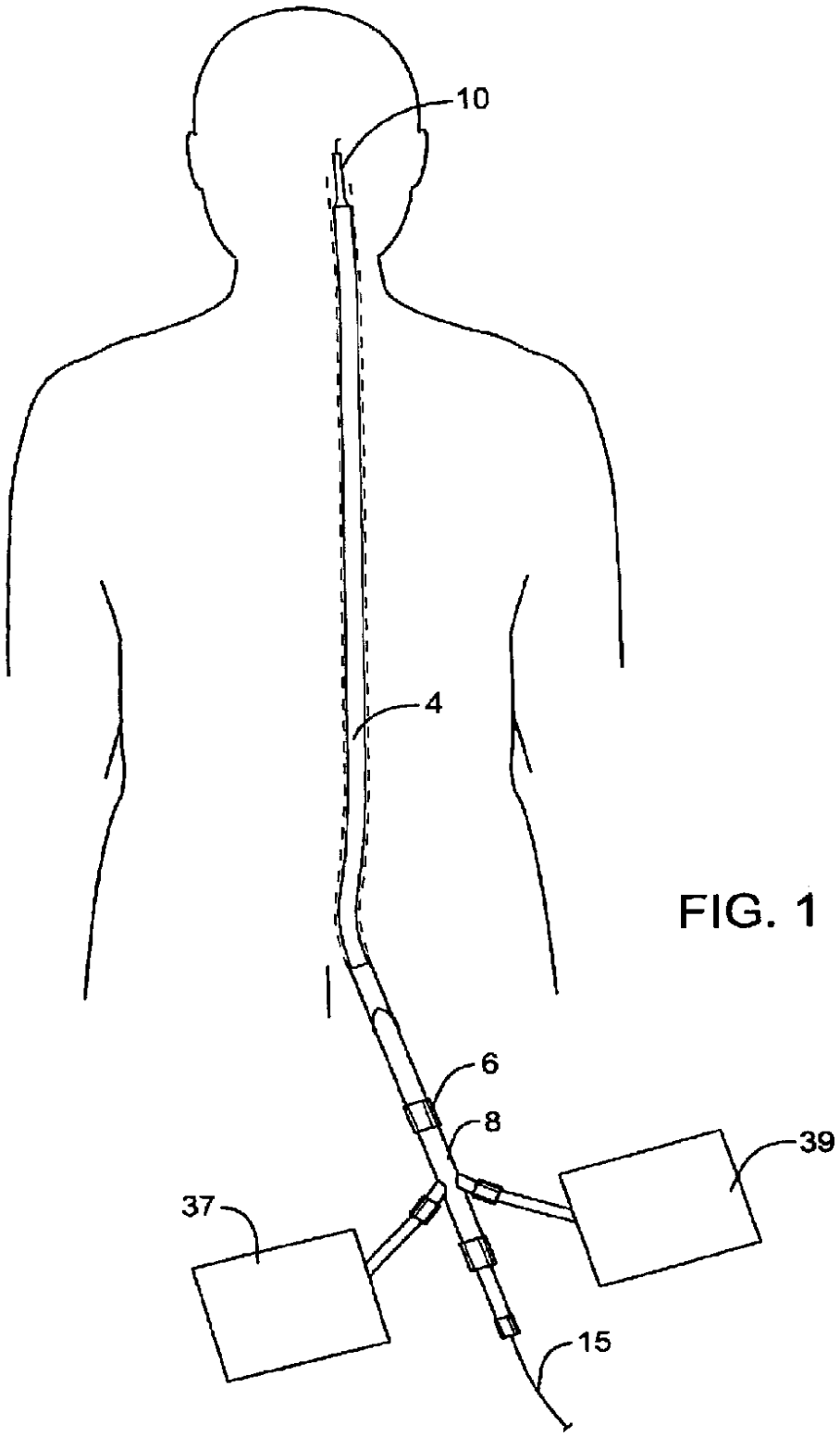


FIG. 1

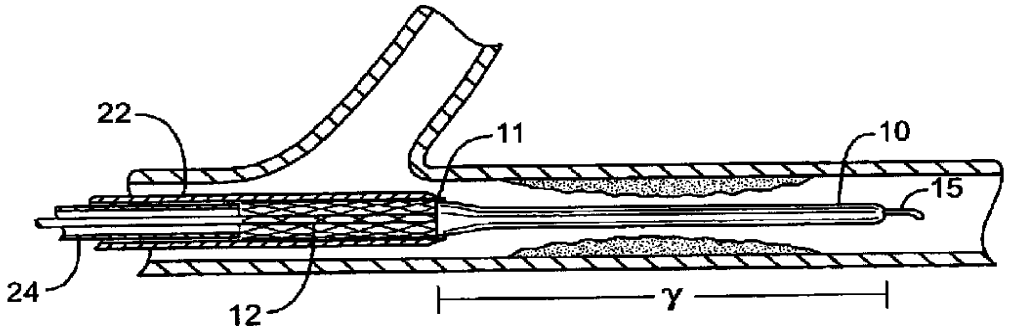


FIG. 2

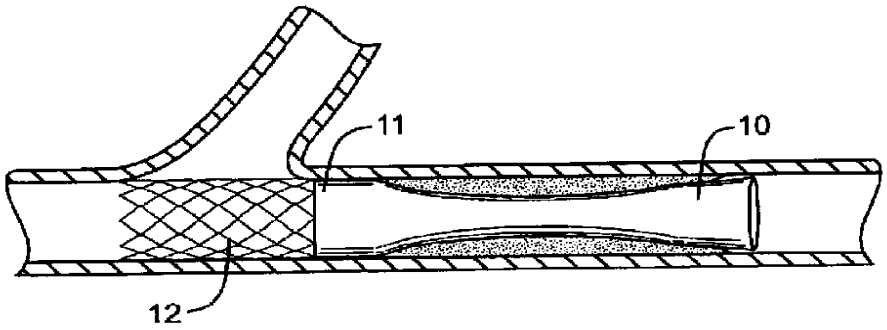


FIG. 3

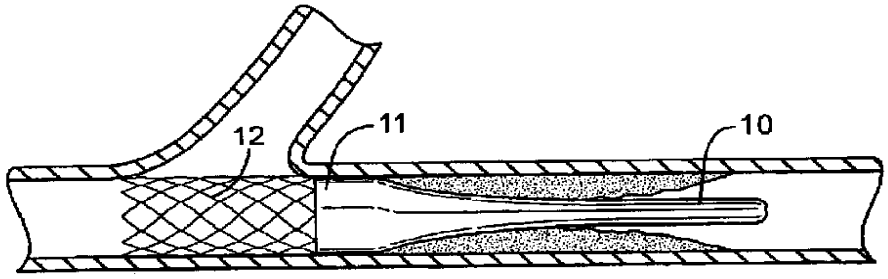


FIG. 4

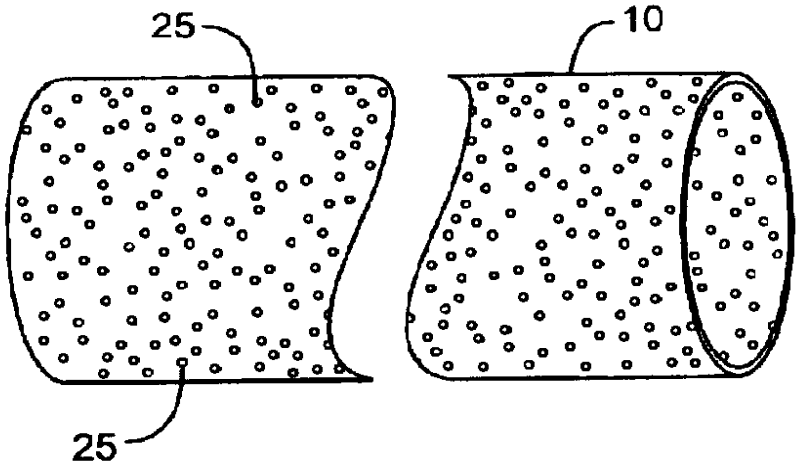


FIG. 6A

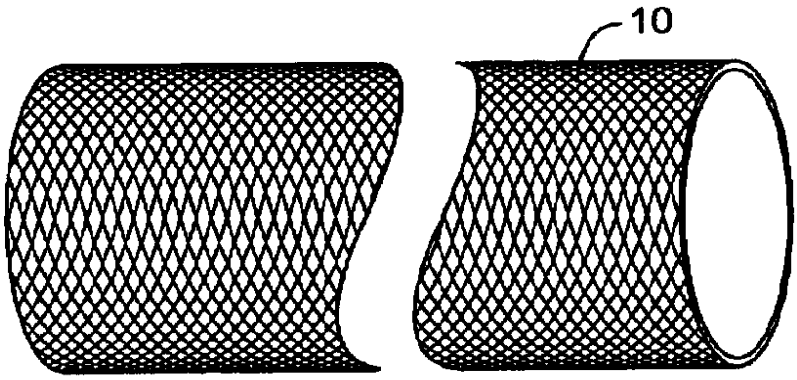


FIG. 5

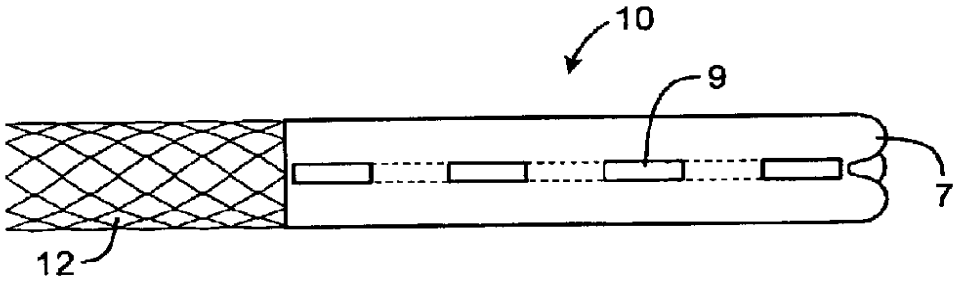


FIG. 6B

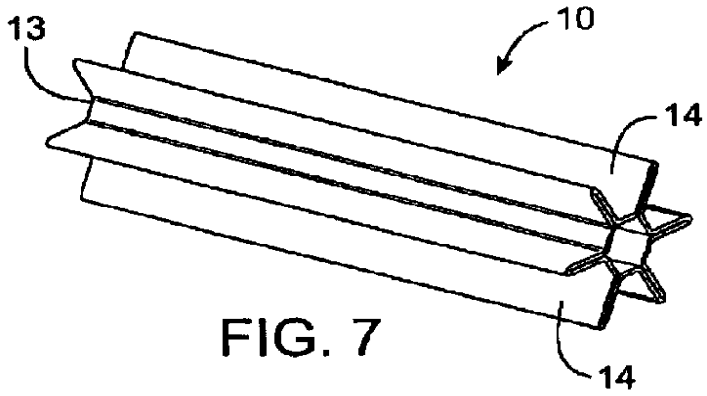


FIG. 7

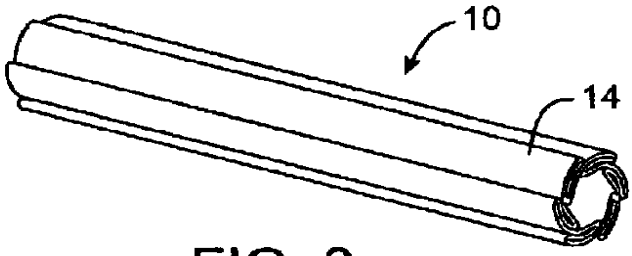


FIG. 8

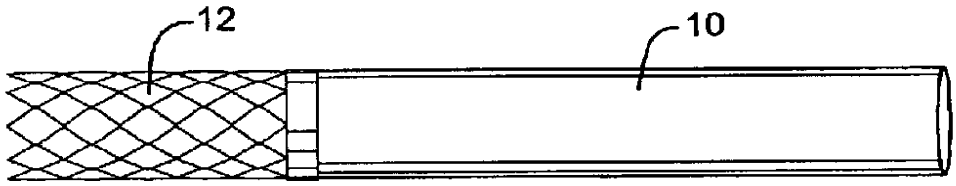


FIG. 19

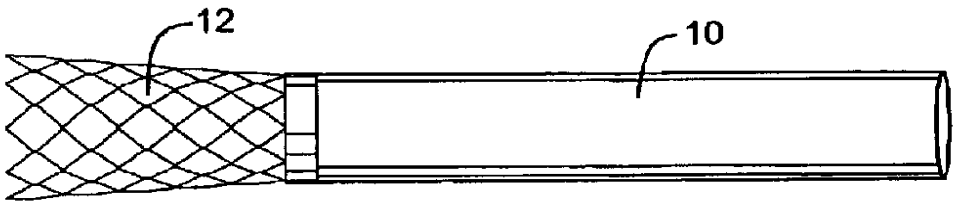


FIG. 20

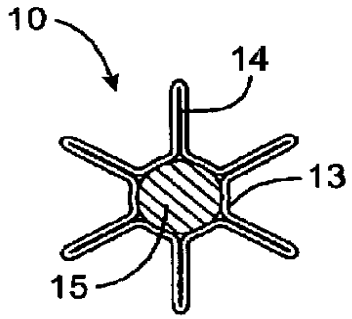


FIG. 9

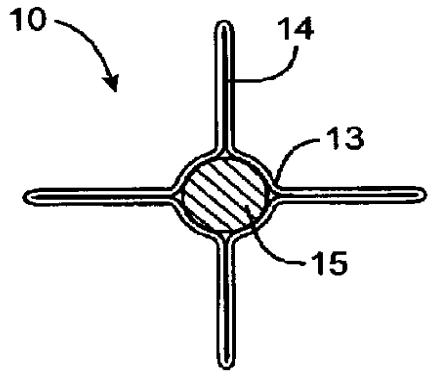


FIG. 11

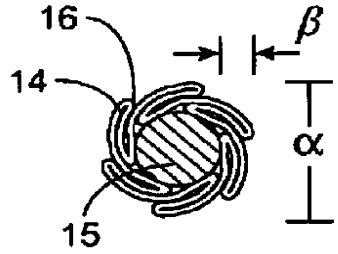


FIG. 10

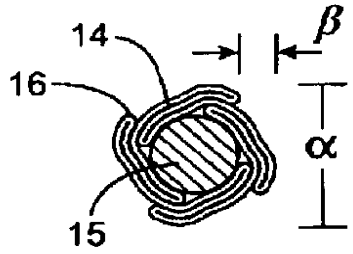


FIG. 12

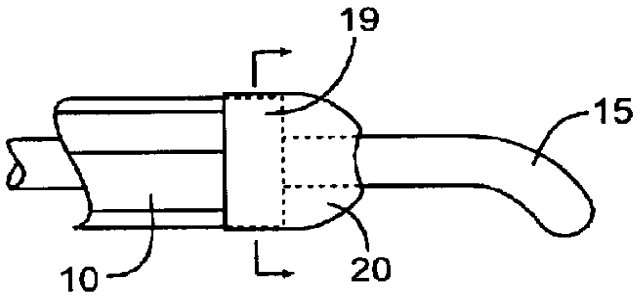


FIG. 13

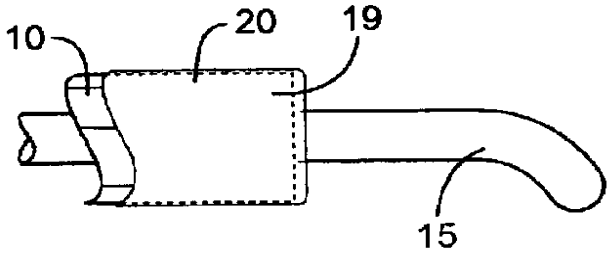


FIG. 14

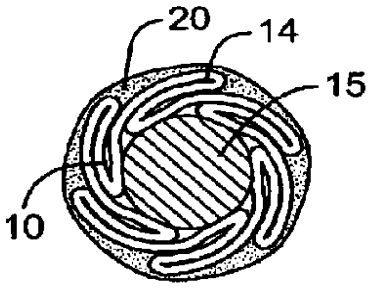


FIG. 15

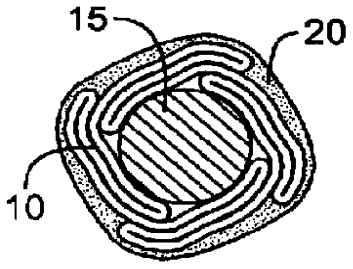


FIG. 16

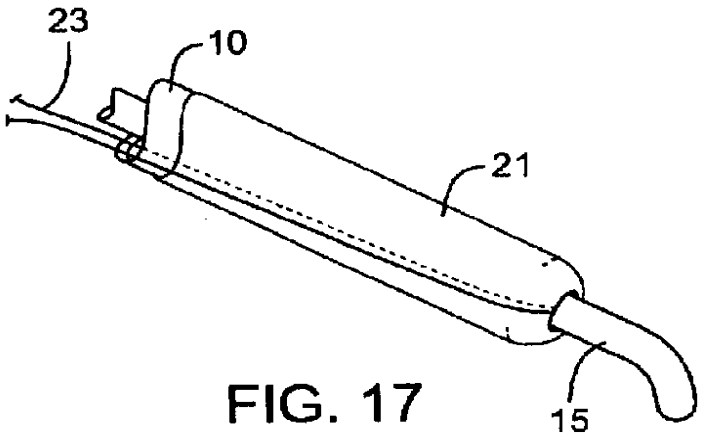


FIG. 17

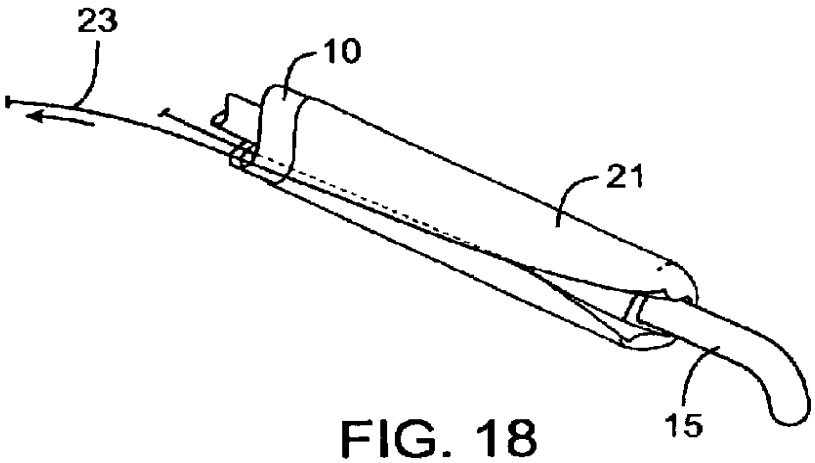


FIG. 18

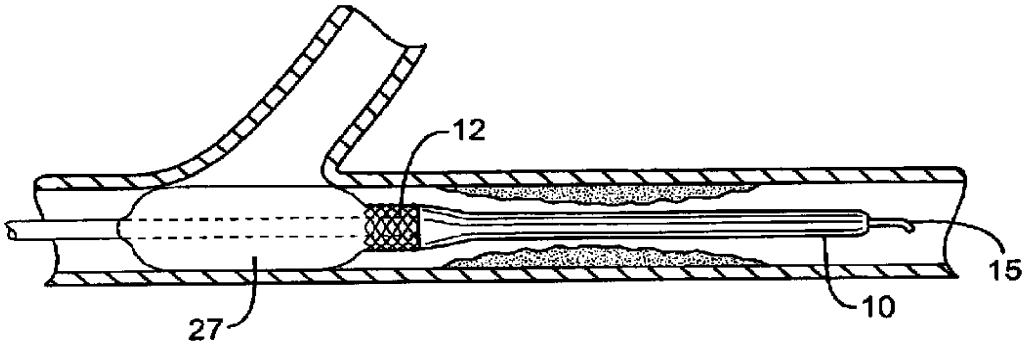


FIG. 21

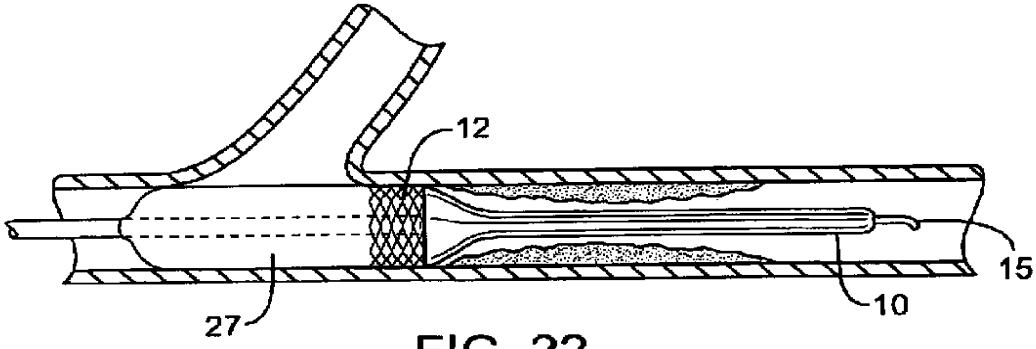


FIG. 22

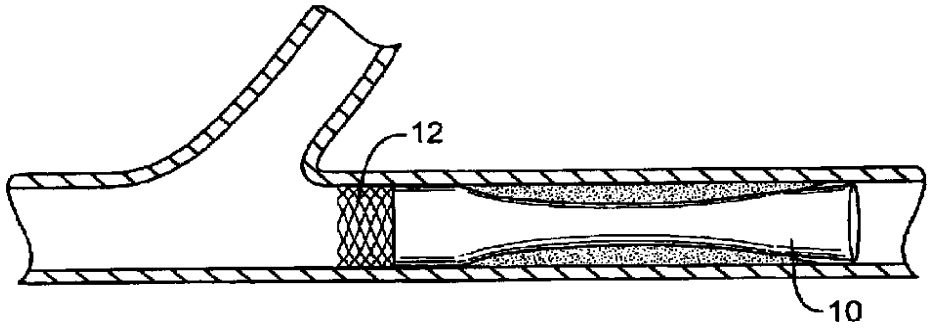


FIG. 23

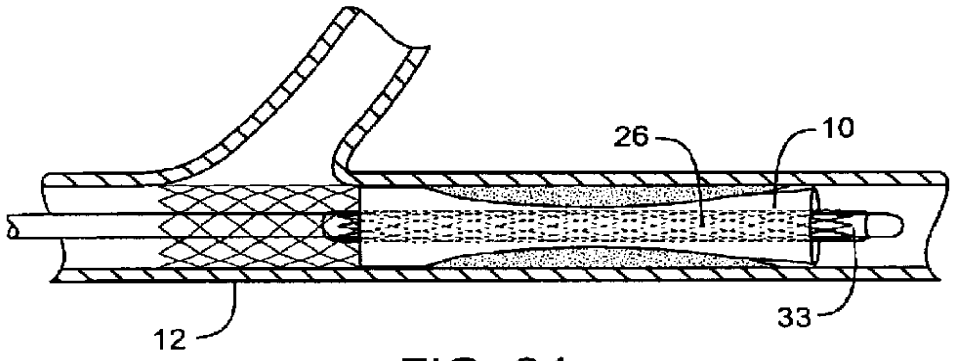


FIG. 24

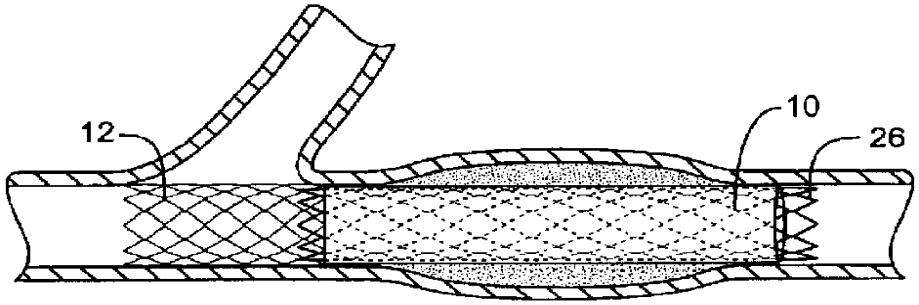


FIG. 25

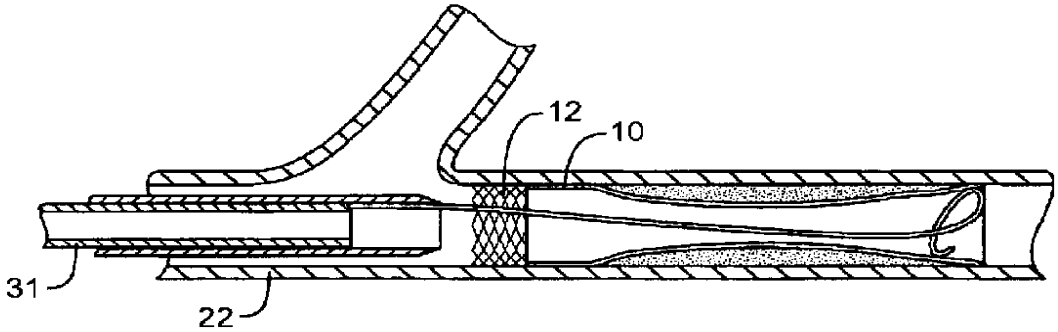


FIG. 26A

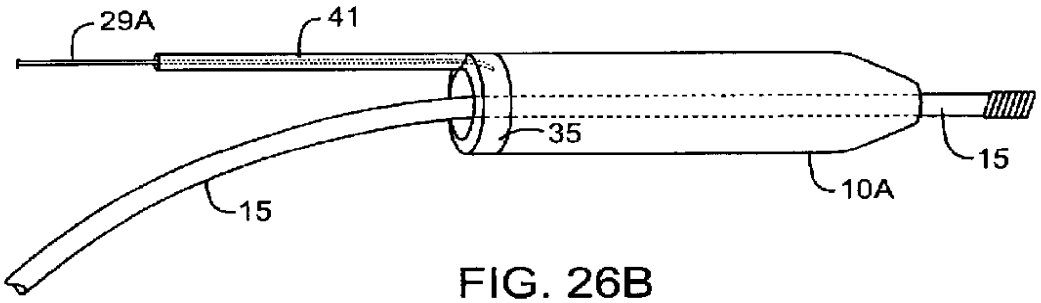


FIG. 26B

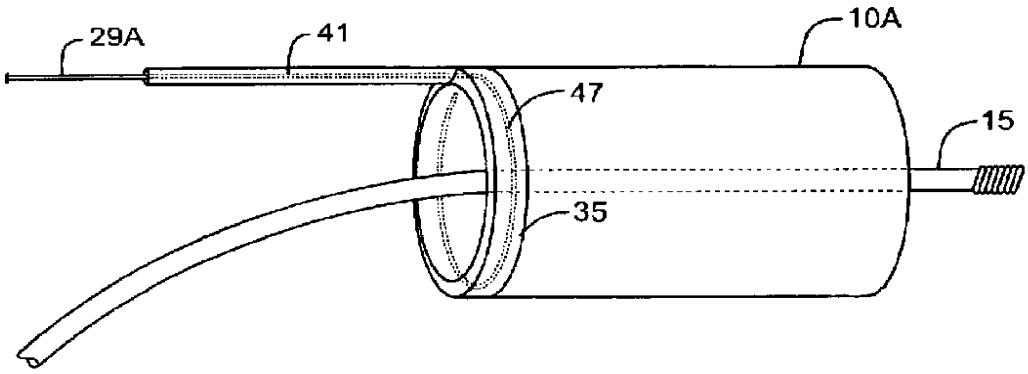


FIG. 26C

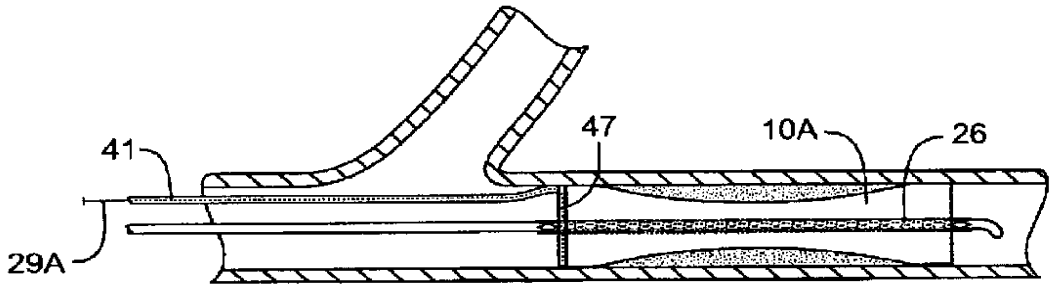


FIG. 26D

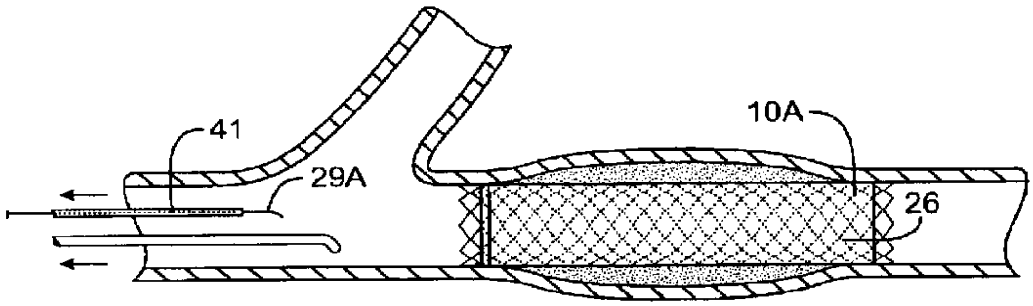


FIG. 26E

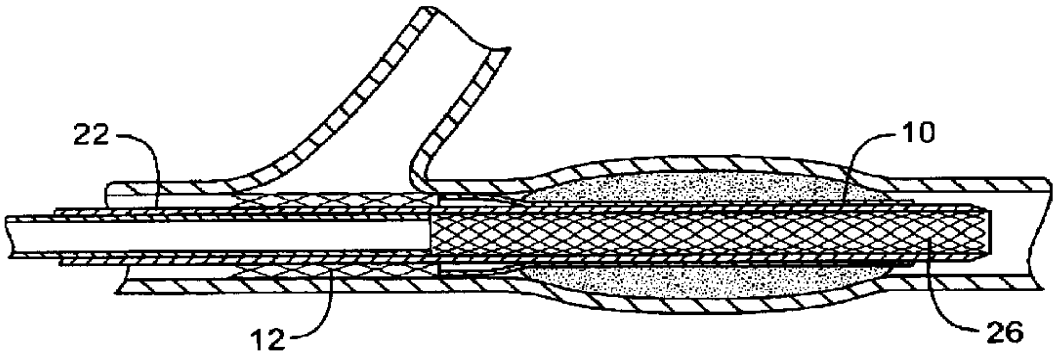


FIG. 27

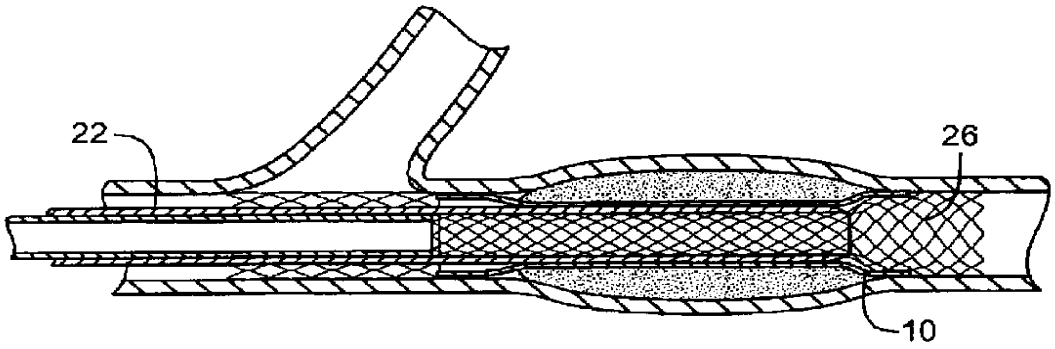


FIG. 28

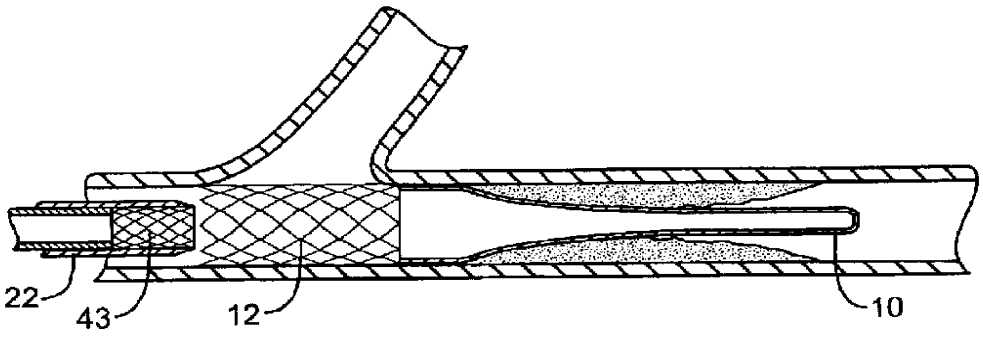


FIG. 29

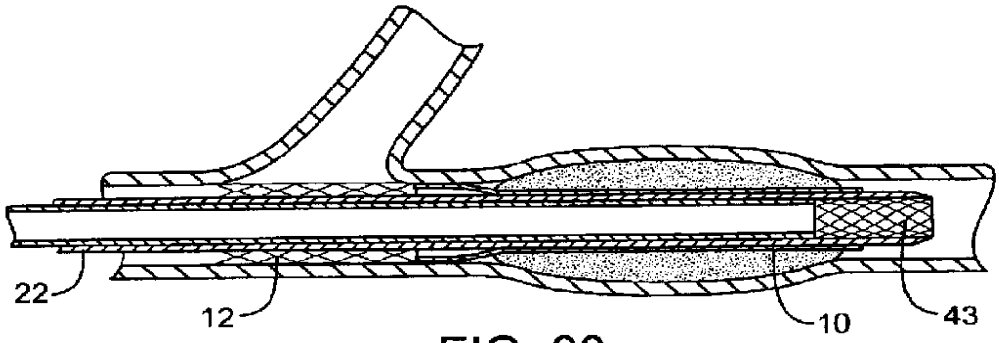


FIG. 30

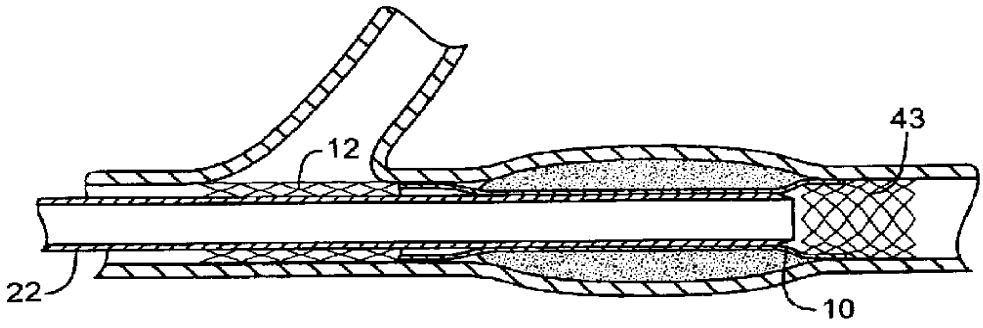


FIG. 31

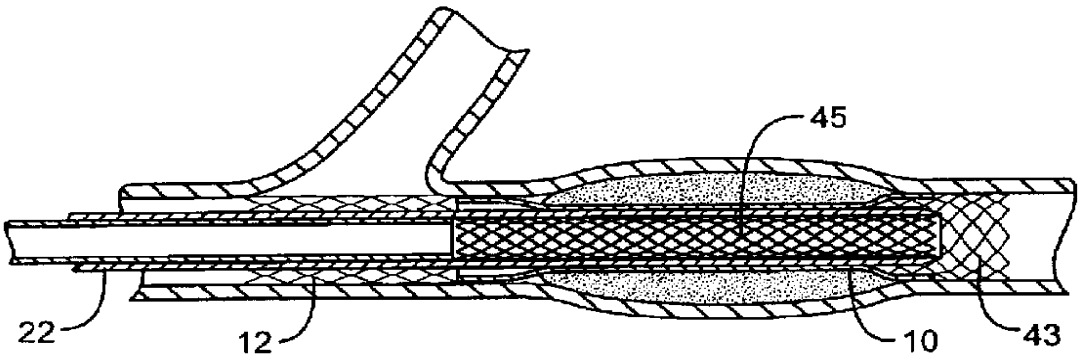


FIG. 32

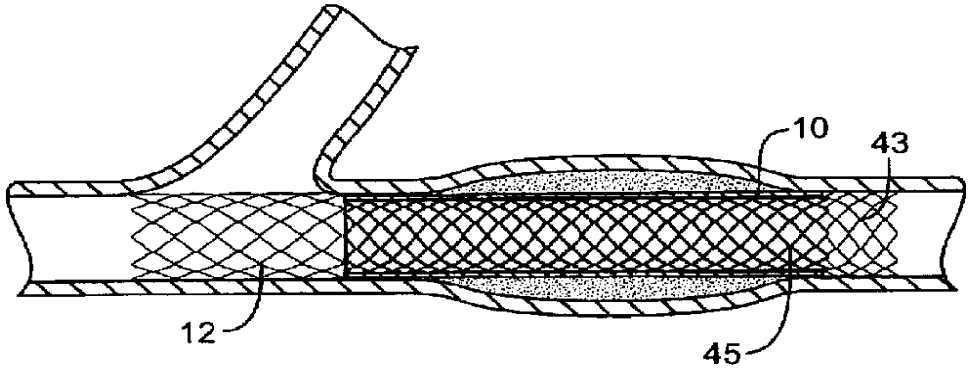


FIG. 33

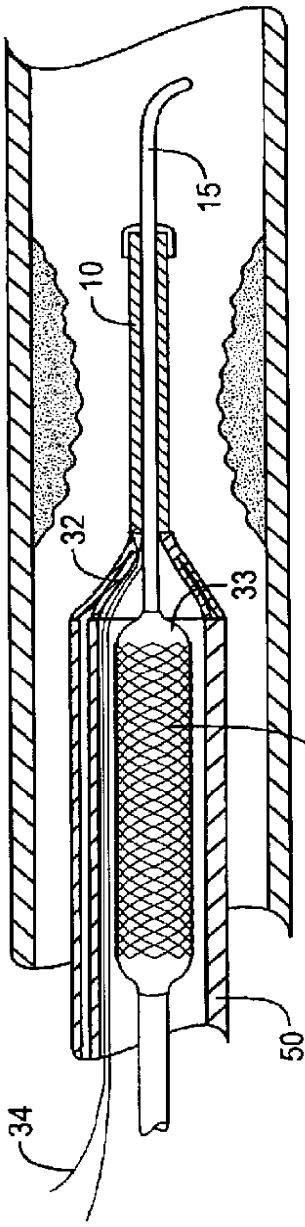


FIG. 34

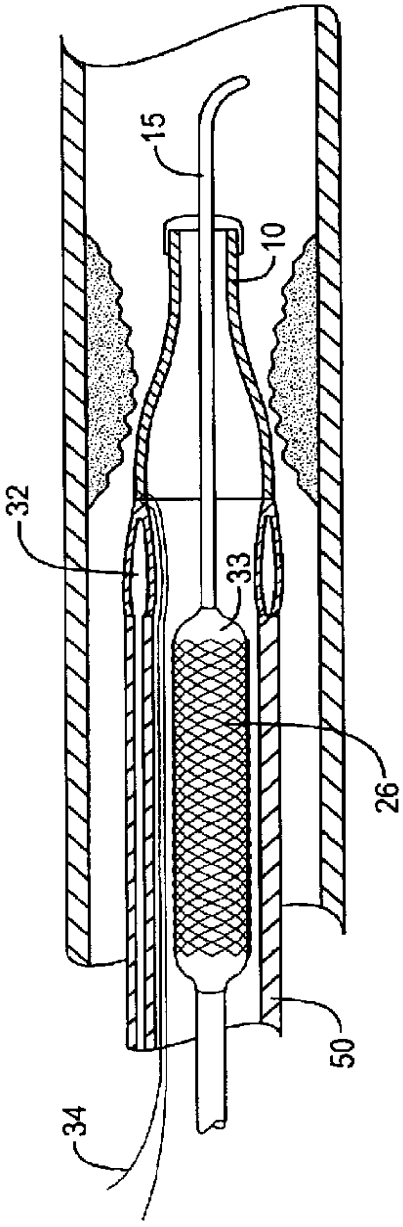


FIG. 35

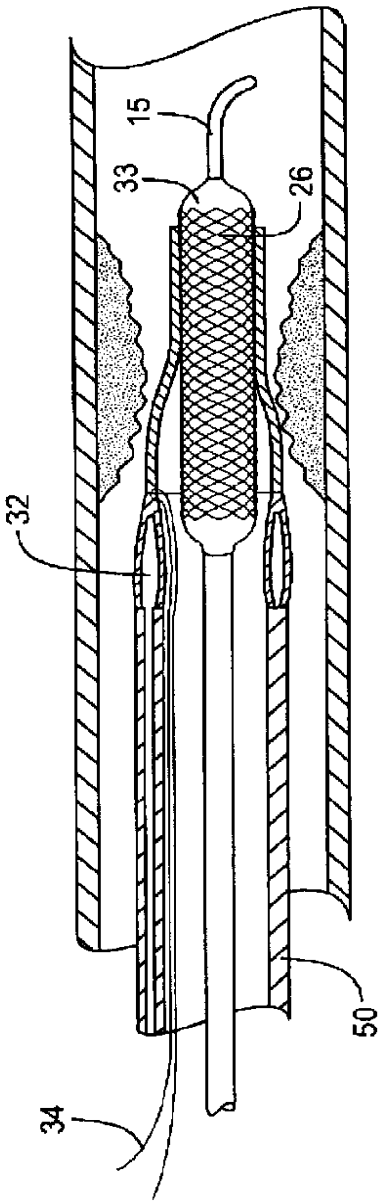


FIG. 36

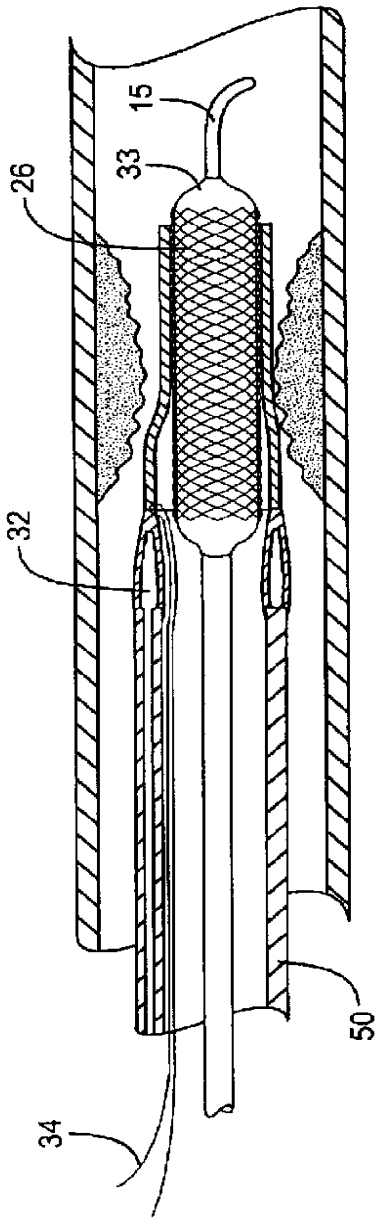


FIG. 37

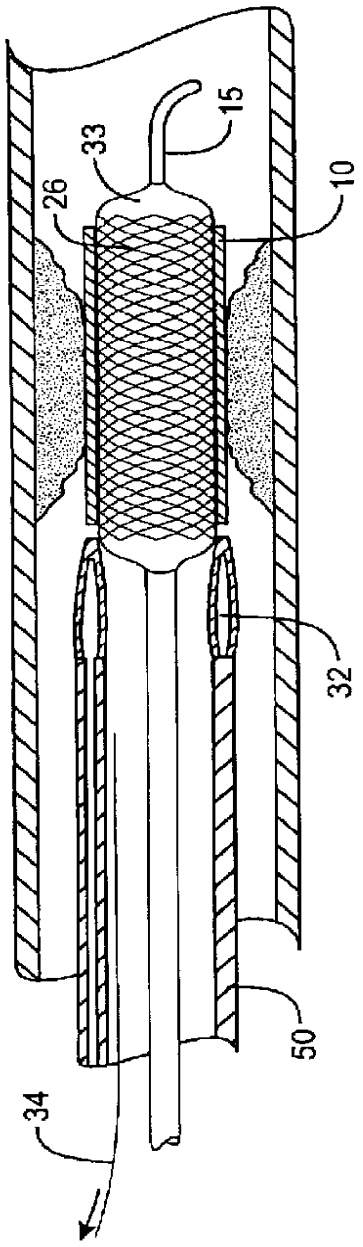


FIG. 38

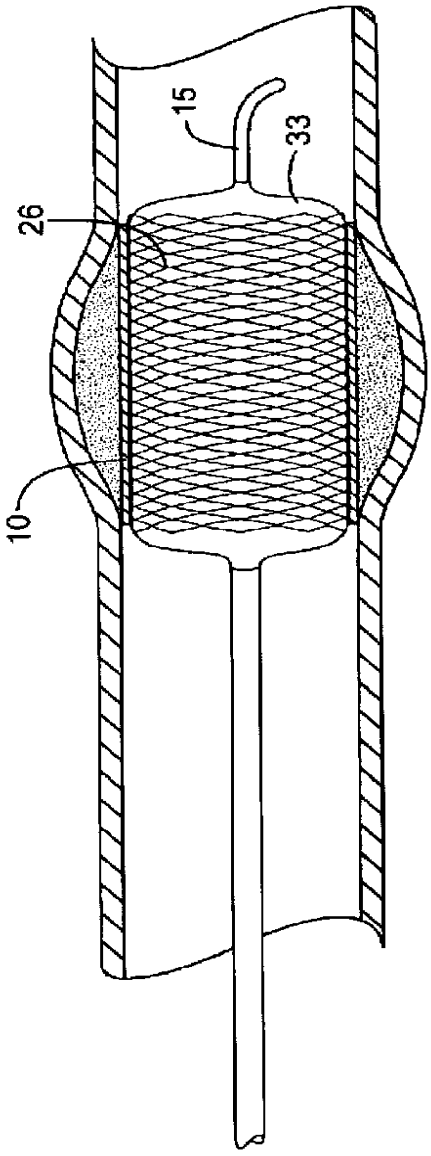


FIG. 39

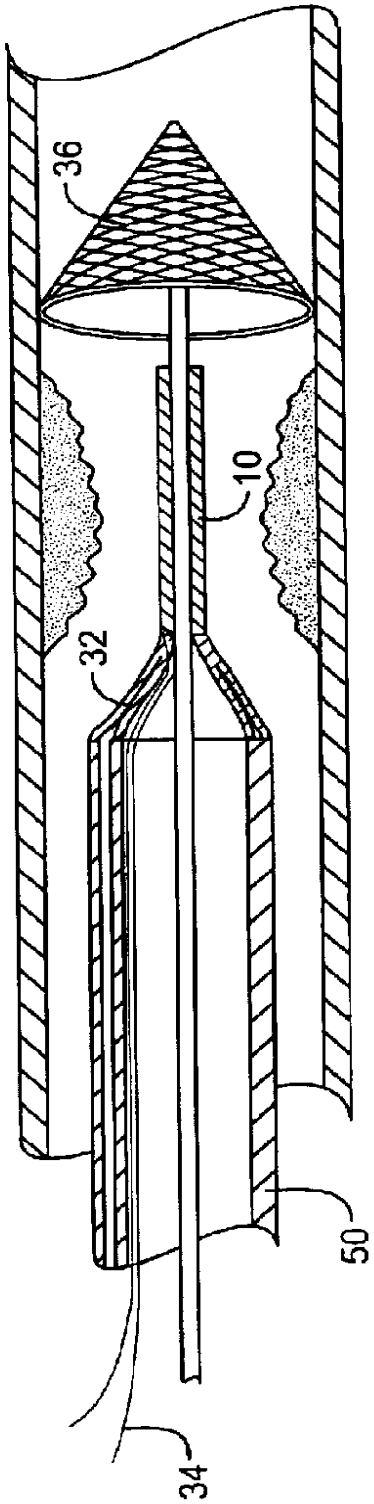


FIG. 40

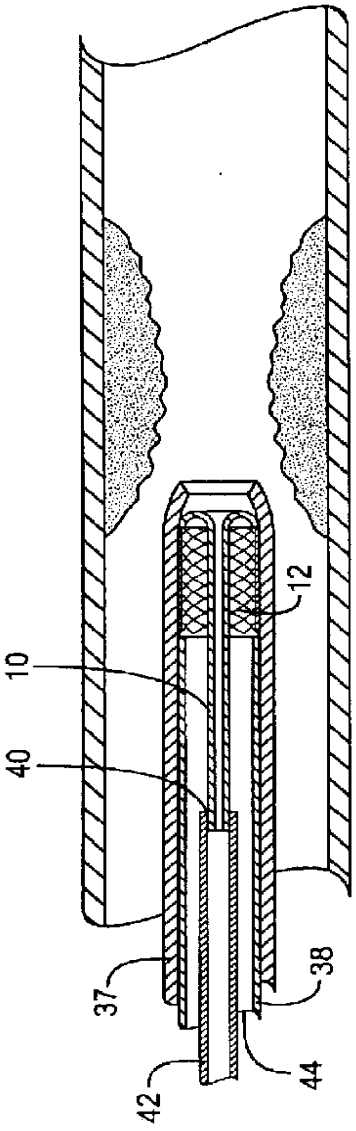


FIG. 41

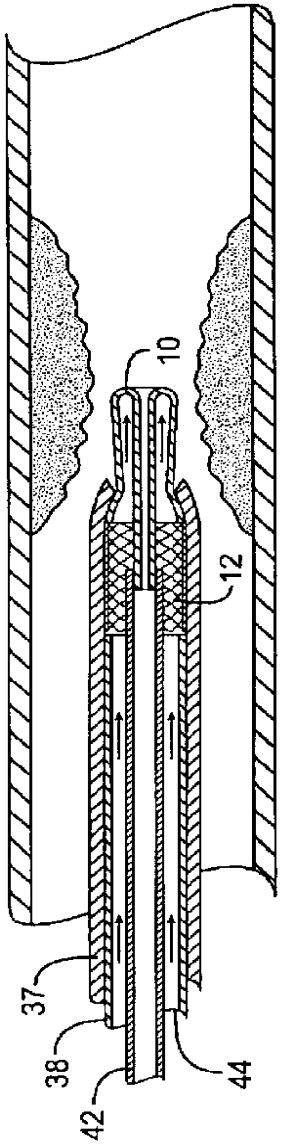


FIG. 42

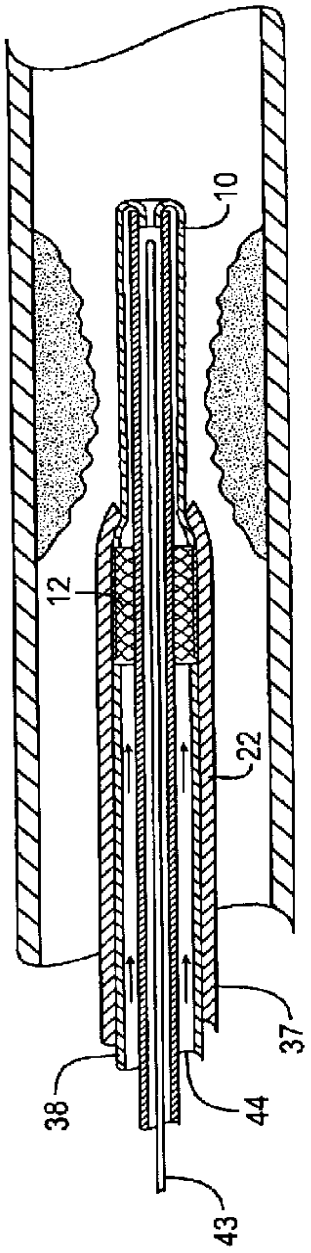


FIG. 43

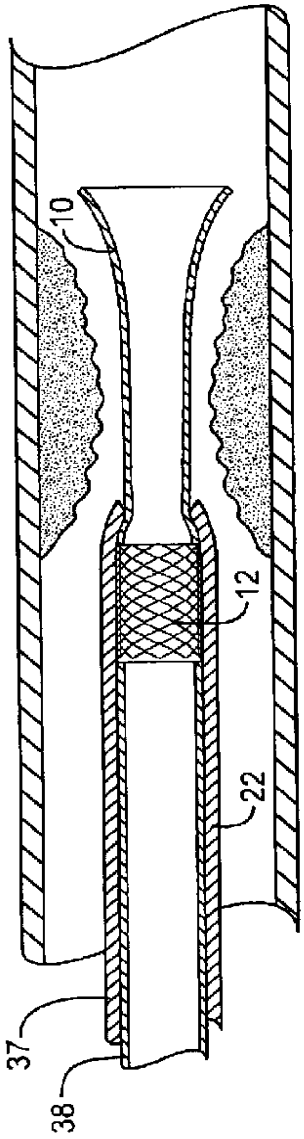


FIG. 44

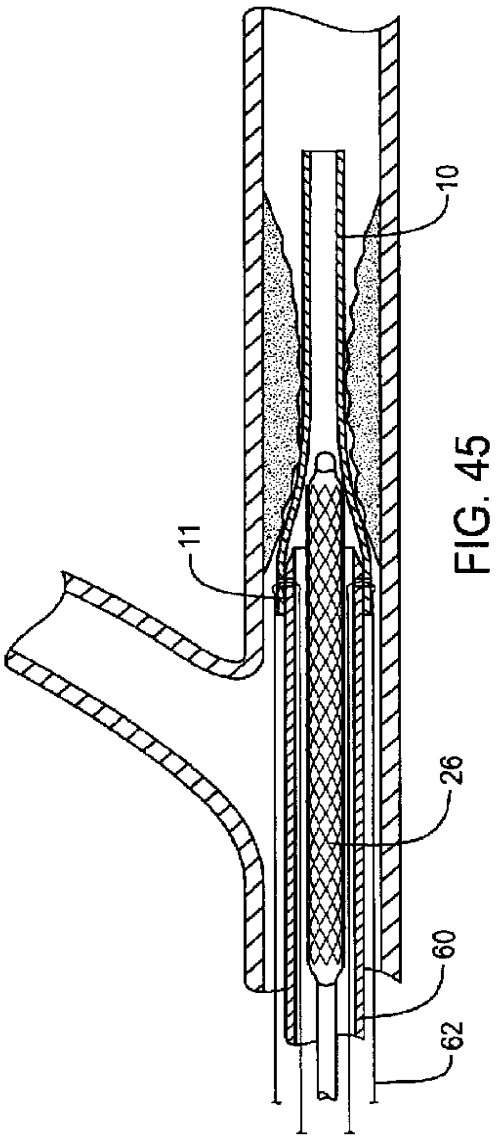


FIG. 45

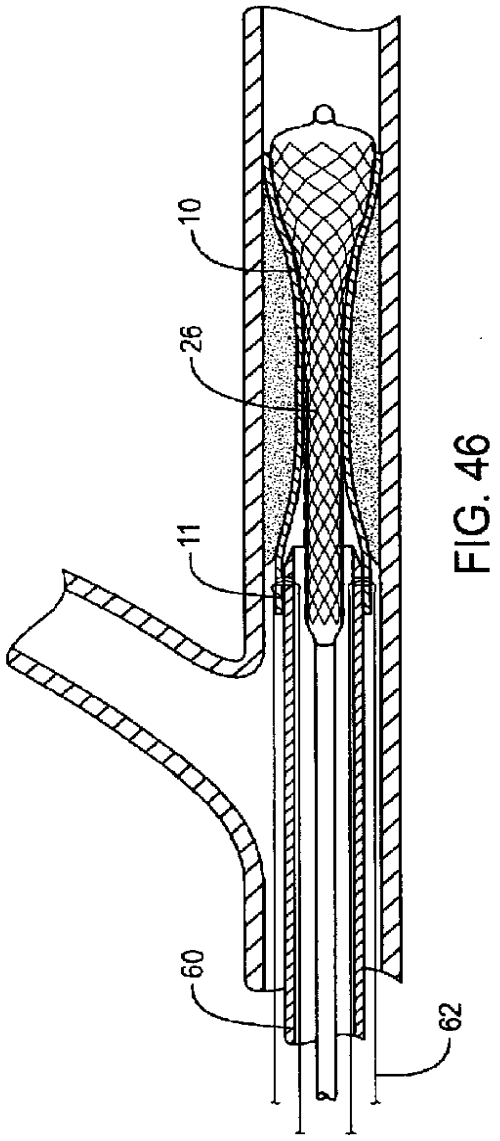


FIG. 46

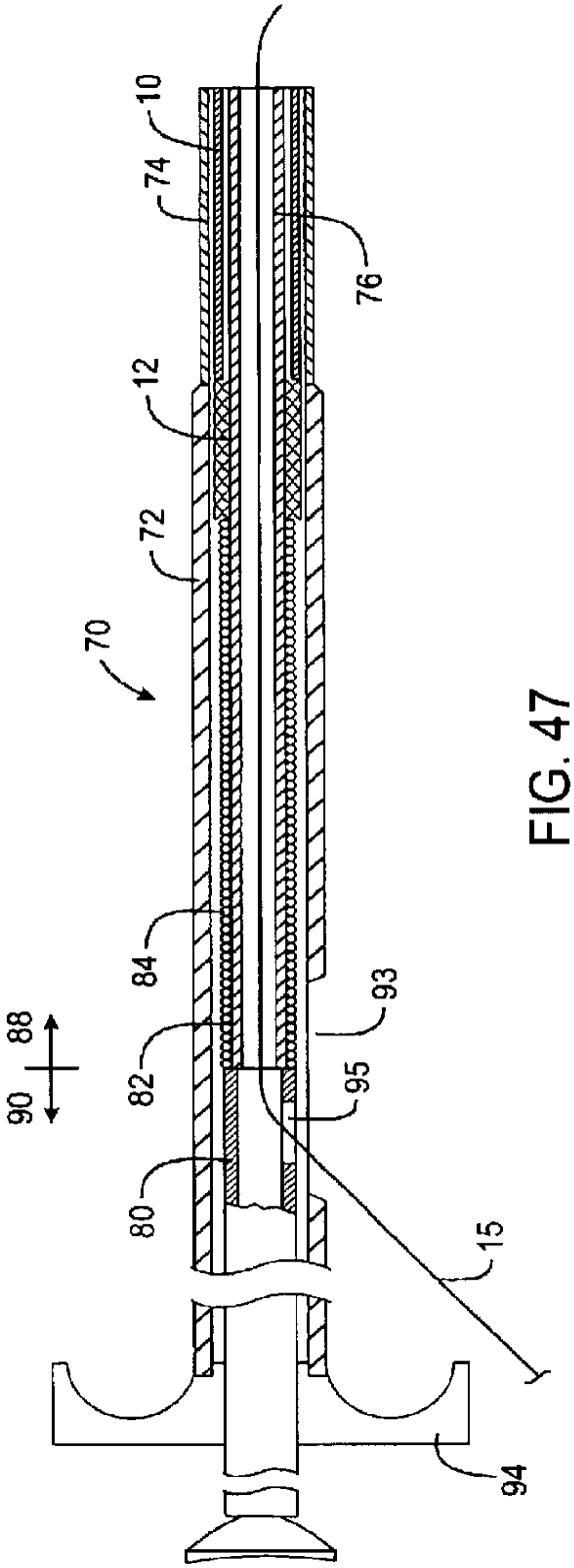


FIG. 47

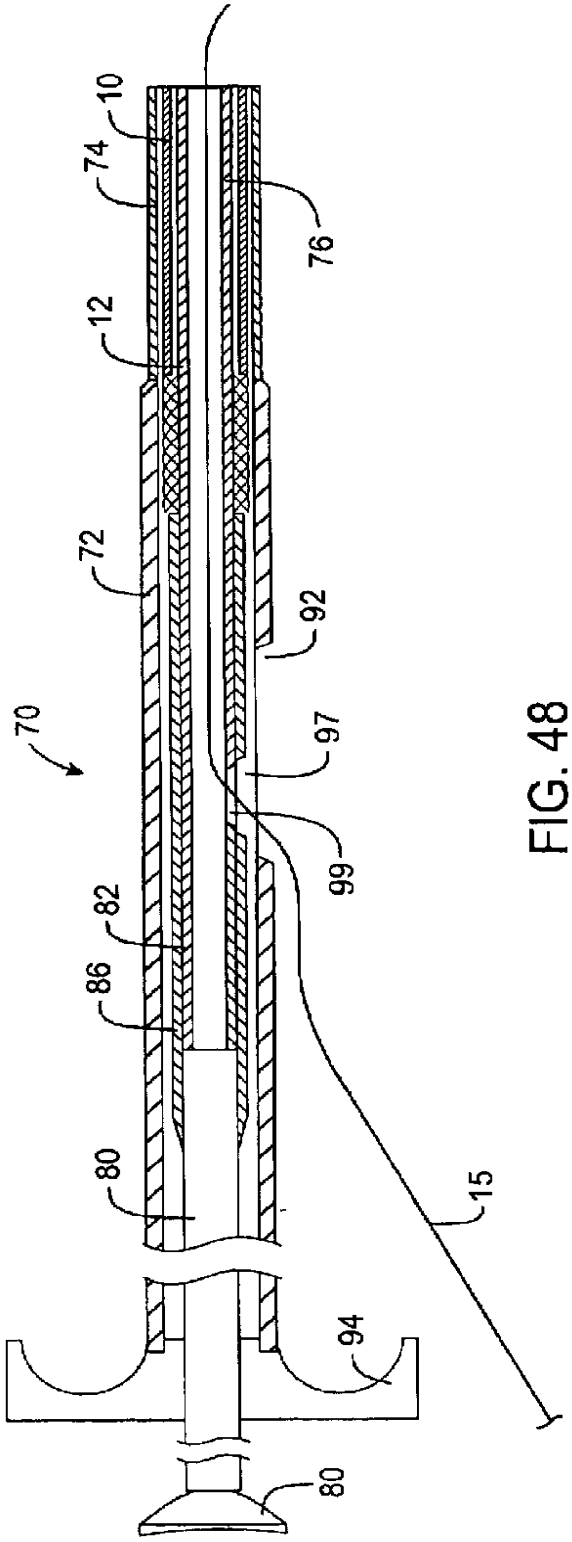
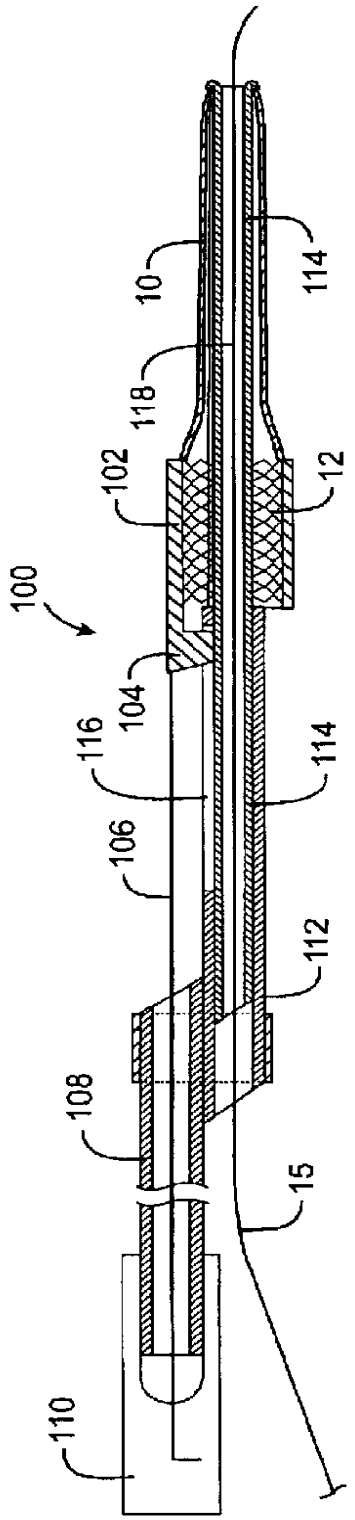


FIG. 48


100
10
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118
102
12
104
116
114
106
112
108
15
110

FIG. 49

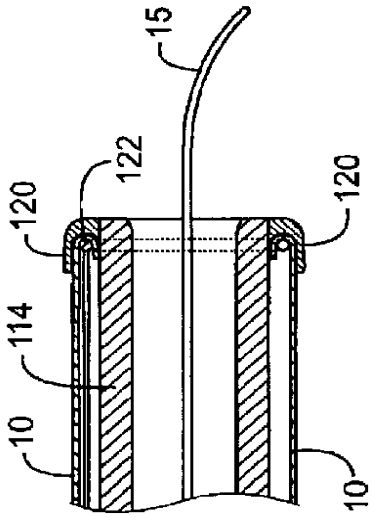
15
122
120
120
114
10
10

FIG. 50

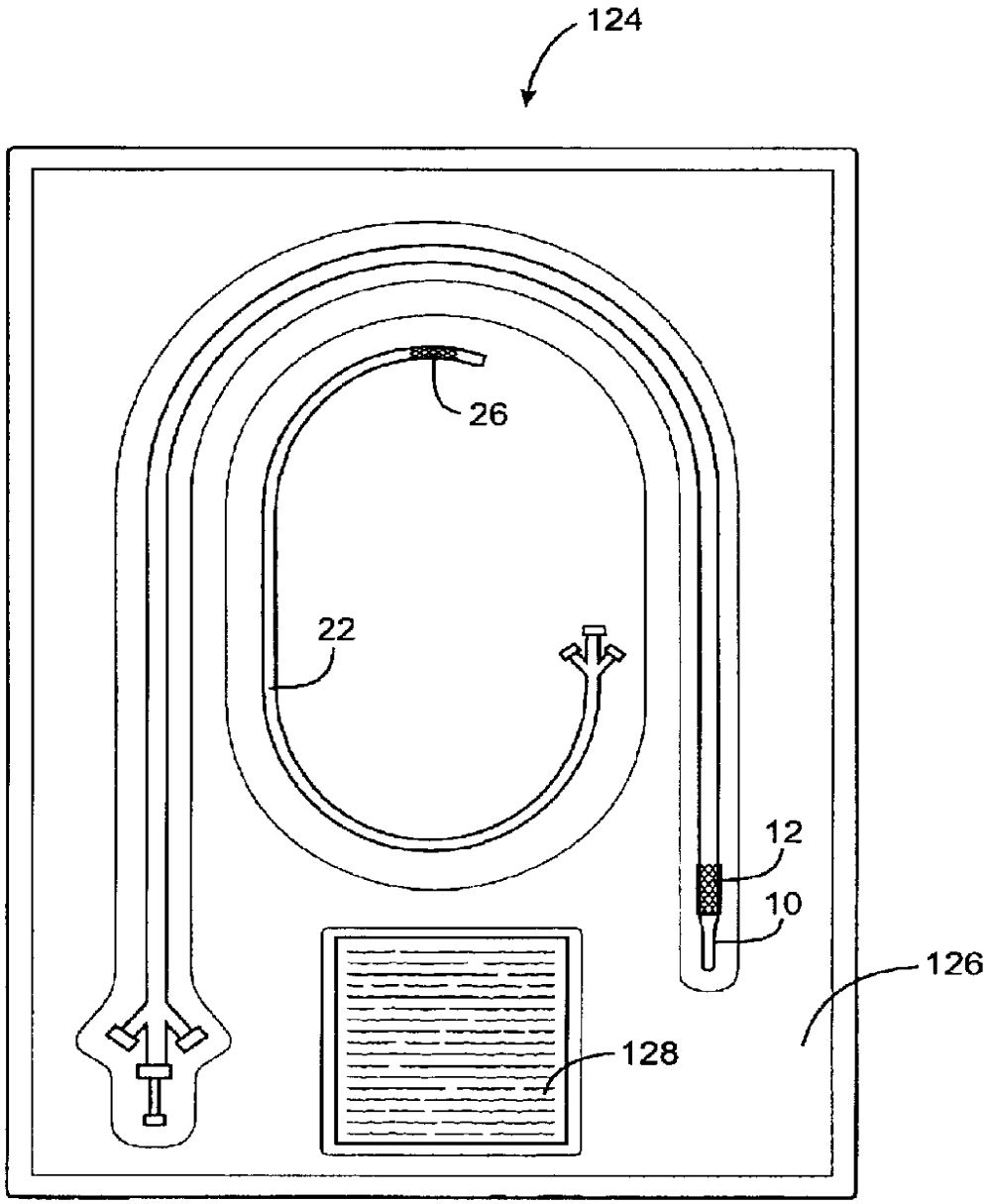

FIG. 51

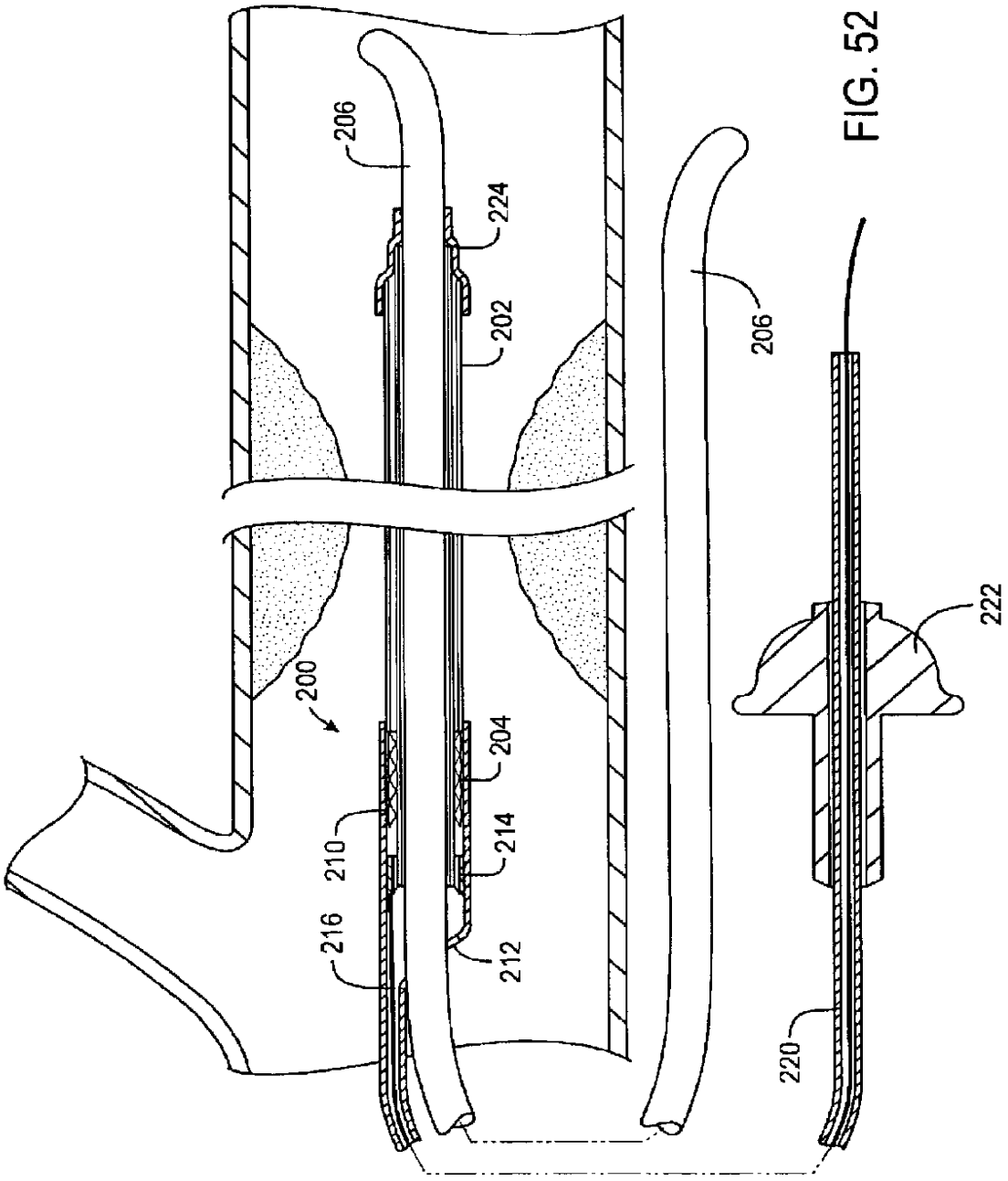

FIG. 52

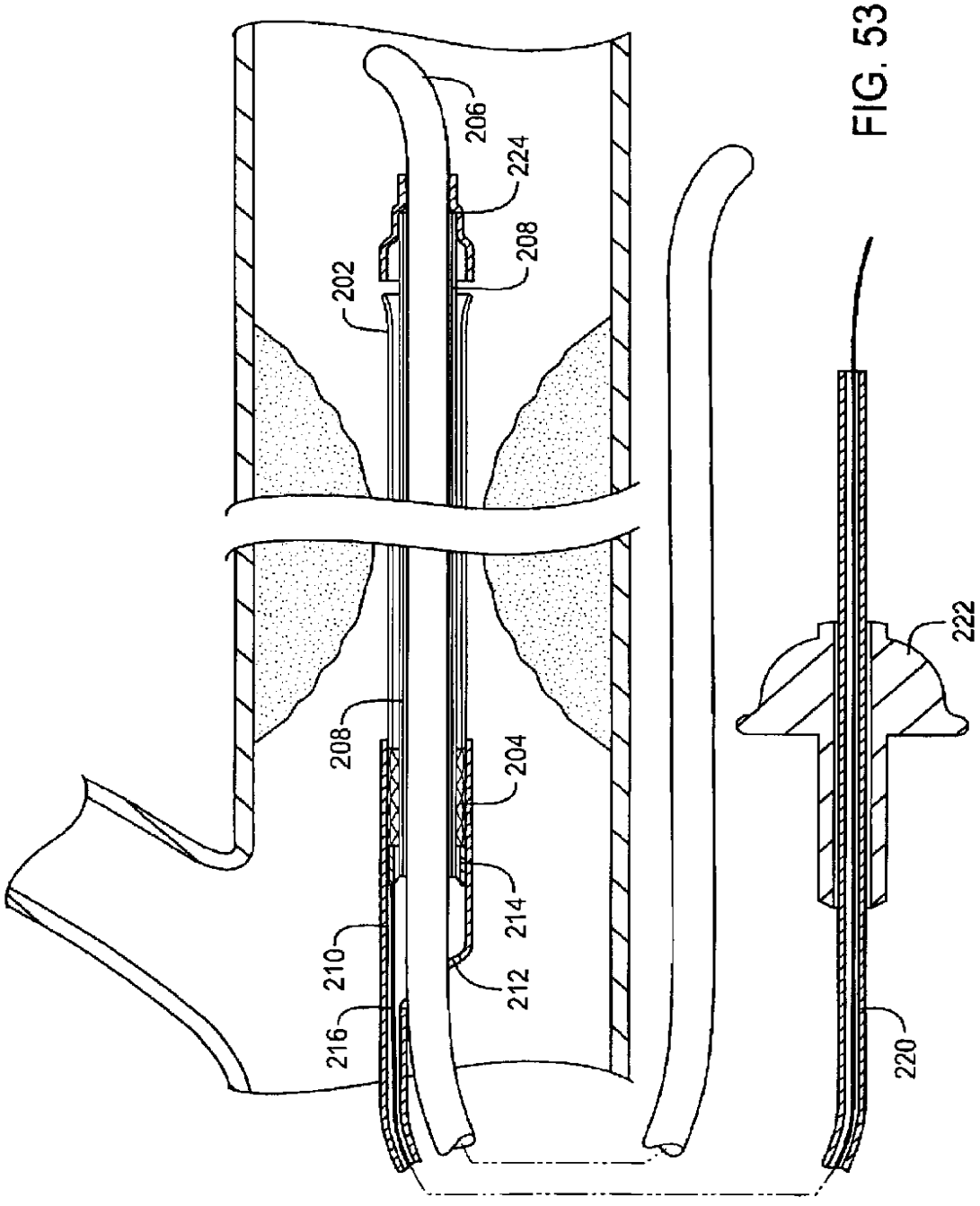

FIG. 53

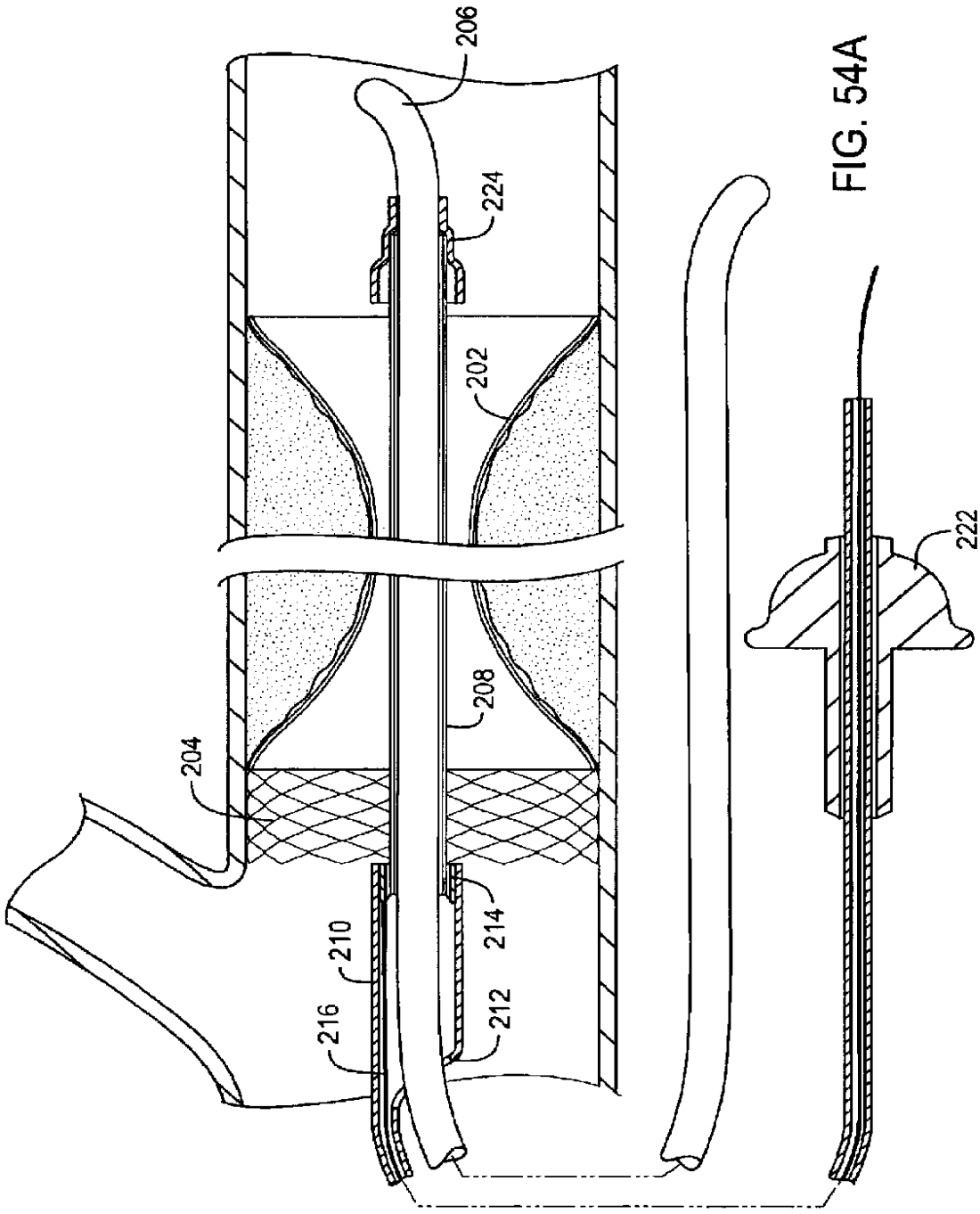

FIG. 54A

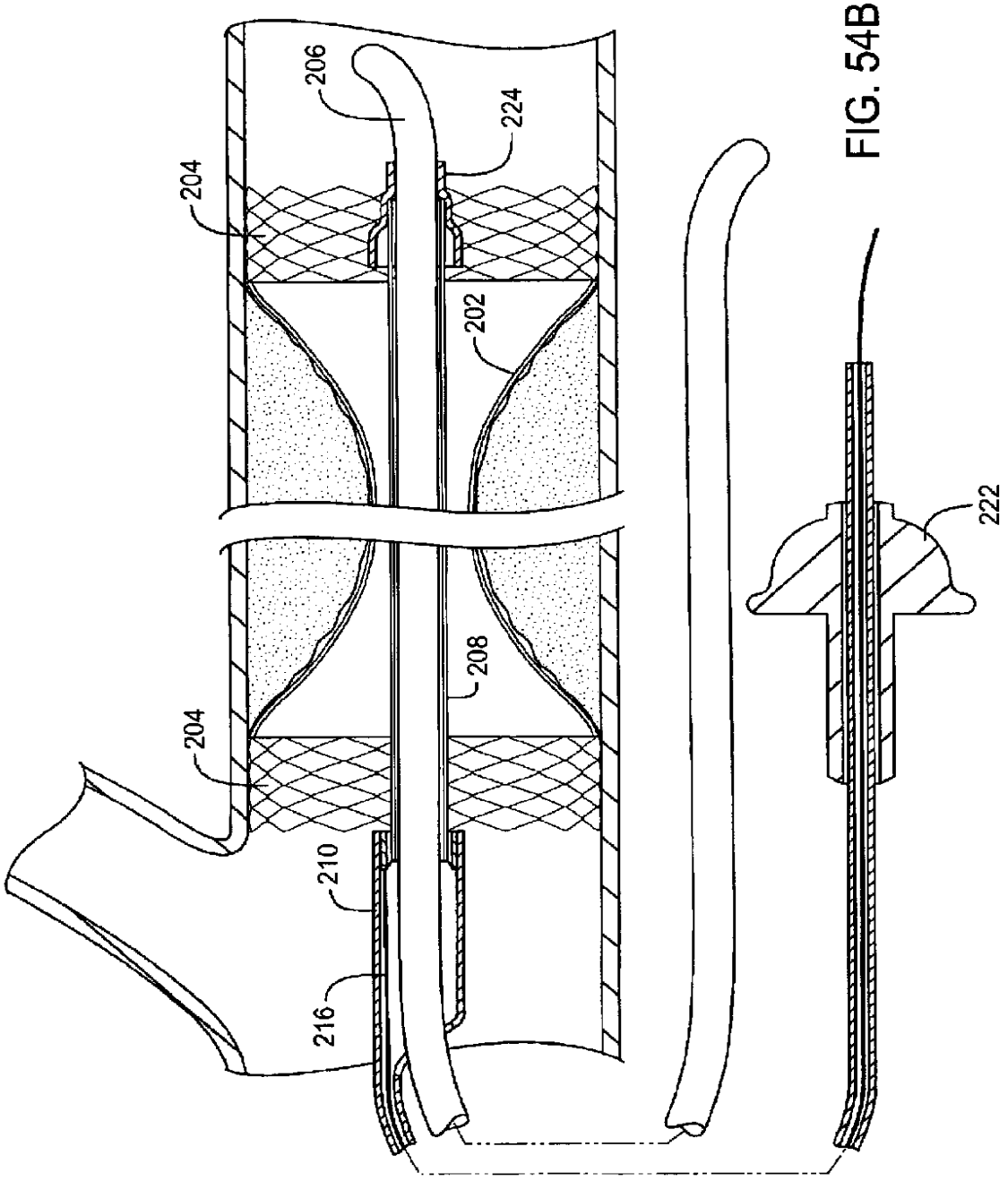

FIG. 54B

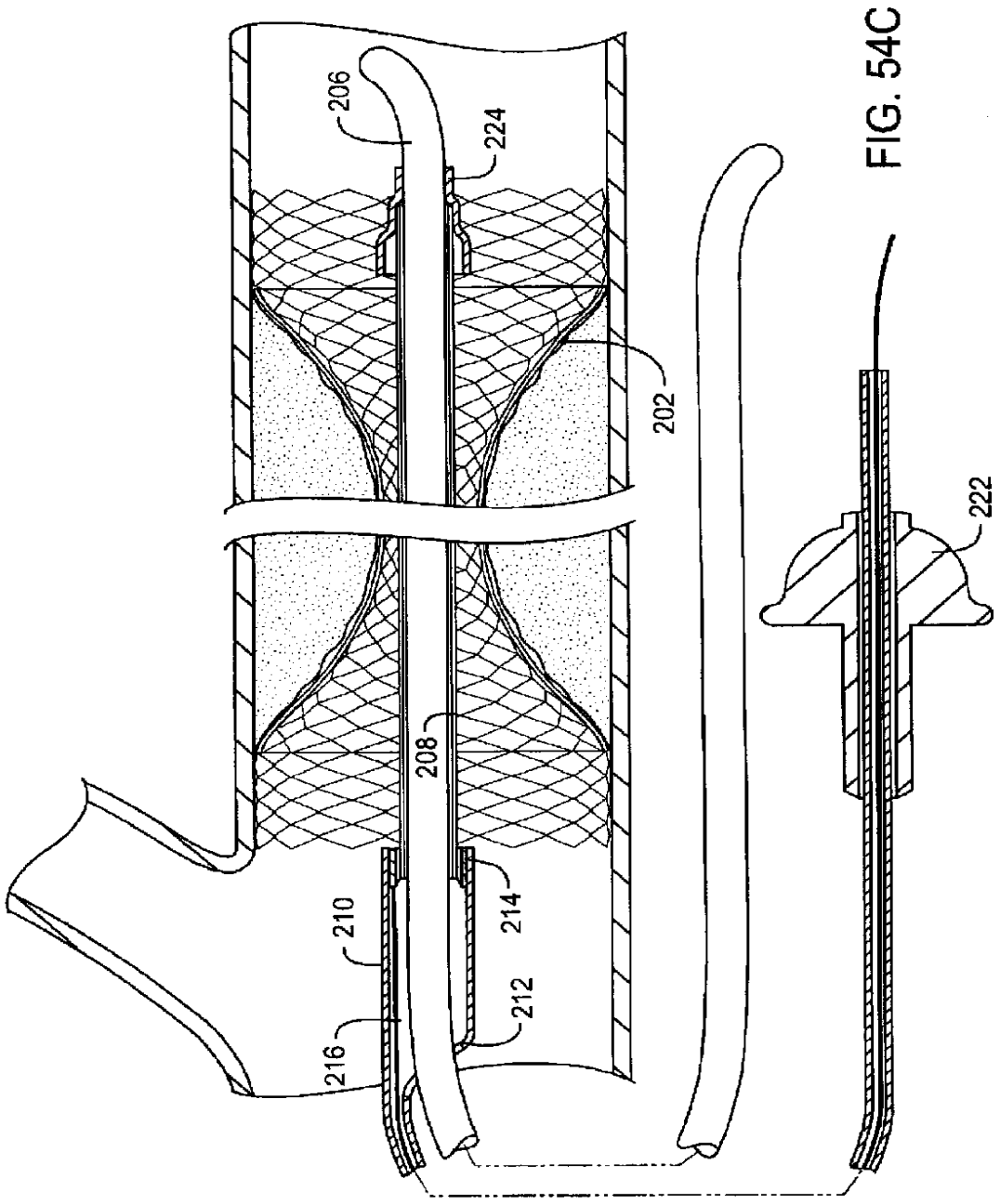

FIG. 54C

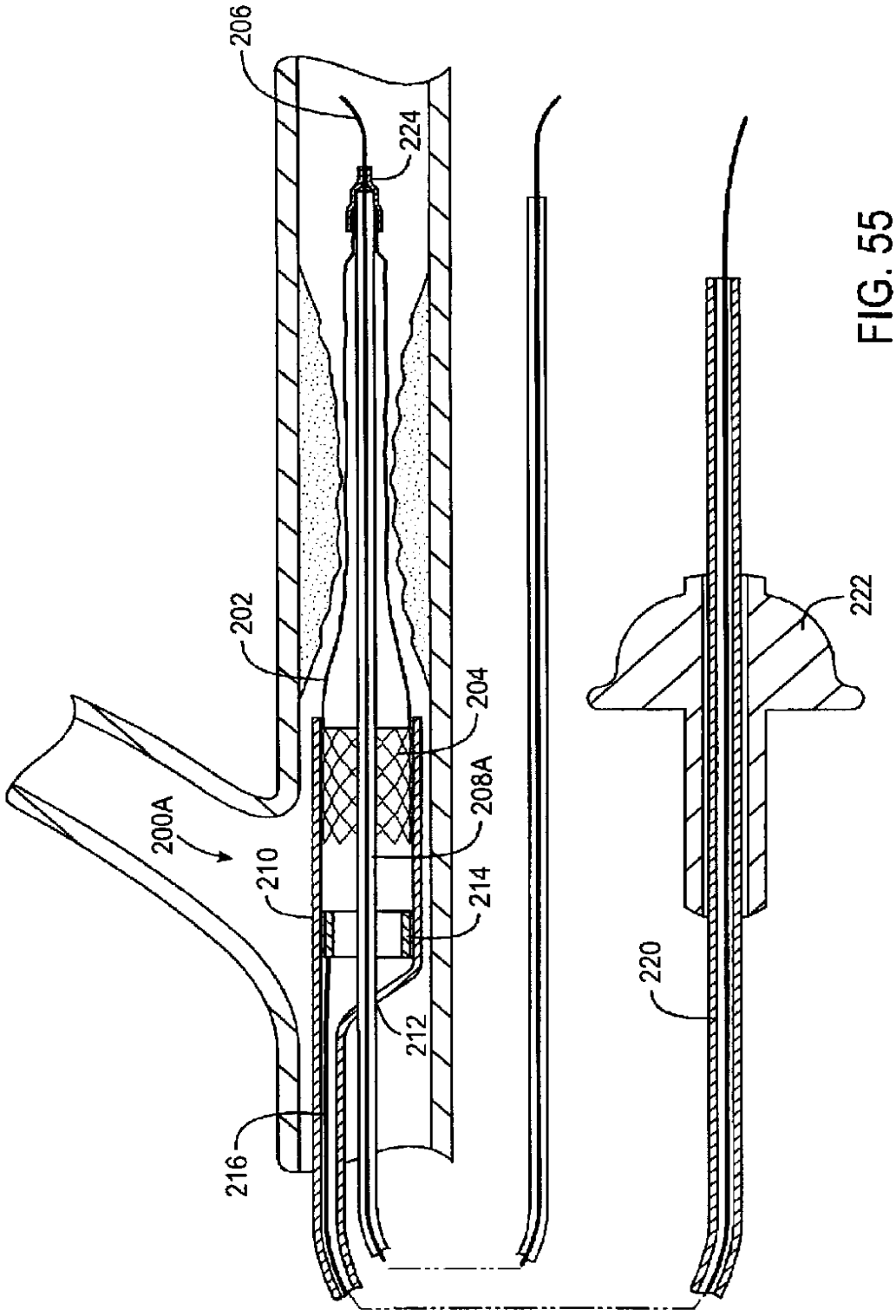

FIG. 55

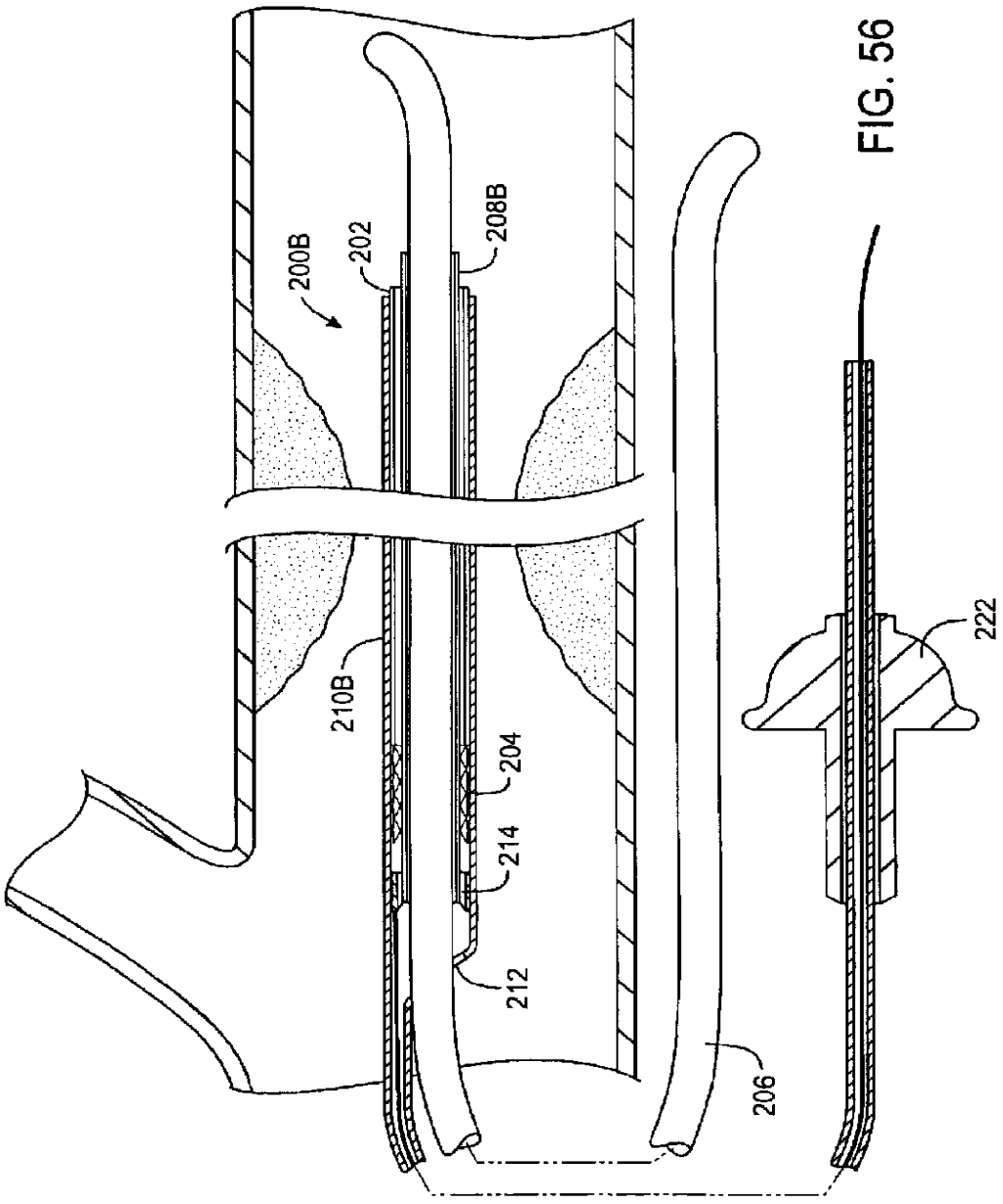

FIG. 56

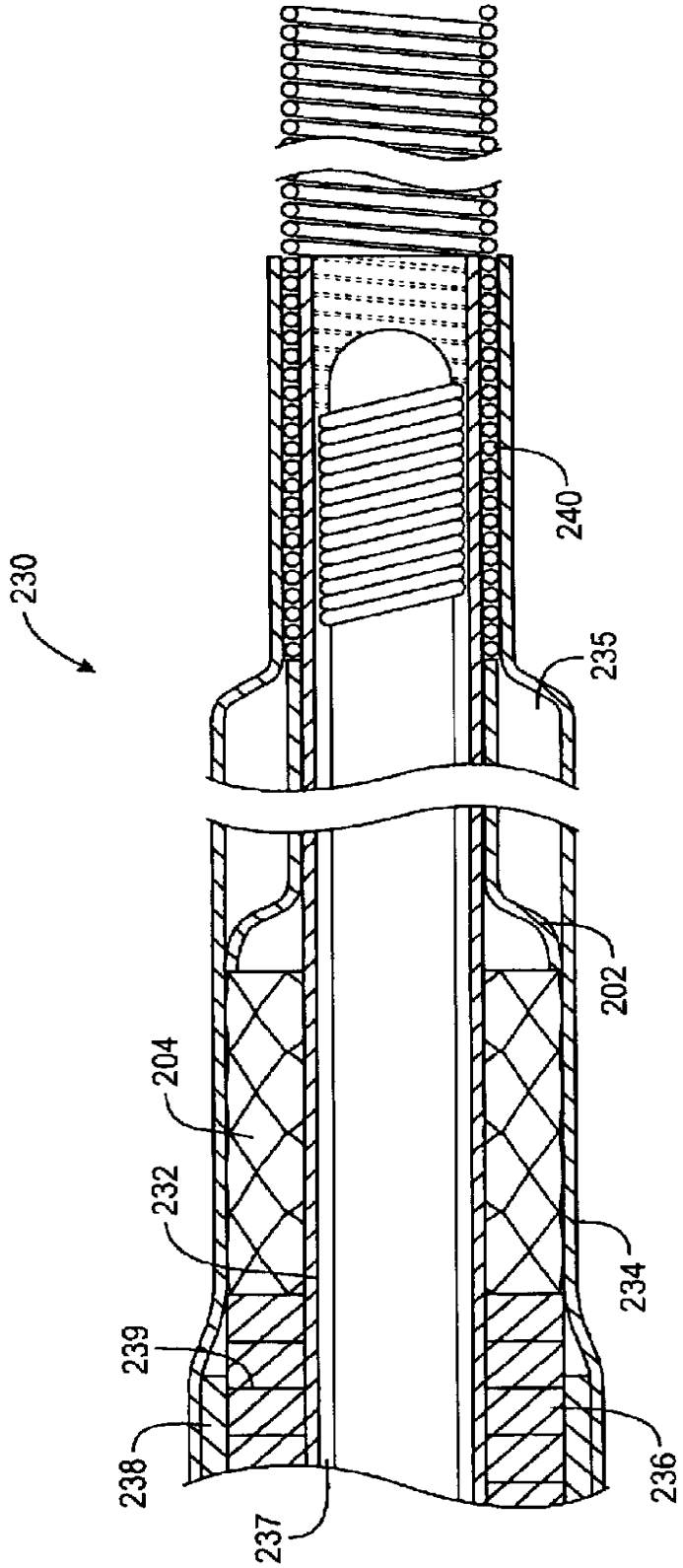

FIG. 57

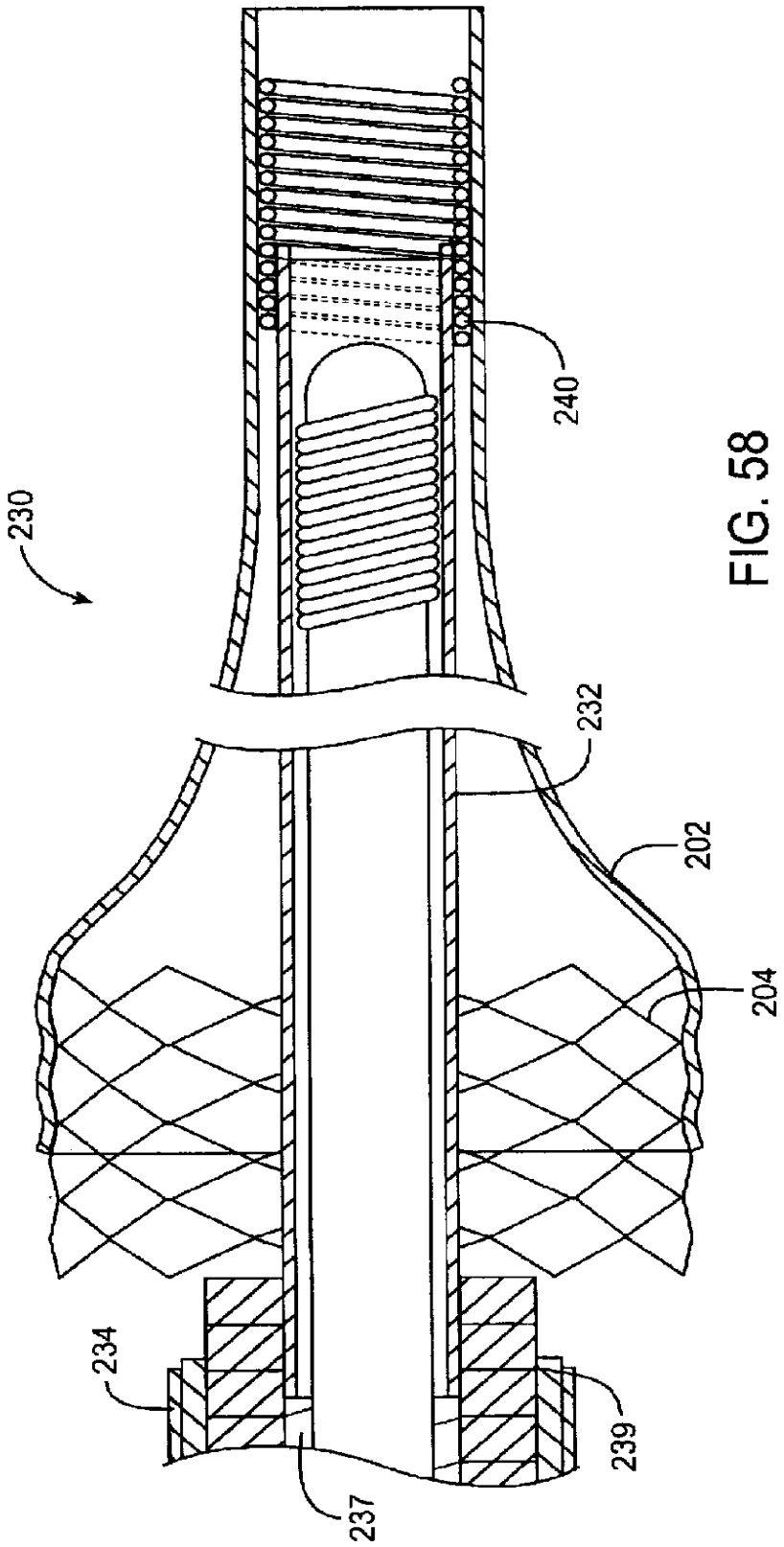

FIG. 58

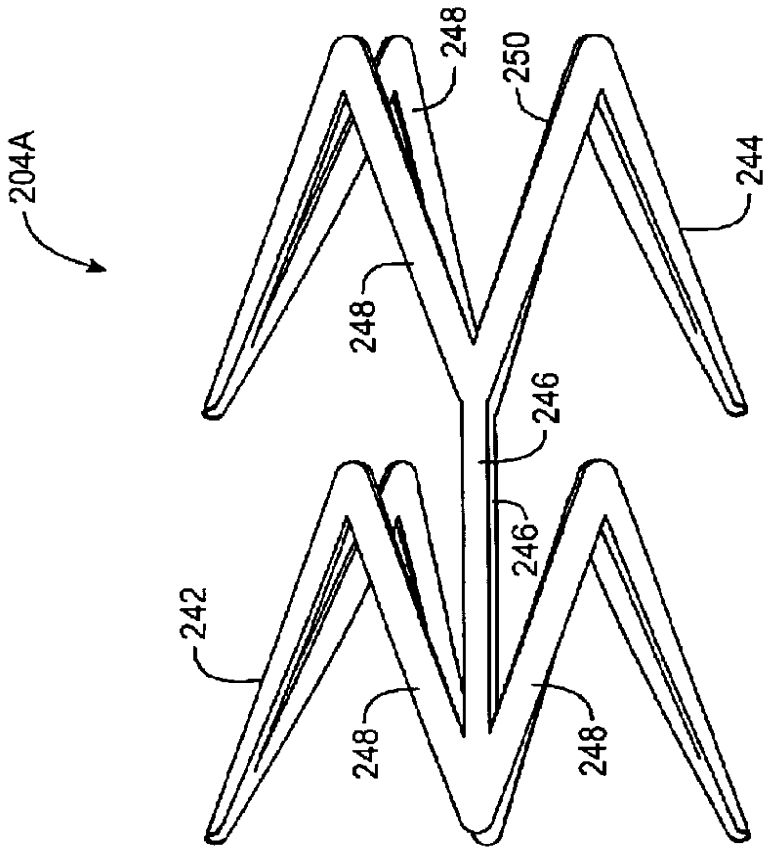

FIG. 59

METHODS AND DEVICES FOR LINING A BLOOD VESSEL AND OPENING A NARROWED REGION OF A BLOOD VESSEL

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of 09/416,309, filed Oct. 12, 1999, which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention is directed to methods and devices for protecting a passageway in a body when advancing devices through the passageway. A specific application of the present invention is for treatment of blood vessels although the invention may be used in any part of the body. For example, the present invention is used to protect blood vessels during intravascular procedures for treating aneurysms, arteriovenous malformations, and atherosclerotic disease of vessels. A particular application of the present invention is for atherosclerotic disease of the carotid arteries or saphenous vein grafts. Carotid artery atherosclerotic occlusive disease contributes to hundreds of thousands of strokes annually in the United States. Atherosclerotic disease of the internal carotid artery is particularly problematic since plaque from the internal carotid artery leads directly to the cerebral vasculature.

A conventional method of treating carotid artery occlusive disease is by surgical removal of the plaque (carotid endarterectomy). The carotid artery is opened surgically, the plaque is removed and the carotid artery is then closed. Carotid endarterectomies have demonstrated significant clinical benefit over conservative treatment with medication by reducing strokes over the next five years. Although carotid endarteretomy reduces strokes over a period of time after the procedure, the procedure still has a 6% risk of death or stroke.

Another method of treating carotid artery disease is to use interventional devices such as stents. A problem with treating carotid artery occlusive disease with stents is that the user is wary of dislodging plaque when advancing the stent through the carotid artery. Any plaque which breaks free during introduction of the stent travels directly to the patient's brain and can cause a stroke or death.

Yet another method of treating carotid artery occlusive disease is to introduce a filter through the carotid artery to trap emboli released during subsequent deployment of a stent or angioplasty balloon. This method suffers the same drawback in that advancement of the filter itself may dislodge plaque. Moreover, exchange of various therapeutic catheters over the filter element result in undesirable movement of the filter with attendant risk of losing filtered emboli or damaging the vessel wall with the filter.

The present invention is directed to improved methods of protecting a body passageway when advancing devices through the body passageway. The present invention is also directed to improved methods of treating atherosclerotic vessels and, in particular, occlusive disease of the internal carotid artery.

SUMMARY OF THE INVENTION

In accordance with the objects of the invention, a liner is provided to protect a body passageway during introduction of other devices into the passageway. In a specific application, the methods and devices of the present invention are used to protect blood vessels, such as the internal carotid artery, during intravascular procedures. It is understood that use of the present invention for protection of blood vessels is discussed as an example of how the present invention may be used, however, the invention may be used in any other part of the body without departing from the scope of the invention. The liner is collapsed for introduction into the patient and advanced to a narrowed region of a blood vessel. The liner is passed through a region of the blood vessel in the collapsed condition and an intravascular device, such as a stent or filter, is then introduced into the liner. The liner may be used to protect vessels from any type of problem including atherosclerotic disease, perforation, aneurysm or AVM.

The liner protects the vessel as the intravascular device is passed through the region to prevent the device from dislodging plaque. When the device is a stent, the stent is preferably expanded within the liner to trap the liner between the stent and the vessel. The liner may be expanded by the stent or may be partially or fully expanded before introduction of the stent. The devices and methods of the present invention are particularly useful for treating occlusive disease of the internal carotid artery. The liner may be any suitable material and suitable materials include expanded PTFE, woven dacron, nylon, low durometer silicone, or thin-walled polyethylene.

The liner is preferably mounted to a delivery catheter and is advanced over a guidewire. The liner may have an anchor at a proximal end which is used to open the proximal end of the liner. The anchor may be self-expanding or balloon expandable. Once the proximal end of the liner is opened, the liner can be designed so that blood pressure opens the liner. Alternatively, the liner may open automatically or may be opened with a separate device, the delivery catheter or the stent itself. When treating occlusive disease of the internal carotid artery, the anchor may be positioned completely in the internal carotid artery or may extend from the common carotid artery across the bifurcation of the internal and external carotid arteries and into the internal common carotid. The anchor preferably has an open structure which permits blood flow into the external carotid artery.

The liner may be an elastic liner or may be folded into a collapsed position. The liner may be collapsed in any suitable manner and preferably has a number of folded sections which are wrapped around one another. The folded sections are preferably adhered to one another to hold the liner in the collapsed position. The folded sections may be adhered together by application of heat or with an adhesive or coating. The distal end of the liner may be coated to form a curved surface which covers the ends of the folded sections. Alternatively, the ends of the liner may be scalloped or contoured so that when folded the edge tapers down more cleanly.

The liner may also be designed to evert when expanding. The everting liner reduces sliding between the liner and vessel so that plaque is not dislodged when introducing the liner. An end of the everting liner may be releasably attached to the delivery catheter.

The proximal end of the liner may also be opened with an expandable device, such as a balloon, on the delivery catheter rather than with an anchor attached to the liner. Once the proximal end is open, the stent or other device is advanced through the liner.

In yet another aspect of the invention, the catheter holds the proximal end partially open. The stent or other device is then advanced through the open proximal end. The liner can be released when using a stent or may be removed after use.

These and other features and advantages of the invention will become evident from the following description of the preferred embodiments.

The present invention is also directed to a device for lining a vessel which has an expandable anchor movable from a collapsed shape to an expanded shape. The liner attached to the anchor and extends from an end of the anchor. The liner is held between thin, flexible inner and outer layers which are preferably shrink tubing. The outer layer is retracted to expose and free the liner. The outer layer may also hold the anchor in the collapsed position.

The inner and outer layers preferably have a thickness of 0.0005–0.002 inch. The outer layer stretches over a tapered portion and is preferably flexible enough to stretch over the tapered portion as it passes over the tapered portion. The outer layer has a diameter of no more than 0.055 inch, and more preferably no more than 0.050 inch, when in the collapsed position. A radiopaque coil may also be provided which extends beyond the distal end of the liner and between the inner and outer layers. The inner layer is preferably attached to an inner element and the outer layer is preferably attached to an outer element.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a system for advancing devices through a narrowed region of a blood vessel such as the internal carotid artery.

FIG. **2** shows a liner advanced through the narrowed region in a collapsed position.

FIG. **3** shows the liner detached from the delivery catheter and expanded.

FIG. **4** shows only the proximal end of the liner expanded with an anchor.

FIG. **5** shows the liner having openings or perforations.

FIG. **6**A shows the liner having a woven or braided configuration.

FIG. **6**B shows the liner having a radiopaque maker and a scalloped distal end.

FIG. **7** shows the liner folded into six folded sections.

FIG. **8** shows the folded sections wrapped around one another.

FIG. **9** shows an end view of the liner of FIG. **7**.

FIG. **10** shows an end view of the liner of FIG. **8** with the liner wrapped around a guidewire.

FIG. **11** shows the liner having four folded sections.

FIG. **12** shows the liner of FIG. **11** with the folds wrapped around one another.

FIG. **13** shows a coating over a distal end of the liner.

FIG. **14** shows the coating extending over the length of the liner.

FIG. **15** is a cross-sectional view of the liner and coating with four folded sections.

FIG. **16** is a cross-sectional view of the liner and coating with six folded sections.

FIG. **17** shows a sheath covering the liner in the collapsed condition.

FIG. **18** shows a filament tearing a distal end of the sheath.

FIG. **19** shows the liner attached to the anchor.

FIG. **20** shows the liner attached to a tapered anchor.

FIG. **21** shows an anchor contained entirely within the internal carotid artery.

FIG. **22** shows the balloon expanding the anchor and blocking blood flow into the internal carotid artery.

FIG. **23** shows the liner and anchor of FIG. **22** deployed.

FIG. **24** shows a balloon-expandable stent introduced into the liner.

FIG. **25** shows the stent expanded.

FIG. **26**A shows an elongate element which opens the distal end of the liner.

FIG. **26**B shows the elongate element contained within a tube during delivery the liner.

FIG. **26**C shows the elongate element of FIG. **26**B advanced into a pocket of the liner to open the proximal end of the liner.

FIG. **26**D shows the stent introduced into the liner of FIG. **26**C.

FIG. **27** shows the delivery catheter for the anchor used to deliver a stent into the liner.

FIG. **28** shows the distal end of the stent of FIG. **27** expanded to trap plaque behind the liner.

FIG. **29** shows the delivery catheter for the anchor used to deliver a distal anchor.

FIG. **30** show the delivery catheter in position for delivering the distal anchor.

FIG. **31** shows the distal anchor deployed so that the proximal and distal ends of the liner are expanded.

FIG. **32** shows another stent delivered between the proximal and distal anchors.

FIG. **33** shows the stent of FIG. **32** expanded.

FIG. **34** shows a delivery catheter having an expandable section for opening the proximal end of the liner.

FIG. **35** shows the proximal end of the liner opened with the expandable section.

FIG. **36** shows the stent advanced through the liner.

FIG. **37** shows the stent partially expanded.

FIG. **38** shows the stent expanded into contact with the vessel wall and the liner released from the delivery catheter.

FIG. **39** shows the stent fully expanded.

FIG. **40** show a filter passed through the liner.

FIG. **41** shows the liner everting when deployed.

FIG. **42** shows the liner partially everted.

FIG. **43** shows the liner almost completely everted and the distal end released.

FIG. **44** shows the liner released from the delivery catheter.

FIG. **45** shows another delivery catheter which holds the proximal end of the liner open.

FIG. **46** shows the stent advanced through the liner of FIG. **45**.

FIG. **47** shows another delivery catheter for the liner.

FIG. **48** shows still another delivery catheter for the liner.

FIG. **49** shows yet another delivery catheter for the liner.

FIG. **50** shows a distal end of the liner trapped in a fold.

FIG. **51** shows a kit having devices and instructions for use in accordance with the present invention.

FIG. **52** shows still another liner in accordance with the present invention.

FIG. **53** shows the liner of FIG. **52** with a bumper advanced adjacent to the anchor.

FIG. **54**A shows the retention element retracted to expose the anchor and permit the anchor to expand.

FIG. **54**B shows the liner having anchors at both ends.

FIG. **54**C shows the liner having the anchor extending the length of the liner.

FIG. **55** shows an alternative embodiment of the device of FIG. **52**.

FIG. **56** shows another alternative embodiment of the device of FIG. **52**.

FIG. **57** shows yet another liner in accordance with the present invention.

FIG. **58** shows the device of FIG. **57** with the anchor expanded and the liner released.

FIG. **59** shows a preferred anchor in an expanded position.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A system **2** for protecting vessels during intravascular procedures is shown in FIGS. **1–4**. Although the present invention is described in relation to treatment of atherosclerotic disease of the internal carotid artery and the particular problems encountered when working in the carotid arteries, the liner may be used in other vessels such as saphenous vein grafts of coronary bypass procedures, iliac and coronary arteries. A guide catheter **4** is introduced through the femoral artery and advanced to the common carotid artery in the conventional manner. The guide catheter **4** has a hemostasis valve **6** which receives a liner delivery catheter **8**. The guide catheter **4** may be omitted without departing from the scope of the invention.

A liner **10** is used to protect the body passageway when passing other devices through the body passageway. For example, the liner **10** may be used to protect the carotid artery to prevent plaque from being dislodged when passing other devices through the carotid artery. A proximal end **11** of the liner **10** may be attached to an anchor **12** which expands and opens the liner **10** and holds the liner **10** against the vessel wall to reduce or eliminate flow around the liner. The liner is preferably non-metallic and is relatively flexible to conform to the body passageway. The anchor **12**, as will be discussed below, is mounted to one end of the liner **10** while the other end of the liner **10** is preferably free. Of course, the anchor **12** may be provided at both ends or throughout the liner **10** without departing from the scope of various aspects of the present invention. The liner **10** is advanced through the vessel in the collapsed condition of FIG. **2** so that the liner **10** can be advanced through small or highly stenosed vessels. After the liner **10** is in position, other devices, such as a stent **26** (FIG. **25**) or filter (FIG. **40**), may be passed through the liner **10** so that the liner **10** prevents contact between the device and the vessel wall. The liner **10** may also be used to protect the vessel when advancing other devices such as angioplasty balloons, drug delivery catheters, laser catheters or ultrasound catheters. FIG. **3** shows both ends of the liner **10** opened to trap plaque behind the liner **10** so that loose plaque cannot flow downstream. The liner **10** is preferably delivered over a conventional guidewire **15** which has a 0.010–0.018 inch diameter but may be of any other suitable size depending upon the vascular site.

The liner **10** is preferably made of expanded PTFE having a thickness of 0.006 to 0.0005 inch, more preferably 0.001 to 0.002 inch and most preferably about 0.001+/–0.0005 inch although any other suitable material may be used. For example, the liner **10** may have a woven construction such as silk or polyester as shown in FIG. **5**. The liner **10** may also have small openings **25** or perforations which act similar to a filter in that they permit blood to flow through but prevent large emboli from escaping (FIG. **6A**). The openings **25** also may promote tissue growth. The liner **10** is also preferably thin enough and has a porosity sufficient to allow tissue throughgrowth. Referring to FIG. **6B**, the liner **10** may also have a scalloped distal end **7** to form a smoother transition at the distal end when collapsed. The liner **10** may also have a radiopaque marker **9**, such as a 0.002 inch by 0.008 inch platinum ribbon, embedded, sewn, or folded into the liner **10**. The liner **10** may have the markers **9** extending longitudinally (FIG. **6B**) or circumferentially. When the markers **9** extend longitudinally, three markers **9** are preferably provided 120 degrees apart.

The liner **10** may also be elastic so that the liner **10** remains substantially cylindrical and without folds in the collapsed and expanded positions. When using an elastic liner **10**, the liner **10** is preferably a tube of low durometer silicone, latex or natural rubber, thermoplastic elastomers such as Kraton or hydrogenated thermoplastic isoprenes having a thickness of 0.001 to 0.0005 inch. Alternatively, the liner **10** could be made of an inelastic but plastically deformable material. Initially the liner **10** would be sized to allow easy passage of the devices such as the balloons, stents and filters described herein. The liner **10** is then plastically deformed by the devices which pass therethrough. For example, a pre-dilatation balloon may be introduced to dilate the liner **10**. The stent **27** can then be advanced into the dilated liner **10** and expanded to open the narrowed vessel. Expansion of the stent continues plastic deformation of the liner **10** to a final size. Any of the liners **10** described herein may be substituted for any of the other liners **10** without departing from the scope of the invention.

FIGS. **7–12** show a preferred method of collapsing the liner **10**. The liner **10** is folded longitudinally along creases **13** to create at least 2 and preferably 4–6 folded sections **14**. Four folded sections **14** are shown in FIG. **11** and six folded sections **14** are shown in FIG. **7** and **9**. The folds **14** are then wrapped as shown in FIGS. **8**, **10** and **12**. The liner **10** may, of course, be wrapped in any other manner. For example, the liner **10** may be spiral wrapped or randomly compressed and set with high pressure and/or heat. The folded sections **14** may be adhered to one another by application of heat which holds the folded sections **14** together without melting and fusing the sections **14** together. Another method of holding the liner **10** in the collapsed position is to apply an adhesive **16** such as medical grade glue, cyanoacrylates, epoxies, ultraviolet activated adhesives, low molecular weight polyvinyl alcohol polymer, gelatin and sucrose. The liner **10** may also be partially or completely covered with a coating **20** which dissolves in blood such as sugar (FIGS. **13–16**). In particular, the distal end **19** of the liner **10** may be covered with the coating **20** to form a smooth, atraumatic end as shown in FIG. **13**. The coating **20** may extend along the length of the liner **10** as shown in FIG. **14** or may be only at the distal end or intermittent as shown in FIG. **13**.

The liner **10** may also be covered by a removable sheath **21** as shown in FIGS. **17** and **18**. The sheath may be removed in any manner such as tearing along perforations or with a chemical, thermal or electrolytically severable bond. A filament **23** may also be used to tear the sheath **21** as shown in FIGS. **17** and **18**. The filament **23** may have both ends extending through the catheter rather than having one end extend out of the catheter. The filament **23** is shown separated from the sheath **21** for clarity but would either pass inside the sheath **21** or would be partially embedded in the sheath **21**. The sheath **21** can also be a simple retractable sheath **21** as is known in the art.

Referring again to FIGS. **10** and **12**, the liner **10** is collapsed onto the guidewire **15** so that the liner **10** has an outer diameter α of no more than 0.065 inch, more prefer-

ably no more than 0.040 inch, and most preferably no more than 0.026 inch. Stated another way, the thickness β of the liner **10** is preferably no more than 0.015 inch, more preferably no more than 0.012 inch, and most preferably no more than 0.008 inch when measured in a radial direction. For a guidewire **15** having a 0.014 inch diameter, the liner **10** is preferably collapsed so that the outer diameter α is 0.020 to 0.032 inch, preferably about 0.026 inch, and the thickness β of the liner **10** is 0.004 to 0.008 inch, preferably about 0.006 inch. For a guidewire **15** having a 0.018 inch diameter, the liner **10** is preferably collapsed so that the outer diameter α is still about 0.020 to 0.032 inch, preferably about 0.026 inch, and the thickness β of the liner **10** is 0.003 to 0.006 inch, preferably about 0.004 inch. The liner **10** also has a high ratio of collapsed cross-sectional area to expanded circumference in the range of 1:10 to 1:30 and preferably at least 1:20.

The relatively small size of the liner **10** advantageously permits the liner **10** to be introduced through small and heavily stenosed vessels. The carotid artery is often occluded 95 to 98% and may have diameters as small as 0.020 inch or even 0.010 inch before surgical or interventional procedures are performed. Conventional stents used in the internal carotid artery have a collapsed diameter of about 0.065 to 0.092 inch and, thus, must often displace the plaque to pass through the vessel. It is believed that some strokes which occur when using stents in the carotid artery are caused by plaque which is dislodged when the stent is advanced through and expanded within highly stenosed regions. The liner **10** of the present invention protects the vessel as the stent or other device is passed through the vessel. The liner **10** preferably has a length γ of at least 2 cm and preferably 2–10 cm (FIG. **2**). The liner **10** and anchor **12** have a diameter of 4–10 mm in the expanded condition with the specific size selected depending upon the size of the vessel being treated. The relative dimensions shown in the drawing have been exaggerated to illustrate the features of the invention. In fact, the liner **10** has a length to width ratio (γ to α) in the collapsed position of at least 20 to 1, 50 to 1, 80 to 1, and even up to 200 to 1 depending upon the particular application. The liner **10** preferably increases in outer diameter at least 5, more preferably at least 6 and most preferably at least 8 times when moving from the collapsed to expanded positions.

Referring again to FIGS. **3** and **4**, the anchor **12** may be attached to the proximal end **11** of the liner **10** to expand the end **11** of the liner **10**, hold the liner **10** in position and reduce flow around the liner **10**. The anchor **12** may be any suitable device including a commercially available nitinol or stainless steel stent such as the MULTILINK manufactured by ACS and the NIR manufactured by Scimed. The liner **10** is attached to a portion of the anchor **12** with an adhesive, mechanical interconnection, thermal bond, suture or the like, or fused or soldered with radiopaque wire or ribbon. The liner **10** may, of course, be attached in any other manner. The liner **10** may also be encapsulated between layers of expanded PTFE.

The anchor **12** and liner **10** may form a continuous, cylindrical shape in the expanded position (FIG. **19**) or the anchor **12** may have a tapered shape, (FIG. **20**). The tapered shape of the anchor **12** may be useful when used in the carotid arteries with the small end positioned in the internal carotid artery and the large end in the common carotid. A method of forming the expanded shape of FIG. **20** is for the anchor **12** to have a larger diameter than the liner **10** so that the liner **10** holds an end of the anchor **12** at a smaller diameter. For example, the anchor **12** may be a stent having an 8 mm diameter with the liner **10** having a 6 mm expanded diameter so that the liner **10** holds the end **11** of the anchor **12** to about 6 mm. Alternatively, the anchor **12** could be designed to expand to different predetermined diameters at different points along its length by varying strut lengths along its length.

The anchor **12** is positioned within an anchor retention catheter **22** (FIG. **2**). The anchor **12** is naturally biased to the expanded condition of FIG. **3** and is held in the collapsed position by the retention catheter **22**. The anchor **12** is deployed by retracting the catheter **22** while an inner element **24** holds the anchor **12** at the desired location in the vessel. The liner **10** is advanced over the guidewire **15** which is advanced ahead of the catheter **22**.

The anchor **12** may be deployed to extend into the common carotid artery at the bifurcation of the external and internal carotid arteries (FIG. **2**) or may be contained entirely within the internal carotid artery (FIGS. **21–23**). The anchor **12** may also be deployed by inflating a balloon **27** as shown in FIG. **21** or may be a shape memory material which is heat activated. When using a balloon **27** to expand the anchor **12**, the anchor **12** is preferably a conventional nitinol or stainless steel stent although any suitable stent or device may be used. The balloon **27** is preferably compliant so that a proximal portion of the balloon **27** expands to occlude the vessel as shown in FIG. **21** before expansion of the anchor **12**. Alternatively, the balloon could be non-compliant but designed to inflate at a lower pressure than that required to expand the stent. By occluding the vessel, blood flow through the vessel is stopped so that even if plaque is released the plaque will not flow downstream. Further inflation of the balloon **27** (using inflation source **39**) expands the anchor **12** into engagement with the vessel wall (FIG. **22**). Any of the embodiments of the liner **10** described herein may be used with balloon or self-expanding anchors **12** and stents **26**.

After the anchor **12** has been expanded, the liner **10** can be configured to automatically open with blood pressure (FIG. **3**). Alternatively, the catheter **22** may be advanced through the liner **10** to partially open the liner **10**. The device, such as the stent **26**, may also be advanced through the liner **10** to open the liner **10**. The liner **10** protects the vessel to prevent intravascular devices from dislodging plaque when passing through the vessel. The distal end of the liner **10** may also be opened with an elongate element **29**, such as a nitinol wire, advanced into the liner **10** to open the liner **10** as shown in FIG. **26A**. The element **29** may be advanced and retracted independently with an inner actuator **31**.

Referring to FIGS. **26B** and **26C**, the elongate element **29A** may also be advanced into a pocket **35** in liner **10A**. The pocket **35** is preferably formed by simply inverting or everting the end of the liner **10A** and attaching the end to another part of the liner **10A** to form the pocket **35**. The elongate element **29A** passes through a tube **41**, preferably a hypotube, polymer tube or composite tube, which is releasably attached to the pocket **35**. The tube **41** is preferably released by heat, electrolytic detachment, mechanical detachment, dissolution of a bond by blood, or retraction of a retention cord although any suitable method may be used.

The elongate element **29A** is preferably made of a superelastic material, such as nitinol, which forms a loop **47** in the expanded position. The elongate element **29A** is contained within the tube **41** when the liner **10A** is advanced through the vasculature. The liner **10A** is advanced over the guidewire **15** by pushing the tube **41**. When the user is ready

to expand the proximal end of the liner **10A**, the element **29A** is advanced into the pocket **35** so that the loop **47** opens the liner **10A** as shown in FIGS. **26C** and **26D**. After opening the proximal end of the liner **10A**, the liner **10** may be used in any manner described herein. For example, the stent **26** may be advanced into the liner **10A** to open the narrowed region of the blood vessel as described in further detail below and shown in FIGS. **26D** and **26E**.

When the device introduced into the liner **10** is the stent **26**, the stent **26** is preferably expanded to open the narrowed portion of the vessel as shown in FIG. **25**. The stent **26** is mounted to a balloon **33** which is coupled to an inflation source **37** (FIG. 1) for inflating the balloon **33**. The stent **26** is preferably a conventional nitinol or stainless steel stent. The delivery catheter **22** is preferably introduced into the liner **10** as shown in FIG. **27** with the distal end of the catheter **22** positioned beyond the end of the liner **10**. The catheter **22** is then retracted to expose the distal end of the stent **26**. The distal end of the stent **26** is preferably opened first so that plaque is trapped between the anchor **12** and stent **26** when expanding the rest of the stent **26**. The liner **10** may have the openings **25** (FIG. **5**) which effectively filter blood trapped behind the liner **10** and help to equalize pressure on opposite sides of the liner as the stent **26** is expanded. The catheter **22** may also be used to deliver a distal anchor **43** which holds the distal end of the liner **10** open as shown in FIGS. **29–31**. Of course, the distal anchor **43** may be already attached to the liner **10** before introduction without departing from the scope of the invention. Another stent **45** can then be delivered to expand the liner **10** between the anchor and distal anchor **43** (FIGS. **32** and **33**).

Referring to FIGS. **34–39**, the proximal end of the liner **10** may be expanded by delivery catheter **50** and then released so that the anchor **12** is not required. The catheter **50** has an expanding section **32** which is preferably inflatable but may also be mechanically actuated. The expanding section **32** is coupled to a lumen for inflating Ad the expanding section **32**. The liner **10** is attached to the expanding section **32** with any suitable connection such as glue, suture, or soldered with radiopaque wire or ribbon. The liner **10** is preferably attached to the expanding section **32** with a thread **34** which passes through the liner **10** and expanding section **32**. An end of the thread **34** is pulled to release the liner **10**.

The expanding section **32** is inflated to expand the proximal end of the liner **10** as shown in FIG. **35**. The stent **26** or other device may then be passed through the liner **10** to open the liner **10** further as shown in FIG. **35**. Referring to FIG. **38**, the stent **26** is partially expanded so that the liner **10** is held firmly in place by the stent. The liner **10** is then detached by pulling the thread **34** and the stent **26** is fully expanded. Referring to FIG. **40**, the device may also be a filter **36** which is advanced through the liner **10** to trap dislodged plaque during an angioplasty, stent or other procedure. The liner **10** may then be removed before removing the filter **36** or may be used to line the vessel when deploying the stent **26**.

Referring to FIGS. **41–44**, the liner **10** may also be everted when moving from the collapsed to expanded positions. The liner **10** has the anchor **12** which is self-expanding and held in the collapsed position by retention catheter **37**. Pusher element **38** holds the anchor **12** in place while retracting the retention catheter **37**. A proximal end **40** of the liner **10** is releasably attached to an inner member **42**. The liner **10** is pressurized, preferably with saline, using lumen **44** in the pusher element **38**. Once the liner **10** is pressurized, the inner member **42** is advanced so that the liner **10** everts and moves through the vessel as shown in FIGS. **42–43**. An advantage of the everting liner **10** is that sliding forces between the liner **10** and the vessel wall are reduced when advancing the liner **10**.

After the liner **10** has been fully everted, the retention catheter **37** is retracted so that the anchor **12** expands and holds the proximal end of the liner **10** open. The liner **10** is then detached from the inner member **42**. The liner **10** may have a mechanical connection which is released with a push rod or guidewire **43**. The liner **10** may also have a severable bond with the inner member **42** such as a thermally, chemically or electrolytically severable bond using the guidewire **43**. The device, such as the stent **26**, is then delivered through the liner **10**.

Referring now to FIGS. **45** and **46**, the liner **10** may also be held open slightly at the proximal end **11** by delivery catheter **60**. The proximal end **11** of the liner is preferably held open to a diameter of 6 mm to 8 mm or 4 Fr to 7 Fr. One or more filaments **62** hold the liner to the catheter **60**. The liner **10** extends over the distal end of the catheter **60** but may also be mounted inside the catheter **60**. The filaments are shown separated from the body of the catheter **60** for clarity but would, of course, either pass through the catheter or be held close to the catheter **60**. The distal end of the stent **26** is inflated first to trap the plaque behind the liner **10** and reduce flow around the liner **10**. The rest of the stent **26** is then expanded in the conventional manner.

Referring to FIG. **47**, another catheter **70** for delivering the liner **10** is shown wherein the same or similar reference numbers refer to the same or similar structure. The catheter **70** operates similar to catheter **22** described above in that the liner **10** is mounted to the self-expanding anchor **12**. The anchor **12** is held in the collapsed position of FIG. **47** by an outer wall **72** of the catheter **70**. The outer wall **72** is retracted to expose the anchor **12** and permit the anchor **12** to expand.

The liner **10** is positioned between a flexible sheath **74** and an inner tube **76**. The sheath **74** and inner tube **76** prevent the liner **10** from contacting the walls of the vessel and guidewire **15** when the liner **10** is advanced through the vasculature. The sheath **74** and tube **76** also hold the liner **10** in the collapsed position although the liner **10** may be collapsed without requiring the sheath **74** and tube **76**. The sheath **74** is attached to the outer wall **72** and is retracted together with the outer wall **72**.

A shaft **80** extends through the catheter **70** and a flexible shaft extension **82** extends from the shaft **80**. The shaft extension **82** and inner tube **76** provide a relatively flexible distal portion to navigate tortuous vessels such as the cerebral vasculature. The flexible shaft extension **82** may be a coil **84** as shown in FIG. **47** or may be a tube **86** of material as shown in FIG. **48**. A distal portion **88** of the catheter **70**, which extends from the distal end of the shaft **80**, is preferably more flexible than a proximal portion **90** which terminates at the end of the shaft **80**.

Referring to FIG. **47**, the guidewire **15** passes through slots **93**, **95** in the outer wall **72** and shaft **80** for loading the device on the guidewire **15**. Referring to FIG. **48**, the guidewire **15** may also pass through slots **92**, **97**, **99** in the outer wall **72**, inner tube **76** and shaft extension **82**. The catheter **70** may, of course, have a continuous lumen which extends to the proximal end of the catheter **70**. Referring again to FIG. **47**, a handle **94** is attached to the outer wall **72** and is pulled relative to the shaft **80** to retract the sheath **74** and outer wall **72**. The outer wall **72** is preferably made of high density polyethylene having a thickness of about 0.005 inch and an outer diameter of 0.040 to 0.070 inch, preferably

about 0.055 inch. The outer wall **72** preferably has a length of 110 to 150 cm and preferably about 135 cm. The sheath **74** is preferably made of linear low density polyethylene having a wall thickness of about 0.002 inch and an outer diameter of about 0.049 inch. The inner tube **76** is preferably made of polyimide having a wall thickness of 0.0005 to 0.001 inch and an outer diameter of 0.014 to 0.026 inch, more preferably 0.018 to 0.024 inch and most preferably about 0.022 inch. The liner **10** is collapsed to have a diameter, length, thickness and length to thickness ratios as described above when mounted to the tube **76**. The shaft **80** is preferably a 0.022 inch diameter stainless steel mandrel and the shaft extension **82** is preferably a stainless steel coil. The shaft extension is fused to the inner tube **76** (FIG. **47**). The extension **82** may also be a tube of linear low density polyethylene which is extruded and then irradiated with 25/30 Mrads to an outer diameter of about 0.040 and a wall thickness of about 0.018 inch (FIG. **48**). Any other suitable materials may be used without departing from the scope of the invention.

The catheter **70** and liner **10** are used in substantially the same manner as the catheters and liners **10** described above and the discussion above is equally applicable here. The liner **10** is advanced over the guidewire **15** to a narrowed region of a blood In vessel such as the internal carotid artery. The liner **10** and catheter have a small profile, as discussed above and incorporated here, so that the liner **10** may be advanced into the narrowed region without dislodging plaque. When the liner **10** is at the desired location, the handle **94** and shaft **80** are manipulated to retract the sheath **74** and the outer wall **72**. When the outer wall **72** and sheath **74** are retracted, the anchor **12** is free to expand. The liner **10** may then be used in the manner described above. For example, the stent **26** or filter **36** may be advanced into the liner **10**.

Referring to FIG. **49**, another catheter **100** for delivering the liner **10** is shown. The catheter **100** has the self-expanding anchor **12** which is held in the collapsed position by a collar **102**. An arm **104** is attached to the collar **102** which in turn is attached to a first core-wire **106**. The first core wire **106** passes through a shaft **108** which has a handle **110** mounted to the proximal end. The handle **110** is retracted to pull the core wire **106**, first arm **104** and collar **102** for releasing the self-expanding anchor **12**.

A tube **112** is fused to the shaft **108** and an inner tube **114** is attached to the tube **114**. The arm **104** travels in a slot **116** in the tube **114** to stabilize retraction of the collar **102**. The tube **112** and inner tube **114** form a lumen **118** through which the guidewire **15** passes.

Referring to FIG. **50**, the distal end of the liner **10** is locked into a fold **120** at the end of the inner tube **114**. A wire loop **122** holds the liner **10** in the fold **120**. The wire loop **122** is preferably attached to the collar **102** with a wire **124** embedded in the collar **102**. The wire loop **122** is retracted together with the collar **102** so that the distal end of the liner **10** is released as the collar **102** is retracted. The wire loop **122** is preferably a 0.005 inch diameter stainless steel wire. The fold **120** is preferably made of silicone although other suitable materials may be used. The shaft **108** is preferably made of stainless steel hypotube having a wall thickness of about 0.005 inch and an outer diameter of about 0.024 inch. The tube **112** is preferably made of linear low density polyethylene having a wall thickness of about 0.004 inch and an outer diameter of about 0.040 inch. The inner tube **114** is preferably made of polyimide having a thickness of 0.0005 inch and an outer diameter of about 0.022 inch. The liner **10** is deployed and used in substantially the same manner as described above and the discussion above is applicable here.

Referring to FIG. **52**, yet another device **200** is shown. The device has a liner **202** and an anchor **204** which may be any liner or anchor described herein or any other suitable anchor or liner. The anchor **204** is attached to the proximal end of the liner **200** in any suitable manner such as with an adhesive such as a UV curable polyurethane. As with any of the liners described herein, the liner **200** and anchor **204** may have any of the dimensions and features described herein and may be used in any manner described herein without departing from the scope of the invention. The device **200** is advanced over a guidewire **206** which preferably has a diameter of 0.018 inch but may be any size. The guidewire **206** passes through a guidewire tube **208** which is preferably a polyimide tube having an inner diameter of 0.020 inch and a wall thickness of about 0.001 inch.

The anchor **204** is held in the collapsed position of FIG. **52** by a retention element **210** which has a size of about 4–8 French and preferably about 6 Fr. The retention element **210** has a length of 0.1–1.0 inch and more preferably 0.200–0.600 inch. A proximal end of the retention collar **210** has an opening **212** to receive the guidewire **208**.

A bumper **214** is contained within the retention element **210** and is used to release the anchor **204** from the retention element **210** in the manner described below. An elongate element **216**, such as a cable **218**, is coupled to the bumper **214** for manipulating the bumper **214**. The elongate element **216** passes through an actuator tube **220** coupled to the retention element **210**. The actuator tube **220** is relatively small and has a size of no more than 0.030 inch and preferably no more than 0.025 inch. The elongate element **216** and actuator tube **220** are coupled to an actuator **222** for manipulating the bumper **214**. The actuator **222** is shown schematically and can be formed in any suitable manner to provide relative movement as is known in the art. The bumper **214** is attached to the guidewire tube **208** so that the guidewire tube **208** moves with the bumper **214** in the manner described below. The bumper **214** is preferably a section of hypotube having an outer diameter suitable to slide within the retention element **210**.

The distal end of the liner **200** is trapped by a tip cover **224** which is preferably made of isoprene such as CHRONOPRENE sold by CardioTech. Of course, any other suitable material may be used. The tip cover **224** has an inner diameter which is somewhat smaller, preferably about 0.0005–0.002 inch smaller, than the outer diameter of the guidewire tube **208**. In this manner, the tip cover **224** applies a modest compressive force to the distal end of the liner **202** to hold the liner **202** in the collapsed position. The tip cover **224** lies partially over the guidewire tube **208** and partially over the liner **202**. The tip cover **224** may be bonded to the distal end of the guidewire tube **208** to prevent release of the tip cover **224**. Although the tip cover **2224** is preferred, any other mechanism for holding the sleeve in the collapsed position may be used including those described herein.

Use of the device **200** is now described with reference to FIGS. **52**–**54A**. The liner **202** is advanced over the guidewire **206** to a treatment site such as the internal carotid artery. The treatment site may require any treatment described herein including opening of a narrowed portion of a blood vessel as shown in FIG. **52**. Once the device **200** is in position, the bumper **214** is advanced adjacent to the anchor **204** as shown in FIG. **53** by manipulating the elongate element **216** with the actuator **222**. As the bumper **214** is advanced, the tip cover **224** is moved distally out of engagement with the liner

202 to release the distal end of the liner 202. The retention element 210 is then withdrawn while holding the bumper 214 in the same position to expose the anchor 204 and permit the anchor to expand as shown in FIG. 54A. The liner 202 is now in position to receive another medical device as described above. For example, a balloon could be advanced into the liner 202 and expanded to open the narrowed region. Alternatively, or in addition to use of the balloon, a stent may be advanced into the liner 202 and expanded for opening the narrowed portion of the vessel.

As mentioned above, any of the liners described herein may have the anchor at both ends (FIG. 54B) or throughout the liner (FIG. 54C) without departing from various aspects of the present invention. The anchor preferably has a relatively low opening force and does not significantly open the narrowed portion of the vessel (FIG. 54C). It is believe that barotrauma, or pressure-induced trauma, may contribute to restenosis when using conventional devices. The present invention provides low opening force thereby reducing barotrauma as compared to conventional methods and devices.

Referring to FIG. 55, another device 200A is shown wherein the same or similar reference numbers refer to the same or similar structure. The guidewire 206 has been reduced in size for clarity. The device 200A has the liner 202 and the anchor 204 which may be any liner or anchor described herein and all features, dimensions, methods of use and advantages of the liners and anchors described herein are equally applicable here. The device 200A is similar in structure and use to the device 200 except that the guidewire tube 208A is not attached to the bumper 214. The guidewire tube 208A is separate from the bumper 214 so that bumper 214 can be moved independent of release of the distal end of the liner 202 with the tip cover 224.

The device 200A is used in substantially the same manner as the device 200 except that the guidewire lumen 208A and the retention element 210 are advanced together to the target site. The user may then advance the bumper 214 adjacent to the anchor 204 before releasing the distal end of the liner 202. The anchor is then released by withdrawing the retention element 210. The distal end of the liner 200A is then released by simply advancing the guidewire tube 208A. Alternatively, the user may release the distal end of the liner 200A before advancing the bumper 214.

Referring now to FIG. 56, still another device 200B is shown wherein the same or similar reference numbers refer to the same or similar structure. The device 200B has the liner 202 and the anchor 204 which may be any liner or anchor described herein. The device 200B is similar in structure and use to the device 200 except that a retention element 210B extends over the liner 202 to hold the liner 202 in the collapsed position. The device 200B is used in the same manner as the device 200.

Referring now to FIG. 57, the distal end of another device 230 is shown. The device 230 has the liner 202 and the anchor 204 which may be any liner or anchor described herein and all features, dimensions and advantages of the liners and anchors described herein are equally applicable here. The liner 202 is trapped between an inner layer 232 and an outer layer 234. The liner 202 occupies a space 235 between the inner and outer layers 232, 234 and the manner in which the liner 202 is collapsed is not shown for clarity. The liner 202 is preferably collapsed in the manner described above or another suitable method.

The inner and outer layers 232, 234 are relatively thin and flexible. Specifically, the inner and outer layers 232, 234 have a thickness of no more than 0.002 inch and more preferably no more than 0.001 inch. The inner layer 232 is preferably a shrink tube having a thickness of about 0.0005–0.002 inch, preferably about 0.0005 inch, and an outer diameter of 0.021 inch. The outer layer 234 is preferably a PET shrink tube having a 0.001 inch thickness and an outer diameter of 0.0047 inch. The outer layer 234 preferably applies a modest compressive force to the liner 202 to hold the liner 202 in the collapsed position. To provide such a force, the outer layer 234 is sized about 0.0005–0.002 inch smaller than the collapsed diameter of the liner. The outer layer 234 preferably bas an outer diameter of less than 0.050 inch and more preferably less than 0.045 inch and most preferably about 0.043 inch. The inner and outer layers 232, 234 preferably extend to the proximal end of the device. The inner and outer layers 232, 234 advantageously hold the liner 202 in the collapsed position of FIG. 57 while still maintaining sufficient flexibility to pass through small, tortuous vessels.

The liner 202 may be collapsed in any manner described herein. For example, the liner 202 may have the folds 14 (FIGS. 7–12) which are wrapped around one another. The folds 14 may be formed in any suitable manner and a preferred manner is to tension the liner 202 to naturally create the folds 14. When the liner 202 is tensioned, the liner 202 naturally forms about 10–20 folds 14 which are then wrapped to collapse the liner 202 in the manner shown in FIGS. 7–12. The liner 202 is collapsed to the preferred dimensions described above, for example, tbe liner may have the length, collapsed length, thickness, and expanded sizes described above.

The inner layer 232 is preferably bonded to an inner element 236 and the outer layer 234 is preferably bonded to an outer element 238. The inner and outer elements 236, 238 are preferably tubes but may take other suitable shapes and configurations. The inner and outer elements 236, 238 can be moved relative to one another to retract the outer layer 234 and release the anchor 204 and liner 202 as described below. The outer element 238 may be made of any suitable material and a preferred material is a polyimide tube having a thickness of about 0.003 inch and an outer diameter of about 0.039 inch. Although it is preferred to provide the outer element 238, the device may also be practiced without the outer element 236 and only the outer layer 234 without departing from the scope of the invention.

The inner element 236 provides a lumen 237 for receiving the guidewire. The lumen 237 preferably has a diameter of 0.010–0.030 inch, more preferably 0.015–0.025 inch and most preferably about 0.017 inch. The inner element 236 is preferably polyetherether ketone having a thickness of about 0.007 inch and an outer diameter of about 0.035 inch. The guidewire 206 may have any suitable size and s preferably a 0.014 inch guidewire. The inner element 236 preferably has a spiral cut 39 near the distal end to enhance flexibility and prevent kinking. The spiral cut 239 forms sections having a length of about 0.003–0.004 inch.

As mentioned above, the device, and in particular the liner 202 and the anchors 204, may take any of the dimensions, features and advantages of the other liners and anchors described herein. The device may also have the following dimensions. The diameter of the outer layer extending over the liner and anchor is preferably no more than 0.055 inch, more preferably no more than 0.050 inch and most preferably no more than 0.040 inch. The outer layer 232, liner 202 and inner layer 234 together form a relatively small radial thickness, preferably about 0.007–0.015 and more preferably 0.007–0.013 inch.

The inner and outer layers **232, 234** preferably continue beyond the distal end of the liner and a radiopaque coil **240**, such as a platinum coil, extends between and beyond the layers **232, 234**. The coil **240** preferably has a diameter of 0.003 inch and is wound to a diameter of about 0.018 inch. The coil **240** extends for a total length of about 0.300 inch with an exposed length beyond the inner and outer layers **232, 234** of about 0.250 inch. The outer layer **234** tapers down distal to the liner **202** to a diameter of less than 0.035, more preferably less than 0.030 and most preferably about 0.024 inch.

Use of the device **230** is now described. The device **230** is advanced through the vasculature to a treatment site. The outer layer **238** is then retracted while holding the inner element **236** to expose the liner **202** and anchor **204** thereby permitting the anchor **204** to expand as shown in FIG. **58**. As the anchor **204** expands, the liner **202** is released and expands together with the anchor **204**. After deployment of the liner **202**, any medical device described herein, including a device to open a narrowed region of a blood vessel such as a stent, may be advanced into or through the liner **202**.

Referring to FIG. **59**, a preferred anchor **204A** is shown in an expanded and position. As mentioned herein, any of the anchors may be used with any of the liners without departing from the scope of the invention. The anchor **204A** is formed by laser cutting or etching a tube which is preferably made of a superelastic material such as nitinol. As an example, the anchor **204A** may have an outer diameter of about 0.060 inch and a wall thickness of about 0.006 inch. The tube is cut or etched to form first and second sections **242, 244** connected by longitudinal connecting elements **246**. Each section **242, 244** is formed by struts **248** connected end to end in a zig-zag pattern to form a closed loop **250**. As mentioned above, the anchor **204A** may be similar to a stent or any other suitable device for holding the liner **202** at the desired location. The preferred anchor **204A** of the present invention does, however, differ from conventional stents as described below.

The preferred anchor **204A** of FIG. **59** is shorter than conventional stents to provide reduced interference with branch vessels. The anchor **204A** has a length of less than 15 mm, more preferably less than 10 mm when expanded. The relatively small length provides flexibility to access small, tortuous vessels. The anchor **204A** can be somewhat short since the anchor **204A** is simply holding the liner in place during introduction of other devices, such as the stent, into the liner **202**. The anchor **204A** also preferably has a relatively low opening force since the anchor **204A** is not intended to provide significant opening of the vessel. Although the anchor **204A** is shorter and has a lower opening force than a conventional stent, the anchor **204A** may differ from conventional stents in more or fewer ways without departing from various aspects of the present invention.

The present invention is also directed to kits **124** which include various assemblies as described above. For example, the kit **124** may include the liner **10**, delivery catheter **22** and instructions for use **128** setting forth any of the methods described herein as shown in FIG. **51**. The kits may, of course, also include the stent(s) **26**, anchors **12** and stent delivery catheter(s) **22** and/or the filter **36** as well. The kits **124** will usually include a container **126**, such as a pouch, tray, box, tube, or the like, which contains the devices as well as the instructions for use **128**. The instructions for use **128** may be set forth on a separate instructional sheet within the package or printed in whole or in part on the packaging itself. Optionally, other system components useful for performing the methods of the present invention could be provided within the kit **124**, including guidewires, introductory sheaths, guiding catheters, and the like. Any of the devices described herein may form a kit with instructions setting forth a method of the present invention.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims. For example, any of the delivery catheters may have a balloon for occluding the vessel while delivering the liner or advancing the device through the liner and any of the liners may have perforations to filter blood or may be made of a tightly woven material. Furthermore, the preferred dimensions described herein with respect to any of the embodiments is equally applicable to other embodiments. Finally, all aspects of the present invention may also be practiced with the delivery of drugs, radiation and drugs for anti-restenosis and anti-platelet adhesion.

What is claimed is:

1. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer;

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer; and

a radiopaque coil extending beyond the distal end of the liner and the inner and outer layers, the radiopague coil also being positioned at least partially between the inner and outer layers.

2. The device of claim **1** wherein:

the outer layer holds the anchor in the collapsed position.

3. The device of claim **1** wherein:

the outer layer has a thickness of 0.0005–0.002 inch.

4. The device of claim **1** wherein:

the outer layer stretches over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer.

5. The device of claim **1** further comprising:

an inner element positioned beneath the liner and the anchor, the inner layer being attached to the inner element.

6. The device of claim **5**, wherein:

the inner layer has a thickness of 0.0005–0.002 inch.

7. The device of claim **1** wherein:

the outer layer has a diameter of no more than 0.055 inch when in the collapsed position.

8. The device of claim **1** wherein:

the outer layer has a diameter of no more than 0.050 inch when in the collapsed position.

9. The device of claim **1** wherein:

the outer layer applies a compressive force to the liner to hold the liner in the collapsed position.

10. The device of claim **1** wherein:

the outer layer lies directly over the anchor and holds the anchor in the collapsed position, the outer layer being retracted by an outer element to expose the anchor and permit the anchor to move to the expanded position.

11. The device of claim 1 wherein:

the liner is collapsed by forming a number of folds.

12. The device of claim 1 wherein:

the liner is made of expanded PTFE.

13. The device of claim 1 wherein:

the inner and outer layers extend beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer.

14. The device of claim 1 wherein:

the inner liner is attached to an inner element, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer.

15. The device of claim 14, wherein:

the inner element is spiral cut at a distal end.

16. The device of claim 15, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

17. The device of claim 1 wherein:

the anchor has a length of less than 15 mm when collapsed.

18. A method of lining a vessel, comprising the steps of:

providing an expandable anchor, a liner, an inner layer, and an outer layer, the anchor and liner being movable from a collapsed shape to an expanded shape, the liner being attached to the anchor and extending from an end of the anchor, the outer layer being slidable relative to the inner layer, the outer layer extending over the liner and the anchor in the collapsed position, the radiopaque coil extending beyond the distal end of the liner and the inner and outer layers, the radiopaque coil being positioned at least partially between the inner and outer layers;

advancing a medical device to a treatment site;

retracting the outer layer to expose the liner and the anchor to permit the anchor to expand; and

advancing the medical device into the liner after the retracting step.

19. The method of claim 18 wherein:

the providing step is carried out with the outer layer holding the anchor and the liner in the collapsed position.

20. The method of claim 18 wherein:

the providing step is carried out with the outer layer having a thickness of 0.0005–0.002 inch.

21. The method of claim 18 wherein:

the providing step is carried out with the outer layer having a tapered portion when the anchor is in the collapsed position; and

the retracting step is carried out with the outer layer stretching over the tapered portion as it passes over the tapered portion.

22. The method of claim 21, wherein:

the providing step is carried out with the inner layer having a thickness of 0.0005–0.002 inch.

23. The method of claim 18 wherein:

the providing step is carried out with the outer layer having a diameter of no more than 0.050 inch when in the collapsed position.

24. The method of claim 18 wherein:

the providing step is carried out with the outer layer having a diameter of no more than 0.045 inch when in the collapsed position.

25. The method of claim 18 wherein:

the providing step is carried out with the outer layer lying directly over the anchor to hold the anchor in the collapsed position;

the retracting step being carried out so that the outer layer is retracted to expose the anchor and permit the anchor to expand.

26. The method of claim 18 wherein:

the providing step is carried out with the liner collapsed by forming a number of folds which are folded around one another.

27. The method of claim 18 wherein:

the providing step is carried out with the liner being made of expanded PTFE.

28. The method of claim 18, wherein:

the advancing step is carried out with the medical device being a medical device selected from the group consisting of a stent, an angioplasty balloon, a filter, a drug delivery device, and an atherectomy device.

29. The method of claim 18 wherein:

the providing step is carried out with the inner layer being attached to an inner element; and

the retracting step is carried out with the inner element contacting the anchor to hold the anchor in place while retracting the outer layer.

30. The method of claim 29, wherein:

the providing step is carried out with the inner element having a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

31. The method of claim 18 wherein:

the providing step is carried out with the outer layer attached to an outer element; and

the retracting step is carried out with the outer element being retracted with the outer layer.

32. The method of claim 18 wherein:

the providing step is carried out with the anchor having a length of less than 15 mm when collapsed.

33. A method of opening a narrowed region in a blood vessel, comprising the steps of:

providing a liner movable from a collapsed condition to an expanded condition;

advancing the liner to a narrowed region of a blood vessel with the liner in the collapsed position;

passing at least a portion of the liner through the narrowed region of the blood vessel in the collapsed position;

moving a stent into the liner after the passing step so that the stent is also positioned in the narrowed region of the blood vessel; and

expanding the stent after the moving step so that the stent expands the liner and opens the narrowed region of the vessel.

34. The method of claim 33, wherein:

the advancing and passing steps are carried out with the blood vessel being a vessel selected from the group comprising the internal carotid artery and saphenous vein graft.

35. The method of claim 33, further comprising the step of:

expanding at least part of the liner before expanding the stent.

36. A device for lining a vessel, comprising:

An expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer; and

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer, the outer layer stretching over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer;

wherein the inner layer is attached to an inner element, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer, the inner element being spiral cut at a distal end.

37. The device of claim **36** wherein:

the outer layer holds the anchor in the collapsed position.

38. The device of claim **36** wherein:

the outer layer has a thickness of 0.0005–0.002 inch.

39. The device of claim **36** further comprising:

an inner element positioned beneath the liner and the anchor, the inner layer being attached to the inner element.

40. The device of claim **39** wherein:

the inner layer has a thickness of 0.0005–0.002 inch.

41. The device of claim **36** wherein:

the outer layer has a diameter of no more than 0.055 inch when in the collapsed position.

42. The device of claim **36** wherein:

the outer layer has a diameter of no more than 0.050 inch when in the collapsed position.

43. The device of claim **36** wherein:

the outer layer applies a compressive force to the liner to hold the liner in the collapsed position.

44. The device of claim **36** wherein:

the outer layer lies directly over the anchor and holds the anchor in the collapsed position, the outer layer being retracted by an outer element to expose the anchor and permit the anchor to move to the expanded position.

45. The device of claim **36** wherein:

the liner is collapsed by forming a number of folds.

46. The device of claim **36** wherein:

the liner is made of expanded PTFE.

47. The device of claim **36** further comprising:

radiopaque coil extending beyond the distal end of the liner and being positioned at least partially between the inner and outer layers.

48. The device of claim **47**, wherein:

the radiopaque coil extends beyond the distal end of the inner and outer layers.

49. The device of claim **36**, wherein:

the inner and outer layers extend beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer.

50. The device of claim **36**, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

51. The device of claim **36**, wherein:

the anchor has a length of less than 15 mm when collapsed.

52. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer; and

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer, the inner and outer layers extending beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer;

wherein the inner layer is attached to an inner element, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer, the inner element being spiral cut at a distal end.

53. The device of claim **52**, wherein:

the outer layer holds the anchor in the collapsed position.

54. The device of claim **52**, wherein:

the outer layer has a thickness of 0.0005–0.002 inch.

55. The device of claim **52**, wherein:

the outer layer stretches over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer.

56. The device of claim **52**, further comprising:

an inner element positioned beneath the liner and the anchor, the inner layer being attached to the inner element.

57. The device of claim **56**, wherein:

the inner layer has a thickness of 0.0005–0.002 inch.

58. The device of claim **52**, wherein:

the outer layer has a diameter of no more than 0.055 inch when in the collapsed position.

59. The device of claim **52**, wherein:

the outer layer has a diameter of no more than 0.050 inch when in the collapsed position.

60. The device of claim **52**, wherein:

the outer layer applies a compressive force to the liner to hold the liner in the collapsed position.

61. The device of claim **52**, wherein:

the outer layer lies directly over the anchor and holds the anchor in the collapsed position, the outer layer being retracted by an outer element to expose the anchor and permit the anchor to move to the expanded position.

62. The device of claim **52**, wherein:

the liner is collapsed by forming a number of folds.

63. The device of claim **52**, wherein:

the liner is made of expanded PTFE.

64. The device of claim **52**, further comprising:

a radiopaque coil extending beyond the distal end of the liner and being positioned at least partially between the inner and outer layers.

65. The device of claim **64**, wherein:

the radiopaque coil extends beyond the distal end of the inner and outer layers.

66. The device of claim **52**, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

67. The device of claim **52**, wherein:

the anchor has a length of less than 15 mm when collapsed.

68. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer;

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer; and

an inner element attached to the inner layer, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer, the inner element being spiral cut at a distal end.

69. The device of claim **68**, wherein:

the outer layer holds the anchor in the collapsed position.

70. The device of claim **68**, wherein:

the outer layer has a thickness of 0.0005–0.002 inch.

71. The device of claim **68**, wherein:

the outer layer stretches over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer.

72. The device of claim **68**, wherein:

the inner layer has a thickness of 0.0005–0.002 inch.

73. The device of claim **68**, wherein:

the outer layer has a diameter of no more than 0.055 inch when in the collapsed position.

74. The device of claim **68**, wherein:

the outer layer has a diameter of no more than 0.050 inch when in the collapsed position.

75. The device of claim **68**, wherein:

the outer layer applies a compressive force to the liner to hold the liner in the collapsed position.

76. The device of claim **68**, wherein:

the outer layer lies directly over the anchor and holds the anchor in the collapsed position, the outer layer being retracted by an outer element to expose the anchor and permit the anchor to move to the expanded position.

77. The device of claim **68**, wherein:

the liner is collapsed by forming a number of folds.

78. The device of claim **68**, wherein:

the liner is made of expanded PTFE.

79. The device of claim **68**, further comprising:

a radiopaque coil extending beyond the distal end of the liner and being positioned at least partially between the inner and outer layers.

80. The device of claim **79**, wherein:

the radiopaque coil extends beyond the distal end of the inner and outer layers.

81. The device of claim **68**, wherein:

the inner and outer layers extend beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer.

82. The device of claim **68**, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

83. The device of claim **68**, wherein:

the anchor has a length of less than 15 mm when collapsed.

84. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer;

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer; and

a radiopaque coil extending beyond the distal end of the liner and also being positioned at least partially between the inner and outer layers,

wherein the inner liner is attached to an inner element, the inner element engaging the anchor to hold the anchor when the outer layer is retracted relative to the inner layer, the inner element being spiral cut at a distal end.

85. The device of claim **84**, wherein:

the inner element has a lumen for receiving a guidewire, the lumen having a diameter of 0.015–0.25 inch.

86. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer;

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer, the outer layer stretching over a tapered portion, the outer layer stretching as it passes over the tapered portion when the outer layer is moved proximally relative to the inner layer; and

a radiopaque coil extending beyond the distal end of the liner and being positioned at least partially between the inner and outer layers.

87. The device of claim **86**, wherein:

the radiopaque coil extends beyond the distal end of the inner and outer layers.

88. A device for lining a vessel, comprising:

an expandable anchor movable from a collapsed shape to an expanded shape;

a liner attached to the anchor and extending from an end of the anchor;

an inner layer, the liner being mounted over the inner layer, the inner element being spiral cut at a distal end; and

an outer layer extending over the liner and the anchor, the outer layer being retracted to expose the liner when the outer layer is moved proximally relative to the inner layer, the inner and outer layers extending beyond a distal end of the liner, the outer layer tapering distally and being flexible enough to expand over the tapered section when the outer layer is retracted relative to the inner layer.

* * * * *

US 20040215331A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2004/0215331 A1

Chew et al. (43) Pub. Date: Oct. 28, 2004

(54) APPARATUS AND METHODS FOR DELIVERY OF VARIABLE LENGTH STENTS

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(21) Appl. No.: **10/624,451**

(22) Filed: **Jul. 21, 2003**

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/306,813, filed on Nov. 27, 2002.
Continuation-in-part of application No. 10/306,620, filed on Nov. 27, 2002.
Continuation-in-part of application No. 10/306,622, filed on Nov. 27, 2002.

(60) Provisional application No. 60/336,967, filed on Dec. 3, 2001. Provisional application No. 60/364,389, filed on Mar. 13, 2002. Provisional application No. 60/336,607, filed on Dec. 3, 2001. Provisional application No. 60/336,767, filed on Dec. 3, 2001.

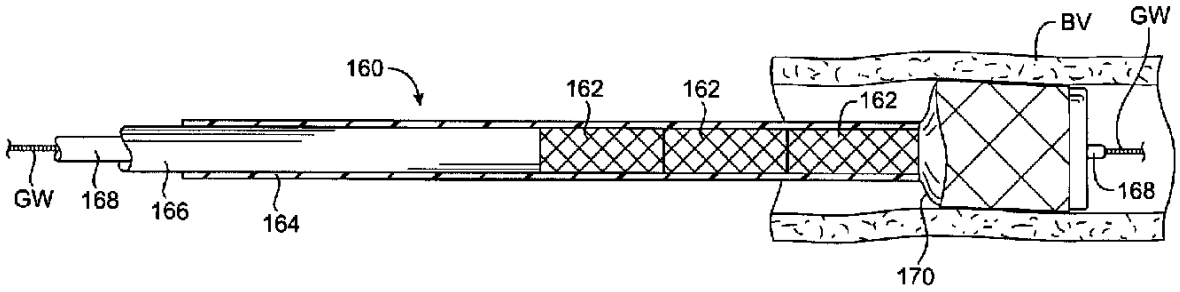
Publication Classification

(51) **Int. Cl.**[7] **A61F 2/38**; A61F 2/42

(52) **U.S. Cl.** **623/1.21**

(57) **ABSTRACT**

Blood vessels and other body lumens are stented using multiple, discreet stent structures, or continuous coiled or mesb stent structures. Stent structures may be balloon expandable or self-expanding and are delivered by a delivery catbeter whicb is repositioned to spaced-apart delivery sights. By coating the stents witb particular biologically active substances, byperplasia within and between the implanted stents can be inbibited. An exemplary delivery catheter comprises a catbeter body baving a deployment mechanism for deploying one or more stents of selectable lengtb into the vessel.



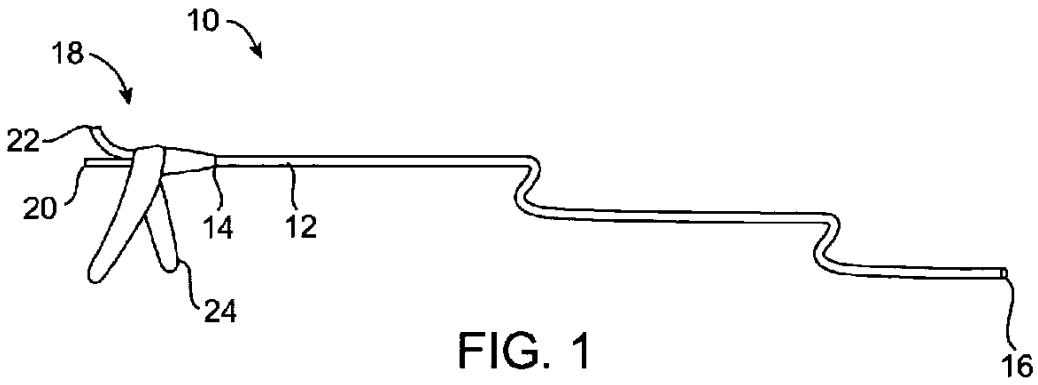


FIG. 1

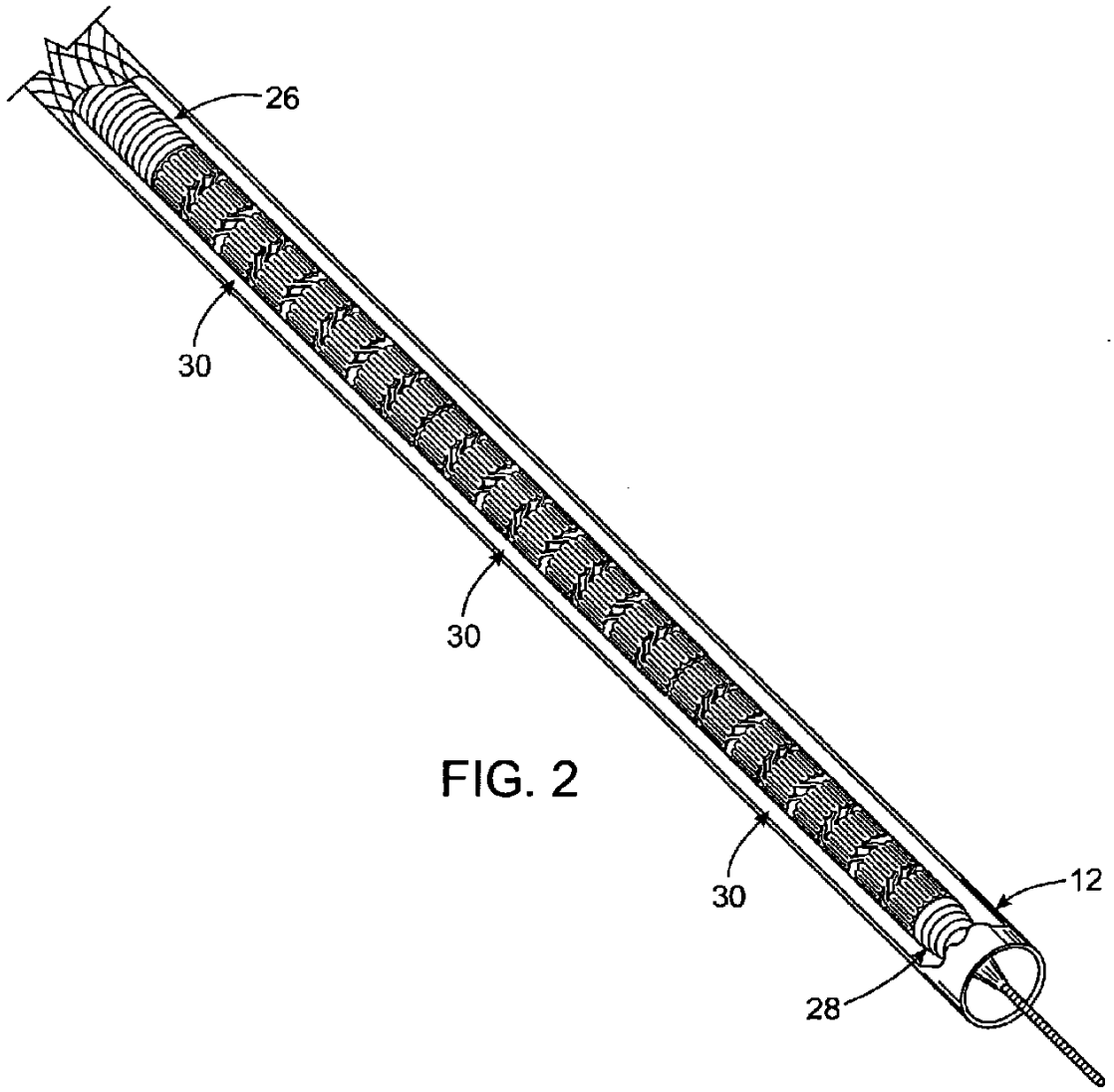


FIG. 2

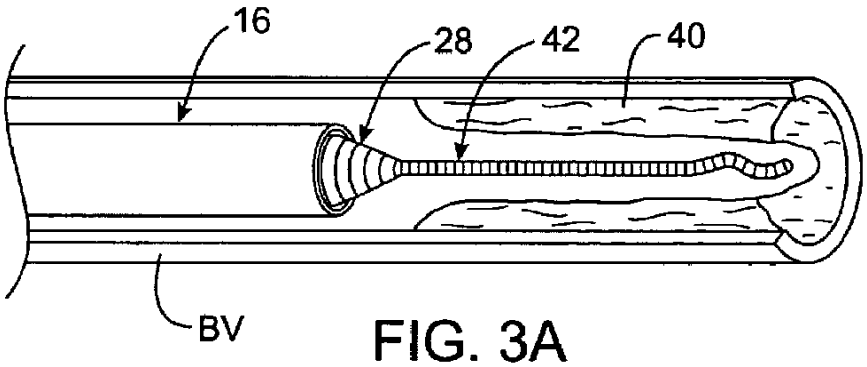


FIG. 3A

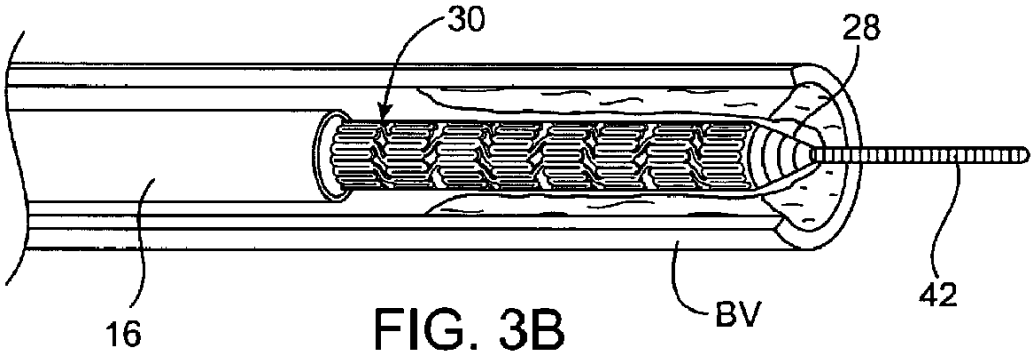


FIG. 3B

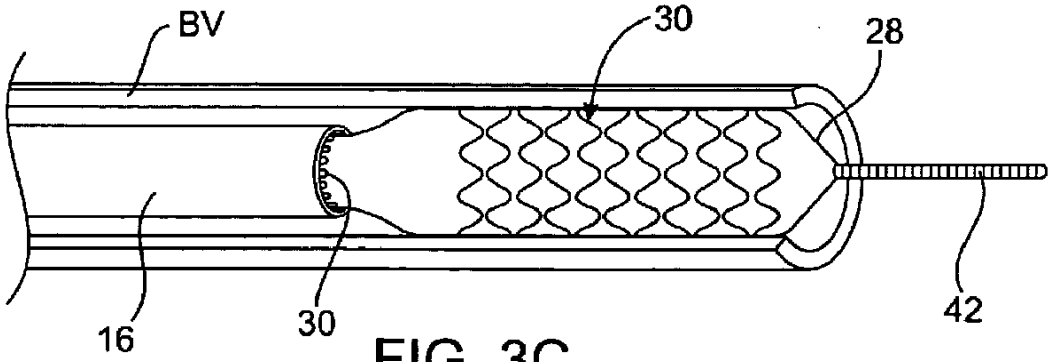


FIG. 3C

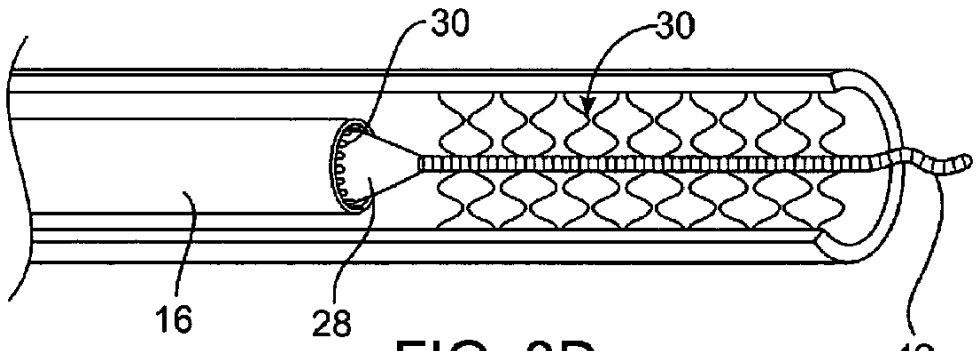


FIG. 3D

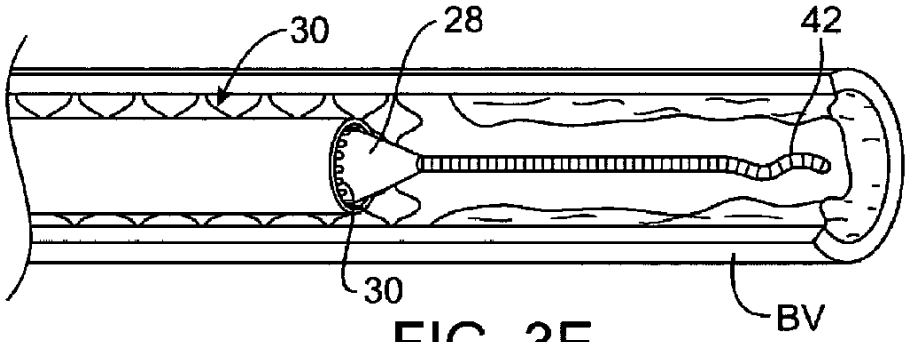


FIG. 3E

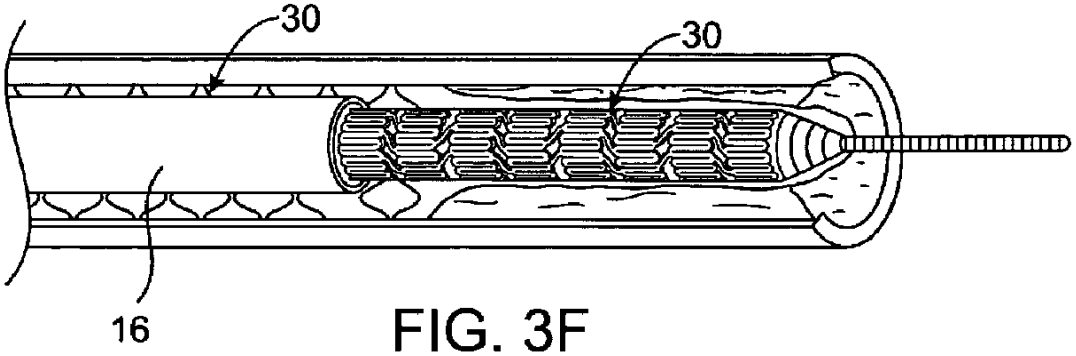


FIG. 3F

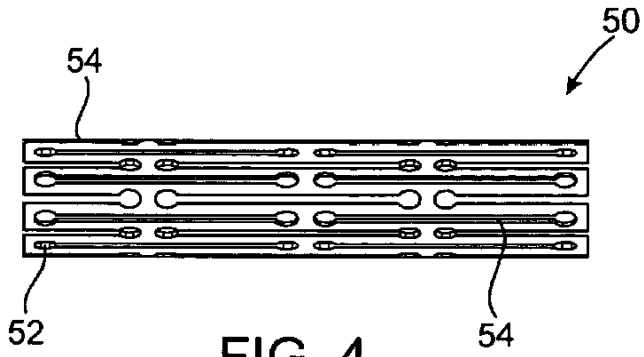


FIG. 4

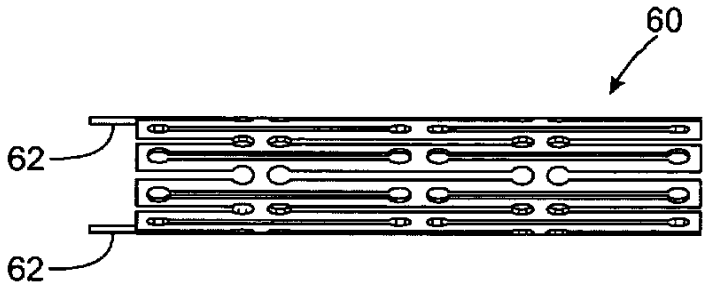


FIG. 5A

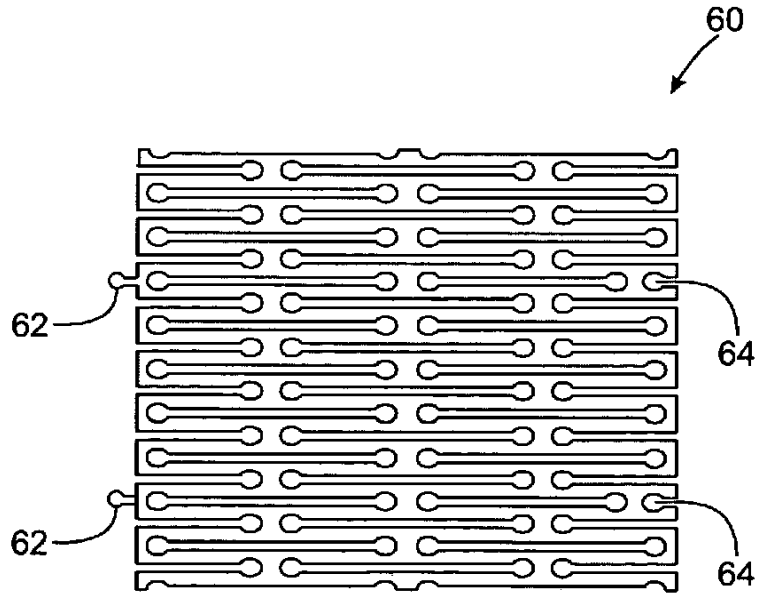


FIG. 5B

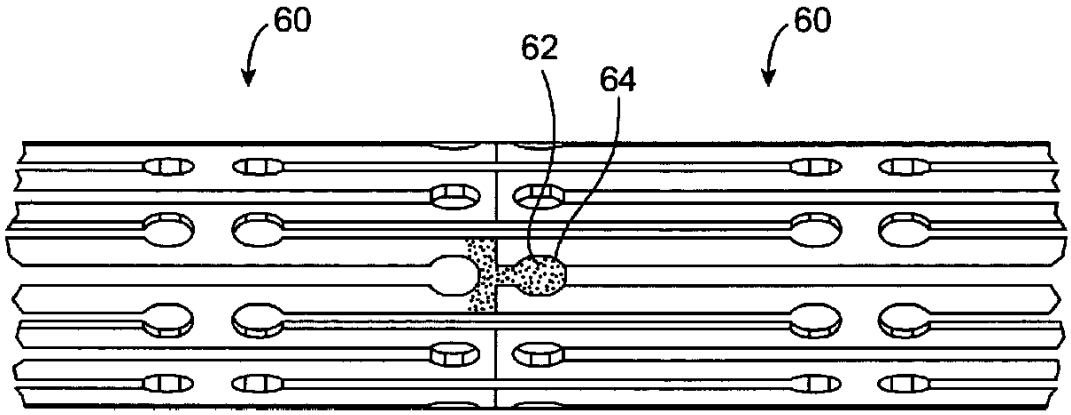


FIG. 5C

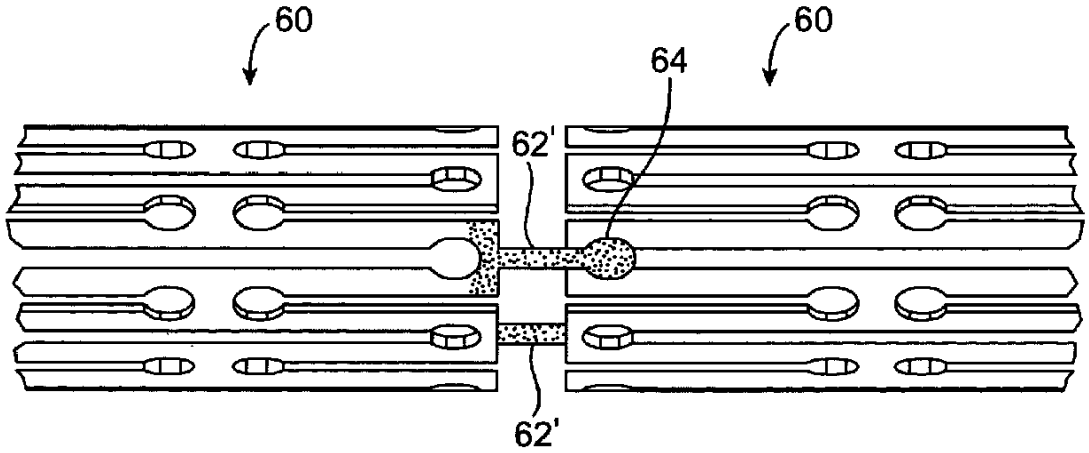


FIG. 5D

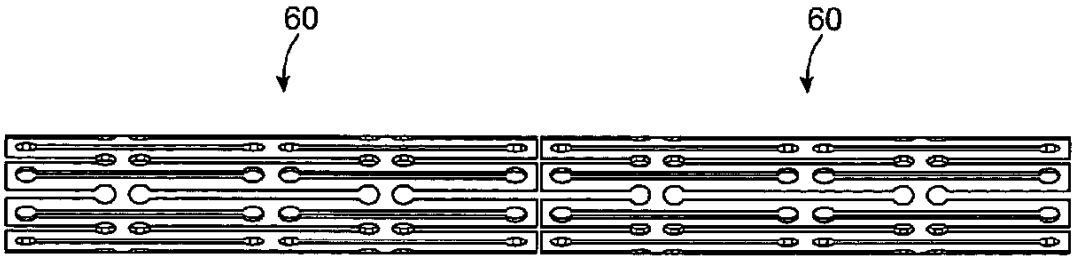


FIG. 5E

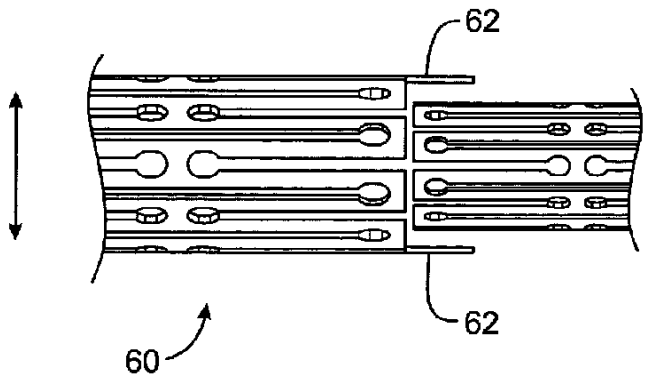


FIG. 5F

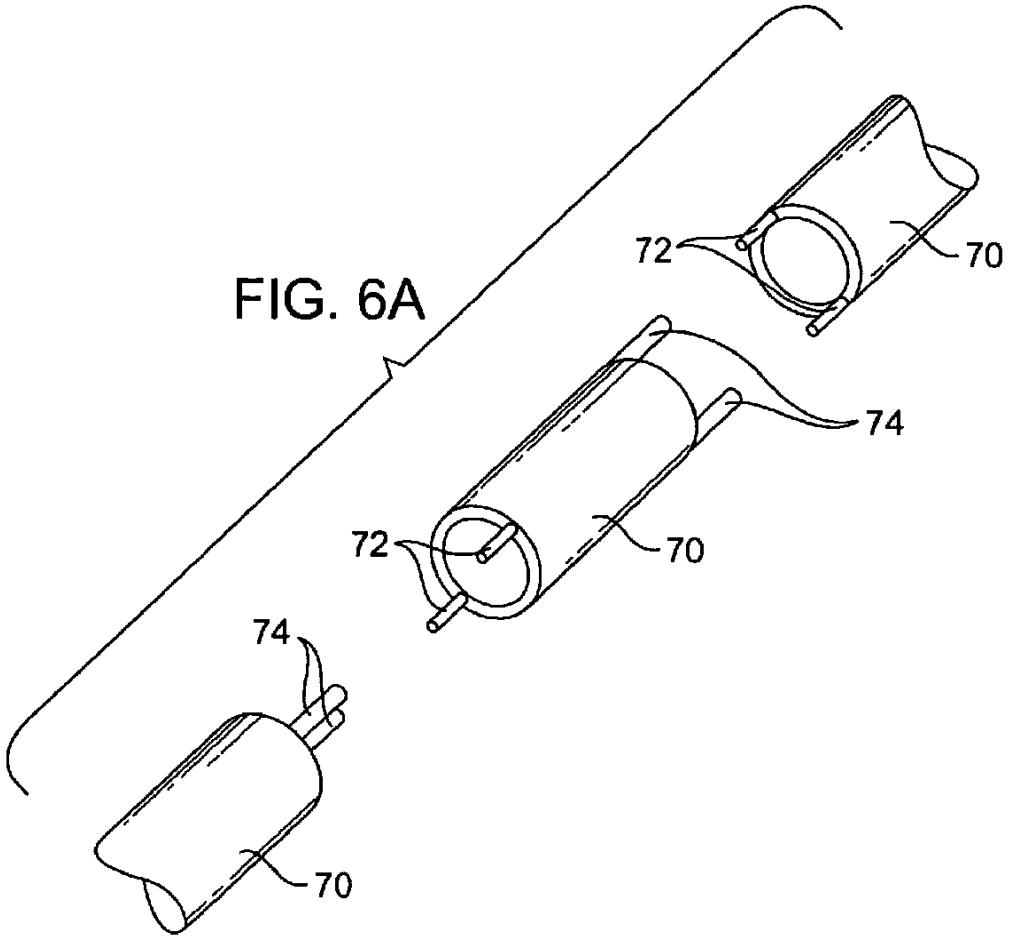


FIG. 6A

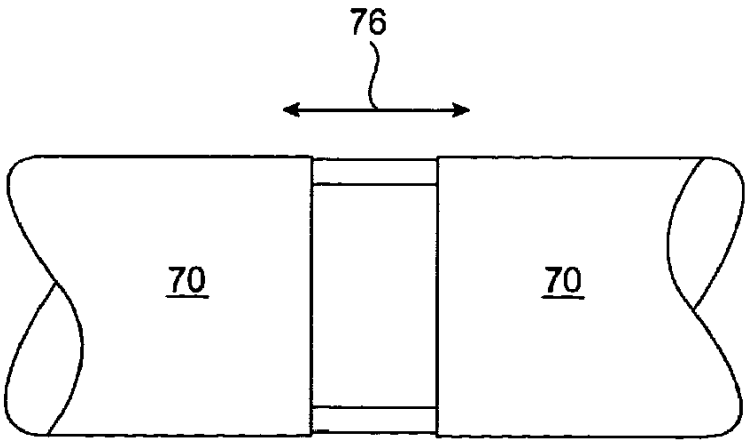


FIG. 6B

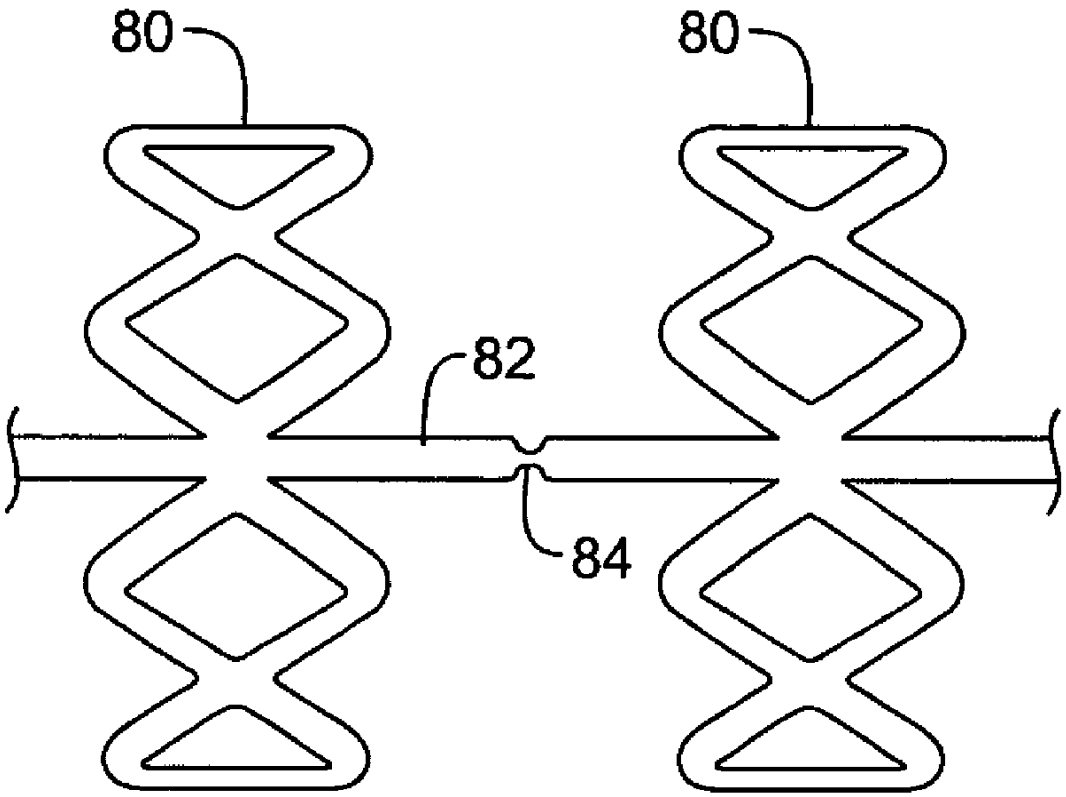


FIG. 7

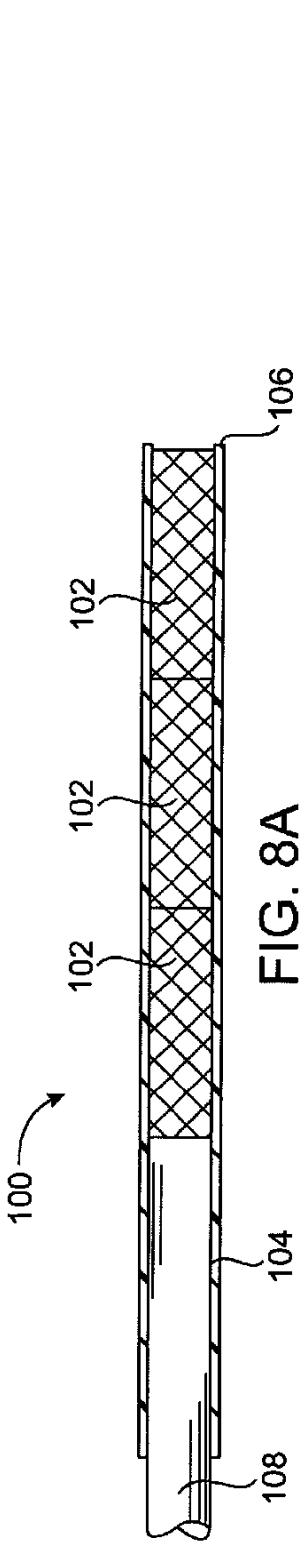


FIG. 8A

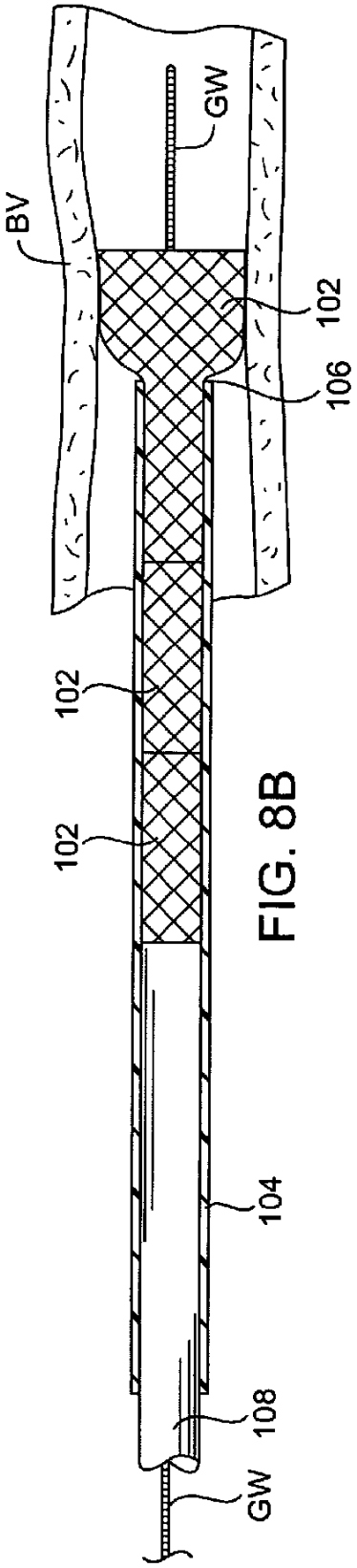


FIG. 8B

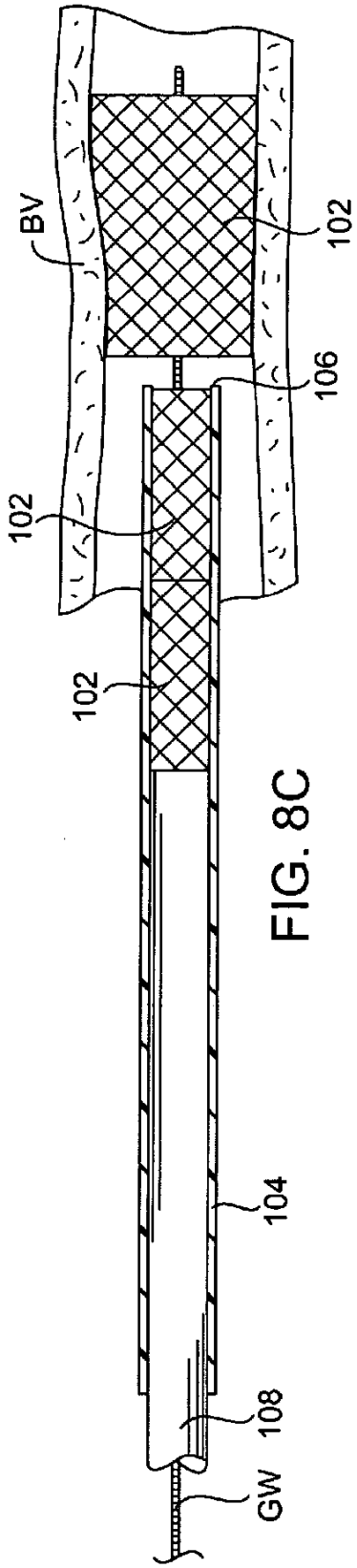


FIG. 8C

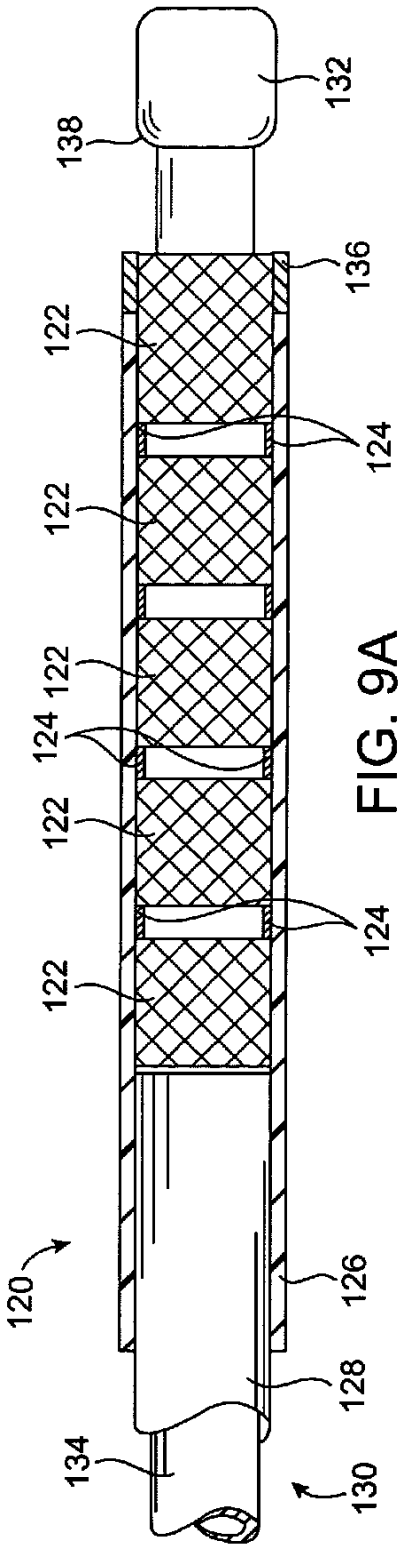

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FIG. 9A

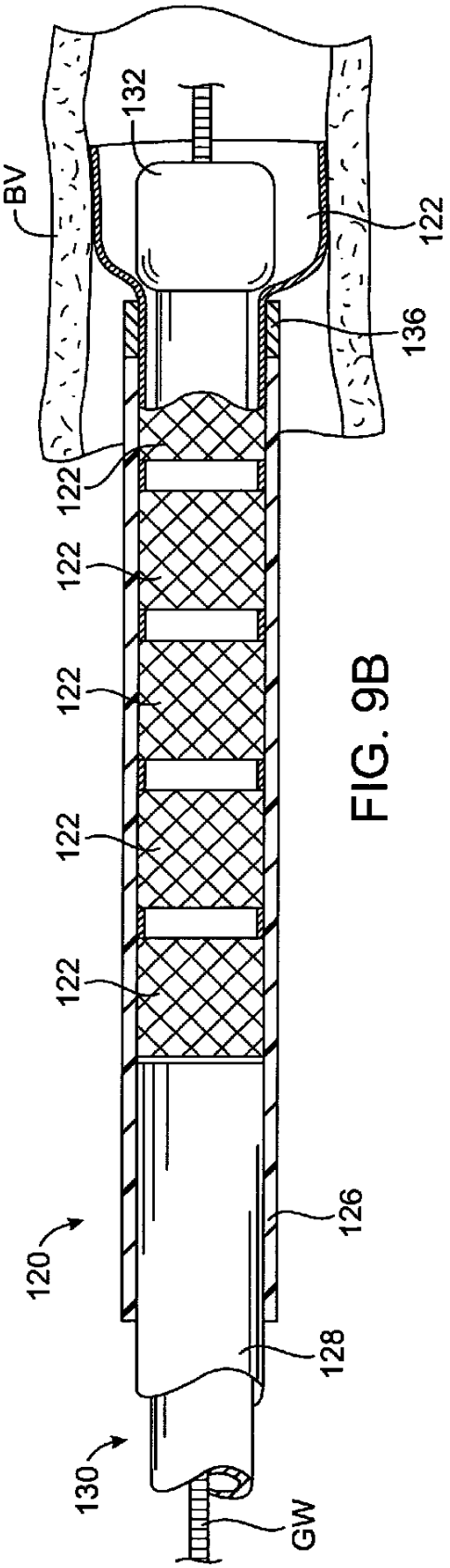
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FIG. 9B

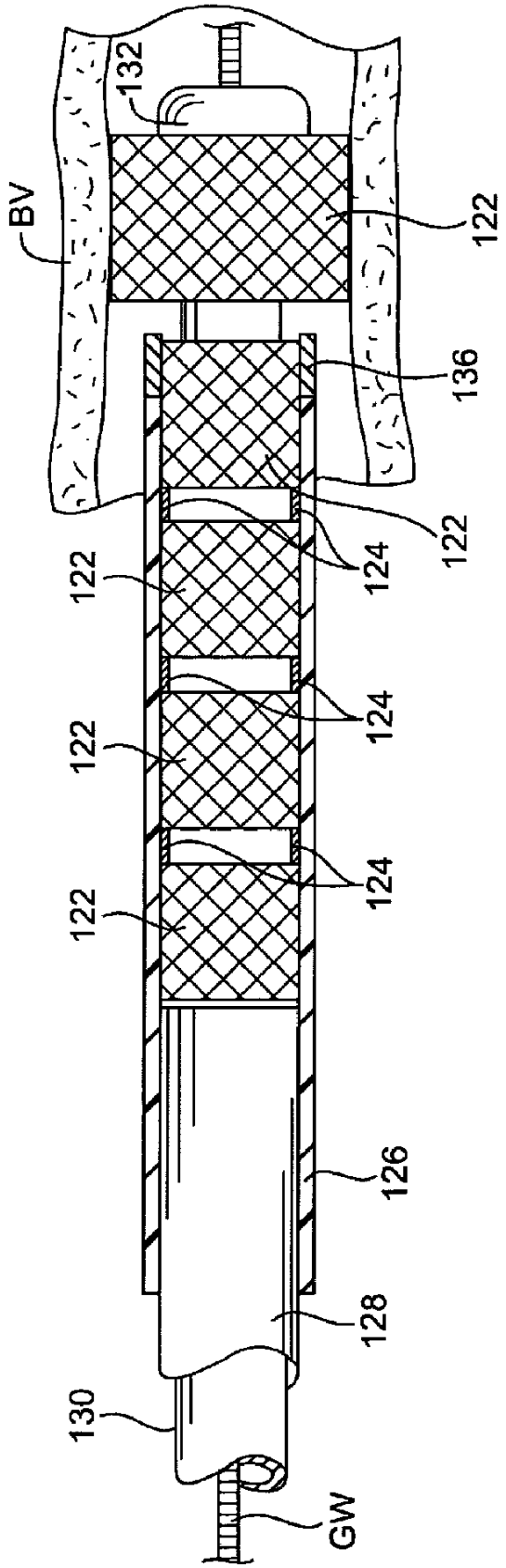

FIG. 9C

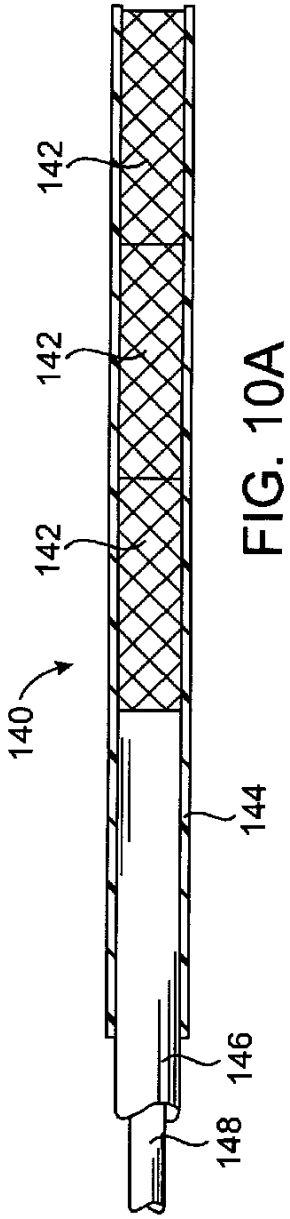

FIG. 10A

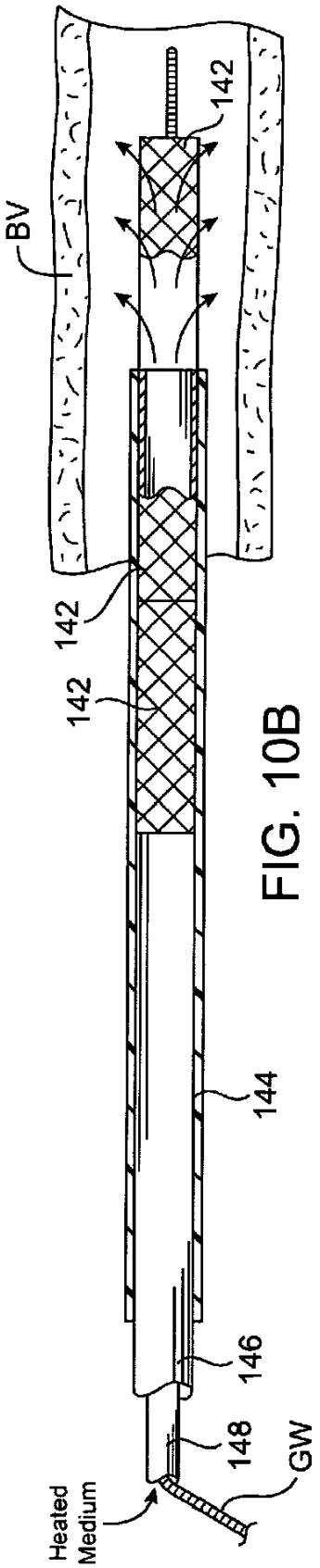

FIG. 10B

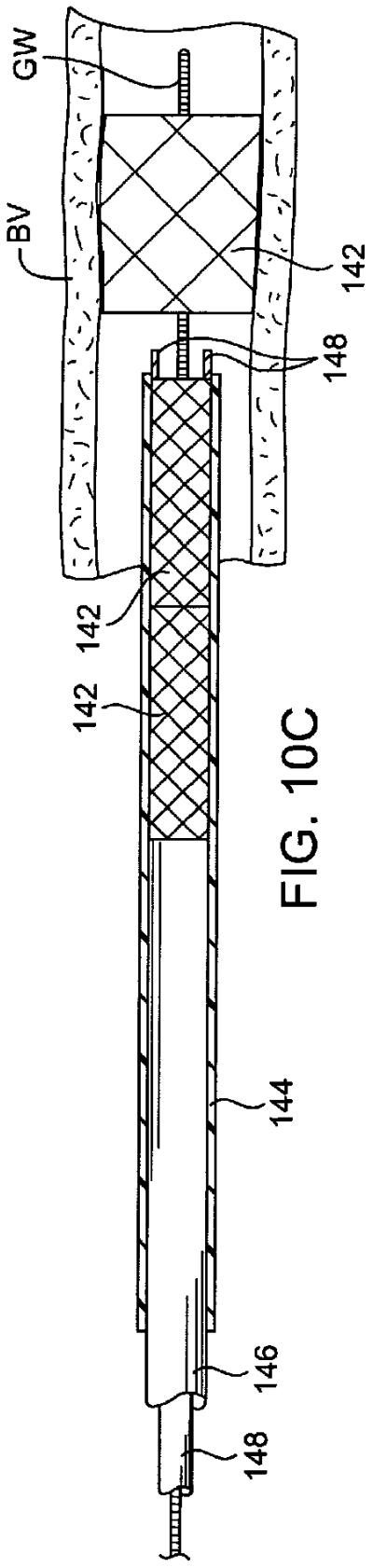

FIG. 10C

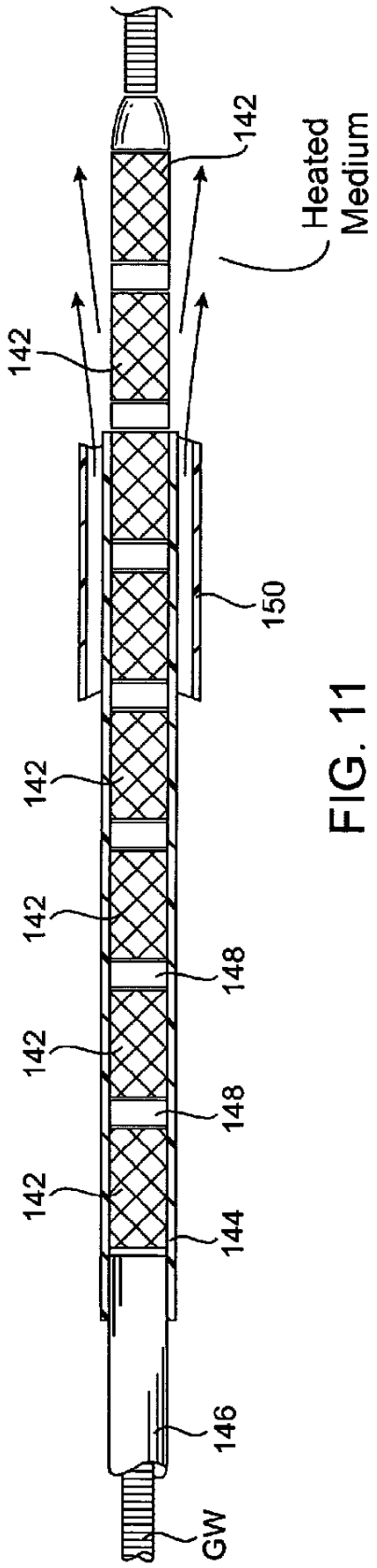

FIG. 11

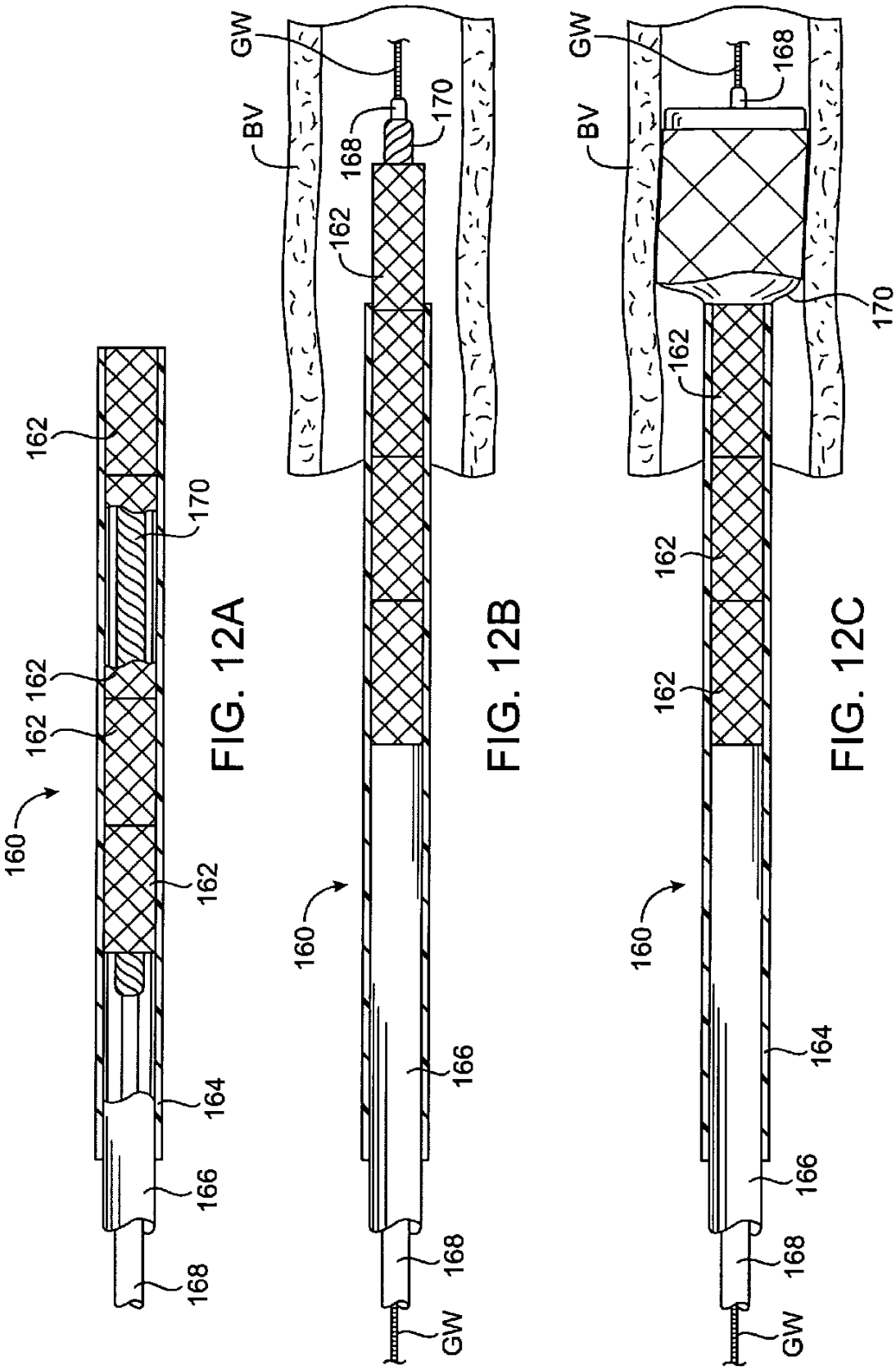
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FIG. 12A
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FIG. 12B
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FIG. 12C

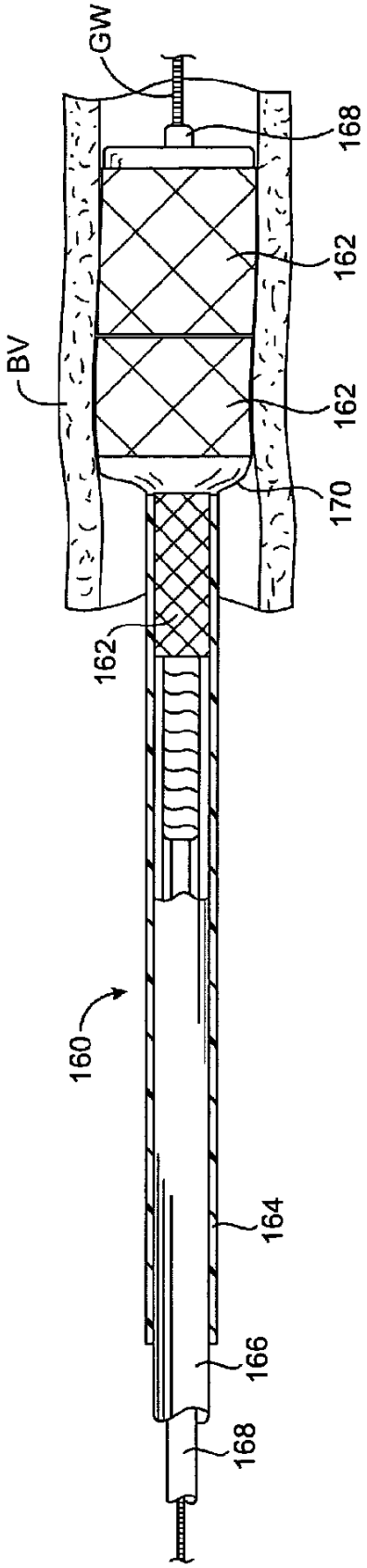


FIG. 12D

FIG. 13A

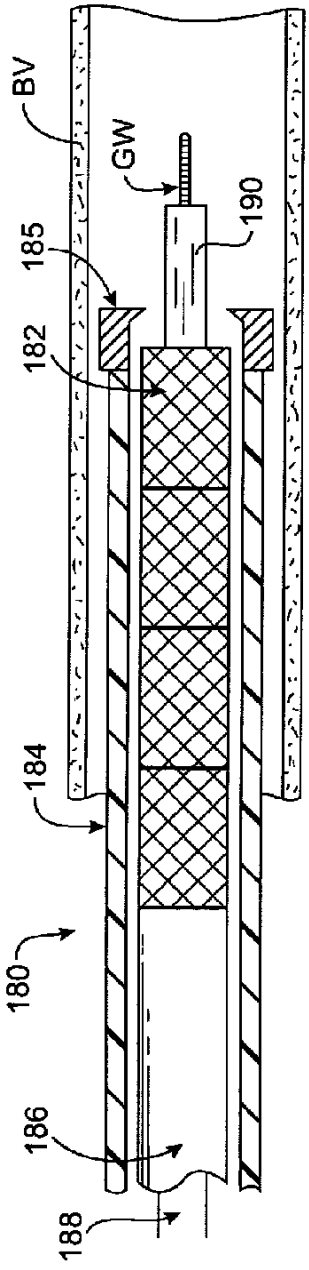


FIG. 13B

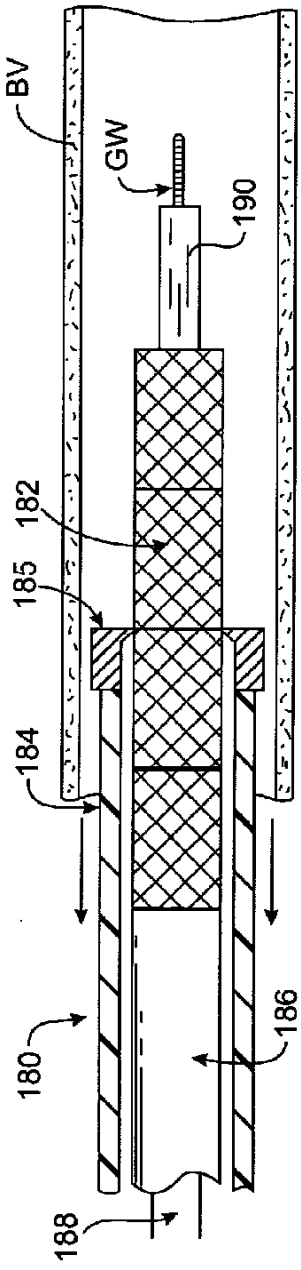
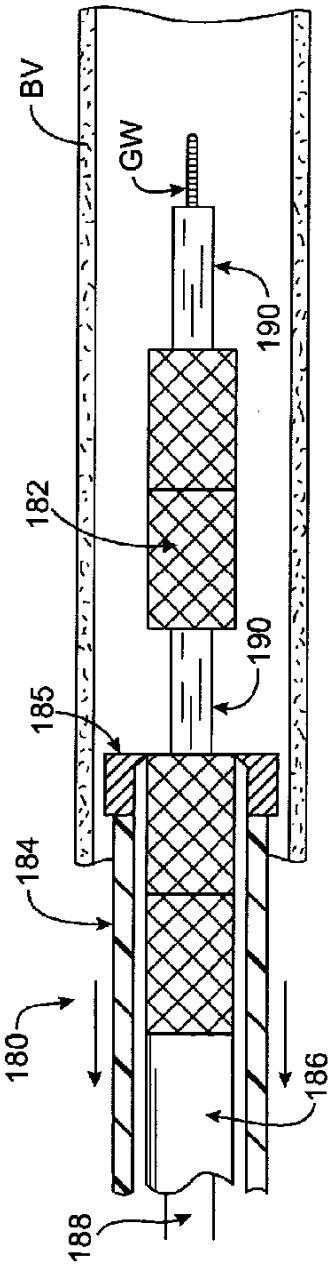


FIG. 13C



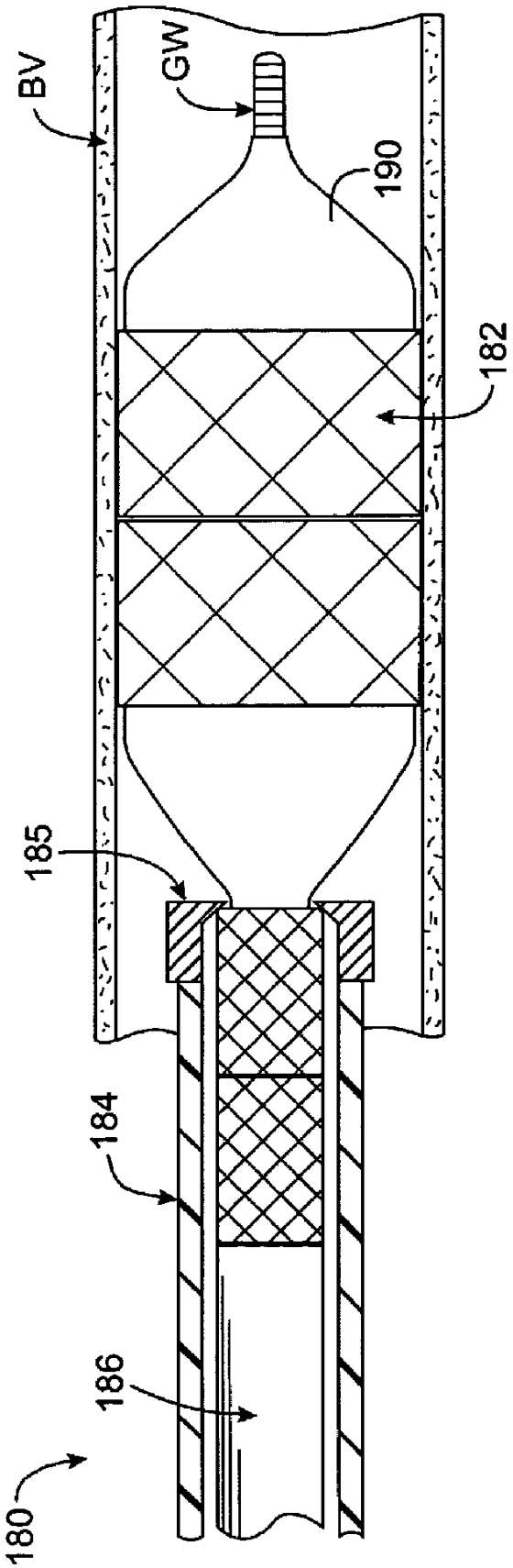


FIG. 13D

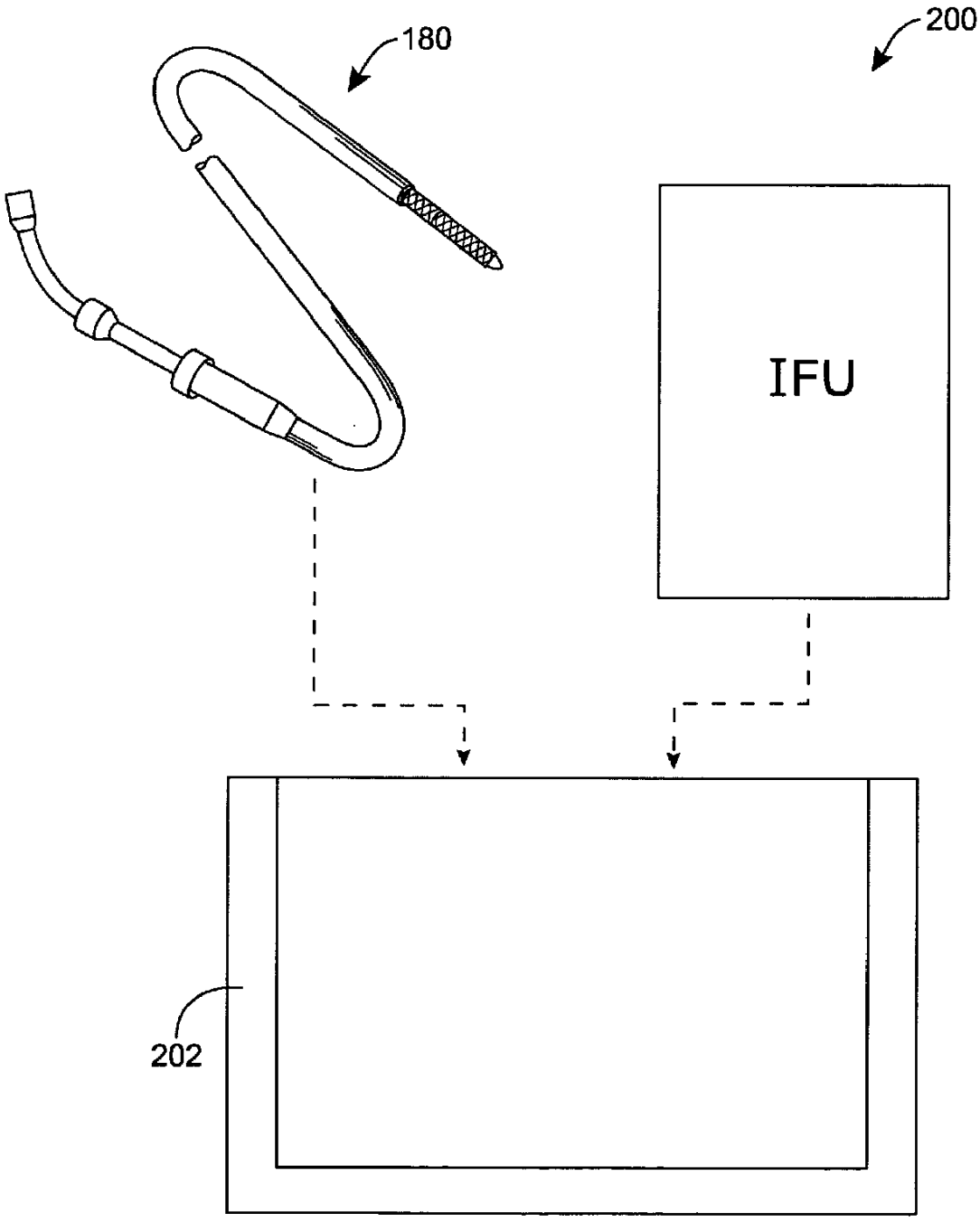


FIG. 14

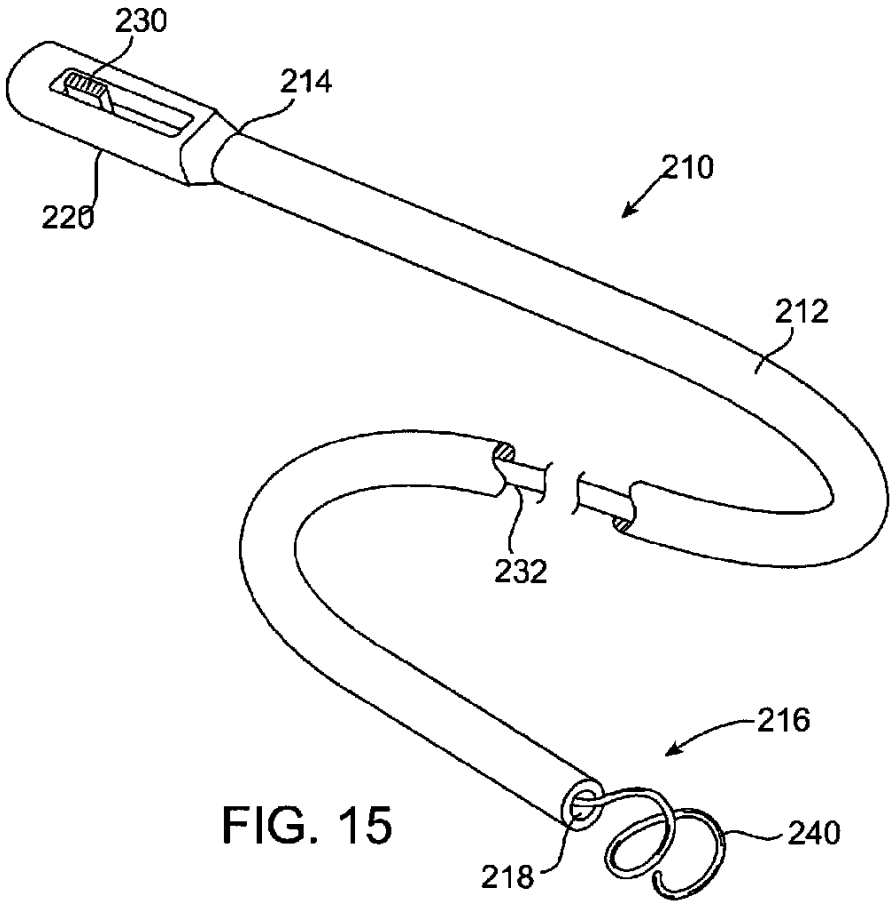


FIG. 15

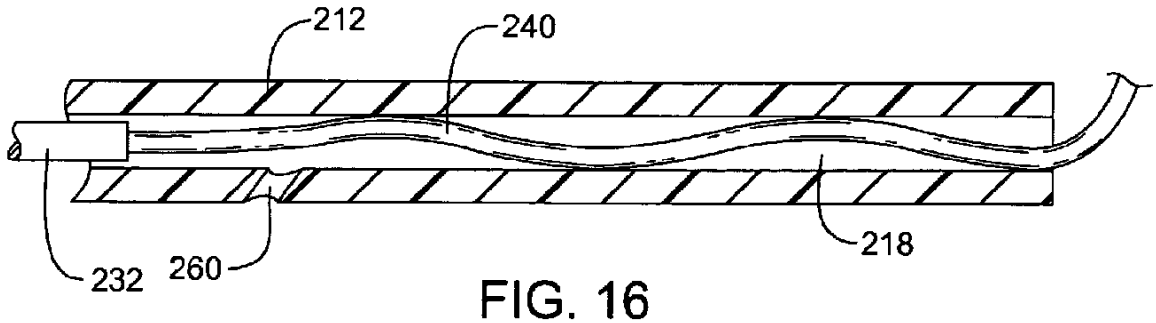


FIG. 16

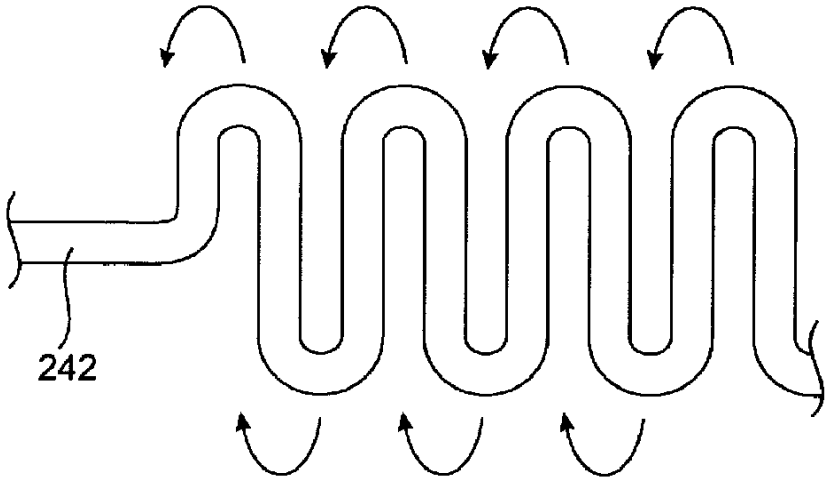


FIG. 15A

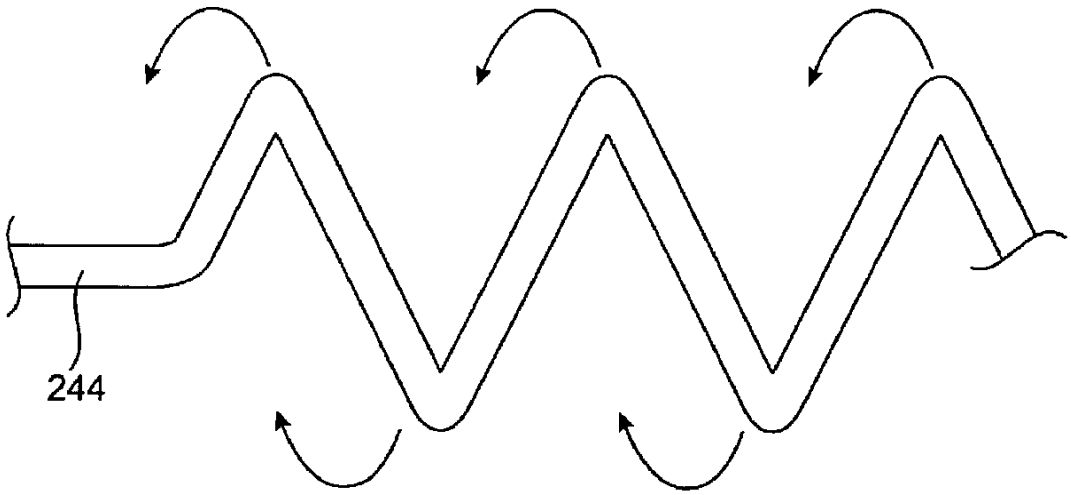


FIG. 15B

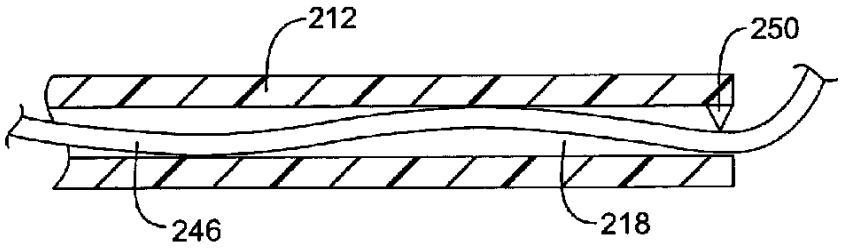


FIG. 17

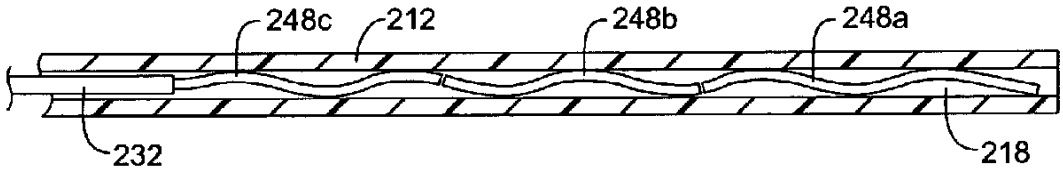


FIG. 18

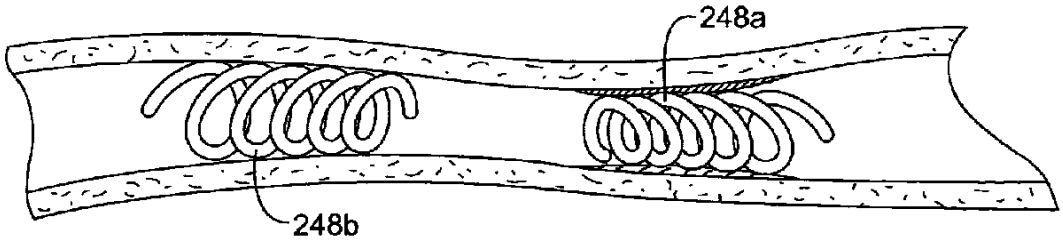


FIG. 19E

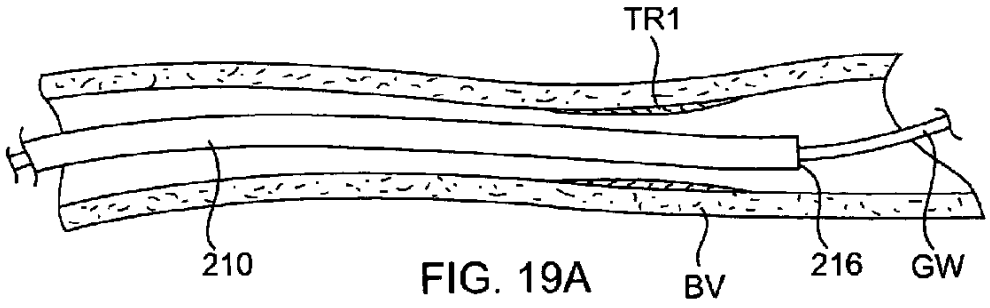


FIG. 19A

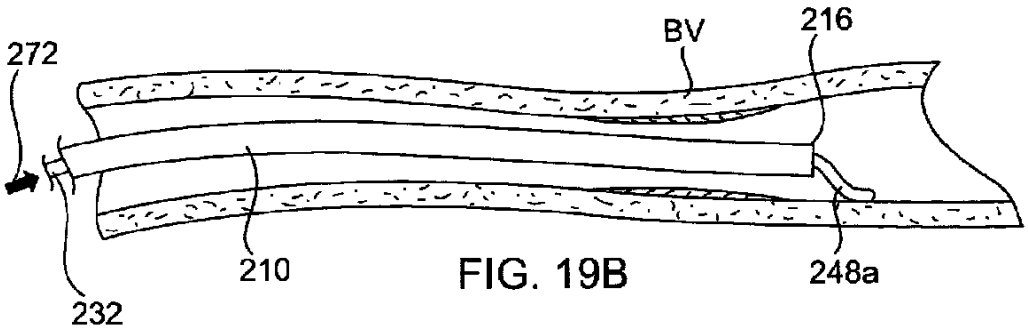


FIG. 19B

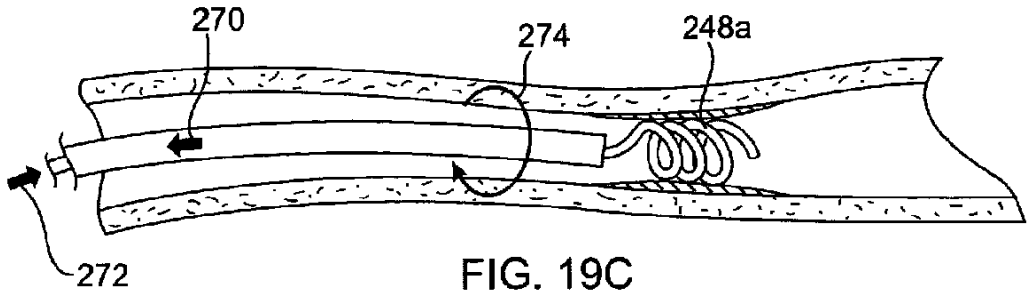


FIG. 19C

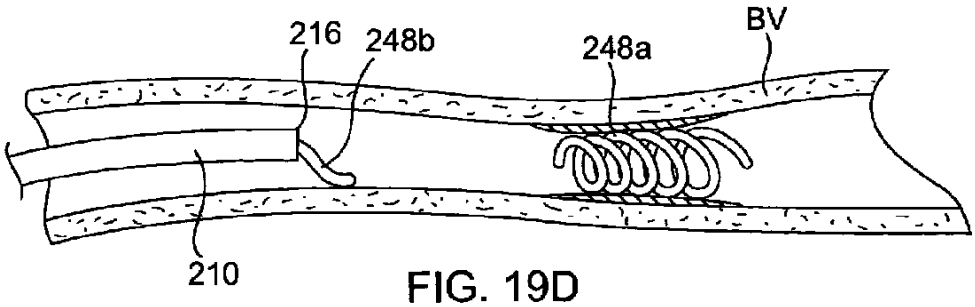


FIG. 19D

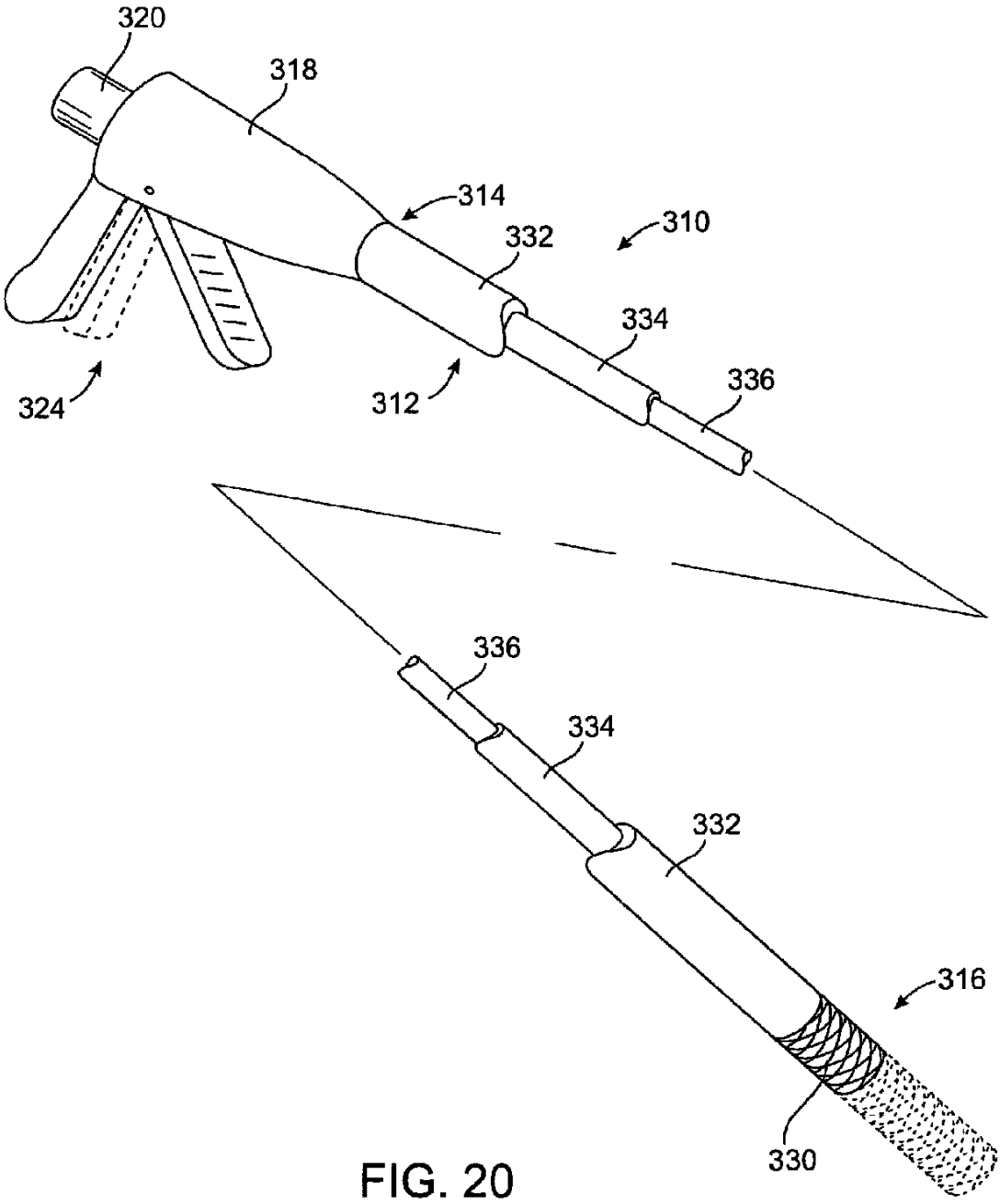


FIG. 20

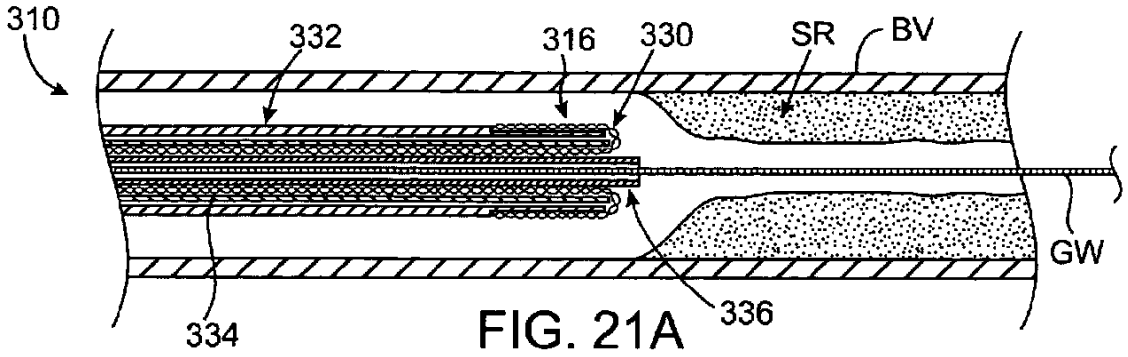


FIG. 21A

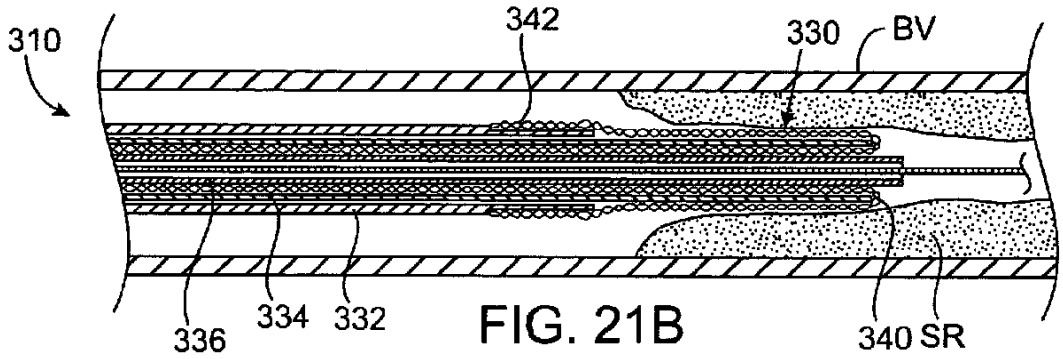


FIG. 21B

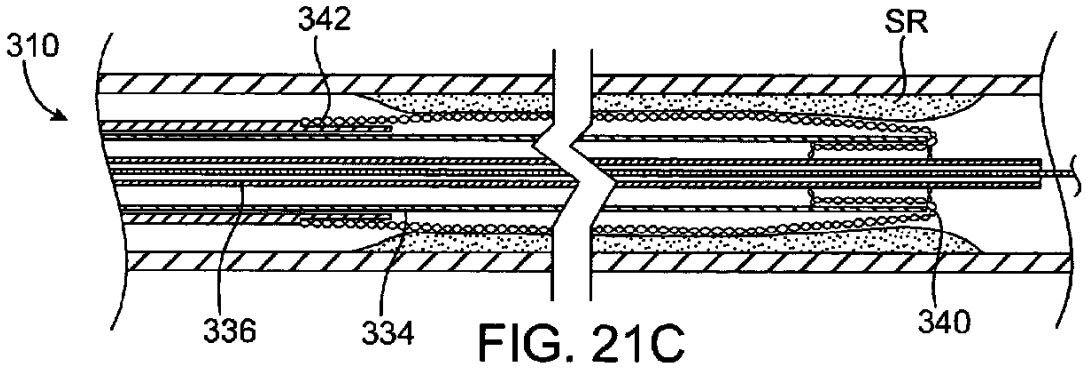


FIG. 21C

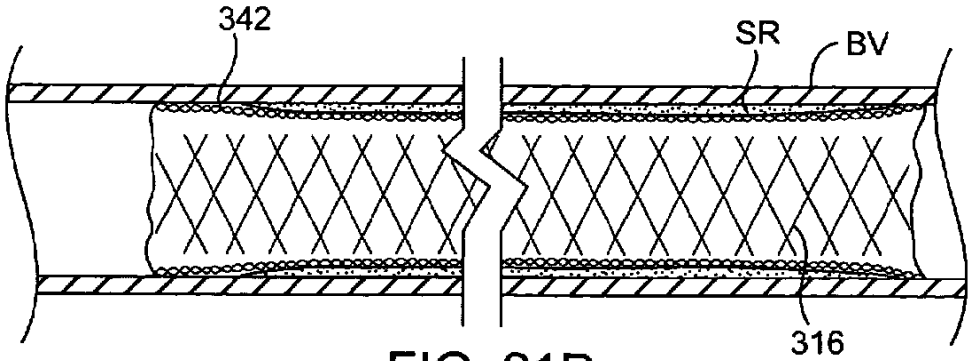


FIG. 21D

APPARATUS AND METHODS FOR DELIVERY OF VARIABLE LENGTH STENTS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of U.S. patent application Ser. No. 10/306,813 (Attorney Docket No. 021629-000320), filed Nov. 27, 2002, which is a non-provisional of U.S. Patent Application Ser. Nos. 60/336,967 (Attorney Docket No. 021629-000300) filed Dec. 3, 2001, and a non-provisional of U.S. Patent Application Ser. No. 60/364,389 (Attorney Docket No. 021629-000310) filed on Mar. 13, 2002, the full disclosures of which are incorporated herein by reference. The present application is also a continuation-in-part of U.S. patent application Ser. No. 10/306,620 (Attorney Docket No. 021629-000210), filed Nov. 27, 2002, which is a non-provisional of U.S. Patent Application Ser. No. 60/336,607 (Attorney Docket No. 021629-200), filed Dec. 3, 2001, the full disclosures of which are also incorporated herein by reference. The present application is also a continuation-in-part of U.S. patent application Ser. No. 10/306,622 (Attorney Docket No. 021629-000110), filed Nov. 27, 2002, which is a non-provisional of U.S. Patent Application Ser. No. 60/336,767 (Attorney Docket No. 021629-100), filed Dec. 3, 2001, the full disclosures of which are also incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention.

The present invention relates generally to medical devices and methods. More particularly, the present invention relates to apparatus and methods for independently delivering a plurality of luminal prostheses within a body lumen, such as a blood vessel.

[0003] Coronary artery disease is the leading cause of death and morbidity in the United States and Western society. In particular, atherosclerosis in the coronary arteries can cause myocardial infarction, commonly referred to as a heart attack, which can be immediately fatal or, even if survived, can cause damage to the heart which can incapacitate the patient.

[0004] While coronary artery bypass surgery can be an effective treatment for stenosed arteries resulting from atherosclerosis or other causes, it is a highly invasive, costly procedure, which typically requires substantial hospital and recovery time. Percutaneous transluminal coronary angioplasty, commonly referred to as balloon angioplasty, is less invasive, less traumatic, and significantly less expensive than bypass surgery. Heretofore, however, balloon angioplasty has not been considered as effective a treatment as bypass surgery. The effectiveness of balloon angioplasty, however, has improved significantly with the introduction of stenting which involves the placement of a scaffold structure within the artery which has been treated by balloon angioplasty. The stent inhibits abrupt reclosure of the artery and has some benefit in inhibiting subsequent restenosis resulting from hyperplasia. Recently, experimental trials have demonstrated that the coating of stents using anti-proliferative drugs, such as paclitaxel, can significantly reduce the occurrence of hyperplasia in angioplasty treated coronary arteries which have been stented with the coated stents.

[0005] While the combination of balloon angioplasty with drug-coated stents holds great promise, significant challenges still remain. Of particular interest to the present invention, the treatment of extended or disseminated disease within an artery remains problematic. Most stents have a fixed length, typically in the range from 10 mm to 30 mm, and the placement of multiple stents to treat disease over a longer length requires the suggestive use of balloon stent delivery catheters. Moreover, it can be difficult to stent an angioplasty-treated region of a blood vessel with the optimum stent length.

[0006] For these reasons, it would be desirable to provide improved stents, stent delivery systems, stenting methods, and the like, for the treatment of patients having coronary artery disease, as well as other occlusive diseases of the vasculature. In particular, it would be desirable to provide stents, delivery systems, and methods for the treatment of disseminated and variable length stenotic regions within the vasculature. For example, it would be desirable to provide a practical method which permits a physician to optimize the length of the treated vessel which is stented according to the nature of the disease. More specifically, it would be desirable to provide apparatus, systems, and methods for facilitating the delivery of multiple stents and other prostheses to blood vessels or other target body lumens. Such apparatus, systems, and methods should be suitable for delivery of individual stents or prostheses having very short lengths, typically as short as 3 mm or shorter, at multiple contiguous and non-contiguous locations within a body lumen for optimized treatment thereof.

[0007] In addition, it would be desirable to provide stents, delivery systems, and methods for the treatment of disseminated and variable length stenotic regions within the vasculature. For example, it would be desirable to provide methods which permit a physician to optimize the length of the treated vessel which is stented according to the nature of the disease, either by adjusting the stent length in situ or by placing multiple stents of the same or different lengths over the treatment region. It would be further desirable to provide a practical method which permits a physician to deliver extended lengths of braided prostheses to blood vessels and other body lumens. At least some of these objectives will be met by the inventions described hereinafter.

[0008] 2. Description of the Background Art.

U.S. Pat. No. 6,258,117 B1 describes a stent having multiple sections connected by separable or frangible connecting regions. Optionally, the connecting regions are severed after the stent structure has been implanted in the blood vessel. U.S. Pat. Nos. 5,571,086; 5,776,141; and 6,143,016 describe an expandable sleeve for placement over a balloon catheter for the delivery of one or two stent structures to the vasculature. U.S. Pat. No. 5,697,948 describes a catheter for delivering stents covered by a sheath. U.S. Pat. No. 6,190,402B1, describes a self-forming vascular implant. U.S. Pat. No. 6,258,117, describes a multiple section stent structure; and U.S. Pat. No. 5,895,398, describes a clot retrieval device having a deployable helical clot snare. U.S. Pat. No. 5,755,772 describes a tubular prosthesis and method for its implantation by positioning the prosthesis at a target site, and everting an end session to lock the stent after expansion has been completed; and U.S. Pat. No. 5,769,882 describes conformable tubular prostheses and their placement in blood vessels.

BRIEF SUMMARY OF THE INVENTION

[0009] The present invention provides methods and apparatus for prosthesis placement, such as stenting of body lumens, typically blood vessels, and more typically coronary arteries. The methods and systems will also find significant use in the peripheral vasculature, the cerebral vasculature, and in other ducts, such as the biliary duct, the fallopian tubes, and the like. The terms "stent" and "stenting" are defined to include any of the wide variety of expandable prostheses and scaffolds which are designed to be intraluminally introduced to a treatment site and expanded in situ to apply a radially outward force against the inner wall of the body lumen at that site. Stents and prostheses commonly comprise an open lattice structure, typically formed from a malleable or elastic metal. When formed from a malleable metal, the stents will typically be expanded by a balloon which causes plastic deformation of the lattice so that it remains opened after deployment. When formed from an elastic metal, including super elastic metals such as nickel-titanium alloys, the lattice structures will usually be radially constrained when delivered and deployed by releasing the structures from such radial constraint so that they "self-expand" at the target site. When the stent or lattice structures are covered with a fabric or polymeric membrane covering, they are commonly referred to as grafts. Grafts may be used for the treatment of aneurysms or other conditions which require placement of a non-permeable or semi-permeable barrier at the treatment site. The terms "prosthesis" and "prostheses" refer broadly to all radially expansible stents, grafts, and other scaffold-like structures which are intended for deployment within body lumens.

[0010] The stents and prostheses of the present invention may have any of a variety of common constructions, including helical structures, counterwound helical structures, expandable diamond structures, serpentine structures, or the like. Such conventional stent structures are well described in the patent and medical literature. Specific examples of suitable stent structures are described in the following U.S. patents, the full disclosures of which are incorporated herein by reference: U.S. Pat. Nos. 6,315,794; 5,980,552; 5,836,964; 5,527,354; 5,421,955; 4,886,062; and 4,776,337, the full disclosures of which are incorporated herein by reference. Preferred structures are described herein with reference to **FIGS. 4 and 5**.

[0011] According to the present invention, the stents which are deployed may have a length of 1 mm or greater, usually 2 mm or greater, and typically of 3 mm or greater, usually being in the range from 1 mm to 100 mm, typically from 2 mm to 50 mm, more typically from 2 mm to 25 mm, and usually from 3 mm to 20 mm. The use of such short stent lengths is advantageous since multiple stents are to be employed.

[0012] The methods and apparatus of the present invention will provide for the deployment of a plurality of stents or other prostheses, usually including at least two stents, from a common stent delivery catheter. Usually, the number of delivered stents will be in the range from 2 to 50, typically from 3 to 30, and most typically from 5 to 25. As more stents are placed on the delivery catheter, the individual stent length will often be somewhat less, although this is not necessarily the case in all instances. The multiple prostheses may be deployed individually or in groups of two or more at single or multiple spaced-apart locations in the body lumen or lumens.

[0013] In a first aspect of the present invention, a method for stenting an extending length of a body lumen comprises introducing a catheter carrying a plurality of, usually at least two, discrete stents to the body lumen. Usually, the introduction is percutaneous and, in the case of intravascular delivery, uses a conventional introduction technique, such as the Seldinger technique. After reaching a target location, at least a first stent is released from the catheter at that first location. The catheter is then repositioned to a second location, and at least a second stent is released from the catheter at the second location. The catheter is then repositioned to a third location, and at least a third stent is released from the catheter at the third location

[0014] In addition to deploying stents and other prostheses at spaced-apart locations within a blood vessel or other body lumen, the methods and apparatus in the present invention can be used for delivering one, two, three, or more discrete stents or other prosthesis segments contiguously at a single location within the body lumen. In this way, the length of the prosthesis which is implanted can be selected and modified to accommodate the length of the vessel to be treated. It will be appreciated that with systems which carry **10, 20, 30** or more quite short prostheses or prosthesis segments, the length of the lumen being treated can be tailored very closely from very short to very long with the selectable intervals depending on the length of the prosthesis or prosthesis segment.

[0015] The deployment steps can, of course, be repeated a sufficient number of times so that all or at least more of the stents carried by the delivery catheter are delivered to and deployed within the body lumen. A particular advantage of this delivery method is that the discrete stents may be distributed along extended lengths of the body lumen, typically in the range from 1 cm to 2 cm, often in the range from 1 cm to 5 cm, and in many instances even longer. Additionally, the stents may be delivered so as to avoid side branches or other regions where placement of the stent is undesirable. Moreover, with the use of drug-coated stents, it may be possible to place the stents apart by discrete distances, typically from one-half to one millimeter (mm), while still achieving vessel patency and hyperplasia inhibition.

[0016] Releasing of the stents from the catheter may be achieved using a balloon to cause balloon expansion of the stent. Alternatively, release of the stent may be achieved by radially constraining an elastic or self-expanding stent within a lumen of the delivery catheter and selectively advancing the stent from the catheter and/or retracting the catheter from over the stent. In one embodiment, a sheath over the stents includes a valve member, or "stent valve," which allows stents to be separated so that a balloon can more accurately inflate deployed stents while other stents remain within the sheath.

[0017] In preferred embodiments, the stents are coated with at least one agent, such as an agent which inhibits hyperplasia. The agent may be biologically active or inert. Particular biologically active agents include anti-neoplastic drugs such as paclitaxel, methotrexate, and batimastal; antibiotics such as doxycycline, tetracycline, rapamycin, and actinomycin; immunosuppressant such as dexamethosone,

methyl prednisolone, nitric oxide sources such as nitroprussides; estrogen; estradiols; and the like. Biologically inert agents include polyethylene glycol (PEG), collagen, polyglycolic acids (PGA), ceramic material, titanium, gold and the like.

[0018] In another aspect, the present invention comprises catheters and apparatus for stenting extended lengths of a body lumen, particularly a blood vessel. The catheters comprise a catheter body having a proximal end and a distal end. At least two discrete stents are carried at or near a distal end of the catheter body. By "discrete," it is meant that the stents are unconnected and can be deployed from the catheter in an unattached manner. (The delivery of attached prostheses is described below.) Deployment of such discrete stents permits the individual stents to be placed at spaced-apart target locations or immediately adjacently within the blood vessel or other body lumen. The catheters further comprise deployment means for deploying the individual stents from the catheter body. For example, the deployment means may comprise one or more balloons for placement and radial expansion of the stents. Alternatively, the deployment means may comprise a pusher or other device for advancing self-expanding stents from the distal end of the catheter body and/or a sheath for selectively retracting over the stents to permit self-expansion. In exemplary embodiments, the catheters will carry at least two discrete stents, at least five discrete stents, and as many as 10 discrete stents, or in some cases, as many as 30 or more discrete stents.

[0019] In a particular embodiment, the catheter comprises a single balloon which is reciprocatively mounted within the catheter body and adapted for receiving individual stents thereover. A pusher or other device for successively and controllably loading individual or multiple stents over the balloon is also provided. In this way, the catheter may carry multiple stents and employ the single balloon for positioning and expansion of the stents.

[0020] In further embodiments, the stents of the present invention are composed at least partly of a bioabsorbable material, such as polyethylene glycol (PEG), collagen, gelatin, polyglycolic acids (PGA), polylactic acids (PLA), and the like. Optionally, one or more bioactive substances are dispersed in the bioabsorbable material such that the bioactive substance will be released over time as the bioabsorbable material degrades. In a particular embodiment, the bioabsorbable material is formed on or within a scaffold composed on a non-bioabsorbable material, typically stainless steel, Nitinol™, or other conventional stent metal material. Other materials, such as gold (e.g., pure or nearly pure gold), platinum, or the like, may also be used.

[0021] In a further aspect of the present invention, a catheter for delivering a plurality of expansible prostheses to a body lumen comprises a catheter body, a sheath, and a plurality of radially expansible prostheses. The catheter body has a proximal end and a distal end, and the sheath is coaxially disposed over the catheter body with the prostheses positionable in an annular space between the inside of the sheath and the exterior of the catheter body. The sheath is preferably retractable relative to the catheter body so that the prostheses may be advanced beyond a distal end of the sheath. Usually, the catheter will further comprise a pusher tube disposed coaxially over the catheter body and within an interior lumen of the sheath. A distal end of the pusher tube will engage a proximal end of the proximal-most prosthesis so that the pusher tube can be distally advanced relative to the sheath to selectively push or deploy individual prostheses from the sheath. Often, such deployment is achieved by holding the pusher tube and prostheses substantially stationary relative to the body lumen while the sheath is retracted proximally to release or deploy the prostheses.

[0022] Usually, at least a distal portion of the sheath will have a greater column strength than that of a distal portion of the catheter body. Additionally or alternatively, the pusher tube may also have a greater column strength than a distal portion of a catheter body. By providing column strength in the outer most portion of the catheter, i.e., the sheath, and optionally the pusher tube, the overall column strength of the catheter can be increased with a minimum increase in its diameter or profile. It will be appreciated that low profile catheters are highly advantageous for accessing remote regions of the vasculature, particularly the small coronary and cerebral arteries. Using the preferred constructions of the present invention, catheters having diameters 2 mm or less, and in some instances as low as 1 mm or less, can be achieved. The constructions will, of course, also be suitable for larger diameter catheters for use in the peripheral and other larger blood vessels.

[0023] The catheter of the present invention will preferably carry at least two prostheses, more preferably carrying at least three prostheses, and often carrying a greater number of prostheses as set forth above in connection with other embodiments. The prostheses will typically be arranged in an end-to-end manner either with or without a physical linkage therebetween. The physical linkage may comprise a frangible component which must be mechanically broken or alternatively may comprise a pair of coupling elements which fit together and which may be separated without any material breakage. Frangible coupling elements will usually comprise a strut, bar, spring, or similar connecting link and will optionally be scored, notched, or otherwise adapted to break along a particular line when a suitable mechanical force is applied. Exemplary separable coupling elements include male and female elements, such as a rod and tube which may be axially separated, a tab and receptacle which may be radially separated, and the like.

[0024] In a specific embodiment of the catheter, the catheter body may comprise an expansion element, such as an inflatable balloon, near its distal end. The expansion element will be positionable distal to the retractable sheath so that it can be used to regularly expand one or more of the prostheses. For example, the inflatable balloon may carry multiple prostheses on its outer surface so that sheath retraction can expose one, two, three, or more of the prostheses. The remaining prostheses will continue to be covered by the sheath. When inflating the balloon, however, only that portion of the balloon and those prostheses carried on the exposed portion of the balloon will be inflated. The remaining (proximal) portion of the balloon will continue to be constrained by the sheath so that neither the balloon nor the prostheses covered by the sheath will be expanded. In this way, any preselected number of the individual prostheses may be expanded at one time, while the remaining prostheses are protected and unexpanded, remaining available for subsequent expansion using the balloon.

[0025] Alternatively or in addition to the balloon, the catheter body may comprise a heater for selectively heating

prostheses which have been advanced distally beyond the sheath. For example, the catheter body may have a lumen for delivering a heated medium, such as heated saline, intravascularly to heat and expand stents or other prostheses formed from suitable heat memory alloys (as described in more detail below). Alternatively, a separate exterior guide catheter or other tube may be used for delivering such a heated medium to effect expansion of the prostheses. As a third alternative, a powered heating element, such as a radio frequency heater, electrical resistance heater, or laser-heated element, may be provided on the catheter body for directly heating the exposed prostheses.

[0026] For the delivery of individual prostheses or stents which are joined by frangible or breakable links, as discussed above, it will often be desirable to provide a shearing mechanism on the catheter. The shearing mechanism will usually be mechanical, but could also be electrolytic, ultrasonic, or chemical. In the exemplary embodiments, the shearing mechanism comprises a first shearing element on a distal region of the catheter body and a second or mating shearing element on a distal region of the sheath. The prostheses may be advanced from the sheath while the shearing mechanism on the catheter body is distally advanced (leaving a space or opening for prosthesis deployment). After a desired number of prostheses have been deployed, the catheter body may be retracted relative to the sheath in order to close the shearing elements to sever the link(s) between the advanced prostheses and those prostheses which remain within the sheath. In other cases, the shearing mechanism could be an electrode for inducing electrolytic breakage of the link, an ultrasonic transducer for mechanically degrading a susceptible link (i.e. a link having a resonant frequency which corresponds to the ultrasonic transducer), a luminal port for releasing a chemical agent selected to chemically degrade the link, or the like.

[0027] In a further alternative embodiment, a catheter constructed in accordance with the principles of the present invention comprises a pusher tube, a plurality of radially expansible prostheses arranged end-to-end and extending distally of the distal end of the pusher tube, and a sheath disposed coaxially over the pusher tube and the prostheses. Optionally, but not necessarily, this embodiment will include a catheter body disposed coaxially within the pusher tube and prostheses. By retracting the sheath proximally relative to the pusher tube, individual ones or groups of the prostheses will be exposed and deployed. The catheter body may be used in any of the ways described previously in order to effect or control deployment of the prostheses. Optionally, the pusher tube, the sheath, or both, may have a greater column strength than the catheter body when the catheter body is employed.

[0028] Systems of detachable expansible prostheses according to the present invention include a plurality of ring-like radially expansible prostheses arranged end-to-end along an elongate axis. At least one pair of coupling elements join each pair of adjacent prostheses, where the coupling elements physically separate without fracture in response to axial tension or differential radial expansion. The coupling elements, however, remain coupled when subjected to axial compression such as may occur as the prostheses are axially advanced within a body lumen or elsewhere. The prostheses may be composed of a malleable material so that they will be expansible in response to an internally applied radially expansive force, such as a balloon expansion force applied by a balloon carried by the catheter body in any of the prior embodiments of the present invention. Alternatively, the prostheses may be composed of a resilient material, such as spring stainless steel, nickel-titanium alloy; or the like, so that they may be "self-expanding," i.e. expand when released from radial constraint. As a third alternative, the prostheses may be composed of a heat memory alloy, such as a nickel titanium alloy, so that they may be induced to expand upon exposure to a temperature above body temperature. Materials suitable for forming each of these three types of prostheses are well described in the patent and medical literature.

[0029] In specific examples of the systems, the coupling elements may be male and female so that they decouple upon the application of an axial force. For example, the coupling elements may be a rod and a tube having a central passageway for receiving the rod. Alternatively, the coupling elements may be configured to decouple upon differential radial expansion. For example, a first coupling element may extend from the end of a first prostheses and have an enlarged portion or end. By providing a cut-out in the adjacent prostheses having a periphery which matches the periphery of the extension on the first prostheses, coupling elements can be mated and locked together. The locking will resist axial separation, but permit radial separation when one of the prostheses is radially expanded.

[0030] The systems of prostheses just described may be preferably employed with any of the catheter delivery systems described previously.

[0031] The present invention further provides methods for stenting extended lengths of the body lumen, where the methods comprise introducing a catheter carrying a plurality of radially expansible prostheses to a target site within the body lumen. The prostheses are arranged end-to-end and are covered by a sheath. The prostheses are then deployed by retracting the sheath relative to the prostheses by a first preselected distance to uncover a first predetermined number of the prostheses. After retraction of the sheath, a first predetermined number of prostheses, which may be anywhere from one up to the entire number of prostheses being carried, are radially expanded at the target site within the target site of the body lumen.

[0032] Prosthesis expansion may be achieved in a variety of ways. In a first instance, the prostheses are expanded by inflating a balloon within the particular prosthesis to be expanded. For example, a single balloon may be disposed under all the prostheses, with the sheath retracted to expose only those prostheses to be deployed. When the balloon is expanded, the balloon will expand the exposed prostheses, with expansion of the prostheses which remain covered being restrained by the sheath. By further retracting the sheath, the previously undeployed prostheses may then be deployed. Optionally, the prostheses are advanced (or at least axially restrained relative to the sheath) by a pusher tube which engages a proximal end of the proximal-most prosthesis.

[0033] As an alternative to balloon expansion, the uncovered prostheses may be expanded by exposure to heat. The heat may be applied by directing a heated medium to the prostheses, directing electrical energy through the prostheses, and/or energizing a heating element positioned adjacent to the uncovered prostheses.

[0034] In preferred aspects of the methods of the present invention, the body lumen will be a blood vessel, preferably a coronary artery, a cerebral artery, or other small artery. The prostheses will preferably be coated with biologically active or inert agent, such as an agent selected to inhibit hyperplasia, more specifically being any of the particular agents set forth hereinabove.

[0035] The catheters of the present invention will comprise a number of coaxial components, such as sheaths, pusher tubes, catheter bodies, and the like. While it will often be described that stents or other prostheses are advanced distally from the sheath, such description will apply to sheaths which are retracted proximally relative to the prostheses to effect the release. Thus, all descriptions of direction are meant to be relative.

[0036] The present invention further provides for improved methods, apparatus, and systems for delivering prostheses to body lumens, particularly stents and grafts to blood vessels in the arterial and venous vasculature. The prostheses comprise scaffold structures formed from linearized elements, typically metal wires having a round diameter, but also including ribbons, multifilar cables, braided structures, composite structures, wires having non-circular cross-sections, and the like. By "linearized element," it is meant that the structural component will be capable of assuming a linearized configuration while the scaffold is being delivered. Most simply, the linearized element will have a non-linear configuration when unconstrained and will assume the linearized configuration when subjected to radial or axial constraint. In such instances, the linearized element will be formed so that it has a "memory" of the non-linear configuration but can be linearized by applying compressive or axial stress. In the exemplary embodiment, the linearized element has a helical memory. When constrained within the lumen of a delivery device, the linearized element assumes a generally straight configuration. When advanced outwardly from the constrained lumen, however, the linearized element returns to its helical configuration. A number of metals will have efficient elasticity to be able to shift between the linearized and non-linear configurations. Some of the metals include spring stainless steels, such as MP35N, Elgiloy, as well as superelastic alloys, such as nickel-titanium alloys, e.g. Nitinol™ alloy.

[0037] While the presently preferred linearized element will be formed from an elastic metal, one skilled in the art will appreciate that a variety of other metal and non-metal materials could be used to form such elements. For example, the elements could be formed from malleable metals, such as malleable stainless steel alloys, where the linearized element is then deformed into the non-linear configuration as it is advanced from the delivery device, e.g., by passing the linearized element over a shaping mandrel in the delivery device. Alternatively, the linearized element could be formed from a heat memory alloy, where the element is heated in situ after deployment in order to effect the change in shape from linear to non-linear. In addition, resilient and malleable polymeric and other non-metal materials might find use. These technologies, as well as others, for changing the shape of metal and non-metal structures within body lumens, are well described in the technical and medical literature.

[0038] The linearized elements of the present invention will be capable of assuming a variety of non-linear configurations. While helical non-linear configurations are presently preferred, it will be appreciated that serpentine, zigzag and other irregular configurations would also be suitable for at least some of the intended purposes of the present invention. Moreover, while it will generally be preferred to form the linearized elements from wire, most usually wire having a circular cross-section, it will also be possible to form the linearized elements from ribbons, flat sheets of material, and other conventional techniques. For example, serpentine or zigzag non-linearized elements could be formed from flat sheets of appropriate metal, e.g. by laser cutting, chemical etching, or the like. For example, a flat sheet could be configured to assume a desired tubular geometry.

[0039] Methods according to the present invention for delivering prostheses to a body lumen comprise introducing a delivery device to an interior of the body lumen, typically the lumen of a blood vessel, where the device carries the linearized element, as discussed above. The element is deployed by advancing the element relative to the delivery device within the interior of the body lumen so that the element assumes its non-linear configuration across the surface region of the interior as the element is advanced. The element is then released from the delivery device after it has assumed its non-linear configuration. Release may be effected by selectively severing the element after a desired length of the element has been reached. Alternatively, the delivery device may carry a plurality of linearized elements, each having a desired length so that each individual element is released after its entire length has been advanced from the delivery device.

[0040] Advancing the linearized element relative to the delivery device may comprise drawing the delivery device proximally relative to the body lumen while pushing the linearized element from the delivery device, typically using an internal pusher element. In such instances, the pusher rod will usually be held in a generally stationary relationship to the body lumen, while the delivery device is retracted proximally relative to both the body lumen and the pusher rod. In this way, the linearized element will deploy within the body lumen, while assuming its non-linear configuration, with little or no relative movement relative to the luminal wall. This is desirable since any movement of the linearized element against the luminal wall may cause injury, particularly in arteries and other blood vessels.

[0041] In order to even further reduce movement of the deploying linearized element against the vessel wall, and thus reducing the risk of trauma to the vessel wall, it will often be desirable to control the deployment to offset the foreshortening of the linearized element as it is deployed. It will be appreciated that when a linearized element assumes a non-linear configuration, such as a helical configuration, the absolute length of the element will shorten. In the case of helical elements, the shortening will be quite significant, typically from 80 percent to 99 percent, depending on the pitch of the helix which is released. In order to minimize motion of the element against the vessel wall as it is deployed, it is therefore desirable to move the delivery device approximately at a rate substantially equal to the axial progress of the deployed helix within the body lumen (which will be much less than the absolute length of the linearized element which is being expelled). Thus, the pusher rod will be moving in a distal direction which is more rapid than the proximal withdrawal of the delivery device.

Moreover, it will be further desirable to rotate the delivery device so that the deploying "helical" element is not caused to rotate within the vessel. Thus, three separate parameters of the deployment will need to be controlled to minimize the relative motion of the helical element against the blood vessel wall. First, the delivery device will be withdrawn proximally at a rate equal to the axial rate of deployment of the helix within the blood vessel. Second, the pusher rod will be distally advanced at a rate equal to the linear deployment rate of the helix within the deployment device. Finally, rotation of the delivery device will be controlled to counteract any tendency of the delivery device to rotate the helix as it is being deployed. All three of these deployment parameters may be manually controlled by the physician by observing the deployment under fluoroscopic imaging. Alternatively, programmable systems may be provided to automatically deploy and control the element deployment.

[0042] In a specific aspect of the method of the present invention, the pitch of the helical element may be controlled by adjusting the rate of drawing the delivery device proximally and/or advancing the linearized element from the delivery device. While the helical configuration of the linearized device will usually have a preferred or natural pitch, the actual pitch within the blood vessel or the body lumen may be controlled to a certain degree by adjusting its rate of advancement and the withdrawal rate of the delivery device to adjust the pitch. Usually, the delivery device will be rotated in order to further control the release geometry of the linearized element.

[0043] In other specific aspects of the method of the present invention, the prostheses are selectively deployed to transverse desired lengths of the vasculature or other body lumen. The covered length can be controlled in either or both of two ways. First, when the delivery device has the ability to sever the linearized element, the treating physician can control the length of the prostheses by simply starting at a first target location, deploying the prostheses as described above (optionally with control of pitch in a helical prostheses), and severing the prostheses from the delivery device when a desired end location has been reached.

[0044] Additionally, the length of the vessel to be treated may be controlled by delivering multiple helical or other prostheses at selected and distributed portions of the luminal wall. Again, the treating physician will choose a beginning point within the body lumen and then deliver a prostheses over a selected length of the body lumen from that point. One, two, three, four or more additional segments of the prostheses may then be deployed.

[0045] Thus, the methods and apparatus of the present invention can be used to treat both short and long diseased segments within the vasculature and other body lumens. Usually, the treated regions will have a length of at least 10 mm and may have a length up to 60 mm and in some instances 100 mm or longer. Typically, when using only a single deployed prostheses, the treated lengths will be from 10 mm to 50 mm, usually from 10 mm to 30 mm. When using multiple prostheses, the lengths may be much greater, typically from 20 mm to 100 mm, more often from 20 mm to 60 mm.

[0046] As a further option, the linearized elements of the present invention may be coated, loaded, or otherwise coupled to or with an active substance intended to enhance the selected therapy. Linearized elements intended for treating blood vessels and other body lumens may be coated with substances intended to inhibit cellular proliferation, inflammation, or other conditions. Exemplary active substances include anti-neoplastic drugs such as paclitaxel, methotrexate, and batimastal; antibiotics such as doxycycline, tetracycline, rapamycin, and actinomycin; immunosuppressants such as dexamethosone, methyl prednisolone, nitric oxide sources such as nitroprussides; estrogen; estradiols; and the like.

[0047] The present invention further comprises catheters and other apparatus for delivering helical prostheses. The catheters comprise a catheter body having a proximal end, a distal end, and at least one lumen through at least a portion thereof. A linearized element is disposed in the lumen, and the mechanism for advancing and releasing at least one length of the linearized element from the lumen is provided. As described above, the linearized elements will assume a non-linear configuration when advanced and released from the catheter body. Usually, the advancing and releasing mechanism will comprise a severing mechanism to selectively cut the linearized element after a desired length has been released. Alternatively, the catheter may carry a plurality of linearized elements which are divided or cut into discrete lengths prior to deployment. Thus, the discrete lengths may be released after they are fully advanced from the lumen of the catheter body. In the latter case, the catheter body may carry from two to twenty discrete elements, typically from three to ten discrete elements.

[0048] In a further aspect, the stents of the present invention will comprise evertible structures which radially expand upon eversion to assume a non-collapsible diameter which remains in place within the body lumen to support the luminal wall. Typically, the evertible stent structures will comprise braided structures, but other structures, such as counterwound helices, will also be capable of eversion. In some instances, laser cut helical and other patterned metal tubes, particularly those formed from nickel titanium and other shape memory alloys, may be used. Thin wall tubes formed from polymeric materials, such as polyethylene terephthalate (PET), expanded polytetrafluoroethyolene (e PTFE), may also find use, even without patterning.

[0049] The braided and other evertible stent structures of the present invention may be formed from metals, including both malleable metals and elastic metals, such as shape memory metals, as well as from polymeric materials. Usually, the braided structures will comprise individual ribbons of the desired material which are interwoven to form a braid so that the braid may be axially elongated to assume a narrow diameter configuration and thereafter be everted to assume a larger diameter configuration. By "evert" it is meant that a leading edge of the prosthesis is turned outwardly and backwardly relative to the narrow diameter portion thereof. In the preferred methods and apparatus of the present invention, as described in more detail below, such eversion will be achieved by initially holding the prosthesis in its narrow diameter configuration with the leading portion everted and fixed to an outer portion of a catheter. This leading portion is referred to as the "fixed end." The remainder of the prosthesis which remains in its narrow diameter configuration is held within a passage or lumen of a delivery catheter, and means are provided for pushing the "advancable end" of the prosthesis which is in

the lumen forwardly relative to the fixed end. In this way, the leading edge of the prosthesis moves forward continuously relative to the fixed end as it everts radially outwardly.

[0050] The use of such braided and other evertible prostheses provides a number of advantages. For example, the braided structure is highly flexible, particularly in its narrow diameter configuration, allowing the introduction of relatively long stent segments without significantly limiting the ability of the delivery catheter to pass through torturous regions of the vasculature or other body lumens. Additionally, by everting the prosthesis so that its outer portion remains stationary relative to the fixed end (and thus also relative to the delivery catheter), the stent will be able to pass through relatively small body lumens since it advances much like a tractor tread in moving forwardly through the lumen. In the case of vascular treatments, the stents of the present invention will usually be used following other primary interventions, such as angioplasty, atherectomy, aneurysm repair, or the like. It will be possible, however, in certain instances, to deliver the stent without prior intervention because of the ability to advance through tight lesions and to dilate the lesion as it passes therethrough.

[0051] Usually, the methods and apparatus of the present invention will be used to deliver a single stent having a predetermined length. In other instances, however, it will be possible to provide a means for severing the stent on the catheter itself. In such cases, the methods and apparatus of the present invention will be capable of delivering variable lengths of stent depending on the nature and extent of the disease being treated. That is, the apparatus will be used to deliver the stent under fluoroscopic or other observation, and after a desired length of stent has been deployed, the deployed length can be severed from the length which remains carried within the delivery catheter.

[0052] In one aspect, methods according to the present invention thus comprise positioning a tubular prosthesis at a target site within a body lumen. The prosthesis is then everted so that an inside surface is exposed radially outwardly and advanced over a length of the wall of the body lumen. Usually, positioning comprises introducing a delivery catheter having a passage which carries the tubular prosthesis at least partly in a radially collapsed configuration. Everting usually comprises pushing the tubular prosthesis from the catheter so that a leading portion of the prosthesis everts and radially expands as it exits the catheter or passage. This is usually accomplished by forwardly advancing a portion of the catheter to push the prosthesis from the catheter. In a preferred aspect of the present invention, an advancable segment of the prosthesis is carried in the passage in the radially collapsed configuration. A fixed end of the prosthesis is held stationary relative to the catheter in a partially everted configuration. Everting then comprises pushing a proximal end (i.e., an end or portion of the prosthesis which is radially collapsed within the delivery catheter) to cause a middle portion of the prosthesis to progressively evert and advance distally relative to the fixed end. In the case of braided prostheses, the braided structure will shorten as the radius expands so that the "advancable" proximal end prosthesis is pushed forward at a rate which is faster than the rate at which the everted prosthesis covers the wall of the body lumen. In preferred embodiments, the prosthesis releases an active substance which inhibits hyperplasia after the prosthesis has been placed in the body lumen.

[0053] In a further aspect of the present invention, apparatus for delivering a prosthesis to a body lumen comprise a catheter having a passage. A tubular prosthesis is carried at least partially in the passage in a radially collapsed configuration. A mechanism for advancing the prosthesis from the passage so that the prosthesis everts and radially expands as it is advanced is also provided. The tubular prosthesis is preferably a braided tube, and the braided tube is composed at least partly from a material selected from the group consisting of stainless steel, shape memory alloys, and polymer resins. Optionally, the prosthesis may carry a source of an active substance, such as a substance which inhibits hyperplasia. Exemplary active substances include anti-neoplastic drugs such as paclitaxel, methotrexate, and batimastal; antibiotics such as doxycycline, tetracycline, rapamycin, and actinomycin; immunosuppressant such as dexamethosone, methyl prednisolone, nitric oxide sources such as nitroprussides; estrogen; estradiols; and the like. Such active substances may be carried on the prosthesis in a variety of ways. For example, they may be coated by spraying, dipping, painting, or the like. Alternatively, they may be stored in reservoirs, i.e., etched depressions or spaces within the prosthesis structure. In the latter case, delivery is often controlled using a microporous, macroporous, or diffusible rate-controlling membrane. In other instances, the active substances may be incorporated in porous or nonporous polymeric layers which are incorporated over or within the braided or other evertible stent structures.

[0054] In an exemplary apparatus of the present invention, the fixed end of the prosthesis is everted over an outside surface of the catheter. An advancable end of the prosthesis remains in the catheter passage. A pusher to push the middle of the prosthesis distally relative to the catheter to evert and advance a leading edge of the prosthesis relative to the fixed end is also provided. Optionally, a central tube is disposed inside of the collapsed portion of the prosthesis, and further optionally, the central tube may be advancable together with the pusher to evert the prosthesis.

[0055] In still another aspect, the invention provides apparatus and methods for deploying stents of variable length into a vessel. An exemplary apparatus for variable length stent deployment comprises a flexible catheter body having a proximal end and a distal end adapted for positioning in the vessel. Stenting structure is releasably held by the catheter body in an unexpanded configuration and is movable from the unexpanded configuration to an expanded configuration adapted to engage a wall of the vessel. The catheter further includes a deployment mechanism coupled to the catheter body adapted to deploy a deployable portion of the stenting structure. The deployable portion is released into the vessel in the expanded configuration while a remaining portion of the stenting structure remains releasably held by the catheter body in the unexpanded configuration. Advantageously, the deployment mechanism enables the deployment of a deployable portion having a selectable length suited to match the length of the vessel or lesion to be treated.

[0056] In an exemplary embodiment, the stenting structure comprises a plurality of stent segments, and the deployment mechanism is adapted to select one or more of the stent segments for inclusion in the deployable portion. The stent segments in the deployable portion are preferably deployed simultaneously. The apparatus may further include a con-

straining element for constraining expansion of a selected stent segment, typically being a sheath disposed over the selected stent segment.

[0057] In one embodiment, the deployment mechanism comprises an expandable member on the catheter body, the deployable portion of the stenting structure being positionable over the expandable member for expansion thereby. Preferably, the length of the expandable member can be adjusted according to the length of the deployable portion, for example by sliding a sheath over a portion of the expandable member to constrain expansion of that portion. The apparatus may further include a stent positioner for moving a selected portion of the stenting structure relative to the expandable member.

[0058] The apparatus may further include a valve member on the catheter body adapted to separate the deployable portion from the remaining portion. In an exemplary embodiment, the valve member is disposed on a sheath extending over the stenting structure.

[0059] In a preferred embodiment, the deployable portion of the stenting structure is deployable from a fixed position relative to the distal end of the catheter body. For example, the stenting structure may have a leading end closest to the distal end of the catheter body, and the deployable portion of the stenting structure extends proximally a selectable length from the leading end thereof. In some embodiments, the deployable portion is deployed distally from the distal end of the catheter body. Alternatively, the deployable portion is deployed radially by an expandable member.

[0060] In an alternative aspect, the stenting structure is continuous throughout the length thereof, and the deployment mechanism is adapted to separate the deployable portion of the stenting structure from a remaining portion of the stenting structure at a selectable location. In an exemplary embodiment, the deployment mechanism is adapted to sever the stenting structure at the selectable location. Usually the deployable portion is severed from the remaining portion of the stenting structure following deployment from the catheter into the vessel. In one embodiment of a continuous stenting structure, the stenting structure is a coil. Alternatively, the stenting structure may be a mesh. Usually in these embodiments, the stenting structure will be self-expanding.

[0061] In a further aspect of the invention, a method of deploying a stent of selectable length in a vessel comprises: endovascularly positioning a catheter in the vessel, the catheter having a distal end and stenting structure releasably disposed therein; positioning a deployable portion of the stenting structure in a position suitable for deployment from the catheter; determining a desired stent length; adjusting the length of the deployable portion to be the desired stent length; and releasing the deployable portion from the catheter into the vessel, wherein the deployable portion expands to engage a wall of the vessel while a remaining portion of the stenting structure remains releasably disposed in the catheter.

[0062] In a preferred aspect, adjusting the length of the deployable portion comprises positioning a first portion of the stenting structure shorter than the desired stent length in a position in the catheter for release into the vessel, and positioning an additional portion of the stenting structure in the catheter adjacent to the first portion for release therewith. This enables the length of the deployable portion to be precisely tailored in situ to the length of the lesion to be treated. Usually, the deployable portion will be separated from the remaining portion by axially moving the deployable portion relative to the remaining portion (or moving the remaining portion relative to the deployable portion).

[0063] Advantageously, the method facilitates the deployment of multiple stents of various lengths without removing the catheter from the patient's vasculature. For example, the method may further include the steps of determining a second stent length; selecting a second portion of the stenting structure having the second stent length; and releasing the second portion in the vessel, wherein the second portion expands to engage a wall of the vessel. Of course, two, three, four or more stents may be deployed from the catheter in succession, all of the same or differing lengths depending on the size of the lesions to be treated.

[0064] Preferably, the deployable portion and the second portion are deployed from a fixed position relative to the distal end of the catheter. To enable this, the stenting structure is axially movable along the catheter to the fixed position of deployment. Typically, the position of deployment will be at the distal end of the catheter and the stenting structure will have a leading end closest to the distal end of the catheter. The step of adjusting the length of the deployable portion will then comprise selecting a desired length of the stenting structure extending proximally from the leading end thereof.

[0065] In some embodiments, the deployable portion will be released by expanding an expandable member. Preferably, the length of the expandable member (or the expandable portion thereof) may be adjusted according to the desired stent length. This may be accomplished by positioning a constraining member such as a sheath over the portion of the expandable member that is to remain unexpanded.

[0066] In one aspect, the stenting structure comprises a plurality of stent segments and adjusting the length of the deployable portion comprises repositioning a first stent segment relative to a second stent segment. In an exemplary embodiment, the stent segments are connected by separable couplings. Alternatively, the stent segments may be unconnected to each other. With such stent segments, the step of adjusting the length of the deployable portion may include constraining expansion of a selected stent segment by, e.g., a sheath.

[0067] The step of adjusting the length of the deployable portion may further include using a valve member on the catheter to separate the deployable portion from a remaining portion of the stenting structure. The valve member is disposed, in one embodiment, on a sheath slidably disposed over the stenting structure.

[0068] As mentioned previously, the stenting structure may be continuously connected through the length thereof. In these embodiments, the deployable portion of the stenting structure is separated from a remaining portion of the stenting structure at a selectable location on the stenting structure. The deployable portion may be severed from the remaining portion at the selectable location. Continuous stenting structures of the invention include coils and mesh structures, and are preferably self-expanding.

[0069] In yet another aspect of the invention, a method of deploying a stent of selectable length in a vessel comprises: endovascularly positioning a catheter in the vessel, the catheter having a distal end; deploying from the catheter a first stent having a first length; and deploying from the catheter a second stent having a second length different than the first length; wherein the first and second stents are deployed from the same location relative to the distal end of the catheter.

[0070] Eurther aspects of the nature and advantages of the invention will become apparent from the following detailed description taken in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0071] **FIG. 1** is a perspective view illustrating a stent delivery catheter constructed in accordance with the principles of the present invention.

[0072] **FIG. 2** is a detailed view of the distal end of the catheter of **FIG. 1** with portions broken away.

[0073] **FIGS. 3A-3F** illustrate use of the catheter of **FIG. 1** for deploying a plurality of stents using balloon expansion.

[0074] **FIG. 4** illustrates an exemplary prosthesis constructed in accordance with the principles of the present invention.

[0075] **FIGS. 5A and 5B** illustrate a prosthesis similar to that shown in **FIG. 4,** but further including coupling elements for permitting detachable coupling of adjacent prostheses.

[0076] **FIG. 5C** illustrates a pair of prostheses, as shown in **FIG. 5A** and **FIG. 5B,** joined together by the coupling elements.

[0077] **FIG. 5D** illustrates a pair of adjacent prostheses coupled by a modified coupling element.

[0078] **FIGS. 5E and 5F** illustrate radial separation of the adjacent prostheses of **FIG. 5C**.

[0079] **FIGS. 6A and 6B** illustrate a second coupling mechanism constructed in accordance with the principles of the present invention.

[0080] **FIG. 7** illustrates a frangible linkage for joining a pair of adjacent prostheses.

[0081] **FIGS. 8A-8C** illustrate a catheter and its use for delivering self-expanding prostheses according to the methods of the present invention.

[0082] **FIGS. 9A and 9C** illustrate an alternative catheter construction intended for delivering self-expanding prostheses according to the methods of the present invention.

[0083] **FIGS. 10A-10C** illustrates use of the catheter for delivering prostheses by a heat-induction method in accordance with the principles of the present invention.

[0084] **FIG. 11** illustrates an alternative catheter construction for delivering multiple prostheses via a heat-induction protocol in accordance with the principles of the present invention.

[0085] **FIGS. 12A-12D** illustrate a catheter for delivering multiple prostheses using balloon expansion in accordance with the methods of the present invention.

[0086] **FIGS. 13A-13D** illustrate a catheter including a stent valve for delivering multiple prostheses using balloon expansion in accordance with the methods of the present invention.

[0087] **FIG. 14** illustrates an exemplary kit constructed in accordance with the principles of the present invention.

[0088] **FIG. 15** is a perspective view of a catheter capable of delivering helical elements constructed in accordance with the principles of the present invention.

[0089] **FIGS. 15A and 15B** illustrate alternatively non-linearized element geometries according to the present invention.

[0090] **FIG. 16** is a detailed view of the distal end of the catheter of **FIG. 15,** shown in section.

[0091] **FIG. 17** is an alternative view of the distal end of the catheter of **FIG. 15,** shown in section.

[0092] **FIG. 18** is a second alternative view of the distal end of the catheter of **FIG. 15,** shown in section.

[0093] **FIGS. 19A-19E** illustrate use of the catheter of **FIG. 15** for delivering multiple, helical prostheses at distributed points in the blood vessel.

[0094] **FIG. 20** is a perspective view illustrating a stent delivery catheter constructed in accordance with the principles of the present invention.

[0095] **FIGS. 21A-21D** illustrate use of the catheter in **FIG. 20** for deploying a braided stent within a stenosed region in a blood vessel.

DETAILED DESCRIPTION OE THE SPECIEIC EMBODIMENTS

[0096] Referring now to **FIG. 1,** the stent delivery catheter **10** comprises a catheter body **12** having a proximal end **14** and a distal end **16**. The catheter body is formed from a conventional catheter material, such as braided or coiled stainless steel, a natural or synthetic polymer, including silicone rubber, polyethylene, polyvinylchloride, polyurethane, polyester, polytetrafluoroethylene, nylon, and the like. The body may be formed as a composite having one or more reinforcement layers incorporated within a polymeric shell in order to enhance strength, flexibility, and toughness. Eor intravascular use, the catheter body will typically have a length in the range from 40 cm to 150 cm, usually being between 40 cm and 120 cm for peripheral blood vessels and between 110 cm and 150 cm for coronary arteries. The outer diameter of the catheter body may vary depending on the intended use, typically being between 3 Erench and 15 Erench, usually from 5 Erench to 9 Erench.

[0097] Catheter **10** will include a handle **18** at its proximal end **14**. The handle may include a guidewire port **20** and a balloon inflation port **22**, as well as a handle grip **24** which advances a pusher shaft whose distal end **26** is shown in **FIG. 2**. Additionally, the handle permits reciprocation of a catheter delivery balloon **28**, also shown in **FIG. 2**.

[0098] A plurality of stents **30** are carried in a lumen of the catheter body **12**, as shown in **FIG. 2**. While three stents **30** are shown, it will be appreciated that additional stents may be carried generally within the ranges disclosed above. The illustrated stents comprise a plurality of serpentine ring

structures joined by offset struts. It will be appreciated, however, that a wide variety of stent structures could be carried by the catheter **10**, generally as described above.

[0099] Referring now to **FIGS. 3A-3F**, the distal end **16** of the catheter **10** is advanced to target location **40** within a diseased blood vessel (BV) over a guidewire **42**, as illustrated in **FIG. 3B**. Balloon **28** carries a first of the three stents **30**, and is advanced distally from the catheter to deploy the stent within the treatment region **40**, as illustrated in **FIG. 3B** (optionally by retracting the catheter body **12** proximally relative to balloon **28**). Once the stent **30** is properly located, the balloon **28** is inflated to deploy the stent (and optionally dilate the treatment region), as illustrated in **FIG. 3C**.

[0100] The balloon is then deflated, and retracted back into the distal end of the catheter **16**, as illustrated in **FIG. 3D**. The expanded stent is left in place. The balloon **28** is retracted back to within the second stent **30**, as illustrated in **FIG. 3E**. The second stent has been advanced using the pusher **26** so that it is properly located over the balloon **28**, and the distal end of the catheter **16** may then be advanced so that the second stent **30** is located within a second treatment region spaced apart from the first treatment region. As illustrated in **FIG. 3F**, the treatment regions are adjacent to each other. It will be appreciated, however, that the second treatment region could be spaced a substantial distance from the first treatment region. Deployment of the second stent **30** is then completed in the same manner as described above for the first stent. Similarly, deployment of third, fourth, fifth, and additional stents **30** may be effected in the same manner. In this way, it will be appreciated that relatively lengthy and/or disseminated regions within a blood vessel may be treated.

[0101] Referring now to **FIG. 4**, an exemplary prosthesis **50** constructed in accordance with the principles of the present invention is illustrated. The prosthesis has a tubular body **52** having a plurality of axial slots **54**, typically formed by laser cutting or chemical etching a tubular stock, such as stainless steel or nickel-titanium hypotube. Prosthesis **50**, which may be delivered in groups of two, three, four, or more in accordance with the principles of the present invention, will have a length within the ranges set forth above. The diameter, prior to expansion, will typically be below 2 mm, preferably being below 1 mm, although in some instances much larger diameters can be used. The diameter of the prosthesis **50** upon expansion, of course, will be much greater, typically being at least twice as large, sometimes being at least three times as large, or even larger.

[0102] Referring now to **FIGS. 5A and 5B**, a prosthesis **60**, similar to prosthesis **50**, includes a pair of coupling elements **62** which are received in mating slots **64**. **FIG. 5B** is a "rolled-out" view of the "rolled-out" view of the prosthesis **60** for better illustrating the coupling element **62** and slots **64** of the prosthesis **60**.

[0103] As shown in **FIG. 5C**, pairs of prosthesis **60** may be joined or coupled by circumferentially aligning the coupling element **62** with the slot **64**. Although only a single coupling element **62** and slot **64** is visible in **FIG. 5C**, it will be appreciated that the second coupling element and slot will be located on the opposite side of the illustrated pair of prostheses.

[0104] In **FIG. 5C**, the two prosthesis **60** are abutted directly against each other. Such a configuration is advantageous in that it provides for a substantially continuous stent or graft structure when the pair is expanded together in a body lumen. The structure, however, is disadvantageous in that it does not provide for flexibility at the point where the two prostheses meet. In order to provide for greater flexibility, as shown in **FIG. 5D**, a coupling element **62'** can have an elongated shank to provide for a desired offset, typically in the range from 0.05 mm to 1 mm, preferably from 0.1 mm to 0.5 mm.

[0105] Referring now to **FIGS. 5E and 5F**, axial separation of the prostheses **60** is achieved by differential radial expansion of at least one of the prostheses. For example, when both prostheses **60** are in their unexpanded configurations, as shown in **FIG. 5E**, the coupling elements **62** are constrained by the slots **64**, as previously described. By radially expanding the left-hand prostheses **60**, as shown in **FIG. 5F**, the coupling elements **62** will be moved radially outwardly from the slots so that the two prostheses are no longer axially linked. It will be appreciated, however, that the two prostheses **60** may be radially expanded together (as described in more detail hereinafter) in a manner which preserves the link created by the coupling elements **62** and slots **64** so that combinations of two, three, four, or more prostheses may be delivered simultaneously and, in effect, provide a continuous prosthesis having a length which is some multiple of the length of each individual prostheses **60**. The combined prostheses may then be separated from any additional prostheses (which remain in a delivery catheter as described below) by the radial expansion of those prostheses which are to be deployed. In this way, stents, grafts, or other prostheses may be delivered to the body lumen in both different lengths (by properly selecting the number of individual prostheses **60**) and at different locations (by releasing individual or multiple prostheses **60** at different portions of the body lumen).

[0106] Axially separable coupling elements may also be provided, as illustrated in **FIGS. 6A and 6B**. Each prosthesis **70** includes a pair of male coupling elements **72** at one end and a pair of female coupling elements **74** at the other end. The male coupling elements **72** are typically short rods which extend axially from the periphery of the prosthesis end and the female coupling elements are typically short tubes having hollow interiors which detachably receive the male coupling elements. Thus, the prostheses **70** may be joined in an end-to-end manner, as shown in **FIG. 6B**. The prostheses are separated by pulling them in an axial direction, as shown by arrow **76**, but will remain linked under axial compression as well as when exposed to a substantial bending moment. Thus, the axially separable coupling structures of **FIGS. 6A and 6B** are advantageous in that they remain linked during deployment of the prostheses **70**, even when deployment involves significant bending and radial stress. Separation may be effected by pullback on the delivery catheter in order to disengage the coupling elements **72** and **74**.

[0107] A third approach for detachably coupling adjacent prostheses **80** is illustrated in **FIG. 7**. Each prosthesis **80** comprises an expansible ring of diamond-shaped members. Other conventional stent or prostheses structures, however, could also be used. The adjacent prostheses **80** are joined by an axial beam **82** which preferably includes a weakened segment **84** near its midpoint. The use of such a joining structure, which will require physical breakage (as opposed

to the simple detachment characteristic of the embodiment of **FIGS. 5 and 6**) is advantageous in that it provides a very strong linkage which permits both the application of axial compression and axial tension without decoupling. The disadvantage of such a linkage is that it usually requires some mechanism or capability to be incorporated in the delivery catheter to permit selective breakage of the couple.

[**0108**] Referring now to **FIGS. 8A-8C**, a catheter **100** suitable for delivering a plurality of self-expanding prostheses **102** will be described. Catheter **100** comprises a sheath **104** having an axial lumen which carries the prostheses **102** near its distal end **106**. A pusher tube **108** is also positioned in the lumen and is located proximally of the proximal most prosthesis **102**. The individual prostheses **102** may be delivered into a body lumen, typically a blood vessel BV, as illustrated in **FIG. 8B**. The catheter is introduced over a guidewire GW to a desired target site in the blood vessel BV. When at the target site, a first of the prostheses **102** is deployed by axially advancing the pusher tube **104** so that the line of prostheses **102** is axially advanced, with the distal-most prostheses being released from the distal end **106** of the catheter. As it is released, the distal-most prostheses **102** expands since it is being released from the radial constraint provided by the sheath **104**.

[**0109**] Catheter **100** of **FIGS. 8A-8C** is intended for delivering prostheses which abut each other in an end-to-end manner, but which are otherwise unconnected. A catheter **120** intended for releasing self-expanding prostheses **122** which are mechanically linked by frangible coupling elements **124** is illustrated in **FIGS. 9A-9C**. The prostheses **122** and coupling elements **124** may be similar to the prosthesis structure shown in **FIG. 7**, or may comprise other linked prosthesis or stent structures, for example as shown in U.S. Pat. No. 6,258,117, the disclosure of which is incorporated herein by reference.

[**0110**] Catheter **120** comprises a sheath **126**, a pusher tube **128**, and a catheter body **130** having a shearing element **132** at its distal end. Conveniently, the pusher tube **128** is coaxially received over a shaft **134** of the catheter body **130**. In this way, the pusher tube may be used to axially advance each prosthesis **122** by pushing on the proximal end of the proximal-most prosthesis, as shown in **FIG. 9B**.

[**0111**] The catheter **120** is advanced over a guidewire GW to a desired target site in a blood vessel BV. After reaching the target site, at least a first prosthesis **122** is advanced from the distal end of the sheath so that it radially expands to engage an inner wall of the blood vessel. After the at least one prosthesis **122** is advanced sufficiently far, the frangible coupling elements **124** will reach a shearing element **136**, typically a metal ring, disposed at the distal end of the sheath **126**. By then axially retracting the catheter body **130**, a chamfered surface **138** of the shearing element **132** is engaged against the shearing element **136** in order to shear the links **122**, releasing the prosthesis **122**, as illustrated in **FIG. 9C**. After deployment and release of the first prosthesis **122**, additional prosthesis **122** may be released adjacent to the first prosthesis or at different, axially spaced-apart locations within the blood vessel.

[**0112**] Referring now to **FIGS. 10A-10C**, a catheter **140** for delivering a plurality of heat expansible prostheses **142** is illustrated. The prostheses **142** are composed of a heat memory alloy, such as a nickel titanium alloy, which has been programmed to remain in an unexpanded configuration when maintained at body temperature or below, and to assume an expanded configuration when exposed to temperatures above body temperature, typically temperatures above 43° C., often above 45° C. The prostheses will have coupling members which anchor successive prostheses **142** together, typically the radially separating anchors illustrated in **FIGS. 5A-5F**.

[**0113**] The catheter **140** includes a sheath **144** and a pusher tube **146**. The catheter **140** is advanced to a desired target site within the blood vessel BV over a guidewire GW in a conventional manner. After the distal-most prostheses **142** has been fully advanced from the sheath **144** (usually by retracting the sheath **144** while the prostheses are held stationary relative to the blood vessel BV using the pusher tube **146**), as shown in **FIG. 10B**, it will remain both unexpanded and attached to the next proximal prosthesis **142** which remains within the sheath. It is important that the advanced prosthesis **142** be anchored or tethered to the remaining prostheses since it has not yet been expanded and it would otherwise be lost into the lumen of the blood vessel.

[**0114**] After the uncovered prostheses is properly positioned, a heated medium may be introduced through a lumen of the catheter body **148** so that it flows outwardly through the interior of the distal-most prosthesis **142**. By properly selecting the temperature of the heated medium, the prosthesis to be deployed can be heated sufficiently to induce radial expansion, as illustrated in **FIG. 1C**. By positioning the catheter body **148** so that its distal tip is coterminous with the distal tip of the sheath **144**, inadvertent heating of the prostheses **142** which remain within the sheath can be avoided. After the prosthesis **142** has radially expanded, it will separate from the coupling elements **148** located on the next prosthesis which remains within the sheath **144**. Additional ones or groups of prostheses **142** may then be deployed, either at the same target site or at a different target site axially spaced-apart within the lumen of the blood vessel BV.

[**0115**] As illustrated in **FIG. 11**, instead of using an internal catheter body **148**, as illustrated in **FIGS. 10A-10C**, an external sheath **150** may be used to deliver the heated medium around one or more deployed prostheses **142**. Other aspects of the construction of catheter **140** may remain the same. Optionally, if prosthesis is martensitic at body temperature, further radial expansion can be achieved by internal balloon expansion.

[**0116**] Referring now to **FIGS. 12A-12D**, catheter **160** intended for delivery of multiple prostheses **162** by balloon deployment is illustrated. Catheter **160** comprises a sheath **164**, pusher tube **166**, and a catheter body **168**. The catheter body **168** includes an expansible balloon **170** over its distal portion. Individual prostheses **162** are deployed, as illustrated in **FIGS. 12B and 12C**, by crossing the target area with catheter **160** and then retracting sheath **164**. A distal portion of the balloon **170** lies within the distal-most deployed prosthesis **162**, as shown in **FIG. 12B**. The remaining proximal portion of the balloon **170** will, of course, remain within the other prostheses **162** which themselves remain within the sheath **164**. The balloon **170** is then inflated, but only the distal portion of the balloon beyond the sheath inflates within the distal prosthesis **162**, as illustrated in **FIG. 12C**. Expansion of the remaining proximal portion

of the balloon is prevented by the sheath **164**. Similarly, the remaining prostheses **162** remain unexpanded since they remain within the sheath **164**. After deployment of prostheses **162**, balloon **170** may be deflated and retracted into sheath **164** and remaining prostheses **162**.

[**0117**] Referring now to **FIG. 12D**, additional prostheses **162** may be deployed, either at the same target location within the blood vessel or at a different, spaced-apart locations within the blood vessel. Deployment of two prostheses **162** is illustrated. The two prostheses **162** are axially exposed as the sheath is retracted over the stents which are positioned over the uninflated balloon **170**. The balloon **170** is then inflated, as illustrated in **FIG. 12D**, thus expanding the prostheses **162** within the blood vessel BV. It will be appreciated that the catheter **160** could carry many more than the four illustrated prostheses **162**, and three, four, five, ten, and even **20** or more individual prostheses could be deployed at one time, with additional single prostheses or groups of prostheses being deployed at different times and/or at different locations within the blood vessel.

[**0118**] Referring now to **FIGS. 13A-13D**, another embodiment of a catheter **180** intended for delivery of multiple prostheses **182** by balloon deployment is illustrated. In this embodiment, catheter **180** comprises a sheath **184** having a valve member **185** at its distal end, a pusher tube **186**, and a catheter body **188**. The catheter body **188** includes an expansible balloon **190** over its distal portion. To deploy prostheses **182**, as illustrated in **FIG. 13B**, a predetermined number of prostheses **182** is first exposed by retracting sheath **184** proximally (arrows) while holding pusher tube **186** in place. As shown in **FIGS. 13B and 13C**, valve member **185** may be used to engage a distal end of one of the prostheses **182** and the sheath **184** and the pusher tube may be retracted proximally together (arrows in **FIG. 13C**) to separate a proximal number of prostheses **182** from a distal number of prostheses **182**. The distal portion of the balloon **190** lies within the distal, deployed prostheses **182**. The remaining proximal portion of the balloon **190** will remain within the other prostheses **182** which themselves remain within the sheath **184**. The balloon **190** is then inflated, as shown in **FIG. 13D**, but only the distal portion of the balloon inflates within the distal prostheses **182**, as illustrated in **FIG. 12C**. Expansion of the remaining proximal portion of the balloon is prevented by the sheath **184**. Similarly, the remaining prostheses **182** remain unexpanded since they remain within the sheath **184**.

[**0119**] Referring now to **FIG. 13D**, single or multiple prostheses **182** may be deployed at the same target location within the blood vessel. Additional prostheses **182** may also be deployed at different, spaced-apart locations within the blood vessel. Deployment of two prostheses **182** is illustrated at one location in **FIG. 13D**. It will be appreciated that the catheter **180** could carry many more than the four illustrated prostheses **182**, and three, four, five, ten, and even **20** or more individual prostheses could be deployed at one time, with additional single prostheses or groups of prostheses being deployed at different times and/or at different locations within the blood vessel.

[**0120**] Referring now to **FIG. 14**, kits **200** according to the present invention comprise a catheter **160** (or any other of the illustrated catheters of the present invention) in combination with instructions for use IFU. The instructions for use set forth any of the methods of the present invention, and in particular set forth how the catheter **180** may be used to implant single or multiple prostheses within a blood vessel or other body lumen. The catheter **180** and instructions for use will typically be packaged together, for example within a conventional package **202**, such as a box, tube, pouch, tray, or the like. Catheter **160** will typically be maintained in a sterile condition within the package **202**. The instructions for use may be provided on a package insert, may be printed in whole or in part on the packaging, or may be provided in other ways, such as electronically over the internet, on an electronic medium, such as a CD, DVD, or the like.

[**0121**] Referring to **FIG. 15**, a delivery device comprising a catheter **210** includes a catheter body **212** having a proximal end **214** and a distal end **216**. The catheter will include at least one lumen **218** (**FIG. 16**) extending over at least a portion thereof, and will further include a proximal hub **220** attached to the proximal end **214**. Hub **214** will include a mechanism for advancing a linearized element **226** from the lumen **218**, such as a thumb slide **230**. In the exemplary embodiment, the thumb slide will be attached to a push rod **232** which extends through the lumen **218** and engages the linearized element(s) **240** to be advanced from the catheter. As shown in **FIG. 15**, the linearized element **240** assumes a helical non-linear configuration as it is advanced from the lumen **218** of the catheter body **212**.

[**0122**] Referring now to **FIG. 15A**, an alternative linearized element **242** is illustrated which will assume a serpentine non-linear configuration when advanced from the catheter or other delivery device. **FIG. 15A** shows the serpentine structure in its flattened or "rolled-out" configuration. It will be appreciated that the scaffold provided by the serpentine structure will be rolled into a generally tubular configuration, as indicated by the arrows in **FIG. 15A**. When linearized, the element **242** will still assume a generally straight configuration, as shown in **FIG. 16**. A second alternative non-linear geometry comprises the zigzag pattern shown in **FIG. 15B**. Again, **FIG. 15B** illustrates this pattern in its flattened or rolled-out configuration. The actual device would be rolled as indicated by the arrows into a generally tubular configuration to serve as a scaffold structure in the present invention.

[**0123**] As illustrated in **FIG. 16**, a single linearized element **240** is pushed by the pusher rod **232** to assume its helical or rather non-linear configuration when fully released from the catheter body **212**. Since the linearized element **240** and the pusher rod **242** are not connected, there is no need to provide a severing or other release mechanism in the embodiment of **FIG. 16**.

[**0124**] **FIG. 17**, in contrast, shows a linearized element **246** having an indeterminate length. That is, the linearized element **246** will be sufficiently long so that it may be divided into two, three, four, or an even larger number of discrete non-linearized elements upon release from the catheter body **212**. In order to effect such release, a severing device **250**, such as an actuable blade, electrochemical, or other severing mechanism, is provided at the distal end of the delivery device. In this way, once a non-linear structure having a sufficient length has been delivered, the transition point between the linearized element and the non-linearized element will be severed using the device **250**. Additional

non-linear scaffold devices may then be delivered using the same catheter over regions space-part within the vasculature or other body lumens.

[0125] Referring now to FIG. 18, a third alternative advancement and release mechanism is illustrated. The embodiment of FIG. 18 is similar to that of FIG. 16, except that a plurality of discrete linearized elements 248*a*, 248*b*, and 248*c*, are carried within lumen 218 and advanced using pusher rod 232. It will be appreciated that since these linearized elements 248*a*-248*c* are separate, and unconnected, they may be released sequentially by advancing the pusher rod (and optionally retracting and/or rotating the catheter body 212) to deliver each non-linearized element. There is no need to provide for a severing mechanism as with the embodiment of FIG. 17. While three discrete linearized elements 248*a*-248*c* are illustrated, it will be appreciated that anywhere from two to 10 linearized elements, or more, could be accommodated using the approach of FIG. 18.

[0126] Referring now to FIGS. 19A-19C, use of the delivery catheter 10 of FIG. 15 and FIG. 17 or FIG. 18 will be illustrated. Catheter 210 is initially delivered so that its proximal end 216 lies past a first target region TR1, as shown in FIG. 19A. The catheter 210 may be introduced over a guide wire GW. The catheter may be an over-the-wire design. In some instances, however, it will be preferable to provide a rapid exchange design having a side guide wire port 260 spaced a short distance from its distal end, as shown in FIG. 16. In this way, the catheter may be introduced by withdrawing the pusher rod 232 and linearized elements approximately so that they lie behind the side guide wire port 260. The catheter may then be introduced over the conventional guide wire GW without the need to completely remove and/or exchange the pusher rod and linearized element assembly with the guide wire. Of course, for catheters having larger diameters, it would be possible to provide a separate guide wire lumen extending the entire length of the catheter for an over-the-wire introduction.

[0127] Once the catheter 210 is in place, the pusher rod 232 will be advanced so that the first non-linearized element 248 is advanced from the distal end 216, as illustrated in FIG. 19B. The pusher rod is pushed in the direction of the arrow and a leading end of the element 248*c* engages the luminal wall of the blood vessel BV.

[0128] After the element 248*c* engages the luminal wall, it is desirable to begin retracting the catheter body in the direction of arrow 270 while advancing the pusher rod 232 in the direction of arrow 272 while preferably rotating the catheter body to counteract the relative rotation of the element 248*c*. The catheter body is thus rotated in the direction of arrow 274. By appropriately controlling each of these three motions, the coil will deploy helically with minimal motion relative to the luminal wall.

[0129] The first prostheses 248*a* will be completely delivered when it is advanced fully from the distal end 216 of catheter 210, as illustrated in FIG. 19D. The catheter 210 may continue to be withdrawn through the vasculature or other body lumen until a second region is reached where it is desired to deliver the second element 248*b*. The steps of delivering the second linearized element 248*b* from the catheter are analogous to those described in FIGS. 5A-5C for the first element 248*a*. A complete deployment of the first linearized element 248*a* into its helical configuration and the second linearized element 248*b* into its helical configuration are illustrated in FIG. 19E.

[0130] It will be appreciated that the lengths, pitches, adjacent spacings, and the like, of the helical and other elements deployed according to the methods of the present invention can be controlled at the discretion of the treating physician. Thus, the methods and apparatus of the present invention provide useful flexibility for the treating physician to treat extended and disseminated disease in the vasculature and other body lumens.

[0131] Referring now to FIG. 320, the stent delivery catheter 310 comprises a catheter body 312 having a proximal end 314 and a distal end 316. The catheter body 312 is formed from a conventional catheter material, such as a natural or synthetic polymer, such as silicone rubber, polyethylene, polyvinylchloride, polyurethane, polyester, polytetrafluoroethylene, nylon, and the like. The body may be formed as a composite having one or more reinforcement layers incorporated within a polymeric shell in order to enhance strength, flexibility, and toughness. For intravascular use, the catheter body will typically have a length in the range from 40 cm to 150 cm, usually being between 40 cm and 120 cm for peripheral blood vessels and between 110 cm and 150 cm for coronary arteries. The outer diameter of the catheter body may vary depending on the intended use, typically being between 3 French and 15 French, usually from 5 French to 9 French (one French=0.33 mm).

[0132] Catheter 310 further comprises a handle 318 at its proximal end 314. The handle has a guidewire port 320 at its distal end as well as a handle grip 324 which is actuable to extend and release evertible prosthesis 330 from the distal end 316. The catheter body 312 comprises an outer tube 332, a middle tube 334 which coaxially and slidably mounted within a lumen of the outer tube 332, and an inner tube 336 which is slidably and coaxially mounted within a lumen of the middle tube 334. Inner tube 336 has a central lumen for receiving a guidewire, as described in detail below.

[0133] Referring now to FIGS. 21A-21D, delivery of the prosthesis 330 within a stenosed region SR of a blood vessel BV is described. The distal end 316 of the catheter 310 is introduced over a guidewire GW to the stenosed region SR as shown in FIG. 21A.

[0134] At that point, the prosthesis 330 is advanced forwardly or distally into the stenosed region SR of the blood vessel BV, as shown in FIG. 21B. In particular, both the inner tube 336 and the middle tube 334 are advanced forwardly or distally relative to the outer tube 332. This causes the leading edge 340 of the prosthesis 330 to advance into the stenosed region SR, engaging and partially dilating the lumen wall within this region.

[0135] As the inner tube 336 and middle tube 334 are further advanced, as shown in FIG. 21C, the leading edge 340 of the prosthesis advances out through the other end of the stenosed region SR. During this entire deployment, fixed end 342 of the prosthesis has remained on the distal end of the outer tube 332 of the delivery catheter 310.

[0136] Once the prosthesis 330 is fully deployed, the outer tube 332 would be disengaged from the fixed end 342 of the prosthesis, e.g., by rotating or otherwise separating the catheter from the prosthesis, leaving the prosthesis 330 in

place, as shown in **FIG. 21D**. As can be seen in **FIG. 21D**, the deployment of the prosthesis **330** has dilated the stenotic region. At this point, if the dilation is insufficient, or further anchoring of the prosthesis **330** is desired, a balloon or other expandable member may be expanded within the prosthesis **330** in a conventional manner. In one embodiment, for example, a balloon may be coupled with the outer tube **332** in such a way as to allow the balloon to be inflated to further anchor the prosthesis **330** in place.

[0137] It will be appreciated that the lengths, pitches, adjacent spacings, and the like, of the braided and other elements deployed according to the methods of the present invention can be controlled at the discretion of the treating physician. Thus, the methods and apparatus of the present invention provide useful flexibility for the treating physician to treat extended and disseminated disease in the vasculature and other body lumens.

[0138] The preferred embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and sprit of the present disclosure.

What is claimed is:

1. A variable length stent deployment apparatus for use in a body vessel comprising:

a flexible catheter body having a proximal end and a distal end adapted for positioning in the vessel;

stenting structure releasably held by the catheter body in an unexpanded configuration, the stenting structure being movable from the unexpanded configuration to an expanded configuration adapted to engage a wall of the vessel; and

a deployment mechanism coupled to the catheter body adapted to deploy a deployable portion of the stenting structure having a selectable length, wherein the deployable portion is released into the vessel in the expanded configuration while a remaining portion of the stenting structure remains releasably held by the catheter body in the unexpanded configuration.

2. The variable length stent deployment apparatus of claim 1 wherein the stenting structure comprises a plurality of stent segments, the deployment mechanism being adapted to select one or more of the stent segments for inclusion in the deployable portion.

3. The variable length stent deployment apparatus of claim 2 wherein the deployment mechanism is adapted to deploy a plurality of stent segments simultaneously.

4. The variable length stent deployment apparatus of claim 2 further comprising a constraining element for constraining expansion of a selected stent segment.

5. The variable length stent deployment apparatus of claim 4 wherein the constraining element is a sheath disposed over the selected stent segment.

6. The variable length stent deployment apparatus of claim 1 wherein the deployment mechanism comprises an expandable member on the catheter body, the deployable portion of the stenting structure being positionable over the expandable member for expansion thereby.

7. The variable length stent deployment apparatus of claim 6 wherein the length of the expandable member can be modified according to the length of the deployable portion.

8. The variable length stent deployment apparatus of claim 7 wherein the length of the expandable member can be modified by a sheath slidably disposed over the expandable member for constraining expansion of a selected portion of the expandable member.

9. The variable length stent deployment apparatus of claim 6 wherein the stenting structure is movable relative to the expandable member, further comprising a stent positioner for moving a selected portion of the stenting structure relative to the expandable member.

10. The variable length stent deployment apparatus of claim 1 further comprising a valve member on the catheter body adapted to separate the deployable portion from the remaining portion.

11. The variable length stent deployment apparatus of claim 1 wherein the stenting structure has a leading end closest to the distal end of the catheter body, and the deployable portion of the stenting structure extends proximally a selectable length from the leading end thereof.

12. The variable length stent deployment apparatus of claim 1 wherein the stenting structure is continuous throughout the length thereof, and the deployment mechanism is adapted to separate the deployable portion of the stenting structure from a remaining portion of the stenting structure at a selectable location.

13. The variable length stent deployment apparatus of claim 12 wherein the deployment mechanism is adapted to sever the stenting structure at the selectable location.

14. The variable length stent deployment apparatus of claim 12 wherein the deployment mechanism is adapted to deploy the stenting structure to the desired length distally from the distal end of the catheter body.

15. The variable length stent deployment apparatus of claim 13 wherein the stenting structure is severed by the deployment mechanism following deployment from the catheter body.

16. The variable length stent deployment apparatus of claim 12 wherein the stenting structure is a coil.

17. The variable length stent deployment apparatus of claim 12 wherein the stenting structure is a mesh.

18. The variable length stent deployment apparatus of claim 12 wherein the stenting structure is self-expanding.

19. The variable length stent deployment apparatus of claim 12 wherein the stenting structure is everted within the catheter body.

20. A method of deploying a stent of selectable length in a vessel, the method comprising:

endovascularly positioning a catheter in the vessel, the catheter having a distal end and stenting structure releasably disposed therein;

positioning a deployable portion of the stenting structure in a position suitable for deployment from the catheter;

determining a desired stent length;

adjusting the length of the deployable portion to be the desired stent length;

releasing the deployable portion from the catheter into the vessel, wherein the deployable portion expands to engage a wall of the vessel while a remaining portion of the stenting structure remains releasably disposed in the catheter.

21. The method of claim 20 wherein adjusting the length of the deployable portion comprises positioning a first

portion of the stenting structure shorter than the desired stent length in a position in the catheter for deployment, and positioning an additional portion of the stenting structure in the catheter adjacent to the first portion for deployment therewith.

22. The method of claim 20 wherein adjusting tbe length of the deployable portion comprises axially moving the deployable portion relative to the remaining portion.

23. The method of claim 20 further comprising:

determining a second stent length different than the desired stent length;

selecting a second portion of the stenting structure having the second stent length; and

releasing the second portion in the vessel, wherein the second portion expands to engage a wall of the vessel.

24. The method of claim 20 wherein releasing the deployable portion comprises expanding an expandable member, further comprising adjusting the length of the expandable member according to the desired stent length.

25. The method of claim 20 wherein the stenting structure comprises a plurality of stent segments and adjusting the length of the deployable portion comprises repositioning a first stent segment relative to a second stent segment.

26. The method of claim 25 wherein the stent segments are connected by separable couplings.

27. The method of claim 25 wherein the stent segments are unconnected to each other.

28. The method of claim 25 wherein adjusting tbe length of the deployable portion comprises constraining expansion of a selected stent segment.

29. The method of claim 26 wherein the selected stent segment is constrained by a sheath disposed over the selected stent segment.

30. The method of claim 20 wherein releasing the deployable portion comprises expanding a balloon coupled to the catheter, the deployable portion being expanded by the balloon.

31. The method of claim 30 further comprising constraining expansion of a selected portion of the balloon.

32. The method of claim 30 wherein the stenting structure is movable relative to the balloon, further comprising moving a portion of the stenting structure relative to the balloon.

33. The method of claim 20 wherein adjusting tbe length of the deployable portion comprises using a valve member on the catheter to separate the deployable portion from a remaining portion of the stenting structure.

34. The method of claim 33 wherein a sheath is slidably disposed over the stenting structure, the valve member being disposed at a distal end of the sheath.

35. The method of claim 23 wherein the deployable portion and the second portion are deployed from a fixed position relative to the distal end of the catheter.

36. The method of claim 20 wherein the stenting structure has a leading end closest to the distal end of the catheter, and wherein adjusting tbe length of the deployable portion comprises selecting a desired length of the stenting structure extending proximally from the leading end thereof.

37. The method of claim 20 wherein the stenting structure is continuously connected through the length thereof, and adjusting the length of the deployable portion comprises separating the deployable portion of the stenting structure from a remaining portion of the stenting structure at a selectable location on the stenting structure.

38. The method of claim 37 wherein adjusting the length of the deployable portion comprises severing the stenting structure at the selectable location.

39. The method of claim 20 wherein adjusting the length of the deployable portion comprises advancing the desired length of the stent structure distally of the catheter.

40. The method of claim 37 wherein the deployable portion is separated following deployment by the deployment mechanism.

41. The method of claim 37 wherein the stenting structure is a coil.

42. The method of claim 37 wherein the stenting structure is a mesh.

43. The method of claim 37 wherein the stenting structure is everted within the catheter body.

44. The method of claim 20 wherein the stenting structure is self-expanding.

45. A method of deploying a stent of selectable length in a vessel, the method comprising:

endovascularly positioning a catheter in the vessel, the catheter having a distal end and stenting structure releasably coupled thereto, the stenting structure having a leading end closest to the distal end of the catheter;

determining a desired stent length;

selecting a deployable portion of the stenting structure, the deployable portion extending from the leading end proximally the desired stent length; and

releasing the deployable portion from the catheter into the vessel, wherein the deployable portion expands to engage a wall of the vessel while a remaining portion of the stenting structure remains coupled to the catheter.

46. A method of deploying a stent of selectable length in a vessel, the method comprising:

endovascularly positioning a catheter in the vessel, the catheter having a distal end and stenting structure releasably disposed near the distal end;

determining a first desired stent length;

selecting a deployable portion of the stenting structure having the first desired stent length;

axially separating the deployable portion from a remaining portion of the stenting structure;

releasing the deployable portion from the catheter into the vessel, wherein the deployable portion expands to engage a wall of the vessel while the remaining portion remains releasably disposed in the catheter;

determining a second desired stent length different than the first desired stent length;

selecting a second portion of the stenting structure having the second stent length; and

releasing the second portion in the vessel, wherein the second portion expands to engage a wall of the vessel.

47. A method of deploying a stent of selectable length in a vessel, the method comprising:

endovascularly positioning a catheter in the vessel, the catheter having a distal end, an expandable member

near the distal end, and stenting structure disposed near the distal end, the expandable member having a length;

determining a desired stent length;

selecting a deployable portion of the stenting structure having the desired stent length;

positioning the deployable portion on the expandable member;

adjusting the length of the expandable member according to the desired stent length; and

expanding the expandable member wherein the deployable portion expands to engage a wall of the vessel while a remaining portion of the stenting structure remains disposed in the catheter.

48. A method of deploying a stent of selectable length in a vessel, the method comprising:

endovascularly positioning a catheter in the vessel, the catheter having a distal end, a deployment mechanism, and stenting structure disposed near the distal end;

positioning a deployable portion of the stenting structure in a position on the catheter suitable for deployment by the deployment mechanism;

determining a desired stent length;

adjusting the length of the deployable portion according to the desired stent length; and

actuating the deployment mechanism to deploy the deployable portion, wherein the deployable portion expands to engage a wall of the vessel while a remaining portion of the stenting structure remains disposed in the catheter.

49. A method of deploying a stent of selectable length in a vessel, the method comprising:

endovascularly positioning a catheter in the vessel, the catheter having a distal end;

deploying from the catheter a first stent having a first length; and

deploying from the catheter a second stent having a second length different than the first length;

wherein the first and second stents are deployed from the same location relative to the distal end of the catheter.

* * * * *

Electronic Acknowledgement Receipt

EFS ID:	4152052
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Sue Bromaghim
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.201
Receipt Date:	21-OCT-2008
Filing Date:	16-JUN-2004
Time Stamp:	17:53:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Appeal Brief Filed	10012-710-201-AmendedAppealBrief.pdf	1978730 dc8f7e7413b5f400d1da06716ff57d19746178ea	no	21

Warnings:

Information:

2	Affidavit/Dec/Exhibit after Notice of Appeal	Bailey_US20010021872.pdf	344324 6ac45d4b673f05cbb7d1be49651d530f54073612	no	15
Warnings:					
Information:					
3	Affidavit/Dec/Exhibit after Notice of Appeal	Gifford_US6712842.pdf	720302 795a9259f80d65effd16c5cb6b00f62b942a5a08	no	49
Warnings:					
Information:					
4	Affidavit/Dec/Exhibit after Notice of Appeal	Chew_US20040215331.pdf	528459 8bbebf7c553345f7666a443d7bfdbbd0bac4c5d8	no	41
Warnings:					
Information:					
		Total Files Size (in bytes):	3571815		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

66854 7590 01/26/2009

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
01/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/870,340	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *1-20,34-37 and 52-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33,38-51,68 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the Appeal Brief filed on 10/21/2008, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or, (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/David J. Isabella/ Supervisory Patent Examiner, Art Unit 3774

Claim Rejections - 35 USC § 112

Claims 26 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In these claims, it is unclear what "approximating the anchor and the replacement valve" is intended to mean.

Claim Objections

Claims 22, 32, 33, 39, and 42-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21, 23-25, 27, 30-33, 38, 40, 41, 45, 47-51, 68, and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Norred (US Pat. No. 6,482,228). Norred discloses the following of the claimed inventions: delivering a valve (82) and an anchor (90) everting an everting portion of the valve (92) about the anchor, during the deployment of the anchor. The valve is between the anchor and the tissue, which may be moved and removed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28, 29, 46, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norred in view of Bailey et al. (US Pub. No. 2001/0021872). Norred discloses the invention substantially as claimed, however, Norred does not teach locking the anchor in its deployed configuration. Bailey et al. teaches a heart valve that locks its anchor in a deployed configuration in paragraph 0069 for the purpose of securing the anchor in place. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Norred by locking the anchors in order to secure the anchors in place.

Response to Arguments

Applicant's arguments with respect to claims 21-33, 38-51, 68, and 69 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/William H. Matthews/
Primary Examiner, Art Unit 3774

Notice of References Cited	Application/Control No. 10/870,340	Applicant(s)/Patent Under Reexamination SALAHIEH ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,482,228	11-2002	Norred, Troy R.	623/2.17
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10870340	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Updated prior search	1/16/2009	AS

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/A. S./ Examiner.Art Unit 3774	

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/870,340	Confirmation No.: 7111
Applicant(s):	Amr Salahieh	
Filed:	June 16, 2004	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☒ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☒ **37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 1/30/09

By: _____
Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08a (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	422	US- 4,326,306	4/27/1982	Poler	
	423	US- 4,423,809	1/3/1984	Mazzocco	
	438	US- 4,602,911	7/29/1986	Ahmadi et al.	
	406	US- 5,476,506	12/19/1995	Lunn	
	437	US- 5,476,510	12/19/1995	Eberhardt et al.	
	407	US- 5,662,671	9/2/1997	Barbut et al.	
	408	US- 5,895,399	4/20/1999	Barbut et al.	
	439	US- 5,984,959	11/16/1999	Robertson et al.	
	409	US- 5,993,469	11/30/1999	McKenzie et al.	
	410	US- 5,997,557	12/7/1999	Barbut et al.	
	411	US- 6,010,522	1/4/2000	Barbut et al.	
	370	US- 6,197,053	3/6/2001	Cosgrove et al.	
	401	US- 6,221,096	4/24/2001	Aiba et al.	
	412	US- 6,231,544	5/15/2001	Tsugita et al.	
	413	US- 6,231,551	5/15/2001	Barbut	
	431	US- 6,336,937	1/8/2002	Vonesh et al.	
	414	US- 6,616,682	9/9/2003	Joergensen et al.	
	415	US- 6,682,543	1/27/2004	Barbut et al.	
	416	US- 6,767,345	7/27/2004	St. Germain et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08a (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	433	US- 6,790,237	9/14/2004	Stinson	
	398	US- 6,821,297	11/23/2004	Snyders	
	400	US- 7,011,681	3/14/2006	Veseley, Ivan	
	417	US- 7,166,097	1/23/2007	Barbut	
	371	US- 7,189,258	3/13/2007	Johnson et al.	
	418	US- 7,374,560	5/20/2008	Ressemann et al.	
	429	US- 2001/0041930 A1	11/15/2001	Globerman et al.	
	424	US- 2002/0029981 A1	3/14/2002	Nigam	
	428	US- 2002/0055769 A1	5/9/2002	Wang	
	425	US- 2002/0082609 A1	6/27/2002	Green	
	432	US- 2002/0188341 A1	12/12/2002	Elliott	
	434	US- 2003/0050694 A1	3/13/2003	Yang et al.	
	426	US- 2003/0070944 A1	4/17/2003	Nigam	
	397	US- 2003/0229390 A1	12/11/2003	Ashton et al.	
	427	US- 2004/0098099 A1	5/20/2004	McCullagh et al.	
	419	US- 2003/0212429 A1	11/13/2003	Keegan et al.	
	420	US- 2004/0049226 A1	3/11/2004	Keegan et al.	
	421	US- 2004/0098022 A1	5/20/2004	Barone	
	404	US- 2005/0033402 A1	2/10/2005	Cully et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08a (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	399	US- 2008/125859-A1	05/29/2008	Salahieh et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08b (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 4

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	403	SALAHIEH, et al., U.S. Pat. App. # 12/132,304 entitled "Low profile heart valve and delivery system," filed 06/03/2008	
	435	SALAHIEH, et al., U.S. Pat. App. # 12/264,082 entitled "Repositionable heart valve and method," filed 11/3/2008	
	436	SALAHIEH, et al., U.S. Pat. App. # 12/269,213 entitled "Everting heart valve," filed 11/12/2008	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Thomas M. Zlogar/Angelica Zuniga
Attorney Docket Number:	10012-710.201

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	4710833
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Angelica Zuniga
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.201
Receipt Date:	30-JAN-2009
Filing Date:	16-JUN-2004
Time Stamp:	17:19:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	3029
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710201.pdf	453484 ec1eaa43bfedaa779a8023f4eaa9e59155195ac4	yes	7

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Information Disclosure Statement Letter	1	3
Information Disclosure Statement (IDS) Filed (SB/08)	4	7

Warnings:

Information:

2	Fee Worksheet (PTO-06)	fee-info.pdf	29585 17d64adb56ba307280e5fc585083abfb726dd9ae	no	2

Warnings:

Information:

Total Files Size (in bytes):	483069

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

FILED VIA EFS ON FEBRUARY 26, 2009

Attorney Docket No. 10012-710.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/870,340	Confirmation No.:	7111
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	June 16, 2004		
Title	:	Everting Heart Valve		
Group Art Unit	:	3774		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.201		
Customer No.	:	66854		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

REQUEST FOR A CORRECTED OFFICE ACTION AND NEW REPLY PERIOD UNDER MPEP 710.06

Remarks

This Request is in response to the non-final Office Action mailed January 26, 2009 ("Office Action"). The Office Action contains an error that affects Applicants' ability to reply to the Office Action. In the first paragraph on page 3 of the Office Action, the Examiner states that claims 32 and 33 (among others) are objected to but would be allowable if rewritten in independent form. The Examiner then rejects claims 32 and 33 under 35 U.S.C 102(e) based on Norred (U.S. 6,482,228). This contradiction affects Applicants' ability to respond to the Office Action as Applicants can not determine if claims 32 and 33 are objected to or rejected. Applicants hereby request the Examiner correct the Office Action.

As this request is being made within 1 month from the mail date of the Office Action, Applicants also request that the Examiner restart the previously set period for reply to start from the date the error is corrected.

Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned at (650) 212-1700.

Respectfully submitted,

Date: 2/26/09

By: _____

Thomas M. Zlogar
Registration No. 55,760

SHAY GLENN LLP
2755 CAMPUS DRIVE, SUITE 210
SAN MATEO, CA 94403
TELEPHONE: 650.212.1700
FACSIMILE: 650.212.7562

Electronic Acknowledgement Receipt

EFS ID:	4869147
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Mary Buggie
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.201
Receipt Date:	26-FEB-2009
Filing Date:	16-JUN-2004
Time Stamp:	19:22:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	10012-710-201-RespOA.pdf	56176 75bc36af15e5be85a34597dee0c9cd0d3bcc8aeb	no	2

Warnings:	
Information:	

Total Files Size (in bytes):	56176

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

FILED VIA EFS ON APRIL 27, 2009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/870,340	Confirmation No.: 7111
Applicant	:	Amr SALAHIEH et al.	
Filing Date	:	June 16, 2004	
Title	:	Everting Heart Valve	
Group Art Unit	:	3774	
Examiner	:	Ann M. SCHILLINGER	
Docket No.	:	10012-710.201	
Customer No.	:	66854	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

AMENDMENT IN RESPONSE TO OFFICE ACTION

Introductory Comments:

This Amendment responds to the non-final Office Action dated January 26, 2009, for which a response is due April 27, 2009.

Please enter the amendments and consider the remarks as follows.

Amendments to the Specification are not being made at this time.

Amendments to the Claims begin on page 2.

Remarks / Arguments begin on page 7 of this paper.

Amendments to the Claims:

Please make the amendments as shown. A complete listing of the claims follows:

1. – 20. (Cancelled)

21. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor; and

expanding the anchor to a deployed configuration.

22. (Currently Amended) ~~The method of claim 21, further comprising~~

A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

using the everting portion of the replacement valve as a seal between the anchor and patient tissue.

23. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises holding the replacement valve between the anchor and patient tissue.

24. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

25. (Original) The method of claim 21, wherein expanding the anchor to the deployed configuration further comprises expanding lip and skirt regions of the anchor into engagement with the patient's heart valve.

26. (Currently Amended) The method of claim 21, further comprising ~~approximating the anchor and the replacement valve~~ moving the anchor and the replacement valve axially closer together.

27. (Original) The method of claim 21, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

28. (Original) The method of claim 27, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

29. (Original) The method of claim 21, further comprising locking the anchor in the deployed configuration.

30. (Original) The method of claim 21, further comprising repositioning the replacement valve and the anchor.

31. (Original) The method of claim 21, further comprising retrieving the replacement valve and the anchor.

32. (Currently Amended) ~~The method of claim 21,~~

A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

33. (Original) The method of claim 32, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

34. – 37. (Cancelled)

38. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor; and

expanding the anchor to a deployed configuration.

39. (Currently Amended) ~~The method of claim 38, further comprising~~

A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

using the wrapping portion of the replacement valve as a seal between the anchor and patient tissue.

40. (Original) The method of claim 38, wherein expanding the anchor to the deployed configuration further comprises holding the wrapping portion of the replacement valve between the anchor and patient tissue.

41. (Original) The method of claim 38, wherein wrapping at least a portion of the replacement valve about the anchor further comprises everting at least a portion of the replacement valve about the anchor.

42. (Currently Amended) ~~The method of claim 38~~

A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

wherein endovascularly delivering the replacement valve and anchor further comprises delivering and deploying the valve and anchor without connecting the valve to expandable portions of the anchor.

43. (Currently Amended) ~~The method of claim 38,~~

A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

44. (Original) The method of claim 43, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

45. (Original) The method of claim 39, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving

the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

46. (Original) The method of claim 45, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

47. (Original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

48. (Currently Amended) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises ~~approximating the anchor and the replacement valve~~ moving the anchor and the replacement valve axially closer together.

49. (Original) The method of claim 39 further comprising locking the anchor in the deployed configuration.

50. (Original) The method of claim 39 further comprising repositioning the replacement valve and the anchor.

51. (Original) The method of claim 39 further comprising retrieving the replacement valve and the anchor.

52. – 67. (Cancelled)

68. (Previously Presented) The method of claim 21 wherein everting at least an everting portion of the replacement valve about the anchor comprises everting at least an everting portion of the replacement valve about the distal end of the anchor.

69. (Previously Presented) The method of claim 38 wherein endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor comprises wrapping at least a wrapping portion of the replacement valve about the distal end of the anchor.

REMARKS

Claim Summary

Claims 22, 26, 32, 39, 42, 43 and 48 are currently amended. Claims 1-20, 34-37 and 52-67 have been cancelled. Claims 21-33, 38-51, 68 and 69 are currently pending.

Information Disclosure Statement

Additional references have been submitted in an Information Disclosure Statement dated 1/30/2009. It is respectfully requested that this Information Disclosure Statement be considered and the PTO Form 1449 be initialed and returned with the next Action.

Claim Rejections Under 35 U.S.C. § 112

Claims 26 and 48 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Without agreeing with or acquiescing to the rejections, Applicants are amending claims 26 and 48 to expedite prosecution of the pending claims. Support for the amendments to claims 26 and 38 can be found in at least Figures 41A-41D, 42A-42B and 44A-44B and accompanying descriptions thereof. A person of ordinary skill in the art would have understood that Applicants were in possession of the inventions recited in amended claims 26 and 48 at time of filing of the application, based on at least the figures and the accompanying descriptions thereof.

Claim Objections

Claims 22, 32, 33, 39 and 42-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants have rewritten claims 22, 32, 39 and 42-43 in independent form including all the limitations of base claim 21 and 38, respectively. Therefore, claims 22, 32, 39 and 42-43 are in condition for allowance.

Claims 33 and 44 depend from now allowable independent claims 32 and 43, respectively. Accordingly, claims 33 and 44 are also in condition for allowance.

Claim Rejections Under 35 U.S.C. § 102

Claims 21, 23-25, 27, 30-33, 38, 40, 41, 45, 47-51, 68 and 69 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Norred, U.S. 6,482,228.

Independent claim 21 recites, in part, endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor; and expanding the anchor to a deployed configuration.

The Examiner states that Norred discloses "everting an everting portion of the valve 92 about the anchor, during the deployment of the anchor." (Office Action, page 3.)

Norred does not anticipate independent claim 21 because Norred does not disclose each and every limitation in claim 21. During patent examination, the pending claims must be "given their broadest reasonable interpretation **consistent with the specification**." MPEP 2111 (emphasis added). The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "**in light of the specification** as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, 70 USPQ2d 1827 (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention **as set forth in the remainder of the specification** and the terms and phrases used in the claims must find clear support or antecedent basis in the description **so that the meaning of the terms in the claims may be ascertainable by reference to the description**." 37 CFR 1.75(d)(1).

Phillips at 1316-1317 (emphasis added); MPEP 2111.

While the Examiner is required to give a claim its broadest reasonable construction, the Examiner has unreasonably interpreted "everting," as claimed, by reliance on the Norred reference.

Norred does not disclose everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor, as is required by independent claim 21. Norred describes a cone-shaped membrane 92 which is secured to each arm 84 and base 88 (Col. 5, lines 40-42), and which merely assumes closed and open configurations to control the flow of

blood through the valve (compare Figures 14 and 16). In particular, Norred describes a valve that includes arms 84 which are hingedly attached to ring 86 of base 88 and which extend upwardly and radially inwardly from the base 88 to form a cone. (*See* Col. 5, lines 33-39 and Figs. 14 and 16). The cone-shaped membrane 92 therefore extends upwardly and radially inward in both the open and closed configuration. The cone-shaped membrane 92 does not, however, evert about arms 84, base 88, or pads 90 during the deployment of any of the arms, the base, or the pads. For at least this reason, claim 21 is not anticipated by Norred.

Dependent claims 23-25, 27, 30, 31 and 68 depend from independent claim 21 and are not anticipated by Norred for at least the reasons set forth above.

Independent claim 38 recites, in part, endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor; and expanding the anchor to a deployed configuration.

Norred does not anticipate independent claim 38 because Norred does not disclose each and every limitation in claim 38. For example, Norred does not disclose endovascularly **wrapping** at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor. Arguments made above with respect to claim 21 similarly apply to independent claim 38, and as such, claim 38 is not anticipated by Norred. Claims 40, 41 and 69 depend from claim 38 and are not anticipated by Norred for at least the reasons set forth above.

Claims 45 and 47-51 depend from amended independent claim 39, which is now in condition for allowance. Claims 45 and 47-51 are therefore also in condition for allowance.

Claim Rejections Under 35 U.S.C. § 103

Claims 28, 29, 46 and 49 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Norred, U.S. 6,482,228, in view of Bailey et al., U.S. 2001/0021872.

Dependent claims 28 and 29 depend from independent claim 21. As discussed above, Norred does not disclose all of the limitations of claim 21. Bailey does not overcome the deficiencies of Norred (Applicants suggest that the Examiner would have to agree with this as the previous rejection based on Bailey has been withdrawn) and for at least this reason claims 28 and 29 are not unpatentable over Norred in view of Bailey. Additionally, Applicants disagree

that Bailey discloses the step of locking a heart valve anchor in a deployed configuration. The Examiner points to paragraph 69 in Bailey, yet there does not appear to be any mention of an anchor locking step in paragraph 69. Applicants invite the Examiner to specifically show where Bailey discloses this step so that Applicants can respond to the rejection.

Claims 46 and 49 depend from independent claim 39, which is now in condition for allowance. As such, claims 46 and 49 are in condition for allowance.

CONCLUSION

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Date: April 27, 2009 By: _____

Thomas M. Zlogar, Reg. No. 55,760

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Justin Paul Thomas/Sue Bromaghim (TZ)
Attorney Docket Number:	10012-710.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Independent claims in excess of 3	2201	2	110	220
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**220**

Electronic Acknowledgement Receipt

EFS ID:	5229239
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Justin Paul Thomas/Sue Bromaghim (TZ)
Filer Authorized By:	Justin Paul Thomas
Attorney Docket Number:	10012-710.201
Receipt Date:	27-APR-2009
Filing Date:	16-JUN-2004
Time Stamp:	20:02:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$220
RAM confirmation Number	5857
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710-201-Amendment.pdf	1088824 2ad12da5826b954e68b537168f6142b62a1ca1f9	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	10

Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	29683 22ea4a361e984cb8d59d0face9fc53801c66b863	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1118507		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
10/870,340	06/16/2004	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 04/27/2009	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 29	Minus	** 69	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 7	Minus	***5	= 2	X $110 =	220	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	220	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/JULIET MCMILLAN/

PTO/SB/08a (06-09)
Approved for use through 07/31/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	443	US- 5,735,842	4/7/1998	Krueger et al.	
	451	US- 5,769,812	6/23/1998	Stevens et al.	
	453	US- 6,454,799	9/24/2002	Schreck	
	447	US- 7,191,018	3/13/2007	Gielen et al.	
	452	US- 2002/0002396-A1	1/3/2002	Fulkerson	
	444	US- 2003/0109930	6/12/2003	Bluni et al.	
	445	US- 2003/0144732	7/31/2003	Cosgrove et al.	
	446	US- 2004/0133274	7/8/2004	Webler et al.	
	448	US- 2005/0043711	2/24/2005	Corcoran et al.	
	449	US- 2008/0288054	11/20/2008	Pulnev et al.	
		US-			
		US-			
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		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08b (06-09)
Approved for use through 07/31/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	450	HAUG et al.; U.S. Pat. App. # 12/492,512 entitled "Everting Heart Valve," filed 06/26/2009	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Thomas M. Zlogar/Angelica Zuniga
Attorney Docket Number:	10012-710.201

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	5886952
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Angelica Zuniga
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.201
Receipt Date:	13-AUG-2009
Filing Date:	16-JUN-2004
Time Stamp:	18:11:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	4433
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710201_IDS.pdf	288115 d06a9c4403197a1f7e3db2cda7ff54c457067215	yes	5

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Transmittal Letter	1	3
Information Disclosure Statement (IDS) Filed (SB/08)	4	5

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	29585 6aae22a2badbbb65a65f206f7c81fc1247bf3d01	no	2

Warnings:

Information:

Total Files Size (in bytes):	317700

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/870,340	Confirmation No.: 7111
Applicant(s):	Amr Salahieh	
Filed:	June 16, 2004	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☒ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☒ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☒ **37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 8/13/09

By: _____
Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

66854 7590 10/14/2009

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/870,340	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-33,38-51,68 and 69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *22,32,33,38-51 and 69* is/are allowed.

6)☒ Claim(s) *9,21,23-31 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Allowable Subject Matter

Claims 22, 32, 33, 38-51, and 69 are allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21, 23-27, 30, 31, and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Norred (US Pat. No. 6,482,228). Norred discloses the following of the claimed inventions: a method for endovascularly replacing a patient's heart valve, the method comprising: endovascularly delivering a replacement valve (82) and an expandable anchor (90) to a vicinity of the heart valve; everting at least an everting portion or wrapping a wrapping portion (92) of the replacement valve about the anchor, during the deployment of the anchor; and expanding the anchor to a deployed configuration (Figs. 14-16; col. 5, lines 43-62). The replacement valve is located between the expandable anchor and the tissue (Figs. 14-16). The expandable anchor may be repositioned/moved closer to the valve, or removed from the general vicinity of the patient's heart, during the deployment of the device (col. 5, lines 15-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norred in view of Bailey et al. (US Pub. No. 2001/0021872). Norred discloses the invention substantially as claimed, however, Norred does not teach locking the anchor in its deployed configuration. Bailey et al. teaches a heart valve that locks its anchor in a deployed configuration in paragraph 0069 for the purpose of securing the anchor in place. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Norred by locking the anchors in order to secure the anchors in place.

Response to Arguments

In view of the amendments submitted on 4/27/2009, the 35 USC 112 rejections are withdrawn.

Applicant's arguments filed 4/27/2009 have been fully considered but they are not persuasive. The Applicant contends that the Norred reference does not disclose an everting portion of the replacement valve that everts about the anchor. The examiner respectfully disagrees. The term "evert" is being interpreted according to its dictionary definition as follows: "To turn inside out or outward" (evert. Dictionary.com. *The American Heritage® Dictionary of*

the English Language, Fourth Edition. Houghton Mifflin Company, 2004. http://dictionary.reference.com/browse/evert (accessed: October 12, 2009)). Figures 14-16 illustrate the everting portion of the valve moving in an outward direction relative to the anchor elements.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	10870340	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Updated prior search	10/10/2009	AS

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/A. S./ Examiner.Art Unit 3774	

PTO/SB/08a (06-09)
Approved for use through 07/31/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	443	US- 5,735,842	4/7/1998	Krueger et al.	
	451	US- 5,769,812	6/23/1998	Stevens et al.	
	453	US- 6,454,799	9/24/2002	Schreck	
	447	US- 7,191,018	3/13/2007	Gielen et al.	
	452	US- 2002/0002396-A1	1/3/2002	Fulkerson	
	444	US- 2003/0109930	6/12/2003	Bluni et al.	
	445	US- 2003/0144732	7/31/2003	Cosgrove et al.	
	446	US- 2004/0133274	7/8/2004	Webler et al.	
	448	US- 2005/0043711	2/24/2005	Corcoran et al.	
	449	US- 2008/0288054	11/20/2008	Pulnev et al.	
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		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

PTO/SB/08b (06-09)
Approved for use through 07/31/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	450	HAUG et al.; U.S. Pat. App. # 12/492,512 entitled "Everting Heart Valve," filed 06/26/2009	

Examiner Signature	/Ann Schillinger/	Date Considered	10/12/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	460	US- 3,409,013	11/5/1968	Berry	
	461	US- 4,655,218	4/7/1987	Kulik et al.	
	462	US- 4,755,181	7/5/1988	Igoe	
	463	US- 4,865,600	9/12/1989	Carpentier et al.	
	456	US- 5,549,665	8/27/1996	Vesely et al.	
	465	US- 5,885,228	3/23/1999	Rosenman et al.	
	466	US- 6,623,518	9/23/2003	Thompson et al.	
	467	US- 6,635,079	10/21/2003	Unsworth et al.	
	468	US- 6,776,791	8/17/2004	Stallings et al.	
	469	US- 7,025,791	4/11/2006	Levine et al.	
	470	US- 7,037,331	5/2/2006	Mitelberg et al.	
	471	US- 7,175,653	2/13/2007	Gaber	
	472	US- 7,175,654	2/13/2007	Bonsignore et al.	
	473	US- 7,235,093	6/26/2007	Gregorich	
	474	US- 7,258,696	8/21/2007	Rabkin et al.	
	455	US- 2002/0188344	12/12/2002	Bolea et al.	
	458	US- 2006/0155312	7/13/2006	Levine et al.	
	457	US- 2005/0197694	9/8/2005	Pai et al.	
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Thomas M. Zlogar/Angelica Zuniga
Attorney Docket Number:	10012-710.201

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	6557024
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Angelica Zuniga
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.201
Receipt Date:	02-DEC-2009
Filing Date:	16-JUN-2004
Time Stamp:	14:49:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	1026
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710201_IDS.pdf	250153 1754d78b6fb768f75bd4b027d48978f0df4e880d	yes	4

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Transmittal Letter	1	3
Information Disclosure Statement (IDS) Filed (SB/08)	4	4

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	29585 a9d798351ebe45d3e4158a29c698ed6f9f2eee63	no	2

Warnings:

Information:

Total Files Size (in bytes):	279738

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/870,340	Confirmation No.: 7111
Applicant(s):	Amr Salahieh	
Filed:	June 16, 2004	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☐ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☒ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☒ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 12/2/09

By: _____

Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

66854 7590 03/12/2010

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
03/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	10/870,340	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Tom Zlogar*. (3)_____.

(2) *Ann Schillinger*. (4)_____.

Date of Interview: *23 February 2010*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *21*.

Identification of prior art discussed: *Norred (US Pat. No. 6,482,228)*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *The claim interpretations were discussed in view of the Norred reference. Potential amendments to the claims make include language describing the everting portion as everting before the anchor is in its fully deployed configuration* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/A. S./ Examiner, Art Unit 3774	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr SALAHIEH et al.
Art Unit	3774
Examiner Name	Ann M. SCHILLINGER
Attorney Docket Number	10012-710.201

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☑ Other Amendment Accompanying RCE, filed herewith

   b. ☑ Enclosed

      i. ☑ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☑ Other TRANSMITTAL-EXT OF TIME

2. Miscellaneous

   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 50-4050.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☑ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☑ Other Any additional claims fees.

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature		Date	MARCH 12, 2010
Name (Print/Type)	THOMAS M. ZLOGAR	Registration No.	55,760

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature	FILED VIA EFS		
Name (Print/Type)	SUE BROMAGHIM	Date	MARCH 12, 2010

FILED VIA EFS ON MARCH 12, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/870,340	Confirmation No.:	7111
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	June 16, 2004		
Title	:	Everting Heart Valve		
Group Art Unit	:	3774		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.201		
Customer No.	:	66854		

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

AMENDMENT ACCOMPANYING RCE

Introductory Comments:

This Amendment accompanies a Request for Continued Examination, and is responsive to the final Office Action mailed October 14, 2009, for which a response is due January 14, 2010. A request for extension of time, up to and including **March 14, 2010**, accompanies this response.

Please enter the amendments and consider the remarks as follows.

Amendments to the Specification are not being made at this time.

Amendments to the Claims begin on page 2.

Remarks / Arguments begin on page 8 of this paper.

Amendments to the Claims:

Please make the amendments as shown. A complete listing of the claims follows:

1. – 20. (Cancelled)

21. (Currently Amended) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

~~everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor; and~~

expanding the anchor to a fully deployed configuration in which the expandable anchor is anchored against tissue; and

everting at least an everting portion of the replacement valve about the expandable anchor before the expandable anchor is in the fully deployed configuration.

22. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

using the everting portion of the replacement valve as a seal between the anchor and patient tissue.

23. (Currently Amended) The method of claim 21, wherein expanding the anchor to the fully deployed configuration further comprises holding the replacement valve between the anchor and patient tissue.

24. (Currently Amended) The method of claim 21, wherein expanding the anchor to the fully deployed configuration further comprises actively foreshortening the anchor.

25. (Currently Amended) The method of claim 21, wherein expanding the anchor to the fully deployed configuration further comprises expanding lip and skirt regions of the anchor into engagement with the patient's heart valve.

26. (Previously Presented) The method of claim 21, further comprising moving the anchor and the replacement valve axially closer together.

27. (Original) The method of claim 21, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

28. (Original) The method of claim 27, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

29. (Original) The method of claim 21, further comprising locking the anchor in the deployed configuration.

30. (Original) The method of claim 21, further comprising repositioning the replacement valve and the anchor.

31. (Original) The method of claim 21, further comprising retrieving the replacement valve and the anchor.

32. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

everting at least an everting portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

33. (Original) The method of claim 32, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

34. – 37. (Cancelled)

38. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor; and

expanding the anchor to a deployed configuration.

39. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

using the wrapping portion of the replacement valve as a seal between the anchor and patient tissue.

40. (Original) The method of claim 38, wherein expanding the anchor to the deployed configuration further comprises holding the wrapping portion of the replacement valve between the anchor and patient tissue.

41. (Original) The method of claim 38, wherein wrapping at least a portion of the replacement valve about the anchor further comprises everting at least a portion of the replacement valve about the anchor.

42. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

wherein endovascularly delivering the replacement valve and anchor further comprises delivering and deploying the valve and anchor without connecting the valve to expandable portions of the anchor.

43. (Previously Presented) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve;

endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor during the deployment of the anchor;

expanding the anchor to a deployed configuration; and

wherein the delivering step comprises endovascularly delivering at least a portion of the replacement valve distal to the anchor.

44. (Original) The method of claim 43, wherein the delivering step comprises endovascularly delivering the entire replacement valve distal to the anchor.

45. (Original) The method of claim 39, wherein the delivering step further comprises endovascularly delivering a replacement valve support, the method further comprising moving

the replacement valve support and at least a portion of the anchor with respect to each other during deployment of the replacement valve.

46. (Original) The method of claim 45, further comprising using the replacement valve support to lock the anchor in the deployed configuration.

47. (Original) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises actively foreshortening the anchor.

48. (Previously Presented) The method of claim 39, wherein expanding the anchor to the deployed configuration further comprises moving the anchor and the replacement valve axially closer together.

49. (Original) The method of claim 39 further comprising locking the anchor in the deployed configuration.

50. (Original) The method of claim 39 further comprising repositioning the replacement valve and the anchor.

51. (Original) The method of claim 39 further comprising retrieving the replacement valve and the anchor.

52. – 67. (Cancelled)

68. (Previously Presented) The method of claim 21 wherein everting at least an everting portion of the replacement valve about the anchor comprises everting at least an everting portion of the replacement valve about the distal end of the anchor.

69. (Previously Presented) The method of claim 38 wherein endovascularly wrapping at least a wrapping portion of the replacement valve about the anchor comprises wrapping at least a wrapping portion of the replacement valve about the distal end of the anchor.

70. (New) The method of claim 32 wherein the replacement valve comprises replacement valve leaflets, and wherein the delivering step comprises endovascularly delivering the replacement valve leaflets distal to the anchor.

71. (New) The method of claim 70 wherein the everting step comprises everting the replacement valve leaflets from a position distal to the anchor to a position within the anchor.

REMARKS

Claim Summary

Claims 21, 23, 24 and 25 are currently amended. Claims 1-20, 34-37 and 52-67 were previously cancelled. No claims are withdrawn from consideration. Claims 21-33, 38-51 and 68-71 are currently pending. Cancellation or amendment of any claim is not to be considered a dedication to the public of any subject matter.

Information Disclosure Statements

Applicants note with thanks that the Examiner has considered all references submitted in an Information Disclosure Statement dated 8/13/2009.

Additional references submitted in Information Disclosure Statements dated 1/30/2009 and 12/2/2009 remain unacknowledged. It is respectfully requested that these Information Disclosure Statements be considered and the PTO Forms 1449 be initialed and returned with the next Action.

Claim Rejections Under 35 U.S.C. § 102

Claims 21, 23-27, 30, 31 and 68 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. 6,482,228 to Norred ("Norred").

Without acquiescing or agreeing with the rejection, independent claim 21 is currently amended and recites, in part, endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; expanding the anchor to a fully deployed configuration in which the expandable anchor is anchored against tissue; and everting at least an everting portion of the replacement valve about the expandable anchor before the expandable anchor is in the fully deployed configuration.

The Examiner relies on pads 90 from Norred as the "expandable anchor" as claimed in claim 21. Pads 90, however, are never anchored against tissue, as is required by claim 21. As Norred does not disclose each and every limitation in claim 21, either expressly or inherently, claim 21 is not anticipated by Norred. Claims 23-27, 30, 31 and 68 depend from claim 21 and are not anticipated by Norred for at least the same reasons as claim 21.

Additionally, claim 68 requires that the everting step comprises everting at least an everting portion of the replacement valve about the distal end of the anchor. If the Examiner is

referring to element 92 from Norred as the "everting portion" as claimed, then elements 92 are never everted about a distal end of pads 90. Norred does not disclose the limitations in claim 68 and therefore Norred does not anticipate claim 68.

Claim Rejections Under 35 U.S.C. § 103

Claims 28 and 29 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Norred, in view of U.S. 2001/0021872 to Bailey et al. ("Bailey").

Claims 28 and 29 depend from claim 21 and as set forth above, Norred does not disclose the limitations in claim 21. Bailey does not overcome the deficiencies of claim 21, and therefore Norred and Bailey do not teach or suggest the limitations in claim 21. Additionally, it would not have been obvious to modify the teachings of Norred and Bailey, alone or in combination, to arrive at claim 21. For at least these reasons claims 28 and 29, which depend from claim 21, are not unpatentable over Norred in view of Bailey.

New Claims

Applicants are adding new dependent claims 70 and 71, which depend from allowed independent claim 32. Claims 70 and 71 are therefore in condition for allowance. Exemplary support for new claims 70 and 71 can be found in paragraphs [00152] and [00153], as well as in Figures 42A and 42B (e.g., see paragraph [0153], lines 1-6).

CONCLUSION

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Date: March 12, 2010 By: _____

Thomas M. Zlogar, Reg. No. 55,760

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/870,340	Confirmation No.: 7111
Applicant(s):	Amr Salahieh	
Filed:	June 16, 2004	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

In accordance with 37 CFR § 1.97-1.98, applicants hereby submit an Information Disclosure Statement, including attached forms(s) PTO/SB/08. A copy of each reference is being submitted herewith, along with a concise explanation in English for those publications in a foreign language.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return a copy of the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and /or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in 37 CFR §1.56.

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:

☐ **1).** Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or

☐ **2).** Within 3 months of entry of a national stage as set forth in § 1.491, or

☐ **3).** Before the mail date of a first Office Action on the merits, or

☒ **4).** Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

☐ **1).** Three months beyond the filing date of a national application, or

☐ **2).** Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or

☐ **3).** The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:

☐ **A).** A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or

☐ **B).** A certification as specified in § 1.97(e) is provided below; thus no fee is required.

☐ **37 CFR § 1.97(d)**

This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

A). A fee of $180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement

--AND--

B). A certification as specified in § 1.97(e) is included below.

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

☒ **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

☒ **1).** Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.

☐ **2).** At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 3/12/10

By: _____
Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	494	US- 5,716,370	2/10/1998	Williamson, IV et al.	
	476	US- 5,807,405	9/15/1998	Vanney et al.	
	477	US- 5,861,024	1/19/1999	Rashidi	
	478	US- 6,416,510	7/9/2002	Altman et al.	
	480	US- 6,663,588	12/16/2003	DuBois et al.	
	482	US- 2002/0177766	11/28/2002	Mogul	
	485	US- 2004/0181140	9/16/2004	Falwell et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	495	PAUL et al.; U.S. Pat. App. # 12/578,463 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	
	496	PAUL et al.; U.S. Pat. App. # 12/578,447 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Justin Paul Thomas/Sue Bromaghim (TZ)
Attorney Docket Number:	10012-710.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 2 months with $0 paid	2252	1	245	245

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**650**

Electronic Acknowledgement Receipt

EFS ID:	7203746
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	Everting heart valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Justin Paul Thomas/Sue Bromaghim (TZ)
Filer Authorized By:	Justin Paul Thomas
Attorney Docket Number:	10012-710.201
Receipt Date:	12-MAR-2010
Filing Date:	16-JUN-2004
Time Stamp:	18:47:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$650
RAM confirmation Number	5336
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		10012-710-201-trans-RCE-Amend-IDS.pdf	1939706 df49b0bd1e08f3d4f6c39878a88757aedeadea31	yes	16

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Extension of Time	1	1
Request for Continued Examination (RCE)	2	2
Amendment Submitted/Entered with Filing of CPA/RCE	3	3
Claims	4	9
Applicant Arguments/Remarks Made in an Amendment	10	11
Transmittal Letter	12	14
Information Disclosure Statement (IDS) Filed (SB/08)	15	16

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	31797 e26a426b4029d31e8971fec7ef6343aae811caad	no	2

Warnings:

Information:

Total Files Size (in bytes):	1971503

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

FILED VIA EFS ON MARCH 12, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/870,340	Confirmation No.:	7111
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	June 16, 2004		
Title	:	Everting Heart Valve		
Group Art Unit	:	3774		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.201		
Customer No.	:	66854		

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

TRANSMITTAL OF AMENDMENT ACCOMPANYING RCE
AND REQUEST FOR TWO-MONTH EXTENSION OF TIME

Transmitted herewith are the following documents in the above-identified application:

(1) Request for Continued Examination;
(2) Amendment Accompanying RCE; and
(3) Information Disclosure Statement.

► Request is hereby made for a two (2) month extension of time to file these documents, up to and including **March 14, 2010**.

► The RCE fee ($405) and extension fee (two months / small entity - $245) are being paid via EFS. Please deduct from or credit to Deposit Account No. 50-4050 any other fees attendant with this matter.

Respectfully submitted,

Date: March 12, 2010 By: _____
Thomas Zlogar, Reg. No. 55,760

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
10/870,340	06/16/2004	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 03/12/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 31	Minus	** 69	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 7	Minus	***7	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/Halley D. Massey/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

66854 7590 04/14/2010

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 04/14/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

TITLE OF INVENTION: EVERTING HEART VALVE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	07/14/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

66854 7590 04/14/2010

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

TITLE OF INVENTION: EVERTING HEART VALVE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	07/14/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
SCHILLINGER, ANN M	3774	623-021000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

66854 7590 04/14/2010

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 04/14/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 515 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 515 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/870,340	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the request for continued examination filed 3/12/2010*.

2. ☒ The allowed claim(s) is/are *21-33,38-51 and 68-71*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 12/2/09, 3/12/10
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Ann Schillinger/ Examiner, Art Unit 3774	/DAVID ISABELLA/ Supervisory Patent Examiner, Art Unit 3774

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas Zlogar on 4/9/2010.

The application has been amended as follows:

In claim 21, line 4, after "heart valve;" please add --maintaining said replacement valve secured to said anchor-- .

In claim 21, line 10, please replace "before" with --prior to expanding the--.

In claim 21, line 10, please replace "is in" with –to--.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
10870340	SALAHIEH ET AL.
Examiner	**Art Unit**
ANN SCHILLINGER	3774

ORIGINAL		INTERNATIONAL CLASSIFICATION														
CLASS	SUBCLASS	CLAIMED									NON-CLAIMED					
623	2.17	A	6	1	F	2 / 06 (2006.01.01)										

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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/ANN SCHILLINGER/ Examiner.Art Unit 3774	4/9/2010	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	31	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	04/10/2010	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	39C

Search Notes	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/870,340	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

SEARCHED			
Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner
Intereference search EAST, see printout		4/9/2010	AS

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
Updated prior search	4/9/2010	AS

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Sheet 1 of 2

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	494	US- 5,716,370	2/10/1998	Williamson, IV et al.	
	476	US- 5,807,405	9/15/1998	Vanney et al.	
	477	US- 5,861,024	1/19/1999	Rashidi	
	478	US- 6,416,510	7/9/2002	Altman et al.	
	480	US- 6,663,588	12/16/2003	DuBois et al.	
	482	US- 2002/0177766	11/28/2002	Mogul	
	485	US- 2004/0181140	9/16/2004	Falwell et al.	
		US-			
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Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	495	PAUL et al.; U.S. Pat. App. # 12/578,463 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	
	496	PAUL et al.; U.S. Pat. App. # 12/578,447 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	

Examiner Signature	/Ann Schillinger/	Date Considered	04/09/2010

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	460	US- 3,409,013	11/5/1968	Berry	
	461	US- 4,655,218	4/7/1987	Kulik et al.	
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	470	US- 7,037,331	5/2/2006	Mitelberg et al.	
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	474	US- 7,258,696	8/21/2007	Rabkin et al.	
	455	US- 2002/0188344	12/12/2002	Bolea et al.	
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		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

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EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	5	(valve and heart and wrap$4 and anchor).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2010/04/09 13:47
L2	31	(endovascularly and expandable and valve and anchor).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2010/04/09 13:48
L3	5	(evert$3 and valve and heart and seal).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2010/04/09 13:50
L4	0	(valve and deliver and wrap$4 and depoly$3 and heart).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2010/04/09 13:50
L5	1	(wrap$4 and seal and anchor and everting and valve).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2010/04/09 13:51

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C:\Documents and Settings\ASchillinger\My Documents\EAST\Workspaces\10870340.wsp

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BIB DATA SHEET

CONFIRMATION NO. 7111

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
10/870,340	06/16/2004 RULE	623	3774	10012-710.201

APPLICANTS

Amr Salahieh, Saratoga, CA;
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Robert A. Geshlider, San Francisco, CA;
Tom Saul, El Granada, CA;
Dwight P. Morejohn, Davis, CA;
Kenneth J. Michlitsch, Livermore, CA;

** CONTINUING DATA **********

** FOREIGN APPLICATIONS **********

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08/03/2004

Foreign Priority claimed	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐	CA	63	67	5
35 USC 119(a-d) conditions met ☐ Yes ☑ No					
Verified and Acknowledged /ANN SCHILLINGER/ Examiner's Signature	Initials				

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SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403
UNITED STATES

TITLE

Everting heart valve

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

66854 7590 06/07/2010

SHAY GLENN LLP
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SUITE 210
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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

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10870340	6/16/2004	SALAHIEH ET AL.	10012-710.201

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3774	20100603

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/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

/A. S./
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PTO-90C (Rev.04-03)

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Sheet 1 of 4

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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

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/A.S./	422	US- 4,326,306	4/27/1982	Poler	
	423	US- 4,423,809	1/3/1984	Mazzocco	
	438	US- 4,602,911	7/29/1986	Ahmadi et al.	
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/A.S./	433	US- 6,790,237	9/14/2004	Stinson	
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/A.S./	404	US- 2005/0033402 A1	2/10/2005	Cully et al.	

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/A.S./	399	US- 2008/125859-A1	05/29/2008	Salahieh et al.	
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Attorney Docket Number	10012-710.201

NON PATENT LITERATURE DOCUMENTS

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/A.S./	403	SALAHIEH, et al., U.S. Pat. App. # 12/132,304 entitled "Low profile heart valve and delivery system," filed 06/03/2008	
/A.S./	435	SALAHIEH, et al., U.S. Pat. App. # 12/264,082 entitled "Repositionable heart valve and method," filed 11/3/2008	
/A.S./	436	SALAHIEH, et al., U.S. Pat. App. # 12/269,213 entitled "Everting heart valve," filed 11/12/2008	

Examiner Signature	/Ann Schillinger/	Date Considered	06/03/2010

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	10/870,340
				Filing Date	June 16, 2004
				First Named Inventor	Ulrich R. Haug
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	2	of	5	Attorney Docket Number	30207-710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AS		US 2005/0203615A1	9/15/2005	Forster	
		US 2005/0203616 A1	9/15/2005	Cribier	
		US 2005/0203617 A1	9/15/2005	Forster, et al.	
		US 4,796,629	1/10/1989	Grayzel	
		US 4,986,830	1/22/1991	Owens, et al.	
		US 5,209,741	5/11/1993	Spaeth	
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		US 5,425,762	6/20/1995	Muller	
		US 5,443,495	8/22/1995	Buscemi, et al.	
		US 5,545,133	8/13/1996	Burns, et al.	
		US 5,843,158	12/1/1998	Lenker, et al.	
		US 5,910,154	06/08/1999	Tsugita et al.	
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		US 6,027,520	02/22/2000	Tsugita et al.	
		~~US 6,143,987~~ 6,142,987	11/07/2000	Tsugita	
		US 6,165,200	12/26/2000	Tsugita et al.	
		US 6,168,579	01/02/2001	Tsugita	
		US 6,171,327	01/09/2001	Daniel et al.	
		US 6,179,859	01/30/2001	Bates	
		US 6,270,513	08/07/2001	Tsugita et al.	
		US 6,336,934	01/08/2002	Gilson et al.	
		US 6,537,297	03/25/2003	Tsuigita et al.	
		US 6,540,768	04/01/2003	Diaz et al.	
		US 6,592,614	7/15/2003	Lenker, et al.	
V		US 6,676,698	01/13/2004	McGuckin, Jr. et al.	
AS		US 6,695,864	02/24/2004	Macoviak et al.	

6/29/10

Examiner Signature	AS	Date Considered	9/11/07

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	5	of	12

Complete if Known	
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AS		US-5,876,448	03/02/1999	Thompson et al.	
		US-5,888,201	03/30/1999	Stinson et al.	
		US-5,891,191	04/06/1999	Stinson	
		US-5,907,893	06/01/1999	Zadno-Azizi et al.	
		US-5,925,063	07/20/1999	Khosravi	
		US-5,944,738	08/31/1999	Amplatz et al.	
		US-5,954,766	09/21/1999	Zadno-Azizi et al.	
		US-5,957,949	09/28/1999	Leonhardt et al.	
		US-5,984,957	11/16/1999	Laptewicz, Jr. et al.	
		US-6,022,370	02/08/2000	Tower	
		US-6,027,525	02/22/2000	Suh et al.	
		US-6,042,598	03/28/2000	Tsugita et al.	
		~~US-6,051,104~~ 6,051,014	04/18/2000	Jang	
		US-6,123,723	09/26/2000	Konya et al.	
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		US-6,221,006	04/24/2001	Dubrul et al.	
		US-6,221,091	04/24/2001	Khosravi	
		US-6,241,757	06/05/2001	An et al.	
		US-6,245,102	06/12/2001	Jayaraman	
		US-6,258,114	07/10/2001	Konya et al.	
		US-6,258,115	07/10/2001	Dubrul	
		US-6,258,120	07/10/2001	McKenzie et al.	
		US-6,277,555	08/21/2001	Duran et al.	
V		US-6,309,417	10/30/2001	Spence et al.	
AS		US-6,319,281	11/20/2001	Patel	

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	Complete if Known
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207.710.201

Sheet 4 of 12

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AS		US-5,217,483	07/08/1993	Tower	
		US-5,217,483	07/08/1993	Tower	
		US-5,332,402	07/26/1994	Teitelbaum et al.	
		US-5,350,398	09/27/1994	Pavcnik et al.	
		US-5,370,685	12/16/1994	Stevens	
		US-5,389,106	02/14/1995	Tower	
		US-5,397,351	03/14/1995	Pavcnik et al.	
		US-5,411,552	05/02/1995	Andersen et al.	
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		US-5,545,211	08/13/1996	An et al.	
		US-5,575,818	11/19/1996	Pinchuk	
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		US-5,817,126	10/06/1998	Imran	
		US-5,824,043	10/20/1998	Cottone Jr.	
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		US-5,855,597	01/05/1999	Jayaraman	
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		US ~~5,860,996~~ 5,860,966	01/19/1999	Tower	
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AS		US-5,868,783	02/09/1999	Tower	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 12

	Complete if Known
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned
Attorney Docket Number	30207.710.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[3] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AB		US-2001/0025196	09/27/2001	Chinn et al.	
		US-2001/0032013	10/18/2001	Marton	
		US-2001/0039450	11/08/2001	Pavenik et al.	
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		US-2003/0125795	07/03/2003	Pavenik et al.	
		US-2003/0149476 08/2003	~~07/08/2003~~	Damm et al.	
		US-2003/0130729	07/10/2003	Paniagua et al.	
		US-2003/0149475	08/07/2003	Hyodoh et al.	
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Examiner Signature	AB	Date Considered	9/11/07

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	Complete if Known
Application Number	10/870,340
Filing Date	06/16/2004
First Named Inventor	Haug
Art Unit	3738
Examiner Name	Not yet assigned
Sheet 4 of 12	Attorney Docket Number 30207.710.201

U.S. PATENT DOCUMENTS

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		US-5,332,402	07/26/1994	Teitelbaum et al.	
		US-5,350,398	09/27/1994	Pavcnik et al.	
		US-5,370,685	12/16/1994	Stevens	
		US-5,389,106	02/14/1995	Tower	
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		US-5,411,552	05/02/1995	Andersen et al.	
		US-5,431,676	07/11/1995	Dubrul et al.	
		US-5,507,767	04/16/1996	Maeda et al.	
		US-5,545,211	08/13/1996	An et al.	
		US-5,575,818	11/19/1996	Pinchuk	
		US-5,645,559	07/08/1997	Hachtman et al.	
		US-5,674,277	10/07/1997	Freitag	
		US-5,695,498	12/09/1997	Tower	
		US-5,713,953	02/03/1998	Vallana et al.	
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		US-5,824,043	10/20/1998	Cottone Jr.	
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AS		US-5,868,783	02/09/1999	Tower	

Examiner Signature	AS	Date Considered	9/11/07

6/30/10

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/870,340
Filing Date	June 16, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.201

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	380	US- 5,720,391 A	2/24/1998	Dohm et al.	
	377	US- 6,712,842	3/30/2004	Gifford et al.	
	384	US- 7,018,406	3/28/2006	Seguin et al.	
	381	US- 2001/0044656 A1	11/22/2001	Williamson et al.	
	382	US- 2002/0032481 A1	3/14/2002	Gabbay, Shlomo	
	379	US- 2002/0120328 A1	8/29/2002	Pathak et al.	
	378	US- 2004/0215331	10/28/2004	Chew et al.	
	383	US- 2006/0259134 A1	11/16/2006	Schwammenthal et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	385	~~WO 02/0041789 A2~~	5/30/2002	Rex Medical, L. P.		
		WO 02/41789 A2				

6/30/10

Examiner Signature	/Ann Schillinger/	Date Considered	02/29/2008

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AS/

PART B - FEE(S) TRANSMITTAL

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Sue Bromaghim	(Depositor's name)
FILED VIA EFS	(Signature)
July 12, 2010	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	06/16/2004	Amr Salahieh	10012-710.201	7111

TITLE OF INVENTION: EVERTING HEART VALVE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	07/14/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
SCHILLINGER, ANN M	3774	623-021000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
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1 Shay Glenn LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Sadra Medical, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Los Gatos, CA

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 504050 (enclose an extra copy of this form).

/X/ Payment via EFS

5. **Change in Entity Status** (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature Thomas M. Zlogar Date July 12, 2010

Typed or printed name Thomas M. Zlogar Registration No. 55,760

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal

Application Number:	10870340
Filing Date:	16-Jun-2004
Title of Invention:	EVERTING HEART VALVE
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	James R. Shay/Sue Bromaghim (TZ)
Attorney Docket Number:	10012-710.201

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	2501	1	755	755
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1055**

Electronic Acknowledgement Receipt

EFS ID:	7998147
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	EVERTING HEART VALVE
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	James R. Shay/Sue Bromaghim (TZ)
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10012-710.201
Receipt Date:	12-JUL-2010
Filing Date:	16-JUN-2004
Time Stamp:	17:45:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1055
RAM confirmation Number	4459
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Issue Fee Payment (PTO-85B)	10012-710-201-Issue_Fee.pdf	236817 b6db4a09b15c937baf242b8b4b87bb5de3c56254	no	1
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	31592 6d4096460cd580d7a9ef29bee15c7c88d797aefd	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	268409		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/870,340	08/24/2010	7780725	10012-710.201	7111

66854 7590 08/04/2010

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 1188 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Amr Salahieh, Saratoga, CA;
Ulrich R. Haug, Campbell, CA;
Hans F. Valencia, Berkeley, CA;
Robert A. Geshlider, San Francisco, CA;
Tom Saul, El Granada, CA;
Dwight P. Morejohn, Davis, CA;
Kenneth J. Michlitsch, Livermore, CA;

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch
Application No.:	10/870340
Filed:	June 16, 2004
For:	Everting Heart Valve
Examiner:	Ann M. Schillinger
Group Art Unit:	3774

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No: S63.2B-15141-US01

REVOCATION OF POWER OF ATTORNEY AND APPOINTMENT OF NEW ATTORNEY

I hereby revoke all previous powers of attorney given in the above identified application.

I hereby appoint all practitioners associated with Customer Number 00490 as my/our attorney(s) or (agent(s) to prosecute the above identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please address all future correspondence to James M. Urzedowski at Customer Number 00490.

I am the:

□ Applicant/Inventor

■ Assignee of record of the entire interest. *(See 37 CFR 3.71)*
Statement under 37 CFR 3.73(b) or copy of previously filed 3.73(b) statement is enclosed.

Respectfully submitted,

SADRA MEDICAL, INC.

Date: 2/9/11

By: _____
Name: Ken Martin
Title: President & CEO

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch
Application No.:	10/870340
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No: S63.2B-15141-US01

NOTIFICATION OF CHANGE OF ENTITY STATUS

Applicant is no longer entitled to claim small entity status. Please update the record to reflect large entity status for this case.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

Electronic Acknowledgement Receipt

EFS ID:	9430984
Application Number:	10870340
International Application Number:	
Confirmation Number:	7111
Title of Invention:	EVERTING HEART VALVE
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	James M. Urzedowski/Samantha Painschab
Filer Authorized By:	James M. Urzedowski
Attorney Docket Number:	10012-710.201
Receipt Date:	11-FEB-2011
Filing Date:	16-JUN-2004
Time Stamp:	17:35:09
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US01_tra_20110211.pdf	84793 dc3889afc64b023cc16af166aa6c2fafc1b37c8d	no	1

Warnings:	
Information:	

2	Assignee showing of ownership per 37 CFR 3.73(b).	15141US01_sta_20110207.pdf	70516 c78e231847a5a7db6d91d5167eaa3feff91e778f	no	1
Warnings:					
Information:					
3	Power of Attorney	15141US01_exeuctedPOA.pdf	27661 1400723c17650cdd1167842bd2201dff9c8811d5	no	1
Warnings:					
Information:					
4	Miscellaneous Incoming Letter	15141US01_entity_status_20110211.pdf	66841 84224a7d61dcfb7dafebf69b18d4b2e0fcd87905	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	249811		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch
Application No.:	10/870340
Filed:	June 16, 2004
For:	Everting Heart Valve
Examiner:	Ann M. Schillinger
Group Art Unit:	3774

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No: S63.2B-15141-US01

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
1 page Revocation of Power of Attorney and Appointment of New Attorney; 1 page Assignee's Statement of Ownership and 1 page Notification of Change of Entity Status.

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on February 11, 2011.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
f:\wpwork\jmu\15141us01_tra_20110211.doc

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch
Application No.:	10/870340
Filed:	June 16, 2004
For:	Everting Heart Valve
Examiner:	Ann M. Schillinger
Group Art Unit:	3774

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No: S63.2B-15141-US01

ASSIGNEE'S STATEMENT OF OWNERSHIP 37 CFR 3.73(B)

Sadra Medical, Inc., a corporation, is the assignee of the entire right, title and interest in the patent application identified above by virtue of a chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From : Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Kenneth Michlitsch
   To: Sadra Medical, Inc.
   The document was recorded in the Patent and Trademark Office at Reel 015421, Frame 0038, or for which a copy thereof is attached.

The undersigned is empowered to sign this statement of ownership certificate on behalf of the assignee.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
f:\wpwork\jmu\15141us01_sta_20110207.doc

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/870,340	06/16/2004	Amr Salahieh	10012-710.201

CONFIRMATION NO. 7111

POWER OF ATTORNEY NOTICE

66854
SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

OC00000046090015

Date Mailed: 02/18/2011

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2011.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/erimando/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/870,340	06/16/2004	Amr Salahieh	S63.2B-15141-US01

CONFIRMATION NO. 7111

490
VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

POA ACCEPTANCE LETTER

OC00000046090044

Date Mailed: 02/18/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2011.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/erimando/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
10/870,340	06/16/2004	3774	1541	S63.2B-15141-US01	67	5

CONFIRMATION NO. 7111

CORRECTED FILING RECEIPT

490
VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

Date Mailed: 02/23/2011

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Amr Salahieh, Saratoga, CA;
Ulrich R. Haug, Campbell, CA;
Hans F. Valencia, Berkeley, CA;
Robert A. Geshlider, San Francisco, CA;
Tom Saul, El Granada, CA;
Dwight P. Morejohn, Davis, CA;
Kenneth J. Michlitsch, Livermore, CA;

Power of Attorney: The patent practitioners associated with Customer Number 00490

Domestic Priority data as claimed by applicant

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)

If Required, Foreign Filing License Granted: 08/03/2004

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 10/870,340**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

EVERTING HEART VALVE

Preliminary Class

623

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).