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(54) REPOSITIONABLE HEART VALVE

NEUPOSITIONIERBARE HERZKLAPPE

VALVE CARDIAQUE REPOSITIONNABLE

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Description

BACKGROUND OF THE INVENTION

[0001] The present invention relates to an apparatus for endovascularly replacing a heart valve as set forth in the claims

[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.

[0004] 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.

[0005] 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.

[0006] 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.

[0007] In recent years, advancements in minimally invasive surgery and interventional cardiology have encouraged some investigators to pursue percutaneous replacement of the aortic heart valve. Percutaneous Valve Technologies ("PVT") of Fort Lee, New Jersey, has developed a balloon-expandable stent integrated with a bioprosthetic valve. The stent/valve device 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 bioprosthetic valve in place of the native valve. PVT's device is designed for delivery in a cardiac catheterization laboratory under local anesthesia using fluoroscopic guidance, thereby avoiding general anesthesia and open-heart surgery. The device was first implanted in a patient in April of 2002.

[0008] PVT's device suffers from several drawbacks. Deployment of PVT's stent is not reversible, and the stent is not retrievable. This is a critical drawback because improper positioning too far up towards the aorta risks blocking the coronary ostia of the patient. Furthermore, a misplaced stent/valve in the other direction (away from the aorta, closer to the ventricle) will impinge on the mitral apparatus and eventually wear through the leaflet as the leaflet continuously rubs against the edge of the stent/valve.

[0009] Another drawback of the PVT device is its relatively large cross-sectional delivery profile. The PVT system's stent/valve combination is mounted onto a delivery balloon, making retrograde delivery through the aorta challenging. An antegrade transseptal approach may therefore be needed, requiring puncture of the septum and routing through the mitral valve, which significantly increases complexity and risk of the procedure. Very few cardiologists are currently trained in performing a transseptal puncture, which is a challenging procedure by itself.

[0010] Other prior art replacement heart valves use self-expanding stents as anchors. 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.

[0011] 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.

[0012] 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 plastically deforming.

[0013] 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.

[0014] U.S. patent application Serial No. 2002/0151970 to Garrison et al. describes a two-piece device for replacement of the aortic valve that is adapted for delivery through a patient's aorta. A stent is percutaneously placed across the native valve, then a replacement valve is positioned within the lumen of the stent. By separating the stent and the valve during delivery, a profile of the device's delivery system may be sufficiently reduced to allow aortic delivery without requiring a transseptal approach. Both the stent and a frame of the replacement valve may be balloon-expandable or self-expanding.

[0015] While providing for an aortic approach, devices described in the Garrison patent application suffer from several drawbacks. First, the stent portion of the device is delivered across the native valve as a single piece in a single step, which precludes dynamic repositioning of the stent during delivery. Stent foreshortening or migration during expansion may lead to improper alignment.

[0016] Additionally, Garrison's stent simply crushes the native valve leaflets against the heart wall and does not engage the leaflets in a manner that would provide positive registration of the device relative to the native position of the valve. This increases an immediate risk of blocking the coronary ostia, as well as a longer-term risk of migration of the device post-implantation. Furthermore, the stent comprises openings or gaps in which the replacement valve is seated post-delivery. Tissue may protrude through these gaps, thereby increasing a risk of improper seating of the valve within the stent.

[0017] In view of drawbacks associated with previously known techniques for percutaneously replacing a heart valve, it would be desirable to provide methods and apparatus that overcome those drawbacks.

[0018] WO 95/28899 describes a surgically implantable stented bioprosthetic heart valve comprising a ring-shaped suturing cuff at the inflow portion of the valve.

[0019] US 2001/0039450 describes a venous valve device having a generally serpentine shape and a corner flap.

SUMMARY OF THE INVENTION

[0020] The present invention is directed to an apparatus for endovascularly replacing a patient's heart valve as set forth in the appended claims. The apparatus comprises an expandable cylindrical anchor supporting a replacement valve. The anchor has a delivery configuration and a deployed configuration. The apparatus has at least one sac disposed about the exterior of the anchor to provide a seal.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021]

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

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

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.

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.

Figures 5A-I show the use of a replacement heart valve and anchor to replace an aortic valve.

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

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

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

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

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

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

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

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

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

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

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

Figure 17 shows an alternative embodiment of a replacement heart valve and anchor and a deployment tool according to the invention in an undeployed configuration.

Figure 18 shows the replacement heart valve and anchor of Figure 17 in a partially deployed configuration.

Figure 19 shows the replacement heart valve and anchor of Figures 17 and 18 in a more fully deployed configuration but with the deployment tool still attached.

Figure 20 shows yet another embodiment of the delivery and deployment apparatus of the invention in

use with a replacement heart valve and anchor.
Figure 21 shows the delivery and deployment apparatus of Figure 20 in the process of deploying a replacement heart valve and anchor.
Figure 22 shows an embodiment of the invention employing seals at the interface of the replacement heart valve and anchor and the patient's tissue.
Figure 23 is a longitudinal cross-sectional view of the seal shown in Figure 22 in compressed form.
Figure 24 is a transverse cross-sectional view of the seal shown in Figure 23.
Figure 25 is a longitudinal cross-sectional view of the seal shown in Figure 22 in expanded form.
Figure 26 is a transverse cross-sectional view of the seal shown in Figure 25.
Figure 27 shows yet another embodiment of the replacement heart valve and anchor of this invention in an undeployed configuration.
Figure 28 shows the replacement heart valve and anchor of Figure 27 in a deployed configuration.
Figure 29 shows the replacement heart valve and anchor of Figures 27 and 28 deployed in a patient's heart valve.
Figures 30A-H show yet another embodiment of a replacement heart valve, anchor and deployment system according to this invention.
Figures 31A-E show more detail of the anchor of the embodiment shown in Figures 30A-H.
Figures 32A-B show further details of the embodiment of Figures 30A-H.
Figures 33 A-C illustrate a method for percutaneously replacing a patient's diseased heart valve.
Figures 34A and 34B show replacement valve apparatus in accordance with the present invention. Figure 34 illustrates the apparatus in a collapsed delivery configuration within a delivery system. Figure 34B illustrates the apparatus in an expanded configuration partially deployed from the delivery system.
Figures 35A-35F show an anchor of the apparatus of Figures 34 in the collapsed delivery configuration and the expanded deployed configuration, as well as the full apparatus in the deployed configuration, and optional locking mechanisms for use with the apparatus.
Figure 36 is a schematic top view of an apparatus for fabricating braided anchors in accordance with the present invention.
Figures 37A-37D are schematic top views illustrating a method of using the apparatus of Figure 36 to fabricate a braided anchor of the present invention.
Figures 38A-38O are schematic detail views illustrating features of braid cells at an anchor edge.
Figures 39A-39E illustrate further features of braid cells at an anchor edge.
Figures 40A-40J are schematic detail views terminations for one or more wire strands forming anchors of the present invention.
Figures 41 A and 41B are schematic side views of alternative embodiments of the anchor portion of the apparatus of the present invention.
Figures 42A-42E are schematic side views of further alternative embodiments of the of the anchor portion of the apparatus of the present invention.
Figures 43A-43D are schematic views of different weave configurations.
Figures 44A-44E are schematic side views of various braided anchor configurations.
Figures 45A-45E are schematic side views of a deployment process.
Figures 46A and 46B illustrate a braided anchor in the heart.
Figures 47A and 47B illustrate a bilaterally symmetrical anchor and an asymmetric anchor, respectively.
Figure 48 illustrates a braided anchor of the present invention with closed end turns Tu.
Figures 49A-49E illustrate additional features for end turns of a braided anchor.
Figures 50A-50F illustrate deployment of an anchor with leaflet engagement elements on the deployment system.
Figure 51 illustrates a deployed anchor with leaflet engagement elements on the proximal end of the anchor.
Figures 52A-52C illustrate deployment of an anchor with anchor registration elements and a seal.
Figures 53A-53B illustrate an embodiment of the apparatus with a seal that does not reach the proximal end of the anchor during both systole and diastole.
Figures 54A-54B illustrate an embodiment of the apparatus with a seal that reaches the proximal end of the anchor during both systole and diastole.

DETAILED DESCRIPTION

[0022] The present invention relates to apparatus and methods for endovascularly or percutaneously delivering and deploying a prosthesis, e.g., an aortic prosthesis, within and/or across a patient's native heart valve, referred to hereinafter as replacing the patient's heart valve. A delivery system and/or deployment tool is provided including a sheath assembly and a guidewire for placing the prosthetic apparatus endovascularly within the patient and a user control allowing manipulation of the prosthetic apparatus from external to the patient through the application of a non-hydraulically expanding or non-pneumatically expanding force on the anchor. A hydraulically or pneumatically expanding force would be, for example, a force applied to the anchor by a balloon expanded within the anchor. In certain embodiments, the application of a non-hydraulically expanding or non-pneumatically expanding force could include the use of a hydraulic component transmitting a proximally or distally directed force on an anchor.
[0023] The apparatus includes an anchor and a replacement valve. The anchor includes an expandable anchor such as a braid. In preferred embodiments, the

expandable braid includes closed edges, but the edges may alternatively be open. The replacement valve is adapted to be secured within the anchor, and as such, be delivered endovascularly to the patient's heart to replace one of the patient's native heart valves. More preferably, the apparatus and methods of the present invention contemplate replacement of the patient's aortic valve.

[0024] 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.

[0025] 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.

[0026] 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 it's final shape by means of balloon expansion. Replacement valve 20 is preferably from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues, alternatively it can be made from tissue engineered materials (such as extracellular matrix material from Small Intestinal Submucosa (SIS)) but alternatively may be prosthetic 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 posts 38.

[0027] 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.

[0028] 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 actuators 50, control actuators 60 (embodied here as rods or tubes) and proximal region control actuators 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 actuators 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 actuators 50 may comprise, for example, strands of suture or wire.

[0029] Actuators 60 are reversibly coupled to apparatus 10 and may be used in conjunction with actuators 50 to actuate anchor 30, e.g., to foreshorten and lock apparatus 10 in the fully deployed configuration. Actuators 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 actuators 60 while proximally retracting actuators 50. As seen in Figures 3, control actuators 62 pass through interior lumens 61 of actuators 60. This ensures that actuators 60 are aligned properly with apparatus 10 during deployment and foreshortening. Control actuators 62 can also actuate anchor 60; proximally directed forces on control actuators 62 contacts the proximal lip region 32 of anchor 30. Actuators 62 also act to couple and decouple actuators 60 from apparatus 10. Actuators 62 may comprise, for example, strands of suture or wire.

[0030] Figures 1A and 2A illustrate anchor 30 in a delivery configuration or in a partially deployed configuration (e.g., after dynamic self-expansion 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.

[0031] In Figures 1A and 2A, replacement valve 20 is collapsed within lumen 31 of anchor 30. Retraction of actuators 50 relative to actuators 60 foreshortens anchor 30, which increases the anchor's width while decreasing its length. Such foreshortening also properly seats re-

placement 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 exerts an outward force on surrounding tissue to engage the tissue in such way to prevent migration of anchor caused by force of blood against closed leaflet during diastole. This anchoring force is preferably 0,454 kg to 0,907 kg [1 to 2 lbs], more preferably 0,907 kg to 1,814 kg [2 to 4 lbs], or more preferably 1,814 kg to 4,536 kg [4 to 10 lbs]. In some embodiments, the anchoring force is preferably greater than 0,454 kg [1 pound], more preferably greater than 0,907 kg [2 pounds], or more preferably greater than 1,814 kg [4 pounds]. 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 is trapped in the anchor. This feature would provide additional means to prevent anchor migration and enhance long term stability of the device.

[0032] 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 actuators 60 from lip section 32 of anchor 30 by retracting one end of each actuator 62 relative to the other end of the actuator, and by retracting one end of each actuator 50 relative to the other end of the actuator until each actuator has been removed from eyelet 45 of its corresponding male interlocking element 44.

[0033] 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.

[0034] 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 actuators 50 and actuators 60, which causes anchor 30 to dynamically self-expand to a partially deployed configuration. Control actuators 50 then are retracted relative to apparatus 10 and actuators 60 to impose foreshortening upon anchor 30, as seen in Figure 3B.

[0035] During foreshortening, actuators 60 push against lip region 32 of anchor 30, while actuators 50 pull on posts 38 of the anchor. Actuators 62 may be retracted along with actuators 50 to enhance the distally-directed pushing force applied by actuators 60 to lip region 32. Continued retraction of actuators 50 relative to actuators 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, actuators 50 and 62 may be removed from apparatus 10, thereby separating delivery system 100 including actuators 60 from the apparatus.

[0036] 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 actuators 50 and/or control actuators 62 and the distally directed forces exerted by actuators 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 actuators 50 and actuators 60/actuators 62 relative to sheath 110. Apparatus 10 then may be removed from the patient or repositioned for subsequent redeployment.

[0037] 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, actuators 50 and actuators 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 actuators 60 to properly orient the apparatus, e.g. relative to a patient's native valve leaflets.

[0038] In Figure 4B, control actuators 50 are retracted while actuators 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.

[0039] 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. Actuators 50 are then pulled through eyelets 45 of male elements 44 to remove the actuators from apparatus 10, and actuators 62 are pulled through the proximal end of anchor 30 to uncouple actuators 60 from the apparatus, thereby separating delivery system 100 from apparatus

10. Fully deployed apparatus 10 is shown in Figure 4F.

[0040] Referring to Figures 5, a method of percutaneously replacing a patient's diseased aortic valve with apparatus 10 and delivery system 100 is described. As seen in Figure 5 A, sheath 110 of delivery system 100, having apparatus 10 disposed therein, is percutaneously 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.

[0041] 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 actuators 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 actuators 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.

[0042] Once properly aligned, actuators 50 are retracted relative to actuators 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.

[0043] As seen in Figure 5F, actuators 50 have been pulled from eyelets 45 of male elements 44 of locks 40, actuators 60 are decoupled from anchor 30, e.g. via actuators 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 further preclude migration of the apparatus and/or reduce paravalvular regurgitation.

[0044] Figures 5G and 5H show further details of deployment using a deployment apparatus. Apparatus 10 is deployed from lumen Lu of sheath 110, for example, under fluoroscopic guidance by proximally retracting proximal handle 111 of sheath 110 relative to shaft 108, such that anchor 30 of apparatus 10 dynamically self-expands to the partially deployed configuration of Figure 5C. Advantageously, apparatus 10 may be retracted within lumen Lu of sheath 110 by retracting shaft 108 relative to the sheath, and thereby retracting actuators 106a coupled to anchor 30 relative to sheath 110. In this manner, anchor 30 may be retrieved even after the anchor 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, 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, a distal region of anchor 30 preferably is disposed distal of the leaflets, while a central region of the anchor is disposed across the leaflets and a proximal region is disposed proximal of the leaflets.

[0045] Once properly aligned, actuators 106b are proximally retracted relative to actuators 106a, e.g., via knob 126 of handle 120, to impose foreshortening upon anchor 30 and further 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. Lock 40 formed by engaging post lock elements 44 of posts 32 with anchor lock elements 34 of anchor 30 maintains imposed foreshortening. Replacement valve 20 is properly seated within anchor 30, and normal blood flow between left ventricle LV and aorta A is thereafter completely regulated by apparatus 10, although valve 20 is functional during deployment as well. Deployment of apparatus 10 advantageously is fully reversible until the locks have been actuated. Releasable lock prevention mechanisms may be provided to ensure that the locks are not actuated prematurely. Furthermore, the locks may be reversible, such that apparatus 10 may be retrieved or repositioned even after actuation of the locks.

[0046] Once apparatus 10 is fully expanded and locked in the expanded configuration, actuators 106a are decoupled from anchor 30 by actuating releasable attachment mechanisms, e.g., by retracting release actuators 112 relative to the actuators 106a via knob 122 of handle 120. Likewise, actuators 106b are decoupled from posts 32 by actuating releasable attachment mechanisms, e.g., by retracting release actuators 112 relative to the actuators 106b via knob 124 of handle 120. As seen in Figure 5E, delivery system 100 then may be 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 to reduce paravalvular regurgitation.

[0047] With reference now to Figures 6, a method of percutaneously 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.

[0048] Delivery system 100' comprises leaflet engagement element 120, which preferably self-expands along with anchor 30. Engagement element 120 is disposed between actuators 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 arid element 120 then may be advanced/dynamically repositioned until 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 actuators 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.

[0049] 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, actuators 50 and actuators 60 are decoupled from the apparatus, and delivery system 100' is removed from the patient, thereby completing the procedure.

[0050] 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.

[0051] 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 8 A, apparatus 10" comprises anchor 30' that maybe 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, actuators 50 and 62 and actuators 60 maybe 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, actuators 50 and 62 and actuators 60 are removed from apparatus 10", and delivery system 100" is removed, as seen in Figure 8C.

[0052] 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 3,04 to 6,08 bar [3 to 6 atm], or more preferably from about 4,05 to 5,07 bar [4 to 5 atm], though higher and lower bar [atm] pressures may also be used (e.g., greater than 3,04 bar [3 atm], more preferably greater than 4,05 bar [4 atm], more preferably greater than 5,07 bar [5 atm], or more preferably greater than 6,08 bar [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.

[0053] 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 actuators 50 and actuators 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".

[0054] 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 0.0889 mm [0.035"], therethrough. Push actuators 60 and pull actuators 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.

[0055] 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.

[0056] In Figure 9C, pull actuators 50 and push actuators 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.

[0057] 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 actuators 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.

[0058] 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.

[0059] Referring now to Figures 11, alternative locks for use with apparatus of the present invention are described. In Figure 11 A, 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.

[0060] In Figure 11 B, 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 actuator 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".

[0061] 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.

[0062] 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"'.

[0063] 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.

[0064] 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.

[0065] 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.

[0066] With reference to Figures 15, illustrative arrangements for sacs 200 are provided. In Figure 15 A, 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.

[0067] With reference to Figures 16, exemplary techniques for fabricating sacs 200 are provided. In Figure 16A, sacs 20 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.

[0068] Figures 17-19 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. 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 confrol actuators (not shown) and actuators 352.

[0069] Figures 20 and 21 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, expandable balloon cathether 360 precedes sheath 110 on guidewire G. When anchor 30 and valve 20 are expanded through the operation of actuators 60 and the control actuators (not shown) as described above, balloon cathether 360 is retracted proximally within the expanded anchor and valve and expanded further as described above with respect to Figures 8.

[0070] Figures 22-26 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 23 and 24, 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 25 and 26.

[0071] Figures 27-29 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 28 and 29, 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.

[0072] Figures 30A-H show another embodiment of a replacement heart valve apparatus in accordance with the present invention. Apparatus 450 comprises replacement valve 460 (see Figures 32B and 33C) 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 herein below, 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.

[0073] As seen in Figure 30A, 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 actuators 424a and 424b seen in Figures 30D-30G. Actuators 424a are configured to expand skirt region 474 of anchor 470, as well as replacement valve 460 coupled thereto, while actuators 424b are configured to expand lip region 472.

[0074] As seen in Figure 30B, 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 30B-30D, catheter 420 is retracted relative to apparatus 450, which causes anchor 470 to dynamically self-expand to a partially deployed configuration. Actuators 424a are then retracted to expand skirt region 474, as seen in Figures 30E and 30F. Preferably, such expansion may be maintained via locking features described hereinafter.

[0075] In Figure 30G, actuators 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, actuators 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 30H.

[0076] 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.

[0077] With reference now to Figures 31A-E, individual cells of anchor 470 of apparatus 450 are described to detail deployment and expansion of the apparatus. In Figure 31A, 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 30. A portion of the cells forming body regions 476, for example, every 'nth' row of cells, comprises locking features.

[0078] 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.

[0079] In Figure 31B, 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 refracting actuators 424 relative to anchor 470, and expanding lip region 472 and skirt region 474 outward, as seen in Figures 31C and 31D. As seen in Figure 31E, 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 31E). Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated.

[0080] With reference to Figures 32A-B, isometric views, partially in section, further illustrate apparatus 450 in the fully deployed and expanded configuration. Figure 32A illustrates the wireframe structure of anchor 470, while Figure 32B 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 32B. 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 33B).

[0081] Referring to Figures 33 A-C, in conjunction with Figures 30 and 31, a method for percutaneously replacing a patient's diseased aortic valve with apparatus 450 is described. Delivery system 410, having apparatus 450 disposed therein, is percutaneously 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 30, 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 refracted within lumen 422 of sheath 420 via actuators 424, even after anchor 470 has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition sheath 420.

[0082] Once properly positioned, elements 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 31. In Figure 33 A, 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.

[0083] Elements 424b are then actuated external to the patient in order to expand lip region 472, as previously described in Figures 30. 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. Elements 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.

[0084] As seen in Figure 33B, 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 33C 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.

[0085] Figures 34A and 34B illustrate one embodiment of a delivery system/deployment tool and apparatus in accordance with the present invention. As seen in Figure

34 A, apparatus 10 may be collapsed for delivery within delivery system/deployment tool 100. Delivery system 100 includes guidewire G, nosecone 102, anchor actuation elements 106, multi-lumen shaft or catheter 108 having optional central lumen 109 and a plurality of circumferentially disposed lumens Lu, external sheath 110 having optional proximal handle 111, and confrol handle 120. Nosecone 102 may, for example, be manipulated via a shaft extending through central lumen 109 of multi-lumen catheter 108.

[0086] Anchor actuation elements 106 preferably comprise both proximal anchor actuation elements and distal anchor actuation elements. The proximal anchor actuation elements may, for example, comprise actuators 106a that are releasably coupled to a proximal region of anchor 30 of apparatus 10 via releasable attachment mechanisms for manipulating a proximal region of apparatus 10. The distal anchor actuation elements may comprise actuators 106b that are releasably coupled to a distal region of anchor 30 via releasable attachment mechanisms for manipulating the distal region of apparatus 10. In some embodiments, the distal anchor actuation elements may comprise posts or anchor attachment elements 32 of anchor 30 and the releasable attachment mechanisms connecting actuators 106b to posts 32. In an alternative configuration, the proximal anchor actuation elements may be releasably coupled to a proximal region of apparatus 10 through posts and releasable attachment mechanisms for manipulation of a proximal region of the apparatus, while the distal anchor actuation elements may connect to a distal region of anchor 30 via releasable attachment mechanisms to manipulate a distal region of the apparatus. As another alternative, both proximal and distal anchor actuation element may connect to anchor 30 via releasable attachment mechanisms.

[0087] In the embodiment shown in Figures 34, actuators 106a may, for example, include stiff finger elements extending from a distal region of multi-lumen shaft 108, while actuators 106b may include control elements (e.g., stands of suture, or metal or polymer wires) which pass through one or more lumens Lu of shaft 108. Release actuators 112 for the releasable attachment mechanisms for both sets of actuators also may pass through one or more lumens Lu of shaft 108. The release actuators may comprise, for example, control elements (e.g., strands of suture, or metal or polymer wires), covers, mandrels, elongated elements, friction surfaces, wrap portions, interference shapes, etc. The release actuators preferably are movable relative to anchor actuation elements 106, e.g., via control handle 120.

[0088] Control handle 120 is coupled to multi-lumen shaft 108. Knob 122 disposed in slot 123 may actuate release actuators 112 that couple actuators 106a of anchor actuation elements 106 to apparatus 10. Likewise, knob 124 disposed in slot 125 may actuate release actuators 112 that couple actuators 106b of anchor actuation elements 106 to posts 32 of anchor 30 of apparatus 10. Handle 120 also comprises knob 126 for, e.g., manipulating the actuators 106b to control movement of the distal region of apparatus 10 relative to its proximal region. Conversely, controlled movement of the proximal region of apparatus 10 relative to its distal region may be achieved by holding knob 126 stationary while advancing or retracting handle 120. Knob 126 optionally may move actuators 106b in unison with their concomitant release actuators 112.

[0089] Apparatus 10 comprises anchor 30 and replacement valve 20. Anchor 30 preferably comprises a braid. Such braid can have closed ends at either or both its ends. Replacement valve 20 is preferably coupled to the anchor along posts 32, e.g., along a valve attachment structure, such as a tab and/or a plurality of holes. Posts 32, therefore, may function as valve supports and may be adapted to support the replacement valve within the anchor, h the embodiment shown, there are three posts, corresponding to the valve's three commissural attachment points. The posts can be attached to the braid portion of anchor 30. The posts can be attached to the braid's distal end, as shown in Figure 35A, central region, or proximal end. Replacement valve 20 can be composed of a synthetic material and/or may be derived from animal tissue. Replacement valve 20 is preferably configured to be secured within anchor 30.

[0090] Anchor 30 comprises a plurality of anchor lock elements 34, e.g., buckles 34, attached to its proximal region, one for each post 32. Posts 32 may comprise a lock element that forms a two-part locking mechanism with anchor lock elements 34 for maintaining anchor 30 in a deployed or expanded configuration (e.g., as illustrated in Figures 34B, 35B and 35C).

[0091] In this embodiment, anchor 30 is formed from a collapsible and expandable wire braid. Anchor braid 30 is preferably self-expanding and is preferably formed from a material such as Nitinol, cobalt-chromium steel or stainless steel wire using one or more strands of wire. Delivery and deployment of braided anchor 30 is similar to the delivery and deployment of the anchors described in U.S. Patent Appl. Ser. No. 10/746,120. Specifically, in one embodiment described below, during deployment braided anchor 30 is actively foreshortened by proximally retracting the actuators 106b relative to the actuators 106a to expand and lock the anchor in place. In some embodiments, foreshortening may expand anchor 30 to a radially symmetrical, bilaterally symmetrical, or asymmetrical expanded shape. The foreshortening step can include expanding a first region of the anchor to a first diameter and a second region of the anchor to a second diameter larger than the first diameter. A third region may also be expanded to a diameter larger than the first diameter. The expansion of various regions of the anchor (e.g., the distal region) can be especially useful in locating the aortic valve and centering the anchor within it. Preferably, the secured anchor does not interfere with the mitral valve or the ostia. In some embodiments, the anchor is allowed to self-expand prior to the foreshortening

step.

[0092] As seen in Figures 34, after endovascular delivery through sheath 110 to the vicinity of the patient's native valve (such as the aortic valve), apparatus 10 may be expanded from the collapsed delivery configuration of Figure 34 A to the expanded deployed configuration of Figure 34B using delivery system/deployment tool 100. To deploy apparatus 10, external sheath 110 may be retracted relative to apparatus 10 by proximally retracting sheath handle 111 relative to control handle 120. Sheath 110 is thereby removed from the exterior of apparatus 10, permitting the anchor 30 to self-expand. For example, if anchor braid 30 is composed of a shape memory material, it may self-expand to or toward its "at-rest" configuration. This at-rest configuration of the braid can be, for example its expanded configuration, a collapsed configuration, or a partially expanded configuration between the collapsed configuration and the expanded configuration, or some combination. In preferred embodiments, the anchor's at-rest configuration is between the collapsed configuration and the expanded configuration. Depending on the at-rest diameter of the braid and the diameter of the patient's anatomy at the chosen deployment location, the anchor may or may not self-expand to come into contact with the diameter of the patient's anatomy at that location.

[0093] In its collapsed configuration, anchor 30 preferably has a collapsed delivery diameter between about 3 to 30 Fr, or more preferably 6 to 28 Fr, or more preferably 12 to 24 Fr. In some embodiments, anchor 30 in its collapsed configuration will have a length ranging from about 5 to about 170 mm, more preferably from about 10 to about 160 mm, more preferably from about 15 to about 150 mm, more preferably from about 20 to about 140 mm, or more preferably from about 25 mm to about 130 mm.

[0094] Similarly, in its expanded configuration, anchor 30 preferable has a diameter ranging between about 10 to about 36 mm, or more preferably from about 24 to about 33 mm, or more preferably from about 24 to about 30 mm. In some embodiments, anchor 30 in its expanded configuration will have a length ranging from about 1 to about 50 mm, more preferably from about 2 to about 40 mm, more preferably from about 5 to about 30 mm, or more preferably from about 7 to about 20 mm.

[0095] Overall, the ratio of deployed to collapsed/sheathed lengths is preferably between about 0.05 and 0.5, more preferably about 0.1 to 0.35, or more preferably about 0.15 to 0.25. In any of the embodiments herein, anchor 30 in its expanded configuration preferably has a radial crush strength that maintains the anchor substantially un-deformed in response to a pressure of up to about 0,51 bar [0.5 atm] directed substantially radially inward toward the central axis, or more preferably up to about 2,03 bar [2 atm] directed substantially radially inward toward the central axis, in addition, in any of the embodiments herein, the anchor preferably has an axial spring constant of between about 10 to 250 g/cm, more preferably between about 20 to 200 g/cm, or more preferably between about 40 to 160 g/cm. In addition, in any of the embodiments herein, the anchor is preferably adapted to support the replacement valve at the anchor site in response to a differential pressure of up to about 120 mm Hg, more preferably up to about 240 mm Hg, or more preferably up to about 320 mm Hg.

[0096] As seen in Figure 34B, anchor 30 may be expanded to a fully deployed configuration from a partial deployed configuration (e.g., self-expanded configuration) by actively foreshortening anchor 30 during endovascular deployment. In some embodiments, foreshortening of the apparatus involves applying a distally directed force on the proximal end of the anchor by one or more anchor actuation elements to move the proximal end of the anchor distally while maintaining the position of the distal end of the anchor. For example, the proximal region of anchor 30 may be pushed distally by certain anchor actuation elements 106, e.g., actuators 106a. Alternatively, foreshortening of the apparatus involves applying a proximally directed force on the distal end of the anchor by one or more anchor actuation elements to move the distal end of the anchor proximally while maintaining the position of the proximal end of the anchor. For example, the distal region of anchor 30 may be pulled proximally via a proximally directed force applied by post actuation elements 106b, this force opposed by anchor actuators 106a.

[0097] Anchor actuation elements 106 preferably are adapted to expand radially as the anchor expands radially and to contract radially as the anchor contracts radially. Furthermore, proximally or distally directed forces by the anchor actuation elements on one end of the anchor do not diametrically constrain the opposite end of the anchor. In addition, when a proximally or distally directed force is applied on the anchor by the anchor actuation elements, it is preferably applied without passing any portion of a deployment system through a center opening of the replacement valve. This arrangement enables the replacement valve to operate during deployment and before removal of the deployment system.

[0098] The distal anchor actuation elements may include, for example, actuators 106b and/or release actuators 112 that are controlled, e.g., by control knobs 124 and 126 of confrol handle 120. Similarly, the proximal regions of anchor 30 may be pushed distally via proximal anchor actuation elements, e.g., actuators 106a, at the proximal region of the anchor. The proximal anchor actuation elements facilitate application of a distally directed force to the proximal end of anchor 30 to move or constrain the proximal end of the anchor distally and are controlled through motion of shaft 108 relative to the distal anchor actuation elements. Control knob 122 of control handle 120 may control release actuators 112 for releasing the proximal anchor actuation elements from the braid. The proximal anchor actuation elements may be further adapted to expand as the proximal end of the anchor expands radially during application of a distally

directed force on the proximal end of the anchor. Preferably, the proximal anchor actuation elements apply a distally directed force on the proximal end of the anchor system through a plurality of actuators 106a in order to expand the braid of anchor 30. Such braid expansion optionally may be assisted via inflation of a balloon catheter (see Figures 20 and 21) reversibly disposed within apparatus 10, as described in U.S. Patent Appl. Ser. No. 10/746,120.

[0099] In the fully deployed configuration, lock elements of posts 32 and anchor lock elements or buckles 34 of anchor 30 may be used to lock and maintain the anchor in the deployed configuration. Apparatus 10 may be repositioned or retrieved from the patient until the lock elements of posts 32 have been interlocked with anchor lock elements 34 of anchor 30 to form lock 40. In one embodiment, actuators 106b and attendant release actuators 112 comprise control elements attached to posts 32 that are threaded through buckles 34 so that the proximally directed force exerted on posts 32 by the control elements during deployment pulls a lock element of posts 32 toward and through buckles 34 to form lock 40. In this manner, the control elements may act as both anchor actuators and lock actuators.

[0100] Such lock optionally may be selectively reversible to allow for repositioning and/or retrieval of apparatus 10 during or post-deployment. When the lock is selectively reversible, the apparatus may be repositioned and or retrieved as desired, i.e., even after actuation of lock 40.

[0101] Locks used herein may also include a plurality of levels of locking wherein each level of locking results in a different amount of expansion. For example, the anchor lock elements at the proximal end of the post can have multiple configurations for locking within the buckle wherein each configuration results in a different amount of anchor expansion (see, e.g., Figure 35F). Such locking mechanisms may, for example, comprise ratchets having multiple lock locations. Furthermore, lock alignment features may be provided to facilitate alignment of the post and anchor lock elements, such as a hinge or an oversized width of the post or anchor lock elements. Furthermore, lock prevention mechanisms may be provided to preclude locking until desired by a medical practitioner.

[0102] When apparatus 10 is placed across a patient's diseased heart valve, anchor 30 may be used to displace the patient's native valve leaflets, and replacement valve 20 will thereafter serve in place of the native valve. After final positioning and expansion, apparatus 10 may be decoupled from delivery system 100 by decoupling the proximal and distal anchor actuation elements 106 from the apparatus via releasable attachment mechanisms, e.g., by decoupling proximal actuators 106a from braided anchor 30 and distal actuators 106b from posts 32 of the anchor via the releasable attachment mechanisms. Moving release actuators 112, e.g., using knobs 122 and 124 of handle 120, may, for example, actuate the releasable attachment mechanisms. Preferably, the releasable attachment mechanisms may be actuated by moving the release actuator(s) less than about 2,54 cm [1 inch]. After decoupling, delivery system/deployment tool 100 may be removed from the patient, thereby completing endovascular replacement of a patient's heart valve.

[0103] Prior to implantation of replacement valve apparatus described herein, it may be desirable to perform a valvuloplasty on the patient's diseased valve by inserting a balloon into the valve and expanding it using, e.g., 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.

[0104] Figures 35A-35C show further details of anchor 30 of apparatus 10. Figure 35A shows the apparatus in a collapsed configuration, such as for delivery within a sheath or other lumen or for retrieval and recapture into a sheath or other lumen. Figures 35B and 35C show the anchor and valve in an expanded and locked configuration.

[0105] As shown in Figure 35B, anchor 30 illustratively has three posts and three buckles. As seen in Figure 35C, the three leaflets of replacement valve 20 may be, coupled to the three posts 32 along valve support structures. Thus, posts 32 act as valve supports. The posts, unlike the braid, do not collapse or expand. In some embodiments, a post 32 has one or more proximal slots 33, at least one proximal hole 36a and at least one distal hole 36b. Leaflet tissue may, for example, be passed through slot 33 and sutured in place via suture routed through one or more proximal holes 36a. In this manner, slot(s) 33 and hole(s) 36a may form a valve support structure. Alternative valve support structures known in the art for fixing valve leaflets to posts may also be employed.

[0106] Posts 32 may be coupled to anchor braid 30 via one or more distal holes 36b. For example, anchor braid 30 may be woven through holes 36b, or a suture or wire may be routed through holes 36b and tied to the braid. Yet another proximal hole (not shown) in post 32 serves as an anchor lock element that interfaces with the anchor lock element provided by buckle 34 to form lock 40. Buckles 34 may likewise be attached to anchor braid 30 via weaving or suturing.

[0107] Alternative locks may be used to lock the anchor of the present invention in the foreshortened configuration, as shown, e.g., in Figures 35D-35F. Preferably, a lock of the present invention can have multiple locking options such that locking can confer a plurality of amounts of expansion. Furthermore, the locking option can be employed asymmetrically to confer non-cylindrical shapes to the anchor. In Figure 35D, lock 40' comprises male lock element 44 disposed on post 32 and anchor lock element 34 disposed on braided anchor 30. Anchor lock element 34 illustratively comprises triangular protrusion or eyelet 42 of anchor 30. The triangular shape of female lock element 42 may facilitate mating of male lock element 44 with the female lock element without necessitating deformation of the male lock element. One or more

holes 45 may be provided through post 32, e.g., for releasably attaching an actuator 106b to the post.

[0108] In Figure 35E, lock 40" comprises alternative male lock element 44' having multiple in-line arrowheads 46 along posts 32. Each arrowhead comprises resiliently deformable appendages 48 to facilitate passage through female lock element 42', which illustratively comprises a rounded eyelet. Appendages 48 optionally comprise holes 49, such that releasable lock prevention mechanism 47, illustratively a control wire, may pass through the holes to constrain the appendages in the deformed configuration. To actuate lock 40", one or more arrowheads 46 of male lock element 44' are drawn through female lock element 42', e.g., via a post/lock actuator, and the lock prevention mechanism is removed from holes 49, thereby causing appendages 48 to resiliently expand and actuate lock 40".

[0109] Advantageously, providing multiple arrowheads 46 along posts 32 yields a ratchet that facilitates in-vivo determination of a degree of foreshortening and expansion imposed upon anchor 30. Furthermore, optionally constraining appendages 48 of arrowheads 46 via mechanism 47 prevents actuation of lock 40" (and thereby deployment of apparatus 10) even after male element 44' has been advanced through female element 42'. Only after a medical practitioner has removed lock prevention mechanism 47, which constrains appendages 48, is lock 40" fully engaged and is deployment no longer reversible.

[0110] Lock 40"' of Figure 35F is similar to lock 40" of Figure 35E, except that holes 49 on appendages 48 have been eliminated, and the lock prevention mechanism comprises overtube or cover 47. Overtube 47 constrains 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. Lock 40"' may, for example, be actuated by applying a proximally-directed force to actuator 106b. Actuator 106b illustratively comprises a control wire releasably disposed through hole 45 in post 32. Lock prevention mechanism 47 then is withdrawn proximally relative to anchor 30, which causes the appendages to resiliently expand, thereby fully actuating lock 40"'.

[0111] Figure 36 illustrates an exemplary apparatus for fabricating braided anchors. Such apparatus includes a cylindrical braiding fixture 200. The cylindrical braiding fixture 200 comprises proximal circumference of inner posts 202a separated by a distance x from distal circumference of inner posts 202b. x can be, for example, 10 to 60 mm, more preferably 20 to 50 mm, or more preferably 30 to 40 mm. Optionally, the fixture may also comprise proximal and distal circumferences of outer posts 204a and 204b, respectively. 204a and 204b can be situated about 2-10 mm from 202a and 202b, respectively. Posts 202a/b and 204a/b project from fixture 200 and may be used to route wire, e.g., for forming anchor braid 30. Inner posts 202a and 202b generally facilitate formation of a braid, while outer posts 204a and 204b generally facilitate formation of desired features at the ends of the braid, as described hereinafter with respect to Figures 38-41.

[0112] In some embodiments, fixture 200 comprises approximately 6-20 posts, more preferably 8-18 posts, or more preferably 10-16 posts around its circumference, though any alternative number of posts may be provided. Likewise, fixture 200 preferably has a diameter of about 2-40mm, more preferably 4-30 mm, or more preferably 6-20mm, though any alternative diameter may be provided. The diameter of fixture 200 preferably is the diameter of the braid in its "at rest" configuration.

[0113] Fixture 200 can optionally further comprise circumferential grooves 206 to facilitate interweaving of a first section of wire underneath an adjacent section of wire. The fixture optionally also may comprise localized depressions or holes 208 in addition, or as an alternative, to grooves 206. Depressions 208 may be provided at locations where wire segments cross to act as a visual guide for formation of anchor braid 30, as well as to facilitate the interweaving of a first section of wire beneath an adjacent section of wire.

[0114] Referring now to Figures 37A-D, an illustrative method of using fixture 200 to fabricate braided anchors in accordance with the present invention is described. Figure 37A provides a detail view of a proximal front side region of fixture 200 during formation of a braided anchor. Figure 37B shows a detail backside view of a central section of the fixture. Figure 37C shows a full-length front-side view of the fixture and Figure 37D shows the completed braid, in Figures 37, anchor braid 30 is formed from a single strand of wrapped and interwoven wire W. However, it should be understood that anchor braid 30 alternatively may be formed from multiple strands of wire.

[0115] As seen in Figure 37 A, formation of anchor braid 30 begins with wire W being routed from starting position P near the proximal end of fixture 200 past outer proximal posts 204a and inner proximal posts 202a. Wire W preferably is formed from a superelastic and/or shape-memory material, such as Nitinol. However, alternative wire materials may be utilized, including Cobalt-Chromium, Steel and combinations thereof, as well as additional materials that will be apparent to those of skill in the art.

[0116] After passing inner proximal posts 202a, wire W encircles fixture 200 in a helical spiral while extending towards the distal posts, as seen in Figures 37B and 37C. The wire illustratively encircles fixture 200 a full 360° revolution plus one additional post. However, any alternative degree of winding may be provided (e.g., a full 360° plus 2 additional posts, a full 360° plus 3 additional posts, o a number of posts less than a full 360°). As will be apparent to those of skill in the art, altering the degree of winding will alter the expansion characteristics of the resultant braid in ways per se known.

[0117] At distal inner posts 202b, wire W forms turn Tu and is rerouted back towards proximal imier posts 202a. It should be noted that wire W can form turn Tu in either

inner posts 202 or outer posts 204. Turn Tu forms a closed end of the braid. Additional sets of inner and outer posts are also contemplated. The wire once again encircles fixture 200 in a full 360° helical revolution plus one additional post before reaching the proximal inner posts and being rerouted back towards the distal inner posts. This process is repeated with the wire repetitively interwoven at crossing locations between the proximal and distal posts, e.g., via grooves 206 and/or depressions 208, to define the cells of the braid that will provide anchor 30 with desired characteristics. As seen in Figure 37D, wire W turns both proximally and distally in order to complete formation of the braid, in this embodiment, wire W terminates in the central portion of the braid at T. Termination T may be formed, for example, by welding the wires together, applying a shrink tube about the overlap, using a crimp, braising the wires, etc. Additional techniques will be apparent to those of skill in the art.

[0118] When anchor braid 30 is formed from a shape-memory material, the braid may be heat set such that it maintains a desired degree of expansion in an at-rest configuration. The heat set at-rest configuration may comprise, for example, the delivery configuration (e.g., collapsed configuration) of Figure 35A, the deployed configuration (e.g., expanded configuration) of Figures 35B and 35C, or any desired configuration therebetween. In preferred embodiments, the anchor is heat-set in a configuration between the delivery configuration and the deployed configuration. Anchor braid 30 may be heat set while still disposed on fixture 200 to maintain an at-rest configuration as formed on the fixture, which preferably is a configuration between the delivery and deployed configurations. Alternatively, the braid may be heat set after complete or partial removal from the fixture. As yet another alternative, the braid may be initially heat set while still disposed on the fixture, but thereafter may be additionally heat set in a different shape, for example, a more expanded configuration. It is expected that heat setting anchor braid 30 will provide the braid with desired delivery and/or deployment characteristics.

[0119] Referring now to Figures 38A-38O, in conjunction with Figures 35C and 37, an anchor braid 30 may be defined by a set of cells that is different than other cells. Such cells may be formed to provide anchor braid 30 with one or more edge features (for either or both the distal and proximal ends). These edge features can, for example, reduce or relieve sfress within the braid during delivery and deployment, which in turn may reduce the incidence of anchor material fatigue caused by the pulsatile anchor motion of the anchor site. As will be apparent to those of skill in the art, forming braid 31 from a single strand of wire W (or from multiple strands of wire W that form turns or that are joined together) may lead to sfress concentration at turns Tu in the wire where the wire changes direction and extends back towards the opposite end of the braid. Such stress concentration may be most pronounced while the braid is disposed in its extreme configurations, i.e. when the braid is disposed in the collapsed delivery configuration of Figure 35A or the expanded deployed configuration of Figures 35B and 35C.

[0120] Stress concentration may increase the rigidity of an anchor braid and/or may impede delivery and deployment, as well as sheathing, of the braid. Thus, in preferred embodiments, a group of cells can be configured to reduce the sheathing force as described herein. Furthermore, to enhance deliverability, sfress concentration may require that anchor braid 30 be fabricated from a relatively thin wire W. However, thin wire may not provide anchor braid 30 with adequate radial strength to displace a patient's diseased native heart valve leaflets and/or to anchor apparatus 10 against a patient's anatomy. Conversely, use of a relatively thick wire W may increase stiffness, thereby precluding retrograde delivery of apparatus 10, as well as a risk of kinking at turns in the braid. Thus, in some embodiments, wires varying in thickness may be used, or multiple wires having different thickness may be woven together. Also, wires made from different materials may be used to form an anchor braid.

[0121] It may be desirable to reduce sfress concentration at the edges of anchor 30 where wire W changes direction and/or to reduce the circumferential stiffness of the anchor braid. The edge characteristics of the anchor may be altered by altering the shape of substantially all anchor braid cells at the anchor's edge (e.g., distal edge and/or proximal edge). Wire turns that confrol the shape of the edge cells may be formed within anchor braid 30 by routing wire W around optional outer posts 204 of fixture 200 during formation of the braid. Figure 38 A illusfrates a detail view of a standard end turn Tu in an anchor braid resulting in a braid with substantially uniform cell size and shape. Figure 38B illustrates a turn that has been elongated to lengthen the distance over which forces concentrated in the turn may be distributed, resulting in an anchor braid having edge cells that are longer along the anchor axis than the other cells defined by the braid. This elongated turn feature may be formed by routing the wire of braid about outer posts 204 of fixture 200, and then heat setting the wire.

[0122] Figure 38 C illustrates an alternative anchor edge cell configuration, wherein the tip of the elongated wire turn has been bent out of a cylindrical shape defined by the braid of anchor braid 30. This may be achieved, for example, via a combination of routing of wire W within fixture 200 and heat setting. The out-of-plane bend of turn Tu in the anchor edge cells in Figure 38 C may reduce stress in some configurations, and may also provide a lip for engaging the patient's native valve leaflets to facilitate proper positioning of apparatus 10 during deployment.

[0123] In Figure 38D, a W-shaped turn feature has been formed at the wire turn, e.g., by routing the wire of anchor braid 30 about a central inner post 202 and two flanking outer posts 204 of fixture 200. As with the elongated braid cells of Figures 38B and 38C, the W-shape may better distribute sfress about turn Tu. The anchor

edge cell configuration in Figure 38E includes a loop formed in braid 31 at the turn, which may be formed by looping wire W around an inner or outer post of fixture 200. Figure 38F provides another alternative anchor edge cell configuration having a figure-eight shape. Such a shape may be formed, for example, by wrapping wire W about an inner post 202 and an aligned outer post 204 in a figure-eight fashion, and then heat setting the wire in the resultant shape.

[0124] In Figure 38 G, the edge cells of braid 31 include a heart-shaped configuration, which may be formed by wrapping the wire about an aligned inner and outer post of fixture 200 in the desired manner. In Figure 38H, the edge cells of braid 31 have an asymmetric loop at turn Tu. The asymmetric loop will affect twisting of braid 31 during expansion and collapse of the braid, in addition to affecting stress concentration, in Figure 38I, the anchor edge cells have a double-looped turn configuration, e.g. via wrapping about two adjacent inner or outer posts of fixture 200. Additional loops may also be employed. The double loop turn feature may be formed with a smooth transition between the loops, as in Figure 38I, or may be heat set with a more discontinuous shape, as in Figure 38 J.

[0125] Figure 38K illustrates that the edge cells of braid 31 may have multiple different configurations about the anchor's circumference. For example, the anchor edge cells shown in Figure 38K have extended length cells as in Figure 38B disposed adjacent to standard size edge cells, as in Figure 38A. The anchor edge cells of Figure 38L have an extended turn configuration having an extended loop. The anchor edge cells shown in Figure 38M have an alternative extended configuration with a specified heat set profile. Finally, the anchor edge cells shown in Figure 38N that overlap or are interwoven to be coupled to one another.

[0126] In preferred embodiments, the edge cells may be wrapped using wire, string, or sutures, at a location where the wire overlaps after an end turn as is illustrated in Figure 38O. This tied-end turn feature prevents cells from interlocking with each other during deployment.

[0127] The edge cell configuration of Figure 38 may be heat set independently of the rest of the braid. The anchor edge cell configurations of Figures 38 are provided only for the sake of illustration and should in no way be construed as limiting. Additional turn features within the scope of the present invention will apparent to those of skill in the art in view of Figures 38. Furthermore, combinations of any such turn features may be provided to achieve desired characteristics of anchor braid 30.

[0128] Referring now to Figures 39A-E, additional configurations for reducing sfress concentration and/or circumferential stiffness of anchor braid 30 are illustrated. Such configurations can be used independently or in conjunction with other configurations disclosed herein. Such configurations are preferably used at the anchor's edges to locally reduce the cross-sectional area of substantially all cells or all cells in the anchor braid's edge (e.g., proximal and/or distal). As seen in Figures 39A and 39B, turns Tu in wire W typically may have a substantially continuous (e.g., round) cross-sectional profile. As seen in Figure 39C, modifying the edge cell configuration by locally reducing the thickness or cross-sectional area of wire W at turn(s) Tu will reduce stress concentration within the wire at the turns and facilitate collapse and/or expansion of anchor braid 30 from the delivery to the deployed configurations. Furthermore, it is expected that such localized reduction in thickness or cross-sectional area will reduce a risk of kinking, fatigue or other failure at turns Tu.

[0129] Localized reduction may be achieved via a localized etching and/or electropolishing process. Alternatively or additionally, localized grinding of the turns may be utilized. Additional processing techniques will be apparent to those of skill in the art. As seen in Figures 39D-39E, wire W may, for example, comprise an oval or rectangular cross-sectional profile, respectively, after localized reduction. The wire alternatively may comprise a round profile of reduced cross-sectional area (not shown). Additional profiles will be apparent. Localized reduction can take place at any time (e.g., before or after a braid is woven). Preferably, localized reduction occurs after weaving. However, in some embodiments, a wire of a given length may be etched or ground at preset segments and subsequently woven.

[0130] Referring now to Figures 40 A- J, instead of terminating the beginning and end of wire W of braid 31 at an overlap within the braid, as discussed previously, the two ends of the wire may be terminated at the anchor's edge. Likewise, when braid 31 is fabricated from multiple wires W, the wires (or a subset of the wires) optionally may be joined together or terminated at turn(s) of the braid. In Figure 40 A, wire termination T at the ends of wire(s) W comprises a hinged termination with hinge post 38. In Figure 40B termination T comprises a clipped or crimped termination with end cap 39. In Figure 40C, cap 39 is wrapped about the ends of wire W to form wrapped termination T.

[0131] In Figure 40D, cap 39 is placed over the wire ends, which are then bent to provide a swivel termination, in Figure 40E, the wire ends are potted within cap 39 at termination T. In Figure 40F, cap 39 is swaged about the wire ends. In Figure 40G, the wire ends are welded or glued together, in Figure 40 G, the wire ends are spot welded together. Alternatively, the wire ends may be braised to form termination T, as in Figure 40H. As yet another alternative, cap 39 may be placed about the wire ends, and kinks K may be formed in wire W to provide the ends of the wire with an 'over-center' bias that maintains termination T, e.g., swivel termination T. Additional terminations will be apparent to those of skill in the art.

[0132] With reference now to Figures 41A-B, alternative anchors of the present invention are described having anchor edge features that facilitate sheathing of the apparatus and reduce the sheathing force. In Figure 41 A, the edge cells of anchor 30 have inwardly canted configurations at the wire turns Tu about a proximal circum-

ference of the anchor. These edge cell configurations provide the proximal circumference with a conical profile that facilitates sheathing of the apparatus within a delivery system, e.g., previously described delivery system 100, by allowing collapse of anchor 30 to proceed in a more gradual and/or continuous manner, and tunneling the anchor into the sheath.

[0133] Figure 41B illusfrates another alternative anchor 30 having edge cell configurations formed by wire turns Tu about its proximal circumference that first cant outward, and then cant inward. The inward cant provides the proximal circumference with a conical profile and may facilitate sheathing, while the outward cant may facilitate anchoring at a treatment site, e.g., may engage a patient's native valve leaflets. As will be apparent, the edge cell configurations of Figures 8, as well as those of Figures 38-40, optionally may be provided at either the proximal or distal ends of the anchor, or both. The edge cell configurations of Figures 41, as well as those of Figures 38 and 40, may, for example, be formed by heat setting braid 31 in the desired configuration.

[0134] Referring now to Figures 42, further alternative anchors are described having edge cell configurations adapted to lock the anchor in the deployed configuration to maintain expansion. In Figure 42 A, anchor 30 comprises elongated, hooked edge cells formed from wire turns Tu that are configured to snag braid 31 and maintain the anchor in the deployed configuration, as shown, in Figure 42B, the hooked turn features have been elongated, such that the hooks are configured to snag the opposing end of anchor 30 to maintain expansion.

[0135] In Figure 42C, anchor edge cells defined by wire turns TuP and distal turn features TuD are configured to interlock between the ends of anchor braid 30 in order to maintain the deployed configuration of anchor 30. The proximal edge cells form a hook adapted to engage elongated turns of the distal turn features. As will be apparent, the disposition of all or a portion of the proximal and distal edge cell configurations optionally may be reversed, i.e. the proximal edge cells may form hooks and the distal edge cells may be configured as elongated turns. Figure 42D illusfrates interlocking proximal and distal edge cell configurations of more complex geometry. Figure 42E illustrates interlocking proximal and distal edge cell configurations while anchor 30 is disposed in the collapsed delivery configuration. The locking turn features of Figures 42 may, for example, be formed by heat setting anchor braid 30 (or locking features only) in the desired configuration. Additional locking turn features will be apparent to those of skill in the art. In preferred embodiments, the anchor locking mechanism can be set to have alternative locking options that allow for various amounts of expansion.

[0136] Figures 43A-43D illustrate various embodiments of anchor braids. An anchor braid can be made of one or more wire and can be used to form various density braids. The density of the braid can be assessed by the size of cells formed by the weave. In some embodiments, two or more different density braids may be woven together. For example, Figure 43A illusfrates two groups of cells or two braids interwoven in the center. The top group of cells forms a more open weave than the bottom group of cells, which forms a denser weave. Figure 43B illusfrates another embodiment of an anchor braid having three groups of cells. The top and bottom (proximal and distal) edges of the anchor braid have denser cells than the central portion of the anchor. Also, the edges of the anchor are woven from a thinner filament than the central portion. In another embodiment illustrated by Figure 43C, all three sections of an anchor valve are woven by more than one wire. The wires of each section are made of a different material and/or thickness. Wires at the sectional boundaries may or may not interconnect with wires from a different section. Each of the sections of the braid anchor may be composed of a different number of wires. Figure 43D illustrates another embodiment of a braided anchor having three sections, i this embodiment, all sections are composed of a single wire. The proximal and distal sections/edges of the braided anchor have the same pitch. The central region of the braided anchor has a different pitch than the edge sections.

[0137] Figures 44A-44E illustrate side views of braided anchor having more than one braid pitch. Varying pitch within the anchor allows localized variations in foreshortening across the anchor, as greater foreshortening is achieved by higher pitch of the braid. Moreover, the localized foreshortening features allow for the design of a braid which incorporates various diameters depending upon the amount of foreshortening. (The greater the foreshortening, the greater the diameter increase upon deployment.)

[0138] Figure 44 A, for example, is a side view representation of braided anchor of Figure 43D. On the left side of the figure, the expanded anchor is illustrated having a denser weave (shorter pitch) at the distal and proximal ends; hence the dots are located closer to each other. The middle section of the anchor is composed of a looser weave that is generated by a higher pitch braid and is represented by dots that are farther away from each other. On the right side of the figure, the braided anchor is foreshortened and the dots are collapsed closer to each other. In this case, the central portion of the anchor foreshortened more than the proximal and distal edges. Figure 44B illustrates a side view of a foreshortened braided anchor that is created by low pitch at the edges and high pitch in the middle. Figure 44C illustrates a side view of a foreshortened braided anchor that is created by high pitch edges and low pitch middle section. Figure 44D illusfrates a side view of a foreshortened braided anchor that includes a sealing feature or space filling feature at both ends. This type of anchor can be created by a high pitch braid at edges, low pitch braid in the middle and heat setting the edges to curl upon unsheathing. This end feature is useful in facilitating anchoring by functioning as a locator and sealing. Figure 44E illustrates a side view of a foreshortened braided

anchor that is associated with an everting valve or locational features.

[0139] In preferred embodiments, the middle section of the anchor may be composed of thicker wire(s) than edge section(s)

[0140] Figures 45A-45C illustrate an example of the process of deploying the anchor, such as the one illustrated in Figure 44B above. Figure 45 A illusfrates a braided anchor 30 in its expanded configuration. The anchor is composed of three sections. The distal and proximal sections of the anchor are made of a fine weave (low pitch) braid. The middle section of the anchor is made of a higher pitch braid and are preferably heat set to roll upon unsheathing. Furthermore, in preferred embodiments, the filaments of the distal and proximal sections may be thinner (e.g..005 [0,127 mm] in thickness) than the filaments of the middle section (e.g., .010 [0,254 mm] in thickness). Posts 32 are coupled to the middle section of the anchor. For deployment, proximal actuators 106 are coupled to the anchor's middle section. Figure 45B illusfrates the process of deployment. As the anchor is pushed distally by the proximal actuators and pulled proximally by the distal actuators, it is unsheathed and begins foreshortening. The distal section rolls up and can act as a locator, assisting the operator in locating the aortic valve. It then functions as a seal preventing leakage. The proximal section may optionally also roll up. In Figure 45C, the device may be configured such that the middle section of the valve may form an hour glass shape or a round shape. The actuators may subsequently be removed as described before. Figure 45 D is another illustration of the braided anchor in its elongated configuration. Figure 45E is another illustration of the braided anchor in its foreshortened configuration.

[0141] Figures 46A-46B illustrate another embodiment of a braided anchor. In this embodiment, the anchor includes two sections - a distal section made of a fine weave and a higher pitch braid than the proximal section. In Figure 46 A the device is deployed such that the distal section made of the fine weave is distal to the aortic valve. In Figure 46B, the distal section is foreshortened, either by heat set memory or actively. The foreshortening of the distal section allows the operator to locate the valve and situate the anchor prior to release.

[0142] The anchors described herein can be, for example, radially symmetrical, bilaterally symmetrical, or asymmetrical. A radially symmetrical anchor is one for which symmetry exists across any diameter. A bilaterally symmetrical anchor is one for which symmetry exists across a finite number if diameters). An asymmetrical anchor is one for which there exists no diameter across which a symmetry may be found. Figure 35B illustrates one embodiment of a radially symmetrical anchor. Figure 47A illustrates one embodiment of a bilaterally symmetrical anchor. Figure 47B illusfrates two embodiments (side and top views) of asymmetrical anchors. The benefits of bilaterally symmetrical an asymmetrical anchors is their ability to avoid interfering with anatomical features, such as, for example the coronary ostial and/or mitral valve. Thus, in preferred embodiments, a braided anchor includes a region adapted to prevent expansion of the anchor into the mitral valve, as is illustrated in Figure 47 A.

[0143] In preferred embodiments, the anchor includes a leaflet engagement element and/or a seal inverting element situated on its proximal end. The leaflet engagement element is adapted for engaging the native leaflets of the patient's heart, or more preferably the proximal edge and/or the commissural attachments of the native leaflets. The leaflet engagement v element need not extend all the way into the pocket or the distal end of the native leaflet. Preferred embodiments of the apparatus herein are depicted in Figures 27-29, 34, 35, 38 and 43-54, which are discussed in more detail below.

[0144] Figure 48 provides a detail view of a front side region of anchor braid 30 with closed end turns Tu. Anchor braid 30 includes various cells, some having an end turn (Tu). End turns can serve various functions. For example, end turns can be configured to reduce the sheathing force, to reduce stress within the braid during delivery and deployment, to prevent distal migration during expansion of the anchor, and/or to positively register the anchor against the native valve during deployment. In preferred embodiments, an end turn feature functions to prevent distal migration and to register the anchor by engaging the native leaflets. In preferred embodiments, the proximal end of an anchor comprises embodiments (Tu).

[0145] Figures 38 A-38N provide multiple examples of edge cells having end turn feature. The end turn features disclosed and others known in the art may be used as leaflet engagement elements to engage the native heart leaflets with the anchor. The leaflet engagement elements are preferably integral with the anchor, or more preferably part of a braided anchor. The end turn features can occur at the proximal end, the distal end, or both proximal and distal ends of the anchor.

[0146] For example, Figure 38 A illustrates a detail view of a standard end turn Tu in an anchor braid resulting in a braid with substantially uniform cell size and shape.

[0147] Figure 38B illusfrates a turn that has been elongated to lengthen the distance over which forces concentrated in the turn may be distributed, resulting in an anchor braid having edge cells that are longer along the anchor axis than the other cells defined by the braid. This elongated turn feature may be formed by routing the wire of braid about outer posts and then heat setting the wire.

[0148] Figure 38 C illustrates an alternative anchor edge cell configuration, wherein the tip of the elongated wire turn may be bent out of a cylindrical shape defined by the braid of anchor braid 30. This may be achieved, for example, via a combination of routing of wire W within a fixture and then heat setting. Such a turn Tu in the anchor edge cells in Figure 38 C may reduce stress in some configurations without increasing height, and may also provide a lip for engaging the patient's native valve

leaflets to facilitate proper positioning of apparatus 10 during deployment.

[0149] In Figure 38D, a W-shaped turn feature has been formed at the wire turn, e.g., by routing the wire of anchor braid 30 about a central inner post and two flanking outer posts. As with the elongated braid cells of Figures 38B and 38 C, the W-shape may better distribute stress about turn Tu.

[0150] The anchor edge cell configuration in Figure 38E includes a loop formed in braid 30 at the turn, which may be formed by looping wire W around an inner or outer post.

[0151] Figure 38F provides another alternative anchor edge cell configuration having a figure-eight shape. Such a shape may be formed, for example, by wrapping wire W about an inner post and an aligned outer post in a figure-eight fashion, and then heat setting the wire in the resultant shape.

[0152] In Figure 38G, the edge cells of braid 30 include a heart-shaped configuration, which may be formed by wrapping the wire about an aligned inner and outer post in the desired mamier.

[0153] In Figure 38H, the edge cells of braid 30 have an asymmetric loop at turn Tu. The asymmetric loop will affect twisting of braid 30 during expansion and collapse of the braid, in addition to affecting stress concentration.

[0154] In Figure 38I, the anchor edge cells have a double-looped turn configuration, e.g. via wrapping about two adjacent inner or outer posts. Additional loops may also be employed.

[0155] The double loop turn feature may be formed with a smooth transition between the loops, as in Figure 38I, or may be heat set with a more discontinuous shape, as in Figure 38 J.

[0156] Figure 38K illustrates that the edge cells of braid 30 may have multiple different configurations about the anchor's circumference. For example, the anchor edge cells shown in Figure 38K have extended length cells as in Figure 38B disposed adjacent to standard size edge cells, as in Figure 38 A.

[0157] The anchor edge cells of Figure 38 L have an extended turn configuration having an extended loop.

[0158] The anchor edge cells shown in Figure 38M have an alternative extended configuration with a specified heat set profile.

[0159] In Figure 38N, some or all anchor edge cells are interwoven. When interwoven, one or more edge cells may be shorter or longer than an adjacent edge cell. This permits one or more edge cells to extend into one or more leaflet pocket(s). For example, in Figure 38N the middle Tu may be taller than the two adjacent edge cells thus permitting the edge cell to be situated within a leaflet pocket.

[0160] In any of the embodiments herein, edge cells may be wrapped using wire, string, or sutures, at a location where the wire overlaps after an end turn as is illustrated in Figure 38O. This tied-end turn feature prevents cells from interlocking with each other during deployment.

[0161] The anchor and any of its features may be heat set at different configurations. For example, the anchor may be heat set ay its "at rest" configuration such that upon unsheathing it expands radially. The end turn features/leaflet engagement elements may be heat set at a different "at rest" configuration than the rest of the anchor. In preferred embodiment, end turn features are heat set to "flower" and then "evert" upon unsheathing.

[0162] The end turn features of Figures 38 are provided only for the sake of illustration and should in no way be construed as limiting. Additional turn features within the scope of the present invention will apparent to those of skill in the art in view of Figures 38. Furthermore, combinations of any such end turn features may be provided to achieve the desired characteristics of anchor 30.

[0163] Referring now to Figures 49A-E, additional configurations for reducing and/or circumferential stiffness of an anchor braid and/or leaflet engagement elements are illustrated. Such configurations can be used independently or in conjunction with other configurations disclosed herein. Such configurations are preferably used at the anchor's edges to locally reduce the cross-sectional area of substantially all cells or all cells in the anchor braid's edge (e.g., proximal and/or distal). As seen in Figures 49A and 49B, turns Tu in wire W typically may have a substantially continuous (e.g., round) cross-sectional profile. As seen in Figure 49C, modifying the edge cell configuration by locally reducing the thickness or cross-sectional area of wire W at turn(s) Tu will reduce stress concentration within the wire at the turns and facilitate collapse and/or expansion of anchor braid 30 from the delivery to the deployed configurations. Furthermore, it is expected that such localized reduction in thickness or cross-sectional area will reduce a risk of kinking, fatigue or other failure at turns Tu.

[0164] In any of the embodiments herein, localized reduction of an anchor wire may be achieved via a localized etching and/or electropolishing process. Alternatively or additionally, localized grinding of the turns may be utilized. Additional processing techniques will be apparent to those of skill in the art. As seen in Figures 49D-49E, wire W may, for example, comprise an oval or rectangular cross-sectional profile, respectively, after localized reduction. The wire alternatively may comprise a round profile of reduced cross-sectional area (not shown). Additional profiles will be apparent. Localized reduction can take place at any time (e.g., before or after a braid is woven). Preferably, localized reduction occurs after weaving. However, in some embodiments, a wire of a given length may be etched or ground at preset segments and subsequently woven.

[0165] With reference now to Figures 50A-F, a method of endovascularly replacing a patient's diseased aortic valve is provided. The method involves endovascularly delivering an anchor/valve apparatus and properly positioning such apparatus via positive registration with the patient's native valve leaflets. Registration with the native

valve leaflet preferably occurs using the leaflet engagement elements.

[0166] In Figure 50 A, modified delivery system 100' delivers apparatus 10 to diseased aortic valve AV within sheath 110. Apparatus 10 is delivered in a collapsed delivery configuration.

[0167] As seen in Figures 50B and 50C, apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance. Sheath 110 includes at its distal end leaflet engagement elements 120. Upon deployment, anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration. This causes elements 60 to also dynamically expand, as well as membrane filter (or braid) 61A and leaflet engagement elements 120. As when deployed via delivery system 100, deployment of apparatus 10 via delivery system 100' is fully reversible until locks 40 have been actuated.

[0168] Thus, delivery system 100' comprises leaflet engagement element 120, which preferably self-expands along with anchor 30. In preferred embodiments, the distal end of leaflet engagement elements 120 expands a greater radial distance than anchor 30. Moreover, engagement elements 120 maybe disposed between elements 60 of delivery system 100' and lip region 32 of anchor 30. However, leaflet engagement elements 120 may also be disposed on the proximal end of an anchor (as is illustrated in Figure 51). Leaflet engagement elements 120 releasably engage the anchor. As seen in Figure 50C, the leaflet engagement elements 120 are initially deployed proximal of the patient's native valve leaflets L. Apparatus 10 and element 120 then maybe advanced/dynamically repositioned until engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus 10. The leaflet engagement element engages with the proximal edges of the native valve leaflets and/or the commissural attachments. The leaflet engagement element need not extend all the way to the distal edge of the native leaflets (the leaflet pockets). In preferred embodiments, a leaflet engagement element length is less than about 20 mm, more preferably less than about 15 mm, or more preferably less than about 10 mm. Once leaflet engagement element 120 is registered against the native valve leaflets and/or commissural attachments, apparatus 10 deploys substantially distal to the coronary ostia of the heart.

[0169] In any of the embodiments herein, delivery system 100' can include filter structure 61A (e.g., filter membrane or braid) as part of push elements 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 50C show blood flow through filter structure 61A where blood is allowed to flow but emboli is frapped in the delivery system and removed with it at the end of the procedure.

[0170] Active foreshortening may be imposed upon anchor 30 while element 120 is disposed proximal of the leaflets, as is illustrated in Figure 50D. Active foreshortening can be accomplished by actuating distal anchor actuation elements (e.g., elements 50) and/or proximal anchor actuation elements (e.g., elements 60). 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 50E details engagement of element 120 against the native leaflets.

[0171] As seen in Figure 50F, once apparatus 10 is fully deployed, anchor 30 may be locked (reversibly or irreversibly). Subsequently, structure 61A leaflet engagement, elements 120, elements 50 and/or elements 60 may be decoupled from the apparatus, and delivery system 100' may be removed from the patient, thereby completing the procedure.

[0172] Figure 51 illustrates an alternative embodiment of the apparatus of Figures 50A-F described above, wherein leaflet engagement elements 120 are coupled to anchor 30 of apparatus 10' rather than to delivery system 100. In the embodiment illustrated in Figure 106, leaflet engagement elements 120 remain implanted near the patient's native heart valve after the deployment of apparatus 10' and removal of delivery system 100. Leaflets L may be sandwiched between the proximal region of anchor 30 and leaflet engagement element 120 in the fully deployed configuration. In this manner, element 120 positively registers apparatus 10' relative to the leaflets L and precludes distal migration of the apparatus over time.

[0173] Figures 52A-52C illustrate another embodiment for endovascularly delivering an apparatus of the present invention. In Figure 52 A, a catheter 600 is delivered percutaneously in a retrograde fashion to the aortic valve. The catheter passes through the native aortic valve before an operator actuates the unseathing of the anchor/valve apparatus. As the sheathing catheter is pulled proximally out of the native valve, anchor 30 and replacement valve 20 become unsheathed. Immediately the portion of the unsheathed anchor 30 dynamically self-expands to its "at rest" position, and replacement valve 20 within the anchor regains an uncollapsed structure, allowing it to begin to function. In preferred embodiments in its "at rest" position, anchor 30 presses against the native leaflets limiting blood from flowing in between the anchor and leaflet. Also, in preferred embodiments, anchor 30 portions relatively adjacent to the valve is externally covered by a seal 60, more preferably the entire exterior contour of anchor 30 excluding the leaflet engagement elements is externally covered by a seal, or more preferably the entire contour of anchor 30 including the external face of the leaflet engagement elements is externally covered by a seal. A seal can be composed of any material that prevents or limits the flow of blood through the anchor. In preferred embodiments, a seal is composed of a thin, elastic polymer or any other type of fabric. The seal can be attached by any means known in the art to the anchor and, in some embodiments, to the

distal end of the valve. In preferred embodiments, a seal is attached to the anchor by suturing.

[0174] In Figure 52B, as the catheter is further pulled proximally, the proximal end of anchor 30 and fingers 50 are unsheathed. In this embodiment, it is possible to visualize that the seal covers the entire contour of the anchor including the external face of the leaflet engagement element 70. As soon as the proximal end of the anchor is exposed, it also dynamically expands. Furthermore, when fingers 50 become exposed, replacement valve 20 begins to function permitting blood to flow through replacement valve 20, between fingers 50, and around the catheter 600. This also permits blood to flow into the coronary ostias. In other embodiments where the seal does not cover the proximal end of the anchor, the replacement valve can begin to function as soon as the unsealed portion of the anchor is unsheathed. This causes the leaflet engagement elements 70 to radially expand to their heat set position and engage with the native heart leaflets.

[0175] Next, Figure 52C, as the apparatus is actively foreshortened using proximal (e.g., fingers) and/or distal actuators (e.g., elements 55), the leaflet engagement elements positively register with the native valve leaflets. Foreshortening can cause seal 60 to bunch up and create pleats. These pleats can then fill pockets thereby improving the paravalvular seal. In preferred embodiments, wherein the leaflet engagement elements are covered with a seal, at least a portion of the seal is also positioned between the native valve leaflets and the aortic wall. Once the anchor is fully compressed within the aortic valve, the anchor is locked, the fingers and post mandrels are disengaged, and the seal is adapted to further limit blood flow around the replacement valve. The catheter is subsequently' withdrawn, leaving behind valve 20, seal 60 and anchor 70. When fully deployed, the anchor is substantially distal to the coronary ostia of the patient such that it will not interfere with blood flow through the ostia.

[0176] Figures 53A-53B illustrate an embodiment wherein only a distal portion anchor 30 is covered by seal 60 and wherein anchor 30 is only partially deployed since the blood can escape through the proximal end of the anchor braid. As anchor 30 in this embodiment is unsheathed, it presses against the native valve leaflets. At this point replacement valve 20 is functional even though anchor 30 is not fully deployed since blood can escape through the proximal end of the anchor braid. This allows blood to flow through replacement valve 20 and out of holes in the distal end of anchor 30 during systole (Figure 53A) while preventing backflow during diastole (Figure 53B).

[0177] Figures 54A-54B illustrate a similar embodiment wherein seal 60 around anchor 30 surrounds the entire contour of anchor 30. In this embodiment, valve 20 does not become functional until both anchor 30 and a portion of fingers 50 are unsheathed. As soon as a portion of fingers 50 is unsheathed, replacement valve 20 is fully functional. This allows blood to flow through replacement valve 20 and anchor 30, out of fingers 50, and around catheter 60 into the aorta and coronary ostias during systole. Similarly, during diastole, replacement valve 20 closes preventing blood backflow from entering the chamber.

[0178] In any of the embodiments herein the anchor is preferably a self-expanding anchor braid. Anchor braid of the present invention can be made from one or more wires, more preferably 2-20 wires, more preferably 3-15 wires, or more preferably 4-10 wires. Moreover, the density of the braid can be modified by various forms of weave used.

[0179] Figures 27-29 illustrate the process of forming a pleated seal around a replacement valve to prevent leakage. Figure 27 illusfrates a fabric seal 380 prior to deployment and foreshortening of the anchor/valve apparatus. In Figure 27, the fabric seal 380 extends from the distal end of valve 20 proximally over anchor 30 during delivery. During deployment, as illustrated in Figure 28, anchor 30 foreshortens and the fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382. The bunched up fabric or pleats occur, in particular, when the pockets are filled with blood in response to backflow blood pressure. The pleating can create a seal around the replacement valve. Figure 29 illustrates anchor 30, surrounded by fabric seal 380 in between native valve leaflets 382. In preferred embodiments, at least a portion of a seal is captured between the leaflets and the wall of the heart when the anchor is fully deployed.

Claims

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

   an expandable cylindrical anchor (30) supporting a replacement valve (20),
   the anchor (30) having a delivery configuration and a deployed configuration, and
   at least one sac (200) disposed about the exterior of the anchor (30) to provide a seal.

2. The apparatus of claim 1, wherein the at least one sac (200) is adapted to be filled with blood.

3. The apparatus of any of the preceding claims, wherein the at least one sac (200) is adapted to be filled by blood washing past the at least one sac (200).

4. The apparatus of any of the preceding claims, wherein the at least one sac (200) comprises one or more slots (202) that can be used to back-fill the at least one sac with ambient blood passing through the replacement valve (20).

5. The apparatus of any of the preceding claims, where-

in the at least one sac (200) comprises one or more pores (204) that can be used to fill the at least one sac (200).

6. The apparatus of any of the preceding claims, wherein the at least one sac (200) is adapted to provide a seal along an irregular interface between the native valve leaflets and the anchor (30).

7. The apparatus of any of the preceding claims, wherein the at least one sac (200) is provided as a continuous cylinder.

8. The apparatus of any of the preceding claims, wherein the at least one sac (200) is provided with a cylindrical shape.

9. The apparatus of any of the preceding claims, wherein sacs (200) are provided as discrete sacs at different positions.

10. The apparatus of any of the preceding claims, wherein the at least one sac (200) is adapted to be filled with an appropriate material such as water, blood, foam or a hydrogel.

11. The apparatus of any of the preceding claims, wherein the at least one sac is a compliant sac.

12. The apparatus of any of the preceding claims, wherein the expandable anchor (30) has a delivery length in a delivery configuration that is substantially greater than a deployed length in a deployed configuration.

13. The apparatus of any of the preceding claims, wherein the anchor (30) foreshortens during deployment.

14. The apparatus of any of the preceding claims, wherein the delivery configuration is a collapsed configuration and the deployed configuration is an expanded configuration.

15. The apparatus of any of the preceding claims, wherein the anchor (30) self-expands from the delivery configuration.

16. The apparatus of any of the preceding claims, wherein the anchor (30) is balloon expandable.

17. The apparatus of any of the preceding claims, wherein the apparatus is configured to be implanted at the site of a diseased aortic valve.

Patentansprüche

1. Vorrichtung zum endovaskulären Ersetzen der Herzklappe eines Patienten, wobei die Vorrichtung umfasst:

eine expandierbare zylindrische Befestigung (30), die eine Ersatzklappe stützt, wobei die Befestigung eine Zuführkonfiguration und eine eingesetzte Konfiguration hat, und
zumindest ein Beutel (200), der um die Außenseite der Befestigung (30) angeordnet ist, um eine Abdichtung bereitzustellen.

2. Vorrichtung nach Anspruch 1, wobei der zumindest eine Beutel (200) geeignet ist, um mit Blut gefüllt zu werden.

3. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der zumindest eine Beutel (200) geeignet ist, um mit Blut gefüllt zu werden, das an dem zumindest einen Beutel (200) vorbeigespült wird.

4. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der zumindest eine Beutel eine oder mehrere Aussparungen (202) umfasst, die zum Füllen des zumindest einen Beutels mit um die Ersatzklappe (20) fließenden Blutes, verwendet werden können.

5. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der zumindest eine Beutel (200) eine oder mehrere Poren (204) umfasst, die zum Füllen des zumindest einen Beutels (200) verwendet werden können.

6. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der zumindest eine Beutel (200) ausgelegt ist, eine Abdichtung entlang einer irregulären Oberfläche zwischen den nativen Klappensegeln und der Befestigung (30) bereitzustellen.

7. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der zumindest eine Beutel (200) als durchgehender Zylinder bereitgestellt ist.

8. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der zumindest eine Beutel (200) mit einer zylindrischen Form bereitgestellt ist.

9. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei Beutel (200) als diskrete Beutel an verschiedenen Positionen bereitgestellt sind.

10. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der zumindest eine Beutel (200) ausgelegt ist, um mit einem geeigneten Material wie beispielsweise Wasser, Blut, Schaumstoff oder einem Hydrogel gefüllt zu werden.

11. Die Vorrichtung nach einem der vorhergehenden

Ansprüche, wobei der zumindest eine Beutel ein fügsamer Beutel ist.

12. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die expandierbare Befestigung (30) eine Zuführlänge in einer Zuführkonfiguration hat, die wesentlich größer ist als die eingesetzte Länge in einer eingesetzten Konfiguration.

13. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei sich die Befestigung während des Einsetzens verkürzt.

14. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Zuführkonfiguration eine kollabierte Konfiguration und die eingesetzte Konfiguration eine expandierte Konfiguration ist.

15. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Befestigung (30) aus der Zuführkonfiguration selbstexpandiert.

16. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Befestigung (30) balloonexpandierbar ist.

17. Die Vorrichtung nach einem der vorhergehenden Ansprüche, wobei die Vorrichtung ausgelegt ist, an dem Ort einer erkrankten Aortenklappe implantiert zu werden.

Revendications

1. Appareil pour remplacer par voie vasculaire une valvule cardiaque d'un patient, l'appareil comprenant :

   une ancre cylindrique (30) extensible soutenant une valvule de remplacement (20), l'ancre (30) ayant une configuration de livraison et une configuration de déploiement, et
   au moins une poche (200) disposée autour de l'extérieur de l'ancre (30) pour assurer une étanchéité.

2. Appareil selon la revendication 1, dans lequel ladite poche (200) est apte à être remplie de sang.

3. Appareil selon l'une quelconque des revendications précédentes, dans lequel ladite poche (200) est apte à être remplie par du sang baignant ladite poche (200).

4. Appareil selon l'une quelconque des revendications précédentes, dans lequel ladite poche (200) comprend une ou plusieurs fentes (202) qui peuvent servir à remplir ladite poche avec du sang ambiant traversant la valvule de remplacement (20).

5. Appareil selon l'une quelconque des revendications précédentes, dans lequel ladite poche (200) comprend une ou plusieurs pores (204) qui peuvent servir à remplir ladite poche (200).

6. Appareil selon l'une quelconque des revendications précédentes, dans lequel ladite poche (200) est apte à assurer une étanchéité le long d'une interface irrégulière entre les clapets naturels de valvule et l'ancre (30).

7. Appareil selon l'une quelconque des revendications précédentes, dans lequel ladite poche (200) est proposée sous forme d'un cylindre continu.

8. Appareil selon l'une quelconque des revendications précédentes, dans lequel ladite poche (200) est disposée avec une forme cylindrique.

9. Appareil selon l'une quelconque des revendications précédentes, dans lequel des poches (200) sont disposées en différents emplacements sous forme de poches distinctes.

10. Appareil selon l'une quelconque des revendications précédentes, dans lequel ladite poche (200) est apte à être remplie avec une matière appropriée, par exemple eau, sang, mousse ou un hydrogel.

11. Appareil selon l'une quelconque des revendications précédentes, dans lequel ladite poche est une poche souple.

12. Appareil selon l'une quelconque des revendications précédentes, dans lequel l'ancre (30) extensible a une longueur de livraison dans sa configuration de livraison qui est considérablement supérieure à une longueur déployée dans sa configuration déployée.

13. Appareil selon l'une quelconque des revendications précédentes, dans lequel l'ancre (30) se raccourcit pendant son déploiement.

14. Appareil selon l'une quelconque des revendications précédentes, dans lequel la configuration de livraison est une configuration affaissée et la configuration déployée est une configuration dilatée.

15. Appareil selon l'une quelconque des revendications précédentes, dans lequel l'ancre (30) s'auto-dilate à partir de la configuration de livraison.

16. Appareil selon l'une quelconque des revendications précédentes, dans lequel l'ancre (30) peut se dilater par ballonnet.

17. Appareil selon l'une quelconque des revendications précédentes, configuré pour être implanté à l'empla-

cement d'une valvule aortique lésée.

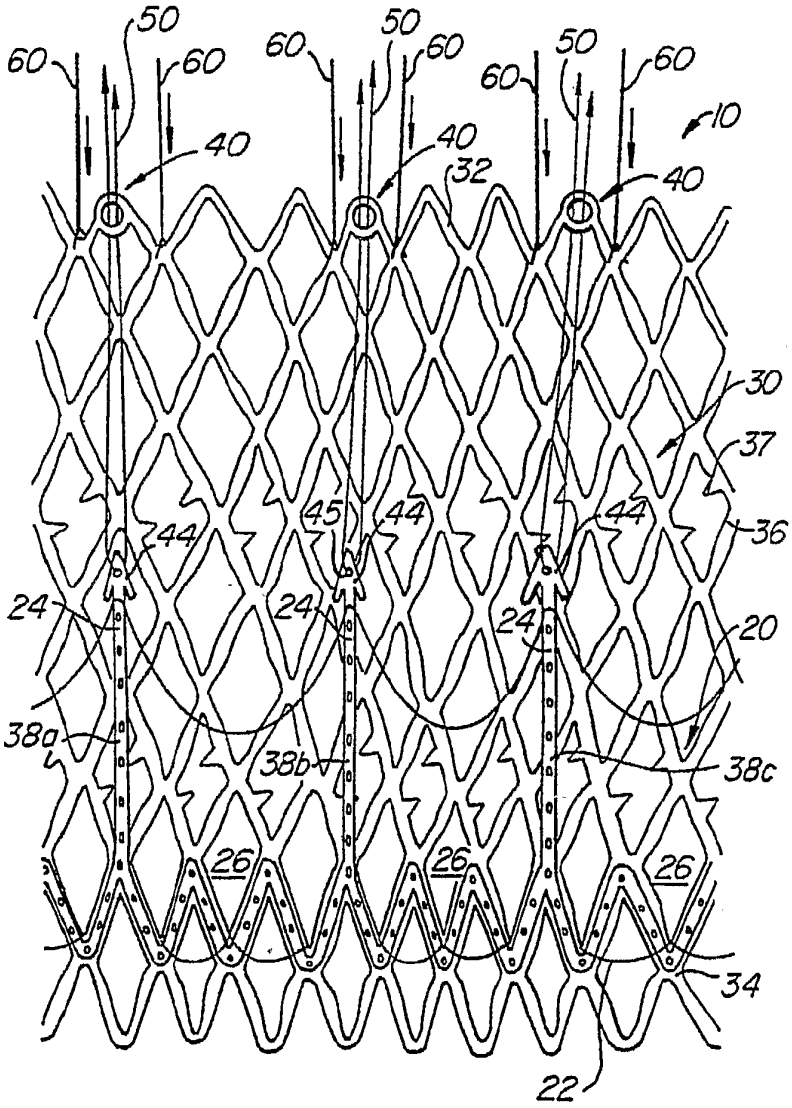

FIG. 1A

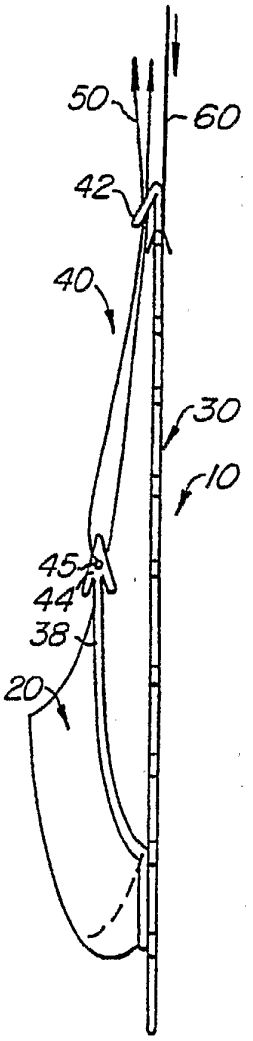

FIG. 2A

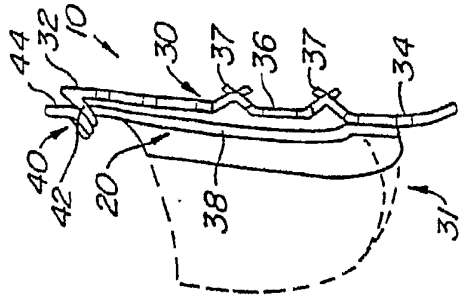

FIG. 2B

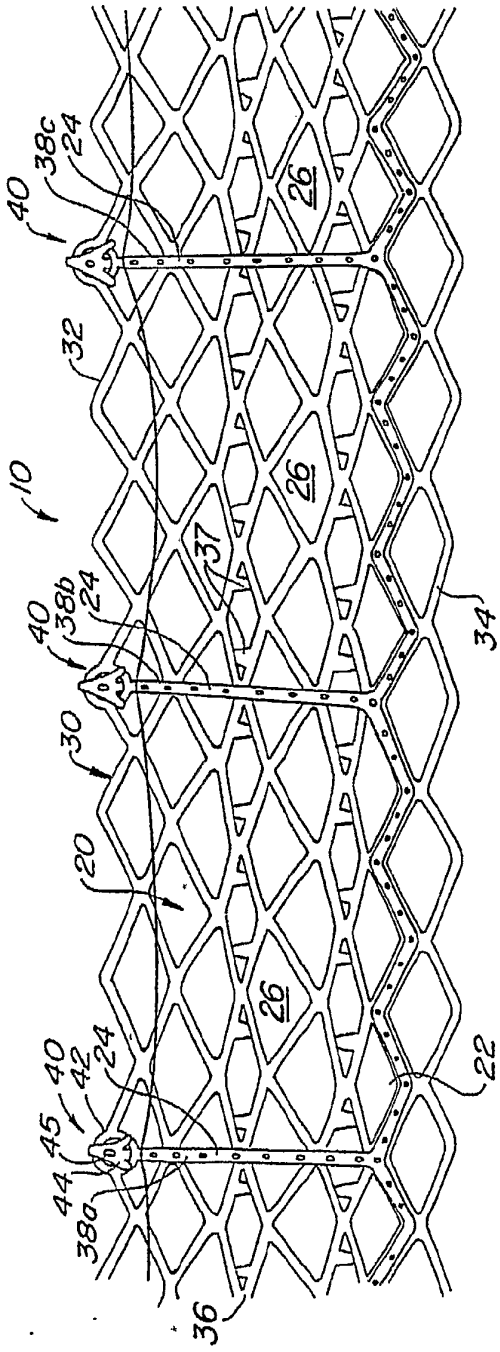

FIG. 1B

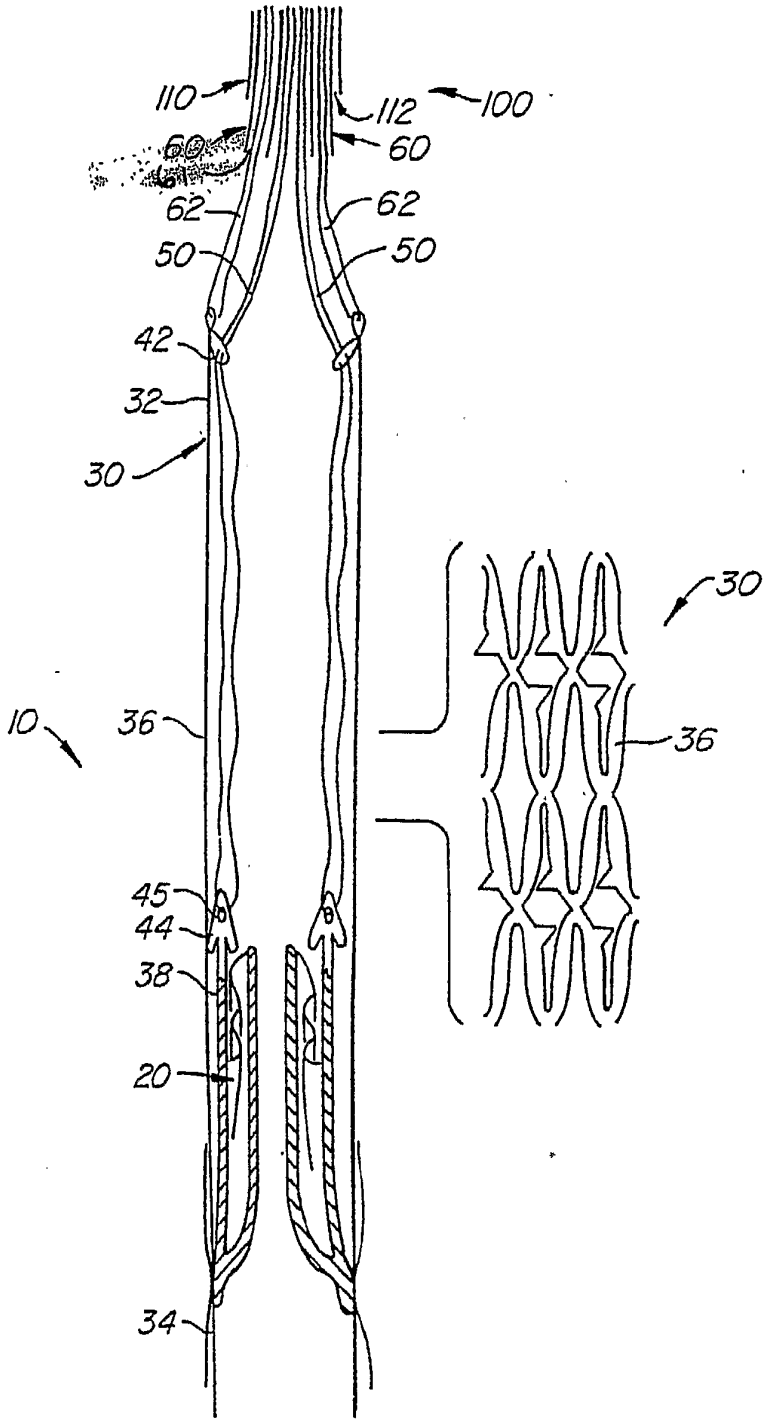

FIG. 3A

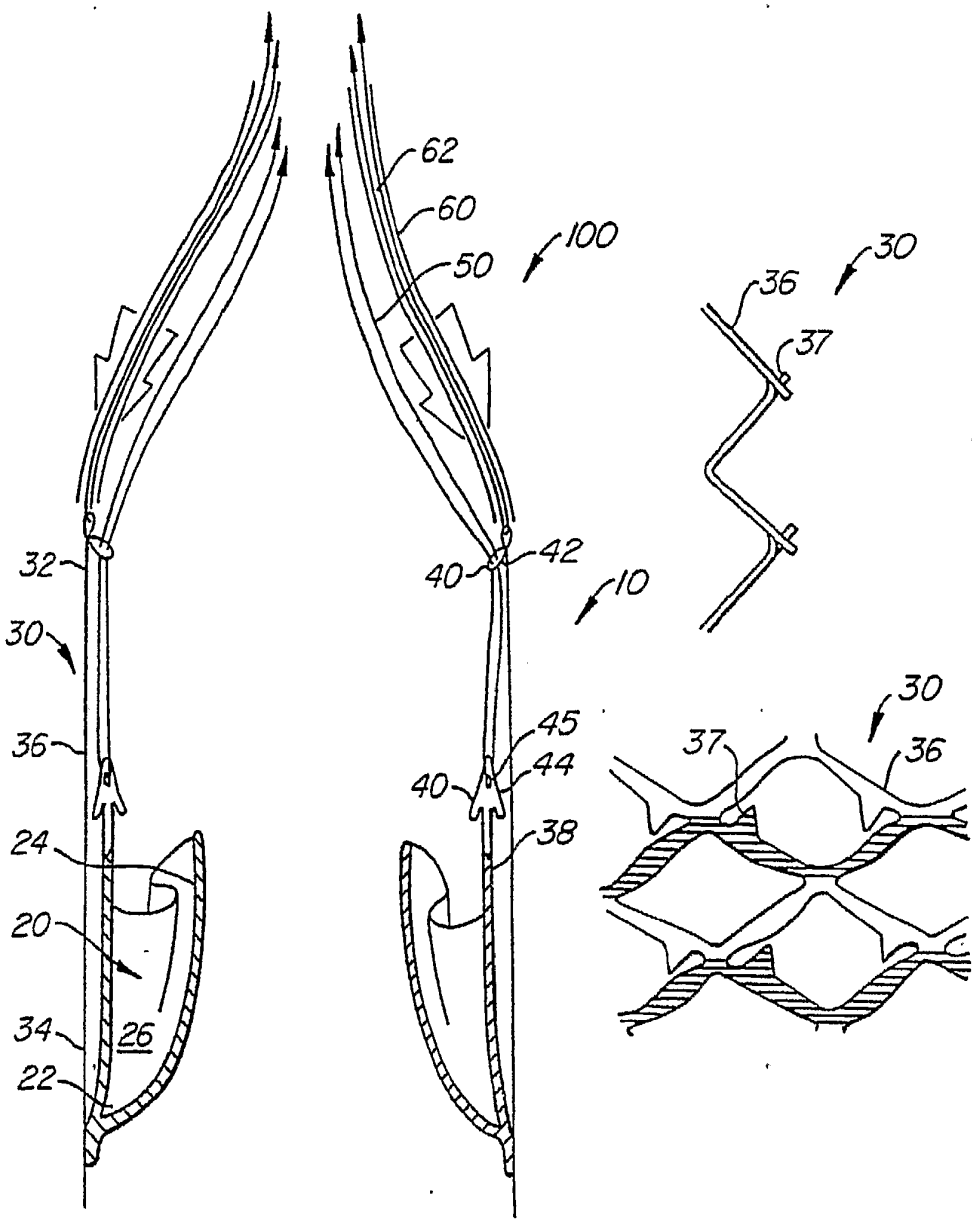

FIG. 3B

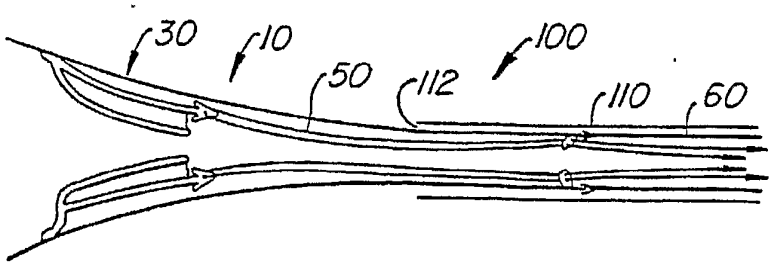

FIG. 4A

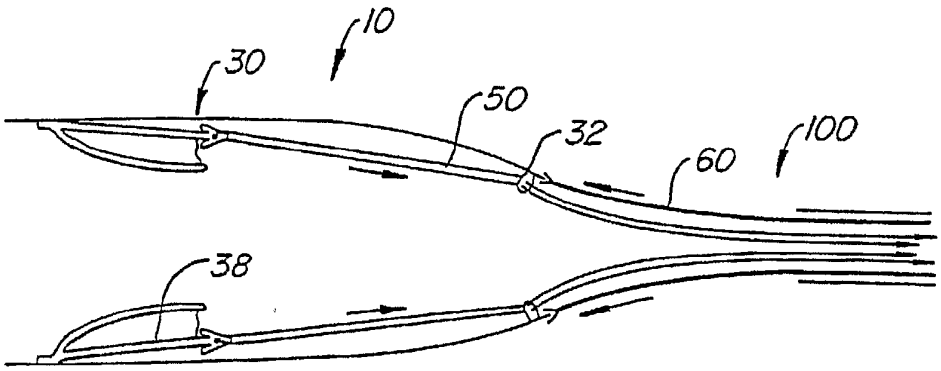

FIG. 4B

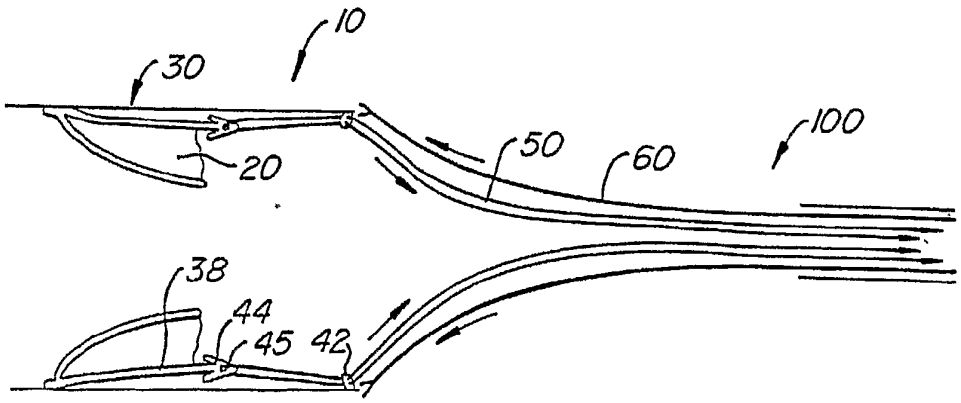

FIG. 4C

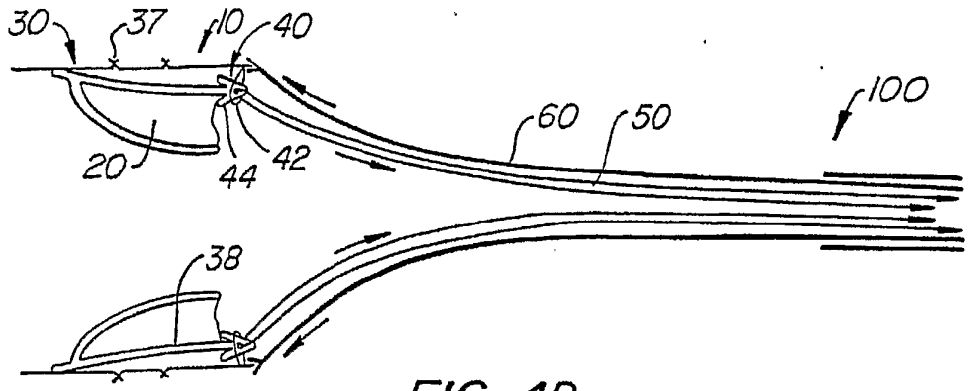

FIG. 4D

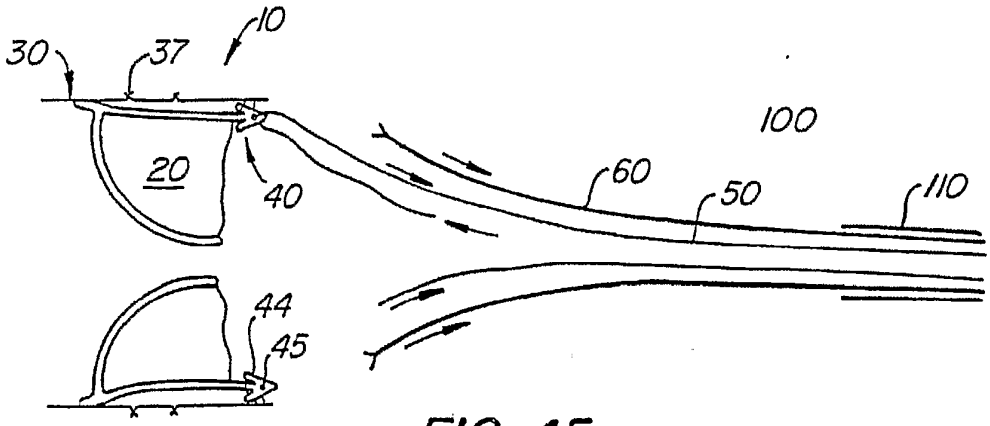

FIG. 4E

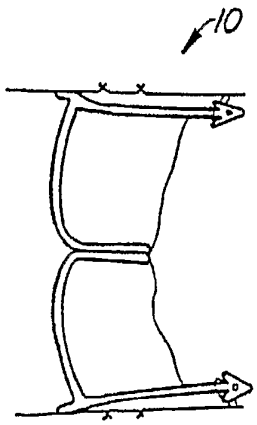

FIG. 4F

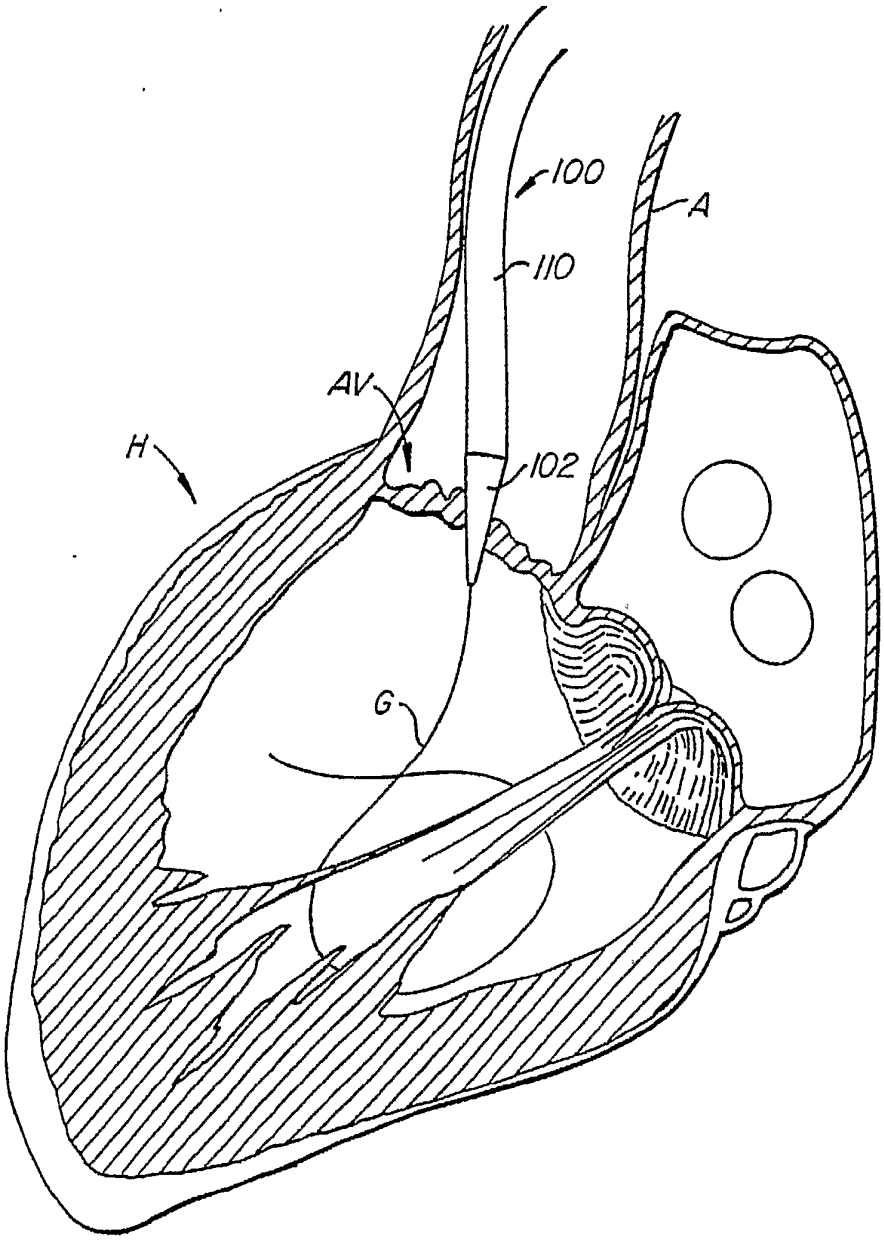

FIG. 5A

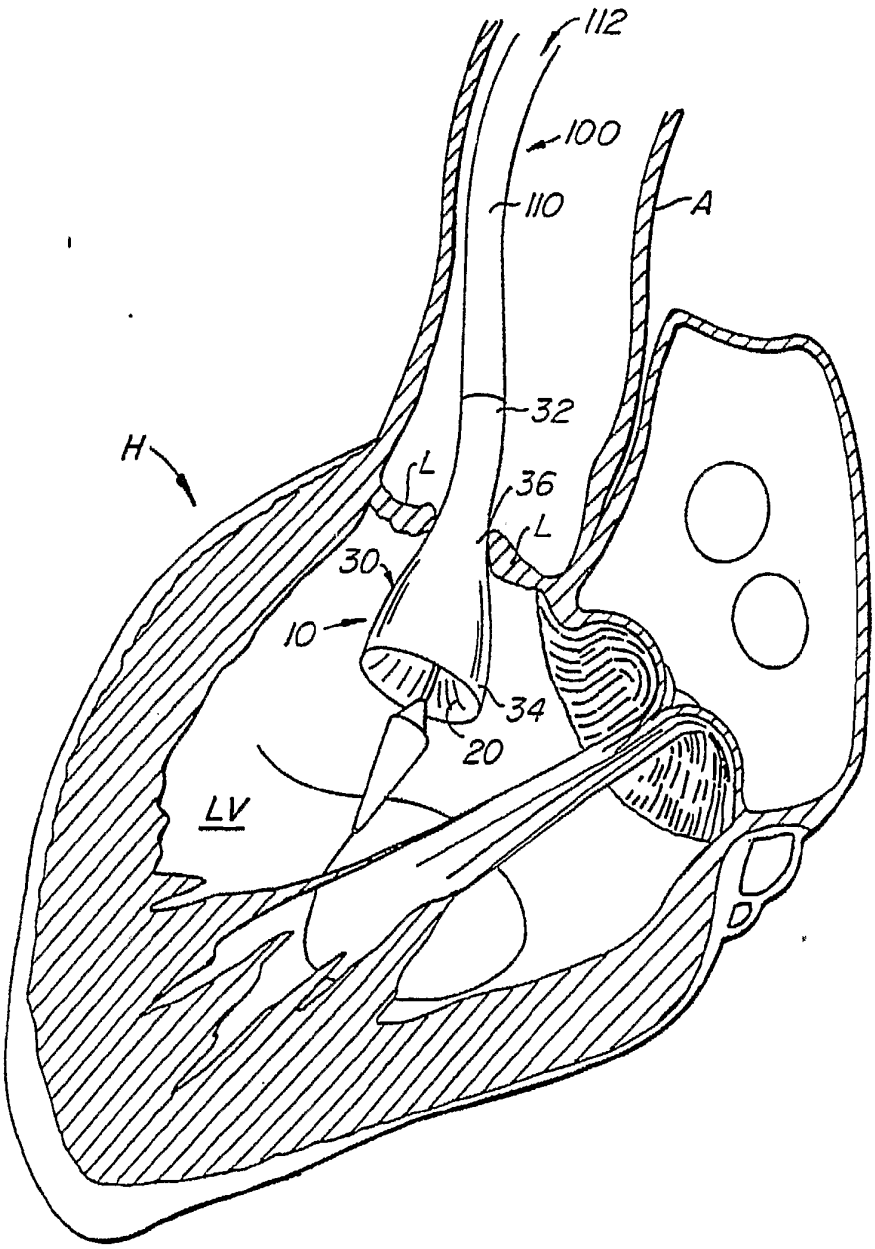

FIG. 5B

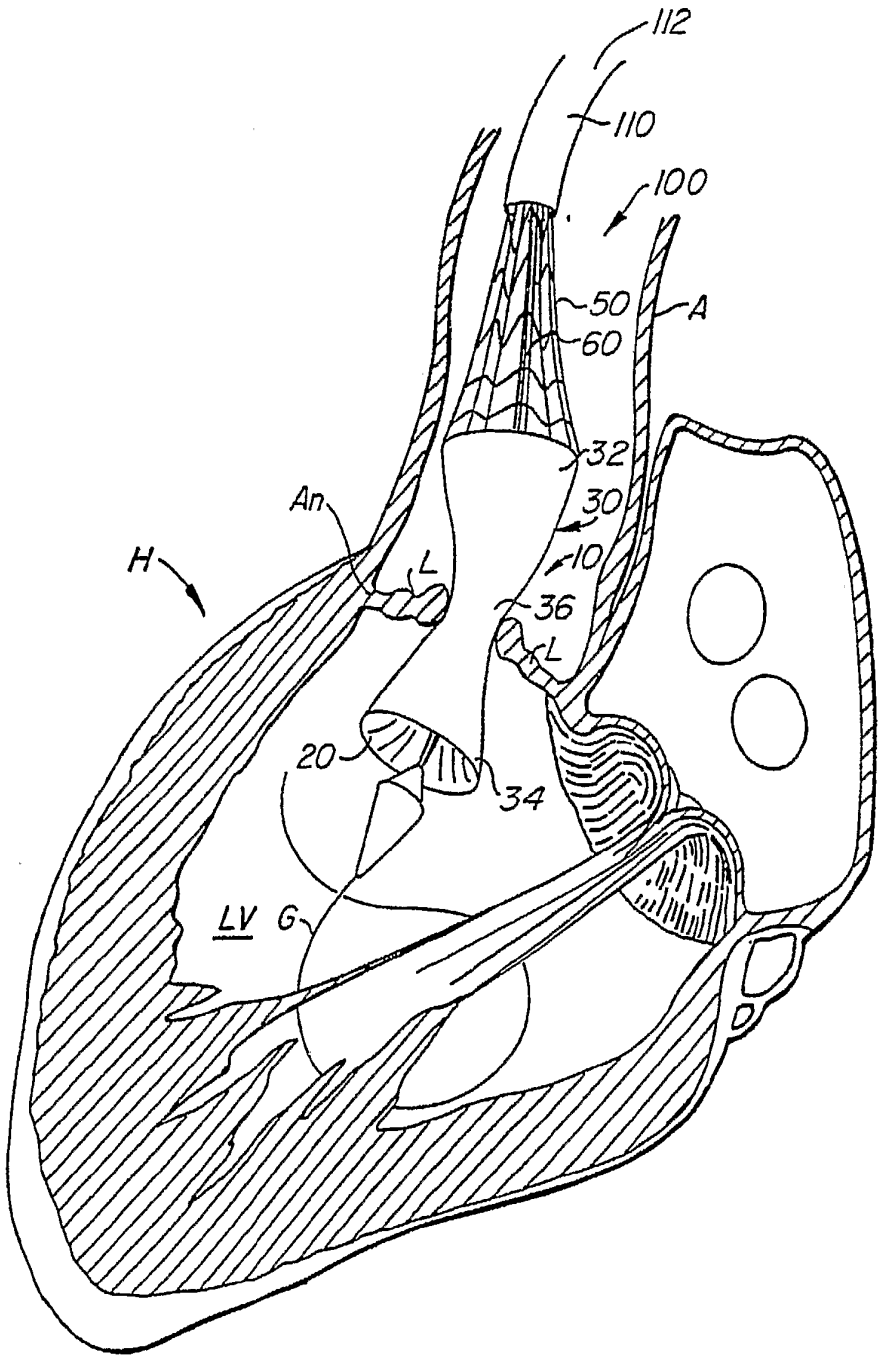

FIG. 5C

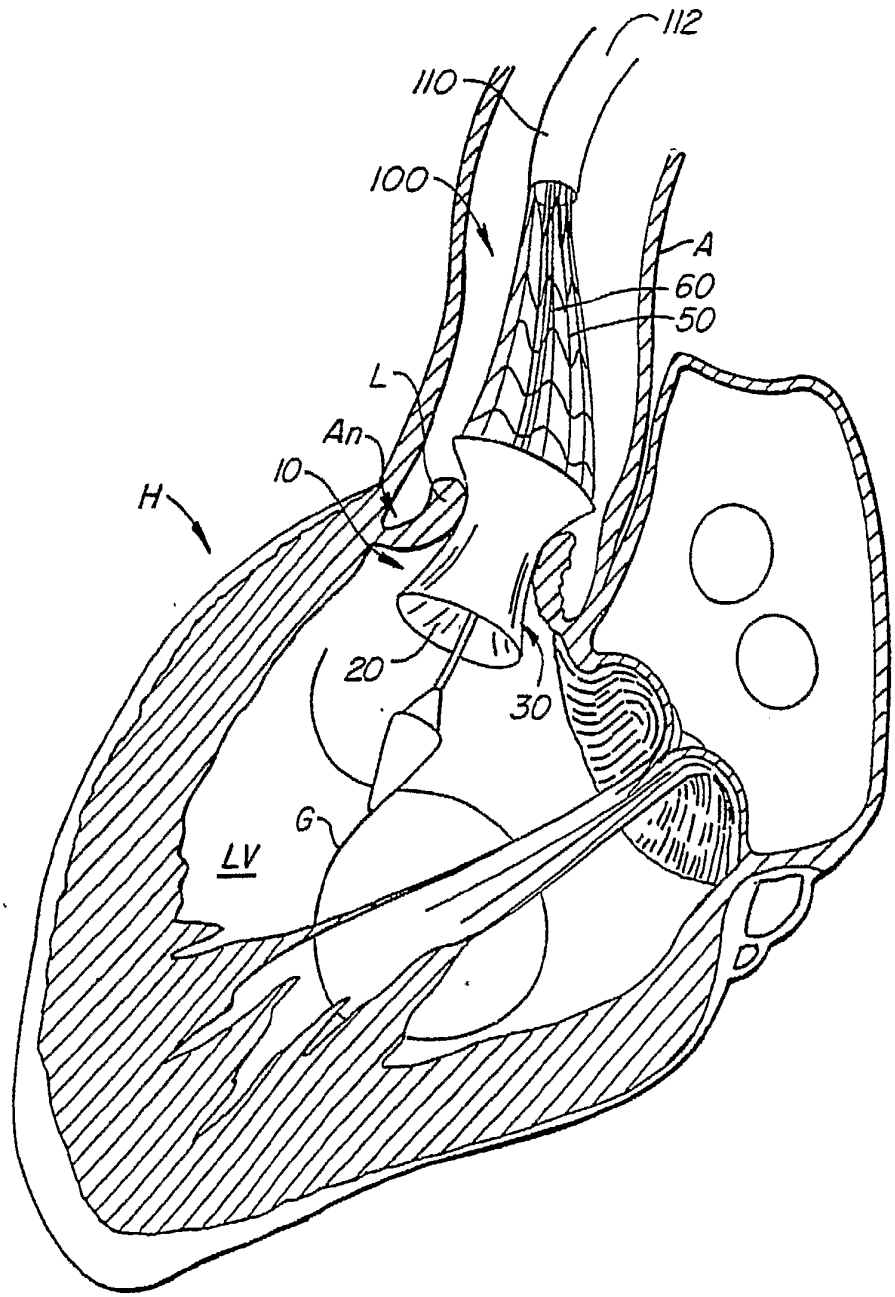

FIG. 5D

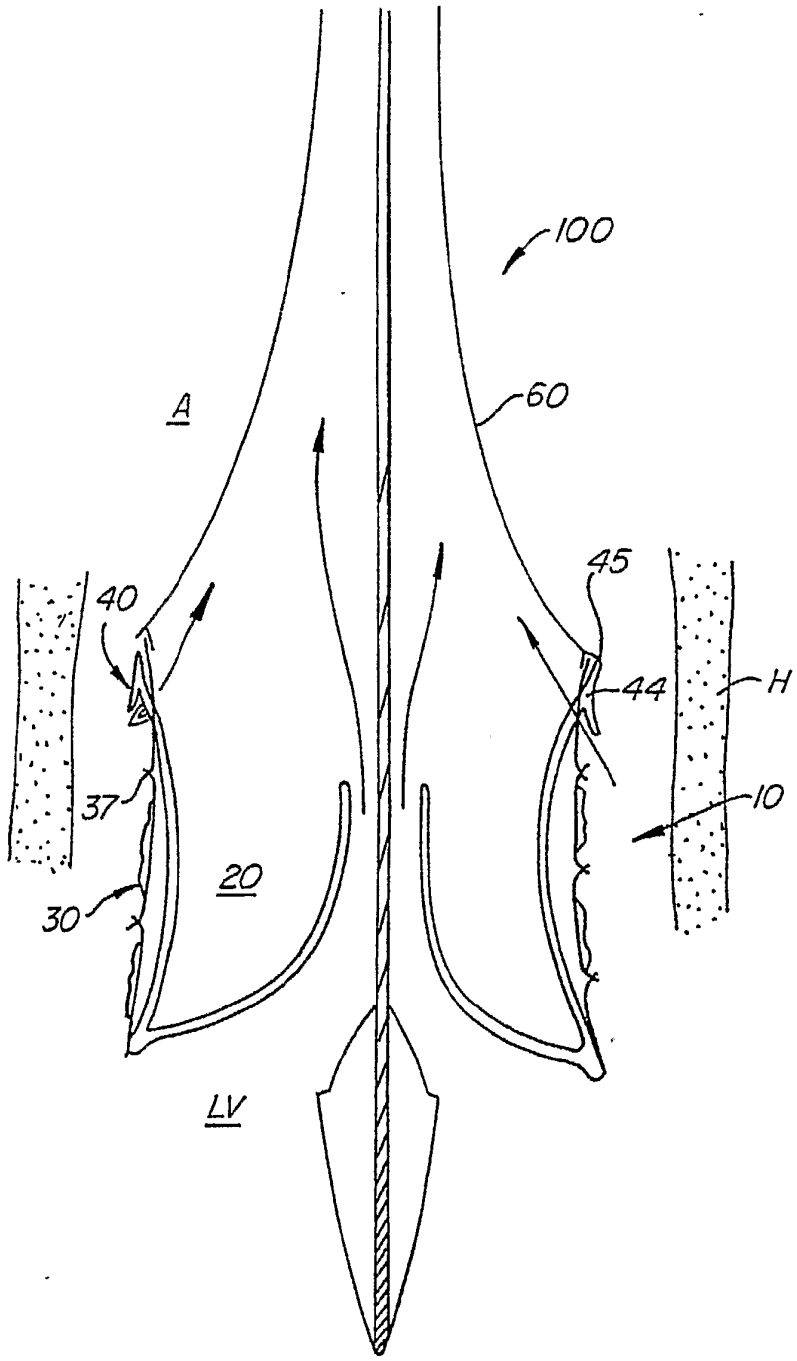

FIG. 5E

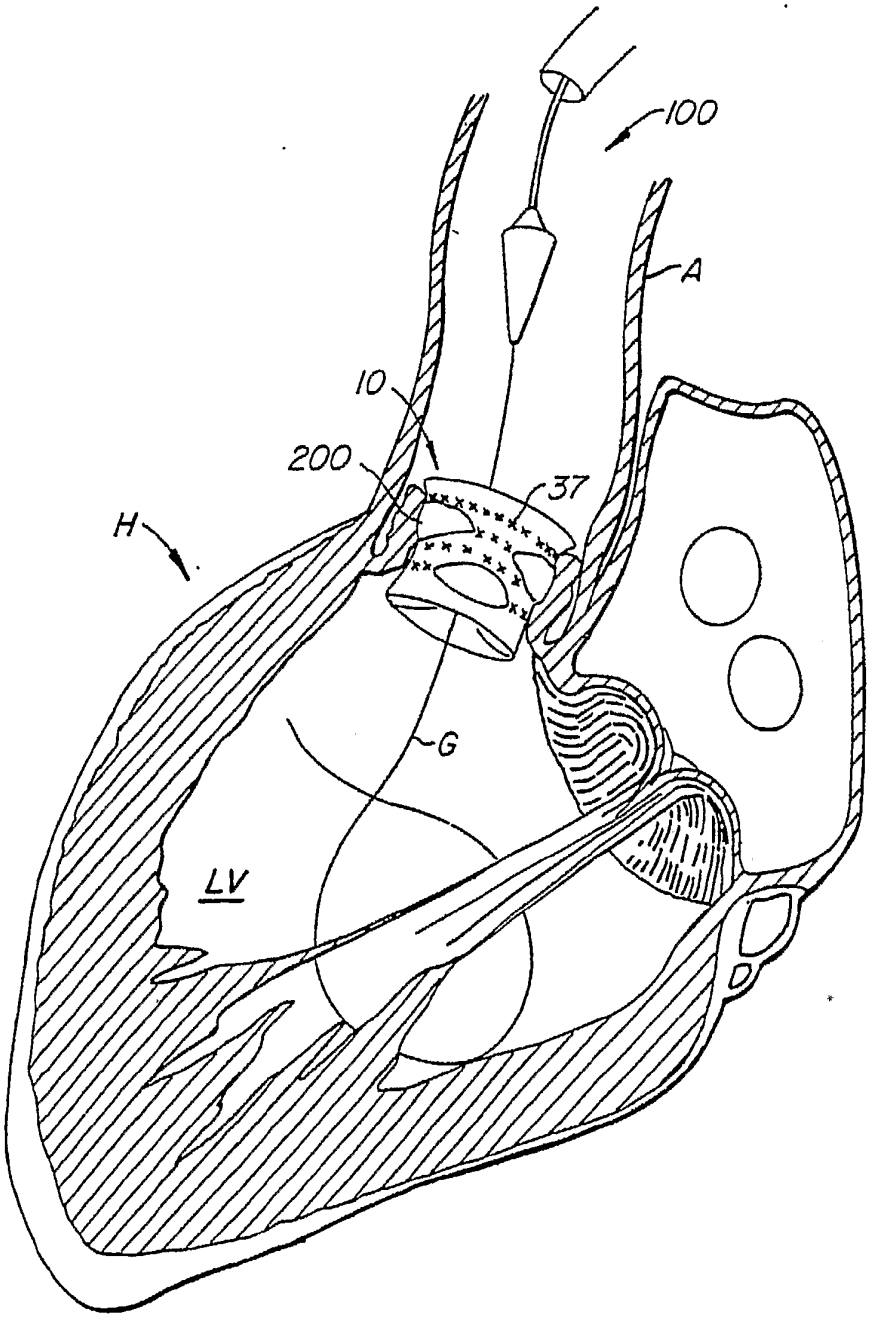

FIG. 5F

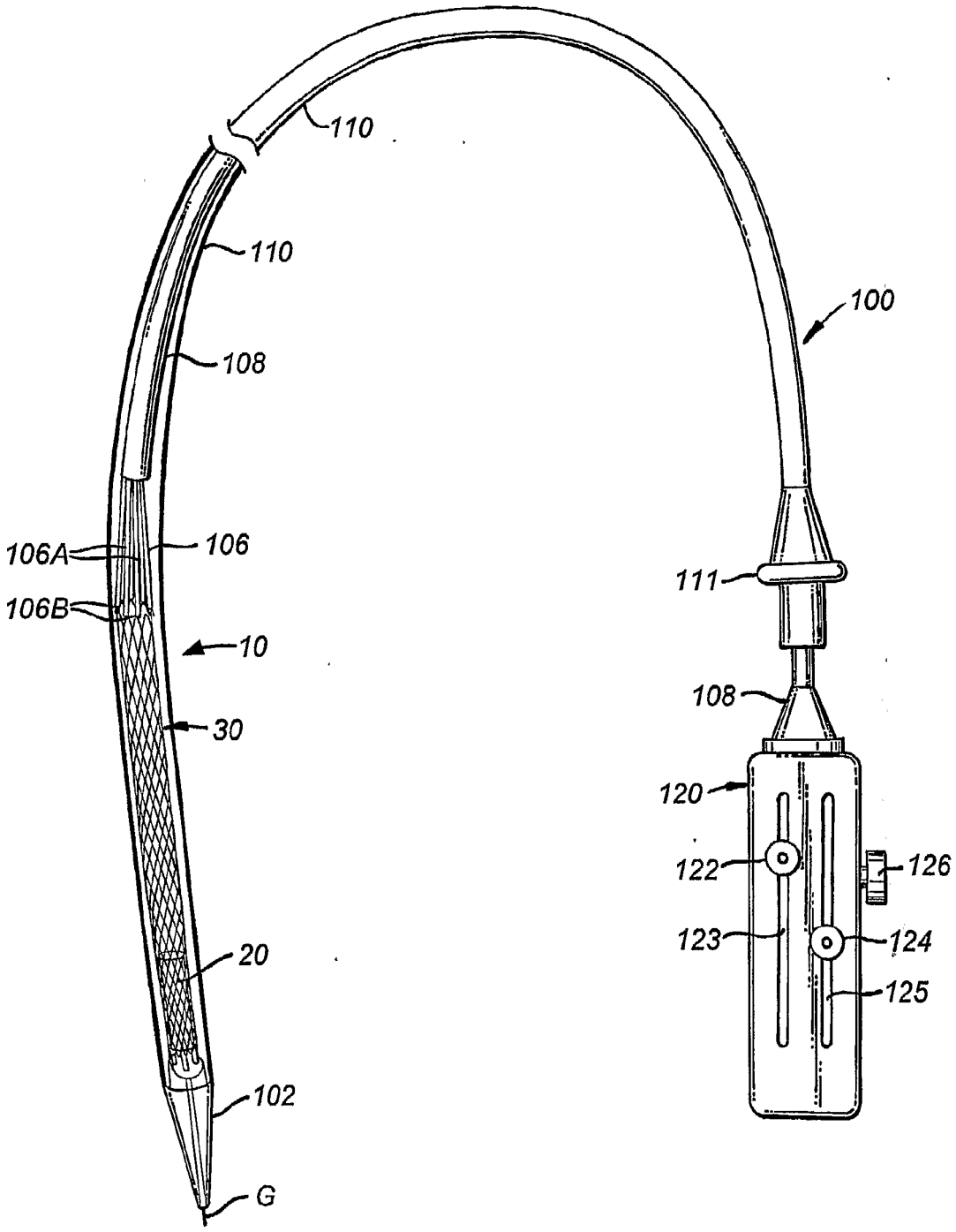

FIG. 5G

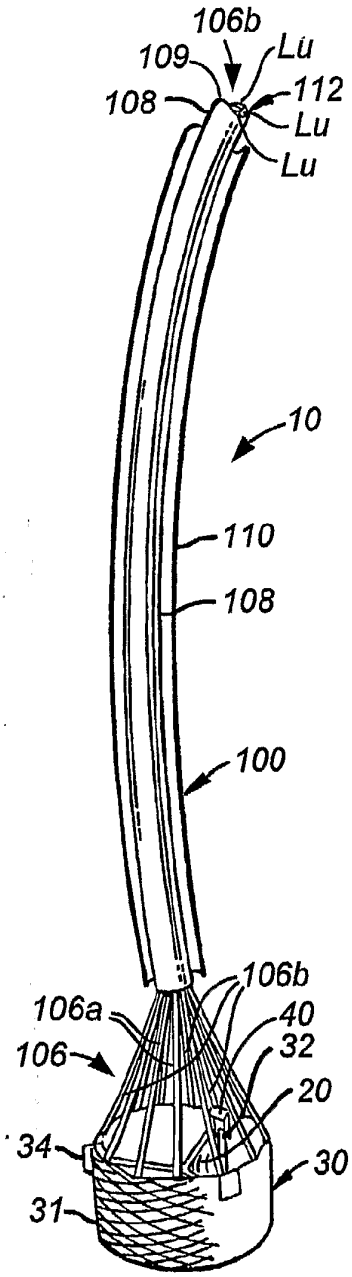

FIG. 5H

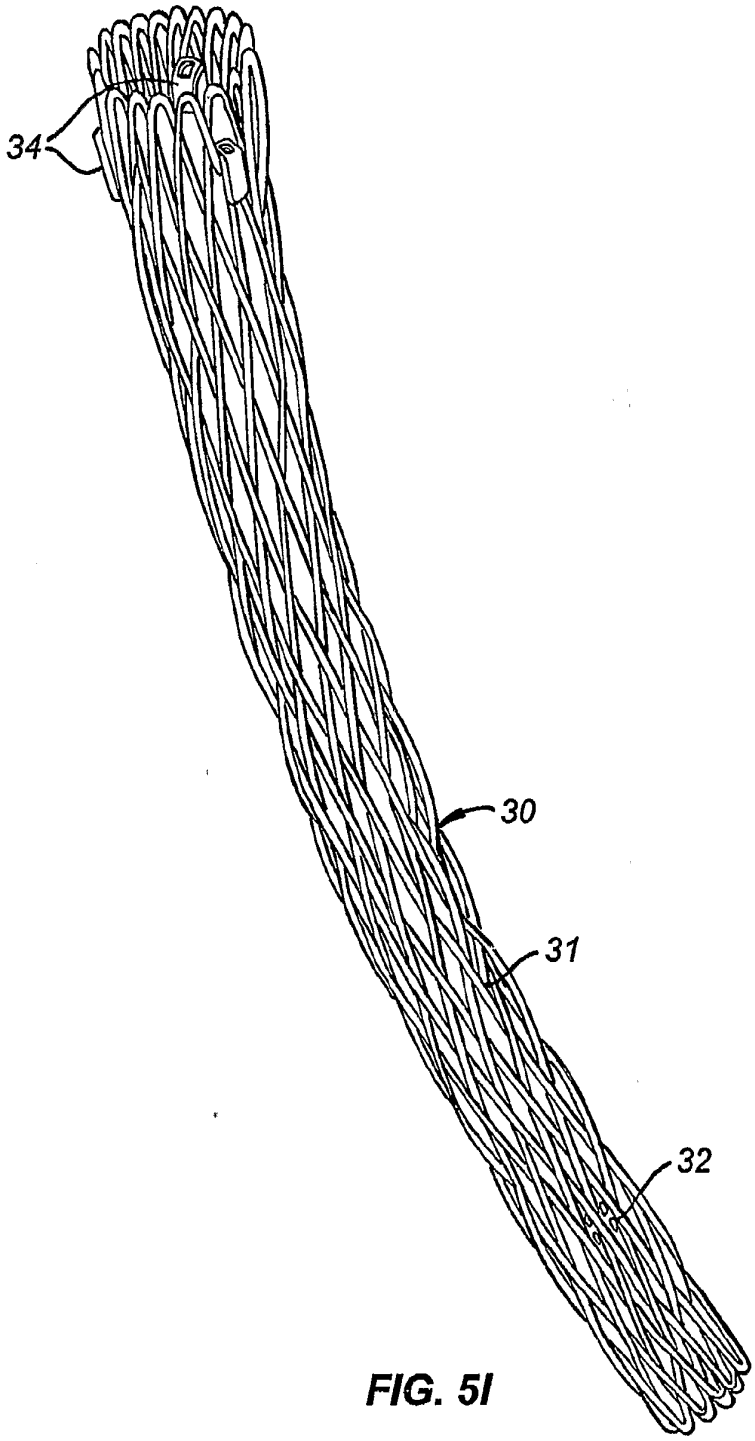

FIG. 5I

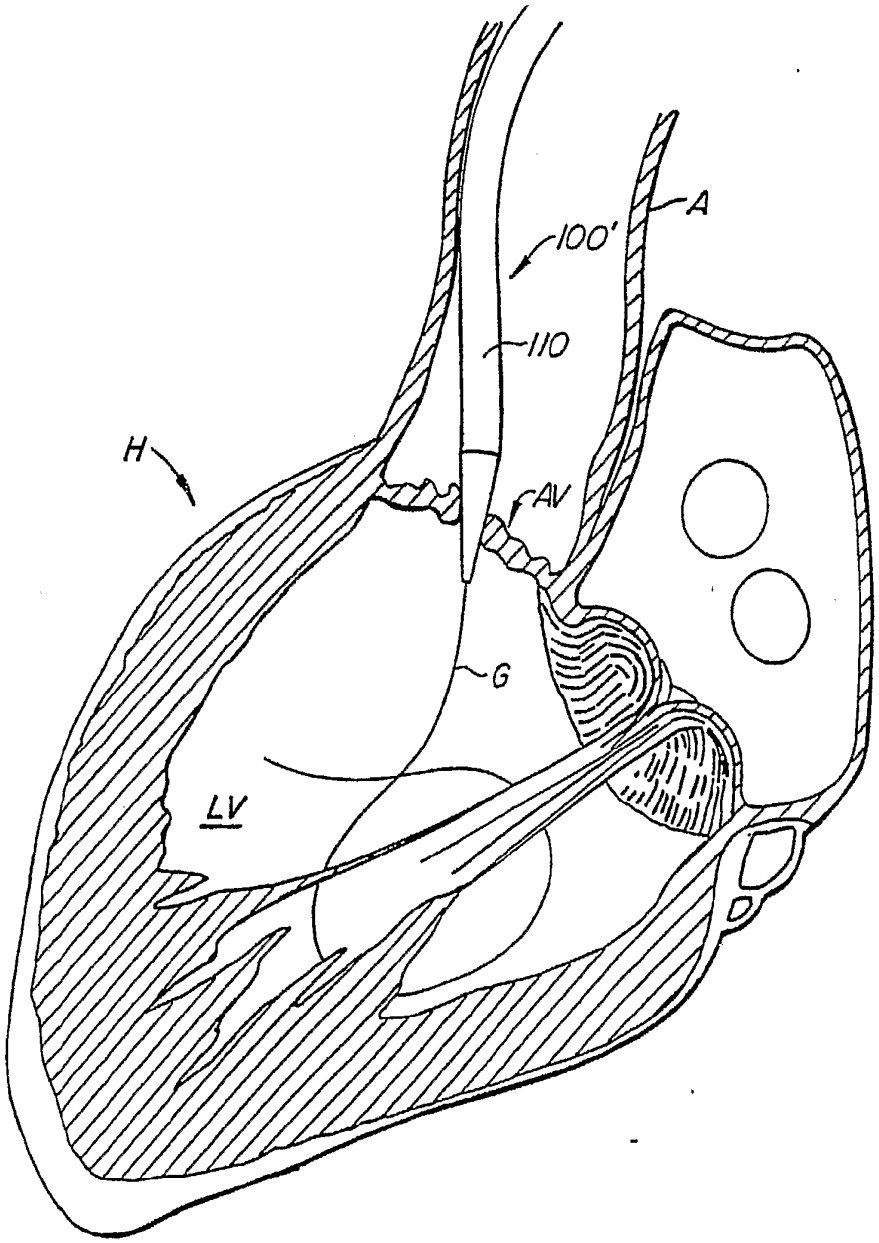

FIG. 6A

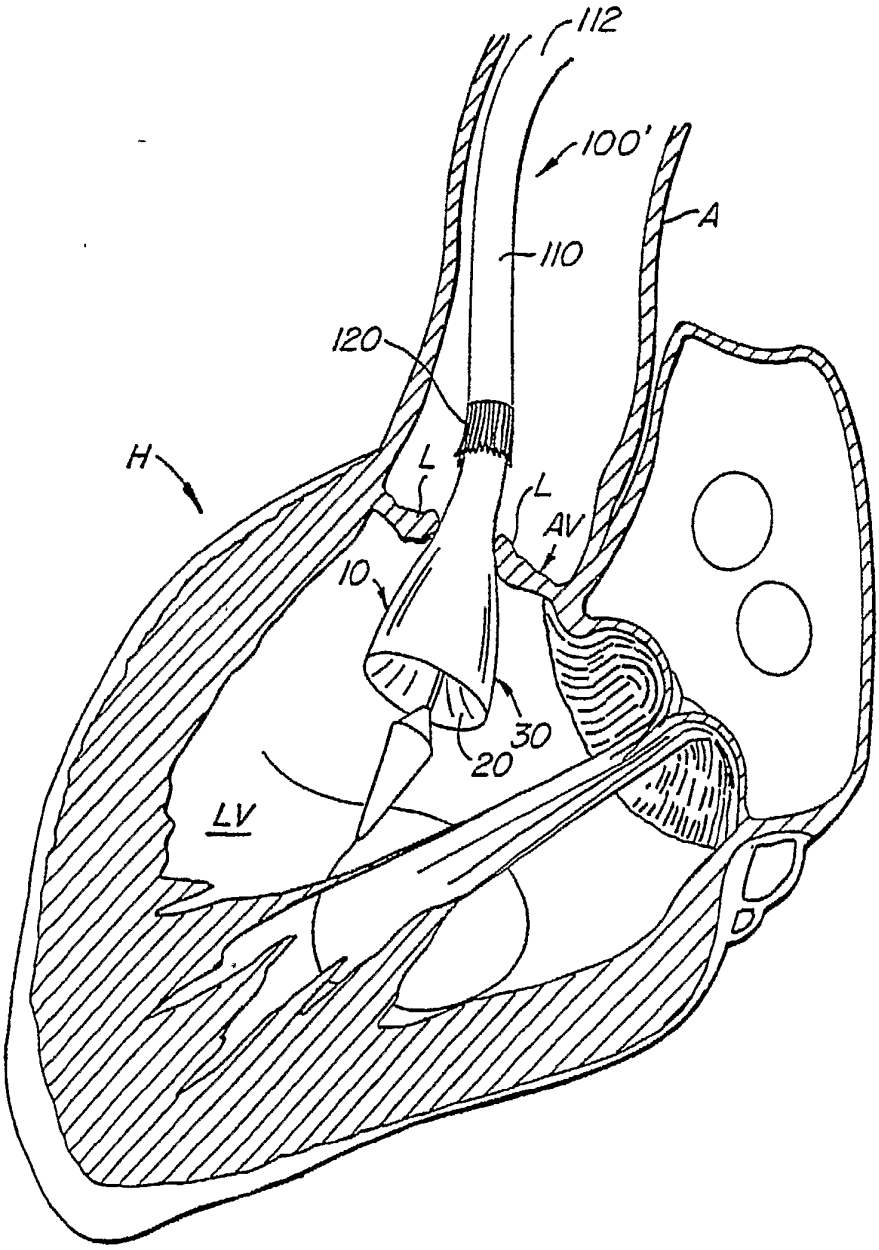

FIG. 6B

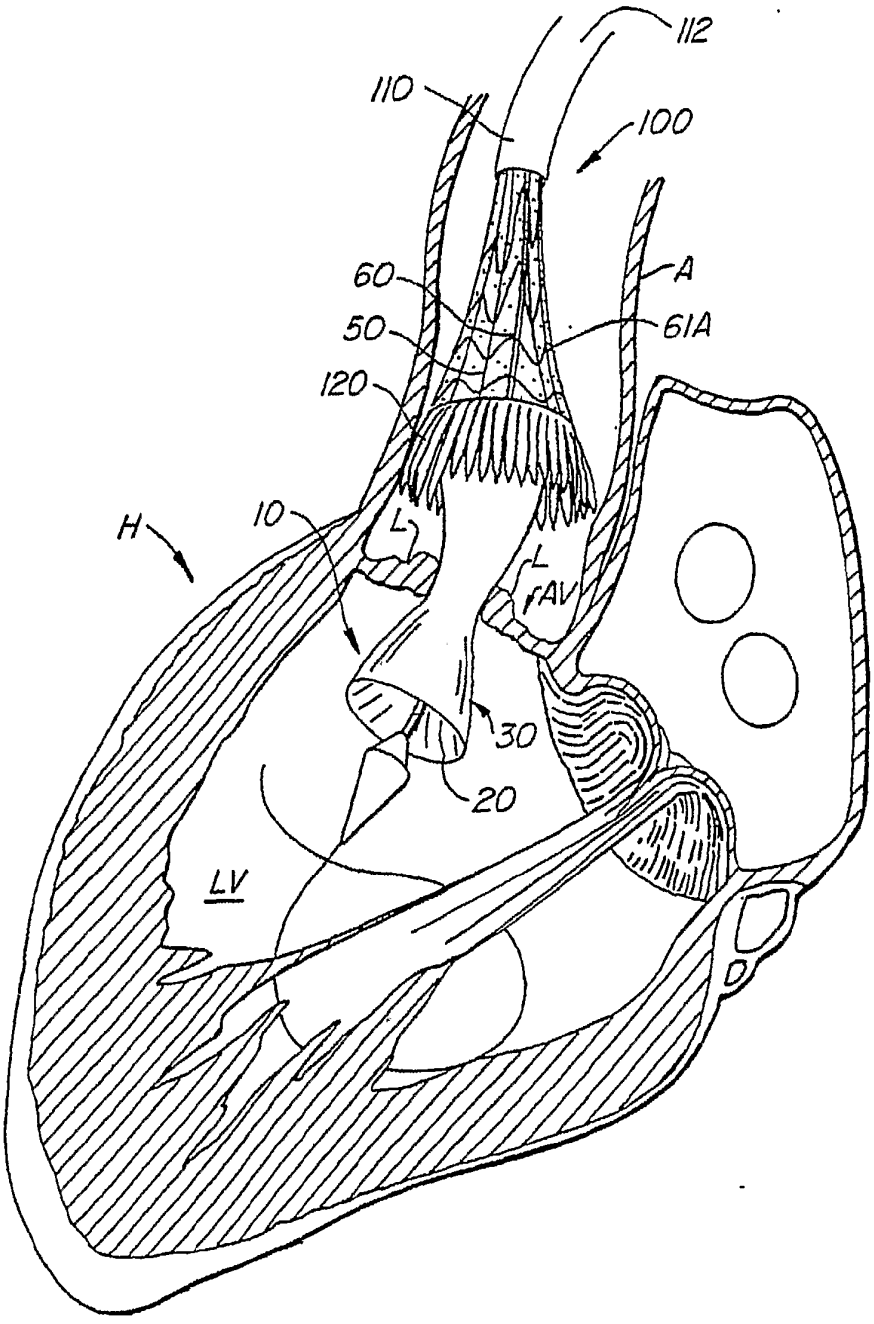

FIG. 6C

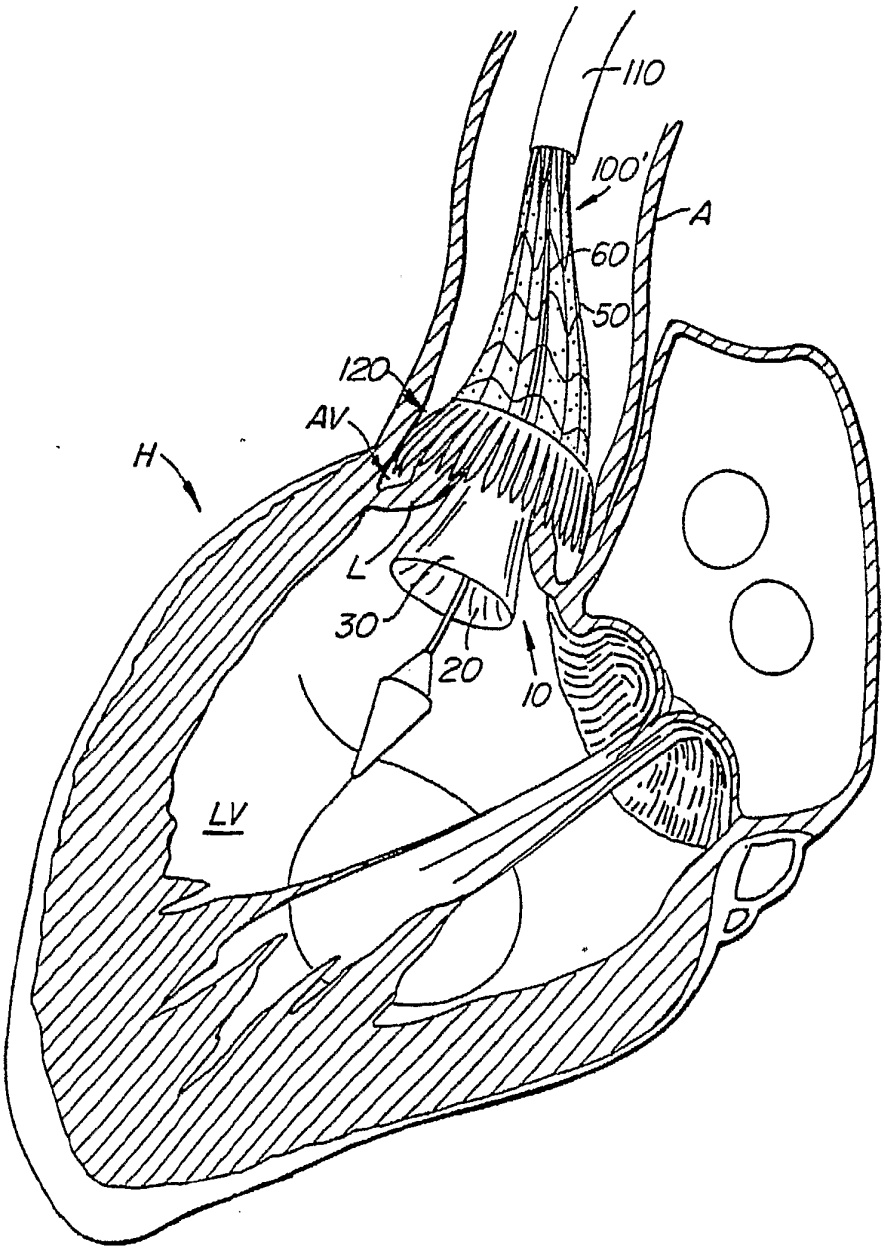

FIG. 6D

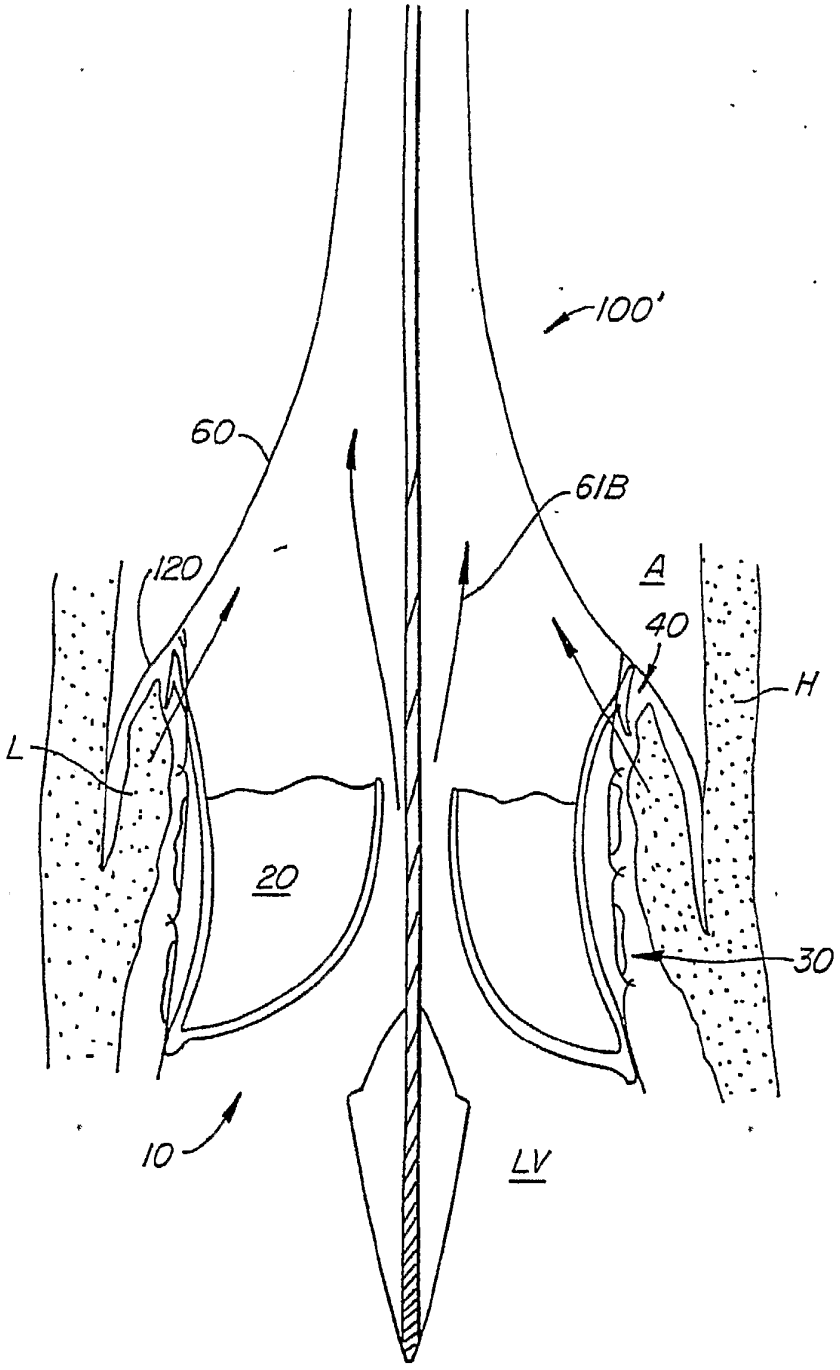

FIG. 6E

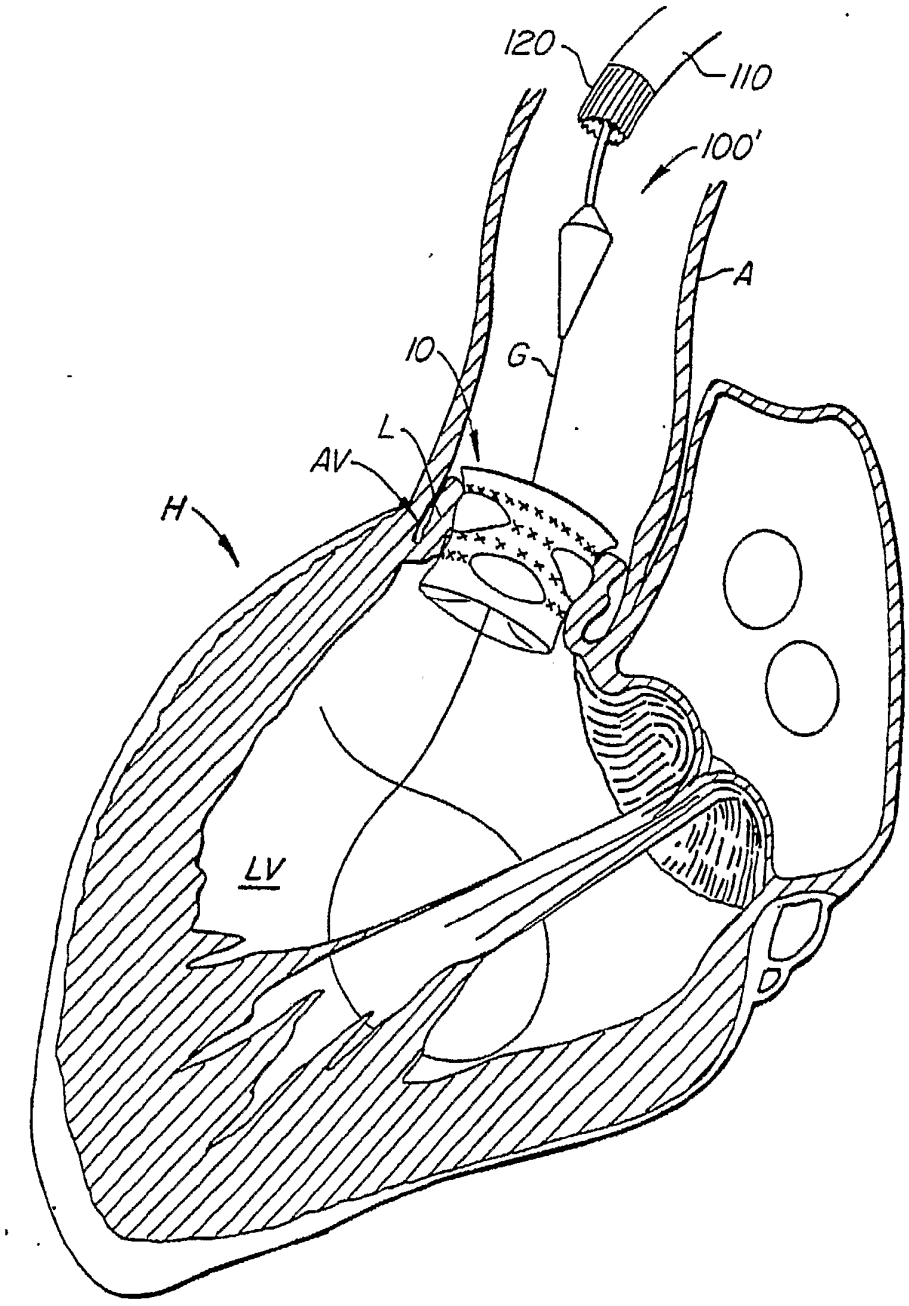

FIG. 6F

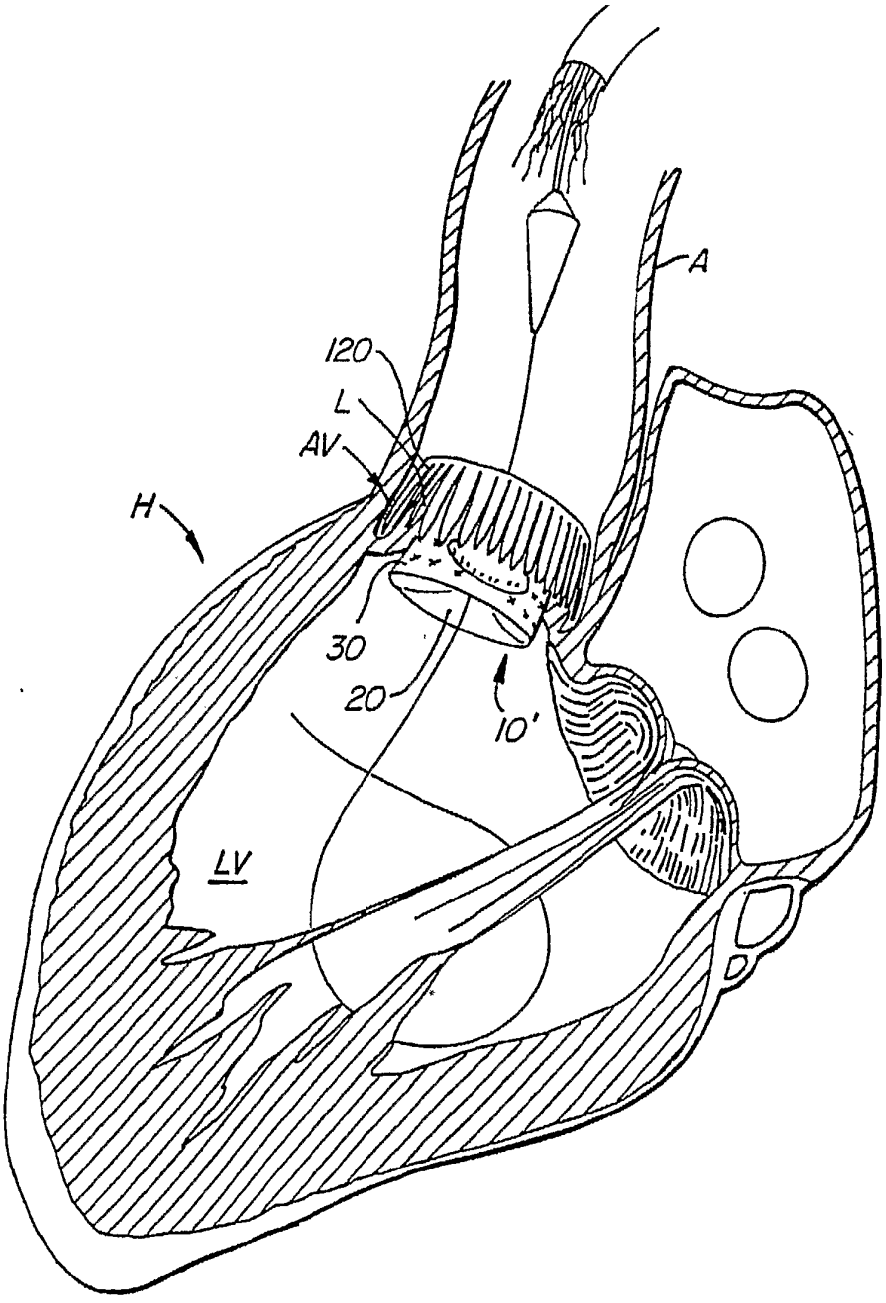

FIG. 7

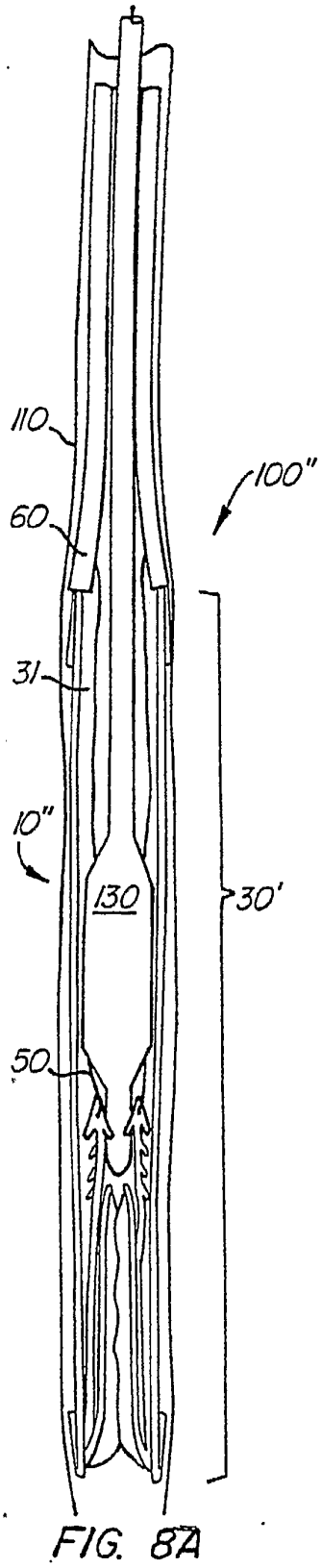

FIG. 8A

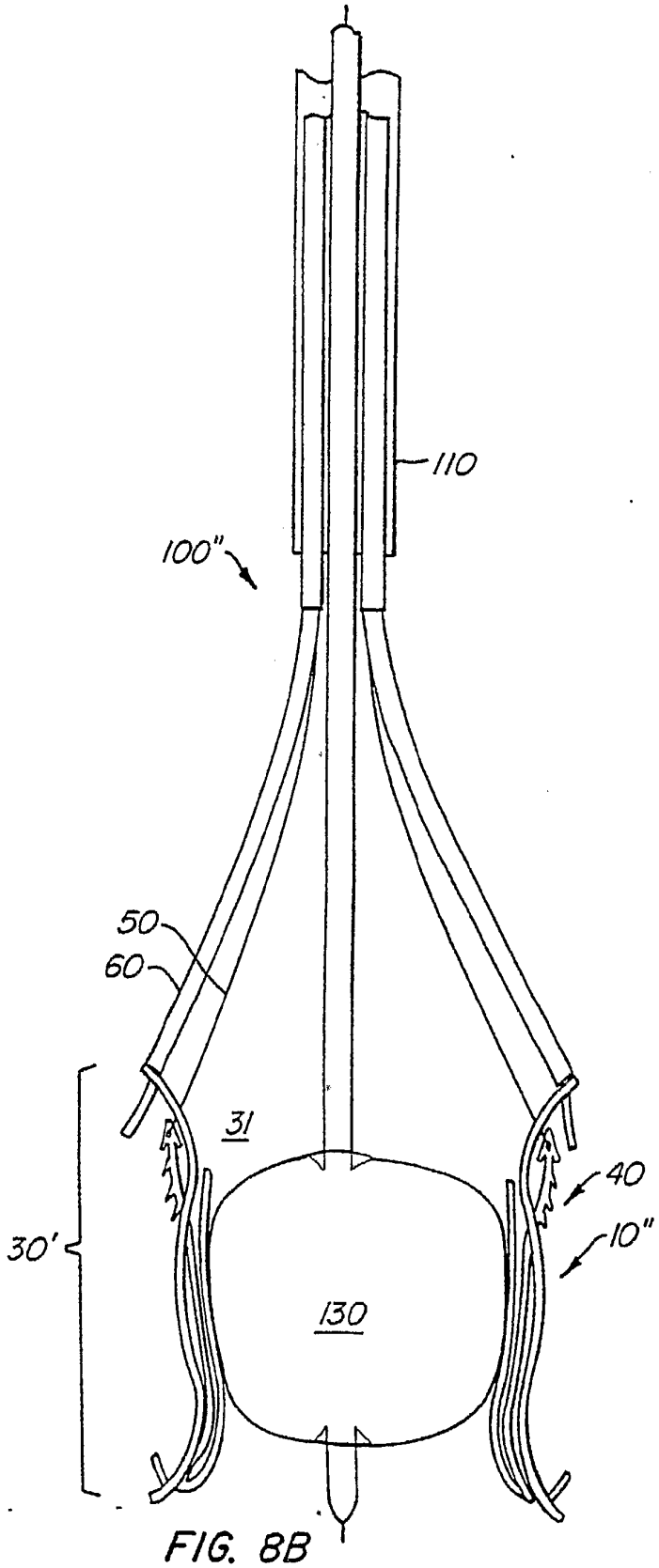

FIG. 8B

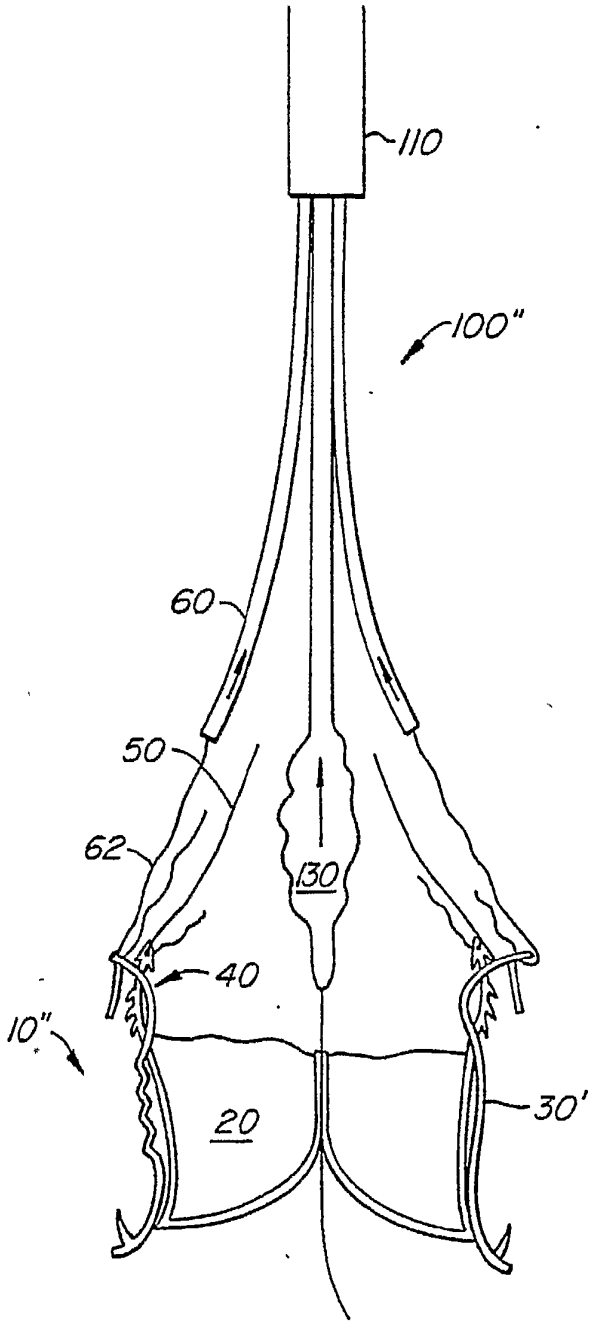

FIG. 8C

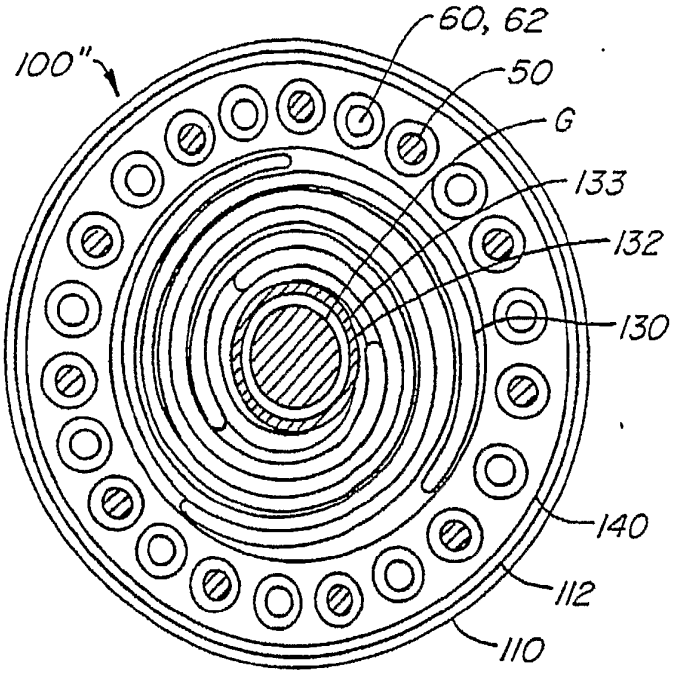

FIG. 10

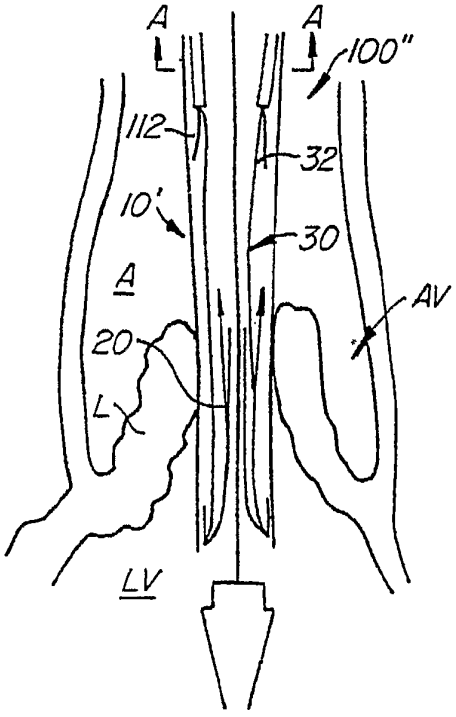

FIG. 9A

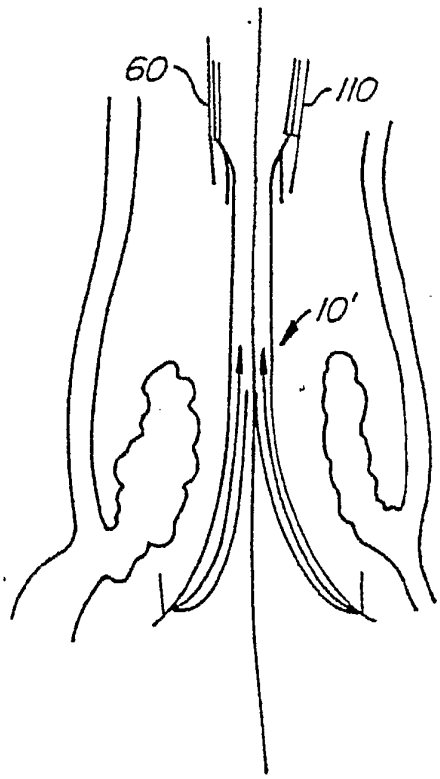

FIG. 9B

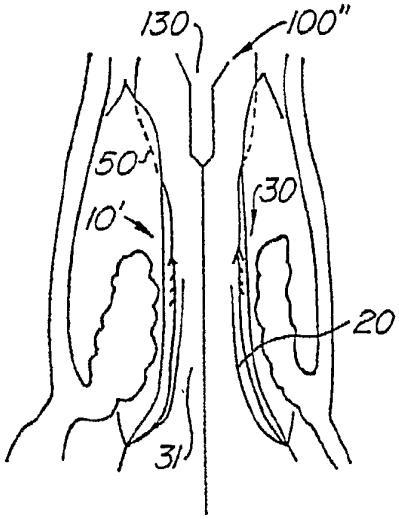

FIG. 9C

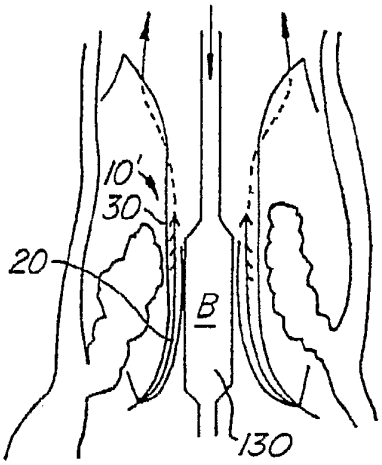

FIG. 9D

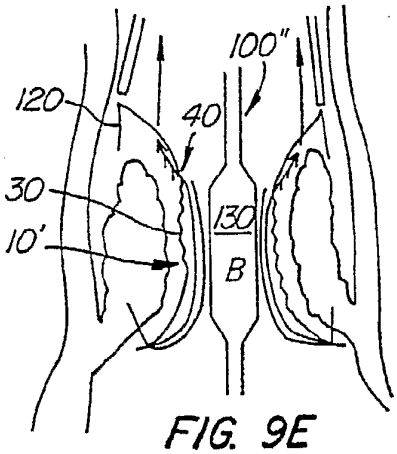

FIG. 9E

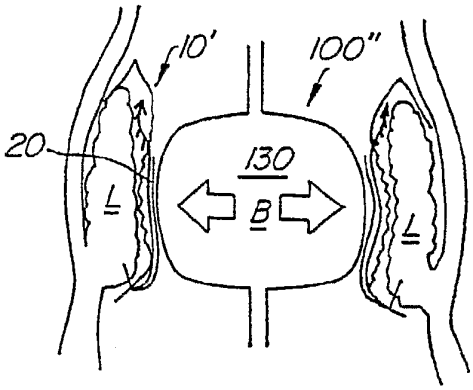

FIG. 9F

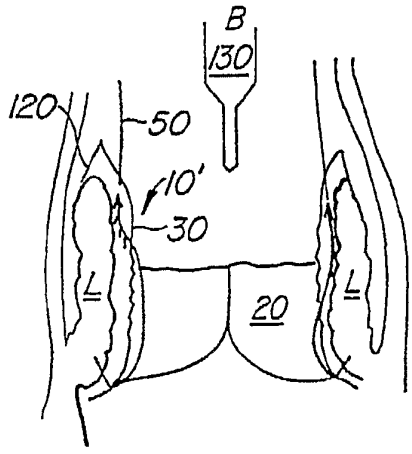

FIG. 9G

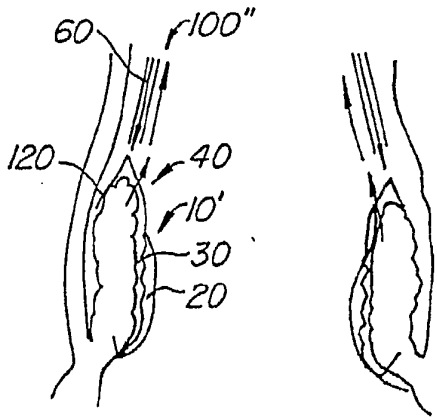

FIG. 9H

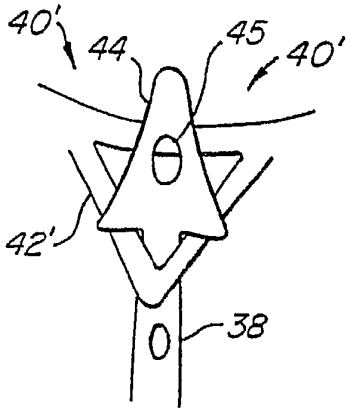

FIG. IIA

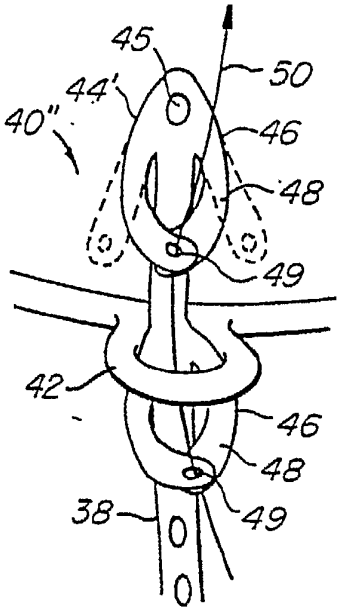

FIG. IIB

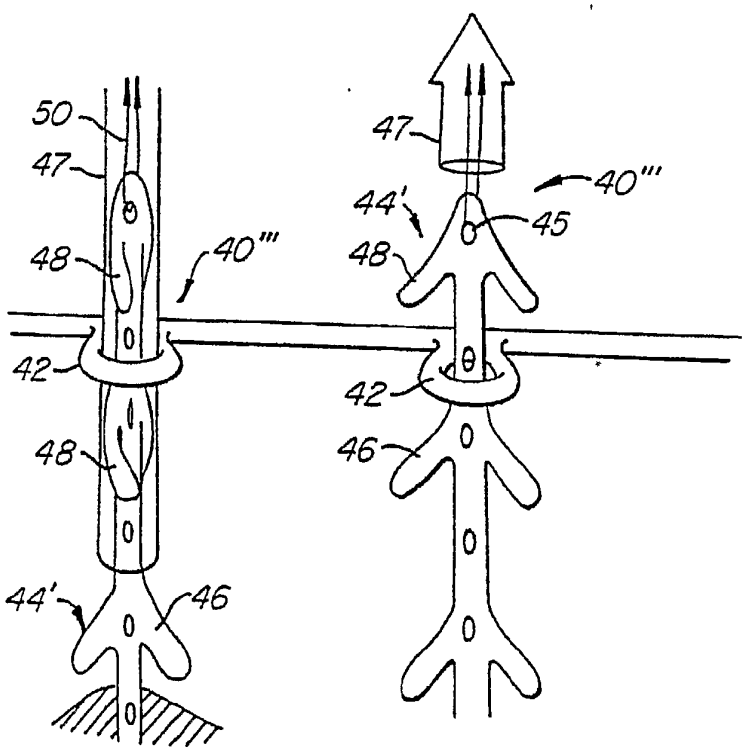

FIG. IIC

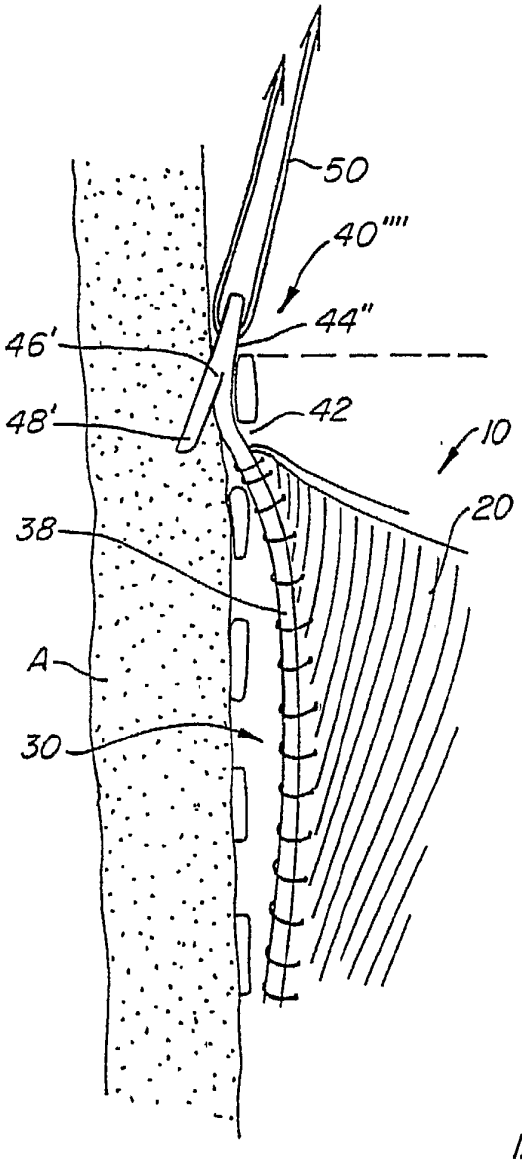

FIG. 12C

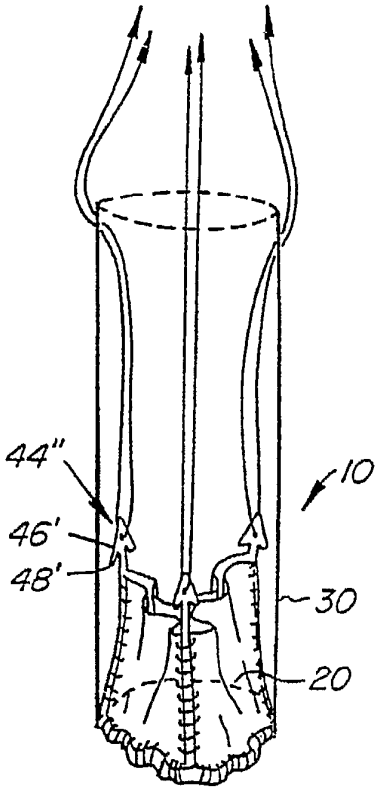

FIG. 12A

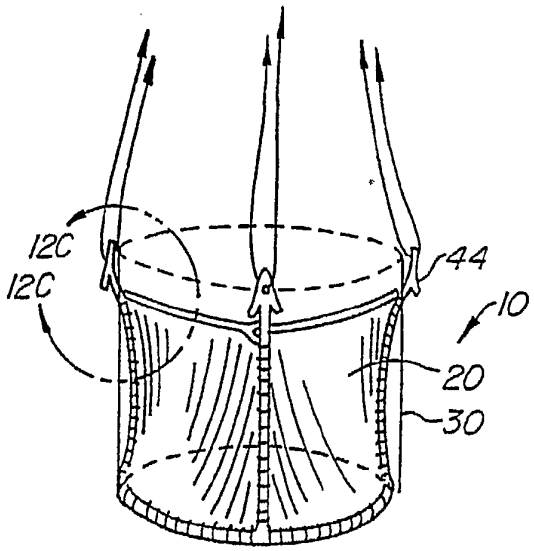

FIG. 12B

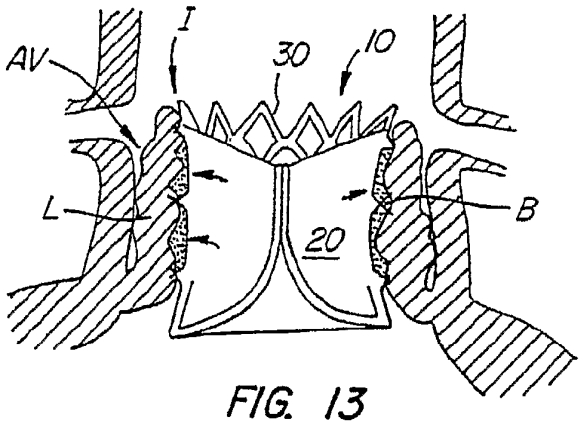

FIG. 13

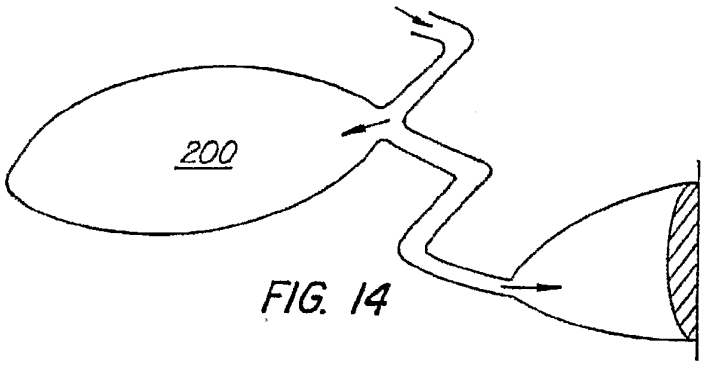

FIG. 14

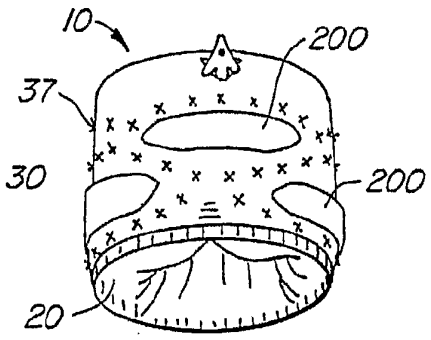

FIG. 15A

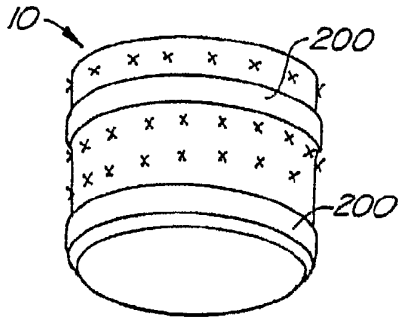

FIG. 15B

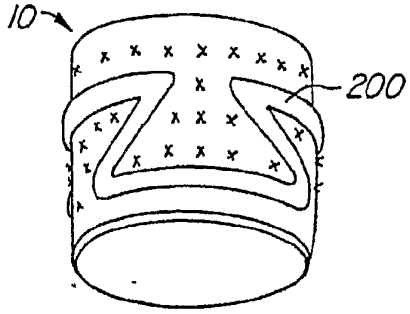

FIG. 15C

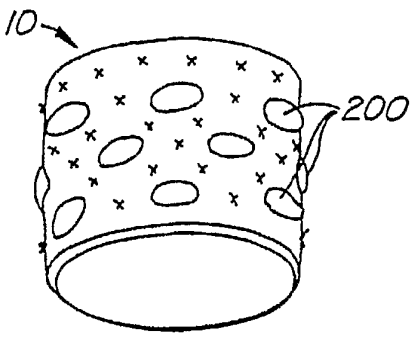

FIG. 15D

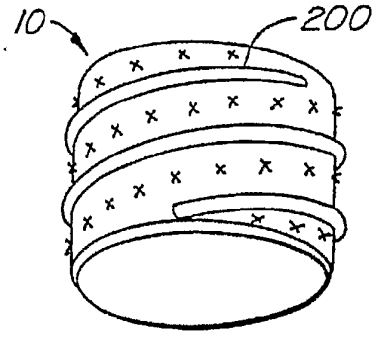

FIG. 15E

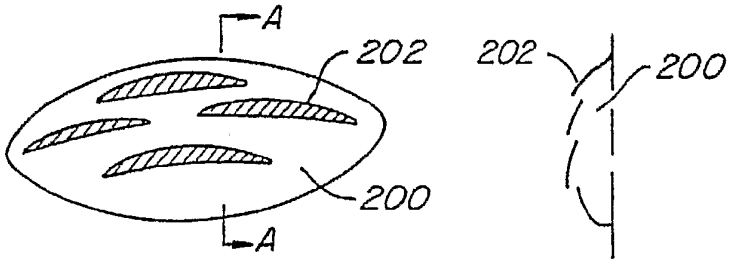

FIG. 16A

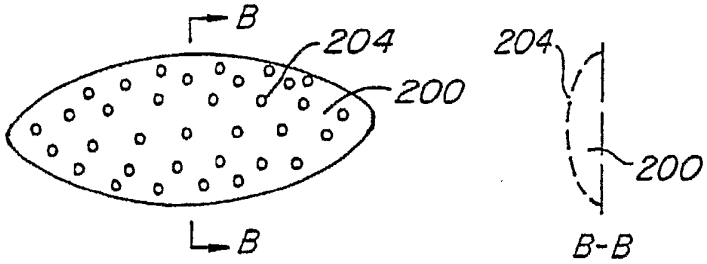

FIG. 16B

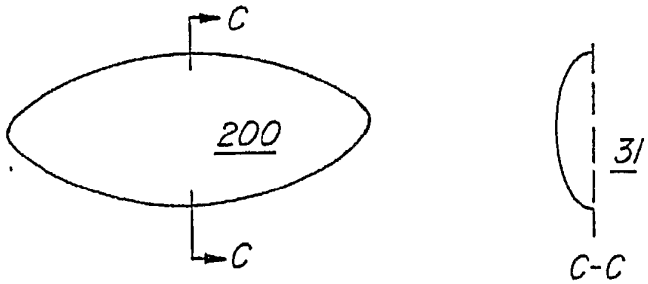

FIG. 16C

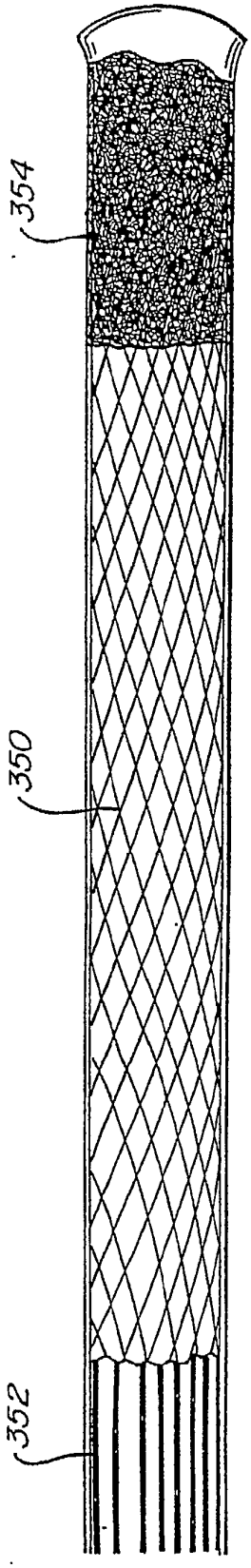

FIG. 17

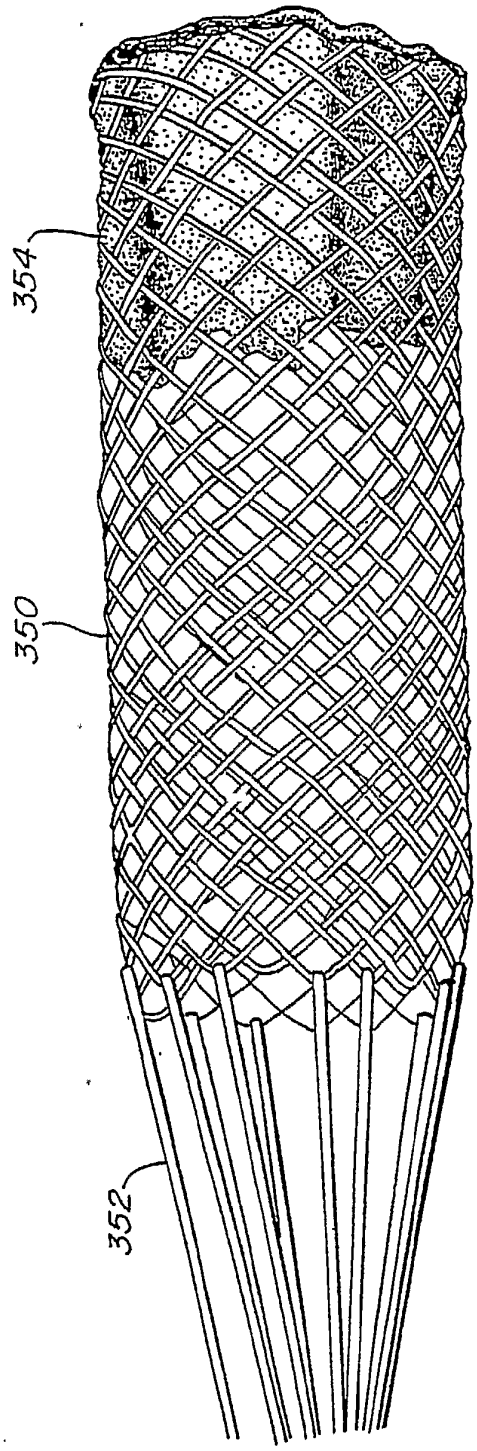

FIG. 18

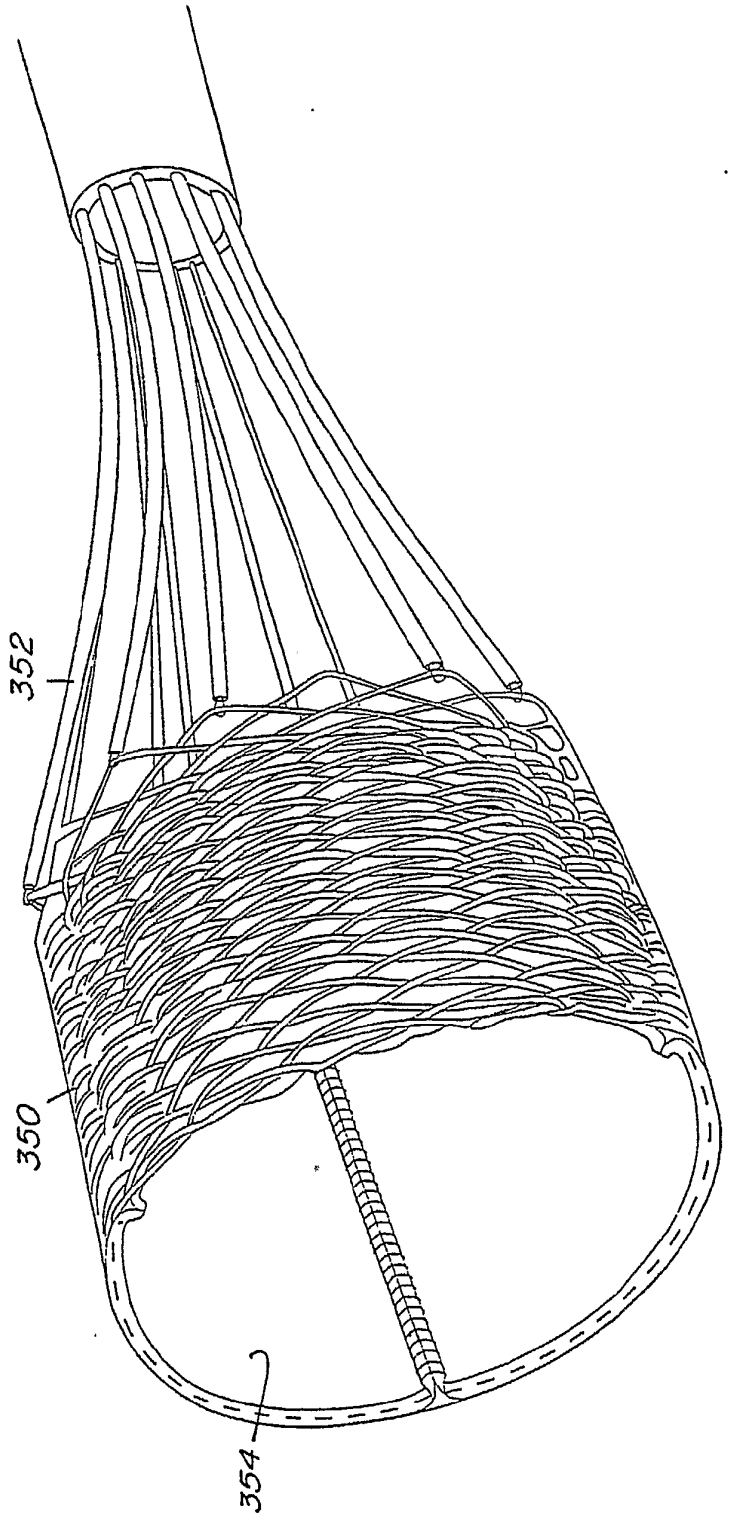

FIG. 19

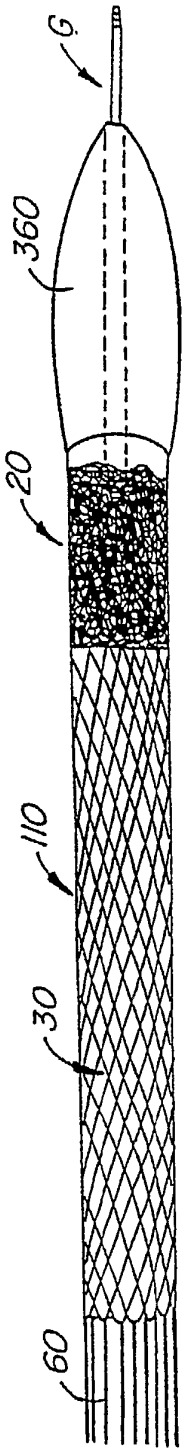

FIG. 20

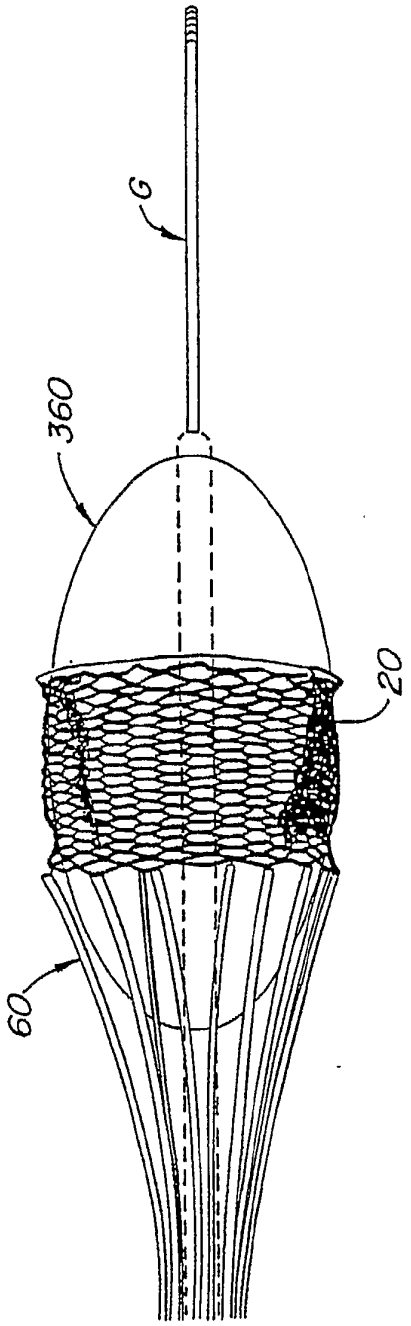

FIG. 21

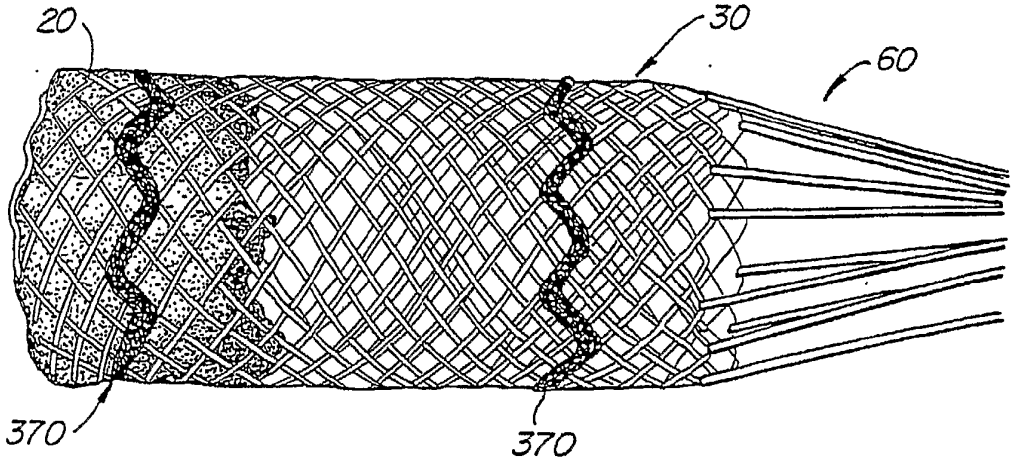

FIG. 22

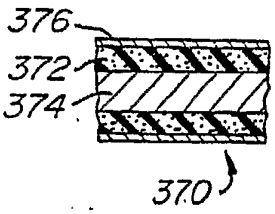

FIG. 23

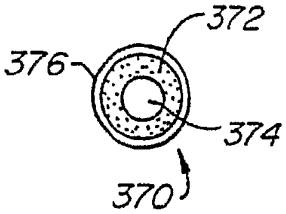

FIG. 24

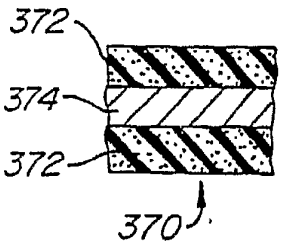

FIG. 25

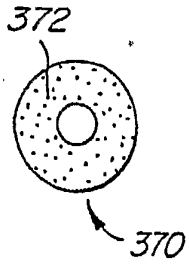

FIG. 26

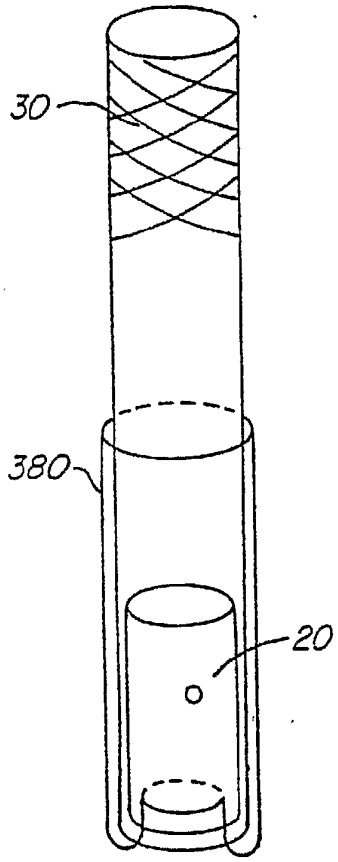

FIG. 27

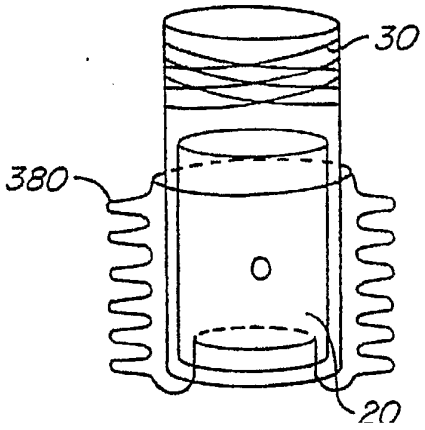

FIG. 28

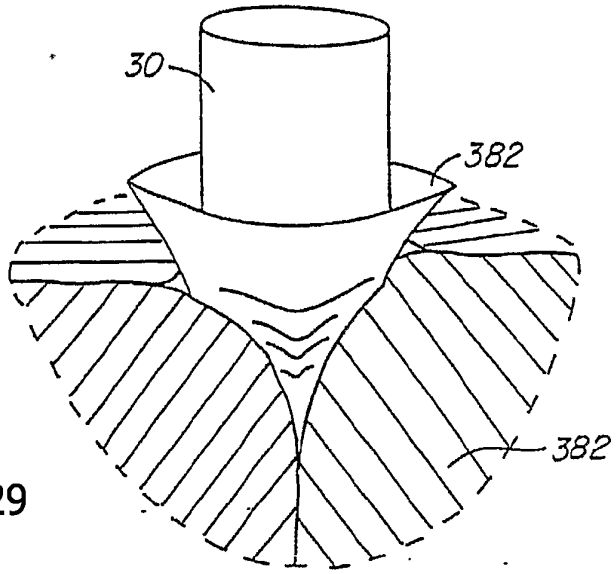

FIG. 29

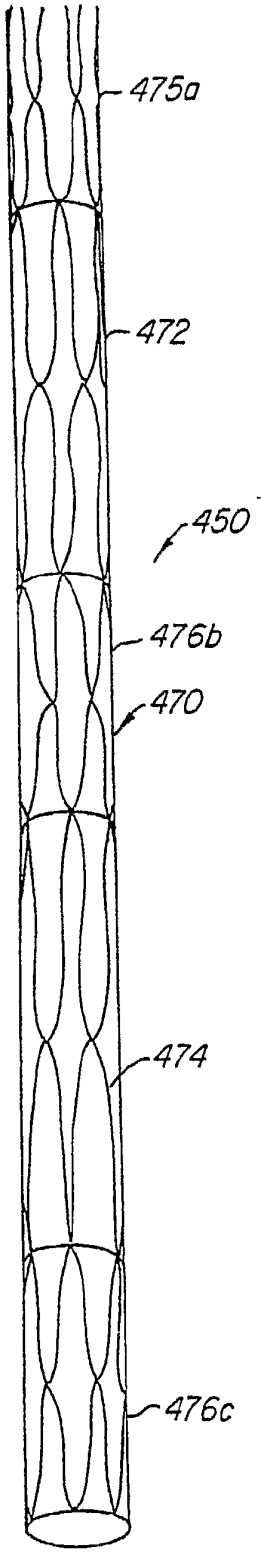

FIG. 30A

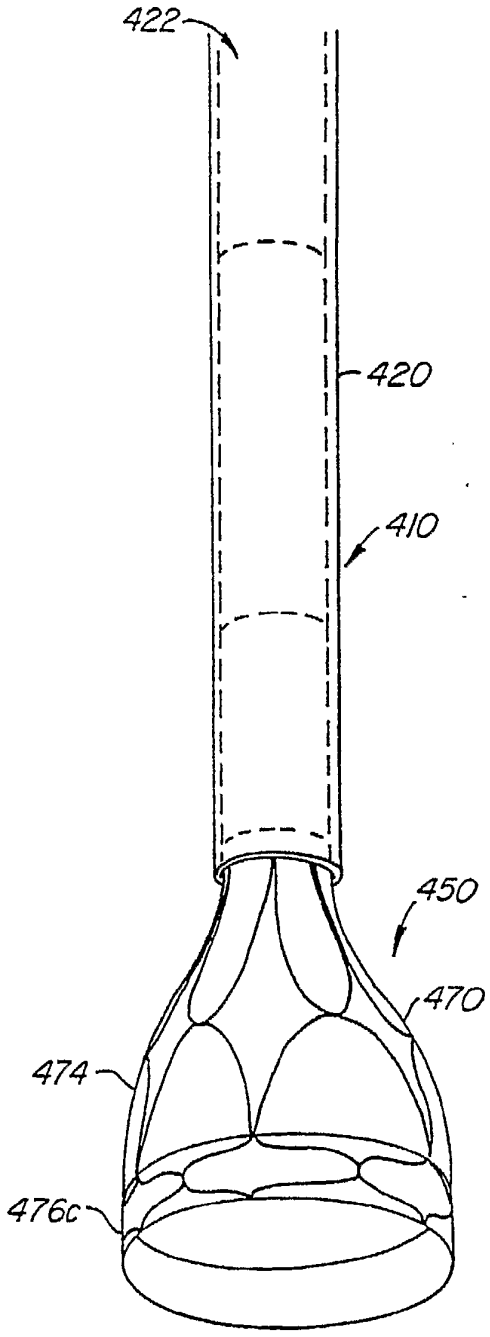

FIG. 30B

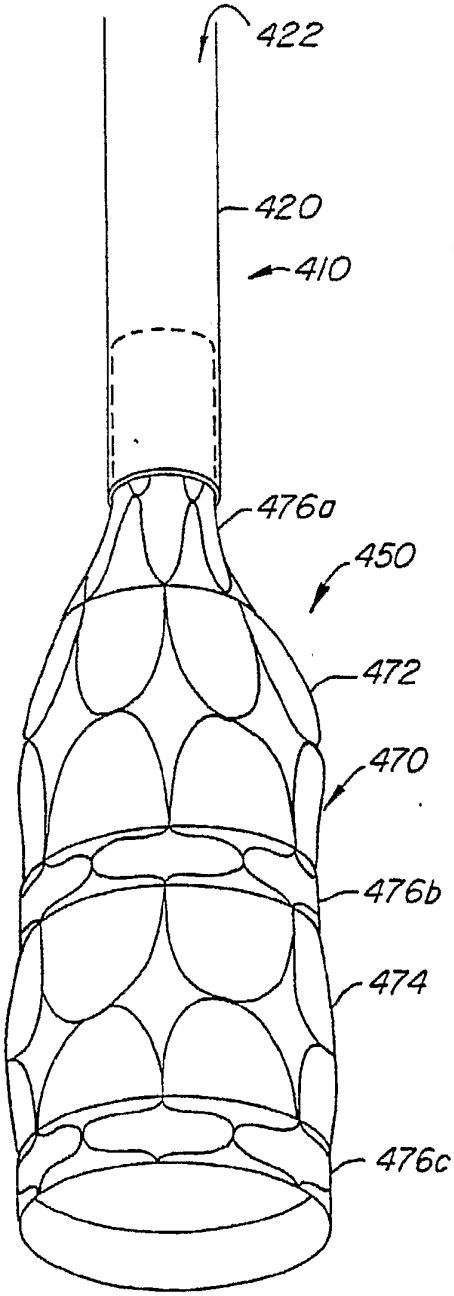

FIG. 30C

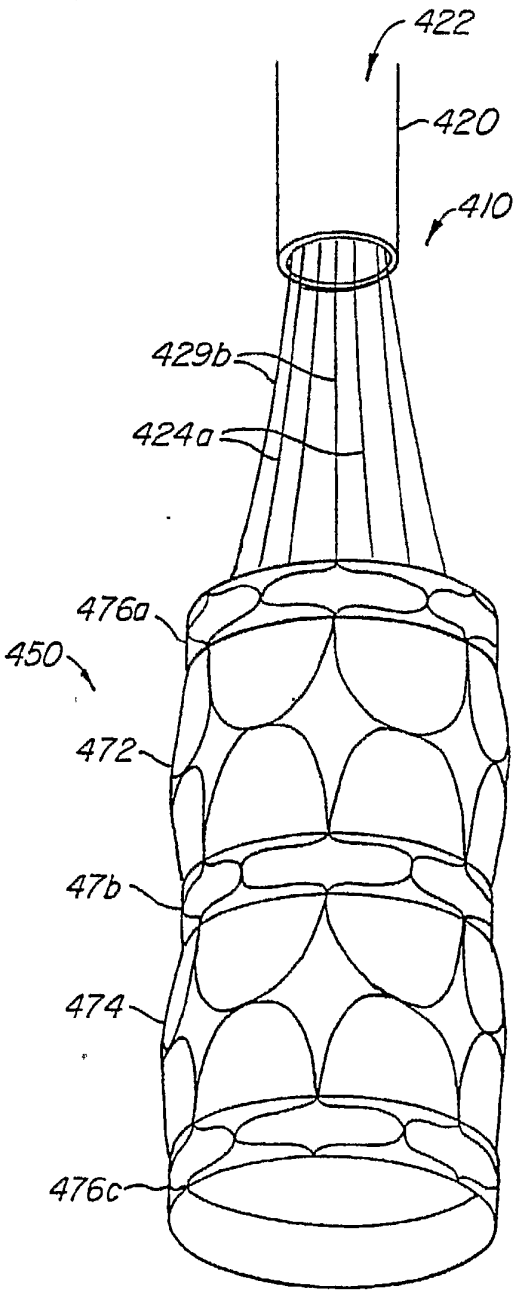

FIG. 30D

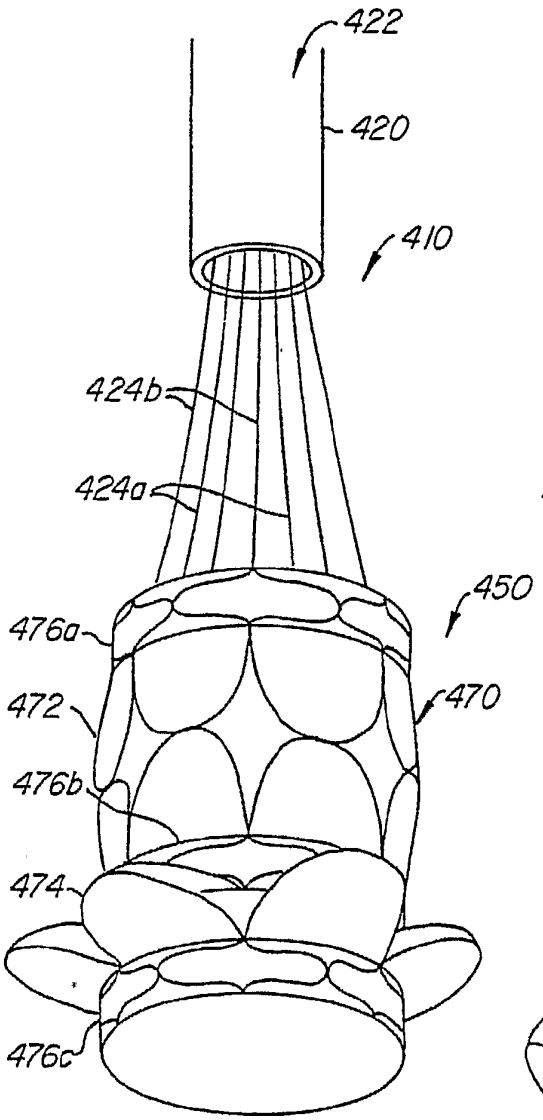

FIG. 30E

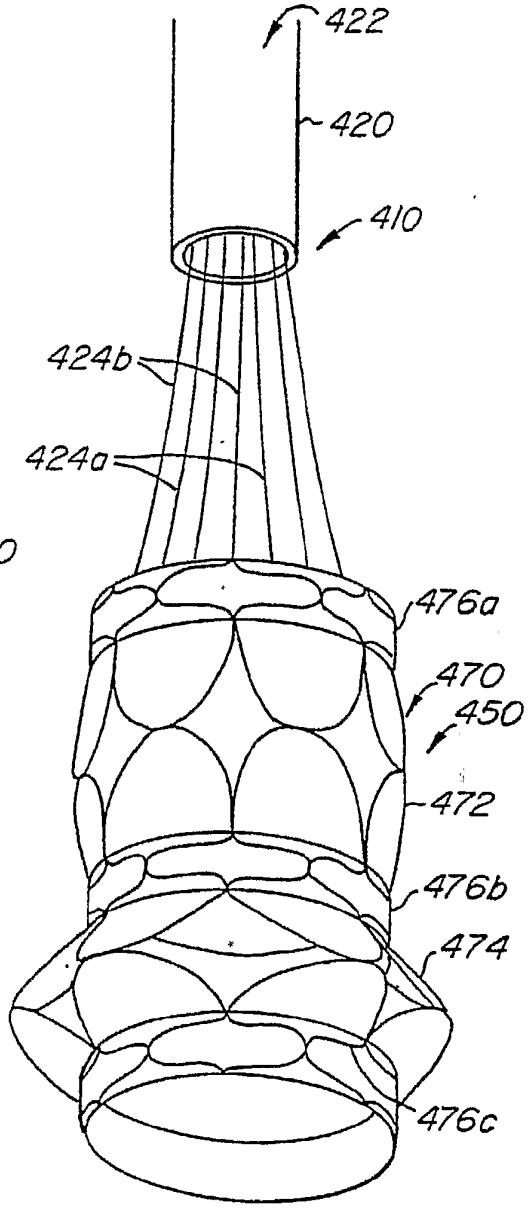

FIG. 30F

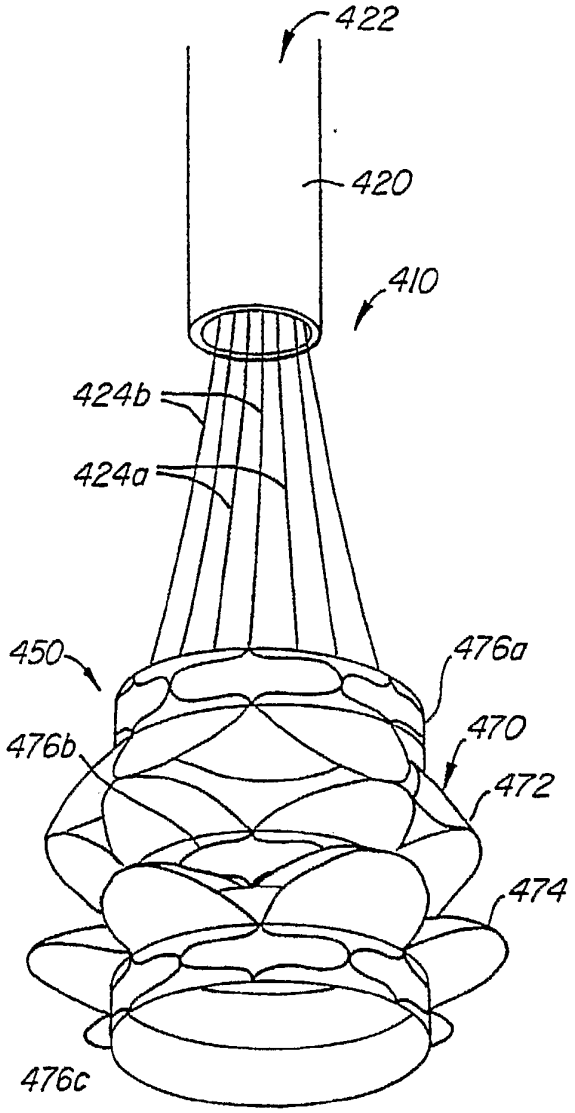

FIG. 30G

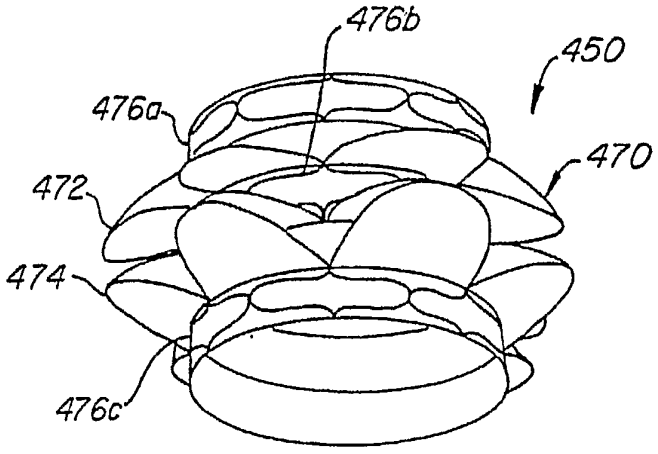

FIG. 30H

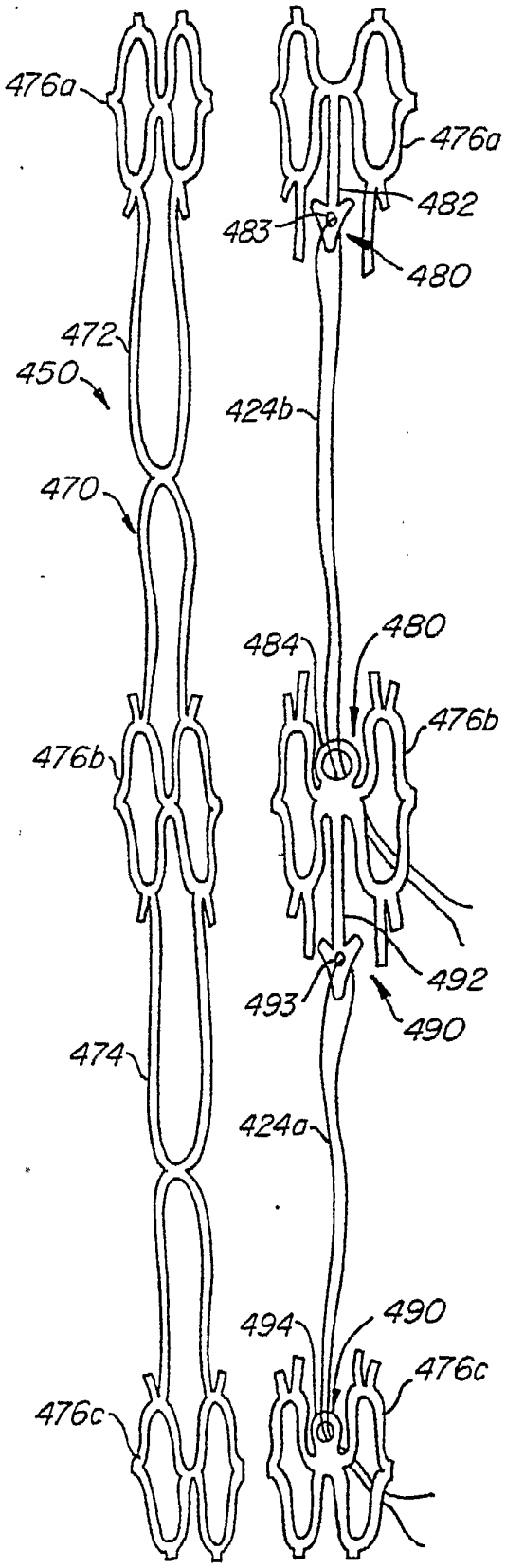

FIG. 31A

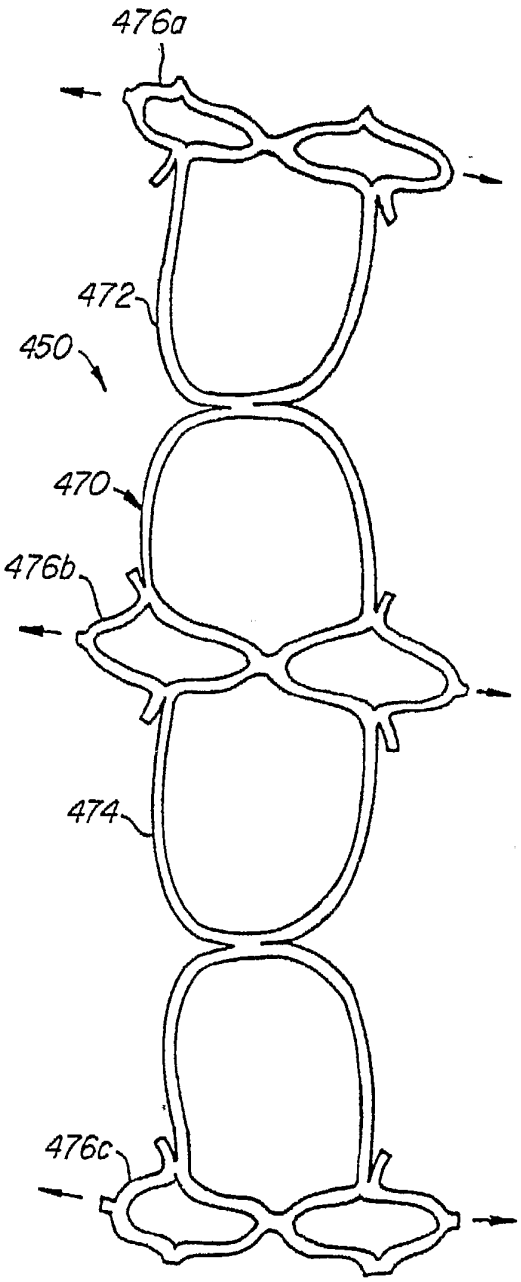

FIG. 31B

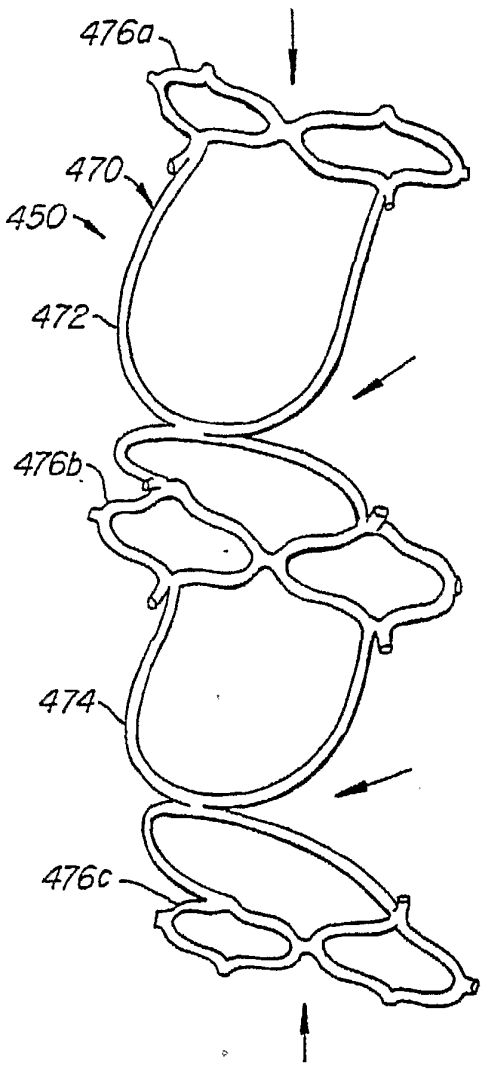

FIG. 31C

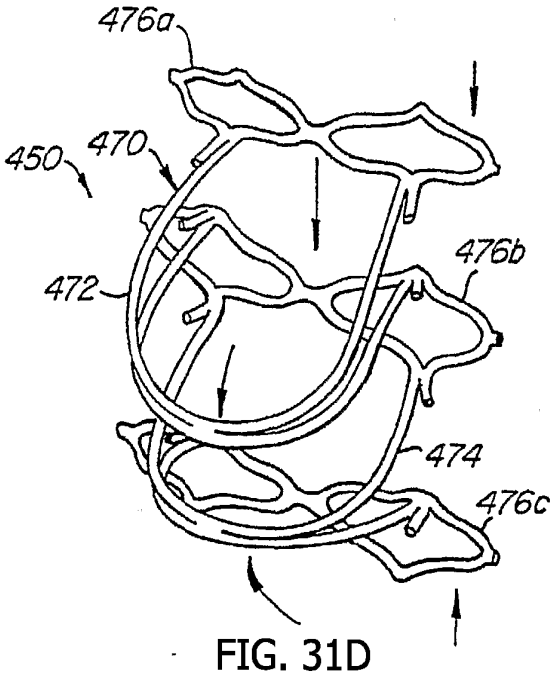

FIG. 31D

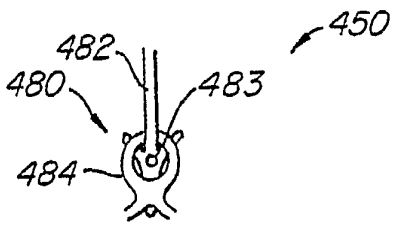

FIG. 31E

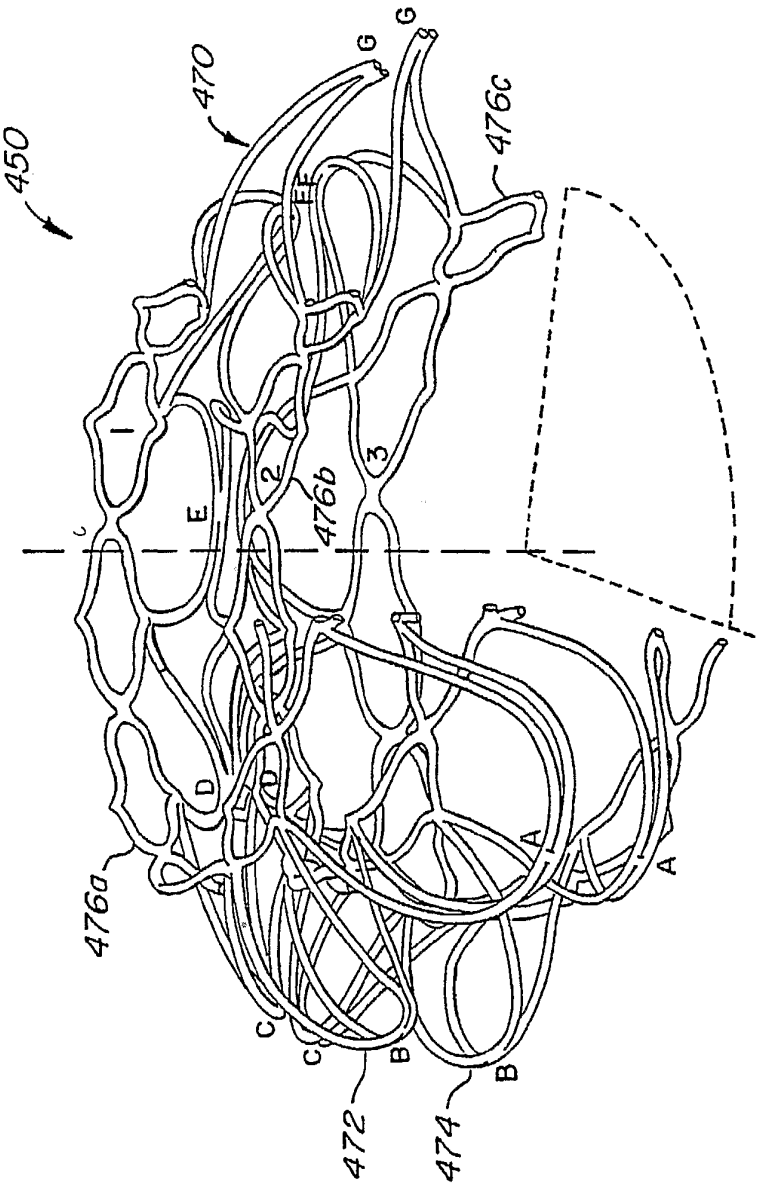

FIG. 32A

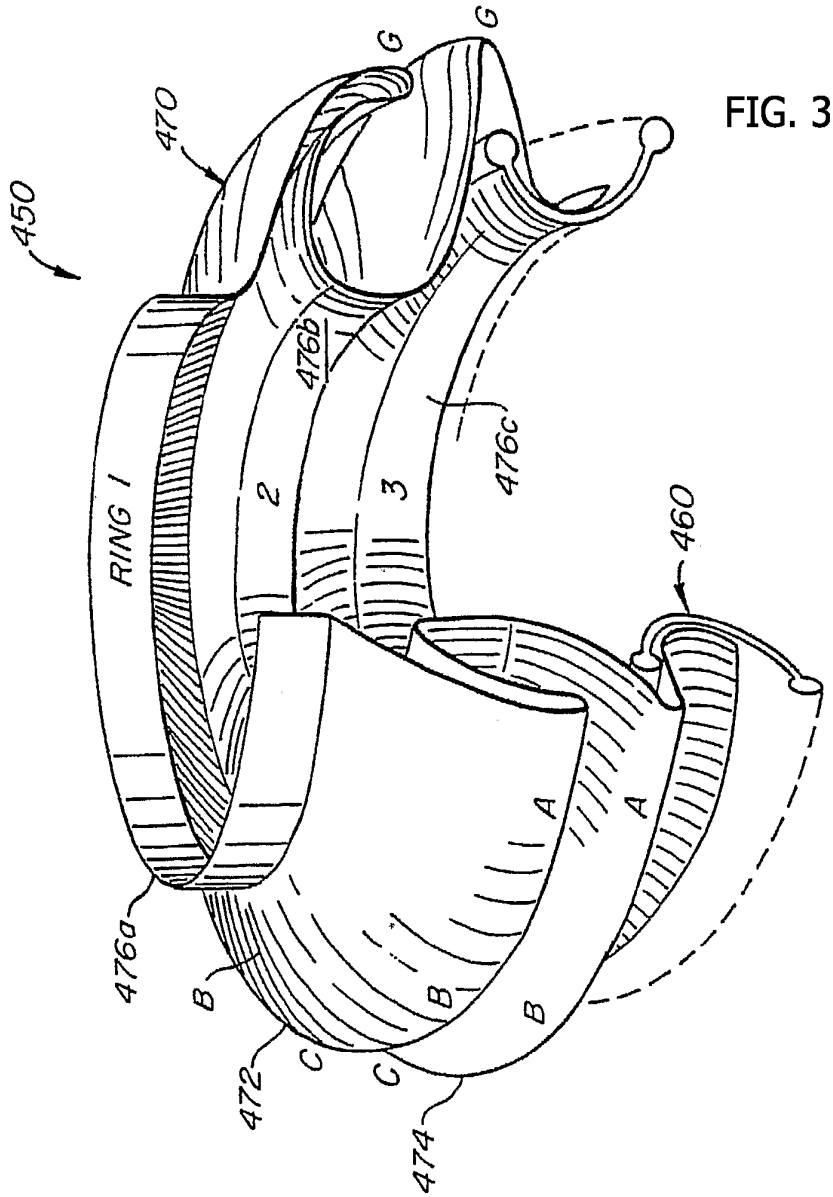

FIG. 32B

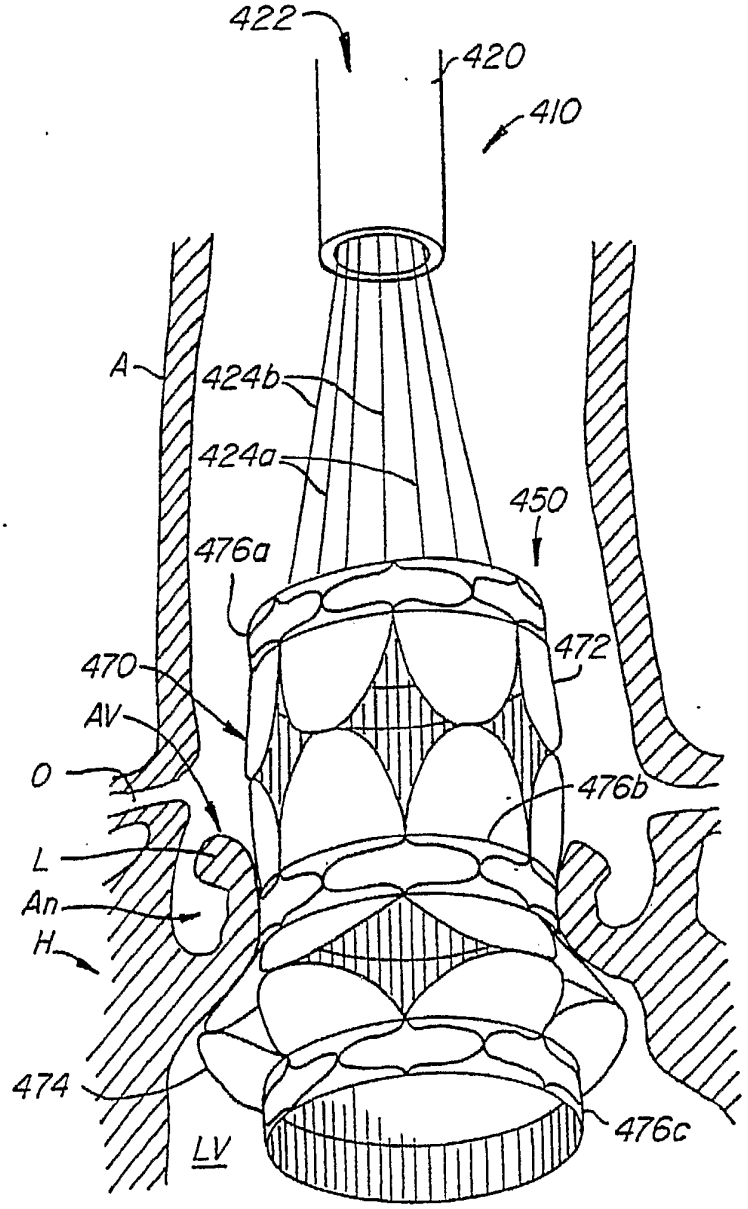

FIG. 33A

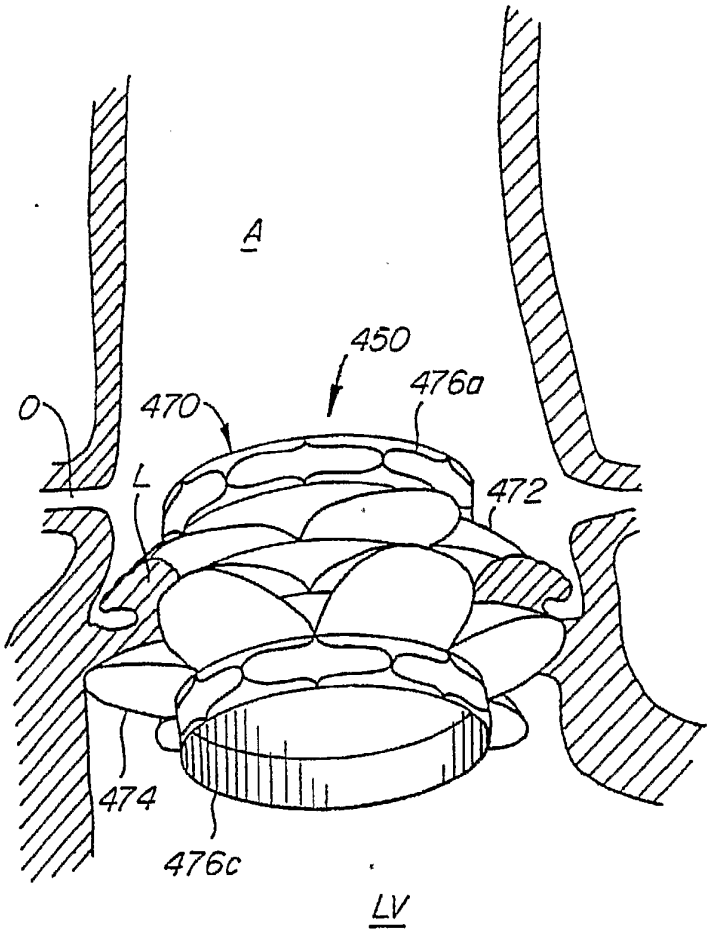

FIG. 33B

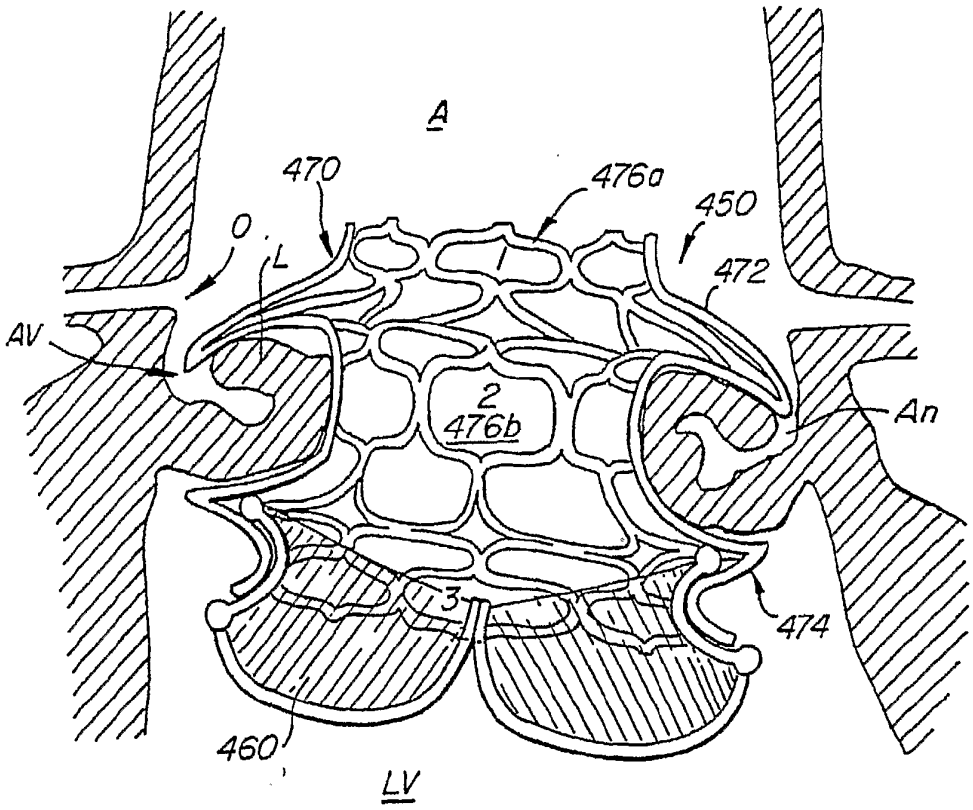

FIG. 33C

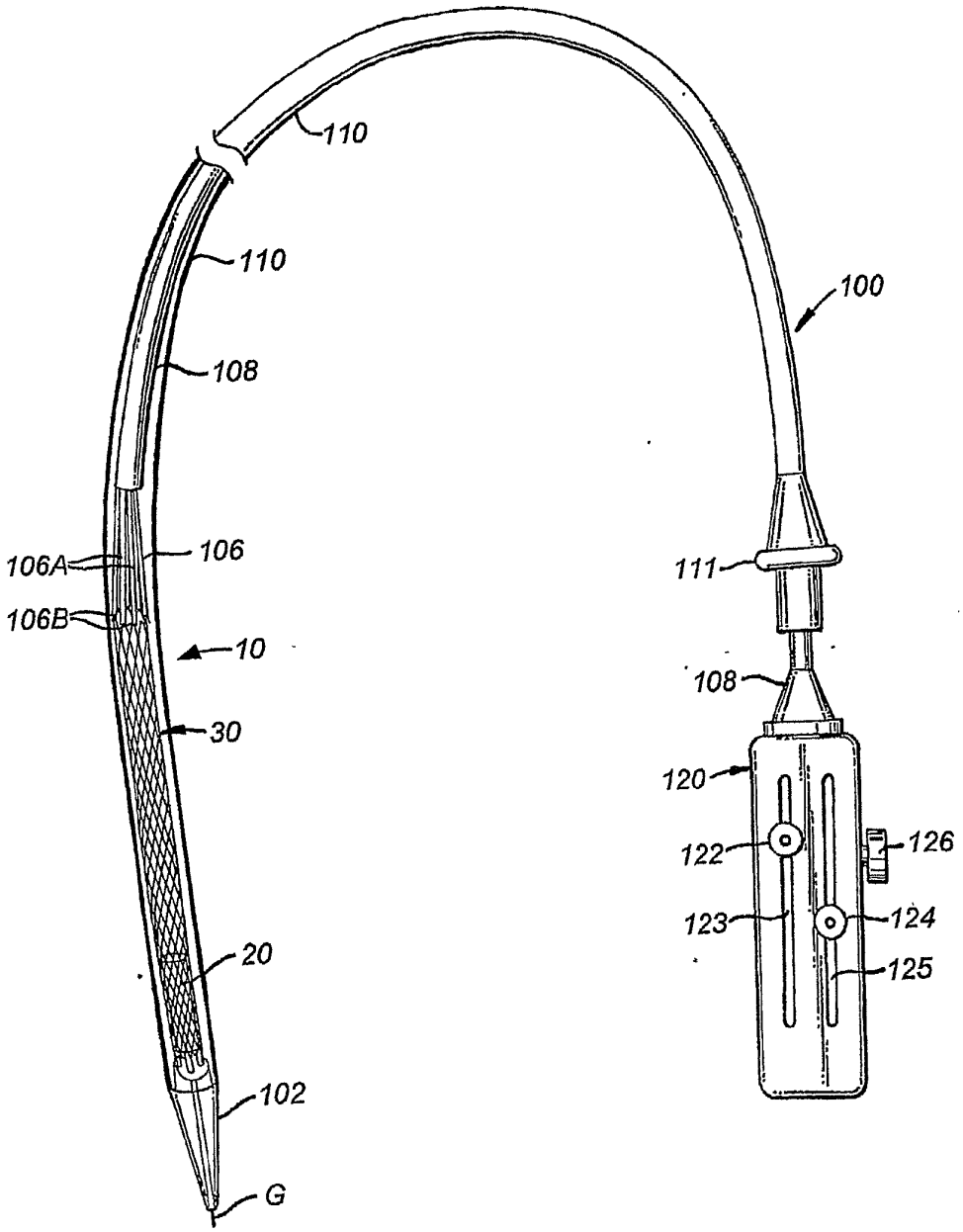

FIG. 34A

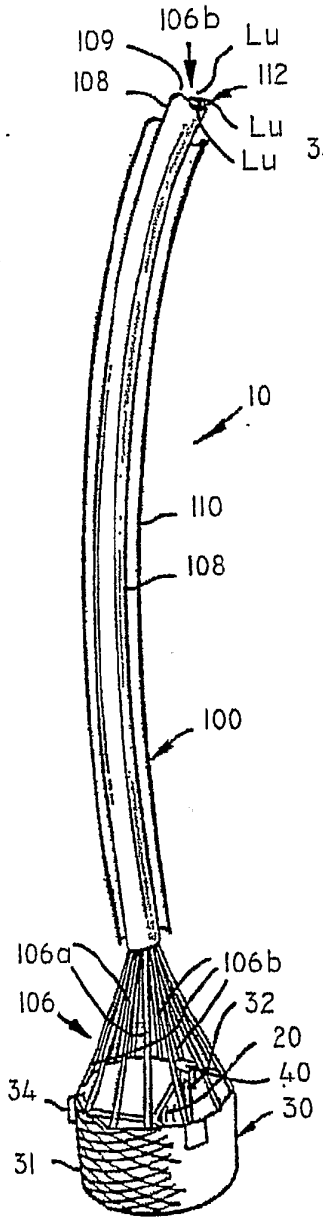

FIG. 34B

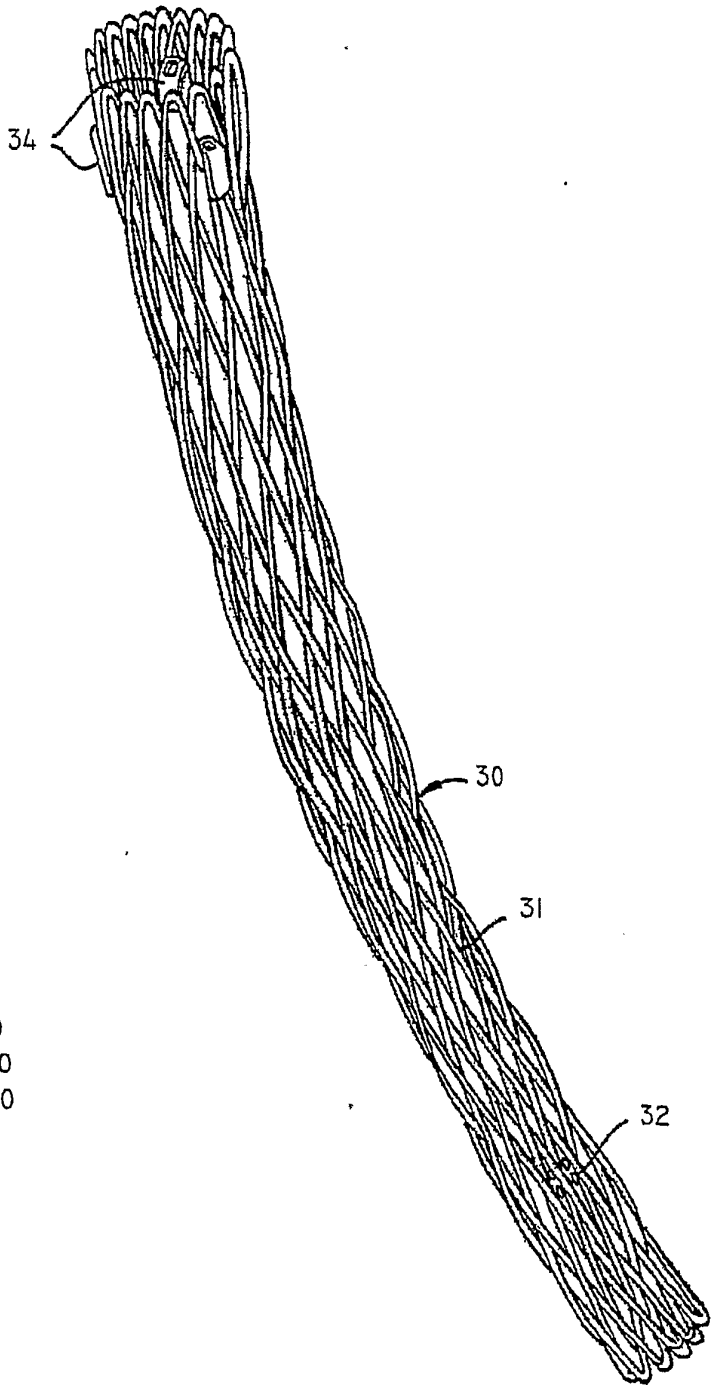

FIG. 35A

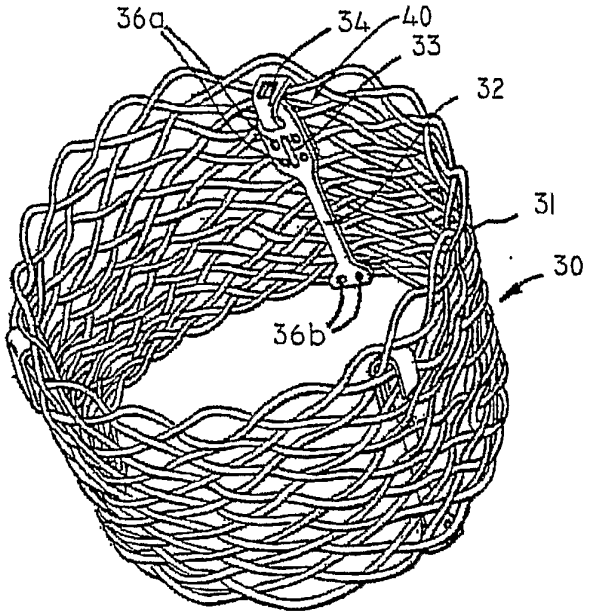

FIG. 35B

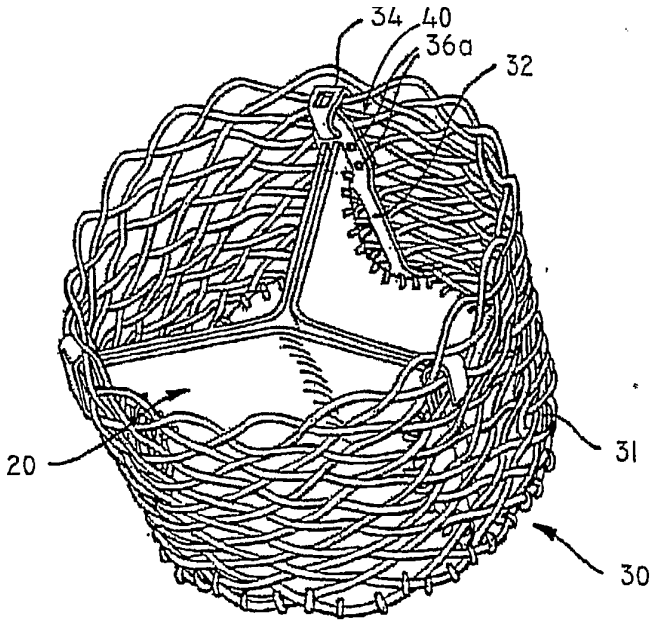

FIG. 35C

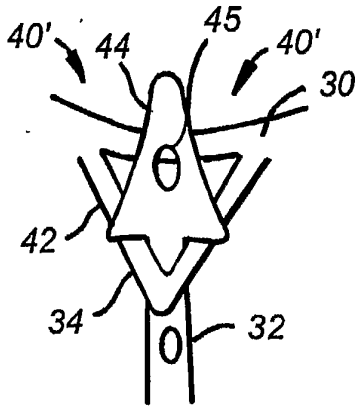

FIG. 35D

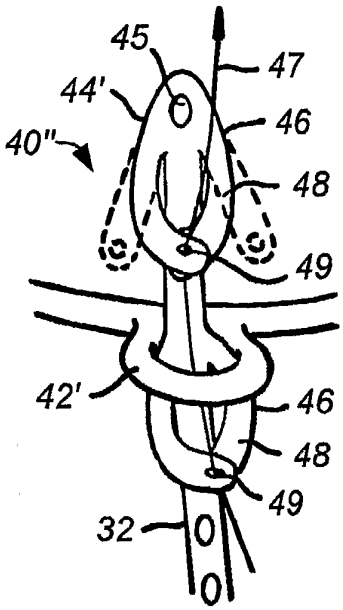

FIG. 35E

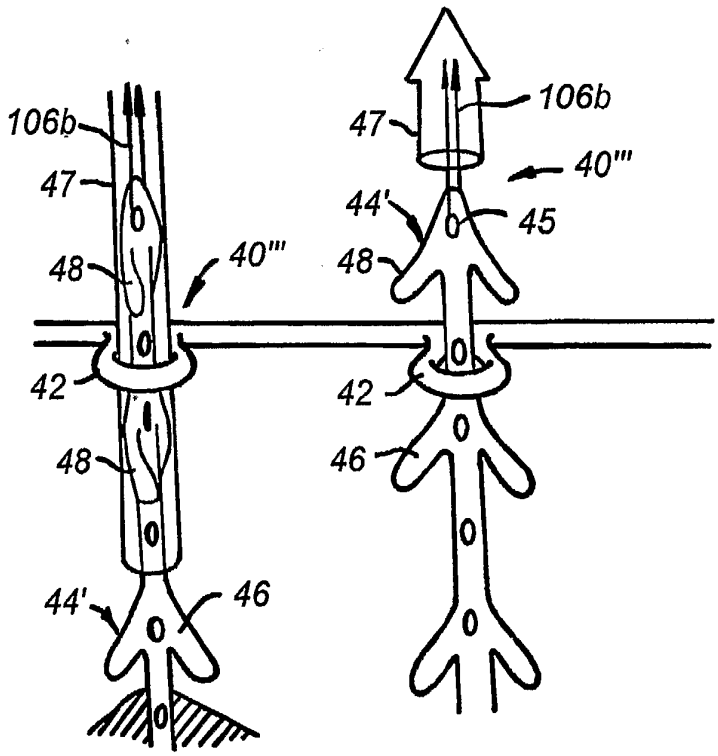

FIG. 35F

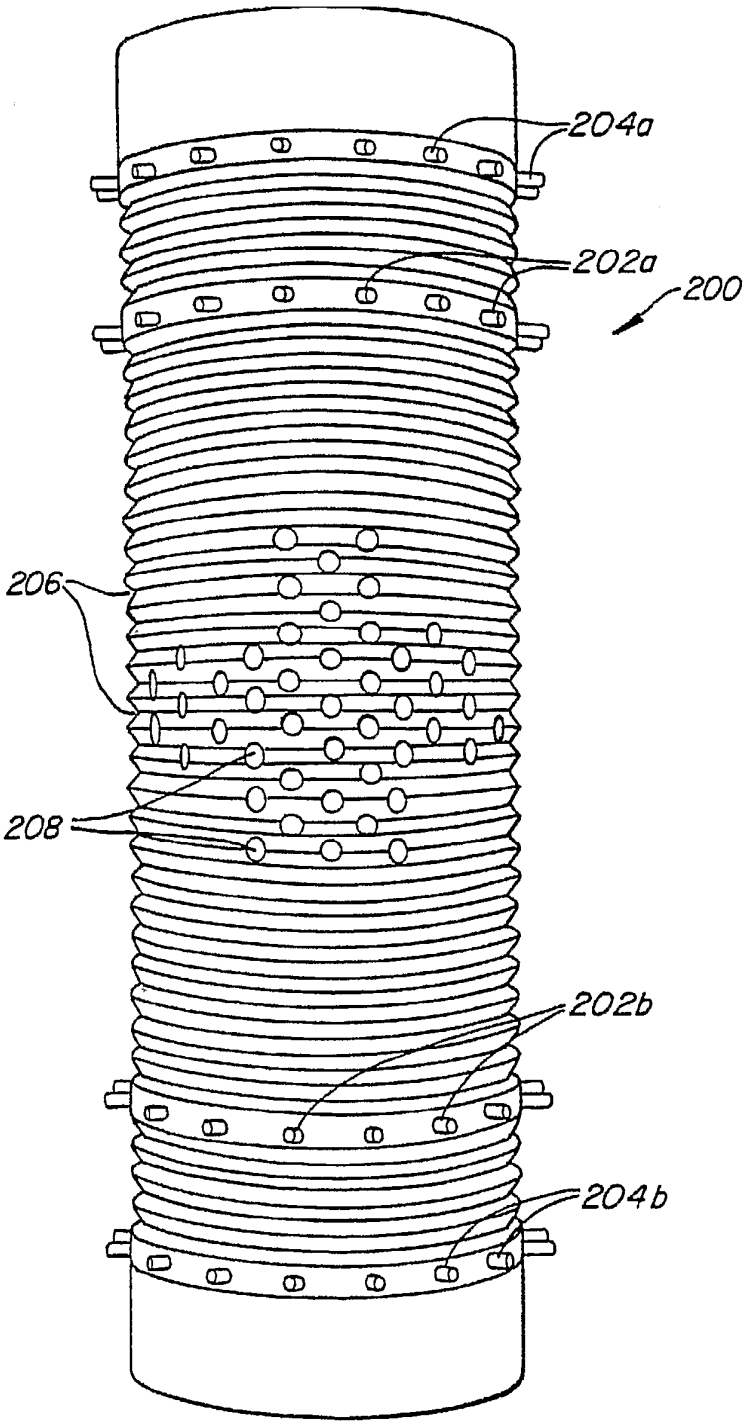

FIG. 36

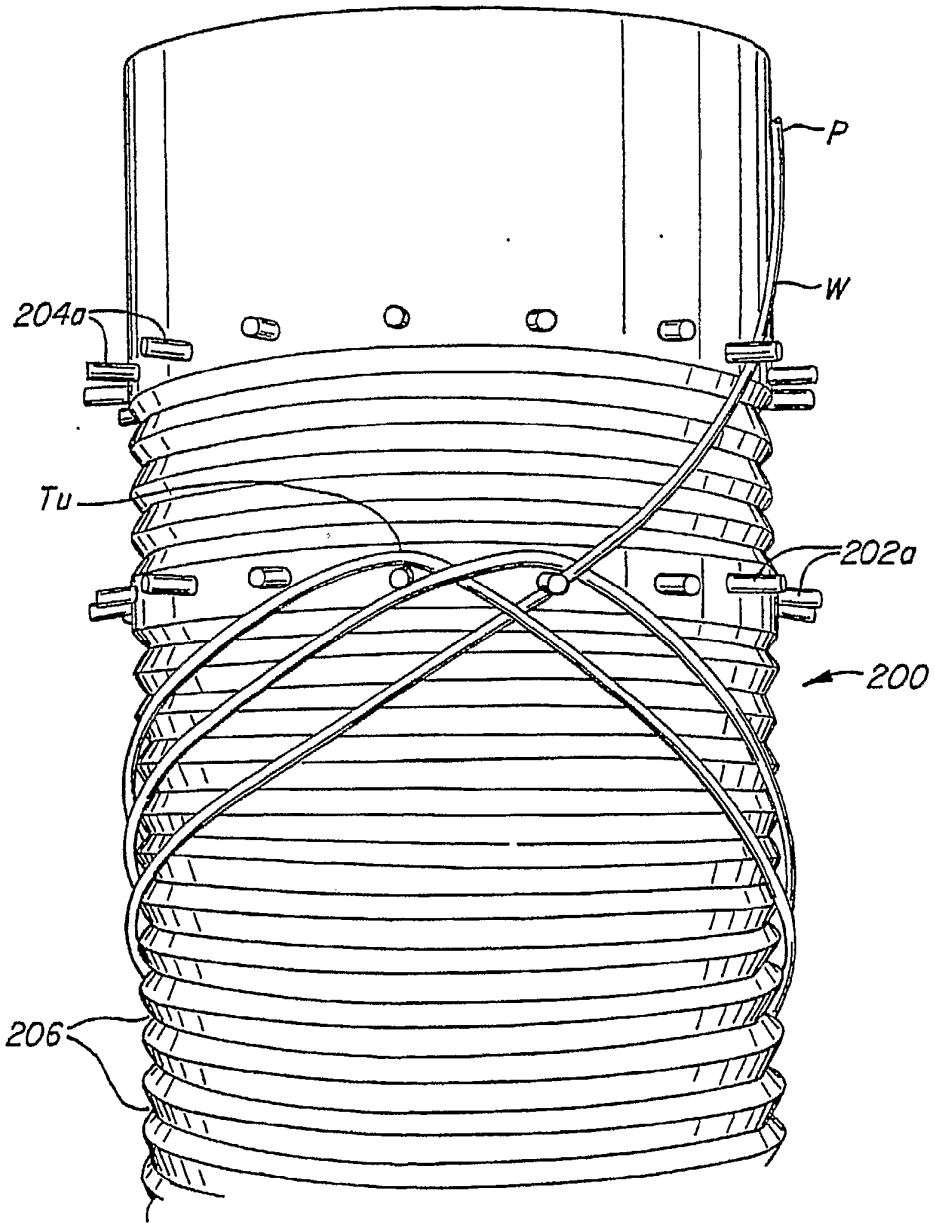

FIG. 37A

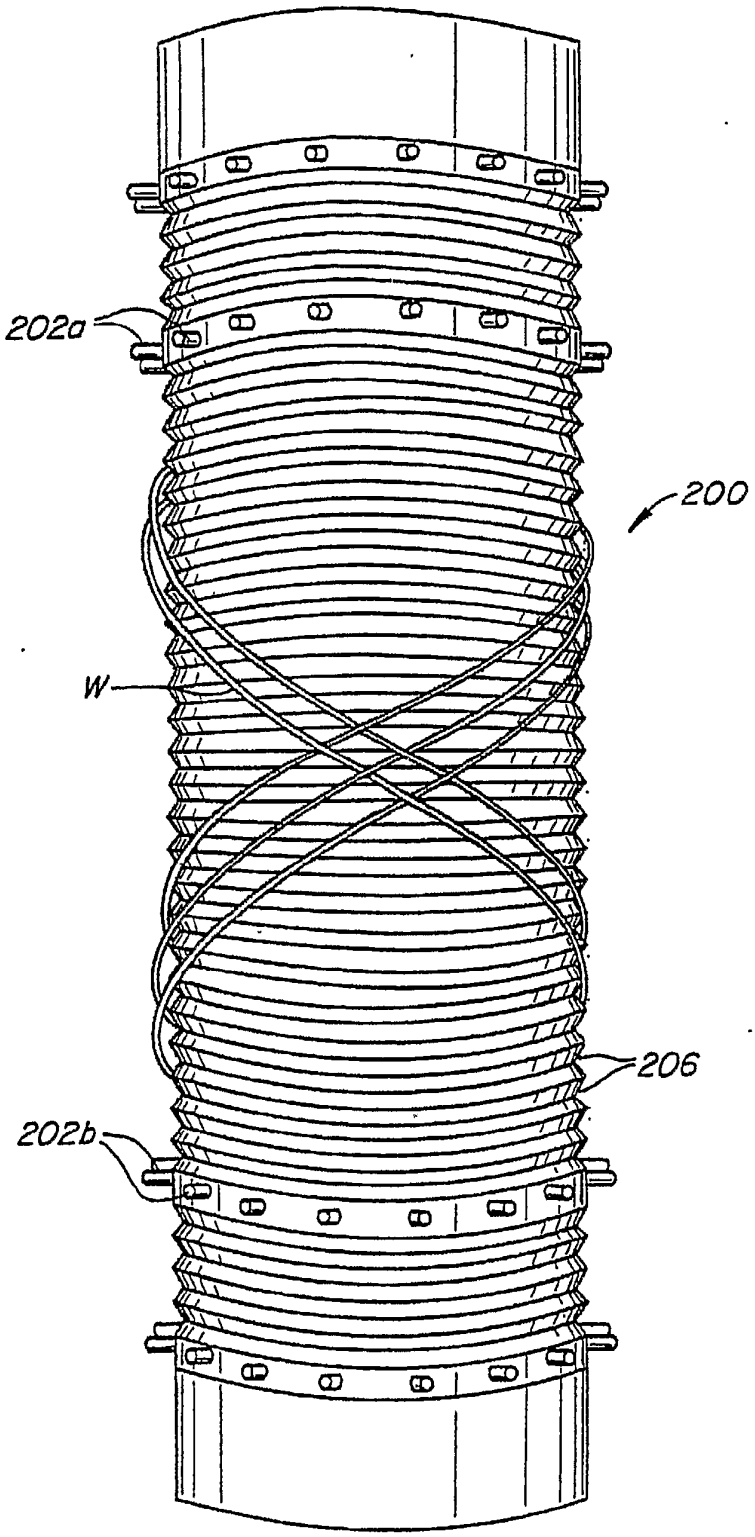

FIG. 37B

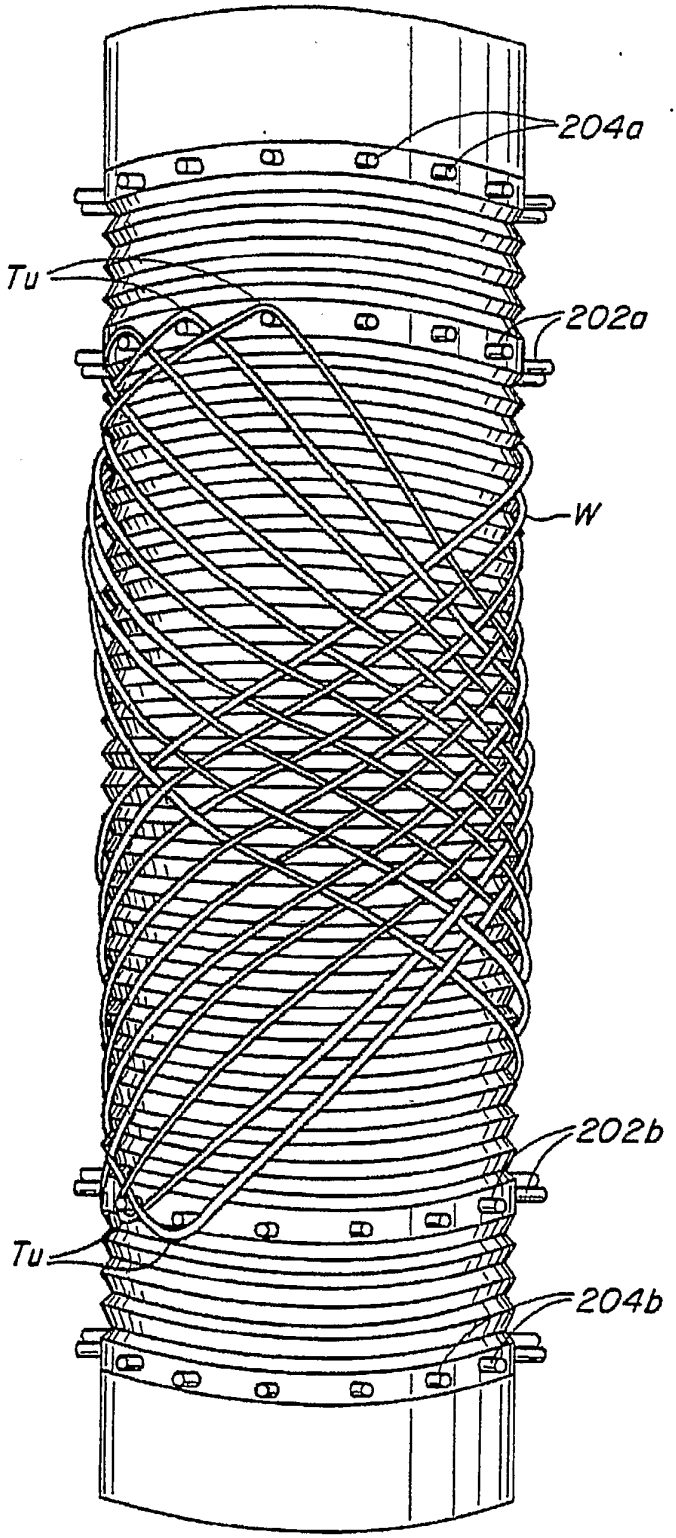

FIG. 37C

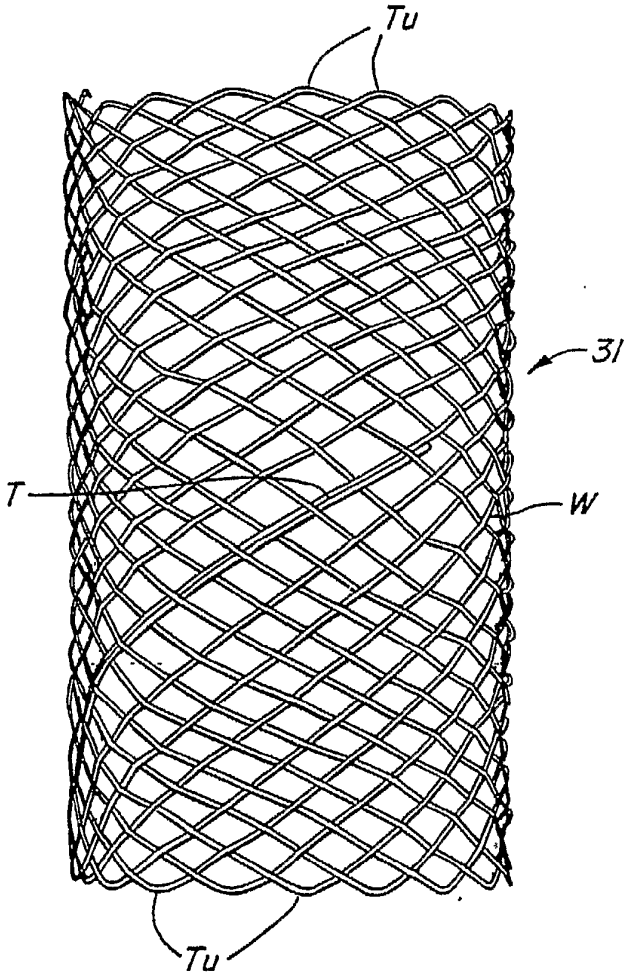

FIG. 37D

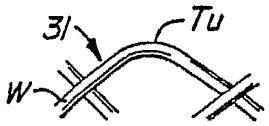

FIG. 38A

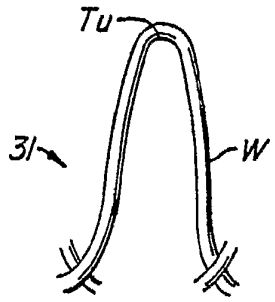

FIG. 38B

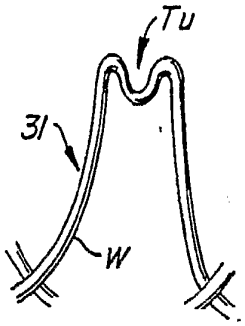

FIG. 38C

FIG. 38D

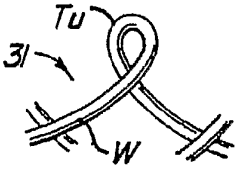

FIG. 38E

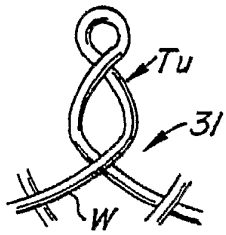

FIG. 38F

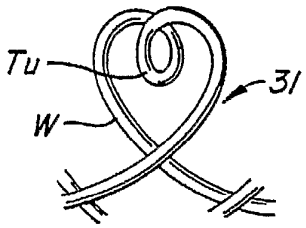

FIG. 38G

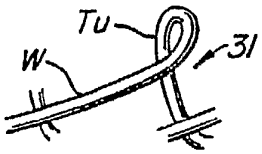

FIG. 38H

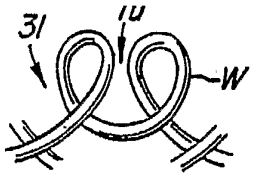

FIG. 38I

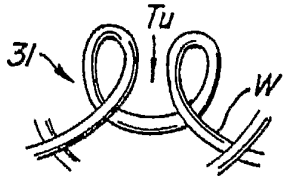

FIG. 38J

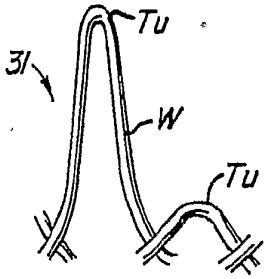

FIG. 38K

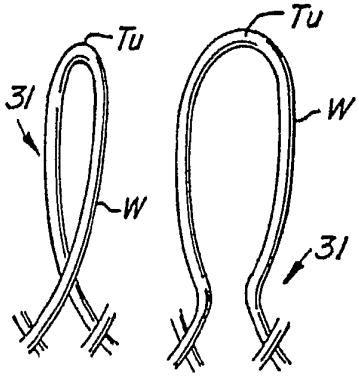

FIG. 38L FIG. 38M

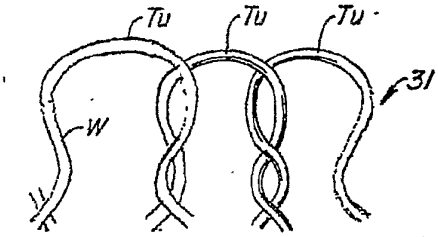

FIG. 38N

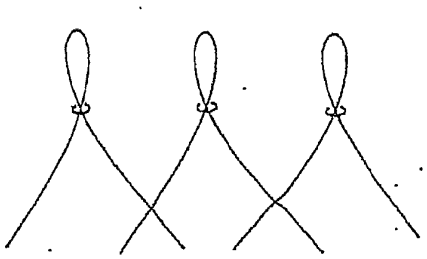

FIG. 38O

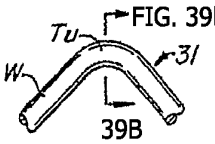

FIG. 39A

FIG. 39B

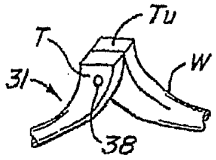

FIG. 40A

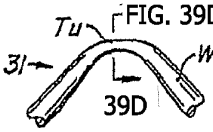

FIG. 39C

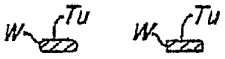

FIG. 39D FIG.39E

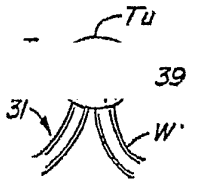

FIG. 40B

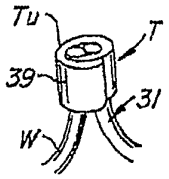

FIG. 40C

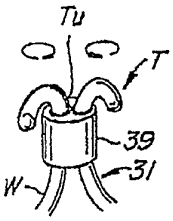

FIG. 40D

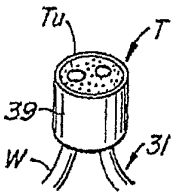

FIG. 40E

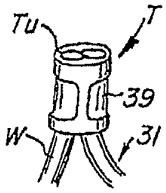

FIG. 40F

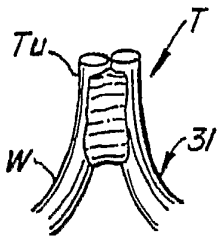

FIG. 40G

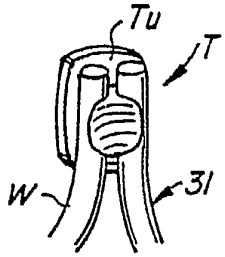

FIG. 40H

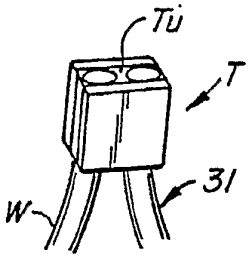

FIG. 40I

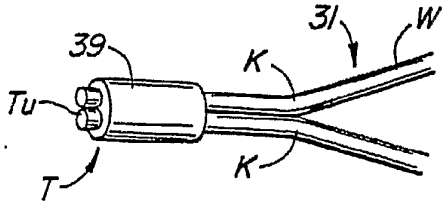

FIG. 40J

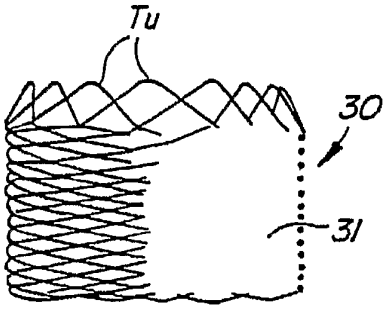

FIG. 41A

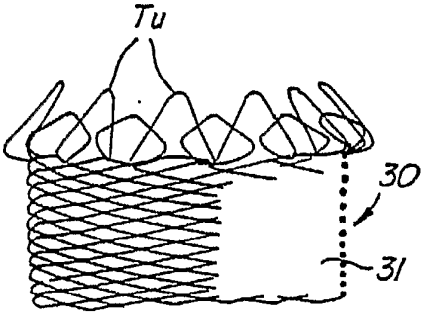

FIG. 41B

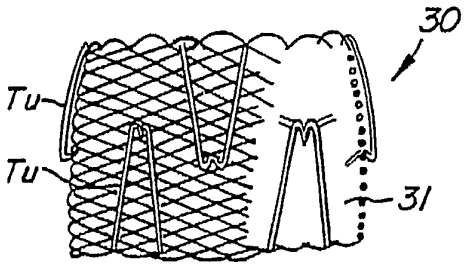

FIG. 42A

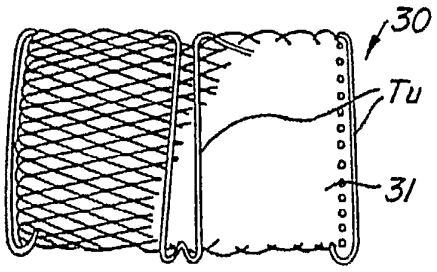

FIG. 42B

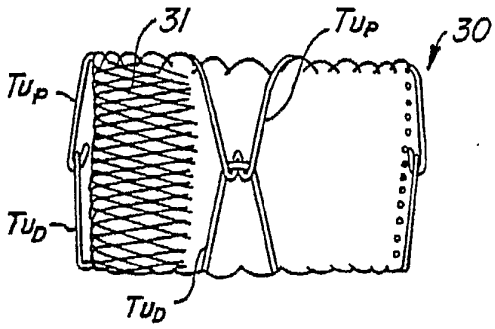

FIG. 42C

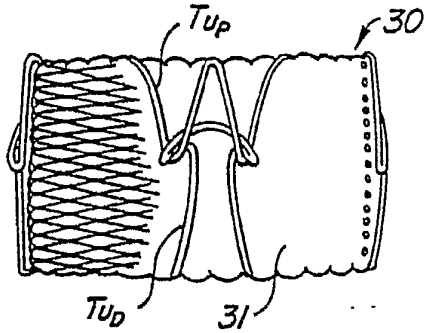

FIG. 42D

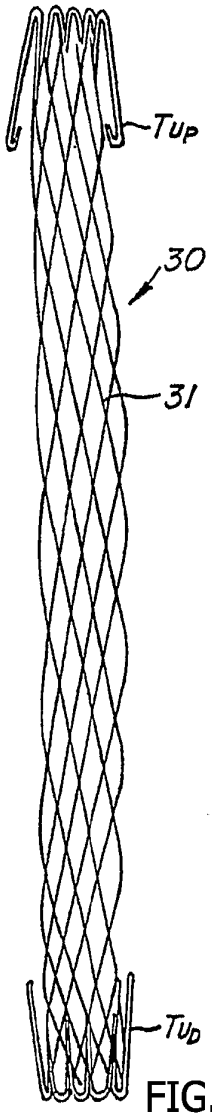

FIG. 42E

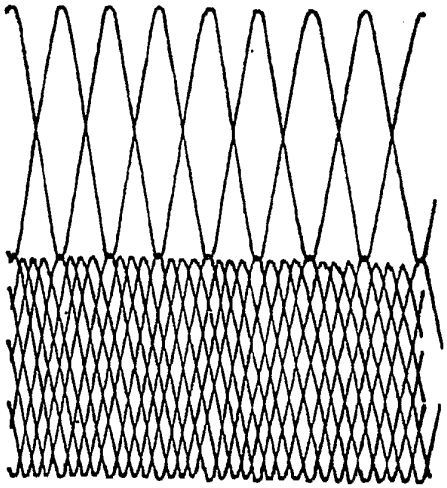

FIG. 43A

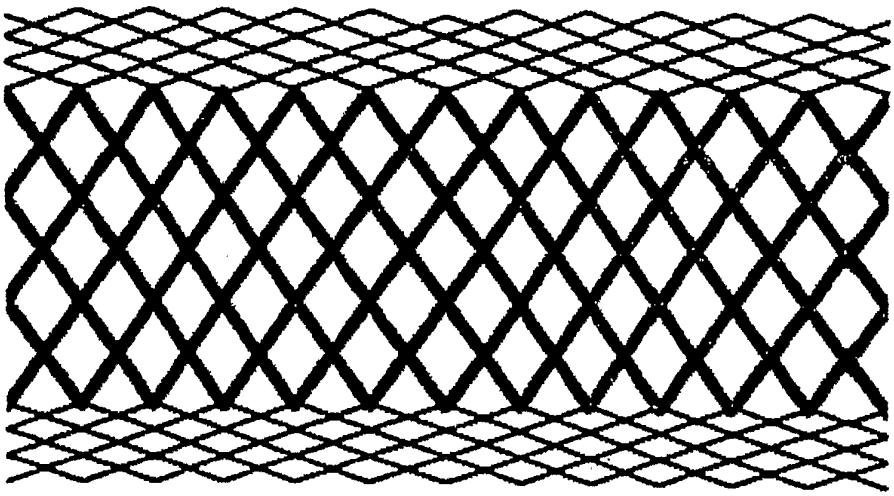

FIG. 43B

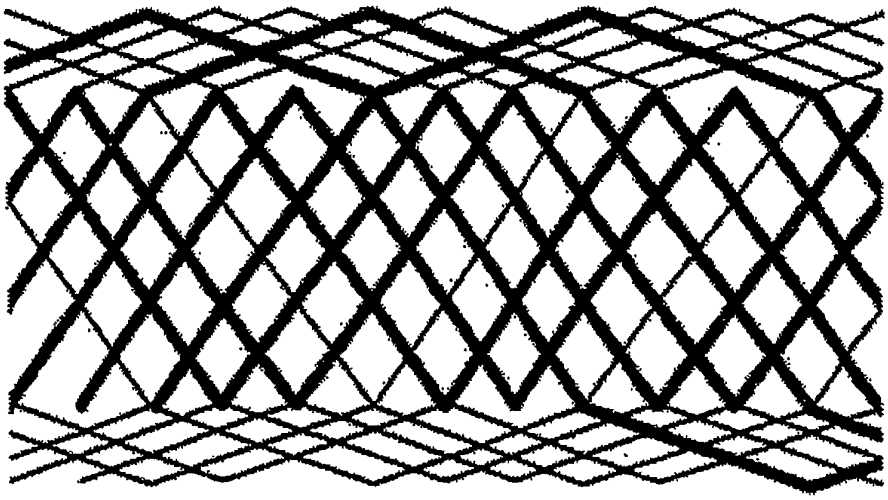

FIG. 43C

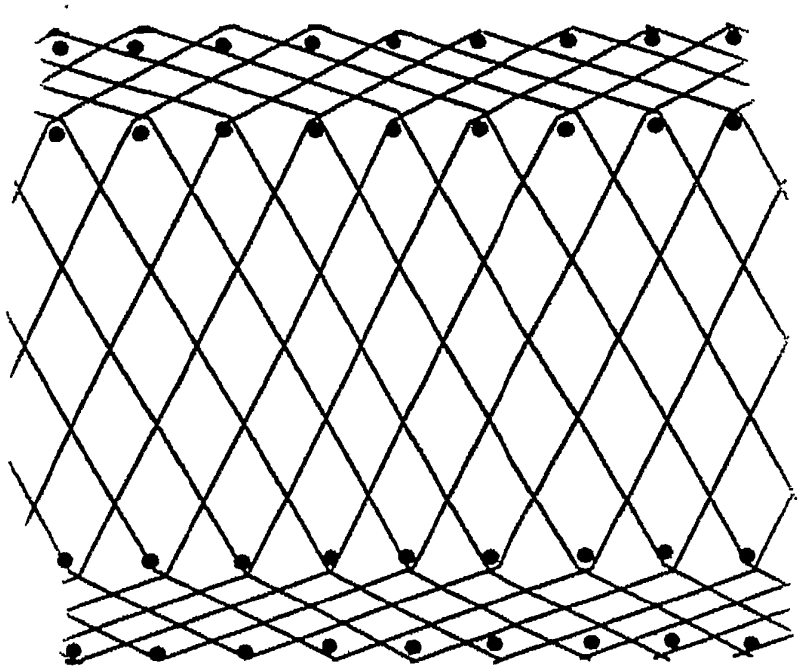

FIG. 43D

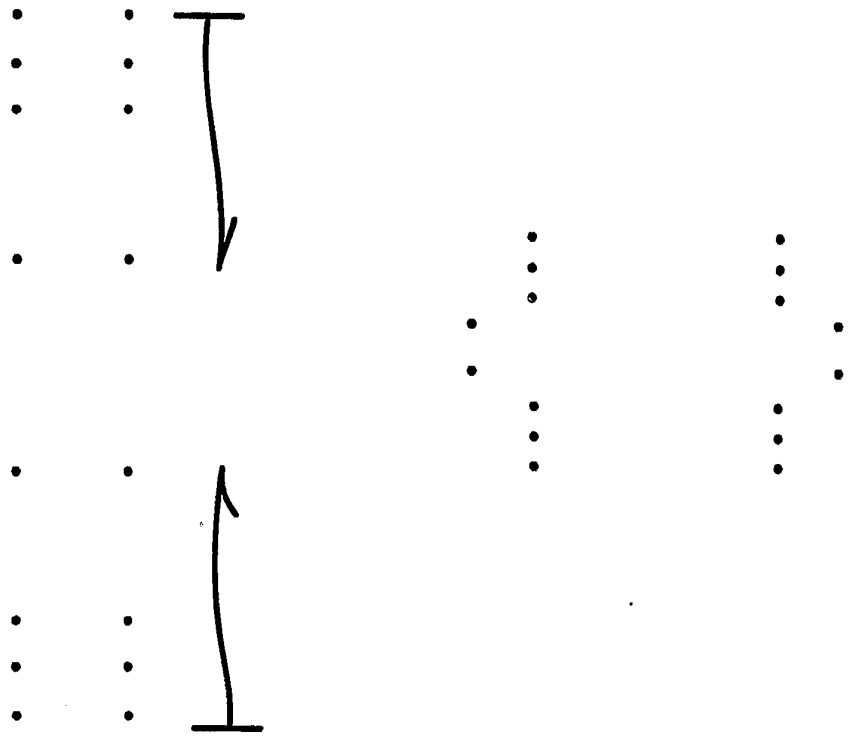

FIG. 44A

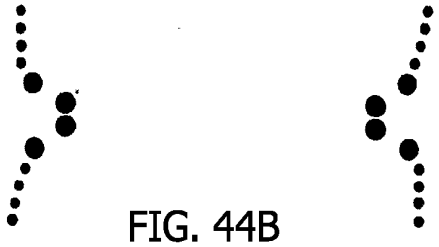

FIG. 44B

FIG. 44C

FIG. 44D

FIG. 44E

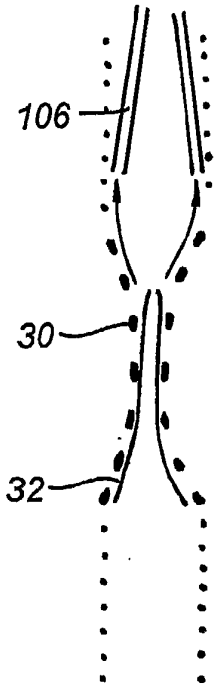

FIG. 45A

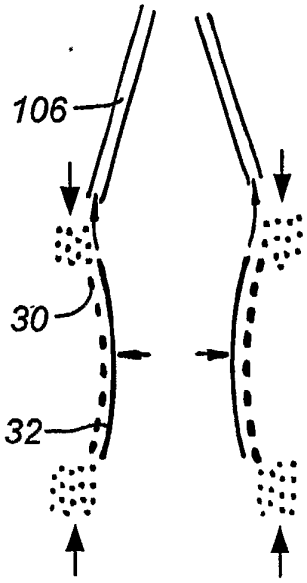

FIG. 45B

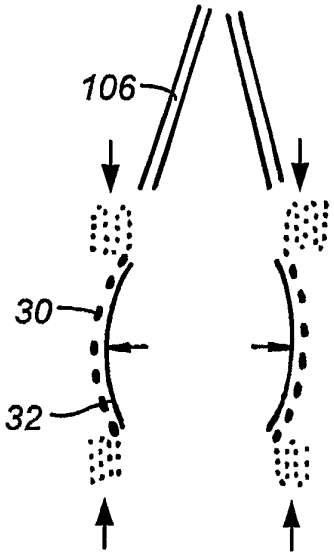

FIG. 45C

FIG. 45D

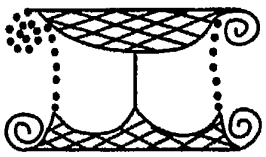

FIG. 45E

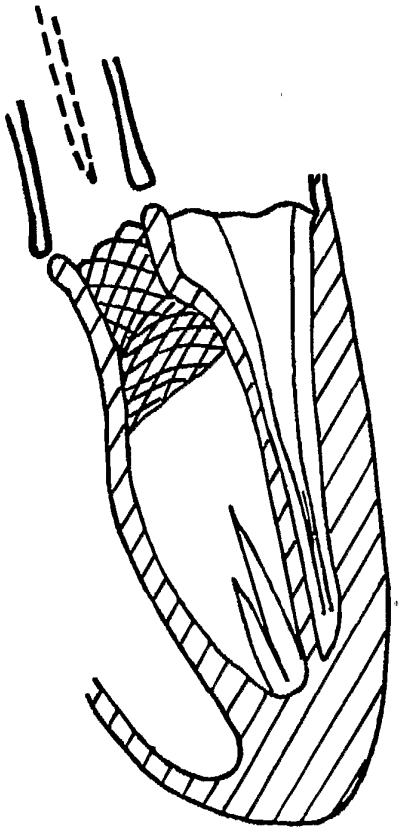

FIG. 46A

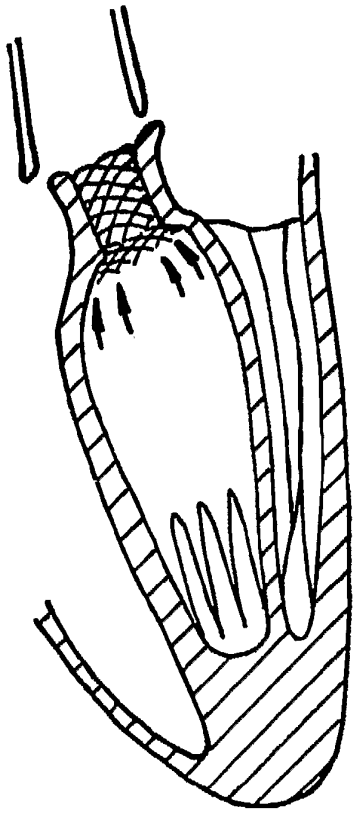

FIG. 46B

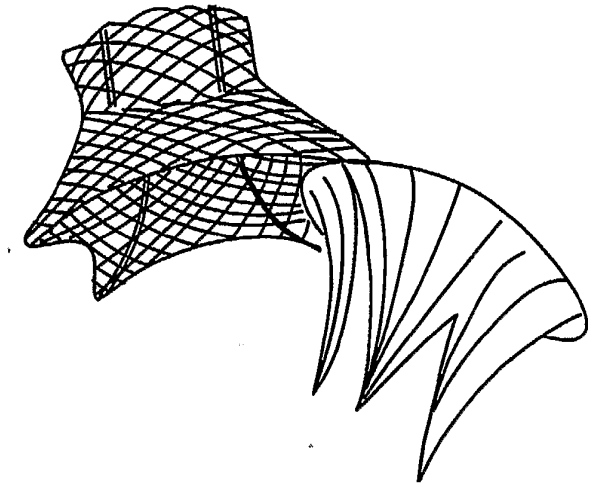

FIG. 47A

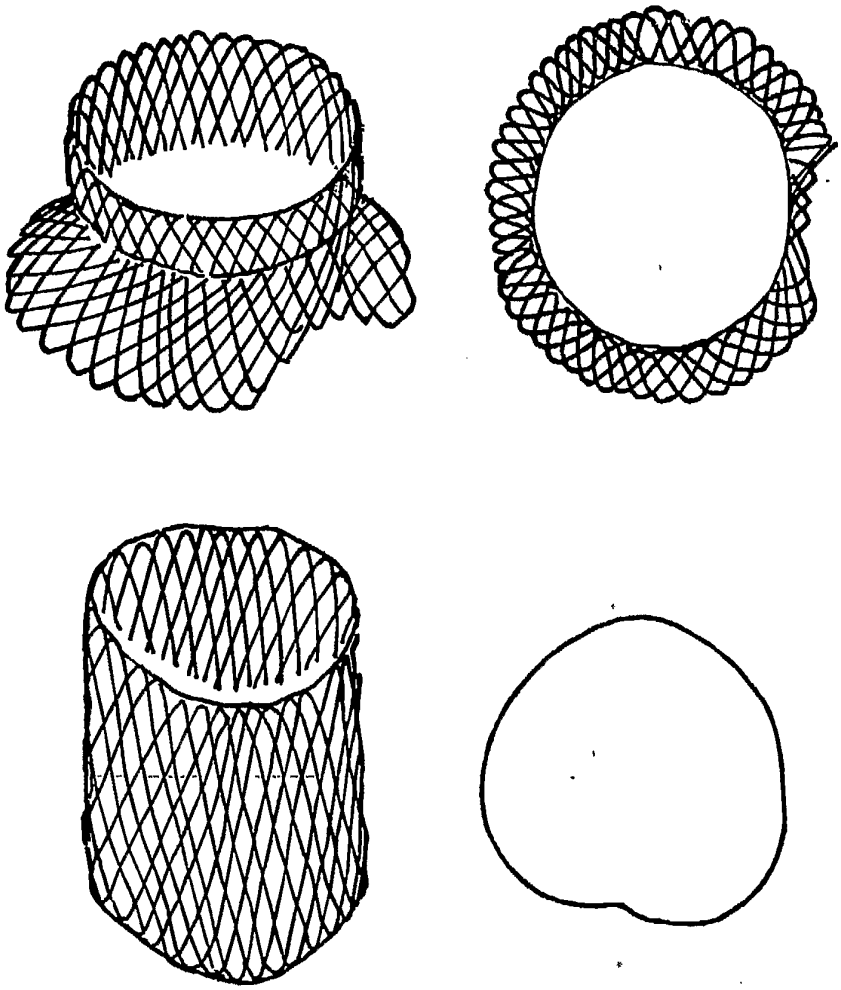

FIG. 47B

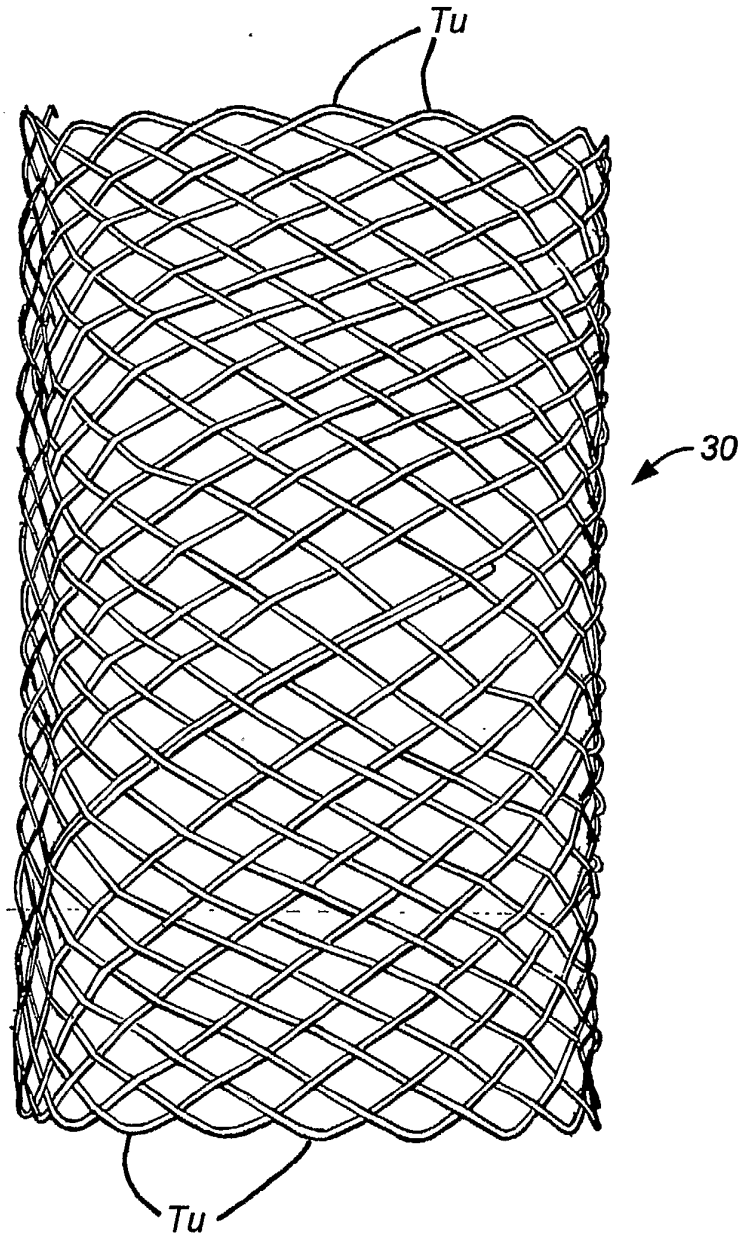

FIG. 48

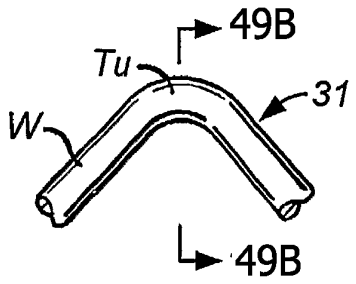

FIG. 49A

FIG. 49B

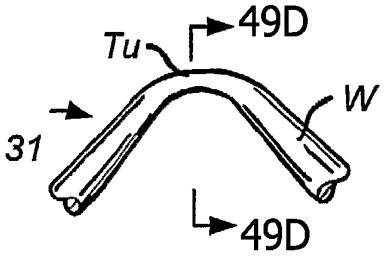

FIG. 49C

FIG. 49D

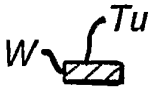

FIG. 49E

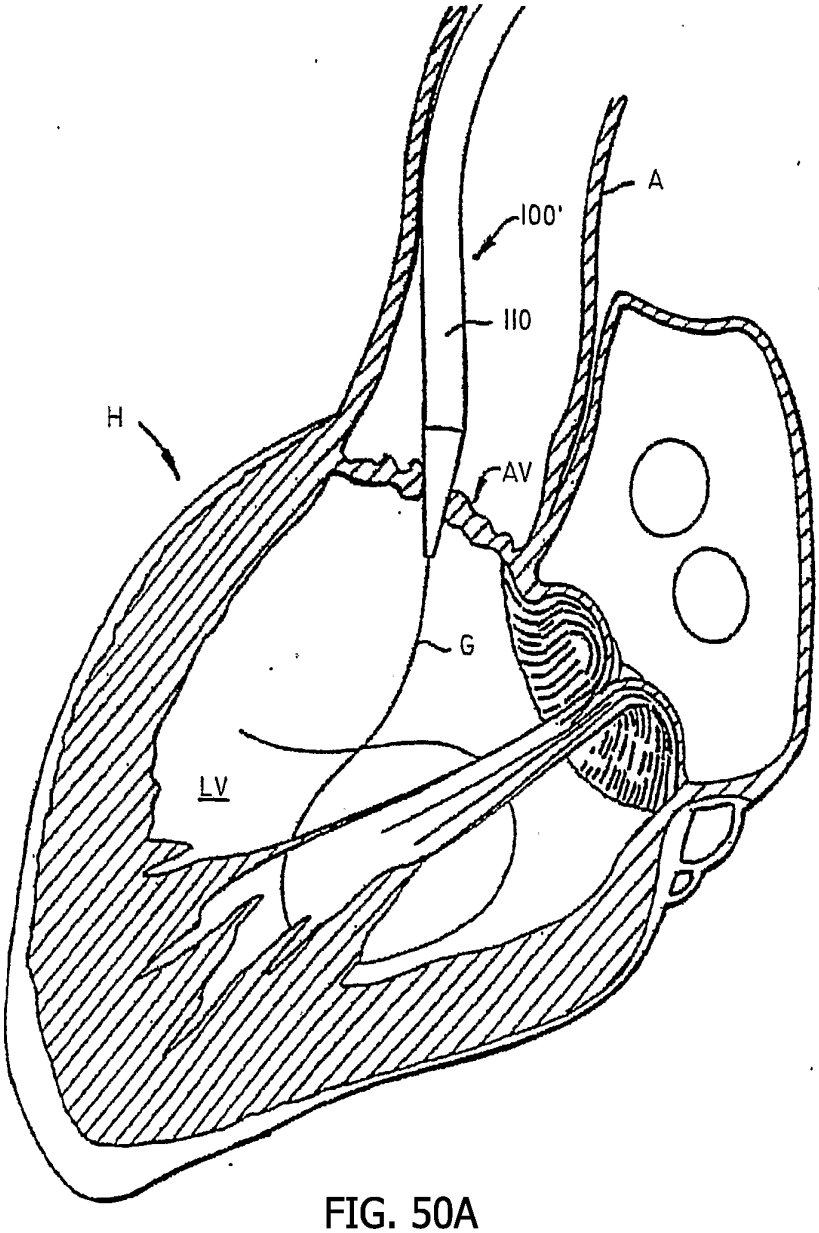

FIG. 50A

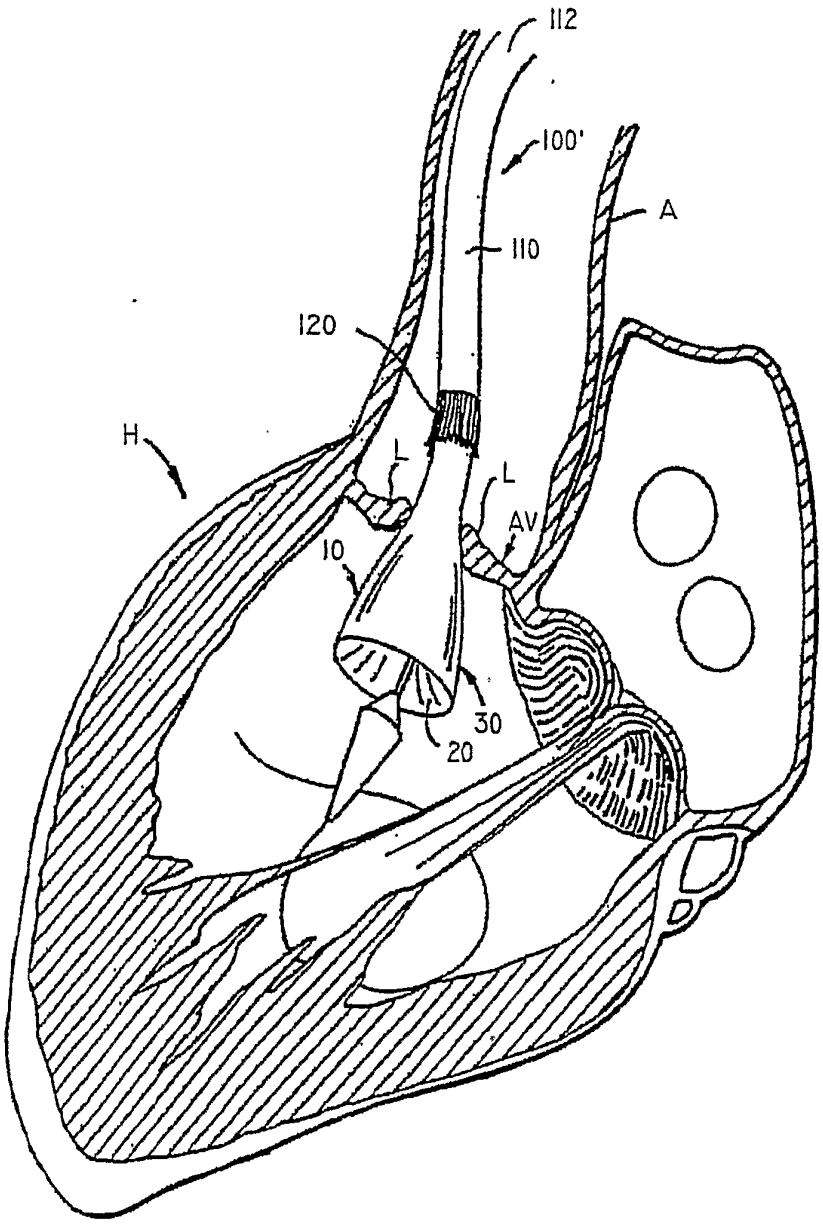

FIG. 50B

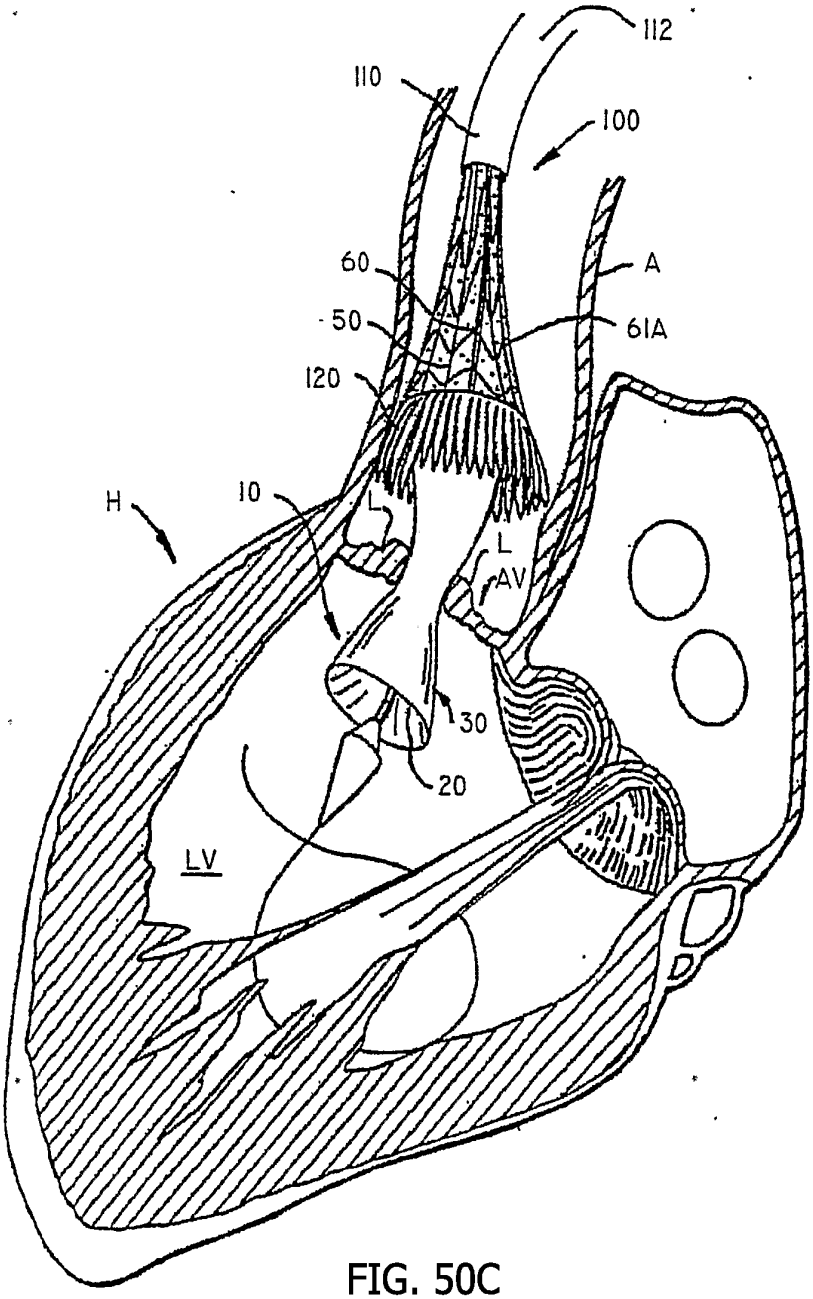

FIG. 50C

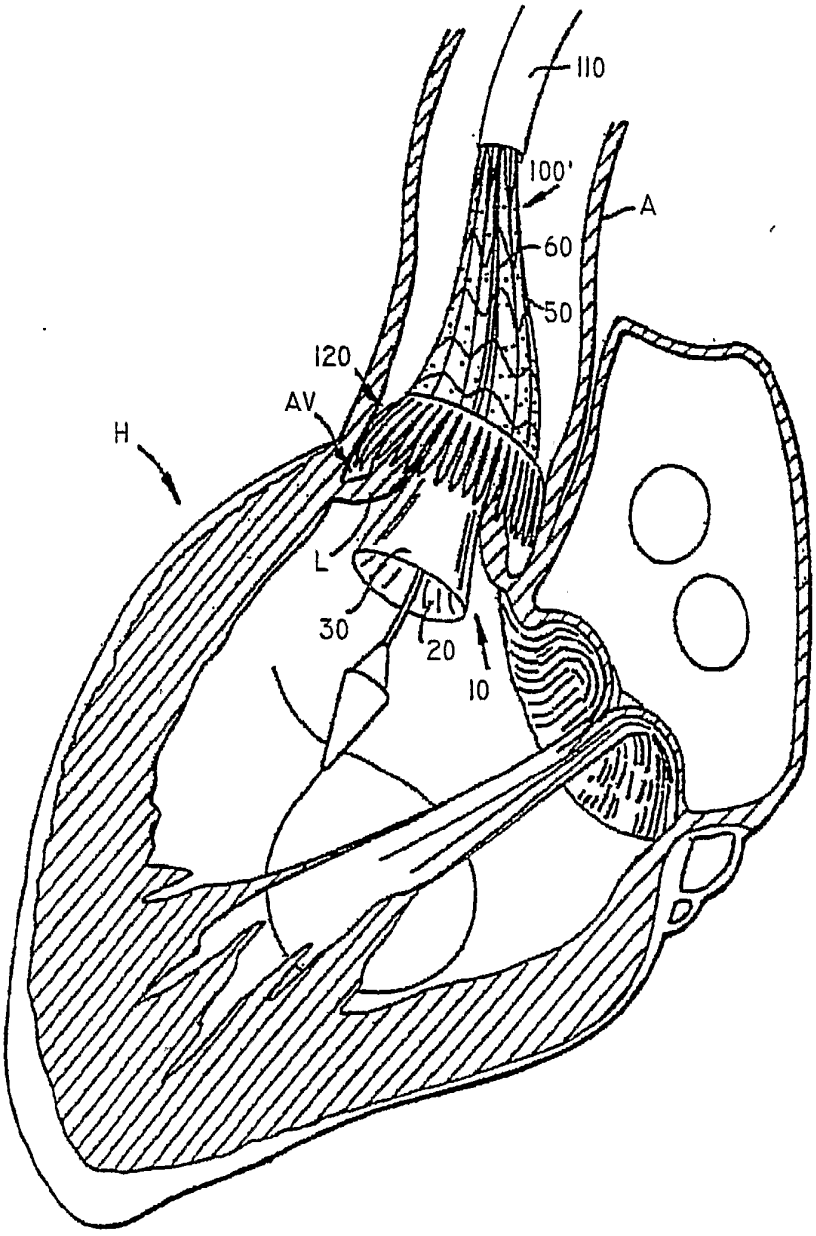

FIG. 50D

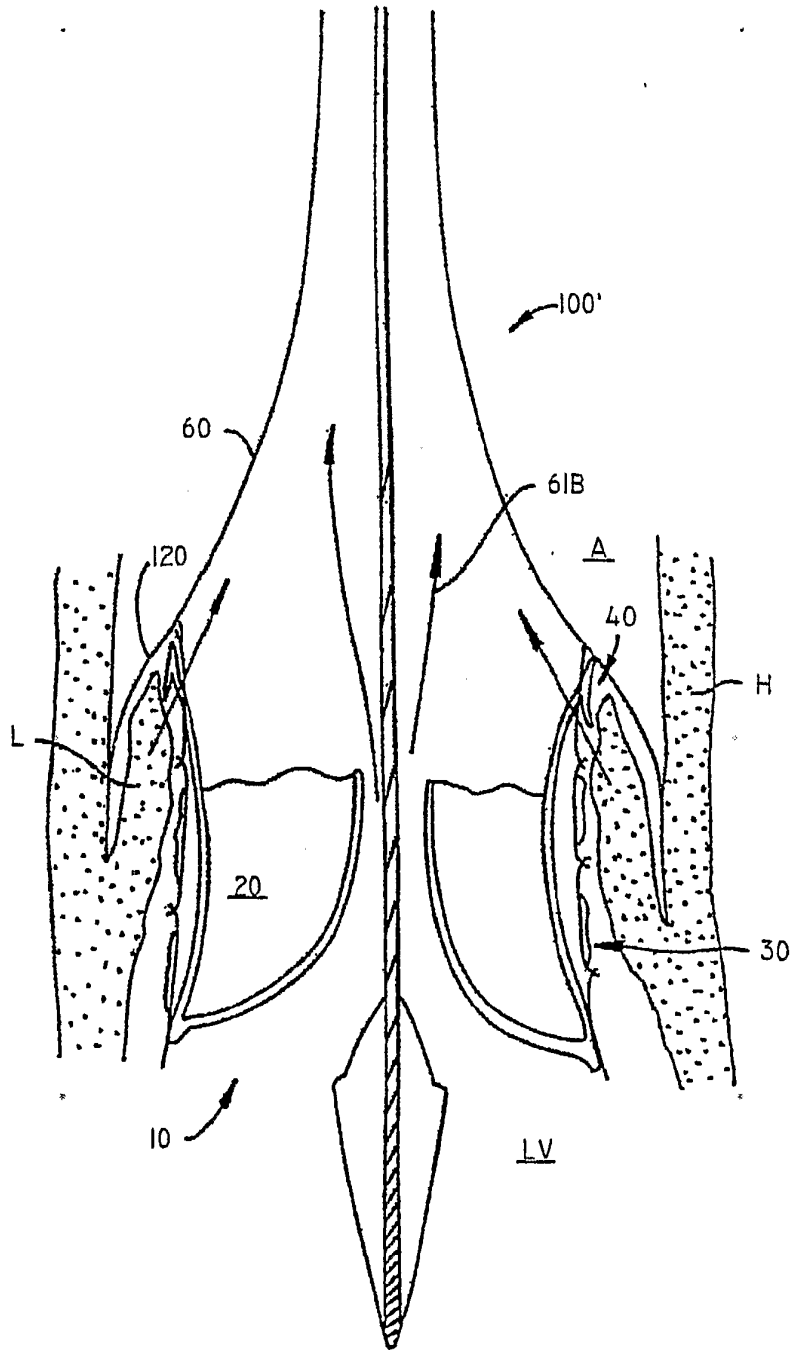

FIG. 50E

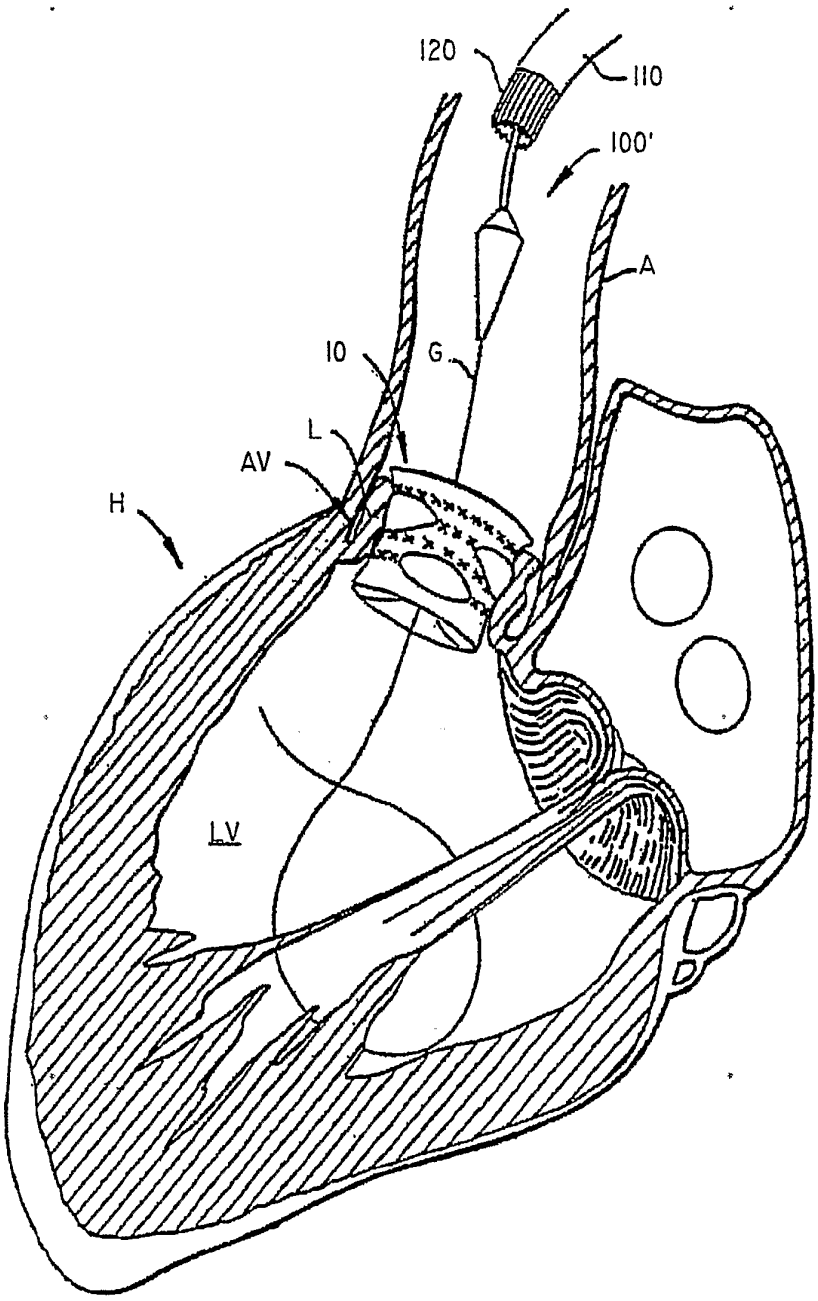

FIG. 50F

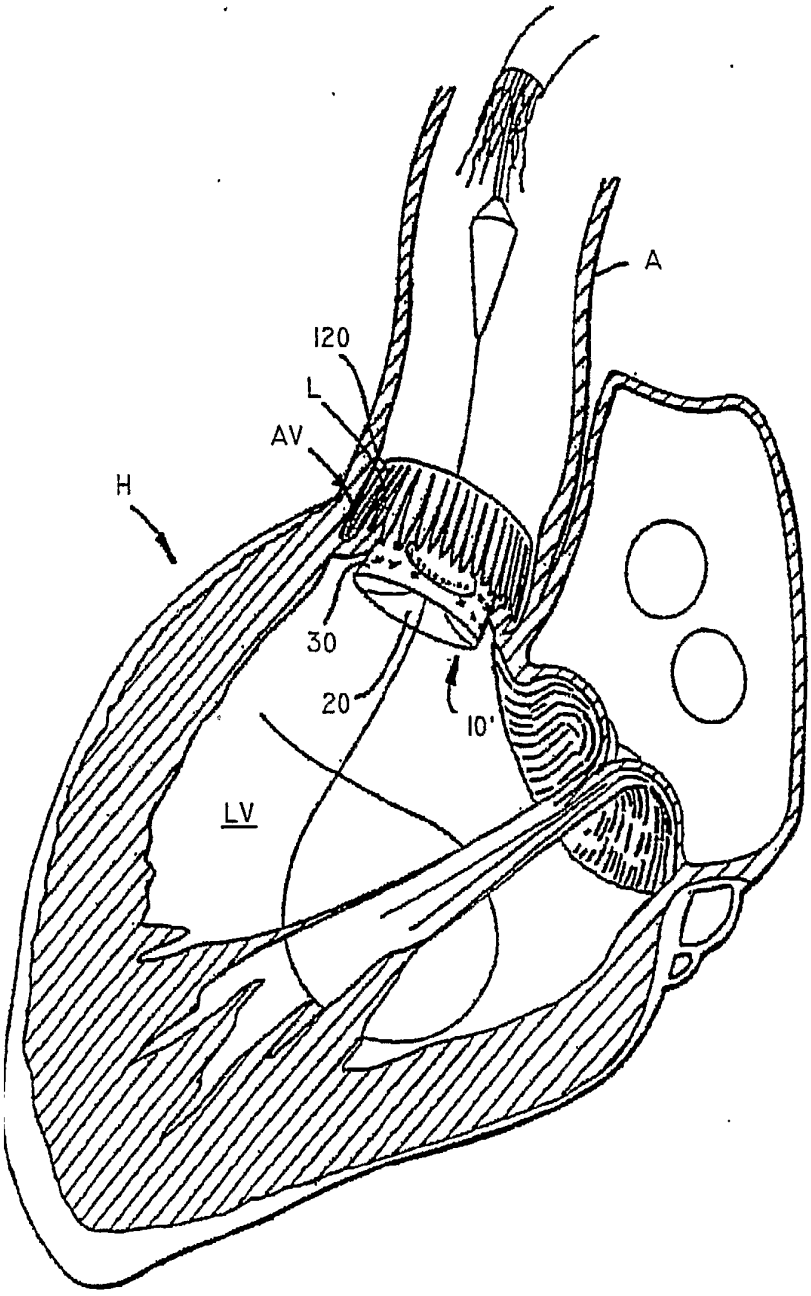

FIG. 51

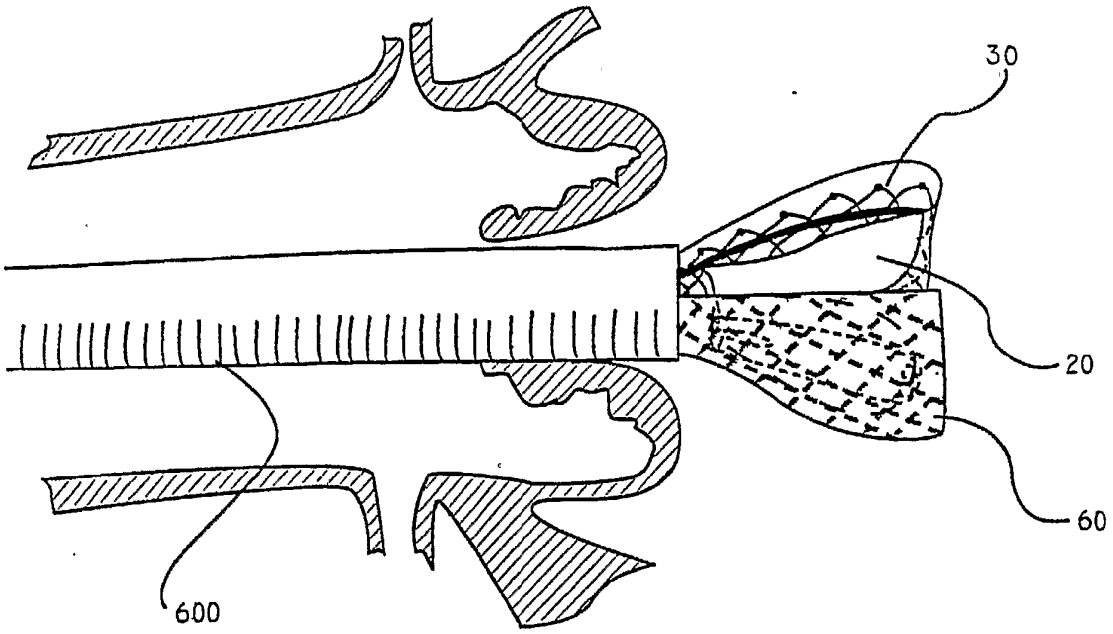

FIG. 52A

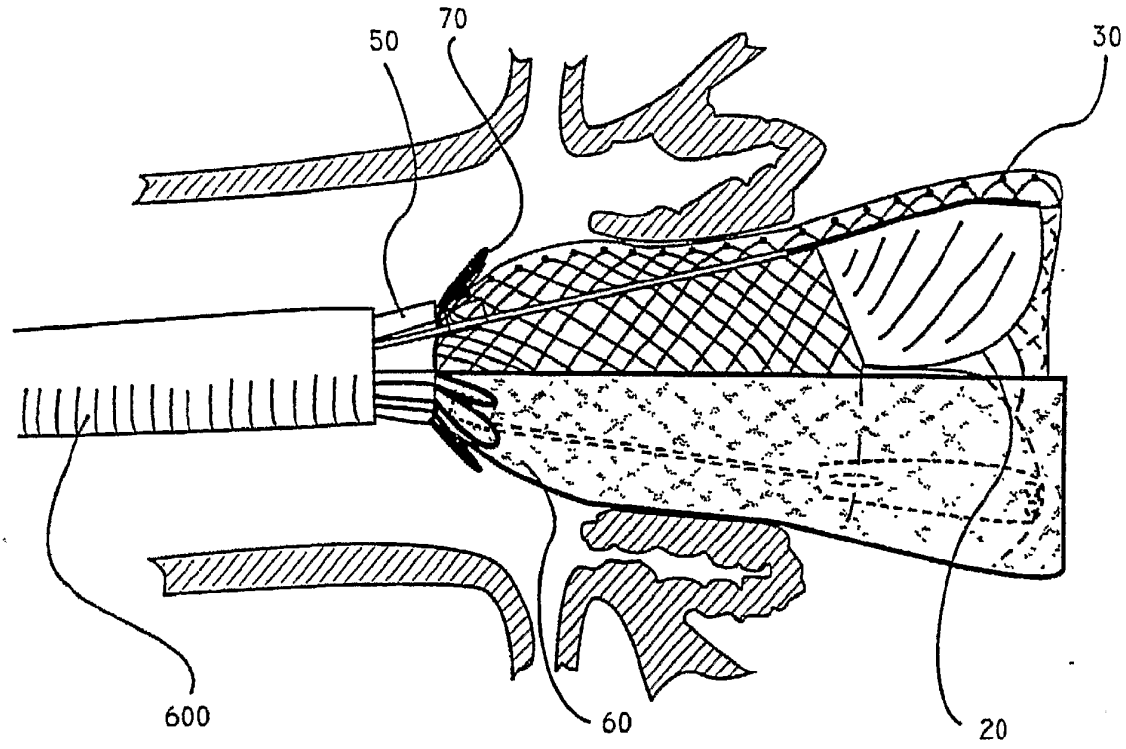

FIG. 52B

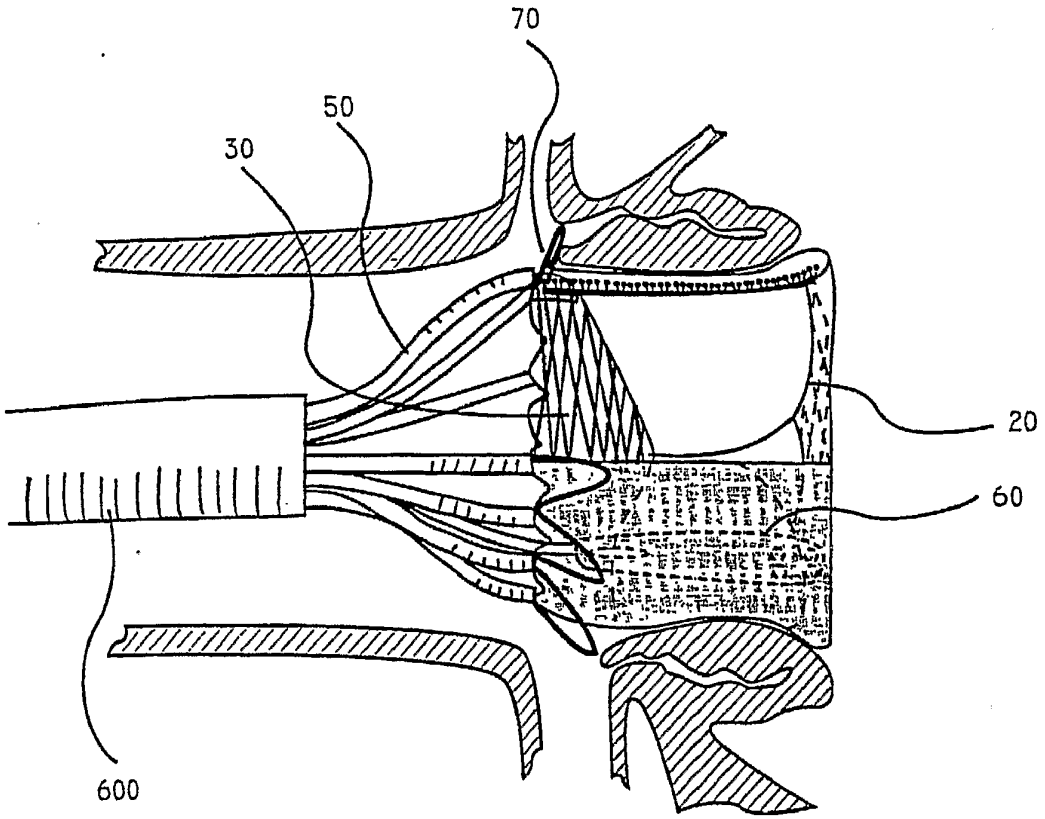

FIG. 52C

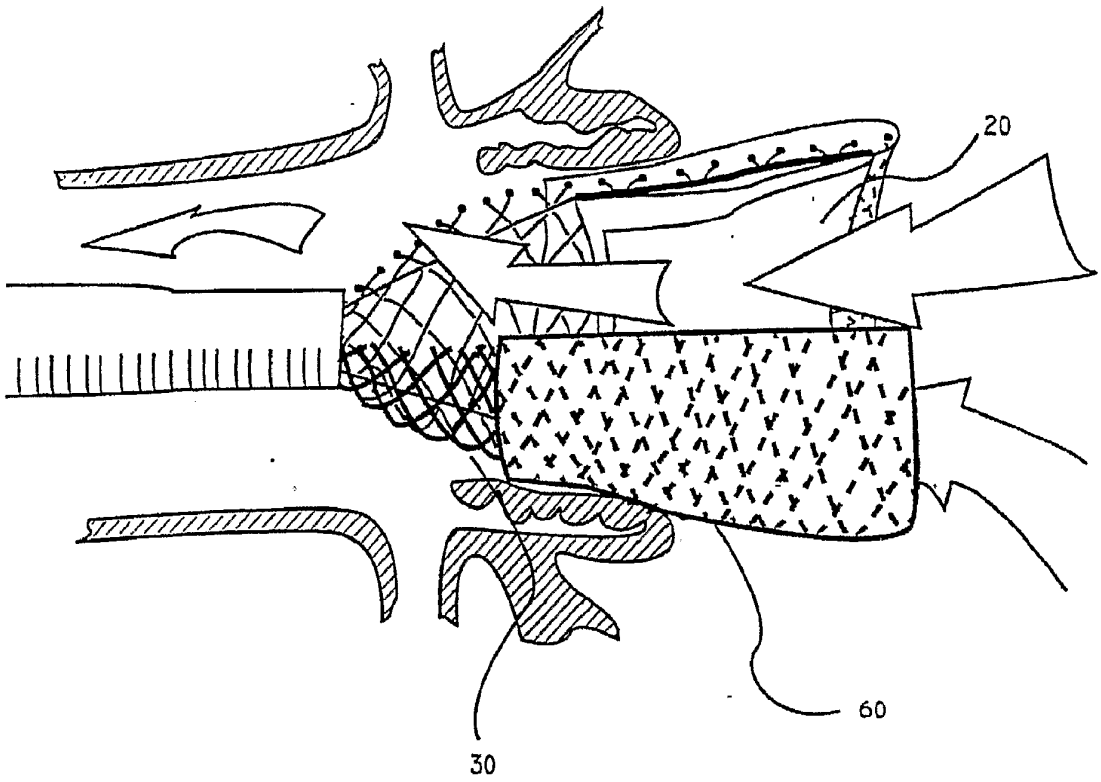

FIG. 53A

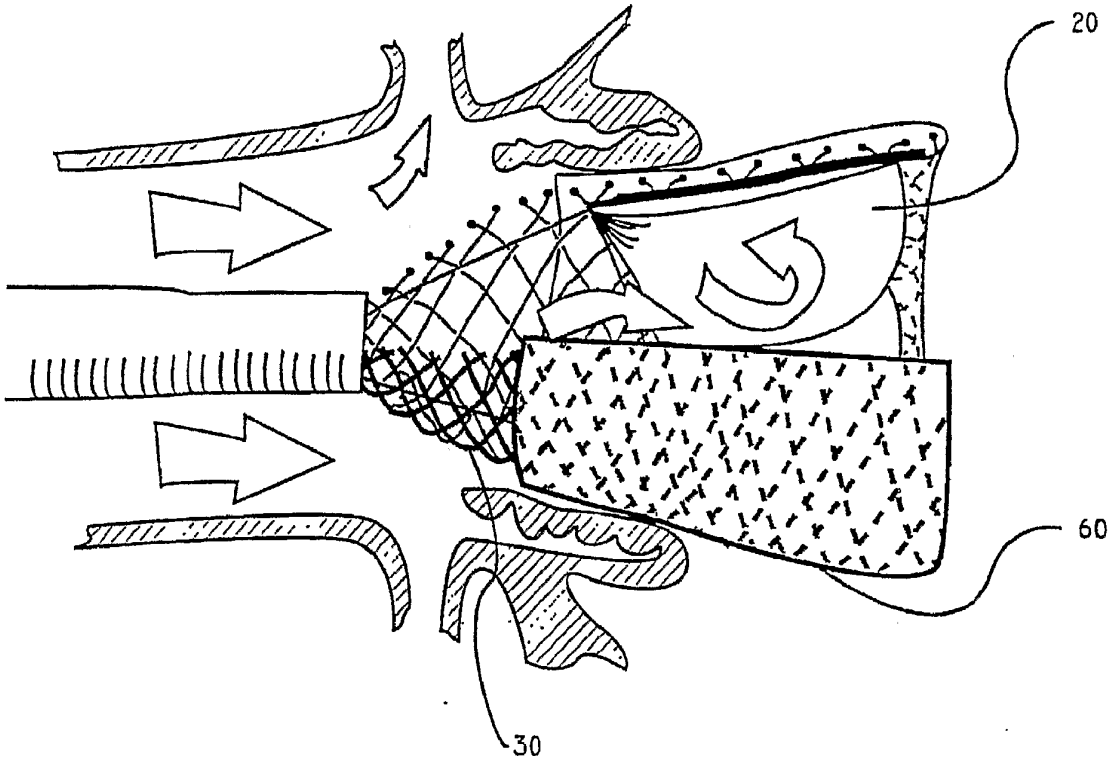

FIG. 53B

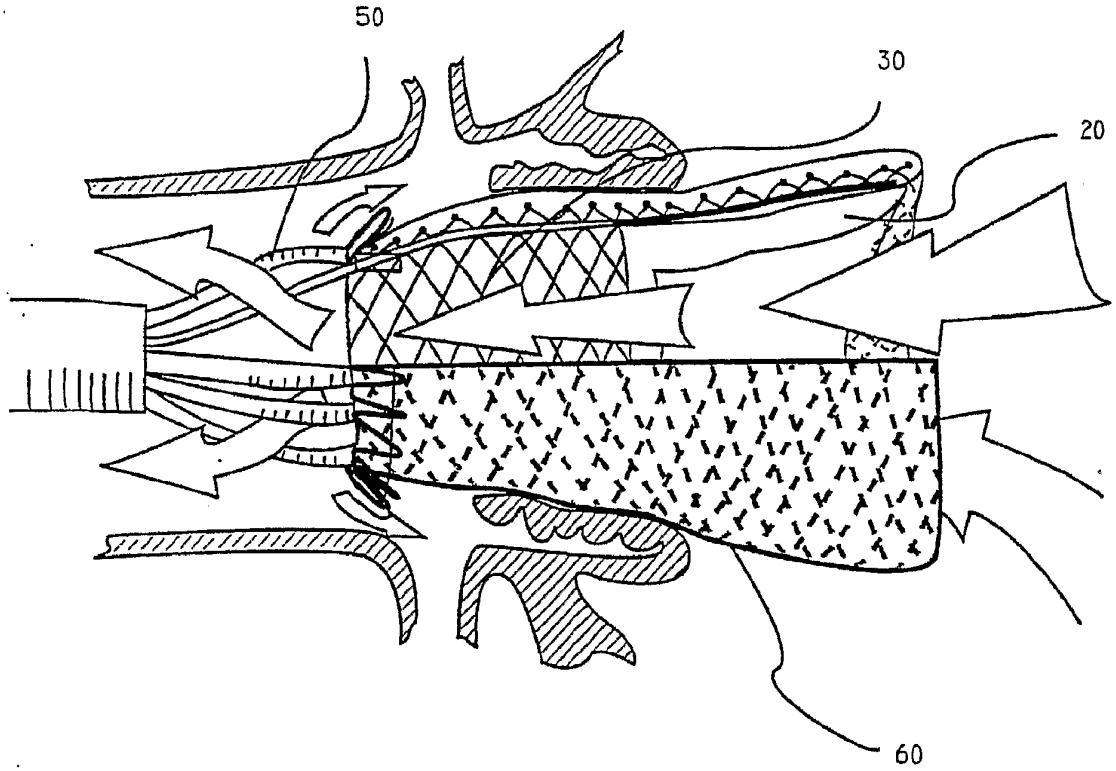

FIG. 54A

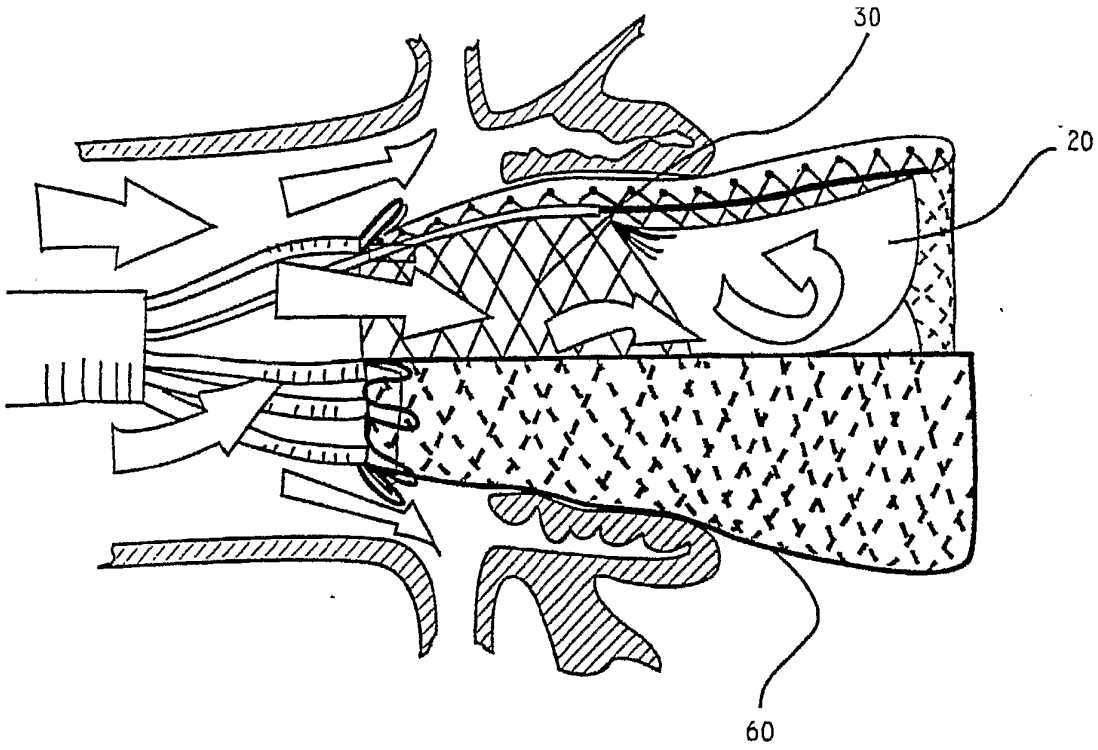

FIG. 54B

REFERENCES CITED IN THE DESCRIPTION

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- US 20010039450 A **[0019]**
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