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UTILITY PATENT APPLICATION TRANSMITTAL

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

Attorney Docket No.	10012-710.301
First Inventor	Amr SALAHIEH
Title	Everting Heart Valve
Express Mail Label No.	FILED VIA EFS

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (e.g., PTO/SB/17)
   (Submit an original and a duplicate for fee processing)
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification** [*Total Pages* 35]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. ☑ **Drawing(s)** (*35 U.S.C. 113*) [*Total Sheets* 63]
5. **Oath or Declaration** [*Total Sheets* 4]
   a. ☐ Newly executed (original or copy)
   b. ☑ A copy from a prior application (37 CFR 1.63(d))
   (for continuation/divisional with Box 18 completed)
   i. ☐ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
   (if applicable, items a. – c. are required)
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
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ADDRESS TO: **Commissioner for Patents**
P.O. Box 1450
Alexandria VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee _____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☐ **Return Receipt Postcard** (MPEP 503)
    (Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
    (if foreign priority is claimed)
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☑ Other: Communication re Order of Inventors

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☑ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 10/870,340

Prior application information: *Examiner* Ann M. Schillinger *Art Unit:* 3774

19. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 66854 **OR** ☐ Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	Thom Zl	Date	NOVEMBER 12, 2008
Name (Print/Type)	THOMAS M. ZLOGAR	Registration No. (Attorney/Agent)	55,760

FILED VIA EFS ON NOVEMBER 12, 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:		Confirmation No.:
Applicant	:	Amr SALAHIEH et al.	
Filing Date	:	November 12, 2008 *(herewith)*	
Title	:	Everting Heart Valve	
Group Art Unit	:		
Examiner	:		
Docket No.	:	10012-710.301	
Customer No.	:	66854	

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

COMMUNICATION RE ORDER OF INVENTORS

This communication accompanies a new application, which is a continuation of US Application No. 10/870,340. In that application, a petition was filed and granted, changing the order of inventors as follows:

Amr SALAHIEH,
Ulrich R. HAUG,
Hans. F. VALENCIA,
Robert A. GESHLIDER,
Tom SAUL,
Dwight P. MOREJOHN and
Kenneth J. MICHLITSCH.

Copies of the granted petition and the corrected filing receipt are attached. It is requested that the subject continuation herein retain the same order of inventors.

Respectfully submitted,

Date: November 12, 2008 By: _____

Thomas Zlogar, Reg. No. 55,760

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JB/MS

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OFFICE OF PETITIONS

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

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

The petition is **Granted.**

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

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

This matter is being referred to Technology Center AU 3738.

Karen Creasy

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

ATTACHMENT: CORRECTED FILING RECEIPT

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

CONFIRMATION NO. 7111

021971
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CORRECTED FILING RECEIPT
OC000000018061255
OC000000018061255

Date Mailed: 02/15/2006

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

Applicant(s)

Amr Salahieh, Saratoga, CA;
Ulrich R. Haug, Campbell, CA;
Hans F. Valencia, Berkeley, CA;
Robert A. Geshlider, San Francisco, CA;
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Dwight P. Morejohn, Davis, CA;
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Power of Attorney: The patent practitioners associated with Customer Number **021971**.

Domestic Priority data as claimed by applicant

Foreign Applications

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

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

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Everting heart valve

Preliminary Class

623

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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Attorney Docket No. 10012-710.301

UNITED STATES PATENT APPLICATION

EVERTING HEART VALVE

Inventor(s): **SALAHIEH,** Amr,
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FILED VIA EFS ON NOVEMBER 12, 2008

EVERTING HEART VALVE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation of pending U.S. Application No. 10/870,340, filed June 16, 2004, entitled "Everting Heart Valve", the disclosure of which is incorporated by reference in its entirety as if fully set forth herein.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to methods and apparatus for endovascularly replacing a heart valve. More particularly, the present invention relates to methods and apparatus for endovascularly replacing a heart valve with a replacement valve and an expandable and retrievable anchor. The replacement valve preferably is not connected to the expandable anchor and may be wrapped about an end of the anchor, for example, by everting during endovascular deployment.

[0003] 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.

[0004] Valve replacement may be indicated when there is a narrowing of the native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates. When replacing the valve, the native valve is excised and replaced with either a biologic or a mechanical valve. Mechanical valves require lifelong anticoagulant medication to prevent blood clot formation, and clicking of the valve often may be heard through the chest. Biologic tissue valves typically do not require such medication. Tissue valves may be obtained from cadavers or may be porcine or bovine, and are commonly attached to synthetic rings that are secured to the patient's heart.

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

[0008] 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.

[0009] 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.

[0010] Another drawback of prior art self-expanding replacement heart valve systems is their lack of radial strength. In order for self-expanding systems to be easily delivered through a delivery sheath, the metal needs to flex and bend inside the delivery catheter without being plastically deformed. In arterial stents, this is not a challenge, and there are many commercial arterial stent systems that apply adequate radial force against the vessel wall and yet can collapse to a small enough of a diameter to fit inside a delivery catheter without plastic deformation. However when the stent has a valve fastened inside it, as is the case in aortic valve replacement, the anchoring of the stent to vessel walls is significantly challenged during diastole. The force to hold back arterial pressure and prevent blood from going back inside the ventricle during diastole

will be directly transferred to the stent/vessel wall interface. Therefore, the amount of radial force required to keep the self-expanding stent/valve in contact with the vessel wall and not sliding will be much higher than in stents that do not have valves inside of them. Moreover, a self-expanding stent without sufficient radial force will end up dilating and contracting with each heartbeat, thereby distorting the valve, affecting its function and possibly migrating and dislodging completely. Simply increasing strut thickness of the self-expanding stent is not a practical solution as it runs the risk of larger profile and/or plastic deformation of the self-expanding stent.

[0011] In view of drawbacks associated with previously known techniques for endovascularly replacing a heart valve, it would be desirable to provide methods and apparatus that overcome those drawbacks.

SUMMARY OF THE INVENTION

[0012] One aspect of the present invention provides apparatus for endovascularly replacing a patient's heart valve, the apparatus including: a replacement valve; and an expandable anchor, wherein the replacement valve and expandable anchor are configured for endovascular delivery to the vicinity of the heart valve, and wherein at least a portion of the replacement valve is configured to evert about the anchor during endovascular deployment.

[0013] Another aspect of the invention provides a method for endovascularly replacing a patient's heart valve. In some embodiments the method includes the steps of: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve; everting at least a portion of the replacement valve about the anchor; and expanding the anchor to a deployed configuration.

[0014] Yet another aspect of the invention provides apparatus for endovascularly replacing a patient's heart valve including: an anchor comprising a lip region and a skirt region; and a replacement valve, wherein at least a portion of the replacement valve is configured to evert about the anchor during endovascular deployment, and wherein the lip region and skirt region are configured for percutaneous expansion to engage the patient's heart valve.

[0015] Still another aspect of the present invention provides a method for endovascularly replacing a patient's heart valve, the method including: endovascularly delivering a replacement valve and an expandable anchor to a vicinity of the heart valve, endovascularly wrapping at least

a portion of the replacement valve about the anchor, and expanding the anchor to a deployed configuration.

[0016] Another aspect of the present invention provides apparatus for endovascularly replacing a patient's heart valve, the apparatus including: a replacement valve, and an expandable anchor, wherein the replacement valve and the anchor are configured for endovascular delivery to a vicinity of the patient's heart valve, and wherein at least a portion of the replacement valve is wrapped about an end of the anchor in a deployed configuration.

INCORPORATION BY REFERENCE

[0017] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0019] Figures 1A-B are elevational views of a replacement heart valve and anchor according to one embodiment of the invention.

[0020] Figures 2A-B are sectional views of the anchor and valve of Figures 1.

[0021] 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.

[0022] 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.

[0023] Figures 5A-F show the use of a replacement heart valve and anchor to replace an aortic valve.

[0024] Figures 6A-F show the use of a replacement heart valve and anchor with a positive registration feature to replace an aortic valve.

[0025] Figure 7 shows the use of a replacement heart valve and anchor with an alternative positive registration feature to replace an aortic valve.

[0026] Figures 8A-C show another embodiment of a replacement heart valve and anchor according to the invention.

[0027] Figures 9A-H show delivery and deployment of the replacement heart valve and anchor of Figures 8.

[0028] Figure 10 is a cross-sectional drawing of the delivery system used with the method and apparatus of Figures 8 and 9.

[0029] Figures 11A-C show alternative locks for use with replacement heart valves and anchors of this invention.

[0030] Figures 12A-C show a vessel wall engaging lock for use with replacement heart valves and anchors of this invention.

[0031] Figure 13 demonstrates paravalvular leaking around a replacement heart valve and anchor.

[0032] Figure 14 shows a seal for use with a replacement heart valve and anchor of this invention.

[0033] Figures 15A-E show alternative arrangements of seals on a replacement heart valve and anchor.

[0034] Figures 16A-C show alternative seal designs for use with replacement heart valves and anchors.

[0035] Figures 17 show an alternative anchor lock embodiment in an unlocked configuration.

[0036] Figures 18A-B show the anchor lock of Figure 17 in a locked configuration.

[0037] Figure 19 shows an alternative anchor deployment tool attachment and release mechanism for use with the invention.

[0038] Figure 20 shows the attachment and release mechanism of Figure 19 in the process of being released.

[0039] Figure 21 shows the attachment and release mechanism of Figures 19 and 20 in a released condition.

[0040] Figure 22 shows an alternative embodiment of a replacement heart valve and anchor and a deployment tool according to the invention in an undeployed configuration.

[0041] Figure 23 shows the replacement heart valve and anchor of Figure 22 in a partially deployed configuration.

[0042] Figure 24 shows the replacement heart valve and anchor of Figures 22 and 23 in a more fully deployed configuration but with the deployment tool still attached.

[0043] Figure 25 shows yet another embodiment of the delivery and deployment apparatus of the invention in use with a replacement heart valve and anchor.

[0044] Figure 26 shows the delivery and deployment apparatus of Figure 25 in the process of deploying a replacement heart valve and anchor.

[0045] Figure 27 shows an embodiment of the invention employing seals at the interface of the replacement heart valve and anchor and the patient's tissue.

[0046] Figure 28 is a longitudinal cross-sectional view of the seal shown in Figure 27 in compressed form.

[0047] Figure 29 is a transverse cross-sectional view of the seal shown in Figure 28.

[0048] Figure 30 is a longitudinal cross-sectional view of the seal shown in Figure 27 in expanded form.

[0049] Figure 31 is a transverse cross-sectional view of the seal shown in Figure 30.

[0050] Figure 32 shows yet another embodiment of the replacement heart valve and anchor of this invention in an undeployed configuration.

[0051] Figure 33 shows the replacement heart valve and anchor of Figure 32 in a deployed configuration.

[0052] Figure 34 shows the replacement heart valve and anchor of Figures 32 and 33 deployed in a patient's heart valve.

[0053] Figures 35A-H show yet another embodiment of a replacement heart valve, anchor and deployment system according to this invention.

[0054] Figures 36A-E show more detail of the anchor of the embodiment shown in Figures 35A-H.

[0055] Figures 37A-B show other embodiments of the replacement heart valve and anchor of the invention.

[0056] Figures 38A-C illustrate a method for endovascularly replacing a patient's diseased heart valve.

[0057] Figures 39A-G are side views, partially in section, as well as an isometric view, illustrating a method for endovascularly replacing a patient's diseased heart valve with an embodiment of the present invention comprising a replacement valve that is not connected to the

expandable anchor, the replacement valve wrapped about the anchor, illustratively by everting during deployment.

[0058] Figures 40A-D are side views, partially in section, illustrating a method for endovascularly replacing a patient's diseased heart valve with another everting embodiment of the present invention.

[0059] Figures 41A-E are side views, partially in section, illustrating a method for endovascularly replacing a patient's diseased heart valve with yet another everting embodiment of the present invention, wherein the replacement valve and the anchor are telescoped relative to one another during endovascular delivery.

[0060] Figures 42A-B are side-sectional views of alternative everting apparatus comprising everting valve leaflets.

[0061] Figures 43A-B, are side-sectional views of further alternative everting apparatus comprising a locking mechanism coupled to the everting segment.

[0062] Figures 44A-B are side-sectional views of telescoping embodiments of the present invention comprising U-shaped valve frames.

DETAILED DESCRIPTION OF THE INVENTION

[0063] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. For example, for the two-part locking mechanisms described hereinafter, it will be apparent that the locations of the male and female elements may be reversed. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

[0064] 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.

[0065] 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.

[0066] Anchor 30 preferably is fabricated by using self-expanding patterns (laser cut or chemically milled), braids and materials, such as a stainless steel, nickel-titanium ("Nitinol") or cobalt chromium, but alternatively may be fabricated using balloon-expandable patterns where the anchor is designed to plastically deform to its final shape by means of balloon expansion. Replacement valve 20 is preferably made from biologic tissues, e.g. porcine valve leaflets or bovine or equine pericardium tissues or human cadaver tissue. Alternatively, it can be made from tissue engineered materials (such as extracellular matrix material from Small Intestinal Submucosa (SIS)) or may be prosthetic and made from an elastomeric polymer or silicone, Nitinol or stainless steel mesh or pattern (sputtered, chemically milled or laser cut). The leaflet may also be made of a composite of the elastomeric or silicone materials and metal alloys or other fibers such Kevlar or carbon. Annular base 22 of replacement valve 20 preferably is coupled to skirt region 34 of anchor 30, while commissures 24 of replacement valve leaflets 26 are coupled to and supported by posts 38.

[0067] 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.

[0068] A deployment tool is used to actuate, reposition, lock and/or retrieve anchor 30. In order to avoid delivery of anchor 30 on a balloon for balloon expansion, a non-hydraulic or non-pneumatic anchor actuator is used. In this embodiment, the actuator is a deployment tool that includes distal region control wires 50, control rods or tubes 60 and proximal region control wires 62. Locks 40 include posts or arms 38 preferably with male interlocking elements 44 extending from skirt region 34 and mating female interlocking elements 42 in lip region 32. Male interlocking elements 44 have eyelets 45. Control wires 50 pass from a delivery system for apparatus 10 through female interlocking elements 42, through eyelets 45 of male interlocking elements 44, and back through female interlocking elements 42, such that a double strand of wire 50 passes through each female interlocking element 42 for manipulation by a medical practitioner external to the patient to actuate and control the anchor by changing the anchor's shape. Control wires 50 may comprise, for example, strands of suture.

[0069] Tubes 60 are reversibly coupled to apparatus 10 and may be used in conjunction with wires 50 to actuate anchor 30, e.g., to foreshorten and lock apparatus 10 in the fully deployed configuration. Tubes 60 also facilitate repositioning and retrieval of apparatus 10, as described hereinafter. For example, anchor 30 may be foreshortened and radially expanded by applying a distally directed force on tubes 60 while proximally retracting wires 50. As seen in Figures 3, control wires 62 pass through interior lumens 61 of tubes 60. This ensures that tubes 60 are aligned properly with apparatus 10 during deployment and foreshortening. Control wires 62 can also actuate anchor 60; proximally directed forces on control wires 62 contacts the proximal lip region 32 of anchor 30. Wires 62 also act to couple and decouple tubes 60 from apparatus 10. Wires 62 may comprise, for example, strands of suture.

[0070] Figures 1A and 2A illustrate anchor 30 in a delivery configuration or in a partially deployed configuration (e.g., after dynamic self-expansion from a constrained delivery configuration within a delivery sheath). Anchor 30 has a relatively long length and a relatively small width in the delivery or partially deployed configuration, as compared to the foreshortened and fully deployed configuration of Figures 1B and 2B.

[0071] In Figures 1A and 2A, replacement valve 20 is collapsed within lumen 31 of anchor 30. Retraction of wires 50 relative to tubes 60 foreshortens anchor 30, which increases the anchor's width while decreasing its length. Such foreshortening also properly seats replacement valve 20 within lumen 31 of anchor 30. Imposed foreshortening will enhance radial

force applied by apparatus 10 to surrounding tissue over at least a portion of anchor 30. In some embodiments, the anchor is capable of exerting an outward radial force on surrounding tissue to engage the tissue in such way to prevent migration of anchor. This outward radial force is preferably greater than 2 psi, more preferably greater than 4 psi, more preferably greater than 6 psi, more preferably greater than 8 psi, more preferably greater than 10 psi, more preferably greater than 20 psi, or more preferably greater than 30 psi. Enhanced radial force of the anchor is also important for enhanced crush resistance of the anchor against the surrounding tissue due to the healing response (fibrosis and contraction of annulus over a longer period of time) or to dynamic changes of pressure and flow at each heart beat. In an alternative embodiment, the anchor pattern or braid is designed to have gaps or areas where the native tissue is allowed to protrude through the anchor slightly (not shown) and, as the foreshortening is applied, the tissue and anchor become intertwined and immobilized. This feature would provide additional means to prevent anchor migration and enhance long-term stability of the device.

[0072] Deployment of apparatus 10 is fully reversible until lock 40 has been locked via mating of male interlocking elements 44 with female interlocking elements 42. Deployment is then completed by decoupling tubes 60 from lip section 32 of anchor 30 by retracting one end of each wire 62 relative to the other end of the wire, and by retracting one end of each wire 50 relative to the other end of the wire until each wire has been removed from eyelet 45 of its corresponding male interlocking element 44.

[0073] 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.

[0074] With reference now to Figures 3, a delivery and deployment system for a self-expanding embodiment of apparatus 10 including a sheath 110 having a lumen 112. Self-expanding anchor 30 is collapsible to a delivery configuration within lumen 112 of sheath 110, such that apparatus 10 may be delivered via delivery system 100. As seen in Figure 3A, apparatus 10 may be deployed from lumen 112 by retracting sheath 110 relative to apparatus 10, control wires 50 and tubes 60, which causes anchor 30 to dynamically self-expand to a partially deployed configuration. Control wires 50 then are retracted relative to apparatus 10 and tubes 60 to impose foreshortening upon anchor 30, as seen in Figure 3B.

[0075] During foreshortening, tubes 60 push against lip region 32 of anchor 30, while wires 50 pull on posts 38 of the anchor. Wires 62 may be retracted along with wires 50 to enhance the distally directed pushing force applied by tubes 60 to lip region 32. Continued retraction of wires 50 relative to tubes 60 would lock locks 40 and fully deploy apparatus 10 with replacement valve 20 properly seated within anchor 30, as in Figures 1B and 2B. Apparatus 10 comprises enhanced radial strength in the fully deployed configuration as compared to the partially deployed configuration of Figure 3A. Once apparatus 10 has been fully deployed, wires 50 and 62 may be removed from apparatus 10, thereby separating delivery system 100 and tubes 60 from the apparatus.

[0076] Deployment of apparatus 10 is fully reversible until locks 40 have been actuated. For example, just prior to locking the position of the anchor and valve and the operation of the valve may be observed under fluoroscopy. If the position needs to be changed, by alternately relaxing and reapplying the proximally directed forces exerted by control wires 50 and/or control wires 62 and the distally directed forces exerted by tubes 60, expansion and contraction of the lip and skirt regions of anchor 30 may be independently controlled so that the anchor and valve can be moved to, e.g., avoid blocking the coronary ostia or impinging on the mitral valve. Apparatus 10 may also be completely retrieved within lumen 112 of sheath 110 by simultaneously proximally retracting wires 50 and tubes 60/wires 62 relative to sheath 110. Apparatus 10 then may be removed from the patient or repositioned for subsequent redeployment.

[0077] Referring now to Figures 4, step-by-step deployment of apparatus 10 via delivery system 100 is described. In Figure 4A, sheath 110 is retracted relative to apparatus 10, wires 50 and tubes 60, thereby causing self-expandable anchor 30 to dynamically self-expand apparatus 10 from the collapsed delivery configuration within lumen 112 of sheath 110 to the partially deployed configuration. Apparatus 10 may then be dynamically repositioned via tubes 60 to properly orient the apparatus, e.g. relative to a patient's native valve leaflets.

[0078] In Figure 4B, control wires 50 are retracted while tubes 60 are advanced, thereby urging lip region 32 of anchor 30 in a distal direction while urging posts 38 of the anchor in a proximal direction. This foreshortens apparatus 10, as seen in Figure 4C. Deployment of apparatus 10 is fully reversible even after foreshortening has been initiated and has advanced to the point illustrated in Figure 4C.

[0079] In Figure 4D, continued foreshortening causes male interlocking elements 44 of locks 40 to engage female interlocking elements 42. The male elements mate with the female elements, thereby locking apparatus 10 in the foreshortened configuration, as seen in Figure 4E. Wires 50 are then pulled through eyelets 45 of male elements 44 to remove the wires from apparatus 10, and wires 62 are pulled through the proximal end of anchor 30 to uncouple tubes 60 from the apparatus, thereby separating delivery system 100 from apparatus 10. Fully deployed apparatus 10 is shown in Figure 4F.

[0080] Referring to Figures 5, a method of endovascularly replacing a patient's diseased aortic valve with apparatus 10 and delivery system 100 is described. As seen in Figure 5A, sheath 110 of delivery system 100, having apparatus 10 disposed therein, is endovascularly advanced over guide wire **G**, preferably in a retrograde fashion (although an antegrade or hybrid approach alternatively may be used), through a patient's aorta **A** to the patient's diseased aortic valve **AV**. A nosecone 102 precedes sheath 110 in a known manner. In Figure 5B, sheath 110 is positioned such that its distal region is disposed within left ventricle **LV** of the patient's heart **H**.

[0081] Apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance, such that anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration, as in Figure 5C. Advantageously, apparatus 10 may be retracted within lumen 112 of sheath 110 via wires 50 - even after anchor 30 has dynamically expanded to the partially deployed configuration, for example, to abort the procedure or to reposition apparatus 10 or delivery system 100. As yet another advantage, apparatus 10 may be dynamically repositioned, e.g. via sheath 110 and/or tubes 60, in order to properly align the apparatus relative to anatomical landmarks, such as the patient's coronary ostia or the patient's native valve leaflets **L**. When properly aligned, skirt region 34 of anchor 30 preferably is disposed distal of the leaflets, while body region 36 is disposed across the leaflets and lip region 32 is disposed proximal of the leaflets.

[0082] Once properly aligned, wires 50 are retracted relative to tubes 60 to impose foreshortening upon anchor 30 and expand apparatus 10 to the fully deployed configuration, as in Figure 5D. Foreshortening increases the radial strength of anchor 30 to ensure prolonged patency of valve annulus **An**, as well as to provide a better seal for apparatus 10 that reduces paravalvular regurgitation. As seen in Figure 5E, locks 40 maintain imposed foreshortening. Replacement valve 20 is properly seated within anchor 30, and normal blood flow between left

ventricle **LV** and aorta **A** is thereafter regulated by apparatus 10. Deployment of apparatus 10 advantageously is fully reversible until locks 40 have been actuated.

[0083] As seen in Figure 5F, wires 50 are pulled from eyelets 45 of male elements 44 of locks 40, tubes 60 are decoupled from anchor 30, e.g. via wires 62, and delivery system 100 is removed from the patient, thereby completing deployment of apparatus 10. Optional barb elements 37 engage the patient's native valve leaflets, e.g. to preclude migration of the apparatus and/or reduce paravalvular regurgitation.

[0084] With reference now to Figures 6, a method of endovascularly replacing a patient's diseased aortic valve with apparatus 10 is provided, wherein proper positioning of the apparatus is ensured via positive registration of a modified delivery system to the patient's native valve leaflets. In Figure 6A, modified delivery system 100' delivers apparatus 10 to diseased aortic valve **AV** within sheath 110. As seen in Figures 6B and 6C, apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance, such that anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration. As when deployed via delivery system 100, deployment of apparatus 10 via delivery system 100' is fully reversible until locks 40 have been actuated.

[0085] Delivery system 100' comprises leaflet engagement element 120, which preferably self-expands along with anchor 30. Engagement element 120 is disposed between tubes 60 of delivery system 100' and lip region 32 of anchor 30. Element 120 releasably engages the anchor. As seen in Figure 6C, the element is initially deployed proximal of the patient's native valve leaflets **L**. Apparatus 10 and element 120 then may be advanced/dynamically repositioned until the engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus 10. Also, delivery system 100' includes filter structure 61A (e.g., filter membrane or braid) as part of push tubes 60 to act as an embolic protection element. Emboli can be generated during manipulation and placement of anchor, from either diseased native leaflet or surrounding aortic tissue, and can cause blockage. Arrows 61B in Figure 6E show blood flow through filter structure 61A where blood is allowed to flow but emboli is trapped in the delivery system and removed with it at the end of the procedure.

[0086] Alternatively, foreshortening may be imposed upon anchor 30 while element 120 is disposed proximal of the leaflets, as in Figure 6D. Upon positive registration of element 120 against leaflets **L**, element 120 precludes further distal migration of apparatus 10 during

additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. Figure 6E details engagement of element 120 against the native leaflets. As seen in Figure 6F, once apparatus 10 is fully deployed, element 120, wires 50 and tubes 60 are decoupled from the apparatus, and delivery system 100' is removed from the patient, thereby completing the procedure.

[0087] 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.

[0088] Referring now to Figures 8, an alternative delivery system adapted for use with a balloon expandable embodiment of the present invention is described. In Figure 8A, apparatus 10'' comprises anchor 30' that may be fabricated from balloon-expandable materials. Delivery system 100'' comprises inflatable member 130 disposed in a deflated configuration within lumen 31 of anchor 30'. In Figure 8B, optional outer sheath 110 is retracted, and inflatable member 130 is inflated to expand anchor 30' to the fully deployed configuration. As inflatable member 130 is being deflated, as in earlier embodiments, wires 50 and 62 and tubes 60 may be used to assist deployment of anchor 30' and actuation of locks 40, as well as to provide reversibility and retrievability of apparatus 10'' prior to actuation of locks 40. Next, wires 50 and 62 and tubes 60 are removed from apparatus 10'', and delivery system 100'' is removed, as seen in Figure 8C.

[0089] As an alternative delivery method, anchor 30' may be partially deployed via partial expansion of inflatable member 130. The inflatable member would then be advanced within replacement valve 20 prior to inflation of inflatable member 130 and full deployment of apparatus 10''. Inflation pressures used will range from about 3 to 6 atm, or more preferably from about 4 to 5 atm, though higher and lower atm pressures may also be used (e.g., greater than 3 atm, more preferably greater than 4 atm, more preferably greater than 5 atm, or more preferably greater than 6 atm). Advantageously, separation of inflatable member 130 from replacement valve 20, until partial deployment of apparatus 10'' at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This

profile reduction may facilitate retrograde delivery and deployment of apparatus 10'', even when anchor 30' is balloon-expandable.

[0090] Although anchor 30' has illustratively been described as fabricated from balloon-expandable materials, it should be understood that anchor 30' alternatively may be fabricated from self-expanding materials whose expansion optionally may be balloon-assisted. In such a configuration, anchor 30' would expand to a partially deployed configuration upon removal of outer sheath 110. If required, inflatable member 130 then would be advanced within replacement valve 20 prior to inflation. Inflatable member 130 would assist full deployment of apparatus 10'', for example, when the radial force required to overcome resistance from impinging tissue were too great to be overcome simply by manipulation of wires 50 and tubes 60. Advantageously, optional placement of inflatable member 130 within replacement valve 20, only after dynamic self-expansion of apparatus 10'' to the partially deployed configuration at a treatment site, is expected to reduce a delivery profile of the apparatus, as compared to previously known apparatus. This reduction may facilitate retrograde delivery and deployment of apparatus 10''.

[0091] With reference to Figures 9 and 10, methods and apparatus for a balloon-assisted embodiment of the present invention are described in greater detail. Figures 9 and 10 illustratively show apparatus 10' of Figures 7 used in combination with delivery system 100'' of Figures 8. Figure 10 illustrates a sectional view of delivery system 100''. Inner shaft 132 of inflatable member 130 preferably is about 4 Fr in diameter, and comprises lumen 133 configured for passage of guidewire **G**, having a diameter of about 0.035", therethrough. Push tubes 60 and pull wires 50 pass through guidetube 140, which preferably has a diameter of about 15 Fr or smaller. Guide tube 140 is disposed within lumen 112 of outer sheath 110, which preferably has a diameter of about 17 Fr or smaller.

[0092] 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.

[0093] In Figure 9C, pull wires 50 and push tubes 60 are manipulated from external to the patient to foreshorten anchor 30 and sufficiently expand lumen 31 of the anchor to facilitate advancement of inflatable member 130 within replacement valve 20. Also shown is the tip of an angioplasty catheter 130 being advanced through delivery system 110.

[0094] The angioplasty balloon catheter or inflatable member 130 then is advanced within the replacement valve, as in Figure 9D, and additional foreshortening is imposed upon anchor 30 to actuate locks 40, as in Figure 9E. The inflatable member is inflated to further displace the patient's native valve leaflets **L** and ensure adequate blood flow through, and long-term patency of, replacement valve 20, as in Figure 9F. Inflatable member 130 then is deflated and removed from the patient, as in Figure 9G. A different size angioplasty balloon catheter could be used repeat the same step if deemed necessary by the user. Push tubes 60 optionally may be used to further set leaflet engagement element 120, or optional barbs **B** along posts 38, more deeply within leaflets **L**, as in Figure 9H. Then, delivery system 100'' is removed from the patient, thereby completing percutaneous heart valve replacement.

[0095] 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.

[0096] Referring now to Figures 11, alternative locks for use with apparatus of the present invention are described. In Figure 11A, lock 40' comprises male interlocking element 44 as described previously. However, female interlocking element 42' illustratively comprises a triangular shape, as compared to the round shape of interlocking element 42 described previously. The triangular shape of female interlocking element 42' may facilitate mating of male interlocking element 44 with the female interlocking element without necessitating deformation of the male interlocking element.

[0097] In Figure 11B, lock 40'' comprises alternative male interlocking element 44' having multiple in-line arrowheads 46 along posts 38. Each arrowhead comprises resiliently deformable appendages 48 to facilitate passage through female interlocking element 42. Appendages 48 optionally comprise eyelets 49, such that control wire 50 or a secondary wire

may pass therethrough to constrain the appendages in the deformed configuration. To actuate lock 40'', one or more arrowheads 46 of male interlocking element 44' are drawn through female interlocking element 42, and the wire is removed from eyelets 49, thereby causing appendages 48 to resiliently expand and actuate lock 40''.

[0098] 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.

[0099] 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'''.

[00100] 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.

[00101] 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.

[00102] 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.

[00103] With reference to Figures 15, illustrative arrangements for sacs 200 are provided. In Figure 15A, sacs 200 are provided as discrete sacs at different positions along the height of anchor 30. In Figure 15B, the sacs are provided as continuous cylinders at various heights. In Figure 15C, a single sac is provided with a cylindrical shape that spans multiple heights. The sacs of Figure 15D are discrete, smaller and provided in larger quantities. Figure 15E provides a spiral sac. Alternative sac configurations will be apparent to those of skill in the art.

[00104] With reference to Figures 16, exemplary techniques for fabricating sacs 200 are provided. In Figure 16A, sacs 200 comprise 'fish-scale' slots 202 that may be back-filled, for example, with ambient blood passing through replacement valve 20. In Figure 16B, the sacs comprise pores 204 that may be used to fill the sacs. In Figure 16C, the sacs open to lumen 31 of anchor 30 and are filled by blood washing past the sacs as the blood moves through apparatus 10.

[00105] Figures 17 and 18 show yet another alternative embodiment of the anchor lock. Anchor 300 has a plurality of male interlocking elements 302 having eyelets 304 formed therein. Male interlocking elements are connected to braided structure 300 by inter-weaving elements 302 (and 308) or alternatively suturing, soldering, welding, or connecting with adhesive. Valve commissures 24 are connected to male interlocking elements 302 along their length. Replacement valve 20 annular base 22 is connected to the distal end 34 of anchor 300 (or 30) as is illustrated in figures 1A and 1B. Male interlocking elements 302 also include holes 306 that mate with tabs 310 extending into holes 312 in female interlocking elements 308. To lock, control wires 314 passing through eyelets 304 and holes 312 are pulled proximally with respect to the proximal end of braided anchor 300 to draw the male interlocking elements through holes 312 so that tabs 310 engage holes 306 in male interlocking elements 302. Also shown is release wires 314B that pass through eyelet 304B in female interlocking element 308. If needed, during the procedure, the user may pull on release wires 314B, thereby reversing orientation of tabs 310, releasing the anchor and allowing for repositioning of the device or its removal from the patient. Only when finally positioned as desired by the operating physician, would release wire 314B and control wire 314 be cut and removed from the patient with the delivery system.

[00106] Figures 19-21 show an alternative way of releasing the connection between the anchor and its actuating tubes and control wires. Control wires 62 extend through tubes 60 from outside the patient, loop through the proximal region of anchor 30 and extend partially back into tube 60. The doubled up portion of control wire 62 creates a force fit within tube 60 that maintains the control wire's position with respect to tube 60 when all control wires 62 are pulled proximally to place a proximally directed force on anchor 30. When a single control wire 62 is pulled proximally, however, the frictional fit between that control wire and the tube in which it is disposed is overcome, enabling the end 63 of control wire 62 to pull free of the tube, as shown in Figure 21, thereby releasing anchor 30.

[00107] Figures 22-24 show an alternative embodiment of the anchor. Anchor 350 is made of a metal braid, such as Nitinol or stainless steel. A replacement valve 354 is disposed within anchor 350 and supported by a replacement valve support, such as the posts described in earlier embodiments. Anchor 350 preferably is fabricated from a single strand of metal wire wound into the braid. It is expected that fabricating anchor 350 from a single strand of wire will facilitate deployment of the anchor, as well as retrieval of the anchor, by more evenly distributing forces applied to the anchor. Fabrication from a single strand is also expected to facilitate coupling of replacement valve 354 to the anchor, as well as coupling and decoupling of control wires (not shown) and tubes 352 thereto. Anchor 350 is actuated in substantially the same way as anchor 30 of Figures 1-4 through the application of proximally and distally directed forces from control wires and tubes 352 and may be locked in its expanded deployed configuration, as described above. The employed configuration of anchor 354 may have the shape and anchoring characteristics described with respect to other embodiments as well.

[00108] The braid forming anchor 350 (as well as that forming previously described anchor 30) optionally may be locally increased in diameter, e.g. via dipping in silicone or a hydrogel, in order to provide a better or complete seal against the patient's anatomy. An improved seal is expected to reduce paravalvular leakage, as well as migration of the anchor over time. The local increase in diameter of the braid may, for example, be provided over a full radial segment of anchor 350.

[00109] Figures 25 and 26 show yet another embodiment of the delivery and deployment apparatus of the invention. As an alternative to the balloon expansion method described with respect to Figures 8, in this embodiment the nosecone (e.g., element 102 of Figures 5) is replaced

by an angioplasty balloon catheter 360. Thus, angioplasty balloon catheter 360 precedes sheath 110 on guidewire G. When anchor 30 and valve 20 are expanded through the operation of tubes 60 and the control wires (not shown) as described above, balloon catheter 360 is retracted proximally within the expanded anchor and valve and expanded further as described above with respect to Figures 8.

[00110] As an alternative, or in addition, to further expansion of balloon catheter 360 within valve 20 and expanded anchor 30 to further expand the anchor, the balloon may be deflated prior to proximal retraction within and past the valve and anchor. In this manner, balloon catheter 360 may act as an atraumatic nosecone during delivery of valve 20 and anchor 30, but then may be deflated to provide a reduced profile, as compared to a standard nosecone, during retrieval of the balloon catheter through the deployed valve. It is expected that a smaller balloon catheter 360 may be provided when the catheter is utilized merely in place of a nosecone than when the catheter is also utilized to complete expansion of anchor 30.

[00111] Figures 27-31 show seals 370 that expand over time to seal the interface between the anchor and valve and the patient's tissue. Seals 370 are preferably formed from Nitinol wire surrounded by an expandable foam. As shown in cross-section in Figures 28 and 29, at the time of deployment, the foam 372 is compressed about the wire 374 and held in the compressed form by a time-released coating 376. After deployment, coating 376 dissolves in vivo to allow foam 372 to expand, as shown in Figures 30 and 31.

[00112] Figures 32-34 show another way to seal the replacement valve against leakage. A fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery. When deployed, as shown in Figures 33 and 34, fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382, particularly when the pockets are filled with blood in response to backflow blood pressure. This arrangement creates a seal around the replacement valve.

[00113] Figures 35A-H show another embodiment of a replacement heart valve apparatus in accordance with the present invention. Apparatus 450 comprises replacement valve 460 (see Figures 37B and 38C) disposed within and coupled to anchor 470. Replacement valve 460 is preferably biologic, e.g. porcine, but alternatively may be synthetic. Anchor 470 preferably is fabricated from self-expanding materials, such as a stainless steel wire mesh or a nickel-titanium alloy ("Nitinol"), and comprises lip region 472, skirt region 474, and body regions 476a, 476b

and 476c. Replacement valve 460 preferably is coupled to skirt region 474, but alternatively may be coupled to other regions of the anchor. As described hereinbelow, lip region 472 and skirt region 474 are configured to expand and engage/capture a patient's native valve leaflets, thereby providing positive registration, reducing paravalvular regurgitation, reducing device migration, etc.

[00114] As seen in Figure 35A, apparatus 450 is collapsible to a delivery configuration, wherein the apparatus may be delivered via delivery system 410. Delivery system 410 comprises sheath 420 having lumen 422, as well as wires 424a and 424b seen in Figures 35D-35G. Wires 424a are configured to expand skirt region 474 of anchor 470, as well as replacement valve 460 coupled thereto, while wires 424b are configured to expand lip region 472.

[00115] As seen in Figure 35B, apparatus 450 may be delivered and deployed from lumen 422 of catheter 420 while the apparatus is disposed in the collapsed delivery configuration. As seen in Figures 35B-35D, catheter 420 is retracted relative to apparatus 450, which causes anchor 470 to dynamically self-expand to a partially deployed configuration. Wires 424a are then retracted to expand skirt region 474, as seen in Figures 35E and 35F. Preferably, such expansion may be maintained via locking features described hereinafter.

[00116] In Figure 35G, wires 424b are retracted to expand lip region 472 and fully deploy apparatus 450. As with skirt region 474, expansion of lip region 472 preferably may be maintained via locking features. After both lip region 472 and skirt region 474 have been expanded, wires 424 may be removed from apparatus 450, thereby separating delivery system 410 from the apparatus. Delivery system 410 then may be removed, as seen in Figure 35H.

[00117] 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.

[00118] With reference now to Figures 36A-E, individual cells of anchor 470 of apparatus 450 are described to detail deployment and expansion of the apparatus. In Figure 36A, individual cells of lip region 472, skirt region 474 and body regions 476a, 476b and 476c are shown in the collapsed delivery configuration, as they would appear while disposed within

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

[00119] 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.

[00120] In Figure 36B, anchor 470 is shown in the partially deployed configuration, e.g., after deployment from lumen 422 of sheath 420. Body regions 476, as well as lip region 472 and skirt region 474, self-expand to the partially deployed configuration. Full deployment is then achieved by retracting wires 424 relative to anchor 470, and expanding lip region 472 and skirt region 474 outward, as seen in Figures 36C and 36D. As seen in Figure 36E, expansion continues until the male elements engage the female interlocking elements of lip lock 480 and skirt lock 490, thereby maintaining such expansion (lip lock 480 shown in Figure 36E). Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated.

[00121] With reference to Figures 37A-B, isometric views, partially in section, further illustrate apparatus 450 in the fully deployed and expanded configuration. Figure 37A illustrates the wireframe structure of anchor 470, while Figure 37B illustrates an embodiment of anchor 470 covered in a biocompatible material **B**. Placement of replacement valve 460 within apparatus 450 may be seen in Figure 37B. The patient's native valve is captured between lip region 472 and skirt region 474 of anchor 470 in the fully deployed configuration (see Figure 38B).

[00122] Referring to Figures 38A-C, in conjunction with Figures 35 and 36, a method for endovascularly replacing a patient's diseased aortic valve with apparatus 450 is described.

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

[00123] Once properly positioned, wires 424a are retracted to expand skirt region 474 of anchor 470 within left ventricle **LV**. Skirt region 474 is locked in the expanded configuration via skirt lock 490, as previously described with respect to Figures 36. In Figure 38A, skirt region 474 is maneuvered such that it engages the patient's valve annulus **An** and/or native valve leaflets **L**, thereby providing positive registration of apparatus 450 relative to the anatomical landmarks.

[00124] Wires 424b are then actuated external to the patient in order to expand lip region 472, as previously described in Figures 35. Lip region 472 is locked in the expanded configuration via lip lock 480. Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated. Wires 424 are pulled from eyelets 483 and 493, and delivery system 410 is removed from the patient. As will be apparent, the order of expansion of lip region 472 and skirt region 474 may be reversed, concurrent, etc.

[00125] As seen in Figure 38B, lip region 472 engages the patient's native valve leaflets **L**, thereby providing additional positive registration and reducing a risk of lip region 472 blocking the patient's coronary ostia **O**. Figure 38C illustrates the same in cross-sectional view, while also showing the position of replacement valve 460. The patient's native leaflets are engaged and/or captured between lip region 472 and skirt region 474. Advantageously, lip region 472 precludes distal migration of apparatus 450, while skirt region 474 precludes proximal migration. It is expected that lip region 472 and skirt region 474 also will reduce paravalvular regurgitation.

[00126] Referring now to Figures 39, an embodiment of apparatus in accordance with the present invention is described, wherein the replacement valve is not connected to the expandable portion of the anchor. Rather, the replacement valve is wrapped about an end of the anchor. Such wrapping may be achieved, for example, by everting the valve during endovascular deployment.

[00127] In Figures 39, apparatus 500 comprises expandable anchor 30' and everting replacement valve 520, as well as delivery system 100' for endoluminally delivering and deploying the expandable anchor and everting valve. Expandable anchor 30' illustratively is described as substantially the same as previously described anchor 30 of Figures 1-4; however, it should be understood that anchor 30' alternatively may be substantially the same as anchor 300 of Figures 17 and 18, anchor 350 of Figures 24-26, or anchor 470 of Figures 35. As with anchor 30, anchor 30' comprises posts 38 and locks (comprised of elements 523 and 532). Alternative locks may be provided, such as locks 40', 40'', 40''' or 40'''' of Figures 11 and 12, or the reversible lock of anchor 300 described with respect to Figures 17 and 18.

[00128] Everting valve 520 is similar to previously described valve 20, in that commissures 524 of replacement valve leaflets 526 are coupled to and supported by posts 38 of anchor 30'. However, annular base 522 of replacement valve 520 is not coupled to anchor 30'. Rather, annular base 522 is coupled to everting segment 528 of everting replacement valve 520. Everting segment 528 is disposed distal of anchor 30' in the delivery configuration and is configured to wrap about the distal end of the anchor during deployment, such as by everting, thereby holding (such as by friction locking) replacement valve 520 between the anchor and the patient's tissue, thereby creating a seal between the anchor and the patient's tissue. In this manner, replacement valve 520 is entirely disconnected from the expandable/collapsible portion of anchor 30', and a delivery profile of apparatus 500 is reduced, as compared to previously described apparatus 10.

[00129] Everting segment 528 of valve 520 may be fabricated from the same material as valve leaflets 526, e.g., a biologic tissue or a polymeric material. Alternatively, the segment may comprise a fabric, such as a permeable or impermeable fabric, a fabric that promotes or retards tissue ingrowth, a sealing foam, etc. Additional materials will be apparent.

[00130] Delivery system 100' for use with anchor 30' and replacement valve 520, is similar to previously described delivery system 100. The delivery system comprises sheath 110'

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

[00131] Control wires 550 are coupled to a distal region of everting segment 528 of valve 520, and then pass proximally out of the patient external to anchor 30' for manipulation by a medical practitioner. Control wires 550 preferably are kept taut to keep everting segment 528 in tension. Upon retraction of sheath 110' relative to anchor 30' and valve 520 (or advancement of the anchor and valve relative to the sheath), the tension applied to segment 528 by wires 550 causes the segment to evert and wrap about the distal end of anchor 30'. Anchor 30' then may be expanded and deployed as described previously, thereby friction locking everting segment 528 between the anchor and the patient's anatomy.

[00132] Figures 39 illustrate a device and method for endovascularly replacing a patient's diseased aortic valve utilizing apparatus 500. In Figure 39A, sheath 110' of delivery system 100', having expandable anchor 30' and everting valve 520 disposed therein within lumen 112', is endovascularly advanced over guide wire **G**, preferably in a retrograde fashion (although an antegrade or hybrid approach alternatively may be used), through a patient's aorta **A** to the patient's diseased aortic valve **AV**. Balloon catheter nosecone 360 precedes sheath 110'. Sheath 110' is positioned such that its distal region is disposed within left ventricle **LV** of the patient's heart **H.** In Figure 39A, wires 550 pass from segment 528 and lumen 112' to the exterior of sheath 110' via through-holes 111a', and then more proximally pass back into the interior of sheath 110' via through-holes 111b', which are disposed proximal of anchor 30'.

[00133] Figure 39B is a blow-up of the intersection of tubes 60, wires 62 and anchor 30'.

[00134] Figure 39C illustrates the beginning of the everting process wherein everting segment 528 is being pulled proximally over the exterior of anchor 30'. As seen in Figure 39C, which provides and isometric view of the device, the inflatable element of balloon catheter 360 is deflated and further distally advanced within left ventricle **LV** along guide wire **G** relative to sheath 110'. Anchor 30' and replacement valve 520 then are advanced relative to the sheath via

tubes 60 and control wires 62, thereby deploying everting segment 528 of valve 520, as well as a distal region of anchor 30', from the distal end of lumen 112'. Tension applied to everting segment 528 via control wires 550 connected through eyelets 529 causes the segment to wrap about the distal region of anchor 30' by everting.

[00135] In Figure 39C, wires 550 may pass distally from everting segment 528 out the distal end of lumen 112' of sheath 110', then proximally along the interior surface of the sheath all the way out of the patient. Optional through-holes 111b' allow wires 550 to be disposed within lumen 112' along a majority of their length. Wires 550 may also pass back into multi-lumen sheath 180.

[00136] Figure 39D provides a cross sectional view of apparatus 500 after replacement valve 520 has everted about anchor 30'. This and other cross sectional figures portray a 120° view of the apparatus herein. Sheath 110' is then retracted relative to anchor 30' and valve 520, which deploys a remainder of the anchor and the replacement valve from lumen 112' of the sheath. Such deployment may be conducted, for example, under fluoroscopic guidance. Anchor 30' dynamically self-expands to a partially deployed configuration.

[00137] Advantageously, anchor 30' and replacement valve 520 may be retrieved and retracted within the lumen of sheath 110' via retraction of multi-lumen catheter 180 to which tubes 60 are attached and release of wires 50. Such retrieval of apparatus 500 may be achieved even after segment 528 has been wrapped about anchor 30', and even after anchor 30' has dynamically expanded to the partially deployed configuration. Retrieval of apparatus 500 may be utilized, for example, to abort the procedure or to reposition the apparatus. As yet another advantage, anchor 30' and valve 520 may be dynamically repositioned, e.g. via proximal retraction of multi-lumen catheter 180 and/or release of wires 50, in order to properly align the apparatus relative to anatomical landmarks, such as the patient's coronary ostia **O** or the patient's native valve leaflets **L**.

[00138] Once properly aligned sheath 110', tubes 60 and wires 62 are advanced relative to wires 50 and 550 to impose foreshortening upon anchor 30', thereby expanding the anchor to the fully deployed configuration, as in Figure 39G. Foreshortening friction locks everting segment 528 of valve 520 between anchor 30' and annulus **An**/leaflets **L** of the patient's diseased valve, thus properly seating the valve within the anchor while providing an improved seal between the replacement and native valves that is expected to reduce paravalvular regurgitation.

Foreshortening also increases a radial strength of anchor 30', which is expected to prolong patency of valve annulus **An**. Furthermore, foreshortening actuates the anchor's locks, which maintain such imposed foreshortening.

[00139] Deployment of anchor 30' and replacement valve 520 advantageously is fully reversible until the anchor locks have been actuated. Furthermore, if the anchor's locks are reversible locks or buckles, such as those described in conjunction with anchor 300 of Figures 17 and 18, deployment of the anchor and valve may be fully reversible even after actuation of the locks/buckles, right up until delivery system 100' is decoupled from the replacement apparatus.

[00140] As seen in Figure 39G, in order to complete deployment of anchor 30' and replacement valve 520, wires 50 of delivery system 100' are decoupled from posts 38 of anchor 30', tubes 60 are decoupled from anchor 30', e.g. via wires 62, and wires 550 are decoupled from friction-locked everting segment 528 of replacement valve 520. Figure 39E illustrates how wires 50 are associated with posts 38. In one example, wires 50 are decoupled from posts 38 by pulling on one of the wires. Decoupling of the wires and tubes may also be achieved, for example, via eyelets (see Figures 4E, 19-21 and 39E) or via cutting of the wires. Delivery system 100' then is removed from the patient, as are deflated balloon catheter 360 and guide wire **G**, both of which are retracted proximally across the replacement valve and anchor. Normal blood flow between left ventricle **LV** and aorta **A** thereafter is regulated by replacement valve 520. Figure 39F is a blow up illustration of replacement valves 526 which are connected to everting segment 528, wherein everting segment 528 has been everted around anchor 30'.

[00141] Referring now to Figures 40, an alternative embodiment of everting apparatus in accordance with the present invention is described, wherein the posts are connected and the everting valve is disposed within the anchor to the proximal end of the anchor in the delivery configuration. In Figures 40, apparatus 600 comprises everting replacement valve 620 and anchor 630, as well as previously described delivery system 100'. Replacement valve 620 and anchor 630 are substantially the same as valve 520 and anchor 30' of Figures 39, except that valve 620 is initially seated more proximally within anchor 630, such that everting segment 628 of valve 620 is initially disposed within the anchor. Locking mechanisms as described previously may be implemented at the distal end of the post and anchor or proximal end of everted segment and anchor.

[00142] As with replacement valve 520, everting segment 628 of valve 620 is configured to wrap about the distal end of anchor 630 by everting during deployment, thereby friction locking the replacement valve between the anchor and the patient's anatomy. Furthermore, replacement valve 620 is entirely disconnected from the expandable/collapsible portion of anchor 630. In the delivery configuration, since only a single circumferential layer of valve 620 is present along any cross section of apparatus 600, a delivery profile of the apparatus is reduced, as compared to previously described apparatus 10. With apparatus 10, two circumferential layers of valve 20 are present in the cross section where annular base 22 of the valve is coupled to the expandable anchor 30.

[00143] Figures 40 illustrate a method of endovascularly replacing a patient's diseased aortic valve utilizing apparatus 600. In Figure 40A, apparatus 600 is endovascularly advanced into position with valve 620 and anchor 630 disposed within lumen 112' of sheath 110' of delivery system 100'. As seen in Figure 40B, the valve and anchor are advanced relative to the sheath and/or the sheath is retracted relative to the valve and anchor, which deploys everting segment 628 of the valve, as well as a distal region of the anchor. Tension applied to the everting segment via control wires 550 causes the segment to evert and wrap about the distal region of anchor 630. Control wires 550 may enter the multi-lumen catheter at the distal end of the catheter or more proximally as is illustrated in 40C. Further retraction of sheath 110' deploys a remainder of replacement valve 620 and anchor 630 from lumen 112' of the sheath. Such deployment may be conducted, for example, under fluoroscopic guidance. Anchor 630 dynamically self-expands to a partially deployed configuration.

[00144] Once the anchor and valve have been properly aligned in relation to anatomical landmarks, foreshortening is imposed upon anchor 630 to expand the anchor to the fully deployed configuration, as in Figure 40C. At this point, Locks may be actuated as previously described. Foreshortening friction locks everting segment 628 of valve 620 between anchor 630 and annulus **An**/leaflets **L** of the patient's diseased valve, thus properly seating the valve within the anchor while providing an improved seal between the replacement and native valves. Foreshortening also increases a radial strength of anchor 630, which is expected to prolong patency of valve annulus **An**. Deployed valve 620 and anchor 630 then are decoupled from delivery system 100', as in Figure 40D, thereby completing deployment of apparatus 600.

Thereafter, normal blood flow between left ventricle **LV** and aorta **A** is regulated by replacement valve 620.

[00145] As with apparatus 500, apparatus 600 may be dynamically repositioned during deployment, for example, in order to properly align the apparatus relative to anatomical landmarks. Furthermore, apparatus 600 advantageously may be retrieved at any point at least up until actuation of optimal locks maintaining foreshortening. When the optional locks are reversible, retrieval may be achieved until valve 620 and anchor 630 are separated from delivery system 100'.

[00146] Figures 41 illustrate an alternative embodiment of the present invention wherein the everting valve is distal to the anchor and the posts are not connected to the braid in the delivery configuration. As is illustrated in Figure 41A, apparatus 700 comprises everting valve 720 and expandable anchor 730, as well as delivery system 750. Delivery system 750 includes multi-lumen catheter 180. Anchor 730 is fabricated from an expandable braid and comprises female/male element 732 of a locking mechanism, which is preferably reversible. Everting valve 720 comprises valve leaflets 726 and everting segment 728. Everting valve 720 further comprises posts 722 to which valve leaflets 726 are attached to provide commissure support. Posts 722, which are non-expandable and non-collapsible, comprise opposite male/female elements 723 of locking mechanism comprising eyelets. In the delivery configuration of Figure 41A, anchor 730 may extend distally far enough to just overlap the proximal-most section of valve 720.

[00147] Delivery system 750 is similar to previously described delivery system 100' and includes multi-lumen catheter 180. As with previous embodiments, delivery system 750 facilitates dynamic repositioning and/or retrieval of apparatus 700 after partial or full deployment of the apparatus, e.g., right up until the apparatus is separated from the delivery system.

[00148] As seen in Figure 41A, wires 50 pass from the multi-lumen catheter 180 through the female/male locking mechanism 732, which is associated with anchor 730. Wires 50 then further pass through female/male locking mechanism 723, which is at the proximal end of posts 722. Preferably, a double strand of each wire 50 is provided to facilitate decoupling of wires 50 from valve 720 and anchor 730 in the manner described previously. When wires 50 are pulled proximally into the multi lumen catheter 180, posts 722 move proximally within anchor 730, and

the female/male element 723 interacts with female/male element 732 of anchor 730. In this embodiment, when element 723 is male, then element 732 is female, and vice versa.

[00149] Thus, valve 720 and anchor 730 are entirely decoupled from one another in the delivery configuration. Wires 50 are configured to approximate the telescoped valve and anchor, as well as to actuate locking mechanism 740 and contribute to foreshortening of anchor 730. By separating valve 720 and anchor 730 within lumen 112' of sheath 110', a delivery profile of apparatus 700 may be reduced.

[00150] In Figure 41A, apparatus 700 is endovascularly advanced into position with valve 720 and anchor 730 spaced from one another within lumen 112' of sheath 110' of delivery system 750. Substantially all of valve 720 and its supporting posts 722 are disposed distal to the anchor during delivery. As seen in Figure 41B, to evert valve 720, sheath 110' is pulled proximally around anchor 730.

[00151] Next, in Figure 41C, to approximate anchor 730 and valve 720, the elongated braid of anchor 730 is pushed distally to the base of posts 722 using tubes 60 maintained in association with anchor 730 by wire 62. Anchor 730 will engage with the distal end of posts 722 - an anchor engagement feature 729. In some embodiments, as illustrated in Figure 41C, wires 550 re-enter sheath 110' proximal to the distal end of the multi-lumen catheter 180.

[00152] In Figure 41D, the multi-lumen catheter 180 is held steady, while wires 50 are pulled proximally. This allows the foreshortening of anchor 730 and the engagement of the male and female elements of locking mechanism of 740. Foreshortening friction locks segment 728 of valve 720 against valve annulus **An**/leaflets **L**, thereby properly seating the valve within anchor 730. Foreshortening also completes expansion of anchor 730 and actuates locking mechanism 740, which maintains such expansion of the anchor. Delivery system 750 then may be decoupled from valve 720 and anchor 730, thereby completing deployment of apparatus 700. Normal blood flow between left ventricle **LV** and aorta **A** thereafter is regulated by replacement valve 720.

[00153] With reference now to Figures 42, yet another alternative embodiment of everting apparatus in accordance with the present invention is described, wherein the replacement valve leaflets evert and wrap about the distal region of the anchor. Apparatus 800 comprises everting replacement valve 820 and expandable anchor 830. Valve 820 comprises posts 822, to which valve leaflets 826 are attached. The valve further comprises everting segment 828. Proximal

regions 823 of posts 822 are rotatably coupled to a distal region of anchor 830, while distal regions 824 of the posts are coupled to control wires 50.

[00154] In the delivery configuration of Figure 42A, posts 822 (and, thus, valve leaflets 826) and everting segment 828 of replacement valve 820 are disposed distal of anchor 830. Figure 42B illustrates deployment of apparatus 800, whereby tubes 60/wires 62 (see, e.g., Figures 41) are actuated in conjunction with control wires 50 to actively foreshorten anchor 830 and rotate posts 822 into position within the lumen of anchor 830, thereby everting valve leaflets 826 into position within the anchor. Furthermore, eversion wires 550 are actuated to evert segment 828 and wrap the segment about the exterior of anchor 830. Locks 840 maintain expansion and foreshortening of anchor 830.

[00155] Referring to Figures 43, an everting embodiment of the present invention is described wherein a portion of the locking mechanism configured to maintain expansion of the anchor is coupled to the everting segment of the replacement valve instead of, or in addition to, the anchor posts and anchor posts P are only loosely associated with the anchor 930. Apparatus 900 comprises replacement valve 920 and anchor 930. Everting segment 928 of the replacement valve comprises male elements 942 of locks 940, while anchor 930 comprises female elements 944 of locks 940. Upon deployment of apparatus 900 from the delivery configuration of Figure 43A to the deployed configuration of Figure 43B, segment 928 of replacement valve 920 everts to wrap about the exterior of anchor 930, which is actively foreshortened during expansion. Locks 940 maintain anchor expansion.

[00156] With reference to Figures 44, another telescoping embodiment of the present invention is described wherein the replacement valve comprises a U-shaped frame configured to receive the anchor. Optionally, the valve may comprise an everting segment that everts about the frame and/or the anchor during deployment. Apparatus 1000 comprises replacement valve 1020 and expandable anchor 1030. Replacement valve 1020 comprises frame 1022, leaflets 1026 and optional everting segment 1028.

[00157] Valve 1020 and anchor 1030 are configured for relative movement, such that the valve and anchor may be telescoped and spaced apart during delivery, thereby reducing a delivery profile of apparatus 1000, but may be approximated during deployment. Everting segment 1028 of valve 1020 optionally may be disposed distal of valve frame 1022 during

delivery, thereby further reducing a delivery profile of apparatus 1000, then everted during deployment.

[00158] As seen in Figure 44A, the U-shape of valve frame 1022 preferably tilts leaflets 1026 of replacement valve 1020 slightly inward relative to blood flow through apparatus 1000. As seen in Figure 44B, valve frame 1022 optionally may comprise a symmetric U-shape, which captures anchor 1030 on both sides in the deployed configuration. Frame 1022 may comprise lock 1040 that closes the frame's U-shape into an elliptical shape in the deployed configuration, thereby maintaining expansion of anchor 1030.

[00159] Prior to implantation of one of the replacement valves described above, it may be desirable to perform a valvuloplasty on the diseased valve by inserting a balloon into the valve and expanding it using saline mixed with a contrast agent. In addition to preparing the valve site for implant, fluoroscopic viewing of the valvuloplasty will help determine the appropriate size of replacement valve implant to use.

WHAT IS CLAIMED IS:

1. A system for replacing a heart valve, comprising:

an expandable anchor comprising a braided material,

a replacement heart valve; and

a delivery device, wherein the expandable anchor and the replacement heart valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device,

wherein the expandable anchor is axially spaced from the replacement heart valve when the expandable anchor is in the delivery configuration within the delivery device.

2. The system of claim 1 wherein the expandable anchor and the replacement heart valve are coupled to each other.

3. The system of claim 1 wherein the replacement heart valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration within the delivery device.

4. The system of claim 1 wherein at least a portion of the replacement heart valve is disposed within the expandable anchor when the expandable anchor is in a fully deployed configuration.

5. The system of claim 4 wherein at least a portion of the replacement heart valve is disposed axially within the expandable anchor when the expandable anchor is in the fully deployed configuration.

EVERTING HEART VALVE

ABSTRACT OF THE DISCLOSURE

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

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

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

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

As a below named Inventor, I hereby declare that:

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

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

EVERTING HEART VALVE

(Title of the Invention)

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

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

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

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

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

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

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

Application Number(s)	Filing Date (MM/DD/YYYY)

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

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

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

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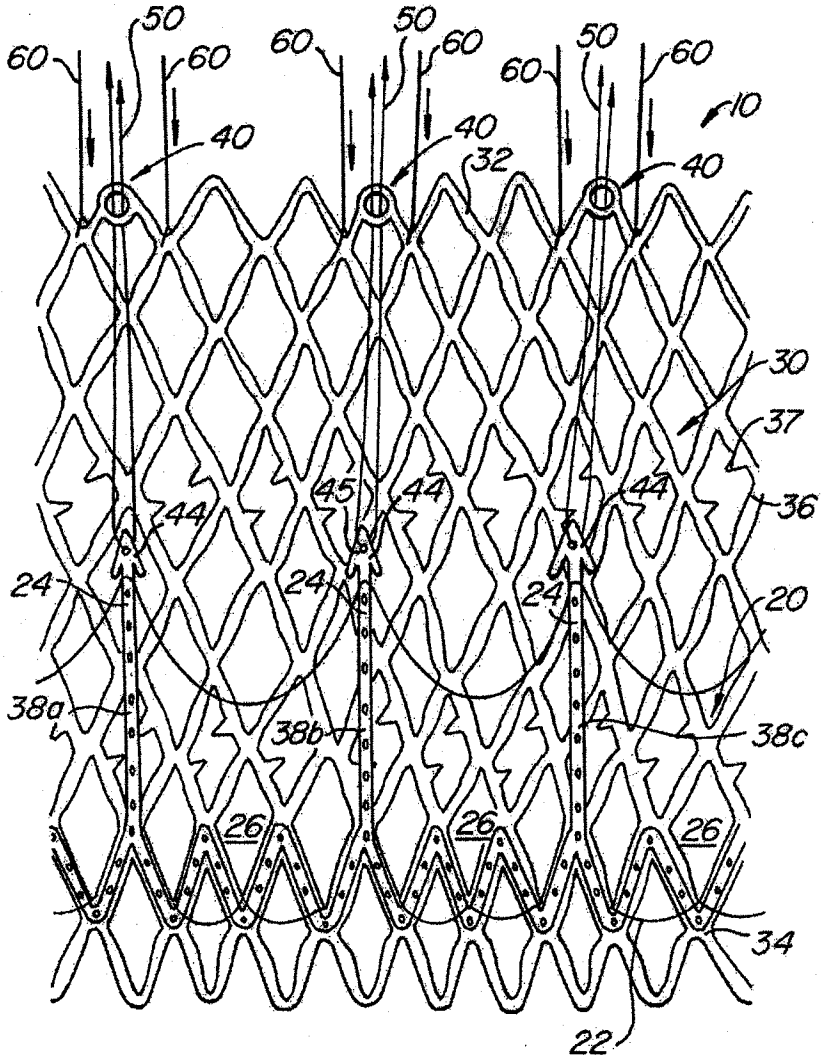
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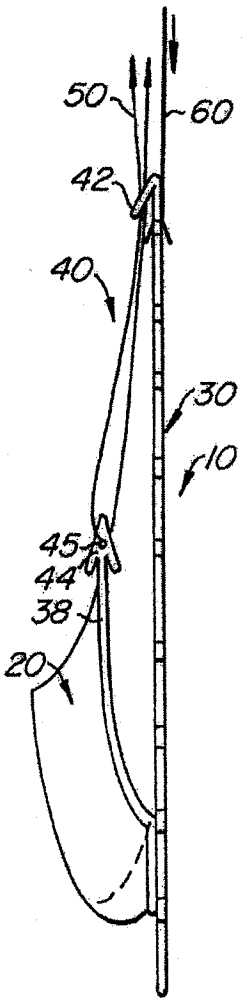
FIG. 1A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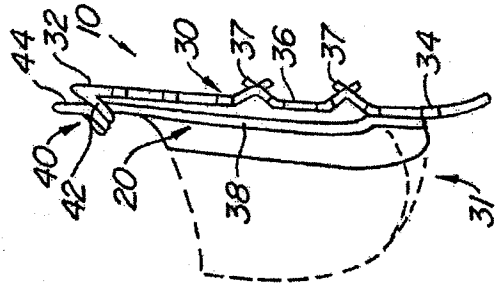
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FIG. 2B

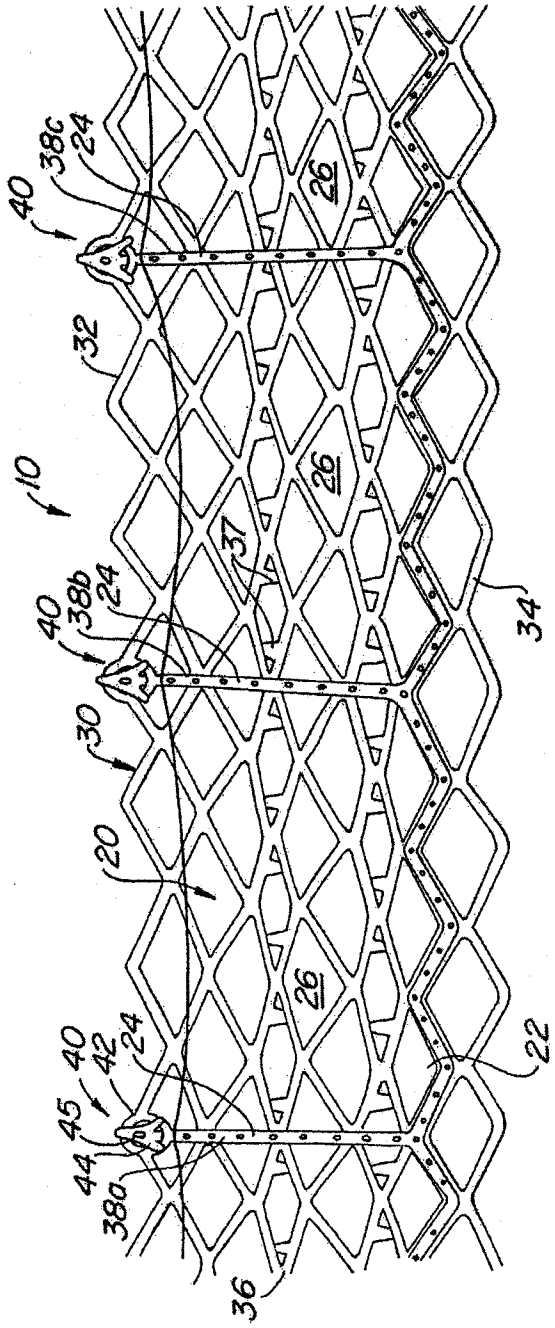
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FIG. 1B

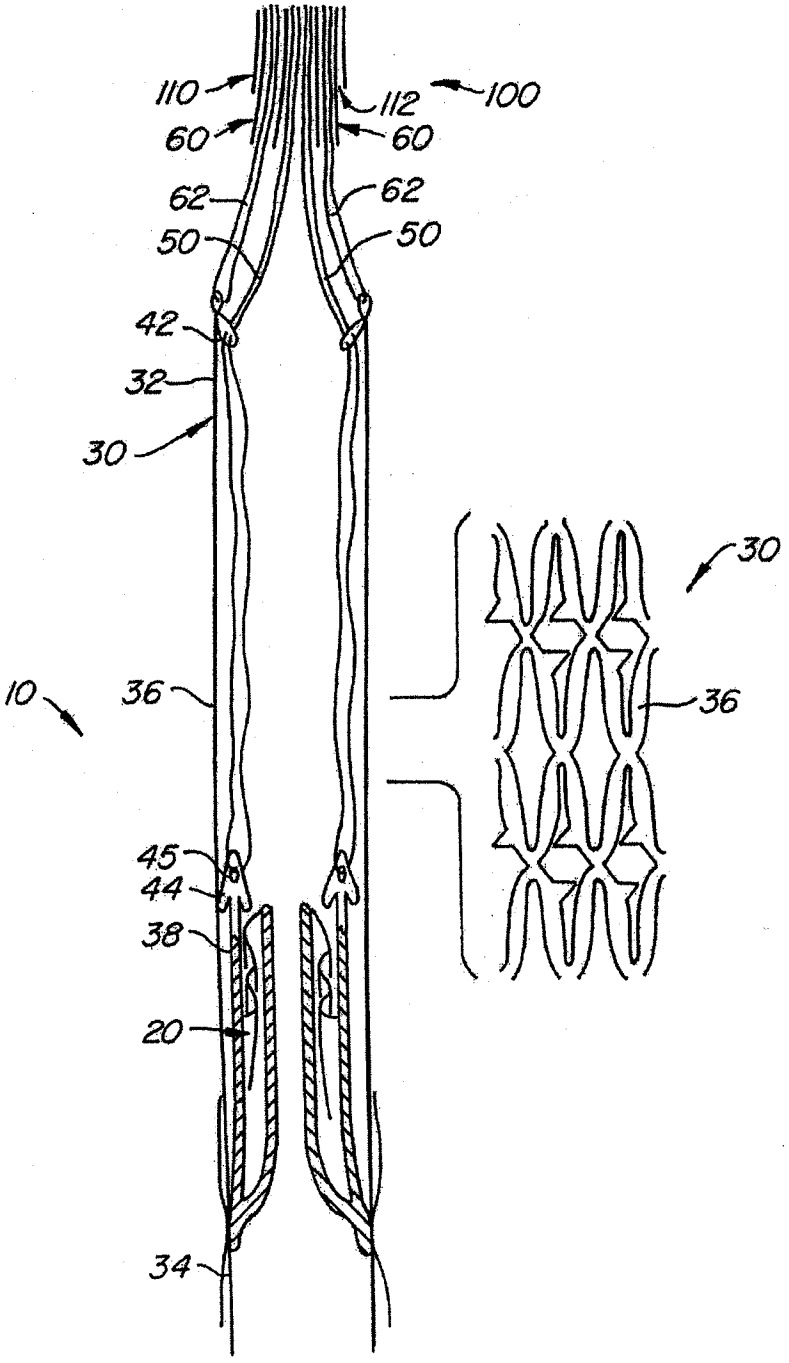

FIG. 3A

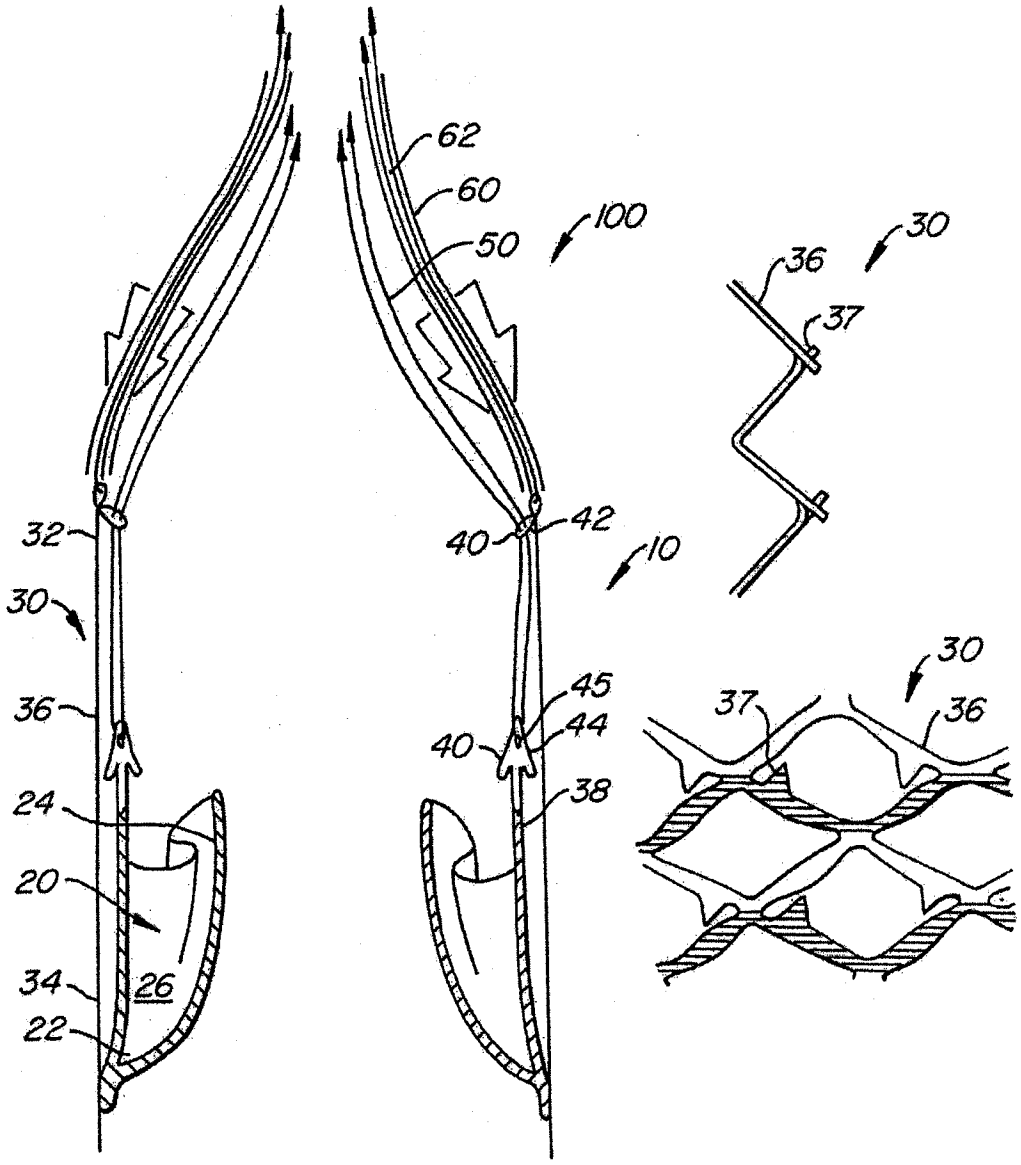
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FIG. 3B

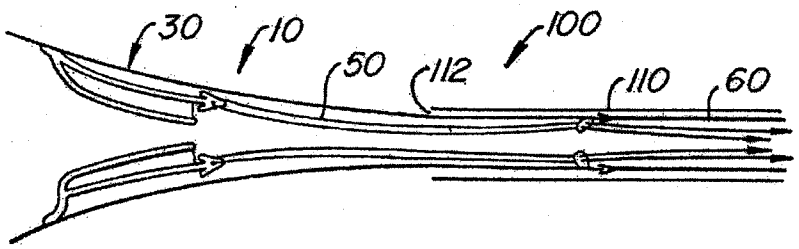


FIG. 4A

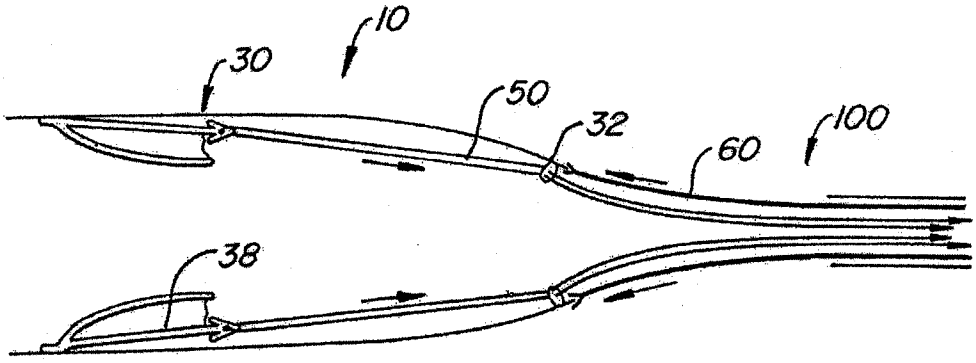


FIG. 4B

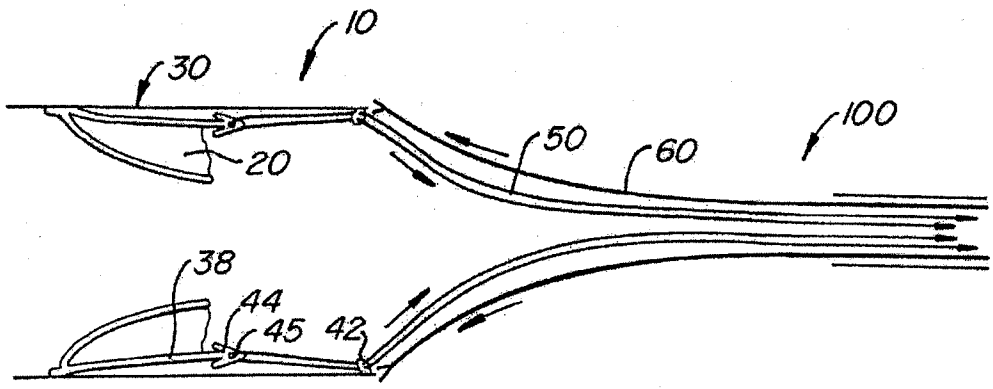
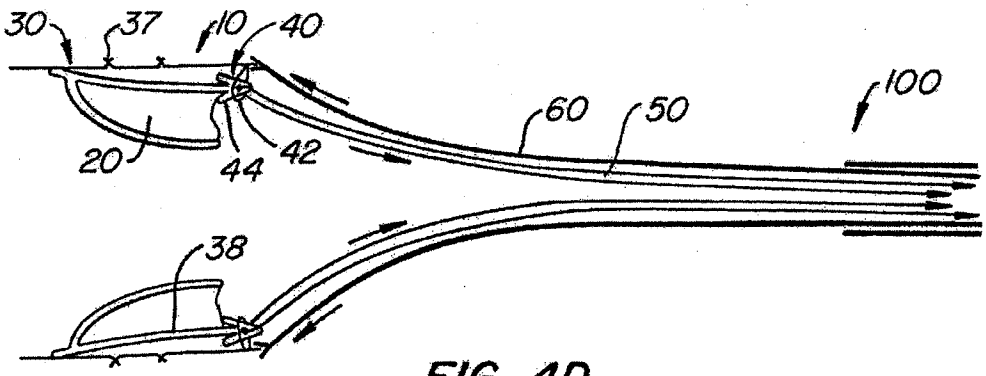


FIG. 4C



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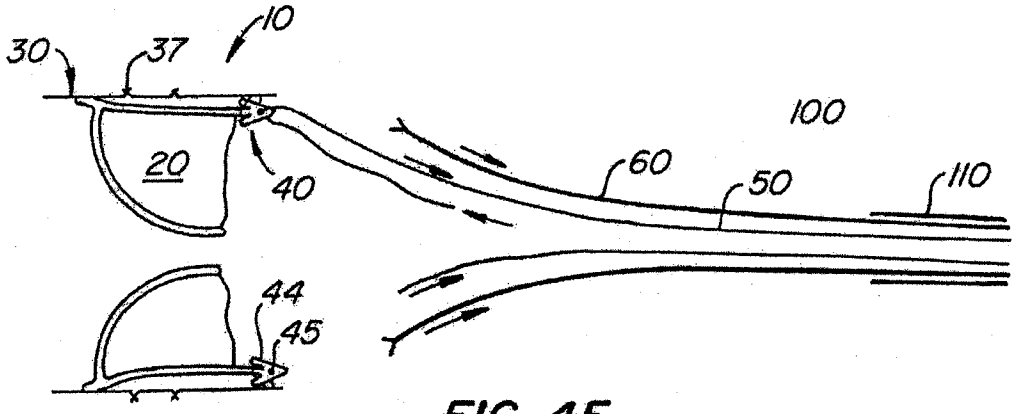

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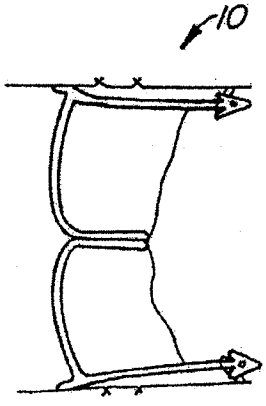


FIG. 4F

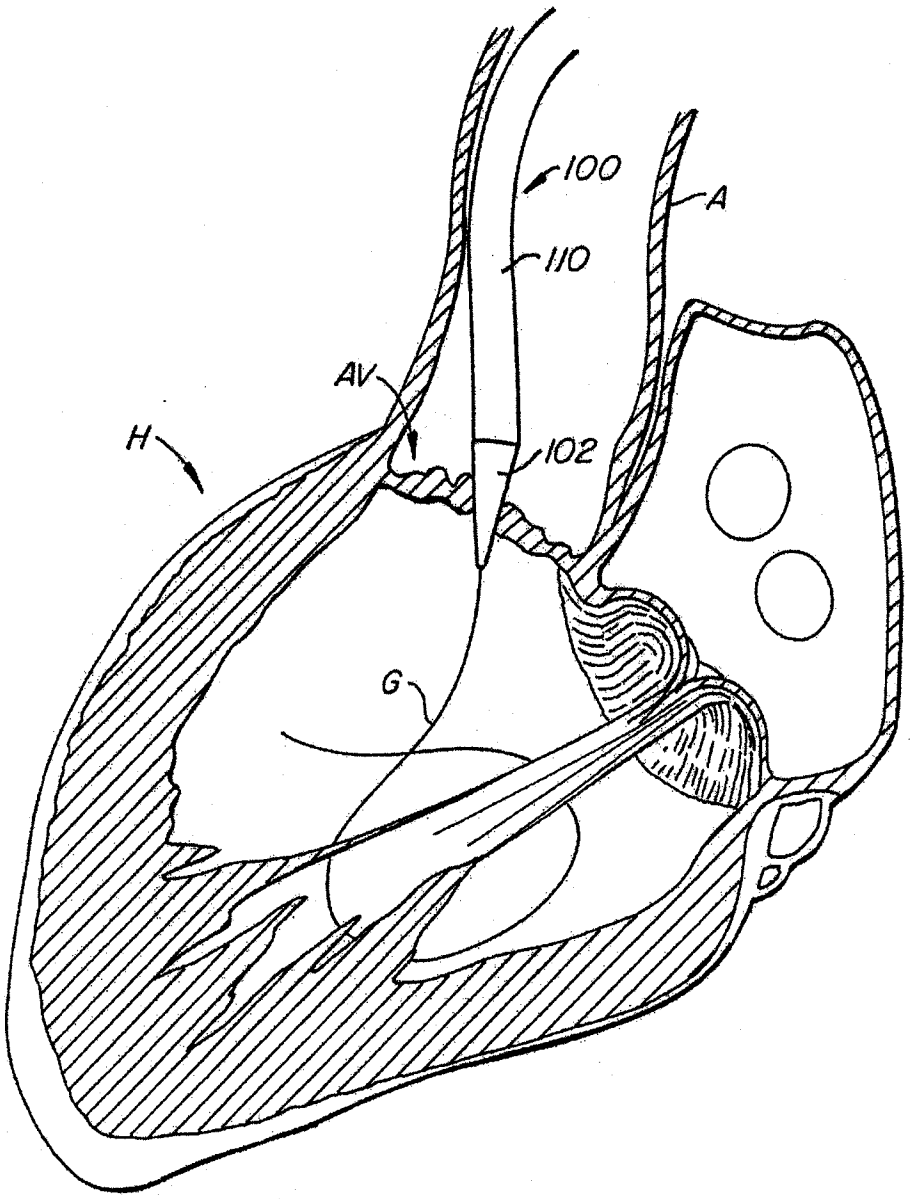


FIG. 5A

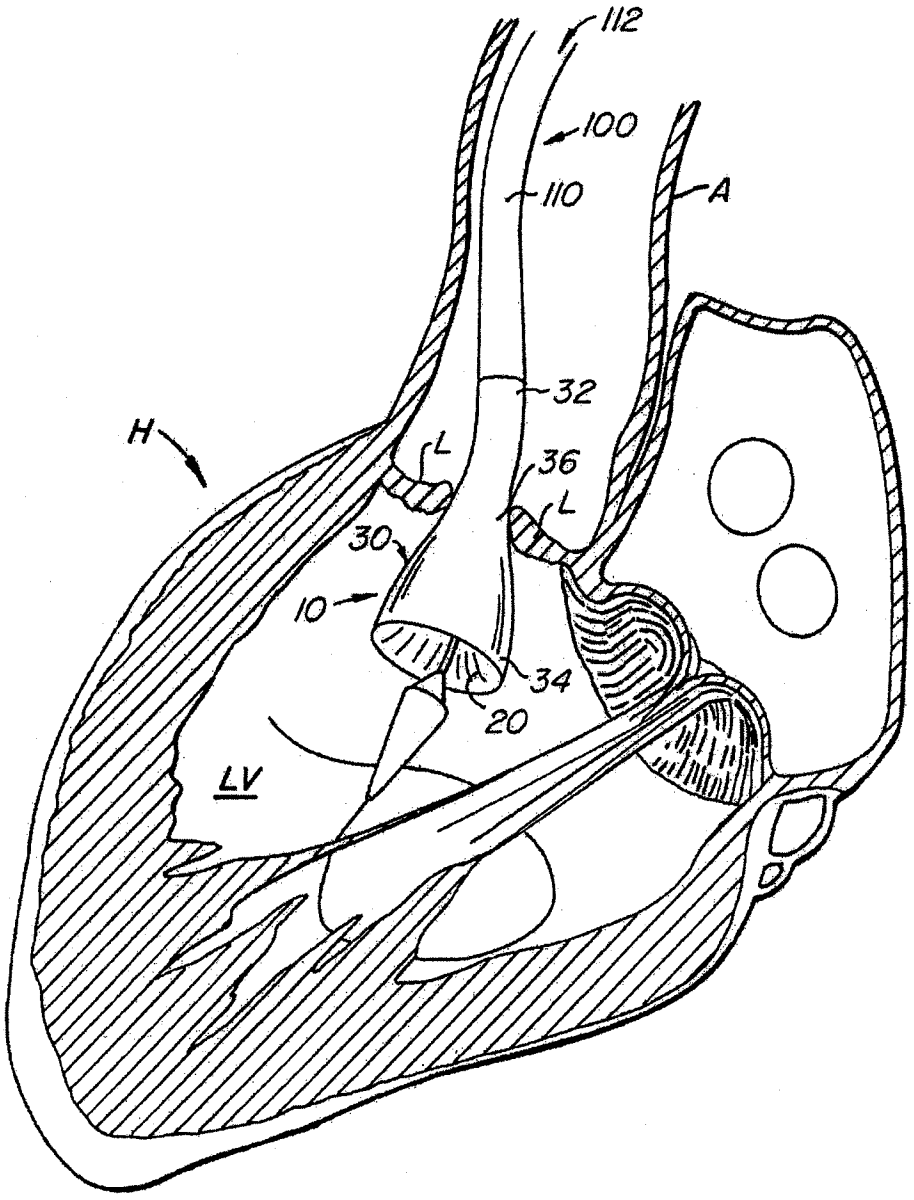


FIG. 5B

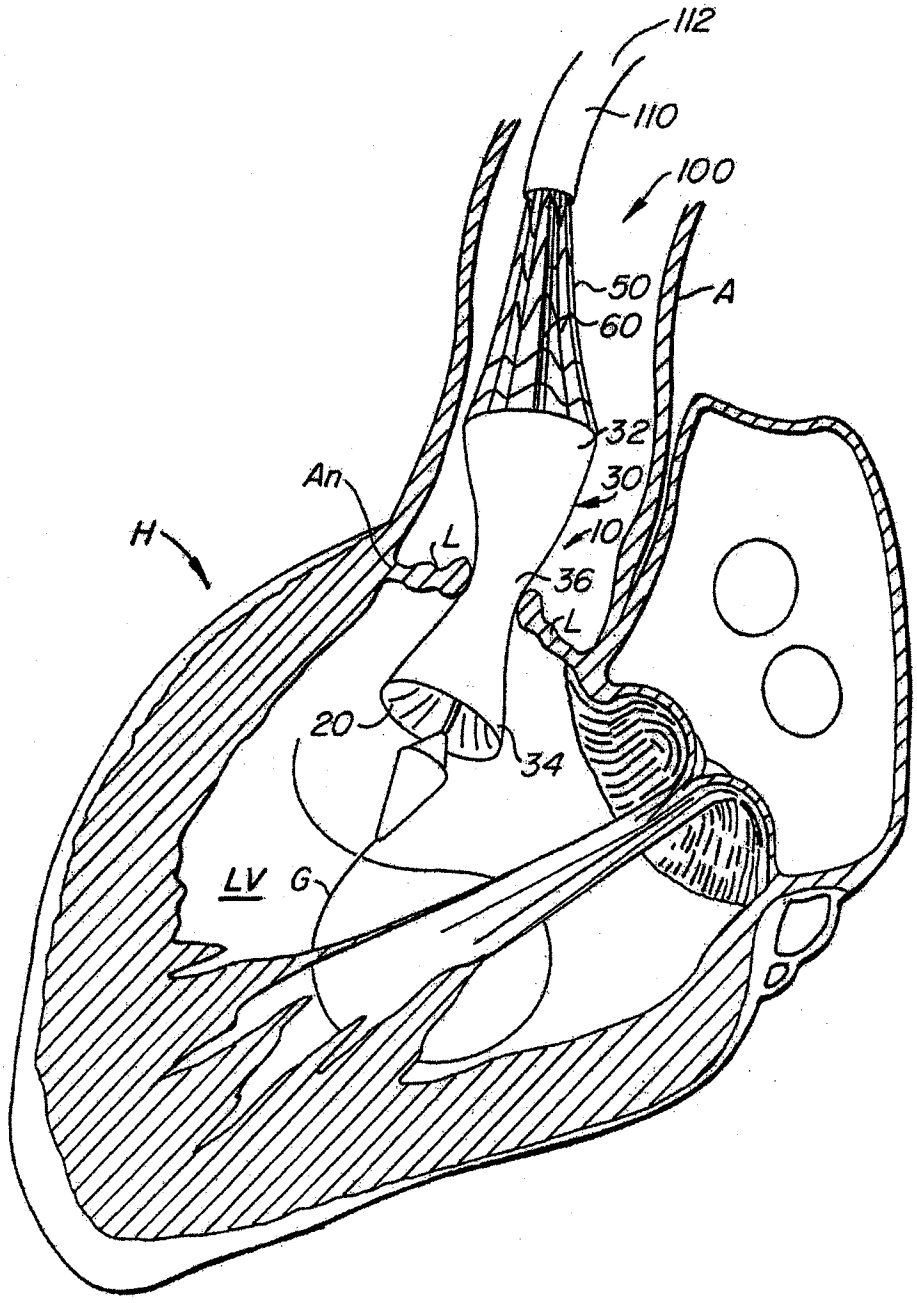


FIG. 5C

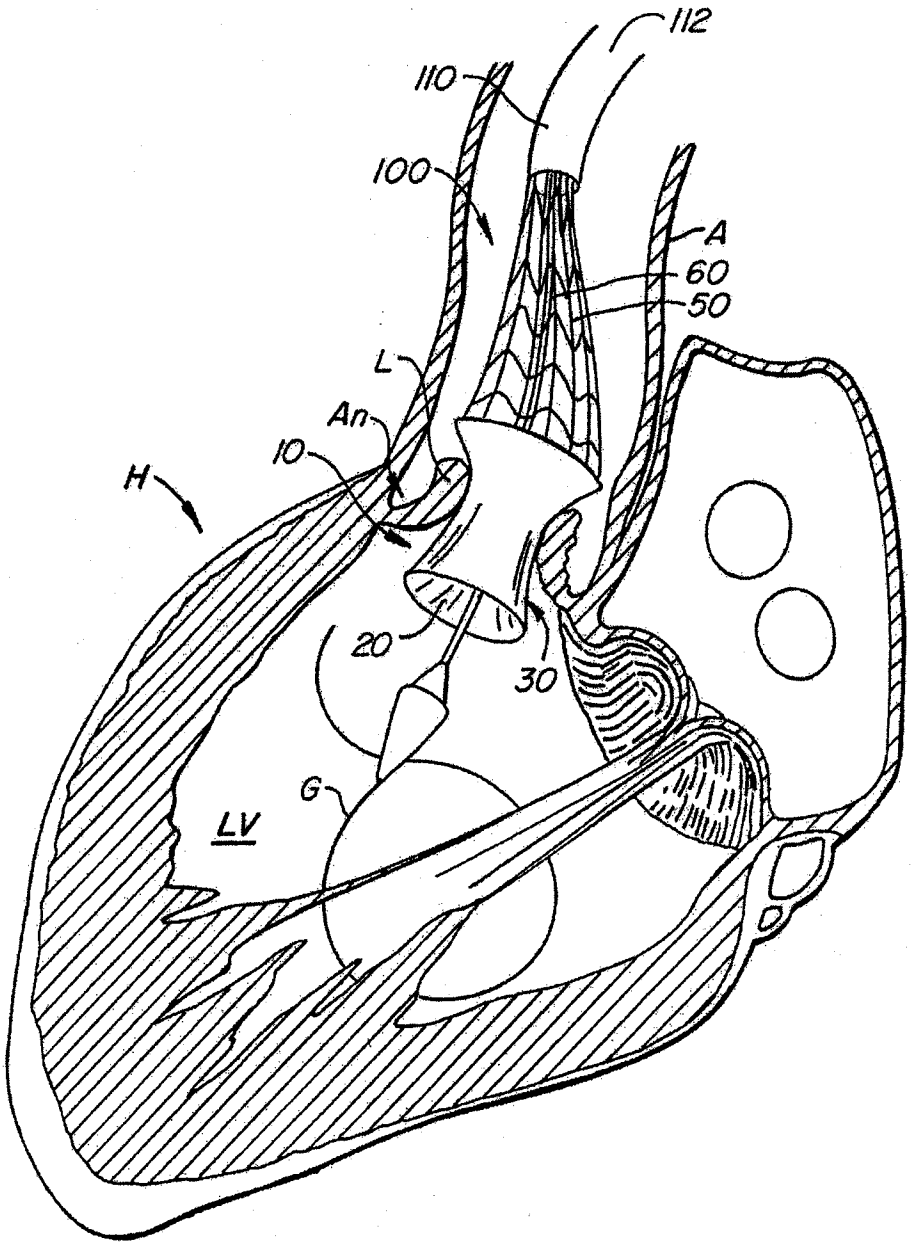
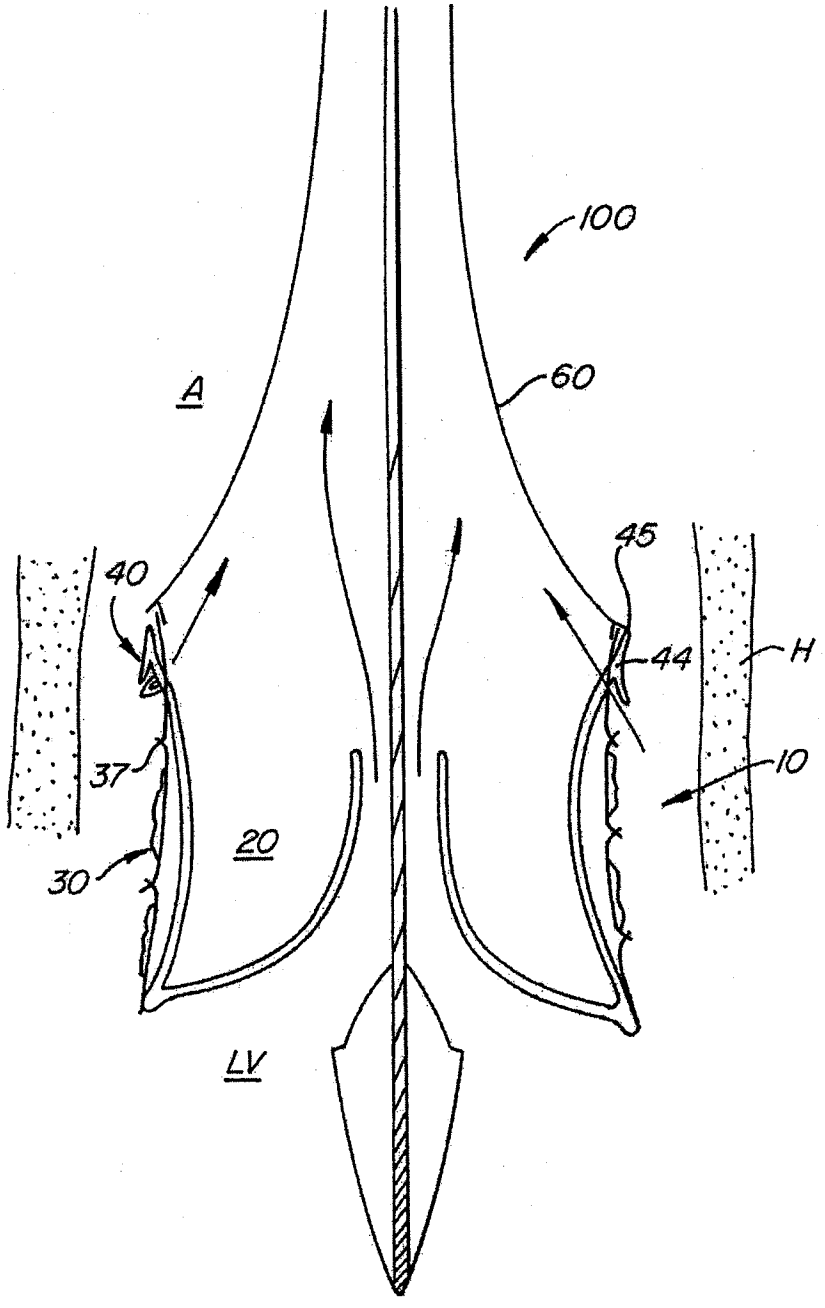


FIG. 5D



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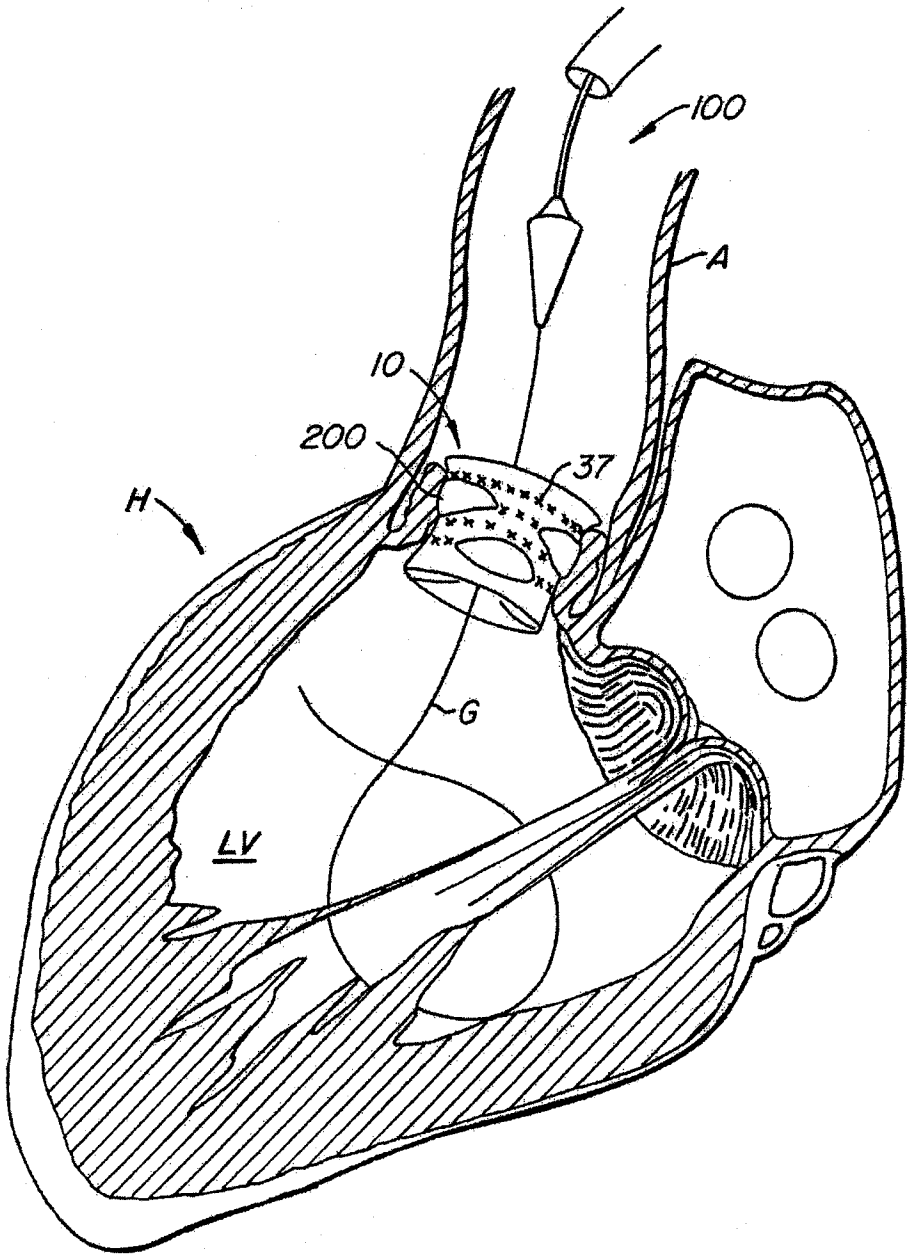

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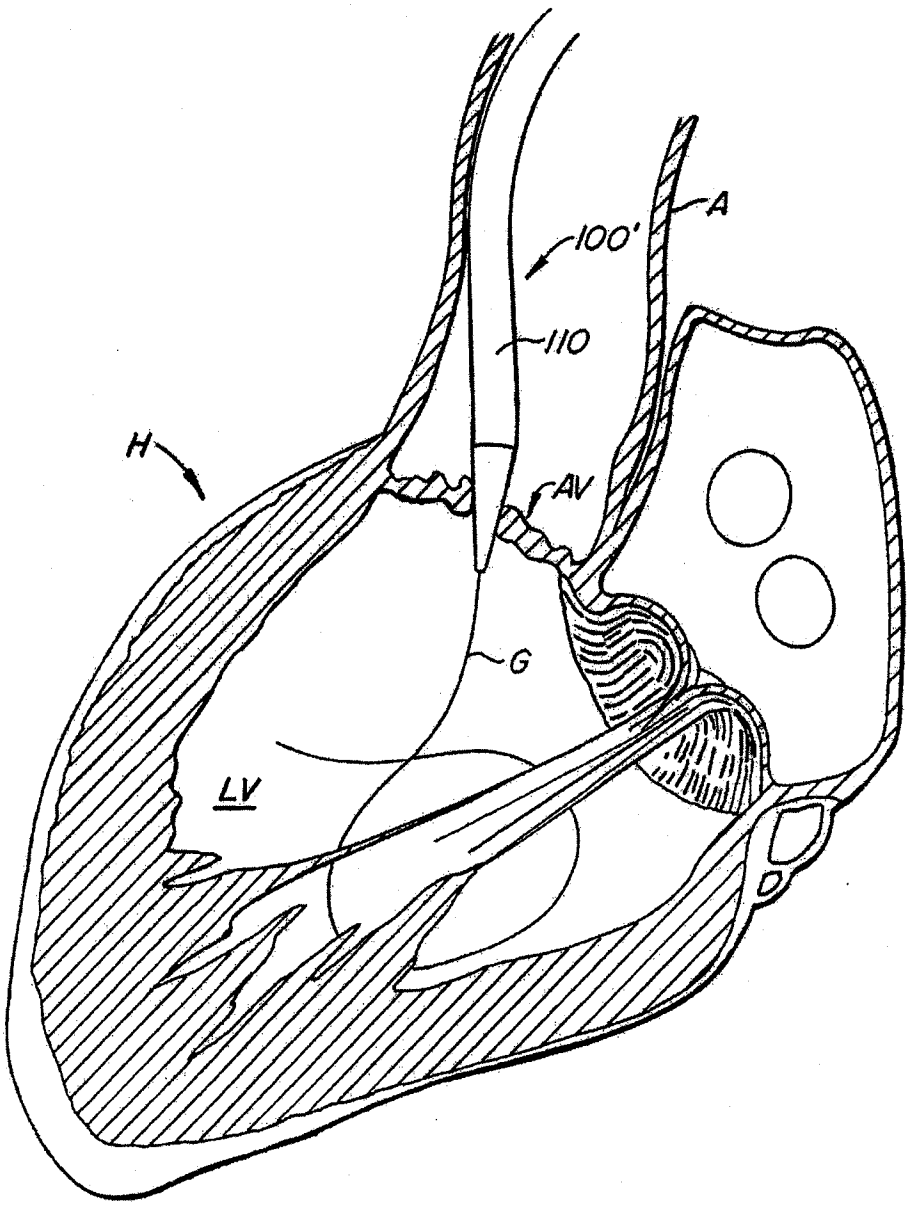

FIG. 6A

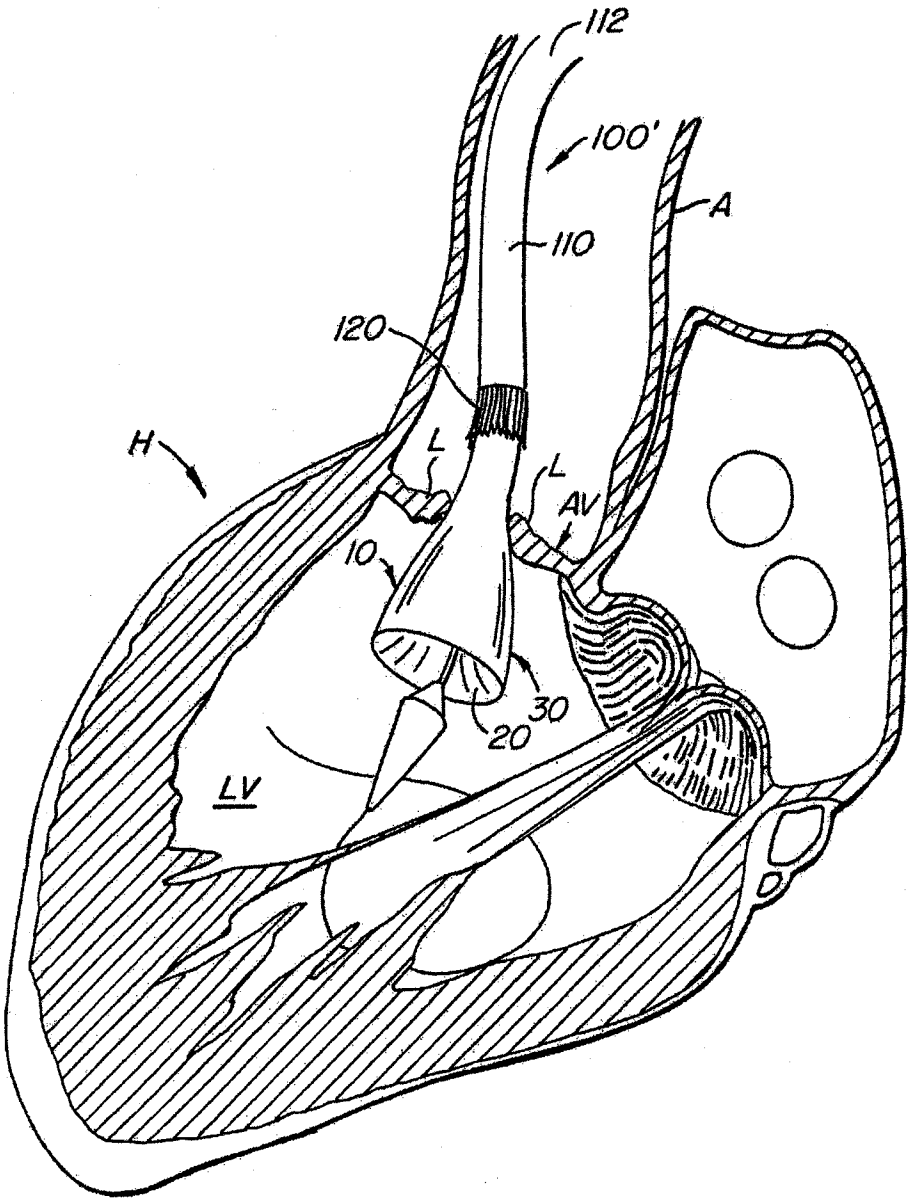

FIG. 6B

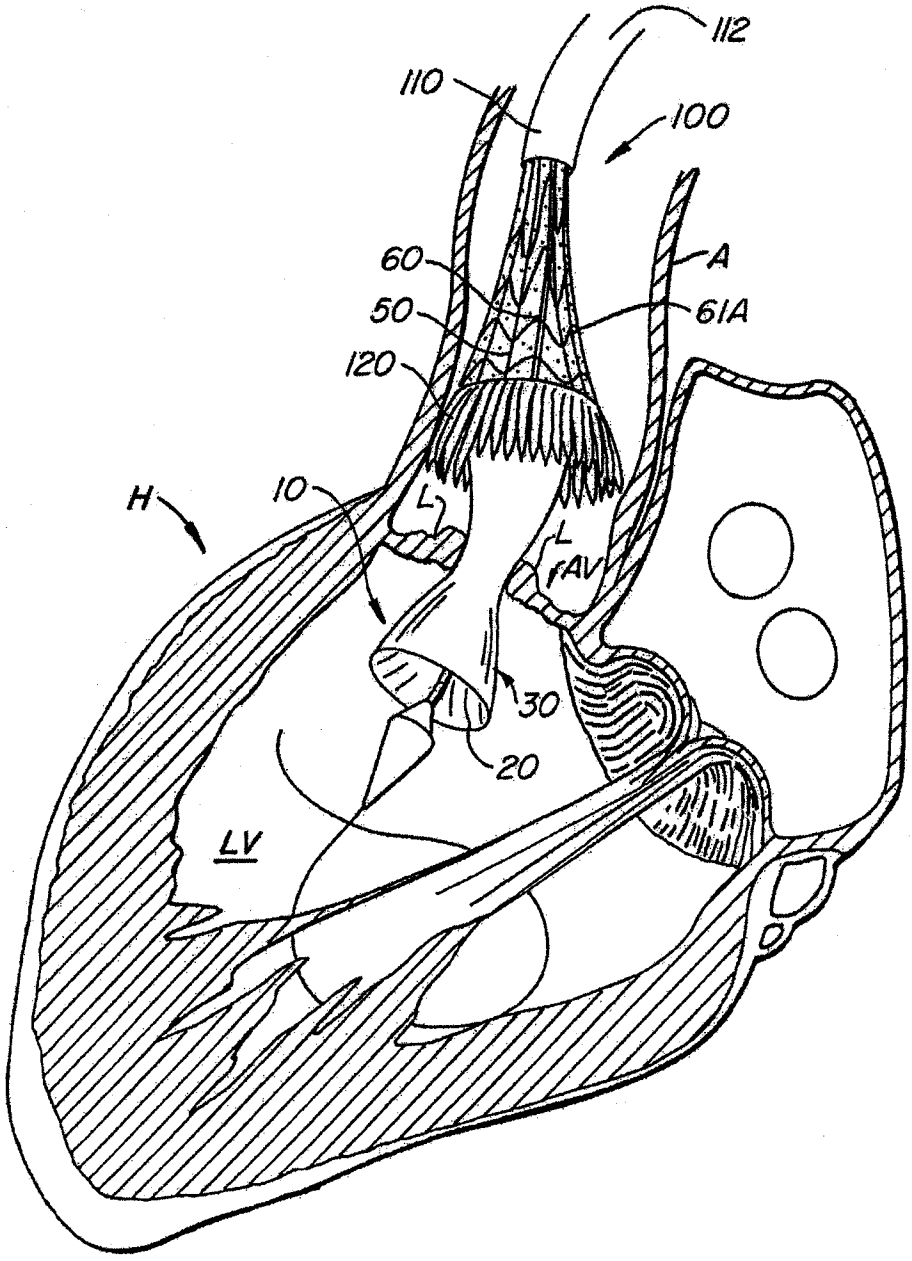

FIG. 6C

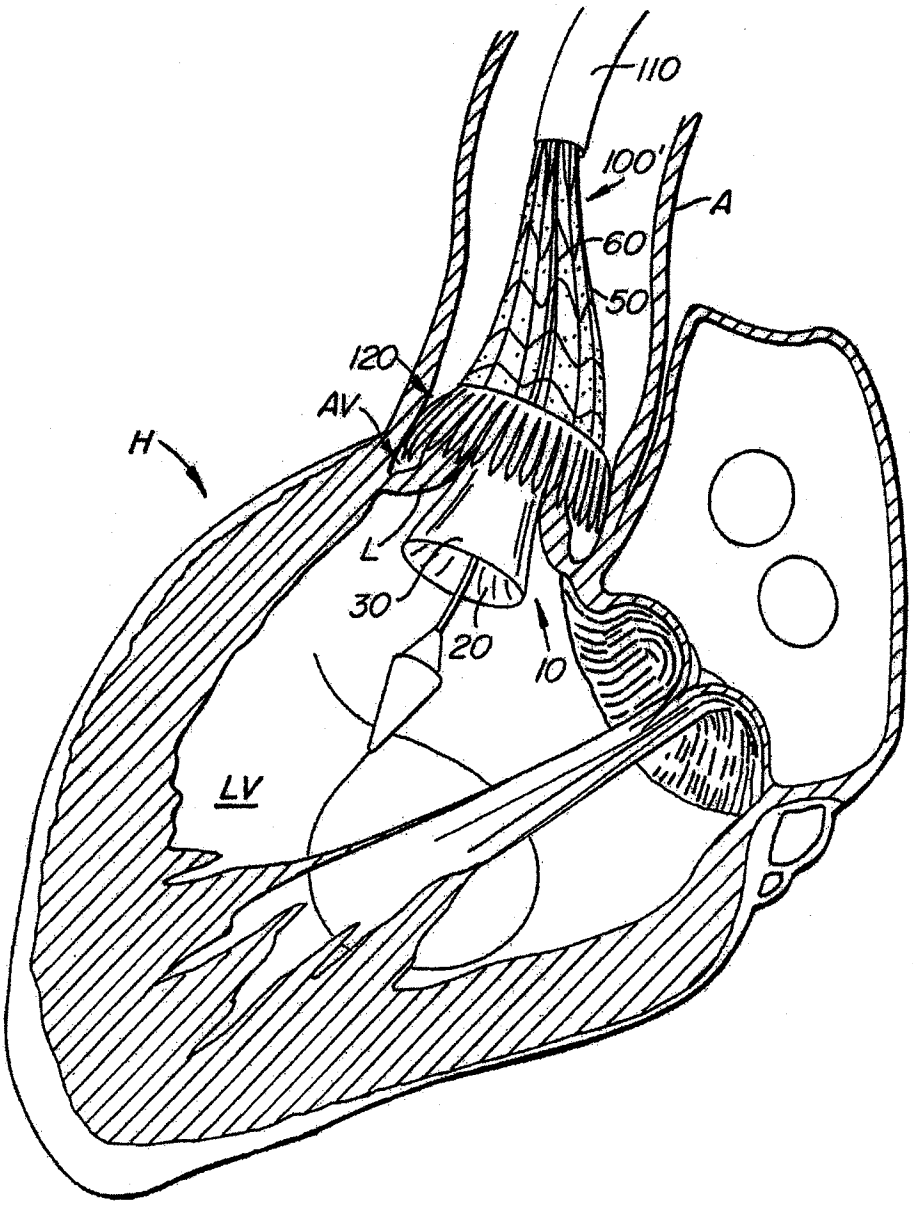

FIG. 6D

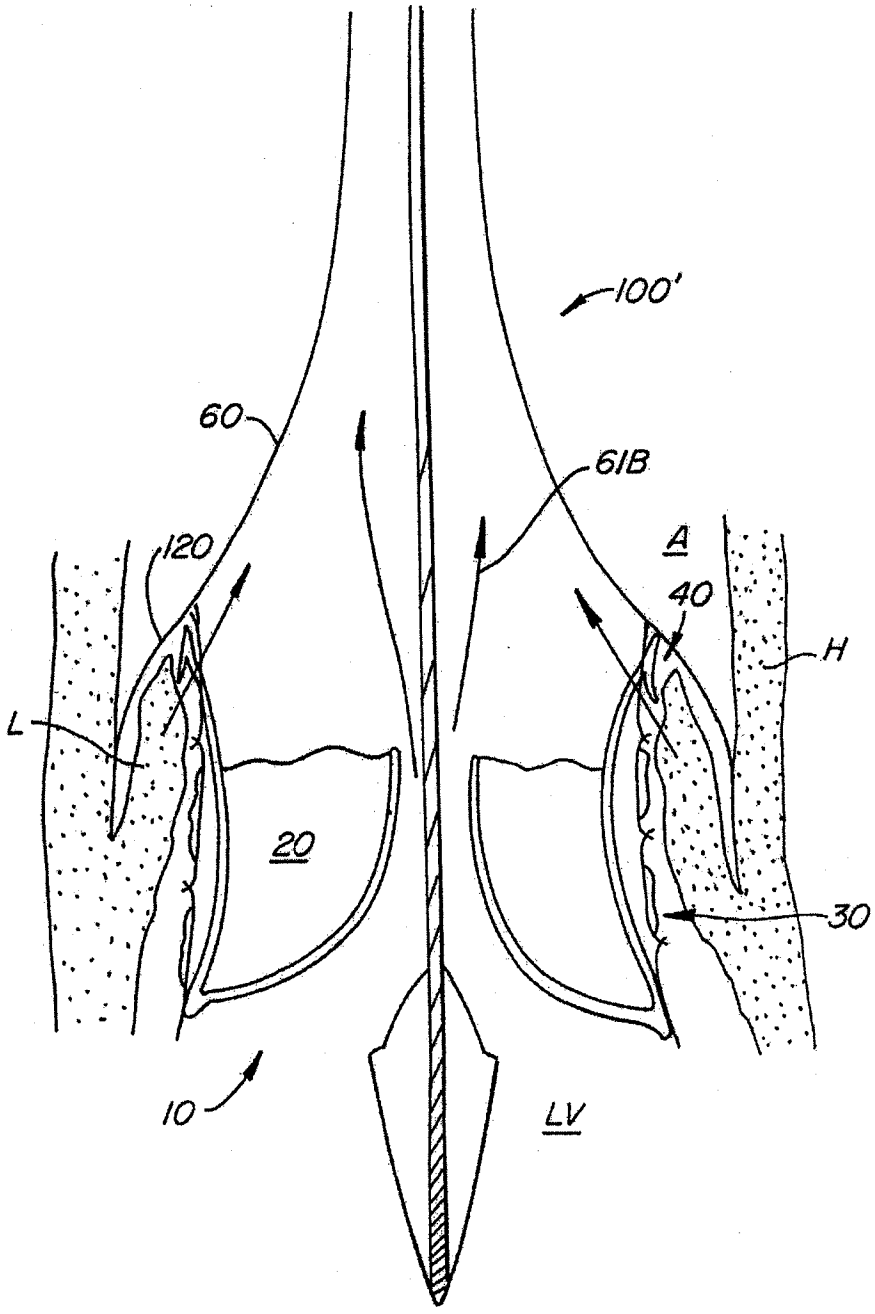

FIG. 6E

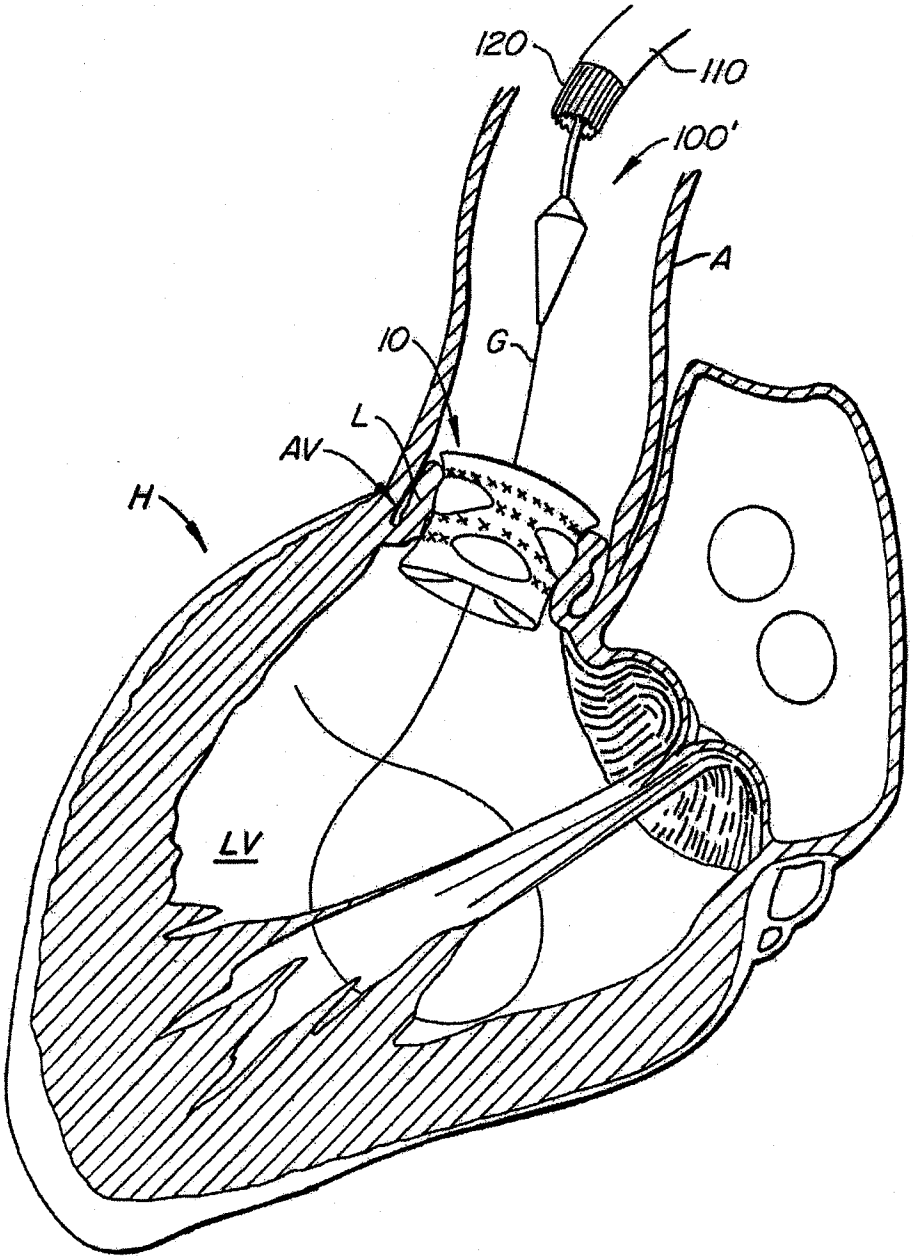

FIG. 6F

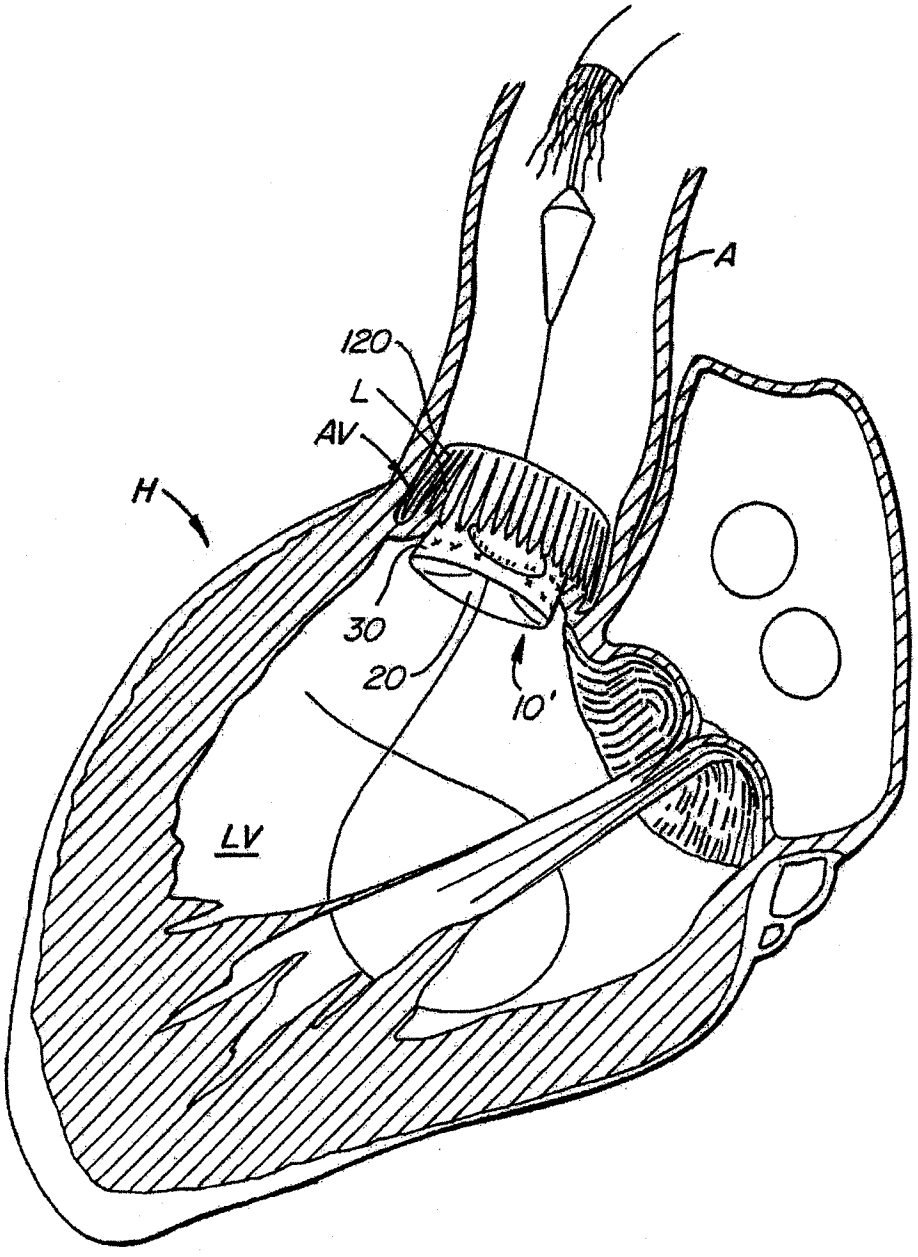

FIG. 7

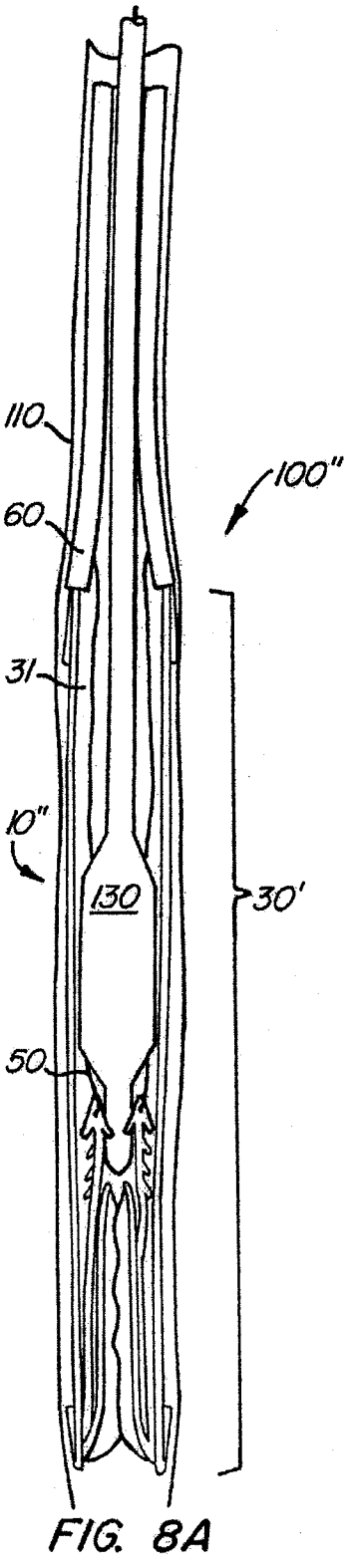

FIG. 8A

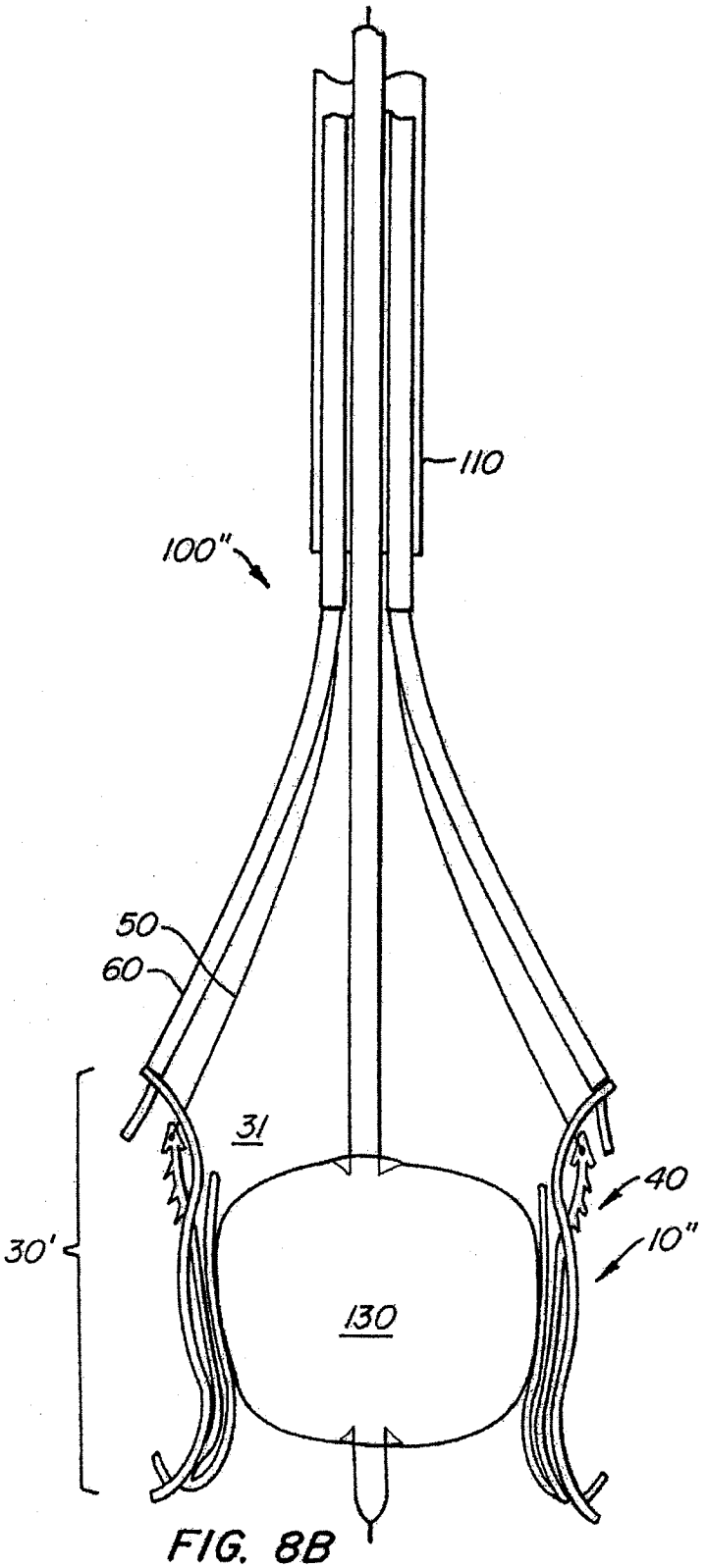

FIG. 8B

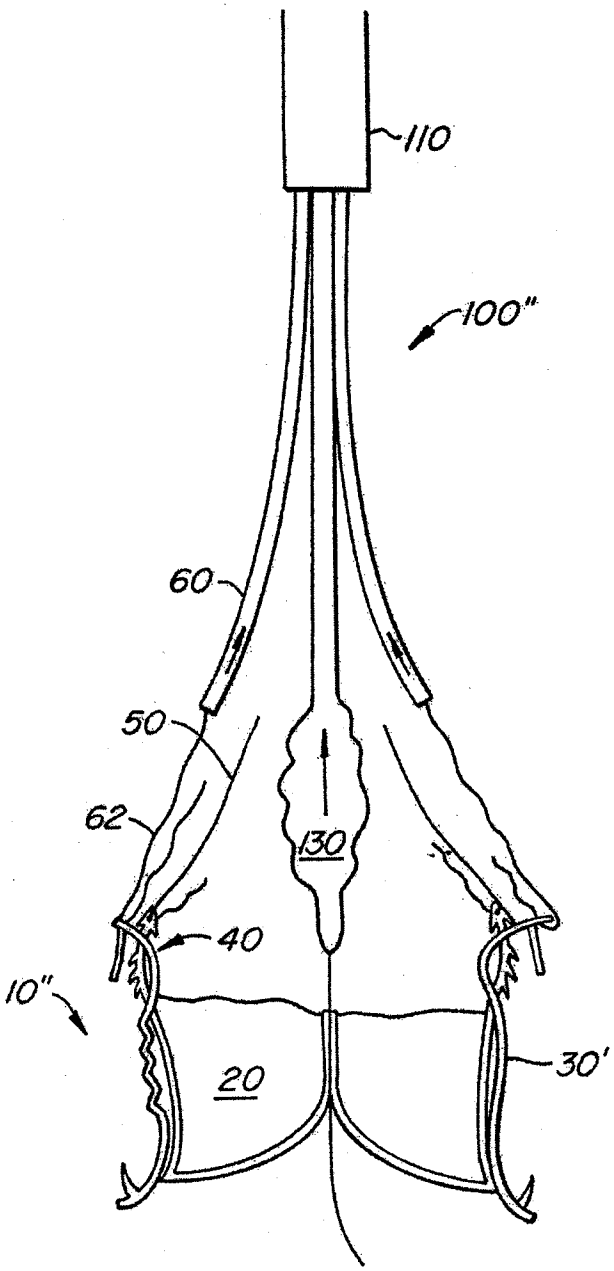

FIG. 8C

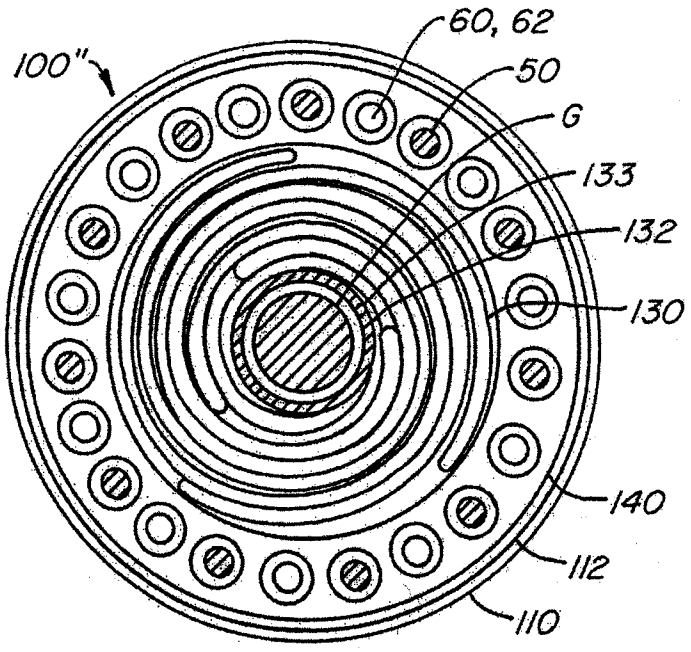

FIG. 10

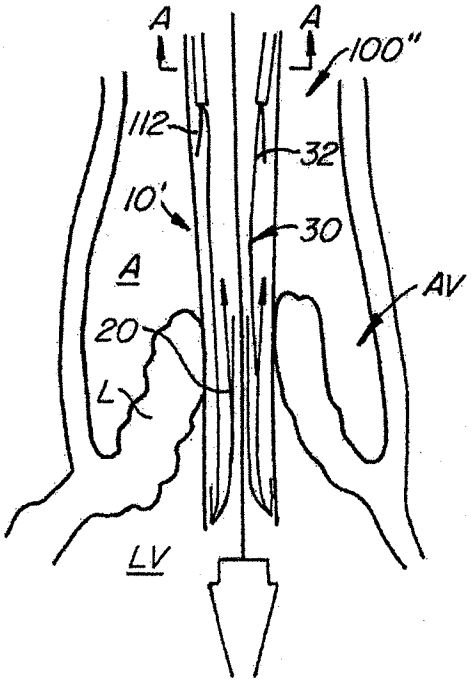

FIG. 9A

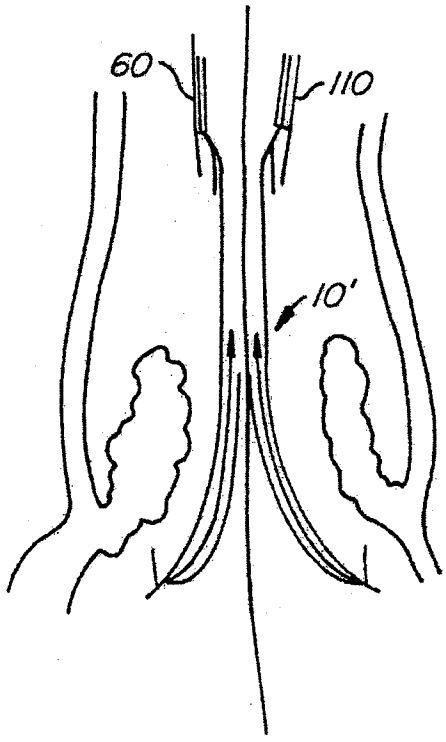

FIG. 9B

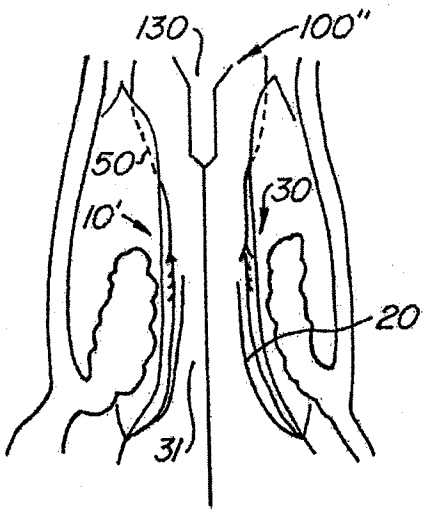

FIG. 9C

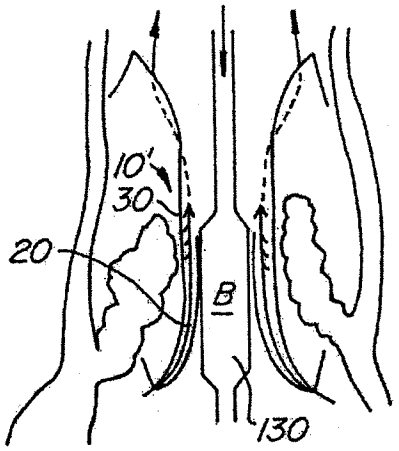

FIG. 9D

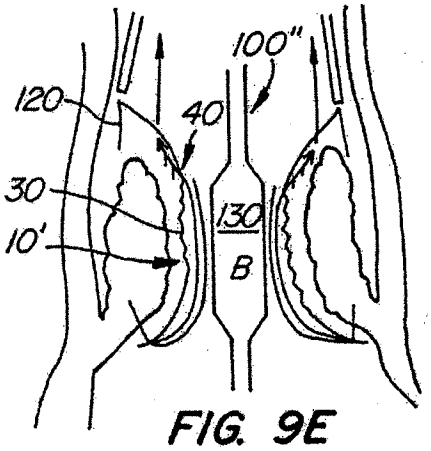

FIG. 9E

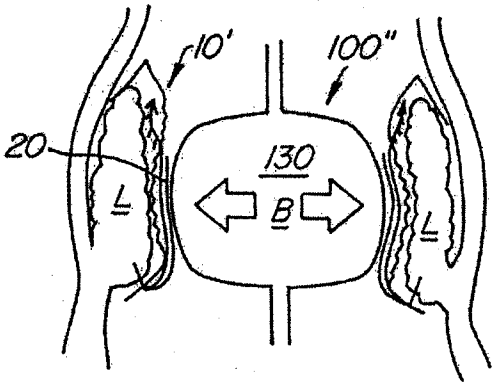

FIG. 9F

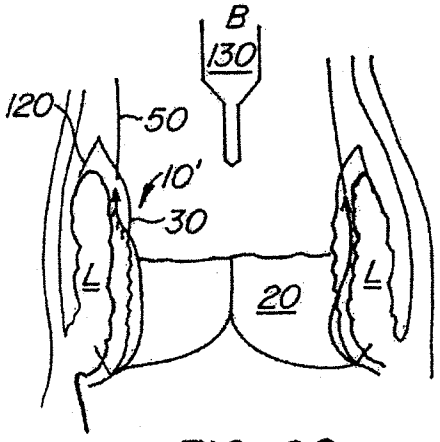

FIG. 9G

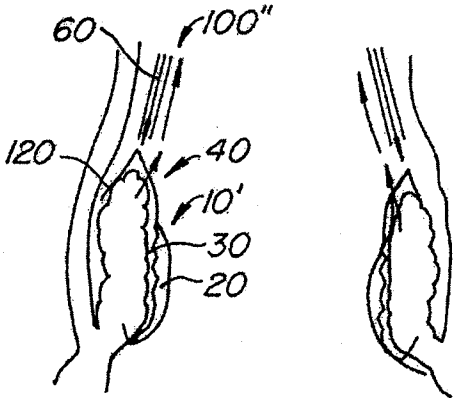

FIG. 9H

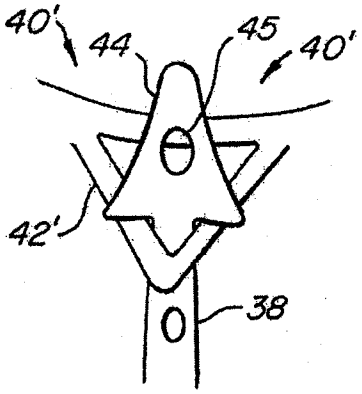

FIG. IIA

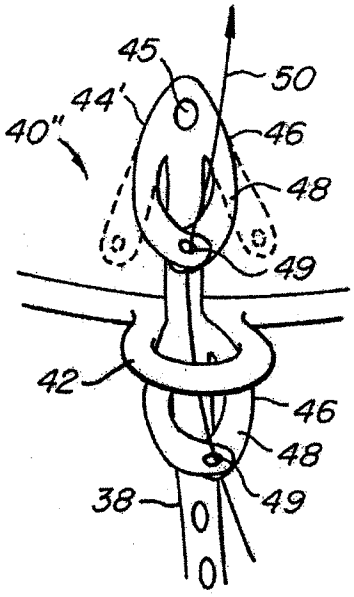

FIG. IIB

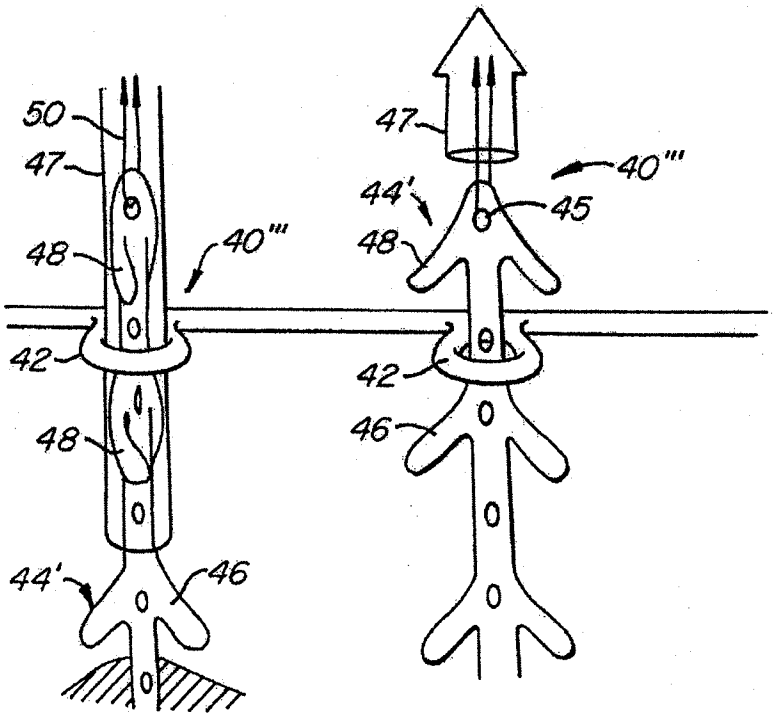

FIG. IIC

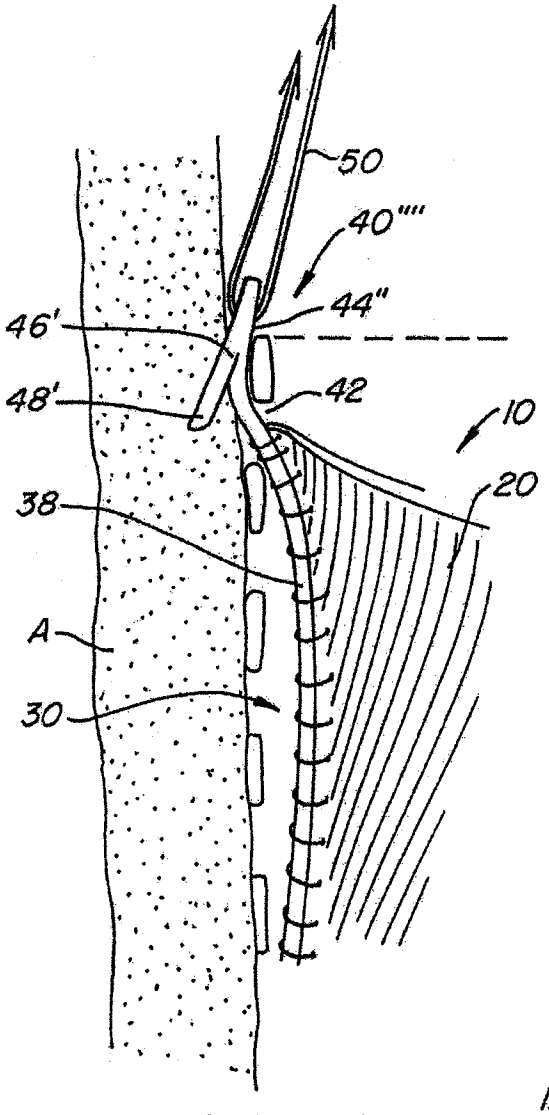

FIG. 12C

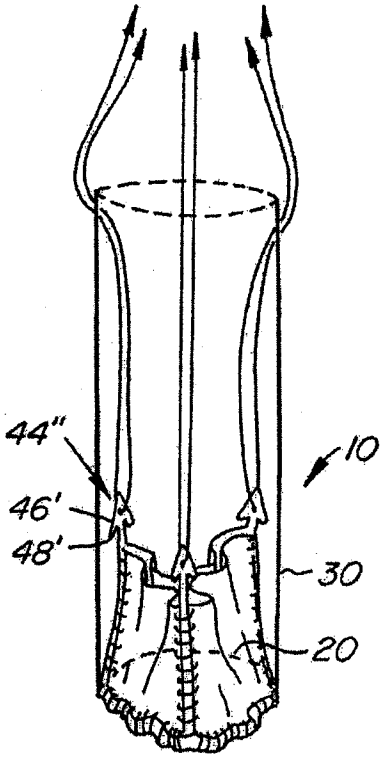

FIG. 12A

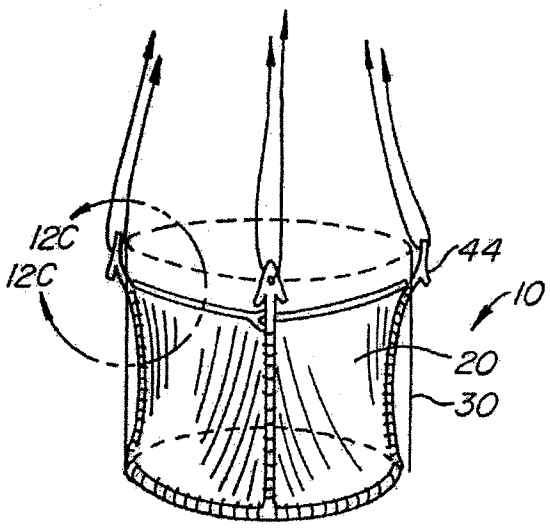

FIG. 12B

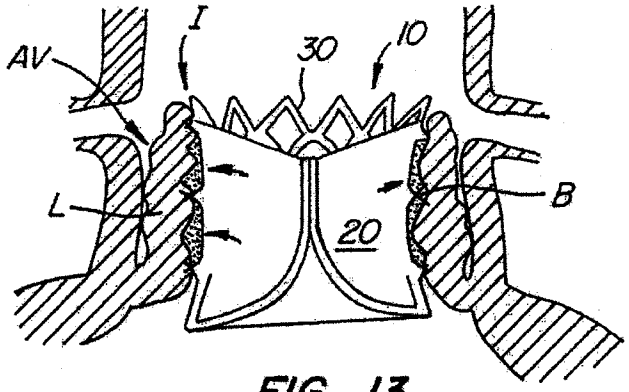

FIG. 13

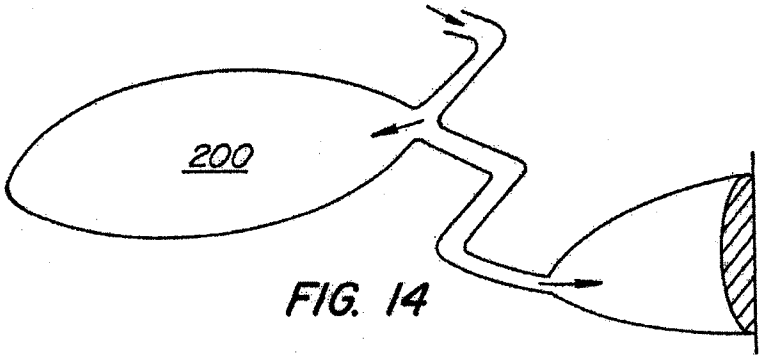

FIG. 14

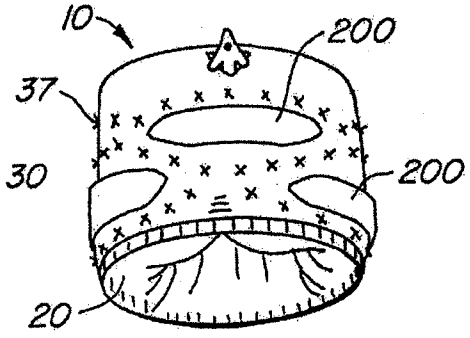

FIG. 15A

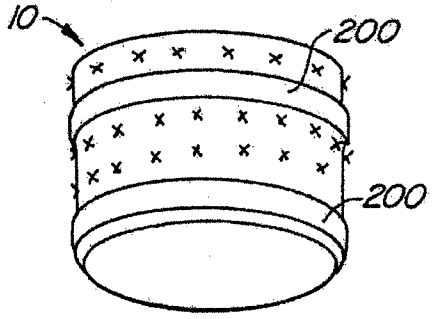

FIG. 15B

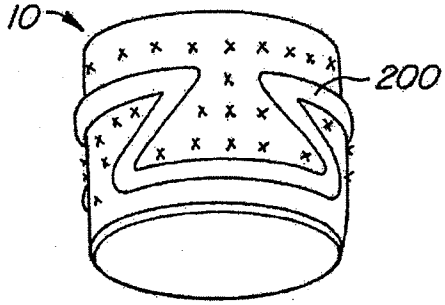

FIG. 15C

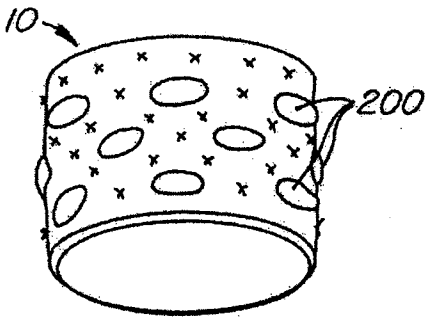

FIG. 15D

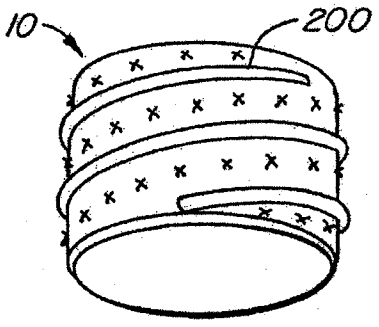

FIG. 15E

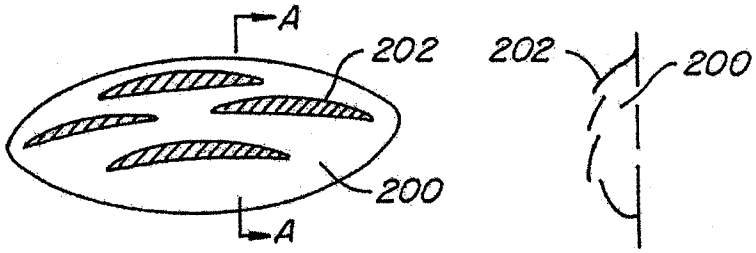

FIG. 16A

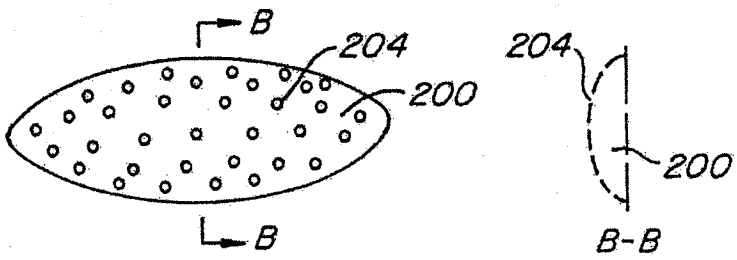

FIG. 16B

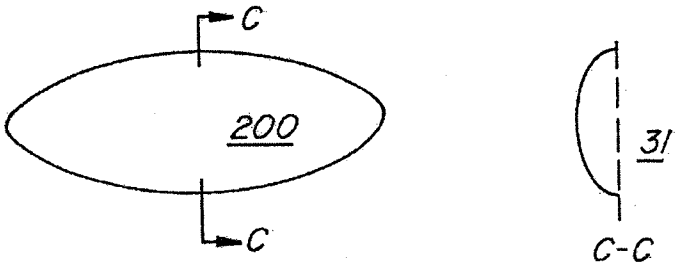

FIG. 16C

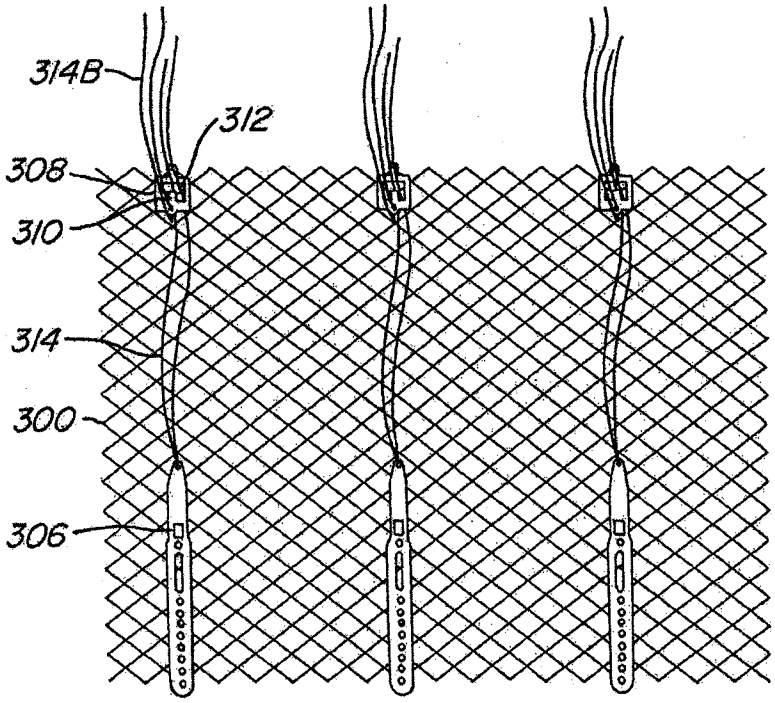

FIG. 17A

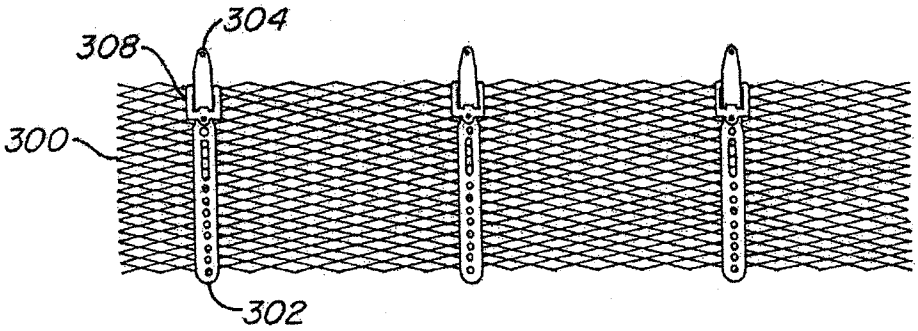

FIG. 18A

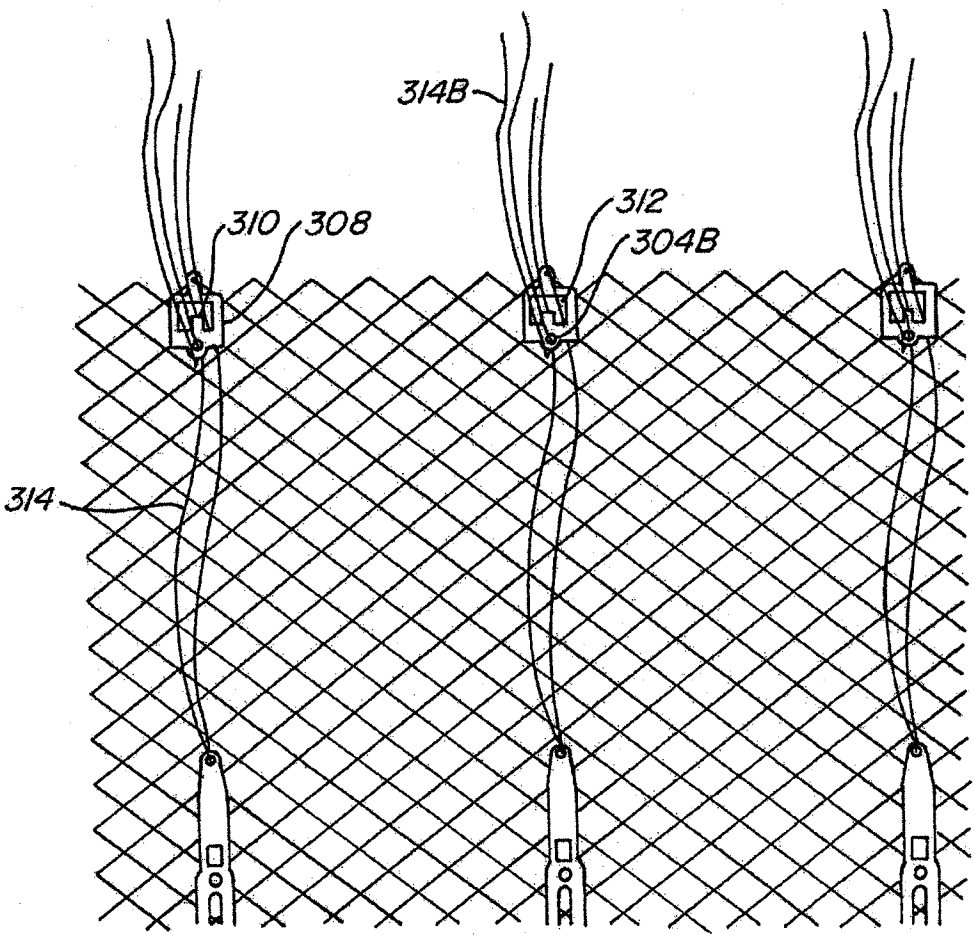

FIG. 17B

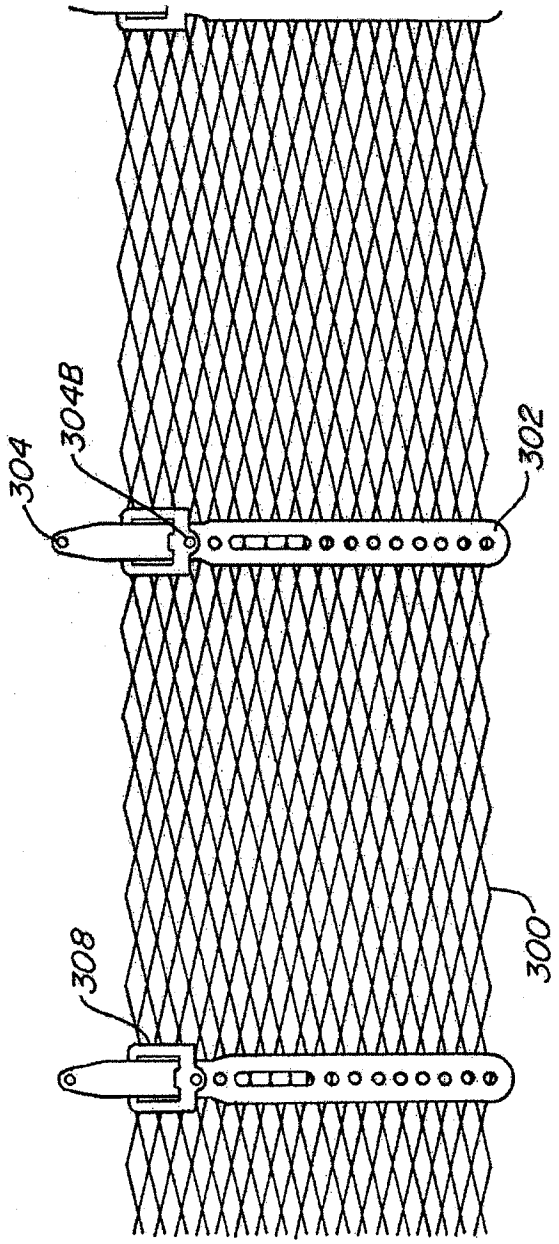

FIG. 18B

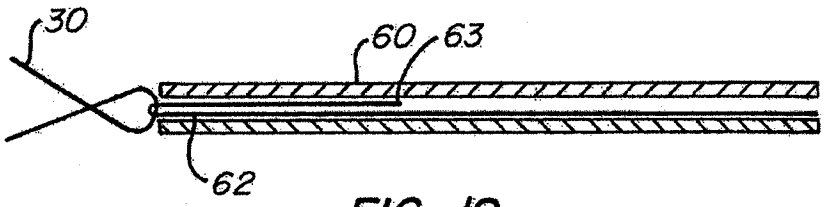

FIG. 19

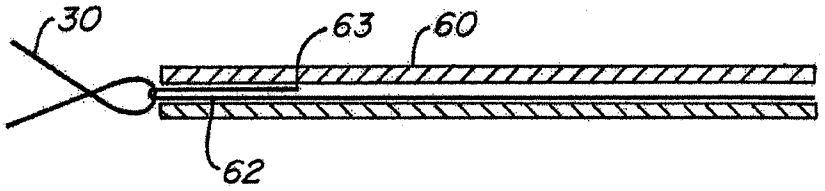

FIG. 20

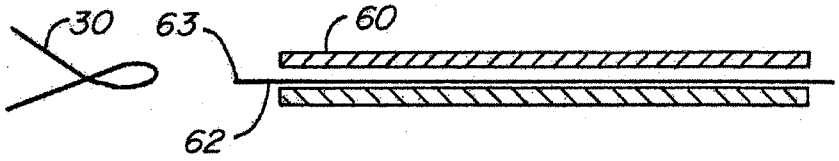

FIG. 21

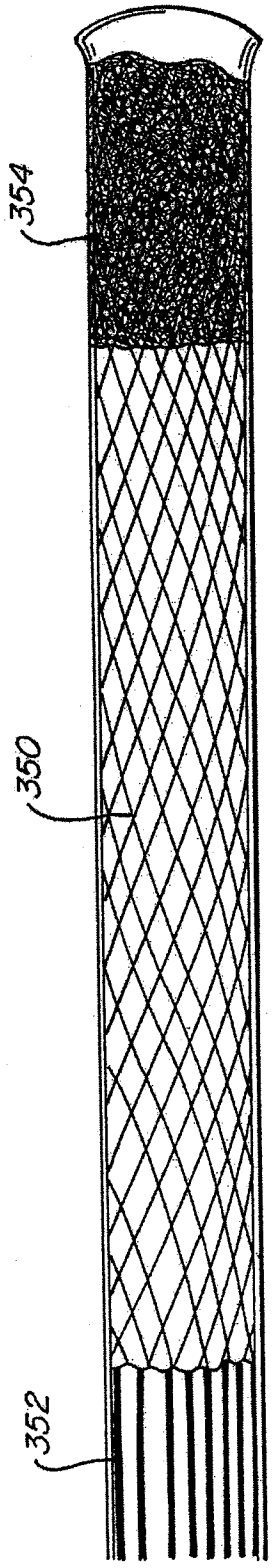

FIG. 22

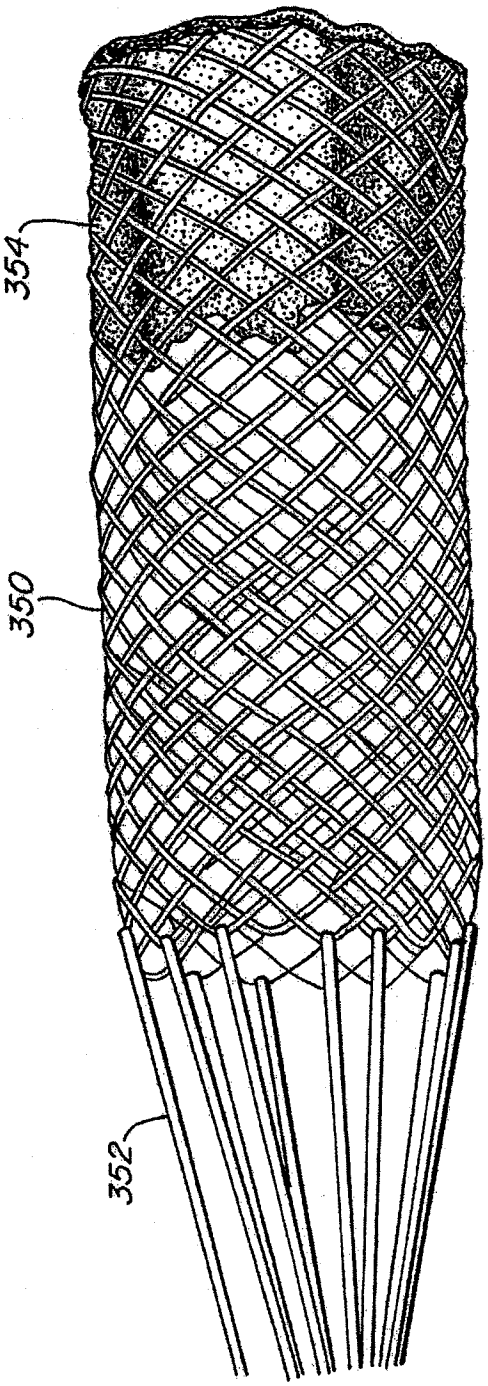

FIG. 23

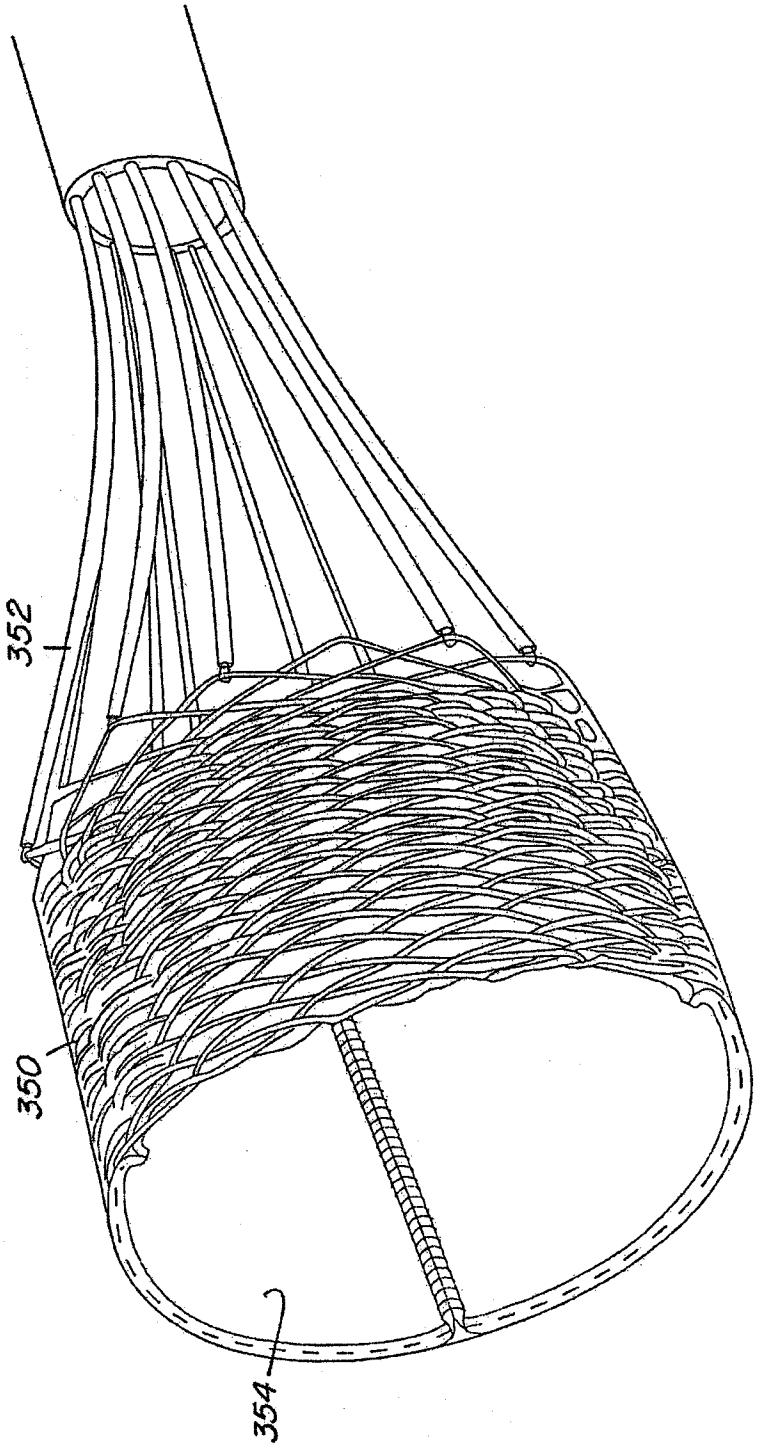

FIG. 24

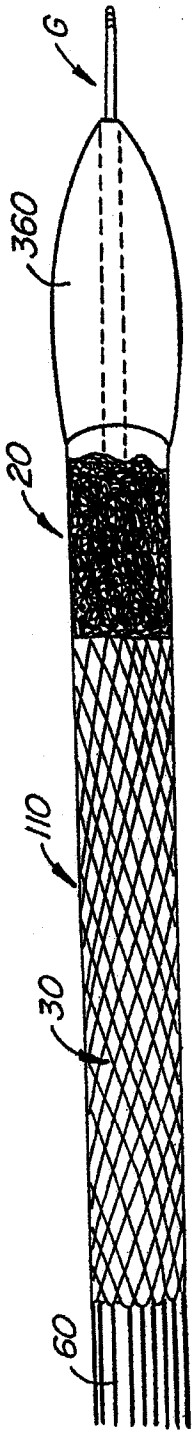

FIG. 25

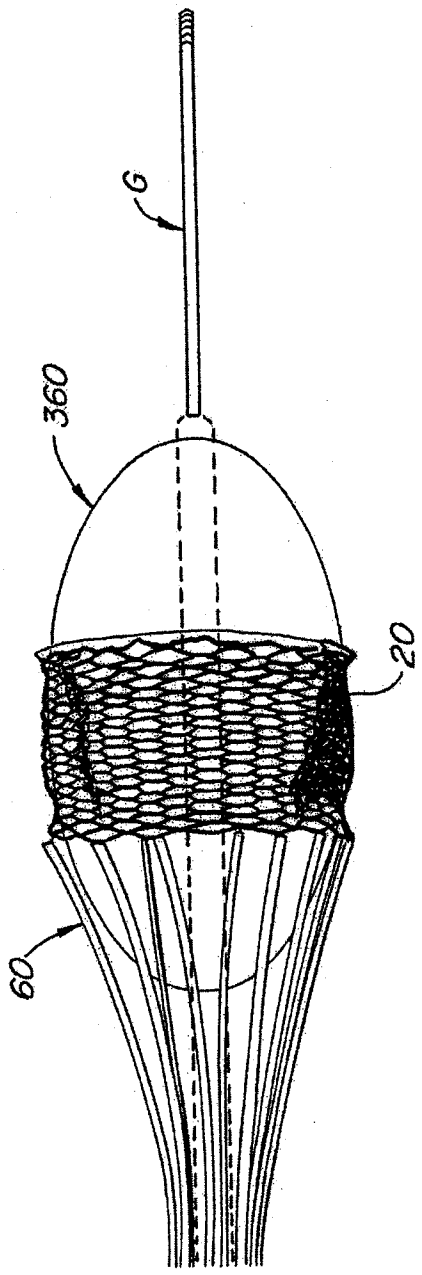

FIG. 26

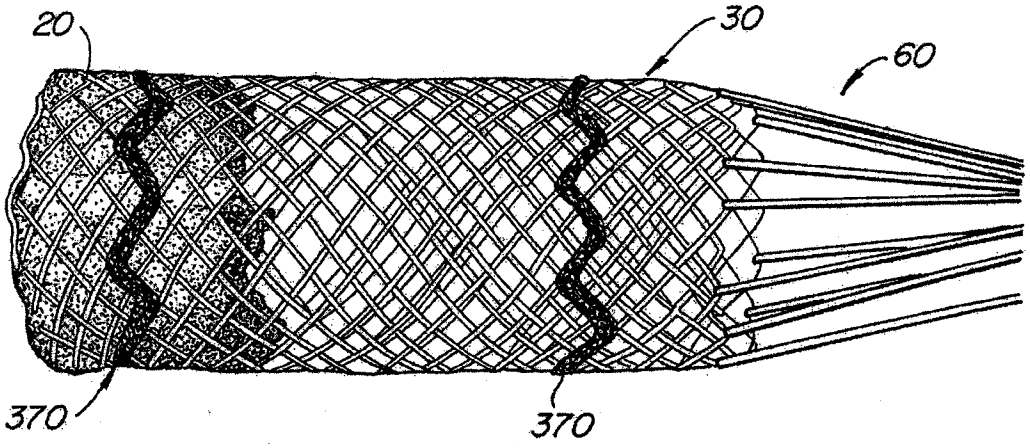

FIG. 27

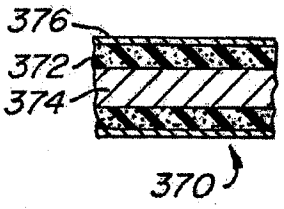

FIG. 28

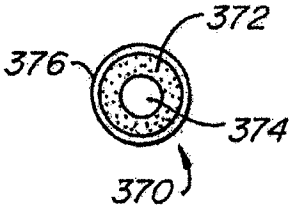

FIG. 29

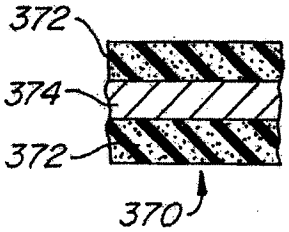

FIG. 30

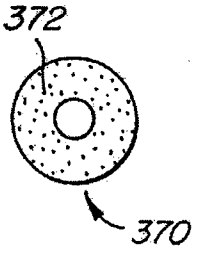

FIG. 31

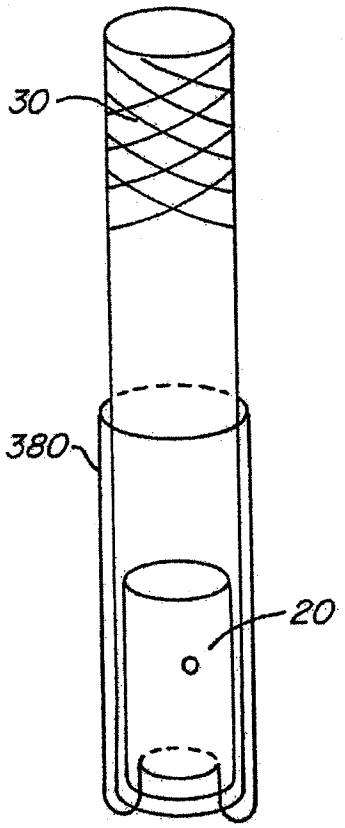

FIG. 32

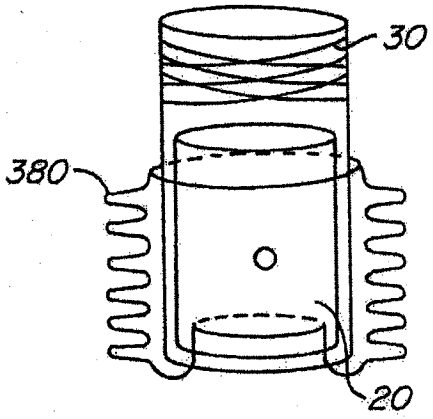

FIG. 33

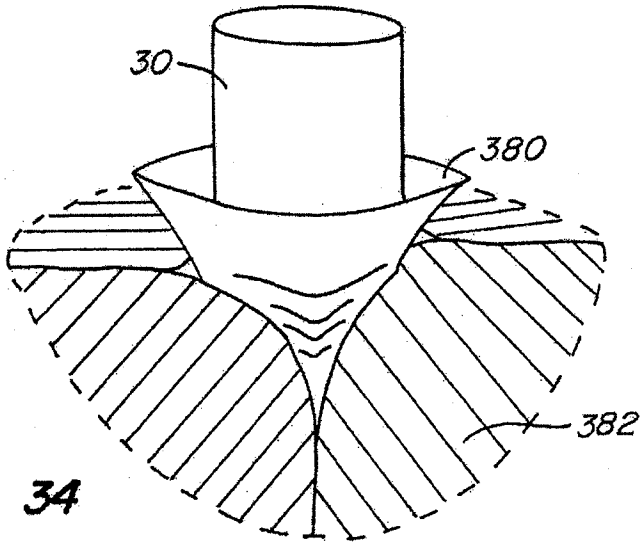

FIG. 34

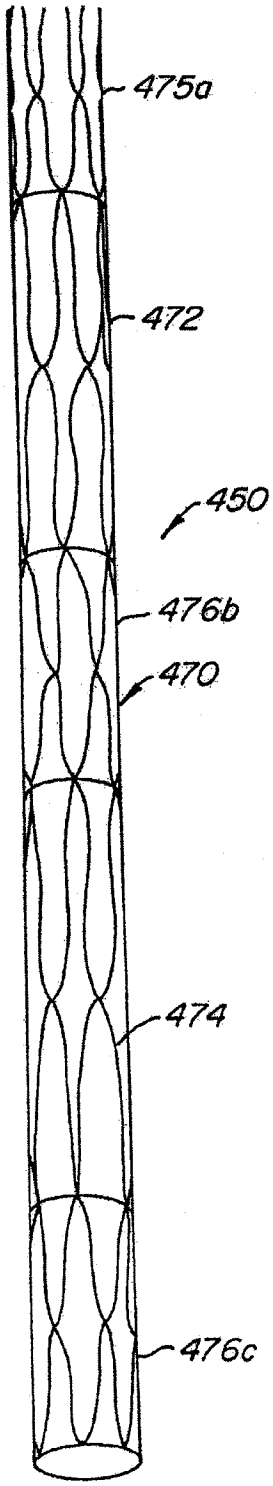

FIG. 35A

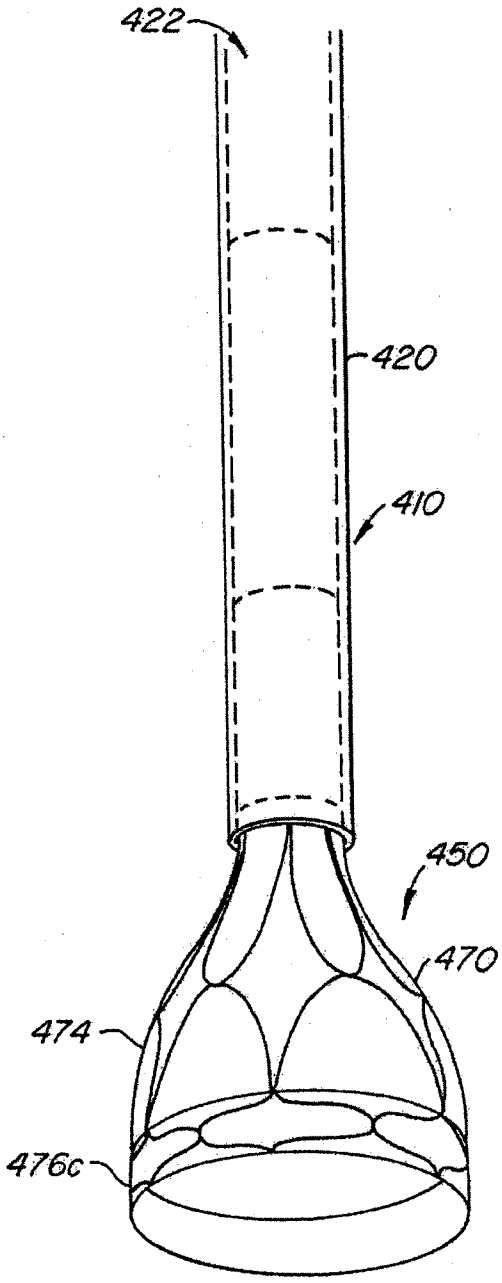

FIG. 35B

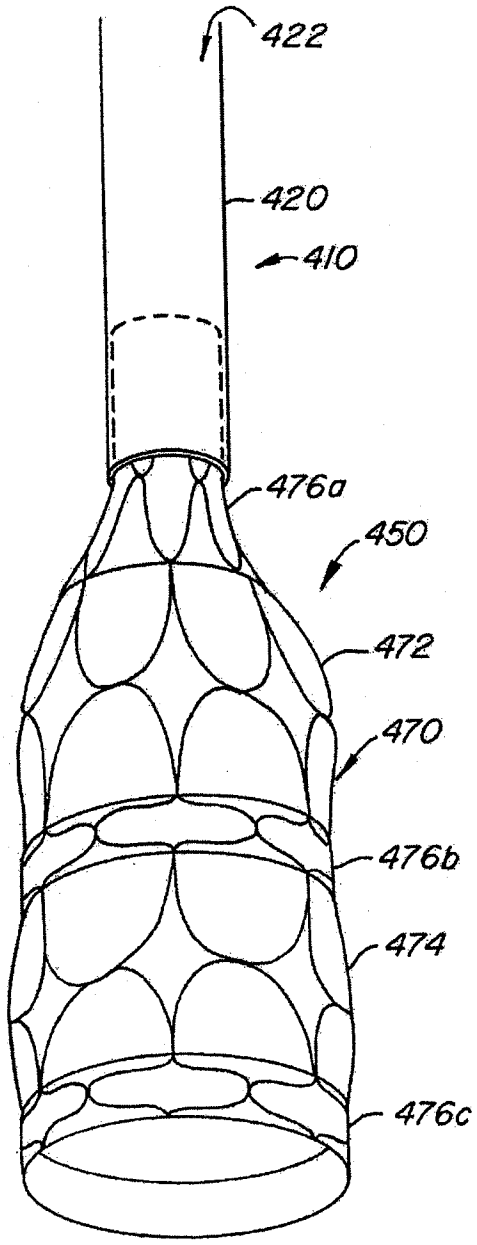

FIG. 35C

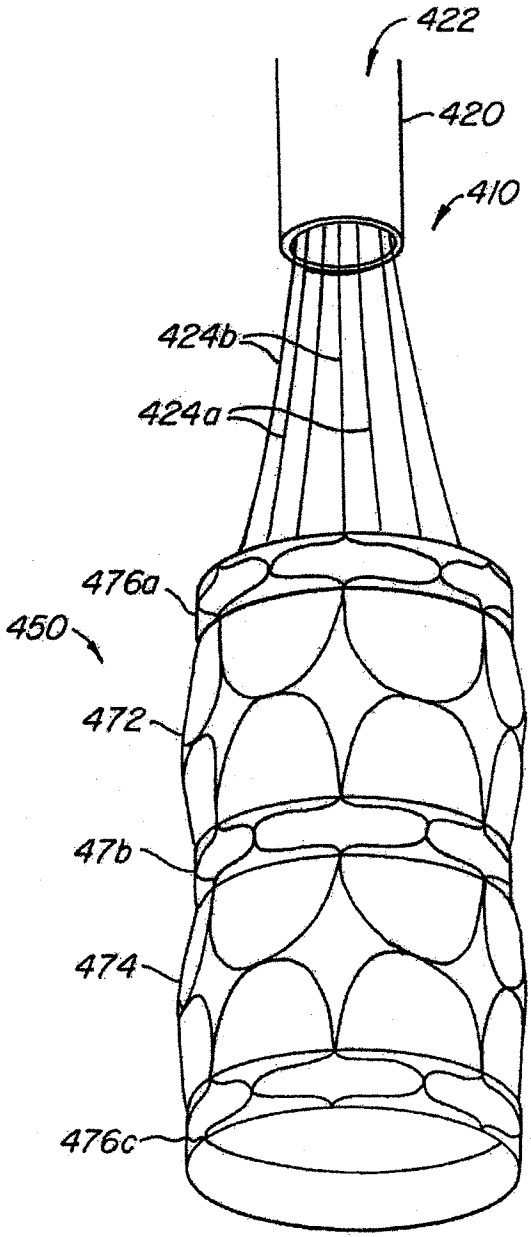

FIG. 35D

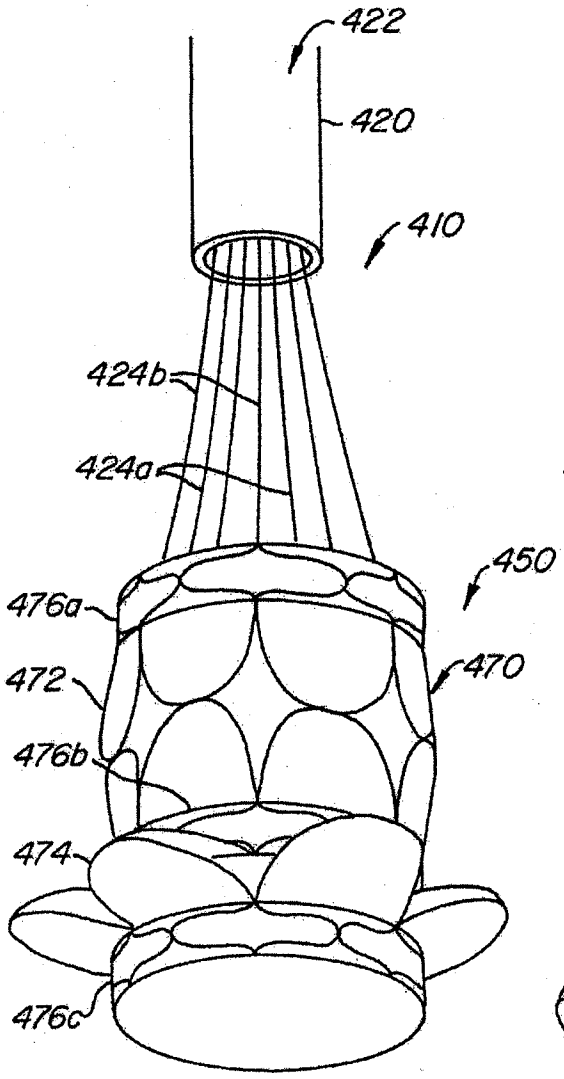

FIG. 35E

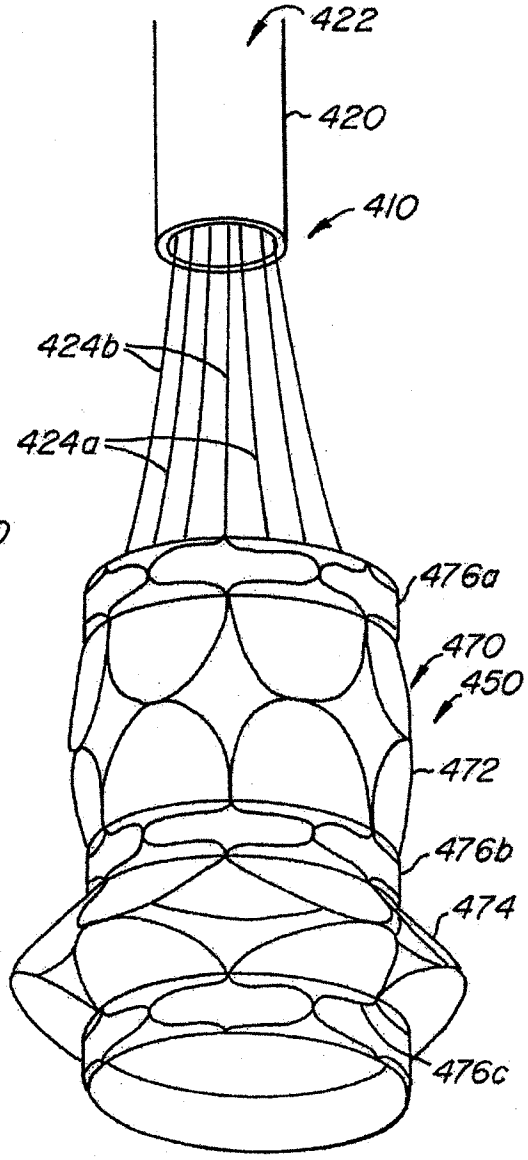

FIG. 35F

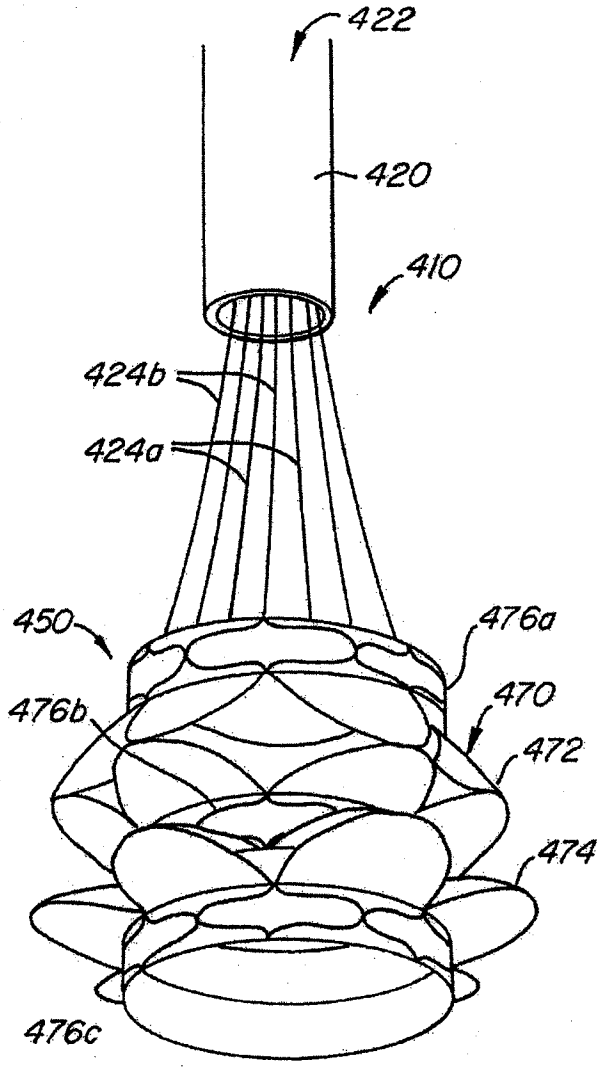

FIG. 35G

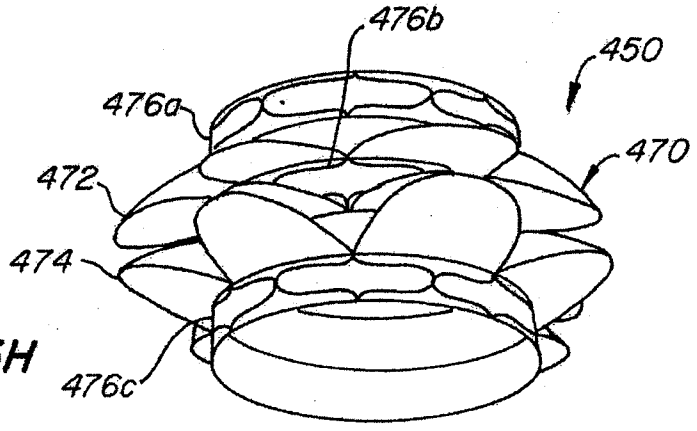

FIG. 35H

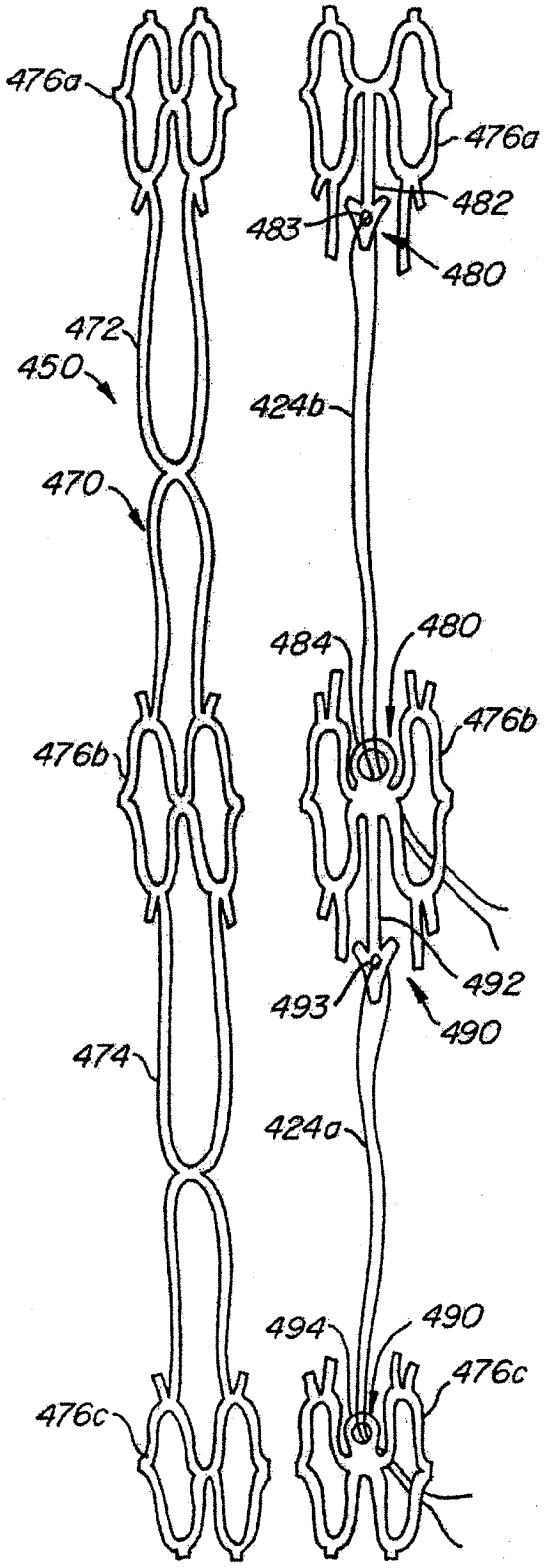

FIG. 36A

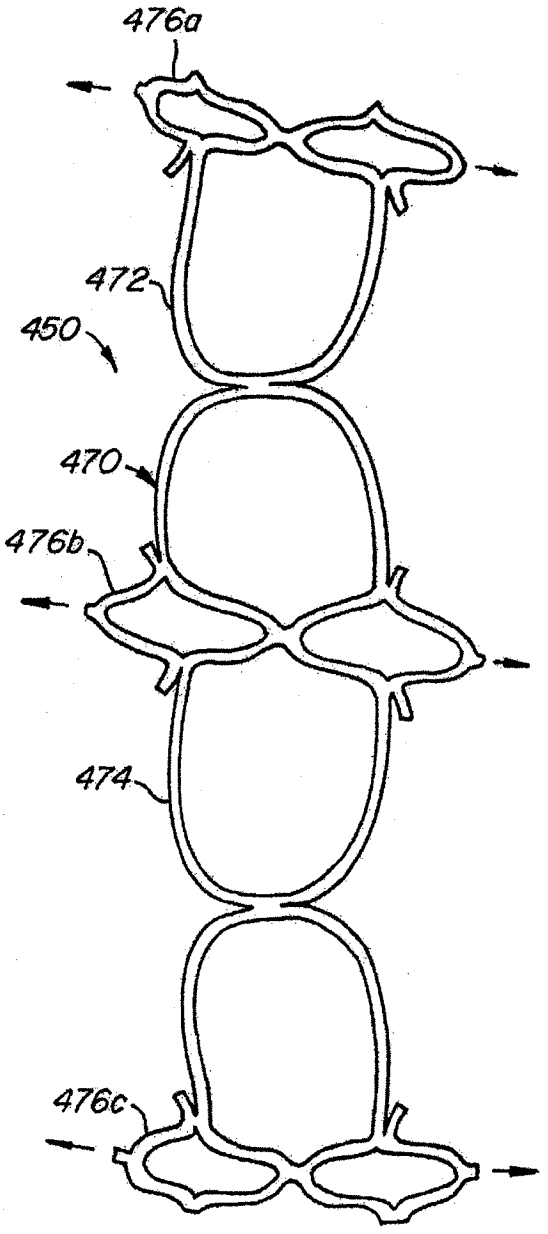

FIG. 36B

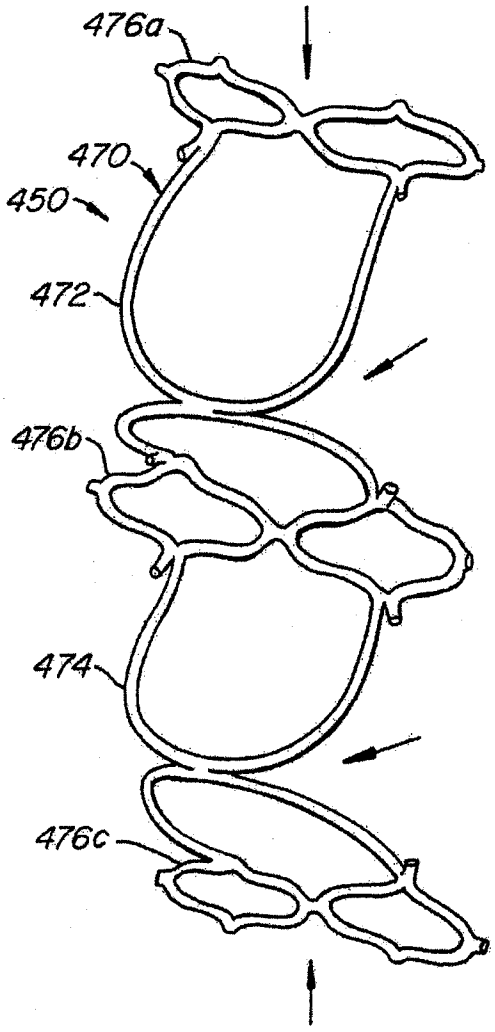

FIG. 36C

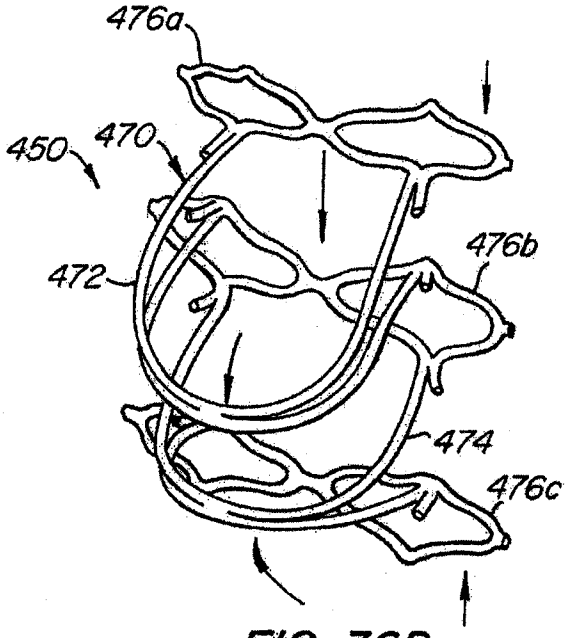

FIG. 36D

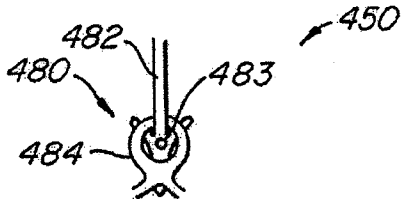

FIG. 36E

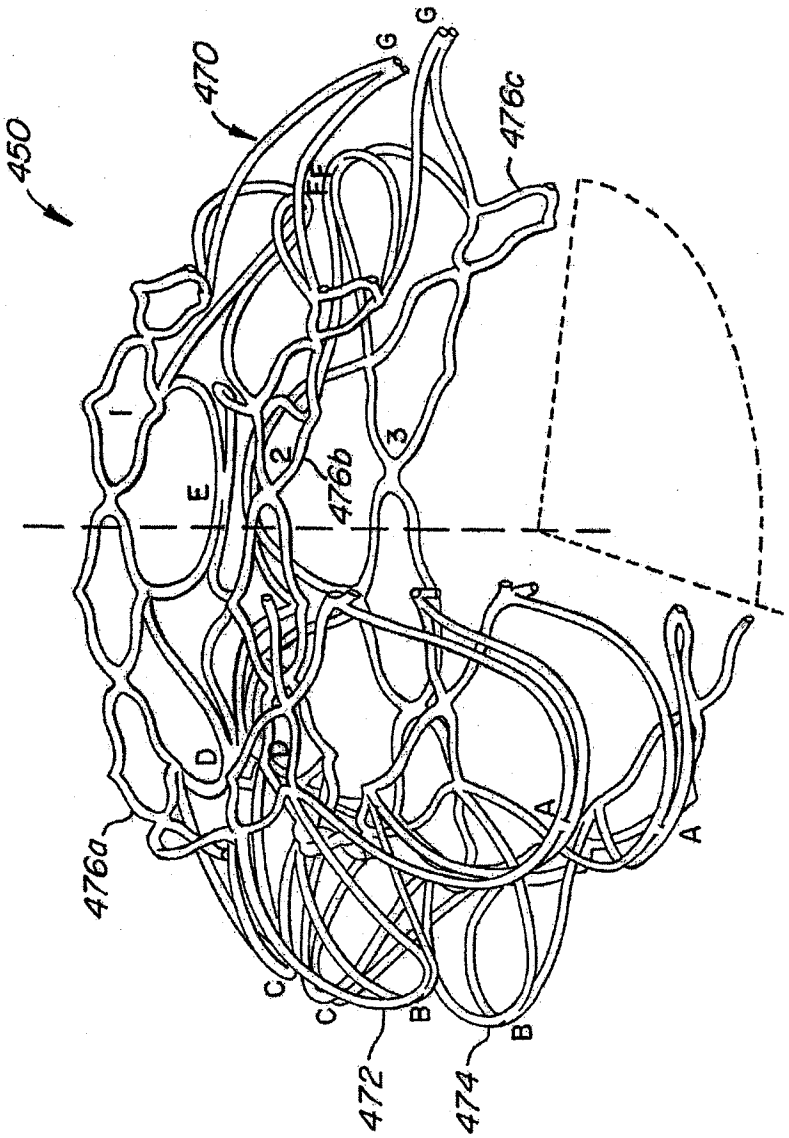

FIG. 37A

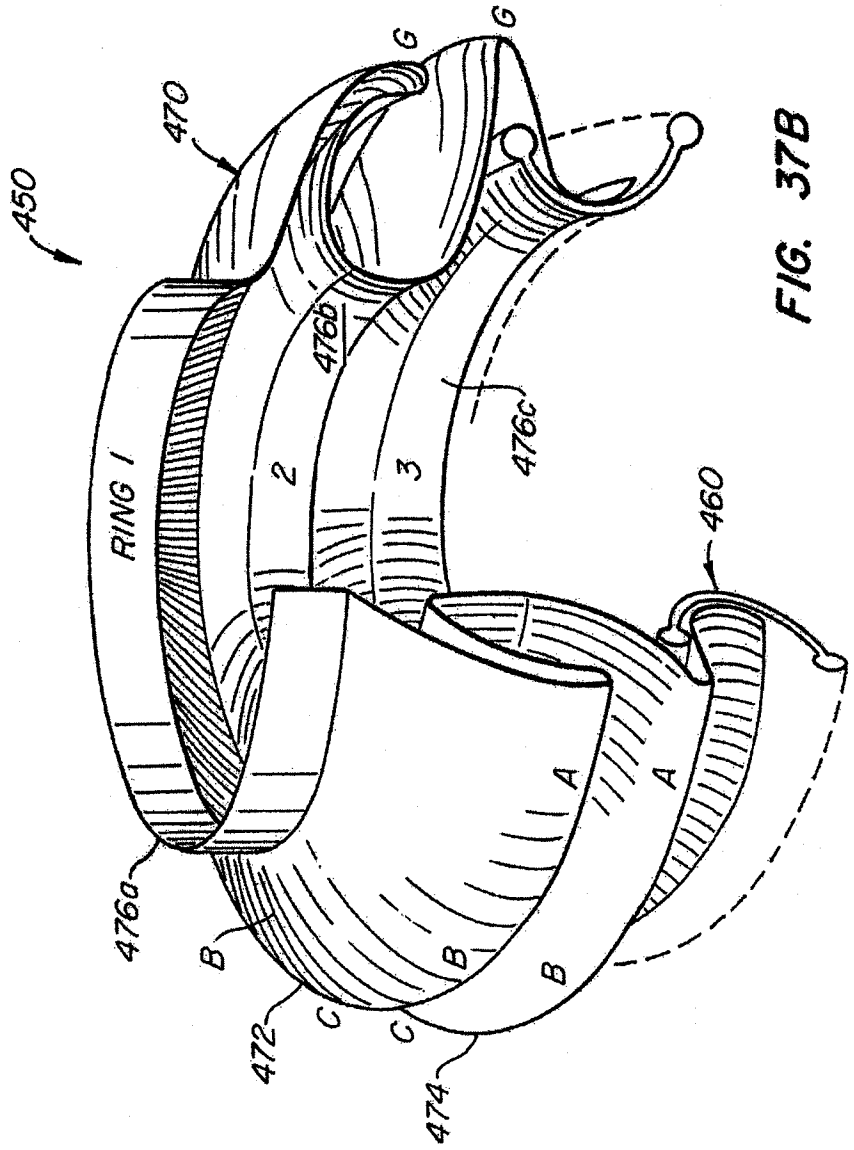

FIG. 37B

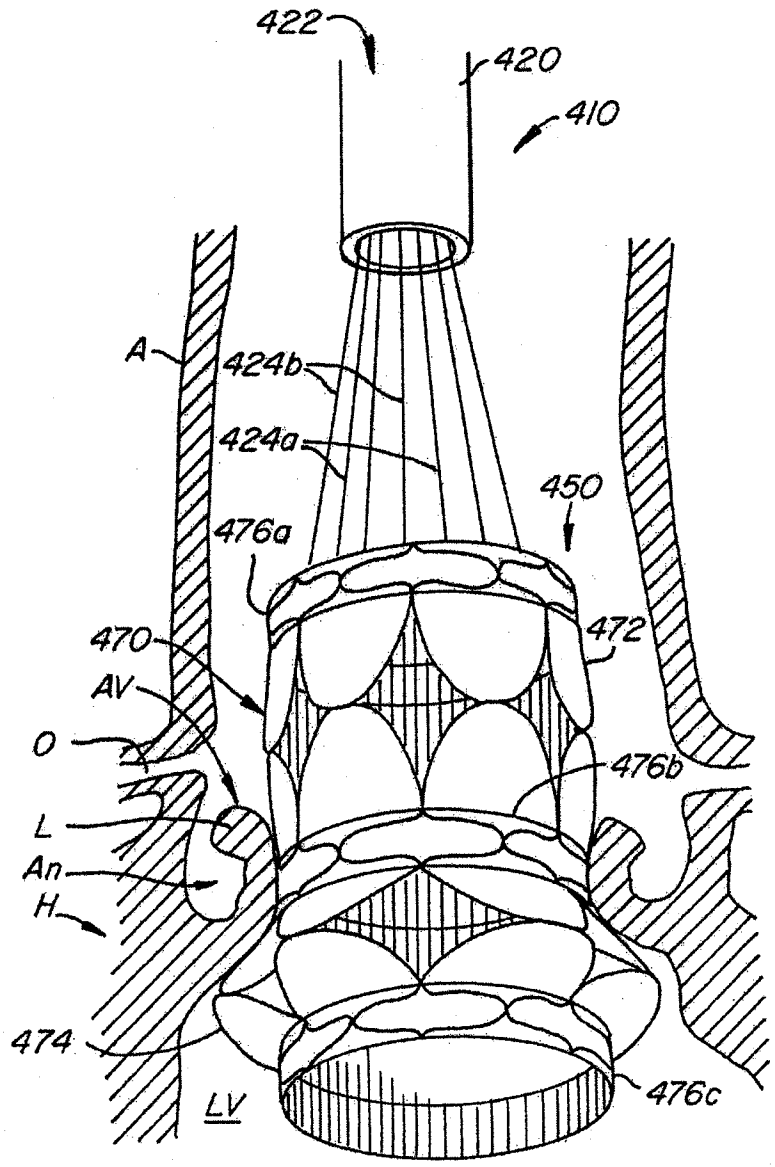
422
420
410
A
424b
424a
450
476a
472
470
AV
O
476b
L
An
H
474
LV
476c

FIG. 38A

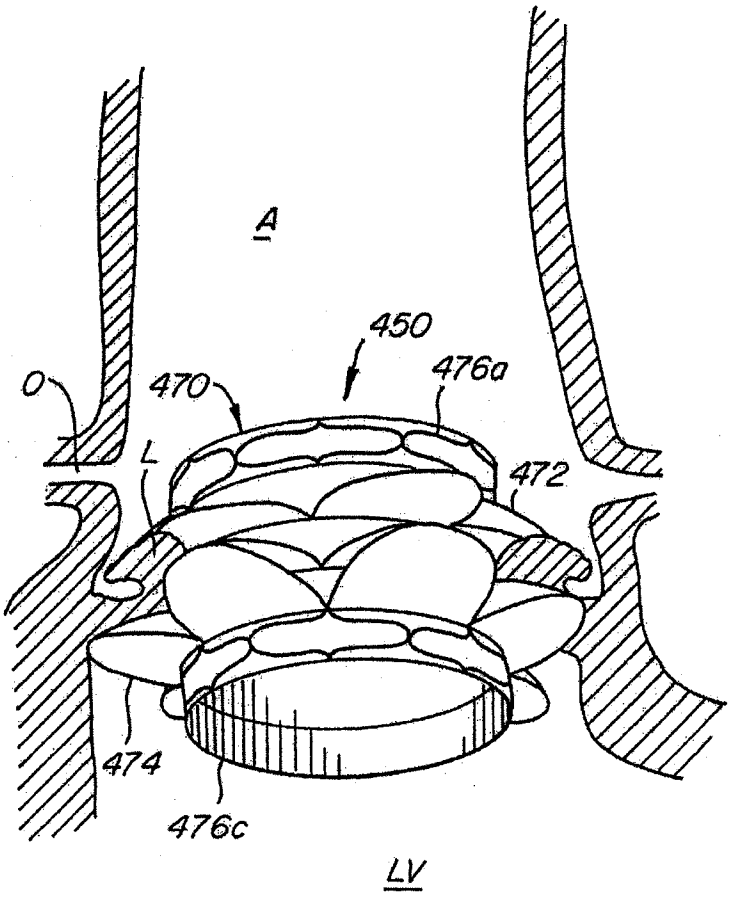

FIG. 38B

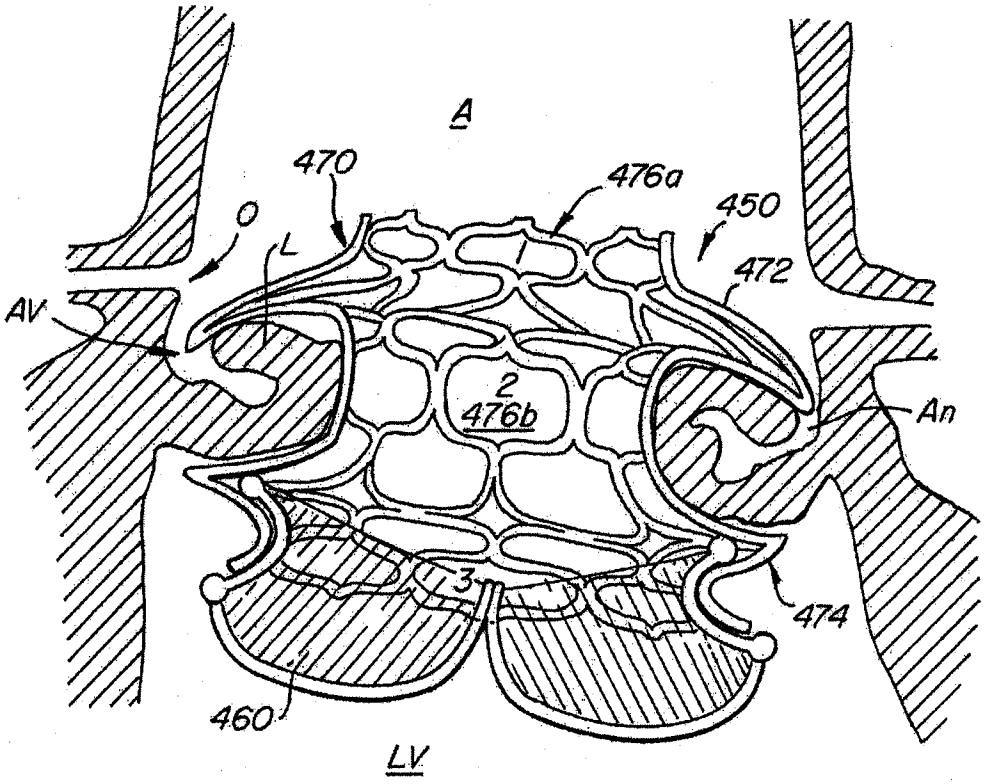

FIG. 38C

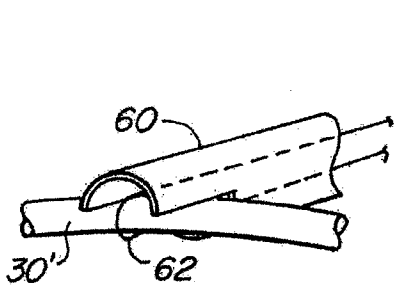

FIG. 39B

FIG. 39A

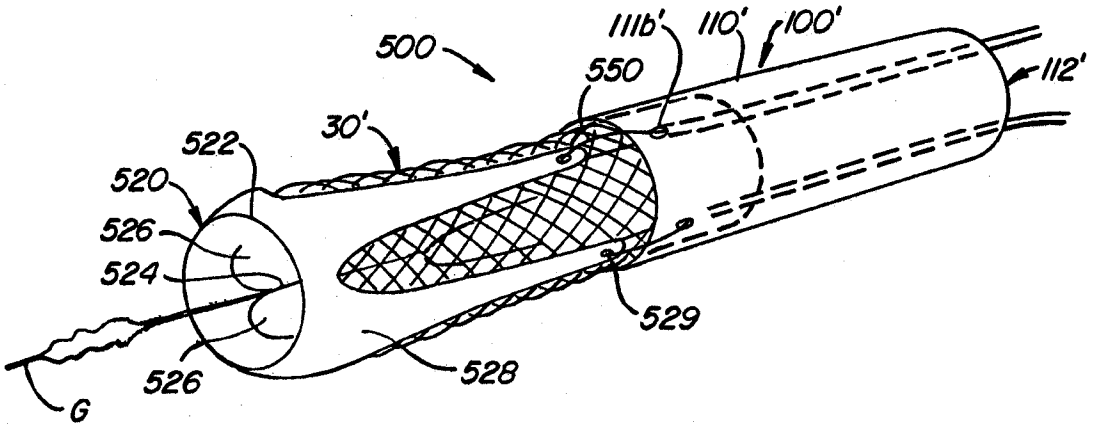

FIG. 39C

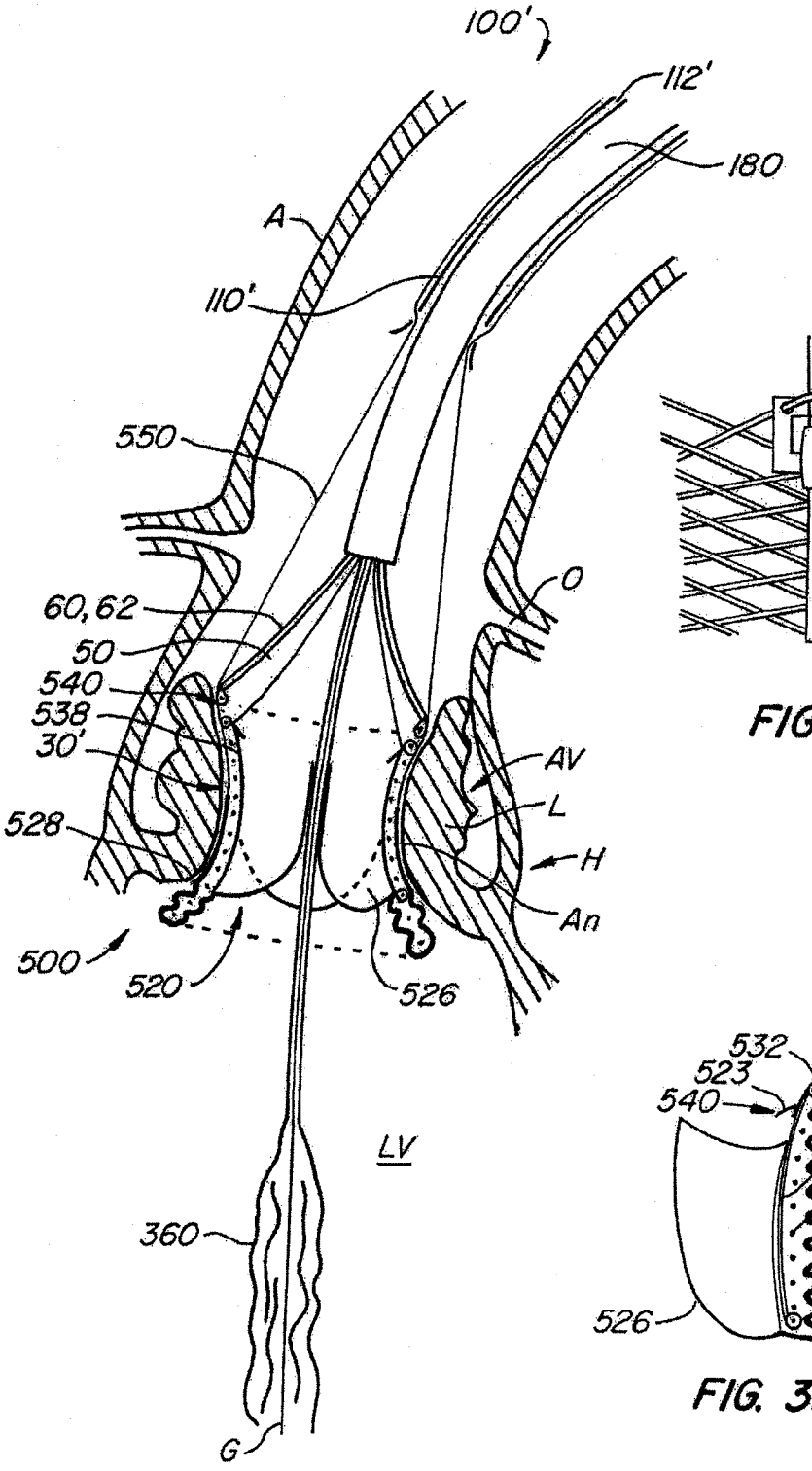

FIG. 39D

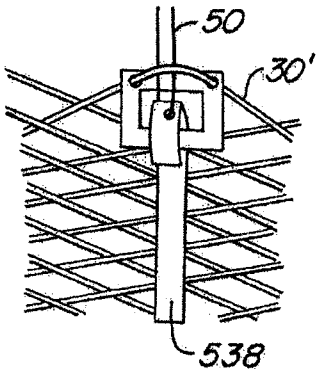

FIG. 39E

FIG. 39F

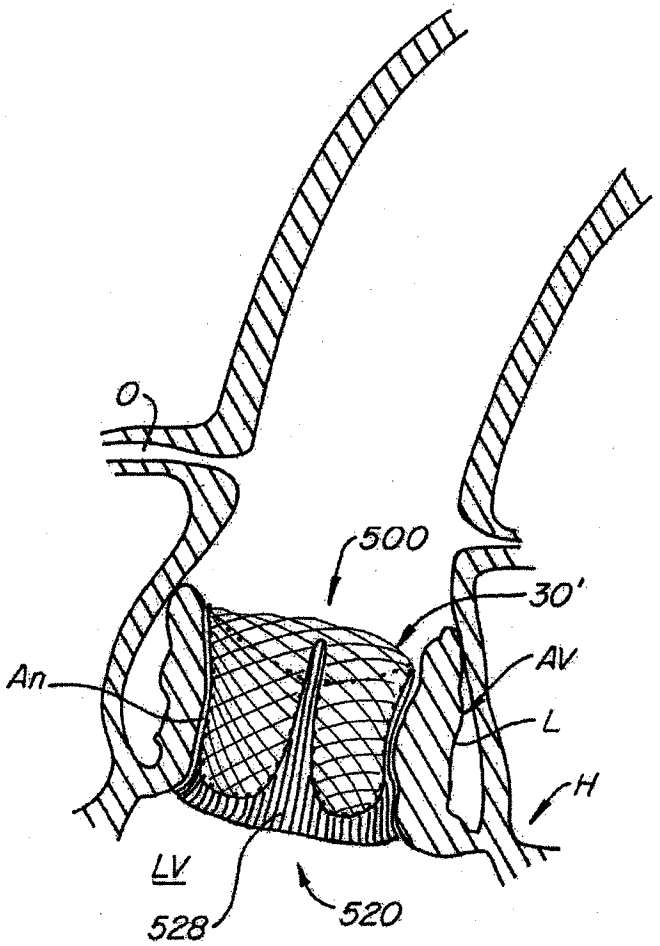

FIG. 39G

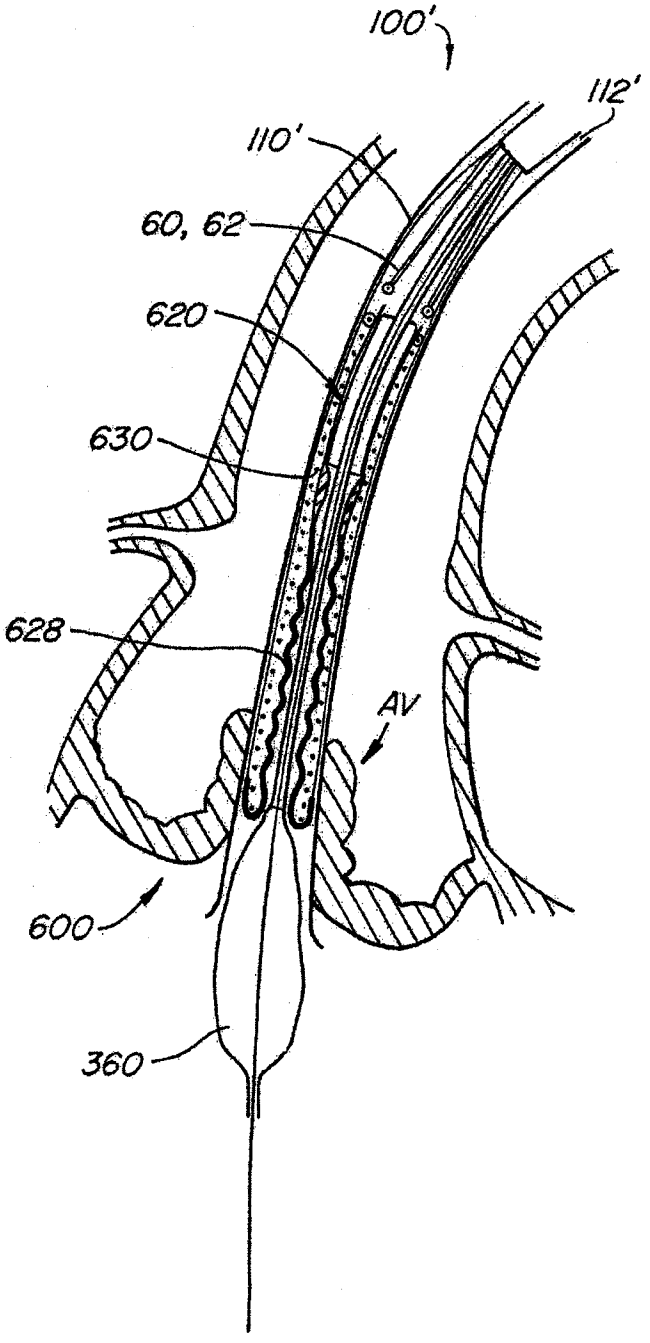

FIG. 40A

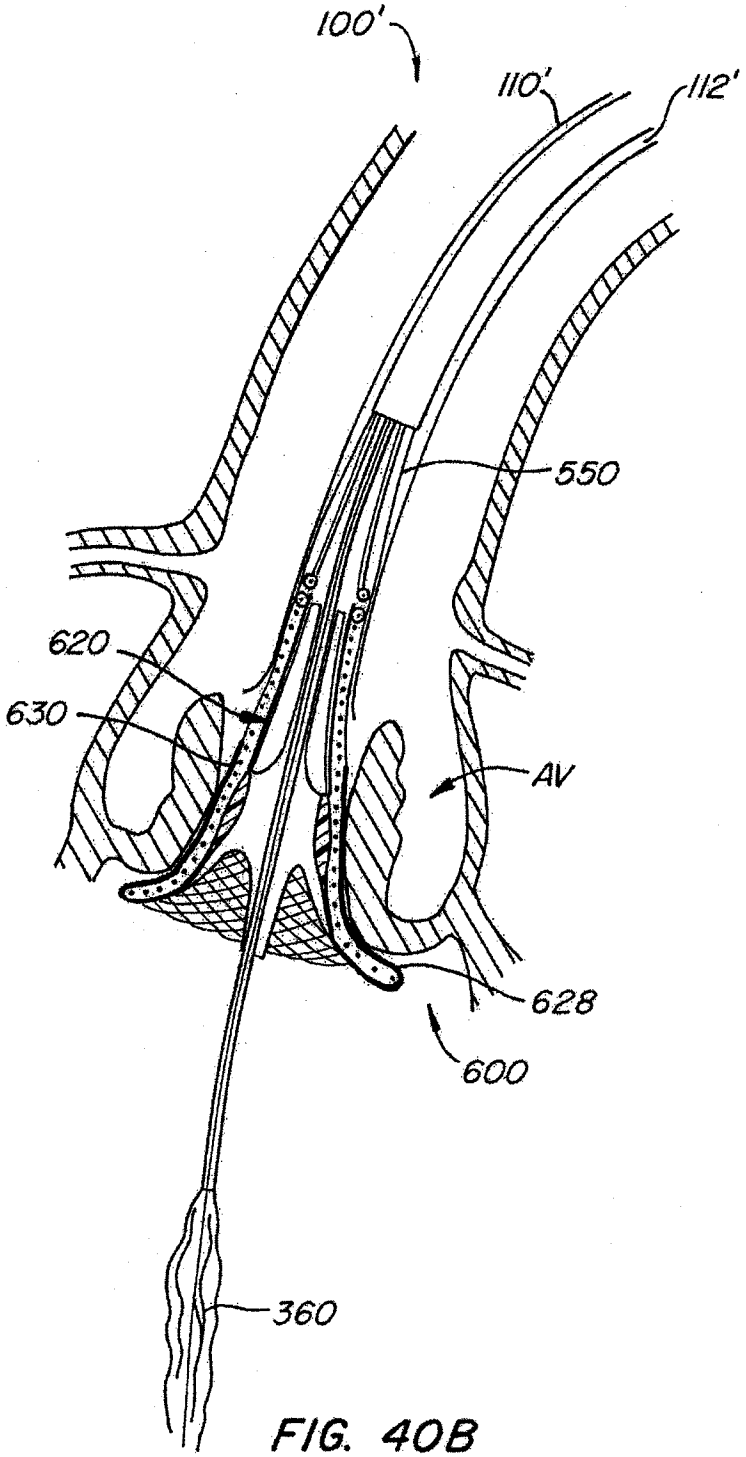

FIG. 40B

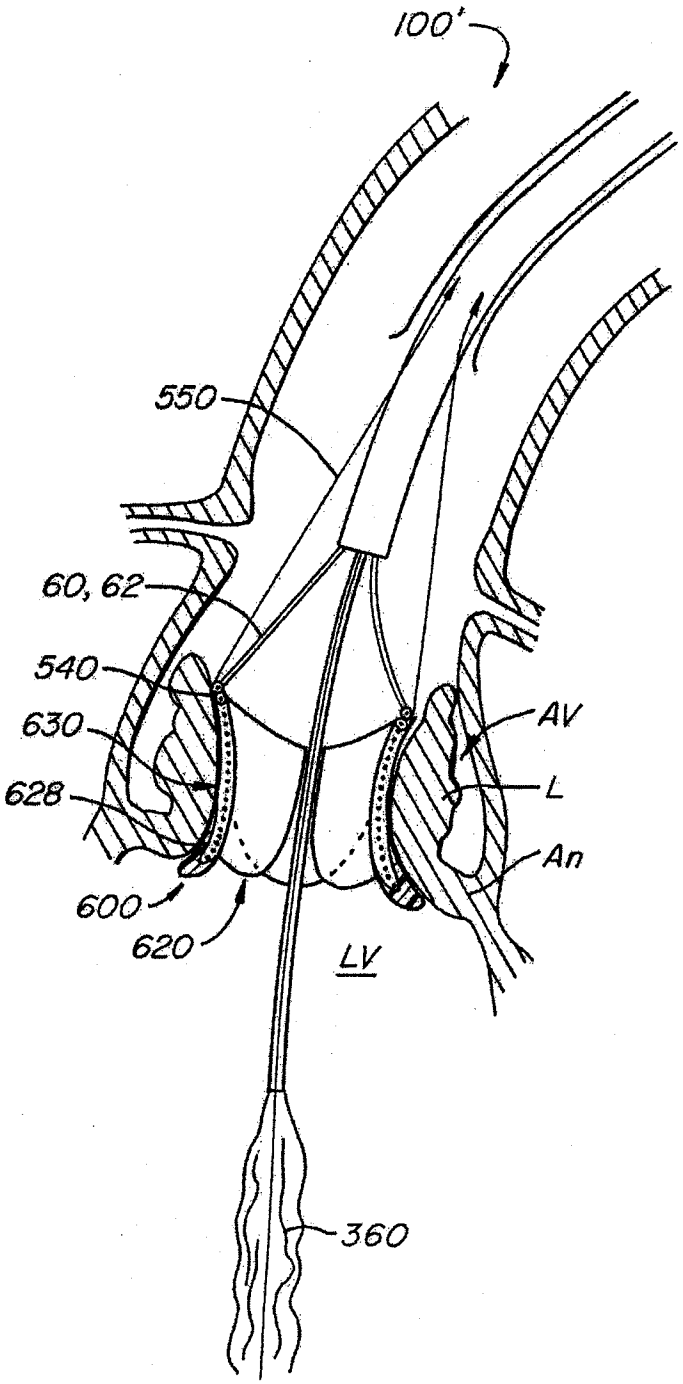

FIG. 40C

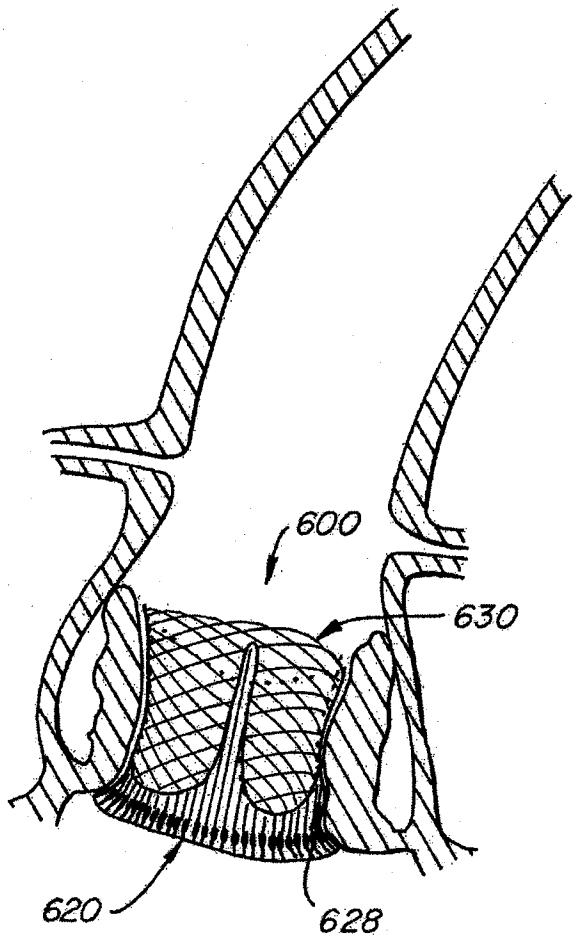

FIG. 40D

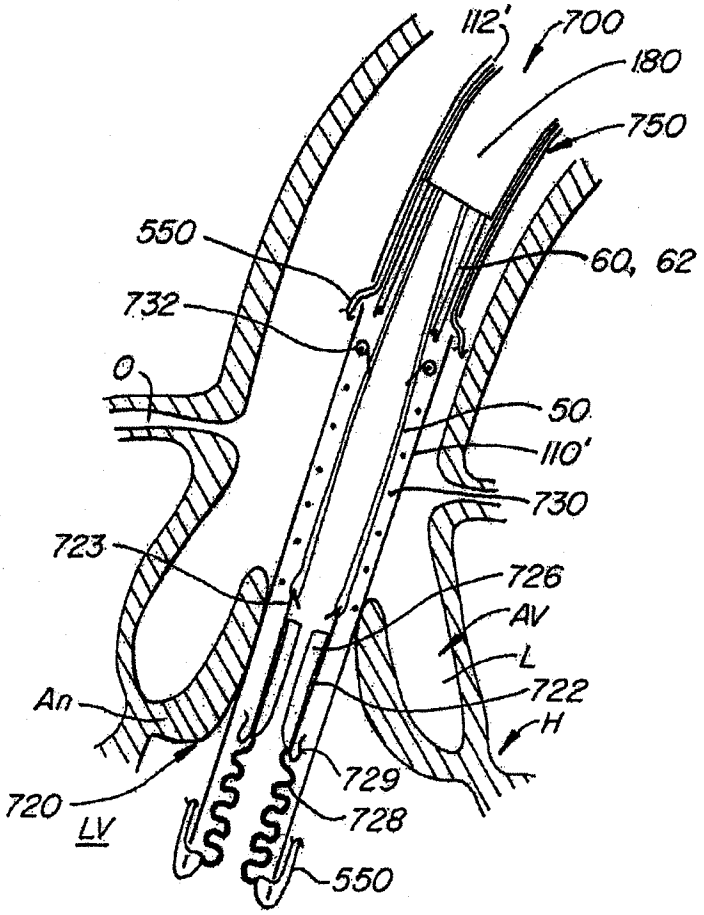
112'
700
180
750
550
60, 62
732
0
50
110'
730
723
726
AV
L
722
An
H
729
720
LV
728
550

FIG. 41A

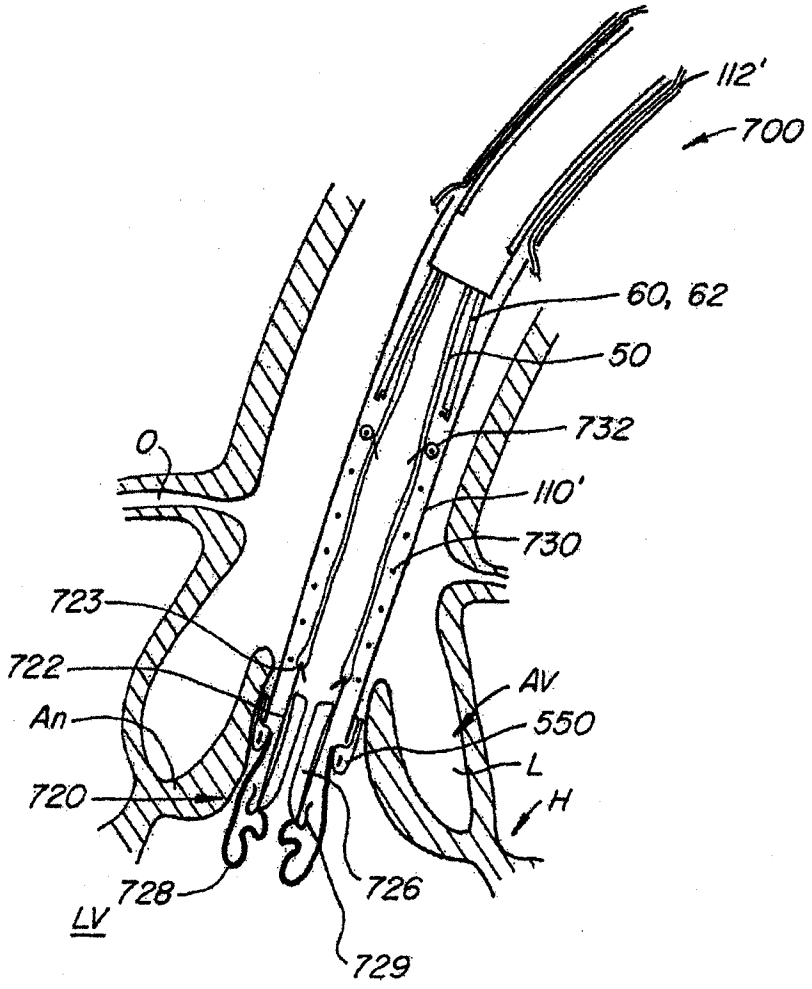
112'
700
60, 62
50
732
110'
730
O
723
722
An
720
AV
550
L
H
728
726
LV
729

FIG. 41B

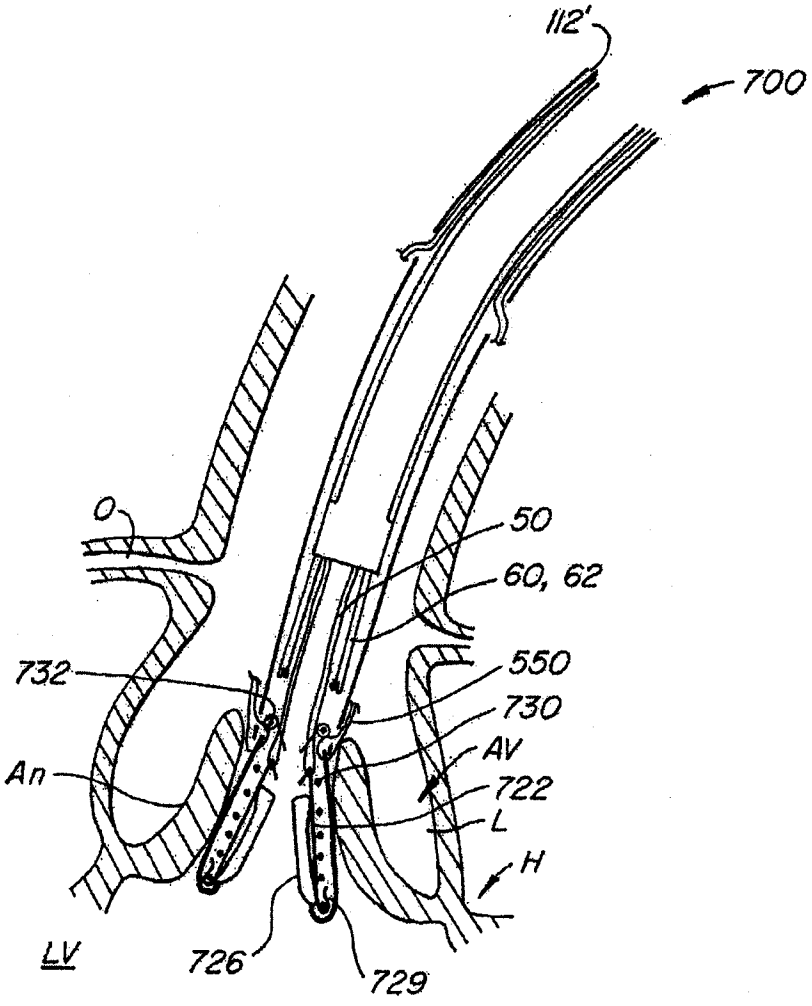

FIG. 41C

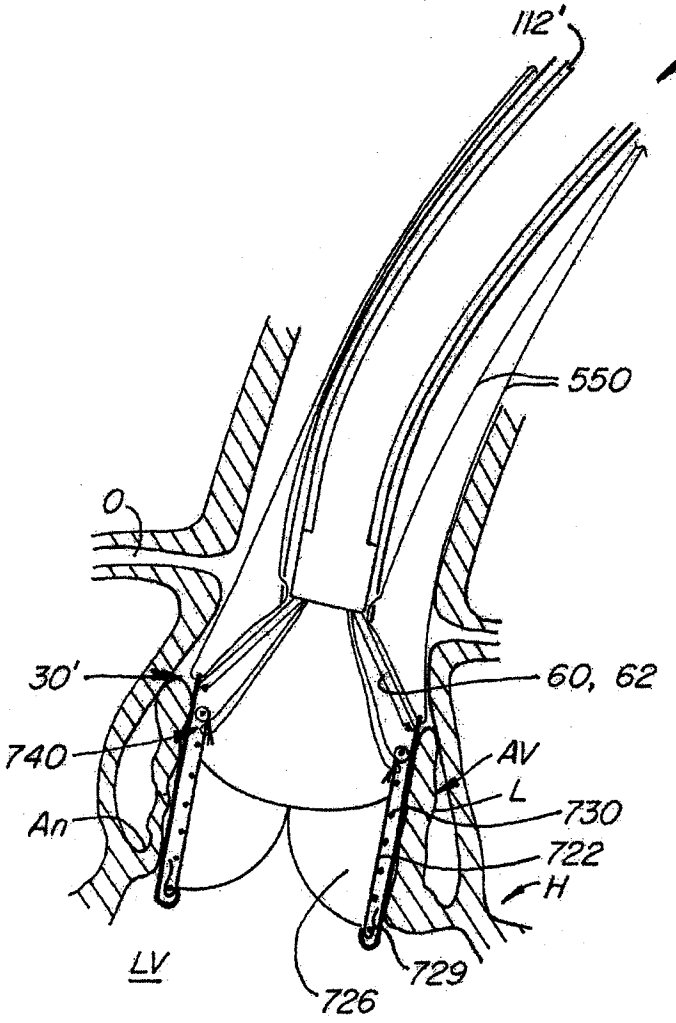

FIG. 41D

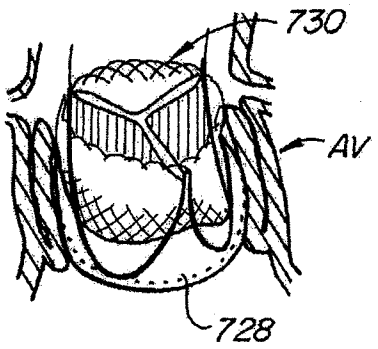

FIG. 41E

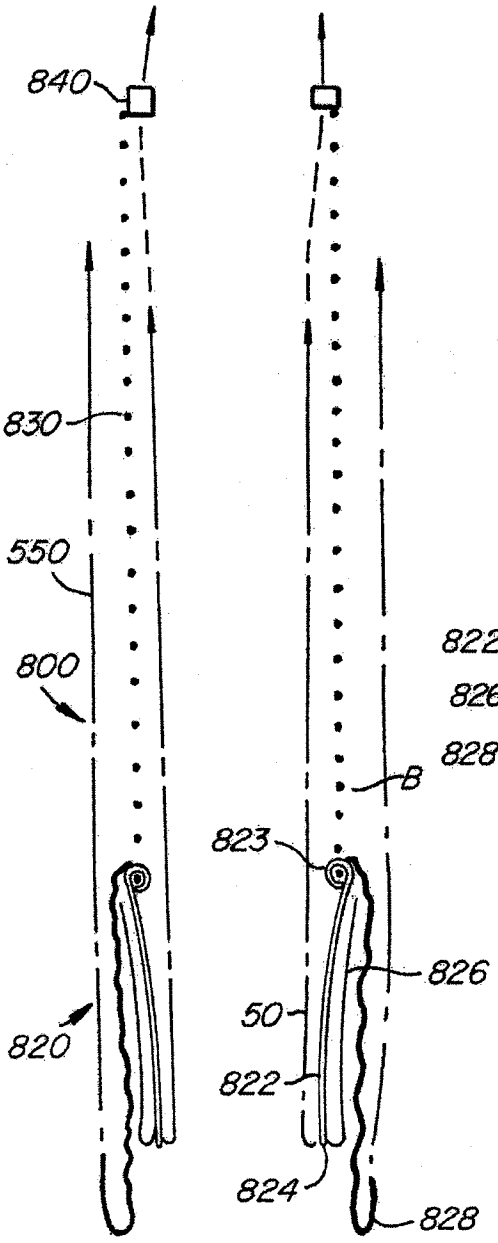

FIG. 42A

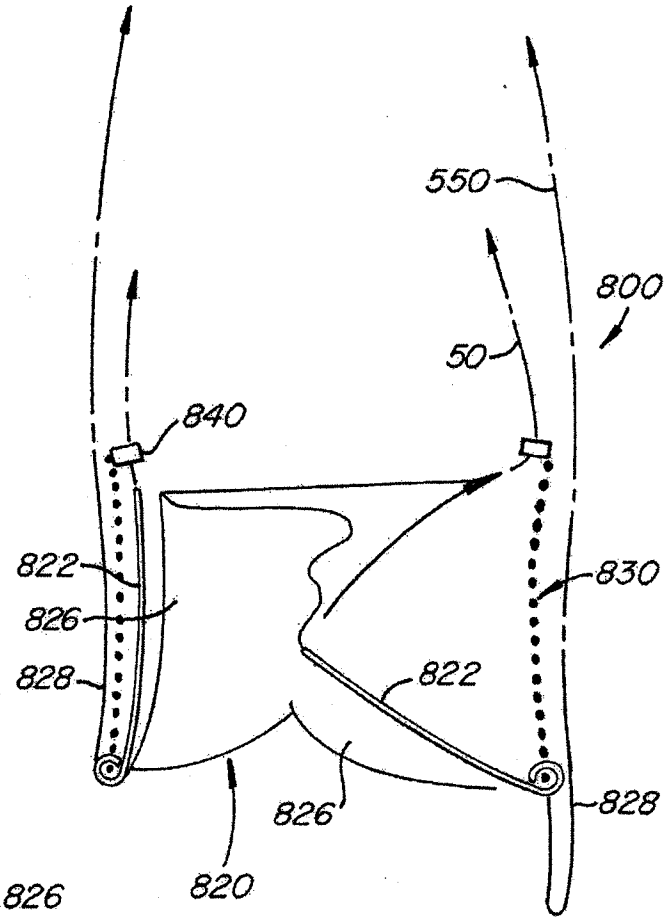

FIG. 42B

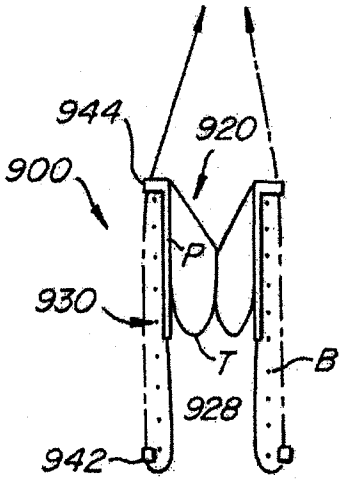

FIG. 43A

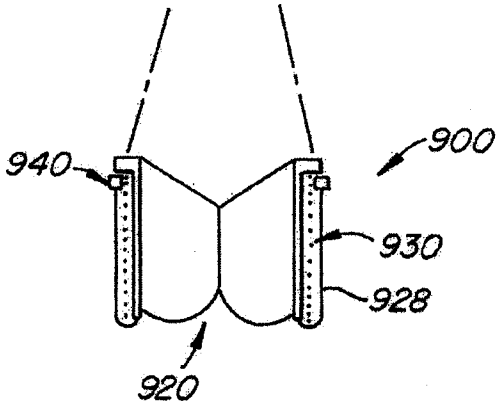

FIG. 43B

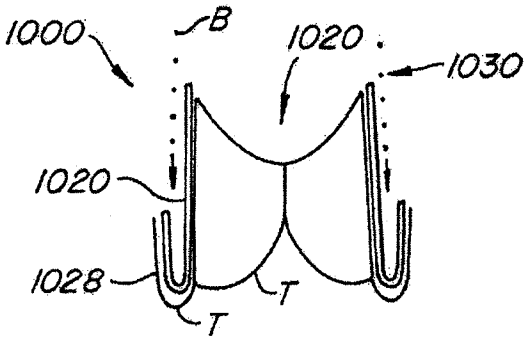

FIG. 44A

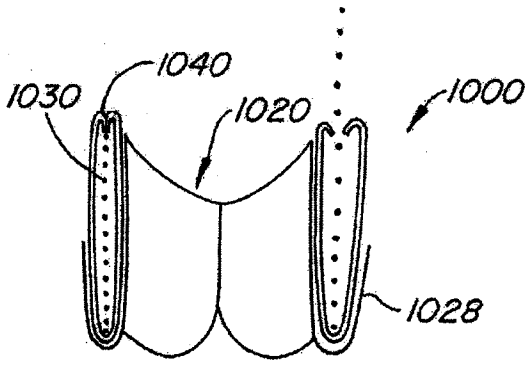

FIG. 44B

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Thomas M. Zlogar/Sue Bromaghim
Attorney Docket Number:	10012-710.301

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	82	82
Utility Search Fee	2111	1	270	270
Utility Examination Fee	2311	1	110	110
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**462**

Electronic Acknowledgement Receipt

EFS ID:	4274337
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Sue Bromaghim
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	12-NOV-2008
Filing Date:	
Time Stamp:	13:23:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$462
RAM confirmation Number	15224
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710-301-trans-comm-appln-decl.pdf	6658036 a6d1e0b8bb61bdf9ee95ddcc0ccb73b4f5d6457e	yes	45

Multipart Description/PDF files in .zip description

Document Description	Start	End
Transmittal of New Application	1	1
Miscellaneous Incoming Letter	2	6
Specification	7	39
Claims	40	40
Abstract	41	41
Oath or Declaration filed	42	45

Warnings:

Information:

2	Drawings-only black and white line drawings	10012-710-310-drawings.pdf	4794663 5019f3a15cfbd7f4dab8feb9fdd5b6aba078146f	no	63

Warnings:

Information:

3	Fee Worksheet (PTO-06)	fee-info.pdf	32390 2f4bbfd41d0f40343ad8691aaa3e85c673a11838	no	2

Warnings:

Information:

Total Files Size (in bytes):	11485089

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (12-04)

Filing Date: 11/12/08

Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number: 12/269,213

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	82		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	270		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	110		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	12 minus 20 =		x$26		OR	x$52	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*	x$110			x$220	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $260 ($130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			195			390	
			TOTAL	462		TOTAL	

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

APPLICATION AS AMENDED – PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
						TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
						TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

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

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

FILED VIA EFS ON NOVEMBER 24, 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	12/269,213	Confirmation No.:	9828
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	November 12, 2008		
Title	:	Everting Heart Valve		
Group Art Unit	:			
Examiner	:			
Docket No.	:	10012-710.301		
Customer No.	:	66854		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

PRELIMINARY AMENDMENT

Introductory Comments:

Preliminarily to examination on the merits, please amend the above-referenced application as follows:

Amendments to the Specification are not being made at this time.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 4 of this paper.

Amendments to the Claims / Claim Listing

A complete listing of the claims follows.

1. (original) A system for replacing a heart valve, comprising:

an expandable anchor comprising a braided material,

a replacement heart valve; and

a delivery device, wherein the expandable anchor and the replacement heart valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device,

wherein the expandable anchor is axially spaced from the replacement heart valve when the expandable anchor is in the delivery configuration within the delivery device.

2. (original) The system of claim 1 wherein the expandable anchor and the replacement heart valve are coupled to each other.

3. (original) The system of claim 1 wherein the replacement heart valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration within the delivery device.

4. (original) The system of claim 1 wherein at least a portion of the replacement heart valve is disposed within the expandable anchor when the expandable anchor is in a fully deployed configuration.

5. (original) The system of claim 4 wherein at least a portion of the replacement heart valve is disposed axially within the expandable anchor when the expandable anchor is in the fully deployed configuration.

6. (new) A system for replacing a heart valve, comprising

an expandable anchor having a collapsed delivery configuration and an expanded configuration;

a replacement valve commissure support element attached to the expandable anchor;

a commissure portion of a replacement valve leaflet attached to the commissure support element; and

a seal at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration, wherein the seal is adapted to prevent blood from flowing between the seal and heart tissue,

wherein a distal end of the replacement valve leaflet is attached to the seal.

7. (new) The system of claim 6 wherein the expandable anchor is not attached to the replacement valve leaflet.

8. (new) The system of claim 6 wherein the distal end of the replacement valve leaflet is attached to a distal end of the seal when the expandable anchor is in the expanded configuration.

9. (new) The system of claim 6 wherein the commissure support element is configured to interface with an anchor actuator.

10. (new) The system of claim 9 wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor.

11. (new) The system of claim 6 further comprising a lock comprising a first lock element and a second lock element, wherein the first and second lock elements are attached to the expandable anchor and adapted to engage with one another to lock the expandable anchor in the expanded configuration, and

wherein the commissure support element includes the first lock element.

12. (new) The system of claim 11 wherein the second lock element is attached to the expandable anchor and is disposed proximal to the first lock element when the expandable anchor is in the collapsed configuration within a delivery catheter.

REMARKS

New claims 6-12 have been added, support for which can be found in the specification. No new matter has been added.

Respectfully submitted,

Date: November 24, 2008

By: _____
Thomas M. Zlogar, Reg. No. 55,760

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

Electronic Acknowledgement Receipt

EFS ID:	4346948
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Sue Bromaghim
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	24-NOV-2008
Filing Date:	
Time Stamp:	18:23:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710-301-PrelimAmend.pdf	315664 1e79394930973 59dc4b0e606e7aa6863054e9581	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	315664	

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

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

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/269,213	11/12/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	82		N/A	
☒ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	270		N/A	
☒ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	110		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	12 minus 20 =	* 0	X $26 =	0	OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	* 0	X $110 =	0		X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	462		TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 11/24/2008	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 12	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/ADRIANE S. WINSTON/

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/269,213	11/12/2008		462	10012-710.301	12	2

CONFIRMATION NO. 9828

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

FILING RECEIPT

OC000000033444031

Date Mailed: 12/09/2008

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

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

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

Domestic Priority data as claimed by applicant

This application is a CON of 10/870,340 06/16/2004

Foreign Applications

If Required, Foreign Filing License Granted: 12/04/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/269,213**

Projected Publication Date: 03/19/2009

Non-Publication Request: No

Early Publication Request: No
** **SMALL ENTITY** **

Title

Everting Heart Valve

Preliminary Class

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

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

NOT GRANTED

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

Electronic Acknowledgement Receipt

EFS ID:	4693129
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Sue Bromaghim
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	28-JAN-2009
Filing Date:	12-NOV-2008
Time Stamp:	17:54:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	10012-710-301-POA.pdf	463437 3e4c07375772155cec226b4fd042f79b13d9f480	no	1

Warnings:	
Information:	

Total Files Size (in bytes):	463437

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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

The undersigned ASSIGNEE of the entire interest in:

☐ U.S. Patent No.

☒ U.S. Application No. 12/269,213, filed on November 12, 2008

hereby appoints all Shay Glenn LLP attorneys registered to practice before the United States Patent and Trademark Office, as associated with:

CUSTOMER NO. 66854

to prosecute this application and transact all business in the United States Patent and Trademark Office in connection therewith and hereby revokes all prior powers of attorney; said appointment to be to the exclusion of the inventors and the inventors' attorneys in accordance with the provisions of 37 C.F.R. § 3.71.

STATEMENT PURSUANT TO 37 C.F.R. § 3.73(b)

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

(complete one of the following)

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

☐ the Assignment recorded on _____ at reel _____, beginning at frame _____, pursuant to 37 C.F.R. § 3.11.

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

Direct all correspondence and telephone calls to:

Name	James R. Shay					
Address	Shay Glenn LLP					
Address	2755 Campus Drive, Suite 210					
City	San Mateo	State	CA	Zip	94403	Customer No.: 66854
Country	USA	Telephone	650.212.1700	Fax	650.212.7562	

The undersigned is authorized and empowered to act on behalf of said Assignee.

ASSIGNEE: **SADRA MEDICAL, INC.**

Name: Amr Salahieh Signature: _____

Title: Chief Technology Officer Date: 1/28/09

ASSIGNMENT OF APPLICATION	Docket Number 30207-710.201

Whereas, the undersigned:

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

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

EVERTING HEART VALVE

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

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

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

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

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

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

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

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

Date: 10/06/04 — Ulrich R. Haug

Date: 10/08/04 — Hans F. Valencia

Date: 10/8/04 — Robert A. Geshlider

Date: 10/06/04 — Tom Saul

Date: 10/8/04 — Amr Salahieh

Date: 10-20-04 — Dwight Morejohn

Date: 11/1/04 — Kenneth J. Michlitsch

Electronic Acknowledgement Receipt

EFS ID:	4693236
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Sue Bromaghim
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	28-JAN-2009
Filing Date:	12-NOV-2008
Time Stamp:	18:03:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	10012-710-301-POA.pdf	513976 94222fc50f84f2bc51db7de5be0f2b90a97b8dce	no	2

Warnings:	
Information:	

Total Files Size (in bytes):	513976

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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

The undersigned ASSIGNEE of the entire interest in:

☐ U.S. Patent No.

☒ U.S. Application No. 12/269,213, filed on November 12, 2008

hereby appoints all Shay Glenn LLP attorneys registered to practice before the United States Patent and Trademark Office, as associated with:

CUSTOMER NO. 66854

to prosecute this application and transact all business in the United States Patent and Trademark Office in connection therewith and hereby revokes all prior powers of attorney; said appointment to be to the exclusion of the inventors and the inventors' attorneys in accordance with the provisions of 37 C.F.R. § 3.71.

STATEMENT PURSUANT TO 37 C.F.R. § 3.73(b)

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

(complete one of the following)

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

☐ the Assignment recorded on _____ at reel _____, beginning at frame _____, pursuant to 37 C.F.R. § 3.11.

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

Direct all correspondence and telephone calls to:

Name	James R. Shay					
Address	Shay Glenn LLP					
Address	2755 Campus Drive, Suite 210					
City	San Mateo	State	CA	Zip	94403	Customer No.: 66854
Country	USA	Telephone	650.212.1700	Fax	650.212.7562	

The undersigned is authorized and empowered to act on behalf of said Assignee.

ASSIGNEE: **SADRA MEDICAL, INC.**

Name: Amr Salahieh Signature: _____

Title: Chief Technology Officer Date: 1/28/09

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/269,213	Confirmation No.: 9828
Applicant(s):	Amr Salahieh	
Filed:	November 12, 2008	
Art Unit:	3774	
Examiner:	Unassigned	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

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

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

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

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

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

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

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

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

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

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

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

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

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

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

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

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

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

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

☐ **37 CFR § 1.97(d)**

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

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

--AND--

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

☒ **37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☒ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☒ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☒ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 1/7-/09

By: _____

Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08a (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 22

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	106	US- 3,334,629	8/8/1967	Cohn	
	107	US- 3,540,431	11/17/1970	Mobin-Uddin	
	108	US- 3,628,535	12/21/1971	Ostrowsky et al.	
	109	US- 3,642,004	2/15/1972	Osthagen et al.	
	110	US- 3,657,744	4/25/1972	Ersek	
	111	US- 3,671,979	6/27/1972	Moulopoulos	
	112	US- 3,795,246	3/5/1974	Sturgeon	
	113	US- 3,839,741	10/8/1974	Haller	
	114	US- 3,868,956	3/4/1975	Alfidi et al.	
	115	US- 3,874,388	4/1/1975	King et al.	
	116	US- 4,056,854	11/8/1977	Boretos et al.	
	117	US- 4,106,129	8/15/1978	Carpentier et al.	
	118	US- 4,233,690	11/18/1980	Akins	
	119	US- 4,291,420	9/29/1981	Reul	
	422	US- 4,326,306	4/27/1982	Poler	
	423	US- 4,423,809	1/3/1984	Mazzocco	
	120	US- 4,425,908	1/17/1984	Simon	
	121	US- 4,501,030	2/26/1985	Lane	
	122	US- 4,580,568	4/8/1986	Gianturco	

FOREIGN PATENT DOCUMENTS

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	308	EP 0819013	6/23/2004	Heartport, Inc.		
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	310	EP 1000590 A1	5/17/2000	Cordis Corporation		
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Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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	137	US- 4,917,102	4/17/1990	Miller et al.	
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	317	EP 1229864 B1	4/27/2005	Boston Scientific Limited		
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Art Unit	3774
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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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EFS ID:	4708755
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Angelica Zuniga
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	30-JAN-2009
Filing Date:	12-NOV-2008
Time Stamp:	15:39:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710301.pdf	2045894 40e8426489495ab90735eacd4ec269d665e66449	yes	25

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Information Disclosure Statement Letter		1	3	
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Warnings:					
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Warnings:					
Information:					
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Information:					

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Information:					
		Total Files Size (in bytes):	78832489		

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

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

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	4709108
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Angelica Zuniga
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	30-JAN-2009
Filing Date:	12-NOV-2008
Time Stamp:	15:55:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	NPL Documents	NPL_Andersen_et_al.pdf	743447 8422e22bff7bbbb0c6acef3568838b429fb452bc	no	5

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/269,213	11/12/2008	Amr Salahieh	10012-710.301

CONFIRMATION NO. 9828

POA ACCEPTANCE LETTER

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

OC000000034342043

Date Mailed: 02/10/2009

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/28/2009.

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

/hchristian/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/269,213	11/12/2008	Amr Salahieh	10012-710.301

CONFIRMATION NO. 9828

POWER OF ATTORNEY NOTICE

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

OC000000034341988

Date Mailed: 02/10/2009

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/28/2009.

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

/hchristian/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/269,213	11/12/2008	Amr Salahieh	10012-710.301

CONFIRMATION NO. 9828

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

PUBLICATION NOTICE

OC000000035078460

Title: Everting Heart Valve

Publication No.US-2009-0076598-A1
Publication Date:03/19/2009

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

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Approved for use through 02/28/2009. OMB 0651-0031
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	November 12, 2008
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	440	CN1338951A (Eng Abs)	03/06/2002	Impella Cardiotechnik AG		

Examiner Signature		Date Considered	

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

Electronic Acknowledgement Receipt

EFS ID:	5129643
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Angelica Zuniga
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	09-APR-2009
Filing Date:	12-NOV-2008
Time Stamp:	16:45:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710301.pdf	229511 02f18899d8ed53a460bf37e95d0d787d3f775830	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Filed (SB/08)	4	4

Warnings:					
Information:					
2	Foreign Reference	CN1338951A.pdf	1270365 b45810bc911e30a0fbf53e0c5be3bc52cc93959d	no	14
Warnings:					
Information:					
		Total Files Size (in bytes):	1499876		

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

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

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

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/269,213	Confirmation No.: 9828
Applicant(s):	Amr Salahieh	
Filed:	November 12, 2008	
Art Unit:	3774	
Examiner:	SCHILLLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

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

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

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

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

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

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

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

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

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

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

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

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

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

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

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

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

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

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

☐ **37 CFR § 1.97(d)**

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

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

--AND--

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

☐ **37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☒ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☒ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 4/7/09

By: _____

Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	10012-710.301	9828

66854 7590 04/15/2009

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/269,213	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to system for replacing heart valve including anchors, valve and delivery device classified in class 623, subclass 2.11.

II. Claims 5-8, drawn to system for replacing heart valve including anchors, commissure support and seal, classified in class 623, subclass 2.17.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group 1 and group 2 are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination 1, consisting of the heart valve, has a separate utility where it may be used as a teaching device. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to

provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

FILED VIA EFS ON JUNE 10, 2009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	12/269,213	Confirmation No.:	9828
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	November 12, 2008		
Title	:	Everting Heart Valve		
Group Art Unit	:	3774		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.301		
Customer No.	:	66854		

RESPONSE TO RESTRICTION REQUIREMENT

MailStop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

This communication is in response to the Office Action dated April 15, 2009, for which a reply is due May 15, 2009. A request for extension of time, up to and including **June 15, 2009**, accompanies this response.

Prior to reconsidering this application on the merits, please amend the application as follows:

Amendments to the Specification are not being made.

Amendments to the Claims / Claim Listing begin on page 2 of this paper.

Remarks / Arguments begin on page 3 of this paper.

Amendments to the Claims / Claim Listing

A complete listing of the claims follows.

1. (original) A system for replacing a heart valve, comprising:

an expandable anchor comprising a braided material,

a replacement heart valve; and

a delivery device, wherein the expandable anchor and the replacement heart valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device,

wherein the expandable anchor is axially spaced from the replacement heart valve when the expandable anchor is in the delivery configuration within the delivery device.

2. (original) The system of claim 1 wherein the expandable anchor and the replacement heart valve are coupled to each other.

3. (original) The system of claim 1 wherein the replacement heart valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration within the delivery device.

4. (original) The system of claim 1 wherein at least a portion of the replacement heart valve is disposed within the expandable anchor when the expandable anchor is in a fully deployed configuration.

5. (original) The system of claim 4 wherein at least a portion of the replacement heart valve is disposed axially within the expandable anchor when the expandable anchor is in the fully deployed configuration.

6. - 12. (canceled).

REMARKS

Claim Summary

Claims 1-5 are pending. Claims 6-12 are canceled.

Restriction Requirement

The Examiner required restriction to one of two allegedly distinct inventions as stated in the Office Action of April 15, 2009. Applicants note that the Examiner indicated that the two groups were claims 1-4 and 5-8, respectively. Applicants assume that Examiner meant to state that the two groups were claims 1-5 and 6-12, respectively. Applicants elect group 1, claims 1-5, based on this assumption. Claims 6-12 are canceled.

CONCLUSION

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Date: June 10, 2009 By: _____

Thomas M. Zlogar, Reg. No. 55,760

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/269,213	Confirmation No.: 9828
Applicant(s):	Amr Salahieh	
Filed:	November 12, 2008	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

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

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

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

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

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

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

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

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

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

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

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

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

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

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

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

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

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

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

☐ **37 CFR § 1.97(d)**

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

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

--AND--

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

☐ **37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 6/10/09

By: _____
Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08a (06-09)
Approved for use through 06/30/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	443	US- 5,735,842	4/7/1998	Krueger et al.	
	447	US- 7,191,018	3/13/2007	Gielen et al.	
	444	US- 2003/0109930-A1	6/12/2003	Bluni et al.	
	445	US- 2003/0144732-A1	7/31/2003	Cosgrove et al.	
	446	US- 2004/0133274-A1	7/8/2004	Webler et al.	
	441	US- 2008/0269878-A1	10/30/2008	Iobbi	
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FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	12269213
Filing Date:	12-Nov-2008
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Thomas M. Zlogar/Sue Bromaghim
Attorney Docket Number:	10012-710.301

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	65	65

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**65**

Electronic Acknowledgement Receipt

EFS ID:	5494134
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Sue Bromaghim
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	10-JUN-2009
Filing Date:	12-NOV-2008
Time Stamp:	18:45:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$65
RAM confirmation Number	15721
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		10012-710-301-trans-RespRR-IDS.pdf	887660 e287591ff4da4e64c2381bef6556dc882ea798c1	yes	8

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Extension of Time	1	1
Response to Election / Restriction Filed	2	2
Claims	3	3
Applicant Arguments/Remarks Made in an Amendment	4	4
Transmittal Letter	5	7
Information Disclosure Statement (IDS) Filed (SB/08)	8	8

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	29900 25bc6c36bc00556894b3cec15fe868d2510217af	no	2

Warnings:

Information:

Total Files Size (in bytes):	917560

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

FILED VIA EFS ON JUNE 10, 2009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	12/269,213	Confirmation No.:	9828
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	November 12, 2008		
Title	:	Everting Heart Valve		
Group Art Unit	:	3774		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.301		
Customer No.	:	66854		

TRANSMITTAL OF RESPONSE TO RESTRICTION REQUIREMENT AND REQUEST FOR ONE-MONTH EXTENSION OF TIME TO FILE SAME

MailStop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

Transmitted herewith are the following documents for filing in the above-identified application:

(1) Response to Restriction Requirement, for which no claims fee is due; and
(2) Information Disclosure Statement.

► Request is hereby made for a one-month extension of time to file these documents, up to and including **June 15, 2009**.

☒ The extension fee (one month/small entity) of $65 is authorized via EFS. Please also deduct from Deposit Account 50-4050 any deficit in these fees.

Respectfully submitted,

Date: June 10, 2009 By: _____
Thomas M. Zlogar, Reg. No. 55,760

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Fax: 650.212.7562

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/269,213	11/12/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	06/10/2009	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 5	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/LINDA A. WASHINGTON/

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	10012-710.301	9828

66854 7590 10/02/2009

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
10/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/269,213	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/09, 4/9/09, 6/10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 6/10/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-12 are cancelled from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/10/2009.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. (US Pat. No. 6,425,916) in view of Pai et al. (US Pub. No. 2005/0197694). Garrison et al. discloses the following of the claimed invention: a system for replacing a heart valve,

comprising: an expandable anchor (8), a replacement heart valve (6); and a delivery device (4), wherein the expandable anchor and the replacement heart valve are adapted to be delivered within the delivery device to a vicinity of a heart valve (col. 5, line 61 through col. 6, line 34), and wherein the expandable anchor has a delivery configuration within the delivery device (Figs. 3-4; col. 4, lines 45-65), wherein the expandable anchor is axially spaced from the replacement heart valve when the expandable anchor is in the delivery configuration within the delivery device (Figs. 3-4). Garrison et al. discloses claim 2 as shown in Figures 4-6 and col. 7, line 29 through col. 8, line 9. Claim 3 is shown in Figures 3-4. Claims 4 and 5 are shown in Figures 4-6.

Garrison et al. does not teach the expandable anchor comprising a braided material. Pai et al. teaches prosthetic heart valve and their associated anchors which comprise braided portions in paragraph 0133 for the purpose of allowing a variety of materials to be used to make the anchor, and thus increase its tensile strength. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Garrison et al. to have a braided anchor in order to use a variety of materials, and thus increase its tensile strength.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774

Notice of References Cited	Application/Control No. 12/269,213	Applicant(s)/Patent Under Reexamination SALAHIEH ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,425,916	07-2002	Garrison et al.	623/2.11
*	B	US-2005/0197694	09-2005	Pai et al.	623/002.1
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12269213	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

SEARCHED			
Class	Subclass	Date	Examiner
623	2.1-2.42	9/29/2009	AS

SEARCH NOTES		
Search Notes	Date	Examiner

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/A. S./ Examiner.Art Unit 3774	

PTO/SB/08a (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 22

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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	106	US- 3,334,629	8/8/1967	Cohn	
	107	US- 3,540,431	11/17/1970	Mobin-Uddin	
	108	US- 3,628,535	12/21/1971	Ostrowsky et al.	
	109	US- 3,642,004	2/15/1972	Osthagen et al.	
	110	US- 3,657,744	4/25/1972	Ersek	
	111	US- 3,671,979	6/27/1972	Moulopoulos	
	112	US- 3,795,246	3/5/1974	Sturgeon	
	113	US- 3,839,741	10/8/1974	Haller	
	114	US- 3,868,956	3/4/1975	Alfidi et al.	
	115	US- 3,874,388	4/1/1975	King et al.	
	116	US- 4,056,854	11/8/1977	Boretos et al.	
	117	US- 4,106,129	8/15/1978	Carpentier et al.	
	118	US- 4,233,690	11/18/1980	Akins	
	119	US- 4,291,420	9/29/1981	Reul	
	422	US- 4,326,306	4/27/1982	Poler	
	423	US- 4,423,809	1/3/1984	Mazzocco	
	120	US- 4,425,908	1/17/1984	Simon	
	121	US- 4,501,030	2/26/1985	Lane	
	122	US- 4,580,568	4/8/1986	Gianturco	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	307	EP 0409929 B1	4/23/1997	Boston Scientific Corp.		
	308	EP 0819013	6/23/2004	Heartport, Inc.		
	309	EP 0937439B1	9/17/2003	Heartport, Inc.		
	310	EP 1000590 A1	5/17/2000	Cordis Corporation		
	311	EP 1042045 B1	5/19/2004	Domnick Hunter Ltd.		
	312	EP 1057459	12/6/2000	Numed, Inc.		

Examiner Signature		Date Considered	

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

PTO/SB/08a (09-08)
Approved for use through 10/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 22

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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	438	US- 4,602,911	7/29/1986	Ahmadi et al.	
	123	US- 4,610,688	9/9/1986	Silvestrini et al.	
	124	US- 4,647,283	3/3/1987	Carpentier et al.	
	125	US- 4,648,881	3/10/1987	Carpentier et al.	
	126	US- 4,655,771	4/7/1987	Wallsten	
	127	US- 4,662,885	5/5/1987	DiPisa, Jr.	
	128	US- 4,665,906	5/19/1987	Jervis	
	129	US- 4,710,192	12/1/1987	Liotta et al.	
	130	US- 4,733,665	3/29/1988	Palmaz	
	131	US- 4,796,629	1/10/1989	Grayzel	
	132	US- 4,819,751	4/11/1989	Shimada et al.	
	133	US- 4,834,755	5/30/1989	Silvestrini et al.	
	134	US- 4,856,516	8/15/1989	Hillstead	
	135	US- 4,872,874	10/10/1989	Taheri	
	136	US- 4,909,252	3/20/1990	Goldberger	
	137	US- 4,917,102	4/17/1990	Miller et al.	
	138	US- 4,954,126	9/4/1990	Wallsten	
	139	US- 4,986,830	1/22/1991	Owens et al.	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	313	EP 1057460	12/6/2000	Numed, Inc.		
	314	EP 1059894 B1	7/20/2005	Boston Scientific Limited		
	315	EP 1078610 B1	8/10/2005	Cordis Corp.		
	316	EP 1156757 B1	12/7/2005	Board of Regents, The Univer		
	317	EP 1229864 B1	4/27/2005	Boston Scientific Limited		
	318	EP 1340473 A2	9/3/2003	3F Therapeutics, Inc.		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 22

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

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	141	US- 5,002,559	3/26/1991	Tower	
	142	US- 5,064,435	11/12/1991	Porter	
	143	US- 5,161,547	11/10/1992	Tower	
	144	US- 5,163,953	11/17/1992	Vince	
	145	US- 5,209,741	5/11/1993	Spaeth	
	146	US- 5,217,483	7/8/1993	Tower	
	147	US- 5,258,042	11/2/1993	Mehta	
	148	US- 5,332,402	7/26/1994	Teitelbaum	
	149	US- 5,350,398	9/27/1994	Pavcnik et al.	
	150	US- 5,370,685	12/6/1994	Stevens	
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	152	US- 5,397,351	3/14/1995	Pavcnik et al.	
	153	US- 5,411,552	5/2/1995	Andersen et al.	
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	156	US- 5,443,495	8/22/1995	Buscemi et al.	
	394	US- 5,443,499	8/22/1995	Schmitt, Peter	
	406	US- 5,476,506	12/19/1995	Lunn	
	437	US- 5,476,510	12/19/1995	Eberhardt et al.	

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	319	EP 1356793	10/29/2003	Numed, Inc.		
	320	EP 1430853 A2	6/8/2005	M. I. Tech Co., Ltd.		
	321	EP 1469797(German w/ Eng. Claims	11/2/2005	Figulla, Hans-Reiner		
	322	EP 1576937 A2	9/21/2005	Board of Regents, The Univer		
	323	EP 1582178 A2	10/5/2005	Board of Regents, The Univer		
	324	EP 1582179 A2	10/5/2005	Board of Regents, The Univer		

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Sheet 4 of 22

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Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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	157	US- 5,507,767	4/16/1996	Maeda et al.	
	158	US- 5,545,133	8/13/1996	Burns et al.	
	159	US- 5,545,211	8/13/1996	An et al.	
	160	US- 5,554,185	9/10/1996	Block et al.	
	161	US- 5,575,818	11/19/1996	Pinchuk	
	162	US- 5,645,559	7/8/1997	Hachtman et al.	
	407	US- 5,662,671	9/2/1997	Barbut et al.	
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	165	US- 5,695,498	12/9/1997	Tower	
	166	US- 5,713,953	2/3/1998	Vallana et al.	
	380	US- 5,720,391	2/24/1998	Dohm et al.	
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	325	EP 1600121A1	11/30/2005	William Cook Europe ApS		
	326	EP 1616531	1/18/2006	Boston Scientific Limited		
	327	WO 00/09059	2/24/2000	Prodesco, Inc.		
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Sheet 5 of 22

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Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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	184	US- 5,910,154	6/8/1999	Tsugita et al.	
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	331	WO 00/67661	11/16/2000	Ortiz, Mark		
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	333	WO 01/08596 A1	2/8/2001	Scimed Life Systems, Inc.		
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Sheet 6 of 22

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Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
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Attorney Docket Number	10012-710.301

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	190	US- 5,968,070	10/19/1999	Bley et al.	
	191	US- 5,984,957	11/16/1999	Laptewicz, Jr. et al.	
	439	US- 5,984,959	11/16/1999	Robertson et al.	
	409	US- 5,993,469	11/30/1999	McKenzie et al.	
	410	US- 5,997,557	12/7/1999	Barbut et al.	
	411	US- 6,010,522	1/4/2000	Barbut et al.	
	192	US- 6,022,370	2/8/2000	Tower	
	193	US- 6,027,520	2/22/2000	Tsugita et al.	
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	195	US- 6,042,598	3/28/2000	Tsugita et al.	
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	197	US- 6,123,723	9/26/2000	Konya et al.	
	198	US- 6,162,245	12/19/2000	Jayaraman	
	199	US- 6,165,200	12/26/2000	Tsugita et al.	
	200	US- 6,168,579	1/2/2001	Tsugita	
	201	US- 6,168,614	1/2/2001	Andersen et al.	
	202	US- 6,171,327	1/9/2001	Daniel et al.	
	203	US- 6,179,859	1/30/2001	Bates	
	370	US- 6,197,053	3/6/2001	Cosgrove et al.	

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	337	WO 01/64137(German w/ Eng. Ab)	9/7/2001	Fraunhofer-Gesellschaft Zur F		
	385	WO 02/0041789 A2	5/30/2002	Rex Medical, L. P.		
	338	WO 02/100297	12/19/2002	Rex Medical, L. P.		
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	340	WO 03/003943	1/16/2003	Advanced Bio Prosthetic Surf		
	341	WO 03/003949(French W/ Eng Ab)	1/16/2003	Seguin		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 22

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Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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	204	US- 6,200,336	3/13/2001	Pavcnik et al.	
	205	US- 6,221,006	4/24/2001	Dubrul et al.	
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	401	US- 6,221,096	4/24/2001	Aiba et al.	
	412	US- 6,231,544	5/15/2001	Tsugita et al.	
	413	US- 6,231,551	5/15/2001	Barbut	
	207	US- 6,241,757	6/5/2001	An et al.	
	208	US- 6,245,102	6/12/2001	Jayaraman	
	209	US- 6,258,114	7/10/2001	Konya et al.	
	210	US- 6,258,115	7/10/2001	Dubrul	
	211	US- 6,258,120	7/10/2001	McKenzie et al.	
	212	US- 6,270,513	8/7/2001	Tsugita et al.	
	213	US- 6,277,555	8/21/2001	Duran et al.	
	214	US- 6,309,417	10/30/2001	Spence et al.	
	215	US- 6,319,281	11/20/2001	Patel	
	216	US- 6,327,772	12/11/2001	Zadno-Azizi et al.	
	217	US- 6,336,934	1/8/2002	Gilson et al.	
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	342	WO 03/011195(AB TRN)	2/13/2003	Seguin, Jacques		
	343	WO 03/015851	11/27/2003	Scimed Life Systems, Inc.		
	344	WO 2004/014256 A1	2/19/2004	Abbott Laboratories Vascular		
	345	WO 2004/019811	3/11/2004	Heart Leaflet Technologies		
	346	WO 2004/023980	3/25/2004	3F Therapeutics, Inc.		
	347	WO 2004/026117 A2	4/1/2004	3F Therapeutics, Inc.		

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	348	WO 2004/041126	5/21/2004	Seguin, Jacques		
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 9 of 22

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

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Art Unit	3774
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Attorney Docket Number	10012-710.301

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Application Number	12/269,213
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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
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This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

PTO/SB/08a (01-09)
Approved for use through 02/28/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	November 12, 2008
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	440	CN1338951A (Eng Abs)	03/06/2002	Impella Cardiotechnik AG		

Examiner Signature	/Ann Schillinger/	Date Considered	09/30/2009

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

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Sheet 1 of 1

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	443	US- 5,735,842	4/7/1998	Krueger et al.	
	447	US- 7,191,018	3/13/2007	Gielen et al.	
	444	US- 2003/0109930-A1	6/12/2003	Bluni et al.	
	445	US- 2003/0144732-A1	7/31/2003	Cosgrove et al.	
	446	US- 2004/0133274-A1	7/8/2004	Webler et al.	
	441	US- 2008/0269878-A1	10/30/2008	Iobbi	
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Examiner Signature	/Ann Schillinger/	Date Considered	09/30/2009

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

FILED VIA EFS ON JANUARY 4, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	12/269,213	Confirmation No.:	9828
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	November 12, 2008		
Title	:	Everting Heart Valve		
Group Art Unit	:	3774		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.301		
Customer No.	:	66854		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

AMENDMENT IN RESPONSE TO OFFICE ACTION

Introductory Comments:

This Amendment responds to the non-final Office Action dated October 2, 2009, for which a response is due January 2 (Saturday) or January 4, 2009.

Please enter the amendments and consider the remarks as follows.

Amendments to the Specification are not being made at this time.

Amendments to the Claims begin on page 2.

Remarks / Arguments begin on page 4 of this paper.

Amendments to the Claims:

Please make the amendments as shown. A complete listing of the claims follows:

1. (Currently Amended) A system for replacing a heart valve, comprising:

a replacement heart valve comprising

an expandable anchor comprising a braided material, and

a replacement ~~heart~~ valve; and

a delivery device, wherein the expandable anchor and the replacement ~~heart~~ valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device,

wherein the expandable anchor is axially spaced from the replacement ~~heart~~ valve when the expandable anchor is in the delivery configuration within the delivery device.

2. (Currently Amended) The system of claim 1 wherein the expandable anchor and the replacement ~~heart~~ valve are coupled to each other.

3. (Currently Amended) The system of claim 1 wherein the replacement ~~heart~~ valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration within the delivery device.

4. (Currently Amended) The system of claim 1 wherein at least a portion of the replacement ~~heart~~ valve is disposed within the expandable anchor when the expandable anchor is in a fully deployed configuration.

5. (Currently Amended) The system of claim 4 wherein at least a portion of the replacement ~~heart~~ valve is disposed axially within the expandable anchor when the expandable anchor is in the fully deployed configuration.

6. - 12. (Canceled)

13. (New) The system of claim 1 further comprising an delivery system actuation element which is reversibly coupled to the replacement heart valve.

14. (New) The system of claim 13 wherein the delivery system actuation element remains reversibly coupled to the replacement heart valve after the expandable anchor is deployed from the delivery device.

15. (New) The system of claim 13 wherein the delivery system actuation element is reversibly coupled to a proximal end of the replacement heart valve.

REMARKS

Claim Summary

Claims 1-5 are currently amended. Claims 6-12 were previously canceled. No claims are withdrawn from consideration. Claims 13-15 are new. Claims 1-5 and 13-15 are pending. Cancellation or amendment of any claim is not to be considered a dedication to the public of any subject matter.

Information Disclosure Statements

Applicants note with thanks that the Examiner has considered all references submitted in Information Disclosure Statements dated 1/30/2009, 4/9/2009, and 6/10/2009.

Claim Objections

Claim 3 is objected to as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants respectfully traverse. Claim 3 recites that the replacement valve is *distally* spaced from the expandable anchor, while claim 1 (from which claim 3 depends) recites that the replacement valve is *axially* spaced from the expandable anchor. Claim 3 further limits the subject matter of claim 1 and Applicants therefore request that the objection to claim 3 be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. 6,425,916 to Garrison et al. ("Garrison") in view of U.S. 2005/0197694 to Pai et al. ("Pai").

Independent claim 1 is currently amended to recite, in part, that the replacement heart valve comprises an expandable anchor and a replacement valve. Support for the amendment to claim 1 can be found throughout the application as filed, and as such no new matter is added.

The Examiner maintains that while Garrison does not teach an expandable anchor comprising a braided material, "Pai et al. teaches a prosthetic heart valve and their associated anchor which comprise braided portions," and that "it would have been obvious ... to modify the device of Garrison et al. to have a braided anchor." (page 3, Office Action mailed 10/02/2009). Applicants respectfully disagree. Pai does not teach replacement heart valves, but rather discloses and teaches a mitral valve annuloplasty device which is positioned in the coronary

sinus adjacent the mitral valve. Pai also discloses and teaches devices that pierce the myocardium to reinforce sections of infarcted myocardial tissue. Neither of these types of devices are replacement heart valves as the Examiner suggests. The devices in Pai are positioned in completely different anatomical locations than replacement heart valves and function completely differently than replacement heart valves. Neither of the two general types of devices disclosed in Pai includes a replacement valve to regulate the flow of blood through a lumen. It would not have been obvious to simply combine a structural element from a portion of a device in Pai with a replacement heart valve which includes a replacement valve. For at least these reasons it would not have been obvious to combine the disclosure of Garrison, which teaches a replacement heart valve, with the disclosure of Pai, which does not teach a replacement heart valve. Claim 1 is therefore not unpatentable over Garrison in view of Pai. Claims 2-5 depend from claim 1 and are not unpatentable over Garrison in view of Pai for at least the reasons set forth above.

New Claims

Applicants are adding new dependent claims 13 -15. Exemplary support for claims 13-15 can be found in, at least, paragraphs [0069] and [0130]. No new matter is added. Claims 13-15 depend from claim 1 and are patentable over Garrison and Pai for at least the same reasons set forth above with respect to claim 1.

CONCLUSION

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Date: January 4, 2010

By: _____
Thomas M. Zlogar, Reg. No. 55,760

SHAY GLENN LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
Telephone: 650.212.1700
Facsimile: 650.212.7562

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/269,213	Confirmation No.: 9828
Applicant(s):	Amr Salahieh	
Filed:	November 12, 2008	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

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

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

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

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

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

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

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

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

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

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

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

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

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

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

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

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

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

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

☐ **37 CFR § 1.97(d)**

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

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

--AND--

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

☒ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 1/4/10

By: _____

Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PTO/SB/08a (07-09)
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(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	460	US- 3,409,013	11/5/1968	Berry	
	461	US- 4,655,218	4/7/1987	Kulik et al.	
	462	US- 4,755,181	7/5/1988	Igoe	
	463	US- 4,865,600	9/12/1989	Carpentier et al.	
	456	US- 5,549,665	8/27/1996	Vesely et al.	
	443	US- 5,735,842	4/7/1998	Krueger et al.	
	451	US- 5,769,812	6/23/1998	Stevens et al.	
	465	US- 5,885,228	3/23/1999	Rosenman et al.	
	453	US- 6,454,799	9/24/2002	Schreck	
	466	US- 6,623,518	9/23/2003	Thompson et al.	
	467	US- 6,635,079	10/21/2003	Unsworth et al.	
	468	US- 6,776,791	8/17/2004	Stallings et al.	
	469	US- 7,025,791	4/11/2006	Levine et al.	
	470	US- 7,037,331	5/2/2006	Mitelberg et al.	
	471	US- 7,175,653	2/13/2007	Gaber	
	472	US- 7,175,654	2/13/2007	Bonsignore et al.	
	447	US- 7,191,018	3/13/2007	Gielen et al.	
	473	US- 7,235,093	6/26/2007	Gregorich	
	474	US- 7,258,696	8/21/2007	Rabkin et al.	

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Examiner Signature		Date Considered	

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(Use as many sheets as necessary)

Sheet 2 of 2

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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

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	452	US- 2002/0002396	01/03/2002	Fulkerson	
	455	US- 2002/0188344	12/12/2002	Bolea et al.	
	458	US- 2006/0155312	7/13/2006	Levine et al.	
	444	US- 2003/0109930	06/12/2003	Bluni et al.	
	445	US- 2003/0144732	07/31/2003	Cosgrove et al.	
	446	US- 2004/0133274	07/08/2004	Webler et al.	
	448	US- 2005/0043711	02/24/2005	Corcoran et al.	
	449	US- 2008/0288054	11/20/2008	Pulnev et al.	
	450	US- 2009/0264997**	10/22/2009	Haug et al.	
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Electronic Patent Application Fee Transmittal

Application Number:	12269213
Filing Date:	12-Nov-2008
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	James R. Shay/Sue Bromaghim (TZ)
Attorney Docket Number:	10012-710.301

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	6745639
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	James R. Shay/Sue Bromaghim (TZ)
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10012-710.301
Receipt Date:	04-JAN-2010
Filing Date:	12-NOV-2008
Time Stamp:	18:15:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	4556
Deposit Account	504050
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1		10012-710-301-Amend-IDS.pdf	1263882 ec22b4461e092f9e08dc6f26292f249194aef224	yes	10

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	3
Applicant Arguments/Remarks Made in an Amendment	4	5
Transmittal Letter	6	8
Information Disclosure Statement (IDS) Filed (SB/08)	9	10

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	29997 2d54dcf11c8c104a6a97a9a4a6a6ffe565bdceba	no	2

Warnings:

Information:

Total Files Size (in bytes):	1293879

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/269,213	11/12/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	82		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	82		TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 01/04/2010

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 8	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/KIMBERLY JONES/

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	497	US- 4,617,932	10/21/1986	Kornberg	
	498	US- 5,002,556	3/26/1991	Ishida et al.	
	499	US- 5,336,258	8/9/1994	Quintero et al.	
	500	US- 5,480,423	1/2/1996	Ravenscroft et al.	
	501	US- 5,693,083	12/2/1997	Baker et al.	
	494	US- 5,716,370	2/10/1998	Williamson, IV et al.	
	502	US- 5,733,325	3/31/1998	Robinson et al.	
	476	US- 5,807,405	9/15/1998	Vanney et al.	
	477	US- 5,861,024	1/19/1999	Rashidi	
	503	US- 6,165,209	12/26/2000	Patterson et al.	
	504	US- 6,187,016	2/13/2001	Hedges et al.	
	505	US- 6,214,036	4/10/2001	Letendre et al.	
	506	US- 6,267,783	7/31/2001	Letendre et al.	
	478	US- 6,416,510	7/9/2002	Altman et al.	
	480	US- 6,663,588	12/16/2003	DuBois et al.	
	507	US- 6,676,692	1/13/2004	Rabkin et al.	
	508	US- 6,814,746	11/9/2004	Thompson et al.	
	509	US- 6,837,901	1/4/2005	Rabkin et al.	
	510	US- 6,843,802	1/18/2005	Villalobos et al.	

FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

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

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Usa as many sheets as nacessary)

Sheet 2 of 3

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	511	US- 6,881,220	4/19/2005	Edwin et al.	
	512	US- 6,936,058	8/30/2005	Forde et al.	
	513	US- 7,632,298	12/15/2009	Hijlkema et al.	
	482	US- 2002/0177766	11/28/2002	Mogul	
	485	US- 2004/0181140	9/16/2004	Falwell et al.	
	514	US- 2005/0182486	8/18/2005	Gabbay	
	516	US- 2007/0016286	1/18/2007	Herrmann et al.	
	487	US- 2008/0188928**	08/07/2008	Salahieh et al.	
		US-			
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FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

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

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 3

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	495	PAUL et al.; U.S. Pat. App. # 12/578,463 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	
	496	PAUL et al.; U.S. Pat. App. # 12/578,447 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	

Examiner Signature		Date Considered	

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

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	12269213
Filing Date:	12-Nov-2008
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Thomas M. Zlogar/Angelica Zuniga
Attorney Docket Number:	10012-710.301

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	7294021
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Angelica Zuniga
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	26-MAR-2010
Filing Date:	12-NOV-2008
Time Stamp:	14:04:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	324
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710301_IDS.pdf	897271 ddfdfea75e3f93f7d1c0ef6ae6b8858f8bc2440e	yes	6

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Transmittal Letter	1	3
Information Disclosure Statement (IDS) Filed (SB/08)	4	6

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	29763 79a530013d1d7afc84efcd825938a713b8a6ea50	no	2

Warnings:

Information:

Total Files Size (in bytes):	927034

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/269,213	Confirmation No.: 9828
Applicant(s):	Amr Salahieh	
Filed:	November 12, 2008	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

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

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

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

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

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

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

FILING OF INFORMATION DISCLOSURE STATEMENT

☐ **37 CFR §1.97(b)**

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

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

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

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

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

☒ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

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

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

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

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

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

☐ **37 CFR § 1.97(d)**

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

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

--AND--

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

☒ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 7/25/10

By: _____

Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	10012-710.301	9828

66854 7590 04/14/2010

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
04/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/269,213	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/4/10, 3/26/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. (US Pat. No. 6,425,916) in view of Pai et al. (US Pub. No. 2005/0197694). Garrison et al. discloses the following of the claimed invention: a system for replacing a heart valve, comprising: a replacement heart valve (Figs. 5-6) comprising: an expandable anchor (8), a replacement valve (6); and a delivery device (4), wherein the expandable anchor and the replacement heart valve are adapted to be delivered within the delivery device to a vicinity of a heart valve (col. 5, line 61 through col. 6, line 34), and wherein the expandable anchor has a delivery configuration within the delivery device (Figs. 3-4; col. 4, lines 45-65), wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration within the delivery device (Figs. 3-4). Garrison et al. discloses claim 2 as shown in Figures 4-6 and col. 7, line 29 through col. 8, line 9. Claim 3 is shown in Figures 3-4. Claims 4 and 5 are shown in Figures 4-6. Regarding claims 13-15, the examiner is interpreting the delivery system actuation element to be the balloon expandable members of Garrison et al. (please see elements 50 and 52). These elements are reversibly coupled to the replacement heart valve as they may be retracted and removed from the replacement heart valve after performing their expanding functions (Figures 3-6; col. 7, line 49 through col. 8, line 9).

Garrison et al. does not teach the expandable anchor comprising a braided material. Pai et al. teaches prosthetic heart valve and their associated anchors which comprise braided portions in paragraph 0133 for the purpose of allowing a variety of materials to be used to make the anchor, and thus increase its tensile strength. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Garrison et al. to have a braided anchor in order to use a variety of materials, and thus increase its tensile strength.

Response to Arguments

Applicant's arguments, see response, filed 1/4/2010, with respect to the objection to claim 3 have been fully considered and are persuasive. The objection to claim 3 of the office action dated 10/2/2009 has been withdrawn.

The Applicant contends that Garrison et al. and Pai et al. may not be combined because Pai et al. does not teach a replacement heart valve. The examiner respectfully disagrees. It has been held that a prior art reference must either be in the field of Applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the Applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Pai et al. is reasonably pertinent to the particular problem with which the Applicant was concerned. The Pai et al. reference looks to provide tensioning structures to improve congestive heart disease and related valvular dysfunction. One of ordinary skill in the art could reasonably apply these tensioning/anchoring devices of Pai et al. to Garrison et al. in order to have a steady anchorage system of increased tensile strength.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

PTO/SB/08a (07-09)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	460	US- 3,409,013	11/5/1968	Berry	
	461	US- 4,655,218	4/7/1987	Kulik et al.	
	462	US- 4,755,181	7/5/1988	Igoe	
	463	US- 4,865,600	9/12/1989	Carpentier et al.	
	456	US- 5,549,665	8/27/1996	Vesely et al.	
	443	US- 5,735,842	4/7/1998	Krueger et al.	
	451	US- 5,769,812	6/23/1998	Stevens et al.	
	465	US- 5,885,228	3/23/1999	Rosenman et al.	
	453	US- 6,454,799	9/24/2002	Schreck	
	466	US- 6,623,518	9/23/2003	Thompson et al.	
	467	US- 6,635,079	10/21/2003	Unsworth et al.	
	468	US- 6,776,791	8/17/2004	Stallings et al.	
	469	US- 7,025,791	4/11/2006	Levine et al.	
	470	US- 7,037,331	5/2/2006	Mitelberg et al.	
	471	US- 7,175,653	2/13/2007	Gaber	
	472	US- 7,175,654	2/13/2007	Bonsignore et al.	
	447	US- 7,191,018	3/13/2007	Gielen et al.	
	473	US- 7,235,093	6/26/2007	Gregorich	
	474	US- 7,258,696	8/21/2007	Rabkin et al.	

FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

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(Use as many sheets as necessary)

Sheet 2 of 2

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Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

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	452	US- 2002/0002396	01/03/2002	Fulkerson	
	455	US- 2002/0188344	12/12/2002	Bolea et al.	
	458	US- 2006/0155312	7/13/2006	Levine et al.	
	444	US- 2003/0109930	06/12/2003	Bluni et al.	
	445	US- 2003/0144732	07/31/2003	Cosgrove et al.	
	446	US- 2004/0133274	07/08/2004	Webler et al.	
	448	US- 2005/0043711	02/24/2005	Corcoran et al.	
	449	US- 2008/0288054	11/20/2008	Pulnev et al.	
	450	US- 2009/0264997**	10/22/2009	Haug et al.	
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Examiner Signature	/Ann Schillinger/	Date Considered	02/02/2010

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Sheet 1 of 3

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	497	US- 4,617,932	10/21/1986	Kornberg	
	498	US- 5,002,556	3/26/1991	Ishida et al.	
	499	US- 5,336,258	8/9/1994	Quintero et al.	
	500	US- 5,480,423	1/2/1996	Ravenscroft et al.	
	501	US- 5,693,083	12/2/1997	Baker et al.	
	494	US- 5,716,370	2/10/1998	Williamson, IV et al.	
	502	US- 5,733,325	3/31/1998	Robinson et al.	
	476	US- 5,807,405	9/15/1998	Vanney et al.	
	477	US- 5,861,024	1/19/1999	Rashidi	
	503	US- 6,165,209	12/26/2000	Patterson et al.	
	504	US- 6,187,016	2/13/2001	Hedges et al.	
	505	US- 6,214,036	4/10/2001	Letendre et al.	
	506	US- 6,267,783	7/31/2001	Letendre et al.	
	478	US- 6,416,510	7/9/2002	Altman et al.	
	480	US- 6,663,588	12/16/2003	DuBois et al.	
	507	US- 6,676,692	1/13/2004	Rabkin et al.	
	508	US- 6,814,746	11/9/2004	Thompson et al.	
	509	US- 6,837,901	1/4/2005	Rabkin et al.	
	510	US- 6,843,802	1/18/2005	Villalobos et al.	

FOREIGN PATENT DOCUMENTS

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Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Usa as many sheets as nacessary)

Sheet 2 of 3

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Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

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	511	US- 6,881,220	4/19/2005	Edwin et al.	
	512	US- 6,936,058	8/30/2005	Forde et al.	
	513	US- 7,632,298	12/15/2009	Hijlkema et al.	
	482	US- 2002/0177766	11/28/2002	Mogul	
	485	US- 2004/0181140	9/16/2004	Falwell et al.	
	514	US- 2005/0182486	8/18/2005	Gabbay	
	516	US- 2007/0016286	1/18/2007	Herrmann et al.	
	487	US- 2008/0188928**	08/07/2008	Salahieh et al.	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 3

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Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	495	PAUL et al.; U.S. Pat. App. # 12/578,463 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	
	496	PAUL et al.; U.S. Pat. App. # 12/578,447 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	

Examiner Signature	/Ann Schillinger/	Date Considered	04/06/2010

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12269213	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Updated prior search	4/4/2010	AS

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/A. S./ Examiner.Art Unit 3774	

Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Request for Continued Examination (RCE) Transmittal

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

Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr SALAHIEH et al.
Art Unit	3774
Examiner Name	Ann M. SCHILLINGER
Attorney Docket Number	10012-710.301

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☑ Other Amendment Accompanying RCE, filed herewith

   b. ☑ Enclosed

      i. ☑ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☑ Other Disclosure Transmittal Letter

2. Miscellaneous

   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 50-4050.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	Thom Z	Date	JUNE 23, 2010
Name (Print/Type)	THOMAS M. ZLOGAR	Registration No.	55,760

CERTIFICATE OF MAILING OR TRANSMISSION

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

Signature	FILED VIA EFS		
Name (Print/Type)	SUE BROMAGHIM	Date	JUNE 23, 2010

FILED VIA EFS ON JUNE 23, 2010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	12/269,213	Confirmation No.:	9828
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	November 12, 2008		
Title	:	Everting Heart Valve		
Group Art Unit	:	3774		
Examiner	:	Ann M. SCHILLINGER		
Docket No.	:	10012-710.301		
Customer No.	:	66854		

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

AMENDMENT ACCOMPANYING RCE

Introductory Comments:

This Amendment accompanies a Request for Continued Examination, and is responsive to the final Office Action mailed April 14, 2010, for which a response is due July 14, 2010.

Please enter the amendments and consider the remarks as follows.

Amendments to the Specification are not being made at this time.

Amendments to the Claims begin on page 2.

Remarks / Arguments begin on page 5 of this paper.

Amendments to the Claims:

Please make the amendments as shown. A complete listing of the claims follows:

1. (Currently Amended) A system for replacing a heart valve, comprising:

a replacement heart valve comprising

an expandable anchor comprising a braided material, and

a replacement valve; ~~and~~

a delivery device, wherein the expandable anchor and the replacement valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device[[,]]; and

a plurality of delivery system actuation elements reversibly coupled to a proximal end of the replacement heart valve when the expandable anchor is in the delivery configuration,

wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration within the delivery device.

2. (Previously Presented) The system of claim 1 wherein the expandable anchor and the replacement valve are coupled to each other.

3. (Previously Presented) The system of claim 1 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration within the delivery device.

4. (Previously Presented) The system of claim 1 wherein at least a portion of the replacement valve is disposed within the expandable anchor when the expandable anchor is in a fully deployed configuration.

5. (Previously Presented) The system of claim 4 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in the fully deployed configuration.

6. - 13. (Canceled)

14. (Currently Amended) The system of claim 13 wherein the plurality of delivery system actuation ~~element remains~~ elements remain reversibly coupled to the replacement heart valve after the expandable anchor is deployed from the delivery device.

15. (Canceled)

16. (New) A system for replacing a heart valve, comprising:

a replacement heart valve comprising

an expandable anchor comprising a braided material, and

a replacement valve;

a delivery device, wherein the expandable anchor and the replacement valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device; and

a delivery system control element adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration,

wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration.

17. (New) The system of claim 16 wherein the system comprises a plurality of delivery system control elements adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration.

18. (New) The system of claim 16 wherein the expandable anchor and the replacement valve are coupled to each other.

19. (New) The system of claim 16 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration.

20. (New) The system of claim 16 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in a fully deployed configuration.

21. (New) The system of claim 16 wherein the control element is adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is outside of the delivery device.

22. (New) The system of claim 1 wherein the plurality of actuation elements are adapted to apply a distally directed force on the replacement heart valve when reversibly coupled thereto.

REMARKS

Claim Summary

Claims 1 and 14 are currently amended. Claims 13 and 15 are canceled. Claims 6-12 were previously canceled. Claims 16-22 are new. Claims 1-5, 14 and 16-22 are currently pending. Cancellation or amendment of any claim herein is not to be considered a dedication to the public of any subject matter.

Interview Summary

Applicants thank the Examiner for conducting the telephone interview on June 22, 2010 with the undersigned. During the interview the Garrison reference was discussed, as were potential amendments to the claims. The Examiner indicated that amendments made herein appeared to overcome the rejections, but would consider the arguments further when filed in a response.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-5 and 13-15 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. 6,425,916 to Garrison et al. ("Garrison") in view of U.S. 2005/0197694 to Pai et al. ("Pai").

Without agreeing or acquiescing with the rejection, claim 1 is currently amended to expedite prosecution of the pending claims. Claim 1 recites, in part, a system for replacing a heart valve, including a replacement heart valve comprising an expandable anchor comprising a braided material, and a replacement valve; and a plurality of delivery system actuation elements reversibly coupled to a proximal end of the replacement heart valve when the expandable anchor is in the delivery configuration. Exemplary support for the amendment to claim 1 can be found in at least Figures 4A-4E, Figure 23, Figure 24, Figure 27, Figure 40C, 41A-41D, and the accompanying descriptions thereof.

While Applicants do not agree with the Examiner's reliance on the expansion balloon from Garrison as a teaching of a delivery system actuation element as claimed, claim 1 is amended and recites, in part, "a plurality of delivery system actuation elements reversibly coupled to a proximal end of the replacement heart valve." The expansion balloon in Garrison can not be interpreted as "a plurality of delivery system actuation elements" as required by claim

1. For at least this reason Garrison does not teach or suggest the limitations in claim 1. Pai does not overcome the deficiencies of Garrison, and for at least this reason claim 1 is not unpatentable over Garrison in view of Pai. Claims 2-5 and 14 depend from claim 1 and are not unpatentable over Garrison in view of Pai for at least the same reasons as claim 1. Claims 13 and 15 are canceled and thus those rejections are moot.

New Claims

Applicants are adding new independent claim 16 and claims 17-21 depending therefrom. Independent claim 16 is similar to claim 1, but recites "a delivery system control element adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration." Exemplary support for a "control element adapted to pass through a proximal region of the replacement heart valve," as claimed, can be found in a "control wire" 62 that "loop[s] through the proximal region" of the replacement valve. (paragraph [0106] of the published application; also see "control wires 62" in paragraph [0130]). Additional support for the new claims can be found in the original claims. No new matter is being added.

Garrison does not teach or suggest "a delivery system control element adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration," as recited in independent claim 16. Pai does not overcome the deficiencies of Garrison, and for at least this reason independent claim 16 and dependent claims 17-21 are patentable over Garrison in view of Pai.

New claim 22 depends from independent claim 1, support for which can be found throughout the application as filed. Claim 22 is patentable over Garrison in view of Pai for at least the same reasons as claim 1.

CONCLUSION

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Date: June 23, 2010

By: 
Thomas M. Zlogar, Reg. No. 55,760

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Facsimile: 650.212.7562

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/269,213	Confirmation No.: 9828
Applicant(s):	Amr Salahieh	
Filed:	November 12, 2008	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

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

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

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

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

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

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

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

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

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

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

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

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

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

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

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

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

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

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

☐ **37 CFR § 1.97(d)**

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

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

--AND--

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☒ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☐ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 6/23/10

By: Thomas Zlogar

Thomas Zlogar Reg. # 55760

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Customer No. 66854

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	525	US- 5,571,215	11/5/1996	Sterman et al.	
	528	US- 6,142,987	11/7/2000	Tsugita	
	524	US- 2001/0044652	11/22/2001	Moore	
	526	US- 2002/0026233	2/28/2002	Shaknovich	
	527	US- 2004/0148021	7/29/2004	Cartledge et al.	
		US-			
		US-			
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		US-			
		US-			

FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

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

PTO/SB/08b (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use es meny sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	529	SALAHIEH et al.; U.S. Pat. App. # 12/777,161 entitled "Two-Part Package for Medical Implant," filed 5/10/2010	

Examiner Signature		Date Considered	

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

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

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

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

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/269,213	Confirmation No.: 9828
Applicant(s):	Amr Salahieh	
Filed:	November 12, 2008	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

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

DISCLOSURE TRANSMITTAL LETTER:
COMMONLY-OWNED APPLICATION(S) / PATENT(S)

Sir:

The following page contains a list of commonly-owned patent applications, publications and/or patents, along with their corresponding cite numbers. The items identified on the list have been included in Information Disclosure Statements submitted previously in the above-identified application.

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions issued in any of the commonly-owned applications, publications and/or patents identified on the list, please inform the undersigned.

Respectfully Submitted,

Dated: 6/23/10

By: Thomas Zlogar
Thomas Zlogar Reg. # 55760

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Customer No. 66854

Cite No.	*Application No.*	*Publication No.*	*Patent No.*
77			7,329,279
74			7,381,219
84			7,445,631
303			7,712,606
70		2005/0137686	
71		2005/0137687	
72		2005/0137688	
73		2005/0137689	
75		2005/0137691	
76		2005/0137692	
78		2005/0137694	
304		2005/0137695	
79		2005/0137696	
80		2005/0137697	
81		2005/0137698	
82		2005/0137699	
83		2005/0137701	
85		2005/0143809	
99		2005/0283231	
298		2006/0058872	
302		2006/0173524	
297		2006/0253191	
296		2006/0287668	
305		2007/0010876	
306		2007/0010877	
299		2007/0112355	
301		2007/0118214	
374		2007/0162107	
372		2007/0203503	
373		2007/0244552	
399		2008/0125859	
403		2008/0234814	
435		2009/0054969	

Electronic Patent Application Fee Transmittal

Application Number:	12269213
Filing Date:	12-Nov-2008
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Thomas M. Zlogar/Sue Bromaghim
Attorney Docket Number:	10012-710.301

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**405**

Electronic Acknowledgement Receipt

EFS ID:	7879298
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Sue Bromaghim
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	23-JUN-2010
Filing Date:	12-NOV-2008
Time Stamp:	17:43:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$405
RAM confirmation Number	4582
Deposit Account	504050
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710-301-RCE-Amend-IDS-MiscLtr.pdf	1572087 ff6d663d9633ff7ea3c3e203e0e4111b43ef7090	yes	15

Multipart Description/PDF files in .zip description

Document Description	Start	End
Request for Continued Examination (RCE)	1	1
Amendment Submitted/Entered with Filing of CPA/RCE	2	2
Claims	3	5
Applicant Arguments/Remarks Made in an Amendment	6	8
Transmittal Letter	9	11
Information Disclosure Statement (IDS) Filed (SB/08)	12	13
Miscellaneous Incoming Letter	14	15

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	30005 b841983d366314541186ab1347f772acf43b1485	no	2

Warnings:

Information:

Total Files Size (in bytes):	1602092

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/269,213	11/12/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 06/23/2010	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 13	Minus	** 20	= 0	X $26 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/DAWN BREWER/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	10012-710.301	9828

66854 7590 06/28/2010

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
06/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	12/269,213	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Thomas Zlogar*. (3)_____.

(2) *Ann Schillinger*. (4)_____.

Date of Interview: *6/22/2010*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *1*.

Identification of prior art discussed: *Garrisom et al. (US Pat. No. 6,425,916); Pai et al. (US Pub. No. 2005/0197694)*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *The claims were discussed in light of the Garrison et al. and the Pai et al. references. Potential amendments to the claims may include further describing the delivery system of the replacement heart valve* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/A. S./ Examiner, Art Unit 3774	/DAVID ISABELLA/ Supervisory Patent Examiner, Art Unit 3774

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	538	US- 5,534,007	7/9/1996	St. Germain et al.	
	533	US- 5,860,966	1/19/1999	Tower	
	539	US- 6,093,203	7/25/2000	Uflacker	
	536	US- 6,251,135	6/26/2001	Stinson et al.	
	540	US- 6,676,668	1/13/2004	Mercereau et al.	
	541	US- 6,764,503	7/20/2004	Ishimaru	
	537	US- 7,201,772	4/10/2007	Schwammenthal et al.	
	531	US- 2003/0040791	2/27/2003	Oktay	
	543	US- 2003/0114912	6/19/2003	Sequin et al.	
	544	US- 2003/0135257	7/17/2003	Taheri	
	545	US- 2003/0225445	12/4/2003	Derus et al.	
	546	US- 2004/0220655	11/4/2004	Swanson et al.	
		US-			
		US-			
		US-			
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		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	534	WO03/030776 A2	4/17/2003	Gabbay, Shlomo		
	535	WO03/094797	11/20/2003	Cordis Corporation		

Examiner Signature		Date Considered	

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

Electronic Acknowledgement Receipt

EFS ID:	8521750
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Angelica Zuniga
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-710.301
Receipt Date:	29-SEP-2010
Filing Date:	12-NOV-2008
Time Stamp:	11:50:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-710301_IDS.pdf	593371 8fc260f5e1ea9577020a1ebf799c7652482f9423	yes	4

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	3	
	Information Disclosure Statement (IDS) Filed (SB/08)		4	4	
Warnings:					
Information:					
2	Foreign Reference	WO03030776A2.pdf	2784905 253450eaddc03d43eb1af14b95214a6bbe2d7054	no	56
Warnings:					
Information:					
3	Foreign Reference	WO03094797A1.pdf	2870914 2b974b3ca1847c151a590324ddcd04451b2bf440	no	92
Warnings:					
Information:					
		Total Files Size (in bytes):	6249190		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/269,213	Confirmation No.: 9828
Applicant(s):	Amr Salahieh	
Filed:	November 12, 2008	
Art Unit:	3774	
Examiner:	SCHILLINGER, ANN M	
Title:	EVERTING HEART VALVE	
Customer No.:	66854	

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

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98

Sir:

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

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

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

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

FILING OF INFORMATION DISCLOSURE STATEMENT

☒ **37 CFR §1.97(b)**

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

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

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

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

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

☐ **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

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

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

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

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

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

☐ **37 CFR § 1.97(d)**

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

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

--AND--

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

☐ **3).** Items identified by a double asterisk (**) on the SB08A are *commonly-owned U.S. patents and U.S. patent application publications.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), *Commonly-owned, unpublished U.S. applications cited**

☐ **1).** A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.

☐ **2).** A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **3).** A copy of each application specification is not submitted because the application is stored in the IFW.

Applicant(s) assume the Examiner has access to the file histories of these items. However, if the Examiner would like to receive copies of Office Actions in any of the commonly-owned applications, publications and/or patents identified on the attached SB08, please inform the undersigned and copies will be provided.

☐ **37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**

☐ **1).** A legible copy of each publication or that portion which caused it to be listed is attached.

☐ **2).** A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☒ **37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**

☒ **1).** A legible copy of each foreign patent or that portion which caused it to be listed is attached.

☐ **2).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

☐ **37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**

☐ **1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached **--AND—**

☐ **2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:

--OR--

☐ **2b).** A copy of a written, English-language translation or portion thereof is readily available and attached,

--OR--

☐ **2c).** An English language copy of a foreign search report is submitted.

--OR--

☐ **3).** A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date: .

STATEMENT UNDER 37 CFR § 1.97(e)

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

FEE AUTHORIZATION

☒ The Commissioner is hereby authorized to charge the above-referenced fees of $0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 9/28/10

By: Thomas Zlogar

Thomas Zlogar Reg. # 55760

Shay Glenn LLP
2755 Campus Drive, Suite 210
San Mateo, CA 94403
(650) 212-1700
Customer No. 66854

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch
Application No.:	12/269213
Filed:	November 12, 2008
For:	Everting Heart Valve
Examiner:	Ann M. Schillinger
Group Art Unit:	3774

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

Docket No: S63.2N-15141-US02

REVOCATION OF POWER OF ATTORNEY AND APPOINTMENT OF NEW ATTORNEY

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

I hereby appoint all practitioners associated with Customer Number 00490 as my/our attorney(s) or (agent(s) to prosecute the above identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please address all future correspondence to James M. Urzedowski at Customer Number 00490.

I am the:

□ Applicant/Inventor

■ Assignee of record of the entire interest. *(See 37 CFR 3.71)*
Statement under 37 CFR 3.73(b) or copy of previously filed 3.73(b) statement is enclosed.

Respectfully submitted,

SADRA MEDICAL, INC.

Date: 2/9/11

By: _____
Name: Ken Martin
Title: President & CEO

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch
Application No.:	12/269213
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No: S63.2N-15141-US02

NOTIFICATION OF CHANGE OF ENTITY STATUS

Applicant is no longer entitled to claim small entity status. Please update the record to reflect large entity status for this case.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

Electronic Acknowledgement Receipt

EFS ID:	9431023
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	James M. Urzedowski/Samantha Painschab
Filer Authorized By:	James M. Urzedowski
Attorney Docket Number:	10012-710.301
Receipt Date:	11-FEB-2011
Filing Date:	12-NOV-2008
Time Stamp:	17:37:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US02_tra_20110211.pdf	84451 d172aa09df907849a285f9900d6115e838c667b9	no	1

Warnings:	
Information:	

2	Assignee showing of ownership per 37 CFR 3.73(b).	15141US02_sta_20110207.pdf	70574 32f84b823fe3bf211ad683534035fd9bfe907df7	no	1
Warnings:					
Information:					
3	Power of Attorney	15141US02_executedPOA.pdf	27723 e341db0979559a126b11904e6146dccec2d017ed	no	1
Warnings:					
Information:					
4	Miscellaneous Incoming Letter	15141US02_entity_status_20110211.pdf	66490 2501ea33e3aeaed5dbd95b9208235a65118b9a51	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	249238		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch
Application No.:	12/269213
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Group Art Unit:	3774

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

Docket No: S63.2N-15141-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
1 page Revocation of Power of Attorney and Appointment of New Attorney; 1 page Assignee's Statement of Ownership and 1 page Notification of Change of Entity Status.

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on February 11, 2011.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch
Application No.:	12/269213
Filed:	November 12, 2008
For:	Everting Heart Valve
Examiner:	Ann M. Schillinger
Group Art Unit:	3774

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

Docket No: S63.2N-15141-US02

ASSIGNEE'S STATEMENT OF OWNERSHIP 37 CFR 3.73(B)

Sadra Medical, Inc., a corporation, is the assignee of the entire right, title and interest in the patent application identified above by virtue of a chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From : Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth Michlitsch
   To: Sadra Medical, Inc.
   The document was recorded in the Patent and Trademark Office at Reel 022289, Frame 0822, or for which a copy thereof is attached.

The undersigned is empowered to sign this statement of ownership certificate on behalf of the assignee.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/269,213	11/12/2008	Amr Salahieh	S63.2N-15141-US02

CONFIRMATION NO. 9828

490
VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

POA ACCEPTANCE LETTER

OC000000046059651

Date Mailed: 02/18/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2011.

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

/erimando/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/269,213	11/12/2008	Amr Salahieh	10012-710.301

CONFIRMATION NO. 9828

POWER OF ATTORNEY NOTICE

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Date Mailed: 02/18/2011

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2011.

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

/erimando/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/269,213	11/12/2008	3774	462	S63.2N-15141-US02	12	2

CONFIRMATION NO. 9828

CORRECTED FILING RECEIPT

490
VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

Date Mailed: 02/25/2011

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

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

Power of Attorney: The patent practitioners associated with Customer Number 00490

Domestic Priority data as claimed by applicant

This application is a CON of 10/870,340 06/16/2004 PAT 7,780,725

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)

If Required, Foreign Filing License Granted: 12/04/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/269,213**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

Everting Heart Valve

Preliminary Class

623

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

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

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

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/269,213
	Filing Date	11/12/2008
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Client Number	BostonScientificScimedInc.
Page 1 of 14	**Matter Number**	S63.2-15141-US02

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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	2	20010002445	5/31/2001	Vesely	
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	29	20040049266	3/11/2004	Anduiza et al.	
	30	20040059409	3/25/2004	Stenzel	

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U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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Page 3 of 14	**Matter Number**	S63.2-15141-US02

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Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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Page 4 of 14	**Matter Number**	S63.2-15141-US02

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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	119	3755823	9/4/1973	Hancock	
	120	3997923	12/21/1976	Possis	

Examiner Signature		**Date Considered**	
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U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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	149	4873978	10/17/1989	Ginsburg	
	150	4878495	11/7/1989	Grayzel	

Examiner Signature		**Date Considered**	
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Page 6 of 14	**Matter Number**	S63.2-15141-US02

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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	175	5360444	11/1/1994	Kusuhara	
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	177	5443446	8/22/1995	Shturman	
	178	5443449	8/22/1995	Buelna	
	179	5480424	1/2/1996	Cox	
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Examiner Signature		**Date Considered**	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/269,213
	Filing Date	11/12/2008
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Client Number	BostonScientificScimedInc.
Page 7 of 14	**Matter Number**	S63.2-15141-US02

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Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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Page 8 of 14	**Matter Number**	S63.2-15141-US02

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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Page 12 of 14	**Matter Number**	S63.2-15141-US02

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GENERAL
Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed. Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING
In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT
No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

FEE
No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

SIGNATURE			
Signature	/James M. Urzedowski/	Date	3/23/2012
Name	James M. Urzedowski	Registration Number	48596

Electronic Acknowledgement Receipt

EFS ID:	12379867
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	James M. Urzedowski/Samantha Painschab
Filer Authorized By:	James M. Urzedowski
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	23-MAR-2012
Filing Date:	12-NOV-2008
Time Stamp:	14:20:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US02_tra_20120323.pdf	80309 4ba8da8464329816c8bbbfdc07cd54db4e557b13	no	1

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
14 page Information Disclosure Statement; 17 Non-Patent Literature Documents; 41 Foreign References.

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on March 23, 2012.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: March 23, 2012

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
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Respectfully submitted,

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Date: March 23, 2012

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Registration No.: 48596

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
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f:\wpwork\jmu\15141us02_tra2_20120323.doc

Electronic Acknowledgement Receipt

EFS ID:	12380385
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	James M. Urzedowski/Samantha Painschab
Filer Authorized By:	James M. Urzedowski
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	23-MAR-2012
Filing Date:	12-NOV-2008
Time Stamp:	14:42:55
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US02_tra2_20120323.pdf	80035 5c43369cb4b2879494fe793b1dd326cfddbd7042	no	1

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10	Foreign Reference	WO2005004753A1.pdf	1569937 9a99f094ab7ce0dd9f338ef8ac6f888a5271b319	no	54
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New Applications Under 35 U.S.C. 111

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

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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6364895		2002-04-02	Greenhalgh	
	2	6346116		2002-02-12	Brooks, et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20020161390		2002-10-31	Mouw	
	2	20030100919		2003-05-29	Hopkins, et al.	
	3	20030057156		2003-03-27	Peterson, et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Examiner's First Report on AU Patent Application No. 2011202667, issued on May 17, 2012.	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/James M. Urzedowski/	Date (YYYY-MM-DD)	2012-06-29
Name/Print	James M. Urzedowski	Registration Number	48596

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	13141760
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	James M. Urzedowski/Samantha Painschab
Filer Authorized By:	James M. Urzedowski
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	29-JUN-2012
Filing Date:	12-NOV-2008
Time Stamp:	12:38:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US02_tra_20120627.pdf	80623 b144e9e367f60f83c05ecb8dac356b3188992c75	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	15141US02_IDS_20120627.pdf	612399 2aebf38843d4d7c6d1a88ad27c5e12b565722a41	no	4
Warnings:					
Information:					
3	Non Patent Literature	Examiners_First_Report_on_AU_App_No_2011202667.pdf	272422 23dccfd1453abcfe4b8e6dea5a9718058fc42758	no	3
Warnings:					
Information:					
			Total Files Size (in bytes):	965444	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
4 page Supplemental IDS; 1 Non-Patent Literature Document.

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on June 29, 2012.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: June 29, 2012

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

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Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
v:\wpwork\jmu\15141us02_tra_20120627.doc

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8226710		2012-07-24	Nguyen et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040019374		2004-01-29	Hojeibane et al.	
	2	20060149360		2006-07-06	Schwammenthal et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/James A. Zak, Esq./	Date (YYYY-MM-DD)	2012-09-11
Name/Print	James A. Zak	Registration Number	60190

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	13715079
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	James Anthony Zak
Filer Authorized By:	
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	11-SEP-2012
Filing Date:	12-NOV-2008
Time Stamp:	17:40:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US02_tra_20120911.pdf	80777 52957b41acae4053978cd7a25163a3a84d29bd83	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	15141US02_suppids_20120905.pdf	612151 d4e3967dd96d1a31ebfb2f7468912ec2343998be	no	4

Warnings:	
Information:	
Total Files Size (in bytes):	692928

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached: **4 page Supplemental Information Disclosure Statement.**

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on September 11, 2012.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

Date: September 11, 2012

By: /James A. Zak, Esq./
James A. Zak
Registration No.: 60190

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
v:\wpwork\jaz\15141us02_tra_20120911.doc

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	S63.2N-15141-US02	9828

490 7590 09/13/2012

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
SUITE 400, 6640 SHADY OAK ROAD
6640 Shady Oak Rd.
EDEN PRAIRIE, MN 55344

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
09/13/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mail@vaslaw.com
rleaf@vaslaw.com
rarrett@vaslaw.com

Office Action Summary	Application No.	Applicant(s)	
	12/269,213	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-5,14 and 16-22* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5,14 and 16-22* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/23/10,9/29/10,3/23/12,6/29/12*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

Claims 1-5, 14, and 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vesely (US Pub. No. 2001/0002445) in view of Pai et al. (US Pub. No. 2005/0197694). Vesely discloses the following of the claimed invention: a system for replacing a heart valve, comprising: a replacement heart valve (Figs. 22, 24) comprising: an expandable anchor (100), a replacement valve (109, 120); and a delivery device (31, 33), wherein the expandable anchor and the replacement heart valve are adapted to be delivered within the delivery device to a vicinity of a heart valve (paras. 0117-0118), and wherein the expandable anchor has a delivery configuration within the delivery device (paras. 0117-0118); and a plurality of delivery system actuation elements (32) reversibly coupled to a proximal end of the replacement heart valve when the expandable anchor is in the delivery configuration, wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration within the delivery device (Figs. 22-25A).

Vesely does not teach the expandable anchor comprising a braided material. Pai et al. teaches prosthetic heart valve and their associated anchors which comprise braided portions in paragraph 0133 for the purpose of allowing a variety of materials to be used to make the anchor,

and thus increase its tensile strength. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vesely to have a braided anchors extending from its anchoring base in order to use a variety of materials, and thus increase its tensile strength.

Vesely teaches the following regarding claim 2: the system of claim 1 wherein the expandable anchor and the replacement valve are coupled to each other (Fig. 22).

Vesely teaches the following regarding claim 3: the system of claim 1 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration within the delivery device (Figs. 22, 25A).

Vesely teaches the following regarding claim 4: the system of claim 1 wherein at least a portion of the replacement valve is disposed within the expandable anchor when the expandable anchor is in a fully deployed configuration (Fig. 22).

Vesely teaches the following regarding claim 5: the system of claim 4 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in the fully deployed configuration.

Vesely teaches the following regarding claim 14: the system of claim 13 wherein the plurality of delivery system actuation elements remain reversibly coupled to the replacement heart valve after the expandable anchor is deployed from the delivery device (paras. 0117-0121).

Vesely teaches the following regarding claim 16: a system for replacing a heart valve, comprising: a replacement heart valve (Figs. 22, 24) comprising: an expandable anchor (100), and a replacement valve (109, 120); a delivery device (31, 33), wherein the expandable anchor and the replacement valve are adapted to be delivered within the delivery device to a vicinity of a

heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device (Figs. 22, 25A; paras. 0117-0118); and a delivery system control element (32) adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration, wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration (paras. 0117-0121; Figs. 22-25A).

Vesely teaches the following regarding claim 17: the system of claim 16 wherein the system comprises a plurality of delivery system control elements (32) adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration (Fig. 24).

Vesely teaches the following regarding claim 18: the system of claim 16 wherein the expandable anchor and the replacement valve are coupled to each other (Fig. 22).

Vesely teaches the following regarding claim 19: the system of claim 16 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration (Figs. 22, 25A).

Vesely teaches the following regarding claim 20: the system of claim 16 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in a fully deployed configuration (Fig. 22).

Vesely teaches the following regarding claim 21: the system of claim 16 wherein the control element is adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is outside of the delivery device (Fig. 24).

Vesely teaches the following regarding claim 22: the system of claim 1 wherein the plurality of actuation elements are adapted to apply a distally directed force on the replacement heart valve when reversibly coupled thereto (paras. 0117-0121).

Response to Arguments

Applicant's arguments with respect to claims 1-5, 14, and 16-22 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571)272-6652. The examiner can normally be reached on Monday-Friday (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, David Isabella, at 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

Notice of References Cited	Application/Control No. 12/269,213	Applicant(s)/Patent Under Reexamination SALAHIEH ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	Page 1 of 1

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	C	US-			
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	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes (continued)	Application/Control No.	Applicant(s)/Patent under Reexamination
	12/269,213	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

SEARCHED			
Class	Subclass	Date	Examiner
623	2.1-2.42	9/4/2012	AS

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

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Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	525	US- 5,571,215	11/5/1996	Sterman et al.	
	528	US- 6,142,987	11/7/2000	Tsugita	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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Sheet 2 of 2

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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	529	SALAHIEH et al.; U.S. Pat. App. # 12/777,161 entitled "Two-Part Package for Medical Implant," filed 5/10/2010	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/269,213
	Filing Date	11/12/2008
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Client Number	BostonScientificScimedInc.
Page 1 of 14	**Matter Number**	S63.2-15141-US02

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Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/269,213
	Filing Date	11/12/2008
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Client Number	BostonScientificScimedInc.
Page 7 of 14	**Matter Number**	S63.2-15141-US02

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Page 13 of 14	**Matter Number**	S63.2-15141-US02

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Examiner Signature	/Ann Schillinger/	**Date Considered**	09/04/2012
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	First Named Inventor	Ulrich R. Haug
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	Client Number	BostonScientificScimedInc.
Page 14 of 14	**Matter Number**	S63.2-15141-US02

GENERAL
Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed. Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING
In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT
No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

FEE
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SIGNATURE			
Signature	/James M. Urzedowski/	Date	3/23/2012
Name	James M. Urzedowski	Registration Number	48596

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Sheet 1 of 1

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	534	WO03/030776 A2	4/17/2003	Gabbay, Shlomo		
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Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

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	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

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	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/James M. Urzedowski/	Date (YYYY-MM-DD)	2012-06-29
Name/Print	James M. Urzedowski	Registration Number	48596

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

AMENDMENT

This Amendment is in response to the Office Action dated **September 13, 2012.**

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicants hereby petition for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

Please amend the application as follows:

Amendments To The Claims:

1. (Previously Presented) A system for replacing a heart valve, comprising:

a replacement heart valve comprising

an expandable anchor comprising a braided material, and

a replacement valve;

a delivery device, wherein the expandable anchor and the replacement valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device; and

a plurality of delivery system actuation elements reversibly coupled to a proximal end of the replacement heart valve when the expandable anchor is in the delivery configuration,

wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration within the delivery device.

2. (Previously Presented) The system of claim 1 wherein the expandable anchor and the replacement valve are coupled to each other.

3. (Previously Presented) The system of claim 1 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration within the delivery device.

4. (Previously Presented) The system of claim 1 wherein at least a portion of the replacement valve is disposed within the expandable anchor when the expandable anchor is in a fully deployed configuration.

5. (Previously Presented) The system of claim 4 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in the fully deployed configuration.

6-13. (Canceled)

14. (Previously Presented) The system of claim 13 wherein the plurality of delivery system actuation elements remain reversibly coupled to the replacement heart valve after the expandable anchor is deployed from the delivery device.

15. (Canceled)

16. (Currently Amended) A system for replacing a heart valve, comprising:

a replacement heart valve comprising

an expandable anchor comprising a braided material, and

a replacement valve;

a delivery device, wherein the expandable anchor and the replacement valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device; and

a delivery system control element ~~adapted to~~ passing through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration,

wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration.

17. (Previously Presented) The system of claim 16 wherein the system comprises a plurality of delivery system control elements adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration.

18. (Previously Presented) The system of claim 16 wherein the expandable anchor and the replacement valve are coupled to each other.

19. (Previously Presented) The system of claim 16 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration.

20. (Previously Presented) The system of claim 16 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in a fully deployed configuration.

21. (Previously Presented) The system of claim 16 wherein the control element is adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is outside of the delivery device.

22. (Previously Presented) The system of claim 1 wherein the plurality of actuation elements are adapted to apply a distally directed force on the replacement heart valve when reversibly coupled thereto.

23. (New) A system for replacing a heart valve, comprising:

a sheath defining a lumen;

an implantable prosthetic collapsed within said lumen comprising:

a replacement valve, and

an expandable anchor axially spaced from said replacement valve; and

a first control rod and a second control rod within said lumen, said first control rod and said second control rod reversibly coupled to a proximal end of said expandable anchor.

24. (New) The system of claim 23 further comprising, a first control wire passing through said first control rod and a second control wire passing through said second control rod, said first control wire coupling said first control rod to the proximal end of said expandable anchor, and said second control wire coupling said second control rod to the proximal end of said expandable anchor.

25. (New) The system of claim 24 wherein said first control wire extends through said first control rod, loops through the proximal end of said expandable anchor and extends at least partially back into said first control rod.

26. (New) The system of claim 23 wherein a distal end of said first control rod defines a notch.

27. (New) The system of claim 23 further comprising a valve segment distal to said expandable anchor and a valve control wire coupled to said valve segment.

28. (New) The system of claim 23 further comprising a base coupled to a distal end of said expandable anchor; a post extending proximally from said base; and a female element within the proximal end of said expandable anchor.

29. (New) The system of claim 28 further comprising, a distal region control wire passing through said female element, through said post and back through said female element.

Remarks

This Amendment is in response to the Office Action dated **September 13, 2012.**

Amendments to the Claims

Claim 16 has been amended to recite the delivery system control element passes through a proximal region of the replacement heart valve.

Claims 23-29 are newly added claims; support for which can be found in ¶¶[0064]-[0066], [0068], [0069], [0074], [0106], [0128] and [0131] and Figures 1A, 2A, 3A-C and 39A and B of the Application as published.

Claims Rejections – 35 U.S.C. § 103

Claims 1-5, 14 and 16-22 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Vesely (U.S. Publication No. 2001/0002445) in view of Pai et al. (U.S. Publication No. 2005/0197694). Applicants respectfully traverse this rejection to the extent it is maintained in view of the amendments made to the claims and the following remarks.

Claims 1-5 and 14

Claim 1 requires "a plurality of delivery system actuation elements reversibly ***coupled to a proximal end of the replacement heart valve***". The Examiner maintains this element can be found within wire snares 32 of the valve system disclosed by Vesely.

Wire snares 32 are not coupled to the proximal end of the replacement heart valve 109. Instead, as shown in Figures 24 and 26C of Vesely (reproduced below), valve 109 is independent of snares 32. Additionally, as shown in Figure 24, snares 32 engage retaining clips

144 of permanent base unit 100. Accordingly, snares 32 are not coupled to a replacement heart valve as required by claim 1.

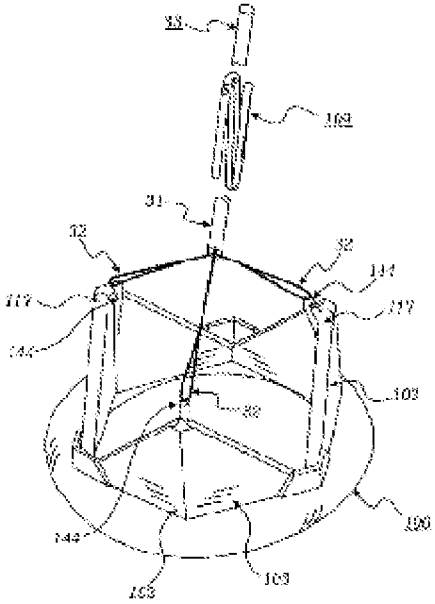

Fig. 24

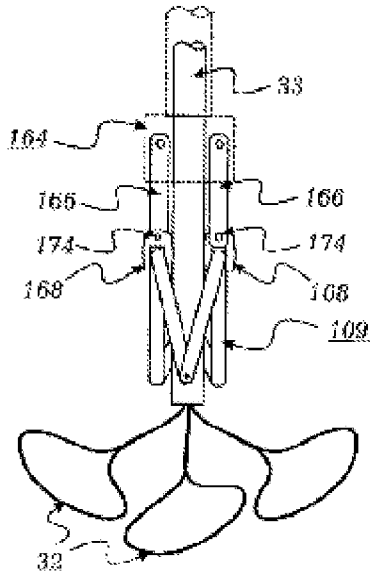

Fig. 26C

Failing to teach delivery system actuation elements coupled to a replacement valve, Vesely does not teach or suggest all the limitations of claim 1. Pai does not overcome this deficiency of Vesely. The combination of Vesely and Pai, therefore, does not teach all the elements of claim 1 and its dependent claims 2-5 and 14. Consequently, the combination of Vesely and Pai fails to establish prima facie obviousness of claims 1-5 and 14.

In view of the foregoing, Applicants respectfully request the Examiner reconsider and withdraw this rejection.

Claims 16-22

Claim 16 requires "a delivery system control element ***passing through a proximal region of the replacement heart valve***". The Examiner maintains this element can be found

within wire snares 32 of the valve system disclosed by Vesely.

Wire snares 32 do not pass through the proximal region of the replacement heart valve 109. Instead, as shown in Figures 24 and 26C of Vesely (reproduced below), valve 109 is independent of snares 32. Additionally, as shown in Figure 24, snares 32 engage retaining clips 144 of permanent base unit 100. Accordingly, snares 32 do not pass through a proximal region of a replacement valve as required by claim 16.

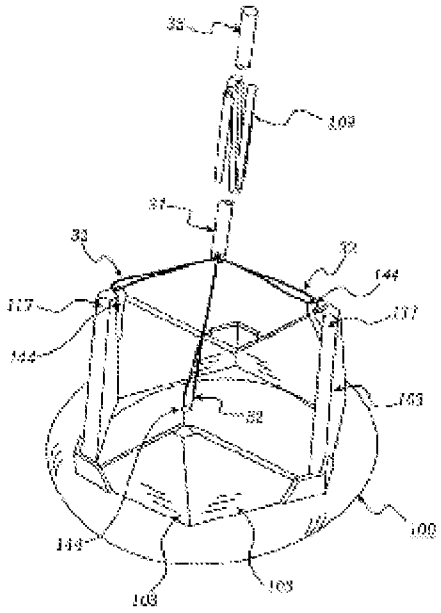

Fig. 24

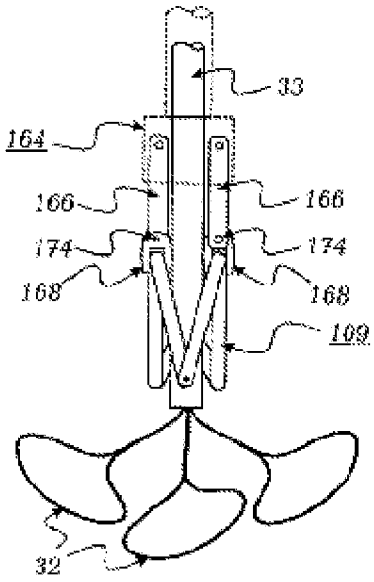

Fig. 26C

Failing to teach a delivery system control element passing through a proximal region of a replacement valve, Vesely does not teach or suggest all the limitations of claim 16. Pai does not overcome this deficiency of Vesely. The combination of Vesely and Pai, therefore, does not teach all the elements of claim 16 and its dependent claims 17-22. Consequently, the combination of Vesely and Pai fails to establish prima facie obviousness of claims 16-22.

In view of the foregoing, Applicants respectfully request the Examiner reconsider and withdraw this rejection.

CONCLUSION

Claims 1-5, 14 and 16-29 are pending in the Application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3044 to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: December 13, 2012

By: /James A. Zak, Esq./
James A. Zak
Registration No.: 60190

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Electronic Acknowledgement Receipt

EFS ID:	14461656
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	James Anthony Zak
Filer Authorized By:	
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	13-DEC-2012
Filing Date:	12-NOV-2008
Time Stamp:	16:24:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		15141US02_amend_docs_20121213.pdf	209729 db8aca39eaaf2c6875f24b82679bfb68c8f9a675	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	1
	Amendment/Req. Reconsideration-After Non-Final Reject	2	10
Warnings:			
Information:			
	Total Files Size (in bytes):	209729	

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

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

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

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached: **9 page Amendment.**

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on December 13, 2012.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

Date: December 13, 2012

By: /James A. Zak, Esq./
James A. Zak
Registration No.: 60190

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PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/269,213	11/12/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 12/13/2012

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $ =		OR	X $62=	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $ =		OR	X $250=	0
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/DORIS BURNS/

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6352554	B2	2002-03-05	Sulzer Vascutek Limited	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/James M. Urzedowski/	Date (YYYY-MM-DD)	2013-02-13
Name/Print	James M. Urzedowski	Registration Number	48596

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	12269213
Filing Date:	12-Nov-2008
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	James M. Urzedowski/Rebecca Leaf
Attorney Docket Number:	S63.2N-15141-US02

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	14949615
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	James M. Urzedowski/Rebecca Leaf
Filer Authorized By:	James M. Urzedowski
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	13-FEB-2013
Filing Date:	12-NOV-2008
Time Stamp:	14:54:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	1364
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Transmittal Letter	15141US02_tra_20130213.pdf	103466 c2e223ad0a95ac058d643c6508a10f9984a17692	no	1
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	15141US02_IDS_20130213.pdf	612175 b0648d7898b249acc6d1ef128ecbe9745ff4e541	no	4
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30234 1c15666020ceb6c6d036f20a69f4178d25377081	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	745875		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
4 page Information Disclosure Statement.

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on February 13, 2013.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 13, 2013

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

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UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	S63.2N-15141-US02	9828

490 7590 02/27/2013

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
02/27/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mail@vaslaw.com
rleaf@vaslaw.com
rarrett@vaslaw.com

Office Action Summary	Application No.	Applicant(s)	
	12/269,213	SALAHIEH ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-5 and 14-29* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-5 and 14-29* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/2012*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 14, and 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vesely (US Pub. No. 2001/0002445) in view of Pai et al. (US Pub. No. 2005/0197694). Vesely discloses the following of the claimed invention: a system for replacing a heart valve, comprising: a replacement heart valve (Figs. 22, 24) comprising: an expandable anchor (100), a replacement valve (109, 120); and a delivery device (31, 33), wherein the expandable anchor and the replacement heart valve are adapted to be delivered within the delivery device to a vicinity of a heart valve (paras. 0117-0118), and wherein the expandable anchor has a delivery configuration within the delivery device (paras. 0117-0118); and a plurality of delivery system actuation elements (32) reversibly coupled to a proximal end of the replacement heart valve when the expandable anchor is in the delivery configuration, wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration within the delivery device (Figs. 22-25A).

Vesely does not teach the expandable anchor comprising a braided material. Pai et al. teaches prosthetic heart valve and their associated anchors which comprise braided portions in paragraph 0133 for the purpose of allowing a variety of materials to be used to make the anchor,

and thus increase its tensile strength. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vesely to have a braided anchors extending from its anchoring base in order to use a variety of materials, and thus increase its tensile strength.

Vesely teaches the following regarding claim 2: the system of claim 1 wherein the expandable anchor and the replacement valve are coupled to each other (Fig. 22).

Vesely teaches the following regarding claim 3: the system of claim 1 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration within the delivery device (Figs. 22, 25A).

Vesely teaches the following regarding claim 4: the system of claim 1 wherein at least a portion of the replacement valve is disposed within the expandable anchor when the expandable anchor is in a fully deployed configuration (Fig. 22).

Vesely teaches the following regarding claim 5: the system of claim 4 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in the fully deployed configuration.

Vesely teaches the following regarding claim 14: the system of claim 13 wherein the plurality of delivery system actuation elements remain reversibly coupled to the replacement heart valve after the expandable anchor is deployed from the delivery device (paras. 0117-0121).

Vesely teaches the following regarding claim 16: a system for replacing a heart valve, comprising: a replacement heart valve (Figs. 27A, 30) comprising: an expandable anchor (100), and a replacement valve (109, 120); a delivery device (31, 33), wherein the expandable anchor and the replacement valve are adapted to be delivered within the delivery device to a vicinity of a

heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device (paras. 0119-0126); and a delivery system control element (32, 180) passing through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration, wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration (paras. 0119-0126; Figs. 27A-30).

Vesely teaches the following regarding claim 17: the system of claim 16 wherein the system comprises a plurality of delivery system control elements (32) adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration (Figs 29A-30).

Vesely teaches the following regarding claim 18: the system of claim 16 wherein the expandable anchor and the replacement valve are coupled to each other (Fig. 27A).

Vesely teaches the following regarding claim 19: the system of claim 16 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration (Figs. 27A).

Vesely teaches the following regarding claim 20: the system of claim 16 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in a fully deployed configuration (Fig. 27A).

Vesely teaches the following regarding claim 21: the system of claim 16 wherein the control element is adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is outside of the delivery device (Fig. 29A-30).

Vesely teaches the following regarding claim 22: the system of claim 1 wherein the plurality of actuation elements are adapted to apply a distally directed force on the replacement heart valve when reversibly coupled thereto (paras. 0119-0126).

Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. (US Pub. No. 2004/0220655) in view of Vesely. Swanson et al. teaches the following regarding claim 23: a system for replacing a heart valve, comprising: a sheath (700) defining a lumen (Fig. 28B); and a first control rod and a second control rod (539) within said lumen, said first control rod and said second control rod reversibly coupled to a proximal end of said expandable anchor (paras. 0155-0156).

Swanson et al. does not teach implanting a replacement heart valve. Vesely teaches a heart valve prosthesis with the claimed structural features including an expandable anchor comprising a base (100) and a post (110, 112), a replacement valve (109, 120), and a valve segment (103) as shown in Figures 22, 24, and/or 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the delivery system of Swanson et al. to deliver a replacement heart valve, as replacing the therapeutic device of Swanson et al. with that of Vesely will yield predictable results and provide a stable means of insertion.

Swanson et al. teaches the following regarding claim 24: the system of claim 23 further comprising, a first control wire (708) passing through said first control rod and a second control wire passing through said second control rod (Figs. 28B-31), said first control wire coupling said first control rod to the proximal end of said expandable anchor, and said second control wire coupling said second control rod to the proximal end of said expandable anchor (paras. 0155-0156).

Swanson et al. teaches the following regarding claim 25: the system of claim 24 wherein said first control wire extends through said first control rod, loops through the proximal end of said expandable anchor and extends at least partially back into said first control rod (Fig. 31; para. 0156).

Swanson et al. teaches the following regarding claim 26: the system of claim 23 wherein a distal end of said first control rod defines a notch (Fig. 31; para. 0156).

Swanson et al. teaches the following regarding claim 27: the system of claim 23 further comprising a valve segment distal to said expandable anchor and a valve control wire (708) coupled to said valve segment.

Swanson et al. teaches the following regarding claim 28: the system of claim 23 further comprising a base coupled to a distal end of said expandable anchor; a post extending proximally from said base; and a female element (714) within the proximal end of said expandable anchor.

Swanson et al. teaches the following regarding claim 29: the system of claim 28 further comprising, a distal region control wire passing through said female element, through said post and back through said female element (Fig. 31; para. 0156).

Response to Arguments

Applicant's arguments filed 12/13/2012 have been fully considered but they are not persuasive. The Applicant contends that Vesely does not teach a plurality of delivery system actuation elements that are reversibly coupled to the proximal end of the heart valve. The examiner respectfully disagrees. As shown in Figure 24, the actuation elements (32) are attached to the upper/proximal portion of the heart valve prosthesis via element 144.

Regarding claims 16-22, the claims have been amended to now positively recite the delivery control system element passing through a proximal region of the heart replacement valve. Therefore, a different embodiment of the Vesely reference has been interpreted to read on the claims, as described above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571)272-6652. The examiner can normally be reached on Monday-Friday (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, David Isabella, at 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

Notice of References Cited	Application/Control No. 12/269,213	Applicant(s)/Patent Under Reexamination SALAHIEH ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2004/0220655	11-2004	Swanson et al.	623/001.11
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	8226710		2012-07-24	Nguyen et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040019374		2004-01-29	Hojeibane et al.	
	2	20060149360		2006-07-06	Schwammenthal et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213 12269213 - GAU: 3774
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Ann Schillinger/	Date Considered	02/04/2013

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213 12269213 - GAU: 3774
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/James A. Zak, Esq./	Date (YYYY-MM-DD)	2012-09-11
Name/Print	James A. Zak	Registration Number	60190

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12269213	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Updated prior search	4/4/2010	AS
Updated prior search	2/4/2013	AS

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/A. S./ Examiner.Art Unit 3774	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/269,213
	Filing Date	11/12/2008
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Client Number	
Page 1 of 2	**Matter Number**	S63.2-15141-US02

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	1	20050060016	03/17/2005	Wu et al.	
	2	20050090890	04/28/2005	Wu et al.	
	3	20050149159	07/07/2005	Andreas et al.	
	4	20100094399	04/15/2010	Dorn et al.	
	5	5443477	08/22/1995	Marin et al.	
	6	6572643	06/03/2003	Gharibadeh	
	7	6755854	06/29/2004	Gillick et all.	
	8	6866669	03/15/2005	Buzzard et al.	
	9	6939352	09/06/2005	Buzzard et al.	
	10	7326236	02/05/2008	Andreas et al.	
	11	7491232	02/17/2009	Bolduc et al.	
	12	7674282	03/09/2010	Wu et al.	
	13	7722638	05/25/2010	Deyette, Jr. et al.	
	14	7736388	06/15/2010	Goldfarb et al.	
	15	7758625	07/20/2010	Wu et al.	
	16	7799065	09/21/2010	Pappas	
	17	7892292	02/22/2011	Stack et al.	

Examiner Signature		**Date Considered**	
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/269,213
	Filing Date	11/12/2008
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Client Number	
Page 2 of 2	**Matter Number**	S63.2-15141-US02

GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

FEE

No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

If necessary, the Director is hereby authorized to charge or credit Deposit Account No. 22-0350 for any additional fees, or any underpayment or credit for overpayment in connection herewith. Please reference attorney docket number BostonScientificScimedInc.-S63.2-15141-US02 for any such charge or credit.

SIGNATURE

Signature	/Michael J. McKeen/	Date	5/28/2013
Name	Michael J. McKeen	Registration Number	66069

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

AMENDMENT AFTER FINAL

This Amendment is in response to the Final Office Action dated **February 27, 2013.**

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicants hereby petition for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

Please amend the application as follows:

Amendments To The Claims:

1. (Currently Amended) A system for replacing a heart valve, comprising:

a replacement heart valve, the replacement heart valve having ~~comprising~~:

an expandable anchor comprising a braided material, and

a replacement valve comprising an everting segment;

a delivery device, wherein the expandable anchor and the replacement valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device; and

a plurality of delivery system actuation elements reversibly coupled to a proximal end of the replacement heart valve when the expandable anchor is in the delivery configuration,

wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration within the delivery device.

2. (Previously Presented) The system of claim 1 wherein the expandable anchor and the replacement valve are coupled to each other.

3. (Previously Presented) The system of claim 1 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration within the delivery device.

4. (Previously Presented) The system of claim 1 wherein at least a portion of the replacement valve is disposed within the expandable anchor when the expandable anchor is in a fully deployed configuration.

5. (Previously Presented) The system of claim 4 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in the fully deployed configuration.

6-13. (Canceled)

14. (Previously Presented) The system of claim 13 wherein the plurality of delivery system actuation elements remain reversibly coupled to the replacement heart valve after the expandable anchor is deployed from the delivery device.

15. (Canceled)

16. (Currently Amended) A system for replacing a heart valve, comprising:

a replacement heart valve having: ~~comprising~~

an expandable anchor comprising a braided material, and

a replacement valve comprising an everting segment;

a delivery device, wherein the expandable anchor and the replacement valve are adapted to be delivered within the delivery device to a vicinity of a heart valve, and wherein the expandable anchor has a delivery configuration within the delivery device; and

a delivery system control element passing through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration,

wherein the expandable anchor is axially spaced from the replacement valve when the expandable anchor is in the delivery configuration.

17. (Previously Presented) The system of claim 16 wherein the system comprises a plurality of delivery system control elements adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is in the delivery configuration.

18. (Previously Presented) The system of claim 16 wherein the expandable anchor and the replacement valve are coupled to each other.

19. (Previously Presented) The system of claim 16 wherein the replacement valve is distally spaced from the expandable anchor when the expandable anchor is in the delivery configuration.

20. (Previously Presented) The system of claim 16 wherein at least a portion of the replacement valve is disposed axially within the expandable anchor when the expandable anchor is in a fully deployed configuration.

21. (Previously Presented) The system of claim 16 wherein the control element is adapted to pass through a proximal region of the replacement heart valve when the expandable anchor is outside of the delivery device.

22. (Previously Presented) The system of claim 1 wherein the plurality of actuation elements are adapted to apply a distally directed force on the replacement heart valve when reversibly coupled thereto.

23. (Currently Amended) A system for replacing a heart valve, comprising:

a sheath defining a lumen;

an implantable prosthetic collapsed within said lumen, said implantable prosthetic having: ~~comprising:~~

a replacement valve comprising an everting segment, and

an expandable anchor axially spaced from said replacement valve; and

a first control rod and a second control rod within said lumen, said first control rod and said second control rod reversibly coupled to a proximal end of said expandable anchor.

24. (Previously Presented) The system of claim 23 further comprising, a first control wire passing through said first control rod and a second control wire passing through said second control rod, said first control wire coupling said first control rod to the proximal end of said expandable anchor, and said second control wire coupling said second control rod to the proximal end of said expandable anchor.

25. (Previously Presented) The system of claim 24 wherein said first control wire extends through said first control rod, loops through the proximal end of said expandable anchor and extends at least partially back into said first control rod.

26. (Previously Presented) The system of claim 23 wherein a distal end of said first control rod defines a notch.

27. (Currently Amended) The system of claim 23 further comprising ~~a valve segment distal to said expandable anchor and~~ a valve control wire coupled to said everting ~~valve~~ segment.

28. (Previously Presented) The system of claim 23 further comprising a base coupled to a distal end of said expandable anchor; a post extending proximally from said base; and a female element within the proximal end of said expandable anchor.

29. (Currently Amended) The system of claim 28 further comprising[[,]] a distal region control wire passing through said female element, through said post and back through said female element.

Remarks

This Amendment is in response to the Final Office Action dated **February 27, 2013.** In the Final Office Action, the Examiner rejected claims 1-5, 14, and 16-22 under 35 USC § 103(a) over Vesely (US Pub. No. 2001/0002445) in view of Pai (US Pub. No. 2005/0197694) and rejected claims 23-29 under 35 USC § 103(a) over Swanson (US Pub. No. 2004/0220655) in view of Vesely.

Independent claims 1, 16, and 23 are herein amended and to provide additional clarity. Support for these amendments can be found in the Specification at least in paragraph [00128] of the Application as-filed.

Additionally, dependent claim 27 is amended in light of the amendment to claim 23 and dependent claim 29 is amended to provide additional clarity.

In light of the foregoing amendments and following comments, Applicants request reconsideration.

Claim Rejections – Section 103

Claims 1-5, 14, and 16-22

The Examiner rejected claims 1-5, 14, and 16-22 under 35 USC § 103(a) over Vesely in view of Pai. Without acquiescing to the validity of the rejection, independent claims 1 and 16 are herein amended to recite, in-part, "a replacement valve comprising an everting segment, . . ." By way of example, such a replacement valve is discussed in paragraphs [00128] – [00140] and shown in FIG. 39C, below, of the Application as-filed. Paragraph [00134] states, in-part, "FIG. 39C illustrates the beginning of the everting process wherein everting segment 528 is being pulled proximally over the exterior of anchor 30'.

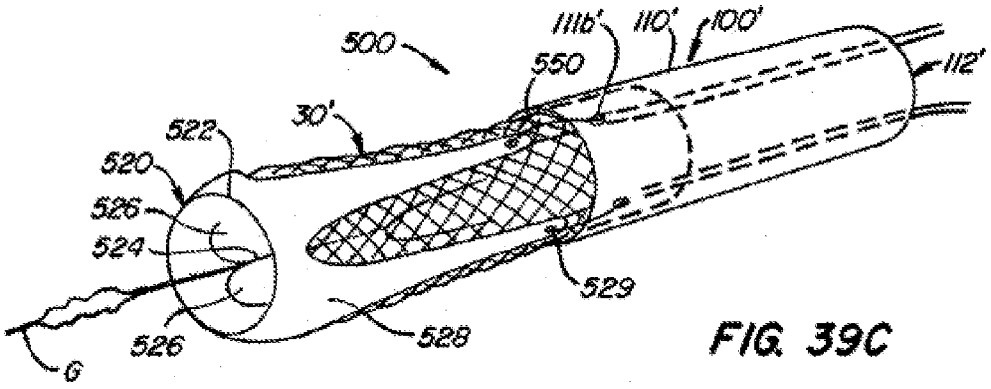

FIG. 39C

Neither Vesely nor Pai, whether considered independently or in combination, discloses, teaches, suggests, or otherwise renders obvious a system for replacing a heart valve having "a replacement valve comprising an everting segment," as is claimed. As such, Applicants request withdrawal of the rejection of independent claims 1 and 16, and dependent claims 2-5, 14, and 17-22, over Vesely in view of Pai.

Claims 23-29

The Examiner further rejected claims 23-29 under 35 USC § 103(a) over Swanson in view of Vesely. Without acquiescing to the validity of the rejection, independent claim 23 is herein amended to recite, in-part, "a replacement valve comprising an everting segment, ..." Whether considered independently or in combination, neither Swanson nor Vesely discloses, teaches, suggests, or otherwise renders obvious a system for replacing a heart valve having "a replacement valve comprising an everting segment," as is claimed. As such, Applicants request withdrawal of the rejection of independent claim 23 and dependent claims 24-29, which depend either directly or indirectly therefrom.

Conclusion

Based on at least the foregoing remarks, Applicants request allowance of claims 1-5, 14, and 16-29. Favorable consideration and prompt allowance of these claims is earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: May 28, 2013

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached: **7 page Amendment After Final; 3 page Request for Continued Examination; 2 page Supplemental Information Disclosure Statement.**

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on May 28, 2013.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: May 28, 2013

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

6640 Shady Oak Rd., Suite 400
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Facsimile: (952) 563-3001

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Electronic Patent Application Fee Transmittal

Application Number:	12269213
Filing Date:	12-Nov-2008
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Michael James McKeen
Attorney Docket Number:	S63.2N-15141-US02

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
RCE - 2nd and Subsequent Request	1820	1	1700	1700
		Total in USD ($)		**1700**

Electronic Acknowledgement Receipt

EFS ID:	15881086
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	Michael James McKeen
Filer Authorized By:	
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	28-MAY-2013
Filing Date:	12-NOV-2008
Time Stamp:	15:34:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1700
RAM confirmation Number	2307
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Request for Continued Examination (RCE)	15141US02_RCE_20130528.pdf	697606 60a385f0fe0a915f20d616b3eb12c0c93a1fd0fb	no	3
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	15141US02_IDS_signed_20130528.pdf	67322 e1defbfa521b77237d847ae9aa25db11f13e2cd4	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3		15141US02_amd_20130429.pdf	134636 8f56ae4fb4be3d85f78f54bc72a06460beaa2e3e	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment After Final	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	7

Warnings:					
Information:					
4	Transmittal Letter	15141US02_tra_20130524.pdf	102873 507d9fb8c4306c98f5dcf9896f5be18b6da67822	no	1
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	29969 e1051fd84d19347591391 0a16ad30a63b566d5a5	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1032406		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	12269213	Filing Date	2008-11-12	Docket Number (if applicable)	S63.2-15141-US02	Art Unit	3774
First Named Inventor	Amr Salahieh			Examiner Name	Ann M Schillinger		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed affer the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 220350

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Michael J. McKeen/	Date (YYYY-MM-DD)	2013-05-28
Name	Michael J. McKeen	Registration Number	66069

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/269,213	Filing Date 11/12/2008	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)		
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

		(Column 1)		(Column 2)	(Column 3)		
AMENDMENT	05/28/2013	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/THUY TA/

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	96/40012	WO		1996-12-19	St. Jude Medical, Inc.		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Michael J. McKeen/	Date (YYYY-MM-DD)	2013-07-24
Name/Print	Michael J. McKeen	Registration Number	66069

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	16403304
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	Michael James McKeen/Wendy Skelly
Filer Authorized By:	Michael James McKeen
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	24-JUL-2013
Filing Date:	12-NOV-2008
Time Stamp:	14:53:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US02_tra_20130723.pdf	80430 231421dee6dfb761e743b9b712cccc0b0b828419	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	15141US02_IDS_20130723.pdf	611981 f0349f010d3550a07c77caa6016d215092338b18	no	4

Warnings:

Information:

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

3	Foreign Reference	15141US02_NPL_20130723.pdf	1195954 8b30d300b1a1807b43965111ef026369560a3873	no	31

Warnings:

Information:

Total Files Size (in bytes):	1888365

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached: **4 page Information Disclosure Statement and 1 Foreign Reference**

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on July 24, 2013.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: July 24, 2013

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

v:\wpwork\mjm\15141us02_tra_20130723.doc

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6363938		2002-04-02	Saadat, et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040148018		2004-07-29	Carpentier, et al.	
	2	20040199245		2004-10-07	Lauterjung	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

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☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Michael J. McKeen/	Date (YYYY-MM-DD)	2013-09-17
Name/Print	Michael J. McKeen	Registration Number	66069

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	16879290
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	Michael James McKeen/Wendy Skelly
Filer Authorized By:	Michael James McKeen
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	17-SEP-2013
Filing Date:	12-NOV-2008
Time Stamp:	17:08:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US02_tra_20130917.pdf	80426 38530fb88f3230d4b7ab21b64a09011479b203f7	no	1

Warnings:	
Information:	

2	Miscellaneous Incoming Letter	15141US02_Letter_IDS_20130917.pdf	88397 bca974879cd6091e8ad614acf1a1e49508062f9e	no	2
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	15141US02_IDS_20130917.pdf	612278 918fe15578c9baa6ea99d12dc15fafd929ff3936	no	4
Warnings:					
Information:					
			Total Files Size (in bytes):	781101	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-I5I4I-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached: **4 page Information Disclosure Statement and 2 page Letter Regarding IDS**

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on September 17, 2013.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: September 17, 2013

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2N-15141-US02

INFORMATION DISCLOSURE STATEMENT

Applicant has listed, on the accompanying form, information for consideration in the above-mentioned application. Applicant respectfully requests that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicant requests that the Examiner return an initialed copy of the accompanying form(s) indicating that the listed information has been considered, in accordance with MPEP § 609. This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability.

For information submitted herewith in a foreign language, Applicant includes herewith a concise explanation of relevance as it is presently understood by the undersigned Attorney and/or an English language abstract, in accordance with 37 C.F.R. § 1.98(a)(3) and M.P.E.P. § 609.

Applicant respectfully requests that any copies of unpublished US applications submitted herewith be excluded from the file wrapper pursuant to 37 C.F.R. § 1.14.

The present application is a continuation of and claims priority under 35 U.S.C. § 120 to U.S. Pat. Appl. Ser. No. 10/870,340, filed June 16, 2004. Pursuant to 37 C.F.R. § 1.98(d), copies of documents cited by or submitted to the United States Patent and Trademark Office in a

previous application to which priority was claimed under 35 U.S.C. § 120 need not be submitted and are not submitted herewith.

If a $180 fee is due for consideration of this Information Disclosure Statement and full payment has not been submitted herewith, the Commissioner is hereby authorized to charge any additional fees associated with this communication to Deposit Account No. 22-0350. The Commissioner is hereby authorized to credit any overpayment associated with this communication to Deposit Account No. 22-0350.

Applicant requests that this Information Disclosure Statement be considered if it is timely submitted under any of the provisions of 37 C.F.R. §1.97.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: September 17, 2013

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

490 7590 01/15/2014

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
SUITE 400, 6640 SHADY OAK ROAD
6640 Shady Oak Rd.
EDEN PRAIRIE, MN 55344

EXAMINER
SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 01/15/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	S63.2N-15141-US02	9828

TITLE OF INVENTION: EVERTING HEART VALVE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	04/15/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

490 7590 01/15/2014
VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
SUITE 400, 6640 SHADY OAK ROAD
6640 Shady Oak Rd.
EDEN PRAIRIE, MN 55344

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	S63.2N-15141-US02	9828

TITLE OF INVENTION: EVERTING HEART VALVE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	04/15/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
SCHILLINGER, ANN M	3774	623-021000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	S63.2N-15141-US02	9828

490 7590 01/15/2014

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
SUITE 400, 6640 SHADY OAK ROAD
6640 Shady Oak Rd.
EDEN PRAIRIE, MN 55344

EXAMINER	
SCHILLINGER, ANN M	

ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 01/15/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 654 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 654 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 12/269,213	Applicant(s) SALAHIEH ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the Request for Continued Examination filed 5/28/2013*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-5,14 and 16-29*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 2/13/13,5/28/13,7/24/13,9/17/13
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/A. S./ Examiner, Art Unit 3774	/DAVID ISABELLA/ Supervisory Patent Examiner, Art Unit 3774

The present application is being examined under the pre-AIA first to invent provisions.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In claim 14, line 1, replace "claim 13" with --claim 1--.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571)272-6652. The examiner can normally be reached on Monday-Friday (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, David Isabella, at 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12269213	SALAHIEH ET AL.
	Examiner	**Art Unit**
	ANN SCHILLINGER	3774

CPC		
Symbol	**Type**	**Version**

CPC Combination Sets				
Symbol	**Type**	**Set**	**Ranking**	**Version**

/ANN SCHILLINGER/ Examiner.Art Unit 3774	1/8/2014	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	01/09/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	41

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12269213	SALAHIEH ET AL.
	Examiner	**Art Unit**
	ANN SCHILLINGER	3774

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
623	2.18	A	6	1	F	2 / 24 (2006.0)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

/ANN SCHILLINGER/ Examiner.Art Unit 3774	1/8/2014	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	01/09/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	41

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12269213	SALAHIEH ET AL.
	Examiner	**Art Unit**
	ANN SCHILLINGER	3774

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	9	17												
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	11	18	27												
	12	19	28												
	13	20	29												
6	14														
	15														
8	16														

/ANN SCHILLINGER/ Examiner.Art Unit 3774	1/8/2014	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	01/09/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	41

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	96/40012	WO		1996-12-19	St. Jude Medical, Inc.		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213 12269213 - GAU: 3774
	Filing Date	2008-11-12
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Ann Schillinger/	Date Considered	01/09/2014

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213 12269213 - GAU: 3774
	Filing Date	2008-11-12
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Michael J. McKeen/	Date (YYYY-MM-DD)	2013-07-24
Name/Print	Michael J. McKeen	Registration Number	66069

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

BIB DATA SHEET

CONFIRMATION NO. 9828

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/269,213	11/12/2008	623	3774	S63.2N-15141-US02

APPLICANTS

INVENTORS

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

**** CONTINUING DATA ***************************

This application is a CON of 10/870,340 06/16/2004 PAT 7780725

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

12/04/2008

Foreign Priority claimed	☐ Yes ☑ No	☐ Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☐ Yes ☑ No					
Verified and Acknowledged	/ANN SCHILLINGER/ Examiner's Signature	Initials	CA	63	12	2

ADDRESS

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
SUITE 400, 6640 SHADY OAK ROAD
6640 Shady Oak Rd.
EDEN PRAIRIE, MN 55344
UNITED STATES

TITLE

Everting Heart Valve

FILING FEE RECEIVED		
462	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6363938		2002-04-02	Saadat, et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040148018		2004-07-29	Carpentier, et al.	
	2	20040199245		2004-10-07	Lauterjung	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213 12269213 - GAU: 3774
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Ann Schillinger/	Date Considered	01/09/2014

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

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OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Michael J. McKeen/	Date (YYYY-MM-DD)	2013-09-17
Name/Print	Michael J. McKeen	Registration Number	66069

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/269,213
	Filing Date	11/12/2008
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Client Number	
Page 1 of 2	**Matter Number**	S63.2-15141-US02

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	1	20050060016	03/17/2005	Wu et al.	
	2	20050090890	04/28/2005	Wu et al.	
	3	20050149159	07/07/2005	Andreas et al.	
	4	20100094399	04/15/2010	Dorn et al.	
	5	5443477	08/22/1995	Marin et al.	
	6	6572643	06/03/2003	Gharibadeh	
	7	6755854	06/29/2004	Gillick et all.	
	8	6866669	03/15/2005	Buzzard et al.	
	9	6939352	09/06/2005	Buzzard et al.	
	10	7326236	02/05/2008	Andreas et al.	
	11	7491232	02/17/2009	Bolduc et al.	
	12	7674282	03/09/2010	Wu et al.	
	13	7722638	05/25/2010	Deyette, Jr. et al.	
	14	7736388	06/15/2010	Goldfarb et al.	
	15	7758625	07/20/2010	Wu et al.	
	16	7799065	09/21/2010	Pappas	
	17	7892292	02/22/2011	Stack et al.	

Examiner Signature	/Ann Schillinger/	**Date Considered**	01/09/2014
Examiner: Please initial if citation considered, whether or not citation is in conformance with MPEP Section 609. Please draw a line through the citation if it is not in conformance and it is not considered. Please include a copy of this form with the next communication to the applicant.			

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	Art Unit	3774
	Client Number	
Page 2 of 2	**Matter Number**	S63.2-15141-US02

GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

FEE

No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

If necessary, the Director is hereby authorized to charge or credit Deposit Account No. 22-0350 for any additional fees, or any underpayment or credit for overpayment in connection herewith. Please reference attorney docket number BostonScientificScimedInc.-S63.2-15141-US02 for any such charge or credit.

SIGNATURE

Signature	/Michael J. McKeen/	Date	5/28/2013
Name	Michael J. McKeen	Registration Number	66069

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6352554	B2	2002-03-05	Sulzer Vascutek Limited	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12269213 12269213 - GAU: 3774
	Filing Date	2008-11-12
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US02

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Ann Schillinger/	Date Considered	01/09/2014

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

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213 12269213 - GAU: 3774
Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/James M. Urzedowski/	Date (YYYY-MM-DD)	2013-02-13
Name/Print	James M. Urzedowski	Registration Number	48596

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	7	(heart and valve and evert$4 and delivery and device).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/01/09 14:05
L268	3	(control and rod and lumen and heart and valve and replacement).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/01/09 14:11
L269	12	(anchor and braid$3 and expand$4 and heart and valve and delivery and device).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/01/09 14:15
L270	8	(replacement and heart and valve and anchor and braid$3 and delivery and device).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/01/09 14:18
L271	7	(actuation and elements and replacement and heart and valve and anchor and braid$3).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/01/09 14:22

1/9/2014 2:25:13 PM
C:\Users\aschillinger\Documents\EAST\Workspaces\12269213.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12269213	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	2.1-2.42	9/29/2008	AS

SEARCH NOTES		
Search Notes	Date	Examiner
Updated prior search	4/4/2010	AS
Updated prior search	2/4/2013	AS
Updated prior search	1/8/2014	AS
Interference search EAST, see printout	1/8/2014	AS

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
623	2.1-2.42	1/8/2014	AS

/A. S./ Examiner.Art Unit 3774	

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

490 7590 01/15/2014
VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
SUITE 400, 6640 SHADY OAK ROAD
6640 Shady Oak Rd.
EDEN PRAIRIE, MN 55344

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	11/12/2008	Amr Salahieh	S63.2N-15141-US02	9828

TITLE OF INVENTION: EVERTING HEART VALVE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	04/15/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
SCHILLINGER, ANN M	3774	623-021000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☒ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Vidas, Arrett &
2 Steinkraus, P.A.
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Sadra Medical, Inc.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Los Gatos, California

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date January 21, 2014
Typed or printed name Michael J. McKeen Registration No. 66069

Electronic Patent Application Fee Transmittal

Application Number:	12269213
Filing Date:	12-Nov-2008
Title of Invention:	EVERTING HEART VALVE
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Michael James McKeen/Wendy Skelly
Attorney Docket Number:	S63.2N-15141-US02

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt

EFS ID:	17972639
Application Number:	12269213
International Application Number:	
Confirmation Number:	9828
Title of Invention:	EVERTING HEART VALVE
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	490
Filer:	Michael James McKeen/Wendy Skelly
Filer Authorized By:	Michael James McKeen
Attorney Docket Number:	S63.2N-15141-US02
Receipt Date:	21-JAN-2014
Filing Date:	12-NOV-2008
Time Stamp:	15:32:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$960
RAM confirmation Number	1817
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Transmittal Letter	15141US02_tra_20140121.pdf	81145 10ede939c901b92f20a9b3b17f138ed9f5919a31	no	1
Warnings:					
Information:					
2	Post Allowance Communication - Incoming	15141US02_fee_20140121.pdf	70330 c02f71f839508f4b63f5b6690cf0ecb946d90c7f	no	1
Warnings:					
Information:					
3	Issue Fee Payment (PTO-85B)	15141US02_IssueFee_20140121.pdf	189603 a602eab3ad7e00ed6c59598fe1123a88a0069209	no	1
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30289 1acde60a7faa0a622ea20dede7fee7f12920fe7d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	371367		

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/269213**
Filed:	**November 12, 2008**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2N-15141-US02

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached: **1 page Fee Address Indication Form and 1 page Part B – Fee(s) Transmittal**

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on January 21, 2014.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: January 21, 2014

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

v:\wpwork\mjm\15141us02_tra_20140121.doc

PATENT

FEE ADDRESS INDICATION FORM

Mail Stop M Correspondence
Director of the U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the following customer number for the following patents:

81995

Patent Number (if known)	Application Number	Patent Date (if known)	U.S. Filing Date
Not Assigned	12/269213	Not Assigned	November 12, 2008

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: January 21, 2014

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

v:\wpwork\mjm\15141us02_fee_20140121.doc

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (07-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	12269213
Filing Date	2008-11-12
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US02

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6352554	B2	2002-03-05	De Paulis ~~Gulzer Vascutek Limited~~	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

Change(s) applied to document, /M.G./ 1/24/2014

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	452	US- 2002/0002396	01/03/2002	Fulkerson	
	455	US- 2002/0188344	12/12/2002	Bolea et al.	
	458	US- 2006/0155312	7/13/2006	Levine et al.	
	444	US- 2003/0109930	06/12/2003	Bluni et al.	
	445	US- 2003/0144732	07/31/2003	Cosgrove et al.	
	446	US- 2004/0133274	07/08/2004	Webler et al.	
	448	US- 2005/0043711	02/24/2005	Corcoran et al.	
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Change(s) applied to document, /M.G./ 1/28/2014

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

Examiner Signature	/Ann Schillinger/	Date Considered	02/02/2010

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 5 of 22

Complete if Known	
Application Number	12/269,213
Filing Date	November 12, 2008
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

Change(s) applied to document, /M.G./ 1/28/2014

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Signature		Date Considered	

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Sheet 4 of 22

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Application Number	12/269,213
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Attorney Docket Number	10012-710.301

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Change(s) applied to document
/M.G./
1/28/2014

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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
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Sheet 3 of 22

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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.301

U. S. PATENT DOCUMENTS

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/269,213	03/11/2014	8668733	S63.2N-15141-US02	9828

490 7590 02/19/2014

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 654 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

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