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UTILITY PATENT APPLICATION TRANSMITTAL

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

Attorney Docket No.	10012-710.401
First Inventor	Amr SALAHIEH et al.
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* 29]
   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
   c. ☐ Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents**
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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.: 12/269,213

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	Thomas Z	Date	JUNE 26, 2009
Name (Print/Type)	THOMAS M. ZLOGAR	Registration No. (Attorney/Agent)	55,760

FILED VIA EFS ON JUNE 26, 2009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:		Confirmation No.:
Applicant	:	Amr SALAHIEH et al.	
Filing Date	:	June 26, 2009 *(herewith)*	
Title	:	Everting Heart Valve	
Group Art Unit	:		
Examiner	:		
Docket No.	:	10012-710.401	
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 divisional of U.S. Application No. 12/269,213, which in turn 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 divisional application herein retain the same order of inventors.

Respectfully submitted,

Date: June 26, 2009 By: Thomas Zlogar

Thomas Zlogar, Reg. No. 55,760

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FEB 16 2006

OFFICE OF PETITIONS

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

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

The petition is **Granted.**

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

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

This matter is being referred to Technology Center AU 3738.

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

ATTACHMENT: CORRECTED FILING RECEIPT

UNITED STATES PATENT AND TRADEMARK OFFICE

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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
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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;
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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.

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.

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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. 10012-710.401

UNITED STATES PATENT APPLICATION

EVERTING HEART VALVE

Inventor(s): **SALAHIEH,** Amr,
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FILED VIA EFS ON JUNE 26, 2009

EVERTING HEART VALVE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is a divisional of pending U.S. Application No. 12/269,213, filed November 12, 2008; which application is a continuation of pending U.S. Application No. 10/870,340, filed June 16, 2004, entitled "Everting Heart Valve", the disclosures of which are incorporated by reference in their entirety.

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. Patent 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 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.

2. The system of claim 1 wherein the expandable anchor is not attached to the replacement valve leaflet.

3. The system of claim 1 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.

4. The system of claim 1 wherein the commissure support element is configured to interface with an anchor actuator.

5. The system of claim 4 wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor.

6. The system of claim 1 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.

7. The system of claim 6 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.

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
			☐	☐	☐
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			☐	☐	☐
			☐	☐	☐

☐ 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				
Dwight P.			Morejohn				
Inventor's Signature	Dwight P. Morejohn				Date	10-20-04	
Residence: City	Davis	State	CA	Country	USA	Citizenship	USA
Post Office Address	731 N. Campus Way, Davis, CA 95616						
Post Office Address							
City	San Francisco	State	CA	ZIP	95616	Country	USA

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

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

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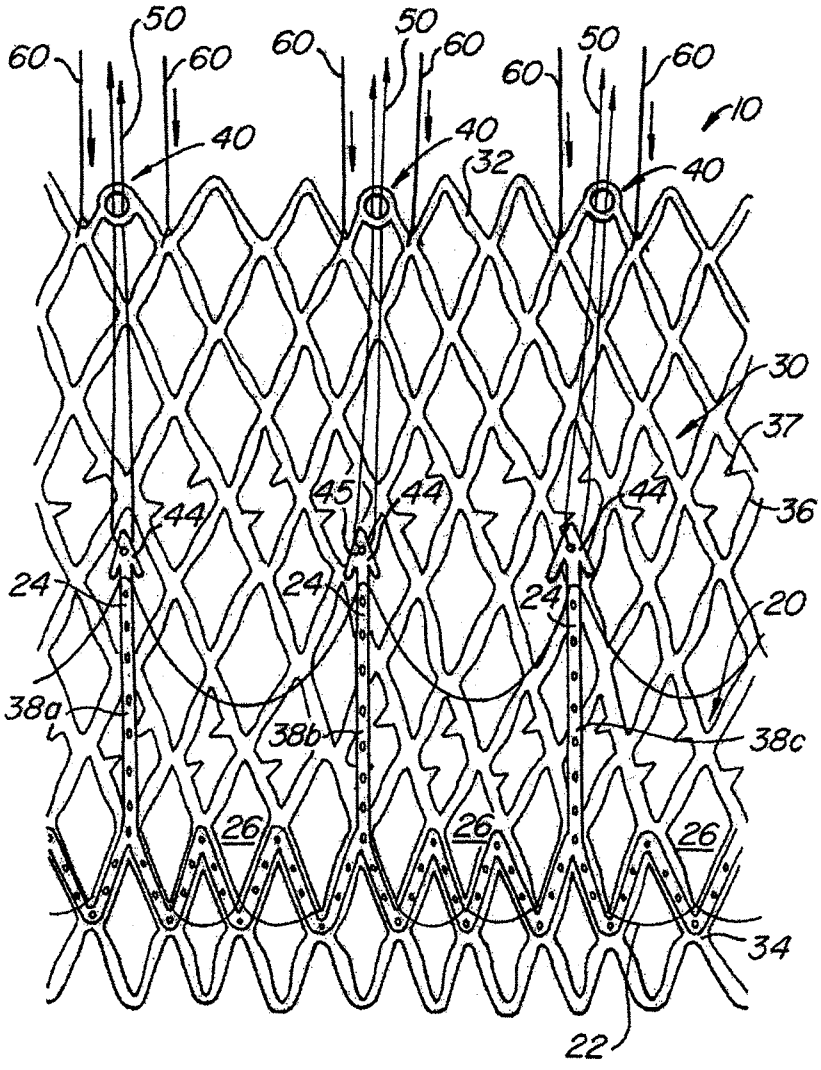
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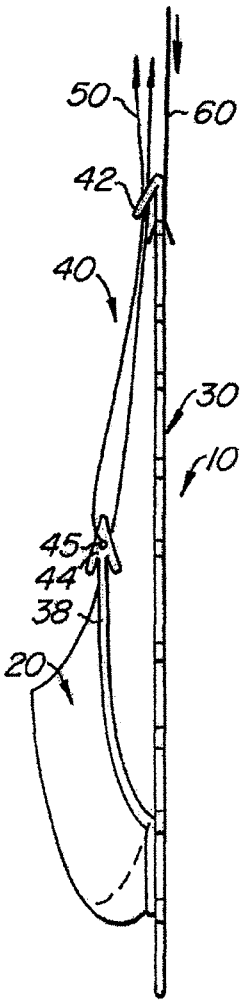
FIG. 1A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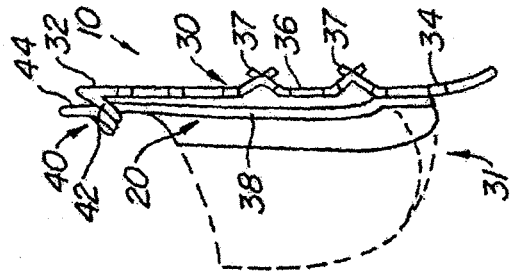
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FIG. 2B

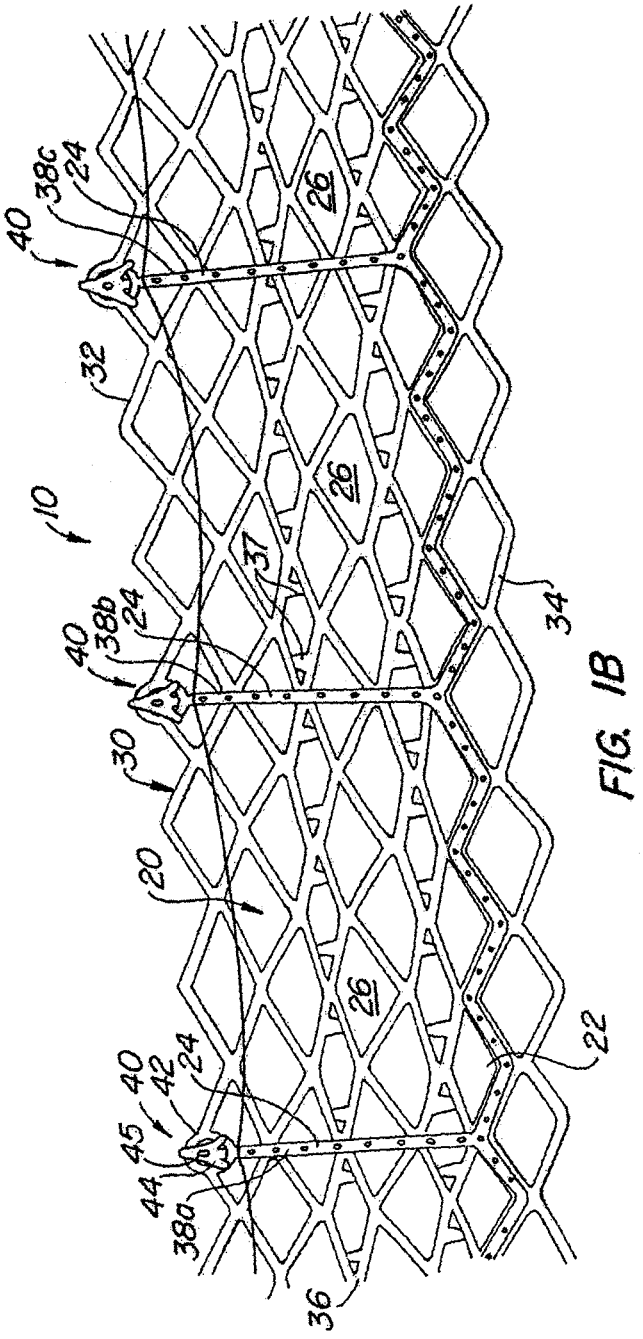
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FIG. 1B

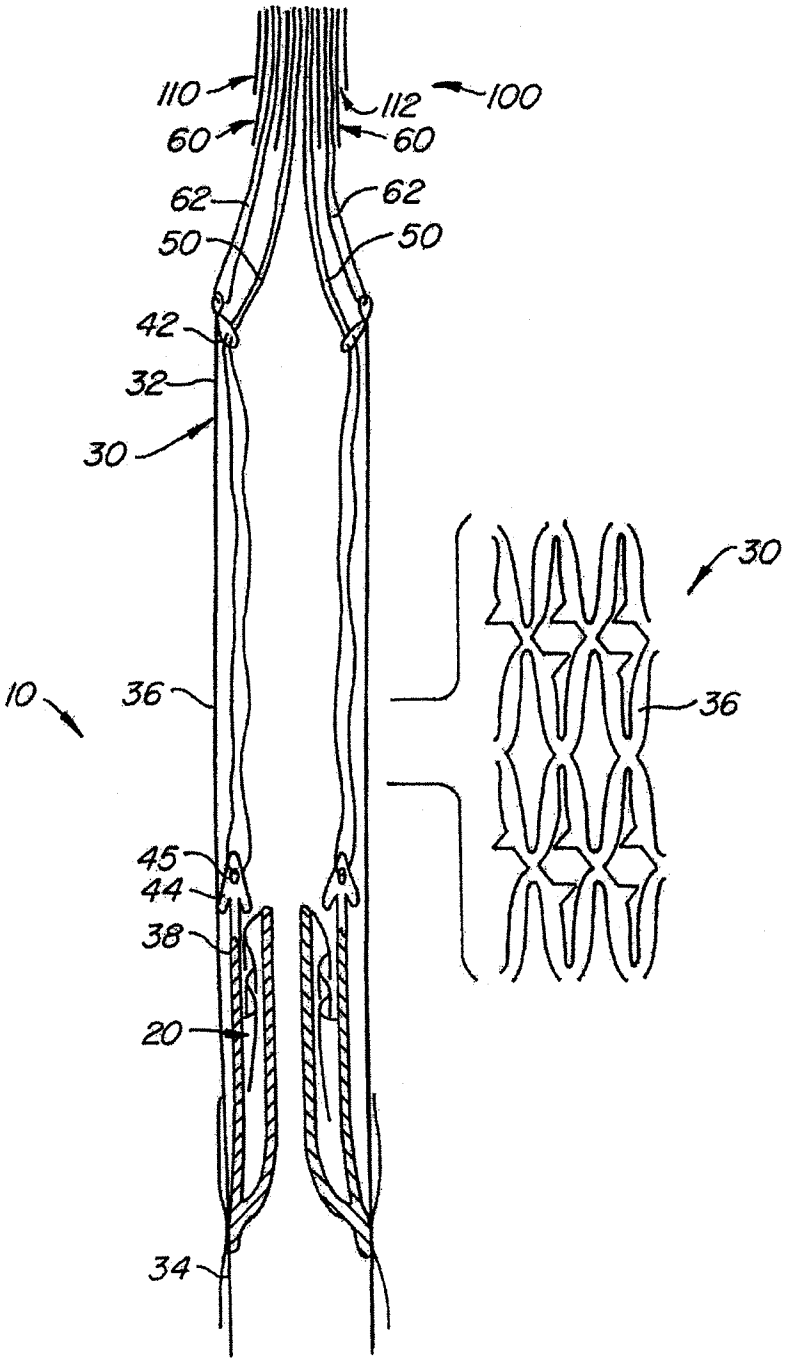

FIG. 3A

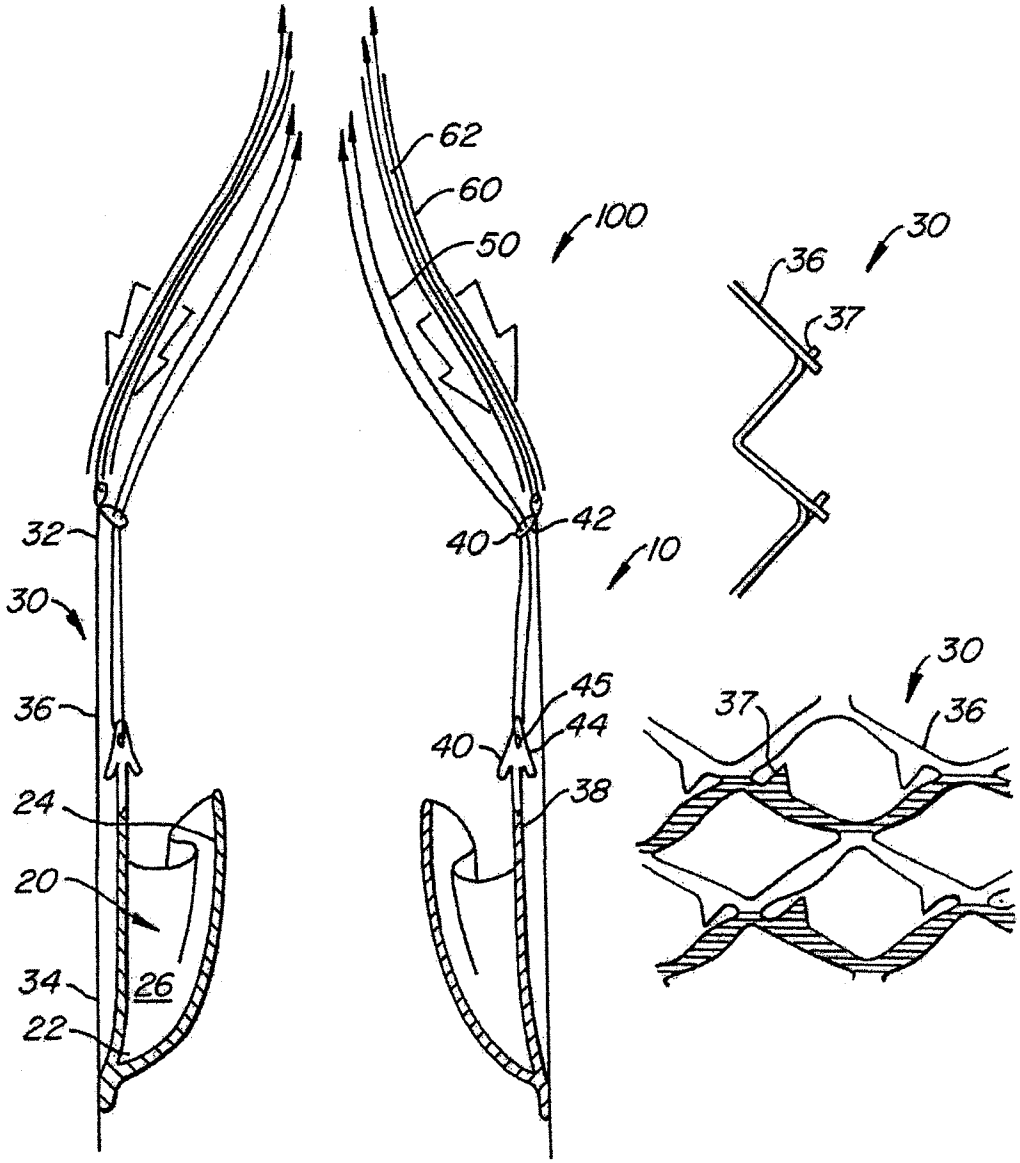
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FIG. 3B

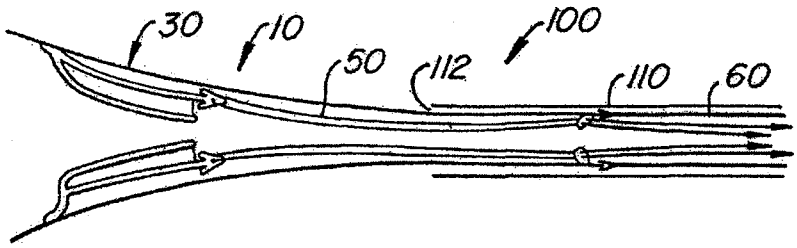
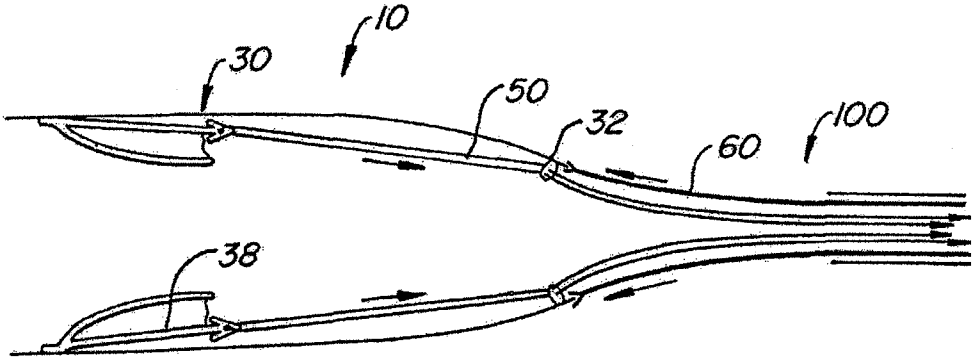


FIG. 4A



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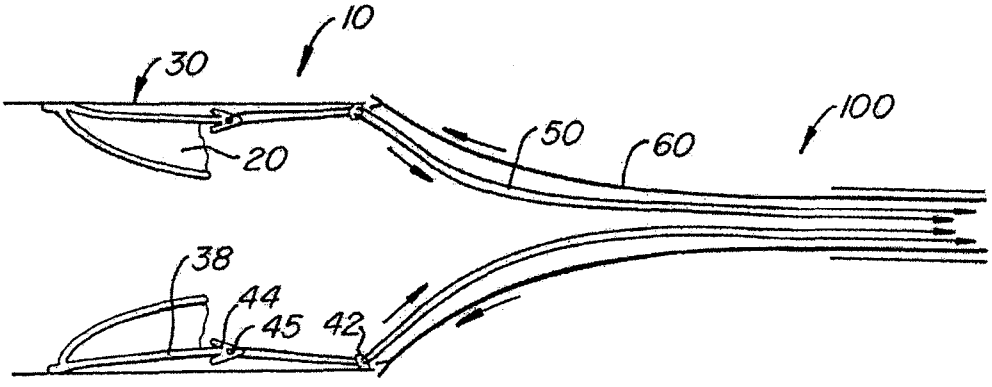


FIG. 4C

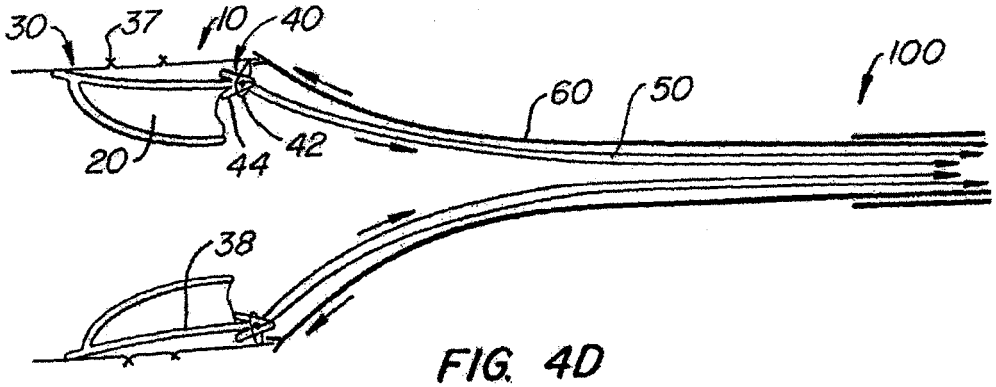


FIG. 4D

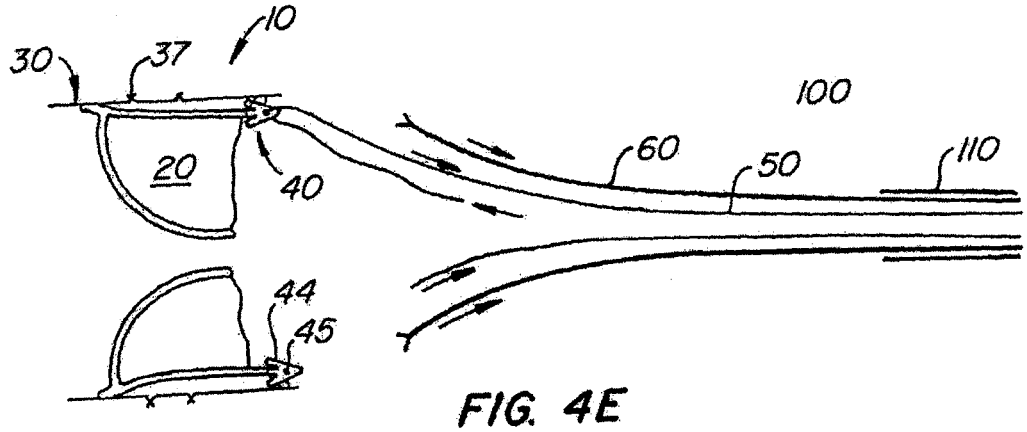


FIG. 4E

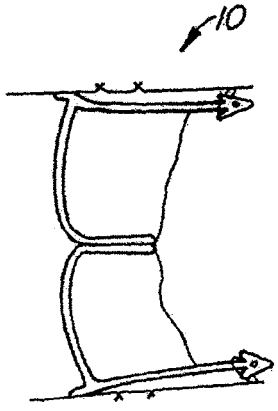


FIG. 4F

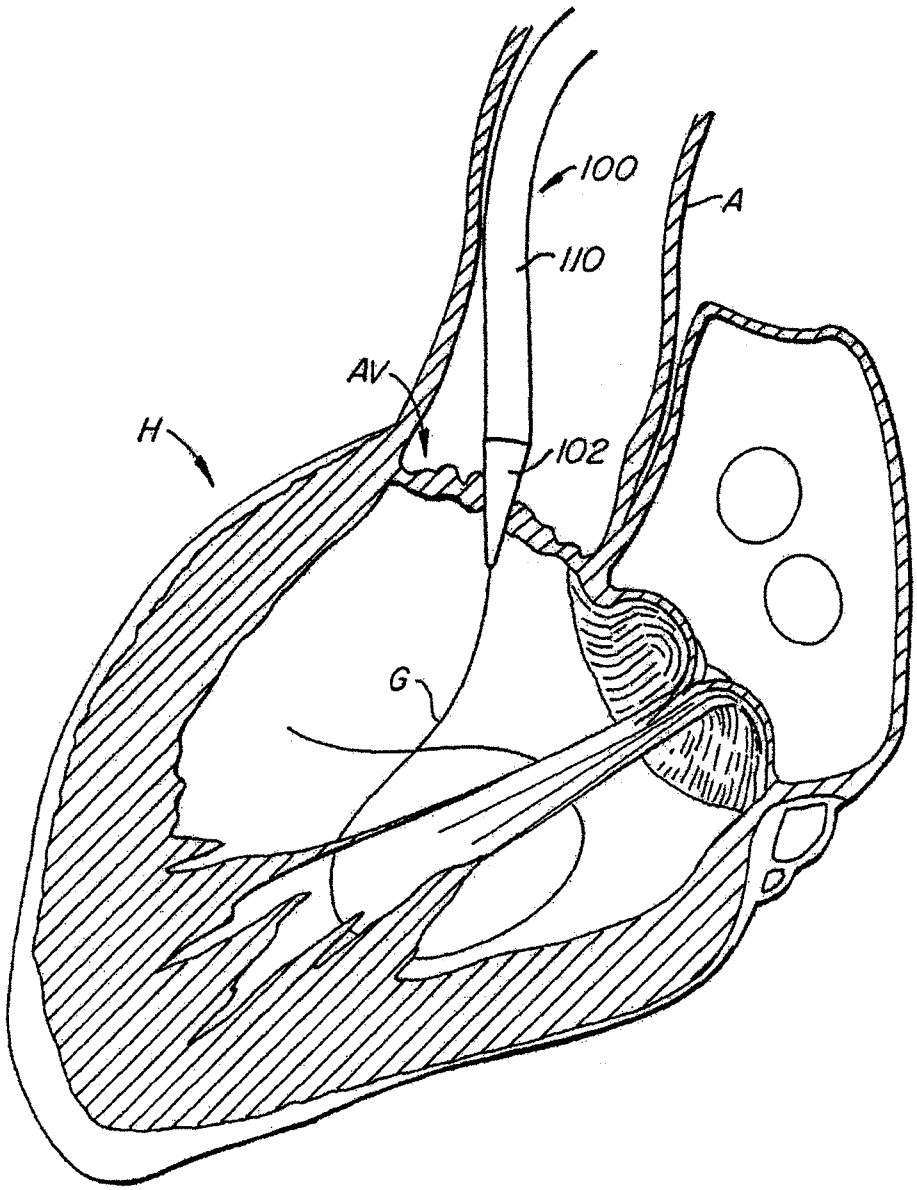


FIG. 5A

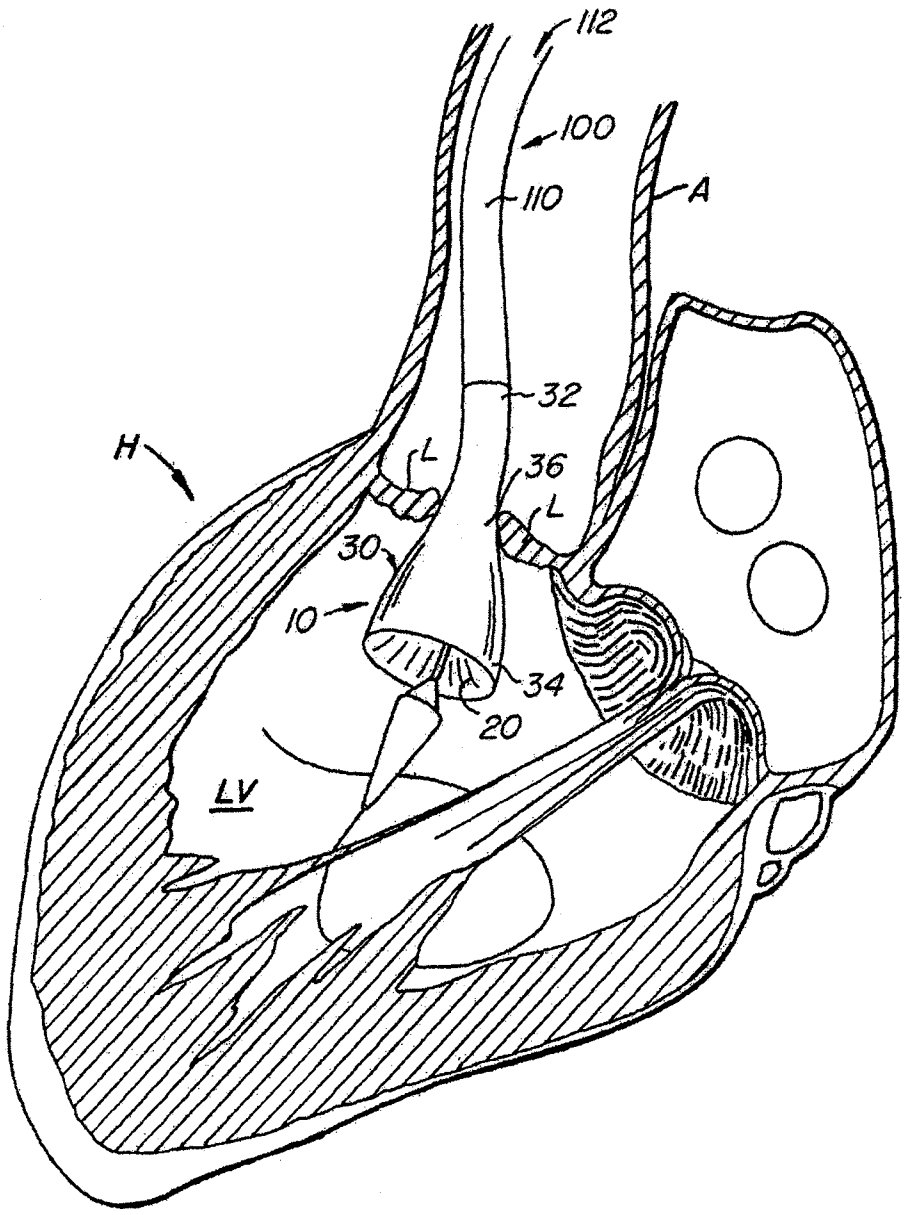


FIG. 5B

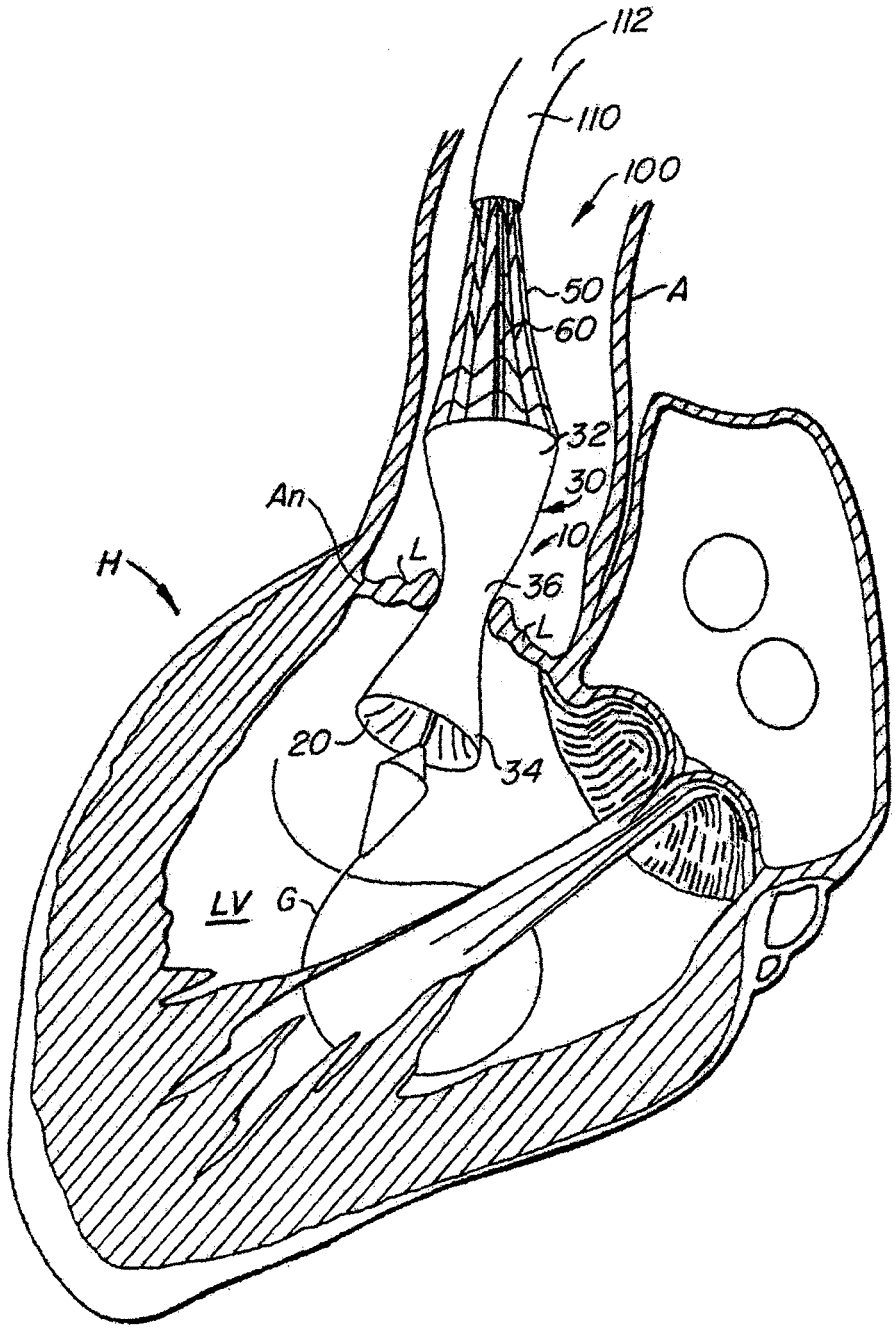
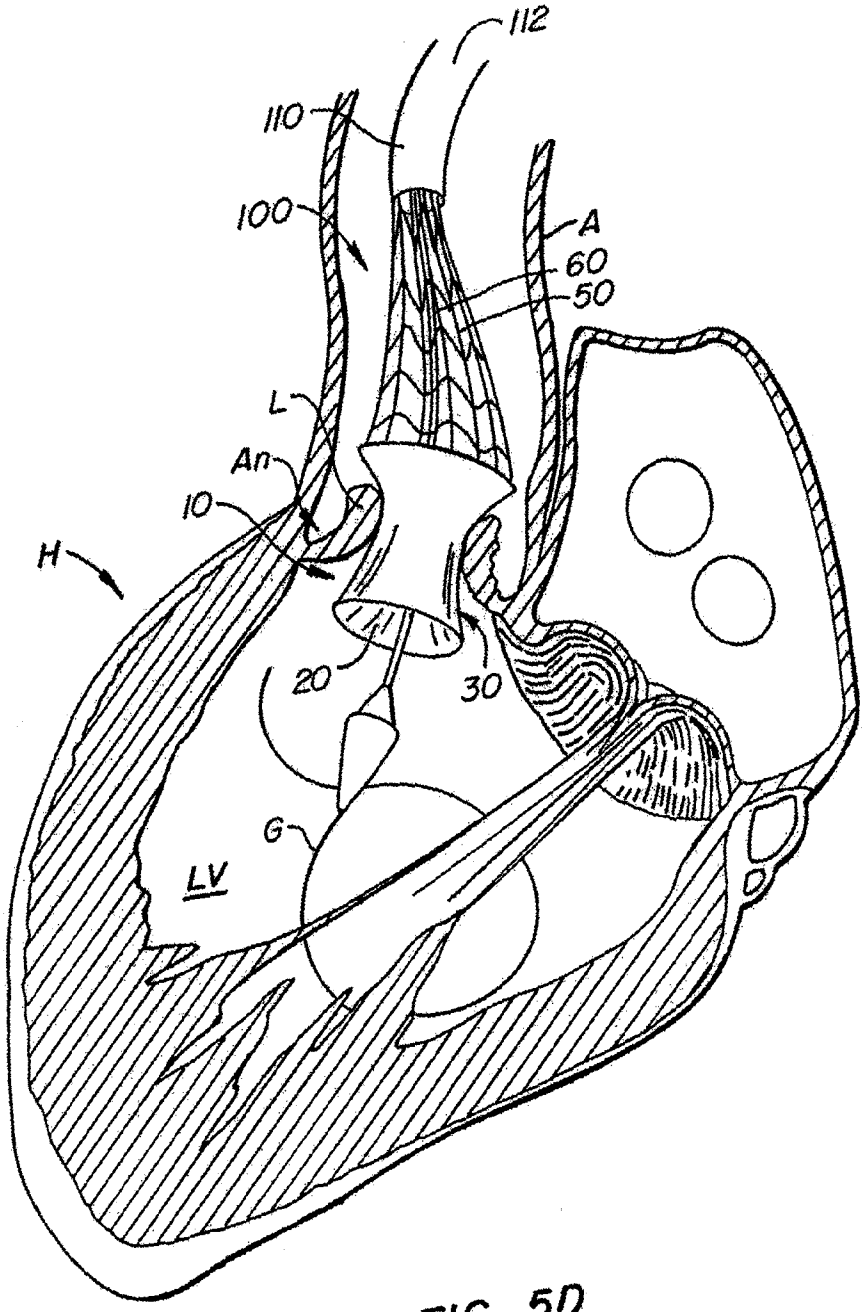


FIG. 5C



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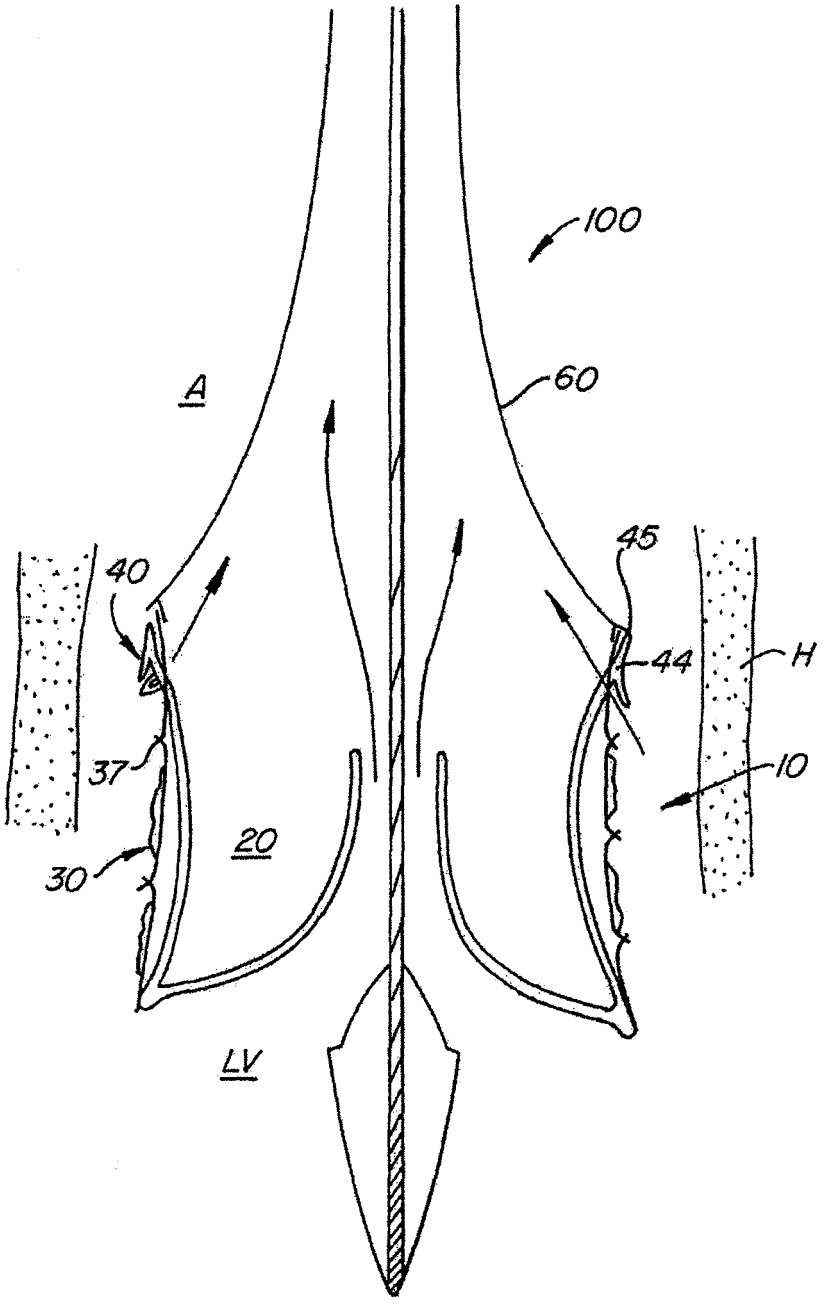

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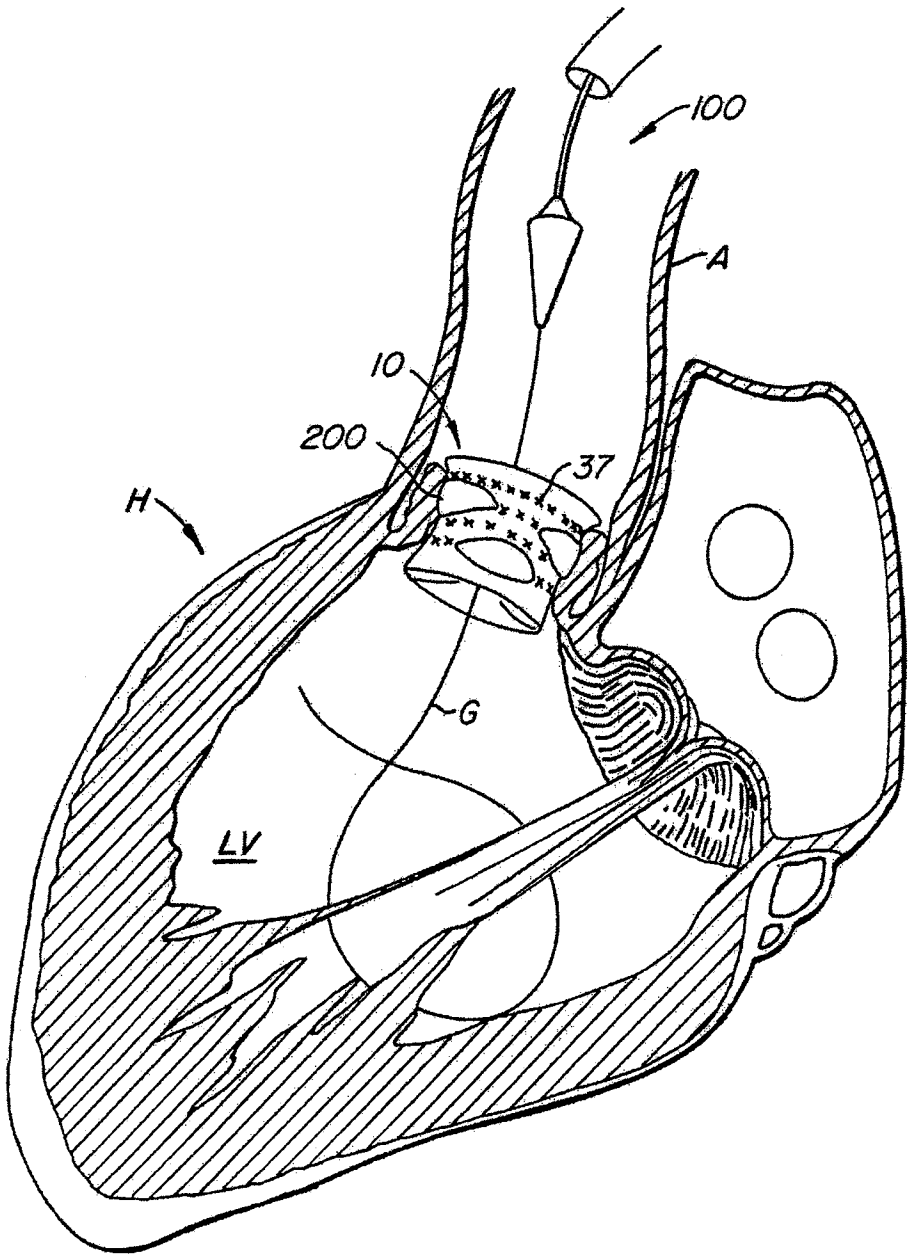

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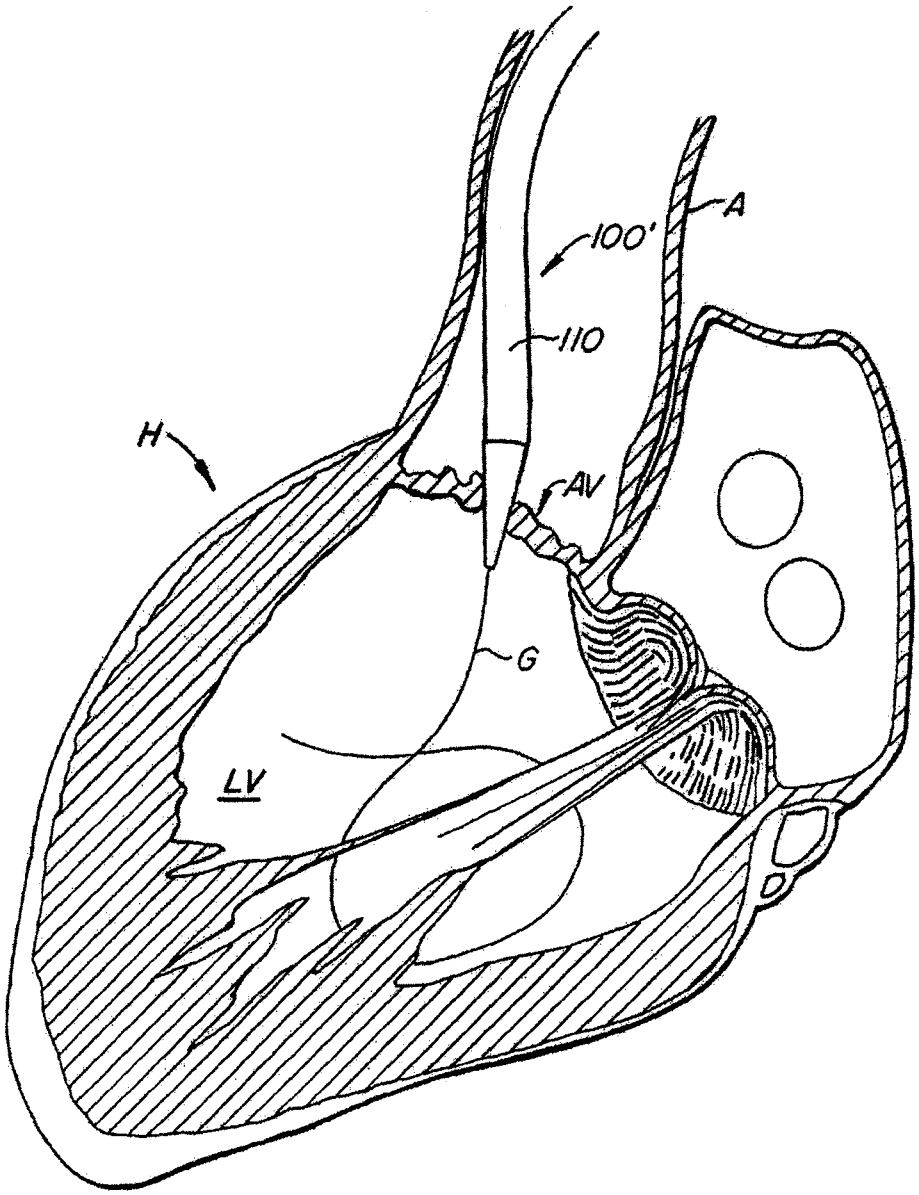


FIG. 6A

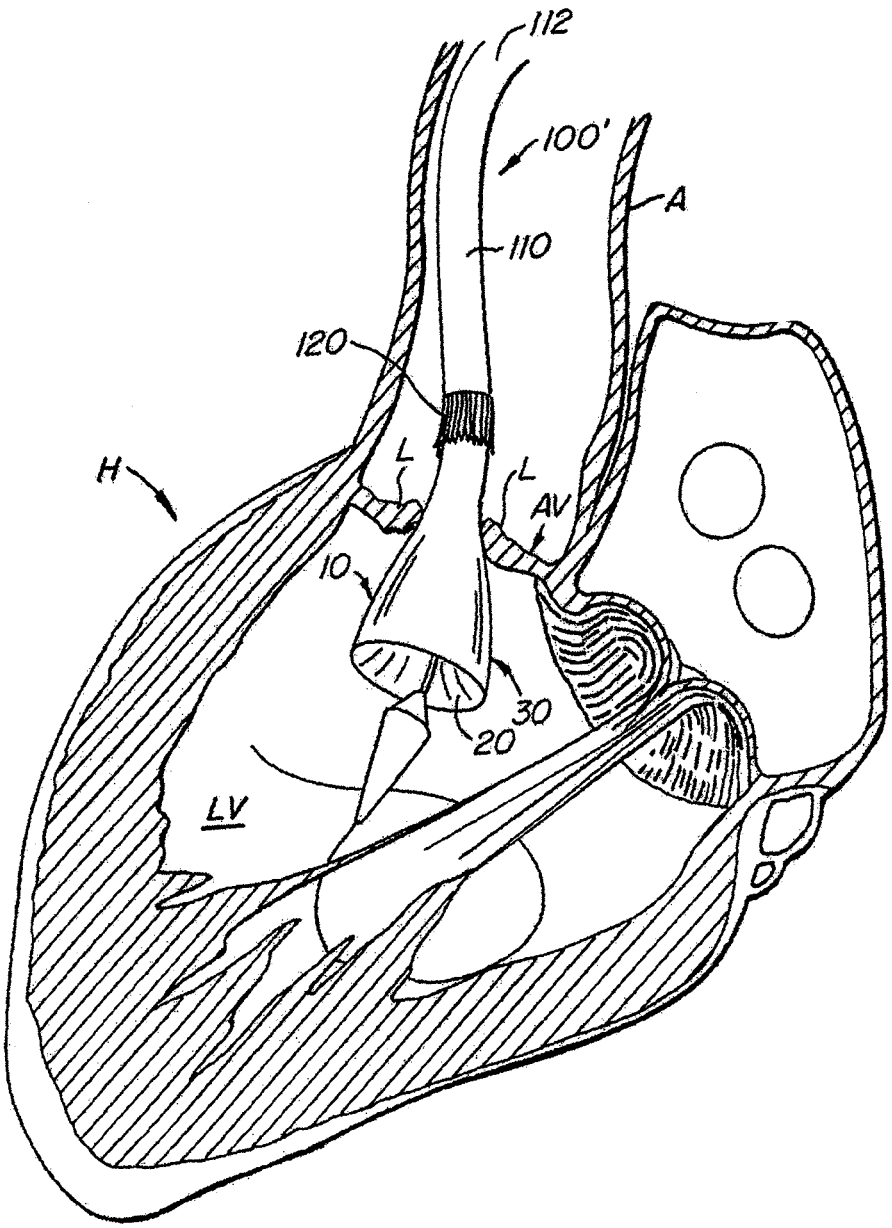


FIG. 6B

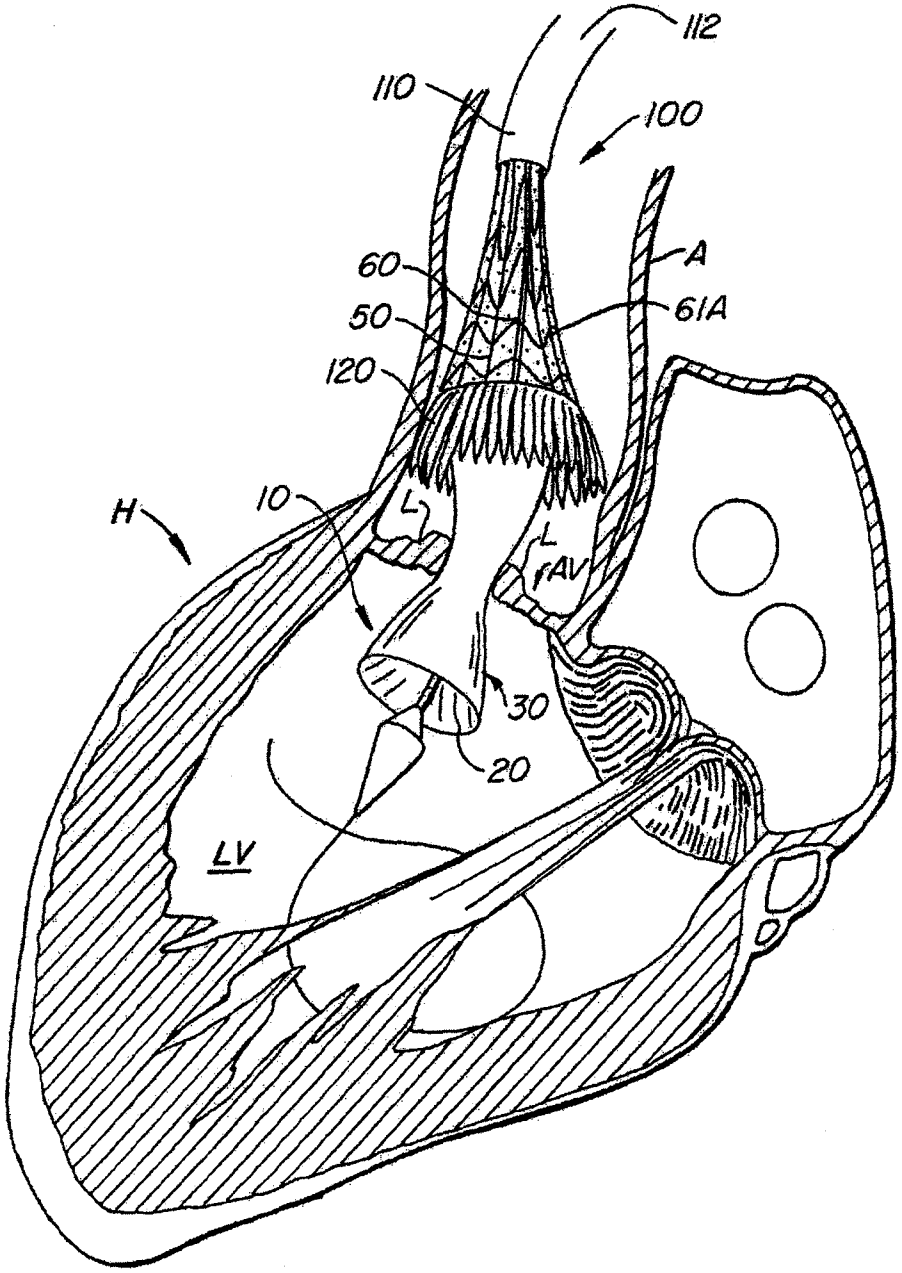


FIG. 6C

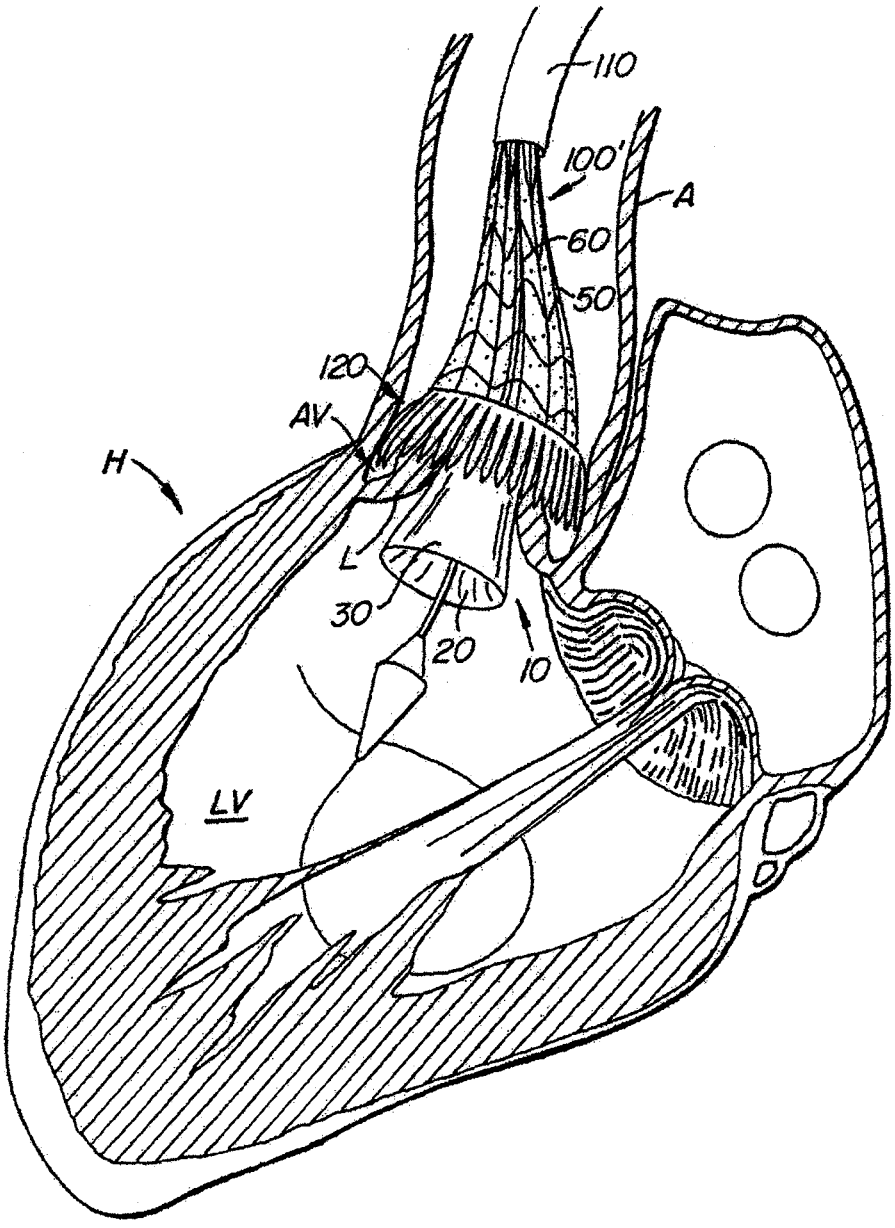


FIG. 6D

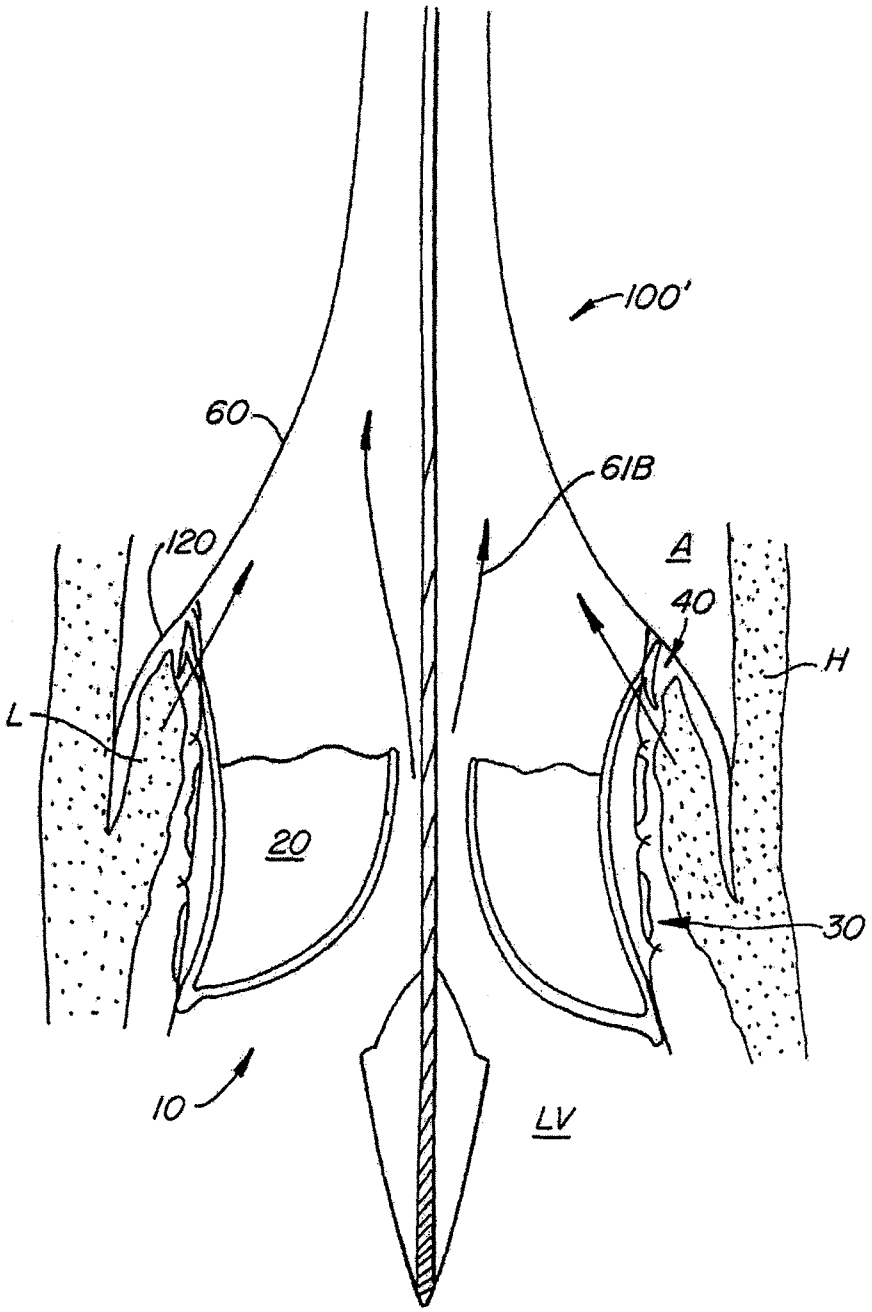


FIG. 6E

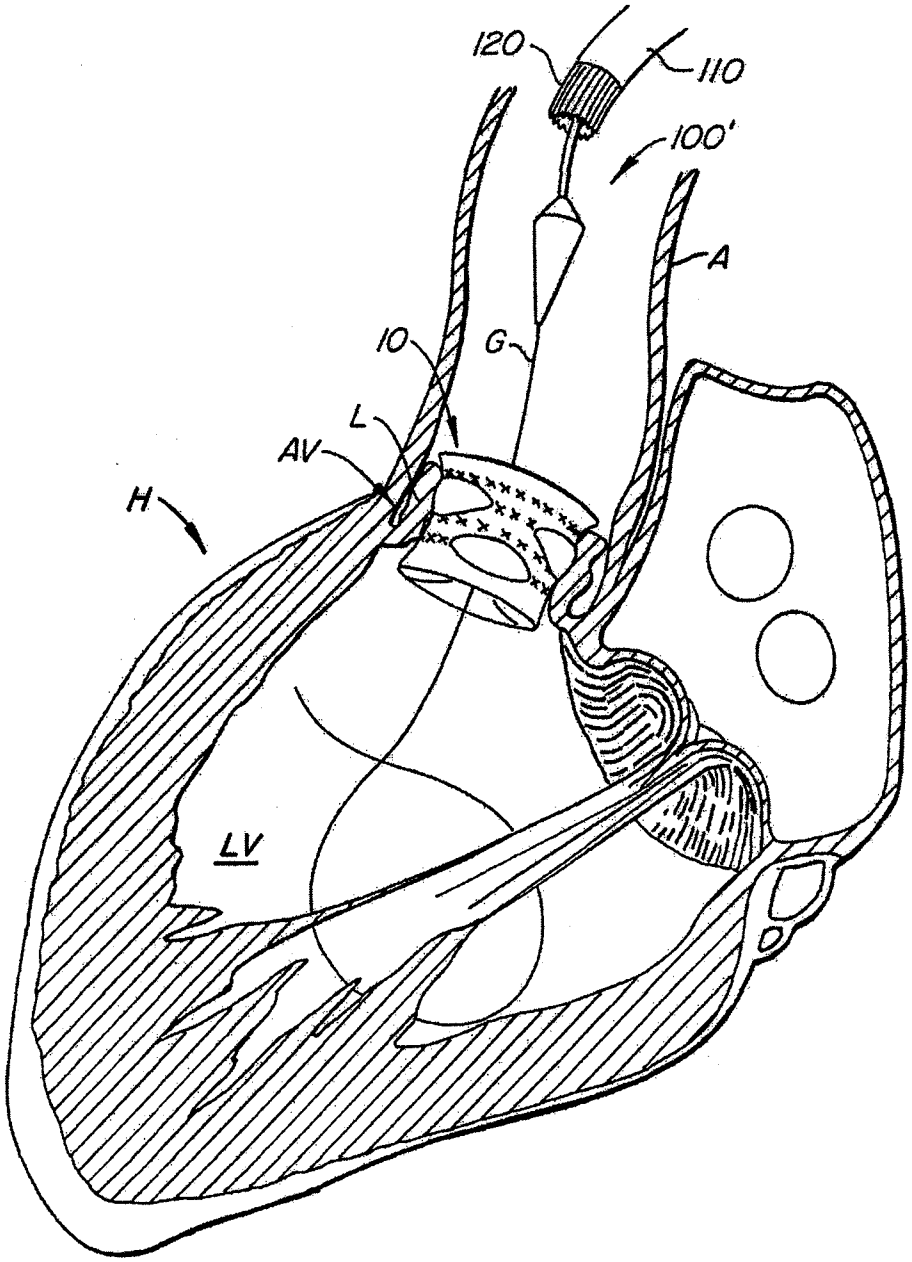


FIG. 6F

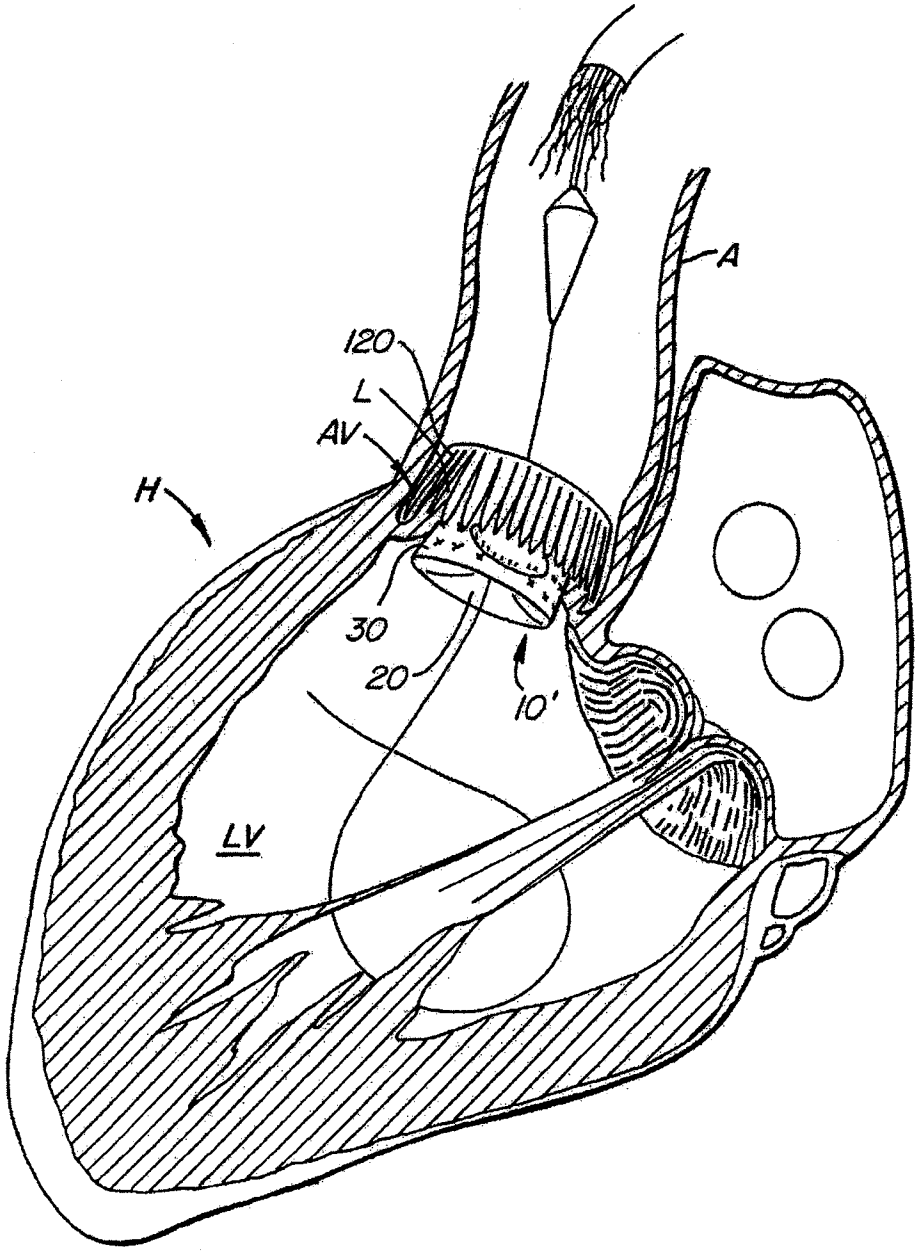


FIG. 7

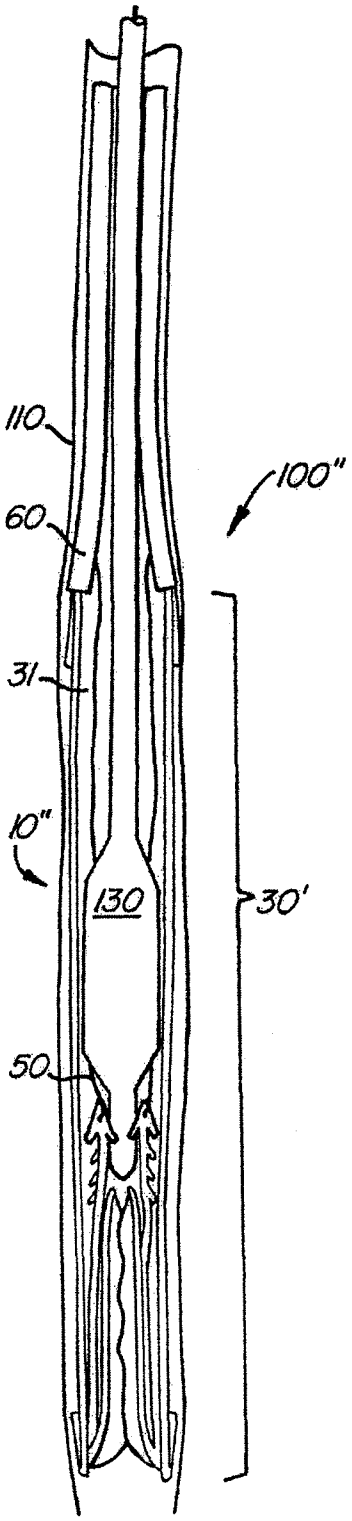


FIG. 8A

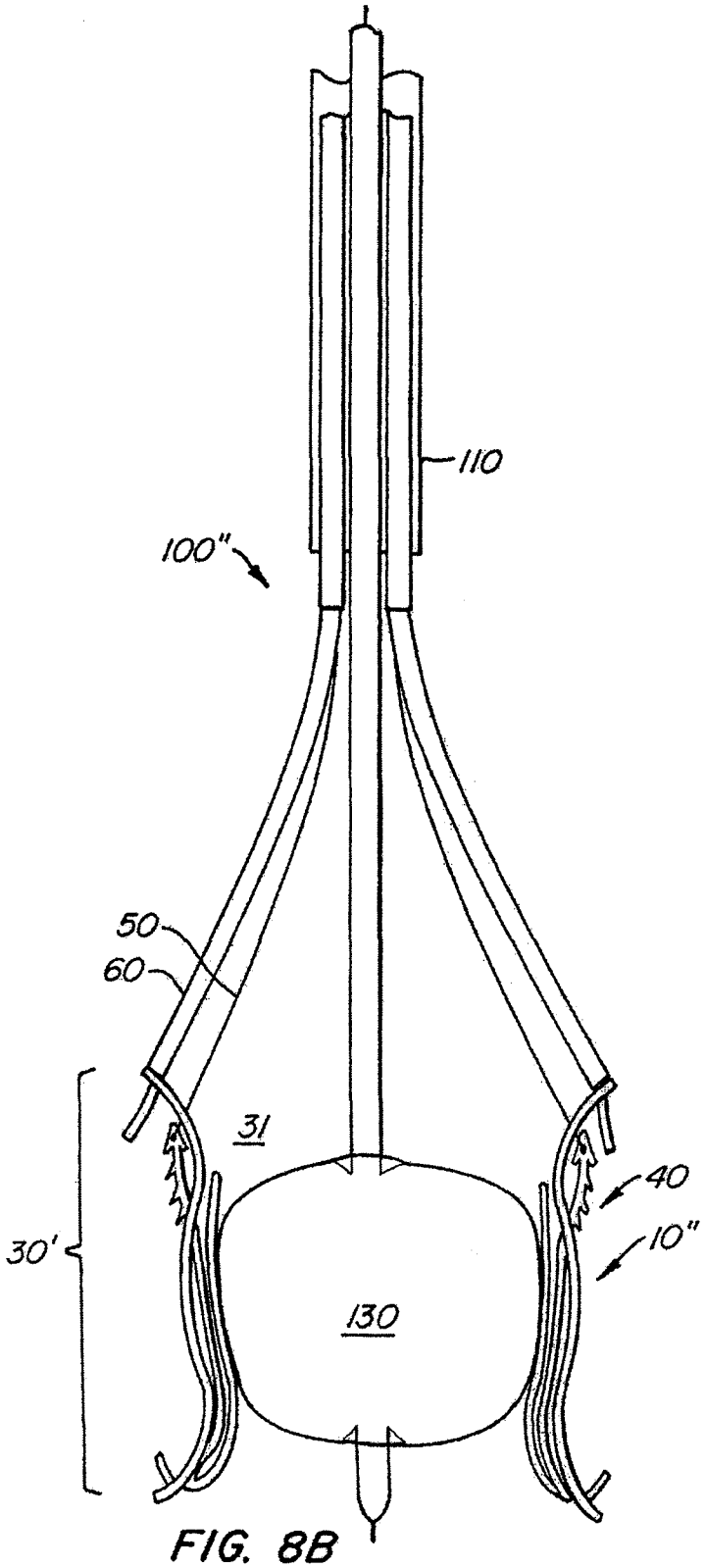
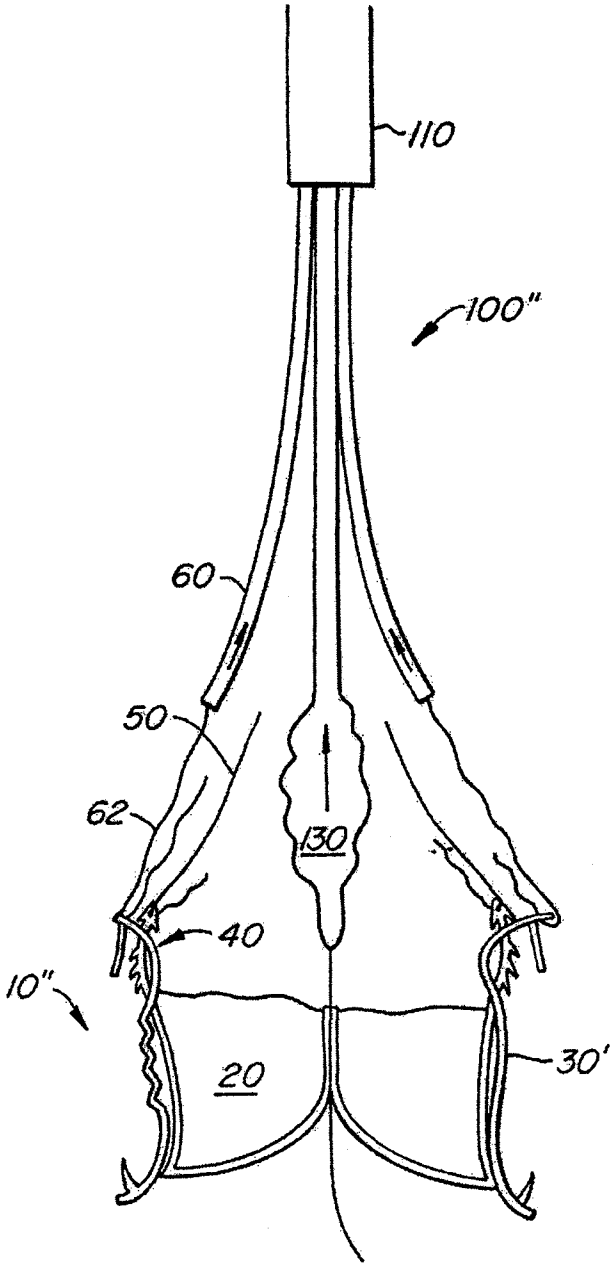


FIG. 8B



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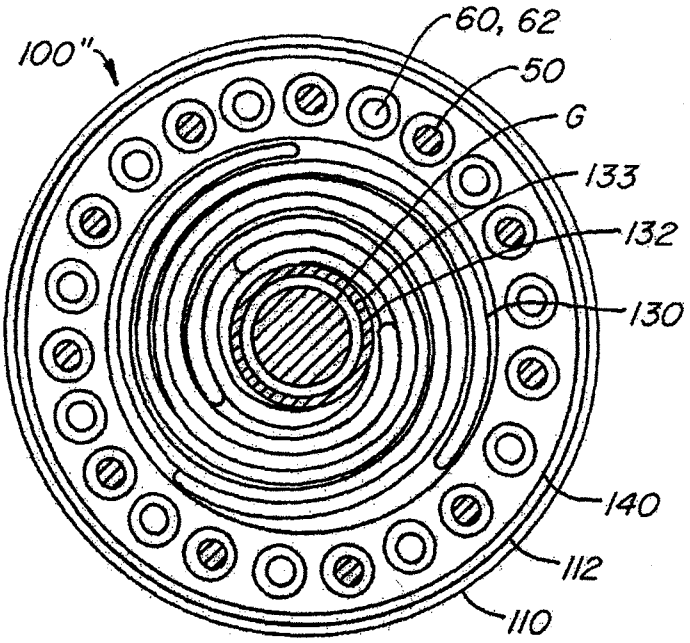


FIG. 10

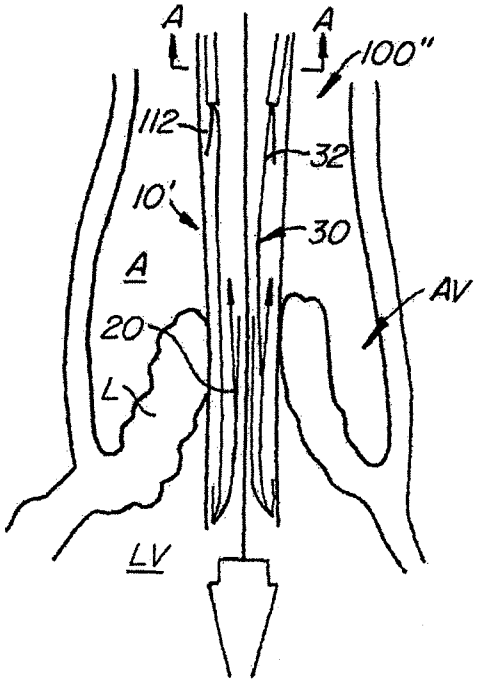
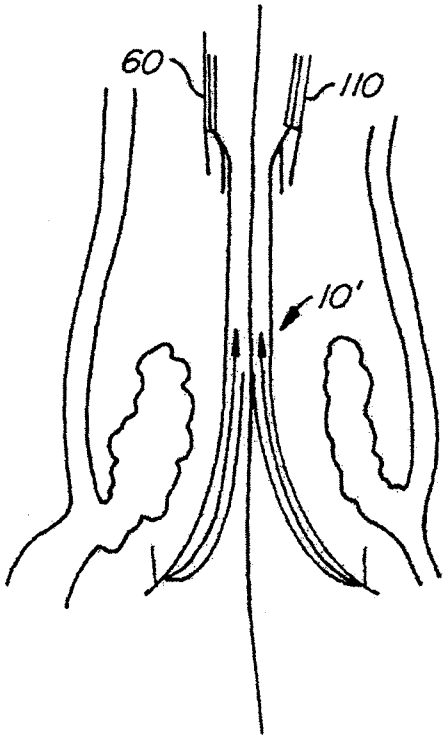


FIG. 9A



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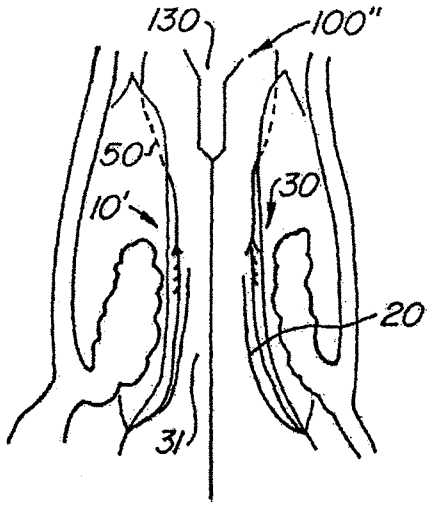

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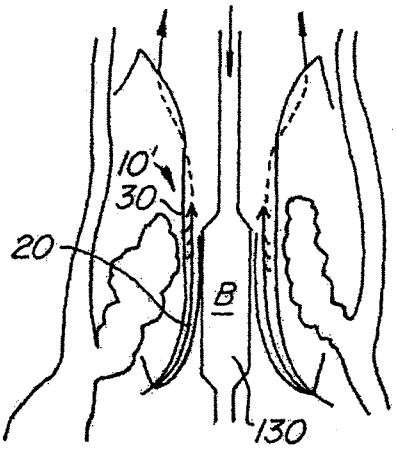


FIG. 9D

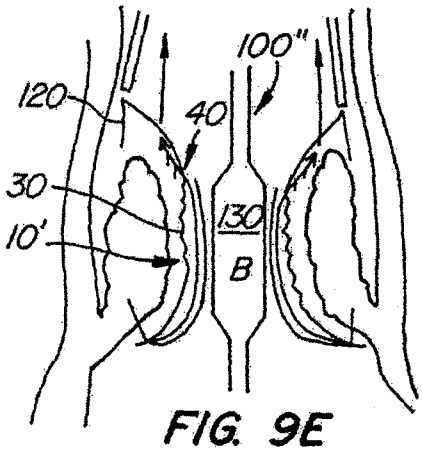


FIG. 9E

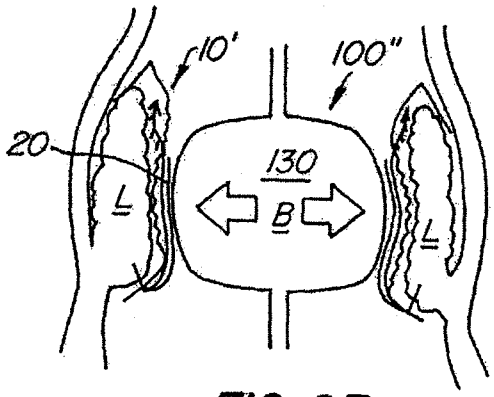


FIG. 9F

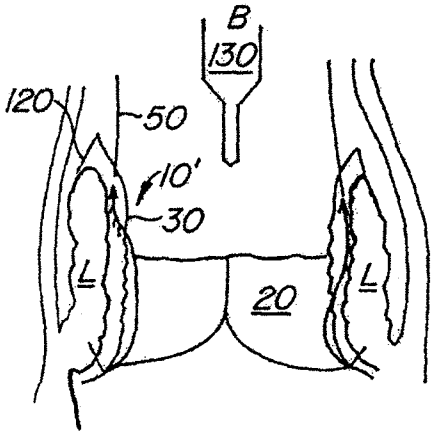


FIG. 9G

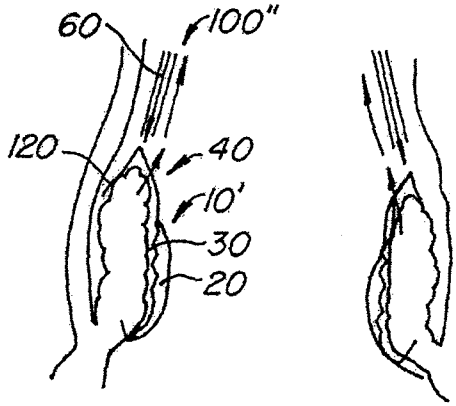


FIG. 9H

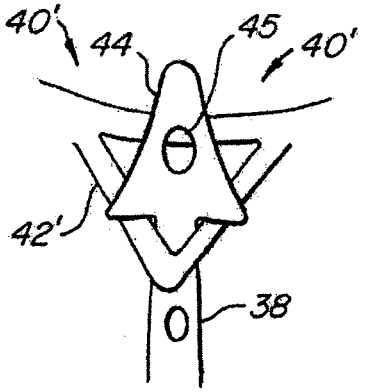


FIG. 11A

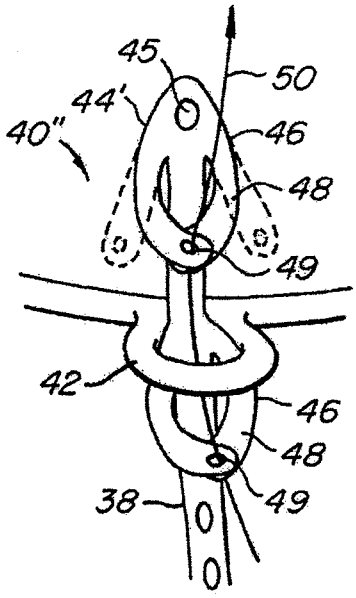


FIG. 11B

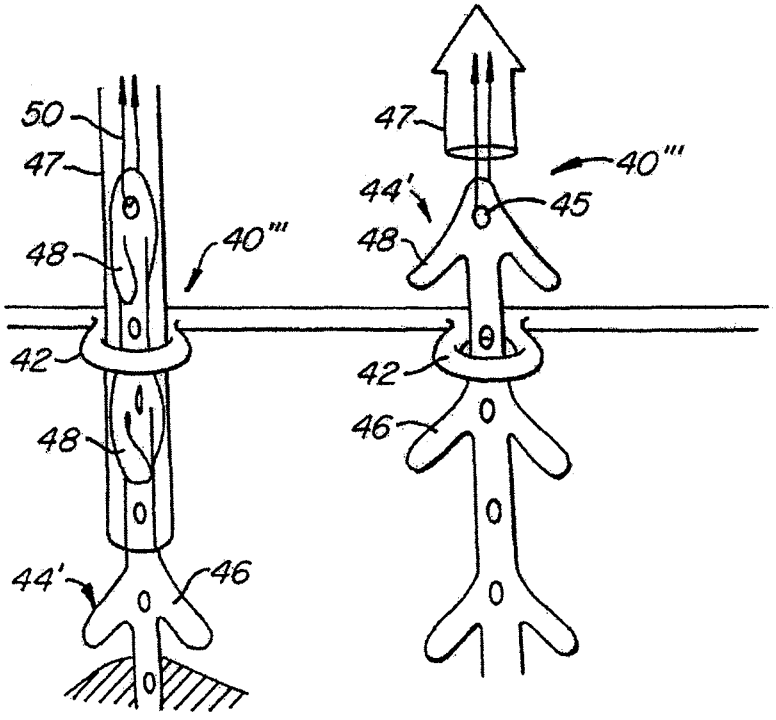


FIG. 11C

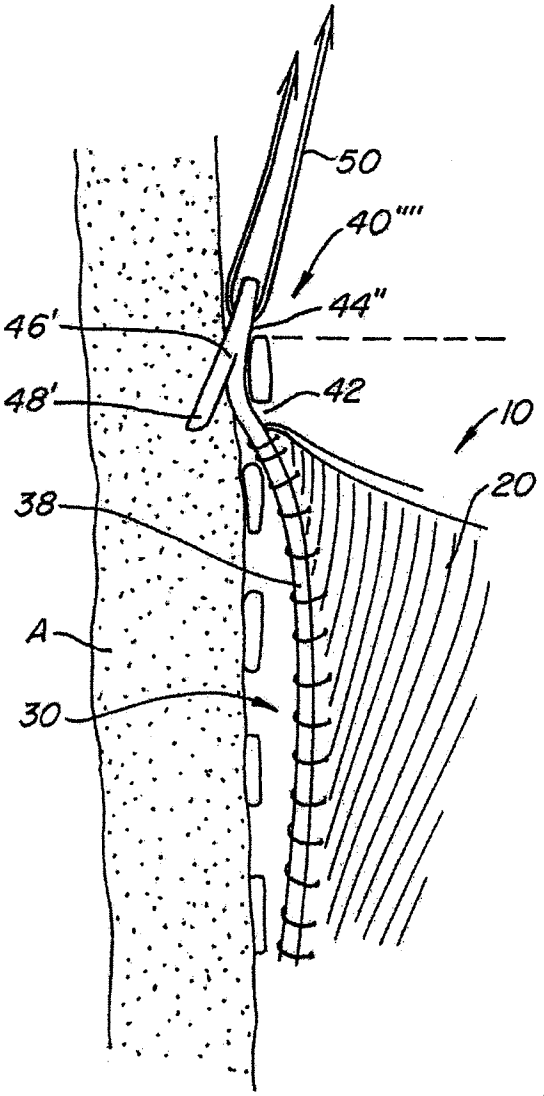


FIG. 12C

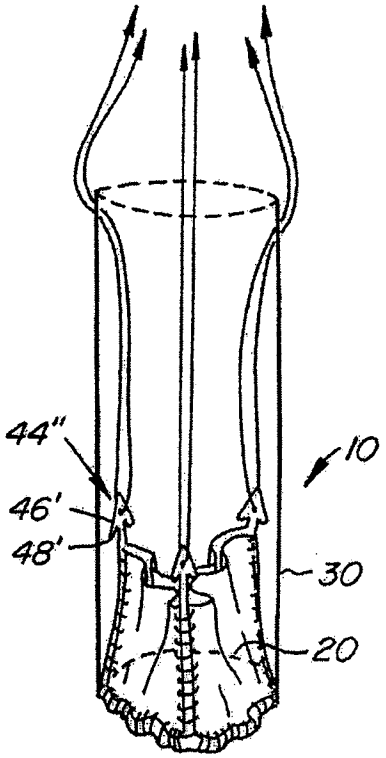


FIG. 12A

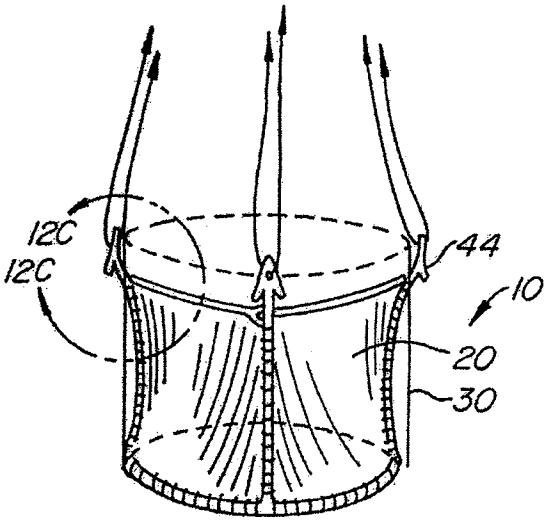


FIG. 12B

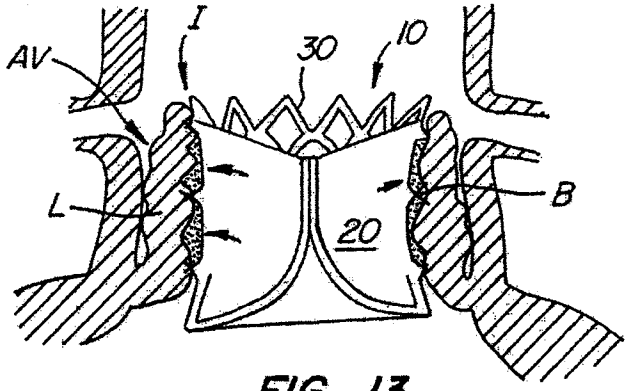


FIG. 13

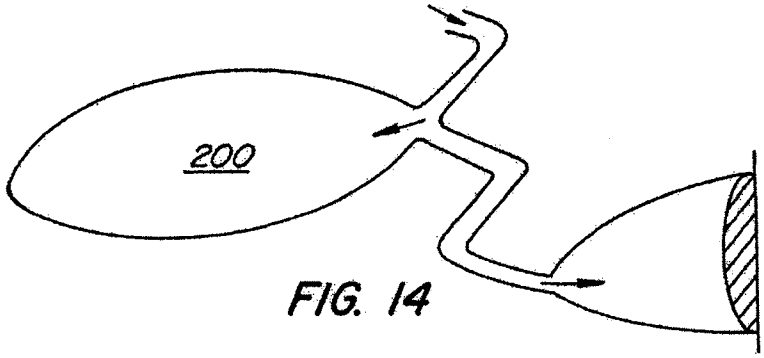


FIG. 14

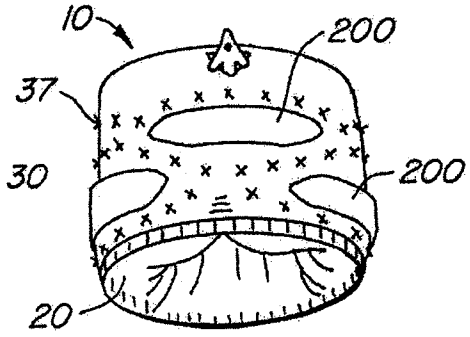


FIG. 15A

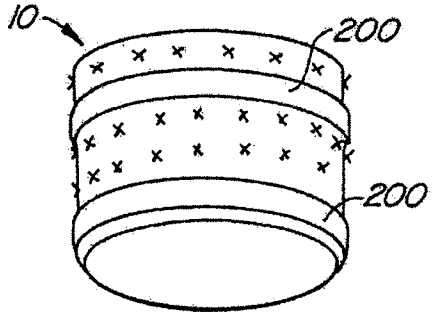


FIG. 15B

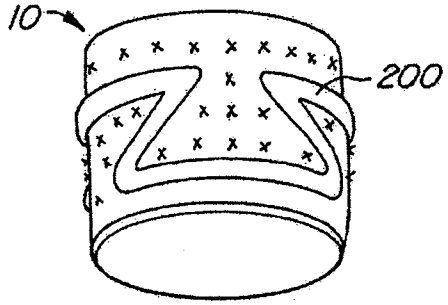


FIG. 15C

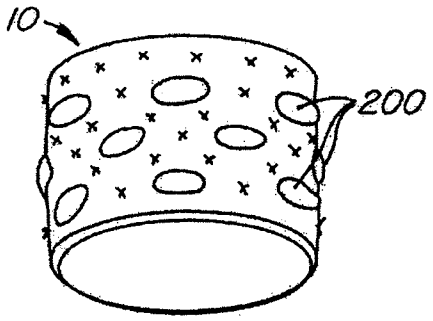


FIG. 15D

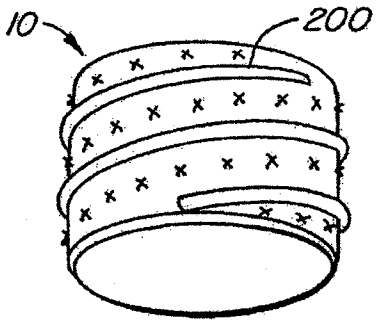


FIG. 15E

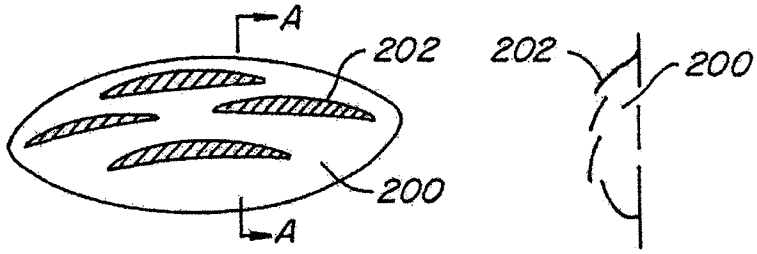


FIG. 16A

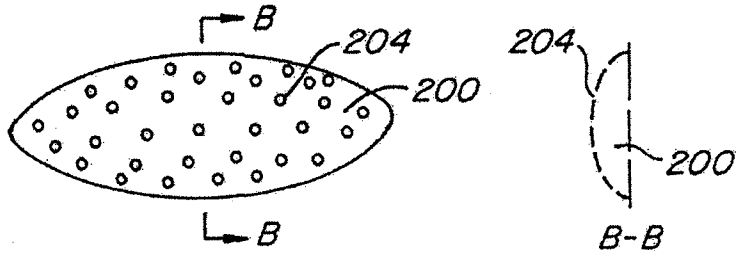


FIG. 16B

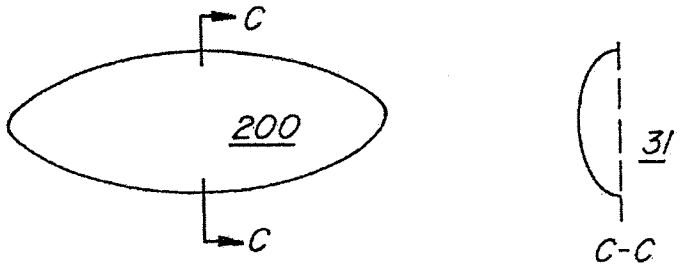


FIG. 16C

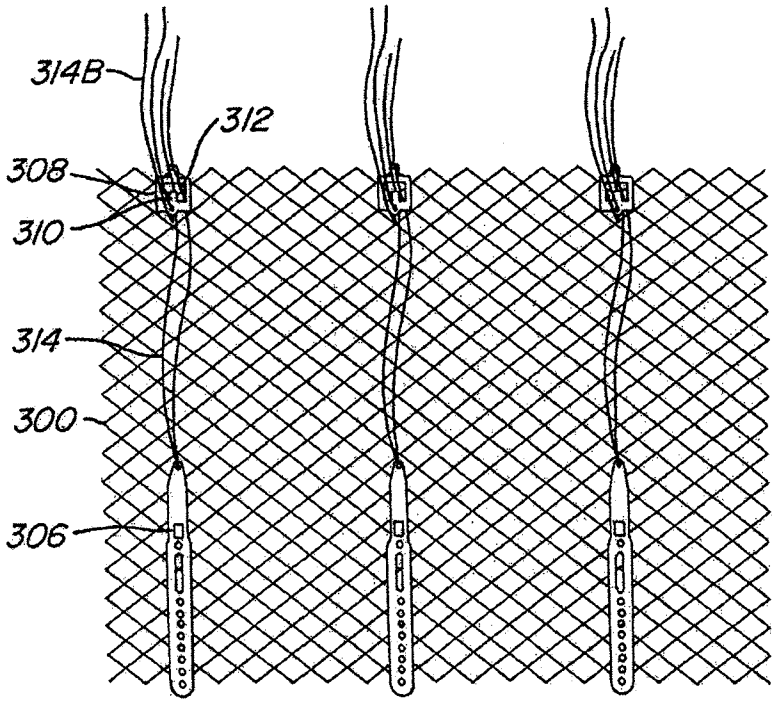


FIG. 17A

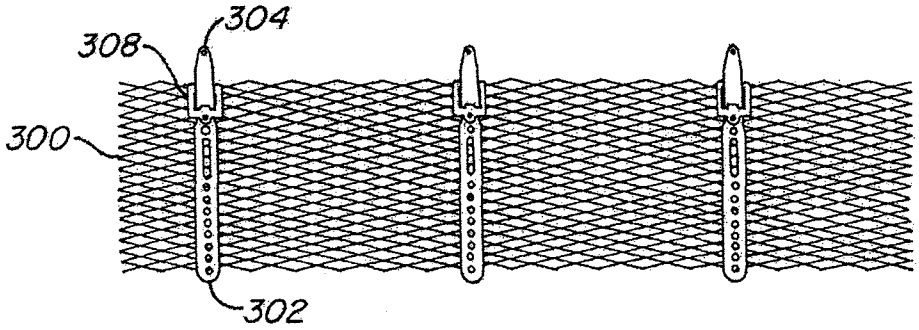


FIG. 18A

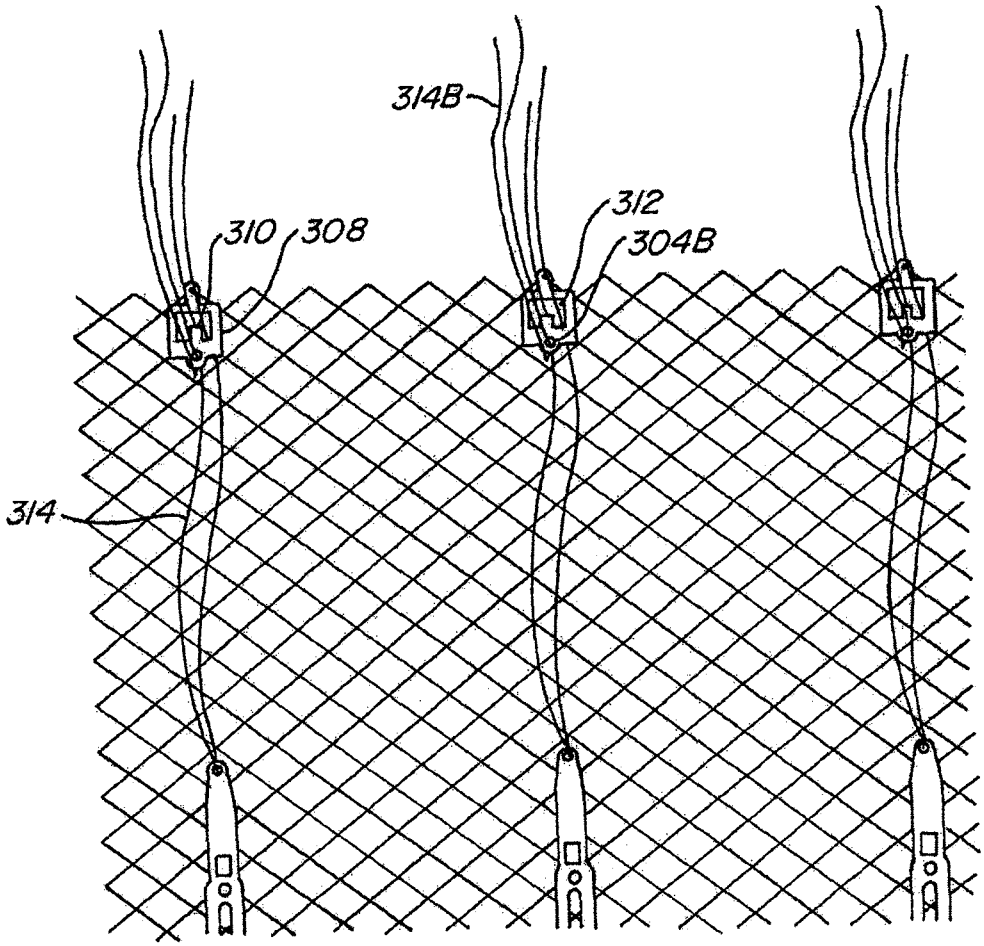


FIG. 17B

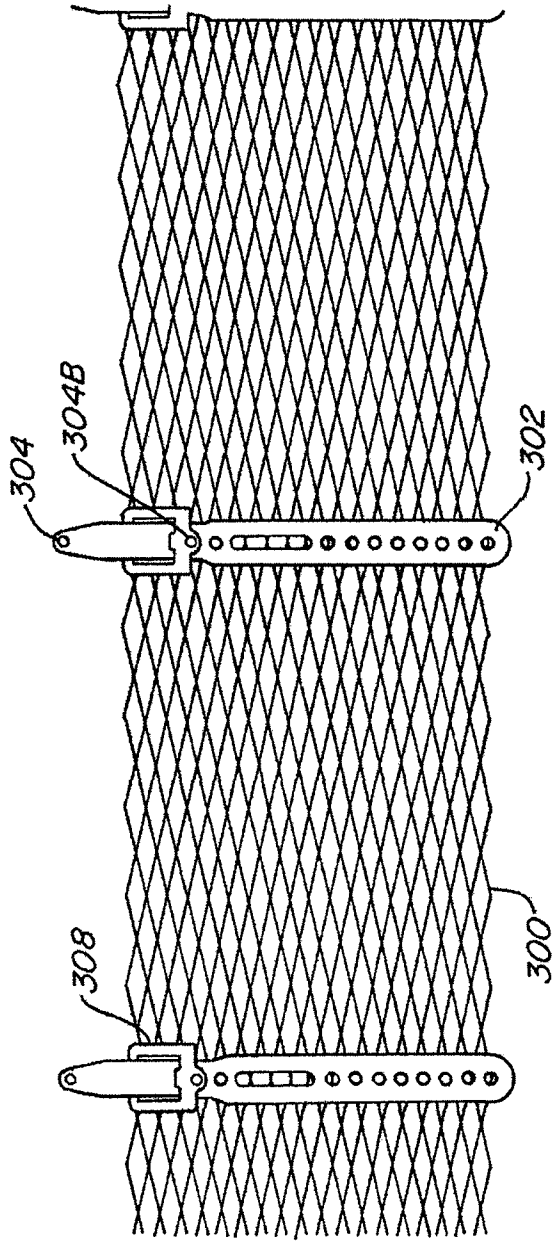


FIG. 18B

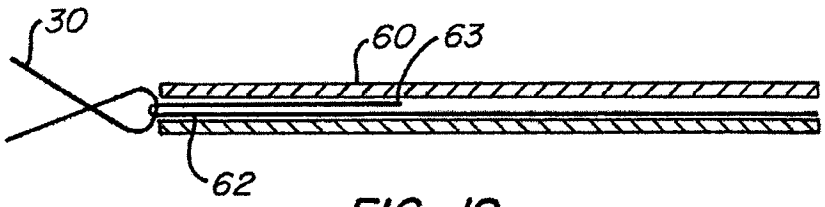


FIG. 19

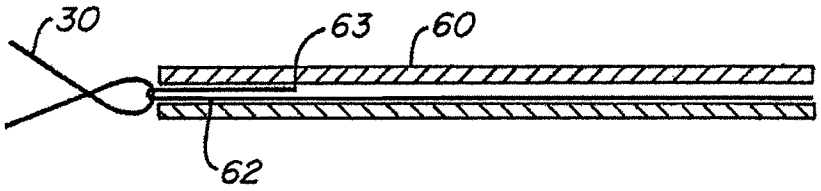


FIG. 20

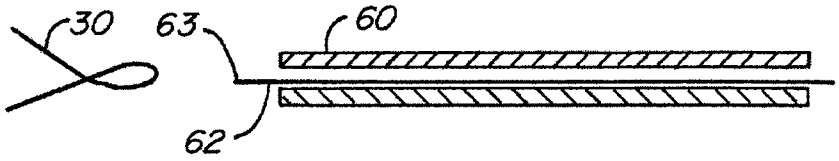


FIG. 21

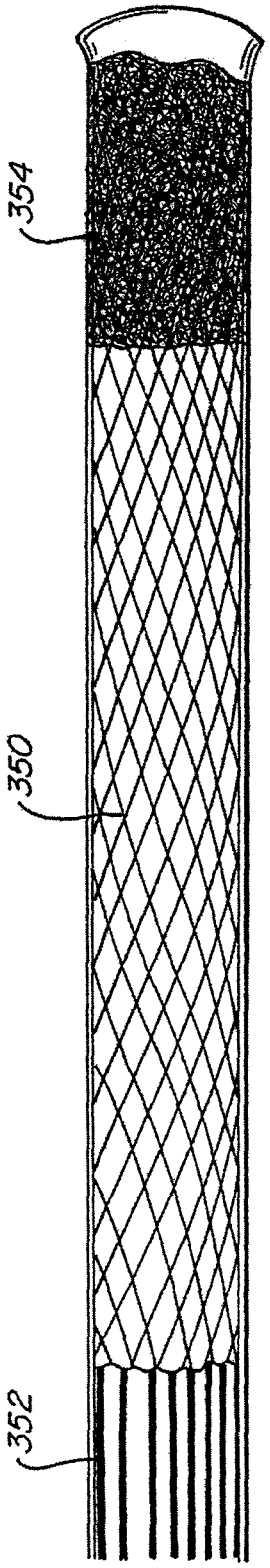


FIG. 22

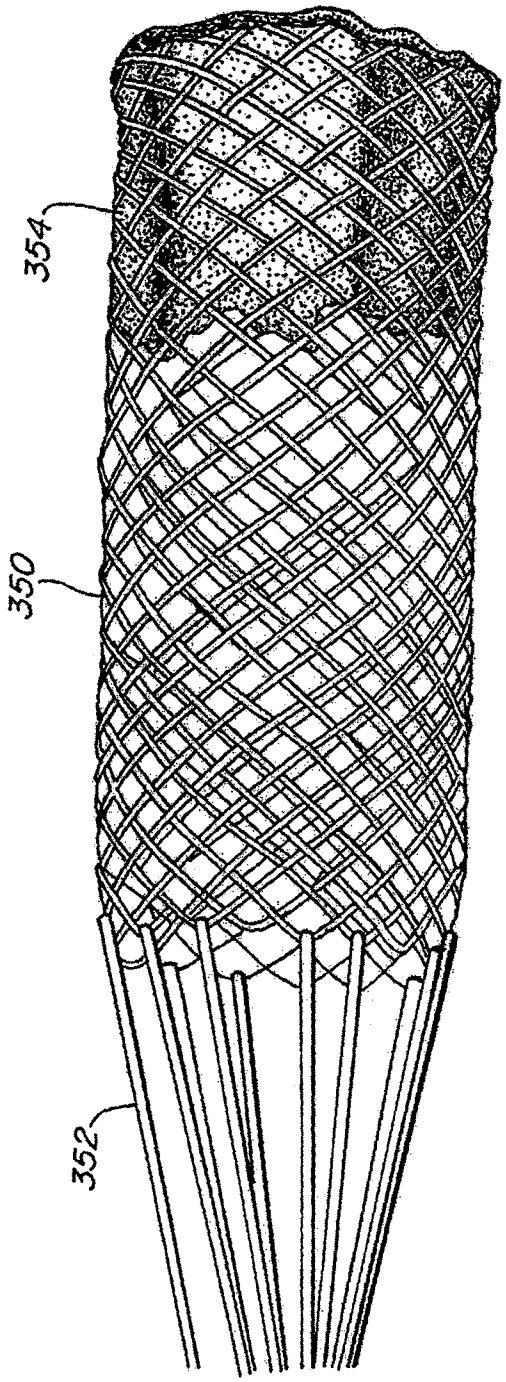


FIG. 23

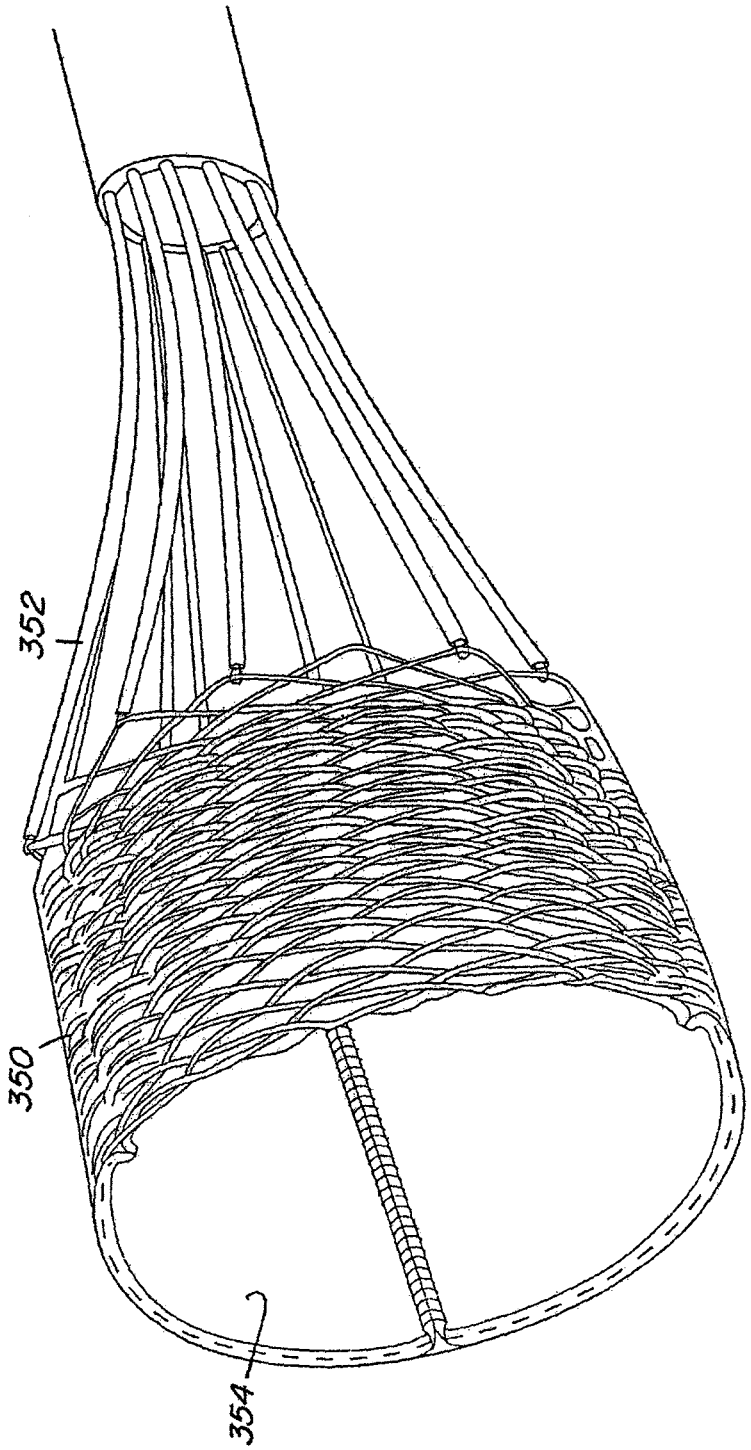


FIG. 24

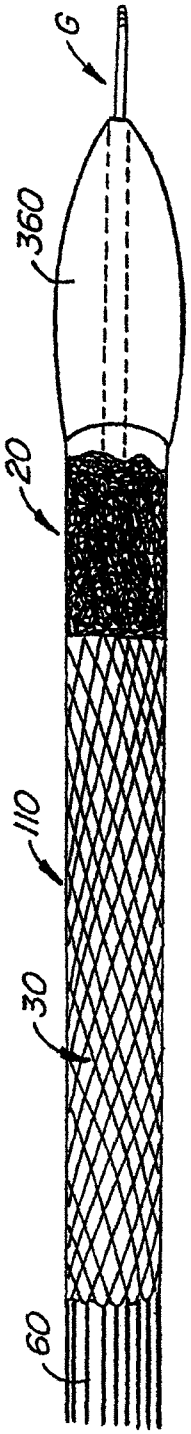


FIG. 25

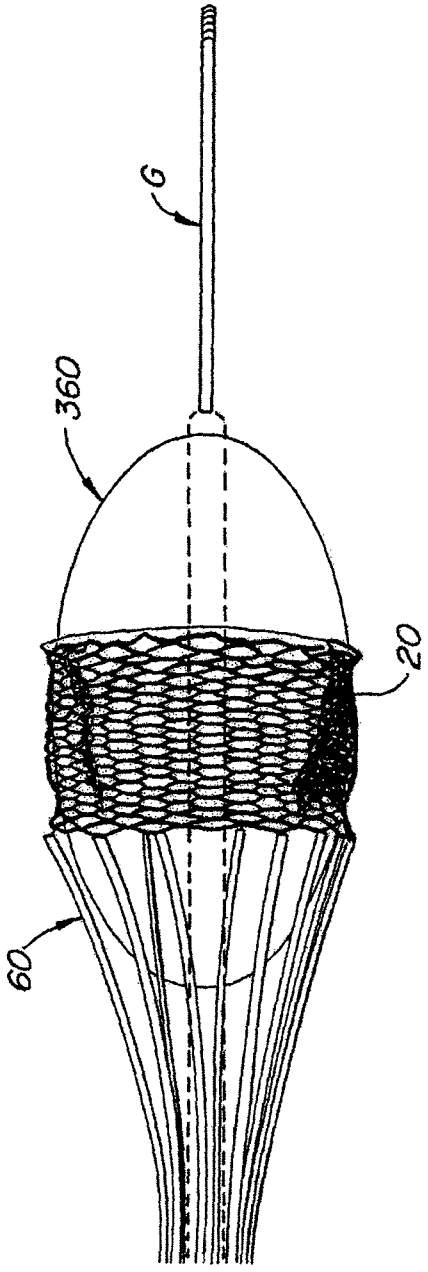


FIG. 26

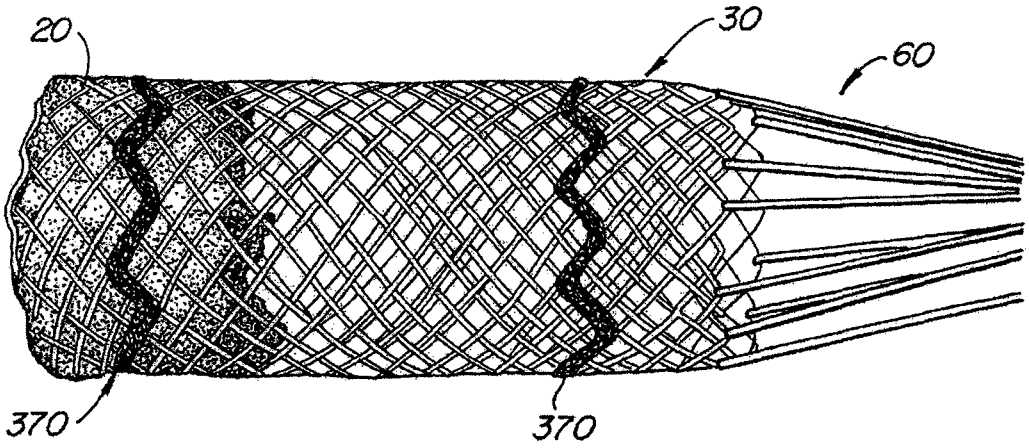


FIG. 27

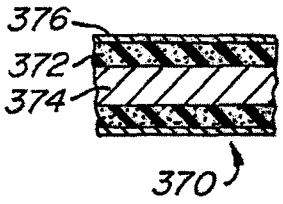


FIG. 28

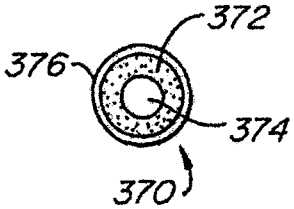


FIG. 29

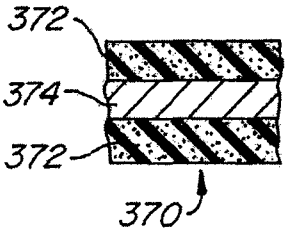


FIG. 30

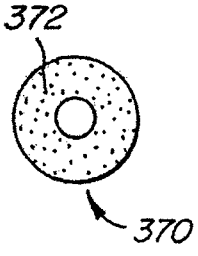


FIG. 31

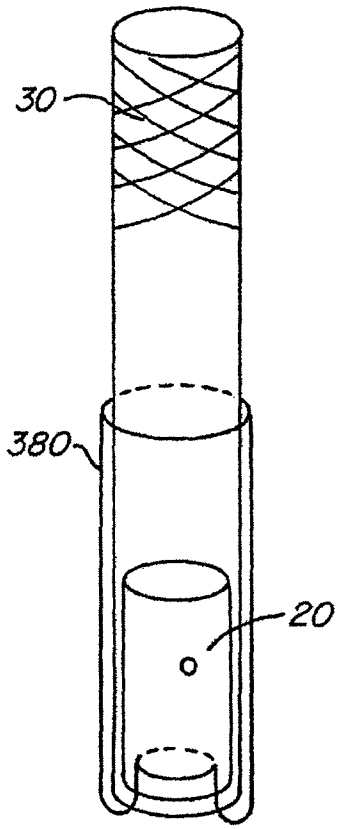


FIG. 32

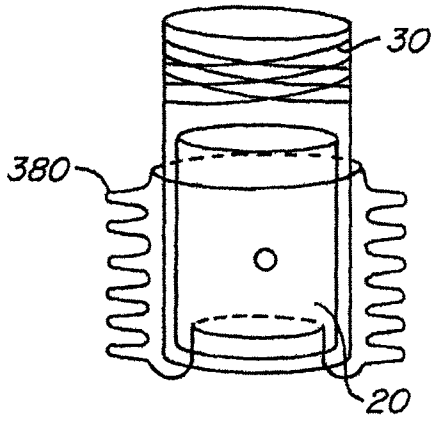


FIG. 33

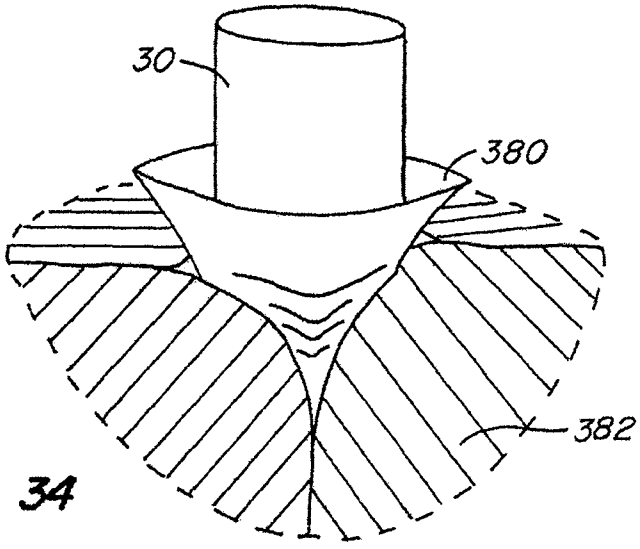


FIG. 34

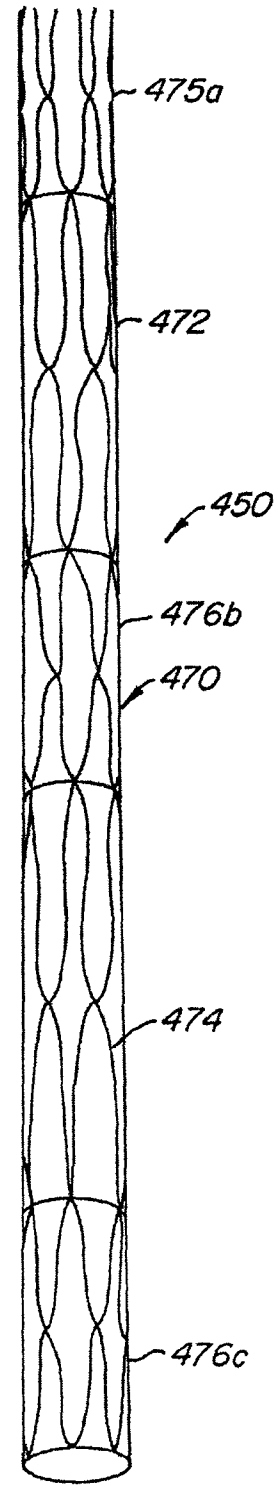


FIG. 35A

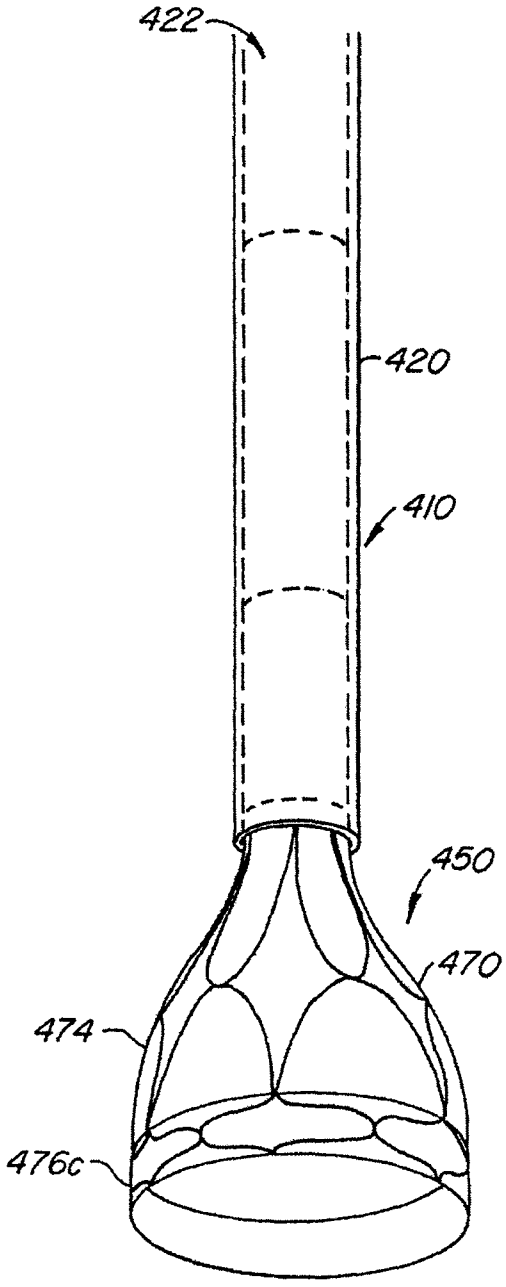


FIG. 35B

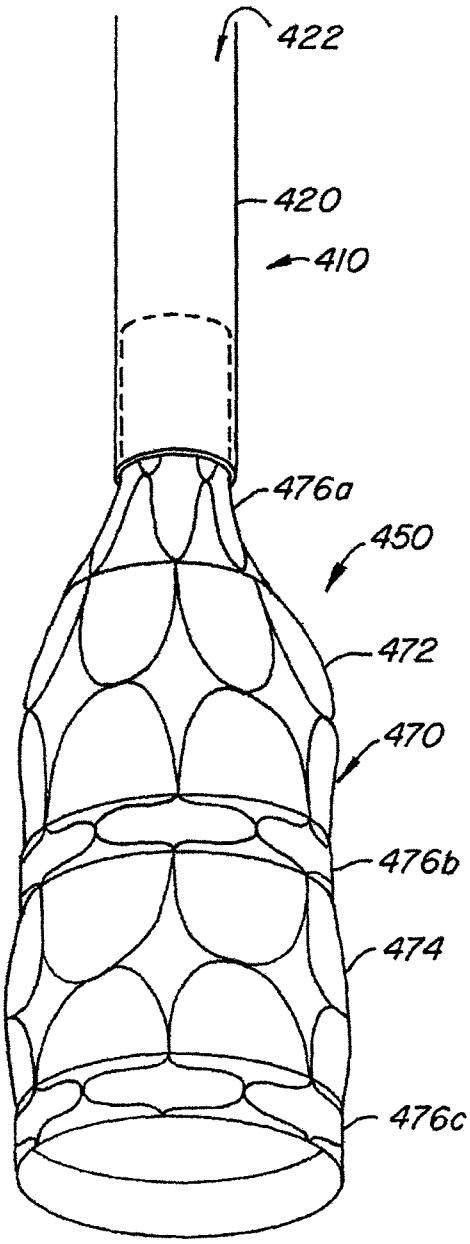


FIG. 35C

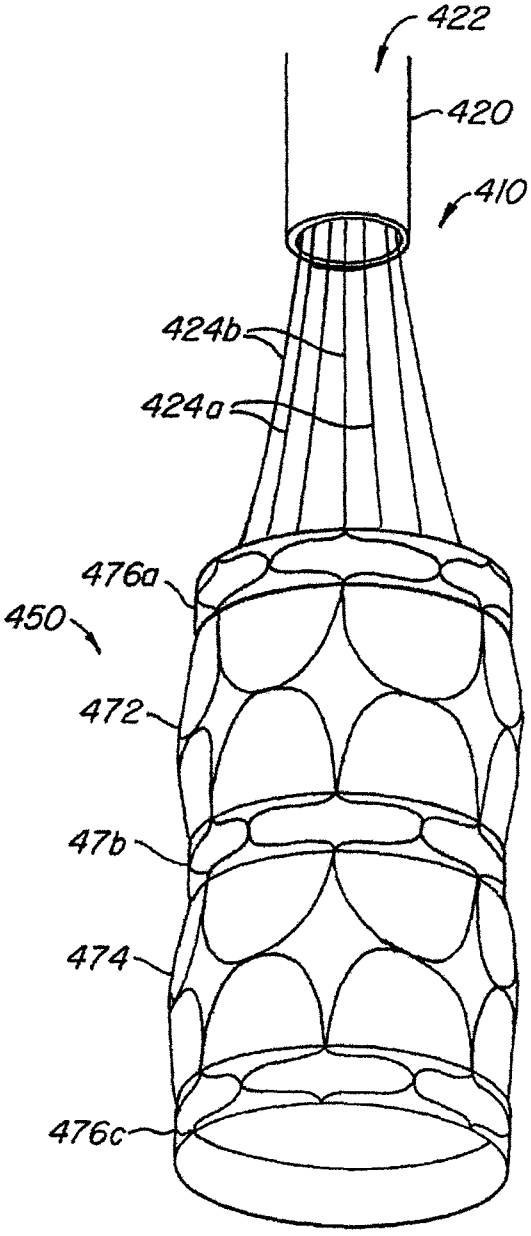


FIG. 35D

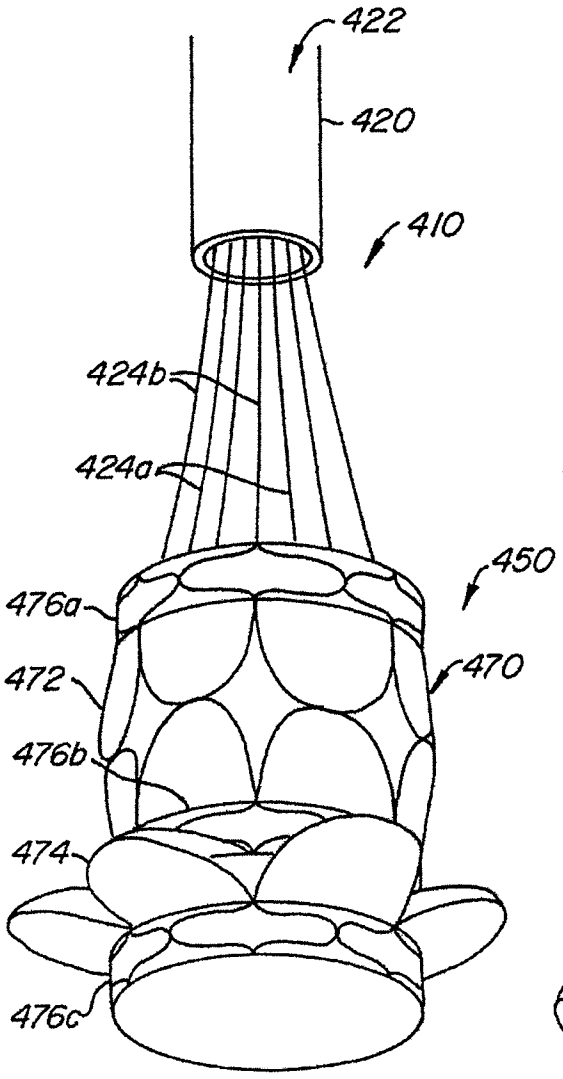


FIG. 35E

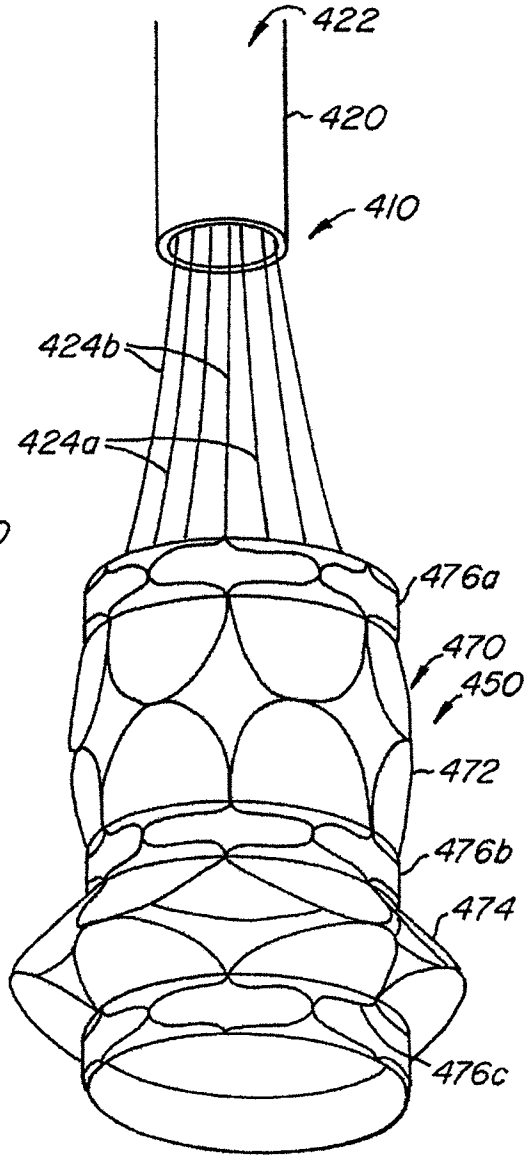


FIG. 35F

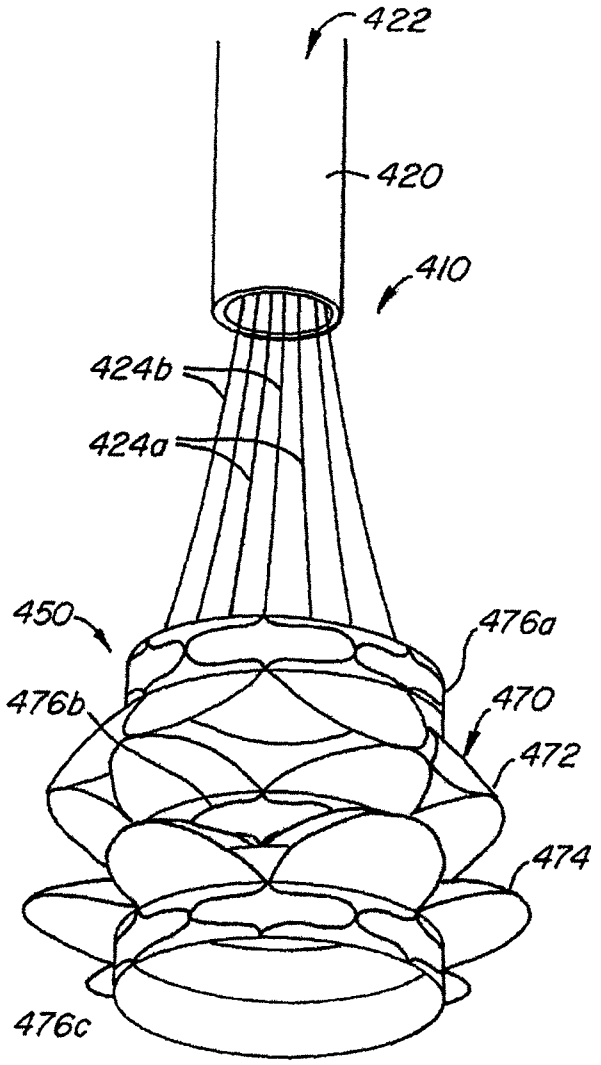


FIG. 35G

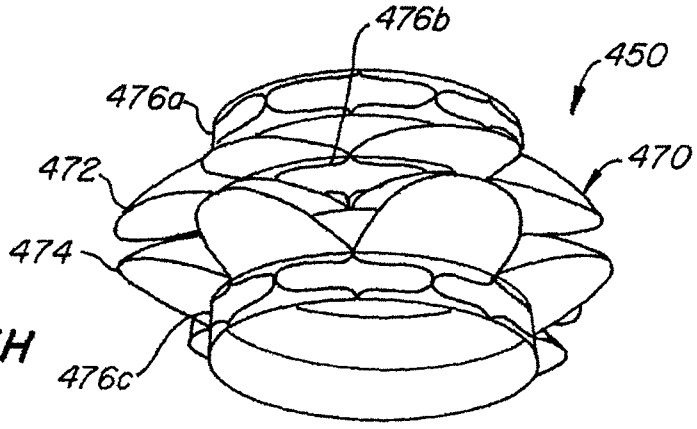


FIG. 35H

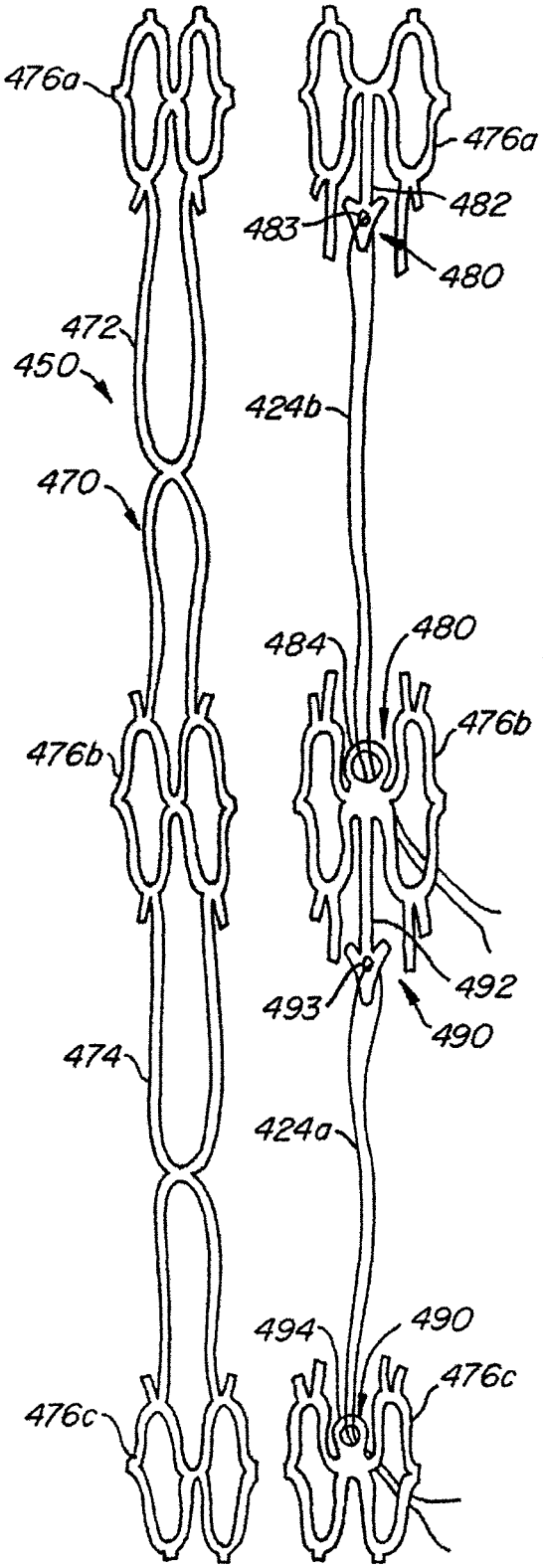


FIG. 36A

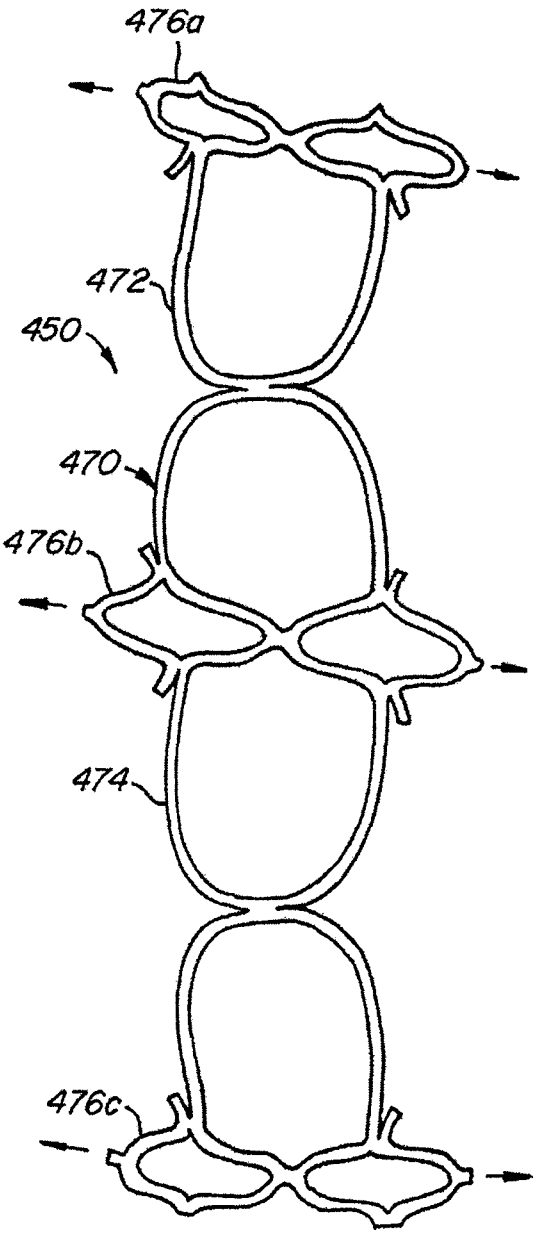


FIG. 36B

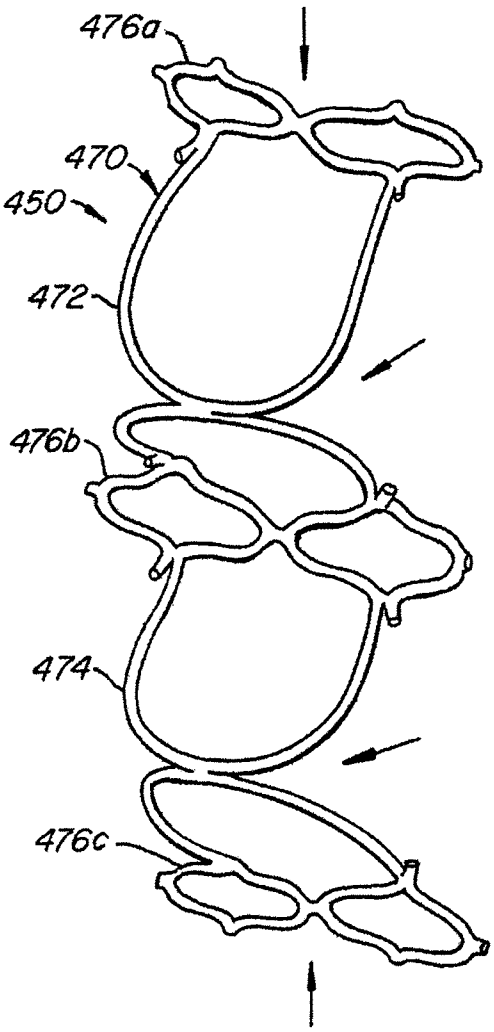


FIG. 36C

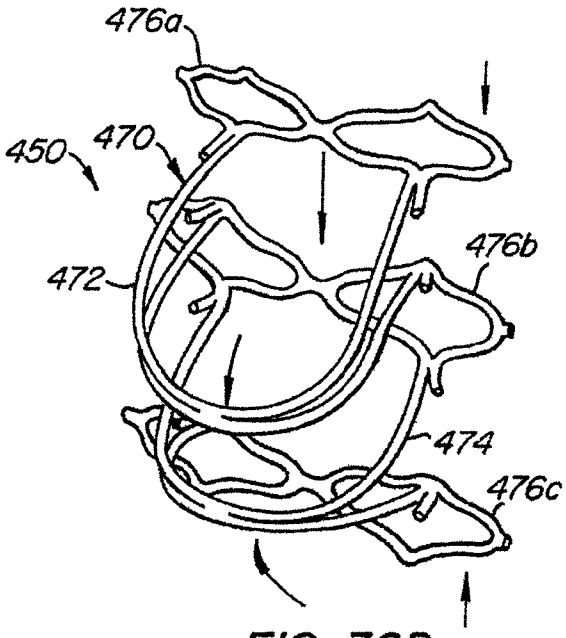


FIG. 36D

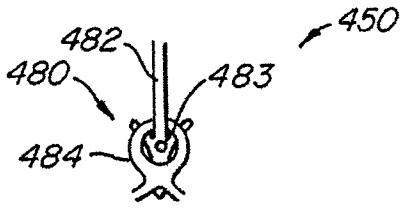


FIG. 36E

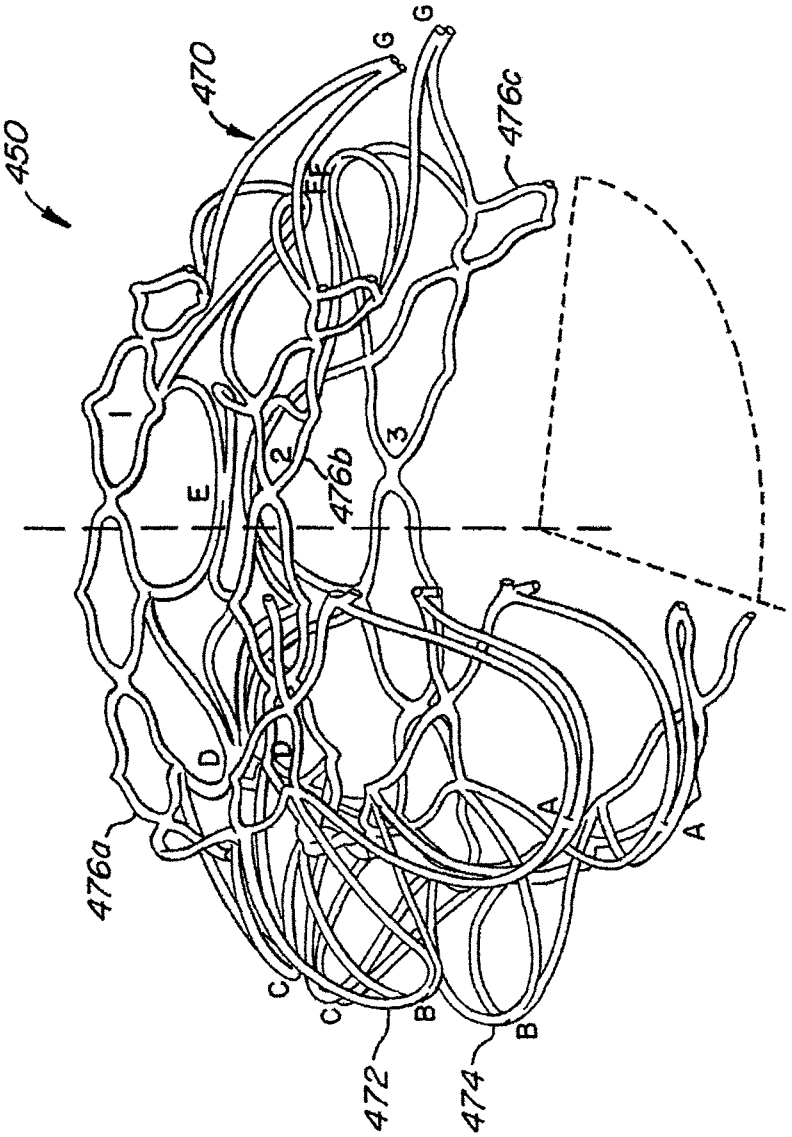


FIG. 37A

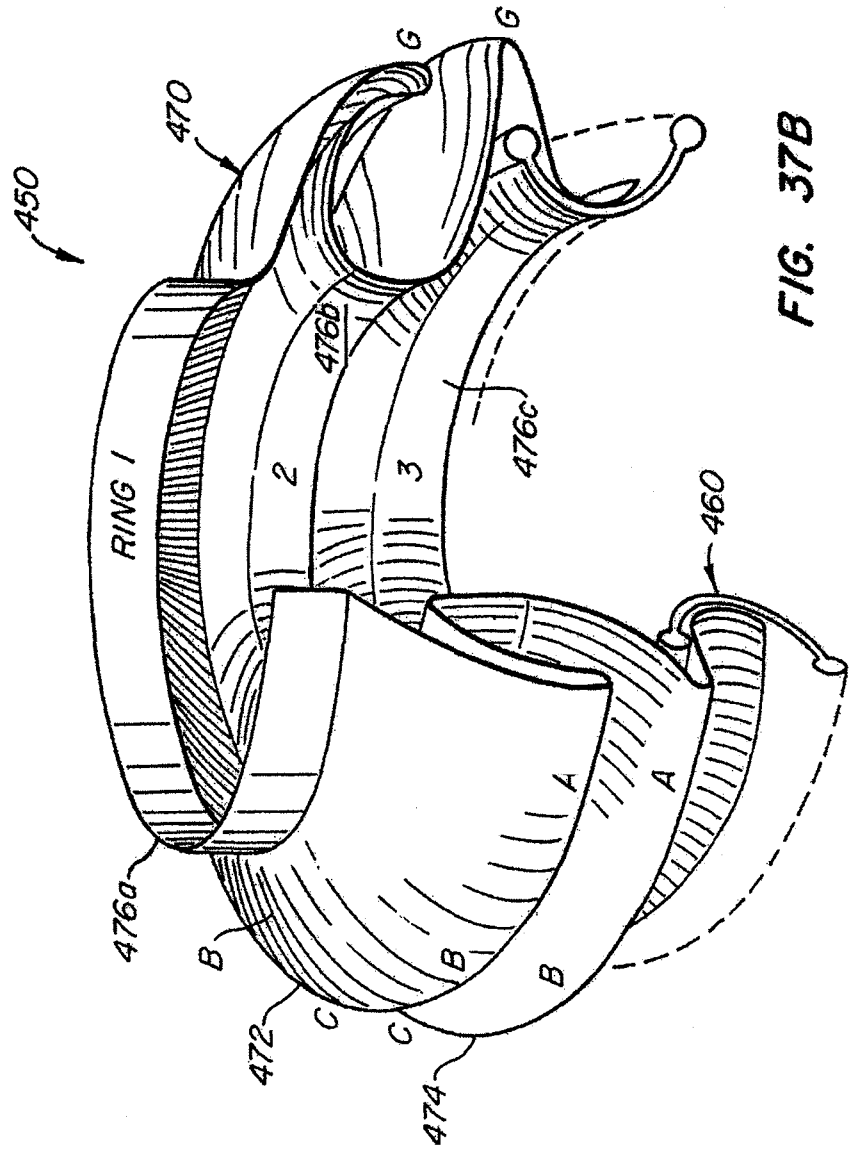
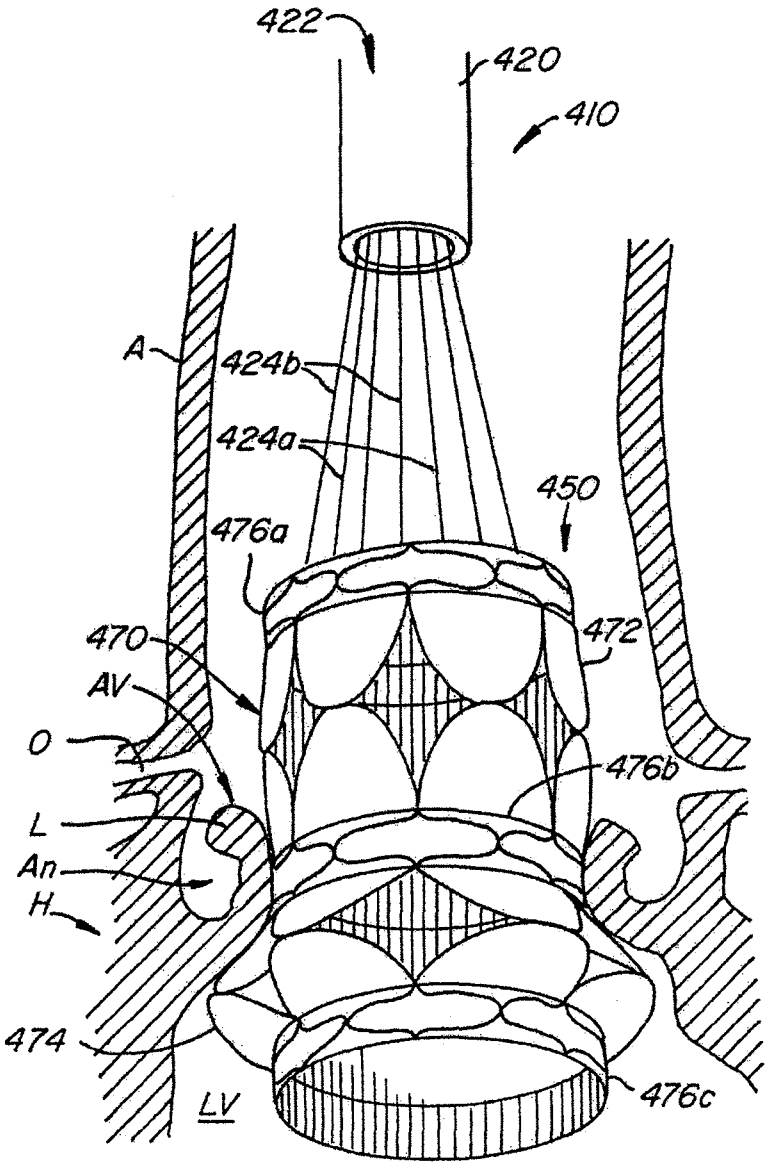


FIG. 37B


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

FIG. 38A

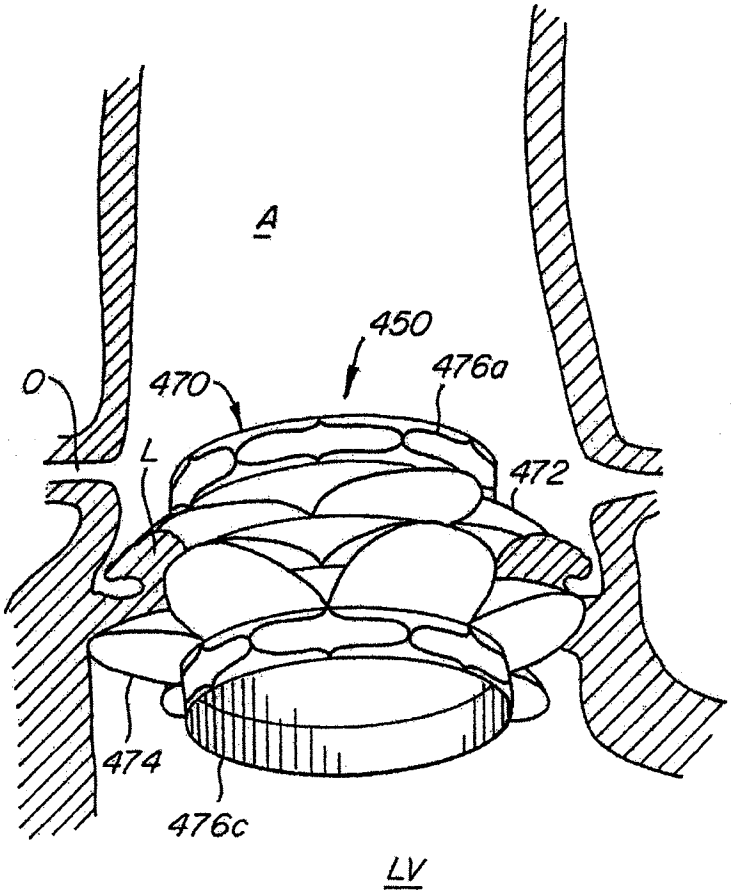


FIG. 38B

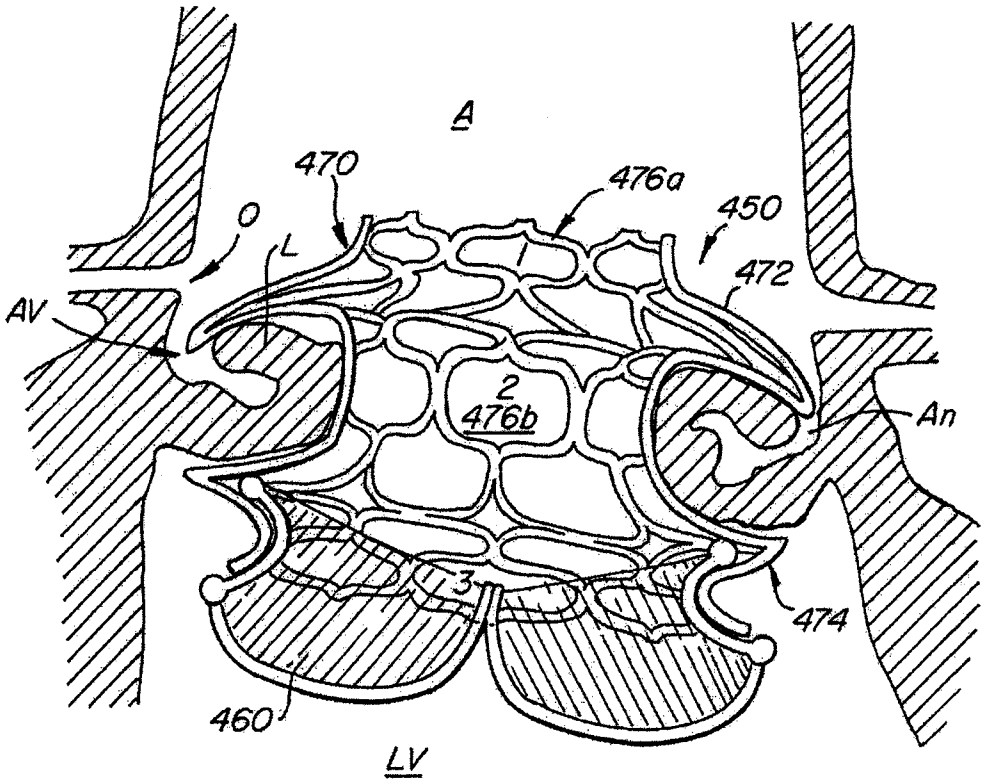


FIG. 38C

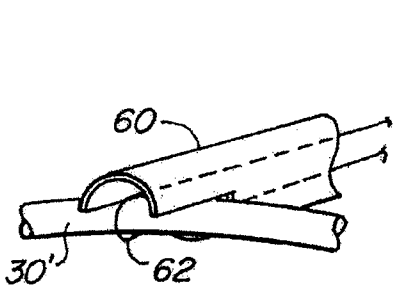


FIG. 39B

FIG. 39A

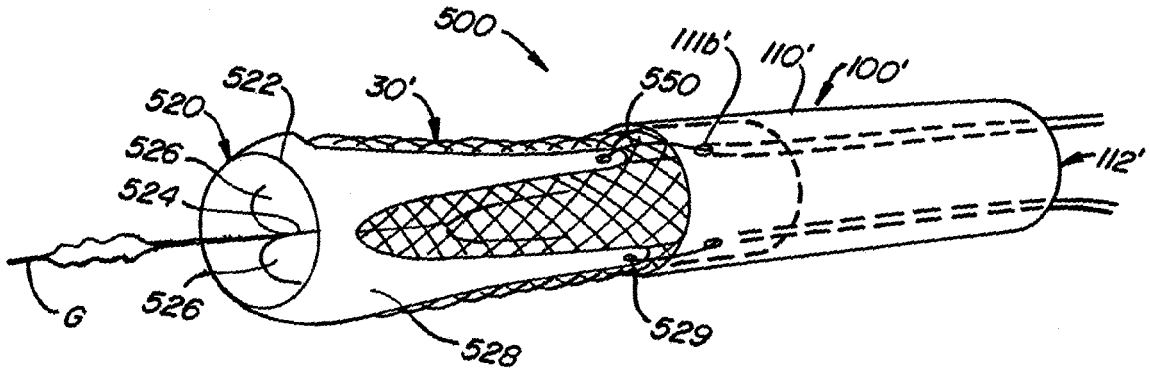


FIG. 39C

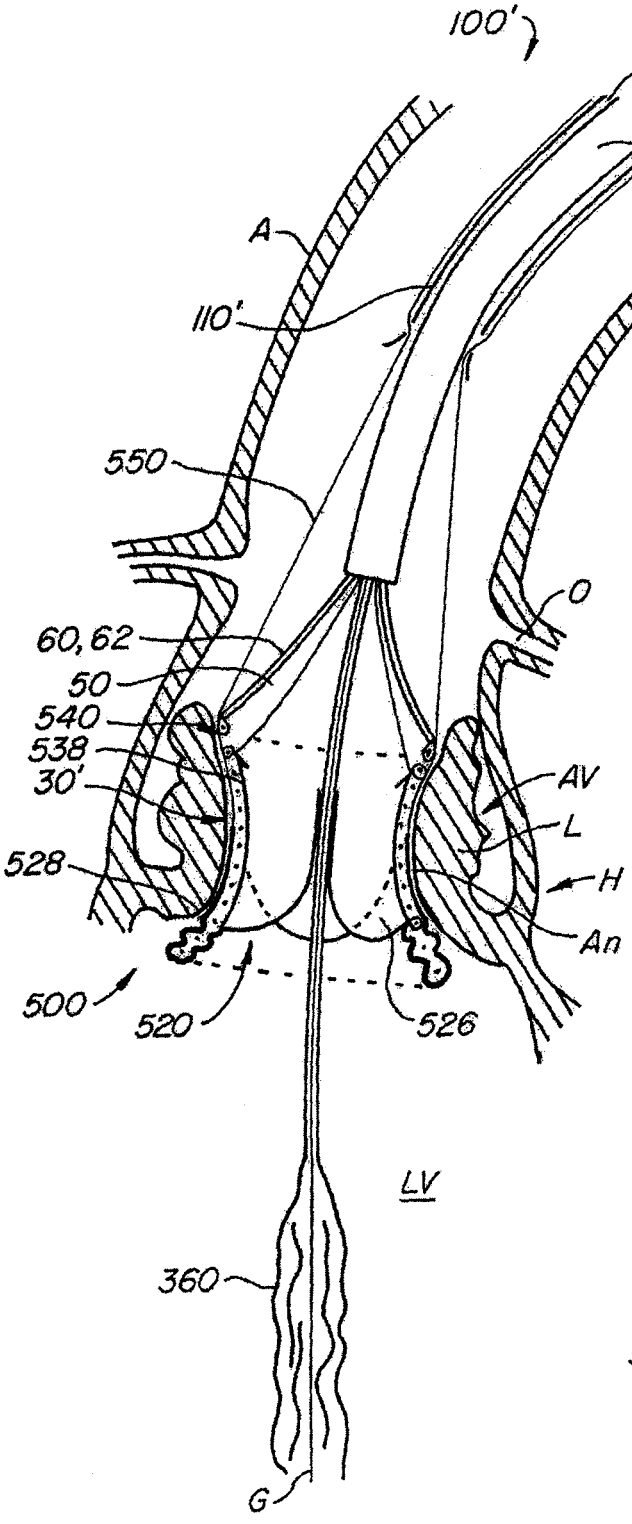


FIG. 39D

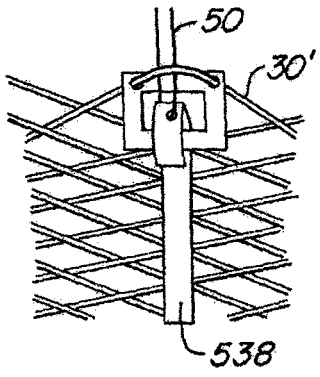


FIG. 39E

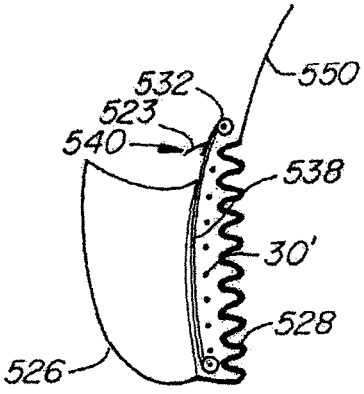


FIG. 39F

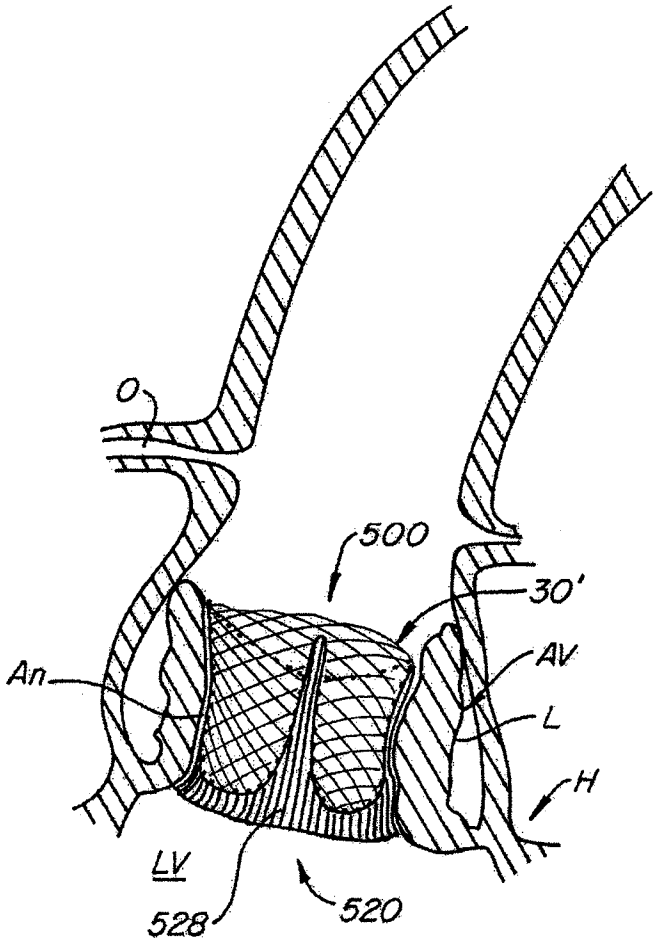


FIG. 39G

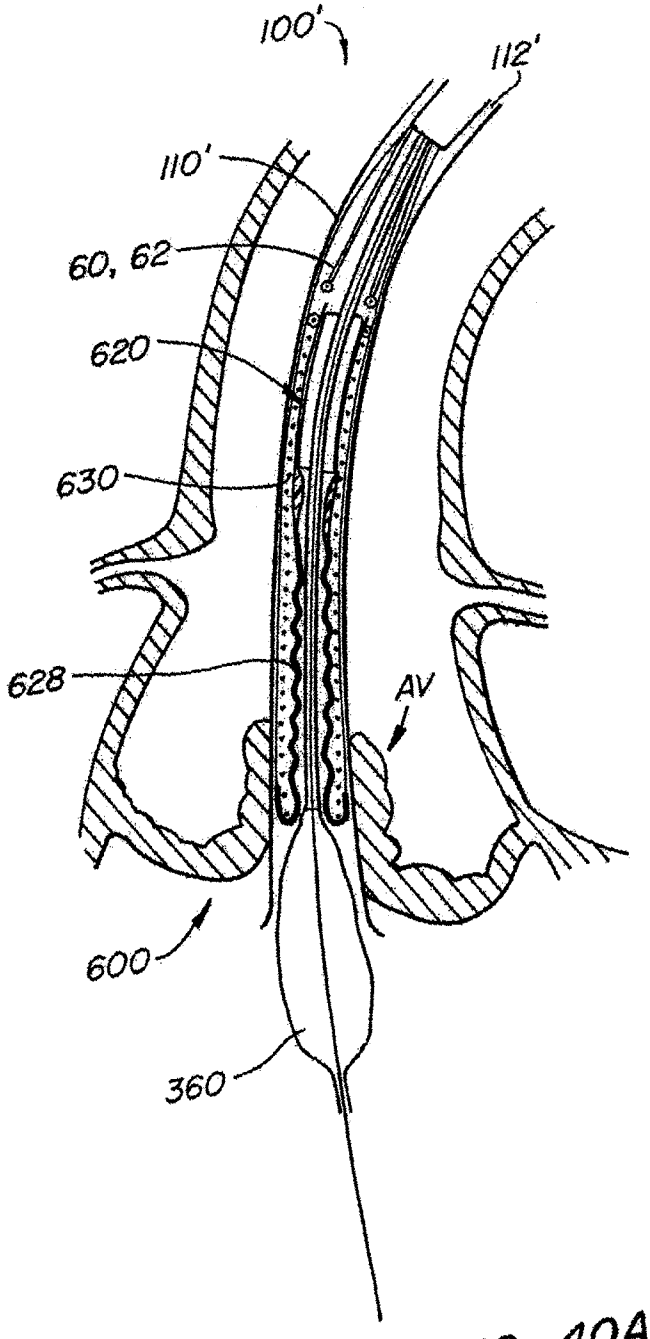


FIG. 40A

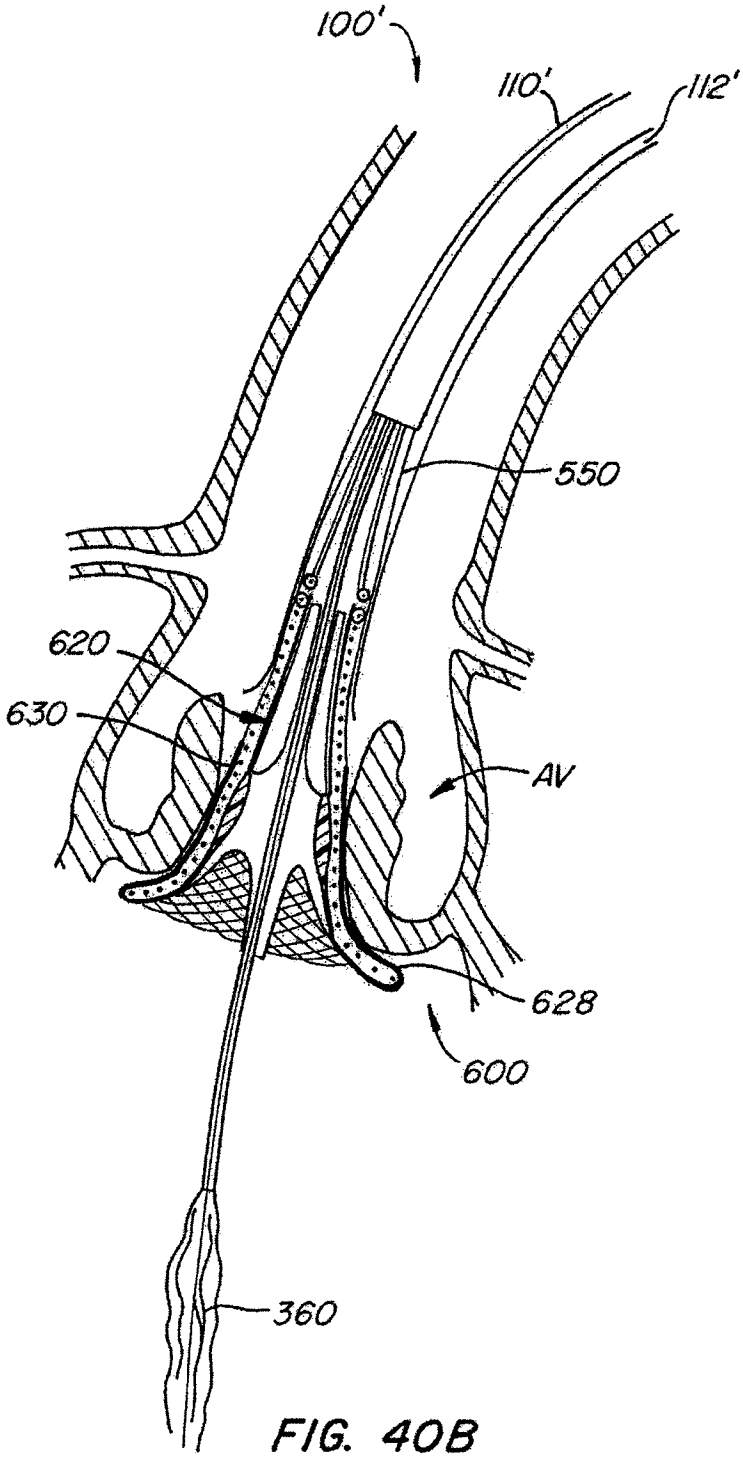


FIG. 40B

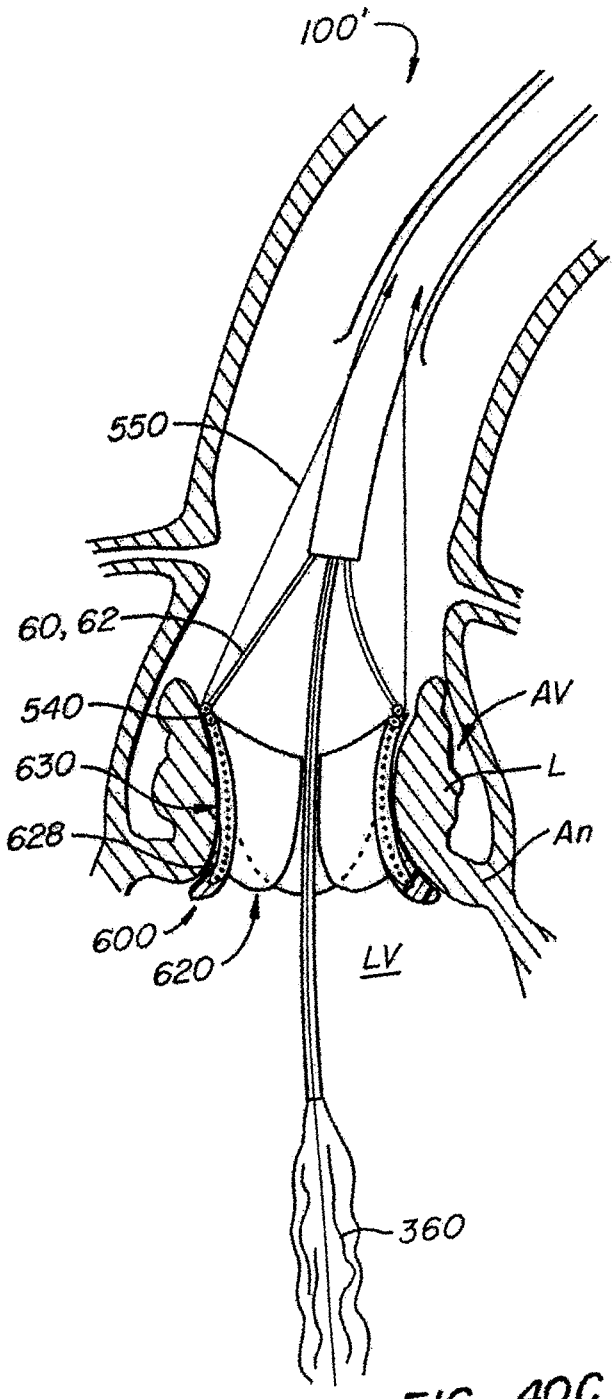


FIG. 40C

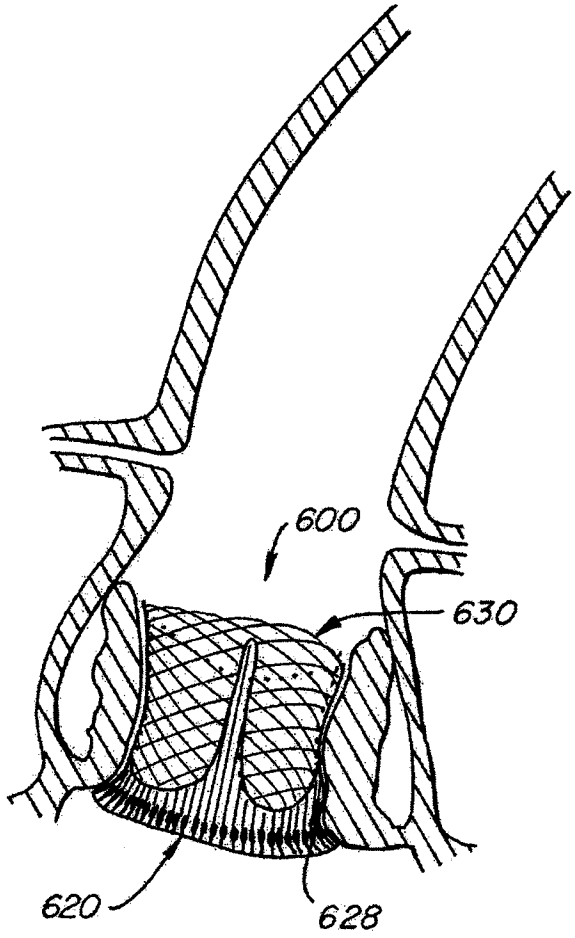
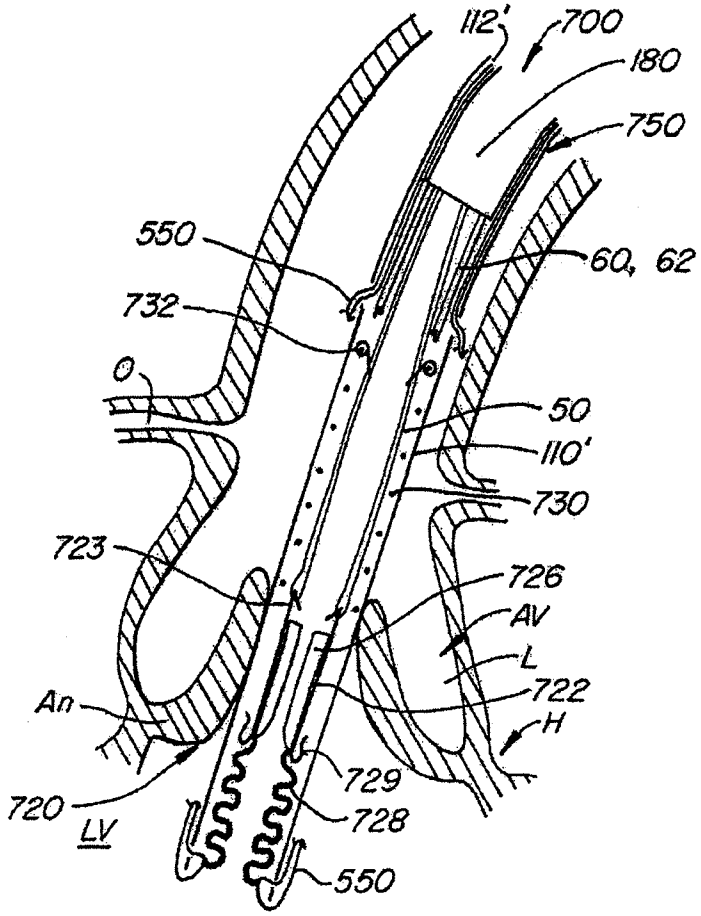


FIG. 40D


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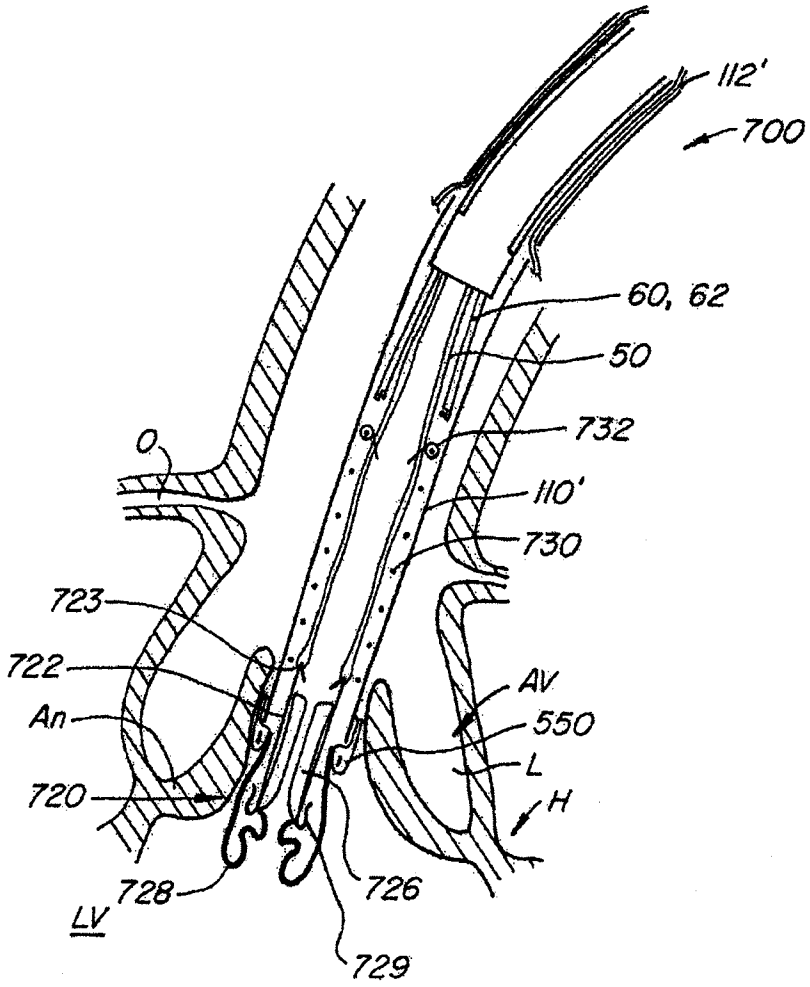
723
726
AV
L
722
An
H
729
720
728
LV
550

FIG. 41A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732
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LV
729

FIG. 41B

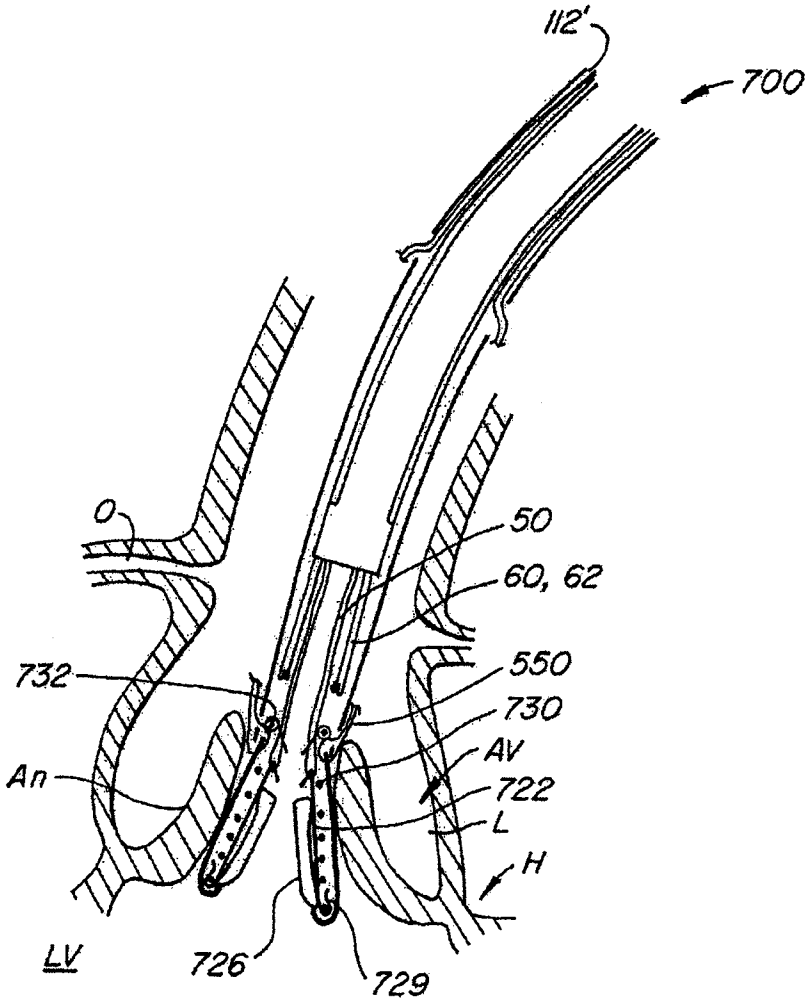

FIG. 41C

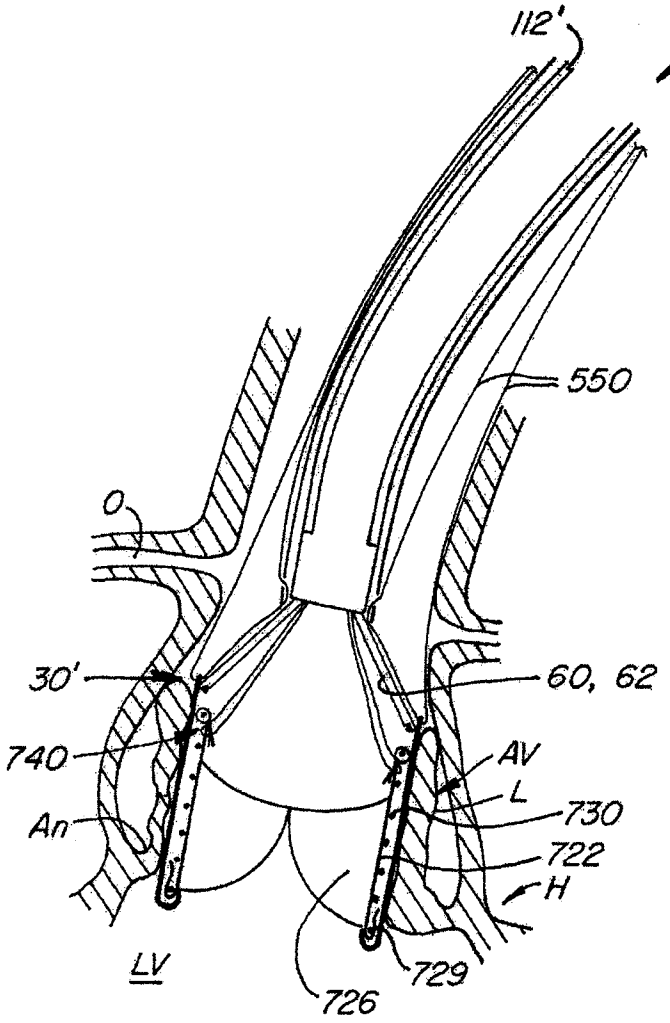

FIG. 41D

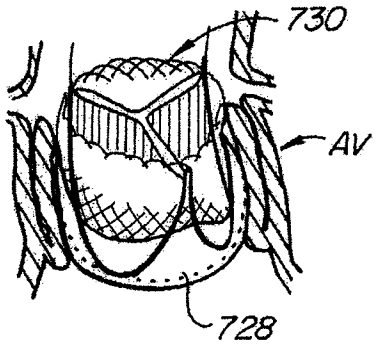

FIG. 41E

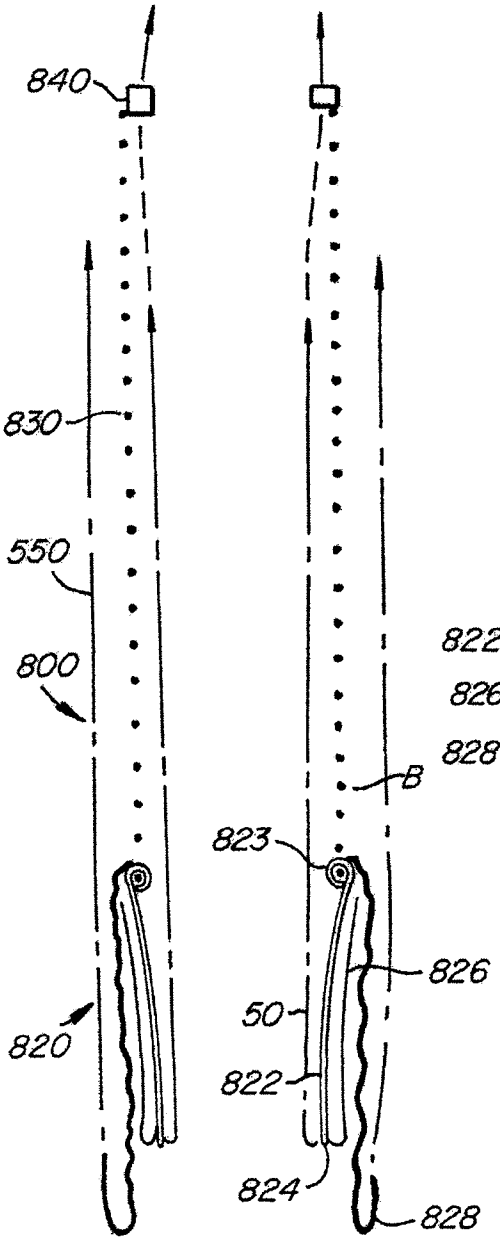

FIG. 42A

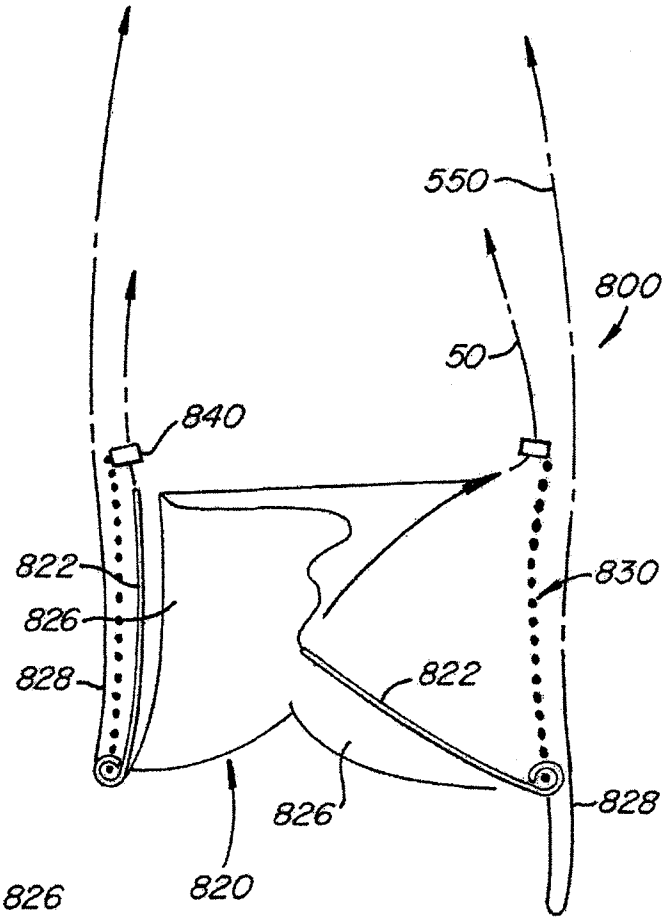

FIG. 42B

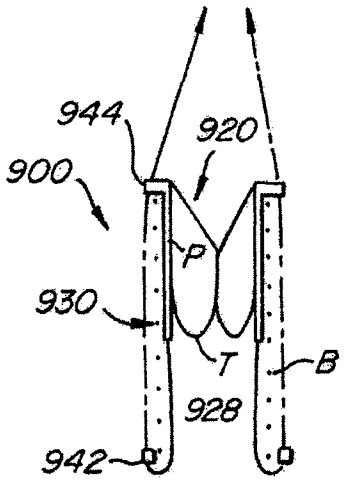

FIG. 43A

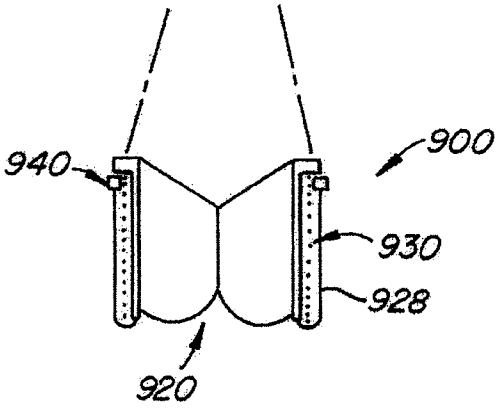

FIG. 43B

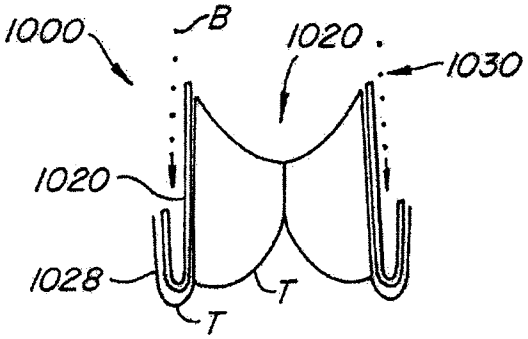

FIG. 44A

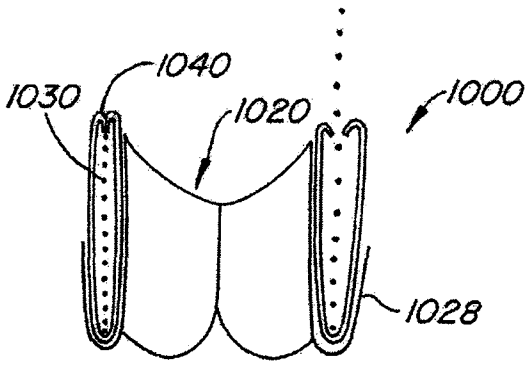

FIG. 44B

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:	10012-710.401

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:	5595509
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	10012-710.401
Receipt Date:	26-JUN-2009
Filing Date:	
Time Stamp:	14:22:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$462
RAM confirmation Number	525
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		10012-710-401-trans-comm-app-decl.pdf	6358328 62065256888eb2d7e45b655ef543c68eec9b89c0	yes	39

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Transmittal of New Application	1	1
Miscellaneous Incoming Letter	2	6
Specification	7	33
Claims	34	34
Abstract	35	35
Oath or Declaration filed	36	39

Warnings:					
Information:					
2	Drawings-only black and white line drawings	10012-710-401-drawings.pdf	1706989 8e650dc62ce1b6dc99fc64cc9ef341f527ab1163	no	63
Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	32389 7fcff10f9649e0e60ba724140702891b36199fd4	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	8097706		

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: **06/26/09**

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 12/492,512

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))	**7** minus 20 =		x$26		OR	x$52	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	**1** 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	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
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.

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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
12/492,512	06/26/2009	3738	462	10012-710.401	7	1

CONFIRMATION NO. 7439

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

FILING RECEIPT

OC000000036815329

Date Mailed: 07/14/2009

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)

Ulrich R. Haug, Campbell, CA;
Hans F. Valencia, Berkeley, CA;
Robert A. Geshlider, San Francisco, CA;
Tom Saul, El Granada, CA;
Amr Salahieh, Saratoga, 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 DIV of 12/269,213 11/12/2008
which is a CON of 10/870,340 06/16/2004

Foreign Applications

If Required, Foreign Filing License Granted: 07/07/2009

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/492,512**

Projected Publication Date: 10/22/2009

Non-Publication Request: No

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

Title

Everting Heart Valve

Preliminary Class

623

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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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.

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FILED VIA EFS ON JULY 22, 2009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	12/492,512	Confirmation No.:	7439
Applicant	:	Amr SALAHIEH et al.		
Filing Date	:	June 26, 2009		
Title	:	Everting Heart Valve		
Group Art Unit	:	3738		
Examiner	:	*unassigned*		
Docket No.	:	10012-710.401		
Customer No.	:	66854		

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

REQUEST FOR CORRECTED FILING RECEIPT

Please change the order of inventors as shown on the attached receipt, and as shown on the COMMUNICATION RE ORDER OF INVENTORS filed with this application. This Communication accompanied a granted petition in the parent application, as well as a corrected filing receipt.

It is again requested that this granted order of inventors be maintained in this application and that a corrected filing receipt reflecting such order be issued for the instant application.

Please charge any fees for the issuance of this corrected filing receipt to Deposit Account No. 50-4050.

Respectfully submitted,

Date: July 22, 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

UNITED STATES PATENT AND TRADEMARK OFFICE

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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
12/492,512	06/26/2009	3738	462	10012-710.401	7	1

CONFIRMATION NO. 7439

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

SHAY GLENN LLP
DOCKET
C/M# 10012-710.401
Attorney: TMZ
Action: Rest C-ER
Due Date: 8/17/09
Final:
Docketed: 7/17/09 By: jll

FILING RECEIPT

OC000000036815329

Date Mailed: 07/14/2009

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Applicant(s)

2— Ulrich R. Haug, Campbell, CA;
3— Hans F. Valencia, Berkeley, CA;
4—Robert A. Geshlider, San Francisco, CA;
5—Tom Saul, El Granada, CA;
1. — Amr Salahieh, Saratoga, CA;
6.— Dwight P. Morejohn, Davis, CA;
7.— 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 DIV of 12/269,213 11/12/2008
which is a CON of 10/870,340 06/16/2004

Foreign Applications

If Required, Foreign Filing License Granted: 07/07/2009

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/492,512**

Projected Publication Date: 10/22/2009

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.

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Electronic Acknowledgement Receipt

EFS ID:	5749129
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Ulrich R. Haug
Customer Number:	66854
Filer:	James R. Shay/Sue Bromaghim (TZ)
Filer Authorized By:	James R. Shay
Attorney Docket Number:	10012-710.401
Receipt Date:	22-JUL-2009
Filing Date:	26-JUN-2009
Time Stamp:	15:16:37
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	Request for Corrected Filing Receipt	10012-710-401-Req_Corrected_FR.pdf	517857 4090addb3425c7ba2ecb3435d98386e3b1109e7e	no	4

Warnings:	
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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	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/492,512	06/26/2009	3774	462	10012-710.401	7	1

CONFIRMATION NO. 7439

CORRECTED FILING RECEIPT

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

Date Mailed: 07/27/2009

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 23

Complete if Known	
Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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

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)	3/6/2002	Impella Cardiotechnik AG		
	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.		

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Sheet 2 of 23

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Attorney Docket Number	10012-710.401

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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.	
	140	US- 4,994,077	2/19/1991	Dobben	

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]
	312	EP 1057459	12/6/2000	Numed, Inc.		
	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		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 23

Complete if Known	
Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
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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	
	151	US- 5,389,106	2/14/1995	Tower	
	152	US- 5,397,351	3/14/1995	Pavcnik et al.	
	153	US- 5,411,552	5/2/1995	Andersen et al.	
	154	US- 5,425,762	6/20/1995	Muller	
	155	US- 5,431,676	7/11/1995	Dubrul et al.	
	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.	

FOREIGN PATENT DOCUMENTS

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	318	EP 1340473 A2	9/3/2003	3F Therapeutics, Inc.		
	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 Univ		

Examiner Signature		Date Considered	

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	158	US- 5,545,133	8/13/1996	Burns et al.	
	159	US- 5,545,211	8/13/1996	An et al.	
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Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 23

Complete if Known	
Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 9 of 23

Complete if Known	
Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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Art Unit	3774
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Attorney Docket Number	10012-710.401

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Sheet 13 of 23

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Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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Sheet 18 of 23

Complete if Known	
Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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
	90	US- 2005/0203615 A1	9/15/2005	Forster	
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Sheet 19 of 23

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Application Number	12/492,512
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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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Sheet 20 of 23

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Application Number	12/492,512
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Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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Sheet 22 of 23

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Application Number	12/492,512
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First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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EFS ID:	5865160
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	10012-710.401
Receipt Date:	11-AUG-2009
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Application Type:	Utility under 35 USC 111(a)

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41	Foreign Reference	WO01064137.pdf	707456 7a562a2f4956804bcefb5768824bb5b77f765c5d	no	21
Warnings:					
Information:					
42	Foreign Reference	WO02036048.pdf	1251564 2f2b09ec083572b24c782cb90f941e8e40fdf954	no	32
Warnings:					
Information:					
43	Foreign Reference	WO0241789A2.pdf	1567495 d4960bf261be5048c9408a68ec8a028cd0ad4a62	no	38
Warnings:					
Information:					
44	Foreign Reference	WO02100297.pdf	2608941 4bbee1d0fb88d3a69d7dc8ed742ff7d193e9690f	no	69
Warnings:					
Information:					

45	Foreign Reference	WO03003943.pdf	2440160 a9cdbaba622a6664c0b7ff6c5df0022ae1f7a710	no	41
Warnings:					
Information:					
46	Foreign Reference	WO03003949.pdf	1160861 ea3e7d479c771a547ebda108d1841ef45920c603	no	24
Warnings:					
Information:					
47	Foreign Reference	WO03011195.pdf	1135645 4d0d82cc68bc2547e358340a8f51777f6cce49f6	no	28
Warnings:					
Information:					
48	Foreign Reference	WO03015851.pdf	674069 7f6faa83a39e98c054ba90faf5fdadbb3837945c	no	18
Warnings:					
Information:					
49	Foreign Reference	WO04014256.pdf	1168909 baffcb77fdcf6f967e565c26916a737f2cfc1e0b	no	32
Warnings:					
Information:					
50	Foreign Reference	WO04019811.pdf	2351774 c5147eca697f2c786bbc0ff1e95c703ba24049b3	no	56
Warnings:					
Information:					
51	Foreign Reference	WO04023980.pdf	1414882 6fdd164a876c75a0eac35893b2ae0cc9be3491b7	no	34
Warnings:					
Information:					
52	Foreign Reference	WO04026117.pdf	3758688 0e7eae6d87817e5452798005db6f7f0c38f579d2	no	67
Warnings:					
Information:					
53	Foreign Reference	WO04041126.pdf	1037237 3e2c60e0701a11beff9defea1746b62968470fda	no	22
Warnings:					
Information:					

54	Foreign Reference	WO04047681.pdf	1207008 eebde9ad20a74395d87ccd7547a758d360eb02ca	no	25
Warnings:					
Information:					
55	Foreign Reference	WO04066876.pdf	691831 5b7de050a548f04d360c381bc16a03c9e9bd0ee6	no	19
Warnings:					
Information:					
56	Foreign Reference	WO04082536.pdf	3043970 afdc399c03fa9aca3d48ea84f2c52c3fab5619d9	no	95
Warnings:					
Information:					
57	Foreign Reference	WO05084595.pdf	3771691 2dd9bc4e4a9f4be322817c6da83c1fb8ab6ef9a0	no	76
Warnings:					
Information:					
58	Foreign Reference	WO05087140.pdf	1830921 15c46aa51fcb27966cc33c7baebf7df8598d3e00	no	42
Warnings:					
Information:					
59	Foreign Reference	EP1469797B1.pdf	455488 034e8fa9377e646cb619acc12d1a39fa57982136	no	29
Warnings:					
Information:					
			Total Files Size (in bytes):	83797002	

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.:	12/492,512	Confirmation No.: 7439
Applicant(s):	Amr Salahieh	
Filed:	June 26, 2009	
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: 8/11/09

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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/492,512	06/26/2009	Amr Salahieh	10012-710.401

CONFIRMATION NO. 7439

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

PUBLICATION NOTICE

OC000000038412183

Title: Everting Heart Valve

Publication No.US-2009-0264997-A1
Publication Date:10/22/2009

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/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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

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	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	460	US- 3,409,013	11/5/1968	Berry	
	461	US- 4,655,218	4/7/1987	Kulik et al.	
	462	US- 4,755,181	7/5/1988	Igoe	
	463	US- 4,865,600	9/12/1989	Carpentier et al.	
	456	US- 5,549,665	8/27/1996	Vesely et al.	
	465	US- 5,885,228	3/23/1999	Rosenman et al.	
	466	US- 6,623,518	9/23/2003	Thompson et al.	
	467	US- 6,635,079	10/21/2003	Unsworth et al.	
	468	US- 6,776,791	8/17/2004	Stallings et al.	
	469	US- 7,025,791	4/11/2006	Levine et al.	
	470	US- 7,037,331	5/2/2006	Mitelberg et al.	
	471	US- 7,175,653	2/13/2007	Gaber	
	472	US- 7,175,654	2/13/2007	Bonsignore et al.	
	473	US- 7,235,093	6/26/2007	Gregorich	
	474	US- 7,258,696	8/21/2007	Rabkin et al.	
	455	US- 2002/0188344	12/12/2002	Bolea et al.	
	458	US- 2006/0155312	7/13/2006	Levine et al.	
	457	US- 2005/0197694	9/8/2005	Pai et al.	
		US-			

FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

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

Electronic Acknowledgement Receipt

EFS ID:	6557481
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	10012-710.401
Receipt Date:	02-DEC-2009
Filing Date:	26-JUN-2009
Time Stamp:	15:12:31
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		10012-710401_IDS.pdf	251589 b78f0cd07395484400394748c56b6735cd308863	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:			
	Total Files Size (in bytes):	251589	

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.:	12/492,512	Confirmation No.: 7439
Applicant(s):	Amr Salahieh	
Filed:	June 26, 2009	
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:

☐ **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: 12/2/09

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

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. 12/492,512, filed on June 26, 2009

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 11/20/2009 at reel/frame 023551/0485 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:

Name: Ken Martin Signature: [signature]

Title: President and CEO Date: 3/16/2010

Electronic Acknowledgement Receipt

EFS ID:	7221564
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	10012-710.401
Receipt Date:	16-MAR-2010
Filing Date:	26-JUN-2009
Time Stamp:	17:00:36
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	Power of Attorney	10012-710-401-POA.pdf	50789 586c7be0d23555914cf6ead43197695f7834 32f1	no	1

Warnings:	
Information:	

Total Files Size (in bytes):	50789

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

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

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/492,512	06/26/2009	Amr Salahieh	10012-710.401

CONFIRMATION NO. 7439

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

POA ACCEPTANCE LETTER

OC000000040740142

Date Mailed: 03/22/2010

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/16/2010.

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.

/tnnguyen/

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/492,512	06/26/2009	Amr Salahieh	10012-710.401

CONFIRMATION NO. 7439

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

POWER OF ATTORNEY NOTICE

OC000000040740109

Date Mailed: 03/22/2010

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/16/2010.

- 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).

/tnnguyen/

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

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	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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

(Use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

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**	8/7/2008	Salahieh et al.	
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FOREIGN PATENT DOCUMENTS

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

Examiner Signature		Date Considered	

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

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

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	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Unassigned
Attorney Docket Number	10012-710.401

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	495	PAUL et al.; U.S. Pat. App. # 12/578,463 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	
	496	PAUL et al.; U.S. Pat. App. # 12/578,447 entitled "Medical Devices and Delivery Systems for Delivering Medical Devices," filed 10/13/2009	

Examiner Signature		Date Considered	

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

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

Electronic Acknowledgement Receipt

EFS ID:	7294161
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	10012-710.401
Receipt Date:	26-MAR-2010
Filing Date:	26-JUN-2009
Time Stamp:	14:11:31
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		10012-710401_IDS.pdf	904734 55f762e0b2230427e32435f613ea776906d05af0	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:			
	Total Files Size (in bytes):	904734	

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.

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VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/492,512	Confirmation No.: 7439
Applicant(s):	Amr Salahieh	
Filed:	June 26, 2009	
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:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

--OR--

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

--OR--

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

--OR--

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

STATEMENT UNDER 37 CFR § 1.97(e)

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

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

FEE AUTHORIZATION

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

Respectfully Submitted,

Dated: 3/25/10

By: _____
Thomas Zlogar Reg. # 55760

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

VIA EFS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	12/492,512	Confirmation No.: 7439
Applicant(s):	Amr Salahieh	
Filed:	June 26, 2009	
Art Unit:	3774	
Examiner:	Unassigned	
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: 4/19/10

By: _____
Thomas Zlogar Reg. # 55760

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

Cite No.	*Application No.*	*Publication No.*	*Patent No.*
77			7,329,279
74			7,381,219
84			7,445,631
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	
303		2007/0061008	
299		2007/0112355	
301		2007/0118214	
374		2007/0162107	
372		2007/0203503	
373		2007/0244552	
399		2008/0125859	
403		2008/0234814	
435		2009/0054969	
436		2009/0076598	

Electronic Acknowledgement Receipt

EFS ID:	7443024
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	10012-710.401
Receipt Date:	19-APR-2010
Filing Date:	26-JUN-2009
Time Stamp:	17:23:22
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	Miscellaneous Incoming Letter	10012-710401.pdf	178898 d5c0e667c885b2fe91ae952b3b6daea67c428a48	no	2

Warnings:	
Information:	

Total Files Size (in bytes):	178898

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

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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	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.401

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	
	531	US- 2003/0040791	2/27/2003	Oktay	
	527	US- 2004/0148021	7/29/2004	Cartledge et al.	
	533	US- 5,860,966	01/19/1999	Tower	
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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

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	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.401

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.

Electronic Acknowledgement Receipt

EFS ID:	8034848
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	10012-710.401
Receipt Date:	16-JUL-2010
Filing Date:	26-JUN-2009
Time Stamp:	16:31:42
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		10012-710401_IDS.pdf	686010 1018ff5a487a4aaf30c08eb922e9fce735c8fd1a	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Filed (SB/08)	4	5
Warnings:			
Information:			
	Total Files Size (in bytes):	686010	

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.:	12/492,512	Confirmation No.: 7439
Applicant(s):	Amr Salahieh	
Filed:	June 26, 2009	
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: 7/16/10

By: Thomas Z

Thomas Zlogar Reg. # 55760

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

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	12/492,512
Filing Date	June 26, 2009
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	SCHILLINGER, ANN M
Attorney Docket Number	10012-710.401

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.	
	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.	
	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.	
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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]
	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:	8521849
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	10012-710.401
Receipt Date:	29-SEP-2010
Filing Date:	26-JUN-2009
Time Stamp:	11:57:43
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		10012-710401_IDS.pdf	589855 2431d972a2ec80cc7c2bac2c7c0c6027f9896ebb	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):	6245674		

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.:	12/492,512	Confirmation No.: 7439
Applicant(s):	Amr Salahieh	
Filed:	June 26, 2009	
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

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.
12/492,512	06/26/2009	Amr Salahieh	10012-710.401	7439

66854 7590 12/17/2010

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
12/17/2010	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)	
	12/492,512	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 *26 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) *1-6* 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) *1-6* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/11/09,12/2/09,3/26/10,7/16/10,9/29/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (US Pub. No. 2001/0021872). Bailey et al. discloses the following regarding claim 1: a system for replacing a heart valve, comprising: an expandable anchor (12) having a collapsed delivery configuration and an expanded configuration (para. 0021); a replacement valve commissure support element (24) attached to the expandable anchor; a commissure portion of a replacement valve leaflet (26) attached to the commissure support element (Fig. 2); 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 (Fig. 4; paras. 0021-0022, 0049).

Bailey et al. discloses the following regarding claim 2: the system of claim 1 wherein the expandable anchor is not attached to the replacement valve leaflet (Fig. 2).

Bailey et al. discloses the following regarding claim 3: the system of claim 1 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 (Figs. 1, 13).

Bailey et al. discloses the following regarding claim 4: the system of claim 1 wherein the commissure support element is configured to interface with an anchor actuator (13).

Bailey et al. discloses the following regarding claim 5: the system of claim 4 wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor (paras. 0050, 0051).

Please note that language such as "configured to/for" and "adapted to/for" is functional language. The functional language of the claims has been considered to the extent that it further defines the structure of the claimed device.

Bailey et al. discloses the following regarding claim 6: the system of claim 1 further comprising a lock comprising a first lock element and a second lock element (anchoring flanges, shown in element 22), 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.

Bailey et al. discloses the following regarding claim 7: the system of claim 6 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 (Figs. 1-2; para. 0022).

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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
12492512	12492512	SALAHIEH ET AL.
	Examiner	**Art Unit**
	ANN SCHILLINGER	3774

SEARCHED			
Class	**Subclass**	**Date**	**Examiner**
623	1.11-1.54	12/15/2010	AS

SEARCH NOTES		
Search Notes	**Date**	**Examiner**

INTERFERENCE SEARCH			
Class	**Subclass**	**Date**	**Examiner**

/A. S./ Examiner.Art Unit 3774	

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.:	12/492512
Filed:	June 26, 2009
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: S63.2Q-15141-US03

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.:	12/492512
Filed:	June 26, 2009
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Group Art Unit:	3774

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

Docket No: S63.2Q-15141-US03

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:	9431059
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	10012-710.401
Receipt Date:	11-FEB-2011
Filing Date:	26-JUN-2009
Time Stamp:	17:40:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US03_tra_20110211.pdf	84873 d46b345f1743818f62dca9b54bdc3d4e77bb3fdb	no	1

Warnings:	
Information:	

2	Assignee showing of ownership per 37 CFR 3.73(b).	15141US03_sta_20110207.pdf	70962 c2c6357a76a6e8530f57365f515f6140e9a1ba35	no	1
Warnings:					
Information:					
3	Power of Attorney	15141US03_executedPOA.pdf	27429 997a238f86b0e213330d0609000c8fcfcf43ea4d	no	1
Warnings:					
Information:					
4	Miscellaneous Incoming Letter	15141US03_entity_status_20110211.pdf	66923 327c2060ca2114f6b29da8cffac4db38c91a994e	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	250187	

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.:	12/492512
Filed:	June 26, 2009
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: S63.2Q-15141-US03

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
1 page Revocation of Power of Attorney and Appointment of New Attorney; 1 page Assignee's Statement of Ownership and 1 page Notification of Change of Entity Status.

2. With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.

5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on February 11, 2011.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
f:\wpwork\jmu\15141us03_tra_20110211.doc

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.:	12/492512
Filed:	June 26, 2009
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: S63.2Q-15141-US03

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 023551, Frame 0485, or for which a copy thereof is attached.

The undersigned is empowered to sign this statement of ownership certificate on behalf of the assignee.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
f:\wpwork\jmu\15141us03_sta_20110207.doc

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/492,512	06/26/2009	Amr Salahieh	10012-710.401

CONFIRMATION NO. 7439

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

POWER OF ATTORNEY NOTICE

OC000000046060664

Date Mailed: 02/18/2011

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2011.

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

/erimando/

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03

CONFIRMATION NO. 7439

490
VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

POA ACCEPTANCE LETTER

Date Mailed: 02/18/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/11/2011.

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

/erimando/

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/492,512	06/26/2009	3774	462	S63.2Q-15141-US03	7	1

CONFIRMATION NO. 7439

CORRECTED FILING RECEIPT

490
VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

Date Mailed: 02/24/2011

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 DIV of 12/269,213 11/12/2008
which 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: 07/07/2009

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/492,512**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

Everting Heart Valve

Preliminary Class

623

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

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

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

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

NOT GRANTED

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

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.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

COMMUNICATION

This communication is in response to the Office Action dated **December 17, 2010.**

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.

The Claims:

Claim 1. (Original) 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.

Claim 2. (Original) The system of claim 1 wherein the expandable anchor is not attached to the replacement valve leaflet.

Claim 3. (Original) The system of claim 1 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.

Claim 4. (Original) The system of claim 1 wherein the commissure support element is configured to interface with an anchor actuator.

Claim 5. (Original) The system of claim 4 wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor.

Claim 6. (Original) The system of claim 1 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.

Claim 7. (Original) The system of claim 6 wherein the second lock element is attached to the expandable anchor and is disposed proximal to first lock element when the expandable anchor is in the collapsed configuration within a delivery catheter.

Remarks

This Communication is in response to the Office Action dated **December 17, 2010.** Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (US Pub. No. 2001/0021872, hereinafter Bailey). Applicants note that even though the text of the Office Action rejects claims 1-7, the Office Action Summary sheet only states claims 1-6 are pending and rejected. Applicants assume that the text of the Office Action is correct.

The rejections to claims 1-7 are traversed in this Communication. Reconsideration in view of the following remarks is respectfully requested.

35 U.S.C. 102 – Claim Rejections

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey. The rejections are traversed in this Communication.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP 2131, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1 is an independent claim. Claim 1 structurally requires an expandable anchor, a replacement valve commissure support element, and a commissure portion of a replacement valve leaflet. Claim 1 further requires "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."

The Office Action apparently identifies the stent body member 12 in Bailey as being the expandable anchor of the instant claims. The valve arm 24 in Bailey is asserted to be the

replacement valve commissure support member, and the valve body 26 in Bailey is asserted to correspond to the commissure portion of a replacement valve leaflet. (Figure 2, and paragraphs [0049] and [0050] of Bailey.) The Office Action also implies that Bailey discloses a seal at least partially disposed around an exterior portion to prevent blood from flowing between the seal and heart tissue. The Office Action however, fails to identify any structural component in Bailey corresponding to the seal or the requisite structural characteristics of the seal presented in the instant claims. The failure of Bailey to disclose all of the features of the instant claims, including the recited seal, is fatal to the Office's assertion that Bailey anticipates the instant claims.

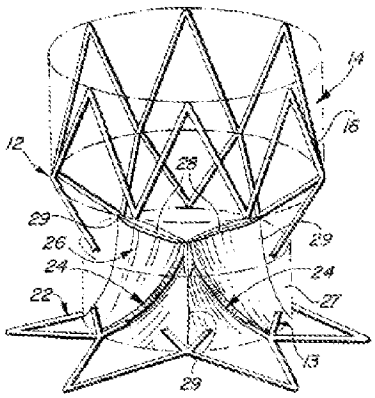

Figure 2 of Bailey

It is clear from the figures and disclosure (Figures 15A-E, paragraphs [0102] and [0103].) that the recited "seal" is a structurally distinguishable component.

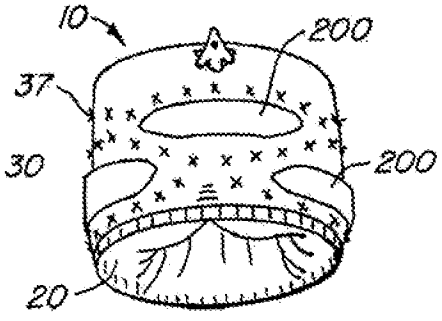

Figure 15 A

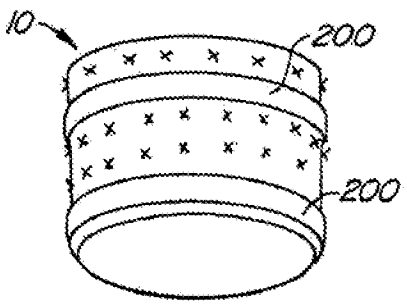

Figure 15B

Rather than provide a seal component, Bailey merely discloses that a valve prosthesis is deployed within the native valve annular space so that the intermediate annular stent section abuts and outwardly radially compresses the anatomic valve leaflets against the vascular wall. (Paragraph [0022] of Bailey.) Nowhere does Bailey teach or suggest the presence of a seal that is "disposed around an exterior portion of the expandable anchor" to prevent blood flow between the seal and heart tissue as claim 1 required. In light of at least this failure, Applicants respectfully request withdrawal of rejections under 35 U.S.C. 102(b).

Claims 2-7 are dependent over claim 1 directly or indirectly, and therefore patentable at least for the reasons cited for claim 1. Applicants respectfully request withdrawal of rejections under 35 U.S.C. 102(b).

Conclusion

Based on at least the foregoing remarks, Applicants respectfully submit this application in condition for allowance. Favorable consideration and prompt allowance of claims 1-7 are 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: March 7, 2011

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

6640 Shady Oak Rd., Suite 400
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Electronic Acknowledgement Receipt

EFS ID:	9595176
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	00490
Filer:	James M. Urzedowski/Rebecca Leaf
Filer Authorized By:	James M. Urzedowski
Attorney Docket Number:	S63.2Q-15141-US03
Receipt Date:	07-MAR-2011
Filing Date:	26-JUN-2009
Time Stamp:	10:00:45
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	15141US03_tra_20110306.pdf	92122 3df990943fc452bc55fdd7995ddb5616c6127ff6	no	1

Warnings:	
Information:	

2		15141US03_amd_20110307.pdf	172838 4f2776da014d5bc3ef32ef8ea13cb52aee3d6077	yes	6

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	2
Applicant Arguments/Remarks Made in an Amendment	3	6

Warnings:	
Information:	
Total Files Size (in bytes):	264960

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.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
6 page Communication.

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 7, 2011.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: March 7, 2011

By: /James M. Urzedowski/
James M. Urzedowski
Registration No.: 48596

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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
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/492,512	06/26/2009	

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))							
			TOTAL			TOTAL	

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

APPLICATION AS AMENDED – PART II

AMENDMENT	03/07/2011	(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))	* 7	Minus	** 20	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $ =		OR	X $220=	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:
/ROSA HOLLAND/

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.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

490 7590 04/08/2011

VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	**PAPER NUMBER**
3774	

MAIL DATE	DELIVERY MODE
04/08/2011	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)	
	12/492,512	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 *07 January 2011*.

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) *1-7* 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) *1-7* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

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

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (US Pub. No. 2001/0021872). Bailey et al. discloses the following regarding claim 1: a system for replacing a heart valve, comprising: an expandable anchor (12) having a collapsed delivery configuration and an expanded configuration (para. 0021); a replacement valve commissure support element (24) attached to the expandable anchor; a commissure portion of a replacement valve leaflet (26) attached to the commissure support element (Fig. 2); 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 (Fig. 4; paras. 0021-0022, 0049).

Bailey et al. discloses the following regarding claim 2: the system of claim 1 wherein the expandable anchor is not attached to the replacement valve leaflet (Fig. 2).

Bailey et al. discloses the following regarding claim 3: the system of claim 1 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 (Figs. 1, 13).

Bailey et al. discloses the following regarding claim 4: the system of claim 1 wherein the commissure support element is configured to interface with an anchor actuator (13).

Bailey et al. discloses the following regarding claim 5: the system of claim 4 wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor (paras. 0050, 0051).

Please note that language such as "configured to/for" and "adapted to/for" is functional language. The functional language of the claims has been considered to the extent that it further defines the structure of the claimed device.

Bailey et al. discloses the following regarding claim 6: the system of claim 1 further comprising a lock comprising a first lock element and a second lock element (anchoring flanges, shown in element 22), 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.

Bailey et al. discloses the following regarding claim 7: the system of claim 6 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 (Figs. 1-2; para. 0022).

Response to Arguments

Applicant's arguments filed 3/7/2011 have been fully considered but they are not persuasive. The Applicant contends that Bailey et al. does not disclose a seal at least partially disclosed around the exterior of the anchor. The examiner respectfully disagrees. Bailey et al. describes in paragraph 0049 that the device may have an outer graft member that is disposed

around an exterior portion of the anchor. Examiner maintains that the graft member may be broadly construed as providing a sealing function i.e. will act as a seal when the device is expanded to be flush against vessel walls (paragraphs 0021-0022). When the device is expanded it will force the blood to flow through the valve, and will not allow the blood to leak past the sides of the device between the outer graft member and the vessel walls.

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.

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

/A. S./
Examiner, Art Unit 3774

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Updated prior search	3/29/2011	AS

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/A. S./ Examiner.Art Unit 3774	

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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

AMENDMENT AFTER FINAL AND REQUEST FOR RECONSIDERATION

In response to the Final Office Action dated **April 8, 2011**, the period of response for which runs through July 2011, please amend the application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of the Claims:

Claim 1 (Currently Amended): 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 the seal comprises an expandable foam disposed around a circumference of a wire, and

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

Claim 2 (Original): The system of claim 1 wherein the expandable anchor is not attached to the replacement valve leaflet.

Claim 3 (Original): The system of claim 1 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.

Claim 4 (Original): The system of claim 1 wherein the commissure support element is configured to interface with an anchor actuator.

Claim 5 (Original): The system of claim 4 wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor.

Claim 6 (Original): The system of claim 1 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.

Claim 7 (Original): The system of claim 6 wherein the second lock element is attached to the expandable anchor and is disposed proximal to first lock element when the expandable anchor is in the collapsed configuration within a delivery catheter.

Claim 8 (New): The system of claim 1, wherein the seal has a compressed state and a deployed state, and wherein in the compressed state, the seal further comprises a dissolvable coating disposed about the foam.

Claim 9 (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 fabric 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 the fabric seal has an undeployed state and a deployed state, wherein in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets, and

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

Claim 10 (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 the seal comprises at least one sac disposed about the exterior of the anchor, and

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

Claim 11 (New): The system of claim 10, wherein the at least one sac is filled with a substance selected from the group consisting of water, blood, foam, and hydrogel.

Claim 12 (New): The system of claim 10, wherein the at least one sac comprises a first discrete sac and a second discrete sac, the first sac and the second sac being disposed at different positions along a height of the anchor.

Claim 13 (New): The system of claim 10, wherein the at least one sac comprises a first discrete cylindrical sac and a second discrete cylindrical sac, the first sac and the second sac being disposed at different positions along a height of the anchor.

Claim 14 (New): The system of claim 10, wherein the at least one sac comprises a single cylindrical sac that is disposed at different positions along a height of the anchor.

Claim 15 (New): The system of claim 10, wherein the at least one sac comprises a single sac that is disposed in a spiral along a height of the anchor.

REMARKS

This Amendment is responsive to the Final Office Action dated **April 8, 2011**. Applicant has amended claim 1 and added new claims 8-15. No new matter has been added. Claims 1-15 are pending upon entry of this Amendment.

Applicant respectfully requests that the Amendment be entered as it is believed to place the application in condition for allowance or better form for appeal.

Claim Rejections—35 U.S.C. § 102

In the Office Action, the Office rejected claims 1-7 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2001/0021872 to Bailey et al. ("Bailey"). Applicant respectfully traverses the rejection to the extent such rejection is considered applicable to the amended claims.

In the Office Action, the Office indicated[1] that Bailey discloses 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, as required by claim 1 as presented previously. In the Response to Arguments section of the Office Action, the Office indicated[2] that the "graft member [of Bailey] may be broadly construed as providing a sealing function i.e. will act as a seal when the device is expanded to be flush against vessel walls (paragraphs 0021-0022)." Although Applicant disagrees with this assertion, Applicant has nevertheless amended claim 1 to further define claim 1 over Bailey. Amended claim 1 recites the following features:

> 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

[1] Office Action, dated April 8, 2011, page 2.
[2] *Id.* at page 4.

> flowing between the seal and heart tissue, wherein the seal comprises an expandable foam disposed around a circumference of a wire, and
>
> wherein a distal end of the replacement valve leaflet is attached to the seal.

Support for the amendment may be found throughout Applicant's disclosure, including, for example, Applicant's specification at paragraph [0111] and FIGS. 27-31.

Bailey fails to disclose or suggest a seal that comprises an expandable foam disposed around a circumference of a wire, particular in combination with the other features recited in amended claim 1. That is, even if the graft of Bailey is considered to be a seal,[3] the graft does not comprise an expandable foam disposed around a circumference of a wire, as required by amended claim 1. Rather, Bailey discloses the following with respect to graft 11:

> The graft member 11 is preferably made of biologically-derived membranes or biocompatible synthetic materials such as DACRON or expanded polytetrafluoroethylene.[4]
>
> In accordance with one embodiment of the present invention, the graft member 11 consists of an outer or ablumenal graft member 11a and an inner or lumenal graft member 11b. The outer graft member 11a encloses at least a portion of the ablumenal surface of the intermediate annular section 20 of the stent body member, while the inner graft member 11b is coupled, on the lumenal surface of the intermediate annular section 20 of the stent body member 12, to the outer graft member 11a through the interstices 14 of the stent body member.[5]

Biocompatible synthetic materials such as DACRON or expanded polytetrafluoroethylene, however, are not examples of expandable foam, as required by amended claim 1. In addition, enclosing at least a portion of the ablumenal surface of intermediate annular section 20 of stent body member 12 and coupling inner graft member 11a and outer graft member 11b through the interstices 14 of the stent body member does not amount to a seal that comprises an expandable foam disposed around a circumference of a wire, as required by amended claim 1. As such, Bailey fails to disclose all the features of amended claim 1.

---

[3] As asserted by the Office, and not agreed to be Applicant.
[4] Bailey, paragraph [0048].

Consequently, claim 1 is novel over Bailey. Claims 2-8 depend from independent claim 1. At least by virtue of their dependency, claims 2-8 are also novel over Bailey. Applicant respectfully requests that the rejection be withdrawn and that claims 1-8 be allowed.

New Claims:

Applicant has added new claims 8-15 to the pending application. No new matter has been added. The applied reference fails to disclose all the features recited in Applicant's new claims, and provide no apparent reason for modification to include such features.

Support for new claim 8 may be found at least at paragraph [0111] and FIGS. 27-31 of Applicant's disclosure. Support for new claim 9 may found at least at paragraph [0112] and FIGS. 32-34 of Applicant's disclosure. Support for new claims 10-15 may be found at least at paragraphs [0102]-[0104] and FIGS. 14-16C.

[5] *Id.* at paragraph [0049].

CONCLUSION

In light of the amendments contained herein, Applicants submit that the application is in condition for allowance, for which early action is requested.

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.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: May 2, 2011

By: /James L. Shands/
James L. Shands
Registration No.: 54439

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Electronic Acknowledgement Receipt

EFS ID:	10000270
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	00490
Filer:	James Lee Shands/Samantha Painschab
Filer Authorized By:	James Lee Shands
Attorney Docket Number:	S63.2Q-15141-US03
Receipt Date:	02-MAY-2011
Filing Date:	26-JUN-2009
Time Stamp:	16:19:47
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	15141US03_tra_20110502.pdf	80141 28e25b70347feddfa47ace0ca9e9c563620368bc	no	1

Warnings:	
Information:	

2		15141US03_amd_20110502.pdf	113597 3ff7da43f9fe3061a7dd514ffd8ff858f082233e	yes	8

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment After Final	1	1
Claims	2	4
Amendment/Req. Reconsideration-After Non-Final Reject	5	8

Warnings:

Information:

Total Files Size (in bytes):	193738

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.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
8 page Amendment After Final and Request for Reconsideration.

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 2, 2011.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: May 2, 2011

By: /James L. Shands/
James L. Shands
Registration No.: 54439

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Facsimile: (952) 563-3001
f:\wpwork\jls\15141us03_tra_20110502.doc

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
12/492,512	06/26/2009	

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 05/02/2011	(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))	* 15	Minus	** 20	= 0	X $ =		OR	X $52=	0
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $ =		OR	X $220=	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:
/NINA RATANAVONG/

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.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

490 7590 05/19/2011

VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
05/19/2011	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.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 12/492,512	**Applicant(s)** SALAHIEH ET AL.	
	Examiner ANN SCHILLINGER	**Art Unit** 3774	

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

THE REPLY FILED 02 May 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-7*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

/A. S./
Examiner, Art Unit 3774

Continuation of 3. NOTE: Amended independent claim 1 now requires a seal having an expandable foam disposed around a wire. New claim 9 requires a fabric seal wherein the fabric seal comprises flaps. These new limitations necessitate further search and consideration.

DO NOT ENTER: /A.S./
05/15/2011

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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

AMENDMENT AFTER FINAL AND REQUEST FOR RECONSIDERATION

In response to the Final Office Action dated **April 8, 2011**, the period of response for which runs through July 2011, please amend the application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

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	12492512	Filing Date	2009-06-26	Docket Number (if applicable)	S63.2-15141-US03	Art Unit	3774
First Named Inventor	Ulrich R. Haug			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 after 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	/James L. Shands/	Date (YYYY-MM-DD)	2011-06-10
Name	James L. Shands	Registration Number	54439

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.

Electronic Patent Application Fee Transmittal

Application Number:	12492512
Filing Date:	26-Jun-2009
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	James Lee Shands/Samantha Painschab
Attorney Docket Number:	S63.2Q-15141-US03

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($)
Miscellaneous:				
Request for continued examination	1801	1	810	810
		Total in USD ($)		**810**

Electronic Acknowledgement Receipt

EFS ID:	10278438
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	00490
Filer:	James Lee Shands/Samantha Painschab
Filer Authorized By:	James Lee Shands
Attorney Docket Number:	S63.2Q-15141-US03
Receipt Date:	10-JUN-2011
Filing Date:	26-JUN-2009
Time Stamp:	14:12:38
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$810
RAM confirmation Number	302
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	15141US03_tra_20110610.pdf	79750 1397b41c5562e1790e2b27eec0d87406f3337d2c	no	1
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	15141US03_RCE_20110610.pdf	697848 07bea7bee7d627ae7f222912d3ce2a8e8a7cd36d	no	3
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30098 94fac370cca50d3764871e27de044811923 6b316	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	807696		

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.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
3 page Request for Continued Examination.

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 10, 2011.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: June 10, 2011

By: /James L. Shands/
James L. Shands
Registration No.: 54439

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Eden Prairie, MN 55344-7834
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f:\wpwork\jls\15141us03_tra_20110610.doc

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
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	Filing Date	☐ To be Mailed
12/492,512	06/26/2009	

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	06/10/2011	(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))	* 15	Minus	** 20	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $ =		OR	X $220=	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:
/LINDA WASHINGTON/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Client Number	BostonScientificScimedInc.
Page 1 of 14	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	1	0015192	6/24/1856	F. Peale	
	2	20010002445	5/31/2001	Vesely	
	3	20010007956	7/12/2001	Letac et al.	
	4	20010010017	7/26/2001	Letac et al	
	5	20010025196	9/27/2001	Chinn et al.	
	6	20010032013	10/18/2001	Marton	
	7	20020029014	3/7/2002	Jayaraman	
	8	20020032480	3/14/2002	Spence et al.	
	9	20020042651	4/11/2002	Liddicoat et al.	
	10	20020052651	5/2/2002	Myers et al.	
	11	20020055767	5/9/2002	Forde et al.	
	12	20020123802	9/5/2002	Snyders	
	13	20020138138	9/26/2002	Yang	
	14	20020165576	11/7/2002	Boyle et al.	
	15	20020183781	12/5/2002	Casey et al.	
	16	20020193871	12/19/2002	Beyersdorf et al.	
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	18	20030028247	2/6/2003	Cali	
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	20	20030040792	2/27/2003	Gabbay	
	21	20030069492	4/10/2003	Abrams et al.	
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	23	20030100918	5/29/2003	Duane	
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	29	20040059409	3/25/2004	Stenzel	
	30	20040093060	5/13/2004	Seguin 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.			

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Page 2 of 14	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	31	20040097788	5/20/2004	Mourlas et al.	
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	35	20040117009	6/17/2004	Cali et al.	
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	37	20040127936	7/1/2004	Salahieh et al.	
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	48	20040243221	12/2/2004	Fawzi et al.	
	49	20040260390	12/23/2004	Sarac et al.	
	50	20050010287	1/13/2005	Macoviak et al.	
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	59	20050065594	3/24/2005	DiMatteo et al.	
	60	20050075584	4/7/2005	Cali	

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Page 3 of 14	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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	62	20050075717	4/7/2005	Nguyen et al.	
	63	20050075719	4/7/2005	Bergheim	
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	69	20050143807	6/30/2005	Pavcnik et al.	
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	90	20080221672	9/11/2008	Lamphere et al.	

Examiner Signature		**Date Considered**	

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	Art Unit	3774
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Page 4 of 14	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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	92	20090005863	1/1/2009	Goetz et al.	
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	106	3099016	7/30/1963	M. L. Edwards	
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	108	3130418	4/28/1964	L. R. Head et al.	
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	119	4035849	7/19/1977	Angell et al.	
	120	4222126	9/16/1980	Boretos et al.	

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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
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Page 5 of 14	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	121	4265694	5/5/1981	Boretos et al.	
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	124	4339831	7/20/1982	Johnson	
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	126	4345340	8/24/1982	Rosen	
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	129	4470157	9/11/1984	Love	
	130	4484579	11/27/1984	Meno et al.	
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	133	4574803	3/11/1986	Storz	
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	148	4878495	11/7/1989	Grayzel	
	149	4878906	11/7/1989	Lindemann et al.	
	150	4883458	11/28/1989	Shiber	

Examiner Signature		**Date Considered**	
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	Art Unit	3774
	Client Number	BostonScientificScimedInc.
Page 6 of 14	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
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	155	4969890	11/13/1990	Sugita et al.	
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	159	5032128	7/16/1991	Alonso	
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	166	5141494	8/25/1992	Danforth et al.	
	167	5152771	10/6/1992	Sabbaghian et al.	
	168	5159937	11/3/1992	Tremulis	
	169	5167628	12/1/1992	Boyles	
	170	5215541	6/1/1993	Nashef et al.	
	171	5282847	2/1/1994	Trescony et al.	
	172	5295958	3/22/1994	Shturman	
	173	5360444	11/1/1994	Kusuhara	
	174	5409019	4/25/1995	Wilk	
	175	5443446	8/22/1995	Shturman	
	176	5443449	8/22/1995	Buelna	
	177	5480424	1/2/1996	Cox	
	178	5500014	3/19/1996	Quijano et al.	
	179	5545209	8/13/1996	Roberts et al.	
	180	5545214	8/13/1996	Stevens	

Examiner Signature		**Date Considered**	
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Page 7 of 14	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	181	5571175	11/5/1996	Vanney et al.	
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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	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Client Number	BostonScientificScimedInc.
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Examiner Signature		**Date Considered**	

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Page 11 of 14	**Matter Number**	S63.2-15141-US03

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	Art Unit	3774
	Client Number	BostonScientificScimedInc.
Page 12 of 14	**Matter Number**	S63.2-15141-US03

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Page 13 of 14	**Matter Number**	S63.2-15141-US03

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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:	12381090
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	23-MAR-2012
Filing Date:	26-JUN-2009
Time Stamp:	15:13:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US03_tra_20120323.pdf	80365 bedb0038f1e914f51565144bd5b425743f5aff8e	no	1

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4	Non Patent Literature	Atwood_etal_Insertion_of_Heart_Valves_by_Catheterization_2007.pdf	4150302 efc5956c51b65dc8570823a1b6de244ed662a530	no	95
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14	Non Patent Literature	Laborde_etal_Percutaneous_implantation_of_the_corevalve_2006.pdf	1311847 de79731a4555fbba52237c469716fc0e75d86773	no	3
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15	Non Patent Literature	Levy_etal_Mycobacterium_Chelonei_Infection_of_Porcine_Heart_Valves_1977.pdf	424052 668924d1e8ea4fc0bfb3105cc287bf2508a048ce	no	2
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45	Foreign Reference	EP1589902.pdf	1339580 dc203bdf0d2853d1b5c013f63f4d4583b0f1eb61	no	22
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46	Foreign Reference	EP1605871B1.pdf	425270 eac7acfef6ddcf7a15965203f2f7b4bf8cc18d1	no	44

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47	Foreign Reference	WO1991017720A1.pdf	519864 33ec53d85332070960c446b41d17babf428ff8ec	no	21
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49	Foreign Reference	WO1993001768A1.pdf	931985 6a089d06724e6de961d95e0d0860dc661fb9c285	no	36
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50	Foreign Reference	WO1998029057A1.pdf	1471603 b832904a50ecb542d197695e9765e669abbb5887	no	67
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51	Foreign Reference	WO1999033414A1.pdf	736018 23fb62b6f0770dc7abb9c6b53e165dae19ef2d04	no	34
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52	Foreign Reference	WO1999040964A1.pdf	494640 9d6df52b4aadcb7003abb105587dfce23cb23ba5	no	26
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53	Foreign Reference	WO1999047075A1.pdf	371169 cf650b71f86656da1414087bf020510e0533cd40	no	18
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55	Foreign Reference	WO2000044311A2.pdf	3156891 [illegible]	no	100

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Information:					
		Total Files Size (in bytes):	65710711		

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.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

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
f:\wpwork\jmu\15141us03_tra_20120323.doc

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.:	**12/492512**
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P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2Q-15141-US03

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached:
33 Foreign References.

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Respectfully submitted,

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6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
f:\wpwork\jmu\15141us03_tra2_20120323.doc

Electronic Acknowledgement Receipt

EFS ID:	12381442
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	23-MAR-2012
Filing Date:	26-JUN-2009
Time Stamp:	15:28:48
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.)
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10	Foreign Reference	WO2004105651A1.pdf	976253 fb7517137f01abecc6f3ed2745a35808e05b217d	no	35
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13	Foreign Reference	WO2005009285A2.pdf	546512 b8f7eb3b6941ab41fc70338cd0046ef373e4e511	no	29
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21	Foreign Reference	WO2005062980A2.pdf	6547837 a70f844f6b55b1e9ea1bcab4f2a05d57ebf16cd4	no	264
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22	Foreign Reference	WO2005065585A1.pdf	1020731 1a459a9e642439c4667f552550f77a51eb23fcca	no	46
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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

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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	12492512
Filing Date	2009-06-26
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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.	

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	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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

	1							☐

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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]
	1	Examiner's First Report on AU Patent Application No. 2011202667, issued on May 17, 2012.	☐

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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:	13141912
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	29-JUN-2012
Filing Date:	26-JUN-2009
Time Stamp:	12:47:07
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	15141US03_tra_20120627.pdf	80686 cdeccac18ae9f3c60e4038461880754ca5b1cd63	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDS_20120627.pdf	612392 f8aff49a7260ddd15015f01a40f57756feb77933	no	4
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Information:					
3	Non Patent Literature	Examiners_First_Report_on_AU_App_No_2011202667.pdf	272422 23dccfd1453abcfe4b8e6dea5a9718058fc42758	no	3
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Information:					
			Total Files Size (in bytes):	965500	

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.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

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\15141us03_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	12492512
Filing Date	2009-06-26
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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.

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:	13715112
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	11-SEP-2012
Filing Date:	26-JUN-2009
Time Stamp:	17:41:49
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	15141US03_tra_20120911.pdf	80858 694872ddffcf88e77c7cd0b9d73a9aecc414c811	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	15141US03_suppids_20120905.pdf	612150 bcd867f18bd38b48c5826272d837edda53d3a1ab	no	4

Warnings:	
Information:	
Total Files Size (in bytes):	693008

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

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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.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

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
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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	12492512
Filing Date	2009-06-26
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

	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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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.

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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:	14949353
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	13-FEB-2013
Filing Date:	26-JUN-2009
Time Stamp:	14:43:42
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	15141US03_tra_20130213.pdf	103581 fa4632afb6d129ef547053eb19a3bde58738901a	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDS_20130213.pdf	612175 414505dd1bb9d976f785a64b023ce730a84a5eca	no	4

Warnings:	
Information:	
Total Files Size (in bytes):	715756

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

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

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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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

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

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
v:\wpwork\jmu\15141us03_tra_20130213.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	12492512
Filing Date	2009-06-26
First Named Inventor	Haug et al.
Art Unit	3774
Examiner Name	Not yet assigned
Attorney Docket Number	S63.2-15141-US03

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	5443477		1995-08-22	Marin et al.	
	2	6572643		2003-06-03	Gharibadeh	
	3	6755854		2004-06-29	Gillick et al.	
	4	6866669		2005-03-15	Buzzard et al.	
	5	6939352		2005-09-06	Buzzard et al.	
	6	7326236		2008-02-05	Andreas et al.	
	7	7491232		2009-02-17	Bolduc et al.	
	8	7674282		2010-03-09	Wu et al.	

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	Attorney Docket Number	S63.2-15141-US03

	9	7722638		2010-05-25	Deyette, Jr. et al.	
	10	7736388		2010-06-15	Goldfarb et al.	
	11	7758625		2010-07-20	Wu et al.	
	12	7799065		2010-09-21	Pappas	
	13	7892292		2011-02-22	Stack et al.	
	14	7918880		2011-04-05	Austin	
	15	7938851		2011-05-10	Olson et al.	
	16	8192351		2012-06-05	Fishler et al.	
	17	8236049		2012-08-07	Rowe et al.	
	18	8252051		2012-08-28	Chau et al.	
	19	8308798		2012-11-13	Pintor et al.	

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	Examiner Name	Not yet assigned
	Attorney Docket Number	S63.2-15141-US03

	20	8323335		2012-12-04	Rowe et al.	
	21	8376865		2013-02-19	Forster et al.	
	22	8377117		2013-02-19	Keidar et al.	
	23	8398708		2013-03-19	Meiri 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	20050060016		2005-03-17	Wu et al.	
	2	20050090890		2005-04-28	Wu et al.	
	3	20050149159		2005-07-07	Andreas et al.	
	4	20080255661		2008-10-16	Straubinger et al.	
	5	20090093877		2009-04-09	Keidar et al.	

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	6	20100094399		2010-04-15	Dorn et al.	
	7	20100191326		2010-07-29	Alkhatib	
	8	20130030520		2013-01-31	Lee 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

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		☐

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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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12492512
	Filing Date	2009-06-26
	First Named Inventor	Haug et al.
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	Examiner Name	Not yet assigned
	Attorney Docket Number	S63.2-15141-US03

[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	12492512
	Filing Date	2009-06-26
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	Examiner Name	Not yet assigned
	Attorney Docket Number	S63.2-15141-US03

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)	2013-05-06
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:	15701994
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	06-MAY-2013
Filing Date:	26-JUN-2009
Time Stamp:	16:32:05
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	15141US03_tra_20130506.pdf	103562 a47123e685eb2463621fe7a79389de86bd094ca1	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDS_20130506.pdf	613122 492615daa3c0fc3c4d6e737229194a7847897f38	no	7

Warnings:	
Information:	
Total Files Size (in bytes):	716684

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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

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 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.

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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 6, 2013.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: May 6, 2013

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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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

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Application Number	12492512
Filing Date	2009-06-26
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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
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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	20060287717	A1	2006-12-21	Rowe et al.	
	2	20080033541	A1	2008-02-07	Gelbart 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	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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12492512
	Filing Date	2009-06-26
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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		☐

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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.

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	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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☐ See attached certification statement.

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☒ 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)	2013-07-12
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.**

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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:	16302074
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	12-JUL-2013
Filing Date:	26-JUN-2009
Time Stamp:	14:42:43
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	15141US03_tra_20130712.pdf	103579 50fa69dd7dc9ac713e283fc3155925beadacdb2b	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDS_20130712.pdf	612274 cf94e1d433d81dc9ce4ba7edf6d7b287ac77551a	no	4
Warnings:					
Information:					
3	Foreign Reference	15141US03_WO1996040012.pdf	4663156 8356b9e363a19ea35e04d290698ad1d852759121	no	31
Warnings:					
Information:					
			Total Files Size (in bytes):	5379009	

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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

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 copy of 1 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 12, 2013.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: July 12, 2013

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
v:\wpwork\jmu\15141us03_tra_20130712.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	12492512
Filing Date	2009-06-26
First Named Inventor	Ulrich R. Haug
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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)	2013-09-17
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:	16879013
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	17-SEP-2013
Filing Date:	26-JUN-2009
Time Stamp:	17:13:05
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	15141US03_tra_20130917.pdf	80504 c6a993b68190875fd97887ab5f147390d2b7b1b8	no	1

Warnings:	
Information:	

2	Miscellaneous Incoming Letter	15141US03_Letter_ids_20130917.pdf	89014 b5343874d7efb1eec6c9edb61374f52c429efb9b	no	2
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDS_20130917.pdf	612169 4104ece5c326bfc8a5cb6be0df8baad0c8a79910	no	4
Warnings:					
Information:					
		Total Files Size (in bytes):	781687		

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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

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 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 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:	**Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Amr Salahieh, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

Letter Regarding IDS

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 division of and claims priority under 35 U.S.C. § 120 to U.S. Pat. Appl. Ser. No. 12/269,213, filed on November 12, 2008; which is a continuation of 10/870,340 filed on 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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

490 7590 12/30/2013

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
12/30/2013	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. 12/492,512	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 --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTHS 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 *6/10/2011*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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) *1-15* 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) _____ is/are rejected.

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

9)☒ Claim(s) *1-15* 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).

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)).

** 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/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

The claim(s) is/are directed to the following disclosed patentably distinct species: Species A: a system for replacing a heart valve comprising a seal made from an expandable foam; Species B: a system for replacing a heart valve comprising a fabric seal with flaps to extend into the spaces of the native valve leaflets; and Species C: a system for replacing a heart valve having seals made of sacs disposed around the valve anchor. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

The disparate nature of the currently claimed species may hinder a quality and thorough examination of the claims on the merits.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species** or grouping of patentably indistinct species, including

any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, 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 or pre-AIA 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.

A telephone call was made to Michael McKeen on 12/19/2013 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing 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 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

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.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

RESPONSE TO RESTRICTION REQUIREMENT

This communication is in response to the Requirement for Species Election dated **December 30, 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.

Status of the Claims

Claims 1-8 (Canceled)

Claim 9 (Previously Presented): 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 fabric 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 the fabric seal has an undeployed state and a deployed state, wherein in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets, and

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

Claims 10-15 (Canceled)

Claim 16 (New): The system of claim 9, wherein the expandable anchor comprises a distal end, and wherein, when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends over the distal end of the expandable anchor.

Claim 17 (New): The system of claim 9, wherein, in the deployed state, the fabric seal defines a plurality of pockets.

Claim 18 (New): The system of claim 17, wherein the pockets are adapted to fill with blood in response to backflow blood pressure.

Claim 19 (New): The system of claim 9, wherein the expandable anchor is formed from stainless steel or nickel-titanium alloy.

Claim 20 (New): The system of claim 9, wherein the commissure support element is configured to interface with an anchor actuator.

Claim 21 (New): The system of claim 20, wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor.

Claim 22 (New): The system of claim 1 further comprising a lock having a first lock element and a second lock element, the first and second lock elements being attached to the expandable anchor and configured to interlockingly engage one another to lock the expandable anchor in the expanded configuration.

Claim 23 (New): The system of claim 22, wherein the commissure support element includes the first lock element.

Claim 24 (New): The system of claim 23, 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 delivery configuration.

REMARKS

This communication is in response to the Requirement for Species Election of December 30, 2013.

The Requirement identified three species and required the election of a single species, as follows:

> The claim(s) is/are directed to the following disclosed patentably distinct species: Species A: a system for replacing a heart valve comprising a seal made from an expandable foam; Species B: a system for replacing a heart valve comprising a fabric seal with flaps to extend into the spaces of the native valve leaflets; and Species C: a system for replacing a heart valve having seals made of sacs disposed around the valve anchor.

Applicants are not herein making any admission that the identification of species is accurate as there could be other features that are identified as being patentably distinct. Moreover, Applicants note that in addition to those species identified in the Requirement as corresponding to specific figures depicted in the Application, additional species may exist which are described in the specification and claims and which are not subject to the restriction requirement identified by the Requirement.

Also, Applicants understand that the Examiner has made a determination that the subject matter any of the claims specific to any of the various species does not render obvious the subject matter of any claim specific to any of the other species. *See* MPEP 802.01 (II).

With that understanding, the Applicants provisionally elect species B. Claims 9 and 16-24 are readable upon the elected species.

If the Examiner does not agree with this characterization of the determination, the election is made with traverse on the grounds that the requirement has not complied with 35 U.S.C. 121 and MPEP 802.01. Patentable distinction between species means exactly that prior art showing only the subject matter of one species does not render obvious another species.

Additionally, Applicants have canceled claims 1-8 and 10-15 without prejudice or disclaimer and reserve the right to prosecute these claims in one or more divisional applications.

Claims 16-24 are added and depend, either directly or indirectly, from independent claim 9. Support for these claims can be found in the Specification at least in paragraphs [0068], [0069], [00112], and [00113], and at least in FIGs. 1A, 1B, and 32-34.

Conclusion

In view of the foregoing it is believed that the present application, with claims 9 and 16-24 is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 28, 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
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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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

Letter Regarding IDS

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.

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 division of and claims priority under 35 U.S.C. § 120 to U.S. Pat. Appl. Ser. No. 12/269,213, filed on November 12, 2008; which is a continuation of 10/870,340 filed on 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: February 28, 2014

By: /Michael J. McKeen/
Michael J. McKeen
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6640 Shady Oak Rd., Suite 400
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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	12492512
Filing Date	2009-06-26
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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	20040167620		2004-08-26	Ortiz, 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

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

	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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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)	2014-02-28
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:	18336529
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	28-FEB-2014
Filing Date:	26-JUN-2009
Time Stamp:	14:56:17
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	15141US03_tra_20140228.pdf	80606 ef152c242af1a259b81b0ab016b7783c055604d0	no	1

Warnings:	
Information:	

2	Response to Election / Restriction Filed	15141US03_rsp_20140128.pdf	105227 58e4bfd5fd3a7628ce47a40ee1cfdffa71264322	no	5
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	15141US03_ids_20140228.pdf	89172 951a2456fbc6ccecafa32c54f5c0c0070abb24b1	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDSFORM_20140225.pdf	611931 460ebcea4fd2285db144c592fcf4c78413d25f6d	no	4
Warnings:					
Information:					
		Total Files Size (in bytes):	886936		

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:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached: **5 page Response to Restriction Requirement, 2 page Letter Regarding IDS, and 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 28, 2014.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 28, 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

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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 12/492,512	Filing Date 06/26/2009	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) 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

AMENDMENT	02/28/2014	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 10	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 1	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

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) 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
/BRENDA TURNER/

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.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

490 7590 04/10/2014

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	

NOTIFICATION DATE	DELIVERY MODE
04/10/2014	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. 12/492,512	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 --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS 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 *2/28/2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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) *9 and 16-24* 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) *9 and 16-24* 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).

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)).

** 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/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *See Continuation Sheet*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

Continuation of Attachment(s) 2). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/23/12,6/29/12,9/11/12,2/13/13,5/6/13,7/12/13,9/17/13,2/28/14.

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species B in the reply filed on 2/28/2014 is acknowledged. Claims 1-8 and 10-15 are canceled from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species A, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/28/2014.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 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 9 and 16-21 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leonhardt et al. (US Pat. No. 5,957,949) in view of De Paulis (US Pat. No. 6,352,554). Leonhardt et al. teaches the following regarding claim 9: a system for replacing a heart valve, comprising: an expandable anchor (26) having a collapsed delivery configuration and an expanded configuration; a replacement valve commissure support element (22) attached to the expandable anchor (Fig. 4); a commissure portion (68) of a replacement valve leaflet attached to the commissure support element; and a fabric seal (24) 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 and

wherein a distal end of the replacement valve leaflet is attached to the seal. (Fig. 4; col. 5, line 53 through col. 6, line 8).

Leonhardt et al. does not teach the fabric seal comprising flaps and pockets. An implantable fabric having pleats and pockets is well known in the art, as taught by De Paulis in Figure 2, and it would have been obvious to one of ordinary skill in the art to modify seal of Leonhardt et al. to include pleats as an obvious alternate design choice. At least a portion of Leonhardt et al.'s seal is adapted to be filled with blood, and captured between the leaflets (14) and a wall of the patient's heart (18) when the anchor and replacement valve are fully deployed.

Leonhardt et al. teaches the following regarding claim 16: the system of claim 9, wherein the expandable anchor comprises a distal end (Figs. 3A-3B), and wherein, when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends over the distal end of the expandable anchor (Fig. 4).

Leonhardt et al. teaches the following regarding claim 19: the system of claim 9, wherein the expandable anchor is formed from stainless steel or nickel-titanium alloy (col. 5, lines 11-22).

Leonhardt et al. teaches the following regarding claim 20: the system of claim 9, wherein the commissure support element is configured to interface with an anchor actuator (cols. 10-11).

Leonhardt et al. teaches the following regarding claim 21: the system of claim 20, wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor (cols. 10-11).

Claims 22-24 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leonhardt et al. in view of De Paulis further in view of Artof et al. (US Pub. No. 2005/0075731).

Leonhardt et al., as modified by De Paulis, does not teach the device comprising a lock having a first and a second interlocking elements. Artof et al. teaches a first lock element (35) on its commissure support interlocking with a second lock element (54) that may be attached to an anchor (53) as shown in Figures 11-13. 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 Leonhardt et al. and De Paulis to include a lock in order to better stabilize the device.

Response to Arguments

Applicant's arguments with respect to claims 9 and 16-24 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571)272-6652. The examiner can normally be reached on 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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	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	3/29/2011	AS
Updated prior search	4/2/2014	AS

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/A. S./ Examiner.Art Unit 3774	

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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

AMENDMENT

This Amendment is in response to the Office Action dated **April 10, 2014.**

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:

Claims 1-8 (Canceled)

Claim 9 (Currently Amended): A system for replacing a heart valve, comprising:

an expandable anchor having a collapsed delivery configuration and an expanded configuration, the expandable anchor comprising a distal end;

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 fabric seal at least partially disposed around an exterior portion of the expandable anchor when the anchor is in the expanded configuration, the fabric seal having an undeployed state and a deployed state, ~~wherein the seal is adapted to prevent blood from flowing between the seal and heart tissue, wherein the fabric seal has an undeployed state and a deployed state,~~ wherein in the deployed state the fabric seal comprises flaps that extend into spaces formed by native valve leaflets;~~, and~~

wherein a distal end of the replacement valve leaflet is attached to the fabric seal and when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor, the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue.

Claims 10-16 (Canceled)

Claim 17 (Previously Presented): The system of claim 9, wherein, in the deployed state, the fabric seal defines a plurality of pockets.

Claim 18 (Previously Presented): The system of claim 17, wherein the pockets are adapted to fill with blood in response to backflow blood pressure.

Claim 19 (Previously Presented): The system of claim 9, wherein the expandable anchor is

formed from stainless steel or nickel-titanium alloy.

Claim 20 (Previously Presented): The system of claim 9, wherein the commissure support element is configured to interface with an anchor actuator.

Claim 21 (Previously Presented): The system of claim 20, wherein the anchor actuator is adapted to apply a proximally directed force on the commissure support element to foreshorten the expandable anchor.

Claim 22 (Currently Amended): The system of claim [[1]]9 further comprising a lock having a first lock element and a second lock element, the first and second lock elements being attached to the expandable anchor and configured to interlockingly engage one another to lock the expandable anchor in the expanded configuration.

Claim 23 (Previously Presented): The system of claim 22, wherein the commissure support element includes the first lock element.

Claim 24 (Previously Presented): The system of claim 23, 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 delivery configuration.

Remarks

This Amendment is in response to the Office Action dated **April 10, 2014.** In the Office Action, the Examiner rejected claims 9 and 16-21 under 35 USC § 103(a) over Leonhardt (US 5,957,949) in view of De Paulis (US 6,352,554) and rejected claims 22-24 under 35 USC § 103(a) over Leonhardt in view of De Paulis in further view of Artof (US Pub. No. 2005/0075731).

Without acquiescing to the validity of the rejections, independent claim 9 is herein amended to incorporate the subject matter of previous claim 16 and to provide additional clarity. Support for the amendment can be found in the Specification at least in paragraph [00112] and at least in FIG. 32 of the Application as-filed.

Claim 16 is accordingly canceled without prejudice or disclaimer.

Dependent claim 22 is amended to depend from claim 9.

In light of the foregoing amendments and following comments, Applicants request reconsideration.

Claim Rejections – 35 USC § 103(a)

Without acquiescing to the validity of the rejection of claims 9 and 16-21 over Leonhardt in view of De Paulis, independent claim 9 is herein amended to recite, in-part, "when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor, the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue."

As shown for example in FIG. 32 of the immediate Application, reproduced below, the fabric seal doubles over the distal end of the expandable anchor. Further, paragraph [00112] states, in-part, "a fabric seal 380 extends from the distal end of valve 20 and back proximally over anchor 30 during delivery."

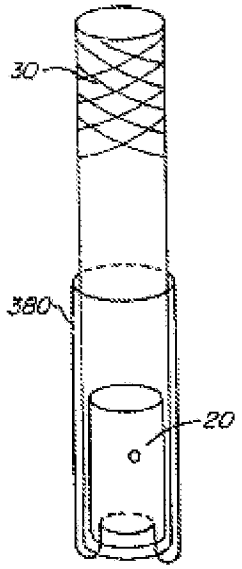

FIG. 32

In contrast, neither Leonhardt nor De Paulis, whether considered independently or in combination, teaches, suggests, or otherwise renders obvious a "when the expandable anchor is in the collapsed delivery configuration, the fabric seal extends from the distal end of the replacement valve and back proximally over the expandable anchor, the fabric seal being adapted to prevent blood from flowing between the fabric seal and heart tissue," as is claimed. Consequently, Applicants request withdrawal of the rejection and reconsideration of independent claim 9 and dependent claims 17-21, which depend either directly or indirectly therefrom.

The Examiner rejected claims 22-24 over Leonhardt in view of De Paulis and Artof. Each of dependent claims 22-24 depends either directly or indirectly from independent claim 9 and the addition of Artof does not remedy the deficiencies of Leonhardt and De Paulis as discussed above with respect to independent claim 9. As such, Applicants request withdrawal of the rejection of dependent claims 22-24 over Leonhardt in view of De Paulis and Artof.

Conclusion

Based on at least the foregoing remarks and amendments, Applicants request withdrawal of the rejections and allowance of claims 9 and 17-23. 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: July 9, 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

/home/mmckeen/Desktop/15141US03_Amendment_20140527.doc

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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

Letter Regarding IDS

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.

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 division of and claims priority under 35 U.S.C. § 120 to U.S. Pat. Appl. Ser. No. 12/269,213, filed on November 12, 2008; which is a continuation of 10/870,340 filed on 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: July 9, 2014

By: /Michael J. McKeen/
Michael J. McKeen
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6640 Shady Oak Rd., Suite 400
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Client Number	
Page 1 of 2	Matter Number	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	Cite No.	Document Number	Issue/Publication Date	First Named Inventor	T
	1	20130018457	01/17/2013	Gregg et al.	
	2	20130158656	06/20/2013	Sutton et al.	
	3	20130304199	11/14/2013	Sutton et al.	
	4	20140018911	01/16/2014	Zhou et al.	
	5	5725549	03/10/1998	Lam	
	6	5876419	03/02/1999	Carpenter et al.	
	7	6623521	09/23/2003	Steinke et al.	
	8	7004176	02/28/2006	Lau	
	9	7141063	11/28/2006	White et al.	
	10	7722662	05/25/2010	Steinke 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	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
	Client Number	
Page 2 of 2	Matter Number	S63.2-15141-US03

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.

SIGNATURE			
Signature	/Michael J. McKeen/	Date	7/9/2014
Name	Michael J. McKeen	Registration Number	66069

SyncIDS.com

Electronic Patent Application Fee Transmittal

Application Number:	12492512
Filing Date:	26-Jun-2009
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Michael James McKeen/Wendy Skelly
Attorney Docket Number:	S63.2Q-15141-US03

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:	19533043
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	09-JUL-2014
Filing Date:	26-JUN-2009
Time Stamp:	16:00:53
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	2415
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	15141US03_VASTransmittal_20140709.pdf	80571 5f73c3eebf344590bc56394d150fd145b8713af6	no	1
Warnings:					
Information:					
2	Amendment/Req. Reconsideration-After Non-Final Reject	15141US03_Amendment_20140527.pdf	95097 1cfce51bb0dfd7f2657b7c89346284fed221b823	no	6
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	15141US03_ids_20140709.pdf	89159 3b2db4da8d2c7c7fd91e6d825168cf3c755ad572	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDSFORM_20140709.pdf	345418 b4fe1b27254104cf40a104defb29f9b641b2e067	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
5	Fee Worksheet (SB06)	fee-info.pdf	30161 ffa644e0122ef132e2e2e08004209d4dd6ab956c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	640406		

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:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/492512**
Filed:	**June 26, 2009**
For:	**Everting Heart Valve**
Examiner:	**Ann M. Schillinger**
Group Art Unit:	**3774**

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

Docket No.: S63.2Q-15141-US03

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached: **6 page Amendment, 2 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 July 9, 2014.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: July 9, 2014

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
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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 12/492,512	Filing Date 06/26/2009	☐ 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	07/09/2014	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 9	Minus	** 20	=	X $ =	
	Independent (37 CFR 1.16(h))	* 1	Minus	***3	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

		(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
/SONYA HILLIARD/

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Alexandria, Virginia 22313-1450
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NOTICE OF ALLOWANCE AND FEE(S) DUE

490 7590 10/06/2014

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
9531 West 78th Street
Suite 400
Eden Prairie, MN 55344

EXAMINER
SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 10/06/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

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	01/06/2015

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 10/06/2014

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
9531 West 78th Street
Suite 400
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.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

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	01/06/2015

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. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

490 7590 10/06/2014

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
9531 West 78th Street
Suite 400
Eden Prairie, MN 55344

EXAMINER	
SCHILLINGER, ANN M	

ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 10/06/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

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. 12/492,512	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 amendment made after a non-final rejection filed on 4/10/2014*.
   ☐ 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 *9 and 17-24*. 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 7/9/2014
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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

CPC- SEARCHED		
Symbol	Date	Examiner
A61F2/2412; A61F2/2427; A61F2220/0016; A61F2/24; A61F2/2454; A61F2/07	9/25/2014	AS

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Updated prior search	3/29/2011	AS
Updated prior search	4/2/2014	AS
Updated prior search	9/25/2014	AS
Interference search EAST, see printout	9/25/2014	AS

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61F	A61F2/2412; A61F2/2427; A61F2220/0016; A61F2/24; A61F2/2454; A61F2/07	9/25/2014	AS

/A. S./ Examiner.Art Unit 3774	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	SALAHIEH ET AL.
	Examiner	**Art Unit**
	ANN SCHILLINGER	3774

CPC						
Symbol					**Type**	**Version**
A61F		2	/	2418	F	2013-01-01
A61F		2	/	2439	I	2013-01-01
A61F		2	/	2433	A	2013-01-01
A61F		2	/	2436	A	2013-01-01
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CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

/A.S./ Examiner.Art Unit 3774	09/25/2014	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	9	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	09/28/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	32

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	SALAHIEH ET AL.
	Examiner	**Art Unit**
	ANN SCHILLINGER	3774

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
623	2.38	A	6	1	F	2 / 24 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

/A.S./ Examiner.Art Unit 3774	09/25/2014	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	9	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	09/28/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	32

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	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	2	17												
	2	3	18												
	3	4	19												
	4	5	20												
	5	6	21												
	6	7	22												
	7	8	23												
	8	9	24												
1	9														
	10														
	11														
	12														
	13														
	14														
	15														
	16														

/A.S./ Examiner.Art Unit 3774	09/25/2014	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	9	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	09/28/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	32

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. 7439

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/492,512	06/26/2009	623	3774	S63.2Q-15141-US03

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 DIV of 12/269,213 11/12/2008 PAT 8668733
which is a CON of 10/870,340 06/16/2004 PAT 7780725

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

07/07/2009

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ANN SCHILLINGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	63	7	1

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

EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	6	(heart and valve and commissure and seal and fabric).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/09/25 17:37
L6	3	(replacement and heart and valve and delivery and blood and seal and vessel).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/09/25 17:50
L7	3	(support and element and heart and valve and commissure and blood and seal).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/09/25 17:52
L8	1	(expand$4 and replacement and valve and commissure and fabric and seal and leaflet).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/09/25 17:58
L9	0	(deployed and state and heart and valve and fabric and seal and flaps).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/09/25 18:00

9/25/2014 6:01:09 PM
C:\Users\aschillinger\Documents\EAST\Workspaces\12492512.wsp

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	12492512	Filing Date	2009-06-26	Docket Number (if applicable)	S63.2-15141-US03	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 after 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)	2014-11-26
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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
Page 1 of 3	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	1	20110257735	10/20/2011	Salahieh et al.	
	2	20120022642	01/26/2012	Haug et al.	
	3	20120029627	02/02/2012	Salahieh et al.	
	4	20120041550	02/16/2012	Salahieh et al.	
	5	20120053683	03/01/2012	Salahieh et al.	
	6	20120089224	04/12/2012	Haug et al.	
	7	20120330409	12/27/2012	Haug et al.	
	8	20130190865	07/25/2013	Anderson	
	9	20140094904	04/03/2014	Salahieh et al.	
	10	20140114405	04/24/2014	Paul et al.	
	11	20140114406	04/24/2014	Salahieh et al.	
	12	20140121766	05/01/2014	Salahieh et al.	
	13	20140135912	05/15/2014	Salahieh et al.	
	14	20140243967	08/28/2014	Salahieh et al.	
	15	5258023	11/02/1993	Reger	
	16	7824442	11/02/2010	Salahieh et al.	
	17	7824443	11/02/2010	Salahieh et al.	
	18	7959666	06/14/2011	Salahieh et al.	
	19	7959672	06/14/2011	Salahieh et al.	
	20	7988724	08/02/2011	Salahieh et al.	
	21	8048153	11/01/2011	Salahieh et al.	
	22	8052749	11/08/2011	Salahieh et al.	
	23	8182528	05/22/2012	Salahieh et al.	
	24	8231670	07/31/2012	Salahieh et al.	
	25	8246678	08/21/2012	Salahieh et al.	
	26	8252052	08/28/2012	Salahieh et al.	
	27	8328868	12/11/2012	Paul et al.	
	28	8343213	01/01/2013	Salahieh et al.	
	29	8579962	11/12/2013	Salahieh et al.	
	30	8603160	12/10/2013	Salahieh 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	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
Page 2 of 3	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	31	8617236	12/31/2013	Paul et al.	
	32	8623076	01/07/2014	Salahieh et al.	
	33	8623078	01/07/2014	Salahieh et al.	
	34	8668733	03/11/2014	Haug et al.	
	35	8828078	09/09/2014	Salahieh et al.	
	36	8840662	09/23/2014	Salahieh et al.	
	37	8840663	09/23/2014	Salahieh et al.	
	38	8858620	10/14/2014	Salahieh 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	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
Page 3 of 3	**Matter Number**	S63.2-15141-US03

SIGNATURE			
Signature	/Michael J. McKeen/	Date	11/26/2014
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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

Letter Regarding IDS

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. Moreover, no aspect of this submission constitutes a disclaimer of claim scope.

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 division of and claims priority under 35 U.S.C. § 120 to U.S. Pat. Appl. Ser. No. 12/269,213, filed on November 12, 2008; which is a continuation of 10/870,340 filed on 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.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 26, 2014

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

9531 West 78th Street, Suite 400
Eden Prairie, MN 55344-8006
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

v:\wpwork\mjm\15141us03_informationdisclosurestatement_20141126.doc

Electronic Patent Application Fee Transmittal

Application Number:	12492512
Filing Date:	26-Jun-2009
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Michael James McKeen/Wendy Skelly
Attorney Docket Number:	S63.2Q-15141-US03

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:	20807575
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	26-NOV-2014
Filing Date:	26-JUN-2009
Time Stamp:	11:46:20
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	55
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	15141US03_VASTransmittal_20141126.pdf	80777 ff6c8a3263ae7344e81aa3c5934cc9d5b4350a77	no	1
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	15141US03_RCE_20141125.pdf	697611 5e28742fc7d3d8b2ee20cc8a980cb09128c511fb	no	3
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDS_20141125.pdf	612784 8f7e418a9d16886a8c4f4b5d016be4b9d5dbce3c	no	5
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDS2_20141125.pdf	39202 8aeaa839ffb4c4415ccdb3535fc5a2bc54558aa0	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
5	Miscellaneous Incoming Letter	15141US03_InformationDisclosureStatement_20141126.pdf	89909 33402f733df01ba8a908903900dc1a4bc320a9ae	no	2
Warnings:					
Information:					
6	Foreign Reference	15141US03_FR1_20141125.pdf	2378335 37f6ebf39676f817bf729b791b1aff8a9abd293c	no	26
Warnings:					
Information:					
7	Foreign Reference	15141US03_FR2_20141125.pdf	2177492 db5e6459c092ecf89a3a840791c8a3d8c70b137a	no	54
Warnings:					
Information:					
8	Foreign Reference	15141US03_FR3_20141125.pdf	2626955 279e33b8540623dbd51f5451a8785c6f74ff060b	no	64
Warnings:					
Information:					
9	Foreign Reference	15141US03_FR4_20141125.pdf	2407205 05098afc75261fa259aaf3c4da80e4438347e646	no	29

Warnings:					
Information:					
10	Foreign Reference	15141US03_FR5_20141125.pdf	744283 27fd6cac5b5298bf7ed3c7e56a781d96469a97fe	no	20
Warnings:					
Information:					
11	Foreign Reference	15141US03_FR6_20141125.pdf	5991154 87cc13a00ebeaf24b5f0b33e92b72f73cc0f0647	no	97
Warnings:					
Information:					
12	Foreign Reference	15141US03_FR7_20141125.pdf	745574 76b47ae6385abebdc1e5e642ef9f5795d2a8a874	no	24
Warnings:					
Information:					
13	Fee Worksheet (SB06)	fee-info.pdf	30128 dbaa42c41f905c70e7074977ef21741f7953ddde	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	18621409	

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:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **1** page transmittal letter, we are submitting the attached: **5 page Information Disclosure Statement, 3 page Information Disclosure Statement, 3 page Request for Continued Examination, 2 page Letter Regarding IDS, and 7 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 November 26, 2014.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 26, 2014

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

9531 West 78th Street, Suite 400
Eden Prairie, MN 55344-8006
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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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	12492512
Filing Date	2009-06-26
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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	6402736		2002-06-11	Brown et al.	
	2	5755783		1998-05-26	Stobie et al.	
	3	6585766		2003-07-01	Huynh et al.	
	4	6258129		2001-07-10	Dybdal 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	20030195609		2003-10-16	Berenstein et al.	
	2	20030171803		2003-09-11	Shimon	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

	3	20030199759		2003-10-23	Richard	

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	2004021922	WO		2004-03-18	Morrill et al.		☐
	2	2004006804	WO		2004-01-22	EV3 Inc.		☐
	3	2004006803	WO		2004-01-22	EV3 Inc.		☐
	4	2003047648	WO		2003-06-12	Sagax Inc.		☐
	5	2002056955	WO		2002-07-25	Embol-X, Inc.		☐
	6	2004043293	WO		2004-05-27	Viacor, Inc.		☐
	7	2004019817	WO		2004-03-11	Belson et al.		☐

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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)	2014-11-26
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.

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	12492512
Filing Date	2009-06-26
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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	2006/005015	WO	A2	2006-01-12	EDWARDS LIFESCIENCES PVT INC		☐
	2	2001/76510	WO	A2	2001-10-18	EDWARDS LIFESCIENCES CORP		☐

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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	12492512
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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)	2014-12-03
Name/Print	Michael J. McKeen	Registration Number	66069

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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:	20857411
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	03-DEC-2014
Filing Date:	26-JUN-2009
Time Stamp:	16:57:33
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	Transmittal Letter	15141US03_VASTransmittal_20141203.pdf	80617 3aa9a91b5c4ad330daa87b46921d0c6a26ea7412	no	1

Warnings:	
Information:	

2	Miscellaneous Incoming Letter	15141US03_InformationDisclosureStatement_20141203.pdf	89899 659c9d859c34b9348197d0d703137259239cd919	no	2
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	15141US03_IDS_20141201.pdf	612096 1bf4a7a3124fba003fd6097a59042c58b259ff3f	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.					
4	Foreign Reference	15141US03_FR1_20141201.pdf	2564344 a5266506b94fdec680da9509a34c3b2c2cd1d28d	no	68
Warnings:					
Information:					
5	Foreign Reference	15141US03_FR2_20141201.pdf	1839898 7588216c8433c3f5779a6b5b5ea84c43c8eb2600	no	39
Warnings:					
Information:					
			Total Files Size (in bytes):	5186854	

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:	**Amr Salahieh, Ulrich R. Haug, Hans F. Valencia, Robert A. Geshlider, Tom Saul, Dwight P. Morejohn, Kenneth J. Michlitsch**
Application No.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

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 page Letter Regarding IDS and 2 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 December 3, 2014.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: December 3, 2014

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

9531 West 78th Street, Suite 400
Eden Prairie, MN 55344-8006
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

v:\wpwork\mjm\15141us03_vastransmittal_20141203.doc

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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

Letter Regarding IDS

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. Moreover, no aspect of this submission constitutes a disclaimer of claim scope.

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 division of and claims priority under 35 U.S.C. § 120 to U.S. Pat. Appl. Ser. No. 12/269,213, filed on November 12, 2008; which is a continuation of 10/870,340 filed on 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.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: December 3, 2014

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

9531 West 78th Street, Suite 400
Eden Prairie, MN 55344-8006
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

v:\wpwork\mjm\15141us03_informationdisclosurestatement_20141203.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

NOTICE OF ALLOWANCE AND FEE(S) DUE

490 7590 02/12/2015

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
9531 West 78th Street
Suite 400
Eden Prairie, MN 55344

EXAMINER
SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 02/12/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

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	05/12/2015

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 02/12/2015

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
9531 West 78th Street
Suite 400
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.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

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	05/12/2015

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. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

490 7590 02/12/2015

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
9531 West 78th Street
Suite 400
Eden Prairie, MN 55344

EXAMINER	
SCHILLINGER, ANN M	

ART UNIT	PAPER NUMBER
3774	

DATE MAILED: 02/12/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

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. 12/492,512	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 on 11/26/2014*.
   ☐ 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 *9 and 17-24*. 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 11/26/14,11/26/14,12/3/14
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

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BIB DATA SHEET

CONFIRMATION NO. 7439

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/492,512	06/26/2009 RULE	623	3774	S63.2Q-15141-US03

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 DIV of 12/269,213 11/12/2008 PAT 8668733
which is a CON of 10/870,340 06/16/2004 PAT 7780725

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

07/07/2009

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ANN SCHILLINGER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	63	7	1

ADDRESS

VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
9531 West 78th Street
Suite 400
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

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	SALAHIEH ET AL.
	Examiner	**Art Unit**
	ANN SCHILLINGER	3774

CPC							
Symbol						**Type**	**Version**
A61F		2	/	2418		F	2013-01-01
A61F		2	/	2433		A	2013-01-01
A61F		2	/	2436		A	2013-01-01
A61F		2	/	2439		I	2013-01-01
A61F		2220	/	0016		A	2013-01-01
A61F		2220	/	005		A	2013-01-01
A61F		2220	/	0058		A	2013-01-01
A61F		2220	/	0075		A	2013-01-01
A61F		2230	/	005		A	2013-01-01
A61F		2230	/	0054		A	2013-01-01
A61F		2230	/	0065		A	2013-01-01
A61F		2230	/	0078		A	2013-01-01
			/				
			/				
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CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

/A.S./ Examiner.Art Unit 3774	02/04/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	9	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	02/08/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	32

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	SALAHIEH ET AL.
	Examiner	**Art Unit**
	ANN SCHILLINGER	3774

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
623	2.38	A	6	1	F	2 / 24 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											

/A.S./ Examiner.Art Unit 3774	02/04/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	9	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	02/08/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	32

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	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	2	17												
	2	3	18												
	3	4	19												
	4	5	20												
	5	6	21												
	6	7	22												
	7	8	23												
	8	9	24												
1	9														
	10														
	11														
	12														
	13														
	14														
	15														
	16														

/A.S./ Examiner.Art Unit 3774	02/04/2015	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	9	
/DAVID ISABELLA/ Supervisory Patent Examiner.Art Unit 3774	02/08/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	32

EAST Search History

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	6	(heart and valve and commissure and seal and fabric).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/02/04 14:37
L2	3	(replacement and heart and valve and delivery and blood and seal and vessel).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/02/04 14:42
L3	3	(support and element and heart and valve and commissure and blood and seal).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/02/04 14:44
L4	1	(expand$4 and replacement and valve and commissure and fabric and seal and leaflet).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/02/04 14:45
L5	0	(deployed and state and heart and valve and fabric and seal and flaps).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/02/04 15:07

2/4/2015 3:08:03 PM
C:\Users\aschillinger\Documents\EAST\Workspaces\12492512.wsp

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
Page 1 of 3	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	1	20110257735	10/20/2011	Salahieh et al.	
	2	20120022642	01/26/2012	Haug et al.	
	3	20120029627	02/02/2012	Salahieh et al.	
	4	20120041550	02/16/2012	Salahieh et al.	
	5	20120053683	03/01/2012	Salahieh et al.	
	6	20120089224	04/12/2012	Haug et al.	
	7	20120330409	12/27/2012	Haug et al.	
	8	20130190865	07/25/2013	Anderson	
	9	20140094904	04/03/2014	Salahieh et al.	
	10	20140114405	04/24/2014	Paul et al.	
	11	20140114406	04/24/2014	Salahieh et al.	
	12	20140121766	05/01/2014	Salahieh et al.	
	13	20140135912	05/15/2014	Salahieh et al.	
	14	20140243967	08/28/2014	Salahieh et al.	
	15	5258023	11/02/1993	Reger	
	16	7824442	11/02/2010	Salahieh et al.	
	17	7824443	11/02/2010	Salahieh et al.	
	18	7959666	06/14/2011	Salahieh et al.	
	19	7959672	06/14/2011	Salahieh et al.	
	20	7988724	08/02/2011	Salahieh et al.	
	21	8048153	11/01/2011	Salahieh et al.	
	22	8052749	11/08/2011	Salahieh et al.	
	23	8182528	05/22/2012	Salahieh et al.	
	24	8231670	07/31/2012	Salahieh et al.	
	25	8246678	08/21/2012	Salahieh et al.	
	26	8252052	08/28/2012	Salahieh et al.	
	27	8328868	12/11/2012	Paul et al.	
	28	8343213	01/01/2013	Salahieh et al.	
	29	8579962	11/12/2013	Salahieh et al.	
	30	8603160	12/10/2013	Salahieh 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.			

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
Page 2 of 3	**Matter Number**	S63.2-15141-US03

U.S. PATENT DOCUMENTS					
Initials	**Cite No.**	**Document Number**	**Issue/Publication Date**	**First Named Inventor**	**T**
	31	8617236	12/31/2013	Paul et al.	
	32	8623076	01/07/2014	Salahieh et al.	
	33	8623078	01/07/2014	Salahieh et al.	
	34	8668733	03/11/2014	Haug et al.	
	35	8828078	09/09/2014	Salahieh et al.	
	36	8840662	09/23/2014	Salahieh et al.	
	37	8840663	09/23/2014	Salahieh et al.	
	38	8858620	10/14/2014	Salahieh et al.	

Examiner Signature	/Ann Schillinger/	**Date Considered**	02/04/2015
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.			

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	12/492,512
	Filing Date	6/26/2009
	First Named Inventor	Ulrich R. Haug
	Art Unit	3774
Page 3 of 3	**Matter Number**	S63.2-15141-US03

SIGNATURE			
Signature	/Michael J. McKeen/	Date	11/26/2014
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	12492512
Filing Date	2009-06-26
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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	6402736		2002-06-11	Brown et al.	
	2	5755783		1998-05-26	Stobie et al.	
	3	6585766		2003-07-01	Huynh et al.	
	4	6258129		2001-07-10	Dybdal et al.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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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	20030195609		2003-10-16	Berenstein et al.	
	2	20030171803		2003-09-11	Shimon	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12492512 12492512 - GAU: 3774
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

	3	20030199759		2003-10-23	Richard	

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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	2004021922	WO		2004-03-18	Morrill et al.		☐
	2	2004006804	WO		2004-01-22	EV3 Inc.		☐
	3	2004006803	WO		2004-01-22	EV3 Inc.		☐
	4	2003047648	WO		2003-06-12	Sagax Inc.		☐
	5	2002056955	WO		2002-07-25	Embol-X, Inc.		☐
	6	2004043293	WO		2004-05-27	Viacor, Inc.		☐
	7	2004019817	WO		2004-03-11	Belson et al.		☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	12492512 12492512 - GAU: 3774
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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		☐

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EXAMINER SIGNATURE

Examiner Signature	/Ann Schillinger/	Date Considered	02/04/2015

*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	12492512 12492512 - GAU: 3774
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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)	2014-11-26
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.

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
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	12492512
Filing Date	2009-06-26
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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					

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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	2006/005015	WO	A2	2006-01-12	EDWARDS LIFESCIENCES PVT INC		☐
	2	2001/76510	WO	A2	2001-10-18	EDWARDS LIFESCIENCES CORP		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

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	12492512 12492512 - GAU: 3774
	Filing Date	2009-06-26
	First Named Inventor	Amr Salahieh
	Art Unit	3774
	Examiner Name	Ann M. Schillinger
	Attorney Docket Number	S63.2-15141-US03

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	02/04/2015

*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	12492512 12492512 - GAU: 3774
Filing Date	2009-06-26
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	Ann M. Schillinger
Attorney Docket Number	S63.2-15141-US03

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.

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☒ 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)	2014-12-03
Name/Print	Michael J. McKeen	Registration Number	66069

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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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12492512	SALAHIEH ET AL.
	Examiner	Art Unit
	ANN SCHILLINGER	3774

CPC- SEARCHED		
Symbol	Date	Examiner
A61F2/2412; A61F2/2427; A61F2220/0016; A61F2/24; A61F2/2454; A61F2/07	9/25/2014	AS

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Updated prior search	3/29/2011	AS
Updated prior search	4/2/2014	AS
Updated prior search	9/25/2014	AS
Interference search EAST, see printout	9/25/2014	AS
Updated prior search	2/4/2015	AS
Interference search EAST, see printout	2/4/2015	AS

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61F	A61F2/2412; A61F2/2427; A61F2220/0016; A61F2/24; A61F2/2454; A61F2/07	9/25/2014	AS
A61F	A61F2/2412; A61F2/2427; A61F2220/0016; A61F2/24; A61F2/2454; A61F2/07	2/4/2015	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 02/12/2015
VIDAS, ARRETT & STEINKRAUS, P.A.
Richard A. Arrett
9531 West 78th Street
Suite 400
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.
12/492,512	06/26/2009	Amr Salahieh	S63.2Q-15141-US03	7439

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	05/12/2015

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 &
Steinkraus, P.A.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Sadra Medical, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Los Gatos, 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 February 23, 2015

Typed or printed name Michael J. McKeen Registration No. 66069

Electronic Patent Application Fee Transmittal

Application Number:	12492512
Filing Date:	26-Jun-2009
Title of Invention:	Everting Heart Valve
First Named Inventor/Applicant Name:	Amr Salahieh
Filer:	Michael James McKeen/Wendy Skelly
Attorney Docket Number:	S63.2Q-15141-US03

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt

EFS ID:	21572124
Application Number:	12492512
International Application Number:	
Confirmation Number:	7439
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:	S63.2Q-15141-US03
Receipt Date:	23-FEB-2015
Filing Date:	26-JUN-2009
Time Stamp:	15:52:52
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	2596
Deposit Account	
Authorized User	

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

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15141US03_VASTransmittal_20150223.pdf	81300 c44062f4c1973e00d99b75652eb3f91fc86ef94e	no	1
Warnings:					
Information:					
2	Post Allowance Communication - Incoming	15141US03_FeeAddressIndicationForm_20150223.pdf	71197 68d4cc2ae62c2a9089d450badabbc4d3424069b3	no	1
Warnings:					
Information:					
3	Issue Fee Payment (PTO-85B)	15141US03_IssueFee_20150223.pdf	55047 43afa2b480d38316b04d870b8b3a605041ce6f4d	no	1
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30143 a516d2932739f01f8efb905820ed47deac48b353	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	237687		

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.

<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.

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.:	**12/492512**
Filed:	**June 26, 2009**
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.: S63.2Q-15141-US03

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 February 23, 2015.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 23, 2015

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

9531 West 78th Street, Suite 400
Eden Prairie, MN 55344-8006
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

v:\wpwork\mjm\15141us03_vastransmittal_20150223.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	12/492512	Not Assigned	June 26, 2009

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 23, 2015

By: /Michael J. McKeen/
Michael J. McKeen
Registration No.: 66069

9531 West 78th Street, Suite 400
Eden Prairie, MN 55344-8006
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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/492,512	03/31/2015	8992608	S63.2Q-15141-US03	7439

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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 88 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.

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