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# UTILITY PATENT APPLICATION TRANSMITTAL

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

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First Inventor	Amr Salahieh et al.
Title	LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF
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## APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

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- Fee Transmittal Form (e.g., PTO/SB/17)  
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- Applicant claims small entity status. See 37 CFR 1.27.
- Specification [Total Pages 26]  
(preferred arrangement set forth below)
  - Descriptive title of the invention
  - Cross References to Related Applications
  - Statement Regarding Fed sponsored R&D
  - Reference to sequence listing, a table, or a computer program listing appendix
  - Background of the Invention
  - Brief Summary of the Invention
  - Brief Detailed Description of the Drawings (if filed)
  - Detailed Description
  - Claim(s)
  - Abstract of the Disclosure
- Drawing(s) (35 U.S.C. 113) [Total Sheets 27]
- Oath or Declaration [Total Pages     ]
  - Newly executed (original or copy)
  - Copy from a prior application (37 CFR 1.63(d))  
(for continuation/divisional with Box 18 completed)
    - DELETION OF INVENTOR(S)  
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
- Application Data Sheet. See 37 CFR 1.76

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## ACCOMPANYING APPLICATION PARTS

- Assignment Papers (cover sheet & document(s))
- 37 CFR 3.73(b) Statement  Power of Attorney  
(when there is an assignee)
- English Translation Document (if applicable)
- Information Disclosure Statement (IDS)/PTO-1449  Copies of IDS Citations
- Preliminary Amendment
- Return Receipt Postcard (MPEP 503)  
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- Certified Copy of Priority Document(s)  
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- Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i).  
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## 18. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information below in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76.)

Continuation  Divisional  Continuation-in-part (CIP) of prior application No. 10/746,240

Prior application information: Examiner \_\_\_\_\_ Art Unit: 3738

For CONTINUATION OF DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

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PATENT APPLICATION

**LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF**

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## LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF

### CROSS-REFERENCE

**[0001]** This application is a continuation-in-part application of Application Serial No. 10/746,240, filed December 23, 2003, which is incorporated herein by reference in its entirety and to which application we claim priority under 35 USC § 120.

### 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 using an expandable and retrievable anchor.

**[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. However, the current devices suffer from several drawbacks.

[0008] First, many of the devices available today can become mispositioned with respect to the native valve. This is a critical drawback because improper positioning too far up towards the aorta risks blocking the coronary ostia of the patient. Furthermore, a misplaced stent/valve in the other direction (away from the aorta, closer to the ventricle) will impinge on the mitral apparatus and eventually wear through the leaflet as the leaflet continuously rubs against the edge of the stent/valve.

[0009] Moreover, some stent/valve devices simply crush the native valve leaflets against the heart wall and do not engage the leaflets in a manner that would provide positive registration of the device relative to the native position of the valve. This increases an immediate risk of blocking the coronary ostia, as well as a longer-term risk of migration of the device post-implantation.

[0010] Another drawback of the devices known today is that during implantation they may still require the patient to be on life support as the valve does not function for a portion of the procedure. This further complicates the implantation procedure.

[0011] Furtherstill, the stent comprises openings or gaps, thereby increasing a risk of improper seating of the valve within the stent and increasing the risk of paravalvular leaks. The interface between the stent and the native valve may additionally comprise gaps which again would increase the risks of paravalvular leaks.

[0012] 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**

[0013] One aspect of the invention provides an apparatus for endovascularly replacing a patient's heart valve. The apparatus includes: an expandable anchor and a replacement valve, wherein both are adapted for percutaneous delivery and deployment. The expandable anchor further includes a leaflet engagement element on its proximal end to



engage the leaflets of the patient's heart valve. When the leaflets engagement element is engaged, the anchor is substantially distal to the coronary ostia of the patient. Moreover, once engaged, the leaflet engagement element prevents the distal movement of the anchor. In some embodiments, the leaflet engagement element is integral with the anchor or part of the anchor (especially when the anchor is an anchor braid). In other embodiments, the leaflet engagement element is attached to the proximal end of the anchor. In any of the embodiments herein, the anchor may be adapted for active foreshortening during deployment. Active foreshortening can occur by actuating the proximal and/or distal actuation elements of the anchor. The anchor herein may also be configured for locking and may include a locking element. The replacement valve of the apparatus herein is situated within the anchor and is adapted to permit blood flow and prevent blood backflow both during and after deployment.

**[0014]** 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 an anchor comprising a leaflet engagement element on its proximal end and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration; unsheathing the anchor allowing it to take a relaxed configuration intermediate between its sheathed and expanded configurations; expanding the anchor; and, engaging the leaflet engagement element with the native leaflets. The expanding step may further comprise actively foreshortening the anchor. Active foreshortening can include actuating proximal and/or distal actuation elements of the anchor. The method may also include the step of locking the anchor after it is in its deployed configuration. In some embodiments, when the anchor engages the patient's heart, the anchor is substantially distal to the coronary ostia. In any of the embodiments herein, leaflet engagement element prevents the anchor from distally migrating at its proximal end.

#### **INCORPORATION BY REFERENCE**

**[0015]** 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

[0016] 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:

[0017] Figures 1A and 1B are schematic views of an anchor and valve apparatus in accordance with the present invention. Figure 1A illustrates the apparatus in a collapsed delivery configuration within a delivery system. Figure 1B illustrates the apparatus in an expanded configuration partially deployed from the delivery system.

[0018] Figure 2 illustrates an anchor of Figures 1 in the collapsed delivery configuration with locking elements separated.

[0019] Figure 3 illustrates a braided anchor of the present invention with closed end turns Tu.

[0020] Figures 4A-4O are schematic detail views illustrating end turns for a braided anchor.

[0021] Figures 5A-5E illustrate additional features for end turns of a braided anchor.

[0022] Figures 6A-6F illustrate deployment of an anchor with leaflet engagement elements on the deployment system.

[0023] Figure 7 illustrates a deployed anchor with leaflet engagement elements on the proximal end of the anchor.

[0024] Figures 8A-8C illustrate deployment of an anchor with anchor registration elements and a seal.

[0025] Figures 9A-9B illustrate an embodiment of the apparatus with a seal that does not reach the proximal end of the anchor during both systole and diastole.

[0026] Figures 10A-10B illustrate an embodiment of the apparatus with a seal that reaches the proximal end of the anchor during both systole and diastole.

[0027] Figures 11A-11D are schematic side views of various braided anchor configurations.

[0028] Figures 12A-12E are schematic side views of a deployment process for an anchor braid.

**[0029]** Figures 13A-13E are schematic views of different weave configurations for an anchor braid.

**[0030]** Figures 14A-14C illustrate an embodiment of a replacement heart valve and anchor in the undeployed and deployed configurations.

### **DETAILED DESCRIPTION OF THE INVENTION**

**[0031]** The present invention relates to an apparatus and methods for endovascularly delivering and deploying an aortic prosthesis within a patient's native heart valve, referred to here out as "replacing" a patient's heart valve. The delivery system includes a sheath assembly, a multi-lumen shaft, and a guide wire for placing the apparatus endovascularly within a patient and a user control allowing manipulation of the aortic prosthesis. The apparatus includes an anchor and a replacement valve. The anchor and the replacement valve are adapted for percutaneous delivery and deployment within a patient's heart valve. In preferred embodiments, the anchor includes a leaflet engagement element and/or a seal inverting element situated on its proximal end. The leaflet engagement element is adapted for engaging the native leaflets of the patient's heart, or more preferably the proximal edge and/or the commissural attachments of the native leaflets. The leaflet engagement element need not extend all the way into the pocket or the distal end of the native leaflet. Preferred embodiments of the apparatus herein are depicted in Figures 1-14, which are discussed in more detail below.

**[0032]** Figures 1A and 1B illustrate one embodiment of a delivery system and the apparatus of the present invention.

**[0033]** As illustrated by Figure 1A, apparatus 10 may be collapsed for delivery within a delivery system 100. Delivery system 100 includes a guidewire 102, a nosecone 104, anchor actuation elements 106 (in this case fingers) coupled to a multi-lumen shaft 108, an external sheath 110 having a proximal handle 111, and a control handle 120. Delivery system 100 further comprises distal region control elements (not shown), comprised of or actuated by control wires 112, which pass through one or more lumens of shaft 108 and are reversibly coupled to posts 32 of anchor 30 for manipulating a distal region of apparatus 10. Thus, the distal region control elements may function as a distal actuation element.

**[0034]** The delivery system also comprises proximal region control elements comprised of or actuated by control wires 112 that pass through one or more lumens of shaft 108 and anchor actuation elements 106 to reversibly couple the control tubes to a proximal region of anchor 30.

The control wires may comprise, for example, strands of suture, or metal or polymer wires. Control handle 120 is coupled to multi-lumen shaft 108. In some embodiments, these fingers and wires may be referred to as proximal actuation elements. A knob 122 disposed in slot 123 is coupled to the distal region control wires for controlling movement of the distal region of apparatus 10. Likewise, a knob 124 disposed in slot 125 is coupled to proximal region control wires 112 for control of the proximal region of apparatus 10. Handle 120 may also have a knob 126 for, e.g., decoupling the proximal and/or distal region control wires from apparatus 10, or for performing other control functions.

**[0035]** As illustrated by Figure 1B, apparatus 10 comprises an anchor 30 and a replacement valve 20. Anchor 30 preferably comprises a braid. Such braid can have closed ends at either or both of its ends but preferably at least in its proximal end. Replacement valve 20 is preferably coupled to the anchor at posts 32 attached at distal region of the anchor. Post 32 therefore, may function as valve support and may be adapted to support the replacement valve within the anchor. In the embodiment shown, there are three posts, corresponding to the valve's three commissure attachments. The posts can be attached to braid portion of anchor 30. The posts can be attached to the braid's distal end, as shown in Figure 2, central region, or proximal end. Replacement valve 20 can be composed of a metal, a synthetic material and/or may be derived from animal tissue. Replacement valve 20 is preferably configured to be secured within anchor 30.

**[0036]** In preferred embodiments, anchor 30 is collapsible and/or expandable and is formed from material such as Nitinol™, cobalt-chromium steel or stainless steel wire. More preferably, an anchor 30 is self-collapsing and/or self-expanding and is made out of shape memory material, such as Nitinol™. An anchor composed of shape memory material may self-expand to or toward its "at-rest" configuration. This "at rest" configuration of an anchor can be, for example its expanded configuration, its collapsed configuration, or a partially expanded configuration (between the collapsed configuration and the expanded configuration). In preferred embodiments, an anchor's at-rest configuration is between its collapsed configuration and its expanded configuration. Depending on the "at rest" diameter of the anchor and the diameter of the patient's anatomy at the chosen deployment location, the anchor may or may not self-expand to come into contact with the diameter of the patient's anatomy at that location.

**[0037]** Anchor 30 may be expanded to a fully deployed configuration from a partial deployed configuration (e.g., self-expanded configuration) by actively foreshortening anchor 30 during endovascular deployment. Active foreshortening is described in more detail in U.S. Patent Appl. Ser. No. 10/746,280, which is incorporated herein by reference in its entirety. During active foreshortening, the distal region of anchor 30 may be pulled proximally via a proximally directed force applied to posts 32 via a distal deployment system interface comprised of the distal system control elements. The distal deployment system interface is adapted to expand radially during application of a proximally directed force on the distal end of the anchor when opposed by a distally directed force applied to the proximal end of the anchor.

**[0038]** In some embodiments, actuating foreshortening of the apparatus involves applying a proximally directed force on a deployment system interface at the distal end of the anchor, while maintaining the proximal end of the anchor in the same location. In other embodiments, foreshortening of the apparatus involves applying a distally directed force on proximal end of the anchor (e.g., by applying a distally directed force on the anchor actuation elements).

**[0039]** Anchor actuation elements 106 (e.g., fingers, tubes, posts, and control wires connecting to posts) are preferably adapted to expand radially as the anchor expands radially and to contract radially as the anchor contracts radially. Furthermore, proximally or distally directed forces by the anchor actuation elements on one end of the anchor do not diametrically constrain the opposite end of the anchor. In addition, when a proximally or distally directed force is applied on the anchor by the anchor actuation elements, it is preferably applied without passing any portion of a deployment system through a center opening of the replacement valve. This arrangement enables the replacement valve to operate during deployment and before removal of the deployment system.

**[0040]** The distal deployment system interface may include control wires that are controlled, e.g., by control knob 122 of control handle 120. Similarly, the proximal regions of anchor 30 may be pushed distally via a proximal deployment system interface at the proximal end of the anchor. The proximal deployment system interface is adapted to permit deployment system to apply a distally directed force to the proximal end of anchor 30 through, e.g., fingers, which are controlled by, e.g., control knob 124 of control handle 120. The proximal deployment system interface may be further adapted to expand radially during application of a distally

directed force on the proximal end of the anchor. Preferably, the proximal deployment system interface is adapted to permit deployment system to apply a distally directed force on the proximal end of the anchor system through a plurality of deployment system fingers or tubes 160. Such expansion optionally may be assisted via inflation of a balloon catheter (not shown) reversibly disposed within apparatus 10, as described in U.S. Patent Appl. Ser. No. 10/746,280.

**[0041]** Once anchor 30 is fully deployed, posts 32 and buckles 34 of anchor 30 may be used to lock and maintain the anchor in the deployed configuration. In one embodiment, the control wires attached to posts 32 are threaded through buckles 34 so that the proximally directed force exerted on posts 32 by the control wires during deployment pulls the proximal locking end of posts 32 toward and through buckles 34. Such lock optionally may be selectively reversible to allow for repositioning and/or retrieval of apparatus 10 during or post-deployment. Apparatus 10 may be repositioned or retrieved from the patient until the two-part locking mechanism of posts 32 and buckles 34 of anchor 30 have been actuated. When the lock is selectively reversible, the apparatus may be repositioned and/or retrieved as desired, e.g., even after actuation of the two-part locking mechanism. Once again, further details of this and other anchor locking structures may be found in U.S. Patent Appl. Ser. No. 10/746,280. Locking mechanisms used herein may also include a plurality of levels of locking wherein each level of locking results in a different amount of expansion. For example, the proximal end of the post can have multiple configurations for locking within the buckle wherein each configuration results in a different amount of anchor expansion. Figure 2 illustrates a braided anchor of Figures 1 in the collapsed delivery configuration with locking elements separated.

**[0042]** Figure 3 provides a detail view of a front side region of anchor braid 30 with closed end turns Tu. Anchor braid 30 includes various cells, some having an end turn (Tu). End turns can serve various functions. For example, end turns can be configured to reduce the sheathing force, to reduce stress within the braid during delivery and deployment, to prevent distal migration during expansion of the anchor, and/or to positively register the anchor against the native valve during deployment. In preferred embodiments, an end turn feature functions to prevent distal migration and to register the anchor by engaging the native leaflets. In preferred embodiments, the proximal end of an anchor comprises embodiments (Tu).

**[0043]** Figures 4A-4N provide multiple examples of edge cells having end turn feature. The end turn features disclosed and others known in the art may be used as leaflet engagement

elements to engage the native heart leaflets with the anchor. The leaflet engagement elements are preferably integral with the anchor, or more preferably part of a braided anchor. The end turn features can occur at the proximal end, the distal end, or both proximal and distal ends of the anchor.

[0044] For example, Figure 4A illustrates a detail view of a standard end turn Tu in an anchor braid resulting in a braid with substantially uniform cell size and shape.

[0045] Figure 4B illustrates a turn that has been elongated to lengthen the distance over which forces concentrated in the turn may be distributed, resulting in an anchor braid having edge cells that are longer along the anchor axis than the other cells defined by the braid. This elongated turn feature may be formed by routing the wire of braid about outer posts and then heat setting the wire.

[0046] Figure 4C illustrates an alternative anchor edge cell configuration, wherein the tip of the elongated wire turn may be bent out of a cylindrical shape defined by the braid of anchor braid 30. This may be achieved, for example, via a combination of routing of wire W within a fixture and then heat setting. Such a turn Tu in the anchor edge cells in Figure 4C may reduce stress in some configurations without increasing height, and may also provide a lip for engaging the patient's native valve leaflets to facilitate proper positioning of apparatus 10 during deployment.

[0047] In Figure 4D, a W-shaped turn feature has been formed at the wire turn, e.g., by routing the wire of anchor braid 30 about a central inner post and two flanking outer posts. As with the elongated braid cells of Figures 4B and 4C, the W-shape may better distribute stress about turn Tu.

[0048] The anchor edge cell configuration in Figure 4E includes a loop formed in braid 30 at the turn, which may be formed by looping wire W around an inner or outer post.

[0049] Figure 4F provides another alternative anchor edge cell configuration having a figure-eight shape. Such a shape may be formed, for example, by wrapping wire W about an inner post and an aligned outer post in a figure-eight fashion, and then heat setting the wire in the resultant shape.

[0050] In Figure 4G, the edge cells of braid 30 include a heart-shaped configuration, which may be formed by wrapping the wire about an aligned inner and outer post in the desired manner.

[0051] In Figure 4H, the edge cells of braid 30 have an asymmetric loop at turn Tu. The asymmetric loop will affect twisting of braid 30 during expansion and collapse of the braid, in addition to affecting stress concentration.

[0052] In Figure 4I, the anchor edge cells have a double-looped turn configuration, e.g. via wrapping about two adjacent inner or outer posts. Additional loops may also be employed.

[0053] The double loop turn feature may be formed with a smooth transition between the loops, as in Figure 4I, or may be heat set with a more discontinuous shape, as in Figure 4J.

[0054] Figure 4K illustrates that the edge cells of braid 30 may have multiple different configurations about the anchor's circumference. For example, the anchor edge cells shown in Figure 4K have extended length cells as in Figure 4B disposed adjacent to standard size edge cells, as in Figure 4A.

[0055] The anchor edge cells of Figure 4L have an extended turn configuration having an extended loop.

[0056] The anchor edge cells shown in Figure 4M have an alternative extended configuration with a specified heat set profile.

[0057] In Figure 4N, some or all anchor edge cells are interwoven. When interwoven, one or more edge cells may be shorter or longer than an adjacent edge cell. This permits one or more edge cells to extend into one or more leaflet pocket(s). For example, in Figure 4N the middle Tu may be taller than the two adjacent edge cells thus permitting the edge cell to be situated within a leaflet pocket.

[0058] In any of the embodiments herein, edge cells may be wrapped using wire, string, or sutures, at a location where the wire overlaps after an end turn as is illustrated in Figure 4O. This tied-end turn feature prevents cells from interlocking with each other during deployment.

[0059] The anchor and any of its features may be heat set at different configurations. For example, the anchor may be heat set at its "at rest" configuration such that upon unsheathing it expands radially. The end turn features/leaflet engagement elements may be heat set at a different "at rest" configuration than the rest of the anchor. In preferred embodiment, end turn features are heat set to "flower" and then "evert" upon unsheathing.

[0060] The end turn features of Figures 4 are provided only for the sake of illustration and should in no way be construed as limiting. Additional turn features within the scope of the present invention will be apparent to those of skill in the art in view of Figures 4. Furthermore,



combinations of any such end turn features may be provided to achieve the desired characteristics of anchor 30.

**[0061]** Referring now to Figures 5A-E, additional configurations for reducing stress concentration and/or circumferential stiffness of an anchor braid and/or leaflet engagement elements are illustrated. Such configurations can be used independently or in conjunction with other configurations disclosed herein. Such configurations are preferably used at the anchor's edges to locally reduce the cross-sectional area of substantially all cells or all cells in the anchor braid's edge (e.g., proximal and/or distal). As seen in Figures 5A and 5B, turns Tu in wire W typically may have a substantially continuous (e.g., round) cross-sectional profile. As seen in Figure 5C, modifying the edge cell configuration by locally reducing the thickness or cross-sectional area of wire W at turn(s) Tu will reduce stress concentration within the wire at the turns and facilitate collapse and/or expansion of anchor braid 30 from the delivery to the deployed configurations. Furthermore, it is expected that such localized reduction in thickness or cross-sectional area will reduce a risk of kinking, fatigue or other failure at turns Tu.

**[0062]** In any of the embodiments herein, localized reduction of an anchor wire may be achieved via a localized etching and/or electropolishing process. Alternatively or additionally, localized grinding of the turns may be utilized. Additional processing techniques will be apparent to those of skill in the art. As seen in Figures 5D-5E, wire W may, for example, comprise an oval or rectangular cross-sectional profile, respectively, after localized reduction. The wire alternatively may comprise a round profile of reduced cross-sectional area (not shown). Additional profiles will be apparent. Localized reduction can take place at any time (e.g., before or after a braid is woven). Preferably, localized reduction occurs after weaving. However, in some embodiments, a wire of a given length may be etched or ground at preset segments and subsequently woven.

**[0063]** With reference now to Figures 6A-F, a method of endovascularly replacing a patient's diseased aortic valve is provided. The method involves endovascularly delivering an anchor/valve apparatus and properly positioning such apparatus via positive registration with the patient's native valve leaflets. Registration with the native valve leaflet preferably occurs using the leaflet engagement elements.

**[0064]** In Figure 6A, modified delivery system 100' delivers apparatus 10 to diseased aortic valve AV within sheath 110. Apparatus 10 is delivered in a collapsed delivery configuration.

**[0065]** As seen in Figures 6B and 6C, apparatus 10 is deployed from lumen 112 of sheath 110, for example, under fluoroscopic guidance. Sheath 110 includes at its distal end leaflet engagement elements 120. Upon deployment, anchor 30 of apparatus 10 dynamically self-expands to a partially deployed configuration. This causes tubes 60 to also dynamically expand, as well as membrane filter (or braid) 61A and leaflet engagement elements 120. As when deployed via delivery system 100, deployment of apparatus 10 via delivery system 100' is fully reversible until locks 40 have been actuated.

**[0066]** Thus, delivery system 100' comprises leaflet engagement element 120, which preferably self-expands along with anchor 30. In preferred embodiments, the distal end of leaflet engagement elements 120 expands a greater radial distance than anchor 30. Moreover, engagement elements 120 may be disposed between tubes 60 of delivery system 100' and lip region 32 of anchor 30. However, leaflet engagement elements 120 may also be disposed on the proximal end of an anchor (as is illustrated in Figure 7). Leaflet engagement elements 120 releasably engage the anchor. As seen in Figure 6C, the leaflet engagement elements 120 are initially deployed proximal of the patient's native valve leaflets L. Apparatus 10 and element 120 then may be advanced/dynamically repositioned until engagement element positively registers against the leaflets, thereby ensuring proper positioning of apparatus 10. The leaflet engagement element engages with the proximal edges of the native valve leaflets and/or the commissural attachments. The leaflet engagement element need not extend all the way to the distal edge of the native leaflets (the leaflet pockets). In preferred embodiments, a leaflet engagement element length is less than about 20 mm, more preferably less than about 15 mm, or more preferably less than about 10 mm. Once leaflet engagement element 120 is registered against the native valve leaflets and/or commissural attachments, apparatus 10 deploys substantially distal to the coronary ostia of the heart.

**[0067]** In any of the embodiments herein, delivery system 100' can include 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 6C 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.

[0068] Active foreshortening may be imposed upon anchor 30 while element 120 is disposed proximal of the leaflets, as is illustrated in Figure 6D. Active foreshortening can be accomplished by actuating distal anchor actuation elements (e.g., wires 50) and/or proximal anchor actuation elements (e.g., tubes 60). Upon positive registration of element 120 against leaflets L, element 120 precludes further distal migration of apparatus 10 during additional foreshortening, thereby reducing a risk of improperly positioning the apparatus. Figure 6E details engagement of element 120 against the native leaflets.

[0069] As seen in Figure 6F, once apparatus 10 is fully deployed, anchor 30 may be locked (reversibly or irreversibly). Subsequently, structure 61A leaflet engagement, elements 120, wires 50 and/or tubes 60 may be decoupled from the apparatus, and delivery system 100' may be removed from the patient, thereby completing the procedure.

[0070] Figure 7 illustrates an alternative embodiment of the apparatus of Figures 6A-F described above, wherein leaflet engagement elements 120 are coupled to anchor 30 of apparatus 10' rather than to delivery system 100. In the embodiment illustrated in Figure 7, leaflet engagement elements 120 remain implanted near the patient's native heart valve after the deployment of apparatus 10' and removal of delivery system 100. Leaflets L may be sandwiched between the proximal region of anchor 30 and leaflet engagement element 120 in the fully deployed configuration. In this manner, element 120 positively registers apparatus 10' relative to the leaflets L and precludes distal migration of the apparatus over time.

[0071] Figures 8A-8C illustrate another embodiment for endovascularly delivering an apparatus of the present invention. In Figure 8A, a catheter 600 is delivered percutaneously in a retrograde fashion to the aortic valve. The catheter passes through the native aortic valve before an operator actuates the unseathing of the anchor/valve apparatus. As the sheathing catheter is pulled proximally out of the native valve, anchor 30 and replacement valve 20 become unsheathed. Immediately the portion of the unsheathed anchor 30 dynamically self-expands to its "at rest" position, and replacement valve 20 within the anchor regains an uncollapsed structure, allowing it to begin to function. In preferred embodiments in its "at rest" position, anchor 30 presses against the native leaflets limiting blood from flowing in between the anchor and leaflet. Also, in preferred embodiments, anchor 30 portions relatively adjacent to the valve

is externally covered by a seal 60, more preferably the entire exterior contour of anchor 30 excluding the leaflet engagement elements is externally covered by a seal, or more preferably the entire contour of anchor 30 including the external face of the leaflet engagement elements is externally covered by a seal. A seal can be composed of any material that prevents or limits the flow of blood through the anchor. In preferred embodiments, a seal is composed of a thin, elastic polymer or any other type of fabric. The seal can be attached by any means known in the art to the anchor and, in some embodiments, to the distal end of the valve. In preferred embodiments, a seal is attached to the anchor by suturing.

[0072] In Figure 8B, as the catheter is further pulled proximally, the proximal end of anchor 30 and fingers 50 are unsheathed. In this embodiment, it is possible to visualize that the seal covers the entire contour of the anchor including the external face of the leaflet engagement element 70. As soon as the proximal end of the anchor is exposed, it also dynamically expands. Furthermore, when fingers 50 become exposed, replacement valve 20 begins to function permitting blood to flow through replacement valve 20, between fingers 50, and around the catheter 600. This also permits blood to flow into the coronary ostias. In other embodiments where the seal does not cover the proximal end of the anchor, the replacement valve can begin to function as soon as the unsealed portion of the anchor is unsheathed. This causes the leaflet engagement elements 70 to radially expand to their heat set position and engage with the native heart leaflets.

[0073] Next, Figure 8C, as the apparatus is actively foreshortened using proximal (e.g., fingers) and/or distal actuators (e.g., wires 55), the leaflet engagement elements positively register with the native valve leaflets. Foreshortening can cause seal 60 to bunch up and create pleats. These pleats can then fill pockets thereby improving the paravalvular seal. In preferred embodiments, wherein the leaflet engagement elements are covered with a seal, at least a portion of the seal is also positioned between the native valve leaflets and the aortic wall. Once the anchor is fully compressed within the aortic valve, the anchor is locked, the fingers and post mandrels are disengaged, and the seal is adapted to further limit blood flow around the replacement valve. The catheter is subsequently withdrawn, leaving behind valve 20, seal 60 and anchor 70. When fully deployed, the anchor is substantially distal to the coronary ostia of the patient such that it will not interfere with blood flow through the ostia.

**[0074]** Figures 9A-9B illustrate an embodiment wherein only a distal portion anchor 30 is covered by seal 60 and wherein anchor 30 is only partially deployed since the blood can escape through the proximal end of the anchor braid. As anchor 30 in this embodiment is unsheathed, it presses against the native valve leaflets. At this point replacement valve 20 is functional even though anchor 30 is not fully deployed since blood can escape through the proximal end of the anchor braid. This allows blood to flow through replacement valve 20 and out of holes in the distal end of anchor 30 during systole (Figure 9A) while preventing backflow during diastole (Figure 9B).

**[0075]** Figures 10A-10B illustrate a similar embodiment wherein seal 60 around anchor 30 surrounds the entire contour of anchor 30. In this embodiment, valve 20 does not become functional until both anchor 30 and a portion of fingers 50 are unsheathed. As soon as a portion of fingers 50 is unsheathed, replacement valve 20 is fully functional. This allows blood to flow through replacement valve 20 and anchor 30, out of fingers 50, and around catheter 60 into the aorta and coronary ostias during systole. Similarly, during diastole, replacement valve 20 closes preventing blood backflow from entering the chamber.

**[0076]** In any of the embodiments herein the anchor is preferably a self-expanding anchor braid. Anchor braid of the present invention can be made from one or more wires, more preferably 2-20 wires, more preferably 3-15 wires, or more preferably 4-10 wires. Moreover, the density of the braid can be modified by various forms of weave used.

**[0077]** Figures 11A-11D illustrate various anchor braid embodiments contemplated by the present invention.

**[0078]** Figure 11A illustrates two groups of cells or two braids interwoven in the center. The top group of cells forms a more open weave than the bottom group of cells, which forms a denser weave.

**[0079]** Figure 11B illustrates another embodiment of an anchor braid having three groups of cells. The top and bottom (proximal and distal) edges of the anchor braid have denser cells than the central portion of the anchor. Also, the edges of the anchor are woven from a thinner filament than the central portion.

**[0080]** In another embodiment illustrated by Figure 11C, all three sections of an anchor valve are woven by more than one wire. The wires of each section are made of a different material and/or thickness. Wires at the sectional boundaries may or may not interconnect with

wires from a different section. Each of the sections of the braid anchor may be composed of a different number of wires.

**[0081]** Figure 11D illustrates another embodiment of a braided anchor having three sections. In this embodiment, all sections are composed of a single wire. The proximal and distal sections/edges of the braided anchor have the same pitch. The central region of the braided anchor has a different pitch than the edge sections.

**[0082]** Figures 12A-12E illustrate side views of braided anchor having more than one braid pitch. Varying pitch within the anchor allows localized variations in foreshortening across the anchor, as greater foreshortening is achieved by higher pitch of the braid. Moreover, the localized foreshortening features allow for the design of a braid which incorporates various diameters depending upon the amount of foreshortening. (The greater the foreshortening, the greater the diameter increase upon deployment.)

**[0083]** Figures 12A, is a side view representation of the braided anchor of Figure 11D. On the left side of the figure, the expanded anchor is illustrated having a denser weave (shorter pitch) at the distal and proximal ends; hence the dots are located closer to each other. The middle section of the anchor is composed of a looser weave that is generated by a higher pitch braid and is represented by dots that are farther away from each other. On the right side of the figure, the braided anchor is foreshortened and the dots are collapsed closer to each other. In this case, the central portion of the anchor foreshortened more than the proximal and distal edges.

**[0084]** Figure 12B illustrates a side view of a foreshortened braided anchor that is created by low pitch at the edges and high pitch in the middle.

**[0085]** Figure 12C illustrates a side view of a foreshortened braided anchor that is created by high pitch edges and low pitch middle section.

**[0086]** Figure 12D illustrates a side view of a foreshortened braided anchor that includes a sealing feature or space filling feature at both ends. This type of anchor can be created by a high pitch braid at edges, low pitch braid in the middle and heat setting the edges to curl upon unsheathing. These end features can be useful in facilitating anchoring by functioning as a locator and/or sealing. In preferred embodiment the curled ends of the anchor in Figure 12D can be used as leaflet engagement elements.

**[0087]** Figure 12E illustrates a side view of a foreshortened braided anchor that is associated with an everting valve or locational features. In preferred embodiments, the middle

section of the anchor may be composed of thicker wire(s) than edge section(s). The everting feature at the proximal end can function as a leaflet engagement element as disclosed herein.

[0088] Figures 13A-13E illustrate an example of the process of deploying an anchor, such as the one illustrated in Figure 12B above.

[0089] Figure 13A illustrates a braided anchor 30 in its expanded or elongated configuration. The anchor is composed of three sections. The distal and proximal sections of the anchor are made of a fine weave, low pitch braid and the middle section of the anchor is made of a thicker thread and higher pitch braid. The distal and proximal section are preferably heat set to roll upon unsheathing, though some rolling may occur simply from active for shortening of the fine weave braid. In preferred embodiments, the filaments of the fine weave braid are less than 0.01 cm, or more preferably less than 0.005 cm in thickness. On the other hand, thicker filaments of the middle section are preferably 0.01 cm or greater in thickness or more preferably 0.015 cm or greater in thickness. Posts 32 are coupled to the middle section of the anchor. For deployment, tubes (or fingers) 106 are coupled to the anchor's middle section.

[0090] Figure 13B illustrates an anchor during the process of deployment after the anchor is unsheathed. The anchor is pushed distally by tubes and pulled proximally by wires and begins foreshortening. In some embodiment the distal section rolls up and can act as a locator, assisting the operator in locating the aortic valve, or as a seal preventing leakage. In some embodiments, the proximal section may roll down and be used as a leaflet engagement element to prevent distal migration or as a proximal seal.

[0091] In Figure 13C, the device may be configured such that the middle section of the valve may form an hour glass shape or a round shape. The tubes may subsequently be removed as described before.

[0092] Figure 13D is another illustration of the braided anchor in its elongated configuration.

[0093] Figure 13E is another illustration of the braided anchor in its foreshortened configuration.

[0094] Figures 14A-14C illustrate the process of forming a pleated seal around a replacement valve to prevent leakage. Figure 14A illustrates a fabric seal 380 prior to deployment and foreshortening of the anchor/valve apparatus. In Figure 14A, the fabric seal 380 extends from the distal end of valve 20 proximally over anchor 30 during delivery. During

deployment, as illustrated in Figure 14B, anchor 30 foreshortens and the fabric seal 380 bunches up to create fabric flaps and pockets that extend into spaces formed by the native valve leaflets 382. The bunched up fabric or pleats occur, in particular, when the pockets are filled with blood in response to backflow blood pressure. The pleating can create a seal around the replacement valve. Figure 14C illustrates anchor 30, surrounded by fabric seal 380 in between native valve leaflets 382. In preferred embodiments, at least a portion of a seal is captured between the leaflets and the wall of the heart when the anchor is fully deployed.



WHAT IS CLAIMED IS:

1. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage leaflets of the patient's heart valve.
2. The apparatus of claim 1 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.
3. The apparatus of claim 1 wherein the anchor is further adapted to be actively foreshortened during deployment.
4. The apparatus of claim 3 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.
5. The apparatus of claim 3 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.
6. The apparatus of claim 3 further comprising a lock adapted to lock the anchor in a deployed shape.
7. The apparatus of claim 1 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.
8. The apparatus of claim 1 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.
9. The apparatus of claim 1 wherein the leaflet engagement elements are integral with the anchor.
10. The apparatus of claim 9 wherein the anchor comprises a braid, the leaflet engagement elements being part of the braid.
11. The apparatus of claim 1 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow to the chamber of the heart through the replacement valve during deployment of the anchor and replacement valve.

12. The apparatus of claim 1 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

13. The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter but before the anchor completely exits the catheter.

14. The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor.

15. The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

16. The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

17. The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

18. The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

19. The apparatus of claim 1 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

20. The apparatus of claim 19 wherein the seal comprises a pleated seal.

21. The apparatus of claim 19 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

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

endovascularly delivering an anchor and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage native valve leaflets;

expanding the anchor; and

engaging the leaflet engagement elements with native valve leaflets.

23. The method of claim 22 further comprising expanding the anchor into engagement with the patient's heart such that the anchor is substantially distal to coronary ostia of the heart.

24. The method of claim 23 wherein the expanding step comprises actively foreshortening the anchor.

25. The method of claim 24 wherein the actively foreshortening step comprises actuating distal anchor actuation elements.

26. The method of claim 24 wherein the actively foreshortening step comprises actuating proximal anchor actuation elements.

27. The method of claim 24 further comprising locking the anchor in a deployed configuration.

28. The method of claim 22 further comprising resisting distal movement of the proximal end of the anchor after the engaging step.

29. The method of claim 22 further comprising moving the leaflet engagement elements further apart radially during the anchor expanding step.

30. The method of claim 22 further comprising permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve during deployment of the anchor and replacement valve.

31. The method of claim 22 further comprising:  
delivering the anchor and replacement valve to a vicinity of the heart in a delivery catheter;

removing the anchor and the replacement valve from the catheter; and

permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

32. The method of claim 31 wherein the permitting and preventing steps are performed before the anchor completely exits the catheter.

33. The method of claim 31 wherein the permitting step comprises allowing the anchor to self-expand.

34. The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

35. The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

36. The method of claim 22 further comprising sealing between the replacement valve and the heart.

37. The method of claim 36 wherein the sealing step comprises pleating a seal.

38. The method of claim 36 wherein the sealing step comprises capturing at least a portion of a seal between the leaflets and a wall of the heart.

39. Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising a braid, the braid comprising leaflet engagement elements adapted to engage leaflets of the patient's heart valve.

40. The apparatus of claim 39 wherein the leaflet engagement elements extend from a proximal end of the anchor.

41. The apparatus of claim 39 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.

42. The apparatus of claim 39 wherein the anchor is further adapted to be actively foreshortened during deployment.

43. The apparatus of claim 42 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

44. The apparatus of claim 42 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

45. The apparatus of claim 42 further comprising a lock adapted to lock the anchor in a deployed shape.

46. The apparatus of claim 40 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

47. The apparatus of claim 40 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

48. The apparatus of claim 40 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow through the replacement valve during deployment of the anchor and replacement valve.

49. The apparatus of claim 40 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

50. The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before the anchor completely exits the catheter.

51. The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor.

52. The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

53. The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

54. The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

55. The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

56. The apparatus of claim 40 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

57. The apparatus of claim 56 wherein the seal comprises a pleated seal.

58. The apparatus of claim 56 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

## **LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF**

### **ABSTRACT**

The present invention relates to apparatus for methods for endovascularly replacing a patient's heart valve. The apparatus includes an expandable anchor with leaflet engagement elements on the proximal end of the anchor and a replacement valve. The leaflet engagement elements can be used to prevent distal migration and insure proper positioning of the apparatus.

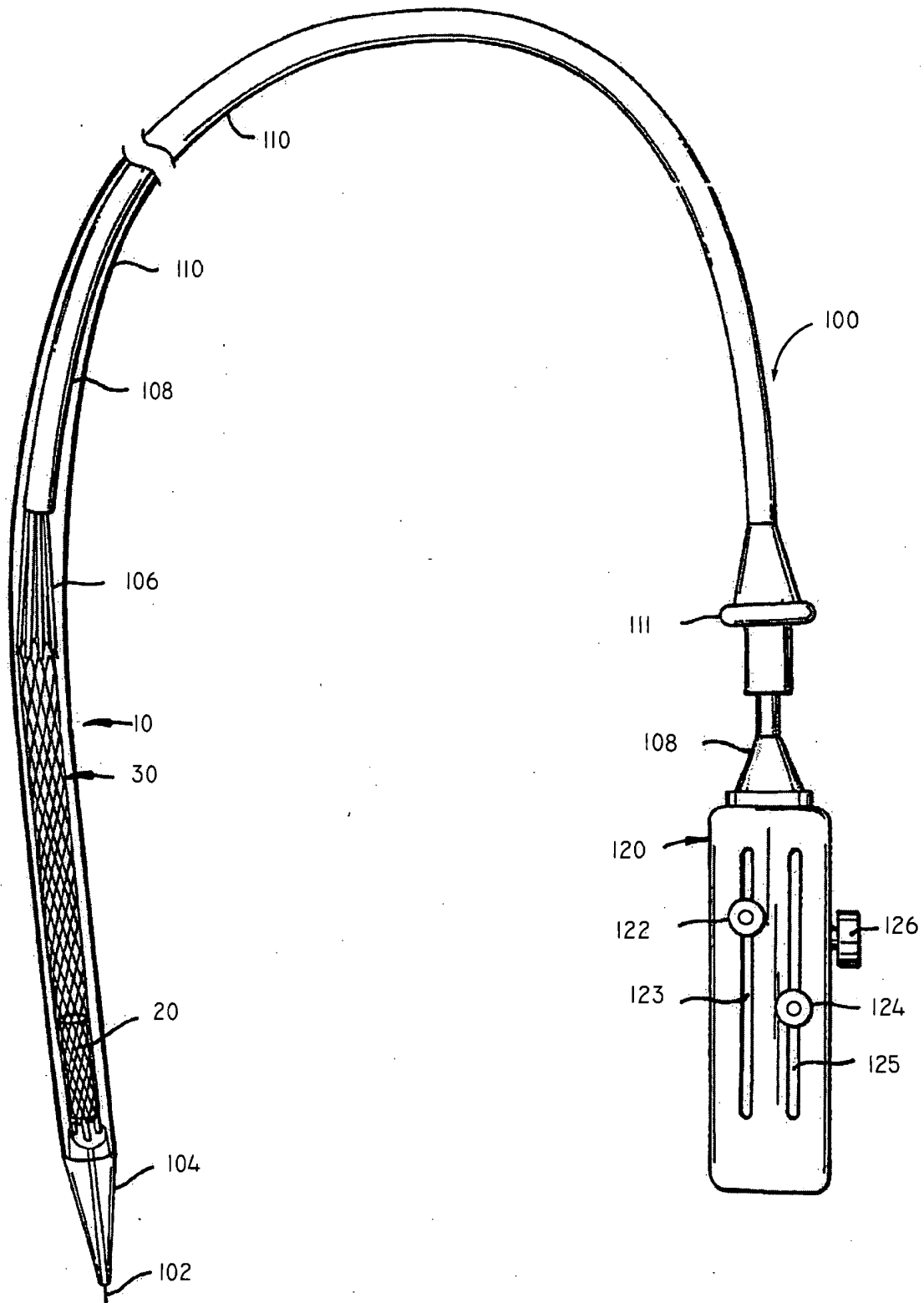


FIG 1A



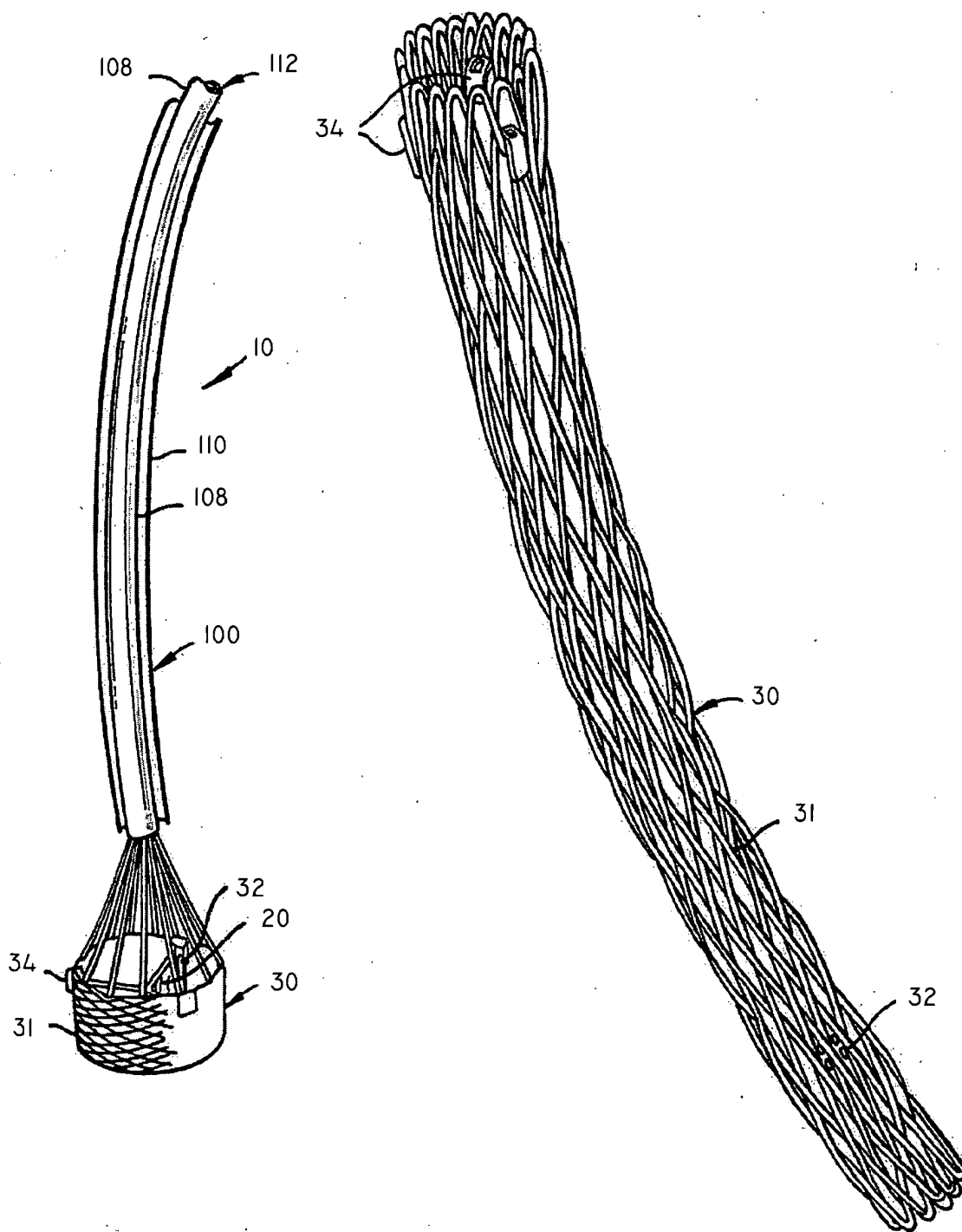


FIG 1B

FIG 2

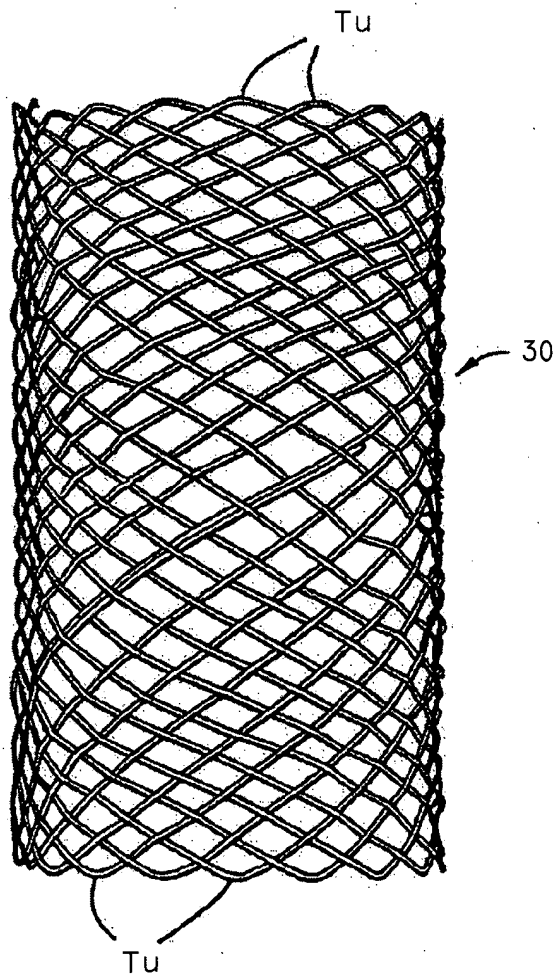
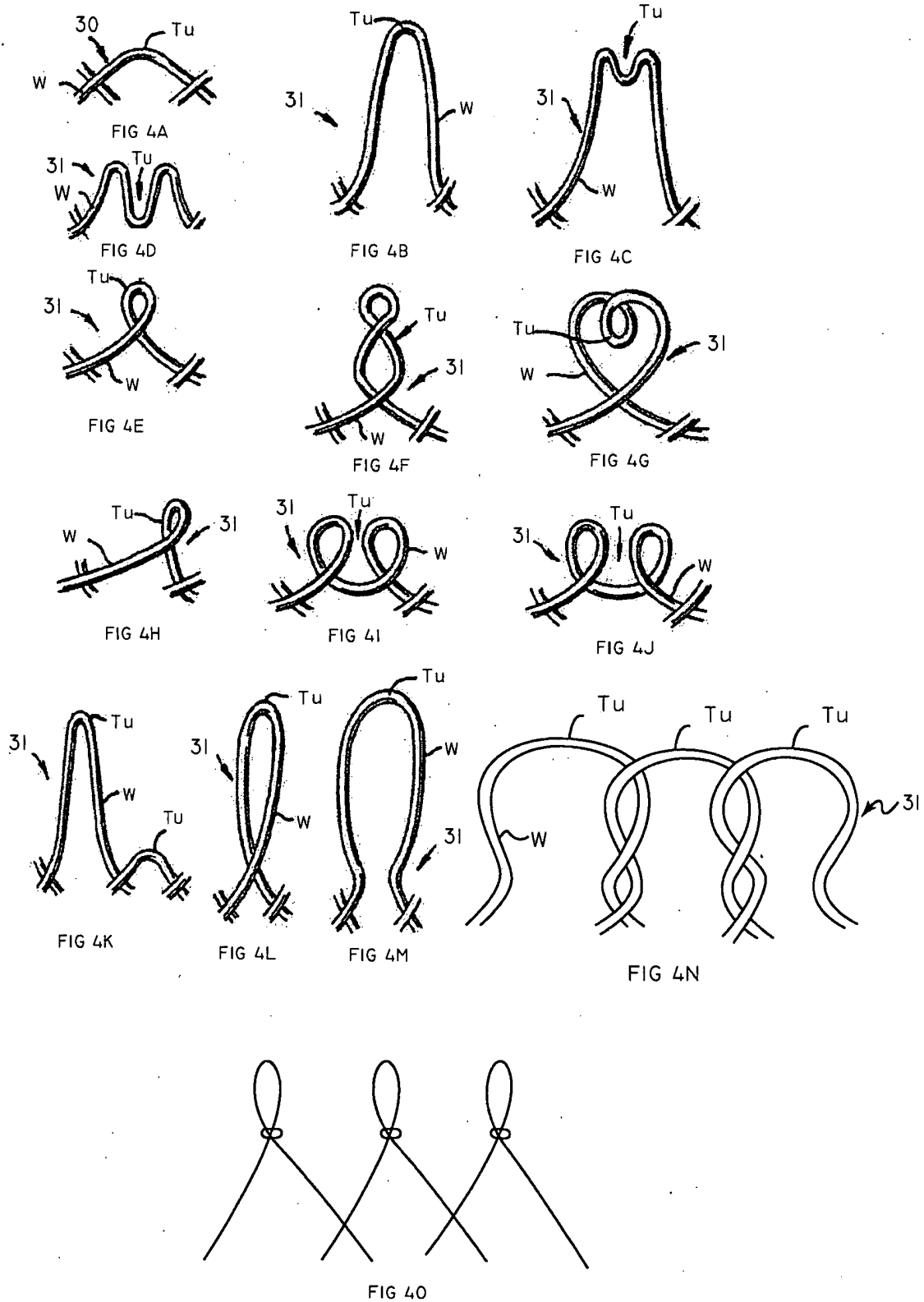
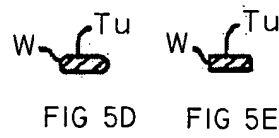
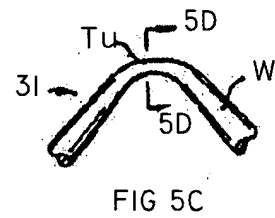
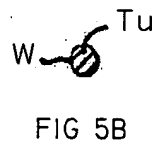
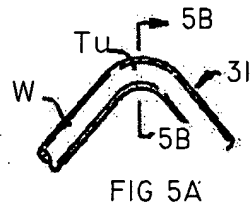


FIG 3





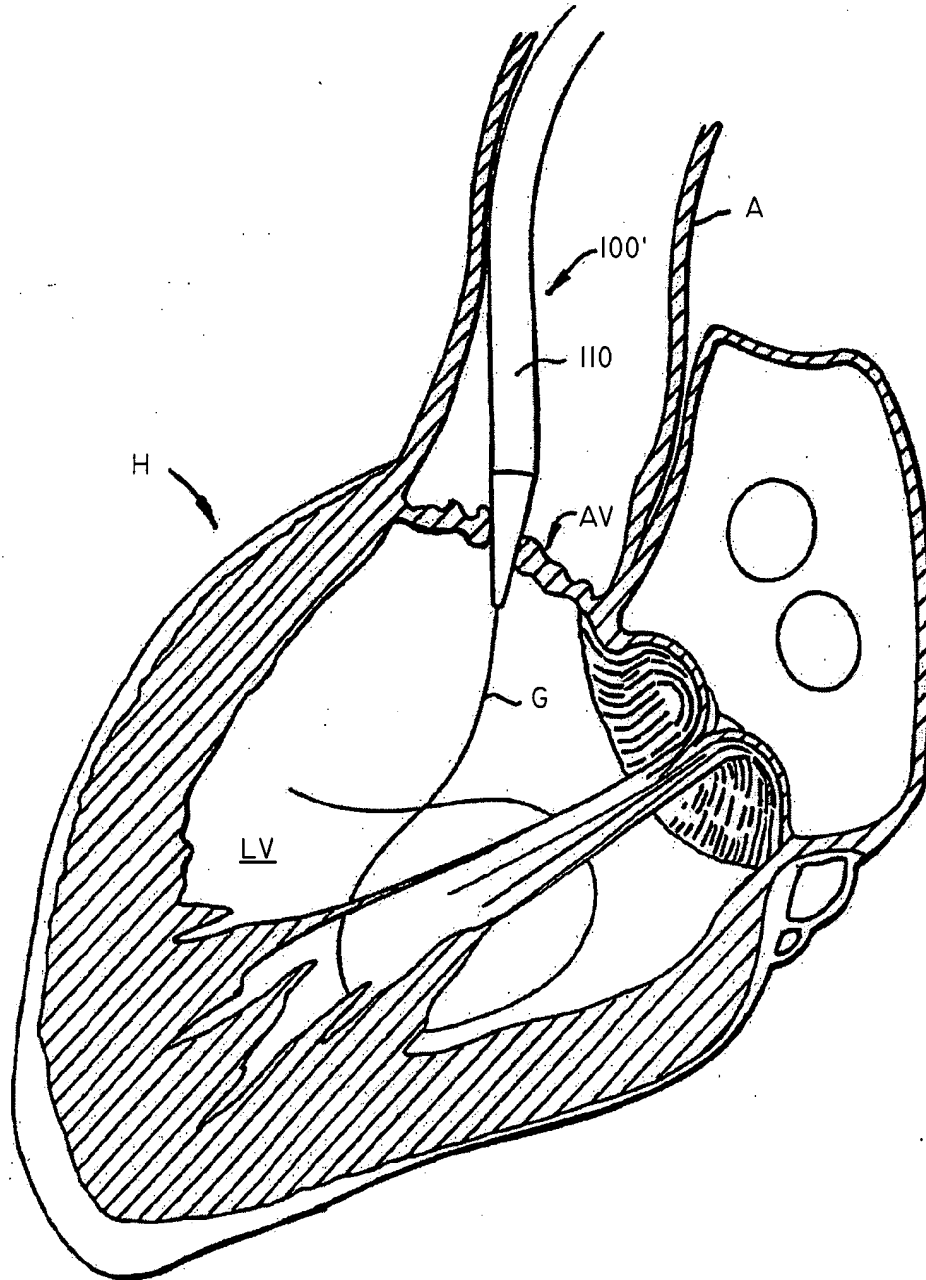


FIG 6A

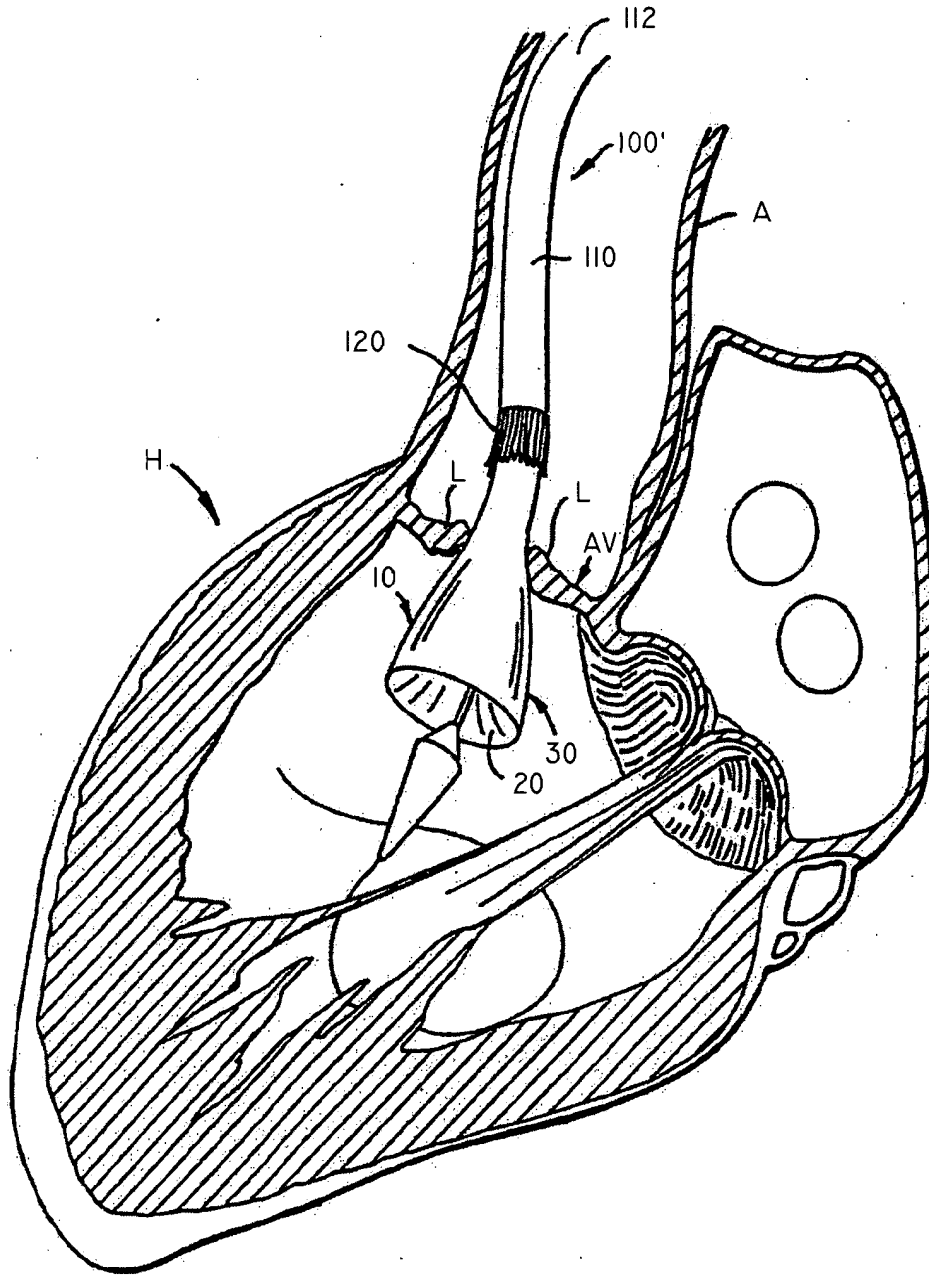


FIG 6B

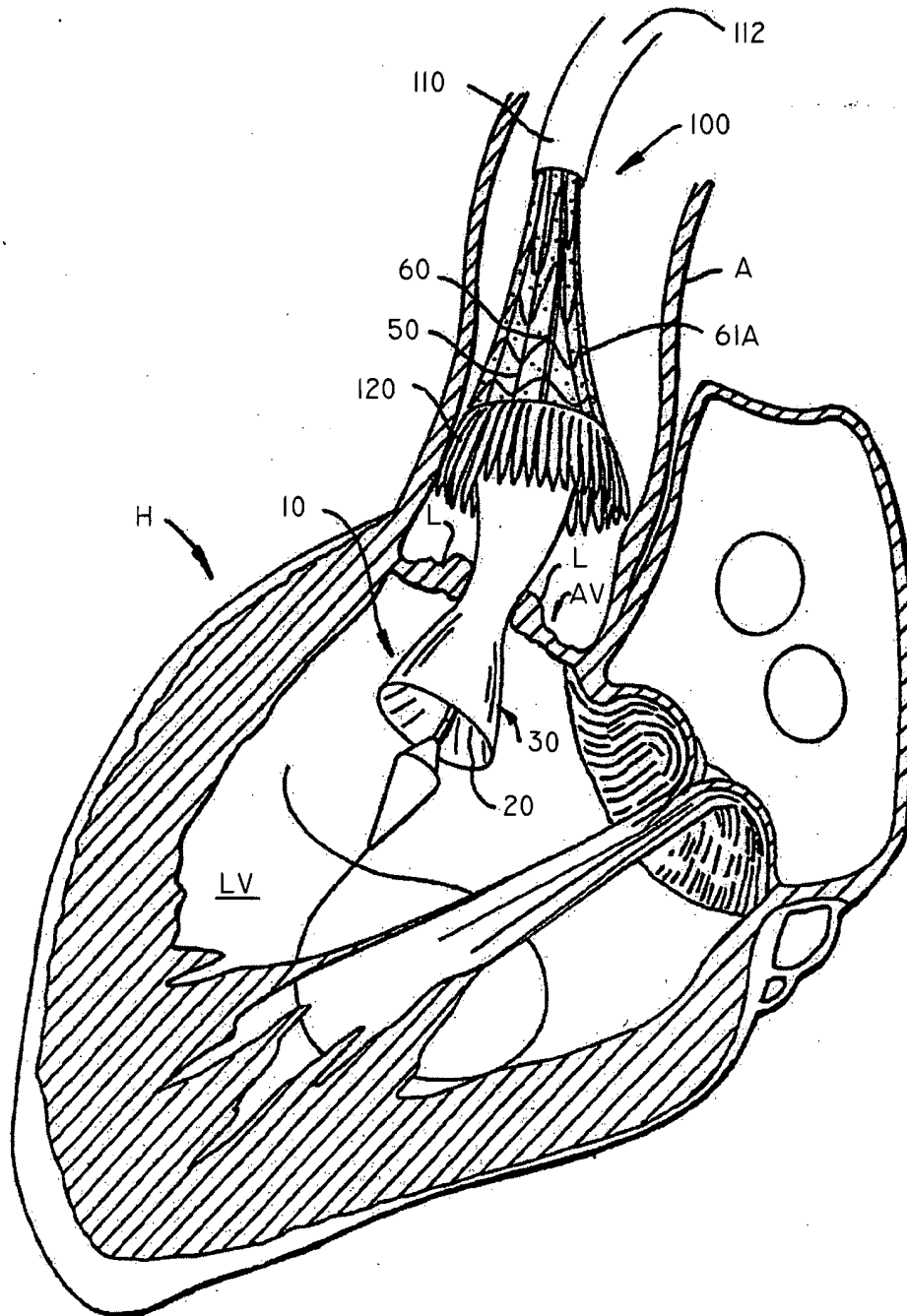


FIG 6C

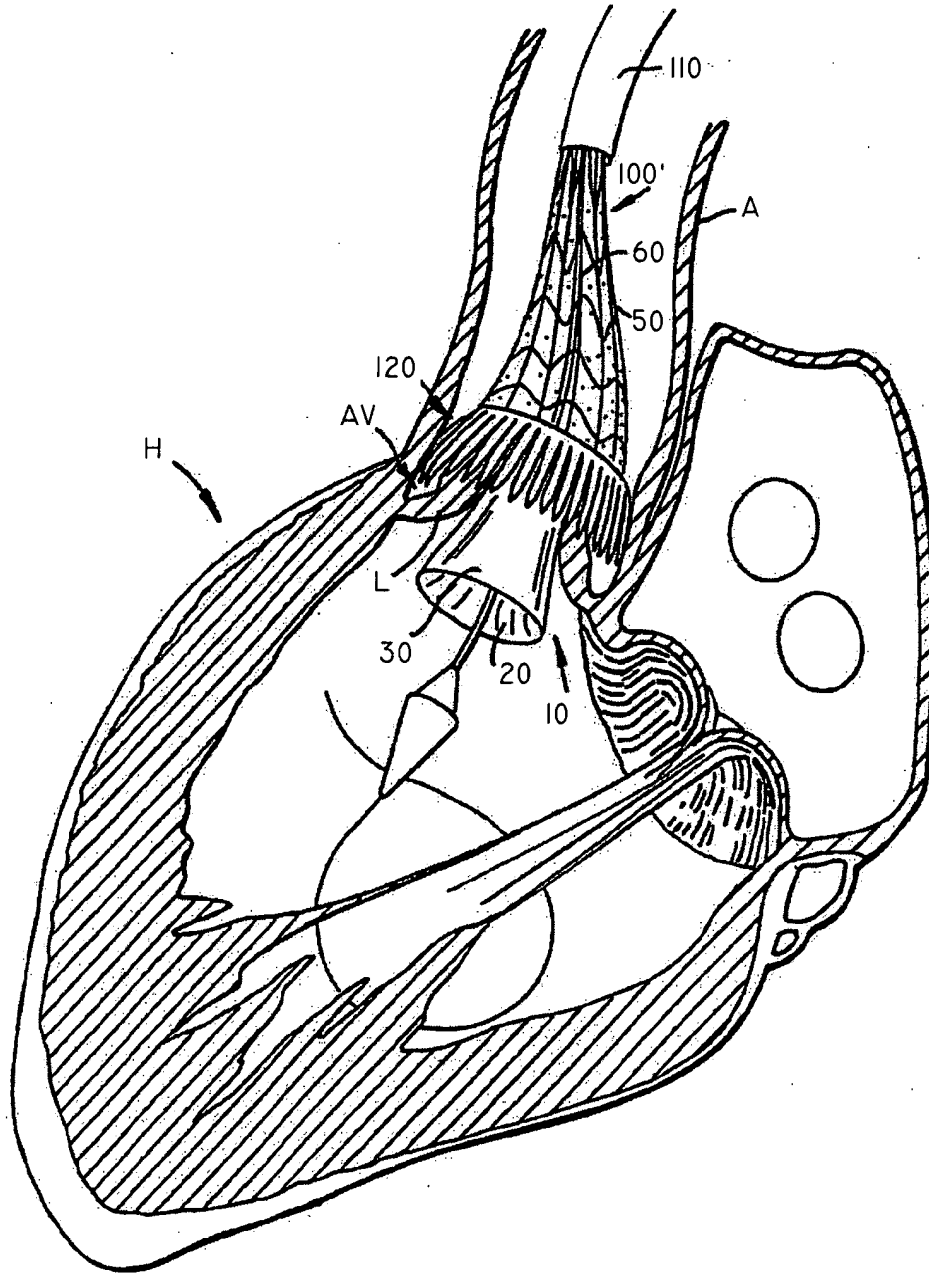
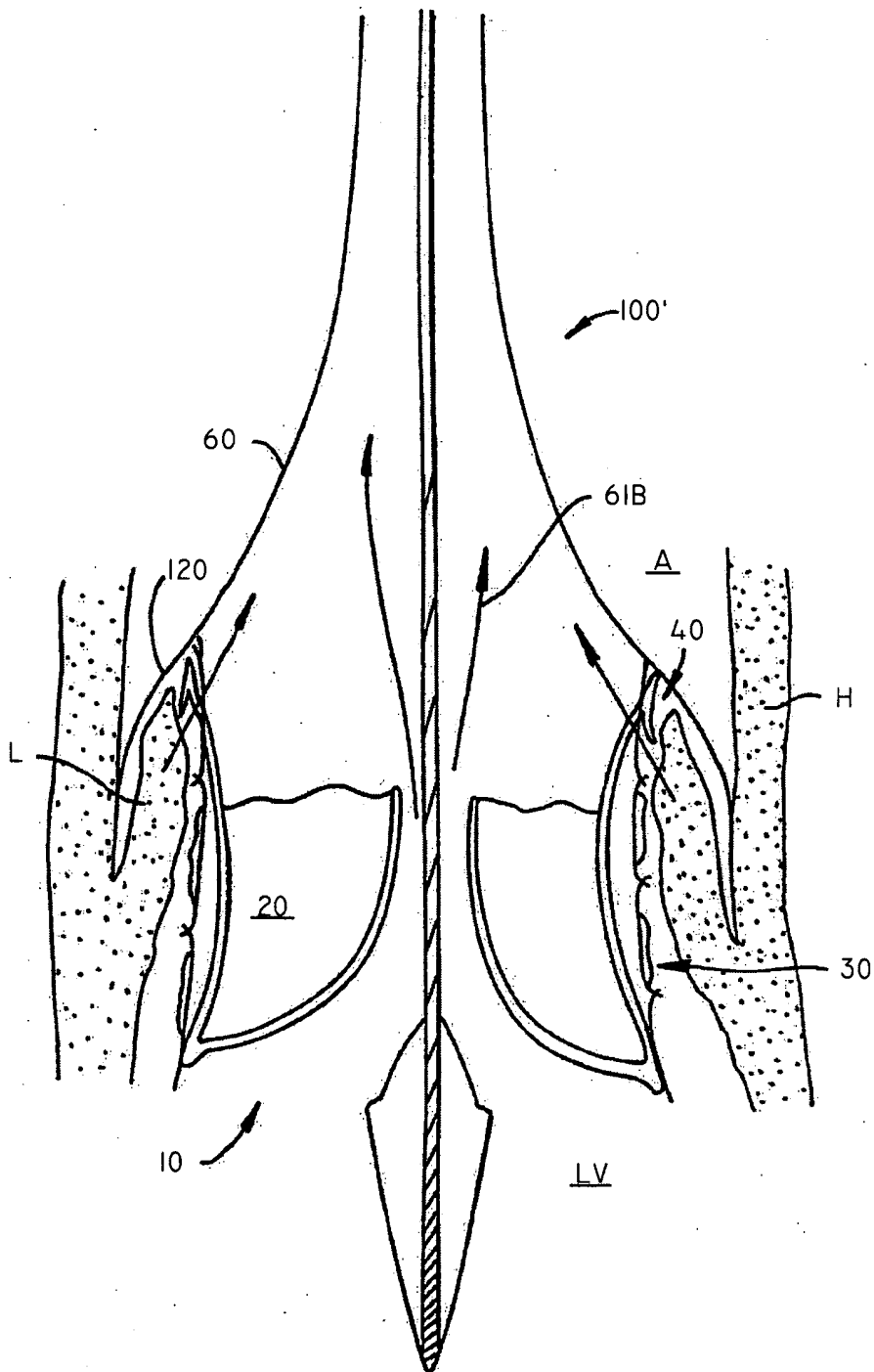


FIG 6D





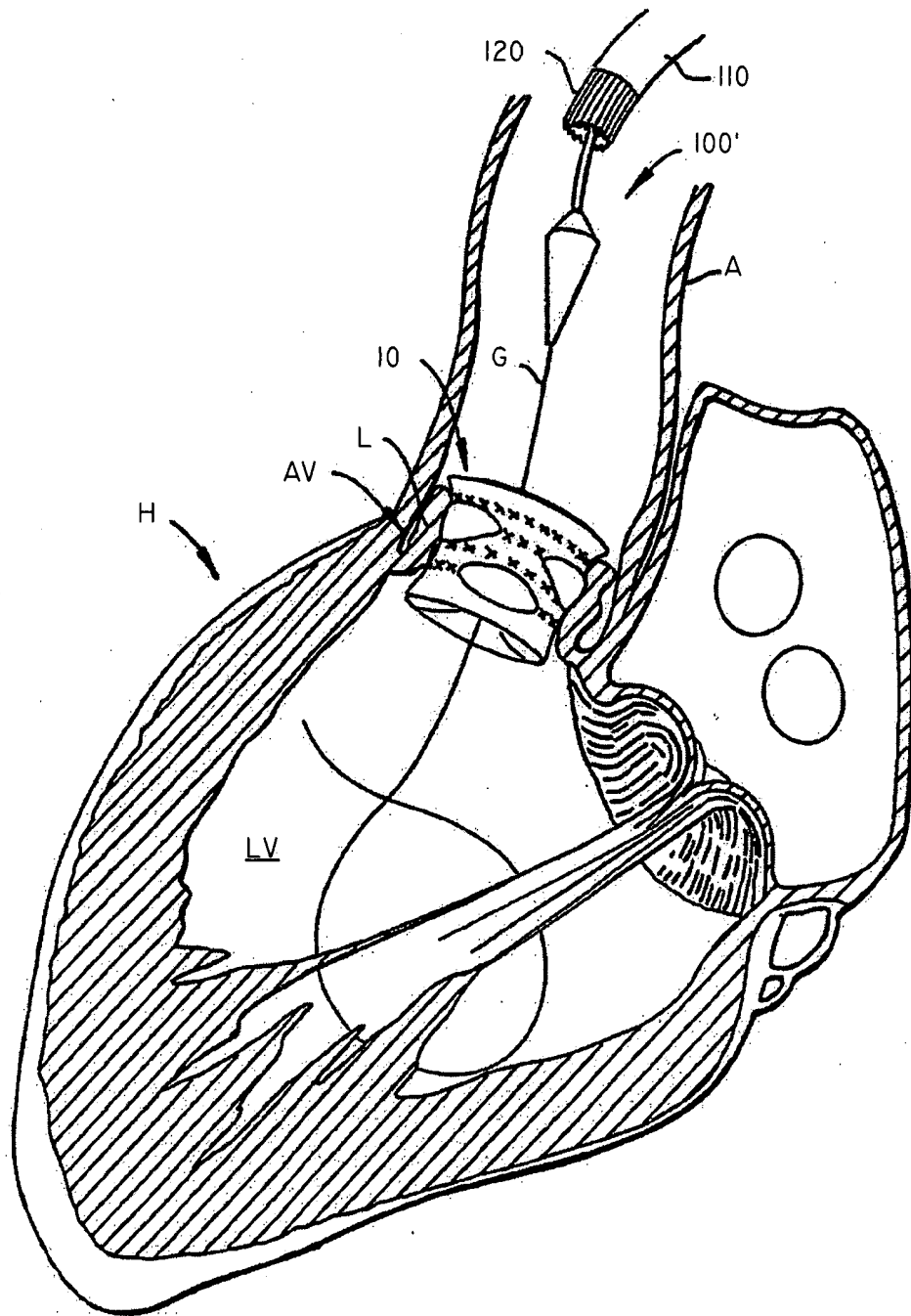


FIG 6F

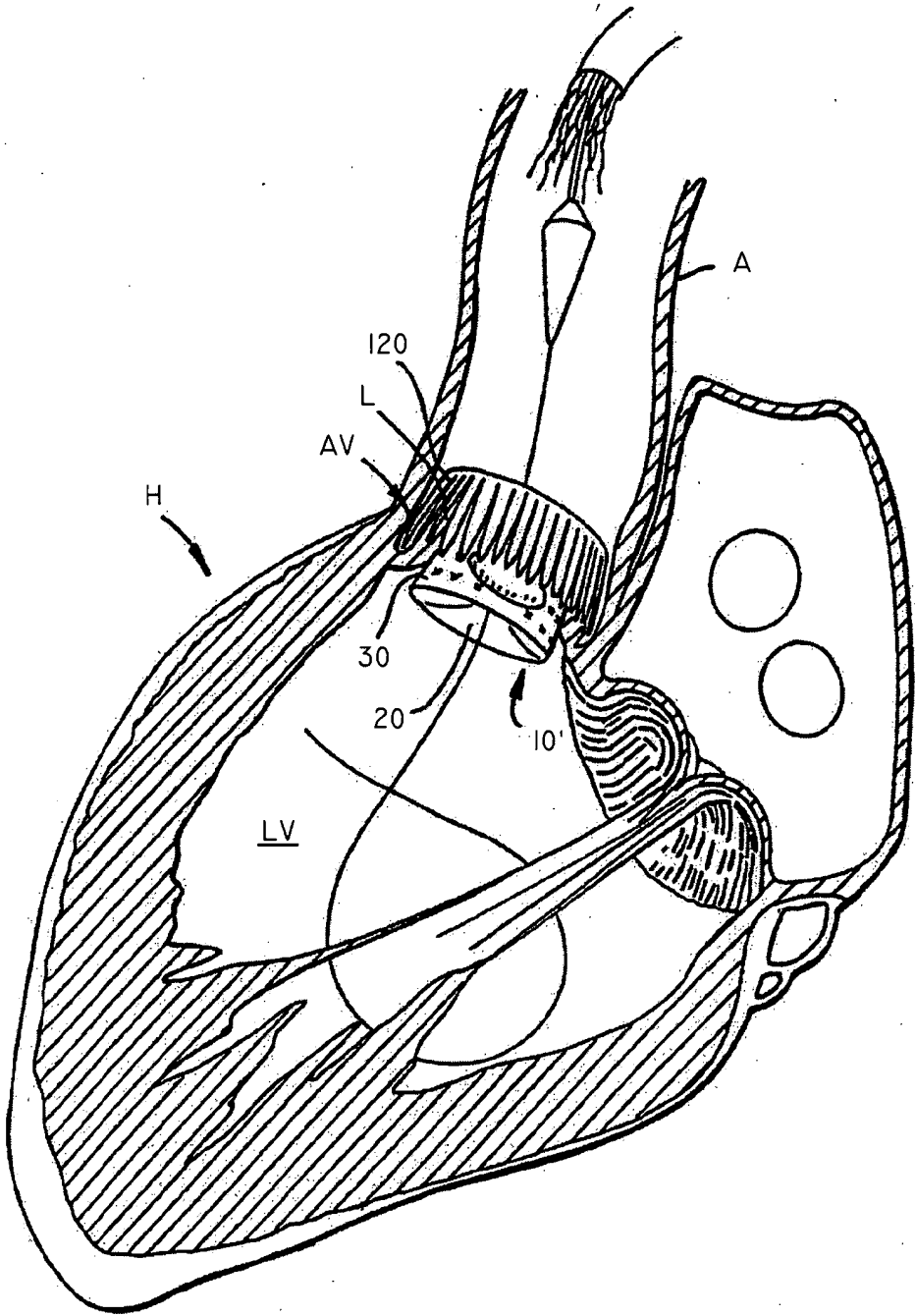


FIG 7

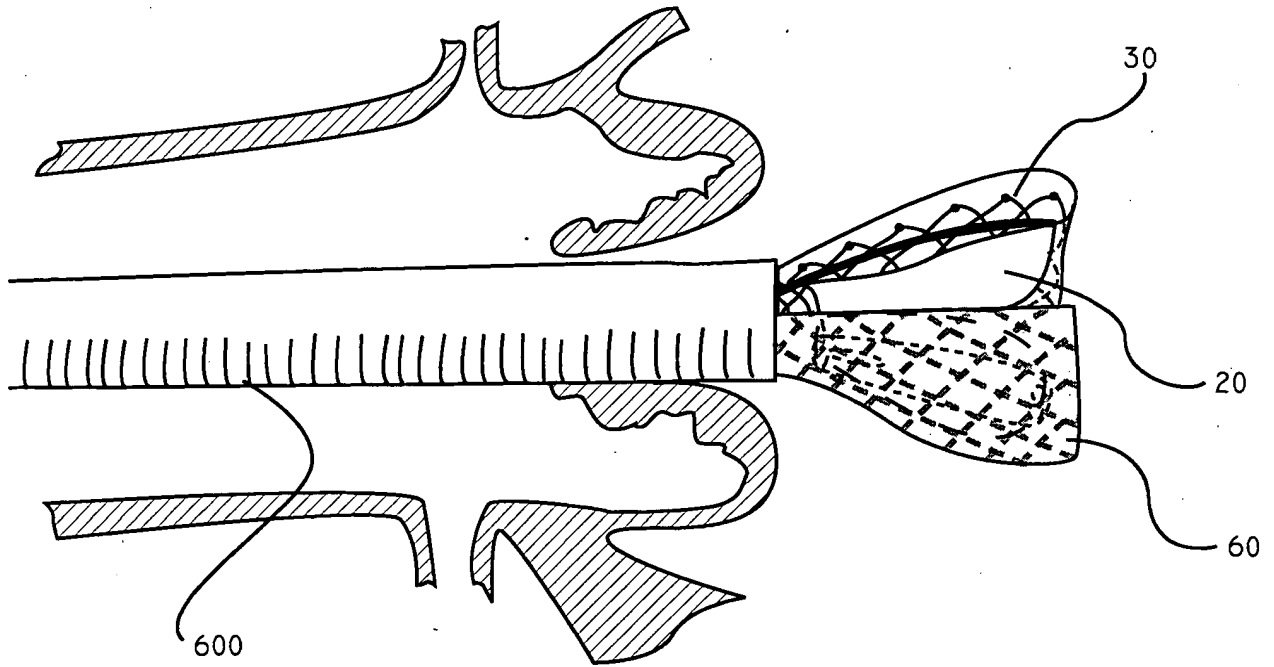


FIG 8A

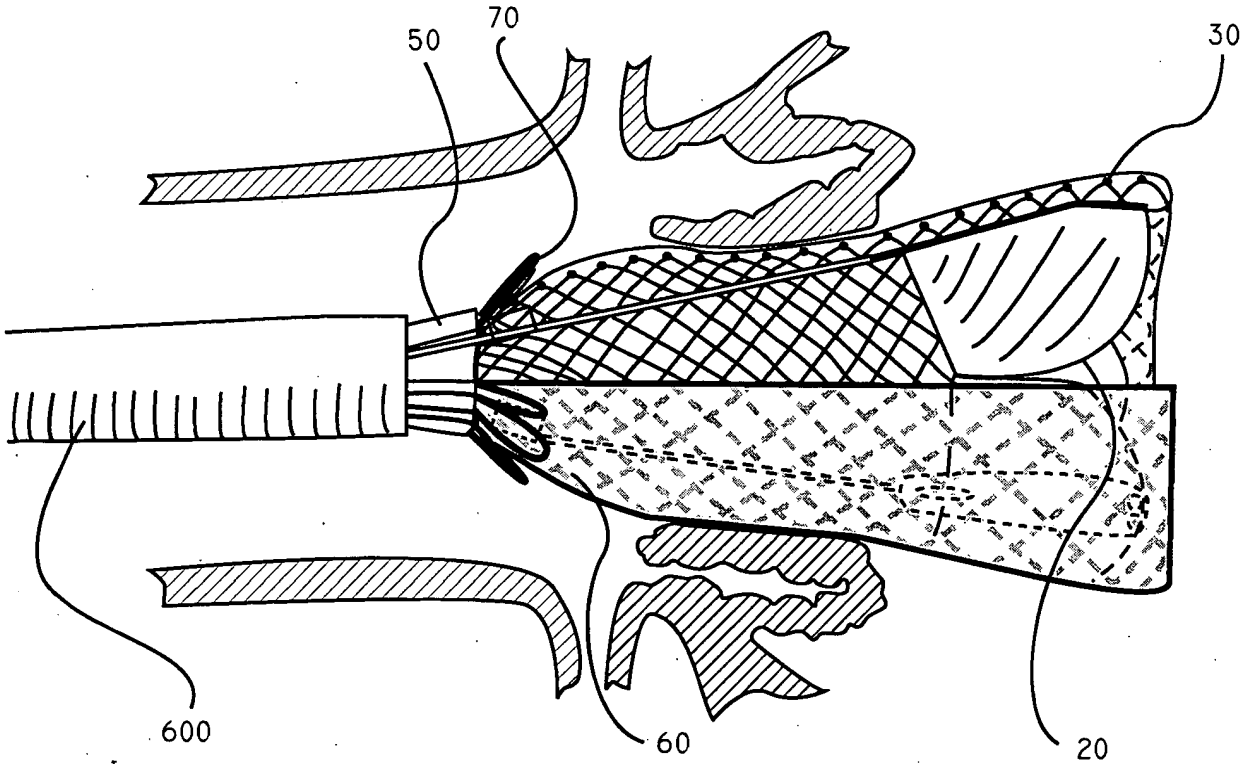


FIG 8B

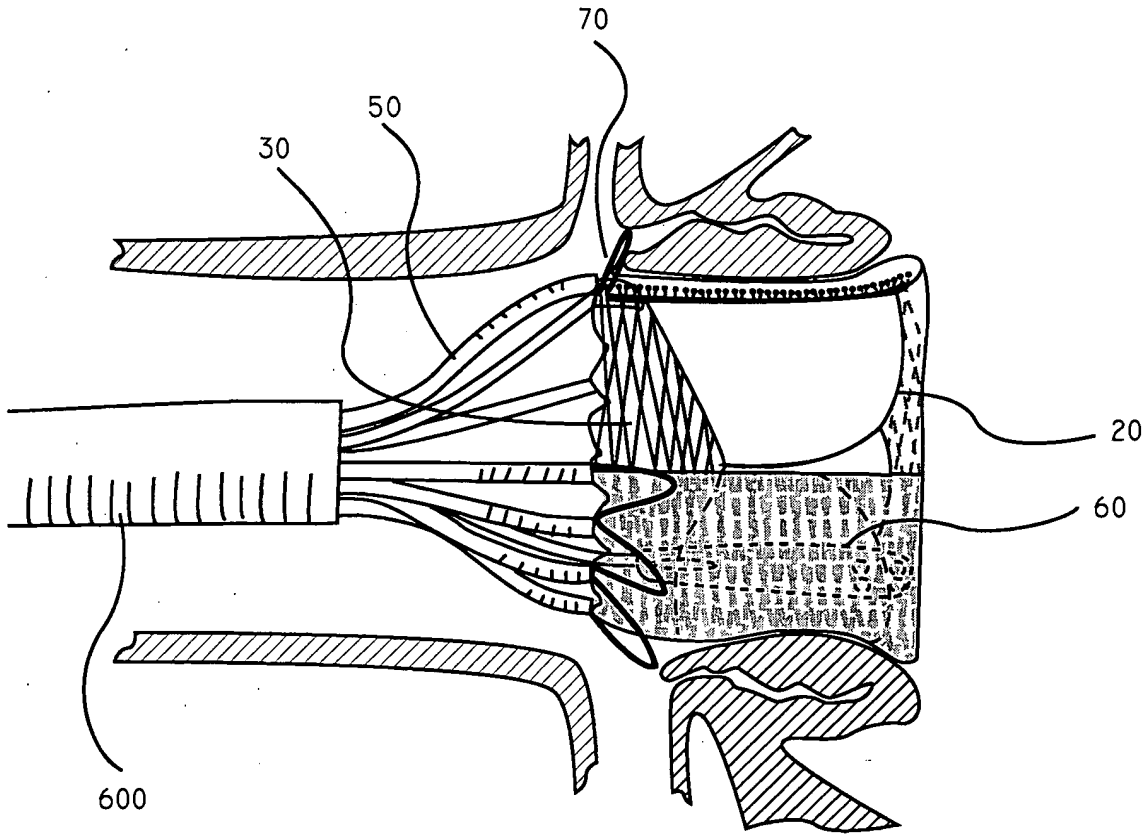


FIG 8C

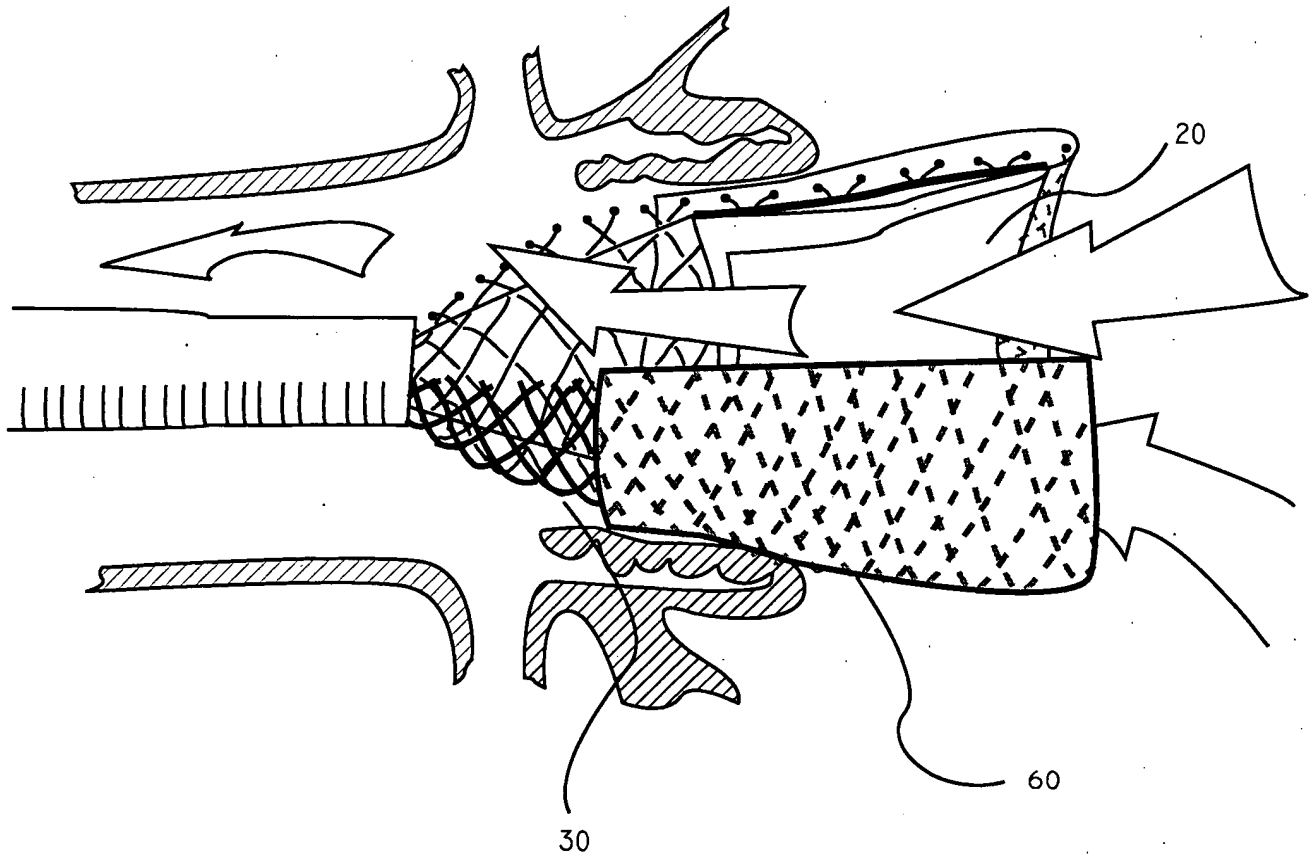


FIG 9A

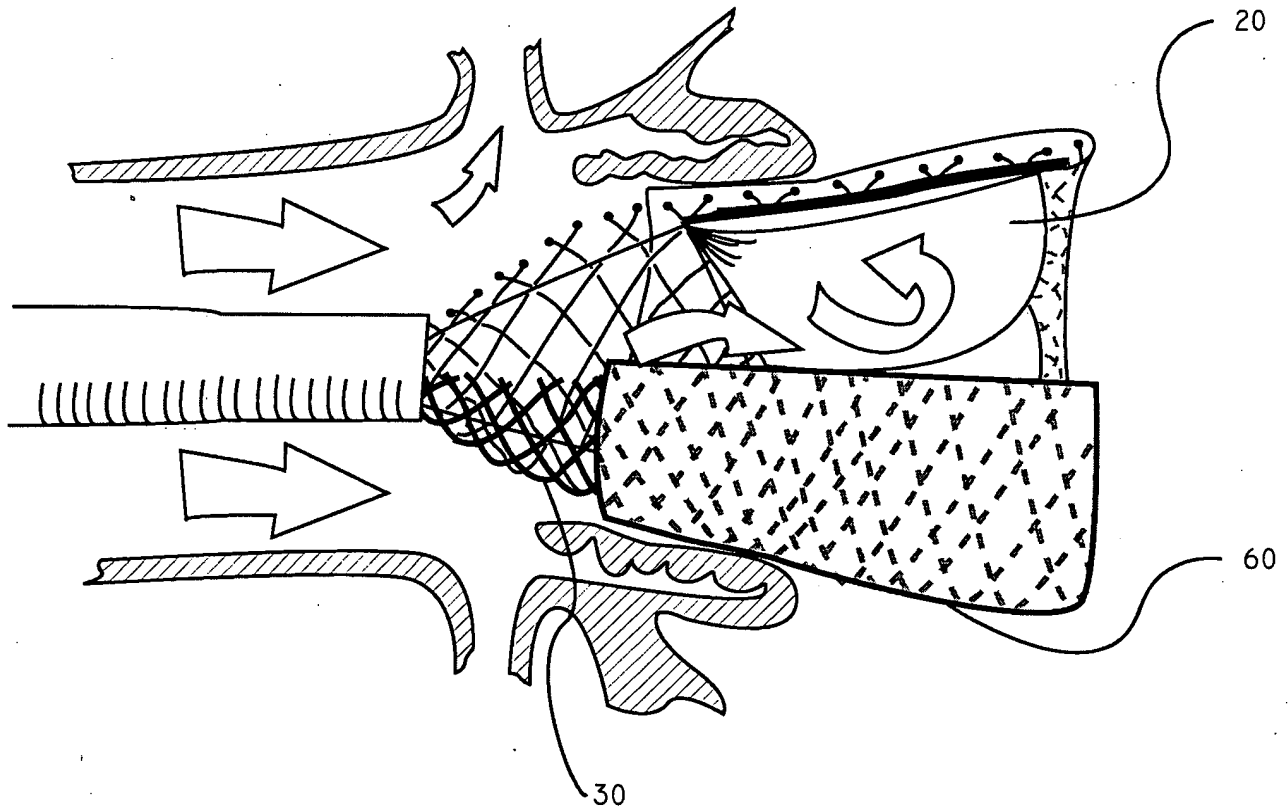


FIG 9B



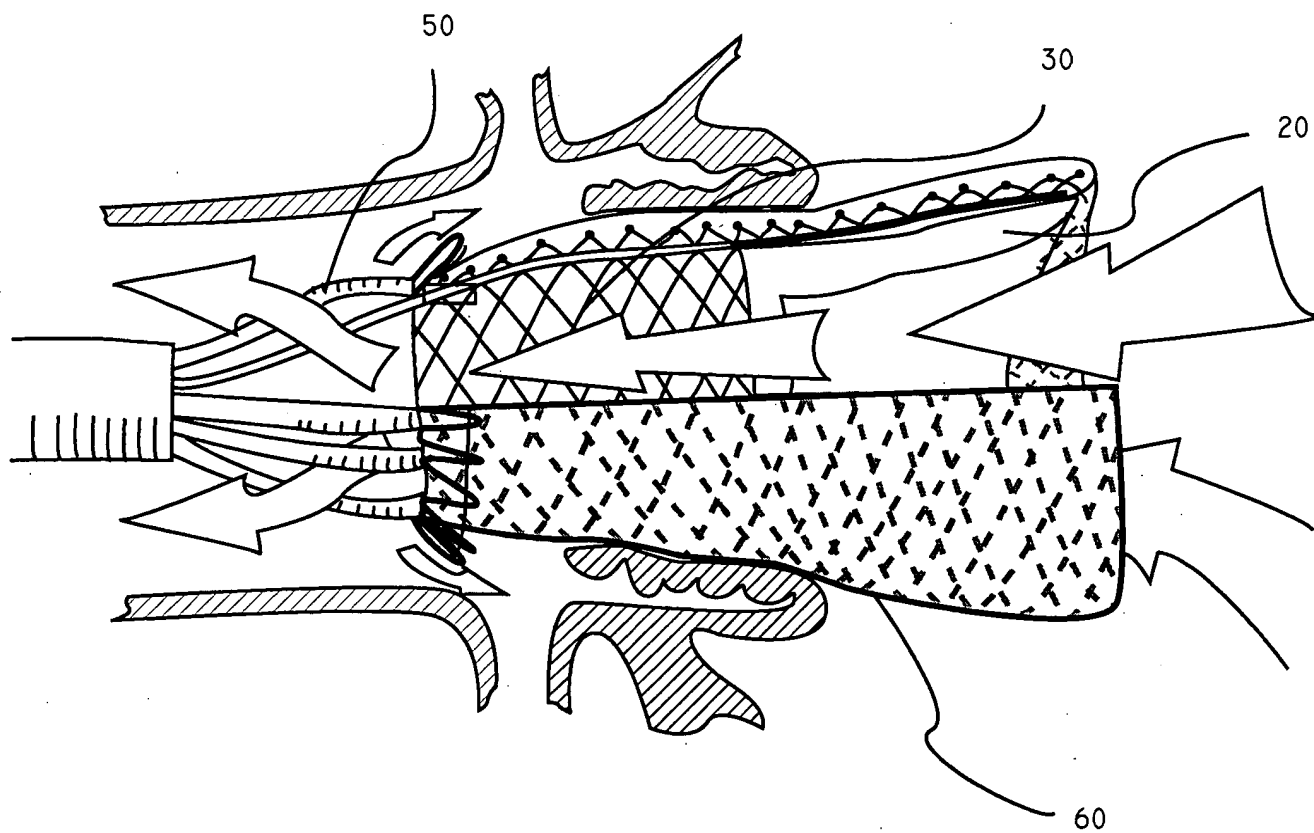


FIG 10A

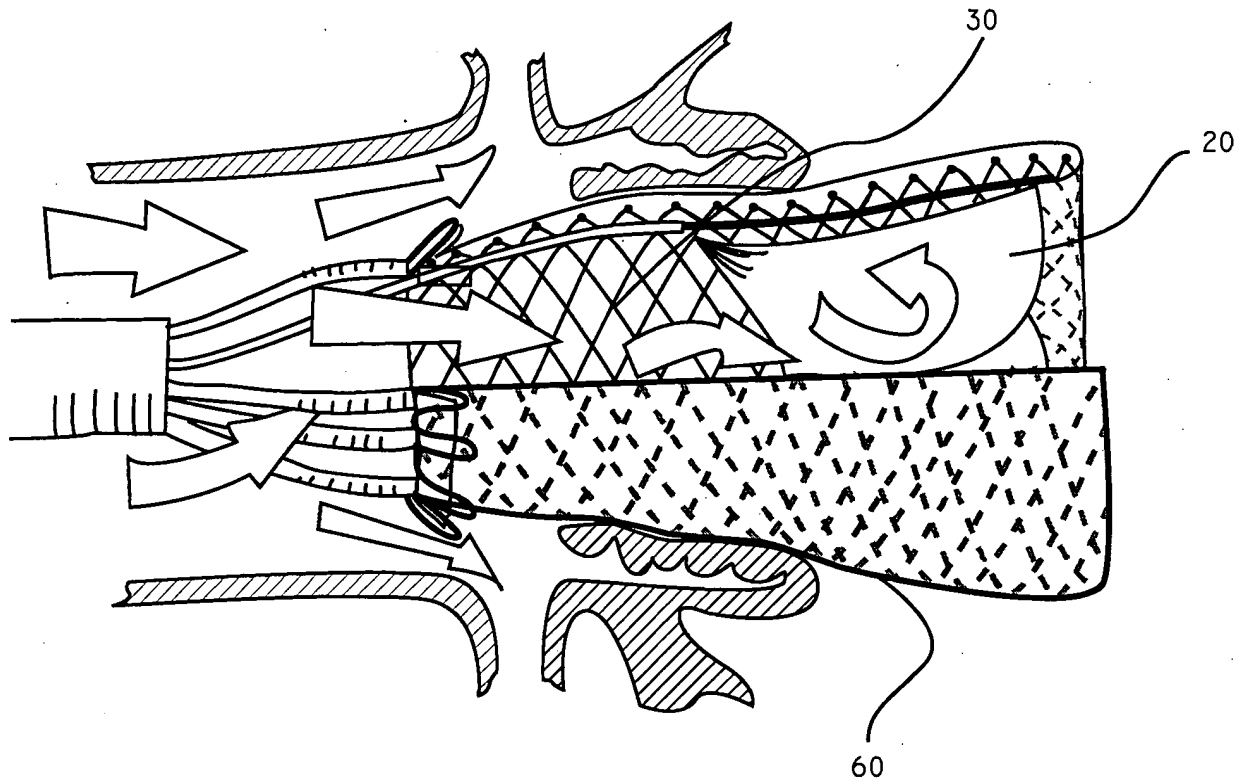


FIG10B

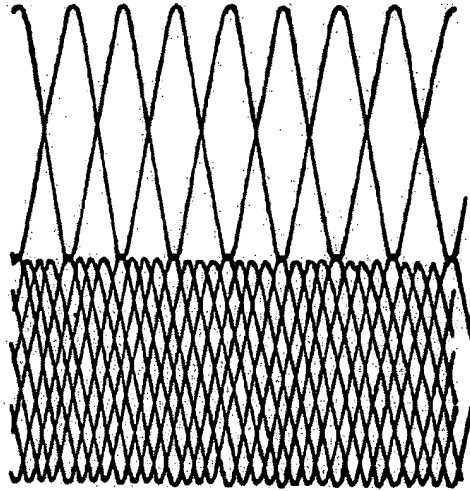


FIG IIA

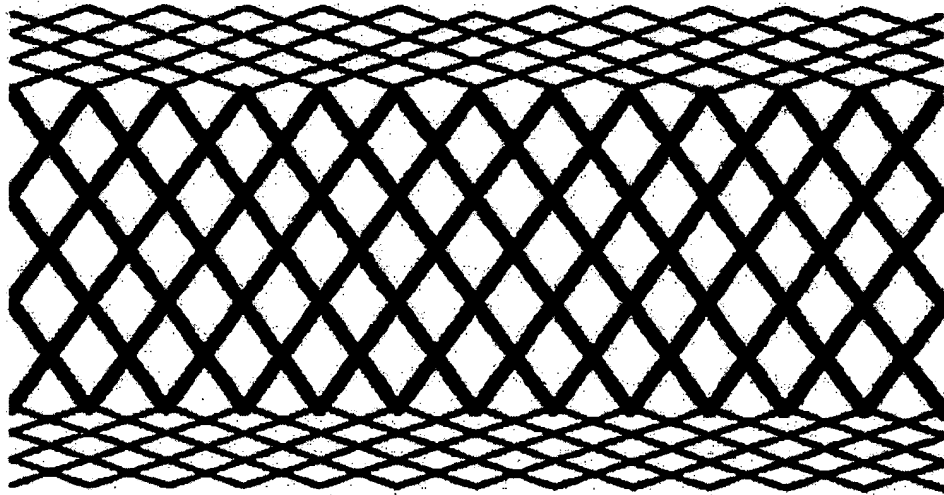


FIG IIB

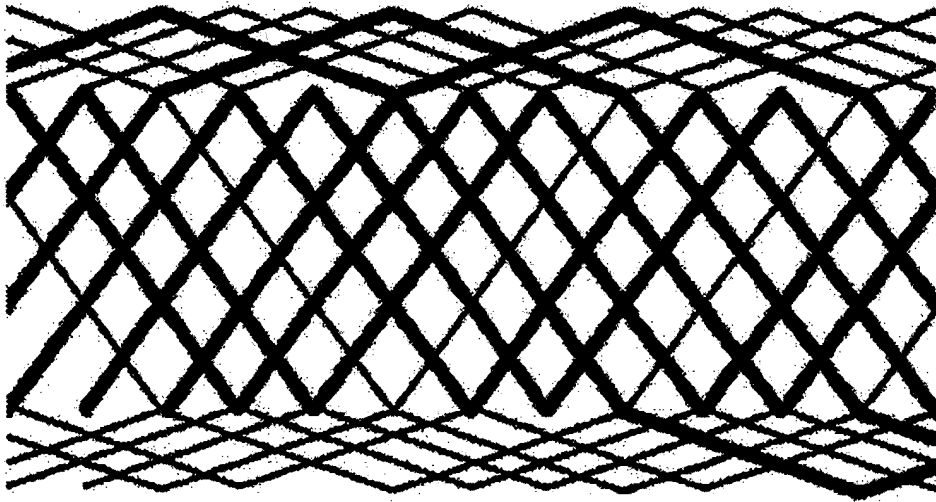


FIG IIC

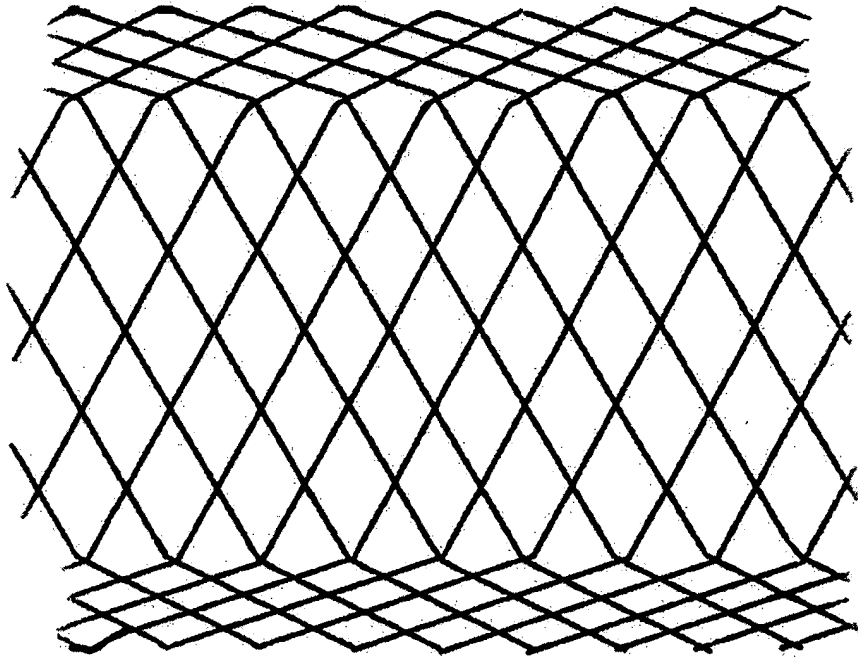


FIG IID

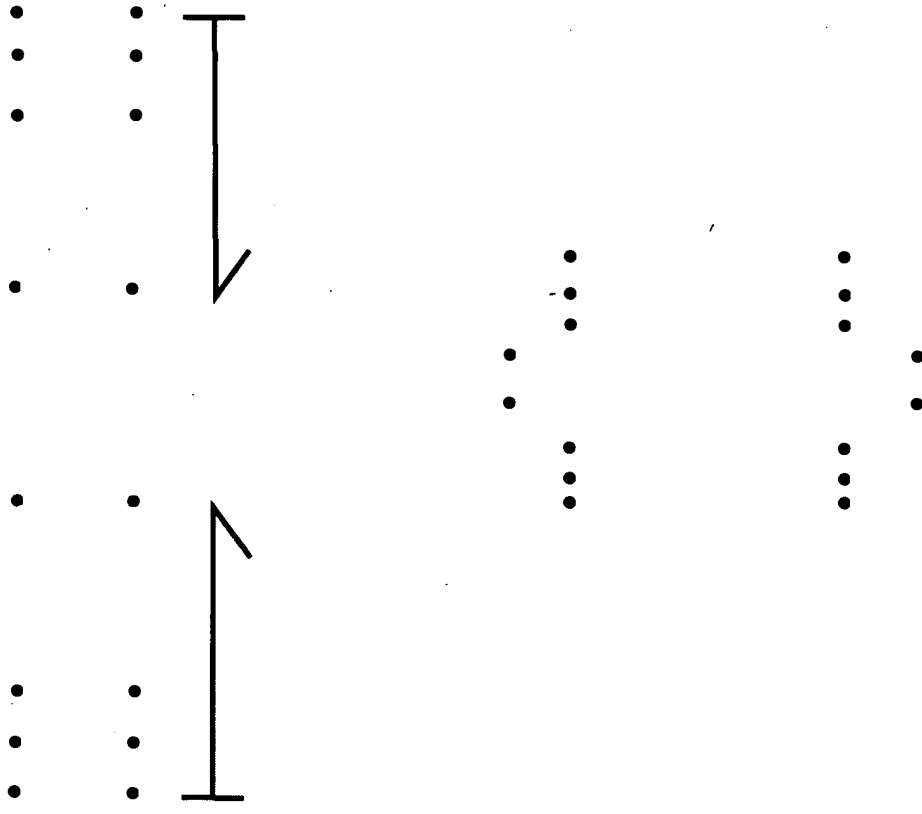


FIG 12A

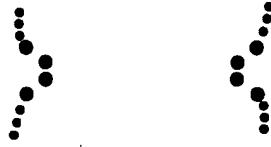


FIG 12B

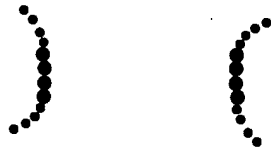


FIG 12C



FIG 12D



FIG 12E



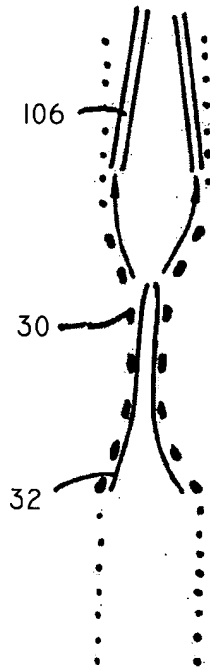


FIG 13A

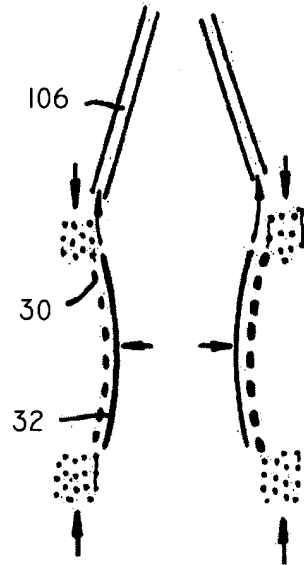


FIG 13B

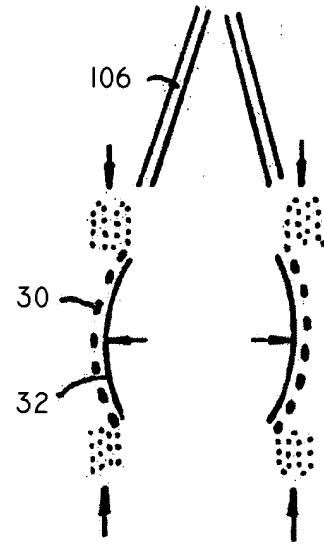


FIG 13C



FIG 13D

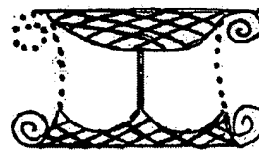


FIG 13E

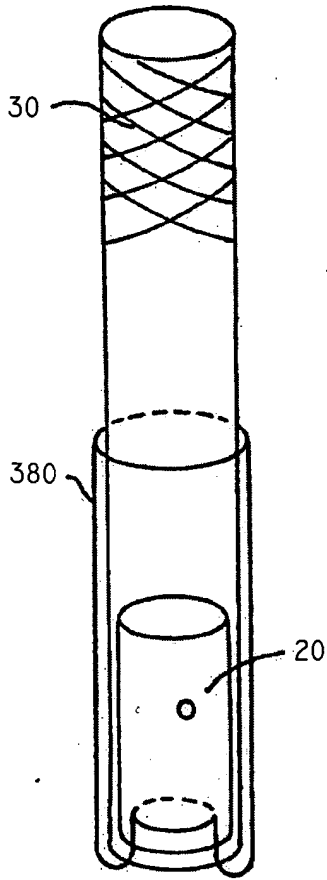


FIG 14A

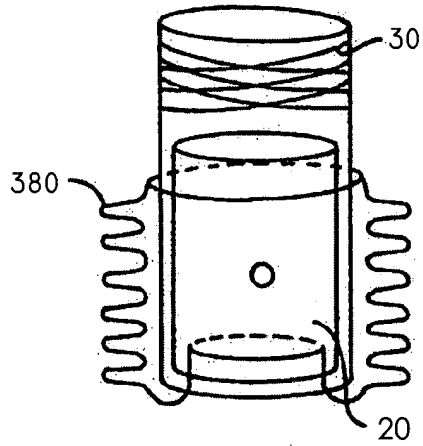


FIG 14B

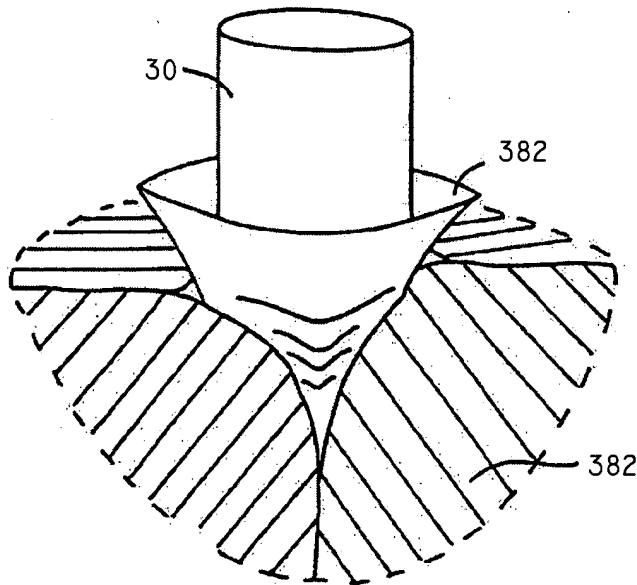


FIG 14C

**PATENT APPLICATION FEE DETERMINATION RECORD**  
Effective December 8, 2004

10/972,287

**CLAIMS AS FILED - PART I**

	(Column 1)	(Column 2)
TOTAL CLAIMS	58	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	58 minus 20=	* 38
INDEPENDENT CLAIMS	3 minus 3 =	* -
MULTIPLE DEPENDENT CLAIM PRESENT <input type="checkbox"/>		

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

**CLAIMS AS AMENDED - PART II**

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <input type="checkbox"/>			

\* 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.

**SMALL ENTITY TYPE**  OR

**OTHER THAN SMALL ENTITY**

RATE	FEE
BASIC FEE	395
X\$ 25=	950
X100=	-
+180=	-
TOTAL	1345 <sup>0</sup>

RATE	FEE
BASIC FEE	
X\$50=	
X200=	
+360=	
TOTAL	

**SMALL ENTITY TYPE**  OR

**OTHER THAN SMALL ENTITY**

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$ 25=	
X100=	
+180=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$50=	
X200=	
+360=	
TOTAL ADDIT. FEE	



IFW

**PATENT**

**Attorney Docket No. 30207.702.501**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Amr SALAHIEH et al.	)	
	)	Art Unit: Not yet assigned
Application No.: 10/972,287	)	
	)	Examiner: Not yet assigned
Filed: October 21, 2004	)	
	)	
Title: Leaflet engagement elements and methods for use thereof	)	
	)	

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

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

Sir:

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

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

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

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

- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- a certification as specified in §1.97(e) is provided below; or
  - a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
  - B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; and
  - C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.     ), copies are not enclosed herewith.
  - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- Copies of only foreign patent documents and non-patent literature are provided in PDF format on the attached CD ROM, clearly titled by publication number or author, in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- Attached are the following non-published pending patent applications which may be deemed relevant.
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.702.501).

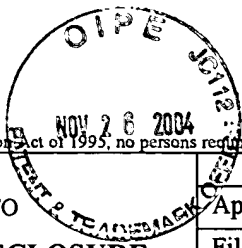
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 11-22-04

By: Maya Skubatch  
Maya Skubatch, Reg. No. 30207.702.501

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



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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>			
				Application Number		10/972,287	
				Filing Date		10/21/2004	
				First Named Inventor		Salahieh	
				Art Unit		Not yet assigned	
Examiner Name		Not yet assigned					
Sheet	1	of	12	Attorney Docket Number	30207.702.501		

**U.S. PATENT DOCUMENTS**

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

Examiner Signature	Date Considered
--------------------	-----------------

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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	2	of	12	Attorney Docket Number	30207.702.501

### U.S. PATENT DOCUMENTS

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

Examiner Signature	Date Considered
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				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	3	of	12	Attorney Docket Number	30207.702.501

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		Number-Kind Code <sup>2</sup> (if known)			
		US-3,868,956	03/04/1975	Alfidi et al.	
		US-3,874,388	04/01/1975	King et al.	
		US-4,056,854	11/08/1977	Boretos et al.	
		US-4,106,129	08/15/1978	Carpentier et al.	
		US-4,233,690	11/18/1980	Akins	
		US-4,291,420	09/29/1981	Reul	
		US-4,425,908	01/17/1984	Simon	
		US-4,501,030	02/26/1985	Lane	
		US-4,580,568	04/08/1986	Gianturco	
		US-4,610,688	09/09/1986	Silvestrini et al.	
		US-4,647,283	03/03/1987	Carpentier et al.	
		US-4,648,881	03/10/1987	Carpentier et al.	
		US-4,655,771	04/07/1987	Wallsten	
		US-4,662,885	05/05/1987	DiPisa, Jr.	
		US-4,665,906	05/19/1987	Jervis	
		US-4,710,192	12/01/1987	Liotta et al.	
		US-4,733,665	03/29/1988	Palmaz	
		US-4,819,751	04/11/1989	Shimada et al.	
		US-4,834,755	05/30/1989	Silvestrini et al.	
		US-4,856,516	08/15/1989	Hillstead	
		US-4,872,874	10/10/1989	Taheri	
		US-4,909,252	03/20/1990	Goldberger	
		US-4,917,102	04/17/1990	Miller et al.	
		US-4,954,126	09/04/1990	Wallsten	
		US-4,994,077	02/19/1991	Dobben	
		US-5,002,559	03/26/1991	Tower	
		US-5,161,547	11/10/1992	Tower	
		US-5,163,953	11/17/1992	Vince	

Examiner Signature	Date Considered
-----------------------	--------------------

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				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	4	of	12	Attorney Docket Number	30207.702.501

U.S. PATENT DOCUMENTS					
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		Number-Kind Code <sup>2</sup> (if known)			
		US-5,217,483	07/08/1993	Tower	
		US-5,217,483	07/08/1993	Tower	
		US-5,332,402	07/26/1994	Teitelbaum et al.	
		US-5,350,398	09/27/1994	Pavcnik et al.	
		US-5,370,685	12/16/1994	Stevens	
		US-5,389,106	02/14/1995	Tower	
		US-5,397,351	03/14/1995	Pavcnik et al.	
		US-5,411,552	05/02/1995	Andersen et al.	
		US-5,431,676	07/11/1995	Dubrul et al.	
		US-5,507,767	04/16/1996	Maeda et al.	
		US-5,545,211	08/13/1996	An et al.	
		US-5,575,818	11/19/1996	Pinchuk	
		US-5,645,559	07/08/1997	Hachtman et al.	
		US-5,674,277	10/07/1997	Freitag	
		US-5,695,498	12/09/1997	Tower	
		US-5,713,953	02/03/1998	Vallana et al.	
		US-5,800,456	09/01/1998	Maeda et al.	
		US-5,817,126	10/06/1998	Imran	
		US-5,824,043	10/20/1998	Cottone Jr.	
		US-5,824,053	10/20/1998	Khosravi et al.	
		US-5,824,056	10/20/1998	Rosenberg	
		US-5,824,064	10/20/1998	Taheri	
		US-5,840,081	11/24/1998	Andersen et al.	
		US-5,855,597	01/05/1999	Jayaraman	
		US-5,855,601	01/05/1999	Bessler et al.	
		US-5,860,996	01/19/1999	Tower	
		US-5,861,028	01/19/1999	Angell	
		US-5,868,783	02/09/1999	Tower	

Examiner Signature	Date Considered
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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	5	of	12	Attorney Docket Number	30207.702.501

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-5,876,448	03/02/1999	Thompson et al.	
		US-5,888,201	03/30/1999	Stinson et al.	
		US-5,891,191	04/06/1999	Stinson	
		US-5,907,893	06/01/1999	Zadno-Azizi et al.	
		US-5,925,063	07/20/1999	Khosravi	
		US-5,944,738	08/31/1999	Amplatz et al.	
		US-5,954,766	09/21/1999	Zadno-Azizi et al.	
		US-5,957,949	09/28/1999	Leonhardt et al.	
		US-5,984,957	11/16/1999	Laptewicz, Jr. et al.	
		US-6,022,370	02/08/2000	Tower	
		US-6,027,525	02/22/2000	Suh et al.	
		US-6,042,598	03/28/2000	Tsugita et al.	
		US-6,051,104	04/18/2000	Jang	
		US-6,123,723	09/26/2000	Konya et al.	
		US-6,146,366	11/14/2000	Schachar	
		US-6,162,245	12/19/2000	Jayaraman	
		US-6,168,614	01/02/2001	Andersen et al.	
		US-6,200,336	03/13/2001	Pavcnik et al.	
		US-6,221,006	04/24/2001	Dubrul et al.	
		US-6,221,091	04/24/2001	Khosravi	
		US-6,241,757	06/05/2001	An et al.	
		US-6,245,102	06/12/2001	Jayaraman	
		US-6,258,114	07/10/2001	Konya et al.	
		US-6,258,115	07/10/2001	Dubrul	
		US-6,258,120	07/10/2001	McKenzie et al.	
		US-6,277,555	08/21/2001	Duran et al.	
		US-6,309,417	10/30/2001	Spence et al.	
		US-6,319,281	11/20/2001	Patel	

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Examiner Name	Not yet assigned				
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		US-6,327,772	12/11/2001	Zadno-Azizi et al.	
		US-6,338,735	01/15/2002	Stevens	
		US-6,348,063	02/19/2002	Yassour et al.	
		US-6,352,708	03/05/2002	Duran et al.	
		US-6,371,970	04/16/2002	Khosravi et al.	
		US-6,371,983	04/16/2002	Lane	
		US-6,379,383	04/30/2002	Palmaz et al.	
		US-6,398,807	06/04/2002	Chouinard et al.	
		US-6,409,750	06/25/2002	Hyodoh et al.	
		US-6,425,916	07/30/2002	Garrison et al.	
		US-6,440,164	08/27/2002	DiMatteo et al.	
		US-6,458,153	10/01/2002	Bailey et al.	
		US-6,468,303	10/22/2002	Amplatz et al.	
		US-6,475,239	11/05/2002	Campbell et al.	
		US-6,482,228	11/19/2002	Norred	
		US-6,494,909	12/17/2002	Greenhalgh	
		US-6,503,272	01/07/2003	Duerig et al.	
		US-6,508,833	01/21/2003	Pavcnik et al.	
		US-6,527,800	03/04/2003	McGuckin, Jr. et al.	
		US-6,530,949	03/11/2003	Konya et al.	
		US-6,562,058	05/13/2003	Seguin et al.	
		US-6,592,546	07/15/2003	Barbut et al.	
		US-6,622,604	09/23/2003	Chouinard et al.	
		US-6,632,243	10/14/2003	Zadno-Azizi et al.	
		US-6,635,068	10/21/2003	Dubrul et al.	
		US-6,652,571	11/25/2003	White et al.	
		US-6,652,578	11/25/2003	Bailey et al.	
		US-6,663,663	12/16/2003	Kim et al.	

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		Number-Kind Code <sup>2</sup> (if known)				
		US-6,669,724		12/30/2003	Park et al.	
		US-6,673,089		01/06/2004	Yassour et al.	
		US-6,673,109		01/06/2004	Cox	
		US-6,682,558		01/27/2004	Tu et al.	
		US-6,682,559		01/27/2004	Myers et al.	
		US-6,685,739		02/03/2004	DiMatteo et al.	
		US-6,689,144		02/10/2004	Gerberding	
		US-6,689,164		02/10/2004	Seguin	
		US-6,692,512		02/17/2004	Jang	
		US-6,702,851		03/09/2004	Chinn et al.	
		US-6,719,789		04/13/2004	Cox	
		US-6,730,118		05/04/2004	Spenser et al.	
		US-6,730,377		05/04/2004	Wang	
		US-6,733,525		05/11/2004	Yang et al.	
		US-6,736,846		05/18/2004	Cox	
		US-6,752,828		06/22/2004	Thornton	
		US-6,758,855		07/06/2004	Fulton, III et al.	

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		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>5</sup> (if known)				
		EP 1057459	12/06/2000	Numed, Inc.		
		EP 1057460	12/06/2000	Numed, Inc.		
		EP 1340473	09/09/2003	3F Therapeutics, Inc.		
		EP 1356793	10/29/2003	Numed, Inc.		
		EP 0937439B1	09/17/2003	Heartport, Inc.		
		EP 0819013	06/23/2004	Heartport, Inc.		
		WO 93/15693	08/19/1993	Vince Medical Company Limited		
		WO 95/04556	02/16/1995	Active Control Experts, Inc.		
		WO 95/29640	11/09/1995	Aesculap AG		X
		WO 96/14032	05/17/1996	Duran, Carlos		
		WO 98/36790	08/27/1998	Conado Medical Devices Corporation		
		WO 00/09059	02/24/2000	Prodesco, Inc.		
		WO 00/44308	08/03/2000	Board of Regents, The University of Texas System		
		WO 00/44313	08/03/2000	Viacor Inc.		
		WO 00/67661	11/16/2000	Ortiz, Mark		
		WO 01/05331	01/25/2001	Biocompatibles Ltd.		
		WO 01/35870	05/25/2001	Seguin, Jacques		X
		WO 01/64137	09/07/2001	Fraunhofer-Gesellschaft Zur Forderung Der Angewandten Forschung E.V.		X
		WO 02/36048	05/10/2002	Seguin, Jacques		X
		WO 02/100297	12/19/2002	Rex Medical, L. P.		

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		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		WO 03/003943	01/16/2003	Advanced Bio Prosthetic Surfaces, Ltd.		
		WO 03/003949	01/16/2003	Seguin, Jacques		X
		WO 03/011195	02/13/2003	Seguin, Jacques		X
		WO 03/015851	11/27/2003	Scimed Life Systems, Inc.		
		WO 2004/019811	03/11/2004	Heart Leaflet Technologies		
		WO 2004/023980	03/25/2004	3F Therapeutics, Inc.		
		WO 2004/041126	05/21/2004	Seguin, Jacques		
		WO 2004/047681	06/10/2004	Boudjemline Younes		X

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<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
		ANDERSEN, H.R. et al., "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs". Euro. Heart J. (1992) 13:704-708.	
		ATWOOD, A. et al., "Insertion of Heart Valves by Catheterization". Project Supervised by Prof. Y. Muftu of Northeastern University (2001-2002) 36-40.	
		BODNAR, E. et al., Replacement Cardiac Valves, Pergamon Publishing Corporation, New York, (1991), 307-322.	
		BOUDJEMLINE, Y. et al., "Percutaneous implantation of a valve in the descending aorta in lambs". Euro. Heart J. (2002) 23:13, 1045-1049.	
		BOUDJEMLINE, Y. et al., "Percutaneous Pulmonary Valve Replacement in a Large Right Ventricular Outflow Tract". J. of Am. College of Cardio. (2004) 43:6, 1082-1087.	
		BOUDJEMLINE, Y. et al., "Percutaneous valve insertion: A new approach?" J. of Thoracic and Cardio. Surg. (2003) 125:3, 741-743.	
		BOUDJEMLINE, Y. et al., "Steps Toward Percutaneous Aortic Valve Replacement." Circulation (2002) 775-778.	
		CRIBIER, A. et al., "Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis". J. of Am. Coll. of Cardio. (2004) 43:4, 698-703.	
		CRIBIER, A., et al., "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description," Circulation (2002) 3006-3008.	
		CRIBIER, A., et al., "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case". Percutaneous Valve Technologies, Inc. (2002).	

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Sheet	11	of	12	Attorney Docket Number	30207.702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
		FERRARI, M. et al., "Percutaneous transvascular aortic valve replacement with self expanding stent-valve device". Poster from the presentation given at SMIT 2000, 12 <sup>th</sup> International Conference (September 5, 2000).	
		HIJAZI, Z.M., "Transcatheter Valve Replacement: A New Era of Percutaneous Cardiac Intervention Begins". J. of Am. College of Cardio. (2004) 43:6, 1088-1089.	
		HUBER, C.H. et al., "Do valved stents compromise coronary flow?" European Journal of Cardio-thoracic Surgery, (2004) 25:754-759.	
		KNUDSEN, L. L. et al., "Catheter-implanted prosthetic heart valves". Int'l J. of Art. Organs, (1993) 16:5, 253-263	
		KORT, S. et al., "Minimally invasive aortic valve replacement: Echocardiographic and clinical results". Am. Heart J. (2001) 142:3, 476-481.	
		LOVE, C. et al., The Autogenous Tissue Heart Valve: Current Status, Journal of Caridac Surgery, (1991) 6:4, 499-507.	
		LUTTER, G. et al., "Percutaneous aortic valve replacement: An experimental study. I. Studies on implantation," J. of Thoracic and Cardio. Surg. (2002) 123:4, 768-776.	
		MOULOPOULOS, S. D. et al., "Catheter-Mounted Aortic Valves," Annals of Thoracic Surg. (1971) 11:5, 423-430.	
		PANIAGUA, D. et al., "Percutaneous heart valve in the chronic in vitro testing model". Circulation (2002), 106:e51-e52, American heart Association, Inc.	
		PANIAGUA, D. et al., Heart Watch (2004), Spring, 2004 Edition, Texas Heart Institute	

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.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

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

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	12	of	12	Attorney Docket Number	30207.702.501

<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
		PAVCNIK, D. et al., "Percutaneous bioprosthetic venous valve: A long-term study in sheep". J. of Vascular Surg. (2002) 35:3, 598-603.	
		PHILLIPS, S. J. at al., "A Temporary Catheter-Tip Aortic Valve: Hemodynamic Effects on Experimental Acute Aortic Insufficiency". Annals of Thoracic Surg. (1976) 21:2, 134-136.	
		SOCHMAN, J. et al., "Percutaneous Transcatheter Aortic Disc Valve Prosthesis Implantation: A Feasibility Study". Cardiovasc. Intervent. Radiol. (2000) 23, 384-388.	
		STUART, M., "In Heart Valves, A Brave, New Non-Surgical World". Start-Up (2004) 9-17.	
		VAHANIAN, A. et al., "Percutaneous Approaches to Valvular Disease". Circulation (2004) 109, 1572-1579.	
		VAN HERWERDEN, L. A. et al., "Percutaneous valve implantation: back to the future?" Euro. Heart J. (2002) 23:18, 1415-1416.	
		ZHOU, J. Q. et al., "Self-expandable valved stent of large size: off-bypass implantation in pulmonary position". Eur. J. Cardiothorac. (2003) 24, 212-216	

Examiner signature		Date Considered	
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\*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.

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

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

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

## ARTIFACT SHEET

Enter artifact number below. Artifact number is application number + artifact type code (see list below) + sequential letter (A, B, C ...). The first artifact folder for an artifact type receives the letter A, the second B, etc.. Examples: 59123456PA, 59123456PB, 59123456ZA, 59123456ZB

10 972 287 UA

Indicate quantity of a single type of artifact received but not scanned. Create individual artifact folder/box and artifact number for each Artifact Type.

CD(s) containing:

computer program listing

Doc Code: Computer

pages of specification

and/or sequence listing

and/or table

Doc Code: Artifact

content unspecified or combined

Doc Code: Artifact

Artifact Type Code: P

Artifact Type Code: S

Artifact Type Code: U

Stapled Set(s) Color Documents or B/W Photographs

Doc Code: Artifact    Artifact Type Code: C

Microfilm(s)

Doc Code: Artifact    Artifact Type Code: F

Video tape(s)

Doc Code: Artifact    Artifact Type Code: V

Model(s)

Doc Code: Artifact    Artifact Type Code: M

Bound Document(s)

Doc Code: Artifact    Artifact Type Code: B

Confidential Information Disclosure Statement or Other Documents marked Proprietary, Trade Secrets, Subject to Protective Order, Material Submitted under MPEP 724.02, etc.

Doc Code: Artifact    Artifact Type Code X

Other, description: \_\_\_\_\_

Doc Code: Artifact    Artifact Type Code: Z

March 8, 2004



UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
www.uspto.gov

Table with 4 columns: APPLICATION NUMBER (10/972,287), FILING OR 371 (c) DATE (10/21/2004), FIRST NAMED APPLICANT (Amr Salahieh), ATTORNEY DOCKET NUMBER (30207-702.501)

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

CONFIRMATION NO. 7706

FORMALITIES LETTER



\*OC000000014923099\*

Date Mailed: 01/11/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

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

- The statutory basic filing fee is missing. Applicant must submit \$ 395 to complete the basic filing fee for a small entity.
The oath or declaration is missing. A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

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

- Additional claim fees of \$950 as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is \$1410 for a Small Entity

- \$395 Statutory basic filing fee.
\$65 Late oath or declaration Surcharge.
Total additional claim fee(s) for this application is \$950

- \$950 for 38 total claims over 20.

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

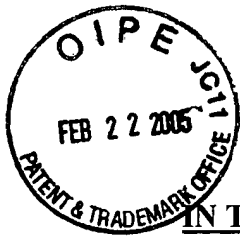
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*A copy of this notice **MUST** be returned with the reply.*

*M. Byrne*  
\_\_\_\_\_  
Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY



772

PATENT

Attorney Docket No. 30207.702.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Amr SALAHIEH et al.	)	
	)	Art Unit: 3738
Application No.: 10/972,287	)	
	)	Examiner: Not yet assigned
Filed: October 21, 2004	)	
	)	Confirmation No.: 7706
Title: Leaflet engagement elements and methods for use thereof	)	
	)	

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

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

Sir:

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

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

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

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

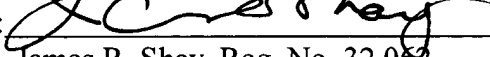
- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- a certification as specified in §1.97(e) is provided below; **or**
  - a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
  - B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
  - C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.     ), copies are not enclosed herewith.
  - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- Copies of only foreign patent documents and non-patent literature are provided in PDF format on the attached CD ROM, clearly titled by publication number or author, in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- Attached are the following non-published pending patent applications which may be deemed relevant.
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 2/16/05

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

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

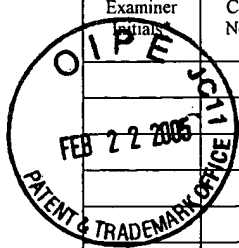


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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	3738
Examiner Name	Not yet assigned				
Sheet	1	of	1	Attorney Docket Number	30207.702.501

## U.S. PATENT DOCUMENTS

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



## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>2</sup> - Kind Code <sup>4</sup> (if known)				
		EP 1000590A1	05/17/2000	Cordis Corporation		

Examiner Signature		Date Considered	
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

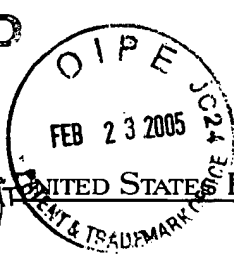
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Page 1 of 2

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JAN 14 2005



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P.O. Box 1450  
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/972,287	10/21/2004	Amr Salahieh	30207-702.501

CONFIRMATION NO. 7706

FORMALITIES LETTER



\*OC00000014923099\*

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

Date Mailed: 01/11/2005

**NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION**

02/28/2005 CNGUYEN 00000100 232415 10972287

FILED UNDER 37 CFR 1.53(b)

01 FC:2051 65.00 DA  
02 FC:2001 395.00 DA  
03 FC:2202 950.00 DA

Filing Date Granted

**Items Required To Avoid Abandonment:**

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

- The statutory basic filing fee is missing.  
*Applicant must submit \$ 395 to complete the basic filing fee for a small entity.*
- The oath or declaration is missing.  
*A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

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

- Additional claim fees of **\$950** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

**SUMMARY OF FEES DUE:**

Total additional fee(s) required for this application is **\$1410** for a Small Entity

- **\$395** Statutory basic filing fee.
- **\$65** Late oath or declaration Surcharge.
- Total additional claim fee(s) for this application is **\$950**

- \$950 for 38 total claims over 20.

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

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

  
Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



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.

<h2>TRANSMITTAL FORM</h2> <p><i>(to be used for all correspondence after initial filing)</i></p>	Application Number	10/972,287
	Filing Date	October 21, 2004
	First Named Inventor	Amr Salahieh
	Art Unit	3738
	Examiner Name	Unassigned
Total Number of Pages in This Submission	Attorney Docket Number	30207-702.501

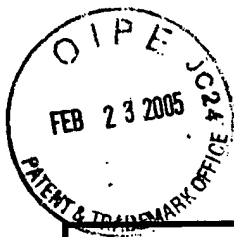
ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input checked="" type="checkbox"/> Response to Missing Parts/ Incomplete Application <input checked="" type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input checked="" type="checkbox"/> Declaration <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input checked="" type="checkbox"/> Power of Attorney By Assignee <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Copy of Assignment and recordation cover sheet
<div style="border: 1px solid black; padding: 2px; display: inline-block;">Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT	
Firm or Individual name	Maya Skubatch, Reg. No. 52,505, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	February 23, 2005

CERTIFICATE OF EXPRESS MAIL NO. EV 578081297 US			
I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated below and addressed to: M/S Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: Feb. 23, 2005.			
Typed or printed name	Donna L. Hengst		
Signature		Date	February 23, 2005

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

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



Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). <b>FEE TRANSMITTAL          for FY 2005</b>		<b>Complete if Known</b>	
		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
<input checked="" type="checkbox"/> applicant claims small entity status. See 37 CFR 1.27.		Examiner Name	Unassigned
TOTAL AMOUNT OF PAYMENT	(\$) 1,515.00	Art Unit	3738
		Attorney Docket No.	30207-702.501

**METHOD OF PAYMENT** (check all that apply)

Check    Credit card    Money Order    None    Other (please identify): \_\_\_\_\_

Deposit Account: Deposit Account Number: 23-2415      Deposit Account Name: Wilson Sonsini Goodrich & Rosati  
 For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below       Charge fee(s) indicated below, **except for the filing fee**  
 Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17       Credit any overpayment

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	\$500.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Small Entity Fee (\$)	Fee Paid (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

**Total Claims**      **Extra Claims**      **Fee (\$)**      **Fee Paid (\$)**  
 58 - 20 or HP = 38 x \$25.00 = \$950.00

HP = highest number of total claims paid for, if greater than 20

**Indep. Claims**      **Extra Claims**      **Fee (\$)**      **Fee Paid (\$)**  
 3 - 3 or HP = \_\_\_\_\_ x \$ \_\_\_\_\_ = \$0

HP = highest number of total claims paid for, if greater than 3

**3. APPLICATION SIZE FEE**

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 fractions thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

**Total Sheets**      **Extra Sheets**      **Number of each additional 50 or fraction thereof**      **Fee (\$)**      **Fee Paid (\$)**  
 53 - 100 = \_\_\_\_\_ / 50 = \_\_\_\_\_ (round up to a whole number) x 0 = 0

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other: Late surcharge. - for Declaration      \$65.00

**SUBMITTED BY**

Signature		Registration No. (Attorney/Agent)	52,505	Telephone	650-493-9300
Name (Print/Type)	Maya Skubatch	Date	Feb. 23, 2005		

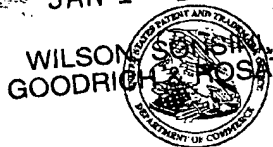
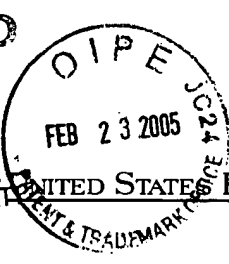
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Page 1 of 2

IFW

JAN 14 2005



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/972,287	10/21/2004	Amr Salahieh	30207-702.501

CONFIRMATION NO. 7706

FORMALITIES LETTER



\*OC00000014923099\*

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

Date Mailed: 01/11/2005

**NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION**

02/28/2005 CNGUYEN 00000100 232415 10972287

FILED UNDER 37 CFR 1.53(b)

01 FC:2051 65.00 DA  
02 FC:2001 395.00 DA  
03 FC:2202 950.00 DA

Filing Date Granted

**Items Required To Avoid Abandonment:**

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

- The statutory basic filing fee is missing.  
*Applicant must submit \$ 395 to complete the basic filing fee for a small entity.*
- The oath or declaration is missing.  
*A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The applicant needs to satisfy supplemental fees problems indicated below.

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

- Additional claim fees of **\$950** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

**SUMMARY OF FEES DUE:**

Total additional fee(s) required for this application is **\$1410** for a Small Entity

- **\$395** Statutory basic filing fee.
- **\$65** Late oath or declaration Surcharge.
- Total additional claim fee(s) for this application is **\$950**

- \$950 for 38 total claims over 20.

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

---

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

  
Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



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.

<h1>TRANSMITTAL FORM</h1> <p><i>(to be used for all correspondence after initial filing)</i></p>	Application Number	10/972,287
	Filing Date	October 21, 2004
	First Named Inventor	Amr Salahieh
	Art Unit	3738
	Examiner Name	Unassigned
Total Number of Pages in This Submission	Attorney Docket Number	30207-702.501

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input checked="" type="checkbox"/> Response to Missing Parts/ Incomplete Application <input checked="" type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input checked="" type="checkbox"/> Declaration <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input checked="" type="checkbox"/> Power of Attorney By Assignee <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Copy of Assignment and recordation cover sheet
<div style="border: 1px solid black; padding: 2px; display: inline-block;">Remarks</div>		

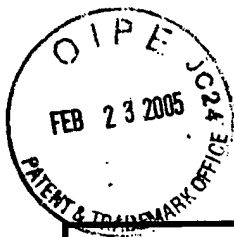
SIGNATURE OF APPLICANT, ATTORNEY OR AGENT	
Firm or Individual name	Maya Skubatch, Reg. No. 52,505, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	February 23, 2005

CERTIFICATE OF EXPRESS MAIL NO. EV 578081297 US			
I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated below and addressed to: M/S Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: Feb. 23, 2005.			
Typed or printed name	Donna L. Hengst		
Signature		Date	February 23, 2005

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

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





Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). <b>FEE TRANSMITTAL          for FY 2005</b>		<b>Complete if Known</b>	
		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
<input checked="" type="checkbox"/> applicant claims small entity status. See 37 CFR 1.27.		Examiner Name	Unassigned
TOTAL AMOUNT OF PAYMENT	(\$) 1,515.00	Art Unit	3738
		Attorney Docket No.	30207-702.501

**METHOD OF PAYMENT** (check all that apply)

Check    Credit card    Money Order    None    Other (please identify): \_\_\_\_\_

Deposit Account: Deposit Account Number: 23-2415      Deposit Account Name: Wilson Sonsini Goodrich & Rosati  
 For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below       Charge fee(s) indicated below, **except for the filing fee**  
 Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17       Credit any overpayment

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	\$500.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Small Entity Fee (\$)	Fee Paid (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than the original patent	50	25
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**Indep. Claims**      **Extra Claims**      **Fee (\$)**      **Fee Paid (\$)**  
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**Total Sheets**      **Extra Sheets**      **Number of each additional 50 or fraction thereof**      **Fee (\$)**      **Fee Paid (\$)**  
 53 - 100 = \_\_\_\_\_ / 50 = \_\_\_\_\_ (round up to a whole number) x 0 = 0

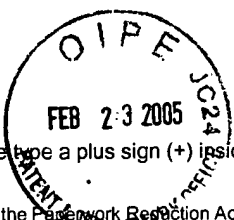
**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other: Late surcharge. - for Declaration      \$65.00

**SUBMITTED BY**

Signature		Registration No. (Attorney/Agent)	52,505	Telephone	650-493-9300
Name (Print/Type)	Maya Skubatch	Date	Feb. 23, 2005		



Please type a plus sign (+) inside this box +

PTO/SB/01 (08-03)

Approved for use through 07/31/2006. 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 contains a valid OMB control number.

<b>DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)</b>  <input type="checkbox"/> Declaration Submitted With Initial Filing <b>OR</b> <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e) required))	Attorney Docket Number	30207-702.501
	First Named Inventor	Amr Salahieh
	<b>COMPLETE IF KNOWN</b>	
	Application Number	10/972,287
	Filing Date	October 21, 2004
	Art Unit	3738
Examiner Name	Unassigned	

**I hereby declare that:**

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF**

*(Title of the Invention)*

the specification of which

is attached hereto

**OR**

was filed on (MM/DD/YYYY) 10/21/2004 as United States Application Number or PCT International Application Number 10/972,287 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, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), 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, inventor's or plant breeder's rights certificate(s), 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	Yes	No
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

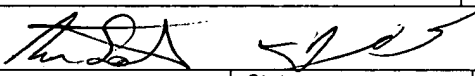
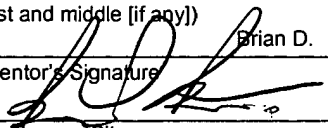
Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 21 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.*

Please type a plus sign (+) inside this box +

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

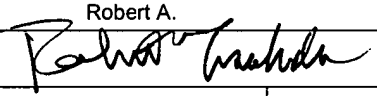
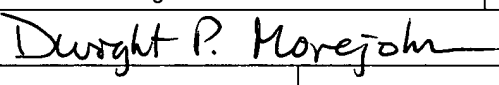
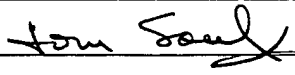
## DECLARATION — Utility or Design Patent Application

Direct all correspondence to: <input checked="" type="checkbox"/> Customer Number <span style="border: 1px solid black; padding: 2px 20px;">021971</span> OR <input type="checkbox"/> Correspondence address below			
Name Maya Skubatch			
Address Wilson Sonsini Goodrich & Rosati			
Address 650 Page Mill Road			
City Palo Alto	State CA	ZIP 94304	
Country U.S.	Telephone 650-493-9300	Fax 650-493-6811	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.			
<b>NAME OF SOLE OR FIRST INVENTOR:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any)) Amr		Family Name or Surname Salahieh	
Inventor's Signature 		Date 2/8/05	
Residence: City Saratoga	State CA	Country USA	Citizenship USA
Mailing Address 18729 Metler Court			
City Saratoga	State CA	ZIP 95070	Country USA
<b>NAME OF SECOND INVENTOR:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any)) Brian D.		Family Name or Surname Brandt	
Inventor's Signature 		Date 02/04/05	
Residence: City Santa Clara	State CA	Country USA	Citizenship USA
Mailing Address 3015 Cameron Way			
City Santa Clara	State CA	ZIP 95051	Country USA
<input checked="" type="checkbox"/> Additional inventors or legal representative are being named on the <u>1</u> supplemental sheet(s) PTO/SB/02A or 02LR attached hereto:			

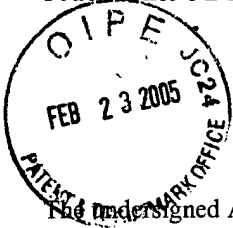
Please Type a plus sign (+) inside this box +

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.

<b>DECLARATION</b>	<b>ADDITIONAL INVENTOR(S) Supplemental Sheet</b>
<b>Page 1 of 1</b>	

<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Robert A.		Gleslider	
Inventor's Signature 		Date 2/4/05	
Residence: City San Francisco	State CA	Country USA	Citizenship USA
Mailing Address 233 27 <sup>th</sup> Street			
Mailing Address			
City San Francisco	State CA	ZIP 94131	Country USA
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> 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 		Date 2-7-05	
Residence: City Davis	State CA	Country USA	Citizenship USA
Mailing Address 731 N. Campus Way			
Mailing Address			
City Davis	State CA	ZIP 95616	Country USA
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Tom		Saul	
Inventor's Signature 		Date 2/4/05	
Residence: City El Granada	State CA	Country USA	Citizenship USA
Mailing Address 151 Madrid Avenue			
Mailing Address			
City El Granada	State CA	ZIP 94018	Country USA

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 21 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.



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

The undersigned ASSIGNEE of the entire interest in:

- U.S. Patent No.
- U.S. application no. 10/972,287, filed on October 21, 2004

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

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

*(complete one of the following)*

- a copy of an Assignment attached hereto, which Assignment has been (or is herewith) forwarded to the Patent and Trademark Office for recording; or
- the Assignment recorded on \_\_\_ at reel \_\_\_, frames \_\_\_-\_\_\_.

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

**CHANGE OF CORRESPONDENCE ADDRESS**

Direct all correspondence and telephone calls to:

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

ASSIGNEE: SADRA MEDICAL, INC.

Name: Anr Salahieh

Print

Signature

Title: President & CEO

Date: 2/8/05



4-29-05

IFC

EXPRESS MAIL LABEL NO.: EV 518896122 US

PATENT

Attorney Docket No. 30207.702.501

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Amr SALAHIEH et al.	)	
	)	Art Unit: 3738
Application No.: 10/972,287	)	
	)	Examiner: Not yet assigned
Filed: October 21, 2004	)	
	)	Confirmation No.: 7706
Title: Leaflet engagement elements and methods for use thereof	)	
	)	

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

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

Sir:

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

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

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

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

- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- a certification as specified in §1.97(e) is provided below; **or**
  - a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
  - B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
  - C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith in PDF format on the attached CD ROM, clearly titled by application number or author, in accordance with 37 CFR 1.98 (a)(2).
- Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.     ), copies are not enclosed herewith.
  - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- Attached are non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: \_\_\_\_\_

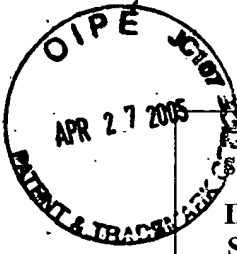
4/29/05

By: \_\_\_\_\_

  
Maya Skubatch, Reg. No. 52,505

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





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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	1	of	2	Attorney Docket Number	30207.702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
		SALAHIEH, A. et al. US Patent Application No. 10/746,280 entitled "Repositionable heart valve and method", filed 12/23/2003 (Docket No. 30207.701.201).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,131 entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (Docket No. 30207.701.501).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,151, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.502).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,143, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.503).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,142, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.504).	
		SALAHIEH, A. et al. US Patent Application No. 10/920,736, entitled "Apparatus and methods for protecting against embolization during endovascular heart replacement", filed 08/17/2004 (30207.701.505).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,240, entitled "Heart valve anchor and method", filed 12/23/2003 (30207.702.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/971,535, entitled "Leaflet engagement elements and methods for use thereof", filed 10/21/2004 (30207.702.502).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,120, entitled "Externally expandable heart valve anchor and method", filed 12/23/2003 (30207.703.201).	

Examiner signature	Date Considered
--------------------	-----------------

\*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.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	3738
Examiner Name	Not yet assigned				
Sheet	2	of	2	Attorney Docket Number	30207.702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
		SALAHIEH, A. et al., US Patent Application No. 10/982,388, entitled "Methods and apparatus for endovascularly replacing a heart valve", filed 11/05/2004 (30207.703.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,285, entitled "Retrievable heart valve anchor and method", filed 12/23/2003 (30207.704.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/982,692, entitled "Retrievable heart valve anchor and method", filed 11/05/2004 (30207.704.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,887, entitled "Low profile heart valve and delivery system", filed 12/23/2003 (30207.705.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,872, entitled "Locking heart valve anchor", filed 12/23/2003 (30207.706.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/911,059, entitled "Replacement valve and anchor", filed 08/03/2004 (30207.706.301).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,942, entitled "Two-piece heart valve and anchor", filed 12/23/2003 (30207.707.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/870,340, entitled "Everting heart valve", filed 06/16/2004 (30207.710.201).	
Examiner signature		Date Considered	

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

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

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

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

## ARTIFACT SHEET

Enter artifact number below. Artifact number is application number + artifact type code (see list below) + sequential letter (A, B, C ...). The first artifact folder for an artifact type receives the letter A, the second B, etc..  
Examples: 59123456PA, 59123456PB, 59123456ZA, 59123456ZB

10972287 UB

Indicate quantity of a single type of artifact received but not scanned. Create individual artifact folder/box and artifact number for each Artifact Type.

CD(s) containing:

computer program listing

Doc Code: Computer

pages of specification

and/or sequence listing

and/or table

Doc Code: Artifact

content unspecified or combined

Doc Code: Artifact

Artifact Type Code: P

Artifact Type Code: S

Artifact Type Code: U

Stapled Set(s) Color Documents or B/W Photographs

Doc Code: Artifact    Artifact Type Code: C

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Doc Code: Artifact    Artifact Type Code: V

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Doc Code: Artifact    Artifact Type Code: B

Confidential Information Disclosure Statement or Other Documents marked Proprietary, Trade Secrets, Subject to Protective Order, Material Submitted under MPEP 724.02, etc.

Doc Code: Artifact    Artifact Type Code X

Other, description: \_\_\_\_\_

Doc Code: Artifact    Artifact Type Code: Z

March 8, 2004



IFW

**CERTIFICATE OF MAILING**

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

Mi Kyong Shin

**PATENT**

**Attorney Docket No. 30207.702.501**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Amr SALAHIEH et al.	)	
	)	Art Unit: 3738
Application No.: 10/972,287	)	
	)	Examiner: Not yet assigned
Filed: October 21, 2004	)	
	)	Confirmation No.: 7706
Title: Leaflet engagement elements and methods for use thereof	)	
	)	

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

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

Sir:

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

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

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

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

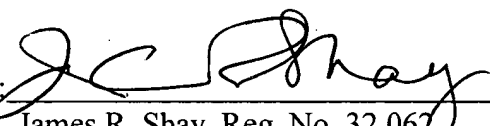
- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- a certification as specified in §1.97(e) is provided below; **or**
  - a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
  - B. a 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.
- Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. ), copies are not enclosed herewith.
  - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
  - Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed.)

- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- Attached are the following non-published pending patent applications which may be deemed relevant.
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.702.501).

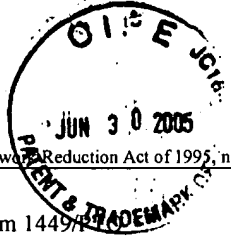
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 6/27/05

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

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



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Substitute for form 1449 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>		
				Application Number	10/972,287	
				Filing Date	10/21/2004	
				First Named Inventor	Salahieh et al.	
				Art Unit	3738	
				Examiner Name	Not yet assigned	
Sheet	1	of	1	Attorney Docket Number	30207.702.501	

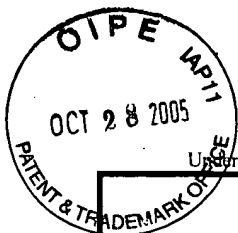
U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-2005/0085841	04/21/2005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

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

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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



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PTO/SB/21 (02-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/972,287
	Filing Date	October 21, 2004
	First Named Inventor	Amr Salahieh
	Art Unit	3738
	Examiner Name	Not yet assigned
Total Number of Pages in This Submission		Attorney Docket Number 30207-702.501

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

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT	
Firm or Individual name	Maya Skubatch, Reg. No. 52,505, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	October 26, 2005

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	Frank Chen		
Signature		Date	October 26, 2005

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

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





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Amr SALAHIEH, et al.

Serial Number: 10/972,287

Filing Date: October 21, 2004

Title: LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF

Group Art Unit: 3738

Examiner: Not yet assigned

CONFIRMATION NO: 7706

Certificate of Mailing or Transmission  
37 CFR §1.8

I hereby certify that this paper is being:  deposited with the U.S. Postal Service with sufficient postage as first class mail and addressed to Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450; or  transmitted by facsimile to the Patent and Trademark Office in accordance with §1.6(d) to facsimile number on October 26, 2005.

Signature

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

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

Sir:

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

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

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

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

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

- (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
- (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;  
-- OR --
- (3) It is being filed before the mailing date of the first Office Action on the merits;  
-- OR --
- (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

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

- a certification as specified in §1.97(e) provided concurrently herewith;  
-- OR --
- a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

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

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

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

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

- Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.  
-- OR --
- Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.  
-- AND/OR --
- Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).  
-- AND/OR --
- Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

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

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

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

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

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


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

*Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 30207-702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: October 26, 2005

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

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



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

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
Examiner Name	Not yet assigned				
Sheet	1	of	5	Attorney Docket Number	30207-702.501

**U.S. PATENT DOCUMENTS**

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

Examiner Signature	Date Considered
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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

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

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				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	2	of	5	Attorney Docket Number	30207-702.501

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

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









IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Amr SALAHIEH, et al.

Serial Number: 10/972,287

Filing Date: October 21, 2004

Title: LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF

Group Art Unit: 3738

Examiner: Unassigned

CONFIRMATION NO: 7706

FILED ELECTRONICALLY ON: April 6, 2006

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

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97**

Sir:

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

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

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

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

- A.  *37 CFR §1.97(b)*. This Information Disclosure Statement should be considered by the Office because:
- (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
  - (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;  
-- OR --
  - (3) It is being filed before the mailing of a first Office action on the merits;  
-- OR --
  - (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B.  *37 CFR §1.97(c)*. Although this Information Disclosure Statement is being filed after the period specified in *37 CFR §1.97(b)*, above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- a statement as specified in §1.97(e) provided concurrently herewith;  
-- OR --
  - a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C.  *37 CFR §1.97(d)*. Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);  
-- AND --
  - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D.  *37 CFR §1.97(e)*. Statement.
- A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);  
-- AND/OR --
  - A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);  
-- AND/OR --
  - A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E.  *Statement Under 37 C.F.R. §1.704(d)*. Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

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

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

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

-- OR --

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

-- AND/OR --

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

-- AND/OR --

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

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

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

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

-- OR --

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

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

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

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

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

Application in which the information was submitted: \_\_\_\_\_

Information Disclosure Statement(s) filed on: \_\_\_\_\_

AND

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

- I.  *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207-702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: April 6, 2006

By: 

Maya Skobatch, Reg. No. 52,505

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

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

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Unassigned
Sheet	1	Of	3	Attorney Docket Number	30207-702.501

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 2005/0209580 A1	09/22/2005	Freyman	
		US 2005/0228472 A1	10/13/2005	Case et al.	
		US 2005/0251250	11/10/2005	Verhoeven et al.	
		US 2005/0251251	11/10/2005	Cribier	
		US 2005/0261759 A1	11/24/2005	Lambrecht et al.	
		US 2005/0267560 A1	12/1/2005	Bates	
		US 2005/0283231	12/22/2005	Haug, et al.	
		US 2005/0283962	12/29/2005	Boudjemline	
		US 2006/0004439	01/05/2006	Spenser et al.	
		US 2006/0004442	01/05/2006	Spenser et al.	
		US 2006/0015168	01/19/2006	Gunderson	
		US 6,042,607	03/28/2000	Williamson, IV et al.	
		US 6,953,332	10/11/2005	Kurk et al.	
		US 6,96,4673	11/15/2005	Tsugita et al.	
		US 6,974,464	12/13/2005	Quijano et al.	
		US 6,974,474	12/13/2005	Pavcnik et al.	
		US 6,974,476	12/23/2005	McGuckin, Jr. et al.	
		US 6,979,350	12/27/2005	Moll et al.	
		US 6,984,242	01/10/2006	Campbell et al.	

Examiner Signature	Date Considered
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.15 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Unassigned
Sheet	2	Of	3	Attorney Docket Number	30207-702.501

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (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 <sup>6</sup>
		EP 1156757 B1	12/07/2005	Board of Regents, The University of Texas System		
		EP 1469797 in German with English Claims	11/02/2005	Figulla, Hans-Reiner		
		EP 1576937 A2	09/21/2005	Board of Regents, The University of Texas System		
		EP 1582178 A2	510/5/2005	Board of Regents, The University of Texas System		
		EP 1582179 A2	10/05/2005	Board of Regents, The University of Texas System		
		EP 1589902 (WO 2004/066876)	08/12/2004	Ave Connaught		
		EP 1600121A1	11/30/2005	William Cook Europe ApS		
		EP 1605871 (WO 2004/082536 A1)	09/30/2004	Aortech International PLC		
		EP 1616531	01/18/2006	Boston Scientific Limited		
		WO 2005/087140 A1	09/22/2005	Percutaneous Cardiovascular Solutions PTY Ltd.		

Examiner Signature	Date Considered
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Unassigned
Sheet	3	Of	3	Attorney Docket Number	30207-702.501

UNPUBLISHED PATENT APPLICATIONS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>6</sup>
		FAWZI, et al., U.S. Patent Application No 11/155309, entitled "Apparatus and methods for intravascular embolic protection," filed 06/16/2005 (WSGR Reference No. 30207-719.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/232441, entitled "Methods and apparatus for endovascular heart valve replacement comprising tissue grasping elements," filed 09/20/2005 (WSGR Reference No. 30207-702.503)	
		SALAHIEH, et al., U.S. Patent Application No 11/232444, entitled "Methods and apparatus for endovascular heart valve replacement comprising tissue grasping elements," filed 09/20/2005 (WSGR Reference No. 30207-702.504)	
		SALAHIEH, et al., U.S. Patent Application No 11/274889, entitled "Medical implant deployment tool," filed 11/14/2005 (WSGR Reference No. 30207- 718.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/314183, entitled "Medical Device Delivery," filed 12/20/2005 (WSGR Reference No. 30207-725.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/314969, entitled "Methods And Apparatus For Performing Valvuloplasty," filed 12/20/2005 (WSGR Reference No. 30207-727.201)	

Examiner Signature	Date Considered
--------------------	-----------------

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

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

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

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	1018910
<b>Application Number:</b>	10972287
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor:</b>	Amr Salahieh
<b>Customer Number:</b>	21971
<b>Filer:</b>	Vernon A. Norviel/Frank Chen (VN/MSK/fc)
<b>Filer Authorized By:</b>	Vernon A. Norviel
<b>Attorney Docket Number:</b>	30207-702.501
<b>Receipt Date:</b>	06-APR-2006
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	20:09:09
<b>Application Type:</b>	Utility
<b>International Application Number:</b>	

### Payment information:

Submitted with Payment	no
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### File Listing:

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



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

<b>Warnings:</b>					
<b>Information:</b>					
11	Information Disclosure Statement (IDS) Filed	IDS-30207-702-501-04-06-06.pdf	341904	no	7
<b>Warnings:</b>					
<b>Information:</b>					
This is not an USPTO supplied IDS fillable form					
12	NPL Documents	US30207-719-201.pdf	1852786	no	54
<b>Warnings:</b>					
<b>Information:</b>					
13	NPL Documents	US30207-702-503.pdf	4673537	no	64
<b>Warnings:</b>					
<b>Information:</b>					
14	NPL Documents	US30207-702-504.pdf	5800562	no	66
<b>Warnings:</b>					
<b>Information:</b>					
15	NPL Documents	US30207-718-201.pdf	2074084	no	42
<b>Warnings:</b>					
<b>Information:</b>					
16	NPL Documents	US30207-725-201.pdf	1868947	no	40
<b>Warnings:</b>					
<b>Information:</b>					
17	NPL Documents	US30207-727-201.pdf	1695717	no	38
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			30832533		

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

**New Applications Under 35 U.S.C. 111**

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

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Amr SALAHIEH, et al.

Serial Number: 10/972,287

Filing Date: October 21, 2004

Title: LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF

Group Art Unit: 3738

Examiner: Unassigned

**CONFIRMATION NO: 7706**

FILED ELECTRONICALLY ON: July 12, 2006

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

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97**

Sir:

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

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

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

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

- A.  37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:
- (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
  - (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;  
-- OR --
  - (3) It is being filed before the mailing of a first Office action on the merits;  
-- OR --
  - (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B.  37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- a statement as specified in §1.97(e) provided concurrently herewith;  
-- OR --
  - a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C.  37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);  
-- AND --
  - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D.  37 CFR §1.97(e). Statement.
- A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);  
-- AND/OR --
  - A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);  
-- AND/OR --
  - A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E.  Statement Under 37 C.F.R. §1.704(d). Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

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

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

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

-- OR --

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

-- AND/OR --

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

-- AND/OR --

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

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

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

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

-- OR --

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

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

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

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

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

Application in which the information was submitted: \_\_\_\_\_

Information Disclosure Statement(s) filed on: \_\_\_\_\_

AND


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

- I.  *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207-702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: July 12, 2006 \_\_\_\_\_

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

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

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

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
Examiner Name	Unassigned	Attorney Docket Number	30207-702.501		
Sheet	1	Of	2		

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 2005/0137695	06/23/2005	Salahieh et al.	
		US 3,657,744	04/25/1972	Ersek	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (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 <sup>6</sup>
		EP 0409929 B1	04/23/1997	Boston Scientific Corp.		
		WO 96/24306 A1 (in French with English abstract)	08/15/1996	De Fays, Robert		
		WO 98/57599 A2	12/23/1998	Camilli, Sante		

Examiner Signature	Date Considered
--------------------	-----------------

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

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

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



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

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Unassigned
Sheet	2	Of	2	Attorney Docket Number	30207-702.501

UNPUBLISHED PATENT APPLICATIONS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>6</sup>
		SALAHIEH, et al., U.S. Patent Application No. 11/275,912, entitled "Medical Implant Delivery and Deployment Tool," filed 02/02/2006 (WSGR Reference No. 30207-722.501)	
		SALAHIEH, et al., U.S. Patent Application No. 11/275,913, entitled "Two-Part Package for Medical Implant," filed 02/02/2006 (WSGR Reference No. 30207-723.201)	

Examiner Signature	Date Considered
-----------------------	--------------------

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

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

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

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	1111048
<b>Application Number:</b>	10972287
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor:</b>	Amr Salahieh
<b>Customer Number:</b>	21971
<b>Filer:</b>	Vernon A. Norviel/Frank Chen (VN/MSK/FC)
<b>Filer Authorized By:</b>	Vernon A. Norviel
<b>Attorney Docket Number:</b>	30207-702.501
<b>Receipt Date:</b>	12-JUL-2006
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	20:07:53
<b>Application Type:</b>	Utility
<b>International Application Number:</b>	

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part	Pages
1	Information Disclosure Statement (IDS) Filed	IDS30207-702-501-07-12-06.pdf	268020	no	6

<b>Warnings:</b>					
<b>Information:</b>					
This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	EP04.PDF	1025699	no	15
<b>Warnings:</b>					
<b>Information:</b>					
3	Foreign Reference	WO96.PDF	1127284	no	34
<b>Warnings:</b>					
<b>Information:</b>					
4	Foreign Reference	WO98.PDF	885222	no	24
<b>Warnings:</b>					
<b>Information:</b>					
5	NPL Documents	722-501.PDF	2359623	no	36
<b>Warnings:</b>					
<b>Information:</b>					
6	NPL Documents	723-201.PDF	1332786	no	33
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			6998634		
<p>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.</p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  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.</p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  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.</p>					

02-01-07

JFW



PATENT WSGR Docket No. 30207-702.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:
Inventor: Amr Salahieh
Application No.: 10/972,287
Filed: October 21, 2004
Title: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF

Confirmation No.: 7706
Examiner: Unassigned
Group Art Unit: 3738
Customer No. 021971

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

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

I hereby appoint the practitioners associated with Customer Number: 66854

Please change the correspondence address for the above-identifies application to: The address associated with Customer Number: 66854

STATEMENT UNDER 37 CFR 3.73(b)

Sadra Medical, Inc. a Delaware corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is: the assignee of the entire right, title and interest; in the patent application/patent identified above by virtue of either:

An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 016315, Frame 0771, or for which a copy thereof is attached.

OR

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

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

I am an authorized representative of the:

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

SIGNATURE of Assignee of Record

Signature

Name/Title Amr Salahieh, CEO

Date 1/29/2007

Telephone No. (408) 370-1550


**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/972,287	10/21/2004	Amr Salahieh	30207-702.501

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

**CONFIRMATION NO. 7706**



Date Mailed: 02/12/2007

**NOTICE REGARDING CHANGE OF POWER OF ATTORNEY**

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

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

---


  
 SHARON KUANG  
 PTOSS (703) 305-3006

OFFICE COPY


**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/972,287	10/21/2004	Amr Salahieh	30207-702.501

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

**CONFIRMATION NO. 7706**



\*OC000000022469927\*

Date Mailed: 02/12/2007

**NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY**

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

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




---

 SHARON KUANG  
 PTOSS (703) 305-3006

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*JPL*

<b>TRANSMITTAL FORM</b> <small>(to be used for all correspondence after initial filing)</small>	Application Number	10/972,287	
	Filing Date	October 21, 2004	
	First Named Inventor	Amr Salahieh	
	Art Unit	3738	
	Examiner Name	William H. Matthews	
Total Number of Pages in This Submission	6	Attorney Docket Number	10012-702.501

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
<div style="border: 1px solid black; padding: 2px; display: inline-block;">Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm	Shay Law Group LLP		
Signature			
Printed Name	Thomas Zlogar		
Date	3/15/07	Reg. No.	55,760

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Signature			
Typed or printed name	Angelica Zuniga	Date	3/15/07

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 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.



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application: 10/972,287  
Inventors: Amr Salahieh  
Filed: October 21, 2004  
Title: **LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF**

Confirmation No.: 7706  
Examiner: William H. Matthews  
Group Art Unit: 3738

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

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

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



**FILING OF INFORMATION DISCLOSURE STATEMENT**

- 37 CFR §1.97(b)**  
This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:
- 1). Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d),
  - 2). Within 3 months of entry of a national stage as set forth in § 1.491,
  - 3). Before the mail date of a first Office Action on the merits,
  - 4). Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.
- 37 CFR § 1.97(c)**  
This statement is being filed after the latest of:
- 1). Three months beyond the filing date of a national application,
  - 2). Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application,
  - 3). The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
    - A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement
    - B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.
- 37 CFR § 1.97(d)**  
This statement is being filed after the mailing date of the earlier of a Final Office action or a Notice of Allowance under § 1.311, but before payment of the issue fee, and then:
- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement
  - AND--
  - B). A certification as specified in § 1.97(e) is included below.

**CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER  
37 CFR § 1.98**

- 37 CFR §1.98 (a)(2)(ii) U.S. patents or patent application publication(s) cited**
- 1). Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
  - 2). At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:
- 37 CFR §1.98 (a)(2)(iii) Pending unpublished U.S. applications cited**  
A copy of each application specification including the claim(s), and any drawing of the application, or that portion of the application that caused it to be listed, including any claims directed to that portion, is attached.
- 37 CFR §1.98 (a)(2)(iii) English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**  
A legible copy of each publication or that portion which caused it to be listed is attached.
- 37 CFR §1.98 (a)(2)(i) Foreign patent(s) in English cited**  
A legible copy of each foreign patent is attached.

- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) Foreign patent(s) or other foreign documents not in English cited
- 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached,
- AND--
- 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:
- OR--
- 2b). A copy of the translation of a written English-language translation, or portion thereof, is readily available and is attached.

**STATEMENT UNDER 37 CFR § 1.97(e)**


- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

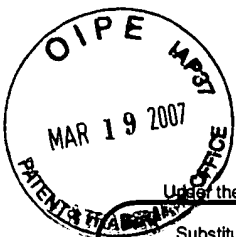
**FEE AUTHORIZATION**

- The Commissioner is hereby authorized to charge the above-referenced fees of \$00.0 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 3/15/07  
Shay Law Group  
2755 Campus Drive, Suite 210  
San Mateo, CA 94403  
(650) 212-1700  
Customer No. 66854

By:   
Thomas Zlogar Reg. # 55760



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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

of 2

### Complete if Known

Application Number	10/972,287
Filing Date	October 21, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket Number	10012-702.501

### U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	366	US- 2003/0233117-A1	12/18/2003	Adams et al.	
	364	US- 2004/0153094-A1	08/05/2004	Dunfee et al.	
	367	US- 2005/0107822-A1	05/19/2005	WasDyke, Joel	
	368	US- 6,610,077	08/26/2003	Hancock et al.	
	369	US- 6,790,229	09/14/2004	Berrekouw, Eric	
	365	US- 6,969,395	11/29/2005	Eskuri et al.	
	363	US- 6,361,545	03/26/2002	Macoviak et al.	
	142	US- 5,064,435	11/12/1991	Porter	
	262	US- 6,712,843	03/30/2004	Elliott	
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### FOREIGN PATENT DOCUMENTS

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

Examiner Signature	Date Considered
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\*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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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

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

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>			
				Application Number	10/972,287		
				Filing Date	October 21, 2004		
				First Named Inventor	Amr Salahieh		
				Art Unit	3738		
				Examiner Name	William H. Matthews		
Sheet	2	of	2	Attorney Docket Number	10012-702.501		

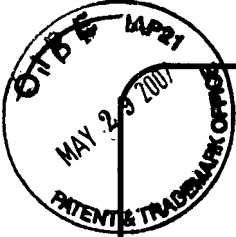
NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	305	SALAHIEH, et al., U.S. Patent App. 11/531,980, "Externally expandable heart valve anchor and method," filed 09/14/2006 SLG Ref 10012-703.301(formerly 30207-703.301)	
	306	SALAHIEH, et al., U.S. Patent 11/532,019, "Methods and apparatus for endovascularly replacing heart valve," filed 09/14/2006 SLG Ref 10012-703.302(formerly 30207-703.302)	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.  
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IFW



# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number		10/972,287
Filing Date		October 21, 2004
First Named Inventor		Amr Salahieh
Art Unit		3738
Examiner Name		William H. Matthews
Total Number of Pages in This Submission	5	Attorney Docket Number
		10012-702.501

### ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) ____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Postcard
<div style="border: 1px solid black; padding: 2px;">Remarks</div>		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm	Shay Law Group LLP		
Signature			
Printed Name	Thomas Zlogar		
Date	5/24/07	Reg. No.	55,760

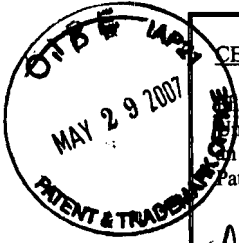
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Signature		Date	05/29/07
Typed or printed name	Angelica Zuniga		

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



**CERTIFICATE OF MAILING UNDER 37 CFR 1.8**

Whereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: MailStop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

Date 05/29/07 Angelica Zuniga  
 Date Angelica Zuniga

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application: 10/972,287  
 Inventors: Amr Salahieh  
 Filed: October 21, 2004  
 Title: **LEAFLET ENGAGEMENT ELEMENTS  
 AND METHODS FOR USE THEREOF**

Confirmation No.: **7706**  
 Examiner: William H. Matthews  
 Group Art Unit: 3738

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

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

**FILING OF INFORMATION DISCLOSURE STATEMENT** **37 CFR §1.97(b)**

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

- 1). Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d),
- 2). Within 3 months of entry of a national stage as set forth in § 1.491,
- 3). Before the mail date of a first Office Action on the merits,
- 4). Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

 **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

- 1). Three months beyond the filing date of a national application,
- 2). Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application,
- 3). The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement
- B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

 **37 CFR § 1.97(d)**

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

- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement
- AND--
- B). A certification as specified in § 1.97(e) is included below.

**CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER**  
**37 CFR § 1.98** **37 CFR §1.98 (a)(2)(ii) U.S. patents or patent application publication(s) cited**

- 1). Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
- 2). At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

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

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

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

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

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

A legible copy of each foreign patent is attached.

- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) Foreign patent(s) or other foreign documents not in English cited
- 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached,
- AND--
- 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:
- OR--
- 2b). A copy of the translation of a written English-language translation, or portion thereof, is readily available and is attached.

**STATEMENT UNDER 37 CFR § 1.97(e)**


- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

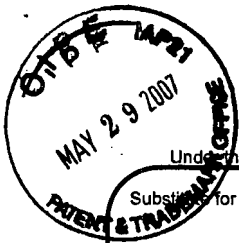
- The Commissioner is hereby authorized to charge the above-referenced fees of \$00.0 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Dated: 5/24/07  
Shay Law Group  
2755 Campus Drive, Suite 210  
San Mateo, CA 94403  
(650) 212-1700  
Customer No. 66854

Respectfully Submitted,

By:   
Thomas Zlogar Reg. # 55760





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.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete If Known</b>	
		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
		Examiner Name	William H. Matthews
Sheet 1	of 1	Attorney Docket Number	10012-702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
	374	Haug, et al; U.S. Pat App. # 11/716,123, entitled "Methods and apparatus for endovascularly replacing a heart valve," filed 3/9/2007 (SLG #10012-701.301).	
	372	SALAHIEH, et al; U.S. Pat App. # 11/706,549, entitled "Systems and Methods for Delivering a Medical Implant," filed 2/14/2007 (SLG #10012-732.201).	
	373	Salahieh, et al; U.S. Pat App. # 11/732,906 entitled "Assessing the location and performance of replacement heart valves," filed 4/4/2007 (SLG #10012-702.505).	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.  
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**JUL 12 2007**

PTO/SB/21 (04-07)

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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>	Application Number	10/972,287
	Filing Date	October 21, 2004
	First Named Inventor	Amr Salahieh
	Art Unit	3738
	Examiner Name	MATTHEWS, WILLIAM H
(to be used for all correspondence after initial filing)		
Total Number of Pages in This Submission	5	Attorney Docket Number 10012-702.501

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Shaw Law Group LLP		
Signature			
Printed name	Thomas Zlogar		
Date	7/12/07	Reg. No.	55,760

CERTIFICATE OF TRANSMISSION/MAILING	
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:	
Signature	
Typed or printed name	Angelica Zuniga
Date	07/12/07

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Docket No.10012-702.501

<b>CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8</b>	
I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at Fax No. 571.273.8300 on	
07/12/07 Date	Angelica Zuniga Angelica Zuniga

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JUL 12 2007

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application: 10/972,287  
Inventors: Amr Salahieh  
Filed: October 21, 2004  
Title: **LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF**

Confirmation No.: 7706  
Examiner: MATTHEWS, WILLIAM H  
Group Art Unit: 3738

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

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

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

Docket No.10012-702.501

**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), and any drawing of the application, or that portion of the application that caused it to be listed, including any claims directed to that portion, is attached.
  - 2). A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
- 37 CFR §1.98 (a)(2)(III) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**
- 1). A legible copy of each publication or that portion which caused it to be listed is attached.
  - 2). A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

Docket No.10012-702.501

- 37 CFR §1.98 (a)(2)(I) and (d), Foreign patent(s) in English cited
  - 1). A legible copy of each foreign patent is attached.
  - 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  
- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:
  - 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached --AND--
  
  - 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith: --OR--
  
  - 2b). A copy of a written, English-language translation or portion thereof is readily available and attached, --OR--
  
  - 2c). An English language copy of a foreign search report is submitted. --OR--
  
  - 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

**STATEMENT UNDER 37 CFR § 1.97(e)**

- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
  
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

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

Respectfully Submitted,



By: Thomas Zlogar Reg. # 55760

Dated: 7/12/07  
Shay Law Group  
2755 Campus Drive, Suite 210  
San Mateo, CA 94403  
(650) 212-1700  
Customer No. 66854

JUL 12 2007

PTO/SB/08A (04-07)

Approved for use through 09/30/2007. OMB 0851-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
		Examiner Name	MATTHEWS, WILLIAM H
Sheet <b>1</b>	of <b>1</b>	Attorney Docket Number	10012-702.501

U. S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)				
	375	US-	US 5,824,041 A	10/20/1998	Lenker, et al.	
	376	US-	US 6,863,868	03/08/2005	Gillespie et al.	
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FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)					

Examiner Signature		Date Considered	
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\*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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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

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



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PTO/SB/21 (04-07)

Approved for use through 09/30/2007. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/972,287	
	Filing Date	October 21, 2004	
	First Named Inventor	Amr Salahieh	
	Art Unit	3774	
	Examiner Name	MATTHEWS, WILLIAM H	
Total Number of Pages in This Submission	5	Attorney Docket Number	10012-702.501

ENCLOSURES <i>(Check all that apply)</i>		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	Postcard
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Shay Glenn LLP		
Signature			
Printed name	Thomas Zlogar		
Date	11/16/07	Reg. No.	55,760

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature			
Typed or printed name	Angelica Zuniga	Date	11/16/07

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

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11/19/07 A. Zuniga  
Date Angelica Zuniga

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 10/972,287 Confirmation No.: 7706  
 Applicant(s): Amr Salahieh  
 Filed: October 21, 2004  
 Art Unit: 3774  
 Examiner: MATTHEWS, WILLIAM H  
 Title: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE  
 THEREOF  
 Customer No.: 66854

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**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), and any drawing of the application, or that portion of the application that caused it to be listed, including any claims directed to that portion, is attached.
  - 2). A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
- 37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**
- 1). A legible copy of each publication or that portion which caused it to be listed is attached.
  - 2). A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

- 37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited
  - 1). A legible copy of each foreign patent or that portion which caused it to be listed is attached.
  - 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  
- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:
  - 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached --AND--
  - 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith: --OR--
  - 2b). A copy of a written, English-language translation or portion thereof is readily available and attached, --OR--
  - 2c). An English language copy of a foreign search report is submitted. --OR--
  - 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

**STATEMENT UNDER 37 CFR § 1.97(e)**


- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

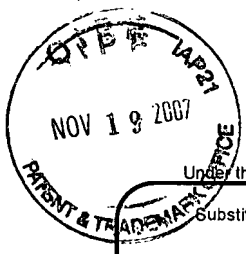
- The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 11/16/07

By:   
Thomas Zlogar Reg. # 55760

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



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

Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

of 1

## Complete if Known

Application Number	10/972,287
Filing Date	October 21, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	MATTHEWS, WILLIAM H
Attorney Docket Number	10012-702.501

### U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	380	US- 5,720,391 A	2/24/1998	Dohm et al.	
	377	US- 6,712,842	3/30/2004	Gifford et al.	
	384	US- 7,018,406	3/28/2006	Seguin et al.	
	381	US- 2001/0044656 A1	11/22/2001	Williamson et al.	
	382	US- 2002/0032481 A1	3/14/2002	Gabbay, Shlomo	
	379	US- 2002/0120328 A1	8/29/2002	Pathak et al.	
	378	US- 2004/0215331	10/28/2004	Chew et al.	
	383	US- 2006/0259134 A1	11/16/2006	Schwammenthal et al.	
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### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	385	WO 02/0041789 A2	5/30/2002	Rex Medical, L. P.		

Examiner Signature	Date Considered
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\*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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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

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

VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/972,287 Confirmation No.: 7706  
Applicant(s): Amr Salahieh  
Filed: October 21, 2004  
Art Unit: 3774  
Examiner: MATTHEWS, WILLIAM H  
Title: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE  
THEREOF  
Customer No.: 66854

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**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), 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,



By: \_\_\_\_\_  
Thomas Zlogar Reg. # 55760

Dated: 2/14/08

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

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

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		<b>Complete if Known</b>	
Sheet	1	of	1
		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3774
		Examiner Name	MATTHEWS, WILLIAM H
		Attorney Docket Number	10012-702.501

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	394	US- 5,443,499	08/22/1995	Schmitt, Peter	
	395	US- 5,824,055	10/20/1998	Spiridigliozzi et al.	
	396	US- 6,893,459 B1	05/17/2005	Macoviak, John	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

Examiner Signature	Date Considered	
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\*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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	2862754
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	Thomas M. Zlogar/Angelica Zuniga
<b>Filer Authorized By:</b>	Thomas M. Zlogar
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	14-FEB-2008
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	17:18:05
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-702501.pdf	225675 <small>04d75087e8eb7d2acf7ead75612a458d93e2c9a3</small>	yes	4



<b>Multipart Description/PDF files in .zip description</b>			
<b>Document Description</b>		<b>Start</b>	<b>End</b>
Information Disclosure Statement Letter		1	3
Information Disclosure Statement (IDS) Filed		4	4

**Warnings:**

**Information:**

<b>Total Files Size (in bytes):</b>	225675
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**This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.**

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004	Amr Salahieh	10012-702.501	7706
66854	7590	03/19/2008	EXAMINER	
SHAY GLENN LLP 2755 CAMPUS DRIVE SUITE 210 SAN MATEO, CA 94403			WALKER, AMANDA H	
			ART UNIT	PAPER NUMBER
			3774	
			MAIL DATE	DELIVERY MODE
			03/19/2008	PAPER

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

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

<b>Office Action Summary</b>	<b>Application No.</b> 10/972,287	<b>Applicant(s)</b> SALAHIEH ET AL.	
	<b>Examiner</b> AMANDA H. WALKER	<b>Art Unit</b> 3774	

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

**Period for Reply**

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

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

**Status**

- 1)  Responsive to communication(s) filed on 21 October 2004.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-58 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) 1-58 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) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

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

- I. Claims 1-21 and 36-58 drawn to an apparatus for performing a heart valve replacement, classified in class 623, subclass 2.11.
- II. Claims 22-35, drawn to a method for performing a heart valve replacement, classified in class 623, subclass 2.11.

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

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus could be used in a different method, such as an open heart surgery instead of an endovascular surgery.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

Art Unit: 3774

- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve 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 restriction 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 invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions 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 inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 3774

This application contains claims directed to the following patentably distinct species relating to leaflet engagement element positions: Species A1 regarding leaflets that are attached to the delivery system (see FIGS. 6A-F) and Species A2 regarding leaflets that are attached to the anchor (see FIG. 7). The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

In addition, this application contains claims directed to the following patentably distinct species relating to the anchor seal: Species B1 regarding a seal that covers only the distal portion of the anchor (FIGS. 9a-b) and Species B2 regarding a seal that covers the entire anchor (FIGS. 10a-b). The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such 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 one of species A1 or A2, as well as one of Species B1 or B2 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims appear to be generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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

Art Unit: 3774

**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 of the species 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.

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

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

A telephone call was made to Thomas Zlogar on 3-6-08 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 amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 3774

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA H. WALKER whose telephone number is (571)270-3296. The examiner can normally be reached on 8-5, M-Th, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

/Alvin J Stewart/  
Primary Examiner, Art Unit 3774

AHW  
3-10-08




**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. 7706**

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
10/972,287	10/21/2004	623	3774	10012-702.501		
<b>APPLICANTS</b>						
Amr Salahieh, Saratoga, CA; Brian D. Brandt, Santa Clara, CA; Robert A. Gleslider, San Francisco, CA; Dwight P. Morejohn, Davis, CA; Tom Saul, El Granada, CA;						
** <b>CONTINUING DATA</b> ***** This application is a CIP of 10/746,240 12/23/2003 ABN						
** <b>FOREIGN APPLICATIONS</b> *****						
** <b>IF REQUIRED, FOREIGN FILING LICENSE GRANTED</b> *** SMALL ENTITY ** 01/10/2005						
Foreign Priority claimed 35 USC 119(a-d) conditions met Verified and Acknowledged	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  /AMANDA H WALKER/ Examiner's Signature	<input type="checkbox"/> Met after Allowance AHW  Initials	<b>STATE OR COUNTRY</b>  CA	<b>SHEETS DRAWINGS</b>  27	<b>TOTAL CLAIMS</b>  58	<b>INDEPENDENT CLAIMS</b>  3
<b>ADDRESS</b>						
SHAY GLENN LLP 2755 CAMPUS DRIVE SUITE 210 SAN MATEO, CA 94403 UNITED STATES						
<b>TITLE</b>						
Leaflet engagement elements and methods for use thereof						
<b>FILING FEE RECEIVED</b> 1410	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit			

FILED VIA EFS ON APRIL 21, 2008

Attorney Docket No. 10012-702.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/972,287 Confirmation No.: 7706  
Applicant : Amr SALAHIEH et al.  
Filing Date : October 21, 2004  
Title : Leaflet Engagement Elements and Methods for Use Thereof  
Group Art Unit : 3774  
Examiner : Amanda H. WALKER  
Docket No. : 10012-702.501  
Customer No. : 66854

**RESPONSE TO RESTRICTION REQUIREMENT**

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

This communication is in response to the Office Action dated March 19, 2008, for which a reply is due April 19 (Saturday) or April 21, 2008.

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

**Amendments to the Specification** are not being made.

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

**Remarks / Arguments** begin on page 10 of this paper.

### **Amendments to the Claims / Claim Listing**

A complete listing of the claims follows:

1. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage leaflets of the patient's heart valve.
2. (Withdrawn) The apparatus of claim 1 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.
3. (Withdrawn) The apparatus of claim 1 wherein the anchor is further adapted to be actively foreshortened during deployment.
4. (Withdrawn) The apparatus of claim 3 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.
5. (Withdrawn) The apparatus of claim 3 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.
6. (Withdrawn) The apparatus of claim 3 further comprising a lock adapted to lock the anchor in a deployed shape.
7. (Withdrawn) The apparatus of claim 1 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.
8. (Withdrawn) The apparatus of claim 1 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.

9. (Withdrawn) The apparatus of claim 1 wherein the leaflet engagement elements are integral with the anchor.

10. (Withdrawn) The apparatus of claim 9 wherein the anchor comprises a braid, the leaflet engagement elements being part of the braid.

11. (Withdrawn) The apparatus of claim 1 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow to the chamber of the heart through the replacement valve during deployment of the anchor and replacement valve.

12. (Withdrawn) The apparatus of claim 1 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

13. (Withdrawn) The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter but before the anchor completely exits the catheter.

14. (Withdrawn) The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor.

15. (Withdrawn) The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

16. (Withdrawn) The apparatus of claim 12 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

17. (Withdrawn) The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

18. (Withdrawn) The apparatus of claim 12 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

19. (Withdrawn) The apparatus of claim 1 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

20. (Withdrawn) The apparatus of claim 19 wherein the seal comprises a pleated seal.

21. (Withdrawn) The apparatus of claim 19 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

22. (Original) A method for endovascularly replacing a patient's heart valve, the method comprising:

endovascularly delivering an anchor and a replacement valve supported within the anchor to a vicinity of the heart valve in a collapsed delivery configuration, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage native valve leaflets;

expanding the anchor; and  
engaging the leaflet engagement elements with native valve leaflets.

23. (Original) The method of claim 22 further comprising expanding the anchor into engagement with the patient's heart such that the anchor is substantially distal to coronary ostia of the heart.

24. (Original) The method of claim 23 wherein the expanding step comprises actively foreshortening the anchor.

25. (Original) The method of claim 24 wherein the actively foreshortening step comprises actuating distal anchor actuation elements.

26. (Original) The method of claim 24 wherein the actively foreshortening step comprises actuating proximal anchor actuation elements.

27. (Original) The method of claim 24 further comprising locking the anchor in a deployed configuration.

28. (Original) The method of claim 22 further comprising resisting distal movement of the proximal end of the anchor after the engaging step.

29. (Original) The method of claim 22 further comprising moving the leaflet engagement elements further apart radially during the anchor expanding step.

30. (Original) The method of claim 22 further comprising permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve during deployment of the anchor and replacement valve.

31. (Original) The method of claim 22 further comprising:

delivering the anchor and replacement valve to a vicinity of the heart in a delivery catheter;

removing the anchor and the replacement valve from the catheter; and

permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

32. (Original) The method of claim 31 wherein the permitting and preventing steps are performed before the anchor completely exits the catheter.

33. (Original) The method of claim 31 wherein the permitting step comprises allowing the anchor to self-expand.

34. (Original) The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

35. (Original) The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

36. (Original) The method of claim 22 further comprising sealing between the replacement valve and the heart.

37. (Original) The method of claim 36 wherein the sealing step comprises pleating a seal.

38. (Withdrawn) The method of claim 36 wherein the sealing step comprises capturing at least a portion of a seal between the leaflets and a wall of the heart.

39. (Withdrawn) Apparatus for endovascularly replacing a patient's heart valve, the apparatus comprising an expandable anchor supporting a replacement valve, the anchor and replacement valve being adapted for percutaneous delivery and deployment to replace the patient's heart valve, the anchor comprising a braid, the braid comprising leaflet engagement elements adapted to engage leaflets of the patient's heart valve.

40. (Withdrawn) The apparatus of claim 39 wherein the leaflet engagement elements extend from a proximal end of the anchor.

41. (Withdrawn) The apparatus of claim 39 wherein the anchor is further adapted to be substantially distal to coronary ostia of the patient when the anchor is fully deployed.

42. (Withdrawn) The apparatus of claim 39 wherein the anchor is further adapted to be actively foreshortened during deployment.

43. (Withdrawn) The apparatus of claim 42 further comprising proximal anchor actuation elements adapted to apply an actuation force on a proximal portion of the anchor.

44. (Withdrawn) The apparatus of claim 42 further comprising distal anchor actuation elements adapted to apply an actuation force on a distal portion of the anchor.

45. (Withdrawn) The apparatus of claim 42 further comprising a lock adapted to lock the anchor in a deployed shape.

46. (Withdrawn) The apparatus of claim 40 wherein the proximal end of the anchor is adapted to resist distal movement during expansion of the anchor after engagement of the valve leaflets by the engagement elements.

47. (Withdrawn) The apparatus of claim 40 wherein the leaflet engagement elements are adapted to move radially apart as the anchor expands.



48. (Withdrawn) The apparatus of claim 40 wherein the anchor and the replacement valve are further adapted to permit blood flow from a chamber of the heart through the replacement valve and to prevent blood flow through the replacement valve during deployment of the anchor and replacement valve.

49. (Withdrawn) The apparatus of claim 40 further comprising a delivery catheter adapted to deliver the anchor and replacement valve to a vicinity of the heart, wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.

50. (Withdrawn) The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and to prevent blood backflow through the replacement valve after the replacement valve exits the catheter and before the anchor completely exits the catheter.

51. (Withdrawn) The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor.

52. (Withdrawn) The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration.

53. (Withdrawn) The apparatus of claim 49 wherein the anchor comprises a self-expanding anchor having a delivery configuration, an at-rest configuration and a deployed configuration, the at-rest configuration having a diameter larger than a diameter of the delivery configuration and smaller than a diameter of the deployed configuration.

54. (Withdrawn) The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.

55. (Withdrawn) The apparatus of claim 49 wherein the anchor and the replacement valve are further adapted to permit blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

56. (Withdrawn) The apparatus of claim 40 further comprising a seal adapted to prevent blood flow around the replacement valve when the anchor and replacement valve are fully deployed.

57. (Withdrawn) The apparatus of claim 56 wherein the seal comprises a pleated seal.

58. (Withdrawn) The apparatus of claim 56 wherein at least a portion of the seal is adapted to be captured between the leaflets of the patient's heart valve and a wall of the patient's heart when the anchor and replacement valve are fully deployed.

## REMARKS

### Claim Summary

Claims 1-58 are pending. Claims 1-21, 38-58 have been withdrawn.

### Restriction Requirement

The Examiner is requiring restriction to one of the following allegedly distinct inventions:

Claim 1-21 and 36-58, drawn to an apparatus for performing a heart valve replacement;  
and

Claims 22-35, drawn to a method for performing a heart valve replacement.

Claims 36-38 are method claims so it appears the Examiner's method group should be claims 22-38 (not 22-35). Applicants therefore elect the method claims 22-38.

The Examiner is requiring election between the following allegedly patentably distinct species:

Species A1 regarding leaflet engagement elements that are attached to the delivery system (see Figs. 6A-F); and

Species A2 regarding leaflet engagement elements that are attached to the anchor (see Fig. 7).

Applicants elect Species A2 but traverse the election requirement. Claims 22-38 read on the elected Species A2. Applicants traverse the election requirement because independent claim 22, on which claims 23-38 depend, requires "the anchor comprising leaflet engagement elements *on a proximal end of the anchor.*" None of claims 22-38 are mutually exclusive to the Examiner's Species A1. The election requirement is therefore improper and Applicants respectfully request the election requirement be withdrawn.

The Examiner is also requesting an election between the following two allegedly patentably distinct species relating to the anchor seal:

Species B1 regarding a seal that covers a distal portion of the anchor (Figs. 9A-B); and

Species B2 regarding a seal that covers the entire anchor (Figs. 10A-B).

Applicants elect Species B1. Claims 22-37 read on the elected Species B1. Claims 22-31 and 33-37 are generic to Species B1 and Species B2.

**CONCLUSION**

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

Respectfully submitted,



Date: April 21, 2008

By:

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

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

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	3185572
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	Thomas M. Zlogar/Sue Bromaghim
<b>Filer Authorized By:</b>	Thomas M. Zlogar
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	21-APR-2008
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	18:20:00
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-702-501-Response-R restriction.pdf	1016354 <small>3253d7e0a54a13e1e8eb70eed354393 6ec8b4f50</small>	yes	11

<b>Multipart Description/PDF files in .zip description</b>			
<b>Document Description</b>		<b>Start</b>	<b>End</b>
Response to Election / Restriction Filed		1	1
Claims		2	9
Applicant Arguments/Remarks Made in an Amendment		10	11

**Warnings:**

**Information:**

**Total Files Size (in bytes):**

1016354

**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.**

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.

<b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875	Application or Docket Number <b>10/972,287</b>	Filing Date <b>10/21/2004</b>	<input type="checkbox"/> To be Mailed
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APPLICATION AS FILED – PART I			OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	SMALL ENTITY <input checked="" type="checkbox"/>	OR			
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A	N/A			N/A	
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>	minus 20 =	*	X \$ =		OR	X \$ =	
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	minus 3 =	*	X \$ =			X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	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).						
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II					OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	(Column 3)		SMALL ENTITY	OR			
AMENDMENT	04/21/2008	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(i))</small>	* 58	Minus ** 58	= 0	X \$25 =	0		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>	* 3	Minus *** 3	= 0	X \$105 =	0		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>						OR		
					TOTAL ADD'L FEE	0		TOTAL ADD'L FEE	

	(Column 1)	(Column 2)	(Column 3)		SMALL ENTITY	OR			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(i))</small>	*	Minus **	=	X \$ =			X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus ***	=	X \$ =			X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>						OR		
					TOTAL ADD'L FEE			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".

Legal Instrument Examiner:  
 /CORALIA BETANCOURT/

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.

VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/972,287 Confirmation No.: 7706  
Applicant(s): Amr Salahieh  
Filed: October 21, 2004  
Art Unit: 3774  
Examiner: WALKER, AMANDA H  
Title: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE  
THEREOF  
Customer No.: 66854

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**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), and any drawing, or that portion of the application that caused it to be listed, is attached.
  - 2). A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  - 3). A copy of each application specification is not submitted because the application is stored in the IFW.
- 37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**
  - 1). A legible copy of each publication or that portion which caused it to be listed is attached.
  - 2). A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

- 37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited
  - 1). A legible copy of each foreign patent or that portion which caused it to be listed is attached.
  - 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  
- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:
  - 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached --AND--
  
  - 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith: --OR--
  
  - 2b). A copy of a written, English-language translation or portion thereof is readily available and attached, --OR--
  
  - 2c). An English language copy of a foreign search report is submitted. --OR--
  
  - 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

**STATEMENT UNDER 37 CFR § 1.97(e)**

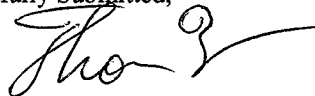
- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
  
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

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

Respectfully Submitted,

Dated: 6/9/08

By:   
Thomas Zlogar Reg. # 55760

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





## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	3435195
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	Thomas M. Zlogar/Angelica Zuniga
<b>Filer Authorized By:</b>	Thomas M. Zlogar
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	10-JUN-2008
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	22:58:05
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-702501.pdf	288035 <small>8fab94635aa7b804efa8c304837af1e2 2a73815</small>	yes	5

Multipart Description/PDF files in .zip description			
	Document Description	Start	End
	Information Disclosure Statement Letter	1	3
	Information Disclosure Statement (IDS) Filed	4	5

**Warnings:**

**Information:**

<b>Total Files Size (in bytes):</b>	288035
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**This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.**

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004	Amr Salahieh	10012-702.501	7706
66854	7590	08/20/2008	EXAMINER	
SHAY GLENN LLP 2755 CAMPUS DRIVE SUITE 210 SAN MATEO, CA 94403			STRASZHEIM, REBECCA L	
			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			08/20/2008	PAPER

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

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

**Office Action Summary**

<b>Application No.</b> 10/972,287	<b>Applicant(s)</b> SALAHIEH ET AL.	
<b>Examiner</b> REBECCA STRASZHEIM	<b>Art Unit</b> 3738	

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

**Period for Reply**

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

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

**Status**

- 1)  Responsive to communication(s) filed on 4/21/2008.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-58 is/are pending in the application.  
4a) Of the above claim(s) 1-21 and 38-58 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 22-37 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 21 October 2004 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 6/10/2008, 2/14/2008, 11/19/2007, 7/12/2007, 5/29/2007, 3/19/2007, 7/12/2006, 4/6/2006, 10/28/2005, 6/30/2005, 4/27/2005, 2/22/2005, 11/26/2004.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_





## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group II, Species B1 in the reply filed on 4/21/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicant's election with traverse of Species A2 (Fig. 7) in the reply filed on 4/21/2008 is acknowledged. The traversal is on the ground(s) that none of the elected claims 22-37 are mutually exclusive to Examiner's Species A1 or A2. This is not found persuasive because claims to the different species recite mutually exclusive characteristics of such species and the species are not obvious variants of each other based on applicant disclosure. In the election between Species A1 and A2 the leaflet engaging elements are attached to different apparatuses.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-21 and 38-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

### ***Information Disclosure Statement***

4. The information disclosure statements filed 6/10/2008, 7/12/2006, 4/27/2005, 11/26/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which

caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Drawings***

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- a. Fig. 1B: 106, 120, 122, 124
- b. Fig. 4C: 30
- c. Fig. 4D: 30
- d. Fig. 4G: 30
- e. Fig. 4H: 30
- f. Fig. 4K: 30
- g. Fig. 5C: 30
- h. Fig. 6B: 32, 40, 60, 61A
- i. Fig. 6C: 32, 61B
- j. Fig. 6F: 30, 50, 60, 61A
- k. Fig. 8C: 55
- l. Fig. 10B: 50
- m. Fig. 14C: 380

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version

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of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

- n. Fig. 1A:20
- o. Fig. 1B: 108, 112, 110, 100, 31
- p. Fig. 2: 31
- q. Fig. 4A: 30, W
- r. Fig. 4B: 31, Tu, W
- s. Fig. 4C: 31, Tu
- t. Fig. 4D: 31, Tu, W
- u. Fig. 4E: 31, Tu, W
- v. Fig. 4F: 31, Tu
- w. Fig. 4G: 31, Tu, W
- x. Fig. 4H: 31, W
- y. Fig. 4I: 31, Tu, W
- z. Fig. 4J: 31, Tu, W

- aa. Fig. 4K: 31, Tu, W
- bb. Fig. 4L: 31, Tu, W
- cc. Fig. 4M: 31, Tu, W
- dd. Fig. 4N: 31, Tu, W
- ee. Fig. 5A: 31
- ff. Fig. 5C: 31
- gg. Fig. 5D: Tu
- hh. Fig. 5E: Tu
- ii. Fig. 6A: A, H, AV, G, LV
- jj. Fig. 6B: A, H, L, AV, 20
- kk. Fig. 6C: A, H, L, AV, LV, 20, 50
- ll. Fig. 6D: A, H, AV, 100', 110, 20, 10
- mm. Fig. 6E: A, H, LV, L, 100', 60, 61B, 40, 30, 20, 10
- nn. Fig. 6F: A, H, L, AV, G, LV, 110, 100'
- oo. Fig. 7: A, H, AV, LV, 20
- pp. Fig. 8C: 600, 30, 50
- qq. Fig. 13B: 106, 30, 32
- rr. Fig. 13C: 106, 30, 32

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures

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appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

7. 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.

8. Claims 22-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (6458153).

9. Bailey teaches a device and method for replacing a heart valve. The device, as can be seen in figs 7-11, is a one way stented valve (40) - - designed for chamber to chamber use (CC) including two leaflet engagement elements - - a distal anchor flange (42) and a proximal anchor flange (44), the replacement valve itself (26), and an abluminal graft portion (11b) (column 6, lines 18-24). The abluminal graft portion is positioned between the heart wall and the stent body and acts as a seal (column 10, lines 46-63). The deployment method of the CC stented valve is the same as the deployment method detailed in figs. 20A-I for the CV stented valve (10) (column 14, lines 56-60). The method includes delivering a valve stent (10), in a compressed state,

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to the aortic valve, withdrawing the stent from a catheter body (501) responsible for holding the valve stent in it's compressed state (column 14, lines 6-55). The valve stent then expands (column 13, lines 46-51) which would cause the leaflet engaging elements (distal anchor/ proximal anchor) to foreshorten around the native valve leaflet trapping it between the stented valve and the wall of the vessel locking it in place.

***Claim Rejections - 35 USC § 103***

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

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

11. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey in view of Lunn (5476506).

12. Bailey discloses the invention substantially as claimed, and as discussed supra. However, Bailey does not disclose the seal being pleated.

13. Lunn teaches a pleated graft attached to the outside of a stent in the analogous art of grafts for the purpose of preventing the graft from being damaged during the expansion of the stent. Specifically, Lunn teaches that a problem with many grafts that are attached directly to the outside of a stent is that during the expansion process the graft may be damaged from not being elastic enough to accommodate the expansion of the stent within it (column 1, line 57-column 2, line 5). Lunn teaches a solution to this problem of attaching a crimped/ pleated graft around the unexpanded stent, and this

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extra material will allow for the stent to expand without straining the graft material (column 2, lines 22-46).

14. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the crimped/pleated graft design taught by Lunn for the graft attached on the outside of the Bailey design in order to prevent damaging the graft during the expansion process.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA STRASZHEIM whose telephone number is (571)270-5233. The examiner can normally be reached on Monday-Friday with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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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.

RLS

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738

<b>Notice of References Cited</b>	Application/Control No. 10/972,287	Applicant(s)/Patent Under Reexamination SALAHIEH ET AL.	
	Examiner REBECCA STRASZHEIM	Art Unit 3738	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-6,458,153	10-2002	Bailey et al.	623/1.24
*	B US-5,476,506	12-1995	Lunn, Anthony C.	623/1.28
	C US-			
	D US-			
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			

**FOREIGN PATENT DOCUMENTS**

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

**NON-PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)				
	U				
	V				
	W				
	X				

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

## EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	61	623/1.28.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 07:51
L2	881	623/1.13.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 07:58
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S9	89	morejohn-dwight\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:22

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S18	276	(S15 NEAR S16) AND S17	US-PGPUB; USPAT	OR	ON	2008/08/11 08:04
S19	18	gainor-john\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/11 09:30
S20	33	lashinski-randall\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/11 09:37

8/ 12/ 2008 9:37:29 AM

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<b><i>Index of Claims</i></b> 	<b>Application/Control No.</b> 10972287	<b>Applicant(s)/Patent Under Reexamination</b> SALAHIEH ET AL.
	<b>Examiner</b> REBECCA STRASZHEIM	<b>Art Unit</b> 3738

✓	<b>Rejected</b>
=	<b>Allowed</b>


-	<b>Cancelled</b>
÷	<b>Restricted</b>

N	<b>Non-Elected</b>
I	<b>Interference</b>

A	<b>Appeal</b>
O	<b>Objected</b>

Claims renumbered in the same order as presented by applicant
  CPA
  T.D.
  R.1.47

CLAIM		DATE							
Final	Original	08/12/2008							
	1	N							
	2	N							
	3	N							
	4	N							
	5	N							
	6	N							
	7	N							
	8	N							
	9	N							
	10	N							
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	26	✓							
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	30	✓							
	31	✓							
	32	✓							
	33	✓							
	34	✓							
	35	✓							
	36	✓							

<b>Index of Claims</b>  	<b>Application/Control No.</b>  10972287	<b>Applicant(s)/Patent Under Reexamination</b>  SALAHIEH ET AL.
	<b>Examiner</b>  REBECCA STRASZHEIM	<b>Art Unit</b>  3738

✓	<b>Rejected</b>
=	<b>Allowed</b>


-	<b>Cancelled</b>
÷	<b>Restricted</b>

N	<b>Non-Elected</b>
I	<b>Interference</b>

A	<b>Appeal</b>
O	<b>Objected</b>

Claims renumbered in the same order as presented by applicant
  CPA
  T.D.
  R.1.47

CLAIM		DATE							
Final	Original	08/12/2008							
	37	✓							
	38	N							
	39	N							
	40	N							
	41	N							
	42	N							
	43	N							
	44	N							
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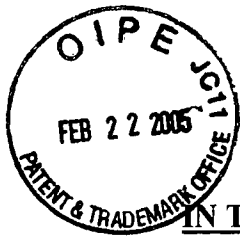
<b>Search Notes</b>  	<b>Application/Control No.</b>  10972287	<b>Applicant(s)/Patent Under Reexamination</b>  SALAHIEH ET AL.
	<b>Examiner</b>  REBECCA STRASZHEIM	<b>Art Unit</b>  3738

<b>SEARCHED</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>
	623/1.28	8/12/2008	RLS

<b>SEARCH NOTES</b>		
<b>Search Notes</b>	<b>Date</b>	<b>Examiner</b>
EAST inventor name search, EAST subject search, discussed search strategy with Primary Examiner Suzette Gherbi	8/12/2008	RLS

<b>INTERFERENCE SEARCH</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>





PATENT

Attorney Docket No. 30207.702.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Amr SALAHIEH et al.	)	
	)	Art Unit: 3738
Application No.: 10/972,287	)	
	)	Examiner: Not yet assigned
Filed: October 21, 2004	)	
	)	Confirmation No.: 7706
Title: Leaflet engagement elements and methods for use thereof	)	
	)	

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

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

Sir:

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

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

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

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

- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
  - (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
    - OR --
  - (2) It is being filed within 3 months of entry of a national stage
    - OR --
  - (3) It is being filed before the mail date of the first Office Action on the merits
    - OR --
  - (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

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

- a certification as specified in §1.97(e) is provided below; **or**
- a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

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

- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
- C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

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

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

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

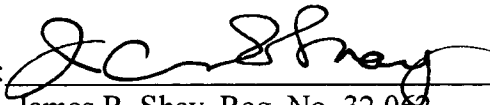
If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- Copies of only foreign patent documents and non-patent literature are provided in PDF format on the attached CD ROM, clearly titled by publication number or author, in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- Attached are the following non-published pending patent applications which may be deemed relevant.
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 2/16/05

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

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

PTO/SB/08A (08-03)

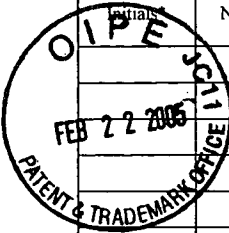
Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	3738
Examiner Name	Not yet assigned				
Sheet	1	of	1	Attorney Docket Number	30207.702.501

**U.S. PATENT DOCUMENTS**

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



**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		EP 1000590A1	05/17/2000	Cordis Corporation		

Examiner Signature	/Rebecca Straszheim/	Date Considered	08/18/2008
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.  
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Receipt date: 03/19/2007

10972287 GAU: 2788



Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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

<b>TRANSMITTAL FORM</b> <small>(to be used for all correspondence after initial filing)</small>	Application Number	10/972,287	
	Filing Date	October 21, 2004	
	First Named Inventor	Amr Salahieh	
	Art Unit	3738	
	Examiner Name	William H. Matthews	
Total Number of Pages in This Submission	6	Attorney Docket Number	10012-702.501

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
<div style="border: 1px solid black; padding: 2px; display: inline-block;">Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm	Shay Law Group LLP		
Signature			
Printed Name	Thomas Zlogar		
Date	3/15/07	Reg. No.	55,760

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Signature			
Typed or printed name	Angelica Zuniga	Date	3/15/07

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 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.



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application: 10/972,287  
Inventors: Amr Salahieh  
Filed: October 21, 2004  
Title: **LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF**

Confirmation No.: 7706  
Examiner: William H. Matthews  
Group Art Unit: 3738

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

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

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

**FILING OF INFORMATION DISCLOSURE STATEMENT** **37 CFR §1.97(b)**

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

- 1). Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d),
- 2). Within 3 months of entry of a national stage as set forth in § 1.491,
- 3). Before the mail date of a first Office Action on the merits,
- 4). Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

 **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

- 1). Three months beyond the filing date of a national application,
- 2). Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application,
- 3). The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement
- B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

 **37 CFR § 1.97(d)**

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

- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement
- AND--
- B). A certification as specified in § 1.97(e) is included below.

**CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER**  
**37 CFR § 1.98** **37 CFR §1.98 (a)(2)(ii) U.S. patents or patent application publication(s) cited**

- 1). Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
- 2). At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

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

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

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

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

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

A legible copy of each foreign patent is attached.

- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) Foreign patent(s) or other foreign documents not in English cited**
  - 1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached,
  - AND--**
  - 2a).** A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:
  - OR--**
  - 2b).** A copy of the translation of a written English-language translation, or portion thereof, is readily available and is attached.

**STATEMENT UNDER 37 CFR § 1.97(e)**


- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

- The Commissioner is hereby authorized to charge the above-referenced fees of \$00.0 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Respectfully Submitted,

Dated: 3/15/07  
 Shay Law Group  
 2755 Campus Drive, Suite 210  
 San Mateo, CA 94403  
 (650) 212-1700  
 Customer No. 66854

By:   
 Thomas Zlogar Reg. # 55760



PTO/SB/08A (09-06)  
 Approved for use through 03/31/2007. OMB 0651-0031  
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO

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

**Complete if Known**

Application Number	10/972,287
Filing Date	October 21, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	William H. Matthews
Attorney Docket Number	10012-702.501

Sheet 1 of 2

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	366	US- 2003/0233117-A1	12/18/2003	Adams et al.	
	364	US- 2004/0153094-A1	08/05/2004	Dunfee et al.	
	367	US- 2005/0107822-A1	05/19/2005	WasDyke, Joel	
	368	US- 6,610,077	08/26/2003	Hancock et al.	
	369	US- 6,790,229	09/14/2004	Berrekouw, Eric	
	365	US- 6,969,395	11/29/2005	Eskuri et al.	
	363	US- 6,361,545	03/26/2002	Macoviak et al.	
	142	US- 5,064,435	11/12/1991	Porter	
	262	US- 6,712,843	03/30/2004	Elliott	
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		US-			

**FOREIGN PATENT DOCUMENTS**

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

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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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

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

PTO/SB/08B (09-06)  
 Approved for use through 03/31/2007. OMB 0651-0031  
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
		Examiner Name	William H. Matthews
Sheet	2	of	2
		Attorney Docket Number	10012-702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
	305	SALAHIEH, et al., U.S. Patent App. 11/531,980, "Externally expandable heart valve anchor and method," filed 09/14/2006 SLG Ref 10012-703.301(formerly 30207-703.301)	
	306	SALAHIEH, et al., U.S. Patent 11/532,019, "Methods and apparatus for endovascularly replacing heart valve," filed 09/14/2006 SLG Ref 10012-703.302(formerly 30207-703.302)	

Examiner Signature	/Rebecca Straszheim/	Date Considered	08/18/2008
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Attorney Docket No. 30207-702.501  
PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Inventor: Amr SALAHIEH, et al.

Group Art Unit: 3738

Serial Number: 10/972,287

Examiner: Unassigned

Filing Date: October 21, 2004

**CONFIRMATION NO: 7706**

Title: LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF

FILED ELECTRONICALLY ON: April **6**, 2006

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

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97**

Sir:

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

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

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

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

- A.  *37 CFR §1.97(b)*. This Information Disclosure Statement should be considered by the Office because:
- (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
  - (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;  
-- OR --
  - (3) It is being filed before the mailing of a first Office action on the merits;  
-- OR --
  - (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B.  *37 CFR §1.97(c)*. Although this Information Disclosure Statement is being filed after the period specified in *37 CFR §1.97(b)*, above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- a statement as specified in §1.97(c) provided concurrently herewith;  
-- OR --
  - a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C.  *37 CFR §1.97(d)*. Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);  
-- AND --
  - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D.  *37 CFR §1.97(e)*. Statement.
- A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);  
-- AND/OR --
  - A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);  
-- AND/OR --
  - A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E.  *Statement Under 37 C.F.R. §1.704(d)*. Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the



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

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

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

-- OR --

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

-- AND/OR --

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

-- AND/OR --

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

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

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

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

-- OR --

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

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

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

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

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

Application in which the information was submitted: \_\_\_\_\_

Information Disclosure Statement(s) filed on: \_\_\_\_\_

AND

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

- I.  *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207-702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: April 6, 2006

By: 

Maya Skobatch, Reg. No. 52,505

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

PTO/SB/08 (07/05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>		
				Application Number	10/972,287	
				Filing Date	October 21, 2004	
				First Named Inventor	Amr Salahieh	
				Art Unit	3738	
				Examiner Name	Unassigned	
Sheet	1	Of	3	Attorney Docket Number	30207-702.501	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 2005/0209580 A1	09/22/2005	Freyman	
		US 2005/0228472 A1	10/13/2005	Case et al.	
		US 2005/0251250	11/10/2005	Verhoeven et al.	
		US 2005/0251251	11/10/2005	Cribier	
		US 2005/0261759 A1	11/24/2005	Lambrech et al.	
		US 2005/0267560 A1	12/1/2005	Bates	
		US 2005/0283231	12/22/2005	Haug, et al.	
		US 2005/0283962	12/29/2005	Boudjemline	
		US 2006/0004439	01/05/2006	Spenser et al.	
		US 2006/0004442	01/05/2006	Spenser et al.	
		US 2006/0015168	01/19/2006	Gunderson	
		US 6,042,607	03/28/2000	Williamson, IV et al.	
		US 6,953,332	10/11/2005	Kurk et al.	
		US 6,96,4673	11/15/2005	Tsugita et al.	
		US 6,974,464	12/13/2005	Quijano et al.	
		US 6,974,474	12/13/2005	Pavcnik et al.	
		US 6,974,476	12/23/2005	McGuckin, Jr. et al.	
		US 6,979,350	12/27/2005	Moll et al.	
		US 6,984,242	01/10/2006	Campbell et al.	

Examiner Signature	Date Considered
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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

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

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Unassigned
Sheet	2	Of	3	Attorney Docket Number	30207-702.501

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (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 <sup>6</sup>
		EP 1156757 B1	12/07/2005	Board of Regents, The University of Texas System		
		EP 1469797 in German with English Claims	11/02/2005	Figulla, Hans-Reiner		
		EP 1576937 A2	09/21/2005	Board of Regents, The University of Texas System		
		EP 1582178 A2	510/5/2005	Board of Regents, The University of Texas System		
		EP 1582179 A2	10/05/2005	Board of Regents, The University of Texas System		
		EP 1589902 (WO 2004/066876)	08/12/2004	Ave Connaught		
		EP 1600121A1	11/30/2005	William Cook Europe ApS		
		EP 1605871 (WO 2004/082536 A1)	09/30/2004	Aortech International PLC		
		EP 1616531	01/18/2006	Boston Scientific Limited		
		WO 2005/087140 A1	09/22/2005	Percutaneous Cardiovascular Solutions PTY Ltd.		

Examiner Signature	Date Considered
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**\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08 (07/05)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

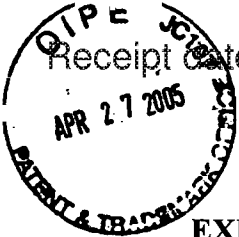
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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Unassigned
Sheet	3	Of	3	Attorney Docket Number	30207-702.501

UNPUBLISHED PATENT APPLICATIONS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>6</sup>
		FAWZI, et al., U.S. Patent Application No 11/155309, entitled "Apparatus and methods for intravascular embolic protection," filed 06/16/2005 (WSGR Reference No. 30207-719.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/232441, entitled "Methods and apparatus for endovascular heart valve replacement comprising tissue grasping elements," filed 09/20/2005 (WSGR Reference No. 30207-702.503)	
		SALAHIEH, et al., U.S. Patent Application No 11/232444, entitled "Methods and apparatus for endovascular heart valve replacement comprising tissue grasping elements," filed 09/20/2005 (WSGR Reference No. 30207-702.504)	
		SALAHIEH, et al., U.S. Patent Application No 11/274889, entitled "Medical implant deployment tool," filed 11/14/2005 (WSGR Reference No. 30207- 718.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/314183, entitled "Medical Device Delivery," filed 12/20/2005 (WSGR Reference No. 30207-725.201)	
		SALAHIEH, et al., U.S. Patent Application No 11/314969, entitled "Methods And Apparatus For Performing Valvuloplasty," filed 12/20/2005 (WSGR Reference No. 30207-727.201)	

Examiner Signature	/Rebecca Straszheim/	Date Considered	08/18/2008
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.  
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If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Receipt Date: 04/27/2005

4-29-05

10972287 - GA 1.738

EXPRESS MAIL LABEL NO.: EV 518896122 US

PATENT

Attorney Docket No. 30207.702.501

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Amr SALAHIEH et al.	)	
	)	Art Unit: 3738
Application No.: 10/972,287	)	
	)	Examiner: Not yet assigned
Filed: October 21, 2004	)	
	)	Confirmation No.: 7706
Title: Leaflet engagement elements and methods for use thereof	)	
	)	

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

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

Sir:

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

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

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

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

- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
  - (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

- 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
  - a certification as specified in §1.97(e) is provided below; **or**
  - a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

- 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
  - A. a certification as specified in §1.97(e) is completed below; and
  - B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
  - C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith in PDF format on the attached CD ROM, clearly titled by application number or author, in accordance with 37 CFR 1.98 (a)(2).

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

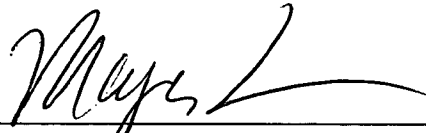
In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.     ), copies are not enclosed herewith.

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

- Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- Attached are non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.702.501).

Respectfully submitted,

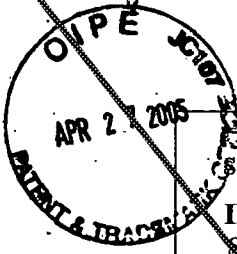
WILSON SONSINI GOODRICH & ROSATI

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

Dated: 4/29/05

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





PTO/SB/08A (08-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	1	of	2	Attorney Docket Number	30207.702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
		SALAHIEH, A. et al. US Patent Application No. 10/746,280 entitled "Repositionable heart valve and method", filed 12/23/2003 (Docket No. 30207.701.201).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,131 entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (Docket No. 30207.701.501).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,151, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.502).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,143, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.503).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,142, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.504).	
		SALAHIEH, A. et al. US Patent Application No. 10/920,736, entitled "Apparatus and methods for protecting against embolization during endovascular heart replacement", filed 08/17/2004 (30207.701.505).	
		SALAHIEH, A. et al. US Patent Application No. 10/746,240, entitled "Heart valve anchor and method", filed 12/23/2003 (30207.702.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/971,535, entitled "Leaflet engagement elements and methods for use thereof", filed 10/21/2004 (30207.702.502).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,120, entitled "Externally expandable heart valve anchor and method", filed 12/23/2003 (30207.703.201).	

Examiner signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/972,287
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				Art Unit	3738
Examiner Name	Not yet assigned				
Sheet	2	of	2	Attorney Docket Number	30207.702.501

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		SALAHIEH, A. et al., US Patent Application No. 10/982,388, entitled "Methods and apparatus for endovascularly replacing a heart valve", filed 11/05/2004 (30207.702.501).		
		SALAHIEH, A. et al., US Patent Application No. 10/746,285, entitled "Retrievable heart valve anchor and method", filed 12/23/2003 (30207.704.201).		
		SALAHIEH, A. et al., US Patent Application No. 10/982,692, entitled "Retrievable heart valve anchor and method", filed 11/05/2004 (30207.704.501).		
		SALAHIEH, A. et al., US Patent Application No. 10/746,887, entitled "Low profile heart valve and delivery system", filed 12/23/2003 (30207.705.201).		
		SALAHIEH, A. et al., US Patent Application No. 10/746,872, entitled "Locking heart valve anchor", filed 12/23/2003 (30207.706.201).		
		SALAHIEH, A. et al., US Patent Application No. 10/911,059, entitled "Replacement valve and anchor", filed 08/03/2004 (30207.706.301).		
		SALAHIEH, A. et al., US Patent Application No. 10/746,942, entitled "Two-piece heart valve and anchor", filed 12/23/2003 (30207.707.201).		
		SALAHIEH, A. et al., US Patent Application No. 10/870,340, entitled "Everting heart valve", filed 06/16/2004 (30207.710.201).		
Examiner signature	/Rebecca Straszheim/		Date Considered	08/18/2008

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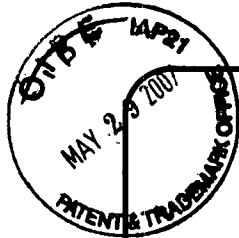
Receipt date: 05/29/2007

10972287 GAU: 3738

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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number		10/972,287
Filing Date		October 21, 2004
First Named Inventor		Amr Salahieh
Art Unit		3738
Examiner Name		William H. Matthews
Total Number of Pages in This Submission	5	Attorney Docket Number
		10012-702.501

### ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	Postcard
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application	<b>Remarks</b>	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm	Shay Law Group LLP		
Signature			
Printed Name	Thomas Zlogar		
Date	5/24/07	Reg. No.	55,760

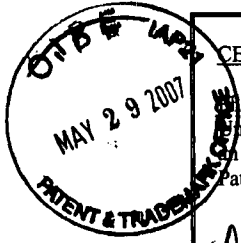
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Signature		Date	05/29/07
Typed or printed name	Angelica Zuniga		

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Date: 05/29/07 Angelica Zuniga  
 Date: Angelica Zuniga

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application: 10/972,287  
 Inventors: Amr Salahieh  
 Filed: October 21, 2004  
 Title: **LEAFLET ENGAGEMENT ELEMENTS  
 AND METHODS FOR USE THEREOF**

Confirmation No.: **7706**  
 Examiner: William H. Matthews  
 Group Art Unit: 3738

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

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

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

**FILING OF INFORMATION DISCLOSURE STATEMENT** **37 CFR §1.97(b)**

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

- 1). Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d),
- 2). Within 3 months of entry of a national stage as set forth in § 1.491,
- 3). Before the mail date of a first Office Action on the merits,
- 4). Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

 **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

- 1). Three months beyond the filing date of a national application,
- 2). Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application,
- 3). The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement
- B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

 **37 CFR § 1.97(d)**

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

- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement
- AND--
- B). A certification as specified in § 1.97(e) is included below.

**CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER**  
**37 CFR § 1.98** **37 CFR §1.98 (a)(2)(ii) U.S. patents or patent application publication(s) cited**

- 1). Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
- 2). At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

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

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

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

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

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

A legible copy of each foreign patent is attached.

- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) Foreign patent(s) or other foreign documents not in English cited**
  - 1).** A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached,  

--AND--

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

--OR--

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

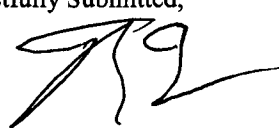
**STATEMENT UNDER 37 CFR § 1.97(e)**

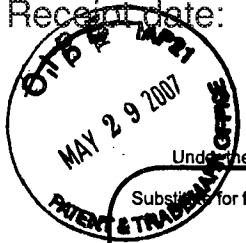
- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

- The Commissioner is hereby authorized to charge the above-referenced fees of \$00.0 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Dated: 5/24/07  
 Shay Law Group  
 2755 Campus Drive, Suite 210  
 San Mateo, CA 94403  
 (650) 212-1700  
 Customer No. 66854

Respectfully Submitted,  
  
 By: \_\_\_\_\_  
 Thomas Zlogar Reg. # 55760



PTO/SB/08B (04-07)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Application Number</b>	10/972,287
		<b>Filing Date</b>	October 21, 2004
		<b>First Named Inventor</b>	Amr Salahieh
		<b>Art Unit</b>	3738
		<b>Examiner Name</b>	William H. Matthews
Sheet 1	of 1	<b>Attorney Docket Number</b>	10012-702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
	374	Haug, et al; U.S. Pat App. # 11/716,123, entitled "Methods and apparatus for endovascularly replacing a heart valve," filed 3/9/2007 (SLG #10012-701.301).	
	372	SALAHIEH, et al; U.S. Pat App. # 11/706,549, entitled "Systems and Methods for Delivering a Medical Implant," filed 2/14/2007 (SLG #10012-732.201).	
	373	Salahieh, et al; U.S. Pat App. # 11/732,906 entitled "Assessing the location and performance of replacement heart valves," filed 4/4/2007 (SLG #10012-702.505).	

<b>Examiner Signature</b>	/Rebecca Straszheim/	<b>Date Considered</b>	08/18/2008
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Application Number	10/972,287												
Filing Date	October 21, 2004												
First Named Inventor	Amr Salahieh												
Art Unit	3774												
Examiner Name	WALKER, AMANDA H												
Attorney Docket Number	10012-702.501												
Sheet 1 of 2													

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	401	US- 6,221,096	4/24/2001	Aiba et al.	
	402	US- 6,714,842	3/30/2004	Ito, Hiroshi	
	398	US- 6,821,297	11/23/2004	Snyders	
	400	US- 7,011,681	3/14/2006	Veseley, Ivan	
	397	US- 2003/0229390 A1	12/11/2003	Ashton et al.	
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FOREIGN PATENT DOCUMENTS						
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		First Named Inventor	Amr Salahieh
		Art Unit	3774
		Examiner Name	WALKER, AMANDA H
Sheet 2	of 2	Attorney Docket Number	10012-702.501

NON PATENT LITERATURE DOCUMENTS			
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	399	<del>HAUG et al., U.S. Pat. App. # 12/028,452 entitled "Methods and apparatus for endovascularly replacing a patient's heart valve," filed 2/8/2008.</del>	

Examiner Signature	/Rebecca Straszheim/	Date Considered	08/18/2008
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 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**CERTIFICATE OF MAILING**

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

Mi Kyong Shin

**PATENT**

**Attorney Docket No. 30207.702.501**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Amr SALAHIEH et al.	)	
	)	Art Unit: 3738
Application No.: 10/972,287	)	
	)	Examiner: Not yet assigned
Filed: October 21, 2004	)	
	)	Confirmation No.: 7706
Title: Leaflet engagement elements and methods for use thereof	)	
	)	

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

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

Sir:

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

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

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

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

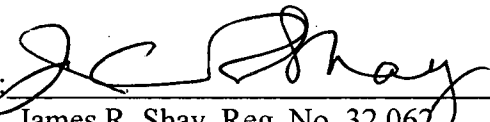
- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
  - (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
  
- 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
  - a certification as specified in §1.97(e) is provided below; or
  - a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
  
- 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
  - A. a certification as specified in §1.97(e) is completed below; and
  - B. a 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.
  
- Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
  
- Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
  - In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. ), copies are not enclosed herewith.
  - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
  - Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed.)

- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- Attached are the following non-published pending patent applications which may be deemed relevant.
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.702.501).

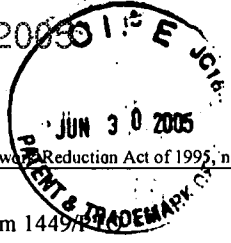
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 6/27/05

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

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



PTO/SB/08A (08-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449 <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh et al.
				Art Unit	3738
Examiner Name	Not yet assigned				
Sheet	1	of	1	Attorney Docket Number	30207.702.501

**U.S. PATENT DOCUMENTS**

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

**FOREIGN PATENT DOCUMENTS**

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

Examiner Signature	/Rebecca Straszheim/	Date Considered	08/18/2008
--------------------	----------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Attorney Docket No. 30207-702.501  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Amr SALAHIEH, et al.

Serial Number: 10/972,287

Filing Date: October 21, 2004

Title: LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF

Group Art Unit: 3738

Examiner: Unassigned

**CONFIRMATION NO: 7706**

FILED ELECTRONICALLY ON: July 12, 2006

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

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97**

Sir:

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

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

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

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

- A.  *37 CFR §1.97(b)*. This Information Disclosure Statement should be considered by the Office because:
- (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
  - (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;  
-- OR --
  - (3) It is being filed before the mailing of a first Office action on the merits;  
-- OR --
  - (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B.  *37 CFR §1.97(c)*. Although this Information Disclosure Statement is being filed after the period specified in *37 CFR §1.97(b)*, above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- a statement as specified in §1.97(e) provided concurrently herewith;  
-- OR --
  - a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C.  *37 CFR §1.97(d)*. Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);  
-- AND --
  - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D.  *37 CFR §1.97(e)*. Statement.
- A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);  
-- AND/OR --
  - A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);  
-- AND/OR --
  - A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E.  *Statement Under 37 C.F.R. §1.704(d)*. Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

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

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

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

-- OR --

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

-- AND/OR --

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

-- AND/OR --

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

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

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

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

-- OR --

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

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

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

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

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

Application in which the information was submitted: \_\_\_\_\_

Information Disclosure Statement(s) filed on: \_\_\_\_\_

AND

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



- I.  *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207-702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: July 12, 2006 \_\_\_\_\_

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

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

PTO/SB/08 (07/05)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>		
				Application Number	10/972,287	
				Filing Date	October 21, 2004	
				First Named Inventor	Amr Salahieh	
				Art Unit	3738	
Examiner Name	Unassigned		Attorney Docket Number	30207-702.501		
Sheet	1	Of	2			

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 2005/0137695	06/23/2005	Salahieh et al.	
		US 3,657,744	04/25/1972	Ersek	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (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 <sup>6</sup>
		EP 0409929 B1	04/23/1997	Boston Scientific Corp.		
		WO 96/24306 A1 (in French with English abstract)	08/15/1996	De Fays, Robert		
		WO 98/57599 A2	12/23/1998	Camilli, Sante		

Examiner Signature	Date Considered
--------------------	-----------------

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

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

PTO/SB/08 (07/05)

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE                  STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Unassigned
Sheet	2	Of	2	Attorney Docket Number	30207-702.501

UNPUBLISHED PATENT APPLICATIONS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>6</sup>
		SALAHIEH, et al., U.S. Patent Application No. 11/275,912, entitled "Medical Implant Delivery and Deployment Tool," filed 02/02/2006 (WSGR Reference No. 30207-722.501)	
		SALAHIEH, et al., U.S. Patent Application No. 11/275,913, entitled "Two-Part Package for Medical Implant," filed 02/02/2006 (WSGR Reference No. 30207-723.201)	

Examiner Signature	/Rebecca Straszheim/	Date Considered	08/18/2008
--------------------	----------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.  
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 If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/21 (04-07)  
 Approved for use through 09/30/2007, OMB 0651-0031  
 U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/972,287
	Filing Date	October 21, 2004
	First Named Inventor	Amr Salahieh
	Art Unit	3738
	Examiner Name	MATTHEWS, WILLIAM H
	Attorney Docket Number	10012-702.501
Total Number of Pages In This Submission		5

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	Remarks	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Shaw Law Group LLP		
Signature			
Printed name	Thomas Zlogar		
Date	7/12/07	Reg. No.	55,760

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:		
Signature		
Typed or printed name	Angelica Zuniga	Date
		07/12/07

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Docket No.10012-702.501

**CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8**

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at Fax No. 571.273.8300 on

07/12/07 *Angelica Zuniga*  
Date Angelica Zuniga

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JUL 12 2007

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application: 10/972,287  
Inventors: Amr Salahieh  
Filed: October 21, 2004  
Title: **LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF**

Confirmation No.: 7706  
Examiner: MATTHEWS, WILLIAM H  
Group Art Unit: 3738

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

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

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

Docket No.10012-702.501

**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), and any drawing of the application, or that portion of the application that caused it to be listed, including any claims directed to that portion, is attached.
- 2). A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
- 37 CFR §1.98 (a)(2)(III) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**
- 1). A legible copy of each publication or that portion which caused it to be listed is attached.
- 2). A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

Docket No.10012-702.501

- 37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited
  - 1). A legible copy of each foreign patent is attached.
  - 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  
- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:
  - 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached --AND--
  - 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:
    - OR--
  - 2b). A copy of a written, English-language translation or portion thereof is readily available and attached,
    - OR--
  - 2c). An English language copy of a foreign search report is submitted.
    - OR--
  - 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

**STATEMENT UNDER 37 CFR § 1.97(e)**

- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

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

Respectfully Submitted,

By:   
Thomas Zlogar Reg. # 55760

Dated: 7/12/07  
Shay Law Group  
2755 Campus Drive, Suite 210  
San Mateo, CA 94403  
(650) 212-1700  
Customer No. 66854

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PTO/SB/08A (04-07)

Approved for use through 09/30/2007. OMB 0851-0031  
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Substitute for form 1449/PTO		<b>Complete if Known</b>	
		Application Number	10/972,287
<b>INFORMATION DISCLOSURE              STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
		Examiner Name	MATTHEWS, WILLIAM H
		Attorney Docket Number	10012-702.501
Sheet	1	of	1

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	375	US- 5,824,041 A	10/20/1998	Lenker, et al.	
	376	US- 6,863,868	03/08/2005	Gillespie et al.	
		US-			
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

Examiner Signature	/Rebecca Straszheim/	Date Considered	08/18/2008
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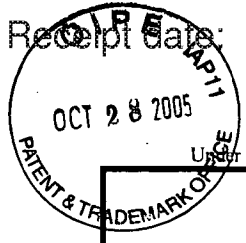
\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./  
 Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 252 of 630





PTO/SB/21 (02-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<h2>TRANSMITTAL FORM</h2> <p><i>(to be used for all correspondence after initial filing)</i></p>	Application Number	10/972,287
	Filing Date	October 21, 2004
	First Named Inventor	Amr Salahieh
	Art Unit	3738
	Examiner Name	Not yet assigned
Total Number of Pages in This Submission	Attorney Docket Number	30207-702.501

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

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT	
Firm or Individual name	Maya Skubatch, Reg. No. 52,505, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	October 26, 2005

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	Frank Chen		
Signature		Date	October 26, 2005

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

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



Attorney Docket No. 30207-702.501  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Amr SALAHIEH, et al.

Group Art Unit: 3738

Serial Number: 10/972,287

Examiner: Not yet assigned

Filing Date: October 21, 2004

CONFIRMATION NO: 7706

Title: LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF

Certificate of Mailing or Transmission  
37 CFR §1.8

I hereby certify that this paper is being:  deposited with the U.S. Postal Service with sufficient postage as first class mail and addressed to Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450; or  transmitted by facsimile to the Patent and Trademark Office in accordance with §1.6(d) to facsimile number on October 26, 2005.

Signature

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

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

Sir:

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

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

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

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

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

- (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
- (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;  
-- OR --
- (3) It is being filed before the mailing date of the first Office Action on the merits;  
-- OR --
- (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

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

- a certification as specified in §1.97(e) provided concurrently herewith;  
-- OR --
- a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

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

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

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

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

- Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.  
-- OR --
- Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.  
-- AND/OR --
- Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).  
-- AND/OR --
- Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

- 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.  
  
EP 1562515 A1 (WO 2004/047681) was published in French. The English language abstract and the drawings are sufficient to convey the scope of its disclosure.  
  
Should the Examiner believe that a complete translation of any of the above mentioned publications is necessary to understand its disclosure, Applicant(s) will endeavor to provide such translations at the Examiner's request.
- Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith.
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 30207-702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: October 26, 2005

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

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



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

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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number	10/972,287	
				Filing Date	October 21, 2004	
				First Named Inventor	Amr Salahieh	
				Art Unit	3738	
Examiner Name	Not yet assigned					
Sheet	1	of	5	Attorney Docket Number	30207-702.501	

**U.S. PATENT DOCUMENTS**

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

Examiner Signature	Date Considered
--------------------	-----------------

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

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

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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE                  STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
Examiner Name	Not yet assigned				
Sheet	2	of	5	Attorney Docket Number	30207-702.501

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)	MM-DD-YYYY		
		US 2005/0203615A1	9/15/2005	Forster	
		US 2005/0203616 A1	9/15/2005	Cribier	
		US 2005/0203617 A1	9/15/2005	Forster, et al.	
		US 4,796,629	1/10/1989	Grayzel	
		US 4,986,830	1/22/1991	Owens, et al.	
		US 5,209,741	5/11/1993	Spaeth	
		US 5,258,042	11/2/1993	Mehta	
		US 5,425,762	6/20/1995	Muller	
		US 5,443,495	8/22/1995	Buscemi, et al.	
		US 5,545,133	8/13/1996	Burns, et al.	
		US 5,843,158	12/1/1998	Lenker, et al.	
		US 5,910,154	06/08/1999	Tsugita et al.	
		US 5,911,734	06/15/1999	Tsugita et al.	
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		US 6,537,297	03/25/2003	Tsuigita et al.	
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		US 6,592,614	7/15/2003	Lenker, et al.	
		US 6,676,698	01/13/2004	McGuckin, Jr. et al.	
		US 6,695,864	02/24/2004	Macoviak et al.	

Examiner Signature		Date Considered	
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE                  STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
Examiner Name	Not yet assigned				
Sheet	4	of	5	Attorney Docket Number	30207-702.501

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		EP 1042045 B1	05/19/2004	Domnick Hunter Ltd.		
		EP 1059894 B1 (WO 99/44540)	7/20/2005	Scimed Life Systems, Inc.		
		EP 1078610 B1	8/10/2005	Cordis Corp.		
		EP 1430853 A3	6/8/2005	M. I. Tech Co., Ltd.		
		EP 1551274 A2 (WO 04/026117)	7/13/2005	3F Therapeutics, Inc.		
		EP 1551336 A1(WO 04/014256)	7/13/2005	Abbott Laboratories Vascular Enterprises		
		EP 1562515 A1 (WO 2004/047681)	8/17/2005	Boudjemline		✓
		WO 98/50103 A1	11/12/1998	Embol-X, Inc.		
		WO 99/44542 A2	09/10/1999	Scimed Life Systems, Inc.		
		WO 00/49970 A1	08/31/2000	Scimed Life Systems, Inc.		
		WO 01/08596 A1	02/08/2001	Scimed Life Systems, Inc.		
		WO 01/10320 A1	02/15/2001	Scimed Life Systems, Inc.		
		WO 01/10343 A1	02/15/2001	Scimed Life Systems, Inc.		
		WO 2005/084595 A1	9/15/2005	Cardiacmd, Inc.		

Examiner Signature	Date Considered
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### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

of 1

#### Complete if Known

Application Number	10/972,287
Filing Date	October 21, 2004
First Named Inventor	Amr Salahieh
Art Unit	3774
Examiner Name	MATTHEWS, WILLIAM H
Attorney Docket Number	10012-702.501

#### U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	380	US- 5,720,391 A	2/24/1998	Dohm et al.	
	377	US- 6,712,842	3/30/2004	Gifford et al.	
	384	US- 7,018,406	3/28/2006	Seguin et al.	
	381	US- 2001/0044656 A1	11/22/2001	Williamson et al.	
	382	US- 2002/0032481 A1	3/14/2002	Gabbay, Shlomo	
	379	US- 2002/0120328 A1	8/29/2002	Pathak et al.	
	378	US- 2004/0215331	10/28/2004	Chew et al.	
	383	US- 2006/0259134 A1	11/16/2006	Schwammenthal et al.	
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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	385	WO 02/0041789 A2	5/30/2002	Rex Medical, L. P.		

Examiner Signature	/Rebecca Straszheim/	Date Considered	08/18/2008
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*IFW*

**PATENT**

**Attorney Docket No. 30207.702.501**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Amr SALAHIEH et al.	)	
	)	Art Unit: Not yet assigned
Application No.: 10/972,287	)	
	)	Examiner: Not yet assigned
Filed: October 21, 2004	)	
	)	
Title: Leaflet engagement elements and methods for use thereof	)	
	)	

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

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

Sir:

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

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

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

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

- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
  - (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

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

- a certification as specified in §1.97(e) is provided below; or
- a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

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

- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; and
- C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

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

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

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

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

- Copies of only foreign patent documents and non-patent literature are provided in PDF format on the attached CD ROM, clearly titled by publication number or author, in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).
- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- Attached are the following non-published pending patent applications which may be deemed relevant.
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.702.501).

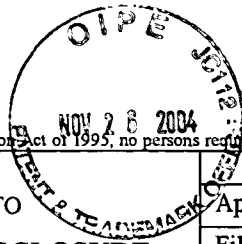
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: 11-22-04

By: Maya Skubatch  
Maya Skubatch, Reg. No. 30207.702.501

650 Page Mill Road  
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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<i>Complete if Known</i>			
				Application Number		10/972,287	
				Filing Date		10/21/2004	
				First Named Inventor		Salahieh	
				Art Unit		Not yet assigned	
Examiner Name		Not yet assigned					
Sheet	1	of	12	Attorney Docket Number	30207.702.501		

**U.S. PATENT DOCUMENTS**

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		Number-Kind Code <sup>2</sup> (if known)			
		US-2001/0025196	09/27/2001	Chinn et al.	
		US-2001/0032013	10/18/2001	Marton	
		US-2001/0039450	11/08/2001	Pavcnik et al.	
		US-2001/0041928	11/15/2001	Pavcnik et al.	
		US-2002/0032480	03/14/2002	Spence et al.	
		US-2002/0052651	05/02/2002	Myers et al.	
		US-2002/0058995	05/16/2002	Stevens	
		US-2002/0077696	06/20/2002	Zadno-Azizi et al.	
		US-2002/0095209	07/18/2002	Zadno-Azizi et al.	
		US-2002/0111674	08/15/2002	Chouinard et al.	
		US-2002/0151970	10/17/2002	Garrison et al.	
		US-2002/0161392	10/31/2002	Dubrul	
		US-2002/0161394	10/31/2002	Macoviak et al.	
		US-2002/0193871	12/19/2002	Beyersdorf et al.	
		US-2003/0014104	01/16/2003	Cribier	
		US-2003/0023303	01/30/2003	Palmaz et al.	
		US-2003/0028247	02/06/2003	Cali	
		US-2003/0036791	02/20/2003	Philipp et al.	
		US-2003/0040771	02/27/2003	Hyodoh et al.	
		US-2003/0040772	02/27/2003	Hyodoh et al.	
		US-2003/0055495	03/20/2003	Pease et al.	
		US-2003/0109924	06/12/2003	Cribier	
		US-2003/0125795	07/03/2003	Pavcnik et al.	
		US-2003/0149476	07/08/2003	Damm et al.	
		US-2003/0130729	07/10/2003	Paniagua et al.	
		US-2003/0149475	08/07/2003	Hyodoh et al.	
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		US-2003/0153974	08/14/2003	Spenser et al.	
		US-2003/0181850	09/25/2003	Diamond et al.	

Examiner Signature	Date Considered
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				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	2	of	12	Attorney Docket Number	30207.702.501

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		Number-Kind Code <sup>2</sup> (if known)			
		US-2003/0199913	10/23/2003	Dubrul et al.	
		US-2003/0199971	10/23/2003	Tower et al.	
		US-2003/0199972	10/23/2003	Zadno-Azizi et al.	
		US-2003/0212452	11/13/2003	Zadno-Azizi et al.	
		US-2003/0212454	11/13/2003	Scott et al.	
		US-2004/0034411	02/19/2004	Quijano et al.	
		US-2004/0039436	02/26/2004	Spenser et al.	
		US-2004/0049224	03/11/2004	Buehlmann et al.	
		US-2004/0049262	03/11/2004	Obermiller et al.	
		US-2004/0049266	03/11/2004	Anduiza et al.	
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		US-2004/0088045	05/06/2004	Cox	
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		US-2004/0215339	10/28/2004	Drasler et al.	
		US-3,334,629	08/08/1967	Cohn	
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		US-3,795,246	03/05/1974	Sturgeon	
		US-3,839,741	10/08/1974	Haller	

Examiner Signature	Date Considered
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				First Named Inventor	Salahieh
				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	3	of	12	Attorney Docket Number	30207.702.501

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		US-3,868,956	03/04/1975	Alfidi et al.	
		US-3,874,388	04/01/1975	King et al.	
		US-4,056,854	11/08/1977	Boretos et al.	
		US-4,106,129	08/15/1978	Carpentier et al.	
		US-4,233,690	11/18/1980	Akins	
		US-4,291,420	09/29/1981	Reul	
		US-4,425,908	01/17/1984	Simon	
		US-4,501,030	02/26/1985	Lane	
		US-4,580,568	04/08/1986	Gianturco	
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		US-4,710,192	12/01/1987	Liotta et al.	
		US-4,733,665	03/29/1988	Palmaz	
		US-4,819,751	04/11/1989	Shimada et al.	
		US-4,834,755	05/30/1989	Silvestrini et al.	
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		US-4,872,874	10/10/1989	Taheri	
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		US-4,917,102	04/17/1990	Miller et al.	
		US-4,954,126	09/04/1990	Wallsten	
		US-4,994,077	02/19/1991	Dobben	
		US-5,002,559	03/26/1991	Tower	
		US-5,161,547	11/10/1992	Tower	
		US-5,163,953	11/17/1992	Vince	

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				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	4	of	12	Attorney Docket Number	30207.702.501

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

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				First Named Inventor	Salahieh
				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
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U.S. PATENT DOCUMENTS					
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		Number-Kind Code <sup>2</sup> (if known)			
		US-5,876,448	03/02/1999	Thompson et al.	
		US-5,888,201	03/30/1999	Stinson et al.	
		US-5,891,191	04/06/1999	Stinson	
		US-5,907,893	06/01/1999	Zadno-Azizi et al.	
		US-5,925,063	07/20/1999	Khosravi	
		US-5,944,738	08/31/1999	Amplatz et al.	
		US-5,954,766	09/21/1999	Zadno-Azizi et al.	
		US-5,957,949	09/28/1999	Leonhardt et al.	
		US-5,984,957	11/16/1999	Laptewicz, Jr. et al.	
		US-6,022,370	02/08/2000	Tower	
		US-6,027,525	02/22/2000	Suh et al.	
		US-6,042,598	03/28/2000	Tsugita et al.	
		US-6,051,104	04/18/2000	Jang	
		US-6,123,723	09/26/2000	Konya et al.	
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		US-6,162,245	12/19/2000	Jayaraman	
		US-6,168,614	01/02/2001	Andersen et al.	
		US-6,200,336	03/13/2001	Pavcnik et al.	
		US-6,221,006	04/24/2001	Dubrul et al.	
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		US-6,277,555	08/21/2001	Duran et al.	
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		US-6,319,281	11/20/2001	Patel	

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				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
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		Number-Kind Code <sup>3</sup> (if known)	MM-DD-YYYY		
		US-6,327,772	12/11/2001	Zadno-Azizi et al.	
		US-6,338,735	01/15/2002	Stevens	
		US-6,348,063	02/19/2002	Yassour et al.	
		US-6,352,708	03/05/2002	Duran et al.	
		US-6,371,970	04/16/2002	Khosravi et al.	
		US-6,371,983	04/16/2002	Lane	
		US-6,379,383	04/30/2002	Palmaz et al.	
		US-6,398,807	06/04/2002	Chouinard et al.	
		US-6,409,750	06/25/2002	Hyodoh et al.	
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		US-6,440,164	08/27/2002	DiMatteo et al.	
		US-6,458,153	10/01/2002	Bailey et al.	
		US-6,468,303	10/22/2002	Amplatz et al.	
		US-6,475,239	11/05/2002	Campbell et al.	
		US-6,482,228	11/19/2002	Norred	
		US-6,494,909	12/17/2002	Greenhalgh	
		US-6,503,272	01/07/2003	Duerig et al.	
		US-6,508,833	01/21/2003	Pavcnik et al.	
		US-6,527,800	03/04/2003	McGuckin, Jr. et al.	
		US-6,530,949	03/11/2003	Konya et al.	
		US-6,562,058	05/13/2003	Seguin et al.	
		US-6,592,546	07/15/2003	Barbut et al.	
		US-6,622,604	09/23/2003	Chouinard et al.	
		US-6,632,243	10/14/2003	Zadno-Azizi et al.	
		US-6,635,068	10/21/2003	Dubrul et al.	
		US-6,652,571	11/25/2003	White et al.	
		US-6,652,578	11/25/2003	Bailey et al.	
		US-6,663,663	12/16/2003	Kim et al.	

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				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	7	of	12	Attorney Docket Number	30207.702.501

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

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FOREIGN PATENT DOCUMENTS						
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		<del>EP 1057459</del>	<del>12/06/2000</del>	<del>Numed, Inc.</del>		
		EP 1057460	12/06/2000	Numed, Inc.		
		EP 1340473	09/09/2003	3F Therapeutics, Inc.		
		<del>EP 1356703</del>	<del>10/30/2003</del>	<del>Numed, Inc.</del>		
		<del>EP 0937439B1</del>	<del>09/17/2003</del>	<del>Heartport, Inc.</del>		
		<del>EP 0810013</del>	<del>06/23/2004</del>	<del>Heartport, Inc.</del>		
		WO 93/15693	08/19/1993	Vince Medical Company Limited		
		<del>WO 95/04556</del>	<del>02/16/1995</del>	<del>Active Control Experts, Inc.</del>		
		<del>WO 95/29640</del>	<del>11/09/1995</del>	<del>Aesculap AG</del>		X
		<del>WO 90/14052</del>	<del>03/17/1990</del>	<del>Duran, Carlos</del>		
		<del>WO 98/26700</del>	<del>08/27/1998</del>	<del>Conda Medical Devices Corporation</del>		
		<del>WO 00/09059</del>	<del>02/24/2000</del>	<del>Prodesco, Inc.</del>		
		<del>WO 00/44308</del>	<del>08/03/2000</del>	<del>Board of Regents, The University of Texas System</del>		
		WO 00/44313	08/03/2000	Viacor Inc.		
		<del>WO 00/67661</del>	<del>11/16/2000</del>	<del>Orte, Mark</del>		
		<del>WO 01/05331</del>	<del>01/25/2001</del>	<del>Disocompatibles Ltd.</del>		
		WO 01/35870	05/25/2001	Seguin, Jacques		X
		WO 01/64137	09/07/2001	Fraunhofer-Gesellschaft Zur Forderung Der Angewandten Forschung E.V.		X
		WO 02/36048	05/10/2002	Seguin, Jacques		X
		<del>WO 02/100297</del>	<del>12/19/2002</del>	<del>Rex Medical, L.P.</del>		

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				First Named Inventor	Salahieh	
				Art Unit	Not yet assigned	
Examiner Name	Not yet assigned					
Sheet	9	of	12	Attorney Docket Number	30207.702.501	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
		WO 03/003943	01/16/2003	Advanced Bio Prosthetic Surfaces, Ltd.		
		WO 03/003949	01/16/2003	Seguin, Jacques		X
		<del>WO 03/011195</del>	<del>02/13/2003</del>	<del>Seguin, Jacques</del>		<del>X</del>
		<del>WO 03/015051</del>	<del>11/27/2003</del>	<del>Boimed Life Systems, Inc.</del>		
		WO 2004/019811	03/11/2004	Heart Leaflet Technologies		
		WO 2004/023980	03/25/2004	3F Therapeutics, Inc.		
		<del>WO 2004/041126</del>	<del>05/21/2004</del>	<del>Seguin, Jacques</del>		
		<del>WO 2004/047691</del>	<del>06/10/2004</del>	<del>Bendjamine, Younes</del>		<del>X</del>

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>		
				Application Number	10/972,287	
				Filing Date	10/21/2004	
				First Named Inventor	Salahieh	
				Art Unit	Not yet assigned	
				Examiner Name	Not yet assigned	
Sheet	10	of	12	Attorney Docket Number	30207.702.501	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
		<del>ANDERSEN, H.P. et al., "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs". Euro. Heart J. (1992) 13:704-708.</del>	
		<del>ATWOOD, A. et al., "Insertion of Heart Valves by Catheterization". Project Supervised by Prof. Y. Muftu of Northeastern University (2001-2002) 36-40.</del>	
		<del>BODNAR, E. et al. Replacement Cardiac Valves. Pergamon Publishing Corporation New York, (1991), 307-322.</del>	
		<del>BOUDJEMLINE, Y. et al., "Percutaneous implantation of a valve in the descending aorta in lambs". Euro. Heart J. (2002) 23:13, 1045-1049.</del>	
		<del>BOUDJEMLINE, Y. et al., "Percutaneous Pulmonary Valve Replacement in a Large Right Ventricular Outflow Tract". J. of Am. College of Cardio. (2004) 43:6, 1082-1087.</del>	
		<del>BOUDJEMLINE, Y. et al., "Percutaneous valve insertion: A new approach?" J. of Thoracic and Cardio. Surg. (2003) 125:3, 741-743.</del>	
		<del>BOUDJEMLINE, Y. et al., "Steps Toward Percutaneous Aortic Valve Replacement." Circulation (2002) 775-778.</del>	
		<del>CRIBIER, A. et al., "Early Experience with Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the Treatment of End-Stage Inoperable Patients with Calcific Aortic Stenosis". J. of Am. Coll. of Cardio. (2004) 43:4, 698-703.</del>	
		<del>CRIBIER, A. et al., "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description," Circulation (2002) 3006-3008.</del>	
		<del>CRIBIER, A. et al., "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case". Percutaneous Valve Technologies, Inc. (2002).</del>	

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				Art Unit	Not yet assigned
Examiner Name	Not yet assigned				
Sheet	11	of	12	Attorney Docket Number	30207.702.501

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		<del>FERRARI, M. et al., "Percutaneous transvascular aortic valve replacement with self-expanding stent-valve device". Poster from the presentation given at SMIT 2000, 12<sup>th</sup> International Conference (September 5, 2000).</del>	
		<del>HIJAZI, Z.M., "Transcatheter Valve Replacement: A New Era of Percutaneous Cardiac Intervention Begins". J. of Am. College of Cardio. (2004) 43:6, 1088-1089.</del>	
		<del>HUBER, C.H. et al., "Do valved stents compromise coronary flow?" European Journal of Cardio-thoracic Surgery, (2004) 25:754-759.</del>	
		<del>KNUDSEN, L. L. et al., "Catheter implanted prosthetic heart valves". Int'l J. of Art. Organs, (1993) 16:5, 253-263</del>	
		<del>KORT, S. et al., "Minimally invasive aortic valve replacement: Echocardiographic and clinical results". Am. Heart J. (2001) 142:3, 476-481.</del>	
		<del>LOVE, C. et al., The Autogenous Tissue Heart Valve: Current Status, Journal of Caridac Surgery, (1991) 6:4, 499-507.</del>	
		<del>LUTTER, G. et al., "Percutaneous aortic valve replacement: An experimental study. I. Studies on implantation," J. of Thoracic and Cardio. Surg. (2002) 123:4, 768-776.</del>	
		<del>MOULOPOULOS, S. D. et al., "Catheter Mounted Aortic Valves," Annals of Thoracic Surg. (1971) 11:5, 423-430.</del>	
		<del>PANIAGLIA, D. et al., "Percutaneous heart valve in the chronic in vitro testing model", Circulation (2002), 106:e51-e52, American heart Association, Inc.</del>	
		<del>PANIAGLIA, D. et al., Heart Watch (2004), Spring, 2004 Edition, Texas Heart Institute</del>	

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Examiner Name	Not yet assigned				
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		DAVGNIK, D. et al., "Percutaneous bioprothetic venous valve: A long term study in sheep". J. of Vascular Surg. (2002) 35:3, 598-603.	
		PHILLIPS, S. J. et al., "A Temporary Catheter Tip Aortic Valve: Hemodynamic Effects on Experimental Acute Aortic Insufficiency". Annals of Thoracic Surg. (1976) 21:2, 134-136.	
		SOCHMAN, J. et al., "Percutaneous Transcatheter Aortic Disc Valve Prosthesis Implantation: A Feasibility Study". Cardiovasc. Intervent. Radiol. (2000) 23, 384-388.	
		STUART, M., "In Heart Valves, A Brave, New Non-Surgical World". Start-Up (2004) 9-17.	
		VAHANIAN, A. et al., "Percutaneous Approaches to Valvular Disease". Circulation (2004) 109, 1572-1579.	
		VAN HERWERDEN, L. A. et al., "Percutaneous valve implantation: back to the future?" Euro. Heart J. (2002) 23:18, 1415-1416.	
		ZHOU, J. Q. et al., "Self-expandable valved stent of large size: off-bypass implantation in pulmonary position". Eur. J. Cardiothorac. (2003) 24, 212-216	

Examiner signature	/Rebecca Straszheim/	Date Considered	08/18/2008
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VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/972,287 Confirmation No.: 7706  
Applicant(s): Amr Salahieh  
Filed: October 21, 2004  
Art Unit: 3738  
Examiner: STRASZHEIM, REBECCA L  
Title: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE  
THEREOF  
Customer No.: 66854

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

**INFORMATION DISCLOSURE STATEMENT UNDER  
37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

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

**FILING OF INFORMATION DISCLOSURE STATEMENT** **37 CFR §1.97(b)**

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

- 1). Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or
- 2). Within 3 months of entry of a national stage as set forth in § 1.491, or
- 3). Before the mail date of a first Office Action on the merits, or
- 4). Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

 **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

- 1). Three months beyond the filing date of a national application, or
- 2). Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or
- 3). The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
  - A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or
  - B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

 **37 CFR § 1.97(d)**

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

- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement
- AND--
- B). A certification as specified in § 1.97(e) is included below.

**CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER  
37 CFR § 1.98** **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

- 1). Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
- 2). At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

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

- 1). A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.
- 2). A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
- 3). A copy of each application specification is not submitted because the application is stored in the IFW.

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

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

- 37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited
  - 1). A legible copy of each foreign patent or that portion which caused it to be listed is attached.
  - 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  
- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:
  - 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached --AND--
  
  - 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith: --OR--
  
  - 2b). A copy of a written, English-language translation or portion thereof is readily available and attached, --OR--
  
  - 2c). An English language copy of a foreign search report is submitted. --OR--
  
  - 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

**STATEMENT UNDER 37 CFR § 1.97(e)**

- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
  
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

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

Respectfully Submitted,



By: \_\_\_\_\_  
Thomas Zlogar Reg. # 55760

Dated: 10/21/08

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

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 6

**Complete if Known**

Application Number	10/972,287
Filing Date	October 21, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	STRASZHEIM, REBECCA L
Attorney Docket Number	10012-702.501

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	370	US- 6,197,053 B1	3/6/2001	Cosgrove et al.	
	371	US- 7,189,258 B2	3/13/2007	Johnson et al.	
	404	US- 2005/0033402 A1	2/10/2005	Cully et al.	
	407	US- 5,662,671	9/2/1997	Barbut et al.	
	408	US- 5,895,399	4/20/1999	Barbut et al.	
	409	US- 5,993,469	11/30/1999	McKenzie et al.	
	410	US- 5,997,557	12/7/1999	Barbut et al.	
	411	US- 6,010,522	1/4/2000	Barbut et al.	
	412	US- 6,231,544	5/15/2001	Tsugita et al.	
	413	US- 6,231,551	5/15/2001	Barbut	
	414	US- 6,616,682	9/9/2003	Joergensen et al.	
	415	US- 6,682,543	1/27/2004	Barbut et al.	
	416	US- 6,767,345	7/27/2004	St. Germain et al.	
	417	US- 7,166,097	1/23/2007	Barbut	
	418	US- 7,374,560	5/20/2008	Ressemann et al.	
	419	US- 2003/0212429 A1	11/13/2003	Keegan et al.	
	420	US- 2004/0049226 A1	3/11/2004	Keegan et al.	
	421	US- 2004/0098022 A1	5/20/2004	Barone	
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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	308	EP 0819013	6/23/2004	Heartport, Inc.		
	309	EP 0937439B1	9/17/2003	Heartport, Inc.		
	312	EP 1057459	12/6/2000	Numed, Inc.		
	319	EP 1356793	10/29/2003	Numed, Inc.		
	327	WO 00/09059	2/24/2000	Prodesco, Inc.		
	328	WO 00/44308	8/3/2000	Board of Regents, The Univer		

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SignatureDate  
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Examiner Name	STRASZHEIM, REBECCA L												
Attorney Docket Number	10012-702.501												
Sheet <b>2</b> of <b>6</b>													

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-			
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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	331	WO 00/67661	11/16/2000	Ortiz, Mark		
	332	WO 01/05331	1/25/2001	Biocompatibles Ltd.		
	338	WO 02/100297	12/19/2002	Rex Medical, L. P.		
	342	WO 03/011195(AB TRN)	2/13/2003	Seguin, Jacques		
	343	WO 03/015851	11/27/2003	Scimed Life Systems, Inc.		
	348	WO 2004/041126	5/21/2004	Seguin, Jacques		

Examiner Signature	Date Considered
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Substitute for form 1449/PTO  <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;"><i>(Use as many sheets as necessary)</i></p>	<h3 style="text-align: center;">Complete if Known</h3> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/972,287</td> </tr> <tr> <td>Filing Date</td> <td>October 21, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Amr Salahieh</td> </tr> <tr> <td>Art Unit</td> <td>3738</td> </tr> <tr> <td>Examiner Name</td> <td>STRASZHEIM, REBECCA L</td> </tr> <tr> <td>Attorney Docket Number</td> <td>10012-702.501</td> </tr> </table>	Application Number	10/972,287	Filing Date	October 21, 2004	First Named Inventor	Amr Salahieh	Art Unit	3738	Examiner Name	STRASZHEIM, REBECCA L	Attorney Docket Number	10012-702.501
Application Number	10/972,287												
Filing Date	October 21, 2004												
First Named Inventor	Amr Salahieh												
Art Unit	3738												
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Attorney Docket Number	10012-702.501												
Sheet <b>3</b> of <b>6</b>													

U. S. PATENT DOCUMENTS					
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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	355	WO 95/04556	2/16/1995	Active Control Experts, Inc.		
	356	WO 95/29640 (AB TRN)	11/9/1995	Aesculap AG		
	357	WO 96/14032	5/17/1996	Duran, Carlos		
	359	WO 98/36790	8/27/1998	Conado Medical Devices Corp		

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		Application Number	10/972,287		
		Filing Date	October 21, 2004		
		First Named Inventor	Amr Salahieh		
		Art Unit	3738		
		Examiner Name	STRASZHEIM, REBECCA L		
Sheet	4	of	6	Attorney Docket Number	10012-702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
	263	ANDERSEN, H.R. et al. "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs." Euro. Heart J. 1992; 13:704-708.	
	264	ATWOOD, A. et al. "Insertion of Heart Valves by Catheterization." Project Supervised by Prof. S. Muftu of Northeastern University 2001-2002: 36-40.	
	265	BODNAR, E. et al. Replacement Cardiac Valves R Chapter 13: Extinct cardiac valve prostheses. Pergamon Publishing Corporation. New York, 1991: 307-322.	
	267	BOUDJEMLINE, Y. et al. "Percutaneous implantation of a valve in the descending aorta in lambs." Euro. Heart J. 2002; 23: 1045-1049.	
	269	BOUDJEMLINE, Y. et al. "Percutaneous valve insertion: A new approach?" J. of Thoracic and Cardio. Surg. 2003; 125(3): 741-743.	
	272	CRIBIER, A., et al. "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description." Circulation. 2002; 106: 3006-3008.	
	273	CRIBIER, A., et al. "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case." Percutaneous Valve Technologies, Inc. 2002: 16 pages.	
	274	FERRARI, M. et al. "Percutaneous transvascular aortic valve replacement with self expanding stent-valve device." Poster from the presentation given at SMIT 2000, 12th International Conference. September 5, 2000.	
	277	KNUDSEN, L. L. et al. "Catheter-implanted prosthetic heart valves." Int'l J. of Art. Organs. 1993; 16(5): 253-262.	
	278	KORT, S. et al. "Minimally invasive aortic valve replacement: Echocardiographic and clinical results." Am. Heart J. 2001; 142(3): 476-481.	

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Sheet	5	of	6	Attorney Docket Number	10012-702.501

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	279	LOVE, C. et al. "The Autogenous Tissue Heart Valve: Current Stat.f Journal of Cardiac Surgery. 1991; 6(4): 499-507.	
	280	LUTTER, G. et al. "Percutaneous aortic valve replacement: An experimental study. I. Studies on implantation." J. of Thoracic and Cardio. Surg. 2002; 123(4): 768-776.	
	281	MOULOPOULOS, S. D. et al. "Catheter-Mounted Aortic Valves." Annals of Thoracic Surg. 1971; 11(5): 423-430.	
	282	PANIAGUA, D. et al. "Percutaneous heart valve in the chronic in vitro testing model." Circulation. 2002; 106: e51-e52.	
	283	PANIAGUA, D. et al. Heart Watch (2004). Texas Heart Institute. Spring, 2004 Edition: 8 pages.	
	284	PAVCNIK, D. et al. "Percutaneous bioprosthetic veno valve: A long-term study in sheep." J. of Vascular Surg. 2002; 35(3): 598-603.	
	285	PHILLIPS, S. J. et al. "A Temporary Catheter-Tip Aortic Valve: Hemodynamic Effects on Experimental Acute Aortic Insufficiency." Annals of Thoracic Surg. 1976; 21(2): 134-136.	
	286	SOCHMAN, J. et al. "Percutaneous Transcatheter Aortic Disc Valve Prosthesis Implantation: A Feasibility Study." Cardiovasc. Intervent. Radiol. 2000; 23: 384-388.	
	289	VAN HERWERDEN, L. A. et al., "Percutaneous valve implantation: back to the future?" Euro. Heart J. 2002; 23(18): 1415-1416.	
	290	ZHOU, J. Q. et al. "Self-expandable valved stent of large size: off-bypass implantation in pulmonary position." Eur. J. Cardiothorac. 2003; 24: 212-216	

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## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	10972287
<b>Filing Date:</b>	21-Oct-2004
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Filer:</b>	Thomas M. Zlogar/Angelica Zuniga
<b>Attorney Docket Number:</b>	10012-702.501

Filed as Large Entity

### Utility under 35 USC 111(a) Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Miscellaneous:</b>				
Submission- Information Disclosure Stmt	1806	1	180	180
<b>Total in USD (\$)</b>				<b>180</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	4152752
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	Thomas M. Zlogar/Angelica Zuniga
<b>Filer Authorized By:</b>	Thomas M. Zlogar
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	21-OCT-2008
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	19:02:03
<b>Application Type:</b>	Utility under 35 USC 111(a)

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Payment Type	Deposit Account
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	Information Disclosure Statement (IDS) Filed (SB/08)		4	9	
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<b>Information:</b>					
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<b>Information:</b>					
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<b>Information:</b>					
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<b>Warnings:</b>					
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28	NPL Documents	NPL_Love_et_al.pdf	1478115 ab96c3fd07e075671a68a1605b3f3178ea5444e0	no	9
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29	NPL Documents	NPL_Lutter_et_al.pdf	1049639 7a8b9d211e9583f5e78cd579617ccd5f7fa5f9de	no	9
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30	NPL Documents	NPL_Moulopoulos_et_al.pdf	913162 6d63a9e90532f9db8929b2b610753f84b5e8dce6	no	8
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31	NPL Documents	NPL_Paniagua_et_al_106.pdf	418366	no	2
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32	NPL Documents	NPL_Paniagua_et_al_8pgs.pdf	695060	no	8
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**Warnings:**

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33	NPL Documents	NPL_Pavcnik_et_al.pdf	806147	no	6
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**Information:**

34	NPL Documents	NPL_Phillips_et_al.pdf	459663	no	4
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**Information:**

35	NPL Documents	NPL_Sochman_et_al.pdf	692101	no	5
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**Information:**

36	NPL Documents	NPL_VanHerwerden_et_al.pdf	175741	no	2
			b50a8a81d2520c2dcd0a8aee2c70cfbe1d5951585		

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**Information:**

37	NPL Documents	NPL_Zhou_et_al.pdf	614116	no	5
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38	Fee Worksheet (PTO-06)	fee-info.pdf	29690	no	2
			27bb4107e2b924fdbc7c303d11dec09d58cd77		
Warnings:					
Information:					
Total Files Size (in bytes):				46213631	
<p><b>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.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  <b>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.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  <b>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.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>  <b>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.</b></p>					

**FILED VIA EFS ON NOVEMBER 20, 2008**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/972,287 Confirmation No.: 7706  
Applicant : Amr SALAHIEH et al.  
Filing Date : October 21, 2004  
Title : Leaflet Engagement Elements and Methods for Use Thereof  
Group Art Unit : 3738  
Examiner : Rebecca L. STRASZHEIM  
Docket No. : 10012-702.501  
Customer No. : 66854

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

**AMENDMENT IN RESPONSE TO OFFICE ACTION**

**Introductory Comments:**

This Amendment responds to the non-final Office Action dated August 20, 2008, for which a response is due November 20, 2008.

Please enter the amendments and consider the remarks as follows.

**Amendments to the Specification** begin on page 2.

**Amendments to the Claims** begin on page 17.

**Remarks / Arguments** begin on page 21 of this paper.

**An Appendix**, containing annotated drawing sheets 4 and 5, and new drawing sheets 28-51, follows page 26.

**Amendments to the Specification:**

At page 15, please amend Paragraph [0073] as shown below.

[0073] Next, Figure 8C, as the apparatus is actively foreshortened using proximal (e.g., fingers) and/or distal actuators (e.g., ~~wires 55~~), wires 50), the leaflet engagement elements positively register with the native valve leaflets. Foreshortening can cause seal 60 to bunch up and create pleats. These pleats can then fill pockets thereby improving the paravalvular seal. In preferred embodiments, wherein the leaflet engagement elements are covered with a seal, at least a portion of the seal is also positioned between the native valve leaflets and the aortic wall. Once the anchor is fully compressed within the aortic valve, the anchor is locked, the fingers and post mandrels are disengaged, and the seal is adapted to further limit blood flow around the replacement valve. The catheter is subsequently withdrawn, leaving behind valve 20, seal 60 and anchor 70. When fully deployed, the anchor is substantially distal to the coronary ostia of the patient such that it will not interfere with blood flow through the ostia.

At page 19 of the originally filed application, please add the following new paragraphs [0095] – [0142] as shown below.

[0095] Figures 15A-H show another embodiment of a replacement heart valve apparatus in accordance with the present invention. Apparatus 450 comprises replacement valve 460 (see Figures 17B and 18C) 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.

**[0096]** As seen in Figure 15A, 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 15D-15G. 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.

**[0097]** As seen in Figure 15B, 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 15B-15D, 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 15E and 15F. Preferably, such expansion may be maintained via locking features described hereinafter.

**[0098]** In Figure 15G, 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 15H.

**[0099]** 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.

**[0100]** With reference now to Figures 16A-E, individual cells of anchor 470 of apparatus 450 are described to detail deployment and expansion of the apparatus. In Figure 16A, 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 15. A portion of the cells forming body regions 476, for example, every 'nth' row of cells, comprises locking features.

**[0101]** 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.

**[0102]** In Figure 16B, 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 16C and 16D. As seen in Figure 16E, 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 16E). Advantageously, deployment of apparatus 450 is fully reversible until lip lock 480 and/or skirt lock 490 has been actuated.

**[0103]** With reference to Figures 17A-B, isometric views, partially in section, further illustrate apparatus 450 in the fully deployed and expanded configuration. Figure 17A illustrates the wireframe structure of anchor 470, while Figure 17B 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 17B. 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 18B).

**[0104]** Referring to Figures 18A-C, in conjunction with Figures 15 and 16, 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 15, 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.

**[0105]** 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 16. In Figure 18A, 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.

**[0106]** Wires 424b are then actuated external to the patient in order to expand lip region 472, as previously described in Figures 15. 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.

**[0107]** As seen in Figure 18B, 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 18C 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.



**[0108]** With reference to Figures 19-21, a first embodiment of two-piece apparatus of the present invention adapted for percutaneous replacement of a patient's heart valve is described. As seen in Figures 21, apparatus 510 comprises a two-piece device having custom-designed expandable anchor piece 550 of Figures 19 and expandable replacement valve piece 600 of Figures 20. Both anchor piece 550 and valve piece 600 have reduced delivery configurations and expanded deployed configurations. Both may be either balloon expandable (e.g. fabricated from a stainless steel) or self-expanding (e.g. fabricated from a nickel-titanium alloy ("Nitinol") or from a wire mesh) from the delivery to the deployed configurations.

**[0109]** When replacing a patient's aortic valve, apparatus 510 preferably may be delivered through the patient's aorta without requiring a transseptal approach, thereby reducing patient trauma, complications and recovery time. Furthermore, apparatus 510 enables dynamic repositioning of anchor piece 550 during delivery and facilitates positive registration of apparatus 510 relative to the native position of the patient's valve, thereby reducing a risk of device migration and reducing a risk of blocking or impeding flow to the patient's coronary ostia. Furthermore, the expanded deployed configuration of apparatus 510, as seen in Figure 21D, is adapted to reduce paravalvular regurgitation, as well as to facilitate proper seating of valve piece 600 within anchor piece 550.

**[0110]** As seen in Figures 19, anchor piece 550 preferably comprises three sections. Lip section 560 is adapted to engage the patient's native valve leaflets to provide positive registration and ensure accurate placement of the anchor relative to the patient's valve annulus during deployment, while allowing for dynamic repositioning of the anchor during deployment. Lip section 560 also maintains proper positioning of composite anchor/valve apparatus 510 post-deployment to preclude distal migration. Lip section 560 optionally may be covered or coated with biocompatible film **B** (see Figures 21) to ensure engagement of the native valve leaflets. It is expected that covering lip section 560 with film **B** especially would be indicated when the native leaflets are stenosed and/or fused together

**[0111]** Groove section 570 of anchor piece 550 is adapted to engage an expandable frame portion, described hereinbelow, of valve piece 600 to couple anchor piece 550 to valve piece 600. As compared to previously known apparatus, groove section 570 comprises additional material and reduced openings or gaps **G**, which is expected to reduce tissue protrusion through

the gaps upon deployment, thereby facilitating proper seating of the valve within the anchor. Groove section 570 optionally may be covered or coated with biocompatible film **B** (see Figures 21) to further reduce native valve tissue protrusion through gaps **G**.

**[0112]** Finally, skirt section 580 of anchor piece 550 maintains proper positioning of composite anchor/valve apparatus 510 post-deployment by precluding proximal migration. When replacing a patient's aortic valve, skirt section 580 is deployed within the patient's left ventricle. As with lip section 560 and groove section 570, skirt section 580 optionally may be covered or coated with biocompatible film **B** (see Figures 21) to reduce paravalvular regurgitation. As will be apparent to those of skill in the art, all, a portion of, or none of anchor piece 50 may be covered or coated with biocompatible film **B**.

**[0113]** In Figure 19A, a portion of anchor piece 550 has been flattened out to illustrate the basic anchor cell structure, as well as to illustrate techniques for manufacturing anchor piece 550. In order to form the entire anchor, anchor 550 would be bent at the locations indicated in Figure 19A, and the basic anchor cell structure would be revolved to form a joined 360° structure. Lip section 560 would be bent back into the page to form a lip that doubles over the groove section, groove section 570 would be bent out of the page into a 'C'- or 'U'-shaped groove, while skirt section 580 would be bent back into the page. Figure 19B shows the anchor portion after bending and in an expanded deployed configuration.

**[0114]** The basic anchor cell structure seen in Figure 19A is preferably formed through laser cutting of a flat sheet or of a hollow tube placed on a mandrel. When formed from a flat sheet, the sheet would be cut to the required number of anchor cells, bent to the proper shape, and revolved to form a cylinder. The ends of the cylinder would then be joined together, for example, by heat welding.

**[0115]** If balloon expandable, anchor piece 550 would be formed from an appropriate material, such as stainless steel, and then crimped onto a balloon delivery catheter in a collapsed delivery configuration. If self-expanding and formed from a shape-memory material, such as a nickel-titanium alloy ("Nitinol"), the anchor piece would be heat-set such that it could be constrained within a sheath in the collapsed delivery configuration, and then would dynamically self-expand to the expanded deployed configuration upon removal of the sheath. Likewise, if anchor piece 550 were formed from a wire mesh or braid, such as a spring steel braid, the anchor

would be constrained within a sheath in the delivery configuration and dynamically expanded to the deployed configuration upon removal of the sheath.

**[0116]** In Figures 20, valve piece 600 is described in greater detail. Figure 20A illustrates valve piece 600 in a collapsed delivery configuration, while Figure 20B illustrates the valve piece in an expanded deployed configuration. Valve piece 600 comprises replacement valve 610 coupled to expandable frame 620. Replacement valve 610 is preferably biologic, although synthetic valves may also be used. Replacement valve 610 preferably comprises three leaflets 611 coupled to three posts 621 of expandable frame 620. Expandable frame 620 is preferably formed from a continuous piece of material and may comprise tips 622 in the collapsed delivery configuration, which expand to form hoop 624 in the deployed configuration. Hoop 624 is adapted to engage groove section 570 of anchor piece 550 for coupling anchor piece 550 to valve piece 600. As with anchor piece 550, valve piece 600 may be balloon expandable and coupled to a balloon delivery catheter in the delivery configuration. Alternatively, anchor piece 550 may be self-expanding, e.g. Nitinol or wire mesh, and constrained within a sheath in the delivery configuration.

**[0117]** Referring again to Figures 21, a method for deploying valve piece 600 and coupling it to deployed anchor piece 550 to form two-piece apparatus 510 is described. In Figure 21A, valve piece 600 is advanced within anchor piece 550 in an at least partially compressed delivery configuration. In Figure 21B, tips 622 of frame 620 are expanded such that they engage groove section 570 of anchor piece 550. In Figure 21C, frame 620 continues to expand and form hoop 624. Hoop 624 flares out from the remainder of valve piece 600 and acts to properly locate the hoop within groove section 570. Figure 21D shows valve piece 600 in a fully deployed configuration, properly seated and friction locked within groove section 570 to form composite anchor/valve apparatus 510.

**[0118]** Anchor piece 550 and valve piece 600 of apparatus 510 preferably are spaced apart and releasably coupled to a single delivery catheter while disposed in their reduced delivery configurations. Spacing the anchor and valve apart reduces a delivery profile of the device, thereby enabling delivery through a patient's aorta without requiring a transeptal approach. With reference to Figure 22, a first embodiment of single catheter delivery system 700 for use

with apparatus 510 is described. Delivery system 700 is adapted for use with a preferred self-expanding embodiment of apparatus 510.

**[0119]** Delivery system 700 comprises delivery catheter 710 having inner tube 720, middle distal tube 730, and outer tube 740. Inner tube 720 comprises lumen 722 adapted for advancement over a standard guide wire, per se known. Middle distal tube 730 is coaxially disposed about a distal region of inner tube 720 and is coupled to a distal end 724 of the inner tube, thereby forming proximally-oriented annular bore 732 between inner tube 720 and middle tube 730 at a distal region of delivery catheter 710. Outer tube 740 is coaxially disposed about inner tube 720 and extends from a proximal region of the inner tube to a position at least partially coaxially overlapping middle distal tube 730. Outer tube 740 preferably comprises distal step 742, wherein lumen 743 of outer tube 740 is of increased diameter. Distal step 742 may overlap middle distal tube 730 and may also facilitate deployment of valve piece 600, as described hereinbelow with respect to Figures 25.

**[0120]** Proximally-oriented annular bore 732 between inner tube 720 and middle distal tube 730 is adapted to receive skirt section 580 and groove section 570 of anchor piece 550 in the reduced delivery configuration. Annular space 744 formed at the overlap between middle distal tube 730 and outer tube 740 is adapted to receive lip section 560 of anchor piece 550 in the reduced delivery configuration. More proximal annular space 746 between inner tube 720 and outer tube 740 may be adapted to receive replacement valve 610 and expandable frame 620 of valve piece 600 in the reduced delivery configuration.

**[0121]** Inner tube 720 optionally may comprise retainer elements 726a and 726b to reduce migration of valve piece 600. Retainer elements 726 preferably are fabricated from a radiopaque material, such as platinum-iridium or gold, to facilitate deployment of valve piece 600, as well as coupling of the valve piece to anchor piece 550. Additional or alternative radiopaque elements may be disposed at other locations about delivery system 700 or apparatus 510, for example, in the vicinity of anchor piece 550.

**[0122]** With reference now to Figure 23, an alternative delivery system for use with apparatus of the present invention is described. Delivery system 750 comprises two distinct catheters adapted to deliver the anchor and valve pieces, respectively: anchor delivery catheter 710' and valve delivery catheter 760. In use, catheters 710' and 760 may be advanced

sequentially to a patient's diseased heart valve for sequential deployment and coupling of anchor piece 550 to valve piece 600 to form composite two-piece apparatus 510.

[0123] Delivery catheter 710' is substantially equivalent to catheter 710 described hereinabove, except that catheter 710' does not comprise retainer elements 726, and annular space 746 does not receive valve piece 600. Rather, valve piece 600 is received within catheter 760 in the collapsed delivery configuration. Catheter 760 comprises inner tube 770 and outer tube 780. Inner tube 770 comprises lumen 772 for advancement of catheter 760 over a guide wire. The inner tube optionally may also comprise retainer elements 774a and 774b, e.g. radiopaque retainer elements 774, to reduce migration of valve piece 600. Outer tube 780 is coaxially disposed about inner tube 770 and preferably comprises distal step 782 to facilitate deployment and coupling of valve piece 600 to anchor piece 550, as described hereinbelow. Valve piece 600 may be received in annular space 776 between inner tube 770 and outer tube 780, and more preferably may be received within annular space 776 between retainer elements 774.

[0124] Referring now to Figure 24, another alternative delivery system is described. As discussed previously, either anchor piece 550 or valve piece 600 (or portions thereof or both) may be balloon expandable from the delivery configuration to the deployed configuration. Delivery system 800 is adapted for delivery of an embodiment of apparatus 510 wherein the valve piece is balloon expandable. Additional delivery systems – both single and multi-catheter - for deployment of alternative combinations of balloon and self-expandable elements of apparatus of the present invention will be apparent to those of skill in the art in view of the illustrative delivery systems provided in Figures 22-24.

[0125] In Figure 24, delivery system 800 comprises delivery catheter 710''. Delivery catheter 710'' is substantially equivalent to delivery catheter 710 of delivery system 700, except that catheter 710'' does not comprise retainer elements 726, and annular space 746 does not receive the valve piece. Additionally, catheter 710'' comprises inflatable balloon 802 coupled to the exterior of outer tube 740'', as well as an inflation lumen (not shown) for reversibly delivering an inflation medium from a proximal region of catheter 710'' into the interior of inflatable balloon 802 for expanding the balloon from a delivery configuration to a deployed configuration. Valve piece 600 may be crimped to the exterior of balloon 802 in the delivery

configuration, then deployed and coupled to anchor piece 550 *in vivo*. Delivery catheter 710'' preferably comprises radiopaque marker bands 804a and 804b disposed on either side of balloon 802 to facilitate proper positioning of valve piece 600 during deployment of the valve piece, for example, under fluoroscopic guidance.

[0126] With reference now to Figures 25, in conjunction with Figures 19-22, an illustrative method of endovascularly replacing a patient's diseased heart valve using apparatus of the present invention is described. In Figure 25A, a distal region of delivery system 700 of Figure 22 has been delivered through a patient's aorta **A**, e.g., over a guide wire and under fluoroscopic guidance using well-known percutaneous techniques, to a vicinity of diseased aortic valve **AV** of heart **H**. Apparatus 510 of Figures 19-21 is disposed in the collapsed delivery configuration within delivery catheter 710 with groove section 570 and skirt section 580 of anchor piece 550 collapsed within annular bore 732, and lip section 560 of anchor piece 550 collapsed within annular space 744. Valve piece 600 is disposed in the collapsed delivery configuration between retainer elements 726 within more proximal annular space 746. Separation of anchor piece 550 and valve piece 600 of apparatus 510 along the longitudinal axis of delivery catheter 710 enables percutaneous aortic delivery of apparatus 510 without requiring a transseptal approach.

[0127] Aortic valve **AV** comprises native valve leaflets **L** attached to valve annulus **An**. Coronary ostia **O** are disposed just proximal of diseased aortic valve **AV**. Coronary ostia **O** connect the patient's coronary arteries to aorta **A** and are the conduits through which the patient's heart muscle receives oxygenated blood. As such, it is critical that the ostia remain unobstructed post-deployment of apparatus 510.

[0128] In Figure 25A, a distal end of delivery catheter 710 has been delivered across diseased aortic valve **AV** into the patient's left ventricle **LV**. As seen in Figure 25B, outer tube 740 is then retracted proximally relative to inner tube 720 and middle distal tube 730. Outer tube 740 no longer coaxially overlaps middle distal tube 730, and lip section 560 of anchor piece 550 is removed from annular space 744. Lip section 560 self-expands to the deployed configuration. As seen in Figure 25C, inner tube 720 and middle tube 730 (or all of delivery catheter 710) are then distally advanced until lip section 560 engages the patient's native valve leaflets **L**, thereby providing positive registration of anchor piece 550 to leaflets **L**. Registration may be confirmed, for example, via fluoroscopic imaging of radiopaque features coupled to apparatus 510 or

delivery system 700 and/or via resistance encountered by the medical practitioner distally advancing anchor piece 550.

[0129] Lip section 560 may be dynamically repositioned until it properly engages the valve leaflets, thereby ensuring proper positioning of anchor piece 550 relative to the native coronary ostia **O**, as well as the valve annulus **An**, prior to deployment of groove section 570 and skirt section 580. Such multi-step deployment of anchor piece 550 enables positive registration and dynamic repositioning of the anchor piece. This is in contrast to previously known percutaneous valve replacement apparatus.

[0130] As seen in Figure 25D, once leaflets **L** have been engaged by lip section 560 of anchor piece 550, inner tube 720 and middle distal tube 730 are further distally advanced within left ventricle **LV**, while outer tube 740 remains substantially stationary. Lip section 560, engaged by leaflets **L**, precludes further distal advancement/migration of anchor piece 550. As such, groove section 570 and skirt section 580 are pulled out of proximally-oriented annular bore 732 between inner tube 720 and middle distal tube 730 when the tubes are distally advanced. The groove and skirt sections self-expand to the deployed configuration, as seen in Figure 25E. Groove section 570 pushes native valve leaflets **L** and lip section 560 against valve annulus **An**, while skirt section 580 seals against an interior wall of left ventricle **LV**, thereby reducing paravalvular regurgitation across aortic valve **AV** and precluding proximal migration of anchor piece 550.

[0131] With anchor piece 550 deployed and native aortic valve **AV** displaced, valve piece 600 may be deployed and coupled to the anchor piece to achieve percutaneous aortic valve replacement. Outer tube 740 is further proximally retracted relative to inner tube 720 such that valve piece 600 is partially deployed from annular space 746 between inner tube 720 and outer tube 740, as seen in Figure 25F. Expandable frame 620 coupled to replacement valve 610 partially self-expands such that tips 622 partially form hoop 624 for engagement of groove section 570 of anchor piece 550 (see Figure 21B). A proximal end of expandable frame 620 is engaged by distal step 742 of outer tube 740.

[0132] Subsequent re-advancement of outer tube 740 relative to inner tube 720 causes distal step 742 to distally advance valve piece 600 within anchor piece 550 until tips 622 of expandable frame 620 engage groove section 570 of anchor piece 550, as seen in Figure 25G. As discussed

previously, groove section 570 comprises additional material and reduced openings or gaps **G**, as compared to previously known apparatus, which is expected to reduce native valve tissue protrusion through the gaps and facilitate engagement of tips 622 with the groove section. Outer tube 740 then is proximally retracted again relative to inner tube 720, and valve piece 600 is completely freed from annular space 746. Frame 620 of valve piece 600 fully expands to form hoop 624, as seen in Figure 25H.

**[0133]** Hoop 624 friction locks within groove section 570 of anchor piece 550, thereby coupling the anchor piece to the valve piece and forming composite two-piece apparatus 510, which provides a percutaneous valve replacement. As seen in Figure 25I, delivery catheter 710 may then be removed from the patient, completing the procedure. Blood may freely flow from left ventricle **LV** through replacement valve 610 into aorta **A**. Coronary ostia **O** are unobstructed, and paravalvular regurgitation is reduced by skirt section 580 of anchor piece 550.

**[0134]** Referring now to Figures 26, an alternative embodiment of two-piece apparatus 510 is described comprising an alignment/locking mechanism. Such a mechanism may be provided in order to ensure proper radial alignment of the expandable frame of the valve piece with the groove section of the anchor piece, as well as to ensure proper longitudinal positioning of the frame within the hoop. Additionally, the alignment/locking mechanism may provide a secondary lock to further reduce a risk of the anchor piece and the valve piece becoming separated post-deployment and coupling of the two pieces to achieve percutaneous valve replacement.

**[0135]** In Figures 26, apparatus 510' comprises valve piece 600' of Figure 26A and anchor piece 550' of Figure 26B. Anchor piece 550' and valve piece 600' are substantially the same as anchor piece 550 and valve piece 600 described hereinabove, except that anchor piece 550' comprises first portion 652 of illustrative alignment/locking mechanism 650, while valve piece 600' comprises second portion 654 of the alignment/locking mechanism for coupling to the first portion. First portion 652 illustratively comprises three guideposts 653 coupled to skirt section 580' of anchor piece 550' (only one guidepost shown in the partial view of Figure 26B), while second portion 654 comprises three sleeves 655 coupled to posts 621' of expandable frame 620' of valve piece 600'.

**[0136]** When anchor piece 550' is self-expanding and collapsed in the delivery configuration, guideposts 653 may be deployed with skirt section 580', in which case guideposts



653 would rotate upward with respect to anchor piece 550' into the deployed configuration of Figure 26B. Alternatively, when anchor piece 550' is either balloon or self-expanding and is collapsed in the delivery configuration, guideposts 653 may be collapsed against groove section 570' of the anchor piece and may be deployed with the groove section. Deploying guideposts 653 with skirt section 580' has the advantages of reduced delivery profile and ease of manufacturing, but has the disadvantage of significant dynamic motion during deployment. Conversely, deploying guideposts 653 with groove section 570' has the advantage of minimal dynamic motion during deployment, but has the disadvantage of increased delivery profile. Additional deployment configurations will be apparent to those of skill in the art. As will also be apparent, first portion 652 of alignment/locking mechanism 650 may be coupled to alternative sections of anchor piece 550' other than skirt section 580'.

[0137] Sleeves 655 of second portion 654 of alignment/locking mechanism 650 comprise lumens 656 sized for coaxial disposal of sleeves 655 about guideposts 653 of first portion 652. Upon deployment, sleeves 655 may friction lock to guideposts 653 to ensure proper radial and longitudinal alignment of anchor piece 550' with valve piece 600', as well as to provide a secondary lock of the anchor piece to the valve piece. The secondary lock enhances the primary friction lock formed by groove section 570' of the anchor piece with hoop 624' of expandable frame 620' of the valve piece.

[0138] To facilitate coupling of the anchor piece to the valve piece, suture or thread may pass from optional eyelets 651a of guideposts 653 through lumens 656 of sleeves 655 to a proximal end of the delivery catheter (see Figure 27). In this manner, second portion 654 of mechanism 650 may be urged into alignment with first portion 652, and optional suture knots (not shown), e.g. pre-tied suture knots, may be advanced on top of the mechanism post-coupling of the two portions to lock the two portions together. Alternatively, guideposts 653 may comprise optional one-way valves 651b to facilitate coupling of the first portion to the second portion. Specifically, sleeves 655 may be adapted for coaxial advancement over one-way valves 651b in a first direction that couples the sleeves to guideposts 653, but not in a reverse direction that would uncouple the sleeves from the guideposts.

[0139] Referring now to Figure 27, an alternative embodiment of apparatus 510' comprising an alternative alignment/locking mechanism is described. Apparatus 510'' is illustratively

shown in conjunction with delivery system 700 described hereinabove with respect to Figure 22. Valve piece 600'' is shown partially deployed from outer tube 740 of catheter 710. For the sake of illustration, replacement valve 610'' of valve piece 600'', as well as inner tube 720 and middle distal tube 730 of delivery catheter 710, are not shown in Figure 27.

[0140] In Figure 27, anchor piece 550'' of apparatus 510'' comprises first portion 652' of alignment/locking mechanism 650', while valve piece 600'' comprises second portion 654' of the alternative alignment/locking mechanism. First portion 652' comprises eyelets 660 coupled to groove section 570'' of anchor piece 550''. Second portion 654' comprises knotted loops of suture 662 coupled to tips 622'' of expandable frame 620'' of valve piece 600''. Suture 661 extends from knotted loops of suture 662 through eyelets 660 and out through annular space 746 between outer tube 740 and inner tube 720 (see Figure 22) of catheter 710 to a proximal end of delivery system 700. In this manner, a medical practitioner may radially and longitudinally align valve piece 600'' with anchor piece 550'' by proximally retracting sutures 661 (as shown by arrows in Figure 27) while distally advancing distal step 742 of outer tube 740 against valve piece 600'' until tips 622'' of the valve piece engage groove section 570'' of anchor piece 550''. Proximal retraction of outer tube 740 then causes expandable frame 620'' to further expand and form hoop 624'' that friction locks with groove section 570'' of anchor piece 550'', thereby forming apparatus 510'' as described hereinabove with respect to apparatus 510. A secondary lock may be achieved by advancing optional suture knots (not shown) to the overlap of eyelets 660 and knotted loops of suture 662. Such optional suture knots preferably are pre-tied.

[0141] With reference now to Figure 28, yet another alternative embodiment of apparatus 510', comprising yet another alternative alignment/locking mechanism 650, is described. First portion 652'' of alignment/locking mechanism 650'' is coupled to anchor piece 550'' of apparatus 510'', while second portion 654'' is coupled to valve piece 600''. The first portion comprises male posts 670 having flared ends 671, while the second portion comprises female guides 672 coupled to tips 622'' of expandable frame 620'' of valve piece 600''.

[0142] Female guides 672 are translatable about male posts 670, but are constrained by flared ends 671 of the male posts. In this manner, anchor piece 550'' and valve piece 600'' remain coupled and in radial alignment with one another at all times – including delivery – but may be longitudinally separated from one another during delivery. This facilitates percutaneous

delivery without requiring a transseptal approach, while mitigating a risk of inadvertent deployment of the anchor and valve pieces in an uncoupled configuration. Additional alignment/locking mechanisms will be apparent in view of the mechanisms described with respect to Figures 26-28.

**Amendments to the Claims:**

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

1. - 21. (Canceled)

22. (Currently Amended) A method for endovascularly replacing a patient's ~~heart~~ aortic valve, the method comprising:

endovascularly delivering an anchor and a replacement valve supported within the anchor to a vicinity of the ~~heart~~ aortic valve in a collapsed delivery configuration, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage native aortic valve leaflets;

expanding the anchor; and

engaging the leaflet engagement elements with native aortic valve leaflets.

23. (Original) The method of claim 22 further comprising expanding the anchor into engagement with the patient's heart such that the anchor is substantially distal to coronary ostia of the heart.

24. (Original) The method of claim 23 wherein the expanding step comprises actively foreshortening the anchor.

25. (Original) The method of claim 24 wherein the actively foreshortening step comprises actuating distal anchor actuation elements.

26. (Original) The method of claim 24 wherein the actively foreshortening step comprises actuating proximal anchor actuation elements.

27. (Original) The method of claim 24 further comprising locking the anchor in a deployed configuration.

28. (Original) The method of claim 22 further comprising resisting distal movement of the proximal end of the anchor after the engaging step.
29. (Original) The method of claim 22 further comprising moving the leaflet engagement elements further apart radially during the anchor expanding step.
30. (Original) The method of claim 22 further comprising permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve during deployment of the anchor and replacement valve.
31. (Original) The method of claim 22 further comprising:  
delivering the anchor and replacement valve to a vicinity of the heart in a delivery catheter;  
removing the anchor and the replacement valve from the catheter; and  
permitting blood flow through the replacement valve and preventing blood backflow through the replacement valve after the replacement valve exits the catheter and before final deployment of the anchor.
32. (Original) The method of claim 31 wherein the permitting and preventing steps are performed before the anchor completely exits the catheter.
33. (Original) The method of claim 31 wherein the permitting step comprises allowing the anchor to self-expand.
34. (Original) The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and around the catheter after the replacement valve exits the catheter and before final deployment of the anchor.
35. (Original) The method of claim 31 wherein the permitting step comprises permitting blood flow through the replacement valve and into coronary ostia of the heart after the replacement valve exits the catheter and before final deployment of the anchor.

36. (Original) The method of claim 22 further comprising sealing between the replacement valve and the heart.

37. (Original) The method of claim 36 wherein the sealing step comprises pleating a seal.

38. (Withdrawn) The method of claim 36 wherein the sealing step comprises capturing at least a portion of a seal between the leaflets and a wall of the heart.

39. - 58. (Canceled)

59. (New) The method of claim 22 wherein the leaflet engagement elements extend distally from the proximal end of the anchor, and wherein engaging the leaflet engagement elements with native aortic valve leaflets comprises sandwiching the native aortic valve leaflets between the anchor and the leaflet engagement elements.

60. (New) A method for endovascularly replacing a patient's native heart valve, the method comprising:

delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein the anchor comprises leaflet engagement elements extending distally from a proximal end of the anchor;

sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor;

expanding the anchor from a collapsed delivery configuration to an expanded configuration to secure the anchor within the native heart valve; and

wherein the replacement valve allows the flow of blood through the replacement valve in a first configuration and prevents the flow of blood through the valve in a second configuration.

61. (New) The method of claim 60 wherein expanding the anchor from a collapsed delivery configuration to an expanded configuration comprises allowing the anchor to self-expand.

62. (New) The method of claim 60 wherein the leaflet engagement elements extend generally parallel to the longitudinal axis of the expandable anchor.
63. (New) The method of claim 60 wherein the expandable anchor and the replacement valve are delivered as two separate elements, the method further comprising deploying the expandable anchor and the replacement valve in the vicinity of the native heart valve in two different steps.
64. (New) The method of claim 63 further comprising engaging the expandable anchor and the replacement valve after they are deployed in the vicinity of the native heart valve to secure the replacement heart valve to the expandable anchor.
65. (New) The method of claim 64 wherein the replacement heart valve comprises an expandable support structure and replacement valve leaflets, and wherein engaging the expandable anchor and the replacement valve in the vicinity of the native heart valve comprises coupling the expandable anchor and the expandable support structure to secure the replacement heart valve to the expandable anchor.

## REMARKS

### Claim Summary

Claims 22-38 and 59-65 are pending. Claim 22 is currently amended. Claim 38 is withdrawn. Claims 1-21 and 39-58 are canceled, and claims 59-65 are newly presented.

### Material Incorporated By Reference

This application is a CIP of Application No. 10/746,240, filed December 23, 2003. The '240 Application was incorporated by reference as of the filing date of the instant application. Applicants are herein adding Figures 35-48 from the '240 Application (renumbered herein as new Figures 15-28, respectively) and paragraphs [0117]-[0164] (renumbered herein as new paragraphs [0095]-[0142], respectively). No new matter is added.

### Drawings

The drawings are objected to as allegedly failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- a. Fig. 1B: 106, 120, 122, 124
- b. Fig. 4C: 30
- c. Fig. 4D: 30
- d. Fig. 4G: 30
- e. Fig. 4H: 30
- f. Fig. 4K: 30
- g. Fig. 5C: 30
- h. Fig. 6B: 32, 40, 60, 61A
- i. Fig. 6C: 32, 61B
- j. Fig. 6F: 30, 50, 60, 61A
- k. Fig. 8C: 55
- l. Fig. 10B: 50
- m. Fig. 14C: 380

37 CFR 1.84(p)(5) states that reference characters not mentioned in the description shall not appear in the drawings, and that reference characters mentioned in the description must appear in the drawings.

While 37 CFR 1.84(p)(5) does state that reference characters mentioned in the description must appear in the drawings, it does not state that a reference character mentioned in the description must appear in a particular drawing. According to 37 CFR 1.84(p)(5), as long as



reference characters that are mentioned in the description appear in at least one drawing, the description and drawings comply with 37 CFR 1.84(p)(5).

Reference characters 106, 120, 122, and 124 appear in at least Figure 1A.

Reference character 30 appears in at least Figure 1A.

Reference character 32 appears in at least Figure 1B

Reference character 40 appears in at least Figure 6E.

Reference character 60 appears in at least Figure 6C.

Reference character 61A appears in at least Figure 6C.

Reference character 61B appears in at least Figure 6E.

Reference character 50 appears in at least Figure 6C.

Reference character 55 in paragraph [0073] has been changed to reference character 50 to correct the error as filed.

Reference character 380 appears in at least Figure 14A.

The drawings are objected to as allegedly failing to comply with 37 CFR 1.84(p)(5) because they include reference character(s) not mentioned in the description:

- n. Fig. 1A: 20
- o. Fig. 1B: 108, 112, 110, 100,31
- p. Fig. 2: 31
- q. Fig. 4A: 30, W
- r. Fig. 4B: 31, Tu, W
- s. Fig. 4C: 31, Tu
- t. Fig. 4D: 31, Tu, W
- u. Fig. 4E: 31, Tu, W
- v. Fig. 4F: 31, Tu
- w. Fig. 4G: 31, Tu, W
- x. Fig. 4H: 31, W
- y. Fig. 4I: 31, Tu, W
- z. Fig. 4J: 31, Tu, W
- aa. Fig. 4K: 31, Tu, W
- bb. Fig. 4L: 31, Tu, W
- cc. Fig. 4M: 31, Tu, W
- dd. Fig. 4N: 31, Tu, W
- ee. Fig. 5A: 31
- ff. Fig. 5C: 31
- gg. Fig. 5D: Tu
- hh. Fig. 5E: Tu
- ii. Fig. 6A: A, H, AV, G, LV
- jj. Fig. 6B: A, H, L, AV, 20
- kk. Fig. 6C: A, H, L, AV, LV, 20, 50
- ll. Fig. 6D: A, H, AV, 100', 110, 20, 10
- mm. Fig. 6E: A, H, LV, L, 100', 60, 61B, 40, 30, 20, 10

- nn. Fig. 6F: A, H, L, AV, G, LV, 110, 100'
- oo. Fig. 7: A, H, AV, LV, 20
- pp. Fig. 8C: 600, 30, 50
- qq. Fig. 13B: 106, 30, 32
- rr. Fig. 13C: 106, 30, 32

While 37 CFR 1.84(p)(5) states that reference characters not mentioned in the description shall not appear in the drawings, it does not state that reference characters must be mentioned in the description of a particular drawing. As long as the reference character is mentioned in the description, the description and drawings comply with 37 CFR 1.84(p)(5).

- Reference character 20 is mentioned in at least paragraph [0035].
- Reference characters 108, 112, 110, 100 are mentioned in at least paragraph [0033].
- Reference character 31 in Figures 4B-5C has been renumbered as "30" to correct the error. No new matter has been added.
- Reference character 30 is mentioned in at least paragraph [0034]
- Reference character W is mentioned in at least paragraph [0046].
- Reference character Tu is mentioned in at least paragraph [0042].
- Reference character 20 is mentioned in at least paragraph [0035].
- Reference character A is mentioned in at least paragraph [0104].
- Reference character H is mentioned in at least paragraph [0104].
- Reference character AV is mentioned in at least paragraph [0064].
- Reference character G in Figures 6A and 6F has been changed to "102" to correct the error as filed.
- Reference character LV is mentioned in at least paragraph [104].
- Reference character L is mentioned in at least paragraph [0066].
- Reference character 20 is mentioned in at least paragraph [0071].
- Reference character 50 is mentioned in at least paragraph [0068]
- Reference character 100' is mentioned in at least paragraph [0066].
- Reference character 110 is mentioned in at least paragraph [0033].
- Reference character 10 is mentioned in at least paragraph [0066].
- Reference character 60 is mentioned in at least paragraph [0067].
- Reference character 61B is mentioned in at least paragraph [0067].
- Reference character 40 is mentioned in at least paragraph [0065].
- Reference character 600 is mentioned in at least paragraph [0071].
- Reference character 106 is mentioned in at least paragraph [0033].
- Reference character 32 is mentioned in at least paragraph [0066].

### **Claim Rejections Under 35 U.S.C. § 102**

Claims 22-36 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Bailey et al. U.S. 6,458,153.

Independent claim 22 is currently amended to recite a method for endovascularly replacing a patient's aortic valve. The method includes endovascularly delivering an anchor and a replacement valve supported within the anchor to a vicinity of the aortic valve in a collapsed delivery configuration, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage native aortic valve leaflets, and engaging the leaflet engagement elements with native aortic valve leaflets. The support for this amendment can be found throughout Applicants' specification.

The Examiner relied on Bailey's chamber-to-chamber (CC) configuration, shown in Figures 7-11, which is particularly well-adapted for mitral valve replacement (Col. 1, lines 22-24). Bailey's chamber-to-vessel device (CV), which is particularly well-suited as an aortic valve prosthesis (Col. 1, lines 18-21), is described in reference to at least Figures 1-5.

Bailey does not anticipate claim 22 because Bailey does not describe, expressly or inherently, each method step in claim 22. Claim 22 is amended to require the step of engaging leaflet engagement elements on a proximal end of the anchor with native aortic valve leaflets. As the Examiner acknowledges by relying on the CC device from Bailey, the only embodiment in Bailey which can be possibly construed as having leaflet engagement elements on a proximal end of the anchor which are engaged with native valve leaflets is the CC device. In contrast, Bailey's CV device is described as having distal anchor section 16 (Bailey's "distal" is analogous to Applicants' "proximal"), which, when delivered, "expands and contacts the luminal wall of the aorta, immediately distal to the aortic valve." (Col. 14, lines 35-36; also see Figures 20F-20I and Figures 6A and 6B). In Bailey's CV device the anchor flange 22, and not the distal anchor section 16, is adapted to "project radially outward away from the central longitudinal axis of the stent body member." (Col. 8, lines 59-60). Bailey therefore does not disclose, teach, suggest, or appreciate engaging leaflet engagement elements on the proximal end of the anchor with native aortic valve leaflets. As such, Bailey does not anticipate currently amended claim 22. Claims 23-36 depend from claim 22 and are not anticipated by Bailey for at least the reasons set forth above with respect to claim 22.

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

Claim 37 stands rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Bailey et al. US 6,458,153 in view of Lunn U.S. 5,476,506.

Claim 37 depends from currently amended claim 22 and incorporate the limitations thereof. As discussed above, Bailey does not disclose, teach, or suggest the limitations of claim 22. Lunn does not overcome the deficiencies of Bailey and therefore claim 37 is not obvious over Bailey in view of Lunn.

### **New Claims**

Applicants have added new claims 59-65. Support for new claim 59 can be found in at least Figure 7 and paragraph [0070] and Figures 25B-25I and the description thereof. Claim 59 depends from claim 22 and as discussed above, claim 22 is not anticipated over Bailey. Claim 59 is not anticipated by Bailey for at least the same reasons. Additionally, the CV device in Bailey does not include leaflet engagement elements on the proximal end of an anchor that extend distally from the proximal end. Additionally, Bailey does not disclose, in any of its embodiments, sandwiching native valve leaflets between an anchor and leaflet engagement elements.

Support for new independent claim 60 can be found in at least Figure 7 and paragraph [0070] and Figures 25B-25I and the description thereof. Claim 60 is patentable over Bailey because Bailey does not disclose, teach, suggest, or appreciate an anchor with leaflet engaging elements extending distally from a proximal end thereof, nor does Bailey teach the step of sandwiching native valve leaflets between an anchor and leaflet engagement elements.

Support for new claim 61 can be found in at least paragraphs [0128]-[0130]. Claim 61 depends from claim 60 and is patentable over Bailey for at least the same reasons stated above.

Support for new claim 62 can be found in at least Figure 7 and paragraph [0070], and Figures 25B-25I and the descriptions thereof. Claim 62 depends from claim 60 and is patentable over Bailey for at least the same reasons stated above.

Support for new claim 63 can be found in at least Figures 19A-21D and the descriptions thereof, and Figures 25A-25I and the descriptions thereof. Claim 63 depends from claim 60 and is patentable over Bailey for at least the same reasons stated above.

Support for new claim 64 can be found in at least Figures 25G-25H and the descriptions thereof. Claim 64 depends from claim 60 and is patentable over Bailey for at least the same reasons stated above.

Support for new claim 65 can be found in at least Figures 20A-21D and the descriptions thereof, and Figures 25G-25H and the descriptions thereof. Claim 65 is patentable over Bailey for at least the same reasons stated above.

**CONCLUSION**

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

Respectfully submitted,

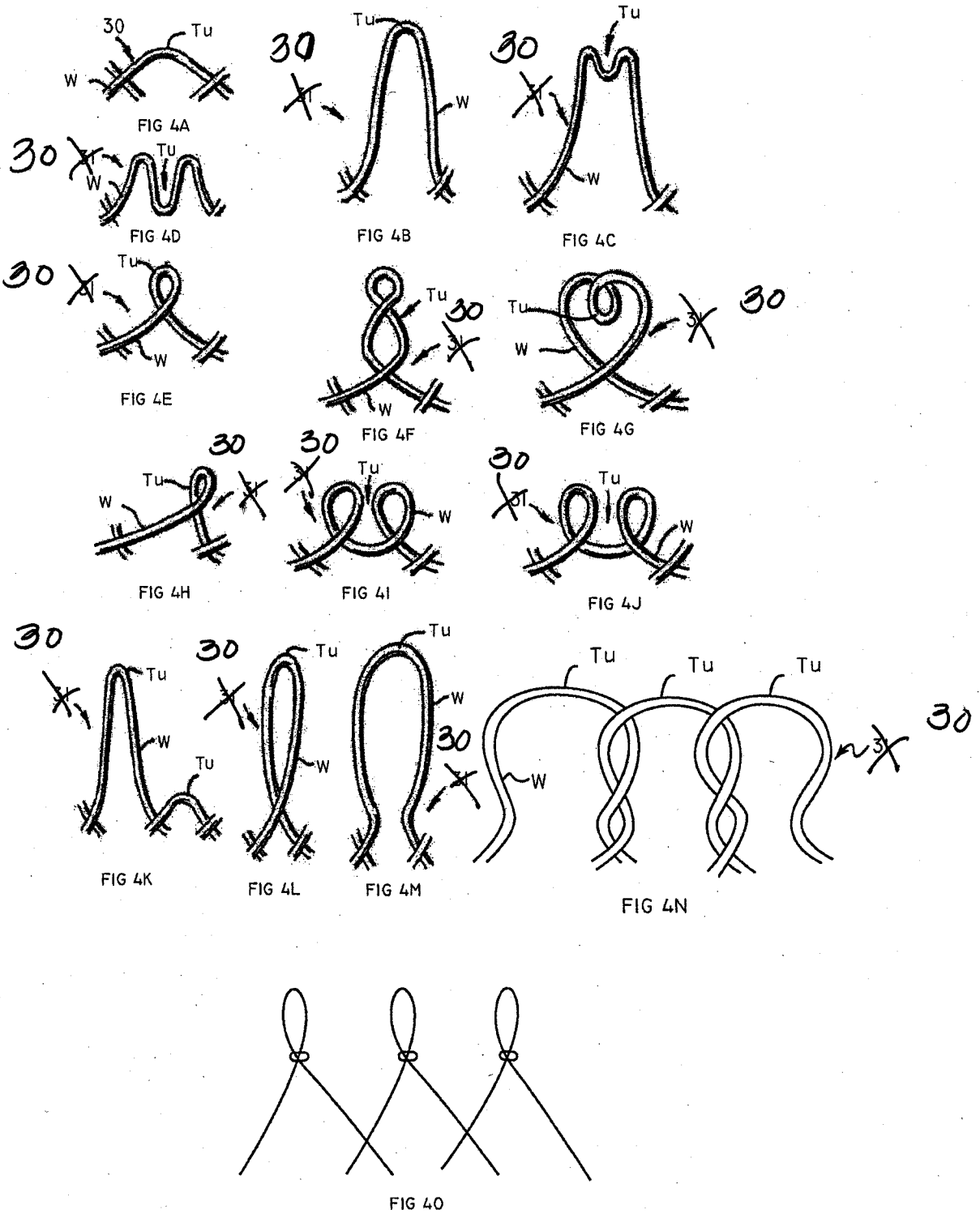
Date: November 20, 2008

By:



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

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San Mateo, CA 94403  
Telephone: 650.212.1700  
Facsimile: 650.212.7562



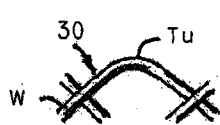


FIG 4A

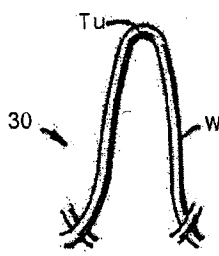


FIG 4B

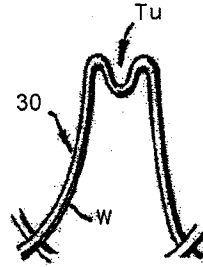


FIG 4C



FIG 4D

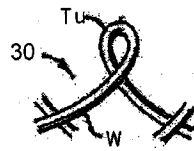


FIG 4E

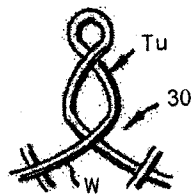


FIG 4F

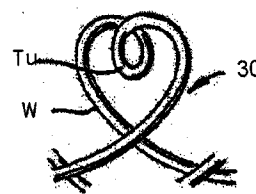


FIG 4G



FIG 4H

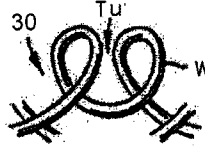


FIG 4I



FIG 4J

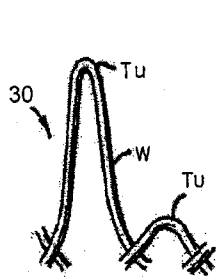


FIG 4K

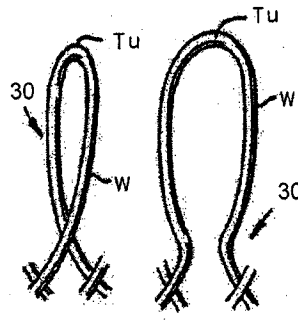


FIG 4L

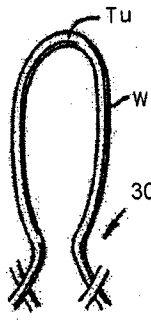


FIG 4M

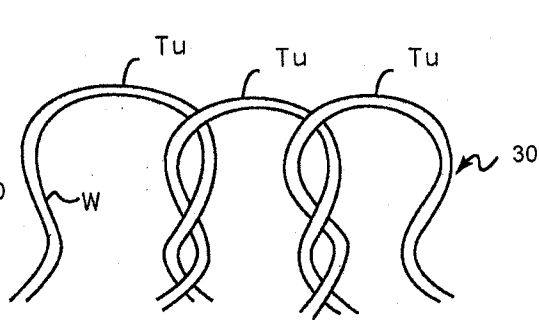


FIG 4N

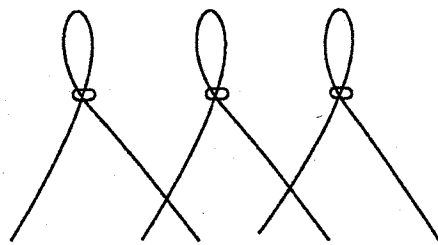
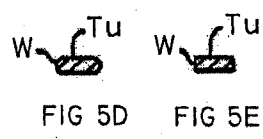
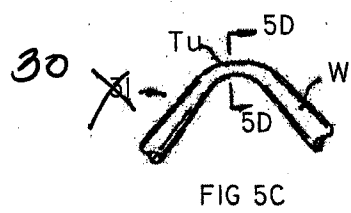
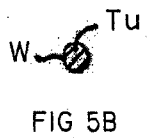
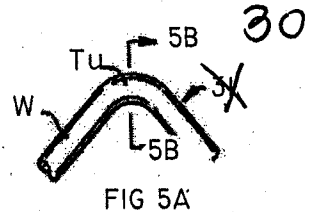
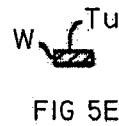
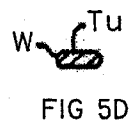
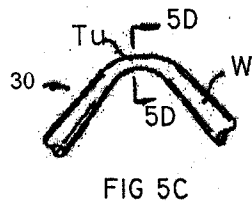
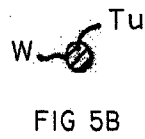
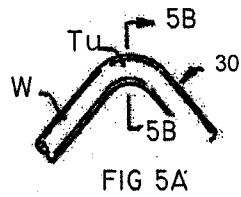


FIG 4O







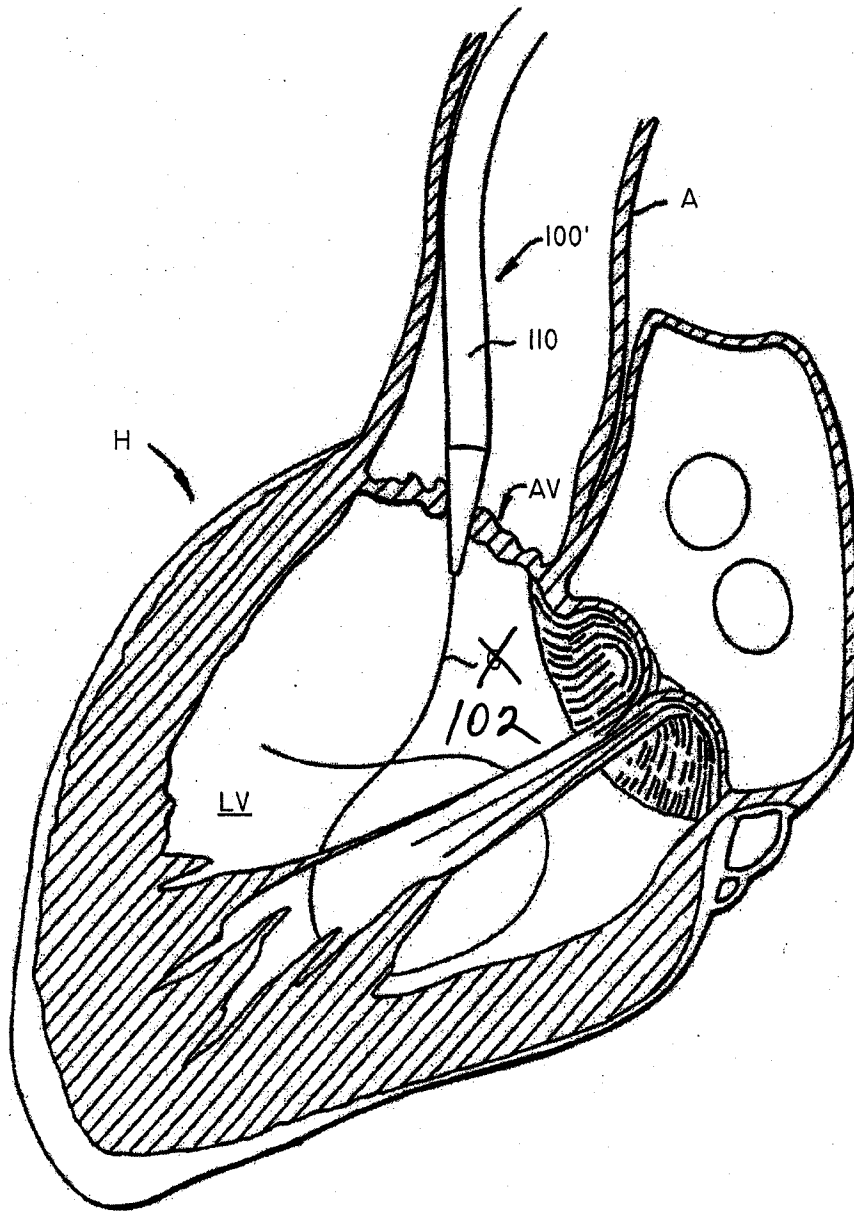


FIG 6A

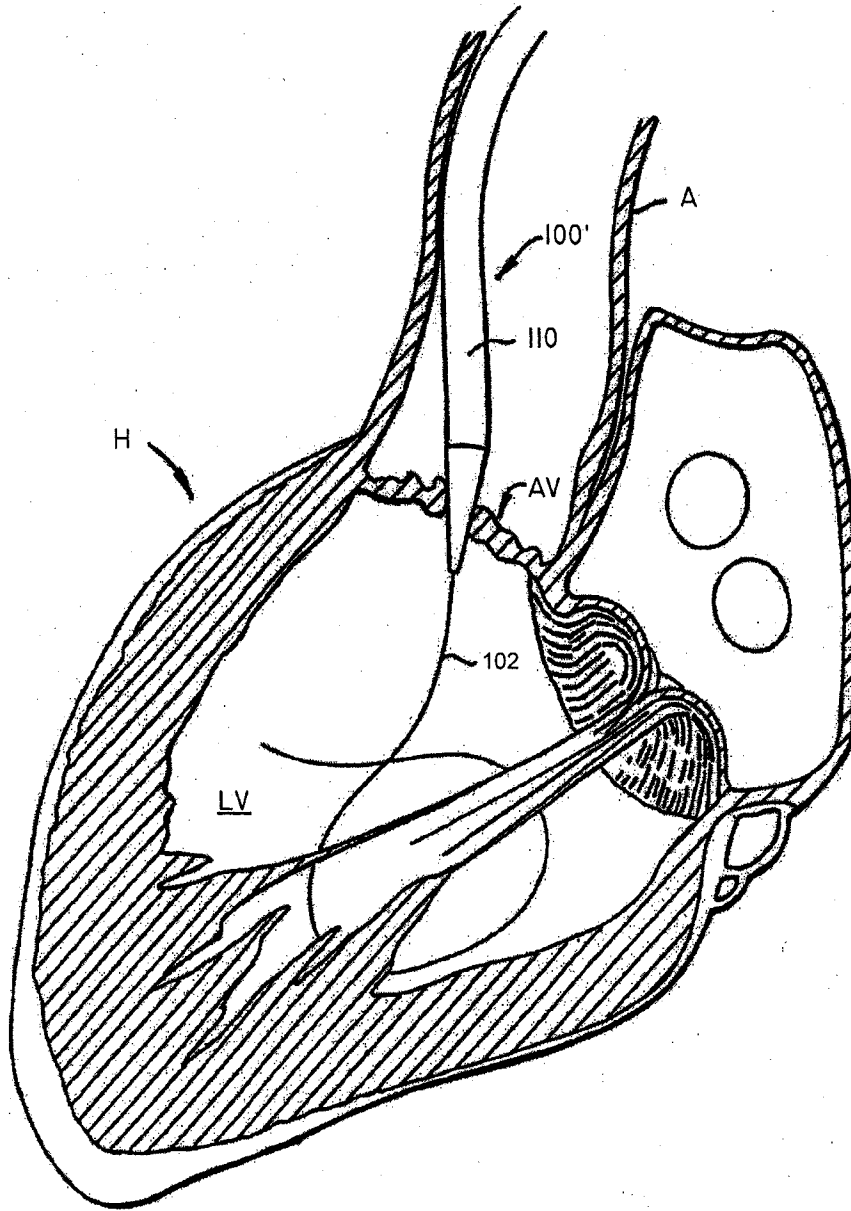


FIG 6A

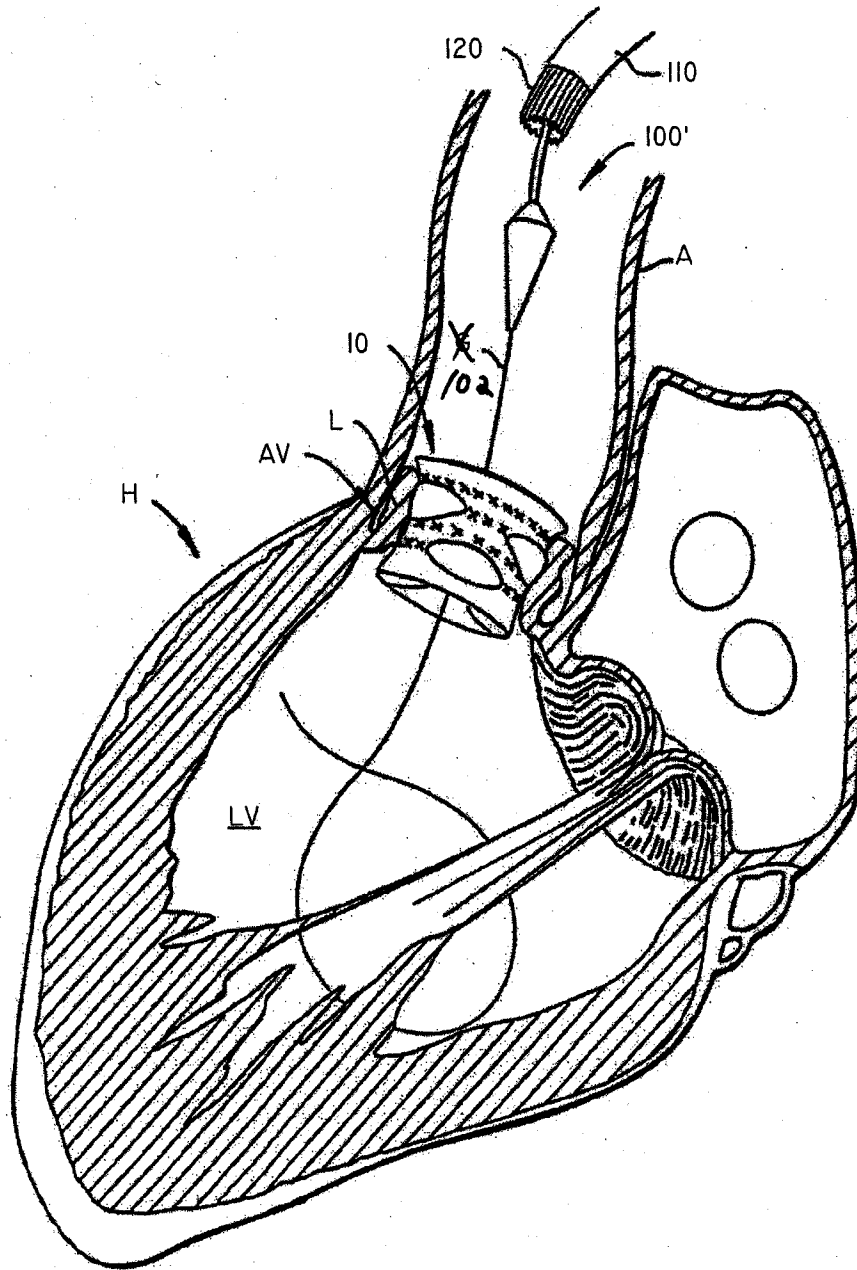


FIG 6F

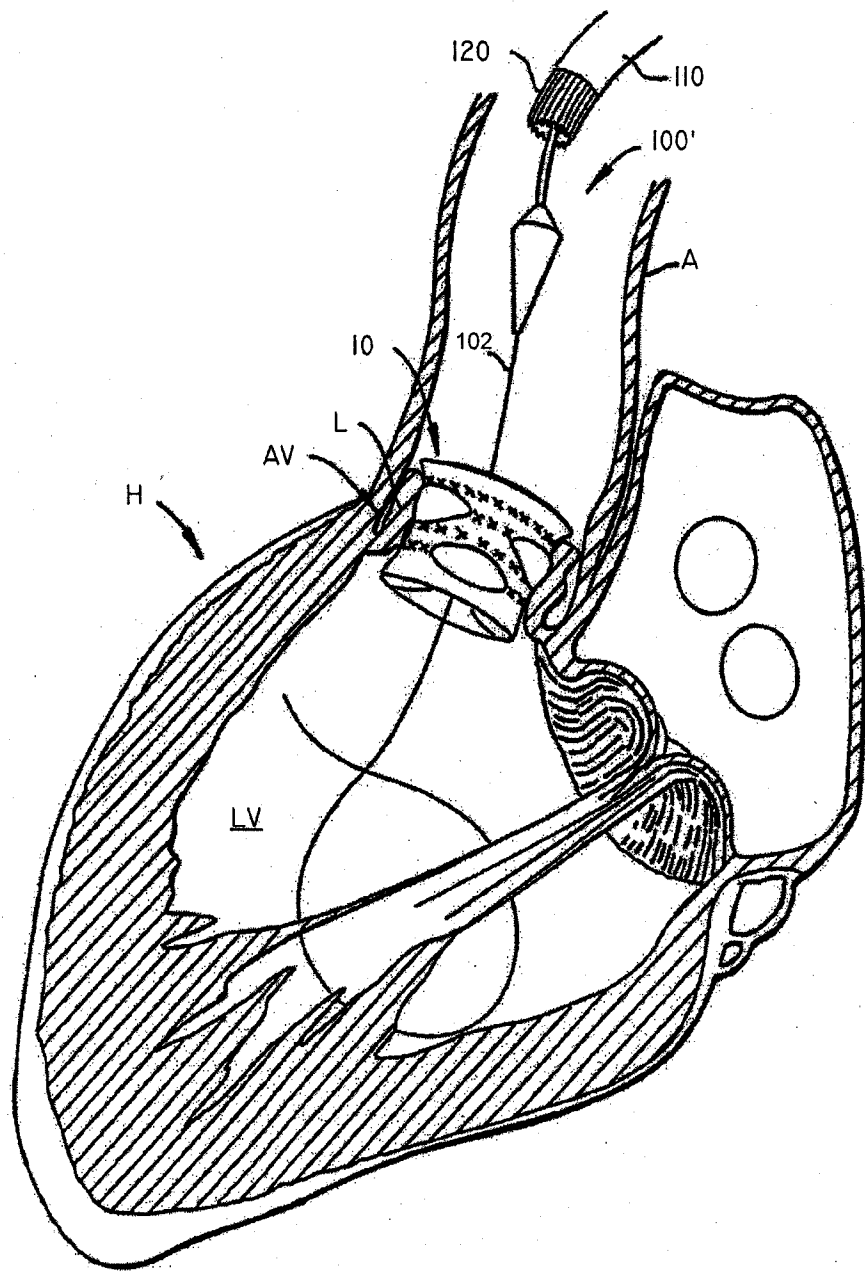
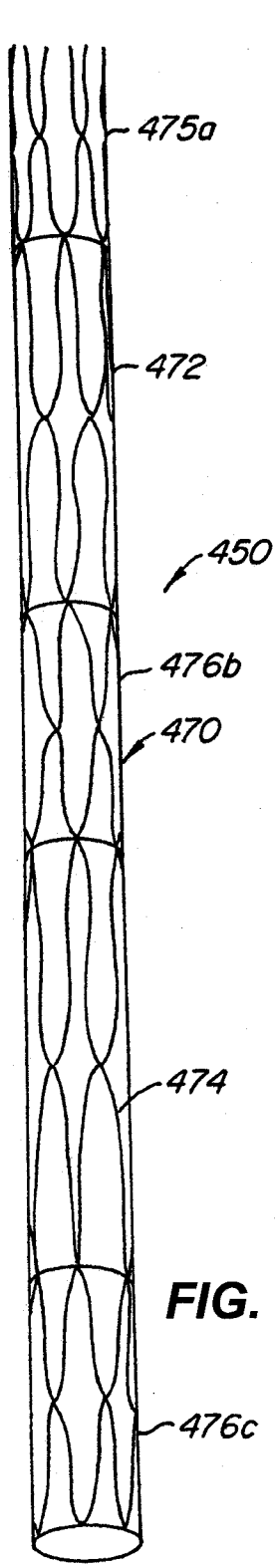
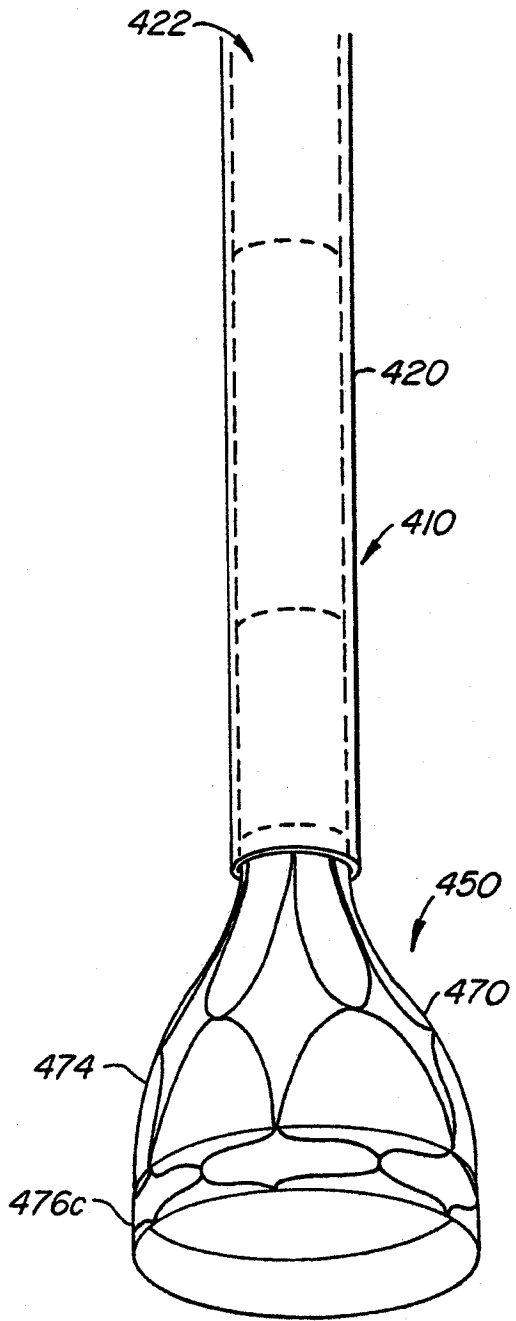


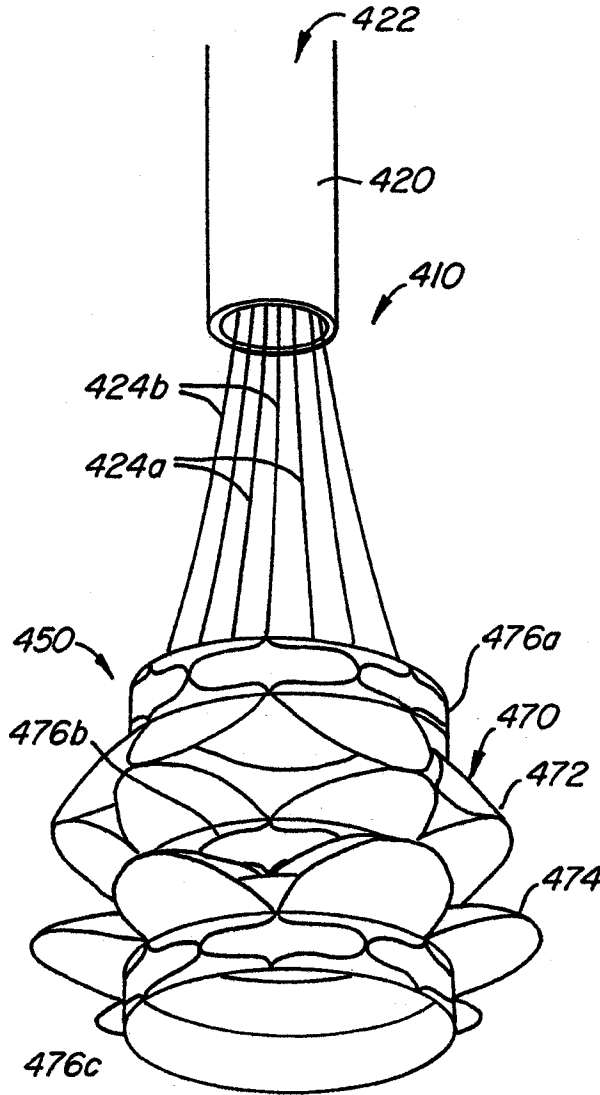
FIG 6F



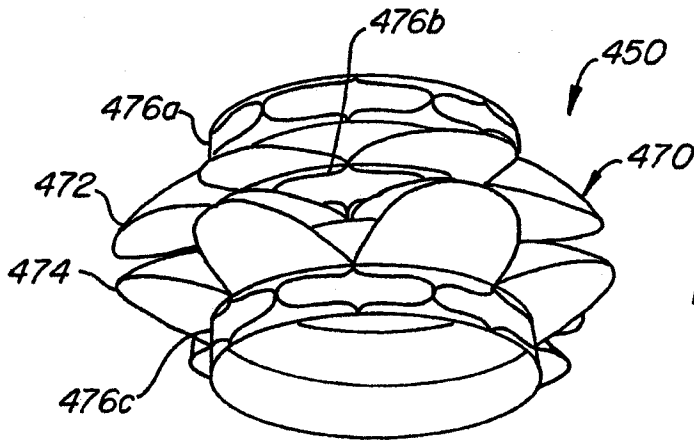
**FIG. 15A**



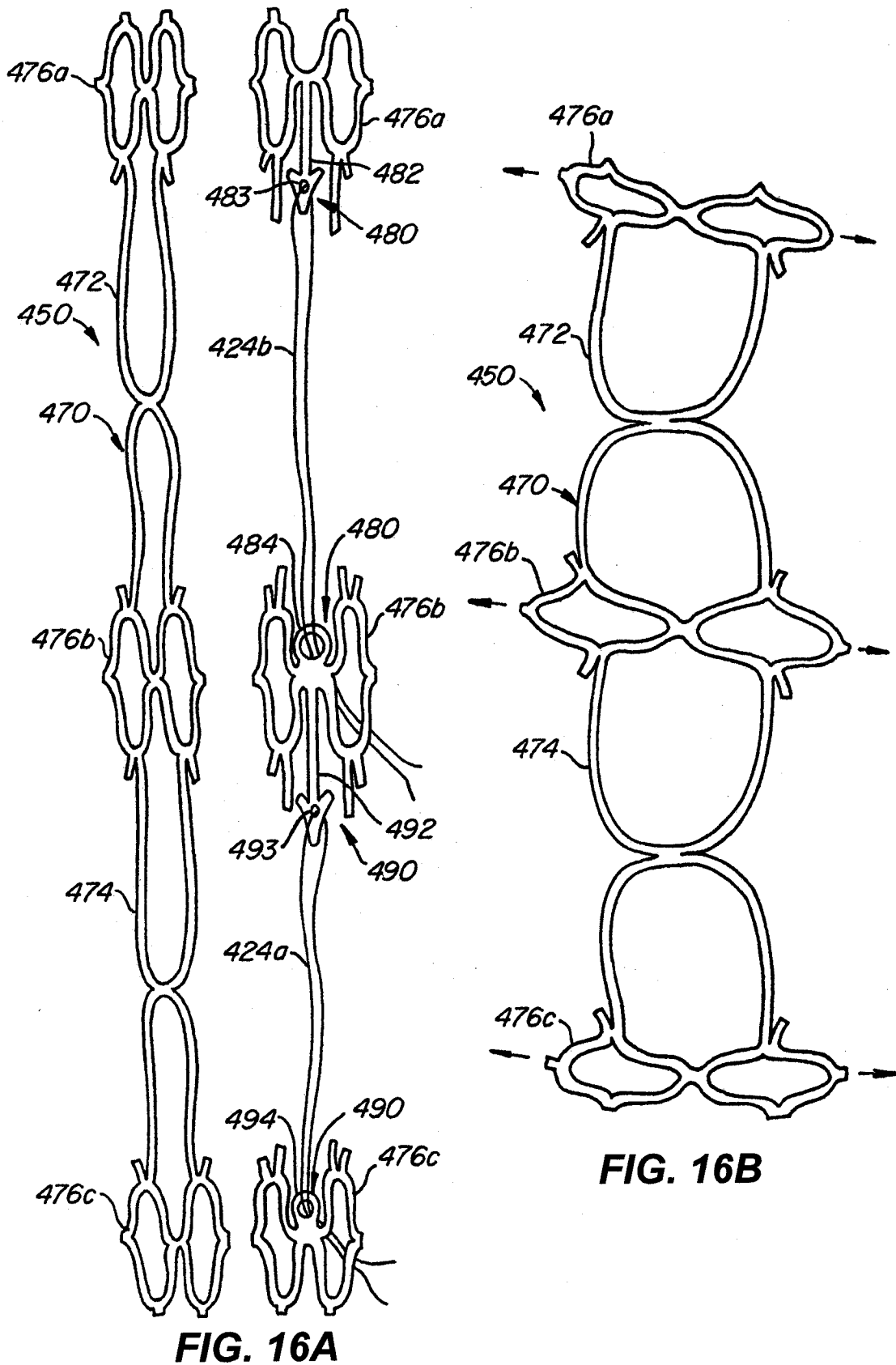
**FIG. 15B**



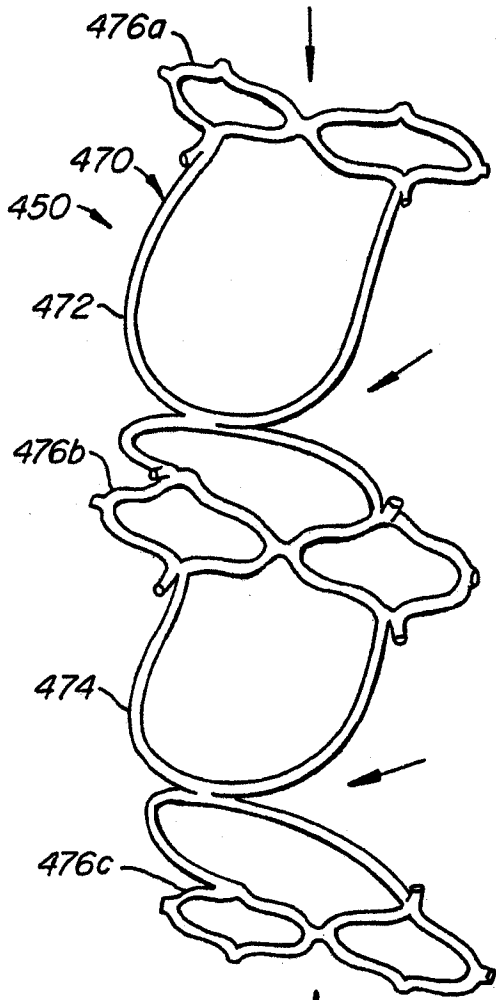
**FIG. 15G**



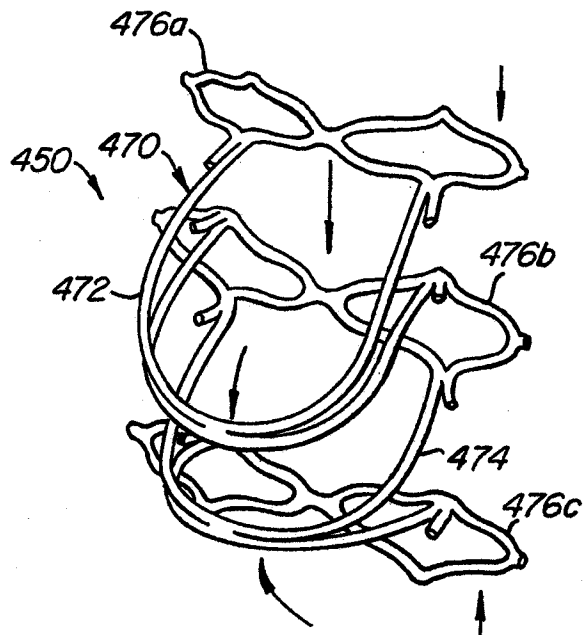
**FIG. 15H**



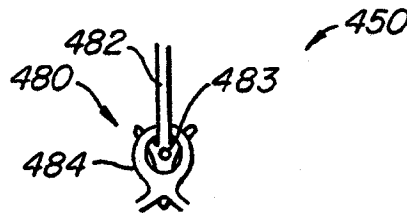




**FIG. 16C**



**FIG. 16D**



**FIG. 16E**

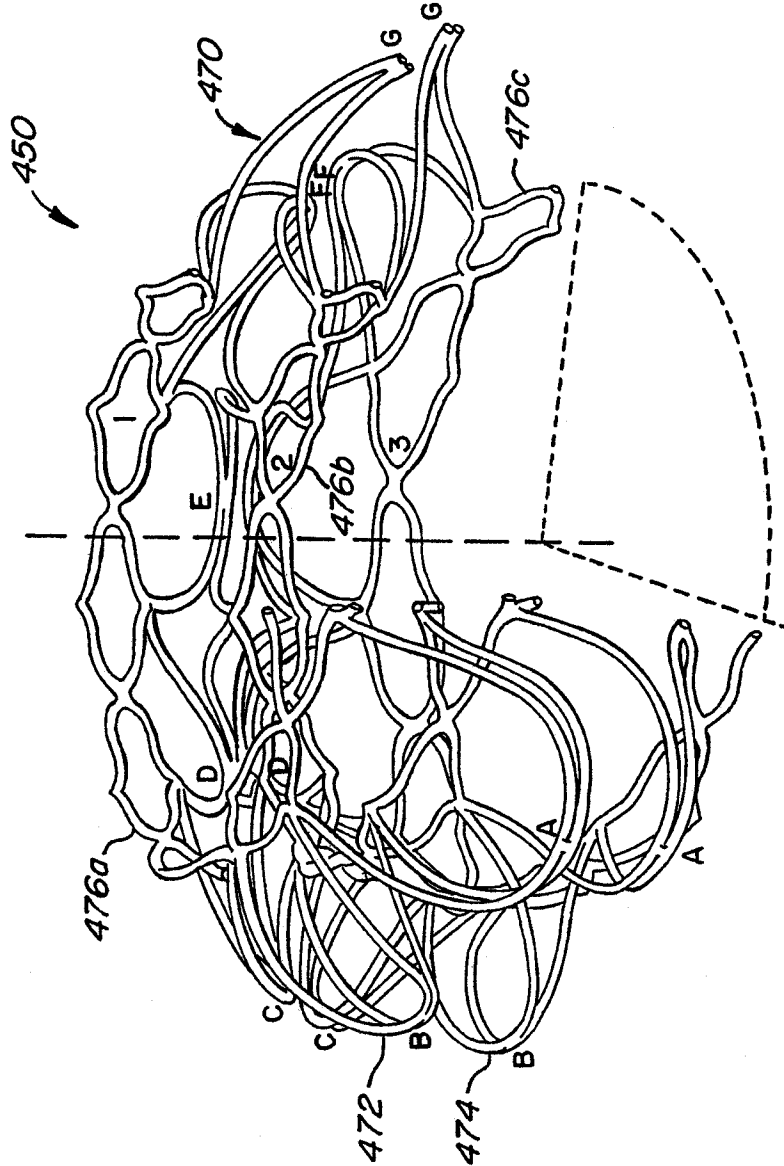


FIG. 17A

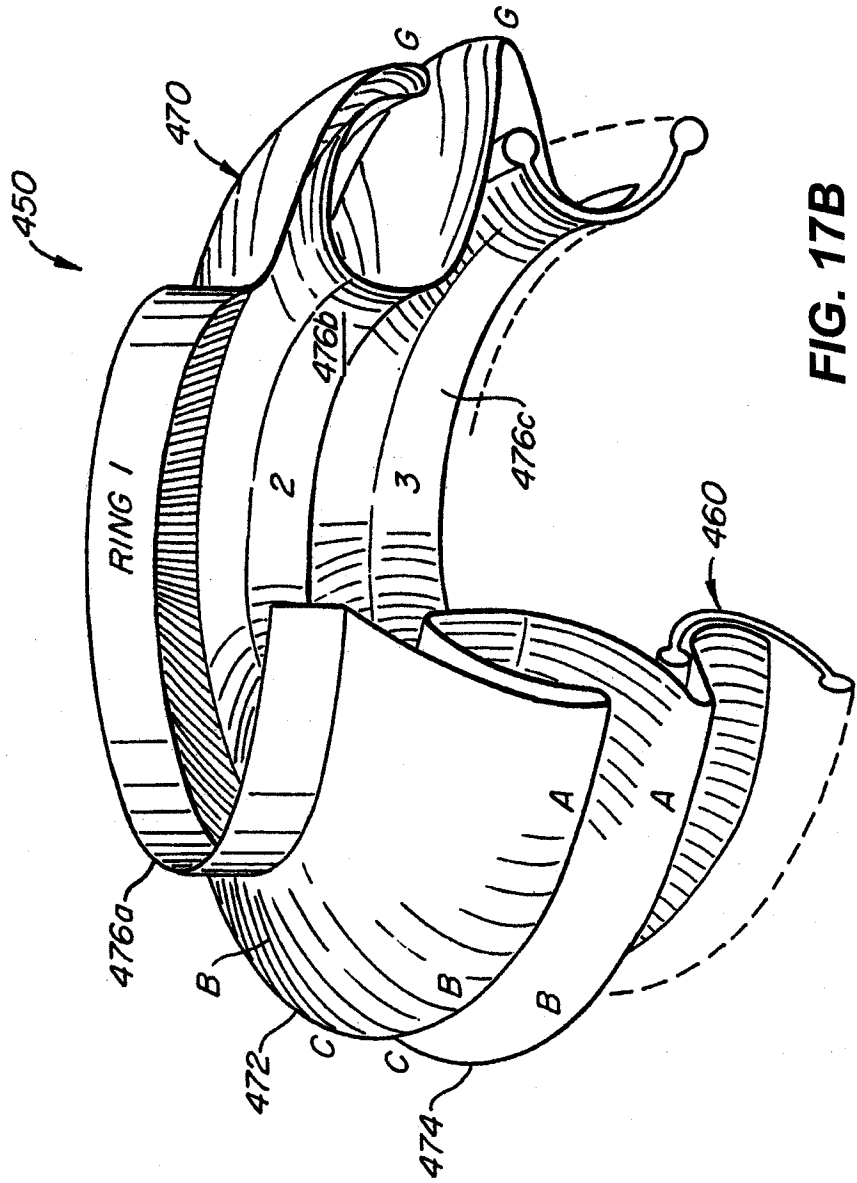
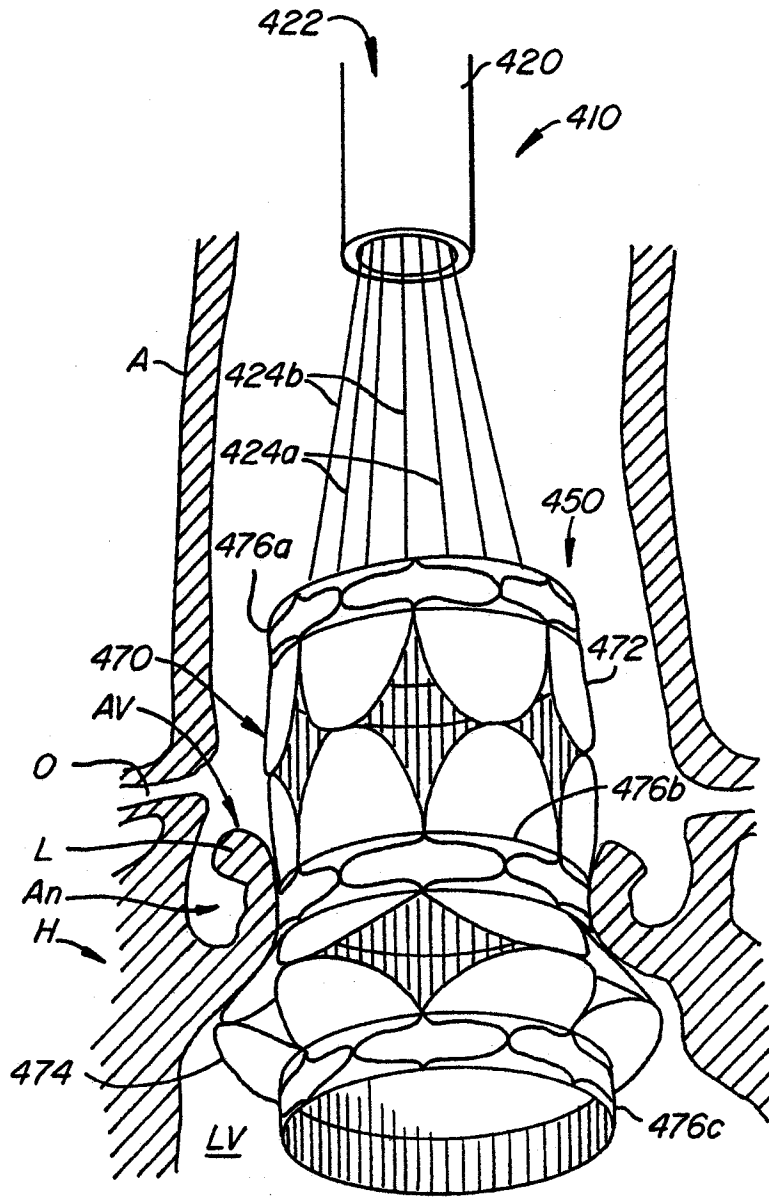
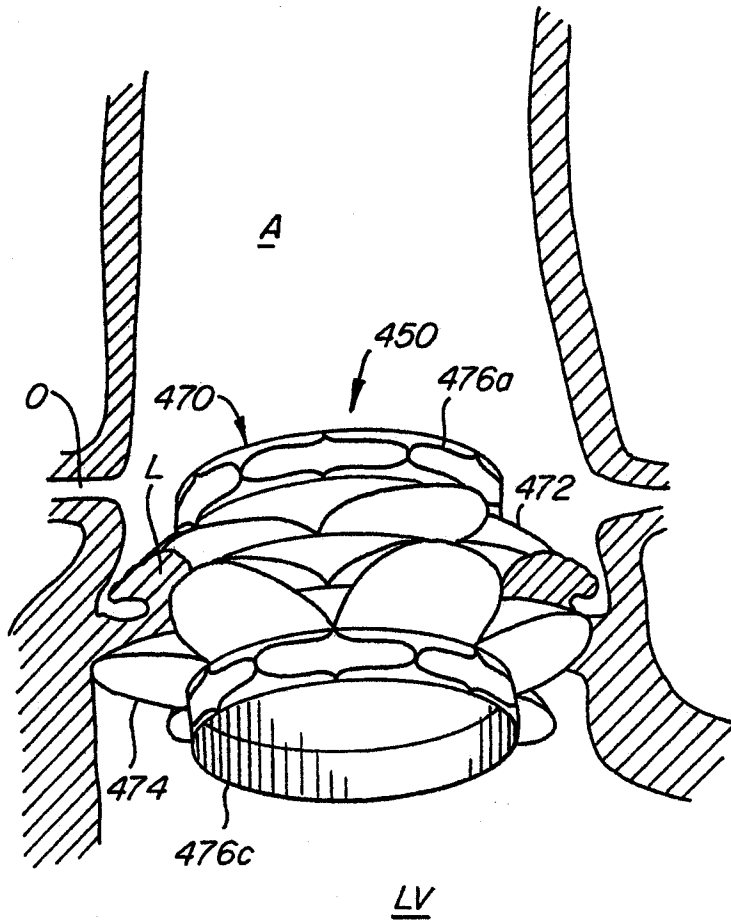


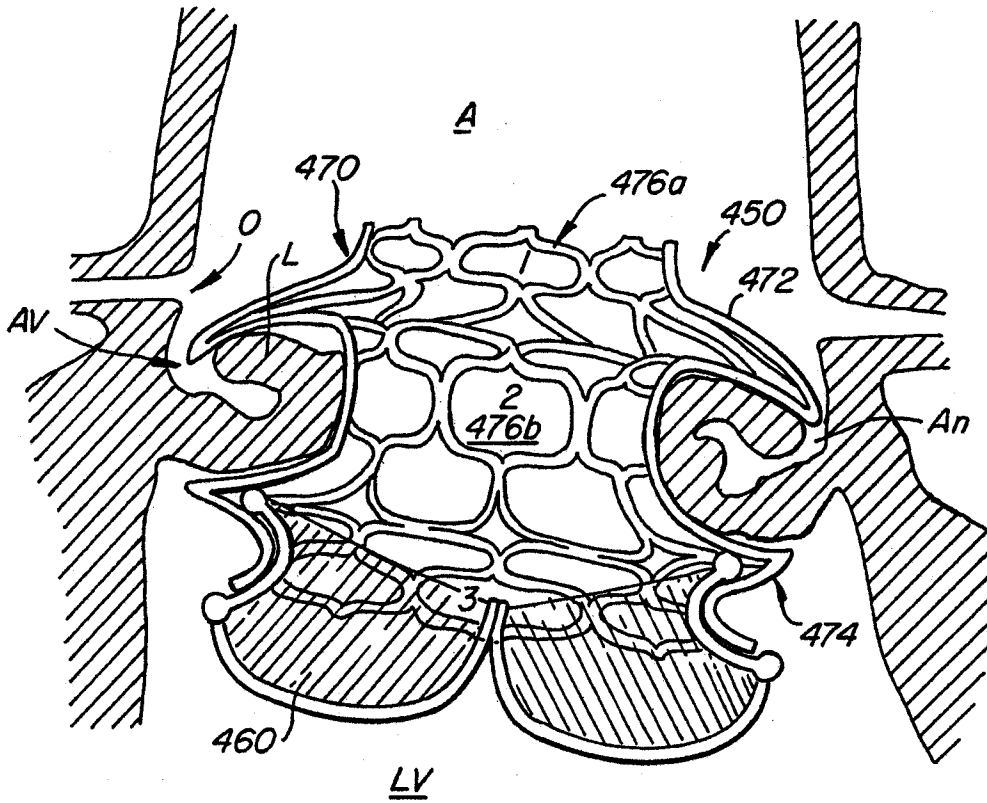
FIG. 17B



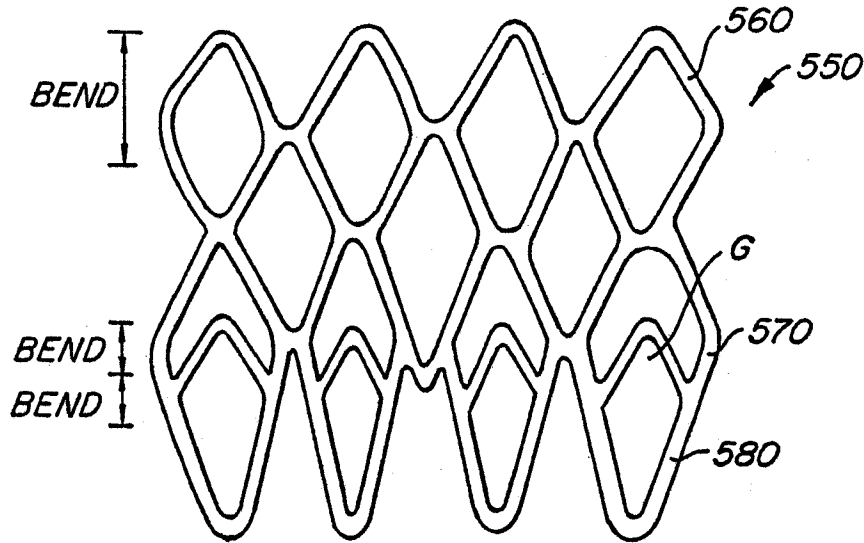
**FIG. 18A**



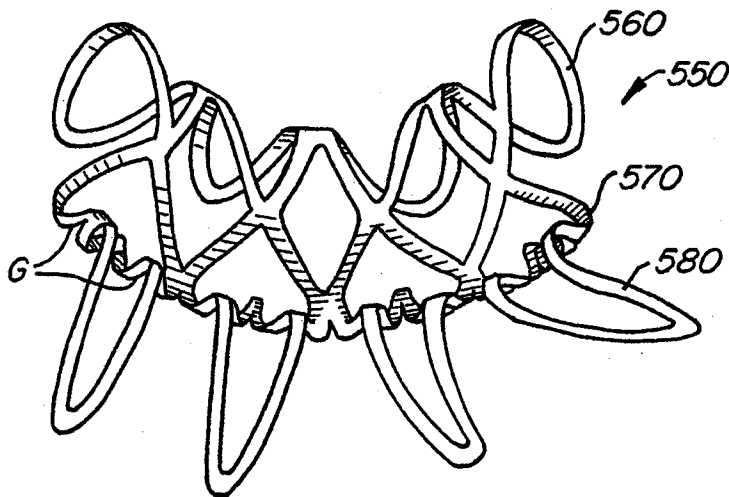
**FIG. 18B**



**FIG. 18C**



**FIG. 19A**



**FIG. 19B**

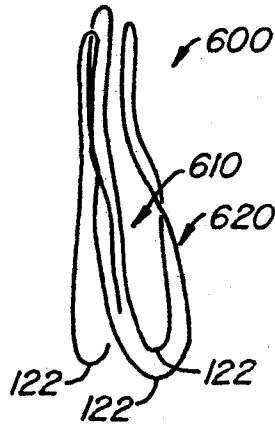


FIG. 20A

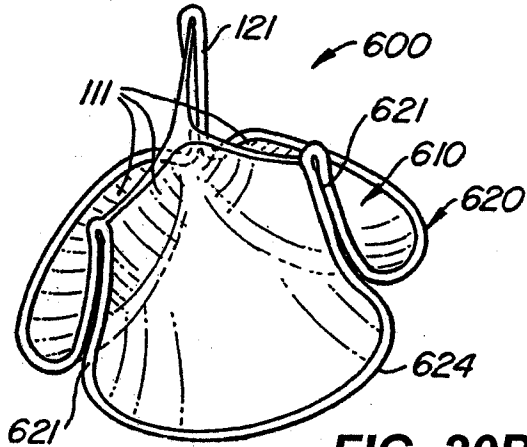


FIG. 20B

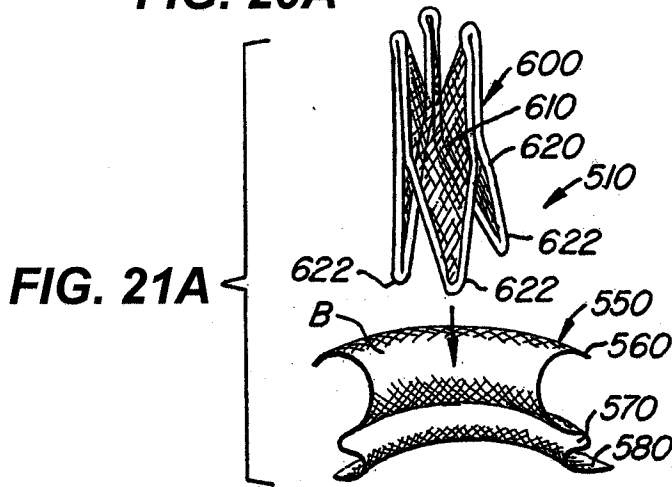


FIG. 21A

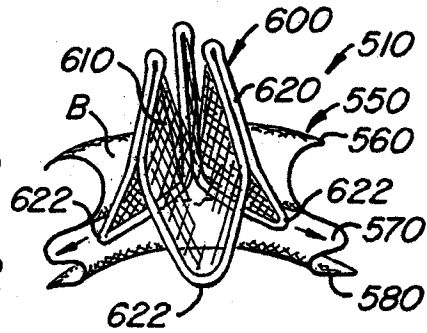


FIG. 21B

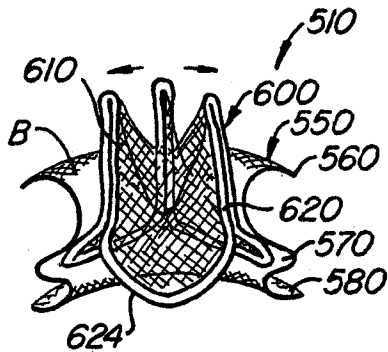


FIG. 21C

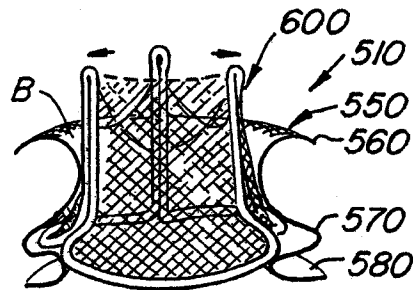


FIG. 21D



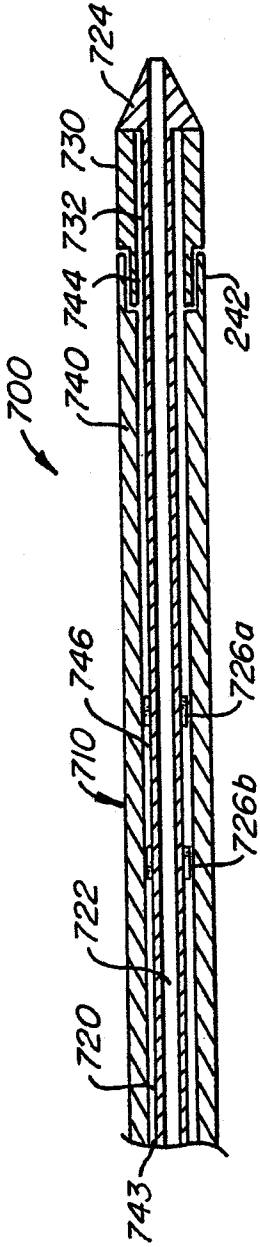


FIG. 22

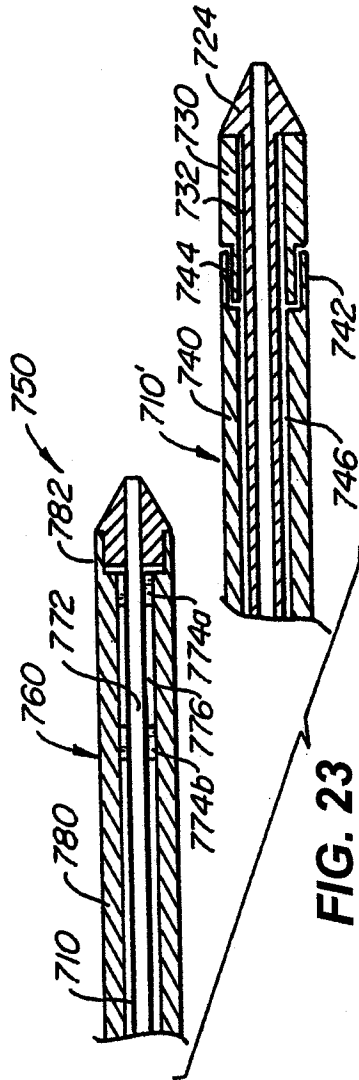


FIG. 23

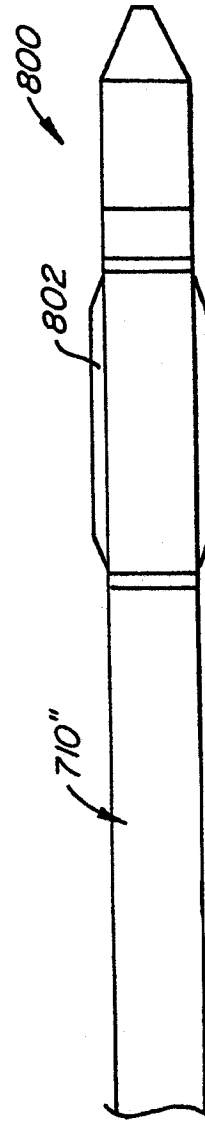
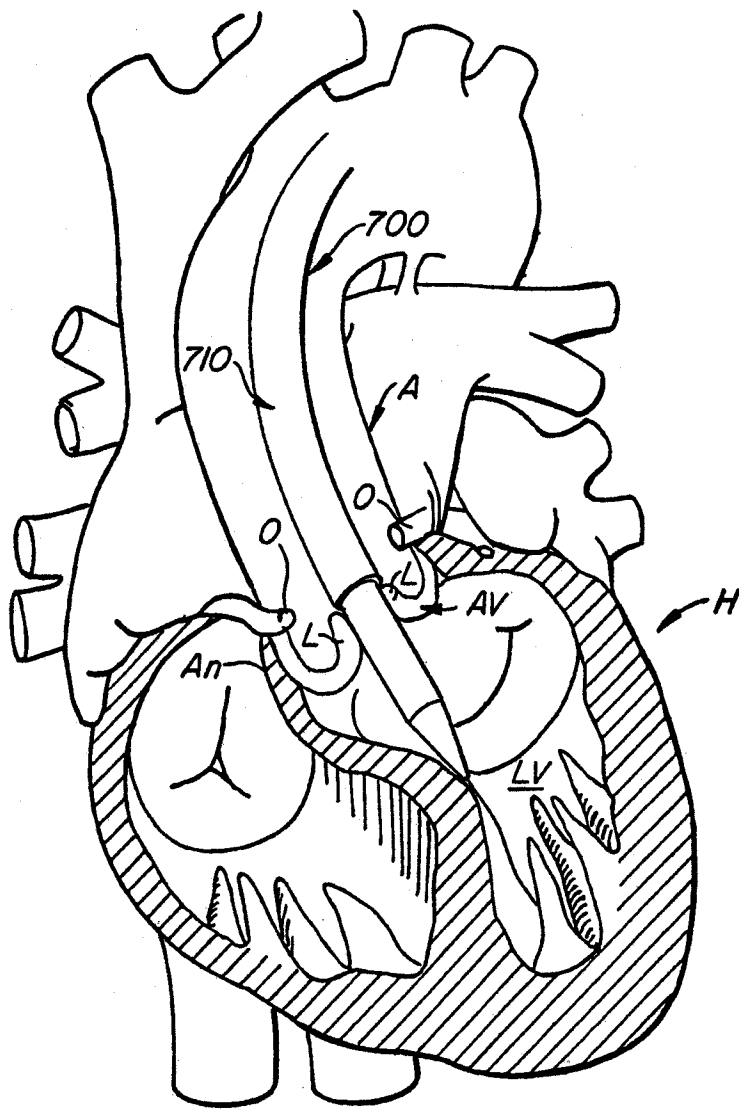
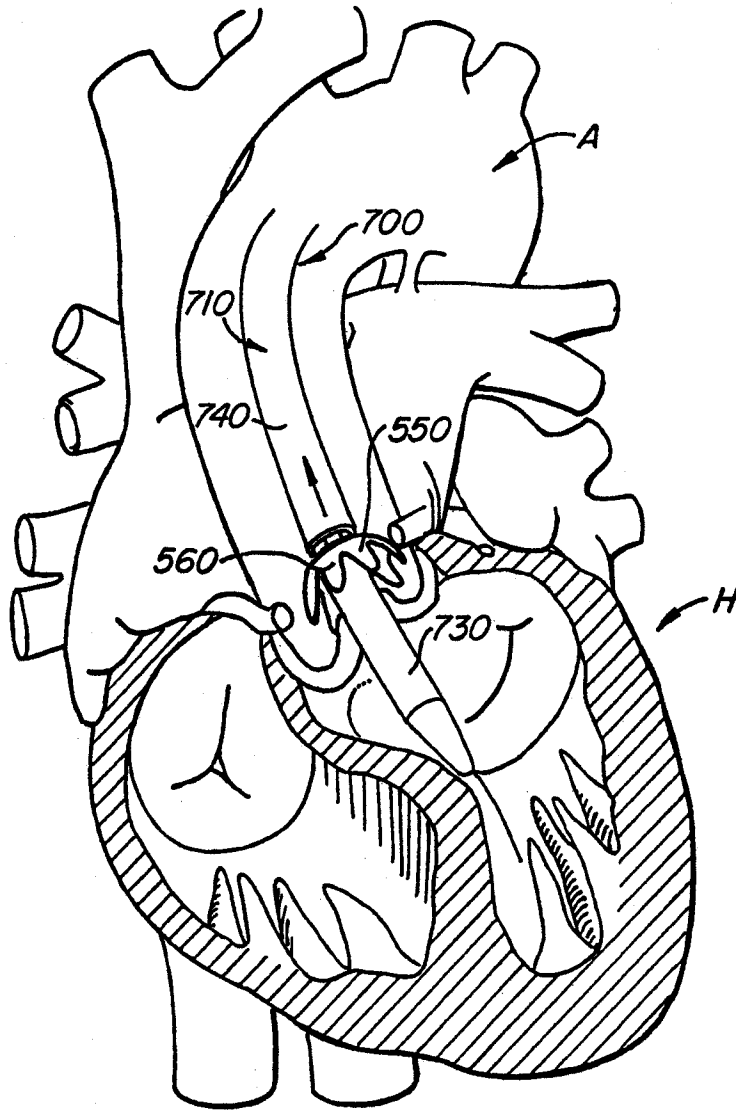


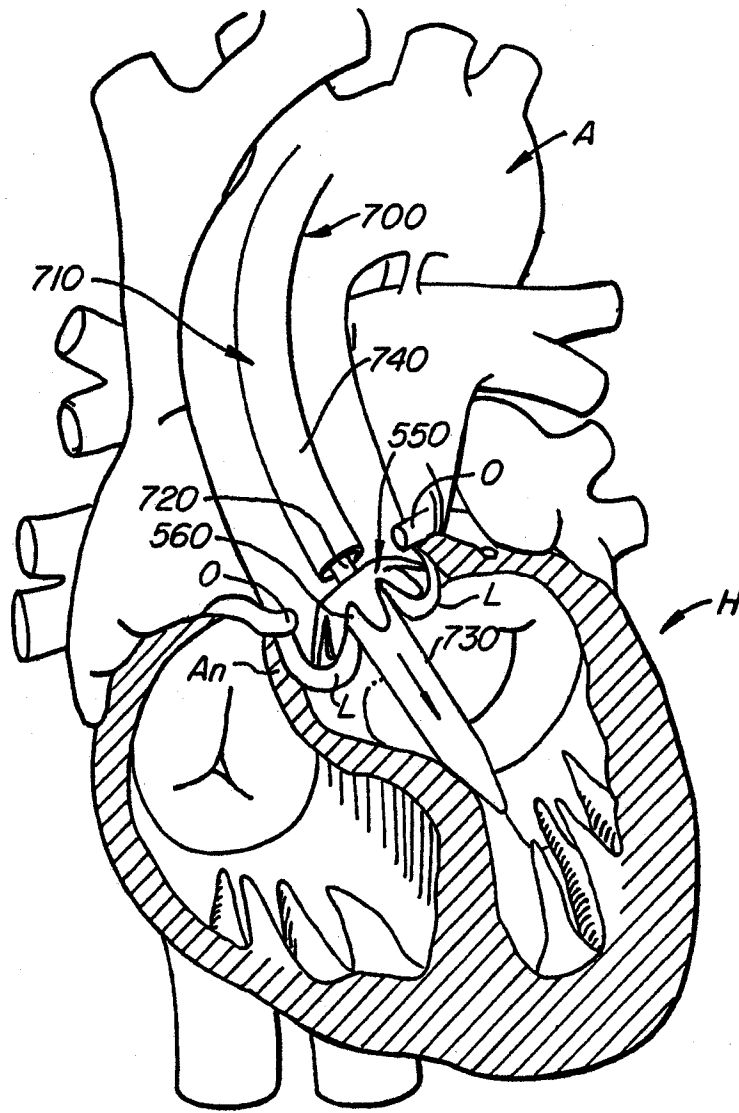
FIG. 24



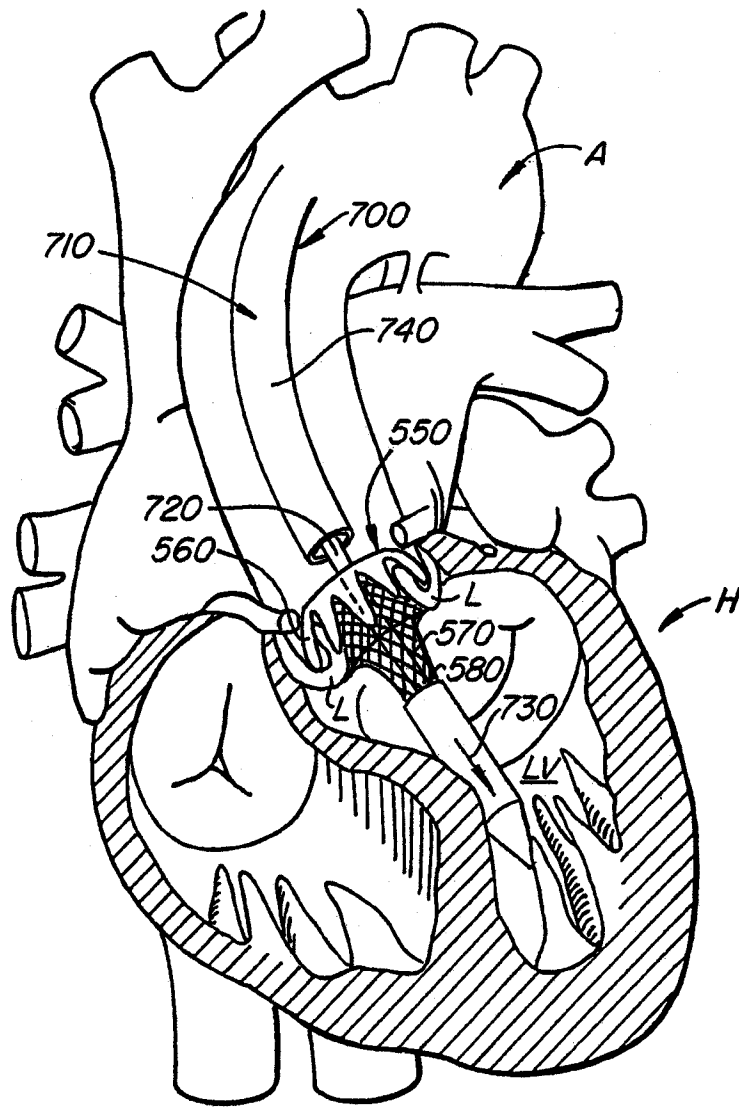
**FIG. 25A**



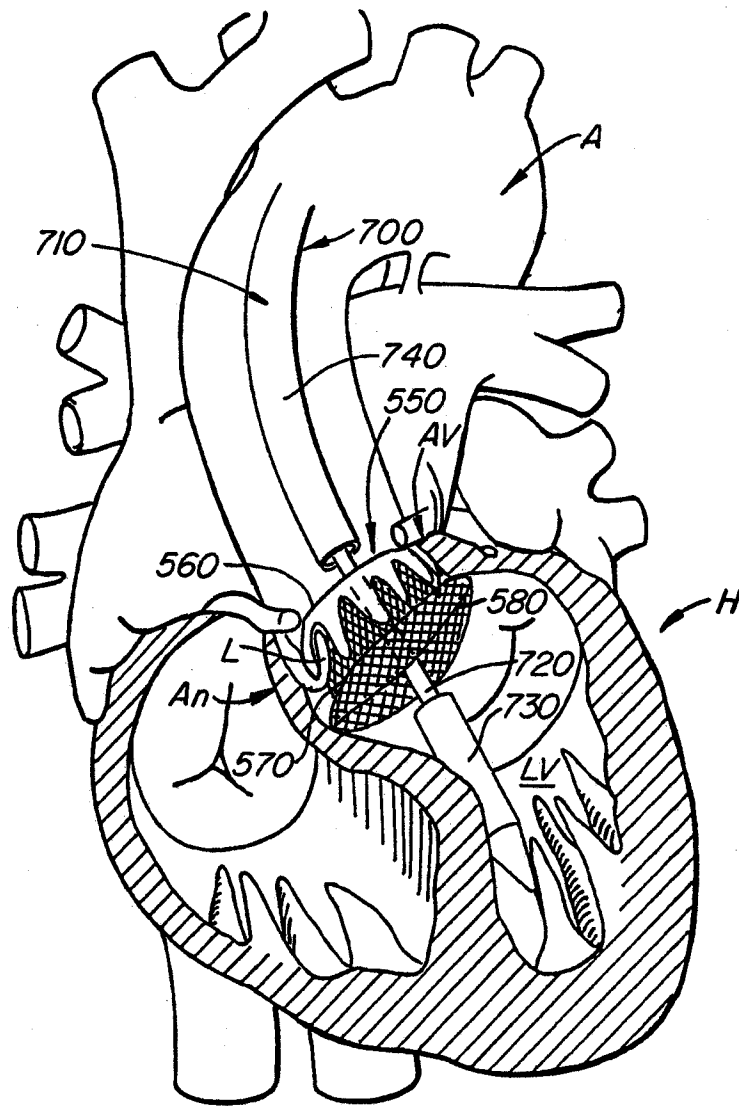
**FIG. 25B**



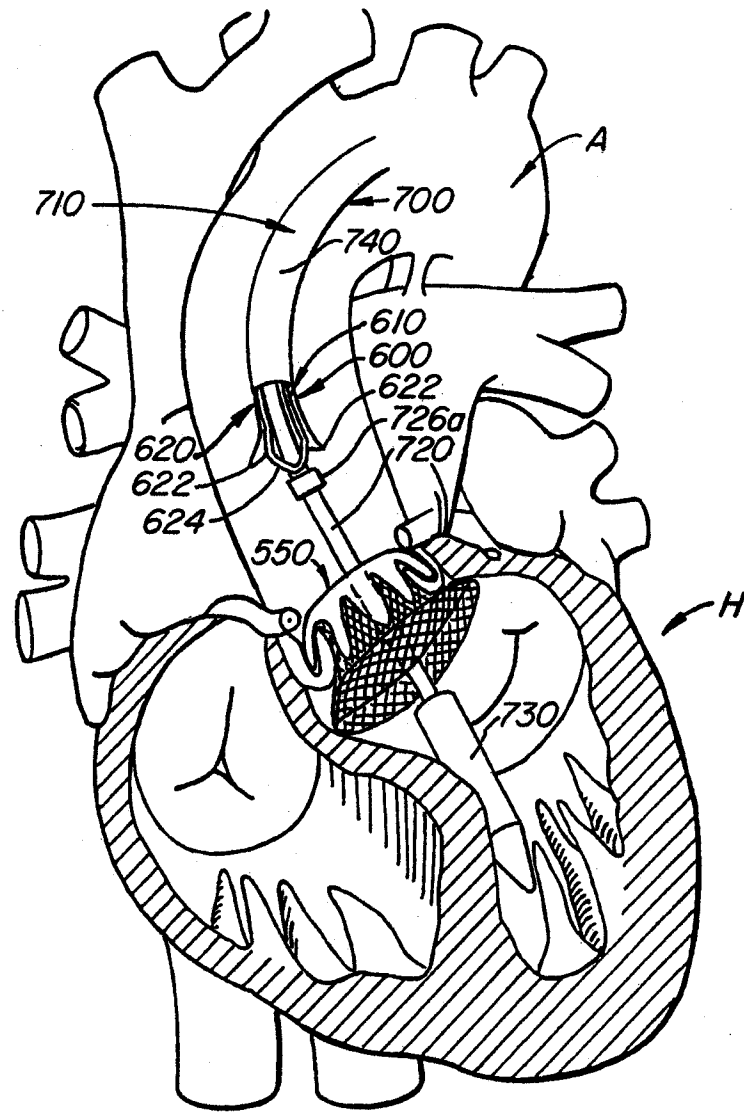
**FIG. 25C**



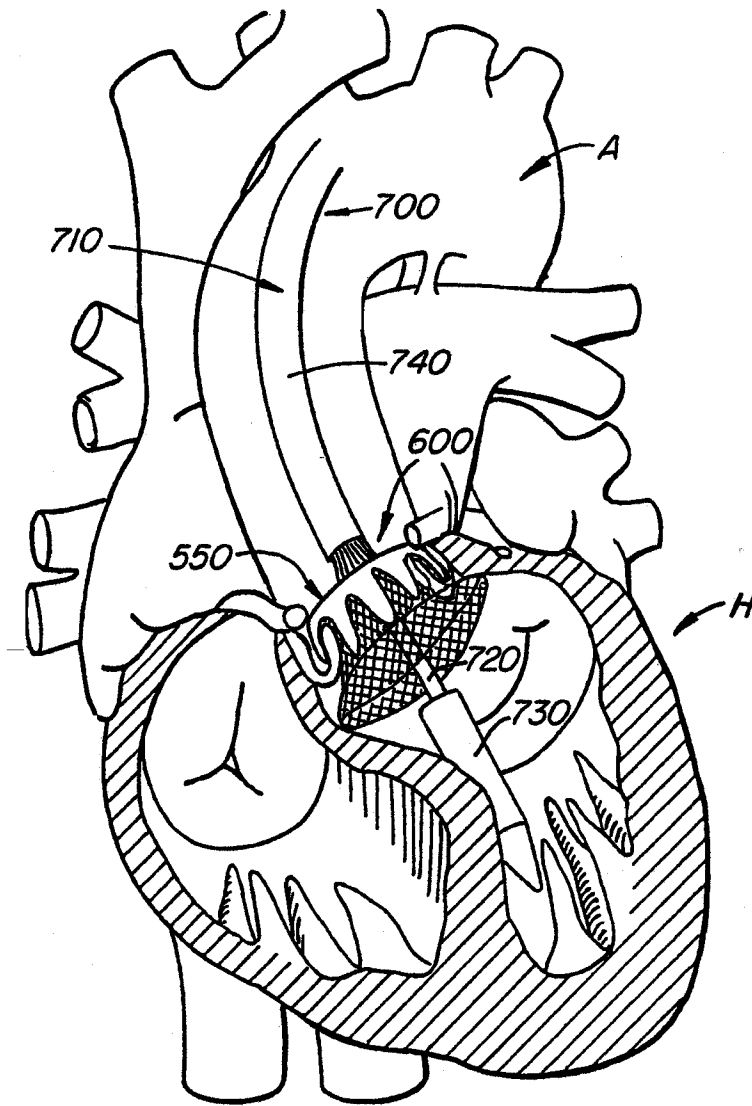
**FIG. 25D**



**FIG. 25E**

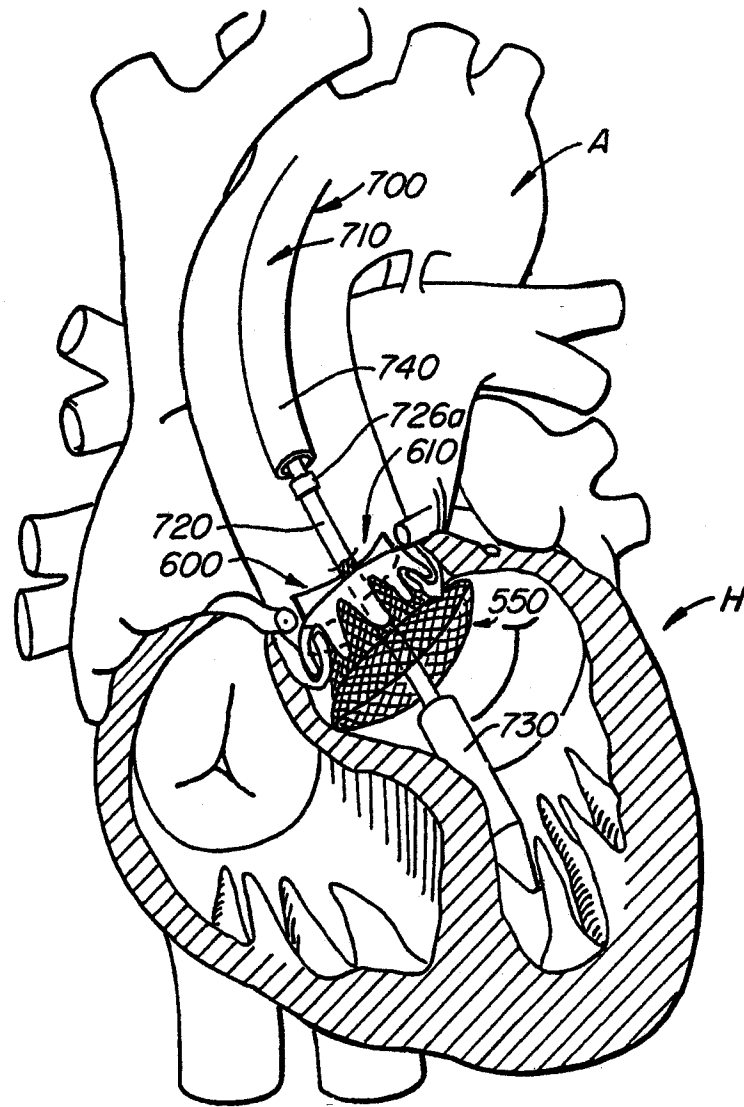


**FIG. 25F**

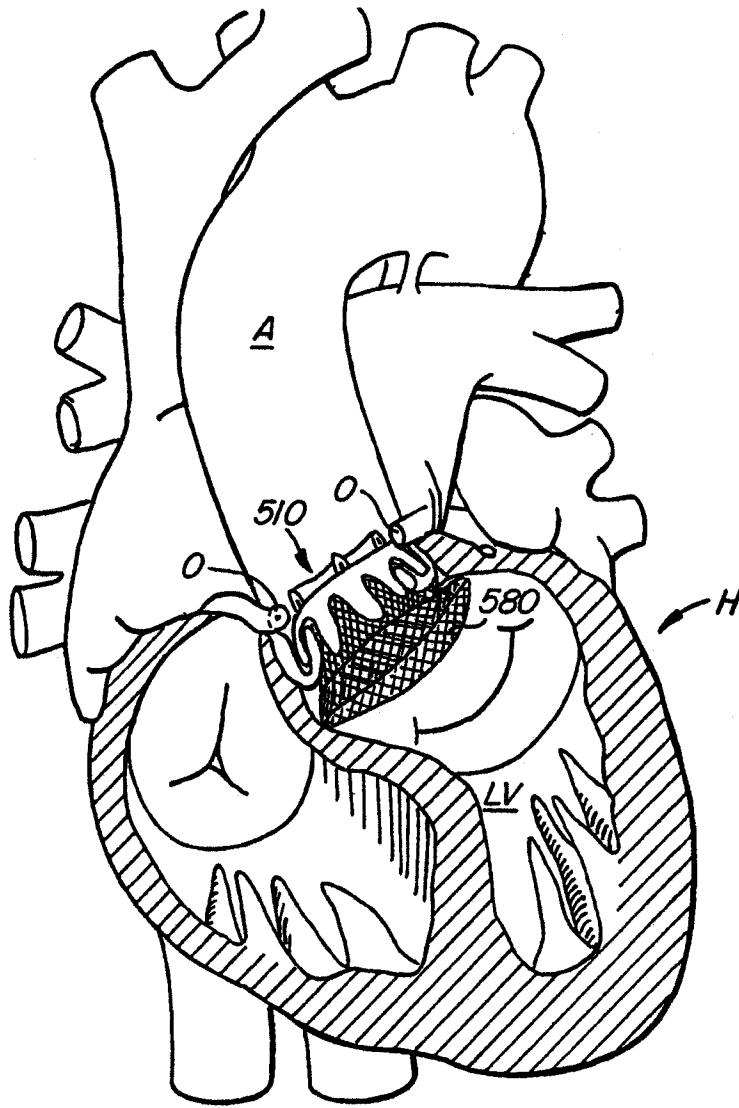


**FIG. 25G**

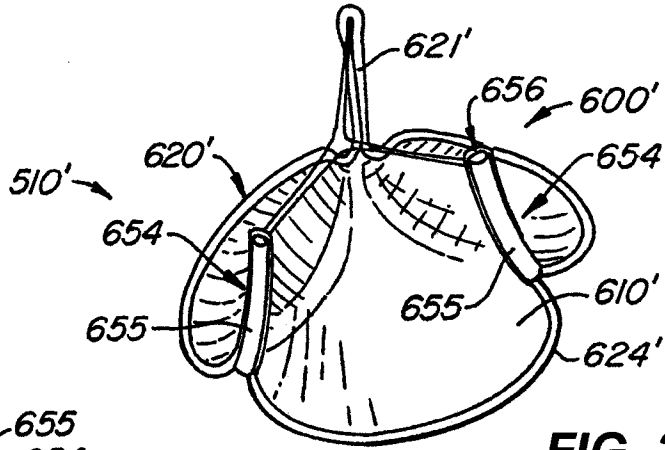




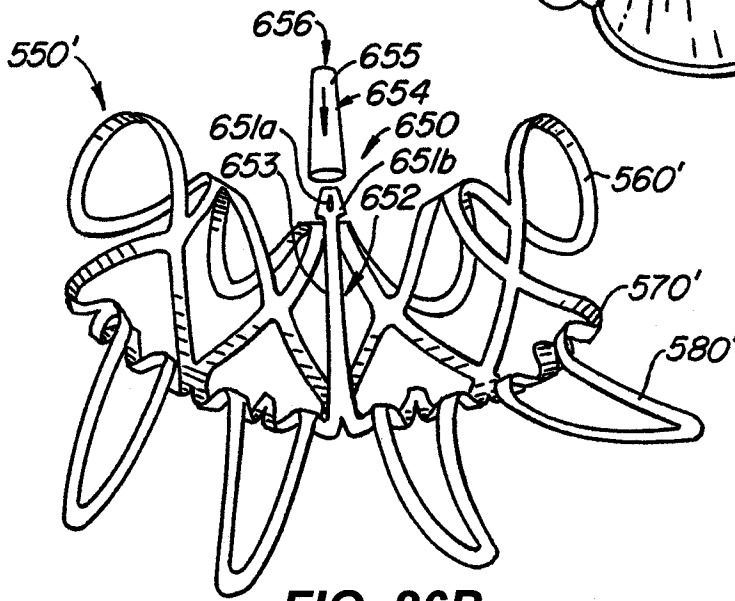
**FIG. 25H**



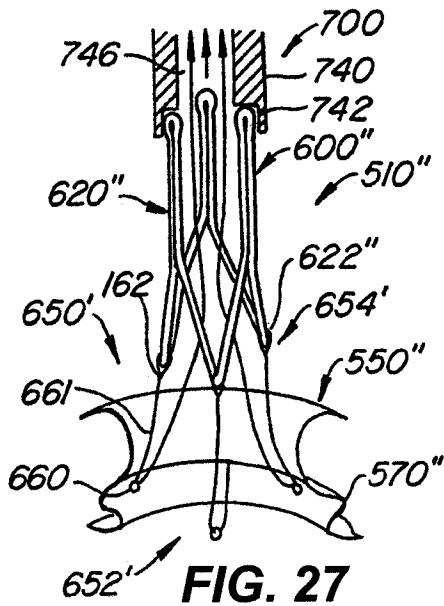
**FIG. 25I**



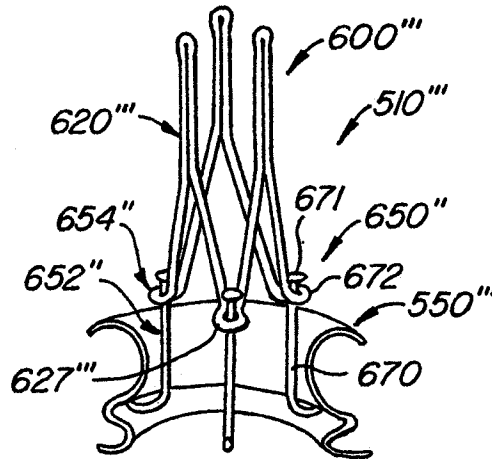
**FIG. 26A**



**FIG. 26B**



**FIG. 27**



**FIG. 28**

VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/972,287 Confirmation No.: 7706  
Applicant(s): Amr Salahieh  
Filed: October 21, 2004  
Art Unit: 3738  
Examiner: STRASZHEIM, REBECCA L  
Title: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE  
THEREOF  
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), and any drawing, or that portion of the application that caused it to be listed, is attached.
  - 2). A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  - 3). A copy of each application specification is not submitted because the application is stored in the IFW.
- 37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**
- 1). A legible copy of each publication or that portion which caused it to be listed is attached.
  - 2). A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

- 37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited**
  - 1). A legible copy of each foreign patent or that portion which caused it to be listed is attached.
  - 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  
- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:**
  - 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached --AND--
  
  - 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:
    - OR--
  - 2b). A copy of a written, English-language translation or portion thereof is readily available and attached,
    - OR--
  - 2c). An English language copy of a foreign search report is submitted.
    - OR--
  - 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

**STATEMENT UNDER 37 CFR § 1.97(e)**

- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
  
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

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

Respectfully Submitted,

Dated: 11/20/08

By:   
Thomas Zlogar Reg. # 55760

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

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<p style="text-align: center;">Substitute for form 1449/PTO</p> <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;"><i>(Use as many sheets as necessary)</i></p>	<p><b>Complete if Known</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Application Number</td> <td>10/972,287</td> </tr> <tr> <td>Filing Date</td> <td>October 21, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Amr Salahieh</td> </tr> <tr> <td>Art Unit</td> <td>3738</td> </tr> <tr> <td>Examiner Name</td> <td>STRASZHEIM, REBECCA L</td> </tr> <tr> <td>Attorney Docket Number</td> <td>10012-702.501</td> </tr> </table>	Application Number	10/972,287	Filing Date	October 21, 2004	First Named Inventor	Amr Salahieh	Art Unit	3738	Examiner Name	STRASZHEIM, REBECCA L	Attorney Docket Number	10012-702.501
Application Number	10/972,287												
Filing Date	October 21, 2004												
First Named Inventor	Amr Salahieh												
Art Unit	3738												
Examiner Name	STRASZHEIM, REBECCA L												
Attorney Docket Number	10012-702.501												
<p>Sheet <b>1</b> of <b>1</b></p>													

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	422	US- 4,326,306	4/27/1982	Poler	
	423	US- 4,423,809	1/3/1984	Mazzocco	
	431	US- 6,336,937	1/8/2002	Vonesh et al.	
	433	US- 6,790,237	9/14/2004	Stinson	
	429	US- 2001/0041930 A1	11/15/2001	Globerman et al.	
	424	US- 2002/0029981 A1	3/14/2002	Nigam	
	428	US- 2002/0055769 A1	5/9/2002	Wang	
	425	US- 2002/0082609 A1	6/27/2002	Green	
	432	US- 2002/0188341 A1	12/12/2002	Elliott	
	434	US- 2003/0050694 A1	3/13/2003	Yang et al.	
	426	US- 2003/0070944 A1	4/17/2003	Nigam	
	427	US- 2004/0098099 A1	5/20/2004	McCullagh et al.	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

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

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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

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

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

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	10972287
<b>Filing Date:</b>	21-Oct-2004
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Filer:</b>	Thomas M. Zlogar/Sue Bromaghim
<b>Attorney Docket Number:</b>	10012-702.501

Filed as Small Entity

### Utility under 35 USC 111(a) Filing Fees

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



Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Miscellaneous:</b>				
Submission- Information Disclosure Stmt	1806	1	180	180
<b>Total in USD (\$)</b>				<b>180</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	4329764
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	Thomas M. Zlogar/Sue Bromaghim
<b>Filer Authorized By:</b>	Thomas M. Zlogar
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	20-NOV-2008
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	21:21:15
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$180
RAM confirmation Number	6931
Deposit Account	504050
Authorized User	

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

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

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

<b>File Listing:</b>					
<b>Document Number</b>	<b>Document Description</b>	<b>File Name</b>	<b>File Size(Bytes)/ Message Digest</b>	<b>Multi Part /.zip</b>	<b>Pages (if appl.)</b>
1		10012-702-501-Amendment-AmdedFigs.pdf	3969247 78cee9c08ef6e59a9839f04fa0b51838d8b0f9ad	yes	34
	<b>Multipart Description/PDF files in .zip description</b>				
	<b>Document Description</b>		<b>Start</b>	<b>End</b>	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Specification		2	16	
	Claims		17	20	
	Applicant Arguments/Remarks Made in an Amendment		21	26	
	Drawings-only black and white line drawings		27	34	
<b>Warnings:</b>					
<b>Information:</b>					
2	Drawings-only black and white line drawings	10012-702-501-Figs-28-51.pdf	1475572 f450675ca8e1d2c37a9154de2e5119781ac111ff	no	22
<b>Warnings:</b>					
<b>Information:</b>					
3		10012-702-501-IDS.pdf	590390 940c565641498ea1cda9fb8ed1fafa0d172ab306	yes	4
	<b>Multipart Description/PDF files in .zip description</b>				
	<b>Document Description</b>		<b>Start</b>	<b>End</b>	
	Information Disclosure Statement Letter		1	3	
Information Disclosure Statement (IDS) Filed (SB/08)		4	4		
<b>Warnings:</b>					
<b>Information:</b>					
4	Fee Worksheet (PTO-06)	fee-info.pdf	29805 7e899d6d126a868c52a2cd44bdde3a4b1bb60348	no	2
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			6065014		

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**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

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.

<b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875	Application or Docket Number <b>10/972,287</b>	Filing Date <b>10/21/2004</b>	<input type="checkbox"/> To be Mailed
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APPLICATION AS FILED – PART I			OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	SMALL ENTITY <input checked="" type="checkbox"/>	OR			
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A	N/A			N/A	
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>	minus 20 =	*	X \$ =		OR	X \$ =	
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	minus 3 =	*	X \$ =			X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	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).						
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II					OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	(Column 3)		SMALL ENTITY	OR			
AMENDMENT	11/20/2008	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 24	Minus ** 58	= 0	X \$26 =	0		X \$ =	
	Independent (37 CFR 1.16(h))	* 2	Minus *** 3	= 0	X \$110 =	0		X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR		
					TOTAL ADD'L FEE	0	OR	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 (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus **	=	X \$ =			X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus ***	=	X \$ =			X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> 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:  
 /RUTH M. LLOYD/

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.**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004	Amr Salahieh	10012-702.501	7706
66854	7590	03/05/2009	EXAMINER	
SHAY GLENN LLP 2755 CAMPUS DRIVE SUITE 210 SAN MATEO, CA 94403			STRASZHEIM, REBECCA L	
			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			03/05/2009	PAPER

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

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

<b>Office Action Summary</b>	<b>Application No.</b> 10/972,287	<b>Applicant(s)</b> SALAHIEH ET AL.	
	<b>Examiner</b> REBECCA STRASZHEIM	<b>Art Unit</b> 3738	

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

**Period for Reply**

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

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

**Status**

- 1)  Responsive to communication(s) filed on 20 November 2008.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 22-38 and 59-65 is/are pending in the application.  
4a) Of the above claim(s) 38 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 22-37 and 59-65 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 20 November 2008 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 10/21/2008, 11/20/2008.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 11/20/2008 have been fully considered but they are not persuasive. With respect to claim 22 – Applicant argues that Bailey does not disclose, teach, suggest or appreciate engaging leaflet elements on the proximal end of the anchor and that in the Bailey's CV device the anchor flange 22, and not the distal anchor section 16, is adapted to 'project radially outward away from the central longitudinal axis of the stent body member'. Applicant does not claim nor define within the specifications which end of the anchor is the proximal end, as such Examiner may interpret the proximal end to be either end of the anchor, also there is no requirement within claim 22 requiring that either the proximal or distal end of the anchor must project radially outward away from the central longitudinal axis – therefore making this argument moot.

### *Claim Rejections - 35 USC § 102*

2. 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.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.



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3. Claims 22-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (6458153 – as previously cited by Examiner).
4. Bailey teaches a device and method for replacing a heart valve. The device, as can be seen in figs. 1-5, is a one way stented valve (10) - designed for chamber to vessel use (CV) including two leaflet engagement elements - a distal anchor flange (16), an intermediate annular section (20) – making up the anchor, a proximal anchor flange (22), the replacement valve itself (26), and an abluminal graft portion (11a) (column 8, lines 28-64). The abluminal graft portion is positioned between the heart wall and the stent body and acts as a seal (column 10, lines 46-63). The method includes delivering a valve stent (10), in a compressed state, to the aortic valve, withdrawing the stent from a catheter body (501) responsible for holding the valve stent in its compressed state (column 14, lines 6-55). The valve stent then expands (column 13, lines 46-51) which would cause the leaflet engaging elements (distal anchor/ proximal anchor) to foreshorten around the native valve leaflet trapping it between the stented valve and the wall of the vessel locking it in place. PLEASE NOTE: As applicant fails to define within the specifications or clearly claim which end of the anchor is the proximal end, either end of the CV stent, which can be divided in two halves along any line, for example - in the middle of the intermediate annular portion, can be the proximal end in which case either the abluminal graft portion or either of the anchor flanges can act as the leaflet engagement elements.
5. Claims 22, 59-60, 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Philipp et al. (2003/0036791).

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6. Philipp teaches a method for replacing a native aorta valve (paragraph [0026]). The valve implantation unit (10), as can be seen in figs. 1-6, includes: a plurality of feeler/ lateral loops/ leaflet engagement elements (30, 31) (paragraph [0026]), a carrier element/ anchor (20) (paragraph [0026]), and the valve unit/ replacement valve (2) (paragraph [0027]). The method of deployment includes: delivering the valve implantation unit within a catheter (60), releasing the lateral loops/ leaflet engagement elements – therefore engaging the native aortic valve leaflets (paragraph [0036]), expanding the cylindrical mesh/ anchor (paragraph [0042]).

***Claim Rejections - 35 USC § 103***

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

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

8. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey in view of Lunn (5476506).

9. Bailey discloses the invention substantially as claimed, and as discussed supra. However, Bailey does not disclose the seal being pleated.

10. Lunn teaches a pleated graft attached to the outside of a stent in the analogous art of grafts for the purpose of preventing the graft from being damaged during the expansion of the stent. Specifically, Lunn teaches that a problem with many grafts that are attached directly to the outside of a stent is that during the expansion process the graft may be damaged from not being elastic enough to accommodate the expansion of

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the stent within it (column 1, line 57-column 2, line 5). Lunn teaches a solution to this problem of attaching a crimped/ pleated graft around the unexpanded stent, and this extra material will allow for the stent to expand without straining the graft material (column 2, lines 22-46).

11. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the crimped/ pleated graft design taught by Lunn for the graft attached on the outside of the Bailey design in order to prevent damaging the graft during the expansion process.

1. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Philipp in view of Paniagua et al. (2003/0130729).

12. Philipp discloses the invention substantially as claimed, as discussed above. However, Philipp does not disclose the anchor to be self-expanding.

13. Paniagua teaches a replacement heart valve comprising a stent/ anchor that can be either self-expanding or balloon expandable (paragraph [0037]).

14. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the balloon expandable carrier element/ anchor, as taught by Philipp, self-expanding, as taught by Paniagua, as the two expansion mechanisms are substitutes for each other.

2. Claims 60-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teitelbaum (5332402) in view of Philipp.

15. Teitelbaum discloses the invention substantially as claimed. Specifically, Teitelbaum teaches a method of replacing a diseased valve including delivering a

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compressed nitinol stent/ anchor (12), as can be seen in fig. 3, to site of the diseased valve, allowing the stent to expand – pressing the native leaflets against the wall of the heart, and finally deploying the valve mechanism (14) (column 5, lines 4-25). The valve mechanism has two parts the loops (16, 18) and the umbrella portion (20), as Applicant fails to claim the structure associated with the expandable support structure and the replacement valve leaflets Examiner is considering the umbrella portion to be the replacement valve leaflets and the loops to be the expandable support structure. However, Teitelbaum does not disclose the use of leaflet engagement elements to sandwich the native valve leaflets between the distally extending leaflet engagement elements and the anchor/ stent.

16. Philipp teaches the use of a plurality of feeler/ lateral loops/ leaflet engagement elements (30, 31) on a carrier element/ anchor (20), as discussed above, for the purpose of positioning and anchoring the device (paragraph [0026]).

17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feeler/ lateral loops/ leaflet engagement elements, as taught by Philipp, on the stent/ anchor, as taught by Teitelbaum in order aid in positioning and anchoring the stent/ anchor.

### ***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA STRASZHEIM whose telephone number is (571)270-5233. The examiner can normally be reached on Monday-Friday with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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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.

RLS

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738

<b>Notice of References Cited</b>	Application/Control No. 10/972,287	Applicant(s)/Patent Under Reexamination SALAHIEH ET AL.	
	Examiner REBECCA STRASZHEIM	Art Unit 3738	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2003/0036791	02-2003	Philipp et al.	623/1.11
*	B	US-5,476,506	12-1995	Lunn, Anthony C.	623/1.28
*	C	US-2003/0130729	07-2003	Paniagua et al.	623/2.11
*	D	US-5,332,402	07-1994	Teitelbaum, George P.	623/2.42
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			


**FOREIGN PATENT DOCUMENTS**

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

**NON-PATENT DOCUMENTS**

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

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

<b>Search Notes</b>  	<b>Application/Control No.</b>  10972287	<b>Applicant(s)/Patent Under Reexamination</b>  SALAHIEH ET AL.
	<b>Examiner</b>  REBECCA STRASZHEIM	<b>Art Unit</b>  3738

SEARCHED			
Class	Subclass	Date	Examiner
	623/1.28	8/12/2008	RLS
	623/1.24, 1.26, 2.1, 2.12, 2.13, 2.14, 2.15, 2.16, 2.17, 2.18, 2.19, 2.38, 2.39, 2.4	2/27/2009	RLS

SEARCH NOTES		
Search Notes	Date	Examiner
EAST inventor name search, EAST subject search, discussed search strategy with Primary Examiner Suzette Gherbi	8/12/2008	RLS
EAST inventor name search, EAST text search, EAST forward and backward citation search	2/27/2009	RLS

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/R. S./ Examiner.Art Unit 3738	
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Substitute for form 1449/PTO  <h2 style="text-align: center; margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; margin: 0;"><i>(Use as many sheets as necessary)</i></p>	<b>Complete if Known</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/972,287</td> </tr> <tr> <td>Filing Date</td> <td>October 21, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Amr Salahieh</td> </tr> <tr> <td>Art Unit</td> <td>3738</td> </tr> <tr> <td>Examiner Name</td> <td>STRASZHEIM, REBECCA L</td> </tr> <tr> <td>Attorney Docket Number</td> <td>10012-702.501</td> </tr> </table>	Application Number	10/972,287	Filing Date	October 21, 2004	First Named Inventor	Amr Salahieh	Art Unit	3738	Examiner Name	STRASZHEIM, REBECCA L	Attorney Docket Number	10012-702.501
Application Number	10/972,287												
Filing Date	October 21, 2004												
First Named Inventor	Amr Salahieh												
Art Unit	3738												
Examiner Name	STRASZHEIM, REBECCA L												
Attorney Docket Number	10012-702.501												
Sheet <b>1</b> of <b>6</b>													

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	370	US- 6,197,053 B1	3/6/2001	Cosgrove et al.	
	371	US- 7,189,258 B2	3/13/2007	Johnson et al.	
	404	US- 2005/0033402 A1	2/10/2005	Cully et al.	
	407	US- 5,662,671	9/2/1997	Barbut et al.	
	408	US- 5,895,399	4/20/1999	Barbut et al.	
	409	US- 5,993,469	11/30/1999	McKenzie et al.	
	410	US- 5,997,557	12/7/1999	Barbut et al.	
	411	US- 6,010,522	1/4/2000	Barbut et al.	
	412	US- 6,231,544	5/15/2001	Tsugita et al.	
	413	US- 6,231,551	5/15/2001	Barbut	
	414	US- 6,616,682	9/9/2003	Joergensen et al.	
	415	US- 6,682,543	1/27/2004	Barbut et al.	
	416	US- 6,767,345	7/27/2004	St. Germain et al.	
	417	US- 7,166,097	1/23/2007	Barbut	
	418	US- 7,374,560	5/20/2008	Ressemann et al.	
	419	US- 2003/0212429 A1	11/13/2003	Keegan et al.	
	420	US- 2004/0049226 A1	3/11/2004	Keegan et al.	
	421	US- 2004/0098022 A1	5/20/2004	Barone	
		US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	308	EP 0819013	6/23/2004	Heartport, Inc.		
	309	EP 0937439B1	9/17/2003	Heartport, Inc.		
	312	EP 1057459	12/6/2000	Numed, Inc.		
	319	EP 1356793	10/29/2003	Numed, Inc.		
	327	WO 00/09059	2/24/2000	Prodesco, Inc.		
	328	WO 00/44308	8/3/2000	Board of Regents, The Univer		

Examiner Signature	Date Considered
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\*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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
		Examiner Name	STRASZHEIM, REBECCA L
Sheet 4	of 6	Attorney Docket Number	10012-702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
	263	ANDERSEN, H.R. et al. "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs." Euro. Heart J. 1992; 13:704-708.	
	264	ATWOOD, A. et al. "Insertion of Heart Valves by Catheterization." Project Supervised by Prof. S. Muftu of Northeastern University 2001-2002: 36-40.	
	265	BODNAR, E. et al. Replacement Cardiac Valves R Chapter 13: Extinct cardiac valve prostheses. Pergamon Publishing Corporation. New York, 1991: 307-322.	
	267	BOUDJEMLINE, Y. et al. "Percutaneous implantation of a valve in the descending aorta in lambs." Euro. Heart J. 2002; 23: 1045-1049.	
	269	BOUDJEMLINE, Y. et al. "Percutaneous valve insertion: A new approach?" J. of Thoracic and Cardio. Surg. 2003; 125(3): 741-743.	
	272	CRIBIER, A., et al. "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description." Circulation. 2002; 106: 3006-3008.	
	273	CRIBIER, A., et al. "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case." Percutaneous Valve Technologies, Inc. 2002: 16 pages.	
	274	FERRARI, M. et al. "Percutaneous transvascular aortic valve replacement with self expanding stent-valve device." Poster from the presentation given at SMIT 2000, 12th International Conference. September 5, 2000.	
	277	KNUDSEN, L. L. et al. "Catheter-implanted prosthetic heart valves." Int'l J. of Art. Organs. 1993; 16(5): 253-262.	
	278	KORT, S. et al. "Minimally invasive aortic valve replacement: Echocardiographic and clinical results." Am. Heart J. 2001; 142(3): 476-481.	

Examiner Signature	Date Considered
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
		Examiner Name	STRASZHEIM, REBECCA L
Sheet	5	of	6
		Attorney Docket Number	10012-702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
	279	LOVE, C. et al. "The Autogenous Tissue Heart Valve: Current Stat.f Journal of Cardiac Surgery. 1991; 6(4): 499-507.	
	280	LUTTER, G. et al. "Percutaneous aortic valve replacement: An experimental study. I. Studies on implantation." J. of Thoracic and Cardio. Surg. 2002; 123(4): 768-776.	
	281	MOULOPOULOS, S. D. et al. "Catheter-Mounted Aortic Valves." Annals of Thoracic Surg. 1971; 11(5): 423-430.	
	282	PANIAGUA, D. et al. "Percutaneous heart valve in the chronic in vitro testing model." Circulation. 2002; 106: e51-e52.	
	283	PANIAGUA, D. et al. Heart Watch (2004). Texas Heart Institute. Spring, 2004 Edition: 8 pages.	
	284	PAVCNIK, D. et al. "Percutaneous bioprosthetic veno valve: A long-term study in sheep." J. of Vascular Surg. 2002; 35(3): 598-603.	
	285	PHILLIPS, S. J. et al. "A Temporary Catheter-Tip Aortic Valve: Hemodynamic Effects on Experimental Acute Aortic Insufficiency." Annals of Thoracic Surg. 1976; 21(2): 134-136.	
	286	SOCHMAN, J. et al. "Percutaneous Transcatheter Aortic Disc Valve Prosthesis Implantation: A Feasibility Study." Cardiovasc. Intervent. Radiol. 2000; 23: 384-388.	
	289	VAN HERWERDEN, L. A. et al., "Percutaneous valve implantation: back to the future?" Euro. Heart J. 2002; 23(18): 1415-1416.	
	290	ZHOU, J. Q. et al. "Self-expandable valved stent of large size: off-bypass implantation in pulmonary position." Eur. J. Cardiothorac. 2003; 24: 212-216	

Examiner Signature		Date Considered	
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		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
		Examiner Name	STRASZHEIM, REBECCA L
Sheet 6 of 6	Attorney Docket Number	10012-702.501	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
	403	SALAHIEH, et al., U.S. Pat. App. # 12/132,304 entitled "Low profile heart valve and delivery system," filed 06/03/2008	

Examiner Signature	/Rebecca Straszheim/	Date Considered	02/27/2009
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## EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L5	3202	((balloon or self) near3 expand\$4) same valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:24
L6	698	((balloon or self) near3 expand\$4) same (heart near3 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:25
L7	50	((balloon or self) near3 expand\$4) same (stent \$3 near3 heart near3 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:27
L8	19	((balloon and self) near3 expand\$4) same (stent\$3 near3 heart near3 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:27
L9	275	623/2.38.ccls. or 623/2.39.ccls. or 623/2.4.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:36
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S19	18	gainor-john\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/11 09:30
S20	33	lashinski-randall\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/11 09:37
S21	61	623/1.28.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 07:51
S22	881	623/1.13.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 07:58
S23	28	623/1.28.ccls. AND stent	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 08:47
S24	221	salahieh-amr\$.in. or brandt-brian\$.in. or geshlider-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 11:43
S25	104	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlider-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 11:44

S26	106	"20010039450"	US-PGPUB	OR	ON	2009/02/18 11:59
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S34	1241	623/1.24.ccls. or 623/1.26.ccls. 623/2.1. ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 14:37
S35	2	"6425916".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 16:53

S36	42	"20010021872"   "20020045936"   "20020090725"   "20020198594"   "20030023300"   "20030028224"   "20030109924"   "20030130729"   "20030171802"   "20030204243"   "20040037813"   "20040225352"   "20050027348"   "20050096736"   "20050113910"   "20050137681"   "20050137682"   "20050240262"   "20060136044"   "4265694"   "4470157"   "4510628"   "4692164"   "5397351"   "5545215"   "5855597"   "5855601"   "5855610"   "5925063"   "5957949"   "6287334"   "6425916"   "6440164"   "6482228"   "6503272"   "6517576"   "6569196"   "6582462"   "6755856"   "7018404").PN. OR ("7261732").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/02/18 17:01
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S44	1409	(leaflet same (sandwich \$4 or between)) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 17:44
S45	104	(leaflet same (sandwich \$4)) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 17:44
S46	1	"20030036791"	US-PGPUB	OR	ON	2009/02/19 08:29
S47	1	"20050137698"	US-PGPUB	OR	ON	2009/02/19 08:58

2/ 27/ 2009 10:24:28 AM

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Substitute for form 1449/PTO  <h2 style="text-align: center; margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; font-size: small;">(Use as many sheets as necessary)</p>	<p style="text-align: center; font-weight: bold; margin: 0;">Complete if Known</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Application Number</td> <td>10/972,287</td> </tr> <tr> <td>Filing Date</td> <td>October 21, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Amr Salahieh</td> </tr> <tr> <td>Art Unit</td> <td>3738</td> </tr> <tr> <td>Examiner Name</td> <td>STRASZHEIM, REBECCA L</td> </tr> <tr> <td>Attorney Docket Number</td> <td>10012-702.501</td> </tr> </table>	Application Number	10/972,287	Filing Date	October 21, 2004	First Named Inventor	Amr Salahieh	Art Unit	3738	Examiner Name	STRASZHEIM, REBECCA L	Attorney Docket Number	10012-702.501
Application Number	10/972,287												
Filing Date	October 21, 2004												
First Named Inventor	Amr Salahieh												
Art Unit	3738												
Examiner Name	STRASZHEIM, REBECCA L												
Attorney Docket Number	10012-702.501												
Sheet <u>1</u> of <u>1</u>													

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	422	US- 4,326,306	4/27/1982	Poler	
	423	US- 4,423,809	1/3/1984	Mazzocco	
	431	US- 6,336,937	1/8/2002	Vonesh et al.	
	433	US- 6,790,237	9/14/2004	Stinson	
	429	US- 2001/0041930 A1	11/15/2001	Globerman et al.	
	424	US- 2002/0029981 A1	3/14/2002	Nigam	
	428	US- 2002/0055769 A1	5/9/2002	Wang	
	425	US- 2002/0082609 A1	6/27/2002	Green	
	432	US- 2002/0188341 A1	12/12/2002	Elliott	
	434	US- 2003/0050694 A1	3/13/2003	Yang et al.	
	426	US- 2003/0070944 A1	4/17/2003	Nigam	
	427	US- 2004/0098099 A1	5/20/2004	McCullagh et al.	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

Examiner Signature	/Rebecca Straszheim/	Date Considered	02/27/2009
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\*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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

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

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

VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/972,287 Confirmation No.: 7706  
Applicant(s): Amr Salahieh  
Filed: October 21, 2004  
Art Unit: 3738  
Examiner: STRASZHEIM, REBECCA L  
Title: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE  
THEREOF  
Customer No.: 66854

---

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

**INFORMATION DISCLOSURE STATEMENT UNDER  
37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

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

**FILING OF INFORMATION DISCLOSURE STATEMENT**

- 37 CFR §1.97(b)**  
 This statement is being submitted under 37 CFR §1.97(b) because the IDS is being filed:
  - 1). Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or
  - 2). Within 3 months of entry of a national stage as set forth in § 1.491, or
  - 3). Before the mail date of a first Office Action on the merits, or
  - 4). Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

- 37 CFR § 1.97(c)**  
 This statement is being filed after the latest of:
  - 1). Three months beyond the filing date of a national application, or
  - 2). Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or
  - 3). The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
    - A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or
    - B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

- 37 CFR § 1.97(d)**  
 This statement is being filed after the mailing date of a Final Office action, a Notice of Allowance under § 1.311, or an action that otherwise closes prosecution, but on or before payment of the issue fee, and then:

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

--AND--

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

**CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER**

**37 CFR § 1.98**

- 37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**
  - 1). Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
  - 2). At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:
- 37 CFR §1.98 (a)(2)(iii) and (d), Pending unpublished U.S. applications cited**
  - 1). A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.
  - 2). A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  - 3). A copy of each application specification is not submitted because the application is stored in the IFW.
- 37 CFR §1.98 (a)(2)(iii) and (d), English language publication (other than U.S. patents, patent applications, or pending unpublished applications) cited**
  - 1). A legible copy of each publication or that portion which caused it to be listed is attached.
  - 2). A copy of each publication or that portion which caused it to be listed is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:



- 37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited
  - 1). A legible copy of each foreign patent or that portion which caused it to be listed is attached.
  - 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  
- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:
  - 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached --AND--
  
  - 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith: --OR--
  
  - 2b). A copy of a written, English-language translation or portion thereof is readily available and attached, --OR--
  
  - 2c). An English language copy of a foreign search report is submitted. --OR--
  
  - 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

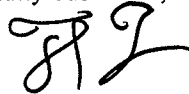
**STATEMENT UNDER 37 CFR § 1.97(e)**

- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
  
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

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

Respectfully Submitted,



By: \_\_\_\_\_  
Thomas Zlogar Reg. # 55760

Dated: 3/12/09

Shay Glenn LLP  
2755 Campus Drive, Suite 210  
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Customer No. 66854

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/972,287
Filing Date	October 21, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	STRASZHEIM, REBECCA L
Attorney Docket Number	10012-702.501

Sheet 1 of 1

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	438	US- 4,602,911	07/29/1986	Ahmadi et al.	
	437	US- 5,476,510	12/19/1995	Eberhardt et al.	
	439	US- 5,984,959	11/16/1999	Robertson et al.	
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**FOREIGN PATENT DOCUMENTS**

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

Examiner  
SignatureDate  
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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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

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

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	10972287
<b>Filing Date:</b>	21-Oct-2004
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Filer:</b>	Thomas M. Zlogar/Angelica Zuniga
<b>Attorney Docket Number:</b>	10012-702.501

Filed as Large Entity

### Utility under 35 USC 111(a) Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Miscellaneous:</b>				
Submission- Information Disclosure Stmt	1806	1	180	180
<b>Total in USD (\$)</b>				<b>180</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	4958527
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	Thomas M. Zlogar/Angelica Zuniga
<b>Filer Authorized By:</b>	Thomas M. Zlogar
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	12-MAR-2009
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	17:57:51
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$180
RAM confirmation Number	3455
Deposit Account	504050
Authorized User	

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

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

<b>File Listing:</b>					
<b>Document Number</b>	<b>Document Description</b>	<b>File Name</b>	<b>File Size(Bytes)/ Message Digest</b>	<b>Multi Part /.zip</b>	<b>Pages (if appl.)</b>
1		10012-702501.pdf	234885 3ba654c928f8ad18b8527a0204ff3cc0bc754df3	yes	4
<b>Multipart Description/PDF files in .zip description</b>					
<b>Document Description</b>			<b>Start</b>	<b>End</b>	
Information Disclosure Statement Letter			1	3	
Information Disclosure Statement (IDS) Filed (SB/08)			4	4	
<b>Warnings:</b>					
<b>Information:</b>					
2	Fee Worksheet (PTO-06)	fee-info.pdf	29690 9ff4a3f4219d2f3391a3d87d1762dd463b93bb47	no	2
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			264575		
<p><b>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.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  <b>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.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  <b>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.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>  <b>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.</b></p>					

**FILED VIA EFS ON MAY 5, 2009**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/972,287 Confirmation No.: 7706  
Applicant : Amr Salahieh et al.  
Filing Date : October 21, 2004  
Title : LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR  
USE THEREOF  
Group Art Unit : 3738  
Examiner : Straszheim, Rebecca L.  
Docket No. : 10012-702.501  
Customer No. : 66854

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

Sir:

**AMENDMENT AFTER FINAL AND REQUEST FOR RECONSIDERATION**

**Introductory Comments:**

This Amendment responds to the final Office Action dated March 5, 2009, for which a response is due June 5, 2009.

Please enter the amendments and consider the remarks as follows.

**Amendments to the Claims** begin on page 2.

**Remarks /Arguments** begin on page 4 of this paper.

**Amendments to the Claims:**

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

1. - 59. (Canceled)

60. (Currently Amended) A method for endovascularly replacing a patient's native heart valve, the method comprising:

delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein ~~the anchor comprises~~ leaflet engagement elements extending distally from a proximal end of the anchor;

sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor; and

expanding the anchor from a collapsed delivery configuration to an expanded configuration to secure the anchor within the native heart valve; ~~and~~

wherein the replacement valve allows the flow of blood through the replacement valve in a first configuration and prevents the flow of blood through the valve in a second configuration.

61. (Currently Amended) The method of claim 60 wherein expanding the anchor from a collapsed delivery configuration to an expanded configuration comprises allowing the anchor to self-expand to thereby sandwich the native valve leaflets between the distally extending leaflet engagement elements and the anchor.

62. (Currently Amended) The method of claim 60 wherein the leaflet engagement elements extend generally parallel to the longitudinal axis of the expandable anchor when the anchor is in the expanded configuration.

63. (Previously Presented) The method of claim 60 wherein the expandable anchor and the replacement valve are delivered as two separate elements, the method further comprising deploying the expandable anchor and the replacement valve in the vicinity of the native heart valve in two different steps.



64. (Previously Presented) The method of claim 63 further comprising engaging the expandable anchor and the replacement valve after they are deployed in the vicinity of the native heart valve to secure the replacement heart valve to the expandable anchor.

65. (Previously Presented) The method of claim 64 wherein the replacement heart valve comprises an expandable support structure and replacement valve leaflets, and wherein engaging the expandable anchor and the replacement valve in the vicinity of the native heart valve comprises coupling the expandable anchor and the expandable support structure to secure the replacement heart valve to the expandable anchor.

## REMARKS

### Claim Summary

Claims 60-62 are currently amended. Claims 1-59 are canceled. Claims 61-65 are currently pending.

### Information Disclosure Statements

Applicants note with thanks that the Examiner has considered all references submitted in Information Disclosure Statements dated 10/21/2008 and 11/20/2008.

References submitted in Information Disclosure Statements dated 4/27/2005, 7/12/2006, and 6/10/2008 were crossed off and not acknowledged, because copies were not submitted. (See non-final office action dated 8/18/2008). Applicants are not required to submit a copy of a reference if it is a copending application available in the IFW. See MPEP 609.04(a), II C. These references are copending applications available in the IFW. Applicants respectfully request the Examiner to consider these references, and initial and return a copy of the PTO Forms 1449 with the next Action.

Additional references have been submitted in an Information Disclosure Statement dated 3/12/2009. It is respectfully requested that this Information Disclosure Statement be considered and the PTO Form 1449 be initialed and returned with the next Action.

### Claim Rejections Under 35 U.S.C. § 102

Claims 22-36 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bailey et al. U.S. 6,458,153.

Cancellation or amendment of the claims is done without prejudice to reintroducing any material removed as a result of these actions in this or any other patent applications. These actions are not to be considered a waiver or abandonment of any technology otherwise fully described in the application as filed. Applicant reserves the right to pursue any canceled or amended subject matter in one or more continuing applications.

Claims 22-36 are currently canceled and the rejections are now moot.

Claims 22, 59-60, and 62 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Phillip et al. U.S. 2003/0036791.

Claims 22 and 59 are canceled and thus the rejections are moot.

Independent claim 60 recites, in part, delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a proximal end of the anchor; sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor; and expanding the anchor from a collapsed delivery configuration to an expanded configuration to secure the anchor within the native heart valve, wherein the replacement valve allows the flow of blood through the replacement valve in a first configuration and prevents the flow of blood through the valve in a second configuration.

Phillip does not anticipate independent claim 60 because Phillip does not disclose each and every limitation in claim 60. For example, Phillip does not disclose delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend *distally from a proximal end of the anchor*, as is required by claim 60. During patent examination, the pending claims must be given their broadest reasonable interpretation *consistent with the specification*. Applicants use the terms distally (or distal) and proximally (or proximal) consistently in the specification. For example, as can be seen in at least Figures 7 and 25 (included in Applicants' previous response), the proximal end of the anchor is relatively further from the left ventricle than the distal end. This relative terminology is used consistently throughout the Applicants' specification. It would therefore be an unreasonable interpretation of the pending claims to use the terms proximal end and distal end to refer to either end of an anchor.

As can be seen in Phillip's Figures 2 and 3, the feeler elements 30 extend *proximally* from a *distal* end of carrier element 20. For at least this reason Phillip does not anticipate independent claim 60.

Claim 60 also requires the step of "sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor." The Examiner states that carrier element 20 from Phillip is disclosure for the anchor as claimed. (Final Office Action, pg 4). As can be seen in Figures and 2 and 3, however, the native valve leaflets are sandwiched between feeler elements 30 and 31, not between feeler elements 30 and carrier element 20. If, however,

the Examiner considered feeler elements 30 to be part of the anchor as claimed and considered feeler elements 31 to be the leaflet engagement elements as claimed, the feeler elements 31 could not be considered to be extending distally from a proximal end of the anchor as required by claim 60. For at least this additional reason claim 60 is also not anticipated by Phillip, and Applicants respectfully ask the Examiner to reconsider the rejection.

Claim 62 depends from claim 60 and is not anticipated by Phillip for at least the same reasons set forth above.

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

Claim 37 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bailey et al. U.S. 6,458,153 in view of Anthony Lunn U.S. 5,476,506.

Claim 37 is canceled and thus the rejection is moot.

Claim 61 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Phillip et al. U.S. 2003/0036791 in view of Paniagua et al., U.S. 2003/0130729.

Claim 61 depends from claim 60 and as discussed above, Phillip does not teach the limitations of claim 60. Paniagua does not overcome the deficiencies of Phillip and for at least this reason claim 61 is not unpatentable over Phillip in view of Paniagua.

Claims 60-65 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over George Teitelbaum U.S. 5,332,402 in view of Phillip et al. U.S. 2003/0036791.

Independent claim 60 recites, in part, delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a proximal end of the anchor; sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor; and expanding the anchor from a collapsed delivery configuration to an expanded configuration to secure the anchor within the native heart valve, wherein the replacement valve allows the flow of blood through the replacement valve in a first configuration and prevents the flow of blood through the valve in a second configuration.

The Examiner acknowledges that Teitelbaum does not disclose leaflet engagement elements that extend distally from a proximal end of the anchor, and sandwiching native valve

leaflets between the distally extending leaflet engagement elements and the anchor, as required by claim 60. The Examiner relies on Phillip to overcome the deficiencies of Teitelbaum. As discussed above, Phillip does not disclose these limitations and therefore does not overcome the deficiencies of Teitelbaum. For at least this reason claim 60 is not unpatentable over Teitelbaum in view of Phillip.

Claims 61-65 depend from claim 60 and are not unpatentable over Teitelbaum in view of Phillip for at least the same reasons set forth above.

### CONCLUSION

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

Respectfully submitted,



Date: May 5, 2009

By:

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

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

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	5281982
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	Thomas M. Zlogar/Mary Buggie
<b>Filer Authorized By:</b>	Thomas M. Zlogar
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	05-MAY-2009
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	18:32:27
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-702-501-RespAF_5-5-09.pdf	287842 d3d2f700bd49186b2ff305d058ec5a686602245e	yes	7

<b>Multipart Description/PDF files in .zip description</b>			
<b>Document Description</b>		<b>Start</b>	<b>End</b>
Amendment After Final		1	1
Claims		2	3
Applicant Arguments/Remarks Made in an Amendment		4	7

**Warnings:**

**Information:**

<b>Total Files Size (in bytes):</b>	287842
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

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

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

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

**New International Application Filed with the USPTO as a Receiving Office**

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

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.

<b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875	Application or Docket Number <b>10/972,287</b>	Filing Date <b>10/21/2004</b>	<input type="checkbox"/> To be Mailed
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APPLICATION AS FILED – PART I			OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	SMALL ENTITY <input checked="" type="checkbox"/>	OR			
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A	N/A			N/A	
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>	minus 20 =	*	X \$ =		OR	X \$ =	
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	minus 3 =	*	X \$ =			X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	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).						
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II					OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	(Column 3)		SMALL ENTITY	OR			
AMENDMENT	<b>05/05/2009</b>	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 6	Minus ** 58	= 0	X \$26 =	0	OR	X \$ =	
	Independent (37 CFR 1.16(h))	* 1	Minus *** 3	= 0	X \$110 =	0	OR	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

	(Column 1)	(Column 2)	(Column 3)		SMALL ENTITY	OR			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus **	=	X \$ =		OR	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus ***	=	X \$ =		OR	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> 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:  
 /SHAUNA I. ZIMMERMAN/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**  
 If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



**FILED VIA EFS ON MAY 5, 2009**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/972,287 Confirmation No.: 7706  
Applicant : Amr Salahieh et al.  
Filing Date : October 21, 2004  
Title : LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR  
USE THEREOF  
Group Art Unit : 3738  
Examiner : Straszheim, Rebecca L.  
Docket No. : 10012-702.501  
Customer No. : 66854

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

Sir:

**AMENDMENT AFTER FINAL AND REQUEST FOR RECONSIDERATION**

**Introductory Comments:**

This Amendment responds to the final Office Action dated March 5, 2009, for which a response is due June 5, 2009.

Please enter the amendments and consider the remarks as follows.

**Amendments to the Claims** begin on page 2.

**Remarks /Arguments** begin on page 4 of this paper.



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

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
10/972,287 10/21/2004 Amr Salahieh 10012-702.501 7706

66854 7590 05/22/2009
SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER

STRASZHEIM, REBECCA L

ART UNIT PAPER NUMBER

3738

MAIL DATE DELIVERY MODE

05/22/2009

PAPER

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

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

**Advisory Action  
Before the Filing of an Appeal Brief**

<b>Application No.</b> 10/972,287	<b>Applicant(s)</b> SALAHIEH ET AL.	
<b>Examiner</b> REBECCA STRASZHEIM	<b>Art Unit</b> 3738	

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

THE REPLY FILED 05 May 2009 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 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: 22-37, 59-65.  
Claim(s) withdrawn from consideration: 38.

**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 of 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:  
See Continuation Sheet.
12.  Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13.  Other: \_\_\_\_\_.

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738

/R. S./  
Examiner, Art Unit 3738

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues two points related to the Phillip reference. The first, is that the claim requires that the leaflet engagement elements extend distally from a proximal end of the anchor, and throughout the specifications the proximal end of the anchor is relatively further from the left ventricle than the distal end. However, Applicant fails within the specification or claims to require that the proximal end of the anchor extends relatively further from the left ventricle than the distal end, as such Examiner can consider which ever end of the carrier element/ anchor taught by Phillip to be the distal end. The second, is that Phillip teaches the native valve leaflets to be sandwiched between the feeler elements/ leaflet engagement elements (30, 31) instead of between the feeler elements/ leaflet engagement elements (30) and carrier element/ anchor (20). Applicant does not claim that the native valve leaflets are sandwiched directly between the leaflet engagement elements, just that they are sandwiched between, as can be seen in fig.3 on one side of the leaflet is carrier/ anchor element and on the other side is feeler element/ leaflet engagement element meeting the claim requirement of sandwiched.

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

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1

of 1

**Complete if Known**

Application Number	10/972,287
Filing Date	October 21, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	STRASZHEIM, REBECCA L
Attorney Docket Number	10012-702.501

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	443	US- 5,735,842	4/7/1998	Krueger et al.	
	447	US- 7,191,018	3/13/2007	Gielen et al.	
	444	US- 2003/0109930-A1	6/12/2003	Bluni et al.	
	445	US- 2003/0144732-A1	7/31/2003	Cosgrove et al.	
	446	US- 2004/0133274-A1	7/8/2004	Webler et al.	
	441	US- 2008/0269878-A1	10/30/2008	lobbi	
	436	US- 2009/0076598-A1	3/19/2009	Salahieh et al.	
	435	US- 2009/0054969-A1	2/26/2009	Salahieh et al.	
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**FOREIGN PATENT DOCUMENTS**

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

Examiner  
SignatureDate  
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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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

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

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	10972287
<b>Filing Date:</b>	21-Oct-2004
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Filer:</b>	James R. Shay/Sue Bromaghim (TZ)
<b>Attorney Docket Number:</b>	10012-702.501

Filed as Small Entity

### Utility under 35 USC 111(a) Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Miscellaneous:</b>				
Request for continued examination	2801	1	405	405
<b>Total in USD (\$)</b>				<b>470</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	5620276
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	James R. Shay/Sue Bromaghim (TZ)
<b>Filer Authorized By:</b>	James R. Shay
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	30-JUN-2009
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	18:32:23
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$470
RAM confirmation Number	6151
Deposit Account	504050
Authorized User	

### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part/.zip (if appl.)	Pages (if appl.)
Edwards Lifesciences Corporation, et al Exhibit 1142, Page 428 of 630					



1		10012-702-501-trans-RCE-Amendment-IDS.pdf	1552921 d01fe170aaa29e879f32c22dd546bd2791b1b563	yes	12
<b>Multipart Description/PDF files in .zip description</b>					
<b>Document Description</b>		<b>Start</b>		<b>End</b>	
Extension of Time		1		1	
Request for Continued Examination (RCE)		2		2	
Amendment Submitted/Entered with Filing of CPA/RCE		3		3	
Claims		4		5	
Applicant Arguments/Remarks Made in an Amendment		6		8	
Transmittal Letter		9		11	
Information Disclosure Statement (IDS) Filed (SB/08)		12		12	
<b>Warnings:</b>					
<b>Information:</b>					
2	Fee Worksheet (PTO-875)	fee-info.pdf	31793 9702b2927c53cb1f5970e8196aac6463a379ac6d	no	2
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			1584714		
<p><b>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.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b> 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.</p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b> 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.</p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b> 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.</p>					

**FILED VIA EFS ON JUNE 30, 2009**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/972,287 Confirmation No.: 7706  
Applicant : Amr SALAHIEH et al.  
Filing Date : October 21, 2004  
Title : Leaflet Engagement Elements and Methods for Use Thereof  
Group Art Unit : 3738  
Examiner : Rebecca L. STRASZHEIM  
Docket No. : 10012-702.501  
Customer No. : 66854

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

**TRANSMITTAL OF AMENDMENT ACCOMPANYING RCE  
AND REQUEST FOR ONE-MONTH EXTENSION OF TIME**

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

- (1) Request for Continued Examination;
- (2) Amendment Accompanying RCE (for which no claims fee is due); and
- (3) Information Disclosure Statement.

- ▶ Request is hereby made for a one (1) month extension of time to file these documents, up to and including **July 5, 2009**.
- ▶ The RCE fee (\$405) and the extension fee (one month / small entity - \$65) are being paid via EFS. Please deduct from or credit to Deposit Account No. 50-4050 any other fees attendant with this matter.

Respectfully submitted,



By:

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

Date: June 30, 2009

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

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.

<b>Request for Continued Examination (RCE) Transmittal</b>  Address to: Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	10/972,287
	Filing Date	October 21, 2004
	First Named Inventor	Amr SALAHIEH et al.
	Art Unit	3738
	Examiner Name	Rebecca L. STRASZHEIM
	Attorney Docket Number	10012-702.501

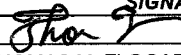
**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**  
 Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).
- a.  Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
    - i.  Consider the arguments in the Appeal Brief or Reply Brief previously filed on \_\_\_\_\_
    - ii.  Other Amendment Accompanying RCE, filed herewith
  - b.  Enclosed
    - i.  Amendment/Reply
    - ii.  Affidavit(s)/ Declaration(s)
    - iii.  Information Disclosure Statement (IDS)
    - iv.  Other TRANSMITTAL-EXT OF TIME

2. **Miscellaneous**
- a.  Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of \_\_\_\_\_ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
  - b.  Other \_\_\_\_\_

3. **Fees** The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed. The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 50-4050.
- a. 
    - i.  RCE fee required under 37 CFR 1.17(e)
    - ii.  Extension of time fee (37 CFR 1.136 and 1.17)
    - iii.  Other \_\_\_\_\_
  - b.  Check in the amount of \$ \_\_\_\_\_ enclosed
  - c.  Payment by credit card (Form PTO-2038 enclosed)

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED			
Signature		Date	JUNE 30, 2009
Name (Print/Type)	THOMAS M. ZLOGAR	Registration No.	55,760

CERTIFICATE OF MAILING OR TRANSMISSION			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.			
Signature	FILED VIA EFS	Date	JUNE 30, 2009
Name (Print/Type)	SUE BROMAGHIM	Date	JUNE 30, 2009

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. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

**FILED VIA EFS ON JUNE 30, 2009**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/972,287 Confirmation No.: 7706  
Applicant : Amr SALAHIEH et al.  
Filing Date : October 21, 2004  
Title : Leaflet Engagement Elements and Methods for Use Thereof  
Group Art Unit : 3738  
Examiner : Rebecca L. STRASZHEIM  
Docket No. : 10012-702.501  
Customer No. : 66854

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

**AMENDMENT ACCOMPANYING RCE**

**Introductory Comments:**

This Amendment accompanies a Request for Continued Examination, and is responsive to the final Office Action mailed March 5, 2009, and the Advisory Action mailed May 22, 2009. A request for extension of time, up to and including **July 5, 2009**, accompanies this response.

Please enter the amendments and consider the remarks as follows.

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

**Amendments to the Claims / Claim Listing** begin on page 2.

**Remarks / Arguments** begin on page 4 of this paper.

**Amendments to the Claims / Claim Listing:**

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

1. - 59. (Canceled)

60. (Currently Amended) A method for endovascularly replacing a patient's native heart valve, the method comprising:

delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a proximal end of the anchor;

sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor; and

expanding the anchor from a collapsed delivery configuration to an expanded configuration to secure the anchor within the native heart valve;

positioning the proximal end of the anchor further from a left ventricle than a distal end of the anchor,

wherein the replacement valve allows the flow of blood through the replacement valve in a first configuration and prevents the flow of blood through the valve in a second configuration.

61. (Previously Presented) The method of claim 60 wherein expanding the anchor from a collapsed delivery configuration to an expanded configuration comprises allowing the anchor to self-expand to thereby sandwich the native valve leaflets between the distally extending leaflet engagement elements and the anchor.

62. (Previously Presented) The method of claim 60 wherein the leaflet engagement elements extend generally parallel to the longitudinal axis of the expandable anchor when the anchor is in the expanded configuration.

63. (Previously Presented) The method of claim 60 wherein the expandable anchor and the replacement valve are delivered as two separate elements, the method further comprising

deploying the expandable anchor and the replacement valve in the vicinity of the native heart valve in two different steps.

64. (Previously Presented) The method of claim 63 further comprising engaging the expandable anchor and the replacement valve after they are deployed in the vicinity of the native heart valve to secure the replacement heart valve to the expandable anchor.

65. (Previously Presented) The method of claim 64 wherein the replacement heart valve comprises an expandable support structure and replacement valve leaflets, and wherein engaging the expandable anchor and the replacement valve in the vicinity of the native heart valve comprises coupling the expandable anchor and the expandable support structure to secure the replacement heart valve to the expandable anchor.

66. (New) A method for endovascularly replacing a patient's native heart valve, the method comprising:

delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a first end of the anchor;

sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor; and

expanding the anchor from a collapsed delivery configuration to an expanded configuration to secure the anchor within the native heart valve;

positioning the first end of the anchor further from a left ventricle than a second end of the anchor,

wherein the replacement valve allows the flow of blood through the replacement valve in a first configuration and prevents the flow of blood through the valve in a second configuration.

## REMARKS

### Claim Summary

After entry of the Amendment After Final dated May 5, 2009 and the amendments herein, claims 60-66 are pending. Claims 1-59 have been cancelled; claim 60 is amended herein; and claim 66 is newly presented.

### Claim Rejections Under 35 U.S.C. § 102

Claims 60 and 62 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Phillip et al. U.S. 2003/0036791.

Currently amended independent claim 60 recites a method for endovascularly replacing a patient's native heart valve, including delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a proximal end of the anchor, sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor; and positioning the proximal end of the anchor further from a left ventricle than a distal end of the anchor. Support for the amendment to claim 60 can be found in, for example, Figure 7, which clearly shows positioning the proximal end of anchor 30 further from left ventricle LV than the distal end of anchor 30, and which shows leaflet engagement elements 120 extending distally from a proximal end of anchor 30. While there may not be explicit support for this amendment in the specification, one of ordinary skill in the art would clearly understand, from a cursory review of at least Figure 7, that Applicants had possession of the invention as claimed as of the filing date of the application. The amendment merely clarifies which end of the anchor is which relative to the left ventricle, thereby clarifying from which end of the anchor the leaflet engagement elements are extending. The terms distal and proximal are used throughout the specification in a manner consistent with the manner in which they are shown in Figure 7 and used to describe Figure 7, and therefore no new matter is added. For example, the specification states that "leaflet engagement elements 120 may also be disposed on the *proximal end* of an anchor (as is illustrated in Figure 7)." Paragraph [0066], lines 5-6 (emphasis added).

Phillip does not anticipate claim 60 because Phillip does not disclose each and every limitation in claim 60. For example, Phillip does not disclose "delivering an expandable anchor

and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a proximal end of the anchor, sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor, and positioning the proximal end of the anchor further from a left ventricle than a distal end of the anchor.” As such, claim 60 is not anticipated by Phillip. Claim 62 depends from claim 60 and is therefore not anticipated by Phillip for at least the same reasons as set forth above with respect to claim 60.

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

Claim 61 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Phillip et al. U.S. 2003/0036791 in view of Paniagua et al., U.S. 2003/0130729.

Claim 61 depends from claim 60 and as set forth above, Phillip does not teach or suggest all of the limitations of claim 60. Paniagua does not overcome the deficiencies of Phillip, and therefore dependent claim 61 is not unpatentable over Phillip in view of Paniagua.

Claims 60-65 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Teitelbaum U.S. 5,332,402 in view of Phillip et al. U.S. 2003/0036791.

As set forth above, Phillip does not teach or suggest all of the limitations of claim 60. Teitelbaum does not overcome the deficiencies of Phillip, and therefore Teitelbaum and Phillip do not teach or suggest the limitations of claim 60. Claim 60 is, at least for this reason, not unpatentable over Teitelbaum in view of Phillip. Claims 61-65 depend from claim 60 and are not unpatentable over Teitelbaum in view of Phillip for at least the same reasons as claim 60.

### **New Claim**

Applicants are adding new claim 66, which is similar to claim 60 but recites a first end and a second end rather than a proximal end and a distal end. Support for new claim 66 can be found throughout the specification as filed, for example, in Figure 7. Claim 66 is patentable over the cited references for at least the same reasons set forth above with respect to claim 60.

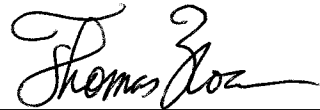


**CONCLUSION**

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

Respectfully submitted,

Date: June 30, 2009

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

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

VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/972,287 Confirmation No.: 7706  
Applicant(s): Amr Salahieh  
Filed: October 21, 2004  
Art Unit: 3738  
Examiner: STRASZHEIM, REBECCA L  
Title: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE  
THEREOF  
Customer No.: 66854

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

**INFORMATION DISCLOSURE STATEMENT UNDER  
37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

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

**FILING OF INFORMATION DISCLOSURE STATEMENT** **37 CFR §1.97(b)**

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

- 1). Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or
- 2). Within 3 months of entry of a national stage as set forth in § 1.491, or
- 3). Before the mail date of a first Office Action on the merits, or
- 4). Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

 **37 CFR § 1.97(c)**

This statement is being filed after the latest of:

- 1). Three months beyond the filing date of a national application, or
- 2). Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or
- 3). The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or
- B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

 **37 CFR § 1.97(d)**

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

- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement
- AND--
- B). A certification as specified in § 1.97(e) is included below.

**CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER  
37 CFR § 1.98** **37 CFR §1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited**

- 1). Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
- 2). At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:

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

- 1). A copy of each application specification including the claim(s)s, and any drawing, or that portion of the application that caused it to be listed, is attached.
- 2). A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
- 3). A copy of each application specification is not submitted because the application is stored in the IFW.

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

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

- 37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited
  - 1). A legible copy of each foreign patent or that portion which caused it to be listed is attached.
  - 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  
- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:
  - 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached --AND--
  
  - 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:
    - OR--
  - 2b). A copy of a written, English-language translation or portion thereof is readily available and attached,
    - OR--
  - 2c). An English language copy of a foreign search report is submitted.
    - OR--
  - 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

**STATEMENT UNDER 37 CFR § 1.97(e)**

- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
  
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

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

Respectfully Submitted,

Dated: 6/30/09

By:   
Thomas Zlogar Reg. # 55760

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

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<b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875	Application or Docket Number <b>10/972,287</b>	Filing Date <b>10/21/2004</b>	<input type="checkbox"/> To be Mailed
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APPLICATION AS FILED – PART I			OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	SMALL ENTITY <input checked="" type="checkbox"/>	OR			
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A	N/A			N/A	
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>	minus 20 =	*	X \$ =		OR	X \$ =	
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	minus 3 =	*	X \$ =			X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	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).						
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II					OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	(Column 3)		SMALL ENTITY	OR			
AMENDMENT	06/30/2009	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(i))</small>	* 7	Minus ** 58	= 0	X \$26 =	0		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>	* 1	Minus *** 3	= 0	X \$110 =	0		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>						OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

	(Column 1)	(Column 2)	(Column 3)		SMALL ENTITY	OR			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total <small>(37 CFR 1.16(i))</small>	*	Minus **	=	X \$ =			X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus ***	=	X \$ =			X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>						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:  
 /SHAUNA I. ZIMMERMAN/

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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004	Amr Salahieh	10012-702.501	7706
66854	7590	08/12/2009	EXAMINER	
SHAY GLENN LLP 2755 CAMPUS DRIVE SUITE 210 SAN MATEO, CA 94403			STRASZHEIM, REBECCA L	
			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			08/12/2009	PAPER

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

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

<b>Office Action Summary</b>	<b>Application No.</b> 10/972,287	<b>Applicant(s)</b> SALAHIEH ET AL.	
	<b>Examiner</b> REBECCA STRASZHEIM	<b>Art Unit</b> 3738	

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

**Period for Reply**

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

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

**Status**

- 1)  Responsive to communication(s) filed on 30 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) 60-66 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) 60-66 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 20 November 2008 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) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/12/2009, 6/30/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 60-65 have been considered but are moot in view of the new ground(s) of rejection.

### *Double Patenting*

2. Applicant is advised that should claim 60 be found allowable, claim 66 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### *Claim Rejections - 35 USC § 102*

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

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 60-62, 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Lobbi (2004/0186563 – as previously cited).

5. Lobbi teaches a prosthetic heart valve and a method for it's implantation (paragraph [0025]). The prosthetic heart valve (22), as can be seen in figs. 2A-



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3C, includes: a support frame/ anchor (50) with three cusps (30) at the inflow end/ distal end and three cusp positioners (42) at the outflow end/ proximal end (paragraph [0062-0063]). Extending from the cusp positioners/ distally from the outflow end/ proximal end, are anti-migration members/ leaflet engaging elements (56) which are designed to become somewhat entrapped/ sandwiched in the native leaflets (paragraph [0071]). The prosthetic heart valve, including the support frame/ anchor, maybe self-expanding (paragraph [0095]). The method includes: delivering a collapsed prosthetic valve to the heart (paragraph [0025]) and allowing the prosthetic heart valve, including the support frame/ anchor, to self-expanding (paragraph [0095]).

***Claim Rejections - 35 USC § 103***

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

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

7. Claims 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobbi in view of Garrison et al. (2002/0151970 – as previously cited).

8. Lobbi discloses the invention substantially as claimed, as discussed above. However, Lobbi does not disclose the support frame/ anchor and the valve to be two separate components which are deployed separately and coupled together after they are deployed.

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9. Garrison teaches a replacement heart valve system that is divided into two components – the valve displacer/ anchor and the replacement valve, including the actual valve and a base/ expandable support structure (41) (paragraphs [0008-0009, 0061]). The two components are preferably delivered separately and then are coupled to each other (paragraph [0010]).

10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to split the support frame/ anchor and valve, as taught by Lobbi, into two separate components which are delivered separately and coupled together after they are deployed, as taught by Garrison, as the two designs are functional equivalents of each other.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA STRASZHEIM whose telephone number is (571)270-5233. The examiner can normally be reached on Monday-Friday with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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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.

RLS

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738

## EAST Search History

## EAST Search History (Prior Art)

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L41	78	((native adj3 (leaflet or cusp)) or (leaflet near4 pocket)) with (sandwich or sandwiching or engaged or engage or engaging or engagement or trap or trapped or trapping or entrap or entrapped or entrapping)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/05 10:10
L42	334	(623/1.28.ccls. or 623/2.38.ccls. or 623/2.39.ccls. or 623/2.4.ccls.)	US-PGPUB; USPAT	OR	ON	2009/08/05 12:37
L43	1178	(623/1.24.ccls. or 623/1.26.ccls. or 623/2.1.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls.)	US-PGPUB; USPAT	OR	ON	2009/08/05 12:40
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S6	113	salahieh-amr\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:21
S7	40	brandt-brian\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:22
S8	29	geshlider-robert\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:22
S9	89	morejohn-dwight\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:22
S10	69	saul-tom\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:23
S11	215	S6 OR S7 OR S8 OR S9 OR S10	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:23
S12	1	"6425916".pn.	USPAT	OR	ON	2008/08/07 15:23
S13	1	"6893459".pn.	USPAT	OR	ON	2008/08/07 15:25
S15	768992	valve	US-PGPUB; USPAT	OR	ON	2008/08/11 08:02



S16	1050533	seal OR gasket OR plug	US-PGPUB; USPAT	OR	ON	2008/08/11 08:03
S17	29353	"623".clas.	US-PGPUB; USPAT	OR	ON	2008/08/11 08:04
S18	276	(S15 NEAR S16) AND S17	US-PGPUB; USPAT	OR	ON	2008/08/11 08:04
S19	18	gainor-john\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/11 09:30
S20	33	lashinski-randall\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/11 09:37
S21	61	623/1.28.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 07:51
S22	881	623/1.13.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 07:58
S23	28	623/1.28.ccls. AND stent	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 08:47
S24	221	salahieh-amr\$.in. or brandt-brian\$.in. or geshlider-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 11:43
S25	104	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlider-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 11:44

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S30	10	("20040220664"   "20040260333"   "20050137691"   "4056854"   "6015431"   "6168614"   "6425916"   "6652578"   "6719781"   "6893457").PN.	US-PGPUB; USPAT	OR	ON	2009/02/18 14:25
S34	1241	623/1.24.ccls. or 623/1.26.ccls. 623/2.1. ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 14:37
S35	2	"6425916".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 16:53



S36	42	"20010021872"   "20020045936"   "20020090725"   "20020198594"   "20030023300"   "20030028224"   "20030109924"   "20030130729"   "20030171802"   "20030204243"   "20040037813"   "20040225352"   "20050027348"   "20050096736"   "20050113910"   "20050137681"   "20050137682"   "20050240262"   "20060136044"   "4265694"   "4470157"   "4510628"   "4692164"   "5397351"   "5545215"   "5855597"   "5855601"   "5855610"   "5925063"   "5957949"   "6287334"   "6425916"   "6440164"   "6482228"   "6503272"   "6517576"   "6569196"   "6582462"   "6755856"   "7018404").PN. OR ("7261732").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/02/18 17:01
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S39	174	native adj leaflet	US-PGPUB; USPAT; USOCR	OR	ON	2009/02/18 17:14
S40	9	("20050075584"   "20050075731"   "20050137695"   "20050143809"   "20050240200"   "20050267573"   "3657744"   "6830585" "7041132").PN.	US-PGPUB; USPAT	OR	ON	2009/02/18 17:29
S41	84	("20020026233"   "20020032481"   "20020186558"   "20030023300"   "20030036791"   "20030040892"   "20030130727"   "20030130729"   "20030171805"   "20030236568"   "20040044402"   "20040059429"   "20040093070"   "20040106976"   "20040186563"   "20040210304"   "20040236411"   "20040260389"   "20050025857"   "20050075720"   "20050096734"   "20050137688"   "20050137690"   "20050137691"   "20050137695"   "20050143809"   "20050182483"   "20050197695"   "20050240200"   "20060025855"   "20060025857"   "20060047338"   "20060052867"   "20060058872"   "20060074485"   "20060149360"	US-PGPUB; USPAT	OR	ON	2009/02/18 17:30

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S43	4949	leaflets same (sandwich \$4 or between)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 17:43

S44	1409	(leaflet same (sandwich \$4 or between)) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 17:44
S45	104	(leaflet same (sandwich \$4)) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 17:44
S46	1	"20030036791"	US-PGPUB	OR	ON	2009/02/19 08:29
S47	1	"20050137698"	US-PGPUB	OR	ON	2009/02/19 08:58
S48	3202	((balloon or self) near3 expand\$4) same valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:24
S49	698	((balloon or self) near3 expand\$4) same (heart near3 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:25
S50	50	((balloon or self) near3 expand\$4) same (stent \$3 near3 heart near3 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:27
S51	19	((balloon and self) near3 expand\$4) same (stent\$3 near3 heart near3 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:27
S52	275	623/2.38.ccls. or 623/2.39.ccls. or 623/2.4.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:36

S53	139	"20010025196" "20010044634" "20020010489" "20020052651" "20020095173" "20020151970" "20020161394" "20020193871" "20030014104" "20030023303" "20030036791" "20030060844" "20030149476" "20030149478" "20030176884" "20030187495" "20030208224" "20030216774" "20040034411" "20040049262" "20040073198" "20040082967" "20040093016" "20040116951" "20040122468" "20040138694" "20040158277" "20040167565" "20040186563" "20040204755" "20040225321" "20040254636" "20050075662" "20050085841" "20050085842" "20050085843" "20050085890" "20050090846" "20050096692" "20050096734" "20050096735" "20050096736" "20050096738" "20050100580" "20050113910" "20050137695" "20050165352" "20050165477" "20050197695" "20050203614" "20050203615" "20050203616" "20050203617" "20050209580" "20050251250" "20050251251" "20050261759"	US-PGPUB; USPAT	OR	ON	2009/02/27 08:57
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S55	12	("20010041930"   "20020029981"   "20020055769"   "20020082609"   "20020188341"   "20030050694"   "20030070944"   "20040098099"   "4326306"   "4423809"   "6336937"   "6790237").PN.	US-PGPUB; USPAT	OR	ON	2009/02/27 09:52
S56	926	valve with leaflet with (engage or engaged or engagement or trap or trapped or trapping or entapping or entrapped or entrapment or press or compress or attach or hook)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 10:48
S57	735	valve with (leaflet near5 (engage or engaged or engagement or trap or trapped or trapping or entapping or entrapped or entrapment or press or compress or attach or hook))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 10:48
S60	229	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlinder-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 14:47
S61	2	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlinder-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and "leaflet engagement". clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 14:53

S62	22	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlinder-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and "leaflet engagement"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 14:53
S63	22	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlinder-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and (leaflet adj (engaging or engagement or engaged))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 14:54
S64	107	"20010039450" "20010041928" "20010044634" "20010044656" "20020002396" "20020010489" "20020032481" "20020058995" "20020077696" "20020095173" "20020095209" "20020111674" "20020120328" "20020151970" "20020161392" "20020161394" "20020188341" "20030023303" "20030036791" "20030040771" "20030040772" "20030055495" "20030060844" "20030109924" "20030125795" "20030130729" "20030149476" "20030149478" "20030176884" "20030181850" "20030187495" "20030199913" "20030199971" "20030199972" "20030208224" "20030212429" "20030212452" "20030212454" "20030216774" "20030229390" "20030233117" "20040034411"	US-PGPUB; USPAT	OR	ON	2009/08/04 15:01

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<b>Search Notes</b>  	<b>Application/Control No.</b>  10972287	<b>Applicant(s)/Patent Under Reexamination</b>  SALAHIEH ET AL.
	<b>Examiner</b>  REBECCA STRASZHEIM	<b>Art Unit</b>  3738

<b>SEARCHED</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>
	623/1.28	8/12/2008	RLS
	623/1.24, 1.26, 2.1, 2.12, 2.13, 2.14, 2.15, 2.16, 2.17, 2.18, 2.19, 2.38, 2.39, 2.4	2/27/2009	RLS
	Updated class/ subclass search	8/5/2009	RLS

<b>SEARCH NOTES</b>		
<b>Search Notes</b>	<b>Date</b>	<b>Examiner</b>
EAST inventor name search, EAST subject search, discussed search strategy with Primary Examiner Suzette Gherbi	8/12/2008	RLS
EAST inventor name search, EAST text search, EAST forward and backward citation search	2/27/2009	RLS
EAST inventor name search, EAST text search	8/5/2009	RLS

<b>INTERFERENCE SEARCH</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>

/R. S./  
Examiner.Art Unit 3738





**FILED VIA EFS ON NOVEMBER 3, 2009**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/972,287 Confirmation No.: 7706  
Applicant : Amr SALAHIEH et al.  
Filing Date : October 21, 2004  
Title : Leaflet Engagement Elements and Methods for Use Thereof  
Group Art Unit : 3738  
Examiner : Rebecca L. STRASZHEIM  
Docket No. : 10012-702.501  
Customer No. : 66854

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

**AMENDMENT IN RESPONSE TO OFFICE ACTION**

**Introductory Comments:**

This Amendment responds to the non-final Office Action dated August 12, 2009, for which a response is due November 12, 2009. Please enter the amendments and consider the remarks as follows.

**Amendments to the Specification** begin on page 2.

**Amendments to the Claims** begin on page 3.

**Remarks / Arguments** begin on page 6 of this paper.



**Amendments to the Specification:**

After Paragraph [0030], please add the following new Paragraphs:

[0030A] Figures 15A-H show yet another embodiment of a replacement heart valve, anchor and deployment system according to this invention.

[0030B] Figures 16A-E show more detail of the anchor of the embodiment shown in Figures 15A-H.

[0030C] Figures 17A-B show other embodiments of the replacement heart valve and anchor of the invention.

[0030D] Figures 18A-C illustrate a method for endovascularly replacing a patient's diseased heart valve.

[0030E] Figures 19A-B show an anchor for use in a two-piece replacement heart valve and anchor embodiment of the invention.

[0030F] Figures 20A-B show a replacement heart valve for use in a two-piece replacement heart valve and anchor embodiment of the invention.

[0030G] Figures 21A-D show a method of coupling the anchor of Figures 19 and the replacement heart valve of Figures 20.

[0030H] Figure 22 shows a delivery system for use with the apparatus shown in Figures 19-21.

[0030I] Figure 23 shows an alternative embodiment of a delivery system for use with the apparatus shown in Figures 19-21.

[0030J] Figure 24 shows yet another alternative embodiment of a delivery system for use with the apparatus shown in Figures 19-21.

[0030K] Figures 25A-I illustrate a method of delivering and deploying a two-piece replacement heart valve and anchor.

[0030L] Figures 26A-B show another embodiment of a two-piece replacement heart valve and anchor according to this invention.

[0030M] Figure 27 shows yet another embodiment of a two-piece replacement heart valve and anchor according to this invention.

[0030N] Figure 28 shows yet another embodiment of a two-piece replacement heart valve and anchor according to this invention.

**Amendments to the Claims:**

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

1. - 59. (Canceled)

60. (Previously Presented) A method for endovascularly replacing a patient's native heart valve, the method comprising:

delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a proximal end of the anchor;

sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor; and

expanding the anchor from a collapsed delivery configuration to an expanded configuration to secure the anchor within the native heart valve;

positioning the proximal end of the anchor further from a left ventricle than a distal end of the anchor,

wherein the replacement valve allows the flow of blood through the replacement valve in a first configuration and prevents the flow of blood through the valve in a second configuration.

61. (Previously Presented) The method of claim 60 wherein expanding the anchor from a collapsed delivery configuration to an expanded configuration comprises allowing the anchor to self-expand to thereby sandwich the native valve leaflets between the distally extending leaflet engagement elements and the anchor.

62. (Previously Presented) The method of claim 60 wherein the leaflet engagement elements extend generally parallel to the longitudinal axis of the expandable anchor when the anchor is in the expanded configuration.

63. (Previously Presented) The method of claim 60 wherein the expandable anchor and the replacement valve are delivered as two separate elements, the method further comprising

deploying the expandable anchor and the replacement valve in the vicinity of the native heart valve in two different steps.

64. (Previously Presented) The method of claim 63 further comprising engaging the expandable anchor and the replacement valve after they are deployed in the vicinity of the native heart valve to secure the replacement heart valve to the expandable anchor.

65. (Previously Presented) The method of claim 64 wherein the replacement heart valve comprises an expandable support structure and replacement valve leaflets, and wherein engaging the expandable anchor and the replacement valve in the vicinity of the native heart valve comprises coupling the expandable anchor and the expandable support structure to secure the replacement heart valve to the expandable anchor.

66. (Currently Amended) A method for endovascularly replacing a patient's native heart valve, the method comprising:

delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a first end of the anchor;

sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor; and

expanding the anchor from a collapsed delivery configuration to an expanded configuration to secure the anchor within the native heart valve;

positioning the first end of the anchor further from a left ventricle than a second end of the anchor,

wherein the replacement valve allows the flow of blood through the replacement valve in a first configuration and prevents the flow of blood through the valve in a second configuration.

67. (New) A method for endovascularly replacing a patient's native heart valve, the method comprising:

delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a proximal region of the anchor;

sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor; and

expanding the anchor from a collapsed delivery configuration to an expanded configuration;

positioning a proximal end of the anchor further from a left ventricle than a distal end of the anchor,

wherein the replacement valve allows the flow of blood through the replacement valve in a first configuration and prevents the flow of blood through the valve in a second configuration.

## **REMARKS**

### **Claim Summary**

Claim 66 is currently amended. Claims 1-59 were previously canceled. Claim 67 is new. Claims 60-67 are currently pending. Cancellation or amendment of any claim herein is not to be considered a dedication to the public of any subject matter.

### **Brief Description of the Drawings**

Applicants added Figures 15-28 in the response filed November 20, 2008. These figures were incorporated by reference in the application as filed, and thus no new matter was added. Applicants are herein adding the brief description of Figures 15-28, also incorporated by reference in the original application, and thus no new matter is being added.

### **Information Disclosure Statements**

Applicants note with thanks that the Examiner has considered all references submitted in Information Disclosure Statements dated 3/12/2009 and 6/30/2009.

References submitted in Information Disclosure Statements dated 4/27/2005, 7/12/2006, and 6/10/2008 were crossed off and not acknowledged, because copies were not submitted. (See non-final Office Action dated 8/18/2008). Applicants are not required to submit a copy of a reference if it is a copending application available in the IFW. *See* MPEP 609.04(a), II C. These references are copending applications available in the IFW. Applicants respectfully request the Examiner to consider these references, and initial and return a copy of the PTO Forms 1449 with the next Action.

### **Claim Rejections Under 35 U.S.C. § 102**

Claims 60-62 and 66 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. 2004/0186563 to Lobbi ("Lobbi").

Independent claim 60 recites, in part, "delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a proximal end of the anchor," and "sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor."

The Examiner maintains that Lobbi expressly or inherently describes the step of sandwiching the native leaflets between the anti-migration members 56 and the support frame because Lobbi states that “the anti-migration members 56 are designed to contact and become somewhat entrapped in the native leaflets.” (paragraph [0071], lines 12-14). Applicants respectfully disagree. Lobbi states that “[t]he cusp positioners 42 preferably extend radially farther outward than the commissures 32 and *compress the leaflets L against the natural sinus cavities* formed just above the aortic valve AV annulus.” (paragraph [0063], lines 16-17). This compression of the leaflets by the cusp positioners 42 can be seen in Figure 2B. If Lobbi did in fact describe the method step of sandwiching the native leaflets L between the members 56 and the support frame, the leaflets would be sandwiched therebetween, preventing the outwardly extending cusp positioners 42 from being able to compress the leaflets against the sinus cavities. Lobbi, however, explicitly teaches the step of compressing the native leaflets L against the lumen wall with a radially outward force from the cusp positioners 42. Sandwiching the native leaflets between the members 56 and the support frame is therefore contradictory to the teachings of Lobbi.

Lobbi’s members 56 are, as can be clearly seen in Figure 2B, simply assisting with the radially outward compression of the native leaflets and the anchoring of the replacement valve in place. Lobbi supports this position by stating that “the general idea being that the anti-migration members 56 *enhances the ability of the associated cusp positioner 42 to anchor to the surrounding tissue.*” (paragraph [0071], lines 18-21, emphasis added; *also see* paragraph [0071], lines 1-4, “Each cusp positioner 42 further includes at least one anti-migration member 56 rigidly affixed thereto and designed *to help anchor the support frame 50 to the surrounding tissue.*” (emphasis added).

Lobbi further supports this position by saying that “[t]he natural leaflets are desirably compressed against the lumen of the aortic valve annulus by the prosthetic heart valve 22, as seen in FIG. 2B.” (paragraph [0062], lines 6-9). This statement, along with that which is shown in Figure 2, teaches that the leaflets are compressed *directly* against the lumen, without any portion of the device in between the native leaflets and the lumen. The native leaflets are therefore not sandwiched between an expandable anchor and another portion of the replacement heart valve. In fact, the only objects between which the native leaflets in Lobbi could be

considered to be sandwiched would be the cusp positioners/anti-migration members and the lumen wall.

For at least the reasons set forth above, Lobbi does not expressly or inherently describe the method step of “sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor,” as is required by independent claim 60. Lobbi therefore does not anticipate claim 60. Additionally, it would not have been obvious to modify the teachings of Lobbi to arrive at independent claim 60 as Lobbi teaches compressing the cusp positioners against the native leaflets. As stated above, if the native leaflets were sandwiched between the members 56 and the support frame, the cusp positioners would not be able to perform the function of compressing the native leaflets as is described throughout Lobbi.

Claims 61 and 62 depend from claim 60 and are therefore not anticipated by Lobbi for at least the reasons set forth above with respect to claim 60.

Independent claim 66 is currently amended and, similar to independent claim 60, recites the steps of “delivering an expandable anchor and a replacement valve to a vicinity of the native heart valve, wherein leaflet engagement elements extend distally from a first end of the anchor, and “sandwiching native valve leaflets between the distally extending leaflet engagement elements and the anchor.” Arguments made above regarding the patentability of claim 60 over Lobbi similarly apply to independent claim 66, and for at least these reasons Lobbi does not anticipate claim 66.

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

Claims 63-65 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lobbi in view of U.S. 2002/0151970 to Garrison et al. (“Garrison”).

Claims 63-65 depend from claim 60 and therefore include the limitations thereof. As set forth above, Lobbi does not teach the limitations of claim 60. As Garrison does not overcome the deficiencies of Lobbi, Lobbi and Garrison, alone or combined, do not teach or suggest the limitations of claims 63-65. For at least this reason claims 63-65 are not unpatentable over Lobbi in view of Garrison.

**New Claim**

Applicants are adding new independent claim 67. Exemplary support for new claim 67 can be found throughout the application as filed, such as in, for example, Figure 7 and the accompanying textual description thereof.

**CONCLUSION**

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

Respectfully submitted,

Date: November 3, 2009

By:



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

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



VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/972,287 Confirmation No.: 7706  
 Applicant(s): Amr Salahieh  
 Filed: October 21, 2004  
 Art Unit: 3738  
 Examiner: STRASZHEIM, REBECCA L  
 Title: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE  
 THEREOF  
 Customer No.: 66854

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

**INFORMATION DISCLOSURE STATEMENT UNDER**  
**37 CFR § 1.97 & § 1.98**

Sir:

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

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

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

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

**FILING OF INFORMATION DISCLOSURE STATEMENT**

**37 CFR §1.97(b)**

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

- 1). Within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d), or
- 2). Within 3 months of entry of a national stage as set forth in § 1.491, or
- 3). Before the mail date of a first Office Action on the merits, or
- 4). Before the mailing of a first Office Action after filing a request for continued examination under § 1.114.

**37 CFR § 1.97(c)**

This statement is being filed after the latest of:

- 1). Three months beyond the filing date of a national application, or
- 2). Three months beyond the date of entry of the national stage as set forth in § 1.491 in an international application, or
- 3). The mailing date of a first Office Action on the merits, but before the mailing date of the earlier of a final Office Action under § 1.113 or a Notice of Allowance under § 1.311, and then either:
  - A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. or
  - B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

**37 CFR § 1.97(d)**

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

- A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or payment is included with other papers filed together with this statement
- AND--
- B). A certification as specified in § 1.97(e) is included below.

**CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER**  
**37 CFR § 1.98**

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

- 1). Since not requested by the Office, U.S. patents and U.S. patent application publications are not included.
- 2). At the request of the Office, a copy of the following U.S. patent or patent application publication is attached:
- 3). Items identified by a double asterisk (\*\*) on the SB08A are \*commonly-owned U.S. patents and U.S. patent application publications.

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

- 1). A copy of each application specification including the claim(s), and any drawing, or that portion of the application that caused it to be listed, is attached.
- 2). A copy of each application specification is not submitted because the specification was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
- 3). A copy of each application specification is not submitted because the application is stored in the IFW.

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

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

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

- 37 CFR §1.98 (a)(2)(i) and (d), Foreign patent(s) in English cited
  - 1). A legible copy of each foreign patent or that portion which caused it to be listed is attached.
  - 2). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:
  
- 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) and MPEP 609(B), Foreign patent(s) or other foreign documents not in English cited. Either:
  - 1). A legible copy of each foreign patent, each publication or that portion which caused it to be listed, is attached --AND--
  
  - 2a). A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56 (c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language is provided herewith:
    - OR--
  - 2b). A copy of a written, English-language translation or portion thereof is readily available and attached,
    - OR--
  - 2c). An English language copy of a foreign search report is submitted.
    - OR--
  - 3). A copy of each foreign patent is not submitted because the publication was previously submitted in the IDS of the following, earlier filed application relied on for an earlier effective filing date:

**STATEMENT UNDER 37 CFR § 1.97(e)**

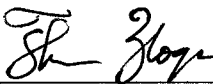
- Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
  
- No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

**FEE AUTHORIZATION**

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

Respectfully Submitted,

Dated: 11/3/09

By:   
Thomas Zlogar Reg. # 55760

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

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1

of 3

**Complete if Known**

Application Number	10/972,287
Filing Date	October 21, 2004
First Named Inventor	Amr Salahieh
Art Unit	3738
Examiner Name	STRASZHEIM, REBECCA L
Attorney Docket Number	10012-702.501

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	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.	
	451	US- 5,769,812	6/23/1998	Stevens et al.	
	465	US- 5,885,228	3/23/1999	Rosenman et al.	
	453	US- 6,454,799	9/24/2002	Schreck	
	466	US- 6,623,518	9/23/2003	Thompson et al.	
	467	US- 6,635,079	10/21/2003	Unsworth et al.	
	468	US- 6,776,791	8/17/2004	Stallings et al.	
	469	US- 7,025,791	4/11/2006	Levine et al.	
	470	US- 7,037,331	5/2/2006	Mitelberg et al.	
	471	US- 7,175,653	2/13/2007	Gaber	
	472	US- 7,175,654	2/13/2007	Bonsignore et al.	
	473	US- 7,235,093	6/26/2007	Gregorich	
	474	US- 7,258,696	8/21/2007	Rabkin et al.	
	452	US- 2002/0002396	1/3/2002	Fulkerson	
	455	US- 2002/0188344	12/12/2002	Bolea et al.	

**FOREIGN PATENT DOCUMENTS**

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

Examiner Signature	Date Considered
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\*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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE                  STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
		Examiner Name	STRASZHEIM, REBECCA L
Sheet 3	of 3	Attorney Docket Number	10012-702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
	450	HAUG et al.; U.S. Pat. App. # 12/492,512 entitled "Everting Heart Valve," filed 06/26/2009	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	10972287
<b>Filing Date:</b>	21-Oct-2004
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Filer:</b>	Thomas M. Zlogar/Sue Bromaghim
<b>Attorney Docket Number:</b>	10012-702.501

Filed as Small Entity

### Utility under 35 USC 111(a) Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Miscellaneous:</b>				
Submission- Information Disclosure Stmt	1806	1	180	180
<b>Total in USD (\$)</b>				<b>180</b>



## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	6385961
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	Leaflet engagement elements and methods for use thereof
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	Thomas M. Zlogar/Sue Bromaghim
<b>Filer Authorized By:</b>	Thomas M. Zlogar
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	03-NOV-2009
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	18:42:18
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$180
RAM confirmation Number	4749
Deposit Account	504050
Authorized User	

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

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

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-702-501-Amendment-IDS.pdf	1932024 <small>7a8d8e8ac9d4c6aa03bcbd486c02328047ef2d51</small>	yes	15

**Multipart Description/PDF files in .zip description**

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Specification	2	2
Claims	3	5
Applicant Arguments/Remarks Made in an Amendment	6	9
Transmittal Letter	10	12
Information Disclosure Statement (IDS) Filed (SB/08)	13	15

**Warnings:****Information:**

2	Fee Worksheet (PTO-875)	fee-info.pdf	29805 <small>1ccf8057c1f0a09382a708b6c37a708e45137768</small>	no	2
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**Warnings:****Information:****Total Files Size (in bytes):**

1961829

**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.**

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.

<b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875	Application or Docket Number <b>10/972,287</b>	Filing Date <b>10/21/2004</b>	<input type="checkbox"/> To be Mailed
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APPLICATION AS FILED – PART I			OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	SMALL ENTITY <input checked="" type="checkbox"/>	OR			
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A	N/A			N/A	
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A	N/A			N/A	
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>	minus 20 =	*	X \$ =		OR	X \$ =	
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	minus 3 =	*	X \$ =			X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	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).						
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II					OTHER THAN SMALL ENTITY				
	(Column 1)	(Column 2)	(Column 3)		SMALL ENTITY	OR			
AMENDMENT	11/03/2009	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	<small>Total (37 CFR 1.16(i))</small>	* 8	Minus ** 58	= 0	X \$26 =	0	OR	X \$ =	
	<small>Independent (37 CFR 1.16(h))</small>	* 3	Minus *** 3	= 0	X \$110 =	0	OR	X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>						OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

	(Column 1)	(Column 2)	(Column 3)		SMALL ENTITY	OR			
AMENDMENT	Total (37 CFR 1.16(i))	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	*	Minus	**	=	X \$ =		OR	X \$ =	
	<small>Independent (37 CFR 1.16(h))</small>	*	Minus	***	X \$ =		OR	X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>						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:  
 /DEBORAH POLLARD/

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.



NOTICE OF ALLOWANCE AND FEE(S) DUE

66854 7590 02/26/2010

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

EXAMINER: STRASZHEIM, REBECCA L
ART UNIT: 3738 PAPER NUMBER:
DATE MAILED: 02/26/2010

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

10/972,287 10/21/2004 Amr Salahieh 10012-702.501 7706

TITLE OF INVENTION: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF

Table with 7 columns: APPLN. TYPE, SMALL ENTITY, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE

nonprovisional YES \$755 \$300 \$0 \$1055 05/26/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

**PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

66854 7590 02/26/2010

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

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

**Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004	Amr Salahieh	10012-702.501	7706

TITLE OF INVENTION: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	05/26/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
STRASZHEIM, REBECCA L	3738	128-898000

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, 1 \_\_\_\_\_

(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. 2 \_\_\_\_\_

3 \_\_\_\_\_

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

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

(A) NAME OF ASSIGNEE \_\_\_\_\_ (B) RESIDENCE: (CITY AND STATE OR COUNTRY) \_\_\_\_\_

Please check the appropriate assignee category or categories (will not be printed on the patent) :  Individual  Corporation or other private group entity  Government

4a. The following fee(s) are submitted:

Issue Fee

Publication Fee (No small entity discount permitted)

Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

A check is enclosed.

Payment by credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.  b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_ Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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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

Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO., EXAMINER, ART UNIT, PAPER NUMBER. Includes application details for Amr Salahieh and examiner STRASZHEIM, REBECCA L.

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

The Patent Term Adjustment to date is 744 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 744 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

**Notice of Allowability**

<b>Application No.</b> 10/972,287	<b>Applicant(s)</b> SALAHIEH ET AL.	
<b>Examiner</b> REBECCA STRASZHEIM	<b>Art Unit</b> 3738	

-- 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 Applicant's argument/ remarks dated 11/3/2009.
- 2.  The allowed claim(s) is/are 60-67.
- 3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All   b)  Some\*   c)  None   of the:
    - 1.  Certified copies of the priority documents have been received.
    - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
    - 3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

- 4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  - 5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
    - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
- 6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- 1.  Notice of References Cited (PTO-892)
- 2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 11/3/2009
- 4.  Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5.  Notice of Informal Patent Application
- 6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_ .
- 7.  Examiner's Amendment/Comment
- 8.  Examiner's Statement of Reasons for Allowance
- 9.  Other \_\_\_\_\_.

/R. S./  
Examiner, Art Unit 3738

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738

## EAST Search History

## EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	"20050137698"	US-PGPUB	OR	ON	2008/08/07 11:04
S2	1	"20050137687"	US-PGPUB	OR	ON	2008/08/07 11:09
S3	97	( "20010025196"   "20010032013"   "20010039450"   "20010041928"   "20010044634"   "20010044656"   "20020010489"   "20020032480"   "20020032481"   "20020052651"   "20020058995"   "20020077696"   "20020095173"   "20020095209"   "20020111674"   "20020120328"   "20020151970"   "20020161392"   "20020161394"   "20020193871"   "20030014104"   "20030023303"   "20030028247"   "20030036791"   "20030040771"   "20030040772"   "20030055495"   "20030060844"   "20030109924"   "20030125795"   "20030130729"   "20030149475"   "20030149476"   "20030149478"   "20030153974"   "20030176884"   "20030181850"   "20030187495"   "20030199913"   "20030199971"   "20030199972"   "20030208224"   "20030212452"   "20030212454"   )	US-PGPUB	OR	ON	2008/08/07 11:14



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S6	113	salahieh-amr\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:21
S7	40	brandt-brian\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:22
S8	29	geshlider-robert\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:22

S9	89	morejohn-dwight\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:22
S10	69	saul-tom\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:23
S11	215	S6 OR S7 OR S8 OR S9 OR S10	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/07 14:23
S12	1	"6425916".pn.	USPAT	OR	ON	2008/08/07 15:23
S13	1	"6893459".pn.	USPAT	OR	ON	2008/08/07 15:25
S15	768992	valve	US-PGPUB; USPAT	OR	ON	2008/08/11 08:02
S16	1050533	seal OR gasket OR plug	US-PGPUB; USPAT	OR	ON	2008/08/11 08:03
S17	29353	"623".clas.	US-PGPUB; USPAT	OR	ON	2008/08/11 08:04
S18	276	(S15 NEAR S16) AND S17	US-PGPUB; USPAT	OR	ON	2008/08/11 08:04
S19	18	gainor-john\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/11 09:30
S20	33	lashinski-randall\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/11 09:37
S21	61	623/1.28.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 07:51
S22	881	623/1.13.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 07:58
S23	28	623/1.28.ccls. AND stent	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 08:47

S24	221	salahieh-amr\$.in. or brandt-brian\$.in. or geshlider-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 11:43
S25	104	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlider-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 11:44
S26	106	("20010039450"   "20010041928"   "20010044634"   "20010044656"   "20020010489"   "20020032481"   "20020058995"   "20020077696"   "20020095173"   "20020095209"   "20020111674"   "20020120328"   "20020151970"   "20020161392"   "20020161394"   "20020188341"   "20030023303"   "20030036791"   "20030040771"   "20030040772"   "20030055495"   "20030060844"   "20030109924"   "20030125795"   "20030130729"   "20030149476"   "20030149478"   "20030176884"   "20030181850"   "20030187495"   "20030199913"   "20030199971"   "20030199972"   "20030208224"   "20030212429"   "20030212452"   "20030212454"   "20030216774"   "20030229390"   "20030233117"   "20040034411"   "20040039436"   "20040049224"   "20040049226"   "20040049262"   "20040073198"   "20040082904"	US-PGPUB	OR	ON	2009/02/18 11:59

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S28	139	("20010025196"   "20010044634"   "20020010489"   "20020052651"   "20020095173"   "20020151970"   "20020161394"   "20020193871"   "20030014104"   "20030023303"   "20030036791"   "20030060844"   "20030149476"   "20030149478"   "20030176884"   "20030187495"   "20030208224"   "20030216774"   "20040034411"   "20040049262"   "20040073198"   "20040082967"   "20040093016"   "20040116951"   "20040122468"   "20040138694"   "20040158277"   "20040167565"   "20040186563"   "20040204755"   "20040225321"   "20040254636"   "20050075662"   "20050085841"   "20050085842"   "20050085843"   "20050085890"   "20050090846"   "20050096692"   "20050096734"   "20050096735"   "20050096736"   "20050096738"   "20050100580"   "20050113910"   "20050137695"   "20050165352"   "20050165477"   "20050197695"   "20050203614"   "20050203615"   "20050203616"   "20050203617"   "20050209580"   "20050251250"   "20050251251"   "20050261759"	US-PGPUB; USPAT	OR	ON	2009/02/18 13:27
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S34	1241	623/1.24.ccls. or 623/1.26.ccls. 623/2.1. ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/900.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 14:37
S35	2	"6425916".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 16:53
S36	42	("20010021872"   "20020045936"   "20020090725"   "20020198594"   "20030023300"   "20030028224"   "20030109924"   "20030130729"   "20030171802"   "20030204243"   "20040037813"   "20040225352"   "20050027348"   "20050096736"   "20050113910"   "20050137681"   "20050137682"   "20050240262"   "20060136044"   "4265694"   "4470157"   "4510628"   "4692164"   "5397351"   "5545215"   "5855597"   "5855601"   "5855610"   "5925063"   "5957949"   "6287334"   "6425916"   "6440164"   "6482228"   "6503272"   "6517576"   "6569196"   "6582462"   "6755856"   "7018404").PN. OR ("7261732").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2009/02/18 17:01

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S41	84	("20020026233"   "20020032481"   "20020186558"   "20030023300"   "20030036791"   "20030040892"   "20030130727"   "20030130729"   "20030171805"   "20030236568"   "20040044402"   "20040059429"   "20040093070"   "20040106976"   "20040186563"   "20040210304"   "20040236411"   "20040260389"   "20050025857"   "20050075720"   "20050096734"   "20050137688"   "20050137690"   "20050137691"   "20050137695"   "20050143809"	US-PGPUB; USPAT	OR	ON	2009/02/18 17:30

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S43	4949	leaflets same (sandwich \$4 or between)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 17:43
S44	1409	(leaflet same (sandwich \$4 or between)) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 17:44
S45	104	(leaflet same (sandwich \$4)) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 17:44
S46	1	"20030036791"	US-PGPUB	OR	ON	2009/02/19 08:29
S47	1	"20050137698"	US-PGPUB	OR	ON	2009/02/19 08:58



S48	3202	((balloon or self) near3 expand\$4) same valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:24
S49	698	((balloon or self) near3 expand\$4) same (heart near3 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:25
S50	50	((balloon or self) near3 expand\$4) same (stent \$3 near3 heart near3 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:27
S51	19	((balloon and self) near3 expand\$4) same (stent \$3 near3 heart near3 valve)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:27
S52	275	623/2.38.ccls. or 623/2.39.ccls. or 623/2.4.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/27 08:36
S53	139	("20010025196"   "20010044634"   "20020010489"   "20020052651"   "20020095173"   "20020151970"   "20020161394"   "20020193871"   "20030014104"   "20030023303"   "20030036791"   "20030060844"   "20030149476"   "20030149478"   "20030176884"   "20030187495"   "20030208224"   "20030216774"   "20040034411"   "20040049262"   "20040073198"   "20040082967"   "20040093016"   "20040116951"   "20040122468"   "20040138694"   "20040158277"   "20040167565"   "20040186563"   "20040204755"	US-PGPUB; USPAT	OR	ON	2009/02/27 08:57

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S55	12	("20010041930"   "20020029981"   "20020055769"   "20020082609"   "20020188341"   "20030050694"   "20030070944"   "20040098099"   "4326306"   "4423809"   "6336937"   "6790237"). PN.	US-PGPUB; USPAT	OR	ON	2009/02/27 09:52
S56	926	valve with leaflet with (engage or engaged or engagement or trap or trapped or trapping or entapping or entrapped or entrapment or press or compress or attach or hook)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 10:48
S57	735	valve with (leaflet near5 (engage or engaged or engagement or trap or trapped or trapping or entapping or entrapped or entrapment or press or compress or attach or hook))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 10:48

S60	229	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlinder-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 14:47
S61	2	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlinder-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and "leaflet engagement". clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 14:53
S62	22	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlinder-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and "leaflet engagement"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 14:53
S63	22	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlinder-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and (leaflet adj (engaging or engagement or engaged))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/04 14:54
S64	107	("20010039450"   "20010041928"   "20010044634"   "20010044656"   "20020002396"   "20020010489"   "20020032481"   "20020058995"   "20020077696"   "20020095173"   "20020095209"   "20020111674"   "20020120328"   "20020151970"   "20020161392"   "20020161394"   "20020188341"   "20030023303"   "20030036791"   "20030040771"   "20030040772"   "20030055495"   "20030060844"   "20030109924"   "20030125795"   "20030130729"   "20030149476"   "20030149478"   "20030176884"   "20030181850"	US-PGPUB; USPAT	OR	ON	2009/08/04 15:01

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S84	16	("20010007956"   "20010010017"   "20030014104"   "20030036791"   "20030036795"   "20030109924"   "20030130729"   "20030199971"   "20040034411"   "20040049262"   "20040049266"   "20050137682"   "5713953"   "6299637"   "6458159"   "6605112"). PN.	US-PGPUB; USPAT	OR	ON	2009/08/05 09:17
S85	38	("20030023300"   "20030130729"   "20030149478"   "20040186563"   "20040236411"   "20040260389"   "20050075720"   "20050137688"   "20050137690"   "20050137691"   "20050137695"   "20050143809"   "20050182483"   "20050197695"   "20050240200"   "20060025855"   "20060025857"   "20060047338"   "20060052867"   "20060058872"   "20060074485"   "20060149360"   "20060259134"   "20060259136"   "20080071363"   "5344442"   "5354330"   "5908451"   "6296662"   "6312465"   "6458153"   "6558418"   "6730118"   "7018406"   "7018408"   "7137184"   "7201772"   "7267686").PN.	US-PGPUB; USPAT	OR	ON	2009/08/05 09:19
S86	149	S74 or S75 or S76 or S77 or S78 or S79 or S80 or S81 or S82 or S83 or S84 or S85	US-PGPUB; USPAT	OR	ON	2009/08/05 09:19
S87	1	("5053008").PN.	US-PGPUB; USPAT	OR	ON	2009/08/05 09:47

S88	76	("20010051822"   "20020032481"   "20030036791"   "20030036795"   "20030040792"   "20030050694"   "20030055495"   "20030065386"   "20030139796"   "20030139803"   "20030212410"   "20040006380"   "20040039436"   "20040049204"   "20040049262"   "20040186563"   "20040193180"   "20050033220"   "20050043790"   "20050049692"   "20050075725"   "20050096726"   "20050096736"   "20050113910"   "20050137687"   "20050137688"   "20050137690"   "20050137697"   "20050137698"   "20050137702"   "20050143804"   "20050150775"   "20050251243"   "20050251251"   "20060229718"   "20060229719"   "20060287717"   "20060287719"   "20070100440"   "20070142906"   "20080147182"   "4950227"   "5201757"   "5332402"   "5411552"   "5433723"   "5456713"   "5683451"   "5755777"   "5824041"   "5840081"   "5876434"   "6077297"   "6102944"   "6126685"   "6143021"   "6146415"   "6168614"   "6183481"   "6254564"   "6344044"   "6350278"   "6478819"   "6540782"   "6562063"   "6582462"   "6673101"   "6736845"   "6767362"   "6790230"   "6808529"   "6821297"   "6881199"	US-PGPUB; USPAT	OR	ON	2009/08/05 09:48
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S90	204	("20010011187"   "20010039450"   "20020032481"   "20020055775"   "20020123790"   "20020133226"   "20020143387"   "20020198594"   "20030023300"   "20030027332"   "20030036791"   "20030036795"   "20030036795"   "20030040792"   "20030050694"   "20030055495"   "20030065386"   "20030114913"   "20030125795"   "20030139796"   "20030139803"   "20030153974"   "20030195620"   "20030236570"   "20040006380"   "20040039436"   "20040039436"   "20040049262"   "20040049262"   "20040073289"   "20040078950"   "20040117004"   "20040117009"   "20040148018"   "20040186558"   "20040186563"   "20040186563"   "20040186565"   "20040193244"   "20040210301"   "20040260389"   "20050033220"   "20050043790"   "20050049692"   "20050075725"   "20050075725"   "20050096726"   "20050096736"   "20050096736"   "20050098547"   "20050113910"   "20050113910"   "20050119728"   "20050125075"   "20050137687"   "20050137688"   "20050137690"	US-PGPUB; USPAT	OR	ON	2009/08/05 09:51
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S91	182	(S88 or S87 or S89 or S90) not S86	US-PGPUB; USPAT	OR	ON	2009/08/05 09:51
S92	78	((native adj3 (leaflet or cusp)) or (leaflet near4 pocket)) with (sandwich or sandwiching or engaged or engage or engaging or engagement or trap or trapped or trapping or entrap or entrapped or entrapping)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/08/05 10:10
S93	334	(623/1.28.ccls. or 623/2.38.ccls. or 623/2.39.ccls. or 623/2.4.ccls.)	US-PGPUB; USPAT	OR	ON	2009/08/05 12:37
S94	1178	(623/1.24.ccls. or 623/1.26.ccls. or 623/2.1.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls.)	US-PGPUB; USPAT	OR	ON	2009/08/05 12:40
S95	10	("5735842"   "7191018"   "20030109930"   "20030144732"   "20040133274"   "20080269878"   "0090076598"   "20090054969"   "4602911"   "5476510"   "5984959").pn.	US-PGPUB; USPAT	OR	ON	2009/08/05 12:48
S96	62	(salahieh-amr\$.in. or brandt-brian\$.in. or geshlinder-robert\$.in. or morejohn-dwight\$.in. or saul-tom\$.in.) and valve. clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 09:40

S97	186	(US-20060058872-\$ or US-20050137698-\$ or US-20050137687-\$ or US-20050197695-\$ or US-20050137695-\$ or US-20030023303-\$ or US-20030014104-\$ or US-20020032481-\$ or US-20010021872-\$ or US-20060004442-\$ or US-20060149360-\$ or US-20040236411-\$ or US-20050137682-\$ or US-20050159811-\$ or US-20050222674-\$ or US-20040092858-\$ or US-20060052867-\$ or US-20060195183-\$ or US-20060259135-\$ or US-20070162107-\$ or US-20080071361-\$ or US-20040106976-\$ or US-20040098099-\$ or US-20060265054-\$ or US-20070021828-\$ or US-20070179590-\$).did. or (US-20070293936-\$ or US-20030135265-\$ or US-20040176740-\$ or US-20010041930-\$ or US-20020055769-\$ or US-20030135263-\$ or US-20040098119-\$ or US-20010044649-\$ or US-20020138138-\$ or US-20090112309-\$ or US-20080082166-\$ or US-20060276874-\$ or US-20030036791-\$ or US-20090076598-\$ or US-20090054969-\$ or US-20080234814-\$ or US-20080125859-\$ or US-20070244552-\$ or US-20070203503-\$ or US-20070010877-\$ or US-20070010876-\$ or US-20060253191-\$ or US-20050283231-\$ or US-20050143809-\$ or US-20050137702-\$ or US-20050137701-\$ or US-20050137697-\$).did. or (US-20050137696-\$ or US-20050137694-\$ or US-20050137691-\$ or US-20050137690-\$ or	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 09:51
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		US-20050137689-\$ or US-20050137688-\$ or US-20050137686-\$ or US-20090182419-\$ or US-20020052648-\$ or US-20090054968-\$ or US-20090240320-\$ or US-20050137699-\$ or US-20080177381-\$ or US-20080255660-\$ or US-20080269878-\$ or US-20090005863-\$).did. or (US-6458153-\$ or US- 6652578-\$ or US- 6468303-\$ or US- 5957949-\$ or US- 7201772-\$ or US- 3898701-\$ or US- 5545211-\$ or US- 6616675-\$ or US- 7018406-\$ or US- 6258115-\$ or US- 7041127-\$ or US- 6468301-\$ or US- 6520983-\$ or US- 5815904-\$ or US- 6547818-\$ or US- 6083257-\$ or US- 6733525-\$ or US- 7261732-\$ or US- 7381219-\$ or US- 7329279-\$ or US- 6425916-\$ or US- 3739402-\$ or US- 4079468-\$ or US- 7201771-\$ or US- 7276078-\$ or US- 7377938-\$).did. or (US- 7399315-\$ or US- 7422603-\$ or US- 7445631-\$ or US- 7534260-\$ or US- 7547322-\$).did.				
S98	120	(US-20060253191-\$ or US-20060259134-\$ or US-20060004442-\$ or US-20050197695-\$ or US-20030023303-\$ or US-20020151970-\$ or US-20020032481-\$ or US-20010021872-\$ or US-20020138135-\$ or US-20030023300-\$ or US-20040106976-\$ or US-20050060029-\$ or US-20040210304-\$ or US-20050056292-\$ or	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 09:52

		US-20040215339-\$ or US-20010053929-\$ or US-20020169494-\$ or US-20030097169-\$ or US-20030163190-\$ or US-20050004647-\$ or US-20020188341-\$ or US-20050137698-\$ or US-20060058872-\$ or US-20090112309-\$ or US-20080082166-\$ or US-20060276874-\$).did. or (US-20030036791-\$ or US-20090076598-\$ or US-20090054969-\$ or US-20080234814-\$ or US-20070244552-\$ or US-20070010876-\$ or US-20050283231-\$ or US-20050137701-\$ or US-20050137697-\$ or US-20050137696-\$ or US-20050137695-\$ or US-20050137691-\$ or US-20050137690-\$ or US-20050137689-\$ or US-20050137688-\$ or US-20050137687-\$ or US-20050137686-\$ or US-20010049547-\$ or US-20020002396-\$ or US-20030040771-\$ or US-20030216807-\$).did. or (US-6790229-\$ or US- 6712843-\$ or US- 6676698-\$ or US- 6652578-\$ or US- 6468303-\$ or US- 6458153-\$ or US- 6425916-\$ or US- 5957949-\$ or US- 7025780-\$ or US- 7201772-\$ or US- 7311730-\$ or US- 7338520-\$ or US- 7377938-\$ or US- 6245100-\$ or US- 6361545-\$ or US- 6336937-\$ or US- 6635078-\$).did.				
S99	237	S97 or S98	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 09:52

S100	1491	(623/1.24.ccls. or 623/1.26.ccls. or 623/2.1.ccls. or 623/2.12.ccls. or 623/2.13.ccls. or 623/2.14.ccls. or 623/2.15.ccls. or 623/2.16.ccls. or 623/2.17.ccls. or 623/2.18.ccls. or 623/2.19.ccls. or 623/2.38.ccls. or 623/2.39.ccls. or 623/2.4.ccls.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 10:46
S102	556096	(confin\$5 or captur\$3 or grasp\$4 or engag\$3 or engagement\$2 or entrap\$6 or trap\$5 or sandwich\$3 or compress\$3 or clasp\$3) with (valve or leaflet or cusp or tissue)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 11:30
S103	322950	(captur\$3 or grasp\$4 or engag\$3 or engagement\$2 or entrap\$6 or trap\$5 or sandwich\$3) with (valve or leaflet or cusp or tissue)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 11:30
S106	4163	(captur\$3 or grasp\$4 or engag\$3 or engagement\$2 or entrap\$6 or trap\$5 or sandwich\$3) with (valve or leaflet or cusp or tissue) and ("623". clas.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 11:32
S107	3318	(captur\$3 or grasp\$4 or engag\$3 or engagement\$2 or entrap\$6 or trap\$5 or sandwich\$3) with (leaflet or cusp or tissue) and ("623". clas.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 11:33
S108	230	(captur\$3 or grasp\$4 or engag\$3 or engagement\$2 or entrap\$6 or trap\$5 or sandwich\$3) with ((native or damag\$3 or diseas\$3) near3 (leaflet or cusp or tissue)) and ("623". clas.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 11:34
S109	1827	(captur\$3 or grasp\$4 or engag\$3 or engagement\$2 or entrap\$6 or trap\$5 or sandwich\$3) with ((native or damag\$3 or diseas\$3) near3 (leaflet or cusp or tissue))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 11:34

S110	322	(captur\$3 or grasp\$4 or engag\$3 or engagement \$2 or entrap\$6 or trap\$5 or sandwich\$3) with ((native or damag\$3 or diseas\$3) near3 (valve or leaflet or cusp or tissue)) and ("623". clas.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 11:35
S111	2400	(captur\$3 or grasp\$4 or engag\$3 or engagement \$2 or entrap\$6 or trap\$5 or sandwich\$3) with ((native or damag\$3 or diseas\$3) near3 (valve or leaflet or cusp or tissue))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 11:36
S114	43	(US-20050137698-\$ or US-20050137687-\$ or US-20030023303-\$ or US-20080125859-\$ or US-20060253191-\$ or US-20050137701-\$ or US-20050137699-\$ or US-20050137697-\$ or US-20050137695-\$ or US-20050137691-\$ or US-20050137689-\$ or US-20050004652-\$ or US-20060276874-\$ or US-20030036791-\$ or US-20050240200-\$ or US-20090005863-\$ or US-20080071369-\$ or US-20080071368-\$ or US-20040186563-\$ or US-20050137694-\$ or US-20080071361-\$ or US-20080071362-\$ or US-20080071363-\$ or US-20080071366-\$ or US-20080082166-\$ or US-20090112309-\$).did. or (US-20090138079-\$ or US-20080255661-\$ or US-20080255660-\$ or US-20070142906-\$ or US-20080269878-\$ or US-20050137696-\$ or US-20090216310-\$).did. or (US-6652578-\$ or US-6458153-\$ or US-6425916-\$ or US-5957949-\$ or US-7201772-\$ or US-7261732-\$ or US-7377938-\$ or US-	US-PGPUB; USPAT	OR	ON	2010/01/25 12:52

		7429269-\$ or US-5332402-\$ or US-7399315-\$).did.				
S117	26	(entrap\$5 or trap\$5) and S114	US-PGPUB; USPAT	OR	ON	2010/01/25 14:02
S118	135	(valve or stent or endoprosthesis) with (inclin\$3 or declin\$3 or angl\$4) near4 (barb or anchor or staple)	US-PGPUB; USPAT	OR	ON	2010/01/25 16:31
S120	2	("5855601"   "20070239272").pn.	US-PGPUB; USPAT	OR	ON	2010/01/25 16:45
S123	1342	((retain\$3 adj arch) or migration or feeler or finger or palpation or runner) near8 (valve or leaflet or cusp or tissue) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 16:48
S124	1631	(captur\$3 or grasp\$4 or engag\$3 or engagement \$2 or entrap\$6 or trap\$5 or sandwich\$3) near10 ((native or damag\$3 or diseas\$3) near3 (valve or leaflet or cusp or tissue))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/25 16:49
S125	946	(captur\$3 or grasp\$4 or engag\$3 or engagement \$2 or entrap\$6 or trap\$5 or sandwich\$3) with (valve or leaflet or cusp or tissue) and (128/898.ccls.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 08:43
S126	49	(native adj (leaflet or cusp)) with (barb or anchor or hook)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 10:24
S127	296	(native adj2 (leaflet or cusp)) and (623/1.\$2.ccls. or 623/2.1\$.ccls.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 10:28
S128	652	(leaflet or cusp) near10 (barb or anchor or hook)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 11:03
S129	330	(leaflet or cusp) near10 (barb or anchor or hook) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 11:03


S130	381	623/1.36.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 11:31
S131	153	623/1.36.ccls. and valve	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 11:31
S133	1905	(leaflet or cusp or valve) near15 (barb or anchor or hook or retain\$4 or feeler or palpation or finger or runner) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 11:44
S134	1575	(leaflet or cusp or valve) near15 (barb or anchor or hook or retain\$4 or feeler or palpation or finger or runner) and "623".clas. not S129	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 11:44
S135	1	"20030137687"	US-PGPUB	OR	ON	2010/01/26 15:20
S136	5	"10746240"	US-PGPUB	OR	ON	2010/01/26 15:21
S137	24420	(inclin\$3 or declin\$3 or angl\$4 or slop\$3) near6 (barb or anchor or staple or hook)	US-PGPUB; USPAT	OR	ON	2010/01/26 15:27
S139	268	(inclin\$3 or declin\$3 or angl\$4 or slop\$3) near6 (barb or anchor or staple or hook) and (623/1.\$2.ccls. or 623/2.2\$.ccls.)	US-PGPUB; USPAT	OR	ON	2010/01/26 15:28
S140	52	(US-20050137698-\$ or US-20050137687-\$ or US-20030023303-\$ or US-20080125859-\$ or US-20060253191-\$ or US-20050137701-\$ or US-20050137699-\$ or US-20050137697-\$ or US-20050137695-\$ or US-20050137691-\$ or US-20050137689-\$ or US-20050004652-\$ or US-20060276874-\$ or US-20030036791-\$ or US-20050240200-\$ or US-20090005863-\$ or US-20080071369-\$ or US-20080071368-\$ or	US-PGPUB; USPAT; USOCR	OR	ON	2010/01/26 15:52



		US-20040186563-\$ or US-20050137694-\$ or US-20080071361-\$ or US-20080071362-\$ or US-20080071363-\$ or US-20080071366-\$ or US-20080082166-\$ or US-20090112309-\$).did. or (US-20090138079-\$ or US-20080255661-\$ or US-20080255660-\$ or US-20070142906-\$ or US-20080269878-\$ or US-20050137696-\$ or US-20090216310-\$ or US-20030130571-\$ or US-20060052867-\$ or US-20080215143-\$).did. or (US-6652578-\$ or US- 6458153-\$ or US- 6425916-\$ or US- 5957949-\$ or US- 7201772-\$ or US- 7261732-\$ or US- 7377938-\$ or US- 7429269-\$ or US- 5332402-\$ or US- 7399315-\$ or US- 6702844-\$ or US- 7524330-\$ or US- 7628805-\$ or US- 7611535-\$ or US- 5489295-\$).did. or (US- 3143742-\$).did.				
S141	46	S140 and (barb or anchor or hook)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/01/26 15:52
S142	23	("20020002396"   "20020188344"   "20050043711"   "20050197694"   "20060155312"   "20080288054"   "3409013"   "4655218"   "4755181"   "4865600"   "5549665"   "5769812"   "5885228"   "6454799"   "6623518"   "6635079"   "6776791"   "7025791"   "7037331"   "7175653"   "7175654"   "7235093"   "7258696").PN.	US-PGPUB; USPAT	OR	ON	2010/01/26 16:09

1 / 27 / 2010 8:21:37 AM

**C:\ Documents and Settings\ rstraszheim\ My Documents\ EAST\ Workspaces\ 10972287.wsp**


<b>Search Notes</b>  	<b>Application/Control No.</b>  10972287	<b>Applicant(s)/Patent Under Reexamination</b>  SALAHIEH ET AL.
	<b>Examiner</b>  REBECCA STRASZHEIM	<b>Art Unit</b>  3738

<b>SEARCHED</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>
	623/1.28	8/12/2008	RLS
	623/1.24, 1.26, 2.1, 2.12, 2.13, 2.14, 2.15, 2.16, 2.17, 2.18, 2.19, 2.38, 2.39, 2.4	2/27/2009	RLS
	Updated class/ subclass search	8/5/2009	RLS
	Updated class/ subclass search	1/26/2010	RLS

<b>SEARCH NOTES</b>		
<b>Search Notes</b>	<b>Date</b>	<b>Examiner</b>
EAST inventor name search, EAST subject search, discussed search strategy with Primary Examiner Suzette Gherbi	8/12/2008	RLS
EAST inventor name search, EAST text search, EAST forward and backward citation search	2/27/2009	RLS
EAST inventor name search, EAST text search	8/5/2009	RLS
EAST inventor name search, EAST text search, EAST test limited class/ subclass search (623, 128/898)	1/26/2010	RLS

<b>INTERFERENCE SEARCH</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>
UPAD, USPAT	EAST inventor name search, EAST claim text search	1/26/2010	RLS

/R. S./ Examiner.Art Unit 3738	
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<b>Issue Classification</b> 	<b>Application/Control No.</b> 10972287	<b>Applicant(s)/Patent Under Reexamination</b> SALAHIEH ET AL.
	<b>Examiner</b> REBECCA STRASZHEIM	<b>Art Unit</b> 3738

ORIGINAL					INTERNATIONAL CLASSIFICATION									
CLASS		SUBCLASS			CLAIMED				NON-CLAIMED					
128		898			A	6	1	F	2 / 24 (2006.01.01)					
<b>CROSS REFERENCE(S)</b>														
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)													
623	1.26	2.14												

<input type="checkbox"/> <b>Claims renumbered in the same order as presented by applicant</b> <input type="checkbox"/> <b>CPA</b> <input type="checkbox"/> <b>T.D.</b> <input type="checkbox"/> <b>R.1.47</b>															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17		33		49	8	65						
	2		18		34		50	2	66						
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	9		25		41		57								
	10		26		42		58								
	11		27		43		59								
	12		28		44	3	60								
	13		29		45	4	61								
	14		30		46	5	62								
	15		31		47	6	63								
	16		32		48	7	64								

/R. S./ Examiner.Art Unit 3738  (Assistant Examiner)	01/27/2010  (Date)	<b>Total Claims Allowed:</b> 8	
/CORRINE M MCDERMOTT/ Supervisory Patent Examiner.Art Unit 3738  (Primary Examiner)	01/30/2010  (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 7

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Substitute for form 1449/PTO  <h2 style="text-align: center; margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; font-size: small;">(Use as many sheets as necessary)</p>	<h3 style="text-align: center; margin: 0;">Complete if Known</h3> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/972,287</td> </tr> <tr> <td>Filing Date</td> <td>October 21, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Amr Salahieh</td> </tr> <tr> <td>Art Unit</td> <td>3738</td> </tr> <tr> <td>Examiner Name</td> <td>STRASZHEIM, REBECCA L</td> </tr> <tr> <td>Attorney Docket Number</td> <td>10012-702.501</td> </tr> </table>	Application Number	10/972,287	Filing Date	October 21, 2004	First Named Inventor	Amr Salahieh	Art Unit	3738	Examiner Name	STRASZHEIM, REBECCA L	Attorney Docket Number	10012-702.501
Application Number	10/972,287												
Filing Date	October 21, 2004												
First Named Inventor	Amr Salahieh												
Art Unit	3738												
Examiner Name	STRASZHEIM, REBECCA L												
Attorney Docket Number	10012-702.501												
Sheet <u>1</u> of <u>3</u>													

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	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.	
	451	US- 5,769,812	6/23/1998	Stevens et al.	
	465	US- 5,885,228	3/23/1999	Rosenman et al.	
	453	US- 6,454,799	9/24/2002	Schreck	
	466	US- 6,623,518	9/23/2003	Thompson et al.	
	467	US- 6,635,079	10/21/2003	Unsworth et al.	
	468	US- 6,776,791	8/17/2004	Stallings et al.	
	469	US- 7,025,791	4/11/2006	Levine et al.	
	470	US- 7,037,331	5/2/2006	Mitelberg et al.	
	471	US- 7,175,653	2/13/2007	Gaber	
	472	US- 7,175,654	2/13/2007	Bonsignore et al.	
	473	US- 7,235,093	6/26/2007	Gregorich	
	474	US- 7,258,696	8/21/2007	Rabkin et al.	
	452	US- 2002/0002396	1/3/2002	Fulkerson	
	455	US- 2002/0188344	12/12/2002	Bolea et al.	

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

Examiner Signature	Date Considered
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Substitute for form 1449/PTO	<b>Complete if Known</b>	
	Application Number	10/972,287
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>	Filing Date	October 21, 2004
	First Named Inventor	Amr Salahieh
	Art Unit	3738
	Examiner Name	STRASZHEIM, REBECCA L
	Attorney Docket Number	10012-702.501
	Sheet 2 of 3	

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	458	US- 2006/0155312	7/13/2006	Levine et al.	
	448	US- 2005/0043711	2/24/2005	Corcoran et al.	
	457	US- 2005/0197694	9/8/2005	Pai et al.	
	449	US- 2008/0288054	11/20/2008	Pulnev et al.	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

Examiner Signature	Date Considered
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		Application Number	10/972,287
		Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
		Examiner Name	STRASZHEIM, REBECCA L
Sheet 3	of 3	Attorney Docket Number	10012-702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
	450	HAUG et al.; U.S. Pat. App. # 12/492,512 entitled "Everting Heart Valve," filed 06/26/2009	

Examiner Signature	/Rebecca Straszheim/	Date Considered	01/26/2010
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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE                  STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	2	of	5	Attorney Docket Number	30207-702.501

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US 2005/0203615A1	9/15/2005	Forster	
		US 2005/0203616 A1	9/15/2005	Cribier	
		US 2005/0203617 A1	9/15/2005	Forster, et al.	
		US 4,796,629	1/10/1989	Grayzel	
		US 4,986,830	1/22/1991	Owens, et al.	
		US 5,209,741	5/11/1993	Spaeth	
		US 5,258,042	11/2/1993	Mehta	
		US 5,425,762	6/20/1995	Muller	
		US 5,443,495	8/22/1995	Buscemi, et al.	
		US 5,545,133	8/13/1996	Burns, et al.	
		US 5,843,158	12/1/1998	Lenker, et al.	
		US 5,910,154	06/08/1999	Tsugita et al.	
		US 5,911,734	06/15/1999	Tsugita et al.	
		US 5,968,070	10/19/1999	Bley, et al.	
		US 6,027,520	02/22/2000	Tsugita et al.	
		<del>US 6,143,987</del> 6142987	11/07/2000	Tsugita	
		US 6,165,200	12/26/2000	Tsugita et al.	
		US 6,168,579	01/02/2001	Tsugita	
		US 6,171,327	01/09/2001	Daniel et al.	
		US 6,179,859	01/30/2001	Bates	
		US 6,270,513	08/07/2001	Tsugita et al.	
		US 6,336,934	01/08/2002	Gilson et al.	
		US 6,537,297	03/25/2003	Tsugita et al.	
		US 6,540,768	04/01/2003	Diaz et al.	
		US 6,592,614	7/15/2003	Lenker, et al.	
		US 6,676,698	01/13/2004	McGuckin, Jr. et al.	
		US 6,695,864	02/24/2004	Macoviak et al.	

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 Attorney Docket No. 30207-702.501

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



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

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

Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Unassigned
Sheet	2	Of	3	Attorney Docket Number	30207-702.501

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> - Number <sup>2</sup> - Kind Code <sup>3</sup> (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 <sup>4</sup>
		EP 1156757 B1	12/07/2005	Board of Regents, The University of Texas System		
		EP 1469797 in German with English Claims	11/02/2005	Figulla, Hans-Reiner		
		EP 1576937 A2	09/21/2005	Board of Regents, The University of Texas System		
		EP 1582178 A2	<del>10/2005</del> 5/10/5/2005	Board of Regents, The University of Texas System		
		EP 1582179 A2	10/05/2005	Board of Regents, The University of Texas System		
		EP 1589902 (WO 2004/066876)	08/12/2004	Ave Connaught		
		EP 1600121A1	11/30/2005	William Cook Europe ApS		
		EP 1605871 (WO 2004/082536 A1)	09/30/2004	Aortech International PLC		
		EP 1616531	01/18/2006	Boston Scientific Limited		
		WO 2005/087140 A1	09/22/2005	Percutaneous Cardiovascular Solutions PTY Ltd.		

UB  
4/1/04

Examiner Signature	Date Considered
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.  
 If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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

**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)

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.

66854 7590 02/26/2010

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

**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.

<b>Sue Bromaghim</b>	(Depositor's name)
<b>FILED VIA EFS</b>	(Signature)
<b>May 25, 2010</b>	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004	Amr Salahieh	10012-702.501	7706

TITLE OF INVENTION: LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	05/26/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
STRASZHEIM, REBECCA L	3738	128-898000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). <input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. <input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. <b>Use of a Customer Number is required.</b>	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 <b>Shay Glenn LLP</b> 2 _____ 3 _____
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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 3.111. Completion of this form is NOT a substitute for filing an assignment.

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

(B) RESIDENCE: (CITY and STATE OR COUNTRY) **Los Gatos, CA**

Please check the appropriate assignee category or categories (will not be printed on the patent):  Individual  Corporation or other private group entity  Government

4a. The following fee(s) are submitted: <input checked="" type="checkbox"/> Issue Fee <input checked="" type="checkbox"/> Publication Fee (No small entity discount permitted) <input type="checkbox"/> Advance Order - # of Copies _____	4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) <input type="checkbox"/> A check is enclosed. <b>/X/ PAYMENT VIA EFS</b> <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. <input checked="" type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number <b>504050</b> (enclose an extra copy of this form).
--	---

5. Change in Entity Status (from status indicated above)

a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.  b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature: Thomas M. Zlogar Date: **May 25, 2010**

Typed or printed name: **Thomas M. Zlogar** Registration No.: **55,760**

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	10972287
<b>Filing Date:</b>	21-Oct-2004
<b>Title of Invention:</b>	LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Filer:</b>	Thomas M. Zlogar/Sue Bromaghim
<b>Attorney Docket Number:</b>	10012-702.501

Filed as Small Entity

### Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				
Utility Appl issue fee	2501	1	755	755
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Extension-of-Time:</b>				
<b>Miscellaneous:</b>				
<b>Total in USD (\$)</b>				<b>1055</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	7685355
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	Thomas M. Zlogar/Sue Bromaghim
<b>Filer Authorized By:</b>	Thomas M. Zlogar
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	25-MAY-2010
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	16:53:34
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$1055
RAM confirmation Number	3184
Deposit Account	504050
Authorized User	

### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part / .zip (if appl.)	Pages (if appl.)
Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 601 of 630					

1	Issue Fee Payment (PTO-85B)	10012-702-501- IssueFeeTransmittal.pdf	249986  78a8c4ecb0894782d7e5b99e79234fef1d7 dfbd8	no	1
<b>Warnings:</b>					
<b>Information:</b>					
2	Fee Worksheet (PTO-875)	fee-info.pdf	31727  83ab267e87e8f6fcc660bf60a2157bea023 4ec1	no	2
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			281713		
<p><b>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.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  <b>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.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  <b>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.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>  <b>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.</b></p>					



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

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
10/972,287 10/21/2004 Amr Salahieh 10012-702.501 7706

66854 7590 06/02/2010
SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER

STRASZHEIM, REBECCA L

ART UNIT PAPER NUMBER

3738

MAIL DATE DELIVERY MODE

06/02/2010

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.

<b>Interview Summary</b>	<b>Application No.</b> 10/972,287	<b>Applicant(s)</b> SALAHIEH ET AL.	
	<b>Examiner</b> REBECCA STRASZHEIM	<b>Art Unit</b> 3738	

All participants (applicant, applicant's representative, PTO personnel):

(1) REBECCA STRASZHEIM. (3)\_\_\_\_\_.

(2) SUE BROWMAGHIM. (4)\_\_\_\_\_.

Date of Interview: 13 May 2010.

Type: a)  Telephonic b)  Video Conference  
c)  Personal [copy given to: 1)  applicant 2)  applicant's representative]

Exhibit shown or demonstration conducted: d)  Yes e)  No.  
If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: N/A.

Identification of prior art discussed: N/A.

Agreement with respect to the claims f)  was reached. g)  was not reached. h)  N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Sue Browmaghim, speaking on behalf of Tom Zlogar, pointed out to Examiner Straszheim that some of the references from the IDSs' dated 4/27/2005, 7/12/2006, 6/10/2008 had previously been noted as not considered. However, as was discussed in Applicants' arguments/ remarks, dated 5/5/2009, this was due to an error on the Examiners part. Examiner has considered all the references from the afore mentioned IDSs' and has attached the newly annotated afore mentioned IDSs'.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/R. S./  
Examiner, Art Unit 3738



## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

**Supplemental  
Notice of Allowability**

<b>Application No.</b> 10/972,287	<b>Applicant(s)</b> SALAHIEH ET AL.	
<b>Examiner</b> REBECCA STRASZHEIM	<b>Art Unit</b> 3738	

**-- 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 a telephone call by Applicants' Attorney.
2.  The allowed claim(s) is/are 60-67.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                                 |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>See Continuation Sheet</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                                 | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|  | 9. <input type="checkbox"/> Other _____.  |

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 4/27/2005, 7/12/2006, 6/10/2008.



Receipt date: 04/27/2005

4-29-05

10972287 - GAL: 5708

EXPRESS MAIL LABEL NO.: EV 518896122 US

PATENT

Attorney Docket No. 30207.702.501

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application	)	<u>PATENT APPLICATION</u>
	)	
Inventor(s): Amr SALAHIEH et al.	)	
	)	Art Unit: 3738
Application No.: 10/972,287	)	
	)	Examiner: Not yet assigned
Filed: October 21, 2004	)	
	)	Confirmation No.: 7706
Title: Leaflet engagement elements and methods for use thereof	)	
	)	

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

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

Sir:

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

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

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

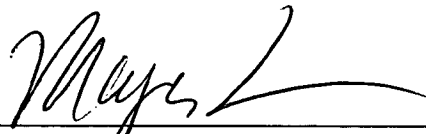
This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
  - (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
  
- 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
  - a certification as specified in §1.97(e) is provided below; **or**
  - a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
  
- 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
  - A. a certification as specified in §1.97(e) is completed below; and
  - B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
  - C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
  
- Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith in PDF format on the attached CD ROM, clearly titled by application number or author, in accordance with 37 CFR 1.98 (a)(2).
  
- Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
  - In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.     ), copies are not enclosed herewith.
  - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- There are no listed references which are not in the English language.
- The relevance of those listed references which are not in the English language is as follows:
- Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- Attached are non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
- Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207.702.501).

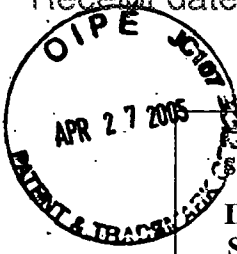
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

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

Dated: 4/29/05

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



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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number	10/972,287	
Sheet		1	of	2	Examiner Name	Not yet assigned
					Attorney Docket Number	30207.702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
		SALAHIEH, A. et al. US Patent Application No. 10/746,280 entitled "Repositionable heart valve and method", filed 12/23/2003 (Docket No. 30207.701.201).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,131 entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (Docket No. 30207.701.501).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,151, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.502).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,143, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.503).	
		SALAHIEH, A. et al. US Patent Application No. 10/893,142, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.504).	
		SALAHIEH, A. et al. US Patent Application No. 10/920,736, entitled "Apparatus and methods for protecting against embolization during endovascular heart replacement", filed 08/17/2004 (30207.701.505).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,240, entitled "Heart valve anchor and method", filed 12/23/2003 (30207.702.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/971,535, entitled "Leaflet engagement elements and methods for use thereof", filed 10/21/2004 (30207.702.502).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,120, entitled "Externally expandable heart valve anchor and method", filed 12/23/2003 (30207.703.201).	

Examiner signature	Date Considered
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\*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.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

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

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	10/21/2004
				First Named Inventor	Salahieh
				Art Unit	3738
Examiner Name	Not yet assigned				
Sheet	2	of	2	Attorney Docket Number	30207.702.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>2</sup>
		SALAHIEH, A. et al., US Patent Application No. 10/982,388, entitled "Methods and apparatus for endovascularly replacing a heart valve", filed 11/05/2004 (30207.703.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,285, entitled "Retrievable heart valve anchor and method", filed 12/23/2003 (30207.704.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/982,692, entitled "Retrievable heart valve anchor and method", filed 11/05/2004 (30207.704.501).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,887, entitled "Low profile heart valve and delivery system", filed 12/23/2003 (30207.705.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,872, entitled "Locking heart valve anchor", filed 12/23/2003 (30207.706.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/911,059, entitled "Replacement valve and anchor", filed 08/03/2004 (30207.706.301).	
		SALAHIEH, A. et al., US Patent Application No. 10/746,942, entitled "Two-piece heart valve and anchor", filed 12/23/2003 (30207.707.201).	
		SALAHIEH, A. et al., US Patent Application No. 10/870,340, entitled "Everting heart valve", filed 06/16/2004 (30207.710.201).	

Examiner signature	/Rebecca Straszheim/	Date Considered	05/19/2010
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\*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.  
<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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







Attorney Docket No. 30207-702.501  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Amr SALAHIEH, et al.

Serial Number: 10/972,287

Filing Date: October 21, 2004

Title: LEAFLET ENGAGEMENT ELEMENTS  
AND METHODS FOR USE THEREOF

Group Art Unit: 3738

Examiner: Unassigned

**CONFIRMATION NO: 7706**

FILED ELECTRONICALLY ON: July 12, 2006

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

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97**

Sir:

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

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

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

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

- A.  *37 CFR §1.97(b)*. This Information Disclosure Statement should be considered by the Office because:
- (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --
  - (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;  
-- OR --
  - (3) It is being filed before the mailing of a first Office action on the merits;  
-- OR --
  - (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B.  *37 CFR §1.97(c)*. Although this Information Disclosure Statement is being filed after the period specified in *37 CFR §1.97(b)*, above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- a statement as specified in §1.97(e) provided concurrently herewith;  
-- OR --
  - a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C.  *37 CFR §1.97(d)*. Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);  
-- AND --
  - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D.  *37 CFR §1.97(e)*. Statement.
- A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);  
-- AND/OR --
  - A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);  
-- AND/OR --
  - A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.
- E.  *Statement Under 37 C.F.R. §1.704(d)*. Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

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

- F.  37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:
- Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

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

-- AND/OR --

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

-- AND/OR --

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

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

- Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.
- Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

- A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: \_\_\_\_\_
- Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

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

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

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

Application in which the information was submitted: \_\_\_\_\_

Information Disclosure Statement(s) filed on: \_\_\_\_\_

AND

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

- I.  *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30207-702.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: July 12, 2006

By: 

Maya Skubatch, Reg. No. 52,505

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

PTO/SB/08 (07/05)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>		
				Application Number	10/972,287	
				Filing Date	October 21, 2004	
				First Named Inventor	Amr Salahieh	
				Art Unit	3738	
Examiner Name	Unassigned		Attorney Docket Number	30207-702.501		
Sheet	1	Of	2			

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 2005/0137695	06/23/2005	Salahieh et al.	
		US 3,657,744	04/25/1972	Ersek	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (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 <sup>6</sup>
		EP 0409929 B1	04/23/1997	Boston Scientific Corp.		
		WO 96/24306 A1 (in French with English abstract)	08/15/1996	De Fays, Robert		
		WO 98/57599 A2	12/23/1998	Camilli, Sante		

Examiner Signature	Date Considered
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\*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. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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

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

PTO/SB/08 (07/05)

Approved for use through 07/31/2006. OMB 0651-0031  
 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE                  STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
				Art Unit	3738
				Examiner Name	Unassigned
Sheet	2	Of	2	Attorney Docket Number	30207-702.501

UNPUBLISHED PATENT APPLICATIONS			
Examiner Initials*	Cite No. <sup>1</sup>	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 <sup>6</sup>
		SALAHIEH, et al., U.S. Patent Application No. 11/275,912, entitled "Medical Implant Delivery and Deployment Tool," filed 02/02/2006 (WSGR Reference No. 30207-722.501)	
		SALAHIEH, et al., U.S. Patent Application No. 11/275,913, entitled "Two-Part Package for Medical Implant," filed 02/02/2006 (WSGR Reference No. 30207-723.201)	

Examiner Signature	/Rebecca Straszheim/	Date Considered	05/19/2010
--------------------	----------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.  
 If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.





APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	07/06/2010	7748389	10012-702.501	7706

66854 7590 06/16/2010  
SHAY GLENN LLP  
2755 CAMPUS DRIVE  
SUITE 210  
SAN MATEO, CA 94403

### ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 1211 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Amr Salahieh, Saratoga, CA;  
Brian D. Brandt, Santa Clara, CA;  
Robert A. Gleshlider, San Francisco, CA;  
Dwight P. Morejohn, Davis, CA;  
Tom Saul, El Granada, CA;

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<b>In Re Application of:</b>	Amr Salahieh, Brian D. Brant, Robert A. Geshliger, Dwight P. Morejohn, Tom Saul
<b>Application No.:</b>	10/972287
<b>Filed:</b>	December 21, 2004
<b>For:</b>	Leaflet Engagement Elements and Methods for Use Thereof
<b>Examiner:</b>	Rebecca L. Straszheim
<b>Group Art Unit:</b>	3738

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

Docket No: S63.2H-15126-US01

**REVOCAION 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.

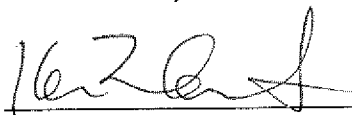
I am the:

- 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

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

<b>In Re Application of:</b>	Amr Salahieh, Brian D. Brant, Robert A. Geshlider, Dwight P. Morejohn, Tom Saul
<b>Application No.:</b>	10/972287
<b>Filed:</b>	December 21, 2004
<b>For:</b>	Leaflet Engagement Elements and Methods for Use Thereof
<b>Examiner:</b>	Rebecca L. Straszheim
<b>Group Art Unit:</b>	3738

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

**Docket No: S63.2H-15126-US01**

**NOTIFICATION OF CHANGE OF ENTITY STATUS**

Applicant is no longer entitled to claim small entity status. Please update the record to reflect large entity status for this case.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/

James M. Urzedowski  
Registration No.: 48596

6640 Shady Oak Rd., Suite 400  
Eden Prairie, MN 55344-7834  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	9430308
<b>Application Number:</b>	10972287
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	7706
<b>Title of Invention:</b>	LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF
<b>First Named Inventor/Applicant Name:</b>	Amr Salahieh
<b>Customer Number:</b>	66854
<b>Filer:</b>	James M. Urzedowski/Samantha Painschab
<b>Filer Authorized By:</b>	James M. Urzedowski
<b>Attorney Docket Number:</b>	10012-702.501
<b>Receipt Date:</b>	11-FEB-2011
<b>Filing Date:</b>	21-OCT-2004
<b>Time Stamp:</b>	17:50:15
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	15126US01_tra_20110211.pdf	84088 <small>30969caa15c7a4e243271a53e43255bceb79c5e3</small>	no	1

### Warnings:

### Information:

2	Assignee showing of ownership per 37 CFR 3.73(b).	15126US01_sta_20110207.pdf	70781 27ca020e51fef1b144cae3599eab3452fb4d8fcc	no	1
<b>Warnings:</b>					
<b>Information:</b>					
3	Power of Attorney	15126US01_executedPOA.pdf	28062 b3becc2a42df8a451a8745de74a5e3a3dda5162	no	1
<b>Warnings:</b>					
<b>Information:</b>					
4	Miscellaneous Incoming Letter	15126US01_entity_status_20110211.pdf	65596 ff8f80e1e022555aa6a3f69774893bd902377eb	no	1
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>				248527	

**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

<b>In Re Application of:</b>	Amr Salahieh, Brian D. Brant, Robert A. Geshliger, Dwight P. Morejohn, Tom Saul
<b>Application No.:</b>	10/972287
<b>Filed:</b>	December 21, 2004
<b>For:</b>	Leaflet Engagement Elements and Methods for Use Thereof
<b>Examiner:</b>	Rebecca L. Straszheim
<b>Group Art Unit:</b>	3738

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

**Docket No: S63.2H-15126-US01**

## TRANSMITTAL LETTER

- 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.**
- With respect to fees, applicant believes the fees required herein, if any, are being paid electronically.
- 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.
- 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.**
- 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  
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Telephone: (952) 563-3000  
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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<b>In Re Application of:</b>	Amr Salahieh, Brian D. Brant, Robert A. Geshlider, Dwight P. Morejohn, Tom Saul
<b>Application No.:</b>	10/972287
<b>Filed:</b>	December 21, 2004
<b>For:</b>	Leaflet Engagement Elements and Methods for Use Thereof
<b>Examiner:</b>	Rebecca L. Straszheim
<b>Group Art Unit:</b>	3738

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

**Docket No: S63.2H-15126-US01**

## ASSIGNEE'S STATEMENT OF OWNERSHIP 37 CFR 3.73(B)

Sadra Medical, Inc., a corporation, is the assignee of the entire right, title and interest in the patent application identified above by virtue of a chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From : Amr Salahieh, Brian D. Brandt, Robert A. Geshlider, Dwight P. Morejohn, Tom Saul  
To: Sadra Medical, Inc.  
The document was recorded in the Patent and Trademark Office at Reel 015768, Frame 0556, or for which a copy thereof is attached.
2. From : Amr Salahieh, Brian D. Brandt, Robert A. Geshlider, Dwight P. Morejohn, Tom Saul  
To: Sadra Medical, Inc.  
The document was recorded in the Patent and Trademark Office at Reel 016315, Frame 0771, 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

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f:\wpwork\jmu\15126us01\_sta\_20110207.doc



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/972,287	10/21/2004	Amr Salahieh	10012-702.501

**CONFIRMATION NO. 7706**

**POWER OF ATTORNEY NOTICE**



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

Date Mailed: 02/22/2011

**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).

/skiflemariam/

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  
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/972,287	10/21/2004	Amr Salahieh	S63.2H-15126-US01

**CONFIRMATION NO. 7706**

**POA ACCEPTANCE LETTER**

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



Date Mailed: 02/22/2011

**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.

/skiflemariam/

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

Large Entity Declaration

**PATENT  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Application Number:** 10/972,287

**Filing Date:** October 21, 2004

**Patent Number:** 7,748,389 ✓

**Issue Date:** July 6, 2010

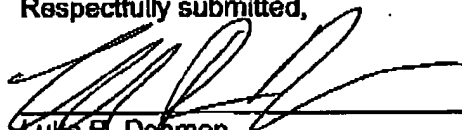
**CHANGE OF ENTITY STATUS PURSUANT TO 37 C.F.R. §1.27 (g)(2)**

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

Sir:

This communication hereby notifies the United States Patent and Trademark Office that small entity status is no longer applicable for the above-identified patent.

Respectfully submitted,



Luke R. Dohmen  
Vice President – Patent Legal

Date: December 19, 2013

Sadra Medical, Inc.  
1717 Dell Avenue  
Campbell, CA 95008