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(Type) Maya Skubatch (Attorney/Agent)	Fax No.

PATENT APPLICATION

LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF

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WSGR Docket No. 30207.702.501

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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

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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

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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.

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[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 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.

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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 selfexpand 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.

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

[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 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 value is provided. The method involves endovascularly delivering an anchor/value apparatus and properly positioning such apparatus via positive registration with the patient's native value leaflets. Registration with the native value leaflet preferably occurs using the leaflet engagement elements.

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[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

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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

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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 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.

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[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.

[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

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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.

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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.

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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.

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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.

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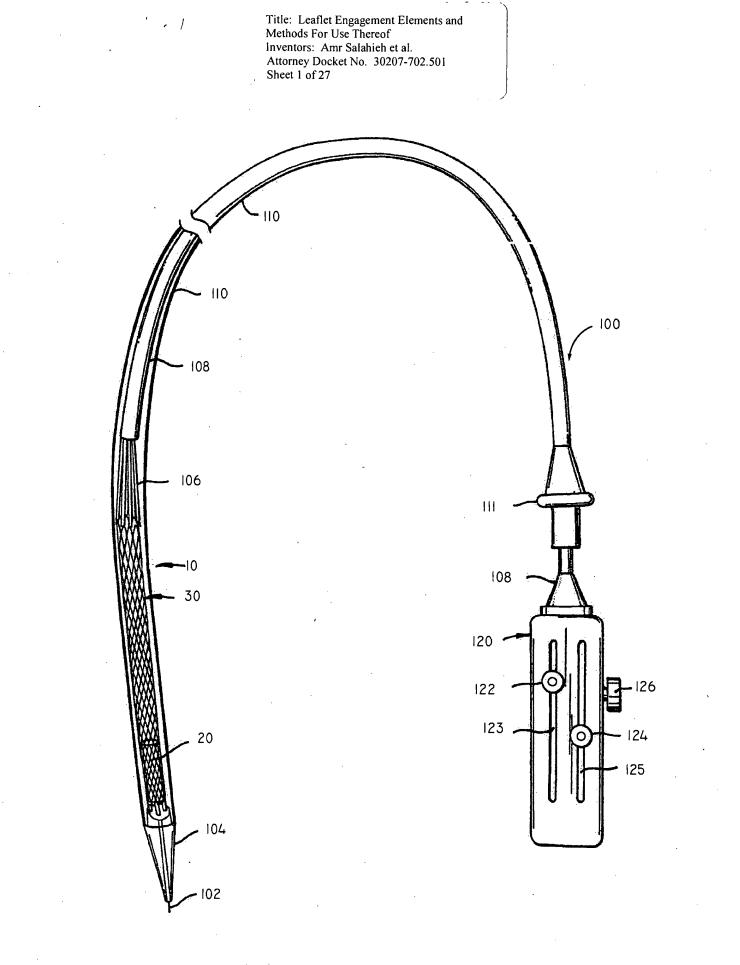
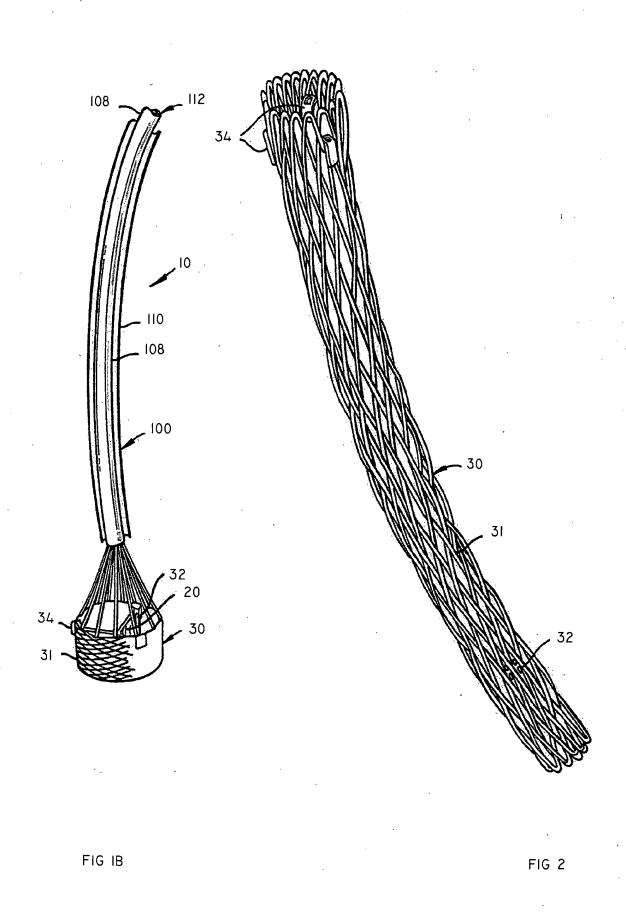


FIG IA

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Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 3 of 27

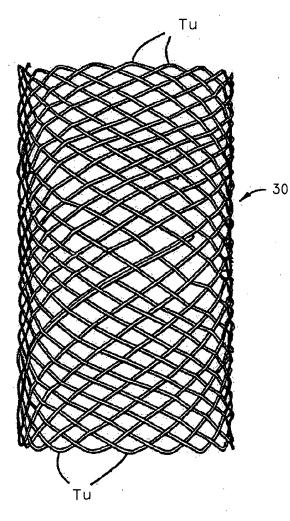
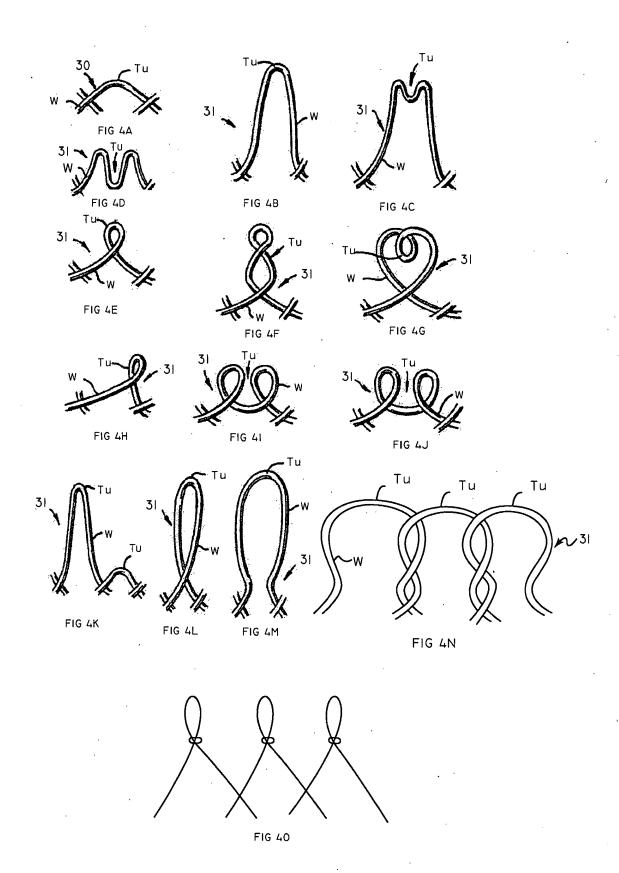


FIG 3 ·

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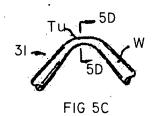
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W L_{5B} 3I

FIG 5A

FIG 5B

Tu



W FIG 5D FIG 5E

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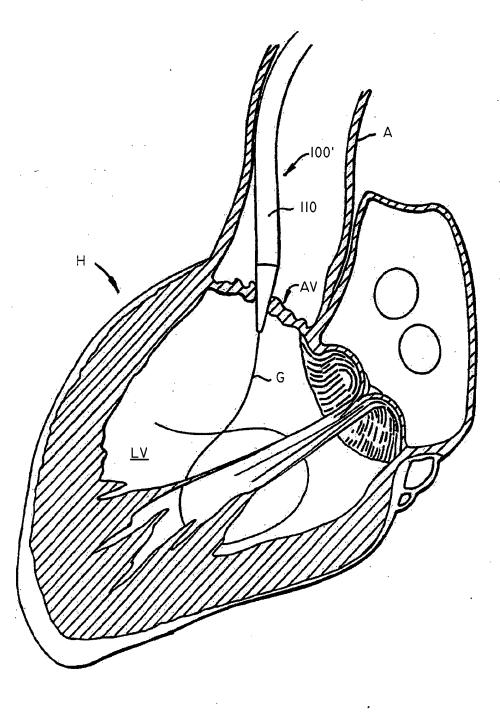
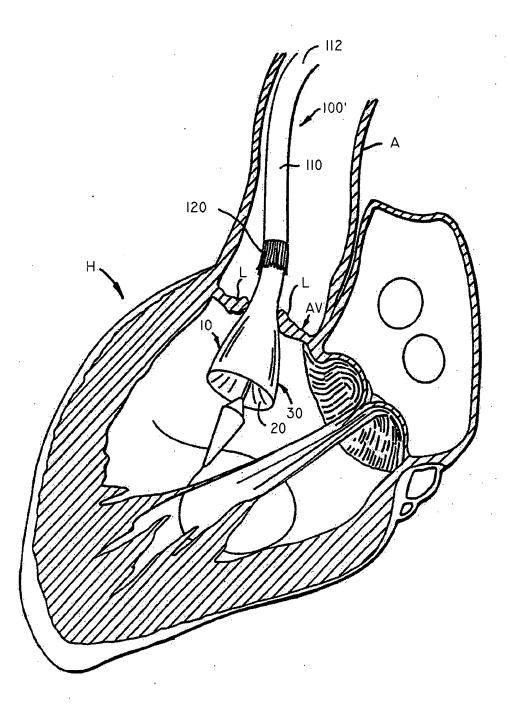


FIG 6A

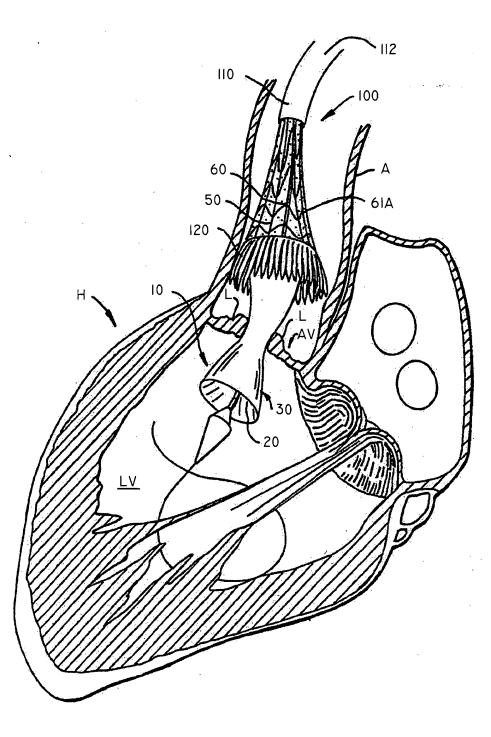
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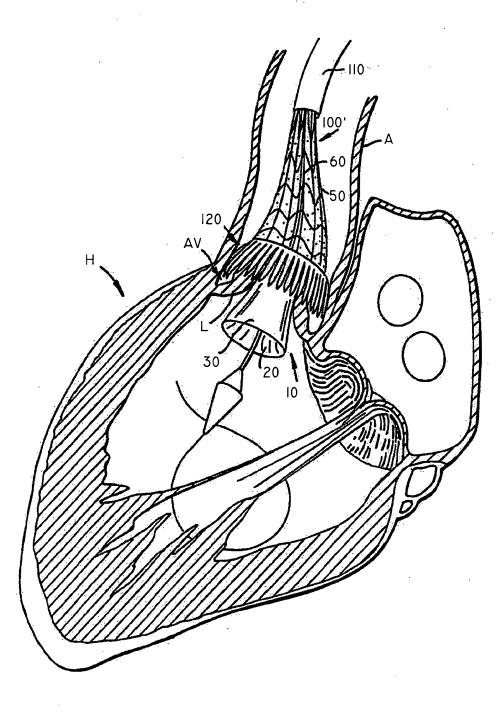
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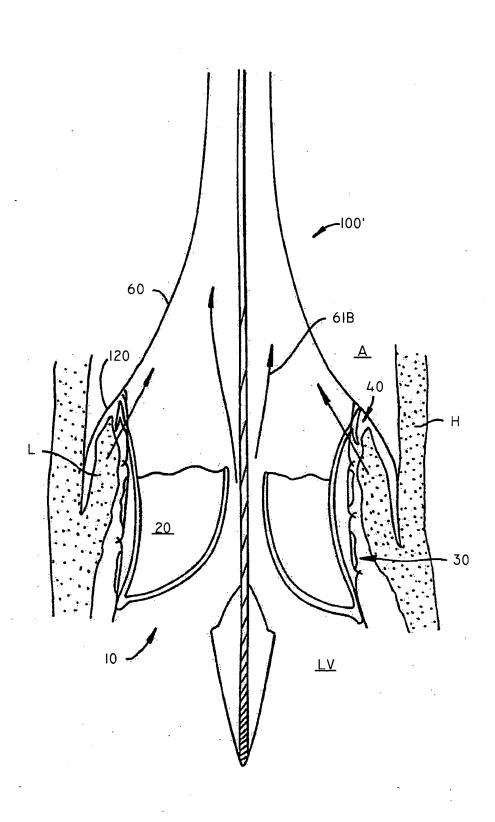
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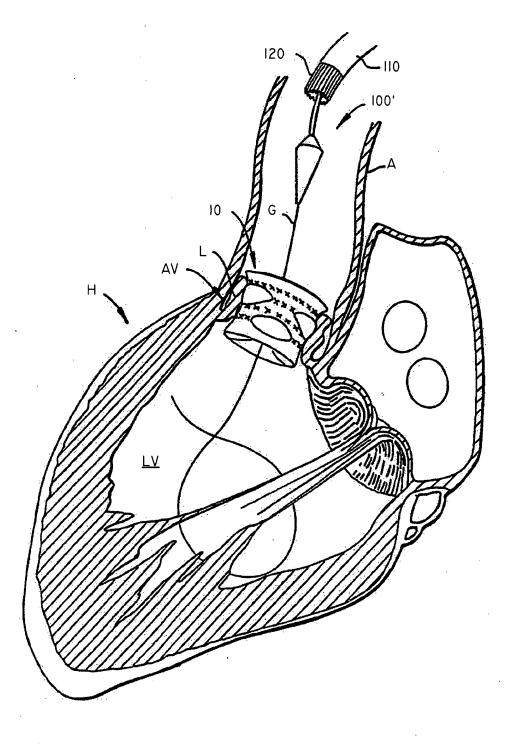
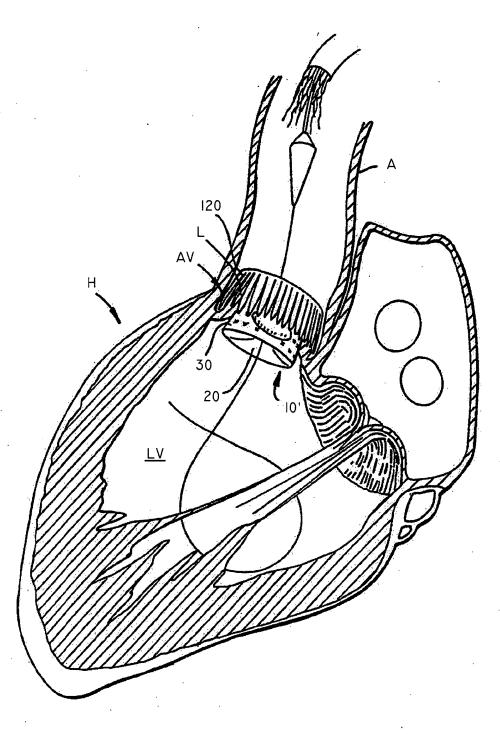


FIG 6F

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Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 13 of 27

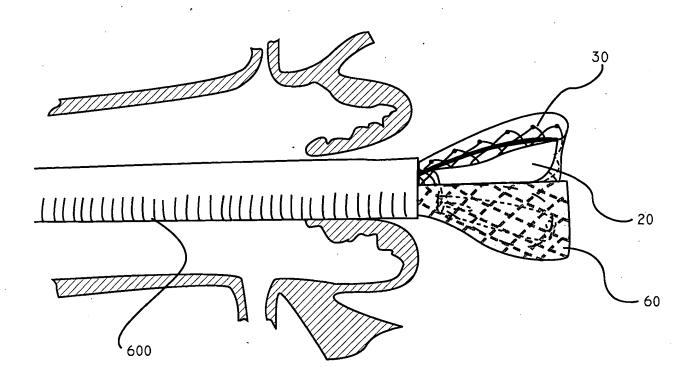
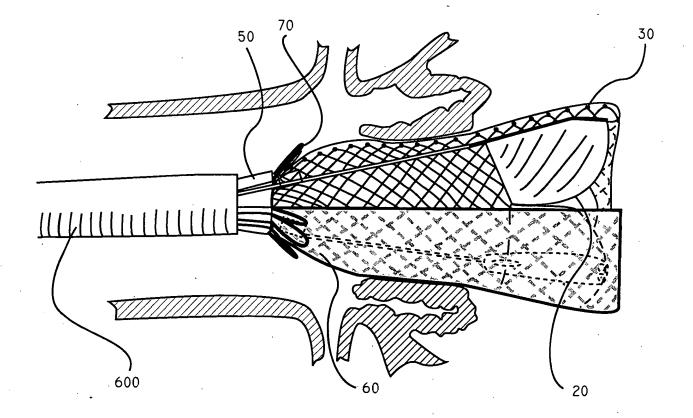


FIG 8A

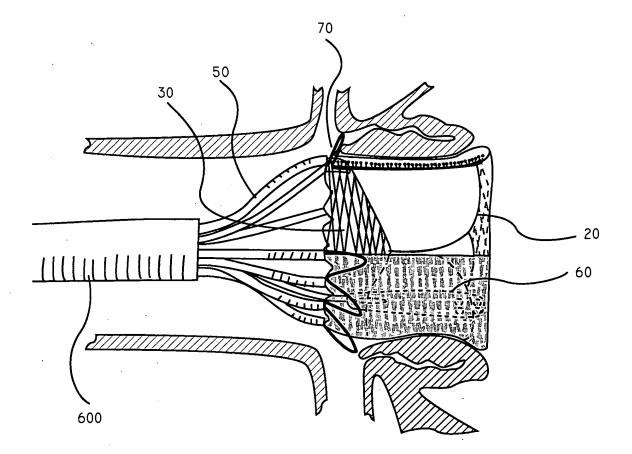
Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 40 of 630

Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 14 of 27



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Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 16 of 27

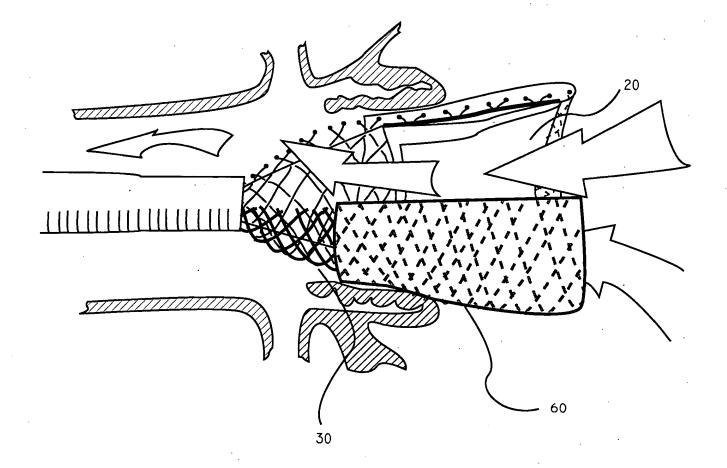


FIG 9A

Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 17 of 27

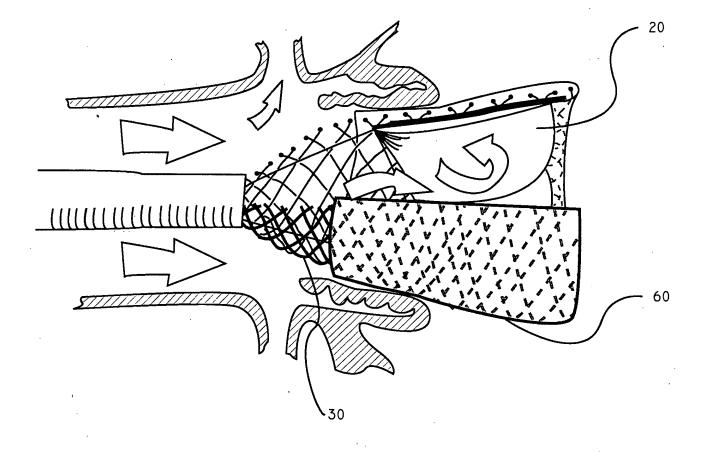


FIG 9B

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Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 18 of 27

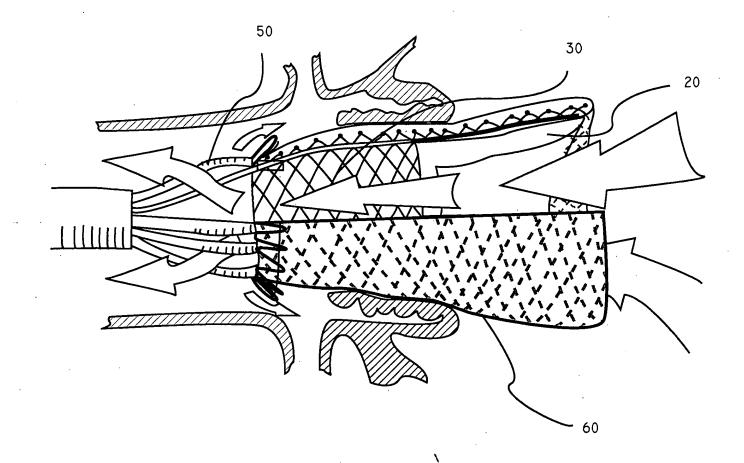
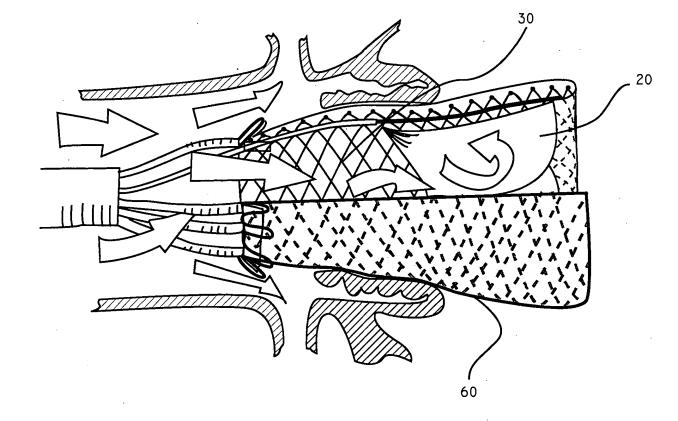


FIG IOA

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Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 19 of 27



FIGIOB

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Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 20 of 27

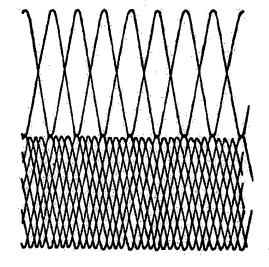


FIG IIA

Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 21 of 27

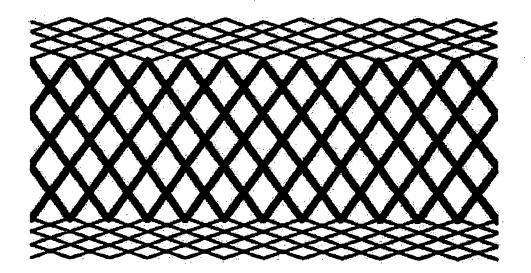


FIG IIB

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Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 22 of 27

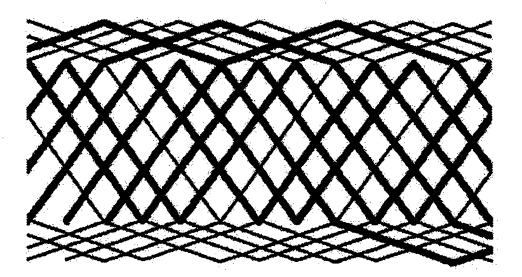


FIG IIC

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Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 23 of 27

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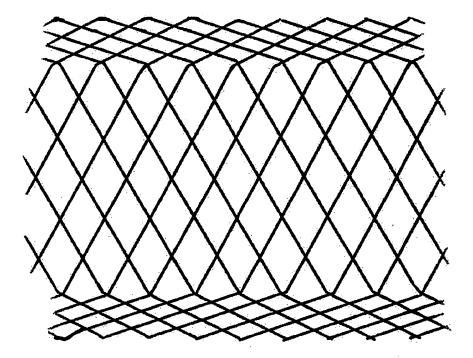


FIG IID

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Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 24 of 27

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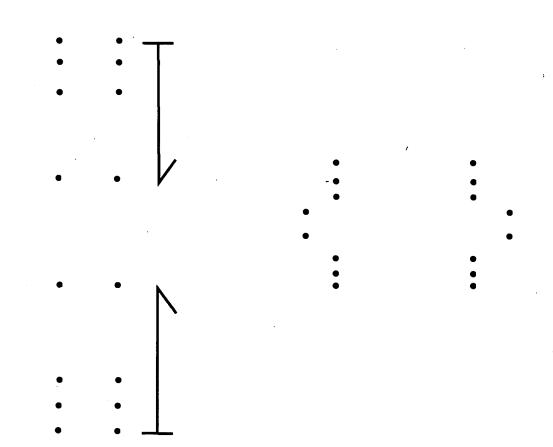
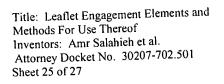


FIG 12A

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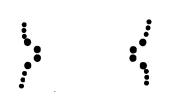


FIG 12B



FIG I2C



FIG 12D

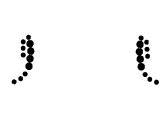
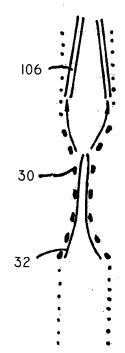


FIG 12E

Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 26 of 27



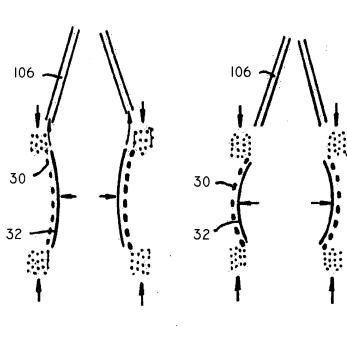


FIG I3A







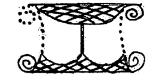
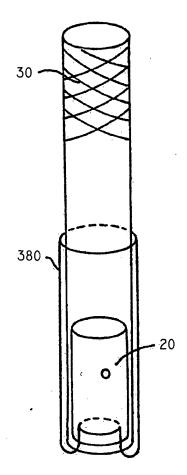


FIG I3D

Title: Leaflet Engagement Elements and Methods For Use Thereof Inventors: Amr Salahieh et al. Attorney Docket No. 30207-702.501 Sheet 27 of 27



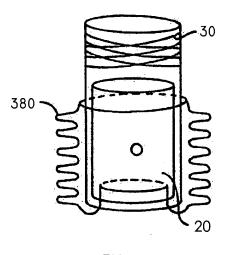


FIG 14B

FIG 14A

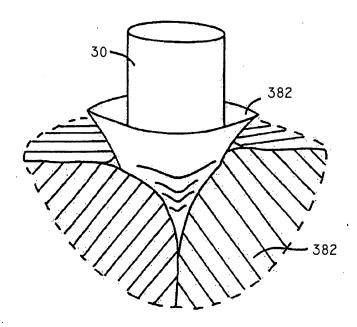


FIG I4C

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PATENT Attorney Docket No. 30207.702.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

Inventor(s): Amr SALAHIEH et al.

Application No.: 10/972,287

Filed: October 21, 2004

Title: Leaflet engagement elements and methods for use thereof

PATENT APPLICATION

Art Unit: Not yet assigned

Examiner: Not yet assigned

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. \S 1.97, subsection (b) because:

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- (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.

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

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- \square 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:
- \square 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).
- П Attached are the following non-published pending patent applications which may be deemed relevant.
- \square 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

11-22-04 Dated:

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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Figures Appear				nd Code ² (if known)			
		Chinn et al.	09/27/2001		US-2001/0025	. <u> </u>	
		Marton	10/18/2001		US-2001/0032		
		Pavcnik et al.	11/08/2001		US-2001/0039		
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	l	Macoviak et a	10/31/2002		US-2002/0161		
		Beyersdorf et	12/19/2002		US-2002/0193		
		Cribier	01/16/2003	104	US-2003/0014		
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		Cali	02/06/2003	247	US-2003/0028		
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	· · · ·	Pease et al.	03/20/2003	495	US-2003/0055	· · ·	
		Cribier	06/12/2003	924	US-2003/0109		
		Pavenik et al.	07/03/2003	795	US-2003/0125		
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		Figulla et al.	08/07/2003	9478	US-2003/0149		
		Spenser et al.	08/14/2003	974	US-2003/0153		
<u>_</u>		Diamond et al	09/25/2003	850	US-2003/0181		

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			LICANT	First Named Inventor	Salahieh	
(Use as	s many sheel	ts as nec	cessary)	Art Unit	Not yet assigned	
				Examiner Name	Not yet assigned	
Sheet	2	of	12	Attorney Docket Number	30207.702.501	

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Initials* No.1		Number-Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	
		US-2003/0199913	10/23/2003	Dubrul et al.	r igatos r ppcul	
		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.		
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		US-3,839,741	10/08/1974	Haller		

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(Use a	s many sheel	ts as neo	cessary)	Art Unit	Not yet assigned	
				Examiner Name	Not yet assigned	
Sheet	3	of	12	Attorney Docket Number	30207.702.501	

U.S. PATENT DOCUMENTS Examiner Cite Document Number Publication Date Name of Patentee or Pages, Columns, Lines, Where No.1 MM-DD-YYYY Applicant of Cited Document Initials* Relevant Passages or Relevant Number-Kind Code² (if known) Figures Appear US-3,868,956 03/04/1975 Alfidi et al. US-3,874,388 04/01/1975 King et al. 11/08/1977 US-4,056,854 Boretos et al. 08/15/1978 US-4,106,129 Carpentier et al. US-4,233,690 11/18/1980 Akins US-4,291,420 09/29/1981 Reul 01/17/1984 US-4,425,908 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. 04/07/1987 US-4,655,771 Wallsten US-4,662,885 05/05/1987 DiPisa, Jr. 05/19/1987 US-4,665,906 Jervis US-4,710,192 12/01/1987 Liotta et al. US-4,733,665 03/29/1988 Palmaz 04/11/1989 US-4,819,751 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 03/26/1991 US-5,002,559 Tower US-5,161,547 11/10/1992 Tower Vince US-5,163,953 11/17/1992

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Substitute fo	or form 1449	9/PTO		Application Number	10/972,287	
INFORM	IATION	DISC	LOSURE	Filing Date	10/21/2004	
			LICANT	First Named Inventor	Salahieh	
(Use as	many sheet	s as nee	cessary)	Art Unit	Not yet assigned	
				Examiner Name	Not yet assigned	
Sheet	4	of	12	Attorney Docket Number	30207.702.501	

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
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				Con	Complete if Known		
Substitute f	or form 1449)/PTO		Application Number	10/972,287		
INFORM	IATION	DISC	LOSURE	Filing Date	10/21/2004		
	MENT BY			First Named Inventor	Salahieh		
(Use a	s many sheet.	s as ne	cessary)	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 Document Number Publication Date Cite Name of Patentee or Pages, Columns, Lines, Where MM-DD-YYYY Initials* No Applicant of Cited Document Relevant Passages or Relevant Number-Kind Code² (if known) Figures Appear US-5,876,448 03/02/1999 Thompson et al. US-5,888,201 03/30/1999 Stinson et al. US-5,891,191 04/06/1999 Stinson US-5,907,893 06/01/1999 Zadno-Azizi et al. US-5,925,063 07/20/1999 Khosravi US-5,944,738 08/31/1999 Amplatz et al. US-5,954,766 09/21/1999 Zadno-Azizi et al. US-5,957,949 09/28/1999 Leonhardt et al. US-5,984,957 11/16/1999 Laptewicz, Jr. et al. US-6,022,370 02/08/2000 Tower US-6,027,525 02/22/2000 Suh et al. US-6,042,598 03/28/2000 Tsugita et al. US-6,051,104 04/18/2000 Jang US-6,123,723 09/26/2000 Konya et al. US-6,146,366 11/14/2000 Schachar US-6,162,245 12/19/2000 Jayaraman US-6,168,614 01/02/2001 Andersen et al. US-6,200,336 03/13/2001 Pavenik 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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Substitute for	or form 1449	/PTO		Application Number	10/972,287	
INFORM	1ATION I	DISC	LOSURE	Filing Date	10/21/2004	
			LICANT	First Named Inventor	Salahieh	
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				Examiner Name	Not yet assigned	
Sheet	6	of	12	Attorney Docket Number	30207.702.501	

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Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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(Use as	s many sheet	s as neo	cessary)	Art Unit	Not yet assigned	
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				Con	nplete if Known
Substitute f	for form 144	9/PTO		Application Number	10/972,287
INFORM	MATION	DISCI	LOSURE	Filing Date	10/21/2004
	MENT BY			First Named Inventor	Salahieh
(Use a	s many shee	ts as nec	essary)	Art Unit	Not yet assigned
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Sheet	8	of	12	Attorney Docket Number	30207.702.501

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		EP 1057459	12/06/2000	Numed, Inc.		\square
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		WO 02/36048	05/10/2002	Seguin, Jacques		X
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Examiner	Date
Signature	Considered
*EYAMINED I	nitial if reference considered whether or not obtain is in conformance with MREP 600. Draw line through aitation if not in conformance and not

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				Con	nplete if Known
Substitute for form 1449/PTO INFORMATION DISCLOSURE				Application Number	10/972,287
				Filing Date	10/21/2004
	STATEMENT BY APPLICANT			First Named Inventor	Salahieh
(Use a.	s many sheet	s as ne	cessary)	Art Unit	Not yet assigned
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Sheet	9	of	12	Attorney Docket Number	30207.702.501

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		WO 03/003943	01/16/2003	Advanced Bio Prosthetic Surfaces, Ltd.		
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<u> </u>		WO 03/011195	02/13/2003	Seguin, Jacques		T
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Examiner				Date		
Signature				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. ¹Applicant's unique citation designation number (optional). ¹See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document by the appropriate symbols as indicated on the document under WIPO Standard ST .16 if possible. ⁶Applicant is to place a check mark here if English language Translation is statched. 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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				Complete if Known				
Substitute fo	or form 1449	PTO		Application Number	10/972,287			
INFORM	IATION I	DISC	LOSURE	Filing Date	10/21/2004			
			LICANT	First Named Inventor	Salahieh			
(Use as	many sheet:	s as ne	cessary)	Art Unit	Not yet assigned			
				Examiner Name	Not yet assigned			
Sheet	10	of	12	Attorney Docket Number	30207.702.501			

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

Examiner signature

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¹Applicant's unique citation designation number (optional). ²Applicant 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 gathening, 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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				Complete if Known		
Substitute fo	or form 1449	/PTO		Application Number	10/972,287	
INFORM	IATION I	DISC	LOSURE	Filing Date	10/21/2004	
	STATEMENT BY APPLICANT			First Named Inventor	Salahieh	
(Use as	many sheet:	s as ne	cessary)	Art Unit	Not yet assigned	
				Examiner Name	Not yet assigned	
Sheet	11	of	12	Attorney Docket Number	30207.702.501	

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

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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

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Substitute fo	or form 1449	/PTO		Application Number	10/972,287
INFORM	ATION I	DISC	LOSURE	Filing Date	10/21/2004
STATEM	1ENT BY	APP	LICANT	First Named Inventor	Salahieh
(Use as	many sheets	s as ne	cessary)	Art Unit	Not yet assigned
				Examiner Name	Not yet assigned
Sheet	12	of	12	Attorney Docket Number	30207.702.501

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		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	Date	
signature	Considered	

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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 10972287UA

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 Artifact Type Code: P pages of specification and/or sequence listing and/or table Doc Code: Artifact Artifact Type Code: S content unspecified or combined Doc Code: Artifact 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		

UNITED STAT	tes Patent and Tradema	ARK OFFICE UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandra, Vrignia 22313-1450 www.uspic.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	
021971	· .	FORMAL	CONFIRMATION NO. 7706	

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

Date Mailed: 01/11/2005

OC000000014923099

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

A copy of this notice <u>MUST</u> be returned with the reply.

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Customer Service Center Initial Patent Examination Division (703) 308-1202 PART 3 - OFFICE COPY



PATENT Attorney Docket No. 30207.702.501

RADEN N THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application
Inventor(s): Amr SALAHIEH et al.
Application No.: 10/972,287
Filed: October 21, 2004
Title: Leaflet engagement elements and methods for use thereof

PATENT APPLICATION

Art Unit: 3738

Examiner: Not yet assigned

Confirmation No.: 7706

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:

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- (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.

 \bigcirc 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. <u>23-2415 (Docket No.30207.702.501)</u>.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

10/06 Dated:

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

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

PTO/SB/08A (08-03)

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				Con	nplete if Known
Substitute f	or form 144	9/PTO		Application Number	10/972,287
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date	10/21/2004		
		First Named Inventor	Salahieh		
(Use as	s many shee	ts as neo	cessary)	Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	1	of	1	Attorney Docket Number	30207.702.501

U.S. PATENT DOCUMENTS

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	Examiner	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
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<u> </u>	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or	T		
		Country Code3 - Number4 - Kind Code3 (if known)	1		Relevant Figures Appear			
		EP 1000590A1	05/17/2000	Cordis Corporation				
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Examiner				Date				
Signature	1			Considered				

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2994761_1.DOC Attorney Docket No. 30207.702.501

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GOODRI	APPLICATION NUMBER		United State Address: COMMI PO. Box Alexandr www.uspi	ia, Virginia 22313-1450 10.gov	
	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 GOODRIG 650 PAGE MILL ROAD PALO ALTO, CA 943041050	CH & ROSATI			

Date Mailed: 01/11/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

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01 FC:2051 02 FC:2001 03 FC:2202		DA	·

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

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Alexandria VA 22313-1450

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

Undershie Paperwork Reduction Act of 1995	, no persons are requ	U.S. Patent and Tra	PTO/SB/21 (02-0 Approved for use through 07/31/2006. OMB 0651-00 demark Office; U.S. DEPARTMENT OF COMMERC prmation unless it displays a valid OMB control numbe
& TRAUPARAN		Application Number	10/972,287
TRANSMITTA	T,	Filing Date	October 21, 2004
FORM		First Named Inventor	Amr Salahieh
(to be used for all correspondence after ini	tial filing)	Art Unit	3738
		Examiner Name	Unassigned
Total Number of Pages in This Submission		Attorney Docket Number	30207-702.501
	ENCLOSU	RES (Check all that apply)	
Fee Transmittal Form	Declarat	ion	After Allowance communication to Technology Center (TC)
Fee Attached	Licensin	g-related Papers	Appeal Communication to Board of Appeals and Interferences
Amendment/Reply	Petition		Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
After Final		to Convert to a	Proprietary Information
Affidavits/declaration(s)	-	nal Application f Attorney By Assignee	Status Letter
Extension of Time Request		1 Disclaimer	Other Enclosure(s)
Express Abandonment Request	Request for Refund		(please identify below): Copy of Assignment and
Information Disclosure Statement		nber of CD(s)	recordation cover sheet
Certified Copy of Priority	Remarks		
Document(s) Response to Missing Parts/			
Incomplete Application Response to Missing Parts			· .
under 37 CFR 1.52 or 1.53			
Firm	TURE OF APP	LICANT, ATTORNEY OR A	
or Maya Skubatch, Reg. No. Individual name	52,505, WILSON	SONSINI GOODRICH & RO	OSATI
Signature Mary			
Date February 23, 2005			
CERTIF I hereby certify that this correspondence is be Addressee" service under 37 C.F.R. §1.10 on P.O. Box 1450, Alexandria, VA 22313-1450	ing deposited with the date indicate	d below and addressed to: M/S	vice "Express Mail Post Office to
Typed or printed name Donna L. Hengst			
Signature Donna	L N	enast Date	February 23, 2005

application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is required to qotain or retain a benefit by the public which is to the (and by the USP10 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 USP10. 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.

Utility300150500250200100\$20Design2001001005013065Plant20010030015016080Reissue300150500250600300Provisional20010000002. EXCESS CLAIM FEESSFee DescriptionEach claim over 20 or, for Reissues, each independent claim more than the original patent50Each claim over 20 or, for Reissues, each independent claim more than in the original patent50Each claims over 20 or, for Reissues, each independent claim more than in the original patent360Total ClaimsExtra ClaimsFee (\$)Fee (\$)Fee Paid (\$)Multiple Dependent Claims58- 20 or HP = 38x \$25.00= \$250.00HP = highest number of total claims paid for, if greater than 20Multiple Dependent ClaimsIndep. ClaimsExtra ClaimsFee (\$)Fee Paid (\$)3APPLICATION SIZE FEEIf greater than 3APPLICATION SIZE FEEIf 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 SheetsExtra SheetsNumber of each additional 50 or fraction thereofFee (\$)53-100 =/ 50 =(round up to a whole number) ×004. OTHER FEE(\$)NumeRegistration No. (Attorney/Agent)52,5									TPE
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GOODR	APPLICATION NUMBER	FILING OR 371 (c) DATE	United State Address: COMM P.O. Box	ia, Virginia 22313-1450	
	10/972,287	10/21/2004	Amr Salahieh	30207-702.501	
	021971 WILSON SONSINI GOODRIG 650 PAGE MILL ROAD PALO ALTO, CA 943041050			CONFIRMATION NO. 7706 ITIES LETTER	

Date Mailed: 01/11/2005

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

02/28/2005	CNGUYEN 00000100	232415	10972287 F	:1
01 FC:2051 02 FC:2001 03 FC:2202				••

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.

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

Undershie Paperwork Reduction Act of 1995	, no persons are requ	U.S. Patent and Tra	PTO/SB/21 (02-0 Approved for use through 07/31/2006. OMB 0651-00 demark Office; U.S. DEPARTMENT OF COMMERC prmation unless it displays a valid OMB control numbe
& TRAUPARAN		Application Number	10/972,287
TRANSMITTA	T,	Filing Date	October 21, 2004
FORM		First Named Inventor	Amr Salahieh
(to be used for all correspondence after ini	tial filing)	Art Unit	3738
		Examiner Name	Unassigned
Total Number of Pages in This Submission		Attorney Docket Number	30207-702.501
	ENCLOSU	RES (Check all that apply)	
Fee Transmittal Form	Declarat	ion	After Allowance communication to Technology Center (TC)
Fee Attached	Licensin	g-related Papers	Appeal Communication to Board of Appeals and Interferences
Amendment/Reply	Petition		Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
After Final		to Convert to a	Proprietary Information
Affidavits/declaration(s)	-	nal Application f Attorney By Assignee	Status Letter
Extension of Time Request		1 Disclaimer	Other Enclosure(s)
Express Abandonment Request	Request for Refund		(please identify below): Copy of Assignment and
Information Disclosure Statement		nber of CD(s)	recordation cover sheet
Certified Copy of Priority	Remarks		
Document(s) Response to Missing Parts/			
Incomplete Application Response to Missing Parts			· .
under 37 CFR 1.52 or 1.53			
Firm	TURE OF APP	LICANT, ATTORNEY OR A	
or Maya Skubatch, Reg. No. Individual name	52,505, WILSON	SONSINI GOODRICH & RO	OSATI
Signature Mary			
Date February 23, 2005			
CERTIF I hereby certify that this correspondence is be Addressee" service under 37 C.F.R. §1.10 on P.O. Box 1450, Alexandria, VA 22313-1450	ing deposited with the date indicate	d below and addressed to: M/S	vice "Express Mail Post Office to
Typed or printed name Donna L. Hengst			
Signature Donna	L N	enast Date	February 23, 2005

application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is required to qotain or retain a benefit by the public which is to the (and by the USP10 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 USP10. 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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Fees pursuant to the Conso			Applicatio	n Number	10/972,2	287	
FEE T	RANSMI	TTAL	Filing Date		October	21, 2004	
fo	or FY 200	5		ed Inventor	Amr Sal	ahieh	
applicant claims smal			Examiner	Name	Unassig	ned	
			Art Unit		3738		
TOTAL AMOUNT OF	PAYMENT	(\$) 1,515.00	Attorney I	Oocket No.	30207-7	02.501	
METHOD OF PAYME	NT (check all that	apply)		· · · · · · · · · ·		_	
Check Credit ca	ard 🗌 Money 🤅	Order 🗌 None	🗌 Other (pleas	e identify):			· · ·
⊠ Charge fee(s) ⊠ Charge any ad	ed deposit accoun indicated below	nber: <u>23-2415</u> t, the Director is hereby underpayments of fee(s		(check all that ap	ply) s) indicated belov	<u>n Sonsini Goodric</u> w, except for the	
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1. BASIC FILING, SEA	RCH, AND EXA FILING FE	ES	SEARCH FEE		EXAMINA		
Application Type	Fee (\$)	Small Entity Fee (\$) F	Tee (\$)	<u>Small Entity</u> Fee (\$)	Fee (\$)	<u>Small Entity</u> Fee (\$)	Fees Paid (\$
Utility	300	150	500	250	200	100	\$500.00
Design	200		100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300		500	250	600	300	
Provisional	200	100	0	0	0	0	<u> </u>
2. EXCESS CLAIM FE		100		, v	Ū		Small Entity
Fee Description Each claim over 20 or, for F		a over 20 and more than	the original notes			<u>Fee (\$)</u>	Fee (\$)
Each independent claim ove Multiple dependent claims	er 3 or, for Reissues	, each independent clairr				50 200 360	25 100 180
$\frac{\text{Total Claims}}{58} - 20 \text{ or HP}$ HP = highest number of tota	al claims paid for, it	x \$25.00 = greater than 20	<u></u>	-	<u>Multip</u> Fee (\$	le Dependent Clai 5) Fee Paic	
Indep. Claims 3 - 3 or HP =	Extra Claims	<u>Fee (\$)</u> × \$ =	<u>Fee Paid (\$</u> = \$0	<u>D</u>			
 HP = highest number of tota APPLICATION SIZE If the specification and 	al claims paid for, in E FEE drawings exceed 50 sheets or fracti	greater than 3 100 sheets of paper, the ons thereof. See 35 U.	e application siz S.C. 41(a)(1)(G) and 37 CFR 1.1	6(s).	entity)	
<u>Total Sheets</u> 53 - 100 =	Extra Sheets	50 = <u>Number o</u>		al 50 or fraction t up to a whole nun		<u>Fee (\$)</u> 0 =	<u>v </u>
4. OTHER FEE(S) Non-English Specification	on, \$130 fee (no s	mall entity discount)	. .				<u>Fees Paid (\$</u>
Other: Late surcharge.							# < # 00
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Please type a plus sign (+) inside this box +	U.S. Patent and Tradem	PTO/SB/01 (08-03) oved for use through 07/31/2006.OMB 0651-0032 ark Office: U.S. DEPARTMENT OF COMMERCE ion unless it contains a valid OMB control number.
DECLARATION FOR UTILITY OR	Attorney Docket Number	30207-702.501
DESIGN	First Named Inventor	Amr Salahieh
PATENT APPLICATION	COMP	LETE IF KNOWN
(37 CF <u>R</u> 1.63)	Application Number	10/972,287
Declaration Submitted OR Submitted after Initial	Filing Date	October 21, 2004
With Initial Filing (surcharge Filing (37 CFR 1.16(e)	Art Unit	3738
required)	Examiner Name	Unassigned
Each inventor's residence, mailing address, and citize I believe the inventor(s) named below to be the origin which a patent is sought on the invention entitled:		
LEAFLET ENGAGEMENT ELE	·	
(the specification of which	Title of the Invention)	
is attached hereto		
<i>OR</i>	United States Application Number	or PCT International
Application Number 10/972,287 and was amended of	n (MM/DD/YYYY) (if app	icable).
I hereby state that I have reviewed and understand the amended by any amendment specifically referred to about		ed specification, including the claims, as
I acknowledge the duty to disclose information which continuation-in-part applications, material information w and the national or PCT international filing date of the co	hich became available betwee	defined in 37 CFR 1.56, including for n the filing date of the prior 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 Co Yes	ppy Attached? No
Additional foreign application	on numbers are lis	ted on a supplemental price	ority data sheet PTO/SB/	2B attached here	to.

[Page 1 of 2]

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.

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DECLARATION — Utility or Design Patent Application

+

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Name			
Maya Skubatch			
Address			<u> </u>
Wilson Sonsini Goodrich & Rosati Address	• • • • • • • • • • • • • • • • • • • •		
650 Page Mill Road		State	ZIP
Palo Alto	Talanhana	CA	94304
Country	Telephone		Fax
U.S.	650-493-9300		650-493-6811
I hereby declare that all statements made her are believed to be true; and further that thes made are punishable by fine or imprisonment validity of the application or any patent issued	e statements were mad , or both, under 18 U.S.	e with the knowledge	that willful false statements and the like so
NAME OF SOLE OR FIRST INVEN		petition has been filed f	or this unsigned inventor
Given Name (first and middle [if any]) Amr		Family Name or Surname	Salahieh
Inventor's Signature			
Inventor's signature	5/03	-	Date 2/8/05
Residence: City	State	Country	Citizenship
Saratoga	CA	USA	USA
Mailing Address			
18729 Metler Court			
City	State	ZIP	Country
Saratoga	CA	95070	USA
NAME OF SECOND INVENTOR:	A petition	has been filed for this u	nsigned inventor
Given Name (first and middle [if any]) Prian D.		amily Name r Surname	Brandt
Inventor's Signature	· · · · · · · · · · · · · · · · · · ·		Date 02/04/05
Residence: City	State	Country	Citizenship /
Santa Clara	CA	USA	USA
Mailing Address			
3015 Cameron Way			
City	State	ZIP	Country
Santa Clara	CA	95051	USA
Additional inventors or legal representative are t	peing named on the 1 supp	lemental sheet(s) PTO/SE	0/02A or 02LR attached hereto:

[Page 2 of 2]

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Under the Paperwork Reduction Act of 1995, no per DECLARATION		ADDITIONAL INVENTOR(S Supplemental Sheet			
Name of Additional Joint Inventor,	if any:	A petition has been filed	for this unsigned inventor		
Given Name (first and middle (if	any)	Family Name or Surname			
Robert A.		GI	eshlider		
Inventor's Signature	hdn		Date 2 4 05		
Residence: City San Francisco	State CA	Country USA	Citizenship USA		
Mailing Address 233 27 th Street			:		
Mailing Address					
City San Francisco	State CA	ZIP 94131	Country USA		
Name of Additional Joint Inventor,	if any:	A petition has been filed	for this unsigned inventor		
Given Name (first and middle (if a	any))	Family Name or Surname			
Dwight P.		Morejohn			
Inventor's Durght P. M.	orejoh_		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		
Name of Additional Joint Inventor,	if any:	A petition has been filed	for this unsigned inventor		
Given Name (first and middle (if a	any))	Family Name or Surname			
Tom			Saul		
Inventor's Signature for Soul		· · · · · · · · · · · · · · · · · · ·	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. 1 (and by the USPTO to process) an application. Confiden complete, including gathering, preparing, and submitting	tiality is governed by 3	5 U.S.C. 122 and 37 CFR 1.14. This co	llection 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.

	Practitioner's	5 Docket No.: 30207-702.501	PATENT
(FEB 23 2005	POWER OF ATTORNEY BY ASSIGNEE TO EXCLUSION OF INVENTOR UNDER 37 C.F.R. § 3.71 WITH REVOCATION OF PRIOR POWERS ed ASSIGNEE of the entire interest in:	
	\square	U.S. Patent No. U.S. application no. <u>10/972,287</u> , filed on <u>October 21, 2004</u>	
	Trademark Of States Patent a	ts all Wilson Sonsini Goodrich & Rosati attorneys registered to practice before the United Stat fice, as associated with Customer No. 021971, to prosecute this application and transact all bus and Trademark Office in connection therewith and hereby revokes all prior powers of attorney; ision of the inventors and the inventors' attorneys in accordance with the provisions of 37 C.F.I	siness in the United said appointment to
	The following	evidentiary documents establish a chain of title from the original owner to the Assignee:	
		(complete one of the following)	
	\boxtimes	a copy of an Assignment attached hereto, which Assignment has been (or is herewith) forw and Trademark Office for recording; or	varded to the Patent

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 Sonsi	Wilson Sonsini Goodrich and Rosati							
Address	650 Page Mil	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:

4-29-05

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

Inventor(s): Amr SALAHIEH et al.

Application No.: 10/972,287

Filed: October 21, 2004

Title: Leaflet engagement elements and methods for use thereof

PATENT APPLICATION

Art Unit: 3738

Examiner: Not yet assigned

Confirmation No.: 7706

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.

\boxtimes	This s	tatemen	t qualifies under 37 C.F.R. $\S1.97$, 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
	\boxtimes	(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.
	the fil nation a first	ing date al stage Office	97(c). If this statement is being filed after the latest of: (1) three months beyond e of a national application; (2) three months beyond the date of entry of the as set forth in §1.491 in an international application; or (3) the mailing date of action on the merits, but before the mailing date of the earlier of a final office 1.113 or a notice of allowance under §1.311, then:
		a certi:	fication as specified in §1.97(e) is provided below; or
			of \$180.00 as set forth in \$1.17(p) is authorized below, enclosed, or included ne payment of other papers filed together with this statement.
	final o		97(d). If this statement is being filed after the mailing date of the earlier of a tion under $\$1.113$ or a notice of allowance under $\$1.311$, but before payment of hen:
	А.	a certi	fication as specified in $\$1.97(e)$ is completed below; and
	B.	-	ion under 37 C.F.R. §1.97(d) requesting consideration of this statement is ted herewith; and
	C.		f 130.00 as set forth in $1.17(i)(1)$ is authorized below, enclosed, or included as payment of other papers filed together with this statement.
\boxtimes	in PD	F forma	n of the references listed on the attached Form PTO-1449 are enclosed herewith t on the attached CD ROM, clearly titled by application number or author, in th 37 CFR 1.98 (a)(2).
	Copies THAT		rences listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT
			w of the voluminous nature of references, and the likelihood that these are available to the Examiner in the file history of the parent application 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.
3055272			

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- 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:

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

Dated:

Maya Skulfatch, Reg. No. 52,505

OIPE	Cian Under the	• e paperwork Re	duction A		U.S. Patent and Tr	PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031 ademark Office; U.S. DEPARTMENT OF COMMERCE formation unless it contains a valid OMB control number
APR 27 200				,		nplete if Known
	-	or form 1449)/PTO		Application Number	10/972,287
No.	SUP INFORM	IATION	DISC	LOSURE	Filing Date	10/21/2004
- DRACO	PR 2 1 200 Substitute for form 1449/PTO		First Named Inventor	Salahieh		
Filing Date Filing Date Filing Date First Named Art Unit Examiner Na	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. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	т
		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	Date	
signature	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

¹ 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 12 minutes to complete, including gathering, preparing, and submitting the complete this form and/or surgestions for the USPTO. Time will vary depending upon the individual case. Any comment of time your require to complete this form and/or surgestions for reducing this burden should be sent to the Chele Information Office. 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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3055272_1.DOC Attorney Docket No. 30207.702.501

PTO/SB/08A (08-03)

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				Con	nplete if Known
Substitute for	Substitute for form 1449/PTO			Application Number	10/972,287
INFORM	ATION I	DISC	LOSURE	Filing Date	10/21/2004
STATEM	IENT BY	APP	LICANT	First Named Inventor	Salahieh
(Use as	many sheets	as ne	cessary)	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. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		SALAHIEH, A. et al., US Patent Application No. 10/982,388, 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 beart 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.

¹Applicant's unique citation designation number (optional). ²Applicant 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.

3055272_1.DOC Attorney Docket No. 30207.702.501

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 10972237 MB

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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

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 95 of 630



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 ρ

Mi Kyong Shin

PATENT

Attorney Docket No. 30207.702.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

Inventor(s): Amr SALAHIEH et al.

Application No.: 10/972,287

Filed: October 21, 2004

Title: Leaflet engagement elements and methods for use thereof

PATENT APPLICATION

Art Unit: 3738

Examiner: Not yet assigned

Confirmation No.: 7706

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.

2679731_1.DOC Attorney Docket No. 30207.702.501

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 96 of 630

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. $\S 1.97(c)$. 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 $\S 1.491$ 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 $\S 1.113$ or a notice of allowance under $\S 1.311$, 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. $\S 1.97(d)$. If this statement is being filed after the mailing date of the earlier of a final office action under $\S 1.113$ or a notice of allowance under $\S 1.311$, 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.)

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Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 97 of 630

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:

James R. Shay, Reg. No. 32,06

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

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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

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

U.S. PATENT DOCUMENTS

Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	No. ¹	Number-Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		US-2005/0085841	04/21/2005	Eversull et al.	
		US-2005/0085842	04/21/2005	Eversull et al.	- 17
		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.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	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	Te
·		EP 1229864 B1	04/27/2005	Boston Scientific Limited	· · · · · · · · · · · · · · · · · · ·	
					•	
Examiner			<u> </u>	Date		

¹ 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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ³Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant 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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User the Paperwork Reduction Act of 1995, no persons are required to regood to collection of information unless it displays a valid OMB control number Application Number 10/972,287 TRANSMITTAL FORM (to be used for all correspondence after initial filing) Art Unit 3738 Examiner Name Not yet assigned Total Number of Pages in This Submission Attorney Docket Number ENCLOSURES (Check all that apply) Fee Transmittal Form Drawing(s) Fee Attached Licensing-related Papers 7 Amendment/Reply Petition to Convert to a Provisional Application Provisional Application Provisional Application Affidavits/declaration(s) Power of Attorney, Revocation Affidavits/declaration(s) Power of Attorney, Revocation Affidavits/declaration(s) Request for Refund Information Disclosure Statement CD, Number of CD(s) Remarks Request for Refund Remarks Response to Missing Parts/	2 8 2005 Uptor the Paperwork Reduction Act of 199	5, no persons are req	U.S. Patent and uired to respond to a collection of	Trademark O	FTO/SB/21 (02 for use through 07/31/2006. OMB 0651 - ffice; U.S. DEPARTMENT OF COMME unless it displays a valid OMB control nun
TRANSMITTAL Fing Date October 21, 2004 FORM First Named Inventor Amr Salahieh (to be used for all correspondence after initial filing) 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) E Fee Transmittal Form Drawing(s) After Allowance communication to Board of Appeals and Interferences Fee Attached Licensing-related Papers Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) After Final Petition to Convert to a Provisional Application Proprietary Information Affidavits/declaration(s) Power of Attorney, Revocation Change of Correspondence Address Other Enclosure(s) (please identify below): return receipt postcard Extension of Time Request Terminal Disclaimer Other Enclosure(s) (please identify below): return receipt postcard Information Disclosure Statement CD, Number of CD(s) Encantes Certified Copy of Priority Document(s) Remarks	ADEMARYO		Application Number	10/	972,287
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Aff of int 37.38 Examiner Name Not yet assigned Total Number of Pages in This Submission Attorney Docket Number 30207-702.501 ENCLOSURES (Check all that apply) 30207-702.501 After Allowance communication Technology Center (TC) After Allowance Communication to Board of Appeals and Interferences Appeal Communication to Board of Appeals and Interferences Amendment/Reply Petition Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) After Final Provisional Application Proprietary Information Affidavits/declaration(s) Power of Attorney, Revocation Change of Correspondence Address Other Enclosure(s) (please identify below): return receipt postcard Express Abandonment Request Request for Refund Minormation Of CD(s) Emerks Certified Copy of Priority Document(s) Remarks Emerks Emerks			First Named Inventor	An	n Salahieh
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	Response to Missing Parts under 37 CFR 1.52 or 1.53			DACENT	、
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under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY OR AGENT Firm or Individual name Signature Maya Skubatch, Reg. No. 52,505, WILSON SONSINI GOODRICH & ROSATI Date October & , 2005	I hereby certify that this correspondence is being	facsimile transmitte	ed to the USPTO or deposited w	ith the Unite	
under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY OR AGENT Firm or Individual name Signature Date October , 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	Typed or printed name Frank Chen				
under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY OR AGENT Firm or Individual name Signature Maya Skubatch, Reg. No. 52,505, WILSON SONSINI GOODRICH & ROSATI Date October (), 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	Signature 700-		Date	Octob	per 26,2005

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.

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

1 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 2.6 , 2005.

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 --
- 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).
 - $37 \ CFR \ \S 1.98(a)(2)$. 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).

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 \boxtimes 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

db Dated: October 2005

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

By:

Maya Skubatch, Reg. No. 52,505

PTO/SB/08A (07-05) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Application Number 10/972,287 Substitute for form 1449/PTO & TRADE Filing Date October 21, 2004 **INFORMATION DISCLOSURE** First Named Inventor STATEMENT BY APPLICANT Amr Salahieh (Use as many sheets as necessary) Art Unit 3738 Examiner Name Not yet assigned Sheet of 5 Attorney Docket Number 30207-702.501 1 **U.S. PATENT DOCUMENTS** Examiner Cite Document Number Publication Date Name of Patentee or Pages, Columns, Lines, Where Initials* No. MM-DD-YYYY Applicant of Cited Document Relevant Passages or Relevant Number-Kind Code² (if known) Figures Appear US 2001/0044634 11/22/2001 Don Michael et al. US 2002/0010489 A1 1/24/2002 Gravzel, 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 Gilson et al. US 2004/0073198 04/15/2004 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 Lowe et al. 08/12/2004 US 2004/0167565 Beulke et al. 08/26/2004 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. 5/5/2005 US 2005/0096736 A1 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		Date	
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If you need assistance in completing the form, coll 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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				Complete if Known			
Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/972,287		
			LOSURE	Filing Date	October 21, 2004		
			LICANT	First Named Inventor	Amr Salahieh		
(Use as	(Use as many sheets as necessary)		Art Unit	3738			
		Examiner Name	Not yet assigned				
Sheet	2	of	5	Attorney Docket Number	30207-702.501		

U.S. PATENT DOCUMENTS

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

Examiner Signature

Date Considered

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				Con	aplete if Known
Substitute for form 1449/PTO				Application Number	10/972,287
INFORMATION DISCLOSURE			LOSURE	Filing Date	October 21, 2004
STATEM	STATEMENT BY APPLICANT			First Named Inventor	Amr Salahieh
(Use as	(Use as many sheets as necessary)		Art Unit	3738	
		Examiner Name	Not yet assigned		
Sheet	3	of	5	Attorney Docket Number	30207-702.501

U.S. PATENT DOCUMENTS

Examiner	Cite	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where
lnitials*	No. ¹	Number-Kind Code ² (if known)	mber-Kind Code ² (if known)		Relevant Passages or Relevant Figures Appear
		US 6,695,865	02/24/2004	Boyle et al.	
		US 6,773,454	08/10/2004	Wholey, et al.	
		US 6,890,340	05/10/2005	Duane	
		US 6,905,743	6/14/2005	Chen, et al.	
		US 6,911,036	6/28/2005	Douk, et al.	
		US 6,936,067	8/30/2005	Buchanan	
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Signature		Considered	
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/972,287 October 21, 2004		
			LOSURE	Filing Date			
				First Named Inventor	Amr Salahieh		
			cessary)	Art Unit	3738		
				Examiner Name	Not yet assigned		
Sheet	4	of	5	Attorney Docket Number	30207-702.501		

F	C'h		PATENT DO			r
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ – Number ⁴ – Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т
		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. 1. 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.		
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Substitute for form 1449/PTO				Application Number	10/972,287	
INFORM	IATION	DISC	CLOSURE	Filing Date	October 21, 2004	
STATEMENT BY APPLICANT				First Named Inventor	Amr Salahieh	
(Use as many sheets as necessary)				Art Unit	3738	
				Examiner Name	Not yet assigned	
Sheet	5	of	5	Attorney Docket Number	30207-702.501	

NON PATENT LITERATURE DOCUMENTS					
Examiner Inilials*	Cile No. ¹	publisher, city and/or country where published.			
		Boudjemline, Y. et al., "Percutaneious implantation of a biological valve in the aorta to treat aortic valve insufficiency - a sheep study", Med Sci.Monit. (2002) Vol. 8, No. 4, pages BR113- 116			

Examiner	Date	
signature	Considered	

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 ²Applicant is to place a check mark here if English language Translation is attached.
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Attorney Docket No. 30207-702.501 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Amr SALAHIEH, et al.

Group Art Unit: 3738

Examiner: Unassigned

Serial Number: 10/972,287

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.

- 1 -

- A. X 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. \Box 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:

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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. \Box 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

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 110 of 630

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. \boxtimes 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. \boxtimes 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.

2854352_1.DOC Attorney Docket No. 30207-702.501

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- 3 -

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 111 of 630

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

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

ву:_____

Maya Skabatch, Reg. No. 52,505

Dated: <u>April</u> <u>6</u>, 2006 650 Page Mill Road

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

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

				Complete if Known			
Substitute for form 1449/PTO .		Application Number	10/972,287				
INFORMATION DISCLOSURE			LOSURE	Filing Date	October 21, 2004		
	STATEMENT BY APPLICANT			First Named Inventor	Amr Salahieh		
(Use a	s many sheet	ts as neo	cessary)	Art Unit	3738		
		Examiner Name	Unassigned				
Sheet	1	Of	3	Attorney Docket Number	30207-702.501		

Examiner Cite Initials* No. ¹		Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		US 2005/0209580 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.		
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Examiner	Date
Signature	Considered

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				Complete if Known			
Substitute fo	or form 144	9/PTO		Application Number	10/972,287		
INFORM	INFORMATION DISCLOSURE		Filing Date	October 21, 2004			
	STATEMENT BY APPLICANT		First Named Inventor	Amr Salahieh			
(Use as	many shee	ts as nece	essary)	Art Unit	3738		
				Examiner Name	Unassigned		
Sheet	2	Of	3	Attorney Docket Number	30207-702.501		

		FOREIGN	N PATENT DO	OCUMENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ – Number ⁴ – Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₆
		EP 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			Date	
Signature			Considered	·
ADICIA (D. (D.)		 0 1 1 1 (DED (00		

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

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.

2854352 1.DOC Attorney Docket No. 30207-702.501

- 2 -

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 114 of 630

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				Complete if Known		
Substitute fo	or form 144	9/ PTO		Application Number	10/972,287	
INFORM	IATION	DISCI	LOSURE	Filing Date	October 21, 2004	
	STATEMENT BY APPLICANT			First Named Inventor	Amr Salahieh	
(Use as	many shee	ts as nec	essary)	Art Unit	3738	
				Examiner Name	Unassigned	
Sheet	3	Of	3	Attorney Docket Number	30207-702.501	

	UNPUBLISHED PATENT APPLICATIONS	
 Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	FAWZ1, 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)	
	SALAH1EH, 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		Date	
Signature		Considered	
*FXAMINER	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

"EAUXILIVER: Initial if reference considered, whether of not cutation is in contormance with MPET 695. Draw line through citation if not in contormance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04, ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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2854352_1.DOC Attorney Docket No. 30207-702.501

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

Payment information:

Submitted with Payment	no
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File Listing:

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

Warnings:					
Information:					
2	Foreign Reference	2.pdf	455304	no	29
Warnings:			I	I	
Information:					
3	Foreign Reference	3.pdf	876476	no	88
Warnings:				I	
Information:					
4	Foreign Reference	4.pdf	878362	no	88
Warnings:			I	I	
Information:					
5	Foreign Reference	5.pdf	859808	no	88
Warnings:					
Information:				1	
6	Foreign Reference	6.pdf	832582	no	20
Warnings:			I	I	
Information:					
7	Foreign Reference	7.pdf	5287563	no	96
Warnings:					
Information:				1	
8	Foreign Reference	8.pdf	240497	no	11
Warnings:			·	·	
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9	Foreign Reference	9.PDF	280722	no	16
Warnings:			·	·	
Information:					
10	Foreign Reference	10.PDF	2056394	no	42

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 117 of 630

Warnings:					
Information:					
11	Information Disclosure Statement (IDS) Filed	IDS-30207-702-501-04-06-0 6.pdf	341904	no	7
Warnings:					
Information:					
This is not an	USPTO supplied IDS fillable form				
12	NPL Documents	US30207-719-201.pdf	1852786	no	54
Warnings:					
Information:					
13	NPL Documents	US30207-702-503.pdf	4673537	no	64
Warnings:		I I_			
Information:					
14	NPL Documents	US30207-702-504.pdf	5800562	no	66
Warnings:					
Information:					
15	NPL Documents	US30207-718-201.pdf	2074084	no	42
Warnings:					
Information:					
16	NPL Documents	US30207-725-201.pdf	1868947	no	40
Warnings:		I			
Information:					
17	NPL Documents	US30207-727-201.pdf	1695717	no	38
Warnings:				·	
Information:					
		Total Files Size (in bytes):	30	832533	

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.

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.

- 1 -

A. \boxtimes 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) 1t 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. \Box 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. \Box 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.

 \square

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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

- 2 -

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 121 of 630

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. \boxtimes 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. \boxtimes 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.

2914360_1.DOC Attorney Docket No. 30207-702.501

 \square

- 3 -

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 122 of 630

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

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: July 2006

By: May

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 Office: U.S. DEPARTMENT OF COMMERCE U.S. Patent and

Under the	e paperwork Rea	duction Ac	t of 1995, no perso		formation unless it contains a valid OMB control number.			
				Complete if Known				
Substitute f	or form 1449)/PTO		Application Number	10/972,287			
INFORM	1ATION	DISCI	LOSURE	Filing Date	October 21, 2004			
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(Use as	s many sheet	s as nec	essary)	Art Unit	3738			
				Examiner Name	Unassigned			
Sheet	1	Of	2	Attorney Docket Number	30207-702.501			

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

	FOREIGN PATENT DOCUMENTS						
Examiner Cite Initials* No. ¹		Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date Name of Patentee or MM-DD-YYYY Applicant of Cited Document		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		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		Date	
Signature		Considered	
	11 110 Company with MPEP 600	Oraw line through	citation if not in conformance and not considered. Include copy

*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. ¹Applicant's unique citation designation number (optional). ⁵See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the patent document. ¹Kind of document by the appropriate symbols as indicated on the document, under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached. The information is attached. The information is attached to obtain or ratein a heast to the nublic which is to file (and by the USPTO to process) and

check mark here it 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.SC. 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. FORMS TO THIS ADORESS. 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.

2914360 1.DOC Attorney Docket No. 30207-702.501

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 124 of 630

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

				Complete if Known				
Substitute f	or form 144	19/PTO		Application Number	10/972,287			
INFORM	1ATION	DISCLO	OSURE	Filing Date	October 21, 2004			
	STATEMENT BY APPLICANT		First Named Inventor	Amr Salahieh				
(Use a.	s many shee	ets as neces	sary)	Art Unit	3738			
				Examiner Name	Unassigned			
Sheet	2	Of	2	Attorney Docket Number	30207-702.501			

	UNPUBLISHED PATENT APPLICATIONS	
Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	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)	
		Cite No.1 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. 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

Examiner		Date	
Signature		Considered	
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	and the second	1) Con Vinda Cod	ion of HEBTO Batant Doguments of yousy usedo you or MDED

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

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.

2914360 I.DOC Attorney Docket No. 30207-702.501

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 125 of 630

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

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

Warnings:					
Information	:				
This is not an	USPTO supplied IDS fillable form				
2	Foreign Reference	EP04.PDF	1025699	no	15
Warnings:				I	
Information	:				
3	Foreign Reference	WO96.PDF	1127284	no	34
Warnings:					
Information					
4	Foreign Reference	WO98.PDF	885222	no	24
Warnings:				•	
Information	:				
5	NPL Documents	722-501.PDF	2359623	no	36
Warnings:				1	
Information	:				
6	NPL Documents	723-201.PDF	1332786	no	33
Warnings:				I	
Information	:				
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02-01-07

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 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

AND

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)

	a Medical, Inca Delaware corporation	
	s that it is: the assignee of the entire right, title and interest; in the patent application	partnership, university, government agency, etc.) on/patent identified above by virtue of
A. 🗵	An assignment from the inventor(s) of the patent application/patent identified in the United States Patent and Trademark Office at Reel <u>016315</u> , Frame <u>0771</u> , attached.	
OR		
В.	A chain of title from the inventor(s), of the patent application/patent identified shown below:	-
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		office at
	Reel, Frame, or for which a copy thereof is attached.	
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I om on	in authorized representative of the:	
	Assignee of record of the entire interest. See 37 CFR 3.71. Statement under AT CFR 3. 3(4) is incorporated herein.	
	Sutement under of CFR 5. Add is incorporated herein.	
	SIGNATURE of Assignee of Record	
Signatur	ire reoal Child	
Name/Ti	Title Amr Salahieh, CEO	
Date	1 29 2007 Telephone No.	(408) 370-1550

3036554_1.DOC

UNITED STAT	tes Patent and Tradema	UNITED STA United State Addres: COMMI P.O. Box	ia, Virginia 22313-1450
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

Date Mailed: 02/12/2007

OC00000022469889

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 STATE	s Patent and Tradema	UNITED STA United State: Addres: COMMI PO. Box	a, Virginia 22313-1450
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
6854 HAY LAW GROUP, LLP 755 CAMPUS DRIVE UITE 210		*0C000000	

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.

SAN MATEO, CA 94403

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

OFFICE COPY

2007 Under the Paperwork Reduction Ac TRANSMITTAL FORM		Application Number		10/972,287
TRANSMITTAL		Filing Date		October 21, 2004
FORM		First Named Invento		Amr Səlahieh
		Art Unit		3738
		Examiner Name		William H. Matthews
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Fee Transmittal Form				After Allowance Communication
Fee Attached		ng-related Papers		Appeal Communication to Board of Appeals and Interferences
Amendment / Reply	Petition		ו	Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
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Extension of Time Request	Terminal Disclaimer		[Other Enclosure(s) (please identify below):
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Information Disclosure Statement		mber of CD(s) andscape Table on CD		
Certified Copy of Priority Document(s)	Remarks		I	
Reply to Missing Parts/ Incomplete Application				
Reply to Missing Parts under 37 CFR1.52 or 1.53				
SIGN	ATURE O	F APPLICANT, ATTOR	NEY, OR	AGENT
Firm	Shay Law Gr	oup LLP		
Signature	7	13		
Printed Name	Thomas Zlog	ar	·	
Date	3[15]	07	Reg. No.	55,760
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I hereby certify that this corresponden Service with sufficient postage as fin	ce is being f st class mai	acsimile transmitted to th	e USPTO c sed to: Co	or deposited with the United States

TAU

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 epplication. 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 Petents, P.O. Box 1450, Alexandria, VA 22313-1450.

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



Docket No. 10012-702.501

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 \S 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 \S 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,

 \square 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.

<u>CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.98</u>

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

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

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

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

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

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

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

37 CFR §1.98 (a)(2)(i) Foreign patent(s) in English cited A legible copy of each foreign patent is attached.

37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) Foreign patent(s) or other foreign documents not in English cited

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

--AND--

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

--OR---

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

STATEMENT UNDER 37 CFR § 1.97(e)

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

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

FEE AUTHORIZATION

The Commissioner is hereby authorized to charge the above-referenced fees of \$00.0 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

JUS 07-Dated: Shay Law Group 2755 Campus Drive, Suite 21

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

PTO/SB/08A (09-06) Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent end Trademark Office; U.S. DEPARTMENT OF COMMERCE

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ARRAN TANK Substitute for form 1449/PTO

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Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 12

Coi	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					
Attomey Docket Number	10012-702.501					

			U. S. PATEN	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	366	^{US-} 2003/0233117-A1	12/18/2003	Adams et al.	
	364	^{US-} 2004/0153094-A1	08/05/2004	Dunfee et al.	
	367	^{US-} 2005/0107822-A1	05/19/2005	WasDyke, Joel	
	368	^{US-} 6,610,077	08/26/2003	Hancock et al.	
	369	^{US-} 6,790,229	09/14/2004	Berreklouw, Eric	
	365	^{US-} 6,969,395	11/29/2005	Eskuri et al.	
	363	^{US-} 6,361,545	03/26/2002	Macoviak et al.	
	142	^{US-} 5,064,435	11/12/1991	Porter	
	262	^{US-} 6,712,843	03/30/2004	Elliott	
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		FOREI	GN PATENT DOCU	MENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Τ ⁶
	<u> </u>					
	-					
Examinar				Date		

Examiner Signature

*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. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant 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 gethering, 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 end/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexendria, 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.

Considered

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 Under the Peperwork 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		Compiete if Known
	Application Number	10/972,287
INFORMATION DISCLOSURE	Filing Date	October 21, 2004
STATEMENT BY APPLICANT	First Named Inventor	Amr Salahieh
(Use as many sheets as necessary)	Art Unit	3738
	Examiner Name	William H. Matthews
Sheet 2 of 2	Attorney Docket Number	10012-702.501

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

Examiner Signature

*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.

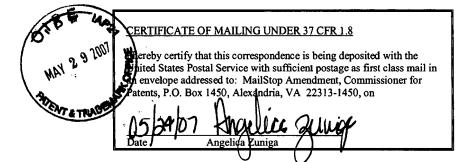
Date

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TRANSMITTAL FORM Filing Date October 21, 2004 Filing Date October 21, 2004 Filing Date Amr Salahieh Art Unit 3738 Ito be used for all correspondence after Initial filing) Examiner Name William H. Matthews Ital Number of Pages In This Submission 5 Attorney Docket Number 10012-702.501 ENCLOSURES (check all that apply Ge et all correspondence after Initial filing) Examiner Name William H. Matthews Interview of Pages In This Submission 5 Attorney Docket Number 10012-702.501 ENCLOSURES (check all that apply Ge et attorney Theorem Other Allowance Communication to Doard of Appeal Communication to Doard of Appeal Communication to Doard of Appeal Communication to TO (Appeal Notce, Biref, Reply Biref) Aftidevits/declaration(s) Pretition Proprietary Information Proprietary Information Proprietary Information Status Letter Extension of Time Request Request for Refund CO, Number of CD(s)	N BI			Application Number	er 🗌	10/972,287
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(b be used for all correspondence after hills) filing) Examiner Name William H. Matthews tal Number of Pages in This Submission 5 Attorney Docket Number 10012-702.501 Fee Transmittal Form Drawing(s) After Allowance Communication to TC Pee Attached Licensing-related Papers After Allowance Communication to Board of Appeals and Interferences Amendment / Reply Petition Appeal Communication to TC (Appeal Communication to TC Comvisional Application After Final Power of Attorney, Revocation Charge of Correspondence Address Status Letter Extension of Time Request Terminal Disclaimer Other Enclosure(s) (please identify below); Postcard C.D, Number of CD(S) Postcard Information Disclosure Statement Landscape Table on CD Postcard Reply to Missing Parts under 37 CFR1.52 or 1.53 Status Group LLP Stay Group LLP Signature Thomas Zlogar Thomas Zlogar 55,760 CerrificAt Port th tub scorrespondence is being facismilite transmitted to the USPTO or deposited with the United States Postal Stores Address intell in an envelope addressed to: Communication to Poste Postismes Addresse income to Poste Postismes Address Information Disclosure Statement Landscape Table on CD 55,760 CerrifieCATE	S/ FORM				tor	
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Fee Transmittal Form Drawing(s) After Allowance Communication to TC Fee Attached Licensing-related Papers After Allowance Communication to Board of Appeals and Interferences Amendment / Reply Petition Appeal Communication to Board of Appeals and Interferences After Allowance Communication to Covert to a Provisional Application Provisional Application Provisional Application Affidavits/declaration(s) Power of Attomey, Revocation Change of Correspondence Address Status Letter Extension of Time Request Terminal Disclaimer Other Enclosure(s) (please idantify below): Information Disclosure Statement C.D. Number of CD(s) Postcard Incomplete Application Remarks Signature Remarks Signature Signature Status Correspondence to the USPTO or deposite with the United States Postal service with stiffer or patents, P.O. Box 1450. Date S/24 / 0.7 Reg. 55,780 CERTIFICATE OF TRANSMISSION/MAILING Description an envelope addressed to: Commissioner for yeaters, P.O. Box 1450.			ENCLO	SURES (check all that	t apply)	
□ Fee Attached □ Licensing-related Papers □ Appeal Communication to Board of Appeals and Interferences □ Amendment / Reply □ Petition □ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) □ After Final □ Petition to Convert to a Provisional Application □ Proprietary Information □ Affidavits/declaration(s) □ Power of Attomey, Revocation Change of Correspondence Address □ Status Letter □ Affidavits/declaration(s) □ Terminal Disclaimer ☑ Other Enclosure(s) (plasse identify beiow): Postcard □ Express Abandonment Request □ Request for Refund □ CD, Number of CD(s) Postcard □ Information Disclosure Statement □ Landscape Table on CD Postcard □ Reply to Missing Parts/ □ Landscape Table on CD Stignature □ Signature □ Shey Law Group LLP Signature Stignature □ Stignature □ Stignature Stignature Stignature □ Date Stignature Stignature Stignature	Fee Transmittal Form					After Allowance Communication to TC
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□ Arter Pinal □ Provisional Application □ Propretary Information □ Affidavits/declaration(s) □ Provisional Application □ Propretary Information □ Affidavits/declaration(s) □ Terminal Disclaimer □ Status Letter □ Extension of Time Request □ Terminal Disclaimer □ Other Enclosure(s) (please (dentify below): □ Express Abandonment Request □ Request for Refund □ Dother Enclosure(s) □ Information Disclosure Statement □ Landscape Table on CD □ Postcard □ Certified Copy of Priority Document(s) Remarks □ Remarks Signature □ Signature OF APPLICANT, ATTORNEY, OR AGENT Firm Shay Law Group LLP Signature □ S/24 / 0 7 □ Date \$/24 / 0 7 □ Status Sion/IMAILING hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal sories own for Patents, P.O. Box 1450,	Amendment / Reply					
L Affidavits/declaration(s) Change of Correspondence Address Status Letter Extension of Time Request □ Terminal Disclaimer Other Enclosure(s) Express Abandonment Request □ Request for Refund □ CD, Number of CD(s) Information Disclosure Statement □ Landscape Table on CD Postcard Certified Copy of Priority Document(s) □ Remarks Postcard Reply to Missing Parts/ under 37 CFR1.52 or 1.53 Remarks Incomplete Application Firm Signature Signature Printed Name Thomas Zlogar Date \$2/24/07 Reely certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal is now evelope addressed to: Commissioner for Patents, P.O. Box 1450, No. 1450	After Final					Proprietary Information
Extension of Time Request Request Request for Refund Request for Refund Express Abandonment Request Request for Refund Postcard Information Disclosure Statement Landscape Table on CD Postcard Certified Copy of Priority Document(s) Remarks Remarks Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR1.52 or 1.53 Reply to Missing Parts Signature Shay Law Group LLP Shay Law Group LLP Signature Thomas Zlogar Date S/24 /07 Reg. No. 55,760 CERTIFICATE OF TRANSMISSION/MAILING States Postal service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450,	Affidavits/declarati	on(s)			ress	Status Letter
Express Abandonment Request Information Disclosure Statement Information Disclosure Statement Landscape Table on CD Certified Copy of Priority Remarks Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Shay Law Group LLP Signature Thomas Zlogar Date S/24 / 07 Reg. Date S/24 / 07 Reg. Normal Signature State of the USPTO or deposited with the United States Postal hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal	Extension of Time Rec	luest	Terminal	ninal Disclaimer		
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Certified Copy of Priority Document(s) Remarks Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Signature Of Application Signature Image: Shay Law Group LLP Signature Image: Signature Date S/24 / 07 Reg. No. 55,760 CERTIFICATE OF TRANSMISSION/MAILING 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,	Information Disclosure	Statement				
Incomplete Application Reply to Missing Parts under 37 CFR1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Shay Law Group LLP Signature Image: Signature Printed Name Thomas Zlogar Date S/24/07 Reg. No. 55,760 CERTIFICATE OF TRANSMISSION/MAILING 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,		ity				
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Signature Thomas Zlogar Date S/24/07 Reg. No. 55,760 CERTIFICATE OF TRANSMISSION/MAILING 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,		SIG	NATURE OF	APPLICANT, ATTOR	RNEY, OF	AGENT
Printed Name Thomas Zlogar Date S/24/07 Reg. No. 55,760 CERTIFICATE OF TRANSMISSION/MAILING 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,	Fim		Shay Law Grou	ıp LLP		
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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,	Date		5/24	107		55,760
Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450,			CERTIFICA	TE OF TRANSMISS	ION/MAIL	ING
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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 end 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 \S 1.53(d),

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

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

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

37 CFR § 1.97(c)

This statement is being filed after the latest of:

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

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

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

A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement
 B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

37 CFR § 1.97(d)

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

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

--AND---

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

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

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

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

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

37 CFR §1.98 (a)(2)(i) Foreign patent(s) in English cited A legible copy of each foreign patent is attached. 37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) Foreign patent(s) or other foreign documents not in English cited

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

--AND---

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

--OR---

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

STATEMENT UNDER 37 CFR § 1.97(e)

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

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

FEE AUTHORIZATION

The Commissioner is hereby authorized to charge the above-referenced fees of 0.0 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 0.4050.

Dated:

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

Respectfully Submitted,

Bv

Thomas Zlogar Reg. # 55760

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AVEN	TRADE				Application Number	10/972,287	
	INFO	ORMATION	I DIS	CLOSURE	Filing Date	October 21, 2004	
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		lose as many site			Examiner Name	William H. Matthews	
,	Sheet	1	of	1	Attorney Docket Number	10012-702.501	

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²			
	374	Haug, et al; U.S. Pat App. # 11/716,123, entitled "Methods and apparatus for endovascularly replacing a heart valve," filed 3/9/2007 (SLG #10012-701.301).				
	372	SALAHIEH, et al; U.S. Pat App. # 11/706,549, entitled "Systems and Methods for Delivering a Medical Implant," filed 2/14/2007 (SLG #10012-732.201).				
	373	Salahieh, et al; U.S. Pat App. # 11/732,906 entitled "Assessing the location and performance of replacement heart valves," filed 4/4/2007 (SLG #10012-702.505).				
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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 conformence and not considered. Include copy of this form with next communication to applicant.

1 Applicent's unique citation designation number (optional). 2 Applicent 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 getharing, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individuel 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. Petent 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.

07/12/2007 THU 10:24 FAX 16502127562

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Under the Paperwork Reduction Act of 1995. TRANSMITTAL FORM (to be used for all correspondence after initial fil	Filing Date Filing Date First Named Inventor Art Unit Examiner Name	PTO/SB/21 (04-07) Approved for use through 09/30/2007. OMB 0651-0031 Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Inction of Information unless it displays a valid OMB control number. 10/972,287 October 21, 2004 Amr Salahieh 3738 MATTHEWS, WILLIAM H								
	Attomey Docket Number	10012-702.501								
Total Number of Pages in This Submission 5										
ENCLOSURES (Check all that apply)										
Fee Transmittal Form Fee Atteched Amendment/Reply After Finel Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Diaclosure Statement Certified Copy of Priority Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53		Address Status Letter Other Enclosure(s) (plaase identify below):								
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SIGNAT	URE OF APPLICANT, ATTO	RNEY, OR AGENT								
Shaw Law Group LLP	×									
Signature										
Printed neme Thomas Zlogar										
Date 7/12/07	F	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 commenta on the amount of time you require to complete his form end/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: Commissionar 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.

PAGE 1/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/2 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-46

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 142 of 630

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
Dato Averlice Zunige

Docket No.10012-702.501

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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.

PAGE 2/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/2 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-46

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 143 of 630

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:

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

37 CFR § 1.97(d)

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

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

-AND-

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

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

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

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

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

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

PAGE 3/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/2 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-46

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 144 of 630

Docket No.10012-702.501

] 37 CFR §1.98 (a)(2)(l) 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.

1/12/0

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

Dated:

Respectfully Submitted,

Thomas Zlogar Reg. # 55760

PAGE 4/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/2 * DNIS:2738300 * CSID:18502127562 * DURATION (mm-ss):02-46

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 145 of 630

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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. Complete If Known

Substitute for form 1449/PTO Application Number 10/972,287 Filing Date October 21, 2004 INFORMATION DISCLOSURE First Named Inventor Amr Salahieh STATEMENT BY APPLICANT Art Unit 3738 (Use as many sheets as necessary) MATTHEWS, WILLIAM H Examiner Name 10012-702.501 Attorney Docket Number Sheet 11 of 1

	U. S. PATENT DOCUMENTS						
Examiner Initiale*	Cite No.1	Document Number Number-Kind Code ² ^(7 Incord)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pegee, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	375	^{US-} US 5,824,041 A	10/20/1998	Lenker, et el.			
	376	^{US-} US 6,863,668	03/08/2005	Gillespla et al.			
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		FOREIGI	N PATENT DOCU	MENTS		
Examiner Iniliais*	Cite No.1	Foreign Petent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code [®] "Number [®] "Kind Code [®] (If known)	MM-DD-YYYY		Or Relevant Figures Appear	
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Signature	Considered
*EXAMINER:	Initial If reference considered, whather or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and no
considared. I	Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional), 2 See Kinds Codes of
USPTO Pate	ant Documents at www.uspto.gov or MPEP 901.04. * Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). * F

Japanese patent documents at <u>www.uspto.dov</u> or MPEP 901.04. "Enter Office that issued the document, by the two-latter code (WIPO Standard ST.3). "For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. "Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible." Applicant is to place a check mark here if English language Translation is attached.

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 commenta 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, Alexandrie, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandrie, the form call 1.800-PTC-9199 (1.800-786-9199) and select onlion 2

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

PAGE 5/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daylight Time] * SVR:USPTD-EFXRF-1/2 * DNIS:2738300 * CSID: 16502127562 * DURATION (mm-ss):02-46

2005/005

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 146 of 630

Under the Pa	aperwork Reduction Act of 1995. no p	ersons are required to respond to a co Application Number	llection_of inf	rademark Office; U.S. DEPARTMENT OF COMMERCE formation unless it displays a valid OMB control number.		
TF 🎽	RANSMITTAL	Filing Date	October 2	1, 2004		
	FORM	First Named Inventor	Amr Salah	ieh		
		Art Unit	3774			
(to be used for	r all correspondence after initial filing)	Examiner Name	MATTHEV	VS, WILLIAM H		
	of Pages in This Submission 5	Attorney Docket Number	10012-702	2.501		
Totar Number 0						
	E	NCLOSURES (Check all	that apply			
Fee Trar	ismittal Form	Drawing(s)		After Allowance Communication to TC		
F	ee Attached	Licensing-related Papers		Appeal Communication to Board of Appeals and Interferences		
Amendm	ent/Reply	Petition		Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)		
		Petition to Convert to a				
	fter Final	 Provisional Application Power of Attorney, Revocation 		Proprietary Information		
	ffidavits/declaration(s)	Change of Correspondence Address Catus Letter Other Enclosure(s) (please Id				
Extensio	n of Time Request	Terminal Disclaimer		below):		
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 Informati 	on Disclosure Statement					
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Incomple	Missing Parts/ te Application					
	teply to Missing Parts nder 37 CFR 1.52 or 1.53					
	SIGNATUR	RE OF APPLICANT, ATTO	RNEY, C	DR AGENT		
Firm Name	Shay Glenn LLP					
Signature Printed name Printed name Thomas Zlogar Date 11/16/07				,		
		Reg. No. 55,760				
	CERT	IFICATE OF TRANSMISS	ION/MAI	LING		

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

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

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 E	ELEMENTS AND METHODS FOR USE
	THEREOF	
Customer No.:	66854	

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

<u>INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.97 & § 1.98</u>

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)

 \boxtimes

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:

 \square 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 \square 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.

<u>CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.98</u>

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

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

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

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

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

2). A copy of each application specification is not submitted because the specification was previously submitted in the 1DS 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

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

	\square	37 CFR	§1.98 (a)(2)(i) and (d)	. Foreign patent(s	i) in	English	cite
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 \square 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,

Bv:

Thomas Zlogar Reg. # 55760

Dated: 11/16/07

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

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 150 of 630

PTO/SB/08A (04-07) Approved for use through 09/30/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Sheet 1

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

of

Cor	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					

				DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	380	^{US-} 5,720,391 A	2/24/1998	Dohm et al.	
	377	^{US-} 6,712,842	3/30/2004	Gifford et al.	
	384	^{US-} 7,018,406	3/28/2006	Seguin et al.	
	381	^{US-} 2001/0044656 A1	11/22/2001	Williamson et al.	
	382	^{US-} 2002/0032481 A1	3/14/2002	Gabbay, Shlomo	
	379	^{US-} 2002/0120328 A1	8/29/2002	Pathak et al.	
-	378	^{US-} 2004/0215331	10/28/2004	Chew et al.	
	383	^{US-} 2006/0259134 A1	11/16/2006	Schwammenthal et al.	
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		FOREIG	ON PATENT DOCU	JMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T ⁶
	385	WO 02/0041789 A2	5/30/2002	Rex Medical, L. P.		

Examiner Signature Date Considered

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

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

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

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	

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:

 \square 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 \square 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.

<u>CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.98</u>

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 1FW.

37 CFR §1.98 (a)(2)(iii) and (d), 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.
 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:

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 153 of 630

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.

2/14/08 Dated:

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

Respectfully Submitted By:

Thomas Zlogar Reg. # 55760

PTO/SB/08A (04-07)

Approved for use through 09/30/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	394	US- 5,443,499	08/22/1995	Schmitt, Peter	
	395	^{US-} 5,824,055	10/20/1998	Spiridigliozzi et al.	
	396	^{US-} 6,893,459 B1	05/17/2005	Macoviak, John	
		US-			
		US-			
		ÚS-			
		US-			

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

Signature

*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. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the

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.

Considered

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

Payment information:

Submitted wi	th Payment	no			
File Listir	ng:				
Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-702501.pdf	225675	Vec	4
I		10012-702001.pdf	04d75087e8eb7d2ac17ead75612a458d 93e2c9a3	yes	4

	Multipart Description/PDF files in .zip description					
	Document Description	Start	End			
	Information Disclosure Statement Letter	1	3			
	Information Disclosure Statement (IDS) Filed	4	4			
Warnings:						
Information						
	Total Files Size (in bytes):	225	5675			
characterize similar to a	vledgement Receipt evidences receipt on the noted date by the od by the applicant, and including page counts, where applicable Post Card, as described in MPEP 503.					
characterize similar to a <u>New Applica</u> If a new app 37 CFR 1.53	d by the applicant, and including page counts, where applicable	e. It serves as ev y components for ued in due course	ridence of receipt r a filing date (see			
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Receipt will establish the international filing date of the application.

Unit	ed States Patent 4	AND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.usplo.gov	FOR PATENTS
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 SHAY GLENN 2755 CAMPUS			EXAM WALKER, A	
SUITE 210 SAN MATEO,	CA 94403		ART UNIT	PAPER NUMBER
Statimates,	en y Hos		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.

		Application No.	Applicant(s)
		10/972,287	SALAHIEH ET AL.
	Office Action Summary	Examiner	Art Unit
		AMANDA H. WALKER	3774
Period fo	The MAILING DATE of this communication ap or Reply	pears on the cover sheet with t	the correspondence address
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL CHEVER IS LONGER, FROM THE MAILING E nsions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statut reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICA 136(a). In no event, however, may a reply will apply and will expire SIX (6) MONTHS e, cause the application to become ABAND	TION. be timely filed S from the mailing date of this communication. DONED (35 U.S.C. § 133).
Status			
1)🖂	Responsive to communication(s) filed on 21 (October 2004.	
·		s action is non-final.	
3)	/		, prosecution as to the merits is
,	closed in accordance with the practice under	-	
Disposit	ion of Claims		
•	Claim(s) <u>1-58</u> is/are pending in the application	ı	
	4a) Of the above claim(s) is/are withdra		
	Claim(s) is/are allowed.		
	Claim(s) is/are rejected.		
	Claim(s) is/are objected to.		
· · · · ·	Claim(s) $1-58$ are subject to restriction and/or	election requirement.	
·	ion Papers		
· · _	•		
	The specification is objected to by the Examin		
10)	The drawing(s) filed on is/are: a)∏ ac		
	Applicant may not request that any objection to the		
	Replacement drawing sheet(s) including the correct		
11)	The oath or declaration is objected to by the E	xaminer. Note the attached O	ffice Action or form PTO-152.
Priority (ınder 35 U.S.C. § 119		
	Acknowledgment is made of a claim for foreig ☐ All b)	n priority under 35 U.S.C. § 11	19(a)-(d) or (f).
a)	1. Certified copies of the priority documen	ts have been received	
	2. Certified copies of the priority document		lication No
	3. Copies of the certified copies of the prior		
	application from the International Burea	•	ceived in this National Stage
* (See the attached detailed Office action for a lis		solved
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Attachmen	t(s)		
	e of References Cited (PTO-892)	4) 🔲 Interview Sum	mary (PTO-413)
2) 🔲 Notic	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/M	lail Date
	mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	5) 🛄 Notice of Inform 6) 🛄 Other:	mal Patent Application
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PTOL-326 (F		ction Summary	Part of Paper No./Mail Date 20080310

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DETAILED ACTION

Election/Restrictions

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

- 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 <u>and</u> 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;

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- (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.

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

Application/Control Number: 10/972,287 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).

Application/Control Number: 10/972,287 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 NUN	IRFR	FILING or	371(c)		CLASS	GR	OUP ART		ΑΤΤΟ	RNEY DOCKET
10/972,28		DAT 10/21/2	EÍ		623		3774	UNIT		NO. 0012-702.501
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Foreign Priority claim 35 USC 119(a-d) con	ditions met		Met af Allowa	ter ince	STATE OR COUNTRY	-	IEETS WINGS	TOT. CLAII		INDEPENDENT CLAIMS
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TITLE										
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FILING FEE						ng Ext. of time)				
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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 M	fethods for Use Thereo:	f
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.

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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.

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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 selfexpanding anchor.

15. (Withdrawn) The apparatus of claim 12 wherein the anchor comprises a selfexpanding 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.

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16. (Withdrawn) The apparatus of claim 12 wherein the anchor comprises a selfexpanding 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;

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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:

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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.

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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.

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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 selfexpanding anchor.

52. (Withdrawn) The apparatus of claim 49 wherein the anchor comprises a selfexpanding 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 selfexpanding 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.

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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.

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<u>REMARKS</u>

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).

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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.

By:

Respectfully submitted,

Date: April 21, 2008

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

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 176 of 630

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

Payment information:

Submitted wi	th Payment	no			
File Listir	ng:				
Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		10012-702-501-Response-R	1016354	Vec	11
		estriction.pdf	3253d7e0a54a13e1e8eb70eed354393 6ec8b4f50	yes	

	Multipart Description/PDF files in .zip description					
	Document Description	Start	End			
	Response to Election / Restriction Filed	1	1			
	Claims	2	9			
	Applicant Arguments/Remarks Made in an Amendment	10	11			
Warnings:		1				
Information:						
	Total Files Size (in bytes):	10	16354			

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

P/				to a collection of information unle Application or Docket Number 10/972,287			plays a valid ing Date 21/2004	To be Mailed				
APPLICATION AS FILED – PART I (Column 1) (Column 2)							SMALL ENTITY			OTHER THAN OR SMALL ENTITY		
	FOR	N	NUMBER FILED		NUMBER EXTRA		RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)	
	BASIC FEE (37 CFR 1.16(a), (b),	or (c))	N/A		N/A		N/A			N/A		
	SEARCH FEE (37 CFR 1.16(k), (i), (or (m))	N/A		N/A		N/A			N/A		
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A			N/A		
	FAL CLAIMS CFR 1.16(i))		min	us 20 = *	= *		X \$ =		OR	X \$ =		
	EPENDENT CLAIM CFR 1.16(h))	S	minus 3 =		*		X \$ =			X \$ =		
	APPLICATION SIZE (37 CFR 1.16(s))	FEE shee is \$2 addit	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
	MULTIPLE DEPEN		,	3,,								
* If the difference in column 1 is less than zero, enter "0" in column 2.							TOTAL			TOTAL		
APPLICATION AS AMENDED – PART II (Column 1) (Column 2) (Column 3)							SMAL	L ENTITY	OR		ER THAN ALL ENTITY	
AMENDMENT	04/21/2008	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	additional Fee (\$)		RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 58	Minus	** 58	= 0		X \$25 =	0	OR	X \$ =		
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0		X \$105 =	0	OR	X \$ =		
	Application Size Fee (37 CFR 1.16(s))											
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								OR			
						• •	TOTAL ADD'L FEE	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 (\$)		RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=		X \$ =		OR	X \$ =		
	Independent (37 CFR 1.16(h))	*	Minus	***	=		X \$ =		OR	X \$ =		
	Application Size Fee (37 CFR 1.16(s))											
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								OR			
							TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
** If *** I The This c	the entry in column the "Highest Numb f the "Highest Numb "Highest Number P collection of informal	er Previously Paid per Previously Paid reviously Paid For tion is required by	For" IN TH For" IN T " (Total or 37 CFR 1.	IS SPACE is less HIS SPACE is less Independent) is the 16. The information	than 20, enter "20" 5 than 3, enter "3". e highest number f n is required to obt	oun ain e	/CORAL d in the appro or retain a ber	efit by the public	DURT/ mn 1. which is	s to file (and b	y the USPTO to 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, 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						

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

<u>INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.97 & § 1.98</u>

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

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

 \Box 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:

 \square 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 \square 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.

<u>CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.98</u>

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

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

6/9/08 Dated:

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

Respectfully Submitted. Bv:

Thomas Zlogar Reg. # 55760

PTO/SB/08A (04-07)

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

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Substitute for form 1449/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 2

Complete if Known					
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				

			U. S. PATEN	F DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	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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		FOREIG	N PATENT DOCU	MENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ^{4 -} Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
;'	'	Country Code Number Kind Code (ir 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. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English lenguage 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 (04-07)

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

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

Complete if Known			
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		
	Filing Date First Named Inventor Art Unit Examiner Name		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	399	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.	
· .			

Examiner Signature

Considered

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

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

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

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

Date

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

Payment information:

Submitted with Payment		no	no				
File Listir	ng:						
Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)		
1	4	10012-702501.pdf	288035	Vec	5		
		10012-702501.pdf	8fab94635aa7b804efa8c304837af81e2 2a73815	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							
	Total Files Size (in bytes):	288	8035				
characterize similar to a	vledgement Receipt evidences receipt on the noted date by the d by the applicant, and including page counts, where applicabl Post Card, as described in MPEP 503.						
characterize similar to a <u>New Applica</u> If a new app 37 CFR 1.53 shown on th	d by the applicant, and including page counts, where applicabl Post Card, as described in MPEP 503. <u>ations Under 35 U.S.C. 111</u> lication is being filed and the application includes the necessar (b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be iss his Acknowledgement Receipt will establish the filing date of the	e. It serves as ev y components for ued in due course	idence of receipt r a filing date (see				
characterize similar to a <u>New Applica</u> If a new app 37 CFR 1.53 shown on th <u>National Sta</u> If a timely so of 35 U.S.C.	d by the applicant, and including page counts, where applicabl Post Card, as described in MPEP 503. <u>Ations Under 35 U.S.C. 111</u> lication is being filed and the application includes the necessar (b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issu is Acknowledgement Receipt will establish the filing date of the <u>ge of an International Application under 35 U.S.C. 371</u> Jubmission to enter the national stage of an international applica 371 and other applicable requirements a Form PCT/DO/EO/903 as a national stage submission under 35 U.S.C. 371 will be issue	e. It serves as ev y components for ued in due course application. tion is compliant indicating accept	idence of receipt r a filing date (see and the date with the condition ance of the				

Receipt will establish the international filing date of the application.

Unit	ED STATES PATENT	AND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.uspto.gov	FOR PATENTS
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004	Amr Salahieh	10012-702.501	7706
SHAY GLENN 2755 CAMPUS			EXAM	
SUITE 210 SAN MATEO,	CA 94403		ART UNIT	PAPER NUMBER
Sin (Miribo,			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.

		Application No.	Applicant(s)
		10/972,287	SALAHIEH ET AL.
	Office Action Summary	Examiner	Art Unit
		REBECCA STRASZHEIM	3738
Period f	The MAILING DATE of this communication ap or Reply	ppears on the cover sheet with th	he correspondence address
WHI - Exte afte - If N - Faile Any	ORTENED STATUTORY PERIOD FOR REPL CHEVER IS LONGER, FROM THE MAILING I ensions of time may be available under the provisions of 37 CFR 1 r SIX (6) MONTHS from the mailing date of this communication. D period for reply is specified above, the maximum statutory period ure to reply within the set or extended period for reply will, by statu reply received by the Office later than three months after the mailin and patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICAT .136(a). In no event, however, may a reply b d will apply and will expire SIX (6) MONTHS te, cause the application to become ABANDO	TON. be timely filed from the mailing date of this communication. ONED (35 U.S.C. § 133).
Status			
1)🖂	Responsive to communication(s) filed on $\frac{4/2}{2}$	1/2008.	
		is action is non-final.	
3)	Since this application is in condition for allow	ance 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.
Disposit	ion of Claims		
4)	Claim(s) <u>1-58</u> is/are pending in the application	n.	
	4a) Of the above claim(s) <u>1-21 and 38-58</u> is/a		n.
5)	Claim(s) is/are allowed.		
6)🖂	Claim(s) <u>22-37</u> is/are rejected.		
7)	Claim(s) is/are objected to.		
8)	Claim(s) are subject to restriction and/	or election requirement.	
Applicat	ion Papers		
 9)□	The specification is objected to by the Examin	ier.	
· ·	The drawing(s) filed on <u>21 October 2004</u> is/ar		ted to by the Examiner.
	Applicant may not request that any objection to the	e drawing(s) be held in abeyance.	See 37 CFR 1.85(a).
	Replacement drawing sheet(s) including the correct	ction is required if the drawing(s) is	s objected to. See 37 CFR 1.121(d).
11)	The oath or declaration is objected to by the E	Examiner. Note the attached Off	fice Action or form PTO-152.
Priority	under 35 U.S.C. § 119		
12)	Acknowledgment is made of a claim for foreig	n priority under 35 U.S.C. § 119	9(a)-(d) or (f).
	All b) Some * c) None of:		
	1. Certified copies of the priority documer	nts have been received.	
	2. Certified copies of the priority documer	nts have been received in Appli	cation No
	3. Copies of the certified copies of the price	ority documents have been rec	eived in this National Stage
	application from the International Burea	· · · · ·	
*	See the attached detailed Office action for a lis	t of the certified copies not rece	eived.
Attachmer	nt(s)		
	ce of References Cited (PTO-892)	4) 🔲 Interview Summ	
	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Ma 5) 🔲 Notice of Inform	nil Date nal Patent Application
Pape	er No(s)/Mail Date 6/10/2008, 2/14/2008, 11/19/2007, 7/12	2/2007, 6) Other:	
	<u>3/19/2007, 7/12/2006, 4/6/2006, 10/28/2005, 6/30/2005, 4</u> <u>11/26/2004</u> .	4/2//2005 <u>,</u>	
U.S. Patent and	Trademark Office		

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 189 of 630

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
- I. 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

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
- II. 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

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 bee 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 ablumenal graft portion (11b) (column 6, lines 18-24). The ablumenal 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,

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 negatived 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

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 used 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.

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

Notice of References Cited	Application/Control No. 10/972,287	Applicant(s)/F Reexaminatic SALAHIEH E	on
Notice of References Offen	Examiner	Art Unit	
	REBECCA STRASZHEIM	3738	Page 1 of 1
	DATENT DOCUMENTO		

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	А	US-6,458,153	10-2002	Bailey et al.	623/1.24
*	В	US-5,476,506	12-1995	Lunn, Anthony C.	623/1.28
	С	US-			
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*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.

Notice of References Cited

Part of Paper No. 20080811

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
L6	28	623/1.28.ccls. AND stent	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/08/12 08:47
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Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 203 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My%...2287/EASTSearchHistory.10972287_AccessibleVersion.htm (5 of 6)8/12/2008 9:37:34 AM

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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

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	Index of C	Claims		10972287					SALAHIEH ET AL.				
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	Application/Control No.	Applicant(s)/Patent Under Reexamination				
Search Notes	10972287	SALAHIEH ET AL.				
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	REBECCA STRASZHEIM	3738				

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Class	Subclass	Date	Examiner
	623/1.28	8/12/2008	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

	INTERFERENCE SEA	RCH	
Class	Subclass	Date	Examiner

10972287 - GAU: 3738

PTO/SB/08A (04-07)

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

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

Substitute for form 1	449/PTO	Col	mplete if Known
		Application Number	10/972,287
	TION DISCLOSURE	Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
STATEME	ENT BY APPLICANT	Art Unit	3774
(Use as	many sheets as necessary)	Examiner Name	MATTHEWS, WILLIAM H
Sheet 1	of 1	Attorney Docket Number	10012-702.501

Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	No.1	Number-Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
	394	^{US-} 5,443,499	08/22/1995	Schmitt, Peter	
	395	^{US-} 5,824,055	10/20/1998	Spiridigliozzi et al.	
	396	^{US-} 6,893,459 B1	05/17/2005	Macoviak, John	
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Examiner Signature

re /Rebecca Straszheim/

*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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant 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 208 of 630

Date

Considered

08/18/2008

Receipt date: 02/22/2005



PATENT Attorney Docket No. 30207.702.501

TRADEMARK OFFICE

)

In re Application Inventor(s): Amr SALAHIEH et al. Application No.: 10/972,287 Filed: October 21, 2004 Title: Leaflet engagement elements and methods for use thereof PATENT APPLICATION

Art Unit: 3738

Examiner: Not yet assigned

Confirmation No.: 7706

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:

- 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.
- \bigcirc 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 $\S1.97(e)$ 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. <u>23-2415 (Docket No.30207.702.501)</u>.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

100/06 Dated:

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

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

10972287 - GAU: 3738

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.

				Con	nplete if Known
Substitute fo	Substitute for form 1449/PTO		Application Number	10/972,287	
INFORM	IATION	DISC	LOSURE	Filing Date	10/21/2004
			LICANT	First Named Inventor	Salahieh
(Use as	r many sheet	ts as neo	cessary)	Art Unit	3738
				Examiner Name	Not yet assigned
Sheet	1	of	1	Attorney Docket Number	30207.702.501

U.S. PATENT DOCUMENTS

Examiner	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	5	US-2004/0186563	09/23/2004	Lobbi	
	121	US-5,554,185	09/10/1996	Block et al.	,
EB 2 2 000	L.			·	
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		FOREIGN	PATENT DC	CUMENTS			
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of P Applicant of Ci		Pages, Columns, Lines, Where Relevant Passages or	T
		Country Code3 - Number4 - Kind Code3 (if known)	1			Relevant Figures Appear	
		EP 1000590A1	05/17/2000	Cordis Corp	oration		
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		1			·		
Examiner Signature		/Rebecca Straszheim/		Date Considered	08/18/20	008	

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

2994761_1.DOC Attorney Adde NR BPE/RENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 212 of 630

2007 Under the Paperwork Reduction Ar		Application Number	10/972,287
	_	Application Number	
FORM	-	Filing Date	October 21, 2004
		First Named Inventor	Amr Salahieh
		Art Unit	3738
(to be used for all correspondence after	initial filing)	Examiner Name	William H. Matthews
otal Number of Pages in This Submiss	ion 6	Attomey Docket Num	ber 10012-702.501
	ENCLO	OSURES (check all that a	pply)
Fee Transmittal Form	Drawing(s)	After Allowance Communication t
Fee Attached	Licensing	g-related Papers	Appeal Communication to Board
Amendment / Reply			of Appeals and Interferences Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
After Final	Provision	o Convert to a nal Application	Proprietary Information
Affidavits/declaration(s)		Attorney, Revocation of Correspondence Addres	s Status Letter
Extension of Time Request	Terminal	Disclaimer	Other Enclosure(s) (pleese identify below):
Express Abandonment Request		for Refund hber of CD(s)	
Information Disclosure Statement	_	ndscape Table on CD	
Certified Copy of Priority Document(s)	Remarks	····	
Reply to Missing Parts/ Incomplete Application			
Reply to Missing Parts			
under 37 CFR1.52 or 1.53			
SIG	NATURE OF	APPLICANT, ATTORN	EY, OR AGENT
Fim	Shay Law Gro	up LLP	
Signature	7	13	
Printed Name	Thomas Zloga	r	
Date	3/15/		Reg. 55,760 Io.
		ATE OF TRANSMISSIC	N/MAILING
Service with sufficient postage as fill	nce is being fai rst class mail	in an envelope addresse	USPTO or deposited with the United States I d to: Commissioner for Patents, P.O. Box
Service with sufficient postage as fin Alexandria, VA 22313-1450 on the dat	nce is being fa rst class mail e shown below	in an envelope addresse	USPTO or deposited with the United States d to: Commissioner for Patents, P.O. Box

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 epplication. 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 farm 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 Petents, 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.

te: 03/19/2007

MAR 1 9 2007

10972287 - GAU: 3738 Docket No. 10012-702.501

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.

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),

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

 \boxtimes 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,

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

A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement
 B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

37 CFR § 1.97(d)

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

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

--AND---

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

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

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

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

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

37 CFR §1.98 (a)(2)(i) Foreign patent(s) in English cited A legible copy of each foreign patent is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 215 of 630

10972287 - GAU: 3738

Docket No. 10012-702.501

37 CFR §1.98 (a)(2)(i), (a)(3)(i-ii) Foreign patent(s) or other foreign documents not in English cited

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

--AND--

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

--OR---

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

STATEMENT UNDER 37 CFR § 1.97(e)

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

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

FEE AUTHORIZATION

The Commissioner is hereby authorized to charge the above-referenced fees of 0.0 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: Shay Law Group 2755 Campus Drive, Suite 210 San Mateo, CA 94403 (650) 212-1700 Customer No. 66854

3/15/07

daux 03/19/2007 10972287 - GAU: 3738 MAR 1 9 2007 PTO/SB/08A (09-06) Approved for use through 03/31/2007. OMB 0651-0031 U.S. Petent and Tredemark Office; U.S. DEPARTMENT OF COMMERCE ALL REAL FOR 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. Complete if Known Substitute for form 1449/PTO 10/972,287 Application Number Filing Date October 21, 2004 INFORMATION DISCLOSURE Amr Salahieh First Named Inventor STATEMENT BY APPLICANT Art Unit 3738 (Use as many sheets as necessary) William H. Matthews Examiner Name 10012-702.501 Attomey Docket Number of 2 11 Sheet **U.S. PATENT DOCUMENTS** Publication Date Name of Patentee or Pages, Columns, Lines, Where Examiner Cite Document Number **Relevant Passages or Relevant** MM-DD-YYYY Applicant of Cited Document Initials* No. Figures Appear Number-Kind Code^{2 (# known)} ^{0S-}2003/0233117-A1 12/18/2003 Adams et al. 366 ^{US-} 2004/0153094-A1 08/05/2004 Dunfee et al. 364 ^{US-} 2005/0107822-A1 05/19/2005 WasDyke, Joel 367 ^{US-} 6,610,077 08/26/2003 Hancock et al. 368 US-09/14/2004 Berreklouw, Eric 369 6,790,229 US-6,969,395 11/29/2005 Eskuri et al. 365 03/26/2002 Macoviak et al. ^{US-} 6,361,545 363 ^{US-} 5,064,435 11/12/1991 Porter 142 Elliott ^{US-} 6,712,843 03/30/2004 262 US-US-US-US-US-US-ับร-US-US-US-

FOREIGN PATENT DOCUMENTS										
Exeminer Initials*	Cite No. ¹	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	T6				
		Country Code Number Kind Code (ir known)								
	<u> </u>									
	•									
Examinar				Date						

Examiner Signature

*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. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant 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 (end 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, end 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.

Considered

10972287 - GAU: 3738

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

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

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

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

Examiner Signature

/Rebecca Straszheim/

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.

Applicant's unique clatic designation number (optional). 2 Applicant is to place e check mark here if English language Trenslation is ettached. 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) en 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.

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

Date

Receipt date: 04/06/2006

10972287 - GAU: 3738

Attorney Docket No. 30207-702.501 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Amr SALAHIEH, et al.

Group Art Unit: 3738

Examiner: Unassigned

Serial Number: 10/972,287

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.

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

2854352_1.DOC Attorney Docket No. 30207-702.501

- 1 -

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 219 of 630 Receipt date: 04/06/2006

П

- A. \boxtimes 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. \square 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. \Box 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 <u>thirty (30) days</u> prior to the filing of this information disclosure statement. This statement is made pursuant to the

2854352_1.DOC Attorney Docket No. 30207-702.501

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 220 of 630 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. \boxtimes 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. \boxtimes 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.

2854352_1.DOC Attorney Docket No. 30207-702.501

- 3 -

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 221 of 630 Receipt date: 04/06/2006

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

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: April 6, 2006

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

By:

Maya Skabatch, Reg. No. 52,505

2854352_1.DOC Attorney Docket No. 30207-702.501

- 4 -

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 222 of 630

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	Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless if contains a valid OMB control number.								
				Cor	mplete if Known				
Substitute for form 1449/PTO .				Application Number	10/972,287				
INFORM	INFORMATION DISCLOSURE			Filing Date	October 21, 2004				
STATEN	-			First Named Inventor	Amr Salahieh				
(Use as	s many shee	ts as nec	essary)	Art Unit	3738				
				Examiner Name	Unassigned				
Sheet	1	Of	3	Attorney Docket Number	30207-702.501				

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 2005/0209580 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	Date	
Signature	Considered	
*EVALOUTED. 1	Den Cardenal	the star of the second s

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

This collection of information is required by 35 U.S.C. 122 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 former, 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-P36-9199) and select option 2.

2854352_1.DOC Attorney Docket No. 30207-702.501

-1-

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 223 of 630

PTO/SB/08 (07/05)

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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.

				Con	nplete if Known
Substitute for form 1449/PTO				Application Number	10/972,287
INFORMATION DISCLOSURE			LOSURE	Filing Date	October 21, 2004
STATEMENT BY APPLICANT				First Named Inventor	Amr Salahieh
(Use as	(Use as many sheets as necessary)			Art Unit	3738
		Examiner Name	Unassigned		
Sheet	2	Of	3	Attorney Docket Number	30207-702.501

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ⁵ – Number ⁴ – Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6		
		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	Date	
Signature	Considered	
APPAR IN THE PROPERTY		

*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. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 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 23313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

2854352 1.DOC Attorney Docket No. 30207-702.501

- 2 -

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 224 of 630

10972287 - GAU: 3738

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

				Сог	nplete if Known
Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/972,287
				Filing Date	October 21, 2004
				First Named Inventor	Amr Salahieh
(Use a	s many shee	ts as neo	cessary)	Art Unit	3738
		Examiner Name	Unassigned		
Sheet	3	Of	3	Attorney Docket Number	30207-702.501

		UNPUBLISHED PATENT APPLICATIONS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т
		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
*EXAMINER: In	nitial if reference considered, whether or not citation is in conformance with MPEP 60	9. Draw line through	citation if not in conformance and not considered. Include copy

*EXAMPLYING: Initial if reference considered, whether of not chausen is in constraince with NP DF 905. Draw the informatice and not considered, whether of the constraince and not considered. Infente objy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²Sec Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04, ³Enter Office that issued the document, by the two-letter gode (WPIO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

check mark nere it 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.

2854352_1.DOC Attorney Docket No. 30207-702.501

- 3 -

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 225 of 630

4-29-05

10972287 - GAU

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

Inventor(s): Amr SALAHIEH et al.

Application No.: 10/972,287

Filed: October 21, 2004

te: 04/27/2005

1 2005

Title: Leaflet engagement elements and methods for use thereof

PATENT APPLICATION

Art Unit: 3738

Examiner: Not yet assigned

Confirmation No.: 7706

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.

ÉRÊNCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 226 of 630

3055272_1 DOC Attorney Docket N

Receipt date: 04/27/2005

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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. $\S1.97(d)$. If this statement is being filed after the mailing date of the earlier of a final office action under $\S1.113$ or a notice of allowance under $\S1.311$, 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.

3055272_1.DOC

Attorney Docket No. 30202 702 501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 227 of 630

Receipt date: 04/27/2005

- 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 Skulatch, Reg. No. 52,505

Dated: 410103650 Page Mill Road

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

Under the paperwork Reduction Act of 1995, no persons reguired to respond to a collection of information unless it contains a valid OMB Gubstitute for form 1449/PTO Complete if Known INFORMATION DISCLOSURE Application Number 10/972,287 Filing Date 10/972,287 Filing Date 10/21/2004 First Named Inventor Salahich Art Unit 3738 Examiner Not yet assigned Sheet 1 of 2 NON PATENT LITERATURE DOCUMENTS NON PATENT LITERATURE pocuments itilde of the article (when appropriate), title of the article (w	ι	Unde	er the r	• aperv	vork Red	uction A	act of 1995, no perso	U.S. Patent and ns required to respond to a collection of	Approved for use through 07/31/ Trademark Office; U.S. DEPARTM information unless it contains a value	ENT OF COMME
Art Unit 3738 Examiner Name Not yet assigned Sheet 1 of 2 Attorney Docket Number 30207.702.501 NON PATENT LITERATURE DOCUMENTS include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the art valve and method", filed 12/23/2003 (Docket No. 30207.70.201). 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 (30207.701.502). 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).							, , , , , , , , , , , , , , , , , , , ,			
Art Unit 3738 Examiner Name Not yet assigned Sheet 1 of 2 Attorney Docket Number 30207.702.501 NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the appropriate), title of the article (when appropriate), the art value and method", filed 12/23/2003 (Docket No. 30207.701.501). SALAHIEH, A. et al. US Patent Application No. 10/893,143, entitled "Methods and apparatus for endovascularly replacing a patient's heart value", filed 07	ubs	titu	te for	forr	n 1449	/PTO		Application Number	10/972,287	
Art Unit 3738 Examiner Name Not yet assigned Sheet 1 of 2 Attorney Docket Number 30207.702.501 NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of appratus for ondovascularly 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 appratus 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 appratus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.504).	NF	O	RM	АТІ	ION I	DISC	LOSURE	Filing Date	10/21/2004	
Examiner Name Not yet assigned Sheet 1 of 2 Attorney Docket Number 30207.702.501 NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number publisher. Initials* No.* SALAHIEH, A. et al. US Patent Application No. 10/746,280 entitled "Repositionab 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 (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. 10/893,142, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (3								First Named Inventor	Salahieh	
Sheet 1 of 2 Attorney Docket Number 30207.702.501 NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the article approximate), title of the article approximate and method", filed 12/23/2003 (Docket No. 30207.701.201). 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 (30207.701.503). 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 art methods for protecting a		(Us	e as r	nany	sheets	as ne	cessary)	Art Unit	3738	
NON PATENT LITERATURE DOCUMENTS Examiner Initials* Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), target and method'', filed 12/23/2003 (Docket No. 30207.701.501). SALAHIEH, A. et al. US Patent Application No. 10/93,151, 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. 10/893,142, 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. 10/920,736, entitled "Methods and apparatus for endovascularly replacing a patient's heart valve", filed 07/15/2004 (30207.701.504).<		AND SHARE HAD						Examiner Name	Not yet assigned	
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engagement elements and methods for use thereof', filed 10/21/2004 (30207.702.50										
SALAHIEA, A. et al., US Patent Application No. 10/746,120, ontitled "Externally expandable heart valve anchor and method", filed 12/23/2003 (30207.703.201).										

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Substitute for form 1449/PTO				Application Number	10/972,287			
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STATEMENT BY APPLICANT				First Named Inventor	Salahieh			
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	*	NON PATENT LITERATURE DOCUMENTS	
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		SALAHIEH, A. et al., US Patent Application No. 10/982,388, entitled "Methods and apparatus for endovascularly replacing a heart valve", filed 11/05/2004 (30207.703,501).	
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		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 08/18/2008 Considered	

*EXAMINER: Initial if reference on the interior of the interio

¹ 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's attached. This collection of information's 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 your require to to complete this form and/or subscittion form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time your require to the complete the form and/or subscittion form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time your require to complete the form and/or subscittion form to the use of the public which is to be to be to be to be the public to complete the form and/or subscittion form to the user to the check of the fully public which is formed to the table to be to be the public which is burden to be the public which is burden to be about the section of the fully public which is burden to be about the section of the fully public which is the fully public 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 Tragemark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Complissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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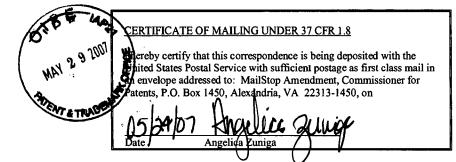
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FERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. / Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 230 of 630

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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 \S 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,

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

A). A fee of \$180.00 as set forth in § 1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement
 B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

37 CFR § 1.97(d)

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

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

--AND---

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

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

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

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

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

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

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

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

37 CFR §1.98 (a)(2)(i) Foreign patent(s) in English cited A legible copy of each foreign patent is attached.

Docket No. 10012-702.501

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:

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

Receit	I date	e: 05/29/20	007			10972287 - GAU:	3738
MAY		\$ /	luction A	ct of 1995, no persons ar		PTC/SB/08B (04-07) Approved for use through 09/30/2007. OMB 0651-0031 and Trademark Office; U.S. DEPARTMENT OF COMMERCE of information unless it contains a valid OMB control number. Complete If Known	
AVEN	Substit	for form 1449/PTO			Application Number	10/972,287	
	INFO	ORMATION	I DIS	SCLOSURE	Filing Date	October 21, 2004	
	STA	TEMENT E	3Y A	PPLICANT	First Named Inventor	Amr Salahieh	
(Use as many sheets as necessary)				accessed	Art Unit	3738	
		lose as many she	7013 05 1	10003901 y)	Examiner Name	William H. Matthews	
	Sheet	1	of	1	Attorney Docket Number	10012-702.501	

NON PATENT LITERATURE DOCUMENTS								
ixaminer Cite 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.								
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).							
	· · · · · · · · · · · · · · · · · · ·							
	374 372	Cite No.1 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. 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). Salahieh, et al; U.S. Pat App. # 11/732,906 entitled "Assessing the location and performance of						

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.

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 gethering, 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. Petent and Trademark Office, 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 235 of 630 Sheet 1

10972287 - GAU: 3738

PTO/SB/08A (04-07)

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

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 2

Coi	mplete if Known	
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	

			U. S. PATEN	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (f known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	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										
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Pa Applicant of Cite		Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	τ ⁶				
	L	Country Code ³ "Number ⁴ -Kind Code ⁵ (if known)					Ľ.				
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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English lenguage 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 236 of 630

Receipt date: 06/10/2008

10972287 - GAU: 3738

PTO/SB/08B (04-07)

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

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/	Substitute for form 1449/PTO			Complete if Known			
			Application Number	10/972,287			
INFORMATI	ON DIS	CLOSURE	Filing Date	October 21, 2004			
STATEMEN	STATEMENT BY APPLICANT			Amr Salahieh			
(ilse as mar	ny sheets as n	acessent)	Art Unit	3774			
	iy sheets as h	ecessary)	Examiner Name	WALKER, AMANDA H			
Sheet 2	of	2	Attorney Docket Number	10012-702.501)		

NON PATENT LITERATURE DOCUMENTS									
Examiner Initials*									
		HAWG at alm U.S. Pat. App. # 12/028,152 antitled "Mothede and apparatus for and vascularly replacing a							
	399	patient's heart valve," filed 2/8/2008.							

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

I his 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.

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 237 of 630

Receipt date: 06/30/2805	10972287 - GAU. 643
CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited sufficient postage as first class mail in an envelope addressed Box 1450 Alexandria, VA 22313;1450, on Mi Kyong Shin	with the U.S. Postal Service with o: Commissioner of Patents, P.O.
•	PATENT
	Attorney Docket No. 30207.702.501
IN THE UNITED STATES PAT	TENT AND TRADEMARK OFFICE
In re Application) <u>PATENT APPLICATION</u>
)
Inventor(s): Amr SALAHIEH et al.	

Application No.: 10/972,287

Filed: October 21, 2004

Title: Leaflet engagement elements and methods for use thereof

Art Unit: 3738

Examiner: Not yet assigned

Confirmation No.: 7706

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.

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Attorney Pathet NREPERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 238 of 630 \boxtimes

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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. $\S1.97(c)$. 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 $\S1.491$ 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. $\S 1.97(d)$. If this statement is being filed after the mailing date of the earlier of a final office action under $\S 1.113$ or a notice of allowance under $\S 1.311$, 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.)

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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:

ames R. Shay, Reg. No. 32,06

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

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Substitute for	form 1449	RICU		Application N	umber	10/972,28	
INFORM				Filing Date		10/21/200	
STATEM				First Named I	nventor	Salahieh e	t al.
(Use as n	nany sheet:	s as neo	cessary)	Art Unit	·	3738	
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Sheet	1	of	11	Attorney Doc	ket Number	30207.702	2.501
			U.S. P	ATENT DOG	UMENTS		
xaminer Cite		Docun	nent Number	Publication Date		Patentee or	Pages, Columns, Lines, Where
nitials* No. ¹	Nui	nber-Kin	nd Code ² (if known)	MM-DD-YYYY	Applicant of C	ited Document	Relevant Passages or Relevant Figures Appear
	US-200	5/0085	841	04/21/2005	Eversull et al		
	US-200	5/0085	842	04/21/2005	Eversull et al		
	US-200	5/0085	843	04/21/2005	Opolski et al		
	US-200	5/0085	890	04/21/2005	Rasmussen e	t al.	
	US-200	5/0096	692	05/05/2005	Linder et al.		
	US-200	5/0096	734	05/05/2005	Majercak et a	al.	
	US-200	5/0096	735	05/05/2005	Hojeibane et	al.	
	US-200	5/0096	738	05/05/2005	Cali et al.		
	US-200		580	05/12/2005	Osborne et a	l.	
	US-5,6	-		09/16/1997	Bynon et al.		
	US-6,8	87,266		05/03/2005	Williams et a	d.	
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Examiner Initials*	Cite No.'	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of P Applicant of C		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
· · ·		EP 1229864 B1	04/27/2005	Boston Scie	ntific		
				Limited			
Examiner Signature		/Rebecca Straszheim/	<u> </u>	Date Considered	08/18/200	8	

*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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. ⁶Applicant 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 farm, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

2679731_1.DOC Autorney Autorne Receipt date: 07/12/2006

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.

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- A. \boxtimes 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. \Box 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. \Box 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. \Box 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

2914360_1.DOC Attorney Docket No. 30207-702.501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 243 of 630 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. \boxtimes 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. \boxtimes 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 ---

 \square

- 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. \square 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.

2914360 1.DOC

-3-Attorney Docket No. 30207-702.501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 244 of 630 Receipt date: 07/12/2006

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

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: July 2006

By:___/lay

Maya Skubatch, Reg. No. 52,505

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

2914360_1.DOC Attorney Docket No. 30207-702.501 - 4 -ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 245 of 630

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

Figures Appear	Pages, Colu Relevant Pa Figu	f Cited Document	Name of I Applicant of C	Publication Date MM-DD-YYYY)	Document Number Number-Kind Code ² (if known)	Cite Io. ¹	Examiner Initials*
		et al.	Salahieh et	06/23/2005		2005/0137695		
			Ersek	04/25/1972		3,657,744		
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FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.'	Foreign Patent Document Country Code ⁸ - Number ⁴ - Kind Code ⁸ (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			
		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				
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Examiner	Date
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of this form with ne 901.04. ³ Enter Offi precede the serial m check mark here if? This collection of i application. Confi- completed applicati reducing this burde	Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through ditation if not in nonformance and not considered. Include copy ext communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP lice that issued the document, by the two-latter code (WIPO Standard ST .3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must number of the patent document. ³ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST .16 if possible. ⁴ Applicant is to place a English language Translation is statached. 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 identiality 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 ion form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to and/or suggestions for e., should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. <i>ADDRESS.</i> SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. <i>If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.</i>
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Attorney Dock	ket No. 30207-702.501 - 1 -

Date

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 246 of 630

Under the	e paperwork R(eduction Act	of 1995, no perso	U.S. Patent and Tr	PTO/SB/08 (07/05) Approved for use through 07/31/2006. OMB 0651-0031 ademark Office; U.S. DEPARTMENT OF COMMERCE formation unless it contains a valid OMB control number.		
		Complete if Known					
Substitute for form 1449/PTO				Application Number	10/972,287		
INFORM	INFORMATION DISCLOSURE			Filing Date	October 21, 2004		
STATEM				First Named Inventor	Amr Salahieh		
(Use as	s many shee	ts as nece	ssary)	Art Unit	3738		
				Examiner Name	Unassigned		
Sheet	2	Of	2	Attorney Docket Number	30207-702.501		

		UNPUBLISHED PATENT APPLICATIONS	
Examiner Cite Initials* No. ¹		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т ⁶
	*****	SALAHIEH, et al., U.S. Patent Application No. 11/275,912, entitled "Medical Implant Delivery and Deployment Tool," filed 02/02/2006 (WSGR Reference No. 30207-722.501)	
	-	SALAHIEH, et al., U.S. Patent Application No. 11/275,913, entitled "Two-Part Package for Medical Implant," filed 02/02/2006 (WSGR Reference No. 30207-723.201)	
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Examiner Signature	/Rebecca Straszheim/	Considered	08/18/2008	
of this form with next 901.04. ³ Enter Office precede the serial nun check mark here if Er This collection of inf application. Confide completed application reducing this burden.	t communication to applicant. ¹ Applicant's unique citation a that issued the document, by the two-letter code (WIPO St noer of the patent document. ³ Kind of document by the app nglish language Translation is attached. Or mation is required by 37 CFR 1.97 and 1.98. The Informitality is governed by 35 U.S.C. 122 and 37 CFR 1.14. In form to the USPTO. Time will vary depending upon the should be sent to the Chief Information Officer, U.S. Patent DDRESS. SEND TO: Commissioner for Patents, P.O.B. Patent	lesignation number (optional). ³ See Kinds Code: andard ST 3). ⁴ For Japanese patent documents, t ropriate symbols as indicated on the document ur mation is required to obtain or retain a benefit b This collection is estimated to take 2 hours to individual case. Any comments on the amount 4 and Trademark Office, P.O. Box 1450, Alexand	ider WIPO Standard ST.16 if possible. *Applicant is to place a y the public which is to file (and by the USPTO to process) an to complete, including gathering, preparing, and submitting the of time you require to complete this form and/or suggestions for ria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED	
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A			WHERE LINED THROUGH Exhibit 1142, Page 247 of 630	. /R.S./

Receipt date: 07/12/2007 07/12/2007 THU 10:24 FAX 16502127562

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Under the Pa	perwork Reduction Act of 1995	na person:			formation		disclays a valid OMB control number.
	ANSMITTAL	Filing Date	October 2	1.2004			
	FORM		First Named Inventor	Amr Saiat			
1 A.		•	Art Unit	3738			
			Examiner Name	MATTHE	MS WILL		
(to be used for	all correspondence after initial		Attorney Docket Number				·····
Total Number o	Pages in This Submission	5		10012-702	2.301		
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Amendm Amendm A A A A A A Certified Certified Certified Certified Cocumer Reply to I Incomple	smittal Form ee Allached ent/Reply fter Final ffldavits/declaration(s) n of Time Request Abandonment Request on Disclosure Statement Copy of Prionity tt(s) Missing Parts/ te Application eply to Missing Parts nder 37 CFR 1.52 or 1.53		Drawing(s) Licensing-related Papers Petition Petition to Convert to a Provisional Application Powar of Attornay, Revocati Change of Correspondence Ferminal Disclaimer Request for Refund CD, Number of CD(s) Landscape Tabla on C ka	Address		Appea of App Appea (Appaa Proprie Status	Allowance Communication to TC a Communication to Board wals and Interferences a Communication to TC a Notice, Brief, Repty Brief) etary Information Letter Enclosure(s) (plaase Identify):
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Firm Name	Shaw Law Group LLP				•		
Signature	79	-					
Printed name	Thomas Zlogar						
Date	7/12/07	·		Reg. No.	55,760)	
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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 commenta on the amount of time you require to complete his form end/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Petent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DD NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissionar for Petenta, 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.

PAGE 1/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daytight Time] * SVR:USPTO-EFXRF-1/2 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-46

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 248 of 630

Receipt date: 07/12/2007 07/12/2007 THU 10:25 FAX 16502127562

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10972287 - GAU: 373

Docket No.10012-702.501

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JUL 1 2 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

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.

lica Zunie

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.

PAGE 2/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daylight Time] * SVR:USPTO-EPXRF-1/2 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-48

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10972287 - <u>GAU: 3</u>738

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:

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

37 CFR § 1.97(d)

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

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

-AND--

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

CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.98

37 CFR \$1.98 (a)(2)(ii), U.S. patents or patent application publication(s) cited

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

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

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

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

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

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

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

PAGE 3/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/2 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-48

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 250 of 630

Docket No.10012-702.501

10972287 - GAU: 3738

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

Receipt date: 07/12/2007

07/12/2007 THU 10:25 FAX 16502127562

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.

7/12/0

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

Dated:

Respectfully Submitted,

Thomas Zlogar Reg. # 55760

PAGE 4/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/2 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-46

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 251 of 630

Receipt date: 07/12/2007 07/12/2007 THU 10:26 FAX 16502127562

Substitute for form 1449/PTO

Sheet 1

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10972287 - GAU: 3738

2005/005

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

of 1

/Rebecca Straszheim/

mpiete if Known
10/972,287
October 21, 2004
Amr Salahieh
3738
MATTHEWS, WILLIAM H
10012-702.501

08/18/2008

Considered

	U. S. PATENT DOCUMENTS									
Examiner Initiala*	Cite No.1	Document Number Number-Kind Code ² ^(7 knowd)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pagea, Columns, Lines, Whare Relevant Passages or Relevant Figurea Appear					
	375	^{US-} US 5,824,041 A	10/20/1998	Lenker, et al.						
	376	^{US-} US 6,863,668	03/08/2005	Gillespla et al.						
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External and				Date		

Signature

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

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or ratain 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 astimated to take 2 hours to complete, including gettering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any commenta 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 Officer, 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.

PAGE 5/5 * RCVD AT 7/12/2007 1:22:55 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/2 * DNIS:2738300 * CSID:16502127562 * DURATION (mm-ss):02-46

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Updyr the Paperwork Reduction Act of 199:		Application Number	10/972,287		
TRANSMITTA	L	Filing Date	October 21, 20	104	
FORM		First Named Inventor	Amr Salahieh		
(to be used for all correspondence after in	itial filing)	Art Unit	3738	ن	
	·	Examiner Name	Not yet assigned	ed	
Total Number of Pages in This Submission		Attorney Docket Number	30207-702.501	i	
	ENCLOSU	RES (Check all that apply)			
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Fee Attached	Licensir	ng-related Papers	of Appeals	mmunication to Board and Interferences	
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Express Abandonment Request	Request	for Refund			
Information Disclosure Statement	CD, Nu	mber of CD(s)			
Certified Copy of Priority Document(s)	Remarks				
Response to Missing Parts/ Incomplete Application					
Response to Missing Parts under 37 CFR 1.52 or 1.53					
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Date October λ , 2005					
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Typed or printed name Frank Chen		•			
Signature 70	<u> </u>	Date	October 26 , 20	005	

22313-1450.

Receipt date: 10/28/2005

10972287 - GAU: 3738



Attorney Docket No. 30207-702.501 PATENT

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

l 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 2.6 , 2005.

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.

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 \boxtimes 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 --
- 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).
 - $37 \ CFR \ \S 1.98(a)(2)$. 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).

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Attomey Docket No. 10207.702.501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 255 of 630 \square

- \boxtimes 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

db Dated: October 2005

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

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By:

Maya Skubatch, Reg. No. 52,505

Attomey Docket No. 30207-702 501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 256 of 630

NO Un	der the pa	perwork Rec	duction Ac	t of 1995, no persons		S. Patent and Tra a collection of info	demark Office; I	PTO/SB/08A (07-05) e through 07/31/2006. OMB 0651-0031 U.S. DEPARTMENT OF COMMERCE it contains a valid OMB control number.
Substit	ute for	form 1449)/PTO		Application Nu		10/972,2	
Substitute for form 1449/PTO INFORMATION DISCLOSURE					Filing Date		October 2	
				LICANT	First Named In	ventor	Amr Sala	
		any sheet			Art Unit		3738	
				Examiner Nam	e	Not yet as	signed	
Sheet		1	of	5	Attorney Dock	et Number	30207-702	2.501
				U.S. P	ATENT DOC	UMENTS		
Examiner Initials*	Cite No. ¹	Nu		ent Number l Code ² (if known)	Publication Date MM-DD-YYYY	Name of P Applicant of C		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
			01/0044		11/22/2001	Don Michae	el et al.	rigues Appear
		US 20	02/0010	489 A1	1/24/2002	Grayzel, et a	al.	
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•		US 20	03/0208	224	11/06/2003	Broome		
			03/0216		11/20/2003	Larson		
			04/0073		04/15/2004	Gilson et al.		
			04/0082		04/29/2004	Broome et a	al	· · · · · · · · · · · · · · · · · · ·
			04/0093		05/13/2004	Root et al.		
			04/0138		07/15/2004	Tran et al.		
			04/0158		08/12/2004	Lowe et al.		<u></u>
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			04/0223		12/16/2004	Flagle, et al		
			05/0075		4/7/2005	Pedersen, et		
	<u> </u>		05/0090		4/28/2005	Pedersen, et		
			05/0096		5/5/2005	Osse, et al.	- ul.	
	<u> </u>		05/0113		5/26/2005	Paniagua, et	t al.	
4	-		05/0165		7/28/2005	Henry, et al		
			05/0165		7/28/2005	Anduiza, et		
	<u> </u>	US 20	05/0197	695A1	9/8/2005	Stacchino, e		
		US 20	05/0203	614A1	9/15/2005	Forster		

	Examiner		Date	
ł	Signature		Considered	
	*EXAMINER: 1	nitial if reference considered, whether or not citation is in conformance with	MPEP 609 Dr	w line through citation if not in conformance and not

*EXAMINER: initial in 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. ¹Applicant's unique citation designation number (optional). ³See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ³Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant 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, coll 1-800-PTO-9199 (1-800-786-9199) ond select option 2.

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 257 of 630

2749734_1.DOC Attorney Docket No. 30207-702-501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./

Receipt date: 10/28/2005

10972287 - GAU: 3738

PTO/SB/08A (07-05)

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Substitute for form 1449/PTO INFORMATION DISCLOSURE						Application Number 10/972,28			7
						ling Date		October 2	1, 2004
STATEMENT BY APPLICANT				Fi	rst Named In	ventor	Amr Salah	nieh	
(U.	se as mà	ny sheet.	s as nec	cessary)	Ar	t Unit		3738	
				Ex	aminer Nam	e	Not yet as:	signed	
Sheet 2 of 5					At	torney Docke	et Number	30207-702	2.501
				U.S. P	AT	ENT DOCI	JMENTS		
Examiner Initials*	Cite No. ¹		Docun	nent Number		Publication Date	Name of P		Pages, Columns, Lines, Where
minars.	NO.			d Code ² (if known)		MM-DD-YYYY	Applicant of C	ted Document	Relevant Passages or Relevant Figures Appear
			-	3615A1		9/15/2005	Forster		• • • • • • • • • • • • • • • • • • •
				3616 A1	_	9/15/2005	Cribier		
				3617 A1		9/15/2005	Forster, et a	1.	
			96,629			1/10/1989	Grayzel		
			86,830			1/22/1991	Owens, et a	l	
			209,741			5/11/1993	Spaeth		····
			258,042			11/2/1993	Mehta	·	
		· · · ·	25,762			6/20/1995	Muller		
			45,133			8/22/1995	Buscemi, et		
			43,155 343,158			8/13/1996 12/1/1998	Burns, et al. Lenker, et a		
			010,154			06/08/1999	Tsugita et a		
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			68,070			10/19/1999	Bley, et al.	-	
			27,520			02/22/2000	Tsugita et al		
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			65,200			12/26/2000	Tsugita et al		
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			71,327			01/09/2001	Daniel et al.		
			79,859			01/30/2001	Bates		
		US 6,2	70,513	· ·=, .	-+7	08/07/2001	Tsugita et al	l.	
		US 6,3	36,934			01/08/2002	Gilson et al.		······································
		US 6,5	37,297			03/25/2003	Tsuigita et a	il.	
		US 6,5	40,768			04/01/2003	Diaz et al.		
		US 6,5	92,614			7/15/2003	Lenker, et a	1.	
		US 6,6	76,698			01/13/2004	McGuckin,	Jr. et al.	
		US 6,6	95.864	-		02/24/2004	Macoviak et	al	

Examiner	
Signature	

Date Considered

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

2749734_1.DOC Attomey Docket No 30207-702 501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 258 of 630

Receipt date: 10/28/2005

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PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO						Application Number 10/972,287			7		
INFO	INFORMATION DISCLOSURE							October 2	1, 2004		
STATEMENT BY APPLICANT]	First Named In	ventor	Amr Salal	nieh		
(U.	se as ma	ny sheet	's as nec	essary)		Art Unit		3738			
						Examiner Nam	e	Not yet as	signed		
Sheet		3	of	5		Attorney Docke	et Number	30207-702	2.501		
				U.S. P	PA	TENT DOCI	UMENTS				
Examiner	Cite	ļ	Docum	ent Number		Publication Date		atentee or	Pages, Columns, Lines, Where		
Initials*	No. ¹	No.'	N0."	Nu	mber-Kind	ber-Kind Code ² (if known)		MM-DD-YYYY	Applicant of Cited Document		Relevant Passages or Relevant Figures Appear
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	US 6,911,036				6/28/2005	Douk, et al.					
		US 6,9	936,067			8/30/2005	Buchanan				
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considered. Inclu	ude copy of this form with next communication to applicant ¹ Applican	it's unique citation designation number (optional). ² See K	inds Codes of

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

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2749734_1.DOC Attomey Dacket No. 30207-702 50 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 259 of 630

PTO/SB/08A (07-05)

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				Con	plete if Known
Substitute f	for form 144	9/PTO		Application Number	10/972,287
INFORM	ATION	DISC	LOSURE	Filing Date	October 21, 2004
STATE	MENT BY	APP	LICANT	First Named Inventor	Amr Salahieh
(Use a	s many sheel	s as ne	cessary)	Art Unit	3738
			Examiner Name	Not yet assigned	
Sheet	4	of	5	Attorney Docket Number	30207-702.501

			PATENT DO		angenerativ	
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ – Number ⁴ – Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т
		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.		\square
		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		1
		WO 98/50103 A1	11/12/1998	Embol-X, Inc.		
		WO 99/44542 A2	09/10/1999	Scimed Life Systems, lnc.	· ·	
		WO 00/49970 A1	08/31/2000	Scimed Life Systems, lnc.		
·		WO 01/08596 A1	02/08/2001	Scimed Life Systems, lnc.		
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		WO 01/10343 A1	02/15/2001	Scimed Life Systems, lnc.		
	·	WO 2005/084595 A1	9/15/2005	Cardiacmd, Inc.	······································	
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2749734_1.DOC Attomey Docket, No. 30207-702.501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 260 of 630

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PTO/SB/08B (07-05)

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Under the paperwork Reduction Act of 1995, no persons	required to respond to a collection of information unless it contains a valid OMB control n
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				Com	plete if Known
Substitute for form 1449/PTO				Application Number	10/972,287
INFORM	IATION	DISC	LOSURE	Filing Date	October 21, 2004
			LICANT	First Named Inventor	Amr Salahieh
(Use a	as many she	ets as nece	essary)	Art Unit	3738
			Examiner Name	Not yet assigned	
Sheet	5	of	5_	Attorney Docket Number	30207-702.501

		NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	nitials* No. ¹ publisher, city and/or country where published.							
		Boudjemline, Y. et al., "Percutaneious implantation of a biological valve in the aorta to treat aortic valve insufficiency - a sheep study", Med Sci.Monit. (2002) Vol. 8, No. 4, pages BR113- 116						
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signature	/Hebecca Straszheim/	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

 ¹Applicant's unique citation designation number (optional).
 ²Applicant is to place a check mark here if English language Translation is attached.
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Attomey Docket No. 30207-702.501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 261 of 630

10972287 - GAU: 3738 11/19/2007 NOV 1 9 2007 PTO/SB/08A (04-07) Approved for use through 09/30/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE 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. Complete if Known substitute for form 1449/PTO Application Number 10/972.287 Filing Date October 21, 2004 INFORMATION DISCLOSURE First Named Inventor Amr Salahieh STATEMENT BY APPLICANT Art Unit 3774 (Use as many sheets as necessary) Examiner Name MATTHEWS, WILLIAM H 10012-702.501 Attorney Docket Number 1 Sheet of **U. S. PATENT DOCUMENTS** Examiner Name of Patentee or Cite Document Number Publication Date Pages, Columns, Lines, Where Initials* No. MM-DD-YYY Applicant of Cited Document Relevant Passages or Relevant Figures Appear Number-Kind Code2 (if known) ^{US-} 5,720,391 A 380 2/24/1998 Dohm et al. 377 ^{US-} 6,712,842 3/30/2004 Gifford et al. ^{US-} 7,018,406 384 3/28/2006 Seguin et al. ^{US-} 2001/0044656 A1 11/22/2001 381 Williamson et al. ^{US-} 2002/0032481 A1 3/14/2002 382 Gabbay, Shlomo ^{US-} 2002/0120328 A1 8/29/2002 379 Pathak et al. ^{US-} 2004/0215331 10/28/2004 Chew et al. 378 US- 2006/0259134 A1 11/16/2006 383 Schwammenthal et al. USus-US-US-US-US-US-US-US-US-US-

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Examiner Initials*	Cite No. ¹	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	T6
	385	WO 02/0041789 A2	5/30/2002	Rex Medical, L. P.		

Examiner	
Signature	

Date 08/18/2008 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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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10972287 - GAU: 3738

PATENT Attorney Docket No. 30207.702.501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

Inventor(s): Amr SALAHIEH et al.

Application No.: 10/972,287

Filed: October 21, 2004

Title: Leaflet engagement elements and methods for use thereof

PATENT APPLICATION

Art Unit: Not yet assigned

Examiner: Not yet assigned

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.

 \square This statement qualifies under 37 C.F.R. §1.97, subsection (b) because: \square (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 --П It is being filed within 3 months of entry of a national stage (2) -- OR -- \square (3) It is being filed before the mail date of the first Office Action on the merits -- OR ---It is being filed before the mailing of a first Office Action after the filing of a П (4) 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: Π 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 Β. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; and С. 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 \boxtimes 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), copies are not enclosed herewith. (Serial No. If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

- \square 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. _
- \square 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).
- \Box Attached are the following non-published pending patent applications which may be deemed relevant.
- \square 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

11-22 Dated:

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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	INFORMATION DISCLOSURE STATEMENT BY APPLICANT					10/21/2004	
					ventor	Salahieh	· · · · · · · · · · · · · · · · · · ·
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Sheet	1	of	12	Attorney Dock		30207.702	.301
			U.S. P	PATENT DOC	UMENTS		
	ite		ent Number Code ² (if known)	Publication Date MM-DD-YYYY	Name of P Applicant of C		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U	S-2001/00251	96	09/27/2001	Chinn et al.		- <u></u>
	U	S-2001/00320	13	10/18/2001	Marton		
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2925598_1.Doc Attorney Actes NAME AND THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 266 of 630

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				Complete if Known		
Substitute f	for form 144	9/PTO		Application Number	10/972,287	
INFORM	INFORMATION DISCLOSURE			Filing Date	10/21/2004	
			LICANT	First Named Inventor	Salahieh	
(Use a	s many shee	ts as nec	essary)	Art Unit	Not yet assigned	
			Examiner Name	Not yet assigned		
Sheet	2	of	12	Attorney Docket Number	30207.702.501	

US DATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevan
		US-2003/0199913	10/23/2003	Dubrul et al.	Figures Appear
		US-2003/0199971	10/23/2003	Tower et al.	<u> </u>
		US-2003/0199972	10/23/2003	Zadno-Azizi et al.	
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Examiner Signature Date Considered

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STATE				First Named Inventor	Salahieh	
(Use a	s many shee	els as nec	essary)	Art Unit	Not yet assigned	
		Examiner Name	Not yet assigned			
Sheet	3	of	12	Attorney Docket Number	30207.702.501	

	1		Applicant of Cited Document	Pages, Columns, Lines, Wher Relevant Passages or Relevan Figures Appear	
	US-3,868,956	03/04/1975	Alfidi et al.		
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	US-4,056,854	11/08/1977	Boretos et al.	······································	
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 	US-5,161,547	11/10/1992	Tower		
 	US-5,163,953	11/17/1992	Vince		

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(Use as	many sheet	s as nec	essary)	Art Unit	Not yet assigned	
			Examiner Name	Not yet assigned		
Sheet	4	of	12	Attorney Docket Number	30207.702.501	

U.S. PATENT DOCUMENTS Document Number Publication Date Examiner Name of Patentee or Cite Pages, Columns, Lines, Where No MM-DD-YYYY Initials* Applicant of Cited Document Relevant Passages or Relevant Number-Kind Code² (if known) Figures Appear US-5,217,483 07/08/1993 Tower US-5,217,483 07/08/1993 Tower US-5,332,402 07/26/1994 Teitelbaum et al. US-5,350,398 09/27/1994 Paycnik 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. 08/13/1996 US-5,545,211 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 12/09/1997 US-5,695,498 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 Javaraman 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 fo	or form 1449)/PTO		Application Number	10/972,287	
INFORM	INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Filing Date	10/21/2004	
				First Named Inventor	Salahieh	
(Use as	s many sheet.	s as neo	essary)	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. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
	110.	Number-Kind Code ² (if known)		••	Figures Appear
		US-5,876,448	03/02/1999	Thompson et al.	
		US-5,888,201	03/30/1999	Stinson et al.	
		US-5,891,191	04/06/1999	Stinson	
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Substitute f	Substitute for form 1449/PTO INFORMATION DISCLOSURE			Application Number	10/972,287	
INFORM				Filing Date	10/21/2004	
STATE	MENT BY	' APP	LICANT	First Named Inventor	Salahieh	
(Use a.	s many sheel	s as ne	cessary)	Art Unit	Not yet assigned	
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Sheet	6	of	12	Attorney Docket Number	30207.702.501	

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevan
		Number-Kind Code ² (if known)			Figures Appear
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STATE	MENT BY	APP	LICANT	First Named Inventor	Salahieh	
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Sheet	7	of	12	Attorney Docket Number	30207.702.501	

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Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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			WO 01/35870	05/25/2001	Seguin, Jacques		x	
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Examiner Cite				Name of Patentee or	Pages, Columns, Lines,	T
Initials*	No.1		MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	
	1	Country Code ³ - Number ⁴ - Kind Code ³ ( <i>if known</i> ) WO 03/003943	01/16/2003	Advanced Bio Prosthetic	Referant igues repea	
		1 0 05/005245	01/10/2003	Surfaces, Ltd.		
		WO 03/003949	01/16/2003	Seguin, Jacques		x
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Sheet	10	of	12	Attorney Docket Number	30207.702.501		

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Substitute for form 1449/PTO				Application Number	10/972,287		
INFORM	INFORMATION DISCLOSURE			Filing Date	10/21/2004		
	MENT BY			First Named Inventor	Salahieh		
(Use a	s many sheel	ts as nec	essary)	Art Unit	Not yet assigned		
				Examiner Name	Not yet assigned		
Sheet	11	of	12	Attorney Docket Number	30207.702.501		

	NON PATENT LITERATURE DOCUMENTS					
	Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²		
		000000000000000000000000000000000000000	FERRARI, M. et al., "Percutaneous transvascular aortic valve replacement with self expanding stent-valve device". Poster from the presentation given at SMIT 2000, 12 th International Conference (September 5, 2000).			
			HIJAZ1, 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.			
		000000000000000000000000000000000000000	KNUDSEN, L. L. et al., "Catheter implanted presthetic heart valves". Int'l J. of Art. Organs, (1993) 16:5, 253-263			
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			LUTFER, 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.			
			MOULOPOLILOS, S. D. et al., "Catheter-Mounted Aortic Valves," Annals of Thoracic Surg. (1971) 11:5, 423-430.			
*****		000000000000000000000000000000000000000	PANIAGUA, D. et al., "Percutaneous heart value in the chronic in vitro testing model". Circulation (2002), 106:e51-e52, American heart Association, Inc.			
-		000000000000000000000000000000000000000	PANIAGUA, D. et al., Heart Watch (2004), Spring, 2004 Edition, Texas Heart Institute		000000000000000000000000000000000000000	

Examiner	Date	
signature	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.

¹Applicant's unique citation designation number (optional). ²Applicant 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: Cammissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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2925598_1.DOC Attorney Anter MREPERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 276 of 630

## 10972287 - GAU: 3738

PTO/SB/08A (08-03)

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

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	Cite tials*         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.
000000000000000000000000000000000000000	PANCNIK, D. et al., "Percutaneous biopresthetic veneus value; A long term study in
	sheep". J. of Vascular Surg. (2002) 35:3, 598-603.
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	VAHANIAN, A. et al., "Percutaneous Approaches to Valvular Disease". Circulation (2004) 109, 1572-1579.
	VAN HERWERDEN, L. A. st al., "Peroutaneous value implantation back to the
	future?" Euro. Heart J. (2002) 23:18, 1415-1416.
000000000000000000000000000000000000000	ZHOU, J. Q. et al., "Self-expandable valued 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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2925598_1.DOC Attorney Active MERELINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 277 of 630

## 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, REBECC	CAL
Title:	LEAFLET ENGAGEME	NT ELEMENTS AND METHODS FOR USE
	THEREOF	
Customer No.:	66854	

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

#### <u>INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.97 & § 1.98</u>

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  $\S$  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:

 $\square$  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  $\S$  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  $\square$ 

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  $\square$ stored in the IFW.

 $\boxtimes$ 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.

10/21/08 Dated:

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

Respectfully Submitted By:

Thomas Zlogar Reg. # 55760

PTO/SB/08a (09-08)

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Sheet 1

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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					

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

		FORE	IGN PATENT DOCL	JMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T ⁶
	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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Sheet 2

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of 6

Complete if Known					
Application Number	10/972,287				
Filing Date	October 21, 2004				
First Named Inventor	Amr Salahieh				
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Examiner Name	STRASZHEIM, REBECCA L				
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			U. S. PATENT D	OCUMENTS	
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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		
	No. ¹ 331 332 338 342 343	Cite No.1         Foreign Patent Document           Country Code ³ Number ⁴ Kind Code ⁵ (if known)           331         WO 00/67661           332         WO 01/05331           338         WO 02/100297           342         WO 03/011195(AB TRN)           343         WO 03/015851	Cite No.1         Foreign Patent Document         Publication Date MM-DD-YYYY           331         WO 00/67661         11/16/2000           332         WO 01/05331         1/25/2001           338         WO 02/100297         12/19/2002           342         WO 03/011195(AB TRN)         2/13/2003           343         WO 03/015851         11/27/2003	No.1         Date MM-DD-YYYY         Applicant of Cited Document           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.	Cite No.1Foreign Patent DocumentPublication Date MM-DD-YYYYName of Patentee or Applicant of Cited DocumentPages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear331WO 00/6766111/16/2000Ortiz, Mark332332WO 01/053311/25/2001Biocompatibles Ltd.338338WO 02/10029712/19/2002Rex Medical, L. P.342343WO 03/011195(AB TRN)2/13/2003Seguin, Jacques343

Examiner Signəture		Dəte Considered	
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Sheet 3

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	10/972,287 October 21, 2004 Amr Salahieh 3738 STRASZHEIM, REBECCA L					

	U. S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
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		FOREIGI	N PATENT DOCL	JMENTS		
Examiner	Cite		Publication	Name of Patentee or	Pages, Columns, Lines,	
Initials*	No.1	Country Code ³ Number ⁴ Kind Code ⁵ ( <i>if known</i> )	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages Or Relevant Figures Appear	Τ6
	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 Cor		
Eveniner				Data		
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Substitute for form 1449/PTO		Complete if Known		
	Application Number	10/972,287		
INFORMATION DISCLOSU	RE Filing Date	October 21, 2004		
STATEMENT BY APPLICA	NT First Named Inventor	Amr Salahieh		
(Use as many sheets as necessary)	Art Unit	3738		
	Examiner Name	STRASZHEIM, REBECCA L		
Sheet 4 of 6	Attorney Docket Number	10012-702.501		

		NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*				
	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 Northeaster 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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	Application Number	10/972,287	
INFORMATION DISCLOSURE	Filing Date	October 21, 2004	
STATEMENT BY APPLICANT	First Named Inventor	Amr Salahieh	
(Use as many sheets as necessary)	Art Unit	3738	
	Examiner Name	STRASZHEIM, REBECCA L	
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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.			
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	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.			
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Substitu	le for form 1449/PTO			Complete if Known		
				Application Number	10/972,287	
INF	ORMATION	DIS	CLOSURE	Filing Date	October 21, 2004	
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Amr Salahieh	
	(Use as many she	unte as n	ecessary)	Art Unit	3738	
				Examiner Name	STRASZHEIM, REBECCA L	
Sheet	6	of	6	Attorney Docket Number	10012-702.501	

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Electronic Patent Application Fee Transmittal								
Application Number:	10972287							
Filing Date:	21-Oct-2004							
Title of Invention:		Leaflet engagement elements and methods for use thereof						
First Named Inventor/Applicant Name:	Amr Salahieh							
Filer:		Thomas M. Zlogar/Angelica Zuniga						
Attorney Docket Number:	10012-702.501							
Filed as Large Entity								
Utility under 35 USC 111(a) Filing Fees								
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)			
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Claims:								
Miscellaneous-Filing:								
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Description	Fee Code Quantity		Amount	Sub-Total in USD(\$)				
Miscellaneous:								
Submission- Information Disclosure Stmt	1806	1	180	180				
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Electronic Acknowledgement Receipt				
EFS ID:	4152752			
Application Number:	10972287			
International Application Number:				
Confirmation Number:	7706			
Title of Invention:	Leaflet engagement elements and methods for use thereof			
First Named Inventor/Applicant Name:	Amr Salahieh			
Customer Number:	66854			
Filer:	Thomas M. Zlogar/Angelica Zuniga			
Filer Authorized By:	Thomas M. Zlogar			
Attorney Docket Number:	10012-702.501			
Receipt Date:	21-OCT-2008			
Filing Date:	21-OCT-2004			
Time Stamp:	19:02:03			
Application Type:	Utility under 35 USC 111(a)			

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# 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 M	lethods for Use Thereo	of
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.

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## 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.

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**[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.

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**[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,

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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.

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**[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

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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

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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 transseptal approach. With reference to Figure 22, a first embodiment of single catheter delivery system 700 for use

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with apparatus 510 is described. Delivery system 700 is adapted for use with a preferred selfexpanding 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

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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 tuber 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

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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

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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

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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

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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

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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

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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.

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# 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 <u>aortic</u> valve, the method comprising:

endovascularly delivering an anchor and a replacement valve supported within the anchor to a vicinity of the heart <u>aortic</u> valve in a collapsed delivery configuration, the anchor comprising leaflet engagement elements on a proximal end of the anchor adapted to engage native <u>aortic</u> 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.

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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.

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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.

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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.

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# **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 Fig. 4C: 30 b. Fig. 4D: 30 c. d. Fig. 4G: 30 Fig. 4H: 30 e. f. Fig. 4K: 30 g. Fig. 5C: 30 Fig. 6B: 32, 40, 60, 61A h. i. Fig. 6C: 32, 61B Fig. 6F: 30, 50, 60, 61A į. Fig. 8C: 55 k. 1. 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

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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
0.	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. 40: 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
у.	Fig. 41: 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. 50: 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
11.	Fig. 6D: A, H, AV, 100', 110, 20, 10
mm.	Fig. 6E: A, H, LV, L, 100', 60, 61B, 40, 30, 20, 10

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nn.	Fig. 6F: A, H, L, AV, G, LV, 110, 100'
00.	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.

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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 lumenal 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.

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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-251 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.

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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.

By:

Respectfully submitted,

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

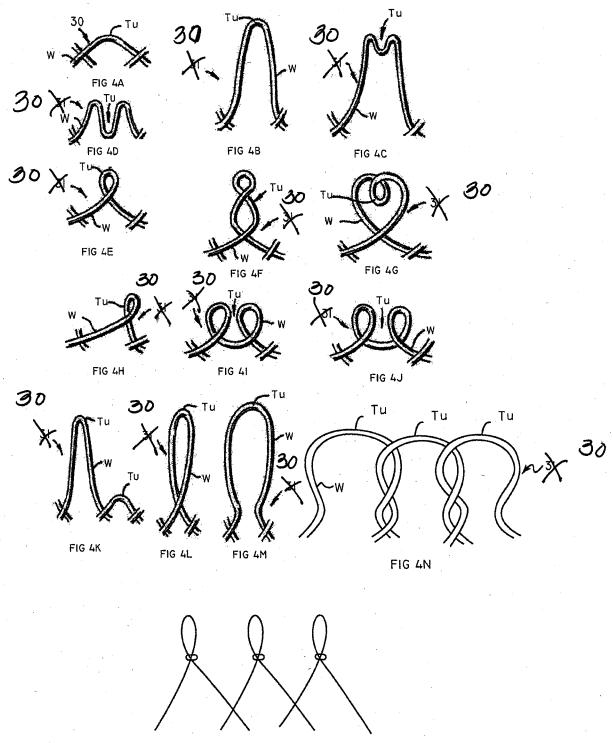
SHAY GLENN LLP 2755 Campus Drive, Suite 210 San Mateo, CA 94403 Telephone: 650.212.1700 Facsimile: 650.212.7562

Date: November 20, 2008

- 26 of 26 - Attorney Docket 10012-702.501

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 321 of 630

## U.S. Appln. No. 10/972,287 Filed 10/21/2004 ANNOTATED SHEET 4 SHOWING CHANGES MADE



F1G 40

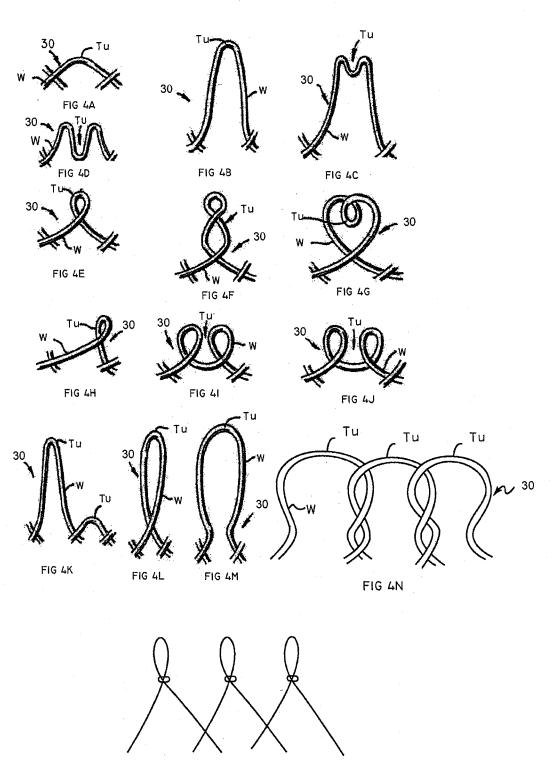
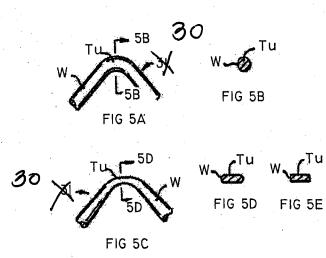
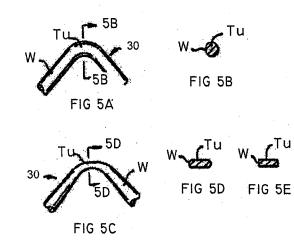


FIG 40

# U.S. Appln. No. 10/972,287 Filed 10/21/2004 ANNOTATED SHEET 5 SHOWING CHANGES MADE



#### U.S. Appln. No. 10/972,287 Filed: 10/21/2004 Inventors: Amr Salahieh et al. ieh et al. Atty Docket: 10012-702.501 REPLACEMENT SHEET 5



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#### U.S. Appln. No. 10/972,287 Filed 10/21/2004 ANNOTATED SHEET 6 SHOWING CHANGES MADE

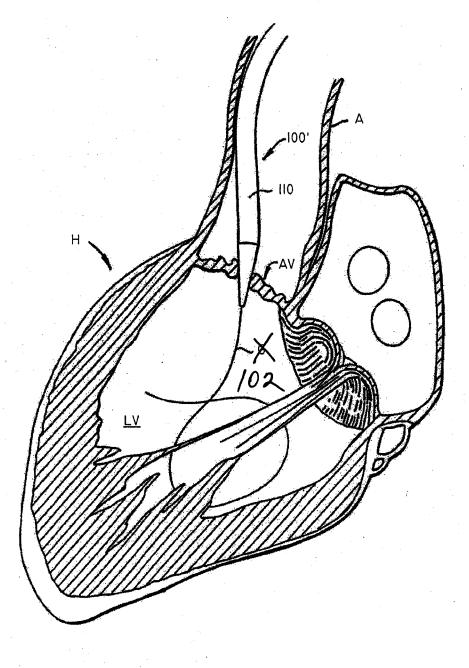


FIG 6A

## U.S. Appln. No. 10/972,287 Filed 10/21/2004 REPLACEMENT SHEET 6

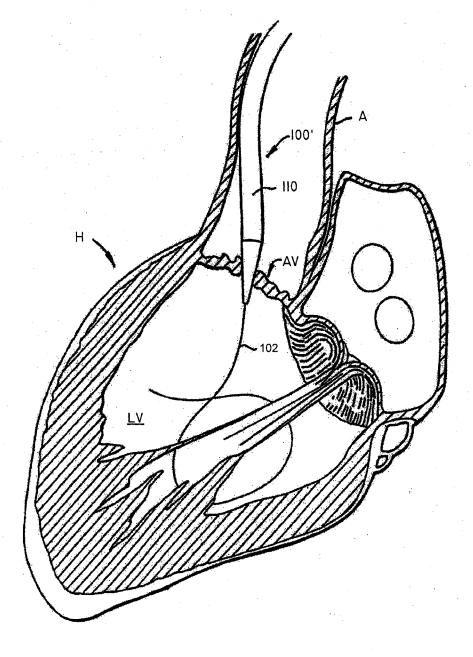


FIG 6A

#### U.S. Appln. No. 10/972,287 Filed 10/21/2004 ANNOTATED SHEET 11 SHOWING CHANGES MADE

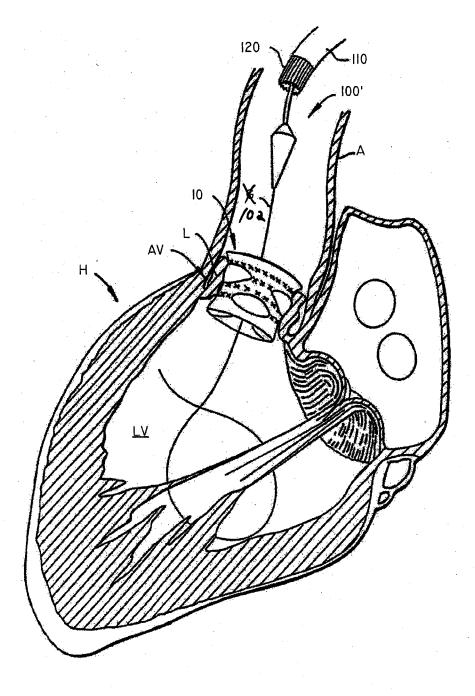


FIG 6F

## U.S. Appln. No. 10/972,287 Filed 10/21/2004 REPLACEMENT SHEET 11

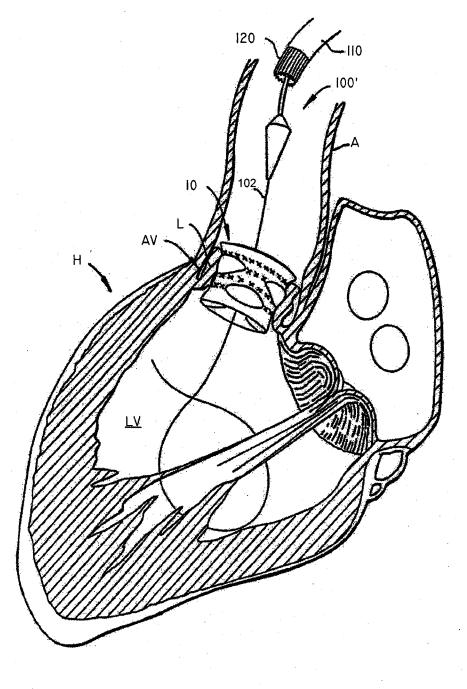
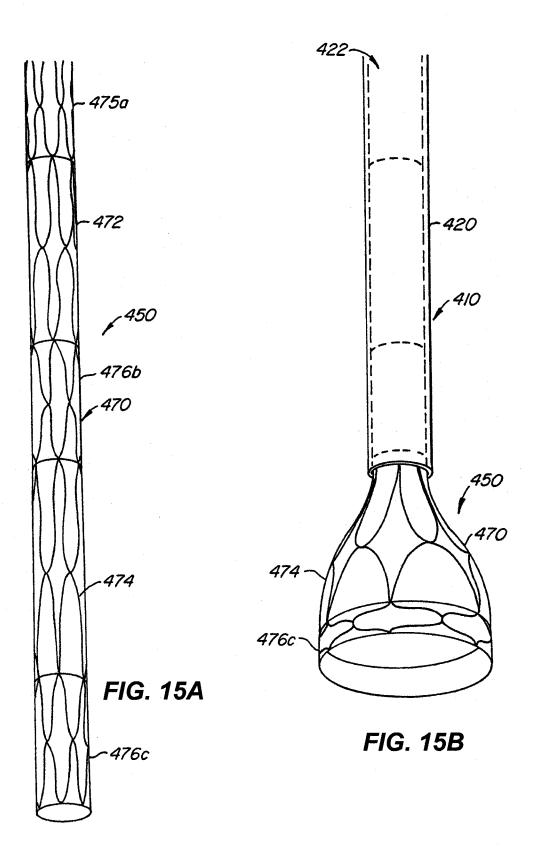
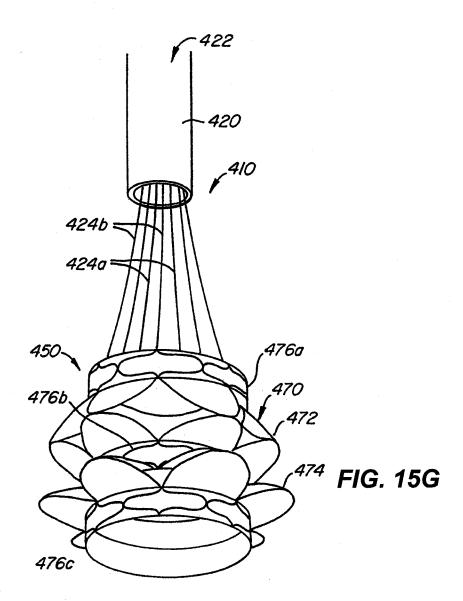


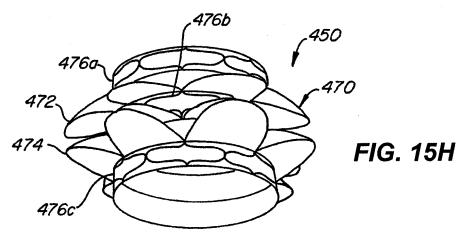
FIG 6F

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SH	HEET 28 / 51

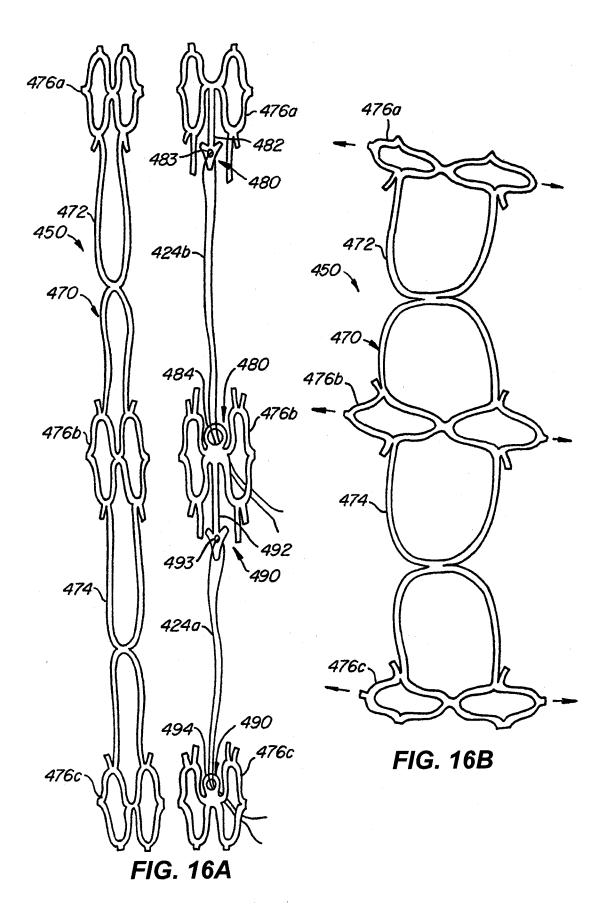


U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
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U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SH	EET 32 / 51



U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHI	EET 33 / 51

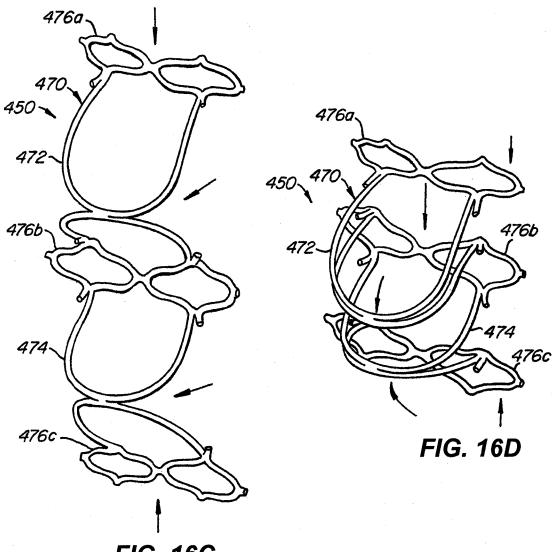
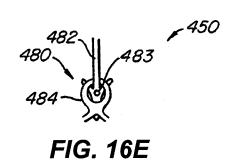


FIG. 16C



U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHI	EET 34 / 51

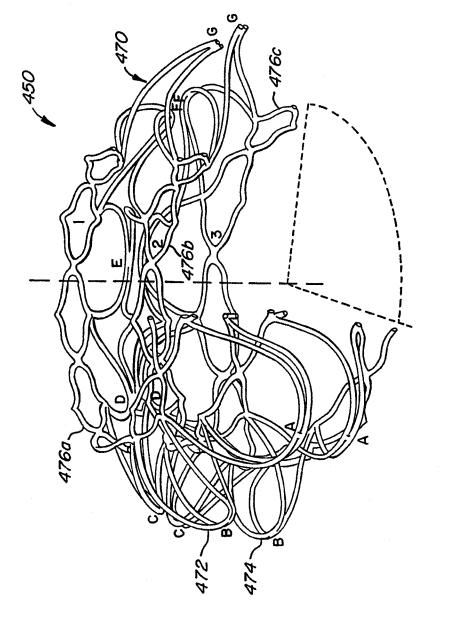
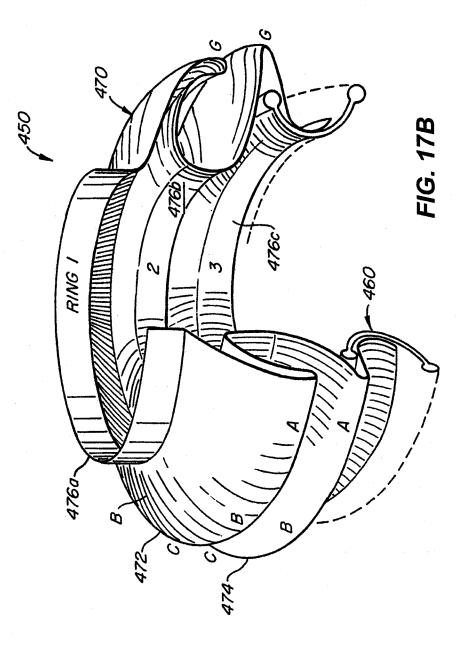


FIG. 17A

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SH	EET 35 / 51



U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHEET 36 / 51	

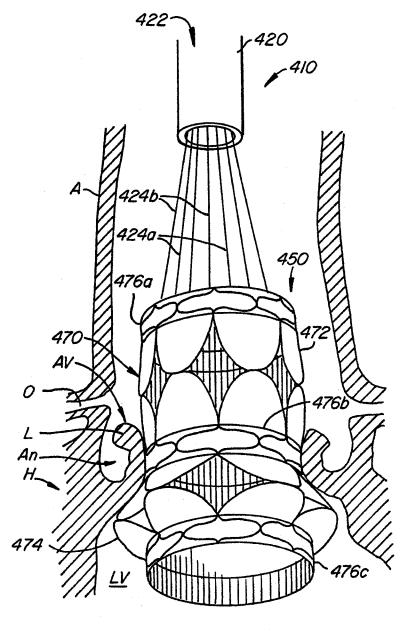


FIG. 18A

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SH	EET 37 / 51

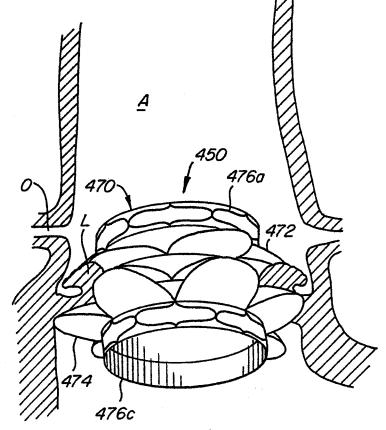
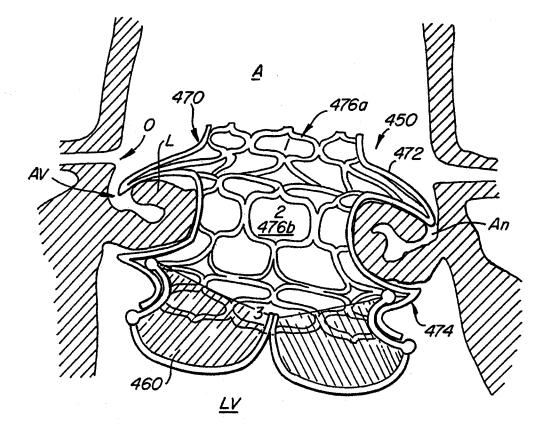




FIG. 18B

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHI	EET 38 / 51





U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHI	EET 39 / 51

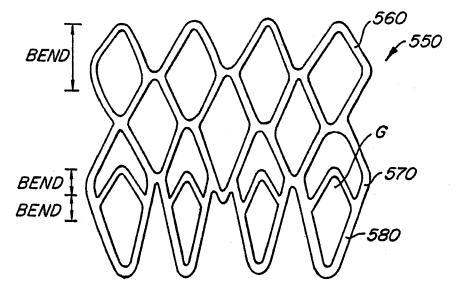


FIG. 19A

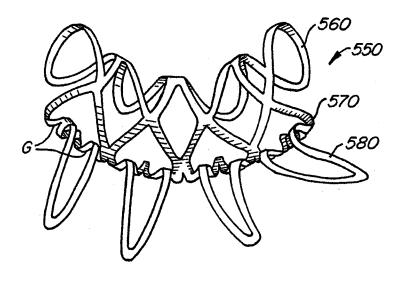


FIG. 19B

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHEET 40 / 51	

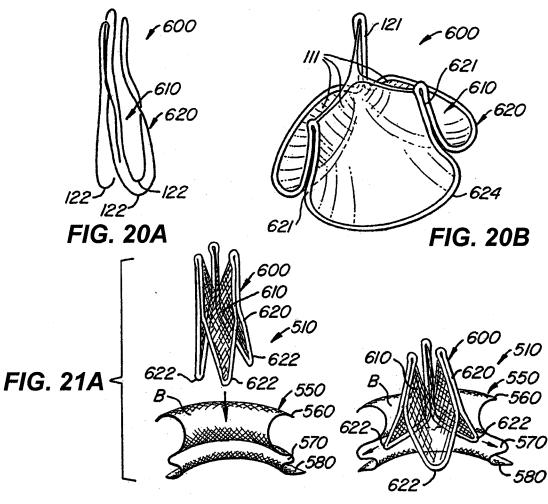
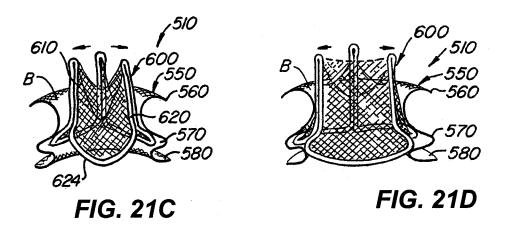
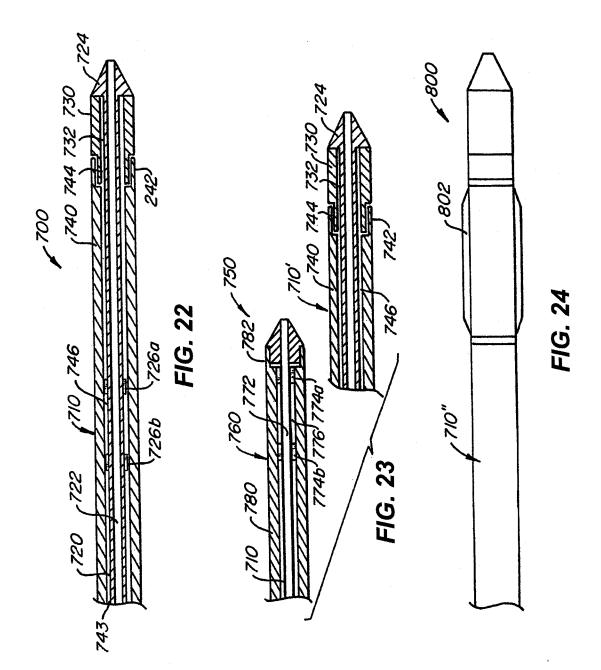


FIG. 21B



U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
 NEW SH	EET 41 / 51



Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 341 of 630

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHI	EET 42 / 51

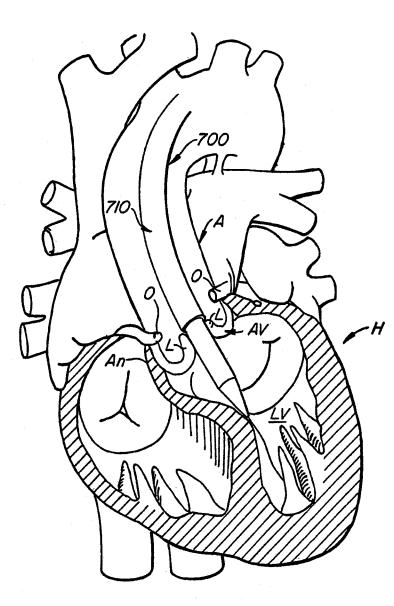


FIG. 25A

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHI	EET 43 / 51

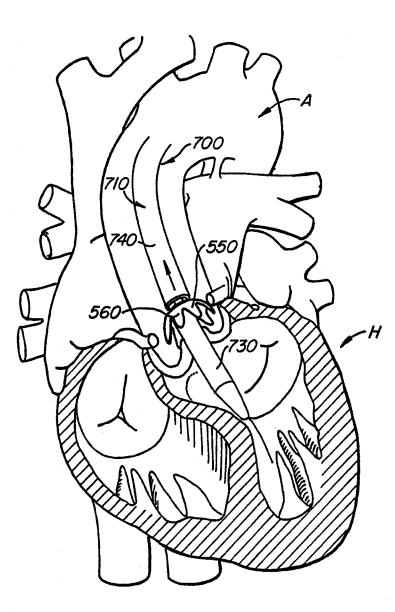


FIG. 25B

U.S. Appln. No. 10/972,287	Filed: 10/21/2004	
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501	
NEW SHEET 44 / 51		

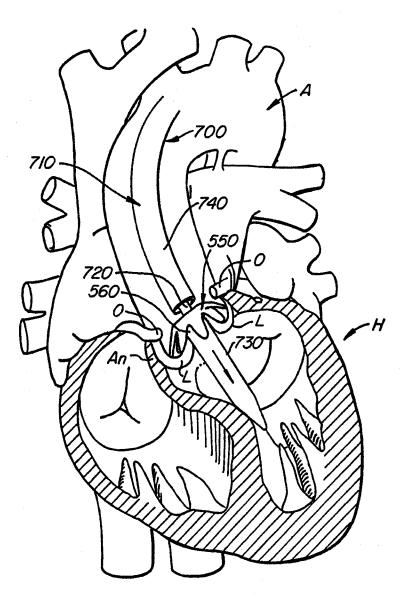


FIG. 25C

U.S. Appln. No. 10/972,287	Filed: 10/21/2004	
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501	
<b>NEW SHEET 45 / 51</b>		

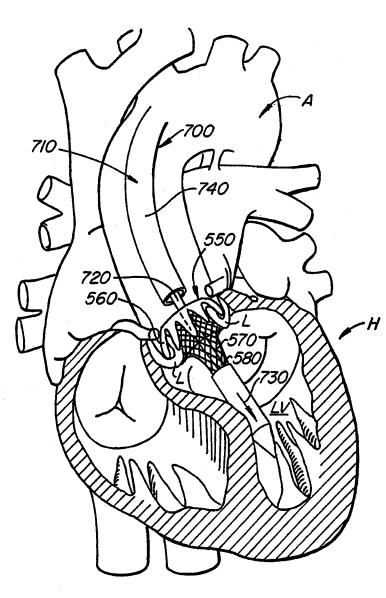


FIG. 25D

U.S. Appln. No. 10/972,287	Filed: 10/21/2004	
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501	
NEW SHEET 46 / 51		

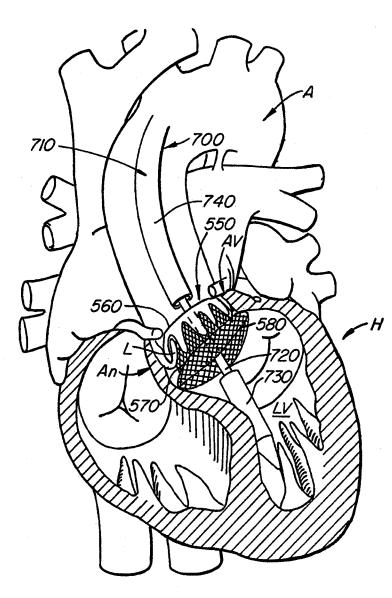


FIG. 25E

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 346 of 630

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SH	EET 47 / 51

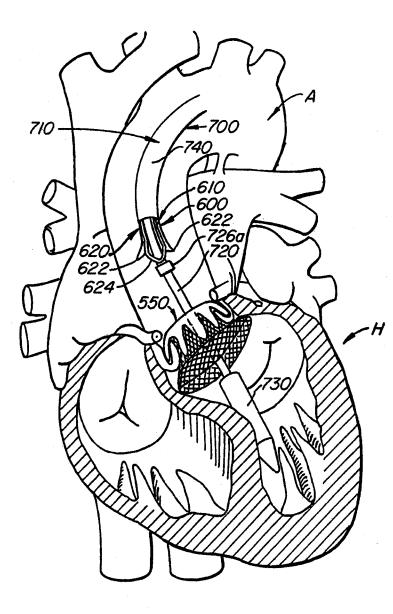


FIG. 25F

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 347 of 630

U.S. Appln. No. 10/972,287	Filed: 10/21/2004	
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501	
NEW SHEET 48 / 51		

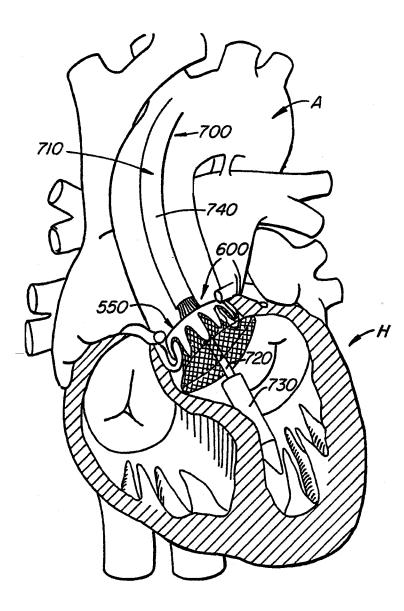


FIG. 25G

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SH	EET 49 / 51

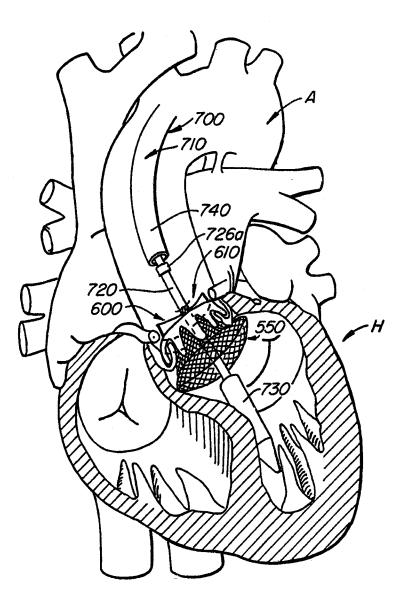


FIG. 25H

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHEET 50 / 51	

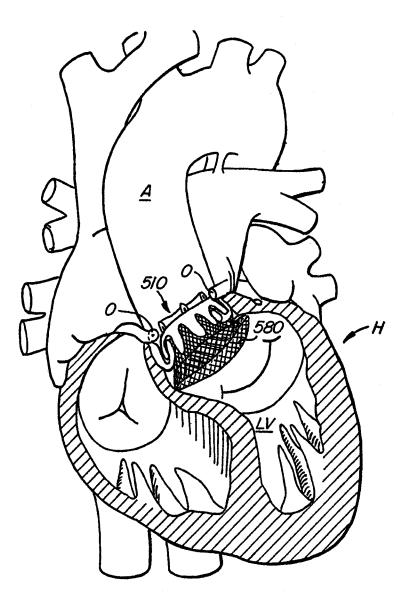
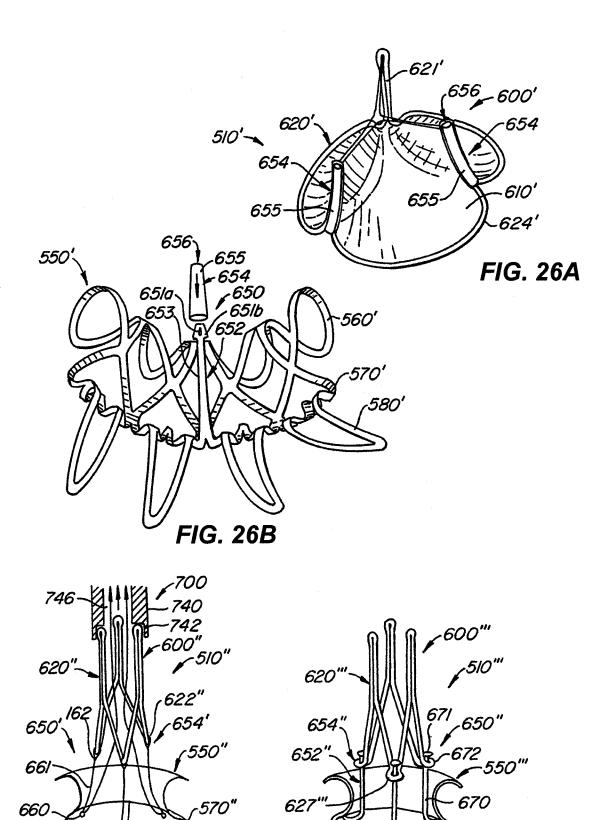


FIG. 251

U.S. Appln. No. 10/972,287	Filed: 10/21/2004
Inventors: Amr Salahieh et al.	Atty Docket: 10012-702.501
NEW SHEET 51 / 51	



660

652''

. FIG. 27

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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	<b>,</b>
Title:	LEAFLET ENGAGEMENT H	ELEMENTS AND METHODS FOR USE
	THEREOF	
Customer No ·	66854	

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

## <u>INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.97 & § 1.98</u>

#### 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:

 $\bigtriangleup$  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  $\square$  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.

#### <u>CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.98</u>

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,

Bv:

Thomas Zlogar Reg. # 55760

Shay Glenn LLP 2755 Campus Drive, Suite 210 San Mateo, CA 94403 (650) 212-1700

Customer No. 66854

Dated:

11/20/08

PTO/SB/08a (09-08)

Approved for use through 10/31/2008. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to re

Substitute for form 1449/PTO

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Sheet

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

11 of

	mplete 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. PATEN	T DOCUMENTS			
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	422	^{US-} 4,326,306	4/27/1982	Poler			
	423	^{US-} 4,423,809	1/3/1984	Mazzocco			
	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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		FOREIC	<b>SN PATENT DOCU</b>	MENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	Т6
	<u> </u>					
			· · · ·	Date		
Examiner				Considered		

Signature

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

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

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

Electronic Patent Application Fee Transmittal							
Application Number:		10972287					
Filing Date:	21	21-Oct-2004					
Title of Invention:		Leaflet engagement elements and methods for use thereof					
First Named Inventor/Applicant Name:	Amr Salahieh						
Filer:	Thomas M. Zlogar/Sue Bromaghim						
Attorney Docket Number:	Attorney Docket Number: 10012-702.501						
Filed as Small Entity							
Utility under 35 USC 111(a) Filing Fees							
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)		
Basic Filing:							
Pages:							
Claims:							
Miscellaneous-Filing:							
Petition:							
Patent-Appeals-and-Interference:							
Post-Allowance-and-Post-Issuance:							
Extension-of-Time:							

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

Electronic Ac	Electronic Acknowledgement Receipt					
EFS ID:	4329764					
Application Number:	10972287					
International Application Number:						
Confirmation Number:	7706					
Title of Invention:	Leaflet engagement elements and methods for use thereof					
First Named Inventor/Applicant Name:	Amr Salahieh					
Customer Number:	66854					
Filer:	Thomas M. Zlogar/Sue Bromaghim					
Filer Authorized By:	Thomas M. Zlogar					
Attorney Docket Number:	10012-702.501					
Receipt Date:	20-NOV-2008					
Filing Date:	21-OCT-2004					
Time Stamp:	21:21:15					
Application Type:	Utility under 35 USC 111(a)					

## Payment information:

Submitted with Payment	yes				
Payment Type	Deposit Account				
Payment was successfully received in RAM	\$180				
RAM confirmation Number	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)					

required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 358 of 630

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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.

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respon <b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875							pplication or l	if information unle Docket Number 2,287	Filing Date 10/21/2004		OMB control number.
APPLICATION AS FILED – PART I (Column 1) (Column 2)							SMALL ENTITY		OTHER THAN OR SMALL ENTITY		
	FOR		NUMBER FIL	ED NUM	/BER EXTRA		RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)
	BASIC FEE (37 CFR 1.16(a), (b),	or (c))	N/A		N/A		N/A			N/A	
	SEARCH FEE (37 CFR 1.16(k), (i), (	or (m))	N/A		N/A		N/A			N/A	
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A			N/A	
	AL CLAIMS CFR 1.16(i))		mir	us 20 = *			X \$ =		OR	X\$ =	
	EPENDENT CLAIM CFR 1.16(h))	S	m	inus 3 = *			X \$ =			X \$ =	
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	APP	(Column 1)		ED – PART II (Column 2)	(Column 3)		SMAL	L ENTITY	OR		ER THAN ILL ENTITY
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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.

	èd States Patent a	ND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22. www.uspto.gov	FOR PATENTS
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 SHAY GLENN 2755 CAMPUS			EXAM	
SUITE 210 SAN MATEO,	CA 94403		ART UNIT	PAPER NUMBER
or a marine,	01171105		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.

	Application No.	Applicant(s)			
	10/972,287	SALAHIEH ET AL.			
Office Action Summary	Examiner	Art Unit			
	REBECCA STRASZHEIM	3738			
The MAILING DATE of this communication app Period for Reply	bears on the cover sheet with the	correspondence address			
<ul> <li>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.</li> <li>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.</li> <li>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.</li> <li>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).</li> </ul>					
Status					
1) Responsive to communication(s) filed on $20 \text{ N}$	lovember 2008.				
	action is non-final.				
3) Since this application is in condition for allowa		osecution as to the merits is			
closed in accordance with the practice under <i>B</i>	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.			
Disposition of Claims					
4)⊠ Claim(s) <u>22-38 and 59-65</u> is/are pending in the	e application.				
4a) Of the above claim(s) <u>38</u> is/are withdrawn t					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>22-37 and 59-65</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/c	or election requirement.				
Application Papers					
9) The specification is objected to by the Examine	er.				
10) The drawing(s) filed on <u>20 November 2008</u> is/a		ted to by the Examiner.			
Applicant may not request that any objection to the		-			
Replacement drawing sheet(s) including the correc	tion is required if the drawing(s) is ob	pjected to. See 37 CFR 1.121(d).			
11) The oath or declaration is objected to by the Ex	caminer. Note the attached Office	e Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(a	ı)-(d) or (f).			
a) All b) Some * c) None of:	to have been reactived				
1.         Certified copies of the priority document           2.         Certified copies of the priority document		ion No			
3. Copies of the certified copies of the prior					
application from the International Burea	•	ed in this National Stage			
* See the attached detailed Office action for a list		ed.			
Attachment(s)	<b>—</b> .				
<ol> <li>1) X Notice of References Cited (PTO-892)</li> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> </ol>	4) 🛄 Interview Summary Paper No(s)/Mail D				
<ul> <li>3) ∑ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/21/2008</u>. <u>11/20/2008</u>.</li> </ul>	5) Notice of Informal I 6) Other:				
U.S. Patent and Trademark Office					

Office Action Summary

Part of Paper No./Mail Date 20090218

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 363 of 630

#### **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.

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 bee 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), a intermediate annular section (20) – making up the anchor, a proximal anchor flange (22), the replacement value itself (26), and an ablumenal graft portion (11a) (column 8, lines 28-64). The ablumenal 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 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. 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).

Page 3

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 negatived 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

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 used 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).

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

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 to.

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

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP
 § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37
 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to 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.

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

Notice of References Cited	Application/Control No. 10/972,287	Applicant(s)/Patent Under Reexamination SALAHIEH ET AL.		
Notice of Nerelences Offed	Examiner	Art Unit		
	REBECCA STRASZHEIM	3738	Page 1 of 1	

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	А	US-2003/0036791	02-2003	Philipp et al.	623/1.11
*	В	US-5,476,506	12-1995	Lunn, Anthony C.	623/1.28
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	F	US-			
	G	US-			
	н	US-			
	-	US-			
	J	US-			
	К	US-			
	L	US-			
	М	US-			

#### FOREIGN PATENT DOCUMENTS

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*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.

Part of Paper No. 20090218

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	10972287	SALAHIEH ET AL.
	Examiner	Art Unit
	REBECCA STRASZHEIM	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

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Class	Subclass	Date	Examiner

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Sheet 1

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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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. PATEN	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Г
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	328	WO 00/44308	8/3/2000	Board of Regents, The Univer		

#### Examiner Signature

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of 6

Complete if Known					
Application Number	10/972,287				
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First Named Inventor	Amr Salahieh				
Art Unit	3738				
Examiner Name	STRASZHEIM, REBECCA L				
Attomey Docket Number	10012-702.501	)			

	U. S. PATENT DOCUMENTS							
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		Number-Kind Code ^{2 (if known)}			Figures Appear			
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	348	WO 2004/041126	5/21/2004	Seguin, Jacques		

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	355	WO 95/04556	2/16/1995	Active Control Experts, Inc.		
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Examiner				Date	<u></u>	
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(Use as many sheets as necessary)	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. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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## 10972287 - GAU: 3738

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STATEMENT BY APPLICANT	First Named Inventor	Amr Salahieh		
(Use as many sheets as necessary)	Art Unit	3738		
	Examiner Name	STRASZHEIM, REBECCA L		
Sheet 5 of 6	Attorney Docket Number	10012-702.501		

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	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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Signature		Considered	
	itial if reference considered, whether or not citation is in conformance with MPEP	609. Draw line through o	itation 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

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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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 377 of 630

Examiner

# 10972287 - GAU: 3738

PTO/SB/08b (09-08)

Approved for use through 10/31/2008. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Substitute for form 1449/PTO	Complete if Known		
	Application Number	10/972,287	
INFORMATION DISCLOSURE	Filing Date	October 21, 2004	
STATEMENT BY APPLICANT	First Named Inventor	Amr Salahieh	
(Use as many sheets as necessary)	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. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²			
	403	SALAHIEH, et al., U.S. Pat. App. # 12/132,304 entitled "Low profile heart valve and delivery system," filed 06/03/2008				
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 Signature
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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.

/Rebecca Straszheim/

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 378 of 630

Date

02/27/2009

#### 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
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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
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Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 379 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (1 of 23)2/27/2009 10:24:34 AM

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Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 381 of 630 file:///CV/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (3 of 23)2/27/2009 10:24:34 AM

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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 386 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (8 of 23)2/27/2009 10:24:34 AM

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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 390 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (12 of 23)2/27/2009 10:24:34 AM

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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 394 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (16 of 23)2/27/2009 10:24:34 AM

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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 395 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (17 of 23)2/27/2009 10:24:34 AM

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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 396 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (18 of 23)2/27/2009 10:24:34 AM

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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 397 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (19 of 23)2/27/2009 10:24:34 AM

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#### PTO/SB/08a (09-08)

Approved for use through 10/31/2008. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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(Use as many sheets as necessary)

of 11

/Rebecca Straszheim/

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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
-	Attorney Docket Number	10012-702.501

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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 use to communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the senal number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant 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 402 of 630

Attorney Docket No.: 10012-702.501

# 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, REBECC	AL
Title:	LEAFLET ENGAGEMEN	TT ELEMENTS AND METHODS FOR USE
	THEREOF	
Customer No.:	66854	

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

# <u>INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.97 & § 1.98</u>

#### 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

 $\square$  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:

 $\square$  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  $\square$  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.

3/12/09 Dated:

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

Respectfully Submitted By:

Thomas Zlogar Reg. # 55760

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

alid OMB control number Under the Paperwork Reduction Act of 1995, no persons are required to re

Substitute for form 1449/PTO

1

Sheet

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

11 of

Cor	mplete 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. PATEN	T DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (If known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	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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Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	<b>T</b> 6
		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	1
	1		III / III / III / III / III			
		-				
	·					
Examiner				Date Considered		

Signature

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

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

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

Electronic Patent Application Fee Transmittal							
Application Number:	10	972287					
Filing Date:	21	-Oct-2004					
Title of Invention:	Leaflet engagement elements and methods for use thereof						
First Named Inventor/Applicant Name:	Amr Salahieh						
Filer:	Thomas M. Zlogar/Angelica Zuniga						
Attorney Docket Number:	10	012-702.501					
Filed as Large Entity							
Utility under 35 USC 111(a) Filing Fees							
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)		
Basic Filing:							
Pages:							
Claims:							
Miscellaneous-Filing:							
Petition:							
Patent-Appeals-and-Interference:							
Post-Allowance-and-Post-Issuance:							
Extension-of-Time:							

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

Electronic Acl	Electronic Acknowledgement Receipt						
EFS ID:	4958527						
Application Number:	10972287						
International Application Number:							
Confirmation Number:	7706						
Title of Invention:	Leaflet engagement elements and methods for use thereof						
First Named Inventor/Applicant Name:	Amr Salahieh						
Customer Number:	66854						
Filer:	Thomas M. Zlogar/Angelica Zuniga						
Filer Authorized By:	Thomas M. Zlogar						
Attorney Docket Number:	10012-702.501						
Receipt Date:	12-MAR-2009						
Filing Date:	21-OCT-2004						
Time Stamp:	17:57:51						
Application Type:	Utility under 35 USC 111(a)						

# Payment information:

Submitted with Payment	yes					
Payment Type	Deposit Account					
Payment was successfully received in RAM	\$180					
RAM confirmation Number	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)						

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 409 of 630

File Listin	g:								
Document Number	<b>Document Description</b>	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)				
1			234885						
1		10012-702501.pdf	3ba654c928f8ad18b8527a0204ff3cc0bc75 4df3	yes	4				
	Multip	art Description/PDF files in	zip description						
	Document De	Document Description Start							
	Information Disclosure	1		3					
	Information Disclosure Stater	4		4					
Warnings:			•						
Information:									
2	Fee Worksheet (PTO-06)	fee-info.pdf	29690	no	2				
2			9ff4a3f4219d2f3391a3d87d1762dd463b93 bb47	110					
Warnings:									
Information:									
		Total Files Size (in bytes)	: 26	54575					
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35									
national stag <u>New Internat</u> If a new inter an internatio and of the In national secu	U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.								

# 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 ELEM USE THEREOF	ENTS AND METHO	DS FOR
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.

# - 1 of 7 -

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 411 of 630

#### 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 valve₃; 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.

- 2 of 7 - Attorney Docket 10012-702.501

#### Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 412 of 630

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.

- 3 of 7 - Attorney Docket 10012-702.501

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 413 of 630

#### **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.

- 4 of 7 - Attorney Docket 10012-702.501

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 414 of 630

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,

# - 5 of 7 - Attorney Docket 10012-702.501

#### Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 415 of 630

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

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#### Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 416 of 630

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.

By:

Respectfully submitted,

Date: May 5, 2009

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

Attorney Docket 10012-702.501

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 417 of 630

Electronic A	Electronic Acknowledgement Receipt						
EFS ID:	5281982						
Application Number:	10972287						
International Application Number:							
Confirmation Number:	7706						
Title of Invention:	Leaflet engagement elements and methods for use thereof						
First Named Inventor/Applicant Name:	Amr Salahieh						
Customer Number:	66854						
Filer:	Thomas M. Zlogar/Mary Buggie						
Filer Authorized By:	Thomas M. Zlogar						
Attorney Docket Number:	10012-702.501						
Receipt Date:	05-MAY-2009						
Filing Date:	21-OCT-2004						
Time Stamp:	18:32:27						
Application Type:	Utility under 35 USC 111(a)						

# Payment information:

Submitted wi	th Payment	no	no						
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.	287842	2405	7				
I		pdf		yes	,				

	Multipart Description/PDF files in .zip description						
	Document Description	Start	End				
	Amendment After Final	1	1				
	Claims	2	3				
	Applicant Arguments/Remarks Made in an Amendment	4	7				
Warnings:	I	I					
Information:							
	Total Files Size (in bytes):	287	7842				

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

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

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

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

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

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

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

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

P/	Under the Paperwork Reduction Act of 1995, no persons are required to <b>TENT APPLICATION FEE DETERMINATION RECO</b> Substitute for Form PTO-875 APPLICATION AS FILED – PART I						pplication or I	7 information unle Docket Number 2,287	Filing Date 10/21/2004		To be Mailed	
	AF	PPLICATION	AS FILE (Column 1		Column 2)		SMALL ENTITY				THER THAN ALL ENTITY	
	FOR	N	UMBER FIL	ED NUN	BER EXTRA		RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)	
BASIC FEE (37 CFR 1.16(a), (b), or (c))		or (c))	N/A		N/A		N/A			N/A		
	SEARCH FEE (37 CFR 1.16(k), (i), (	or (m))	N/A		N/A		N/A			N/A		
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A			N/A		
	FAL CLAIMS CFR 1.16(i))		mir	us 20 = *			X \$ =		OR	X \$ =		
IND	EPENDENT CLAIM CFR 1.16(h))	S	m	inus 3 = *			X \$ =			X \$ =		
	APPLICATION SIZE (37 CFR 1.16(s))	FEE shee is \$2 addit	ts of pap 50 (\$125 ional 50 s	ation and drawing er, the application for small entity) sheets or fraction a)(1)(G) and 37 (	n size fee due for each n thereof. See							
	MULTIPLE DEPEN											
* If t	he difference in colu		,				TOTAL			TOTAL		
	APP	(Column 1)	AMENL	ED – PART II (Column 2)	(Column 3)		SMAL	L ENTITY	OR		ER THAN ALL ENTITY	
ПТ	05/05/2009	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)	
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AMI	Application Si	ize Fee (37 CFR 1	.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								OR			
							TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE		
		(Column 1)	_	(Column 2)	(Column 3)		_					
Г		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	additional Fee (\$)		RATE (\$)	ADDITIONAL FEE (\$)	
Ľ	Total (37 CFR 1.16(i))	*	Minus	**	=		X \$ =		OR	X \$ =		
DM	Independent (37 CFR 1.16(h))	*	Minus	***	=		X \$ =		OR	X \$ =		
AMENDMENT	Application Si	ize Fee (37 CFR 1	.16(s))									
AN	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								OR			
						•	TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
** If *** I The This c	the entry in column the "Highest Numb f the "Highest Numb "Highest Number P collection of informal	er Previously Paid per Previously Pai reviously Paid Fo tion is required by	For" IN TH d For" IN T r" (Total or 37 CFR 1.	HS SPACE is less HIS SPACE is less Independent) is the	than 20, enter "20" a than 3, enter "3". e highest number f n is required to obt	oun ain (	/SHAUN d in the appro or retain a ber	efit by the public	MAN/ mn 1. which is	er:		

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 ELEM USE THEREOF	ENTS AND METHOD	S FOR
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.

# - 1 of 7 -

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 421 of 630

Unit	ed States Patent	AND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.uspto.gov	FOR PATENTS
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 SHAY GLENN 2755 CAMPUS			EXAM	
SUITE 210 SAN MATEO,	CA 94403		ART UNIT	PAPER NUMBER
or a marine,			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.

Γ							
	Application No.	Applicant(s)					
Advisory Action	10/972,287	SALAHIEH ET AL.					
Before the Filing of an Appeal Brief	Examiner	Art Unit					
	REBECCA STRASZHEIM	3738					
The MAILING DATE of this communication appe	ears on the cover sheet with the	correspondence add	ress				
THE REPLY FILED 05 May 2009 FAILS TO PLACE THIS APP	LICATION IN CONDITION FOR AI	LOWANCE.					
application, applicant must timely file one of the following application in condition for allowance; (2) a Notice of App for Continued Examination (RCE) in compliance with 37 C periods:	<ol> <li>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:         <ul> <li>The period for reply expiresmonths from the mailing date of the final rejection.</li> </ul> </li> </ol>						
<ul> <li>a) I he period for reply expiresmonths from the mailing</li> <li>b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire is</li> </ul>	dvisory Action, or (2) the date set forth						
Examiner Note: If box 1 is checked, check either box (a) or ( MONTHS OF THE FINAL REJECTION. See MPEP 706.07(	f).						
Extensions of time may be obtained under 37 CFR 1.136(a). The date have been filed is the date for purposes of determining the period of ex under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the s set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b) NOTICE OF APPEAL	tension and the corresponding amount shortened statutory period for reply orig than three months after the mailing dat	of the fee. The appropria nally set in the final Offic te of the final rejection, e	ate extension fee æ action; or (2) as ven if timely filed,				
<ol> <li>The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exter Notice of Appeal has been filed, any reply must be filed w AMENDMENTS</li> </ol>	nsion thereof (37 CFR 41.37(e)), to	avoid dismissal of the					
3. X The proposed amendment(s) filed after a final rejection, I	out prior to the date of filing a brief	will not be entered be	cause				
<ul> <li>(a) ☐ They raise new issues that would require further co</li> <li>(b) ☐ They raise the issue of new matter (see NOTE belo</li> <li>(c) ☑ They are not deemed to place the application in beto</li> </ul>	nsideration and/or search (see NO ⁻ w);	ΓE below);					
appeal; and/or (d) They present additional claims without canceling a							
NOTE: (See 37 CFR 1.116 and 41.33(a)).							
4. The amendments are not in compliance with 37 CFR 1.12 5. Applicant's reply has overcome the following rejection(s)		mpliant Amendment (	PTOL-324).				
6. Newly proposed or amended claim(s) would be al non-allowable claim(s).		timely filed amendmer	nt canceling the				
7. For purposes of appeal, the proposed amendment(s): a)		l be entered and an e	xplanation of				
how the new or amended claims would be rejected is prov The status of the claim(s) is (or will be) as follows: Claim(s) allowed:	<i>i</i> ided below or appended.						
Claim(s) objected to: Claim(s) rejected: <u>22-37, 59-65</u> .							
Claim(s) withdrawn from consideration: <u>38</u> .							
<ul> <li><u>AFFIDAVIT OR OTHER EVIDENCE</u></li> <li>The affidavit or other evidence filed after a final action, bu because applicant failed to provide a showing of good and was not earlier presented. See 37 CFR 1.116(e).</li> </ul>							
<ul> <li>9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to c showing a good and sufficient reasons why it is necessary</li> </ul>	vercome <u>all</u> rejections under appea	al and/or appellant fail	s to provide a				
10. The affidavit or other evidence is entered. An explanatio			•				
REQUEST FOR RECONSIDERATION/OTHER 11. I 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 <i>Disclosure Statement</i> (s). 13. □ Other:	(PTO/SB/08) Paper No(s)						
/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. 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.

PTO/SB/08a (03-09)

Approved for use through 04/30/2009. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO

Sheet 1

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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. ¹	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 ^{2 (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 DOCU	MENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ "Number ⁴ "Kind Code ⁵ (<i>if known</i>)	MM-DD-YYYY		Or Relevant Figures Appear	⊤ ⁶
						_
Examiner Signature				Date Considered		

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

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademerk 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.

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 425 of 630

Electronic Patent Application Fee Transmittal					
Application Number:	109	972287			
Filing Date:	21-	Oct-2004			
Title of Invention:	Leaflet engagement elements and methods for use thereof				
First Named Inventor/Applicant Name:	Amr Salahieh				
Filer:	James R. Shay/Sue Bromaghim (TZ)				
Attorney Docket Number: 10012-702.501					
Filed as Small Entity					
Utility under 35 USC 111(a) Filing Fees					
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:					
Pages:					
Claims:					
Miscellaneous-Filing:					
Petition:					
Patent-Appeals-and-Interference:					
Post-Allowance-and-Post-Issuance:					
Extension-of-Time:					
Extension - 1 month with \$0 paid Edwards Lifesciene	es C	2251 C orporation, e t	1 t al. Exhib i	⁶⁵ t 1142, Page 4	65 26 of 630

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Request for continued examination	2801	1	405	405
	Tot	al in USD) (\$)	470

Electronic A	Electronic Acknowledgement Receipt					
EFS ID:	5620276					
Application Number:	10972287					
International Application Number:						
Confirmation Number:	7706					
Title of Invention:	Leaflet engagement elements and methods for use thereof					
First Named Inventor/Applicant Name:	Amr Salahieh					
Customer Number:	66854					
Filer:	James R. Shay/Sue Bromaghim (TZ)					
Filer Authorized By:	James R. Shay					
Attorney Docket Number:	10012-702.501					
Receipt Date:	30-JUN-2009					
Filing Date:	21-OCT-2004					
Time Stamp:	18:32:23					
Application Type:	Utility under 35 USC 111(a)					

Payment information:

Submitted wit	h Payment	yes		
Payment Type D		Deposit Account		
Payment was successfully received in RAM		\$470		
RAM confirmation Number		6151		
Deposit Account		504050		
Authorized User				
File Listing	j :			
Document Number	Document Description Edwards Lifesci	File Name File Name Message Digest File Name Message Digest Part /.zip Sif appl.)		

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I		Amendment-IDS.pdf	d01fe170aaa29e879f32c22dd546bd2791b 1b563	yes	12
	Multip	oart Description/PDF files in	zip description		
	Document De	scription	Start	E	nd
	Extension o	1		1	
	Request for Continued I	Examination (RCE)	2		2
	Amendment Submitted/Entere	ed with Filing of CPA/RCE	3		3
	Claims	5	4		5
	Applicant Arguments/Remarks	6		8	
	Transmittal	9		11	
	Information Disclosure Stater	12		12	
Warnings:	L			I	
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2	Fee Worksheet (PTO-875)	fee-info.pdf	31793	no	2
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Warnings:					
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		Total Files Size (in bytes)	15	584714	
characterize Post Card, as <u>New Applica</u> If a new appl 1.53(b)-(d) a Acknowledg <u>National Sta</u> If a timely su U.S.C. 371 ar national stag	vledgement Receipt evidences receip of by the applicant, and including pa s described in MPEP 503. <u>Itions Under 35 U.S.C. 111</u> lication is being filed and the applica nd MPEP 506), a Filing Receipt (37 CI gement Receipt will establish the filin <u>ge of an International Application un</u> Ibmission to enter the national stage and other applicable requirements a F ge submission under 35 U.S.C. 371 w tional Application Filed with the USF	ge counts, where applicable. Ation includes the necessary of FR 1.54) will be issued in due ng date of the application. <u>Inder 35 U.S.C. 371</u> of an international applicat Form PCT/DO/EO/903 indicat ill be issued in addition to th	It serves as evidence components for a filir course and the date s ion is compliant with ing acceptance of the	e of receipt s ng date (see shown on th the conditio	similar to a 37 CFR is ons of 35
lf a new inter an internatio and of the In	rnational application is being filed a onal filing date (see PCT Article 11 an iternational Filing Date (Form PCT/R urity, and the date shown on this Acl	nd the international applicat nd MPEP 1810), a Notification O/105) will be issued in due c	of the International ourse, subject to pres	Application scriptions co	Number oncerning

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	s 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.

Date: June 30, 2009

By:

Respectfully submitted,

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

Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, r	no persons are required to respond to	a collection of informati	ion unless it contains a vali	d OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are reduci			mante a tana eme contro control number.			
Request	Application Number	10/972,287				
for Continued Examination (RCE)	Filing Date	October 21, 2	2004			
Transmittal	First Named Inventor	Amr SALAHI	EH et al.			
Address to: Mail Stop RCE	Art Unit	3738				
Commissioner for Patents P.O. Box 1450	Examiner Name	Rebecca L. S	STRASZHEIM			
Alexandria, VA 22313-1450	Attorney Docket Numbe	10012-702.50	01			
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.						
 Submission required under 37 CFR 1.114 No amendments enclosed with the RCE will be entered in th applicant does not wish to have any previously filed uner amendment(s). 	e order in which they were filed	unless applicant	instructs otherwise. If			
a. Previously submitted. If a final Office action is considered as a submission even if this box is		led after the fina	I Office action may be			
i. Consider the arguments in the Appeal Brief or Reply Brief previously filed on						
li. Other Amendment Accompanying RCE, filed herewith						
b. 🗹 Enclosed						
I. Amendment/Reply iii. Information Disclosure Statement (IDS)						
ii. Affidavit(s)/ Declaration(s)	iv Z	RANSMITTAL-E	XT OF TIME			
2. Miscellaneous						
Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a						
a period of months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)						
b. Cher	<u></u>					
 3. Fees a. Image: 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. <u>50-4050</u>. 						
i. RCE fee required under 37 CFR 1.17(e)					
ii. Extension of time fee (37 CFR 1.136 and						
iii Other						
b. Check in the amount of \$	enclose	b				
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.						
	ANT, ATTORNEY, OR AGENT					
Signature Thomas M ZLOGAR		ate egistration No.	JUNE 30, 2009 55,760			
		-	100,700			
CERTIFICATE OF MAILING OR TRANSMISSION I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.						
Signature FILED VIA EFS						
Name (Print/Type) SUE BROMAGHIM	Da	00112 00, 20				
This collection of information is required by 37 CFR 1.114. The information process) an application. Confidentiality is governed by 35 U.S.C. 12 including gathering, preparing, and submitting the completed application the amount of time you require to complete this form and/or suggestion. Trademark Office, U.S. Department of Commerce, P.O. Box 1450.	22 and 37 CFR 1.11 and 1.14. This in form to the USPTO. Time will vary ns for reducing this burden, should b	collection is estima depending upon th e sent to the Chief	ated to take 12 minutes to complete, to individual case. Any comments on 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 CO 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 There	of
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.

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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_{$\frac{1}{2}$}

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

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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.

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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

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and a replacement value to a vicinity of the native heart value, wherein leaflet engagement elements extend distally from a proximal end of the anchor, sandwiching native value 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.

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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,

homas/

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

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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, REBEC	CAL
Title:	LEAFLET ENGAGEME	NT ELEMENTS AND METHODS FOR USE
	THEREOF	
Customer No :	66851	

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

<u>INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.97 & § 1.98</u>

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 <u>application</u> 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

 \checkmark 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:

 \square 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 \square 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.

<u>CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER</u> 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:

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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.

6/30/09 Dated:

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

Respectfully Submitted,

Bv:

Thomas Zlogar Reg. # 55760

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

P/	ATENT APPL		E DETI	ERMINATION			pplication or I	7 information unle Docket Number 2,287	Fil	ing Date 21/2004	OMB control number.
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	FOR	Ν	IUMBER FIL	ED NUN	BER EXTRA		RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)
	BASIC FEE (37 CFR 1.16(a), (b),	or (c))	N/A		N/A		N/A			N/A	
	SEARCH FEE (37 CFR 1.16(k), (i), (or (m))	N/A		N/A		N/A			N/A	
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A			N/A	
	FAL CLAIMS CFR 1.16(i))		mir	us 20 = *			X \$ =		OR	X \$ =	
	EPENDENT CLAIM CFR 1.16(h))	S	m	inus 3 = *			X \$ =			X \$ =	
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AMENDMENT	Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0		X \$110 =	0	OR	X \$ =	
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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.

Unit	ed States Patent	TAND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.uspto.gov	FOR PATENTS
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004	Amr Salahieh	10012-702.501	7706
SHAY GLENN 2755 CAMPUS			EXAM	
SUITE 210 SAN MATEO,	CA 94403		ART UNIT	PAPER NUMBER
512 102120,			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.

		Application No.	Applicant(s)
		10/972,287	SALAHIEH ET AL.
	Office Action Summary	Examiner	Art Unit
		REBECCA STRASZHEIM	3738
Period fo	The MAILING DATE of this communication ap or Reply	pears on the cover sheet with the c	correspondence address
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL CHEVER IS LONGER, FROM THE MAILING D nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. D period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailin ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION (36(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).
Status			
1)🖂	Responsive to communication(s) filed on <u>30 J</u>	une 2009.	
		s action is non-final.	
3)	Since this application is in condition for allowa	nce except for formal matters, pro	osecution as to the merits is
	closed in accordance with the practice under h	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.
Disposit	ion of Claims		
4)X	Claim(s) 60-66 is/are pending in the applicatio	n	
-	4a) Of the above claim(s) is/are withdra		
	Claim(s) is/are allowed.		
	Claim(s) <u>60-66</u> is/are rejected.		
7) 	Claim(s) is/are objected to.		
8)	Claim(s) are subject to restriction and/o	or election requirement.	
Applicat	ion Papers		
,	The specification is objected to by the Examine		te el te de la Francia en
10)	The drawing(s) filed on <u>20 November 2008</u> is/a		-
	Applicant may not request that any objection to the		
	Replacement drawing sheet(s) including the correc		
	The oath or declaration is objected to by the Ex	xaminer. Note the attached Office	Action of form PTO-152.
Priority u	ınder 35 U.S.C. § 119		
	Acknowledgment is made of a claim for foreigr	n priority under 35 U.S.C. § 119(a)-(d) or (f).
a)	☐ All b) Some * c) None of:		
	1. Certified copies of the priority document		
	2. Certified copies of the priority document		
	3. Copies of the certified copies of the prio	•	ed in this National Stage
* *	application from the International Burea		
* (See the attached detailed Office action for a list	of the certified copies not receive	ed.
Attachmen	t(s)		
	e of References Cited (PTO-892)	4) 🔲 Interview Summary	v (PTO-413)
2) 🔲 Notic	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D	ate
3) 🛛 Inform Page	nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>3/12/2009, 6/30/2009</u> .	5) 🛄 Notice of Informal F 6) 🛄 Other:	ratent Application
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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-

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 negatived 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.

Application/Control Number: 10/972,287 Art Unit: 3738

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://pairdirect.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (tollfree). 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)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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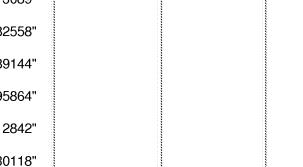
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S 45	104	(leaflet same (sandwich \$4)) and "623".clas.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/02/18 17:44
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S48	3202	((balloon or self) near3 expand\$4) same valve	US-PGPUB; 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
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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

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EAST Search History

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 497 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (50 of 57)8/5/2009 12:50:47 PM

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Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 500 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (53 of 57)8/5/2009 12:50:47 PM

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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	10972287	SALAHIEH ET AL.
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SEARCHED					
Class	Subclass	Date	Examiner		
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SEARCH NOTES

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EAST inventor name search, EAST subject search, discussed search	8/12/2008	RLS
strategy with Primary Examiner Suzette Gherbi		
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EAST inventor name search, EAST text search	8/5/2009	RLS

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

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				DOCUMENTS	
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	438	^{US-} 4,602,911	07/29/1986	Ahmadi et al.	
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	439	^{US-} 5,984,959	11/16/1999	Robertson et al.	
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		FOREIG	N PATENT DOCU	MENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Τ ⁶
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Examine	
Signatur	e

/Rebecca Straszheim/

Date Considered

08/05/2009

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

Sheet 1

10972287 - GAU: 3738

PTO/SB/08a (03-09)

Approved for use through 04/30/2009. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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				
٦	Attorney Docket Number	10012-702.501				

		~~~~~	U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No. ¹	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 ^{2 (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	Salahiah et al.	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	<b>T</b> 6
		Country Code ³ Number ⁴ "Kind Code ⁵ ( <i>if known</i> )	MM-DD-YYYY		Or Relevant Figures Appear	
Examiner Signature		/Rebecca Straszheim/		Date Considered	08/05/2009	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to plece 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. Petent and Tredemerk 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 507 of 630

## 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 N	lethods for Use Thereo	of
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.

### - 1 of 9 -

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 508 of 630

#### 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.

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#### Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 509 of 630

#### 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

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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;

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Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 511 of 630

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.

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Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 512 of 630

#### **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."

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#### Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 513 of 630

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

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#### Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 514 of 630

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.

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#### 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.

By:

Respectfully submitted,

Date: November 3, 2009

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

- 9 of 9 - Attorney Docket 10012-702.501

## 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 E	ELEMENTS AND METHODS FOR USE
	THEREOF	
Customer No.:	66854	

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

#### <u>INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.97 & § 1.98</u>

#### Sir:

Π

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  $\S$  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  $\S$  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

 $\boxtimes$  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:

 $\bigtriangleup$  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  $\square$  B). A certification as specified in § 1.97(e) is provided below; thus no fee is required.

#### **37 CFR § 1.97(d)**

 $\boxtimes$ 

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.

#### <u>CONTENT OF INFORMATION DISCLOSURE STATEMENT UNDER</u> <u>37 CFR § 1.98</u>

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

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

#### 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  $\bowtie$ any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-4050.

Dated:_11/3/01

filing date:

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

Respectfully Submitted,

By: Thomas Zlogar Reg. # 55760

PTO/SB/08a (07-09)

Approved for use through 07/31/2012. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Sheet 1

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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. ¹	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
<u></u>	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.				

		FOREI	<b>GN PATENT DOCU</b>	MENTS		
Examiner Initials*	Cite Na. ¹	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 ₆
		Country Code Number Kind Code (# Known)				
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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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant 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.

PTO/SB/08a (07-09)

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Substitute for form 1449/PTO

Sheet

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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	7				

	U. S. PATENT DOCUMENTS							
Examiner Cite Initials* No. ¹		Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant			
		Number-Kind Code ^{2 (If known)}			Figures Appear			
	458	^{US-} 2006/0155312	7/13/2006	Levine et əl.				
	448	^{US-} 2005/0043711	2/24/2005	Corcoran et al.				
	457	^{US-} 2005/0197694	9/8/2005	Pai et əl.				
	449	^{US-} 2008/0288054	11/20/2008	Pulnev et al.				
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		FOREIG	N PATENT DOCU	MENTS	· · · · · · · · · · · · · · · · · · ·	
Examiner Initials*	Cite No. ¹	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	٣
		· .				
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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language

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.

PTO/SB/08b (07-09)

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Substitut	te for form 1449/PTO			Complete if Known			
				Application Number	10/972,287		
INFO	ORMATION	DIS	CLOSURE	Filing Date	October 21, 2004		
STATEMENT BY APPLICANT Firs			PPLICANT	First Named Inventor	Amr Salahieh		
	llee as many she	ofe ar n	acassani	Art Unit	3738		
(Use as many sheets as necessary)		Examiner Name	STRASZHEIM, REBECCA L				
Sheet	3	of	3	Attorney Docket Number	10012-702.501		

NON PATENT LITERATURE DOCUMENTS           Examiner         Cite         Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of								
Initials*	No. ¹	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²					
	450	HAUG et al.; U.S. Pat. App. # 12/492,512 entitled "Everting Heart Valve," filed 06/26/2009						
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Examiner Signature

Considered

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

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

Electronic Patent Application Fee Transmittal						
Application Number:	10972287					
Filing Date:	21	-Oct-2004				
Title of Invention:       Leaflet engagement elements and methods for u				thods for use there	eof	
First Named Inventor/Applicant Name:	An	nr Salahieh				
Filer:	Thomas M. Zlogar/Sue Bromaghim					
Attorney Docket Number:	Attorney Docket Number: 10012-702.501					
Filed as Small Entity						
Utility under 35 USC 111(a) Filing Fees						
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)	
Basic Filing:						
Pages:						
Claims:						
Miscellaneous-Filing:						
Petition:	Petition:					
Patent-Appeals-and-Interference:						
Post-Allowance-and-Post-Issuance:						
Extension-of-Time:						

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

Electronic Ac	cknowledgement Receipt
EFS ID:	6385961
Application Number:	10972287
International Application Number:	
Confirmation Number:	7706
Title of Invention:	Leaflet engagement elements and methods for use thereof
First Named Inventor/Applicant Name:	Amr Salahieh
Customer Number:	66854
Filer:	Thomas M. Zlogar/Sue Bromaghim
Filer Authorized By:	Thomas M. Zlogar
Attorney Docket Number:	10012-702.501
Receipt Date:	03-NOV-2009
Filing Date:	21-OCT-2004
Time Stamp:	18:42:18
Application Type:	Utility under 35 USC 111(a)

## Payment information:

Submitted with Payment	yes				
Payment Type	Deposit Account				
Payment was successfully received in RAM	\$180				
RAM confirmation Number 4749					
Deposit Account	504050				
Authorized User					
The Director of the USPTO is hereby authorized to charge	e indicated fees and credit any overpayment as follows:				
Charge any Additional Fees required under 37 C.F.R. Se	ction 1.16 (National application filing, search, and examination fees)				
	ction 1.17 (Patent application and reexamination processing fees)				

required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 525 of 630

File Listing	<b>j</b> :					
Document Number	<b>Document Description</b>	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)	
1		10012-702-501-Amendment-	1932024		15	
1		IDS.pdf	7a8d8e8ac9d4c6aa03bcbd486c02328047e f2d51	yes	15	
	Multip	art Description/PDF files in	zip description			
	Document De	scription	Start	End		
	Amendment/Req. Reconsiderati	on-After Non-Final Reject	1		1	
_	Specificat	ion	2		2	
_	Claims		3		5	
_	Applicant Arguments/Remarks	Made in an Amendment	6		9	
_	Transmittal	Letter	10		12	
	Information Disclosure Stater	nent (IDS) Filed (SB/08)	13		15	
Warnings:						
Information:		1	1			
2	Fee Worksheet (PTO-875)	fee-info.pdf	29805	no	2	
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Warnings:						
Information:			1			
		Total Files Size (in bytes)	: 19	61829		
characterized Post Card, as <u>New Applicat</u> If a new appli 1.53(b)-(d) an Acknowledge <u>National Stag</u>	edgement Receipt evidences receip I by the applicant, and including pay described in MPEP 503. <u>ions Under 35 U.S.C. 111</u> cation is being filed and the applica id MPEP 506), a Filing Receipt (37 CF ement Receipt will establish the filin <u>re of an International Application ur</u>	ge counts, where applicable. tion includes the necessary of R 1.54) will be issued in due g date of the application. <u>Inder 35 U.S.C. 371</u>	It serves as evidence components for a filin course and the date s	of receipt s g date (see hown on th	similar to a 37 CFR is	
lf a timely sub U.S.C. 371 and	omission to enter the national stage d other applicable requirements a F e submission under 35 U.S.C. 371 wi	of an international applicat orm PCT/DO/EO/903 indicat	ing acceptance of the	application		
If a new intern an internation and of the Int	ional Application Filed with the USP national application is being filed an nal filing date (see PCT Article 11 an ernational Filing Date (Form PCT/RC rity, and the date shown on this Ack on.	nd the international applicat d MPEP 1810), a Notification D/105) will be issued in due c	of the International <i>l</i> ourse, subject to pres	Application criptions co	Number oncerning	

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

P/	ATENT APPL		E DETI	ERMINATION			pplication or l	of information unle Docket Number 2,287	Fil	plays a valid ing Date 21/2004	OMB control number.
	AI	PPLICATION	AS FILE (Column 1		Column 2)		SMALL	entity 🛛	OR		HER THAN
	FOR		UMBER FIL	, , ,	/BER EXTRA		RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)
	BASIC FEE (37 CFR 1.16(a), (b),		N/A		N/A		N/A			N/A	(.)
	SEARCH FEE (37 CFR 1.16(k), (i), (i), (i), (i), (i), (i), (i), (i		N/A		N/A		N/A			N/A	
	EXAMINATION FE (37 CFR 1.16(o), (p),		N/A		N/A		N/A			N/A	
	FAL CLAIMS CFR 1.16(i))		mir	us 20 = *			X \$ =		OR	X \$ =	
IND	EPENDENT CLAIM CFR 1.16(h))	S	m	inus 3 = *			X \$ =			X \$ =	
	APPLICATION SIZE (37 CFR 1.16(s))	FEE shee is \$2 addi	ets of pap 50 (\$125 tional 50 s	ation and drawing er, the application for small entity) sheets or fraction a)(1)(G) and 37 (	n size fee due for each n thereof. See						
	MULTIPLE DEPEN		,	3,,							
* If t	he difference in colu	umn 1 is less than	zero, ente	r "0" in column 2.			TOTAL			TOTAL	
	APP	(Column 1)	AMEND	DED – PART II (Column 2) HIGHEST	(Column 3)		SMAL	L ENTITY	OR		ER THAN LL ENTITY
AMENDMENT	11/03/2009	REMAINING AFTER AMENDMENT		NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
ME	Total (37 CFR 1.16(i))	* 8	Minus	** 58	= 0		X \$26 =	0	OR	X \$ =	
Ľ.	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0		X \$110 =	0	OR	X \$ =	
AME	Application S	ize Fee (37 CFR ⁻	l.16(s))								
		NTATION OF MULTI	PLE DEPEN	DENT CLAIM (37 CFF	R 1.16(j))				OR		
							TOTAL ADD'L FEE	0	OR	total Add'l Fee	
		(Column 1)		(Column 2)	(Column 3)		-			-	
Г		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=		X \$ =		OR	X \$ =	
DM	Independent (37 CFR 1.16(h))	*	Minus	***	=		X \$ =		OR	X \$ =	
EN	Application S	ize Fee (37 CFR ⁻	l.16(s))								
AN		NTATION OF MULTI	PLE DEPEN	DENT CLAIM (37 CFF	R 1.16(j))				OR		
							TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
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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.



UNITED STATES PATENT AND TRADEMARK OFFICE

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

## NOTICE OF ALLOWANCE AND FEE(S) DUE

66854

02/26/2010

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

7590

EXAMINER

PAPER NUMBER

STRASZHEIM, REBECCA L

3738 DATE MAILED: 02/26/2010

ART UNIT

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

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>. 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 <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED</u>. 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:	If the SMALL ENTITY is shown as NO:
A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.	A. Pay TOTAL FEE(S) DUE shown above, or
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	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.

Page 1 of 3

PTOL-85 (Rev. 08/07) Approved for use throug Definition Lifesciences Corporation, et al. Exhibit 1142, Page 528 of 630

#### 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

				or <u>Fax</u> (57.	1)-2/3-2885			
appropriate. All further	<ul> <li>correspondence including ted below or directed other</li> </ul>	ng the Patent, a	dvance or	ders and notification of m	naintenance fees w	vill be m	nailed to the current	hould be completed where correspondence address as trate "FEE ADDRESS" for
CURRENT CORRESPOND	DENCE ADDRESS (Note: Use BI	ock 1 for any change	e of address)	Fee(spape	s) Transmittal. Thi rs. Each additional	s certific l paper,	cate cannot be used f	or domestic mailings of the for any other accompanying nt or formal drawing, must
66854	7590 02/26	/2010					0	mission
SHAY GLEN 2755 CAMPUS SUITE 210 SAN MATEO,	DRIVE			State	eby certify that this s Postal Service we essed to the Mail	is Fee(s) /ith suffi Stop 19	of Mailing or Trans Transmittal is being icient postage for fir SSUE FEE address ) 273-2885, on the d	g deposited with the United st class mail in an envelope above, or being facsimile
SAN MATEO,	CA 94405							(Depositor's name)
								(Signature)
								(Date)
APPLICATION NO.	FILING DATE		I	FIRST NAMED INVENTOR		ATTOR	NEY DOCKET NO.	CONFIRMATION NO.
10/972,287 10/21/2004				Amr Salahieh		10	0012-702.501	7706
TITLE OF INVENTION	N: LEAFLET ENGAGEN	AENT ELEMEN	NTS AND	METHODS FOR USE TH	EREOF			
APPLN. TYPE	SMALL ENTITY	ISSUE FEE	DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	E FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755		\$300	\$0		\$1055	05/26/2010
EXAN	AINER	ART UN	ΤT	CLASS-SUBCLASS				
STRASZHEIM	I, REBECCA L	3738		128-898000				
The Address" inc PTO/SB/47; Rev 03-1 Number is required 3. ASSIGNEE NAME A PLEASE NOTE: Un	AND RESIDENCE DATA lless an assignee is ident th in 37 CFR 3.11. Com	" Indication form ned. Use of a Cu A TO BE PRIN" ified below, no	m istomer IED ON T assignee o orm is NOT	<ul> <li>(1) the names of up to or agents OR, alternativ</li> <li>(2) the name of a single registered attorney or a 2 registered patent attor listed, no name will be THE PATENT (print or typ data will appear on the pa a substitute for filing an a (B) RESIDENCE: (CITY</li> </ul>	ely, e firm (having as a gent) and the name neys or agents. If printed. e) tent. If an assigne tssignment.	member es of up no name ee is ide	$\begin{array}{cccc} r a & 2 \\ to \\ is & 3 \end{array}$	ocument has been filed for
Please check the appropriate the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of the propriet of t	riate assignee category or	categories (wil	l not be pri	nted on the patent):	Individual 🖵 Co	orporatio	n or other private gro	oup entity Government
	are submitted: No small entity discount p # of Copies			<ul> <li>Payment of Fee(s): (Please</li> <li>A check is enclosed.</li> <li>Payment by credit card</li> <li>The Director is hereby overpayment, to Depose</li> </ul>	I. Form PTO-2038 authorized to char	is attac	hed. cauired fee(s). any de	
a. Applicant clain	atus (from status indicate ns SMALL ENTITY state	us. See 37 CFR		b. Applicant is no long				
NOTE: The Issue Fee ar interest as shown by the	nd Publication Fee (if req records of the United Sta	uired) will not t ites Patent and T	e accepted Frademark	from anyone other than the Office.	ne applicant; a regi	stered at	torney or agent; or th	ne assignee or other party in
Authorized Signature	e				Date			
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an application. Confider submitting the complete	ntiality is governed by 35 ad application form to the tions for reducing this bu Virginia 22313-1450. DO	U.S.C. 122 and USPTO. Time	1 37 CFR 1 will vary	1.14. This collection is esti depending upon the indivi	mated to take 12 r idual case. Any co	ninutes t mments	to complete, includin on the amount of the	d by the USPTO to process) ag gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 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.

	ITED STATES PATE	ENT AND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.uspto.gov	OR PATENTS
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 75	590 02/26/2010		EXAM	IINER
SHAY GLENN I	LLP		STRASZHEIN	I, REBECCA L
2755 CAMPUS D	RIVE		ART UNIT	PAPER NUMBER
SUITE 210 SAN MATEO, CA	94403		3738 DATE MAILED: 02/26/201	0

## 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.

	Application No.	Applicant(c)
		Applicant(s)
Notice of Allowability	10/972,287 Examiner	SALAHIEH ET AL.
	REBECCA STRASZHEIM	3738
The MAILING DATE of this communication appe All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this app or other appropriate communication <b>IGHTS.</b> This application is subject to	plication. If not included will be mailed in due course. <b>THIS</b>
1. X This communication is responsive to the Applicant's argun	nent/ remarks dated 11/3/2009.	
2. $\square$ The allowed claim(s) is/are <u>60-67</u> .		
<ul> <li>3. Acknowledgment is made of a claim for foreign priority ur a) All b) Some* c) None of the: <ol> <li>Certified copies of the priority documents have</li> <li>Certified copies of the priority documents have</li> <li>Copies of the certified copies of the priority do International Bureau (PCT Rule 17.2(a)).</li> <li>* Certified copies not received:</li> </ol> </li> <li>Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.</li> <li>4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give</li> <li>CORRECTED DRAWINGS ( as "replacement sheets") mus (a) including changes required by the Notice of Draftspers 1) hereto or 2) to Paper No./Mail Date</li> <li>Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t 6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT</li> </ul>	e been received. been received in Application No cuments have been received in this is of this communication to file a reply MENT of this application. hitted. Note the attached EXAMINER' res reason(s) why the oath or declara st be submitted. son's Patent Drawing Review (PTO- s Amendment / Comment or in the C .84(c)) should be written on the drawing he header according to 37 CFR 1.121(c) st of BIOLOGICAL MATERIAL n	national stage application from the complying with the requirements 'S AMENDMENT or NOTICE OF tion is deficient. 948) attached Office action of <b>ngs in the front (not the back) of</b> d). nust be submitted. Note the
Attachment(s)         1. □ Notice of References Cited (PTO-892)         2. □ Notice of Draftperson's Patent Drawing Review (PTO-948)         3. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>11/3/2009</u> 4. □ Examiner's Comment Regarding Requirement for Deposit of Biological Material         /R. S./	5. Notice of Informal P 6. Paper No./Mail Dat 7. Examiner's Amendr 8. Examiner's Stateme 9. Other	(PTO-413), ee nent/Comment ent of Reasons for Allowance
Examiner, Art Unit 3738	Supervisory Patent Exa	
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	otice of Allowability	Part of Paper No./Mail Date 20100127

#### **EAST Search History**

### EAST Search History (Prior Art)

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Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 532 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My%...2287/EASTSearchHistory.10972287_AccessibleVersion.htm (1 of 59)1/27/2010 8:21:53 AM

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## Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 534 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My%...2287/EASTSearchHistory.10972287_AccessibleVersion.htm (3 of 59)1/27/2010 8:21:53 AM

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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 535 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My%...2287/EASTSearchHistory.10972287_AccessibleVersion.htm (4 of 59)1/27/2010 8:21:53 AM

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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 536 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My%...2287/EASTSearchHistory.10972287_AccessibleVersion.htm (5 of 59)1/27/2010 8:21:53 AM

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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 546 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (15 of 59)1/27/2010 8:21:53 AM

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## Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 547 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (16 of 59)1/27/2010 8:21:53 AM

EAST Search History

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<b>S</b> 48	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
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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 549 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (18 of 59)1/27/2010 8:21:53 AM

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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
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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
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# Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 560 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (29 of 59)1/27/2010 8:21:53 AM

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## Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 564 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (33 of 59)1/27/2010 8:21:53 AM

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USPAT

OR

ON

2009/08/05

09:17

16

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S84

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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
<b>S</b> 94	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 623/2.15.ccls. or 623/2.16.ccls. or 623/2.18.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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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

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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 623/2.39.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

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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-20030023303-\$ or US-20080125859-\$ or US-20060253191-\$ or US-20050137701-\$ or US-20050137699-\$ or US-20050137697-\$ or US-20050137697-\$ or US-20050137695-\$ or US-20050137699-\$ or US-20050004652-\$ or US-20060276874-\$ or US-20030036791-\$ or US-20030036791-\$ or US-20090005863-\$ or US-20080071369-\$ or US-20080071368-\$ or US-20080071363-\$ or US-20080071363-\$ or US-20080071363-\$ or US-20080071363-\$ or US-20080071363-\$ or US-20080071366-\$ or US-20080071366-\$ or US-20080071366-\$ or US-200800255661-\$ or US-20080255661-\$ or US-20080255661-\$ or US-20080255661-\$ or US-20080255661-\$ or US-20080255661-\$ or US-20080269878-\$ or US-20080269878-\$ or US-20090216310-\$).did. or (US-6652578-\$ or US- 6458153-\$ or US- 6425916-\$ or US- 7201772-\$ or US- 7201772-\$ or US- 7201772-\$ or US- 7201772-\$ or US- 7261732-\$ or US- 7261732-\$ or US-	US-PGPUB; USPAT	OR	ON	2010/01/25

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		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

## Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 587 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (56 of 59)1/27/2010 8:21:54 AM

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-20050137697-\$ or US-20050137697-\$ or US-20050137697-\$ or US-20050137697-\$ or US-20050137691-\$ or US-20050137689-\$ or US-20050004652-\$ or US-20060276874-\$ or US-20060276874-\$ or US-20030036791-\$ or US-20050240200-\$ or US-20090005863-\$ or US-20080071369-\$ or	US-PGPUB; USPAT; USOCR	OR	ON	2010/01/26

## Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 588 of 630 file:///Cl/Documents%20and%20Settings/rstraszheim/My...287/EASTSearchHistory.10972287_AccessibleVersion.htm (57 of 59)1/27/2010 8:21:54 AM

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
S141	46	S140 and (barb or anchor or hook)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR		2010/01/26
		US-20040186563-\$ 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-20080255660-\$ or US-20080269878-\$ or US-20080269878-\$ or US-20090216310-\$ or US-20090216310-\$ or US-20090216310-\$ or US-20080215143-\$).did. or (US-6652578-\$ or US- 6458153-\$ or US- 5957949-\$ or US- 7201772-\$ or US- 7201772-\$ or US- 7261732-\$ or US- 7377938-\$ or US- 7399315-\$ or US- 7399315-\$ or US- 7524330-\$ or US- 7628805-\$ or US- 7611535-\$ or US- 5489295-\$).did. or (US- 3143742-\$).did.				

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	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	10972287	SALAHIEH ET AL.
	Examiner	Art Unit
	REBECCA STRASZHEIM	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					
	Updated class/ subclass search	8/5/2009	RLS					
	Updated class/ subclass search	1/26/2010	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
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

## INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
UPAD, USPAT	EAST inventor name search, EAST claim text search	1/26/2010	RLS

/R. S./ Examiner.Art Unit 3738	

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	10972287	SALAHIEH ET AL.
	Examiner	Art Unit
	REBECCA STRASZHEIM	3738

	ORIGINAL						INTERNATIONAL CLASSIFICATION						ON		
	CLASS			SUBCLASS					С	LAIMED			Ν	ON-	CLAIMED
128			898			А	6	1	F	2 / 24 (2006.01.01)					
	CROSS REFERENCE(S)														
CLASS	SU	BCLASS (ON	E SUBCLAS	S PER BLO	CK)										
623	1.26	2.14													
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	Claims renumbered in the same order as presented by applicant							СР		] T.D.	[	_ R.1.	47		
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	2		18		34		50	2	66						
	3		19		35		51	1	67						
	4		20		36		52								
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	6		22		38		54								
	7		23		39		55								
	8		24		40		56								
	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	01/27/2010	Total Claims Allowed:			
(Assistant Examiner)	(Date)	8			
/CORRINE M MCDERMOTT/ Supervisory Patent Examiner.Art Unit 3738	01/30/2010	O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1	7		

U.S. Patent and Trademark Office

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### Receipt date: 11/03/2009

Sheet 1

## 10972287 - GAU: 3738

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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. ¹	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	460	^{US-} 3,409,013	11/5/1968	Berry	
	461	^{US-} 4,655,218	4/7/1987	Kulik et al.	
	462	^{US-} 4,755,181	7/5/1988	Igoe	
	463	^{US-} 4,865,600	9/12/1989	Carpentier et al.	
	456	^{US-} 5,549,665	8/27/1996	Vesely et al.	
	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.	

		FOREI	<b>GN PATENT DOCU</b>	MENTS		
Examiner Initials*	Cite No.1	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	Т.е
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Examiner Signature				Date Considered		

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### 10972287 - GAU: 3738

#### PTO/SB/08a (07-09)

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 3

Cor	nplete 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
	Application Number Filing Date First Named Inventor Art Unit Examiner Name

			U. S. PATEN	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (If known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	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 əl.	
	449	^{US-} 2008/0288054	11/20/2008	Pulnev et al.	
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## Receipt date: 11/03/2009

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Substitute for form 1449	)/PTO		Complete if Known		
			Application Number	10/972,287	
INFORMAT	ION DIS	CLOSURE	Filing Date	October 21, 2004	
STATEMEN	IT BY A	PPLICANT	First Named Inventor	Amr Salahieh	
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Sheet 3	of	3	Attorney Docket Number	10012-702.501	

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite 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.				
	450 HAUG et al.; U.S. Pat. App. # 12/492,512 entitled "Everting Heart Valve," filed 06/26/2009				
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Examiner Signature	/Rebecca Straszheim/	Date Considered	01/26/2010
*EVANAINED. In	itial if reference considered, whether or not citation is in conformance with MPEP 60	A Draw line through c	itation if not in conformance and not

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

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### 10972287 - GAU: 3738

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Substitute f	or form 1449	)/PTO		Application Number	10/972,287	
INFORM	<b>1ATION</b>	DISC	LOSURE	Filing Date	October 21, 2004	· ·
STATEM	STATEMENT BY APPLICANT			First Named Inventor	Amr Salahieh	
(Use as	s many sheet	s as ne	cessary)	Art Unit	3738	
				Examiner Name	Not yet assigned	
Sheet	2	of	5	Attorney Docket Number	30207-702.501	

Examiner Cite Initials [•] No. ¹		Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		US 2005/0203615A1	9/15/2005	Forster		
		US 2005/0203616 A1	9/15/2005	Cribier		
		US 2005/0203617 A1	9/15/2005	Forster, et al.	······································	
		US 4,796,629	1/10/1989	Grayzel	······	
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		US 5,209,741	5/11/1993	Spaeth		
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		US 5,843,158	12/1/1998	Lenker, et al.		
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		US 6,143,987 6142987	11/07/2000	Tsugita	· · · · · · · · · · · · · · · · · · ·	
		US 6,165,200	12/26/2000	Tsugita et al.		
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		US 6,179,859	01/30/2001	Bates	· · · · · · · · · · · · · · · · · · ·	
		US 6,270,513	08/07/2001	Tsugita et al.	<u> </u>	
		US 6,336,934	01/08/2002	Gilson et al.		
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		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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2749734_1.DOC Attomey Docket, No. 10227-702-501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./

Under the	: paperwork Re	eduction Ac	<u>t of 1995, no perso</u>	U.S. Patent and Tr	PTO/SB/08 (07/05) Approved for use through 07/31/2006. OMB 0651-0031 ademark Office; U.S. DEPARTMENT OF COMMERCE formation unless it contains a valid OMB control number.
•				Cor	mplete if Known
Substitute fo	or form 144	9/PTO		Application Number	10/972,287
INFORM	IATION	DISCI	OSURE	Filing Date	October 21, 2004
STATEN				First Named Inventor	Amr Salahieh
(Use as	many shee	ts as nec	essary)	Art Unit	3738
				Examiner Name	Unassigned
Sheet	2	Of	3	Attorney Docket Number	30207-702.501

[		•	FOREIGN	N PATENT DO	OCUMENTS		
	Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ³ (y known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	<b>T</b> ⁶
			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		
UB 4/1004			EP 1582178 A2	10/2005	Board of Regents, The University of Texas System		
4/154			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	Date
Signature	Considered
of this form with aext communication to applicant. ¹ Applicant's unique class 901.04. ¹ Enter Office that issued the document, by the two-letter code (WII precede the serial number of the patient document. ¹ Skind of document by the check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The application. Confidentiality is governed by 33 US.C. 122 and 37 CFR completed application form to the USPTO. Time will vary depending upon reducing this burden, should be sent to the Chief Information Officer, U.S. 1 FORMS TO THIS ADDRESS. SENT TO: Commissioner for Patents, F	n conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy sion designation number (optional). "See Kindt Codes of USPTO Patent Documents at www.uspto.gov or MPEP O Standard ST .3). "For Japanese patent documents, the indication of the year of the reigo of the Emperor must e appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. "Applicant is to place a information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an 1.14. This collection is azimuted to take 2 hours to complete, including gathering, preparing, and submitting the the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for sect and Transformations (NGC, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED O. Box 1450, Alexandria, VA 22313-1450. ting the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.
2854352_1.DOC Attorney Docket No. 30207-702.501	-2-
ALL REFERENCES C	ONSIDERED EXCEPT WHERE LINED THROUGH. /R.

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 597 of 630

#### PART B - FEE(S) TRANSMITTAL

#### Complete and send this form, together with applicable fee(s), to: <u>Mail</u> Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This appropriate. All further indicated unless correcte maintenance fee notifica	correspondence includin ed below or directed oth	or tran g the erwise	smitting the ISSL Patent, advance or in Block 1, by (a	ders and notification ) specifying a new co	of m orresp	aintenance fees v bondence address;	vill be r and/or	(b) indicating a sepa	ould be completed where correspondence address as rate "FEE ADDRESS" for
CURRENT CORRESPOND	ENCE ADDRESS (Note: Use Bl	ock 1 for	any change of address)		Fee(s	) Transmittal. Thi	is certifi	cate cannot be used for	r domestic mailings of the or any other accompanying nt or formal drawing, must
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SHAY GLENN 2755 CAMPUS SUITE 210	DRIVE				I her State addre trans	eby certify that th	is Fee(s	of Mailing or Transı ) Transmittal is being icient postage for firs SSUE FEE address ) 273-2885, on the da	nission deposited with the United t class mail in an envelope above, or being facsimile ate indicated below.
SAN MATEO, (	CA 94403					ue Broma ILED VIA			(Depositor's name) (Signature)
						ay 25, 2			(Date)
APPLICATION NO. FILING DATE				FIRST NAMED INVEN				RNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004			Amr Salahieh			1	0012-702.501	7706
TITLE OF INVENTION	LEAFLET ENGAGEN	1ENT I	ELEMENTS AND	METHODS FOR US	E TH	EREOF			
APPLN. TYPE	SMALL ENTITY	IS	SUE FEE DUE	PUBLICATION FEE D	UE	PREV. PAID ISSU	E FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES		\$755	\$300		\$0		\$1055	05/26/2010
EXAM	INER		ART UNIT	CLASS-SUBCLASS	'	5 . \$1			
STRASZHEIM	·		3738	128-898000					
<ul> <li>"Fee Address" ind PTO/SB/47; Rev 03-( Number is required.</li> <li>ASSIGNEE NAME A PLEASE NOTE: Un</li> </ul>	ND RESIDENCE DATA less an assignee is ident h in 37 CFR 3.11. Com	" Indic ed. Us	ation form e of a Customer BE PRINTED ON elow, no assignee	data will appear on the	inglo or a attor ll be or typ he pa g an a	ely, e firm (having as a gent) and the nam neys or agents. If printed. e) e) ttent. If an assign ssignment.	a membe les of up no nam	era 2 to to e is 3 entified below, the do	cocument has been filed for
	Medical, Inc		pries (will not be p			tos, CA Individual X C	orporati	on or other private gro	oup entity Government
	are submitted: No small entity discount p # of Copies		ed)	<ul> <li>Payment of Fee(s): (</li> <li>A check is enclos</li> <li>Payment by credition</li> <li>Whe Director is here overpayment, to I</li> </ul>	ed. it car	<b>/X/ PAY</b> d. Form PTO-203	MEN B is atta	r VIA EFS ched.	shown above) ficiency, or credit any n extra copy of this form).
	ns SMALL ENTITY stat	is. See	37 CFR 1.27.			-		TTY status. See 37 Cl	
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United Sta	uired) ites Pat	will not be accepte tent and Trademark	d from anyone other the Office.	nan ti	ne applicant; a reg	istered a	ittorney or agent; or th	ne assignee or other party in
Authorized Signature	Shomas &	logo	<b></b>	da di kara		Date May	25	, 2010	
Typed or printed nam	Thomas M	Z1	ogar	······································		Registration 1			
This collection of inform an application. Confiden submitting the complete this form and/or suggest Box 1450, Alexandria, V Alexandria, Virginia 223 Under the Paperwork Re	515-1450.								d by the USPTO to process) og gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450, number.

PTOL-85 (Rev. 08/07) Approved for use throug Edwards Lifesciences Of popations. Etterla Exhibit 1 942; Page 598 VE 630F COMMERCE

Electronic Patent Application Fee Transmittal						
Application Number:	109	972287				
Filing Date:	21-	Oct-2004				
Title of Invention:	LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF					
First Named Inventor/Applicant Name:	Amr Salahieh					
Filer:	Thomas M. Zlogar/Sue Bromaghim					
Attorney Docket Number:	10012-702.501					
Filed as Small Entity						
Utility under 35 USC 111(a) Filing Fees						
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)	
Basic Filing:						
Pages:						
Claims:						
Miscellaneous-Filing:						
Petition:						
Patent-Appeals-and-Interference:						
Post-Allowance-and-Post-Issuance:						
Utility Appl issue fee		2501	1	755	755	
Publ. Fee- early, voluntary, or normal		1504	1	300	300	

Fee Code	Quantity	Amount	Sub-Total in USD(\$)		
Total in USD (\$) 10					

Electronic Acl	Electronic Acknowledgement Receipt					
EFS ID:	7685355					
Application Number:	10972287					
International Application Number:						
Confirmation Number:	7706					
Title of Invention:	LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF					
First Named Inventor/Applicant Name:	Amr Salahieh					
Customer Number:	66854					
Filer:	Thomas M. Zlogar/Sue Bromaghim					
Filer Authorized By:	Thomas M. Zlogar					
Attorney Docket Number:	10012-702.501					
Receipt Date:	25-MAY-2010					
Filing Date:	21-OCT-2004					
Time Stamp:	16:53:34					
Application Type:	Utility under 35 USC 111(a)					

## Payment information:

Submitted wit	h Payment	yes					
Payment Type		Deposit Account					
Payment was s	successfully received in RAM	\$1055	\$1055				
RAM confirmat	tion Number	3184	3184				
Deposit Accou	int	504050	504050				
Authorized Us	er						
File Listing	<b>j</b> :						
Document Number	Document Description Edwards Lifesci	File Name ences Corporation, et al. Exhibit 1142, Page 6	Multi Pages art /.zip 01-01-030				

1	lssue Fee Payment (PTO-85B)	10012-702-501-	249986	no	1
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Information	1				
2	Fee Worksheet (PTO-875)	fee-info.pdf	31727	no	2
_			83ab267e87e8f6fcc660bf60af2157bea023 4ec1		
Warnings:					
Information	1				
		Total Files Size (in bytes):	2	81713	
	rledgement Receipt evidences receip d by the applicant, and including pa	•			-

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

Post Card, as described in MPEP 503.

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.

	'ED STATES PATENT	T AND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.uspto.gov	FOR PATENTS
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/972,287	10/21/2004	Amr Salahieh	10012-702.501	7706
SHAY GLENN 2755 CAMPUS			EXAM	
SUITE 210 SAN MATEO,	CA 94403		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.

	Application No.	Applicant(s)
Interview Summary	10/972,287	SALAHIEH ET AL.
interview Summary	Examiner	Art Unit
	REBECCA STRASZHEIM	3738
All participants (applicant, applicant's representative, PTO	personnel):	
(1) <u>REBECCA STRASZHEIM</u> .	(3)	
(2) <u>SUE BROWMAGHIM</u> .	(4)	
Date of Interview: <u>13 May 2010</u> .		
Type: a)⊠ Telephonic b)⊡ Video Conference c)⊡ Personal [copy given to: 1)⊡ applicant	2) applicant's representativ	e]
Exhibit shown or demonstration conducted: d) Yes If Yes, brief description:	e)⊠ No.	
Claim(s) discussed: <u>N/A</u> .		
Identification of prior art discussed: <u>N/A</u> .		
Agreement with respect to the claims f) was reached.	g)∏ was not reached. h)⊠ l	N/A.
Substance of Interview including description of the general reached, or any other comments: <u>Sue Browmaghim, spea</u> <u>Straszheim that some of the references from the IDSs' data noted as not considered.</u> However, as was discussed in A <u>due to an error on the Examiners part</u> . Examiner has constant and has attached the newly annotated afore mentioned ID	king on behalf of Tom Zlogar, ed 4/27/2005, 7/12/2006, 6/10 Applicants' arguments/ remark sidered all the references from	pointed out to Examiner 0/2008 had previously been s, dated 5/5/2009, this was
(A fuller description, if necessary, and a copy of the amend allowable, if available, must be attached. Also, where no o allowable is available, a summary thereof must be attache	copy of the amendments that	
THE FORMAL WRITTEN REPLY TO THE LAST OFFICE A INTERVIEW. (See MPEP Section 713.04). If a reply to the GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER INTERVIEW DATE, OR THE MAILING DATE OF THIS INT FILE A STATEMENT OF THE SUBSTANCE OF THE INTE requirements on reverse side or on attached sheet.	e last Office action has alread OF ONE MONTH OR THIRT ERVIEW SUMMARY FORM,	y been filed, APPLICANT IS Y DAYS FROM THIS WHICHEVER IS LATER, TO
/R. S./ Examiner, Art Unit 3738 U.S. Patent and Trademark Office		

U.S. Patent and Trademark Office PTOL-413 (Rev. 04-03)

Interview Summary

Paper No. 20100519

#### **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.

	Application No.	Applicant(s)		
Supplemental				
Notice of Allowability	10/972,287 Examiner	SALAHIEH ET AL.		
	REBECCA STRASZHEIM	3738		
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this app or other appropriate communication <b>IGHTS.</b> This application is subject to	plication. If not included will be mailed in due course. <b>THIS</b>		
1. X This communication is responsive to <u>a telephone call by A</u>	pplicants' Attorney.			
2. 🔀 The allowed claim(s) is/are <u>60-67</u> .				
<ul> <li>3. ☐ Acknowledgment is made of a claim for foreign priority ut</li> <li>a) ☐ All b) ☐ Some* c) ☐ None of the:</li> <li>1. ☐ Certified copies of the priority documents have</li> <li>2. ☐ Certified copies of the priority documents have</li> <li>3. ☐ Copies of the certified copies of the priority do International Bureau (PCT Rule 17.2(a)).</li> <li>* Certified copies not received:</li> <li>Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.</li> <li>4. ☐ A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give</li> </ul>	e been received. been received in Application No cuments have been received in this of this communication to file a reply MENT of this application.	national stage application from the complying with the requirements		
5. CORRECTED DRAWINGS ( as "replacement sheets") mus				
(a) ☐ including changes required by the Notice of Draftspers		948) attached		
1) hereto or 2) to Paper No./Mail Date				
(b) ☐ including changes required by the attached Examiner' Paper No./Mail Date		Office action of		
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t				
<ol> <li>DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT</li> </ol>				
Attachment(s)         1. □ Notice of References Cited (PTO-892)         2. □ Notice of Draftperson's Patent Drawing Review (PTO-948)         3. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date See Continuation Sheet         4. □ Examiner's Comment Regarding Requirement for Deposit of Biological Material	5. ☐ Notice of Informal P 6. ⊠ Interview Summary Paper No./Mail Dat 7. ☐ Examiner's Amendr 8. ☐ Examiner's Stateme 9. ☐ Other /Corrine M McDermott Supervisory Patent Exa	(PTO-413), te ment/Comment ent of Reasons for Allowance		
U.S. Patent and Trademark Office PTOL-37 (Rev. 08-06)	otice of Allowability	Part of Paper No./Mail Date 20100519		

Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 606 of 630

### **Continuation Sheet (PTOL-37)**

#### Application No. 10/972,287

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 4/27/2005, 7/12/2006, 6/10/2008.

4-29-05

10972287 - GAUE

### 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

Inventor(s): Amr SALAHIEH et al.

Application No.: 10/972,287

Filed: October 21, 2004

te: 04/27/2005

Title: Leaflet engagement elements and methods for use thereof

PATENT APPLICATION

Art Unit: 3738

Examiner: Not yet assigned

Corporation, et al. Exhibit 1142, Page 608 of 630

Confirmation No.: 7706

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.

3055272_1.DOC Attorney Docket No. 30207.702.5

### Receipt date: 04/27/2005

 $\boxtimes$ 

 $\square$ 

This statement qualifies under 37 C.F.R.  $\S$ 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.  $\S1.97(d)$ . If this statement is being filed after the mailing date of the earlier of a final office action under  $\S1.113$  or a notice of allowance under  $\S1.311$ , 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.

Receipt date: 04/27/2005

- 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 Skulfatch, Reg. No. 52,505

Dated: 4/21/05

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

Attorney Docket No. 30207.702.501 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit **1142**, Page 610 of 630

OIPE	date: 04/2		*	act of 1995, no persons	U.S. Patent and Tra	10972287 - GA PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031 ademark Office; U.S. DEPARTMENT OF COMMERCE ormation unless it contains a valid OMB control number.	<b>⊥:</b> 3738
APR 2 7 201				,	Com	aplete if Known	
HAR BACE	substitute fo	or form 1449	/PTO	`	Application Number	10/972,287	
ALL -	<b>Just</b> INFORM	IATION I	DISC	LOSURE	Filing Date	10/21/2004	
BAC	STATEM	1ENT BY			First Named Inventor	Salahieh	
	(Use as	many sheets	s as ne	cessary)	Art Unit	3738	
-					Examiner Name	Not yet assigned	
	Sheet	1	of	2	Attorney Docket Number	30207.702.501	

Examiner Initials*	Cite No. ¹	NON PATENT LITERATURE DOCUMENTS 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 T
	110.	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).	1
		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	Date	
signature	 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

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation it not in conformance and no considered. Include copy of this form with next communication to applicant.
¹Applicant's unique citation designation number (optional). ²Applicant 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 his 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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3055272_1.DOC Attorney Docket No. 30207.702.501

## Receipt date: 04/27/2005

#### 10972287 - G 738

PTO/SB/08A (08-03)

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Under the paperwork reduction Act of 1995, no persons				Complete if Known		
Substitute for	or form 1449	9/PTO		Application Number	10/972,287	
INFORM	INFORMATION DISCLOSURE			Filing Date	10/21/2004	
STATEMENT BY APPLICANT				First Named Inventor	Salahieh	
(Use as many sheets as necessary)				Art Unit	3738	
				Examiner Name	Not yet assigned	
Sheet	2	of	2	Attorney Docket Number	30207.702.501	

		NON PATENT LITERATURE D	OCUMENTS					
Examiner Cite Initials* No. ¹		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						
		SALAHIEH, A. et al., US Patent Application N apparatus for endovascularly replacing a heart v (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 beart 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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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached. ¹Applicant's unique citation designation number (optional). ²Applicant 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.

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3055272_1.DOC Attorney Docket No. 30207.702.501 Sheet 1

# 10972287 - GAU: 3738

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Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 2

Cor	mplete if Known
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

· · · · · · ·			U. S. PATEN	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	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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			<b>GN PATENT DOCU</b>	MENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		τ6
	ļ	Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)			Or Relevant Figures Appear	ļ (
			·····			
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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English lenguage 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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# Receipt date: 06/10/2008

# 10972287 - GAU: 3738

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	ite for form 1449/PTC				of information unless it contains a valid OMB control numb Complete if Known	1
				Application Number	10/972,287	
INF	ORMATIO	N DIS	SCLOSURE	Filing Date	October 21, 2004	
STA	TEMENT	BY A	PPLICANT	First Named Inventor	Amr Salahieh	
	(Use as many s	hoote ae i	necessary	Art Unit	3774	
	(oso as many s	110013 03 1	1000330ry/	Examiner Name	WALKER, AMANDA H	
Sheet	2	of	2	Attorney Docket Number	10012-702.501	フ

	NON PATENT LITERATURE DOCUMENTS	
Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	T ²
399	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.	
	No. ¹	Cite No.1       Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.         399       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.

Examiner		Date	
Signature	/Rebecca Straszheim/	Considered	05/19/2010

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

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Receipt date: 07/12/2006

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.

- 1 -

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2914360_1.DOC Attorney Docket No. 30207-702.501

ALL REFEF

## Receipt date: 07/12/2006

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- A.  $\boxtimes$  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.  $\Box$  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.  $\Box$  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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 616 of 630 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.  $\boxtimes$  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.  $\boxtimes$  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.  $\square$  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.

2914360_1.DOC Attorney Docket No. 30207-702.501

- 3 -

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S./ Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 617 of 630 Receipt date: 07/12/2006

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

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: July 2006

By:

Maya Skulatch, Reg. No. 52,505

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

2914360_1.DOC Attorney Docket No. 30207-702.501

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

		FOREIGN	I PATENT DO	DCUMENTS		
Examiner Initials*	Cite No.'	Foreign Patent Document Country Code ⁸ - Number ⁴ - Kind Code ⁸ (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	Т
· · · · ·		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		
<u> </u>						
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Signature Considered	
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"EAAUTIVEN. Initial it reference communication to applicate solution is an initial and an and an and a solution of this force with next communication to applicate." Applicate solution is and exact and an another (optional). "See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP	-

901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Check mark here it 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 i-800-PTO-9199 (1-800-786-9199) and select option 2.

2914360 1.DOC Attorney Docket No. 30207-702.501

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Examiner

Under th	1e paperwork Re	eduction A	et of 1995, no perso	U.S. Patent and Tr	PTO/SB/08 (07/05) Approved for use through 07/31/2006. OMB 0651-0031 ademark Office; U.S. DEPARTMENT OF COMMERCE formation unless it contains a valid OMB control number.
					nplete if Known
Substitute f	for form 144	9/PTO		Application Number	10/972,287
<b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				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	
Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	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)	
		Cite       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.         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

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. 'Applicant's unique citation designation number (optional). ³ See Kinds Codes of USPTO Patent Documents at www.uspto goo tim MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). 'For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 'Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. '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 USC. 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. If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.										
2914360_1.DO Attorney Docke	C et No. 3020 <b>7-7</b> 02.501	- 2 -								
ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /R.S Edwards Lifesciences Corporation, et al. Exhibit 1142, Page 620 of 630										

Date





**SUITE 210** 

SAN MATEO, CA 94403

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 CAMPU	S DRI	VE			

**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;

PATENT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

hieh, Brian D. Brant, Robert A. Geshlider, Dwight P.
, Tom Saul
7
r 21, 2004
ngagement Elements and Methods for Use Thereof
L. Straszheim
]

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

### Docket No: S63.2H-15126-US01

### REVOCATION OF POWER OF ATTORNEY AND APPOINTMENT OF NEW ATTORNEY

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

I hereby appoint all practitioners associated with Customer Number 00490 as my/our attorney(s) or (agent(s) to prosecute the above identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please address all future correspondence to James M. Urzedowski at Customer Number 00490.

I am the:

- Applicant/Inventor
- Assignee of record of the entire interest. (See 37 CFR 3.71) Statement under 37 CFR 3.73(b) or copy of previously filed 3.73(b) statement is enclosed.

Respectfully submitted,

SADRA MEDICAL, INC.

Date: 2/a/11

Bv:	1626	24	4	
Name:	Ken Martin		J	

٨

Title: President & CEO

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

In Re Application of:	Amr Salahieh, Brian D. Brant, Robert A. Geshlider, Dwight P.
	Morejohn, Tom Saul
Application No.:	10/972287
Filed:	December 21, 2004
For:	Leaflet Engagement Elements and Methods for Use Thereof
Examiner:	Rebecca L. Straszheim
Group Art Unit:	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			
EFS ID:	9430308		
Application Number:	10972287		
International Application Number:			
Confirmation Number:	7706		
Title of Invention:	LEAFLET ENGAGEMENT ELEMENTS AND METHODS FOR USE THEREOF		
First Named Inventor/Applicant Name:	Amr Salahieh		
Customer Number:	66854		
Filer:	James M. Urzedowski/Samantha Painschab		
Filer Authorized By:	James M. Urzedowski		
Attorney Docket Number:	10012-702.501		
Receipt Date:	11-FEB-2011		
Filing Date:	21-OCT-2004		
Time Stamp:	17:50:15		
Application Type:	Utility under 35 USC 111(a)		

# Payment information:

Submitted with Payment			no				
File Listing:							
Document Number	<b>Document Description</b>		File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)	
1	Transmittal Letter		15126US01 tra 20110211.pdf	84088	no	1	
				30969caa15c7a4e243271a53e43255bceb7 9c5e3		I	
Warnings:		•					
Information:							

2	Assignee showing of ownership per 37 CFR 3.73(b).	15126US01_sta_20110207.pdf _	70781	no	1
	Crk 3.7 5(0).		27ca020e51fef1b14acae3599eab3452fb4d 8fcc	1	
Warnings:					
Information:					
3	Power of Attorney	15126US01_executedPOA.pdf	28062	no	1
			b3becc2a42df8a4541a8745de74a5e3a3dd a5162	d	
Warnings:					
Information:					
4	Miscellaneous Incoming Letter	15126US01_entity_status_2011	65596	no	1
		0211.pdf	ff8f8f0e1e022555aa6a3f69774893bd90237 7eb		
Warnings:					
Information:	:		1		
		Total Files Size (in bytes)	2.	48527	
characterize Post Card, as <u>New Applica</u>	vledgement Receipt evidences receip d by the applicant, and including pag described in MPEP 503. <u>tions Under 35 U.S.C. 111</u>	ge counts, where applicable.	It serves as evidence	of receipt	similar to a
1.53(b)-(d) a	lication is being filed and the applica nd MPEP 506), a Filing Receipt (37 CF ement Receipt will establish the filin	R 1.54) will be issued in due			
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. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for					
an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

PATENT

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

In Re Application of:	Amr Salahieh, Brian D. Brant, Robert A. Geshlider, Dwight P. Morejohn,				
	Tom Saul				
Application No.:	10/972287				
Filed:	December 21, 2004				
For:	Leaflet Engagement Elements and Methods for Use Thereof				
Examiner:	Rebecca L. Straszheim				
Group Art Unit:	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

1 page Revocation of Power of Attorney and Appointment of New Attorney; 1 page Assignee's Statement of Ownership and 1 page Notification of Change of Entity Status.

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

#### 3. CONDITIONAL PETITION FOR EXTENSION OF TIME

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

- 4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees associated with this communication to the Deposit Account No. 22-0350.
- 5. **Certification:** I hereby certify that this Transmittal Letter and the paper(s) as described herein are being transmitted electronically to the USPTO on February 11, 2011.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/

James M. Urzedowski Registration No.: 48596

6640 Shady Oak Rd., Suite 400 Eden Prairie, MN 55344-7834 Telephone: (952) 563-3000 Facsimile: (952) 563-3001 f:\wpwork\jmu\15126us01_tra_20110211.doc

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Amr Salahieh, Brian D. Brant, Robert A. Geshlider, Dwight P.
	Morejohn, Tom Saul
Application No.:	10/972287
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Examiner:	Rebecca L. Straszheim
Group Art Unit:	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:

- From : <u>Amr Salahieh, Brian D. Brandt, Robert A. Geshlider, Dwight P.</u> <u>Morejohn, Tom Saul</u> To: <u>Sadra Medical, Inc.</u> The document was recorded in the Patent and Trademark Office at Reel <u>015768</u>, Frame <u>0556</u>, or for which a copy thereof is attached.
- From : <u>Amr Salahieh, Brian D. Brandt, Robert A. Geshlider, Dwight P.</u> <u>Morejohn, Tom Saul</u> To: <u>Sadra Medical, Inc.</u> The document was recorded in the Patent and Trademark Office at Reel <u>016315</u>, Frame <u>0771</u>, or for which a copy thereof is attached.

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

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 11, 2011

By: /James M. Urzedowski/

James M. Urzedowski Registration No.: 48596

6640 Shady Oak Rd., Suite 400 Eden Prairie, MN 55344-7834 Telephone: (952) 563-3000 Facsimile: (952) 563-3001 f:\wpwork\jmu\15126us01_sta_20110207.doc

UNITED STA	ates Patent and Trademan	UNITED STA' United States Address: COMMI P.O. Box I	a, Virginia 22313-1450
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
			<b>CONFIRMATION NO. 7706</b>
66854		POWER O	F ATTORNEY NOTICE
SHAY GLENN LLP 2755 CAMPUS DRIVE SUITE 210			C000000046103834*
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

page 1 of 1

United St	ates Patent and Trademai	UNITED STA' United States Address: COMMIS P.O. Box 1	, Virginia 22313-1450
APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/972,287	10/21/2004	Amr Salahieh	\$63.2H-15126-US01
			<b>CONFIRMATION NO. 7706</b>
490		POA ACCI	EPTANCE LETTER
VIDAS, ARRETT & STEIN	NKRAUS, P.A.		
SUITE 400, 6640 SHADY EDEN PRAIRIE, MN 5534			CC000000046103854*
			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