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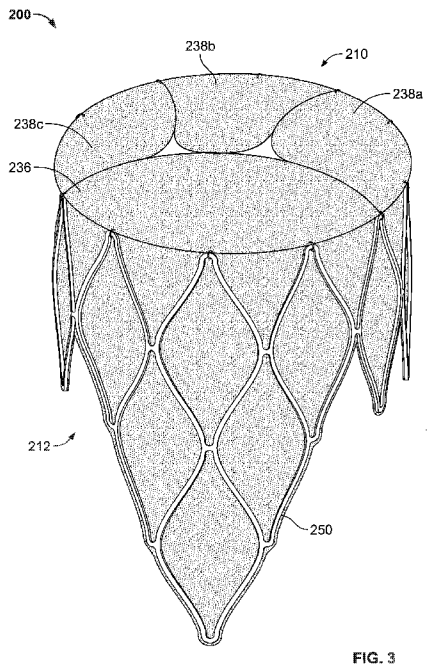

FIG. 3

(57) Abstract: A prosthetic mitral valve (200) includes a collapsible and expandable stent (250) extending from an inflow end (210) to an outflow end (212). A collapsible and expandable valve assembly is disposed within the stent. The valve assembly includes a plurality of anterior leaflets (238a-c) and one posterior leaflet (236). The posterior leaflet has a larger surface area than any of the anterior leaflets. When implanted in the native mitral valve annulus, the smaller size of the anterior leaflets and the corresponding smaller size of an anterior portion of the stent (228) reduce the likelihood of interference with blood flowing through the native aortic valve (140), while also reducing the likelihood of ventricular fibrillation.

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TRANSCATHETER MITRAL VALVE DESIGN

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to the filing date of U.S. Provisional Patent Application No. 62/466,423, filed on March 3, 2017, the disclosure of which is hereby incorporated by reference herein.

BACKGROUND OF THE DISCLOSURE

[0002] The present disclosure relates to prosthetic heart valves and, in particular, collapsible prosthetic mitral valves.

[0003] Prosthetic heart valves that are collapsible to a relatively small circumferential size can be delivered into a patient less invasively than valves that are not collapsible. For example, a collapsible valve may be delivered into a patient via a tube-like delivery apparatus such as a catheter, a trocar, a laparoscopic instrument, or the like. This collapsibility can avoid the need for a more invasive procedure such as full open-chest, open-heart surgery.

[0004] Collapsible prosthetic heart valves typically take the form of a valve structure mounted on a stent. There are two types of stents on which the valve structures are ordinarily mounted: a self-expanding stent and a balloon-expandable stent. To place such valves into a delivery apparatus and ultimately into a patient, the valve must first be collapsed or crimped to reduce its circumferential size.

[0005] When a collapsed prosthetic valve has reached the desired implant site in the patient (*e.g.*, at or near the annulus of the patient's heart valve that is to be replaced by the prosthetic valve), the prosthetic valve can be deployed or released from the delivery apparatus and re-expanded to full operating size. For balloon-expandable valves, this generally involves releasing the entire valve, assuring its proper location, and then expanding a balloon positioned within the valve stent. For self-expanding valves, on the other hand, the stent automatically expands as the sheath covering the valve is withdrawn.

[0006] Prosthetic valves, particularly those for replacement of a native aortic valve, often contain three coapting leaflets as part of a valve assembly having a substantially circular or cylindrical shape, the valve assembly being supported by a substantially cylindrical stent. Although this type of prosthetic valve can be used to replace a native mitral valve, problems may arise from such use. For example, upon implantation in the native mitral valve annulus, a prosthetic heart valve with a cylindrical stent and cylindrical valve assembly having three leaflets may deform substantially to fit the elliptical geometry of the

native mitral valve annulus. This deformation may prevent the three leaflets from properly coapting with one another to form a seal, which in turn may result in a greater degree of regurgitation (*i.e.*, retrograde blood flow through the prosthetic valve). For this and other reasons, it would be desirable to have a prosthetic mitral valve better suited to the geometry of the native mitral valve.

BRIEF SUMMARY

[0007] According to one aspect of the disclosure, a prosthetic mitral valve includes a collapsible and expandable stent extending from an inflow end to an outflow end. A collapsible and expandable valve assembly is disposed within the stent, the valve assembly including a plurality of anterior leaflets each having a surface area and one posterior leaflet having a surface area. The surface area of the posterior leaflet is larger than the surface area of any of the anterior leaflets.

[0008] According to another aspect of the disclosure, a method of implanting a prosthetic mitral valve into a native mitral valve annulus of a patient includes delivering the prosthetic mitral valve in a collapsed condition to the native mitral valve annulus. The prosthetic mitral valve includes a collapsible and expandable stent and a valve assembly disposed within the stent. The valve assembly includes a plurality of anterior leaflets each having a surface area and one posterior leaflet having a surface area. The surface area of the posterior leaflet is larger than the surface area of any of the anterior leaflets. The method includes deploying the prosthetic mitral valve to an expanded condition within the native mitral valve annulus so that the anterior leaflets extend a lesser distance into a left ventricle of the patient than the posterior leaflet.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Fig. 1 is a highly schematic representation of a human heart.

[0010] Fig. 2 is a highly schematic representation of a native mitral valve.

[0011] Fig. 3 is a highly schematic perspective view of a prosthetic mitral valve in an expanded condition according to an aspect of the disclosure.

[0012] Fig. 4 is a highly schematic perspective view of a stent of the prosthetic mitral valve of Fig. 3.

[0013] Fig. 5 is a highly schematic developed view of the stent of Fig. 4.

[0014] Fig. 6 is a plan view of an anterior leaflet of the prosthetic mitral valve of Fig. 3.

[0015] Fig. 7 is a plan view of a posterior leaflet of the prosthetic mitral valve of Fig. 3.

[0016] Fig. 8 is a highly schematic longitudinal cross-section of the prosthetic mitral valve of Fig. 3 with the leaflets in a coapted condition.

DETAILED DESCRIPTION

[0017] Blood flows through the mitral valve from the left atrium to the left ventricle. As used herein, the term "inflow end," when used in connection with a prosthetic mitral valve, refers to the end of the heart valve closest to the left atrium when the heart valve is implanted in a patient, whereas the term "outflow end," when used in connection with a prosthetic mitral valve, refers to the end of the heart valve closest to the left ventricle when the heart valve is implanted in a patient. As used herein, the terms "substantially," "generally," "approximately," and "about" are intended to mean that slight deviations from absolute are included within the scope of the term so modified. When ranges of values are described herein, those ranges are intended to include sub-ranges. For example, a recited range of 1 to 10 includes 2, 5, 7, and other single values, as well as ranges of 2 to 6, 3 to 9, 4 to 5, and others.

[0018] Fig. 1 is a schematic representation of a human heart 100. The human heart includes two atria and two ventricles: a right atrium 112 and a left atrium 122, and a right ventricle 114 and a left ventricle 124. As illustrated in FIG. 1, the heart 100 further includes an aorta 110, and an aortic arch 120. Disposed between the left atrium 122 and the left ventricle 124 is the mitral valve 130. The mitral valve 130, also known as the bicuspid valve or left atrioventricular valve, is a dual-flap valve that opens as a result of increased pressure in the left atrium 122 as it fills with blood. As atrial pressure increases above that of the left ventricle 124, the mitral valve 130 opens and blood flows into the left ventricle. Similarly, disposed between aorta 110 and left ventricle 124 is the aortic valve 140. The aortic valve is a tricuspid valve that opens as a result of increased pressure in the left ventricle 124. Generally, the annulus of the aortic valve 140 is substantially circular or cylindrical, while the annulus of the mitral valve 130 is substantially elliptical. Blood flows through heart 100 in the direction shown by arrows "B".

[0019] An arrow labeled "TA" indicates a transapical approach of implanting a prosthetic heart valve, in this case to replace the mitral valve 130 of a patient. In transapical

delivery, a small incision is made between the ribs and into the apex of the left ventricle 124 to deliver the prosthetic heart valve to the target site.

[0020] Fig. 2 is a more detailed schematic representation of native mitral valve 130 and its associated structures. As previously noted, mitral valve 130 includes two flaps or leaflets, a posterior leaflet 136 and an anterior leaflet 138, disposed between left atrium 122 and left ventricle 124. Anterior leaflet 138 is positioned relatively close to aortic valve 140, while posterior leaflet 136 is positioned relatively far from the aortic valve. Anterior leaflet 138 protrudes a greater length into left ventricle 124, while posterior leaflet 136 protrudes a relatively small distance into the left ventricle. Although posterior leaflet 136 is referred to as a single "leaflet," there are actually three scalloped sections of the posterior leaflet that coapt with anterior leaflet 138, which has a relatively smooth free edge. Cord-like tendons known as chordae tendineae 134 connect the two leaflets 136, 138 to the medial and lateral papillary muscles 132. During atrial systole, blood flows down the pressure gradient from the left atrium 122 to the left ventricle 124. When the left ventricle 124 contracts in ventricular systole, the increased blood pressure in the chamber pushes the leaflets 136 and 138 of the mitral valve 130 to close, preventing the backflow of blood into the left atrium 122. Since the blood pressure in the left atrium 122 is much lower than that in the left ventricle 124, the leaflets attempt to evert to the low pressure regions. The chordae tendineae 134 prevent the eversion by becoming tense, thus pulling on the leaflets and holding them in the closed position.

[0021] The goal of prosthetic heart valves is generally to provide a functional replacement for a malfunctioning native heart valve. Although the approach to creating such a prosthetic heart valve often relies on mimicking the structure of a healthy native valve, that approach may not always be optimal. For example, a prosthetic mitral valve that includes an anterior leaflet that extends a relatively great distance into left ventricle 124 may obstruct blood flowing from the left ventricle toward aorta 110. Further, supporting a long prosthetic anterior leaflet may require a correspondingly long support structure (such as a stent), and that support structure may contact the septal wall between left ventricle 124 and right ventricle 114 and cause ventricular fibrillation.

[0022] A prosthetic mitral valve 200 that may address one or more of the issues addressed above is illustrated schematically in Fig. 3. Prosthetic heart valve 200 is a collapsible prosthetic heart valve designed to replace the function of the native mitral valve of

a patient (see native mitral valve 130 of Figs. 1-2). Generally, prosthetic valve 200 has an inflow end 210, an outflow end 212, and includes a plurality of leaflets attached to a support, the support being a collapsible and expandable stent 250 (best illustrated in Figs. 4-5) in the illustrated embodiment. The prosthetic leaflets include a relatively large posterior leaflet 236 and three relatively small anterior leaflets 238a-c. Prosthetic valve 200 is illustrated in Fig. 3 in a coapted state in which the three anterior leaflets 238a-c coapt with one another and coapt with posterior leaflet 236 along a line of coaptation that is generally "C" or horseshoe-shaped. It should be noted that, although the native mitral valve includes a single large anterior leaflet 138, and a single posterior leaflet 136 with three sections (although some assert the posterior leaflet is actually three leaflets), these leaflet characteristics are reversed in prosthetic valve 200. Fig. 3 shows open space between adjacent coapted leaflets to better distinguish the leaflets in the drawings, but in practice little or no open space would remain between adjacent leaflets in the coapted state.

[0023] Stent 250 of prosthetic mitral valve 200 is illustrated in an expanded condition in Fig. 4, with other components of the prosthetic valve omitted for clarity. Fig. 5 illustrates stent 250 in a flattened or developed condition, as if cut longitudinally and unrolled onto a flat surface. Fig. 4 includes a dashed line 255 that is purely intended to aid in understanding the illustration and forms no part of the invention. Stent 250 may be formed from biocompatible materials that are capable of self-expansion, such as shape memory alloys including Nitinol. Stent 250 may include a plurality of struts 252 that form a plurality of closed cells 254 connected to one another in one or more annular rows around the stent. It should be understood that, in Fig. 5, the cells 254 at the left-most and right-most ends of the drawing are the same cell, with the cell being repeated to illustrate the continuity of the stent 250. Cells 254 may all be of substantially the same size around the perimeter and along the length of stent 250. In the illustrated embodiment, cells 254 are each substantially diamond-shaped in the expanded condition. Stent 250 may be radially expandable to provide a radial force to assist with positioning and stabilizing prosthetic heart valve 200 in the native valve annulus. Although stent 250 is illustrated as having a substantially circular profile, it should be understood that the stent may alternatively have an elliptical profile or a "D"-shaped profile in the expanded condition to better match the shape of the annulus of native mitral valve 130.

[0024] Stent 250 includes an anterior section 228 adapted to support anterior leaflets 238a-c and a posterior section 226 adapted to support posterior leaflet 236. In the view of Fig. 4, the anterior direction is into the page and the posterior direction is out of the page. Stent 250 may include a single annular row of cells 254a connected to one another around the entire circumference of the stent, represented by the dashed line 255 of Fig. 4. The anterior section 228 of stent 250 may be limited to a single row of cells 254a with no additional cells 254 being present. The posterior section 226 of stent 250, on the other hand, may include cells 254a as well as additional cells 254 to support the larger posterior leaflet 236. In the illustrated embodiment, posterior section 226 includes a second row of cells 254b extending in the outflow direction from the first row of cells 254a. As illustrated, second row of cells 254b includes two cells 254, although the second row may include additional cells. However, second row of cells 254b preferably is limited to posterior section 226 and does not extend circumferentially to anterior section 228. Posterior section 226 may also include a third row of cells 254c extending in the outflow direction from the second row of cells 254b. In the illustrated embodiment, the third row of cells 254c includes a single cell 254, although the third row may include additional cells. However, similar to second row of cells 254b, third row of cells 254c preferably is limited to posterior section 226 and does not extend to anterior section 228. If cells 254 are all of substantially the same size, the first row 254a preferably includes more cells than the second row 254b, which in turn preferably includes more cells than the third row 254c.

[0025] The posterior leaflet 236 and anterior leaflets 238a-c may be attached to stent 250 via a commissure attachment features ("CAF") 260. One pair of circumferentially adjacent CAFs 260 may be used to attach posterior leaflet 236 to stent 250, and another pair of circumferentially adjacent CAFs 260 may be used to attach anterior leaflets 238a-c to stent 250. CAFs 260 are preferably positioned at the outflow end 212 of a cell 254, and include one or more apertures or eyelets to accept sutures or other devices for attaching the leaflets to stent 250. Prior to describing the attachment of anterior leaflets 238a and posterior leaflet 236 to stent 250, an exemplary anterior leaflet is described.

[0026] One anterior leaflet 238a of prosthetic valve 200 is illustrated in a flattened condition in Fig. 6. Anterior leaflets 238b-c may be similar, identical or substantially identical to anterior leaflet 238a. Generally, anterior leaflet 238a includes a first edge 274a having a generally arcuate shape and a second or free edge 276a, which may have a less

pronounced arcuate shape than the first edge. A first tab 270a may connect the ends of first edge 274a and second edge 276a on one end of the leaflet, and a second tab 272a may connect the ends of first edge 274a and second edge 276a on the other end of the leaflet. Tabs 270a and 272a may be at least partially rectangular and provide a surface for attachment to stent 250. Each anterior leaflet, including anterior leaflet 238a, may have a height H1 from the top of tabs 270a, 272a to the bottom of first edge 274a (as seen in Fig. 6.). Similarly, each anterior leaflet, including anterior leaflet 238a, may have a width W1 from the outer lateral edge of tab 270a to the outer lateral edge of tab 272a.

[0027] Posterior leaflet 236 of prosthetic valve 200 is illustrated in a flattened condition in Fig. 7. Generally, posterior leaflet 236 includes a first edge 271 having a generally arcuate shape, with the first edge extending from a first tab 273 to a second tab 275, both of which may include rectangular portions. A tapered portion 279 may include two substantially straight edges that extend from the first tab 273 and second tab 275, respectively, and meet one another at a third tab 277, which may also be substantially rectangular. With this configuration, tapered portion 279 is relatively wide adjacent tabs 273 and 275, with the width decreasing in the direction of third tab 277. Posterior leaflet 236, may have a height H2 from the top of tab 277 to the bottom of first edge 271 (as seen in Fig. 7), and a width W2 from the outer lateral edge of tab 273 to the outer lateral edge of tab 275. The height H2 of posterior leaflet 236 is greater than the height H1 of each anterior leaflet 238a-c, and the width W2 of the posterior leaflet is greater than the width W1 of each anterior leaflet. As a result, the surface area of posterior leaflet 236 is greater than the surface area of each anterior leaflet 238a-c.

[0028] Referring back to Fig. 5, each tab of each anterior leaflet 238a-c may be attached to a tab of an adjacent leaflet at one of the CAFs 260 on anterior section 228 of stent 250. The first edge of each anterior leaflet may be coupled to stent 250 via a cuff (not shown) attached to the stent. The cuff may be disposed on the lumenal surface of stent 250, the ablumenal surface, or both surfaces. The cuff may be wholly or partly formed from any suitable biological material, such as bovine or porcine pericardium, or from one or more polymers, such as polytetrafluoroethylene (PTFE), urethanes and the like. For the embodiment of stent 250 illustrated in Figs. 4-5, the cuff preferably covers most or all of the open space within cells 254. The dashed lines of Fig. 5 illustrate the lines along which the first edge of each leaflet is attached to the cuff. For example, the first edge of each leaflet

may be sutured to the cuff, and also to stent 250 if desired, by passing strings or sutures through the cuff and around struts 252. The second or free edge of each anterior leaflet 238a-c may coapt with the free edge of adjacent anterior leaflets. The first edge 271 of posterior leaflet 236 may similarly be attached to stent 250, for example via the cuff, with tabs 273 and 275 coupled to adjacent CAFs 260 on posterior section 226 of stent 250. The third tab 277 of posterior leaflet 236 may be attached to stent 250 at an attachment location 262. Attachment location 262 may take the form of a CAF similar to CAFs 260, or any may take other suitable form. For example, attachment location 262 may simply be the apex of a cell 254, such as the single cell in third row 254c, at which two struts 252 meet one another.

[0029] Referring again to Fig. 6, each anterior leaflet 238a-c may be fully supported by stent 250 by the connection of its tabs, such as tabs 270a and 272a, to corresponding CAFs 260, as well as the attachment of its first edge to the cuff. In other words, when prosthetic heart valve 200 is implanted into a native mitral valve annulus, anterior leaflets 238a-c may coapt with one another and/or with posterior leaflet 236 to stop blood from flowing in the retrograde direction from left ventricle 124 to left atrium 122, without the anterior leaflets everting or otherwise malfunctioning. However, because posterior leaflet 236 is substantially larger than each of the anterior leaflets 238a-c, relatively large forces may be applied to the posterior leaflet as it coapts with the anterior leaflets to resist retrograde blood flow. In native mitral valve 130, as described above, anterior leaflet 138 and posterior leaflet 136 are each attached to papillary muscles 132 via chordae tendinae 134, which helps resist leaflet eversion. The attachment of third tab 277 of posterior leaflet 236 to attachment location 262 may provide similar eversion resistance for the posterior leaflet 236, without requiring any connection between the posterior leaflet and native anatomy, such as chordae tendinae 134 or papillary muscles 132.

[0030] Although the particular size of posterior leaflet 236 compared to the size of anterior leaflets 238a-c may vary, certain relative sizes may be preferable. For example, when posterior leaflet 236 and anterior leaflets 238a-c are in the coapted condition, if the area of the leaflets were projected onto the circle (or ellipse, D-shape, *etc.*) formed by stent 250, the projected area of posterior leaflet 236 would preferably occupy between about 50% and about 60% of the total area, while the anterior leaflets 238a-c would preferably occupy between about 40% and about 50% of that area. In the scenario in which each anterior leaflet 238a-c is identical or similar, the projected area of each individual anterior leaflet 238a-c

preferably would occupy between about 13% and about 17% of the area defined by the circumference of stent 250. Another relative measure of the size of posterior leaflet 236 compared to anterior leaflets 238a-c may be in reference to the distance of the interior circumference of stent 250 occupied by each leaflet. For example, referring to Fig. 5, each anterior leaflet 238a-c may span the circumference of about two cells 254. Posterior leaflet 236 may span the circumference of about four cells 254. Because each cell 254 is about the same size in Fig. 5, each anterior leaflet 238a-c spans about 20% of the interior circumference of stent 250, while posterior leaflet 236 spans about 40% of the interior circumference of the stent.

[0031] Fig. 8 illustrates a schematic cross-section of prosthetic heart valve 200 with the leaflets in a coapted state. In Fig. 8, posterior leaflet 236 and anterior leaflet 238b are shown, but it should be understood that anterior leaflets 238a and 238c would also be coapting with adjacent leaflets to prevent retrograde blood flow. Despite tapered portion 279 being coupled to attachment location 262 via third tab 277, posterior leaflet 236 retains enough slack between first edge 271 and third tab 277 to form a billowing portion 279a which coapts with anterior leaflets 238a-c. In some embodiments, stent 250 may include anchor features, such as anterior anchor 280a to clip over the native anterior leaflet 138 and posterior anchor 280b to clip over the native posterior leaflet 136. Anchor features 280a-b may take any suitable form, including struts integral with stent 250, with free ends that are biased outward in the absence of an applied force, with the anchor features being transitionable to a nested condition within a cell 254 when prosthetic heart valve 200 is in a collapsed condition. With this configuration, anchor features 280a-b may be substantially flush with the remainder of stent 250 during delivery, and upon expansion to the expanded condition, the free ends of anchor features 280a-b may transition radially outwardly so that native mitral valve leaflets 136, 138 may be sandwiched between anchor features 280a-b and the remainder of stent 250.

[0032] In order to implant prosthetic heart valve 200 into the native mitral valve annulus of a patient, the valve 200, including stent 250 and leaflets 236 and 238a-c, may be crimped to a collapsed condition, loaded into a delivery device (not shown), and covered by a sheath of the delivery device to maintain the valve in the collapsed condition. The delivery device is then advanced to the annulus of the native mitral valve 130, for example through the vasculature via an opening in the femoral artery (transfemoral delivery), or through an

incision in the apex of left ventricle 124 (transapical delivery). Other delivery methods, such as transseptal delivery, are also contemplated herein. Once the sheath is positioned at the desired location with respect to the native mitral valve annulus, which may be confirmed by imaging techniques such as fluoroscopy, the sheath may be advanced or retracted relative to the remainder of the delivery device to expose prosthetic heart valve 200. As the sheath is moved from around prosthetic heart valve 200, constrictive forces are removed from the valve, which begins to expand as stent 250 begins to return to its set shape (*i.e.*, the expanded condition). Upon implantation, the inflow end 210 of stent 250 and the first edges of each leaflet 236, 238a-c are oriented toward left atrium 122 while the outflow end 212 of stent 250 and the free edges of each anterior leaflet 238a-c and the tapered portion 279 of posterior leaflet 236 are oriented toward left ventricle 124. If prosthetic heart valve 200 includes anchor features 280a-b, the native posterior leaflet 136 and anterior leaflet 138 may be sandwiched between the anchor features and stent 250 to help stabilized the prosthetic valve within the native mitral valve 130.

[0033] It is desirable that prosthetic valve 200, upon implantation, be oriented such that anterior leaflets 238a-c are positioned nearer native aortic valve 140, and posterior leaflet 236 is positioned farther away from the native aortic valve. As the anterior section 228 of stent 250 and anterior leaflets 238a-c do not extend a substantial distance into left ventricle 124, this configuration may provide at least two benefits. First, the shallow anterior section of the prosthetic heart valve 200 may reduce the likelihood that any structure of prosthetic heart valve will contact the septum separating left ventricle 124 from right ventricle 114, which could cause ventricular fibrillation. Second, the shallow anterior section of prosthetic heart valve 200 may reduce the likelihood of any structure of the prosthetic heart valve obstructing blood flow from the left ventricle to aorta 110 through aortic valve 140. The relatively large posterior leaflet 236, on the other hand, is positioned away from the native aortic valve 140 and the septum separating left ventricle 124 from right ventricle 114. The associated larger size of the posterior portion 226 of stent 250 is also positioned away from native aortic valve 140, reducing the likelihood of interference with the native anatomy.

[0034] According to one embodiment of the disclosure, a prosthetic mitral valve comprises:

a collapsible and expandable stent extending from an inflow end to an outflow end; and

a collapsible and expandable valve assembly disposed within the stent, the valve assembly including a plurality of anterior leaflets each having a surface area and one posterior leaflet having a surface area, the surface area of the posterior leaflet being larger than the surface area of any of the anterior leaflets; and/or

the surface area of each anterior leaflet is about the same; and/or

each anterior leaflet has a first edge coupled to the stent and a free edge nearer the outflow end of the stent than the inflow end of the stent; and/or

the posterior leaflet has a first edge coupled to the stent adjacent the inflow end of the stent; and/or

the posterior leaflet includes a tapered portion extending away from the first edge, the tapered portion having a width that decreases in a direction from the inflow end of the stent toward the outflow end of the stent; and/or

the tapered portion of the posterior leaflet is coupled to the stent adjacent the outflow end of the stent; and/or

the stent includes an anterior section, a posterior section, a first circumferential row of cells, and a second row of cells coupled to the first row of cells, the first row of cells being positioned in the anterior section and the posterior section of the stent, the second row of cells being positioned only in the posterior section of the stent; and/or

the posterior section includes a third row having at least one cell coupled to the second row of cells; and/or

the third row includes a single cell; and/or

the posterior leaflet includes a first edge coupled to the stent adjacent the inflow end of the stent, and a second end opposite the first edge coupled to the single cell in the third row; and/or

the plurality of anterior leaflets includes exactly three anterior leaflets.

[0035] In another embodiment of the disclosure, a method of implanting a prosthetic mitral valve into a native mitral valve annulus of a patient comprises:

delivering the prosthetic mitral valve in a collapsed condition to the native mitral valve annulus, the prosthetic mitral valve including a collapsible and expandable stent and a valve assembly disposed within the stent, the valve assembly including a plurality of anterior leaflets each having a surface area and one posterior leaflet having a surface area, the surface

area of the posterior leaflet being larger than the surface area of any of the anterior leaflets; and

deploying the prosthetic mitral valve to an expanded condition within the native mitral valve annulus so that the posterior leaflet extends a greater distance into a left ventricle of the patient than any of the anterior leaflets; and/or

the surface area of each of the anterior leaflets is about the same; and/or

each anterior leaflet has a first edge coupled to the stent and a free edge nearer an outflow end of the stent than an inflow end of the stent; and/or

the posterior leaflet has a first edge coupled to the stent adjacent an inflow end of the stent; and/or

the posterior leaflet includes a tapered portion extending away from the first edge, the tapered portion having a width that decreases in a direction from the inflow end of the stent toward an outflow end of the stent; and/or

the tapered portion of the posterior leaflet is coupled to the stent adjacent the outflow end of the stent; and/or

the stent includes an anterior section, a posterior section, a first circumferential row of cells, and a second row of cells coupled to the first row of cells, the first row of cells being positioned in the anterior section and the posterior section of the stent, the second row of cells being positioned only in the posterior section of the stent; and/or

the posterior section includes a third row having at least one cell coupled to the second row of cells; and/or

the third row includes a single cell; and/or

the posterior leaflet includes a first edge coupled to the stent adjacent the inflow end of the stent, and a second end opposite the first edge coupled to the single cell in the third row; and/or

the deploying step includes deploying the prosthetic valve so that the anterior leaflets are positioned closer to a native aortic valve than the posterior leaflet.

[0036] Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present

invention as defined by the appended claims. For example, features of one embodiment of the invention may be combined with features of one or more other embodiments of the invention without departing from the scope of the invention.

CLAIMS

1. A prosthetic mitral valve, comprising:

a collapsible and expandable stent extending from an inflow end to an outflow end; and

a collapsible and expandable valve assembly disposed within the stent, the valve assembly including a plurality of anterior leaflets each having a surface area and one posterior leaflet having a surface area, the surface area of the posterior leaflet being larger than the surface area of any of the anterior leaflets.

2. The prosthetic mitral valve of claim 1, wherein the surface area of each anterior leaflet is about the same.

3. The prosthetic mitral valve of claim 1, wherein each anterior leaflet has a first edge coupled to the stent and a free edge nearer the outflow end of the stent than the inflow end of the stent.

4. The prosthetic mitral valve of claim 1, wherein the posterior leaflet has a first edge coupled to the stent adjacent the inflow end of the stent.

5. The prosthetic mitral valve of claim 4, wherein the posterior leaflet includes a tapered portion extending away from the first edge, the tapered portion having a width that decreases in a direction from the inflow end of the stent toward the outflow end of the stent.

6. The prosthetic mitral valve of claim 5, wherein the tapered portion of the posterior leaflet is coupled to the stent adjacent the outflow end of the stent.

7. The prosthetic mitral valve of claim 1, wherein the stent includes an anterior section, a posterior section, a first circumferential row of cells, and a second row of cells coupled to the first row of cells, the first row of cells being positioned in the anterior section and the posterior section of the stent, the second row of cells being positioned only in the posterior section of the stent.

8. The prosthetic mitral valve of claim 7, wherein the posterior section includes a third row having at least one cell coupled to the second row of cells.

9. The prosthetic mitral valve of claim 8, wherein the third row includes a single cell.

10. The prosthetic mitral valve of claim 9, wherein the posterior leaflet includes a first edge coupled to the stent adjacent the inflow end of the stent, and a second end opposite the first edge coupled to the single cell in the third row.

11. The prosthetic mitral valve of claim 1, wherein the plurality of anterior leaflets includes exactly three anterior leaflets.

12. A method of implanting a prosthetic mitral valve into a native mitral valve annulus of a patient, the method comprising:

delivering the prosthetic mitral valve in a collapsed condition to the native mitral valve annulus, the prosthetic mitral valve including a collapsible and expandable stent and a valve assembly disposed within the stent, the valve assembly including a plurality of anterior leaflets each having a surface area and one posterior leaflet having a surface area, the surface area of the posterior leaflet being larger than the surface area of any of the anterior leaflets; and

deploying the prosthetic mitral valve to an expanded condition within the native mitral valve annulus so that all of the anterior leaflets extend a lesser distance into a left ventricle of the patient than the posterior leaflet.

13. The method of claim 12, wherein the surface area of each of the anterior leaflets is about the same.

14. The method of claim 12, wherein each anterior leaflet has a first edge coupled to the stent and a free edge nearer an outflow end of the stent than an inflow end of the stent.

15. The method of claim 12, wherein the posterior leaflet has a first edge coupled to the stent adjacent an inflow end of the stent.

16. The method of claim 15, wherein the posterior leaflet includes a tapered portion extending away from the first edge, the tapered portion having a width that decreases in a direction from the inflow end of the stent toward an outflow end of the stent.

17. The method of claim 16, wherein the tapered portion of the posterior leaflet is coupled to the stent adjacent the outflow end of the stent.

18. The method of claim 12, wherein the stent includes an anterior section, a posterior section, a first circumferential row of cells, and a second row of cells coupled to the first row of cells, the first row of cells being positioned in the anterior section and the posterior section of the stent, the second row of cells being positioned only in the posterior section of the stent.

19. The method of claim 18, wherein the posterior section includes a third row having at least one cell coupled to the second row of cells.

20. The method of claim 19, wherein the third row includes a single cell.

21. The method of claim 20, wherein the posterior leaflet includes a first edge coupled to the stent adjacent the inflow end of the stent, and a second end opposite the first edge coupled to the single cell in the third row.

22. The method of claim 12, wherein the deploying step includes deploying the prosthetic valve so that the anterior leaflets are positioned closer to a native aortic valve than the posterior leaflet.

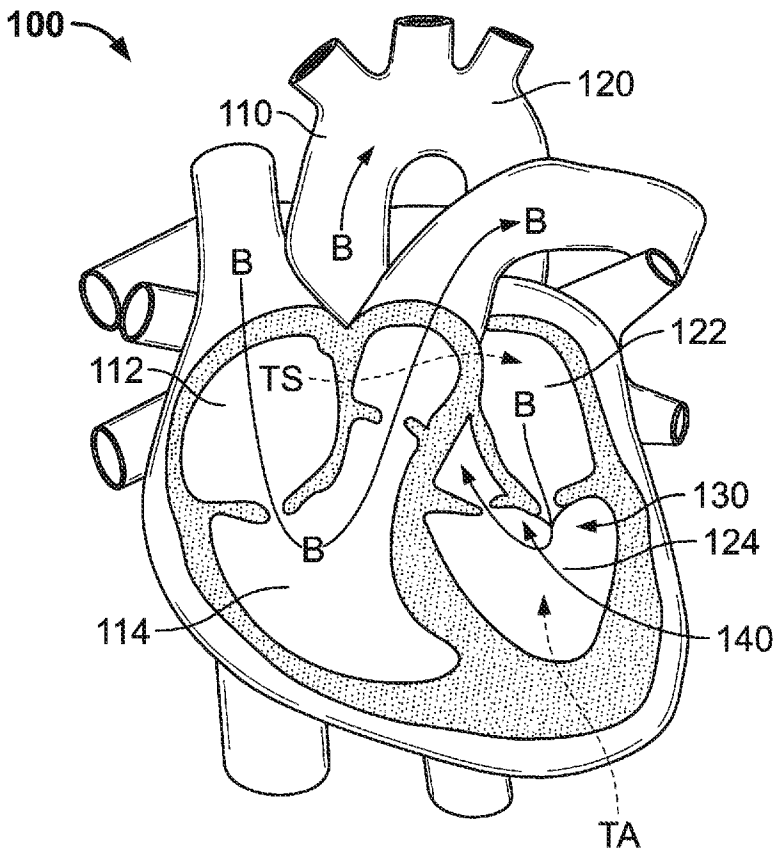

FIG. 1

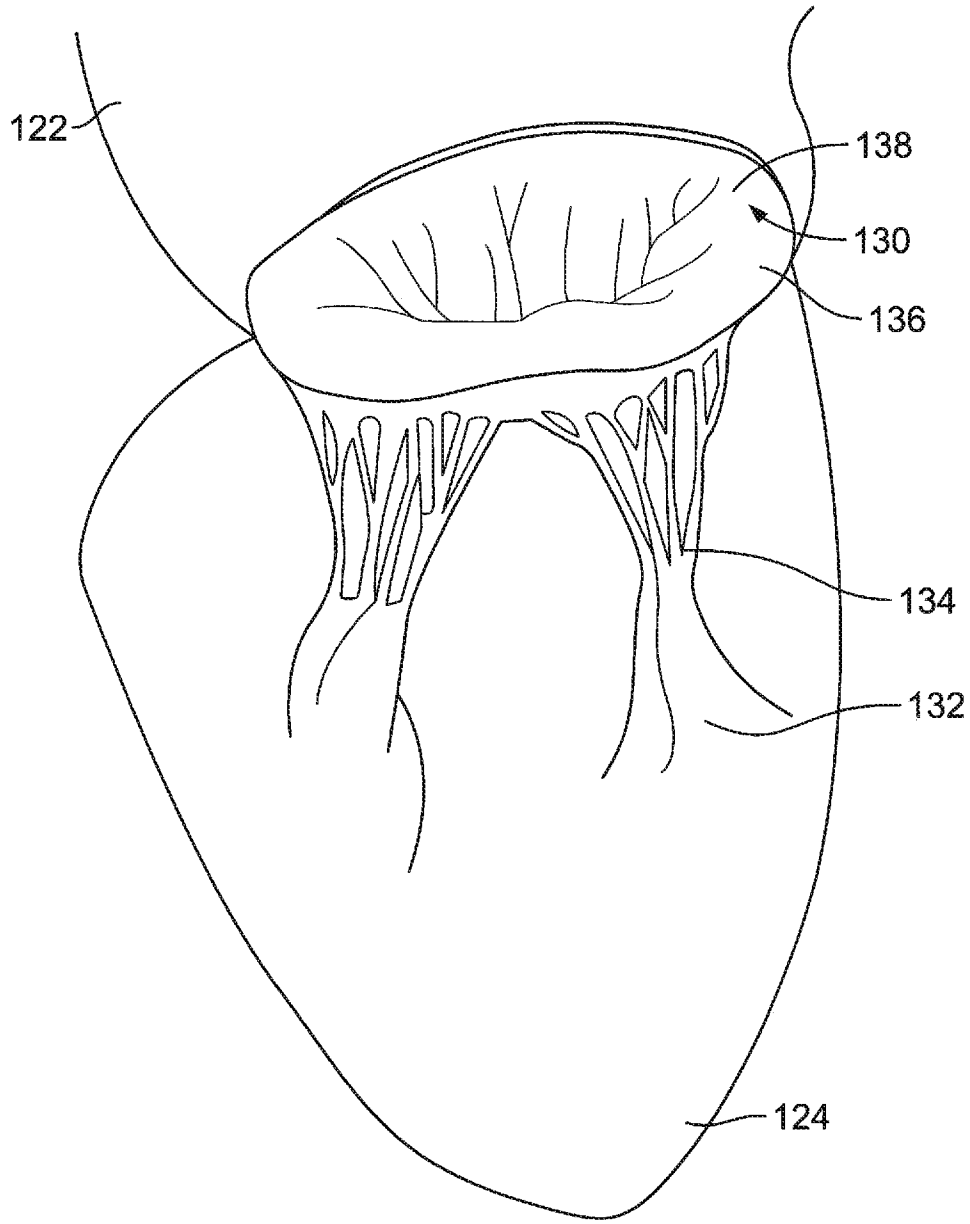

FIG. 2

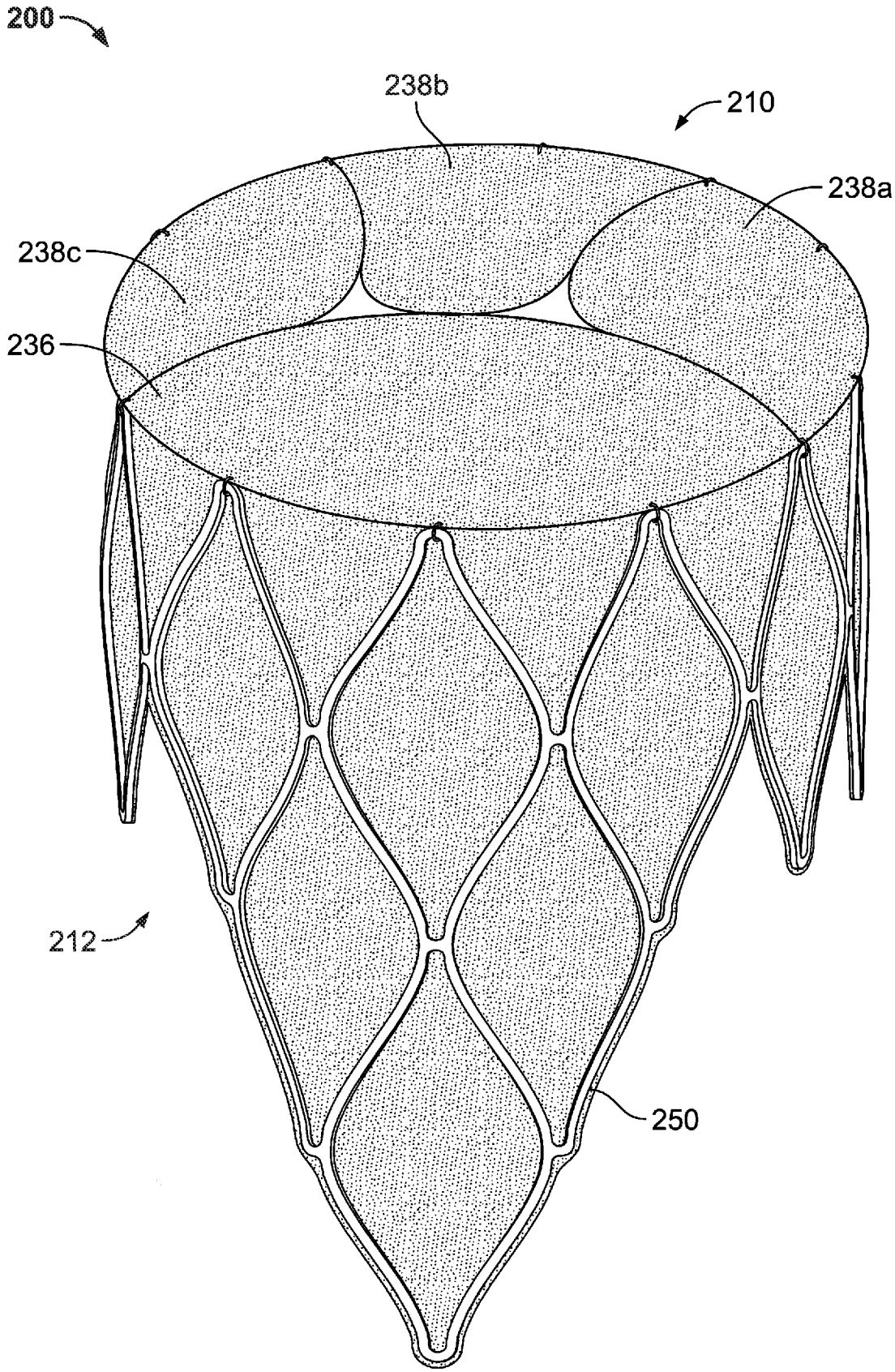

FIG. 3

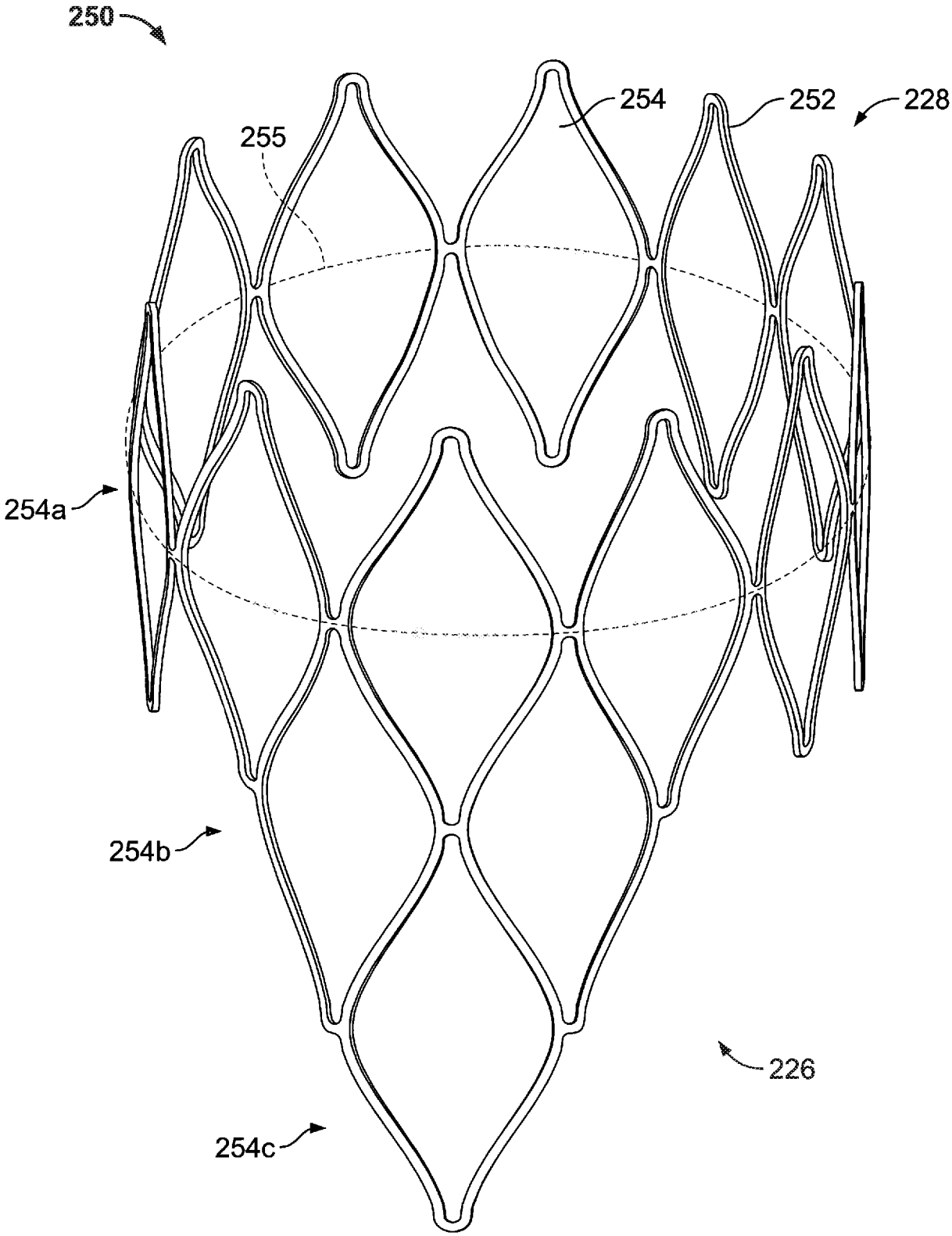

FIG. 4

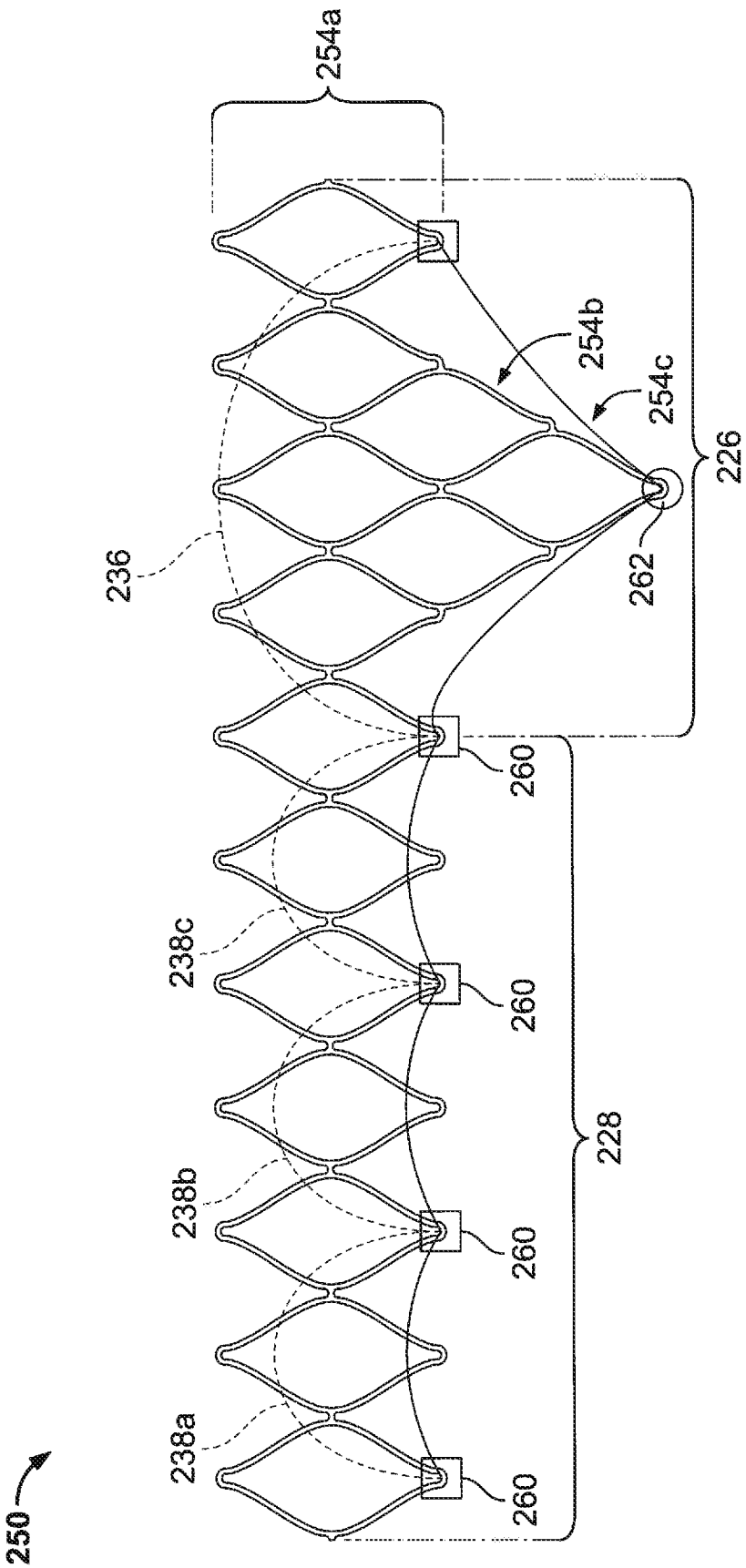
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FIG. 5

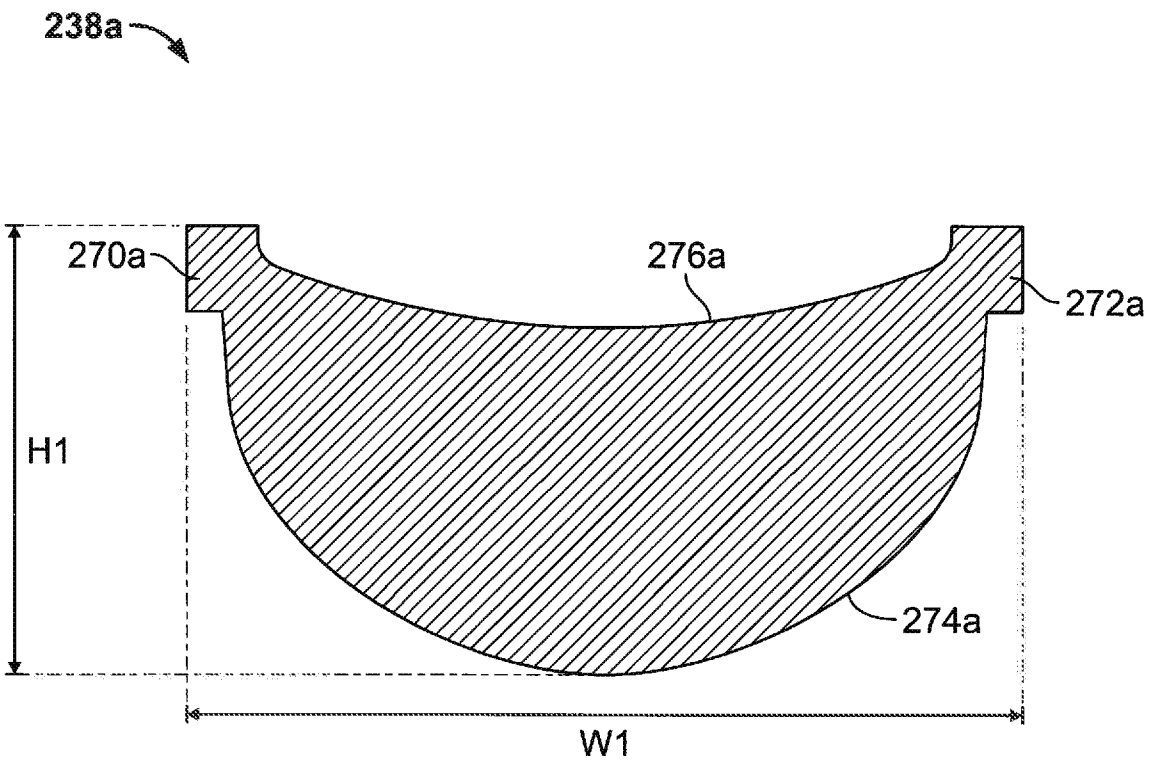

FIG. 6

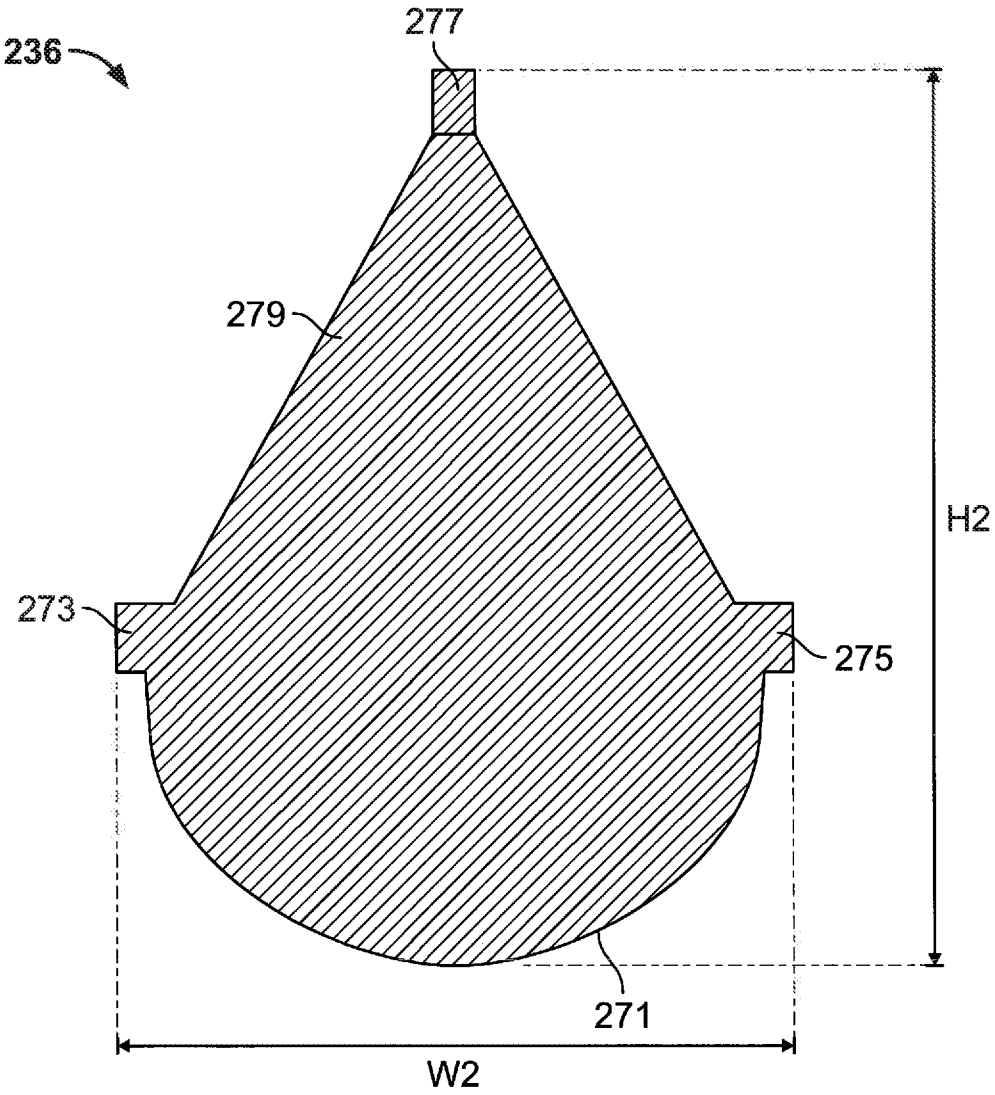

FIG. 7

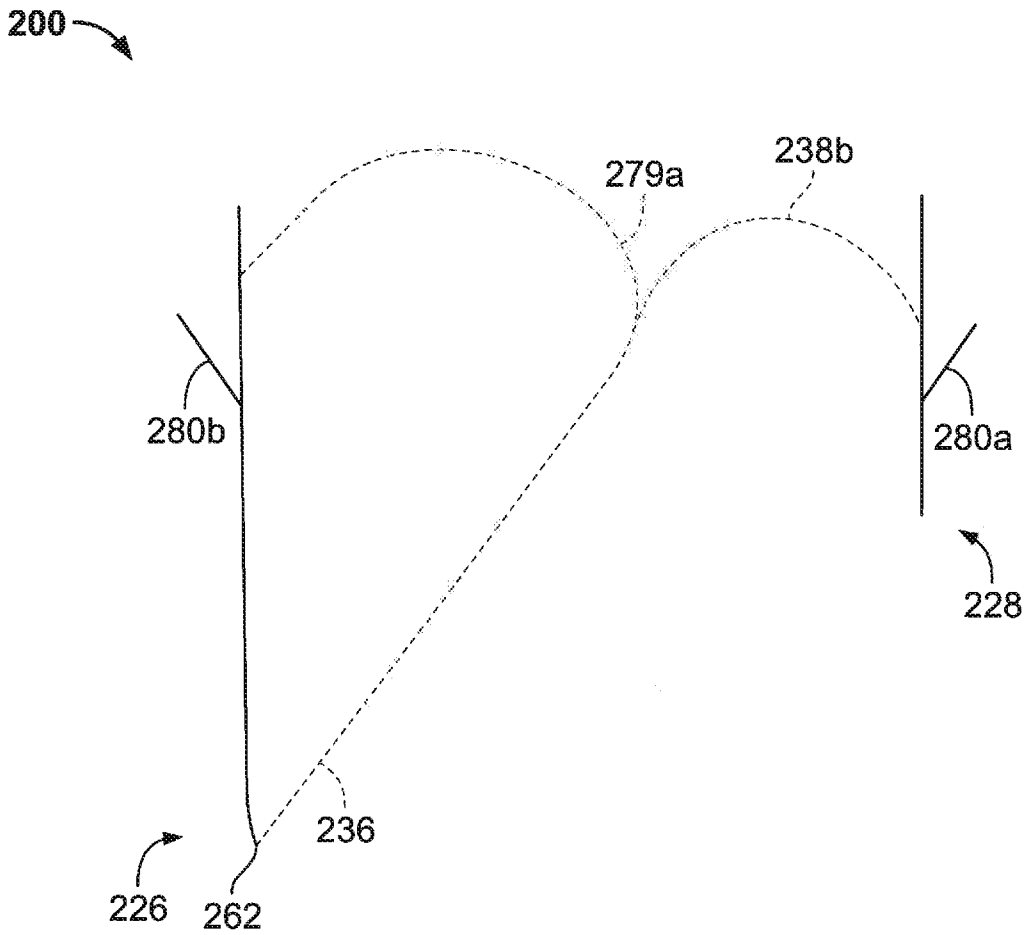

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/020370

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2013/023980 A1 (DRASLER WILLIAM JOSEPH [US]) 24 January 2013 (2013-01-24) paragraphs [005.025], [0034], [0041] - [0047]; figures 5a-7c	1-6,11 7-10
Y A	US 2016/113764 A1 (SHEAHAN EDMOND [IE] ET AL) 28 April 2016 (2016-04-28) paragraphs [0060] - [0062]; figure 10	7-10 1
A	US 2016/158013 A1 (CARPENTIER ALAIN F [FR] ET AL) 9 June 2016 (2016-06-09) paragraphs [0015], [0029], [0044] - [0046], [0069]; figures 3-4, 10a-10b	1-6

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 May 2018	17/05/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Porta, Marcello

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/020370

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12-22
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 12-22 are considered a method for treatment of the human or animal body by surgery (Rule 39.1(iv) PCT) as they involve the insertion and implantation of a mitral valve prosthesis into a mitral valve annulus

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/020370

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2013023980 A1	24-01-2013	NONE	
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		WO 2005072654 A1	11-08-2005