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REPLACEMENT MITRAL VALVES

ABSTRACT

A prosthetic mitral valve includes an anchor assembly, a strut frame, and a plurality of replacement leaflets secured to the annular strut frame. The anchor assembly includes a ventricular anchor, an atrial anchor, and a central portion therebetween. The ventricular anchor and the atrial anchor are configured to flare radially outwards relative to the central portion. The annular strut frame is disposed radially within the anchor assembly and is attached to the anchor assembly. The central portion is configured to align with a native valve orifice and the ventricular anchor and the atrial anchor are configured to compress native cardiac tissue therebetween.

REPLACEMENT MITRAL VALVES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 62/513,877, filed June 1, 2017 and to U.S. Provisional Patent Application No. 62/449,498, filed January 23, 2017, and titled "REPLACEMENT MITRAL VALVES," the entireties of which are incorporated by reference herein.

[0002] This application may also be related to International Patent Application No. PCT/US2016/032550, filed May 13, 2016, titled "REPLACEMENT MITRAL VALVES", to U.S. Patent Application No. 14/170,388, filed January 31, 2014, titled "SYSTEM AND METHOD FOR CARDIAC VALVE REPAIR AND REPLACEMENT," now U.S. Patent No. 8,870,948, and to U.S. Patent Application No. 14/677,320, filed April 2, 2015, titled "REPLACEMENT CARDIAC VALVES AND METHODS OF USE AND MANUFACTURE," the entireties of which are incorporated by reference herein.

INCORPORATION BY REFERENCE

[0003] 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.

BACKGROUND

[0004] The mitral valve lies between the left atrium and the left ventricle of the heart. Various diseases can affect the function of the mitral valve, including degenerative mitral valve disease and mitral valve prolapse. These diseases can cause mitral stenosis, in which the valve fails to open fully and thereby obstructs blood flow, and/or mitral insufficiency, in which the mitral valve is incompetent and blood flows passively in the wrong direction.

[0005] Many patients with heart disease, including those with mitral valve problems, are intolerant of the trauma associated with open-heart surgery. Age or advanced illness may have impaired the patient's ability to recover from the injury of an open-heart procedure. Additionally, the high costs associated with open-heart surgery and extra-corporeal perfusion can make such procedures prohibitive.

[0006] Patients in need of cardiac valve repair or cardiac valve replacement can be served by minimally invasive surgical techniques. In many minimally invasive procedures, small devices are manipulated within the patient's body under visualization from a live imaging source like ultrasound, fluoroscopy, or endoscopy. Minimally invasive cardiac procedures are

inherently less traumatic than open procedures and may be performed without extra-corporeal perfusion, which carries a significant risk of procedural complications.

[0007] Minimally invasive aortic valve replacement devices, such as the Medtronic Corevalve or the Edwards Sapien, deliver aortic valve prostheses through small tubes which may be positioned within the heart through the aorta via the femoral artery or through the apex of the heart. However, the mitral valve differs from the aortic valve in that the shape and anatomy immediately surrounding the valve varies greatly from one side of the valve to the other. Moreover, current cardiac valve prostheses are not designed to function effectively within the mitral valve. Further, current cardiac valve prostheses delivered via a minimally invasive device are often difficult to place correctly within the native valve, difficult to match in size to the native valve, and difficult to retrieve and replace if initially placed incorrectly.

[0008] These and other deficiencies in existing approaches are described herein.

SUMMARY OF THE DISCLOSURE

[0009] In general, in one embodiment, a prosthetic mitral valve includes an anchor assembly, a strut frame, and a plurality of replacement leaflets secured to the annular strut frame. The anchor assembly includes a ventricular anchor, an atrial anchor, and a central portion therebetween. The ventricular anchor and the atrial anchor are configured to flare radially outwards relative to the central portion. The annular strut frame is disposed radially within the anchor assembly and is attached to the anchor assembly at an plurality of attachment locations that are positioned between the central portion and an atrial-most edge of the anchor assembly. The central portion is configured to align with a native valve orifice and the ventricular anchor and the atrial anchor are configured to compress native cardiac tissue therebetween.

[0010] This and other embodiments can include one or more of the following features. An atrial end of the strut frame can be attached to the anchor assembly. Atrial tips of the strut frame can be attached to the anchor assembly. An atrial end of the strut frame can be flared radially outwards. A flare of the strut frame can be configured to substantially conform to a flare of the atrial anchor. A ventricular end of the strut frame can be spaced away from the anchor assembly. The ventricular end of the strut frame can be spaced away from the anchor assembly by a radial distance of 1-15mm. The anchor assembly and the strut frame can be configured to self-expand from a constrained configuration to an expanded configuration. The strut frame can be attached to the anchor assembly with a plurality of rivets. Each of the plurality of attachment locations can be radially aligned with tips of the atrial anchor. The plurality of attachment locations can each be part of the anchor assembly that extends further radially inwards than a remaining portion of the anchor assembly. The anchor assembly can comprise a plurality of diamond-

shaped cells. The plurality of attachment locations can be positioned at a mid-point of the outermost atrial diamond-shaped cells. The strut frame can include a plurality of linear struts and v-shaped connectors therebetween. The anchor assembly can form a substantially hour-glass shape.

[0011] In general, in one embodiment, a prosthetic mitral valve includes an anchor assembly, an annular strut frame, and a plurality of replacement leaflets secured to the annular strut frame. The anchor assembly includes a ventricular anchor, an atrial anchor, and a central portion therebetween. The ventricular anchor and the atrial anchor are configured to flare radially outwards relative to the central portion. Further, the anchor assembly comprises a plurality of diamond-shaped cells. The annular strut frame is disposed radially within the anchor assembly and is attached to the anchor assembly at a plurality of attachment locations that are positioned at a mid-point of the outermost atrial diamond-shaped cells between the central portion and an atrial-most edge of the anchor assembly.

[0012] This and other embodiments can include one or more of the following features. An atrial end of the strut frame can be attached to the anchor assembly. Atrial tips of the strut frame can be attached to the anchor assembly. An atrial end of the strut frame can be flared radially outwards. A flare of the strut frame can be configured to substantially conform to a flare of the atrial anchor. A ventricular end of the strut frame can be spaced away from the anchor assembly. The ventricular end of the strut frame can be spaced away from the anchor assembly by a radial distance of 1-15mm. The anchor assembly and the strut frame can be configured to self-expand from a constrained configuration to an expanded configuration. The strut frame can be attached to the anchor assembly with a plurality of rivets. Each of the plurality of attachment locations can be radially aligned with tips of the atrial anchor. The plurality of attachment locations can each be part of the anchor assembly that extends further radially inwards than a remaining portion of the anchor assembly. The strut frame can include a plurality of linear struts and v-shaped connectors therebetween. The anchor assembly can form a substantially hour-glass shape.

[0013] In general, in one embodiment, a prosthetic mitral valve includes an anchor assembly, an annular strut frame, and a plurality of replacement leaflets secured to the annular strut frame. The anchor assembly further includes a ventricular anchor, an atrial anchor, and a central portion therebetween. The ventricular anchor and the atrial anchor are configured to flare radially outwards relative to the central portion. Further, the atrial anchor includes a plurality of atrial cells and the ventricular anchor includes a plurality of ventricular cells. The annular strut frame is disposed radially within the anchor assembly. A first plurality of the atrial cells are

positioned radially inwards relative to a second plurality of the atrial cells such that the first plurality of cells attach the strut frame to the anchor assembly.

[0014] This and other embodiments can include one or more of the following features. The central portion can be configured to align with a native valve orifice, and the ventricular anchor and the atrial anchor can be configured to compress native cardiac tissue therebetween. An atrial end of the strut frame can be attached to the anchor assembly. Atrial tips of the strut frame can be attached to the anchor assembly. An atrial end of the strut frame can be flared radially outwards. A flare of the strut frame can be configured to substantially conform to a flare of the atrial anchor. A ventricular end of the strut frame can be spaced away from the anchor assembly. The ventricular end of the strut frame can be spaced away from the anchor assembly by a radial distance of 1-15mm. The anchor assembly and the strut frame can be configured to self-expand from a constrained configuration to an expanded configuration. The strut frame can be attached to the anchor assembly with a plurality of rivets. The first plurality of atrial cells can end in disconnected apexes. The disconnected apexes can be radially aligned with outer-most tips of the second plurality of atrial cells. The first plurality of atrial cells can be angled at approximately 70-80 degrees relative to the axis that extends through the central portion. The second plurality of atrial cells can be angled at approximately 20-30 degrees relative to the axis that extends through the central portion. The annular strut frame can flare radially outwards at 70-80 degrees relative to the axis that extends through the central portion.

[0015] In general, in one embodiment, a prosthetic mitral valve includes an anchor assembly, an annular strut frame, and a plurality of replacement leaflets secured to the annular strut frame. The anchor assembly includes a ventricular anchor, an atrial anchor, and a central portion therebetween. The ventricular anchor and the atrial anchor are configured to flare radially outwards relative to the central portion. Further, the atrial anchor includes a plurality of atrial cells. The annular strut frame is disposed radially within the anchor assembly. A first plurality of the atrial cells are interior disconnected apexes and the second plurality of atrial cells are outermost atrial cells. The first plurality positioned radially inwards relative to a second plurality of the atrial cells such that the first plurality of cells attach the strut frame to the anchor assembly.

[0016] This and other embodiments can include one or more of the following features. The central portion can be configured to align with a native valve orifice. The ventricular anchor and the atrial anchor can be configured to compress native cardiac tissue therebetween. An atrial end of the strut frame can be attached to the anchor assembly. Atrial tips of the strut frame can be attached to the anchor assembly. An atrial end of the strut frame can be flared radially outwards. A flare of the strut frame can be configured to substantially conform to a flare of the atrial

anchor. A ventricular end of the strut frame can be spaced away from the anchor assembly. The ventricular end of the strut frame can be spaced away from the anchor assembly by a radial distance of 1-15mm. The anchor assembly and the strut frame can be configured to self-expand from a constrained configuration to an expanded configuration. The strut frame can be attached to the anchor assembly with a plurality of rivets. The disconnected apexes can be radially aligned with outer-most tips of the second plurality of atrial cells. The first plurality of atrial cells can be angled at approximately 70-80 degrees relative to an axis that extends through the central portion. The second plurality of atrial cells can be angled at approximately 20-30 degrees relative to the axis that extends through the central portion. The annular strut frame can flare radially outwards at 70-80 degrees relative to the axis that extends through the central portion.

[0017] In general, in one embodiment, a prosthetic mitral valve includes a valve support assembly that includes a ventricular anchor and an atrial anchor. The valve support assembly has a plurality of slots therethrough. The prosthetic mitral valve further includes a plurality of replacement leaflets. Each leaflet has a leaflet arm extending through one of the plurality of slots. The prosthetic mitral valve further includes a plurality of commissure plates. Each commissure plate is circumferentially and axially aligned with one of the plurality of slots to form a commissure attachment mechanism. Each commissure plate further includes a plurality of channels in the sides thereof. The at least one suture is positioned at each commissure attachment mechanism and is wrapped around a portion of the valve support assembly, through the plurality of indents, and around the commissure plate.

[0018] This and other embodiments can include one or more of the following features. The valve support assembly can include an anchor assembly that includes the ventricular and atrial anchors and an annular strut frame that includes the plurality of slots. The annular strut frame can be positioned radially within the anchor assembly. The plurality of slots can be in a portion of the strut frame that extends past the anchor assembly in the ventricular direction. The anchor assembly can further include a central portion, and the ventricular and atrial anchors can flare radially outwards relative to the central portion. The plurality of channels can extend from the sides of each commissure plate towards a center of the plate. The plurality of channels can be substantially straight. There can be between 6 and 12 channels in each commissure plate. Each of the slots can be in an axially extending strut. Arms of the leaflets can extend through the plurality of slots. The arms can be further be wound around an outer perimeter of an inner strut frame of the valve support assembly. The plurality of slots can be positioned equidistance around a circumference of the valve support assembly. Each of the plurality of slots can be positioned towards a ventricular end of the valve support assembly. The valve support assembly can be configured to self-expand from a constrained configuration to an expanded configuration.

Atrial edges of the leaflets can be sewn around an inner circumference of the valve support assembly. Each of the leaflets further includes a leaflet protector thereon. The leaflet protector can be made of a lubricious fabric and can be configured to protect the respective leaflet from an inner circumference of the valve support assembly.

[0019] In general, in one embodiment, a prosthetic mitral valve includes a valve support assembly. The valve support assembly includes an anchor assembly having a ventricular anchor and an atrial anchor and an annular strut frame positioned radially within the anchor assembly. The annular strut frame includes a plurality of slots therethrough. The prosthetic mitral valve further includes a plurality of replacement leaflets. Each leaflet has a leaflet arm extending through one of the plurality of slots. The prosthetic mitral valve further includes a plurality of commissure plates. Each commissure plate is circumferentially and axially aligned with one of the plurality of slots to form a commissure attachment mechanism. Each commissure plate further includes a plurality of channels in the sides thereof.

[0020] This and other embodiments can include one or more of the following features. The prosthetic mitral valve can include at least one suture at each commissure attachment mechanism. The at least one suture can be positioned around the strut frame, through the plurality of indents, and around the commissure plate. The plurality of slots can be in a portion of the strut frame that extends past the anchor assembly in the ventricular direction. The anchor assembly can further include a central portion, and the ventricular and atrial anchors can be flared radially outwards relative to the central portion. The plurality of channels can extend from the sides of each commissure plate towards a center of the plate. The plurality of channels can be substantially straight. There can be between 6 and 12 channels in each commissure plate. Each of the slots can be in an axially extending strut. The arms of the leaflets can extend through the plurality of slots. The arms can be further be wound around an outer perimeter of the strut frame. The plurality of slots can be positioned equidistance around a circumference of the strut frame. Each of the plurality of slots can be positioned towards a ventricular end of the strut frame. The valve support assembly can be configured to self-expand from a constrained configuration to an expanded configuration. Atrial edges of the leaflets can be sewn around an inner circumference of the strut frame. Each of the leaflets can further include a leaflet protector thereon. The leaflet protector can be made of a lubricious fabric and can be configured to protect the leaflet from an inner circumference of the valve support assembly.

[0021] In general, in one embodiment, a prosthetic mitral valve includes a valve support assembly, a plurality of leaflets secured to the valve support assembly, and a plurality of retention hooks. The valve support assembly includes a ventricular anchor, a central portion, and an atrial anchor. The valve support assembly is configured to self-expand from a collapsed

configuration to an expanded configuration. The plurality of retention hooks are attached to the ventricular anchor. Each of the retention hooks curves radially outwards to point in an atrial direction when the valve support assembly is in the expanded configuration. Each retention hook has a ratio of radius of curvature to thickness of between 4:1 and 6:1.

[0022] This and other embodiments can include one or more of the following features. Each of the plurality of retention hooks can be configured to point at an angle of 50°-80° relative to a central longitudinal axis of the prosthetic mitral valve. The angle can be approximately 65°. A radius of curvature of each of the plurality of retention hooks can be between 3-5mm. A thickness of each retention hooks can be between 0.8mm and 1.6mm. The plurality of retention hooks can be integral with the valve support assembly. The valve support assembly can include an anchor assembly that further includes the ventricular and atrial anchors and the central portion and an annular strut frame positioned radially within the anchor assembly. The plurality of retention hooks can be attached to the anchor assembly. The central portion can be configured to align with a native valve orifice, and the ventricular anchor and the atrial anchors can be configured to compress native cardiac tissue therebetween. The valve support assembly can include a plurality of diamond-shaped cells. Each of the retention hooks can extend from an apex of an interior diamond-shaped cell. A retention hook can extend from each apex in a circumferential line around the prosthetic mitral valve except at positions closest to leaflet attachment points.

[0023] In general, in one embodiment, a prosthetic mitral valve includes a valve support assembly, a plurality of leaflets secured to the valve support assembly, and a plurality of retention hooks. The valve support assembly includes a ventricular anchor, a central portion, and an atrial anchor. Each of the retention hooks is attached to the ventricular anchor and curves radially outwards to point in an atrial direction. Each retention hook has a ratio of radius of curvature to thickness of between 4:1 and 6:1 and points at an angle of 50°-80° relative to a central longitudinal axis of the prosthetic mitral valve.

[0024] This and other embodiments can include one or more of the following features. The angle can be approximately 65°. A radius of curvature of each of the plurality of retention hooks can be between 3-5mm. A thickness of each retention hooks can be between 0.8mm and 1.6mm. The plurality of retention hooks can be integral with the valve support assembly. The valve support assembly can include an anchor assembly that further includes the ventricular and atrial anchors and the central portion and an annular strut frame positioned radially within the anchor assembly. The plurality of retention hooks can be attached to the anchor assembly. The central portion can be configured to align with a native valve orifice, and the ventricular anchor and the atrial anchors can be configured to compress native cardiac tissue therebetween. The valve

support assembly can include a plurality of diamond-shaped cells. Each of the retention hooks can extend from an apex of an interior diamond-shaped cell. A retention hook can extend from each apex in a circumferential line around the prosthetic mitral valve except at positions closest to leaflet attachment points.

[0025] In general, in one embodiment, a replacement mitral valve includes a self-expandable valve support assembly that includes a ventricular anchor, a central portion, and an atrial anchor. The valve support assembly has a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion. The atrial anchor has a larger diameter than the ventricular anchor when the valve assembly is in the self-expanded configuration. The replacement mitral valve further includes a plurality of replacement leaflets secured to the valve assembly.

[0026] This and other embodiments can include one or more of the following features. The ventricular anchor can have outer diameter of less than 55mm. The atrial anchor can have diameter that is 3-10% larger than diameter of ventricular anchor. The valve support assembly can include an anchor assembly that includes the central portion and ventricular and atrial anchors. The valve support assembly can further include an annular strut frame positioned radially within the anchor assembly. The anchor assembly can be made of a plurality of diamond-shaped cells joined together. The valve support assembly can be configured to self-expand from a constrained configuration to an expanded configuration. The anchor assembly can be configured to foreshorten when transitioning from the constrained configuration to the expanded configuration. The anchor assembly can be configured to take on an hour-glass shape. Tips of the atrial anchor can point in a ventricular direction. The atrial and ventricular anchors can be configured to compress native cardiac tissue therebetween. The atrial anchor can include a plurality of atrial tips and the ventricular anchor can include a plurality of ventricular tips. There can be more ventricular tips than atrial tips.

[0027] In general, in one embodiment, a replacement mitral valve includes a valve support assembly that includes a ventricular anchor, a central portion, and an atrial anchor. The valve support assembly has a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion. The atrial anchor has a diameter that is 3-10% larger than a diameter of the ventricular anchor. The replacement mitral valve further includes a plurality of replacement leaflets secured to the valve assembly.

[0028] This and other embodiments can include one or more of the following features. The ventricular anchor can have outer diameter of less than 55mm. The valve support assembly can include an anchor assembly including the central portion and ventricular and atrial anchors. The valve support assembly can further include an annular strut frame positioned radially within the

anchor assembly. The anchor assembly can be made of a plurality of diamond-shaped cells joined together. The valve support assembly can be configured to self-expand from a constrained configuration to an expanded configuration. The anchor assembly can be configured to foreshorten when transitioning from the constrained configuration to the expanded configuration. The anchor assembly can be configured to take on an hour-glass shape. Tips of the atrial anchor can point in a ventricular direction. The atrial and ventricular anchors can be configured to compress native cardiac tissue therebetween. The atrial anchor can include a plurality of atrial tips and the ventricular anchor can include a plurality of ventricular tips. There can be more ventricular tips than atrial tips.

[0029] In general, in one embodiment, a prosthetic mitral valve includes an anchor assembly that includes a ventricular anchor, an atrial anchor, and a central portion therebetween. The anchor assembly is configured to compress native cardiac tissue between the ventricular anchor and the atrial anchor. An annular strut frame is disposed radially within the anchor assembly and attached thereto. The prosthetic mitral valve further includes a plurality of replacement leaflets secured to the annular strut frame. The anchor assembly and annular strut frame are configured to self expand from a collapsed configuration to an expanded configuration. The anchor assembly is configured to foreshorten along a central axis of the prosthetic mitral valve when expanding from the collapsed configuration to the expanded configuration. The annular strut frame is configured to be substantially nonforeshortening along the central axis when expanding from the collapsed configuration to the expanded configuration.

[0030] This and other embodiments can include one or more of the following features. The anchor assembly can include a plurality of diamond-shaped cells. The ventricular anchor can include a plurality of struts and v-shaped connecting members. The ventricular anchor and atrial anchors can flare radially outwards relative to the central portion when in the expanded configuration. The anchor assembly can be configured to foreshorten by 20-30% when self-expanding from the collapsed configuration to the expanded configuration.

[0031] In general, in one embodiment, a prosthetic mitral valve includes an anchor assembly that includes a ventricular anchor, an atrial anchor, and a central portion therebetween. The anchor assembly is configured to compress native cardiac tissue between the ventricular anchor and the atrial anchor. An annular strut frame is disposed radially within the anchor assembly such that the annular strut frame is spaced radially away from the central portion of the anchor assembly. The prosthetic mitral valve further includes a plurality of replacement leaflets secured to the annular strut frame.

[0032] This and other embodiments can include one or more of the following features. The annular strut frame can be spaced radially away from the central portion by 2-3mm. The annular

strut frame can be flared at an atrial end. Atrial tips of the annular strut frame can be attached to the anchor assembly. A portion of the anchor assembly can be pulled radially inwards relative to a remainder of the anchor assembly so as to attach to the annular strut frame.

[0033] In general, in one embodiment, a prosthetic mitral valve includes a valve assembly that includes a ventricular anchor, a central portion, and an atrial anchor. The anchor assembly is configured to expand from a collapsed configuration to an expanded configuration. The atrial anchor includes a plurality of atrial cells forming peaks and valleys around a circumference thereof, and the ventricular anchor includes a plurality of ventricular cells forming peaks and valleys around a circumference thereof. A plurality of replacement leaflets are secured to the valve assembly. A plurality of retention hooks are attached only to the ventricular anchor. Each of the plurality of retention hooks is positioned in a valley between the ventricular cells when the valve assembly is in the expanded configuration.

[0034] This and other embodiments can include one or more of the following features. The plurality of retention hooks can curve to point in the atrial direction when the anchor assembly is in the expanded configuration. The valve assembly can be configured to self-expand. The plurality of retention hooks can point at an angle of 50°-80° relative to a central longitudinal axis of the prosthetic mitral valve. The plurality of retention hooks can be positioned in every valley except valleys closest to leaflet attachment points.

[0035] In general, in one embodiment, a prosthetic mitral valve includes an anchor assembly that includes a ventricular anchor, a central portion, and an atrial anchor. The anchor assembly configured to expand from a collapsed configuration to an expanded configuration. The atrial anchor includes a plurality of atrial cells at an atrial edge of the atrial anchor, and the ventricular anchor includes a plurality of ventricular cells at a ventricular edge of the ventricular anchor. The number of ventricular cells is divisible by 2, and the number of atrial cells is divisible by 3. An annular strut frame is positioned within the anchor assembly and includes a plurality of struts connected by connection members. Three of the struts include commissure attachment points. The three commissure attachment points are spaced equally around a circumference of the annular strut frame. Three replacement leaflets are secured to the annular strut frame at the commissure attachment points.

[0036] This and other embodiments can include one or more of the following features. There can be 30 ventricular cells, 15 atrial cells, and 15 struts. There can be 24 ventricular cells, 12 atrial cells, and 12 struts. There can be more ventricular cells than atrial cells. The number of ventricular cells can also be divisible by 3.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] The novel features of the invention are set forth with particularity in the claims that follow. 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:

[0038] Figures 1A-1C show an exemplary mitral valve prosthesis. Figures 1A-1B show the mitral valve prosthesis in an expanded configuration. Figure 1C shows a portion of the expanded anchor assembly in 2D.

[0039] Figures 2A-2E show another exemplary mitral valve prosthesis. Figures 2A-2B show the mitral valve prosthesis in an expanded configuration. Figure 2C shows a portion of the expanded anchor assembly in 2D. Figure 2D shows the expanded annular strut frame. Figure 2E shows a 2D pattern (pre-expanded) for the strut frame.

[0040] Figure 3A-3C show another exemplary mitral valve prosthesis. Figures 3A-3B show the mitral valve prosthesis in an expanded configuration. Figure 3C shows the expanded annular strut frame.

[0041] Figures 4A-4C show another exemplary mitral valve prosthesis in an expanded configuration.

[0042] Figures 5A-5C show an exemplary nonforeshortening anchor assembly in the expanded configuration.

[0043] Figures 6A-6C show another exemplary nonforeshortening anchor assembly in the expanded configuration.

[0044] Figures 7A-7B show an exemplary anchor assembly before it is heat-set into an hour-glass shape.

[0045] Figures 8A-9G show another exemplary mitral valve prosthesis. Figures 8A-8C show the mitral valve prosthesis in the expanded configuration. Figures 8D-8E show the expanded anchor assembly. Figure 8F shows a portion of the expanded anchor assembly in 2D. Figure 8G shows a 2D pattern (pre-expanded) for the anchor assembly.

[0046] Figures 9A-9D show another exemplary nonforeshortening anchor assembly. Figures 9A-9C show the anchor assembly in the expanded configuration. Figure 9D shows a 2D pattern (pre-expanded) for the anchor assembly.

[0047] Figure 10 shows an exemplary valve assembly including the anchor assembly, strut frame, skirt, and leaflets.

[0048] Figures 11A-11E show one exemplary mechanism of attaching leaflets to the strut frame. Figure 11A shows an exemplary commissure plate. Figure 11B shows a cross-sectional

view of leaflets extending between the two commissure plates. FIG. 11C shows a valve assembly having a strut with a series of holes therein for attachment of leaflets to the valve assembly. Figure 11D shows a cross-sectional view of the leaflets and commissure plates attached to the strut. Figure 1E shows a close-up of a portion of the strut with holes therein.

[0049] Figure 12 shows another exemplary mechanism of attaching leaflets to the strut frame.

[0050] Figures 13A-13B show deployment of a ventricular anchor of an exemplary mitral valve prosthesis out of a sheath.

[0051] Figure 14 is a cross-section showing another exemplary mechanism of attaching leaflets.

[0052] Figure 15A-15C show another exemplary mechanism of attaching leaflets. Figure 15A shows a secondary member including a slot. Figure 15B is a cross-sectional view showing the leaflets passed through the slot of the secondary member and around a strut of the strut frame. Figure 15C shows alignment of the secondary member and the strut.

[0053] Figures 16A-16D show a holder including an exemplary mitral valve prosthesis with a skirt or covering.

[0054] Figures 17A-17J show an exemplary method of deploying a valve prostheses.

[0055] Figures 18A-18E show another exemplary mechanism of attaching leaflets to the strut frame. Figure 18A shows a plate attached to a valve assembly to attach the leaflets thereto. Figures 18B is a cross-sectional view showing the leaflets attached between the plate and a strut. Figure 18C is a top view of the exemplary mechanism. Figure 18D shows the plate positioned over two leaflets and a strut of the valve assembly. Figure 18E shows the plate attached to the strut frame.

[0056] Figure 19 shows a method of sewing leaflets around the circumference of the strut frame.

[0057] Figures 20A-20Q show another exemplary mitral valve prosthesis. Figure 20A shows the exemplary mitral valve prosthesis in the expanded configuration. Figures 20B-20C show the expanded prosthesis without the leaflets or skirt for clarity. Figures 20D-20G show the expanded anchor assembly. Figure 20H shows the atrial end of the expanded valve prosthesis. Figure 20I shows the ventricular end of the expanded valve prosthesis. Figure 20J is a 2D view of the (unexpanded) anchor assembly. Figure 20K shows the expanded strut frame. Figure 20L is a 2D view of the (unexpanded) strut frame. Figure 20M is a side view of the strut frame. Figure 20N is a top (atrial) view of the strut frame. Figure 20O is another view of the expanded anchor assembly. Figures 20P-20Q are additional view of the expanded prosthesis without the leaflets or skirt for clarity.

[0058] Figure 21 shows an exemplary leaflet for use with the mitral valve prostheses described herein.

[0059] Figure 22 shows the inflow edges of the leaflets sewn to the strut frame

[0060] Figures 23A-23C show an exemplary mitral valve prosthesis with a skirt covering thereon.

[0061] Figures 24A-24C show an exemplary mitral valve prosthesis with a first set of dimensions.

[0062] Figures 25A-25C show an exemplary mitral valve prosthesis with a second set of dimensions.

[0063] Figure 26 shows an exemplary mandrel for shaping a skirt.

[0064] Figures 27A-27Q show another exemplary method of attaching leaflets to a mitral valve prosthesis. Figure 27A shows a strut frame with a slot in the strut and a first suture positioned therearound. Figure 27B shows a second suture positioned therearound. Figure 27C shows a third suture positioned therearound. Figure 27D shows the alignment of leaflet protectors. Figure 27E shows the positioning of the leaflets such that they are flush with one another. Figures 27F-27H show placement of the leaflet arms through the slot in the strut frame. Figure 27I shows separation of the two leaflets to attach at additional commissure points. Figure 27J shows an inflow view of the leaflets after they have been attached at the commissure attachment points. Figure 27K shows an outflow view of the leaflets after they have been attached at the commissure attachment points. Figure 27L shows the arms of the leaflets wrapped around the strut frame. Figure 27M shows the leaflet protectors wrapped inside of the strut frame. Figure 27N shows alignment of the leaflet arms with the strut frame. Figure 27O shows placement of the plate over the strut frame. Figure 27P shows wrapping of two sutures around the plate. Figure 27Q shows wrapping of the final suture around the plate to attach the leaflets to the strut frame.

[0065] Figure 28 shows placement of an exemplary valve prosthesis in the native mitral valve orifice.

[0066] Figures 29A-29E show a mitral valve prosthesis with a delivery system attachment mechanism. Figure 29A shows the expanded valve assembly with pins therein. Figure 29B shows a close-up of a pin. Figure 29C shows slots in the skirt to allow for access to the pins. Figure 29D shows a 2D (unexpanded) view of the anchor assembly with pins. Figure 29E shows a close-up of a pin with dimensions.

[0067] Figure 30 shows another exemplary mitral valve prosthesis with a skirt thereon.

DETAILED DESCRIPTION

[0068] This disclosure includes replacement heart valves (also referred to herein as prosthetic heart valves), methods of manufacturing replacement heart valves, including subassemblies thereof, and methods of using replacement heart valves. This disclosure describes the prostheses in the context of replacement mitral valves, but it is conceivable that the prostheses herein can be used or modified to be used as other replacement heart valves. In some embodiments, the replacement heart valves are self-orienting replacement mitral valves configured to be delivered using minimally invasive techniques.

[0069] The replacement heart valves described herein include an anchor assembly that includes an atrial anchor (e.g., configured to be placed on an atrial side of a mitral valve annulus), a ventricular anchor (e.g., configured to be placed on a ventricular side of a mitral valve annulus), and a central portion positioned axially between the atrial and ventricular anchors. The anchor assembly is adapted to collapse to a delivery or collapsed configuration and expand to an expanded configuration. The replacement heart valves also include a strut frame secured to at least one of the central portion, the ventricular anchor, or the atrial anchor for attaching a plurality of replacement leaflets thereto. The strut frame can be configured to deform and collapse as the rest of the anchor assembly is collapsed. The struts of the strut frame extend towards and/or past the ventricular anchor.

[0070] The replacement heart valves described herein are configured to be secured in the native valve orifice by sandwiching the cardiac orifice between ventricular and atrial anchors, which are larger in diameter than the valve orifice, by applying an axial compressive force from the anchors, a radial force from the center portion outward against the cardiac orifice, and/or by using hooks or barbs that extend into the tissue of the orifice.

[0071] Further, the replacement heart valves described herein can be delivered to a cardiac valve orifice, such as the mitral valve, by using minimally invasive techniques to access the cardiac valve. In some embodiments, the mitral valve prostheses can be delivered through a transatrial route, i.e., by making a small incision in the patient's body and passing the prosthesis through the apex of the heart to, for example, the mitral valve. In other embodiments, the mitral valve prostheses can be delivered through the transseptal route, i.e., through the venous system and into the left atrium via a transseptal puncture. In both the transatrial and transseptal delivery methods, the distal-most anchor can be delivered to the ventricle while the proximal-most anchor can be delivered to the atrium.

[0072] Figures 1A-1C show an exemplary mitral valve prosthesis 100 in an expanded configuration. The portion of the replacement valve prosthesis 100 in Figure 1 may be referred to as a prosthesis subassembly, which includes an anchor assembly 101 and a strut frame 105,

but excludes leaflets and any skirts that may be incorporated into the final replacement valve. Anchor assembly 101 includes an atrial anchor 102, a ventricular anchor 104, and a central portion 103 therebetween. In this embodiment, atrial anchor 102 is configured and adapted to be disposed on an atrial side of a mitral valve orifice, and ventricular anchor 104 is configured and adapted to be disposed on a ventricle side of the mitral valve orifice. Further, the central portion 103 can be configured to be situated in the mitral valve orifice. In some embodiments, the central portion 103 has a diameter that is substantially the same size as the native mitral valve annulus (i.e., it is not designed to be larger than the annulus).

[0073] In some embodiments, the anchor assembly 101 and/or strut frame 105 can be made of wire, such as a shape memory metal wire (e.g., a nitinol). In other embodiments, the anchor assembly and/or strut frame can be laser cut from one or more tubes, such as a shape memory metal tube (e.g., nitinol). For example, the anchor assembly 101 can be laser cut from a first hypotube while the strut frame 105 can be laser cut from a second hypotube of smaller diameter. The anchor assembly 101 can be cut, for example, from a 9-12mm diameter tube, such as a 10mm tube, while the strut frame 105 can be cut, for example, from a 7-9mm diameter tube, such as an 8mm tube.

[0074] The valve prosthesis 100 can be configured to expand (e.g., self-expand) from a collapsed or constrained (delivery) configuration to an expanded (treatment) configuration. In the expanded configuration shown in Figures 1A-1B, the atrial anchor 102 and ventricular anchor 104 extend radially outward from central portion 103, and are considered to flare outward relative to central portion 103. The atrial anchor 102 and ventricular anchor 104 can also be considered flanged relative to central portion 103. The flared configuration of atrial and ventricular anchors 102 and 104 relative to central portion 103 is described in the context of a side view of the anchor assembly, as can be best seen in Figure 1B. In some embodiments, the flared configuration of the two anchors 102, 104 and the central portion 103 define a general hour-glass shape in a side view of the anchor assembly 101. That is, the anchors 102, 104 can be flared outwards relative to the central portion 103 and then curved or bent to point at least partially back in the axial direction. It should be understood, however, that an hour-glass configuration is not limited to symmetrical configuration.

[0075] The anchor assembly 101 can be configured to expand circumferentially and foreshorten axially as the valve prosthesis 100 expands from the collapsed delivery configuration to the expanded treatment configuration. For example, as shown in Figures 1A-1C, the anchor assembly 101 can be made of a plurality of cells 111 that are each configured to expand circumferentially and foreshorten axially upon expansion of the anchor assembly 101. As shown best in Figure 1C, the cells 111 can each be diamond-shaped. Further, the cells 111 can be

interconnected and configured such that every diamond apex 117 is connected to another diamond apex 117 except at the atrial or ventricular tips 112, 114 of the assembly 101. The anchor assembly 101 can include, for example, three circumferential rows of diamond cells 111. For example, the atrial anchor 102 can comprises one row of diamond-shaped cells 111 extending circumferentially, the central portion 103 can comprise one row of diamond-shaped cells 111 extending circumferentially, and the ventricular anchor 104 can comprise one row of diamond-shaped cells extending circumferentially 111.

[0076] The strut frame 105 can be configured to expand circumferentially, but maintain the same axial dimension (i.e., be non-foreshortening) as the valve prosthesis 100 expands from the collapsed delivery configuration to the expanded treatment configuration. By being non-foreshortening, the strut frame 105 can advantageously ensure that less strain is placed on the leaflets during delivery and/or packing. Thus, while the anchor assembly 101 is designed to be foreshortening, the strut frame 105 is designed so as to be substantially non-foreshortening. As can be best seen in Figure 1B, the strut frame 105 can include a plurality of longitudinally extending struts 151 and interconnecting v-shaped members 153. Further, in some embodiments, and again as shown in Figures 1A-1B, the strut frame 105 can have fewer v-shaped members 151 extending circumferentially around the diameter thereof than the cells 111 of the anchor assembly 101, such as half the number. Further, the strut frame 105 can flare at radially outwards at the atrial end, e.g., to conform to the flare of the atrial anchor 102.

[0077] The strut frame 105 and the anchor assembly 101 can be coupled together with coupling members, such as rivets. In some embodiments, and as shown in Figures 1A-1B, the atrial tips 129 of the strut frame 105 can be coupled to the atrial tips 112 of the anchor assembly 101. Where there are fewer v-shaped members 151 in the strut frame 105 than cells 111 in the anchor assembly 101 (as shown in Figure 1B), the strut frame 105 can attach to every other atrial tip 112 on the anchor assembly 101.

[0078] The radially inner surfaces of strut frame 105 can substantially define the perimeter of a central opening 106. Replacement leaflets, which are not shown in Figures 1A-1B for clarity, can be secured to the strut frame 105 and can be disposed at least partially in the central opening 106. The leaflets are configured to control blood flow therethrough.

[0079] In some embodiments, the valve 100 can include hooks 188 or barbs to help anchor the assembly in the mitral valve orifice. As shown in Figures 1A-1C, in one embodiment, the hooks 188 can be on the ventricular most tips 114 of the ventricular anchor 104.

[0080] Figures 2A-2E show another exemplary valve prosthesis 200. The valve prosthesis 200 is similar to valve prosthesis 100 and can include many of the same features as valve prosthesis 100, such as an anchor assembly 201 (having atrial anchor 202, a ventricular anchor

204, and a central portion 203) and a strut frame 205. In contrast to the prosthesis 100, the cells 211 of the anchor 201 are not connected together at every interior apex 217. Rather, the middle row of cells 211 can be disconnected at every other atrial apex 219 at the atrial side. As a result, there can be fewer atrial tips 212 than ventricular tips 214, and the atrial-most cells can be truncated or v-shaped (i.e., straddling each disconnected apex 219 and corresponding diamond-shaped cell). For example, there can be 15 atrial tips 212 (and 15 v-shaped cells 211 at the atrial end) and 30 ventricular tips 214 (and 30 diamond-shaped cells at the ventricular end). Advantageously, because the atrial tips 212 are larger/wider than the ventricular tips 214, the atrial tips 212 can be more flexible to allow the atrial anchor 202 to conform to the tissue. The atrial apexes 219 can be radially aligned with the atrial tips 212 and can be positioned approximately mid-way along the diamond-shaped cells at the atrial tips 212 along the central longitudinal axis (as noted above, the outermost cells can also be considered v-shaped, particularly in 2D, as the inner cell and apex 219 sit within the outer larger diamond, making it a v-shape).

[0081] In some embodiments, each of the atrial apexes 219 can have a rivet hole therein for connection to the atrial tips 229 of the strut frame 205. Further, in some embodiments (and as shown in Figures 2A and 2B), the atrial apexes 219 can all be bent slightly radially inwards towards the strut frame 205 (e.g., further radially inwards than the rest of the anchor assembly 201 so as to meet the strut frame 205). The atrial apexes 219 can be radially aligned with the atrial tips 212 of the atrial anchor 202. Further, the apexes 219, when bent radially inwards, can effectively act as an integrated suspension, holding the central portion 203 and ventricular anchor 204 radially outwards relative to, and spatially separated from, the strut frame 205. For example, the ventricular anchor 204 can be separated from the strut frame 205 by a radial distance of, for example, 1-15mm, such as 2-11mm, such as approximately 3mm. Further, the central portion 203 can be separated from the strut frame 205 by a radial distance of, for example, 2-3mm. This separation of the ventricular anchor 204 and/or the central portion 203 can advantageously isolate the leaflets from the anchor assembly 201 on the ventricular side where the greatest amount of distortion is placed on the anchor assembly 201.

[0082] Further, in this embodiment, the strut frame 205 and anchor assembly 201 can be attached at a central point of the atrial anchor 202 (i.e., at apexes 219) rather than at the outer-most or atrial-most tips 212 of the atrial anchor 202. By attaching the inner strut frame 205 to the anchor assembly 201 at a mid-point of the atrial anchor 202 rather than at the atrial tips 212, less torque or torsion is applied to the strut frame 205 as the atrial anchor 202 conforms to the tissue, thereby helping to ensure that the leaflets maintain their required position.

[0083] As shown best in Figures 2D and 2E, the strut frame 205 can include a plurality of struts 221 and v-shaped members 223 (so as to be substantially non-foreshortening as described with respect to strut frame 105). In this embodiment, there are four v-shaped members 223 extending axially between each pair of struts 221. The two ventricular-most v-shaped members 223 and the atrial-most v-shaped member 223 all point in the atrial direction. The last v-shaped member 223 points in the ventricular direction. Having a v-shaped member 223 that points in the ventricular direction can add to the stiffness of the strut frame 205. Additionally, having the last v-shaped member 223 point towards the atrium reduces the length of the struts and reduces the number of vertices that are pointed into the ventricle (to reduce trauma to the ventricle). The atrial tips 229 of the strut frame 205 can be formed by the vertex of the "V" shape. Each atrial tip 229 can include a rivet hole therein for connection to the anchor assembly 201. Further, the strut frame 205 can include a flare at the atrial end thereof to enable the strut frame to meet the apexes 219 and/or to conform to the flare of the atrial anchor 202. Further, in some embodiments (and as shown in Figure 2D), the flare at the atrial end of the strut frame 205 can include relatively flexible members 209 or zig-zag features therein. The flexible members 209 can be configured to allow the atrial flare to easily fold up during packing/delivery.

[0084] In some embodiments, the number of ventricular cells or ventricular tips 214 in valve 200 (or any valve described herein) can be divisible by both 2 and 3. For example, there can be 18, 24, or 30 ventricular cells or tips 214. Because the number of ventricular tips 214 is divisible by 2, there can be half as many atrial tips 212. Further, by having the number of cells divisible by 3, the three attachment points for the three leaflets (e.g., struts 221a,b,c) of the strut frame 205 can be even spaced around the circumference of the central opening 206. Increasing the number of ventricular tips/cells (e.g., from 18 cells to 30 cells) in any given design means that the total amount of required circumferential expansion of each individual cell decreases, thereby allowing the longitudinal lengths of the cells to be shorter, decreasing the overall length of the packed assembly (i.e., during delivery). In some embodiments, the cells have a length of between 4 and 6mm and a width of between 0.2 and 0.4mm when collapsed, e.g., before expansion. With these dimensions, the packed assembly can be, for example, 30-40mm, such as 32-35mm. Further, in some embodiments, the cell dimensions are chosen such that the ratio of width to length yields no more than 8-10% sheathing strain when the anchor assembly is retracted into the catheter for delivery.

[0085] Figures 3A-3C show another exemplary valve prosthesis 300. Valve prosthesis 300 is similar to valve prosthesis 200 (with anchor assembly 301 similar to assembly 201). The strut frame 305, however, includes reduced thickness members 310 in the atrial flare rather than flexible members 209. The reduced thickness members 310 can have a smaller diameter than the

rest of the strut frame 305. The reduced thickness members 310, similar to the flexible members 209, can allow for easier bending at the flare of the strut frame 305, thereby permitting easy packing.

[0086] Figures 4A-4C show another exemplary valve prosthesis 400. The valve 400 is similar to valves 100-300 except that the attachment point between the strut frame 405 and the anchor assembly 401 is at the ventricular end of the strut frame 405. To connect the anchor assembly 401 to the ventricular end of the strut frame 405, connecting members 494 extend from the anchor assembly 401 (e.g., from the central portion 403 or the ventricular anchor 404) to the ventricular tips of the strut frame 405. The connecting members 494 can be integral, for example, with the anchor assembly 401 and then riveted to the strut frame 405. In some embodiments, as shown in Figures 4A-4C, the connecting members 414 can be a single longitudinal member. In other embodiments, the connecting members 494 can be cells or tips 414 of the ventricular anchor 404 that are pulled radially inwards (e.g., every other tip 414 of the ventricular anchor 404 can be pulled inwards). Further, in some embodiments, an additional layer of cells can be coupled or riveted to the ventricular anchor 404 to tune the rigidity thereof. As shown in Figures 4A-4C, the atrial end of the strut frame 405 can still be flared at an angle, e.g., to substantially confirm to the flare of the atrial anchor 402 of the anchor assembly 401.

[0087] Figures 8A-8G show another exemplary valve prosthesis 800 including valve assembly 801 and strut frame 805. Valve prosthesis 800 is similar to valve prosthesis 200 except that valve prosthesis 800 has a greater curvature on the flare of the ventricular anchor 804, which can help improve retention force in some embodiments. For example, the ventricular anchor 804 can flare at an initial angle of 5°-15°, such as 10°, relative to a horizontal plane through the central portion 803 (and/or 75°-95°, such as 80°, relative to a central axis through the prosthesis 800). Additionally, the anchor assembly 801 includes a plurality of barbs or hooks 888 extending from the ventricular anchor 804. Positioning the hooks on the ventricular anchor 804 advantageously helps hold the prosthesis in place, as the ventricular side of the mitral valve undergoes the highest pressure. The hooks 888 are positioned in the valleys between the ventricular tips 814. Further, each hook 888, when the anchor assembly 801 is in the expanded configuration, is curved backwards to point at least partially in the atrial direction.

[0088] Figures 20A-20Q show another exemplary valve prosthesis 2000 including a valve assembly 2001 and a strut frame 2005. Prosthesis 2000 is similar to valve prosthesis 800 except that that the tips 2014 of the ventricular anchor 2004, after flaring radially outwards at the angle of 5-15° relative to the horizontal plane 2020, can curve away from the horizontal axis 2020 to point substantially in the axial (ventricular) direction, such as at an angle of 60-70°, such as 67° relative to the horizontal plane 2020. The curvatures of the two portions can be between 2mm

and 8mm, respectively. Similarly, the atrial anchor 2002 can extend at an initial angle of 20°-30°, such as approximately 26°, relative to the horizontal plane 2020 through the central portion 2003. The tips 2012 of the atrial cells can then curve away from the axis 2020 to point more in the axial (atrial) direction, such as at an angle of 60-70°, such as 67° relative to the horizontal plane 2020. The curvatures of the two portions can be between 2mm and 8mm, respectively. Further, the atrial apexes 2019 with the rivet holes therein can extend at an angle of approximately 50-70°, such as 60° relative to the axis 2020, to meet and affix to the strut frame 2050. Similarly, the atrial tips 2029 of the strut frame 2005 can flare out at approximately 70°-80° relative to the horizontal axis 2020 so as to substantially conform to the flare of the atrial apexes 2019. There can be 30 atrial cells along a single circumference and only 15 ventricular cells.

[0089] Further, as is best shown in Figures 20K-20N, the strut frame 2005 is different from the strut frame 805 in that the strut frame 2205 does not include flexible members (e.g., zig-zag features) in the flare at the atrial end of the strut frame 2005. Rather, the connecting member on the anchoring structure can be made more compliant. Like strut frame 205, the strut frame 2005 includes a plurality of struts 2021 and v-shaped member 2023 so as to be non-foreshortening. In strut frame 2005, however, there are five v-shaped members 2023 extending between each pair of struts 2021 rather than four. The extra v-shaped member 2023 is positioned proximate to the atrial-most v-shaped member 2023 and extends from the struts 2023 in the atrial direction. The extra v-shaped member can advantageously add circumferential strength to the strut frame 2005. The strut frame 2005 can further include one or more slots 2733 in the struts 2021 to allow for attachment of leaflets, as described below.

[0090] The anchor assembly 2001 also includes barbs or hooks 2088 that, similar to hooks 888, are positioned between the ventricular tips 2014 in the valleys and are curved backwards towards the atrial end. Further, in some embodiments, and as shown at Figures 20O-20Q, the hooks 2088 can be positioned between every ventricular cell 2011 (e.g., in the valleys) except those valleys closest to the commissure attachment points. At those points, one or more (such as three) of the hooks 2088 can be removed so as to prevent interference with the commissures and/or leaflets when the prosthesis is in the collapsed configuration.

[0091] In some embodiments, such as for the anchor assembly 2000, the atrial anchor 2002 can have a larger diameter than the ventricular anchor 2004. Having a larger atrial anchor 2002 than a ventricular anchor 2004 allows the anchors 2002, 2004 to grip tissue while preventing the ventricular anchor 2004 from impeding flow to the aortic valve. That is, as shown in Figure 28, if the ventricular anchor is too large, then the Left Ventricular Outflow Tract (LVOT) 2828 may be obstructed and restrict flow through the adjacent aortic valve 2829. In some embodiments,

for example, the atrial anchor 2002 can have a diameter that is 3-10% larger than the diameter of the ventricular anchor 2004. The ventricular anchor 2004 can thus be less than 55mm, such as less than or equal to 54mm, such as less than or equal to 52mm.

[0092] In some embodiments, the prostheses described herein can be made in a plurality of different sizes so as to fit within a range of native valve orifice sizes. For example, referring to Figures 24A-24C, in some embodiments, a valve prosthesis 2400 can have an atrial anchor 2402 with an outer diameter of 54mm, a ventricular anchor 2404 with an outer diameter of 52mm, and a central portion 2403 with an outer diameter of 36mm. Further, the strut frame 2405 can have an inner diameter of 27mm-30mm, such as approximately 29mm. A total height of the prosthesis 2400 can be, for example, 22-28mm, such as 26mm. In contrast, the valve prosthesis 2500 of Figures 25A-25C can have a larger diameter to fit within a larger native valve orifice. For example, the atrial anchor 2502 can have an outer diameter of 59mm, the ventricular anchor can have an outer diameter of 54mm, and the central portion 2503 can have an outer diameter of 40mm. The strut frame 2505, like the strut frame 2405, can have an inner diameter of 27mm-30mm, such as 29mm. To compensate for the increased diameter of the valve assembly 2501 relative to the strut frame 2505, the disconnected atrial apexes 2519 can be pulled further radially inwards (for example, the disconnected atrial apexes 2519 can be pulled downwards in an s-shape to reach further inwards). A total length of the expanded valve 2500 can be 28-29mm. Further, in order to maintain low packing strain, the sheathed or packed length of the valve 2500 can be longer than the packed length of the valve 2400. For example, the packed length of valve 2400 can be 32mm-35mm while the packed length of valve 2500 can be 34mm-37mm.

[0093] Anchor assemblies 101-401, 801, 2001, 2401, and 2501 all foreshorten upon expansion (due to their cellular design). For example, the anchor assemblies can foreshorten by 20%- 30%. In contrast, the corresponding strut frames 105-405, 805, 2005, 2405, and 2505 maintain substantially the same axial length.

[0094] In some embodiments, the prosthesis can be designed such that the entire prosthesis does not foreshorten during expansion. Having the prosthesis not foreshorten advantageously allows the packed length to be much shorter, such as less than 35mm, such than 30mm, or less than 25mm.

[0095] For example, FIGS. 5A-5C show an anchor assembly 501 that includes a plurality of struts 505 and circumferential v-shaped connectors 507 that do not substantially foreshorten upon expansion. The anchor assembly 501 forms a primarily hour-glass shape in the expanded configuration. Further, the atrial end includes flexible members 519 (e.g., zig-zag members) to aid in conforming to the native orifice.

[0096] Figures 6A-6C show another exemplary nonforeshortening anchor assembly 601 with a plurality of struts 605 and circumferential v-shaped connectors 607. In this embodiment, the ventricular anchor 604 is curled inwards at the tips to minimize interaction with the native ventricular anatomy.

[0097] Figures 9A-9D show another exemplary nonforeshortening anchor assembly 901 with a plurality of struts 905 and circumferential v-shaped connectors 907. In this embodiment, there are 5 v-shaped connectors 907 extending between each set of struts 905. The ventricular ends of the ventricular anchor 904, like ventricular anchor 604, curl in at the tips to minimize interaction with the native anatomy. Further, the struts 905 each include a flexible portion 929 (e.g., zig-zag or serpentine section) that extends from the atrial tips to the central portion 903. The flexible portions 929 aid in conforming the atrial anchor 902 to the native orifice. In this embodiment, the strut frame (which can be any strut frame described herein) can be configured to attached mid-way along the atrial anchor 902, such as rivet location 939. Advantageously, by attaching the strut frame at the atrial anchor (i.e., rather than the ventricular anchor), the strut frame can be less prone to distortion that can occur when the ventricular anchor is expanded during delivery.

[0098] Various hook or barb mechanisms can be used with any of the valves described herein. For example, the barb or hook can be riveted to the anchor assembly, can be laser cut from the assembly, and/ can be formed as part of a v-shaped feature of the anchor assembly. The hook or barb mechanisms can be designed such that they point radially outwards during deployment (i.e., not into the tissue) and do not engage with tissue until fully released, thereby preventing interference with the deployment. This can be achieved, for example, by using a hook having the proper radius of curvature to thickness ratio.

[0099] In some embodiments, the hooks can be on the ventricular most tips of the ventricular anchor, as shown in Figures 1A-1C. In other embodiments, the hooks can be in the valleys (i.e., between petals or tips, as shown in Figures 8A-8G and 20A-N). For example, the hooks can be placed in valleys on the ventricular anchor (e.g., from an apex of an interior diamond-shaped cell). When positioned between valleys on the ventricular anchor, the hooks can curve around and point in the atrial direction at an angle of 50°-80°, e.g., 60-65°, such as about 65° relative to the central axis of the device. This angle can advantageously allow the hooks to point in the atrial direction to dig into tissue. Further, each hook can have a ratio of radius of curvature to thickness of between 4:1 and 6:1. The radius of curvature can, for example, be between 3-4mm, and the thickness of the hook can be between 0.8mm and 1.6mm. For example, in one embodiment, the radius of curvature is 3.5mm and the thickness of the hook is between 0.8mm and 1.6mm.

[00100] In some embodiments, the hooks can be riveted to the anchor assembly. In other embodiments (as shown in Figures 7A-7B), the hooks can be tabs that are flared out from the anchor assembly.

[00101] In some embodiments, as shown in Figures 9A-9D, a portion of the anchor assembly 901 can include a portion that is pointed radially outwards to act as a hook or barb in the tissue. For example, one set of the v-shaped circumferential members 907 can be bent to point outwards. The bent v-shaped members can be positioned, for example, on the inner diameter of the ventricular anchor 904 pointing towards the atrium.

[00102] Any of the valve prostheses described herein can include a fabric cover and/or skirt on one or more portions of the device. For example, referring to Figures 16A-16D (valve is shown in a holder for clarity), a covering or skirt 1616 can be sewn along the inner diameter of the atrial anchor 1616 and the flare of the strut frame 1605 and down the entire inner diameter of the strut frame 1605. This skirt 1616 can thus provide a smooth entrance for blood into the leaflets 1622. Further, the skirt 1616 can extend along the entire outer diameter of the anchoring assembly and then around the tips of the ventricular anchor 1604. In some embodiments, the skirt 1616 can be a single piece while in other embodiments, the skirt 1616 can be made of a plurality of pieces.

[00103] In some embodiments, as shown in Figure 20A, the skirt 2016 can leave the ventricular tips of the ventricular anchor 2004 uncovered. In other embodiments, as shown in Figure 30, the skirt 3006 can be wrapped fully around the ventricular tips of the ventricular anchor 3004.

[00104] In some embodiments, the skirt, or a portion of the skirt, can be knit in a three-dimensional shape, e.g., an hour glass shape, to help maintain a consistent seal of the skirt against the prosthesis and to help pack the skirt-covered prosthesis during delivery. For example, as shown in Figures 23A-23C, the skirt 2316 can be cut in an hour-glass shape and configured to cover all of the exposed sections of the valve on the atrial side (leaving only the ventricular side of the ventricular anchor and the outer diameter of the strut frame uncovered).

[00105] Referring to Figure 26, if a skirt is knit or otherwise formed in a three-dimensional shape, an inner mandrel 2626 can be used (i.e., the skirt can be knit or formed over the mandrel). After the skirt has been formed around the mandrel 2626, the mandrel 2626 can dissolve or otherwise break apart to leave the formed skirt. In some embodiments, a woven fabric, such as a polyester weave, can be used to form the skirt over the mandrel 2626. In other embodiments, a polyurethane layer can be painted or otherwise applied over the mandrel 2626. The polyurethane can advantageously create fewer wrinkles than a woven fabric. If a polyurethane layer is used, a

flap of material may be added in order to create some give in the skirt as the valve is packed and/or unpacked.

[00106] Further, in some embodiments, and as shown in Figures 23A-23C, the skirt 2316 can be cut in a saw-tooth pattern on the ventricular side to mimic the pattern of cells that extend to the outermost diameter of the ventricular anchor. Cutting the skirt in such a manner can help pack the ventricular anchor into the delivery device by reducing the packed diameter of the ventricular anchor.

[00107] The skirt can advantageously help block blood flow from one side of the valve over the other. The skirt can also help prevent the anatomy from having an adverse interaction with the frame itself.

[00108] In some embodiments, a coupler can be used to connect the strut frame to the anchor assembly. Rivets herein are an example of a coupler. The locations where components are secured to one another may be referred to as a coupling herein. Coupling also refers to the two components that are secured together. Riveting as used herein is an example of a method that plastically deforms a coupler to secure two or more components together at a coupling. Coupling and rivets are described further in U.S. Patent Application No. 14/677,334, filed April 2, 2015, titled "REPLACEMENT CARDIAC VALVES AND METHODS OF USE AND MANUFACTURE," the entire contents of which are incorporated by reference herein.

[00109] In some embodiments, the valve prostheses have been shown without leaflets for clarity. It is to be understood that each of the embodiments described herein can include replacement leaflets 1022a,b,c attached thereto, as shown in Figure 10. An exemplary leaflet 2122 is shown in Figure 21. The leaflet can include an outflow (or free) edge 2191 configured to float within the strut frame, an inflow edge 2193 configured to be sewn to the strut frame, and two arms 2195a,b. A plurality of sewing holes 2197 can provide for sewing of the leaflet 2122 to the strut frame. Thus, as shown in Figure 19, the outer circumference of the leaflets at the inflow edges can be sewn to the strut frame and/or to the skirt covering the skirt frame. That is, while the commissures or edges of the leaflets can be attached as described above, the inflow edges of the leaflets can be sewn all around the circumference of the strut frame.

[00110] Further, the leaflets can be attached to any of the valve prosthesis designs in a variety of different ways.

[00111] For example, referring to Figures 11A-11F, two commissure plates 1010a,b can be used to sandwich the arms of the leaflets 1022a,b therebetween. The leaflets 1022a,b can then be sewn together (and to the plates 1010a,b) with one or more suture 1011 through holes 1013a,bc. After being sewn together, the joined leaflets and commissure plates can then be attached to the strut frame 1105 through, for example, a series of holes 1113a,b,c in one of the struts 1121 using

a suture 1017 (which can be the same or different than suture 1011). The commissure plates 1010a,b can be made, for example, of stainless steel or plastic. Advantageously, the commissure plates 1010a,b can apply compression to the leaflets 1022a,b and distribute strains along the length of the commissure plates, thereby reducing tearing or strain propagation through the tissue.

[00112] Another exemplary mechanism for leaflet attachment is shown in Figure 12. Here, rather than using two commissure plates, a single u-shaped plate 1110 with a set of holes on either side can be used. In contrast to the commissure plates 1010a,b, the plate 1110 can place a fixed amount of compression on the leaflets that are sandwiched therebetween.

[00113] Additional exemplary mechanisms for leaflet attachment are shown in Figures 14 and 15A-15C. In the version of Figure 14, the arms of two leaflets 1022a,b are pulled through a slot 1333 that is part of a strut 1321 of the strut frame. A secondary member 1313 having a width greater than the width of the slot 1313 is placed against both arms leaflets, and then the arms of the leaflets 1022a,b are wrapped around the secondary member 11313 and attached together with a suture 1311 or staple. The secondary member 1313 can be coupled to the strut frame, for example with a rivet. In a similar embodiment, shown in Figures 15A-15C, the leaflets 1022a,b can be passed through a slot in a secondary member 1515 and then wrapped around a strut 1521 of the strut frame. Advantageously, the mechanisms of Figures 14 and 15A-C evenly distribute high stress areas of leaflet along the length of strut 1312 or riveted slot 1321. The load distribution along the given length of these members decrease stresses in comparison to attachment methods where many stress concentrations are created i.e. sutures.

[00114] Another exemplary mechanism for leaflet attachment is shown in Figures 18A-18E. In this embodiment, a plate 1818 including a plurality of holes 1819 can be positioned on the outside of the strut frame 1805. Further, the strut frame 1805 can include a slot 1833 therethrough. The arms of the leaflets 1822a,b can then be extended through the slot 1833 and flattened against the outer surface of the strut frame 1805. The plate 1818 can be placed against the arms of the leaflets 1822a,b and then sutured to the arms of the leaflets, e.g., through the holes 1819. The arms of the leaflets 1822a,b can thus be sandwiched between the plate 1818 and the strut frame 1805. In some embodiments, the suture is attached to a skirt or fabric layer on the strut frame 1805 rather than directly to the strut frame.

[00115] Another exemplary mechanism for leaflet attachment is shown in Figures 27A-27R. In this embodiment, a plate 2727 with a plurality of channels 2773 (or open slots or indents) in the sides thereof can be positioned on the outside of the strut frame 2705. The channels 2773 can extend diagonally towards the center of the plate 2727. There can be two or more channels 2773, such as between 6 and 12 channels 2773, such as ten channels 2773. Further, the frame

2705 can include three slots 2733 therethrough (one for each attachment point) that are positioned equidistant from one another around the circumference of the strut frame 2705. The slots 2733 can be positioned within a strut 2721 at the ventricular end. To attach the leaflets 2722a,b to the frame 2705, a first suture 2772a can first be threaded between the frame 2705 and skirt 2716 fabric and around the slot 2733. The first suture 2772a can then be slid distally towards the ventricular tips 2777 of the strut frame 2705 (Figure 27A). At Figure 27B, a second suture 2772b is threaded similarly to the first suture 2772a. At Figure 27C, a third suture 2772c is pierced through the fabric just distal to the slot 2733 from the outside and back, wrapping the third suture 2772c around the frame 2705. At Figure 27D, two leaflets 2722a,b can be aligned, and leaflet protectors 2773 (e.g., made of a lubricious fabric, such as a polyester weave) can be placed along the outward-facing side of each arm 2795a,b of the leaflets 1022a,b. At Figure 27E, the arms 2795a,b and leaflet protectors 2773a,b of the leaflets 1022a,b can remain flush. As shown in Figures 27G-I, the leaflet arms 2795a,b can be slid through the slot 2733. As shown in Figure 27F, the arms 2795a,b can be positioned at approximately a 90 degree angle relative to the slot 2733. As shown at Figure 27G, each arm 2795a,b can be slid through the slot 2733 until the beginning of the bump 2778 on the arm 2795a,b is flush with the inside of the slot 2733 (to do so, the inflow edges 2793 can be folded inward towards one another and the central axis. At Figure 27H, the arms 2795a,b can be at approximately 90 degrees relative to the slot 2733 after being pulled therethrough. At Figure 27I, the two leaflets 2722a,b can be separated, and, at Figures 27J and 27K, the process can be repeated for each of the other slots and attachment points (e.g., two additional slots/leaflet attachment points). As shown at Figures 27L and 27M, the leaflet arms 2795a,b can be folded away from one another, and the leaflet protectors 2773a,b can be folded away from one another. As shown at Figure 27N, the edges of each arm 2795a,b can be placed horizontal to the outflow plane and the side/vertical edges can be parallel with the strut members 2721. At Figure 27O, the plate 2727 can be placed onto the leaflet arms and aligned with the slot 2733. The vertical edges 2761 of the retaining plate 2727 can be aligned parallel with the vertical strut members 2721. The top 2762 of the retaining plate 2727 can be aligned with the outflow tips 2777 of the strut frame 2705. The center of the retaining plate 2727 can be aligned with the center of the slot 2733. At Figure 27P, the first suture 2772a can be wound around the top set of indents 2773a,b in the plate 2727 and the third suture 2772c can be wound around the bottom set of indents 2773i,j. At Figure 27Q, the second suture 2772b can be woven around the plate 2727 into the remaining indents 2773c-h in a crisscross pattern (dotted lines represent suture on the backside of the plate 2727). The process can be repeated at each of the commissure attachment points. The sutures can advantageously help prevent translation of the plate 2727 relative to the slot 2733 and frame 2705. Further, the

plate 2727 and slot 2733 can advantageously securely attach the leaflets 2722 to the frame 2705 without damaging the frame 2705, leaflets 2722a,b, and/or skirt 2716.

[00116] In some embodiments, referring to Figure 22, once the arms of the leaflets 2222 are attached to the strut frame 2205, the inflow edges can be sewn to the strut frame 2205. An exemplary sewing line 2525 (close to the rivets 2527 at the atrial end of the strut frame 2205) is shown in Figure 22.

[00117] In some embodiments, a valve prosthesis as described herein can include a delivery system attachment mechanism. For example, as shown in Figures 2A-2B, the atrial tips 212 can each have a pin 215 extending therefrom (e.g., in the ventricular direction) around which tethers from a delivery system can be wound.

[00118] Another delivery system attachment mechanism is shown in Figures 29A-29E. The atrial tips 2912 each have a pin 2915 extending therefrom (e.g., in the ventricular direction). Each pin can be, for example, 0.030 inches long and approximately 0.012 inches thick. Further, as shown in Figure 29E, the skirt 2916 can have slots 2985 therein that are aligned with the pins 2915. The slots 2985 can allow for the passage of the tethers therethrough (i.e., to provide access to the pins 2195).

[00119] An exemplary method of delivering a valve prosthesis 1700 (which can be any of the valves prostheses described herein) after attachment to the tethers of the delivery system is shown in Figures 17A-17J. At Figures 17A and 17B, the valve is packed inside of a sheath such that the tips of the ventricular anchor 1704 point towards the ventricular end (i.e., away from the central portion 1703) and the tips of the atrial anchor 1702 point towards the atrial end (i.e., away from the central portion 1703). The valve 1700 can be delivered, e.g., transseptally, to the native annulus in this packed positioned. At Figures 17C-E, the ventricular anchor 1704 is partially deployed, i.e., to allow the ventricular anchor 1704 to begin to flare outwards. In this embodiments, barbs on the device point radially outwards rather than towards the atrium during the initial deployment steps. At Figures 17F and G, the valve is pulled 1-3cm towards the atrium to seat the ventricular anchor 1704 on the ventricular side of the annulus. At Figure 17H, the ventricular anchor 1704 is fully deployed, allowing the barbs to extend into the tissue. At this point, the strut frame 1705 (holding leaflets) is also fully exposed. At Figure 17I, the atrial anchor 1702 is partially released to allow the anchor 1702 to drop against the wall of the atrium. At Figure 17J, the atrial anchor 1702 is fully released, and the valve 1700 is seated in place.

[00120] The valve prostheses described herein can advantageously pack to a very low packing length, such as less than 4cm, less than 3.8cm, less than 3.6cm, less than 3.2cm, or less than 3.0cm for delivery with a 32 French catheter. This low axial packing length advantageously

allows the prostheses to be delivered transseptally, e.g., be easily maneuvered around the bend through the septum.

[00121] Further, the cells and/or v-shaped patterns of the valve prostheses described herein can be specifically designed so as to ensure that the ventricular side doesn't flare out when delivered. For example, by making the atrial anchor flexible (e.g., with flexible members), the ventricular anchor is less likely to hook around when delivered. As another example, the radius of the valve (the anchor or the strut frame) can be tuned and/or the valve can be made more flexible in specific areas (of the anchor or the strut frame) so as to ensure that the valve is less prone to hooking/flaring out when delivered. That is, referring to Figures 13A and 13B, in one embodiment, a change in the radius of curvature in region 1401 will yield a change in the deployment angle ø of the ventricular anchor in region 1402. Decreasing the curvature in region 1401 will make the frame less prone to wrapping around the catheter tip when the ventricular anchor is exposed from the catheter. In another embodiment, by making region 1401 flexible, but leaving the remaining portions of the ventricular and atrial anchors relatively stiff, the deployment angle ø in region 1402 is less prone to wrapping around the catheter tip when the ventricular anchor is exposed from the catheter tip.

[00122] The valve prostheses described herein can advantageously avoid interference with blood flow through the valve. For example, the skirting and shape of the nitinol on the inflow (or atrial) portion of the valve can be contoured to provide smooth approach to the valve orifice. This helps decrease the risk of any turbulent flow or pockets of stagnant blood. As another example, the attachment point between the inner strut and the outer frame can be adjusted longitudinally to change the relative obstruction of the inner strut with blood flow and the ventricular sub-valvular apparatus. As yet another example, the skirting can be selectively applied to areas only in which there is a risk of blood escaping between the prosthesis and the anatomy. By allowing some cells to be open, particularly on the ventricular anchoring member, there is less impedance to flow.

[00123] Any of the valve features or structural details of any device embodiment described herein can be incorporated or combined with any of the other embodiments herein. For example, the central members described herein are not limited in use with the anchor assemblies and strut frames in the specific embodiment, but can be replaced with any of the features described in any other embodiment.

[00124] In use, when the devices described herein can be used as mitral valve replacements. In some embodiments, when the replacement heart valve has been delivered near the mitral valve, the ventricular anchor can be deployed first in a cardiac chamber, such as the ventricle, and retracted to a seated position against the valve orifice, such as the mitral valve orifice. Then

the center portion and atrial anchor portion may be deployed in another cardiac chamber, such as the atrium, wherein the expansion and reconfiguration of the atrial anchor and the central portion sandwiches the valve orifice securely between the anchors that have been deployed on either side of the annulus. Other exemplary aspects of the methods of delivery described in U.S. Pat. No. 8,870,948, issued October 28, 2014, in International Patent Application No. PCT/US2016/032546, filed May 13, 2016, titled "CARDIAC VALVE DELIVERY DEVICES AND SYSTEMS," and in U.S. Provisional Patent Application Nos. 62/424,021 and 62/424,051, both filed November 18, 2016 and titled "CARDIAC VALVE DELIVERY DEVICES AND SYSTEMS" all of which are incorporated by reference in their entireties.

[00125] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[00126] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[00127] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or

operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[00128] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[00129] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[00130] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical range recited herein is intended to include all sub-ranges subsumed therein.

[00131] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various

device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[00132] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

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CLAIMS

1. A prosthetic mitral valve comprising:

an anchor assembly comprising a ventricular anchor, an atrial anchor, and a central portion therebetween, the anchor assembly having an expanded configuration in which the ventricular anchor and the atrial anchor flare radially outwards relative to the central portion, further wherein the atrial anchor includes a plurality of atrial cells and the ventricular anchor includes a plurality of ventricular cells;

an annular strut frame disposed radially within the anchor assembly, wherein a first plurality of the atrial cells are positioned radially inwards relative to a second plurality of the atrial cells such that the first plurality of the atrial cells and the second plurality of the atrial cells radially overlap, and wherein the first plurality of atrial cells attach the annular strut frame to the anchor assembly; and

a plurality of replacement leaflets secured to the annular strut frame.

2. The prosthetic mitral valve of claim 1, wherein an atrial end of the strut frame is attached to the anchor assembly.

3. The prosthetic mitral valve of claim 1, wherein atrial tips of the strut frame are attached to the anchor assembly.

4. The prosthetic mitral valve of claim 1, wherein an atrial end of the strut frame is flared radially outwards.

5. The prosthetic mitral valve of claim 4, wherein a flare of the strut frame is configured to substantially conform to a flare of the atrial anchor.

6. The prosthetic mitral valve of claim 1, wherein a ventricular end of the strut frame is spaced away from the anchor assembly.

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7. The prosthetic mitral valve of claim 6, wherein the ventricular end of the strut frame is spaced away from the anchor assembly by a radial distance of 1-15mm.

8. The prosthetic mitral valve of claim 1, wherein the anchor assembly and the strut frame are configured to self-expand from a constrained configuration to the expanded configuration.

9. The prosthetic mitral valve of claim 1, wherein the strut frame is attached to the anchor assembly with a plurality of rivets.

10. The prosthetic mitral valve of claim 9, wherein the first plurality of atrial cells end in apexes that are attached to the strut frame and are radially aligned with outer-most tips of the second plurality of atrial cells.

11. The prosthetic mitral valve of claim 1, wherein the anchor assembly comprises a plurality of diamond-shaped cells.

12. The prosthetic mitral valve of claim 1, wherein the strut frame includes a plurality of linear struts and v-shaped connectors therebetween.

13. The prosthetic mitral valve of claim 1, wherein the anchor assembly forms a substantially hour-glass shape.

14. A prosthetic mitral valve comprising:

an anchor assembly comprising a ventricular anchor, an atrial anchor, and a central portion therebetween, the anchor assembly having an expanded configuration in which the ventricular anchor and the atrial anchor flare radially outwards relative to the central portion, further wherein the atrial anchor includes a plurality of atrial cells;

an annular strut frame disposed radially within the anchor assembly, wherein a first plurality of the atrial cells are interior apexes and a second plurality of atrial cells are outermost atrial cells, the first plurality of the atrial cells positioned radially inwards relative to the second plurality of the atrial cells such that the first plurality of the atrial cells and the second plurality of

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the atrial cells radially overlap, and wherein the interior apexes of the first plurality of atrial cells attach the annular strut frame to the anchor assembly; and

a plurality of replacement leaflets secured to the annular strut frame.

15. The prosthetic mitral valve of claim 14, wherein an atrial end of the strut frame is attached to the anchor assembly.

16. The prosthetic mitral valve of claim 14, wherein atrial tips of the strut frame are attached to the anchor assembly.

17. The prosthetic mitral valve of claim 14, wherein an atrial end of the strut frame is flared radially outwards.

18. The prosthetic mitral valve of claim 17, wherein a flare of the strut frame is configured to substantially conform to a flare of the atrial anchor.

19. The prosthetic mitral valve of claim 14, wherein a ventricular end of the strut frame is spaced away from the anchor assembly.

20. The prosthetic mitral valve of claim 19, wherein the ventricular end of the strut frame is spaced away from the anchor assembly by a radial distance of 1-15mm.

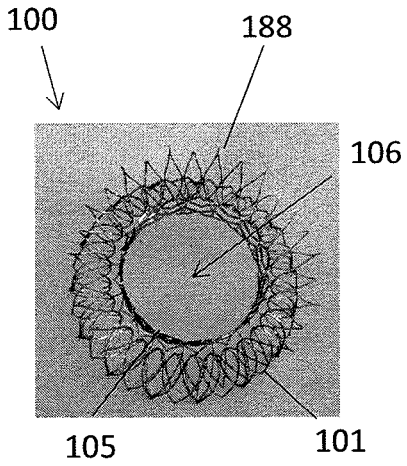


FIG. 1A

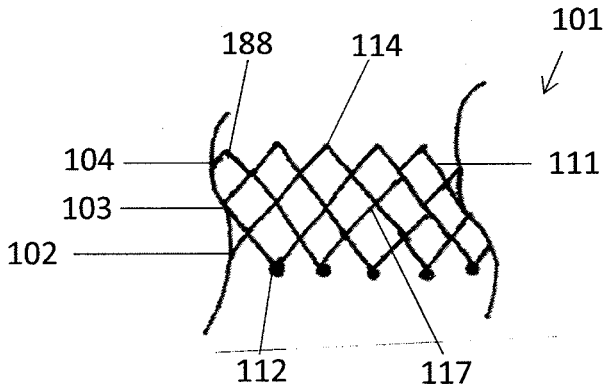


FIG. 1C

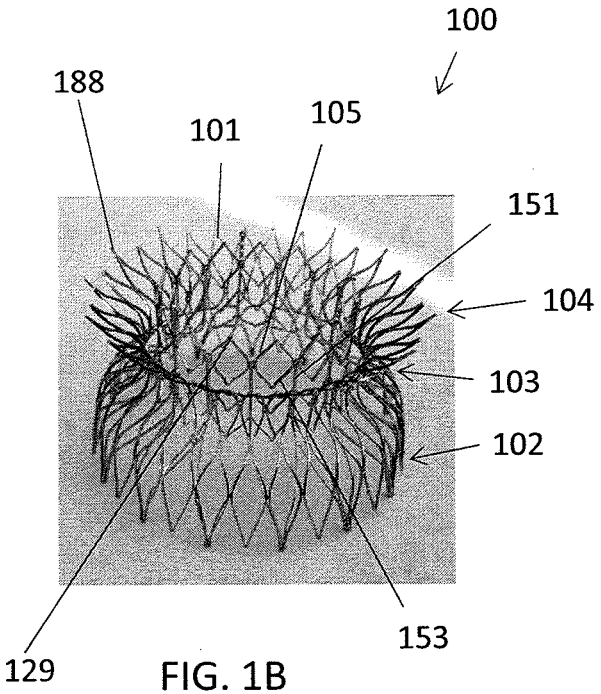


FIG. 1B

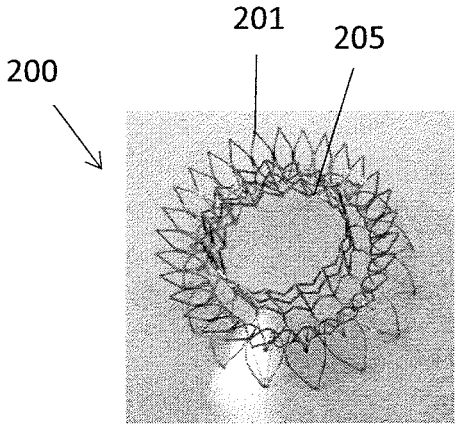


FIG. 2A

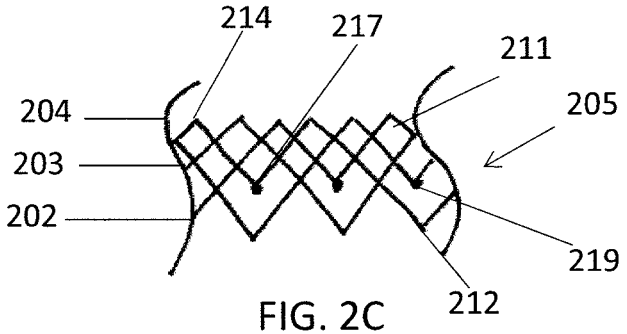


FIG. 2C

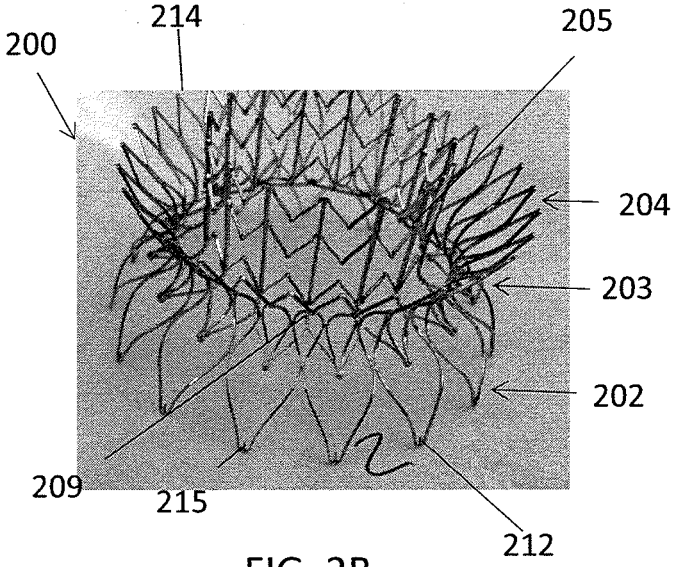


FIG. 2B

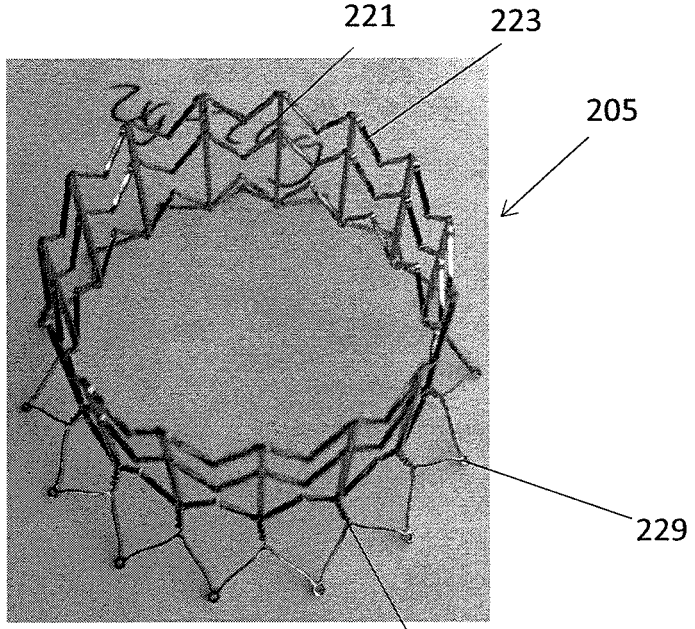


FIG. 2D

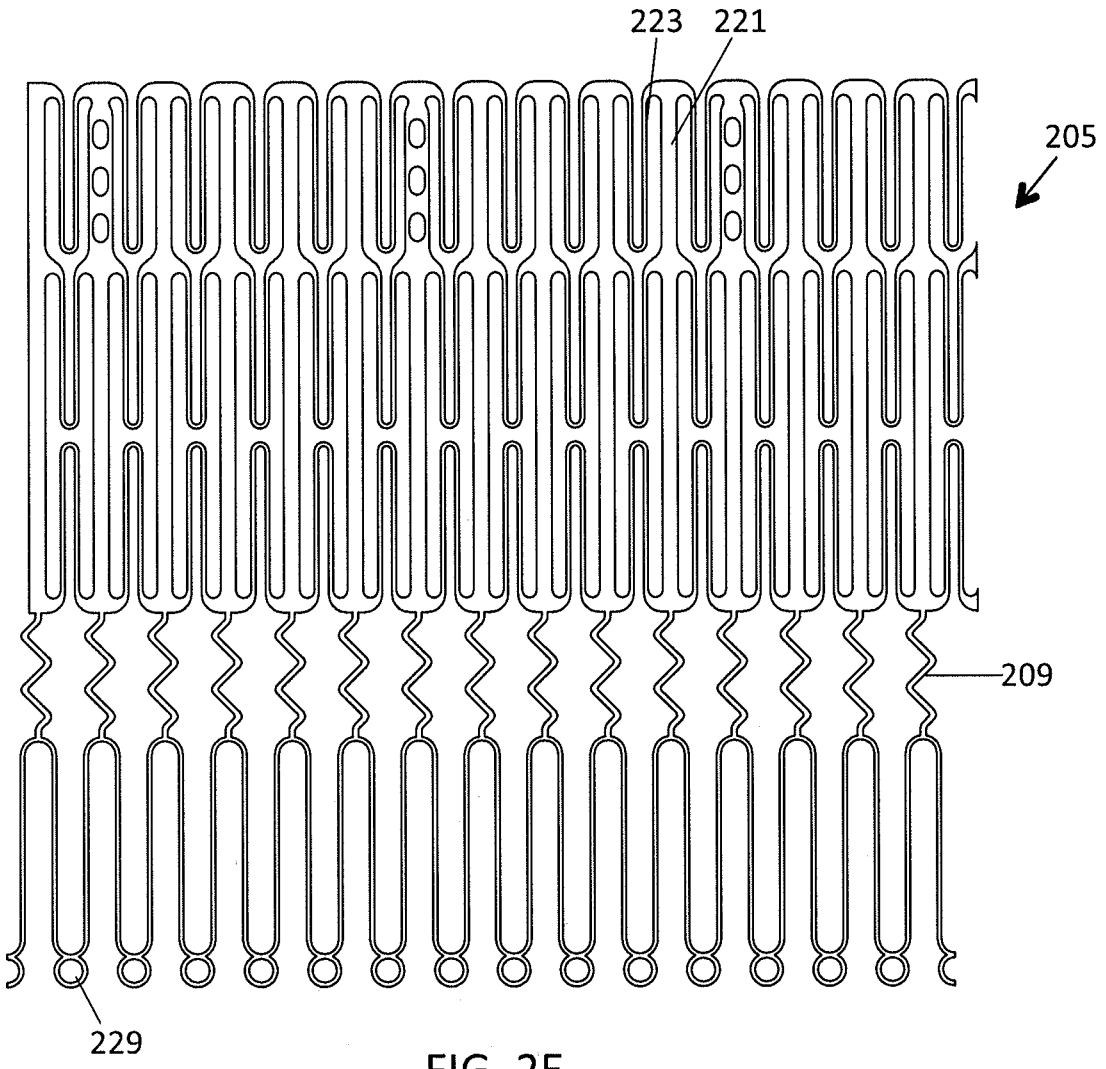


FIG. 2E

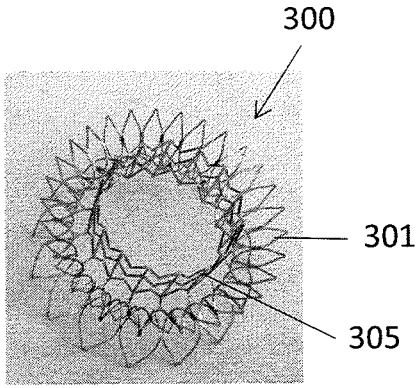


FIG. 3A

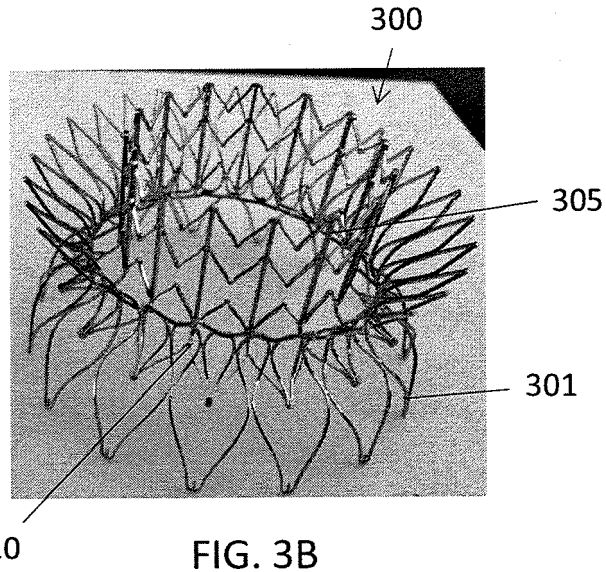


FIG. 3B

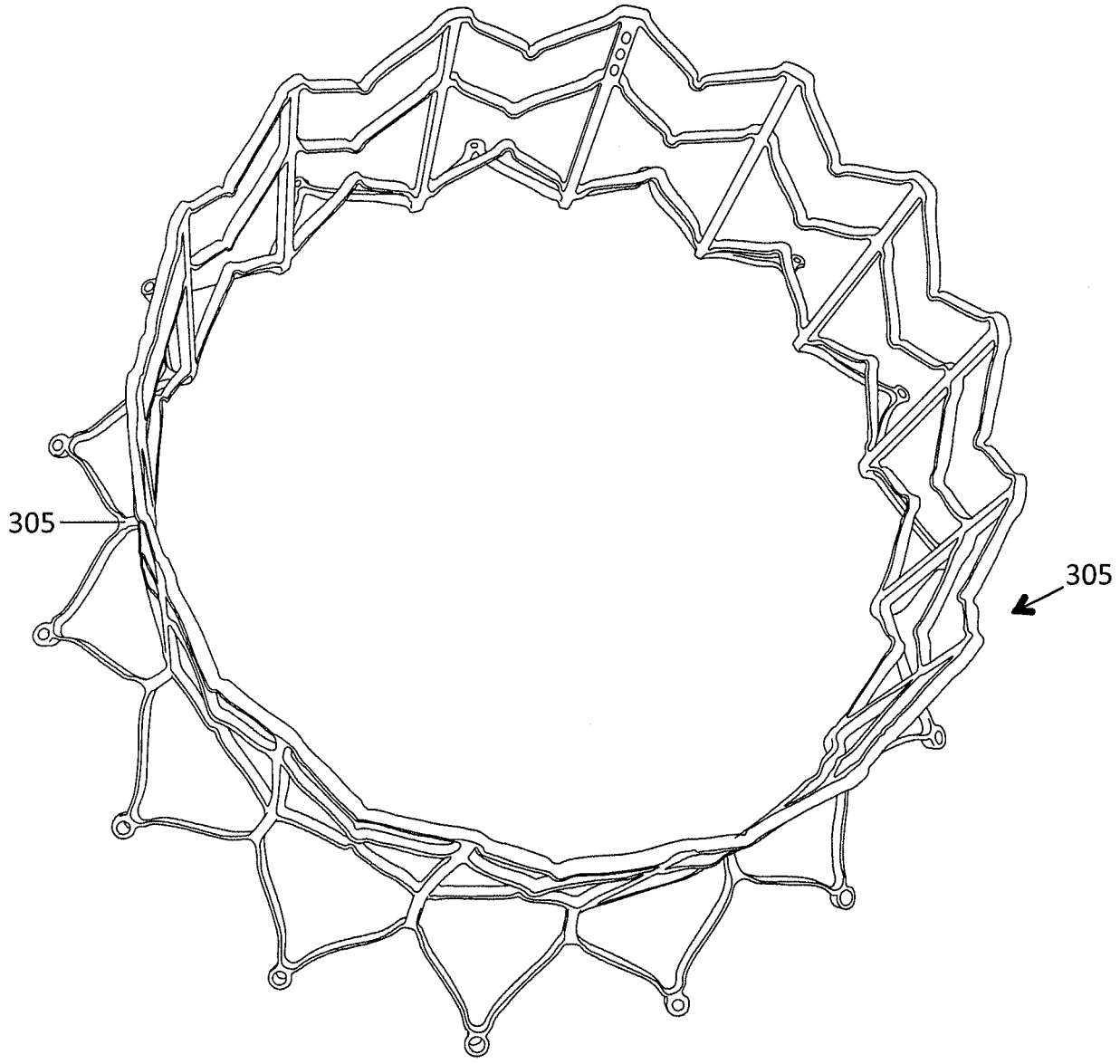


FIG. 3C

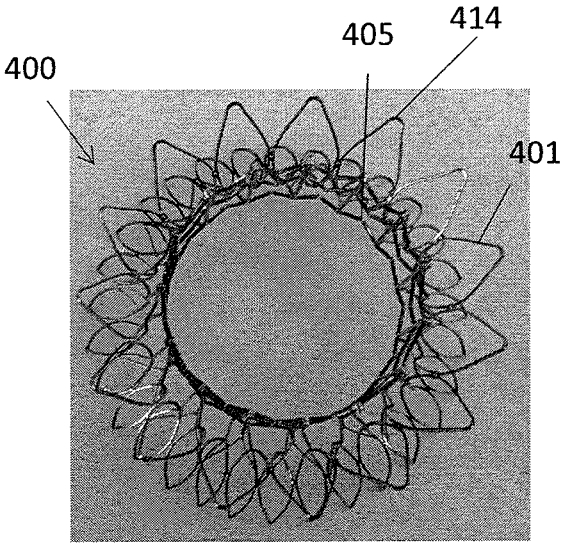


FIG. 4A

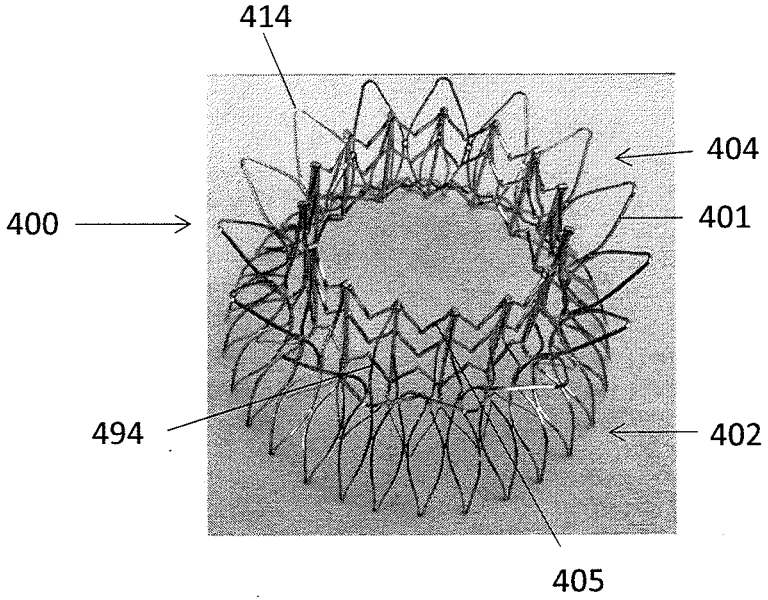


FIG. 4B

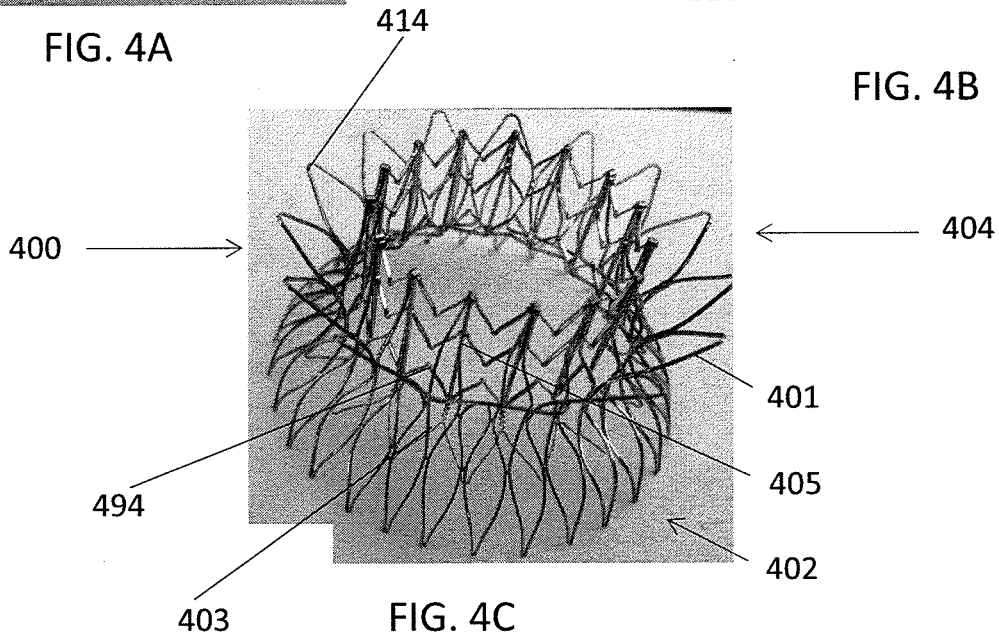


FIG. 4C

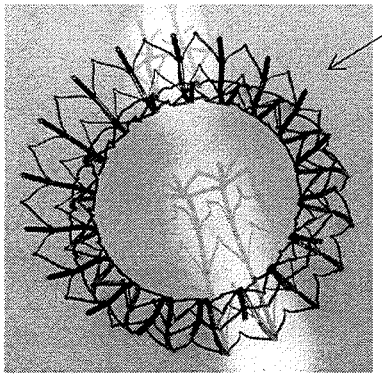


FIG. 5A

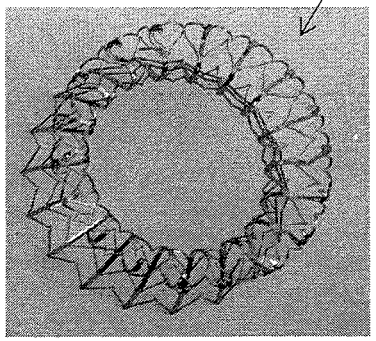


FIG. 6A

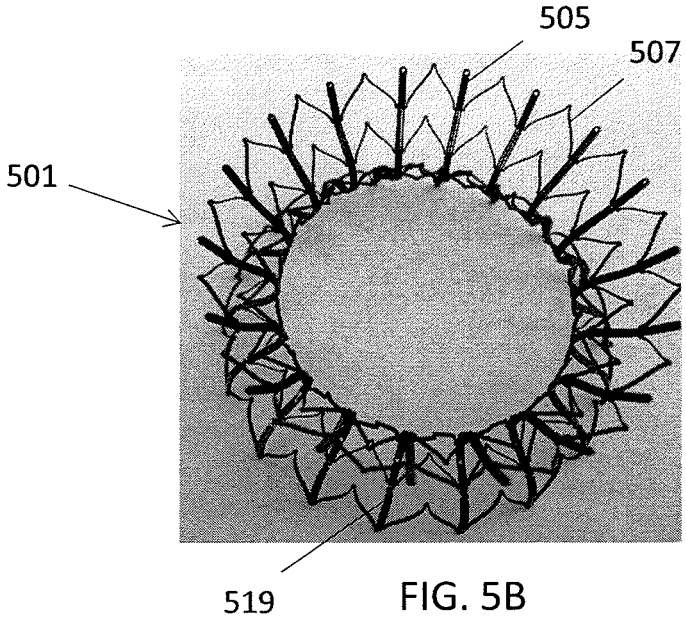


FIG. 5B

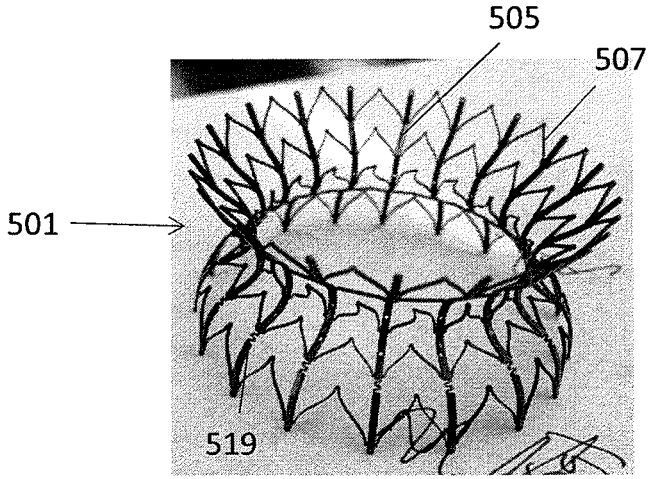


FIG. 5C

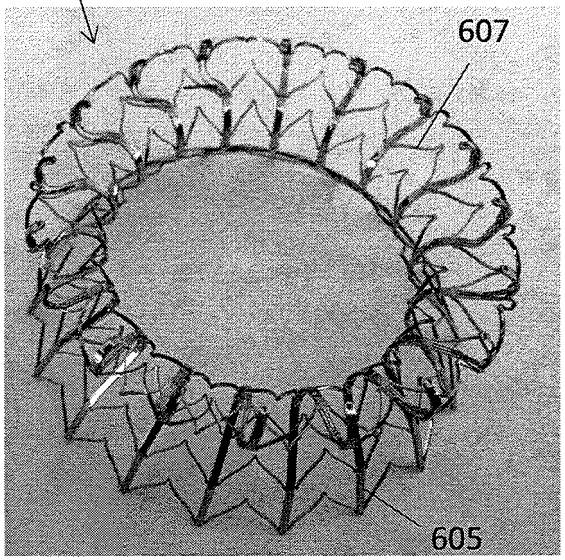


FIG. 6B

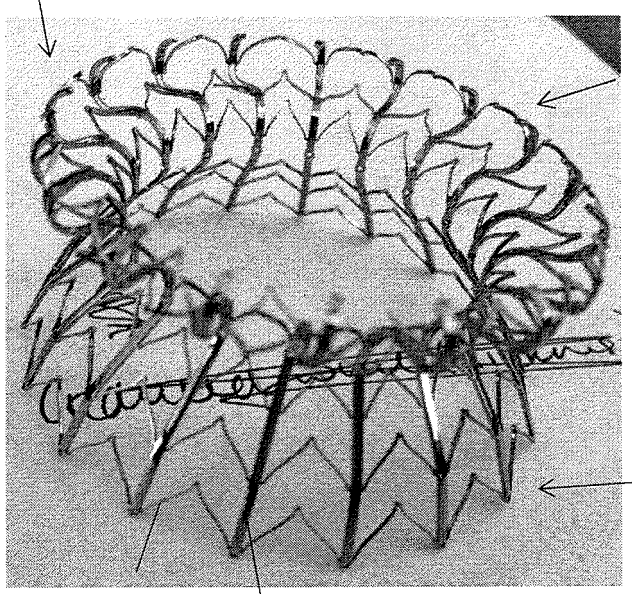


FIG. 6C

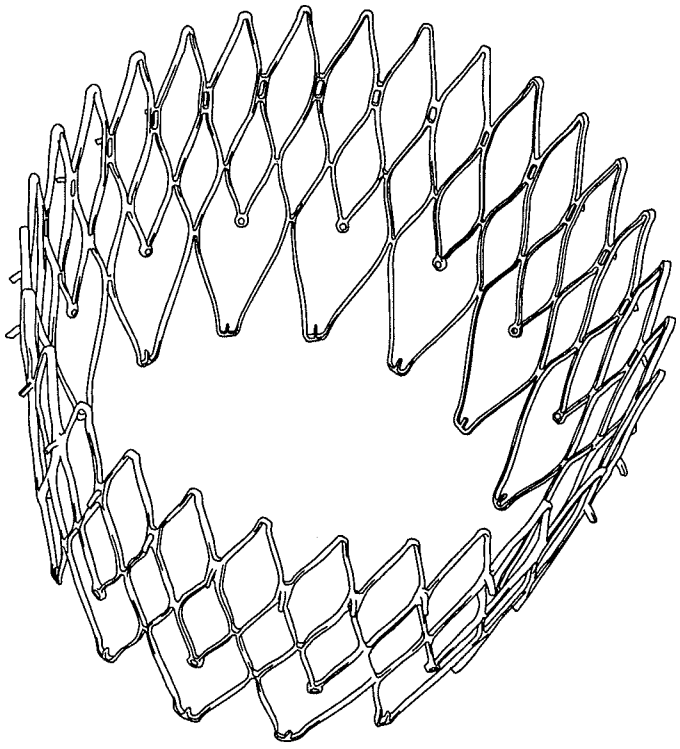


FIG. 7A

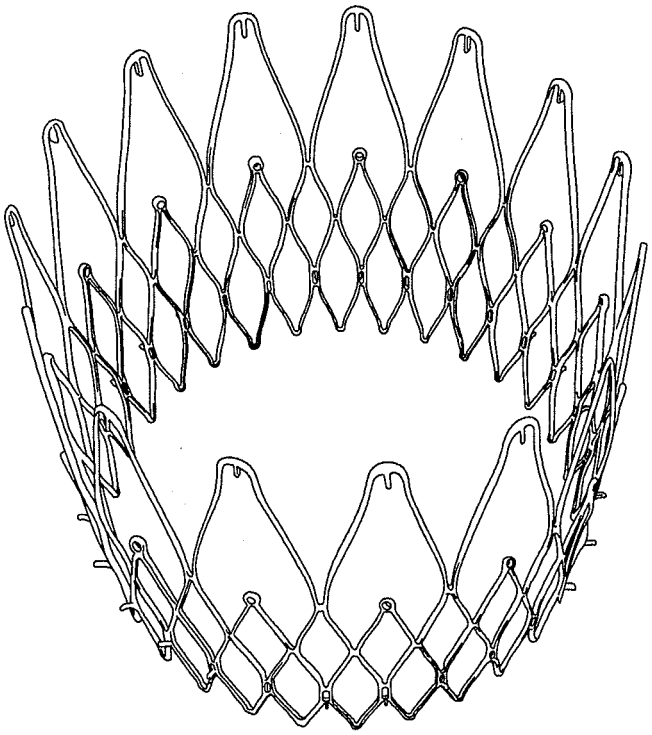


FIG. 7B

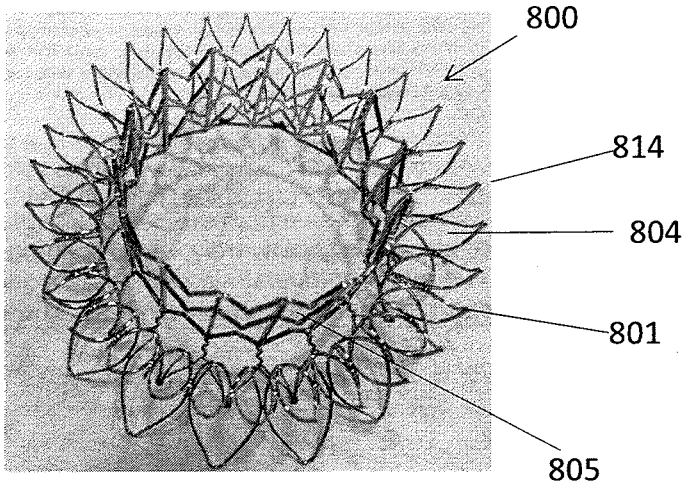


FIG. 8A

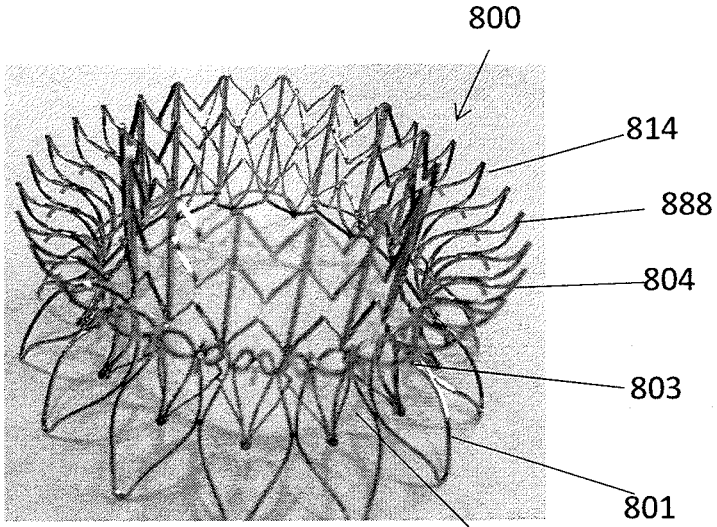


FIG. 8B

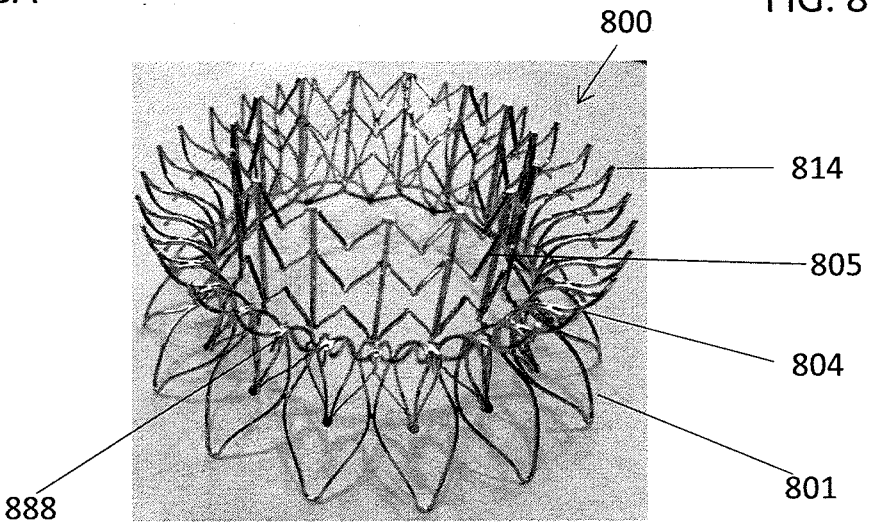


FIG. 8C

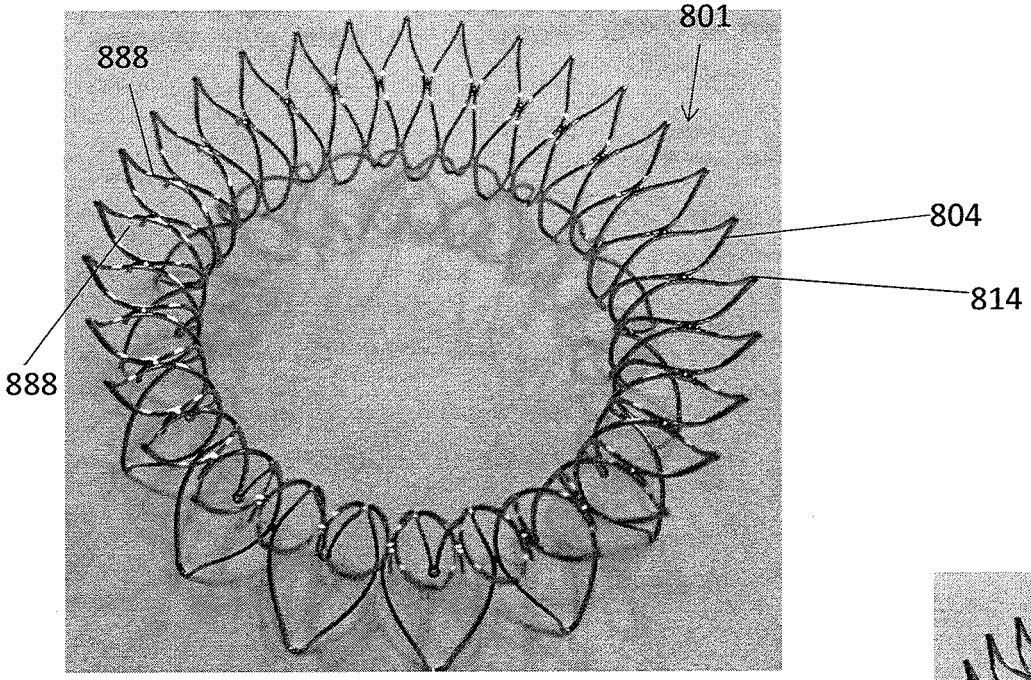


FIG. 8D

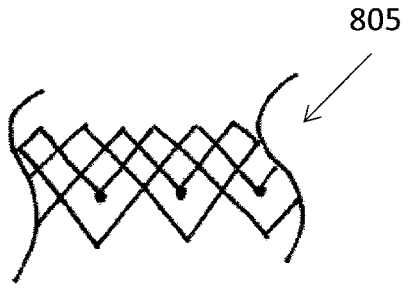


FIG. 8F

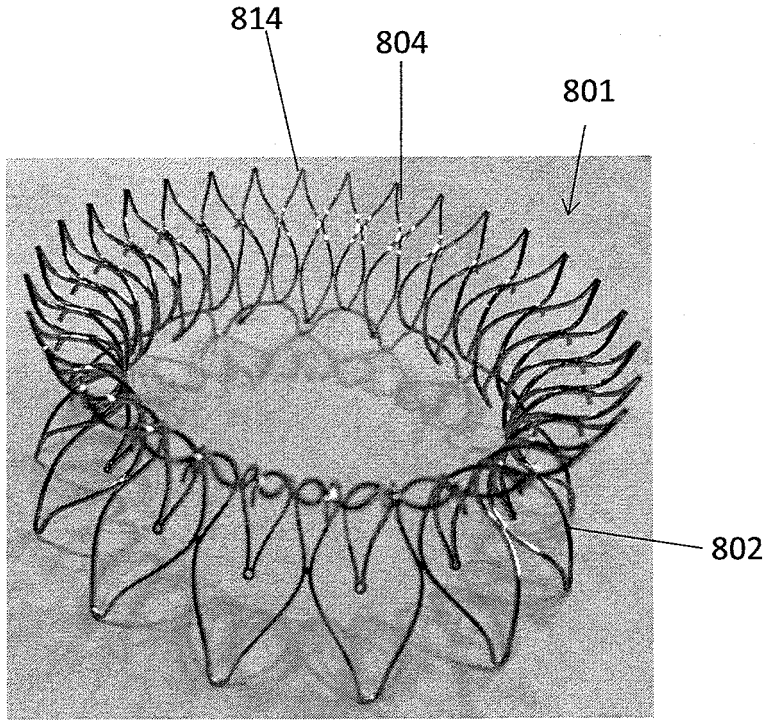


FIG. 8E

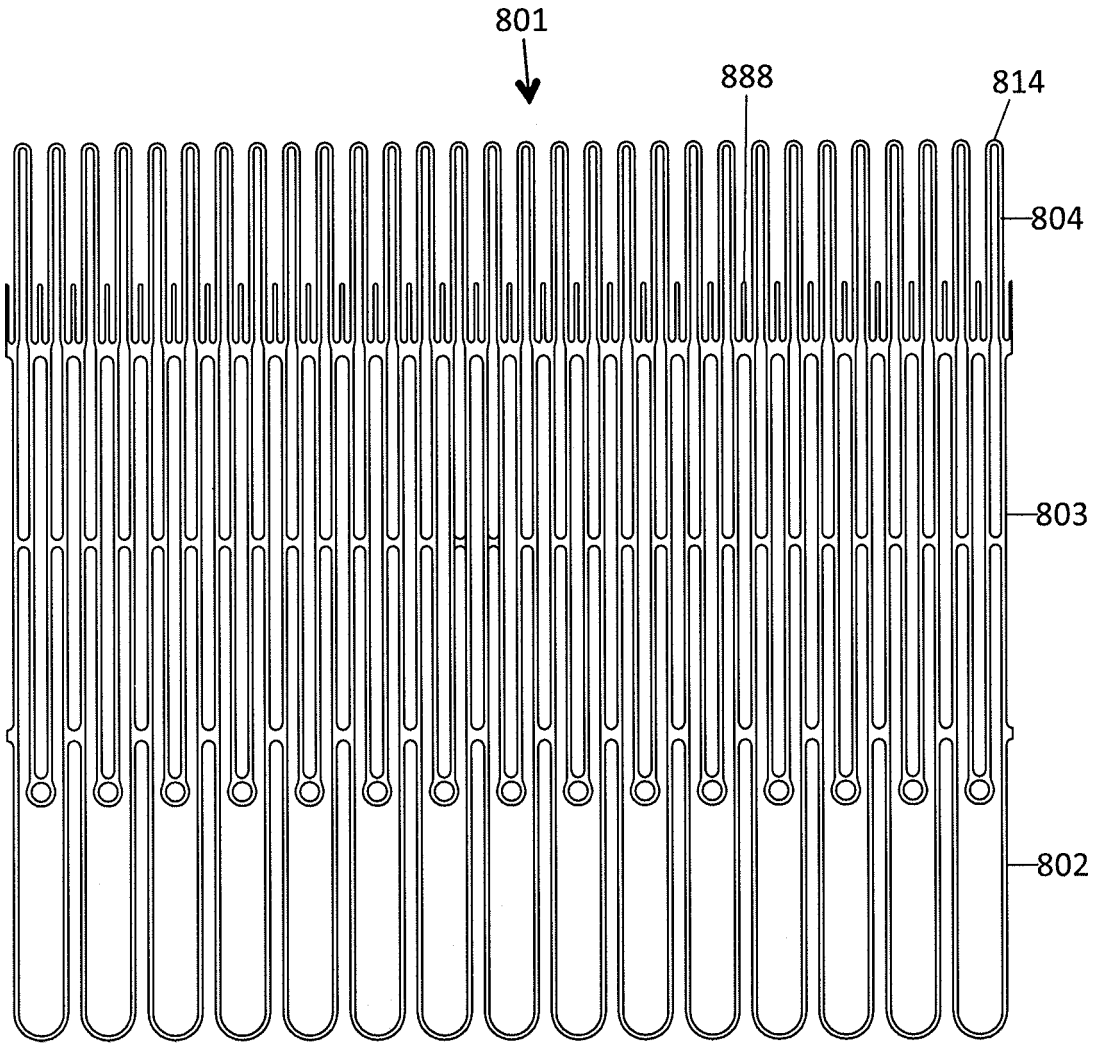


FIG. 8G

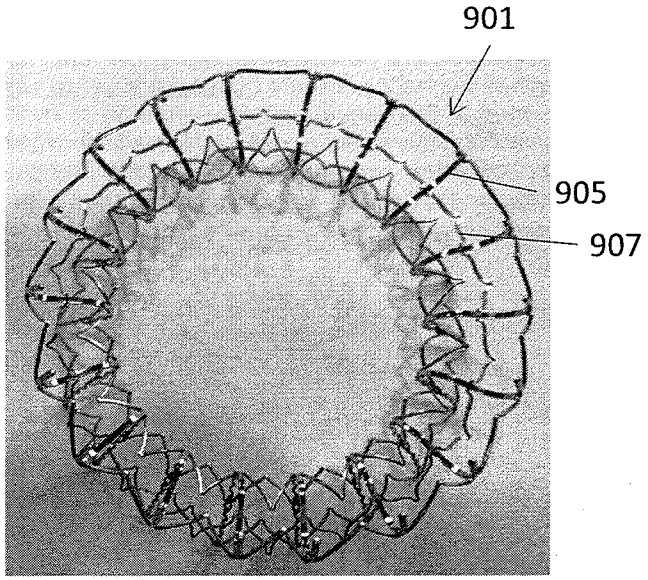


FIG. 9A

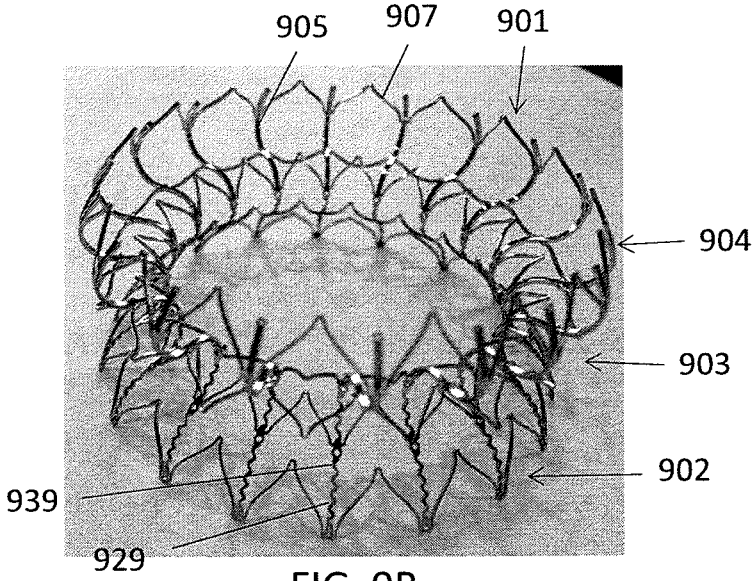


FIG. 9B

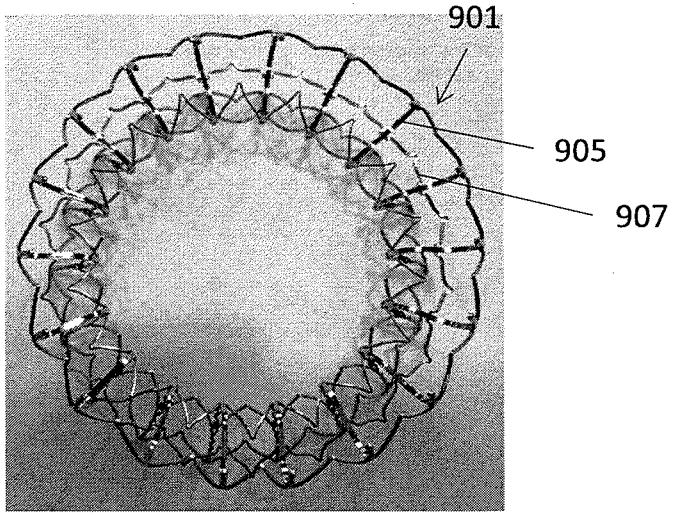


FIG. 9C

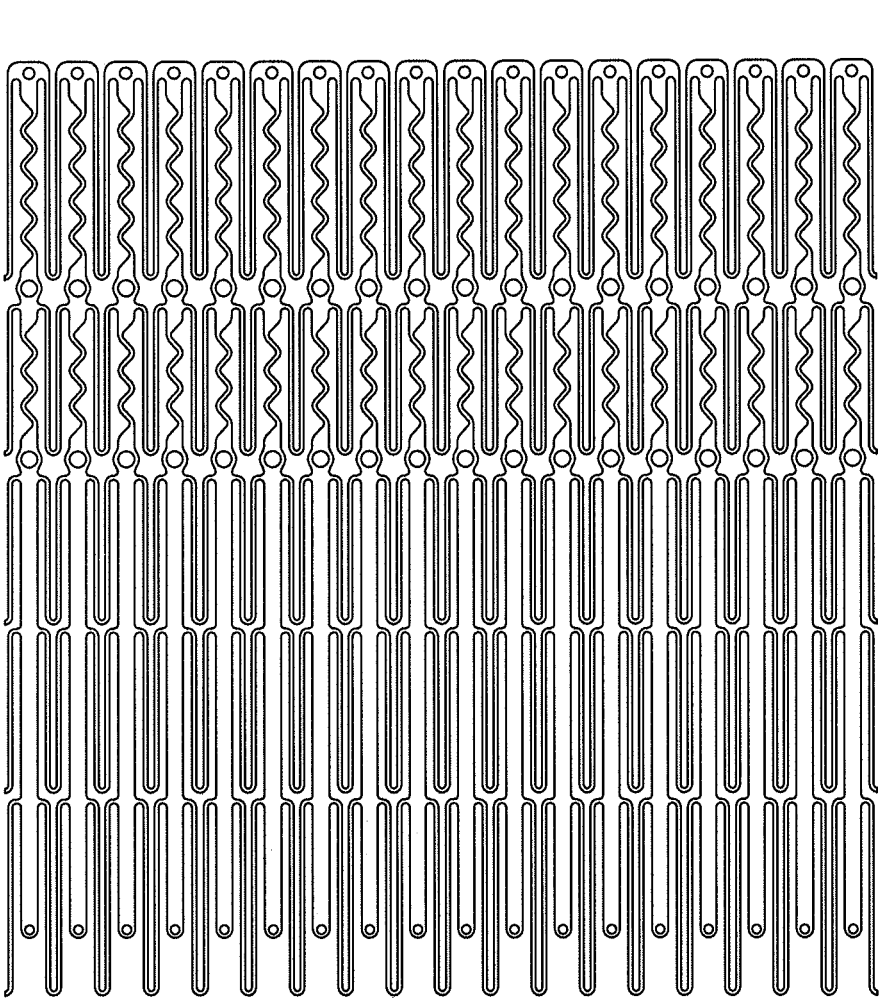


FIG. 9D

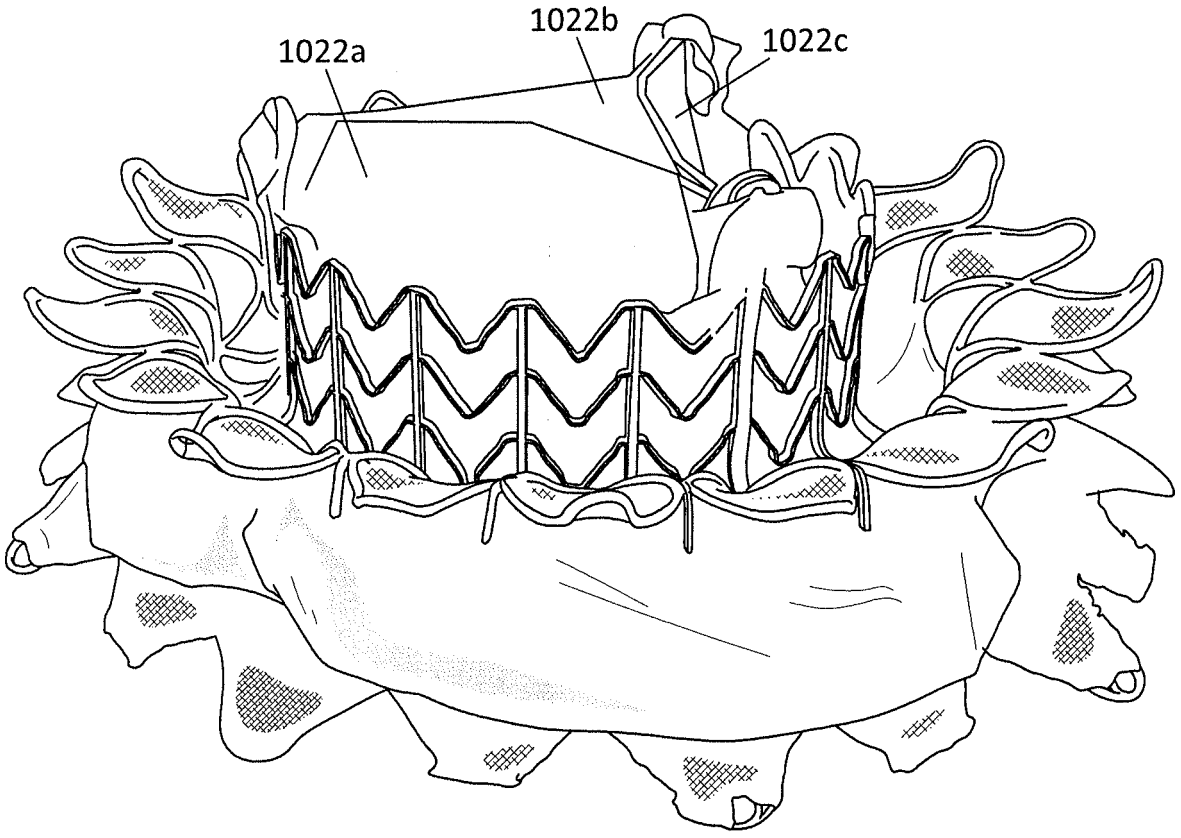


FIG. 10

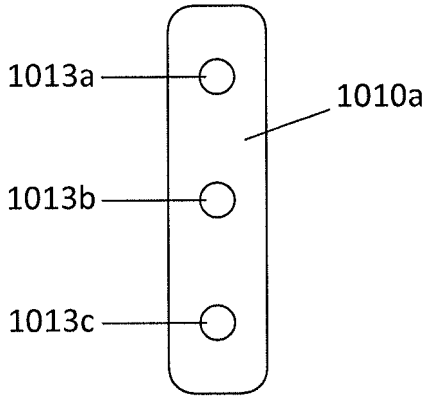


FIG. 11A

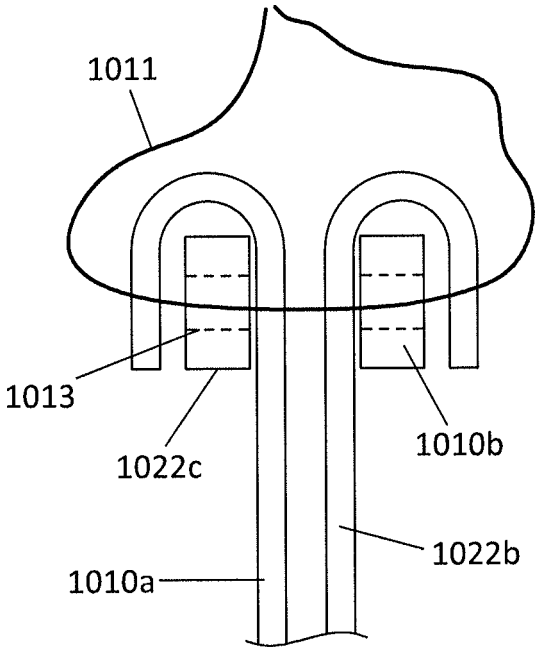


FIG. 11B

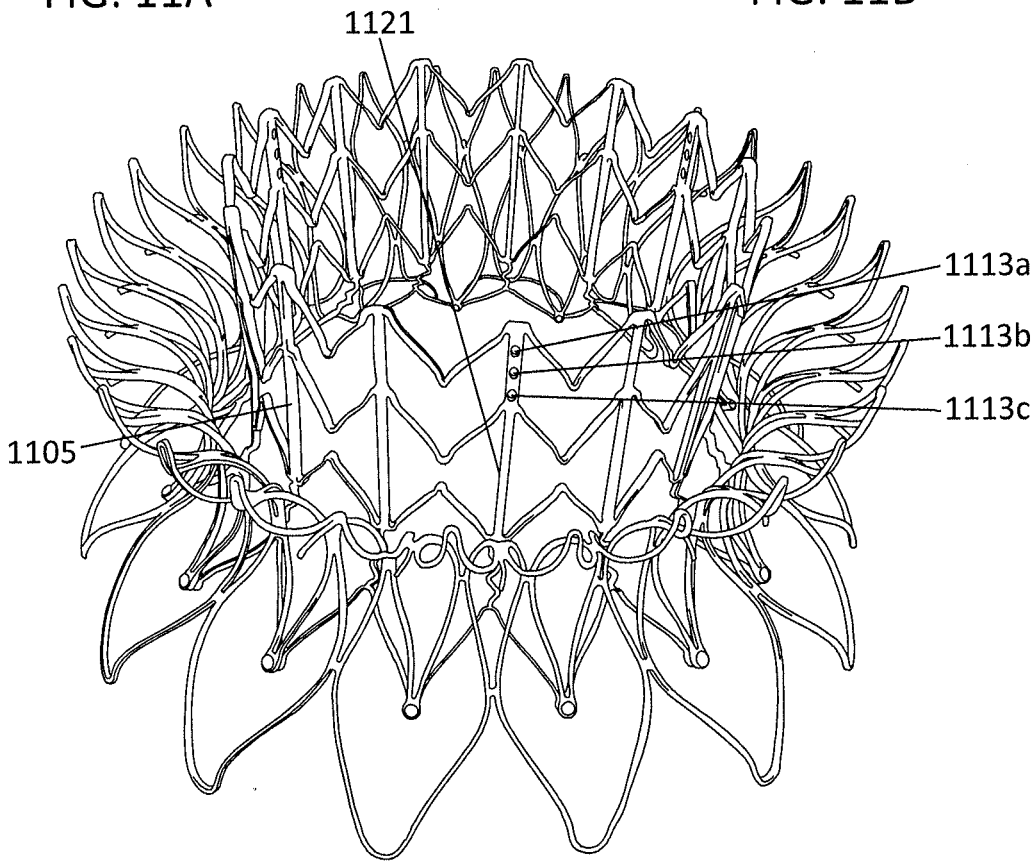


FIG. 11C

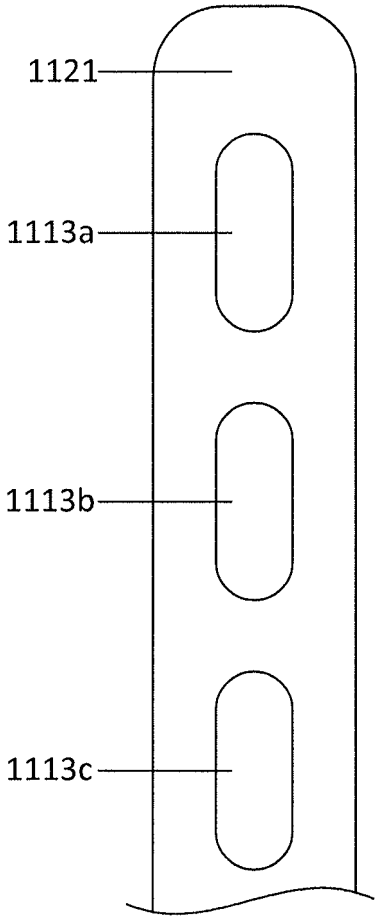


FIG. 11D

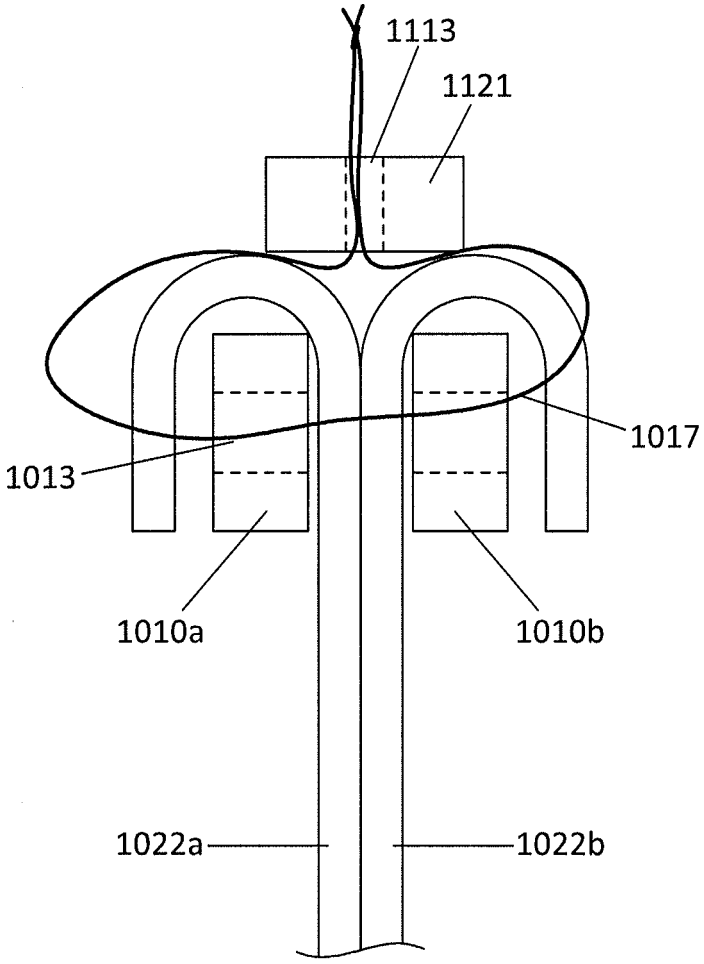


FIG. 11E

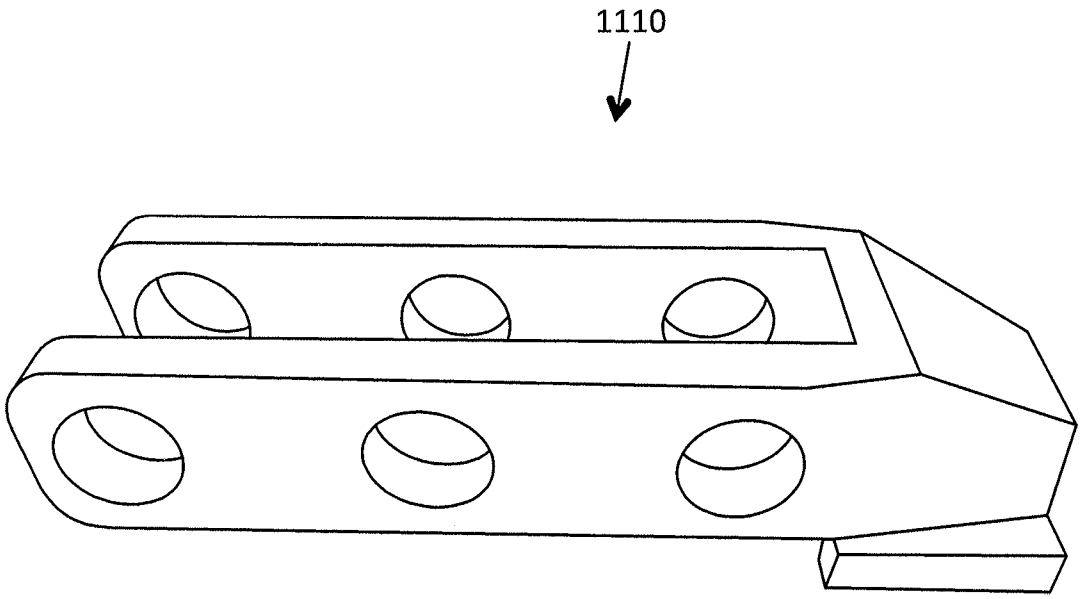


FIG. 12

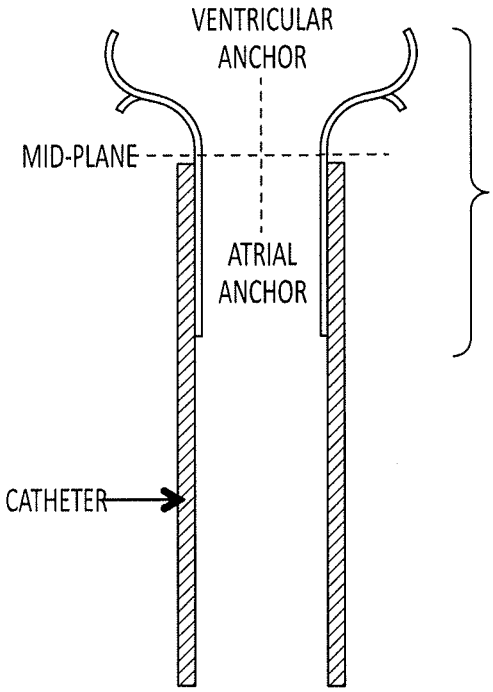


FIG. 13A

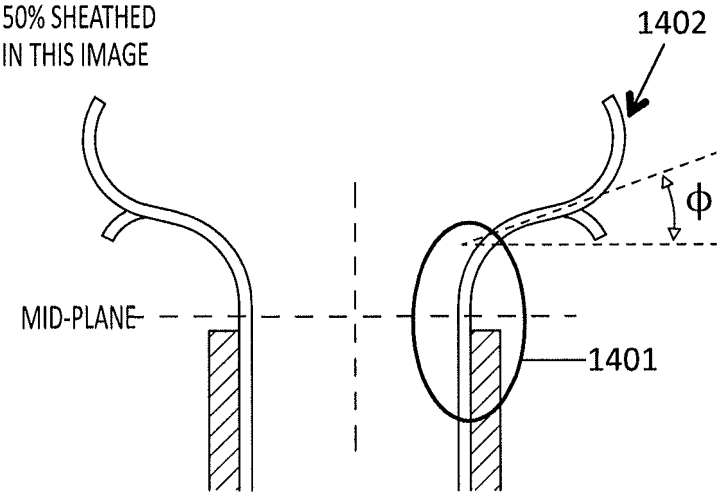


FIG. 13B

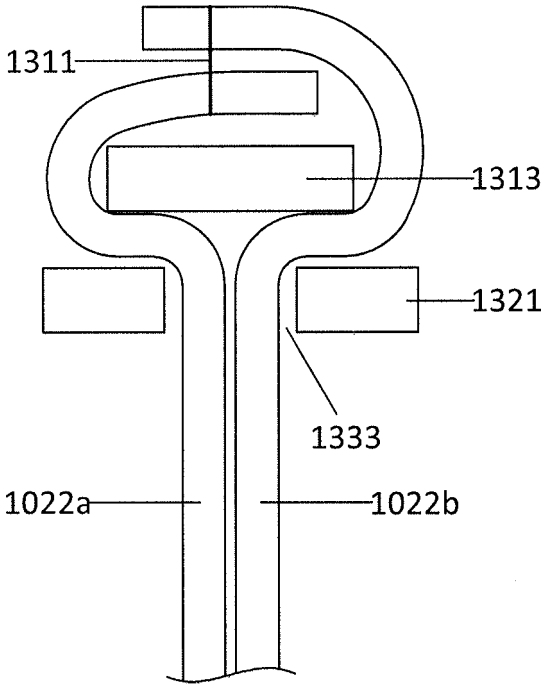


FIG. 14

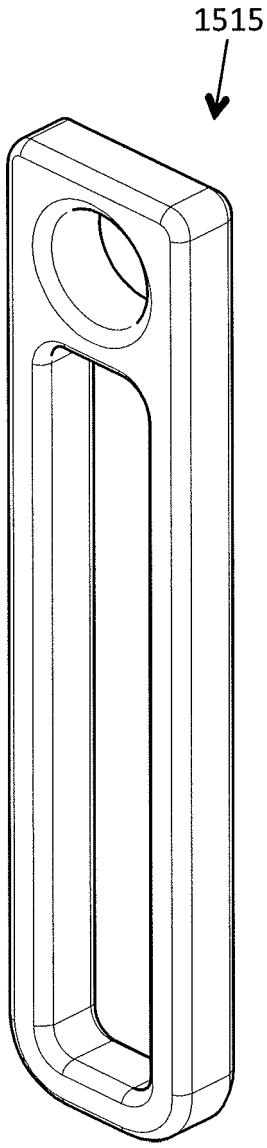


FIG. 15A

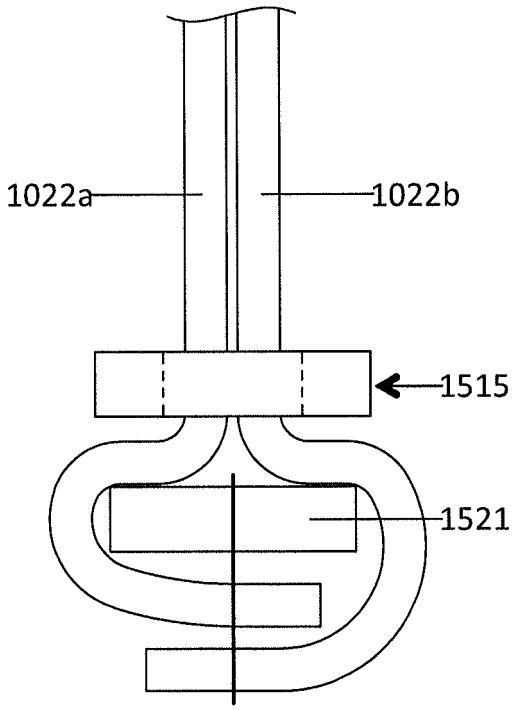


FIG. 15B

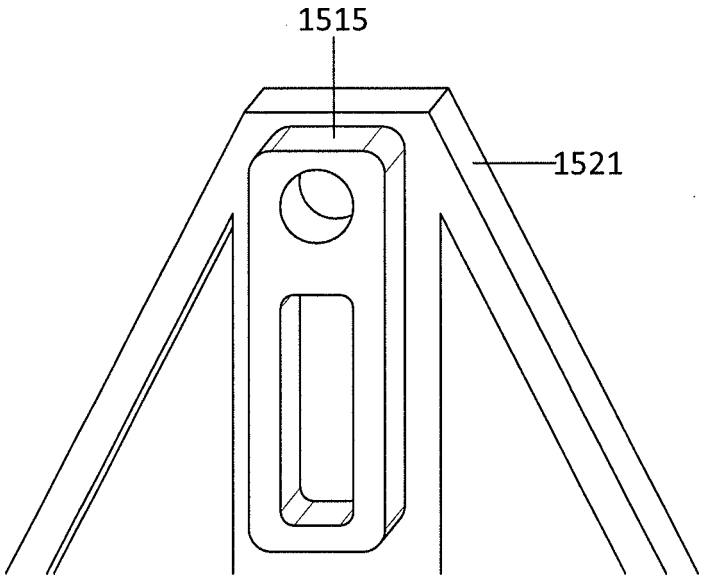


FIG. 15C

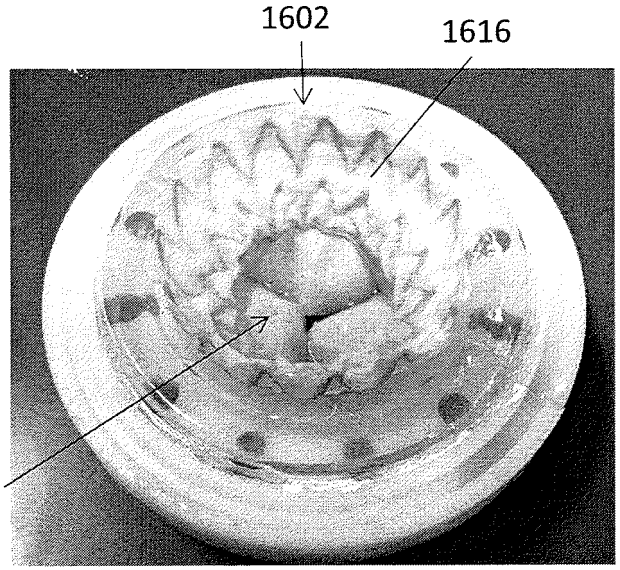


FIG. 16A

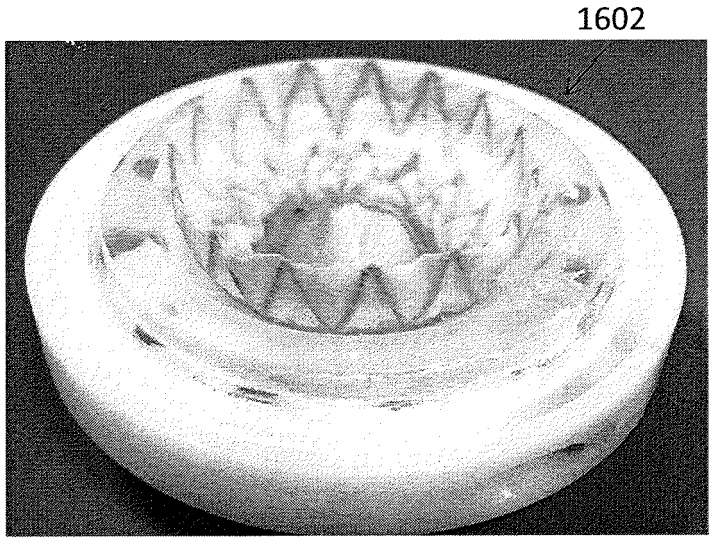


FIG. 16B

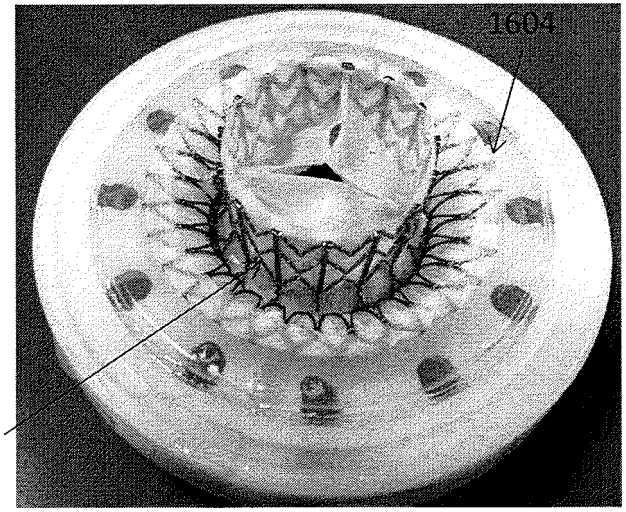


FIG. 16C

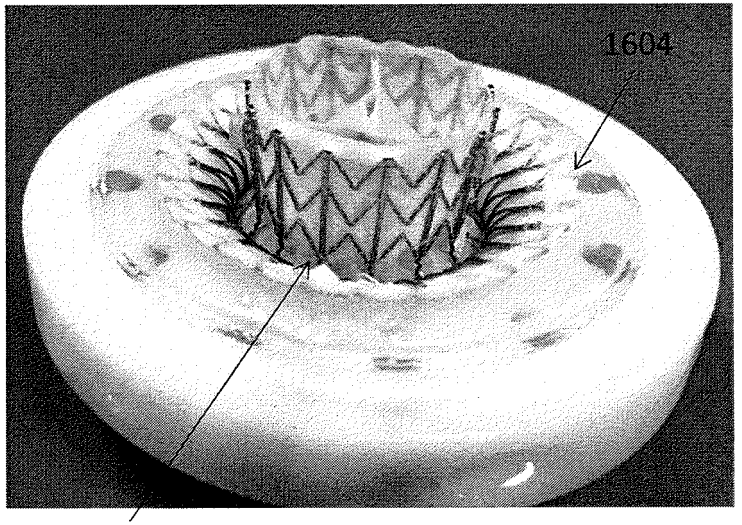


FIG. 16D

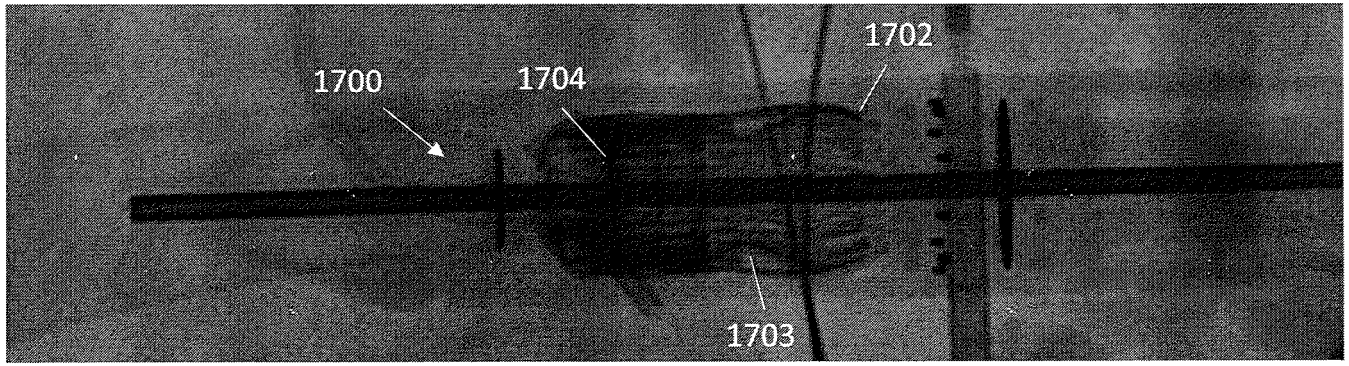


FIG. 17A

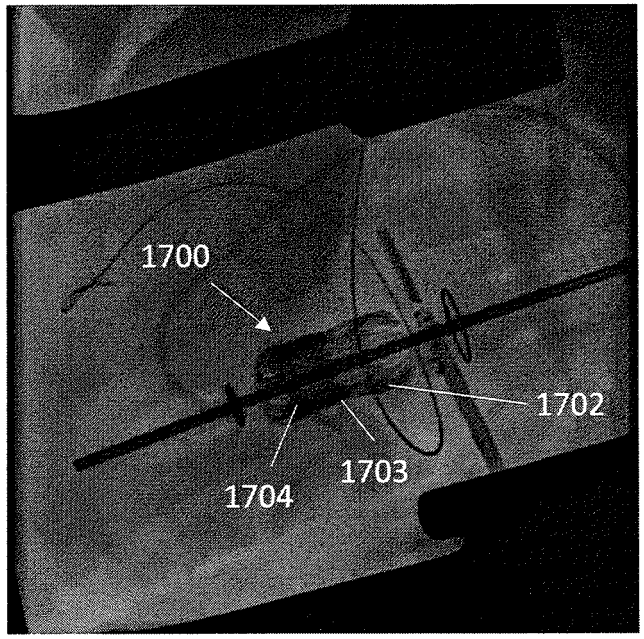


FIG. 17B

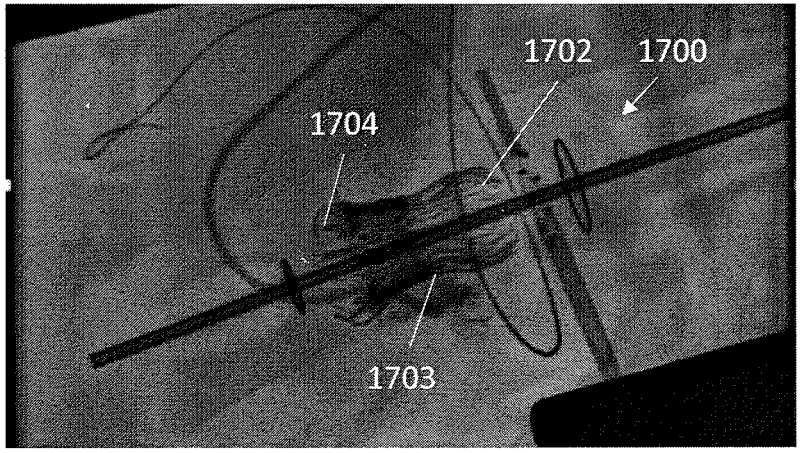


FIG. 17C

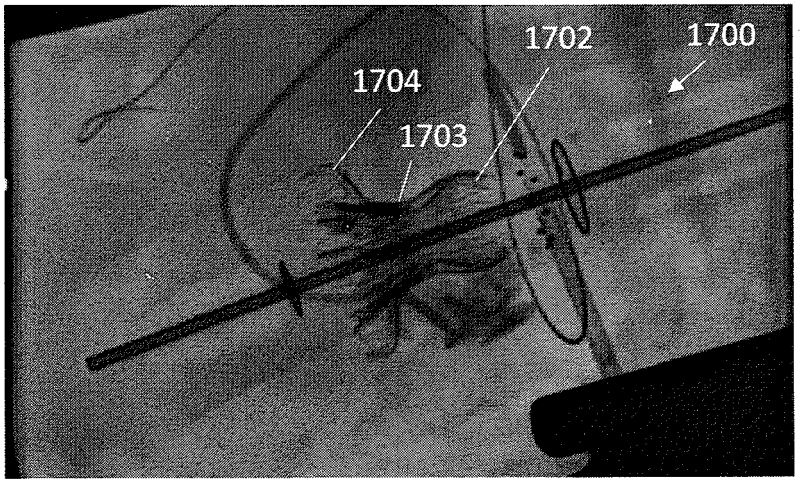


FIG. 17D

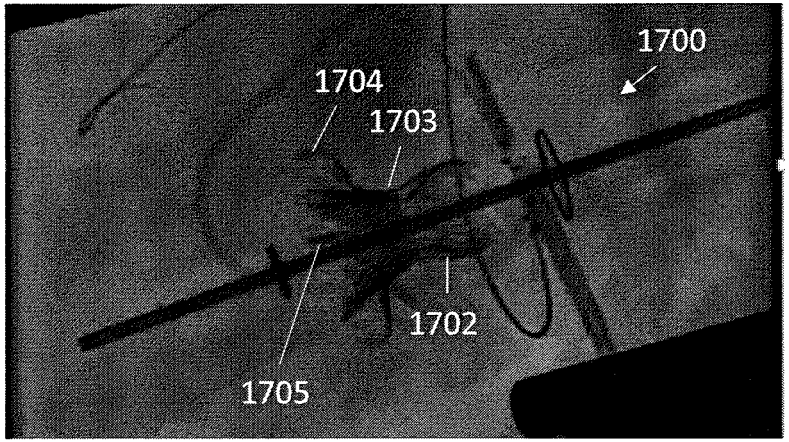


FIG. 17E

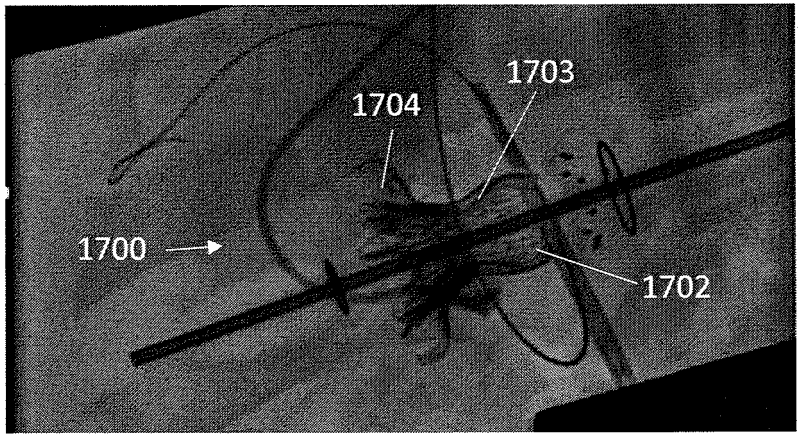


FIG. 17F

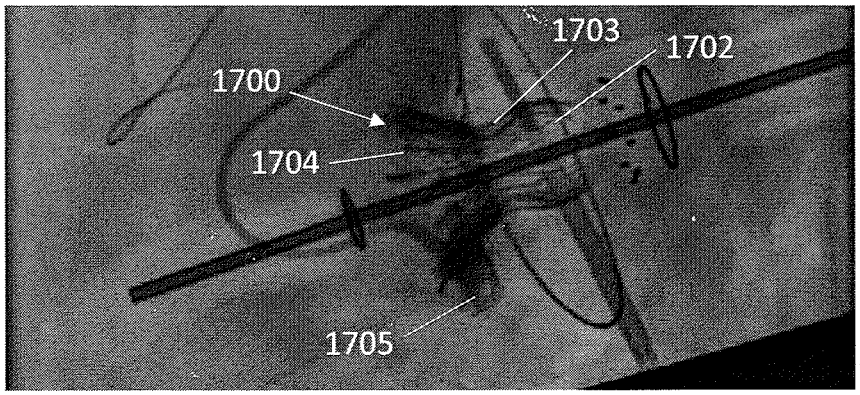


FIG. 17G

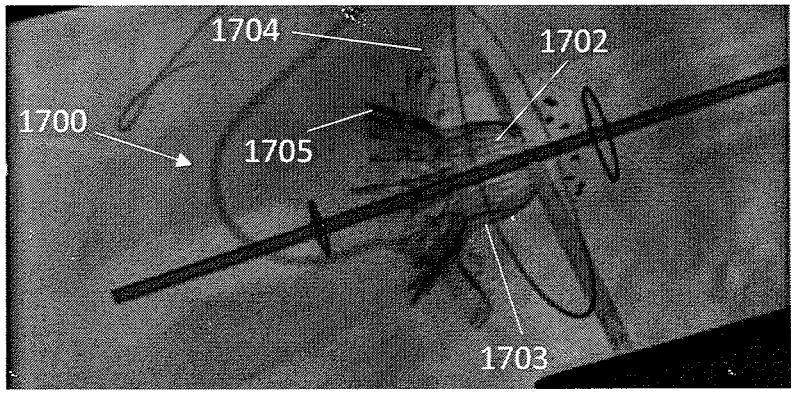


FIG. 17H

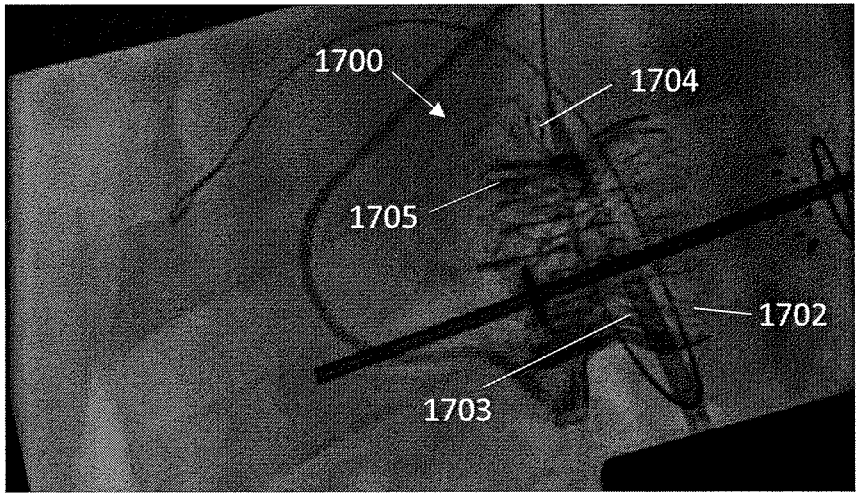


FIG. 17I

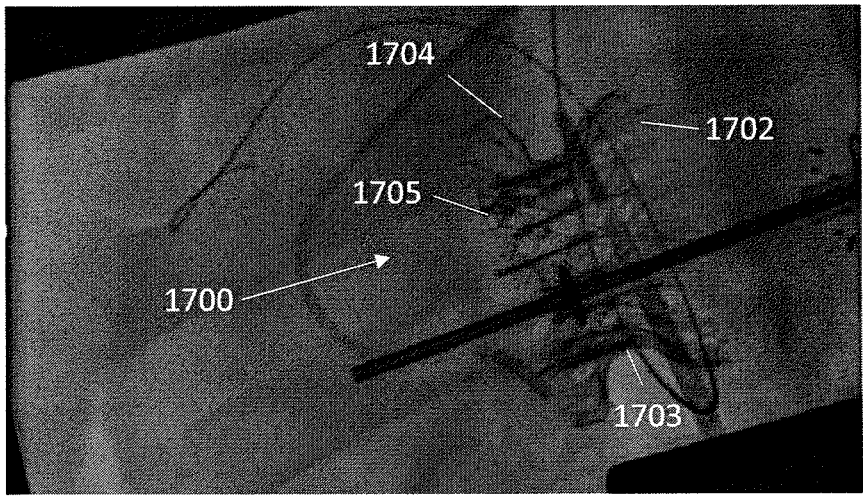


FIG. 17J

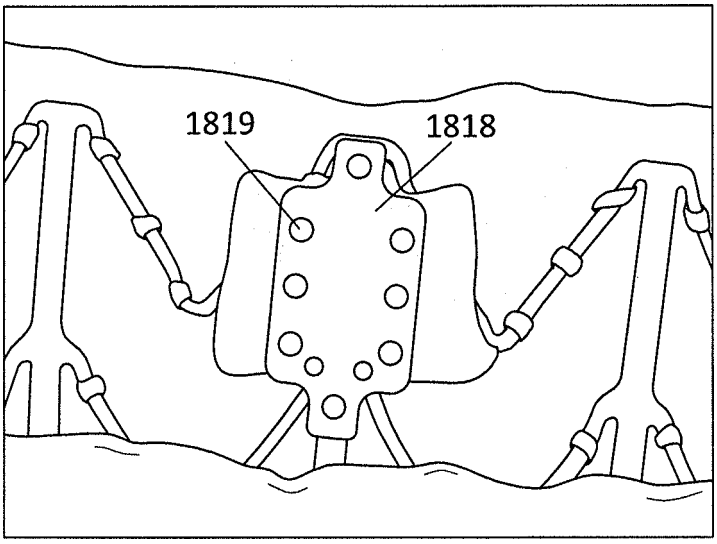


FIG. 18A

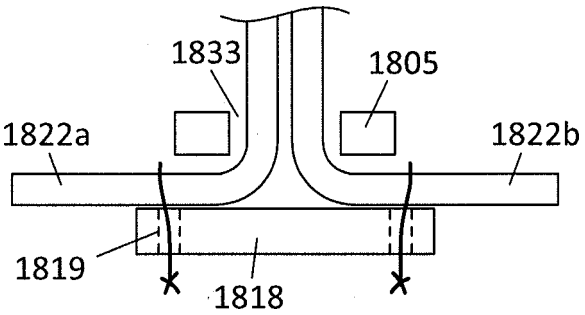


FIG. 18B

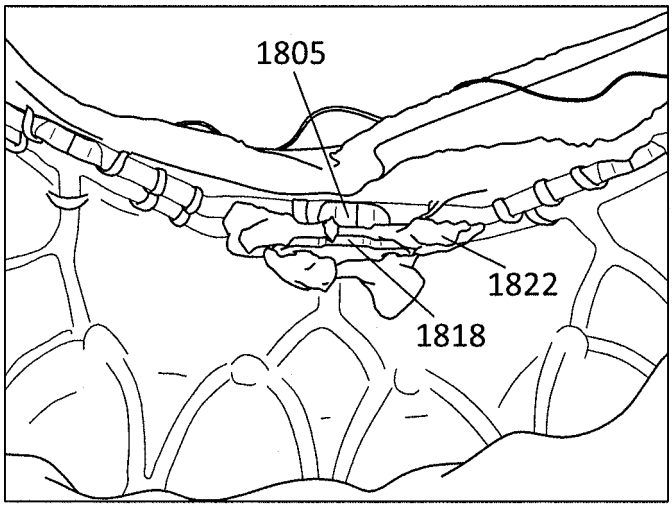


FIG. 18C

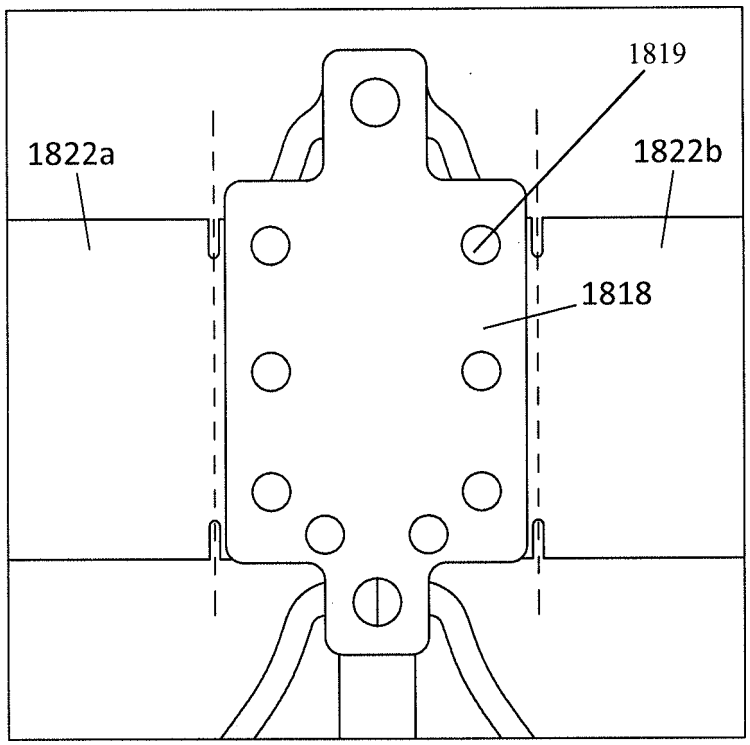


FIG. 18D

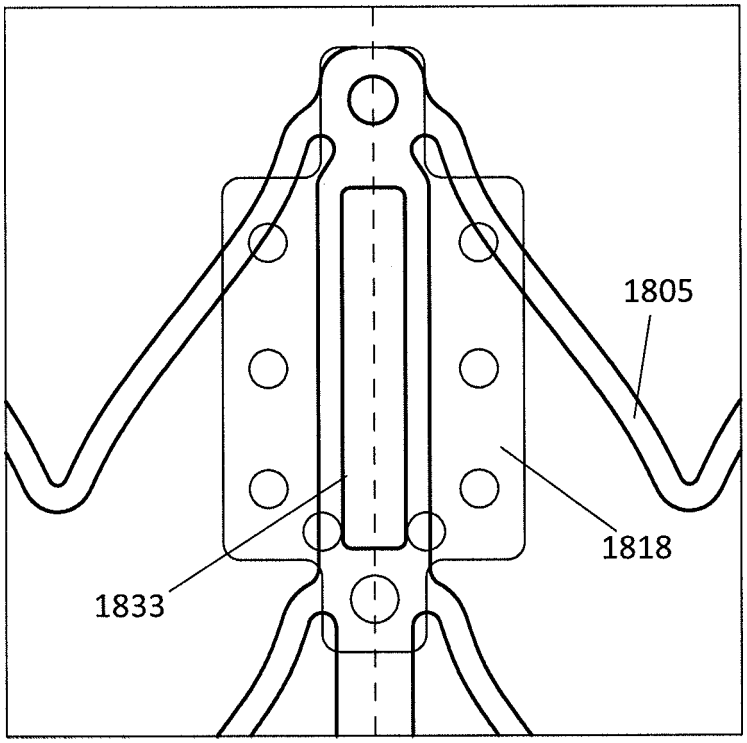


FIG. 18E



FIG. 19

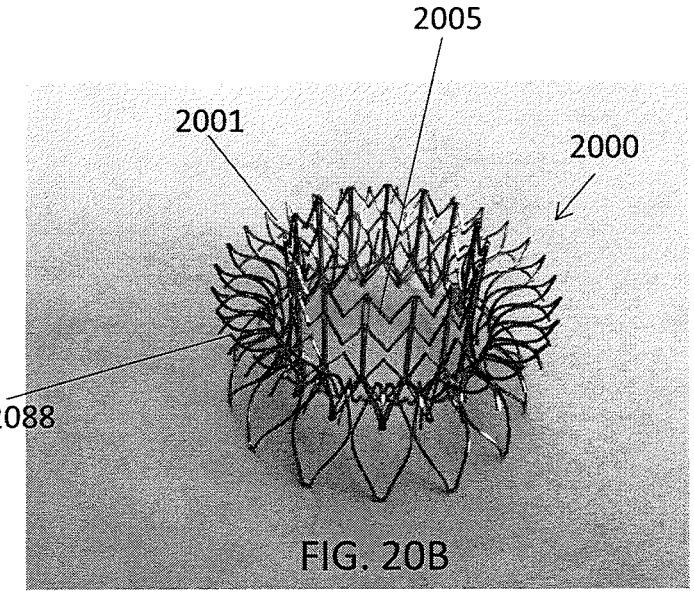


FIG. 20B

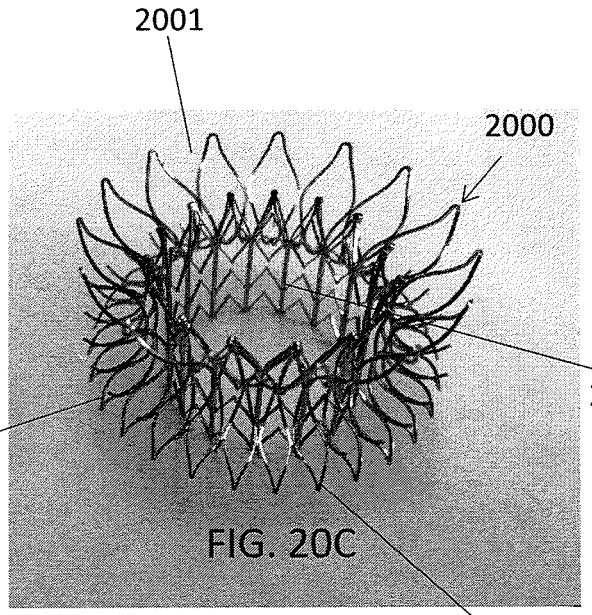


FIG. 20C

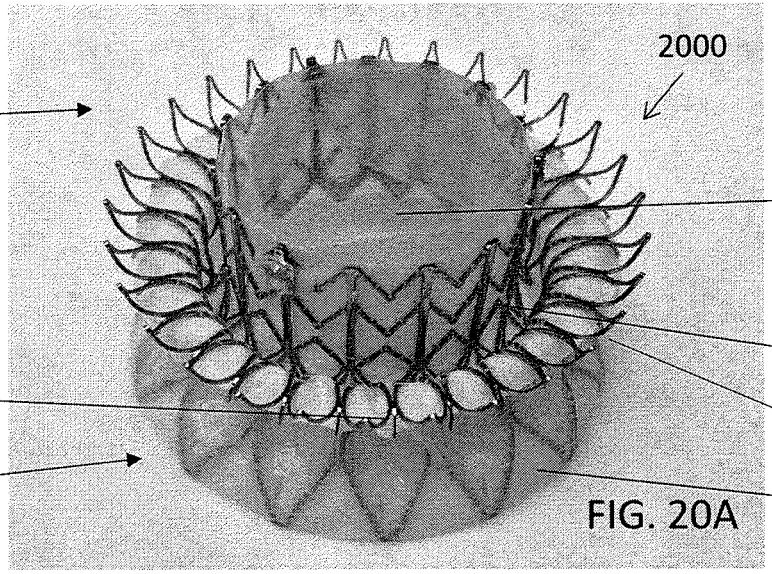


FIG. 20A

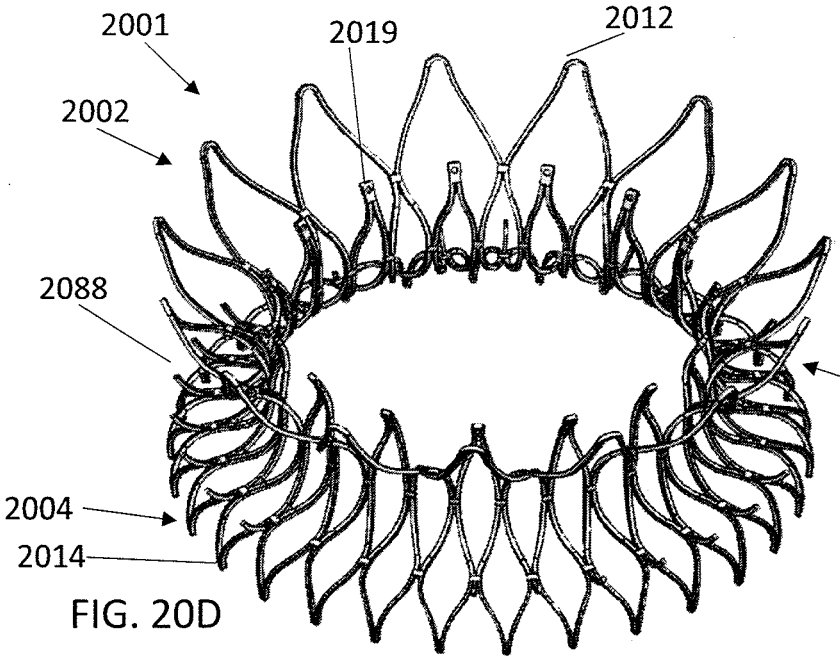


FIG. 20D

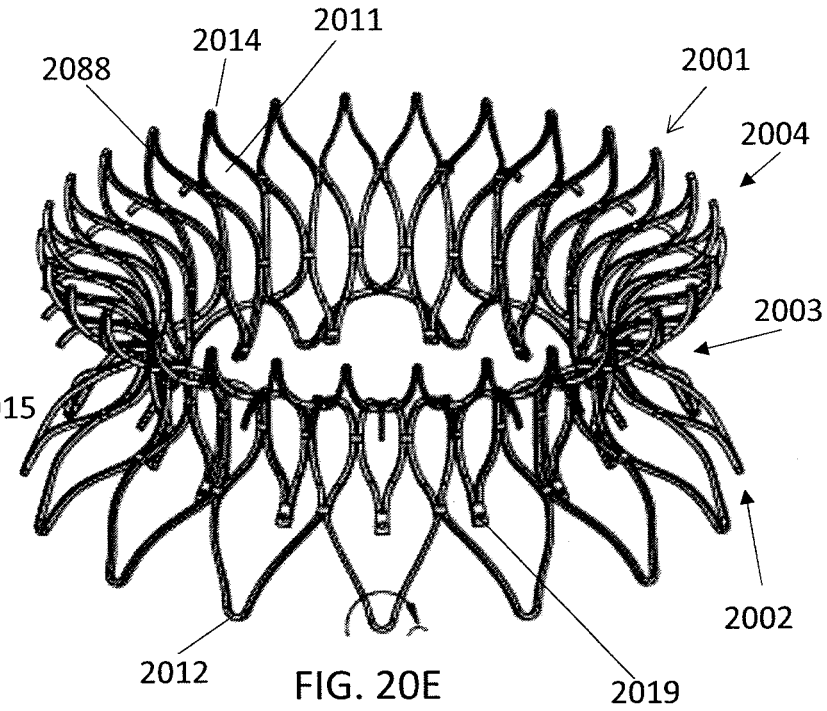


FIG. 20E

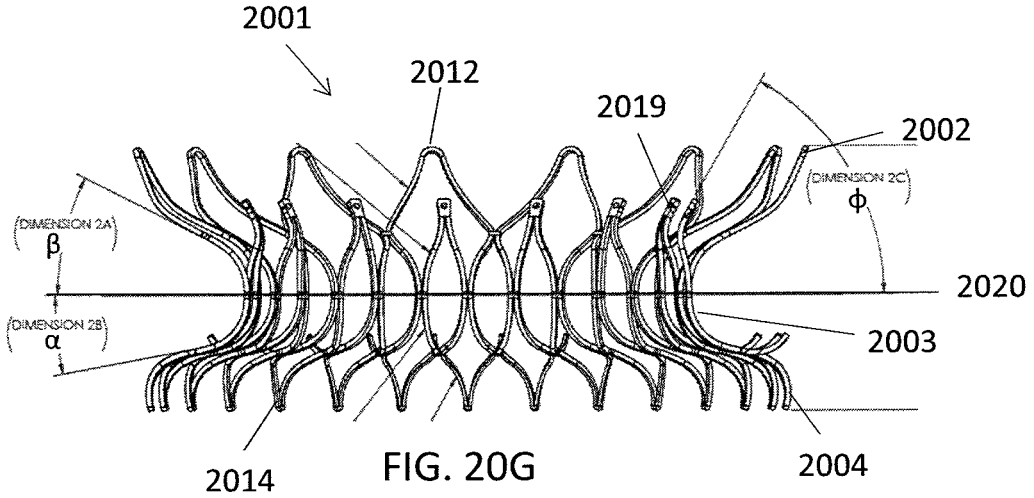


FIG. 20G

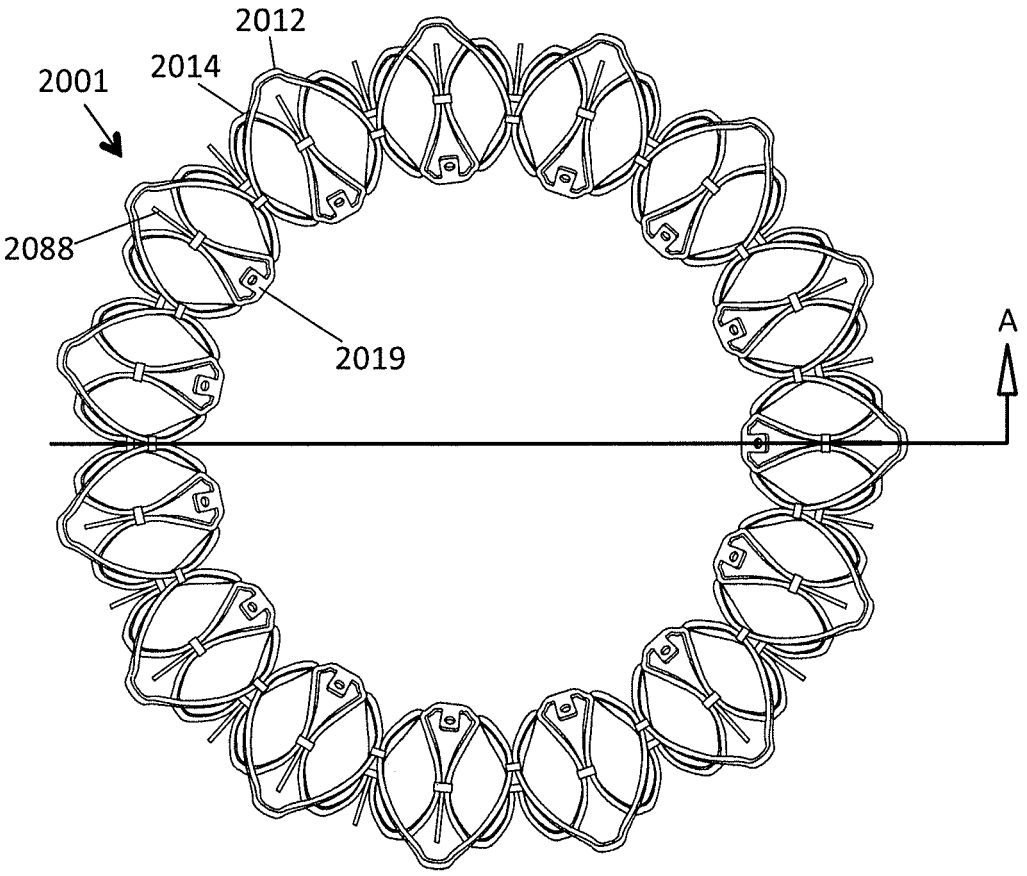


FIG. 20F

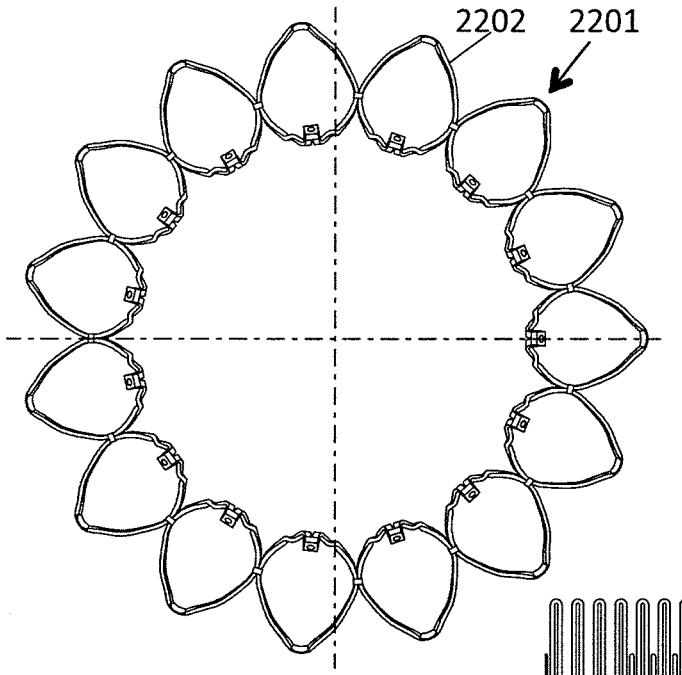


FIG. 20H

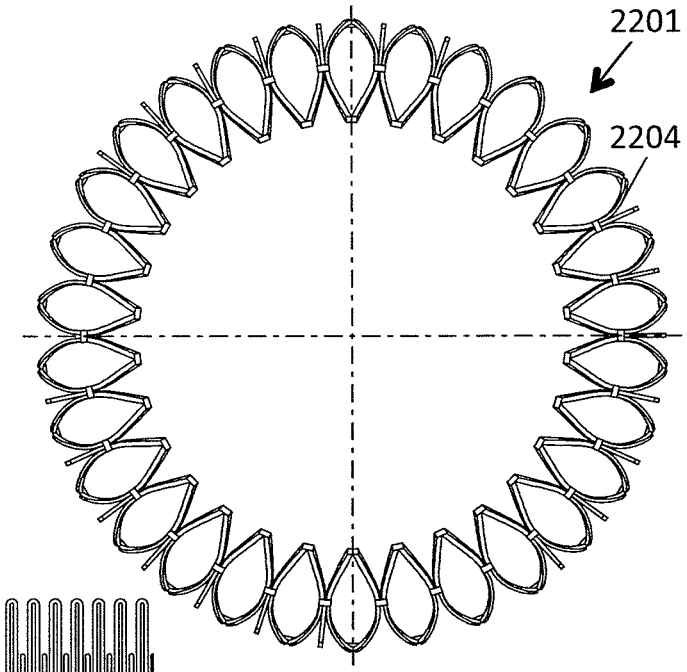


FIG. 20I

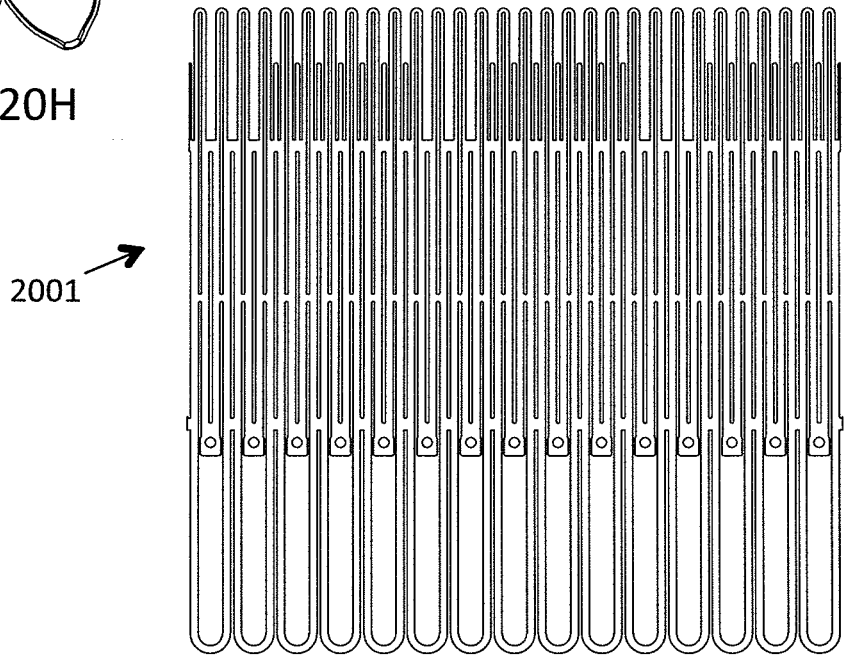


FIG. 20J

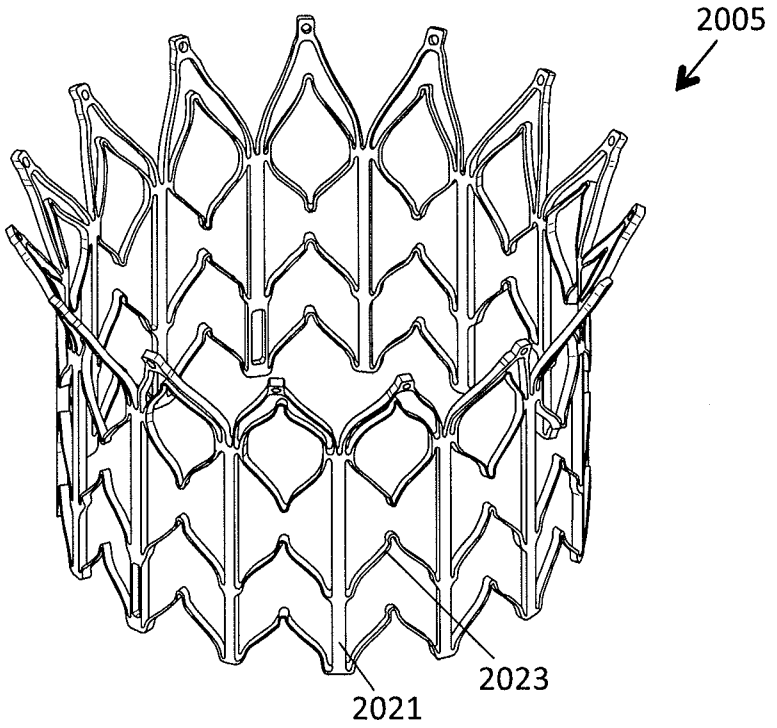


FIG. 20K

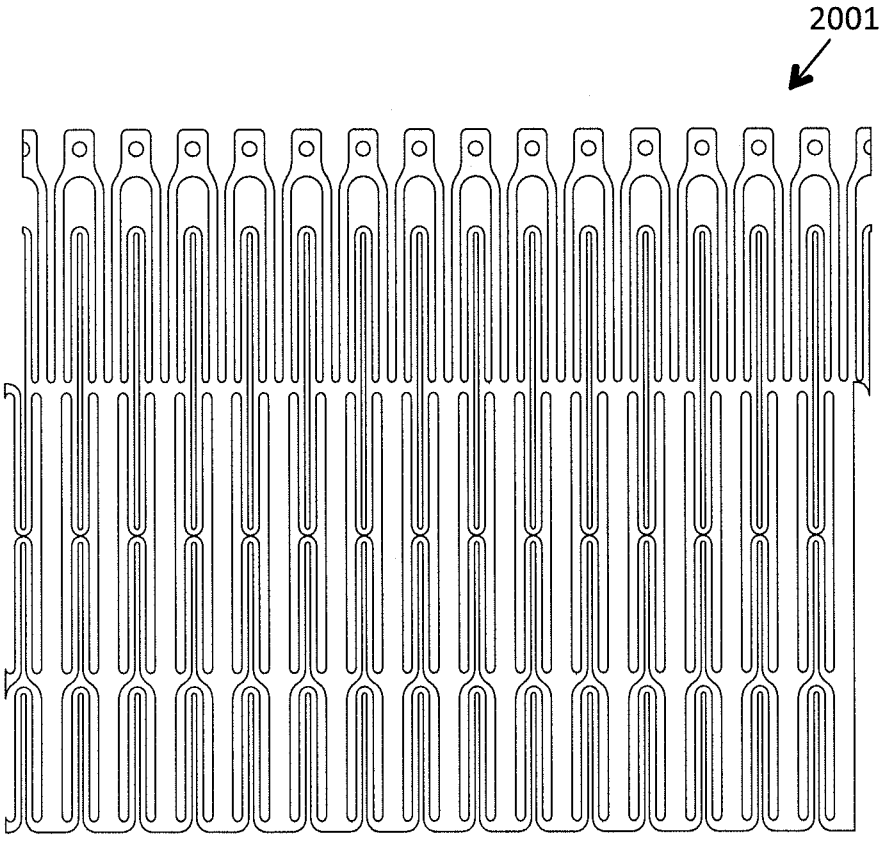


FIG. 20L

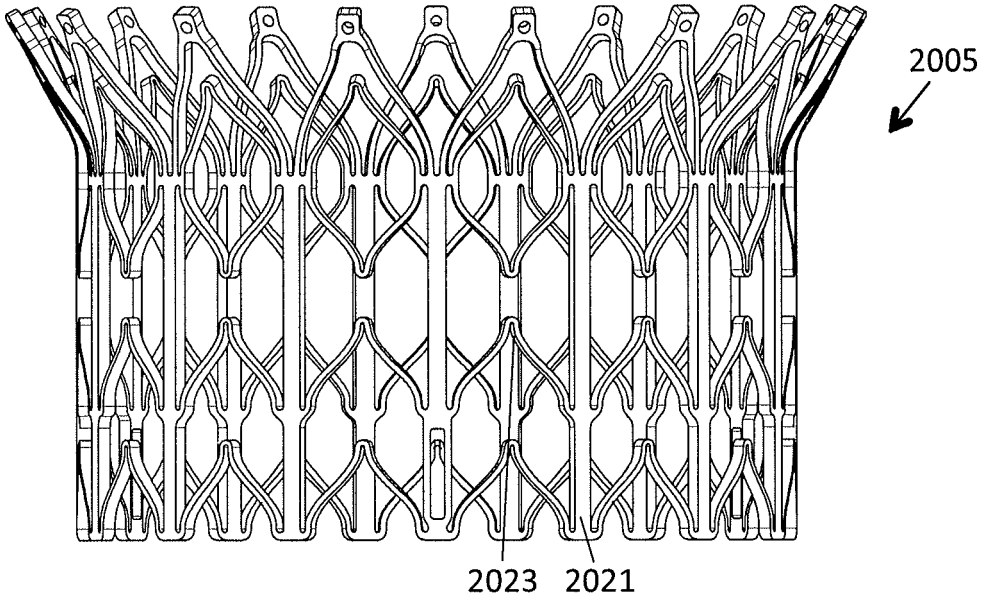


FIG. 20M

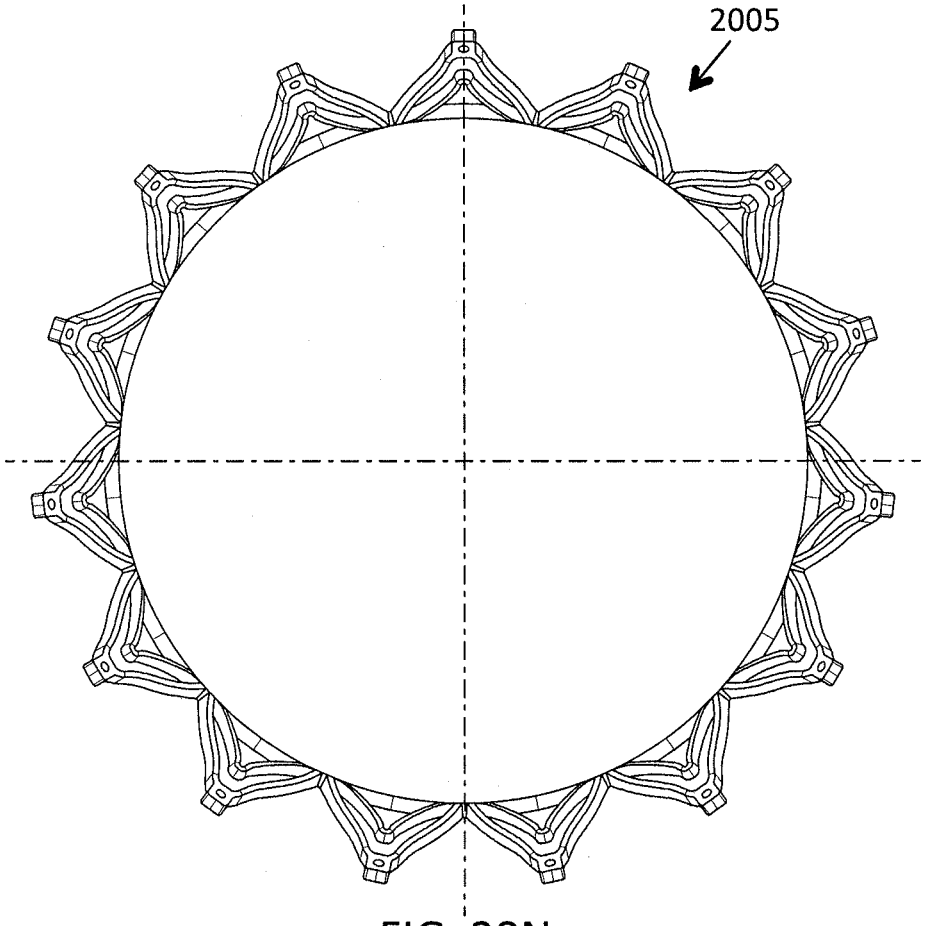


FIG. 20N

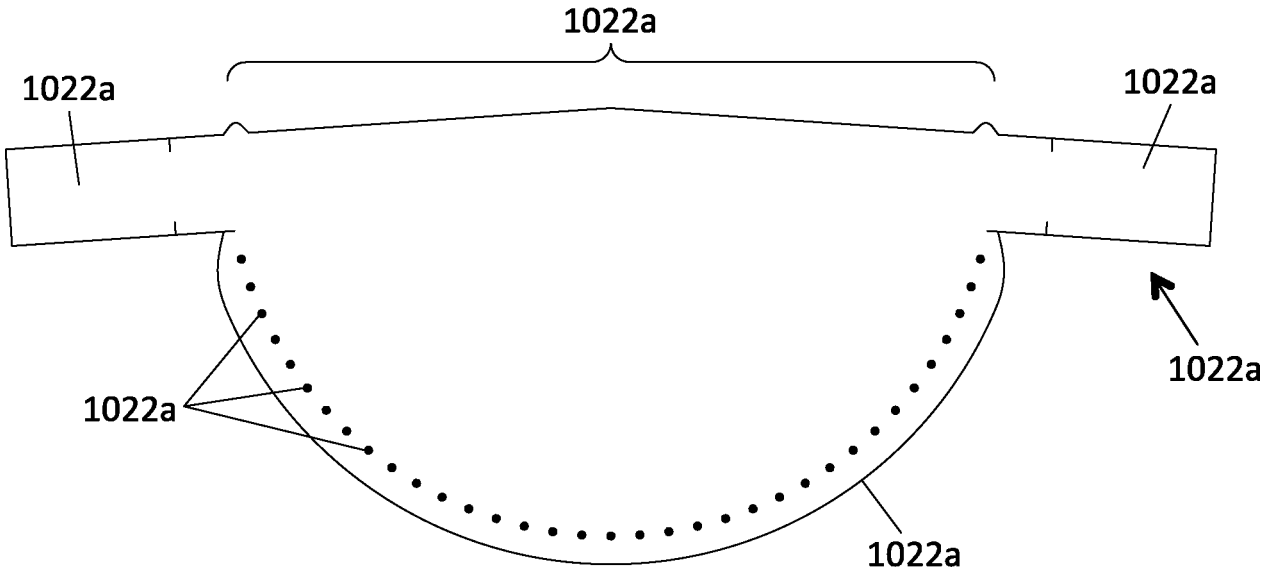


FIG. 21

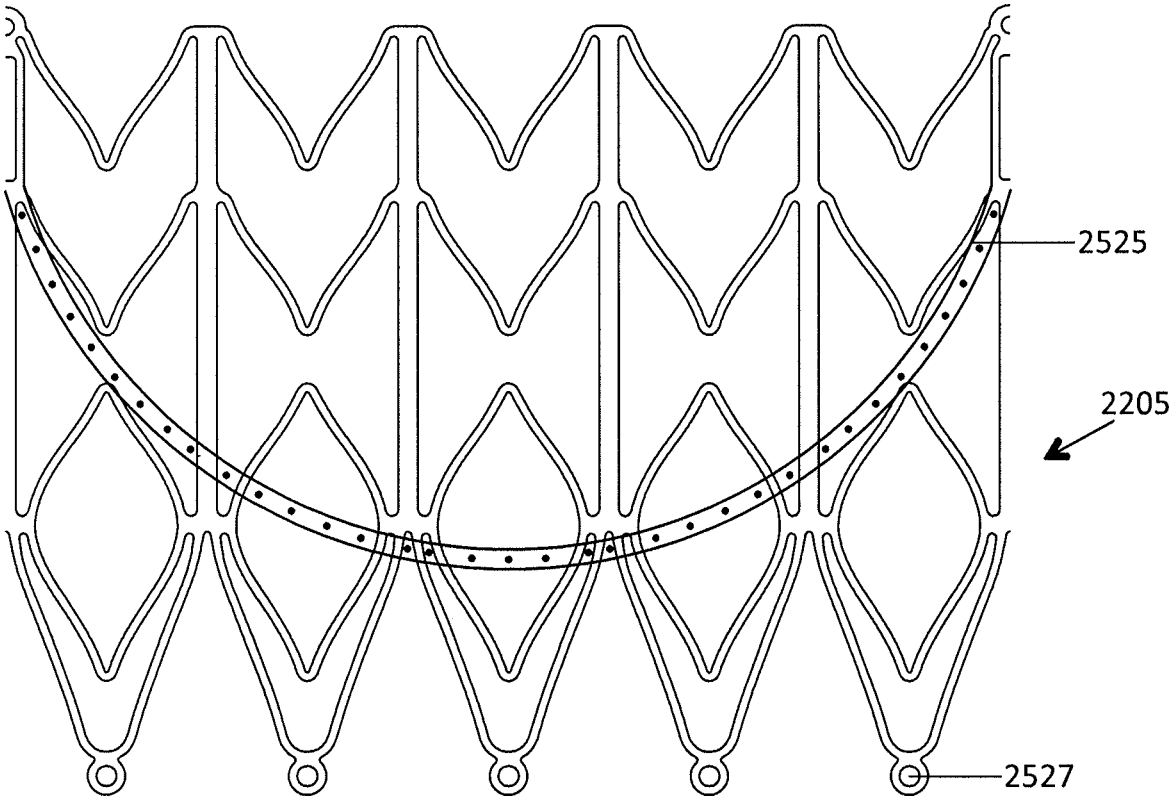


FIG. 22

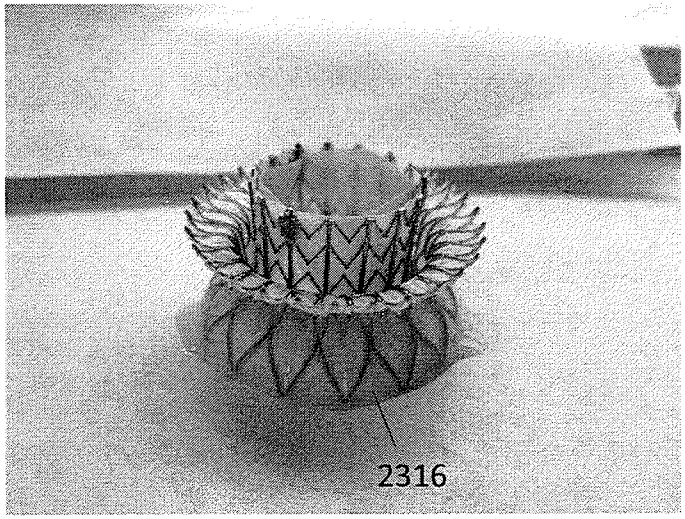


FIG. 23A

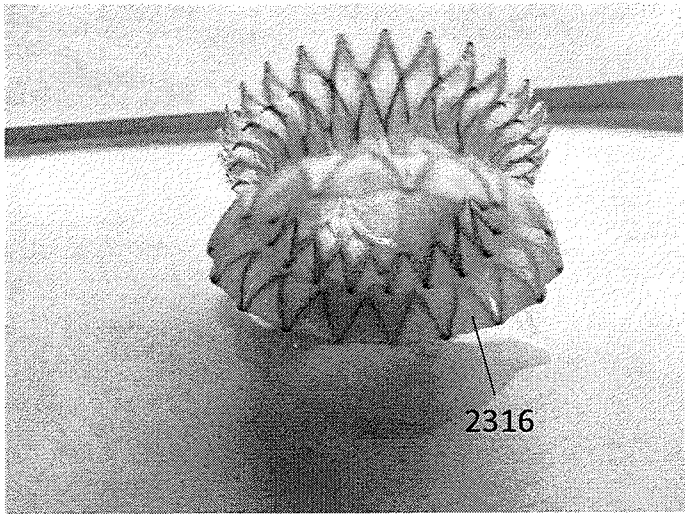


FIG. 23B

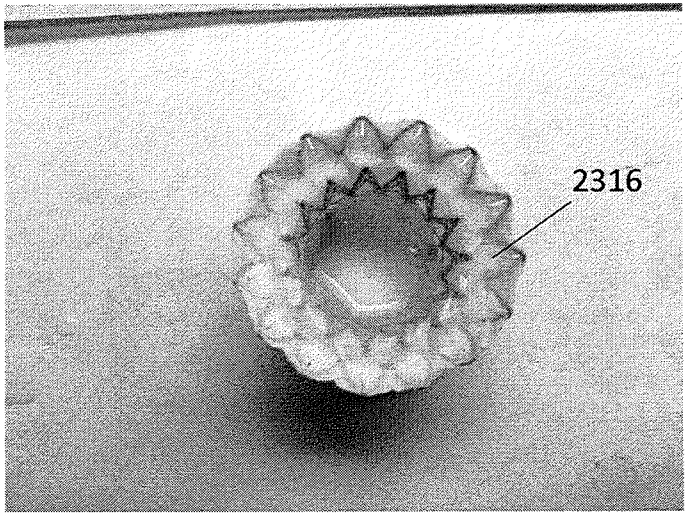


FIG. 23C

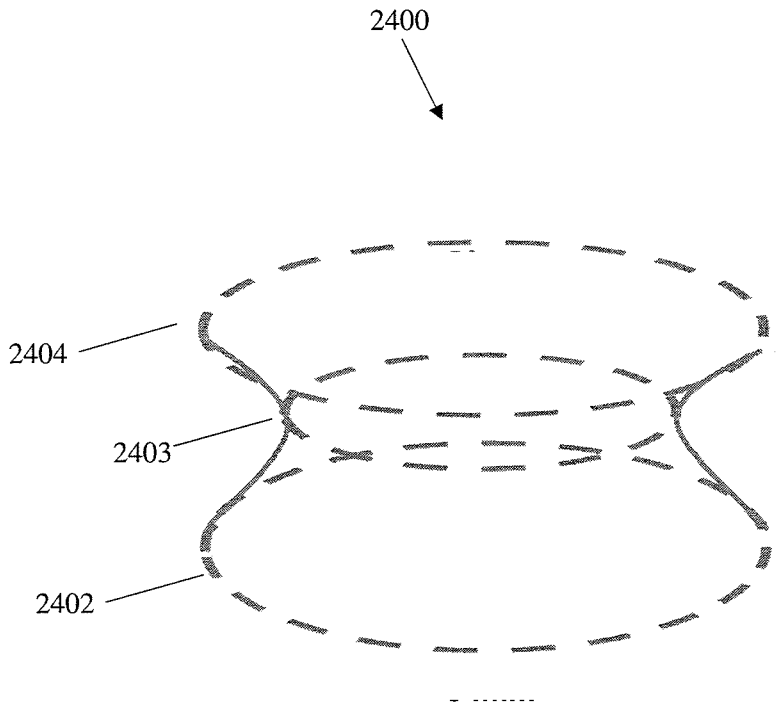


Figure 24A

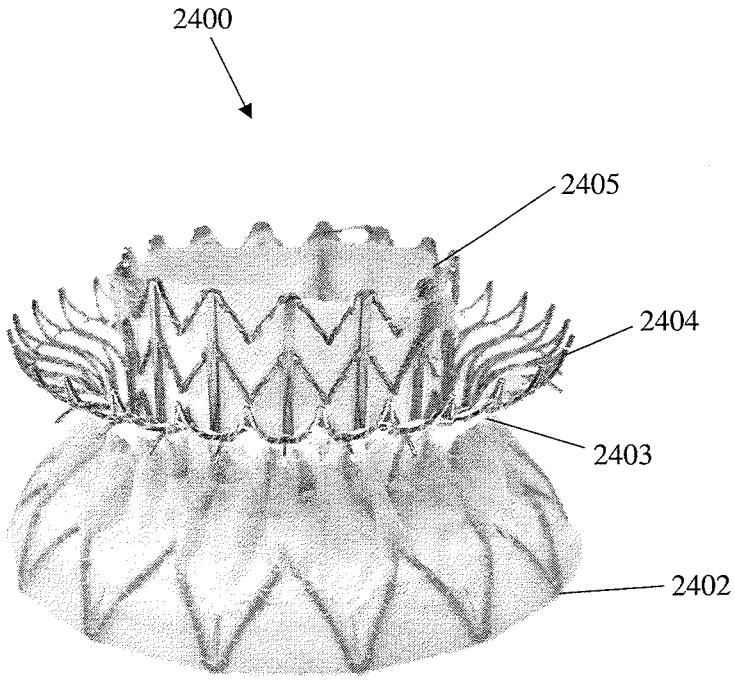


Figure 24B

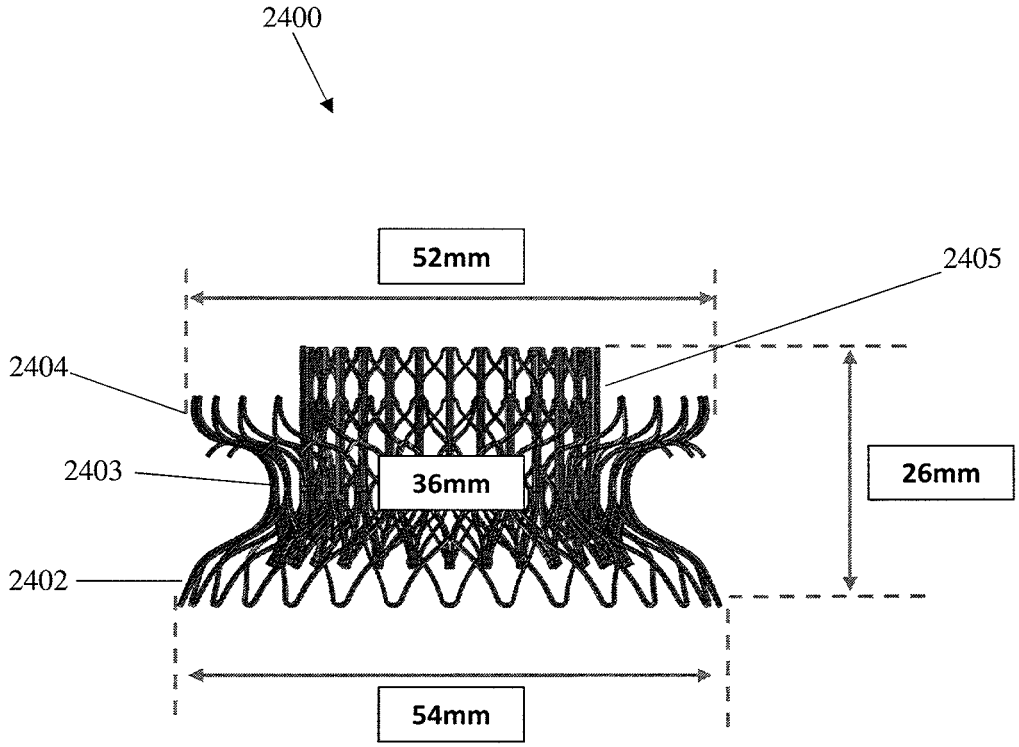


Figure 24C

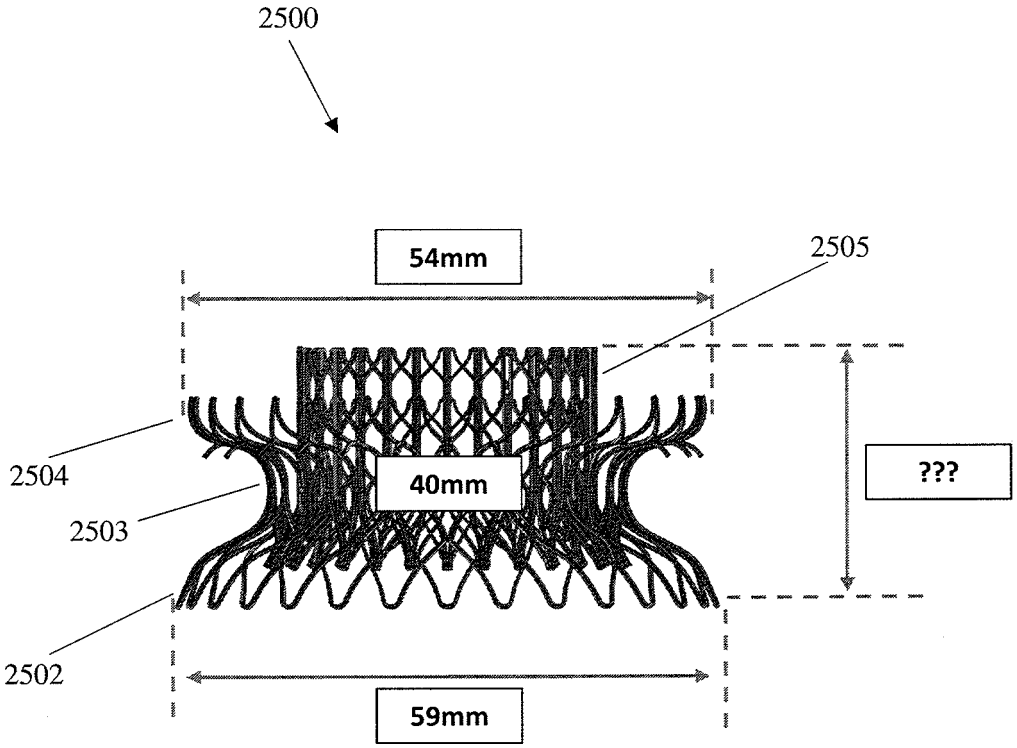


Figure 25A

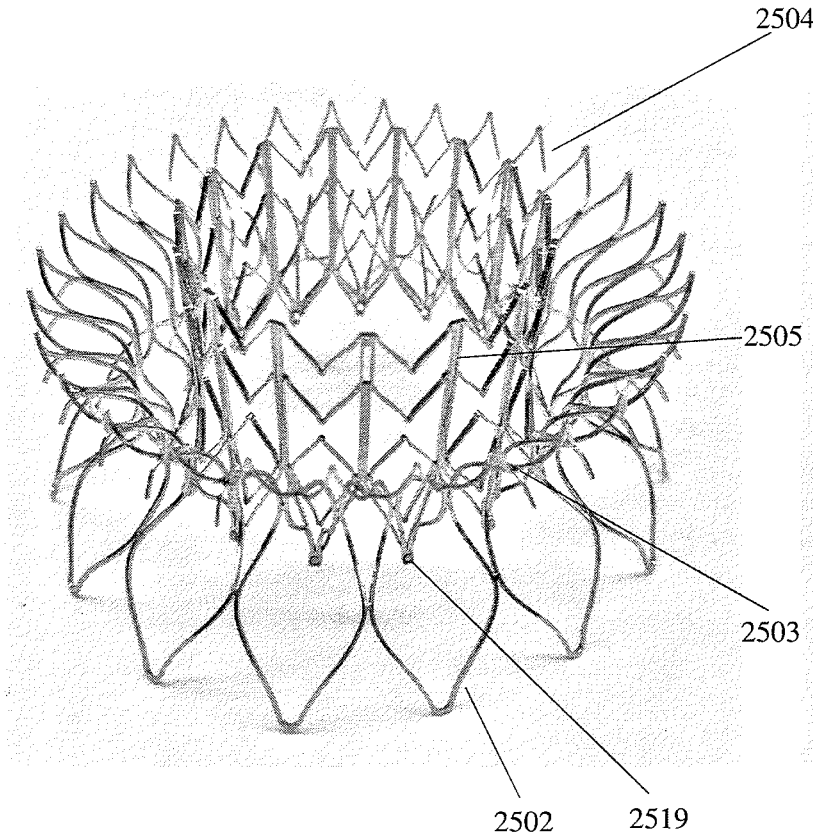


Figure 25B

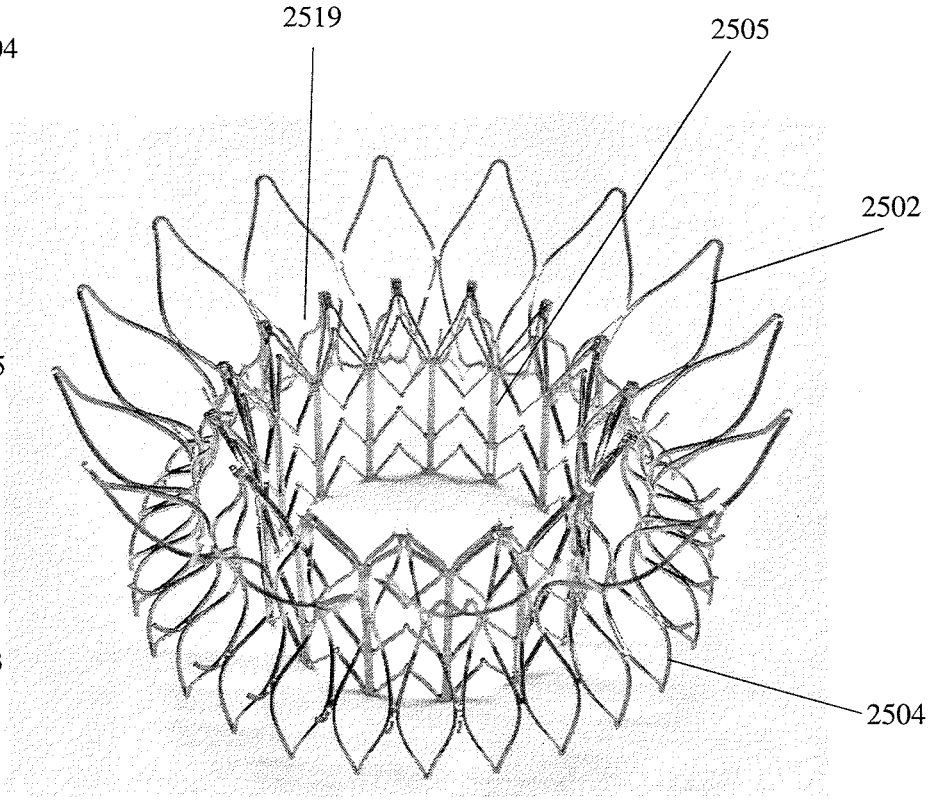


Figure 25C

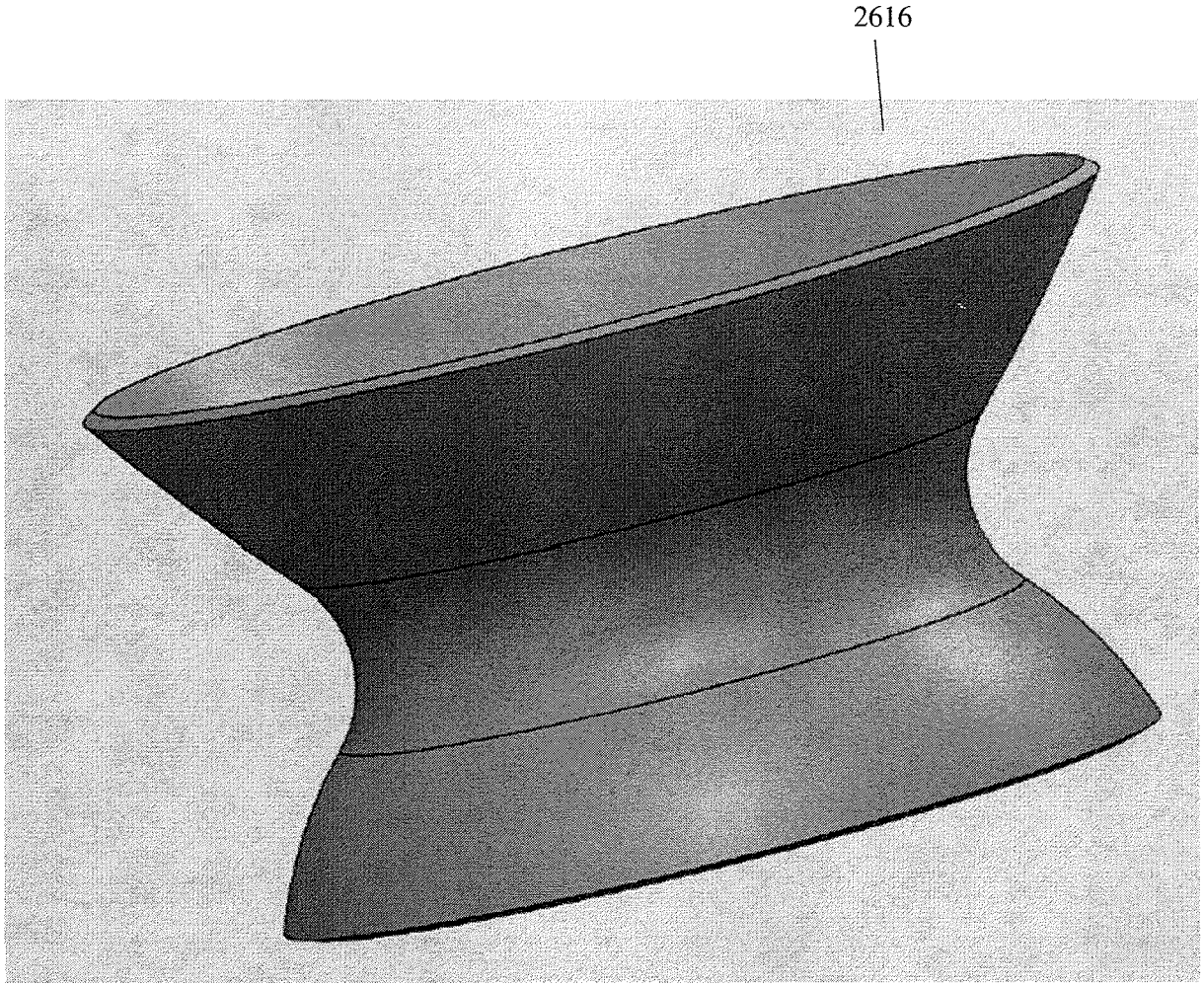


Figure 26

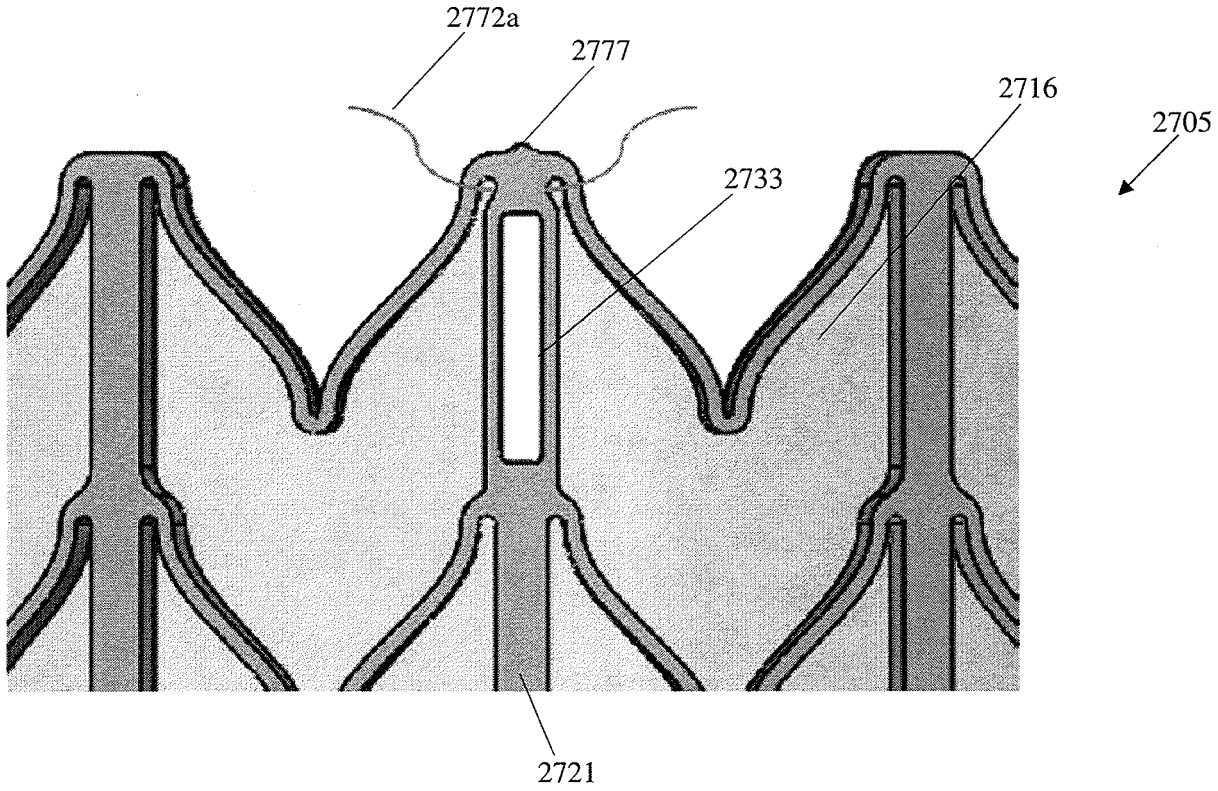


Figure 27A

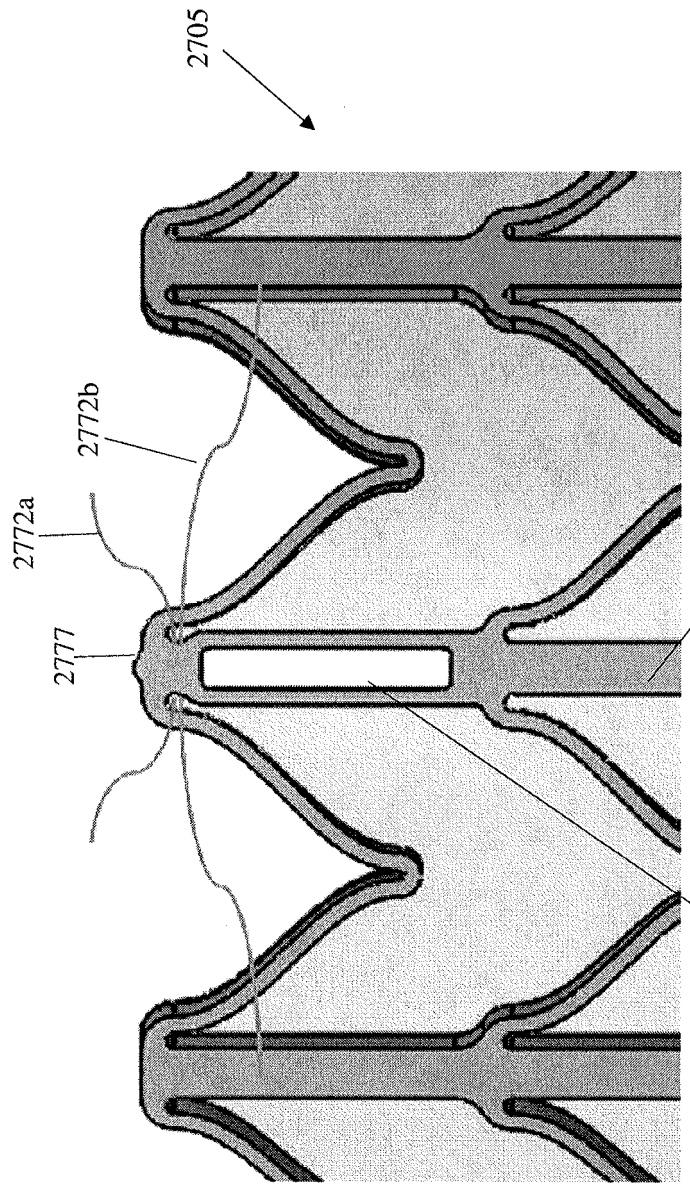


Figure 27B

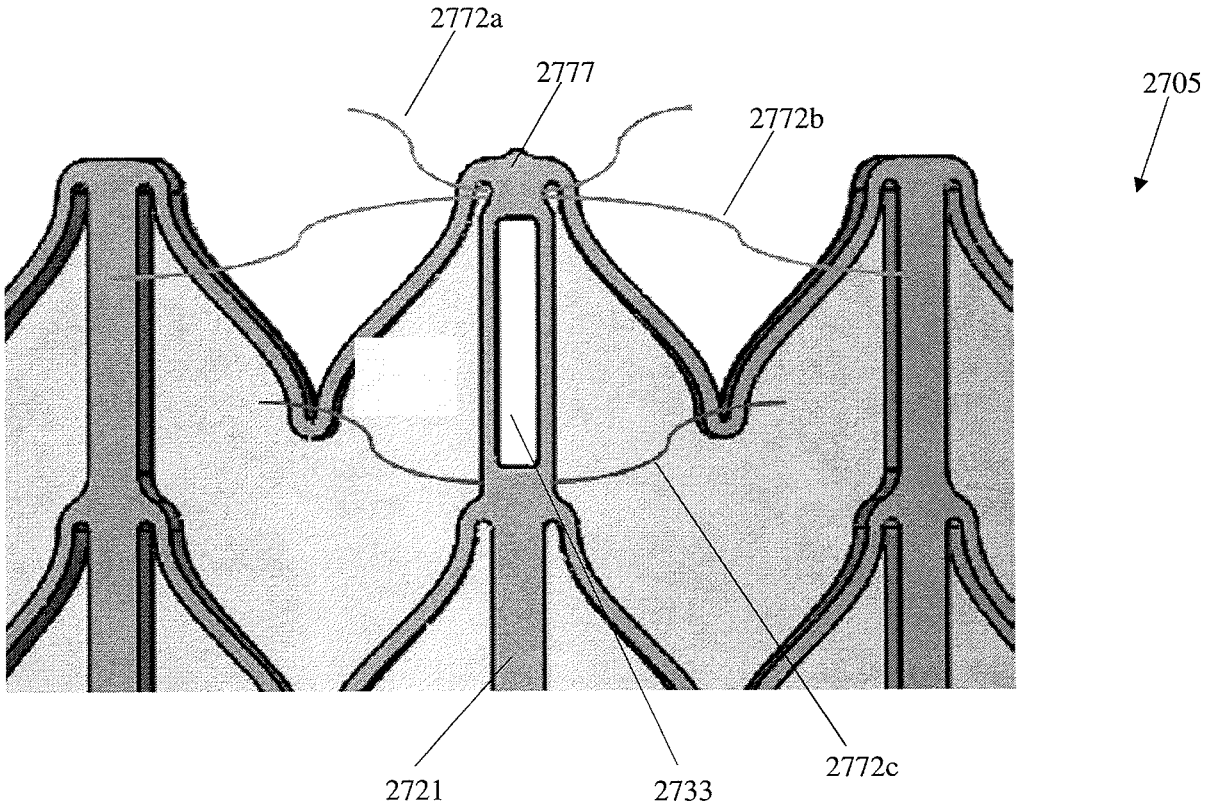


Figure 27C

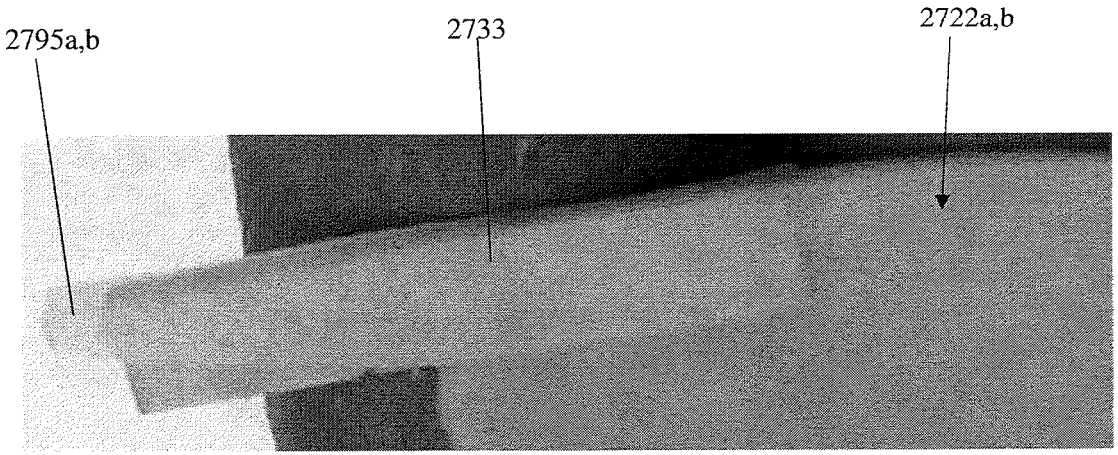


Figure 27D

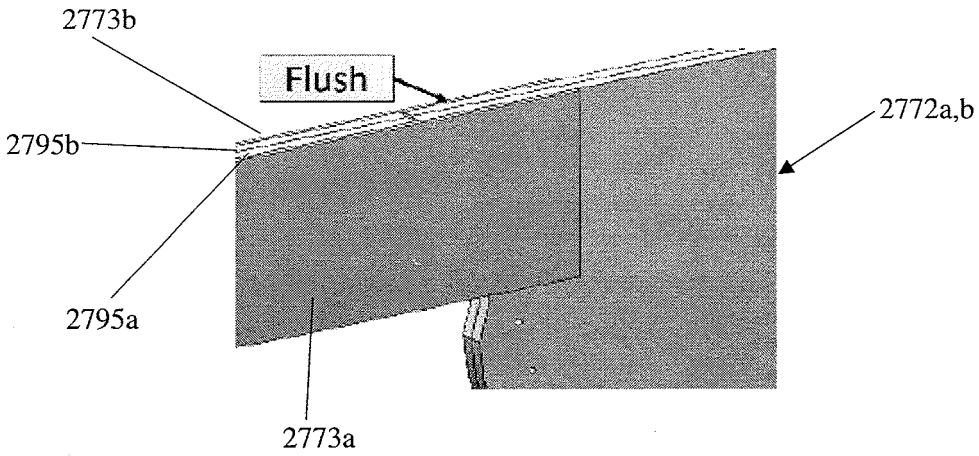


Figure 27E

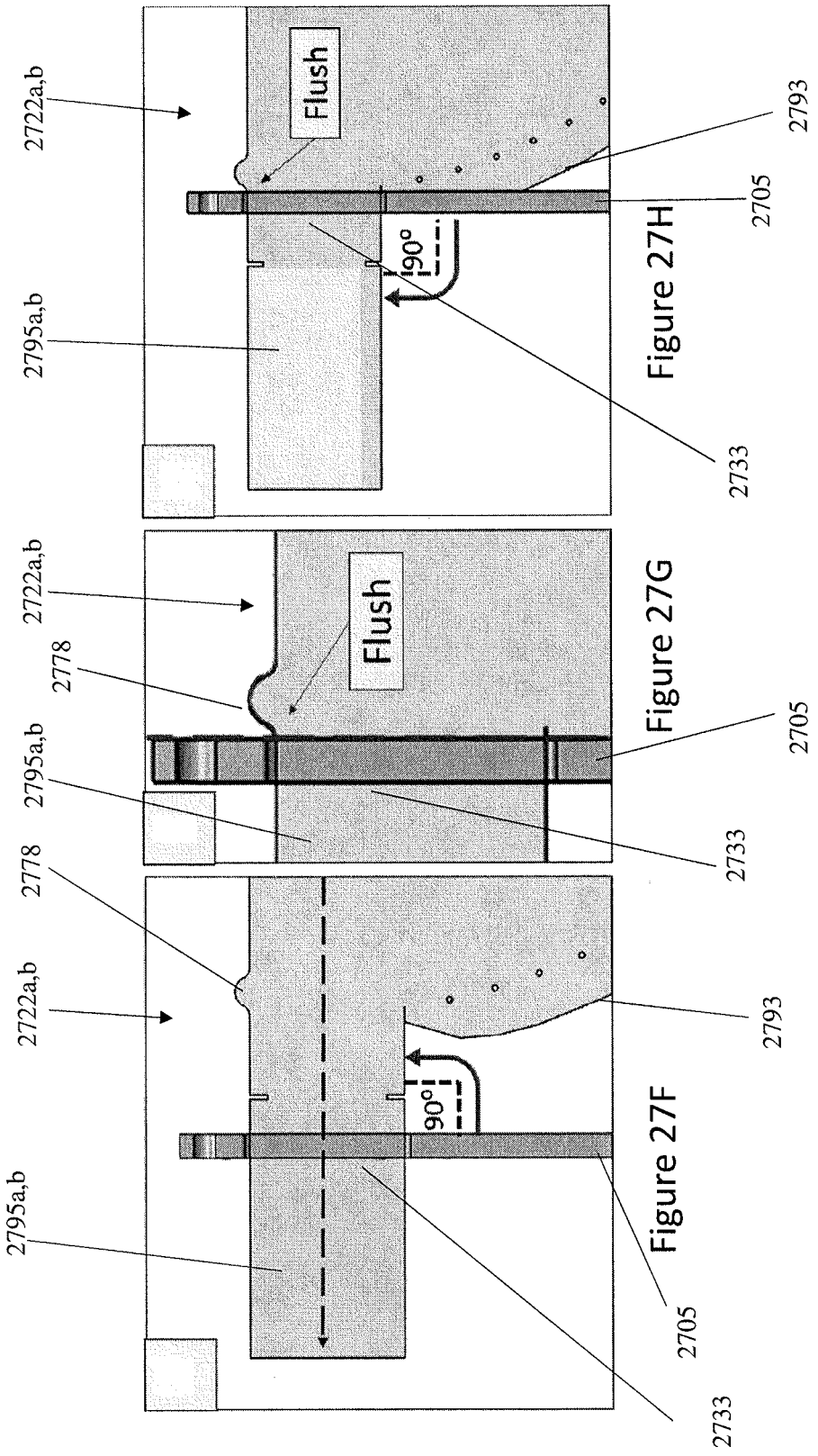


Figure 27H

Figure 27G

Figure 27F

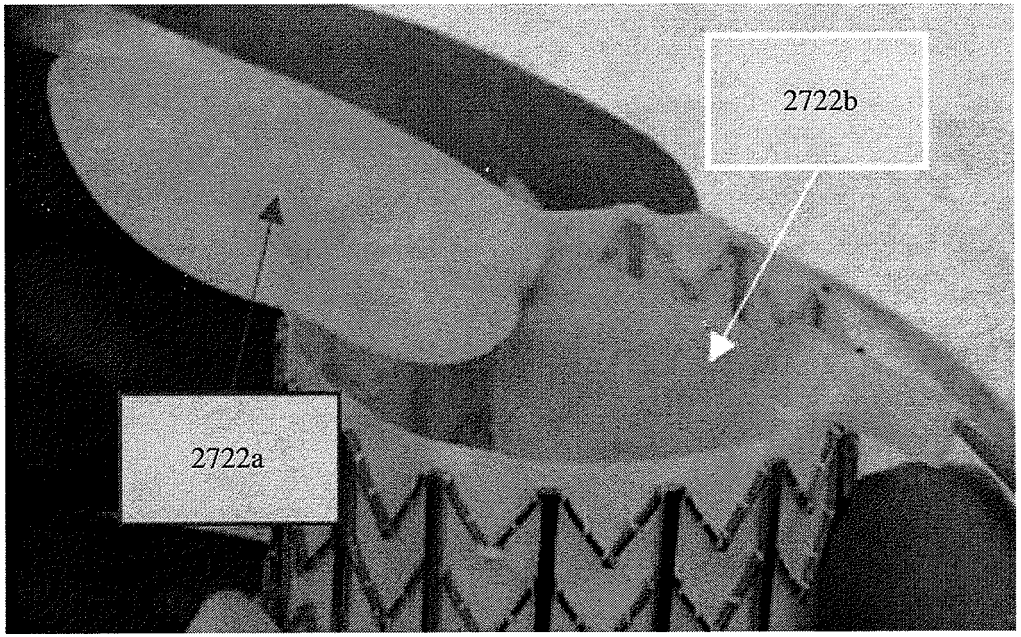
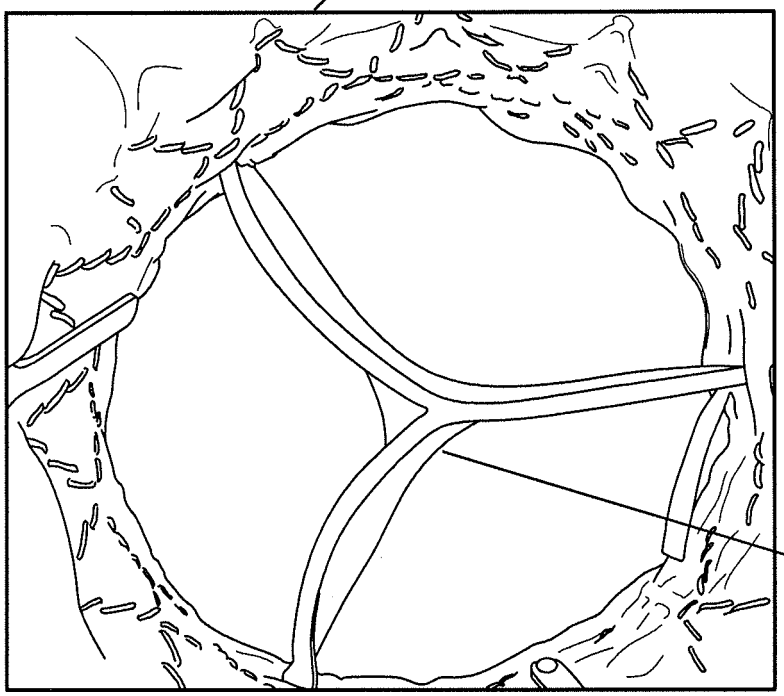
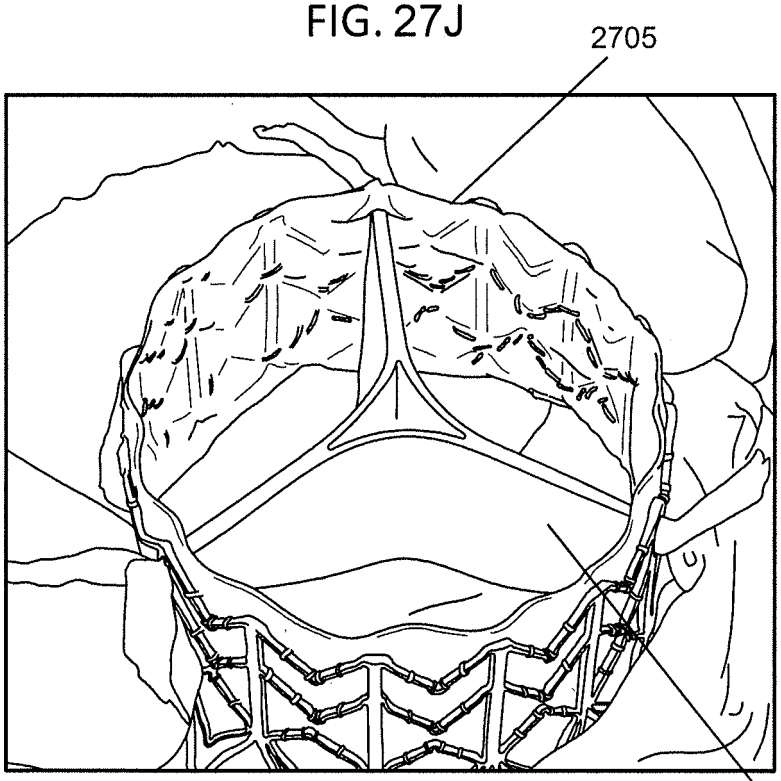


Figure 27l



INFLOW

FIG. 27J



OUTFLOW

FIG. 27K

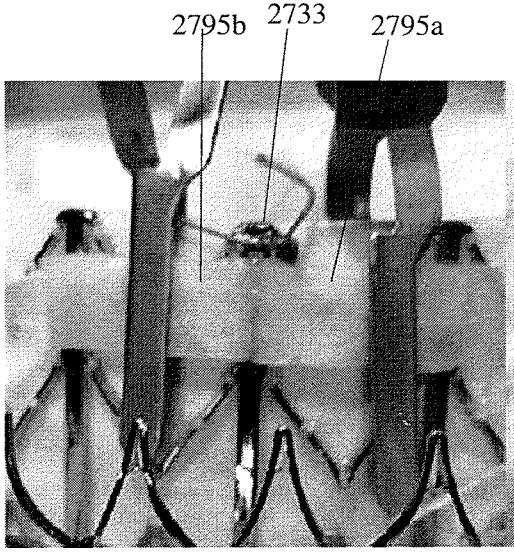


Figure 27L

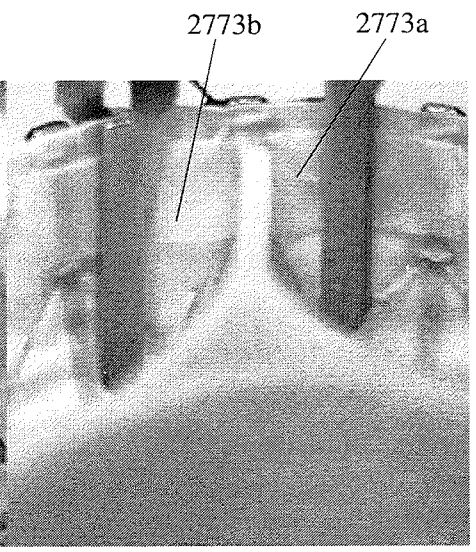


Figure 27M

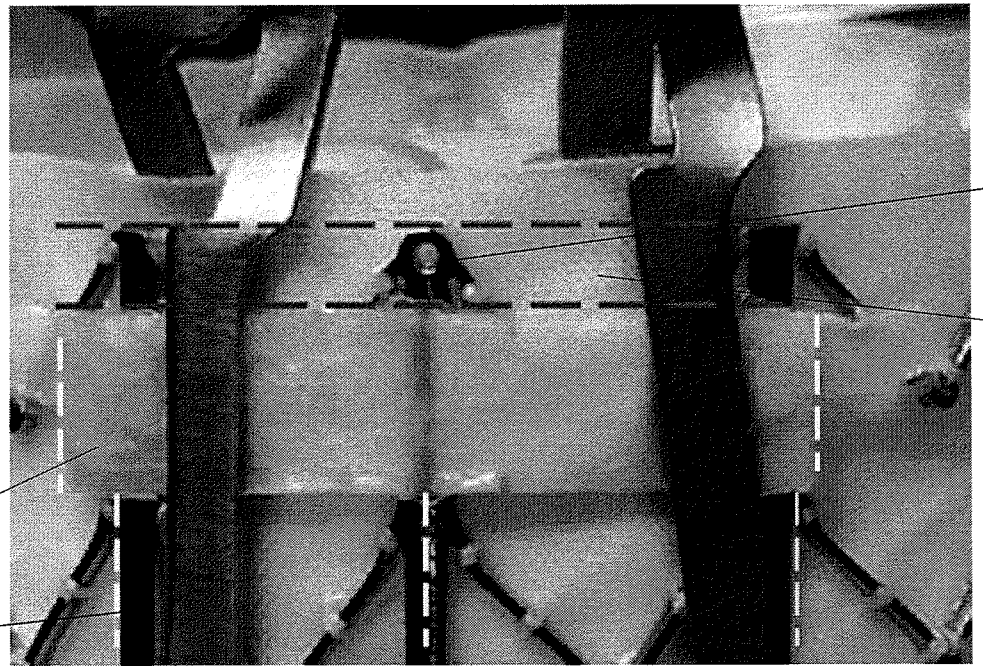


Figure 27N

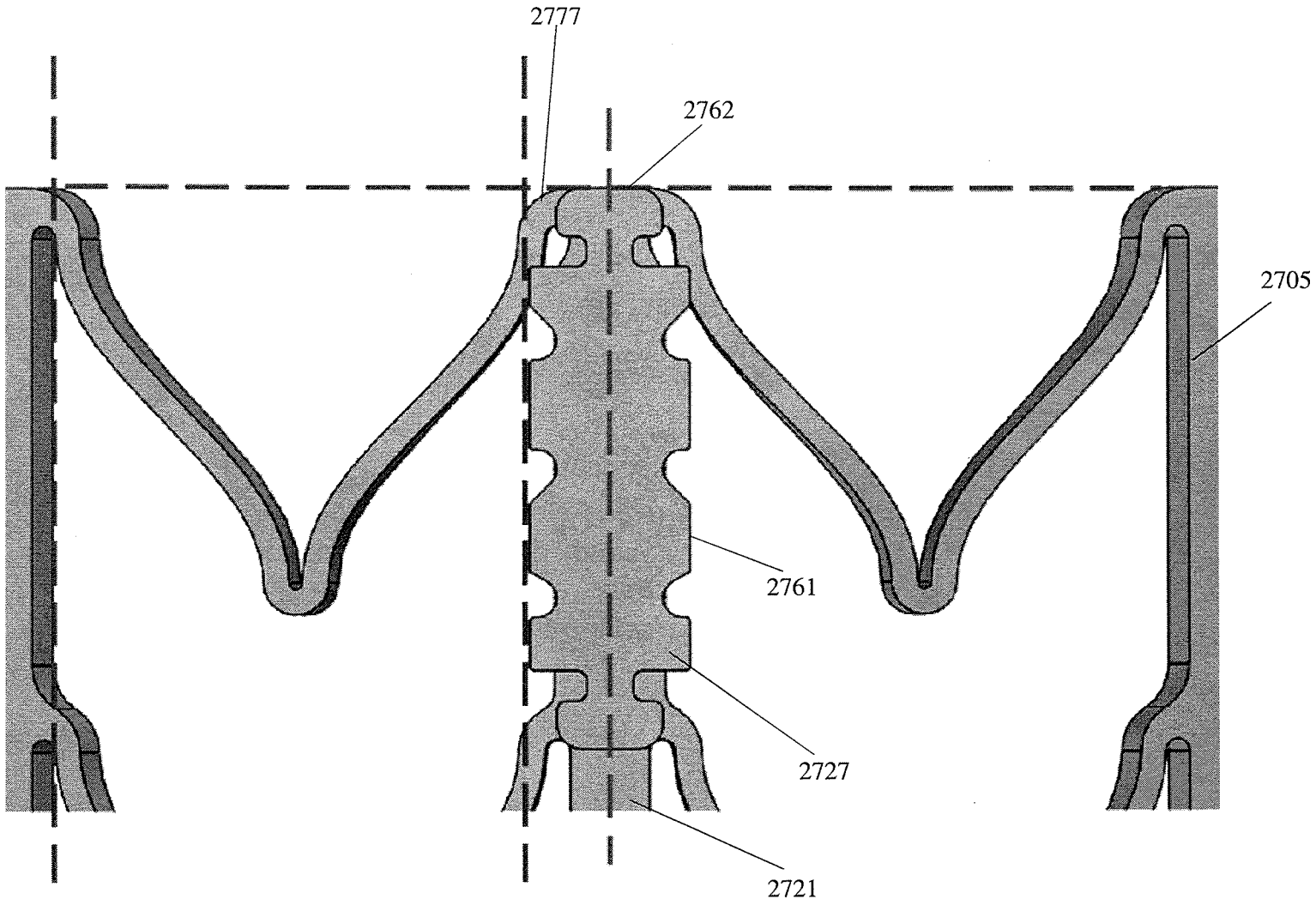


Figure 27O

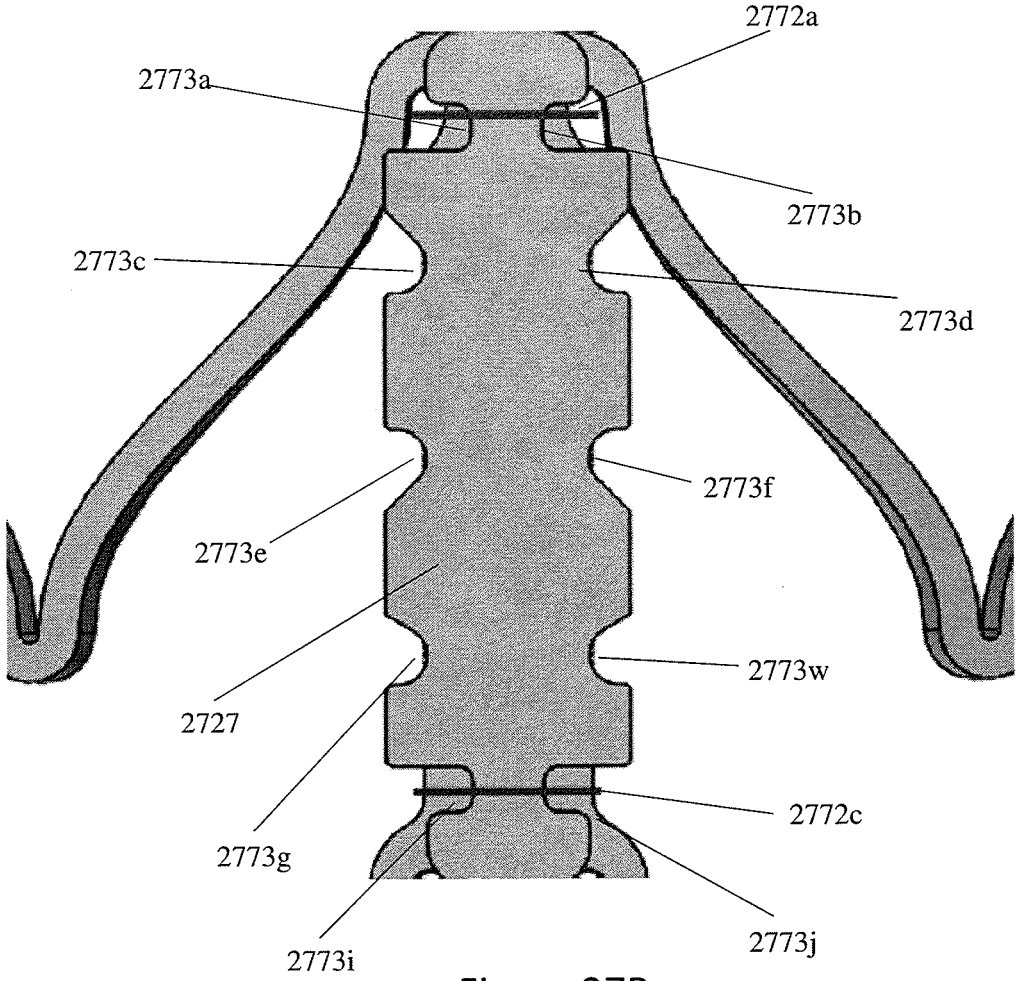

2772a
2773a
2773b
2773c
2773d
2773f
2773e
2773w
2727
2772c
2773g
2773j
2773i

Figure 27P

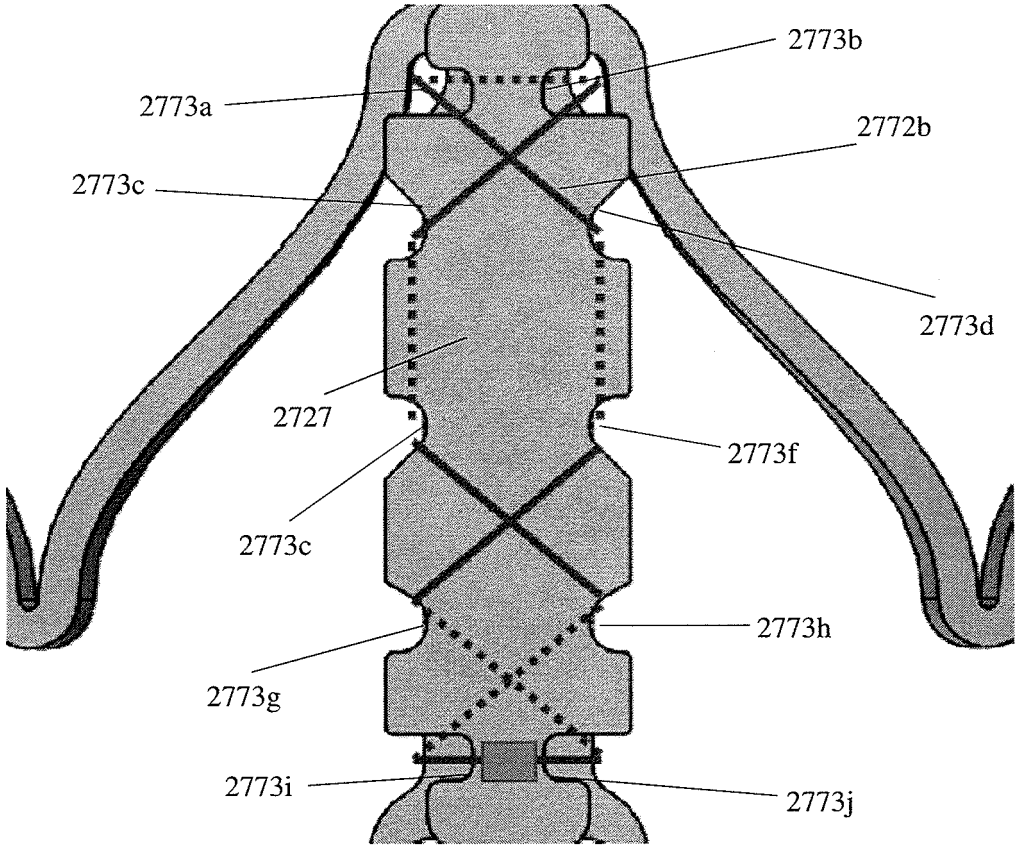

2773b
2773a
2772b
2773c
2773d
2727
2773f
2773c
2773h
2773g
2773i
2773j

Figure 27Q

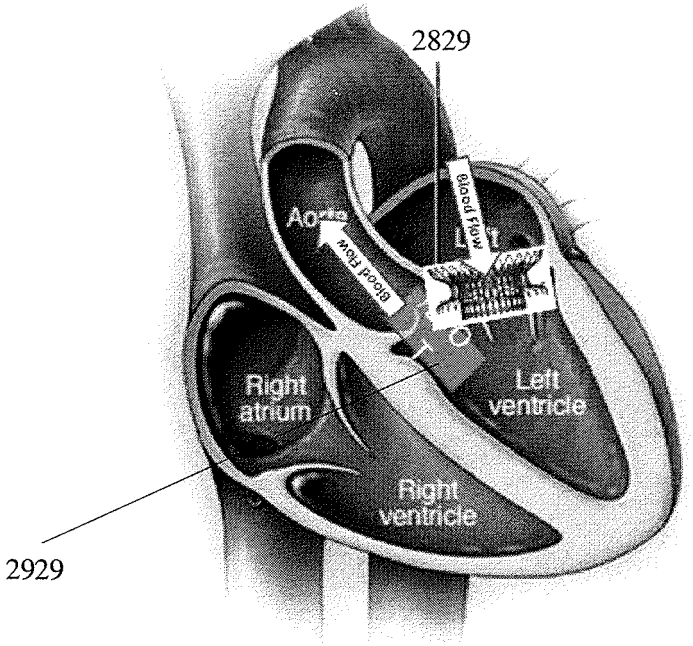

2829
Aorta
Blood flow
Blood flow
Right atrium
Left ventricle
Right ventricle
2929

Figure 28

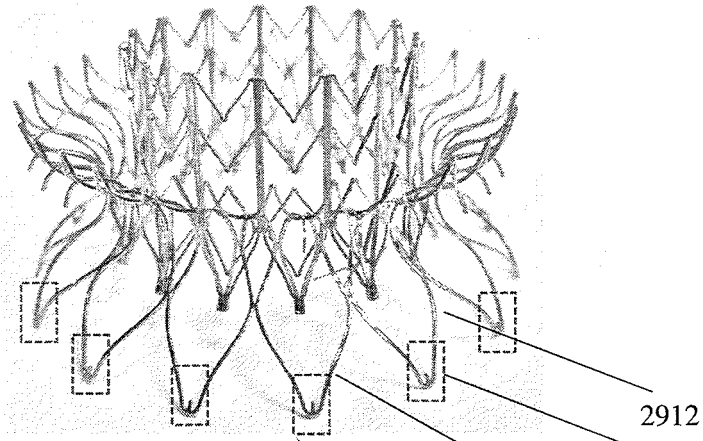


Figure 29A

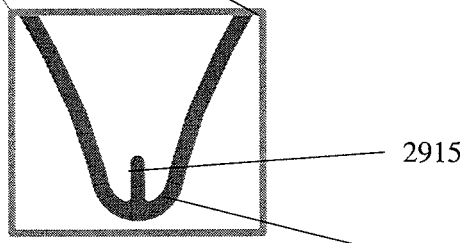


Figure 29B

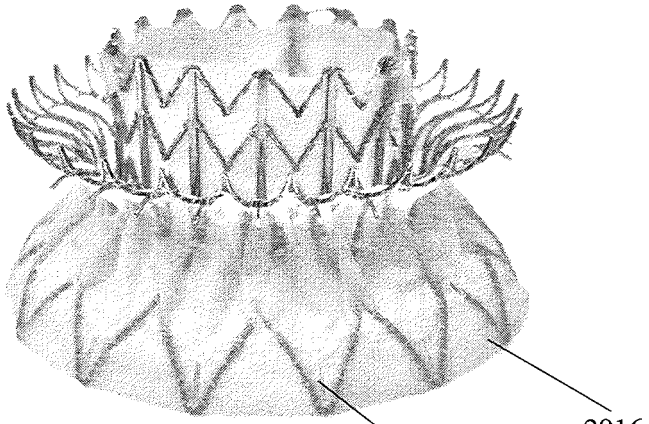


Figure 29C

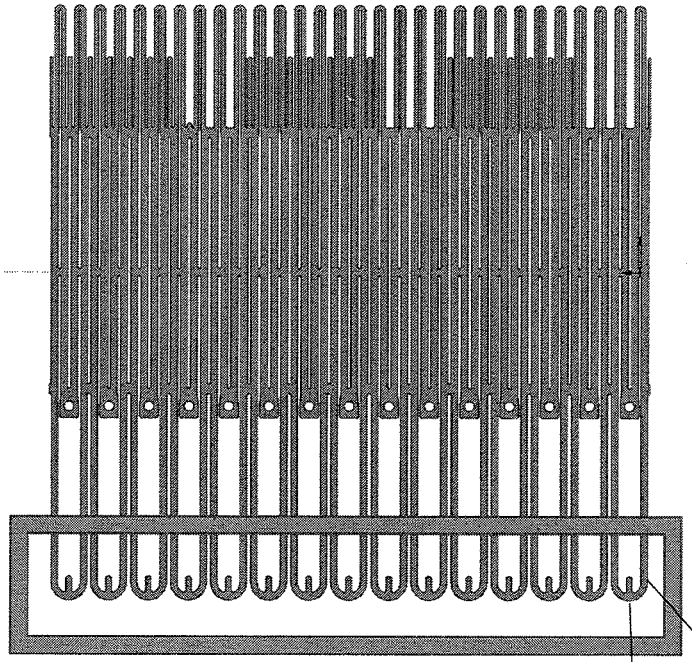


Figure 29D

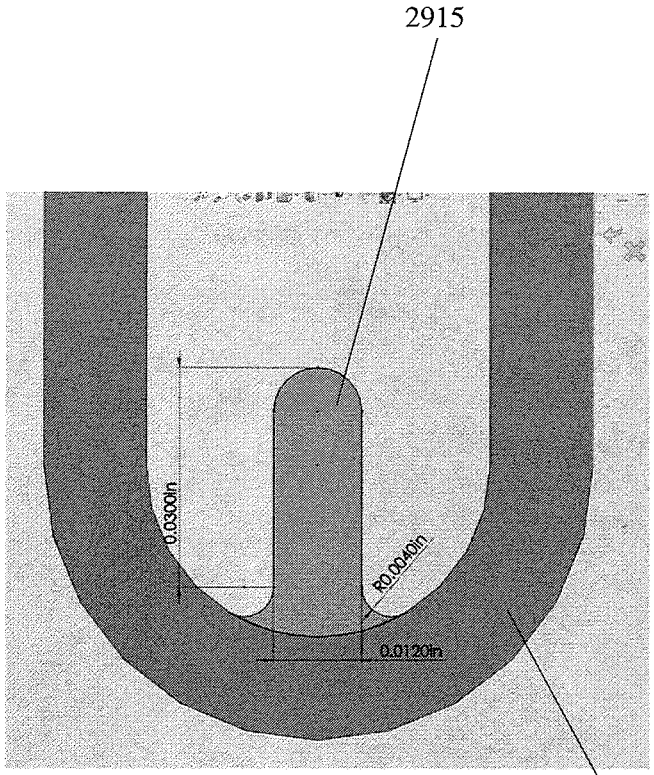


Figure 29E

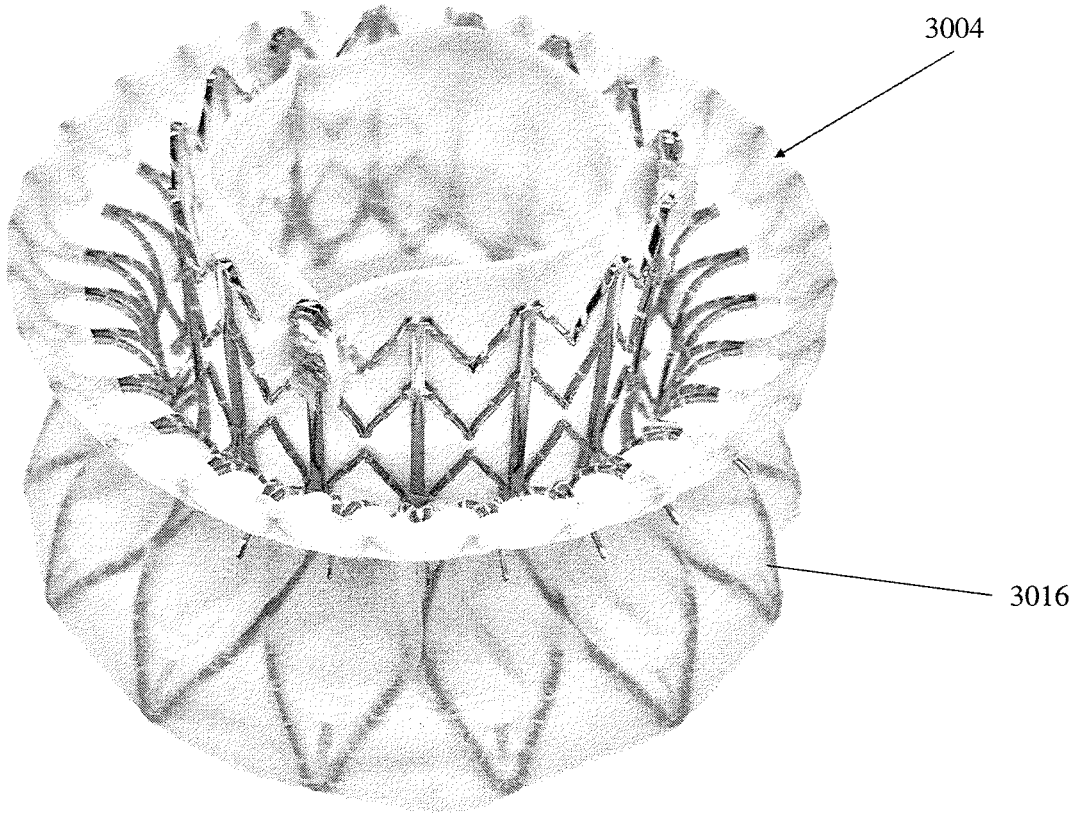


Figure 30