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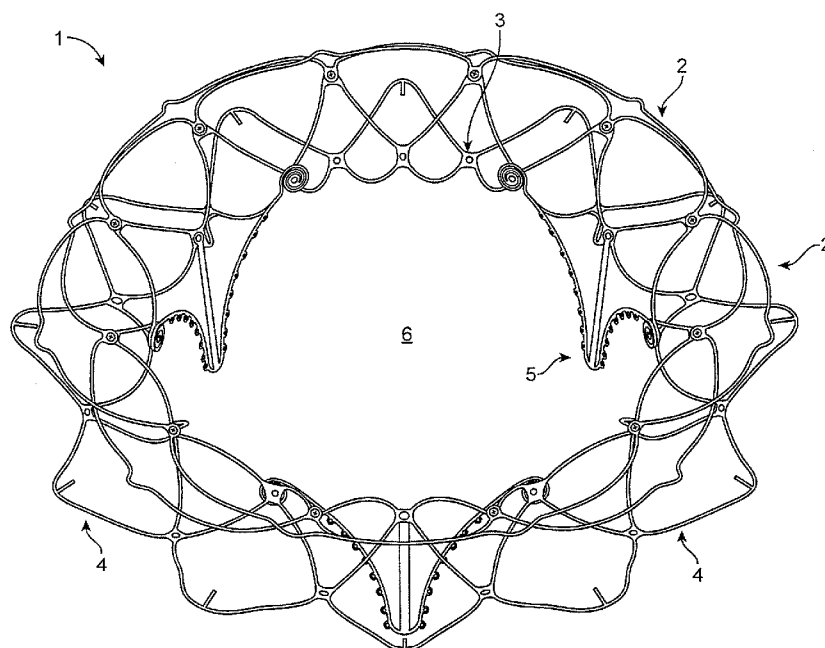


FIG. 1

(57) Abstract: Prosthetic mitral valves and their methods of manufacture and use.



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REPLACEMENT CARDIAC VALVES AND METHODS OF USE AND MANUFACTURE

CROSS REFERENCE TO RELATED APPLICATIONS

- 5 [0001] This application claims priority to Provisional Application No. 62/089,719, filed December 9, 2014, which is incorporated by reference herein.

INCORPORATION BY REFERENCE

- 10 [0002] 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

- 15 [0003] 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.
- [0004] Many patients with heart disease, such as problems with the mitral valve, are 20 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 are associated with open-heart surgery and extra-corporeal perfusion can make such procedures prohibitive.
- [0005] Patients in need of cardiac valve repair or cardiac valve replacement can be served 25 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.
- 30 [0006] 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, current cardiac valve prostheses are not designed to function effectively within the mitral valve. Further, current cardiac valve prostheses delivered via a minimally invasive 35 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. Furthermore, 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. One access route for delivering replacement mitral valves requires a transseptal approach. Delivering a replacement valve transseptally imparts limitations on the size of the delivery device and the delivery profile of the replacement valve within the delivery device, and imparts certain flexibility requirements for the replacement valve itself as it is delivered transseptally to the location of the native mitral valve. In some embodiments a sheath passing through a septum should be at most about 24F – 28F.

[0007] Many current minimally invasive valve devices are made from super-elastic Nickel-Titanium alloys. These super-elastic alloys allow high material strains, usually 6%-8%, without permanent deformation. Therefore, the alloys allow the valve devices to be packed into a small 6-10mm diameter tube for delivery while expanding to around 50mm within the heart. Current manufacturing methods typically involve cutting the valve prosthesis, at least the expandable anchor portion thereof, from a single tubular element that has a uniform thickness along its length. In these cases, the cut expandable anchor may have the same thickness along its length, and thus may not have varying stiffness along the length of the device. The inability to create an expandable anchor with varying thickness throughout can limit the functionality of different regions of the expandable anchor. Certain regions of the expandable anchor may be limited in what they can be configured to perform by creating the valve from a single tubular element. This can be undesirable if there is a need to create certain functionality in different regions of the expandable anchor that result from the regions have different thicknesses. Similarly, traditional expandable anchors made from a single tubular element do not have overlapping components (radially), wherein overlapping components may help impart additional flexibility to portions of the expandable anchor, and/or allow the expandable anchor to be collapsed to have a smaller delivery profile. Furthermore, in a single-piece construction, strains are limited to the elastic strain limit of the material, which may be too low for some applications.

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

SUMMARY OF THE DISCLOSURE

[0009] One aspect of the disclosure is a replacement mitral valve, comprising: a self-expandable anchor comprising a ventricular anchor, a central portion, and an atrial anchor, the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice, the ventricular

anchor having greater stiffness in an axial direction than the atrial anchor when the expandable anchor is in the self-expanded configuration; and a plurality of replacement leaflets secured to the expandable anchor.

[0010] One aspect of the disclosure is a replacement mitral valve, comprising: a self-expandable anchor comprising a ventricular anchor integral with a central portion, and an atrial anchor secured to the central portion but not integral with the central portion, the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice; and a plurality of replacement leaflets secured to the expandable anchor.

[0011] One aspect of the disclosure is a method of manufacturing a replacement mitral valve, comprising creating a ventricular anchor integral with a central portion; securing an atrial anchor to the central portion, the atrial portion not integral with the central portion or the ventricular anchor; and forming a self-expandable anchor that has a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice.

[0012] One aspect of the disclosure is a replacement mitral valve, comprising a self-expandable anchor comprising a ventricular anchor comprising a plurality of ventricular arches, a central portion, and an atrial anchor comprising an annular frame with a plurality of atrial arches and a plurality of atrial apertures therethrough; the atrial anchor secured to the central portion and not integral with the central portion, the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice, wherein the central portion includes a plurality of central apertures therethrough, each of the plurality of atrial apertures in alignment with one of the plurality of central apertures to form a plurality of aligned apertures; a plurality of couplers, each of which extends through one of the plurality of aligned apertures and secures the central portion to the annular frame at the location of the aligned apertures; and a plurality of replacement leaflets secured to the expandable anchor.

[0013] One aspect of the disclosure is a method of manufacturing a replacement mitral valve, comprising: providing a central portion of an expandable anchor, the central portion including a plurality of central apertures therein that are disposed around a central opening; providing an atrial anchor that includes an annular frame comprising a plurality of atrial apertures therethrough; aligning each of the atrial apertures with a central aperture to form

aligned apertures; extending a coupler through each of the aligned apertures from one side of the aligned apertures to a second side of the aligned apertures; plastically deforming each of the couplers to secure the central portion to the annular frame at the location of the couplers; and forming a self-expandable anchor that has a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice.

[0014] One aspect of the disclosure is a replacement mitral valve, comprising: a self-expandable anchor comprising a ventricular anchor, a central portion comprising a plurality of apertures therethrough that are disposed around the central portion, and an atrial anchor, the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice; an annular strut frame comprising a plurality of apertures therethrough around the strut frame, the strut frame disposed radially within the central portion, each of the plurality of annular strut frame apertures aligned with one of the plurality of central portion apertures, the annular strut frame secured to the central portion at the location of the plurality of strut frame apertures; and a plurality of replacement leaflets secured to the annular strut frame.

[0015] One aspect of the disclosure is a method of manufacturing a replacement mitral valve, comprising creating a ventricular anchor, a central portion, and an atrial anchor, the central portion including a plurality of apertures disposed around a central opening defined by the central portion; providing an annular strut frame, the strut frame comprising a plurality of apertures therethrough around the strut frame, positioning the annular strut frame radially within the central portion; aligning each of the plurality of strut frame apertures with an aperture on the central portion to create a plurality of overlapped apertures; providing a plurality of couplers, and extending a coupler through each of the plurality of overlapped apertures; plastically deforming the plurality of couplers to secure the central portion to the annular strut frame at the locations of the plurality of couplers; and forming a self-expandable anchor that has a self-expanded configuration in which the ventricular anchor portion and the atrial anchor portion are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Figure 1 shows a portion of an exemplary valve prosthesis in an expanded configuration.

[0017] Figure 2 is a side view illustrating an exemplary prosthesis including leaflets.

[0018] Figure 3 illustrates an integral central portion and ventricular anchor after being cut from a sheet of material.

[0019] Figure 4 is a perspective view illustrating an integral central portion and ventricular anchor after being rolled with ends secured.

5 [0020] Figures 5A and 5B show formation of an expanded configuration of an integral central portion and ventricular anchor using a heat shaping fixture.

[0021] Figures 6A and 6B show an integral central portion and ventricular anchor after being shape set in an expanded configuration.

[0022] Figures 7A and 7B illustrate atrial frames of an atrial anchor.

10 [0023] Figure 8 illustrates an atrial frame of an atrial anchor secured to a central portion.

[0024] Figure 9 illustrates an expanded anchor after a second atrial frame of an atrial anchor has been secured to the central portion.

[0025] Figure 10 shows formation of an expandable anchor after the atrial anchor has been secured thereto, using a heat shaping fixture.

15 [0026] Figures 11A and 11B illustrate an expandable anchor in an expanded configuration before struts have been secured thereto.

[0027] Figures 12 and 13 illustrate exemplary couplers.

[0028] Figure 14 illustrates an exemplary strut.

20 [0029] Figure 15 illustrates an exemplary expandable anchor with three struts secured thereto.

[0030] Figure 16 illustrates an exemplary prosthesis including leaflets.

[0031] Figure 17 illustrates a prosthesis including leaflets and an atrial skirt.

[0032] Figure 18 illustrates an exemplary sliding valve strut.

[0033] Figure 19 illustrates an exemplary strut frame, including a plurality of struts.

25 [0034] Figure 20 illustrates an exemplary strut frame, including a plurality of struts.

[0035] Figure 21 represents a collapsed expandable anchor, collapsed for delivery.

DETAILED DESCRIPTION

[0036] This disclosure includes replacement heart valves (also referred 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 (at least on one side) replacement mitral valves
35 configured to be delivered using minimally invasive techniques.

[0037] The replacement heart valves herein include an expandable anchor 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 axially between the atrial and ventricular anchors. The expandable anchor is adapted to be collapsed towards a collapsed delivery configuration, and is adapted to expand towards an expandable configuration. The replacement heart valves also include a plurality of struts secured to at least one of the central portion, the ventricular anchor, or the atrial anchor, the struts being secured to a plurality of replacement leaflets. The struts can be considered part of the expandable anchor, and in embodiments herein are configured to deform as the rest of the expandable anchor is collapsed. It may be possible to incorporate struts that are not deformable, but which are still secured to the expandable anchor. These types of struts may not be considered part of the expandable anchor but are secured to the expandable anchor. The struts extend distally, that is, towards the ventricular anchor. In the context of replacement mitral valves, the “distal” end of the replacement valve refers to the end of the replacement valve that is to be positioned on the ventricular side of the annulus, while “proximal” end refers to the end of the replacement valve that is to be positioned on the atrial side of the annulus. “Distally” in the context of delivery can be used to refer to a location closer to the left ventricle than the left atrium, while “proximally” is generally used to refer to a location closer to the left atrium than the left ventricle.

[0038] In some embodiment the expandable anchor is adapted to completely self-expand, and in some embodiments it is configured to be partially self-expanding and partially expand by non-self-expanding influences (e.g., a balloon). The expandable anchors can be made of (or partly made of) a super elastic material such as nitinol.

[0039] One of the advantages of some of the replacement heart valves herein, and the methods of manufacturing provided herein, is that different regions of expandable anchors can have different physical characteristics that would not have been possible with alternative designs. For example, in some embodiments the expandable anchor is manufactured from two or more separate components of material that are secured together during manufacturing. By securing two or more different components together to create the expandable anchor, different starting materials can be used for the different components, and thus different materials with different properties can be used for different regions of the expandable anchor. The different properties can be chosen to impart desired physical characteristics to different regions of the expandable anchor.

[0040] When two components are secured together during manufacturing they are considered to be non-integral, or non-monolithic, components. Different portions of the

expandable anchor that are made from the same starting material are considered to be integral, or monolithic. For example, a manufacturing step could include cutting a strut and an expandable anchor from different pieces of starting material, and securing them together, and they would be considered non-integral. In some embodiments, when one or more components are secured
5 together, the coupling of the two components can be made so that the two components are rigidly secured at the coupling, or so that the two components can move to some degree at the location of the coupling of the two components (e.g., pivotable).

[0041] In methods of use, the prostheses described herein can be delivered to a cardiac valve orifice, such as the mitral valve, by using minimally invasive techniques to access the
10 cardiac valve. Access routes and procedures are known, such as making small incisions in the patient's body and passing the prosthesis through the apex of the heart to, for example, a mitral valve. An additional exemplary access route includes delivering the valve through the venous system and into the left atrium via a transseptal puncture. A transseptal approach can impart size limitations on the delivery and thus the delivery profile of the replacement heart valve.

15 Additionally, a transseptal approach can also impart certain flexibility requirements on the replacement heart valve. The replacement heart valves herein are configured to be collapsed into a delivery configuration so they can fit within a delivery device. The replacement heart valves can be delivered to the treatment site within the delivery device and then deployed from the delivery device. If necessary, the replacement valves can be repositioned, re-sheathed (partially
20 or completely) if necessary, and then re-deployed.

[0042] 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
25 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 can be incorporated into any of the methods of delivery herein.

30 **[0043]** Replacement heart valves 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, and by applying a radial force from the center portion outward against the cardiac orifice. Additional engagement between the prostheses and cardiac tissue can be added with wire hooks extending from the valve prostheses.

[0044] Figure 1 is a perspective view of a portion of an exemplary mitral valve prosthesis in an expanded configuration after an expandable anchor and struts have been secured together.

The portion of the replacement valve shown in Figure 1 may be referred to as an anchor subassembly, which excludes leaflets and any skirts that may be incorporated into the final replacement valve. Figure 1 shows a view from an atrial side to a ventricular side. Expandable anchor 1 includes an atrial anchor 2, a ventricular anchor 4, and a central portion 3 therebetween. In this embodiment atrial anchor 2 is configured and adapted to be disposed on an atrial side of a mitral valve orifice, and ventricular anchor 4 is configured and adapted to be disposed on a ventricle side of the mitral valve orifice. In some uses, however, anchor 1 may be implanted so that atrial anchor 2 as shown is positioned on the ventricle side and ventricular anchor 4 is positioned on the atrial side. Three struts 5 are secured to the expandable anchor, and in this embodiment are secured to central portion 3, and at least a portion of struts 5 are disposed radially inward relative to central portion 3. Struts 5 are extending, or pointing, towards ventricular anchor 4 and away from atrial anchor 2.

[0045] Radially inner surfaces of the expandable anchor and the struts define central opening 6, which is radially within the expandable anchor. The radially inner surfaces of central portion 3 substantially define the perimeter of central opening 6. Replacement leaflets, which are not shown in Figure 1 for clarity, are secured to struts 5 and are disposed at least partially in central opening 6, and are configured to control blood flow therethrough.

[0046] In the expanded configuration shown in Figure 1 (which is also an “as-manufactured” configuration), atrial anchor 2 and ventricular anchor 4 extend radially outward from central portion 3, and are considered to flare outward relative to central portion 4. Atrial anchor 2 and ventricular anchor 4 can also be considered flanged relative to central portion 3. The flared configuration of atrial and ventricular anchors 2 and 4 relative to central portion 3 is described in the context of a side view of the expandable anchor, as can be seen in Figure 2 (which illustrates leaflets secured to struts). In some embodiments one or more of the flared anchors are orthogonal to a longitudinal axis “LA” (illustrated in Figure 2) passing through central opening 6. In some embodiments the flared anchor portions have a smooth curve radially outward. In some flared configuration the two anchors and the central portion define a general “C” or “U” shape in a side view of the expandable anchor. A “C” or “U” configuration is not limited to symmetrical configurations, however, as there can be slight deviation from a true “U” and still be considered to be U-shaped. For example, the expandable anchor could define a “C” configuration, but one of the atrial and ventricular anchors could have a tighter curvature than the other anchor. When the anchor portions are flared and create a “C” shaped configuration, the atrial and ventricular anchors are slightly curved inward towards the central portion at their

respective ends. In some embodiments atrial anchor 2 and ventricular anchor 4 are substantially parallel to one another, such as exactly parallel to one another. In some embodiments the configuration of the flared anchors creates a substantially constant radius of curvature (i.e., a semi-circle) so that stress across anchors 2 and 4, and central portion 4 is balanced, thereby reducing fatigue or wear at any one point along the prosthesis.

[0047] In some embodiments the expanded anchor 1 (not including the struts) has a length "L" (see Figure 2, measured from the atrial end to the ventricular end, parallel to the longitudinal axis LA) of 6-12mm, such as 6-11mm, 6-10mm, 6-9mm, 7-11 mm, 8-10mm, 6 mm, 7mm, 8mm, 9mm, 10mm, 11mm, and 12mm. In some embodiments the length of the expanded prosthesis, including the struts ("LS" as shown in Figure 2), has a length of 16-20mm, such as 17-19mm, 16mm, 17mm, 18mm, 19mm, and 20mm with the struts. In some embodiments, the expanded anchor has an expanded diameter ("D" in Figure 2) of about 35 mm to about 75 mm, such as about 45 mm to about 65 mm. In some of those embodiments the device is configured to be collapsed to a collapsed configuration in which it has a collapsed diameter D of 7mm to 12mm (i.e., the prosthesis can be collapsed down to fit within a 21-36 French catheter). In some embodiments the central opening 6 diameter ("DC" in Figure 10A) is between 20 mm and 45 mm, such as between 25 mm and 40 mm, such as between 28 mm and 38 mm. In embodiments in which central opening 6 is not a perfect circle, the central opening diameter refers to the greatest linear dimension between points on the central portion, when viewed in an end view such as Figure 10A.

[0048] Additionally features of exemplary expandable anchor 1 will now be described in the context of an exemplary method of manufacturing the expandable anchor 1. Other manufacturing processes, whole or partial, can be used as well. Figures 3-6B illustrate an exemplary method of manufacturing a ventricular anchor 4 and central portion 3 that are integral, or monolithic. Figure 3 illustrates integral central portion 4 and ventricular anchor 3 of expandable anchor 1 that have been cut (e.g., laser cut) out of a flat sheet of material. In some embodiments the material is a nitinol sheet, and in some exemplary embodiments the nitinol sheet is 0.3mm to 0.35mm thick. In these embodiments the ventricular anchor and central portion are thus 0.3mm to 0.35mm thick.

[0049] In this embodiment central portion 3, when cut, comprises a plurality of diamond-shaped cells 7 (only one labeled for clarity), as shown in the dotted lines in Figure 3. In this embodiment there are twelve cells 7 in central portion 3, all of which have a general diamond shape when laid flat, as in the view shown in Figure 3. Central portion 3 can have fewer or more cells, the cells can have configurations other than general diamond shapes, and the cells need not all have the same configuration. In this embodiment each central portion cell 7 has an aperture

26 at one of the bends in the diamond shape near the atrial end of central portion 3, but in other embodiments not every cell 7 has an aperture 26. For example, every other cell could have an aperture 26. In this embodiment apertures 26 are aligned axially (i.e., as shown they are in a “row”), but in other embodiments there are not. For example, if the cells have different configuration some apertures 26 may not be aligned, or in the same “row” with other apertures. Central portion 3 also includes a plurality of apertures 36 formed in material where adjacent cells 7 meet, as shown in Figure 3. In this embodiment apertures 36 are axially aligned, but in other embodiments they need not be aligned. In this embodiment apertures 36 are in the middle of cells 7 measured in an atrial-to-ventricular end direction (up and down in Figure 3).

[0050] Expandable anchor 1 also includes ventricular anchor 4. In this embodiment ventricular anchor 4 includes a plurality of arches 42 that extend from the central portion towards the ventricular end. The configurations of arches 42 are generally triangular-shaped, “pointing” towards the ventricular end, and include two sections of material and a bend in between the two sections of material. As shown, in each arch 42, the material first extends away from central portion 4, forms a bend at the ventricular end of the anchor, and then extends back towards central portion 4. Arches 42 are triangular shaped in this embodiment, and the ventricular ends can be described as tips of the arches, and in this embodiment are rounded. A plurality of spaces 49 (only two are labeled for clarity) between adjacent arches 42, the configurations and sizes of which are defined by the configuration of adjacent arches 42, are configured to advantageously allow the sub-valvular structures, such as chords, to slide between adjacent arches 42 when the ventricular anchor is expanded on the ventricular side of the mitral valve annulus. The configuration of arches 42, and thus the plurality of spaces 49, can also provide easier collapse of the ventricular anchor 3 radially inwards when the anchor is collapsed (e.g., for delivery). The arch 42 tips at the ventricular end are rounded, or curved (as opposed to abrupt or sharp) to avoid damaging the tissue when implanted. Additionally, the tip of each arch 42 includes optional hooks 44 extending from the tip. The hooks 44 can face in towards the central opening 15 and embed into the annulus tissue, thereby helping to resist the pressure build-up on the ventricular side of the aorta.

[0051] In some embodiments any of apertures 26, 36, and 46 can be circular. In some embodiments any of the apertures (such as all of them) can be between 0.3mm and 0.8mm in diameter, such as 0.4mm- 0.7mm, 0.5mm – 0.6mm, 0.3mm, 0.4mm, 0.5mm, 0.6mm, 0.7mm, and 0.8mm in diameter.

[0052] In the embodiment in Figure 3 the same starting material is used to make the central portion 3 and ventricular anchor 4. In this embodiment ventricular anchor 4 and central portion 4 are cut from a flat sheet of material (e.g., nitinol). In other embodiments the integral central

portion 3 and ventricular anchor 4 can be cut from a tubular starting material. After ventricular anchor 4 and central portion 3 are cut as shown in Figure 2, a next step in manufacturing the expandable anchor is that it is then rolled into a generally cylindrical configuration and the ends of the material are secured together, as shown in the generally cylindrical configuration in the perspective view of Figure 4. In this embodiment apertures 36a and 36b, and 46a and 46b, (Figure 3) are secured together once the apparatus is reconfigured into the cylindrical configuration in Figure 4. An exemplary method of securing the ends is by riveting the ends at the apertures, wherein a rivet is placed within aligned apertures 36a and 36b, and then the free rivet end is deformed to secure the ends of the apparatus and maintain the cylindrical configuration shown in Figure 4.

[0053] Alternatively, in some embodiments, integral central portion 3 and ventricular anchor 4 can be cut from a tubular element to form the configuration in Figure 4. In these embodiments ends of the device need not be coupled together since the apparatus has the configuration in Figure 3 when cut from the tubular element.

[0054] Once the apparatus is in the cylindrical configuration shown in Figure 4 (whether cut from a flat sheet and rolled, or cut from a tubular element, or from another process), an exemplary subsequent step is to reshape the partial anchor into a shape memory configuration. Figures 5A-6B illustrate an exemplary shaping process and resulting reconfigured apparatus. As shown in Figures 5A and 5B, the generally cylindrical shaped device is placed in a heat shaping fixture 99. Once in the heat shaping fixture, the column can be heated, such as in a salt bath at 915 degrees for 3 minutes, and then quenched in water in order to set the shape of the ventricular anchor and central portion. The shape memory configuration of the integral central portion 3 and ventricular anchor 4 are shown in the perspective views in Figures 6A and 6B. Figure 6A shows a perspective view looking from the central portion to the ventricular anchor, and Figure 6B shows a view looking from the ventricular anchor to the central portion. The reference numbers in Figures 6A and 6B are described herein. A side view of the configuration of the anchor from Figures 6A and 6B can also be seen in the replacement valve in Figure 2, but the atrial anchor and leaflets have not been added yet to the partial device shown in Figures 6A and 6B.

[0055] In this exemplary embodiment, once the integral ventricular anchor 4 and central portion 3 are shape set (as shown in Figures 6A and 6B), atrial anchor 2 is secured to central portion 3. In this embodiment atrial anchor 2 comprises first frame 122 and second frame 222, which are shown in Figures 7A and 7B, respectively. In this embodiment frame 122 and 222 have the same configuration and are interchangeable. In this embodiment second frame 222 is an inner frame, and first frame 122 is an outer frame in that first frame 122 is disposed radially outward relative to inner frame 222. Inner frame 222 also sits proximal to outer frame 122,

although in this embodiment the two atrial frames have the same configuration and thus their designation of inner and outer can be switched.

[0056] As shown in Figures 7A and 7B, atrial frame 122 includes a plurality of arches 111a-111f (also referred to herein as arcs, arcuate portions, curved portions, or petals), and atrial frame 222 includes a plurality of arches 211. In this embodiment each arch 111 includes a peak 113, and adjacent arches meet at valleys 115 (only one peak and two valleys labeled for clarity). A peak is generally considered the location where the radial distance from the valley is greatest. In this embodiment there are six peaks and six valleys in each of frames 122 and 222. In this embodiment each frame includes apertures disposed at each of the frame valleys. Frame 122 includes six apertures 116 (one labeled), in this embodiment one at each valley 115. Frame 222 includes six apertures 226, one at each valley. In other embodiments a frame may include more or fewer arches, such as between two and fifteen arches.

[0057] Atrial frame 222 includes arches 211a-211f, each comprising a peak, and valleys one either side of a peak. The arches 211 meet at the valleys, each of which has an aperture 226 therethrough. In this embodiment all of the arches, on both of frames 122 and 222, comprise a protuberance or extension 118 (only one protuberance labeled, which is on frame 122 in Figure 7A) near the center, or midline, of each arch. The midline is the middle of the length of the arch, as measured linearly between valleys on either side of the arch. The protuberance is a portion of the arch that has increased curvature relative to adjacent portions of the arch. During collapse of the prosthesis, the protuberances 118 can be pulled upon, providing easier collapse and reducing strain in the arches when the anchor is collapsed (e.g., for delivery).

[0058] In some embodiments either or both of atrial frames 122 and 222 are cut out of a flat sheet, such as a sheet of nitinol, as in the case in Figures 7A and 7B. In some embodiments the sheet of nitinol is 0.2 to 0.25mm thick, which results in frames that are 0.2 mm to 0.25 mm thick. In this embodiment all of the arches on each frame are integral, or made from the same starting material. Frames 122 and 222 have an annular configuration, as can be seen in Figures 7A and 7B, even though they are not perfectly annular. Annular in this context refers to structures (e.g., atrial frames) that, once assembled as part of the expandable anchor, subtend 360 degrees around a longitudinal axis LA of the expandable frame. In other words, they are generally annular even though they are not perfectly annular. A longitudinal axis as used herein does not impart symmetry to the replacement heart valve, but generally refers to an axis that passes through a central portion of the central opening in the expandable anchor.

[0059] In the manufacturing of the expandable anchor, atrial frames 122 and 222, once formed (e.g., cut), are secured to central portion 3. In this embodiment there are twelve apertures 26 at one end of central portion 3, as can be seen clearly in Figure 3. Each of frames 122 and

222 has six apertures 116 and 226, respectively, and in this embodiment each one disposed in a valley of the frame between arches. To secure atrial frame 222 to central portion 3, each aperture 226 is aligned with an aperture 26 in central portion, the relative positions of which can be seen in Figure 8. Figure 8 shows frame 222 assembled to central portion 3 at a plurality of aligned apertures. In this embodiment frame 222 and central portion 3 are configured, including the location of the apertures, such that apertures 226 on frame 222 are aligned with alternating apertures 26 in central portion 3, as shown in Figure 8. In this embodiment frame 222 and central portion 3 are secured together at the location of the aligned apertures by riveting the components together at the locations of the apertures. A rivet is placed through two aligned apertures, and then one side of the rivet is plastically deformed to secure the atrial frame to the central portion at the location of the aligned apertures.

[0060] After frame 222 is secured to central portion 3 (which can be seen in Figure 8), frame 122 is secured to central portion 3 in the same manner, except in this embodiment the six apertures 116 in frame 122 are first aligned with the six apertures 26 that are not yet riveted to frame 222 (the six “open” apertures 26 can be seen in Figure 8). Figure 9 shows the expandable anchor after frame 122 is secured to central portion 3, which in this embodiment is also done with rivets like frame 222. Frames 122 and 222 are rotationally offset with one another with respect to central portion (which can be seen in Figure 9), and in this embodiment the peaks of one frame are rotationally aligned with a valley of the other frame. Frames 122 and 222 overlap at frame sections between the valleys and peaks, and are in contact with one another where they overlap (but in other embodiments the memory configuration may be such that frame are slightly apart such that they do not contact one another where they overlap), which can be seen in Figure 9. In this embodiment the frames overlap between the peaks and valleys. In this configuration arches 111 and 211 of the two frames are considered to be out of phase relative to one another, as can be seen in Figure 9. For example, arches 111 can be approximately 30 degrees out of phase relative to arches 211. That is, arches 111 of the first frame 122 can overlap with arches 211 of the second frame 222 such that, for example, a single arch 111 of the first outer frame 122 overlaps with half of two underlying arches 211 of the second outer frame 222. In some embodiments, only some arches are out of phase with one another while other arches are in-phase with one another. When frames 122 and 222 are secured to central portion 3, the combination of overlapping frames 122 and 222 can form a substantially circular, or annular, outer perimeter (in an end view of the device such as in Figure 9), which can provide a smooth surface to sit against the atrial tissue.

[0061] Frames 122 and 222 are secured to central portion 3, but they are not directly attached to one another. This configuration allows for relative movement between frames 122

and 222. The relative movement around atrial anchor 2 may allow for atrial anchor 2 to conform better to the tissue on the atrial side of the annulus (there may be patient to patient variability) and help seal the expandable anchor in place better on the atrial side. For example, an arch 111 can be movable relative to the two arches 211 that it overlaps. That is, the outer perimeter of an arch 111 can flex in the direction of the longitudinal axis (axially) and/or translate relative to the two arches 211 that it overlaps, while the radially inner portions of the frames are secured to the central portion of the expandable anchor. The outer perimeter of the atrial anchor essentially creates a substantially circular, or annular, flexible seal whose arches can flex as needed relative to overlapping arches to better conform to the patient's anatomy and help create a better seal against atrial tissue.

[0062] After atrial anchor 2 is attached to central portion 3 (shown in Figure 9), the expandable anchor can be heat shaped again. Figure 10 shows the expandable anchor (ventricular anchor 4 arches 42 can be seen in Figure 10) after it is placed into a shaping fixture 303 and heated, such as at 915 degrees for 3 minutes, and then quenched in water to form the expandable anchor. The configuration of the expandable anchor after this shape setting step is shown in Figures 11A and 11B, with reference numbers described above.

[0063] The exemplary expandable anchor shown in Figures 11A and 11B, which is shown in an expanded memory configuration, has a ventricular anchor and an atrial anchor that are flared radially outward relative to the central portion such that the self-expandable anchor is configured to secure the replacement mitral valve to a mitral valve orifice in the self-expanded configuration. In this embodiment ventricular anchor 4, which includes plurality of arches 42, has a greater stiffness in the axial direction than the atrial anchor when the expandable anchor is in the expanded configuration. Figure 2 illustrates hypothetical axially forces "F" applied to the ventricular and atrial anchors, upon which ventricular anchor 4 has a greater resistance to deformation than atrial anchor 2. The stiffness comparison is generally considered in response to a hypothetical applied force on the radially outer portions of the ventricular and atrial anchors, as shown by forces F in Figure 2.

[0064] One aspect of the embodiment in Figures 1-11B that contributes to the ventricular anchor being stiffer than the atrial anchor in an axially direction is that, in this embodiment, the arches in the ventricular anchor have a thickness that is greater than the thickness of each of atrial frames 122 and 222, and thus the thickness of the arches in the two atrial frames. In this embodiment, however, the thickness of the atrial anchor at the location where the frames overlap is thicker than the thickness of the ventricular arches due to the double layer of material at the overlapping locations. In some merely exemplary embodiments the ventricular arches are 0.3mm to 0.35mm thick, which can be provided by cutting the ventricular anchor portion from a

sheet of material that is 0.3mm to 0.35mm thick. In some embodiments the atrial anchor frames, and thus the arches, are 0.2mm to 0.25mm thick.

[0065] An additional aspect of the embodiment in Figures 1-11B that contributes to the ventricular anchor being stiffer than the atrial anchor is that the ventricular anchor is formed integrally with the central portion, whereas the atrial anchor portion is made from different starting material and then attached to the central portion. While this embodiment includes two different frames in the atrial anchor portion, in some embodiments the atrial anchor includes only one of the frames. For example, in some alternate embodiments, there is only one atrial frame, which comprises a plurality of peaks and valleys. In these alternative embodiments, while there are not any overlapping arches and thus no relative movement between overlapping arches, the ventricular anchor is still stiffer than the atrial anchor, in part due to the points of attachment between the central portion and the atrial anchor, and because the ventricular anchor has thicker arches than the arches of the atrial anchor.

[0066] In some alternative embodiments the ventricular anchor arches have the same thickness as the atrial arches, but the integral formation of the ventricular arches with the central portion can provide for the increased stiffness relative to the atrial arches. Additionally, even in designs where there is only one atrial anchor frame, the ventricular arches can have the same thickness as the atrial arches, and the greater stiffness of the ventricular arches is due at least partially to the integral formation of the ventricular anchor and the central portion.

[0067] In alternative embodiments, the ventricular anchor, central portion, and atrial anchor (regardless of the number of atrial frames) are all integral, but the ventricular arches are thicker than the atrial arches. In one exemplary method of manufacturing, the entire anchor could be integral and cut from a tube, but the central and atrial portions could be ground down to have a smaller thickness than the ventricular portion. Thus even though the three portions of the expandable anchor are all integral, the ventricular side is still stiffer in the axial direction due at least partially due to the thicker ventricular arches.

[0068] In some embodiments the ventricular portion, central portion, and atrial portion all have different thicknesses. For example, each of the three portions could be made from different starting materials (i.e., non-integral) with different thicknesses, and then secured together.

Alternatively, the three portions could be integral and cut from a tube, and then one or more portion could be ground down to achieve a desired thickness in each portion, wherein the end result is that the three sections can have any desired thickness, such as three different thicknesses.

[0069] Some of the increased flexibility (less stiff) of the atrial arches is also due to the length of the atrial arches (the linear distance between valleys of the atrial arches) compared to

the lengths of the ventricular arches (the linear distances between valleys of the ventricular arches). Ventricular valley linear distance “VV” is shown in Figure 3, and atrial valley linear distance “AV” can be seen in Figure 7A. In the embodiments shown herein the ventricular valley distance is less than the atrial valley distance (for both of the atrial frames in this embodiment).

[0070] In some embodiments the height of the ventricular arches “VH” (shown in Figure 3), before the outward flare is imparted to the arches, is greater than VV. In some embodiments the two distances are substantially the same.

[0071] The embodiment in Figures 1-11B is also an example of a self-expandable anchor comprising a ventricular anchor integral with a central portion, and an atrial anchor secured to the central portion but not integral with the central portion. In this embodiment the expandable anchor (excluding the struts), when in an expanded configuration (which can be self-expandable) has a length L, which can be seen in Figure 2. Midline, or half the length, is indicated as “M” in Figure 2. In this embodiment the atrial anchor is disposed solely on the atrial side of the midline. That is, the atrial anchor portion is secured to the central portion on an atrial side of the expandable anchor. In this embodiment central portion 3 defines the radially innermost portion of the expandable anchor (excluding the struts and related structure).

[0072] In alternative embodiments the ventricular anchor can similarly be non-integral with the central portion and then secured thereto. For example, the ventricular anchor can comprise a ventricular annular frame (similar to an annular atrial frame) that is secured to the central portion, such as with rivets as described with respect to some atrial annular frames herein.

[0073] In embodiments in which the atrial anchor is not integral with the rest of the anchor, and it secured to the rest of the anchor during manufacturing, the coupling between the atrial anchor and the rest of the expandable anchor can be movable or non-movable couplings. In some situations it may be desirable to have some degree of movement between the atrial anchor and the central portion at the location of the coupling(s). In some scenarios it may be desirable to limit as much motion as possible at the location of the couplings. For example, when rivets are used to secure the atrial anchor to the central portion, examples of which are provided herein, the riveting process can be tailored to accommodate the desired degree of movement between the riveted components. Too much movement between components due to the coupling could, however, lead to material fatigue and failure. Movable coupling as used herein can be thought of as hinge points between two components, or hinge locations. The hinge allows for some movement between the two components, which can enhance, for example, the atrial anchor conforming to atrial tissue. In addition, an expandable anchor that is constructed from more than

one component coupled at rivets or hinges may flex freely at the couplings and reduce ultimate material strains.

[0074] Any of the central portion, the ventricular and atrial anchor portions, and the struts

can be formed from different starting materials from one another (i.e., non-integral). Non-

integral components can, if desired, allow the various components to be of different flexibilities and stiffnesses, and it can also provide for radial overlapping (relative to the longitudinal axis of central opening) of the components. For example, described above, the atrial anchor can be configured to be more flexible (less stiff) than the ventricular anchor to provide better conformability and sealing in the atrium, while the stiffer ventricular anchor can provide

sufficient resistance to pressure in the ventricle. In some embodiments, a thicker material can be used to form the central portion and the ventricular anchor while a thinner material can be used to form the atrial anchor. For example, the ventricular anchor can have a thickness of 0.25mm to 0.35mm while the atrial anchor can have a thickness of 0.15mm to 0.25mm. Further, in some embodiments, the length of the arches of the ventricular anchor (also referred to herein as the linear distance between valleys) can be shorter than the lengths of the arches of the atrial anchor to increase the stiffness of the ventricular anchor relative to the proximal anchor. For example, in some embodiments the arches of the atrial anchor are between 25mm and 35mm, such as approximately 30mm long, while the length of the arches of the ventricular anchor are between 15 and 25mm long, such as approximately 20mm long.

[0075] Rivets as used herein are an example of a coupler, as that term or derivatives thereof is used herein. 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.

[0076] Figures 12 and 13 show exemplary rivets that can be used to secure two or more components together herein (including the struts described below). Rivet 130a as shown in Figure 12 is a stepped rivet and rivet 130b as shown in Figure 13 is a straight rivet. The rivets can be inserted through the apertures described herein and the second ends 135 and 137, respectively, can then be plastically deformed using known riveting techniques to secure the two or more components together. The rivets can be made of a suitable implantable material, such as platinum, platinum-iridium alloy, tantalum, nickel-titanium alloy, or titanium and titanium alloys, such as titanium 6-4eli. In some embodiments, the riveted coupling can be such that one or more rivets are not tightened all the way down to the secured components, which allows for hinging of the coupling, if desired. Rivets used for hinging may be made of materials suitable for implantable bearing surfaces such as Nitronic 60 alloy, or nitinol. Hinge pins can be coated

with low-friction, high-durability coatings, such as diamond-like coating, or titanium nitride. Referring to Figure 13, a stepped rivet can be used as a hinge pin. The stepped rivet can include a step, or change of diameter section 131, such that one attached component can ride along a portion of the step. In some embodiments, hinge pins can be used to attach the atrial anchor, thereby providing more flexibility for the atrial anchor. Riveting and hinging can advantageously provide for better collapsing for delivery, including a smaller delivery profile, the advantages of which are described herein, such as for transseptal access to the mitral valve. Exemplary dimensions of rivets are shown in Figures 12 and 13, in millimeters.

[0077] Use of rivets and hinges (as opposed to, for example, crimp tubes) can provide an additional benefit of preventing cracking that can occur as single pieces of material flex and move. Additionally, rivets and hinges can provide various degrees of relevant movement between portions of the valve, which can allow the valve to be collapsed into a smaller delivery profile for delivery. The relative movement can also provide increased flexibility of the valve during delivery. Rivets can also allow for a variation in the relative orientation of the riveted components. In some embodiments, rivets provide increased flexibility that allows for greater trackability during delivery and better self-centering of the anchor against cardiac tissue (i.e., provides advantages for both access and conformability to the anatomy).

[0078] The couplings herein (e.g., riveting) also allow different section of material with different physical properties to be secured to one another. This allows different sections of the expandable anchor to have different properties (e.g., stiffness) than other sections, as may be needed based on, for example, anatomical requirements. For example, atrial anchors can be made thinner than the central portion and/or ventricular anchors.

[0079] The prostheses herein also include a plurality of struts, to which are attached replacement leaflets, which are configured to control blood flow therethrough. Figures 1 and 15 are perspective views illustrating three struts 5 that are individually secured to central portion 3 of the expandable anchor, and are extending distally (towards the ventricular anchor). Figure 1 is a view from the atrial side to the ventricular side, while Figure 12 is a view from the ventricular side to the atrial side. Figure 14 illustrates one of the three struts 5 in the embodiment in Figures 1 and 12. In this exemplary embodiment three individual struts 5 are secured to central portion 3 at riveted couplings, in the same general manner as how the atrial anchor can be secured to the central portion, as described herein. Struts 5 have a ventricular end 59 and an atrial end 61, as shown in Figure 14. Atrial end 61 includes a plurality of apertures 57a, 57b, and 57c, which are configured to be secured to apertures 36 in the central portion, such as using rivets or hinge pins as described herein. Struts 5 includes three elongate portions 55a, 55b, and 55c, each extending from ventricular end 59 and each of which has a free end at the

atrial end 61. The free ends include the apertures 57a-c. Elongate portion 55b has a straight configuration, while elongate portions 55a and 55c are curved and flared outward relative to elongate portion 55b. Struts 5 have a generally triangular configuration, pointing in the distal direction. The triangular struts 5 can provide vertical strength and lateral flexibility. Elongate portions 55a and 55c are curved and have a longer overall length than the middle straight elongate portion 55b so as to provide an arched shape that lowers stress along the leaflets. Further, the atrial ends 61 of each outer elongate portion 55a and 55c can include a spring 51a and 51c, respectively, such as a clock spring, that is configured to compensate for the difference in lengths of elongate portions 55a, 55b, and 55c when the prosthesis 1 is collapsed inwards into a collapsed configuration. The curved elongate portions 55a and 55c further include suture holes 53 and/or striations or bumps 56 along the outer perimeter to provide suture attachment points for the leaflets. The struts herein can be, for example, cut from flat metal sheet or tubing.

[0080] Figure 15 shows three struts 5 from Figure 11 coupled to central portion 3. Figure 15 shows the subassembly from Figure 1, but the view in Figure 15 is from the ventricular side looking towards the atrial side.

[0081] As shown in Figure 15, struts 5 are attached to central portion 3 with the struts extending distally. In some embodiments there can be three struts 5 located approximately 120 degrees away from one another around the circumference of the central portion. In other embodiments, the three strut legs may be located 90 degrees apart from each other with 30 degree gaps between the legs of adjacent three strut legs.

[0082] Referring to Figures 16 and 2, in some embodiments, the valve prosthesis 1 can include valve leaflets 20a, 20b, and 20c attached, such as sewn, to struts 5. There can be three integral valve leaflets 20a, 20b, and 20c, and the leaflets can form a pressure actuated valve that provides uni-directional flow occlusion when the prosthesis 1 is implanted in a valve orifice.

The leaflets 20a-c can be constructed of bio-materials, such as bovine or porcine pericardium, or polymer materials.

[0083] Figure 17 illustrates central portion 4 comprising optional skirt 120 thereon or therearound formed of a biomaterial or thin polymer material. Figure 17 is a perspective view of an exemplary prosthesis 1 with leaflets 20a-c, and skirt 120. The skirt can advantageously help seal prosthesis 1 against the cardiac tissue when implanted. In some embodiments, the ventricular anchor can include a skirt in place of, or in addition to, the skirt 120 on central portion 3. Additionally, a skirt can optionally be on the atrial anchor portion as well.

[0084] Figure 18 illustrates an exemplary strut 70. As shown in the embodiment of strut 70 in Figure 18, a pin and slot mechanism (i.e., having an axially extending slot 83 along the

middle elongate component 75b), could be used to make up for the differences in the lengths of elongate portions 75a-c during collapse.

[0085] Some central portions herein or other portions of other replacement heart valves may be susceptible to undesirable deforming when implanted, such as due to movement during the heartbeat and/or in response to pressures in the heart. In some embodiments the expandable anchor includes an annular strut frame coupled to a radially inner portion of the central portion (i.e., within the central portion). An annular strut frame may distribute forces more evenly over the central portion of the expandable anchor and may reduce the likelihood of undesirable central portion deformation once implanted.

[0086] An annular strut frame, if used, is an additional layer of material secured to the radially inner portion of the central portion, which reinforces and stabilizes the central portion when implanted. Additionally, by creating a coupling between the struts and the central portion (as opposed to having a solid portion of material that can provide additional stability), the flexibility of the coupling allows for relative movement of the struts during collapse of the device. This can reduce stresses on the device as it is collapsed, allowing for a smaller delivery profile, which as discussed herein can be important for delivery, such as a transseptal approach. The term annular in this context does not require a perfect annulus.

[0087] When the prosthesis includes a strut frame, the struts can either be integral to the strut frame or they can be separate components that are secured to the strut frame during manufacturing.

[0088] Figures 19 is a perspective view illustrating an exemplary annular strut frame 1000. Strut frame 1000 includes frame portion 1002 and plurality of struts 1004. Struts 1004 extend further distally (i.e., in the ventricular direction) than frame portion 1002, and are configured to be secured to replacement leaflets as described herein. The strut frame 1000 has a ventricular end 1006 and an atrial end 1008. Strut portion 1002 includes a plurality of arches, which define peaks 1012 and valleys 1014. In this embodiment there are six strut frame arches, with two between adjacent struts 1004. Struts 1004 have an arch configuration defined by first leg 1020 and second leg 1022, each of which has a plurality of suture apertures 1018 therein. Struts 1004 each also have first and second extensions 1024 and 1026 extending away from legs 1020 and 1022 and towards atrial end 1008. Extensions 1024 and 1026 may also be considered part of the frame portion rather than the struts. Replacement leaflets are secured to struts 1004 at holes 1018 (e.g., by suturing). The strut frame also includes a plurality of apertures 1010 near the atrial end 1008, which are used to secure the annular strut frame to the central portion of the expandable anchor. The apertures are located at valleys 1014 in the frame portion. In some embodiments the annular strut frame is positioned radially within the central portion so that each

of apertures 1010 is aligned with an aperture in the central portion, such as apertures 36. A coupler (e.g., rivet) is then advanced through the aligned apertures and one side of the coupler is then plastically deformed to secure the annular strut frame to the central portion.

[0089] Figure 20 illustrates an exemplary annular strut frame 1100. Strut frame 1100 includes three struts 1104 and frame portion 1102, which in this embodiment includes one arch between adjacent struts 1104. Unlike the embodiment in Figure 19, in which there is one coupling aperture 1010 within each strut, in this embodiment there are two apertures 1110 within each strut 1104. Just as in the embodiment in Figure 19, there are also apertures at the ends of each leg of struts. Strut frame 1100 is coupled to a central portion by aligning apertures 1110 with apertures in the central portion, such as aperture 36, and then extending a coupler through each set of aligned apertures, and plastically deforming each coupler to secure the central portion to the annular strut frame at the locations of the couplings.

[0090] Figures 19 and 20 illustrate exemplary strut frames in their expanded configurations, when the rest of the expandable anchor (e.g., ventricular anchor, central portion, and atrial anchor) is also in an expanded configuration. Strut frames 19 and 20 can be secured to, and considered part of, any of the expandable anchors herein.

[0091] In an exemplary method of manufacturing, the strut frame is cut from a tubular element, then expanded, and set in the expanded configuration using shape setting techniques described herein or otherwise known. For example, in an exemplary embodiment, the frame is cut from a 10 mm diameter tube, then expanded to an expanded configuration of about 32 mm (as shown in Figure 19), and set in the expanded configuration. In some exemplary embodiments the strut frames herein are .25 mm to about .45 mm thick, such as about .35 mm thick.

[0092] The annular strut frame can be cut from a flat sheet and rolled up and secured together (examples of which are described above), or it can be cut from a tubular structure.

[0093] Figures 19 and 20 illustrate exemplary annular, or cylindrical, strut frames that are disposed radially within the central portion of the expandable anchor. The central portion and the strut frame can be thought of as creating a composite cylinder when they are coupled together. The composite cylinder is thicker than each of the central portion and strut frame individually. Each of the central portion and strut frame is, however, relatively thin and can flex with respect to the other component. The relative flexibility can make it easier to collapse into a delivery configuration. If the composite region were a single material with a thickness equivalent to the combined thickness of the central portion and strut frame, that modified region may not be able to collapse sufficiently to meet, for example, size constraints without overstraining. The central portion and strut frame acting as a composite structure will not

overstrain when collapsed into a collapsed configuration since the central portion and strut frame can flex independently. The composite central portion and strut frame also, when the expandable anchor expands, has a thickness greater than each component individually, thus providing an increased thickness that may be needed to resist torqueing and other forces on the central portion when implanted. The composite central portion and cylindrical strut frame thus enables collapsing as needed without overstraining, as well as provides a thickness to the central region that resists torqueing and deformation due to forces acting on the expandable anchor when implanted.

[0094] In some embodiments various components of the prosthesis are described as being formed out of a flat sheet of material, but in some embodiments they can be formed out of a tubular element or other shape of material.

[0095] In some embodiments the configuration of the arches on the ventricular anchor portion might be the same as configuration shown herein (such as in Figure 2), but the ventricular anchor portion could be a separate frame that is secured to the central portion, just as some atrial anchors are secured to the central portion in exemplary embodiments herein. Both anchors can be separate components secured to central portion (not integral with central portion), and in some embodiments both ventricular and atrial anchors can be integral with the central portion.

[0096] In some embodiments, a prosthesis can include ventricular and atrial anchor portions that are both configured like anchor portion 2 herein. For example, both the ventricular and atrial anchor portions could be frames that are secured to the central portion. In some embodiments, a prosthesis can include ventricular and atrial anchor portions that are both configured like anchor portion 4 herein.

[0097] The prostheses herein can be configured to self-expand within a cardiac valve orifice such that the central portion lines the valve orifice while the atrial and ventricular anchors sit within the chambers of the heart and pinch tissue of the orifice therebetween, securing the prosthesis in place. Methods of delivery and deployment of prostheses that are fully incorporated herein and can be used to deliver and deploy any of the prostheses herein can be found in, for example, U.S. Pat. No 8,870,948, issued October 28, 2014.

[0098] It is conceivable that the prostheses described herein can be used to replace valves other than the mitral valve, such as the aortic valve, the tricuspid valve, and the pulmonary valve.

[0099] Figure 21 illustrates an exemplary configuration of a portion of expandable anchor 1 (struts and leaflets not shown for clarity) in a collapsed configuration, in which only one atrial anchor frame has been secured to central portion 3. The expandable anchor 1 can be configured to be collapsed for delivery through a catheter. In the collapsed configuration (shown in Figure

21), the atrial and ventricular anchors 2 and 4, respectively, are extended outwards, and the entire expandable anchor can be radially collapsed. All of the arches become narrower, as do the cells in central portion 3. The expandable anchor 1 in its collapsed state can maintain a strain of less than 6% at all locations. A device and method for collapse is described in U.S. Patent

5 Application No. 14/170,388, filed January 31, 2014, and titled "SYSTEM AND METHOD FOR CARDIAC VALVE REPAIR AND REPLACEMENT," now U.S. Patent No. 8,870,948, the entire contents of which are incorporated by reference herein.

[00100] One aspect of the disclosure is a replacement mitral valve, comprising: a self-expandable anchor comprising a ventricular anchor, a central portion, and an atrial anchor, the atrial anchor portion not being integral with the central portion and secured to the central portion, the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the self-expandable anchor is configured to secure the replacement mitral valve to a mitral valve annulus in the self-expanded configuration, wherein the atrial anchor includes a frame having a plurality of arches and a plurality of apertures therethrough, and wherein the central portion includes a plurality of apertures therethrough, at least some of which are in alignment with one of the plurality of frame apertures; securing the frame to the central portion by extending a coupler through a central portion aperture and a frame aperture, and plastically deforming the coupler on one side of the aligned apertures, wherein plastically deforming the coupler secures the central portion and the frame at the location of the coupler; and a plurality of replacement leaflets secured to the expandable anchor.

[00101] Any of the individual components of any prostheses herein can be interchanged with components in any other example, and the examples described herein are not limited to the specific components in those examples.

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CLAIMS

What is claimed is:

1. A replacement mitral valve, comprising:
5 a self-expandable anchor comprising a ventricular anchor, a central portion, and an atrial anchor, the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice,
10 the ventricular anchor having greater stiffness in an axial direction than the atrial anchor when the expandable anchor is in the self-expanded configuration; and
a plurality of replacement leaflets secured to the expandable anchor.
2. The replacement mitral valve of claim 1 wherein the ventricular anchor has a plurality of
15 ventricular arches with a first thickness, the atrial anchor has a plurality of atrial arches with a second thickness less than the first thickness, and wherein the thickness dimensions is measured radially when the expandable anchor is in a collapsed configuration.
3. The replacement mitral valve of claim 2 wherein the atrial anchor includes a first frame with a
20 plurality of first arches and a second frame with a plurality of second arches at least a portion of which overlap the plurality of first arches, the second thickness being the thickness of the plurality of first arches, the plurality of second arches having a third thickness less than the first thickness.
- 25 4. The replacement mitral valve of claim 3 wherein the second thickness is the same as the third thickness.
5. The replacement mitral valve of claim 1, the ventricular anchor having a plurality of ventricular arches with ventricular peaks and valleys, the atrial anchor having a plurality of atrial
30 arches with atrial peaks and valleys, the linear distance between ventricular valleys being less than the linear distance between atrial valleys, when the expandable anchor is in the expanded configuration.
6. The replacement mitral valve of claim 5 wherein the atrial arches are part of a first frame,
35 the atrial anchor further including a second frame with a plurality of second arches with peaks

and valleys, at least one of the atrial arches overlaps with one of the plurality of second arches, the linear distance between ventricular valleys also being less than the linear distance between valleys of the second frame.

5 7. The replacement mitral valve of claim 1, the ventricular anchor having a plurality of ventricular arches with ventricular peaks and the atrial anchor having a plurality of atrial arches defining atrial peaks, wherein midpoints of the ventricular peaks have greater stiffness in the axial direction than midpoints of the atrial peaks.

10 8. The replacement mitral valve of claim 7, wherein the atrial anchor comprises a first frame comprising the plurality of atrial arches, the atrial anchor further comprising a second frame comprising a plurality of second arches.

15 9. The replacement mitral valve of claim 1 wherein the ventricular anchor comprises a plurality of ventricular arches, the atrial anchor includes a first frame with a plurality of first arches and a second frame with a plurality of second arches, at least one of the first arches overlapping with one of the second arches, and wherein the plurality of ventricular arches are stiffer than each of the first arches and the second arches in the axial direction.

20 10. The replacement mitral valve of claim 1 having a ventricular end and an atrial end, the two ends being the radially outermost points of either side of a midline of the expandable anchor when the anchor is in the expanded configuration.

25 11. The replacement mitral valve of claim 1 wherein the ventricular anchor is integral with the central portion, and the atrial anchor is secured to the central portion but not integral with the central portion or the ventricular anchor.

30 12. The replacement mitral valve of claim 11 wherein the ventricular anchor comprises, when the expandable anchor is in a collapsed configuration, a plurality of triangular arches pointing towards a ventricular end of the replacement mitral valve, and the central portion comprises a plurality of triangular central arches pointing towards an atrial end of the replacement mitral valve.

35 13. The replacement mitral valve of claim 1 wherein the atrial anchor includes a first frame with a plurality of first arches and a second frame with a plurality of second arches, at least a

portion of the plurality of first arches overlapping with a portion of the plurality of second arches.

14. The replacement mitral valve of claim 13 wherein at least a portion of the plurality of first arches and at least a portion of the plurality of second arches each comprise a protuberance at a midpoint of the arch.

15. The replacement mitral valve of claim 1 wherein the ventricular anchor comprises a plurality of arches having triangular configurations.

16. The replacement mitral valve of claim 15 wherein the plurality of arches define a plurality of peaks and a plurality of valleys, the height of the peaks being greater than the linear distance between adjacent valleys, the height being measured orthogonal to the linear distance between adjacent valleys.

17. The replacement mitral valve of claim 16 wherein the ventricular anchor comprises a plurality of arches each having the same triangular configuration with a rounded end.

18. The replacement mitral valve of claim 1 further comprising a plurality of struts secured to the self-expandable anchor and the replacement leaflets.

19. The replacement mitral valve of claim 18 further comprising a cylindrical strut frame secured to the self-expandable anchor, the strut frame comprising the plurality of struts.

20. The replacement mitral valve of claim 19 wherein the strut frame is secured to the central portion of the expandable anchor.

21. The replacement mitral valve of claim 20 wherein the strut frame includes a plurality of apertures and the central portion comprises a plurality of apertures, each of the plurality of apertures on the strut frame is aligned with an aperture on the central portion, the central portion secured to the strut frame at the location of the aligned apertures.

22. A replacement mitral valve, comprising:

a self-expandable anchor comprising a ventricular anchor integral with a central portion,
and an atrial anchor secured to the central portion but not integral with the central
portion, the self-expandable anchor having a self-expanded configuration in which the
ventricular anchor and the atrial anchor are flared radially outward relative to the central
portion such that the replacement mitral valve is configured to be secured within a mitral
valve orifice; and
a plurality of replacement leaflets secured to the expandable anchor.

23. The replacement mitral valve of claim 22 wherein the expandable anchor has a midline
along its length in the self-expanded configuration, the atrial anchor being secured to the
central portion on an atrial side of the midline.

24. The replacement mitral valve of claim 22 wherein the atrial anchor comprises a frame
that has a plurality of arches with a plurality of peaks and valleys, the frame being
secured to the central portion at at least a portion of the plurality of valleys of the frame.

25. The replacement mitral valve of claim 24 wherein each of the plurality of the valleys that
are secured to the central portion are secured to a peak of an arch in the central portion.

26. The replacement mitral valve of claim 24 wherein the frame is secured to the central
portion at each of the plurality of valleys.

27. The replacement mitral valve of claim 22 wherein the atrial anchor is secured to the
central portion at a plurality of couplings.

28. The replacement mitral valve of claim 27 wherein the plurality of couplings are movable
couplings between the central portion and the atrial anchor at the location of the couplings.

29. The replacement mitral valve of claim 28 wherein each of the couplings comprises a first
component on the central portion and a second component on the atrial anchor, the first and
second components movably secured to one another.

30. The replacement mitral valve of claim 29 wherein the first and second components each define an aperture and are moveably secured to one another with a rivet that allows for movement between the first and second components.

5 31. The replacement mitral valve of claim 30 wherein the first and second components each define an aperture and are moveably secured to one another with a hinge component that allows for movement between the first and second components.

10 32. The replacement mitral valve of claim 27 wherein the atrial anchor comprises a annular frame, and wherein the annular frame is secured to the central portion at a plurality of couplings.

33. The replacement mitral valve of claim 32 wherein the plurality of couplings are movable couplings between the central portion and the frame at the location of the plurality of couplings.

15 34. The replacement mitral valve of claim 33 wherein each of the plurality of couplings comprises a first component on the central portion and a second component on the frame, the first and second components movably secured to one another.

20 35. The replacement mitral valve of claim 34 wherein the first and second components each define an aperture and are moveably secured to one another with a rivet that allows for movement between the first and second components.

25 36. The replacement mitral valve of claim 35 wherein the first and second components each define an aperture and are moveably secured to one another with a hinge that allows for movement between the first and second components.

30 37. The replacement mitral valve of claim 32 wherein the atrial anchor comprises a second annular frame, wherein the second frame is secured to the central portion at a second plurality of couplings.

38. The replacement mitral valve of claim 37 wherein the first and second plurality of coupling are movable couplings between the central portion and the first and second frames at the location of the first and second plurality of couplings.

39. The replacement mitral valve of claim 38 wherein the first and second couplings alternate around a longitudinal axis of the central portion.

40. The replacement mitral valve of claim 38 wherein the first and second frames each
5 comprise peaks and valleys, and the first and second couplings are valleys of the first and second frames.

41. The replacement mitral valve of claim 22, the ventricular anchor having a plurality of
ventricular arches with a first thickness, the atrial anchor having a plurality of atrial arches with a
10 second thickness less than the first thickness, wherein the thickness dimension is measured
radially when the expandable anchor is in a collapsed configuration.

42. The replacement mitral valve of claim 41 wherein the atrial anchor includes a first frame
with a plurality of first arches and a second frame with a plurality of second arches at least a
15 portion of which overlap the plurality of first arches, the second thickness being the thickness of
the plurality of first arches, the plurality of second arches having a third thickness less than the
first thickness.

43. The replacement mitral valve of claim 42 wherein the second thickness is the same as the
20 third thickness.

44. The replacement mitral valve of claim 22, the ventricular anchor having a plurality of
ventricular arches defining ventricular peaks and valleys, the atrial anchor having a plurality of
atrial arches defining atrial peaks and valleys, the linear distance between ventricular valleys
25 being less than the linear distance between atrial valleys, when the expandable anchor is in the
expanded configuration.

45. The replacement mitral valve of claim 44 wherein the atrial arches are part of a first
frame, the atrial anchor further including a second frame with a plurality of second arches
30 defining peaks and valleys, at least one of the atrial arches overlaps with one of the plurality of
second arches, the linear distance between ventricular valleys also being less than the linear
distance between valleys of the second frame.

46. The replacement mitral valve of claim 22 wherein the ventricular anchor has greater stiffness in an axial direction than the atrial anchor portion when the expandable anchor is in the expanded configuration.

47. The replacement mitral valve of claim 46, the ventricular anchor having a plurality of ventricular arches defining ventricular peaks and the atrial anchor having a plurality of atrial arches defining atrial peaks, wherein midpoints of the ventricular peaks have greater stiffness in the axial direction than midpoints of the atrial peaks.

48. The replacement mitral valve of claim 46 wherein the ventricular anchor comprises a plurality of ventricular arches, the atrial anchor includes a first frame with a plurality of first arches and a second frame with a plurality of second arches, at least one of the first arches overlapping with one of the second arches, and wherein the plurality of ventricular arches are stiffer than each of the first arches and the second arches in the axial direction.

49. The replacement mitral valve of claim 22 wherein the ventricular anchor comprises, when the expandable frame is in a collapsed configuration, a plurality of triangular arches pointing towards a ventricular end of the replacement mitral valve, and the central portion comprises a plurality of triangular central arches pointing towards an atrial end of the replacement mitral valve.

50. The replacement mitral valve of claim 22 wherein the atrial anchor includes a first frame with a plurality of first arches and a second frame with a plurality of second arches, at least a portion of the plurality of first arches overlapping with a portion of the plurality of second arches.

51. The replacement mitral valve of claim 50 wherein at least a portion of the plurality of first arches and at least a portion of the plurality of second arches each comprise a protuberance at a midpoint of the arch.

52. The replacement mitral valve of claim 22 wherein the ventricular anchor comprises a plurality of arches having triangular configurations.

53. The replacement mitral valve of claim 52 wherein the plurality of arches define a plurality of peaks and a plurality of valleys, the height of the peaks being greater than the linear

distance between adjacent valleys, the height being measured orthogonal to the linear distance between adjacent valleys.

54. The replacement mitral valve of claim 52 wherein the ventricular anchor comprises a plurality of arches each having the same triangular configuration with a rounded end.

55. The replacement mitral valve of claim 22 further comprising a plurality of struts secured to the self-expandable anchor and the replacement leaflets.

56. The replacement mitral valve of claim 55 further comprising a cylindrical strut frame secured to the self-expandable anchor, the strut frame comprising the plurality of struts.

57. The replacement mitral valve of claim 56 wherein the strut frame is secured to the central portion.

58. The replacement valve of claim 57 wherein the strut frame includes a plurality of apertures and the central portion comprises a plurality of apertures, each of the plurality of apertures on the strut frame is aligned with an aperture on the central portion, the central portion secured to the strut frame at the location of the aligned apertures.

59. A method of manufacturing a replacement mitral valve, comprising
creating a ventricular anchor integral with a central portion;
securing an atrial anchor to the central portion, the atrial portion not integral with the central portion or the ventricular anchor; and
forming a self-expandable anchor that has a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice.

60. The method of claim 59 further comprising forming the self-expandable configuration of the ventricular anchor and the central portion before securing the atrial anchor to the central portion.

61. The method of claim 60 wherein securing the atrial anchor comprises securing an atrial annular frame comprising a plurality of arches to the central portion.

62. The method of claim 61 wherein securing the atrial annular frame to the central portion comprises aligning one of a plurality of apertures in the atrial frame with one of a plurality of apertures in the central portion, and further comprising positioning a coupling through the aligned apertures and securing the atrial frame to the central portion at the location of the aligned apertures.

63. The method of claim 62 wherein securing the atrial frame to the central portion comprises aligning each of a plurality of apertures in an atrial frame valley with one of a plurality of apertures in a central portion peak.

64. The method of claim 59 further comprising securing an annular strut frame to the central portion, the strut frame including at least two struts adapted to secure replacement leaflets thereto.

65. A replacement mitral valve, comprising:

a self-expandable anchor comprising a ventricular anchor comprising a plurality of ventricular arches, a central portion, and an atrial anchor comprising an annular frame with a plurality of atrial arches and a plurality of atrial apertures therethrough;

the atrial anchor secured to the central portion and not integral with the central portion, the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice,

wherein the central portion includes a plurality of central apertures therethrough, each of the plurality of atrial apertures in alignment with one of the plurality of central apertures to form a plurality of aligned apertures;

a plurality of couplers, each of which extends through one of the plurality of aligned apertures and secures the central portion to the annular frame at the location of the aligned apertures; and

a plurality of replacement leaflets secured to the expandable anchor.

66. The replacement mitral valve of claim 65 wherein at least some of the plurality of couplers are configured to allow for movement in at least one direction between the central portion and the frame at the location of the aligned apertures.

5 67. The replacement mitral valve of claim 65 wherein the atrial anchor further comprises a second annular frame having a plurality of second arches and a plurality of second apertures therethrough, and wherein each of the plurality of second apertures is in alignment with one of the central portion apertures; and
a plurality of second couplers, each of which extends through a central portion aperture and a
10 second frame aperture, and secures the central portion to the second frame at the location of the aligned apertures.

68. The replacement mitral valve of claim 67 wherein the plurality of first arches are in an overlapping arrangement with the plurality of second arches.

15 69. The replacement mitral valve of claim 65 wherein ventricular anchor is integral with the central portion.

70. The replacement mitral valve of claim 65 wherein the ventricular anchor comprises a
20 ventricular annular frame comprising a plurality of ventricular arches, the ventricular annular frame is secured to the central portion and not integral with the central portion.

71. The replacement mitral valve of claim 70 wherein the ventricular annular frame comprises a plurality of ventricular apertures therethrough, each of the plurality of ventricular
25 apertures aligned with a central portion apertures to create a plurality of aligned apertures, the ventricular annular frame secured to the central portion at the location of the plurality of aligned apertures.

72. The replacement mitral valve of claim 65 wherein the central portion comprises a
30 plurality of cells.

73. The replacement mitral valve of claim 65 wherein the central portion includes a plurality of cells each comprising a central peak pointing in the atrial direction, each of the plurality of central apertures being disposed in a central peak.

35

74. A method of manufacturing a replacement mitral valve, comprising:

providing a central portion of an expandable anchor, the central portion including a

5 plurality of central apertures therein that are disposed around a central opening;

providing an atrial anchor that includes an annular frame comprising a plurality of atrial apertures therethrough;

aligning each of the atrial apertures with a central aperture to form aligned apertures;

10 extending a coupler through each of the aligned apertures from one side of the aligned apertures to a second side of the aligned apertures;

plastically deforming each of the couplers to secure the central portion to the annular frame at the location of the couplers; and

15 forming a self-expandable anchor that has a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice.

75. The method of manufacturing of claim 74 wherein plastically deforming the couplers secures the central portion to the annular frame such that there is some degree of movement in at least one direction between the central portion and the frame at at least one of the locations of the
20 couplers.

76. The method of manufacturing of claim 74 further comprising providing a second atrial anchor that includes a second annular frame comprising a plurality of second atrial apertures therethrough;

25 aligning each of the second atrial apertures with a central aperture to form second aligned apertures;

extending a coupler through each of the second aligned apertures from one side of the second aligned apertures to a second side of the second aligned apertures; and

30 plastically deforming each of the couplers to secure the central portion to the second annular frame at the location of the couplers.

77. The method of claim 74 wherein providing a central portion comprises forming a central portion integral with the ventricular anchor.

78. The method of claim 74 further comprising providing a ventricular anchor frame with a plurality of ventricular arches; and
securing the ventricular annular frame to the central portion.

5 79. The method of claim 78 wherein the ventricular annular frame comprises a plurality of ventricular apertures therethrough, the method further comprising aligning each of the plurality of ventricular apertures with a central portion apertures to create a plurality of aligned apertures; and

10 plastically deforming each of a plurality of second couplers to secure the central portion to the ventricular annular frame at the location of the couplers.

80. A replacement mitral valve, comprising:

15 a self-expandable anchor comprising a ventricular anchor, a central portion comprising a plurality of apertures therethrough that are disposed around the central portion, and an atrial anchor, the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice;

20 an annular strut frame comprising a plurality of apertures therethrough around the strut frame, the strut frame disposed radially within the central portion, each of the plurality of annular strut frame apertures aligned with one of the plurality of central portion apertures, the annular strut frame secured to the central portion at the location of the plurality of
25 strut frame apertures; and

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

81. The replacement mitral valve of claim 80 wherein the strut frame comprises a plurality of
30 struts extending distally from a frame portion of the strut frame and distally from the central portion.

82. The replacement mitral valve of claim 81 wherein the strut frame comprises a plurality of
35 strut arches, wherein at least one strut arch is disposed between each of the adjacent struts.

83. The replacement mitral valve of claim 80 further comprising a plurality of couplers extending through the aligned apertures and configured to secure the central portion to the strut frame at the location of the couplers.

5

84. A method of manufacturing a replacement mitral valve, comprising
creating a ventricular anchor, a central portion, and an atrial anchor, the central portion including a plurality of apertures disposed around a central opening defined by the central portion;

10 providing an annular strut frame, the strut frame comprising a plurality of apertures therethrough around the strut frame,

positioning the annular strut frame radially within the central portion;

aligning each of the plurality of strut frame apertures with an aperture on the central portion to create a plurality of overlapped apertures;

15 providing a plurality of couplers, and extending a coupler through each of the plurality of overlapped apertures;

plastically deforming the plurality of couplers to secure the central portion to the annular strut frame at the locations of the plurality of couplers; and

20 forming a self-expandable anchor that has a self-expanded configuration in which the ventricular anchor portion and the atrial anchor portion are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice.

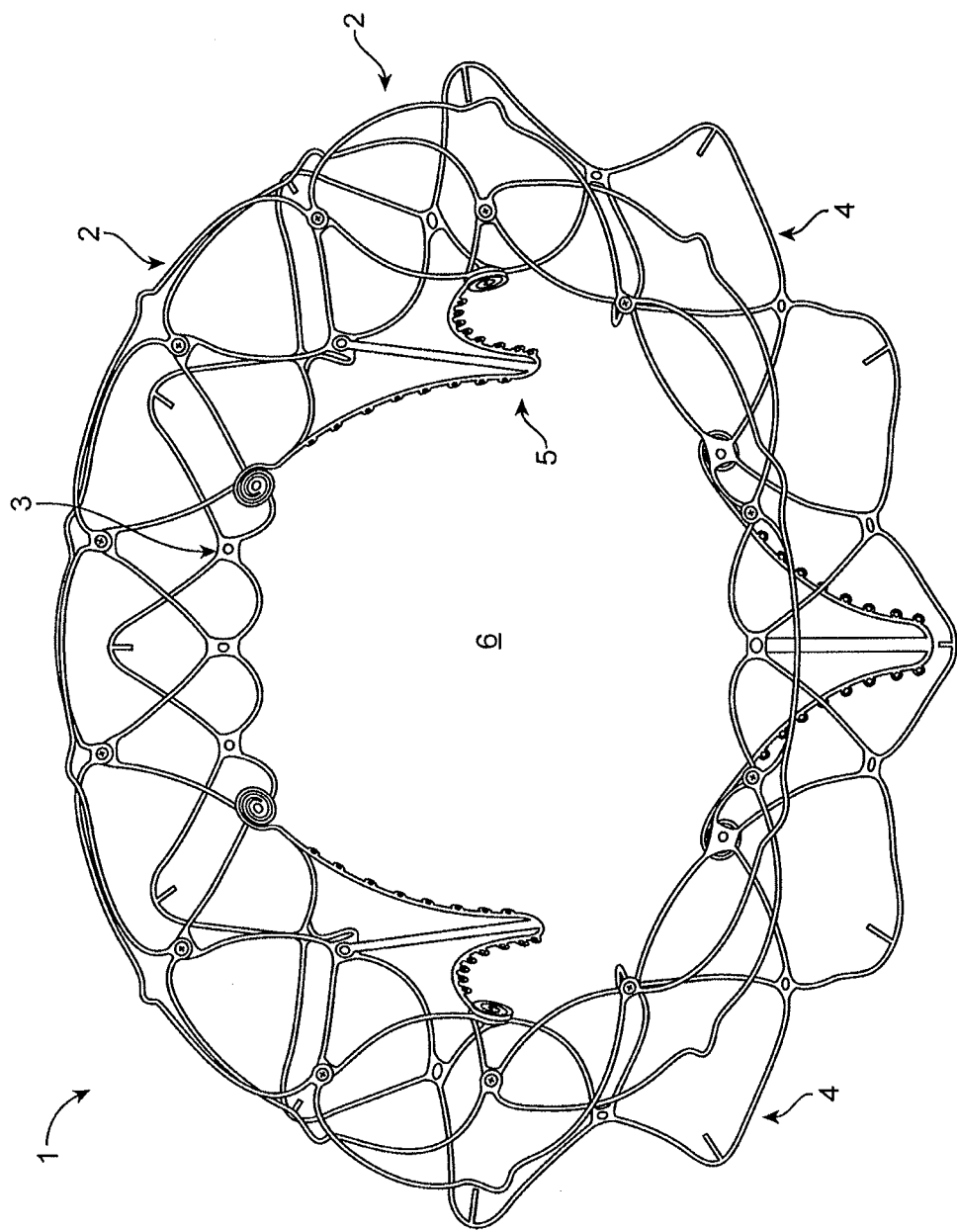


FIG. 1

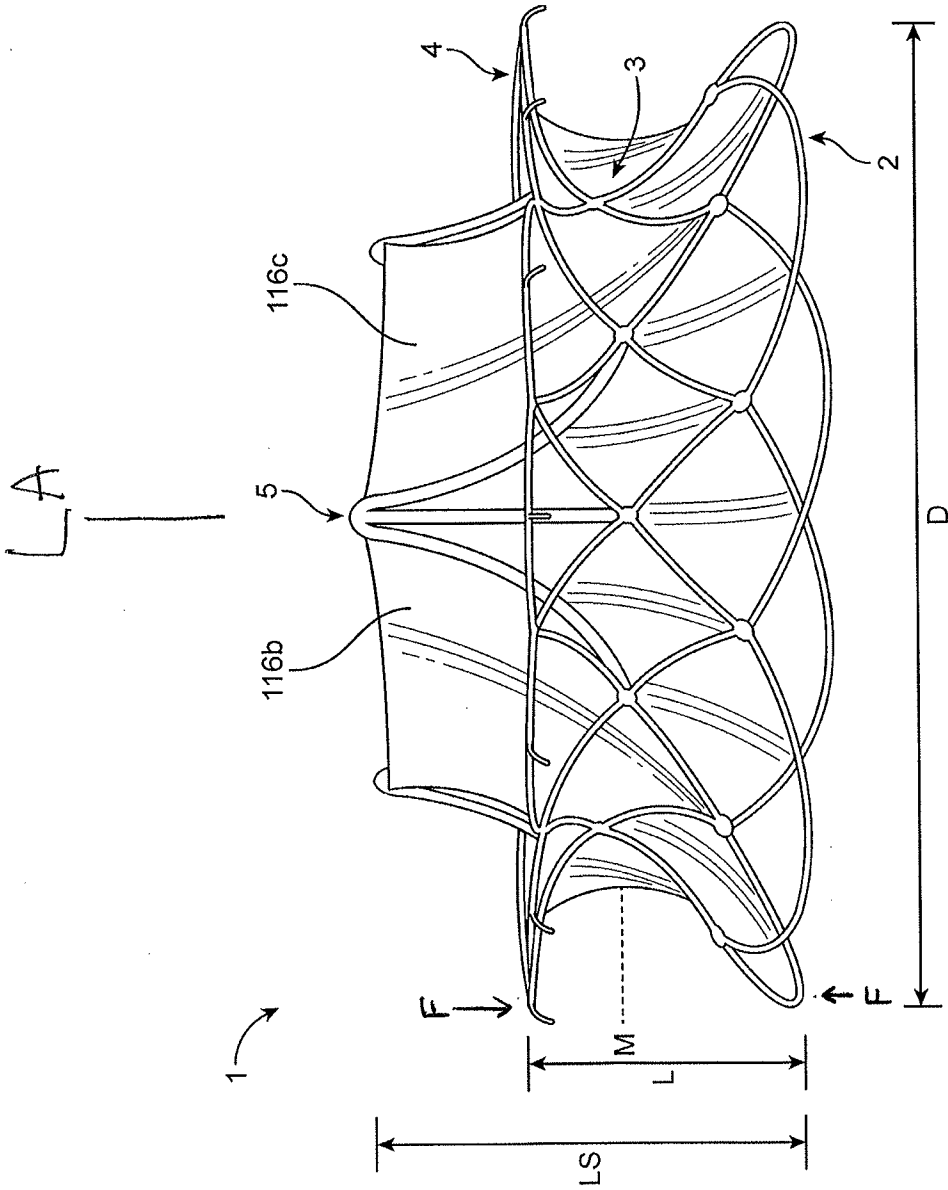


FIG. 2

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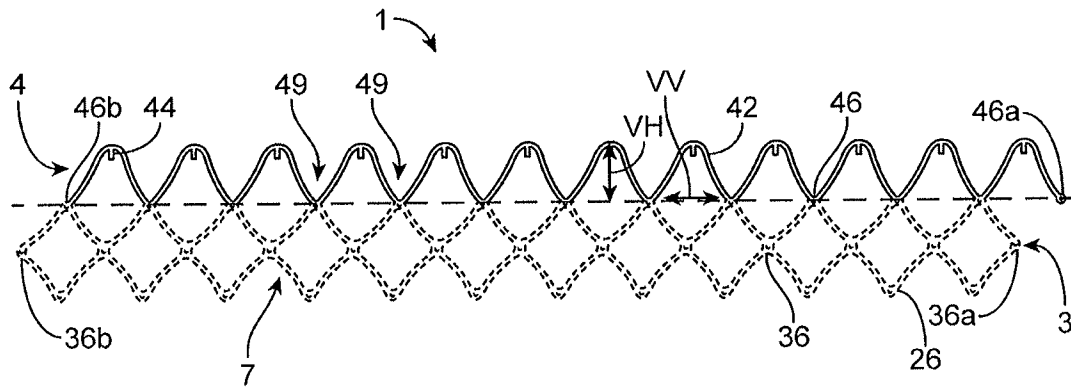


FIG. 3

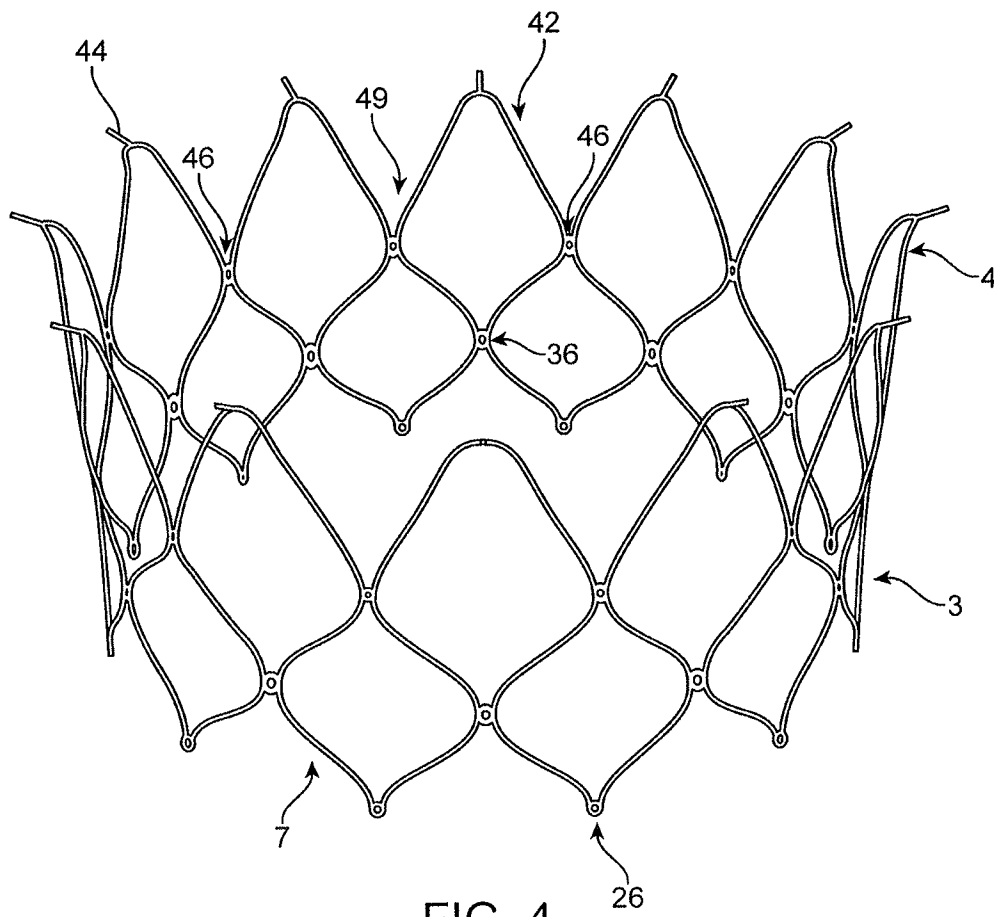


FIG. 4

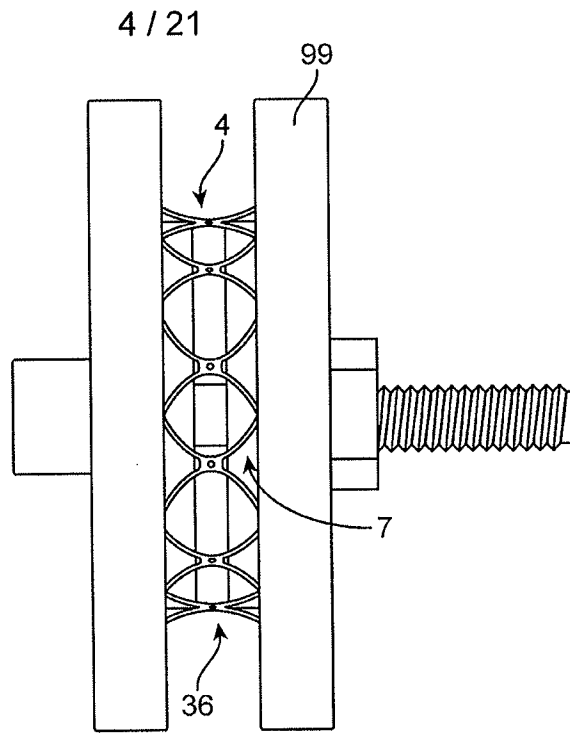


FIG. 5A

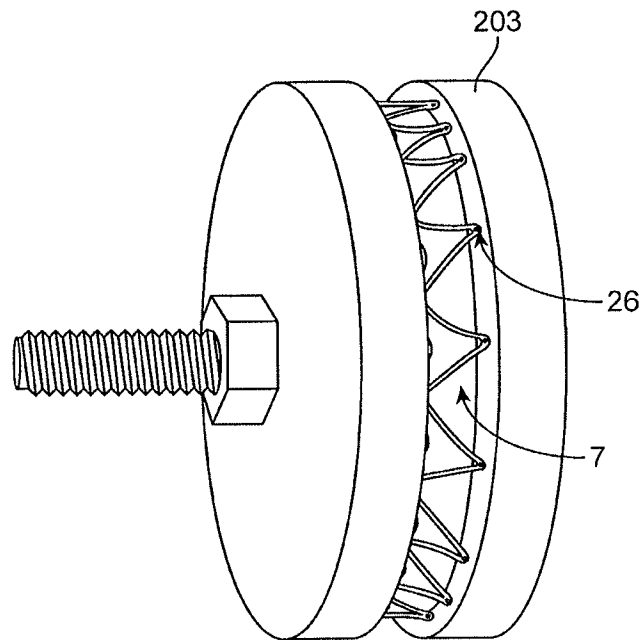


FIG. 5B

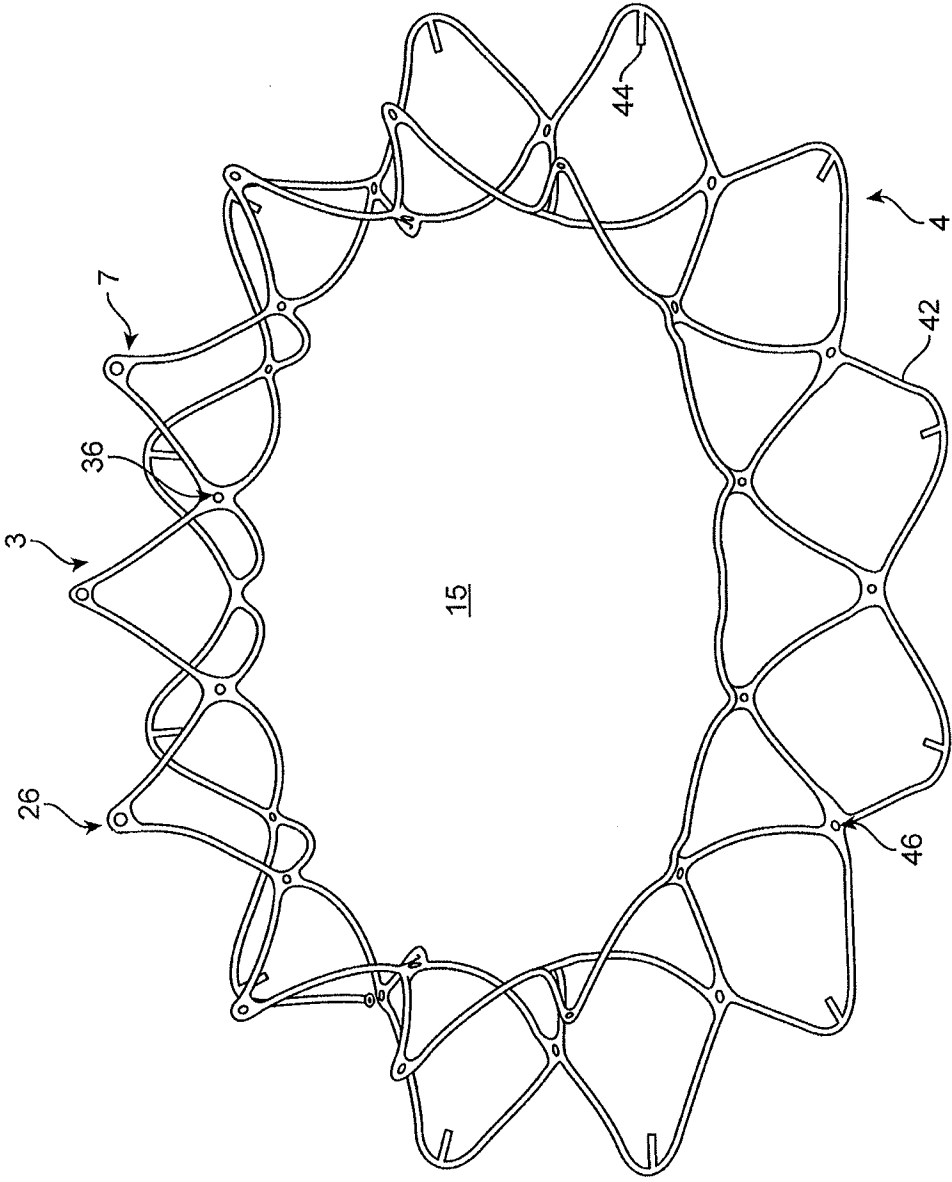


FIG. 6A

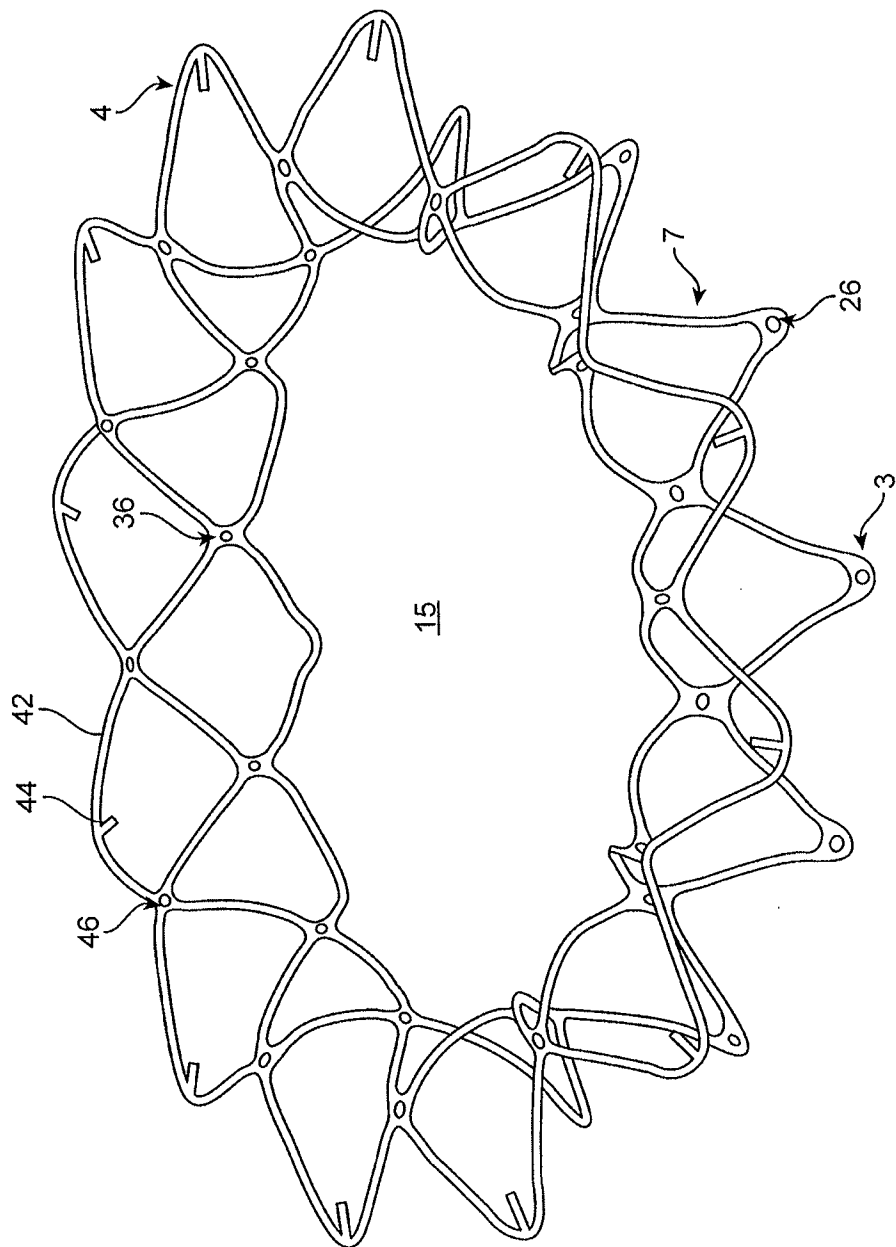


FIG. 6B

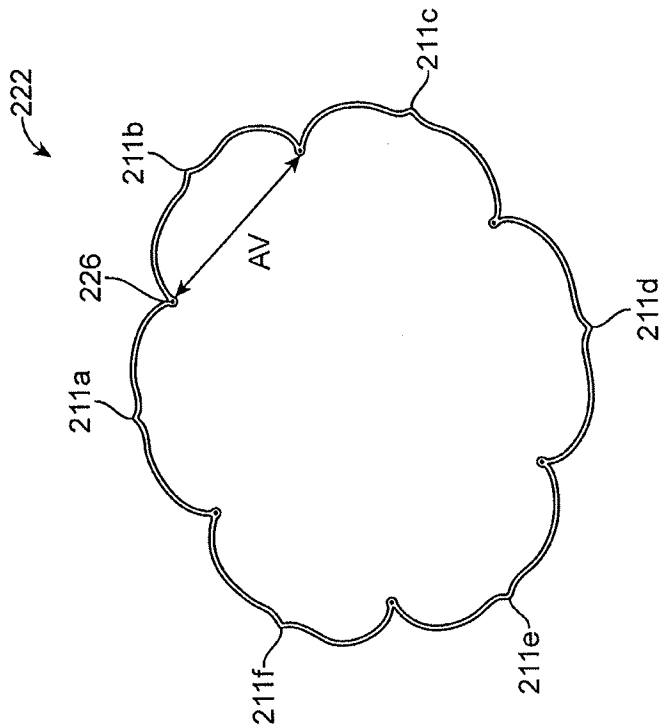


FIG. 7B

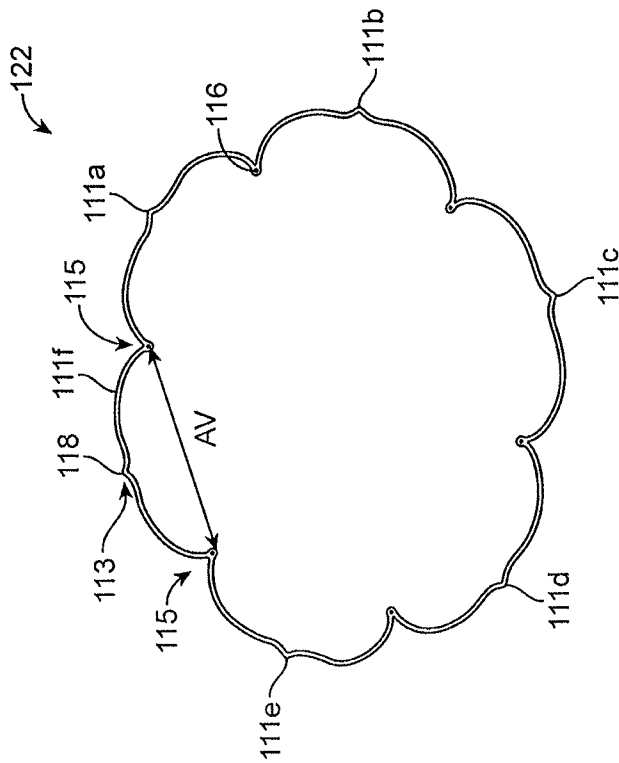


FIG. 7A

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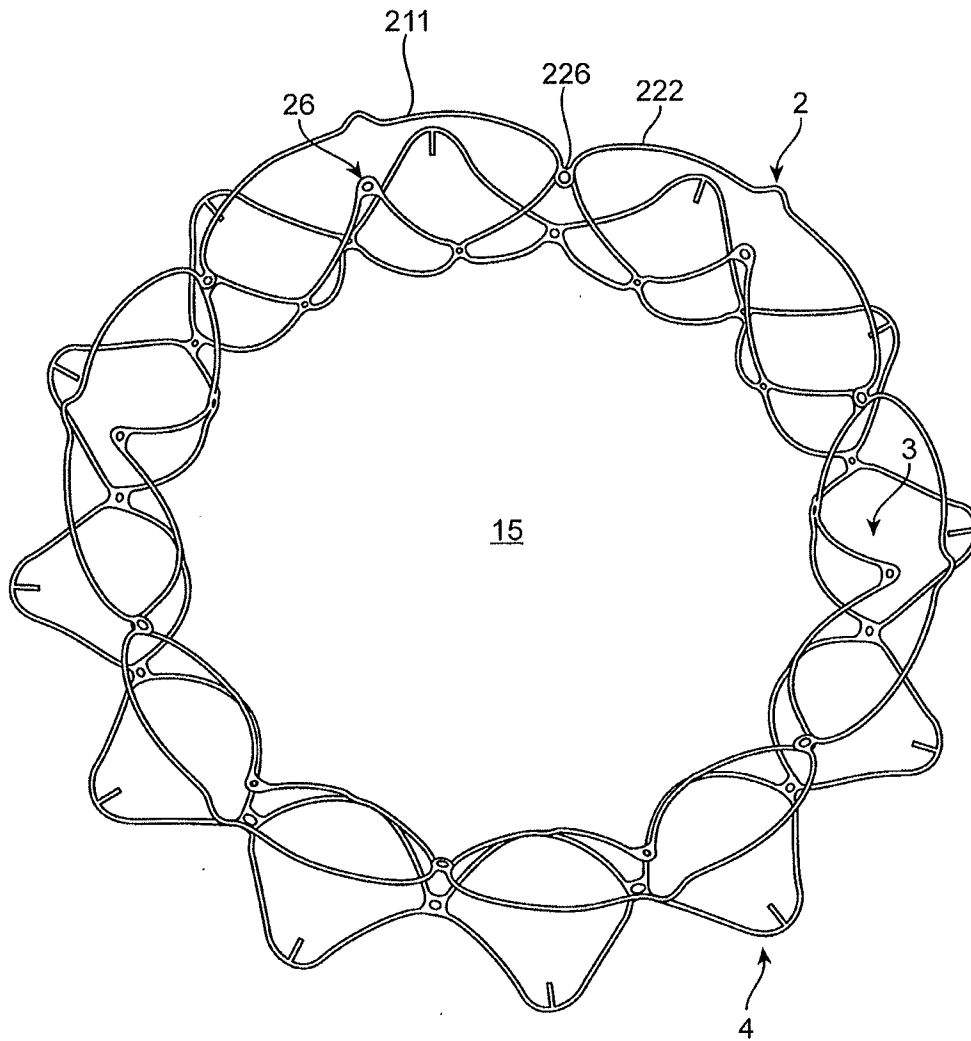


FIG. 8

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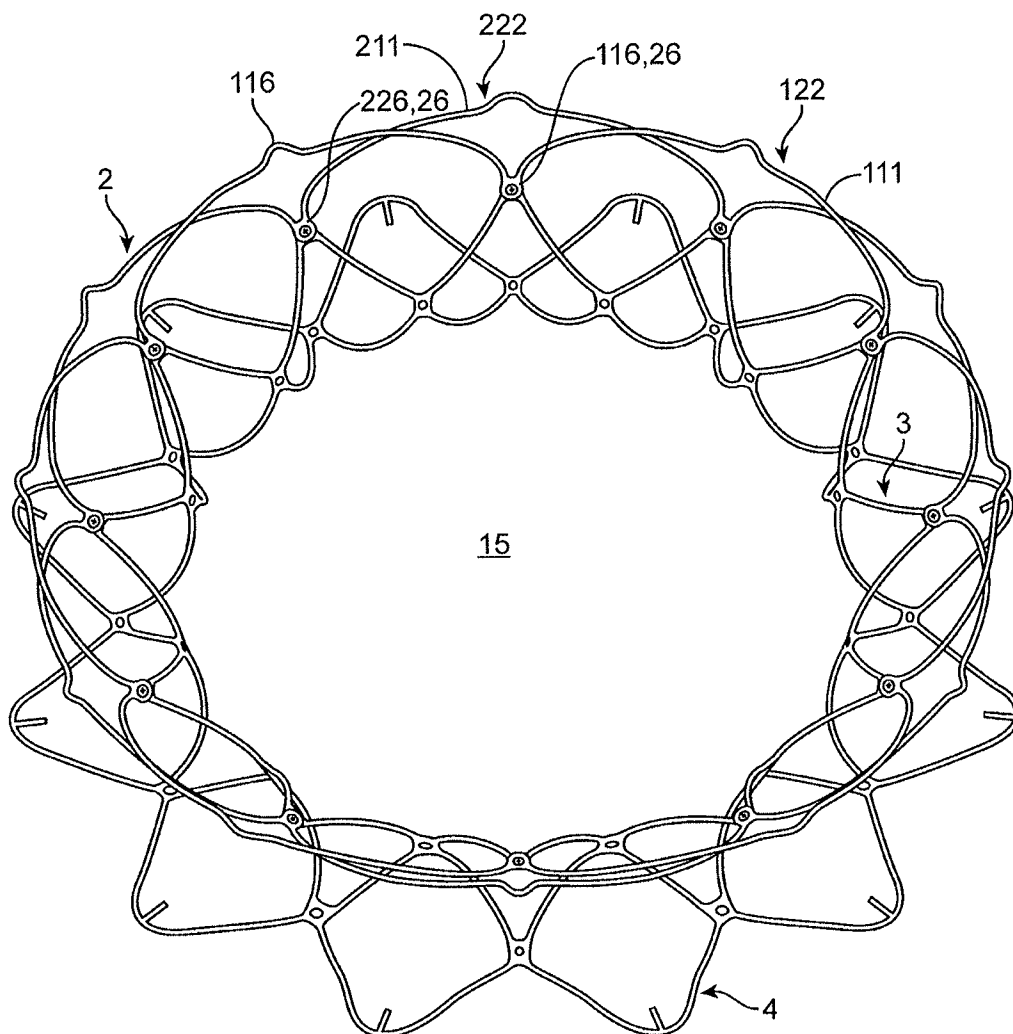


FIG. 9

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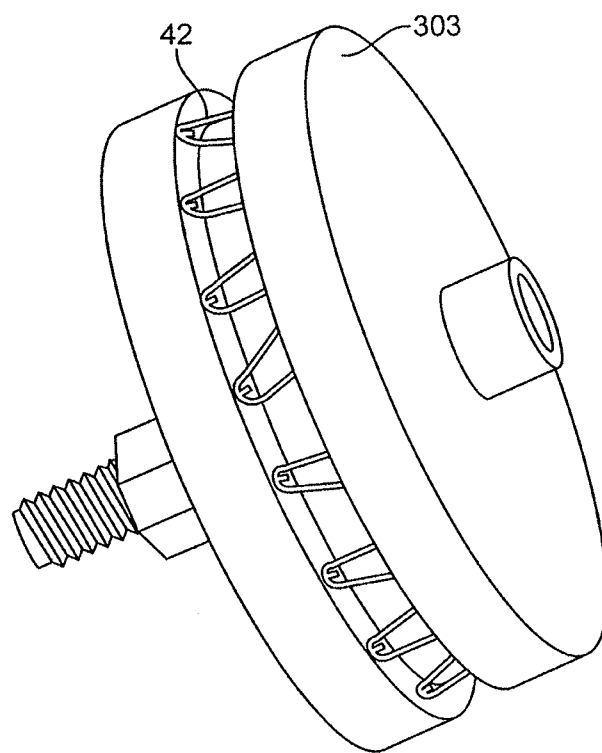


FIG. 10

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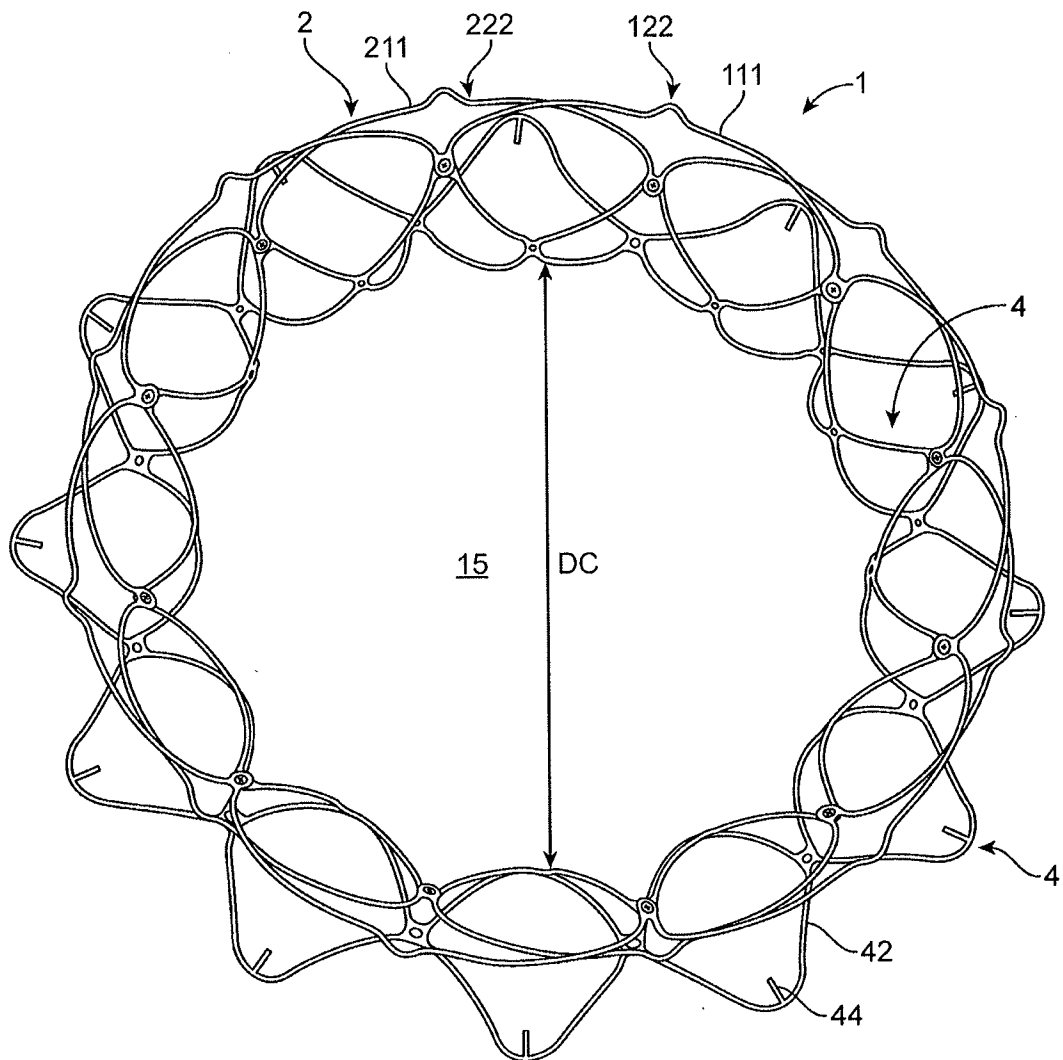


FIG. 11A

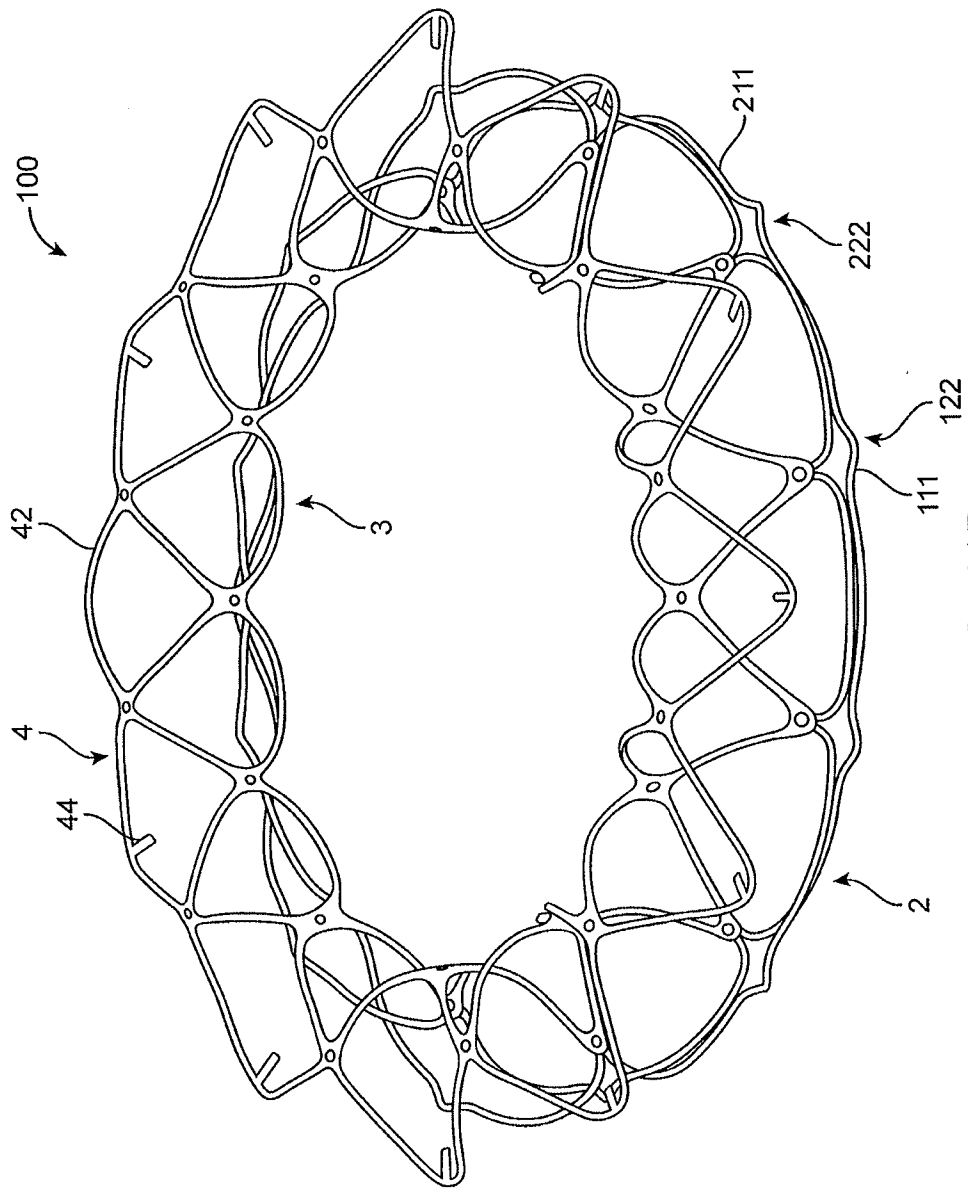


FIG. 11B

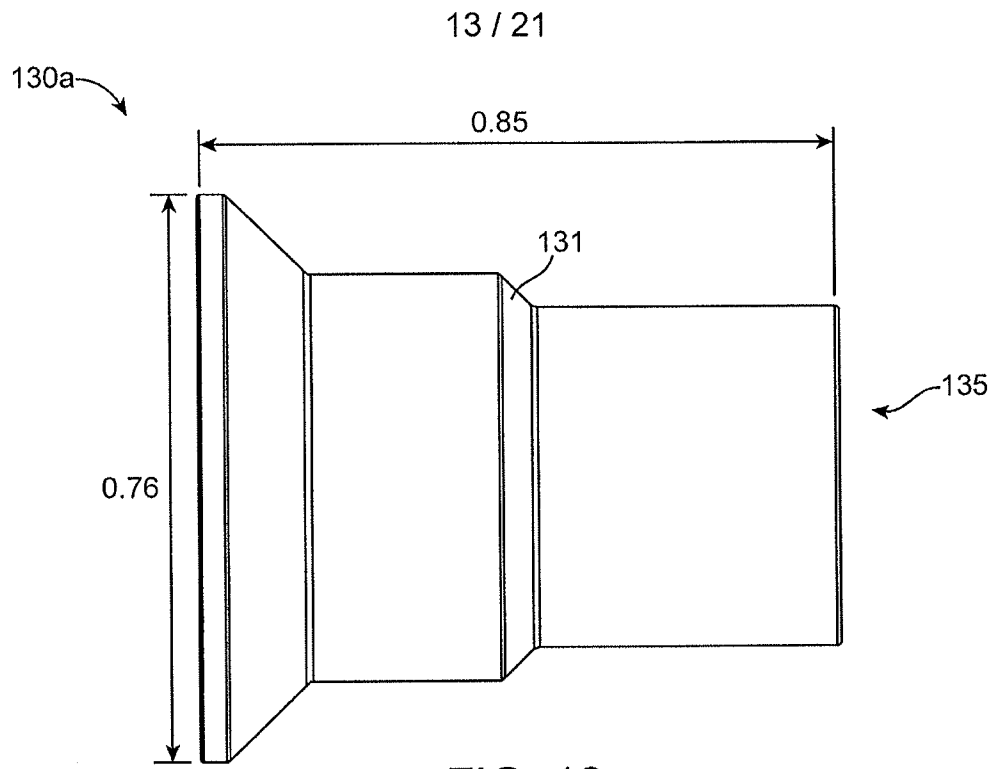


FIG. 12

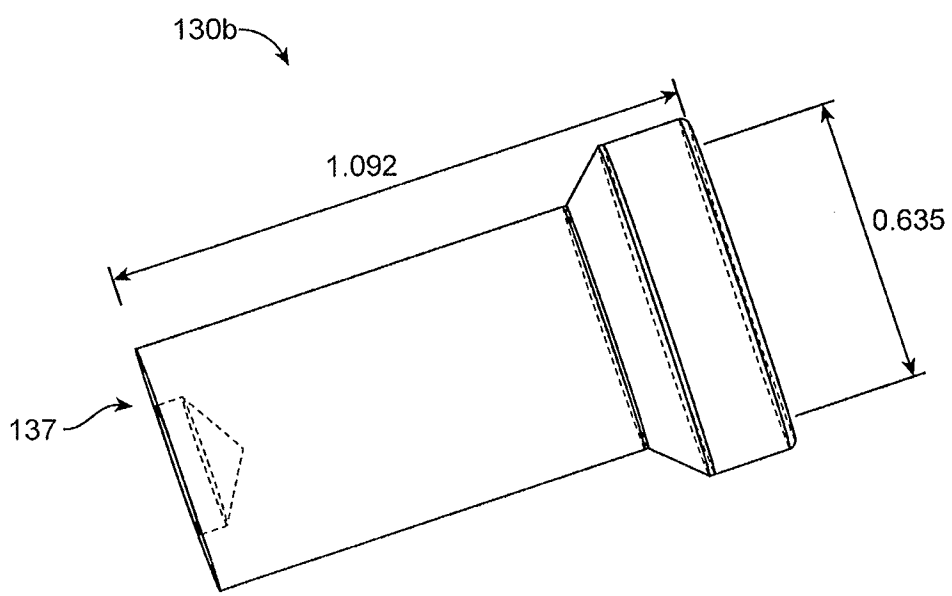


FIG. 13

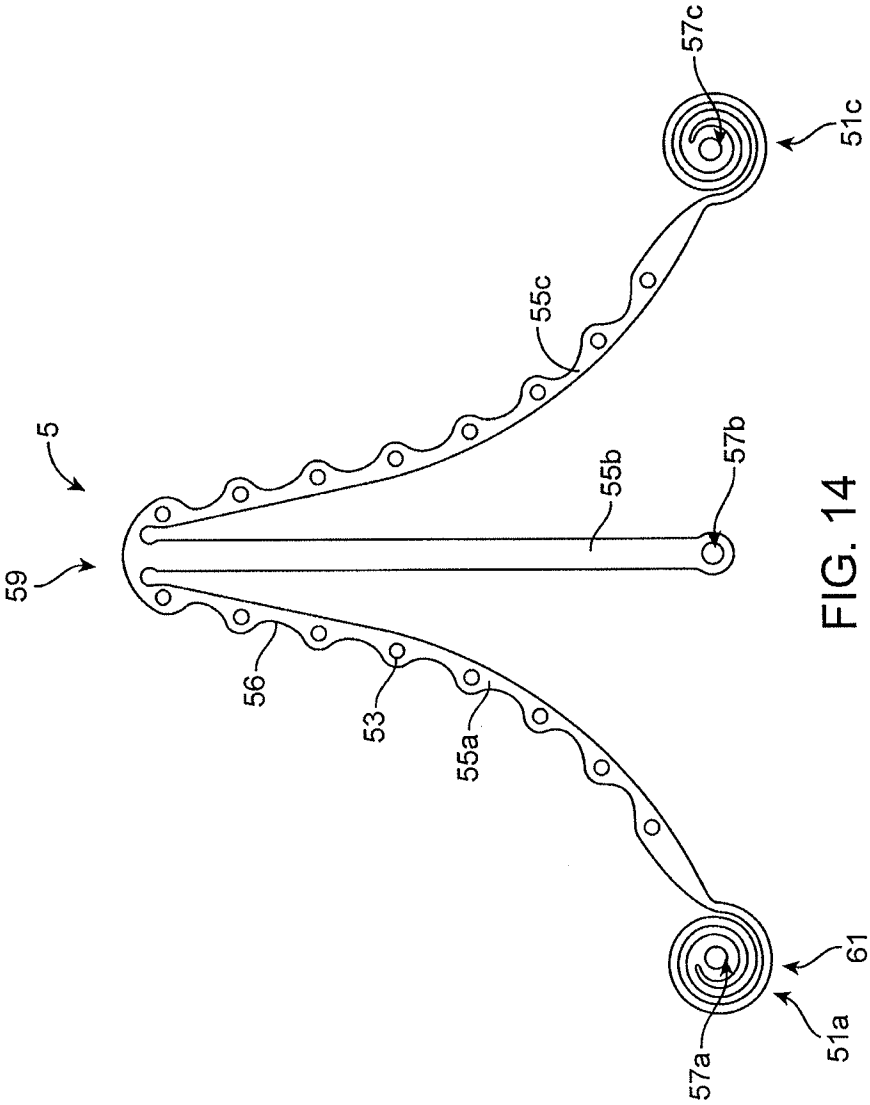


FIG. 14

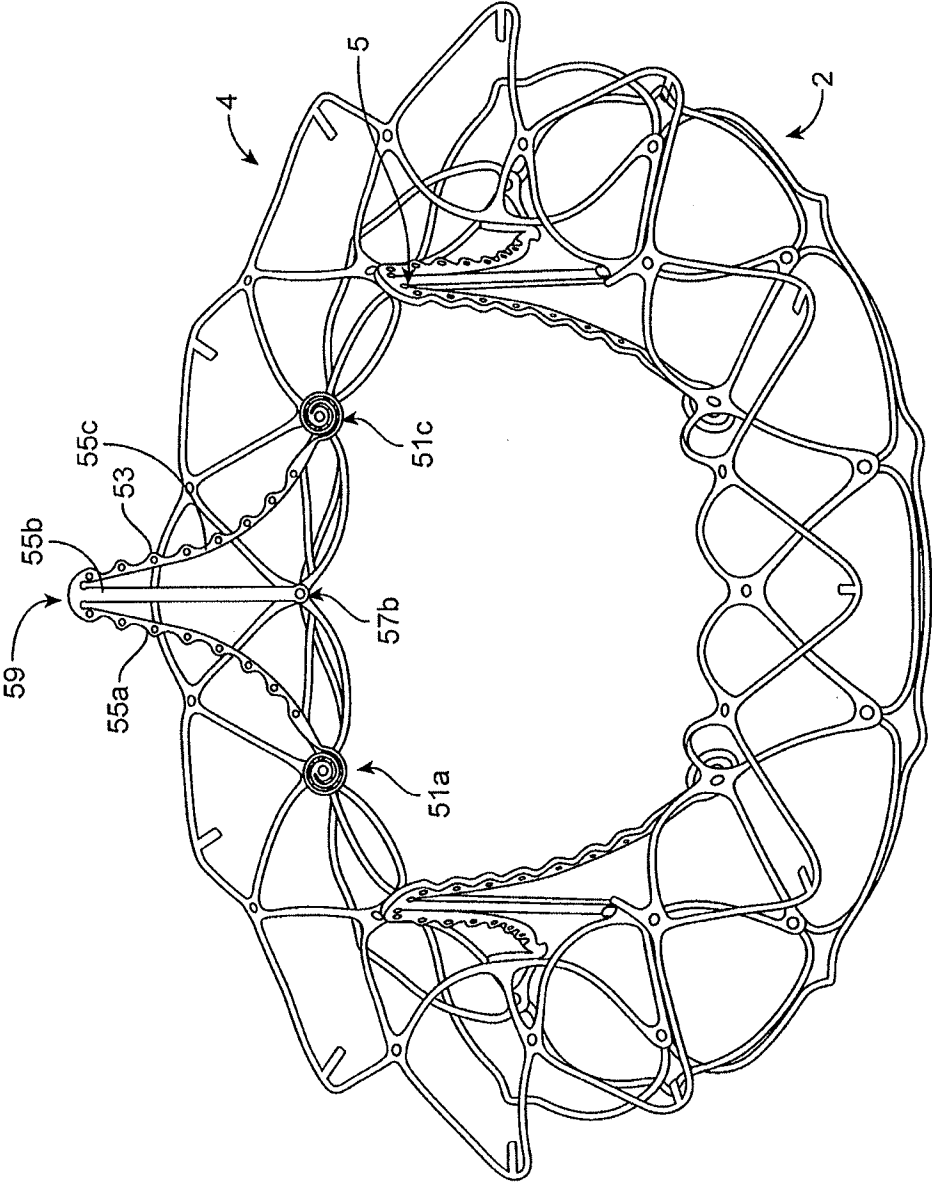


FIG. 15

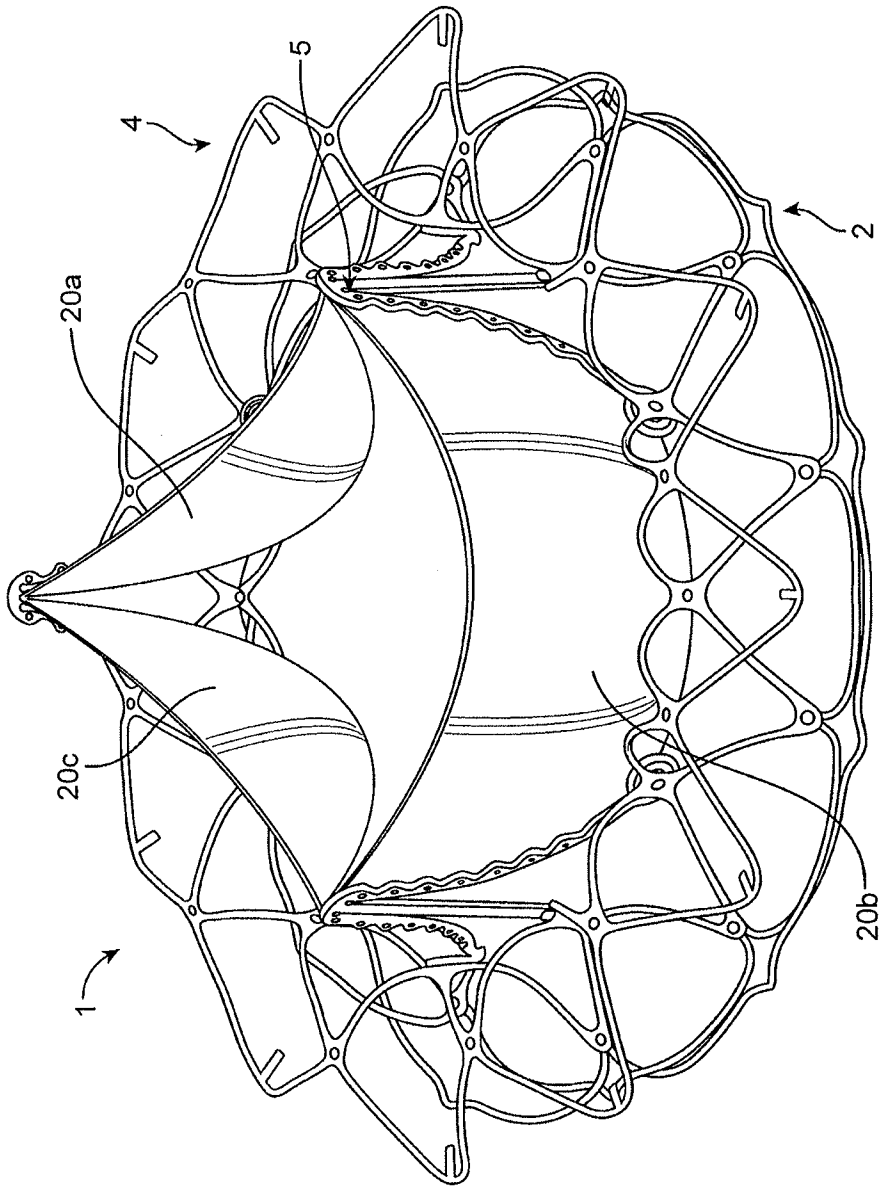


FIG. 16

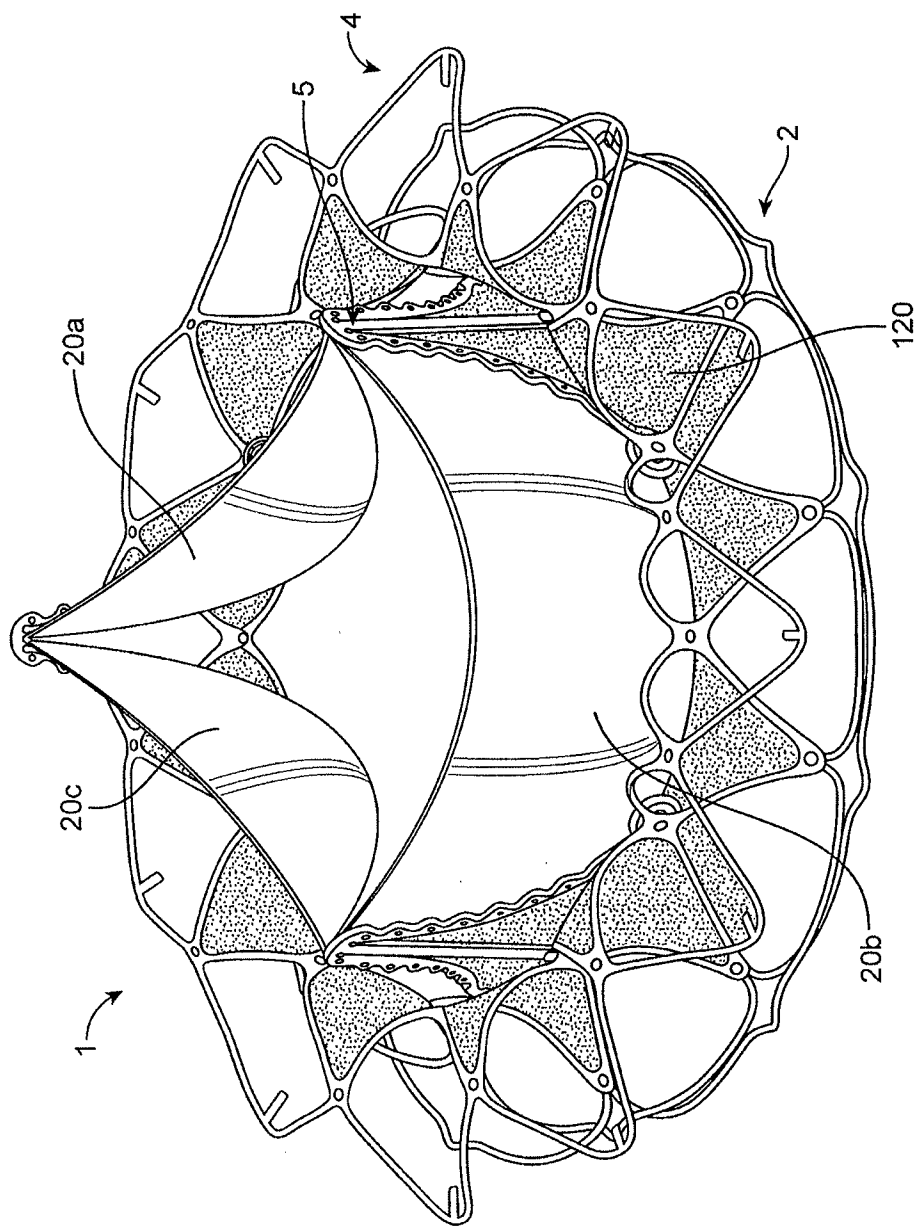


FIG. 17

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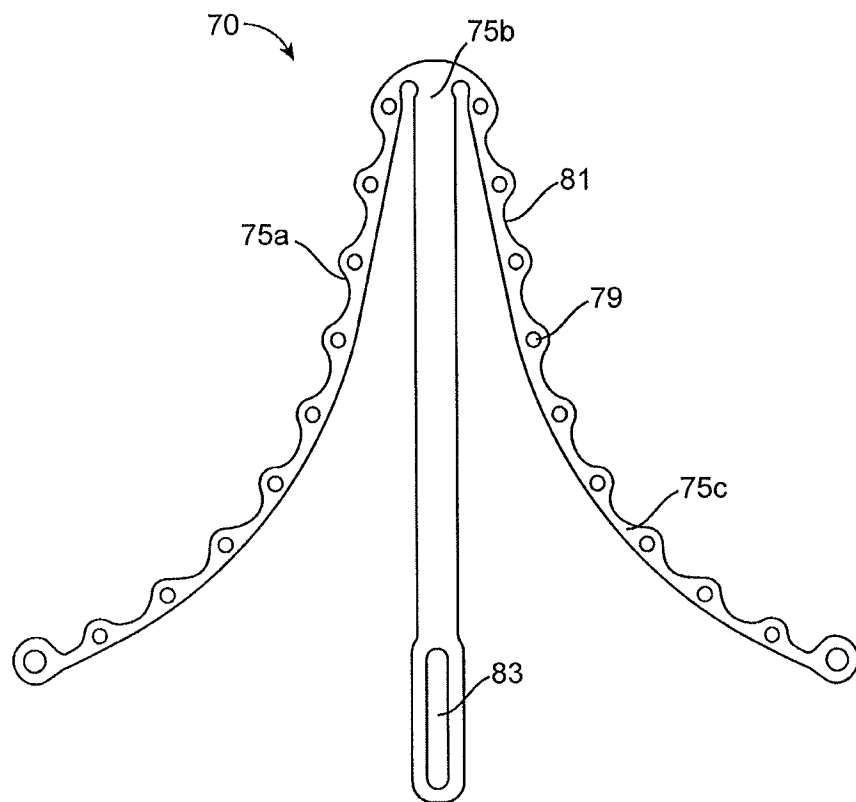


FIG. 18

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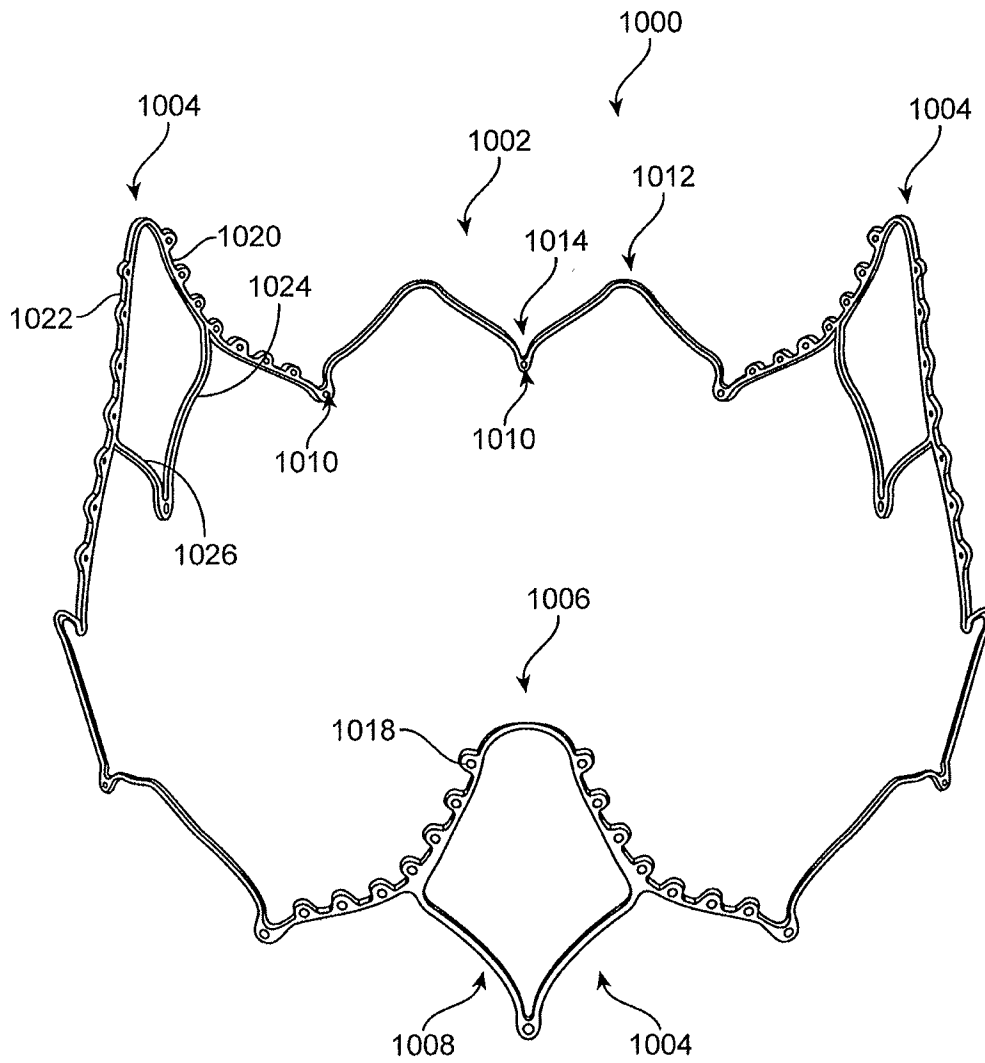


FIG. 19

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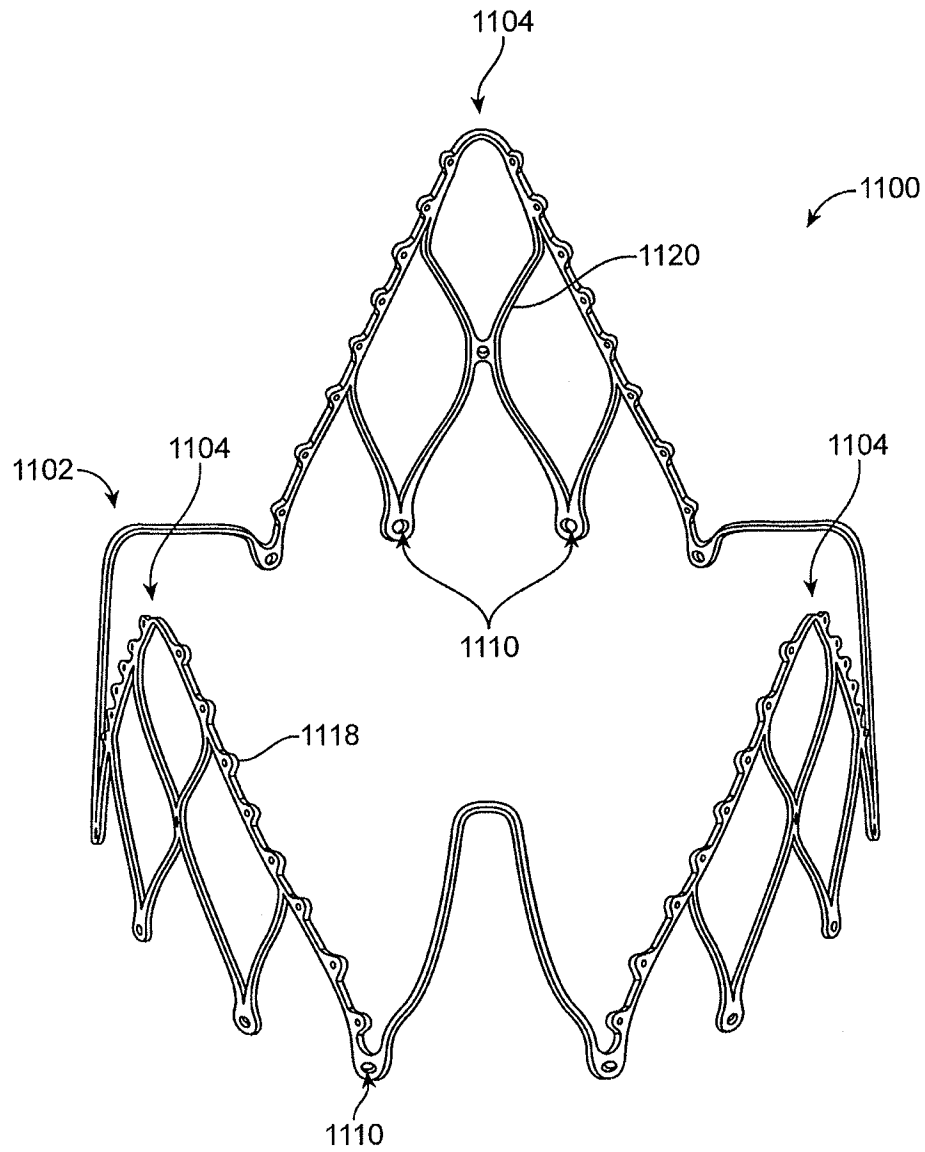


FIG. 20

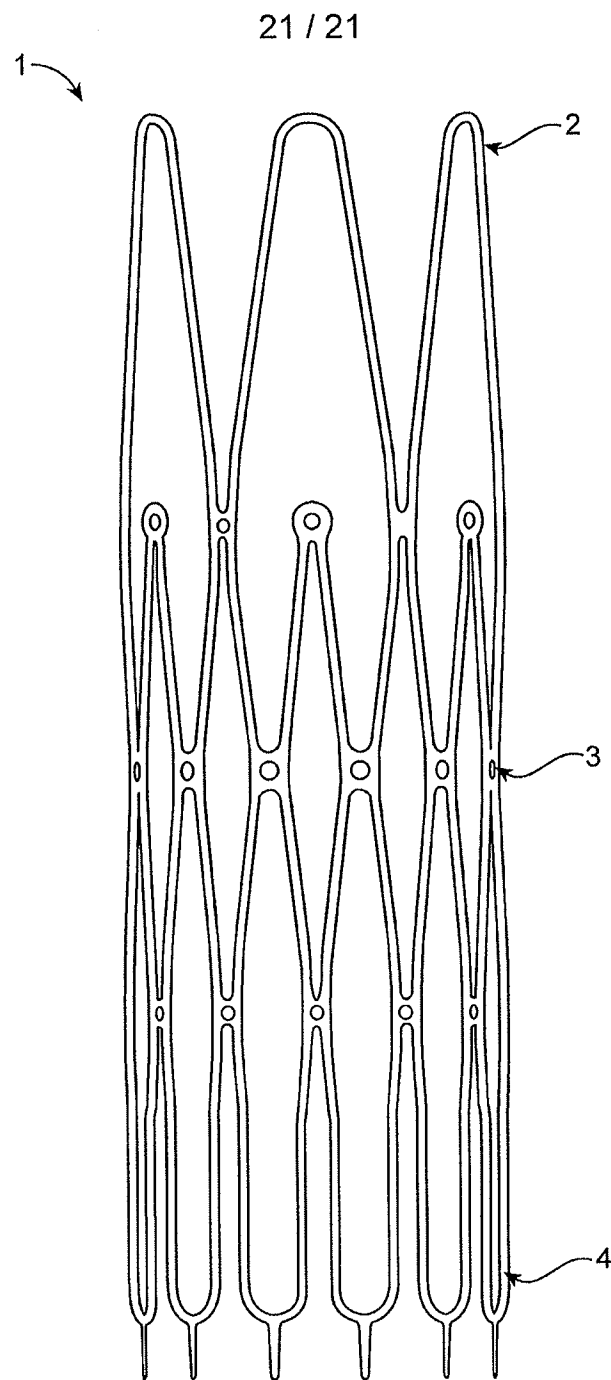


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/24028

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/24 (2015.01)

CPC - A61F 2/2418

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC (8): A61F 2/24 (2015.01)

CPC: A61F 2/2418

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC: A61F 2230/0065, A61F 2/2439, A61F 2/2409, A61F 2/2412; UC: 623/2.1, 623/2.18, 623/2.17

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

PatBase, Google Patent, Google Scholar

Search terms used: Commissure heart valve replacement mitral ventricular arches atrial arch stiffness triangular strut frame aperture
strut* frame* aperture* hole* anchor valve* arch* atri* ventric*

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 8,870,948 B1 (Erzberger et al.) 29 October 2014 (28.10.2014), Entire document	1-11, 13-14, 18-20, 22-23, 27, 32, 37, 41-48, 50-51, 55-57
Y		
A		15-17, 21, 52-54, 58, 65-66, 69-70, 72
		12, 24-26, 28-31, 33-36, 38-40, 49, 67-68, 71, 73, 80-83
Y	US 2014/0039611 A1 (Lane et al.) 06 February 2014 (06.02.2014), Entire document	15-17, 21, 52-54, 58, 65-66, 69-70, 72
A		67-68, 71, 73
A	US 2011/0295363 A1 (Girard et al.) 01 December 2011 (01.12.2011), Entire document	1-58, 65-73, 80-83
A	US 2011/0245911 A1 (Quill et al.) 06 October 2011 (06.10.2011), Entire document	1-58, 65-73, 80-83
A	US 2014/0005778 A1 (Buchbinder et al.) 02 January 2014 (02.01.2014), Entire document	1-58, 65-73, 80-83

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

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

14 August 2015 (14.08.2015)

Date of mailing of the international search report

01 SEP 2015

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/24028

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-58, 65-73, and 80-83 directed to a replacement mitral valve.

Group II: Claims 59-64, 74-79, and 84 directed to a method of manufacturing a replacement mitral valve.

---Continued on Supplemental Page---

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-58, 65-73, 80-83

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Continuation of Box III: Observations where unity of invention is lacking

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group II requires particular method steps such as aligning each of the apertures to form aligned apertures; extending a coupler through each of the aligned apertures from one side of the aligned apertures to a second side of the aligned apertures, and plastically deforming each of the couplers to secure the central portion to the annular frame at the location of the couplers, not required in Group I.

Groups I-II are related as an apparatus (Group I) and a method of manufacturing thereof (Group II) and thus share the technical features of a replacement mitral valve, comprising: a self-expandable anchor comprising a ventricular anchor comprising a plurality of ventricular arches, a central portion, and an atrial anchor comprising an annular frame with a plurality of atrial arches and a plurality of atrial apertures therethrough; the atrial anchor secured to the central portion and not integral with the central portion, the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion such that the replacement mitral valve is configured to be secured within a mitral valve orifice, wherein the central portion includes a plurality of central apertures therethrough, each of the plurality of atrial apertures in alignment with one of the plurality of central apertures to form a plurality of aligned apertures; a plurality of couplers, each of which extends through one of the plurality of aligned apertures and secures the central portion to the annular frame at the location of the aligned apertures; and a plurality of replacement leaflets secured to the expandable anchor.

However, these shared technical features fail to make a contribution over prior art as being obvious over US 8,870,948 B1 to Erzberger et al. (hereinafter Erzberger) in view of US 2014/0039611 A1 to Lane et al. (hereinafter Lane). Erzberger teaches a replacement mitral valve (abstract), comprising: a self-expandable anchor (col 2, ln 43-45) comprising a ventricular anchor (col 5, ln 8-9) comprising a plurality of ventricular arches (plurality of arcs 0 col 5, ln 60-65), a central portion (col 5, ln 10-11), and an atrial anchor (col 5, ln 9-10) comprising an annular frame (col 5, ln 50-55) with a plurality of atrial arches (plurality of arcs - col 5, ln 60-65); the atrial anchor secured to the central portion and not integral with the central portion (joints - col 6, ln 34-44), the self-expandable anchor having a self-expanded configuration in which the ventricular anchor and the atrial anchor are flared radially outward relative to the central portion (diameter greater than a diameter of the central portion - col 2, ln 29-33) such that the replacement mitral valve is configured to be secured within a mitral valve orifice (col 5, ln 17-28), wherein; a plurality of couplers (crimps - col 6, ln 5-10); and a plurality of replacement leaflets secured to the expandable anchor (col 5, ln 12-13), but does not teach a plurality of atrial apertures, wherein the central portion includes a plurality of central apertures therethrough, each of the plurality of atrial apertures in alignment with one of the plurality of central apertures to form a plurality of aligned apertures, or wherein each of the couplers which extends through one of the plurality of aligned apertures and secures the central portion to the annular frame at the location of the aligned apertures. However, Lane teaches apertures in several regions (fig 8, para [0099]) that are configured to allow attachment of an element (para [0099]). Further, couplers (sutures) are intended to pass through the apertures (para [0045]). It would have been obvious to one of ordinary skill in the art to have modified the device of Erzberger with the apertures of Lane so that the device would be as claimed in order to have provided a secure coupling between the different sections.

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.