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Canadian Intellectual Property Office

CA 2900571 C 2021/10/19

(11)(21) **2 900 571**

(12) **BREVET CANADIEN**
CANADIAN PATENT

(13) **C**

(86) Date de dépôt PCT/PCT Filing Date: 2014/03/06
(87) Date publication PCT/PCT Publication Date: 2014/09/18
(45) Date de délivrance/Issue Date: 2021/10/19
(85) Entrée phase nationale/National Entry: 2015/08/07
(86) N° demande PCT/PCT Application No.: CA 2014/000188
(87) N° publication PCT/PCT Publication No.: 2014/138868
(30) Priorités/Priorities: 2013/03/11 (US61/776,566); 2014/03/03 (US14/195,576)

(51) Cl.Int./Int.Cl. *A61F 2/24* (2006.01)

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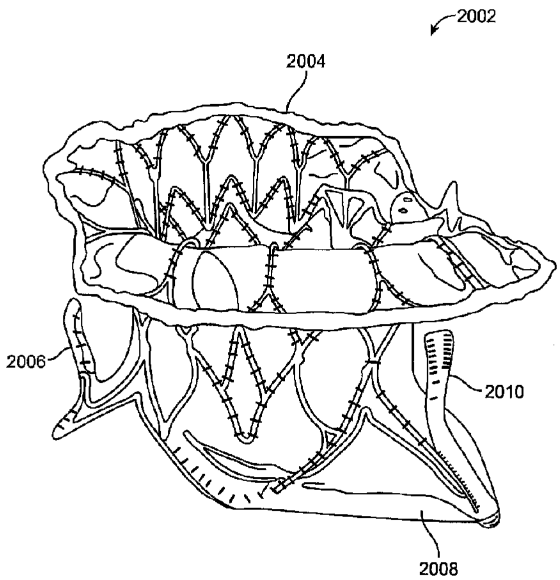
(54) Titre : VALVULE PROTHETIQUE A MECANISME ANTI-PIVOTANT
(54) Title: PROSTHETIC VALVE WITH ANTI-PIVOTING MECHANISM



(57) Abrégé/Abstract:
A prosthetic valve for implanting in a patient's native valve has a self-expanding frame that comprises a first end, a second end opposite the first end, an anterior portion, and a posterior portion. The self-expanding frame has an expanded configuration adapted to engage tissue at a treatment site, and a collapsed configuration adapted to be delivered to the treatment site. The expandable frame also comprises a self-expanding atrial skirt near the second end, a self-expanding ventricular skirt near the first end, a self-expanding annular region disposed between first and second ends, a first self-expanding anterior tab disposed on the anterior portion, and a self-expanding foot coupled to the posterior portion and extending radially outward. The foot has an outer surface for engaging the tissue thereby facilitating anchoring of the prosthetic valve and minimizing or preventing rotation of the prosthetic valve.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 September 2014 (18.09.2014)

(10) International Publication Number
WO 2014/138868 A1

(51) International Patent Classification:
A61F 2/24 (2006.01)

(21) International Application Number:
PCT/CA2014/000188

(22) International Filing Date:
6 March 2014 (06.03.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/776,566 11 March 2013 (11.03.2013) US
14/195,576 3 March 2014 (03.03.2014) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: PROSTHETIC VALVE WITH ANTI-PIVOTING MECHANISM

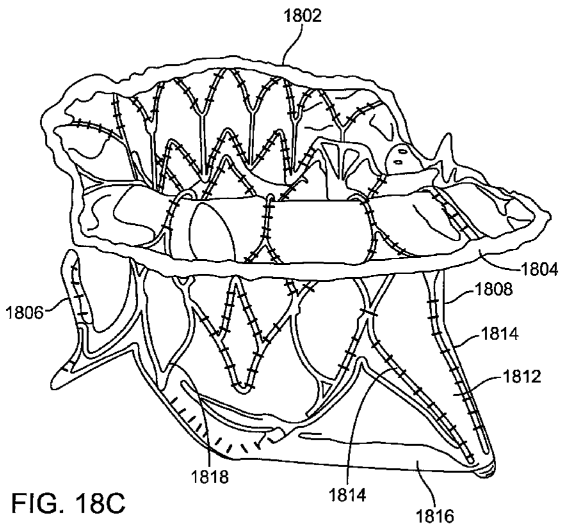

FIG. 18C

(57) **Abstract**: A prosthetic valve for implanting in a patient's native valve has a self-expanding frame that comprises a first end, a second end opposite the first end, an anterior portion, and a posterior portion. The self-expanding frame has an expanded configuration adapted to engage tissue at a treatment site, and a collapsed configuration adapted to be delivered to the treatment site. The expandable frame also comprises a self-expanding atrial skirt near the second end, a self-expanding ventricular skirt near the first end, a self-expanding annular region disposed between first and second ends, a first self-expanding anterior tab disposed on the anterior portion, and a self-expanding foot coupled to the posterior portion and extending radially outward. The foot has an outer surface for engaging the tissue thereby facilitating anchoring of the prosthetic valve and minimizing or preventing rotation of the prosthetic valve.

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PROSTHETIC VALVE WITH ANTI-PIVOTING MECHANISM

[0001]

[0002]

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention. The present invention generally relates to medical devices and methods, and more particularly relates to the treatment of valve insufficiency, such as mitral insufficiency, also referred to as mitral regurgitation. The use of prosthetic valves delivered by traditional surgical implantation methods, or by a less invasive percutaneous catheter or by minimally invasive transapical methods are one possible treatment for valvar insufficiency (also referred to as regurgitation).

[0004] The heart of vertebrate animals is divided into four chambers, and is equipped with four valves (the mitral, aortic, pulmonary and tricuspid valves) that ensure that blood pumped by the heart flows in a forward direction through the cardiovascular system. The mitral valve of a healthy heart prevents the backflow of blood from the left ventricle into the left atrium of the heart, and comprises two flexible leaflets (anterior and posterior) that close when the left ventricle contracts. The leaflets are attached to a fibrous annulus, and their free edges are tethered by subvalvular chordae tendineae to papillary muscles in the left ventricle to prevent them from prolapsing into the left atrium during the contraction of the left ventricle.

[0005] Various cardiac diseases or degenerative changes may cause dysfunction in any of these portions of the mitral valve apparatus, causing the mitral valve to become abnormally narrowed or dilated, or to allow blood to leak (i.e. regurgitate) from the left ventricle back into the left atrium. Any such impairments compromise cardiac sufficiency, and can be debilitating or life threatening.

[0006] Numerous surgical methods and devices have accordingly been developed to treat mitral valve dysfunction, including open-heart surgical techniques for replacing, repairing or re-shaping the native mitral valve apparatus, and the surgical implantation of various prosthetic

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devices such as annuloplasty rings to modify the anatomy of the native mitral valve. More recently, less invasive transcatheter techniques for the delivery of replacement mitral valve assemblies have been developed. In such techniques, a prosthetic valve is generally mounted in a crimped state on the end of a flexible catheter and advanced through a blood vessel or the body of the patient until the valve reaches the implantation site. The prosthetic valve is then expanded to its functional size at the site of the defective native valve.

[0007] While these devices and methods are promising treatments for valvar insufficiency, they can be difficult to deliver and anchor, expensive to manufacture, or may not be indicated for all patients. Some of these prosthetic valves having anchoring mechanisms that secure the valve to various portions of the valve anatomy. For example, some the valves are anchored to the atrial floor, the valve annulus, a ventricular wall, or to the valve leaflets. However, in some situations, depending on anatomy, skill of the physician, as well as other factors, the prosthetic valve may not always be successfully anchored. For example, in the case of a prosthetic mitral valve with anchors for securing the valve to the native anterior and posterior leaflets, if the anchor(s) do not successfully engage the posterior leaflet, the prosthetic valve may be pushed upward toward the atrium during ventricular contraction due to the force of the blood. This may result in an improperly positioned valve which can prevent the valve from properly functioning. Therefore, it would be desirable to provide improved devices and methods for the treatment of valvar insufficiency such as mitral insufficiency. Such devices preferably have alternative or improved anchoring mechanisms to more securely anchor the prosthesis to the valve structure. At least some of these objectives will be met by the devices and methods disclosed below.

[0008] 2. Description of the Background Art. By way of example, PCT international patent number PCT/US2008/054410 (published as PCT international publication No. WO2008/103722), describes a transcatheter mitral valve prosthesis that comprises a resilient ring, a plurality of leaflet membranes mounted with respect to the ring so as to permit blood flow therethrough in one direction, and a plurality of tissue-engaging positioning elements movably mounted with respect to the ring and dimensioned to grip the anatomical structure of the heart valve annulus, heart valve leaflets, and/or heart wall. Each of the positioning elements defines respective proximal, intermediate, and distal tissue engaging regions cooperatively

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configured and dimensioned to simultaneously engage separate corresponding areas of the tissue of an anatomical structure, and may include respective first, second, and third elongate tissue-piercing elements. The valve prosthesis may also include a skirt mounted with respect to the resilient ring for sealing a periphery of the valve prosthesis against a reverse flow of blood around the valve prosthesis.

[0009] PCT international patent number PCT/US2009/041754 (published as PCT international publication No. WO2009/134701), describes a prosthetic mitral valve assembly that comprises an anchor or outer support frame with a flared upper end and a tapered portion to fit the contours of the native mitral valve, and a tissue-based one-way valve mounted therein. The assembly is adapted to expand radially outwardly and into contact with the native heart tissue to create a pressure fit, and further includes tension members anchoring the leaflets of the valve assembly to a suitable location on the heart to function as prosthetic chordae tendineae.

[0010] Also known are prosthetic mitral valve assemblies that utilize a claw structure for attachment of the prosthesis to the heart (see, for example, U.S. Patent Publication No. US2007/0016286 to Hermann et al.), as are prosthetic mitral valve assemblies that rely on the application of axial rather than radial clamping forces to facilitate the self-positioning and self-anchoring of the prosthesis with respect to the native anatomical structure.

[0011] Another method which has been proposed as a treatment of mitral valve regurgitation is the surgical bow tie method, which recently has been adapted into a minimally invasive catheter based treatment where an implant is used to clip the valve leaflets together. This procedure is more fully disclosed in the scientific and patent literature, such as in U.S. Patent No. 6,629,534 to St. Goar et al.

[0012] Other relevant publications include U.S. Patent Publication No. 2011/0015731 to Carpentier et al. and WO2011/137531 to Lane et al. While some of these devices and methods are promising, there still is a need for improved devices and methods that will further allow more accurate positioning of a prosthetic valve and that will also more securely anchor the valve in place. At least some of these objectives will be met by the exemplary embodiments disclosed herein.

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SUMMARY OF THE INVENTION

[0013] The present invention generally relates to medical devices and methods, and more particularly prosthetic valves used to treat mitral regurgitation. While the present disclosure focuses on the use of a prosthetic valve for treating mitral regurgitation, this is not intended to be limiting. The prosthetic valves disclosed herein may also be used to treat other body valves including other heart valves or venous valves. Exemplary heart valves include the aortic valve, the tricuspid valve, or the pulmonary valve.

[0014] In a first aspect of the present invention, a prosthetic valve for implanting in a native valve of a patient, said prosthetic valve comprising: a self-expanding frame having a first end, a second end opposite the first end, an atrial region near the second end, a ventricular region near the first end, an anterior portion, and a posterior portion, wherein the self-expanding frame has an expanded configuration and a collapsed configuration, the expanded configuration adapted to engage native heart tissue at a treatment site, and the collapsed configuration adapted to be delivered to the treatment site, and wherein the expandable frame comprises: a self-expanding atrial skirt disposed in the atrial region; a self-expanding ventricular skirt disposed in the ventricular region, the ventricular skirt comprising a plurality of struts having a length; a self-expanding annular region disposed between the atrial region and the ventricular region; a first self-expanding anterior tab disposed on the anterior portion of the self-expanding frame in the ventricular region; a self-expanding posterior tab disposed on the posterior portion of the self-expanding frame in the ventricular region; and a self-expanding foot coupled to the ventricular region, wherein the foot comprises a wedge shaped element extending laterally and radially outward from a periphery of the ventricular skirt, wherein the foot comprises a plurality of struts having a length greater than the length of the struts in the ventricular skirt, and wherein the posterior tab coupled to and extends from the foot, wherein the foot has an outer surface for engaging the native heart tissue thereby facilitating anchoring of the prosthetic valve and minimizing or preventing rotation of the prosthetic valve.

[0015] The prosthetic valve may be a prosthetic mitral valve. The atrial skirt may have a collapsed configuration and an expanded configuration. The collapsed configuration may be adapted for delivery to the treatment site, and the expanded configuration may be radially expanded relative to the collapsed configuration and adapted to lie over a superior surface of

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the patient's native valve, thereby anchoring the atrial skirt against a superior portion of the native valve. The atrial skirt may comprise a plurality of axially oriented struts connected together with a connector element thereby forming a series of peaks and valleys. After self-expansion of the atrial skirt, the atrial skirt may form a flanged region adjacent the second end of the self-expanding frame. The atrial skirt may have an asymmetrically D-shaped cross-section having a substantially flat anterior portion, and a cylindrically shaped posterior portion after self-expansion. The prosthetic valve may further comprise an alignment element coupled to an anterior portion of the atrial skirt. The alignment element may be adapted to be aligned with an aortic root of a patient's heart and may be adapted to be disposed between two fibrous trigones of an anterior leaflet of the patient's mitral valve.

[0016] At least a portion of the ventricular skirt may be covered with tissue or a synthetic material. After self-expanding, the ventricular skirt may comprise an asymmetrically D-shaped cross-section having a substantially flat anterior portion, and a cylindrically shaped posterior portion. The ventricular skirt may have a collapsed configuration and an expanded configuration. The collapsed configuration may be adapted for delivery to the treatment site, and the expanded configuration may be radially expanded relative to the collapsed configuration and may also be adapted to displace native mitral valve leaflets radially outward. The ventricular skirt may further comprise a plurality of barbs coupled thereto. The plurality of barbs may be adapted to anchor the ventricular skirt into the tissue. The ventricular skirt may comprise a plurality of struts connected together with a connector element thereby forming a series of peaks and valleys. Any of the struts in the prosthetic valve may have one or more suture holes extending through the strut and sized to receive a suture.

[0017] The annular region may have a collapsed configuration and an expanded configuration. The collapsed configuration may be adapted for delivery to the treatment site. The expanded configuration may be radially expanded relative to the collapsed configuration and may be adapted to conform with and may be adapted to engage an annulus of the native valve. After self-expanding, the annular region may have an asymmetrically D-shaped cross-section having a substantially flat anterior portion, and may also have a cylindrically shaped posterior portion. The annular region may comprise a plurality of axially oriented struts connected together with a connector element, and that may form a series of peaks and valleys. One or more of the

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plurality of axially oriented struts may comprise one or more suture holes extending through the strut, and the holes may be sized to receive a suture.

[0018] The first anterior tab may have a tip portion that is adapted to engage a first fibrous trigone on a first side of an anterior leaflet of the patient's mitral valve. The first anterior tab may be adapted to capture the anterior leaflet and adjacent chordae tendineae between the first anterior tab and an outer anterior surface of the ventricular skirt. The prosthetic valve may further comprise a second self-expanding anterior tab disposed on the anterior portion of the self-expanding frame in the ventricular region. The second anterior tab may have a tip portion that is adapted to engage a second fibrous trigone on a second side of the anterior leaflet of the patient's mitral valve opposite the first side of the anterior leaflet. The second anterior tab may be adapted to capture the anterior leaflet and adjacent chordae tendineae between the second anterior tab and the outer surface of the ventricular skirt.

[0019] The prosthetic valve may further comprise a covering disposed over the first or the second anterior tabs. The covering increases contact surface area of the respective first or second anterior tab with the heart or other treatment tissue. The covering may comprise a fabric material disposed over a polymer tab that is coupled to the first or the second anterior tab.

[0020] Rotation of the posterior portion of the prosthetic valve may be minimized or prevented relative to the anterior portion of the prosthetic valve with the foot. Rotation may be minimized or prevented in an upstream direction toward the left atrium of the patient's heart. The foot may be covered with a synthetic material or with tissue. The foot may comprise a wedge shaped element extending radially outward from the self-expanding frame. The foot may comprise a central elongate element and a cover. The cover may be disposed over the central elongate element and the cover may be coupled to a strut on either side thereof. The central elongate element may comprise a pair of struts coupled together to form a U-shape or a V-shape. The foot may form a vestibule on the posterior portion of the prosthetic valve. The foot may comprise barbs, texturing or other surface features for anchoring the foot to tissue.

[0021] The prosthetic valve may further comprise a plurality of prosthetic valve leaflets. Each of the leaflets may have a first end and a free end, and the first end may be coupled with the self-expanding frame and the free end may be opposite of the first end. The prosthetic valve

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leaflets may have an open configuration in which the free ends of the prosthetic valve leaflets are disposed away from one another to allow antegrade blood flow therepast, and a closed configuration in which the free ends of the prosthetic valve leaflets engage one another and substantially prevent retrograde blood flow therepast. The plurality of prosthetic valve leaflets may form a tricuspid valve. At least a portion of one or more prosthetic valve leaflets may comprise tissue or a synthetic material. One or more of the prosthetic valve leaflets may comprise a commissure post having a commissure tab. The commissure tab may be adapted to be releasably engaged with a delivery device. The prosthetic valve may carry a therapeutic agent that is adapted to being eluted therefrom. The prosthetic valve may further comprise a posterior ventricular anchoring tab disposed on a posterior portion of the self-expanding frame. The posterior ventricular anchor tab may be anchored over a posterior leaflet of the patient's mitral valve such that the posterior ventricular anchoring tab is seated between the posterior leaflet and a ventricular wall of the patient's heart. The posterior ventricular anchoring tab may have barbs, texturing or other surface features disposed thereon, and that are adapted to engage tissue and anchor the posterior ventricular tab to the tissue.

[0022]

[0023] Providing the prosthetic valve may further comprise providing a delivery device for delivering the prosthetic valve to the native valve, and the prosthetic valve may be releasably coupled to the delivery device.

[0024] Advancing the prosthetic valve may comprise transapically delivering the prosthetic valve from a region outside of the patient to the patient's heart. Advancing the prosthetic valve may comprise transseptally delivering the prosthetic valve from the right atrium to the left atrium of the patient's heart. Advancing the prosthetic valve may comprise positioning the prosthetic valve across the patient's mitral valve so that the second end is superior to the mitral valve and the first end is inferior to the mitral valve.

[0025] Expanding the first anterior tab may comprise retracting a constraining sheath therefrom and allowing the first anterior tab to self-expand radially outward. The prosthetic valve may further comprise a second anterior tab on the anterior portion of the expandable frame, and the method may further comprise expanding the second anterior tab radially outward such that a tip portion of the second anterior tab engages a second fibrous trigone on a second side of the

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anterior leaflet opposite the first side of the anterior leaflet. The second anterior tab may expand radially outward concurrently with expansion of the first anterior tab. Expanding the second anterior tab may comprise retracting a constraining sheath from the second anterior tab so that the second anterior tab is free to self-expand radially outward. The first and second anterior tabs may both self-expand when a single constraining sheath is retracted.

[0026] Expanding the foot may form a vestibule adjacent the first end of the prosthetic valve, and may increase the size of the first end of the prosthetic valve so that it cannot pass through the native valve. Expanding the foot may comprise retracting a constraint therefrom so that the foot self-expands radially outward. The posterior chordae tendineae may engage the expanded foot. The foot may comprise barbs, texturing, or other surface features. Expanding the foot may engage the barbs, texturing or other surface features with tissue thereby anchoring the foot with the tissue.

[0027] The method may also comprise expanding the ventricular skirt radially outward into engagement with the anterior and posterior leaflets of the native valve. The anterior chordae tendineae may be disposed between the first anterior tab and the outer surface of the ventricular skirt. Expanding the ventricular skirt may comprise retracting a constraining sheath from the ventricular skirt so that the ventricular skirt is free to self-expand radially outward. The ventricular skirt may comprise a plurality of barbs, and expanding the ventricular skirt may comprise anchoring the plurality of barbs into heart tissue. The prosthetic valve may further comprise a plurality of commissures, and expanding the ventricular skirt may displace the anterior and posterior leaflets of the native valve radially outward thereby preventing interference between the commissures and the leaflets. Expanding the ventricular skirt may displace the anterior and posterior leaflets of the native valve radially outward without contacting an inner wall of the left ventricle, and without obstructing a left ventricular outflow tract. Radially expanding the ventricular skirt may expand the ventricular skirt asymmetrically such that an anterior portion of the ventricular skirt is substantially flat, and a posterior portion of the ventricular skirt is cylindrically shaped.

[0028] The method may also include expanding the annular region radially outward so as to engage an annulus of the native valve. Expanding the annular region may comprise retracting a constraining sheath therefrom so that the annular region is free to self-expand radially outward.

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Expanding the annular region may comprise asymmetrically expanding the annular region such that an anterior portion of the annular region is substantially flat, and a posterior portion of the annular region is cylindrically shaped.

[0029] The native valve may be a mitral valve, and the method may further comprise reducing or eliminating mitral regurgitation. The prosthetic valve may carry a therapeutic agent, and the method may further comprise eluting the therapeutic agent from the prosthetic valve into adjacent tissue.

[0030] The prosthetic valve may comprise an alignment element, the method may further comprise aligning the alignment element with an aortic root and disposing the alignment element between the first and second fibrous trigones. Aligning the alignment element may comprise rotating the prosthetic valve.

[0031] The prosthetic valve may further comprise a plurality of commissures with a covering disposed thereover whereby a plurality of prosthetic valve leaflets are formed. The method may further comprise releasing the plurality of prosthetic valve leaflets from a delivery catheter. The plurality of prosthetic valve leaflets may form a tricuspid valve that has an open configuration and a closed configuration. The plurality of prosthetic valve leaflets are disposed away from one another in the open configuration thereby permitting antegrade blood flow therethrough, and the plurality of prosthetic valve leaflets engage one another in the closed configuration thereby substantially preventing retrograde blood flow therethrough. The prosthetic valve may further comprise an atrial skirt adjacent the second end, and the method may further comprise expanding the atrial skirt radially outward so as to lie over a superior surface of the native valve, and engaging the atrial skirt against the superior surface of the native valve. Expanding the atrial skirt may comprise retracting a constraining sheath from the atrial skirt so that the atrial skirt is free to self-expand radially outward. The method may also comprise moving the prosthetic valve upstream or downstream relative to the native valve to ensure that the atrial skirt engages the superior surface of the native valve. Engaging the atrial skirt against the superior surface may seal the atrial skirt against the superior surface of the native valve to prevent or substantially prevent blood flow therebetween. The prosthetic valve may further comprise a posterior ventricular anchoring tab that is disposed on a posterior portion of the self-expanding frame. The method may further comprise anchoring the posterior

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ventricular anchoring tab over a posterior leaflet of the patient's mitral valve such that the posterior ventricular anchoring tab is seated between the posterior leaflet and a ventricular wall of the patient. The posterior ventricular tab may comprise barbs, texturing, or other surface features. Anchoring the posterior ventricular tab may comprise engaging the barbs, texturing or other surface features with tissue.

[0032] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

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[0033]

BRIEF DESCRIPTION OF THE DRAWINGS

[0034] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0035] Fig. 1 is a schematic illustration of the left ventricle of a heart showing blood flow during systole with arrows.

[0036] Fig. 2 is a schematic illustration of the left ventricle of a heart having prolapsed leaflets in the mitral valve.

[0037] Fig. 3 is a schematic illustration of a heart in a patient suffering from cardiomyopathy where the heart is dilated and the leaflets do not meet.

[0038] Fig. 3A shows normal closure of the valve leaflets.

[0039] Fig. 3B shows abnormal closure of the valve leaflets.

[0040] Fig. 4 illustrates mitral valve regurgitation in the left ventricle of a heart having impaired papillary muscles.

[0041] Figs. 5A-5B illustrate anatomy of the mitral valve.

[0042] Fig. 6 illustrates an exemplary embodiment of an uncovered frame in a prosthetic cardiac valve, with the frame flattened out and unrolled.

[0043] Fig. 7 illustrates another exemplary embodiment of an uncovered frame in a prosthetic cardiac valve, with the frame flattened out and unrolled.

[0044] Fig. 8 illustrates still another exemplary embodiment of an uncovered frame in a prosthetic cardiac valve, with the frame flattened out and unrolled.

[0045] Fig. 9A illustrates a perspective view of an uncovered frame in a prosthetic cardiac valve after it has expanded.

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[0046] Fig. 9B illustrates a top view of the embodiment in Fig. 9A.

[0047] Fig. 10 illustrates the frame of Fig. 9A with the covering thereby forming a prosthetic cardiac valve.

[0048] Figs. 11A-11D illustrate an exemplary embodiment of a delivery system used to transapically deliver a prosthetic cardiac valve.

[0049] Figs. 12A-12L illustrate an exemplary method of implanting a prosthetic cardiac valve.

[0050] Figs. 13A-13L illustrate another exemplary method of implanting a prosthetic cardiac valve.

[0051] Figs. 14A-14D illustrate an exemplary embodiment of a tab covering.

[0052] Fig. 15 illustrates a preferred positioning of a prosthetic valve in a native mitral valve.

[0053] Fig. 16 illustrates dislodgement of a prosthetic valve from a native valve.

[0054] Fig. 17 illustrates an alternative embodiment of a prosthetic valve anchored to a native valve.

[0055] Figs. 18A-18B illustrate a schematic diagram of a prosthetic valve with an anti-pivoting mechanism.

[0056] Fig. 18C illustrates a perspective view of a prosthetic valve with an anti-pivoting mechanism.

[0057] Fig. 19 illustrates an exemplary embodiment of an uncovered prosthetic valve flattened out and unrolled.

[0058] Figs. 20A-20B illustrate another exemplary embodiment of a prosthetic valve having an anti-pivoting mechanism and a posterior tab.

[0059] Fig. 21 illustrates an exemplary embodiment of a prosthetic valve having an anti-pivoting mechanism with a posterior tab, and barbs.

DETAILED DESCRIPTION OF THE INVENTION

[0060] Specific embodiments of the disclosed device, delivery system, and method will now be described with reference to the drawings. Nothing in this detailed description is intended to imply that any particular component, feature, or step is essential to the invention.

[0061] Cardiac Anatomy. The left ventricle LV of a normal heart H in systole is illustrated in Fig. 1. The left ventricle LV is contracting and blood flows outwardly through the aortic valve

AV, a tricuspid valve in the direction of the arrows. Back flow of blood or "regurgitation" through the mitral valve MV is prevented since the mitral valve is configured as a "check valve" which prevents back flow when pressure in the left ventricle is higher than that in the left atrium LA. The mitral valve MV comprises a pair of leaflets having free edges FE which meet evenly to close, as illustrated in Fig. 1. The opposite ends of the leaflets LF are attached to the surrounding heart structure along an annular region referred to as the annulus AN. The free edges FE of the leaflets LF are secured to the lower portions of the left ventricle LV through chordae tendineae CT (also referred to herein as the chordae) which include a plurality of branching tendons secured over the lower surfaces of each of the valve leaflets LF. The chordae CT in turn, are attached to the papillary muscles PM which extend upwardly from the lower portions of the left ventricle and interventricular septum IVS.

[0062] Referring now to Figs. 2-4, a number of structural defects in the heart can cause mitral valve regurgitation. Ruptured chordae RCT, as shown in Fig. 2, can cause a valve leaflet LF2 to prolapse since inadequate tension is transmitted to the leaflet via the chordae. While the other leaflet LF1 maintains a normal profile, the two valve leaflets do not properly meet and leakage from the left ventricle LV into the left atrium LA will occur, as shown by the arrow.

[0063] Regurgitation also occurs in the patients suffering from cardiomyopathy where the heart is dilated and the increased size prevents the valve leaflets LF from meeting properly, as shown in Fig. 3. The enlargement of the heart causes the mitral annulus to become enlarged, making it impossible for the free edges FE to meet during systole. The free edges of the anterior and posterior leaflets normally meet along a line of coaptation C as shown in Fig. 3A, but a significant gap G can be left in patients suffering from cardiomyopathy, as shown in Fig. 3B.

[0064] Mitral valve regurgitation can also occur in patients who have suffered ischemic heart disease where the functioning of the papillary muscles PM is impaired, as illustrated in Fig. 4. As the left ventricle LV contracts during systole, the papillary muscles PM do not contract sufficiently to effect proper closure. The leaflets LF1 and LF2 then prolapse, as illustrated. Leakage again occurs from the left ventricle LV to the left atrium LA, as shown by the arrow.

[0065] Fig. 5A more clearly illustrates the anatomy of a mitral valve MV which is a bicuspid valve having an anterior side ANT and a posterior side POST. The valve includes an anterior (aortic) leaflet AL and a posterior (mural) leaflet PL. Chordae tendineae CT couple the valve leaflets AL, PL with the antero-lateral papillary muscle ALPM and the postero-medial papillary muscle PMPM. The valve leaflets AL, PL join one another along a line referred to as the antero-lateral commissure ALC and the posterior-medial commissure PMC. The annulus AN circumscribes the valve leaflets, and two regions adjacent an anterior portion of the annulus, on opposite sides of the anterior leaflet are referred to as the left fibrous trigone LFT and also the right fibrous trigone RFT. These areas are indicted generally by the solid triangles. Fig. 5B more clearly illustrates the left and right fibrous trigones, LFT, RFT.

[0066] While various surgical techniques as well as implantable devices have been proposed and appear to be promising treatments for mitral regurgitation, surgical approaches can require a lengthy recovery period, and implantable devices have varying clinical results. Therefore, there still is a need for improved devices and methods for treating mitral regurgitation. While the embodiments disclosed herein are directed to an implantable prosthetic mitral valve for treating mitral regurgitation, one of skill in the art will appreciate that this is not intended to be limiting, and the device and methods disclosed herein may also be used to treat other cardiac valves such as the tricuspid valve, aortic valve, pulmonary valve, etc, as well as other valves in the body such as venous valves.

[0067] Prosthetic Valve. Prosthetic valves have been surgically implanted in the heart as a treatment for mitral regurgitation. Some of these valves have been valves harvested from animals such as porcine valves, and others have been prosthetic mechanical valves with or without a tissue covering. More recently, minimally invasive catheter technology has been used to deliver prosthetic valves to the heart. These valves typically include an anchor for securing the valve to the patient's heart, and a valve mechanism, either a mechanical valve, a valve with animal tissue, or combinations thereof. The prosthetic valve once implanted, takes over for the malfunctioning native valve, thereby reducing or eliminating valvar insufficiency. While some of these valves appear promising, there still is a need for improved valves. Positioning and anchoring the prosthetic valve in the native anatomy remains a challenge. The following specification discloses exemplary embodiments of a prosthetic valve, a delivery system for the prosthetic valve, and methods of delivering the valve that overcome some of the challenges associated with existing prosthetic valves.

[0068] Fig. 6 illustrates an exemplary embodiment of a prosthetic cardiac valve in the collapsed configuration. Coverings from the frame (e.g. fabric or tissue) have been removed to permit observation of the underlying frame 600. The frame has been unrolled and flattened out. The prosthetic valve frame 600 has an atrial region 606, an annular region 608, and a ventricular region 610. The frame 600 is formed from a plurality of interconnected struts that form a series of peaks and valleys which can expand and contract relative to one another thereby permitting the frame to be loaded onto a delivery catheter in a collapsed configuration, and then radially expanded at a target treatment site for implantation. Preferred embodiments are self-expanding and may be fabricated using superelastic nitinol or other self-expanding materials. Shape memory alloys that spring open above a transition temperature may also be used, and expandable members may also be used to expand the frame when plastic deformation (e.g. balloon expansion) is required to open the frame.

[0069] Atrial region 606 has a skirt 616 which includes a plurality of interconnected struts that form a series of peaks and valleys. In this region, the struts are skewed relative to one another and thus the resulting cell pattern has an enlarged end and the opposite end tapers to a smaller end. In preferred embodiments, the anterior portion of the atrial skirt does not have a flanged region like the posterior portion, thus the anterior portion 602 of the atrial region may have shorter struts than the posterior region 604. Thus the peaks and valleys in the anterior portion are axially offset from those in the remaining posterior portion of the atrial region. This may be advantageous as it prevents the struts in the anterior portion of the atrial skirt from protruding upwards potentially impinging against the left atrium and causing perforations. Additionally, the shortened struts and offset peaks and valleys form an alignment element 614 that can assist the physician with visualization of delivery of the prosthetic valve to the mitral valve and also with alignment of the prosthetic valve prior to expansion of the prosthetic valve. Optional radiopaque markers 614a are disposed on either side of the offset peaks and valleys and further help with visualization during implantation of the valve. The atrial region preferably self-expands to either a cylindrical shape, or it may have a D-shaped cross-section where the anterior portion 602 is substantially flat, and the posterior portion 604 is cylindrically shaped. This allows the atrial skirt to conform to the anatomy of the native mitral valve, thereby preventing obstruction of the left ventricular outflow tract. Additionally, the atrial skirt may also be formed so that upon expansion, the skirt flares outward and forms a flange that can rest against a superior surface of the mitral valve. The flanged region is preferably along the posterior portion of the atrial skirt, and the anterior portion of the atrial skirt remains flangeless. Or, the flange may extend entirely around the atrial skirt. The atrial region is connected to the adjacent annular region 608 with connecting struts which are preferably linear and substantially parallel to the longitudinal axis of the frame.

[0070] The annular region 608 is also comprised of a plurality of axially oriented and interconnected struts that form peaks and valleys that allow radial expansion. The struts are preferably parallel with one another and parallel with the longitudinal axis of the frame. The annular region may also be self-expanding and expand into a cylindrical shape, or more preferably the annular region may expand to have a D-shaped cross-section as described above with respect to the atrial region. Thus, the annular region may similarly have a flat anterior portion, and a cylindrically shaped posterior portion. Upon delivery, the annular region is aligned with and expanded into engagement with the mitral valve annulus. Connector struts join the annular region with the ventricular region 610.

[0071] The ventricular region 610 also includes a plurality of interconnected struts that form peaks and valleys. Additionally, the struts in the ventricular region form the leaflet commissures 613 which are covered with fabric, pericardial tissue, or other materials to form the prosthetic valve leaflets. Holes in the commissures allow suture to be attached thereto. Struts in the ventricular region also form a ventricular skirt 628 which expands outward to engage the anterior and posterior mitral valve leaflets, and struts in the ventricular region also form the anterior tabs 624 and the posterior tab 630. The anterior tabs are designed to capture the anterior mitral valve leaflet between an inner surface of the anterior tab and outer surface of the ventricular skirt. Any adjacent chordae tendineae may also be captured therebetween. Also, the tip of the anterior tab engages the fibrous trigone on an anterior portion of the mitral valve, one on the left and one on the right side. The posterior tab similarly captures the posterior mitral valve leaflet between an inner surface of the posterior tab and an outer surface of the ventricular skirt, along with any adjacent chordae tendineae. This will be described in more detail below.

[0072] By controlling strut length or axial position of the anterior or posterior tabs along the frame, deployment of the tabs may be controlled. Thus in this exemplary embodiment, because the length of the struts in the anterior tabs and posterior tabs 624, 630 as well as their relative position along the frame are the same as one another, when a constraining sheath is retracted away from the tabs, the anterior and posterior tabs will partially spring outward together. As the constraining sheath is further retracted, the remainder of the anterior tabs will self-expand radially outward. Further retraction of the constraining sheath then allows the remainder of the posterior tab to finish its radial expansion, and finally the ventricular skirt will radially expand outward. While strut lengths and axial position of the posterior tab and the ventricular skirt are similar, internal struts connect the ventricular skirt with the commissures, and this delays expansion of the ventricular skirt slightly, thus the posterior tab finishes expansion before the ventricular skirt. Using this sequence of deploying the prosthetic valve may allow the valve to be more accurately delivered and also more securely anchored into position.

[0073] Suture holes 621 are disposed along the struts of the annular region as well as the ventricular region to allow attachment of a cover such as pericardium or a polymer such as Dacron or ePTFE, or another biocompatible material. The suture holes may also be disposed along any other part of the frame. Barbs 623 are disposed along the ventricular skirt 628 to help anchor the prosthetic valve to adjacent tissue. Commissure tabs or tabs 612 are disposed on the tips of the commissures 613 and may be used to releasably couple the commissures with a delivery system as will be described below. This allows the frame to expand first, and then the commissures may be released from the delivery system afterwards. One of skill in the art will appreciate that a number of strut geometries may be used, and additionally that strut dimensions such as length, width, thickness, etc. may be adjusted in order to provide the prosthesis with the desired mechanical properties such as stiffness, radial crush strength, commissure deflection, etc. Therefore, the illustrated geometry is not intended to be limiting.

[0074] The frame may be formed by electrical discharge machining (EDM), laser cutting, photochemical etching, or other techniques known in the art. Hypodermic tubing or flat sheets may be used to form the frame. Once the frame has been cut and formed into a cylinder (if required), it may be radially expanded into a desired geometry and heat treated using known processes to set the shape. Thus, the prosthetic valve may be loaded onto a delivery catheter in a collapsed configuration and constrained in the collapsed configuration with a constraining sheath. Removal of the constraining sheath will allow the prosthesis to self-expand into its unbiased pre-set shape. In other embodiments, an expandable member such as a balloon may be used to radially expand the prosthesis into its preferred expanded configuration by plastic deformation.

[0075] Fig. 7 illustrates another exemplary embodiment of a prosthetic cardiac valve in the collapsed configuration, and similar to the previous embodiment with the major difference being the strut lengths in the anterior tabs, posterior tab, and ventricular skirt. Varying the strut lengths allow the sequence of expansion of the anterior and posterior tabs and ventricular skirt to be controlled. Coverings from the frame (e.g. fabric or tissue) has been removed to permit observation of the underlying frame 700. The frame has been unrolled and flattened out. The prosthetic valve frame 700 has an atrial region 706, an annular region 708, and a ventricular region 710. The frame 700 is formed from a plurality of interconnected struts that form a series of peaks and valleys which can expand and contract relative to one another thereby permitting the frame to be loaded onto a delivery catheter in a collapsed configuration, and then radially expanded at a target treatment site for implantation. Preferred embodiments are self-expanding and may be fabricated using superelastic nitinol or other self-expanding materials. Shape memory alloys that spring open above a transition temperature may also be used, and expandable members may also be used to expand the frame when plastic deformation (e.g. balloon expansion) is required to open the frame.

[0076] Atrial region 706 has a skirt 716 which includes a plurality of interconnected struts that form a series of peaks and valleys. In this region, the struts are skewed relative to one another and thus the resulting cell pattern has an enlarged end and the opposite end tapers to a smaller end. An anterior portion 702 of the atrial region has shorter struts than the posterior region 704. Thus the peaks and valleys in the anterior portion are axially offset from those in the remaining posterior portion of the atrial region. This allows creation of an alignment element 714 to help the physician deliver the prosthetic valve to the mitral valve and align the prosthetic valve prior to expansion of the prosthetic valve. Other aspects of the atrial region 706 are similar to those of the atrial region 606 in Fig. 6. Optional radiopaque markers 714a are disposed on either side of the offset peaks and valleys and help with visualization during implantation of the valve. The atrial region preferably self-expands to either a cylindrical shape, or it may have a D-shaped cross-section where the anterior portion 702 is substantially flat, and the posterior portion 704 is cylindrically shaped. This allows the atrial skirt to conform to the anatomy of the native mitral valve, thereby preventing obstruction of the left ventricular outflow tract. Additionally, the atrial skirt may also be formed so that upon expansion, the skirt flares outward and forms a flange that can rest against a superior surface of the mitral valve. The flanged region is preferably along the posterior portion of the atrial skirt, and the anterior portion of the atrial skirt remains flangeless. Or, the flange may extend entirely around the atrial skirt. The atrial region is connected to the adjacent annular region 708 with connecting struts which are preferably linear and substantially parallel to the longitudinal axis of the frame.

[0077] The annular region 708 is also comprised of a plurality of axially oriented and interconnected struts that form peaks and valleys that allow radial expansion. The struts are preferably parallel with one another and parallel with the longitudinal axis of the frame. The annular region may also be self-expanding and expand into a cylindrical shape, or more preferably the annular region may expand to have a D-shaped cross-section as described above with respect to the atrial region. Thus, the annular region may similarly have a flat anterior portion, and a cylindrically shaped posterior portion. Upon delivery, the annular region is aligned with and expanded into engagement with the mitral valve annulus. Connector struts join the annular region with the ventricular region 710.

[0078] The ventricular region 710 also includes a plurality of interconnected struts that form peaks and valleys. Additionally, the struts in the ventricular region form the leaflet commissures 713 which are covered with fabric, pericardial tissue, or other materials to form the prosthetic valve leaflets. Holes in the commissures allow suture to be attached thereto. Struts in the ventricular region also form a ventricular skirt 728 which expands outward to engage the anterior and posterior mitral valve leaflets, and struts in the ventricular region also form the anterior tabs 724 and the posterior tab 730. The anterior tabs are designed to capture the anterior mitral valve leaflet between an inner surface of the anterior tab and outer surface of the ventricular skirt. Any adjacent chordae tendineae may also be captured therebetween. Also, the tip of the anterior tab engages the fibrous trigone on an anterior portion of the mitral valve, one on the left and one on the right side. The posterior tab similar captures the posterior mitral valve leaflet between an inner surface of the posterior tab and an outer surface of the ventricular skirt, along with any adjacent chordae tendineae. This will be described in more detail below.

[0079] By controlling strut length or axial position of the anterior or posterior tabs along the frame, deployment of the tabs may be controlled. Thus in this exemplary embodiment, because the length of the struts in the anterior tabs and posterior tabs 724, 730 as well as their relative position along the frame are the same as one another, when a constraining sheath is retracted away from the tabs, the anterior and posterior tabs will partially spring outward together. As the constraining sheath is further retracted, the remainder of the anterior tabs will self-expand radially outward because they are the shortest relative to the struts in the ventricular skirt and the posterior tab. Further retraction of the constraining sheath then allows the ventricular skirt to radially expand, and finally further retraction of the sheath allows the remainder of the posterior tab to finish its radial expansion. Using this sequence of deploying the prosthetic valve may allow the valve to be more accurately delivered and also more securely anchored into position.

[0080] Suture holes 721 are disposed along the struts of the annular region as well as the ventricular region to allow attachment of a cover such as pericardium or a polymer such as Dacron or ePTFE. The suture holes may also be disposed along any other part of the frame. Barbs 723 are disposed along the ventricular skirt 728 to help anchor the prosthetic valve to adjacent tissue. Commissure tabs or tabs 712 are disposed on the tips of the commissures 713 and may be used to releasably couple the commissures with a delivery system as will be described below. This allows the frame to expand first, and then the commissures may be released from the delivery system afterwards. One of skill in the art will appreciate that a number of strut geometries may be used, and additionally that strut dimensions such as length, width, thickness, etc. may be adjusted in order to provide the prosthesis with the desired mechanical properties such as stiffness, radial crush strength, commissure deflection, etc. Therefore, the illustrated geometry is not intended to be limiting. The frame may be formed similarly as described above with respect to Fig. 6.

[0081] Fig. 8 illustrates another exemplary embodiment of a prosthetic cardiac valve in the collapsed configuration, and is similar to the previous embodiments, with the major difference being that the posterior tab is designed to expand to form an elongate horizontal section which allows engagement and anchoring of the posterior tab with the sub-annular region between the posterior leaflet and the ventricular wall. Thus, the elongate horizontal section contacts a larger region of the sub-annular region as compared with a posterior tab that only has a tapered tip formed from a single hinge between struts. This provides enhanced anchoring of the prosthetic valve. In this exemplary embodiment, the anterior tabs will completely self-expand first, followed by the posterior tab and then the ventricular skirt. However, in some situations external factors such as the delivery system, anatomy, etc. may alter the sequence of expansion, and therefore this is not intended to be limiting. Coverings from the frame (e.g. fabric or tissue) have been removed to permit observation of the underlying frame 800. The frame has been unrolled and flattened out. The prosthetic valve frame 800 has an atrial region 806, an annular region 808, and a ventricular region 810. The frame 800 is formed from a plurality of interconnected struts that form a series of peaks and valleys which can expand and contract relative to one another thereby permitting the frame to be loaded onto a delivery catheter in a collapsed configuration, and then radially expanded at a target treatment site for implantation. Preferred embodiments are self-expanding and may be fabricated using superelastic nitinol or other self-expanding materials. Shape memory alloys that spring open above a transition temperature may also be used, and expandable members may also be used to expand the frame when plastic deformation (e.g. balloon expansion) is required to open the frame.

[0082] Atrial region 806 has a skirt 816 which includes a plurality of interconnected struts that form a series of peaks and valleys. In this region, the struts are skewed relative to one another and thus the resulting cell pattern has an enlarged end and the opposite end tapers to a smaller end. An anterior portion 802 of the atrial region has shorter struts than the posterior region 804. Thus the peaks and valleys in the anterior portion are axially offset from those in the remaining posterior portion of the atrial region. This allows creation of an alignment element 814 to help the physician deliver the prosthetic valve to the mitral valve and align the prosthetic valve prior to expansion of the prosthetic valve. Other aspects of the atrial region 806 are similar to those of the atrial region 606 in Fig. 6. Optional radiopaque markers 814a are disposed on either side of the offset peaks and valleys and help with visualization during implantation of the valve. The atrial region preferably self-expands to either a cylindrical shape, or it may have a D-shaped cross-section where the anterior portion 802 is substantially flat, and the posterior portion 804 is cylindrically shaped. This allows the atrial skirt to conform to the anatomy of the native mitral valve, thereby preventing obstruction of the left ventricular outflow tract. Additionally, the atrial skirt may also be formed so that upon expansion, the skirt flares outward and forms a flange that can rest against a superior surface of the mitral valve. The flanged region is preferably along the posterior portion of the atrial skirt, and the anterior portion of the atrial skirt remains flangeless. Or, the flange may extend entirely around the atrial skirt. The atrial region is connected to the adjacent annular region 808 with connecting struts which are preferably linear and substantially parallel to the longitudinal axis of the frame.

[0083] The annular region 808 is also comprised of a plurality of axially oriented and interconnected struts that form peaks and valleys that allow radial expansion. The struts are preferably parallel with one another and parallel with the longitudinal axis of the frame. The annular region may also be self-expanding and expand into a cylindrical shape, or more preferably the annular region may expand to have a D-shaped cross-section as described above with respect to the atrial region. Thus, the annular region may similarly have a flat anterior portion, and a cylindrically shaped posterior portion. Upon delivery, the annular region is aligned with and expanded into engagement with the mitral valve annulus. Connector struts join the annular region with the ventricular region 810.

[0084] The ventricular region 810 also includes a plurality of interconnected struts that form peaks and valleys. Additionally, the struts in the ventricular region form the leaflet commissures 813 which are covered with fabric, pericardial tissue, or other materials to form the prosthetic valve leaflets. Holes in the commissures allow suture to be attached thereto. Struts in the ventricular region also form a ventricular skirt 828 which expands outward to engage the anterior and posterior mitral valve leaflets, and struts in the ventricular region also form the anterior tabs 824 and the posterior tab 830. The anterior tabs are designed to capture the anterior mitral valve leaflet between an inner surface of the anterior tab and outer surface of the ventricular skirt. Any adjacent chordae tendineae may also be captured therebetween.

Also, the tip of the anterior tab engages the fibrous trigone on an anterior portion of the mitral valve, one on the left and one on the right side. The posterior tab similarly captures the posterior mitral valve leaflet between an inner surface of the posterior tab and an outer surface of the ventricular skirt, along with any adjacent chordae tendineae. This will be described in more detail below. The posterior tab is similar to the posterior tabs described above in Figs. 6-7, except that in this embodiment, the posterior tab comprises four interconnected struts as opposed to two interconnected struts. Thus, in this embodiment the plurality of interconnected struts form three hinged regions 836 along the tab. Upon expansion of the posterior tab, the hinged regions will also expand, thereby forming an elongate horizontal section which allows engagement and anchoring of the posterior tab with the sub-annular region between the posterior leaflet and the ventricular wall. This may help position and anchor the prosthetic valve better than posterior tabs which only have a smaller footprint or a single tapered tip for engagement with the posterior portion of the mitral valve. The posterior tab in this embodiment, may be substituted with any of the other posterior tabs described in this specification.

[0085] By controlling strut length or axial position of the anterior or posterior tabs along the frame, deployment of the tabs may be controlled. Thus in this exemplary embodiment, because the length of the struts in the anterior tabs and posterior tabs 824, 830 as well as their relative position along the frame are the same as one another, when a constraining sheath is retracted away from the tabs, the anterior and posterior tabs will partially spring outward together. As the constraining sheath is further retracted, the remainder of the anterior tabs will self-expand radially outward because they are the shortest relative to the struts in the ventricular skirt and the posterior tab. Further retraction of the constraining sheath then allows the remainder of the posterior tab to finish self-expanding, followed by self-expansion of the ventricular skirt. Using this sequence of deploying the prosthetic valve may allow the valve to be more accurately delivered and also more securely anchored into position.

[0086] Suture holes 821 are disposed along the struts of the annular region as well as the ventricular region to allow attachment of a cover such as pericardium or a polymer such as Dacron or ePTFE. The suture holes may also be disposed along any other part of the frame. Barbs 823 are disposed along the ventricular skirt 828 to help anchor the prosthetic valve to adjacent tissue. Commissure tabs or tabs 812 are disposed on the tips of the commissures 813 and may be used to releasably couple the commissures with a delivery system as will be described below. This allows the frame to expand first, and then the commissures may be released from the delivery system afterwards. One of skill in the art will appreciate that a number of strut geometries may be used, and additionally strut dimensions such as length, width, thickness, etc. may be adjusted in order to provide the prosthesis with the desired mechanical properties such as stiffness, radial crush strength, commissure deflection, etc. Therefore, the illustrated geometry is not intended to be limiting. The frame may be formed similarly as described above.

[0087] Fig. 9A illustrates the frame 900 of a prosthetic cardiac valve after it has expanded. Any of the frame embodiments described above may take this form as each of the above frames have similar geometry but they expand in different order. The frame includes the atrial skirt 906 with anterior portion 914 and posterior portion 916. A flanged region is formed around the posterior portion and the anterior portion remains flangeless. Additionally, the anterior portion is generally flat, while the posterior portion is cylindrically shaped, thereby forming a D-shaped cross-section which accommodates the mitral valve anatomy. Fig. 9B is a top view of the embodiment in Fig. 9A and more clearly illustrates the D-shaped cross-section.

[0088] The frame also includes the annular region 910 and ventricular skirt 912. Anterior tabs 904 (only one visible in this view) is fully expanded such that a space exists between the inner surface of the anterior tab and an outer surface of the ventricular skirt. This allows the anterior leaflet and adjacent chordae to be captured therebetween. Similarly, the posterior tab 902 is also fully deployed, with a similar space between the inner surface of the posterior tab 902 and an outer surface of the ventricular skirt. This allows the posterior leaflet and adjacent chordae tendineae to be captured therebetween. The commissure posts 908 are also visible and are disposed in the inner channel formed by the frame. The commissure posts are used to form the prosthetic mitral valve leaflets. The overall shape of the expanded frame is D-shaped, with the anterior portion flat and the posterior portion cylindrically shaped.

[0089] Fig. 10 illustrates the expanded frame covered with a cover 1002 such as pericardial tissue or a polymer such as ePTFE or a fabric like Dacron attached to the frame, thereby forming the prosthetic cardiac valve 1000. The atrial skirt may be entirely covered by a material, or in preferred embodiments, the covering is only disposed between adjacent struts 1012 in adjacent cells in the flanged portion of the atrial skirt. The area 1014 between adjacent struts within the same cell remain uncovered. This allows blood flow to remain substantially uninterrupted while the prosthetic valve is being implanted. Suture 1010 may be used to attach the cover to the frame. In this view, only the posterior tab 1006 is visible on the posterior portion of the prosthetic valve along with ventricular skirt 1008 and atrial skirt 1004.

Anti-Pivoting Mechanism

[0090] As discussed above, preferred embodiments of the device anchor the prosthetic valve to the anterior and posterior valve leaflets. Fig. 15 illustrates an example of this where the prosthetic valve 1506 which may be any of the embodiments having both anterior and posterior tabs described herein, is successfully anchored to the mitral valve 1502 of a patient's heart H. The posterior tab 1508 has successfully engaged the posterior leaflet 1504, and the anterior tab 1510 has successfully engaged the anterior leaflet 1512. Proper anterior and posterior anchoring secures the inferior portion of the prosthetic valve and prevents unwanted rotation or pivoting of the prosthetic valve, as well as preventing unwanted axial movement upstream or downstream. However, as previously discussed, in certain situations the posterior tab may not anchor the prosthetic device to the posterior leaflet of native valve. For example, if the physician improperly delivers and deploys the prosthetic valve it may not properly engage the posterior leaflet. Or, in some situations, the posterior leaflet may have an irregular shape or may be fragile and therefore not be strong enough for anchoring with the posterior tab.

[0091] When the posterior tab fails to anchor the prosthetic valve to the posterior leaflet, the prosthetic valve will only be anchored with the anterior tabs and therefore may pivot or rotate counter-clockwise, or upward into the left atrium as seen in Fig. 16 which illustrates the prosthetic valve 1506 rotating due to the retrograde blood pressure from the left ventricle of the heart H and exerted on the prosthesis during systole. The posterior portion of the prosthesis pivots upward into the left atrium creating a leak around the prosthesis as indicated by the arrows.

[0092] Fig. 17 illustrates an alternative embodiment of prosthetic valve that helps prevent posterior pivoting. The prosthetic valve 1702 in this embodiment is a prosthetic mitral valve and it is implanted in a native mitral valve 1502 of a patient's heart H. The prosthetic valve

1702 generally takes the same form as other prosthetic valves described in this specification, with the major exception that it does not have posterior tabs. Instead of the posterior tabs, the prosthetic valve includes a foot 1704 which prevents pivoting. The foot is an enlarged portion of the prosthetic valve that extends radially outward from the body of the prosthesis sufficiently far so that the cross-sectional area of the ventricular portion of the prosthetic valve is large enough to prevent it from pivoting or rotating up into the atrium. Thus, blood flows out the left ventricle into the aorta during systole and retrograde flow into the atrium is eliminated or substantially reduced. Leaks around the prosthetic valve are also reduce or eliminated. The foot may be any number of structures which prevent pivoting of the prosthesis.

[0093] Figs. 18A-18B illustrate a schematic of a prosthetic valve having an anti-pivoting mechanism. Fig. 18A illustrates the prosthetic valve 1802 which is generally the same as any of the other valve embodiments described herein with the major difference being that it does not have a posterior tab. The prosthetic valve 1802 may have any of the features described in any other embodiments disclosed herein. For example, the prosthetic valve may include an atrial flange 1804, an annular region 1808 and a ventricular region or ventricular skirt 1814. The valve preferably also includes two anterior tabs 1806 for engaging the anterior leaflet and the trigones. Also, the valve has a foot 1812 which is a wedge shaped region of the prosthesis that extends radially outward. Fig. 18B illustrates a top view of the prosthetic valve 1802 seen in Fig. 18A.

[0094] Fig. 18C illustrates a perspective view of a prosthetic valve 1802 that generally takes the same form as other valve embodiments described herein with the major difference being that instead of having a posterior tab for anchoring to a valve leaflet, the valve has a foot 1812 which anchors the posterior part of the valve to the posterior portion of the native valve. The valve includes an atrial flange 1804, anterior trigonal tabs 1806, an annular region 1808, and a ventricular skirt region 1818 that generally take the same form as described in other embodiments. The foot 1812 may be any structure which extends radially outward and prevents the prosthetic valve from rotating or pivoting. In some embodiments, the foot may extend radially outward 10 mm or more. In this embodiment, the foot includes a central element 1812 which has been formed from two struts 1814 that are coupled together with a connector to form a V or U-shaped structure that extends radially outward. A cover 1816 such as pericardial tissue, or any of the other cover materials discussed herein is attached to the central element 1812 and to adjacent struts on either side, thereby forming a vestibule similar to that seen on a camping tent, or a cattle pusher on a locomotive engine (sometimes referred to as a pilot). This structure has a larger cross-section than the native valve, and thus it prevents the prosthetic valve from rotating through the valve into the atrium (in the case of a mitral valve prosthesis).

[0095] Fig. 19 illustrates a flat pattern used to cut the prosthetic valve from tubing or a flat sheet which is then rolled and welded into a cylinder. Electrical discharge machining (EDM), laser cutting, or photochemical etching are techniques that may be used to cut the flat pattern. The prosthesis 1902 generally takes the same form as other prosthetic valves disclosed herein, and thus not every feature will be described in detail. The prosthesis 1902 includes an atrial region 1910 having an atrial skirt, an annular region 1912 and a ventricular region 1914. The ventricular region includes anterior tabs 1904 with tips 1908 that engage the fibrous trigones on either side of the anterior leaflet of a mitral valve. The anti-pivoting mechanism is formed from an elongate pair of struts 1906 which extend axially further than the struts of the ventricular region. The struts 1906 may be formed to flare radially outward upon self-expansion and they may be covered with tissue or synthetic material to form the enlarged area of the foot which prevents pivoting. Other aspects of the prosthetic valve such as the atrial flange, the annular region, the ventricular skirt, suture holes, commissure posts, commissure tabs, alignment element, flat anterior shape, cylindrical posterior shape, D-shaped cross-section may generally take the same form as described in other embodiments of this specification. The prosthetic valve is preferably formed from shape memory or superelastic nitinol, or it may be made from other self-expanding materials known in the art. The valve may also be balloon expandable and be made from materials such as stainless steel, cobalt-chromium, or other materials known in the art. The foot may take any number of shapes and may be a combination of metal or fabric and/or polymer features integral with or coupled to the prosthetic valve. The anchoring elements on the prosthetic valve may be deployed in any desired order. However, in preferred embodiments, the atrial skirt deploys first and anchors the valve to the atrial floor followed by deployment of the annular region into the annulus, then the anterior tabs capture the valve leaflets, followed by the foot, and then the ventricular skirt, and then the commissures.

[0096] Figs. 20A-20B illustrate another exemplary embodiment of a prosthetic valve combining features of several previously disclosed embodiments such as the foot and a posterior tab. Fig. 20A illustrates a rear view looking head on at a prosthetic valve 2002 which may take the form of any of the embodiments disclosed herein. The upper end of the prosthesis includes an atrial flange 2004 which helps anchor the device to the floor of the atrium as previously described. The prosthesis also includes a pair of anterior trigonal tabs for anchoring the prosthesis to the fibrous trigones of the anterior portion of the valve annulus. The posterior portion of the prosthesis includes a foot 2008 like the foot previously described above, and a posterior tab 2010 which may take the form of any of the previous embodiments. Other portions of the prosthesis may take the form of any previous embodiment described herein, including but not limited to the annular region, ventricular region, commissures, etc. Having both a posterior tab and a foot provides a fail safe anchoring mechanism on the prosthesis. Thus, in case the posterior tab fails to anchor the device to the posterior portion of the valve, the foot anchors the device as described before and prevents unwanted pivoting of the prosthesis upward toward the left atrium. Fig. 20B illustrates another side view of the prosthesis 2020, this time rotated about its longitudinal axis to more clearly illustrate one anterior tab (the other is obstructed), as well as the foot and the posterior tab. In addition to having a posterior tab and a foot, alternative embodiments may also have barbs, texturing or other surface features on the foot, the posterior tab, or adjacent thereto in order to help further anchor the prosthesis into the tissue.

[0097] Fig. 21 illustrates an exemplary embodiment of a prosthesis 2102 having a foot 2110, posterior tab 2106, anterior tab 2106 and barbs 2112. The barbs may be pointed protrusions, or they may be textured regions. They may be disposed on the foot, on the posterior tab, or on both portions of the device. Other aspects of the prosthesis such as the atrial flange 2104, anterior tab 2106, as well as other features including the annular skirt, ventricular skirt, commissures, etc. may take the form of any embodiment described herein.

[0098] <u>Delivery System</u>. Figs. 11A-11D illustrate an exemplary embodiment of a delivery system that may be used to deliver any of the prosthetic valves disclosed in this specification.

While the delivery system is designed to preferably deliver the prosthetic valve transapically, one of skill in the art will appreciate that it may also be modified so that the prosthetic valve may be delivered via a catheter transluminally, such using a transseptal route. One of skill in the art will appreciate that using a transseptal route may require the relative motion of the various shafts to be modified in order to accommodate the position of the delivery system relative to the mitral valve.

[0099] Fig. 11A illustrates a perspective view of delivery system 1100. The delivery system 1100 includes a handle 1112 near a proximal end of the delivery system and a distal tissue penetrating tip 1110. Four elongate shafts are included in the delivery system and include an outer sheath catheter shaft 1102, a bell catheter shaft 1104 which is slidably disposed in the outer sheath catheter shaft 1102, a hub catheter shaft 1106 which remains stationary relative to the other shafts, but the bell catheter shaft slides relative to the hub shaft, and finally an inner guidewire catheter shaft 1108 which is also fixed relative to the other shafts and has a lumen sized to receive a guidewire which passes therethrough and exits the distal tissue penetrating tip. An actuator mechanism 1114 is used to control movement of the various shafts as will be explained in greater detail below, and flush lines 1116, 1118 with luer connectors are used to flush the annular regions between adjacent shafts. Flush line 1118 is used to flush the annular space between the outer sheath catheter shaft 1102 and the bell catheter shaft 1104. Flush line 1116 is used to flush the annular space between the bell catheter 1104 and the hub catheter 1106. The inner guidewire catheter shaft 1108 is stationary relative to the hub catheter 1106 therefore the annular space may be sealed with an o-ring or other material. Luer connector 1122 allows flushing of the guidewire lumen and a hemostatic valve such as a Tuohy-Borst may be coupled to the luer connector to allow a guidewire to be advanced through the guidewire catheter shaft while maintaining hemostasis. Screws 1120 keep the handle housing coupled together. Fig. 11B illustrates a side view of the delivery system 1100.

[00100] Fig. 11C is a partial exploded view of the delivery system 1100 and more clearly illustrates the components in the handle 1112 and how they interact. The handle 1112 includes a housing having two halves 1112a, 1112b which hold all the components. The handle is preferably held together with screws 1120 and nuts 1120b, although it may also be sealed using other techniques such as a press fit, snap fit, adhesive bonding, ultrasonic welding, etc.

Rotation of actuator wheel 1114 is translated into linear motion of threaded insert 1124. The outer sheath catheter shaft 1102 is coupled to the threaded insert 1124, therefore rotation of actuator wheel 1114 in one direction will advance the sheath catheter shaft 1102, and rotation in the opposite direction will retract the sheath catheter shaft 1102. Further rotation of actuator wheel 1114 retracts threaded insert 1124 enough to bump into pins 1126 which are coupled to insert 1128, thereby also moving insert 1128. The bell catheter shaft 1106 is coupled to insert 1128, therefore further rotation of the actuator wheel 1114 will move the outer shaft 1102 and also move the bell catheter shaft 1106. Rotation of the actuator wheel in the opposite direction advances the sheath and threaded insert 1124 disengages from pins 1126. Spring 1130 returns insert 1128 to its unbiased position, thereby returning the bell catheter shaft to its unbiased position.

[00101] Any of the prosthetic cardiac valves disclosed herein may be carried by delivery system 1100. The atrial skirt, annular skirt, anterior tabs, posterior tab and ventricular skirt are loaded over the bell catheter shaft and disposed under the outer sheath catheter shaft 1102. The ventricular skirt is loaded proximally so that it is closest to the handle 1112 and the atrial skirt is loaded most distally so it is closest to the tip 1110. Therefore, retraction of outer sheath catheter shaft 1102 plays a significant part in controlling deployment of the prosthetic cardiac valve. The atrial skirt therefore expands first when the outer sheath catheter is retracted. The prosthetic valve commissures may be coupled with a hub 1106a on the distal portion of hub catheter 1106 and then the bell catheter shaft is disposed thereover, thereby releasably engaging the commissures with the delivery catheter. Once other portions of the prosthetic cardiac valve have expanded, the commissures may be released.

[00102] Fig. 11D highlights the distal portion of the delivery system 1100. Outer sheath catheter shaft 1102 advances and retracts relative to bell catheter shaft 1104 which is slidably disposed in the outer sheath catheter shaft 1102. Hub catheter shaft 1106 is shown slidably disposed in bell catheter shaft 1104 and with bell catheter shaft 1104 retracted so as to expose the hub 1106a having slots 1106b that hold the prosthetic valve commissures. Inner guidewire catheter shaft 1108 is the innermost shaft and has a tapered conical section 1130 which provides a smooth transition for the prosthetic valve and prevents unwanted bending or buckling of the prosthetic cardiac valve frame. Tissue penetrating tip 1110 is adapted to penetrate tissue, especially in a cardiac transapical procedure.

[00103] Delivery Method. A number of methods may be used to deliver a prosthetic cardiac valve to the heart. Exemplary methods of delivering a prosthetic mitral valve may include a transluminal delivery route which may also be a transseptal technique which crosses the septum between the right and left sides of the heart, or in more preferred embodiments, a transapical route may be used such as illustrated in Figs. 12A-12L. The delivery device previously described above may be used to deliver any of the embodiments of prosthetic valves described herein, or other delivery devices and other prosthetic valves may also be used, such as those disclosed in US Patent No. 8,579,964 . However, in this preferred exemplary embodiment, the prosthetic cardiac valve of Fig. 6 is used so that the anterior tabs deploy first, followed by the posterior tab, and then the ventricular skirt. In the embodiment where the prosthetic valve has a foot instead of a posterior tab, deployment is generally the same, but the foot is expanded instead of the posterior tab.

[00104] Fig. 12A illustrates the basic anatomy of the left side of a patient’s heart including the left atrium LA and left ventricle LV. Pulmonary veins PV return blood from the lungs to the left atrium and the blood is then pumped from the left atrium into the left ventricle across the mitral valve MV. The mitral valve includes an anterior leaflet AL on an anterior side A of the valve and a posterior leaflet PL on a posterior side P of the valve. The leaflets are attached to chordae tendineae CT which are subsequently secured to the heart walls with papillary muscles PM. The blood is then pumped out of the left ventricle into the aorta Ao with the aortic valve AV preventing regurgitation.

[00105] Fig. 12B illustrates transapical delivery of a delivery system 1202 through the apex of the heart into the left atrium LA via the left ventricle LV. The delivery system 1202 may be advanced over a guidewire GW into the left atrium, and a tissue penetrating tip 1204 helps the delivery system pass through the apex of the heart by dilating the tissue and forming a larger channel for the remainder of the delivery system to pass through. The delivery catheter carries prosthetic cardiac valve 1208. Once the distal portion of the delivery system has been advanced into the left atrium, the outer sheath 1206 may be retracted proximally (e.g. toward the operator) thereby removing the constraint from the atrial portion of the prosthetic valve

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1208. This allows the atrial skirt 1210 to self-expand radially outward. In Fig. 12C, as the outer sheath is further retracted, the atrial skirt continues to self-expand and peek out, until it fully deploys as seen in Fig. 12D. The atrial skirt may have a cylindrical shape or it may be D-shaped as discussed above with a flat anterior portion and a cylindrical posterior portion so as to avoid interfering with the aortic valve and other aspects of the left ventricular outflow tract. The prosthesis may be oriented and properly positioned by rotating the prosthesis and visualizing the alignment element previously described. Also, the prosthetic cardiac valve may be advanced upstream or downstream to properly position the atrial skirt. In preferred embodiments, the atrial skirt forms a flange that rests against a superior surface of the mitral valve and this anchors the prosthetic valve and prevents it from unwanted movement downstream into the left ventricle.

[00106] As the outer sheath 1206 continues to be proximally retracted, the annular region of the prosthetic cardiac valve self-expands next into engagement with the valve annulus. The annular region also preferably has the D-shaped geometry, although it may also be cylindrical or have other geometries to match the native anatomy. In Fig. 12E, retraction of sheath 1206 eventually allows both the anterior 1212 and posterior 1214 tabs to partially self-expand outward preferably without engaging the anterior or posterior leaflets or the chordae tendineae. In this embodiment, further retraction of the outer sheath 1206 then allows both the anterior tabs 1212 (only one visible in this view) to complete their self-expansion so that the anterior leaflet is captured between an inner surface of each of the anterior tabs and an outer surface of the ventricular skirt 1216, as illustrated in Fig. 12F. The posterior tab 1214 remains partially open, but has not completed its expansion yet. Additionally, the tips of the anterior tabs also anchor into the left and right fibrous trigones of the mitral valve, as will be illustrated in greater detail below.

[00107] In Fig. 12G, further retraction of the outer sheath 1206 then releases the constraints from the posterior tab 1214 allowing it to complete its self-expansion, thereby capturing the posterior leaflet PL between an inner surface of the posterior tab 1214 and an outer surface of the ventricular skirt 1218. In Fig. 12H, the sheath is retracted further releasing the ventricular skirt 1220 and allowing the ventricular skirt 1220 to radially expand outward, further capturing the anterior and posterior leaflets between the outer surface of the ventricular skirt and their respective anterior or posterior tabs. Expansion of the ventricular skirt also pushes the anterior and posterior leaflets outward, thereby ensuring that the native leaflets do not interfere with any portion of the prosthetic valve or the prosthetic valve leaflets. The prosthetic valve is now anchored in position above the mitral valve, along the annulus, to the valve leaflets, and below the mitral valve, thereby securing it in position.

[00108] Further actuation of the delivery device now retracts the outer sheath 1206 and the bell catheter shaft 1222 so as to remove the constraint from the hub catheter 1224, as illustrated in Fig. 12I. This permits the prosthetic valve commissures 1226 to be released from the hub catheter, thus the commissures expand to their biased configuration. The delivery system 1202 and guidewire GW are then removed, leaving the prosthetic valve 1208 in position where it takes over for the native mitral valve, as seen in Fig. 12J.

[00109] Figs. 12K and 12L highlight engagement of the anterior and posterior tabs with the respective anterior and posterior leaflets. In Fig. 12K, after anterior tabs 1212 have been fully expanded, they capture the anterior leaflet AL and may capture adjacent chordae tendineae between an inside surface of the anterior tab and an outer surface of the ventricular skirt 1220. Moreover, the tips 1228 of the anterior tabs 1212 are engaged with the fibrous trigones FT of the anterior side of the mitral valve. The fibrous trigones are fibrous regions of the valve thus the anterior tabs further anchor the prosthetic valve into the native mitral valve anatomy. One anterior tab anchors into the left fibrous trigone, and the other anterior tabs anchors into the right fibrous trigone. The trigones are on opposite sides of the anterior side of the leaflet. Fig. 12L illustrates engagement of the posterior tab 1214 with the posterior leaflet PL which is captured between an inner surface of the posterior tab and an outer surface of the ventricular skirt 1220. Additionally, adjacent chordae tendineae may be captured between the posterior tab and ventricular skirt.

[00110] Figs. 13A-13L illustrate another exemplary embodiment of a delivery method. This embodiment is similar to that previously described, with the major difference being the order in which the prosthetic cardiac valve self-expands into engagement with the mitral valve. Any delivery device or any prosthetic valve disclosed herein may be used, however in preferred embodiments, the embodiment of Fig. 7 is used. Varying the order may allow better positioning of the implant, easier capturing of the valve leaflets, and better anchoring of the implant. This exemplary method also preferably uses a transapical route, although transseptal may also be used.

[00111] Fig. 13A illustrates the basic anatomy of the left side of a patient's heart including the left atrium LA and left ventricle LV. Pulmonary veins PV return blood from the lungs to the left atrium and the blood is then pumped from the left atrium into the left ventricle across the mitral valve MV. The mitral valve includes an anterior leaflet AL on an anterior side A of the valve and a posterior leaflet PL on a posterior side P of the valve. The leaflets are attached to chordae tendineae CT which are subsequently secured to the heart walls with papillary muscles PM. The blood is then pumped out of the left ventricle into the aorta AO with the aortic valve AV preventing regurgitation.

[00112] Fig. 13B illustrates transapical delivery of a delivery system 1302 through the apex of the heart into the left atrium LA via the left ventricle LV. The delivery system 1302 may be advanced over a guidewire GW into the left atrium, and a tissue penetrating tip 1304 helps the delivery system pass through the apex of the heart by dilating the tissue and forming a larger channel for the remainder of the delivery system to pass through. The delivery catheter carries prosthetic cardiac valve 1308. Once the distal portion of the delivery system has been advanced into the left atrium, the outer sheath 1306 may be retracted proximally (e.g. toward the operator) thereby removing the constraint from the atrial portion of the prosthetic valve 1308. This allows the atrial skirt 1310 to self-expand radially outward. In Fig. 13C, as the outer sheath is further retracted, the atrial skirt continues to self-expand and peek out, until it fully deploys as seen in Fig. 13D. The atrial skirt may have a cylindrical shape or it may be D-shaped as discussed above with a flat anterior portion and a cylindrical posterior portion so as to avoid interfering with the aortic valve and other aspects of the left ventricular outflow tract. The prosthesis may be oriented and properly positioned by rotating the prosthesis and visualizing the alignment element previously described. Also, the prosthetic cardiac valve may be advanced upstream or downstream to properly position the atrial skirt. In preferred embodiments, the atrial skirt forms a flange that rests against a superior surface of the mitral valve and this anchors the prosthetic valve and prevents it from unwanted movement downstream into the left ventricle.

[00113] As the outer sheath 1306 continues to be proximally retracted, the annular region of the prosthetic cardiac valve self-expands next into engagement with the valve annulus. The annular region also preferably has the D-shaped geometry, although it may also be cylindrical or have other geometries to match the native anatomy. In Fig. 13E, retraction of sheath 1306 eventually allows both the anterior 1312 and posterior 1314 tabs to partially self-expand outward preferably without engaging the anterior or posterior leaflets or the chordae tendineae. In this embodiment, further retraction of the outer sheath 1306 then allows both the anterior tabs 1312 (only one visible in this view) to complete their self-expansion so that the anterior leaflet is captured between an inner surface of each of the anterior tabs and an outer surface of the ventricular skirt 1316, as illustrated in Fig. 13F. The posterior tab 1214 remains partially open, but has not completed its expansion yet. Additionally, the tips of the anterior tabs also anchor into the left and right fibrous trigones of the mitral valve, as will be illustrated in greater detail below.

[00114] In Fig. 13G, further retraction of the outer sheath 1306 then releases the constraint from the ventricular skirt 1320 allowing the ventricular skirt to radially expand. This then further captures the anterior leaflets AL between the anterior tab 1312 and the ventricular skirt 1316. Expansion of the ventricular skirt also pushes the anterior and posterior leaflets outward, thereby ensuring that the native leaflets do not interfere with any portion of the prosthetic valve or the prosthetic valve leaflets. Further retraction of sheath 1306 as illustrated in Fig. 13H releases the constraint from the posterior tab 1314 allowing it to complete its self-expansion, thereby capturing the posterior leaflet PL between an inner surface of the posterior tab 1314 and an outer surface of the ventricular skirt 1318. The prosthetic valve is now anchored in position above the mitral valve, along the annulus, to the valve leaflets, and below the mitral valve, thereby securing it in position.

[00115] Further actuation of the delivery device now retracts the outer sheath 1306 and the bell catheter shaft 1322 so as to remove the constraint from the hub catheter 1324, as illustrated in Fig. 13I. This permits the prosthetic valve commissures 1326 to be released from the hub catheter, thus the commissures expand to their unbiased configuration. The delivery system 1302 and guidewire GW are then removed, leaving the prosthetic valve 1308 in position where it takes over for the native mitral valve, as seen in Fig. 13J.

[00116] Figs. 13K and 13L highlight engagement of the anterior and posterior tabs with the respective anterior and posterior leaflet. In Fig. 13K, after anterior tabs 1312 have been fully expanded, they capture the anterior leaflet AL and may capture adjacent chordae tendineae between an inside surface of the anterior tab and an outer surface of the ventricular skirt 1320. Moreover, the tips 1328 of the anterior tabs 1312 are engaged with the fibrous trigones FT of the anterior side of the mitral valve. The fibrous trigones are fibrous regions of the valve thus the anterior tabs further anchor the prosthetic valve into the native mitral valve anatomy. One anterior tab anchors into the left fibrous trigone, and the other anterior tabs anchors into the right fibrous trigone. The trigones are on opposite sides of the anterior side of the leaflet. Fig. 13L illustrates engagement of the posterior tab 1314 with the posterior leaflet PL which is captured between an inner surface of the posterior tab and an outer surface of the ventricular skirt 1320. Additionally, adjacent chordae tendineae may also be captured between the posterior tab and ventricular skirt.

[00117] Deployment of a prosthetic valve that includes a foot element instead of, or in conjunction with the posterior anchor element is similar to the two exemplary methods described above. The major difference being that when the prosthesis does not have a posterior anchor, retraction of the outer sheath allows the foot to self-expand to a profile large enough to minimize or prevent pivoting of the prosthesis upstream into or toward the left atrium. In embodiments having both a posterior anchor and a foot element, retraction of the outer sheath allows both structures to expand. Other aspects of the deployment are generally the same as previously described above.

[00118] Tab Covering. In the exemplary embodiments described above, the tabs (anterior trigonal tabs and posterior ventricular tab) are generally narrow and somewhat pointy. The embodiment previously described with respect to Fig. 8 includes a horizontal strut on the posterior tab that helps distribute force across a greater area and thereby reduces trauma to the tissue. Figs. 14A-14D illustrate another embodiment that is preferably used with the anterior trigonal tabs to help reduce trauma. It may also be used with the posterior tab if desired.

[00119] Fig. 14A illustrates an anterior trigonal tab 1402 having a tip 1404. This tip can be narrow and pointy and thereby induce tissue trauma when deployed into the tissue. Therefore, in some embodiments, it may be desirable to place a cover over the tip to help reduce tissue trauma. Fig. 14B illustrates a polymer tab 1406 that may be attached to the trigonal tab 1402. In other embodiments, the tab may be formed from other materials such as fabric, metals, or other materials known in the art. The polymer tab may be laser cut from a sheet of polymer and includes a long axial portion 1408 and an enlarged head region 1410. A plurality of suture holes 1412 may be pre-cut into the polymer tab 1406 and the holes are sized to receive suture material. Precut holes on the polymer tab may be aligned with pre-cut holes on the trigonal tab and then the polymer tab may be secured to the trigonal tab with sutures, adhesives, or other coupling techniques known in the art. A fabric cover 1414 having two symmetric halves separated by a hinged area 1416 is then wrapped around the polymer tab and attached to the polymer tab by sutures, thereby forming a shroud around the trigonal tab. The fabric may be Dacron, ePTFE, or any other biocompatible material known in the art. Thus, the cover increases the surface area of contact between the trigonal tabs and the tissue thereby reducing potential trauma and likelihood of piercing the heart wall. Additionally, the material may allow tissue ingrowth which further helps to anchor the prosthesis. Materials and dimensions are also selected in order to maintain the low profile of the device during delivery in the collapsed configuration.

[00120] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

EMBODIMENTS IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A prosthetic valve for implanting in a native valve of a patient, said prosthetic valve comprising:

a self-expanding frame having a first end, a second end opposite the first end, an atrial region near the second end, a ventricular region near the first end, an anterior portion, and a posterior portion,

wherein the self-expanding frame has an expanded configuration and a collapsed configuration, the expanded configuration adapted to engage native heart tissue at a treatment site, and the collapsed configuration adapted to be delivered to the treatment site, and wherein the expandable frame comprises:

a self-expanding atrial skirt disposed in the atrial region;

a self-expanding ventricular skirt disposed in the ventricular region, the ventricular skirt comprising a plurality of struts having a length;

a self-expanding annular region disposed between the atrial region and the ventricular region;

a first self-expanding anterior tab disposed on the anterior portion of the self-expanding frame in the ventricular region;

a self-expanding posterior tab disposed on the posterior portion of the self-expanding frame in the ventricular region; and

a self-expanding foot coupled to the ventricular region, wherein the foot comprises a wedge shaped element extending laterally and radially outward from a periphery of the ventricular skirt, wherein the foot comprises a plurality of struts having a length greater than the length of the struts in the ventricular skirt, and wherein the posterior tab coupled to and extends from the foot, wherein the foot has an outer surface for engaging the native heart tissue thereby facilitating anchoring of the prosthetic valve and minimizing or preventing rotation of the prosthetic valve.

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2. The prosthetic valve of claim 1, wherein the prosthetic valve is a prosthetic mitral valve.

3. The prosthetic valve of claim 1, wherein the atrial skirt has a collapsed configuration and an expanded configuration, the collapsed configuration adapted for delivery to the treatment site, and the expanded configuration radially expanded relative to the collapsed configuration and adapted to lie over a superior surface of the patient's native valve, thereby anchoring the atrial skirt against a superior portion of the native valve.

4. The prosthetic valve of claim 1, wherein the atrial skirt comprises a plurality of axially oriented struts, wherein at least some adjacent struts in the plurality of axially oriented struts are connected together with a connector element, the plurality of interconnected struts forming a series of peaks and valleys.

5. The prosthetic valve of claim 1, wherein after self-expansion of the atrial skirt, the atrial skirt forms a flanged region adjacent the second end of the self-expanding frame.

6. The prosthetic valve of claim 5, wherein after self-expanding, the atrial skirt has an asymmetrically D-shaped cross-section having a substantially flat anterior portion, and a cylindrically shaped posterior portion.

7. The prosthetic valve of claim 1, further comprising an alignment element coupled to an anterior portion of the atrial skirt, wherein the alignment element is adapted to be aligned with an aortic root of a patient's heart and adapted to be disposed between two fibrous trigones of an anterior leaflet of the patient's mitral valve.

8. The prosthetic valve of claim 1, wherein at least a portion of the ventricular skirt is configured to be covered with a tissue cover or a synthetic material.

9. The prosthetic valve of claim 1, wherein after self-expanding, the ventricular skirt comprises an asymmetrically D-shaped cross-section having a substantially flat anterior portion, and a cylindrically shaped posterior portion.

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10. The prosthetic valve of claim 1, wherein the ventricular skirt has a collapsed configuration and an expanded configuration, the collapsed configuration adapted for delivery to the treatment site, and the expanded configuration radially expanded relative to the collapsed configuration and adapted to displace native mitral valve leaflets radially outward.

11. The prosthetic valve of claim 1, wherein the ventricular skirt further comprises a plurality of barbs coupled thereto, the plurality of barbs adapted to anchor the ventricular skirt into the native heart tissue.

12. The prosthetic valve of claim 1, wherein the ventricular skirt comprises a plurality of struts, wherein at least some adjacent struts in the plurality of struts are connected together with a connector element, the plurality of interconnected struts forming a series of peaks and valleys.

13. The prosthetic valve of claim 12, wherein one or more of the struts comprise one or more suture holes extending therethrough, the suture holes sized to receive a suture.

14. The prosthetic valve of claim 1, wherein the annular region has a collapsed configuration and an expanded configuration, the collapsed configuration adapted for delivery to the treatment site, and the expanded configuration radially expanded relative to the collapsed configuration and adapted to conform with and adapted to engage an annulus of the native valve.

15. The prosthetic valve of claim 1, wherein after self-expanding, the annular region has an asymmetrically D-shaped cross-section having a substantially flat anterior portion, and a cylindrically shaped posterior portion.

16. The prosthetic valve of claim 1, wherein the annular region comprises a plurality of axially oriented struts, wherein at least some adjacent struts in the plurality of axially oriented struts of the annular region are connected together with a connector element, the plurality of interconnected struts forming a series of peaks and valleys.

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17. The prosthetic valve of claim 16, wherein one or more of the plurality of axially oriented struts comprise one or more suture holes extending therethrough, the suture holes sized to receive a suture.

18. The prosthetic valve of claim 1, wherein the first anterior tab has a tip portion adapted to engage a first fibrous trigone on a first side of an anterior leaflet of the patient's mitral valve, and wherein the first anterior tab is adapted to capture the anterior leaflet and adjacent chordae tendineae between the first anterior tab and an outer anterior surface of the ventricular skirt.

19. The prosthetic valve of claim 18, further comprising a second self-expanding anterior tab disposed on the anterior portion of the self-expanding frame in the ventricular region, and wherein the second anterior tab has a tip portion adapted to engage a second fibrous trigone on a second side of the anterior leaflet of the patient's mitral valve opposite the first side of the anterior leaflet, and wherein the second anterior tab is adapted to capture the anterior leaflet and adjacent chordae tendineae between the second anterior tab and the outer surface of the ventricular skirt.

20. The prosthetic valve of claim 19, further comprising a covering disposed over the first or the second anterior tab, the covering increasing contact surface area of the respective first or second anterior tab with the native heart tissue.

21. The prosthetic valve of claim 20, wherein the covering comprises a fabric material disposed over a polymer tab that is coupled to the first or the second anterior tab.

22. The prosthetic valve of claim 1, wherein rotation of the posterior portion is minimized or prevented relative to the anterior portion of the prosthetic valve.

23. The prosthetic valve of claim 1, wherein rotation is minimized or prevented in a direction toward the left atrium of the patient's heart.

24. The prosthetic valve of claim 1, wherein the foot is configured to be covered with a synthetic material or with a tissue cover.

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25. The prosthetic valve of claim 1, wherein the foot comprises a central elongate element and a cover, wherein the cover is disposed over the central elongate element and the cover is coupled to a strut on either side thereof.

26. The prosthetic valve of claim 25, wherein the central elongate element comprises a pair of struts coupled together to form a U-shape or a V-shape.

27. The prosthetic valve of claim 1, wherein the foot forms a vestibule on the posterior portion.

28. The prosthetic valve of claim 1, wherein the foot comprises barbs, texturing or other surface features for anchoring the foot to the native heart tissue.

29. The prosthetic valve of claim 1, further comprising a plurality of prosthetic valve leaflets, each of the leaflets having a prosthetic leaflet first end and a free end, wherein the prosthetic leaflet first end is coupled with the self-expanding frame and the free end is opposite of the prosthetic leaflet first end, wherein the prosthetic valve leaflets have an open configuration in which the free ends of the prosthetic valve leaflets are disposed away from one another to allow antegrade blood flow therepast, and a closed configuration in which the free ends of the prosthetic valve leaflets engage one another and substantially prevent retrograde blood flow therepast.

30. The prosthetic valve of claim 29, wherein the plurality of prosthetic valve leaflets form a tricuspid valve.

31. The prosthetic valve of claim 29, wherein at least a portion of one or more prosthetic valve leaflets is configured to comprise a tissue cover or a synthetic material.

32. The prosthetic valve of claim 29, wherein one or more of the prosthetic valve leaflets comprise a commissure post having a commissure tab, the commissure tab adapted to be releasably engaged with a delivery device.

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33. The prosthetic valve of claim 1, wherein the prosthetic valve carries a therapeutic agent, the therapeutic agent adapted to being eluted therefrom.

34. The prosthetic valve of claim 1, further comprising barbs, texturing or other surface features disposed on the posterior ventricular anchoring tab, and adapted to engage the native heart tissue and anchor the posterior ventricular tab thereto.

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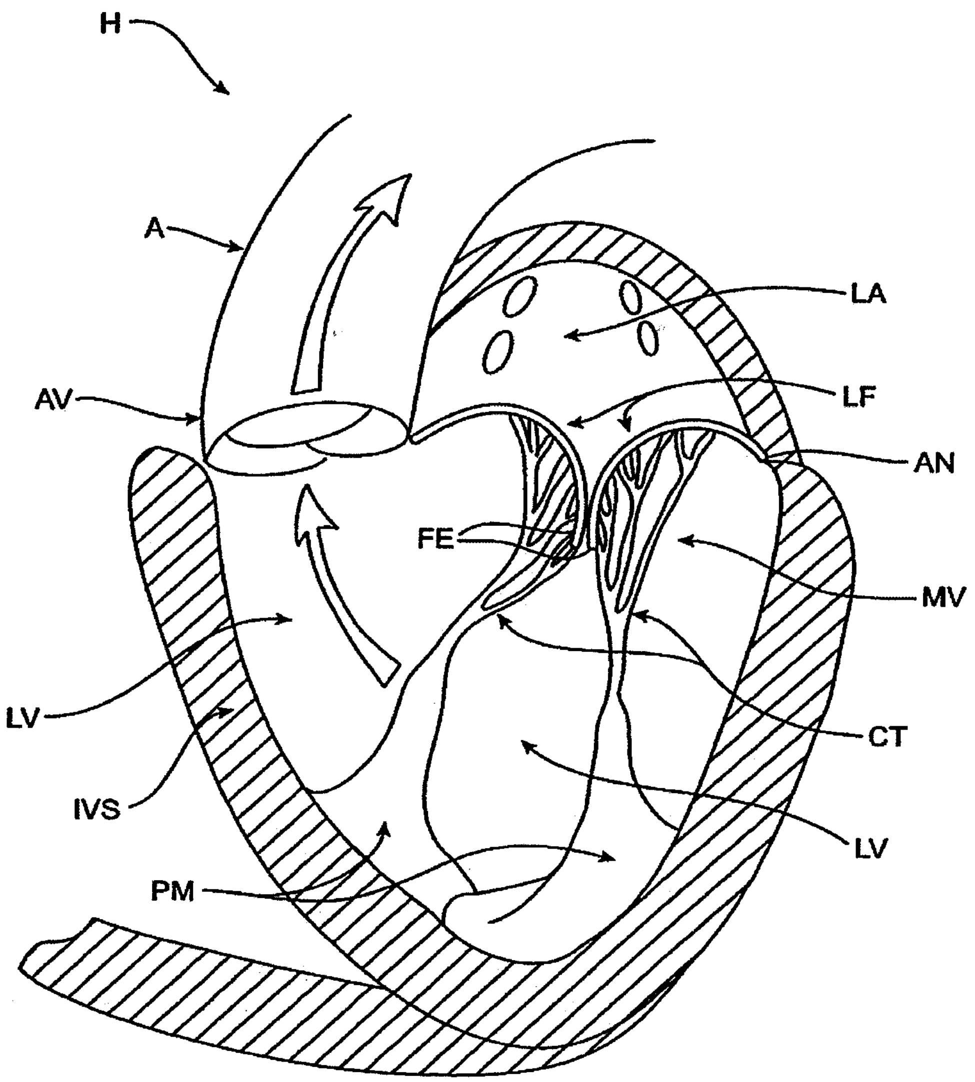


FIG. 1

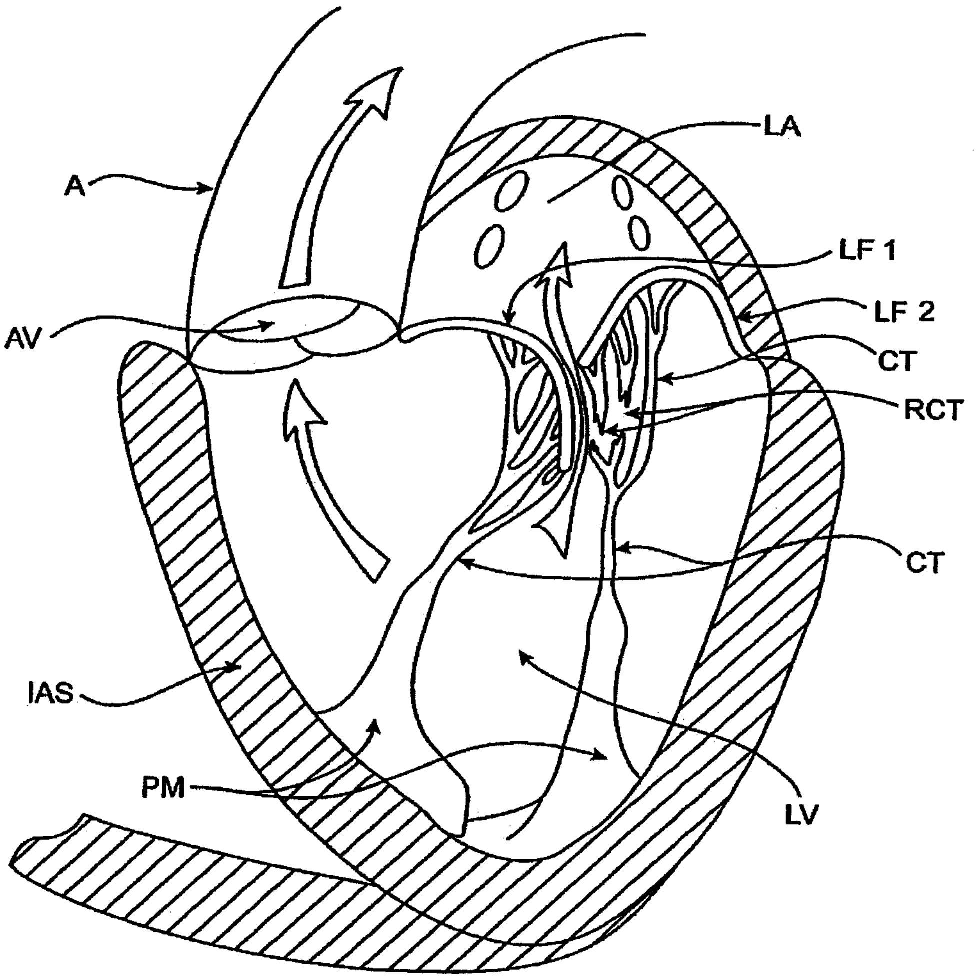


FIG. 2

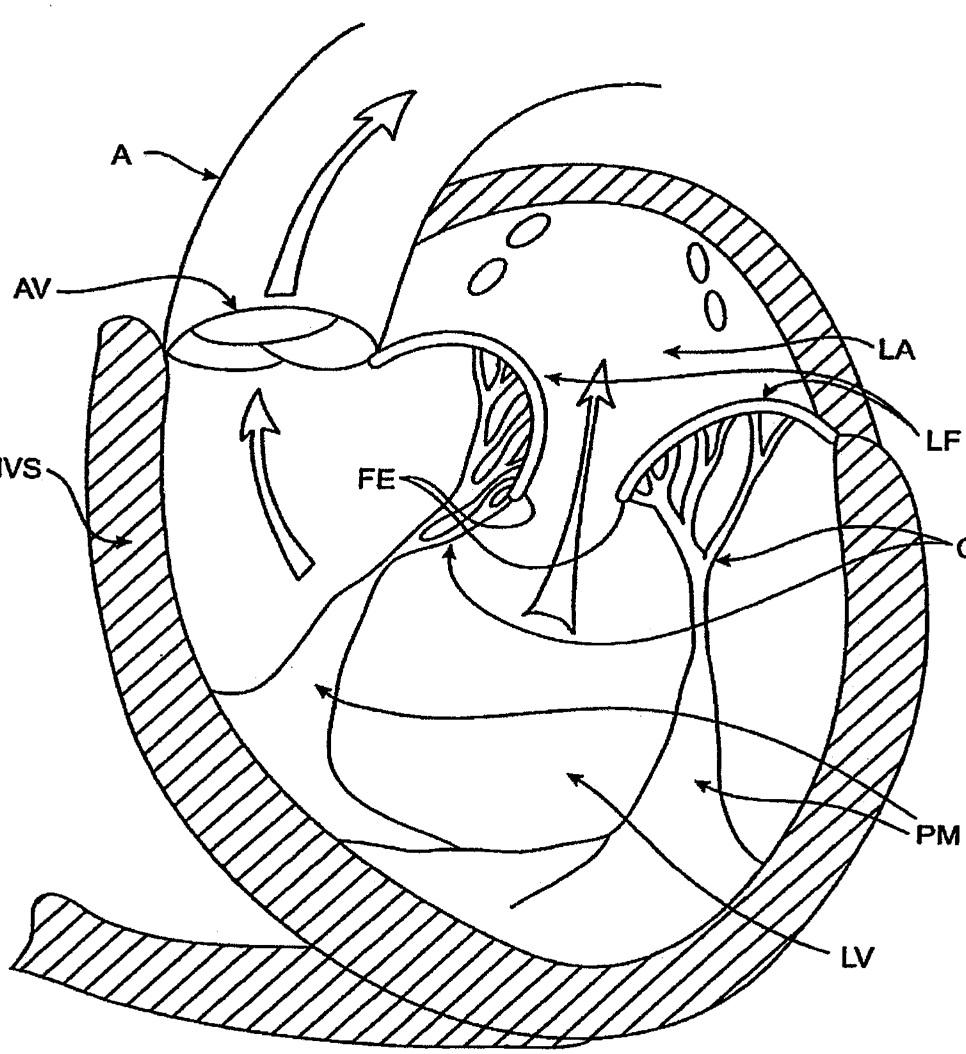


FIG. 3

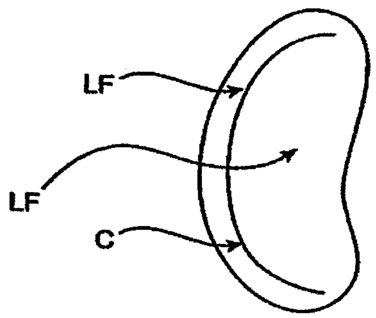


FIG. 3A

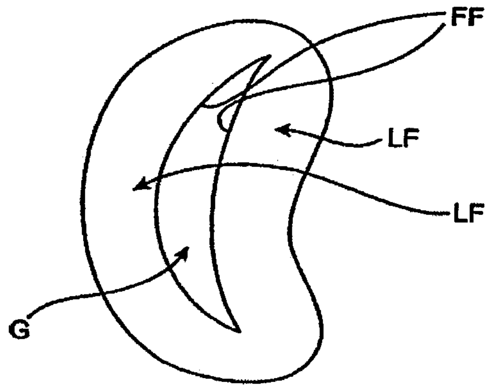


FIG. 3B

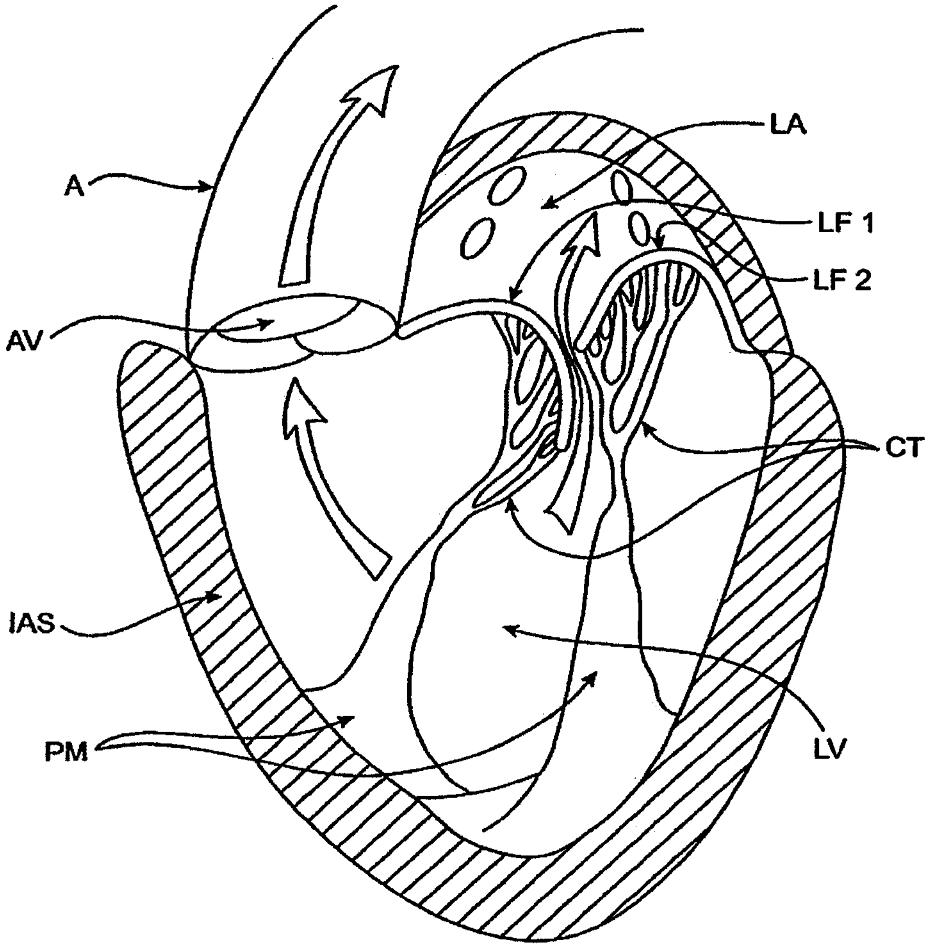


FIG. 4

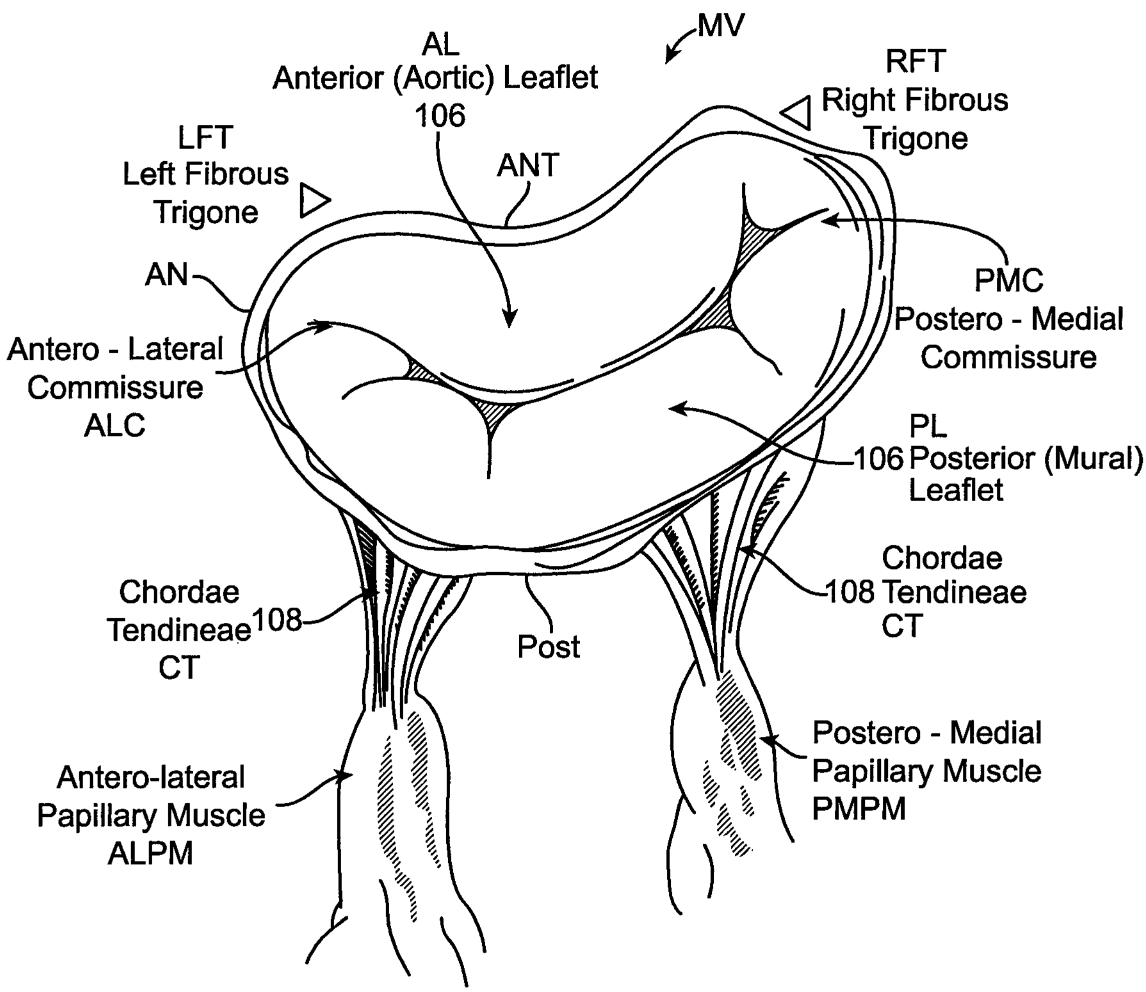

MV
AL
Anterior (Aortic) Leaflet
106
RFT
Right Fibrous
Trigone
LFT
Left Fibrous
Trigone
ANT
AN
PMC
Postero - Medial
Commissure
Antero - Lateral
Commissure
ALC
PL
106 Posterior (Mural)
Leaflet
Chordae
108 Tendineae
CT
Chordae
Tendineae
108
CT
Post
Postero - Medial
Papillary Muscle
PMPM
Antero-lateral
Papillary Muscle
ALPM

FIG. 5A

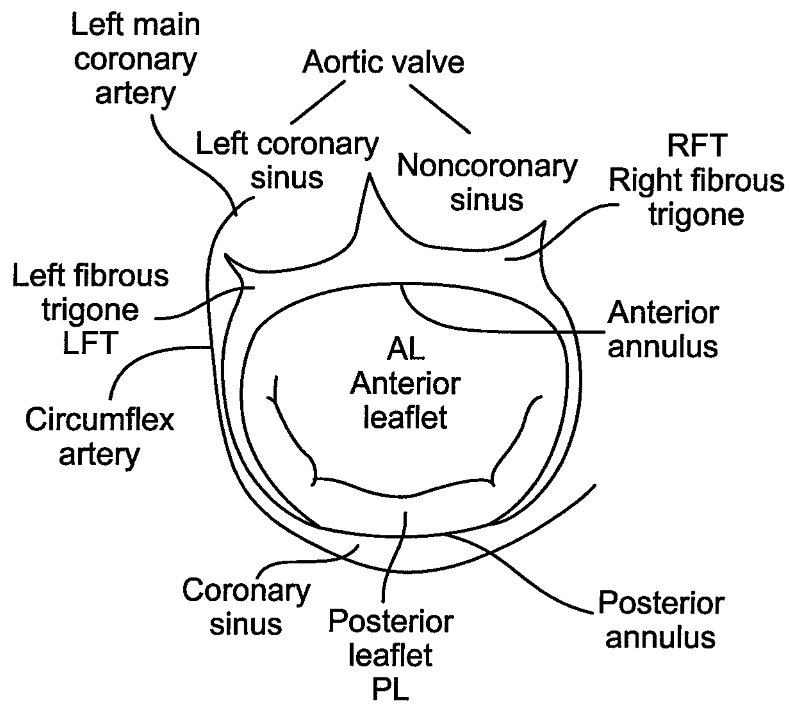

Left main
coronary
artery
Aortic valve
Left coronary
sinus
Noncoronary
sinus
RFT
Right fibrous
trigone
Left fibrous
trigone
LFT
Anterior
annulus
AL
Anterior
leaflet
Circumflex
artery
Coronary
sinus
Posterior
leaflet
PL
Posterior
annulus

FIG. 5B

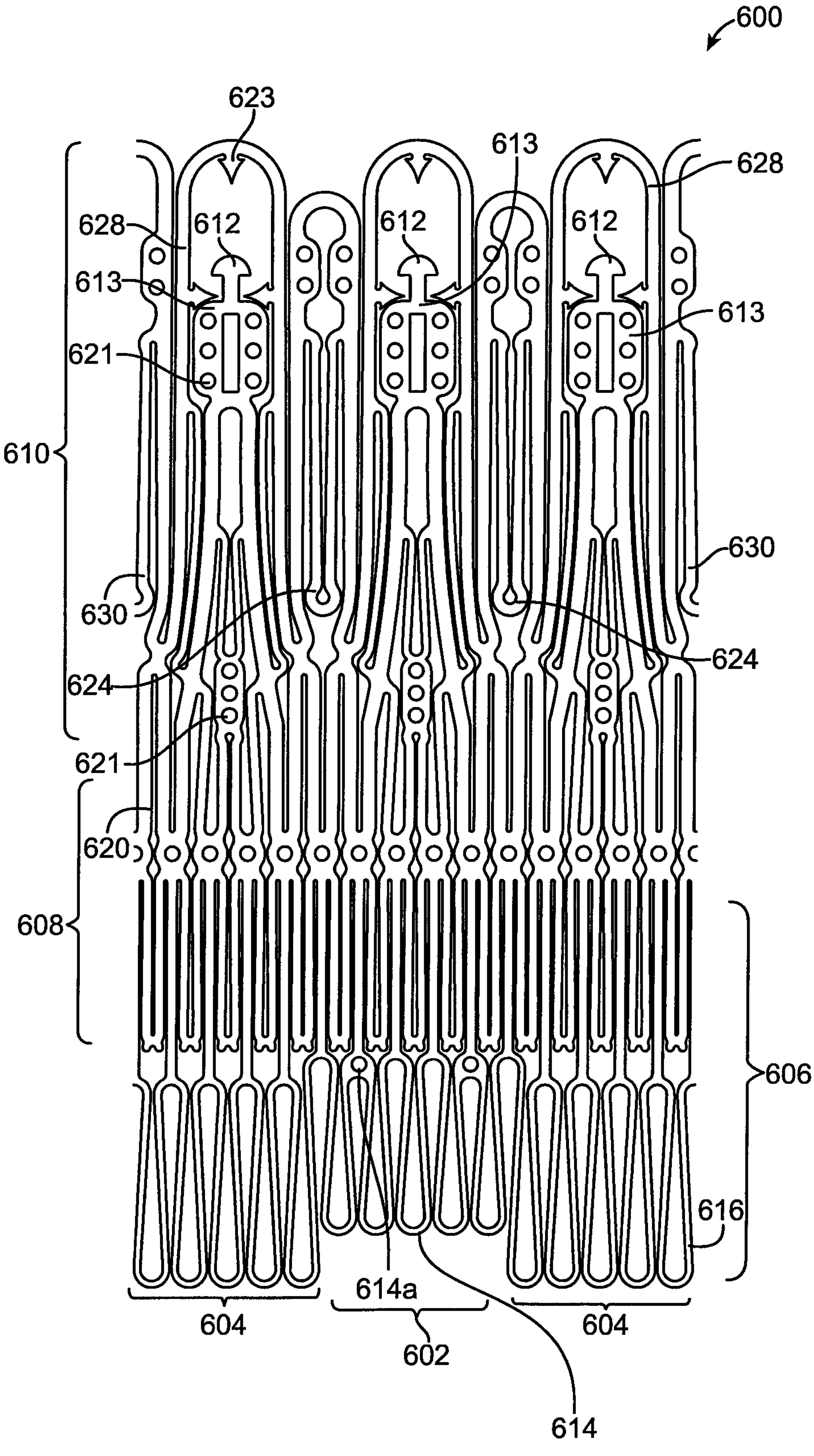

600
623
613
628
628
612
612
612
613
613
621
610
630
630
624
624
621
620
608
606
616
614a
604
602
604
614

FIG. 6

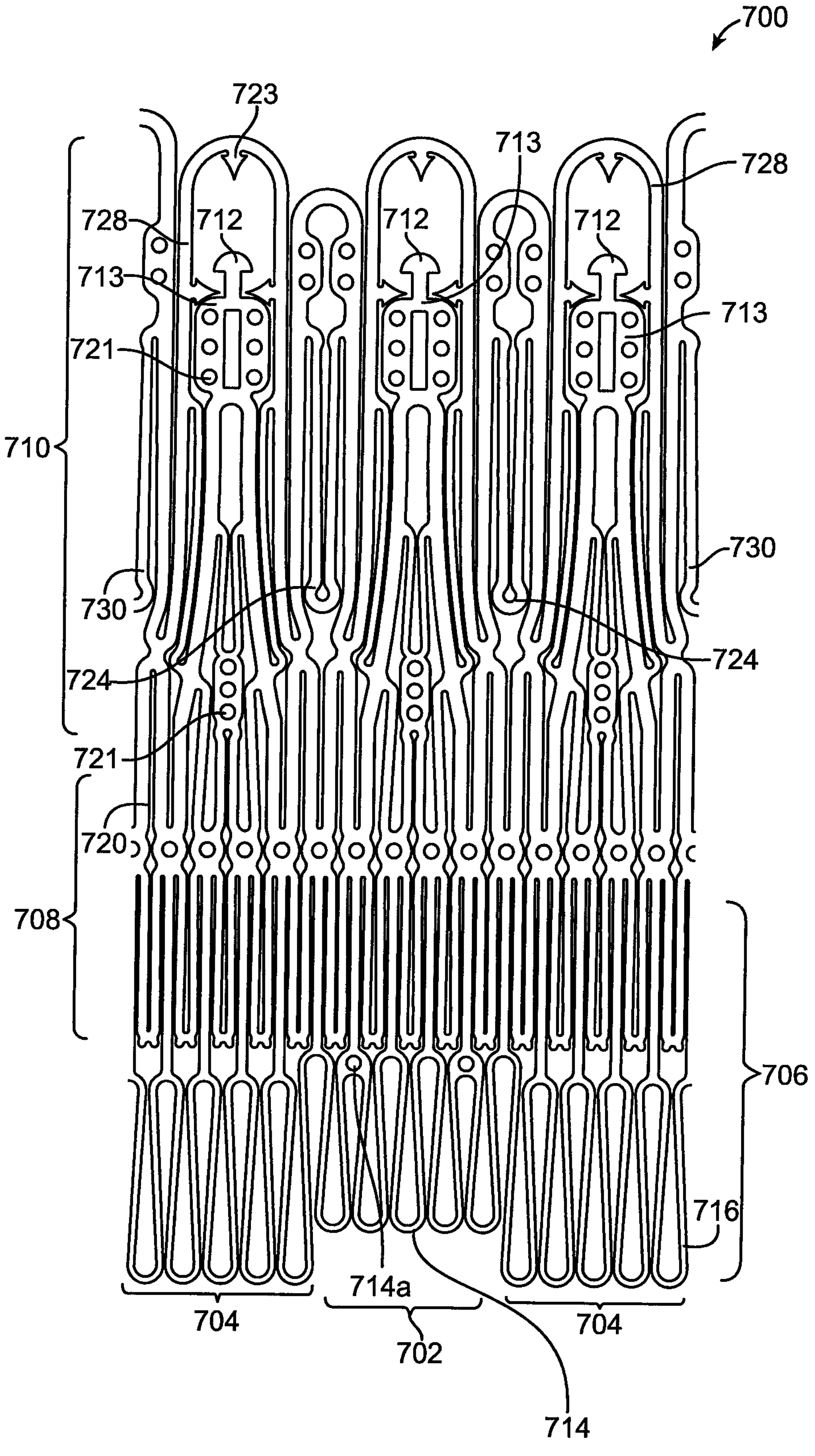

700
723
713
728
728
712
712
712
713
713
721
710
730
730
724
724
721
720
708
706
716
714a
704
702
704
714

FIG. 7

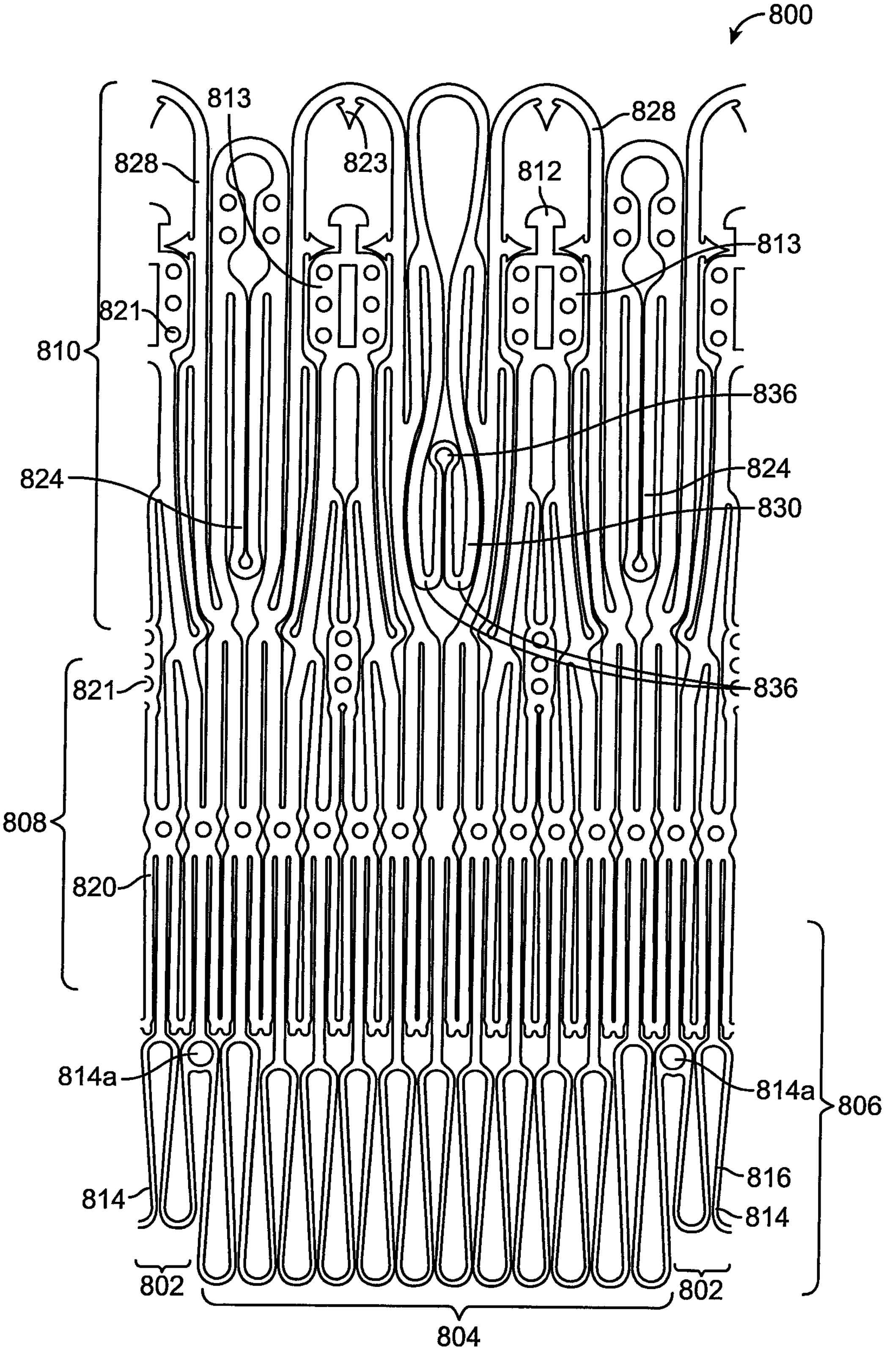

800
813
823
828
828
812
813
821
810
836
824
824
830
836
821
808
820
814a
814a
806
816
814
814
802
802
804

FIG. 8

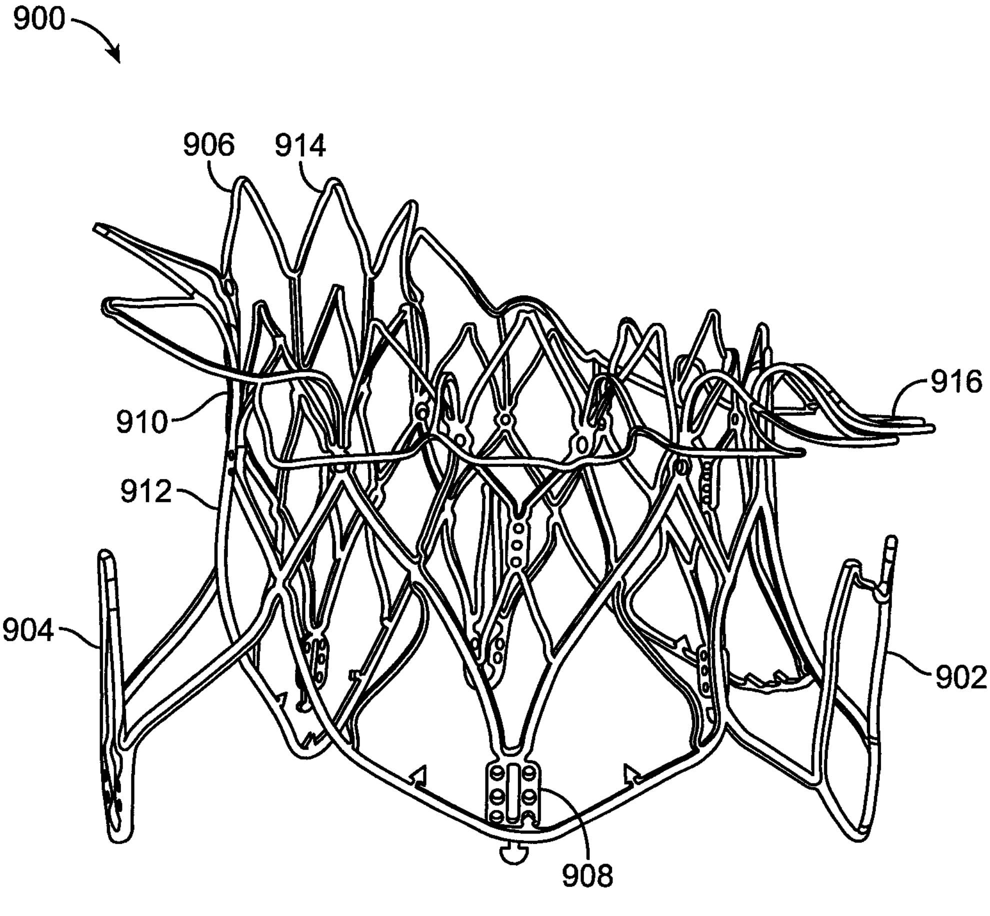


FIG. 9A

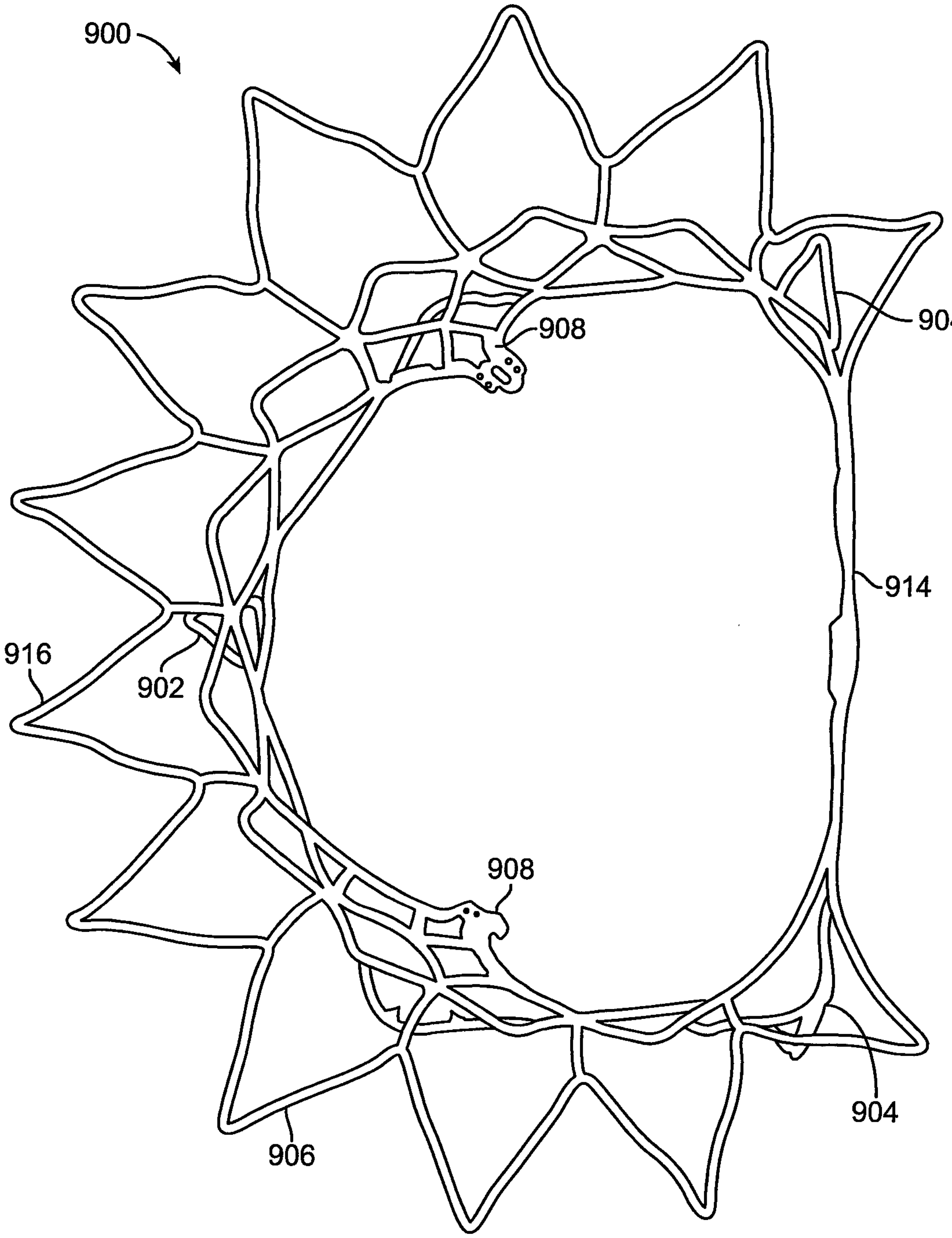


FIG. 9B

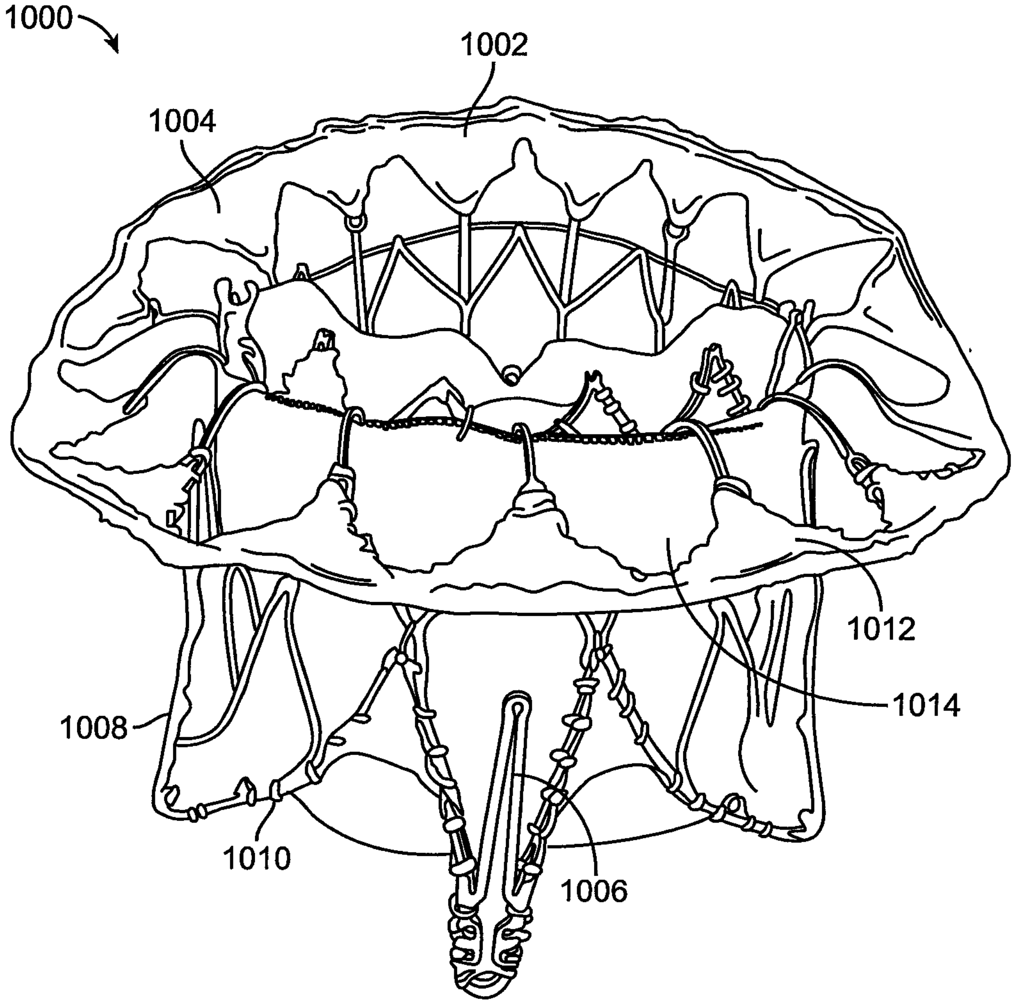


FIG. 10

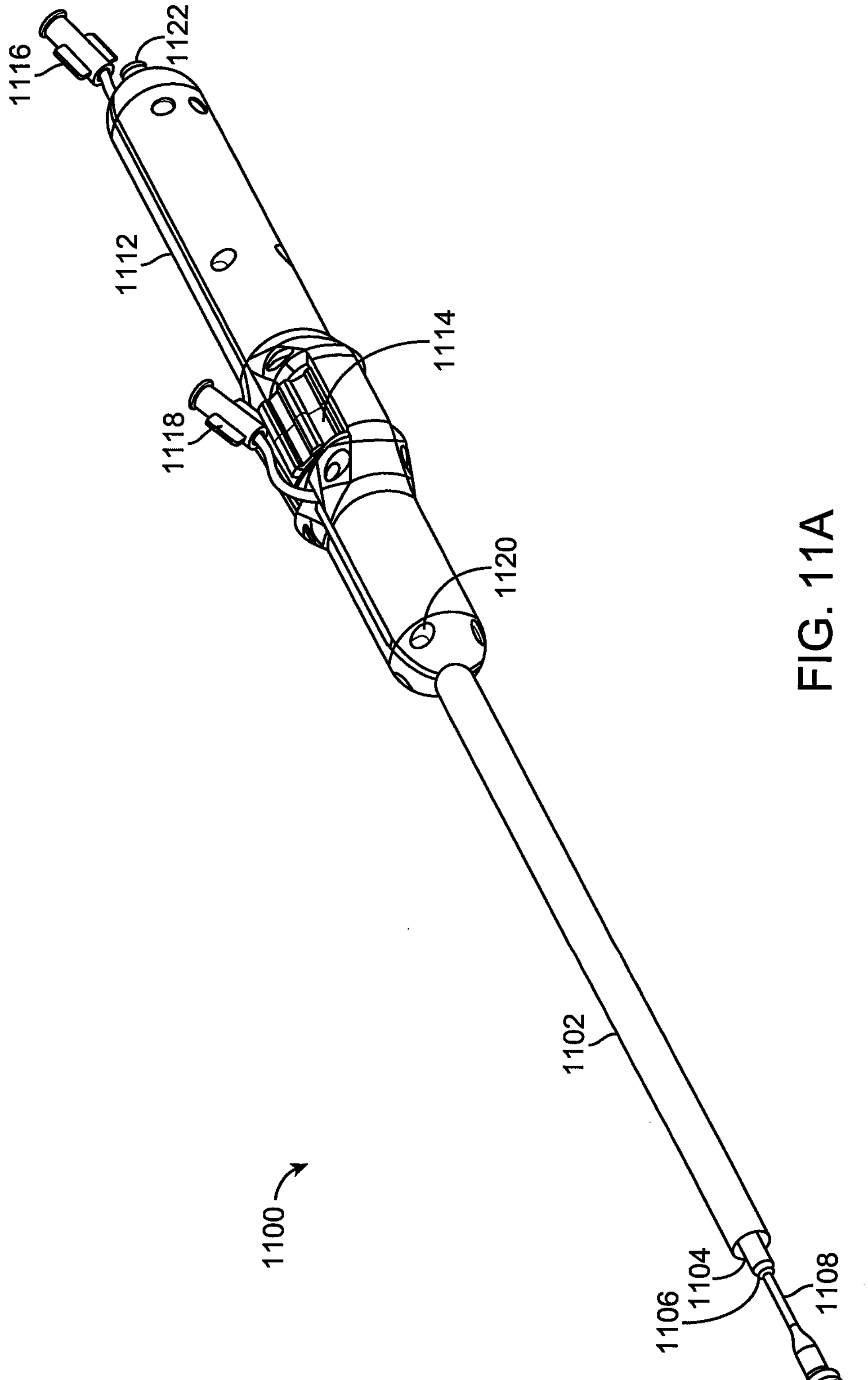


FIG. 11A

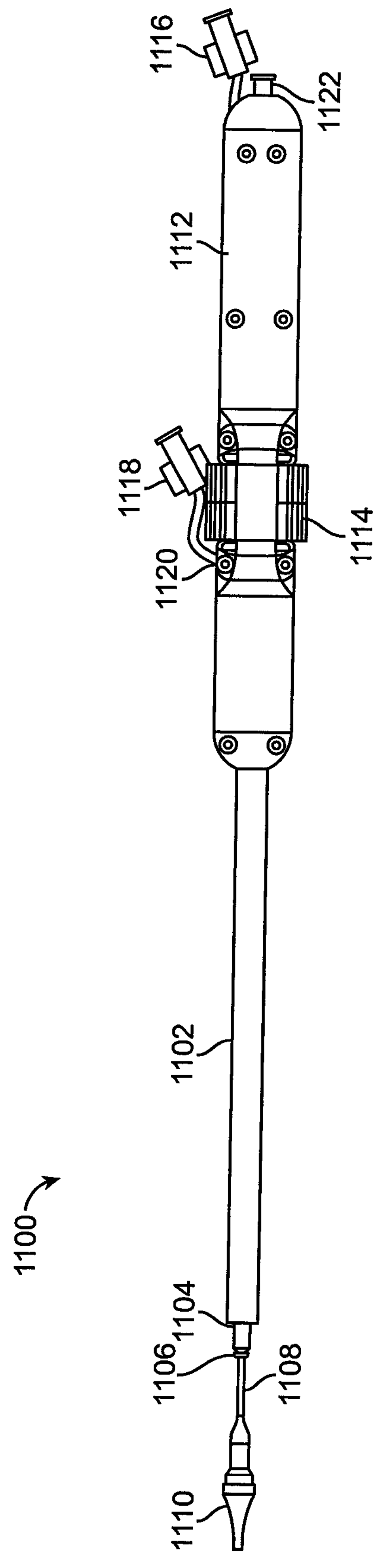


FIG. 11B

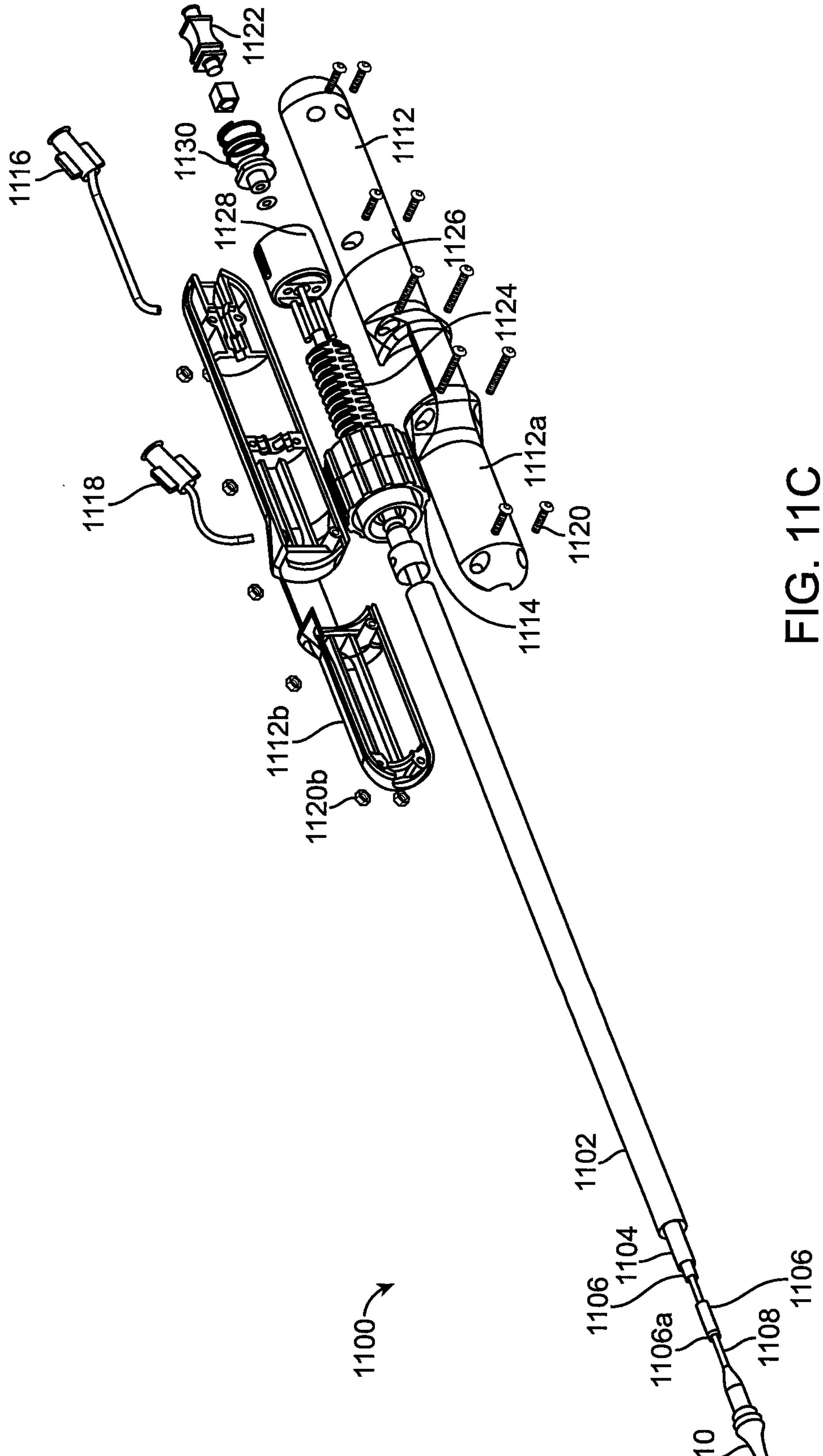

1122
1116
1130
1112
1128
1126
1124
1118
1112a
1120
1114
1112b
1120b
1102
1104
1106
1106
1106a
1108
1100
1110

FIG. 11C

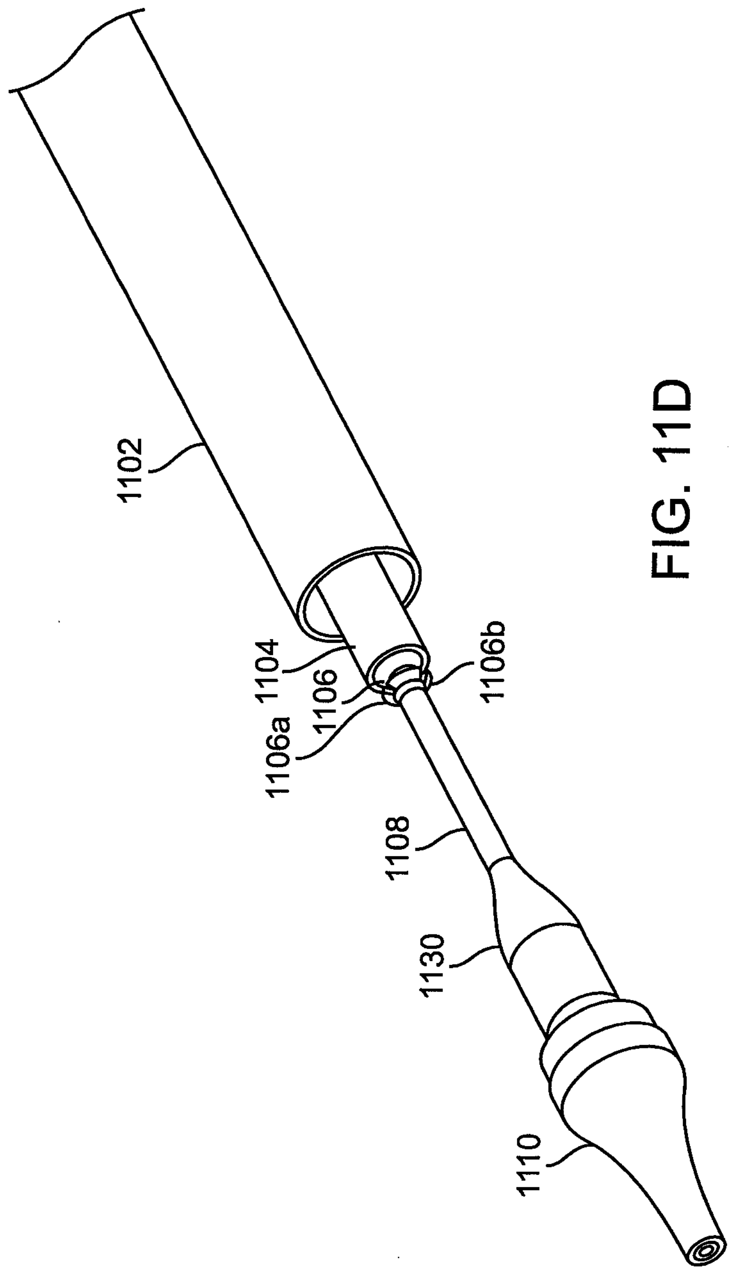


FIG. 11D

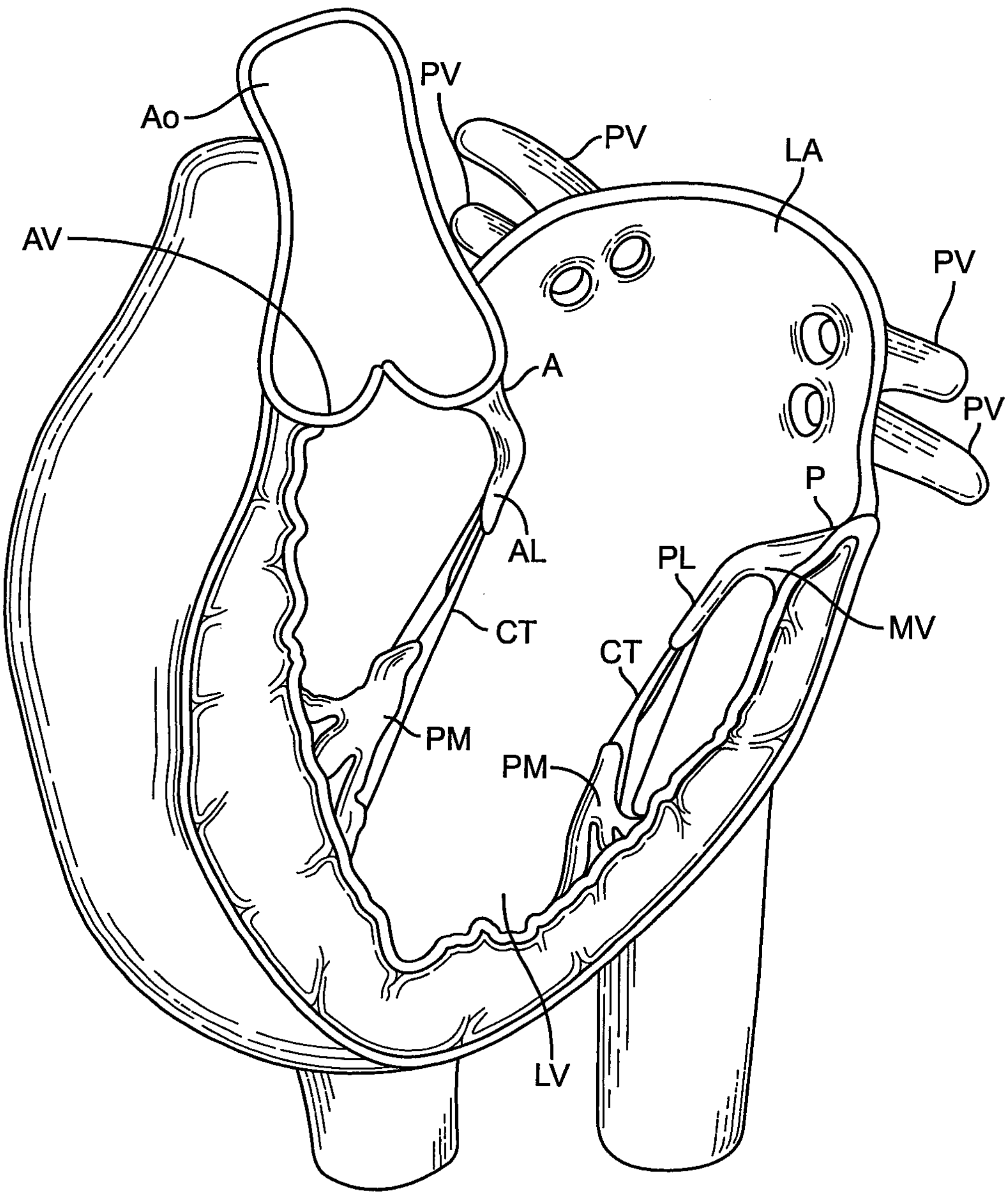


FIG. 12A

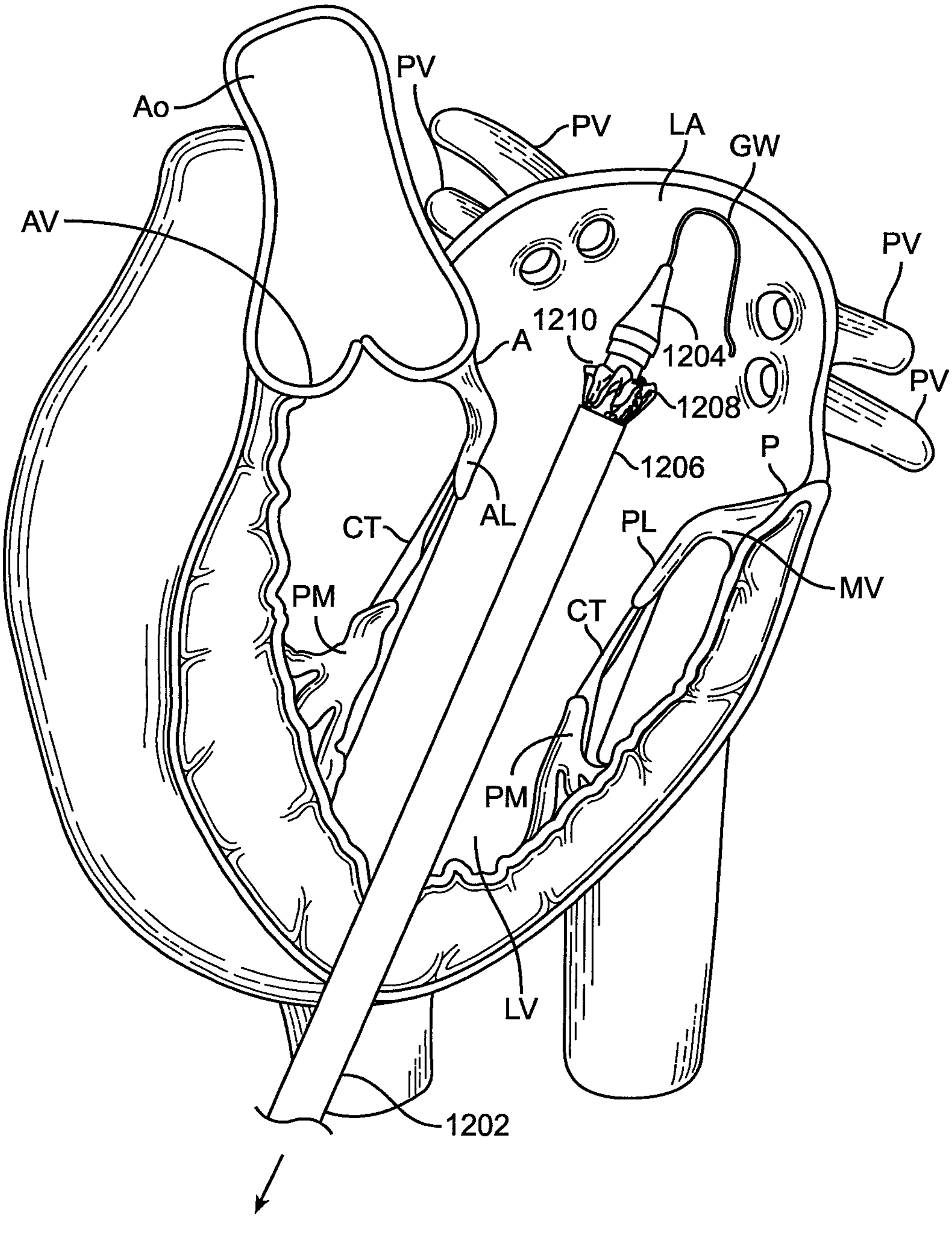

Ao
PV
PV
LA
GW
AV
PV
1210
A
1204
PV
1208
1206
P
AL
CT
PL
MV
PM
CT
PM
LV
1202

FIG. 12B

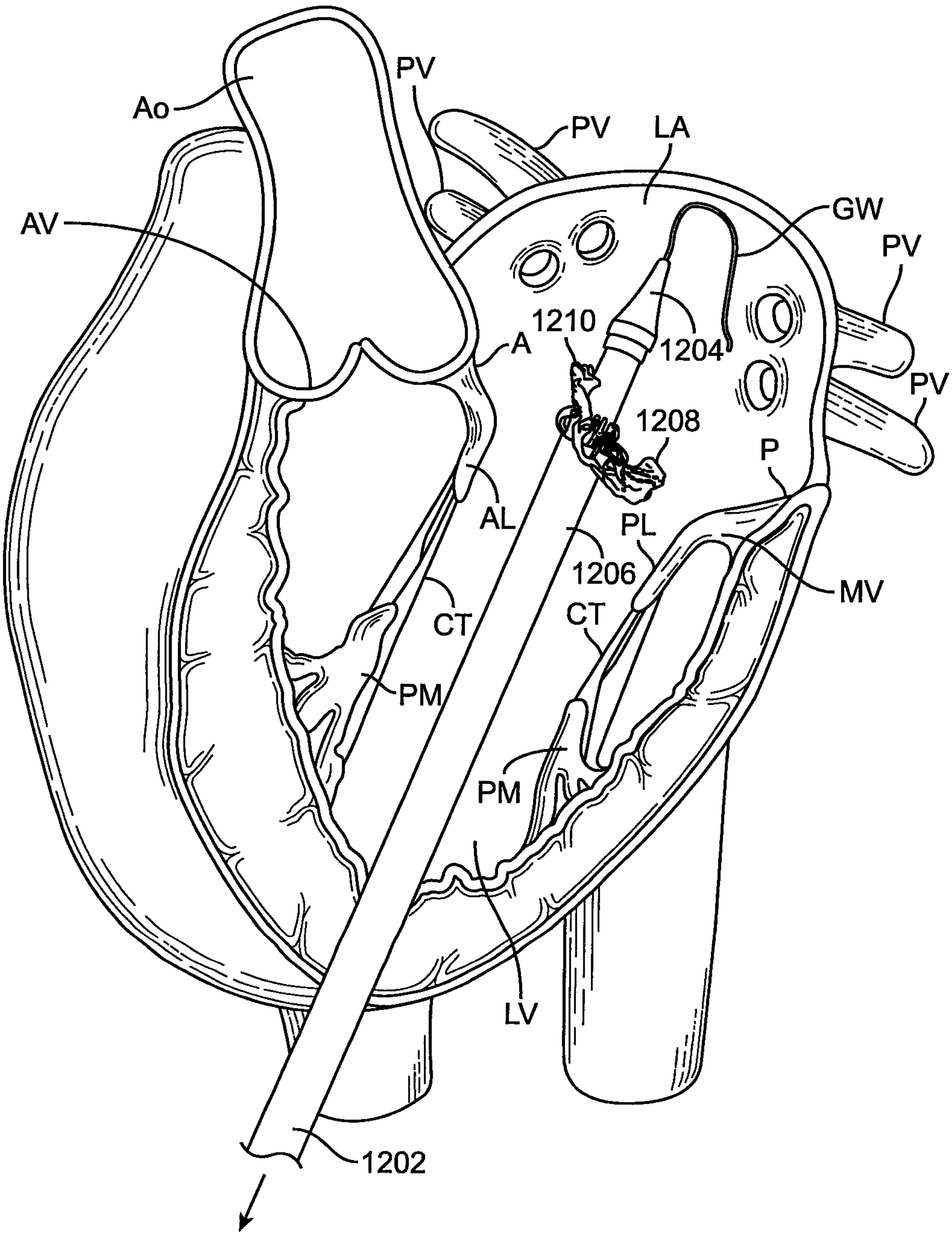

Ao
PV
PV
LA
AV
GW
PV
1210
1204
A
PV
1208
P
AL
PL
1206
MV
CT
CT
PM
PM
LV
1202

FIG. 12C

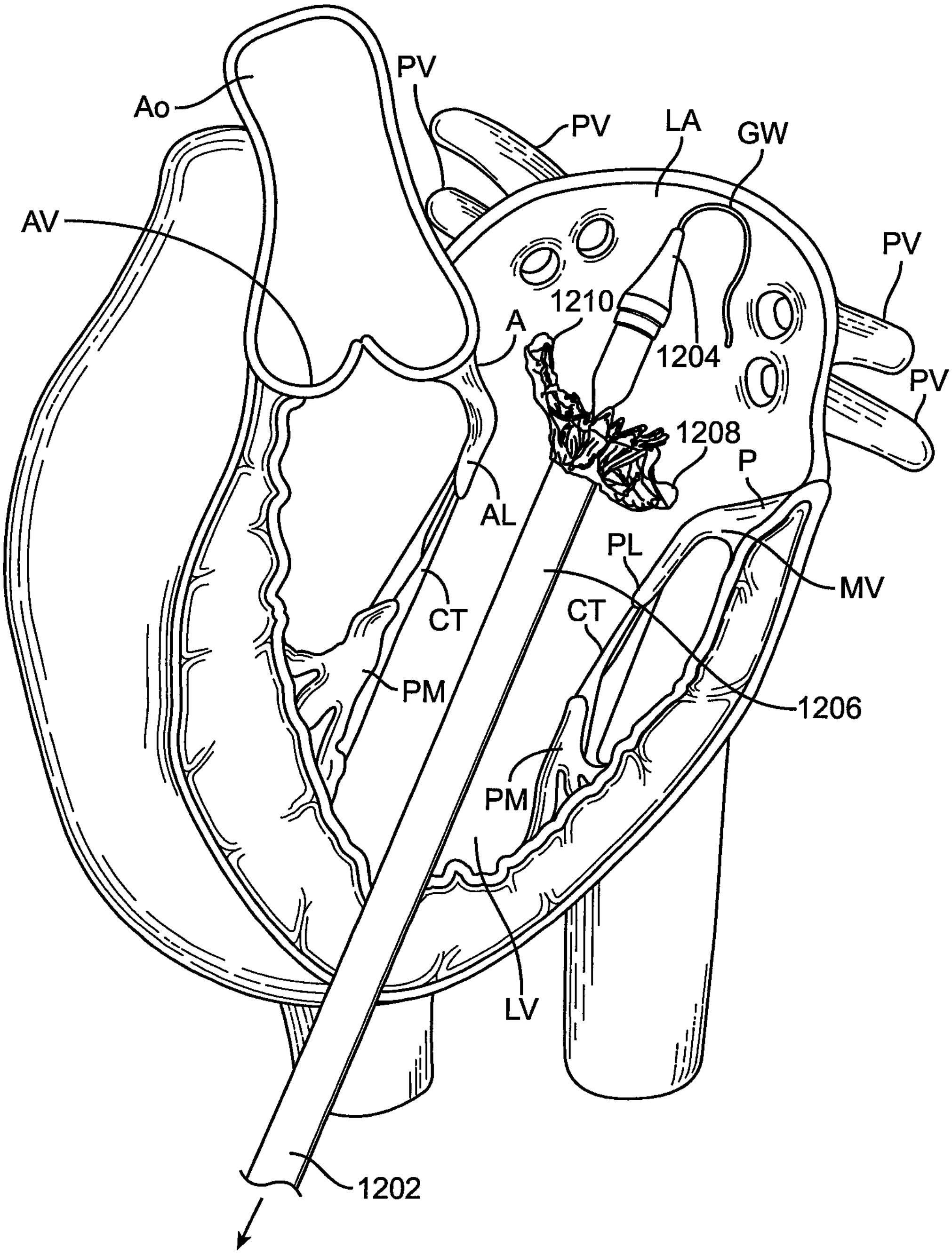

Ao
PV
PV
LA
GW
AV
PV
1210
A
1204
PV
1208
P
AL
PL
MV
CT
CT
PM
1206
PM
LV
1202

FIG. 12D

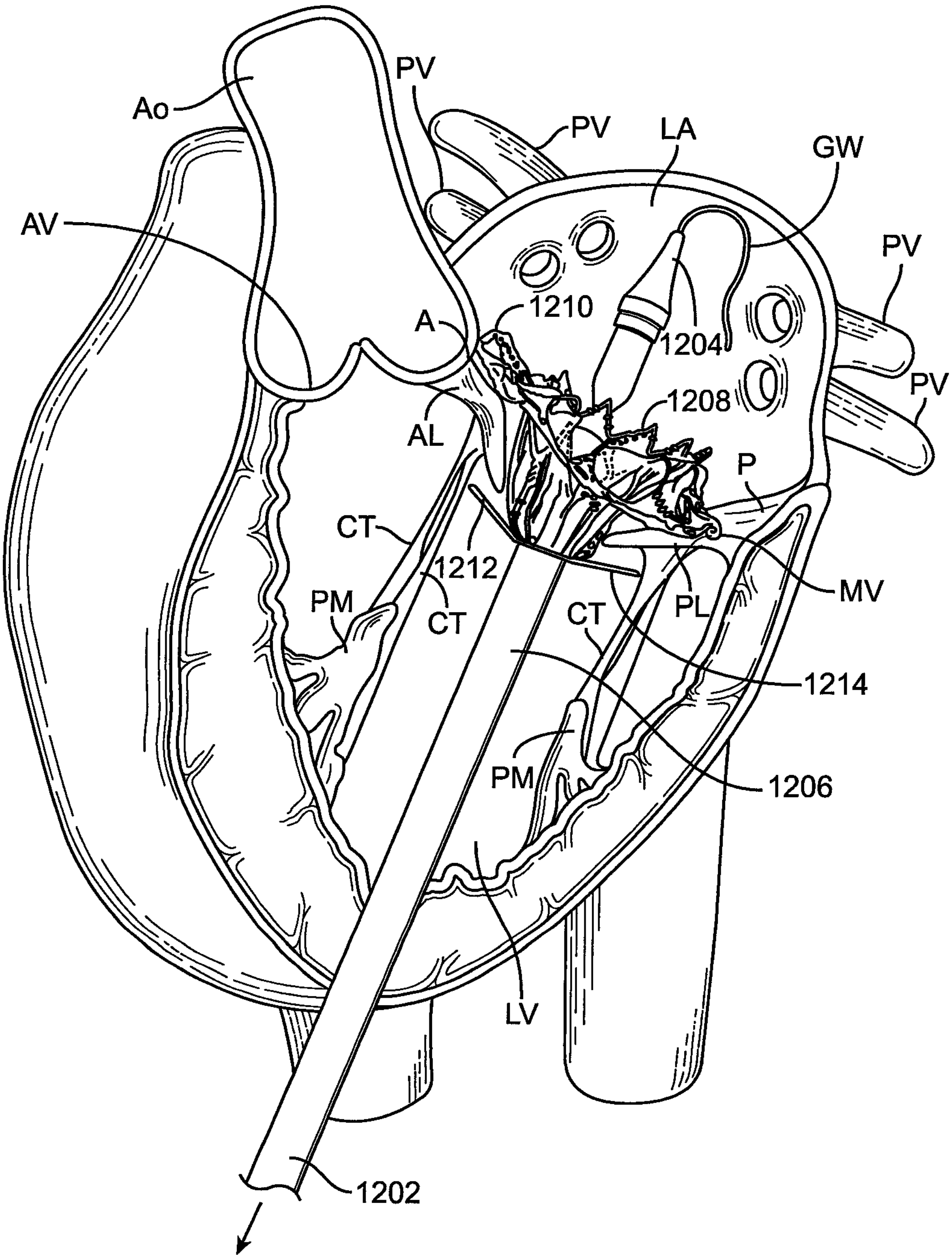

Ao
PV
PV
LA
GW
AV
PV
A
1210
1204
PV
AL
1208
P
CT
1212
MV
PM
CT
CT
PL
1214
1206
PM
LV
1202

FIG. 12E

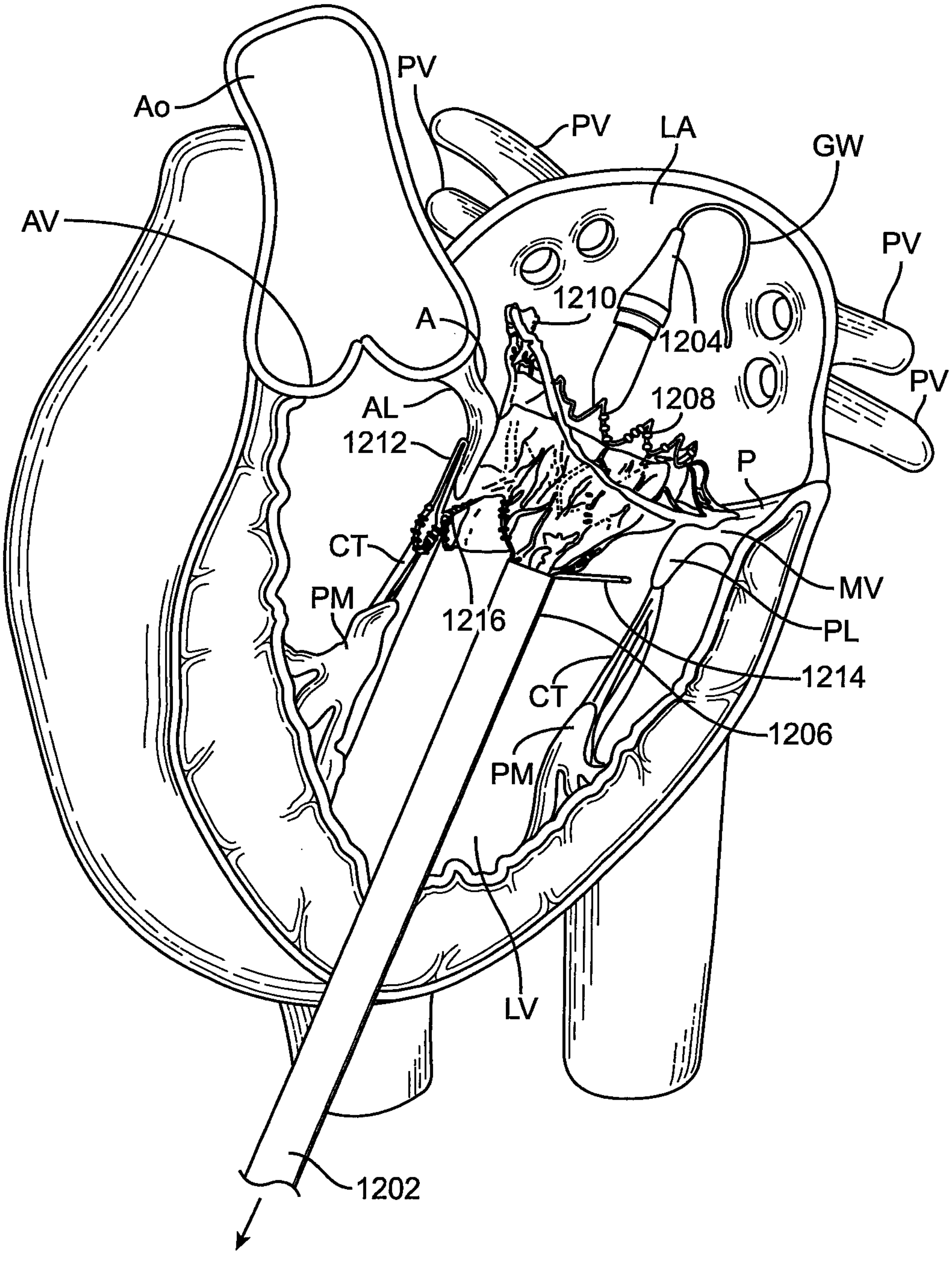

Ao
PV
PV
LA
GW
AV
PV
1210
A
1204
PV
1208
AL
1212
P
CT
MV
PM
1216
PL
1214
CT
1206
PM
LV
1202

FIG. 12F

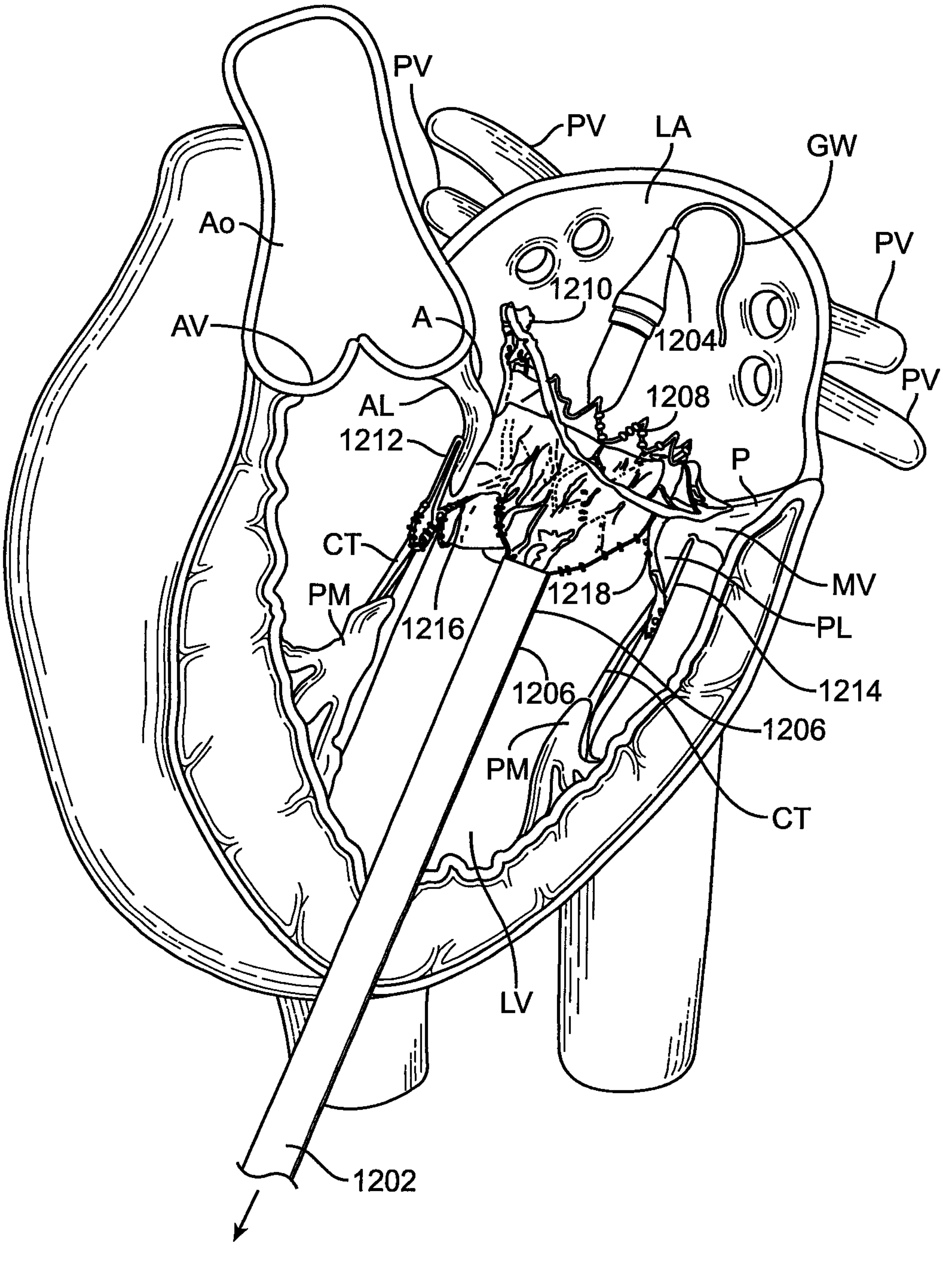

PV
PV
LA
GW
Ao
PV
1210
AV
A
1204
PV
1208
AL
1212
P
CT
MV
PM
1216
1218
PL
1214
1206
1206
PM
CT
LV
1202

FIG. 12G

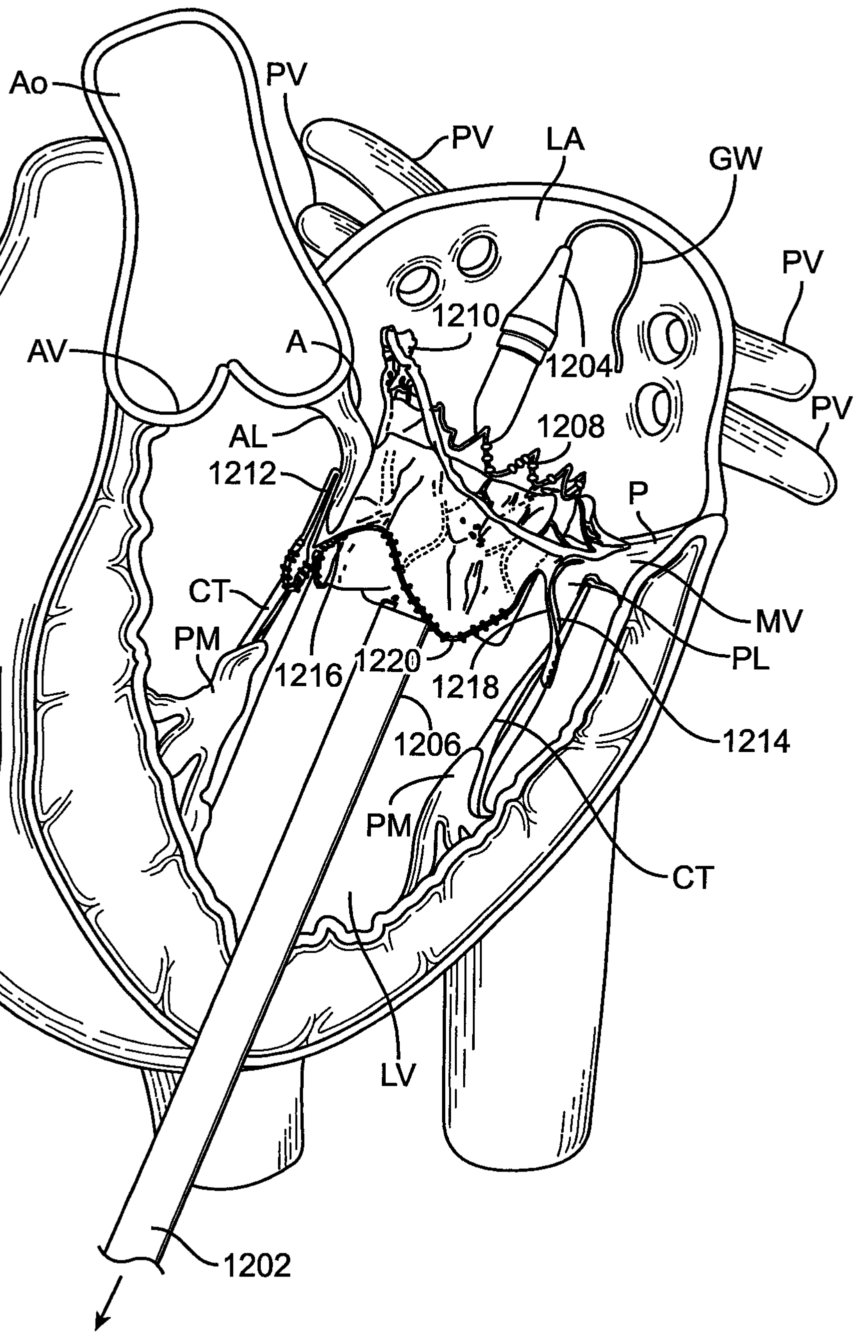

Ao
PV
PV
LA
GW
PV
PV
AV
A
1210
1204
1208
AL
1212
P
CT
PM
1216
1220
1218
MV
PL
1214
1206
PM
CT
LV
1202

FIG. 12H

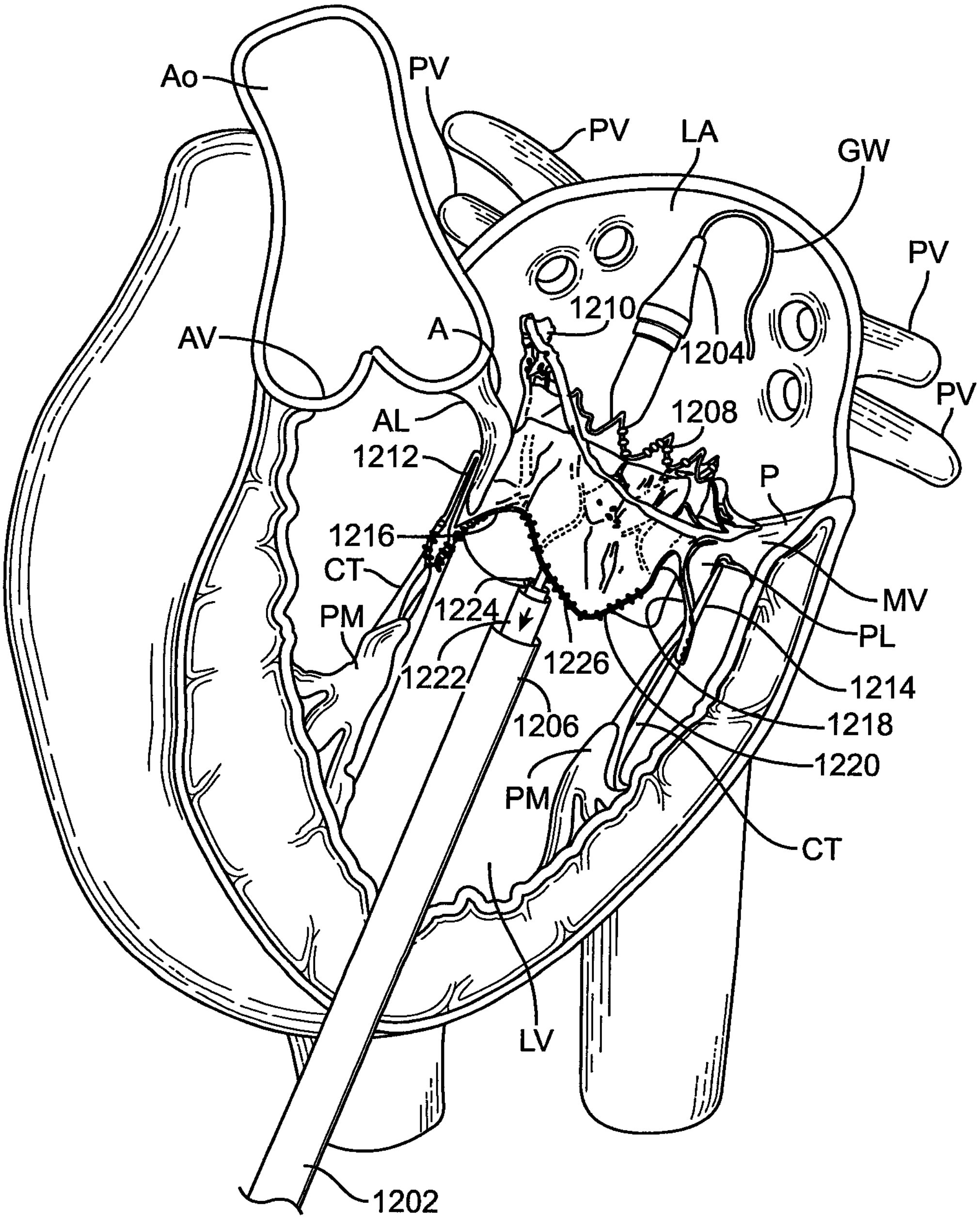

Ao
PV
PV
LA
GW
PV
PV
A
1210
1204
AV
AL
1208
1212
P
1216
CT
MV
PM
1224
PL
1222
1226
1214
1218
1206
1220
PM
CT
LV
1202

FIG. 12I

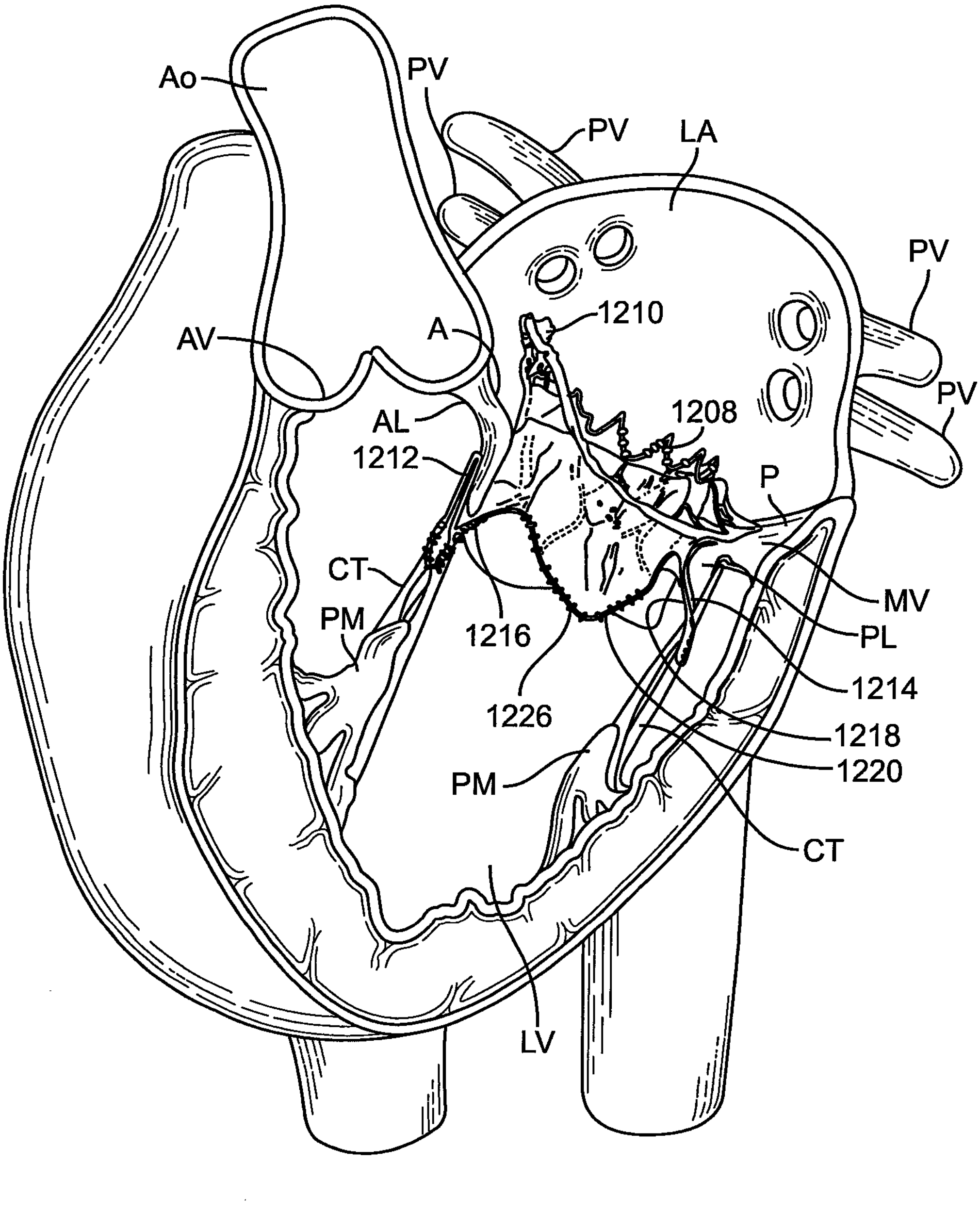

Ao
PV
PV
LA
PV
PV
AV
A
1210
1208
AL
1212
P
CT
MV
PM
1216
PL
1214
1226
1218
1220
PM
CT
LV

FIG. 12J

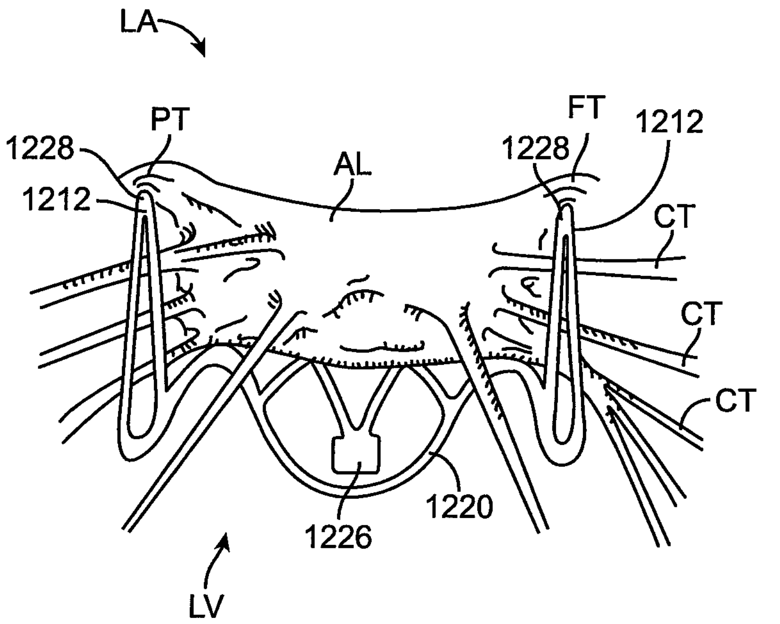


FIG. 12K

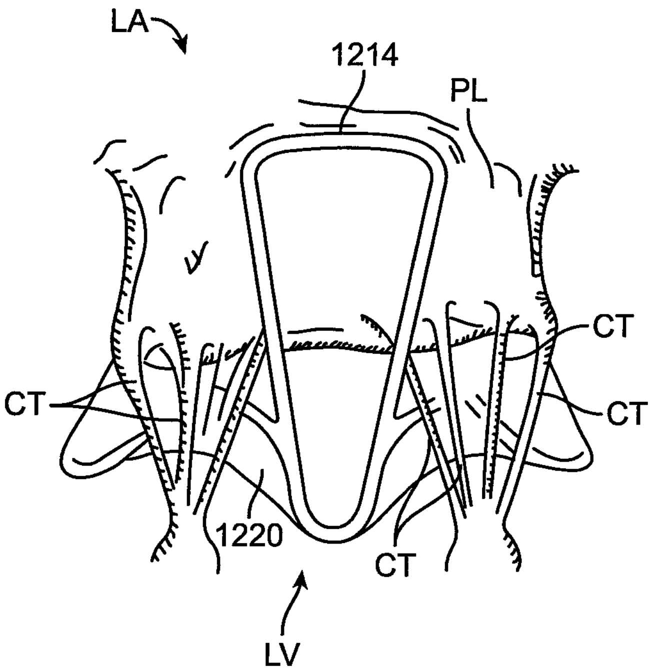


FIG. 12L

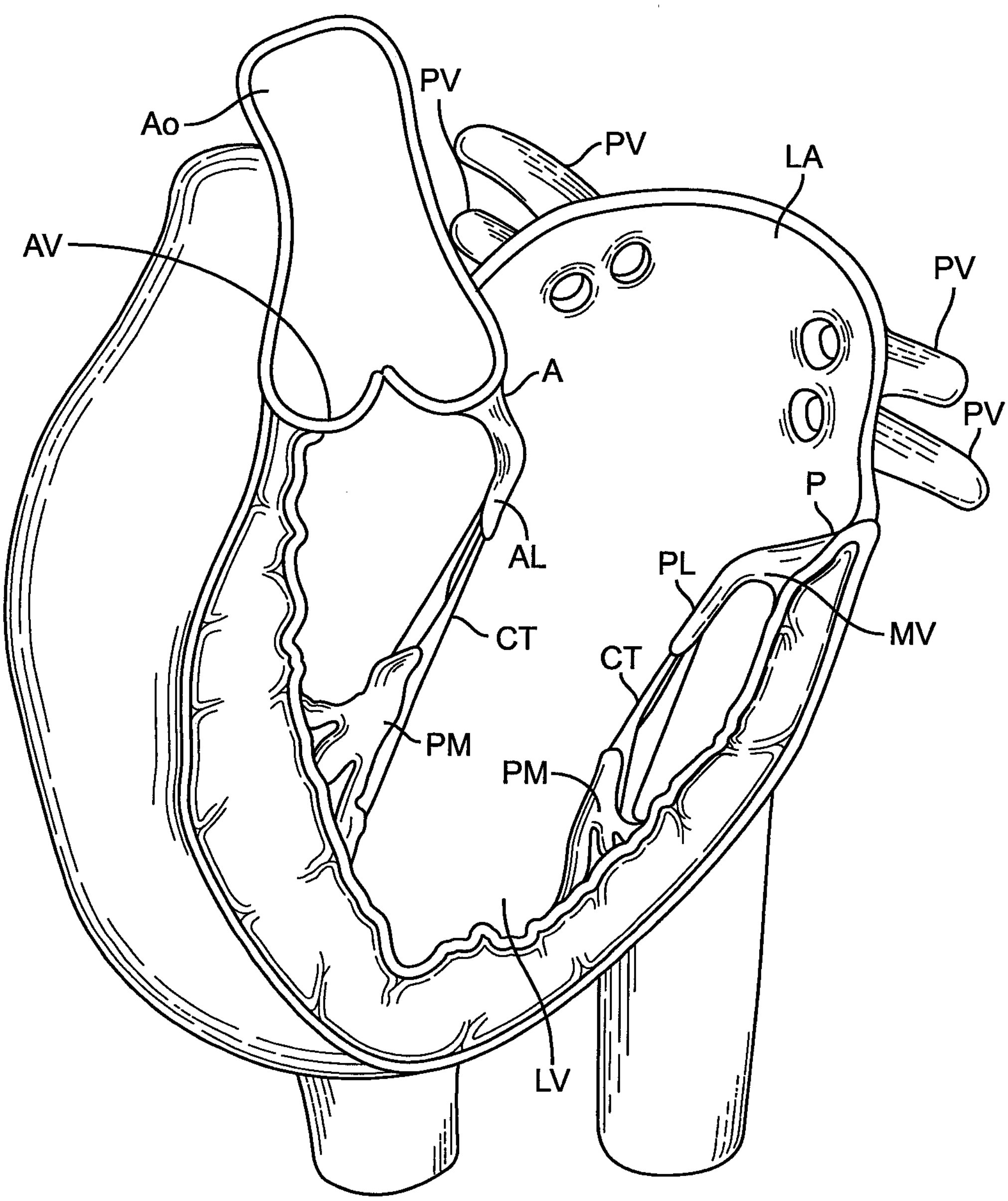


FIG. 13A

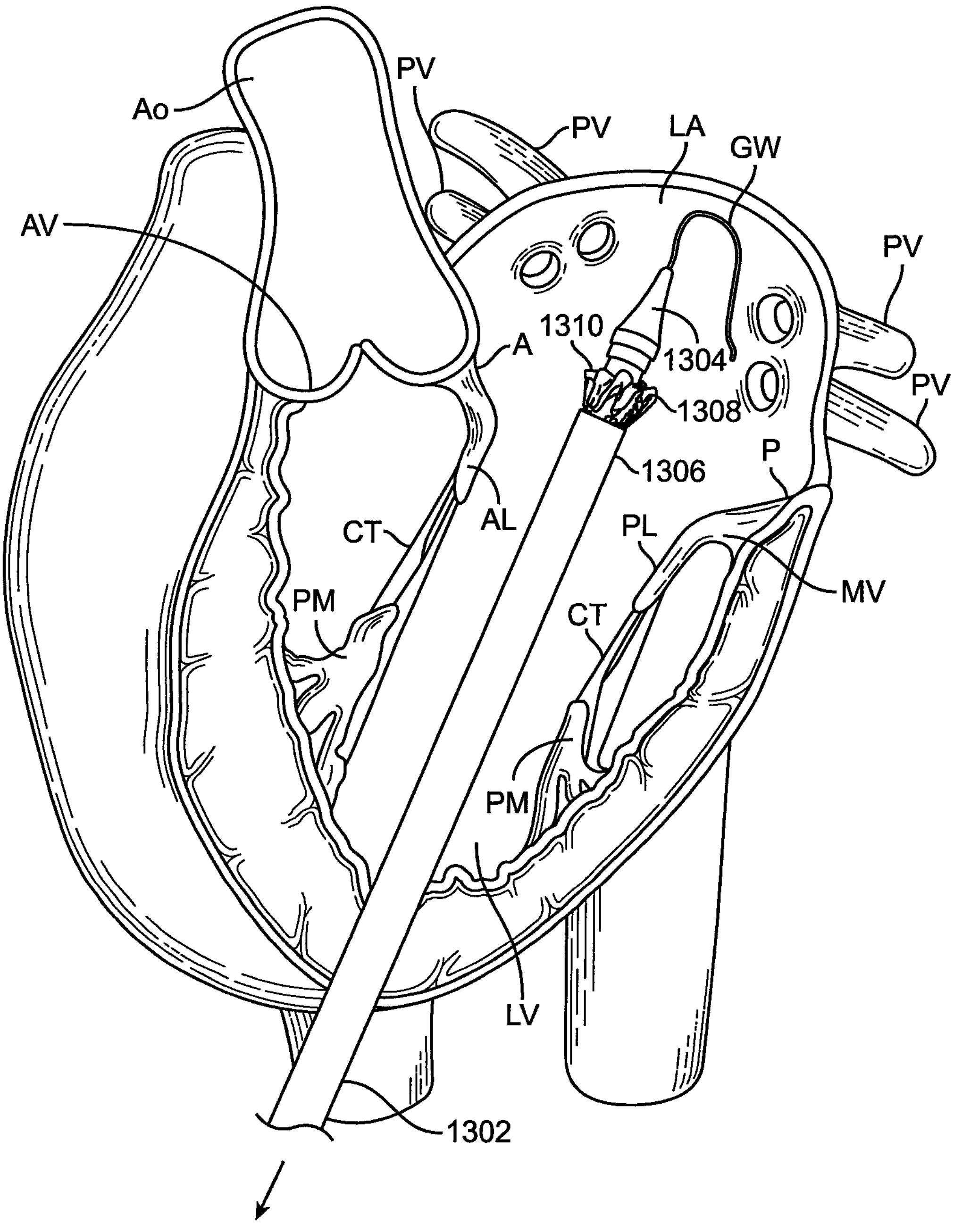

PV
Ao
PV
LA
GW
AV
PV
1310
A
1304
PV
1308
1306
P
AL
PL
CT
MV
PM
CT
PM
LV
1302

FIG. 13B

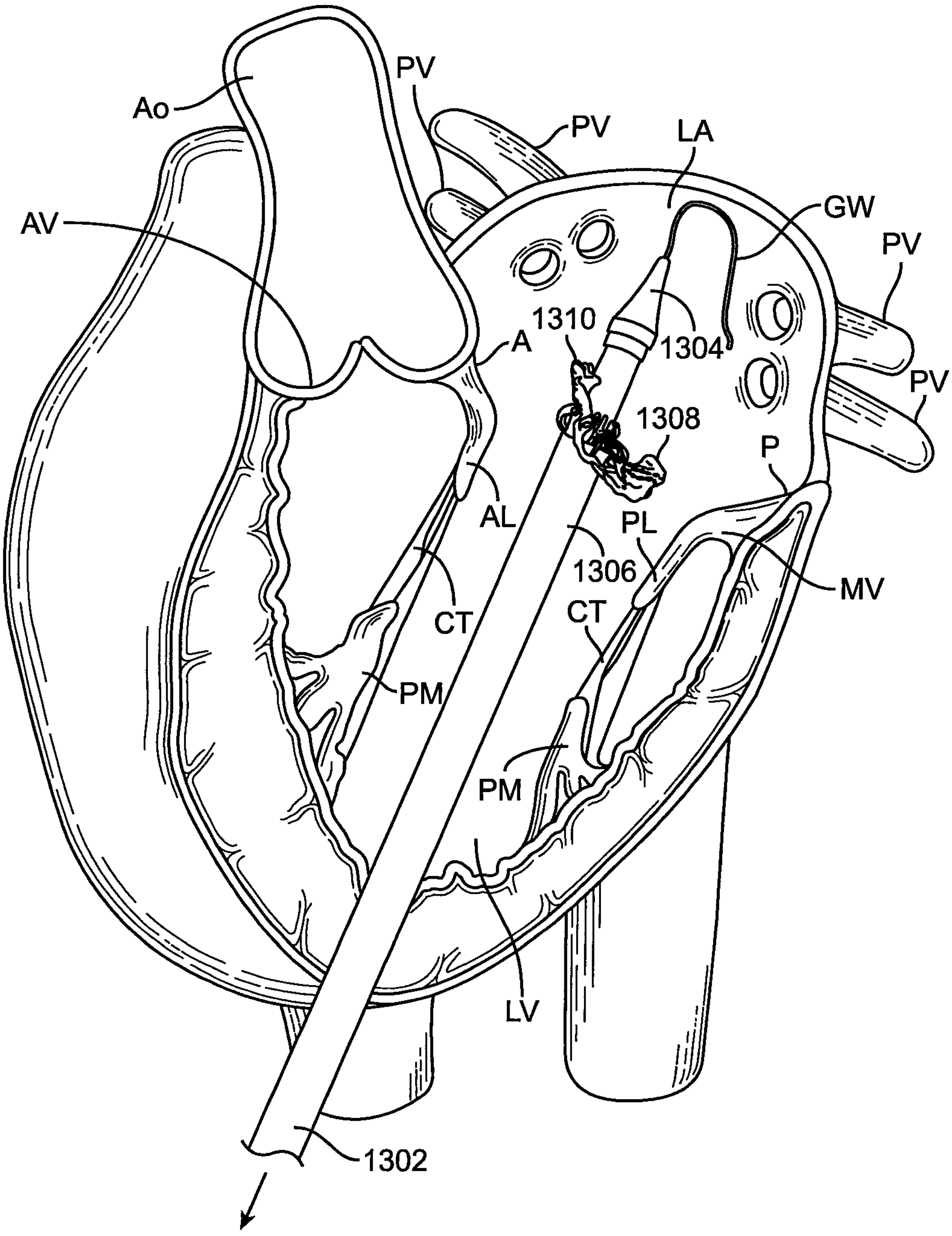

Ao
PV
PV
LA
AV
GW
PV
1310
A
1304
PV
1308
P
AL
PL
1306
MV
CT
CT
PM
PM
LV
1302

FIG. 13C

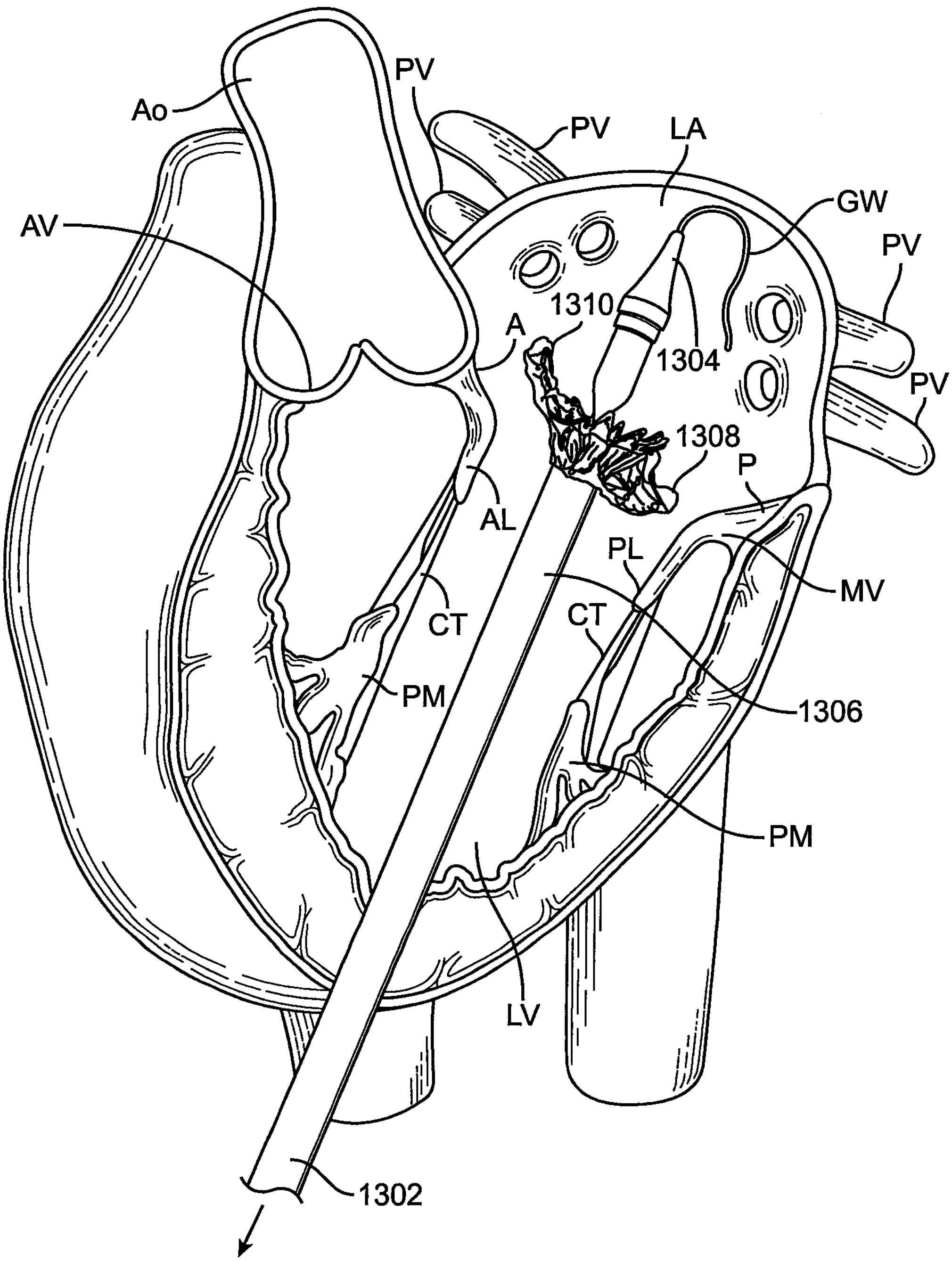

Ao
PV
PV
LA
GW
AV
PV
1310
A
1304
PV
1308
P
AL
PL
MV
CT
CT
1306
PM
PM
LV
1302

FIG. 13D

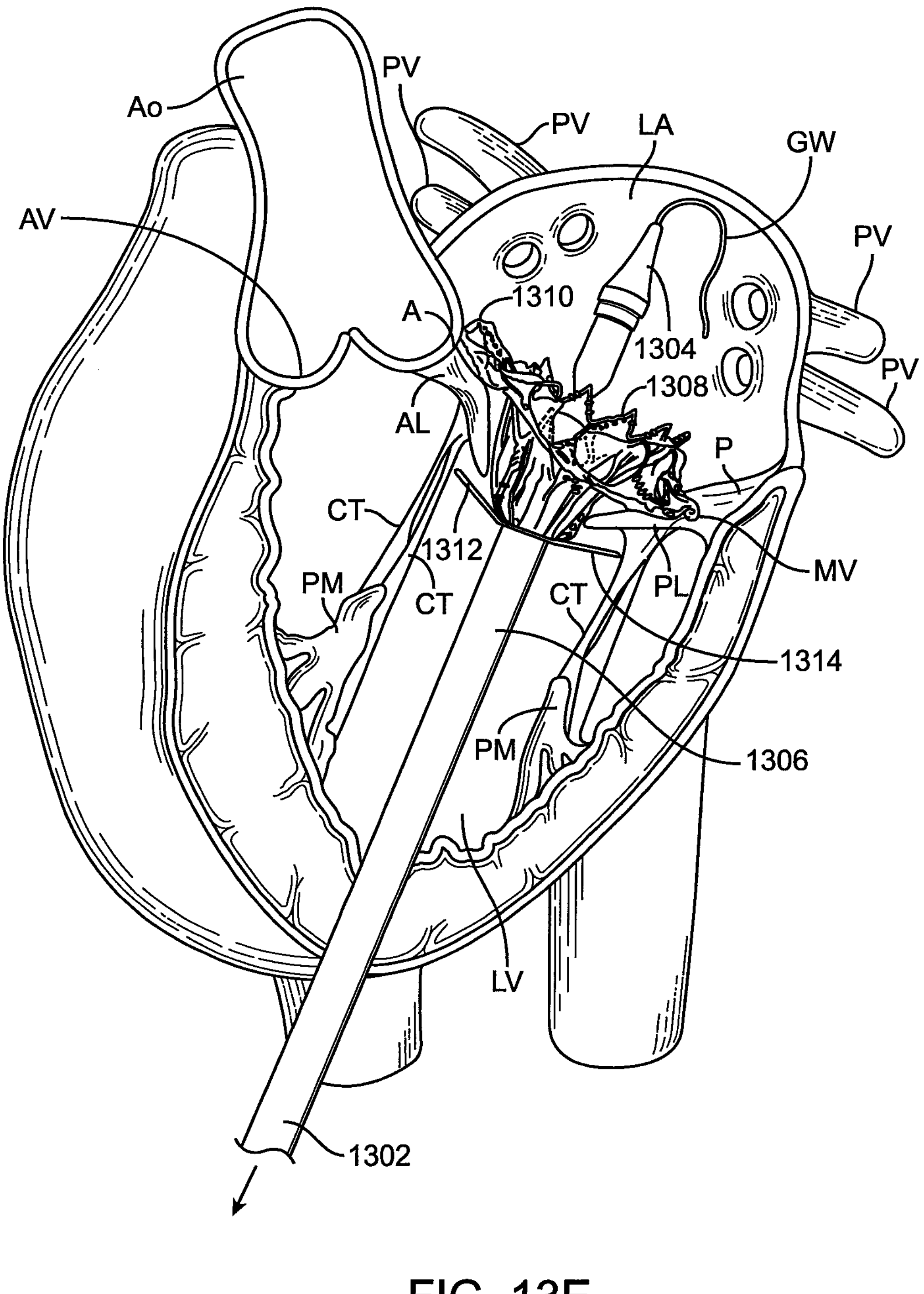

Ao
PV
PV
LA
GW
AV
PV
A
1310
1304
PV
1308
AL
P
CT
1312
MV
PM
CT
CT
PL
1314
PM
1306
LV
1302

FIG. 13E

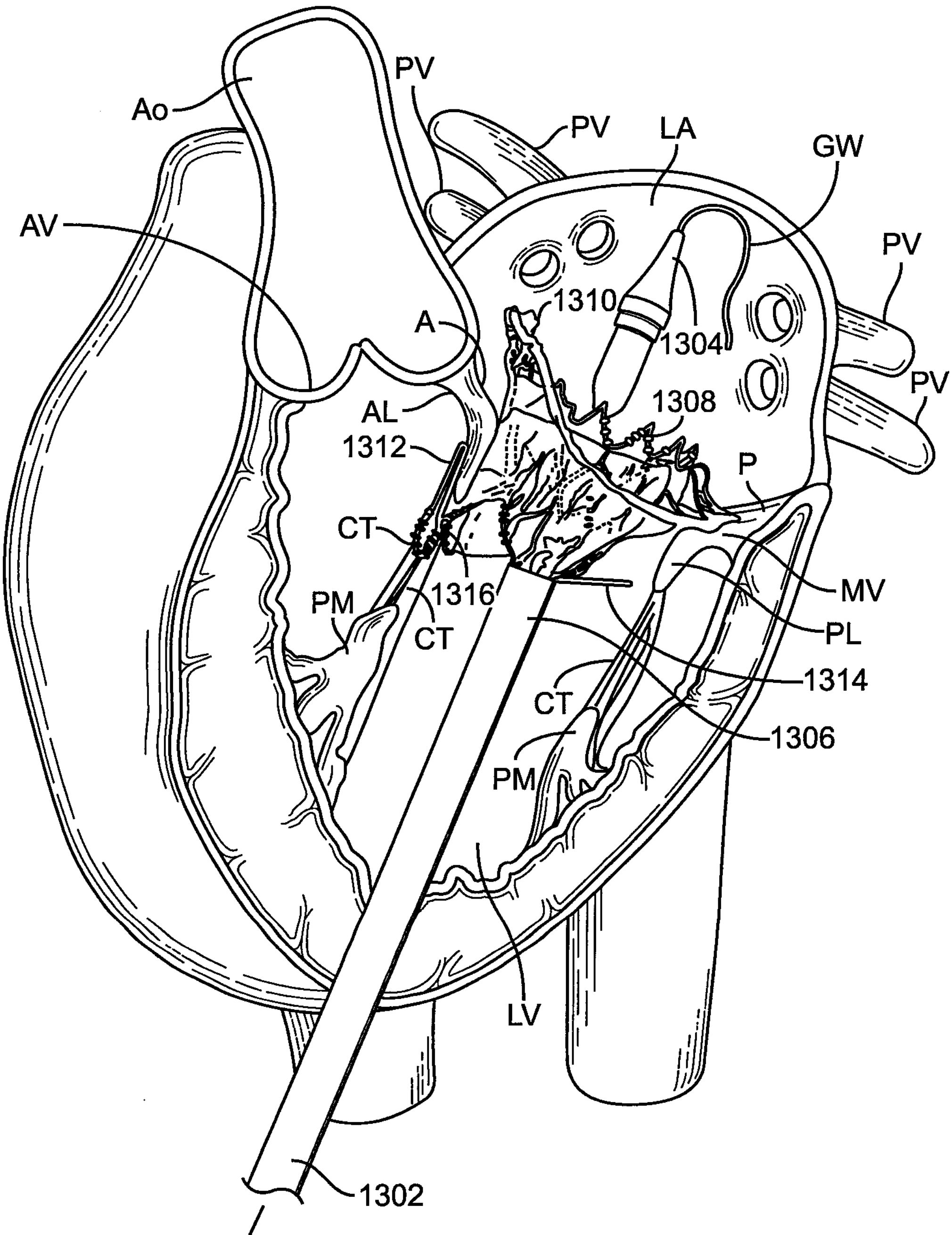

Ao
PV
PV
LA
GW
AV
PV
A
1310
1304
PV
AL
1308
1312
P
CT
MV
1316
PM
PL
CT
1314
CT
1306
PM
LV
1302

FIG. 13F

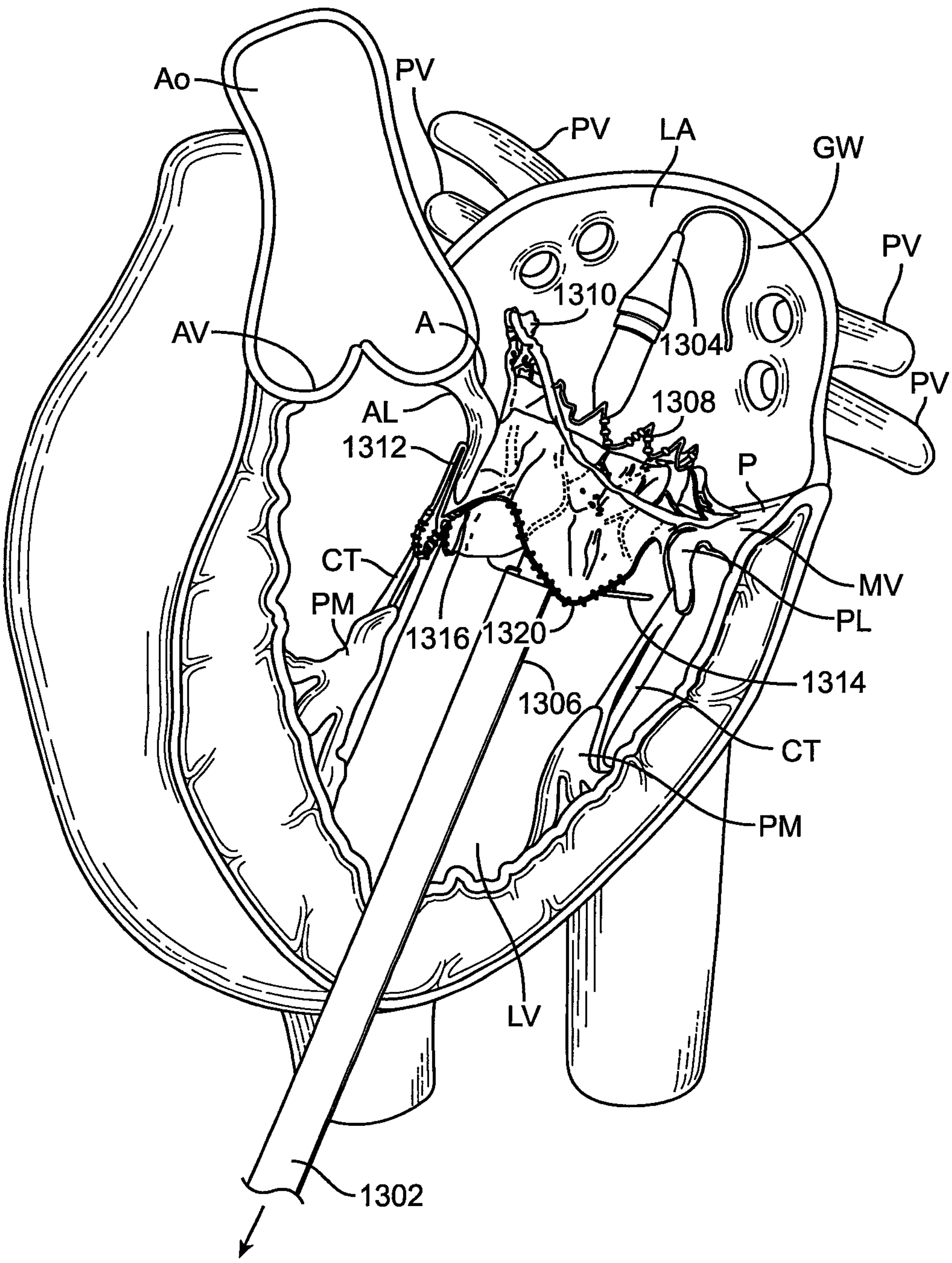

Ao
PV
PV
LA
GW
PV
PV
1310
1304
A
AV
AL
1308
1312
P
CT
MV
PM
1316
1320
PL
1314
1306
CT
PM
LV
1302

FIG. 13G

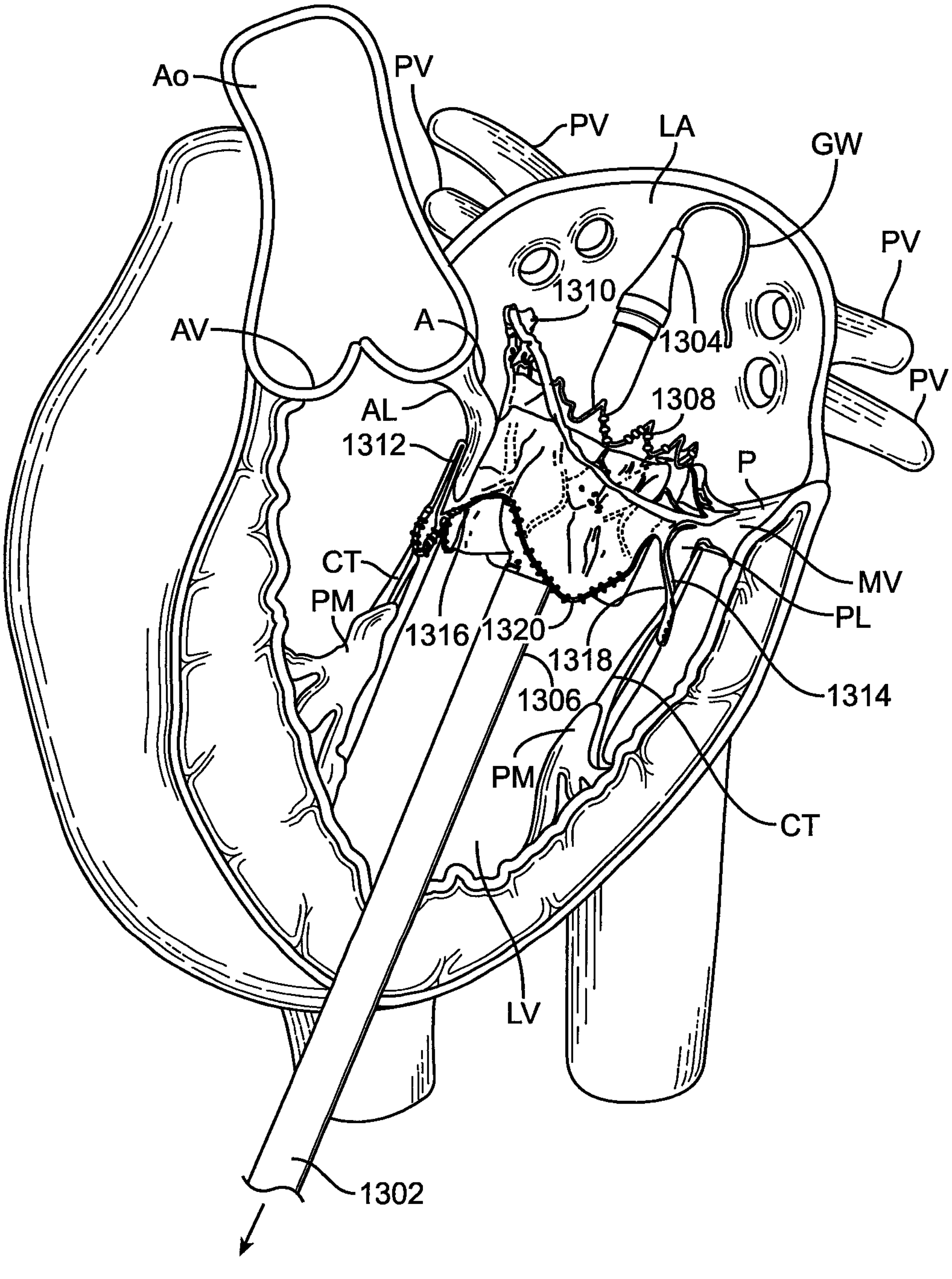

Ao
PV
PV
LA
GW
PV
PV
AV
A
1310
1304
1308
AL
1312
P
CT
MV
PM
1316
1320
PL
1318
1314
1306
PM
CT
LV
1302

FIG. 13H

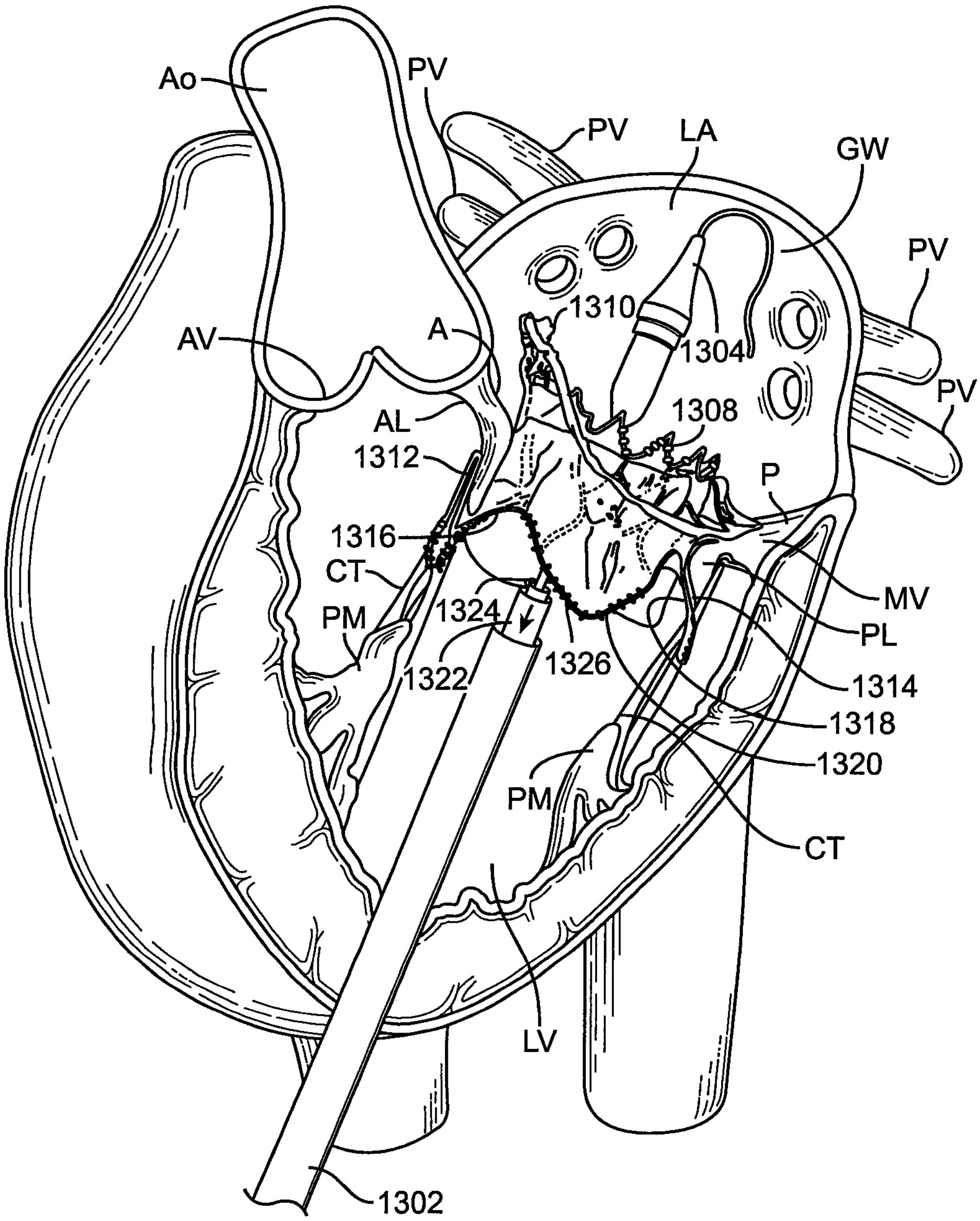

Ao
PV
PV
LA
GW
PV
PV
AV
A
1310
1304
1308
AL
1312
P
1316
CT
MV
PM
1324
PL
1322
1326
1314
1318
1320
PM
CT
LV
1302

FIG. 13I

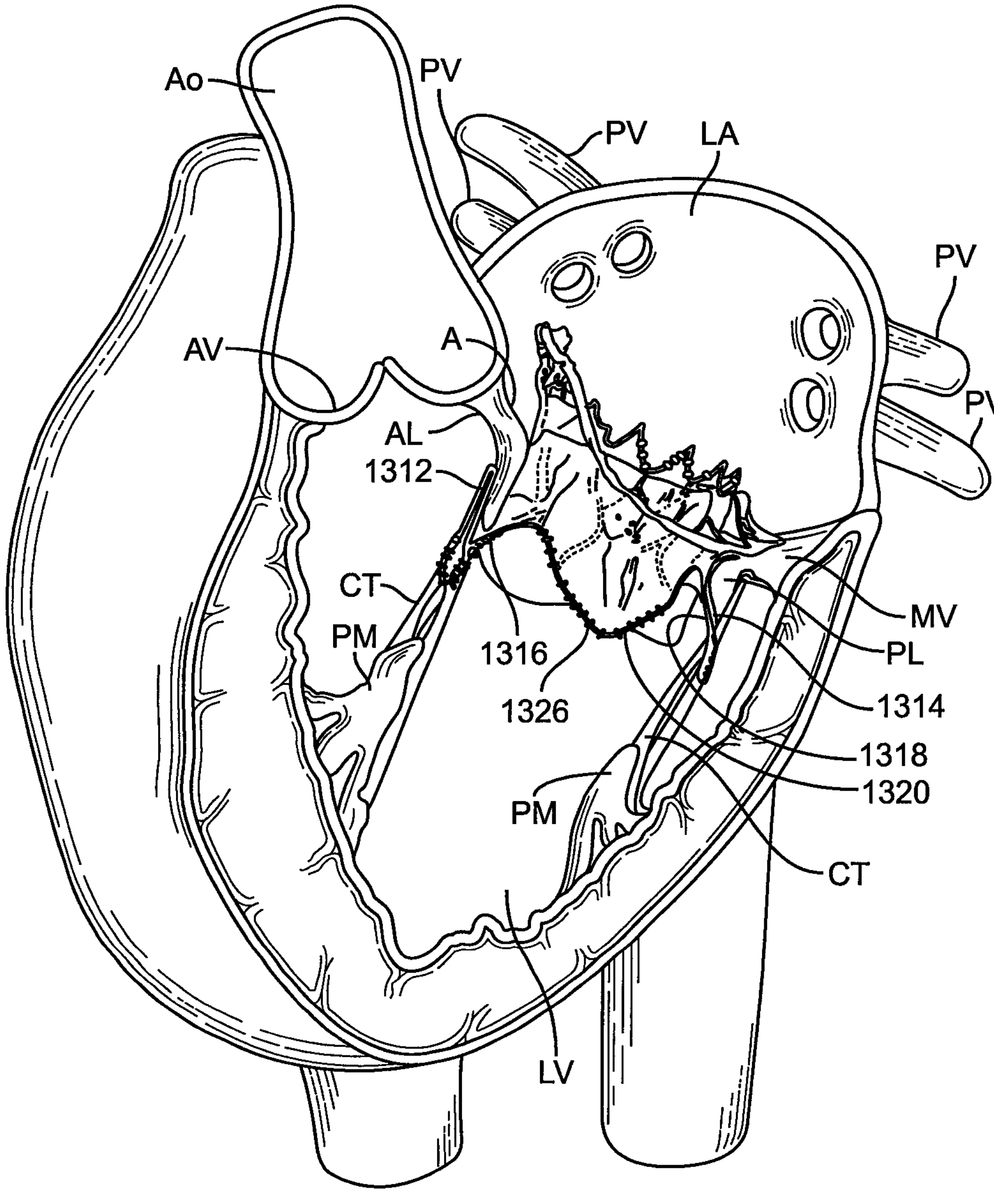

Ao
PV
PV
LA
PV
PV
AV
A
AL
1312
CT
PM
1316
1326
MV
PL
1314
1318
1320
PM
CT
LV

FIG. 13J

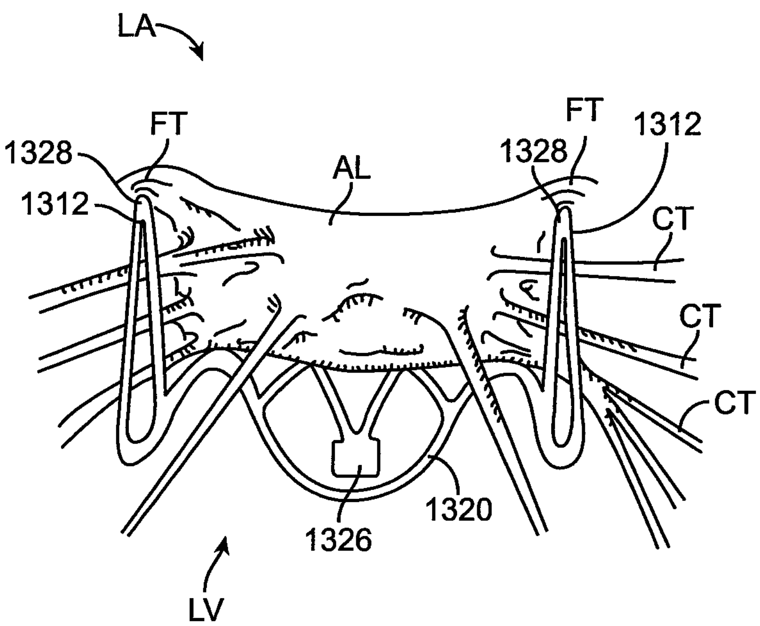


FIG. 13K

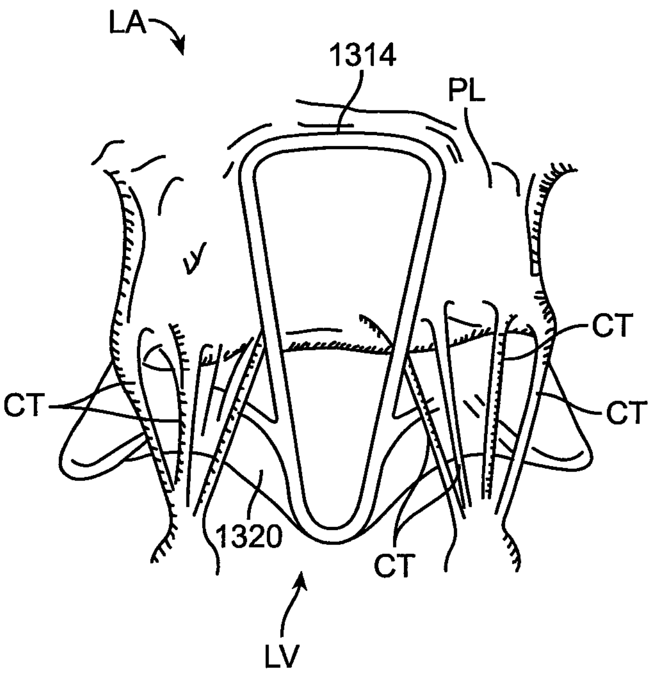


FIG. 13L

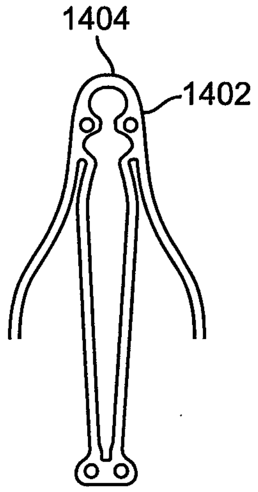


FIG. 14A

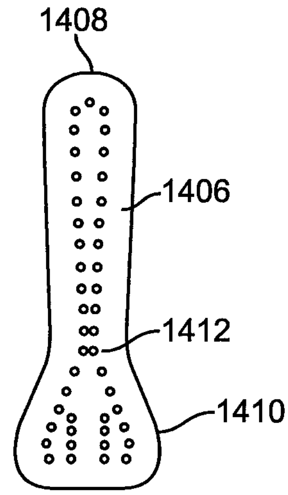


FIG. 14B

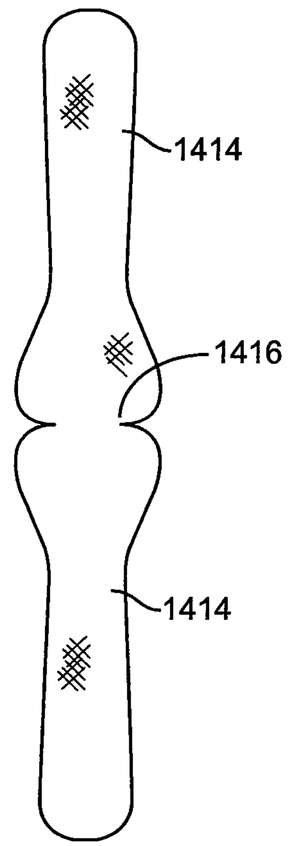


FIG. 14C

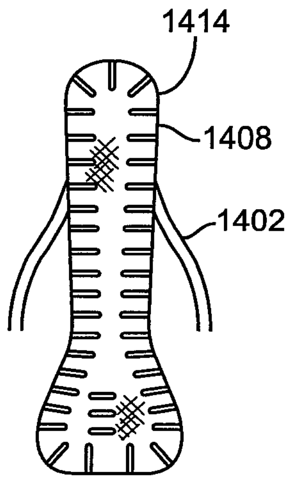


FIG. 14D

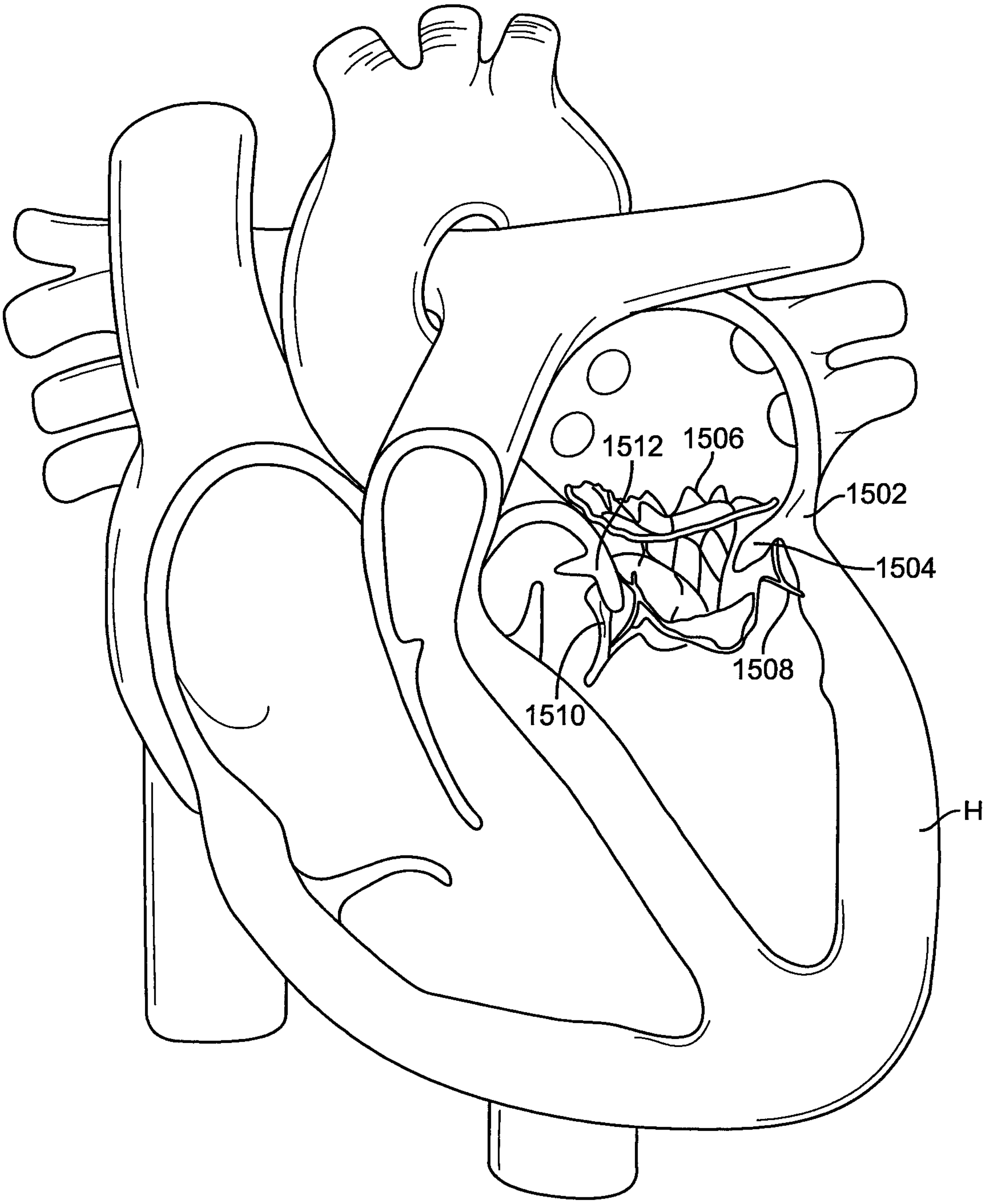


FIG. 15

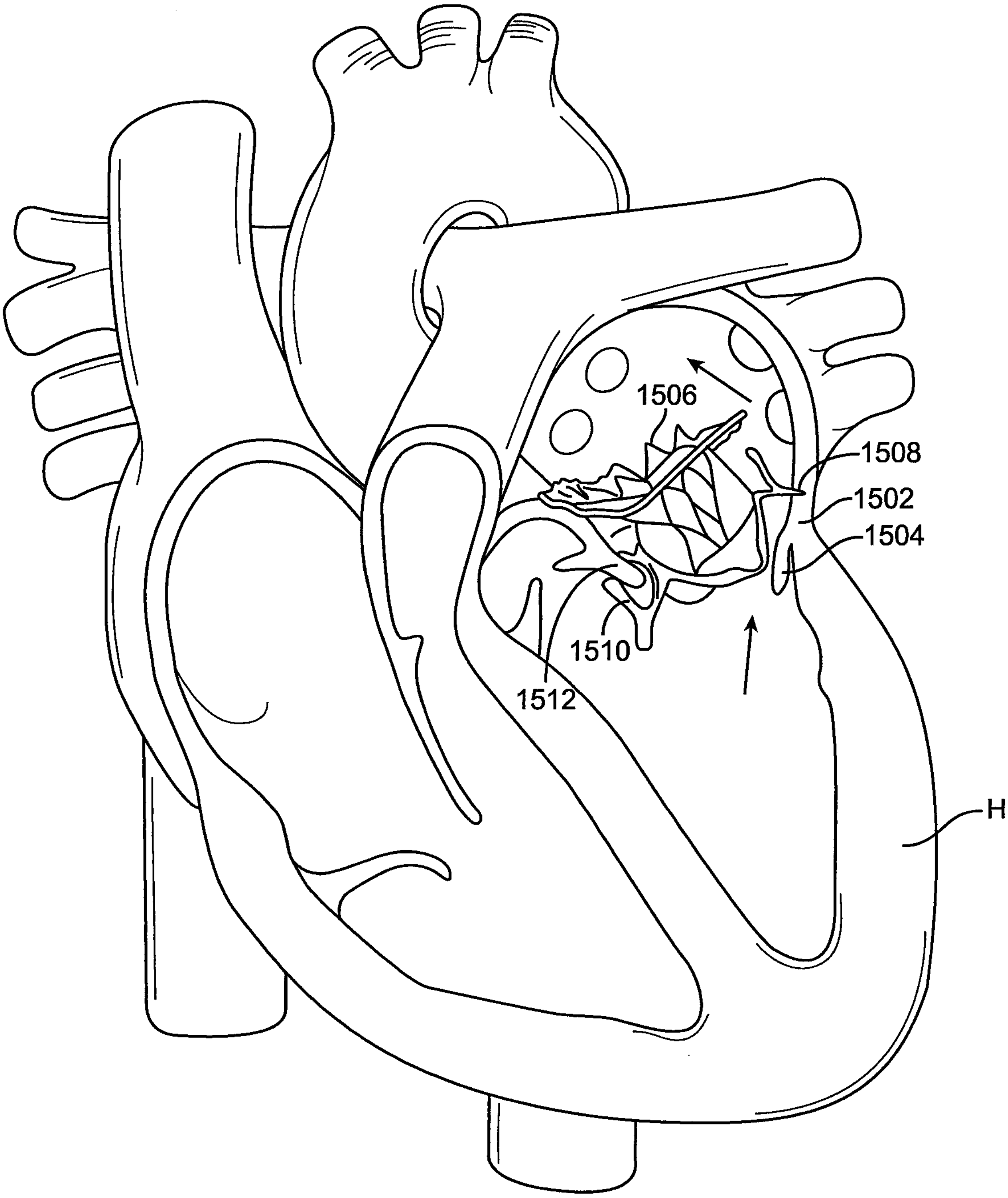


FIG. 16

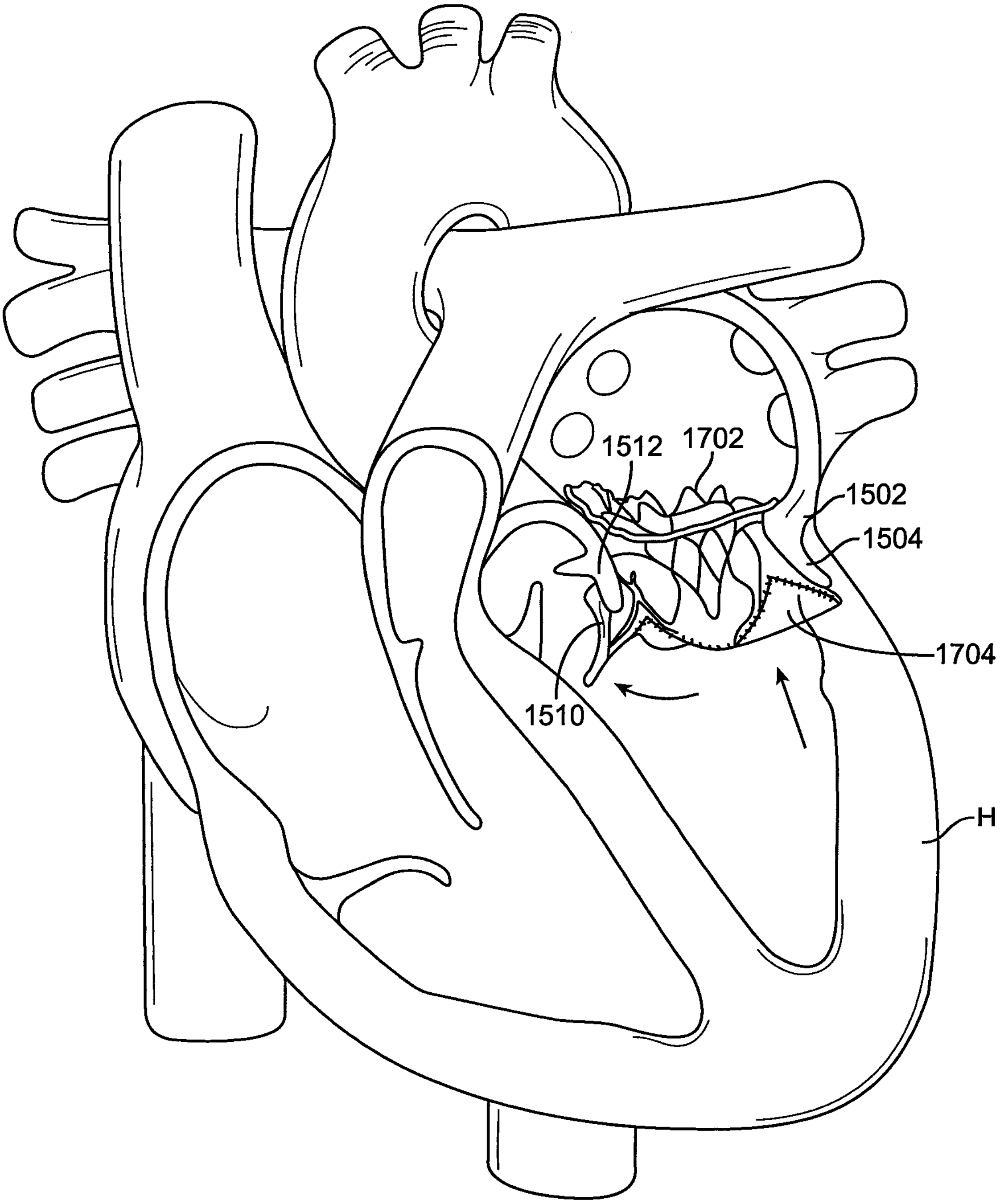


FIG. 17

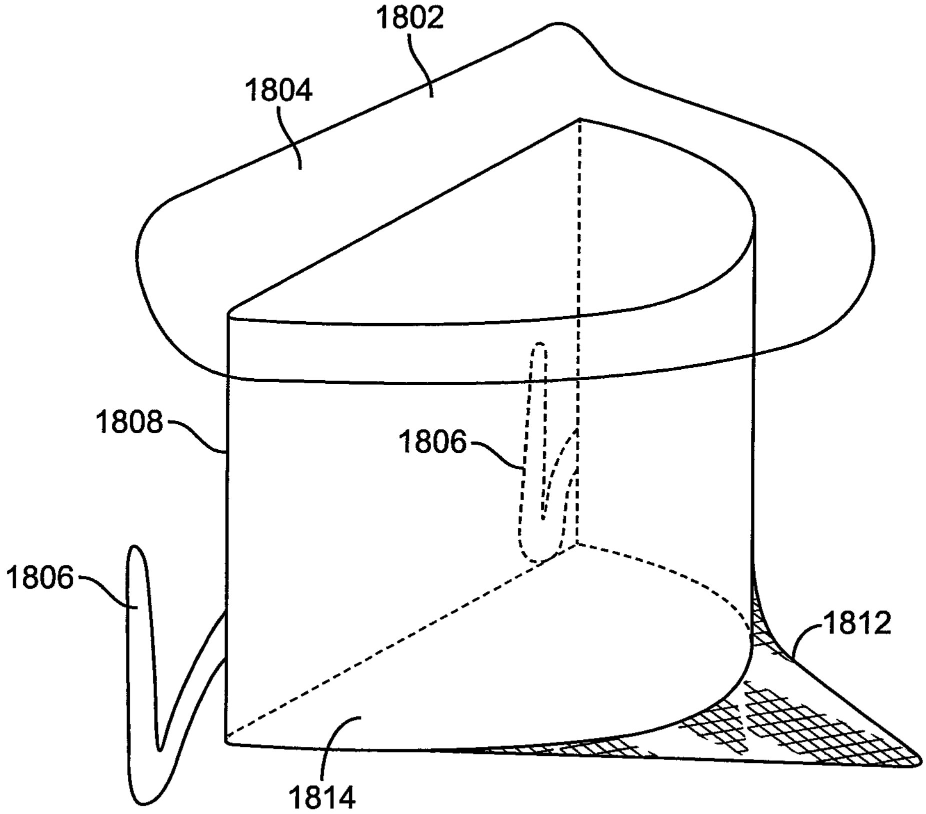


FIG. 18A

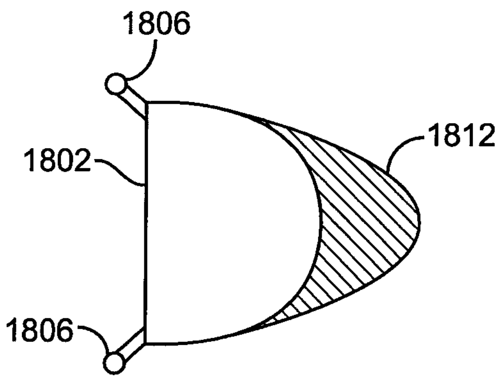


FIG. 18B

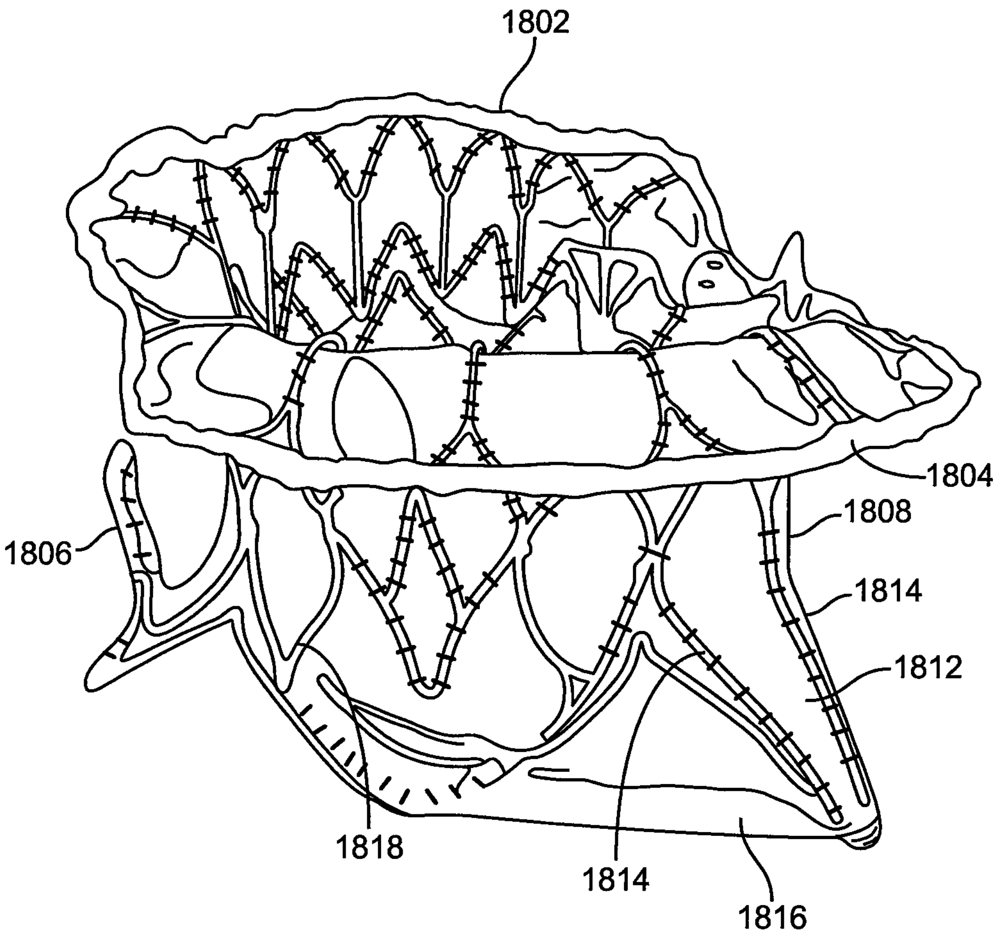


FIG. 18C

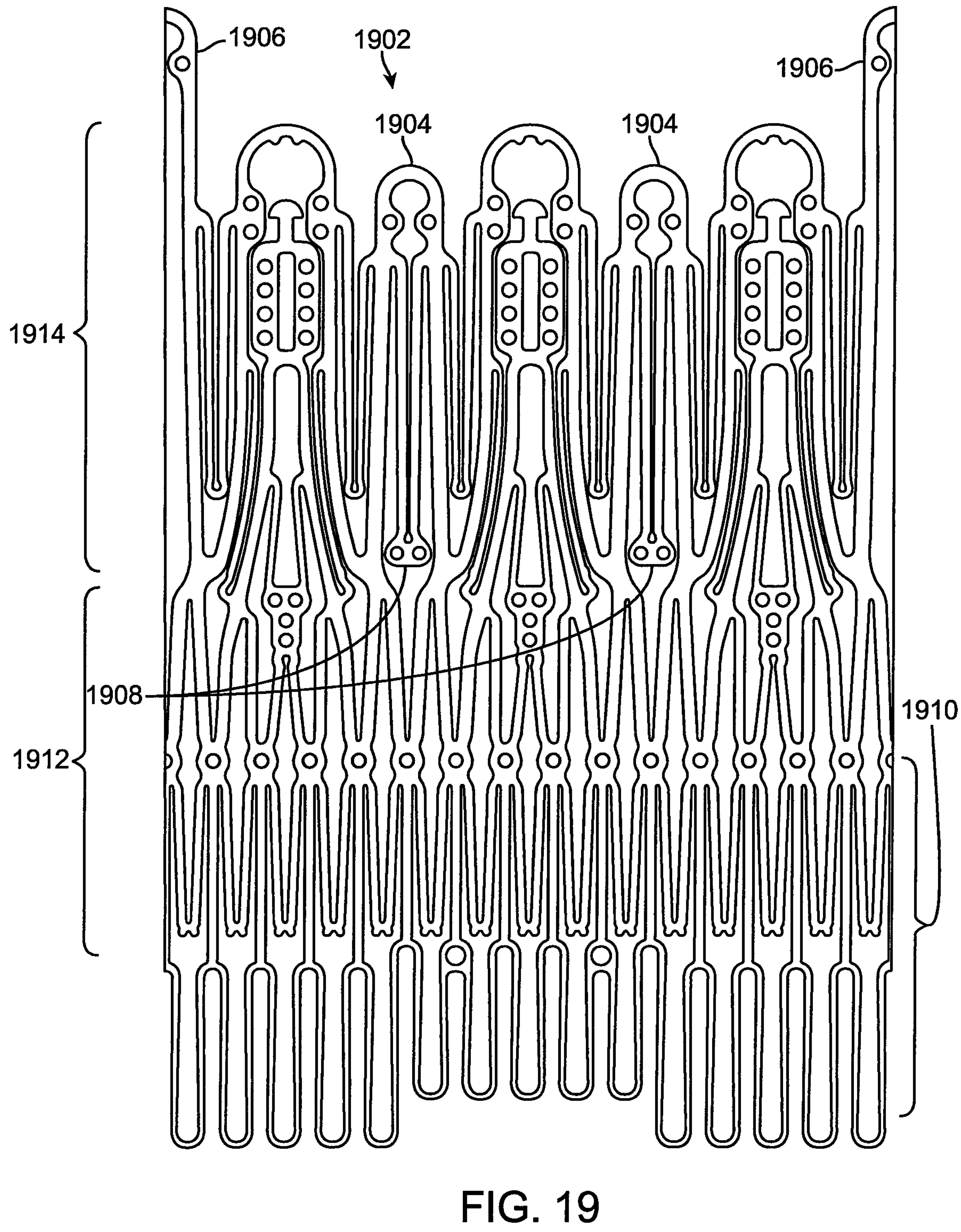


FIG. 19

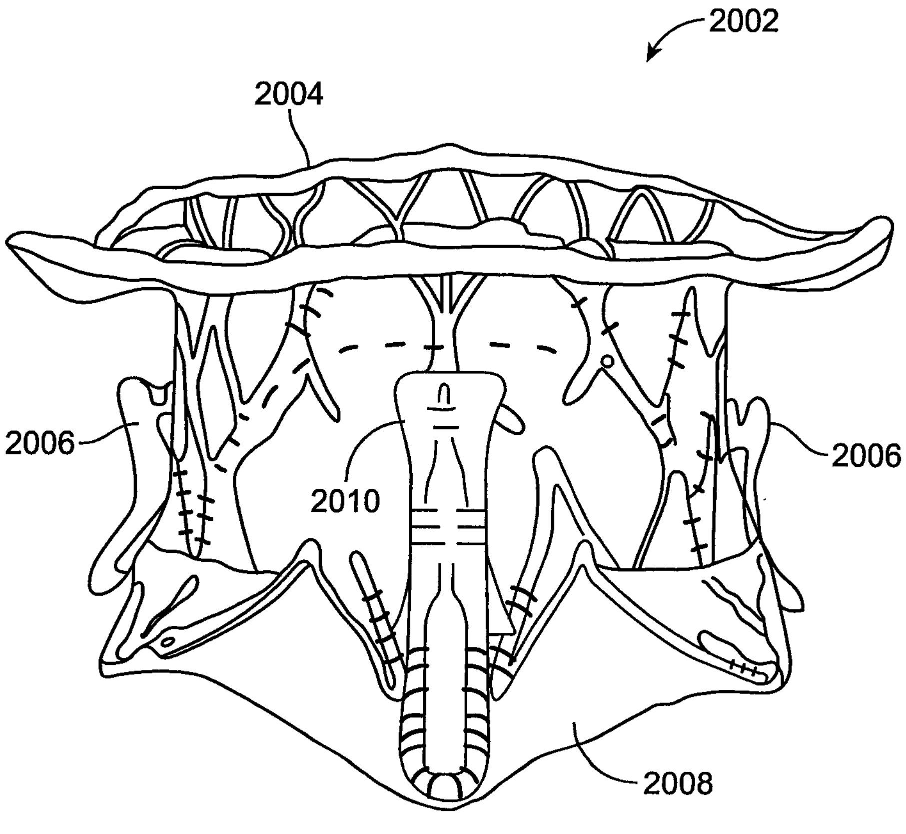


FIG. 20A

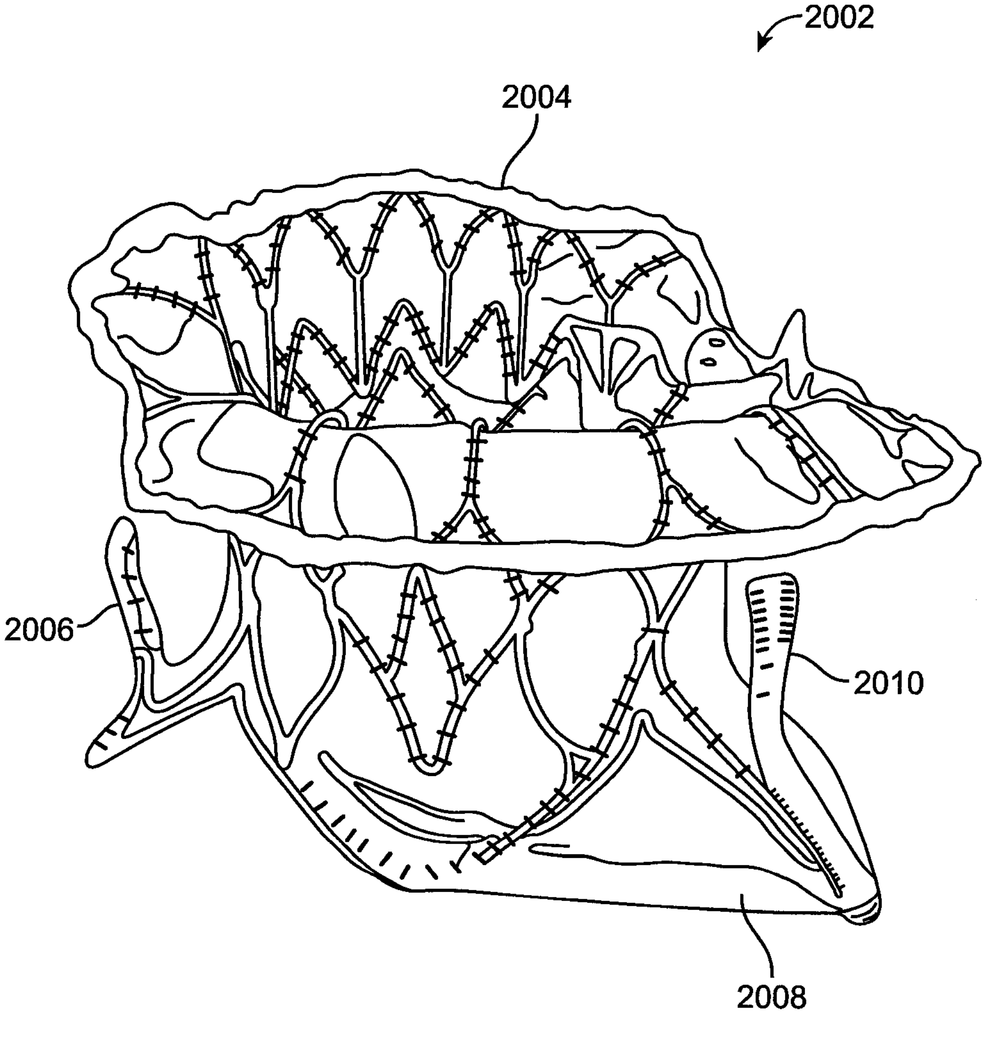


FIG. 18C

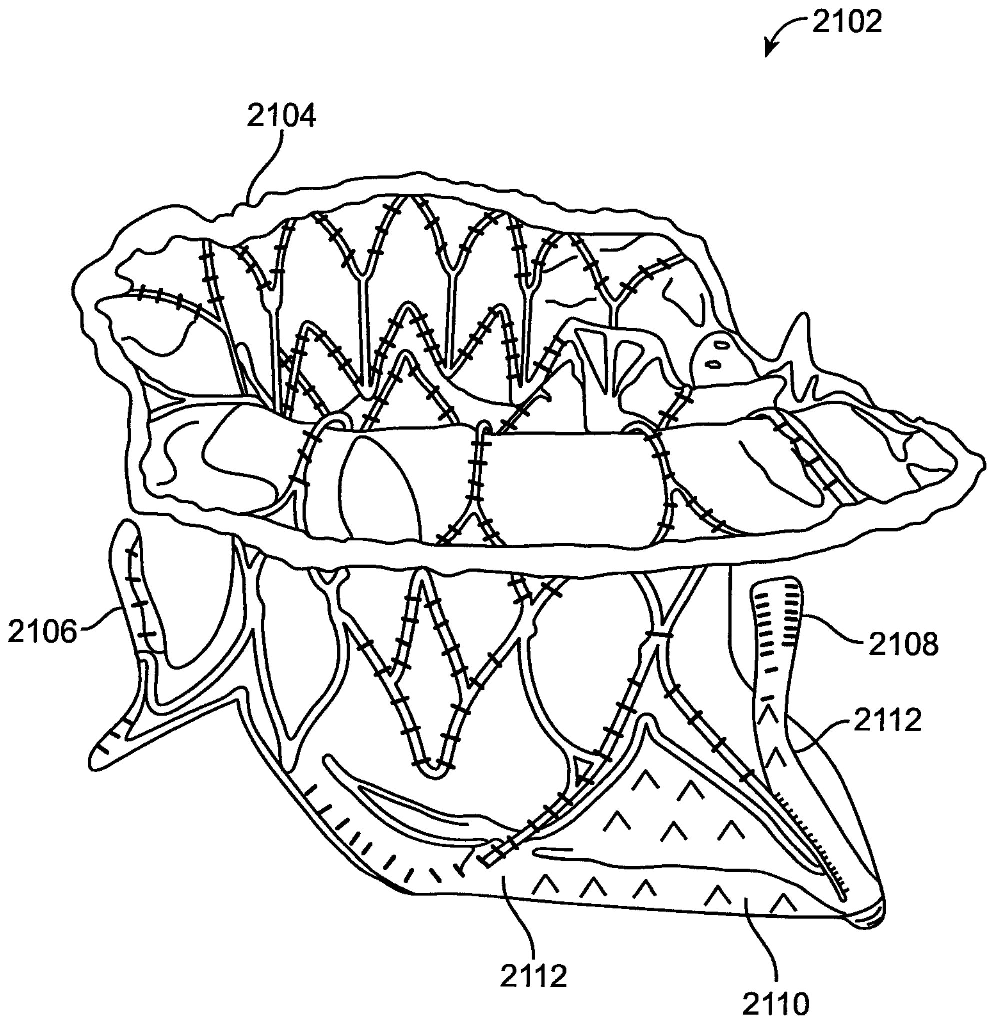
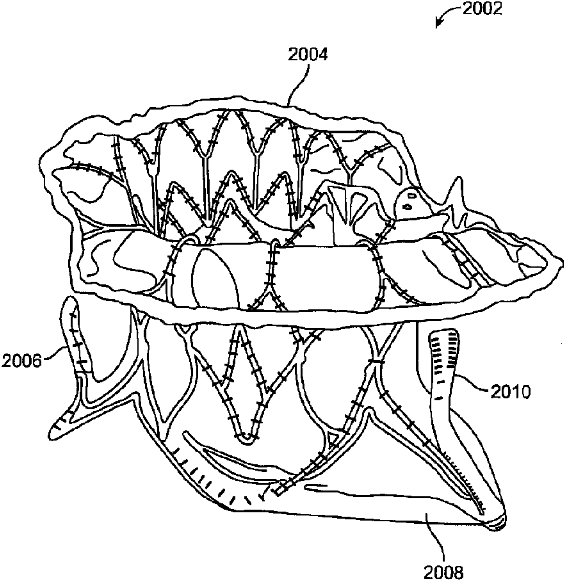


FIG. 21


2002
2004
2006
2010
2008