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(54) **Title**: PROSTHESIS FOR TRANSCATHETER VALVE IMPLANTATION

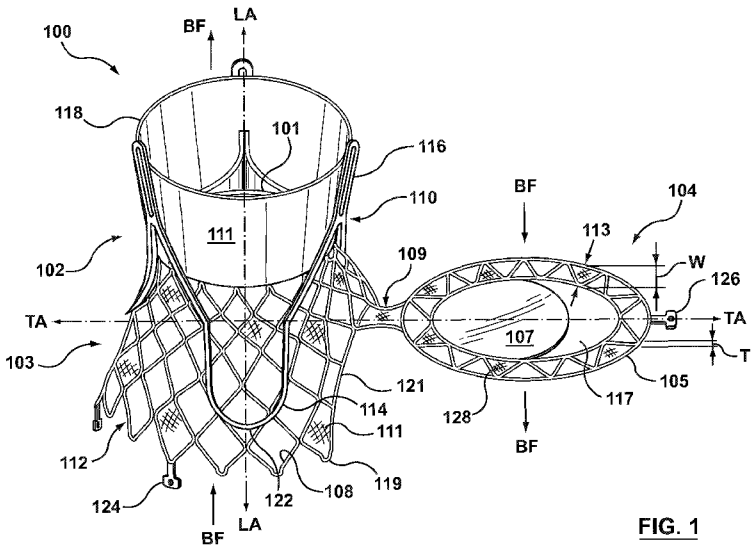


FIG. 1

(57) **Abstract**: A prosthesis (100) having first (102) and second (104) prosthetic sections is disclosed. The first prosthetic section includes a stent structure (103) that may contain a first prosthetic valve (101) secured therein and the second prosthetic section includes an annular frame (105) that may contain a second prosthetic valve (107) secured therein. When the prosthesis is in an expanded configuration, the annular frame extends from the stent structure such that the first and second prosthetic sections are laterally offset from each other. In a method in accordance herewith, the first and second prosthetic sections may include prosthetic aortic and mitral valves, respectively, and the heart valve prosthesis is configured to replace one or both of the native aortic and mitral valves of the heart in a single transcatheter heart valve implantation procedure.

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PROSTHESIS FOR TRANSCATHETER VALVE IMPLANTATION

RELATED APPLICATIONS

[0001] This application is a Continuation in Part of and claims the benefit of United States Patent Application 13/432,497 filed March 28, 2012. The disclosures of which are herein incorporated by reference in their entirety.

FIELD OF THE INVENTION

[0002] The invention relates generally to a prosthetic device for replacing a native valve or a previously implanted prosthetic valve in a non-surgical interventional procedure. In one embodiment, the invention relates to a dual valve prosthesis having a prosthetic aortic valve combined with a prosthetic mitral valve for concurrently replacing the corresponding native valves or previously implanted prosthetic valves in a non-surgical interventional procedure.

BACKGROUND OF THE INVENTION

[0003] A wide range of medical treatments are known that utilize "endoluminal prostheses." As used herein, endoluminal prostheses are intended to mean medical devices that are adapted for temporary or permanent implantation within a body lumen, including both naturally occurring and artificially made lumens. Examples of lumens in which endoluminal prostheses may be implanted include, without limitation: arteries, veins, gastrointestinal tract, biliary tract, urethra, trachea, hepatic and cerebral shunts, and fallopian tubes.

[0004] Stent prostheses are known for implantation within a body lumen for providing artificial radial support to the wall tissue that defines the body lumen. To provide radial support to a blood vessel, such as one that has been widened by a percutaneous transluminal coronary angioplasty, commonly referred to as “angioplasty,” “PTA” or “PTCA”, a stent may be implanted in conjunction with the procedure. Under this procedure, the stent may be collapsed to an insertion diameter and inserted into the vasculature at a site remote from the diseased vessel. The stent may then be delivered to the desired treatment site within the affected vessel and deployed, by self-expansion or radial expansion, to its desired diameter for treatment.

[0005] Recently, flexible prosthetic valves supported by stent structures that can be delivered percutaneously using a catheter-based delivery system have been

developed for heart and venous valve replacement. These prosthetic valves may include either self-expanding or balloon-expandable stent structures with valve leaflets disposed within the interior of the stent structure. The prosthetic valve can be reduced in diameter, by being contained within a sheath component of a delivery catheter or by crimping onto a balloon catheter, and advanced through the venous or arterial vasculature. Once the prosthetic valve is positioned at the treatment site, for instance within an incompetent native or previously implanted prosthetic valve, the stent structure may be expanded to hold the prosthetic valve firmly in place. One embodiment of a prosthetic valve having a stent structure is disclosed in U.S. Pat. No. 5,957,949 to Leonhardt et al. entitled "Percutaneous Placement Valve Stent", which is incorporated by reference herein in its entirety.

[0006] Valvular heart disease is any disease process involving one or more of the valves of the heart, *i.e.*, the aortic and mitral valves on the left and the pulmonary and tricuspid valves on the right. Severe valve damage may be treated with a valve replacement, with aortic valves and severely damaged mitral valves being the most often replaced heart valves. Some patients present with more than one heart valve being damaged so that the patient may need a dual valve replacement requiring more than one heart valve to be repaired or replaced. Whereas the use of minimally invasive techniques may be preferred, such an approach may be difficult in a dual valve replacement as placement of the prosthetic mitral valve prior to or subsequent of placement of the prosthetic aortic valve may be extremely difficult due to the relative locations of the two native valves, the lack of space in the left ventricle, and/or the concern of having to cross the first deployed prosthetic valve with the second delivery system and prosthetic valve under certain circumstances. Moreover, when a prosthetic valve is percutaneously delivered to replace a stenotic or insufficient aortic or mitral valve, a fundamental concern is that the prosthesis be deployed as precisely as possible so as to assure proper functioning, to avoid paravalvular leakage and to minimize any negative impact on the adjacent heart valve, each of which becomes more difficult to achieve with a dual valve replacement performed using multiple prosthetic valves and delivery devices. Further, sufficient prosthetic mitral valve fixation against high systolic pressures is also particularly important as migration or movement of the mitral valve prosthetic device can potentially block the left ventricular outflow tract or inhibit native or replacement aortic valve function. As such patients who must have a dual valve replacement most often undergo open heart surgical

replacement procedures to implant the prosthetic aortic and mitral valves or one of the valves goes untreated. Accordingly a need exists in the art for apparatus and methods that allow a clinician to perform a dual heart valve replacement in a minimally invasive manner.

BRIEF SUMMARY OF THE INVENTION

[0007] One or more embodiments hereof are directed to a dual valve prosthesis having first and second prosthetic valve sections. The first prosthetic valve section includes a stent structure with a first prosthetic valve secured therein and the second prosthetic valve section includes an annular frame with a second prosthetic valve secured therein, wherein the annular frame extends from the stent structure such that the first and second prosthetic valves are laterally offset from each other when the dual valve prosthesis is in an expanded configuration. In one embodiment, the annular frame forms a border that radially extends around the second prosthetic valve to define an apposition surface and has a profile of a flat washer. In a method in accordance herewith, the first and second prosthetic valve sections include prosthetic aortic and mitral valves, respectively, and the dual heart valve prosthesis is configured to replace both the native aortic and mitral valves of the heart in a single transcatheter heart valve implantation procedure. One or more embodiments hereof are directed to a single valve prosthesis having a prosthetic valve section and a section comprising a blood flow lumen or orifice. In some embodiments, the section comprising an orifice or lumen may be configured to receive another medical device, such as an additional prosthetic valve. One or more embodiments hereof are directed to a prosthetic device having two sections comprising a blood flow lumen or orifice. In some embodiments, the two sections may be configured to receive one or more medical devices, such as a prosthetic heart valve. In some embodiments, one or both sections may comprise a support structure or docking station to receive or accept a prosthetic valve.

BRIEF DESCRIPTION OF DRAWINGS

[0008] The foregoing and other features and advantages of the invention will be apparent from the following description of embodiments thereof as illustrated in the accompanying drawings. The accompanying drawings, which are incorporated herein and form a part of the specification, further serve to explain the principles of the

invention and to enable a person skilled in the pertinent art to make and use the invention. The drawings are not to scale.

[0009] FIG. 1 is a perspective view of a dual valve prosthesis in an expanded configuration in accordance with an embodiment hereof.

[0010] FIG. 2 is a sectional view of a distal portion of a delivery catheter with a prosthetic device in a compressed delivery configuration therein.

[0011] FIGS. 3 and 4 illustrate a method of fabricating a stent structure and an annular frame of a prosthetic device in accordance with an embodiment hereof.

[0012] FIGS. 5-7 illustrate a method of delivering a prosthetic device to the native aortic and mitral valves of a beating heart in accordance with an embodiment hereof.

[0013] FIG. 8 is a perspective view of a single valve prosthesis in an expanded configuration in accordance with an embodiment hereof.

[0014] FIG. 9 is a perspective view of a single valve prosthesis in an expanded configuration in accordance with an embodiment hereof.

[0015] FIG. 10 is a perspective view of a support frame prosthesis in an expanded configuration in accordance with an embodiment hereof.

[0016] FIG. 11 is a perspective view of a support frame prosthesis in an expanded configuration in accordance with an embodiment hereof.

[0017]

DETAILED DESCRIPTION OF THE INVENTION

[0018] The following detailed description is merely exemplary in nature and is not intended to limit the invention or the application and uses of the invention. Although the description of embodiments hereof is in the context of concurrent aortic and mitral heart valve replacement, the invention may be adapted to be used for other concurrent valve replacement where it is deemed useful. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

[0019] Specific embodiments of the present invention are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements. The terms “distal” and “proximal” are used in the following description with respect to a position or direction relative to the treating clinician. “Distal” or “distally” are a position distant from or in a direction away from the clinician. “Proximal” and “proximally” are a position near or in a direction toward the

clinician. Further the term "self-expanding" is used in the following description with reference to the stent structure and annular frame of the prosthetic devices and is intended to convey that the stent structure and annular frame are shaped or formed from a material that has a mechanical memory to return to an expanded deployed configuration from a compressed or constricted delivery configuration. Non-exhaustive exemplary materials that may be rendered self-expanding include stainless steel, a pseudo-elastic metal such as a nickel titanium alloy or nitinol, various polymers, and a so-called super alloy, which may have a base metal of nickel, cobalt, chromium, or other metal. Mechanical memory may be imparted to a wire or tubular structure used to form the stent structure and/or annular frame by thermal treatment to achieve a spring temper in stainless steel, for example, or to set a shape memory in a susceptible metal alloy, such as nitinol. Various polymers that can be made to have shape memory characteristics may also be suitable for use in embodiments hereof to include polymers such as polynorbornene, trans-polyisoprene, styrene-butadiene, and polyurethane. As well poly L-D lactic copolymer, oligo caprylactone copolymer and poly cyclo-octene can be used separately or in conjunction with other shape memory polymers.

[0020] One or more embodiments hereof are related to a prosthesis configured for deployment within the mitral and aortic valves of the heart in a single transcatheter heart valve implantation procedure. FIG. 1 is a perspective view of a prosthesis 100 in an expanded, deployed configuration in accordance with an embodiment hereof, with FIG. 2 being a sectional view of a distal portion of a delivery catheter 240 with the prosthesis 100 in a compressed, delivery configuration therein. In one embodiment, prosthesis 100 includes a first tubular section 102 and a second annular section 104. In alternative embodiments, prosthesis 100 may include two tubular sections. In alternative embodiments, prosthesis 100 may include two annular sections. In an embodiment hereof, first tubular section 102 may include a first prosthetic valve 101 for replacing a valve, for example a native aortic valve, and second annular section 104 may include a second prosthetic valve 107 for replacing a valve, for example a native mitral valve.

[0021] First tubular prosthetic valve section 102 includes a self-expanding stent structure 103 for anchoring prosthesis 100 within a beating heart. Stent structure 103 of first prosthetic valve section 102 includes a downstream or aortic portion 110 and an upstream or ventricular portion 112, wherein "upstream" and "downstream" are

relative to a direction of blood flow when dual valve prosthesis 100 is properly implanted in vivo. Each of downstream and upstream portions 110, 112 of stent structure 103 is a collapsible, compressible structure made of a material having resiliency or shape memory characteristics in order to return first prosthetic valve section 102 to the deployed configuration shown in FIG. 1 upon release from a delivery device, such as delivery catheter 240. In an embodiment, downstream and upstream portions 110, 112 of stent structure 103 may be initially formed separately and then joined together by any means known to one of ordinary skill in the art such as, for instance, welding, gluing or suturing.

[0022] Stent structure upstream portion 112 is a patterned tubular device that defines substantially diamond shaped openings 108, although openings 108 may have any one of a variety of other shapes without departing from the scope hereof. Crimping eyelets 124 extend from upstream portion 112 at an upstream or inflow end 119 of first prosthetic valve section 102. Crimping eyelets 124 may be of varying lengths or shapes or may be independently engaged by catheter 240 to permit release of the eyelets in a controlled or sequential manner. Upstream portion 112 has a curved upstream edge defining an arched opening 121 when dual valve prosthesis 100 is in the expanded configuration that allows for the lateral positioning of second prosthetic valve section 104 relative to first prosthetic valve section 102. More particularly, a hinge segment 109 between upstream portion 112 of stent structure 103 and an annular frame 105 of second prosthetic valve section 104 extends from an area of an apex of arched opening 121 to laterally extend annular frame 105 therefrom when dual valve prosthesis 100 is in the expanded configuration as discussed in more detail below.

[0023] Stent structure downstream portion 110 includes three engagement arms 114 that are generally u-shaped and three prosthetic valve supports 116 to which leaflets of first prosthetic valve 101 are attached. Each engagement arm 114 extends upstream between respective prosthetic valve supports 116 to be positioned between upstream end 119 of first prosthetic valve section 102 and a downstream or outflow end 118 of first prosthetic valve section 102. Upstream ends 122 of engagement arms 114 may be described as being radially spaced or flared from the remainder of stent structure 103 and engagement arms 114 may be described as having a curved profile in the deployed/implanted configuration. When compressed for delivery within a sheath component of delivery catheter 240 as shown in FIG. 2, engagement arms 114

will somewhat straighten against upstream portion 112 of stent structure 103. When stent structure 103 is released from the sheath component, engagement arms 114 will return to their curved configuration with stent structure upstream portion 112 returning to its expanded configuration shown in FIG. 1. In an embodiment when first prosthetic valve section 102 is deployed to replace a native aortic valve, engagement arms 114 of downstream portion 110 engage the aortic sinuses and upstream portion 112 of stent structure 103 is deployed to seat within the annulus of the native aortic valve and to extend partially into the left ventricle, as discussed in more detail below.

[0024] In addition to stent structure 103, first prosthetic valve section 102 includes prosthetic valve 101 having three valve leaflets to form a tricuspid replacement valve. The valve leaflets of prosthetic valve 101 are sutured or otherwise securely and sealingly attached to the interior surface of stent structure 103 and/or graft material 111 that encloses or lines stent structure 103 as would be known to one of ordinary skill in the art of prosthetic valve construction. Prosthetic valve 101 is a one-way valve configured to collapse inwardly, *i.e.*, towards a longitudinal axis LA of first prosthetic valve section 102, during diastole in order to inhibit retrograde blood flow and to open outwardly during systole to allow blood flow through first prosthetic valve section 102. In some embodiments hereof, prosthetic valve 101 may be a bioprosthetic trileaflet heart valve, such as any one of the bioprosthetic trileaflet heart valves being used in implantable heart valve devices currently available that has been adapted for use herein.

[0025] Second prosthetic valve section 104 of dual valve prosthesis 100 includes self-expanding annular frame 105 that extends from stent structure 103. Annular frame 105 forms a circumferential border 113 of a width W that radially extends around the second prosthetic valve 107 to define an apposition surface thereabout. In an embodiment, width W may be in the range of 2.5 mm to 7.5 mm. Circumferential border 113 has triangular openings defined by the framework thereof, the triangular openings being shown by way of illustration and not limitation. One or both sides of circumferential border 113 may be covered with a graft material 128, such as any of the materials noted below for graft material 111, to aid in providing a seal against the native anatomy when second prosthetic valve section 104 is deployed within the heart. A crimping eyelet 126 extends from circumferential border 113 of annular frame 105. Annular frame 105 has a shape or a profile of a flat washer with a minimal thickness T that provides second prosthetic valve section 104 with a low ventricular profile that

does not interfere with the left ventricular outflow tract. In an embodiment, thickness T may be in the range of .025 mm to 0.75 mm. Annular frame 105 so described aids in maintaining apposition of second prosthetic valve section 104 against the native anatomy to provide a seal there against. In one embodiment, second prosthetic valve 107 includes two valve leaflets to form a bicuspid replacement valve. The valve leaflets are sutured or otherwise securely and sealingly attached to an inner circumference of annular frame 105 to span a central opening 117 thereof.

[0026] When dual valve prosthesis 100 is in an expanded, deployed configuration, annular frame 105 laterally extends from upstream portion 112 of stent structure 103 such that first and second prosthetic valves 101, 107 are laterally offset from each other. In an embodiment, annular frame 105 is formed with upstream portion 112 of stent structure 103 as a single unit with an integral hinge segment 109 formed to extend therebetween. In such an embodiment, stent structure upstream portion 112 and annular frame 105 with integral hinge segment 109 may be formed by etching or otherwise cutting the patterns thereof from a tube, such as a tube 330 of nitinol, as shown in FIG. 3 and then performing a thermal treatment to shape set the structures in the expanded configuration shown in FIG. 4. When formed in this manner, hinge segment 109 is configured to return annular frame 105 to the shape set expanded configuration of FIG. 4 when prosthesis 100 is released from a compressed delivery configuration. In an embodiment, hinge segment 109 and annular frame 105 will rotate outwardly and upwardly relative to longitudinal axis LA of stent structure 103 when deployed from delivery catheter 240 within the heart to exert an apposition force AF against any heart structure in which annular frame 105 comes in contact. More particularly, when dual valve prosthesis 100 is deployed within the heart such that second prosthetic valve 107 secured within annular frame 105 is utilized as a replacement mitral valve, the apposition surface provided by circumferential border 113 of annular frame 105 exerts an apposition force against a surface of the left ventricle that surrounds the native mitral valve and is intended to seal against perivalvular leakage.

[0027] In another embodiment, annular frame 105 may be formed separately from upstream portion 112 of stent structure 103 with hinge segment 109 formed to integrally extend from annular frame 105 and then subsequently joined to upstream portion 112 or vice versa.

[0028] Depending on the anatomy of the heart in which dual valve prosthesis 100 is to be implanted and particularly in view of the anatomical position of the native aortic valve relative to the native mitral valve, in embodiments hereof second prosthetic valve section 104 in an expanded configuration may extend along an axis TA that is transverse to longitudinal axis LA of first prosthetic valve section 102, as shown in FIG. 1, may extend at an obtuse angle to longitudinal axis LA of first prosthetic valve section 102, as shown in FIG. 4, or may extend at an acute angle to longitudinal axis LA of first prosthetic valve section 102, as shown in FIG. 7. Accordingly in the expanded configuration annular frame 105 may laterally extend from stent structure 103 at an angle in the range of 45 to 135 degrees with respect to longitudinal axis LA of first prosthetic valve section 102, which is by way of example and not limitation as the actual angle may vary due to anatomical differences in the relative positions of the native valves. In each of the aforementioned expanded configurations when deployed within the heart, hinge segment 109 and annular frame 105 are configured or formed to rotate outwardly and upwardly relative to longitudinal axis LA of stent structure 103 to exert an apposition force AF against at least the heart structure that surrounds the native heart valve being replaced by second prosthetic valve 107.

[0029] Prosthetic valves 101, 107 secured within the interior of stent structure 103 and annular frame 105, respectively, are configured as one-way valves to allow blood flow in one direction and thereby regulate blood flow there through. In the embodiment shown and described with reference to FIG. 1, first prosthetic valve 101 includes three valve leaflets to form a tricuspid replacement valve and second prosthetic valve 107 includes two valve leaflets to form a bicuspid replacement valve or other leaflet structure that closes with pressure on the outflow and opens with pressure on the inflow. In other embodiments in accordance herewith, one or both of first and second prosthetic valves 101, 107 may be tricuspid or bicuspid replacement valves. In still other embodiments in accordance herewith, one or both of first and second prosthetic valves 101, 107 may be a single leaflet replacement valve or a replacement valve with more than three leaflets. Natural tissue for forming prosthetic valve leaflets for use in prosthetic valve sections in accordance with embodiments hereof may be obtained from, for example, heart valves, aortic roots, aortic walls, aortic leaflets, pericardial tissue, such as pericardial patches, bypass grafts, blood vessels, intestinal submucosal tissue, umbilical tissue and the like from humans or animals, such as tissue from bovine, equine or porcine origins. Synthetic materials

suitable for use as prosthetic valve leaflets in embodiments hereof include DACRON® polyester commercially available from Invista North America S.A.R.L. of Wilmington, DE, polyurethane, Gore-Tex or other cloth materials, nylon blends, polymeric materials, and vacuum deposition nitinol fabricated materials. One polymeric material from which the replacement valve leaflets can be made is an ultra-high molecular weight polyethylene material commercially available under the trade designation DYNEEMA from Royal DSM of the Netherlands. With certain prosthetic leaflet materials, it may be desirable to coat one or both sides of the replacement valve leaflet with a material that will prevent or minimize overgrowth. It is further desirable that the prosthetic leaflet material is durable and not subject to stretching, deforming, or fatigue.

[0030] The valve leaflets of prosthetic valves 101, 107 are sutured or otherwise securely and sealingly attached to an interior surface of stent structure 103 and an inner circumference of annular frame 105 that defines central opening 117, respectively, and/or prosthetic valve 101 may be sutured or otherwise attached to graft material 111 that encloses or lines stent structures 103 as would be known to one of ordinary skill in the art of prosthetic valve construction. Graft material 111 may be a low-porosity woven fabric, such as polyester, Dacron fabric, or PTFE, which creates a one-way fluid passage when attached to the stent structure 103. In an embodiment, graft material 111 may be knit or woven polyester, such as a polyester or PTFE knit, which can be utilized when it is desired to provide a medium for tissue ingrowth and the ability for the fabric to stretch to conform to a curved surface. Polyester velour fabrics may alternatively be used, such as when it is desired to provide a medium for tissue ingrowth on one side and a smooth surface on the other side. These and other appropriate cardiovascular fabrics are commercially available from Bard Peripheral Vascular, Inc. of Tempe, Ariz., for example. In another embodiment, graft material 111 may also be of a natural material such as pericardium or another membranous tissue such as intestinal submucosa.

[0031] In one embodiment, the general direction of blood flow through dual valve prosthesis 100 when deployed *in vivo* is depicted by arrows BF in FIG. 1. In an embodiment in which dual valve prosthesis 100 is deployed within the heart, as described in more detail below, first prosthetic valve section 102 is a replacement aortic valve positioned to replace the native aortic valve and second prosthetic valve assembly 104 is a replacement mitral valve positioned to replace the native mitral

valve with hinge segment 109 laterally extending therebetween to maintain the relative deployed positions of first and second prosthetic valve sections 102, 104. In certain methods of deploying dual valve prosthesis 100, one or both of hinge segment 109 and annular frame 105 may be deployed to secure the anterior leaflet of the native mitral valve to thereby prevent it from interfering with the operation of the replacement prosthetic aortic and/or mitral valves. In an embodiment, such methods may include advance preparation of the anterior leaflet of the mitral valve in order for subsequent deployment of dual valve prosthesis 100 to function to "catch' or secure the anterior leaflet in the open position and to avoid the mitral chordae.

[0032] FIGS. 5-7 illustrate a method of delivering a prosthetic device to the aortic valve and mitral valve of a beating heart in accordance with an embodiment hereof. Initially with reference to FIG. 2, delivery catheter 240 includes a distal tip 244 with a distal sheath section 243 that is attached to an inner shaft component 234, which extends within distal sheath section 243 and a proximal sheath section 242 to a proximal end (not shown) of delivery catheter 240 to be assessable by a clinician. Proximal and distal sheath sections 242, 243 may be collectively referred to herein as a sheath component that is attached at a proximal end thereof to an outer shaft component 236 that extends to the proximal end of delivery catheter 240 to be assessable by the clinician. In an embodiment hereof, distal tip 244 with distal sheath section 243 are configured to be releasably coupled to a distal end of proximal sheath section 242 at parting line PL. Prosthesis 100 is compressed in a delivery configuration within the sheath component with first and second sections 102, 104 being sequentially loaded therein such that engagement arms 114 of stent structure downstream portion 110 of self-expanding stent structure 103 are held in a compressed state primarily by distal sheath section 243 and stent structure upstream portion 112 and annular frame 105 are held in a compressed state primarily by proximal sheath section 242.

[0033] In the embodiment shown in FIG. 2, a cylindrical rebated retainer 246 is sized to be slidably received within the sheath component and includes a tubular shaft component 248 that slidably extends between inner and outer shaft components 234, 236 to the proximal end of delivery catheter 240 to be assessable to the clinician. Rebated retainer 246 includes a cut-out 245 configured to accommodate second section 104 in a collapsed, compressed state and a plurality of eyelet-shaped

recesses 247 for receiving crimping eyelets 124, 126 of stent structure 103 and annular frame 105, respectively.

[0034] Delivery catheter 240 is shown in FIGS. 5-7 having been introduced into the left ventricle LV via a transapical minimally invasive procedure. In an embodiment, delivery catheter 240 so positioned may have been tracked through a trocar or other introducer device (not shown) that has been inserted through purse-string sutures (not shown) previously placed in the left ventricular apex. The purse-string sutures would be tightened around the trocar or other introducer device and a hemostasis valve would also be used to minimize blood leakage from the heart during the percutaneous replacement valve implantation procedure, as would be understood by one of ordinary skill in the art. As previously noted, the proximal ends (not shown) of delivery catheter 240 and its components extend out of the body to be accessible by a clinician.

[0035] Delivery catheter 240 is shown in FIG. 5 positioned through the native aortic valve AV such that distal tip 244 and distal sheath section 243 extend into the aorta A while proximal sheath section 242 is positioned to extend through the native aortic valve AV. In an embodiment, parting line PL between proximal and distal sheath sections 242, 243 is preferably positioned distal of the leaflets of the native aortic valve in line with the aortic sinuses. With reference to FIG. 6, distal tip 244 with distal sheath section 243 are distally advanced into the aorta relative to the remainder of delivery catheter 240 to release engagement arms 114 of stent structure 103 such that engagement arms 114 implant within the aortic sinuses. In an embodiment, delivery catheter 240 may be proximally retracted concurrent with the release of engagement arms 114, as shown in FIG. 6, to assure engagement arms 114 engage the aortic sinuses when deployed.

[0036] With reference to FIG. 7, proximal retraction of sheath component 240 relative to the remainder of delivery catheter 240 sequentially releases upstream portion 112 of stent structure 103 and then annular frame 105 to complete the deployment of dual valve prosthesis 100. More particularly when the proximal retraction of sheath component 240 uncovers a distal end 747 of rebated retainer 246, crimping eyelets 124 on upstream end 119 of first section 102 are freed from corresponding recesses 247 in rebated retainer distal end 747 to thereby allow stent structure upstream portion 112 to return to its expanded configuration. In this manner, stent structure upstream portion 112 is implanted within the annulus of the native aortic valve and a portion of the left ventricle that surrounds the native aortic valve.

[0037] Continued proximal retraction of sheath component 240 uncovers crimping eyelet 126 on annular frame 105 to free eyelet 126 from its corresponding recess 247 in rebated retainer 246 and thereby releases annular frame 105 to return to its expanded configuration. The release of annular frame 105 from sheath component 242 permits annular frame 105 to rotate outwardly from stent structure 103 at hinge segment 109 until annular frame 105 is in apposition with a surface of the left ventricle that surrounds the native mitral valve. In this manner, the apposition surface of annular frame 105 of the second section 104 exerts an apposition force that acts against the heart structure that surrounds the native mitral valve when deployed to implant second section 104 against the native mitral valve and left ventricle. After implantation of prosthesis 100, delivery catheter 240 and its components are removed from the heart with the purse-string sutures noted above being tightened thereafter to close the opening in the left ventricular apex.

[0038] In an embodiment, deployment of stent structure upstream portion 112 and annular frame 105 is controlled by the clinician to occur when the heart is in diastole such that the anterior leaflet of the native mitral valve is captured and held against the ventricle wall by one or more of stent structure upstream portion 112, hinge segment 109 and annular frame 105 with the posterior leaflet of the native mitral valve being captured and held toward or against the ventricle wall by annular frame 105.

[0039] FIG. 7 depicts one embodiment wherein prosthesis 100 is implanted within the heart with first section 102 implanted in or near the native aortic valve and second section 104 implanted in or near the native mitral valve. With a comparison of FIG. 1 and FIG. 7, prosthetic mitral valve 107 is a one-way bicuspid valve that is configured to be positioned in the heart within the left ventricle to permit blood flow through prosthetic mitral valve 107 in the direction of arrows BF during atrial emptying and ventricular filling when the leaflets of prosthetic mitral valve 107 open or part to allow blood to flow into the left ventricle. Prosthetic aortic valve 101 is a one-way tricuspid valve that is configured to be positioned in the heart between the left ventricle and the aorta within the annulus of the native aortic valve to permit blood flow through inflow end 119 of first prosthetic valve section 102 in the direction of arrows BF during systole when the leaflets of prosthetic aortic valve 101 open or part to allow blood to flow into the aorta. In embodiments hereof, each of prosthetic mitral valve 107 and prosthetic aortic valve 101 may be a bioprosthetic heart valve such as any one of the

bioprosthetic heart valves being used in implantable heart valve devices currently available that has been adapted for use herein.

[0040] It will be appreciated by one of ordinary skill in the art that the stent structure of FIG. 1 is merely an exemplary stent structure and various other forms for stent structures that are suitable to anchor a replacement aortic valve within the native aortic valve may be adapted for use in embodiments hereof. For instance in one embodiment, stent structure 103 of section 102 may a patterned tubular device with a stepped outer diameter such that an aortic portion of the stent structure has an expanded diameter that is greater than an expanded diameter of a ventricular portion of the stent structure. The aortic portion of the stent structure would be sized to be expandable within the aortic sinuses for securing section 102 with respect to the native aortic valve without the use of engagement arms 114. Further as would be appreciated by one of ordinary skill in the art, various methods of fabrication can be used in accordance with embodiments hereof to manufacture self-expanding stent structure 103 and annular frame 105 as either an integral unitary structure, such as by laser cutting or chemical etching the patterns thereof in a flat sheet or a tube, or a plurality of individual structures that are joined, such as by one of welding, soldering, or the like, without departing from the scope of the present invention. Further in other embodiments in accordance herewith, stent structure 103 and annular frame 105 may be made balloon-expandable or one may be self-expandable with the other balloon-expandable.

[0041] One or more embodiments hereof are related to a single valve prosthesis configured for deployment within or near the mitral and aortic valves of the heart in a single transcatheter heart valve implantation procedure. FIGS. 8 and 9 are perspective views of single valve prosthesis 100 in an expanded, deployed configuration in accordance with additional embodiments hereof. In one embodiment, prosthesis 100 includes a tubular support section 102 and an annular support section 104. In an embodiment shown in FIG. 8, section 102 includes a prosthetic valve 101 for replacing or augmenting a native aortic valve and an annular frame 105, which includes central opening 117. Central opening 117 may serve as an orifice or lumen to allow blood flow or it may serve as a docking station for a medical device such as a prosthetic mitral valve. Various types of prosthetic valves well-known in the art may be suitable for docking in central opening 117, including transcatheter, percutaneous,

transfemoral, transapical, surgical, surgical sutureless, tissue, and/or mechanical heart valves, for example.

[0042] Prosthetic valve section 102 includes a self-expanding stent structure 103 for anchoring prosthesis 100 within a beating heart. Stent structure 103 of prosthetic valve section 102 includes a downstream or aortic portion 110 and an upstream or ventricular portion 112, wherein "upstream" and "downstream" are relative to a direction of blood flow when prosthesis 100 is properly implanted in vivo. Each of downstream and upstream portions 110, 112 of stent structure 103 is a collapsible, compressible structure made of a material having resiliency or shape memory characteristics in order to return prosthetic valve section 102 to the deployed configuration shown in FIG. 8 upon release from a delivery device, such as delivery catheter 240. In an embodiment, downstream and upstream portions 110, 112 of stent structure 103 may be initially formed separately and then joined together by any means known to one of ordinary skill in the art such as, for instance, welding, gluing or suturing.

[0043] Stent structure upstream portion 112 is a patterned tubular device that defines substantially diamond shaped openings 108, although openings 108 may have any one of a variety of other shapes without departing from the scope hereof. Crimping eyelets 124 extend from upstream portion 112 at an upstream or inflow end 119 of first prosthetic valve section 102. Crimping eyelets 124 may be of varying lengths or shapes or may be independently engaged by catheter 240 to permit release of the eyelets in a controlled or sequential manner. Upstream portion 112 has a curved upstream edge defining an arched opening 121 when prosthesis 100 is in the expanded configuration that allows for the lateral positioning of annular section 104 relative to prosthetic valve section 102. More particularly, a hinge segment 109 between upstream portion 112 of stent structure 103 and annular frame 105 extends from an area of an apex of arched opening 121 to laterally extend annular section 104 therefrom when prosthesis 100 is in the expanded configuration as discussed in more detail below.

[0044] Stent structure downstream portion 110 includes three engagement arms 114 that are generally u-shaped and three prosthetic valve supports 116 to which leaflets of first prosthetic valve 101 are attached. Each engagement arm 114 extends upstream between respective prosthetic valve supports 116 to be positioned between upstream end 119 of prosthetic valve section 102 and a downstream or outflow end

118 of prosthetic valve section 102. Upstream ends 122 of engagement arms 114 may be described as being radially spaced or flared from the remainder of stent structure 103 and engagement arms 114 may be described as having a curved profile in the deployed/implanted configuration. When compressed for delivery within a sheath component of delivery catheter 240 as shown in FIG. 2, engagement arms 114 will somewhat straighten against upstream portion 112 of stent structure 103. When stent structure 103 is released from the sheath component, engagement arms 114 will return to their curved configuration with stent structure upstream portion 112 returning to its expanded configuration shown in FIG. 8. In an embodiment when prosthetic valve section 102 is deployed to replace a native aortic valve, engagement arms 114 of downstream portion 110 engage the aortic sinuses and upstream portion 112 of stent structure 103 is deployed to seat within the annulus of the native aortic valve and to extend partially into the left ventricle, as discussed in more detail below.

[0045] In addition to stent structure 103, prosthetic valve section 102 includes prosthetic valve 101 having, for example, three valve leaflets to form a tricuspid replacement valve. The valve leaflets of prosthetic valve 101 are sutured or otherwise securely and sealingly attached to the interior surface of stent structure 103 and/or graft material 111 that encloses or lines stent structure 103 as would be known to one of ordinary skill in the art of prosthetic valve construction. Prosthetic valve 101 is a one-way valve configured to collapse inwardly, *i.e.*, towards a longitudinal axis LA of first prosthetic valve section 102, during diastole in order to inhibit retrograde blood flow and to open outwardly during systole to allow blood flow through prosthetic valve section 102. In embodiments hereof, prosthetic valve 101 may be a bioprosthetic trileaflet heart valve, such as any one of the bioprosthetic trileaflet heart valves being used in implantable heart valve devices currently available that has been adapted for use herein.

[0046] Prosthesis 100 includes self-expanding annular frame 105 that extends from stent structure 103. Annular frame 105 forms a circumferential border 113 of a width W that radially extends around the central opening or orifice 117 to define an apposition surface thereabout. In an embodiment, width W may be in the range of 2.5 mm to 7.5 mm. Circumferential border 113 has triangular openings defined by the framework thereof, the triangular openings being shown by way of illustration and not limitation. One or both sides of circumferential border 113 may be covered with a graft material 128, such as any of the materials noted below for graft material 111, to aid in

providing a seal against the native anatomy when annular frame 105 is deployed within the heart. A crimping eyelet 126 extends from circumferential border 113 of annular frame 105. Annular frame 105 has a shape or a profile of a flat washer with a minimal thickness T that provides a low ventricular profile that does not interfere with the left ventricular outflow tract. In an embodiment, thickness T may be in the range of .025 mm to 0.75 mm. Annular frame 105 so described aids in maintaining apposition against the native anatomy to provide a seal there against. In an embodiment, the seal prevents or minimizes paravalvular leakage (PVL). In an embodiment, a medical device, such as a prosthetic valve, may be inserted, placed, or docked into or within central opening 117.

[0047] In an embodiment, annular frame 105 is formed with upstream portion 112 of stent structure 103 as a single unit with an integral hinge segment 109 formed to extend therebetween. In such an embodiment, stent structure upstream portion 112 and annular frame 105 with integral hinge segment 109 may be formed by etching or otherwise cutting the patterns thereof from a tube, such as a tube 330 of nitinol, as shown in FIG. 3 and then performing a thermal treatment to shape set the structures in the expanded configuration shown in FIG. 4. When formed in this manner, hinge segment 109 is configured to return annular frame 105 to the shape set expanded configuration of FIG. 4 when prosthesis 100 is released from a compressed delivery configuration. In an embodiment, hinge segment 109 and annular frame 105 will rotate outwardly and upwardly relative to longitudinal axis LA of stent structure 103 when deployed from delivery catheter 240 within the heart to exert an apposition force AF against any heart structure in which annular frame 105 comes in contact.

[0048] In another embodiment, annular frame 105 may be formed separately from upstream portion 112 of stent structure 103 with hinge segment 109 formed to integrally extend from annular frame 105 and then subsequently joined to upstream portion 112 or vice versa.

[0049] Depending on the anatomy of the heart in which prosthesis 100 is to be implanted and particularly in view of the anatomical position of the native aortic valve relative to the native mitral valve, in embodiments hereof central opening 117 in an expanded configuration may extend along an axis TA that is transverse to longitudinal axis LA of prosthetic valve section 102, as shown in FIG. 8, may extend at an obtuse angle to longitudinal axis LA of prosthetic valve section 102, as shown in FIG. 4, or may extend at an acute angle to longitudinal axis LA of prosthetic valve section 102,

as shown in FIG. 7. Accordingly in the expanded configuration annular frame 105 may laterally extend from stent structure 103 at an angle in the range of 45 to 135 degrees with respect to longitudinal axis LA of prosthetic valve section 102, which is by way of example and not limitation as the actual angle may vary due to anatomical differences in the relative positions of the native valves. In each of the aforementioned expanded configurations when deployed within the heart, hinge segment 109 and annular frame 105 are configured or formed to rotate outwardly and upwardly relative to longitudinal axis LA of stent structure 103 to exert an apposition force AF against at least the heart structure that surrounds the native heart valve.

[0050] Prosthetic valve 101 secured within the interior of stent structure 103 is configured as a one-way valve to allow blood flow in one direction and thereby regulate blood flow there through. In the embodiment shown and described with reference to FIG. 8, prosthetic valve 101 may include three valve leaflets to form a tricuspid replacement valve. In other embodiments in accordance herewith, prosthetic valve 101 may be a tricuspid or a bicuspid replacement valve. In still other embodiments in accordance herewith, prosthetic valve 101 may be a single leaflet replacement valve or a replacement valve with more than three leaflets. Natural tissue for forming prosthetic valve leaflets for use in prosthetic valve sections in accordance with embodiments hereof may be obtained from, for example, heart valves, aortic roots, aortic walls, aortic leaflets, pericardial tissue, such as pericardial patches, bypass grafts, blood vessels, intestinal submucosal tissue, umbilical tissue and the like from humans or animals, such as tissue from bovine, equine or porcine origins. Synthetic materials suitable for use as prosthetic valve leaflets in embodiments hereof include DACRON® polyester commercially available from Invista North America S.A.R.L. of Wilmington, DE, polyurethane, Gore-Tex or other cloth materials, nylon blends, polymeric materials, and vacuum deposition nitinol fabricated materials. One polymeric material from which the replacement valve leaflets can be made is an ultra-high molecular weight polyethylene material commercially available under the trade designation DYNEEMA from Royal DSM of the Netherlands. With certain prosthetic leaflet materials, it may be desirable to coat one or both sides of the replacement valve leaflet with a material that will prevent or minimize overgrowth. It is further desirable that the prosthetic leaflet material is durable and not subject to stretching, deforming, or fatigue.

[0051] The valve leaflets of prosthetic valve 101 are sutured or otherwise securely and sealingly attached to an interior surface of stent structure 103 and/or prosthetic valve 101 may be sutured or otherwise attached to graft material 111 that encloses or lines stent structures 103 as would be known to one of ordinary skill in the art of prosthetic valve construction. Graft material 111 may be a low-porosity woven fabric, such as polyester, Dacron fabric, or PTFE, which creates a one-way fluid passage when attached to the stent structure 103. In an embodiment, graft material 111 may be knitted or woven fiber, such as a polyester or PTFE knit, which can be utilized when it is desired to provide a medium for tissue ingrowth and the ability for the fabric to stretch to conform to a curved surface. Polyester velour fabrics may alternatively be used, such as when it is desired to provide a medium for tissue ingrowth on one side and a smooth surface on the other side. These and other appropriate cardiovascular fabrics are commercially available from Bard Peripheral Vascular, Inc. of Tempe, Ariz., for example. In another embodiment, graft material 111 may also be of a natural material such as pericardium or another membranous tissue such as intestinal submucosa.

[0052] In one embodiment, the general direction of blood flow through prosthesis 100 when deployed *in vivo* is depicted by arrows BF in FIG. 8. In an embodiment in which prosthesis 100 is deployed within the heart, as described in more detail below, prosthetic valve section 102 is a replacement aortic valve positioned to replace the native aortic valve and annular frame 105 is positioned adjacent or near the native mitral valve with hinge segment 109 laterally extending therebetween to maintain the relative deployed positions of prosthetic valve section 102 and annular frame 105. In certain methods of deploying prosthesis 100, one or both of hinge segment 109 and annular frame 105 may be deployed to secure the anterior leaflet of the native mitral valve to thereby prevent it from interfering with the operation of the replacement prosthetic aortic valve and a prosthetic mitral valve that is placed or docked in or within central opening 117. In an embodiment, such methods may include advance preparation of the anterior leaflet of the mitral valve in order for subsequent deployment of prosthesis 100 to function to "catch' or secure the anterior leaflet in the open position and to avoid the mitral chordae.

FIG. 7 depicts prosthesis 100 implanted within the heart with section 102 implanted in or near the native aortic valve and section 104 implanted in or near the native mitral valve. With a comparison of FIG. 8 and FIG. 7, central opening 117 is configured to

be positioned in the heart within the left ventricle to permit blood flow through the native mitral valve in the direction of arrows BF during atrial emptying and ventricular filling when the leaflets of the native mitral valve open or part to allow blood to flow into the left ventricle. Prosthetic aortic valve 101 may be a one-way tricuspid valve that is configured to be positioned in the heart between the left ventricle and the aorta within the annulus of the native aortic valve to permit blood flow through inflow end 119 of section 102 in the direction of arrows BF during systole when the leaflets of prosthetic aortic valve 101 open or part to allow blood to flow into the aorta. In some embodiments hereof, prosthetic aortic valve 101 may be a bioprosthetic heart valve such as any one of the bioprosthetic heart valves being used in implantable heart valve devices currently available that has been adapted for use herein.

In an embodiment shown in FIG. 9, prosthesis 100 includes a tubular section 102, which includes a blood flow lumen or orifice 131, and an annular section 104, which includes a prosthetic valve 107 for replacing or augmenting a valve, for example a native mitral valve. Orifice 131 may serve as an opening or lumen to allow blood flow or serve as a docking station for a prosthetic aortic valve.

[0053] Tubular section 102 includes a self-expanding stent structure 103 for anchoring prosthesis 100 within a beating heart. Stent structure 103 of tubular support section 102 includes a downstream or aortic portion 110 and an upstream or ventricular portion 112, wherein "upstream" and "downstream" are relative to a direction of blood flow when prosthesis 100 is properly implanted in vivo. Each of downstream and upstream portions 110, 112 of stent structure 103 is a collapsible, compressible structure made of a material having resiliency or shape memory characteristics in order to return section 102 to the deployed configuration shown in FIG. 9 upon release from a delivery device, such as delivery catheter 240. In an embodiment, downstream and upstream portions 110, 112 of stent structure 103 may be initially formed separately and then joined together by any means known to one of ordinary skill in the art such as, for instance, welding, gluing or suturing.

[0054] Stent structure upstream portion 112 is a patterned tubular device that defines substantially diamond shaped openings 108, although openings 108 may have any one of a variety of other shapes without departing from the scope hereof. Crimping eyelets 124 extend from upstream portion 112 at an upstream or inflow end 119 of section 102. Upstream portion 112 has a curved upstream edge defining an arched opening 121 when prosthesis 100 is in the expanded configuration that allows

for the lateral positioning of prosthetic valve section 104 relative to tubular section 102. More particularly, a hinge segment 109 between upstream portion 112 of stent structure 103 and an annular frame 105 of prosthetic valve section 104 extends from an area of an apex of arched opening 121 to laterally extend annular frame 105 therefrom when prosthesis 100 is in the expanded configuration as discussed in more detail below.

[0055] Stent structure downstream portion 110 includes three engagement arms 114 that are generally u-shaped and three supports 116. Each engagement arm 114 extends upstream between respective supports 116 to be positioned between upstream end 119 of section 102 and a downstream or outflow end 118 of section 102. Upstream ends 122 of engagement arms 114 may be described as being radially spaced or flared from the remainder of stent structure 103 and engagement arms 114 may be described as having a curved profile in the deployed/implanted configuration. When compressed for delivery within a sheath component of delivery catheter 240 as shown in FIG. 2, engagement arms 114 will somewhat straighten against upstream portion 112 of stent structure 103. When stent structure 103 is released from the sheath component, engagement arms 114 will return to their curved configuration with stent structure upstream portion 112 returning to its expanded configuration shown in FIG. 9. In an embodiment when section 102 is deployed, engagement arms 114 of downstream portion 110 engage the aortic sinuses and upstream portion 112 of stent structure 103 is deployed to seat within the annulus of the native aortic valve and to extend partially into the left ventricle, as discussed in more detail below.

[0056] In addition to stent structure 103, section 102 includes lumen 131. Section 102 may serve as a docking station for a valve, for example, a prosthetic aortic valve, having, for example, three valve leaflets to form a tricuspid replacement valve. Various types of prosthetic valves well-known in the art may be suitable for docking in lumen 131, including transcatheter, percutaneous, transfemoral, transapical, surgical, surgical sutureless, tissue, and/or mechanical heart valves, for example.

[0057] In an embodiment, section 104 includes a prosthetic valve 107, which may include two valve leaflets to form a bicuspid replacement valve. The valve leaflets are sutured or otherwise securely and sealingly attached to an inner circumference of annular frame 105 to span a central opening 117 thereof. Prosthetic valve 107 is a one-way valve. In some embodiments, prosthetic valve 107 may be a bioprosthetic bileaflet heart valve, such as any one of the bioprosthetic bileaflet heart valves being

used in implantable heart valve devices currently available that has been adapted for use herein.

[0058] Prosthetic valve section 104 of prosthesis 100 includes self-expanding annular frame 105 that extends from stent structure 103. Annular frame 105 forms a circumferential border 113 of a width W that radially extends around the central opening 117 to define an apposition surface thereabout. In an embodiment, width W may be in the range of 2.5 mm to 7.5 mm. Circumferential border 113 has triangular openings defined by the framework thereof, the triangular openings being shown by way of illustration and not limitation. One or both sides of circumferential border 113 may be covered with a graft material 128, such as any of the materials noted below for graft material 111, to aid in providing a seal against the native anatomy when section 104 is deployed within the heart. A crimping eyelet 126 extends from circumferential border 113 of annular frame 105. Annular frame 105 has a shape or a profile of a flat washer with a minimal thickness T that provides prosthetic valve section 104 with a low ventricular profile that does not interfere with the left ventricular outflow tract. In an embodiment, thickness T may be in the range of .025 mm to 0.75 mm. Annular frame 105 so described aids in maintaining apposition of section 104 against the native anatomy to provide a seal there against. In an embodiment, the seal prevents or minimizes paravalvular leakage (PVL). In an embodiment, a medical device, such as a prosthetic valve, may be inserted, placed, or docked into or within central opening or orfice 117. More particularly, when prosthesis 100 is deployed within the heart such that prosthetic valve 107 secured within annular frame 105 is utilized as a replacement mitral valve, the apposition surface provided by circumferential border 113 of annular frame 105 exerts an apposition force against a surface of the left ventricle that surrounds the native mitral valve and is intended to seal against paravalvular leakage.

[0059] In an embodiment, annular frame 105 is formed with upstream portion 112 of stent structure 103 as a single unit with an integral hinge segment 109 formed to extend therebetween. In such an embodiment, stent structure upstream portion 112 and annular frame 105 with integral hinge segment 109 may be formed by etching or otherwise cutting the patterns thereof from a tube, such as a tube 330 of nitinol, as shown in FIG. 3 and then performing a thermal treatment to shape set the structures in the expanded configuration shown in FIG. 4. When formed in this manner, hinge segment 109 is configured to return annular frame 105 to the shape set expanded configuration of FIG. 4 when prosthesis 100 is released from a compressed delivery

configuration. In an embodiment, hinge segment 109 and annular frame 105 will rotate outwardly and upwardly relative to longitudinal axis LA of stent structure 103 when deployed from delivery catheter 240 within the heart to exert an apposition force AF against any heart structure in which annular frame 105 comes in contact.

[0060] In another embodiment, annular frame 105 may be formed separately from upstream portion 112 of stent structure 103 with hinge segment 109 formed to integrally extend from annular frame 105 and then subsequently joined to upstream portion 112 or vice versa.

[0061] Depending on the anatomy of the heart in which prosthesis 100 is to be implanted and particularly in view of the anatomical position of the native aortic valve relative to the native mitral valve, in embodiments hereof annular frame 105 in an expanded configuration may extend along an axis TA that is transverse to longitudinal axis LA of tubular section 102, as shown in FIG. 9, may extend at an obtuse angle to longitudinal axis LA of tubular section 102, as shown in FIG. 4, or may extend at an acute angle to longitudinal axis LA of tubular section 102, as shown in FIG. 7. Accordingly in the expanded configuration annular frame 105 may laterally extend from stent structure 103 at an angle in the range of 45 to 135 degrees with respect to longitudinal axis LA of tubular section 102, which is by way of example and not limitation as the actual angle may vary due to anatomical differences in the relative positions of the native valves. In each of the aforementioned expanded configurations when deployed within the heart, hinge segment 109 and annular frame 105 are configured or formed to rotate outwardly and upwardly relative to longitudinal axis LA of stent structure 103 to exert an apposition force AF against at least the heart structure that surrounds the native heart valve being replaced by prosthetic valve 107.

[0062] Prosthetic valve 107 secured within the interior of annular frame 105 is configured as a one-way valve to allow blood flow in one direction and thereby regulate blood flow there through. In the embodiment shown and described with reference to FIG. 9, prosthetic valve 107 may include two valve leaflets to form a bicuspid replacement valve. In other embodiments in accordance herewith, prosthetic valve 107 may be a tricuspid or a bicuspid replacement valve. In still other embodiments in accordance herewith, prosthetic valve 107 may be a single leaflet replacement valve or a replacement valve with more than two leaflets. Natural tissue for forming prosthetic valve leaflets for use in prosthetic valve sections in accordance with embodiments hereof may be obtained from, for example, heart valves, aortic

roots, aortic walls, aortic leaflets, pericardial tissue, such as pericardial patches, bypass grafts, blood vessels, intestinal submucosal tissue, umbilical tissue and the like from humans or animals, such as tissue from bovine, equine or porcine origins. Synthetic materials suitable for use as prosthetic valve leaflets in embodiments hereof include DACRON® polyester commercially available from Invista North America S.A.R.L. of Wilmington, DE, polyurethane, Gore-Tex or other cloth materials, nylon blends, polymeric materials, and vacuum deposition nitinol fabricated materials. One polymeric material from which the replacement valve leaflets can be made is an ultra-high molecular weight polyethylene material commercially available under the trade designation DYNEEMA from Royal DSM of the Netherlands. With certain prosthetic leaflet materials, it may be desirable to coat one or both sides of the replacement valve leaflet with a material that will prevent or minimize overgrowth. It is further desirable that the prosthetic leaflet material is durable and not subject to stretching, deforming, or fatigue.

[0063] The valve leaflets of prosthetic valve 107 are sutured or otherwise securely and sealingly attached to an interior surface of annular frame 105 and/or prosthetic valve 107 may be sutured or otherwise attached to graft material 128 that encloses or lines annular frame 105 as would be known to one of ordinary skill in the art of prosthetic valve construction. Graft material 128 may be a low-porosity woven fabric, such as polyester, Dacron fabric, or PTFE, which creates a one-way fluid passage when attached to the annular frame 105. In an embodiment, graft material 128 may be knitted or woven fiber, such as a polyester or PTFE knit, which can be utilized when it is desired to provide a medium for tissue ingrowth and the ability for the fabric to stretch to conform to a curved surface. Polyester velour fabrics may alternatively be used, such as when it is desired to provide a medium for tissue ingrowth on one side and a smooth surface on the other side. These and other appropriate cardiovascular fabrics are commercially available from Bard Peripheral Vascular, Inc. of Tempe, Ariz., for example. In another embodiment, graft material 128 may also be of a natural material such as pericardium or another membranous tissue such as intestinal submucosa.

[0064] In one embodiment, the general direction of blood flow through prosthesis 100 when deployed *in vivo* is depicted by arrows BF in FIG. 9. In an embodiment in which prosthesis 100 is deployed within the heart, as described in more detail below, prosthetic valve section 104 is a replacement mitral valve positioned to replace the

native mitral valve and tubular support section 102 is positioned adjacent, near, or within the native aortic valve with hinge segment 109 laterally extending therebetween to maintain the relative deployed positions of prosthetic valve section 104 and tubular support section 102. In certain methods of deploying prosthesis 100, one or both of hinge segment 109 and annular frame 105 may be deployed to secure the anterior leaflet of the native mitral valve to thereby prevent it from interfering with the operation of the replacement prosthetic mitral valve and a prosthetic aortic valve that is placed or docked in or within orifice 131. In an embodiment, such methods may include advance preparation of the anterior leaflet of the mitral valve in order for subsequent deployment of prosthesis 100 to function to "catch' or secure the anterior leaflet in the open position and to avoid the mitral chordae.

[0065] FIG. 7 depicts prosthesis 100 implanted within the heart with section 102 implanted in or near the native aortic valve and section 104 implanted in or near the native mitral valve. With a comparison of FIG. 9 and FIG. 7, prosthetic mitral valve 107 is configured to be positioned in the heart within the left ventricle to permit blood flow through the prosthetic mitral valve 107 in the direction of arrows BF during atrial emptying and ventricular filling when the leaflets of the prosthetic mitral valve open or part to allow blood to flow into the left ventricle. In one embodiment, a docked prosthetic aortic valve (not shown) may be a one-way tricuspid valve that is configured to be positioned in the heart between the left ventricle and the aorta within orifice 131 to permit blood flow through inflow end 119 of tubular support section 102 in the direction of arrows BF during systole when the leaflets of a prosthetic aortic valve open or part to allow blood to flow into the aorta. In embodiments hereof, a prosthetic aortic valve may be a bioprosthetic heart valve such as any one of the bioprosthetic heart valves being used in implantable heart valve devices currently available that has been adapted for use herein.

[0066] In one embodiment, prosthesis 100 includes a tubular section 102 and an annular frame section 104. In the embodiment shown in FIG. 10, annular section 104 includes central opening or orfice 117 and tubular section 102 includes an central opening or orifice 131. Central openings 117 and 131 may serve as openings and/or lumens to allow blood flow and/or may serve as docking stations for one or more medical devices such as one or more prosthetic valves.

[0067] Tubular section 102 includes a self-expanding stent structure 103 for anchoring prosthesis 100 within a beating heart. Stent structure 103 of tubular section

102 includes a downstream or aortic portion 110 and an upstream or ventricular portion 112, wherein "upstream" and "downstream" are relative to a direction of blood flow when prosthesis 100 is properly implanted in vivo. Each of downstream and upstream portions 110, 112 of stent structure 103 is a collapsible, compressible structure made of a material having resiliency or shape memory characteristics in order to return tubular support section 102 to the deployed configuration shown in FIG. 10 upon release from a delivery device, such as delivery catheter 240. In an embodiment, downstream and upstream portions 110, 112 of stent structure 103 may be initially formed separately and then joined together by any means known to one of ordinary skill in the art such as, for instance, welding, gluing or suturing.

[0068] Stent structure upstream portion 112 is a patterned tubular device that defines substantially diamond shaped openings 108, although openings 108 may have any one of a variety of other shapes without departing from the scope hereof. Crimping eyelets 124 extend from upstream portion 112 at an upstream or inflow end 119 of section 102. Crimping eyelets 124 may be of varying lengths or shapes or may be independently engaged by catheter 240 to permit release of the eyelets in a controlled or sequential manner. Upstream portion 112 has a curved upstream edge defining an arched opening 121 when prosthesis 100 is in the expanded configuration that allows for the lateral positioning of annular frame 105 relative to section 102. More particularly, a hinge segment 109 between upstream portion 112 of stent structure 103 and annular frame 105 extends from an area of an apex of arched opening 121 to laterally extend annular frame 105 therefrom when prosthesis 100 is in the expanded configuration as discussed in more detail below.

[0069] Stent structure downstream portion 110 includes three engagement arms 114 that are generally u-shaped and three supports 116. Each engagement arm 114 extends upstream between respective supports 116 to be positioned between upstream end 119 of section 102 and a downstream or outflow end 118 of section 102. Upstream ends 122 of engagement arms 114 may be described as being radially spaced or flared from the remainder of stent structure 103 and engagement arms 114 may be described as having a curved profile in the deployed/implanted configuration. When compressed for delivery within a sheath component of delivery catheter 240 as shown in FIG. 2, engagement arms 114 will somewhat straighten against upstream portion 112 of stent structure 103. When stent structure 103 is released from the sheath component, engagement arms 114 will return to their curved configuration with

stent structure upstream portion 112 returning to its expanded configuration shown in FIG. 10. In an embodiment when section 102 is deployed, engagement arms 114 of downstream portion 110 engage the aortic sinuses and upstream portion 112 of stent structure 103 is deployed to seat within the annulus of the native aortic valve and to extend partially into the left ventricle, as discussed in more detail below.

[0070] In addition to stent structure 103, tubular section 102 includes lumen 131. Tubular section 102 may serve as a docking station for a medical device, for example a prosthetic aortic valve, having, for example, three valve leaflets to form a tricuspid replacement valve. Various types of prosthetic valves well-known in the art may be suitable for docking in lumen 131, including transcatheter, percutaneous, transfemoral, transapical, surgical, surgical sutureless, tissue, and/or mechanical heart valves, for example.

[0071] Prosthesis 100 includes self-expanding annular frame 105 that extends from stent structure 103. Annular frame 105 forms a circumferential border 113 of a width W that radially extends around the central opening 117 to define an apposition surface thereabout. In an embodiment, width W may be in the range of 2.5 mm to 7.5 mm. Circumferential border 113 has triangular openings defined by the framework thereof, the triangular openings being shown by way of illustration and not limitation. One or both sides of circumferential border 113 may be covered with a graft material 128, such as any of the materials noted below for graft material 111, to aid in providing a seal against the native anatomy when deployed within the heart. A crimping eyelet 126 extends from circumferential border 113 of annular frame 105. Annular frame 105 has a shape or a profile of a flat washer with a minimal thickness T that provides a low ventricular profile that does not interfere with the left ventricular outflow tract. In an embodiment, thickness T may be in the range of .025 mm to 0.75 mm. Annular frame 105 so described aids in maintaining apposition against the native anatomy to provide a seal there against. In an embodiment, the seal prevents or minimizes paravalvular leakage (PVL). In an embodiment, a medical device, such as a prosthetic valve, may be inserted, placed, or docked into or within central opening 117. More particularly, when prosthesis 100 is deployed within the heart, the apposition surface provided by circumferential border 113 of annular frame 105 exerts an apposition force against a surface of the left ventricle that surrounds the native mitral valve and is intended to seal against paravalvular leakage.

[0072] In an embodiment, annular frame 105 is formed with upstream portion 112 of stent structure 103 as a single unit with an integral hinge segment 109 formed to extend therebetween. In such an embodiment, stent structure upstream portion 112 and annular frame 105 with integral hinge segment 109 may be formed by etching or otherwise cutting the patterns thereof from a tube, such as a tube 330 of nitinol, as shown in FIG. 3 and then performing a thermal treatment to shape set the structures in the expanded configuration shown in FIG. 4. When formed in this manner, hinge segment 109 is configured to return annular frame 105 to the shape set expanded configuration of FIG. 4 when prosthesis 100 is released from a compressed delivery configuration. In an embodiment, hinge segment 109 and annular frame 105 will rotate outwardly and upwardly relative to longitudinal axis LA of stent structure 103 when deployed from delivery catheter 240 within the heart to exert an apposition force AF against any heart structure in which annular frame 105 comes in contact.

[0073] In another embodiment, annular frame 105 may be formed separately from upstream portion 112 of stent structure 103 with hinge segment 109 formed to integrally extend from annular frame 105 and then subsequently joined to upstream portion 112 or vice versa. The joining annular frame 105 and upstream portion 112 may be selected to result in hinge segment 109 being a relatively flexible or a relatively rigid unit.

[0074] Depending on the anatomy of the heart in which prosthesis 100 is to be implanted and particularly in view of the anatomical position of the native aortic valve relative to the native mitral valve, in embodiments hereof annular frame 105 in an expanded configuration may extend along an axis TA that is transverse to longitudinal axis LA of section 102, as shown in FIG. 10, may extend at an obtuse angle to longitudinal axis LA of section 102, as shown in FIG. 4, or may extend at an acute angle to longitudinal axis LA of section 102, as shown in FIG. 7. Accordingly in the expanded configuration annular frame 105 may laterally extend from stent structure 103 at an angle in the range of 45 to 135 degrees with respect to longitudinal axis LA of section 102, which is by way of example and not limitation as the actual angle may vary due to anatomical differences in the relative positions of the native valves. In each of the aforementioned expanded configurations when deployed within the heart, hinge segment 109 and annular frame 105 are configured or formed to rotate outwardly and upwardly relative to longitudinal axis LA of stent structure 103 to exert

an apposition force AF against at least the heart structure that surrounds the native heart valve.

[0075] Prosthesis 100 may serve as a docking station for one or more prosthetic valves configured as one-way valves to allow blood flow in one direction and thereby regulate blood flow there through. In other embodiments in accordance herewith, the one or more prosthetic valves docked in prosthesis 100 may be tricuspid and/or bicuspid replacement valves. In still other embodiments in accordance herewith, the one or more prosthetic valves docked in prosthesis 100 may be single leaflet replacement valves and/or replacement valves with more than three leaflets. Natural tissue for forming prosthetic valve leaflets for use in prosthetic valve sections in accordance with embodiments hereof may be obtained from, for example, heart valves, aortic roots, aortic walls, aortic leaflets, pericardial tissue, such as pericardial patches, bypass grafts, blood vessels, intestinal submucosal tissue, umbilical tissue and the like from humans or animals, such as tissue from bovine, equine or porcine origins. Synthetic materials suitable for use as prosthetic valve leaflets in embodiments hereof include DACRON® polyester commercially available from Invista North America S.A.R.L. of Wilmington, DE, polyurethane, Gore-Tex or other cloth materials, nylon blends, polymeric materials, and vacuum deposition nitinol fabricated materials. One polymeric material from which the replacement valve leaflets can be made is an ultra-high molecular weight polyethylene material commercially available under the trade designation DYNEEMA from Royal DSM of the Netherlands. With certain prosthetic leaflet materials, it may be desirable to coat one or both sides of the replacement valve leaflet with a material that will prevent or minimize overgrowth. It is further desirable that the prosthetic leaflet material is durable and not subject to stretching, deforming, or fatigue.

[0076] Prosthesis 100 may comprise graft materials 128 and 111 that enclose or line annular frame 105 and/or tubular support section 102 as would be known to one of ordinary skill in the art of prosthesis construction. Graft materials 128 and 111 may be a low-porosity woven fabric, such as polyester, Dacron fabric, or PTFE, which prevent the passage of fluid when attached to the annular frame 105 and/or tubular support section 102. In an embodiment, graft materials 128 and 111 may be knitted or woven fiber, such as a polyester or PTFE knit, which can be utilized when it is desired to provide a medium for tissue ingrowth and the ability for the fabric to stretch to conform to a curved surface. Polyester velour fabrics may alternatively be used, such

as when it is desired to provide a medium for tissue ingrowth on one side and a smooth surface on the other side. These and other appropriate cardiovascular fabrics are commercially available from Bard Peripheral Vascular, Inc. of Tempe, Ariz., for example. In another embodiment, graft materials 128 and 111 may also be of a natural material such as pericardium or another membranous tissue such as intestinal submucosa. Graft materials 128 and 111 may be the same or different and may comprise more than one fabric or natural material. In one embodiment, graft materials 128 and 111 comprise a combination of natural material and fabric.

[0077] In one embodiment, the general direction of blood flow through prosthesis 100 when deployed *in vivo* is depicted by arrows BF in FIG. 10. In an embodiment in which prosthesis 100 is deployed within the heart, as described in more detail below, annular frame 105 is positioned adjacent to or near the native mitral valve and tubular support section 102 is positioned adjacent to, near, or within the native aortic valve with hinge segment 109 laterally extending therebetween to maintain the relative deployed positions of annular frame 105 and tubular support section 102. In certain methods of deploying prosthesis 100, one or both of hinge segment 109 and annular frame 105 may be deployed to secure the anterior leaflet of the native mitral valve to thereby prevent it from interfering with the operation of a replacement prosthetic mitral valve that is placed or docked in or within central opening 117. In an embodiment, such methods may include advance preparation of the anterior leaflet of the mitral valve in order for subsequent deployment of prosthesis 100 to function to "catch' or secure the anterior leaflet in the open position and to avoid the mitral chordae.

[0078] In some embodiments, sutures, clips, prongs, barbs, hooks, or the like may be used to attach one or more portions of prosthetic device 100 to tissue or to another prosthetic device, such as, without limitation, a prosthetic valve device or an annuloplasty ring device. In an embodiment, annular frame 105 may be attached to tissue around or near the mitral valve, and annular frame 105 may support the native mitral valve. Annular frame 105 may support the annulus of the native mitral valve or may function as an annuloplasty ring device. It is to be understood that although annular frame 105 is illustrated having a generally circular shape, in some embodiments, it may have other shapes, such as a "D" shape. It is also to be understood that although annular frame 105 is illustrated as comprising two rings joined by struts, in other embodiments, it may comprise one or more rings, bands, and/or hoops, for example.

[0079] In one embodiment, the prosthetic device 300 shown in FIG. 11 may be implanted, for example, to serve as support to the annuli of one or more of the mitral and aortic valves. Prosthetic device 300 may be optionally covered with a graft material, as described above, and it may be covered in such a manner that the graft material reduces, controls, or modulates the flow of blood, for example, by acting as a seal between the tissue and the device. Implantation may be accomplished by one or more of transcatheter, percutaneous, transfemoral, transapical, minimally invasive, or standard surgical techniques. In some embodiments, sutures, clips, prongs, barbs, hooks, or the like may be used to attach one or more portions of the device to tissue or to another prosthetic device, such as, without limitation, a prosthetic valve or an annuloplasty ring. In some embodiments, prosthetic device 300 may serve as a docking station for one or more prosthetic valves that replace or augment one or more native valves, for example, aortic and mitral valves. Prosthetic device 300 may be a docking station that does not extend into the annuli of at least one of the mitral and aortic valves. In another embodiment, the device acts as a docking station that does not interfere with the function of at least one of the native valves.

[0080] In an embodiment, one or more of the prosthetic device 100, the prosthetic device 300, and delivery system 240 may control the rotational angle of the device during delivery, which in some contexts is referred to as "clocking" the device. For example, rotation about the longitudinal axis LA may be controlled to enable annular frame 105 to be placed in a desired location. In other embodiments, the position of annular frame 105 may be adjusted after delivery of prosthetic device 100 using delivery catheter 240 or another medical device. In other embodiments, the delivery and position of prosthetic device 100 may be controlled using surgical procedures.

[0081] In an embodiment, the devices described herein may be used in conjunction with previously implanted devices, such as a prosthetic heart valve or an annuloplasty ring. As a nonlimiting example, tubular section 102 may be inserted into a previously implanted prosthetic aortic valve. As another nonlimiting example, tubular section 102 may be inserted into the annulus of a native valve that is supported by a previously implanted annuloplasty ring. In some embodiments, a clinician treating a patient may implant an annuloplasty ring and a device described herein sequentially.

[0082] While various embodiments have been described above, it should be understood that they have been presented only as illustrations and examples of the present invention, and not by way of limitation. It will be apparent to persons skilled in

the relevant art that various changes in form and detail can be made therein without departing from the spirit and scope of the invention. Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the appended claims and their equivalents. It will also be understood that each feature of each embodiment discussed herein, and of each reference cited herein, can be used in combination with the features of any other embodiment. All patents and publications discussed herein are incorporated by reference herein in their entirety.

CLAIMS

What is claimed is:

1. A prosthesis comprising:

a stent structure; and

an annular frame, wherein when the prosthesis is in an expanded configuration the annular frame laterally extends from the stent structure.

2. The prosthesis of claim 1, wherein the stent structure further comprises a prosthetic valve.

3. The prosthesis of claim 1, wherein the annular frame further comprises a prosthetic valve.

4. The prosthesis of claim 1, wherein the annular frame forms a border that radially extends around a prosthetic valve to define an apposition surface.

5. The prosthesis of claim 1, wherein the annular frame has a profile of a flat washer.

6. The prosthesis of claim 1, wherein a hinge segment laterally extends between the annular frame and the stent structure when the prosthesis is in the expanded configuration.

7. The prosthesis of claim 6, wherein the hinge segment and the annular frame extend from an arched opening defined by an upstream edge of the stent structure.

8. The prosthesis of claim 7, wherein at least an upstream portion of the stent structure, annular frame and hinge segment are an integral self-expanding structure with a shape set to return to the expanded configuration from a compressed delivery configuration.

9. The prosthesis of claim 8, wherein a downstream portion of the stent structure includes a plurality of engagement arms each having an upstream end that is radially spaced from the upstream portion of the stent structure.

10. The prosthesis of claim 1, wherein in the expanded configuration the annular frame laterally extends from the stent structure at an angle in the range of 45 to 135 degrees with respect to a longitudinal axis of the stent structure.

11. A method of implanting a prosthesis within a beating heart comprising:

introducing a delivery catheter transapically into the left ventricle of the heart, wherein a prosthesis disposed within a distal portion of the delivery catheter includes a stent structure and an annular frame, wherein the annular frame laterally extends from the stent structure when the prosthesis is implanted in the heart;

deploying the stent structure to implant within the native aortic valve; and

deploying the annular frame to implant against the native mitral valve, wherein the annular frame exerts an apposition force that acts against the heart structure that surrounds the native mitral valve when deployed.

12. The method of claim 11, wherein the stent structure and the annular frame are self-expanding and wherein the delivery catheter includes a sheath component such that during the step of introducing the delivery catheter the stent structure and annular frame are compressed in a delivery configuration within the distal portion of the delivery catheter by the sheath component.

13. The method of claim 12, wherein a hinge segment extends between the annular frame and the stent structure and wherein the step of deploying the stent structure includes releasing the hinge segment and annular frame from the sheath component to permit the annular frame to rotate outwardly from the stent structure at the hinge segment.

14. The method of claim 12, wherein the step of deploying the stent structure includes positioning the stent structure thereof within the native aortic valve

and releasing engagement arms of the stent structure from the sheath component such that the engagement arms implant within the aortic sinuses.

15. The method of claim 14, wherein the step of deploying the first prosthetic section includes releasing an upstream portion of the stent structure from the sheath component to implant the upstream portion within the annulus of the native aortic valve.

16. The method of claim 15, wherein the step of deploying the annular frame includes releasing the annular frame from the sheath component into apposition with a surface of the left ventricle that surrounds the native mitral valve.

17. The method of claim 16, wherein releasing the engagement arms and upstream portion of the stent structure occurs before releasing the annular frame.

18. The method of claim 11, wherein the delivery catheter includes a rebated retainer within a sheath component thereof that is used to secure crimping eyelets of the stent structure and the annular frame when the prosthesis is in a compressed delivery configuration within the sheath component.

19. The method of claim 18, wherein the crimping eyelets of the stent structure and the annular frame are held within corresponding recesses of the rebated retainer by the sheath component.

20. The method of claim 19, wherein the crimping eyelets of the stent structure are released from the rebated retainer and sheath component during the step of deploying the stent structure prior to the crimping eyelets of the annular frame being released therefrom during the step of deploying the annular frame.

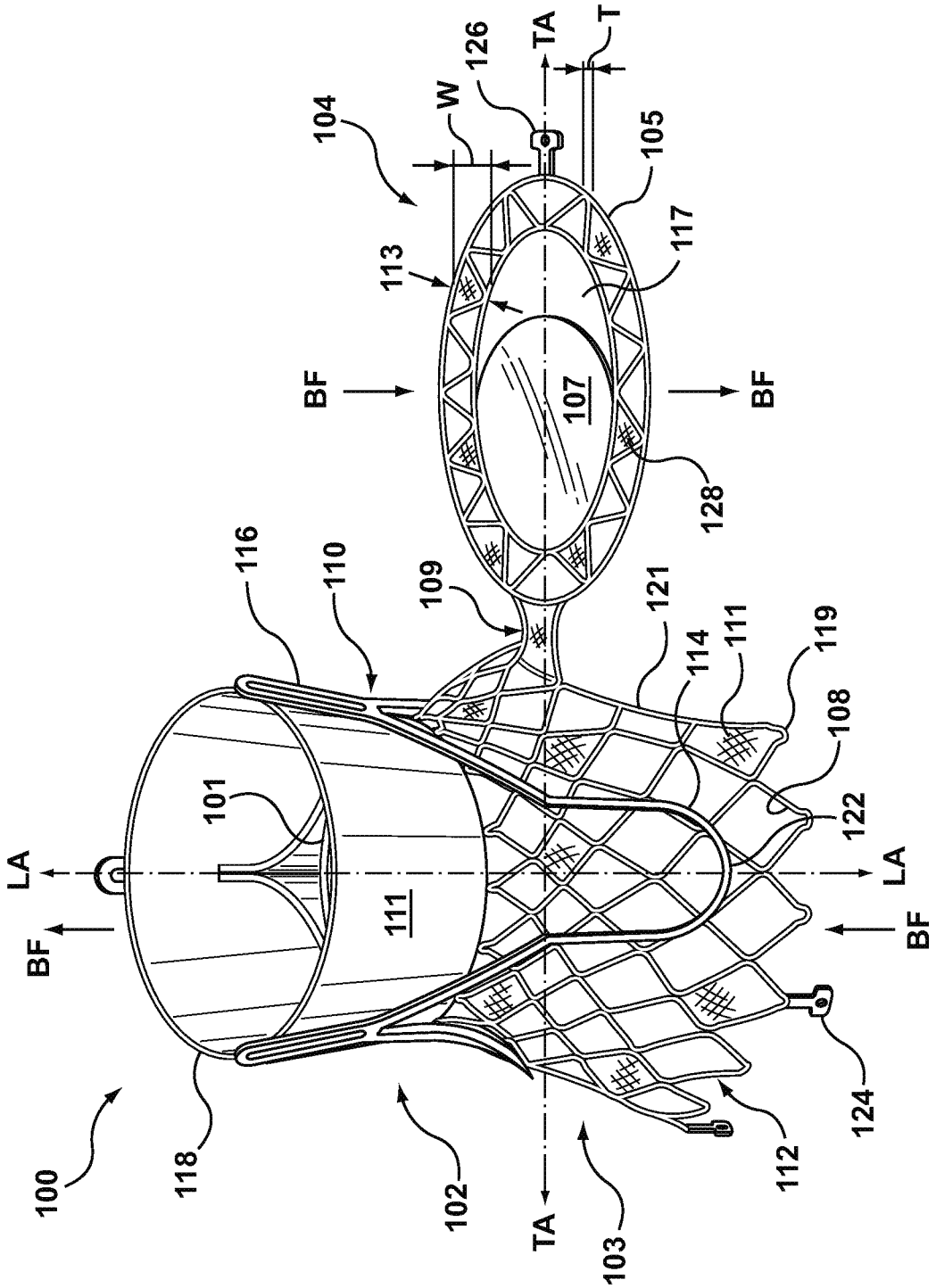

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FIG. 1

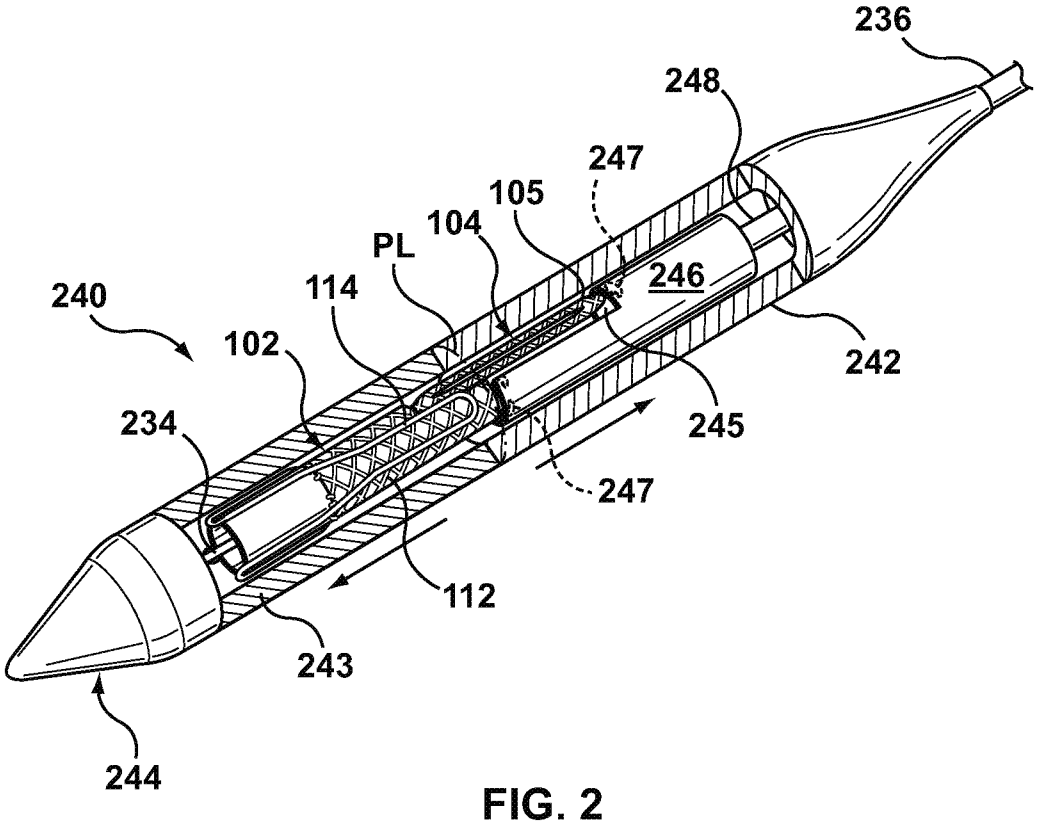


FIG. 2

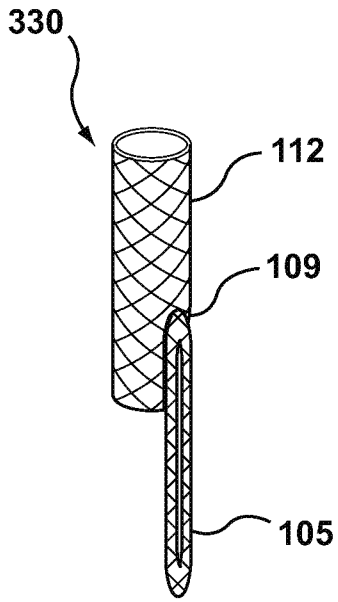


FIG. 3

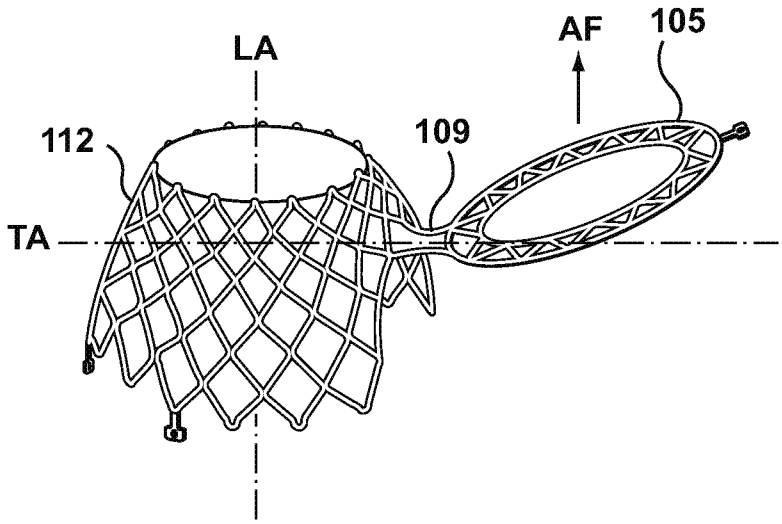


FIG. 4

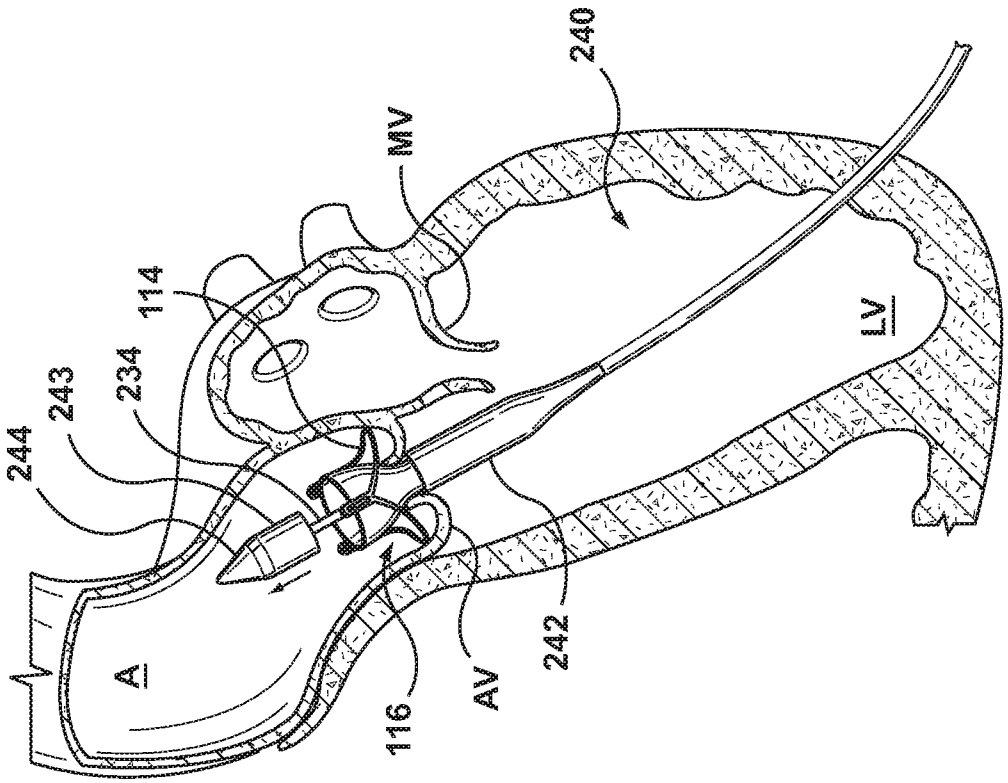


FIG. 6

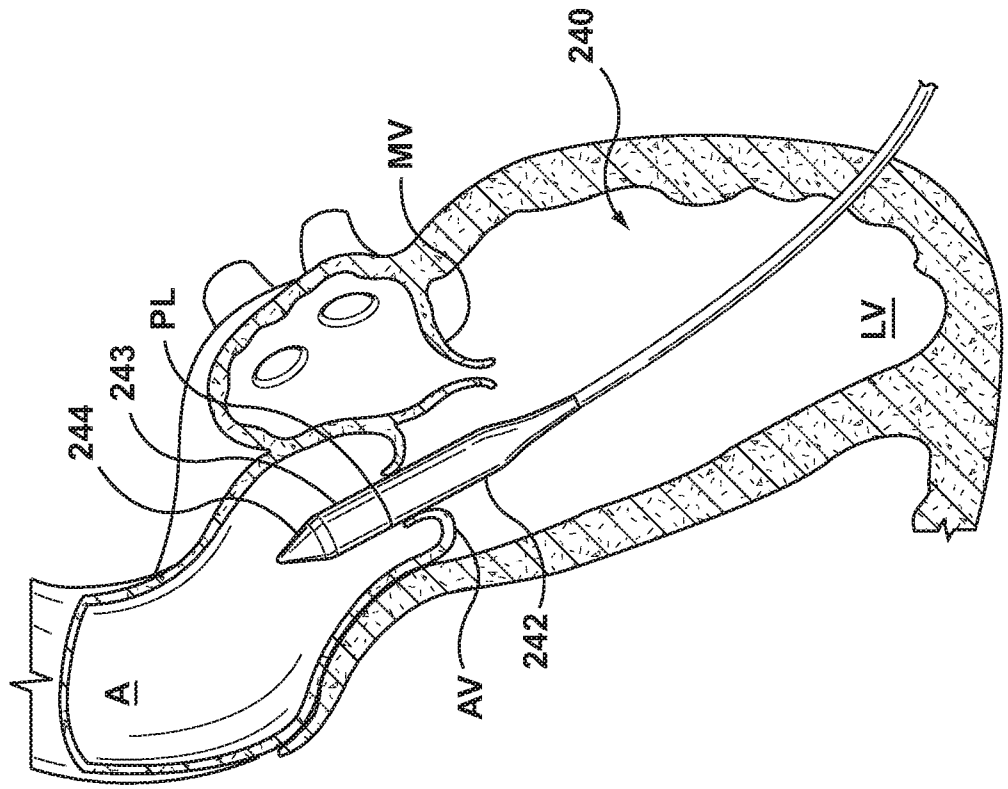


FIG. 5

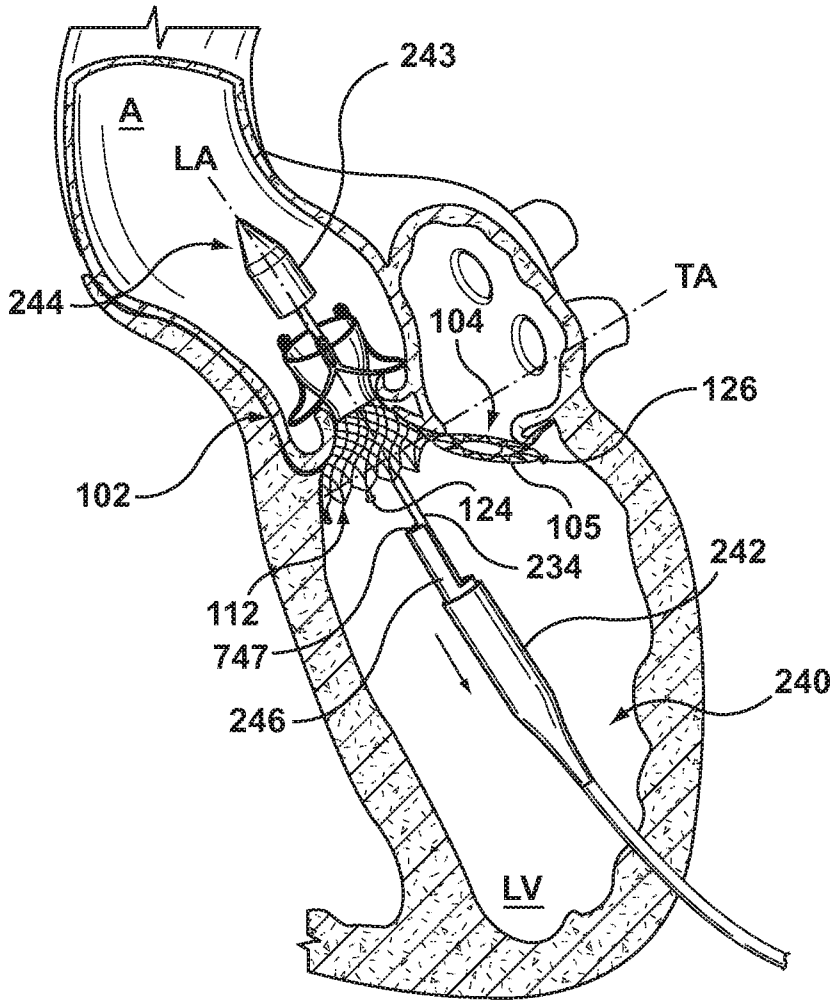


FIG. 7

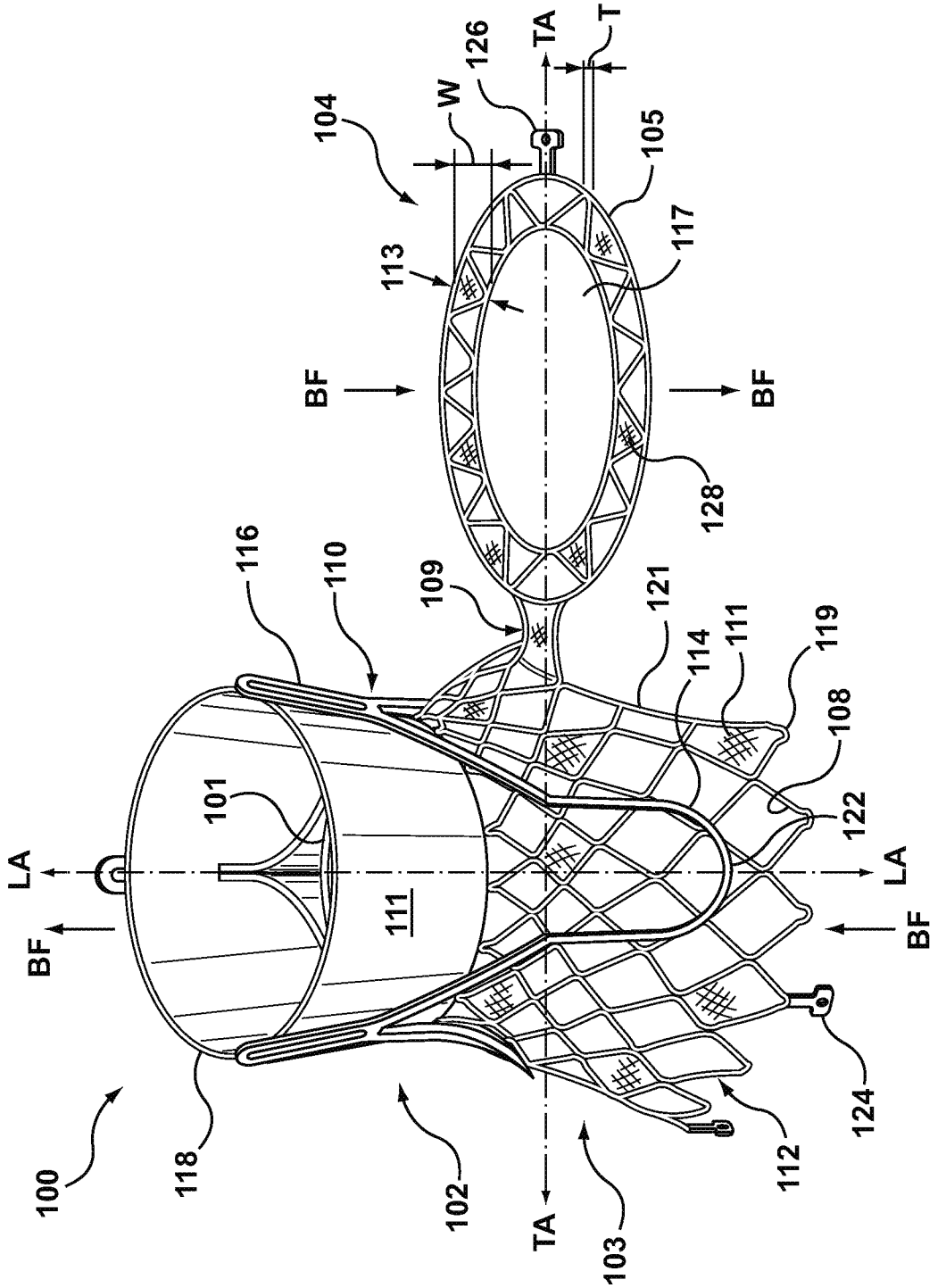

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FIG. 8

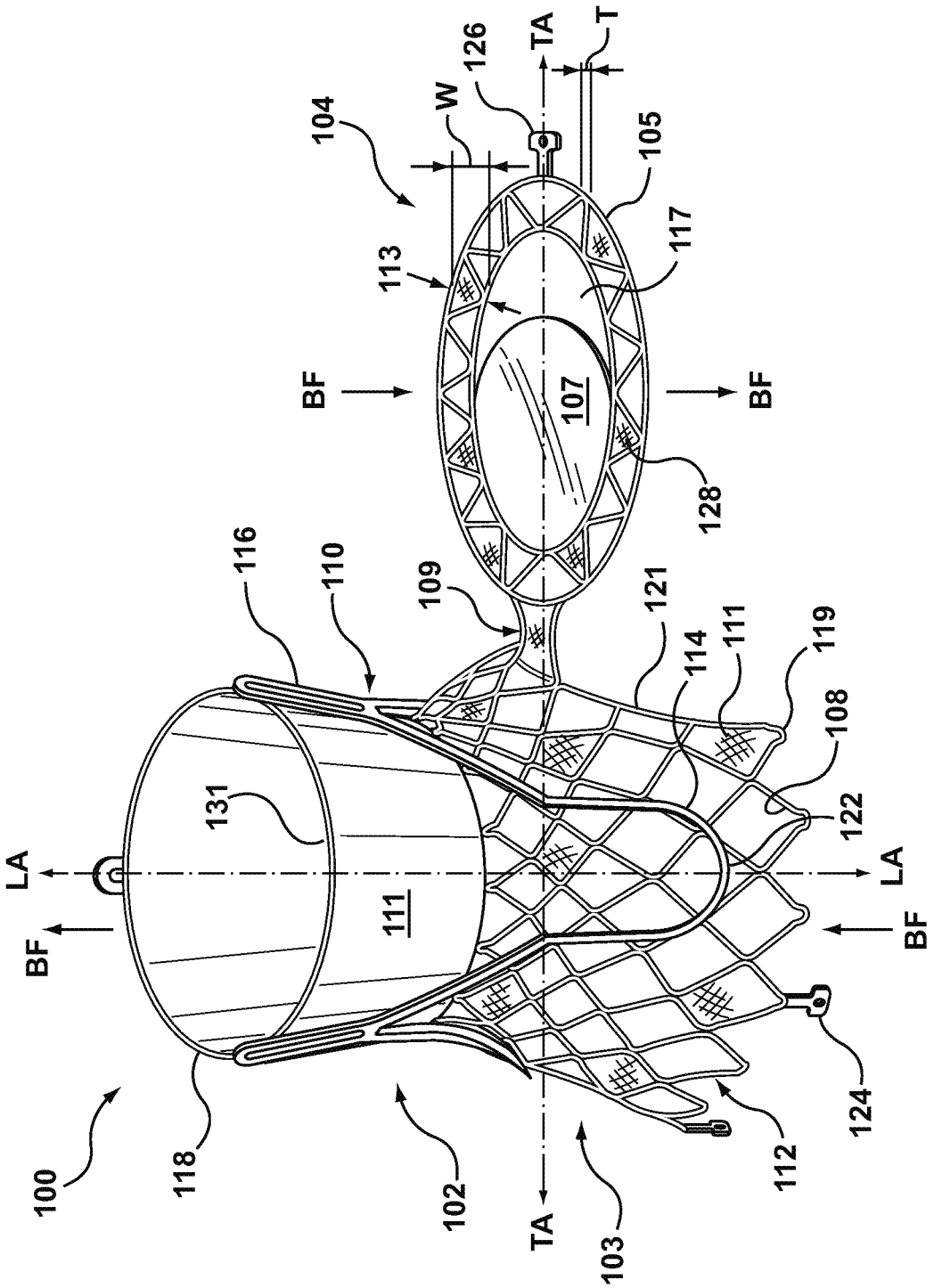

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FIG. 9

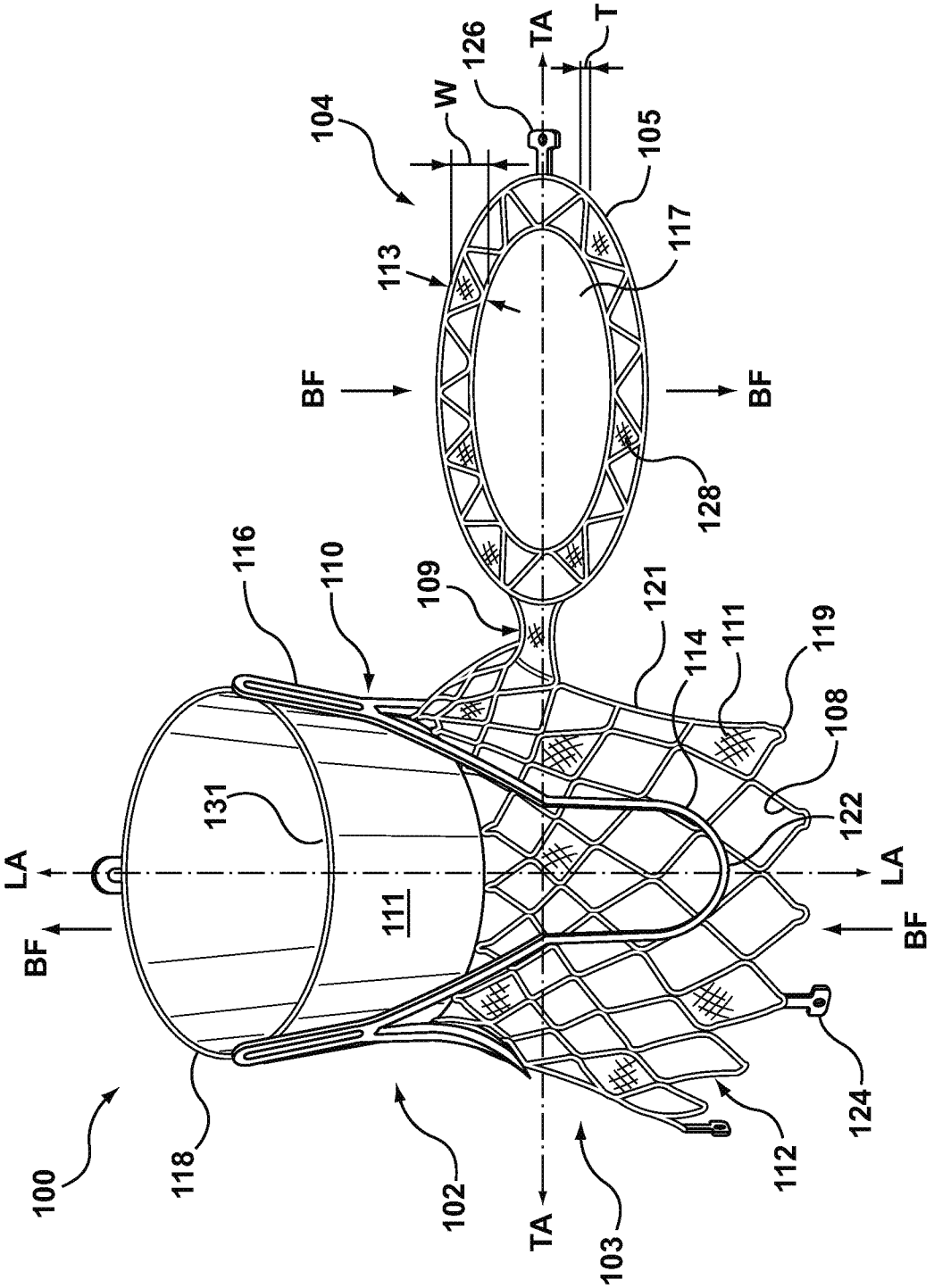

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FIG. 10

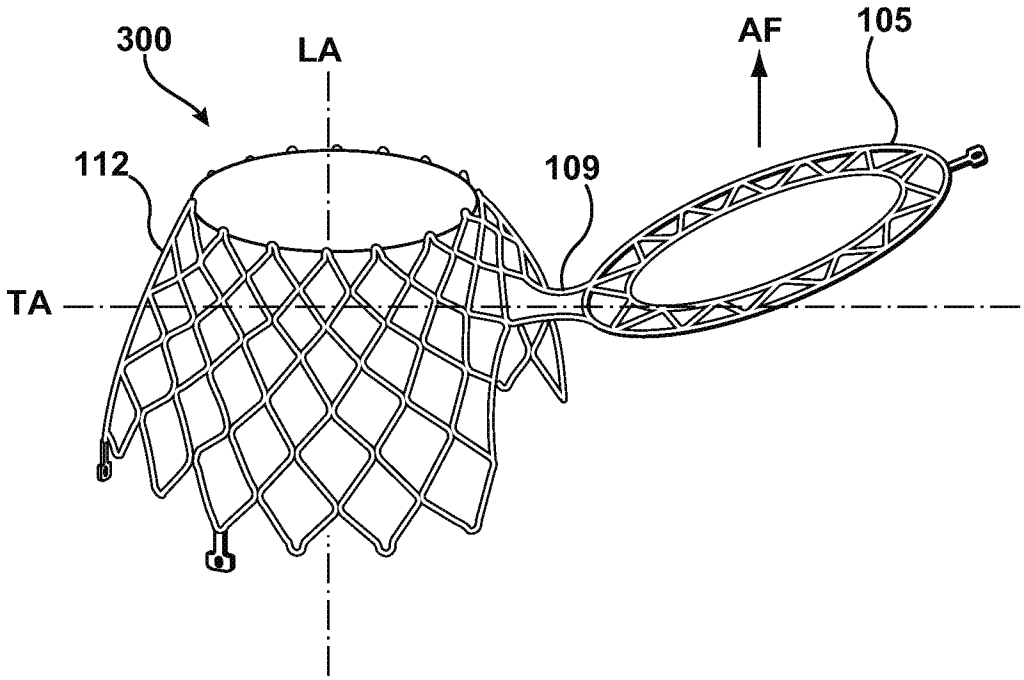


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/020647

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/264991 A1 (PAUL JR RAM H [US] ET AL) 22 October 2009 (2009-10-22) paragraphs [0009] - [0011], [0030], [0033] - [0040], [0042], [0044], [0048] - [0049]; figures 1-3	1-4,6-10
X	WO 2009/126362 A1 (MEDTRONIC INC [US]; BONHOEFFER PHILIPP [GB]) 15 October 2009 (2009-10-15) page 5, lines 22-25 page 8, line 7 - page 13, line 8 figures 1-8	1-9
X,P L	WO 2013/148017 A1 (MEDTRONIC VASCULAR GALWAY LTD [IE]; COSTELLO DECLAN [US]) 3 October 2013 (2013-10-03) the whole document	1-10

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 June 2014	11/06/2014

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

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/020647

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	EP 2 732 796 A1 (NAKOSTECH SARL [FR]) 21 May 2014 (2014-05-21) paragraphs [0009] - [0015], [0022], [0024], [0038], [0040] - [0043]; figures 1-6	1-4,6-10
X,P	WO 2013/059747 A1 (FOUNDRY NEWCO XII INC [US]) 25 April 2013 (2013-04-25) paragraphs [0313] - [0317]; figures 68A, 68B	1,2,4-9
X,P	WO 2013/148019 A1 (MEDTRONIC INC [US]) 3 October 2013 (2013-10-03) the whole document	1

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/020647

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

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

1. [X] Claims Nos.: 11-20
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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

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

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

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

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

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

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

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

Remark on Protest

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

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/020647

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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