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(71) Applicant *(for all designated States except US)*: **MVALVE TECHNOLOGIES LTD.** [IL/IL]; 40 Einstein St., 69102 Tel-Aviv (IL).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **BUCHBINDER, Maurice** [CA/US]; 8501 La Jolla scenic Drive N, La Jolla, CA 92037 (US).

(74) Agents: **PYERNIK Rutman** et al.; P.O.Box 10012, 84001 Beer-Sheva (IL).

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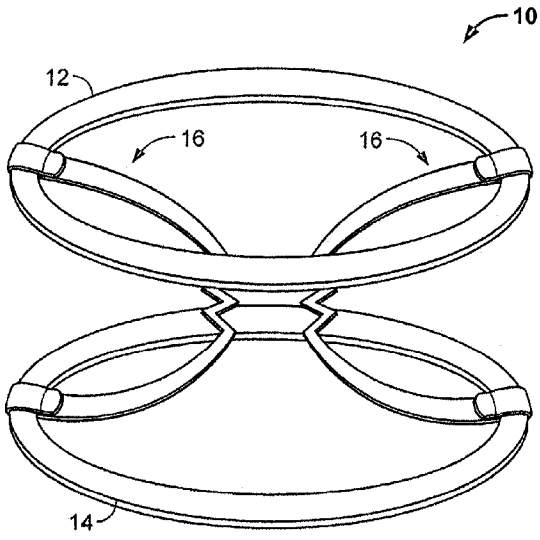

FIG. 1A

(57) Abstract: The present invention provides a cardiac valve support adapted for endovascular delivery to a cardiac valve, comprising first and second support elements and at least two bridging members extending from the first support element to the second support element. The first and second support elements each have a collapsed delivery configuration and a deployed configuration, wherein the bridging members extend radially inward from the first and second support elements in the deployed configuration.

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CARDIAC VALVE SUPPORT STRUCTURE

BACKGROUND OF THE DISCLOSURE

[0001] Heart valve regurgitation occurs when the heart leaflets do not completely close when the heart contracts. When the heart contracts, blood flows back through the improperly closed leaflets. For example, mitral valve regurgitation occurs when blood flows back through the mitral valve and into the left atrium when the ventricle contracts.

[0002] In some instances regurgitation occurs due to disease of the valve leaflets (e.g., primary, or "organic" regurgitation). Regurgitation can also be caused by dilatation of the left ventricle, which can lead to secondary dilatation of the mitral valve annulus. Dilation of the annulus spreads the mitral valve leaflets apart and creates poor tip coaptation and secondary leakage, or so-called "functional regurgitation."

[0003] Currently, primary regurgitation is corrected by attempting to remodel the native leaflets, such as with clips, sutures, hooks, etc., to allow them to close completely when the heart contracts. When the disease is too far advanced, the entire valve needs to be replaced with a prosthesis, either mechanical or biologic. Examples include suture annuloplasty rings all the way to actual valve replacement with leaflets, wherein the suture rings are sutured to the mitral valve annulus. Annuloplasty rings, which are also sutured to the annulus, have also been used to attempt to remodel the annulus, bringing the native leaflets closer together to allow them to properly close.

[0004] Based on the success of catheter-based aortic valve replacement there is growing interest in evaluating similar technologies to replace the mitral valve non-invasively using similar types of replacement valves.

[0005] Unlike the aortic valve, however, the mitral valve annulus does not provide a good landmark for positioning a replacement mitral valve. In patients needing a replacement aortic valve, the height and width of the aortic annulus are generally increased in the presence of degenerative disease associated with calcium formation. These changes in tissue make it easier to properly secure a replacement aortic valve in place due to the reduced cross-sectional area of the aortic annulus. The degenerative changes typically found in aortic valves are not, however, present in mitral valves experiencing regurgitation, and a mitral valve annulus is therefore generally thinner than the annulus of a diseased aortic valve. The thinner mitral valve annulus makes it relatively more difficult to properly seat a replacement mitral valve in the native mitral

valve annulus. The general anatomy of the mitral valve annulus also makes it more difficult to properly anchor a replacement mitral valve in place. The mitral valve annulus provides for a smoother transition from the left atrium to the left ventricle than the transition that the aortic valve annulus provides from the aorta to the left ventricle. The aortic annulus is anatomically more pronounced, providing a larger "bump" to which a replacement aortic valve can more easily be secured in place.

[0006] In general, the aortic valve annulus is smaller than the mitral valve annulus. It has been estimated that the mitral valve annulus is about 2.4 cm to about 5 cm in diameter, while the aortic valve annulus has been estimated to be about 1.6 cm to about 2.5 cm in diameter.

[0007] The larger mitral valve annulus makes it difficult to securely implant current percutaneously delivered valves in the native mitral position. Current replacement aortic valves are limited in the amount of radial expansion they can undergo during deployment and implantation. To provide a replacement aortic valve that has an expanded configuration such that it can be securely anchored in a mitral valve annulus would require that the collapsed delivery profile of the replacement aortic valve be increased. Increasing the collapsed delivery profile, however, would make endovascular delivery more dangerous for the patient and more difficult to navigate the vasculature with a larger diameter delivery system.

[0008] Some attempts have been made to deliver and implant a one-piece replacement mitral valve, but it is difficult to provide a device that can be collapsed down to have a sufficiently small delivery profile and still be able to be expanded and secured in place within the mitral valve via a vascular access site.

[0009] A valve support structure or anchoring device is needed that can be positioned near or within the native mitral valve and that is adapted to secure a replacement mitral valve in place.

SUMMARY OF THE DISCLOSURE

[0010] One aspect of the disclosure is a cardiac valve support suitable for endovascular delivery to a cardiac valve, comprising first and second support elements, wherein said first and second support elements each have a collapsed delivery configuration and a deployed configuration, and wherein at least two bridging members extend from the first support element to the second support element, said bridging members having a delivery configuration and a deployed configuration, wherein said bridging members extend radially inward from the first and second support elements in the deployed configuration.

[0011] In some embodiments the bridging members extend from discrete locations around adjacent support elements, and can be arranged symmetrically around the circumference of said support elements. Thus, in one embodiment, the first and second bridging members can extend from the adjacent support elements at points separated by about 180 degrees along the circumference of said support elements.

[0012] In certain other embodiments, the valve support device may optionally further comprise secondary bridging members (occasionally referred to hereinafter as "bridges") that mutually interconnect two or more main bridging members. In other embodiments, secondary bridging members are used to connect one or more of the main bridging members with the support elements. The term "secondary bridging members" is used in this context to distinguish said optional, additional bridges from the main bridging members that connect the first and second support elements, as disclosed hereinabove.

[0013] In some embodiments at least one of the support elements has an annular shape.

[0014] In some embodiments the bridging members and/or support elements are fitted with replacement valve engagement means adapted to securely engage a replacement heart valve. It is to be noted that the term "valve engagement means" is used herein interchangeably with the term "valve attachment means". In some embodiment, the engagements means can have anchoring and/or locking elements adapted to securely lock with a portion of a replacement heart valve. In other embodiments, the replacement valve engagement means are formed from a soft biocompatible material (such as a biocompatible fabric, silicon, PET etc.) which is fitted to the external surface of portions of the support elements and/or bridging members. In these embodiments, the soft, compressible nature of the biocompatible material permits certain portions thereof to be compressed by the struts or other structural elements of the replacement valve, upon expansion within the lumen of the valve support. Other portions of the soft biocompatible material which are not compressed by the expanded replacement valve protrude into the internal space of said valve between the struts and/or other structural elements. The protrusions formed in this way engage and grip the replacement valve thereby preventing its movement in relation to the valve support. In other embodiments, the replacement valve engagement means comprise rigid anchors of a size and shape such that they are capable of entering the internal space of the replacement valve between its struts and/or other structural elements, upon expansion of said valve within the internal space of the valve support.

[0015] In some embodiments, the support elements and/or bridging members are fitted with heart tissue anchoring means adapted to securely anchor said support elements to the heart wall. Non-limiting examples of such anchoring means include hooks and spirals.

[0016] In some embodiments, the cardiac valve support further comprises one or more stabilizing elements, the function of which is to provide additional stabilization of said support within the ventricle and/or atrium. Although in some cases, the stabilizing means include one or more elements that become physically attached to the cardiac tissue (e.g. in the atrial or ventricular walls), in many other embodiments, said stabilizing means provide additional mechanical stability by means of applying pressure on the inner surface cardiac wall without being physically connected to the subsurface cardiac tissues. In some embodiments, the cardiac valve support comprises one or more intra-ventricular stabilizing elements, one or more intra-atrial stabilizing elements. In other embodiments, the cardiac valve support will be fitted with at least one intra-ventricular stabilizing element and at least one intra-atrial stabilizing element.

[0017] In some embodiments the first and second support elements are adapted to preferentially bend at at least one location.

[0018] In some embodiments the first and second support elements each have a curved portion in their deployed configurations, wherein the curved portions are adapted to assume a tighter curved configuration in the collapsed delivery configurations.

[0019] In some embodiments the first and second bridging members are generally C-shaped in their deployed configurations.

[0020] In some embodiments the first support element has at least one coupling element adapted to reversibly couple to a delivery system. The at least one coupling element can be a threaded bore.

[0021] In some embodiments the second support element has a dimension in the deployed configuration that is larger than a dimension of the first support element in the deployed configuration with or without one or more fixation elements attached and radially engaging in cardiac tissue when needed.

[0022] In some embodiments, the first and second support elements are connected by only two bridging members.

[0023] One aspect of the disclosure is a system adapted for endovascular or transapical delivery to replace a mitral valve, comprising: a cardiac valve support comprising a first support element with a collapsed delivery configuration and a deployed configuration; a second support element with a collapsed delivery configuration and a deployed configuration; at least two

bridging members extending from the first support element to the second support element, said bridging members having a delivery configuration and a deployed configuration; wherein the first and second bridging members extend radially inward from the first and second support elements in the deployed configurations; and a replacement heart valve comprising an expandable anchor and a plurality of leaflets adapted to be secured to the cardiac valve support. For the sake of clarity of description, the above disclosure of a delivery system relates to a cardiac valve support in which the two support elements are connected by two bridging members. However, it is to be recognized that the endovascular delivery system of the present invention may be used to deliver cardiac valve supports in which more than two bridging members mutually connect the two support elements.

[0024] In some embodiments the bridging members and/or support elements are adapted to securingly engage the replacement heart valve. In one such embodiment, the bridging members are formed such that at least one portion thereof comprises a series of folds or pleats (e.g. z-shaped pleats), the purpose of which is to increase the surface area of the bridging members that are available for interacting with the replacement valve. An additional benefit of this embodiment is that the pleated region also assists in the transition between the delivery (closed) conformation of the valve support device and the deployed (open) conformation thereof. In other embodiments, the replacement valve securing means comprise attachment means, such as hooks or other mechanical anchors that are connected, at one of their ends, to the support elements and/or bridging members, and have a free end for attachment to the replacement valve.

[0025] In some embodiments of the invention, the system disclosed hereinabove further comprises pressure measuring elements. These elements may be situated anywhere in the system – including on the surface of the valve support device, attached to the replacement valve, as well as within the guide catheter. In another embodiment, the system of the invention further comprises connection terminals that permit the connection of pacemaker leads to various parts of said system.

[0026] One aspect of the disclosure is a method of replacing a patient's mitral valve, comprising: delivering a valve support to a location near a subject's mitral valve, the valve support comprising a first support element a second support element, and at least two bridging members extending from the first and second support elements; expanding the first support element from a collapsed configuration to a deployed configuration secured against cardiac tissue below the plane of the mitral valve annulus; expanding the bridge members from delivery configurations to deployed configurations positioned in general alignment with the coaptation

points of the native mitral valve leaflets; and expanding the second support element from a collapsed configuration to a deployed configuration secured against left atrial tissue above the plane of the mitral valve annulus.

[0027] In one embodiment, the above-defined method may be employed to deliver the valve support by an endovascular route. In another embodiment, the method may be used to deliver the valve support by a transapical route.

[0028] In some embodiments expanding the first support element comprises allowing the first support element to self-expand against cardiac tissue.

[0029] In certain embodiments, the method further comprises the step of causing cardiac attachment means fitted to the support elements and/or bridging members to become inserted into the ventricular wall. In certain cases, the insertion of said attachment means is effected by means of control wires inserted through the delivery catheter which are used to cause rotation of the valve support device. In other cases, said attachment means may be covered by a sleeve during insertion of the valve support device, said sleeve being removed in order to allow said attachment means to become inserted into the ventricular wall. In still further embodiments, the attachment means may be constructed in the form of an anchor with two or more backwardly-pointing self-opening distal arms, wherein said distal arms are retained in a closed conformation by means of a resorbable suture. Then, after a certain period of time following insertion of said attachment means into the ventricular tissue (e.g. between a few hours and few weeks), said suture dissolves, thereby permitting the distal arms to adopt their open conformation.

[0030] In other embodiments, the above-defined method further comprises the step of causing intra-ventricular stabilizing elements and/or intra-atrial stabilizing elements to engage, respectively, the inner ventricular wall and/or inner atrial wall.

[0031] In some embodiments expanding each of the bridge members comprises allowing the bridge members to assume a deployed configuration in which they extend radially inward from the first and second support elements.

[0032] In some embodiments expanding the second support element against left atrial tissue comprises allowing the second support element to self-expand.

[0033] In some embodiments expanding the first support element comprises expanding the first support element towards a generally annularly shaped deployed configuration.

[0034] In some embodiments expanding the first support element comprises expanding the first support element secured against papillary muscles and chords attached to the native mitral valve, and can be done without displacing them.

[0035] In some embodiments native leaflets continue to function after expanding the second support element.

[0036] In some embodiments expanding the first support element occurs before expanding the second support element.

[0037] In some embodiments expanding the bridge members comprises allowing the bridge members to symmetrically extend from the first support element to the second support element.

[0038] In some embodiments expanding the bridge members comprises allowing the bridge members to extend from the first and second support elements about 180 degrees from one another.

[0039] In some embodiments expanding the second support element comprises expanding the second support element to the deployed configuration in which the second support element has a dimension larger than a dimension of the first support element in the deployed configuration. The second support element may have one or more fixation elements adapted to pierce into cardiac tissue.

[0040] In some embodiments the method further comprises securing a replacement mitral valve to the valve support. Securing the replacement mitral valve to the valve support can comprise expanding the replacement mitral valve from a collapsed delivery configuration to an expanded configuration. Expanding the replacement mitral valve can include expanding the replacement mitral valve with a balloon and/or allowing the replacement mitral valve to self-expand. Securing a replacement mitral valve to the valve support can comprise securing the replacement mitral valve radially within the valve support. Securing a replacement mitral valve to the valve support can comprise locking a replacement mitral valve element with a valve support element to lock the replacement mitral valve to the valve support. The bridge members can each comprise a bridge lock element and the replacement mitral valve can comprise a plurality of lock elements such that the locking step comprises locking one of the plurality of lock elements with one of the bridge lock elements and locking a second of the plurality of lock elements with the other of the bridge lock elements. In other embodiments, the step of securing a replacement valve to the valve support device comprises causing valve attachment means fitted to the valve support elements and/or bridging members to engage said replacement mitral valve.

[0041] In a further embodiment, the above-disclosed method to deliver a valve support and a prosthetic mitral valve may combine two separate delivery approaches – one approach for the support device and a different one for the valve. The advantage of this strategy is that it significantly shortens the time delay between deployment of the valve anchor and the

deployment of the prosthetic valve itself. This is important, since after deployment of the valve support there may be interference with the native mitral valve function (due to interference with the valve leaflets). One example of such an approach is the delivery of a valve support *via* an endovascular, trans-septal route (as described herein), while in parallel delivering the prosthetic mitral valve *via* a transapical or transfemoral route (as known in the art). Conversely, the valve support may be delivered by a transfemoral or transapical approach, while the replacement valve itself is delivered trans-septally. Thus, in one embodiment of the method disclosed above, the replacement mitral valve is delivered by the same route as the valve support. In another embodiment of the method, the replacement mitral valve and the valve support are delivered by different routes, wherein said routes are selected from the group consisting of trans-septal, transfemoral and transapical. The use of these various approaches to delivery replacement valves and other devices is well known to the skilled artisan and has been described in several publications including US 7,753,923 and WO 2008/070797.

[0042] For the sake of clarity of description, the above disclosure of a method for replacing a patient's mitral valve relates to a method that uses a cardiac valve support in which the two support elements are mutually connected by two bridging members. However, it is to be recognized that the endovascular delivery system of the present invention may be used to deliver cardiac valve supports containing more than two support elements and more than two bridging members.

INCORPORATION BY REFERENCE

[0043] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0044] The novel features of the disclosure are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present disclosure will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the disclosure are utilized, and the accompanying drawings of which:

[0045] Figures 1A-1C illustrate an exemplary replacement mitral valve support structure in an expanded configuration.

[0046] Figures 2A-2C illustrate an exemplary delivery system for delivering a replacement mitral valve support structure.

[0047] Figures 3A-3E illustrate an exemplary method of delivering and deploying an exemplary replacement mitral valve support structure.

[0048] Figures 4A-4D illustrate an exemplary method of deploying a replacement mitral valve and securing it to a replacement mitral valve support structure.

[0049] Figures 5A-5D illustrate an exemplary delivery system for delivering a replacement mitral valve support structure.

[0050] Figure 6 illustrates a sectional view of an exemplary replacement mitral valve support.

[0051] Figure 7 illustrates an expanded valve support wherein the lower support element has a diameter that is smaller than the diameter of the upper support element.

[0052] Figures 8A and 8B illustrate an embodiment comprising seals to reduce leakage.

[0053] Figure 9 illustrates an embodiment of the valve support device of the present invention fitted with two vertically-disposed stabilizing elements.

[0054] Figures 10A – 10B depict embodiments of the valve support each having a stabilizing element formed from a stent-like mesh.

[0055] Figure 11 illustrates an embodiment of the valve support in which the stabilizing element contains spring-like constricted regions.

[0056] Figure 12 illustrates an embodiment in which the valve support is fitted with one horizontal stabilizing element and one vertical stabilizing element.

[0057] Figure 13 depicts an embodiment of the valve support having a plurality of stabilizing elements attached to the upper support element.

[0058] Figures 14A – 14C depict embodiments of the valve support of the present invention in which the stabilizing elements are constructed in the form of curved arms.

[0059] Figure 15 illustrates an embodiment of the valve support in which a horizontal ring-shaped stabilizing element is located between the upper and lower support elements.

[0060] Figure 16 depicts a valve support containing spiral-shaped cardiac anchoring means.

[0061] Figure 17 depicts a valve support comprising a plurality of hook-like cardiac anchors.

[0062] Figures 18A – 18B illustrate cardiac attachment anchors having backwardly pointing distal arms which may be retained in a closed position during delivery by means of a resorbable suture loop.

[0063] Figures 19A – 19B illustrate two different embodiments of cover elements that may be used to conceal the cardiac attachment anchors during delivery of the valve support.

[0064] Figures 20A – 20B depict the use of a shape-memory anchor which is maintained in a straight conformation during delivery by means of an overtube.

[0065] Figure 21 illustrates a valve support device of the present invention fitted with two different types of valve engagement means.

[0066] Figures 22A – 22B illustrate support elements fitted with a valve engagement means constructed from a soft biocompatible material.

[0067] Figures 23A - 23B depict an embodiment of the valve support device of the present invention in which the bridging elements, in their closed conformation are disposed very close to each other in the center of said device.

[0068] Figure 24 illustrates a valve support device comprising guide wire retaining elements attached to the medial side of the bridging members.

[0069] Figure 25 illustrates a valve support device constructed form a single wire.

[0070] Figures 26A - 26B schematically depict an embodiment of the valve support in which the bridging members are fitted with a mechanism that permits the height of said support to be altered.

[0071] Figure 27 illustrates an embodiment of the present invention in which the lower support element has an upwardly curved outer margin.

[0072] Figure 28 depicts two support elements, each having the same internal diameter but different external diameters.

[0073] Figures 29A – 29B show a valve support device with a pair of elastic tab-like stabilizing elements attached to the upper support element.

[0074] Figure 30 illustrates clip-like cardiac tissue anchors that are particularly suitable for attaching the support element to the annulus.

DETAILED DESCRIPTION OF THE DISCLOSURE

[0075] The disclosure is generally related to cardiac valve support structures that are adapted to be implanted near or within a native cardiac valve or native valve annulus and are adapted to provide support for a replacement heart valve. The support structures are adapted to interact with a replacement heart valve to secure it in an implanted position near or within the native

valve or native valve annulus. In some embodiments the support structure is adapted to be positioned near or within the mitral valve annulus, and is adapted to interact with a subsequently delivered replacement mitral valve to secure the replacement mitral valve in place to replace the function of the native mitral valve.

[0076] The disclosure also provides for two-step endovascular implantation procedures for replacing a patient's native mitral valve. In general, a support structure is first positioned near or within a mitral valve annulus and secured in place. A replacement mitral valve is subsequently secured to the support structure, securing the replacement valve in place near or within the annulus. By implanting the support structure and replacement mitral valve in two steps, the replacement mitral valve can have a lower delivery profile because it does not have to expand as much to contact native tissue due to the presence of the support structure. This eliminates the need to have a large delivery profile replacement valve as would be required if attempting to position an aortic valve in the native mitral valve, or if attempting to position a one-piece mitral valve implant (i.e., an implant not assembled in-vivo) within the native mitral valve.

[0077] Figures 1A-1C illustrate an exemplary embodiment of a valve support in an expanded configuration. Valve support 10 includes a first support element 12, a second support element 14, and first and second bridge members 16 extending from first support 12 to second support 14. Figure 1A illustrates a perspective view of valve support 10, while Figures 1B and 1C illustrate a side view and top-view, respectively, of valve support 10. As shown in Figure 1B, each of bridge members 16 includes a valve engaging portion 18.

[0078] In some embodiments the first support element and the second support element are generally annular in shape in their expanded configurations (see, for example, Figure 1A). Patient-to-patient variability in the cardiac anatomy can, however, require that the support elements have a variety of sizes and configurations. The support elements can therefore have any configuration as needed to be secured to any anatomical configuration. For example, the support elements can have generally elliptical configurations. Additionally, the support elements need not have the same general configuration. For example, the superior support element can have a generally annular shape and the inferior support element can have a generally elliptical shape. The bridge members operably connect the first and second support elements, and extend generally radially inward and axially away from a first of the support elements before extending radially outward towards the second of the support elements. For example, in the embodiment in Figures 1A-1C, bridge member 16 extends from support 12 in a radially inward direction and axially away from support element 12 and towards support element 14, before extending radially

outward towards support 14. The valve engaging portions of the bridge members are disposed radially inward relative to the support elements. The bridge members are biased to the configurations shown in Figures 1A-1C, with the valve engaging portions disposed radially inward relative to the support elements. Because they are biased towards this configuration, they are adapted to apply a radially inward force to a subsequently positioned replacement mitral valve that is expanded to an expanded configuration within the bridge members (described below). The bridge members are therefore adapted to engage the replacement heart valve to secure the replacement mitral valve to the valve support.

[0079] In the embodiment in Figures 1A-1C, the bridge members extend from the support elements at discrete locations around the support elements. That is, in this embodiment, the bridge members do not extend from the support elements all the way around the support elements. If they did, the valve support would have a general hourglass shape. The bridge members, therefore, are not complete extensions of the support elements. While the embodiment in Figure 1A-1C shows two bridge members extending from the support elements at discrete locations, the valve support may include more than two bridge members extending from the support elements at discrete locations along the support elements.

[0080] In the embodiment in Figures 1A-1C, the bridge members also symmetrically extend from the first and second support elements. That is, there is at least one line or plane extending through the valve that, in at least one view of the valve support, creates portions of the valve support that are symmetrical. For example, in reference to Figure 1C, a line extending through and connecting the bridge members creates symmetrical portions of the valve support. Or, for example, in reference to Figure 1B, a vertical line extending through the center of the valve support creates symmetrical portions of the valve support.

[0081] In some embodiments the first and second support elements and the bridge members are made from a resilient material that can be deformed into a delivery configuration yet are adapted to self-expand to an expanded configuration, with optional additional expansion of one or more components by balloon dilation. For example, the support can be made from Nitinol, relying on its superelastic properties. In some embodiments the valve support is made from a material with shape memory properties, such as nitinol, and is adapted to return to an expanded memory configuration after being heated above its transition temperature. In some embodiments in which the valve support is made from a material such as nitinol, the shape memory properties and the superelastic properties are utilized. In the embodiment in Figures 1A-1C, valve support 10 is adapted to return to the expanded configuration shown, either by self-expansion (relying on

the superelasticity of the material), or by being heated above its transition temperature (such as by exposure to the body's temperature).

[0082] Once the support structure is expanded and secured in place within the native mitral valve, a replacement mitral valve in a collapsed delivery configuration is advanced through the first support structure and positioned within the bridge members. Expansion of the replacement mitral valve (e.g., balloon expansion, self-expansion, etc.) not only expands the replacement mitral valve, but applies an expanding force on the bridge members, expanding them further radially outward towards the native annulus. Expansion of the replacement mitral valve causes the replacement valve to engage the bridge members and secure the replacement mitral valve to the valve support. Because the bridge members are biased towards a configuration in which they extend generally radially inward, the bridge members apply a radially inward force on the replacement mitral valve, helping to secure the replacement mitral valve in place. In one preferred embodiment, before expansion of a prosthetic valve within the support device, said device has a "closed" configuration, with the bridging members being juxtaposed to each other, thereby having a minimal distance between them (for example a distance of approximately 1-2mm). In this closed configuration, the guide wire used to deliver the valve support (and subsequently used to deliver the replacement valve) is compressed between the two mutually apposed bridging members. In order to optimize the ability of the bridging members to compress or grasp the guide wire, the surfaces of the bridges may be non-flat, for example they may have a wavy or saw-tooth profile when viewed from the side. In one particularly preferred design, the wave or saw-tooth form will include three waves, or three teeth. However, in many cases, the bridging members may comprise fewer or more such waves or teeth. Advantageously, in this embodiment, the design of the bridging members is such that they offer minimal friction resistance to the passage of the replacement valve as it is guided axially between said bridging members towards the desired location. In this way, insertion of a replacement valve from above should cause lateral displacement of the bridging members, rather than downward displacement of the valve-support device. In order to achieve this effect, the bridging members of the valve-support will be made out of an appropriate material, such as Nitinol, Cobalt based alloys or stainless steel, and will be designed in an appropriate shape to allow the transfer of force from a downward directional movement, into radial expansion of bridges. The insertion of a replacement valve over a wire in the internal space of a valve support of the present invention is illustrated in Figs. 23A and 23B. Thus, following deployment of a valve support **930** of this type within the region of the mitral annulus, the bridging members **932c** are located very close

together, thereby engulfing the guide wire **934**, as illustrated in Fig. 23A. Then, the replacement valve **936** is inserted over the wire, preferably *via* trans-septal insertion, so that the valve reaches the mitral annulus from the Left Atrium – above the location of the valve support in the annulus. Upon advancing the valve downward over the wire, it comes into contact with the juxtaposed bridging members. The design of these members is such that when the valve is further pushed downward the downward force vector applied by the valve on the bridges is diverted to a radial direction, in such a way that the bridges **932o** are moved apart, "open up" and thereby permit insertion of the valve through them over the wire (as shown in Fig. 23B), until the valve reaches the required position, which is preferably at the level of the annulus, within the support device and disposed with its long axis parallel to the long axis of said support device. An advantage of this embodiment is that it ensures that the bridging members remain in contact with the replacement valve, following its implantation, without interfering with its ability to function, thereby preventing functional problems such as regurgitation.

[0083] In a further preferred embodiment, the central portion of the bridging members are each fitted with one or more curved retaining elements, and arranged such that said retaining elements, taken together, define an incomplete ring. Fig. 24 shows an example of this embodiment, in which each of the two bridging members **948** of valve support device **946** comprise two curved retaining elements **950**. In use, the retaining elements surround the guide wire that is used to deliver the valve support and replacement valve, ensuring that said wire is maintained in the center of said valve support, between the bridging members. This, in turn, ensures that the replacement valve is expanded centrally between the bridging members. However, since the retaining elements are not mutually connected (i.e. they form an incomplete ring), they do not prevent the bridging members from moving apart laterally, upon expansion of the replacement valve (as will be described hereinbelow). In the example shown in Fig. 24, the retaining elements are manufactured by laser cutting, or by soldering a circumferential element, thereby forming an incomplete ring structure that surrounds the wire. Clearly, the width of each 'slot' (separation distance between opposing retaining elements) needs to be smaller than diameter of the guide wire (for example, for a 0.035 inch wire, apertures should be smaller than 0.9mm).

[0084] Further details of exemplary deployment procedures are described below.

[0085] In the embodiment shown in Figures 1A-1C, the bridge members and support elements are separate and distinct elements secured to one another by any suitable technique (e.g., soldering). In some alternative embodiments, the support elements and the bridge

members are manufactured as a single unit without components that need to be secured to one another (see, for example, the exemplary embodiments in Figures 3A-7 below). For example, in some embodiments the manufacturing of the valve support is simplified because it is manufactured from a single tubular shape memory material that is pre-formed with predetermined expansion ratios and forces needed to retain the replacement mitral valve in place. In some preferred embodiments of this type, the valve-support device is constructed of a single wire that has been shaped in a way to construct an upper support element, a lower support element, and two or more bridging elements between them. An example of an embodiment of this type is illustrated in Fig. 25. Suitable wire materials that may be used to manufacture valve supports of this type include (but are not limited to) biocompatible metals and metal alloys, Nitinol, cobalt and stainless steel. One advantage of this design is the fact that its simplicity of construction results in low manufacturing costs. A further significant advantage of the use of a single wire (rather than a broader strip – as depicted in Fig. 1A) is that it may be collapsed to a very small size such that it may be inserted into a small diameter delivery catheter, thereby presenting a reduced crossing profile.

[0086] In some embodiments the height of the valve support, measured from the base of the first support to the top of the second support, is about 1 cm to about 5 cm to be able to accommodate the height of the replacement heart valve, such as a stented heart valve. In some embodiments the height is greater than 5 cm. In some embodiments the height of the valve support is between about 1 cm and about 2.5 cm. For example, a stented heart valve in an expanded configuration can have a height of about 17.5 mm. It should be noted, of course, that these numbers are merely exemplary and are not limiting in any way.

[0087] In one embodiment, as shown in Fig. 26, the bridging members **938** of the valve-support device are fitted with a mechanism **940** that permits the height of the device (i.e. the distance between the upper and lower support elements) to be changed: either lengthened, or (as shown in Fig. 26) shortened. In Fig. 26A, the valve support is shown at its initial height, while Fig. 26B illustrates the same support following height reduction. Suitable mechanisms include a rotatable screw element, the length of which may be altered (shortened or lengthened) by means of rotating a control wire connected to one end of said element. In an alternative implementation, a pulling-mechanism – for example, a hypotube fitted with an internal pulling wire - is arranged such that when the operator pulls said wire, only the distal part of the bridging member is pulled, thereby causing the bridging member to become shortened, thereby decreasing the overall height of the valve support device.

[0088] In some embodiments, the height of the valve support is less than the height of the replacement heart valve. Additionally, the two annular support elements can have different dimensions. For example, the two support elements, if generally annular-shaped, can have different diameters. In some embodiments the first support element has a larger diameter than the second support element because the anatomical position in which it is to be placed is larger than the anatomical position in which the second support element is to be placed. In the embodiment shown in Figures 1A-1C, support element 12 can have a larger diameter than support element 14 due to its expansion in the larger left atrium versus the smaller left ventricle, the papillary tendons and muscles, and other supporting structures in the left ventricle. The possible differences in dimensions of the superior and inferior support elements are discussed in more detail below.

[0089] In other embodiments, the lower support element of the presently-disclosed valve support device has a curved or cambered outer edge. An example of such an embodiment is shown in Fig. 27, in which the outer margins **958** of the lower support element **960** are seen to curve upwards. This type of embodiment is of particular value when the anatomical structure and size of the left ventricle is such that the valve support device may interfere with the normal ejection of blood from said ventricle through the aortic valve during systole, for example by deflecting a portion of the blood away from the aortic valve.

[0090] In most embodiments of the valve support disclosed herein, the sizes of the ring-like support elements may, as depicted in Fig. 28, be defined by two different dimensions – an external diameter **944e** and an internal diameter **944i**. It will be seen that while both of the support elements **942** shown in this figure have the same internal diameter, their external diameters differ. It will be appreciated that the internal diameter defines the space available for implantation of the replacement valve within the valve support device, while the external diameter needs to be the same as the space within the native Mitral annulus (in order to permit stable implantation of the valve support). Since both the expanded diameter of different commercially-available replacement mitral valves and the diameter of the anatomical mitral annulus differs (from patient to patient), it follows that a range of valve support devices needs to be manufactured and made available, such that the clinician can select the valve support having an internal diameter appropriate for the replacement valve to be implanted and an external diameter of the same size as the space within the mitral annulus.

[0091] In the embodiments described herein the support elements do not have a covering element. In some embodiments, however, one or more support elements can have a covering

element such as a sealing skirt to enhance the sealing of blood flow in and around the support structure and replacement heart valve. The covering element can be any type of material that surrounds the support elements and provides the enhanced sealing functionality (e.g. it can prevent fluid leakage between the valve support and the heart wall). In some embodiments, the covering element can be attached (e.g. by the use of a biocompatible adhesive) to the outer surface of the support elements. In other embodiments, the covering element can be attached to the inner surface of the support elements.

[0092] In some embodiments one or more of support structures is covered in a material such as a polyester fabric (e.g., Dacron). Alternatively or in addition to, one or more of the bridge members can be covered in a polyester fabric such as Dacron.

[0093] In certain embodiments, the valve support device may further comprise one or more stabilizing elements attached to the upper support element, the lower support element or to both of said elements. The purpose of the stabilizing elements is to increase the multi-directional stability of the implanted valve support device (and thus also enhance the stability of the implanted replacement valve), by means of stabilizing elements in the form of additional complete ring structures (in some cases, similar to the upper and lower support elements themselves), partial rings or curved arms, whereby said structures are placed such that at least part of their length is in close apposition to the surface of the inner ventricular wall and/or the surface of the inner atrial wall (in the case of stabilizing elements attached to the upper support element). Since the curvature of the inner walls of both the atrium and ventricle may be defined in relation to two mutually-perpendicular axes (horizontal and vertical), the stabilizing elements may be disposed either horizontally (i.e., essentially parallel to the horizontal axis of the valve support device) or vertically (i.e. essentially parallel to the vertical axis of the valve support device.). Additionally, in some embodiments, the stabilizing elements may be disposed such that they are neither parallel to the horizontal axis nor to the vertical axis, but rather are arranged at an acute angle to one of these axes.

[0094] In some cases, the stabilizing elements (which may be formed from either elastic or plastic materials, as will be described hereinbelow) will be manufactured as an integral part of the valve support device. In other cases, said stabilizing elements will be manufactured separately (by casting, milling, laser-cutting or any other suitable technique known to skilled artisans in the field), and later connected to one or both support elements by means of soldering or laser welding.

[0095] Fig. 9 illustrates a valve support device **300** of the present invention fitted with two vertically-disposed ring-shaped stabilizing elements. As shown in the figure, the upper, apical ring **310** is attached at its lower portion to the upper support element **320**, while its upper portion is disposed within the atrium **330**, in close contact with the inner atrial wall. Conversely, the lower, ventricular ring **340** is attached, at its upper end, to the lower support element **350**, while its lower portion is disposed within the ventricle **360**, in close contact with the inner ventricular wall.

[0096] In the case of horizontal stabilizing elements, the element itself can (as explained above) be a complete ring, a partial ring or a curved elongate arm. While in some complete ring embodiments (as shown, for example, in Fig. 9), the stabilizing element is constructed from a single looped wire or solid band, in other embodiments, it may be constructed in the form of a stent-like mesh. Fig. 10A illustrates one embodiment of this type, in which the mesh-like stabilizing element **390** is attached directly to the upper support element **380** of valve support device **370**. Alternatively, as shown in Fig. 10B, the mesh-like stabilizing element **390** may be connected to the upper support element **380** by means of additional bridging members **400**, which serve as spacer arms, increasing the separation distance between the stent-like mesh stabilizer **390** and said support element **380**.

[0097] While the stabilizing element is generally constructed such that its outline shape is that of a smooth curve, in one preferred embodiment, as depicted in Fig. 11, this smooth curve is broken by one or more constricted regions **410**, wherein said regions act as spring-like elements, increasing the force that said stabilizing element **420** is capable of applying to the inner ventricular or atrial wall, and thereby enhancing the ability of said stabilizing element to stabilize the valve support device **370**. The device shown in Fig. 11 contains two vertical stabilizing elements – a ventricular stabilizing element attached to the lower support element and an atrial stabilizing element attached to the upper support element. In other versions of this embodiment, the valve support device may be fitted with one vertical stabilizing element (attached to one support element) and one horizontal stabilizing element (attached to the other support element). In some other embodiments, the valve support device contains only one such stabilizing element (horizontal, vertical or otherwise angled). In still further embodiments, a single valve support device may contain one stabilizing element containing one or more constricted regions **410**, as shown in Fig. 11, together with one or more stabilizing elements of any of the other types disclosed and described herein.

[0098] A further example of a valve support device fitted with a combination of different stabilizing elements is shown in Fig. 12. Thus, lower support element **480** of valve support device **430** is fitted with a vertically aligned ring-like ventricular stabilizing element **460**, while a horizontally-aligned atrial stabilizing element **470** is connected *via* additional bridging elements **450** to upper support element **440**. While only two additional bridging elements **450** are depicted in this figure, as many such elements as necessary may be incorporated into the device. Of course, in other versions, the arrangement of the stabilizing elements shown in Fig. 12 may be reversed, such that the valve support device contains a horizontal lower stabilizing element and a vertical upper stabilizing element. As mentioned above, all possible combinations of the various types of stabilizing element disclosed herein may be used, as appropriate. It should also be noted that more than one stabilizing element may be attached to one or both support elements. Fig. 13 illustrates one embodiment of this type, in which the upper support element **510** of the valve support device **500** is fitted with several (in this case, three) non-horizontal, angled, atrial stabilizing elements **520**.

[0099] As explained hereinabove, the stabilizing element need not be provided in the form of a complete ring, but rather may also have the form of a partial ring or a curved elongate arm. Various examples of the latter type of stabilizing element are shown in Figs. 14A, B and C. (For the sake of clarity, only the upper support element of the valve support device is shown in these figures. It should be noted, however, that in all cases, these valve support devices will all comprise both a first, upper support element that is implanted above the anatomical annulus, and a second, lower support element that is implanted below the annulus.) Thus, Fig. 14A depicts an upper support element **540** of a valve support device of the present invention, wherein said valve support device is connected to – and stabilized by - two curved elongate arms **560** which are disposed vertically downwards along the inner ventricular wall **580**. In the example shown in this figure, the stabilizing elements **560** are constructed from an elastic material (such as cobalt base alloy, nitinol, stainless steel and other biocompatible metals and metal alloys). The curved arms typically have a length of between 1 mm and 50 mm, preferably about 20 mm. As will be seen in the figure, the upper part of each stabilizing element **560** is angled such that it is able to pass around the cardiac annulus **600**. In some embodiments, the elongate, curved elastic arms may be constructed such that they are in a state of pre-load. The elastic properties of the stabilizing elements will cause said element to tend to both grip the annulus and to apply an outward force on the ventricular wall inferior to the annulus. In an alternative embodiment of this aspect of the invention, the curved elongate stabilizing elements may be constructed from a

plastically-deformable material such as stainless steel, cobalt base alloy and nitinol. In this case, the elongate arms are molded around the annulus using a clenching or crimping tool. In this way, the upper sections of the elongate arms will firmly grip the annulus, while the lower sections will be biased outward and downwards along the ventricular wall.

[00100] Fig. 14B illustrates another embodiment of this aspect of the device, wherein the stabilizing elements **560a** attached to upper support element **540** are much shorter than those shown in Fig. 14A, and apply a stabilizing force to the inferior surface of the annulus **600** (rather than to the lateral inner walls of the ventricle). During implantation, the stabilizing elements are brought into position below the annulus, such that the annulus becomes "trapped" between said stabilizing elements and the upper support element itself.

[00101] A still further variant of this embodiment is illustrated in Fig. 14C. This variant differs from the embodiment shown in Fig. 14B, in that the upper support element **540** is fitted with both upper (**560s**) and lower (**560i**) stabilizing elements. During implantation into a patient, the valve support device is manipulated such that the annulus **600** becomes "trapped" between these upper and lower stabilizing elements. In each of the variants of this embodiment, the short stabilizing elements may be brought into position by means of a balloon expansion mechanism, by a mechanical closure mechanism or, alternatively, said stabilizing elements may be self-expanding.

[00102] Fig. 15 depicts an alternative design of the valve support of the present invention, additionally comprising a horizontally-disposed ring-shaped stabilizing element **660**, located between the upper support element **640** and the lower support element (not shown). Elastic members **620** mutually connect the upper support element (**640**) and said additional ring support (**660**). The annulus **600** may thus become trapped or pinched between them (as indicated by the arrows). This design may either be used without any additional stabilization elements, or in combination with any of the stabilization element embodiments described hereinabove.

[00103] In a still further embodiment, as depicted in Fig. 29A, the valve support device as viewed from above is seen to comprise a pair of elastic stabilizing elements **958**, one on each side of the upper support element **960**. These stabilizing elements may be manufactured from biocompatible metals including (but not limited to) Nitinol, Cobalt and Stainless steel, and are manufactured in the form of a spring-like tab that permits the elastic forces applied by the device on the ventricular wall to be distributed over a large surface area, so as to minimize local pressure on the cardiac tissue, thus minimizing the danger of necrosis of cardiac tissue due to high-level mechanical stress. The structure of the tab-like stabilizing elements **958** may be better

seen in the side view of this embodiment of the device, presented in Fig. 29B. As may be seen from these figures, each tab may preferably be covered by a biocompatible fabric or mesh **962** (for example made from Dacron, PTFE etc.), the key functions of which are to assist in distributing the force, as previously explained, and also to encourage growth of cardiac tissue on the device, thus improving the attachment thereof to the heart wall. One particular advantage of using this type of stabilizing element is that it approximates the upper support element to the floor of the left atrium, thus essentially compressing the annulus (the stabilizing element compressing from the ventricular side and the upper support element compressing from the atrial side), thereby forming a "plug" that will prevent paravalvular leakage, even in cases in which the annulus is larger in diameter than the prosthetic valve, provided that the upper support element is larger than the annulus. In this embodiment, the upper support element may be fitted with one or more stabilizing elements of this type, which may be distributed evenly or unevenly around the circumference of said support element. Exemplary dimensions of this tab-like stabilizing element are as follows: width 2-20 mm; and length 2 – 20mm. However, it is to be recognized that these measurements are for the purposes of illustration only, stabilizing elements of dimensions larger or smaller than these ranges being included within the scope of the present invention.

[00104] In some embodiments of the present invention, the careful selection of a correctly-sized valve support device will permit said support device to be self retaining in the region of the annulus following self-expansion during device delivery, as will be described hereinbelow. In other cases, however, the valve support device of the present invention will further comprise one or more heart tissue anchoring means or mechanisms (connected to the support elements and/or bridging members) for firmly anchoring said valve support to the cardiac tissue. In one embodiment of this aspect, the cardiac anchoring means comprise a plurality of spiral or hook-like anchors. An example of this type of anchoring means is illustrated in Fig. 16, which shows a guide catheter **710** being used to deliver a valve support device **700** of the present invention. At the stage of the delivery process shown in this figure (which will be described in more detail hereinbelow), both of the support elements, **720** and **740**, as well as the bridging members have self-expanded into their working conformations. It will be seen that the upper support element is fitted with two spiral cardiac attachment anchors **760**, the sharp free ends of which face laterally. The bases (i.e. medial ends) of the anchors are connected to control wires **780** that pass upwards and proximally through guide catheter **710**, eventually leaving the patient's body and ending at a proximal control console. Once the valve support device has been manipulated into the desired

position (as shown in the figure), the spiral anchors **760** are caused to rotate by means of the operator manipulating the proximal ends of the control wires, thereby becoming inserted within the cardiac tissue and thus firmly anchoring the valve support device in its operating position.

[00105] It is to be noted that Fig. 16 presents only one exemplary design for the cardiac tissue anchors, and many others are possible and included within the scope of the present invention. Thus, in another embodiment, hook-like anchors are attached at various points along the surface of the valve support device, either on the support elements, the bridging members or both. This embodiment is illustrated in Fig. 17 which depicts a typical valve support device **700**, comprising an upper support element **720**, a lower support element **740** and two bridging members **750**, on the surface of all of which are distributed a number of hook-like anchors **770**. (Nine such anchors are shown in the figure.)

[00106] In some situations, it is advantageous for the cardiac tissue anchors to adopt a closed, inactive conformation during insertion of the valve support device into the body, in order to avoid both trauma to the patients tissues and to avoid premature anchoring (for example at an incorrect location). Then, when said device is correctly positioned, the anchors would be caused to move from their closed, inactive conformation to an open active position. There are a number of ways to implement this type of embodiment. Thus, in a first implementation, the cardiac attachment anchor is constructed with two or more backwardly-pointing self-opening distal arms. During insertion and implantation, the distal arms are retained in a closed conformation by means of a small loop of resorbable suture material. Then, after a certain period of time following insertion of said attachment means into the ventricular tissue (e.g. between a few hours and a few weeks), said suture dissolves, thereby permitting the distal arms to adopt their open conformation. This embodiment is illustrated in Figs. 18a and 18b: in Fig. 18a, the distal anchor arms **790** are shown retained in their closed position by means of suture **800**. In Fig. 18b, the required length of time has elapsed (following insertion) and the suture has dissolved, releasing the distal anchor arms and allowing them to spread apart within the cardiac tissue, thereby increasing the resistance to withdrawal offered by said anchor.

[00107] In a further embodiment of this type, the anchor hooks are manufactured from a shape memory material, such as biocompatible nickel-titanium alloys (e.g. Nitinol). During insertion, the anchors are in their closed conformation, but following the implantation procedure the rise in temperature experienced during insertion into the patient's body results in opening of the anchors, as they regain their initial shape.

[00108] In a still further embodiment of this type, as shown in Figs. 19A and 19B, the anchor hooks are protected by a cover element **820** (such as a sleeve or a piece of tubing) which is manufactured from a material with limited flexibility, such as PET, nylon and similar biocompatible plastics. After the operator is satisfied that the valve support device has been implanted at the correct site, control elements **840** attached to the cover elements are pulled, thereby withdrawing them through the guide catheter, thus permitting the anchor hooks to freely adopt their open conformation and to become inserted into the cardiac tissue. In the design shown in Fig. 19A, each anchor is protected by its own individual cover, while in Fig. 19B a single cover element protects all of the anchors (not shown) that are attached to the upper support element.

[00109] Figs. 20A and 20B illustrate a yet further embodiment of this aspect of the invention. Thus Fig. 20A shows a barbed anchor **860s** attached to a support element **880** is maintained in an inactive, straight conformation by means of an overtube **890**, which also serves to protect the patient's tissues from trauma during insertion and implantation of the valve support device. Following implantation at the desired site, as shown in Fig. 20B, overtube **890** is pulled away from the anchor **860c** (for example, by means of pulling a control wire), which now adopts its "natural", curved conformation, during which shape transition, said anchor now pierces the cardiac tissue (indicated by the letter A in the figure). Suitable anchors for use in this embodiment can be manufactured from shape-memory materials or from super-elasticity materials such as Nitinol, cobalt base alloy and spring-tempered stainless steel. Typically, anchors of this type will have a mid-length diameter of between about 0.2 mm and 1 mm, and a length in the range of about 2 to about 10 mm. Suitable overtubes may be manufactured from biocompatible polymers such as braided nylon and PET to a tolerance that permits a tight fit over the anchor.

[00110] It is to be noted that the cardiac tissue anchors described hereinabove may, in certain cases, be used to attach the valve support device of the present invention to the anatomical valve leaflets and chordae (in addition to, or instead of attaching said device to the inner ventricular wall). In this regard, the present invention also encompasses additional types of cardiac tissue anchor which are characterized by having a plurality of anchoring wires that advantageously become entangled within the valve leaflets and chordae. Anchors of this type are particularly suitable for use in attaching the lower support element and bridging members to the aforementioned anatomical structures.

[00111] In one still further embodiment, the cardiac tissue anchors may be provided in the form of small clips (similar to vascular clips used to close blood vessels during surgical procedures, and well known to the skilled artisan). An example of the use of this embodiment is shown in Fig. 30, in which clip **952** is used to attach the upper support element **954** to the annulus **956**. Clips of this type may also be used to attach the upper support element to atrial wall tissue and/or anatomical valve leaflets. In one particularly preferred embodiment the clip is caused to attach to the tissue in the area of the trigone – an anatomical area, on two opposite sides of the mitral valve, which has more fibrous tissue –and which is therefore able to provide a firm base for anchoring the valve support device.

[00112] In another embodiment (not shown), the clip may be an integral part of the upper or lower rings, or the bridges. This may be achieved by attaching one of the jaws of the clip to the valve support device, while the second of the jaws is free to be plastically deformed and to become anchored to the tissue.

[00113] In the case of certain replacement valves that may be used in conjunction with the valve support device of the present invention, the radially-outward forces exerted by the expanded replacement valve are sufficient to stably retain said valve within the inner cavity of said valve support device. However, in some instances – particularly when self-expanding replacement valves are being implanted – the radial force exerted by the expanded valve may be insufficient to ensure that it can withstand all of the physiological forces exerted therein during all stages of the cardiac cycle. In such circumstances, the bridging members and/or support elements of the valve support device may further comprise a valve engagement portion. In one embodiment, the valve engagement portion may comprise a series of zigzag-like folds or pleats in the central, innermost region of the bridging members. These folds or pleats interact with the struts or other structural features of the replacement valve, thereby stabilizing said valve within the valve support device.

[00114] In another embodiment, the valve engagement means comprise either inward facing or outward facing anchors, whose purpose is engage with the external struts of the replacement valve, thereby stabilizing said valve within the support device.

[00115] Fig. 21 depicts a valve support device of the present invention comprising both of the aforementioned embodiments of valve engagement means. Thus, it may be seen that the central portions of the bridging members 850 are folded into a series of pleats 860. In addition, said bridging members are also provided with both inward facing **870** and outward facing **880** anchors.

[00116] Figs. 22A and 22B show a still further embodiment of the valve engagement means, attached to an exemplary support element **900** of the present invention. Thus, in Fig. 22A, four short lengths of a soft biocompatible material (such as a biocompatible fabric, silicon, PET etc.) **920i** are attached to the inner surface of element **900**. Upon expansion of the replacement valve stent within the inner space of the valve support device, the soft material is caused to penetrate between the valve stent struts, thereby forming engagement "teeth" that serve to stabilize the replacement valve – support device assembly. Fig. 22B depicts a very similar set of four valve engagement means **920t** formed from a soft biocompatible material. However, in the case of this version, the soft material is provided in the form of tubular sleeves surrounding (partially or completely) support element **900** at the four locations shown in the figure.

[00117] Figure 2A illustrates an exemplary delivery device and mitral valve support therein in a collapsed delivery configuration. Delivery device 30 includes actuation portion 35 that includes actuator 34. Delivery device 30 also includes elongate body 32, which is secured to actuation portion 35. Delivery device 30 also includes guidewire lumen 42 coupled to luer 38, wherein lumen 42 is adapted to be advanced distally over guidewire 40 (see Figure 2B) to advance delivery device 30 to a target location within the subject. The portion of delivery device 30 to the left of the broken lines can be considered the proximal portion of delivery device 30, at least a portion of which remains external to the patient during the procedure, providing a user access to actuation portion 35. The portion of the device to the right of the broken line can be considered the distal portion, and is generally considered the portion of the delivery device adapted to be advanced through a patient during the procedure. Actuator portion 35 includes actuator 34 that is adapted to be actuated to control the movement of elongate body 32. Specifically, actuation of actuator 34 controls the axial (i.e., proximal and distal) movement of elongate body 32 relative to inner lumen 42 and to valve support 44. In Figures 2A and 2B, rotation of actuator 34 controls the relative axial displacement of elongate body 32, but any other suitable type of actuator can be used and incorporated into the system to control the axial displacement of elongate body 32. Lumen 42 is axially displaceable relative to elongate body 32 by axial movement of the proximal end of lumen 42. Delivery device 30 also includes device coupling members 36, which extend out of the proximal end of the proximal portion of device 30, and also extend distally radially within elongate body 32 yet external to guiding lumen 42. The distal regions of device coupling members 36 are releasably secured to valve support 44 during the deployment procedure (as shown in Figures 2A and 2B), but are also adapted to be controllably released from valve support 44 to release the valve support from the delivery device.

Coupling members 36 can be actuated by actuating their proximal portions external to the patient to control movement of valve support 44. In Figure 2A valve support 44 is in a collapsed delivery configuration within elongate body 32 and disposed external to guiding lumen 42. In the delivery configuration, the annular portions 45 of valve support 44 are collapsed down upon bridge members 47 (only one bridge member shown). When collapsed, roughly each half of an annular support 45 is collapsed down and has a C-shaped configuration with a tighter curved configuration (i.e., a portion with a smaller radius of curvature) than when in the expanded configuration (also see the delivery configuration of the valve support shown in Figure 2C). When in the delivery configuration, bridge members 47 assume a straighter configuration than when in the expanded configuration. As described in more detail below, the annular support elements can be biased to bend at certain locations to ease their collapse during the loading process and during any recollapsing that may be needed. The axial position of the collapsed valve support is controlled by coupling members 36. Figure 2B illustrates a portion of the process for releasing valve support 44 from delivery device 30 (more details of which are described below). Actuation of actuator 34, shown as rotation of actuator 34, causes elongate body 32 to retract in the proximal direction. Guiding lumen 42 can be maintained in position or advanced distally while the elongate body 32 is retracted. The relative movement between elongate body 32 and coupling members 36 (to which valve support 44 is attached) allows valve support 44 to begin to expand as elongate body 32 is moved proximally. In Figure 2B, a first of the valve support's elements (and a small portion of bridge members 47) has expanded. Continued retraction of elongate body allows valve support 44 to fully expand, yet still be coupled to coupling members 36.

[00118] Figure 2C illustrates an alternative perspective view of delivery device 30, illustrating both of the bridging members 47. In Figure 2C, however, support elements 45 are adapted to deform generally axially away from the ends of the bridging members when collapsed within elongate body 32 in the delivery configuration.

[00119] In the embodiments in Figures 2A-2C, elongate body 32 can be, for example without limitation, a catheter, examples of which are well known. Actuation portion 35 can be, for example without limitation, a touhy borst, allowing rotation of actuator 34 to control the axial movement of elongate body 32. Guiding lumen 42 can be, for example without limitation, a corrugated steel reinforced lumen to allow for sufficient flexibility while being advanced through the vasculature. Guiding lumen 42 can also be any other type of suitable guiding lumen.

[00120] Access to the mitral valve or other atrioventricular valve will preferably be accomplished through the patient's vasculature percutaneously (access through the skin). Percutaneous access to a remote vasculature location is well-known in the art. Depending on the point of vascular access, the approach to the mitral valve can be antegrade and require entry into the left atrium by crossing the interatrial septum. Alternatively, approach to the mitral valve may be retrograde where the left ventricle is entered through the aortic valve. Alternatively, the mitral valve can be accessed transapically, a procedure known in the art. Additional details of an exemplary antegrade approach through the interatrial septum and other suitable access approaches can be found in the art, such as in U.S. Patent No. 7,753,923, filed August 25, 2004, the contents of which are incorporated herein by reference.

[00121] While the support structures herein are generally described as a support for replacement mitral valves, they can be delivered to a desired location to support other replacement cardiac valves, such as replacement tricuspid valves, replacement pulmonic valves, and replacement aortic valves.

[00122] Figures 3A-3E illustrate a section view of heart H, illustrating an exemplary method of deploying a valve support within a native mitral valve MV. Access to the mitral valve has been gained using a known approach through the femoral vein, IVC, right atrium, across the interatrial septum S, and into the left atrium LA. Exemplary details of such an approach can be found in, for example, without limitation, U.S. Patent No. 7,753,923. As shown in Figure 3A, guide catheter 50 (e.g., an 18 F guide catheter) has been advanced over guidewire 52 through septum S to provide access to the mitral valve. Guidewire 52 has been advanced through the native mitral valve and into the left ventricle to allow the delivery device to be advanced over guidewire 52 and into position within the native mitral valve. Alternatively, guide catheter 50 can be advanced over guidewire 52 into position, and guidewire 52 can then be removed. The delivery device can then simply be advanced through guide catheter 50 without the use of guidewire 52. Guidewire 52 may preferably be left in place, however, to allow a subsequently delivered replacement mitral valve to be advanced over the guidewire 52.

[00123] In Figure 3B, delivery device 54 with a valve support collapsed therein has been advanced over guidewire 52 and through guide catheter 50, and out of the distal end of guide catheter 50. Delivery device 54 is advanced through the leaflets L of the native mitral valve, such that the distal end of elongate body 55 is disposed in the left ventricle LV, as shown in Figure 3B.

[00124] As shown in Figure 3C, elongate body 55 is then retracted proximally relative to the valve support, releasing the valve support from elongate body 55 (for example, using an actuator such as actuator 34 in Figures 2A-2C). In this embodiment, the valve support is made of a resilient material, such as nitinol, and begins to self-expand as elongate body 55 is retracted. In Figure 3C, first support element 58 has self-expanded to the expanded annular configuration as shown. When support element 58 expands, it engages ventricular cardiac tissue below the plane of the mitral valve annulus, securing itself against tissue. Support element 58 is preferentially positioned in the sub-annular space, anchoring against the papillary muscles and chords with minimal or no damage to any of them so as not to interfere with their functioning. Support element 58 is preferably expanded distal enough such that native mitral valve leaflets can function even after expansion of support element 58. As discussed above, in some embodiments the lower, or inferior, support element has a smaller diameter than the upper, or superior, support element to match interpapillary distance as measured from the subject being considered. The smaller relative diameter provides the lower support element the ability to oppose the papillary tendons without displacing them. The tendons are attached at one end to the papillary muscles and at the other end to the native leaflets, and displacing the tendons or the muscles would prevent the native leaflets from properly closing, causing regurgitation during the expansion of the valve support. The lower support element is therefore secured in place without interfering with the function of the native leaflets. Referring briefly to Figure 7, an exemplary valve support is shown expanded in place. Lower support element 130 is shown with a smaller diameter than upper support element 126. Support element 130 is opposed to tendons 124 but is not displacing them, and as such is not interfering with the function of papillary muscles 122 and tendons 124. Support element 130 is expanded in the sub-annular space, while support element 126 is expanded in the left atrium LA. While the embodiments shown herein may appear to show a lower support element that is displacing the tendons and/or papillary muscles, it is intended that the lower support is properly sized such that it is expanded in the manner shown in Figure 7.

[00125] Referring back to Figure 3C, elongate body 55 has been retracted proximally relative to a portion of bridge members 60, allowing a portion of bridge members 60 to expand. Support element 58 can be recollapsed back within elongate body 55 at this point in the procedure if necessary. The positioning of the valve support can be visualized using known visualization techniques (e.g., fluoroscopy, or any other imaging modalities as necessary) and if it is determined that support element 58 is not positioned properly, elongate body 55 can be advanced distally relative to the valve support, coupling members 64 can be retracted relative to elongate

body 55, or a combination of the two can be performed to recollapse at least a portion of support element 58 back within elongate body 55. The valve support can then be repositioned, and support element 58 can then be re-expanded to secure proper placement in the desired anatomical position or space.

[00126] As shown in Figure 3D, continued proximal retraction of elongate body 55 (not shown in Figure 3D) allows the second support element 62 to self-expand, securing itself against the lateral wall of the atrium above the mitral valve annulus. In some embodiments the second support element includes one or more fixation elements, such as in the form of anchors, barbs, clips, etc., that help secure the second support element against cardiac tissue, or that are adapted to pierce into cardiac tissue to secure the support element to cardiac tissue. One or more fixation elements, if used, can be disposed around the periphery of the support element. They can assume a collapsed, or delivery configuration for delivery of the system, but can deploy to an expanded, or anchoring, configuration, when released from the delivery system. For example, the fixation elements can be an elastic material that self-expands to an anchoring configuration. Alternatively, the fixation elements can be actuated to reconfigure them to a fixation configuration. In some embodiments, however, the one or more fixation elements are not adapted to change configurations. The mitral valve leaflets are not shown in Figure 3D for clarity. Coupling members 64 (only one can be seen in Figure 3D) are still controllably secured to second support element 62. Support element 62 can be recollapsed back within elongate body 55 at this point in the procedure. This can occur as described above with respect to support element 58. In some embodiments support element 62 can be adapted to preferentially bend (for collapsing towards its delivery configuration) at or near the point at which coupling members 64 are secured. If it is determined that support element 62 should be recollapsed within elongate body 55, a proximally directed force can be applied to coupling members 64, thereby applying a force on support element 62. If support element 62 is adapted to preferentially bend at the location at which the coupling members are secured, the force will be applied at the location at which the support is adapted to preferentially bend. This will allow support element 62 to be deformed towards its collapsed configuration more easily and more efficiently. Once support element 62 is collapsed within elongate body 55, continued retracting of coupling members 64 can cause support element 58 to collapse as well. Support element 58, like support element 62, can be adapted to preferentially bend at certain locations, easing the deformation towards its delivery configuration.

[00127] The locations on support element 62 (and support element 58) from which bridge members 60 extend are roughly 180 degrees apart from one another, similar to the roughly 180 separation of the native leaflet coaptation points. In the expanded configuration shown in Figure 3D, the locations on the support elements from which the bridge members extend are generally preferably positioned at the ends of the line of coaptation between the two native valve leaflets. That is, a line connecting the points on the support elements from which the bridge members extend is preferentially (although not necessarily) in alignment with the line of coaptation of the native valve leaflets. One or both support elements may have radiopaque markers at these locations to assist in proper orientation of the valve support in place. By positioning the bridge members in these locations relative to the native leaflets, the bridge members do not interfere with the functioning of the native valve leaflets during the implantation procedure (or at least interfere minimally), even after the valve support is deployed to the fully expanded configuration shown in Figure 3D. Because the native leaflets can function during this part of the procedure, time is not a critical factor during the deployment of the valve support.

[00128] While the support structures herein are generally described as including two bridging elements, the support structures can be have more than two bridging elements disposed in any configuration around the support structures.

[00129] Next, guiding member 56 is retracted from the patient, leaving guidewire 52, guide catheter 50, and elongate body 55 in place, as shown in Figure 3E. Guide catheter 50 and guidewire 52 can now provide access to the mitral valve to allow a replacement mitral valve to be secured to the valve support which has been expanded and secured within the native valve.

[00130] Figures 4A-4D illustrate the subsequent delivery and expansion of an exemplary replacement mitral valve. In Figure 4A, a balloon catheter with balloon 70, along with replacement valve 72 thereon, has been advanced over guidewire 52 and within guide catheter 50 to the position shown radially within the expanded valve support. In general, replacement valve 72, which in this example comprises an expandable stent and replacement leaflets secured thereto, is advanced until it is positioned radially within valve engagement portions 61 of the bridge members. Once the replacement valve is determined to be in an optimal position across the atrio-ventricular line (e.g., using a visualization technique such as echocardiogram), the replacement valve can be expanded.

[00131] As shown in Figure 4B, balloon 70 is expanded by filling it with an expansion fluid, a procedure known in the art. Expansion of balloon 70 expands the expandable stent portion of the replacement valve. Expansion of the stent applies radially outward forces on the bridge

members of the valve support, causing them to expand (or rather, deform in a general radially outward direction). As the stent expands, the stent pushes the native leaflets outward towards the annulus. As the stent expands, apertures in the stent defined by the stent material are adapted to engage with protrusions or other surface features of the valve engagement portion of the bridge members to secure the expandable stent to the bridge members. The radially inward bias of the bridge members also helps secure the replacement valve within the valve support by applying a radially inward securing force on the stent. The stent is applying a radially outward force on the bridge members as well, and the two interact to allow the replacement valve to be secured in place, preventing the replacement valve from being displaced axially as well as from being collapsed. Additionally, the bridge members can be adapted to assume a preferential expanded configuration (such as is shown in Figure 4B) when expanded replacement valve expansion process. For example, the bridge members can be adapted to have bending points 75 at which the bridge members will preferentially bend when expanded, which will prevent the two support members from migrating axially away from one another during the replacement valve expansion process. Bending points 75 can also assist in securing the replacement valve relative to the support structure.

[00132] In another preferred embodiment (not shown here) the stent of the replacement valve is expanded and comes into contact with the upper support element 62, and the radial force of the expanded stent causes friction between the stent and the support element, this force being strong enough to stabilize and hold the stent and replacement valve within the upper support element of the valve support device. In another embodiment, a self expanding stented replacement valve may be expanded and similarly anchor (or expand onto) to the upper support element by means of radially outward forces between the replacement valve and the upper support element.

[00133] After the replacement valve has been expanded and secured in place, balloon 70 is deflated and withdrawn, along with the guidewire, from the patient, as is shown in Figure 4C. Once the balloon is deflated, the leaflets L of the replacement mitral valve begin to function. Three leaflets are shown to illustrate that known replacement aortic valves, mere examples of which are described in U.S. Patent No. 7,585,321, filed May 27, 2005, can be used in this exemplary procedure to replace the native mitral valve.

[00134] While a balloon expandable replacement heart valve has been shown, the replacement heart valve can be self-expanding as well.

[00135] Once the replacement valve is secured in place within the valve support, coupling members 64 are disengaged from support element 62. In this exemplary embodiment the distal

ends of coupling members 64 have threads which adapted to engage threaded bores within support element 62. Rotation of coupling members 64 causes the coupling members 64 to be unscrewed from support element 62, thereby uncoupling the coupling members 64 from support 62. Guide catheter 50 is then removed from the patient, leaving the implant in place, as shown in Figure 4D.

[00136] As set forth above, the mitral valve can be accessed via a transapical approach, or though the apex of the heart. In such an approach, coupling members 64 would be secured to inferior support element 58 rather than superior support element 62, as shown in the embodiments herein. The coupling members 64 could still be actuated in the same manner as described herein.

[00137] Figures 5A-5D illustrate an exemplary delivery device and mitral valve support therein in a delivery configuration. The delivery device and mitral valve support are similar to those shown in the embodiments in Figures 2A-2C. Delivery device 80 includes hemostasis valve 82 comprising rotating male luer lock 81 and female luer sideport 83. Delivery device 80 also includes elongate body 84 secured to actuator 85, wherein actuator 85 is adapted to be rotated to control the axial movement of elongate body 84. Device 100 is collapsed within elongate body 84 and is disposed radially outward relative to lumen 86. Delivery device 80 also includes guidewire lumen 86, which is adapted to receive guidewire 90 therein, coupled to luer 88, which are adapted to move axially relative to elongate body 84. Coupling members 92 are reversibly secured to valve support 100 as set forth in the embodiments above. Other details of delivery device 80 can be the same as those described in the embodiments above.

[00138] In Figure 5B, actuation of actuator 85 causes proximal retraction of elongate body 84 relative to valve support 100. This causes distal support element 101 of valve support 100 to begin to self-expand to a deployed configuration against tissue (anatomy not shown for clarity), such as in the embodiment in Figure 3A-3E. Hemostasis valve 82 can alternatively, or in addition to, be pulled proximally (as indicated in by the arrow in Figure 5B) to cause elongate body 84 to retract relative to valve support 100. In addition, or alternatively, guiding lumen 86 can be advanced distally (as indicated by the arrow in Figure 5B) relative to elongate body 84. These types of motion can cause or assist in the expansion of the valve support.

[00139] As shown in Figure 5C, bridge members 102 of valve support 100 continue to be expanded by relative proximal movement of elongate body 84. This can be performed by proximal movement of the elongate body (as indicated by the arrow), by distally advancing lumen 86, or any combination of the two. Continued relative movement of elongate body 84

eventually causes second support element 103 to expand to a deployed configuration, as shown in Figure 5D. As second support element 103 self-expands, coupling members 92 can extend radially outward along with support element 103.

[00140] Once the valve support is determined to be positioned in place, coupling members 92 can be removed to allow for a replacement heart valve to be positioned within the valve support, an example of which is shown in Figures 4A-4D.

[00141] Figure 6 illustrates a section view of one-piece valve support 110, including first support element 114, second support element 116, bridging members 118, and coupling elements 112, which are shown as threaded bores and are adapted to securingly engage threaded portions of coupling members, examples of which are described above.

[00142] Figures 8A and 8B illustrate an alternative embodiment of a valve support. Valve support 200 includes components to mitigate para-valvular leakage. In addition to support elements 202 and 204 and bridge members 206 and 208, valve support 200 includes one or more flaps 210 and 212. The flaps extend coverage of the valve support system and help mitigate para-valvular leakage, functioning similarly to mudflaps on an automobile. During delivery exemplary flaps 210 and 212 are tucked around or against superior support element 202 as shown in Figure 8B, and upon deployment from the catheter, flaps expand or extend to the configuration shown in figure 8A (native valve not shown for clarity). The flaps can be made of a flexible biocompatible material such as a wide variety of polymeric compositions. The flaps can be secured to the valve support by any suitable mechanism, such as by suturing the flaps to the support element, or to covered material, and using the bridge member to prevent the suture material from being displaced.

[00143] When deployed, in some embodiments the flaps are disposed above the annulus and over the side of the superior support element, which may not be extending all the way to the atrial wall. This can extend coverage of the valve support system for a few millimeters, reducing para-valvular leakage. Alternatively, in some embodiments in which the support element is larger, the flaps are urged against the atrial tissue. In this use, the flaps act as an additional seal when the valve support system is in place. The one or more flaps can therefore be a component of the valve support system that reduces para-valvular leakage and/or acts as an additional seal.

[00144] While some embodiments have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art

without departing from the disclosure. It should be understood that various alternatives to the embodiments of the disclosure described herein may be employed in practicing the disclosure.

CLAIMS

WHAT IS CLAIMED IS:

1. A cardiac valve support adapted for endovascular delivery to a cardiac valve, comprising:

first and second support elements each having a collapsed delivery configuration and a deployed configuration;

and wherein at least two bridging members extend from the first support element to the second support element, said bridging members having a delivery configuration and a deployed configuration, wherein said bridging members extend radially inward from the first and second support elements in the deployed configuration.

2. The cardiac valve support of claim 1 wherein the bridging members extend from discrete locations around the support elements.

3. The cardiac valve support of claim 2 wherein the bridging members are arranged symmetrically around the circumference of the support elements.

4. The cardiac valve support of claim 2 wherein the first and second bridging members extend from adjacent support elements about 180 degrees from one another.

5. The cardiac valve support of claim 1 wherein at least one of the support elements has an annular shape.

6. The cardiac valve support of claim 1 wherein the bridging members and/or the support elements are fitted with replacement valve engagement means adapted to securely engage a replacement heart valve.

7. The cardiac valve support of claim 6 wherein the replacement valve engagement means comprise a soft biocompatible material fitted to the external surface of portions of the support elements and/or bridging members.

8. The cardiac valve support of claim 6 wherein the engagements means each have a locking element adapted to securely lock with a portion of a replacement heart valve.

9. The cardiac valve support of claim 1 wherein the bridging members and/or the support elements are fitted with heart tissue anchoring means adapted to securely anchor said support elements to the heart wall.

10. The cardiac valve support of claim 1, further comprising one or more intra-ventricular stabilizing elements.

11. The cardiac valve support of claim 1, further comprising one or more intra-atrial stabilizing elements.

12. The cardiac valve support of claim 1, further comprising one or more intra-ventricular stabilizing elements and one or more intra-atrial stabilizing elements.

13. The cardiac valve support of claim 1 wherein the first and second support elements are adapted to preferentially bend at at least one location.

14. The cardiac valve support of claim 1 wherein the first and second support elements each have a curved portion in their deployed configurations, wherein the curved portions are adapted to assume a tighter curved configuration in the collapsed delivery configurations.

15. The cardiac valve support of claim 1 wherein the first and second bridging members are generally C-shaped in their deployed configurations.

16. The cardiac valve support of claim 1 wherein the first support element has at least one coupling element adapted to reversibly couple to a delivery system.

17. The cardiac valve support of claim 16 wherein the at least one coupling element is a threaded bore.

18. The cardiac valve support of claim 1 wherein the second support element has a dimension in the deployed configuration that is larger than a dimension of the first support element in the deployed configuration.

19. The cardiac valve support of claim 1, comprising only two bridging members.

20. A system adapted for endovascular delivery or transapical delivery to replace a mitral valve, comprising:

a cardiac valve support according to any one of the previous claims; and

a replacement heart valve comprising an expandable anchor and a plurality of leaflets adapted to be secured to the cardiac valve support.

21. The system of claim 20 wherein the bridging members are adapted to securingly engage the replacement heart valve.

22. A method of replacing a patient's mitral valve, comprising:

delivering a valve support to a location near a subject's mitral valve, the valve support comprising a first support element, a second support element, and at least two bridging members extending from the first and second support elements;

expanding the first support element from a collapsed configuration to a deployed configuration secured against cardiac tissue below the plane of the mitral valve annulus;

expanding the bridge members from delivery configurations to deployed configurations positioned in general alignment with the coaptation points of the native mitral valve leaflets; and

expanding the second support element from a collapsed configuration to a deployed configuration secured against left atrial tissue above the plane of the mitral valve annulus.

23. The method of claim 22, wherein the valve support is delivered endovascularly.

24. The method of claim 22, wherein the valve support is delivered by the transapical route.

25. The method of claim 22, further comprising the step of causing attachment means fitted to the support elements and/or bridging members to become inserted into the ventricular wall.

26. The method according to claim 22, wherein said method further comprises the step of causing intra-ventricular stabilizing elements and/or intra-atrial stabilizing elements to engage, respectively, the inner ventricular wall and/or inner atrial wall.

27. The method of claim 22 further comprising securing a replacement mitral valve to the valve support.

28. The method of claim 27, wherein the replacement mitral valve is delivered by the same route as the valve support.

29. The method of claim 27, wherein the replacement mitral valve and the valve support are delivered by different routes, wherein said routes are selected from the group consisting of trans-septal, transfemoral and transapical.

30. The method of claim 27 wherein securing the replacement mitral valve to the valve support comprises expanding the replacement mitral valve from a collapsed delivery configuration to an expanded configuration.

31. The method of claim 27 wherein securing a replacement mitral valve to the valve support comprises causing valve attachment means fitted on the valve support elements and/or bridging members to engage said replacement mitral valve.

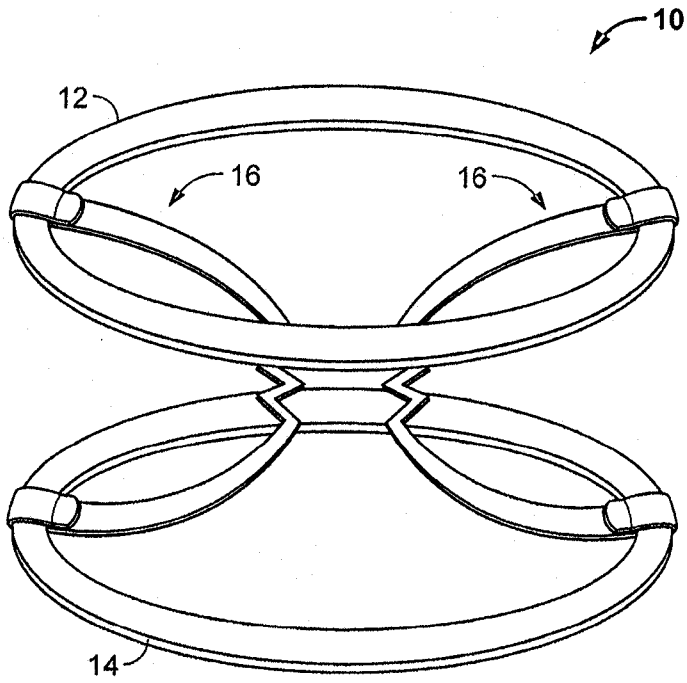


FIG. 1A

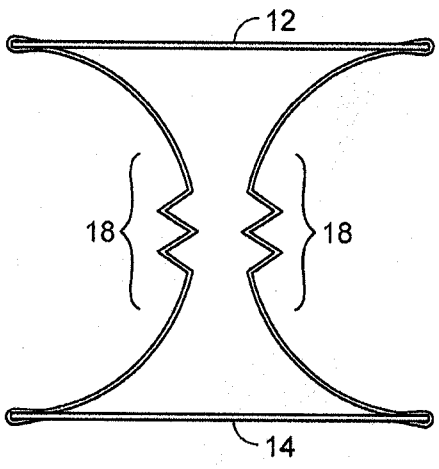


FIG. 1B

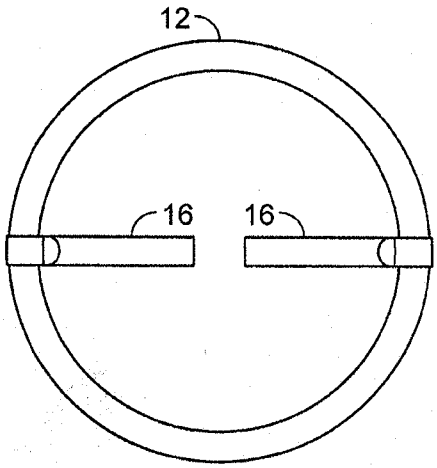


FIG. 1C

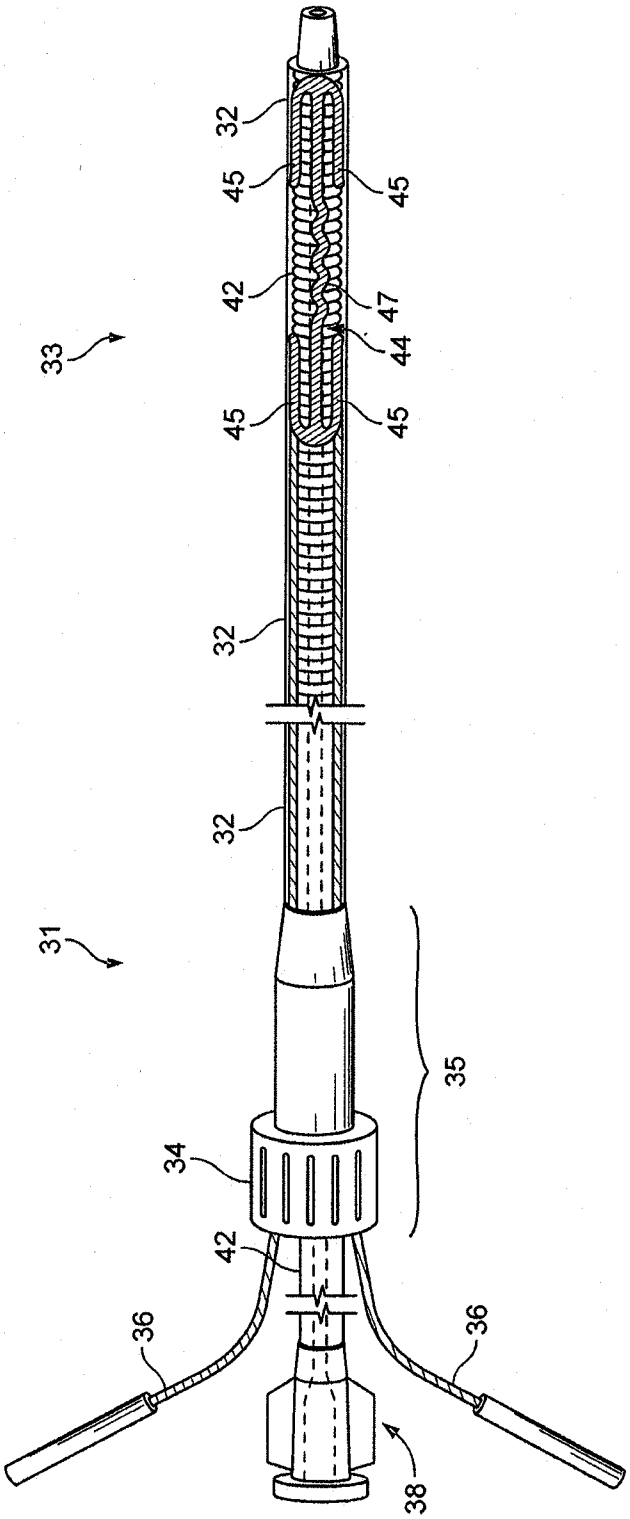
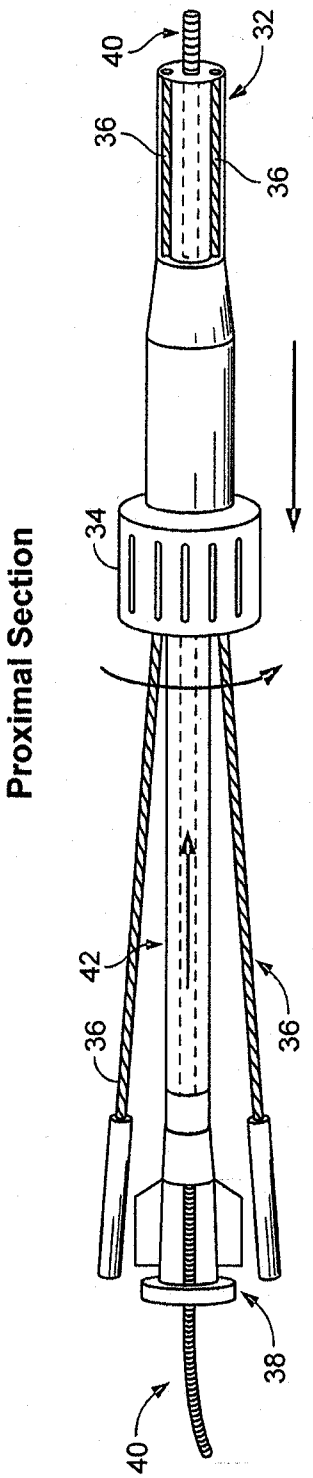


FIG. 2A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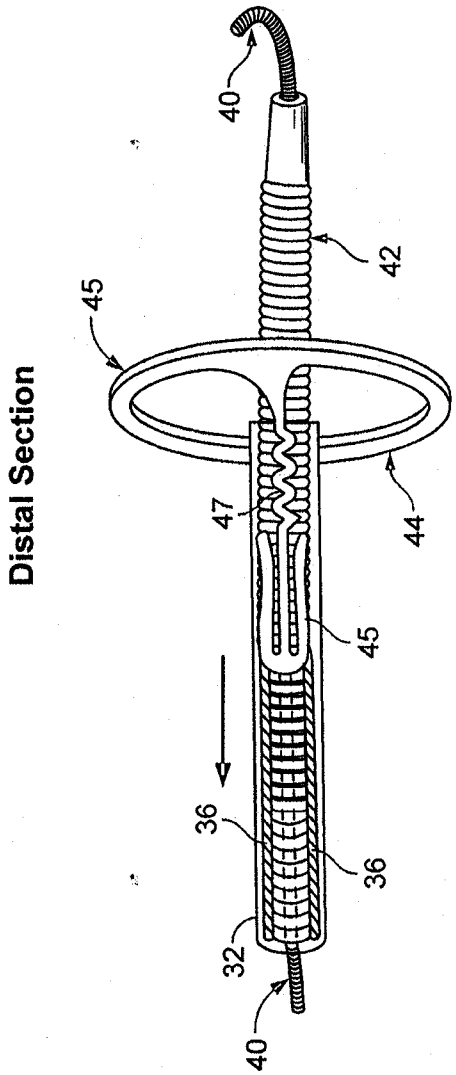
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FIG. 2B

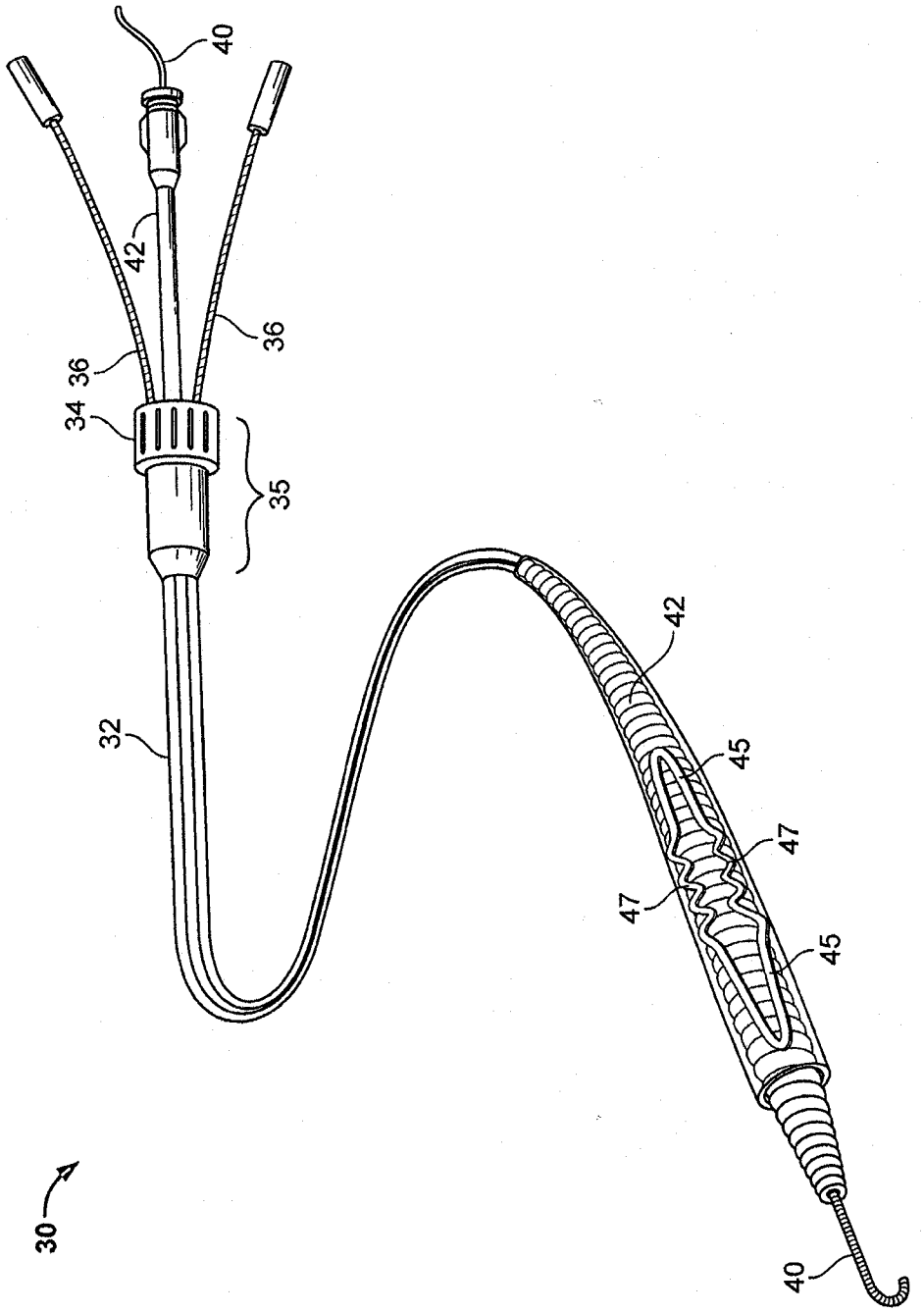


FIG. 2C

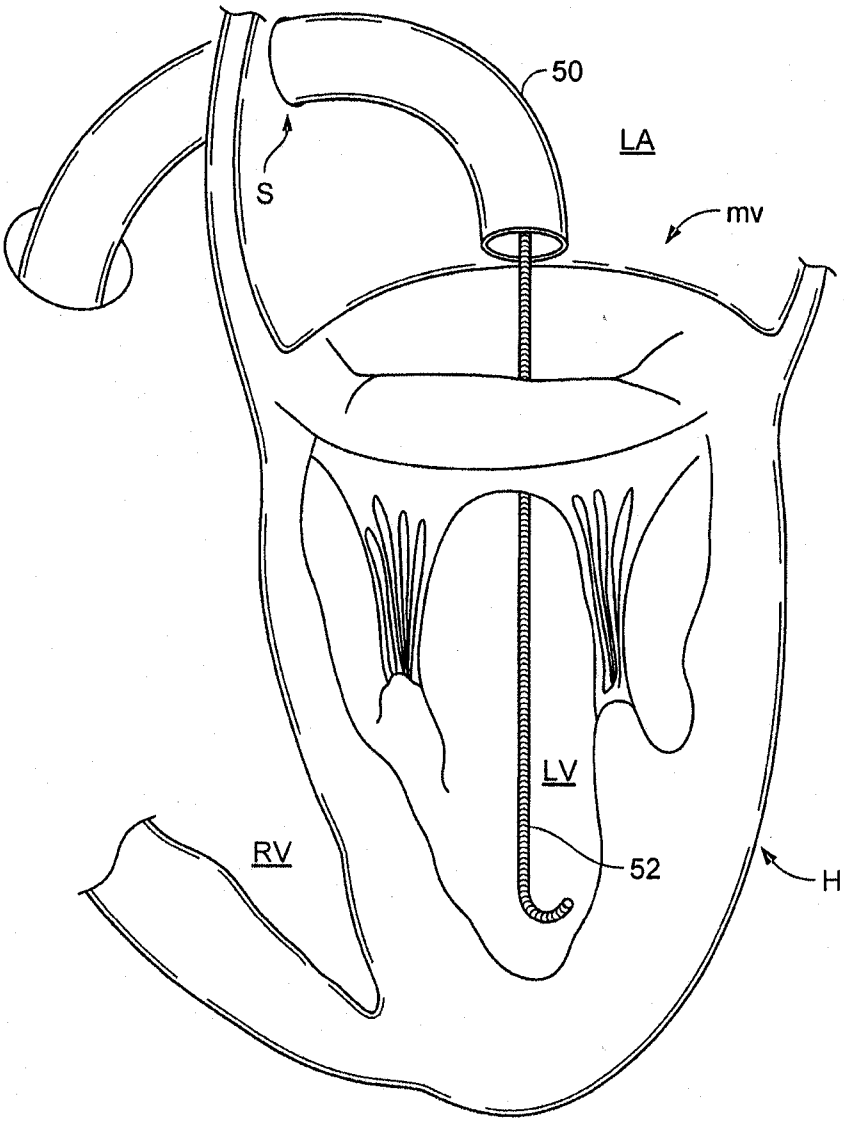


FIG. 3A

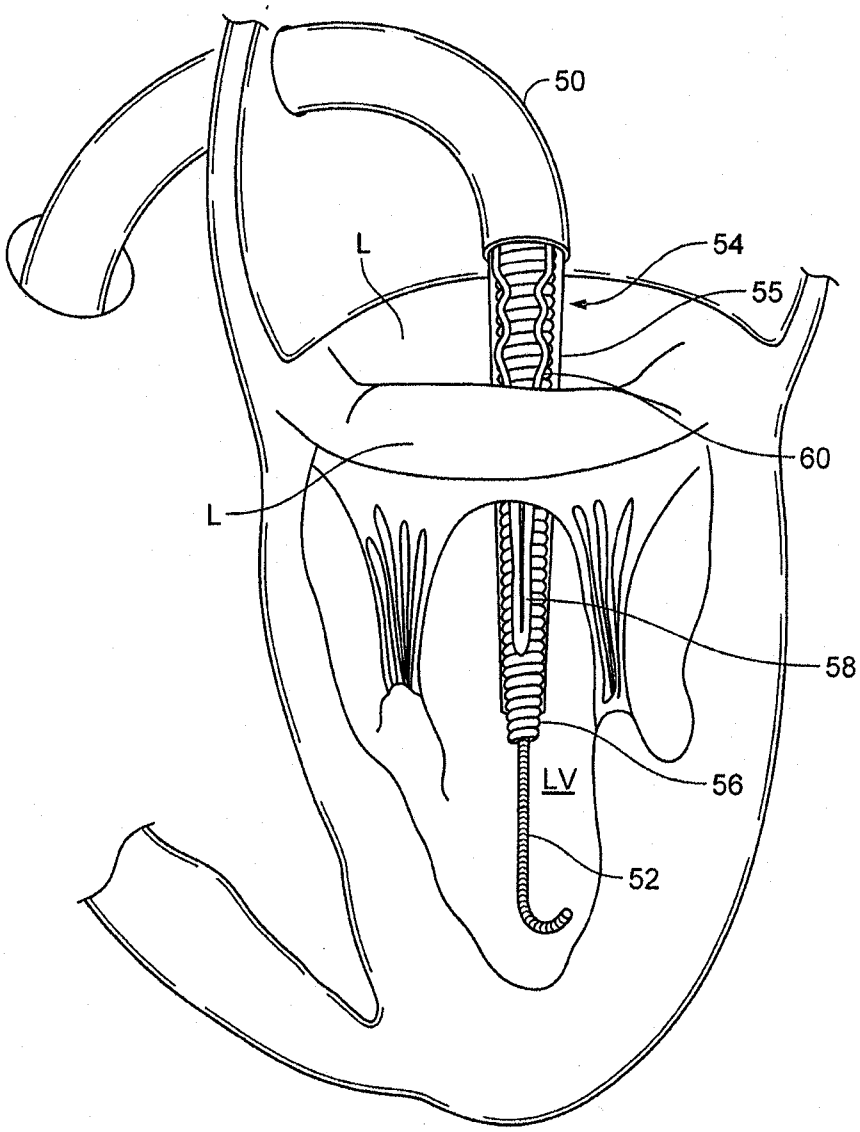


FIG. 3B

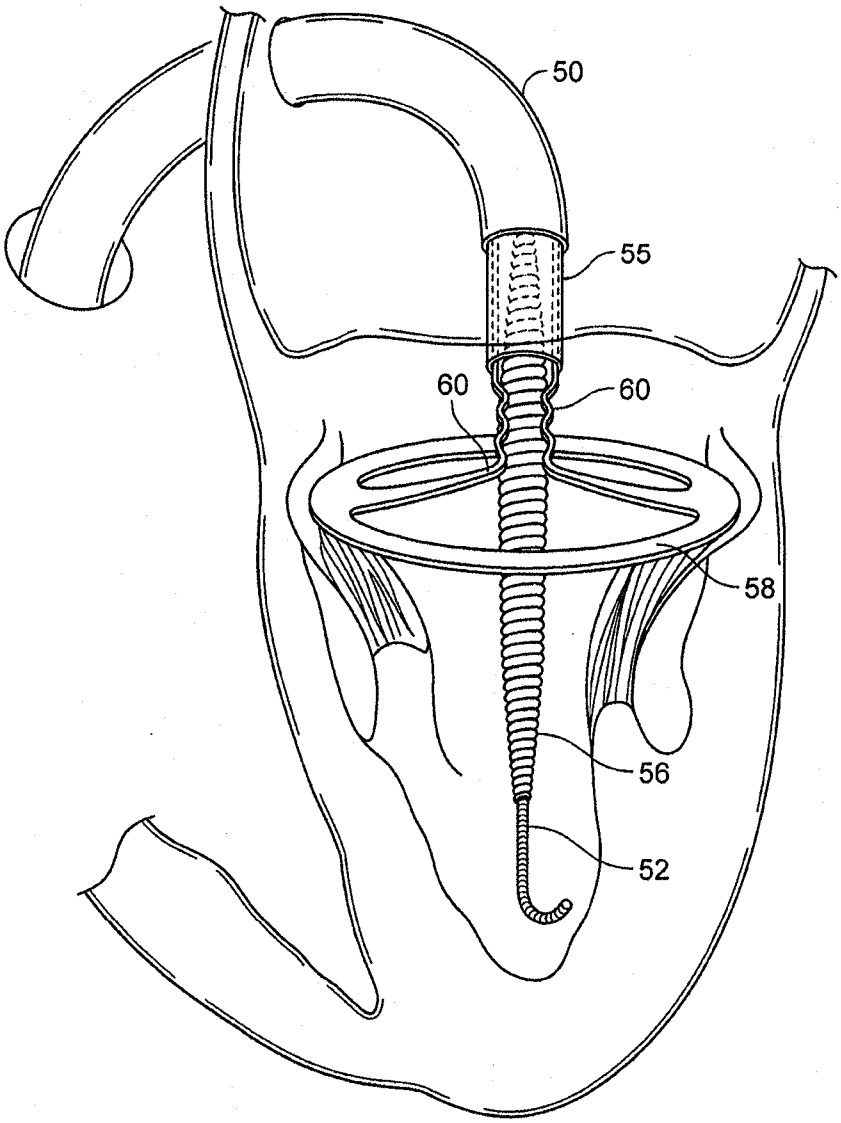


FIG. 3C

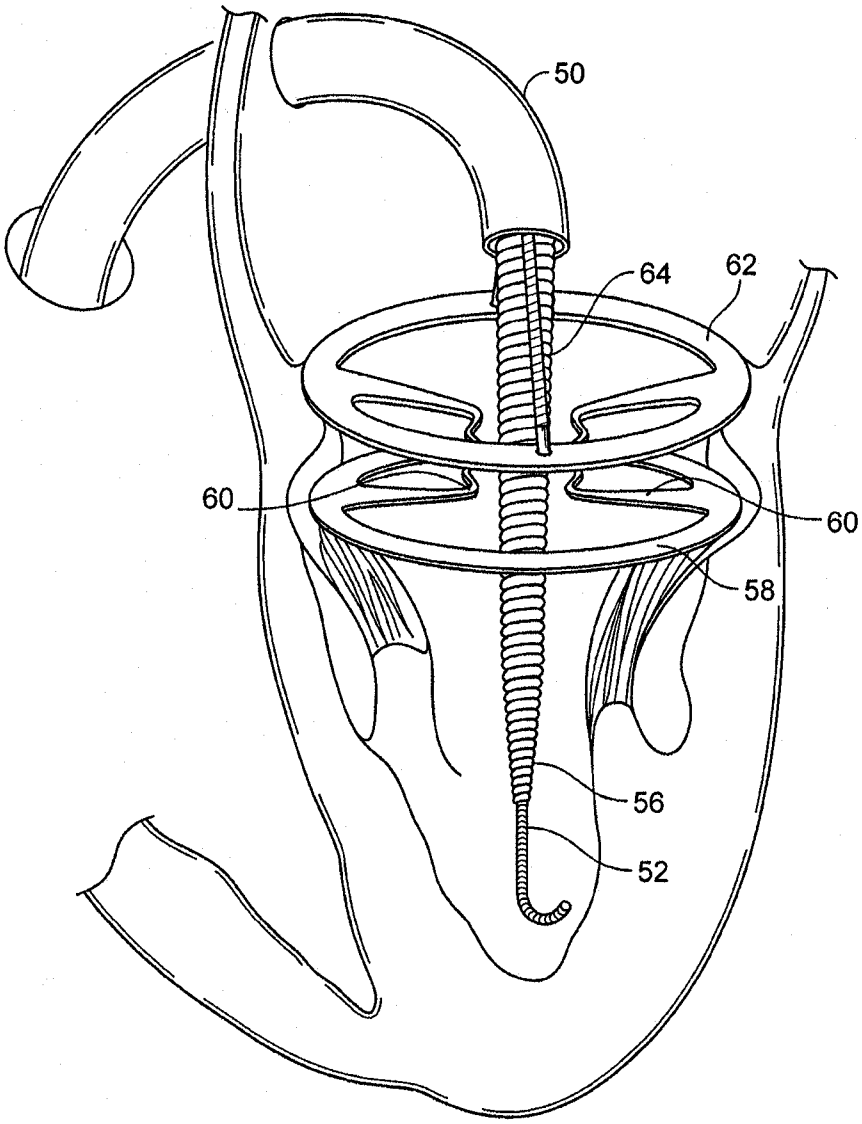


FIG. 3D

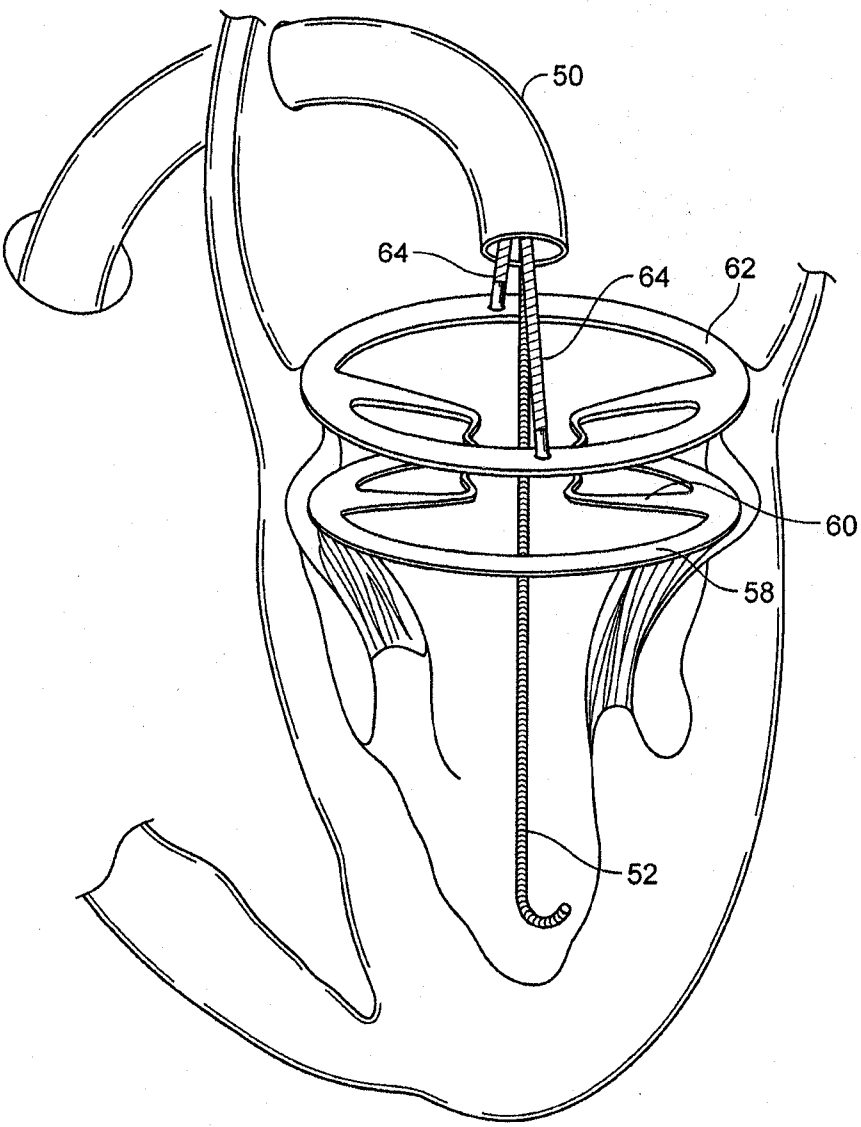


FIG. 3E

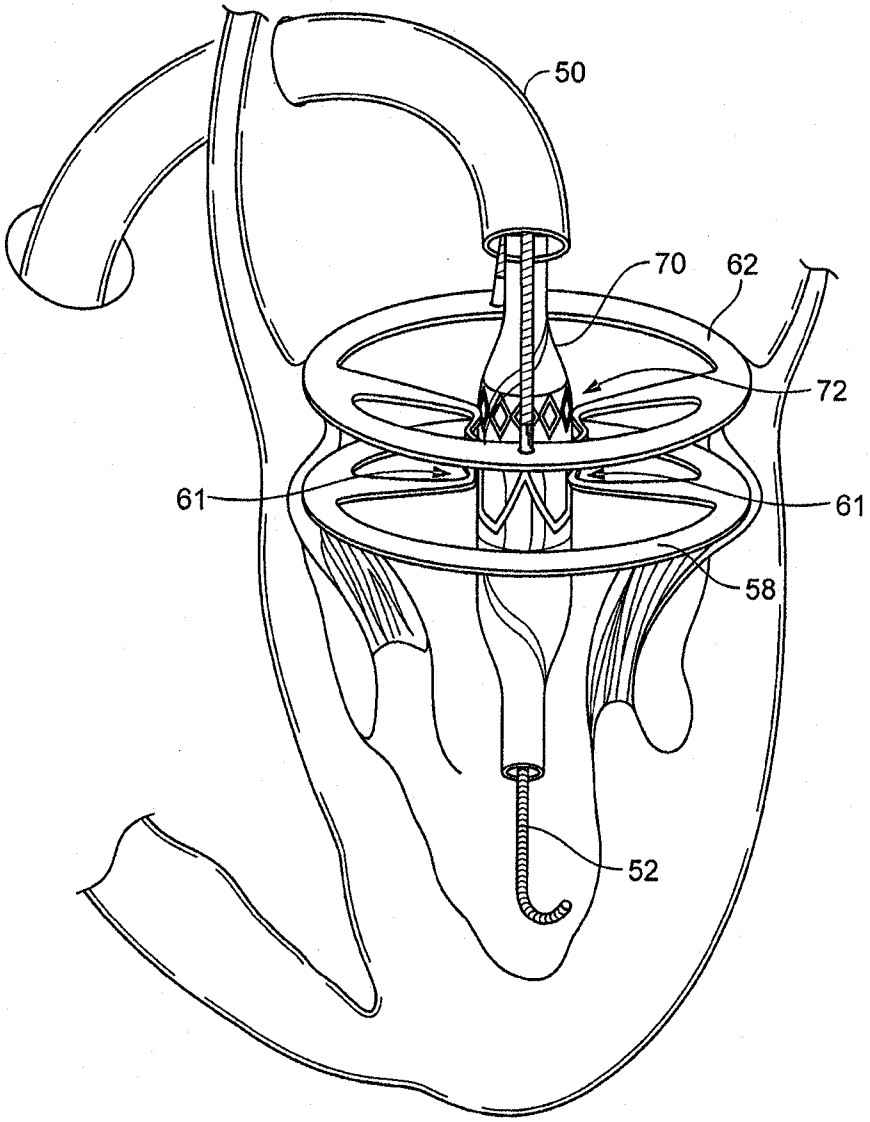


FIG. 4A

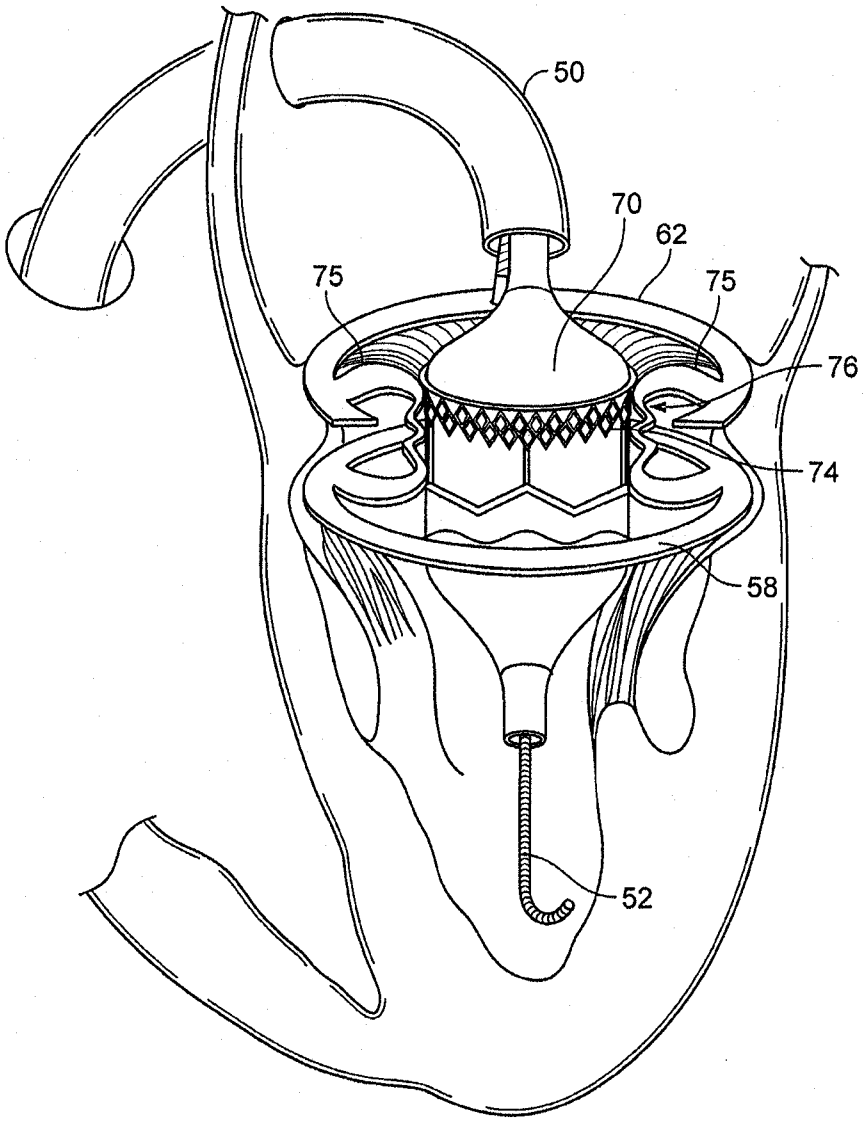


FIG. 4B

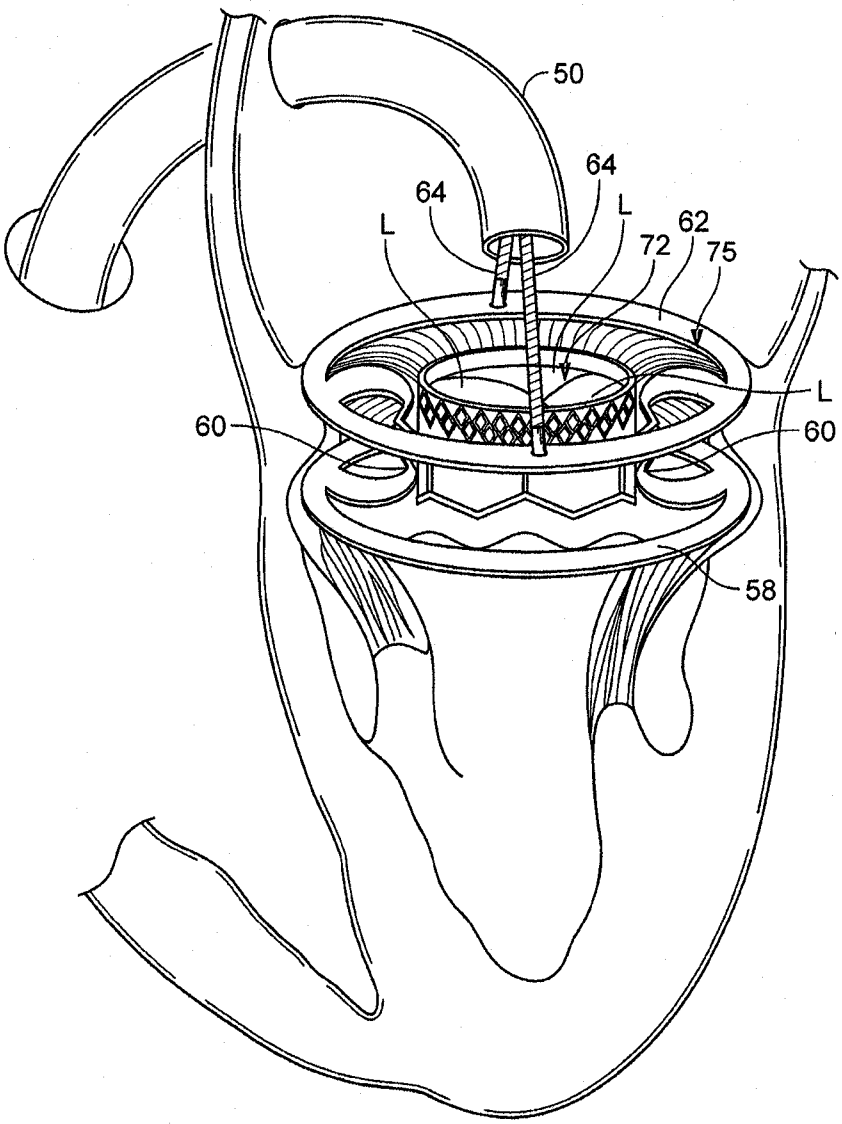


FIG. 4C

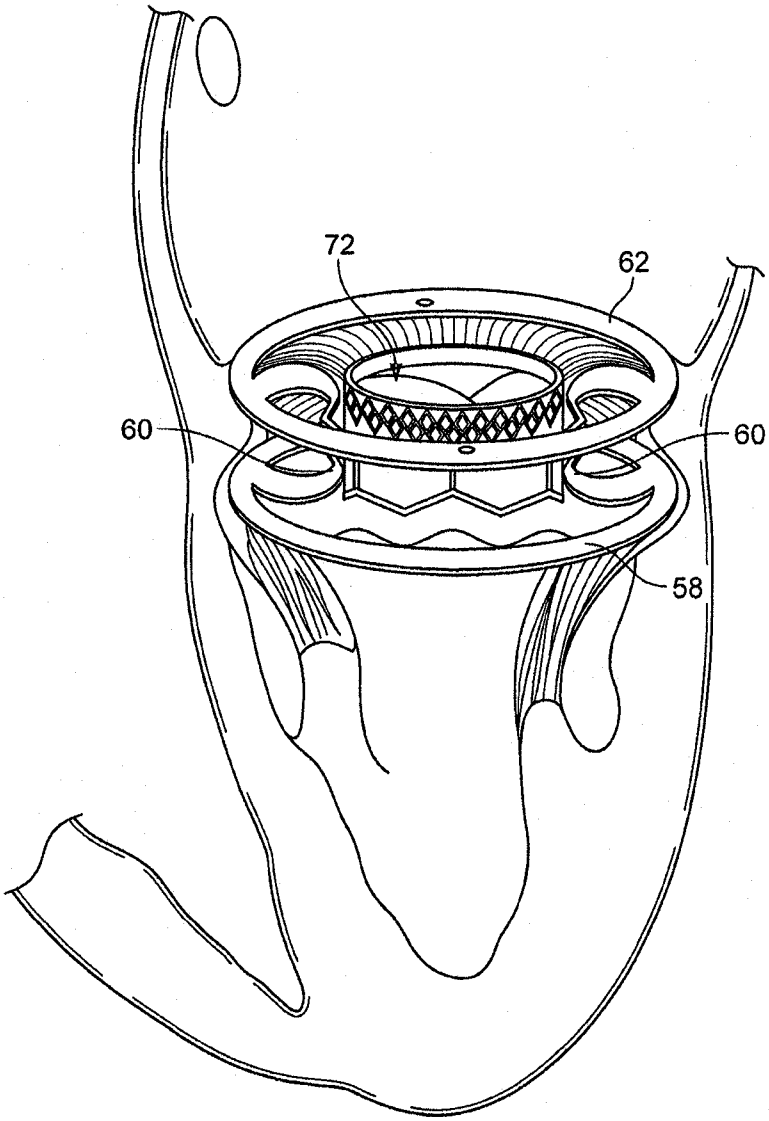


FIG. 4D

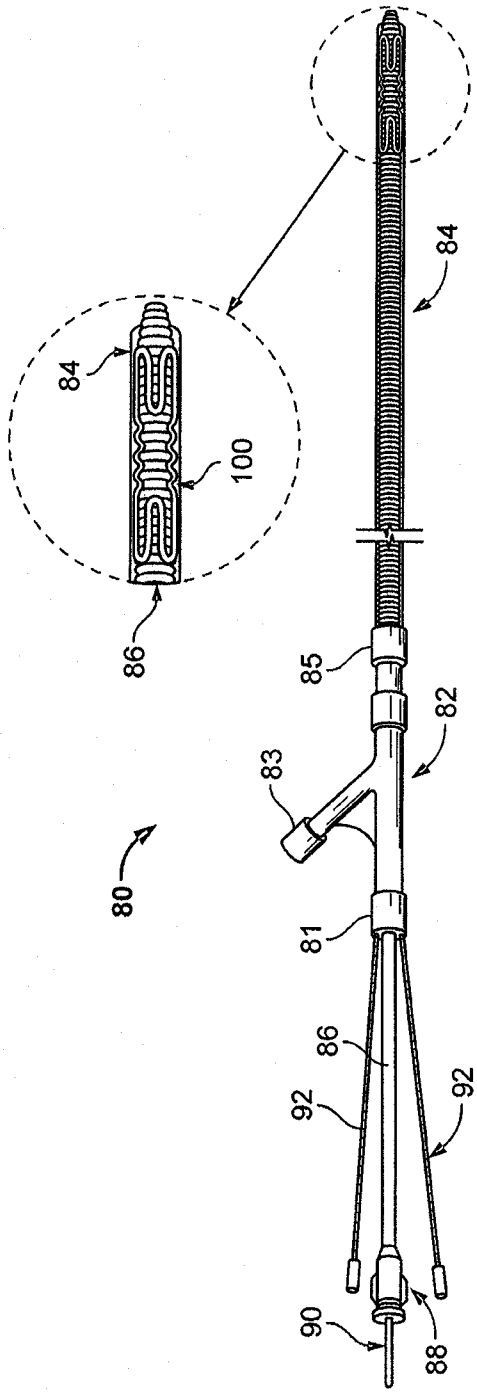
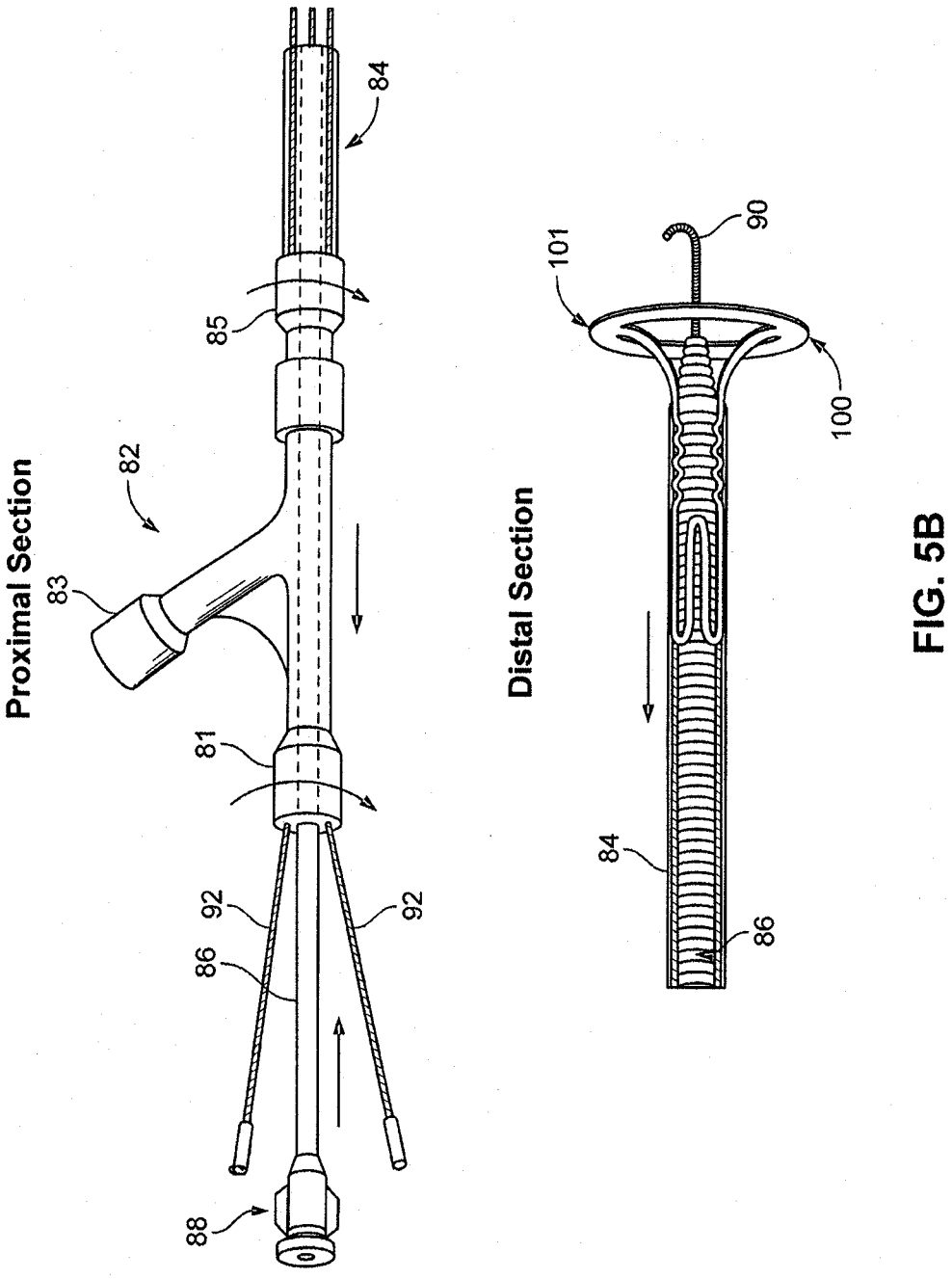


FIG. 5A


Proximal Section
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81
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86
88
Distal Section
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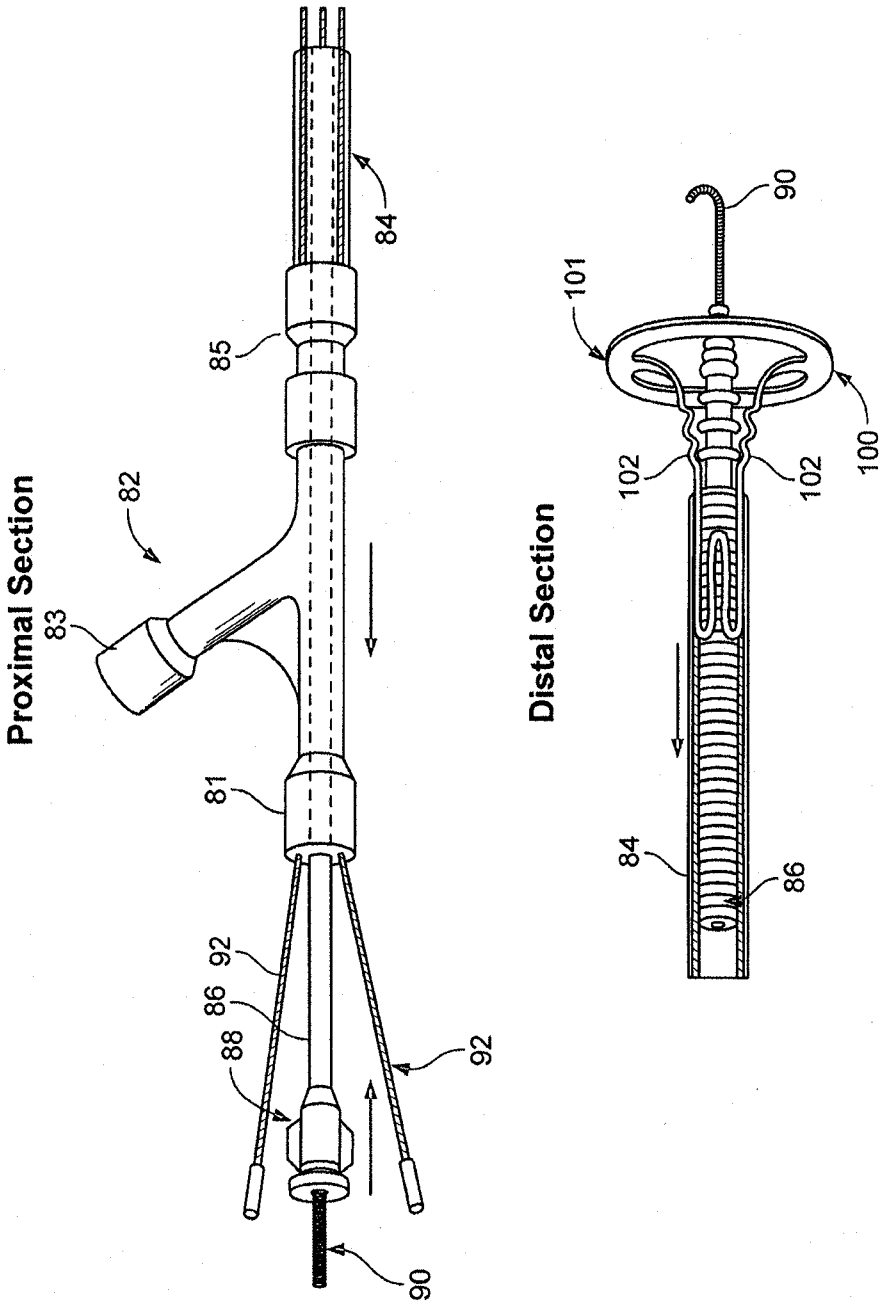
90
100
84
86

FIG. 5B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Distal Section
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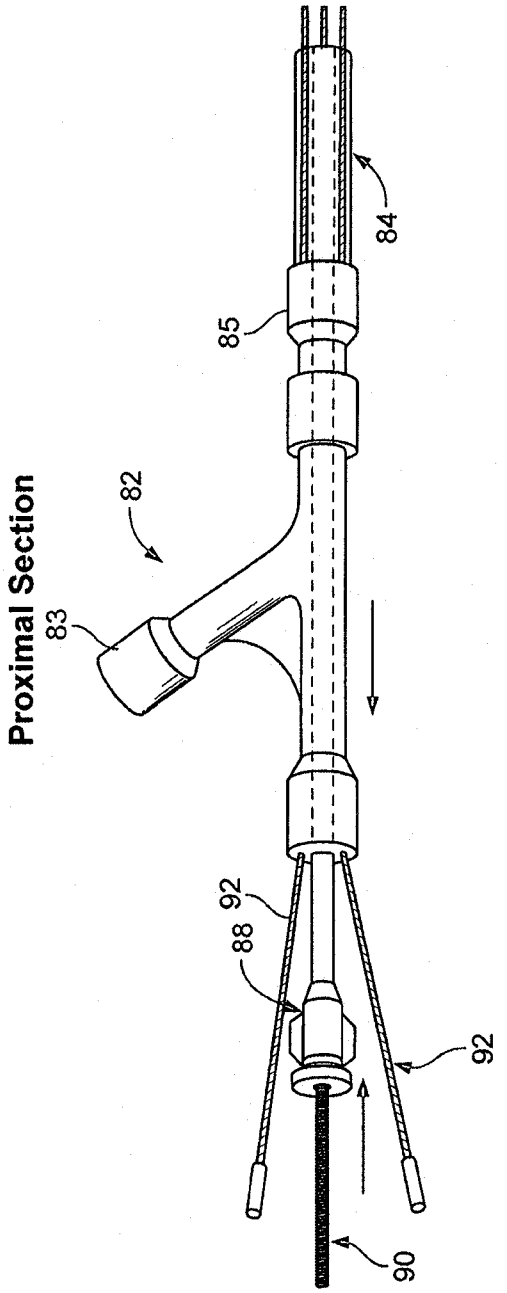
86

FIG. 5C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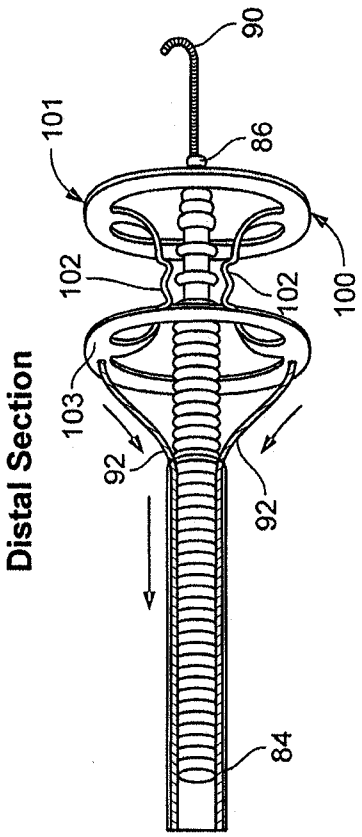
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FIG. 5D

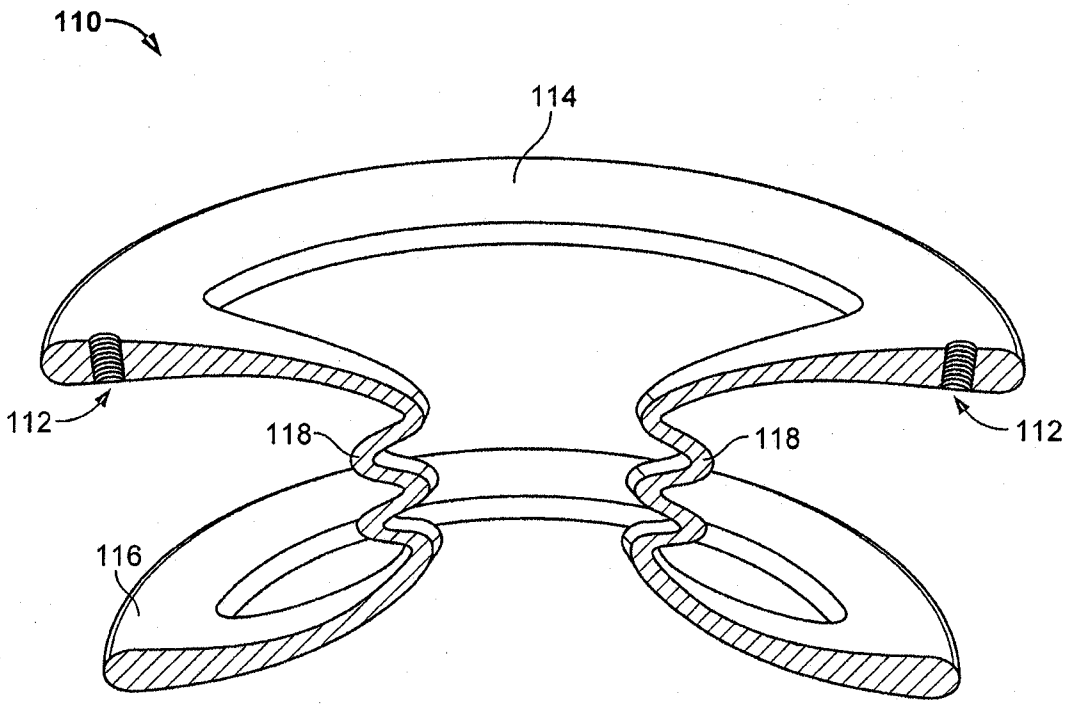


FIG. 6

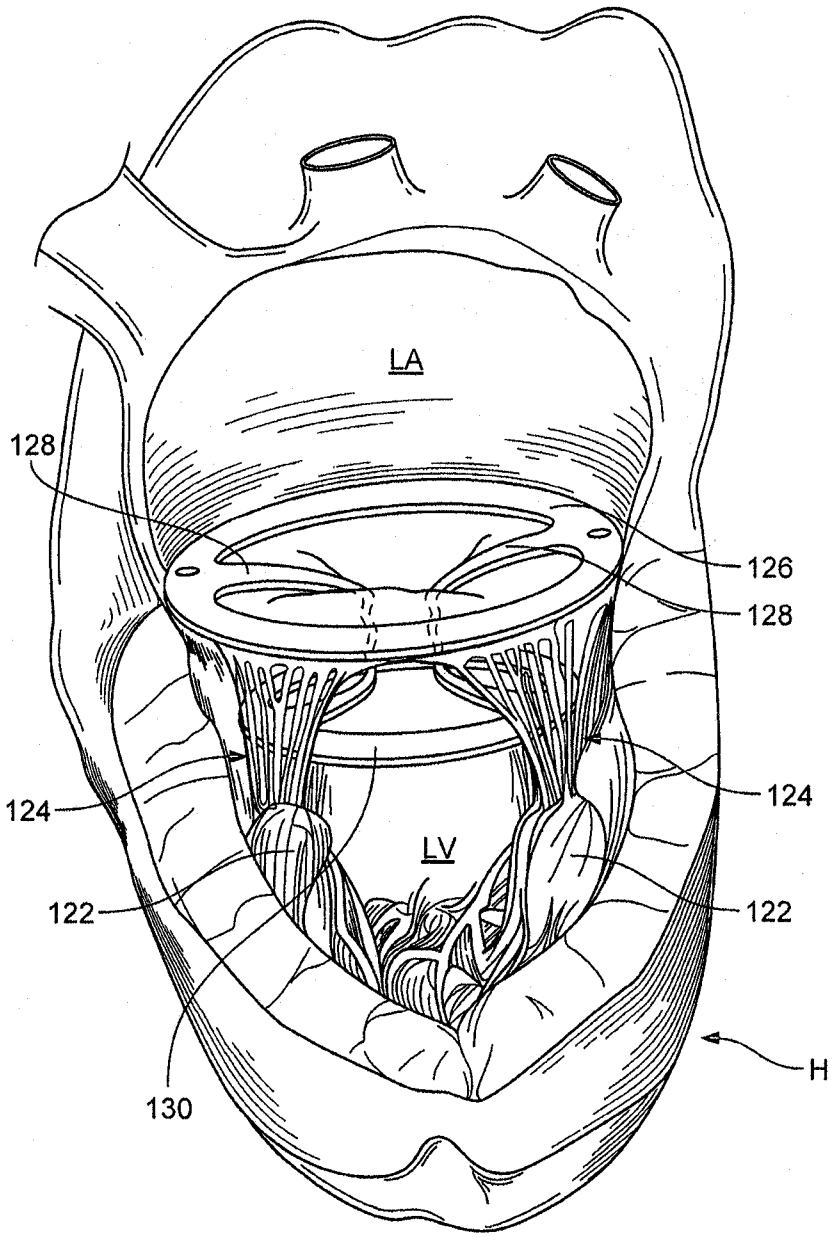


FIG. 7

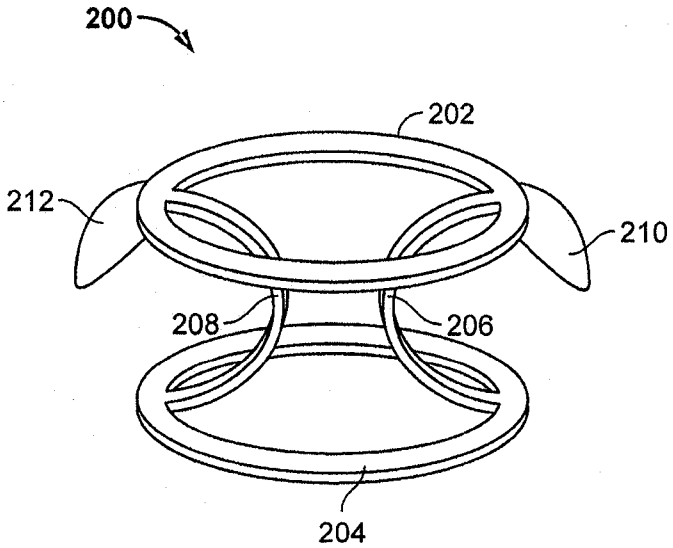


FIG. 8A

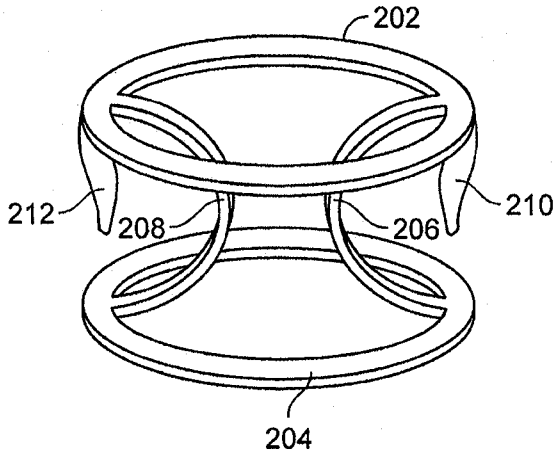


FIG. 8B

Fig. 9

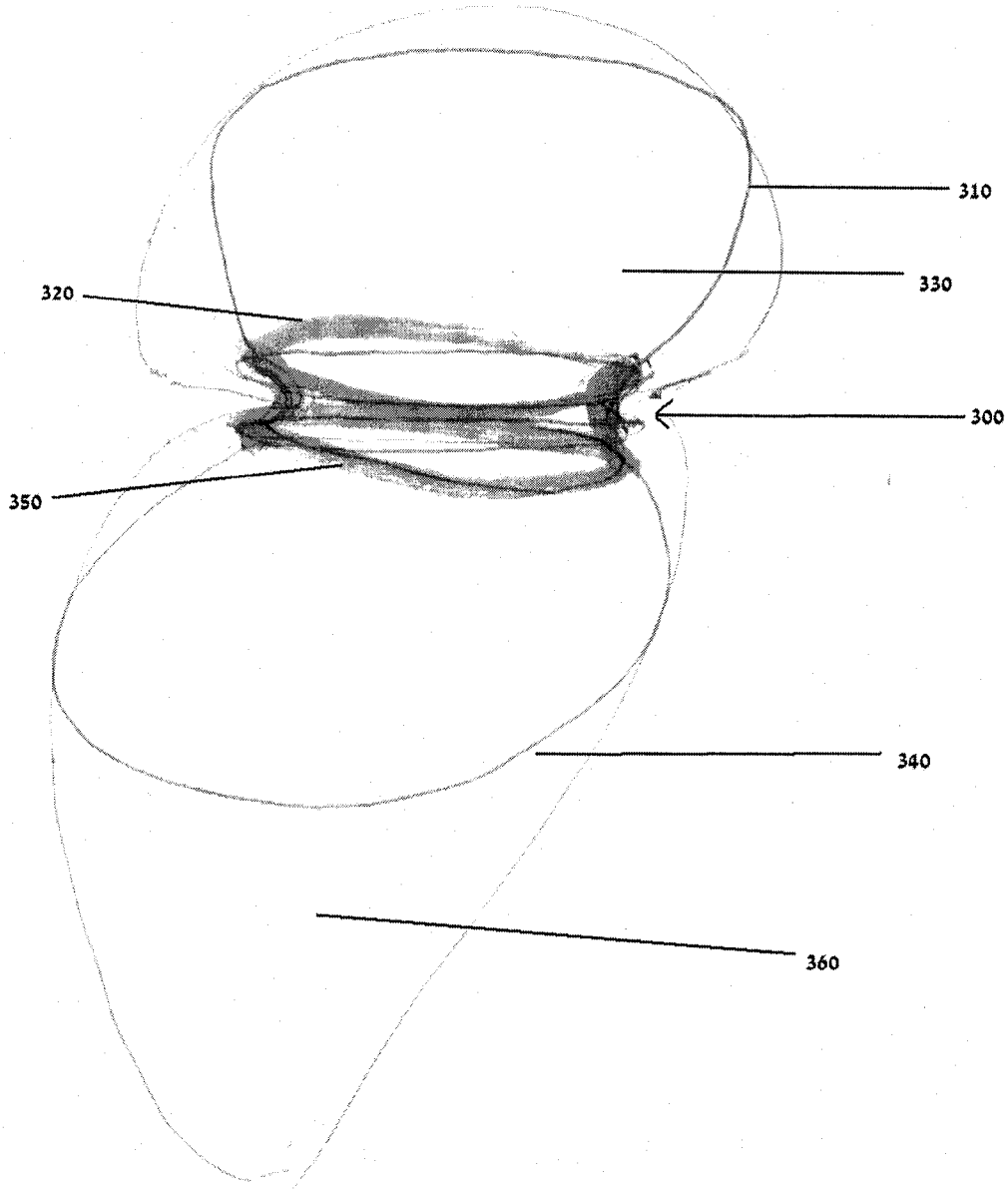


Fig. 10A

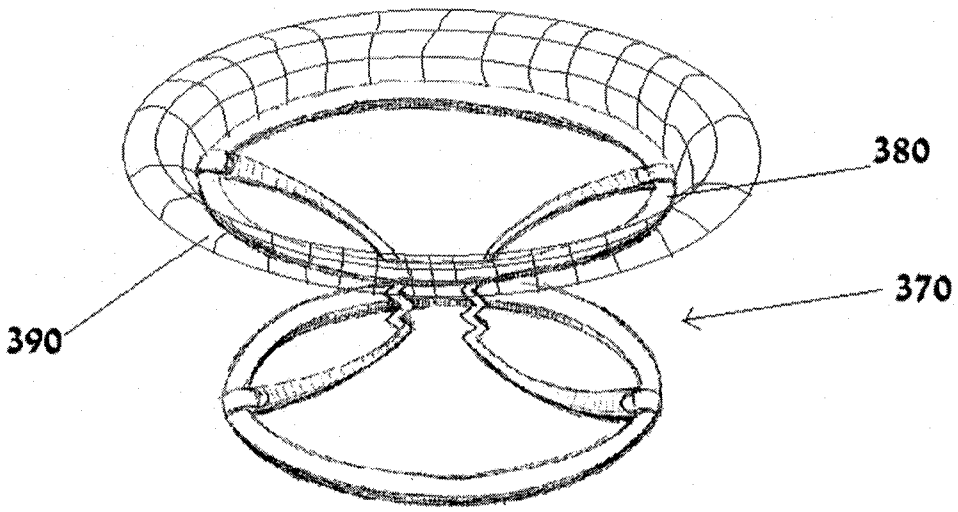


Fig. 10B

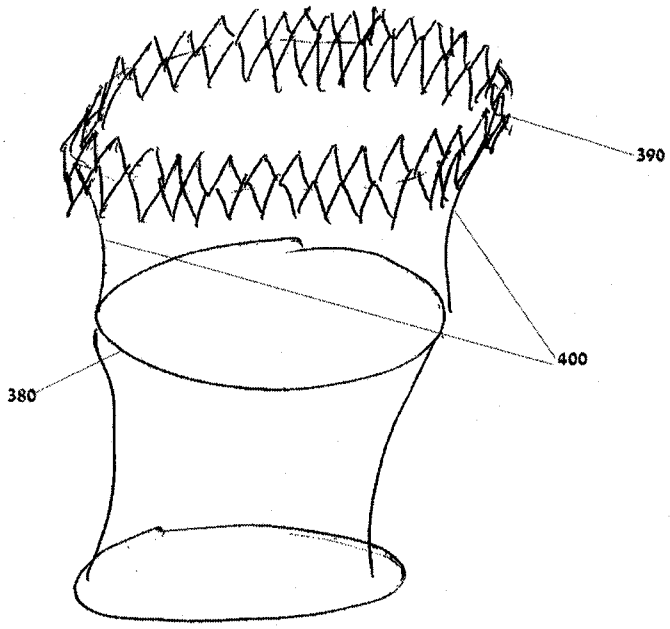


Fig. 11

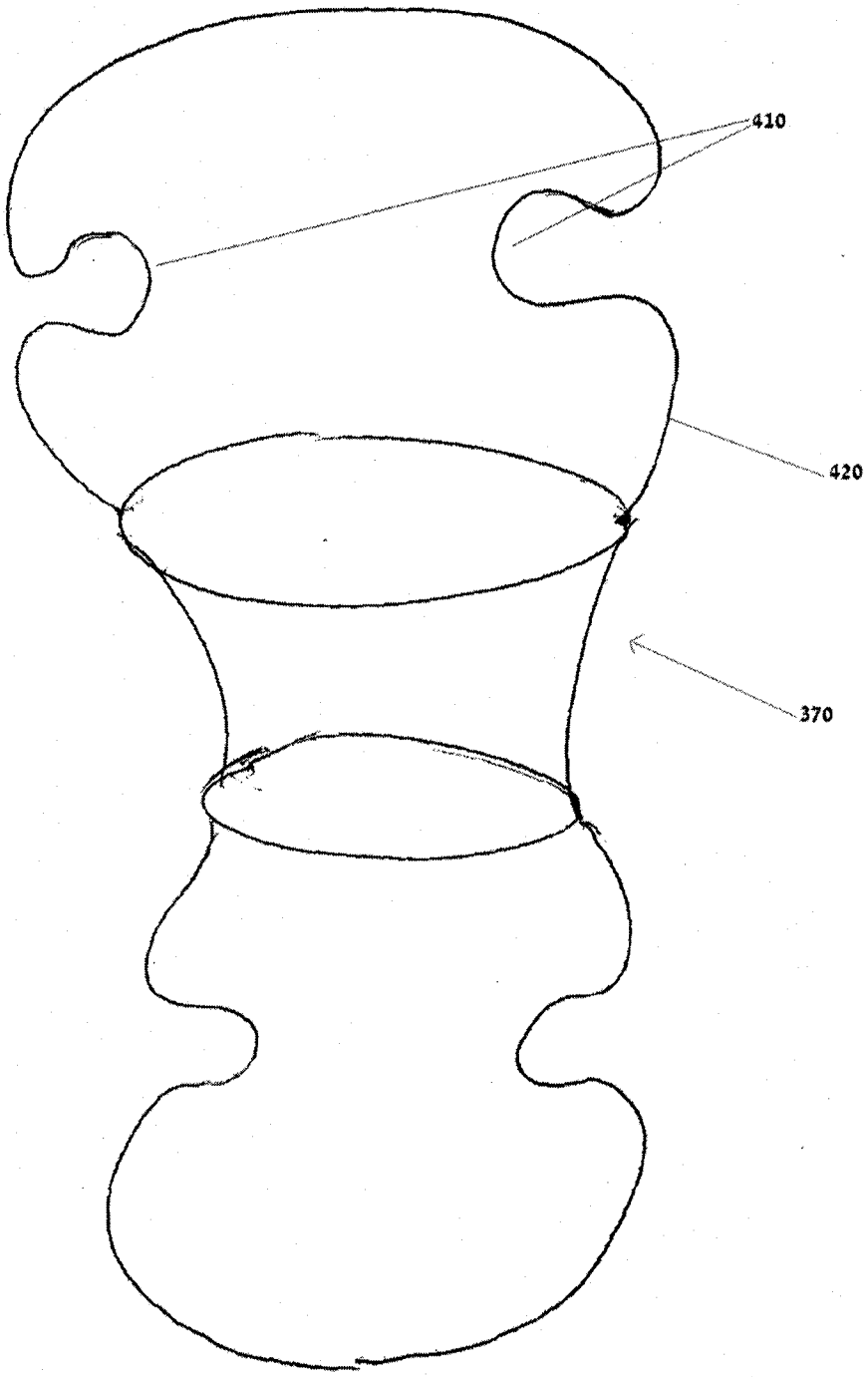


Fig. 12

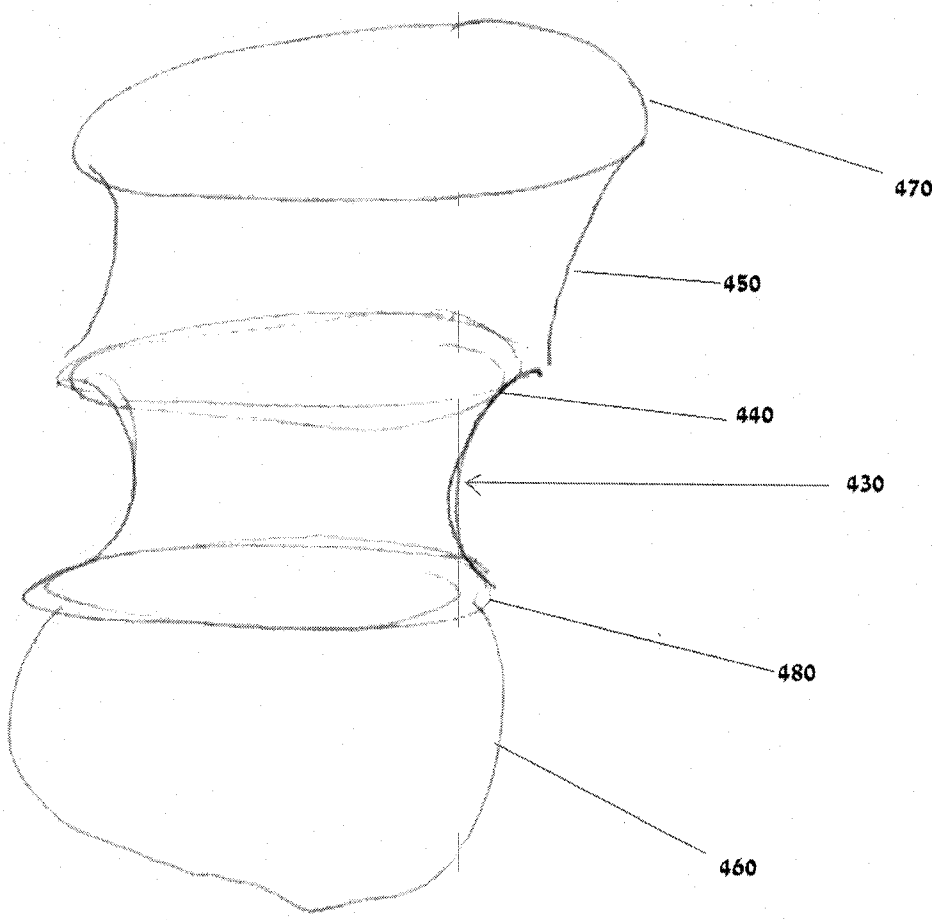


Fig. 13

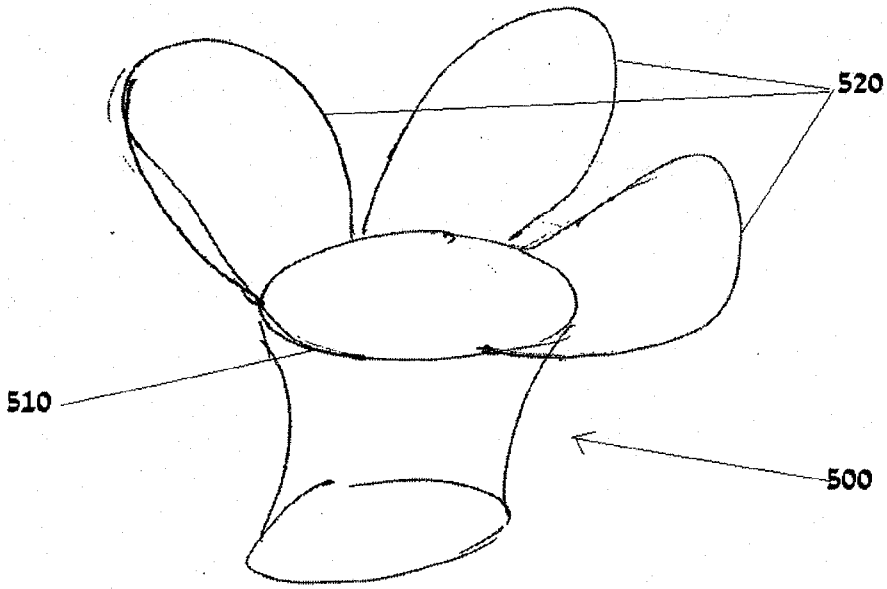


Fig. 14A

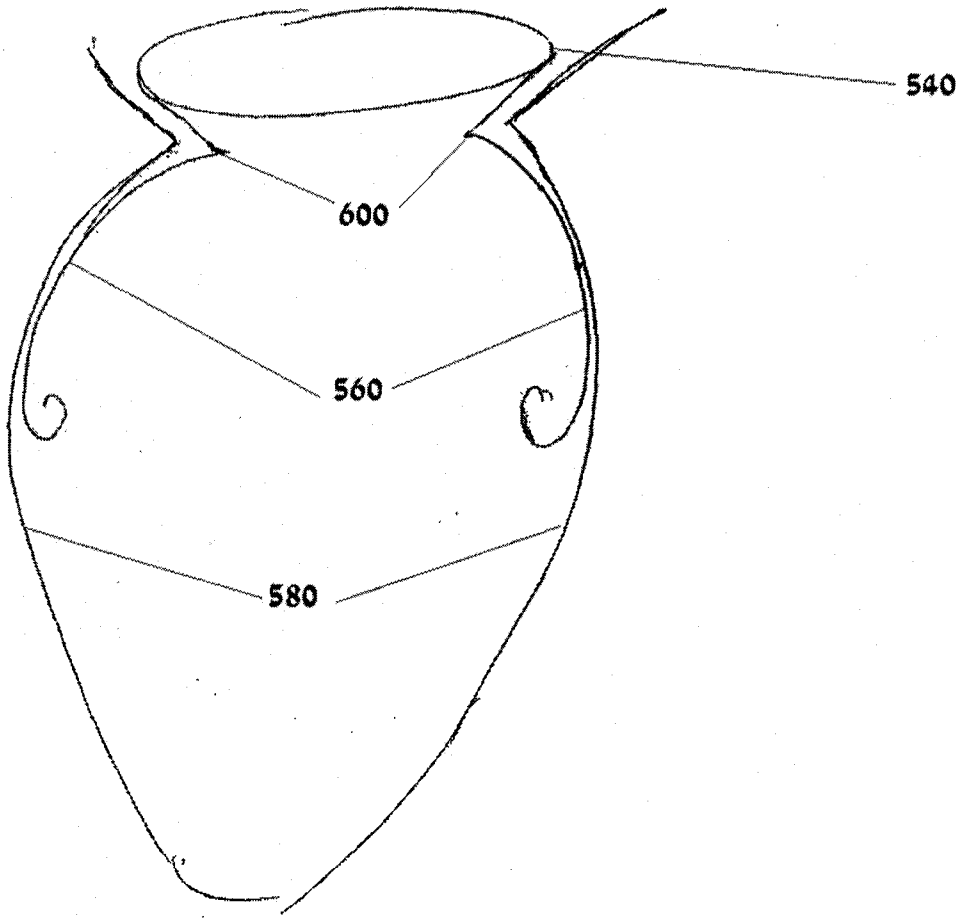


Fig. 14B

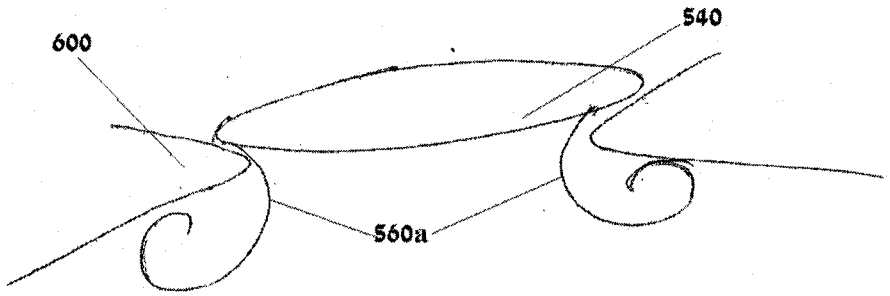


Fig. 14C

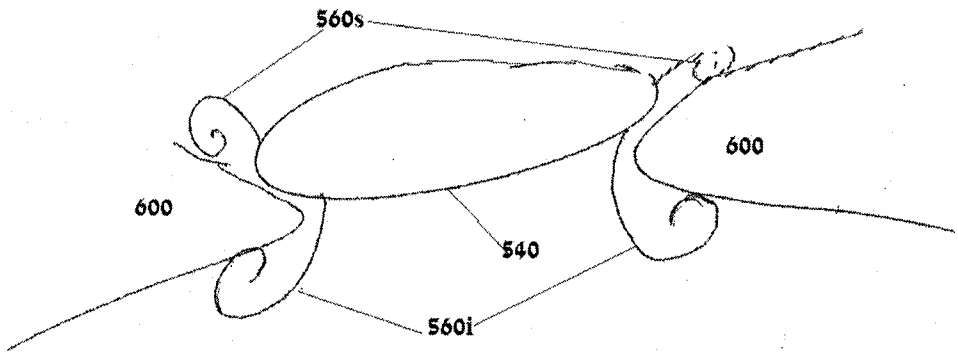


Fig. 15

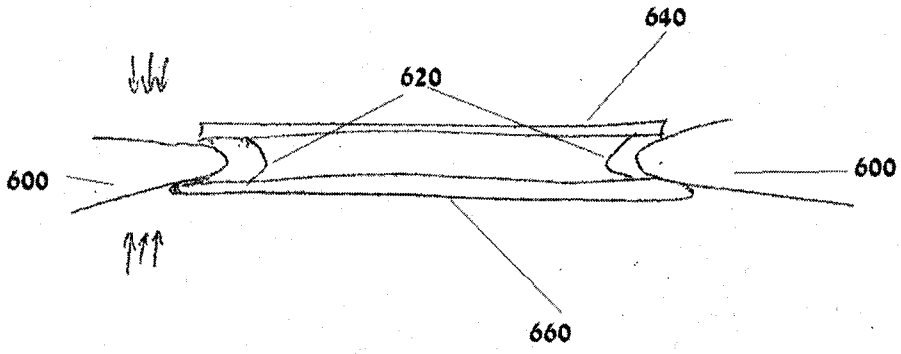


Fig. 16

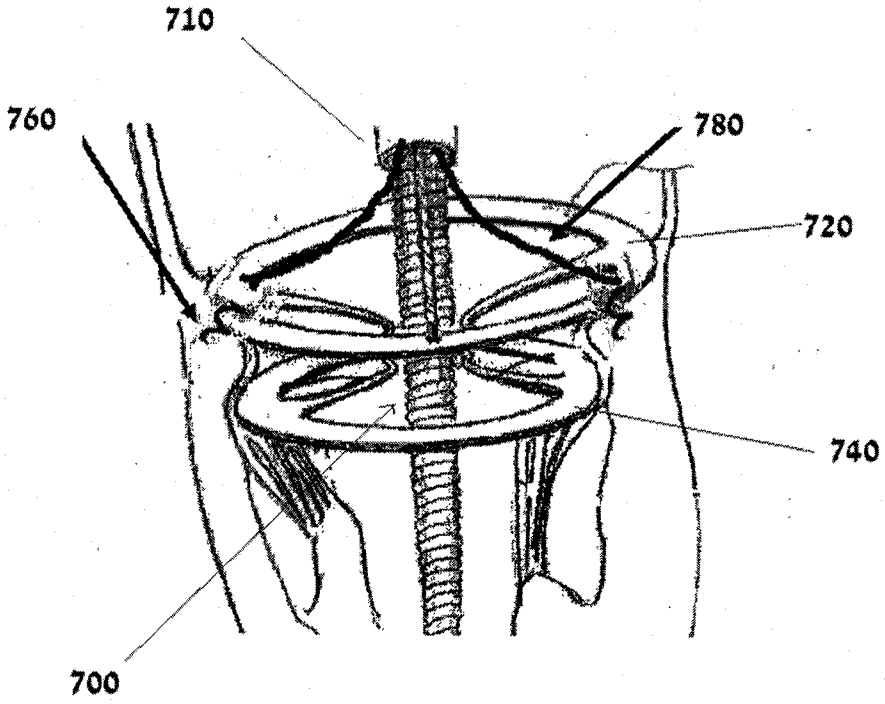


Fig. 17

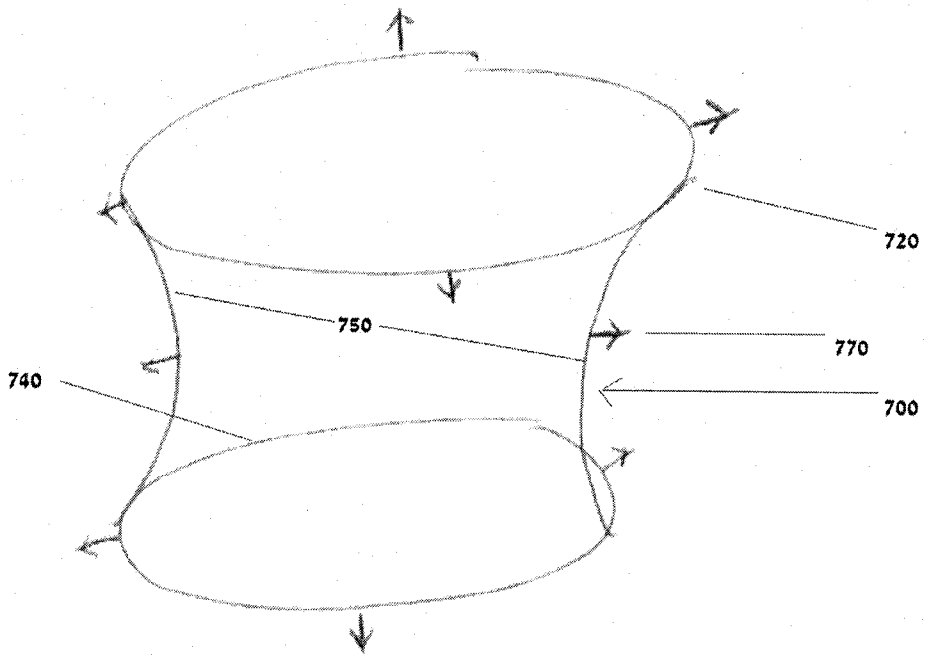
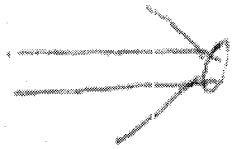


Fig. 18

b.



a.

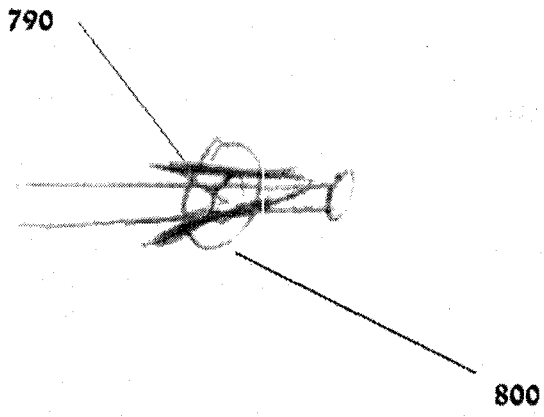


Fig. 19A

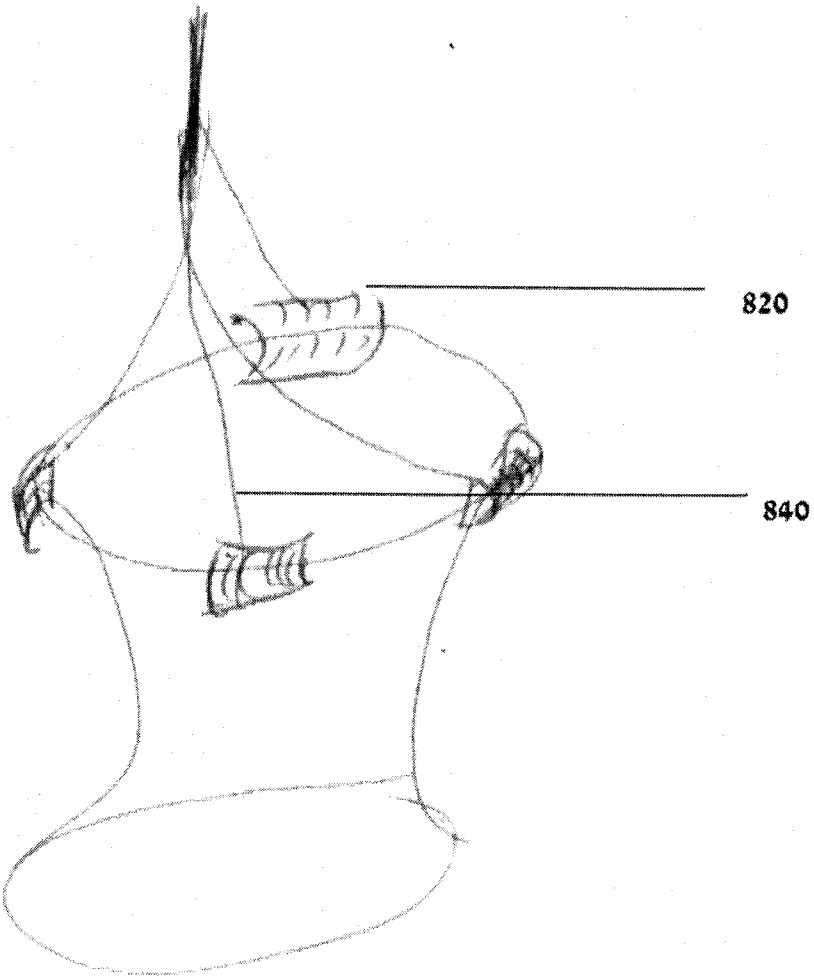


Fig. 19B

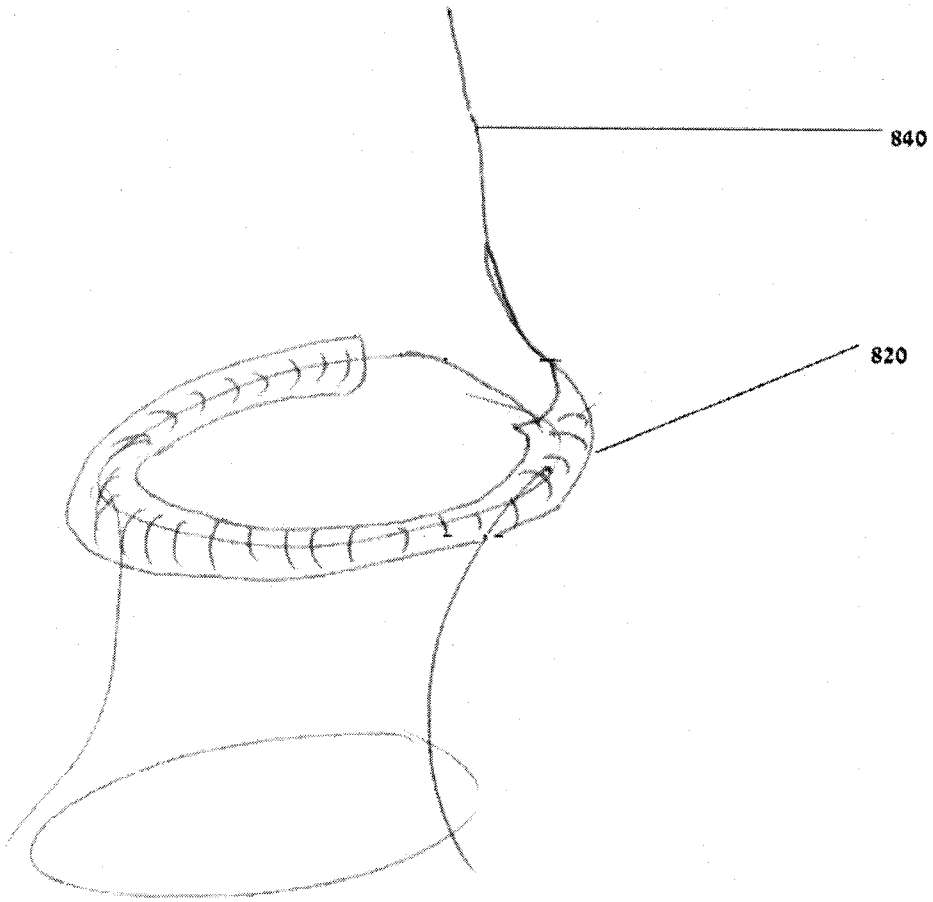


Fig. 20A

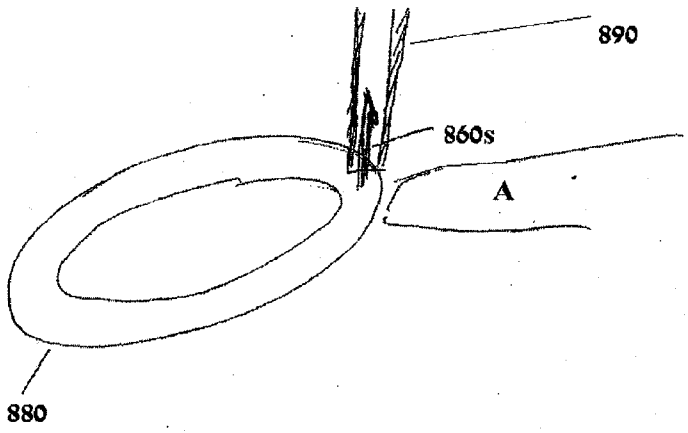


Fig. 20B

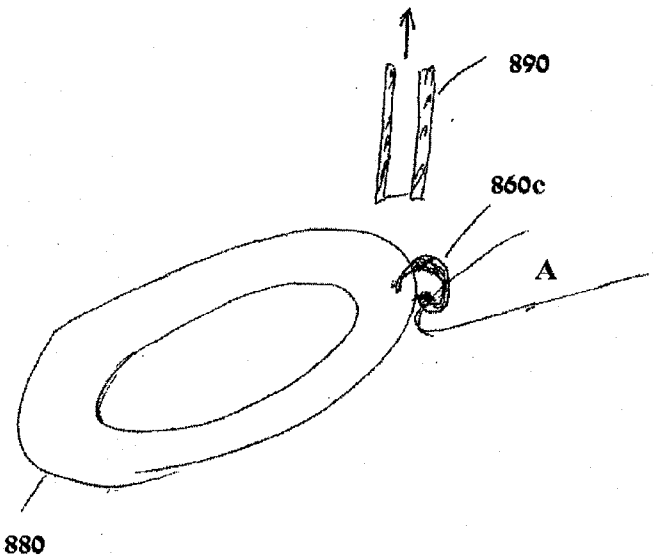
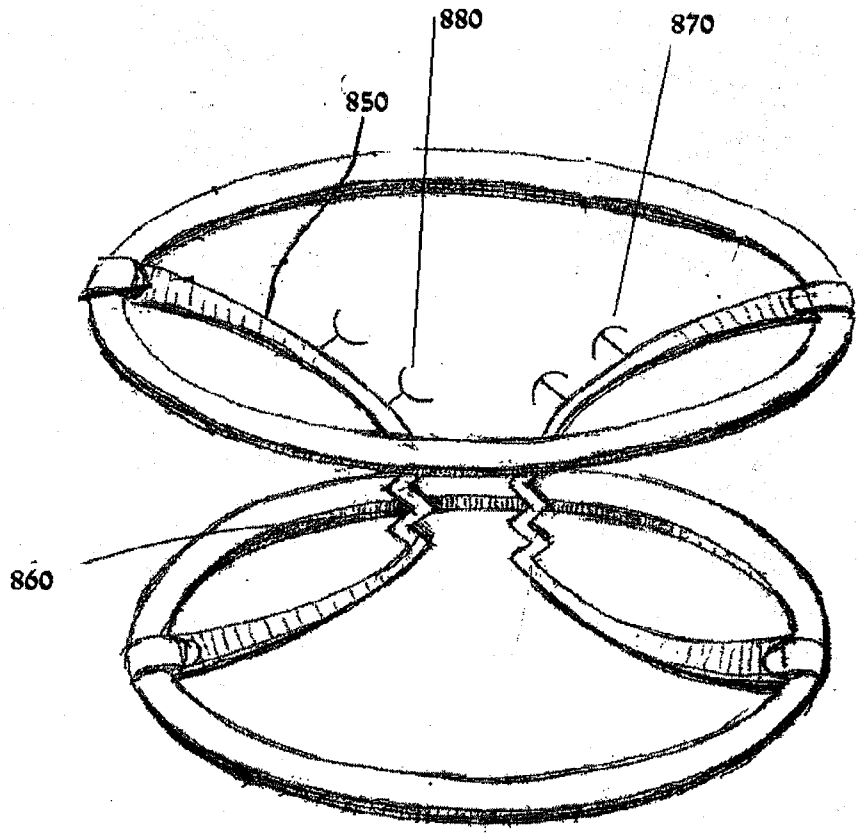


Fig. 21



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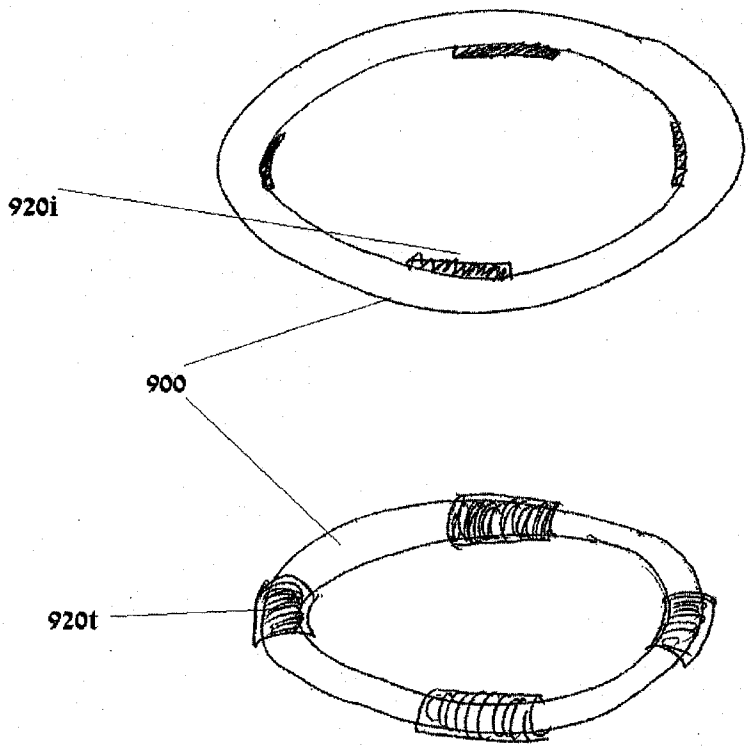


Fig. 22B

Fig. 23A

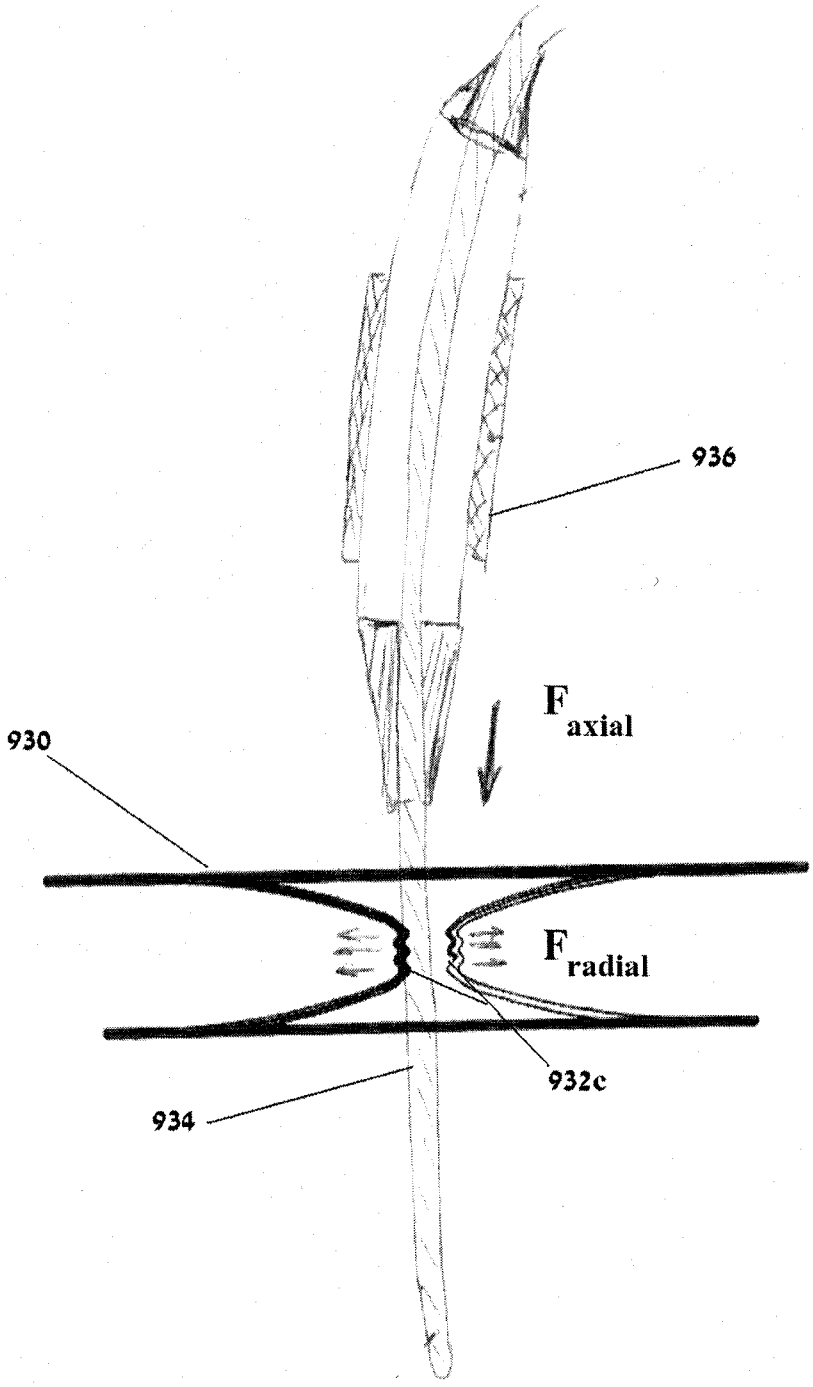


Fig. 23B

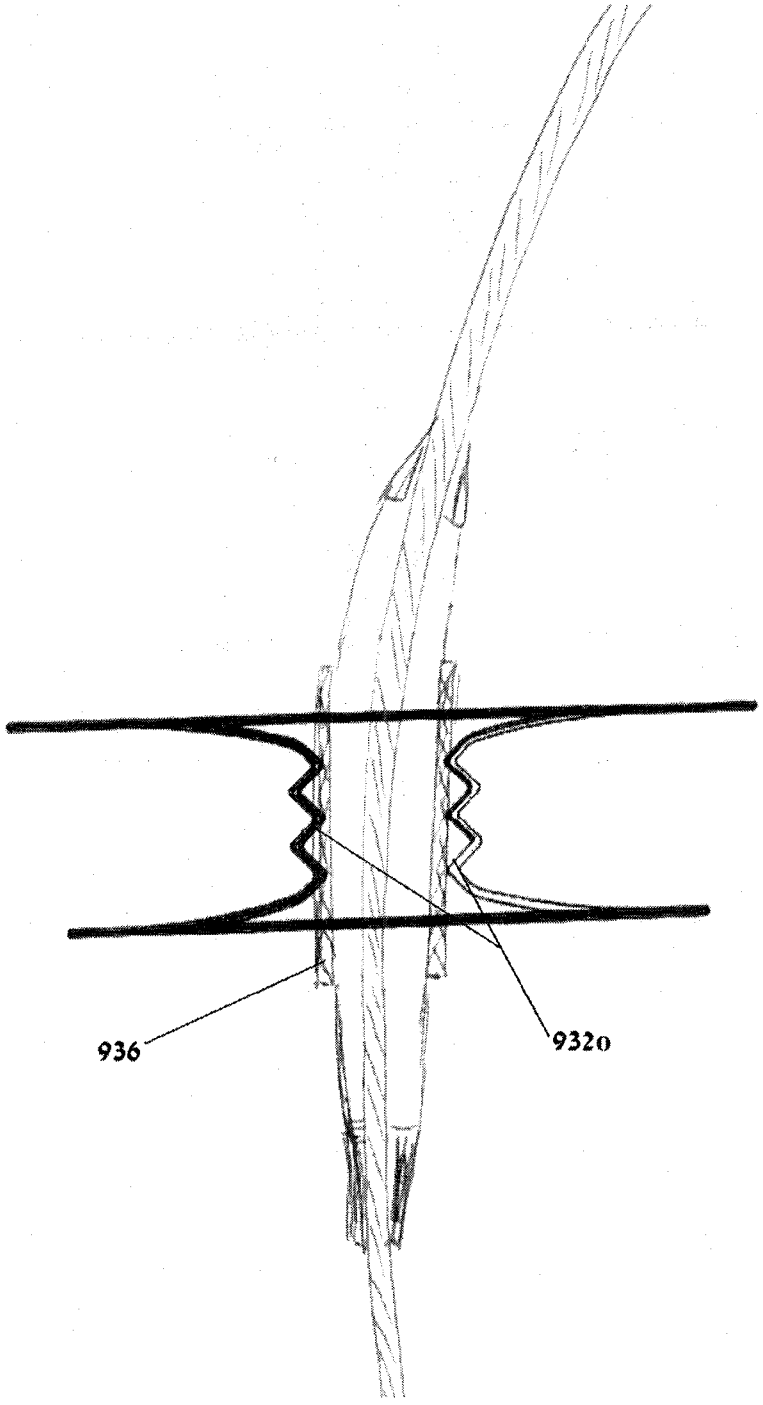


Fig. 24

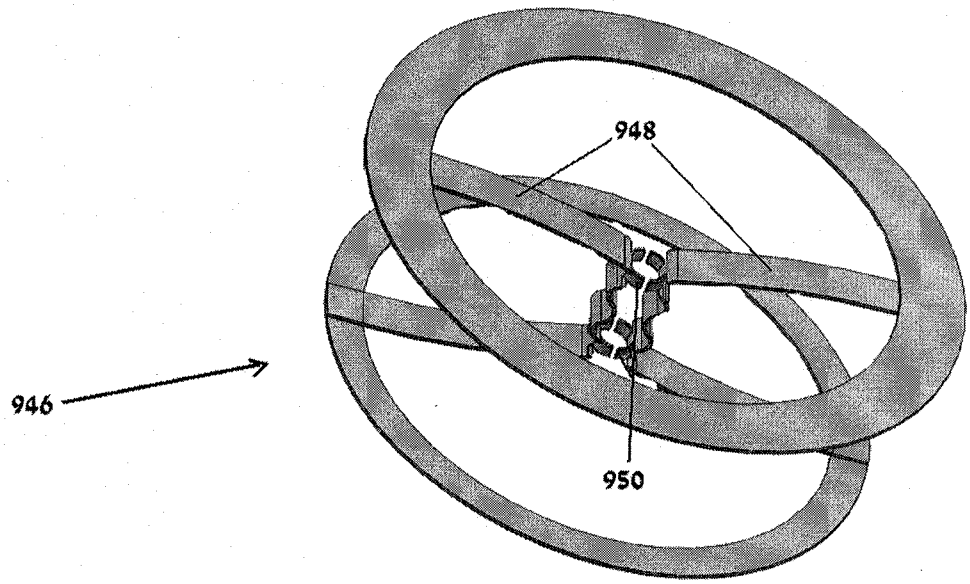


Fig. 25

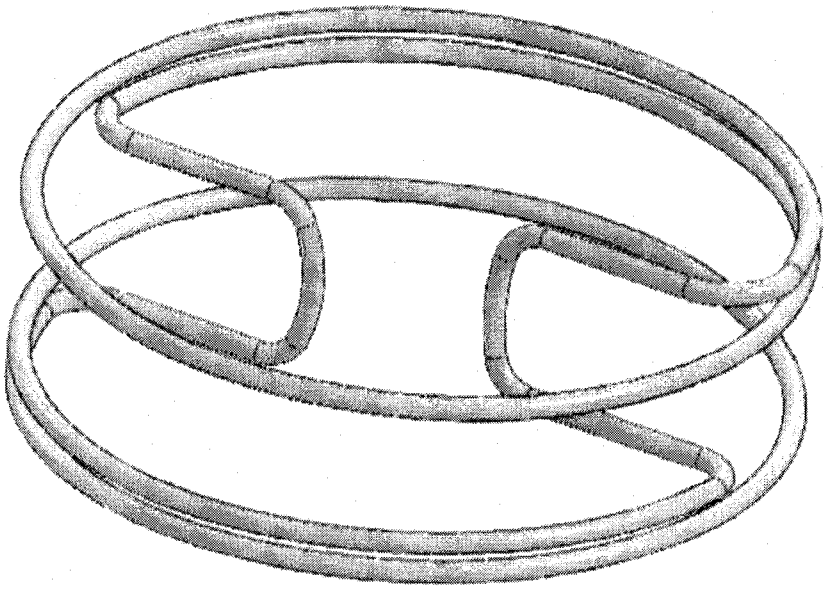


Fig. 26A

Fig. 26B

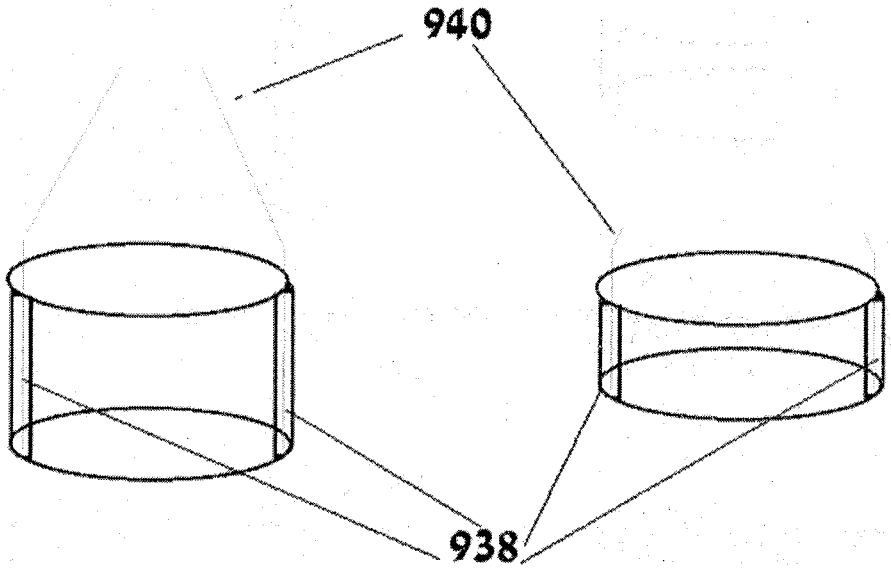


Fig. 27

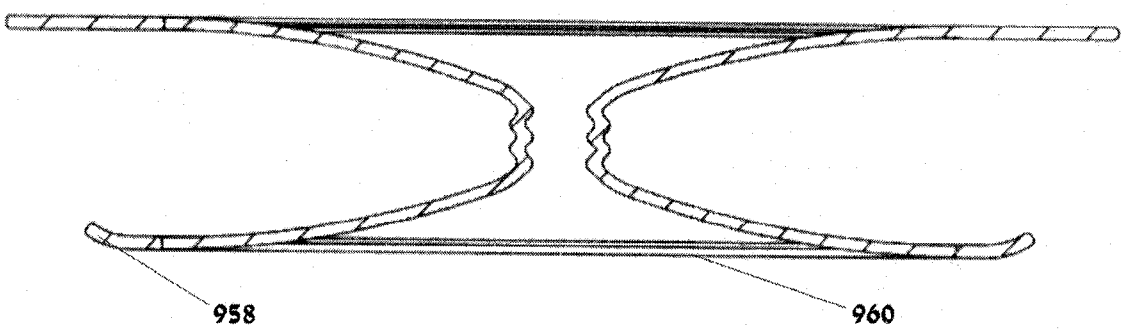


Fig. 28

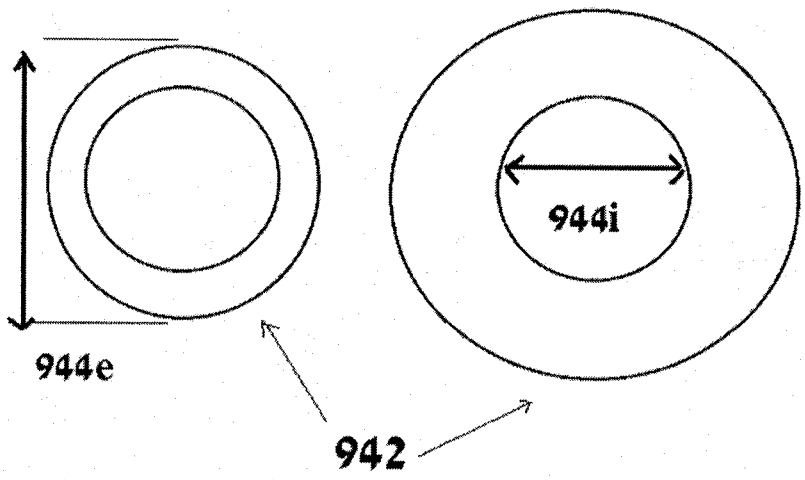


Fig. 29A

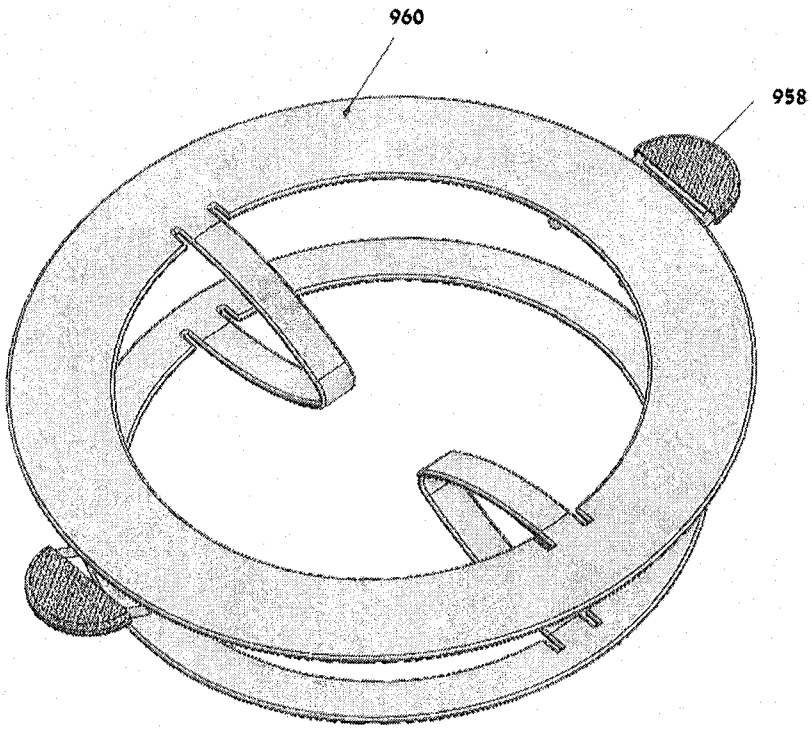


Fig. 29B

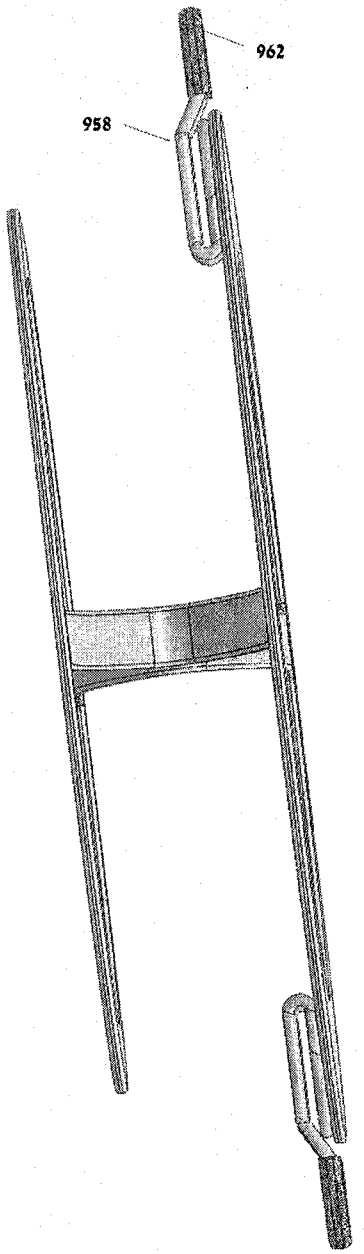
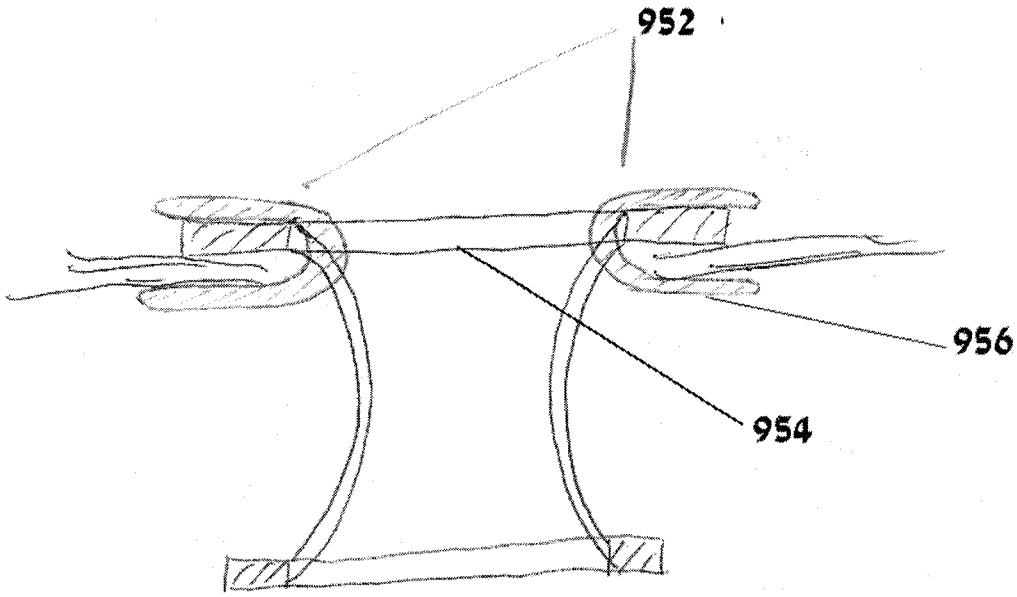


Fig. 30



INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2012/000093

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F2/24 (2012.01)
USPC - 623/2.36
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F2/24 (2012.01)
USPC - 623/2.1, 2.11, 2.12, 2.17, 2.36, 2.37, 2.38

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
ECLA: A61F 2/24R, 2/24R2, 2/24R2D
JCT: 4C097/SB02, SB05, SB06, SB07

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X – Y	US 2010/0204785 A1 (ALKHATIB) 12 August 2010 (12.08.2010) entire document	1-9, 13-15, 18, 19 --- 10-12, 16-17, 20-31
Y	US 2012/0022640 A1 (GROSS et al) 26 January 2012 (26.01.2012) entire document	10-12, 16-17, 20-31
Y	US 2005/0251252 A1 (STOBIE) 10 November 2005 (10.11.2005) entire document	16, 17
Y	US 2004/0049211 A1 (TREMULIS et al) 11 March 2004 (11.03.2004) entire document	29

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"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
05 July 2012	13 JUL 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774