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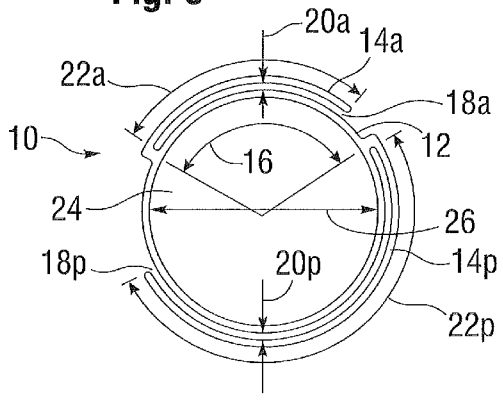
(54) Title: ANCHORING DEVICE AND METHOD FOR REPLACING OR REPAIRING A HEART VALVE

Fig. 3



(57) Abstract: A device for anchoring a prosthetic heart valve or annuloplasty ring to a valve annulus in a heart and a method of im - planting same is disclosed. The device can include a prosthetic valve or annuloplasty ring with one or more anchors configured to be threaded or otherwise passed underneath a native leaflet and/or subvalvular tissue to secure the device at the native annulus.

ANCHORING DEVICE AND METHOD FOR REPLACING OR REPAIRING A HEART VALVE

RELATED APPLICATION

[0001] This application claims priority to United States Provisional Application No. 61/578,758, filed December 21, 2011, the entire disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The current invention generally relates to heart valve repair and replacement. More specifically, the current invention is directed to anchoring devices and methods for prosthetic heart valves and annuloplasty rings configured for rapid implantation and methods for implanting same.

BACKGROUND OF THE INVENTION

[0003] The heart is a hollow muscular organ of a somewhat conical form; it lies between the lungs in the middle mediastinum and is enclosed in the pericardium. The heart rests obliquely in the chest behind the body of the sternum and adjoining parts of the rib cartilages, and typically projects farther into the left than into the right half of the thoracic cavity so that about one-third is situated on the right and two-thirds on the left of the median plane. The heart is subdivided by septa into right and left halves, and a constriction subdivides each half of the organ into two cavities, the upper cavity being called the atrium, the lower the ventricle. The heart therefore consists of four chambers; the right and left atria, and right and left ventricles, with one-way flow valves between respective atria and ventricles and at the outlet from the ventricles.

[0004] The atrioventricular heart valves (i.e., the tricuspid and mitral valves) are located in the center of the heart between the atria and the ventricles of the heart, and play

important roles in maintaining forward flow of blood. Atrioventricular valve dysfunction is also commonly known as "regurgitation" and affects well over one million people globally. The mitral and tricuspid valves are defined by fibrous rings of collagen, each called an annulus, which forms a part of the fibrous skeleton of the heart. The annulus provides peripheral attachments for the two cusps or leaflets of the mitral valve (called the anterior and posterior cusps) and the three cusps or leaflets of the tricuspid valve. The free edges of the leaflets connect to chordae tendinae from more than one papillary muscle. In a healthy heart, these muscles and their tendinous chords support the mitral and tricuspid valves, allowing the leaflets to resist the high pressure developed during contractions (pumping) of the left and right ventricles.

[0005] Although valve regurgitation often occurs due to the dilatation of the valve annulus, mitral and tricuspid valve function and competency frequently depend on the fine geometric and functional integrity of the valve's supporting structures, such as, for example, the associated subvalvular apparatus. The subvalvular apparatus of these heart valves include, among other things, the associated chordae tendinae and papillary muscles.

[0006] As seen in Figures 1 and 2, the mitral valve (MV) is a two-leaflet (or bicuspid) structure of connective tissue separating the left atrium (LA) from the left ventricle (LV). The mitral valve functions to maintain blood flow in one direction, i.e., from the left atrium toward the left ventricle during ventricular relaxation or diastole, while preventing back flow in the opposite direction during ventricular contraction or systole. The anterior leaflet (AL) and posterior leaflet (PL) are separated by the anterior commissure (AC) and posterior commissure (PC). The bases of the two valve leaflets are attached to a circular fibrous structure of the heart called the mitral annulus (AN), and the leaflet free edges are attached to chordae tendinae arising from the papillary muscles of the left ventricle. An anterior leaflet (AL) is relatively large and attaches to the anterior segment of the annulus, while a posterior leaflet (PL) is smaller but extends further circumferentially and attaches to the posterior segment of the annulus. The posterior leaflet presents three scallops

identified as PI, P2, P3, while the corresponding non-scalloped parts of the anterior leaflet are identified as Al, A2, and A3, according to Carpentier's segmentation.

[0007] The tricuspid valve also has subvalvular structures, but is a tricuspid (i.e., three cusp or leaflet) structure as opposed to the bicuspid structure of the mitral valve. Some mitral and tricuspid valve replacement procedures involve the removal of these subvalvular structures. However, the subvalvular structures may play a role in maintaining the proper shape of the ventricles, and thus their preservation may be desirable, depending on the particular circumstances.

[0008] When the left ventricle contracts after filling with blood from the left atrium, the walls of the ventricle move inward and release some of the tension from the papillary muscle and chords. The blood pushed up against the under-surface of the mitral leaflets causes them to rise toward the annulus plane of the mitral valve. As they progress toward the annulus, the leading edges of the anterior and posterior leaflet come together forming a seal and closing the valve. In the healthy heart, leaflet coaptation occurs near the plane of the mitral annulus. The blood continues to be pressurized in the left ventricle until it is ejected into the aorta. Contraction of the papillary muscles is simultaneous with the contraction of the ventricle and serves to keep healthy valve leaflets tightly shut at peak contraction pressures exerted by the ventricle.

[0009] The native heart valves (such as the aortic, pulmonary, tricuspid, and mitral valves) serve critical functions in assuring the forward flow of an adequate supply of blood through the cardiovascular system. These heart valves can be rendered less effective by congenital, inflammatory, infectious conditions, or other disease. Such damage to the valves can result in serious cardiovascular compromise. Heart valve disease is a widespread condition in which one or more of the valves of the heart fails to function properly. Diseased heart valves may be categorized as either stenotic, wherein the valve does not open sufficiently to allow adequate forward flow of blood through the valve, and/or incompetent, wherein the valve does not close completely, causing excessive backward flow of blood or regurgitation through the valve when the leaflets are supposed

to coapt together to prevent regurgitation. Valve disease can be severely debilitating and even fatal if left untreated. For many years the definitive treatment for such disorders was the surgical repair or replacement of the valve during, for example, open heart surgery.

[0010] Various surgical techniques may be used to repair a diseased or damaged valve, which is typically used on minimally calcified valves. Surgical repair of the native valve is commonly conducted using so-called annuloplasty rings. Examples of annuloplasty rings, including methods of use for repairing native valves, are disclosed in U.S. Patent No. 4,055,861, filed April 9, 1976 and entitled "Support for a Natural Heart Valve"; U.S. Patent No. 5,041,130, filed November 30, 1989 and entitled "Flexible Annuloplasty Ring and Holder"; U.S. Patent No. 6,558,416, filed March 6, 2001 and entitled "Annuloplasty Ring Delivery Method"; and in co-pending U.S. patent application Ser. No. 13/019,506, filed February 2, 2011 and entitled "Devices and Methods for Treating a Heart," the entire contents of each of which are incorporated herein by reference.

[001 1] Sometimes actual replacement of the heart valve is the preferred option. Heart valve replacement may be indicated when there is a narrowing of a native heart valve, commonly referred to as stenosis, or when the native valve leaks or regurgitates, such as when the leaflets are calcified. Due to aortic stenosis and other heart valve diseases, thousands of patients undergo surgery each year wherein the defective native heart valve is replaced by a prosthetic valve, either bioprosthetic or mechanical. Prosthetic cardiac valves have been used for many years to treat cardiac valvular disorders.

[0012] When the valve is replaced, surgical implantation of the prosthetic valve typically requires an open-chest surgery during which the heart is stopped and patient placed on cardiopulmonary bypass (a so-called "heart-lung machine"). In one common surgical procedure, the diseased native valve leaflets are excised and a prosthetic valve is sutured to the surrounding tissue at the valve annulus. Because of the trauma associated with the procedure and the attendant duration of extracorporeal blood circulation, some patients do not survive the surgical procedure or die shortly thereafter. It is well known that the risk to the patient increases with the amount of time required on extracorporeal

circulation. Due to these risks, a substantial number of patients with defective valves are deemed inoperable because their condition is too frail to withstand the procedure. By some estimates, about 30 to 50% of the subjects suffering from aortic stenosis who are older than 80 years cannot be operated on for aortic valve replacement.

[0013] Because of the drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches are garnering intense attention. In one technique, a prosthetic valve is configured to be implanted in a much less invasive procedure by way of catheterization. For instance, U.S. Patent No. 5,411,552 to Andersen et al. describes a collapsible valve percutaneously introduced in a compressed state through a catheter and expanded in the desired position by balloon inflation. Although these remote implantation techniques have shown great promise for treating certain patients, replacing a valve via surgical intervention is still the preferred treatment procedure. One hurdle to the acceptance of remote implantation is resistance from doctors who are understandably anxious about converting from an effective, if imperfect, regimen to a novel approach that promises great outcomes but is relatively foreign. In conjunction with the understandable caution exercised by surgeons in switching to new techniques of heart valve replacement, regulatory bodies around the world are moving slowly as well. Numerous successful clinical trials and follow-up studies are in process, but much more experience with these new technologies will be required before they are completely accepted.

[0014] In some situations, replacement of the native heart valve with a prosthetic heart valve may be the desired treatment. There are approximately 60,000 mitral valve replacements (MVR) each year and it is estimated that another 60,000 patients should receive a MVR due to increased risk of operation and age. The large majority of these replacements are accomplished through open-heart surgery, where a prosthetic heart valve is surgically implanted with the patient on pulmonary bypass. Such surgically implanted prosthetic valves have a long and proven record, with high success rates and clinical

improvements noted after such valve replacement. However, it can be desirable to keep the time that the patient spends on pulmonary bypass to a minimum.

[0015] Surgeons relate that one of the most difficult tasks when attempting valve repair or replacement, either in open heart surgeries or minimally invasive heart valve implantations (e.g., through small incisions) is tying the suture knots that hold the valve or repair ring in position. A typical prosthetic mitral valve implant utilizes 12-24 sutures (commonly about 15) distributed evenly around and manually tied on one side of the sewing ring. The implantation process can be very time consuming and difficult to perform, particularly through minimal size incisions due to the numerous pairs of sutures that need to be precisely placed in the annulus and the knots that are typically used to secure the sutures when the valve is parachuted into place. Similarly, in a valve repair procedure numerous pairs of sutures must be precisely placed around the native annulus to attach the repair device. Minimizing or even eliminating the need to use suture (and/or to tie suture knots) for attachment of prosthetic valves or repair devices would greatly decrease the time of the procedure and/or facilitate the use of smaller incisions, thus reducing infection risk, reducing the need for blood transfusions, reducing the time spent on bypass, and allowing more rapid recovery.

[0016] Accordingly, there is a need for an improved device and associated method of use wherein a prosthetic valve or valve repair device can be implanted in a more efficient procedure that reduces the time required on extracorporeal circulation and/or catheterization. It is desirable that such a device and method be capable of helping patients with defective valves that are deemed inoperable because their condition is too frail to withstand a lengthy conventional surgical procedure. The present invention addresses these needs and others.

SUMMARY OF THE INVENTION

[0017] A valve repair or replacement device for implantation at a native valve annulus and method of implanting the same is disclosed. The device may be a prosthetic valve,

annuloplasty ring, or other device for implantation at the native valve annulus. The device has a central portion with one or more anchors extending therefrom from fixed ends secured to the central portion, with the anchors terminating at free ends. The anchors run substantially parallel to the circumference of the central portion in a curved fashion, forming leaflet-receiving slots between the anchors and central portion. The device is configured to be positioned at the native valve annulus, and then rotated (twisted) to place the anchors underneath the resident valve leaflets, with the resident valve leaflets sliding into the leaflet-receiving slots until the device is fully seated. The leaflets are then held within the slots, which may include inward pressure from the anchor arms that press the leaflets between the anchor arms and the central portion of the device.

[0018] The anchors may extend from the central portion, and may include a cross-section configured to have a different stiffness in-plane than the stiffness out-of-plane. There may be one, two, three, four, or more anchors extending from the central portion. The anchors may extend from the central portion at different positions around the circumference thereof, and may be generally equidistantly positioned around the circumference. The anchors may be formed of metal or polymer or other suitable material, and the device may include a cloth covering. The device may include radiopaque markers and other structures to enhance visibility during implantation. For example, an anchor member may have one or more radiopaque markers positioned thereon, such as at the tip of the free end and/or at the fixed end.

[0019] The assembly may form a prosthetic valve formed by support frame and valve leaflets, with the support frame having a central portion and one or more curved anchors extending therefrom to form at least one slot between the anchor(s) and central portion, with the at least one slot sized to slidingly receive a proximal portion of a heart valve leaflet therein. The anchors and slots may be preferably sized and configured to engage resident leaflets. For example, at least one slot may have a width of similar size to the thickness of a native valve leaflet.

[0020] A device for treating a heart according to an embodiment of the invention comprises a prosthetic valve having a support frame and a valve portion. The valve portion may include a plurality of leaflets secured to the support frame and configured to coapt to permit blood flow in a first direction through the valve portion and to prevent blood flow in a second direction through the valve portion, wherein the first direction is opposite to the second direction, wherein the support frame comprises one or more attachment structures configured to be attached, and/or to otherwise facilitate attachment of the device, to tissue at or adjacent an annulus of a native heart valve.

[0021] The prosthetic valve may be configured for surgical implantation, either via traditional open-heart or minimally invasive techniques, and/or via catheterization. The support frame may have supplemental attachment structures (i.e., in addition to the anchors) for securing the prosthetic valve at a desired location at a native heart valve annulus. For example, the support frame may comprise a sewing ring configured to be sutured to tissue of the annulus of the native heart valve, and/or may include other attachment structures configured to secure the support frame at the valve annulus using no (or minimal) suture, such as an expandable stent structure, clamps, skirts, or other elements configured to engage tissue of, or adjacent to, the native annulus in order to secure the prosthetic valve at the desired position. Examples of sutureless securement devices and methods for use with the current invention are disclosed in U.S. Patent Application Serial No. 12/821,628, filed June 23, 2010 and entitled "Unitary Quick-Connect Prosthetic Heart Valve and Deployment System and Methods," and also in U.S. Patent Application Serial No. 13/167,639, filed June 23, 2011 and entitled "Systems and Methods for Rapidly Deploying Surgical Heart Valves," the entire contents of each of which are expressly incorporated herein by reference.

[0022] An embodiment of the invention is a prosthetic heart valve assembly for replacing a resident heart valve, comprising a prosthetic valve and anchors extending therefrom. The prosthetic valve may have a support frame and a valve portion. The valve portion is a one-way valve, which may have a plurality of leaflets secured to the support

frame about a central axis of the prosthetic valve to an internal flow lumen and configured to coapt to permit blood flow in a first direction through the internal flow lumen and to prevent blood flow in a second direction through the internal flow lumen. The prosthetic valve has an exterior surface, which may be configured to engage tissue of a heart. At least one anchor member extends from the support frame, the anchor member comprising a proximal fixed end secured to the support frame and a distal free end. The anchor member extends at least partially around the circumference of the prosthetic valve (radially about the central axis thereof) and substantially parallel to the prosthetic valve exterior to define a leaflet-receiving slot configured to slidingly receive a leaflet of a heart valve. The leaflet-receiving slot extends in continuous, unbroken fashion from the proximal fixed end of the anchor member to the distal free end of the anchor member. The slot is sized and configured to slidingly receive and hold a desired valve leaflet of a resident valve, where a resident valve is a native heart valve or a previously-implanted prosthetic valve. Depending on the particular application, the slot may have a length of 0.25 to 3.5 inches and a width of 0.005 to 0.25 inches.

[0023] The prosthetic valve may be substantially tubular, with the exterior surface forming a substantially continuously curved surface about the circumference thereof, with the anchor member forming a curve which parallels the curved surface of the exterior surface of the valve.

[0024] A valve assembly according to the invention may form a prosthetic mitral valve assembly with first and second anchor members defining first and second leaflet-receiving slots and having first and second fixed ends and first and second free ends, respectively. Each slot extends in continuous, unbroken fashion from the anchor fixed end to the anchor free end. The anchors can be sized and positioned to engage the anterior and posterior leaflets of a native mitral valve, so that the slots are sized to receive these leaflets. The first and second anchors may have fixed ends which are spaced at least 90 degrees apart, and more specifically about 100 to 140 degrees apart, and more specifically 120 degrees apart, about the circumference of the device, with the anchor extending in the same

rotational direction (e.g., clockwise) about the circumference of the device. The first anchor member may pass around the circumference of the prosthetic valve through an angle of at least 90 degrees, with the second anchor passing around the circumference of the prosthetic valve through an angle of at least 120 degrees.

[0025] An assembly according to the invention may form an annuloplasty ring having a support ring having a circumference and comprising a central opening defining a flow axis through which fluid may flow, a covering around the support ring, the covering comprising an outer surface, and a first anchor member extending from the support frame. The first anchor may have a first proximal fixed end secured to the support ring and a first distal free end, wherein the first anchor member extends around at least partially around a circumference of the support ring and substantially parallel to outer surface of the covering to define a first leaflet-receiving slot configured to receive a leaflet of a heart valve. The first leaflet-receiving slot may preferably extend in continuous, unbroken fashion from the first proximal fixed end to the first distal free end. The first anchor member may extend around the circumference of the prosthetic valve through an angle of at least 90 degrees.

[0026] An annuloplasty ring may further include additional anchor members. For example, it may include a second anchor member having a second proximal fixed end secured to the support ring and a second distal free end, wherein the second anchor member extends at least partially around the circumference of the annuloplasty ring and substantially parallel to the exterior thereof to define a second leaflet-receiving slot configured to receive a second leaflet of a heart valve. The second leaflet-receiving slot may extend in continuous, unbroken fashion from the second proximal fixed end to the second distal free end. The second proximal fixed end may be circumferentially displaced from the first anchor proximal fixed end by an angle of at least 90 degrees, by an angle of between 100 and 140 degrees, or by an angle of about 120 degrees. The first anchor may extends around the circumference of the annuloplasty ring through an angle of between 90 and 120 degrees, and the second anchor may extend around the circumference of the

annuloplasty ring through an angle of between 150 and 240 degrees. The support ring may be substantially circular, substantially D-shaped, and/or substantially saddle-shaped.

[0027] Methods of implanting a device (e.g., annuloplasty ring, prosthetic valve, etc.) at a native valve annulus can include providing a device comprising a central portion, a first curved anchor extending from a first fixed end secured to the central portion and passing generally parallel to an outer surface thereof to a first free end of the first curved anchor to form a first leaflet-receiving slot, a second curved anchor extending from a second fixed end secured to the central portion and passing generally parallel to an outer surface thereof to a second free end to form a second leaflet-receiving slot, wherein the central portion defines a flow orifice with a flow axis therethrough. The method may include positioning the device with the first curved anchor and second curved anchor adjacent the native valve annulus, with the fluid flow axis of the device generally parallel to a fluid flow path through the native valve annulus, and with the first free end positioned adjacent a first commissure of a resident valve at the native valve annulus; placing the first free end underneath a first resident valve leaflet; rotating the device substantially about the fluid flow axis thereof to advance the first free end underneath the first resident valve leaflet and thereby slidingly advancing the first resident valve leaflet into the first leaflet-receiving slot; monitoring the position of the second free end with respect to a second commissure of the resident valve; and stopping rotation of the device about the fluid flow axis once the second free end is adjacent the second commissure of the resident valve. Once the second free end is adjacent the second commissure, the surgeon or other user can place the second free end underneath a second resident valve leaflet; recommencing rotating the device substantially about the fluid flow axis thereof to advance the second free end underneath the second resident valve leaflet and thereby slidingly advancing the second resident valve leaflet into the second leaflet-receiving slot while also further advancing the first free end underneath the first resident valve leaflet and further slidingly advancing the first resident valve leaflet into the first leaflet-receiving slot; and stop rotation of the device when the first resident valve leaflet is slidingly advanced into the

first leaflet-receiving slot at a position adjacent the first fixed end, whereby deployment of the device is completed.

[0028] The native valve annulus may be a mitral valve annulus or a tricuspid valve annulus. If the native annulus is a tricuspid annulus, the device may include three anchors spaced around the perimeter of the device, with each anchor configured to slidingly receive one of the three valve leaflets of the resident tricuspid valve. Where the native valve annulus is a mitral valve annulus with intact native mitral valve leaflets, the first commissure may be a PC commissure of a native mitral valve, the first leaflet may be an anterior leaflet of the native mitral valve, the second commissure may be an AC commissure of the native mitral valve, and the second leaflet may be a posterior leaflet of the native mitral valve.

[0029] Methods of implanting the device include open heart surgery, including surgery where prior to positioning the device adjacent the native valve annulus, the surgeon or other user temporarily ceases heart function of the heart and places the patient on cardiopulmonary bypass. After completing deployment of the device, the heart function of the heart may be resumed and the patient then removed from cardiopulmonary bypass.

[0030] Methods of the invention include providing a valve repair or replacement device. The device may comprise an annuloplasty ring with one or more anchors extending therefrom, or may comprise a prosthetic valve with a support frame and leaflets with the leaflets secured to the support frame to form a one-way valve structure and with one or more anchors extending from the support frame. Each anchor has a proximal end secured to the support frame and a free distal end, with a slot defined between the support frame and the anchor. The anchor is positioned adjacent a commissure point of the native valve, and the free end is positioned underneath a native leaflet of the valve (and below the native heart valve annulus). The device (e.g., annuloplasty ring or prosthetic heart valve) is rotated about its central axis to advance the anchor underneath the native leaflet, so that the native leaflet is slidingly advanced into the slot. Advancement and securement can be performed in an open-heart or minimally-invasive procedure. The central portion (e.g.,

ring portion or support frame) may comprise a sewing ring, and securing the support frame to the tissue of the native heart valve annulus may include suturing the sewing ring to tissue of the native heart valve annulus. The device may comprise a stent, with the stent being expanded into contact with native tissue before, during, or after the anchor(s) are rotated underneath the resident leaflets). The native valve annulus may be of any heart valve, with particular application to mitral and tricuspid valves.

[0031] After the central portion is secured to the native valve annulus, the surgeon or other user may add one or more stitches or other securing device/methods to secure the device to the local tissue in order to prevent the device from rotating back out of its deployed position. In such a deployment, the anchors hold the device to prevent movement up, down, sideways, etc., while the sutures or other tissue connectors serve to prevent the device from rotating such that the leaflets rotatingly slide out of the slots to be released from the anchors.

[0032] The method may include temporarily ceasing heart function of the heart and placing the patient on cardiopulmonary bypass, performing various steps (such as advancement and securing of the prosthetic valve to the native annulus), and then resuming heart function of the heart and removing the patient from cardiopulmonary bypass. Deployment of the device may occur with the patient on bypass, or may occur with the patient's heart beating (e.g., after the patient is removed from bypass, with heart function restarted) and with the surgeon or other user monitoring the heart function and/or ventricular shape as the length adjustments are made.

[0033] Methods of the invention may include, prior to securing the support frame to the tissue of the native heart valve annulus, removing some native valve leaflets and/or subvalvular structure (e.g., chordae tendinae) from the heart.

[0034] The foregoing and other objects, features, and advantages of the invention will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] FIG. 1 is a cross-sectional view of the left side of the human heart showing the left atrium separated from the left ventricle by the mitral valve;

[0036] FIG. 2 is a surgeon's or plan view of a mitral valve in the closed position illustrating the anterior leaflet (AL) and the posterior leaflet (PL) attached to the annulus (AN), and indicating identifiable leaflet segments;

[0037] FIG. 3 is a bottom view of an embodiment of a device according to an embodiment of the invention;

[0038] FIGS 4 and 5 are perspective (in partial cross-section) and top views of an embodiment of a device deployed in a heart according to an embodiment of the invention;

[0039] FIGS. 6A-6C are top views of a device being deployed in a mitral valve annulus according to the invention;

[0040] FIGS. 7A-7D are side, bottom, perspective, and top views, respectively of a prosthetic heart valve according to an embodiment of the invention;

[0041] FIGS. 8A and 8B are side views of a device according to an embodiment of the invention;

[0042] FIGS. 9A and 9B are perspective and close-up cross-sectional views of a device according to an embodiment of the invention;

[0043] FIG. 10 is a perspective view of a device according to an embodiment of the invention;

[0044] FIG. 11 is a top view of a device according to an embodiment of the invention;

[0045] FIG. 12 is a top view of a device according to an embodiment of the invention;

[0046] FIG. 13 is a perspective view of a device according to an embodiment of the invention; and

[0047] FIGS. 14A-14B are perspective views of devices according to embodiments of the invention; and

[0048] FIG. 15 is a top view of a device according to an embodiment of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0049] The invention is an anchoring device, including prosthetic heart valves and annuloplasty rings and other devices using that anchoring device, for securement within a patient, such as in a native heart valve annulus in a human heart. The device has particular applicability to devices to be secured at the annulus of a valve (such as the mitral and tricuspid valves) which has subvalvular structures such as chordae tendinae. A mitral valve and its subvalvular structure are depicted in FIGS. 1 and 2.

[0050] FIG. 3 depicts a device 10 for anchoring a prosthetic heart valve or repair ring to the mitral annulus of a heart. The device 10 may be made of a metal such as stainless steel, although other materials (metal or non-metal) may be suitable. The device 10 is composed of a central ring 12 having two semi-circular anchors, namely an anterior anchor 14a and a posterior anchor 14p, attached to and extending from the central ring 12 at positions spaced apart around the circumference of the ring by an angle 16 of approximately 120 degrees. This angle and spacing divides the device 10 into approximately 1/3 and 2/3 sections, thus approximating the proportions of the anterior leaflet and posterior leaflet of a native mitral valve. The anchors 14a, 14p are spaced slightly away from and run substantially parallel to the outer circumference of the central ring 12, and define an anterior leaflet receiving slot 18a and posterior leaflet receiving slot 18p, respectively. The leaflet receiving slots 18a, 18p have a width 20a, 20p which is generally on the order of the thickness of the anterior and posterior leaflets of a mitral valve, i.e., the slots 18a, 18p have a width of about 0.005 to 0.25 inches. These slot widths 20a, 20p are sufficient to permit the anterior and posterior leaflets of a mitral valve to

slidingly enter the slots 18a, 18p. The slots 18a, 18p have lengths 22a, 22p sufficient to receive a substantial portion of the respective mitral valve leaflets. The length 22a of the anterior leaflet receiving slot 18a may be between about 0.25 to 3.5 inches, while the length 22p of the posterior leaflet receiving slot 18p may be between about 0.25 and 3.5 inches. The central ring 12 defines an inner opening 24 having an inner diameter 26. If the device 10 is part of a prosthetic heart valve (e.g., part of a support stent of a prosthetic heart valve), the inner diameter 20 may be between 0.75 to 1.5 inches. If the device 10 is part of a valve repair device such as an annuloplasty ring, the inner diameter may be between 0.75 to 1.5 inches.

[0051] FIGS. 4 and 5 depict the device 10 anchored in a mitral valve annulus AN. The anterior leaflet AL is positioned within the anterior leaflet slot 18a such that the slot 18a holds a proximal portion of the anterior leaflet AL (with the proximal portion of the leaflet being adjacent the annulus AN, as opposed to a distal portion which is adjacent the leaflet edge). Similarly, the posterior leaflet PL is positioned within the posterior leaflet slot 18p such that the slot 18p receives a proximal portion of the posterior leaflet PL (with the proximal portion of the leaflet being adjacent the annulus AN, as opposed to a distal portion which is adjacent the leaflet edge). The anterior and posterior anchors 14a,14p are thus positioned between their respective leaflets AL, PL and the ventricle wall, while the central ring 12 is positioned within the mitral valve annulus AN. The anchors 14a, 14p and slots 18a, 18p thus prevent migration of the device, e.g., into the atrium during systole or into the ventricle during diastole. The leaflet slots 18a, 18p serve to grip the leaflets AL, PL to anchor the device 10 in the desired position in the annulus AN.

[0052] FIGS. 6A-6C depict schematically the installation of the device 10, as viewed from the left atrium (i.e., looking through the mitral valve into the left ventricle). In Fig. 6A, the device 10 is positioned with the central ring 12 generally centrally positioned in the mitral valve annulus AN, and with the posterior anchor free end 28p adjacent the AC commissure. The posterior anchor free end 28p is inserted (e.g., by manipulating the device 10 as a whole and/or by bending the posterior anchor free end 28p away/downward

from its normal position adjacent the central ring 12) between the anterior and posterior leaflets so it is positioned underneath the posterior leaflet PL, and the device 10 is then rotated counter-clockwise, with the posterior leaflet PL sliding into the posterior anchor slot 18p, to the point where the anterior anchor free end 28a is adjacent the PC commissure, as depicted in FIG. 6B. The anterior anchor free end 28a is then inserted (e.g., by manipulating the device 10 as a whole and/or by bending the anterior anchor free end 28a away/downward from its normal position adjacent the central ring 12) between the anterior and posterior leaflets so it is positioned underneath the anterior leaflet AL, and the device 10 is further rotated clockwise with the anterior leaflet AL sliding into the anterior anchor slot 18a (and the posterior leaflet PL further sliding into the posterior anchor slot 18b) until the device is fully seated. When fully seated, as depicted in FIG. 6C, both anchors 14a, 14p are beneath their respective leaflets AL, PL, the attachment bar 30a of the anterior leaflet anchor 14a is positioned at the PC commissure, and the attachment bar 30p of the posterior leaflet anchor 14p is positioned at the AC commissure.

[0053] FIGS. 7A-7D depict a prosthetic mitral valve assembly 40 utilizing an anchoring assembly of the invention. The valve assembly 40 has a tri-leaflet valve portion 42 secured to a support structure 44. The support structure 44 includes an anchoring device 46, which itself has a central ring 48 with posterior and anterior anchors 50a, 50p defining posterior and anterior slots 52a, 52p configured to slidingly receive posterior and anterior leaflets of a mitral valve. The assembly 40 further includes an upstream stent structure 54 which is configured to be expanded into engagement with surrounding tissue, such as with the atrium wall. The stent could be either self-expanding or balloon expandable. The stent 54 would preferably be crimped (in the case of balloon expandable) or restrained (in the case of self-expandable), to a relatively small delivery diameter, as depicted in FIG. 8A, for delivery. Once the anchor portion was fully engaged with the native valve leaflets (i.e., rotated into engagement), the stent could be deployed to its expanded condition, as depicted in FIG. 8B. If the stent portion 54 were self-expanding, the delivery catheter would need a sheath to restrain the stent in its compressed delivery

configuration. If the stent were balloon expandable, the delivery catheter would need a balloon or similar radially expansion device to radially expand the stent.

[0054] The configurations of various elements could vary at different positions on the assembly. For example, the cross-sectional shape of the anchors and/or central ring could be other than rectangular, and/or could vary along their lengths. For example, as depicted in FIGS. 9A and 9B, an anchor assembly 60 could have a central ring 62, with anchor portions 64a, 64p having a "C"-shaped channel cross section. The cross section shape could be designed such that the in-plane stiffness of the anchors was substantially less than their out-of-plane stiffness, or vice-versa. Such differential stiffness could help the anchors conform to the native annulus during insertion while still providing high retention forces in the axial direction.

[0055] FIG. 10 depicts a further embodiment of the device, wherein an anchor assembly 70 has a posterior anchor 72p and an anterior anchor 72a, but the anchors 72a, 72p are secured to separate assembly ring portions 74a, 74p. These separate ring portions 74a, 74p can rotate with respect to each other, thereby permitting separate (independent) rotation of the anchors 72a, 72p with respect to each other. Such independent rotation of the anchors 72a, 72p could make installation of the device easier for the surgeon or other user.

[0056] Various modifications could be made to promote ease of use. For example, an anchor device 80 portion could have anchors 84a, 84p having rounded or otherwise blunted ends, such as the spherical-tipped ends 86a, 86p depicted in FIG. 11, to reduce the potential for the tips to snag on or traumatize the tissue of the leaflets, ventricle wall, chordae, etc., as the leaflets are slid into the slots 88a, 88p. Such structures could make it easier for the anchors 84a, 84p to be threaded behind the valve leaflets. The rounded structures could be formed as a unitary portion (i.e., at the same time, of the same material, etc.) with the anchors, or could be separate pieces attached to the anchors during manufacture. For example, the rounded portions could be formed from PTFE which is press-fit and/or glued to the anchors.

[0057] An anchoring device according to the invention could use various materials, and could include coverings, etc. For example, the structure of the anchoring device (formed of, e.g., metal) could include a cloth covering. Such coverings could serve multiple purposes. For example, covering the device with a biocompatible covering which encourages tissue ingrowth, such as PTFE cloth, would encourage the patient' s native tissue to attach to the device over time, possibly reducing tissue irritation and potential damage from metal-on-tissue contact. The tissue ingrowth could also assist to improve the anchoring of the device, by providing mechanical stability and thereby reduce the chance of migration and embolization. The covering, especially a cloth covering, could also provide the ability for a surgeon or other user to use sutures to further secure the device in place. A flexible/resilient covering, such as cloth, could also provide a surface which would "give way" (e.g., be compressed) to permit the leaflets to be slid into the slots, but would also push back (i.e., rebound) into the slots to engage the leaflets once in place and assist in holding the device in place. A covering could also be used to hold a lubricious coating, such as glycerol, which could facilitate the threading of the anchors between the leaflets and the ventricle.

[0058] Coverings, if present, could be configured to bioresorb or otherwise degrade over time, or could be formed from material(s) that will not biodegrade/bioresorb over time. Examples of such materials for potential use with the invention include PTFEs, polyesters, nylons, and others.

[0059] The structural support portions of devices according to the invention could be formed from metals or non-metals, including stainless steel, nitinol, titanium, CoCr, alloys, polymeric materials, and other biocompatible materials. The structural support portions (i.e., the central ring and anchors) may preferably be formed from materials which are substantially rigid with minimal elasticity, and which are not easily plastically deformed. Devices according to the invention may include radiopaque markers and other structures to enhance visibility during implantation. For example, an anchor member may have one or more radiopaque markers positioned thereon, such as at the tip of the free end

and/or at the fixed end. Such radiopaque markers may be formed from highly-radiopaque materials (e.g., gold, platinum) mounted on, embedded in, formed with, or otherwise secured to the structural support and/or other portions of the device.

[0060] FIG. 12 depicts a further embodiment of an anchor assembly 90, where a central ring 92 has three anchors 94a, 94b, 94c positioned around the perimeter of the device. In the specific embodiment depicted, the anchors 94a, 94b, 94c are spaced at about 120 degrees to each other, although other spacings are within the scope of the invention. The three-anchor design could be applicable for deployment at non-mitral valve locations, such as at the tricuspid valve position (i.e., the valve and annulus between the right ventricle and right atrium). Alternatively, such an assembly could be used for anchoring at the mitral valve, where one of the arms (e.g., arm 94a) was used to be secured to the anterior leaflet, and the other two arms (e.g., arms 94a, 94c) were used to be secured to the posterior leaflet. In order to properly thread the device into place, the surgeon or other user might need to form an incision in the posterior leaflet, such as at the position midway between the commissure points AC and PC near the leaflet/annulus junction, in order to advance the "extra" arm (i.e., arm 94c) underneath the posterior leaflet. The posterior leaflet would then have two anchors - one starting at the AC commissure and one starting at the middle of the posterior leaflet (i.e., in the so-called "P2" section). Such a configuration may provide improved deployment and anchoring capabilities.

[0061] A further embodiment of the invention is depicted in FIG. 13, wherein an anchor assembly 100 has a central portion 102 with anchors 104a, 104p positioned below (e.g., downstream of) the central portion 102. This configuration provides the potential for having a larger central opening 106 on the central portion 102 for a given native valve annulus size, which could thus accommodate a larger prosthetic valve orifice (where the anchor assembly is part of a prosthetic valve assembly) or a larger native valve orifice (where the anchor assembly is part of a repair device such as an annuloplasty ring).

[0062] FIGS. 14A and 14B depict further embodiments of an anchor assembly 110, wherein anchors 112, 112p are secured directly to a central portion in the form of a stent

structure 114. The stent structure 114 is thus the central portion in lieu of a central ring portion such as depicted in FIG. 3. FIG. 14B has the addition of the valve support assembly (i.e., commissure supports 116) being formed with or otherwise attached to the assembly 110. Such anchor assemblies could be useful as part of a prosthetic valve assembly, such as that previously depicted in FIGS. 7A-7D. The embodiments of FIGS. 14A-14B have the additional advantage that the entire anchor assembly can be radially compressed, so that a prosthesis (e.g., annuloplasty ring and/or prosthetic heart valve) could be crimped or otherwise radially compressed into a smaller delivery profile for potential delivery to and deployment at the native annulus via catheterization (e.g., percutaneous/MIS). The device as shown in figure 14 could be delivered through a catheter in a percutaneous or minimally-invasive type intervention, or via open heart.

[0063] Although the embodiments depicted above generally had substantially circular configurations, which may be preferred in some applications such as prosthetic heart valves and annuloplasty rings, the invention is not so limited. For example, non-circular configurations could also be used, such as the generally D-shaped configuration depicted in FIG. 15. The anchor assembly 120 has a central portion 122 which is substantially D-shaped, with anchors 124a, 124p extending therefrom and curving to match the substantially D-shape of the central portion 122. Such non-circular configurations could be particularly useful where the anchor assembly 120 was serving as part of an annuloplasty ring or similar repair device, such as an annuloplasty ring for the mitral valve. Note that an anchor assembly according to the invention, whether circular or non-circular, does not have to be planar. For example, three-dimensional forms, such as a so-called "3D saddle shape" like that disclosed in U.S. Patent No. 6,805,710, issued Oct. 19, 2004 and entitled "Mitral Valve Annuloplasty Ring for Molding Left Ventricle Geometry" (the entire contents of which are incorporated by reference herein) could also be used with the invention in order to form a device to conform to, or to deform/reshape, the native anatomy.

[0064] In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only preferred examples of the invention and should not be taken as limiting the scope of the invention. Rather, the scope of the invention is defined by the following claims.

What is claimed is:

1. An anchoring device for a device intended for implantation at a native heart valve annulus, said anchoring device comprising:

a central portion with one or more anchors extending therefrom, each of said one or more anchors having a proximal fixed end secured to the central portion and terminating in free end, said one or more anchors being spaced slightly away from and running substantially parallel to the circumference of the central portion in a curved fashion, forming valve leaflet-receiving slots between the anchors and the central portion.

2. The anchoring device of claim 1, wherein the anchors include a cross-section configured to have a different stiffness in-plane than the stiffness out-of-plane.

3. The anchoring device of claim 1, wherein the anchors are generally equidistantly positioned around the circumference central portion of the anchoring device.

4. The anchoring device of claim 1, wherein the anchors are formed of metal or polymer.

5. The anchoring device of claim 1, further comprising one or more radiopaque markers positioned thereon.

6. The anchoring device of claim 1, wherein the device has two anchors and the fixed ends of the anchors are spaced at least 90 degrees apart.

7. The anchoring device of claim 1, wherein the device has two anchors and the fixed ends of the anchors are spaced about 120 degrees apart.

8. The anchoring device of claim 1, wherein the device has two anchors, one of which is longer than the other.

9. The anchoring device of claim 1, wherein the device has three anchors.

10. The anchoring device of claim 1, wherein the slots have a length of about 0.25 to 3.5 inches.

11. The anchoring device of claim 1, further comprising a cloth covering.

12. The anchoring device of claim 1, wherein the central portion is substantially circular.

13. The anchoring device of claim 1, wherein the central portion is generally D-shaped.

14. The anchoring device of claim 1, further comprising a prosthetic valve comprising a support frame and a valve portion, wherein the anchoring device is secured to the support frame of the prosthetic valve.

15. The anchoring device of claim 14, wherein at least a portion of the prosthetic valve is substantially tubular and has an exterior surface forming a continuously curved surface, and said one or more anchors form a curve which parallels the curved surface of the exterior surface of the prosthetic valve.

16. The anchoring device of claim 1, further comprising an annuloplasty ring, wherein the anchoring device is secured to the ring such that the one or more anchors extend at least partially around a circumference of the ring and substantially parallel to an outer surface of the ring.

17. A method of implanting a device at a native valve annulus, comprising:

providing a device comprising a central portion, a first curved anchor extending from a first fixed end secured to the central portion and passing generally parallel to an outer surface thereof to a first free end of the first curved anchor to form a first leaflet-receiving slot, a second curved anchor extending from a second fixed end secured to the central portion and passing generally parallel to an outer surface thereof to a second free

end to form a second leaflet-receiving slot, wherein the central portion defines a flow orifice with a fluid flow axis therethrough;

positioning the device with the first curved anchor and second curved anchor adjacent the native valve annulus, with the fluid flow axis of the device generally parallel to a fluid flow path through the native valve annulus, and with the first free end positioned adjacent a first commissure of a resident heart valve at the native valve annulus;

placing the first free end underneath a first resident valve leaflet;

rotating the device substantially about the fluid flow axis thereof to advance the first free end underneath the first resident valve leaflet and thereby slidingly advancing the first resident valve leaflet into the first leaflet-receiving slot;

monitoring the position of the second free end with respect to a second commissure of the resident heart valve;

stopping rotation of the device about the fluid flow axis once the second free end is adjacent the second commissure of the resident heart valve;

placing the second free end underneath a second resident valve leaflet;

recommencing rotating the device substantially about the fluid flow axis thereof to advance the second free end underneath the second resident valve leaflet and thereby slidingly advancing the second resident valve leaflet into the second leaflet-receiving slot while also further advancing the first free end underneath the first resident valve leaflet and further slidingly advancing the first resident valve leaflet into the first leaflet-receiving slot; and

stopping rotation of the device when the first resident valve leaflet is slidingly advanced into the first leaflet-receiving slot at a position adjacent the first fixed end, whereby deployment of the device is completed.

18. The method of claim 17, wherein the device comprises a prosthetic valve, wherein the prosthetic valve comprises a support frame and leaflets with the leaflets secured to the support frame to form a one-way valve structure controlling fluid flow along the flow axis.

19. The method of claim 17, wherein the resident valve annulus is a native mitral valve annulus, the first commissure is a PC commissure of a native mitral valve, the first leaflet is an anterior leaflet of the native mitral valve; the second commissure is an AC commissure of the native mitral valve, and the second leaflet is a posterior leaflet of the native mitral valve.

20. The method of claim 17, wherein the device comprises an annuloplasty ring, with the central portion forming the ring portion of the annuloplasty ring.

Fig. 1

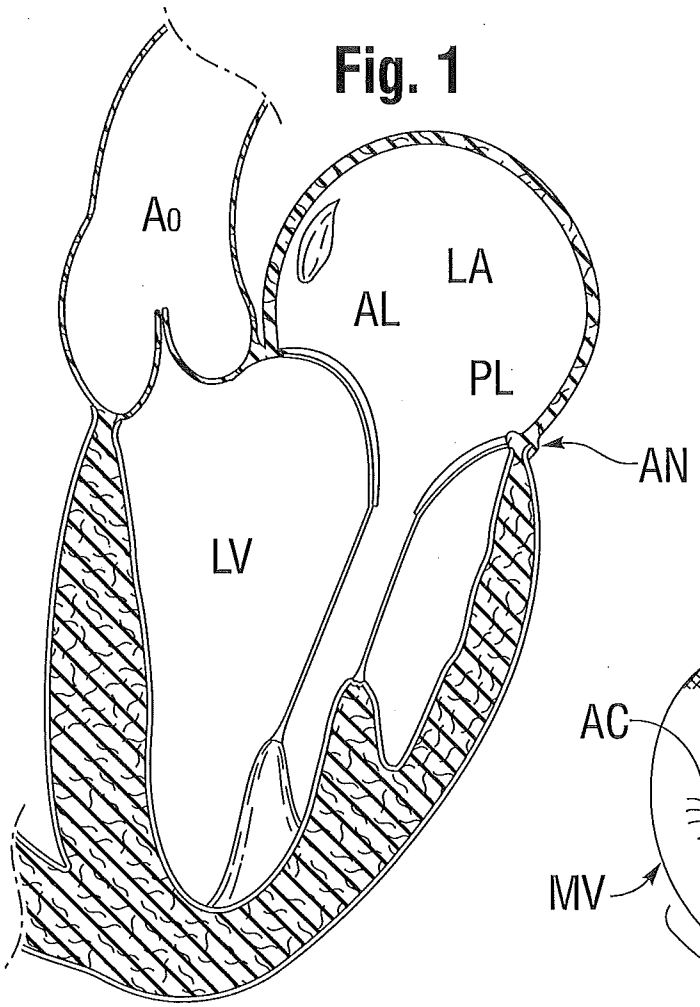


Fig. 2

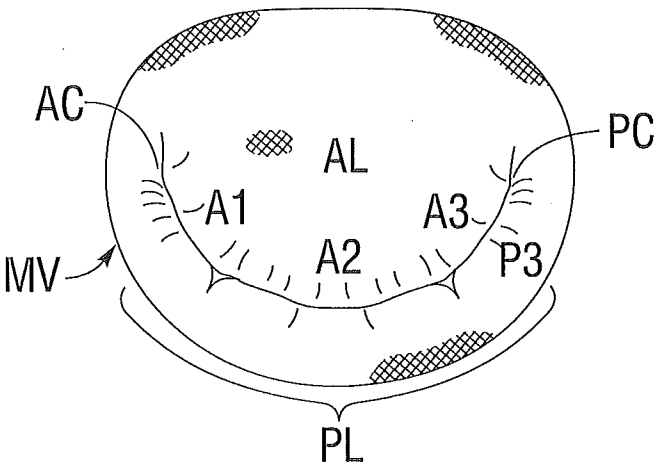


Fig. 3

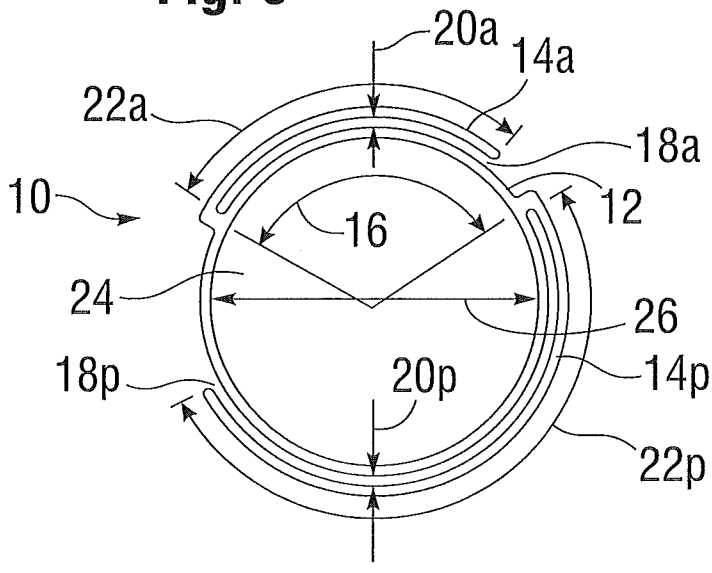


Fig. 4

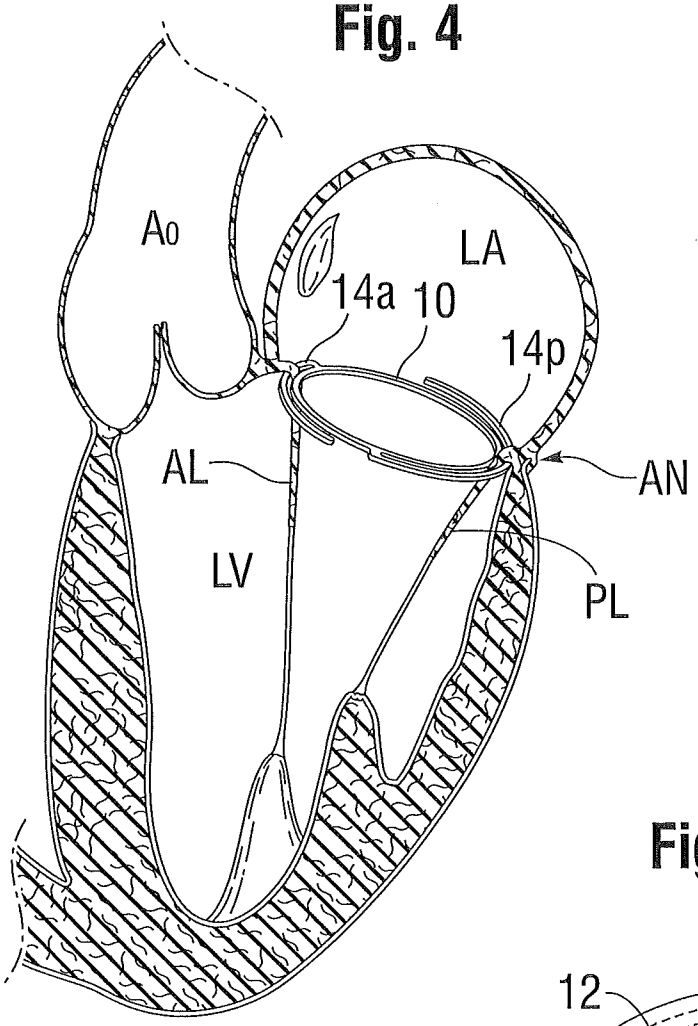


Fig. 5

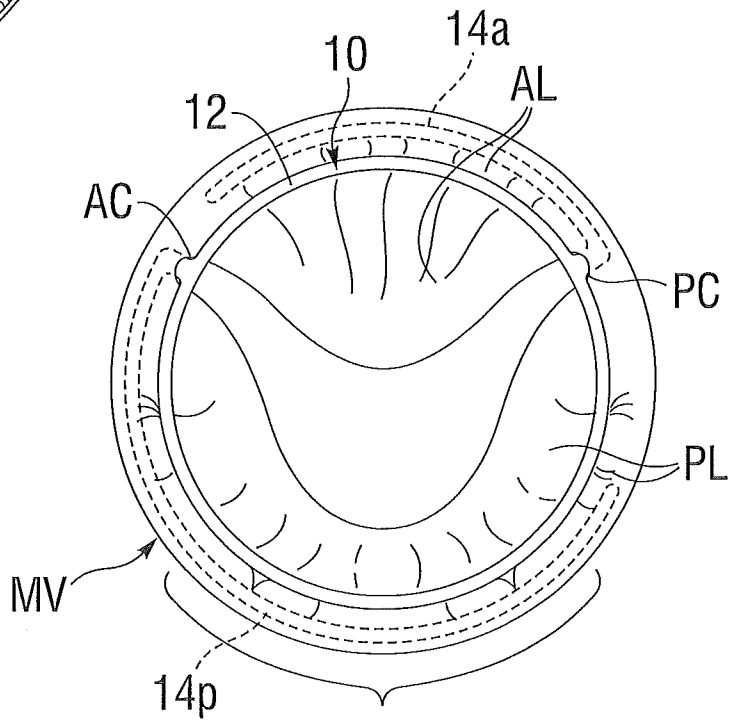


Fig. 6A

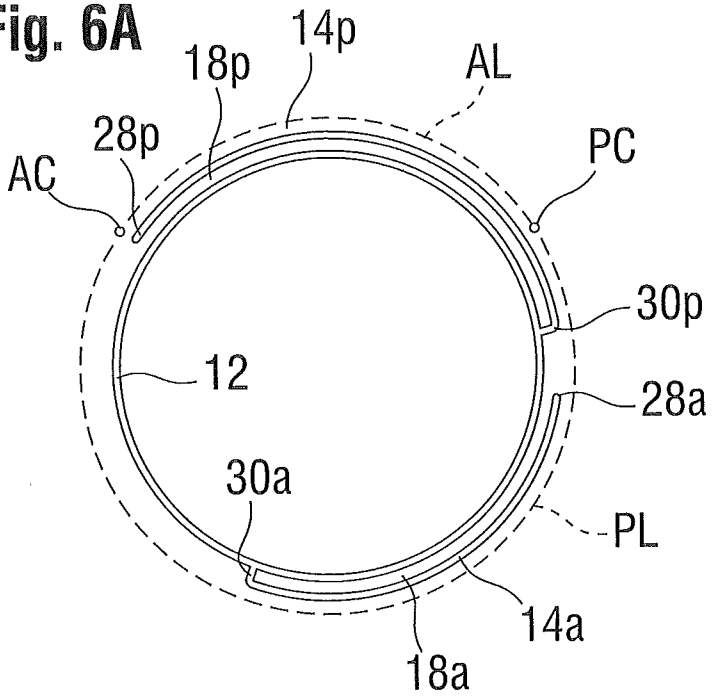


Fig. 6B

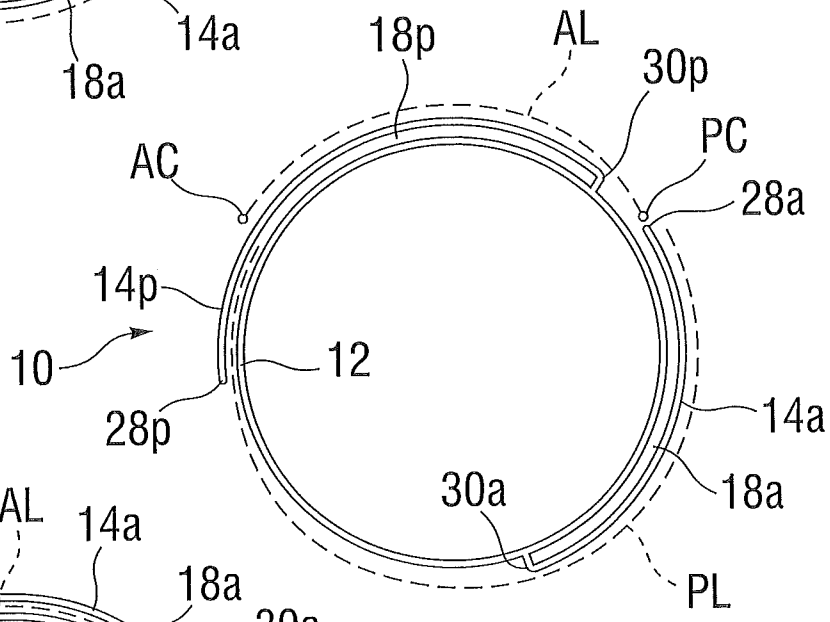


Fig. 6C

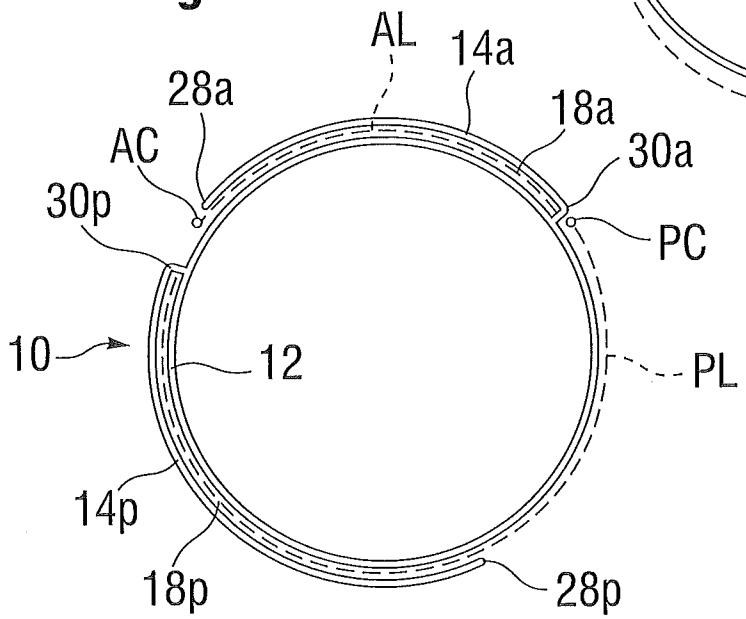


Fig. 7A

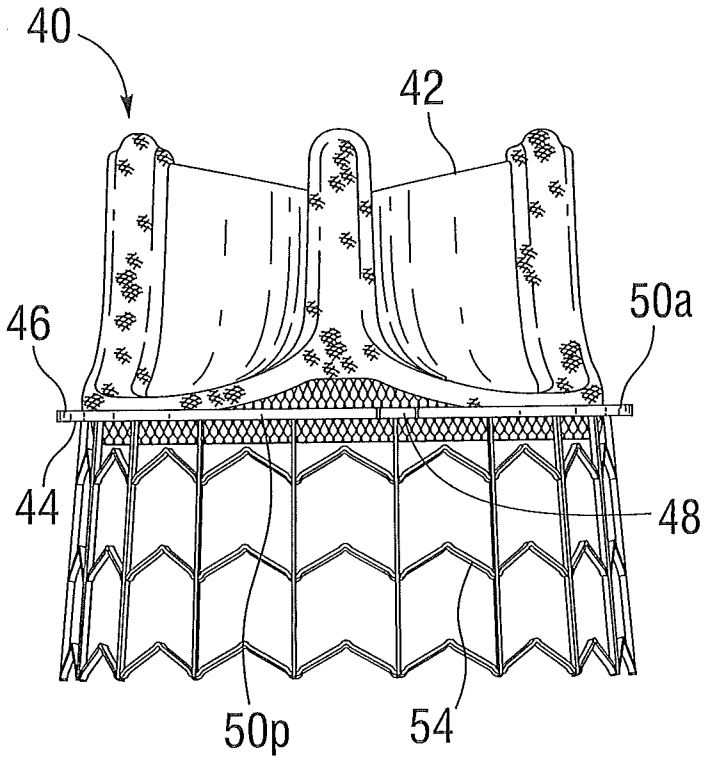


Fig. 7B

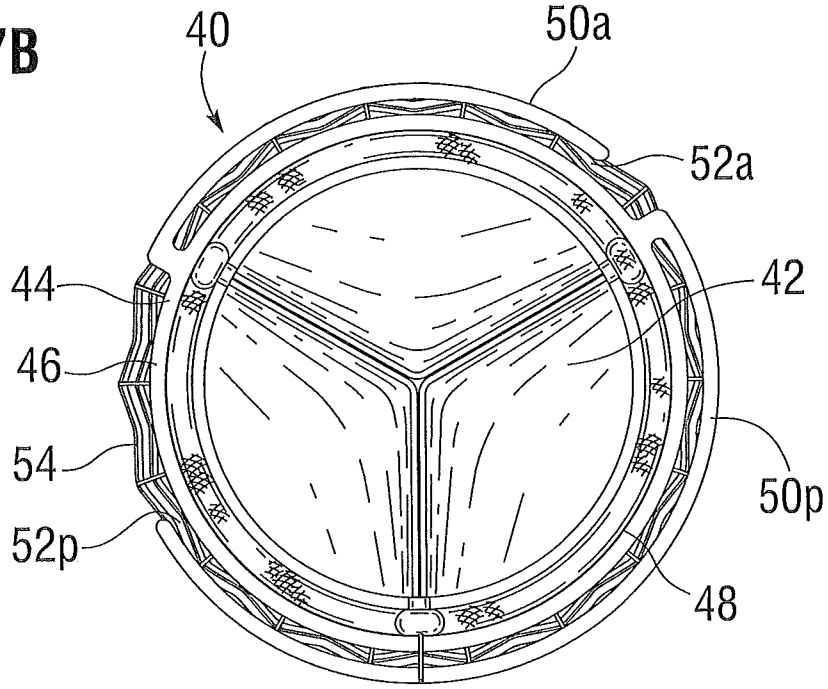


Fig. 7C

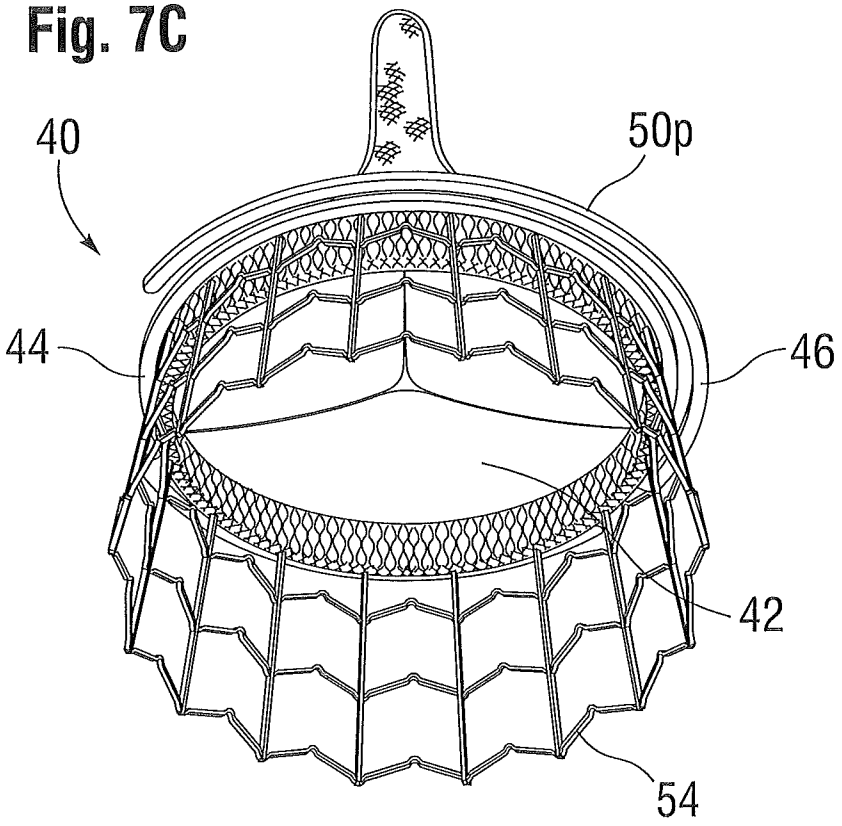


Fig. 7D

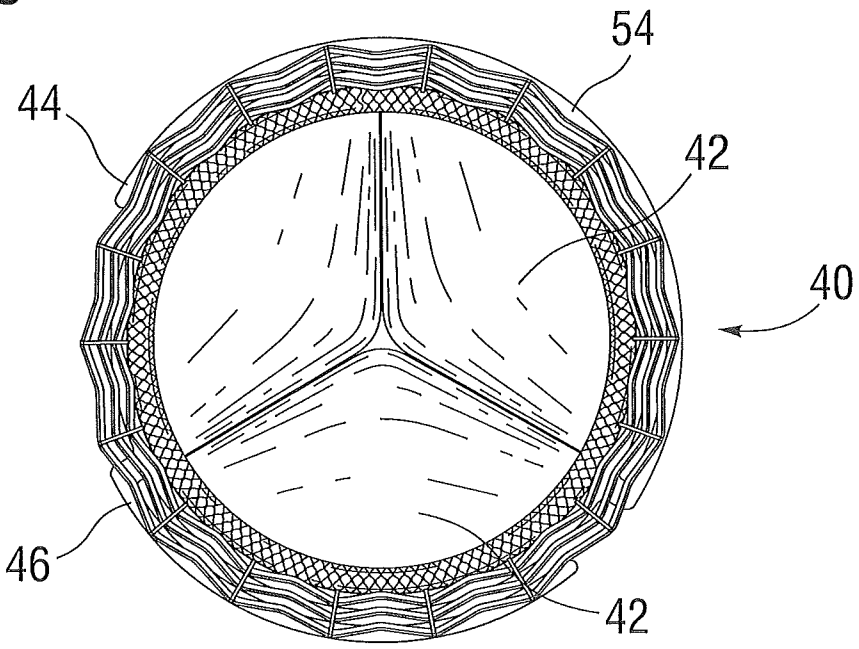


Fig. 8A

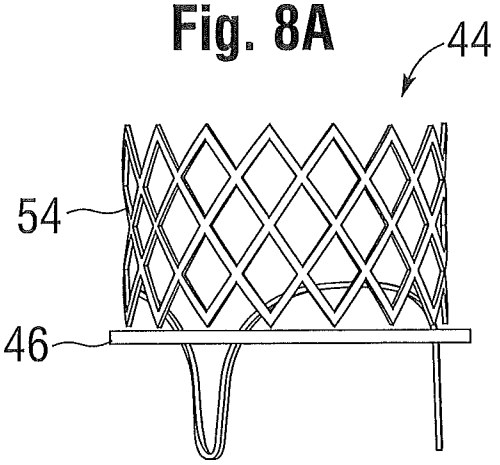


Fig. 8B

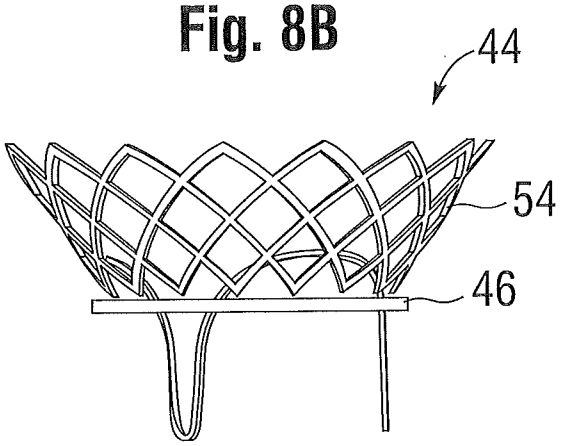


Fig. 9A

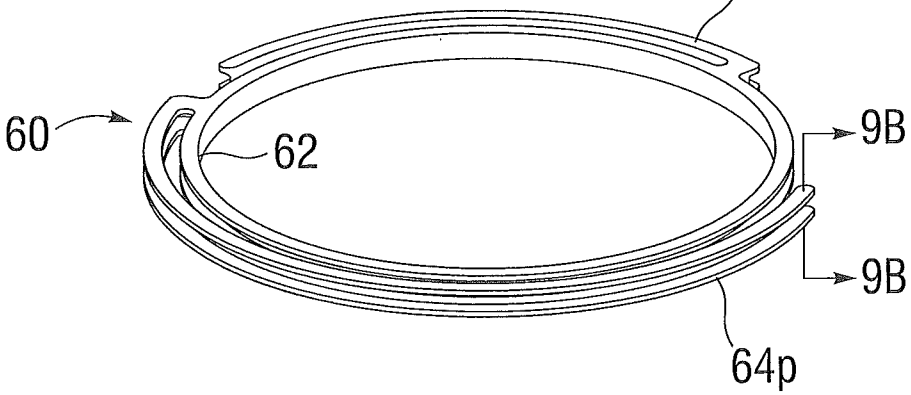


Fig. 9B

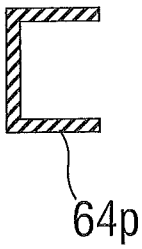


Fig. 10

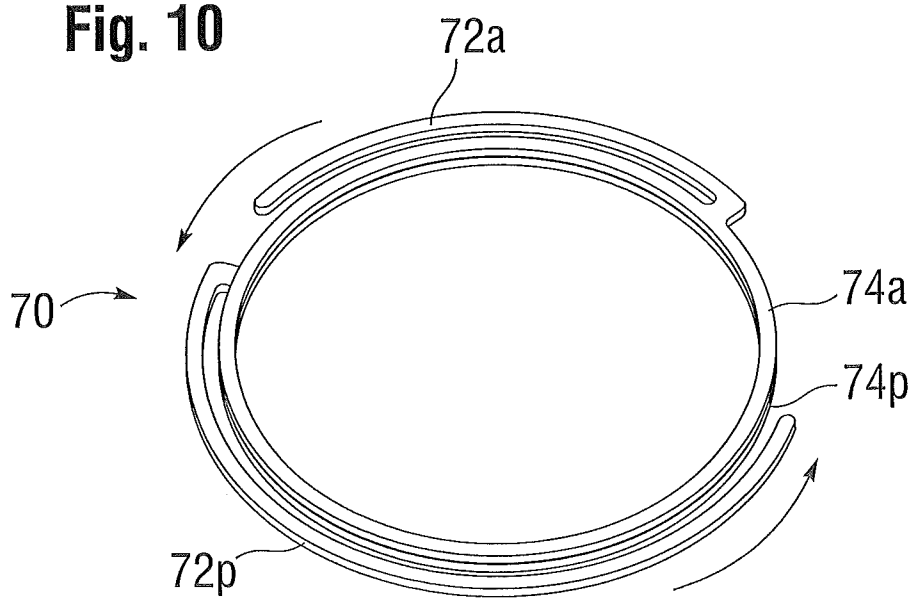


Fig. 11

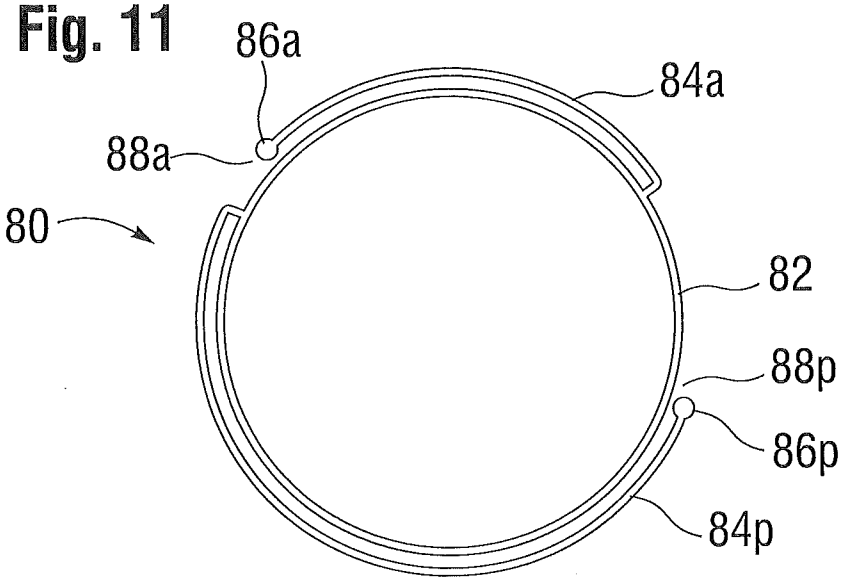


Fig. 12

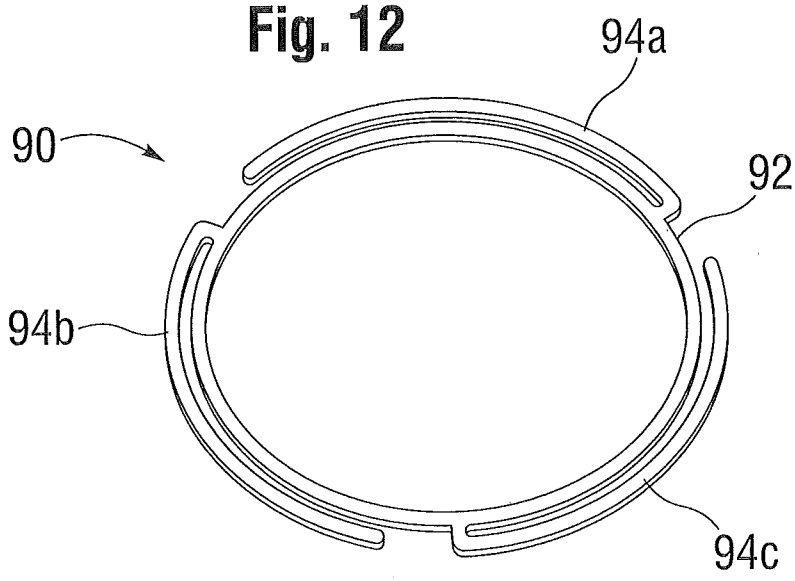


Fig. 13

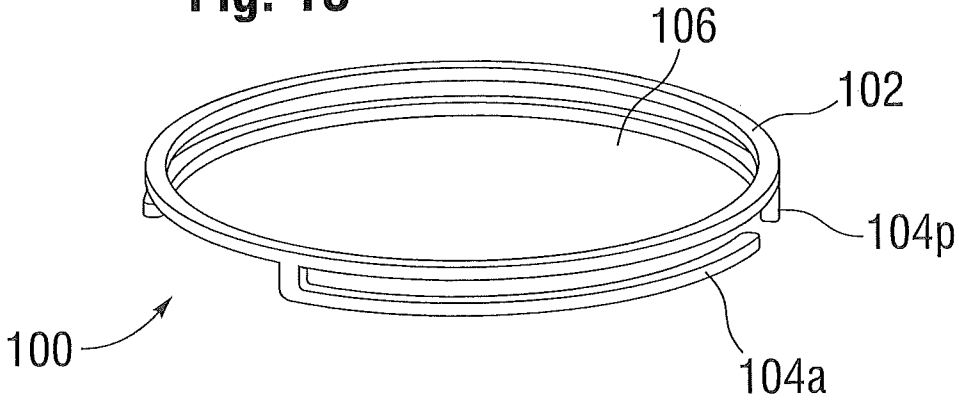


Fig. 14A

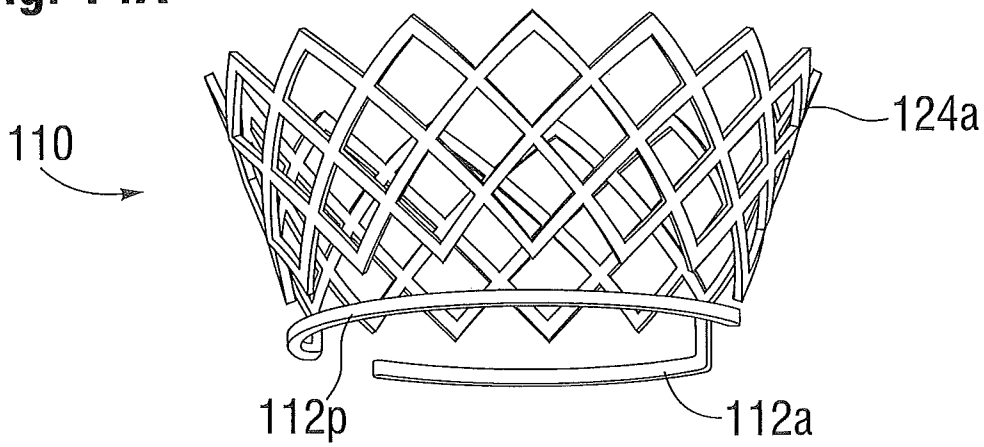


Fig. 14B

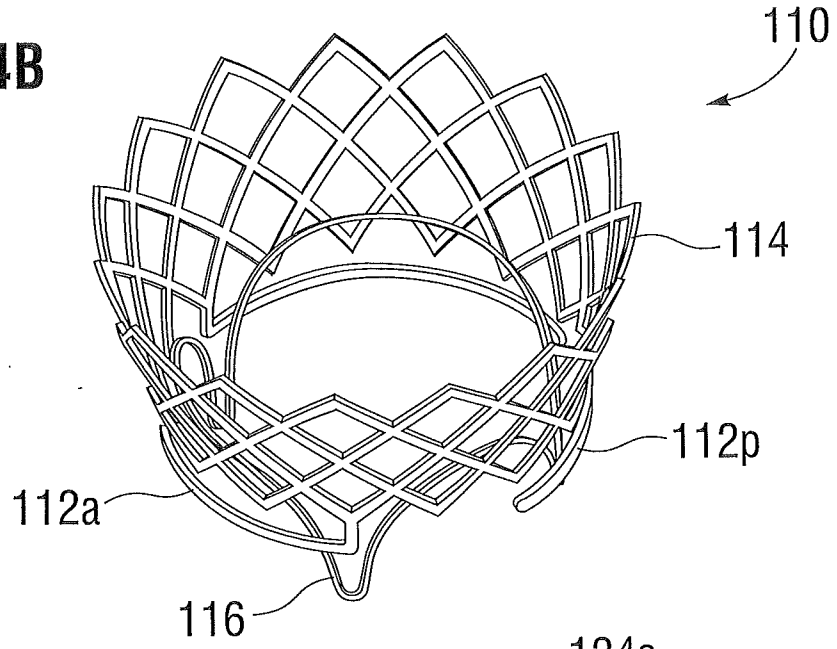
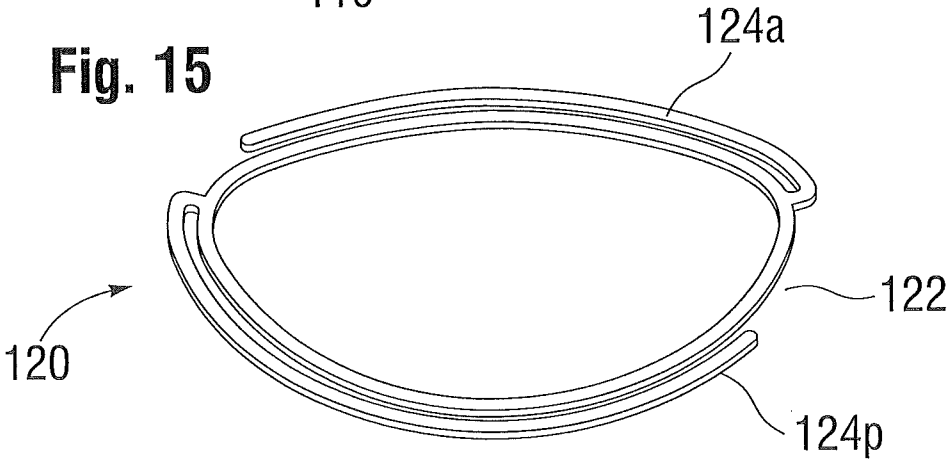


Fig. 15



INTERNATIONAL SEARCH REPORT

International application No.
PCTYUS2012/065312

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/24(2006.01)i, A61M 39/22(2006.01)1, A61L 27/14(2006.01)1, A61L 27/04(2006.01)1

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F 2/24; A61F 2/04; A61B 17/04

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords:anchor,heart,valve,annuloplasty ring

c. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010-0204785 Al (ALKHATIB, Y. F.) 12 August 2010 See abstract ; paragraphs [0050] , [0051] , [0065] , [0089] , [0091] ; and figures IB, 13A.	1-16
Y	US 7377941 B2 (RHEE, R. S. et al.) 27 May 2008 See abstract ; column 35, lines 7-12 , 15-23 , 64-67, column 36, lines 1-12 , 19-22 , 37-52 ; and figures 24 , 25A.	1-16
A	US 2005-0203617 Al (F0RSTER, D. C. et al.) 15 September 2005 See abstract ; paragraphs [0141] , [0142] ; and figures 2A-C.	1-16
A	US 2004-0127982 Al (MACHOLD, T. R. et al.) 1 July 2004 See abstract ; paragraphs [0037] -[0039] , [0099] ; and figures 10 , 11.	1-16
A	US 2009-0043381 Al (MACOVIAK, J. A. et al.) 12 Febraury 2009 See abstract ; paragraphs [0185] -[0188] ; and figures 7A-C.	1-16

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 March 2013 (21.03.2013)	**29 March 2013 (29.03.2013)**
Name and mailing address of the ISA/KR Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-70 1, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer KIM, Tae Hoon Telephone No. 82-42-481-8407

Form PCT/ISA/210 (second sheet) (My 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/065312

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

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

1. ☒ Claims Nos.: 17-25
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 17 to 25 pertain to methods for treatment of the human body by therapy, as well as diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

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

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

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

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

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

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

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

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

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

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