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(54) **Title**: MULTIPLE ORIFICE IMPLANTABLE HEART VALVE AND METHODS OF IMPLANTATION

(57) **Abstract**: A surgically implantable multiple orifice heart valve (10) having a valve frame (12) with at least two orifices (14, 16), each of which can accommodate a tissue valve.

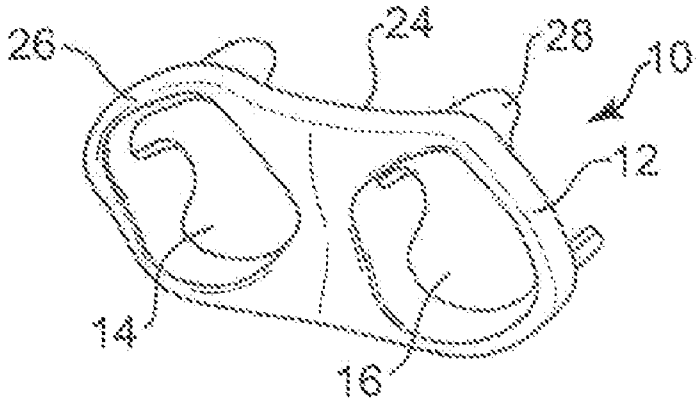

Fig. 1

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MULTIPLE ORIFICE IMPLANTABLE HEART VALVE AND METHODS OF IMPLANTATION

Technical Field

The present invention relates generally to devices and methods for repair of heart valves, and more particularly to prosthetic heart valves for use in replacement of the mitral valve.

Background

One of the two atrio-ventricular valves in the heart is the mitral valve, which is located on the left side of the heart and which forms or defines a valve annulus and valve leaflets. The mitral valve is located between the left atrium and the left ventricle, and serves to direct oxygenated blood from the lungs through the left side of the heart and into the aorta for distribution to the body. As with other valves of the heart, the mitral valve is a passive structure in that it does not itself expend any energy and does not perform any active contractile function.

The mitral valve includes two moveable leaflets that open and close in response to differential pressures on either side of the valve. Ideally, the leaflets move apart from each other when the valve is in an open position, and meet or "coapt" when the valve is in a closed position. However, problems can develop with valves, which can generally be classified as either stenosis, in which a valve does not open properly, or insufficiency (also called regurgitation), in which a valve does not close properly. Stenosis and insufficiency may occur concomitantly in the same valve. The effects of valvular dysfunction vary, with mitral regurgitation or backflow typically having relatively severe physiological consequences to the patient. Regurgitation, along with other abnormalities of the mitral valve, can increase the workload placed on the heart. The severity of this increased stress on the heart and the patient, and the ability of the heart to adapt to it, determine the treatment options that are available for a particular patient. In some cases, medication can be sufficient to treat the patient, which is the preferred option when it is viable; however, in many

cases, defective valves have to be repaired or completely replaced in order to adequately restore the function of the heart.

One situation where repair of a mitral valve is often viable is when the defects present in the valve are associated with dilation of the valve annulus, which not only prevents competence of the valve but also results in distortion of the normal shape of the valve orifice. Remodeling of the annulus is central to these types of reconstructive procedures on the mitral valve. When a mitral valve is repaired, the result is generally a reduction in the size of the posterior segment of the mitral valve annulus. As a part of the mitral valve repair, the involved segment of the annulus is diminished (i.e., constricted) so that the leaflets may coapt correctly on closing, and/or the annulus is stabilized to prevent post-operative dilatation from occurring. Either result is frequently achieved by the implantation of a prosthetic ring or band in the supra annular position. The purpose of the ring or band is to restrict, remodel and/or support the annulus to correct and/or prevent valvular insufficiency. Such repairs of the valve, when technically possible, can produce relatively good long-term results.

However, valve repair is sometimes either impossible, undesirable, or has failed, such as in cases where the problem is not related to dilation of the valve annulus, leaving valve replacement as the most viable option for improving operation of the mitral valve. The two general categories of valves that are used for mitral valve replacement are mechanical valves and bioprosthetic or tissue valves. A wide variety of mechanical valves are available that accommodate the blood flow requirements of the particular location where they will be implanted; however, the use of these mechanical devices in the body can increase the risk of clotting in the blood stream, which can lead to a heart attack or stroke. Thus, mechanical valve recipients must take anti-coagulant drugs for the rest of their lives to minimize the potential of blood clots. The use of tissue valves advantageously eliminates the need for such anti-coagulant drugs; however, tissue valves do not typically last as long as mechanical valves and may need to be replaced at some later point in the patient's life. To implant either mechanical or tissue valves, a surgical procedure is typically used that involves opening the patient's chest to access the mitral valve through the left atrium, and then implanting the new valve in position.

To simplify surgical procedures and reduce patient trauma, there has been a recent increased interest in minimally invasive and percutaneous replacement of cardiac valves. Such a replacement of a heart valve typically does not involve actual physical removal of the diseased or injured native heart valve, but instead includes delivery of a replacement valve in a compressed condition to the native valve site, where it is expanded. One example of such a replacement procedure for a pulmonary valve includes inserting a replacement pulmonary valve into a balloon catheter and delivering it percutaneously via the vascular system to the location of a failed pulmonary valve. There, the replacement valve is expanded by a balloon to compress the native valve leaflets against the right ventricular outflow tract, thereby anchoring and sealing the replacement valve. In the context of percutaneous pulmonary valve replacement, U.S. Patent Application Publication Nos. 2003/0199971 A1 and 2003/0199963 A1, both filed by Tower, et al., describe a valved segment of bovine jugular vein, mounted within an expandable stent, for use as a replacement pulmonary valve. As described in the articles: "Percutaneous Insertion of the Pulmonary Valve", Bonhoeffer, et al., Journal of the American College of Cardiology 2002; 39: 1664-1669 and "Transcatheter Replacement of a Bovine Valve in Pulmonary Position", Bonhoeffer, et al., Circulation 2000; 102: 813-816, a replacement pulmonary valve may be implanted to replace native pulmonary valves or prosthetic pulmonary valves located in valved conduits. Other implantables and implant delivery devices also are disclosed in published U.S. Patent Application Publication No. 2003/0036791 A1 and European Patent Application No. 1 057 460-A1.

The percutaneous valve implantation procedures described above typically involve the movement of a compressed valve through at least some portion of the vasculature of the patient to the delivery site, and are therefore particularly well-suited for implanting relatively small valves, such pulmonary valves or aortic valves. Because a replacement mitral valve is typically relatively large as compared to the portions of the anatomy through which it would need to travel to reach the region of the native mitral valve, the percutaneous valve implantation procedures described in the above journal articles may not be feasible for a mitral valve. However, there is a continued desire to be able to be able to improve mitral valve

replacement devices and procedures to accommodate the physical structure of the heart without causing undue stress to the patient during the operation on the heart, such as providing devices and methods for replacing the mitral valve percutaneously.

Summary

One embodiment of the invention is a surgically implantable multiple orifice heart valve having a valve frame with at least two orifices, each of which can accommodate a tissue valve. The outer peripheral shape of the valve frame can be modeled for implantation in the mitral valve position, and can therefore be generally circular, oval, or elliptical in shape, with at least two adjacent orifices or openings. The orifices in one embodiment are generally circular in shape, although they can have a different shape than circular, if desired. Each of the orifices within a single valve frame may have the same size and shape as each of the other orifices of that valve frame, or the orifices within a single valve frame can each have a different size and/or shape than the other orifices of that frame in order to adapt to the size and shape of the native valve opening.

A bi-leaflet valve, tri-leaflet valve, or differently configured valve can be mounted within each opening. Each of the individual valves are designed for generally simultaneous opening and closing of the multiple valves that are mounted in the same valve frame. That is, regardless of the leaflet structure provided, each of the heart valves should be oriented and designed so that all of the valves within a single valve frame can open and close at generally the same time within the heart cycle in response to changes in blood flow. In this way, the multiple valves function in generally the same manner as the native valve or as a single replacement valve in the patient. In particular, when the leaflets of both valves are in an open position, an internal passage is defined by each orifice through which blood can flow, and when the leaflets of both valves are in a closed position, the internal passages through the orifices do not allow for the flow of blood through the valves. With specific reference to the mitral valve, the leaflets of the valves of the multiple orifice heart valve will generally function in such a way that blood flows toward the left ventricle when the leaflets are in an open position, and so that blood is prevented from moving toward the left atrium when the leaflets are in a closed position.

It is also within the scope of the invention that the two or more orifices of a valve configuration used in a single valve opening in a patient can be independent such that they can move at least slightly relative to each other. That is, two or more separate orifice structures can be implanted into a single valve space in such a way that movement of the orifice structures relative to each other may be possible during and after implantation.

If a tri-leaflet valve is attached within any of the orifices, three commissure posts can extend from one side of the valve frame and be spaced from each other around each of the orifices. The commissure posts define the juncture between adjacent tissue and/or synthetic leaflets secured to the valve frame. Similar or different structures can be provided to extend from or otherwise be attached to the valve frame for other valve configurations (e.g. for bi-leaflet valves). In some embodiments, it is possible for one or more commissure posts to be shared by adjacent valve structures.

The valve frame is the structure of the multiple orifice heart valve that provides a means of fixing the prosthetic heart valve to the patient's native heart valve orifice tissue (e.g, native annulus or valvular rim) that is associated with the native heart valve being repaired or replaced. The valve frame includes a base portion around or over which a suture material (e.g., a cloth-like material) is disposed for suturing the prosthesis to heart tissue. The suture or cloth-like material portion may also cover any support structures, such as the commissure posts described above. It is contemplated that the valve frames of the invention are initially implanted without any attached valve structures. The valves can subsequently be delivered in a minimally invasive manner to the orifices in the valve frame and attached via coalescent clips or other means.

Once the valve frame with attached valve structures (e.g., the prosthetic heart valve with multiple orifices, as described above) is implanted within the patient, the valve can be expected to function without problems for a period of time, and possibly as long as several years, without any noticeable issues. However, if deficiencies occur at any time after implantation in one or more of the valves of the multiple-valve structure, each deficient valve can potentially be replaced by percutaneously delivering a new valve via transcatheter implantation. Each of these

individual valves would be relatively small as compared to the overall valve size that would be required for percutaneous implantation of a comparable mitral valve that fills the mitral valve space. In this way, the complications and risks involved with additional surgical intervention can be minimized or avoided. Another advantage of using multiple valves with a smaller size instead of one larger diameter valve is that the protrusions or other extending structures of the stent frame can be somewhat smaller. Thus, the protrusions will not extend as far into the ventricle when the device is implanted, thereby reducing the potential for obstruction or damage to the ventricle and/or the native valvular apparatus, such as chordae or papillary muscles.

The invention further includes a method of surgically implanting a multiple orifice valve assembly into the mitral valve area of a patient, then percutanteously delivering a replacement valve, such as a stented valve, to at least one of the orifices of the surgically implanted valve assembly. Each percutaneously delivered replacement valve can include features for proper orientation and positioning relative to the orifice of the surgically implanted heart valve. For one example, the percutaneously delivered valve can include a stent having docking features that are designed or selected to cooperate with features of the valve frame for secure anchoring of the elements relative to each other. Thus, it is within the scope of the invention for the valve frame of the multiple orifice valve assembly to have specific features or elements that allow for a certain type of engagement with a replacement valve having corresponding features. In that regard, the multiple orifice valve assembly and replacement valves can be provided as a kit. With any of the embodiments described above, the valve frames, stents, and other corresponding elements should be provided so that there is minimal interference with the functioning of an adjacent aortic valve. In addition, while many of the embodiments are shown and described as having two orifices in a valve frame, it is understood that the valve frames may include three or more orifices, which can help to accommodate the anatomies of patients having particularly large mitral openings.

Brief Description of the Drawings

The present invention will be further explained with reference to the appended Figures, wherein like structure is referred to by like numerals throughout the several views, and wherein:

Figure 1 is a bottom perspective view of one embodiment of a valve frame in accordance with the invention;

Figure 2 is a top plan view of the valve frame of Figure 1 and illustrating exemplary valve leaflets in their closed positions;

Figure 3 is a top plan view of another embodiment of a multiple-orifice valve assembly of the invention;

Figure 4 is a top plan view of another embodiment of a multiple-orifice valve assembly of the invention;

Figure 5 is a perspective view of a distal portion of a delivery system positioned relative to one orifice of a portion of a mitral valve replacement assembly;

Figure 6 is a top schematic plan view of another embodiment of a multiple-orifice valve assembly of the invention;

Figure 7 is a top plan view of another embodiment of a multiple-orifice valve assembly of the invention; and

Figure 8 is a top plan view of a tri-orifice valve assembly of the invention.

Detailed Description

Referring now to the Figures, wherein the components are labeled with like numerals throughout the several Figures, and initially to Figures 1 and 2, one embodiment of a double orifice implantable heart valve 10 in accordance with the invention is illustrated. Although the heart valves of the invention, such as heart valve 10, are generally described herein as being used for mitral valve replacement, it is understood that many of the features of these heart valves can be used for valves in other areas of the heart. For example, the heart valves of the invention can be used in any area of the heart where it would be more advantageous to use multiple valves that are relatively small than to use a single valve that is relatively large. In any case, the heart valves of the invention desirably restore normal functioning of a cardiac valve,

and are initially implanted using surgical techniques that include minimally invasive methods or more traditional open-heart surgical methods. Further, as used throughout this specification, a "prosthetic heart valve" or "heart valve" is intended to encompass bioprosthetic heart valves having leaflets made of biological material (e.g., harvested porcine valve leaflets, or bovine or equine pericardial leaflets), along with synthetic leaflet materials or other materials.

Heart valve 10 includes a valve frame 12 having a first orifice 14 and a second orifice 16. These orifices 14, 16 are illustrated to be generally the same size and shape as each other, and preferably are sized for attachment of a tissue valve within each of their interior portions. Figure 2 illustrates the valve frame 12 with a first tri-leaflet valve 18 in its closed position within the first orifice 14 and a second tri-leaflet valve 20 in its closed position within the second orifice 16. This three-leaflet arrangement of valves 18, 20 is exemplary; alternative configurations include a bi-leaflet valve positioned in both of the orifices, and valves that are different from each other in each of the orifices (e.g., one of the orifices includes a three-leaflet valve while the other orifice includes a bi-leaflet valve). In any case, the multi-orifice valve configurations of the invention advantageously allow for replacement of only one of the valves if only one of the valves fails at some point after implantation (while at least one properly functioning valve remains operational), as will be described in further detail below. If such a valve replacement is performed, the specific rotational orientation of the valve leaflets within the orifice may or may not be a consideration.

Referring again to Figure 1, the valve frame 12 has an outer periphery that is generally oval or elliptical in shape and has a first side 24 and an opposite second side 26. The valve frame 12 is generally shaped or modeled to match the valve space into which it will be surgically implanted. For example, if the valve frame 12 will be placed in the mitral valve space of a patient, characteristics of the specific mitral valve space into which it will be positioned can be taken into account. Thus, the valve frame 12 may have a generally planar surface on its first and second sides 24, 26, or it may have contours and shaping on one or both sides to match the anatomy of the patient. For example, it may be relatively saddle shaped. The valve frame 12 provides a means for fixing the double orifice implantable heart valve 10 to the patient's native heart valve orifice tissue (e.g., the native annulus or valvular rim)

that is associated with the native heart valve being repaired or replaced. In particular, a surgical implantation technique can be employed whereby the heart is stopped (e.g., with the use of cardiopulmonary bypass) and opened, which is followed by optional surgical removal of damaged or diseased natural valve structure. The heart valve 10 can then be oriented within the native valvular area, with the valve frame 12 being seated against or at the native annulus or valvular rim. Sutures can then be used to affix the valve frame 12 to the natural tissue.

With the various multiple valve assemblies of the invention, it is desirable to maximize the overall area of the orifices relative to the frame size in order to minimize the obstruction to blood flow. Thus, it is preferable that the sizes of the structural components of the stent frame are minimized, while the desired structural strength of the frame is maintained.

The first and second orifices 14, 16 are spaced from each other across the width of the valve frame 12, and the spacing and exact orientation of the orifices 14, 16 can be selected to provide desired performance characteristics for the valve. For example, the orifices 14, 16 can be generally circular in shape and arranged relative to their valve frame 12 so that the center points of the orifices 14, 16 generally coincide with a central axis that runs across the width of the valve frame 12. However, it is understood that the orifices 14, 16 can be at least slightly offset relative to the central axis of the valve frame 12 and/or that they can be at least slightly offset relative to each other. The orifices 14, 16 can be at least slightly spaced from each other, as shown, thereby providing a central area of the valve frame 12 between the two orifices 14, 16. Preferably, the portions of the heart valve assembly 10 between the orifices is impermeable to blood flow to resist regurgitation. The illustrated space between the orifices 14, 16 is one exemplary configuration, and can be smaller or larger than shown. Alternatively, there may be no space between two adjacent orifices 14, 16. Longitudinal axes that extend through the orifices (generally in the direction of blood flow) can be generally parallel to each other such that the orifices and corresponding valves lie in the same plane. Alternatively, the longitudinal axes of the orifices may be at least slightly offset relative to each other so that the orifices are at least slightly tilted or tipped toward or away from each other within the valve frame.

As discussed above, in the exemplary embodiment of Figures 1 and 2, the valve frame 12 includes two tri-leaflet valves 18, 20. In order to provide the structure for attachment of these valves, multiple commissure posts 28 extend from the first side 24 of the valve frame 12. In particular, three commissure posts 28 are positioned around each of the orifices 14, 16, where the posts 28 can be spaced generally evenly from each other around the orifices 14, 16, or they can be unevenly spaced, depending on the characteristics of its corresponding valve. The commissure posts can be rigid yet somewhat flexible structures, which can be covered with a cloth-like material. The commissure posts define the juncture between adjacent tissue or synthetic leaflets that are secured within an orifice.

The valves provided in the valve frames described herein may use a preserved bovine jugular vein of the type described in the above-cited Bonhoeffer, et al. and Tower, et al. references. However, other vessels or donor species may alternatively be used for various reasons. For example, in order to provide additional valve strength in the relatively high-pressure conditions that exist in the mitral valve area of the heart, pericardial valves, polymeric valves, or metallic valves may alternatively be used in a tricuspid or bicuspid leaflet configuration.

Figure 3 illustrates another embodiment of a double orifice implantable heart valve 30, which includes two prosthetic valves 32, 34 surrounded by a valve frame 36. In this embodiment, valves 32, 34 can each include stent structures of the type used in areas of the heart that accommodate relatively small, circular valves, such as the pulmonic valve. The valve frame 36 may be a gasket or other member that surrounds the outermost periphery of the valves 32, 34 to provide for sealing against paravalvular leakage and to facilitate pannus in-growth for stabilization of the heart valve 30. The valve frame 36 also preferably provides enough structural strength to position and maintain the valves 32, 34 in their desired arrangement relative to each other. The frame 36 can be relatively rigid to prevent most or all movement of the valves 32, 34 relative to each other, or the frame 36 can be relatively flexible to allow at least some movement of the valves 32, 34 relative to each other.

Another embodiment of a double orifice implantable valve assembly 100 is shown in Figure 6. Valve assembly 100 includes a frame 102 from which two pairs of commissure posts 104 extend. Each commissure post 104 is positioned with another

commissure post 104 located across from it on generally the opposite side of the frame 102. Each pair of commissure posts 104 provides the attachment areas for a bi-leaflet valve, where the frame 102 illustrates a first bi-leaflet valve 106 and a second bi-leaflet valve 108. As shown, valves 106, 108 are attached directly to the frame 102 in such a way that they do not have their own frames or stents. The valves can thus contact each other at least slightly in the central area of the stent frame, as illustrated. Since there is no additional stent structure internal to the frame 102, the size of the valves can be maximized relative to the opening in the frame 102.

The individual valves of the double orifice implantable heart valves described herein are generally shown and described as being cylindrical in shape; however, a number of different stent shapes are also contemplated, such as valves that are oval or elliptical in shape. Another exemplary alternative configuration is illustrated in Figure 4 with a double orifice implantable heart valve 50 that includes a first prosthetic valve 52 and a second prosthetic valve 54, both of which are surrounded by a valve frame or gasket 56. Each of these two valves 52, 54 has a curvilinear surface that can be designed to generally match the shape of the ends of the annulus of a mitral valve, and a generally flat or planar surface that results in more "squared off" corners where the flat surface meets the curvilinear surface. The flat surfaces of the valves 52, 54 are in contact with each other along at least a portion of their lengths at a central area 58. This arrangement provides for less gaps or openings between the individual valves in a multiple valve arrangement than when circular valves are used. The heart valve 10 of Figure 1 may alternatively include orifices that are shaped similarly to the valves 52, 54 of this embodiment in order to utilize valves that are somewhat D-shaped.

Another exemplary configuration of an implantable heart valve assembly of the invention includes a valve frame having two or more individual valves having different sizes and/or shapes from each other. For example, one or both of the valves can be at least slightly elliptical, oval, D-shaped, square, or differently shaped in cross-section when in their expanded conditions. For another example, one of the valves within a valve frame can be at least slightly larger than the other valve or valves of that frame, which would correspond to the orifices in which they are attached. In some cases, the differently sized and/or shaped orifices can help to better

adapt the multiple-orifice heart valve to the native valve opening. The shape of the valves can be designed and selected to provide a proper fit to the patient's anatomy. Another exemplary multiple orifice valve assembly 120 is illustrated in Figure 7. Valve assembly 120 includes a first valve 122 and a second adjacent valve 124, both of which are tri-leaflet valves positioned within a stent frame 126. Stent frame 126 includes a number of commissure posts extending from one of its surfaces that act as the attachment points for the leaflets of the valves 122, 124. In particular, the leaflets of valve 122 are attached at commissure posts 128, 130, 132, and the leaflets of valve 124 are attached at commissure posts 132, 134, 136. Thus, the relatively central stent post 132 is shared by both of the valves 122, 124, thereby providing a relatively large orifice size inside the stent frame 126 with minimal obstructions to blood flow. A similar configuration can alternatively be used with two bi-leaflet valves in a single stent frame, where one of the commissure posts of the assembly is common to both valves. In yet another alternative embodiment, a stent assembly may include one bi-leaflet and one tri-leaflet valve, where both of the valves share one common commissure post.

Other valve assembly arrangements can include more than two valves within a single stent frame, as is contemplated by the present invention. For one example, three valves 150, 152, 154 are illustrated within a stent frame 156 in Figure 8. The valves 150, 152, 154 are shown as having an intermediate stent or strut portion between each two adjacent valves; however, any of the other features described herein relative to stent assemblies with two valves can also be utilized in stent frames with three or more valves. Such multiple valve assemblies can include bi-leaflet valves, tri-leaflet valves, combinations of bi- and tri-leaflet valves that do not include intermediate strut portions, and the like.

Once a valve frame of the invention having attached valve structures (e.g., one of the prosthetic heart valve with multiple orifices described above) is implanted within the patient, the valve can function for a period of time with no noticeable issues. However, if deficiencies occur at any time after implantation in one or more of the valves of the multiple-valve structure, each deficient valve can be replaced by percutaneously delivering a new valve via transcatheter implantation. The invention further includes a method of surgically implanting a multiple orifice

valve assembly into the mitral valve area of a patient, then percutaneously delivering a replacement valve to at least one of the orifices of the surgically implanted valve assembly. Each of these individual valves would be relatively small as compared to the overall valve size that would be required for percutaneous implantation of a comparable mitral valve that fills the mitral valve space, thereby better facilitating percutaneous implantation through a variety of access sites. The replacement valve can be a stented valve that includes an outer stent structure to which a valve structure is attached.

Figure 5 illustrates a distal portion of an exemplary delivery system 70 as it is delivering a replacement stented valve 72 (shown schematically as only a stent of the valve) to a double orifice heart valve 80 that is depicted by two adjacent heart valves 74, 76. Heart valves 74, 76 are the two orifices of the double orifice heart valve 80 of the invention. The device or structure that attaches these valves to each other is gasket or frame 78. That is, the heart valves 74, 76 are intended to represent the two orifices of a single structure 80 that would previously been implanted into a patient, where the single structure could have been implanted to replace a mitral valve, for example. Figure 5 represents the situation where some failure or malfunction of the leaflets of heart valve 74 has occurred, thereby necessitating a replacement of that heart valve. In accordance with the invention, it is possible to replace only this valve 74 of the two-valve system with a replacement stented valve 72, although it may be desirable or necessary to replace both valves 74, 76 with new replacement stented valves. The valve replacement procedure can advantageously be accomplished using a percutaneous valve delivery system.

In order to reduce potential stresses on the valve frames described herein and to reduce potential stresses on the associated annulus, it is also possible to provide multiple orifice structures that can move at least slightly relative to each other within a single native opening. In particular, the valves may be moveable relative to a defined plane and/or may be moveable to be positioned closer or further from each other during and after implantation. In such an embodiment, the stent frames can be made of flexible materials, such as metals, (e.g., Nitinol), polymers, or tissue-based materials.

The stented valves used to replace a deficient valve using the methods of the invention can correspond generally to a stent of the type described in the above-cited Tower, et al. and Bonhoeffer et al. references, for example, although it is understood that a wide variety of stent configurations can be used in accordance with the invention. The replacement stented valves may include a stent structure that is fabricated of platinum, stainless steel, Nitinol, an alloy of the type commercially available under the trade designation MP35N, or other biocompatible metal. The replacement stented valves may alternatively be fabricated using wire stock as described in the above-cited Tower, et al. applications, or the stented valves may be produced by machining or laser cutting the stent from a metal tube, as is commonly employed in the manufacturing of stents. The number of wires, the positioning of such wires, and various other features of the stents can vary considerably from that shown in the figures. In another alternative, the valves used to replace a deficient valve may be stentless valves.

In any case, the replacement stented valves used in the methods of the invention are preferably compressible to a relatively small diameter for insertion into a patient, but are also at least slightly expandable from this compressed condition to a larger diameter when positioned in a desired location in the patient. It is further preferable that the process of compressing the stented valves does not permanently deform the stent in such a way that expansion thereof would be difficult or impossible.

Any of the stent assemblies discussed herein can further include structures that provide a fixation function for securing the stent assembly in its desired location relative to the orifice of a previously implanted heart valve. For example, the stent assembly can include hooks, barbs, or the like that attach to a structure of a valve orifice upon deployment of the stent assembly.

A portion of an exemplary system that can be used to implant a stented valve of the types described above includes an elongated balloon catheter having an inflatable balloon that is connected for fluid communication with a lumen that extends through the length of the catheter. The lumen provides for inflation and deflation of the balloon with a fluid, such as a radio-opaque fluid, during the process of deploying a stented valve within a patient. The delivery system may include a thin guide wire

that extends generally along the length of the catheter, which may be used in a conventional manner to guide the catheter to its desired implant location. When the components of the system are positioned relative to the orifice of a patient, a balloon may be inflated to thereby expand the stent to the desired size relative to the orifice in which it will be positioned. After such stent expansion is complete, the balloon can be deflated and the system can then be withdrawn from the patient.

It is further contemplated that two or more percutaneous valves can be simultaneously or sequentially delivered to a multiple orifice stent using a delivery system that has multiple balloons. For example, if both valves of a double-orifice valve are to be replaced at the same time, a delivery system having two balloons can be used to deliver both valves simultaneously.

The replacement heart valves, along with the multiple-orifice implantable heart valves of the present invention may be positioned within the desired area of the heart via entry in a number of different ways. In one example, the valves may be inserted transatrially, where entry may be done either percutaneously or in a minimally invasive technique on a beating heart in which access is through the side of the heart, or even through a standard open heart valve replacement procedure using heart-lung bypass and sternotomy where the described device would be used as an alternative to the standard replacement. In another example, the valves may be inserted transapically, where entry again may be done either percutaneously or in a minimally invasive technique on a beating heart in which access is through the side of the heart. In yet another example, the valves may be inserted transeptally, where entry can be done percutaneously, such as via the venous system into the right atrium and across a small hole in the septum to enter the left atrium. In yet another example, the valves may be inserted transfemorally through the arterial system. It is also possible that the delivery approaches may include balloons that would be used to facilitate the crossing of the mitral valve, thereby avoiding entanglement in the mitral apparatus.

It is also contemplated that the stented valves of the present invention are self-expanding such that pressure is required to maintain the valve in its compressed condition, and removal of such pressure will allow these stented valves to expand to their desired size. In these cases, the delivery system will be somewhat

different than that described above relative to stents that are not self-expanding, and will instead include a system that only requires removal of external pressure (e.g., a compressive sheath) to allow the stented valves to expand, such as is the case with the delivery of stent grafts for aneurysms in the ascending aorta. These systems may also incorporate means for recapturing and/or repositioning the stented valve, if desired. In any case, it may be desirable to measure the mitral valve area with some type of spacer prior to installing the actual stent assembly in the heart of the patient.

The stented valves may further include a means of facilitating orientation of the assembly relative to the orifice in which they will be implanted, which can be particularly advantageous in cases where the stented valves include asymmetric features and configurations that must be properly oriented relative to the anatomy of the patient. To that end, the stented valves may include portions with materials that are opaque when viewed with various imaging techniques, such as echogenic coatings and radiopaque metals and polymers. Additionally or alternatively, the material used to fabricate the stent itself may be highly visible when using certain imaging techniques so that the user has a clear visibility of the orientation of the device prior to and during deployment.

The present invention has now been described with reference to several embodiments thereof. The foregoing detailed description and examples have been given for clarity of understanding only. No unnecessary limitations are to be understood therefrom. It will be apparent to those skilled in the art that many changes can be made in the embodiments described without departing from the scope of the invention. Thus, the scope of the present invention should not be limited to the structures described herein.

CLAIMS

What is claimed is:

1. A stent assembly for implantation in a body lumen, the stent assembly comprising:

a stent frame comprising a first opening, a second opening spaced from the first opening, and a first intermediate strut portion positioned between the first and second openings.

2. The stent assembly of claim 1, wherein the intermediate strut portion is impermeable to blood flow.

3. The stent assembly of claim 1, wherein each of the first and second openings comprises a tissue valve.

4. The stent assembly of claim 1, wherein each of the first and second openings are circular.

5. The stent assembly of claim 1, wherein the frame further comprises at least two commissure posts extending from a first side of the frame and adjacent to the first opening, and at least two commissure posts extending from the first side of the frame and adjacent to the second opening.

6. The stent assembly of claim 1, wherein the size of the first opening is different from the size of the second opening.

7. The stent assembly of claim 1, wherein the stent frame is relatively rigid for surgical implantation into a patient.

8. The stent assembly of claim 7, wherein the stent frame has an outer shape that is compatible with the shape of a mitral valve in which it will be implanted.

9. The stent assembly of claim 1, further comprising a third opening adjacent to and spaced from the second opening, and a second intermediate strut portion positioned between the second and third openings.

10. A stent assembly comprising a first stent barrel, a second stent barrel adjacent to the first stent barrel, and a stent frame surrounding an outermost periphery of the first and second stent barrels.

11. The stent assembly of claim 10, wherein the stent frame is rigid such that the first and second stent barrels are not moveable relative to each other within the stent frame.

12. The stent assembly of claim 10, wherein the stent frame is flexible such that the first and second stent barrels are moveable relative to each other within the stent frame.

13. The stent assembly of claim 10, wherein at least one of the first and second stent barrels is cylindrical.

14. The stent assembly of claim 10, wherein the first and second stent barrels have generally the same cross-sectional shape and size.

15. The stent assembly of claim 10, wherein the first stent barrel has a different cross-sectional shape than the second stent barrel.

16. A stent assembly for implantation in a body lumen, the stent assembly comprising:

a stent frame comprising first and second commissure posts extending from a first side of the frame and positioned on generally opposite edges of the frame, a first valve attached to the first and second commissure posts, third and fourth commissure posts extending from the first side of the frame and positioned on generally opposite

edges of the frame, and a second valve attached to the third and fourth commissure posts.

17. The stent assembly of claim 16, further comprising a fifth commissure post positioned between the first and second valves, wherein each of the first and second valves is further attached to the fifth commissure post.

18. A method of replacing a surgically implanted multiple orifice valve assembly in a patient, comprising the step of percutaneously delivering a replacement valve to at least one orifice of the valve assembly, wherein each replacement valve comprises at least one anchoring structure that is engageable with at least one docking feature of the multiple orifice valve assembly.

19. The method of claim 18, wherein a replacement valve is delivered to each of the orifices of the multiple valve assembly.

20. The method of claim 18, wherein each replacement valve is a compressible and expandable stented heart valve.

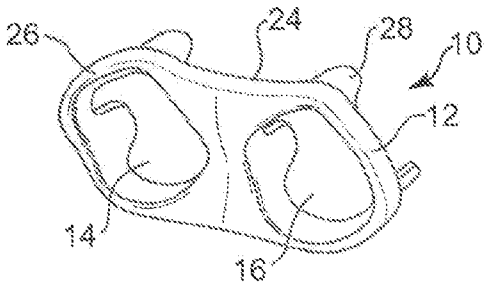

Fig. 1

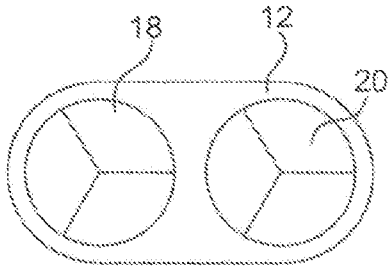

Fig. 2

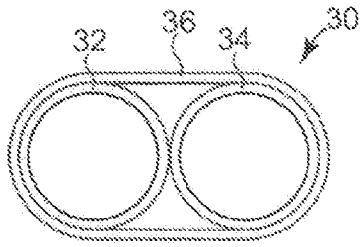

Fig. 3

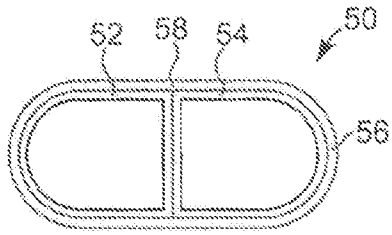

Fig. 4

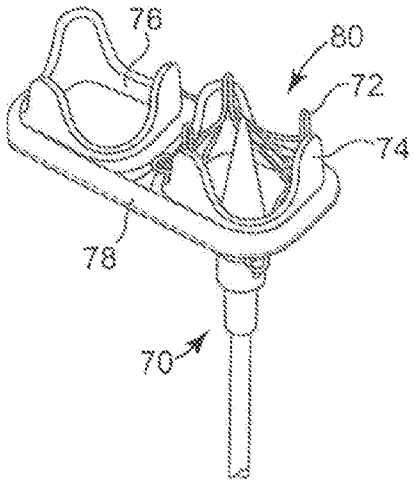

Fig. 5

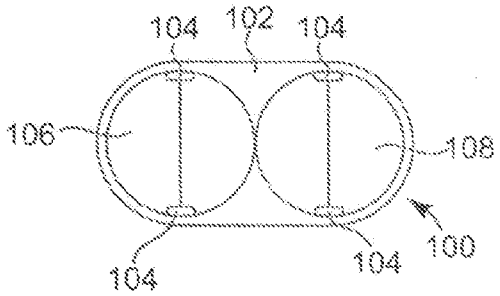

Fig. 6

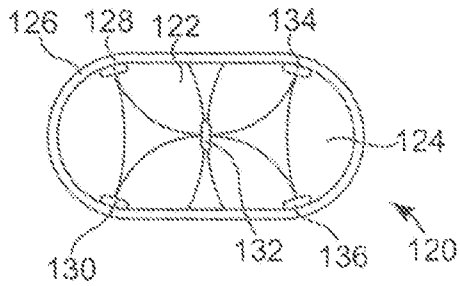

Fig. 7

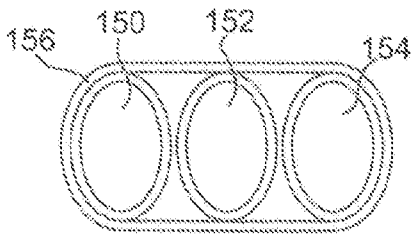

Fig. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/032916

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/058985 A1 (DEPALMA DONALD F [US] ET AL) 16 May 2002 (2002-05-16) paragraphs [0018], [0019], [0034] - [0039]; figures 1,3,7a-7c,8	1,2,4, 10,11, 13,14
X	WO 2004/105651 A (COOK INC [US]; FLAGLE JACOB A [US]; CASE BRIAN C [US]; HOFFA ANDREW K) 9 December 2004 (2004-12-09) paragraphs [0030] - [0038], [0054] - [0061]; figure 6	1,2,4,6, 7,9
A	US 2003/036791 A1 (PHILIPP BONHOEFFER [FR] ET AL) 20 February 2003 (2003-02-20) cited in the application the whole document	1,10,16

☐ 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 document but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 June 2009	23/06/2009

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/032916

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

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

1. [X] Claims Nos.: 18-20
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

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

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

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

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

Remark on Protest

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

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/032916

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