REPLACEMENT HEART VALVE APPARATUS AND METHODS

Cross-Reference to Related Applications

[0001] This application claims the priority of U.S. Provisional Application Serial No. 61/865,657, filed August 14, 2013 (pending); U.S. Provisional Application Serial No. 61/942,300, filed February 20, 2014 (pending); and U.S. Provisional Application Serial No. 61/943,125, filed February 21, 2014 (pending), the disclosures of which are hereby incorporated by reference herein.

Technical Field

[0002] The present invention generally relates to medical procedures and devices pertaining to heart valves such as replacement techniques and apparatus. More specifically, the invention relates to the replacement of heart valves having various malformations and dysfunctions.

Background

[0003] Complications of the mitral valve, which controls the flow of blood from the left atrium into the left ventricle of the human heart, have been known to cause fatal heart failure. In the developed world, one of the most common forms of valvular heart disease is mitral valve leak, also known as mitral regurgitation, which is characterized by the abnormal leaking of blood from the left ventricle through the mitral valve and back into the left atrium. This occurs most commonly due to ischemic heart disease when the leaflets of the mitral valve no longer meet or close properly after multiple infarctions, idiopathic and hypertensive cardiomyopathies where the left ventricle enlarges, and with leaflet and chordal abnormalities, such as those caused by a degenerative disease.

[0004] In addition to mitral regurgitation, mitral narrowing or stenosis is most frequently the result of rheumatic disease. While this has been virtually eliminated in developed countries, it is still common where living standards are not as high.

[0005] Similar to complications of the mitral valve are complications of the aortic valve, which controls the flow of blood from the left ventricle into the aorta. For example, many older patients develop aortic valve stenosis.

Historically, the traditional treatment had been valve replacement by a large open heart procedure. The procedure takes a considerable amount of time for recovery since it is so highly invasive. Fortunately, in the last decade, great advances have been made in replacing this open heart surgery procedure with a catheter procedure that can be performed quickly without surgical incisions or the need for a heart-lung machine to support the circulation while the heart is stopped. Using catheters, valves are mounted on stents or stent-like structures, which are compressed and delivered through blood vessels to the heart. The stents are then expanded and the valves begin to function. The diseased valve is not removed, but instead it is crushed or deformed by the stent which contains the new valve. The deformed tissue serves to help anchor the new prosthetic valve.

[0006] Delivery of the valves can be accomplished from arteries which can be easily accessed in a patient. Most commonly this is done from the groin where the femoral and iliac arteries can be cannulated. The shoulder region is also used, where the subclavian and axillary arteries can also be accessed. Recovery from this procedure is remarkably quick.

[0007] Not all patients can be served with a pure catheter procedure. In some cases the arteries are too small to allow passage of catheters to the heart, or the arteries are too diseased or tortuous. In these cases, surgeons can make a small chest incision (thoractomy) and then place these catheter-based devices directly into the heart. Typically, a purse string suture is made in the apex of the left ventricle and the delivery system is placed through the apex of the heart. The valve is then delivered into its final position. These delivery systems can also be used to access the aortic valve from the aorta itself. Some surgeons introduce the aortic valve delivery system directly in the aorta at the time of open surgery. The valves vary considerably. There is a mounting structure that is often a form of stent. Prosthetic leaflets are carried inside the stent on mounting and retention structure. Typically, these leaflets are made from biologic material that is used in traditional surgical valves. The valve can be actual heart valve tissue from an animal or more often the leaflets are made from pericardial tissue from cows, pigs or horses. These leaflets are treated to reduce their immunogenicity and improve their durability. Many tissue processing techniques have been developed for this purpose. In the future, biologically engineered tissue may be used or polymers or other non-biologic

materials may be used for valve leaflets. All of these can be incorporated into the inventions described in this disclosure.

[0008] There are, in fact, more patients with mitral valve disease than aortic valve disease. In the course of the last decade, many companies have been successful in creating catheter or minimally invasive implantable aortic valves, but implantation of a mitral valve is more difficult and to date there has been no good solution. Patients would be benefited by implanting a device by a surgical procedure employing a small incision or by a catheter implantation such as from the groin. From the patient's point of view, the catheter procedure is very attractive. At this time there is no commercially available way to replace the mitral valve with a catheter procedure. Many patients who require mitral valve replacement are elderly and an open heart procedure is painful, risky and takes time for recovery. Some patients are not even candidates for surgery due to advanced age and frailty. Therefore, there exists a particular need for a remotely placed mitral valve replacement device.

[0009] While previously, it was thought that mitral valve replacement rather than valve repair was associated with a more negative long-term prognosis for patients with mitral valve disease, this belief has come into question. It is now believed that the outcome for patients with mitral valve leak or regurgitation is almost equal whether the valve is repaired or replaced. Furthermore, the durability of a mitral valve surgical repair is now under question. Many patients, who have undergone repair, redevelop a leak over several years. As many of these are elderly, a repeat intervention in an older patient is not welcomed by the patient or the physicians.

[0010] The most prominent obstacle for catheter mitral valve replacement is retaining the valve in position. The mitral valve is subject to a large cyclic load. The pressure in the left ventricle is close to zero before contraction and then rises to the systolic pressure (or higher if there is aortic stenosis) and this can be very high if the patient has systolic hypertension. Often the load on the valve is 150mmHg or more. Since the heart is moving as it beats, the movement and the load can combine to dislodge a valve. Also, the movement and rhythmic load can fatigue materials leading to fractures of the materials. Thus, there is a major problem associated with anchoring a valve.

[0011] Another problem with creating a catheter delivered mitral valve replacement is size. The implant must have strong retention and leak

avoidance features and it must contain a valve. Separate prostheses may contribute to solving this problem, by placing an anchor or dock first and then implanting the valve second. However, in this situation, the patient must remain stable between implantation of the anchor or dock and implantation of the valve. If the patient's native mitral valve is rendered non-functional by the anchor or dock, then the patient may quickly become unstable and the operator may be forced to hastily implant the new valve or possibly stabilize the patient by removing the anchor or dock and abandoning the procedure.

[0012] Another problem with mitral replacement is leak around the valve, or paravalvular leak. If a good seal is not established around the valve, blood can leak back into the left atrium. This places extra load on the heart and can damage the blood as it travels in jets through sites of leaks. Hemolysis or breakdown of red blood cells is a frequent complication if this occurs. Paravalvular leak was one of the common problems encountered when the aortic valve was first implanted on a catheter. During surgical replacement, a surgeon has a major advantage when replacing the valve as he or she can see a gap outside the valve suture line and prevent or repair it. With catheter insertion, this is not possible. Furthermore, large leaks may reduce a patient's survival and may cause symptoms that restrict mobility and make the patient uncomfortable (e.g., short of breathe, edematous, fatigued). Therefore, devices, systems, and methods which relate to mitral valve replacement should also incorporate means to prevent and repair leaks around the replacement valve.

[0013] A patient's mitral valve annulus can also be quite large. When companies develop surgical replacement valves, this problem is solved by restricting the number of sizes of the actual valve produced and then adding more fabric cuff around the margin of the valve to increase the valve size. For example, a patient may have a 45mm valve annulus. In this case, the actual prosthetic valve diameter may be 30mm and the difference is made up by adding a larger band of fabric cuff material around the prosthetic valve. However, in catheter procedures, adding more material to a prosthetic valve is problematic since the material must be condensed and retained by small delivery systems. Often, this method is very difficult and impractical, so alternative solutions are necessary.

[0014] Since numerous valves have been developed for the aortic position, it is desirable to avoid repeating valve development and to take advantage of existing valves. These valves have been very expensive to develop and bring to market, so extending their application can save considerable amounts of time and money. It would be useful then to create a mitral anchor or docking station for such a valve. An existing valve developed for the aortic position, perhaps with some modification, could then be implanted in the docking station. Some previously developed valves may fit well with no modification, such as the Edwards Sapien™ valve. Others, such as the Corevalve™ may be implantable but require some modification for an optimal engagement with the anchor and fit inside the heart.

[0015] A number of further complications may arise from a poorly retained or poorly positioned mitral valve replacement prosthesis. Namely, a valve can be dislodged into the atrium or ventricle, which could be fatal for a patient. Prior prosthetic anchors have reduced the risk of dislodgement by puncturing tissue to retain the prosthesis. However, this is a risky maneuver since the penetration must be accomplished by a sharp object at a long distance, leading to a risk of perforation of the heart and patient injury.

[0016] Orientation of the mitral prosthesis is also important. The valve must allow blood to flow easily from the atrium to the ventricle. A prosthesis that enters at an angle may lead to poor flow, obstruction of the flow by the wall of the heart or a leaflet and a poor hemodynamic result. Repeated contraction against the ventricular wall can also lead to rupture of the back wall of the heart and sudden death of the patient.

[0017] With surgical mitral valve repair or replacement, sometimes the anterior leaflet of the mitral valve leaflet is pushed into the area of the left ventricular outflow and this leads to poor left ventricular emptying. This syndrome is known as left ventricular tract outflow obstruction. The replacement valve itself can cause left ventricular outflow tract obstruction if it is situated close to the aortic valve.

[0018] Yet another obstacle faced when implanting a replacement mitral valve is the need for the patient's native mitral valve to continue to function regularly during placement of the prosthesis so that the patient can remain stable without the need for a heart-lung machine to support circulation.

[0019] In addition, it is desirable to provide devices and methods that can be utilized in a variety of implantation approaches. Depending on a particular patient's anatomy and clinical situation, a medical professional may wish to make a determination regarding the optimal method of implantation, such as inserting a replacement valve directly into the heart in an open procedure (open heart surgery or a minimally invasive surgery) or inserting a replacement valve from veins and via arteries in a closed procedure (such as a catheter-based implantation). It is preferable to allow a medical professional a plurality of implantation options to choose from. For example, a medical professional may wish to insert a replacement valve either from the ventricle or from the atrial side of the mitral valve.

[0020] Therefore, embodiments of the present invention seek to provide devices and methods that address these and other challenges in the art.

Summary

[0021] In one illustrative embodiment, the invention provides a system for replacing a native heart valve including an expansible helical anchor formed as multiple coils adapted to support a heart valve prosthesis. At least one of the coils is normally at a first diameter, and is expandable to a second, larger diameter upon application of radial outward force from within the helical anchor. A gap is defined between two adjacent coils sufficient to prevent engagement by at least one of the two adjacent coils with the native heart valve. An expansible heart valve prosthesis is provided and is configured to be delivered into the helical anchor and expanded inside the multiple coils . This moves at least that coil from the first diameter to the second diameter while securing the helical anchor and the heart valve prosthesis together. The expansible heart valve prosthesis includes a bumper on a blood outflow end of the expansible heart valve prosthesis. The system further includes a seal on the expansible heart valve prosthesis configured to prevent blood leakage past the heart valve prosthesis after implantation of the heart valve prosthesis in the helical anchor.

[0022] The system may include one or more additional aspects. For example, the helical anchor may include another coil that moves from a larger diameter to a smaller diameter as the heart valve prosthesis is expanded inside the multiple coils. The seal may take many alternative forms. For example, the seal can include portions extending between adjacent coils for preventing blood

leakage through the helical anchor and past the heart valve prosthesis. The seal may be comprised of many different alternative materials. The seal may further comprise a membrane or panel extending between at least two coils of the helical anchor after implantation of the heart valve prosthesis in the helical anchor. For example, one example is a biologic material. The helical anchor may further comprise a shape memory material. The heart valve prosthesis includes a blood inflow end and a blood outflow end and at least one of the ends may be unflared and generally cylindrical in shape. In an illustrative embodiment, the blood outflow end is flared radially outward and includes a bumper for preventing damage to tissue structure in the heart after implantation. The gap may be formed by a coil portion of the helical anchor that extends non-parallel to adjacent coil portions of the helical anchor.

[0023] In another illustrative embodiment, a system is provided as generally described above, except that the seal is alternatively or additionally carried on the helical anchor instead of being carried on the heart valve prosthesis. Any other features as described or incorporated herein may be included.

[0024] In another illustrative embodiment, a system for docking a heart valve prosthesis includes a helical anchor formed as multiple coils adapted to support a heart valve prosthesis with coil portions positioned above and/or below the heart valve annulus. An outer, flexible and helical tube carries the coils of the helical anchor to form an assembly. A helical delivery tool carries the assembly and is adapted to be rotated into position through a native heart valve. Additional or optional features may be provided. For example, a heart valve prosthesis may be expanded inside the multiple coils. The outer tube may be formed from a low friction material adapted to slide off of the multiple coils of the helical anchor after rotating into position through the native heart valve. The outer tube may be secured to the helical delivery tool with suture or by any other method. The helical delivery tool may formed with a plurality of coils, and the outer tube may further be secured to the distal end. The distal end may further comprise a bullet or tapered shape to assist with delivery. The distal end can further comprise a resilient element, and the distal ends of the outer tube and the helical delivery tube are secured to the resilient element.

[0025] In another illustrative embodiment, a system for replacing a native heart valve includes a helical anchor formed as multiple coils adapted to

support a heart valve prosthesis at the native heart valve. An expansible heart valve prosthesis is provided in this system and is capable of being delivered into the helical anchor and expanded inside the multiple coils into engagement with the at least one coil to secure the helical anchor and the heart valve prosthesis together. A guide structure on the expansible heart valve prosthesis is configured to guide the helical anchor into position as the helical anchor is extruded from a helical anchor delivery catheter.

[0026] The guide structure may further comprise an opening within a portion of the expansible heart valve prosthesis, such as an opening in a loop, a tube or simply an opening in the stent structure of the expansible heart valve prosthesis, for example. The opening may be configured to receive a helical anchor delivery catheter that carries the helical anchor during the implantation procedure. The opening may be located on an arm of the expansible heart valve prosthesis and the prosthesis may further comprise a plurality of arms configured to engage beneath the native heart valve. The guide structure may further comprise a tubular arm of the expansible heart valve prosthesis.

[0027] In another illustrative embodiment, a system for docking a mitral valve prosthesis and replacing a native mitral valve is provided and includes a coil guide catheter and a helical anchor adapted to be received in and delivered from the coil guide catheter. The helical anchor is formed as multiple coils having a coiled configuration after being delivered from the coil guide catheter and adapted to support the mitral valve prosthesis upon being fully delivered from the coil guide catheter and implanted at the native mitral valve. The system further includes a tissue gathering catheter including loop structure configured to be deployed to surround and gather the native chordea tendinae for allowing easier direction of the helical anchor in the left ventricle.

[0028] In another illustrative embodiment, an anchor for docking a heart valve prosthesis includes an upper helical coil portion, a lower helical coil portion, and a fastener securing the upper helical coil portion to the lower helical coil portion.

[0029] There is disclosed, a method of implanting a heart valve prosthesis in the heart of a patient includes holding a helical anchor in the form of multiple coils within an outer, flexible tube. The assembly of the outer, flexible tube and the helical anchor is secured to a helical delivery tool. The helical delivery tool is rotated adjacent to a native heart valve of the patient to

position the assembly on either or both sides of the native heart valve. The assembly is removed from the helical delivery tool, and the outer tube is removed from the helical anchor. The heart valve prosthesis is then implanted within the helical anchor.

[0030] Securing the assembly may further comprise positioning coils of the assembly generally along adjacent coils of the helical delivery tool. Removing the outer tube may further comprise holding the helical anchor with a pusher element, and pulling the outer tube off the helical anchor.

[0031] There is also disclosed, a method of implanting an expansible heart valve prosthesis in the heart of a patient includes delivering an expansible helical anchor in the form of multiple coils proximate the native heart valve. The expansible heart valve prosthesis is positioned within the multiple coils of the expansible helical anchor with the expansible heart valve prosthesis and the expansible helical anchor in unexpanded states. The expansible heart valve prosthesis is expanded against the expansible helical anchor thereby expanding the expansible heart valve prosthesis while securing the expansible heart valve prosthesis to the expansible helical anchor. A seal is carried on the helical anchor and/or on the heart valve prosthesis and extends between at least two adjacent coils for preventing blood leakage through the helical anchor and past the heart valve prosthesis.

[0032] There is also disclosed, a method of implanting an expansible heart valve prosthesis to replace a native heart valve of a patient includes delivering a helical anchor in the form of multiple coils proximate the native heart valve. The expansible heart valve prosthesis is delivered proximate the native heart valve. The helical anchor is guided generally around a periphery of the expansible heart valve prosthesis using guide structure carried on the expansible heart valve prosthesis. The expansible heart valve prosthesis is expanded against the helical anchor. As discussed above, the guide structure may take many different forms.

[0033] There is also disclosed, a method of implanting a helical anchor for docking a mitral heart valve prosthesis in a patient includes gathering the chordea tendinae using a tissue gathering catheter. A helical anchor is then delivered in the form of multiple coils proximate a native heart valve and around the gathered chordae tendinae.

[0034] There is also disclosed, a method of implanting a helical anchor for docking a heart valve prosthesis in a patient includes delivering an upper helical anchor portion comprised of upper coils to a position above a native heart valve, and delivering a lower helical anchor portion comprised of lower coils to a position below the native heart valve. The upper and lower helical anchor portions are secured together with a fastener either before or after delivery of each helical anchor portion.

[0035] In another illustrative embodiment, a system for replacing a native heart valve is provided and includes an expansible helical anchor formed as multiple coils adapted to support a heart valve prosthesis. At least one of the coils is normally at a first diameter, and is expandable to a second, larger diameter upon application of radial outward force from within the helical anchor. A gap is defined between adjacent coils sufficient to prevent engagement by at least one of the adjacent coils with the native heart valve. An expansible heart valve prosthesis is provided and is capable of being delivered into the helical anchor and expanded inside the multiple coils into engagement with the at least one coil. In this manner, the expansible coil moves from the first diameter to the second diameter while securing the helical anchor and the heart valve prosthesis together. The expansible heart valve prosthesis includes an inflow end and an outflow end. The inflow end is unflared and generally cylindrical, while the outflow end is flared in a radially outward direction.

[0036] Various additional advantages, methods, devices, systems and features will become more readily apparent to those of ordinary skill in the art upon review of the following detailed description of the illustrative embodiments taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

[0037] FIG. 1 is a perspective view schematically illustrating the introduction of a helical anchor to the position of the native mitral valve.

[0038] FIG. 2A is an enlarged cross-sectional view illustrating an initial portion of the procedure shown in FIG. 1, but with use of a deflectable catheter.

[0039] FIG. 2B is a cross-sectional view of the heart similar to FIG. 2A, but illustrating deflection of the delivery catheter and introduction of the helical anchor underneath the native mitral valve.

[0040] FIGS. 3A and 3B are enlarged elevational views illustrating the distal end of the delivery catheter and its deflecting capability.

[0041] FIGS. 4A and 4B are respective top views of FIGS. 3A and 3B.

[0042] FIG. 5A is a side elevational view similar to FIG. 3B, but illustrating the use of a wire within the delivery catheter used for deflecting or steering the distal end.

[0043] FIG. 5B is a cross-sectional, top view of the delivery catheter shown in FIG. 5A.

[0044] FIG. 6A is a perspective view showing the combination of a helical anchor and an outer tube used for assisting with the delivery of the helical anchor to the native mitral valve location.

[0045] FIG. 6B is a perspective view of the helical anchor within the outer tube shown in FIG. 6A.

[0046] FIG. 7A is an elevational view showing a helical delivery tool used to deliver the assembly of FIG. 6B to the native mitral valve location.

[0047] FIG. 7B is a perspective view illustrating the attachment of the assembly shown in FIG. 6B to the helical delivery tool shown in FIG. 7A.

[0048] FIG. 8A is a perspective view showing the heart in cross section and the helical delivery tool being used to implant the assembly of FIG. 6B.

[0049] FIGS. 8B through 8E are perspective views showing further steps in the method of implantation.

[0050] FIG. 8F is a perspective view showing the implanted helical anchor.

[0051] FIG. 8G is a cross-sectional view showing a replacement heart valve, such as a stent mounted valve, within the implanted helical anchor.

[0052] FIG. 9 is a perspective view illustrating another illustrative embodiment of a tool and assembly for implanting a helical anchor.

[0053] FIG. 10 is a partially cross-section top view showing the assembly of FIG. 9.

[0054] FIG. 11A is a cross-sectional view of the distal end of an alternative embodiment of a helical anchor and delivery catheter.

[0055] FIG. 11B is a perspective view of the distal end of another embodiment of a helical anchor and delivery catheter.

[0056] FIG. 12 is a cross-sectional view of an implanted replacement stent mounted valve and helical anchor at a native mitral valve location according to another illustrative embodiment.

[0057] FIG. 13 is an enlarged cross-sectional view showing another illustrative embodiment of a stent mounted replacement heart valve.

[0058] FIG. 13A is an enlarged cross-sectional view showing a non-flared embodiment of the outflow end of the replacement heart valve shown in FIG. 13.

[0059] FIG. 14A is a cross-sectional view illustrating another illustrative embodiment of a replacement heart valve secured within a helical anchor.

[0060] FIG. 14B is an enlarged cross-sectional view of the replacement valve shown in FIG. 14A.

[0061] FIG. 15A is a schematic view showing a heart in cross section and initial introduction of a delivery catheter to the mitral valve location.

[0062] FIG. 15B is an enlarged cross-sectional view of the heart showing a further step in the introduction of a stent mounted replacement heart valve together with a helical anchor.

[0063] FIGS. 15C through 15F are views similar to FIG. 15B, but illustrating progressively further steps in the method of introducing the helical anchor and stent mounted replacement heart valve at the native mitral valve location.

[0064] FIGS. 16A and 16B are schematic elevational views showing the simultaneous deployment of a stent mounted replacement heart valve and a helical anchor using an arm with a loop on the stent valve.

[0065] FIGS. 17A and 17B are similar to FIGS. 16A and 16B, but illustrate another embodiment.

[0066] FIGS. 18A, 18B and 18C are views similar to FIGS. 16A and 16B, however, these views progressively illustrate another embodiment of a method for deploying a helical anchor and a stent mounted replacement heart valve.

[0067] FIG. 19A is a side elevational view of a helical anchor constructed in accordance with another illustrative embodiment.

[0068] FIG. 19B is a cross-sectional view taken along line 19B-19B of FIG. 19A.

[0069] FIG. 20 is a schematic perspective view illustrating another alternative system for delivering a helical anchor.

[0070] FIG. 21A is a schematic perspective view illustrating the initial delivery of an alternative helical anchor.

[0071] FIG. 21B is a schematic perspective view of the fully delivered helical anchor of FIG. 21A.

[0072] FIG. 22A is a cross-sectional view showing another illustrative embodiment of a helical anchor including a seal.

[0073] FIG. 22B is a cross-sectional view similar to FIG. 22A, but showing the helical anchor implanted at the location of a native mitral valve and an expandable stent mounted replacement valve held within the helical anchor.

[0074] FIG. 23A is a schematic elevational view showing another illustrative embodiment of a helical anchor before expansion with a balloon catheter.

[0075] FIG. 23B is an elevational view similar to FIG. 23A, but illustrating the helical anchor during expansion by the balloon catheter.

Detailed Description of the Illustrative Embodiments

[0076] It will be appreciated that like reference numerals throughout this description and the drawings refer generally to like elements of structure and function. The differences between embodiments will be apparent from the drawings and/or from the description and/or the use of different reference numerals in different figures. For clarity and conciseness, description of like elements will not be repeated throughout the description.

[0077] Referring first to FIG. 1 in conjunction with FIGS. 2A and 2B, as previously discussed in Applicant's PCT Application Serial No. PCT/US2013/024114, the disclosure of which is fully incorporated by reference herein, a deflectable catheter 10 makes implantation of a helical anchor 12 much easier. The deflectable tip 10a of the catheter 10 assists with the helical anchor 12 engaging a commissure 14 of the native mitral valve 16, as shown in FIG. 1. The tip 10a of the catheter 10 may be designed and configured such that it can bend downward toward the native leaflets 18, 20 of the mitral valve 16. Once the tip 10a of the catheter 10 is placed generally over the commissure 14 as shown in FIG. 2A, the tip or distal end 10a may be bent downward and it is then relatively easy to push or extrude the helical anchor 12 out of the distal end 10a and downward through the mitral valve 16 as shown in FIG. 2B.

[0078] Now referring to FIGS. 3A, 3B, 4A, 4B, 5A and 5B, the deflectable catheter, or anchor delivery catheter 10, may be deflectable at many different points or locations. Deflecting the catheter tip 10a outward to increase the radius of the delivery catheter tip 10a can be very helpful, as shown in FIGS. 3A, 3B and 4A, 4B which show the "before" and "after" effects of deflecting the distal end 10a. Deflecting the catheter 10 in this way will give the helical anchor 12 a larger diameter starting turn or coil 22. As an example, this turn or coil 22 of the helical anchor 12 may normally be 25mm but operating the distal end 10a of the catheter 10 in this manner can enlarge the diameter to 30mm. Opening up the first turn or coil 22 of the helical anchor 12 in this way would help the helical anchor 12 capture all chordae 24 and leaflets 18, 20 as the helical anchor 12 is introduced as generally discussed above in connection with FIG. 1 and FIGS. 2A and 2B. As the helical anchor 12 advances, the distal end 10a of the delivery catheter 10 could also deflect inward to help the helical anchor 12 capture all of the chordae 24 at the opposite commissure. Moving the distal end 10a of the delivery catheter 10 from side to side as the helical anchor 12 is essentially screwed or rotated into and through the native mitral valve 16 is essentially like tracking the delivery catheter 10 with the turn or coil 22. In this case, however, the delivery catheter 10 is stationary as only the tip 10a is moving with the coils 22. Deflectability of the distal end 10a in any direction may be achieved by embedding a wire 26 that runs the length of the delivery catheter 10. When the wire 26 is pulled, the delivery catheter tip 10a deflects and deforms into various shapes as desired or needed in the procedure.

[0079] A procedure will now be described for introducing or implanting a helical anchor 12 in connection with FIGS. 6A, 6B, 7A, 7B, and 8A through 8C. A helical delivery tool 30 including coils 31 is used to deliver the helical anchor 12 which is contained within an outer tube 32, for example, formed from a Goretex or other low friction material, such as PTFE. Suture 34 is used to secure the combination or assembly of the outer tube 32 and helical anchor 12 in place on the coils 31 of the helical delivery tool 30. A groove (not shown) may be formed in the helical tool 30 so that it provides a secure seat for the suture. Additional suture 36 is used to tie the leading end of the outer tube 32 through a loop 38 at the end of the helical delivery tool 30. The helical delivery tool 30 and outer tube/helical anchor combination 32, 12 is turned into the heart 40, through the mitral valve 16 as shown and the suture 34 is cut, for example,

with a scalpel 42 (FIG. 8B). A pair of forceps 44 is used to turn the tool 30 in through the native mitral valve 16 slightly more and this breaks the suture 36 (FIG. 8C). The helical tool 30 is then rotated in an opposite direction and removed from the heart 40, leaving the helical anchor 12 combined with the outer tube 32 in the heart 40, as shown. A push rod 50 with a cupped end 52 is inserted into the trailing end of the outer tube 32 (FIG. 8D). The outer tube 32 is then pulled backwards or rearward leaving the helical anchor 12 in place while removing the outer tube 32. Due to the low friction material of the outer tube 32, it easily slides off of the helical anchor 12. FIGS. 8F and 8G, respectively, show full implantation of this embodiment of the helical anchor 12 and a replacement heart valve 60 mounted within and firmly against the helical anchor 12. The replacement valve 60 includes leaflets 62, 64, and a body 66 which may be of any suitable design, such as an expandable stent design.

[0080] In another embodiment shown in FIGS. 9 and 10, a bullet shaped head 70 is provided on the helical tool 30. There is a slit 72 on the bullet-shaped head 70 that runs parallel to the helical shaped wire or coil 22 adjacent to the head 70. The bullet-shaped head 70 is formed from resilient, polymer, for example, and the slit 72 opens and closes by way of this resiliency. Again, the outer tube 32 is fixed to the helical delivery tool 30 with a suture (not shown). The leading end 32a of the outer tube 32 is inserted into the bullet-shaped head 70, for example, with forceps 44. In this embodiment, the bullet-shaped head 70 provides for easier insertion due to its tapered shape.

[0081] FIGS. 11A and 11B show additional illustrative embodiments of the combination of a delivery catheter 10 with a helical anchor 12 inside, before deployment. The distal tip 10a of the delivery catheter 10 includes a taper which may be gradually tapered as shown in FIG. 11A, or more rounded as shown in FIG. 11B. In each case, the distal tip 10a configuration allows for smoother, easier delivery to a native mitral valve location and can maneuver through tissue structure, such as native tissue, within the heart 40. For example, the distal end 10a of the delivery catheter 10 may be directed through the mitral valve 16 and may need to encircle the chordae 24 either partially or fully (FIG. 1). As shown in FIG. 11A, the helical anchor 12 may be constructed with an internal wire coil 12a and an external covering or coating 12b such as fabric, and may include a soft tip 12c, such as formed from polymer, to avoid damage to heart tissue during delivery and to enable easier delivery.

[0082] FIG. 12 is a cross-sectional view showing an illustrative stent mounted replacement heart valve or prosthesis 60 at the native mitral valve 16 location docked in a helical anchor 12. In this embodiment, a "bumper" structure 80 has been added to the annular edge at the outflow end of the valve 60. This bumper structure 80 may be formed, for example, from foam 82 covered by a sealing material 84 such as fabric or another suitable material or coating. This sealing layer 84 extends upward over an open stent structure 86 of the valve 60 to prevent blood leakage past the valve 60 and through the coils 22 of the helical anchor 12.

[0083] FIG. 13 is an enlarged view of a replacement heart valve 60 similar to the valve shown in FIG. 12, but showing radially outward flared inflow and outflow ends.

[0084] FIG. 13A is an enlarged sectional view showing a generally cylindrical outflow end, without a radially outward flare.

[0085] FIGS. 14A and 14B illustrate another illustrative embodiment of the invention including a helical anchor 12 docking or mounting a replacement stent valve 60 and including biological tissue seal 90, such as pericardium tissue or other animal tissue used at both the location of the bumper 80 to cover the internal foam layer 82, as well as to seal and cover the open stent structure 86 up to the location of an existing fabric layer 92 circumscribing the replacement heart valve 60. The combination of the existing fabric layer 92 on the stent valve 60 and the seal layer 90 circumscribing the lower or outflow portion of the valve 60 prevents blood flow from leaking past the valve 60 through the stent structure 86. Instead, the blood passes as it should through the leaflets 62, 64 of the replacement valve 60. As further shown in FIG. 14A, the helical anchor 12 is preferably formed of spaced apart coils 22 creating a gap 91 such as configured in any embodiment previously discussed in connection with PCT Application Serial No. PCT/US2014/050525 the disclosure of which is hereby fully incorporated by reference herein, or spaced apart or formed as otherwise desired. As further described in PCT/US2014/050525, the helical anchor 12 is expansible by the stent valve 60.

[0086] Referring to FIGS. 15A-15C, an initial portion of a procedure according to another illustrative embodiment is shown. In this figure, a sheath 100 and delivery catheter 101 have been advanced through a peripheral vein into the right atrium 102 of the heart 40, across the atrial septum 104, to the left

atrium 106. A distal end 10a of the delivery catheter 101 is positioned in the left ventricle 108 by being directed through the native mitral valve 16. This delivery catheter 101 contains a self-expanding or stent mounted mitral prosthesis or replacement valve 60 that is to be implanted at the location of the native mitral valve 16. A super elastic or shape memory type material, such as Nitinol, is typically used to form the frame structure or body 66 of the self-expanding replacement valve 60, but other materials may be used instead. The frame or body 66 includes artificial valve leaflets 18, 20 typically formed from tissue such as pericardial cow or pig tissue. Leaflets 18, 20 could instead be formed of other materials, such as synthetic or other biomaterials, e.g., materials derived from small intestinal mucosa. As described further below, the delivery catheter 101 also contains a helical anchor 12 and delivery system. The helical anchor 12 may generally take the forms described herein or previously disclosed, for example, in PCT Application Serial Nos. PCT/US2014/050525 and PCT/IB2013/000593. The disclosure of the PCT/IB2013/000593 application is also incorporated by reference herein.

[0087] FIG. 15B illustrates the delivery catheter 101 inside the left ventricle 108 with the distal tip 10a just below the native mitral valve leaflets 18, 20. The procedure has been initiated with exposure of the contents of the delivery system.

[0088] FIG. 15C illustrates another portion of the procedure subsequent to FIG. 15B and illustrating that the prosthetic or replacement mitral valve 60 has been partially delivered through the distal end 10a of the catheter 101. The end of the replacement valve 60 that is positioned in the left ventricle 108 has arms 110 that wrap around the native mitral leaflets 18, 20 and serve to anchor the replacement valve 60 firmly against the margins of the native mitral valve leaflets 18, 20. The arrows 112 show how the arms 110 have wrapped around the lower margins of the native mitral leaflets 18, 20 after the arms 110 have been extruded or deployed outwardly from the delivery catheter 101. This replacement valve 60 construction has been shown in the above-incorporated PCT Application Serial No. PCT/IB2013/000593. These arms 110 will help prevent the replacement valve 60 from dislodging upward into the left atrium 106 when the replacement valve 60 is fully positioned, because the arms 110 hook around the edges of the native mitral leaflets 18, 20. Multiple arms 110 are useful to provide a lower plane of attachment of the mitral valve prosthesis

60 to the native mitral valve 16. The arms 110 may vary in length and in character and construction. It will be understood that a plurality of arms 110 is used with this embodiment, but only two arms 110 are shown in these figures for purposes of illustration and simplification. One of the arms 110 includes a loop 120 to direct or control the helical anchor delivery catheter 10 that contains a helical anchor 12. The anchor delivery catheter 10 has been preloaded into the loop 120 before the assembly was loaded into the delivery sheath 100. The arm with the loop 120 may be of heavier construction than the other arms 110 and does not have to resemble the other arms 110. The arms 110 have shape memory property such that when they are extruded or deployed outwardly from the anchor catheter 10 they wrap around the native mitral leaflets 18, 20. The arm 110 with the loop 120 wraps around the native mitral leaflets 18, 20 and the attached helical anchor delivery catheter 10 is carried with it so that the chordae 24 and the native mitral valve leaflets 18, 20 are positioned inside the exposed end of the helical anchor 12.

[0089] When the helical anchor 12 is advanced or extruded as is initially shown in FIG. 15C, it will encircle the chordae tendinae 24 so that all valve and chordae will be trapped inside the helical anchor 12. The loop 120 swings the helical anchor delivery catheter 10 around the native mitral leaflets 18, 20 and above the chordae 24 into a preferred position under the native mitral valve annulus 126. The arm 110 with the loop 120 may have a dual function of attachment of the valve 60 to the native leaflet margin and for guidance during delivery of the helical anchor 12. The loop 120 may be sufficiently large to allow the helical anchor delivery catheter 10 to pivot or swivel as the system is deployed. It is important for the helical anchor 12 to be extruded in a plane close to parallel to the underside of the native mitral valve 16. The helical anchor delivery catheter 10 is also aimed or oriented to this plane by the loop 120. The loop 120 may, in fact, be composed of a short tube (not shown) instead of a wire as shown. A tube would force the helical anchor delivery catheter 10 into a favorable plane and orientation. Alternatively, the helical anchor delivery catheter 10 could be steerable in one of the manners known through steerable catheter technology.

[0090] Other mitral valve prosthesis or replacement valves may be used and have a wide range of attachment arms or wings, or stent structure, that wrap around the native mitral valve leaflets 18, 20. The arms or other similar

structures in such prostheses could all be fitted with a loop 120, or tube or other similar guidance structure, to perform similar functions as the loop 120 described immediately above. This function generally relates to directing the delivery of the helical anchor 12. Furthermore, it is not necessary that a loop 120 directs the helical anchor delivery. For example, a cell or opening of the replacement valve stent structure 86 could also perform the same function as the loop 120 shown and described in these figures. A hook or a tube may also be used in lieu of the illustrated loop 120. Any structure that can function to direct the helical anchor 12 around the native mitral valve leaflets 18, 20 may be added to the prosthetic or replacement heart valve 60. The structure may be permanently fabricated as part of the replacement valve 60 or may be temporary structure used only during the procedure. For example, a loop of suture (not shown) may be used to guide delivery of a helical anchor 12 including any helical anchor delivery catheter 10 associated therewith. After use of the suture, it may be withdrawn from the patient.

[0091] The arms 110 illustrated in these figures are quite narrow or slender. In practice, it may be more useful to have arms that are composed of pairs or triplets of wires that are fused at the ends. The narrow terminal ends of the arms 110 facilitate the arms 110 passing between the chordae tendinae 24 at their margins with the free edge of the native mitral leaflets 18, 20 to allow the arms 110 to wrap around the native leaflets 18, 20. The chordae 24 are closely packed in some areas and slender arms 110 will allow the arms 110 to pass between the chordae tendinae 24. Once the slender portion of the arms 110 pass, thicker portions of the arms 110 may move between the chordae 24 by spreading them apart. Therefore, an arm 110 that is slender or composed of a single wire or fusion of wires at the tip and that is more robust or thicker closer to the main body of the prosthetic or replacement valve 60, may be a desirable arrangement. The wires or arms 110 may also be much shorter than those shown in these illustrative figures. In the illustrated method, delivery of the helical anchor 12 may be started at any desired location and not necessarily at the commissure 14 of the native mitral valve 16. For example, delivery may start in the middle portion of a native mitral leaflet 18 or 20. This would be advantageous for the surgeon who would not have to precisely locate the commissure 14 to begin the procedure, thereby greatly simplifying the procedure.

[0092] FIG. 15D illustrates the helical anchor 12 being delivered under the native mitral leaflets 18, 20. The arrow 130 indicates the helical anchor 12 being extruded from the helical anchor delivery catheter 10 under the native mitral valve 16. Any number of coils or turns 22 of the helical anchor 12 may be extruded depending on the particular configuration of helical anchor 12 being used in the procedure. The inner diameter of the helical anchor 12 would preferentially be slightly less than the outer diameter of the fully expanded mitral valve prosthesis 60 to promote firm engagement or anchoring of the replacement mitral valve 60. The helical anchor 12 may be composed of bare wire, or may have coatings or coverings for various reasons such as those described in the above incorporated PCT applications. The partially delivered mitral valve prosthesis 60 serves an important function to center the delivery of the helical anchor 12. The mitral valve prosthesis or replacement valve 60 also provides a stable platform.

[0093] FIG. 15E illustrates that three turns 22 of the helical anchor 12 have been placed below the native mitral valve 16. These turns or coils 22 have positioned the native mitral valve leaflets 18, 20 between the helical anchor 12 and the prosthetic mitral valve 60 which is shown in a configuration about to be expanded. Once the replacement valve 60 is expanded, this securely positions the replacement valve 60 and prevents leaks around the replacement valve 60 by sealing the native mitral leaflets 18, 20 to the prosthesis 60. The delivery sheath 101 for the replacement valve 60 has been removed and when using a self-expanding valve, the valve 60 would spring open upon removal of the delivery sheath 101. The arrows 132 indicate this process prior to its occurrence. In this figure, the replacement valve 60 is still in a closed position to allow clear visualization of the turns or coils 22 of the helical anchor 12 beneath the native mitral valve 16. In this configuration, there are three helical anchor coils 22 below the native mitral valve 16, however, any number of coils 22 may be used instead. The coils 22 are positioned up against the underside of the mitral valve annulus 126 and leaflets 18, 20 to provide a solid buttress to fix the helical anchor 12 in position and prevent movement into the left atrium 106 when the powerful left ventricle 108 contracts. When the arms 110 wrap around the helical anchor 12, the entire structure or assembly is stabilized in position. This embodiment provides a surgeon or interventionalist a considerable amount of choice due to the fact that the anchor 12 may be

delivered at the same time as the replacement valve 60. Many shape memory framed prosthetic heart valves 60 may be re-sheathed. This means that during a procedure, the replacement valve 60 may be partially advanced from a catheter or sheath 101 and tested for its fit in the heart 40. If the surgeon or interventionalist is not satisfied with the positioning of the replacement valve 60 before the final release of the replacement valve 60, this valve 60 may be pulled back into the sheath or catheter 101. Therefore, a prosthetic or replacement valve 60 may be positioned initially with no helical anchor 12 in place. If subsequent anchoring appeared strong and stable and there was no evidence of movement or leakage, the valve 60 may be released. On the other hand, if the surgeon or interventionalist is not satisfied, the valve 60 may be pulled back into the sheath 101. The helical anchor 12 may be implanted first, and then the valve 60 may be extruded from the delivery sheath 101. This would allow the user to decide on the clinical need for additional anchoring under the native mitral valve 16.

[0094] FIG. 15F illustrates the fully implanted expandable replacement valve 60 shown in proper position. The arms 110 have wrapped around the native mitral valve leaflets 18, 20 to prevent the replacement valve 60 from moving upward into the left atrium 106. The native mitral leaflets 18, 20 are compressed under the arms 110 and a very solid mechanical structure and anchoring has been created to prevent the replacement valve 60 from migrating to an undesirable position. The turns or coils 22 of the helical anchor 12 also compress against the body 66 of the prosthetic or replacement valve 60 to position, orient and prevent movement of the replacement valve 60. Therefore, the helical anchor 12 provides a friction attachment of the replacement valve 60 and serves to anchor the arms 110 that wrap around the helical anchor 12. The upper portion of the native mitral valve 16 is shown with a wider area that sits inside the left atrium 106 to promote attachment to the wall of the left atrium 106. However, the force moving the replacement valve 60 from the left atrium 106 toward the left ventricle 108 is low and this portion of the replacement valve 60 may not be necessary and could be eliminated or reduced from a clinical prosthesis. The turns or coils 22 of the helical anchor 12 are important because they can overcome a wide variety of variations in the lengths of the native mitral leaflets 18, 20 from patient to patient and the length of the chordae tendinae 24 and the attachment points of the chordae 24 in the left ventricle 108. When a

replacement valve 60 with arms 110 wrapping around the native mitral leaflets 18, 20 is used without any helical anchor 12 encircling under the native leaflets 18, 20, the depth of fixation of the prosthetic mitral valve 60 may vary around the perimeter of the implanted replacement valve 60. For example, if the chordae tendinae 24 attached to the middle part of the posterior leaflet 20 were very elongated or ruptured, which is a common situation, the arms 110 may fail to wrap around and engage the native leaflet 20 at this location. Alternatively, there may be a very limited engagement along or at a much higher plane. This portion of the replacement valve 60 would be positioned higher, creating a skew in the replacement valve 60 so that the replacement valve 60 would be positioned at an angle to the plane of inflowing blood through the replacement valve 60. As the heart 40 beats, there is a large load on the replacement valve 60 and it may begin to rock and shift. The heart 40 beats almost 100,000 times per day and after several days or weeks or months, the valve 60 may shift, move and/or dislodge. Also, if the leaflets 18, 20 and/or chordae 24 were very elongated, there may be no contact with the arms 110. This could result in a large perivalvular leak due to lack of engagement of the replacement valve 60 with the native mitral leaflets 18, 20. An anchor 12 under the native mitral valve leaflets 18, 20 would compress native leaflet tissue against the replacement valve 60 and prevent this problem. The helical anchor 12 would be positioned in one plane and prevent problems related to variations in patient anatomy.

[0095] In clinical practice, there are virtually limitless variations in the size of the native mitral leaflets 18, 20, character of the native mitral leaflets 18, 20, the chordal lengths and the attachment of the chordae 24 as well as the diameter of the mitral annulus 126. The use of a helical anchor 12 or other anchor structure under the native leaflets 18, 20 neutralizes many of these variables since the fixation point of the arms 110 may be brought to the lowest coil 22 of the helical anchor 12. This position may also be determined in advance by selecting the number of coils 22 in the helical anchor 12 as well as the thickness of the coils 22 in the helical anchor 12 to match the turning point of the arms 110 on the lowest portion of the replacement valve 60. Thus, an important feature of the helical anchor 12 delivered under the native mitral annulus 126 is that it can create a common and predefined plane for anchoring the arms 110 of the replacement valve 60. In the situation described above in which some of the chordae 24 are stretched, the attachment in this region of the

replacement valve 60 could be to the helical anchor 12. This would create a common plane for the lowest point on the replacement valve 60. To ensure that the valve 60 anchors at a common lowest plane throughout its perimeter, additional coils 22 may be added to the helical anchor 12, or the diameter of the coils 22 may be made larger. Additional options are, for example, waves or undulations may be added to the coils 22 of the helical anchor 12 to expand the overall height of the helical anchor 12. The helical anchor 12 therefore improves stability of the replacement valve 60 by providing an anchoring point or location for the arms of the replacement valve 60 to wrap around while, at the same time, the helical anchor 12 can trap the perimeter of the replacement valve 60 along its length. The combination of these features provides for increased stability to the replacement valve 60 and can also seal the replacement valve 60 against the native mitral valve 16 to prevent perivalvular leakage of blood flow. As mentioned, the native mitral valve and heart structure of patients comes in many varieties and combinations. It is not practical for a manufacturer to make different lengths and depths of anchoring arms 110 and for the user to deliver these products optimally into position for each case. Rather, it is much more practical to adjust for these variations by placing a helical anchor 12 below the native mitral valve 16 and using this to create a lowest plane for the arms 110 to anchor against. The delivery system for the helical anchor 12 may be any delivery or deployment system, for example, described in the above-incorporated PCT applications. It will be appreciated that such deployment methods and apparatus may be used to deliver the helical anchor 12 such that the anchor 12 is positioned only below the native mitral valve 16 as shown herein.

[0096] FIGS. 16A and 16B illustrate another embodiment in which a loop 120 is provided at the end of an arm 110 on the replacement valve 60 that guides the helical anchor delivery catheter 10. This loop 120 allows the delivery catheter 10 to swivel as it is moved into position. In this embodiment, the helical anchor delivery catheter 10 passes through the replacement valve 60 or, in other words, within the replacement valve body 66, however, it may be directed in manners other than that shown, and the helical anchor delivery catheter 10 may be used for additional guidance along the path, such as by being steerable after being directed through the loop 120 farther than as shown in FIGS. 16A and 16B for delivery of the helical anchor 12.

[0097] FIGS. 17A and 17B illustrate another embodiment in which a helical anchor delivery tube 140 has been incorporated into the replacement valve 60 instead of the helical anchor delivery catheter 10 previously described. In this embodiment, one arm of the replacement valve 60 is, in fact, the tube 140 that is loaded with and carries the helical anchor 12. When the tubular arm 140 wraps around the native mitral valve leaflet (not shown), the helical anchor 12 is carried into the correct location and to the correct plane for delivery. Any structure on one of the arms 110 of the replacement valve 60 or any portion of the replacement valve 60 that may guide the helical anchor 12 for delivery may be used instead. In FIG. 17B, the helical anchor 12 has been extruded from the tubular arm 140 for almost one complete rotation or turn. As previously described, multiple turns or coils 22 of the helical anchor 12 may be deployed in this manner for ultimately securing the replacement valve 60 at the native mitral valve 16 location generally as described above. The main difference with this embodiment is that a helical anchor delivery catheter 10 is not needed.

[0098] FIGS. 18A through 18C illustrate another embodiment for replacement valve and helical anchor deployment and implantation. In this regard, the helical anchor delivery catheter 10 and the replacement valve 60 are essentially delivered side by side. FIG. 18A illustrates the helical anchor delivery catheter 10 outside or extruded from the delivery sheath 101 that also delivers the replacement valve 60. The helical anchor delivery catheter 10 passes through a loop 120 in one of the arms 110 of the replacement valve 60. The arrow 150 indicates that the helical anchor 12 is about to be extruded from the end of the helical anchor delivery catheter 10. As shown in FIG. 18B, with the end of the helical anchor delivery catheter 10 still in the loop 120, almost one full turn or coil 22 of the helical anchor 12 has been delivered under the native mitral valve (not shown). FIG. 18C illustrates a further point during the implantation process in which about three turns or coils 22 of the helical anchor 12 have been delivered under the plane 152 of the native mitral valve 16. In this figure, the helical anchor delivery catheter 10 and the sheath 101 delivering the replacement valve 60 have been removed. When the replacement valve 60 is formed with a self-expanding stent, the body 66 of the valve 60 will spring open when the delivery sheath 101 is removed. For purposes of clarity and illustration, the valve 60 is still shown in a closed or unexpanded state simply for

clarity. However, in general, the fully implanted system or assembly will be similar to that shown in FIG. 15F.

[0099] FIGS. 19A and 19B illustrate another embodiment of a helical anchor 12. In this embodiment, the configuration of the helical anchor 12 in terms of the spacings and size of the coils 22 may vary. The cross-sectional construction includes a fabric covering 160 which may, for example, be PET having a thickness of 0.008 +/- 0.002 inch, a weight of 2.12 +/- 0.18 ounce/yard^2 (72 +/- 6 grams/m^2), a wale/inch of 40 +/- 5, courses/inch of 90 +/- 10. A foam layer 162 may, for example, be 2mm thick polyurethane sheet material. The foam may be attached to the fabric 160 using PTFE suture with a light straight stitch. The fabric160 and foam 162 may then be folded around the center wire portion 22a of the coils 22 of the helical anchor 12 and cross-stitched to the wire portion 22a using fiber suture.

[00100] FIG. 20 illustrates another system which may include the delivery of a helical anchor 12 as set forth above and/or in the above incorporated PCT applications. In accordance with this embodiment, however, an additional tissue gathering device 170 is included in the delivery system. The device 170 delivers a temporary ring or loop 172 which can corral or surround the bundles of chordae tendinae 24 into a smaller area. This can facilitate easier placement of the helical anchor 12 without entanglement or obstruction with the chordae tendinae 24. Also, shown in this figure is an introducer sheath 100, a delivery catheter 101 as well as a steerable helical anchor delivery catheter 10 all generally as previously described.

[00101] FIGS. 21A and 21B illustrate another helical anchor device or assembly 12. The assembly 12 is comprised of an upper or atrial helical anchor portion 180 as well as a lower or ventricular helical anchor portion 182. These helical anchor portions 180, 182 are delivered simultaneously by extruding out of a helical anchor delivery catheter 10. The lower anchor portion 182 is delivered through the mitral valve 16 between the native leaflets 18, 20. The upper and lower anchor portions 180, 182 may be coupled together, for example, by a crimp joint 184. The upper anchor portion 180 is deployed above the native mitral valve 16 in the left atrium 106 (FIG. 20). The upper and lower anchor portions 180, 182 may be staggered such that the lower anchor portion 182 is initially directed into the commissure 14 and through the native mitral valve 16. As shown, the upper and lower helical anchor portions 180, 182 wind

or rotate in opposite directions and then may be crimped together, as shown or may be precrimped or otherwise attached prior to loading the catheter 10.

[00102] FIG. 22A and 22B illustrate another embodiment of a helical anchor and replacement valve system similar to those discussed in connection with the above-incorporated PCT Application Serial No. PCT/US2014/050525. In this embodiment, however, the configuration of the helical anchor 12 is shown to have a gap 200 between at least the upper coils 22a and the native mitral valve 16. As in the above incorporated PCT application, the helical anchor 12 includes an annular seal 202 of any desired configuration extending lengthwise through or otherwise along the length of the anchor 12. In this embodiment, a panel or membrane seal 202 is shown extending downwardly from one of the coils 22a and covering the portion of the stent mounted replacement valve 60 that would otherwise be open due to the stent structure 86. The seal 202 therefore prevents leakage of blood past the replacement valve 60 through the open stent structure 86. All other aspects of the assembly as shown in FIGS. 22A and 22B are as described herein and may include any of the options or features described herein or otherwise, for example, in the above-incorporated PCT applications. The gap 200 is formed by a coil portion 22b extending non-parallel to the adjacent coil portions 22a, 22c.

[00103] FIGS. 23A and 23B illustrate another embodiment of a helical anchor 12, again similar to the above-incorporated PCT Application Serial No. PCT/US2014/050525. The difference between this embodiment and the similar embodiment shown in the above-incorporated PCT application is that a gap 200 has been created between two of the middle coils 22a, 22c of the anchor 12. These two figures illustrate the feature of the helical anchor 12 in which the coils 22 will move or rotate as the expandable anchor 12 is expanded by, for example, a balloon catheter 210. As previously described, a gap 200 formed between adjacent coils 22a, 22c may be used to ensure that native mitral tissue is not trapped or engaged by the adjacent coils 22a, 22c. The gap 200 is formed by a coil portion 22b extending non-parallel to the adjacent coil portions 22a, 22c.

[00104] While the present invention has been illustrated by a description of preferred embodiments and while these embodiments have been described in some detail, it is not the intention of the Applicants to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages

and modifications will readily appear to those skilled in the art. The various features and concepts of the invention may be used alone or in any combination depending on the needs and preferences of the operator. This has been a description of the present invention, along with the preferred methods of practicing the present invention as currently known. However, the invention itself should only be defined by the appended claims.

What is claimed is:

1. A system for replacing a native heart valve, the system comprising:

an expansible helical anchor formed as multiple coils adapted to support a heart valve prosthesis, at least one of the coils normally being at a first diameter, and being expandable to a second, larger diameter upon application of radial outward force from within the helical anchor, wherein a gap is defined between two adjacent coils sufficient to prevent engagement by at least one of the two adjacent coils with the native heart valve;

an expansible heart valve prosthesis capable of being delivered into the helical anchor and expanded inside the multiple coils to move the at least one coil from the first diameter to the second diameter while securing the helical anchor and the heart valve prosthesis together, wherein the expansible heart valve prosthesis includes a bumper on a blood outflow end of the expansible heart valve prosthesis; and

a seal on the expansible heart valve prosthesis configured to prevent blood leakage past the heart valve prosthesis after implantation of the heart valve prosthesis in the helical anchor.

2. The system of claim 1, wherein the helical anchor includes another coil that moves from a larger diameter to a smaller diameter as the heart valve prosthesis is expanded inside the multiple coils.

3. The system of claim 2, wherein the seal includes portions extending between adjacent coils for preventing blood leakage through the helical anchor and past the heart valve prosthesis.

4. The system of claim 1, wherein the seal further comprises a biologic material.

5. The system of claim 1, wherein the helical anchor further comprises a shape memory material.

6. The system of claim 1, wherein the seal further comprises a membrane or panel extending between at least two coils of the helical anchor after implantation of the heart valve prosthesis in the helical anchor.

7. The system of claim 1, wherein the heart valve prosthesis includes a blood inflow end, and wherein at least one of the blood inflow end and the blood outflow end is unflared and generally cylindrical in shape.

8. The system of claim 7, wherein the blood outflow end is flared radially outward.

9. The system of claim 1, wherein the gap is formed by a coil portion of the helical anchor that extends non-parallel to adjacent coil portions of the helical anchor.

10. The system of claim 1, wherein the bumper comprises a foam material.

11. The system of claim 10, wherein the bumper further comprises a covering, different from the foam material, that covers the foam material.

12. The system of claim 1, wherein the bumper comprises a biological tissue material configured to cover the blood outflow end of the expansible heart valve prosthesis.

13. The system of claim 12, wherein the biological tissue material is configured to cover a foam layer.

14. The system of claim 12, wherein the expansible heart valve prosthesis includes and open stent structure and the biological tissue material is configured to cover a portion of the open stent structure.

15. The system of claim 12, wherein the biological tissue material is pericardium tissue.