AXISYMMETRIC ADJUSTABLE DEVICE FOR TREATING MITRAL REGURGITATION

Field of the Invention

[0001] The present invention relates to the repair of heart valves, and, more particularly, to methods and apparatuses for the repair of heart valves by positioning a device between valve leaflets to improve valve closure.

Background of the Invention

[0002] In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left and right atria and the left and right ventricles, each provided with its own one-way outflow valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. The valves separate the chambers of the heart, and are each mounted in an annulus therebetween. The annuluses comprise dense fibrous rings attached either directly or indirectly to the atrial and ventricular muscle fibers. The leaflets are flexible collagenous structures that are attached to and extend inward from the annuluses to meet at coapting edges. The aortic, tricuspid, and pulmonary valves usually have three leaflets, while the mitral valve usually has two leaflets.

[0003] The operation of the heart, and thus the patient's health, may be seriously impaired if any of the heart valves is not functioning properly. Various problems can develop with heart valves for a number of clinical reasons. Stenosis in heart valves is a condition in which the valves do not open properly. Insufficiency is a condition which a valve does not close properly. Repair or replacement of the aortic or mitral valves are most common because they reside in the left side of the heart where pressures and stresses are the greatest. In a valve replacement operation, a replacement prosthetic valve is implanted into the native valve annulus, which may involve excision of the native valve leaflets.

[0004] In many patients who suffer from valve dysfunction, surgical or percutaneous repair (i.e., "valvuloplasty") is a desirable alternative to valve replacement. Remodeling of the valve annulus (i.e., "annuloplasty") is central to many reconstructive valvuloplasty procedures. Remodeling of the valve annulus is typically accomplished by implantation of a prosthetic ring (i.e. "annuloplasty ring") to stabilize the annulus and to correct or prevent valvular insufficiency that may result from a dysfunction of the valve annulus. Annuloplasty rings are typically constructed of a resilient core covered with a fabric sewing ring.

Annuloplasty procedures are performed not only to repair damaged or diseased annuli, but may also be performed in conjunction with other procedures, such as leaflet repair.

[0005] Heart valves may lose their ability to close properly due to dilation of an annulus around the valve or a flaccid, prolapsed leaflet. The leaflets may also have shrunk due to disease, such as rheumatic disease, thereby leaving a gap in the valve between the leaflets. The inability of the heart valve to close will cause blood to leak backwards (opposite to the normal flow of blood), commonly referred to as regurgitation. Common examples of such regurgitation include mitral valve regurgitation (i.e., leakage of blood through the mitral valve and back into the left atrium) and aortic valve regurgitation (i.e., leakage through the aortic valve back into the left ventricle). Regurgitation may seriously impair the function of the heart since more blood will have to be pumped through the regurgitating valve to maintain adequate circulation.

[0006] Heart valve regurgitation decreases the efficiency of the heart, reduces blood circulation, and adds stress to the heart. In early stages, heart valve regurgitation leaves a person fatigued and short of breath. If left unchecked, the problem can lead to congestive heart failure, arrhythmias, or death.

[0007] Mitral valve regurgitation may be caused by dysfunction of the mitral valve structure, such as may result from direct injury to the mitral valve leaflets. Such regurgitation can be caused by changes in the shape of the mitral valve annulus, damage to the posterior and/or anterior leaflets, and/or damage to the chordae tendinae. In such regurgitation, the anterior and posterior leaflets no longer coapt together properly to seal the valve, so that instead of the anterior and posterior leaflets coapting to fully close the mitral valve annulus during systole, an opening remains between the edges of the anterior and posterior leaflets.

[0008] Various methods of mitral valve repair are known in the art. Implantation of an annuloplasty ring, typically around the posterior aspect of the mitral valve, has proven successful in a number of cases. Such annuloplasty rings reshape the surrounding annulus, which can lead to proper coaptation of the native leaflets. Another repair technique for the mitral valve is known as a “bow-tie” repair, which involves suturing the anterior and posterior leaflets together in edge-to-edge fashion toward the middle of the leaflets, causing blood to flow through the two side openings thus formed. This process was originally developed by Dr. Ottavio Alfieri, and involved placing the patient on extracorporeal bypass in order to access and suture the mitral valve leaflets. Later adaptations of the bow-tie technique involved beating-heart repairs using percutaneous methods, such using a catheter to install suture or a clip to secure the opposing leaflets together.

[0009] Another approach to repairing a native valve having non-coapting leaflets, including mitral and aortic valves, involves inserting a device between the leaflets, with the device being sized and positioned to block the gap between the otherwise non-coapting leaflets. Examples of such repair devices and techniques are disclosed in U.S. Patent No. 8968395 to Hauser et al. and U.S. Patent Pub. No. 2009/0043382 for Maurer et al. These disclose devices which include an anchor deployed in the lower ventricle which secures a blocking device within the mitral valve annulus.

[0010] There is presently a need for an improved means for performing heart valve repair. The current invention fulfills this need.

SUMMARY OF THE INVENTION

[0011] The present invention provides a number of devices and methods for improving valve function. The devices and methods herein reduce or eliminate valve regurgitation without interfering with normal valve function, i.e., not impeding the natural motion of the leaflets, chordae tendinae, or papillary muscles.

[0012] It should be understood that each of the sealing elements disclosed herein can be used with any and all of the anchor elements disclosed herein, even though the specific combination of sealing element with anchor elements may not be explicitly shown in the figures herein. In other words, based on the explanation of the particular device, one of skill in the art should have little trouble combining the features of certain of two such devices. Therefore, it should be understood that many of the sealing and anchor elements are interchangeable, and the invention covers all permutations thereof. Moreover, each of the sealing elements disclosed herein may be used alone or in combination with other anchor devices, and each of the anchor elements disclosed herein can be used alone or in combination with other implant devices, such as anchor and sealing elements disclosed in U.S. Patent Application No. 16/112,388, filed August 24, 2018 and entitled "Transcatheter Device for Treating Mitral Regurgitation."

[0013] The devices of the present invention can be utilized in standard open surgical procedures, minimally-invasive procedures, or percutaneous procedures. In one embodiment the devices can be delivered through an open chest, e.g., transapically or transatrially. In another embodiment, the devices can be introduced through an incision performed over the roof of the left atrium. In yet another embodiment the devices can be delivered into the left ventricle through the right chest via a thorascope, which may be performed transapically.

The devices can also be delivered percutaneously, such as via a catheter or catheters into the patient's arterial system (e.g. through the femoral or brachial arteries).

[0014] Advantages of the device include a low delivery profile, which is conducive to minimally-invasive and percutaneous delivery methods. The device is configured to interact properly with the native leaflets, ventricle, atrial, and subvalvular apparatus. The device preserves rather than obstructs the mobility and dynamic motion of the native leaflets (except as necessary for proper coaptation). The native leaflets and chordae tendinae are preserved, and continue to operate (including opposing the systolic closing pressure). The subvalvular process and left ventricle coordination are thus preserved. The device may be configured so that it does not expand the native mitral valve leaflets or annulus outward, so that left ventricular outflow tract (LVOT) impingement/obstruction should not be a concern. The shape and low profile of the sealing element minimizes flow resistance during diastole, and there are no areas of stasis created by the device. A single device can be applicable to a wide range of valve sizes.

[0015] The device may be applicable to numerous mitral valve regurgitation conditions, including those caused by leaflet prolapse with varying amounts of annular dilatation (type I), focal leaflet prolapse (type II), and leaflet tethering (type IIIb).

[0016] Embodiments of the present disclosure provide devices and methods for improving the function of a defective heart valve, such as a mitral valve. The devices and methods disclosed herein are desirably delivered into a subject's heart using percutaneous or minimally invasive surgical methods. Accordingly, desirable delivery methods described herein may not require extracorporeal circulation (e.g., blood from a subject's circulation being routed outside the body to have a process applied to and then, returned of the subject's circulation). For example, in one embodiment, a delivery catheter (or similar delivery device) is inserted through an incision in the chest wall and then through the cardiac tissue (e.g., through the apex of the heart) into a chamber of the patient's beating heart. The delivery catheter can allow a prosthetic device to be delivered into the heart in a collapsed configuration and then expanded within the heart for treating a defective heart valve. Because delivery methods may not require extracorporeal circulation, complications can be greatly reduced as compared with traditional open-heart surgery.

[0016a] An aspect of the invention provides a device for treating a mitral valve. The device comprises a prosthetic sealing element and an anchoring element. The prosthetic sealing element has an axisymmetrical or elliptical top cross-sectional profile, the sealing element dimensioned to be deployed in an annulus of a native mitral valve of a heart at a position

between native mitral valve leaflets to contact the native mitral valve leaflets during ventricular systole to create a seal to prevent regurgitation of blood from the left ventricle to the left atrium, wherein the sealing element comprises a delivery configuration wherein the sealing element is generally elongated and radially collapsed, and further comprising a deployed configuration wherein the sealing element is shortened and radially expanded into an axisymmetrical or elliptical top cross-sectional profile and further dimensioned to permit the native mitral valve leaflets to open and close as the heart beats. The anchoring element is adapted for deployment in the heart, the anchoring element coupled to the sealing element and configured to support the sealing element at the desired position between native valve leaflets, wherein the anchoring element is dimensioned to position the sealing element between, wherein the sealing element is configured to be selectively rotated about an axis with respect to the anchoring element, and the prosthetic device comprises a lock configured to selectively lock the sealing element at a selected rotational point with respect to the anchoring element.

[0016b] Another aspect of the invention provides a system for treating a mitral valve. The system comprises a delivery catheter and a prosthetic device. The prosthetic device comprises an anchor member configured to engage heart tissue adjacent a native heart valve, wherein the anchor member is collapsible and expandable, wherein the anchor member configured so that when expanded in the absence of radially compressive forces the anchor member is axisymmetrical in top profile and a prosthetic sealing member that is collapsible and expandable and in an expanded configuration comprises an axisymmetrical or elliptical top profile, wherein the anchor member is configured to expand from a lengthened and radially compressed configuration to a shortened and radially expanded configuration, the sealing member in the expanded state adapted for plugging a gap between leaflets of the heart valve and reducing regurgitation, wherein the sealing member in the expanded state is adapted to engage native valve leaflets during systole while permitting the native valve leaflets to open and close as the heart beats. The anchor member and the prosthetic sealing member are configured to be positioned in a collapsed state within the delivery catheter. The anchor member is coupled to the prosthetic sealing member and configured to support the sealing member at a position between native valve leaflets. The sealing member is configured to be selectively rotated about an axis with respect to the anchor member, and the prosthetic device comprises a lock configured to selectively lock the sealing member at a selected rotational point with respect to the anchor member.

[0016c] There is also disclosed a sealing element

configured for anchoring between native valve leaflets to improve valve function. The sealing element comprises a mesh support frame comprising a delivery configuration and an expanded configuration, wherein in the delivery configuration the mesh support frame is substantially tubular with a delivery diameter, and wherein in the expanded configuration the mesh support frame is radially expanded to an expanded central diameter at a center portion thereof while end portions of the mesh support frame remain in the delivery diameter, wherein the expanded diameter is at least twice the delivery diameter and a covering over the mesh support frame, wherein the covering prevents passage of blood therethrough.

[0017] An embodiment of the invention for treating a mitral valve is a device that includes an expandable prosthetic sealing member having an axisymmetrical top profile (or an elongated or elliptical top profile) when expanded, the sealing member shaped when expanded for contacting the leaflets of the mitral valve. The device also includes an anchoring member

coupled to the sealing member and configured to secure the sealing member at a desired position between the mitral valve leaflets. The anchor member may have an axisymmetrical top profile. The sealing member and anchoring member may be radially collapsible and radially expandable, which may permit the device to be delivered and deployed via a catheter.

[0018] Various anchoring elements are within the scope of the invention. Many of the anchoring elements may be axisymmetric, which is to say symmetrical about an axis running from a lower (e.g., ventricular) end to an upper (e.g., atrial) end. In one embodiment, an anchor element may have an upper portion configured to extend around a mitral valve annulus and contact atrial tissue adjacent the mitral valve annulus, a lower portion configured to extend around native valve leaflets and engage ventricular tissue adjacent the mitral valve annulus without interfering with the movement of the mitral valve leaflets, and a central portion configured to support the sealing member. The anchor element upper portion may have an upper portion may have a plurality of radially-extending arms to engage heart tissue such as atrial tissue adjacent a mitral valve. The lower portion may have a plurality of radially-extending arms to engage heart tissue such as ventricular tissue adjacent a mitral valve, and may be dimensioned such when the lower portion is deployed the native valve leaflets can open and close as the heart beats with limited or no interference from the lower portion. In one embodiment of the device, the native valve leaflets are unrestricted in their opening and closing by any and all portions of the device except for the sealing element, which engages the native valve leaflets during systole to form a seal between the native leaflets and thereby prevent mitral valve regurgitation.

[0019] An anchoring member according to the invention may be configured so that the anchoring member does not expand the native mitral valve annulus, because such annulus expansion might otherwise cause reduction in valve efficiency. For example, the anchoring member may be configured so it does not subject the native mitral valve annulus to radially-expansive forces. The anchoring member may be configured so that the lower anchor portion presses upward against the native valve annulus while the upper anchor portion presses downward against the native valve annulus, so that tissue of the native valve annulus is held between the lower anchor portion and the upper anchor portion but the annulus is not subjected to radially-expansive forces from the anchoring member. Such embodiments may even prevent further annulus expansion by securing the annulus between the opposing anchor portions.

[0020] An anchoring member according to the invention may be self-expandable, such as via construction of a memory material such as nitinol. The anchoring member may alternatively be formed of other materials, such as stainless steel or cobalt chromium.

[0021] Another anchor element according to the invention is configured for deployment in a single heart chamber such as the atrium, with only the sealing element extending out of the chamber and into the heart valve and annulus. For example, an anchor element may have a plurality of upper arms configured to engage the upper portion of the heart chamber, and a plurality of lower arms configured to engage the lower portion of that same heart chamber. The upper or lower arms, or other structure of the anchor element, may have curves configured to act as shock absorbers to permit the anchor element to flex responsive to movements of the heart chamber as the heart beats.

[0022] A sealing element according to the invention is configured to be introduced in a radially collapsed but lengthened configuration, and then be shortened and radially expanded to a desired shape for improving valve function. The sealing element may be axisymmetric or elongated (e.g., elliptical) in top profile, and may dimensioned to be deployed in an annulus of a native valve (e.g., mitral valve) of a heart at a position between native valve leaflets to contact the native valve leaflets during ventricular systole to create a seal to prevent regurgitation of blood from the ventricle to the atrium, while permitting the native valve leaflets to open and close as the heart beats. The sealing element may have an upper end, a lower end, an anterior surface, and a posterior surface. The anterior surface may be configured to coapt with a mitral valve anterior leaflet, and the posterior surface may configured to coapt with a mitral valve posterior leaflet. The sealing element may have a mesh support frame with a delivery configuration where the mesh support frame is substantially tubular with a delivery diameter, and an expanded configuration where the mesh support frame is radially expanded with an expanded central diameter at a center portion thereof while end portions of the mesh support frame remain in the delivery diameter. The expanded central diameter may be at least twice the delivery diameter, at least three times the delivery diameter, at least four times the delivery diameter, at least five times the delivery diameter, etc. A covering may cover the mesh support frame to prevent the passage of blood therethrough. The sealing element in the expanded configuration may comprise an axisymmetrical, elongated, or elliptical top profile.

[0023] A sealing element outer covering may preferably wrap around the exterior and/or interior of the central anchor portion or any other support structure for the sealing element, so that the wireform elements of the central anchor portion or other support frame are covered

and/or encapsulated by the sealing element in order to prevent the native valve leaflets from contacting any frame elements of the central anchor portion.

[0024] A system for treating a mitral valve according to an embodiment of the invention may have a delivery catheter, an anchor member, and a prosthetic sealing member. The anchoring member may be self-expanding and/or axisymmetric, and may have a plurality of radially-extendable arms for engaging heart tissue. The sealing member may be adapted for plugging a gap between the leaflets of the mitral valve and reducing regurgitation. The prosthetic sealing member may have a collapsed state and an expanded state, where in the collapsed state the sealing member is longer and thinner than in the expanded state. The sealing member may have an outer surface formed with biological tissue. The elongated cross-sectional profile of the sealing member may be solid such that blood is forced to flow around the sealing member.

[0025] A method according to the invention for improving the function of a heart valve may involve advancing a distal end of a delivery catheter to a position at a mitral or other heart valve of a patient, wherein within the distal end is a prosthetic device having an anchor member and a sealing member. The sealing member may be configured to expand into a configuration to reduce regurgitation through the mitral valve. The anchor member may have an upper portion configured to expand into engagement with atrial tissue, a central portion configured to expand to support the sealing member, and a lower portion configured to expand into engagement with ventricular tissue. The anchor member may have an upper portion to engage the upper portion of the heart chamber, and a lower portion configured to engage the lower portion of that same heart chamber. The anchor member may be self-expandable, and/or formed of memory material, and may be mounted in a compressed state within a distal end of the delivery catheter. The method may further include releasing the anchor member upper portion from the catheter at a position such that the anchor member upper portion engages desired heart tissue, releasing the sealing member from the catheter, and releasing the anchor member lower portion from the catheter at a position such that the anchor member lower portion engages desired heart tissue. This deployment procedure could be performed in different orders, such as releasing the anchor member lower portion first, then the sealing member, and then the upper portion; or releasing the sealing member before or after the release of the lower and upper anchor portions. After deployment of the anchor member portions and the sealing member, the sealing member should be positioned between leaflets of the mitral valve such that during systole the leaflets coapt against the sealing member. The length and width of the sealing member may be adjusted after initial

deployment by a user to improve heart valve function. The device may be delivered and deployed using various delivery techniques, such as percutaneously or transapically to the mitral or other heart valve.

[0026] Methods of the invention may include advancing a distal end of a delivery catheter to a position at a heart valve (e.g., mitral valve) in a heart of a patient, wherein within the distal end is a prosthetic device having an anchor member and a sealing member, the sealing member being configured to expand into an axisymmetrical or elongated-and-symmetrical (e.g., elliptical) configuration to engage native mitral valve leaflets during systole while still allowing the native mitral valve leaflets to open and close as the heart beats; releasing the anchor member portion from the catheter at a position in the heart at or adjacent the native valve annulus to engage heart tissue and anchor the anchor member within the heart; releasing the sealing member from the catheter; radially expanding the sealing member, wherein the sealing member as it expands shortens in length while increasing in diameter, wherein the sealing member after expansion comprises an axisymmetrical or elongated/elliptical top profile. After release of the anchor member and the sealing member, the sealing member is positioned between leaflets of the mitral valve such that during systole the leaflets coapt against the sealing member and the leaflets can open and close as the heart beats.

[0027] The sealing member after expansion may have a circular top profile, or an elongated top profile (such as an elliptical top profile). The sealing member may be rotated about its central axis and with respect to the native valve annulus to a desired rotational position wherein the sealing member is aligned within the valve annulus with native valve features to improve valve leaflet coaptation against the sealing member. This rotation may be selectively performed by a user, and the user may also lock the sealing member at the desired rotational position. For an elongated sealing element, rotating the sealing member about its central axis may involve aligning a major axis of the sealing member to be substantially parallel (within 10 degrees) of a line between commissures of a mitral valve.

[0028] Deployment of the device may be performed responsive to feedback of valve performance monitoring and/or visualization techniques. For example, while expanding or rotating the sealing element, a user may monitor valve performance and set the final expansion configuration and/or rotational position of the sealing element in a configuration where valve performance is maximized based on the valve performance and/or visualization feedback.

[0029] The anchor member may comprise an upper portion and a lower portion. A central portion may be included, and configured to support the sealing member. In one embodiment, the upper portion is configured to expand into engagement with atrial tissue, and the lower portion is configured to expand into engagement with ventricular tissue. Methods for deploying it may include releasing the upper portion into engagement with atrial tissue, releasing the lower portion into engagement with ventricular tissue. In one embodiment, the upper portion is configured to expand into engagement with upper atrial tissue, and the lower portion is configured to expand into engagement with lower atrial tissue adjacent the native valve annulus. Methods for deploying it may include releasing the upper portion into engagement with upper atrial tissue, and releasing the lower portion into engagement with lower atrial tissue. Releasing the anchor member upper portion from the catheter may occur prior to, simultaneously with, or after releasing the anchor member lower portion from the catheter.

[0030] The device may be delivered using various approaches, including percutaneously or transapically through the subject's vasculature.

[0031] Other objects, features, and advantages of the present invention will become apparent from a consideration of the following detailed description.

Brief Description of the Drawings

[0032] FIG. 1 is a cross-sectional view of a heart;

[0033] FIGS. 2A-2D depict side cross-sectional views of a heart with a repair device deployed therein according to an embodiment of the invention;

[0034] FIGS. 3A-3D depict side views of a sealing element in various stages of expansion according to an embodiment of the invention;

[0035] FIGS. 3E-3H depict top views of the sealing element in the various stages of expansion depicted in FIGS. 3A-3D;

[0036] FIGS. 4A-4B depict side and perspective views, respectively, of a slotted-tube sealing element frame in compressed and expanded configurations, respectively, according to an embodiment of the invention;

[0037] FIGS. 5A-5C depict side views of a braided mesh sealing element in various stages of expansion according to an embodiment of the invention;

[0038] FIGS. 6A-6D depict top views of a sealing element in various stages of expansion according to an embodiment of the invention;

[0039] FIGS. 7A-7C depict perspective views of various mechanisms for controlling the expansion of sealing elements according to embodiments of the invention;

[0040] FIG. 8A depicts a perspective view of a device according to an embodiment of the invention;

[0041] FIGS. 8B-8C depict top and bottom views, respectively, of an anchor according to an embodiment of the invention;

[0042] FIGS. 8D-8G depict side views of heart chambers with the device of FIG. 8A at various stages of deployment therein according to an embodiment of the invention;

[0043] FIG. 9A depicts a side view of a device according to an embodiment of the invention;

[0044] FIGS. 9B-9C depict top and bottom views, respectively, of a frame according to an embodiment of the invention;

[0045] FIGS. 9D-9G depict side views of heart chambers with the device of FIG. 9A at various stages of deployment therein according to an embodiment of the invention;

[0046] FIG. 10A depicts a side view of a device according to an embodiment of the invention;

[0047] FIGS. 10B-10E depict side views of heart chambers with the device of FIG. 10 at various stages of deployment therein according to an embodiment of the invention;

[0048] FIGS. 11A-11C depict perspective views of an anchor frame at with various portions expanded according to an embodiment of the invention; and

[0049] FIG. 11D depicts a device having the anchor element of FIGS. 11A-11C in an expanded configuration according to an embodiment of the invention.

Detailed Description of Several Embodiments

[0050] A cross-sectional view of a human heart 10 is depicted in FIG. 1. The heart 10 has a muscular heart wall 11, an apex 19, and four chambers: right atrium 12; right ventricle 14; left atrium 16; and left ventricle 18. Blood flow is controlled by four main valves: tricuspid valve 20; pulmonary valve 22; mitral valve 24; and aortic valve 26. Blood flows through the superior vena cava 28 and the inferior vena cava 30 into the right atrium 12 of the heart 10. The right atrium 12 pumps blood through the tricuspid valve 20 (in an open configuration) and into the right ventricle 14. The right ventricle 14 then pumps blood out through the pulmonary valve 22 and into the pulmonary artery 32 (which branches into arteries leading to the lungs), with the tricuspid valve 20 closed to prevent blood from flowing from the right ventricle 14 back into the right atrium. Free edges of leaflets of the tricuspid valve 20 are

connected via the right ventricular chordae tendinae 34 to the right ventricular papillary muscles 36 in the right ventricle 14 for controlling the movements of the tricuspid valve 20.

[0051] After leaving the lungs, the oxygenated blood flows through the pulmonary veins 38 and enters the left atrium 16 of the heart 10. The mitral valve 24 controls blood flow between the left atrium 16 and the left ventricle 18. The mitral valve 24 is closed during ventricular systole when blood is ejected from the left ventricle 18 into the aorta 40. Thereafter, the mitral valve 24 is opened to refill the left ventricle 18 with blood from the left atrium 16. Free edges of leaflets 42a, 42p of the mitral valve 24 are connected via the left ventricular chordae tendinae 44 to the left ventricular papillary muscles 46 in the left ventricle 18 for controlling the mitral valve 30. Blood from the left ventricle 18 is pumped through the aortic valve 26 into the aorta 40, which branches into arteries leading to all parts of the body except the lungs. The aortic valve 26 includes three leaflets 48 which open and close to control the flow of blood into the aorta 40 from the left ventricle 18 of the heart as it beats.

[0052] FIGS. 2A-2D depict a device 50 deployed in a native mitral valve 24 and mitral valve annulus 25 according to an embodiment of the invention. The device 50 has a support anchor 52 and a sealing element 54. The support anchor 52 may be configured to permit free movement of the native valve leaflets 42a, 42p. In FIG. 2A, the native mitral valve 24 is in early diastole, with the native leaflets 42a, 42p starting to open and permit blood to flow from the left atrium 16 to fill the left ventricle 18. In full diastole as depicted in FIG. 2B, the mitral valve leaflets 42a, 42p are fully open. In early systole as depicted in FIG. 2C, initial backward flow into the left atrium 16 pushes the mitral valve leaflets 42a, 42p back (upwards) and into engagement with each other and with the sealing element 54. In full systole as depicted in FIG. 2D, the native mitral valve leaflets 42a, 42p wrap tightly against the sealing element 54 under peak systolic pressure, effectively eliminating any regurgitation flow.

[0053] A sealing element 60 according to an embodiment of the invention is depicted in FIGS. 3A-3D and 3E-3H. The sealing element 60 has a fully compressed state, depicted in FIGS. 3A and 3E, which may be useful for delivery via a catheter and where the sealing element 60 may be substantially tubular and have an initial/delivery length 62a and an initial/delivery maximum diameter 64a. The sealing element 60 can be expanded by shortening the length 62b, 62c, thus forcing the sealing element maximum diameter 64a, 64b, to increase, as depicted in FIGS. 3B-3C and 3F-3G. The sealing element 60 can reach its deployed length 62d and deployed maximum diameter 64d, depicted in FIGS. 3D and 3H. A sealing element 60 according to the invention may have an initial/delivery length 62a of

between 15-60 mm; 40-50 mm; 30-55 mm; etc. The sealing element 60 may have an initial/delivery maximum diameter 64a of between 0-10 mm; 5-8 mm; 6 mm; etc. The sealing element 60 according to the invention may have a deployed length 62a of between 20-45 mm; 25-35 mm; around 30 mm; etc., and a deployed maximum diameter 64a of between 5-40 mm; 10-30 mm; 15-25 mm; etc. The ratio of height/length to diameter may vary, depending on the particular application. Example ranges for height/length to diameter ratios are: 10:1, or 5:1, or 3:1, and ranges therebetween, during delivery; and 1:4, or 1:2, or 1:1, or 2:1, and ranges therebetween, at deployment. Note that each of these ratios and ranges for a particular sealing element dimension (e.g., delivery diameter, deployed diameter, delivery height/length, deployed height/length, etc.) may be combined with any and all of the other sealing element dimensions in accordance with the invention.

[0054] A sealing element and/or anchor element according to the invention may include radiopaque or other visualization markers to enhance user visualization of the device. For example, in the embodiment of FIGS. 3A-3F, radiopaque or other visualization markers 63, 65, are included. Markers 63 are positioned toward the ends of the sealing element, and can be used to visualize the height/length of the sealing element. Perimeter markers 65 are positioned toward the perimeter of the sealing element toward its widest point, and can be used to visualize the diameter of the sealing element. All markers can also be used to monitor the position of the sealing element.

[0055] The sealing element 60 may have an expansion control element 66, the length of which can be adjusted to thereby control the overall length and thereby the expansion of the sealing element. The sealing element 60 may preferably have a sealing surface (not shown), which may be in the form of an outer covering that prevents the passage of blood therethrough. The sealing surface may be supported by an expandable support frame (not shown). Note that in the embodiment depicted in FIGS. 3A-3D, the expansion control element 66 corresponds to the central axis of the sealing element 60, about which the sealing element 60 may be axisymmetric during deployment and after expansion.

[0056] An expandable support frame 70 in a so-called “slotted tube” configuration according to an embodiment of the invention is depicted in FIGS. 4A and 4B. As shown in FIG. 4A, in its compressed/delivery configuration the support frame 70 comprises a substantially cylindrical body 72, and a delivery length 74a and delivery maximum diameter 76a. The support frame 70 construction, with slits 78 between rib-like elements 80, permits the support frame 70 to be radially expanded, with the rib-like elements 80 bending outward, with the support frame 70 reaching a deployed length 74b and deployed maximum diameter 76b as

depicted in FIG. 4B. Note that the deployed length 74b is less than the delivery length 74a, while the deployed maximum diameter 76b is greater than the delivery maximum diameter 76a. The delivery configuration is conducive to delivery via a catheter into a human heart. The addition of a sealing surface (not shown), such as in the form of an outer covering, to the support frame 70 will create a sealing element according to an embodiment of the invention. Expansion of the support frame 70 may be accomplished via mechanisms such as tethers, ratchets, etc., and/or may involve constructing the support frame 70 from shape-memory materials such as nitinol.

[0057] A support frame 90 according to an embodiment of the invention may include a braided mesh sleeve, depicted in FIGS. 5A-5C, where strands 92 (such as wires or other strand-like elements) are braided or otherwise formed into a mesh structure defining a generally tubular structure 94. The mesh structure may cause the frame 90 to radially expand when its length is compressed, and to radially reduce when its length is reduced (in similar fashion to contractible finger traps used as children's toys). The support frame 90 has a distal end 96 and proximal end 98, with a length 100a, 100b, 100c and maximum diameter 102a, 102b, 102c. The diameters 104, 106 of the distal end 96 and proximal end 98 may be generally fixed, so that this portion of the support frame 90 is prevented from appreciably radially expanding even as the maximum diameter expands. As the support frame 90 is reduced in length from its delivery length 100a to its deployed length 100c, the support frame 90 increases in maximum diameter from its delivery maximum diameter 102a to its deployed maximum diameter 102c. Note that, depending on how the support frame is formed (e.g., how the strands 92 are braided, the materials used, etc.), the central portion 108 of the support frame 90 may retain a substantially tubular shape even as the central portion 108 and support frame 90 are radially expanded. In other embodiments, the support frame 90 may form a more spherical shape, of even shapes having varying radial dimensions around a circumference of the frame 90. The addition of a sealing surface (not shown), such as in the form of an outer covering, to the support frame 90 will create a sealing element according to an embodiment of the invention. Expansion of the support frame 90 may be accomplished via mechanisms such as tethers, ratchets, etc., and/or may involve constructing the support frame 00 from shape-memory materials such as nitinol.

[0058] Support frames and sealing elements according to the invention may be configured to form non-circular profiles when viewed from the top. For example, in the embodiment of FIGS. 6A-6D, a sealing element 110 which may have side profiles during delivery and expansion similar to that depicted in FIGS. 3A-3D, but instead of having the circular top

profiles as depicted in FIGS. 3E-3H instead forms an elongated/elliptical top profile when deployed, where a major diameter 112d is much larger than the minor diameter 114d when the sealing element 110 is fully expanded as depicted in FIG. 6D. Such a non-circular/elliptical sealing element may include radiopaque or other visualization markers 115, 117, e.g., positioned toward the sealing element perimeter and along/adjacent the major axis 115 and/or minor axis 117, via which a user can visualize not just the dimensions (major diameter and/or minor diameter) but also the rotational orientation of the sealing element about its central axis and with respect to the anchor element and/or native valve. During delivery, the maximum diameter may be between 0-10 mm; 5-8 mm; 6-7 mm; etc. The expanded minor diameter 114d may be between 5-20 mm; 10-15 mm; etc., and the expanded major diameter 112d may be between 10-40 mm; 15-40 mm; 20-30 mm; etc.

[0059] Expansion of sealing elements may be controlled via the use of various mechanisms. For example, as depicted in FIG. 7A, an internal tethering mechanism 120 may comprise a tether line 122 with a first end 124 that may be secured to an end of a support frame (not shown) and a second end 126 that may passed through an opposing end of the support frame. By pulling on the second end 126 and thereby shortening the length of the internal tether that lies within the support frame, the support frame is reduced in length and radially expanded. The internal tethering mechanism may include a lock, such as a knot, one-way lock, or other locking mechanism (not shown), at the opposing end of the support frame for securing the internal tether at the desired length that corresponds to the desired shape (i.e., maximum diameter/length) of the deployed sealing element. Such a tether may be used with any and all sealing elements and support frames of the invention, and may be particularly useful for sealing elements having self-expanding support frames where the tether acts to restrain and control expansion of the support frame.

[0060] Expansion of a sealing element according to the invention may be controlled by a generally rigid rod 130 that resists both tension and compression, as depicted in FIG. 7B. A first end 132 of the rod 130 may be secured to a first end of a support frame (not shown), with the rod 130 passing through a locking mechanism 134 at a second end of the support frame with the second end 134 of the rod 130 on the far side of the locking mechanism from the first end 132. The rod 130 may include tooth-like elements 136 that are selectively engaged by the locking mechanism 134. For example, the locking mechanism 134 may permit the tooth-like elements to pass outwardly through the locking mechanism (as may be desired to shorten the rod 130 and thereby shorten and radially expand a support frame), but prevent the tooth-like elements from passing inwardly through the locking mechanism.

[0061] Another option for controlling expansion of sealing element is a linear screw mechanism 140, where an elongated screw 142 has a first end 144 secured to a first end of a support frame (not shown). A screw-receiving nut 146 is secured via extenders 148 to a second end of the support frame. Either the screw-receiving nut 146 or the screw first end 144 is rotatably secured to the support frame, permitting rotation of the screw with respect to the screw-receiving nut which thereby advances/retracts the screw 142 through the screw-receiving nut 146 and thereby adjusts the length of the linear screw mechanism and the length/expansion of the support frame.

[0062] FIG. 8A depicts a perspective view of a device 150 that is configured for deployment with portions secured in the atrium, ventricle, and valve annulus of a patient. An anchor element 152 anchors and supports a sealing element 154. The anchor element 152 has an atrial portion 156 with atrial arms 158 terminating in atrial arm distal ends 160, with the atrial arms 158 sized and shaped to extend across the lower portion of the atrium and engage the valvular annulus from the atrial side. A ventricular portion 162 has ventricular arms 164 terminating in ventricular arm distal ends 166. The ventricular arms 164 may be sized and shaped to extend around the "swing" area through which the native valve leaflets swing as the heart beats, so as not to engage against the native valve leaflets as the valve leaflets open and shut. The ventricular arms 164 curve around the leaflets swing area and then curve back upward to engage the valvular annulus from the ventricular side. Note that the anchor element 152 depicted when expanded in air or otherwise expanded in the absence of compressive forces (such as compressive forces that might be present when deployed in a heart) is axisymmetrical when viewed directly from above or below, as seen in FIGS. 8B-8C, so that during deployment the surgeon or other user does not have to worry about whether the anchor element 152 of the device 150 is rotated around its central axis to a proper deployment position with respect to the native valve and valve annulus. In the particular embodiment depicted, the expanded diameter 161 of the upper anchor element 156 is slightly larger than the expanded diameter 167 of the lower anchor element 162, although the invention is not limited to this configuration. The lower anchor expanded diameter 167 may be between 25 and 60 mm, and the upper anchor expanded diameter 161 may be between 30 and 70 mm. Note that when expanded in an actual heart, the individual arms 158, 164 of the upper and lower anchor elements 156, 162 will be compressed or otherwise distorted by their interaction with the heart tissue, so that each arm may be contorted by the heart tissue into a shape slightly different from the shapes of other arms.

[0063] The anchor element 152 of FIG. 8A includes a central portion 168 which passes through the sealing element 154. The central portion 168 may be configured to act as a support frame for the sealing element, and/or may be configured to be shortened (e.g., by incorporating shortening mechanisms such as those in FIGS. 7A-7C) in order to effectuate shortening and thereby expansion of the sealing element 154. In the particular embodiment depicted, the sealing element central portion 168 surrounds an axis of the sealing element 154 and of the anchor element 152. Note that the sealing element 154 in top profile (i.e., about its central axis) may be axisymmetric (e.g., circular) as in FIGS. 3E-H, or may be non-circular (e.g., elliptical) as in FIGS. 6A-6D. The sealing element 154, especially if it is non-circular/elliptical in top profile, may be configured for axial rotation (selective or responsive to body operation such as blood flow/valve operation) with respect to the anchor element 152, and a lock may be provided that can be activated to prevent further rotation of the sealing element 154 with respect to the anchor element 152. With such rotation, the surgeon or other user could deploy the axisymmetric anchor element and confirm the anchor element's proper deployment (via direct or indirect viewing, e.g., radioscopy), and then rotate the sealing element to the desired rotational position, and then lock the sealing element at that desired position.

[0064] FIGS. 8D-8G depict side views of left atrium 16, left ventricle 18, mitral valve 24, and mitral valve annulus 25, with the device 150 at various stages of deployment therein according to an embodiment of the invention. The device 150 is secured within a distal end 170 of a delivery catheter 172, and the distal end 170 is advanced percutaneously or minimally-invasively into the mitral valve 24 of the patient via the left atrium 16 of the heart 10, as in FIG. 8D. In Fig. 8E, the ventricular anchor portion 166 is released from the catheter 172 and expanded into contact with heart tissue below the mitral valve 24. In FIG. 8F the sealing element 154 and central anchor portion 168 are positioned between the leaflets 42a, 42p of the mitral valve 24. At this point the sealing element 154 may be expanded, or expansion may not occur until after deployment of the atrial anchor portion 156. Although in FIG. 8F the sealing element is depicted as expanded, note that expansion thereof may occur after deployment of the atrial anchor portion. In FIG. 8G, atrial anchor portion 156 is expanded into contact with heart tissue above the mitral valve 24 as the device 150 is fully released from the catheter 172.

[0065] With the position and function of the device 150 confirmed (such as via radioscopy and/or other methods of remote viewing), the catheter 172 is then withdrawn from the patient.

Although a percutaneous delivery via the atrial side is depicted, note that other deployment approaches are also within the scope of the invention, including transapical approaches.

[0066] FIG. 9A depicts a device 180 that is configured for deployment with anchor portions secured entirely in the atrium of a patient. An anchor element 182 anchors and supports a sealing element 184. The anchor element 182 has an upper atrial portion 186 with upper atrial arms 188 terminating in upper atrial arm distal ends 190. The upper atrial arms 188 are sized and configured to curve upward through the center of the atrium and outward to engage an upper surface of the atrium. The upper atrial arms 188 may include intermediate curves 189 that can act as shock absorbers, flexing and bending to permit the anchor element 182 to be compressed responsive to atrial shape changes as the heart beats. A lower atrial portion 192 has lower atrial arms 194 terminating in lower atrial arm distal ends 196. The lower atrial arms 194 may be sized and shaped to extend outward and across the lower portion of the atrium and engage the valvular annulus from the atrial side. Note that the anchor element 182 depicted may be axisymmetric when expanded in the absence of compressive or other distorting forces, so that during deployment the surgeon or other user does not have to worry about whether the anchor element 182 of the device 180 is rotated around its central axis to a proper deployment position with respect to the native valve and valve annulus. For example, when expanded without compressive/distorting forces (e.g., expanded in air), the anchor element 182 is symmetrical when viewed from above or below, as depicted in FIGS. 9B-9C. In the particular embodiment depicted, the expanded diameter 191 of the upper anchor element 186 is generally equal to the expanded diameter 197 of the lower anchor element 192, although other diameters are also within the scope of the invention. The upper anchor expanded diameter 191 and lower anchor expanded diameter may be in the range between 30 and 70 mm. Note that when expanded in an actual heart, the individual arms 188, 194 of the upper and lower anchor elements 186, 192 will be compressed or otherwise distorted by their interaction with the heart tissue, so that each arm may be contorted by the heart tissue into a shape slightly different from the shapes of other arms.

[0067] The anchor element 182 of FIG. 9A includes a sealing element support portion 200 which passes below the atrial portions 186, 192 and through the sealing element 184, and is configured to hold the sealing element 184 at a desired position within the native valve annulus after the other anchor portions 186, 192 have been deployed in the desired heart chamber, such as the left atrium 16 depicted. In the particular embodiment depicted, the sealing element support portion 200 corresponds to an axis of the sealing element 184 and an axis of the anchor element 182. The sealing element support portion 200 may be configured

to act as a support frame for the sealing element 184, and/or may be configured to be shortened (e.g., by incorporating shortening mechanisms such as those in FIGS. 7A-7C) in order to effectuate shortening and thereby expansion of the sealing element 184. Note that the sealing element 184 in top profile (i.e., about its central axis) may be axisymmetric (e.g., circular) as in FIGS. 3E-H, or may be non-circular (e.g., elliptical) as in FIGS. 6A-6D. The sealing element 184, especially if it is non-circular/elliptical in top profile, may be configured for axial rotation (selective or responsive to body operation such as blood flow/valve operation) with respect to the anchor element 182, and a lock may be provided that can be activated to prevent further rotation of the sealing element 184 with respect to the anchor element 182. With such rotation, the surgeon or other user could deploy the axisymmetric anchor element and confirm the anchor element's proper deployment (via direct or indirect viewing, e.g., radioscopy), and then rotate the sealing element to the desired rotational position, and then lock the sealing element at that desired position.

[0068] As depicted in FIGS. 9D-9G, the device 180 may be deployed via a transapical approach into the heart 10. The device 180 is secured within a distal end 204 of a delivery catheter 202, and the catheter distal end 204 is advanced via an opening 206 in the heart wall 11 (e.g., via an opening in a wall of the left ventricle 18, such as a transapical opening at the apex) and into the mitral valve 24 of the patient. In FIG. 9E, the upper atrial anchor portion 186 is expanded into contact with heart tissue toward the upper area of the left atrium 16 as the device 180 begins to be released from the catheter 202. In FIG. 9F the lower atrial anchor portion 192 is released from the delivery catheter 202 and expanded into contact with the lower portion of the atrium 16. FIG. 9G depicts the sealing element 184 and sealing element support portion 200 positioned between the leaflets of the mitral valve 24, and the sealing element 184 is expanded therebetween. The device 180 is fully released from the catheter 202. With the position and function of the device 180 confirmed (such as via radioscopy and/or other methods of remote viewing), the catheter 202 may then be withdrawn from the patient and the opening 206 closed via suture 208 and/or other methods/devices for closing openings.

[0069] FIG. 10A depicts a device 210 having a sealing element 212 anchored via a tether 214 and anchor 216. The device 210 may be positioned in the distal end 218 of a delivery catheter 220 and advanced into the heart. In one embodiment, the device 210 is advanced transapically into the left ventricle 18 and to the mitral valve 24 via an opening 222 in the heart wall, where the opening 222 may be at the heart apex 19, as depicted in FIG. 10B. The sealing element 212 may be released from the catheter 216 at a position between the native

valve leaflets 42a, 42p, as depicted in FIG. 10C. FIG. 10D depicts the catheter 220 withdrawn as the tether 214 is released from the catheter distal end 218, with the tether 214 being rigid or flexible depending on the desired application. As the catheter is removed from the heart 10, the anchor 216 is deployed in the heart wall 11, as shown in FIG. 10E. The user can then adjust the length of the tether 214 before locking the tether 214 to the anchor 216 at the desired length. Note that locking of the tether 214 to the anchor at the desired tether length can be achieved by known methods, such as via sliding locking mechanisms that initially allow the tether to slide through the lock but then prevent further movement, via knots in the tether line, etc.

[0070] Note that the sealing element 212 may be selectively expanded, fully or partially, at various times during deployment, such as when initially released from the delivery catheter; after the tether is extended; after the anchor is secured; or after the tether length is finalized. The tether length can also be adjusted at various times. For example, the sealing element 212 may be partially expanded when released from the catheter, with full expansion occurring just prior to or as the tether length is finalized in order to confirm proper sealing of the valve leaflets against the sealing element via radioscopy, etc. Although a transapical delivery via the ventricle and heart apex is depicted, note that other deployment approaches are also within the scope of the invention, including percutaneous approaches via blood vessels and/or the atrium side.

[0071] An anchor frame 230 according to the invention may be formed of a memory material such as nitinol, and/or may have a central portion 232 configured to serve as a support frame for a sealing element. For example, as depicted in FIG. 11A, a frame 230 is formed as a generally tubular form of shape memory material with a central portion 232, upper portion 234, and lower portion 236, with each portion composed of slits 238a-c between rib-like elements 240a-c. The central portion 232 may be radially expanded into a desired shape by bending the rib-like elements 240b outward as depicted in FIG. 11B, and the desired shape can be set in the memory material via known methods. The upper and lower portions 234, 236 may similarly be formed to the desired shapes as in FIG. 11C, and the desired shapes set to the memory material. Note that the rib-like elements 240a-c are configured to extend out to form arms and other frame/anchor structures. The addition of a fluid-blocking covering 242 to the frame central portion 232 creates the sealing element 244. Note that the device may have a top opening 246 and/or a lower opening 248 in the sealing element portion, which permits some blood to flow into and out of the sealing element but avoids pooling of

blood within it. Alternatively, one or both of the top and bottom of the sealing element portion may be entirely closed.

[0072] Anchor frames according to the invention may be formed of various biocompatible materials, including metals and polymers. For example, memory materials such as Nitinol may be used, thereby forming an anchor frame that can be compressed onto/into a catheter for minimally-invasive/percutaneous delivery and then will expand to its "memorized" shape upon release from the catheter. Non-memory materials such as stainless steel or cobalt chromium are also within the scope of the invention. The anchor frame may include a biocompatible covering, such as of a Dacron or other fabric. The biocompatible covering may encourage tissue ingrowth to promote tissue anchoring. The biocompatible covering may alternatively resist tissue ingrowth.

[0073] Sealing elements according to the invention may be formed of various biologically compatible materials, including metals, fabrics, plastics, and tissue. Some materials that may be used for such sealing elements include materials currently used in forming leaflets of prosthetic heart valves. For example, synthetic materials (e.g., polymers such as thermoplastic elastomers or resins, including polyurethane and silicone, etc.), natural/treated tissue (e.g., valve leaflet tissue, bovine or equine pericardium, etc.), fabrics (e.g., Dacron), etc. may be used.

[0074] Sealing elements may preferably wrap around the exterior and/or interior of any anchor portions that serve to directly support or frame the sealing element, so that any wireform/rib-like elements of the support frame portion are covered and/or encapsulated by the sealing element material in order to prevent the native valve leaflets from contacting any frame elements of the sealing element support frame, etc..

[0075] During deployment of a device according to the invention, such as the deployment procedures depicted in FIGS. 8D-8G or 9D-9G or 10B-10E, the surgeon or other user may controllably expand the sealing element to a desired diameter/length, or the sealing element may be configured to self-expand to a pre-set configuration such as upon release from the delivery catheter. For example, if the sealing element comprises a memory-material (e.g., nitinol) support frame, that support frame may automatically expand to a pre-set memory material configuration (length/diameter) upon release from radial constraints such as a delivery lumen of the delivery catheter. Alternatively, the surgeon or other user may actively control the expansion of the sealing element to a specifically selected diameter/length, such as by activating length/diameter adjusting elements such as those depicted in FIGS. 7A-7C. Before, during, and/or after sealing element expansion, the surgeon/user may actively

monitor heart valve function and/or leaflet coaptation (with the sealing element) and/or sealing element position/size via various techniques, such as fluoroscopy or other visualization techniques (including the use of radiopaque markers on the sealing element). The surgeon/user may select the final diameter/length of the sealing element based on the information on heart valve function and/or leaflet coaptation. The surgeon/user may also selectively rotate the sealing element about its central axis with respect to the support anchor (before, during, or after deployment of the support anchor) in order to better position the sealing element between the native valve leaflets, such as where the sealing element has an elliptical top profile as depicted in FIGS. 6A-6D. For example, with such an elliptical profiled sealing element, the user may deploy the anchor element, then rotate the sealing element (expanded or unexpanded) with respect to the anchor element and native valve in order to position the minor diameter to extend generally perpendicular to the anterior and posterior mitral valve leaflets, and to position the major diameter to extend between the valve commissural points. Once the desired rotational position is achieved, the sealing element can be locked in that position.

[0076] If the user (e.g., surgeon or other medical staff) is not satisfied with the initial positioning of all or part of the device, the device or parts thereof may be withdrawn (completely or partially) into the catheter and then re-deployed at the desired position. For example, if after initial deployment the sealing element is positioned too high or too low with respect to the mitral valve leaflets, the device or parts thereof can be at least partially withdrawn into the catheter and then re-deployed at a position higher or lower than the previous position. Similarly, if the user is not satisfied with the deployed size of the sealing element, he/she can adjust the length/radius of the sealing element until the desired sealing/coaptation with the native leaflet is achieved. Also, for sealing elements that are non-circular/elliptical in top profile, the user can modify the rotational position of the sealing element to a desired rotational position that may optimize valve function.

[0077] Radiopaque markers or other visibility-enhancing markers may be included with the device in order to make the device and key elements thereof more clearly visible when the device is deployed or inspected using fluoroscopy or other visualization techniques. For example, enhanced visibility markers such as radiopaque markers may be secured to portions of the sealing element and/or the anchor elements, etc.

[0078] Note that FIGS. 3B-3D, 8E, 9A, and 11A-11D are computer-generated to-scale drawings where dimensions are to scale within each drawing. All dimensions listed are by way of example, and devices according to the invention may have dimensions outside those

specific values and ranges. Although in some of the drawings the sealing element material is depicted as extending between frame portions but with the frame portions uncovered, in various embodiments of the invention (including each of the embodiments of the invention depicted in the drawings) the sealing element material may preferably wrap around the exterior and/or interior of the support frame portions, so that the wireform/rib-like frame elements are covered and/or encapsulated by sealing element material in order to prevent the native valve leaflets from contacting any frame element.

[0079] Although the specific embodiments discussed above are directed toward mitral valve repair, the invention may also be applicable for use in repairing other heart valves, including the aortic, tricuspid, and pulmonary valves.

[0080] Unless otherwise noted, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. In order to facilitate review of the various embodiments of the disclosure, the following explanation of terms is provided:

[0081] The singular terms "a", "an", and "the" include plural referents unless context clearly indicates otherwise. The term "or" refers to a single element of stated alternative elements or a combination of two or more elements, unless context clearly indicates otherwise.

[0082] The term "includes" means "comprises." For example, a device that includes or comprises A and B contains A and B, but may optionally contain C or other components other than A and B. Moreover, a device that includes or comprises A or B may contain A or B or A and B, and optionally one or more other components, such as C.

[0083] The term "subject" refers to both human and other animal subjects. In certain embodiments, the subject is a human or other mammal, such as a primate, cat, dog, cow, horse, rodent, sheep, goat, or pig. In a particular example, the subject is a human patient.

[0084] Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present disclosure, suitable methods and materials are described below. In case of conflict, the present specification, including terms, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

[0085] In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only examples of the invention and should not be taken as limiting the scope of the invention. Rather, the scope of the invention is defined by the following claims. We therefore claim as our invention all that comes within the scope and spirit of these claims.

WHAT IS CLAIMED IS:

1. A device for treating a mitral valve, comprising:

a prosthetic sealing element having an axisymmetrical or elliptical top cross-sectional profile, the sealing element dimensioned to be deployed in an annulus of a native mitral valve of a heart at a position between native mitral valve leaflets to contact the native mitral valve leaflets during ventricular systole to create a seal to prevent regurgitation of blood from the left ventricle to the left atrium, wherein the sealing element comprises a delivery configuration wherein the sealing element is generally elongated and radially collapsed, and further comprising a deployed configuration wherein the sealing element is shortened and radially expanded into an axisymmetrical or elliptical top cross-sectional profile and further dimensioned to permit the native mitral valve leaflets to open and close as the heart beats; and

an anchoring element adapted for deployment in the heart, the anchoring element coupled to the sealing element and configured to support the sealing element at the desired position between native valve leaflets, wherein the anchoring element is dimensioned to position the sealing element between the native mitral valve leaflets when the anchoring element is deployed in the heart;

wherein the sealing element is configured to be selectively rotated about an axis with respect to the anchoring element, and the prosthetic device comprises a lock configured to selectively lock the sealing element at a selected rotational point with respect to the anchoring element.

2. The device of claim 1, wherein the anchoring element comprises an upper portion configured to extend into contact with heart tissue, and a lower portion configured to extend into contact with heart tissue.

3. The device of claim 2, wherein the anchoring element upper portion is configured to anchor in the heart by extending into contact with atrial tissue adjacent a mitral valve annulus, and the anchoring element lower portion is configured to anchor in the heart by extending into contact with ventricular tissue adjacent the mitral valve annulus.

4. The device of claim 2, wherein the anchoring element upper portion is configured to anchor in the heart by extending into contact with atrial tissue toward a top portion of an

atrium, and the anchoring element lower portion is configured to anchor in the heart by extending into contact with atrial tissue adjacent an annulus of the mitral valve.

5. The device of claim 1, wherein the anchor element comprises an expanded diameter between 25 and 70 mm.

6. The device of claim 1, wherein the sealing element comprises a delivery diameter of less 10 mm or less, and an expanded diameter of 10 to 35 mm.

7. The device of claim 1, wherein the sealing element when expanded is elongated, and the sealing element comprises a delivery diameter of less 10 mm or less, and an expanded major diameter of 10 to 35 mm and an expanded minor diameter of 5 to 15 mm.

8. The device of claim 1, wherein the anchoring element is axisymmetric when expanded in the absence of radially compressive forces.

9. The device of claim 1, wherein the anchoring element comprises a memory material.

10. A system for treating a heart valve, comprising:

a delivery catheter;

a prosthetic device comprising:

an anchor member configured to engage heart tissue adjacent a native heart valve, wherein the anchor member is collapsible and expandable, wherein the anchor member configured so that when expanded in the absence of radially compressive forces the anchor member is axisymmetrical in top profile; and

a prosthetic sealing member that is collapsible and expandable and in an expanded configuration comprises an axisymmetrical or elliptical top profile, wherein the sealing member is configured to expand from a lengthened and radially compressed configuration to a shortened and radially expanded configuration, the sealing member in the expanded state adapted for plugging a gap between leaflets of the heart valve and reducing regurgitation, wherein the sealing member in the expanded state is adapted to engage native

valve leaflets during systole while permitting the native valve leaflets to open and close as the heart beats;

wherein the anchor member and the prosthetic sealing member are configured to be positioned in a collapsed state within the delivery catheter;

wherein the anchor member is coupled to the prosthetic sealing member and configured to support the sealing member at a position between native valve leaflets;

wherein the sealing member is configured to be selectively rotated about an axis with respect to the anchor member, and the prosthetic device comprises a lock configured to selectively lock the sealing member at a selected rotational point with respect to the anchor member.

11. The system of claim 10, wherein the anchor member comprises an upper portion and a lower portion, wherein the upper portion is adapted to engage atrial tissue adjacent the native valve, and the lower portion is adapted to engage ventricular tissue adjacent the native valve.

12. The system of claim 10, wherein the delivery catheter comprises a distal opening, and the anchor member and the prosthetic sealing member are configured to be advanced in and out of the catheter distal opening in a collapsed state.