

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.

[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.

[0016c] Another aspect of the invention provides 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

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.

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

11. The system of claim 10, wherein the sealing member is configured to rotate about an axis with respect to the anchor member.
12. The system of claim 11, wherein the sealing member is configured to be selectively rotated 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.
13. 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.
14. 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.
15. A sealing element configured for anchoring between native valve leaflets to improve valve function, the sealing element comprising:
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.
16. The sealing element of claim 15, wherein the expanded central diameter is at least three times the delivery diameter.

17. The sealing element of claim 15, wherein the expanded central diameter is at least five times the delivery diameter.
18. The sealing element of claim 15, wherein the sealing element in the expanded configuration comprises an axisymmetrical top profile.
19. The sealing element of claim 15, wherein the sealing element in the expanded configuration comprises an elongated top profile.
20. The sealing element of claim 19, wherein the sealing element in the expanded configuration comprises an elliptical top profile.