

[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

[0020a] An aspect of the present invention provides a system for replacing a native heart valve. The system comprises an expansible helical anchor and an expansible heart valve prosthesis. The expansible helical anchor has at least three coils in an unconstrained state. A first coil of the helical anchor has a first diameter in the unconstrained state, and is expandable to a second diameter larger than the first diameter upon application of radial outward force from within the first coil. The first coil is configured such that it can encircle native leaflets of the native heart valve while a second coil does not encircle the native leaflets. The expansible heart valve prosthesis is capable of being delivered into the helical anchor and expanded inside the first coil to move the first coil from the first diameter to the second diameter while trapping at least a portion of the native leaflets between the first coil and the heart valve prosthesis. The helical anchor includes another coil movable from a larger diameter to a smaller diameter as the heart valve prosthesis is expanded inside the multiple coils and the first coil moves from the first diameter to the second diameter.

[0020b] Another aspect of the present invention provides a system for replacing a native heart valve. The system comprises a helical anchor comprising a plurality of middle region coils, an upper coil extending from an upper end of the plurality of middle region coils and a lower coil extending from a lower end of the plurality of middle region coils. In a relaxed state, at least one

of the plurality of middle coils has a first diameter and the lower coil has a second diameter that is greater than the first diameter. Upon application of an outward radial force, the first diameter expands to a third diameter. The system also comprises a radially expanding prosthetic heart valve configured to be inserted within the plurality of middle coils. The upper coil is configured to remain in the atrium, and the lower coil is configured to encircle the mitral valve leaflets and/or the chordae in the left ventricle. When the prosthetic heart valve is expanded within the plurality of middle coils, at least a portion of native leaflets of the native heart valve are trapped between the helical anchor and the prosthetic heart valve. The lower coil moves from the second diameter to a fourth diameter that is a smaller diameter than the second diameter as the heart valve prosthesis is expanded inside the multiple coils.

[0021] In one illustrative embodiment, a system for docking a heart valve prosthesis is provided and includes a helical anchor formed as multiple coils adapted to support a heart valve prosthesis with coil portions positioned above and below the heart valve annulus and a seal coupled with the helical anchor. The seal includes portions extending between adjacent coils for preventing blood leakage through the helical anchor and past the heart valve prosthesis.

[0022] The system can further include a heart valve prosthesis capable of being delivered to a native heart valve position of a patient and expanded inside the multiple coils and into engagement with leaflets of the heart valve. The seal is engaged with both the helical anchor and the heart valve prosthesis. The coils of the helical anchor may be formed of a superelastic or a shape memory material, or other suitable material. The seal may be a membrane or panel extending over at least two coils of the helical anchor. The membrane or panel is moved between an undeployed state and a deployed state, the undeployed state being adapted for delivery to a site of implantation and the deployed state being adapted for implanting the system and anchoring the heart valve prosthesis. The undeployed state may be a rolled up state on one of the coils of the helical anchor or any other collapsed state. The membrane or panel may include a support element affixed therewith, such as an internal, spring-biased wire. The seal may further include one or more seal elements carried by

What is claimed is:

1. A system for replacing a native heart valve, the system comprising:
an expansible helical anchor having at least three coils in an unconstrained state, wherein a first coil of the helical anchor has a first diameter in the unconstrained state, and is expandable to a second diameter larger than the first diameter upon application of radial outward force from within the first coil, and wherein the first coil is configured such that it can encircle native leaflets of the native heart valve while a second coil does not encircle the native leaflets; and
an expansible heart valve prosthesis capable of being delivered into the helical anchor and expanded inside the first coil to move the first coil from the first diameter to the second diameter while trapping at least a portion of the native leaflets between the first coil and the heart valve prosthesis;
wherein the helical anchor includes another coil movable from a larger diameter to a smaller diameter as the heart valve prosthesis is expanded inside the multiple coils and the first coil moves from the first diameter to the second diameter.
2. The system of claim 1, wherein at least two adjacent coils of the helical anchor are spaced apart, and the adjacent coils move toward each other as the heart valve prosthesis is expanded inside the first coil and the first coil moves from the first diameter to the second diameter.
3. The system of claim 1, wherein the helical anchor further comprises a plurality of fasteners, and the fasteners are moved from an undeployed state to a deployed state as the first coil moves from the first diameter to the second diameter.
4. The system of claim 3, further comprising a seal coupled with the helical anchor and including portions extending between adjacent coils for preventing blood leakage through the helical anchor and past the heart valve prosthesis, wherein the fasteners engage the seal in the deployed state.

5. The system of claim 1, further comprising at least one compressible element on the helical anchor, the compressible element being engaged by the heart valve prosthesis as the heart valve prosthesis is expanded inside the first coil to assist with affixing the heart valve prosthesis to the helical anchor.
6. The system of claim 5, wherein the at least one compressible element further comprises multiple compressible elements spaced along the helical anchor.
7. The system of claim 5, wherein the at least one compressible element further comprises a continuous compressible element extending along the helical anchor.
8. The system of claim 5, wherein the at least one compressible element further comprises a resilient element.
9. The system of claim 5, wherein the heart valve prosthesis further comprises an expansible structure including openings and the openings are engaged by the at least one compressible element as the heart valve prosthesis is expanded inside the first coil.
10. The system of claim 1, wherein the helical anchor includes at least two coils that cross over each other.
11. The system of claim 1, wherein the helical anchor further comprises a shape memory material.
12. The system of claim 1, further comprising a seal coupled with the helical anchor that includes portions extending between adjacent coils.
13. The system of claim 12, wherein the seal further comprises a membrane or panel extending over at least two coils of the helical anchor.
14. The system of claim 13, wherein the membrane or panel is moved between an undeployed state and a deployed state, the undeployed state being

adapted for delivery to a site of implantation and the deployed state being adapted for implanting the system and anchoring the heart valve prosthesis.

15. The system of claim 14, wherein the undeployed state comprises a rolled up state on one of the coils of the helical anchor.

16. The system of claim 14, wherein the undeployed state comprises a collapsed state.

17. The system of claim 13, wherein the membrane or panel includes a support element affixed therewith.

18. The system of claim 12, wherein the seal further comprises one or more seal elements carried by the helical anchor and including overlapping portions configured to seal a space between adjacent coils of the helical anchor.

19. The system of claim 18, wherein the one or more seal elements each include a support element affixed therewith.

20. The system of claim 18, wherein the one or more seal elements are each generally circular in cross sectional shape.

21. The system of claim 18, wherein the one or more seal elements are each oblong in cross sectional shape.

22. The system of claim 18, wherein the one or more seal elements each have a connecting portion affixed to one of the coils and an extension portion extending toward an adjacent coil.

23. A system for replacing a native heart valve, the system comprising:
a helical anchor comprising:
a plurality of middle region coils;
an upper coil extending from an upper end of the plurality of middle region coils;

a lower coil extending from a lower end of the plurality of middle region coils;

wherein, in a relaxed state, at least one of the plurality of middle coils has a first diameter and the lower coil has a second diameter that is greater than the first diameter; and

wherein, upon application of an outward radial force, the first diameter expands to a third diameter; and
a radially expanding prosthetic heart valve configured to be inserted within the plurality of middle coils;

wherein the upper coil is configured to remain in the atrium, and the lower coil is configured to encircle the mitral valve leaflets and/or the chordae in the left ventricle and wherein, when the prosthetic heart valve is expanded within the plurality of middle coils, at least a portion of native leaflets of the native heart valve are trapped between the helical anchor and the prosthetic heart valve; and

wherein the lower coil moves from the second diameter to a fourth diameter that is a smaller diameter than the second diameter as the heart valve prosthesis is expanded inside the multiple coils.

24. The system of claim 23, further comprising a seal structure over at least a portion of the plurality of coils.