

**[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, the present invention provides devices and methods that address these and other challenges in the art.

### **Summary**

**[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 a first end coil portion positioned above a heart valve annulus and a second end coil portion positioned below the heart valve annulus, wherein a middle coil portion has a diameter smaller than a diameter of the first end coil portion and a diameter of the second end coil portion 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

the helical anchor with overlapping portions configured to seal a space between adjacent coils of the helical anchor. The one or more seal elements may each include a support element such as an internal wire, which may be a spring-biased coil or other configuration, affixed therewith. The one or more seal elements may be cross sectional shape, with examples being generally circular or oblong. The one or more seal elements may each have a connecting portion affixed to one of the coils and an extension portion extending toward an adjacent coil for providing the seal function between coils.

**[0023]** In another illustrative embodiment a system for replacing a native heart valve includes an expansible helical anchor formed as multiple coils adapted to support a heart valve prosthesis. A first coil is normally being at a first diameter, and is expandable to a second, larger diameter upon application of radial outward force from within the helical anchor. A second coil is movable from a larger diameter to a smaller diameter as the first coil expands from the first diameter to the second diameter. The system further includes an expansible heart valve prosthesis capable of being delivered into the helical anchor and expanded inside the multiple coils to move the at least one coil from the first diameter to the second diameter while securing the helical anchor and the heart valve prosthesis together.

**[0024]** As a further aspect the helical anchor may include another coil that moves from a larger diameter to a smaller diameter as the heart valve prosthesis is expanded inside the multiple coils. At least two adjacent coils of the helical anchor may be spaced apart, and the adjacent coils move toward each other as the heart valve prosthesis is expanded inside the multiple coils. The helical anchor may further includes a plurality of fasteners, and the fasteners are moved from an undeployed state to a deployed state as the at least one coil moves from the first diameter to the second, larger diameter. A seal may be coupled with the helical anchor and include portions extending between adjacent coils for preventing blood leakage through the helical anchor and past the heart valve prosthesis. The system can further include 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 multiple coils to assist with affixing the heart valve prosthesis to the helical anchor. The compressible element may take any of several forms, such as fabric or other soft material, or resilient, springy material such as polymer or foam. The at least one compressible element further may

What is claimed is:

1. A system for docking a heart valve prosthesis, comprising:
  - a helical anchor formed as multiple coils adapted to support a heart valve prosthesis with a first end coil portion positioned above a heart valve annulus and a second end coil portion positioned below the heart valve annulus, wherein a middle coil portion has a diameter smaller than a diameter of the first end coil portion and a diameter of the second end coil portion; and
  - 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.
2. The system of claim 1, further comprising:
  - a heart valve prosthesis capable of being delivered to the heart valve position of a patient and expanded inside the multiple coils and into engagement with leaflets of the heart valve, the seal engaged with both the helical anchor and the heart valve prosthesis.
3. The system of claim 1, wherein the helical anchor further comprises a shape memory material.
4. The system of claim 1, wherein the seal further comprises a membrane or panel extending over at least two coils of the helical anchor.
5. The system of claim 4, 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.
6. The system of claim 5, wherein the undeployed state comprises a rolled up state on one of the coils of the helical anchor.

7. The system of claim 5, wherein the undeployed state comprises a collapsed state.

8. The system of claim 4, wherein the membrane or panel includes a support element affixed therewith.

9. The system of claim 1, 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.
10. The system of claim 9, wherein the one or more seal elements each include a support element affixed therewith.
11. The system of claim 9, wherein the one or more seal elements are each generally circular in cross sectional shape.
12. The system of claim 9, wherein the one or more seal elements are each oblong in cross sectional shape.
13. The system of claim 9, 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.
14. A system for replacing a native heart valve, the system comprising:  
an expansible helical anchor formed as multiple coils adapted to support a heart valve prosthesis, a first coil being normally at a first diameter, and being expandable to a second, larger diameter upon application of radial outward force from within the helical anchor, and a second coil movable from a larger diameter to a smaller diameter as the first coil expands from the first diameter to the second diameter; and  
an expansible heart valve prosthesis capable of being delivered into the helical anchor and expanded inside the multiple coils to move the at least one coil from the first diameter to the second diameter while securing the helical anchor and the heart valve prosthesis together.

15. The system of claim 14, 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 multiple coils.

16. The system of claim 14, 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 multiple coils.

17. The system of claim 14, 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 at least one coil moves from the first diameter to the second, larger diameter.

18. The system of claim 17, 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.

19. The system of claim 14, 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 multiple coils to assist with affixing the heart valve prosthesis to the helical anchor.

20. The system of claim 19, wherein the at least one compressible element further comprises multiple compressible elements spaced along the multiple coils.

21. The system of claim 19, wherein the at least one compressible element further comprises a continuous compressible element extending along the multiple coils.

22. The system of claim 19, wherein the at least one compressible element further comprises a resilient element.

23. The system of claim 19, 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 multiple coils.

24. The system of claim 14, wherein the multiple coils of the helical anchor include at least two coils that cross over each other.
25. The system of claim 14, wherein the helical anchor further comprises a shape memory material.
26. The system of claim 14, 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.
27. The system of claim 26, wherein the seal further comprises a membrane or panel extending over at least two coils of the helical anchor.
28. The system of claim 27, 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.
29. The system of claim 28, wherein the undeployed state comprises a rolled up state on one of the coils of the helical anchor.
30. The system of claim 28, wherein the undeployed state comprises a collapsed state.
31. The system of claim 27, wherein the membrane or panel includes a support element affixed therewith.
32. The system of claim 26, 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.
33. The system of claim 32, wherein the one or more seal elements each include a support element affixed therewith.

34. The system of claim 32, wherein the one or more seal elements are each generally circular in cross sectional shape.

35. The system of claim 32, wherein the one or more seal elements are each oblong in cross sectional shape.

36. The system of claim 32, 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.