

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

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

Summary

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

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

What is claimed is:

1. A system for replacing a native heart valve, the system comprising:
an expansible helical anchor formed as multiple coils adapted to support a heart valve prosthesis, at least one of the coils normally being at a first diameter, and being expandable to a second, larger diameter upon application of radial outward force from within the helical anchor, wherein a gap is defined between two adjacent coils sufficient to prevent engagement by at least one of the two adjacent coils with the native heart valve;
an expansible heart valve prosthesis capable of being delivered into the helical anchor and expanded inside the multiple coils to move the at least one coil from the first diameter to the second diameter while securing the helical anchor and the heart valve prosthesis together, wherein the expansible heart valve prosthesis includes a bumper on a blood outflow end of the expansible heart valve prosthesis; and
a seal on the expansible heart valve prosthesis configured to prevent blood leakage past the heart valve prosthesis after implantation of the heart valve prosthesis in the helical anchor.
2. The system of claim 1, wherein the helical anchor includes another coil that moves from a larger diameter to a smaller diameter as the heart valve prosthesis is expanded inside the multiple coils.
3. The system of claim 2, wherein the seal includes portions extending between adjacent coils for preventing blood leakage through the helical anchor and past the heart valve prosthesis.
4. The system of claim 1, wherein the seal further comprises a biologic material.
5. The system of claim 1, wherein the helical anchor further comprises a shape memory material.

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

7. The system of claim 1, wherein the heart valve prosthesis includes a blood inflow end, and wherein at least one of the blood inflow end and the blood outflow end is unflared and generally cylindrical in shape.
8. The system of claim 7, wherein the blood outflow end is flared radially outward.
9. The system of claim 1, wherein the gap is formed by a coil portion of the helical anchor that extends non-parallel to adjacent coil portions of the helical anchor.
10. The system of claim 1, wherein the bumper comprises a foam material.
11. The system of claim 10, wherein the bumper further comprises a covering, different from the foam material, that covers the foam material.
12. The system of claim 1, wherein the bumper comprises a biological tissue material configured to cover the blood outflow end of the expansible heart valve prosthesis.
13. The system of claim 12, wherein the biological tissue material is configured to cover a foam layer.
14. The system of claim 12, wherein the expansible heart valve prosthesis includes an open stent structure and the biological tissue material is configured to cover a portion of the open stent structure.
15. The system of claim 12, wherein the biological tissue material is pericardium tissue.