

SUMMARY

[005] Examples of a radially collapsible and expandable prosthetic valve are disclosed herein that include an improved outer skirt for controlling perivalvular leakage, as well as methods of crimping, and apparatuses including, such prosthetic valves. In several embodiments, the disclosed prosthetic valves are configured as replacement heart valves for implantation into a subject.

[005a] In one aspect, the present disclosure refers to a balloon-expandable prosthetic aortic heart valve with a radially collapsed state and radially expanded state, comprising:

- a balloon-expandable frame comprising a material selected from a group comprising stainless steel and a cobalt-chromium alloy, the frame comprising:

- an inflow row of openings at an inflow end portion of the frame,

- an outflow row of openings at an outflow end portion of the frame; and

- at least one intermediate row of openings between the inflow row of openings and outflow row of openings;

- wherein the inflow row of openings is formed by a circumferentially extending lower row of angled struts arranged end-to-end and a circumferentially extending first intermediate row of angled struts arranged end-to-end, the lower and first intermediate rows of angled struts interconnected by a plurality of substantially straight, axially extending struts; and

- wherein the outflow row of openings is formed by a circumferentially extending upper row of angled struts arranged end-to-end and a circumferentially extending second intermediate row of angled struts arranged end-to-end, the upper and second intermediate rows of angled struts interconnected by a plurality of axially extending struts and a plurality of angularly spaced, axially extending commissure window frame portions, wherein each axially extending strut and each commissure window frame portion of the outflow row of openings extends from a location defined by the convergence of the lower ends of two angled struts of the upper row of angled struts to another location defined by the convergence of the upper ends of two angled struts of the second intermediate row of angled struts;

- a leaflet structure positioned within the frame and secured thereto; and

an annular outer skirt positioned around an outer surface of the frame, wherein the outer skirt comprises:

an inflow edge secured to the frame at a first location,

an outflow edge secured to the frame at a second location;

an intermediate portion between the inflow edge and the outflow edge that comprises slack that buckles radially outwards from the inflow and outflow edges of the annular outer skirt when the valve is in the expanded configuration; and

(a) a fabric that is stiffer in the axial direction of the valve compared to a circumferential direction to enhance the radial outward buckling of the slack; and/or

(b) a self-expandable fabric comprising fibers made of shape memory material having a shape memory set to enhance the radially outward buckling of the slack of the outer skirt.

[006] In several examples, a radially compressible and expandable prosthetic heart valve is provided comprising an annular frame having an inflow end portion and an outflow end portion, a leaflet structure positioned within the frame, and an annular outer skirt positioned around an outer surface of the frame. The outer skirt comprises an inflow edge radially secured to the frame at a first location, an outflow edge radially secured to the frame at a second location, and an intermediate portion between the inflow edge and the outflow edge. The intermediate portion of the outer skirt comprises slack that buckles or billows radially outward from the inflow and outflow edges of the outer skirt when the prosthetic valve is in the expanded configuration. When the prosthetic valve is collapsed to the collapsed configuration, the axial distance between the inflow edge of the outer skirt and the outflow edge of the outer skirt increases, reducing the slack in the intermediate portion of the outer skirt. The outer skirt can comprise one of (a) a fabric that is stiffer in the axial direction of the valve compared to a circumferential direction to enhance the radial outward buckling of the slack, and/or (b) a self-expandable fabric comprising fibers made of shape memory material having a shape memory set to enhance the radially outward buckling of the slack of the outer skirt.

[007] In examples wherein the outer skirt comprises the fabric that is stiffer in the axial direction of the valve compared to a circumferential direction, the outer skirt can comprise a weave of a first set of fibers parallel with the axial direction of the prosthetic valve and a second set of fibers perpendicular to the axial direction of the prosthetic valve. In some examples, the fibers in the first set of fibers are stiffer than the fibers in the second set of fibers. The first set of fibers can comprise a set of monofilament fibers. The second set of fibers can comprise a set of microfilament fibers, a set of multifilament fibers, or a set of a microfilament fibers and multifilament fibers.

In further examples, the second set of fibers comprises fibers that do not comprise residual strain after the prosthetic valve is expanded to the expanded configuration from the collapsed configuration.

[008] In examples wherein the outer skirt comprises the self-expandable fabric comprising fibers made of shape memory material, the self-expandable fabric can comprise a weave of warp fibers and weft fibers, wherein one or more of the weft fibers comprise the fibers made of shape memory material. The weave of warp and weft fibers can comprise a combination of multiple weave patterns. For example, the weave of warp and weft fibers can comprise a combination of a plain weave pattern comprising warp fibers and weft fibers made of non-shape memory material, and a satin weave pattern comprising warp fibers made of non-shape memory material and weft fibers made of the shape memory material. In some examples, the shape memory material can be a nickel titanium alloy, for example, the fibers made of the shape memory material can be nickel titanium wires comprising a diameter of from 0.5 to 15 Mils.

[009] An exemplary example of an assembly for implanting a prosthetic heart valve in a patient's body comprises a delivery apparatus comprising an elongated shaft and a radially expandable prosthetic heart valve mounted on the shaft in a radially collapsed configuration for delivery into the body.

[009a] In another aspect, the present disclosure refers to an assembly for implanting a prosthetic heart valve in a patient's body comprising: a delivery apparatus comprising an elongated shaft; and the prosthetic heart valve as disclosed herein mounted on the shaft in a radially collapsed configuration for delivery into the body.

[010] In some examples, a method of crimping a prosthetic valve comprises partially inserting the prosthetic valve in the expanded configuration into the crimping jaws of a crimping device, wherein a portion of the prosthetic valve comprising an outer skirt extends outside of the crimper jaws. The prosthetic valve is then crimped to a first partially collapsed configuration, after which the prosthetic valve is fully inserted into the jaws of the crimping device. The prosthetic valve is then crimped to a second partially collapsed configuration, and optionally crimped to a fully collapsed configuration, before removal from the crimping device.

[011] The foregoing and other features and advantages of this disclosure will become more apparent from the following detailed description of several examples which proceeds with reference to the accompanying figures.

WE CLAIM:

1. A balloon-expandable prosthetic aortic heart valve with a radially collapsed state and radially expanded state, comprising:

a balloon-expandable frame comprising a material selected from a group comprising stainless steel and a cobalt-chromium alloy, the frame comprising:

an inflow row of openings at an inflow end portion of the frame,
an outflow row of openings at an outflow end portion of the frame; and
at least one intermediate row of openings between the inflow row of openings and outflow row of openings;

wherein the inflow row of openings is formed by a circumferentially extending lower row of angled struts arranged end-to-end and a circumferentially extending first intermediate row of angled struts arranged end-to-end, the lower and first intermediate rows of angled struts interconnected by a plurality of substantially straight, axially extending struts; and

wherein the outflow row of openings is formed by a circumferentially extending upper row of angled struts arranged end-to-end and a circumferentially extending second intermediate row of angled struts arranged end-to-end, the upper and second intermediate rows of angled struts interconnected by a plurality of axially extending struts and a plurality of angularly spaced, axially extending commissure window frame portions, wherein each axially extending strut and each commissure window frame portion of the outflow row of openings extends from a location defined by the convergence of the lower ends of two angled struts of the upper row of angled struts to another location defined by the convergence of the upper ends of two angled struts of the second intermediate row of angled struts;

a leaflet structure positioned within the frame and secured thereto; and

an annular outer skirt positioned around an outer surface of the frame, wherein the outer skirt comprises:

an inflow edge secured to the frame at a first location,
an outflow edge secured to the frame at a second location;

an intermediate portion between the inflow edge and the outflow edge that comprises slack that buckles radially outwards from the inflow and outflow edges of the annular outer skirt when the valve is in the expanded configuration; and

(a) a fabric that is stiffer in the axial direction of the valve compared to a circumferential direction to enhance the radial outward buckling of the slack; and/or

(b) a self-expandable fabric comprising fibers made of shape memory material having a shape memory set to enhance the radially outward buckling of the slack of the outer skirt.

2. The valve of claim 1, wherein the outflow edge of the outer skirt comprises a plurality of alternating projections and notches, the projections secured to the frame at the second location, the notches not directly secured to the frame.

3. The valve of claim 1 or claim 2, wherein when the frame is in the collapsed configuration, the axial distance between the inflow edge of the outer skirt and the outflow edge of the outer skirt is greater than when the valve is in the expanded configuration, reducing the slack in the intermediate portion of the outer skirt.

4. The valve of any of claims 1-3, wherein the fabric comprises fibers that do not comprise residual strain after the frame is expanded to the expanded configuration from the collapsed configuration.

5. The valve of any of the preceding claims, wherein the annular outer skirt comprises the fabric that is stiffer in the axial direction of the valve compared to a circumferential direction, and wherein the fabric comprises:

a plurality of first fibers parallel to the axial direction of the frame; and

a plurality of second fibers perpendicular to the plurality of first fibers; and

wherein at least some of the fibers in the plurality of first fibers are stiffer than the fibers in the plurality of second fibers.

6. The valve of claim 5, wherein the plurality of first fibers comprises monofilament fibers.

7. The valve of claim 5 or claim 6, wherein the plurality of second fibers comprises microfilament fibers, multifilament fibers, or a combination of microfilament fibers and multifilament fibers.

8. The valve of any of claims 5-7, wherein the plurality of second fibers comprises fibers that do not comprise residual strain after the frame is expanded to the expanded configuration from the collapsed configuration.

9. The valve of any of the claims 1-4, wherein the self-expandable fabric comprises a weave of warp fibers and weft fibers.

10. The valve of claim 9, wherein the weft fibers comprise the fibers made of shape memory material.

11. The valve of claim 9 or claim 10, wherein the weave of warp fibers and weft fibers comprises:
a plain weave pattern comprising fibers made of non-shape memory material; and
a satin weave pattern comprising the fibers made of the shape memory material.

12. The valve claim 11, wherein the satin weave pattern comprises warp fibers made of non-shape memory material and weft fibers made of the shape memory material.

13. The valve of any one of claims 1 or 9-12, wherein the shape-memory material is a nickel titanium alloy.

14. The valve of any one of claims 1 or 9-13, wherein the fibers made of shape memory material comprise a diameter of from 0.5 to 15 Mils.

15. The valve of any of the preceding claims, wherein the annular frame comprises a plurality of leaflet attachment portions; and the leaflet structure is secured to the leaflet attachment portions of the frame.

16. An assembly for implanting a prosthetic heart valve in a patient's body comprising:

a delivery apparatus comprising an elongated shaft; and

the prosthetic heart valve of any of claims 1-15 mounted on the shaft in a radially collapsed configuration for delivery into the body.