

apparatus comprising an elongate shaft, and a prosthetic heart valve mounted on the shaft in a radially collapsed configuration for delivery into a body. The prosthetic heart valve comprises an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame defining an axial direction extending from the inflow end to the outflow end, a leaflet structure positioned within the frame and secured thereto, and an annular outer skirt positioned around an outer surface of the frame. The outer skirt comprises an inflow edge secured to the frame at a first location, an outflow edge comprising a plurality of alternating projections and notches, wherein the projections are secured to the frame at a second location, and the notches are not directly secured to the frame, and an intermediate portion between the inflow edge and the outflow edge that comprises a plurality of openings, and a plurality of axially extending creases. Each of the openings of the outer skirt is circumferentially aligned with a respective crease of the outer skirt.

[014a] In another representative embodiment, an implantable prosthetic valve is provided. The implantable prosthetic valve comprises an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame defining an axial direction extending from the inflow end to the outflow end. A leaflet structure is positioned within the frame and secured thereto. An annular outer skirt is positioned around an outer surface of the frame. The outer skirt comprises an inflow edge secured to the frame at a first location, an outflow edge comprising a plurality of alternating projections and notches, wherein the projections are secured to the frame at a second location and the notches are not directly secured to the frame, an intermediate portion between the inflow edge and the outflow edge that comprises a plurality of openings and a plurality of axially extending creases, wherein each of the creases of the outer skirt is circumferentially aligned with a respective projection of the outer skirt.

[014b] In another representative embodiment, an implantable prosthetic valve is provided. The implantable prosthetic valve comprises an annular frame comprising an

inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame defining an axial direction extending from the inflow end to the outflow end. A leaflet structure is positioned within the frame and secured thereto. An annular outer skirt is positioned around an outer surface of the frame. The outer skirt comprises an inflow edge secured to the frame at a first location, an outflow edge comprising a plurality of alternating projections and notches, wherein the projections are secured to the frame at a second location, and the notches are not directly secured to the frame, an intermediate portion between the inflow edge and the outflow edge that comprises a plurality of openings, and a plurality of axially extending creases, wherein the outer skirt is positioned relative to the frame such that each of the creases of the outer skirt is circumferentially positioned between a respective pair of apices formed by struts at the inflow end of the frame; wherein each of the creases of the outer skirt is circumferentially aligned with a respective projection of the outer skirt.

[014c] In another representative embodiment, an implantable prosthetic valve is provided. The prosthetic valve comprises an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame defining an axial direction extending from the inflow end to the outflow end. A leaflet structure is positioned within the frame and secured thereto. An annular outer skirt is positioned around an outer surface of the frame, the outer skirt comprises an inflow edge secured to the frame at a first location, an outflow edge comprising a plurality of alternating projections and notches, wherein the projections are secured to the frame at a second location, and the notches are not directly secured to the frame, and an intermediate portion between the inflow edge and the outflow edge that comprises a plurality of openings. The outer skirt comprises a first height, and the frame in the radially expanded configuration comprises a second height. A ratio of the first height to the second height is 0.75 to 0.95. The outer skirt comprises a plurality of axially extending creases, and each of the creases of the outer skirt is circumferentially aligned with a respective projection of the outer skirt.

[015] In another representative embodiment, a method of manufacturing a prosthetic valve is provided. The method can comprise forming at least one permanent crease in an annular outer skirt of the prosthetic valve, and securing the outer skirt to an annular frame of the prosthetic valve. In some embodiments, forming the at least one crease comprises suturing and/or ultrasonic welding portions of the outer skirt to each other.

[016] In some embodiments, the method can further comprise forming at least one opening in the outer skirt, wherein the at least one opening is circumferentially aligned with a respective at least one crease. In some embodiments, the method can further comprise positioning the outer skirt relative to an annular frame such that the at least one crease is circumferentially disposed between struts of the frame.

[017] In another representative embodiment, an implantable prosthetic valve can comprise an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame defining an axial direction extending from the inflow end to the outflow end, 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, a plurality of axially extending creases, wherein the creases are configured to cause at least a portion of the outer skirt to retract radially within the frame when the frame is radially collapsed from the expanded configuration.

[018] In some embodiments, the outer skirt can further comprise an intermediate portion between the inflow edge and the outflow edge that comprises a plurality of openings.

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

WE CLAIM:

1. An implantable prosthetic valve comprising:
an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame defining an axial direction extending from the inflow end to the outflow end;
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 comprising a plurality of alternating projections and notches, wherein the projections are secured to the frame at a second location, and the notches are not directly secured to the frame;
an intermediate portion between the inflow edge and the outflow edge that comprises a plurality of openings; and
a plurality of axially extending creases, wherein each of the openings of the outer skirt is circumferentially aligned with a respective crease of the outer skirt.
2. The prosthetic valve of claim 1, 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, increasing tension of the intermediate portion of the outer skirt.
3. The prosthetic valve of claim 1, wherein the outer skirt comprises a first height, and the frame in the radially expanded configuration comprises a second height, and wherein a ratio of the first height to the second height about 0.75 to about 0.95.
4. The prosthetic valve of claim 3, wherein the ratio of the first height to the second height is 0.86.

5. The prosthetic valve of claim 1, wherein the creases are formed by suturing portions of the outer skirt to each other.

6. The prosthetic valve of claim 1, wherein the creases are formed by ultrasonic welding portions of the outer skirt to each other.

7. The prosthetic valve of claim 1, wherein each of the creases of the outer skirt is circumferentially aligned with a respective projection of the outer skirt.

8. The prosthetic valve of claim 1, wherein the outer skirt is positioned relative to the frame such that each of the creases of the outer skirt is circumferentially positioned between a respective pair of apices formed by struts at the inflow end of the frame.

9. The prosthetic valve of claim 8, wherein each of the creases is positioned equidistantly between a respective pair of apices.

10. The prosthetic valve of claim 1, further comprising an annular inner skirt positioned around an inner surface of the frame, wherein the inner skirt comprises an inflow edge secured to the frame at a third location, and an outflow edge secured to the frame at a fourth location.

11. The prosthetic valve claim 10, wherein the inflow edge of the outer skirt is attached to the inflow edge of the inner skirt.

12. The prosthetic valve of claim 11, wherein the inflow edge of the outer skirt is attached to the inflow edge of the inner skirt with sutures.

13. The prosthetic valve of claim 11, wherein the inflow edge of the outer skirt is attached to the inflow edge of the inner skirt by ultrasonic welding.

14. The prosthetic valve of claim 1, wherein at least a portion of the outer skirt is configured to retract radially within the frame when the frame is in the radially collapsed configuration.

15. The prosthetic valve of claim 1, wherein the outer skirt is configured such that blood can flow through the openings and the notches of the outer skirt and blood can flow through a space between the outer skirt and the frame.

16. The prosthetic valve of claim 1, wherein the outer skirt is attached to the frame such that each of the projections of the outer skirt is circumferentially positioned between a respective pair of apices formed by struts at the inflow end of the frame.

17. An implantable prosthetic valve comprising:
an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame defining an axial direction extending from the inflow end to the outflow end;
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 comprising a plurality of alternating projections and notches, wherein the projections are secured to the frame at a second location, and the notches are not directly secured to the frame;
- an intermediate portion between the inflow edge and the outflow edge that comprises a plurality of openings; and
- a plurality of axially extending creases, wherein each of the creases of the outer skirt is circumferentially aligned with a respective projection of the outer skirt.

18. An implantable prosthetic valve comprising:

an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame defining an axial direction extending from the inflow end to the outflow end;

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 comprising a plurality of alternating projections and notches, wherein the projections are secured to the frame at a second location, and the notches are not directly secured to the frame;
- an intermediate portion between the inflow edge and the outflow edge that comprises a plurality of openings; and
- a plurality of axially extending creases, wherein the outer skirt is positioned relative to the frame such that each of the creases of the outer skirt is circumferentially positioned between a respective pair of apices formed by struts at the inflow end of the frame; wherein each of the creases of the outer skirt is circumferentially aligned with a respective projection of the outer skirt.

19. The prosthetic valve of claim 18, wherein each of the creases is positioned equidistantly between a respective pair of apices.

20. An implantable prosthetic valve comprising:

an annular frame comprising an inflow end and an outflow end and being radially collapsible and expandable between a radially collapsed configuration and a radially expanded configuration, the frame defining an axial direction extending from the inflow end to the outflow end;

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 comprising a plurality of alternating projections and notches, wherein the projections are secured to the frame at a second location, and the notches are not directly secured to the frame; and

an intermediate portion between the inflow edge and the outflow edge that comprises a plurality of openings,

wherein the outer skirt comprises a first height, and the frame in the radially expanded configuration comprises a second height, wherein a ratio of the first height to the second height is 0.75 to 0.95, wherein the outer skirt comprises a plurality of axially extending creases, and wherein each of the creases of the outer skirt is circumferentially aligned with a respective projection of the outer skirt .

21. The prosthetic valve of claim 20, wherein the ratio of the first height to the second height is 0.86.

22. The prosthetic valve of claim 20, wherein the outer skirt is positioned relative to the frame such that each of the creases of the outer skirt is circumferentially positioned between a respective pair of apices formed by struts at the inflow end of the frame.

23. The prosthetic valve of claim 22, wherein each of the openings of the outer skirt is circumferentially aligned with a respective crease of the outer skirt.