

SUMMARY

[005] Embodiments 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, there is provided 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 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 embodiments, 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 embodiments 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 embodiments, 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 embodiments, 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 embodiments 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 embodiments, 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.

[008a] In one aspect, there is provided 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.

[009] An exemplary embodiment 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 one aspect, there is provided method of radially compressing a prosthetic valve, comprising:

partially inserting the valve while in a radially expanded configuration into a crimping device comprising crimping jaws, wherein a portion of the valve comprising an outer skirt extends outside of the crimper jaws;

crimping the valve to a first partially collapsed configuration;

further inserting the valve into the crimping device, such that the outer skirt is between the crimper jaws;

crimping the valve to a second partially collapsed configuration; and
optionally crimping the valve to a fully crimped configuration.

[010] In some embodiments, 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 embodiments which proceeds with reference to the accompanying figures.