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Inventor(s)	Darekar; Yogesh et al.

Skirt-reinforcement members for prosthetic valve devices

Abstract

A prosthesis includes a frame and a skirt coupled to a surface of the frame. The skirt extends over at least one side opening of a plurality of side openings of the frame. The prosthesis also includes a skirt-reinforcement member that spans the at least one side opening from a first crown or strut edge defining the at least one side opening to a second crown or strut edge defining the at least one side opening. The skirt-reinforcement member has a first end, a second end, and a length therebetween. The first end of the skirt-reinforcement member is attached to the first crown or strut edge and the second end of the skirt-reinforcement member is attached to the second crown or strut edge. The skirt-reinforcement member is attached to the skirt along an unsupported portion of the skirt that spans the at least one side opening.

Inventors: **Darekar; Yogesh (Irvine, CA), McIntire; Brenda (Walnut Creek, CA), Pierce; Eric (Mission Viejo, CA)**

Applicant: **Medtronic, Inc.** (Minneapolis, MN)

Family ID: **1000008747916**

Assignee: **MEDTRONIC, INC. (Minneapolis, MN)**

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Primary Examiner: Mathew; Seema

Attorney, Agent or Firm: MEDLER FERRO WOODHOUSE & MILLS PLLC

Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application claims the benefit of U.S. Provisional Patent Application Ser. No. 63/129,166, filed Dec. 22, 2020, which is hereby incorporated by reference in its entirety for all purposes.

FIELD

(1) The present technology is generally related to prosthetic valve devices, and in particular is directed to prosthetic valve devices including a skirt.

BACKGROUND

(2) The human heart is a four chambered, muscular organ that provides blood circulation through the body during a cardiac cycle. The four main chambers include the right atrium and right ventricle which supplies the pulmonary circulation, and the left atrium and left ventricle which supplies oxygenated blood received from the lungs into systemic circulation. To ensure that blood flows in one direction through the heart, atrioventricular valves (tricuspid and mitral valves) are present between the junctions of the atrium and the ventricles, and semi-lunar valves (pulmonary valve and aortic valve) govern the exits of the ventricles leading to the lungs and the rest of the body. These valves contain leaflets or cusps that open and shut in response to blood pressure changes caused by the contraction and relaxation of the heart chambers. The valve leaflets move apart from each other to open and allow blood to flow downstream of the valve, and coapt to close and prevent backflow or regurgitation in an upstream manner.

(3) Diseases associated with heart valves, such as those caused by damage or a defect, can include stenosis and valvular insufficiency or regurgitation. For example, valvular stenosis causes the valve

to become narrowed and hardened which can prevent blood flow to a downstream heart chamber from occurring at the proper flow rate and may cause the heart to work harder to pump the blood through the diseased valve. Valvular insufficiency or regurgitation occurs when the valve does not close completely, allowing blood to flow backwards, thereby causing the heart to be less efficient. A diseased or damaged valve, which can be congenital, age-related, drug-induced, or in some instances, caused by infection, can result in an enlarged, thickened heart that loses elasticity and efficiency. Some symptoms of heart valve diseases can include weakness, shortness of breath, dizziness, fainting, palpitations, anemia and edema, and blood clots which can increase the likelihood of stroke or pulmonary embolism. Symptoms can often be severe enough to be debilitating and/or life threatening.

(4) Heart valve prostheses have been developed for repair and replacement of diseased and/or damaged heart valves. Such heart valve prostheses can be percutaneously delivered and deployed at the site of the diseased heart valve through catheter-based delivery systems. Such heart valve prostheses are delivered in a radially compressed or crimped configuration so that the heart valve prosthesis can be advanced through the patient's vasculature. Once positioned at the treatment site, the heart valve prosthesis is expanded to engage tissue at the diseased heart valve region to, for instance, hold the heart valve prosthesis in position.

(5) The present disclosure relates to improvements in a heart valve prosthesis to ensure that the heart valve prosthesis has a low profile for transcatheter delivery through a patient's vasculature.

SUMMARY

(6) According to a first embodiment hereof, the present disclosure provides a prosthesis having a radially expanded configuration and a radially compressed configuration. The prosthesis includes a frame including a plurality of crowns and a plurality of struts with each crown being formed between a pair of opposing struts. A plurality of side openings is defined by edges of the plurality of crowns and the plurality of struts. The prosthesis also includes a skirt coupled to a surface of the frame. The skirt extends over at least one side opening of the plurality of side openings of the frame. The prosthesis also includes a skirt-reinforcement member that spans the at least one side opening from a first crown or strut edge defining the at least one side opening to a second crown or strut edge defining the at least one side opening. The skirt-reinforcement member has a first end, a second end, and a length therebetween. The first end of the skirt-reinforcement member is attached to the first crown or strut edge and the second end of the skirt-reinforcement member is attached to the second crown or strut edge. The skirt-reinforcement member is attached to the skirt along an unsupported portion of the skirt that spans the at least one side opening.

(7) In an aspect of the first embodiment, and in combination with any other aspects herein, the disclosure provides that the skirt-reinforcement member includes a suture forming a plurality of stitches.

(8) In an aspect of the first embodiment, and in combination with any other aspects herein, the disclosure provides that the skirt-reinforcement member includes tissue.

(9) In an aspect of the first embodiment, and in combination with any other aspects herein, the disclosure provides that the skirt-reinforcement member includes fabric.

(10) In an aspect of the first embodiment, and in combination with any other aspects herein, the disclosure provides that the at least one side opening is substantially diamond-shaped. In an embodiment, each side opening of the plurality of side openings is substantially diamond-shaped. In an embodiment, an end of the frame includes a row of side openings around a circumference of the frame, the row including between six and nine side openings.

(11) In an aspect of the first embodiment, and in combination with any other aspects herein, the disclosure provides that the first end of the skirt-reinforcement member is offset from the second end of the skirt-reinforcement member such that the skirt-reinforcement member is angled relative to an axis of the frame.

(12) In an aspect of the first embodiment, and in combination with any other aspects herein, the

disclosure provides that the first end of the skirt-reinforcement member is aligned with the second end of the skirt-reinforcement member such that the skirt-reinforcement member extends substantially perpendicular relative to an axis of the frame. In an embodiment, the at least one side opening includes a maximum width and the skirt-reinforcement member spans across the at least one side opening at the maximum width. In an embodiment, the frame includes a plurality of nodes, each node being a region where two of the plurality of crowns of the frame meet, and the skirt-reinforcement member spans across the at least one side opening from one node to another node.

(13) In an aspect of the first embodiment, and in combination with any other aspects herein, the disclosure provides that the frame includes a row of side openings around a circumference of the frame and a skirt-reinforcement member spans each side opening of the row of side openings around the circumference of the frame.

(14) In an aspect of the first embodiment, and in combination with any other aspects herein, the disclosure provides that the frame is an inner frame and the prosthesis further comprises an outer frame coupled to the inner frame, the outer frame having a greater diameter than the inner frame.

(15) In an aspect of the first embodiment, and in combination with any other aspects herein, the disclosure provides that the prosthesis is a heart-valve prosthesis and the prosthesis further comprises a prosthetic valve component disposed within and secured to the frame, the prosthetic valve being configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame. In an embodiment, the heart-valve prosthesis is configured for placement within a mitral valve in situ.

(16) According to a second embodiment hereof, the present disclosure provides a prosthesis having a radially expanded configuration and a radially compressed configuration. The prosthesis includes a frame including a plurality of crowns and a plurality of struts with each crown being formed between a pair of opposing struts. A plurality of side openings is defined by edges of the plurality of crowns and the plurality of struts. The prosthesis also includes a skirt coupled to a surface of the frame. The skirt extends over at least one side opening of the plurality of side openings of the frame. The prosthesis also includes a skirt-reinforcement member that circumscribes an outer surface of the frame. A diameter of the skirt-reinforcement member is approximately the same as a diameter of the frame when the prosthesis is in the radially expanded configuration. The skirt-reinforcement member is attached to the skirt along an unsupported portion of the skirt that spans the at least one side opening of the plurality of side openings of the frame and the skirt-reinforcement member is not directly attached to the frame.

(17) In an aspect of the second embodiment, and in combination with any other aspects herein, the disclosure provides that the skirt-reinforcement member is a ring of an elastic material.

(18) In an aspect of the second embodiment, and in combination with any other aspects herein, the disclosure provides that the at least one side opening of the plurality of side openings is substantially diamond-shaped and is defined by at least two struts. In an embodiment, each side opening of the plurality of side openings is substantially diamond-shaped and is defined by at least four struts. In an embodiment, an end of the frame includes a row of side openings around a circumference of the frame, the row including between six and nine side openings.

(19) In an aspect of the second embodiment, and in combination with any other aspects herein, the disclosure provides that the frame is an inner frame and the prosthesis further comprises an outer frame coupled to the inner frame, the outer frame having a greater diameter than the inner frame.

(20) In an aspect of the second embodiment, and in combination with any other aspects herein, the disclosure provides that the prosthesis is a heart-valve prosthesis and the prosthesis further comprises a prosthetic valve component disposed within and secured to the frame, the prosthetic valve being configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame. In an embodiment, the heart-valve prosthesis is configured for placement within a mitral valve in situ.

(21) The details of one or more aspects of the disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the techniques described in this disclosure will be apparent from the description and drawings, and from the claims.

Description

BRIEF DESCRIPTION OF DRAWINGS

(1) The foregoing and other features and advantages of the invention will be apparent from the following description of embodiments thereof as illustrated in the accompanying drawings. The accompanying drawings, which are incorporated herein and form a part of the specification, further serve to explain the principles of the invention and to enable a person skilled in the pertinent art to make and use the invention. The drawings are not to scale.

(2) FIG. **1** depicts a perspective view of a transcatheter heart valve prosthesis in accordance with an aspect of the disclosure.

(3) FIG. **2** depicts a perspective view of a valve support of the transcatheter heart valve prosthesis of FIG. **1** with a prosthetic valve component secured therein in accordance with an aspect of the disclosure.

(4) FIG. **3** depicts an atrial end view of the transcatheter heart valve prosthesis shown in FIG. **1** in accordance with an aspect of the disclosure.

(5) FIG. **4** depicts a ventricular end view of the transcatheter heart valve prosthesis shown in FIG. **1** in accordance with an aspect of the disclosure.

(6) FIG. **5** is an enlarged side view of a side opening of the valve support of FIG. **2**.

(7) FIG. **6**A is a perspective atrial end view of the transcatheter heart valve prosthesis shown in FIG. **1** in accordance with an aspect of the disclosure.

(8) FIG. **6**B is an atrial end view of the transcatheter heart valve prosthesis shown in FIG. **1** in accordance with an aspect of the disclosure.

(9) FIG. **7**A is a side view of the valve support of the transcatheter heart valve prosthesis of FIG. **1**, wherein the valve support further includes a plurality of skirt-reinforcement members in accordance with an aspect of the disclosure.

(10) FIG. **7**B is a perspective atrial end view of the valve support of FIG. **7**A.

(11) FIG. **7**C is an enlarged view of a side opening of the valve support of FIG. **7**A.

(12) FIG. **8**A is a side view of the valve support of the transcatheter heart valve prosthesis of FIG. **1**, wherein the valve support further includes a plurality of skirt-reinforcement members in accordance with another aspect of the disclosure.

(13) FIG. **8**B is a perspective atrial end view of the valve support of FIG. **8**A.

(14) FIG. **8**C is an enlarged view of a side opening of the valve support of FIG. **8**A.

(15) FIG. **9**A is a side view of the valve support of the transcatheter heart valve prosthesis of FIG. **1**, wherein the valve support further includes a plurality of skirt-reinforcement members in accordance with another aspect of the disclosure.

(16) FIG. **9**B is a perspective atrial end view of the valve support of FIG. **9**A.

(17) FIG. **9**C is an enlarged view of a side opening of the valve support of FIG. **9**A.

(18) FIG. **10**A is a side view of the valve support of the transcatheter heart valve prosthesis of FIG. **1**, wherein the valve support further includes a plurality of skirt-reinforcement members in accordance with another aspect of the disclosure.

(19) FIG. **10**B is a perspective atrial end view of the valve support of FIG. **10**A.

(20) FIG. **10**C is an enlarged view of a side opening of the valve support of FIG. **10**A.

(21) FIG. **11**A is a side view of the valve support of the transcatheter heart valve prosthesis of FIG. **1**, wherein the valve support further includes a plurality of skirt-reinforcement members in

accordance with another aspect of the disclosure.
(22) FIG. **11**B is a perspective atrial end view of the valve support of FIG. **11**A.
(23) FIG. **11**C is an enlarged view of a side opening of the valve support of FIG. **11**A.
(24) FIG. **12**A is a side view of the valve support of the transcatheter heart valve prosthesis of FIG. **1**, wherein the valve support further includes a plurality of skirt-reinforcement members in accordance with another aspect of the disclosure.
(25) FIG. **12**B is a perspective atrial end view of the valve support of FIG. **12**A.
(26) FIG. **12**C is an enlarged view of a side opening of the valve support of FIG. **12**A.
(27) FIG. **13**A is a side view of the valve support of the transcatheter heart valve prosthesis of FIG. **1**, wherein the valve support includes a skirt-reinforcement member that circumscribes an outer surface of the valve support.
(28) FIG. **13**B is a top view of the skirt-reinforcement member of FIG. **13**A, wherein the skirt-reinforcement member is removed from the valve support for purposes of illustration only.
(29) FIG. **14** depicts a perspective view of a transcatheter heart valve prosthesis in accordance with another aspect of the disclosure, wherein the frame further includes a plurality of skirt-reinforcement members.
(30) FIG. **14**A is an enlarged view of a side opening of the transcatheter heart valve prosthesis of FIG. **14**.
(31) FIG. **14**B is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in a vertical orientation.
(32) FIG. **14**C is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in an angled orientation.
(33) FIG. **15** depicts a perspective view of a transcatheter heart valve prosthesis in accordance with another aspect of the disclosure, wherein the frame further includes a plurality of skirt-reinforcement members.
(34) FIG. **15**A is an enlarged view of a side opening of the transcatheter heart valve prosthesis of FIG. **15**.
(35) FIG. **15**B is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in a vertical orientation.
(36) FIG. **15**C is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in an angled orientation.
(37) FIG. **16** depicts a perspective view of a transcatheter heart valve prosthesis in accordance with another aspect of the disclosure, wherein the frame further includes a plurality of skirt-reinforcement members.
(38) FIG. **16**A is an enlarged view of a side opening of the transcatheter heart valve prosthesis of FIG. **16**.
(39) FIG. **16**B is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in a vertical orientation.
(40) FIG. **16**C is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in an angled orientation.
(41) FIG. **17** depicts a perspective view of a transcatheter heart valve prosthesis in accordance with another aspect of the disclosure, wherein the frame further includes a plurality of skirt-reinforcement members.
(42) FIG. **17**A is an enlarged view of a side opening of the transcatheter heart valve prosthesis of

FIG. **17**.
(43) FIG. **17**B is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in a vertical orientation.
(44) FIG. **17**C is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in an angled orientation.
(45) FIG. **17**D is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein two skirt-reinforcement members are disposed over a single side opening of the transcatheter valve prosthesis.
(46) FIG. **18** depicts a perspective view of a transcatheter heart valve prosthesis in accordance with another aspect of the disclosure, wherein the frame further includes a plurality of skirt-reinforcement members.
(47) FIG. **18**A is an enlarged view of a side opening of the transcatheter heart valve prosthesis of FIG. **18**.
(48) FIG. **18**B is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in a vertical orientation.
(49) FIG. **18**C is an enlarged view of a side opening of a transcatheter heart valve prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in an angled orientation.
(50) FIG. **19** depicts a perspective view of a docking prosthesis in accordance with another aspect of the disclosure, wherein a frame of the docking prosthesis includes a plurality of skirt-reinforcement members.
(51) FIG. **19**A is an enlarged view of a side opening of the docking prosthesis of FIG. **19**.
(52) FIG. **19**B is an enlarged view of a side opening of a docking prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in a vertical orientation.
(53) FIG. **19**C is an enlarged view of a side opening of a docking prosthesis according to another embodiment hereof, wherein a skirt-reinforcement member extends in an angled orientation.
(54) FIG. **20** is a perspective view of the docking prosthesis of FIG. **19** and a valve prosthesis disposed in the docking prosthesis.

DETAILED DESCRIPTION

(55) Specific embodiments of the present invention are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements. The terms “distal” and “proximal”, when used in the following description to refer to a native vessel, native valve, or a device to be implanted into a native vessel or native valve, such as a transcatheter heart valve prosthesis, are with reference to the direction of blood flow. Thus, “distal” and “distally” refer to positions in a downstream direction with respect to the direction of blood flow and the terms “proximal” and “proximally” refer to positions in an upstream direction with respect to the direction of blood flow.
(56) Embodiments hereof relate to a skirt-reinforcement member for supporting or reinforcement a skirt that spans across a side opening of a stent or frame of a valve prosthesis. The skirt-reinforcement member provides the valve prosthesis with a reinforced composite skirt having long-lasting durability and superior implant performance. In addition, as will be explained in more detail herein, the skirt-reinforcement member is configured to prevent billowing of the skirt material that spans across the side opening of the frame of the valve prosthesis, as such billowing may undesirably result in contact between the skirt and the leaflets of the valve prosthesis after the valve prosthesis is deployed in situ. If the leaflets of the valve prosthesis contact the skirt during opening and closing in situ, such contact may cause early leaflet tissue abrasion as well as early skirt abrasion due to the undesired billowing of the skirt. Additionally, the greater relative motion

between the skirt and the frame may further induce early skirt abrasion. Early leaflet tissue abrasion and/or early skirt abrasion has a negative impact on the long-term durability of the valve prosthesis. The skirt-reinforcement members disclosed herein reinforce the material of the skirt that spans across the side opening of the frame of the valve prosthesis to limit the radial motion or billowing of the skirt material, thereby minimizing risk of damage to both the skirt and the leaflets.

(57) FIGS. **1**-**6** illustrate a transcatheter heart valve prosthesis **100** that may be utilized with embodiments of skirt-reinforcement members described herein. The heart valve prosthesis **100** is illustrated herein in order to facilitate description of the present invention. The following description of the transcatheter heart valve prosthesis **100** is merely exemplary in nature and is not intended to limit the invention or the application and uses of the invention. It is understood that any number of alternate heart valve prostheses can be used with the skirt-reinforcement members described herein. Other non-limiting examples of transcatheter heart valve prostheses that can be used with the skirt-reinforcement members described herein are described in U.S. application Ser. No. 16/853,851 to McVeigh et al., U.S. Pat. No. 9,034,032 to McLean et al. and International Patent Application No. PCT/US2014/029549 to McLean et al, U.S. Patent Application Publication No. 2012/0101572 to Kovalsky et al., U.S. Patent Application Publication No. 2012/0035722 to Tuval, U.S. Patent Application Publication No. 2006/0265056 to Nguyen et al., U.S. Patent Application Publication No. 2007/05409266 to Birdsall, and U.S. Patent Application Publication No. 2007/05409269 to Dolan et al., each of which is incorporated by reference herein in its entirety. Although the transcatheter heart valve prosthesis **100** is a heart valve prosthesis configured for placement within a mitral heart valve, embodiments of skirt-reinforcement members described herein may be utilized with any valve prosthesis having a skirt. For example, embodiments of skirt-reinforcement members described herein may be utilized with a transcatheter heart valve configured for placement within a pulmonary, aortic, mitral, or tricuspid valve, or may be utilized with a transcatheter valve prosthesis configured for placement within a venous valve or within other body passageways where it is deemed useful. There is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description. In addition, embodiments of skirt-reinforcement members described herein may be utilized with any stent or frame having a skirt for which reinforcement thereof is desirable to limit billowing, and it is not required that the stent or frame include a prosthetic valve component disposed therein.

(58) A perspective view of the transcatheter heart valve prosthesis **100** in accordance with an aspect of the disclosure is shown in FIG. **1**. The transcatheter heart valve prosthesis **100** is configured to be radially compressed into a reduced-diameter crimped configuration for delivery within a vasculature (not shown) and to return to an expanded, deployed configuration, as shown in FIG. **1**. Stated another way, the transcatheter heart valve prosthesis **100** has a crimped configuration for delivery within a vasculature and an expanded configuration for deployment within a native heart valve. In accordance with embodiments hereof, when in the crimped configuration, the transcatheter heart valve prosthesis **100** has a low profile suitable for delivery to and deployment within a native heart valve via a suitable delivery catheter that may be tracked to the deployment site of the native heart valve of a heart via any one of a transseptal, retrograde, or transapical approach. The transcatheter heart valve prosthesis **100** includes a stent or frame **102** and a prosthetic valve component **108** including at least one leaflet disposed within and secured to the frame **102**.

(59) Any portion of the frame **102** described herein as an element of a heart valve prothesis **100** may be made from any number of suitable biocompatible materials, e.g., stainless steel, nickel titanium alloys such as Nitinol™, cobalt chromium alloys such as MP35N, other alloys such as ELGILOY® (Elgin, Ill.), various polymers, pyrolytic carbon, silicone, polytetrafluoroethylene (PTFE), or any number of other materials or combination of materials. A suitable biocompatible material would be selected to provide the transcatheter heart valve prothesis **100** to be configured

to be compressed into a reduced-diameter crimped configuration for transcatheter delivery to a native valve, whereby release from a delivery catheter returns the prosthesis to an expanded, deployed configuration.

(60) In an aspect of the disclosure, the frame **102** of the transcatheter heart valve prosthesis **100** includes a valve support **104** at least partially surrounded by and coupled to an anchor element **106**. The valve support **104** is a tubular stent-like or frame structure that defines a central lumen **110** from an inflow end **101** of the valve support **104** to an outflow end **103** of the valve support **104**. The valve support **104** is configured to support the prosthetic valve component **108** therein, which will be described in more detail below. In an embodiment, the valve support **104** has a substantially cylindrical shape in which the outflow end **103** of the valve support **104** has a diameter that is substantially the same as a diameter of the inflow end **101** of the valve support **104**.

(61) The valve support **104** includes a skirt **112** coupled to a surface thereof. More particularly, the skirt **112** is coupled to an inner surface of the valve support **104** to line a portion thereof. Alternatively, the skirt **112** may be coupled to an outer surface of the valve support **104** to enclose a portion thereof as would be known to one of ordinary skill in the art of prosthetic valve construction. The skirt **112** may be a natural or biological material such as pericardium or another membranous tissue such as intestinal submucosa. Alternatively, the skirt **112** may be a low-porosity woven fabric, such as polyester, Dacron fabric, or PTFE, which creates a one-way fluid passage when attached to the stent. In one embodiment, the skirt **112** may be a knit or woven polyester, such as a polyester or PTFE knit, which can be utilized when it is desired to provide a medium for tissue ingrowth and the ability for the fabric to stretch to conform to a curved surface. Polyester velour fabrics may alternatively be used, such as when it is desired to provide a medium for tissue ingrowth on one side and a smooth surface on the other side. These and other appropriate cardiovascular fabrics are commercially available from Bard Peripheral Vascular, Inc. of Tempe, Ariz., for example.

(62) In an aspect of the disclosure, the anchor element **106** is a stent-like or frame structure that functions as an anchor for the transcatheter heart valve prosthesis **100** to secure its deployed position within a native annulus. The anchor element **106** is a substantially cylindrically-shaped structure that is configured to engage heart tissue at or below an annulus of a native heart valve, such as an annulus of a native mitral valve. At the inflow end **101** of the valve support **104**, the anchor element **106** is radially spaced a distance S from the valve support **104** to mechanically isolate the inflow end **101** of the valve support **104** from the anchor element **106**. The anchor element **106** includes one or more cleats or prongs **114** that extend outward from an exterior side thereof to engage heart tissue. In another embodiment, the anchor element **106** may employ barbs, spikes, or other tissue fixation mechanisms for engaging heart tissue.

(63) The transcatheter heart valve prosthesis **100** further includes a brim or rim element **116** that extends outwardly from an upstream end of the anchor element **106**. The brim element **116** includes overlapping, 180 degree out of phase sinusoidal wire forms that are attached and hinged to the anchor element **106** by a suitable biocompatible low-profile fabric **117** used in bioprosthetic implants namely endovascular grafts, heart valves or left atrial appendage devices to promote bio-integration, such as woven polyethylene terephthalate (PET) fabric. The brim element **116** may act as an atrial retainer, if present, and to serve such a function the brim element **116** may be configured to engage tissue above a native annulus, such as a supra-annular surface or some other tissue in the left atrium, to thereby inhibit downstream migration of a prosthetic heart valve **100**, for e.g., during atrial systole.

(64) The prosthetic valve component **108** of the transcatheter heart valve prosthesis **100** is capable of regulating flow therethrough via valve leaflets that may form a replacement valve. FIGS. **1-6** illustrate an exemplary prosthetic valve component having three leaflets, although a single leaflet or bicuspid leaflet configuration may alternatively be used in embodiments hereof. When deployed in situ, the prosthetic valve component **108** in a closed state is configured to block blood flow in

one direction to regulate blood flow through the central lumen **110** of the valve support **104**. FIG. **2** depicts a perspective view of the valve support **104** with a prosthetic valve component **108** secured therein, the valve support **104** being shown in FIG. **2** removed from the remainder of the transcatheter heart valve prosthesis **100** shown in FIG. **1** for ease of illustration. FIG. **3** depicts an atrial or inflow end view of the transcatheter heart valve prosthesis **100** shown in FIG. **1**, and FIG. **4** depicts a ventricular or outflow end view of the transcatheter heart valve prosthesis **100** shown in FIG. **1**. The prosthetic valve component **108** includes valve leaflets **109**, e.g., three valve leaflets **109**, that are disposed to coapt within an upstream portion of the valve support **104** with leaflet commissures **109**A, **109**B, **109**C of the valve leaflets **109** being secured within a downstream portion of the valve support **104**, such that the valve leaflets **109** open during diastole. Leaflets **109** are attached along their bases to the valve support **104**, for example, using sutures or a suitable biocompatible adhesive. A margin of attachment, or MOA, is formed at the junction of the leaflets **109** to the valve support **104**. Adjoining pairs of leaflets **109** are attached to one another at their lateral ends to form leaflet commissures **109**A, **109**B, **109**C. The orientation of the leaflets **109** within the valve support **104** depends upon on which end of the transcatheter heart valve prosthesis **100** is the inflow end and which end of the transcatheter heart valve prosthesis **100** is the outflow end, thereby ensuring one-way flow of blood through the transcatheter heart valve prosthesis **100**.
(65) The valve leaflets **109** may be attached to the skirt **112**. The valve leaflets **109** may be formed of various flexible materials including, but not limited to natural pericardial material such as tissue from bovine, equine or porcine origins, or synthetic materials such as polytetrafluoroethylene (PTFE), DACRON® polyester, pyrolytic carbon, or other biocompatible materials. With certain prosthetic leaflet materials, it may be desirable to coat one or both sides of the replacement valve leaflet with a material that will prevent or minimize overgrowth. It is further desirable that the prosthetic leaflet material is durable and not subject to stretching, deforming, or fatigue.
(66) For delivery, the transcatheter heart valve prosthesis **100** is radially compressed into a reduced-diameter crimped configuration onto a delivery system for delivery within a vasculature. As known in the art, the delivery system includes an inner shaft that receives the transcatheter heart valve prosthesis **100** on a distal portion thereof and an outer sheath or capsule that is configured to compressively retain the transcatheter heart valve prosthesis **100** on the distal portion of the inner shaft during delivery. Stated another way, the outer sheath or capsule surrounds and constrains the transcatheter heart valve prosthesis **100** in the radially compressed or crimped configuration. An exemplary delivery system for delivering the transcatheter heart valve prosthesis **100** is described in U.S. Pat. No. 9,034,032 to McLean et al. and International Patent Application No. PCT/US2014/029549 to McLean et al, previously incorporated by reference herein. However, it will be apparent to one of ordinary skill in the art that other delivery systems may be utilized and that the components of the delivery system may vary depending upon the configuration and structure of the transcatheter valve prosthesis that is being delivered.
(67) Referring to FIG. **2** as well as FIG. **5**, the structure of the valve support **104** will now be described in more detail. FIG. **5** is an enlarged side view of a plurality of side openings **118** of the valve support **104**. The valve support **104** includes a plurality of crowns **120** and a plurality of struts **122** with each crown **120** being formed between a pair of opposing struts **122**. Each crown **120** is a curved segment or bend extending between opposing struts **122**. The valve support **104** is tubular, with the plurality of side openings **118** being defined by edges of the plurality of crowns **120** and the plurality of struts **122**. In an embodiment, the plurality of side openings **118** may be substantially diamond-shaped. The valve support **104** includes a plurality of nodes **121**. A node **121** is defined as a region where two crowns of the plurality of crowns **120** within the valve support **104** meet or connect. As best shown in FIG. **5**, in this embodiment, the skirt **112** is attached to an inner surface of the valve support **104** around a circumference thereof. The skirt **112** lines the inner surface of the valve support **104** and spans across or extends over each side opening **118** of the plurality of side openings **118**. Notably, as shown in FIG. **5**, it is not required that the skirt **112**

extend over the full opening of each side opening **118**. Rather, the skirt **112** may span or cover only a portion of the side opening **118** as shown in FIG. **5**.

(68) A series of endmost inflow crowns **120**A are formed at the inflow end **101** of the valve support **104**, and a series of endmost outflow crowns **120**B are formed at the outflow end **103** of the valve support **104**. In an embodiment, the inflow end **101** of the valve support **104** has a total of nine endmost inflow crowns **120**A around a circumference thereof. The inflow end **101** of the valve support **104** includes a row of side openings **118** around a circumference thereof, and the row has a total of nine side openings **118**. Further, outflow end **103** of the valve support **104** has a total of nine endmost inflow crowns **120**B around a circumference thereof. The outflow end **103** of the valve support **104** includes a row of side openings **118** around a circumference thereof, and the row has a total of nine side openings **118**. In another embodiment hereof (not shown), each of the inflow end **101** and the outflow end **103** of the valve support **104** has between six and nine endmost inflow crowns **120**A, **120**B around a circumference thereof and includes the row of side openings **118** around a circumference thereof that includes between six and nine side openings **118**.

(69) A width W of the side openings **118** is relatively wider as compared to other stents or frames known in the art, thereby resulting a relatively lower total of side openings **118** around a circumference of the valve support **104**. In an embodiment, width W is between 1/24.sup.th and ⅙.sup.th of the circumference of the valve support **104**, or stated another way, between 4% and 16% of the circumference of the valve support **104**. By increasing the width of the side openings **118**, a lesser amount of material is required for the valve support **104** such that a lower profile may be achieved when the valve support **104** is crimped into a radially compressed configuration for delivery. More particularly, since the frame **102** includes both the valve support **104** and the anchor element **106**, it is a challenge to reduce the profile of the transcatheter valve prosthesis **100** in the crimped or radially compressed configuration. The challenge with reducing the profile is that, in the crimped or radially compressed configuration, the incompressible material of the frame **102** imparts high compressive forces on the soft tissue material of the leaflets **109**. Such high compressive forces may alter the integrity of the leaflets **109**, thereby impacting the long-term durability of the transcatheter valve prosthesis **100**. However, increasing the width W of the side openings **118** provides a reduction of the incompressible material of the frame **102**, thereby enabling a lower profile in the crimped or radially compressed configuration.

(70) However, reducing the incompressible material of the frame **102** means that the skirt **112** spans a longer distance between nodes **121** or between struts **122**. Stated another way, with the width of the side openings **118** being relatively increased as described above, the amount of material of the skirt **112** that spans across the side openings **118** likewise increases and thus a greater amount of material of the skirt **112** is unattached to the valve support **104**. Referring now to FIGS. **6**A and **6**B, when an increased amount of material of the skirt **112** spans across the side openings **118**, there is an increased chance of the skirt **112** billowing or moving radially inwards towards the leaflets **109** as indicated by directional arrows **124**. The skirt **112** may billow during valve opening and closing in situ, and the leaflets **109** may contact the skirt **112**. Such billowing may undesirably result in contact between the skirt **112** and the leaflets **109** of the transcatheter heart valve prosthesis **100**. If the leaflets **109** of the transcatheter heart valve prosthesis **100** contact the skirt **112** during opening and closing, such contact may cause early leaflet tissue abrasion as well as early skirt abrasion. Additionally, the greater relative motion between the skirt **112** and the valve support **104** may further induce early skirt abrasion.

(71) Embodiments hereof relate to skirt-reinforcement members that reinforce the material of the skirt **112** that spans across the side openings **118** of the valve support **104** to limit the radial motion or billowing of the skirt material, thereby minimizing risk of damage to both the skirt **112** and the leaflets **109**. For sake of illustration, the skirt-reinforcement members described herein are incorporated onto the valve support **104**, as the structure of the valve support **104** has already been described in detail above. However, as previously stated, the skirt-reinforcements members

described herein may be incorporated onto any stent or frame having a skirt for which reinforcement thereof is desirable to limit billowing, and it is not required that the stent or frame include a prosthetic valve component disposed therein.

(72) Turning to FIGS. **7**A and **7**B, a skirt-reinforcement member **1330** according to an aspect of the disclosure is illustrated. More particularly, FIG. **7**A and FIG. **7**B are side and perspective atrial end views, respectively, of the valve support **104** including a plurality of skirt-reinforcement members **730**. In the embodiment of FIGS. **7**A and **7**B, the valve support **104** includes a row of side openings **118** around a circumference thereof and a skirt-reinforcement member **730** spans across or extends over each side opening **118** of the row of side openings **118** around the circumference of the valve support **104**. However, it is not required that a skirt-reinforcement member **730** be utilized on every side opening **118** of the row of side openings **118** around the circumference of the valve support **104**. Rather, a skirt-reinforcement member **730** may be utilized only on the side openings **118** having skirt material that may come into contact with leaflets **109** when the leaflets are opening and closing in situ. At least one side opening **118** must include a skirt-reinforcement member **730** according to an aspect of the present disclosure. Each skirt-reinforcement member **730** spans a side opening **118** from a first crown or strut edge defining the at least one side opening **118** to a second crown or strut edge defining the at least one side opening **118**.

(73) In the embodiment of FIGS. **7**A and **7**B, each skirt-reinforcement member **730** is a filament or strand **731** of suture that forms a plurality of stitches **740**. Exemplary suture materials include but are not limited to a monofilament or plastic suture material, such as polypropylene. Each skirt-reinforcement member **730** is configured to restrict or prevent billowing, or radial motion, of the skirt **112** that spans across or extends over the respective side opening **118**. More particularly, each skirt-reinforcement member **730** has a first end **732**, a second end **734**, and a length L therebetween. The skirt-reinforcement member **730**, which includes the plurality of stitches **740**, is directly attached to the skirt **112** along its length L. Stated another way, the skirt-reinforcement member **730** is directly attached to the skirt **112** along an unsupported portion of the skirt **112** that spans the respective side opening **118**. As used herein, “unsupported portion of the skirt” refers to areas of the skirt **112** in which a surface of the skirt does not directly contact or abut against the valve support **104**. The plurality of stitches **740** of the skirt-reinforcement member **730** extends or weaves through the material of the skirt **112** to ensure that the skirt-reinforcement member **730** applies tension to the skirt **112** and thereby prevents undesired billowing of the skirt material.

(74) The first end **732** of the skirt-reinforcement member **730** is attached to a first edge **736** defining the respective side opening **118** and the second end **734** of the skirt-reinforcement member **730** is attached to a second or opposing edge **738** defining the respective side opening **118**. Attaching the first and second ends **732**, **734** of the skirt-reinforcement member **730** to the valve support **104** ensures that the skirt-reinforcement member **730** has sufficient rigidity to apply tension to the skirt **112** and prevent billowing. More particularly, the first and second ends **732**, **734** of the skirt-reinforcement member **730** are attached to the valve support **104** such that the skirt-reinforcement member **730** has sufficient tension along its length L to minimize radial movement of the skirt **112** throughout the cardiac cycle.

(75) As will be described in more detail herein, the first and second ends **732**, **734** of the skirt-reinforcement member **730** may be attached to a crown **120** or a strut **122** of the valve support **104**. Stated another way, the first and second edges **736**, **738** defining the respective side opening **118** may be edges of a crown **120** or a strut **122** of the valve support. In the embodiment depicted in FIGS. **7**A and **7**B, the first end **732** of the skirt-reinforcement member **730** is circumferentially aligned with the second end **734** of the skirt-reinforcement member **730** such that the skirt-reinforcement member **732** extends substantially perpendicular relative to an axis LA of the valve support **104**. The skirt-reinforcement member **730** extends over the side opening **118** in a center or middle thereof, such that the skirt-reinforcement member **730** spans across or extends over the side opening **118** at a maximum width MW thereof. The skirt-reinforcement member **730** spans across

the side opening **118** from one node **121** to another node **121** of the valve support **104**.
(76) In the embodiment depicted in FIGS. **7**A and **7**B, adjacent skirt-reinforcement members **730** are circumferentially aligned such that the skirt-reinforcement members **730** collectively circumscribe the valve support **104**. However, adjacent skirt-reinforcement members **730** are not required to be circumferentially aligned and further each side opening **118** is not required to include a skirt reinforcement member as described above.
(77) Other placements of the skirt-reinforcement members are contemplated herein. For example, in the embodiment depicted in FIGS. **8**A and **8**B, a first end **832** of a skirt-reinforcement member **830** is circumferentially offset from a second end **834** of the skirt-reinforcement member **830** such that the skirt-reinforcement member **830** is angled relative to the axis LA of the valve support **104**. The first end **832** of the skirt-reinforcement member **830** is attached to a first edge **836** defining the respective side opening **118** and the second end **834** of the skirt-reinforcement member **830** is attached to a second or opposing edge **838** defining the respective side opening **118**. The skirt-reinforcement member **830** spans diagonally across the side opening **118** from a top end of one node **121** to a bottom end of another node **121** of the valve support **104**, or alternatively may span diagonally across the side opening **118** from a node **121** to a strut **122** of the valve support **104**. In the embodiment depicted in FIGS. **8**A and **8**B, adjacent skirt-reinforcement members **830** have alternating orientations (i.e., diagonally downward and diagonally upward) such that the first end **832** of a skirt-reinforcement member **830** circumferentially aligns with a second end **834** of an adjacent skirt-reinforcement member **830** and the skirt-reinforcement members **830** collectively circumscribe the valve support **104** in a zig-zag configuration. However, adjacent skirt-reinforcement members **830** are not required to have alternating orientations and further each side opening **118** is not required to include a skirt reinforcement member as described above.
(78) In another embodiment depicted in FIGS. **9**A and **9**B, a first end **932** of a skirt-reinforcement member **930** is aligned with a second end **934** of the skirt-reinforcement member **930** such that the skirt-reinforcement member **932** extends substantially perpendicular relative to the axis LA of the valve support **104** similar to the skirt-reinforcement member **730** described above. The first end **932** of the skirt-reinforcement member **930** is attached to a first edge **936** defining the respective side opening **118** and the second end **934** of the skirt-reinforcement member **930** is attached to a second or opposing edge **938** defining the respective side opening **118**. However, in the embodiment of FIGS. **9**A and **9**B, the skirt-reinforcement member **930** extends over the side opening **118** in a lower region thereof, the lower region having width W**2** that is less than the maximum width MW. The skirt-reinforcement member **930** thus spans across or extends over the side opening **118** at the width W**2** thereof. The skirt-reinforcement member **930** spans across the side opening **118** from one node **121** to another node **121** of the valve support **104**, or alternatively may span across the side opening **118** from one strut **122** to another strut **122** of the valve support **104**. In the embodiment depicted in FIGS. **9**A and **9**B, adjacent skirt-reinforcement members **930** are circumferentially aligned such that the skirt-reinforcement members **930** collectively circumscribe the valve support **104**. However, adjacent skirt-reinforcement members **930** are not required to be circumferentially aligned and further each side opening **118** is not required to include a skirt reinforcement member as described above.
(79) Although the above embodiments depict the skirt-reinforcement members **730**, **830**, **930** having a generally linear or straight configuration within a side opening **118**, other configurations of the skirt-reinforcement members are contemplated herein. For example, the skirt-reinforcement members **730**, **830**, **930** may have a wavy, sinusoidal, or zig-zag configuration along its length or may be configured as “T” or “X” within a side opening **118**.
(80) Turning to FIGS. **10**A and **10**B, a skirt-reinforcement member **1030** according to another aspect of the disclosure is illustrated. More particularly, FIG. **10**A and FIG. **10**B are side and perspective atrial end views, respectively, of the valve support **104** including a plurality of skirt-reinforcement members **1030**. In the embodiment of FIGS. **10**A and **10**B, the valve support **104**

includes a row of side openings **118** around a circumference thereof and a skirt-reinforcement member **1030** spans across or extends over each side opening **118** of the row of side openings **118** around the circumference of the valve support **104**. However, it is not required that a skirt-reinforcement member **1030** be utilized on every side opening **118** of the row of side openings **118** around the circumference of the valve support **104**. Rather, a skirt-reinforcement member **1030** may be utilized only on the side openings **118** having skirt material that may come into contact with leaflets **109** when the leaflets are opening and closing in situ. At least one side opening **118** must include a skirt-reinforcement member **1030** according to an aspect of the present disclosure. Each skirt-reinforcement member **1030** spans a side opening **118** from a first crown or strut edge defining the at least one side opening **118** to a second crown or strut edge defining the at least one side opening **118**.

(81) Each skirt-reinforcement member **1030** is similar to the skirt-reinforcement member **730** except that each skirt-reinforcement member **1030** further includes a strip **1042** of fabric or tissue in addition to a filament or strand **1031** of suture that forms a plurality of stitches **1040**. The strips **1042** are attached to the skirt **112** via the plurality of stitches **1040** and may be disposed on an outer surface or an inner surface of the skirt **112**. Thus, as compared to the skirt-reinforcement member **730** described above which includes a plurality of stitches **740** formed by suture alone, the skirt-reinforcement member **1030** further includes strips **1042** of tissue or fabric in addition to the plurality of stitches **1040** formed by suture and thus provides more robust support or reinforcement.

(82) Similar to the skirt-reinforcement member **730**, each skirt-reinforcement member **1030** is configured to restrict or prevent billowing, or radial motion, of the skirt **112** that spans across or extends over the respective side opening **118**. More particularly, each skirt-reinforcement member **1030** has a first end **1032**, a second end **1034**, and a length L therebetween. The length L of the skirt-reinforcement member **1030**, which includes the plurality of stitches **1040** and one or more strips **1042** of tissue or fabric, is directly attached to the skirt **112** along its length L. Stated another way, the skirt-reinforcement member **1030** is directly attached to the skirt **112** along an unsupported portion of the skirt **112** that spans the respective side opening **118**. The plurality of stitches **1040** of the skirt-reinforcement member **1030** extends or weaves through the material of the skirt **112** and through the material of the strips **1042** of tissue or fabric, to ensure that the skirt-reinforcement member **1030** applies tension to the skirt **112** and thereby prevents undesired billowing of the skirt material.

(83) The first end **1032** of the skirt-reinforcement member **1030** is formed by the strand **1031** of suture of the skirt-reinforcement member **1030**, and is attached to a first edge **1036** defining the respective side opening **118**. The second end **1034** of the skirt-reinforcement member **1030** is also formed by the strand **1031** of suture of the skirt-reinforcement member **1030**, and is attached to a second or opposing edge **1038** defining the respective side opening **118**. Attaching the first and second ends **1032**, **1034** of the skirt-reinforcement member **1030** to the valve support **104** ensures that the skirt-reinforcement member **1030** has sufficient rigidity to apply tension to the skirt **112** and prevent billowing. More particularly, the first and second ends **1032**, **1034** of the skirt-reinforcement member **1030** are attached to the valve support **104** such that the skirt-reinforcement member **1030** has sufficient tension along its length L to minimize radial movement of the skirt **112** throughout the cardiac cycle.

(84) The first and second ends **1032**, **1034** of the skirt-reinforcement member **1030** may be attached to a crown **120** or a strut **122** of the valve support **104**. Stated another way, the first and second edges **1036**, **1038** defining the respective side opening **118** may be edges of a crown **120** or a strut **122** of the valve support. In the embodiment depicted in FIGS. **10**A and **10**B, the first end **1032** of the skirt-reinforcement member **1030** is aligned with the second end **1034** of the skirt-reinforcement member **1030** such that the skirt-reinforcement member **1032** extends substantially perpendicular relative to an axis LA of the valve support **104**. The skirt-reinforcement member **1030** extends over the side opening **118** in a center or middle thereof, such that the skirt-

reinforcement member **1030** spans across or extends over the side opening **118** at a maximum width MW thereof. The skirt-reinforcement member **1030** spans across the side opening **118** from one node **121** to another node **121** of the valve support **104**.

(85) The strips **1042** may be a natural or biological material such as pericardium or another membranous tissue such as intestinal submucosa. Alternatively, the strips **1042** may be a low-porosity woven or knit fabric, such as polyester, Dacron fabric, or PTFE knit. Exemplary suture materials for the strand **1031** include but are not limited to a monofilament or plastic suture material, such as polypropylene.

(86) The strips **1042** are relatively thin and have a thickness between 0.1 mm and 0.5 mm, and have a height (in the axial direction of the valve support **104**) between 0.2 mm up to the full height of the side opening **118**. The length of each strip **1042** is substantially the same as the length L of the strip-reinforcement member **1030** such that the strip **1042** extends substantially between the first end **1032** and the second end **1034** of the strip-reinforcement member **1030**.

(87) In another embodiment, the strip **1042** of fabric or tissue may be attached to the skirt **112** with a different fixation mechanism as an alternative to the plurality of stitches **1040**. For example, in another embodiment, the strip **1042** of fabric or tissue may be attached to the skirt **112** using adhesive. When utilizing adhesive as a fixation mechanism, the strip **1042** of fabric or tissue is disposed onto the skirt in a taut configuration to ensure that the skirt-reinforcement member **1030** applies tension to the skirt **112** and thereby prevents undesired billowing of the skirt material. Further, the adhesive may retract as it cures to apply further tension to the skirt material. Adhesive as a fixation mechanism provides more predictable packing or folding of the valve support **104** when the valve support **104** is collapsed into the radially compressed or crimped configuration for delivery.

(88) In the embodiment depicted in FIGS. **10**A and **10**B, adjacent skirt-reinforcement members **1030** are circumferentially aligned such that the skirt-reinforcement members **1030** collectively circumscribe the valve support **104**. However, adjacent skirt-reinforcement members **1030** are not required to be circumferentially aligned and further each side opening **118** is not required to include a skirt reinforcement member as described above.

(89) Other placements of the skirt-reinforcement member **1030** are contemplated herein. For example, in the embodiment depicted in FIGS. **11**A and **11**B, a first end **1132** of a skirt-reinforcement member **1130** is offset from a second end **1134** of the skirt-reinforcement member **1130** such that the skirt-reinforcement member **1130** is angled relative to the axis LA of the valve support **104**. The first end **1132** of the skirt-reinforcement member **1130** is attached to a first edge **1136** defining the respective side opening **118** and the second end **1134** of the skirt-reinforcement member **1130** is attached to a second or opposing edge **1138** defining the respective side opening **118**. The skirt-reinforcement member **1130** spans diagonally across the side opening **118** from a top end of one node **121** to a bottom end of another node **121** of the valve support **104**, or alternatively may span diagonally across the side opening **118** from a node **121** to a strut **122** of the valve support **104**. In the embodiment depicted in FIGS. **11**A and **11**B, adjacent skirt-reinforcement members **1130** have alternating orientations (i.e., diagonally downward and diagonally upward) such that the first end **1132** of a skirt-reinforcement member **1130** circumferentially aligns with a second end **1134** of an adjacent skirt-reinforcement member **1130** and the skirt-reinforcement members **1130** collectively circumscribe the valve support **104** in a zig-zag configuration. However, adjacent skirt-reinforcement members **1130** are not required to have alternating orientations and further each side opening **118** is not required to include a skirt reinforcement member as described above.

(90) In another embodiment depicted in FIGS. **12**A and **12**B, a first end **1232** of a skirt-reinforcement member **1230** is aligned with a second end **1234** of the skirt-reinforcement member **1230** such that the skirt-reinforcement member **1232** extends substantially perpendicular relative to the axis LA of the valve support **104** similar to the skirt-reinforcement member **1030** described

above. The first end **1232** of the skirt-reinforcement member **1230** is attached to a first edge **1236** defining the respective side opening **118** and the second end **1234** of the skirt-reinforcement member **1230** is attached to a second or opposing edge **1238** defining the respective side opening **118**. However, in the embodiment of FIGS. **12**A and **12**B, the skirt-reinforcement member **1230** extends over the side opening **118** in a lower region thereof, the lower region having width W**2** that is less than the maximum width MW. The skirt-reinforcement member **1230** thus spans across or extends over the side opening **118** at the width W**2** thereof. The skirt-reinforcement member **1230** spans across the side opening **118** from one node **121** to another node **121** of the valve support **104**, or alternatively may span across the side opening **118** from one strut **122** to another strut **122** of the valve support **104**. In the embodiment depicted in FIGS. **12**A and **12**B, adjacent skirt-reinforcement members **1230** are circumferentially aligned such that the skirt-reinforcement members **1230** collectively circumscribe the valve support **104**. However, adjacent skirt-reinforcement members **1230** are not required to be circumferentially aligned and further each side opening **118** is not required to include a skirt reinforcement member as described above.

(91) Although the above embodiments depict the skirt-reinforcement members **1030**, **1130**, **1230** having a generally linear or straight configuration, other configurations of the skirt-reinforcement members are contemplated herein. For example, the skirt-reinforcement members **1030**, **1130**, **1230** may have a wavy, sinusoidal, or zig-zag configuration along its length or may be configured as "T" or "X" within the side opening **118**.

(92) Turning now to FIG. **13**A and FIG. **13**B, a skirt-reinforcement member **1330** according to another aspect of the disclosure is illustrated. More particularly, FIG. **13**A is side view of the valve support **104** including the skirt-reinforcement member **1330** and FIG. **13**B illustrates a top view of the skirt-reinforcement member **1330** removed from the valve support **104** for sake of illustration. In the embodiment of FIG. **13**A and FIG. **13**B, the skirt-reinforcement member **1330** is a continuous band or ring **1344** that extends 360° around an outer surface **105** of the valve support **104**. Stated another way, the skirt-reinforcement member **1330** is circumferentially disposed around the perimeter of the valve support **104** and encircles or circumscribes the outer surface **105** of the valve support **104**. The ring **1344** is an elastic material and a diameter D**1** of the skirt-reinforcement member **1330** is approximately the same as a diameter D**2** of the valve support **104** when the valve support **104** is in its radially expanded configuration.

(93) Notably, the ring **1344** is directly attached to the skirt **112** along portions thereof that span across or extend over the side openings **118** of the valve support **104** but the ring **1344** is not directly attached to the valve support **104**. Stated another way, when the ring **1344** and the valve support **104** meet or intersect, the ring **1344** overlaps or overlays the valve support **104** but is not otherwise attached thereto. The ring **1344** is however attached to the skirt **112** to apply tension to the skirt **112** and thereby restrict or prevent billowing of the skirt **112** that spans across or extends over the side openings **118** of the valve support **104**. Thus, when the ring **1344** and the skirt **112** meet or intersect, the ring **1344** overlaps or overlays the skirt **112** and is further directly attached thereto. Since the ring **1344** is directly attached to the skirt **112**, is formed from an elastic material, and has the diameter D that is approximately the same as the expanded diameter of the valve support **104**, the skirt-reinforcement member **1330** has sufficient tension to minimize radial movement of the skirt **112** throughout the cardiac cycle. As such, the skirt-reinforcement member **1330** is configured to minimize radial movement of the skirt **112** and better protect the leaflets **109** from abrasion as well as prevent skirt degradation.

(94) The ring **1344** may be attached to the skirt **112** via any suitable attachment mechanism, including but not limited to suture, adhesive, or welding. Suitable elastic materials for the ring **1344** include but are not limited to polymer materials such as polyurethane or silicone, as well as biological or natural materials such as pericardium or another membranous tissue such as intestinal submucosa. "Elastic" as used herein includes materials that may be stretched or elongated to fit over and around the outer surface **105** of the valve support **104**, while also having sufficient

resiliency to resume their original size/configuration and conform to the outer surface **105** of the valve support **104**. The elastic material of the ring **1344** has sufficient resiliency to conform to and be secured over the outer surface **105** of the valve support **104**, but does not exert an amount of force that would result in constriction or reduction of the inner diameter of the valve support **104**.
(95) As stated above, the skirt-reinforcement members **730**, **830**, **930**, **1030**, **1130**, **1230**, **1330** may be utilized on any transcatheter heart valve prosthesis that includes a skirt on a portion thereof. The skirt-reinforcement members **730**, **830**, **930**, **1030**, **1130**, **1230**, **1330** serve to limit the radial motion or billowing of the skirt material, thereby minimizing risk of damage to both the skirt and the leaflets. Depending on the configuration of the frame, the particular placement of the skirt-reinforcement members may vary. In an embodiment, the skirt-reinforcement members are positioned downstream of a margin of attachment (MOA) of the leaflets of the transcatheter heart valve prosthesis and are positioned over a side opening of the frame that includes skirt material over a portion thereof. The configuration of the frame and the configuration of the side opening of the frame is non-limiting and may vary, as exemplified in the following figures.
(96) FIG. **14** depicts a perspective view of a transcatheter heart valve prosthesis **1400** in accordance with another aspect of the disclosure. The transcatheter heart valve prosthesis **1400** includes a stent or frame **1402** and a prosthetic valve component **1408** including at least one leaflet disposed within and secured to the frame **1402**. The frame **1402** includes a plurality of crowns **1420** and a plurality of struts **1422** with each crown **1420** being formed between a pair of opposing struts **1422**. Each crown **1420** is a curved segment or bend extending between opposing struts **1422**. The frame **1402** is tubular, with the plurality of side openings **1418** being defined by edges of the plurality of crowns **1420** and the plurality of struts **1422**. In an embodiment, the plurality of side openings **1418** may be substantially diamond-shaped.
(97) The frame **1402** includes a skirt **1412** coupled to a surface thereof. More particularly, the skirt **1412** is coupled to an inner surface of the frame **1402** to line a portion thereof. Alternatively, the skirt **1412** may be coupled to an outer surface of the frame **1402** to enclose a portion thereof as would be known to one of ordinary skill in the art of prosthetic valve construction. The skirt **1412** may be formed from the same materials described above with respect to the skirt **112**.
(98) The prosthetic valve component **1408** of the transcatheter heart valve prosthesis **1400** is capable of regulating flow therethrough via valve leaflets that may form a replacement valve. FIG. **14** illustrates an exemplary prosthetic valve component having three leaflets **1409**, although a single leaflet or bicuspid leaflet configuration may alternatively be used in embodiments hereof. As described above with respect to the prosthetic valve component **108**, when deployed in situ, the prosthetic valve component **1408** in a closed state is configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame **1402**.
(99) The valve leaflets **1409** may be attached to the skirt **1412**. The skirt **1412** may billow during valve opening and closing in situ, and the leaflets **1409** may contact the skirt **1412**. Such billowing may undesirably result in contact between the skirt **1412** and the leaflets **1409** of the transcatheter heart valve prosthesis **1400**. If the leaflets **1409** of the transcatheter heart valve prosthesis **1400** contact the skirt **1412** during opening and closing, such contact may cause early leaflet tissue abrasion as well as early skirt abrasion. Additionally, the greater relative motion between the skirt **1412** and the frame **1402** may further induce early skirt abrasion. Thus, the transcatheter heart valve prosthesis **1400** further includes a plurality of skirt-reinforcement members **1430**. As described above with respect to the skirt-reinforcement members **730** described above, the skirt-reinforcement members **1430** reinforce the material of the skirt **1412** that spans across the side openings **1418** of the frame **1402** to limit the radial motion or billowing of the skirt material, thereby minimizing risk of damage to both the skirt **1412** and the leaflets **1409**.
(100) In the embodiment of FIG. **14**, the frame **1402** includes a row of side openings **1418** around a circumference thereof and a skirt-reinforcement member **1430** spans across or extends over each side opening **1418** of the row of side openings **1418** around the circumference of the frame **1402**.

However, it is not required that a skirt-reinforcement member **1430** be utilized on every side opening **1418** of the row of side openings **1418** around the circumference of the frame **1402**. Rather, a skirt-reinforcement member **1430** may be utilized only on the side openings **1418** having skirt material that may come into contact with leaflets **1409** when the leaflets are opening and closing in situ. At least one side opening **1418** must include a skirt-reinforcement member **1430** according to an aspect of the present disclosure. Further, the placement of the skirt-reinforcement members **1430** is exemplary only and the skirt-reinforcement members **1430** may be disposed on side openings **1418** of different rows from that depicted on FIG. **14**.

(101) FIG. **14**A is an enlarged view of a side opening **1418** of the frame **1402** that includes a skirt-reinforcement member **1430**. Each skirt-reinforcement member **1430** spans a side opening **1418** from a first crown or strut edge defining the at least one side opening **1418** to a second crown or strut edge defining the at least one side opening **1418**. In the embodiments of FIGS. **14**-**14**A, the skirt-reinforcement members **1430** are the same as the skirt-reinforcement members **730**. Each skirt-reinforcement member **1430** is a filament or strand **1431** of suture that forms a plurality of stitches **1440**. The skirt-reinforcement member **1430** is directly attached to the skirt **1412** along an unsupported portion of the skirt **1412** that spans the respective side opening **1418**. The plurality of stitches **1440** of the skirt-reinforcement member **1430** extends or weaves through the material of the skirt **1412** to ensure that the skirt-reinforcement member **1430** applies tension to the skirt **1412** and thereby prevents undesired billowing of the skirt material. The first and second ends **1432**, **1434** of the skirt-reinforcement member **1430** are attached to the frame **1402** such that the skirt-reinforcement member **1430** has sufficient tension along its length to minimize radial movement of the skirt **1412** throughout the cardiac cycle.

(102) In FIGS. **14** and **14**A, the skirt-reinforcement member **1430** extends in a horizontal orientation over the side opening **1418** in a center or middle thereof. However, other placements of the skirt-reinforcement members are contemplated herein. For example, in the embodiment depicted in FIG. **14**B, a skirt-reinforcement member **1430**B extends in a vertical orientation over the side opening **1418** in a center or middle thereof. A first end **1432**B of a skirt-reinforcement member **1430**B is longitudinally offset from a second end **1434**B of the skirt-reinforcement member **1430**B such that the skirt-reinforcement member **1430**B is parallel or substantially parallel relative to the axis LA of the frame. The first end **1432**B of the skirt-reinforcement member **1430**B is attached to a first crown **1420**B defining the respective side opening **1418** and the second end **1434**B of the skirt-reinforcement member **1430** is attached to a second or opposing crown **1420**B defining the respective side opening **1418** such that the skirt-reinforcement member **1430**B spans vertically across the side opening **1418**.

(103) In another embodiment depicted in FIG. **14**C, a first end **1432**C of a skirt-reinforcement member **1430**C is circumferentially offset from a second end **1434**C of the skirt-reinforcement member **1430**C such that the skirt-reinforcement member **1430**C is angled relative to the axis LA of the frame. The first end **1432**C of the skirt-reinforcement member **1430**C is attached to a first edge **1436**C defining the respective side opening **1418** and the second end **1434**C of the skirt-reinforcement member **1430**C is attached to a second or opposing edge **1438**C defining the respective side opening **1418**. Adjacent skirt-reinforcement members **1430**C may have alternating orientations (i.e., diagonally downward and diagonally upward) such that the skirt-reinforcement members **1430**C collectively circumscribe the frame in a zig-zag configuration. However, adjacent skirt-reinforcement members **1430**C are not required to have alternating orientations and further each side opening **1418** is not required to include a skirt reinforcement member as described above.

(104) Similar to the skirt-reinforcement members **1030**, **1130**, **1230** described above, the skirt-reinforcement members **1430**, **1430**B, **1430**C may include a strip of fabric or tissue in addition to a filament or strand of suture that forms a plurality of stitches. In addition, an alternative to the plurality of skirt-reinforcement members **1430**, the transcatheter heart valve prosthesis **1400** may include a continuous band or ring that extends 360° around an outer surface of the frame **1402**. The

ring would be attached to the skirt **1412** and may be the same as the skirt-reinforcement member **1330** described above. The ring would be positioned over the same row of side openings **1418** as shown with respect to the skirt-reinforcement members **1430** in FIG. **14**.

(105) FIG. **15** depicts a perspective view of a transcatheter heart valve prosthesis **1500** in accordance with another aspect of the disclosure. The transcatheter heart valve prosthesis **1500** includes a stent or frame **1502** and a prosthetic valve component **1508** including at least one leaflet disposed within and secured to the frame **1502**. The frame **1502** includes a plurality of crowns **1520** and a plurality of struts **1522** with each crown **1520** being formed between a pair of opposing struts **1522**. Each crown **1520** is a curved segment or bend extending between opposing struts **1522**. The frame **1502** is tubular, with the plurality of side openings **1518** being defined by edges of the plurality of crowns **1520** and the plurality of struts **1522**. In an embodiment, the plurality of side openings **1518** may be substantially hexagonal-shaped.

(106) The frame **1502** includes a skirt **1512** coupled to a surface thereof. More particularly, the skirt **1512** is coupled to an inner surface of the frame **1502** to line a portion thereof. Alternatively, the skirt **1512** may be coupled to an outer surface of the frame **1502** to enclose a portion thereof as would be known to one of ordinary skill in the art of prosthetic valve construction. The skirt **1512** may be formed from the same materials described above with respect to the skirt **112**.

(107) The prosthetic valve component **1508** of the transcatheter heart valve prosthesis **1500** is capable of regulating flow therethrough via valve leaflets that may form a replacement valve. FIG. **15** illustrates an exemplary prosthetic valve component having three leaflets **1509**, although a single leaflet or bicuspid leaflet configuration may alternatively be used in embodiments hereof. As described above with respect to the prosthetic valve component **108**, when deployed in situ, the prosthetic valve component **1508** in a closed state is configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame **1502**.

(108) The valve leaflets **1509** may be attached to the skirt **1512**. The skirt **1512** may billow during valve opening and closing in situ, and the leaflets **1509** may contact the skirt **1512**. Such billowing may undesirably result in contact between the skirt **1512** and the leaflets **1509** of the transcatheter heart valve prosthesis **1500**. If the leaflets **1509** of the transcatheter heart valve prosthesis **1500** contact the skirt **1512** during opening and closing, such contact may cause early leaflet tissue abrasion as well as early skirt abrasion. Additionally, the greater relative motion between the skirt **1512** and the frame **1502** may further induce early skirt abrasion. Thus, the transcatheter heart valve prosthesis **1500** further includes a plurality of skirt-reinforcement members **1530**. As described above with respect to the skirt-reinforcement members **730** described above, the skirt-reinforcement members **1530** reinforce the material of the skirt **1512** that spans across the side openings **1518** of the frame **1502** to limit the radial motion or billowing of the skirt material, thereby minimizing risk of damage to both the skirt **1512** and the leaflets **1509**.

(109) In the embodiment of FIG. **15**, the frame **1502** includes a row of side openings **1518** around a circumference thereof and a skirt-reinforcement member **1530** spans across or extends over each side opening **1518** of the row of side openings **1518** around the circumference of the frame **1502**. However, it is not required that a skirt-reinforcement member **1530** be utilized on every side opening **1518** of the row of side openings **1518** around the circumference of the frame **1502**. Rather, a skirt-reinforcement member **1530** may be utilized only on the side openings **1518** having skirt material that may come into contact with leaflets **1509** when the leaflets are opening and closing in situ. At least one side opening **1518** must include a skirt-reinforcement member **1530** according to an aspect of the present disclosure. Further, the placement of the skirt-reinforcement members **1530** is exemplary only and the skirt-reinforcement members **1530** may be disposed on side openings **1518** of different rows from that depicted on FIG. **15**.

(110) FIG. **15**A is an enlarged view of a side opening **1518** of the frame **1502** that includes a skirt-reinforcement member **1530**. Each skirt-reinforcement member **1530** spans a side opening **1518** from a first crown or strut edge defining the at least one side opening **1518** to a second crown or

strut edge defining the at least one side opening **1518**. In the embodiments of FIGS. **15-15**A, the skirt-reinforcement members **1530** are the same as the skirt-reinforcement members **730**. Each skirt-reinforcement member **1530** is a filament or strand **1531** of suture that forms a plurality of stitches **1540**. The skirt-reinforcement member **1530** is directly attached to the skirt **1512** along an unsupported portion of the skirt **1512** that spans the respective side opening **1518**. A plurality of stitches **1540** of the skirt-reinforcement member **1530** extends or weaves through the material of the skirt **1512** to ensure that the skirt-reinforcement member **1530** applies tension to the skirt **1512** and thereby prevents undesired billowing of the skirt material. The first and second ends **1532**, **1534** of the skirt-reinforcement member **1530** are attached to the frame **1502** such that the skirt-reinforcement member **1530** has sufficient tension along its length to minimize radial movement of the skirt **1512** throughout the cardiac cycle.

(111) In FIGS. **15** and **15**A, the skirt-reinforcement member **1530** extends in a horizontal orientation over the side opening **1518** in a center or middle thereof. However, other placements of the skirt-reinforcement members are contemplated herein. For example, in the embodiment depicted in FIG. **15**B, a skirt-reinforcement member **1530**B extends in a vertical orientation over the side opening **1518** in a center or middle thereof. A first end **1532**B of a skirt-reinforcement member **1530**B is longitudinally offset from a second end **1534**B of the skirt-reinforcement member **1530**B such that the skirt-reinforcement member **1530**B is parallel or substantially parallel relative to the axis LA of the frame. The first end **1532**B of the skirt-reinforcement member **1530**B is attached to a first crown **1520**B defining the respective side opening **1518** and the second end **1534**B of the skirt-reinforcement member **1530** is attached to a second or opposing crown **1520**B defining the respective side opening **1518** such that the skirt-reinforcement member **1530**B spans vertically across the side opening **1518**.

(112) In another embodiment depicted in FIG. **15**C, a first end **1532**C of a skirt-reinforcement member **1530**C is circumferentially offset from a second end **1534**C of the skirt-reinforcement member **1530**C such that the skirt-reinforcement member **1530**C is angled relative to the axis LA of the frame. The first end **1532**C of the skirt-reinforcement member **1530**C is attached to a first edge **1536**C defining the respective side opening **1518** and the second end **1534**C of the skirt-reinforcement member **1530**C is attached to a second or opposing edge **1538**C defining the respective side opening **1518**. Adjacent skirt-reinforcement members **1530**C may have alternating orientations (i.e., diagonally downward and diagonally upward) such that the skirt-reinforcement members **1530**C collectively circumscribe the frame in a zig-zag configuration. However, adjacent skirt-reinforcement members **1530**C are not required to have alternating orientations and further each side opening **1518** is not required to include a skirt reinforcement member as described above.

(113) Similar to the skirt-reinforcement members **1030**, **1130**, **1230** described above, the skirt-reinforcement members **1530**, **1530**B, **1530**C may include a strip of fabric or tissue in addition to a filament or strand of suture that forms a plurality of stitches. In addition, an alternative to the plurality of skirt-reinforcement members **1530**, the transcatheter heart valve prosthesis **1500** may include a continuous band or ring that extends 360° around an outer surface of the frame **1502**. The ring would be attached to the skirt **1512** and may be the same as the skirt-reinforcement member **1330** described above. The ring would be positioned over the same row of side openings **1518** as shown with respect to the skirt-reinforcement members **1530** in FIG. **15**.

(114) FIG. **16** depicts a perspective view of a transcatheter heart valve prosthesis **1600** in accordance with another aspect of the disclosure. The transcatheter heart valve prosthesis **1600** includes a stent or frame **1602** and a prosthetic valve component **1608** including at least one leaflet disposed within and secured to the frame **1602**. The frame **1602** includes a plurality of crowns **1620** and a plurality of struts **1622** with each crown **1620** being formed between a pair of opposing struts **1622**. Each crown **1620** is a curved segment or bend extending between opposing struts **1622**. The frame **1602** is tubular, with the plurality of side openings **1618** being defined by edges of the plurality of crowns **1620** and the plurality of struts **1622**. In an embodiment, the plurality of side

openings **1618** may be substantially diamond-shaped.
(115) The frame **1602** includes a skirt **1612** coupled to a surface thereof. More particularly, the skirt **1612** is coupled to an inner surface of the frame **1602** to line a portion thereof. Alternatively, the skirt **1612** may be coupled to an outer surface of the frame **1602** to enclose a portion thereof as would be known to one of ordinary skill in the art of prosthetic valve construction. The skirt **1612** may be formed from the same materials described above with respect to the skirt **112**.
(116) The prosthetic valve component **1608** of the transcatheter heart valve prosthesis **1600** is capable of regulating flow therethrough via valve leaflets that may form a replacement valve. FIG. **16** illustrates an exemplary prosthetic valve component having three leaflets **1609**, although a single leaflet or bicuspid leaflet configuration may alternatively be used in embodiments hereof. As described above with respect to the prosthetic valve component **108**, when deployed in situ, the prosthetic valve component **1608** in a closed state is configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame **1602**.
(117) The valve leaflets **1609** may be attached to the skirt **1612**. The skirt **1612** may billow during valve opening and closing in situ, and the leaflets **1609** may contact the skirt **1612**. Such billowing may undesirably result in contact between the skirt **1612** and the leaflets **1609** of the transcatheter heart valve prosthesis **1600**. If the leaflets **1609** of the transcatheter heart valve prosthesis **1600** contact the skirt **1612** during opening and closing, such contact may cause early leaflet tissue abrasion as well as early skirt abrasion. Additionally, the greater relative motion between the skirt **1612** and the frame **1602** may further induce early skirt abrasion. Thus, the transcatheter heart valve prosthesis **1600** further includes a plurality of skirt-reinforcement members **1630**. As described above with respect to the skirt-reinforcement members **730** described above, the skirt-reinforcement members **1630** reinforce the material of the skirt **1612** that spans across the side openings **1618** of the frame **1602** to limit the radial motion or billowing of the skirt material, thereby minimizing risk of damage to both the skirt **1612** and the leaflets **1609**.
(118) In the embodiment of FIG. **16**, the frame **1602** includes exactly three skirt-reinforcement members **1630** (although two skirt-reinforcement members are obscured from view). The skirt-reinforcement members **1630** are disposed at the leaflet commissures and are spaced at substantially equal intervals around a circumference of the frame **102**. However, the placement of the skirt-reinforcement members **1630** is exemplary only and the skirt-reinforcement members **1630** may be disposed at different side openings **1618** from those depicted on FIG. **16**.
(119) FIG. **16**A is an enlarged view of a side opening **1618** of the frame **1602** that includes a skirt-reinforcement member **1630**. Each skirt-reinforcement member **1630** spans a side opening **1618** from a first crown or strut edge defining the at least one side opening **1618** to a second crown or strut edge defining the at least one side opening **1618**. In the embodiments of FIGS. **16**-**16**A, the skirt-reinforcement members **1630** are the same as the skirt-reinforcement members **730**. Each skirt-reinforcement member **1630** is a filament or strand **1631** of suture that forms a plurality of stitches **1640**. The skirt-reinforcement member **1630** is directly attached to the skirt **1612** along an unsupported portion of the skirt **1612** that spans the respective side opening **1618**. A plurality of stitches **1640** of the skirt-reinforcement member **1630** extends or weaves through the material of the skirt **1612** to ensure that the skirt-reinforcement member **1630** applies tension to the skirt **1612** and thereby prevents undesired billowing of the skirt material. The first and second ends **1632**, **1634** of the skirt-reinforcement member **1630** are attached to the frame **1602** such that the skirt-reinforcement member **1630** has sufficient tension along its length to minimize radial movement of the skirt **1612** throughout the cardiac cycle.
(120) In FIGS. **16** and **16**A, the skirt-reinforcement member **1630** extends in a horizontal orientation over the side opening **1618** in a center or middle thereof. However, other placements of the skirt-reinforcement members are contemplated herein. For example, in the embodiment depicted in FIG. **16**B, a skirt-reinforcement member **1630**B extends in a vertical orientation over the side opening **1618** in a center or middle thereof. A first end **1632**B of a skirt-reinforcement

member **1630**B is longitudinally offset from a second end **1634**B of the skirt-reinforcement member **1630**B such that the skirt-reinforcement member **1630**B is parallel or substantially parallel relative to the axis LA of the frame. The first end **1632**B of the skirt-reinforcement member **1630**B is attached to a first crown **1620**B defining the respective side opening **1618** and the second end **1634**B of the skirt-reinforcement member **1630** is attached to a second or opposing crown **1620**B defining the respective side opening **1618** such that the skirt-reinforcement member **1630**B spans vertically across the side opening **1618**.

(121) In another embodiment depicted in FIG. **16**C, a first end **1632**C of a skirt-reinforcement member **1630**C is circumferentially offset from a second end **1634**C of the skirt-reinforcement member **1630**C such that the skirt-reinforcement member **1630**C is angled relative to the axis LA of the frame. The first end **1632**C of the skirt-reinforcement member **1630**C is attached to a first edge **1636**C defining the respective side opening **1618** and the second end **1634**C of the skirt-reinforcement member **1630**C is attached to a second or opposing edge **1638**C defining the respective side opening **1618**.

(122) Similar to the skirt-reinforcement members **1030**, **1130**, **1230** described above, the skirt-reinforcement members **1630**, **1630**B, **1630**C may include a strip of fabric or tissue in addition to a filament or strand of suture that forms a plurality of stitches. In addition, an alternative to the plurality of skirt-reinforcement members **1630**, the transcatheter heart valve prosthesis **1600** may include a continuous band or ring that extends 360° around an outer surface of the frame **1602**. The ring would be attached to the skirt **1612** and may be the same as the skirt-reinforcement member **1330** described above.

(123) FIG. **17** depicts a perspective view of a transcatheter heart valve prosthesis **1700** in accordance with another aspect of the disclosure. The transcatheter heart valve prosthesis **1700** includes a stent or frame **1702** and a prosthetic valve component **1708** including at least one leaflet disposed within and secured to the frame **1702**. The frame **1702** includes a plurality of crowns **1720** and a plurality of struts **1722** with each crown **1720** being formed between a pair of opposing struts **1722**. Each crown **1720** is a curved segment or bend extending between opposing struts **1722**. The frame **1702** is tubular, with the plurality of side openings **1718** being defined by edges of the plurality of crowns **1720** and the plurality of struts **1722**. In an embodiment, the plurality of side openings **1718** may be substantially heart-shaped, with each side opening **1718** being formed by six struts **1722** and six crowns **1720**.

(124) The frame **1702** includes a skirt **1712** coupled to a surface thereof. More particularly, the skirt **1712** is coupled to an inner surface of the frame **1702** to line a portion thereof. Alternatively, the skirt **1712** may be coupled to an outer surface of the frame **1702** to enclose a portion thereof as would be known to one of ordinary skill in the art of prosthetic valve construction. The skirt **1712** may be formed from the same materials described above with respect to the skirt **112**.

(125) The prosthetic valve component **1708** of the transcatheter heart valve prosthesis **1700** is capable of regulating flow therethrough via valve leaflets that may form a replacement valve. FIG. **17** illustrates an exemplary prosthetic valve component having three leaflets **1709**, although a single leaflet or bicuspid leaflet configuration may alternatively be used in embodiments hereof. As described above with respect to the prosthetic valve component **108**, when deployed in situ, the prosthetic valve component **1708** in a closed state is configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame **1702**.

(126) The valve leaflets **1709** may be attached to the skirt **1712**. The skirt **1712** may billow during valve opening and closing in situ, and the leaflets **1709** may contact the skirt **1712**. Such billowing may undesirably result in contact between the skirt **1712** and the leaflets **1709** of the transcatheter heart valve prosthesis **1700**. If the leaflets **1709** of the transcatheter heart valve prosthesis **1700** contact the skirt **1712** during opening and closing, such contact may cause early leaflet tissue abrasion as well as early skirt abrasion. Additionally, the greater relative motion between the skirt **1712** and the frame **1702** may further induce early skirt abrasion. Thus, the transcatheter heart

valve prosthesis **1700** further includes a plurality of skirt-reinforcement members **1730**. As described above with respect to the skirt-reinforcement members **730** described above, the skirt-reinforcement members **1730** reinforce the material of the skirt **1712** that spans across the side openings **1718** of the frame **1702** to limit the radial motion or billowing of the skirt material, thereby minimizing risk of damage to both the skirt **1712** and the leaflets **1709**.

(127) In the embodiment of FIG. **17**, the frame **1702** includes a row of side openings **1718** around a circumference thereof and a skirt-reinforcement member **1730** spans across or extends over each side opening **1718** of the row of side openings **1718** around the circumference of the frame **1702**. However, it is not required that a skirt-reinforcement member **1730** be utilized on every side opening **1718** of the row of side openings **1718** around the circumference of the frame **1702**. Rather, a skirt-reinforcement member **1730** may be utilized only on the side openings **1718** having skirt material that may come into contact with leaflets **1709** when the leaflets are opening and closing in situ. At least one side opening **1718** must include a skirt-reinforcement member **1730** according to an aspect of the present disclosure. Further, the placement of the skirt-reinforcement members **1730** is exemplary only and the skirt-reinforcement members **1730** may be disposed on side openings **1718** of different rows from that depicted on FIG. **17**.

(128) FIG. **17**A is an enlarged view of a side opening **1718** of the frame **1702** that includes a skirt-reinforcement member **1730**. Each skirt-reinforcement member **1730** spans a side opening **1718** from a first crown or strut edge defining the at least one side opening **1718** to a second crown or strut edge defining the at least one side opening **1718**. In the embodiments of FIGS. **17**-**17**A, the skirt-reinforcement members **1730** are the same as the skirt-reinforcement members **730**. Each skirt-reinforcement member **1730** is a filament or strand **1731** of suture that forms a plurality of stitches **1740**. The skirt-reinforcement member **1730** is directly attached to the skirt **1712** along an unsupported portion of the skirt **1712** that spans the respective side opening **1718**. A plurality of stitches **1740** of the skirt-reinforcement member **1730** extends or weaves through the material of the skirt **1712** to ensure that the skirt-reinforcement member **1730** applies tension to the skirt **1712** and thereby prevents undesired billowing of the skirt material. The first and second ends **1732**, **1734** of the skirt-reinforcement member **1730** are attached to the frame **1702** such that the skirt-reinforcement member **1730** has sufficient tension along its length to minimize radial movement of the skirt **1712** throughout the cardiac cycle.

(129) In FIGS. **17** and **17**A, the skirt-reinforcement member **1730** extends in a horizontal orientation over the side opening **1718**. However, other placements of the skirt-reinforcement members are contemplated herein. For example, in the embodiment depicted in FIG. **17**B, a skirt-reinforcement member **1730**B extends in a vertical orientation over the side opening **1718** in a center or middle thereof. A first end **1732**B of a skirt-reinforcement member **1730**B is longitudinally offset from a second end **1734**B of the skirt-reinforcement member **1730**B such that the skirt-reinforcement member **1730**B is parallel or substantially parallel relative to the axis LA of the frame. The first end **1732**B of the skirt-reinforcement member **1730**B is attached to a first crown **1720**B defining the respective side opening **1718** and the second end **1734**B of the skirt-reinforcement member **1730** is attached to a second or opposing crown **1720**B defining the respective side opening **1718** such that the skirt-reinforcement member **1730**B spans vertically across the side opening **1718**.

(130) In another embodiment depicted in FIG. **17**C, a first end **1732**C of a skirt-reinforcement member **1730**C is circumferentially offset from a second end **1734**C of the skirt-reinforcement member **1730**C such that the skirt-reinforcement member **1730**C is angled relative to the axis LA of the frame. The first end **1732**C of the skirt-reinforcement member **1730**C is attached to a first edge **1736**C defining the respective side opening **1718** and the second end **1734**C of the skirt-reinforcement member **1730**C is attached to a second or opposing edge **1738**C defining the respective side opening **1718**. Adjacent skirt-reinforcement members **1730**C may have alternating orientations (i.e., diagonally downward and diagonally upward) such that the skirt-reinforcement

members **1730**C collectively circumscribe the frame in a zig-zag configuration. However, adjacent skirt-reinforcement members **1730**C are not required to have alternating orientations and further each side opening **1718** is not required to include a skirt reinforcement member as described above.
(131) In another embodiment depicted in FIG. **17**D, two skirt-reinforcement members **1730**D.sub.1, **1730**D.sub.2 extend in a horizontal orientation over a single side opening **1718**. Each skirt-reinforcement member **1730**D.sub.1, **1730**D.sub.2 spans the side opening **1718** from a first crown or strut edge defining the side opening **1718** to a second crown or strut edge defining the at least one side opening **1718**. In the depicted embodiment, each skirt-reinforcement member **1730**D.sub.1, **1730**D.sub.2 has a first end attached to a first crown **1720** defining the respective side opening **1718** and a second end attached to a second or opposing crown **1720** defining the respective side opening **1718**. In the depicted embodiment, each skirt-reinforcement member **1730**D.sub.1, **1730**D.sub.2 are aligned with each other and have the same orientation, but the placement of the skirt-reinforcement members **11730**D.sub.1, **1730**D.sub.2 are exemplary only and the skirt-reinforcement members **1730**D.sub.1, **1730**D.sub.2 may be disposed in different orientations from that depicted on FIG. **17**.
(132) Similar to the skirt-reinforcement members **1030**, **1130**, **1230** described above, the skirt-reinforcement members **1730**, **1730**B, **1730**C may include a strip of fabric or tissue in addition to a filament or strand of suture that forms a plurality of stitches. In addition, an alternative to the plurality of skirt-reinforcement members **1730**, the transcatheter heart valve prosthesis **1700** may include a continuous band or ring that extends 360° around an outer surface of the frame **1702**. The ring would be attached to the skirt **1712** and may be the same as the skirt-reinforcement member **1330** described above. The ring would be positioned over the same row of side openings **1718** as shown with respect to the skirt-reinforcement members **1730** in FIG. **17**.
(133) FIG. **18** depicts a perspective view of a transcatheter heart valve prosthesis **1800** in accordance with another aspect of the disclosure. The transcatheter heart valve prosthesis **1800** includes a stent or frame **1802** and a prosthetic valve component **1808** including at least one leaflet disposed within and secured to the frame **1802**. The frame **1802** includes a plurality of crowns **1820** and a plurality of struts **1822** with each crown **1820** being formed between a pair of opposing struts **1822**. Each crown **1820** is a curved segment or bend extending between opposing struts **1822**. The frame **1802** is tubular, with the plurality of side openings **1818** being defined by edges of the plurality of crowns **1820** and the plurality of struts **1822**. The frame **1802** includes five rows of side openings **1818**, labeled as rows r.sub.1, r.sub.2, r.sub.3, r.sub.4, r.sub.5 on FIG. **18**. In an embodiment, the plurality of side openings **1818** on each of rows r.sub.3, r.sub.4, r.sub.5, may be substantially diamond-shaped, while the side openings **1818** on row r.sub.2 are each defined by five struts **1822** and the side openings **1818** on row r.sub.1 are each defined by six struts **1822**.
(134) The frame **1802** includes a skirt **1812** coupled to a surface thereof. More particularly, the skirt **1812** is coupled to an inner surface of the frame **1802** to line a portion thereof. Alternatively, the skirt **1812** may be coupled to an outer surface of the frame **1802** to enclose a portion thereof as would be known to one of ordinary skill in the art of prosthetic valve construction. The skirt **1812** may be formed from the same materials described above with respect to the skirt **112**.
(135) The prosthetic valve component **1808** of the transcatheter heart valve prosthesis **1800** is capable of regulating flow therethrough via valve leaflets that may form a replacement valve. FIG. **18** illustrates an exemplary prosthetic valve component having three leaflets **1809**, although a single leaflet or bicuspid leaflet configuration may alternatively be used in embodiments hereof. As described above with respect to the prosthetic valve component **108**, when deployed in situ, the prosthetic valve component **1808** in a closed state is configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame **1802**.
(136) The valve leaflets **1809** may be attached to the skirt **1812**. The skirt **1812** may billow during valve opening and closing in situ, and the leaflets **1809** may contact the skirt **1812**. Such billowing may undesirably result in contact between the skirt **1812** and the leaflets **1809** of the transcatheter

heart valve prosthesis **1800**. If the leaflets **1809** of the transcatheter heart valve prosthesis **1800** contact the skirt **1812** during opening and closing, such contact may cause early leaflet tissue abrasion as well as early skirt abrasion. Additionally, the greater relative motion between the skirt **1812** and the frame **1802** may further induce early skirt abrasion. Thus, the transcatheter heart valve prosthesis **1800** further includes a plurality of skirt-reinforcement members **1830**. As described above with respect to the skirt-reinforcement members **730** described above, the skirt-reinforcement members **1830** reinforce the material of the skirt **1812** that spans across the side openings **1818** of the frame **1802** to limit the radial motion or billowing of the skirt material, thereby minimizing risk of damage to both the skirt **1812** and the leaflets **1809**.

(137) In the embodiment of FIG. **18**, a skirt-reinforcement member **1830** spans across or extends over each side opening **1818** of row r.sub.2 of side openings **1818** around the circumference of the frame **1802** and as well as each side opening **1818** of row r.sub.4 of side openings **1818** around the circumference of the frame **1802**. However, it is not required that a skirt-reinforcement member **1830** be utilized on every side opening **1818** of the rows r.sub.2, r.sub.4 of the side openings **1818** around the circumference of the frame **1802**. Rather, a skirt-reinforcement member **1830** may be utilized only on the side openings **1818** having skirt material that may come into contact with leaflets **1809** when the leaflets are opening and closing in situ. At least one side opening **1818** must include a skirt-reinforcement member **1830** according to an aspect of the present disclosure. Further, the placement of the skirt-reinforcement members **1830** on rows r.sub.2, r.sub.4 of side openings **1818** is exemplary only and the skirt-reinforcement members **1830** may be disposed on the side openings **1818** of different rows from those depicted on FIG. **18**.

(138) FIG. **18**A is an enlarged view of a side opening **1818** of the frame **1802** that includes a skirt-reinforcement member **1830**. Each skirt-reinforcement member **1830** spans a side opening **1818** from a first crown or strut edge defining the at least one side opening **1818** to a second crown or strut edge defining the at least one side opening **1818**. In the embodiments of FIGS. **18**-**18**A, the skirt-reinforcement members **1830** are the same as the skirt-reinforcement members **730**. Each skirt-reinforcement member **1830** is a filament or strand **1831** of suture that forms a plurality of stitches **1840**. The skirt-reinforcement member **1830** is directly attached to the skirt **1812** along an unsupported portion of the skirt **1812** that spans the respective side opening **1818**. A plurality of stitches **1840** of the skirt-reinforcement member **1830** extends or weaves through the material of the skirt **1812** to ensure that the skirt-reinforcement member **1830** applies tension to the skirt **1812** and thereby prevents undesired billowing of the skirt material. The first and second ends **1832**, **1834** of the skirt-reinforcement member **1830** are attached to the frame **1802** such that the skirt-reinforcement member **1830** has sufficient tension along its length to minimize radial movement of the skirt **1812** throughout the cardiac cycle.

(139) In FIGS. **18** and **18**A, the skirt-reinforcement member **1830** extends in a horizontal orientation over the side opening **1818** in a center or middle thereof. However, other placements of the skirt-reinforcement members are contemplated herein. For example, in the embodiment depicted in FIG. **18**B, a skirt-reinforcement member **1830**B extends in a vertical orientation over the side opening **1818** in a center or middle thereof. A first end **1832**B of a skirt-reinforcement member **1830**B is longitudinally offset from a second end **1834**B of the skirt-reinforcement member **1830**B such that the skirt-reinforcement member **1830**B is parallel or substantially parallel relative to the axis LA of the frame. The first end **1832**B of the skirt-reinforcement member **1830**B is attached to a first crown **1820**B defining the respective side opening **1818** and the second end **1834**B of the skirt-reinforcement member **1830** is attached to a second or opposing crown **1820**B defining the respective side opening **1818** such that the skirt-reinforcement member **1830**B spans vertically across the side opening **1818**.

(140) In another embodiment depicted in FIG. **18**C, a first end **1832**C of a skirt-reinforcement member **1830**C is circumferentially offset from a second end **1834**C of the skirt-reinforcement member **1830**C such that the skirt-reinforcement member **1830**C is angled relative to the axis LA

of the frame. The first end **1832**C of the skirt-reinforcement member **1830**C is attached to a first crown **1820**, or a first edge, defining the respective side opening **1818** and the second end **1834**C of the skirt-reinforcement member **1830**C is attached to a second or opposing crown **1820**, or a second or opposing edge, defining the respective side opening **1818**. Adjacent skirt-reinforcement members **1830**C may have alternating orientations (i.e., diagonally downward and diagonally upward) such that the skirt-reinforcement members **1830**C collectively circumscribe the frame in a zig-zag configuration. However, adjacent skirt-reinforcement members **1830**C are not required to have alternating orientations and further each side opening **1818** is not required to include a skirt reinforcement member as described above.

(141) Similar to the skirt-reinforcement members **1030**, **1130**, **1230** described above, the skirt-reinforcement members **1830**, **1830**B, **1830**C may include a strip of fabric or tissue in addition to a filament or strand of suture that forms a plurality of stitches. In addition, an alternative to the plurality of skirt-reinforcement members **1830**, the transcatheter heart valve prosthesis **1800** may include a continuous band or ring that extends 360° around an outer surface of the frame **1802**. The ring would be attached to the skirt **1812** and may be the same as the skirt-reinforcement member **1330** described above. The ring may be positioned over the same rows of side openings **1818** as shown with respect to the skirt-reinforcement members **1830** in FIG. **18**.

(142) Although embodiments above depict various transcatheter valve prostheses having at least one skirt-reinforcement member, the skirt-reinforcement members described herein may be applied to a docking prosthesis that is configured to receive a valve prosthesis therein. Such docking prostheses may include a skirt on a portion thereof that may come into contact with a leaflet of the valve prosthesis received therein when the leaflets are opening and closing in situ. For example, FIG. **19** depicts a perspective view of a docking prosthesis **1900** in accordance with another aspect of the disclosure. The docking prosthesis **1900** includes a stent or frame **1902**. The frame **1902** includes a plurality of crowns **1920** and a plurality of struts **1922** with each crown **1920** being formed between a pair of opposing struts **1922**. Each crown **1920** is a curved segment or bend extending between opposing struts **1922**. The frame **1902** is tubular, with the plurality of side openings **1918** being defined by edges of the plurality of crowns **1920** and the plurality of struts **1922**. In an embodiment, the plurality of side openings **1918** may be substantially diamond-shaped.

(143) The frame **1902** includes a skirt **1912** coupled to a surface thereof. More particularly, the skirt **1912** is coupled to an inner surface of the frame **1902** to line a portion thereof. Alternatively, the skirt **1912** may be coupled to an outer surface of the frame **1902** to enclose a portion thereof. The skirt **1912** may be formed from the same materials described above with respect to the skirt **112**.

(144) With reference to FIG. **20**, the docking prosthesis **1900** is configured to receive a valve prosthesis **2000** therein. The valve prosthesis **2000** includes a frame **2002** and a prosthetic valve component **2008** including at least one leaflet disposed within and secured to the frame **2002**. The prosthetic valve component **2008** of the valve prosthesis **2000** is capable of regulating flow therethrough via valve leaflets that may form a replacement valve. The prosthetic valve component **2008** may have three leaflets **2009**, although a single leaflet or bicuspid leaflet configuration may alternatively be used in embodiments hereof. As described above with respect to the prosthetic valve component **108**, when deployed in situ, the prosthetic valve component **2008** in a closed state is configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame **2002**. The valve leaflets **2009** may be attached to the frame **2002**.

(145) The skirt **1912** of the docking prosthesis **1900** may billow during opening and closing of the leaflets **2009** in situ, and the leaflets **2009** may contact the skirt **1912**. Such billowing may undesirably result in contact between the skirt **1912** of the docking prosthesis **1900** and the leaflets **2009** of the valve prosthesis **2000**. If the leaflets **2009** contact the skirt **1912** during opening and closing, such contact may cause early leaflet tissue abrasion as well as early skirt abrasion. Additionally, the greater relative motion between the skirt **1912** and the frame **1902** may further induce early skirt abrasion. Thus, the docking prosthesis **1900** further includes a plurality of skirt-

reinforcement members **1930**. As described above with respect to the skirt-reinforcement members **730** described above, the skirt-reinforcement members **1930** reinforce the material of the skirt **1912** that spans across the side openings **1918** of the frame **1902** to limit the radial motion or billowing of the skirt material, thereby minimizing risk of damage to both the skirt **1912** and the leaflets **2009**.

(146) In the embodiment of FIG. **19**, the frame **1902** includes a row of side openings **1918** around a circumference thereof and a skirt-reinforcement member **1930** spans across or extends over each side opening **1918** of the row of side openings **1918** around the circumference of the frame **1902**. However, it is not required that a skirt-reinforcement member **1930** be utilized on every side opening **1918** of the row of side openings **1918** around the circumference of the frame **1902**. Rather, a skirt-reinforcement member **1930** may be utilized only on the side openings **1918** having skirt material that may come into contact with leaflets **2009** when the leaflets are opening and closing in situ. At least one side opening **1918** must include a skirt-reinforcement member **1930** according to an aspect of the present disclosure. Further, the placement of the skirt-reinforcement members **1930** is exemplary only and the skirt-reinforcement members **1930** may be disposed on side openings **1918** of different rows from that depicted on FIG. **19**.

(147) FIG. **19**A is an enlarged view of a side opening **1918** of the frame **1902** that includes a skirt-reinforcement member **1930**. Each skirt-reinforcement member **1930** spans a side opening **1918** from a first crown or strut edge defining the at least one side opening **1918** to a second crown or strut edge defining the at least one side opening **1918**. In the embodiments of FIGS. **19**-**19**A, the skirt-reinforcement members **1930** are the same as the skirt-reinforcement members **730**. Each skirt-reinforcement member **1930** is a filament or strand **1931** of suture that forms a plurality of stitches **1940**. The skirt-reinforcement member **1930** is directly attached to the skirt **1912** along an unsupported portion of the skirt **1912** that spans the respective side opening **1918**. A plurality of stitches **1940** of the skirt-reinforcement member **1930** extends or weaves through the material of the skirt **1912** to ensure that the skirt-reinforcement member **1930** applies tension to the skirt **1912** and thereby prevents undesired billowing of the skirt material. The first and second ends **1932**, **1934** of the skirt-reinforcement member **1930** are attached to the frame **1902** such that the skirt-reinforcement member **1930** has sufficient tension along its length to minimize radial movement of the skirt **1912** throughout the cardiac cycle.

(148) In FIGS. **19** and **19**A, the skirt-reinforcement member **1930** extends in a horizontal orientation over the side opening **1918** in a center or middle thereof. However, other placements of the skirt-reinforcement members are contemplated herein. For example, in the embodiment depicted in FIG. **19**B, a skirt-reinforcement member **1930**B extends in a vertical orientation over the side opening **1918** in a center or middle thereof. A first end **1932**B of a skirt-reinforcement member **1930**B is longitudinally offset from a second end **1934**B of the skirt-reinforcement member **1930**B such that the skirt-reinforcement member **1930**B is parallel or substantially parallel relative to the axis LA of the frame. The first end **1932**B of the skirt-reinforcement member **1930**B is attached to a first crown **1920**B defining the respective side opening **1918** and the second end **1934**B of the skirt-reinforcement member **1930** is attached to a second or opposing crown **1920**B defining the respective side opening **1918** such that the skirt-reinforcement member **1930**B spans vertically across the side opening **1918**.

(149) In another embodiment depicted in FIG. **19**C, a first end **1932**C of a skirt-reinforcement member **1930**C is circumferentially offset from a second end **1934**C of the skirt-reinforcement member **1930**C such that the skirt-reinforcement member **1930**C is angled relative to the axis LA of the frame. The first end **1932**C of the skirt-reinforcement member **1930**C is attached to a first edge **1936**C defining the respective side opening **1918** and the second end **1934**C of the skirt-reinforcement member **1930**C is attached to a second or opposing edge **1938**C defining the respective side opening **1918**. Adjacent skirt-reinforcement members **1930**C may have alternating orientations (i.e., diagonally downward and diagonally upward) such that the skirt-reinforcement

members **1930**C collectively circumscribe the frame in a zig-zag configuration. However, adjacent skirt-reinforcement members **1930**C are not required to have alternating orientations and further each side opening **1918** is not required to include a skirt reinforcement member as described above.
(150) Similar to the skirt-reinforcement members **1030**, **1130**, **1230** described above, the skirt-reinforcement members **1930**, **1930**B, **1930**C may include a strip of fabric or tissue in addition to a filament or strand of suture that forms a plurality of stitches. In addition, an alternative to the plurality of skirt-reinforcement members **1930**, the docking prosthesis **1900** may include a continuous band or ring that extends 360° around an outer surface of the frame **1902**. The ring would be attached to the skirt **1912** and may be the same as the skirt-reinforcement member **1330** described above. The ring would be positioned over the same row of side openings **1918** as shown with respect to the skirt-reinforcement members **1930** in FIG. **19**.
(151) It should be understood that various aspects disclosed herein may be combined in different combinations than the combinations specifically presented in the description and accompanying drawings. It should also be understood that, depending on the example, certain acts or events of any of the processes or methods described herein may be performed in a different sequence, may be added, merged, or left out altogether (e.g., all described acts or events may not be necessary to carry out the techniques). In addition, while certain aspects of this disclosure are described as being performed by a single module or unit for purposes of clarity, it should be understood that the techniques of this disclosure may be performed by a combination of units or modules associated with, for example, a medical device.

Claims

1. A prosthesis having a radially expanded configuration and a radially compressed configuration, the prosthesis comprising: a frame including a plurality of crowns and a plurality of struts with each crown being formed between a pair of opposing struts, wherein a plurality of side openings is defined by edges of the plurality of crowns and the plurality of struts; a skirt coupled to a surface of the frame, wherein the skirt extends over at least one side opening of the plurality of side openings of the frame; a prosthetic valve component including a plurality of leaflets disposed within and secured to the frame, the prosthetic valve being configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame, wherein a margin of attachment is formed at the junction of the leaflets to the skirt; and a skirt-reinforcement member that spans the at least one side opening of the plurality of side openings of the frame from a first crown or strut edge defining the at least one side opening to a second crown or strut edge defining the at least one side opening, wherein the skirt-reinforcement member is longitudinally spaced apart from the margin of attachment, the skirt-reinforcement member having a first end, a second end, and a length therebetween, wherein the first end of the skirt-reinforcement member is attached to the first crown or strut edge and the second end of the skirt-reinforcement member is attached to the second crown or strut edge, and wherein the skirt-reinforcement member is attached to the skirt along an unsupported portion of the skirt that spans the at least one side opening.
2. The prosthesis of claim 1, wherein the skirt-reinforcement member includes a suture forming a plurality of stitches.
3. The prosthesis of claim 1, wherein the skirt-reinforcement member includes tissue.
4. The prosthesis of claim 1, wherein the skirt-reinforcement member includes fabric.
5. The prosthesis of claim 1, wherein an end of the frame includes a row of side openings around a circumference of the frame, the row including between six and nine side openings.
6. The prosthesis of claim 1, wherein the first end of the skirt-reinforcement member is circumferentially offset from the second end of the skirt-reinforcement member such that the skirt-reinforcement member is angled relative to an axis of the frame.
7. The prosthesis of claim 1, wherein the first end of the skirt-reinforcement member is

circumferentially aligned with the second end of the skirt-reinforcement member such that the skirt-reinforcement member extends substantially perpendicular relative to an axis of the frame.
8. The prosthesis of claim 7, wherein the at least one side opening includes a maximum width and the skirt-reinforcement member spans across the at least one side opening at the maximum width.
9. The prosthesis of claim 7, wherein the frame includes a plurality of nodes, each node being a region where two of the plurality of crowns of the frame meet, and wherein the skirt-reinforcement member spans across the at least one side opening from one node to another node.
10. The prosthesis of claim 1, wherein the frame includes a row of side openings around a circumference of the frame and a skirt-reinforcement member spans each side opening of the row of side openings around the circumference of the frame.
11. The prosthesis of claim 1, wherein the frame is an inner frame and the prosthesis further comprises an outer frame coupled to the inner frame, the outer frame having a greater diameter than the inner frame.
12. The prosthesis of claim 1, wherein the prosthesis is a heart-valve prosthesis and the skirt-reinforcement member is positioned downstream of the margin of attachment.
13. The prosthesis of claim 12, wherein the heart-valve prosthesis is configured for placement within a mitral valve in situ.
14. A prosthesis having a radially expanded configuration and a radially compressed configuration, the prosthesis comprising: a frame including a plurality of crowns and a plurality of struts with each crown being formed between a pair of opposing struts, wherein a plurality of side openings is defined by edges of the plurality of crowns and the plurality of struts; a skirt coupled to a surface of the frame, wherein the skirt extends over at least one side opening of the plurality of side openings of the frame; a prosthetic valve component including a plurality of leaflets disposed within and secured to the frame, the prosthetic valve being configured to block blood flow in one direction to regulate blood flow through a central lumen of the frame, wherein a margin of attachment is formed at the junction of the leaflets to the skirt; and a skirt-reinforcement member that circumscribes an outer surface of the frame, wherein at least a portion of the skirt-reinforcement member is longitudinally spaced apart from the margin of attachment, wherein skirt-reinforcement member is attached to the skirt along an unsupported portion of the skirt that spans the at least one side opening of the plurality of side openings of the frame and wherein the skirt-reinforcement member is not directly attached to the frame.
15. The prosthesis of claim 14, wherein the skirt-reinforcement member is a ring of an elastic material.
16. The prosthesis of claim 14, wherein the at least one side opening of the plurality of side openings is substantially diamond-shaped.
17. The prosthesis of claim 14, wherein an end of the frame includes a row of side openings around a circumference of the frame, the row including between six and nine side openings.
18. The prosthesis of claim 14, wherein the frame is an inner frame and the prosthesis further comprises an outer frame coupled to the inner frame, the outer frame having a greater diameter than the inner frame.
19. The prosthesis of claim 14, wherein the prosthesis is a heart-valve prosthesis and the skirt-reinforcement member is positioned downstream of the margin of attachment.
20. The prosthesis of claim 19, wherein the heart-valve prosthesis is configured for placement within a mitral valve in situ.