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Inventor(s)

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### **Stationary intra-annular halo designs for paravalvular leak (PVL) reduction—active channel filling cuff designs**

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#### **Abstract**

A prosthetic heart valve may include a collapsible and expandable stent extending in a flow direction between a proximal end and a distal end, a cuff attached to an annulus section of the stent and having an outer surface facing in a radial direction orthogonal to the flow direction, a plurality of prosthetic valve leaflets attached to the cuff, and a sealing structure attached to the annulus section of the stent at an inner edge of the sealing structure. The flow direction may be defined from the proximal end toward the distal end. The sealing structure may have an outer edge remote from the inner edge. The sealing structure may have a collapsed condition with the outer edge disposed adjacent the outer surface of the cuff and an expanded condition with the outer edge spaced apart from the outer surface of the cuff.

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## **Background/Summary**

CROSS-REFERENCE TO RELATED APPLICATIONS (1) The present application is a continuation of U.S. patent application Ser. No. 16/680,782 filed Nov. 12, 2019, now U.S. Pat. No. 11,419,716, which is a continuation of U.S. patent application Ser. No. 15/710,007 filed Sep. 20, 2017, now U.S. Pat. No. 10,500,039, which is a divisional application of U.S. patent application Ser. No. 14/601,810 filed Jan. 21, 2015, now U.S. Pat. No. 9,820,852, which claims the benefit of the filing date of U.S. Provisional Patent Application No. 61/931,265 filed Jan. 24, 2014, the disclosures of which are hereby incorporated herein by reference.

### **BACKGROUND OF THE INVENTION**

(1) The present disclosure relates in general to heart valve replacement and, in particular, to collapsible prosthetic heart valves. More particularly, the present disclosure relates to devices and methods for positioning and sealing collapsible prosthetic heart valves within a native valve annulus.

(2) Prosthetic heart valves that are collapsible to a relatively small circumferential size can be delivered into a patient less invasively than valves that are not collapsible. For example, a collapsible valve may be delivered into a patient via a tube-like delivery apparatus such as a catheter, a trocar, a laparoscopic instrument, or the like. This collapsibility can avoid the need for a more invasive procedure such as full open-chest, open-heart surgery.

(3) Collapsible prosthetic heart valves typically take the form of a valve structure mounted on a stent. There are two common types of stents on which the valve structures are ordinarily mounted: a self-expanding stent or a balloon-expandable stent. To place such valves into a delivery apparatus and ultimately into a patient, the valve must first be collapsed or crimped to reduce its circumferential size.

(4) When a collapsed prosthetic valve has reached the desired implant site in the patient (e.g., at or near the annulus of the patient's heart valve that is to be replaced by the prosthetic valve), the prosthetic valve can be deployed or released from the delivery apparatus and re-expanded to full operating size. For balloon-expandable valves, this generally involves releasing the entire valve, and then expanding a balloon positioned within the valve stent. For self-expanding valves, on the other hand, the stent automatically expands as the sheath covering the valve is withdrawn.

### **BRIEF SUMMARY OF THE INVENTION**

(5) Prosthetic heart valves and methods of expanding a prosthetic heart valve between native leaflets of a native aortic annulus of a patient are disclosed.

(6) A prosthetic heart valve configured to be expanded between leaflets of a native aortic valve of a patient may include a collapsible and expandable stent extending in a flow direction between a proximal end and a distal end, a cuff attached to an annulus section of the stent and having an outer surface facing in a radial direction orthogonal to the flow direction, a plurality of prosthetic valve leaflets attached to the cuff, and a sealing structure attached to the annulus section of the stent at an inner edge of the sealing structure.

(7) The annulus section of the stent may be adjacent the proximal end, and the stent may include a plurality of struts shaped to form a plurality of cells connected to one another in a plurality of annular rows around the stent. The flow direction may be defined from the proximal end toward the distal end. The sealing structure may have an outer edge remote from the inner edge. The sealing

structure may have a collapsed condition with the outer edge disposed adjacent the outer surface of the cuff and an expanded condition with the outer edge spaced apart from the outer surface of the cuff.

(8) In the expanded condition of the sealing structure, a top surface of the cuff extending between the inner and outer edges thereof may generally face toward the distal end of the stent in the flow direction. The top surface may include a plurality of openings in fluid communication with an interior of the sealing structure. The top surface of the sealing structure may include a porous material having a multitude of small apertures adapted to allow unidirectional blood flow into an interior of the sealing structure. The sealing structure may extend continuously around a circumference of the stent.

(9) In the expanded condition of the sealing structure, an inner end portion of the top surface may be disposed adjacent the outer surface of the cuff and an outer end portion of the top surface may extend away from the outer surface of the cuff at a transverse angle to the flow direction. The prosthetic heart valve may also include a plurality of support members each extending between the stent and the outer edge of the sealing structure. The prosthetic heart valve may also include at least one stored energy element biased to provide a force to the sealing structure away from the cuff in a radial direction orthogonal to the flow direction when at least a portion of the sealing structure is radially compressed toward the cuff.

(10) The at least one stored energy element may include a plurality of storage elements circumferentially spaced apart from one another between the inner edge and the outer edge of the sealing structure. The at least one stored energy element may include a spring that extends in at least one complete loop about a circumference of the sealing structure between the inner edge and the outer edge.

(11) A prosthetic heart valve configured to be expanded between leaflets of a native aortic valve of a patient may include a collapsible and expandable stent extending in a flow direction between a proximal end and a distal end, a cuff attached to an annulus section of the stent and having an outer surface facing in a radial direction orthogonal to the flow direction, a plurality of prosthetic valve leaflets attached to the cuff, and a plurality of sealing members each attached to the annulus section of the cuff.

(12) The annulus section of the stent may be adjacent the proximal end, and the stent may include a plurality of struts shaped to form a plurality of cells connected to one another in a plurality of annular rows around the stent. The flow direction may be the direction from the proximal end toward the distal end. Each sealing member may have an open side facing generally toward the distal end of the stent and a closed side facing generally toward the proximal end of the stent, so that blood flowing in a direction opposite the flow direction will enter at least one of the sealing members through the open side and cause an outer surface of the at least one sealing member to move away from the outer surface of the cuff.

(13) Each sealing member may have a shape selected from the group consisting of generally triangular, generally crescent-shaped, generally rectangular, or generally square. The plurality of sealing members may collectively extend completely around a circumference of the stent. Each of the sealing members may be entirely located between the proximal end of the stent and locations at which the leaflets are attached to the cuff. The stent may include commissure features each located at a juncture of adjacent ones of the leaflets. At least a portion of each leaflet may be attached to one of the commissure features. Each of the sealing members may be substantially aligned in the flow direction with a corresponding one of the commissure features.

(14) The plurality of sealing members may include a first group of sealing members having a first width and a second group of sealing members having a second width less than the first width. Each of the sealing members in the first group may extend around a greater portion of a circumference of the stent than each of the sealing members in the second group. The stent may include commissure features each located at a juncture of adjacent ones of the leaflets. At least a portion of each leaflet

may be attached to one of the commissure features. The sealing members in the first group may be substantially aligned in the flow direction with the commissure features.

(15) Each of the sealing members in the second group may be substantially aligned in the flow direction with portions of the leaflets that are attached to the cuff closest to the proximal end of the stent. The sealing members may include lower sealing members and upper sealing members. The upper sealing members may be spaced in the flow direction of the stent above the lower sealing members.

(16) The plurality of sealing members may include a group of lower sealing members and a group of upper sealing members. The open sides of the sealing members in the lower group may be spaced a first distance from the proximal end of the stent in the flow direction. Open sides of the sealing members in the upper group may be spaced a second distance from the proximal end of the stent in the flow direction. The second distance may be greater than the first distance.

(17) The open sides of the lower sealing members may be spaced apart about a circumference of the stent by first openings. The open sides of the upper sealing members may be spaced apart about the circumference of the stent by second openings. The open sides of the upper sealing members may be aligned in the flow direction with the first openings, and the open sides of the lower sealing members may be aligned in the flow direction with the second openings, such that any blood flow in a direction opposite the flow direction along the outer surface of the cuff will encounter at least one of the open sides of the upper or lower sealing members.

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## **Description**

### **BRIEF DESCRIPTION OF THE DRAWINGS**

- (1) Various embodiments of heart valves are disclosed herein with reference to the drawings, wherein:
- (2) FIG. 1 is a side elevational view of a conventional prosthetic heart valve;
- (3) FIG. 2A is a highly schematic cross-sectional view taken along line A-A of FIG. 1 and showing the prosthetic heart valve disposed within a native valve annulus;
- (4) FIG. 2B is a highly schematic cross-sectional view showing a prosthetic mitral valve disposed within a native valve annulus;
- (5) FIG. 3A is a highly schematic side view of another embodiment of a heart valve having a sealing ring intended to fill irregularities between the heart valve and the native valve annulus;
- (6) FIG. 3B is a schematic end view of the prosthetic heart valve of FIG. 3A as seen from the annulus end toward the aortic end of the heart valve;
- (7) FIG. 3C is a highly schematic side view of a variation of the embodiment shown in FIGS. 3A and 3B;
- (8) FIG. 4 is a side view of another embodiment of a heart valve having a higher cuff height;
- (9) FIG. 5A is a highly schematic perspective view of an alternative sealing ring embodiment that can be used with the stent, cuff, and leaflets of FIG. 3A;
- (10) FIG. 5B is a highly schematic top view of an alternative sealing ring embodiment that can be used with the stent, cuff, and leaflets of FIG. 3A;
- (11) FIGS. 5C-5F are highly schematic perspective views of alternative sealing ring embodiments that can be used with the stent, cuff, and leaflets of FIG. 3A;
- (12) FIG. 5G is a highly schematic cross-sectional view of an alternative sealing ring embodiment that can be used with any of the sealing ring embodiments of FIGS. 5A-5F;
- (13) FIG. 6A is a schematic side view of another embodiment of a heart valve having a sealing ring intended to fill irregularities between the heart valve and the native valve annulus;
- (14) FIGS. 6B-6F are highly schematic top views of alternative sealing ring embodiments that can be used with the stent, cuff, and leaflets of FIG. 6A;

- (15) FIGS. 7A and 7B are schematic side views of alternative embodiments of heart valves having a sealing ring intended to fill irregularities between the heart valve and the native valve annulus;
- (16) FIG. 8A is a partial developed view of the stent, sealing members, and cuff of another embodiment of a heart valve having sealing members intended to fill irregularities between the heart valve and the native valve annulus;
- (17) FIGS. 8B and 8C are developed views of the stent and cuff of FIG. 8A, with alternative sealing members;
- (18) FIG. 9A is a developed view of the stent, sealing members, and leaflets of another embodiment of a heart valve having sealing members intended to fill irregularities between the heart valve and the native valve annulus;
- (19) FIGS. 9B-9D are developed views the stent and leaflets of FIG. 9A, with alternative sealing members;
- (20) FIG. 10A is a developed view of the stent, sealing members, and leaflets of another embodiment of a heart valve having sealing members intended to fill irregularities between the heart valve and the native valve annulus; and
- (21) FIG. 10B is a side view of a heart valve having the stent and sealing members of FIG. 10A.
- (22) Various embodiments of the present disclosure will now be described with reference to the appended drawings. It is to be appreciated that these drawings depict only some embodiments of the disclosure and are therefore not to be considered limiting of its scope.

#### DETAILED DESCRIPTION

- (23) With conventional self expanding valves, clinical success of the valve is dependent on accurate deployment and anchoring. One possibility on valve implantation is leakage of blood between the implanted heart valve and the native valve annulus, commonly referred to as perivalvular leakage (also known as “paravalvular leakage”). In aortic valves, this leakage enables blood to flow from the aorta back into the left ventricle, reducing cardiac efficiency and putting a greater strain on the heart muscle. Additionally, calcification of the aortic valve may affect performance and the interaction between the implanted valve and the calcified tissue is believed to be relevant to leakage, as will be outlined below.
- (24) Moreover, anatomical variations from one patient to another may cause a fully deployed heart valve to function improperly, requiring removal of the valve from the patient. Removing a fully deployed heart valve increases the length of the procedure as well as the risk of post-operative problems. Thus, methods and devices are desirable that would reduce the need to remove a prosthetic heart valve from a patient. Methods and devices are also desirable that would reduce the likelihood of perivalvular leakage due to gaps between the implanted heart valve and patient tissue.
- (25) As used herein, the term “proximal,” when used in connection with a prosthetic heart valve, refers to the end of the heart valve closest to the heart when the heart valve is implanted in a patient, whereas the term “distal,” when used in connection with a prosthetic heart valve, refers to the end of the heart valve farthest from the heart when the heart valve is implanted in a patient. When used in connection with devices for delivering a prosthetic heart valve or other medical device into a patient, the terms “trailing” and “leading” are to be taken as relative to the user of the delivery devices. “Trailing” is to be understood as relatively close to the user, and “leading” is to be understood as relatively farther away from the user. Also as used herein, the terms “generally,” “substantially,” “approximately,” and “about” are intended to mean that slight deviations from absolute are included within the scope of the term so modified.
- (26) When used to indicate relative locations within the aortic annulus, the aortic root, and the ascending aorta of a patient, the terms “above” and “below” are to be taken as relative to the juncture between the aortic annulus and the left ventricle. “Above” is to be understood as relatively farther from the left ventricle, and “below” is to be understood as relatively closer to the left ventricle.
- (27) When used to indicate relative locations within the prosthetic heart valve, the terms

“longitudinal” and “vertical” are to be taken as the direction of the axis extending between the proximal end and the distal end of the stent of the heart valve, along the direction of intended blood flow; the term “flow direction” is to be taken as the direction from the proximal end to the distal end of the stent of the heart valve, along the direction of intended blood flow; and the terms “above,” “below,” “high,” and “low” are to be taken as relative to the proximal end of the stent. “Above” and “high” are to be understood as relatively farther from the proximal end of the stent in the flow direction toward the distal end of the stent, and “below” and “low” are to be understood as relatively closer to the proximal end of the stent in the flow direction. When used to indicate relative locations within the prosthetic heart valve, the term “circumferential” is to be taken as the direction of rotation about an axis extending in the flow direction of the stent.

(28) The sealing portions of the present disclosure may be used in connection with collapsible prosthetic heart valves. FIG. 1 shows one such collapsible stent-supported prosthetic heart valve **100** including a stent **102** and a valve assembly **104** as is known in the art. The prosthetic heart valve **100** is designed to replace a native tricuspid valve of a patient, such as a native aortic valve. It should be noted that while the inventions herein are described predominantly in connection with their use with a prosthetic aortic valve and a stent having a shape as illustrated in FIG. 1, the valve could be a bicuspid valve, such as the mitral valve, and the stent could have different shapes, such as a flared or conical annulus section, a less-bulbous aortic section, and the like, and a differently shaped transition section.

(29) The stent **102** may be formed from biocompatible materials that are capable of self-expansion, such as, for example, shape memory alloys, such as the nickel-titanium alloy known as “Nitinol” or other suitable metals or polymers. The stent **102** extends from a proximal or annulus end **130** to a distal or aortic end **132**, and includes an annulus section **140** adjacent the proximal end **130**, a transition section **141**, and an aortic section **142** adjacent the distal end **132**. The annulus section **140** has a relatively small cross-section in the expanded condition, while the aortic section **142** has a relatively large cross-section in the expanded condition. The annulus section **140** may be in the form of a cylinder having a substantially constant diameter along its length. The transition section **141** may taper outwardly from the annulus section **140** to the aortic section **142**.

(30) Each of the sections of the stent **102** includes a plurality of struts **160** forming cells **162** connected to one another in one or more annular rows around the stent. For example, as shown in FIG. 1, the annulus section **140** may have two annular rows of complete cells **162** and the aortic section **142** and the transition section **141** may each have one or more annular rows of partial cells **162**. The cells **162** in the aortic section **142** may be larger than the cells **162** in the annulus section **140**. The larger cells in the aortic section **142** better enable the prosthetic valve **100** to be positioned in the native valve annulus without the stent structure interfering with blood flow to the coronary arteries.

(31) The stent **102** may include one or more retaining elements **168** at the distal end **132** thereof, the retaining elements **168** being sized and shaped to cooperate with female retaining structures (not shown) provided on the deployment device. The engagement of the retaining elements **168** with the female retaining structures on the deployment device helps maintain the prosthetic heart valve **100** in assembled relationship with the deployment device, minimizes longitudinal movement of the prosthetic heart valve relative to the deployment device during unsheathing or resheathing procedures, and helps prevent rotation of the prosthetic heart valve relative to the deployment device as the deployment device is advanced to the target location and the heart valve deployed.

(32) The prosthetic heart valve **100** includes a valve assembly **104** preferably positioned in the annulus section **140** of the stent **102** and secured to the stent. The valve assembly **104** includes a cuff **176** and a plurality of leaflets **178** which collectively function as a one-way valve by coapting with one another. As a prosthetic aortic valve, the prosthetic heart valve **100** has three leaflets **178**. However, it will be appreciated that other prosthetic heart valves with which the sealing portions of the present disclosure may be used may have a greater or lesser number of leaflets **178**.

(33) Although the cuff **176** is shown in FIG. **1** as being disposed on the luminal or inner surface of the annulus section **140**, it is contemplated that the cuff **176** may be disposed on the abluminal or outer surface of the annulus section **140** or may cover all or part of either or both of the luminal and abluminal surfaces. Both the cuff **176** and the leaflets **178** may be wholly or partly formed of any suitable biological material or polymer such as, for example, polytetrafluoroethylene (PTFE), polyvinyl alcohol (PVA), ultra-high molecular weight polyethylene (UHMWPE), silicone, urethane and the like.

(34) The leaflets **178** may be attached along their belly portions to the cells **162** of the stent **102**, with the commissure between adjacent leaflets **178** being attached to commissure features **166**. As can be seen in FIG. **1**, each commissure feature **166** may lie at the intersection of four cells **162**, two of the cells being adjacent one another in the same annular row, and the other two cells being in different annular rows and lying in end-to-end relationship. Preferably, the commissure features **166** are positioned entirely within the annulus section **140** or at the juncture of the annulus section **140** and the transition section **141**. The commissure features **166** may include one or more eyelets which facilitate the suturing of the leaflet commissure to the stent **102**.

(35) The prosthetic heart valve **100** may be used to replace a native aortic valve, a surgical heart valve, or a heart valve that has undergone a surgical procedure. The prosthetic heart valve **100** may be delivered to the desired site (e.g., near the native aortic annulus) using any suitable delivery device. During delivery, the prosthetic heart valve **100** is disposed inside the delivery device in the collapsed condition. The delivery device may be introduced into a patient using a transfemoral, transapical, transseptal, transradial, transsubclavian, transaortic or any other percutaneous approach. Once the delivery device has reached the target site, the user may deploy the prosthetic heart valve **100**. Upon deployment, the prosthetic heart valve **100** expands so that the annulus section **140** is in secure engagement within the native aortic annulus. When the prosthetic heart valve **100** is properly positioned inside the heart, it works as a one-way valve, allowing blood to flow from the left ventricle of the heart to the aorta, and preventing blood from flowing in the opposite direction.

(36) Problems may be encountered when implanting the prosthetic heart valve **100**. For example, in certain procedures, collapsible valves may be implanted in a native valve annulus without first resecting the native valve leaflets. The collapsible valves may have critical clinical issues because of the nature of the stenotic leaflets that are left in place. Additionally, patients with uneven calcification, bi-cuspid aortic valve disease, and/or valve insufficiency cannot be treated well, if at all, with the current collapsible valve designs.

(37) The reliance on unevenly-calcified leaflets for proper valve placement and seating could lead to several problems, such as perivalvular leakage ("PV leak"), which can have severe adverse clinical outcomes. To reduce these adverse events, the optimal valve would anchor adequately and seal without the need for excessive radial force that could harm nearby anatomy and physiology.

(38) PV leak may also be caused by the implantation of a valve having an expanded diameter that is too small relative to the native aortic annulus diameter, a prosthetic valve that is deployed in a tilted orientation relative to the native aortic annulus (such that the longitudinal axis of the valve and the native aortic annulus are misaligned), lack of full radial expansion of the valve due to the stent catching on calcific nodules in the native aortic annulus, and placing the valve at a non-optimal longitudinal position relative to the native aortic annulus (either too high or too low along a longitudinal axis of the native aortic annulus).

(39) FIG. **2A** is a highly schematic cross-sectional illustration of the prosthetic heart valve **100** disposed within a native valve annulus **250A**. As seen in the figure, the prosthetic heart valve **100** has a substantially circular cross-section which is disposed within the non-circular native valve annulus **250A**. At certain locations around the perimeter of the heart valve **100**, gaps **200A** form between the heart valve **100** and the native valve annulus **250A**. Blood flowing through these gaps and past the valve assembly **104** of the prosthetic heart valve **100** can cause regurgitation and other



inefficiencies which reduce cardiac performance. Such improper fitment may be due to suboptimal native valve annulus geometry due, for example, to calcification of the native valve annulus **250A** or to unresected native leaflets.

(40) FIG. 2B is a similar cross-sectional illustration of a prosthetic mitral valve **100B** disposed within a native valve annulus **250B**. As seen in the figure, the prosthetic mitral valve **100B** has a substantially D-shaped cross-section that is disposed within the irregularly-shaped annulus **250B**. At certain locations around the perimeter of the heart valve **100B**, gaps **200B** form between the heart valve **100B** and the native valve annulus **250B**. Regurgitation and other inefficiencies may thus result after deployment of a prosthetic mitral valve. Though the following examples show aortic valves, it will be understood that the present devices and methods may be equally applicable to mitral heart valves, as well as to pulmonary valves and tricuspid valves.

(41) FIGS. 3A and 3B illustrate a prosthetic heart valve **300** in accordance with another embodiment. As can be seen in FIG. 3A, the prosthetic heart valve **300** extends between a proximal end **302** and a distal end **304**, and may generally include a stent **306** formed of a plurality of struts **307**, and a valve assembly **308** having a plurality of leaflets **310** and a cuff **312**.

(42) The prosthetic heart valve **300** further includes a generally toroidal-shaped sealing ring **350A** that may be annularly disposed around the abluminal surface of the stent **306** at the proximal end **302** of the prosthetic heart valve **300** (e.g., at a position that will lie at least partially below the native valve annulus when the prosthetic heart valve is deployed into a patient). The sealing ring **350A** may be formed, for example, from a long, thin rectangle of material about 10 mm in width that is folded approximately in half longitudinally, and the opposed longitudinal edges may be stitched to one another to create a flattened tube about 5 mm in diameter. The lateral ends of the flattened tube may be stitched to one another to create the sealing ring **350A**.

(43) Although the sealing ring **350A** is shown in FIG. 3A as having a circular cross-section, that need not be the case. The sealing ring **350A** may be flattened in the flow direction, or it may have a cross-section that is square, rectangular, triangular, or other shapes. It is to be understood that all of the “sealing rings” described herein are not to be understood to be limited to having a circular cross-section. Any of the sealing rings described herein may be flattened in the flow direction, or they may have a cross-section that is square, rectangular, triangular, or other shapes.

(44) A proximal surface **323** of the sealing ring is substantially aligned in the flow direction of the stent with the proximalmost junctions **309A** (FIG. 3A) of the stent. The sealing ring **350A** may have a radius larger than that of the valve assembly **308**, the larger radius of the sealing ring being capable of filling and/or blocking blood flow through gaps between the prosthetic heart valve **300** and the native valve annulus (not shown).

(45) The longitudinal seam of the sealing ring **350A** may be stitched to an abluminal surface of the cuff **312** and to select struts **307** of the stent **306** by sutures that secure the sealing ring in place. In some examples, the sutures may be the same sutures as are used to attach the cuff **312** to the struts **307** so that no extra steps or bulk is added.

(46) In one example, as seen in the enlarged schematic view of FIG. 3A, end struts **360a** and **360b** of the stent **306** meet to form a horseshoe-shaped end **370** having a partial slot **372** therebetween. A number of locking stitches **LS1** may be tied around the horseshoe-shaped ends **370**, and specifically through each slot **372** and around the sealing ring **350A** to secure it to the stent **306**. The locking stitches **LS1** may be formed of a suture, string, or any other suitable biocompatible thread.

(47) It will be understood that, though three locking stitches are shown around the circumference of the prosthetic heart valve to couple the sealing ring **350A** to the stent **306**, any number of locking stitches may be used. Although the locking stitches **LS1** are shown in FIGS. 3A and 3B as extending completely around the sealing ring **350A**, that need not be the case. In other examples, the sealing ring **350A** may be attached to the stent **306** by sutures stitched through a portion of an inner diameter of the sealing ring. Other techniques for maintaining the shape of the sealing ring

**350A** may also be used including adhesive, glue, shape memory fabric, or the like.

(48) The sealing ring **350A** may be formed of the same material as the cuff **312**, or of a different material that is sutured, glued or otherwise affixed to the proximal end of the cuff. In one example, the sealing ring **350A** may be made of a thin tubular fabric material. In other examples, the sealing ring **350A** may include thin porcine pericardial tissue between about 0.005 inches and about 0.007 inches in thickness, or UHMWPE or PET fabric between about 0.003 inches and about 0.005 inches in thickness.

(49) Alternatively, a variety of other materials may be used, including bovine tissue (e.g., glycerol impregnated or freeze dried), tissue with support structures therein, wire mesh, radiopaque wire, fabric, braided or woven fabric (e.g., PTFE, PTE, or UHMWPE), fabric coated with PTFE or collagen, or a multi-layered composite of one or more of the aforementioned materials (e.g., a fabric and tissue composite). Any of the sealing rings or sealing members disclosed herein may be made of any one of the aforementioned materials or a combination thereof.

(50) The sealing ring **350A** may be at least partially radiopaque, i.e., the sealing ring may include one or more materials having enhanced visibility to a user under fluoroscopy. For example, the sealing ring **450C** may include fabric or wire mesh material having radiopaque fibers or entirely comprised of radiopaque fibers. The sealing ring **450C** may include radiopaque marker beads, a thin radiopaque wire, radiopaque paint, or impregnation by soaking in a radiopaque material such as silver, iodine, barium, platinum, or the like. Any of the sealing rings or sealing members disclosed herein may be made of any one of the aforementioned radiopaque materials or a combination thereof.

(51) FIG. 3B illustrates the prosthetic heart valve **300** in native valve annulus **380** after formation of the sealing ring **350A** as seen from the proximal end **302** (e.g., as seen from the annulus end toward the aortic end of the heart valve). The sealing ring **350A** has been secured to the stent **306** via a series of locking stitches **LS1**. The outer diameter of the stent **306** at the proximal end is indicated with a dashed line. The sealing ring **350A** extends radially outward from the outer diameter of the stent **306** at the proximal end of the prosthetic heart valve **300** by a radial distance  $r1$ . In at least some examples, the radial distance  $r1$  may be between about 1.0 mm and about 2.5 mm. The radial distance  $r1$  may preferably be between at least 2.0 mm.

(52) As can be seen in FIGS. 3A and 3B, the sealing ring **350A** is configured to radially expand to a diameter greater than the diameter of the proximal end **302** of the stent **306** when the stent is radially expanded, extending radially outward from the outer diameter of the stent by the radial distance  $r1$ , for example. To ensure that the sealing ring **350A** radially expands to a diameter greater than the diameter of the proximal end **302** of the stent **306** when the prosthetic heart valve **300** is deployed into a patient, the sealing ring **350A**, and all of the other sealing rings described herein, may have sufficient elasticity that it has a spring bias that tends to provide a force in a radially outward direction when the sealing ring is radially compressed.

(53) However, the outward spring bias of the sealing ring **350A**, and of all of the other sealing rings described herein, is preferably small enough that the sealing ring may expand a greater radial distance at locations along the circumference of the sealing ring at which there is minimal radial force applied to the sealing ring from the native anatomy (i.e., at locations at which voids or gaps between the stent **306** and the native anatomy are present), while the sealing ring may expand a lesser radial distance at locations along the circumference of the sealing ring at which there is greater radial force applied to the sealing ring from the native anatomy (i.e., locations at which there are no such voids or gaps).

(54) FIG. 3C illustrates a heart valve **300C**, which is a variant of the heart valve **300** of FIGS. 3A and 3B. The heart valve **300C** has a sealing ring **350C** disposed at a higher location along the stent **306** than the sealing ring **350A** of FIG. 3A, which may permit the prosthetic heart valve **300C** to achieve improved sealing against the native annulus and the native leaflets in some patients.

(55) Compared to the sealing ring **350A** of FIGS. 3A and 3B, all of the other sealing rings

described herein, including the sealing ring **350C**, have structures that may provide different surface areas and thicknesses of material at different longitudinal and circumferential locations relative to the stent to provide different advantages in sealing voids or gaps between the stent and the native anatomy when the heart valves are deployed into a patient. Such differences in surface areas and thicknesses of material at certain longitudinal and circumferential locations may make some sealing ring configurations preferable for certain native anatomies and other sealing ring configurations preferable for other native anatomies, depending on the anticipated locations of voids or gaps between a deployed prosthetic heart valve and the native anatomy. Such anticipated locations of voids or gaps between a deployed prosthetic heart valve and the native anatomy may be determined by a variety of methods, including imaging of the native anatomy before deployment of a prosthetic heart valve, for example.

(56) The heart valve **300C** extends between a proximal end **302** and a distal end **304**, and may generally include a stent **306** formed of struts **307**, and a valve assembly **308** having a plurality of leaflets **310** and a cuff **312**. The sealing ring **350C** has been positioned so that the proximal surface **323C** of the sealing ring lies above the proximal end **302** of the stent **306** and closer to the leaflets **310** than the sealing ring **350A** (e.g., at a position that will lie within the native valve annulus when the prosthetic heart valve is deployed into a patient). After positioning the sealing ring **350C** at the appropriate position, locking stitches **LS2** may be coupled to the sealing ring **350C** and to upper junctions **309B** of the proximalmost struts **307** of the stent **306** to secure the sealing ring in place.

(57) FIG. 4 illustrates a prosthetic heart valve **400**, which is a variant of the prosthetic heart valve **100** of FIG. 1. The heart valve **400** extends between a proximal end **402** and a distal end **404**, and may generally include a stent **406** formed of struts **407**, and a valve assembly **408** having a plurality of leaflets **410** and a cuff **412**.

(58) As shown in FIG. 4, in the prosthetic heart valve **400**, the cuff **412** may extend over a greater distance in a flow direction of the stent **406** compared to the cuff **112** of FIG. 1. For example, when the stent **406** is in an expanded use condition, a landing zone (i.e., continuous cylindrical portion) of the cuff **412** may extend over a length of about 16 mm to about 18 mm in the flow direction from the proximal end **402** toward the distal end **404**, compared to a landing zone of about 8 mm to about 10 mm for the cuff **112** of the prosthetic heart valve **100**. Furthermore, the bellies of the leaflets **410** may be attached to the stent **406** and the cuff **412** a greater distance away from the proximal end **402** in the flow direction than the bellies of the leaflets **110** of the prosthetic heart valve **100**. In one example, the belly of each of the leaflets **410** may be attached to the stent **406** and the cuff **412** a distance **D1** of at least 10 mm from the proximal end **402** of the stent.

(59) The prosthetic valve **400** having a cuff **412** with a relatively large landing zone may be used with any of the sealing rings disclosed herein. The large landing zone of the cuff **412** may permit a plurality of sealing rings to be attached thereto, the sealing rings being separated from one another in the flow direction (e.g., FIG. 5F).

(60) FIGS. 5A-5F illustrate variants of sealing rings that may be used with prosthetic heart valves **300** or **300C** in place of the sealing rings shown in FIGS. 3A-3C. Each of the sealing rings **550A-550F** shown in FIGS. 5A-5F may be formed in the same manner, attached to the stent and cuff in the same manner, and made of the same material or materials described above with reference to the sealing rings **350A** and **350C**. Each of the sealing rings **550A-550F** may be attached to a stent in any location along the longitudinal axis of the stent. A prosthetic heart valve, such as the prosthetic heart valve **300**, may include one of the sealing rings **550A-550F**, or alternatively, the prosthetic heart valve may include two or more of the sealing rings, as will be described in more detail below.

(61) FIG. 5A shows a sealing ring **550A** having a toroidal shape, similar to the toroidal-shaped sealing ring **350A** shown in FIGS. 3A and 3B. The sealing ring **550A** has openings **563** in a top surface **564** thereof. Any number of openings **563** may be provided in the sealing ring **550A**, such as three, six, nine, twelve, fifteen, or eighteen, for example. The openings **563** may be round holes, as shown in FIG. 5A, or may be holes having any other shape or slits having any shape. For

example, the sealing ring **550B** shown in FIG. 5B has six openings **563B** in the shape of oblong slits each extending partially around the sealing ring in a circumferential direction thereof. All of the other sealing rings described herein may include any number of openings in a top surface thereof, and such openings may be holes or slits having any shape.

(62) The sealing ring **550A** may be attached to a stent and cuff of a prosthetic heart valve in a similar manner as that described above with reference to the sealing ring **350A** shown in FIGS. 3A and 3B. When the sealing ring **550A** is attached to a stent and cuff of a prosthetic heart valve, the openings **563** and the top surface **564** will preferably face toward the distal end of the stent. When deployed in a patient, the openings **563** may allow the sealing ring **550A** to fill with blood, which may augment the sealing ability of the sealing ring against the native aortic annulus or other native tissue structures. Instead of or in addition to the openings **563**, the sealing ring **550A**, and of all of the other sealing rings described herein, may include expanding materials within the interior of the sealing ring, such as polyacrylimide or other hydroscopic materials, PVA, shape memory foam, bovine gelatin or collagen, or the like.

(63) FIG. 5C shows a sealing ring **550C** in the shape of a bent or saddle-shaped toroid that alternates between peaks **560C** and valleys **570C** around the circumference of the sealing ring, the peaks and valleys being substantially evenly distributed about the circumference. As shown in FIG. 5C, the sealing ring **550C** has two peaks **560C** and two valleys **570C**, but the sealing ring may have other numbers of peaks and valleys, such as three, for example.

(64) FIG. 5D shows a sealing ring **550D** having a zigzag shape. The sealing ring **550D** alternates between peaks **560D** and valleys **570D** around the circumference of the sealing ring, the peaks and valleys being substantially evenly distributed about the circumference. As shown in FIG. 5D, the sealing ring **550D** has nine peaks **560D** and nine valleys **570D**, but the sealing ring may have other numbers of peaks and valleys, such as three or six, for example. A sealing ring having a zigzag shape may be stitched to the stent and the cuff along the struts. However, in other embodiments, the sealing ring **550D** may be stitched to the stent and/or the cuff at other locations.

(65) FIG. 5E shows a sealing ring **550E** having a zigzag shape with alternating peak heights. The sealing ring **550E** alternates between peaks **560E** and valleys **570E** around the circumference of the sealing ring, the peaks and valleys being substantially evenly distributed about the circumference. As shown in FIG. 5E, the sealing ring **550E** has eight peaks **560E** and eight valleys **570E**, but the sealing ring may have other numbers of peaks and valleys, such as four or six, for example.

(66) The peaks **560E** include low peaks **561** that extend by a first height **H1** above the valleys **570E** and high peaks **562** that extend by a second height **H2** above the valleys, the second height being greater than the first height. As shown in FIG. 5E, the peaks **560E** may include four low peaks **561** and four high peaks **562**, with one low peak separating adjacent ones of the high peaks. In other embodiments, there may be other numbers of high and low peaks. For example, a sealing ring having varying peak heights may include six low peaks and three high peaks, with two low peaks separating adjacent ones of the high peaks. In another example, a sealing ring having varying peak heights may include three low peaks and six high peaks, with two high peaks separating adjacent ones of the low peaks.

(67) Such a configuration of a sealing ring having low peaks **561** and high peaks **562** at alternating heights may permit a smaller crimped diameter of the prosthetic heart valve when loaded into a delivery device. When the prosthetic heart valve is crimped into a delivery device, the low peaks **561** will be disposed at a different longitudinal location along the stent than the high peaks **562**, thereby distributing the bulk of the peaks so that only half of the peaks are at any single longitudinal location.

(68) FIG. 5F shows a stacked arrangement of two sealing rings **550E** each having a zigzag shape with alternating peak heights. As shown in FIG. 5F, the two sealing rings **550E** are identical in structure and are aligned with one another such that the peaks **560E** and valleys **570E** of the upper sealing ring are substantially aligned longitudinally with the peaks and valleys of the lower sealing

ring, and such that the low peaks **561** and high peaks **562** of the upper sealing ring are substantially aligned longitudinally with the low peaks and high peaks of the lower sealing ring, respectively. In other embodiments, the peaks **560E** and valleys **570E** of the two sealing rings **550E**, and the low peaks **561** and the high peaks **562** of the two sealing rings need not be longitudinally aligned. In other embodiments, the two sealing rings need not have an identical structure.

(69) FIG. **5G** illustrates a radial cross-section of a sealing ring **550G** that may be incorporated into any of the sealing rings described herein. The sealing ring **550G** shown in FIG. **5G** may be formed in the same manner, attached to the stent and cuff in the same manner, and made of the same material or materials as described above with reference to the sealing rings **350A** and **350C**.

(70) The top surface **564** of the sealing ring **550G** may be made of a porous material having many small openings **563G** that are adapted to allow unidirectional blood flow into the interior **565** of the sealing ring. The sealing ring **550G** may have a bottom surface **566** without openings, and therefore may be substantially less permeable than the top surface **564**. The bottom surface **566** may be made of a low-porosity material such as a tightly-woven fabric that may have a collagen or PVA coating, for example. The sealing ring **550G** may be coated on the exterior of the top surface **564** and/or the bottom surface **566** with a material (e.g., Ag or a drug compound) to prevent a thrombus or infection from forming thereon.

(71) As a result of this construction, the sealing ring **550G** is adapted to allow blood to fill the interior **565** but not to escape. The porous material may be such that blood can only flow through the openings **563G** into the interior **565** of the sealing ring when the pressure outside the sealing ring exceeds the pressure in the interior. When the pressure in the interior **565** equals or exceeds the pressure outside the sealing ring, the openings **563G** will not permit blood to flow out of the interior.

(72) Blood that flows into the interior **565** of the sealing ring **550G** may coagulate and/or in-grow into the material of the sealing ring **550G**, which may help provide stiffness to the sealing ring in a radial direction. To assist the blood to coagulate and/or in-grow, the openings **563G** may be funneled so that the openings have a smaller diameter facing the interior **565** and a larger diameter at the top surface **564**, and/or the material of the sealing ring **550G** may be smooth on outside (e.g., on the top surface and/or the bottom surface **566**) and rough on the surface facing the interior to provide a greater surface area of contact between the blood and the material of the sealing ring.

(73) In one variation (not shown), the top surface **564** and the bottom surface **566** of the sealing ring **550G** may be made of a porous material having many small openings that are adapted to allow blood flow into the interior **565** of the sealing ring. In this variation, before blood coagulation and/or in-growth, blood flowing into the openings **563G** in the top surface **564** may be retained within the interior **565** because the native aortic annulus and/or native leaflets of the patient may at least partially block the openings in the bottom surface **566**.

(74) FIG. **6A** illustrates a prosthetic heart valve **600** in accordance with another embodiment. As can be seen in FIG. **6A**, the prosthetic heart valve **600** extends between a proximal end **602** and a distal end **604**, and may generally include a stent **606** formed of a plurality of struts **607**, and a valve assembly having a plurality of leaflets (not shown) and a cuff **612**.

(75) The prosthetic heart valve **600** further includes a generally flattened ring-shaped sealing ring **650A** flattened in the flow direction of the stent **606**, in contrast to the sealing ring **350A** of FIGS. **3A** and **3B**, which is generally toroidal-shaped. Similar to the sealing ring **350A**, the sealing ring **650A** may be formed, for example, from a long, thin rectangle of material about 10 mm in width that is folded approximately in half longitudinally, and the opposed longitudinal edges may be stitched to one another to create a flattened tube about 5 mm in diameter. The sealing ring **650A** may be annularly disposed around the abluminal surface of the stent **606** at the proximal end **602** of the prosthetic heart valve **600**. The prosthetic heart valve **600** may include one of the sealing rings **650A**, or alternatively, the prosthetic heart valve may include two or more of the sealing rings.

(76) Alternatively, the sealing ring **650A** may be made from a thin flat skirt cut from a strip or

circle of porcine tissue without a seam. In one example, the circle of tissue comprising the sealing ring **650A** may have an inner diameter **D2** of about 29 mm, an outer diameter **D3** of about 34 mm, and a width **W1** between the inner diameter and the outer diameter of about 5 mm.

(77) An inner edge **651** of the sealing ring **650A** may be sutured to upper junctions **609B** of the proximalmost struts **607** of the stent **606** to secure the sealing ring in place near the proximal end **602**, using a running stitch, for example. An outer edge **652** of the sealing ring **650A** may be a free edge that is not sutured to the stent **606** or the cuff **612**. The outer edge **652** may be supported by a plurality of support members in the form of sutures **670** each extending between the outer edge and an upper junction **609D** of certain struts **607** of the stent **606**. Non-elastic or elastic sutures **670** may be used.

(78) In one variation, sutures **670** may be used that shorten when heated, such that during loading of the prosthetic heart valve **600** into a delivery device, the sutures are long enough to permit the outer edge **652** of the sealing ring **650A** to be pushed proximally away from the leaflets **610**, to permit the valve to have a smaller crimped diameter. Then, when the prosthetic heart valve **600** is deployed into a patient, the heat from the patient may cause the sutures **670** to shorten, thereby pulling the outer edge **652** of the sealing ring **650A** toward the position shown in FIG. 6A.

(79) The sealing ring **650A** may be configured such that when the prosthetic heart valve **600** is radially compressed within a delivery device, its top surface **664** folded up to confront the outer surface of the cuff **612**. When the prosthetic heart valve **600** is released from the delivery device and deployed into a native aortic annulus, the sealing ring **650A** may billow open when blood flows in a retrograde direction **D.sub.R** between the top surface **664** of the sealing ring and the outer surface of the cuff **612**. The suture **670** can provide support to the outer edge **652** of the sealing ring **650A** to prevent the sealing ring from opening beyond a position generally perpendicular to the cuff **612**. When the sealing ring **650A** is open to a position generally perpendicular to the cuff **612**, the outer edge **652** of the sealing ring may extend up to about 5 mm radially outward from the stent **606**, for example.

(80) When the prosthetic heart valve **600** is deployed into a native aortic annulus, the blood flowing in the retrograde direction **D.sub.R** between the outer surface of the cuff **612** and the top surface **664** of the sealing ring may push the sealing ring **650A** a greater radial distance away from the cuff at locations along the circumference of the sealing ring at which there is minimal radial force applied to the sealing ring from the native anatomy (i.e., at locations at which voids or gaps between the stent **606** and the native anatomy are present). The sealing ring **650A** may expand a lesser radial distance at locations along the circumference of the sealing ring at which there is greater radial force applied to the sealing ring from the native anatomy (i.e., locations at which there are no such voids or gaps).

(81) FIGS. 6B-6F illustrate prosthetic heart valve configurations that have embodiments of sealing rings that are variants of the sealing ring **650A** shown in FIG. 6A, in which the sealing ring embodiments include stored energy elements in the form of springs that are configured to force portions of the outer edge of the sealing ring away from the cuff in locations at which voids or gaps between the stent **606** and the native anatomy are present.

(82) Each of the sealing rings **650B-650F** shown in FIGS. 6B-6F may be formed in the same manner, attached to the stent and cuff in the same manner, and made of the same material or materials described above with reference to the sealing ring **650A**, with the exception of the addition of a stored energy element. Each of the sealing rings **650B-650F** may be attached to the stent in any location along the longitudinal axis of the stent. A prosthetic heart valve, such as the prosthetic heart valve **600**, may include one of the sealing rings **650B-650F**, or alternatively, the prosthetic heart valve may include two or more of the sealing rings. Each of the sealing rings **650B-650F** may be used with or without support members, such as the sutures **670** described above.

(83) FIG. 6B shows a sealing ring **650B** in the shape of a toroid similar to the toroidal-shaped sealing ring **650A** shown in FIG. 6A. The sealing ring **650B** has a plurality of stored energy

elements in the form of springs **680B** circumferentially spaced apart from one another about the sealing ring. Each spring **680B** has a first end **681** located at the inner edge **651** of the sealing ring **650B** and a second end **682** located at the outer edge **652**. Each spring **680B** preferably extends away from the inner edge **651** in a direction substantially perpendicular to the flow direction.

(84) At least partially due to the capability of the springs **680B** to store energy, the sealing ring **650B** may have sufficient elasticity that it has a spring bias that tends to provide a force in a radially outward direction when the sealing ring is radially compressed. To provide this spring bias, each spring **680B** may be made from a material having a shape memory, such as nitinol wire or spring steel. When a prosthetic heart valve having the sealing ring **650B** is released from a delivery device, the second end **682** of each spring **680B** preferably moves radially outward away from the cuff **612** according to its bias, thereby pushing the outer edge **652** of the sealing ring away from the cuff and the stent **606**.

(85) FIG. **6C** shows a sealing ring **650C** that is the same as the sealing ring **650B** of FIG. **6B**, except that the springs **680C** preferably extend away from the inner edge **651** of the sealing ring such that all of the springs lie substantially in a plane that is perpendicular to the longitudinal axis of the prosthetic heart valve **600**, with each spring **680C** oriented at an acute angle with respect to the circumference of the stent **606**. When viewed from the top surface **664** of the sealing ring **650C**, as shown in FIG. **6C**, the springs **680C** may be oriented in a clockwise direction about the longitudinal axis of the sealing ring from their first end **681** to their second end **682**. Alternatively, the springs **680C** may be oriented in a counterclockwise direction about the longitudinal axis of the sealing ring from their first end **681** to their second end **682**.

(86) FIG. **6D** shows a sealing ring **650D** that is the same as the sealing ring **650B** of FIG. **6B**, except that the stored energy element is in the form of a coiled spring **680D** that extends continuously about the circumference of the sealing ring or along substantial portions of the circumference of the sealing ring. To provide a radially-outward spring bias to the sealing ring **650D**, the spring **680D** may be made from a material having a shape memory, such as nitinol wire.

(87) When a prosthetic heart valve having the sealing ring **650D** is radially compressed inside a delivery device, the spring **680D** will be under radial compression against its bias. When the prosthetic valve having the sealing ring **650D** is released from the delivery device, the spring **680D** will radially expand, such that the outer edge **652** of the sealing ring moves radially outward from the cuff **612** according to the bias of the spring.

(88) FIG. **6E** shows a sealing ring **650E** that is the same as the sealing ring **650D** of FIG. **6D**, except that the stored energy element is in the form of a leaf spring **680E** that extends in at least one complete loop about the circumference of the sealing ring, such that the first end **681** and the second end **682** of the spring each overlap another portion of the spring in the circumferential direction of the sealing ring. Similar to the sealing ring **650D**, when a prosthetic valve having the sealing ring **650E** is released from a delivery device, the spring **680E** will radially expand, such that the outer edge **652** of the sealing ring moves radially outward from the cuff **612** according to the bias of the spring.

(89) FIG. **6F** shows a sealing ring **650F** that is the same as the sealing ring **650E** of FIG. **6E**, except that the leaf spring **680F** includes a ratchet element **683** that slidably couples either the first end **681** or the second end **682** of the spring to another portion of the spring. The ratchet element **683** is configured to allow the leaf spring to radially expand but not to radially contract. Similar to the sealing ring **650E**, when a prosthetic valve having the sealing ring **650F** is released from a delivery device, the spring **680F** will radially expand, such that the outer edge **652** of the sealing ring moves radially outward from the cuff **612** according to the bias of the spring. Once the spring **680F** has expanded, it will substantially maintain its diameter due to the ratchet element **683** preventing the spring from re-collapsing to a smaller radial profile.

(90) FIG. **7A** illustrates a heart valve **700A**, which is a variant of the heart valve **600** of FIG. **6A**. The heart valve **700A** extends between a proximal end **702** and a distal end **704**, and may generally

include a stent **706** formed of struts **707**, and a valve assembly having a plurality of leaflets (not shown) and a cuff **712**. The heart valve **700A** further includes a sealing ring **750A** that is generally in the shape of a toroid flattened in the flow direction of the stent **706**. The sealing ring **750A** may be used with or without support members, such as the sutures **670** described above. In addition, the sealing ring **750A** may be used with or without any energy storage elements, such as the springs **680B-680F** described above.

(91) Similar to the sealing ring **650A** shown in FIG. **6A**, the sealing ring **750A** may be configured such that when the prosthetic heart valve **700** is radially compressed within a delivery device, the sealing ring extends distally from the location where it is attached to the cuff **712** and/or the stent **706**, such that a top surface **764** of the sealing ring is folded up to confront the outer surface of the cuff **712**. When the prosthetic heart valve **700A** is released from the delivery device and deployed into a native aortic annulus, the sealing ring **750A** may billow open when blood flows in a retrograde direction D.sub.R between the top surface **764** of the sealing ring and the outer surface of the cuff **712**. When the sealing ring **750A** is billowed open, it may flare outwardly and proximally from the cuff **712** in the flow direction of the prosthetic valve **700**, so that the outer edge **752** is spaced apart from the cuff.

(92) The sealing ring **750A** may have sufficient rigidity that, when blood flows in a retrograde direction D.sub.R between the top surface **764** of the sealing ring and the outer surface of the cuff **712**, the sealing ring will resist bending of the outer edge **752** too far away from the outer surface of the cuff, so that no portion of the top surface **764** opens beyond a perpendicular position relative to the cuff. To provide such a bending resistance, the sealing ring **750A** may be reinforced with shape memory materials such as the springs **680B-680F** described above, and/or the sealing ring may be made of a material that is elastic and/or has shape memory, so that when deployed, the sealing ring will be biased to take the shape shown in FIG. **7A**. Also, to resist bending of the outer edge **752** too far away from the outer surface of the cuff, the outer edge of the sealing ring **750A** may be sutured to certain ones of the struts **707**. Non-elastic or elastic sutures may be used. In one variation, sutures that shorten when heated may be used.

(93) After deployment into a patient, the sealing ring **750A** may experience tissue ingrowth from the native tissue structures, which may help the sealing ring to resist bending when blood flows in the retrograde direction D.sub.R against the top surface **764** of the sealing ring. Also, the material of the sealing ring **750A** may be configured so that certain areas therein have residual stress, so that when deployed, the sealing ring will be biased to take the shape shown in FIG. **7A**.

(94) To help provide the sealing ring **750A** with the aforementioned rigidity, the sealing ring **750A** may be sutured to the stent **706** at a location slightly spaced apart from the inner edge **751** of the sealing ring, so that the portion of the top surface **764** adjacent the inner edge is held substantially parallel to the outer surface of the cuff **712**.

(95) FIG. **7B** shows a sealing ring **750B** that is the same as the sealing ring **750A** of FIG. **7A**, except that the sealing ring **750B** is oriented in the opposite direction. When the prosthetic heart valve **700B** is radially compressed within a delivery device, the sealing ring **750B** extends proximally from the location where it is attached to the cuff **712** and/or the stent **706**, such that when the sealing ring **750B** is billowed open, it may flare outwardly and distally from the cuff **712** in the flow direction of the prosthetic valve **700**. The sealing ring **750B** may be sutured to upper junctions **709B** of the proximalmost struts **707** of the stent **706** at a location slightly spaced apart from the inner edge **751** of the sealing ring, so that the portion of the top surface **764** adjacent the inner edge is disposed substantially parallel to the outer surface of the cuff **712**.

(96) The outer edge **752** of the sealing ring **750B** may extend below the proximal end **702** of the prosthetic heart valve **700B** when the prosthetic heart valve **700B** is in both its collapsed and expanded positions. Such a configuration may more evenly distribute the material of the leaflets and the sealing ring along the length of the prosthetic heart valve **700B**, which may permit a smaller crimped diameter of the prosthetic heart valve when loaded into a delivery device.



(97) Since the sealing ring **750B** flares outwardly and distally from the cuff **712**, blood flowing in a retrograde direction D.sub.R against the top surface **764** of the sealing ring may apply a radially inward force against the top surface that may tend to push the outer edge **752** of the sealing ring radially inward.

(98) To counteract this radially inward force so that the sealing ring **750B** maintains its outwardly flared shape along at least some portions of its circumference when deployed into a native annulus, the sealing ring may be used with energy storage elements, such as the springs **680B-680F**

described above, and/or the sealing ring may be made of a material that is elastic and/or has shape memory, so that when deployed, the sealing ring will be biased to take the shape shown in FIG. 7B. (99) Also, to counteract this radially inward force, the outer edge **752** of the sealing ring **750B** may be sutured to certain ones of the struts **707**. Non-elastic or elastic sutures may be used. In one variation, sutures that shorten when heated may be used, so that when deployed into a patient, the heat from the patient will shorten the sutures, thereby preventing the outer edge **752** from being pushed too far radially inward by blood flowing in a retrograde direction D.sub.R against the top surface **764** of the sealing ring.

(100) Similar to the sealing ring **750A**, after deployment into a patient, the sealing ring **750B** may experience tissue ingrowth from the native tissue structures, which may help the sealing ring to resist bending when blood flows in the retrograde direction D.sub.R against the top surface **764** of the sealing ring. Also, the material of the sealing ring **750A** may be configured so that certain areas therein have residual stress, so that when deployed, the sealing ring will be biased to take the shape shown in FIG. 7B.

(101) FIG. 8A illustrates a portion of a prosthetic heart valve **800** according to an embodiment of the disclosure. The prosthetic heart valve **800** extends between a proximal end **802** and a distal end (not shown), and may generally include an expandable stent **806** formed of struts **807**, and a valve assembly having a plurality of leaflets (not shown) and a cuff **812**. Preferably, the cuff **812** has a relatively straight proximal end **811** at the proximal end **802** of the stent. In the illustrated embodiment, the cuff **812** is positioned on the luminal side of the stent **806** and is attached to the stent, for example, by sutures.

(102) The prosthetic heart valve **800** includes an active sealing mechanism for sealing against a perivalvular leak in the form of one or more sealing members **820**. In this example, the sealing members **820** take the form of parachute-like elements that billow open when blood flows in a retrograde direction D.sub.R into the parachute-like elements. If retrograde flow occurs on the abluminal side of prosthetic heart valve **800**, the blood may enter one or more sealing members **820**, causing the sealing members to billow open and facilitating the sealing of gap spaces between the patient's anatomy and the valve.

(103) It should also be noted that, for this and other embodiments described herein, the sealing members **820** may help seal a gap space between the prosthetic valve **800** and the native anatomy even if there is little or no perivalvular leak to cause the sealing members to billow open. This may be due to, for example, the additional material of sealing members **820** filling gap spaces by virtue of the material being positioned in those gap spaces.

(104) The sealing members **820** may take the form of generally triangular patches of material, although other shapes may be used (e.g., FIGS. 9A-10B). The sealing members **820** may be attached to the cuff **812** during valve assembly, or after valve assembly is otherwise complete. Any suitable attachment method, such as sewing, may be used. Preferably, a distal side **821** of each sealing member **820**, in this case the distal side of the triangular patch, is left partially or completely unconnected to the cuff **806** while the other sides of the sealing member are connected to the cuff and/or stent so as to form a pocket open on one side.

(105) For example, if sewing the triangular patch to the cuff **812** and/or the stent **806**, two proximal sides **822**, **823** of the triangle, meeting at a proximalmost point **824**, are sewn to the cuff and/or struts **807**, but the distal side **821** of the triangle facing the distal end **804** of the prosthetic heart

valve **800** is not sewn to the cuff. With this configuration, the distal or open side **821** of sealing member **820** remains capable of widening upon retrograde blood flow, so that the pocket between the sealing member **820** and the cuff **812** fills with blood. As described above with reference to FIGS. **3A** and **3B**, at least some of the suturing used to attach the sealing members **820** to the struts **807** (and any of the other sealing members described herein) may be the same sutures that are used to attach the cuff **812** to the struts so that no extra steps or bulk is added.

(106) The proximal sides **822**, **823** of the sealing members **820** may be sewn to the cuff substantially along the contour of the struts **807**. As shown in FIG. **8A**, proximal sides **822**, **823** are sewn to the cuff **812** along the contour of every strut of the bottom half of the first full row **813** of cells **815** between the proximalmost junctions **809A** of the stent and the upper junctions **809B** of the proximalmost struts **807** of the stent.

(107) The closed proximal sides **822**, **823** of the sealing members **820** that are connected to the cuff **812** may restrict blood from exiting the sealing members in the retrograde direction D.sub.R. The proximal sides **822**, **823** may be sewn such that the open sides **821** are loose or floppy, and not taught, thereby enabling blood to flow into sealing members **820**. As described above, if retrograde blood flow does occur on the abluminal side of the prosthetic heart valve **800**, the parachuting or billowing action of the sealing members **820** upon blood flowing therein facilitates active sealing between the prosthetic heart valve and the native tissue surrounding the valve.

(108) In a variation that may be applied to any of the embodiments of the sealing members described herein (e.g., any of the sealing members of FIGS. **8A** through **10B**), another design that may restrict blood flow from exiting the sealing members may have one or more portions of the open sides **821** of the sealing members **820** stitched (or joined in another way) to the cuff **812** and/or the stent **806**. For example, the left and right peripheral quarters of the length of the open sides **821** may be stitched to the cuff **812**, while the center half of the length of the open sides may remain unconnected to the cuff. In another example, one of the left or right halves of the length of the open sides **821** may be stitched to the cuff **812**, while the other half may remain unconnected to the cuff.

(109) Such a variation may improve the ability of the sealing members **820** to retain blood therein without expelling emboli. Although this variation has been described above as having half of the length of the open side **821** stitched to the cuff **812** and half of the length unconnected to the cuff, that need not be the case. In other variations, any portion or portions of the open side **821** of the sealing members **820** may be attached to the cuff **812** and/or the stent **806**, and any remaining portion of the open side may remain unconnected to the cuff and/or stent.

(110) FIGS. **8B** and **8C** show prosthetic heart valves **800B** and **800C** that are variants of the prosthetic heart valve **800** of FIG. **8A**. Compared to the prosthetic heart valve **800** of FIG. **8A**, the prosthetic heart valves **800B** and **800C** may reduce the volume of the material of the sealing members, which may permit a smaller crimped diameter of the prosthetic heart valve when loaded into a delivery device, and therefore may reduce the force required to load the prosthetic heart valve into a delivery device and to perform any resheathing procedure.

(111) Referring to FIG. **8B**, rather than having a sealing member disposed in every open cell **815** of the first row of cells **813** of the stent **806**, the prosthetic heart valve **800B** may have three narrow sealing members **820B** that are the same as the sealing members **820** of FIG. **8A** and three wide sealing members **825B** that each extend in a circumferential direction across two cells. Each of the wide sealing members **825B** may be substantially aligned in the flow direction with a commissure feature **866**, and each of the narrow sealing members **820B** may be substantially aligned in the flow direction with the lowest positions **811** at which the bellies of the leaflets **810** attach to the cuff **812**.

(112) Referring to FIG. **8C**, the prosthetic heart valve **800C** may have one narrow sealing member **820C** that is the same as the sealing members **820** of FIG. **8A** and four wide sealing members **825C** that each extend in a circumferential direction across two cells. Two of the wide sealing members **825C** may be substantially aligned in the flow direction with a commissure feature **866**, while the

other two wide sealing members may be aligned in the flow direction between a commissure feature and the lowest positions **811** at which the bellies of the leaflets **810** attach to the cuff **812**. The narrow sealing member **820C** may be aligned in the flow direction with the lowest position **811** at which the belly of one of the leaflets **810** attaches to the cuff **812**.

(113) FIGS. **9A-9D** show prosthetic heart valves **900A-900D** that are variants of the prosthetic heart valve **800** of FIG. **8A**. Compared to the prosthetic heart valve **800** of FIG. **8A**, the prosthetic heart valves **900A-900D** may reduce the volume of the material of the sealing members, which may permit a smaller crimped diameter of the prosthetic heart valve when loaded into a delivery device, and therefore may reduce the force required to load the prosthetic heart valve into a delivery device and to perform any resheathing procedure.

(114) Referring to FIG. **9A**, the prosthetic heart valve **900A** is the same as the prosthetic heart valve **800C** of FIG. **8C**, except that the wide sealing members **925A** and the narrow sealing member **920A** are crescent shaped rather than triangular shaped, and each crescent extends only a portion of the longitudinal distance from the upper junctions **909B** of the proximalmost struts **907** of the stent **906** proximally toward the proximalmost junctions **909A** of the stent. Each sealing member **920A** and **925A** may have a distal or open side **921** facing the distal end **904** of the stent **906** that is not sewn to the cuff, and a proximal or closed side **922** facing the proximal end **902** of the stent that is sewn to the cuff.

(115) Referring to FIG. **9B**, the prosthetic heart valve **900B** is the same as the prosthetic heart valve **800B** of FIG. **8B**, except that the wide sealing members **925B** and the narrow sealing members **920B** are crescent shaped rather than triangular shaped, and each crescent extends only a portion of the longitudinal distance from the upper junctions **909B** of the proximalmost struts **907** of the stent **906** proximally toward the proximalmost junctions **909A** of the stent. Each sealing member **920B** and **925B** may have a distal or open side **921** facing the distal end **904** of the stent **906** that is not sewn to the cuff, and a proximal or closed side **922** facing the proximal end **902** of the stent that is sewn to the cuff.

(116) Referring to FIG. **9C**, the prosthetic heart valve **900C** is the same as the prosthetic heart valve **900A** of FIG. **9A**, except that the wide sealing members **925C** each extend in the circumferential direction across three cells of the stent **906**, and the narrow sealing members are omitted. The wide sealing members **925C** each extend in the flow direction approximately between the upper junctions **909C** of certain cells in a first full row **913** of complete cells **915** and upper junctions **909B** of the proximalmost struts **907** of the stent. Each of the wide sealing members **925C** is substantially aligned in the flow direction with a commissure feature **966**.

(117) FIG. **9D** shows a prosthetic heart valve **900D** that is a variant of the prosthetic heart valve **900C** of FIG. **9C**. The prosthetic heart valve **900D** has six wide crescent-shaped sealing members each extending circumferentially across two cells, the sealing members being located at two different heights in the flow direction of the stent **906**.

(118) The prosthetic heart valve **900D** has three lower sealing members **925D** that have the same shape as the wide sealing members **925A** of FIG. **9A**. Each of the lower sealing members **925D** extends across a portion of the longitudinal distance from the upper junctions **909B** of the proximalmost struts **907** of the stent **906** proximally toward the proximalmost junctions **909A** of the stent, and is substantially aligned in the flow direction with a commissure feature **966**.

(119) The prosthetic heart valve **900D** also has three upper sealing members **926D** that have the same shape as the sealing members **925D**. Each of the upper sealing members **926D** extends across a portion of the longitudinal distance from the upper junctions **909C** of certain cells in a first full row **913** of complete cells **915** and upper junctions **909B** of the proximalmost struts **907** of the stent **906**. Each of the upper sealing members **926D** is substantially aligned in the flow direction with the lowest positions **911** at which the bellies of the leaflets **910** attach to the cuff **912**.

(120) Each lower sealing member **925D** overlies two upper sealing members **926D** in the flow direction of the stent **906**, while each upper sealing member **926D** overlies two lower sealing

members **925D** in the flow direction of the stent. It is preferred that the lower sealing members **925D** and the upper sealing members **926D** be attached to a cuff having a higher cuff height in the flow direction of the stent **906**, such as the cuff **412** of FIG. 4.

(121) FIGS. **10A** and **10B** illustrate a prosthetic heart valve **1000** in accordance with another embodiment. As can be seen in FIGS. **10A** and **10B**, the prosthetic heart valve **1000** extends between a proximal end **1002** and a distal end **1004**, and may generally include a stent **1006** formed of a plurality of struts **1007**, and a valve assembly **1008** having a plurality of leaflets **1010** and a cuff **1012**. Preferably, the cuff **1012** has a relatively straight proximal end **1011** at the proximal end **1002** of the stent.

(122) The prosthetic heart valve **1000** further includes nine independent sealing members **1020** that may take the form of generally rectangular patches of material, although other shapes may be used. Preferably, a distal side **1021** of each sealing member **1020** is left partially or completely unconnected to the cuff **1012**, and a proximal side **1022** is sewn to the proximal end **1011** of the cuff. With this configuration, the distal or open sides **1021** of the sealing members **1020** are capable of opening upon retrograde blood flow, with the open side facing the distal end **1004** of the prosthetic heart valve **1000**.

(123) Each sealing member **1020** may independently billow radially outward by a different amount, depending on the contour of the adjacent native anatomy. The sealing members **1020** may be used with support members, such as the sutures **670** described above, in order to limit the outward billowing of the sealing members. In addition, the sealing members **1020** may be used with energy storage elements, such as the plurality of springs **680B-680C** described above, with one spring **680B** or **680C** attached to each sealing member **1020**, for example, so that the outer edge **1052** of one or more sealing members may be forced away from the cuff **1012** in locations at which voids or gaps between the stent **1006** and the native anatomy are present.

(124) Furthermore, the sealing members **1020** may be configured to flare outwardly and proximally from the cuff **1012** in the flow direction of the prosthetic valve **1000** in a manner similar to the sealing rings **750A** or **750B**. The sealing members **1020** may have sufficient rigidity to resist bending of the outer edge **1052** too far away from the outer surface of the cuff **1012** when retrograde blood flow extends between the sealing members and the outer surface of the cuff, so that no portion of the top surface **1064** opens beyond a perpendicular position relative to the cuff.

(125) Although some of the various sealing structures have been described herein as “sealing rings,” it is to be understood that the term “sealing ring” as used herein may describe one or more discontinuous sealing structures that do not completely extend around the circumference of the stent of a prosthetic heart valve.

(126) Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

(127) It will be appreciated that the various dependent claims and the features set forth therein can be combined in different ways than presented in the initial claims. It will also be appreciated that the features described in connection with individual embodiments may be shared with others of the described embodiments.

## Claims

1. A prosthetic heart valve configured to be expanded in an annulus of a native aortic valve of a patient, the prosthetic heart valve comprising: a stent extending in a flow direction from an inflow end to an outflow end, the stent having an expanded condition and a collapsed condition and including an annulus section adjacent to the inflow end and a plurality of struts shaped to form a

plurality of cells connected to one another in a plurality of annular rows around the stent, the plurality of annular rows of cells including a first full row of cells at the inflow end of the stent, each cell in the first full row of cells being diamond-shaped and having two proximalmost struts, the proximalmost struts of each cell in the first full row of cells meeting at a proximalmost junction of the stent, pairs of adjacent ones of the proximalmost struts meeting at respective upper junctions; a cuff attached to the annulus section of the stent and having an outer surface facing in radial directions orthogonal to the flow direction, the cuff having a straight proximal end; a plurality of prosthetic valve leaflets attached to the cuff; and at least one sealing member comprising (i) a first proximal side, whereby one or more sutures attach the first proximal side to a first one of the two proximalmost struts of a respective cell in the first full row of cells, (ii) a second proximal side, whereby one or more sutures attach the second proximal side to a second one of the two proximalmost struts of the respective cell in the first full row of cells, and (iii) a distal side unconnected to the cuff; wherein in the expanded condition of the prosthetic heart valve, the at least one sealing member forms a pocket between the sealing member and the cuff.

2. The prosthetic heart valve of claim 1, wherein the at least one sealing member billows radially outward when retrograde blood flow occurs on an abluminal side of the prosthetic heart valve when the prosthetic heart valve is expanded in the annulus of the native aortic valve of the patient.
3. The prosthetic heart valve as claimed in claim 1, wherein the proximal end of the cuff is attached to the stent by cuff sutures, and the first and second proximal sides of the at least one sealing member are attached to the proximal end of the cuff by the cuff sutures.
4. The prosthetic heart valve of claim 1, wherein the first and second proximal sides of the at least one sealing member are sewn to the cuff substantially along a contour of one or more struts at the inflow end of the stent.
5. The prosthetic heart valve of claim 1, wherein the at least one sealing member is annularly disposed around an abluminal surface of the stent at the inflow end of the prosthetic heart valve.
6. The prosthetic heart valve of claim 1, wherein the at least one sealing member extends completely around a circumference of the stent.
7. The prosthetic heart valve of claim 1, wherein the at least one sealing member is formed from a triangular patch of material.
8. The prosthetic heart valve of claim 1, wherein each leaflet is attached to the cuff along a belly portion, the belly portion including an attachment point at which the leaflet is closest to the inflow end of the stent, each of the attachment points is at a predetermined distance from the inflow end of the stent, the attachment points collectively define a positioning line circumscribing a circumference of the stent at the predetermined distance from the inflow end of the stent, and the distal side of the at least one sealing member is located between the outflow end of the stent and the positioning line.
9. A prosthetic heart valve configured to be expanded in an annulus of a native aortic valve of a patient, the prosthetic heart valve comprising: a stent extending in a flow direction from an inflow end to an outflow end, the stent having an expanded condition and a collapsed condition and including an annulus section adjacent to the inflow end and a plurality of struts shaped to form a plurality of cells connected to one another in a plurality of annular rows around the stent, the plurality of annular rows of cells including a first full row of cells at the inflow end of the stent, each cell in the first full row of cells being diamond-shaped and having two proximalmost struts, the proximalmost struts of each cell in the first full row of cells meeting at a proximalmost junction of the stent, pairs of adjacent ones of the proximalmost struts meeting at respective upper junctions; a cuff attached to the annulus section of the stent and having an outer surface facing in radial directions orthogonal to the flow direction, the cuff having a straight proximal end; a plurality of prosthetic valve leaflets attached to the cuff; and an active sealing mechanism for sealing against a perivalvular leak, the active sealing mechanism comprising at least one sealing member, the active sealing mechanism comprising (i) a first proximal side, whereby one or more sutures attach the first

proximal side to a first one of the two proximalmost struts of a respective cell in the first full row of cells, (ii) a second proximal side, whereby one or more sutures attach the second proximal side to a second one of the two proximalmost struts of the respective cell in the first full row of cells, and (iii) a distal side unconnected to the cuff; wherein in the expanded condition of the prosthetic heart valve, the at least one sealing member forms a pocket between the sealing member and the cuff.

10. The prosthetic heart valve of claim 9, wherein the active sealing mechanism billows radially outward when retrograde blood flow occurs on an abluminal side of the prosthetic heart valve when the prosthetic heart valve is expanded in the annulus of the native aortic valve of the patient.

11. The prosthetic heart valve as claimed in claim 9, wherein the proximal end of the cuff is attached to the stent by cuff sutures, and the first and second proximal sides of the active sealing mechanism are attached to the proximal end of the cuff by the cuff sutures.

12. The prosthetic heart valve of claim 9, wherein the first and second proximal sides of the active sealing mechanism are sewn to the cuff substantially along a contour of one or more struts at the inflow end of the stent.

13. The prosthetic heart valve of claim 9, wherein the active sealing mechanism is annularly disposed around an abluminal surface of the stent at the inflow end of the prosthetic heart valve.

14. The prosthetic heart valve of claim 9, wherein the active sealing mechanism extends completely around a circumference of the stent.

15. The prosthetic heart valve of claim 9, wherein the active sealing mechanism is formed from a triangular patch of material.

16. The prosthetic heart valve of claim 9, wherein each leaflet is attached to the cuff along a belly portion, the belly portion including an attachment point at which the leaflet is closest to the inflow end of the stent, each of the attachment points is at a predetermined distance from the inflow end of the stent, the attachment points collectively define a positioning line circumscribing a circumference of the stent at the predetermined distance from the inflow end of the stent, and the distal side of the active sealing mechanism is located between the outflow end of the stent and the positioning line.

17. A prosthetic heart valve configured to be expanded in an annulus of a native aortic valve of a patient, the prosthetic heart valve comprising: a stent extending in a flow direction from an inflow end to an outflow end, the stent having an expanded condition and a collapsed condition and including an annulus section adjacent to the inflow end and a plurality of struts shaped to form a plurality of cells connected to one another in a plurality of annular rows around the stent, the plurality of annular rows of cells including a first full row of cells at the inflow end of the stent, each cell in the first full row of cells being diamond-shaped and having two proximalmost struts, the proximalmost struts of each cell in the first full row of cells meeting at a proximalmost junction of the stent, pairs of adjacent ones of the proximalmost struts meeting at respective upper junctions; a cuff attached to the annulus section of the stent and having an outer surface facing in radial directions orthogonal to the flow direction, the cuff having a straight proximal end; a plurality of prosthetic valve leaflets attached to the cuff; and a sealing structure extending continuously around a circumference of the stent, the sealing structure comprising at least one sealing member comprising (i) a first proximal side, whereby one or more sutures attach the first proximal side to a first one of the two proximalmost struts of a respective cell in the first full row of cells, (ii) a second proximal side, whereby one or more sutures attach the second proximal side to a second one of the two proximalmost struts of the respective cell in the first full row of cells, and (iii) a distal side unconnected to the cuff; wherein in the expanded condition of the prosthetic heart valve, the at least one sealing member forms a pocket between the sealing member and the cuff.

18. The prosthetic heart valve of claim 17, wherein the sealing structure billows radially outward when retrograde blood flow occurs on an abluminal side of the prosthetic heart valve when the prosthetic heart valve is expanded in the annulus of the native aortic valve of the patient.

19. The prosthetic heart valve of claim 17, wherein the sealing structure is annularly disposed around an abluminal surface of the stent at the inflow end of the prosthetic heart valve.

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