Title: GASKET WITH COLLAR FOR PROSTHETIC HEART VALVES AND METHODS FOR USING THEM

Abstract: A heart valve assembly includes a prosthesis for receiving a prosthetic valve to replace a preexisting natural or prosthetic heart valve within a biological annulus adjacent a sinus cavity. The prosthesis includes an annular member implantable within the biological annulus for contacting tissue surrounding the biological annulus to provide an opening through the biological annulus, a collar extending upwardly from the annular member, and a sewing cuff extending radially outwardly from the annular member and/or collar. Optionally, the annular member and/or collar may be resiliently compressible, expandable, and/or otherwise biased. A valve member, e.g., a mechanical or bioprosthetic valve may be coupled to the collar, e.g., using a drawstring, sutures, or other connectors, to secure the valve member to the gasket member.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
GASKET WITH COLLAR FOR PROSTHETIC HEART VALVES AND METHODS FOR USING THEM

FIELD OF THE INVENTON

The present invention relates generally to heart valves that may be implanted within a patient, and, more particularly, to multiple component heart valve assemblies that may be assembled together, and to apparatus and methods for using them.

BACKGROUND

Prosthetic heart valves can replace defective human valves in patients. For example, one piece valves have been suggested that include sewing rings or suture cuffs that are attached to and extend around the outer circumference of a prosthetic valve. In addition, multiple component valves have also been suggested that include a sewing ring that is separate from a valve component. The sewing rings of either type of prosthetic valve can be tedious and time consuming to secure within a target site, i.e., within an annulus of a heart where a natural heart valve has been removed.

For example, to implant a sewing ring within an annulus of a heart, between twelve and twenty sutures may be secured initially to tissue surrounding the annulus. The sewing ring and/or the entire prosthetic valve may then be advanced or “parachuted” down the sutures into the annulus. Knots may then be tied with the sutures to secure the sewing ring within the annulus, whereupon the sutures may be cut. Consequently, this procedure can be very complicated, requiring management and manipulation of many sutures. The complexity of the procedure also provides a greater opportunity for mistakes and requires a patient to be on cardiopulmonary bypass for a lengthy period of time.

Because the annulus of the heart may not match the circular cross-section of the sewing ring and/or prosthetic valve, the prosthetic valve may not fit optimally within the annulus. As a result, natural blood hemodynamics through and around the valve may be impaired, resulting in clotting, possible emboli production, and eventual calcification of the valve structure.

To address this concern, flexible sewing rings have been suggested for use with multiple component valves. The sewing ring may be implanted within the annulus, e.g., using the procedure described above, i.e., parachuted down an arrangement of sutures. The sewing ring may conform at least partially to the anatomy of the annulus.
Alternatively, instead of using sutures, it has also been suggested to drive staples through the sewing ring into the surrounding tissue to secure the sewing ring.

When a mechanical or prosthetic valve is then attached to the sewing ring, however, the valve and sewing ring may not mate together effectively, e.g., if the shape of the sewing ring has been distorted to conform to the annulus, which may also impair natural blood hemodynamics, create leaks, and/or otherwise impair performance of the prosthetic valve.

**SUMMARY OF THE INVENTION**

The present invention is directed to heart valves that may be implanted within a patient, and, more particularly, to multiple component heart valve assemblies that may be assembled together, and to apparatus and methods for making and implanting them.

In accordance with one embodiment, a prosthesis is provided for receiving a prosthetic valve to replace a preexisting natural or prosthetic heart valve within a biological annulus adjacent a sinus cavity. The prosthesis may include an annular member implantable within the biological annulus for contacting tissue surrounding the biological annulus to provide an opening through the biological annulus, a collar extending upwardly from the annular member, and a sewing cuff extending radially outwardly from the annular member and/or collar. Optionally, the annular member and/or collar may be resiliently compressible, expandable, and/or otherwise biased.

In accordance with another embodiment, a heart valve assembly is provided for implantation within a biological annulus. The heart valve assembly may include an annular prosthesis implantable within a biological annulus that includes an annular member for contacting tissue surrounding the biological annulus, and a collar extending upwardly from the annular member. The heart valve assembly also includes a prosthetic valve, e.g., including a mechanical or bioprosthesis heart valve, which may have a circular or multiple lobular shape for implantation above the biological annulus.

Optionally, one or more connectors may be provided on at least one of the annular prosthesis and the prosthetic valve for securing the prosthetic valve to the annular prosthesis. For example, the one or more connectors may include a drawstring on the collar for engaging a frame of the prosthetic valve. Alternatively, the one or more connectors may include one or more latches, detents, interlocking elements on the prosthetic valve and/or the annular prosthesis.
In one embodiment, the collar may be formed from resiliently flexible material, e.g., silicone covered with a fabric covering. The collar may be formed as a unitary piece with a sewing ring and/or annular member, which may be covered with one or more pieces of fabric. Alternatively, the collar, sewing ring, and/or annular member may be separate components that are attached to one another, either before or after being covered with fabric.

In accordance with yet another embodiment, a method is provided for implanting a prosthetic heart valve assembly to replace a natural or prosthetic heart valve implanted within a biological annulus below a sinus cavity. An annular member may be introduced into the biological annulus, e.g., to direct tissue surrounding the biological annulus outwardly, e.g., to at least partially dilate the biological annulus. A flexible sewing cuff or skirt may extend around the annular member that may receive one or more connectors, e.g., sutures, clips, and the like, to secure the annular member within the annulus.

A valve prosthesis, e.g., a mechanical or bioprosthetic valve, may be advanced into the sinus cavity, and secured relative to the annular member. In one embodiment, a collar or stand-off extends upwardly from the annular member for receiving the valve prosthesis. The valve prosthesis may be secured to the collar using one or more connectors, e.g., a drawstring in the collar, one or more sutures, clips detents, and/or other cooperating connectors, e.g., on the collar and a frame of the valve prosthesis.

The collar may support the valve prosthesis above the tissue annulus, e.g., within the sinus of valsalva. The collar may allow the valve prosthesis to have a larger size than the annular member, thereby enhancing the fluid flow or other performance characteristics of the implanted heart valve assembly. Optionally, the collar may include a funnel or other tapered shape that may provide a transition from a relatively larger valve prosthesis to the annular member within the tissue annulus. In addition, the collar may support the valve prosthesis away from a wall of the sinus or other supra-annular space, while still allowing blood to flow easily into the coronary arteries around the valve prosthesis.

In accordance with still another embodiment, a heart valve prosthesis is provided that includes an annular prosthesis implantable within a biological annulus, and a prosthetic valve member secured to the annular prosthesis. The annulus prosthesis may include an annular member sized for implantation within the biological annulus, a sewing cuff extending radially from the annular member, and an annular transition extending upwardly from the annular member. The valve member may include a frame secured to
the annular transition, the frame having a cross-section that is substantially larger than the annular member.

In accordance with yet another embodiment, a method is provided for implanting a prosthetic heart valve assembly within a biological annulus. The heart valve assembly includes an annular member sized for delivery into the biological annulus, an annular transition extending upwardly from the annular ring, and a valve member secured to the annular transition that has a cross-section larger than the annular member. The heart valve assembly may be introduced towards the biological annulus such that the annular member is disposed within the biological annulus and the valve member is disposed above the biological annulus, and the heart valve assembly may be secured to tissue adjacent the biological annulus.

In one embodiment, a valve member is selected having a predetermined size corresponding to a sinus cavity above the biological annulus, and the selected valve member is secured to the annular transition before introduction into the biological annulus. In another embodiment, the valve member is secured to the annular transition during manufacturing and provided preassembled. In still another embodiment, the annular transition may be implanted within the biological annulus, and then the valve member may be introduced and secured to the annular transition.

Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The drawings illustrate exemplary embodiments of the invention, in which:

FIG. 1 is a perspective view of a two piece heart valve assembly including a gasket member and a mechanical valve.

FIG. 2 is a perspective view of an exemplary mechanical valve that may be provided with the heart valve assembly of FIG. 1.

FIGS. 3A and 3B are perspective and top views, respectively, of an exemplary embodiment of a gasket member (with a fabric covering removed for clarity) that may be provided with the heart valve assembly of FIG. 1.

FIG. 3C is a cross-sectional view of the gasket member of FIG. 3B taken along line A-A.
FIG. 3D is a cross-sectional view of the gasket member of FIG. 3C taken along line B-B.

FIGS. 4A and 4B are perspective and partial cross-sectional side views, respectively, of the heart valve assembly of FIG. 1.

FIG. 5 is a cross-sectional view showing the heart valve assembly of FIGS. 4A and 4B implanted within a tissue annulus of a patient.

FIGS. 6A-6D are top, two perspective, and side views, respectively, of a core for a collar that may be included in a gasket member.

FIGS. 7A-7C show a method for covering the core of FIGS. 6A-6D with fabric to provide a collar for a gasket member.

FIG. 8A is a perspective view of a mechanical valve secured to the collar of FIG. 7C by a drawstring.

FIG. 8B is a perspective view of the mechanical valve of FIG. 8A being secured to a completed gasket member by a drawstring.

FIGS. 9A and 9B are perspective view of the gasket member of FIGS. 3A-3D, showing flexibility of a collar of the gasket member allowing the collar to be compressed or diverted to provide access to a sewing ring of the gasket member.

FIG. 10 is a perspective view of a mechanical valve including a frame disposed adjacent a portion of a collar, showing a groove in the frame that may engage with the collar when a drawstring on the collar is tightened.

**DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

Turning to the drawings, FIG. 1 shows an exemplary embodiment of a heart valve assembly 10 that generally includes a gasket member 12 and a valve member 14. As shown, the valve member 14 may be a mechanical valve including an annular frame 32 supporting a pair of valve members 33 that open and close within the frame 32 (e.g., see FIGS. 5 and 4A, respectively). Optionally, as best seen in FIG. 2, the valve member 14 may include a pair of ears 34 extending downwardly from the frame 32, e.g., for pivotally securing the valve members 33 to the frame 32.

In an exemplary embodiment, the valve member 14 may be a mechanical valve, such as the “Regent” Bileaflet Valve manufactured by St. Jude Medical. In alternative embodiments, the valve member 14 may be other mechanical or bioprosthetic valves, such as those disclosed in co-pending applications Serial Nos. 10/646,63, filed August 22,

Turning to FIGS. 3A-3D, an exemplary embodiment of the gasket member 12 is shown that generally includes an annular ring 18, a sewing cuff 20, and a collar or stand-off 22. A fabric covering, which may be provided on one or more components of the gasket member 12 has been omitted for clarity. In one embodiment, the annular ring 18 may have a generally circular shape, although alternatively, the annular ring 18 may have a multi-lobular shape about the circumference, e.g., including three lobes separated by scallops or cusps (not shown). Optionally, the annular ring 18 may be expandable and/or contractible such that the diameter may be adjusted, e.g., based upon the anatomy of the patient encountered during a procedure. In one embodiment, the annular ring 18 may be biased to expand to a predetermined diameter. Thus, the annular ring 18 may be contracted radially to a smaller diameter, e.g., to facilitate delivery into an annulus, yet may be resiliently expandable to dilate tissue surrounding the annulus and/or to facilitate securing the gasket member 12 within the annulus. In addition, if the sewing cuff 20 and/or collar 22 are substantially flexible, they may also be at least partially folded or otherwise compressed to facilitate introduction into a biological annulus.

With additional reference to FIG. 4B, the annular ring 18 may be formed from an elastic or superelastic material, such as Nitinol, or any of the other materials described in the applications referenced above. For example, the annular ring 18 may be cut from a flat sheet of base material having a desired thickness for the annular ring 18, for example, by laser cutting, mechanical cutting, and the like. Thus, the annular ring 18 may be initially formed as a long band of material, having a width corresponding to the desired width of the annular ring 18. The band may be wrapped around a mandrel or otherwise restrained in a generally cylindrical shape with the ends adjacent to one another, and the band may be heat treated or otherwise processed to program the generally cylindrical shape to create the annular ring 218. The generally cylindrical shape may include the ends overlapping one another, spaced apart from one another to provide an open “C” shape, or attached to one another.

When the annular ring 18 is at least partially covered with fabric, as shown in FIG. 1, e.g., for tissue ingrowth, the fabric may be wrapped around the annular ring 18, while accommodating expansion and contraction of the annular ring 18. For example, at least near the ends (not shown) of the annular ring 18, the fabric may not be secured to the
annular ring 18, allowing the ends to slide circumferentially relative to the fabric. Optionally, sutures and the like (not shown) may be used to secure the fabric to the annular ring 18 at locations removed from the ends, e.g., at an intermediate location about the circumference of the annular ring 18. Alternatively, the entire annular ring 18 may be free to slide within the fabric wrapped around the annular ring 18.

The sewing cuff 20 may be attached to or otherwise extend around the annular ring 18. The sewing cuff 20 may simply be a layer of fabric or other material covering at least a portion of the annular ring 218. As shown in FIGS. 3A-3D, the sewing cuff 20 may include flexible core material, such as silicone or other elastomeric material, foam, fabric, and the like, which may be attached to or otherwise extend around the annular ring 18, e.g., from an upper edge of the annular ring 18. The core may include a solid wall or a lattice structure, and may be maintained adjacent the annular ring 18 by the surrounding fabric or may be attached to the annular ring 18, e.g., along an upper edge of the annular ring 18. Additional information on materials and methods for making and using the gasket member 12, e.g., the annular ring 18, sewing cuff 20, and/or other components may be found in application Serial No. 11/069,081.

The collar 22 may be attached to or otherwise extend upwardly from the annular ring 18 and/or the sewing cuff 20. As shown, the collar 22 may include a core 23, which may be separate from the core of the sewing cuff 20. The core 23 and the core of the sewing cuff 20 may be attached to one another, e.g., by bonding, fusing, interference fit, and the like, and/or may be maintained adjacent one another by the surrounding fabric. Alternatively, the core 23 of the collar 22 and the core of the sewing cuff 22 may be formed as a unitary piece, e.g., by molding, cutting and/or machining from a blank, and the like. In a further alternative, the collar 22 may be disposed adjacent the sewing cuff 20 and/or annular ring 18, and attached thereto, e.g., using one or more sutures or other connectors (not shown).

The material of the core 23 may be substantially flexible, e.g., manufactured in a desired annular shape, yet easily deformed, e.g., deflected, stretched, and/or compressed, as demonstrated in FIGS. 9A and 9B. Exemplary materials for the core include silicone or other elastomeric materials, foam, fabric, felt, polymers, and the like, e.g. similar to the sewing cuff 20. The materials may be molded or otherwise formed into the core, e.g., using known molding, extrusion, cutting, machining, or other manufacturing procedures.
In the embodiment shown in FIGS. 6A-6D, the core 23 may be formed from a cylindrical or tubular section of material, e.g., silicone, which may have portions cut away or otherwise removed to provide the final shape and/or features of the core 23. Alternatively, the core 23 may be molded or otherwise formed to include its final shape and/or features. The core 23 may have a substantially uniform inner and/or outer diameter, or, alternatively, the core 23 may be tapered, e.g., such that a lower edge of the core 23 is narrower than an upper edge, as described further below.

As shown in FIGS. 7A-7C, the core 23 may be covered with fabric 25. Optionally, one or more connectors may be attached to or otherwise provided on the core 23. For example, as shown in FIG. 7C, a drawstring 30 has been provided that at least partially surrounds the core 23. The drawstring 30 may include one or more threads or other filaments that extend around the circumference of the core 23. The fabric 25 may be wrapped around the core 23 such that the fabric 25 also covers the filament of the drawstring 30. Ends 31 of the drawstring 30 may extend through opening in the fabric 25, thereby allowing the ends 31 to be pulled by a user, e.g., to constrict and/or compress the core 23 radially inwardly. Alternatively, other connectors (not shown) may be provided on the collar 22 that may interlock or otherwise engage mating connectors or other features on the valve member 14, e.g., such as those disclosed in applications Serial Nos. 60/748,639, filed December 7, 2005, 11/279,246, filed April 10, 2006, and 60/746,038, filed April 29, 2006, or in the other applications referenced above.

As best seen in FIG. 3C, the collar 22 may include one or more grooves or pockets 24 formed within the collar 22. For example, the collar 22 may include a pair of opposing grooves on an inner surface thereof, which may accommodate the ears 34 of the valve member 14 shown in FIG. 2. The collar 22 may have sufficient height to accommodate receiving the frame 32 of the valve member 14 without the ears 34 extending down into the annular ring 18, e.g., as can be seen in FIG. 5, which may otherwise at least partially obstruct the passage through a biological annulus. The collar 22 may have sufficient structural integrity to support the valve member 14, yet be sufficiently flexible to be deformable to facilitate introduction into a patient’s body and/or to move the collar 22 away to accommodate delivery of one or more connectors into the sewing cuff 20, as described elsewhere herein.

During use, the gasket member 12 may be implanted within a patient’s body, e.g., within or adjacent to a biological annulus 90, as shown in FIG. 5, similar to the methods
disclosed in the applications referenced above. The biological annulus 90 may be the site for replacement of an existing natural or previously implanted prosthetic valve, such as a tricuspid, mitral, aortic, or pulmonary valve within a patient's heart (not shown). The biological annulus may extend from a supra annular region, e.g., the Sinus of Valsalva for an aortic valve, through a native valve site, e.g., a site where the aortic valve has been removed, to a sub-annular region.

With the annular ring 18 contracted into a relatively small diameter (if the annular ring 18 is radially compressible), the gasket member 12 may be advanced into the annulus 90 using a delivery tool (not shown). The gasket member 12 may be advanced until the annular ring 18 extends at least partially into the biological annulus 90. In one embodiment, the annular ring 18 may extend entirely through the biological annulus 90, with the lower edge of the annular ring 18 remaining free within the sub-annular space below the biological annulus 90. Optionally, as shown in FIGS. 4B and 5, the gasket member 12 may include a flexible skirt 26 that extends through the annulus 90. The skirt 26 may be biased to extend outwardly as shown to provide a smooth transition and/or enhance a seal between the heart valve assembly 10 and the biological annulus 90.

If the annular ring 18 is expandable or otherwise compressed, the annular ring 18 may then be expanded within the biological annulus 90, e.g., to dilate the biological annulus 90 or otherwise direct the surrounding tissue outwardly against the underlying tissue structures. For example, the annular ring 218 may simply be released by the delivery tool, whereupon the annular ring 18 may resiliently expand against the tissue surrounding the biological annulus 90, thereby substantially securing the annular ring 18 (and consequently, the gasket member 12) relative to the biological annulus 90. In addition or alternatively, a dilation tool (not shown) may be advanced into the gasket member 12 and expanded to forcibly (e.g., plastically) expand the annular ring 18 within the biological annulus 90.

If the sewing cuff 20 is restrained by the delivery tool, the sewing cuff 20 may be released to allow the sewing cuff 20 to contact the surrounding tissue, e.g., within the aortic root above the biological annulus 90. The sewing cuff 20 may contact the tissue within the supra-annular space above the biological annulus 90, as shown in FIG. 5, although the sewing cuff 20 may not provide any structural support of the annular ring 18. Because of the floppy (i.e., flexible and conformable) nature of the core of the sewing cuff 20, the sewing cuff 20 may adopt the shape of the surrounding tissue, e.g., lying flatter
within the coronary sinus regions, while becoming more vertical adjacent the commissures, as explained in the applications referenced above.

With the gasket member 12 in place, a plurality of fasteners, e.g., clips, staples, sutures, and the like (not shown), may be directed through the sewing cuff 20 into the tissue surrounding the biological annulus to secure the gasket member 12 relative to the biological annulus. If necessary to facilitate access to the sewing cuff 20, local portions of the collar 22 may be at least partially deflected out of the way, as shown in FIGS. 9A and 9B. The collar 22 may be sufficiently resilient to return to its annular shape upon release. Additional information on fasteners and apparatus and methods for delivering them may be found in applications Serial Nos. 10/681,700, filed October 8, 2003 and 11/004,445, filed December 3, 2004.

The valve member 14 may then be advanced into the biological annulus, e.g. using another delivery tool or the same tool (not shown) used to deliver the gasket member 12. The valve member 14 may then be secured to the collar 22, e.g., using one or more connectors. For example, as described above, in one embodiment, the collar 22 may include a drawstring 30, as shown in FIG. 7C. After inserting the valve member 14 at least partially into the collar 22, as shown in FIGS. 8A and 8B, the ends 31 may be pulled to tighten the drawstring 30 around the frame 32 of the valve member 14 to secure the valve member 14 relative to the collar 22. Optionally, the frame 32 may include an annular groove 36 or other feature(s) (not shown) that may receive a portion of the collar 22 or otherwise engage the collar when the drawstring 30 is tightened.

Alternatively, one or more sutures 40 may be directed through a sewing cuff 39 on the valve member 14 and the fabric and/or core of the collar 22, e.g., as shown in FIG. 1. In a further alternative, the valve member 14 and/or collar 22 may include cooperating clips, detents, and the like (not shown) that may self-engage when the valve member 14 is docked into the collar 22, similar to the embodiments described in the applications referenced above. In still another alternative, the gasket member 12 may include a plurality of leaders or other elongate guides (not shown), which may be directed through a sewing cuff 39 or other portion of the valve member 14, similar to the apparatus and methods disclosed in applications Serial Nos. 60/748,639 and 60/746,038. For example, the leaders may be sutures, and knots may be directed down the sutures to secure the valve member 14 to the collar 22, whereupon the sutures may be cut or otherwise severed. Alternatively, other guide members (not shown) may be provided that may be directed
through the sewing cuff 39, e.g., through receivers or other mating connectors (also not shown) in the sewing cuff 22 or simply by “picking up” strands of the fabric of the sewing cuff 22, as described in the applications referenced above.

Once the valve member 14 is secured, any tools may be removed, and the procedure completed using known methods.

In an alternative embodiment, the valve member 14 may be secured to the collar 22 (or otherwise to the gasket member 12, as described elsewhere herein) before introduction into the patient’s body. For example, immediately before implantation, a user may select a desired size valve member 14 and direct the valve member into engagement with the collar 22, e.g., using one or more cooperating detents or other connectors as described herein or in the applications referenced above. In a further alternative, the valve member 14 may be secured to the collar 22 during manufacturing, and shipped pre-assembled as a single piece.

The resulting heart valve assembly 10 may be introduced into a tissue annulus, e.g., a site of a native or previously implanted prosthetic valve (not shown), as a single component. For example, a plurality of sutures may be placed in tissue surrounding the tissue annulus, e.g., using conventional needle and suture devices. The sutures may be directed through a portion of the heart valve assembly 10, e.g., through the sewing cuff 20, valve frame, or other portion of the heart valve assembly 10. In one embodiment, a needle on one end of each suture may be directed through fabric on the heart valve assembly, i.e., to pick up one or more strands of the fabric.

Once several sutures have been directed through the heart valve assembly 10, e.g., spaced apart around the circumference of the heart valve assembly 10, the heart valve assembly 10 may be advanced or “parachuted” down the sutures into the tissue annulus. Knots may be tied in the sutures to secure the heart valve assembly 10 within or otherwise to the tissue annulus. Excess suture material may then be cut off or otherwise severed. Optionally, other connectors, e.g., staples, clips, and the like, may be delivered through the sewing cuff 20 and/or other portion of the heart valve assembly 10 into the surrounding tissue, in addition to or instead of the sutures. Thus, the heart valve assembly 10 may be delivered more analogously to a one-piece valve.

One advantage of the apparatus and methods described herein is that a valve member 14 may be selected that is larger than conventional one-piece valves. Because the valve member 14 is secured to or otherwise supported by the collar 22, the valve member
14 may be disposed above the tissue annulus, e.g., within the sinus of Valsalva, upon implantation within the aortic valve annulus. Because this space is larger than the tissue annulus, a relatively larger valve member 14 may be selected than if the valve member 14 were disposed within the aortic valve annulus.

The collar 22 may provide a substantially smooth and/or continuous transition from the valve member 14 into the tissue annulus, thereby providing improved flow through the heart valve assembly 10 and/or tissue annulus after implantation. Thus, an inner surface of the collar 22 may be designed to transition substantially smoothly from a larger upper edge, corresponding to the size of the valve member 14 down to a lower edge corresponding to the size of the annular member 18 extending through the biological annulus. This may enhance hemodynamics of blood flowing through the biological annulus, as compared to conventional valves.

It will be appreciated that elements or components shown with any embodiment herein are exemplary for the specific embodiment and may be used on or in combination with other embodiments disclosed herein.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.
We claim:

1. A prosthesis for receiving a prosthetic valve to replace a preexisting natural or prosthetic heart valve within a biological annulus adjacent a sinus cavity, comprising:
   - an annular member implantable within the biological annulus for dilating tissue surrounding the biological annulus;
   - a sewing cuff extending radially outwardly from the annular member, the sewing cuff being conformable for adopting a shape of tissue surrounding the sinus cavity above the biological annulus; and
   - a collar extending upwardly from the annular member for engaging a portion of a prosthetic valve.

2. The prosthesis of claim 1, further comprising one or more connectors on the collar for securing a prosthetic valve to the annular member.

3. The prosthesis of claim 1, wherein the collar comprises one or more grooves therein for receiving features of the prosthetic valve.

4. A heart valve assembly, comprising:
   - an annular prosthesis implantable within a natural valve annulus, the annulus prosthesis comprising an annular member configured to be received in a biological annulus, a sewing cuff extending radially outwardly from the annular member, and a collar extending upwardly from the annular member; and
   - a prosthetic valve comprising a frame securable to the collar.

5. The heart valve assembly of claim 4, further comprising one or more connectors for securing the prosthetic valve to the annular prosthesis.

6. The heart valve assembly of claim 5, wherein the one or more connectors comprises a drawstring on the collar.

7. The heart valve assembly of claim 4, wherein the frame comprises one or more ears extending downwardly, and the collar comprises one or more grooves for receiving the one or more ears.
8. The heart valve assembly of claim 4, wherein the prosthetic valve comprises a mechanical valve.

9. The heart valve assembly of claim 4, wherein the prosthetic valve comprises a bioprosthetic valve.

10. A method for implanting a prosthetic heart valve assembly to replace a natural or prosthetic heart valve implanted within a biological annulus below a sinus cavity, the method comprising:
    introducing an annular member into the biological annulus such that a sewing cuff extending from the annular member is disposed within the sinus cavity;
    implanting the annular member within the biological annulus by directing a plurality of fasteners through the sewing cuff into tissue adjacent the biological annulus;
    advancing a valve prosthesis into the sinus cavity; and
    securing the valve prosthesis to a collar extending upwardly from the annular member.

11. A prosthesis for receiving a prosthetic valve to replace a preexisting natural or prosthetic heart valve within a biological annulus, comprising:
    an annular member implantable within the biological annulus for dilating tissue surrounding the biological annulus;
    a sewing cuff extending radially from the annular member; and
    a collar extending upwardly from the annular member for engaging a portion of a prosthetic valve, the collar comprising an upper edge and an inner surface that transitions inwardly from the upper edge towards the annular member.

12. The prosthesis of claim 11, further comprising one or more connectors on the collar for securing a prosthetic valve to the annular member.

13. The prosthesis of claim 11, wherein the inner surface of the collar comprises a generally frustoconical shape that transitions from the upper edge towards the annular member.
14. A heart valve assembly, comprising:
an annular prosthesis implantable within a biological annulus, the annulus
prosthesis comprising an annular member sized for implantation within the biological
annulus, a sewing cuff extending radially from the annular member, and an annular
transition extending upwardly from the annular member; and
a prosthetic valve comprising a frame securable to the collar, the frame having a
cross-section that is substantially larger than the annular member.

15. The heart valve assembly of claim 14, further comprising one or more
connectors for securing the prosthetic valve to the annular prosthesis.

16. The heart valve assembly of claim 15, wherein the one or more connectors
comprises a drawstring on the collar.

17. The heart valve assembly of claim 14, wherein the annular transition
comprises an upper edge and an inner surface that transitions inwardly from the upper
dge towards the annular member.

18. The heart valve assembly of claim 14, wherein the inner surface of the
collar provides a substantially smooth transition from the frame of the prosthetic valve to
the annular member.

19. The heart valve assembly of claim 14, wherein the prosthetic valve
comprises at least one of a bioprosthetic valve and a mechanical valve.

20. A method for assembling a prosthetic heart valve assembly to replace a
natural or prosthetic heart valve implanted within a biological annulus below a sinus
cavity, the method comprising:

providing a gasket member comprising an annular ring sized for delivery into the
biological annulus, the gasket member comprising an annular transition extending
upwardly from the annular ring;

selecting a valve member that has a cross-section larger than the annular ring; and
connecting the valve member to the annular transition to provide a heart valve assembly that may be introduced into a biological annulus such that the annular ring is disposed within the biological annulus and the valve member is disposed within the sinus cavity.

21. A method for implanting a prosthetic heart valve assembly within a biological annulus, comprising:

providing a heart valve assembly comprising an annular member sized for delivery into the biological annulus, an annular transition extending upwardly from the annular ring, and a valve member secured to the annular transition that has a cross-section larger than the annular member;

introducing the heart valve assembly towards the biological annulus such that the annular member is disposed within the biological annulus and the valve member is disposed above the biological annulus; and

securing the heart valve assembly to tissue adjacent the biological annulus.
FIG. 4A

FIG. 4B

SUBSTITUTE SHEET (RULE 26)