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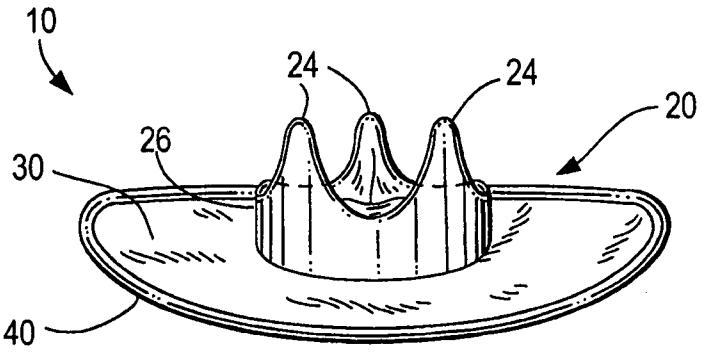
(54) **Title:** PROSTHETIC HEART VALVE STRUCTURES AND RELATED METHODS



(57) **Abstract:** A prosthetic heart valve includes a valve core and a mounting retainer that extends radially out from the core to an outer perimeter portion. The outer perimeter portion has a different shape than a perimeter of the valve core when both perimeters are viewed along an axis that will be the axis of blood flow through the valve core when the prosthetic heart valve is in use in a patient. The outer perimeter portion is used to mount the valve to another structure such as a native valve annulus in a valve replacement procedure. The mounting retainer bridges the gap(s) between the valve core and the outer perimeter portion, and may also provide attachment sites for other native tissue structures (like chordae tendonae), which attachment sites can be at or at least closer to original (native) attachment sites for those tissue structures.

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PROSTHETIC HEART VALVE STRUCTURES AND RELATED METHODS

Background of the Invention

[0001] This invention relates to prosthetic or replacement heart valves, and to methods of using such valves. While the invention will be initially described in its use in replacing a patient's mitral heart valve, the invention also has other uses, some of which will be specifically mentioned later in this specification.

[0002] The mitral valve is located between the left atrium and the left ventricle of the heart. Various conditions can cause a person's mitral valve to become either incompetent (i.e., no longer closing properly) or stenotic (i.e., no longer opening properly). For example, inability of the mitral valve to close properly allows blood to regurgitate from the left ventricle back into the right atrium during contractions of the left ventricle. Such mitral regurgitation ("MR") increases the load on the heart and/or decreases blood flow throughout most of the body, which can have serious adverse consequences for the individual.

[0003] Among the possible treatments for mitral valve diseases are replacement of the mitral valve with an artificial, prosthetic valve. An alternative treatment is so-called "repair," which often involves implanting an "annuloplasty ring" inside the left atrium around the base of the native mitral valve. Such a ring can be beneficial by ensuring that the valve annulus cannot enlarge and/or change shape in such a way that the leaflets of the valve no longer meet one another (or coapt) in the interior of the valve when the valve is supposed to be closed.

[0004] As currently practiced, each of these treatments (i.e., replacement or repair) may have certain advantages and disadvantages (or at least suboptimal aspects). For example, valve replacement typically involves implanting a relatively large prosthetic valve having a rigid or relatively rigid circular perimeter in the native mitral valve annulus, the native shape of which tends to be D-shaped rather than circular. The result can be some reshaping of the annulus from the native D shape to a more nearly circular shape. This may not be optimal for the left ventricle or other adjacent structures of the heart. The chordae tendonae and papillary muscles that are naturally connected between the mitral valve leaflets and lower portions of the left ventricle may be preserved in some way, but at the very least they are displaced by the replacement valve. This displacement changes their alignment, which can be suboptimal for ventricular function. On the other hand, repair using an annuloplasty ring means that the valve must continue to rely on its native leaflets, and those leaflets may have deficiencies of various kinds (or may develop such

deficiencies over time), which may still (or again) leave the patient with suboptimal mitral valve performance.

Summary of the Invention

[0005] In accordance with the present invention a prosthetic heart valve includes a heart valve per se ("heart valve core") and a mounting retainer structure that extends out from the heart valve core to an outer perimeter of the entire assembly. As viewed along the axis along which blood will flow through the heart valve core when the apparatus is in use in a patient, the outer perimeter of the heart valve core is smaller and has a different shape than the outer perimeter of the entire assembly. (The outer perimeter of the entire assembly may be alternatively referred to as the outer perimeter of the mounting retainer structure.) For example, the outer perimeter of the heart valve core may be circular or substantially circular, while the outer perimeter of the mounting retainer structure may be non-circular (e.g., shaped somewhat like the letter D ("D-shaped")).

[0006] The outer perimeter of the mounting retainer structure may be or may include a cuff or cuff structure for use in securing the entire assembly in the patient (e.g., by attachment to the patient's native valve apparatus). For example, the cuff structure may be or may include a sewing cuff structure that is designed for sutures to pass through and thereafter be retained by the structure. The cuff structure may also be or may include structure that can affect the shape of the native valve annulus (e.g., by helping it retain its native shape, by helping to

restore it to its native shape, or by providing some deliberate therapeutic modification relative to the native shape).

[0007] Structure of the mounting retainer structure between the heart valve core and the outer perimeter of the mounting retainer structure may provide one or more sites for attachment of chordae tendonae (or tissue associated with chordae tendonae). These sites can be at or at least closer to native attachment sites, which can be an additional advantage of the invention.

[0008] Further features of the invention, its nature and various advantages, will be more apparent from the accompanying drawings and the following detailed description.

Brief Description of the Drawings

[0009] FIG. 1 is a simplified "top" or "plan" view of an illustrative embodiment of a prosthetic heart valve structure in accordance with the invention.

[0010] FIG. 2 is a simplified perspective view of an illustrative embodiment of a prosthetic heart valve structure in accordance with the invention.

[0011] FIG. 3 is similar to FIG. 2, but shows another illustrative embodiment of a prosthetic heart valve structure in accordance with the invention.

[0012] FIG. 4 is a simplified top view of a native heart valve that may be in need of replacement in accordance with the invention.

[0013] FIG. 5 is a simplified top view of a native heart valve structure at an intermediate stage in a valve replacement procedure in accordance with the invention.

[0014] FIG. 6 is a view similar to FIG. 5 showing additional possible features in accordance with the invention.

[0015] FIG. 7 is a view similar to FIG. 1 showing additional possible features in accordance with the invention.

Detailed Description

[0016] An illustrative embodiment 10 of a heart valve structure in accordance with the invention is shown in FIG. 1. Heart valve structure 10 includes a portion 20, which is a heart valve per se. To simplify the terminology used herein, the entirety of structure 10 is generally referred herein to as the heart valve or the heart valve structure, while the actual valve portion 20 of the structure is generally referred to as the heart valve core.

[0017] Heart valve core 20 can be constructed in any of many different ways, using any of many different materials and having any of many different sizes, shapes, operating characteristics, etc. In general, almost any known heart valve construction can be used for heart valve core 20. The illustrative core 20 shown in FIG. 1 is a tri-leaflet core. Such valves typically have relatively flexible leaflets 22, e.g., of tissue or polymer material. Illustrative core 20 is shown having three commissure regions 24 (see also FIGS. 2 and 3). Leaflets 22 and commissures 24 are shown surrounded by an annular core perimeter structure 26 (see again FIGS. 2 and 3). As is the case in most known prosthetic heart valves, core perimeter structure 26 is basically circular in plan view (i.e., a view like FIG. 1 that is taken along what will be the

axis of blood flow through the valve when the valve is in use in a patient). Perimeter structure 26 has the structural integrity required to keep commissures 24 and the bases of leaflets 22 in proper spatial relationship to one another.

[0018] Again, the foregoing depiction and description of core 20 is only illustrative, and core 20 can instead have any of many other constructions. For example, core 20 could instead be a single-leaflet mechanical valve, a bi-leaflet mechanical valve, a ball-type mechanical valve, or any other type of mechanical valve. Similarly, the shape (e.g., the plan view perimeter shape) of core 20 can be different from the shape shown in FIGS. 1-3. Core 20 (e.g., the perimeter 26 of core 20) can be rigid or relatively rigid or can have any desired degree of flexibility. In short, a vast range of options is available for use in constructing core 20.

[0019] Valve structure 10 typically takes advantage of the fact that many modern prosthetic heart valves have extremely good flow characteristics when open. Thus valve core 20 can be considerably smaller than the native heart valve that it will be used to replace and still provide adequate blood flow when in use in a patient. This is especially true for a mitral valve, which has a relatively long period of time during which it is open and which has relatively low blood flow velocity through it; but it can also be true for other heart valves. Accordingly, valve core 20 is typically sized to be smaller than the native valve that valve 10 will be used to replace. In particular, perimeter 26 is typically sized to be smaller than the native valve annulus (or other surrounding native structure).

[0020] FIG. 1 shows valve core 20 surrounded by a mounting retainer structure 30 (see also FIGS. 2 and 3). Retainer structure 30 is secured to perimeter 26 and extends radially out from that perimeter annularly all the way around core 20 (or at least part of the way around core 20). The attachment of retainer structure 30 to perimeter 26 is preferably sufficiently fluid-tight, and structure 30 itself is also preferably impervious to blood flow, at least after healing (although it may at least initially have one or more openings or through-apertures as will be described later). Retainer structure 30 can be flat or relatively flat, or it can have any desired three-dimensional shape. It can be relatively thin, or it can have any desired thickness, which can be different in different areas of the retainer structure. Retainer structure 30 can be rigid, relatively rigid, or flexible to any desired degree, and elements of different relative rigidity or flexibility or of different constructions can be combined to produce structure 30. At a minimum, mounting structure 30 preferably has sufficient structural integrity to support core 20 at least at an approximate desired location relative to an outer perimeter portion 40 of structure 30.

[0021] The above-mentioned outer perimeter portion 40 of mounting structure 30 warrants further discussion as follows. Outer perimeter portion 40 is typically used to secure valve 10 in a patient. For example, outer perimeter portion 40 may be sutured to the native valve annulus. (At least most of the native valve leaflets will have been removed or at least displaced prior to thus implanting valve 10.) This

suturing is typically done annularly all the way around portion 40 and the native valve annulus. In plan view (i.e., looking along the axis of blood flow through core 20 when the valve is in use in a patient), outer perimeter portion 40 is both larger and different in shape than the outer perimeter 26 of core 20. For example, core perimeter 26 may be circular or substantially circular, while the outer perimeter 40 of the entire valve may be D-shaped. Other material of mounting retainer structure 30 spans and at least substantially fills the space(s) or radial distance between core perimeter 26 and ultimate outer perimeter 40.

[0022] If desired, at least the outer perimeter portion 40 of valve 10 can have any of a range of special properties. For example, these properties can be or can include any of the many properties that are known for prosthetic heart valve cuffs (e.g., sewing cuffs). Alternatively or in addition outer perimeter portion can be made with any desired degree of rigidity or flexibility. Similarly, outer perimeter portion 40 can be flat or substantially flat and in a plane that is substantially perpendicular to the axis of blood flow through valve core 20 in use, or it can have any desired three-dimensional shape (e.g., the undulating or saddle shape shown in FIG. 3). If outer perimeter portion 40 is or includes a structural member (e.g., to give it at least some degree of rigidity), that structural member may extend only part way around perimeter 40. For example, the structural member may be C-shaped, rather than a complete D shape.

[0023] Some of the possibilities mentioned in the preceding paragraph are illustrated by FIGS. 2 and 3.

Thus FIG. 2, for example, illustrates a valve 10 having a flat or relatively flat mounting retainer structure 30 and associated outer perimeter portion 40. FIG. 3, on the other hand, illustrates an alternative embodiment in which outer perimeter portion 40 is rigid or substantially rigid and three-dimensional (i.e., an undulating or saddle shape as one proceeds annularly around the ring). Again, rigidity or flexibility of portion 40 can be different between different embodiments, and so can many other shape and/or constructional aspects of portion 40.

[0024] Continuing on with some of the possible features of outer perimeter portion 40, that portion may be especially adapted for suturing into a patient. Thus, as has been said, portion 40 may be constructed to include what may be called a sewing cuff that is well suited for sutures to pass through but to also retain sutures that have been passed through. Alternatively or additionally, portion 40 may include a solid core (e.g., of metal), which can be helpful to give portion 40 a particular shape (in either two dimensions or three dimensions as described earlier) and to enable portion 40 to hold that shape.

[0025] Mounting retainer structure 30 and/or outer perimeter portion 40 can be made of or can include any of many different materials. Examples include typical valve sewing cuff materials such as polyester fabric, other synthetic materials such as reinforced silicone, polyurethane, acetal resin (Delrin®), or PEEK, metals or metal alloys such as nitinol or titanium, biological materials such as animal pericardium, and combinations thereof.

[0026] It is important to note that mounting retainer structure 30 and its outer perimeter portion are not merely a structure like a sewing cuff around valve core 20. The typical sewing cuff around a valve has the same plan view perimeter shape as the perimeter of the valve itself. For example, both of these perimeters may be circles (typically concentric). In accordance with the present invention, these two perimeters have different plan view shapes (e.g., circular for the perimeter of valve core 20 and D-shaped for outer perimeter 40). This enables outer perimeter portion 40 to be made with any plan view shape that is best for attachment to a native tissue structure such as a native mitral valve annulus, while valve core 20 can have the different plan view perimeter shape that is best for the valve portion per se. Thus again, outer perimeter portion 40 preferably has approximately the same size and shape as the anticipated healthy native tissue structure (e.g., native valve annulus 120 (FIG. 4)) to which portion 40 is or will be attached. As has been said, valve core 20 can be significantly smaller and has a different perimeter shape than portion 40. Mounting retainer structure 30 bridges what would otherwise be the gap(s) or space(s) between elements 20 and 40.

[0027] If desired, valve 10 can be used to provide attachment points or locations for native tissue structures that are associated with the native valve and that are not excised as part of the valve replacement procedure. An example of this are chordae tendonae of the mitral valve. FIG. 4 shows a native mitral valve 100 that is going to be replaced by a valve 10. Valve 100 includes annulus 120, anterior

leaflet 130a, and posterior leaflet 130p. Reference number 140 indicates the general location where one of the load-bearing chordae is attached to anterior leaflet 130a. (Other such chordae are attached to the leaflets at other locations, but only representative location 140 is indicated in FIG. 4 to avoid unnecessarily complicating the drawing.) In preparation for implanting valve 10, leaflet 130a is cut as indicated by dotted line 150. Some or all of the leaflet tissue (which is still attached to the upper end of the representative one 140 of the chordae) may be folded over on itself as shown at 160 in FIG. 5. Sutures may be used to stabilize this folding of tissue. These sutures or additional sutures may be used to secure folded tissue 160 to mounting retainer 30 at the approximate original (native) location of the upper end of the representative one 140 of the chordae as shown in FIG. 4. This is done as valve 10 is being placed in the site of the native valve. Again, feature 160 is only one representative feature, which may be replicated at other locations for other chordae of the valve (see FIG. 6 in which in addition to feature 160 from FIG. 5, similar features 160b, 160c, and 160d are provided for other chordae at other locations and used in the same way that feature 160 is described as being used in connection with FIG. 5).

[0028] Continuing with FIGS. 5 and 6, even if it is not possible to attach some or all of features 160, 160b, 160c, and 160d to mounting retainer structure 30 at exactly their original locations (e.g., because of the presence of valve core 20), the construction of valve 10 typically allows such features to be anchored

closer to their original locations (i.e., at least somewhat radially inward from valve annulus 120) than would be possible if the native valve were replaced by a conventional prosthetic valve (which would be larger than core 20 and which would therefore substantially fill the entire orifice defined by annulus 120). The best that can be done for the chordae in the conventional case is to leave them attached at or very close to the native valve annulus. This is not close to their native attachment locations and may therefore be suboptimal for such purposes as having the chordae help to maintain the native shape of the left ventricle. Attachment of the chordae to mounting retainer 30 closer to their native attachment locations is closer to optimal. For example, it comes closer to having the chordae maintain their original (native) angular alignment relative to the papillary muscle tissue.

[0029] FIG. 7 shows an alternative to FIG. 1 in which mounting retainer structure 30 is provided with features 230, 230b, 230c, and 230d that can used to facilitate attachment of features like 160, 160b, 160c, and 160d, respectively, in FIGS. 5 and 6 to retainer 30. In the particular example shown in FIG. 7, each of features 230, 230b, etc., is a slit though retainer 30. As valve 10 is being implanted, each of features 160, 160b, etc., can be passed through the corresponding one of slits 230, 230b, etc. Each of features 160, 160b, etc. can then be attached (e.g., sutured) to retainer 30. Slits 230, 230b, etc. become closed and leak-proof as a result of these operations. In addition to facilitating attachment of features 160, etc. to valve 10, pre-located and preformed slits 230, etc.

help to get chordae like 140 attached to valve 10 at the best locations.

[0030] It will be understood that slits or other features having different shapes and locations can be incorporated into retainer 30 to accommodate various surgical techniques and facilitate preservation of native tissue structures associated with the valve that is being replaced.

[0031] An example of another possible use of a valve (like 10) of this invention is as a prosthetic replacement for a patient's native tricuspid valve.

[0032] In addition to the advantages already described (e.g., the ability to re-attach subvalvular apparatus like chordae at or near the original (native) location(s)), valves in accordance with this invention can have other important advantages. For example, in a double valve replacement procedure (e.g., replacement of the mitral and aortic valves), the smaller core 20 of the present valves can help reduce the possibility of interference between the two valves. Another possible advantage is that by spacing valve core 20 radially inward from perimeter portion 40, the valve design of this invention allows greater freedom of choice with respect to various aspects of each of these two components. For example, the shape of perimeter portion 40 can be selected relatively independently of the shape of the perimeter 26 of valve core 20. Perimeter 26 can be circular as shown in FIG. 1, which may be best for optimal performance of valve core 20, while perimeter portion 40 is D-shaped (as is also shown in FIG. 1), which may be best for helping to preserve the native shape of native valve annulus 120 (FIG. 4) (or perimeter portion 40 may have a shape and

rigidity to influence the geometry and/or functionality of anatomical structures affected by the use of a valve). Mounting retainer 30 spans the space(s) between perimeters 26 and 40 and can therefore fill a gap or gaps having any shape(s) (in either two or three dimensions) between perimeters 26 and 40 that are differently sized and/or shaped in any way. Stated another way, this invention allows virtually any valve technology (for core 20) to be combined with virtually any mounting technology (for perimeter portion 40). The mounting technology choices that are thus available for selection include, for example, virtually any cuff (e.g., sewing cuff) technology.

[0033] It will be understood that the foregoing is only illustrative of the principles of this invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, although non-mechanical valve cores 20 are shown in the FIGS., it has been made clear above that mechanical valve cores can be used instead if desired.

What Is Claimed Is:

1. A prosthetic heart valve comprising:

a valve core; and

a mounting retainer structure that extends radially out from the valve core to an outer perimeter portion that is adapted for attaching the heart valve to another structure, the outer perimeter portion having a different shape than a perimeter of the valve core when both perimeters are viewed along an axis that will be the axis of blood flow through the valve core when the prosthetic heart valve is in use in a patient.

2. The prosthetic heart valve defined in claim 1 wherein the shape of the valve core perimeter is substantially circular, and wherein the shape of the outer perimeter portion is non-circular.

3. The prosthetic heart valve defined in claim 2 wherein the shape of the outer perimeter portion is approximately D-shaped.

4. The prosthetic heart valve defined in claim 1 wherein the outer perimeter portion lies in a plane that is substantially perpendicular to the axis of blood flood.

5. The prosthetic heart valve defined in claim 1 wherein the outer perimeter portion undulates transverse to a plane that is substantially perpendicular to the axis of blood flow, the undulation being along the outer perimeter portion as one proceeds around the valve core.

6. The prosthetic heart valve defined in claim 1 wherein the mounting retainer structure between the valve core and the outer perimeter portion is adapted for use in attaching another native tissue structure to the mounting retainer structure.

7. The prosthetic heart valve defined in claim 6 wherein the mounting retainer structure includes a through-aperture located between the valve core and the outer perimeter portion for passage of the another native tissue structure through the through-aperture.

8. A prosthetic heart valve comprising:

a valve core; and

a mounting retainer structure that extends radially out from the valve core to an outer perimeter portion that is adapted for attaching the heart valve to another structure, the outer perimeter portion being substantially rigid.

9. The prosthetic heart valve defined in claim 8 wherein the outer perimeter portion and a perimeter of the valve core have different shapes when viewed along the axis of blood flow through the valve core when the prosthetic valve is in use in a patient.

10. The prosthetic heart valve defined in claim 9 wherein the shape of the valve core perimeter is substantially circular, and wherein the shape of the outer perimeter portion is non-circular.

11. The prosthetic heart valve defined in claim 10 wherein the shape of the outer perimeter portion is approximately D-shaped.

12. The prosthetic heart valve defined in claim 8 wherein the outer perimeter portion lies in a plane that is substantially perpendicular to the axis of blood flood.

13. The prosthetic heart valve defined in claim 8 wherein the outer perimeter portion undulates transverse to a plane that is substantially perpendicular to the axis of blood flow, the undulation being along the outer perimeter portion as one proceeds around the valve core.

14. The prosthetic heart valve defined in claim 8 wherein the mounting retainer structure between the valve core and the outer perimeter portion is adapted for use in attaching another native tissue structure to the mounting retainer structure.

15. The prosthetic heart valve defined in claim 14 wherein the mounting retainer structure includes a through-aperture located between the valve core and the outer perimeter portion for passage of the another native tissue structure through the through-aperture.

16. A method of replacing a patient's native heart valve with a prosthetic heart valve comprising:

providing a prosthetic heart valve that includes a valve core and a mounting retainer structure that extends radially out from the valve core to an

outer perimeter portion, the outer perimeter portion having a different shape than a perimeter of the valve core when both perimeters are viewed along an axis that will be the axis of blood flow through the valve core when the prosthetic heart valve is in use in a patient; and

using the outer perimeter portion to secure the prosthetic heart valve to tissue of the patient.

17. The method defined in claim 16 further comprising:

attaching other tissue of the patient that was attached to a leaflet of the patient's native heart valve to the mounting retainer structure intermediate the valve core and the outer perimeter portion.

18. The method defined in claim 17 wherein the other tissue includes chordae tendonae.

19. A method of replacing a patient's native heart valve with a prosthetic heart valve comprising:

providing a prosthetic heart valve that includes a valve core and a mounting retainer structure that extends radially out from the valve core to an outer perimeter portion, the outer perimeter portion being substantially rigid; and

using the outer perimeter portion to secure the prosthetic heart valve to tissue of the patient.

20. The method defined in claim 19 further comprising:

attaching other tissue of the patient that was attached to a leaflet of the patient's native heart valve to the mounting retainer structure intermediate the valve core and the outer perimeter portion.

21. The method defined in claim 20 wherein the other tissue includes chordae tendonae.

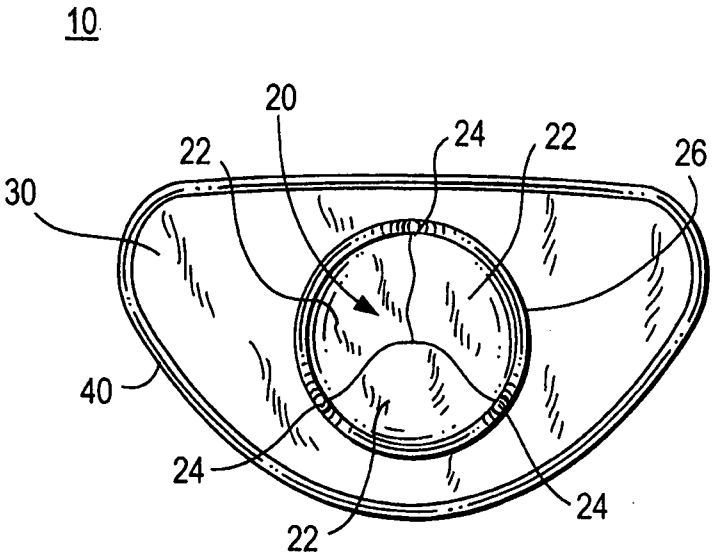

FIG. 1

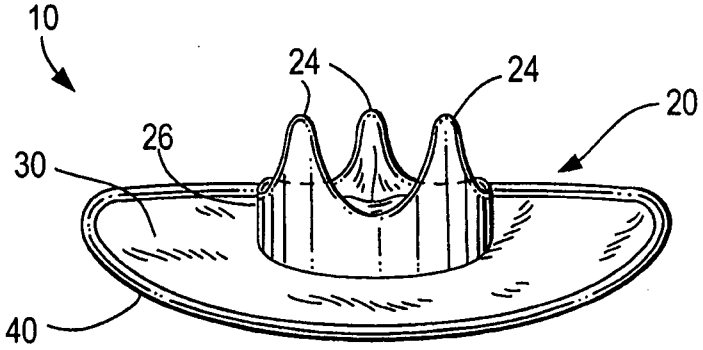

FIG. 2

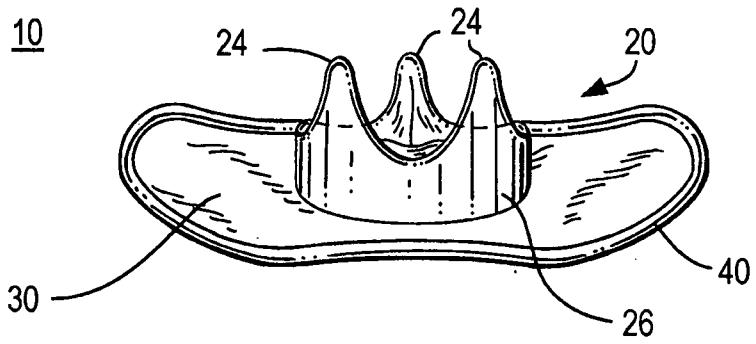

FIG. 3

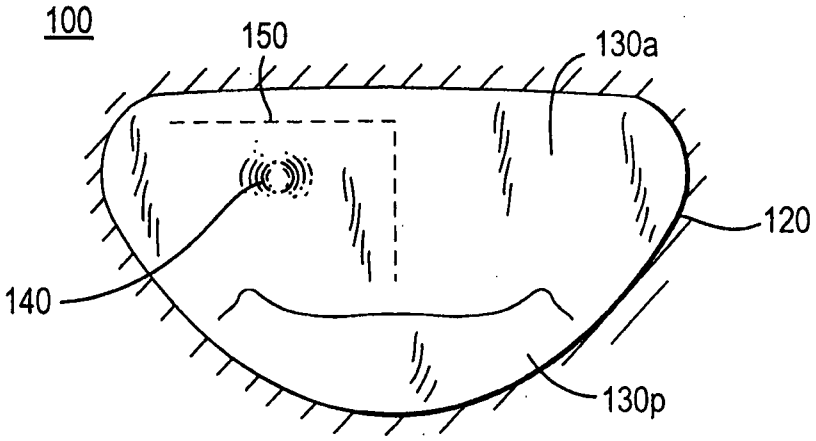

FIG. 4

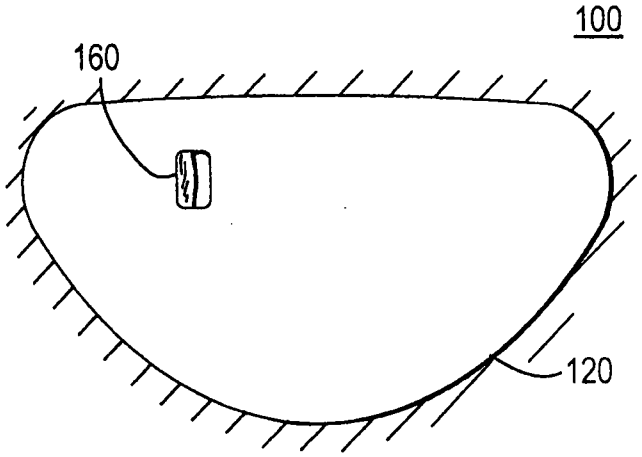

FIG. 5

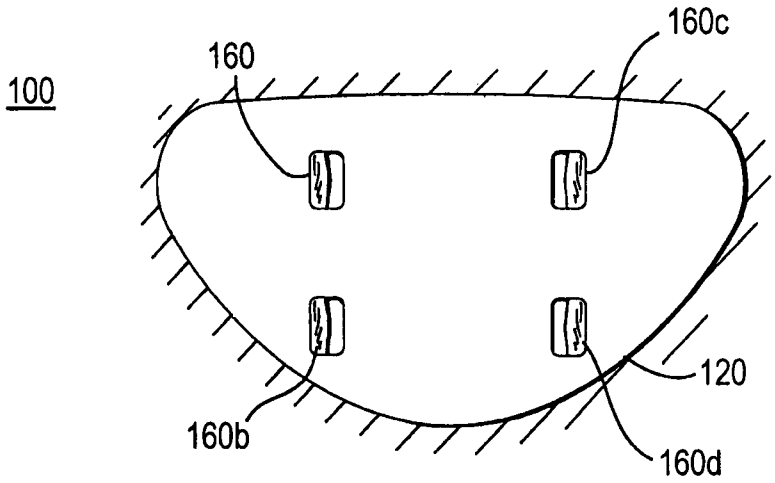

FIG. 6

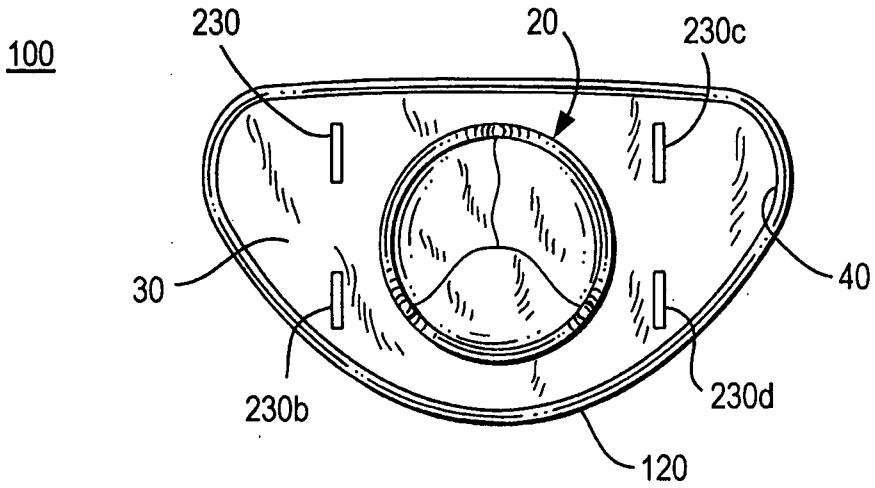

FIG. 7