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(54) SIZING APPARATUS FOR CARDIAC PROSTHESES AND METHOD OF USING SAME

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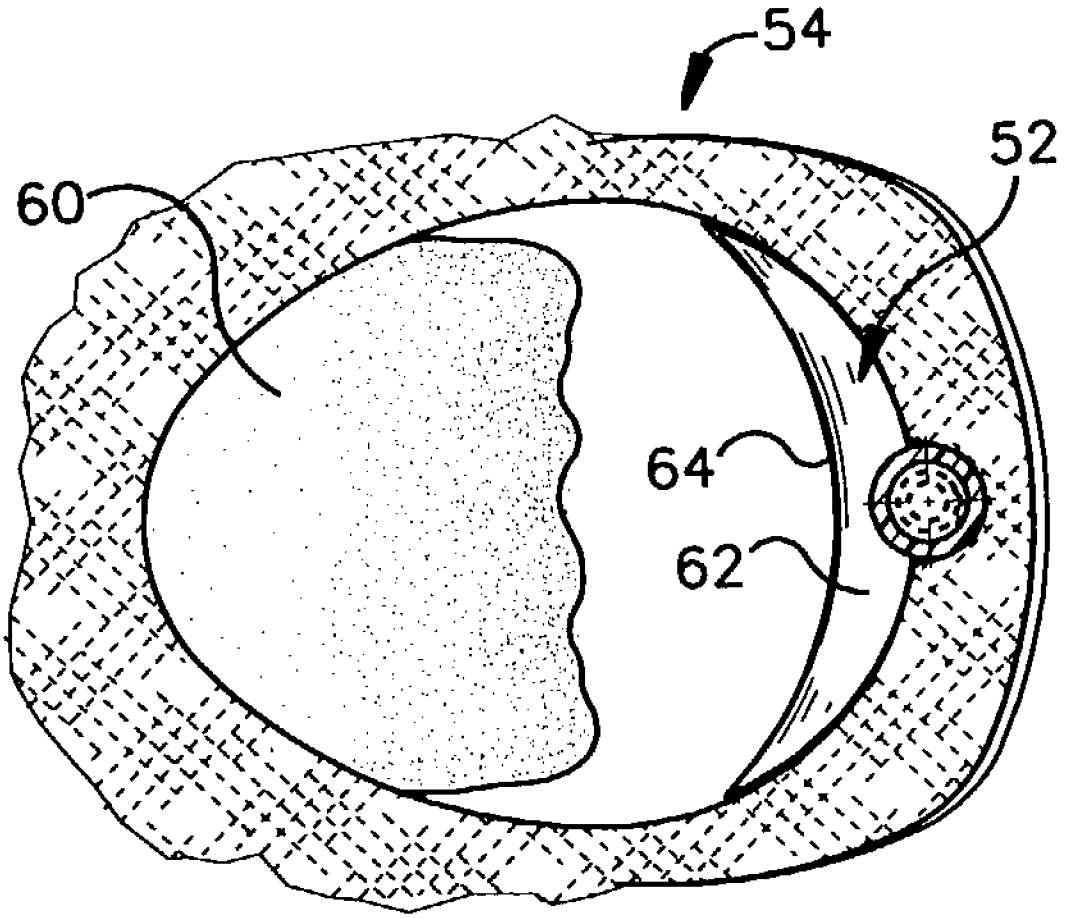
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(57) **ABSTRACT**

A sizing apparatus and a method for ascertaining a size for a cardiac prosthesis are disclosed. Specifically, the sizing is implemented by positioning a contact member at a patient's heart valve for engagement by one or more viable leaflets of the patient's valve. The size is determined based on the engagement between the contact member and the leaflet (or leaflets) of the patient's valve.



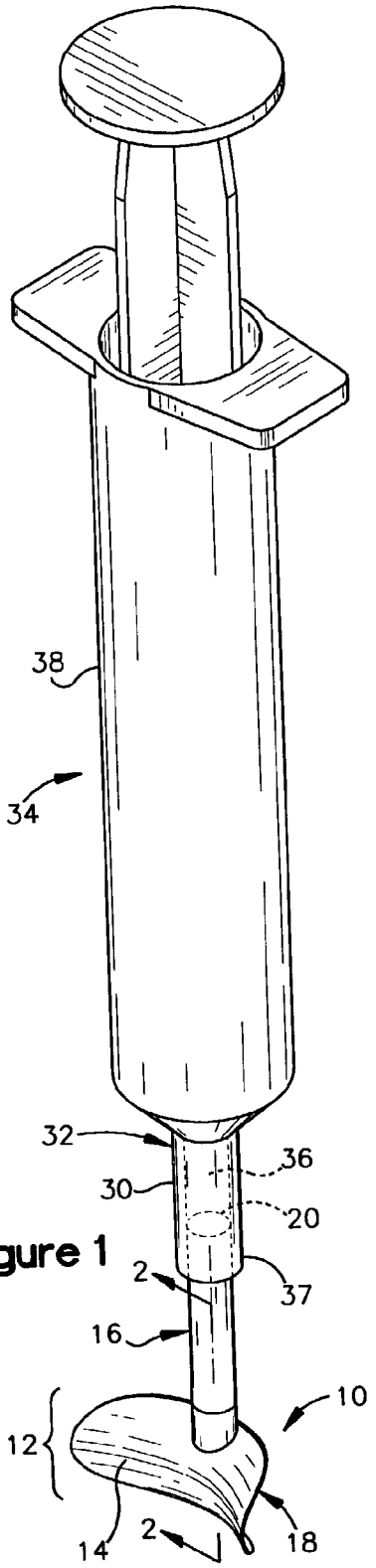


Figure 1

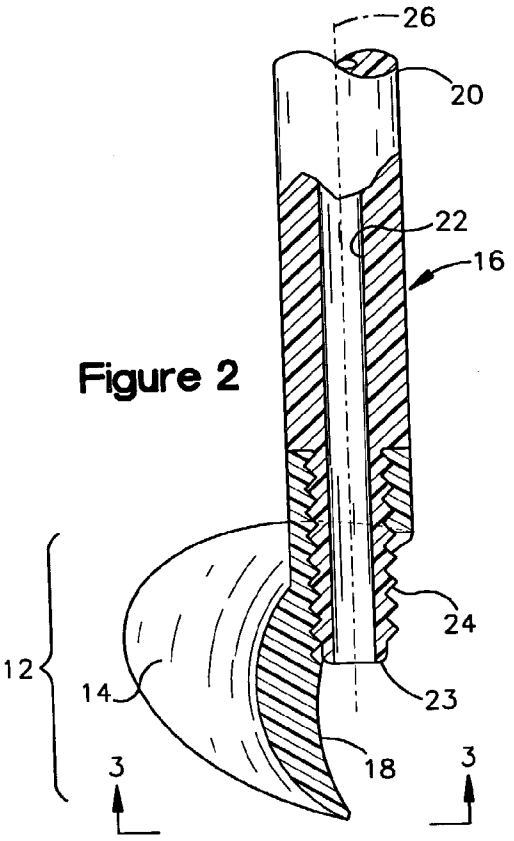


Figure 2

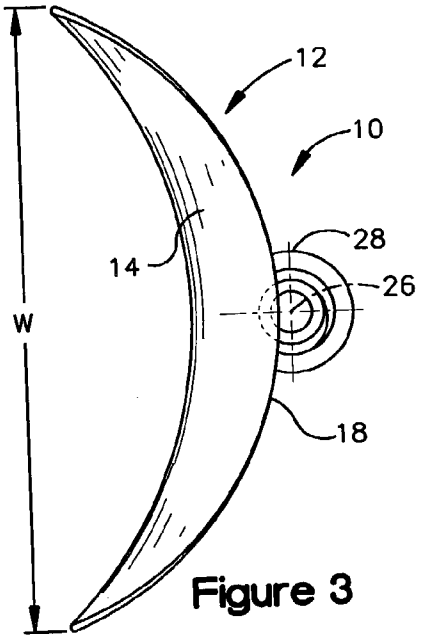


Figure 3

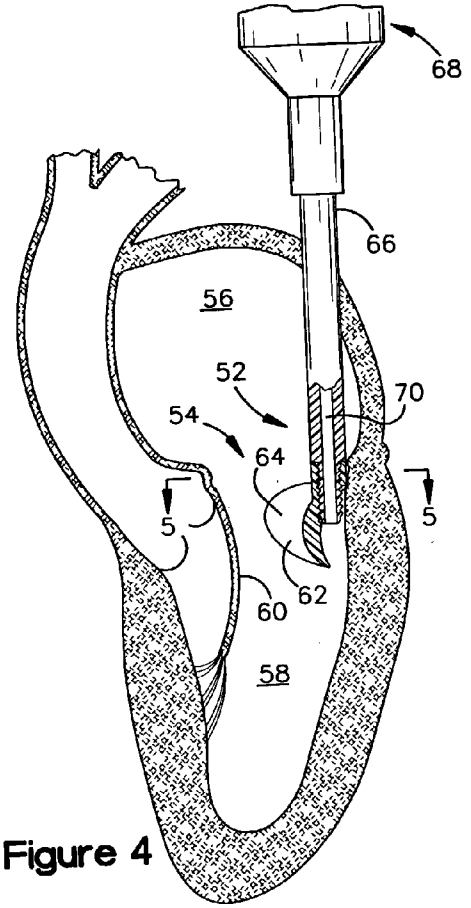


Figure 4

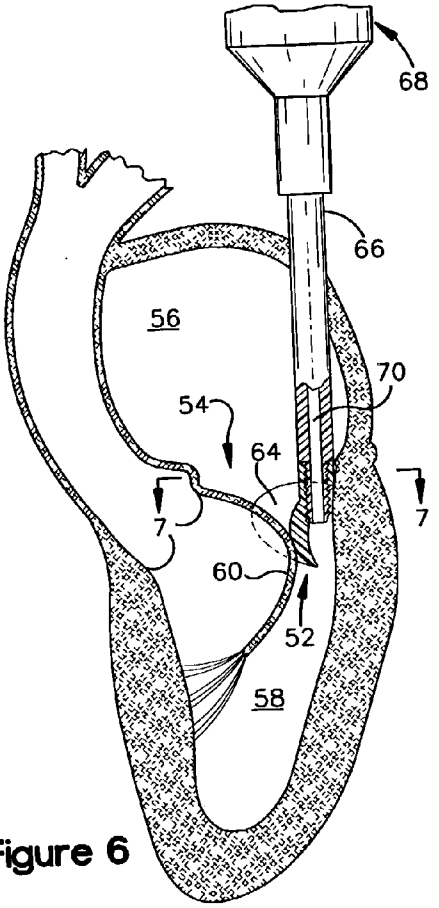


Figure 6

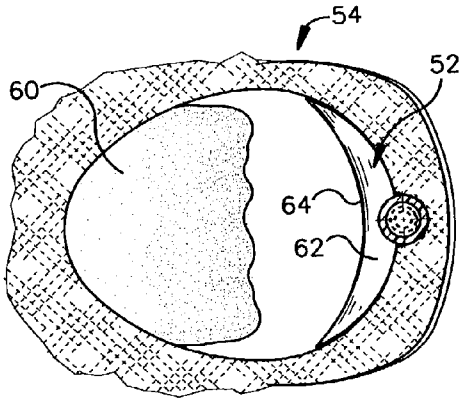


Figure 5

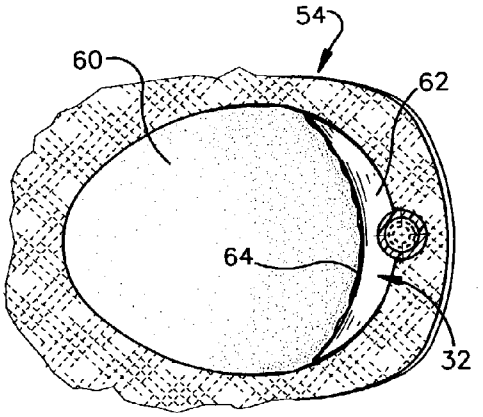


Figure 7

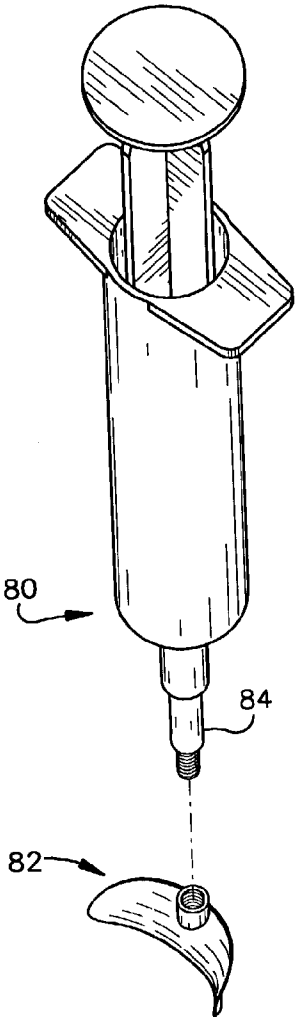


Figure 8

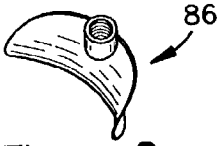


Figure 9

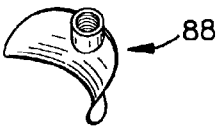


Figure 10

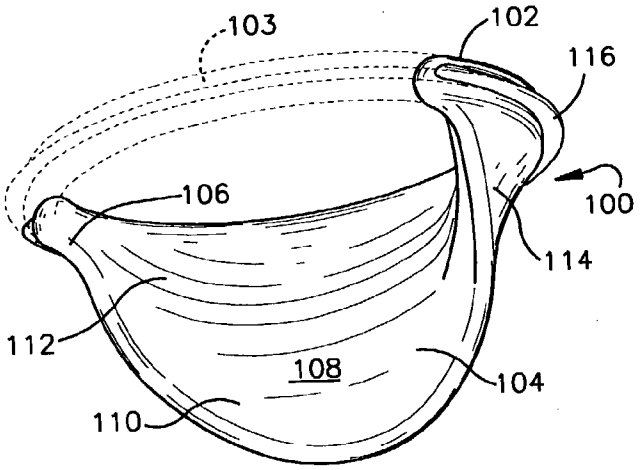


Figure 11

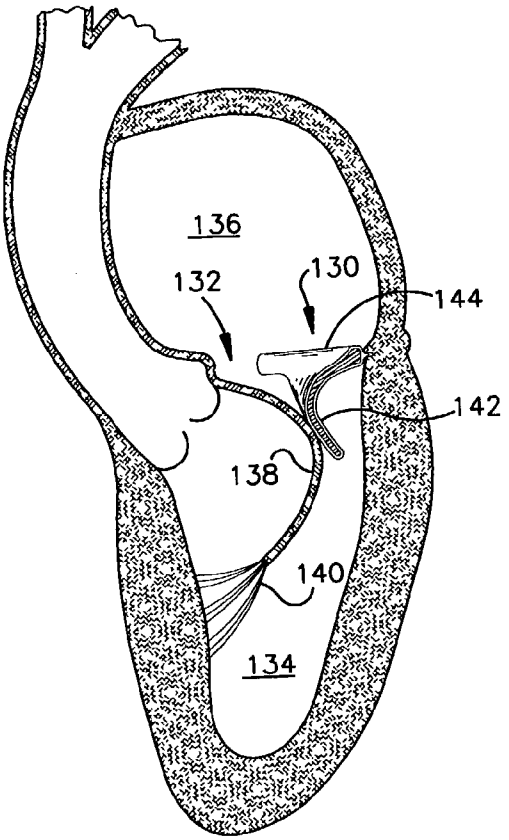


Figure 12

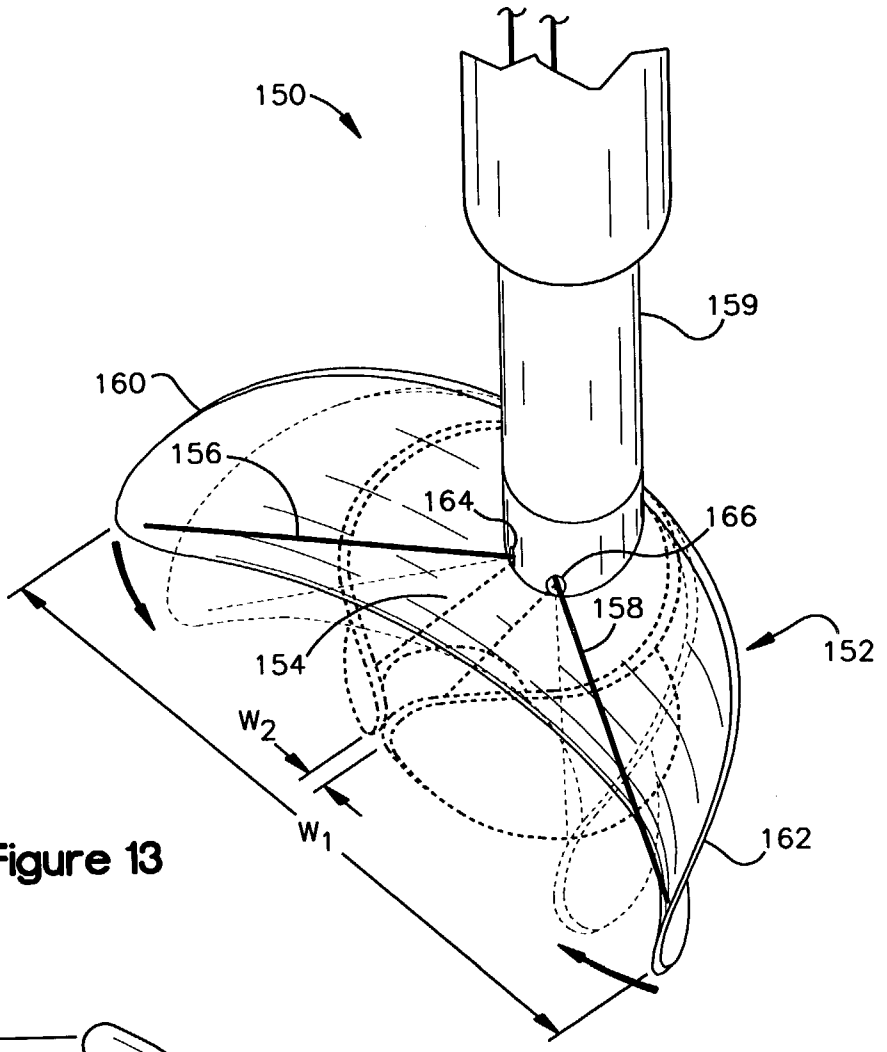


Figure 13

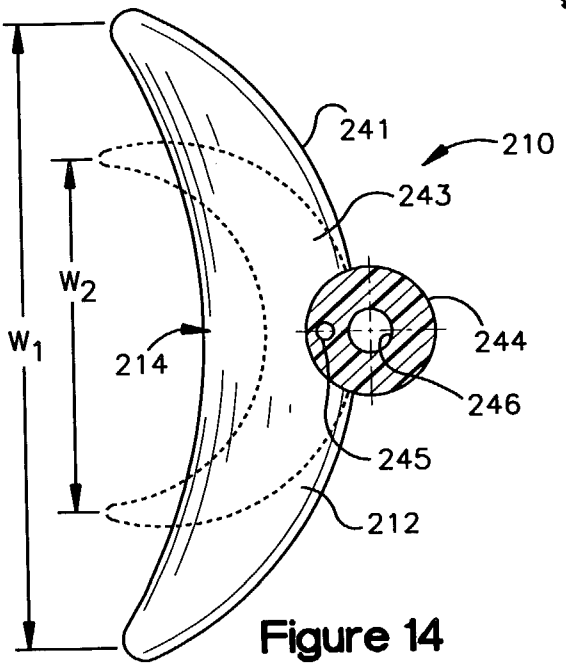


Figure 14

SIZING APPARATUS FOR CARDIAC PROSTHESES AND METHOD OF USING SAME

TECHNICAL FIELD

[0001] The present invention relates generally to cardiac prostheses and, more particularly, to a sizing apparatus for a cardiac prosthesis and method of using the apparatus.

BACKGROUND

[0002] A heart valve can become defective or damaged, such as resulting from congenital malformation, disease, or aging. When the valve becomes defective or damaged, the leaflets may not function properly. One common problem associated with a degenerating heart valve is an enlargement of the valve annulus (e.g., dilation). Other problems that may result in valve dysfunction are chordal elongation and lesions developing on one or more of the leaflets.

[0003] The bicuspid or mitral valve is located in the left atrioventricular opening of the heart for passing blood unidirectionally from the left atrium to the left ventricle of the heart. The mitral valve is encircled by a dense fibrous annular ring and includes two valve leaflets of unequal size. A larger valve leaflet, which is known as the anterior leaflet, is located adjacent the aortic opening. The smaller leaflet is the posterior leaflet.

[0004] When a mitral valve functions properly, for example, it prevents regurgitation of blood from the ventricle into the atrium when the ventricle contracts. In order to withstand the substantial backpressure and prevent regurgitation of blood into the atrium during the ventricular contraction, the cusps are held in place by fibrous cords (cordae tendinae) that anchor the valve cusps to the muscular wall of the heart.

[0005] By way of example, if an annulus enlarges or dilates to a point where the attached leaflets are unable to fully close (malcoaptation), regurgitation or valve prolapse might occur. Adverse clinical symptoms, such as chest pain, cardiac arrhythmias, dyspnea, may manifest in response to valve prolapse or regurgitation. As a result, surgical correction, either by valve repair procedures or by valve replacement, may be required.

[0006] Surgical reconstruction or repair procedures may include plication, chordal shortening, or chordal replacement. Another common repair procedure relates to remodeling of the valve annulus (e.g., annuloplasty), which may be accomplished by implantation of a prosthetic ring to help stabilize the annulus and to correct or help prevent valvular insufficiency which may result from defect or dysfunction of the valve annulus. Properly sizing and implanting the annuloplasty ring can substantially restore the valve annulus restored to its normal, undilated, circumference. In situations where the valve leaflets exhibit lesions, it also may be necessary to reconstruct one or more valve leaflets by securing grafts or patches to the leaflets, such as over lesions or holes formed in the leaflet. The repair or reconstruction of the leaflets may be complicated and time consuming, the results of which are not readily reproducible.

SUMMARY

[0007] The following presents a simplified summary of the invention in order to provide a basic understanding of some aspects of the invention. This summary is not an extensive overview of the invention. It is intended to neither identify key or critical elements of the invention nor delineate the scope of the invention. Its sole purpose is to present some concepts of the invention in a simplified form as a prelude to the more detailed description that is presented later.

[0008] The present invention relates generally to a sizing apparatus for a prosthetic device intended for implantation at a heart valve to improve operation of a defective or damaged valve. The apparatus includes a contact member having a curved surface that is configured to be engaged by one or more functioning leaflets of a heart valve within a patient when the contact member is positioned at the heart valve. A user can observe engagement between the functioning leaflet and the contact member to determine an appropriate size of cardiac prosthesis. The observations, for example, can be made under direct vision (e.g., during an open chest procedure) or via an appropriate vision system (e.g., during an open or closed chest procedure). Additionally, where the curved surface is not of an appropriate size, the cross-sectional dimension of the contact member can be changed, such as by either employing a different contact member or by using a contact member in which the size of the curved surface is adjustable, until an appropriate size is can be determined. Alternatively, a user may be able to gauge an appropriate size based on observed a sizing discrepancy between the leaflet and the contact member. An appropriately sized prosthetic device can then be implanted based on the sizing.

[0009] In accordance with another aspect of the invention, a sizing apparatus for a prosthetic device includes a contact member and an elongated member extending from the contact member and terminating in a proximal end. The contact member includes a curved surface that is configured to be engaged by at least one functioning leaflet of a heart valve within a patient when the contact member is positioned at the heart valve. The elongated member includes an aperture extending through from a proximal end of the elongated member and terminating in an opening proximal the contact member. The aperture facilitates the flow of fluid through the contact member into a chamber of the heart to urge the functioning leaflet toward the contact member.

[0010] In accordance with yet another aspect of the invention, a sizing apparatus for a prosthetic device includes a contact member and an elongated member extending from the contact member and terminating in a proximal end. The contact member includes a curved surface that is configured to be engaged by at least one functioning leaflet of a heart valve within a patient when the contact member is positioned at the heart valve. The contact surface is configured to have a variable cross-sectional dimension. The contact surface can assume at least a reduced cross-sectional dimension to facilitate positioning of the contact member at the heart valve. The contact surface can be selectively expanded to an expanded cross sectional dimension, such that the at least one leaflet can engage the contact member to facilitate determining the size of a desired cardiac prosthesis.

[0011] To the accomplishment of the foregoing and related ends, the invention, then, comprises the features hereinafter fully described and particularly pointed out in the claims. The following description and the annexed drawings set forth in detail certain illustrative aspects of the invention.

These aspects are indicative, however, of but a few of the various ways in which the principles of the invention may be employed. Other objects, advantages and novel features of the invention will become apparent from the following detailed description of the invention when considered in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1** is an elevated side view of an example apparatus in accordance with an aspect of the present invention.

[0013] **FIG. 2** is a cross-sectional view of the taken along line **2-2** of **FIG. 1**.

[0014] **FIG. 3** is a view of the apparatus taken along line **3-3** of **FIG. 2**.

[0015] **FIG. 4** is a cross-sectional view of the apparatus positioned within the heart valve of a patient, illustrating a first condition of the heart valve.

[0016] **FIG. 5** is an overhead (inflow) view of the apparatus positioned within the heart valve of a patient, illustrating a first condition of the heart valve.

[0017] **FIG. 6** is a cross-sectional view of the apparatus positioned within the heart valve of a patient, similar to **FIG. 4**, illustrating a second condition of the heart valve.

[0018] **FIG. 7** is an overhead (inflow) view of the heart valve and the apparatus, similar to **FIG. 5**, illustrating a second condition of the heart valve.

[0019] **FIG. 8** is an assembly view of an apparatus in accordance with an aspect of the present invention with a contact member detached from the elongated member.

[0020] **FIG. 9** is an example of a contact member in accordance with an aspect of the present invention.

[0021] **FIG. 10** is another example of a contact member in accordance with an aspect of the present invention.

[0022] **FIG. 11** is an isometric view of a cardiac prosthesis that can be employed in accordance with an aspect of the present invention.

[0023] **FIG. 12** is a cross-sectional view of a part of a heart in which the cardiac prosthesis is implanted at a heart valve in accordance with an aspect of the present invention.

[0024] **FIG. 13** is an elevated side view of a sizing apparatus in accordance with another aspect of the present invention.

[0025] **FIG. 14** is an overhead view of a sizing apparatus in accordance with yet another aspect of the present invention.

DESCRIPTION

[0026] The present invention relates generally to a sizing apparatus for a cardiac prosthesis. The sizing apparatus can be used to determine the appropriate size for a cardiac prosthesis (e.g., a valvuloplasty device) that can be implanted into the heart valve to cooperate with at least one of the leaflets of the patient's own valve, which can be the patient's native valve or a previously implanted prosthesis. Specifically, the sizing tool of the present invention includes a contact member that can be engaged by one or more viable leaflets of a patient's heart valve to ascertain the proper size for a cardiac prosthesis.

[0027] FIGS. **1-3** illustrate a sizing apparatus **10** in accordance with one aspect of the invention. The apparatus **10** includes a contact member **12**. The contact member **12** has a curved surface **14** configured to be engaged by a leaflet within a heart valve. For example, the curved surface **14** can be configured to engage the anterior leaflet of the mitral valve of a patient's heart.

[0028] In accordance with the present aspect of the invention, the contact member **12** can be fabricated from any substantially rigid, durable material that is substantially biocompatible. By substantially rigid, it is meant that the contact member **12** should be capable of holding its basic shape under a moderate amount of pressure. By durable, it is meant that the device should be able to withstand standard sterilization techniques, such as by an autoclave or other sterilizer. Example materials that can be used for the contact member include durable plastics (e.g., formed of DELRIN®) and non-reactive metals, such as surgical steel. Those skilled in the art will understand and appreciate other types of materials that also could be employed to form the contact member, all of which are contemplated as falling within the scope of the present invention.

[0029] An elongated member **16** extends from the contact member **12** to terminate in a proximal end **20** that is spaced apart from the contact member. In the example of FIGS. **1-3**, the elongated member is depicted as a generally cylindrical, elongated rod or tube, which can be hollow. As shown in **FIG. 2**, an aperture **22** extends through the elongated member **16** from its proximal end **20** to an opening located near a surface **18** of the contact member **12** opposite the surface **14**.

[0030] The elongated member **16** can be formed of a durable and generally rigid material. The elongated member **16** can be formed of the same or a different material than the contact member **12**. The length and composition of the elongated member **16** can vary, depending on the application. For example, some applications can require a lengthy elongated member **16** or an elongated member formed form a more flexible material. Those skilled in the art will appreciate that different materials and lengths can be selected depending on the design of the device and the desired application.

[0031] The elongated member **16** can also be formed of multiple portions, which can be the same or different materials. For example, the elongated member illustrated in **FIG. 2** begins at its proximal end **20** as a plastic material. The inside of that portion of elongated member can be threaded (or otherwise configured) to accept a spout **24**, which can be made from stainless steel (or any other generally rigid material) that terminates near the contact member **12**. Alternatively, the contact member **12** can be formed from a single material, such as a metal or plastic material.

[0032] The contact member **12** is dimensioned to a size consistent with that of a leaflet within a heart valve. For example, a contact member **12** approximating the size of a leaflet within an adult human mitral valve can have a width (indicated at W in **FIG. 3**) ranging from fifteen to fifty millimeters. Those skilled in the art will appreciate that the

width of the contact member can vary according to the application. For example, in a heart valve sizing apparatus intended for use in children or small animals, a width smaller than fifteen millimeters may be appropriate. An apparatus intended for use in large animals, such as horses, might require a contact member with a width greater than fifty millimeters.

[0033] As shown in **FIG. 2, a** longitudinal axis **26** extends longitudinally through the elongated member **16** substantially parallel to the aperture **22**. While the member **16** is depicted as being substantially straight, it will be appreciated that it alternatively could be curved or formed a flexible material to facilitate curving the member. The contact surface **14** is curved in a convex manner relative to the axis **26**. Another axis **28**, shown in **FIG. 3**, is substantially perpendicular to the axis **26** and coincides with the longest dimension (e.g., the width W) of the contact member **12**. The contact surface **14** is curved relative to the horizontal axis **28** in a concave manner (e.g., curves away). As a result of this curvature, the contact member **12** is configured to approximate a leaflet of a heart valve at closure of the valve.

[0034] The proximal end **20** of the elongated member **16** can connect to a sleeve-like conduit interface **30**, as depicted in **FIG. 1**. The conduit interface **30** can be made from any durable, flexible material that is substantially biocompatible. Example materials include rubber or silicon, although other types of materials can also be used. The proximal end **32** of the conduit interface **30** is adapted to connect to a fluid source **34**, which can include a syringe or other type of device capable of injecting fluid through the aperture **22**. This adaptation allows the conduit interface **30** to fit tightly over a nozzle **36** of the fluid source **34**, while the other end **37** of the conduit interface connects to the proximal end **20** of the elongated member **16**. The conduit interface **30** thus can interconnect the elongated member **16** and the nozzle **36** to provide a substantially fluid-tight seal to enable the flow of fluids therethrough.

[0035] The fluid source **34** contains a quantity of a fluid that can be passed through the aperture **22** of the elongated member **16**. A number of fluids can be used, including air, water, saline, and blood to name a few. In the illustrated apparatus, the fluid source includes a syringe **38**. The syringe **38** can be used to expel fluid from the fluid source **34** through the nozzle **36** and into the aperture **22** of the elongated member **16**. One skilled the art will perceive other devices for controlling the flow of fluid from the fluid source, such as stop cocks and mechanical or electric pumps, and the use of these devices is intended to be encompassed within the claimed invention. The fluid source **34** can be formed from a number of materials. For example, transparent materials, such as clear plastics and glass, can be used, as they allow a user to determine more easily the fluid level within the fluid source **34**.

[0036] In view of various structural features of a sizing apparatus, in accordance with an aspect of the invention, use of such an apparatus to facilitate implantation of cardiac prosthesis will be better appreciated with reference to FIGS. **4-12**. For example, as illustrated in FIGS. **4-7**, implantation of a prosthesis can include the use of a sizing tool **52** to ascertain an appropriate size for a prosthetic device in accordance with an aspect of the present invention.

[0037] In **FIG. 4**, the sizing tool **52** has been inserted into a heart valve **54**. Solely for the purpose of example, the valve **54** is illustrated in FIGS. **4-12** as a mitral valve within a human heart, and the method is discussed in the context of implanting a prosthesis to replace the posterior leaflet within the mitral valve. One skilled in the art will appreciate, however, that the apparatus of the present invention may be used in other valves within the human heart, such as the tricuspid, pulmonary, or aortic valves, as well as in valves within animal hearts. Likewise, the present invention may be used to size a replacement for any leaflet, including the anterior leaflet of the mitral valve or the leaflets of any of the aforementioned valves. Such uses are intended to be encompassed in the appended claims.

[0038] The chamber above the mitral valve **54** is the left atrium **56** and the chamber below the valve is the left ventricle **58**. In **FIG. 4**, the anterior leaflet **60** is present and viable, but the posterior leaflet (not shown) is either nonviable or has been removed. A contact member **62** of the sizing tool **52** is positioned at the position formerly occupied by the posterior leaflet, with a contact surface **64** facing the anterior leaflet **60**. In accordance with one aspect of the present invention, the contact member **62** can be positioned manually by a user holding an elongated handle **66** or other structure attached to the member. An inflow view of the open valve **54** and sizing apparatus **52** is shown in **FIG. 5**.

[0039] The user would employ a fluid source **68** in fluid communication with the apparatus **52** to supply fluid into the ventricle **58**. Such fluid thus flows through an aperture **70** within the elongated handle **66** into the left ventricle **58**. As discussed previously, this can be accomplished by a number of methods, such as a pump, syringe, or a stopcock. As the left ventricle fills **58** with fluid, the anterior leaflet **60** is urged toward its closed position and toward the contact member **62**. Depending on whether the apparatus **52** is an appropriate size, the anterior leaflet **60** can engage with the contact member **62** to close the valve, as illustrated in **FIG. 6**.

[0040] Once the anterior leaflet **60** has been urged into a closed position, the surgeon can examine the engagement between the anterior leaflet and the contact member **62**. Where the leaflet **60** and the contact member **62** coapt, as to substantially prevent the flow of fluid through from the valve, a size of a corresponding prosthesis can be determined according to the size of the contact member **62**. An inflow view of a leaflet **60** coapting with a contact member **62** is illustrated in **FIG. 7**. When the leaflet **60** and the contact member **62** coapt properly, the surgeon will know that a prosthetic device matching the size and shape of the contact member **62** is appropriate for a prosthetic replacement. Where there is not sufficient coaptation between the leaflet **60** and the contact member **62**, a differently sized prosthesis should be used.

[0041] For example, where the contact member **62** is too small to effectively coapt the leaflet **60**, the surgeon may see small spaces or gaps between the leaflet and the contact member. This indicates a larger size prosthesis may be needed. This can be confirmed by repeating the sizing process with a larger sized contact member.

[0042] Where the contact member **62** is too large, the annulus of the valve **54** may distort, thereby preventing desired coaptation between the contact member **62** and the leaflet. Additionally or alternatively, the orifice between the contact member **62** and the leaflet may be considered be too

small. A surgeon thus can readily ascertain that a prosthetic device matching the size of the contact member would be too large and seek a smaller device.

[0043] **FIG. 8** illustrates an apparatus **80** is provided where a contact member **82** can be made selectively detachable from an elongated member **84** In accordance with an aspect of the present invention. The selective attachment allows a surgeon to select from a number of alternate contact members of different size if the original contact member **82** is too large or too small. By way of example, the distal end of the elongated member **84** can be threaded to allow a contact member to be screwed onto the elongated member. Those skilled in the art will appreciate other types of connections or fittings (e.g., friction fitting, snap fitting, and the like).

[0044] **FIGS. 9 and 10** illustrate examples of alternative contact members, **86** and **88**. With the new contact member, the surgeon can repeat the sizing procedure described above to better approximate the size of an appropriate prosthetic leaflet. A desired one of the contact members **82**, **86**, **88** can be attached to the elongated member by any of a number of means known in the art.

[0045] **FIG. 11** illustrates an example of a cardiac prosthesis **100** that can be implanted according to the present method. For example, the prosthesis **100** can be of the type shown and described in U.S. patent application Ser. No. 10/215,800, filed on Aug. 4, 2002, to Gabbay, which is hereby incorporated by reference.

[0046] The prosthesis **100** includes a generally arcuate base portion **102** that can be closed or C-shaped. In accordance with an aspect of the present invention, a section of the base portion, indicated as a dotted portion **103**, can be removable from the prosthesis **100** (e.g., by cutting) so that a surgeon can select the type of annulus desired—ring-like or C-shaped. The base portion **102** includes a support ring, which can be formed of a flexible, resilient, or generally rigid material. The support ring can have an elastic property that returns the ring to its original shape when deflected from its original (or rest) condition. The support ring, for example, can be a plastic-like material (e.g., a polymer, a resin, etc.) or a metal (e.g., stainless steel, a shape memory alloy, such as NITINOL), such as in the form of a wire. It will be understood and appreciated that other types of generally rigid, elastic, and/or resilient materials also can be used in accordance with the present invention. In addition, a suitable inelastically deformable material also could be used to form the support ring.

[0047] A buttress **104** extends generally axially from an outflow side **106** of the base portion **102**. Briefly stated, a proximal portion **108** of the buttress **104** extends generally axially and radially inward from the base portion **102**. A distally extending portion **110** of the buttress **104** extends from the proximal portion **108** and curves radially outwardly therefrom for the remaining length of the buttress. The buttress **104** has a radially inner surface **112** that provides a surface against which a leaflet (e.g., an anterior leaflet of a mitral valve) can coapt at valve closure.

[0048] The prosthesis **100**, including the buttress **104**, can be selected according to the dimensions and configuration of a contact member from a sizing apparatus that has been determined to provide desired coaptation. Consequently, when the prosthesis **100** is implanted within a heart valve, a leaflet (or leaflets) can engage the buttress **104** to close the valve and provide substantially unidirectional flow of blood therethrough. The leaflet (or leaflets) is able to coapt with the inner surface **112** of the buttress **104**, thereby inhibiting regurgitation of blood when the ventricle contracts.

[0049] The prosthesis **100** can also include an outer sheath **114** of a flexible, biocompatible material covering the apparatus. The apparatus **100** also can include an implantation flange **116** (or sewing ring) that circumscribes the base portion **102** of the apparatus. The implantation flange **116** extends radially outwardly from the base portion **102** for facilitating implantation of the apparatus **100** at a heart valve. Each of the outer sheath **114** and the implantation flange **116** can be formed of any suitable flexible, biocompatible material, such as a cloth-like or fabric (natural or synthetic) material or a biological material, such as collagen or an animal tissue material. An acceptable animal tissue material is smooth animal pericardium (e.g., equine, bovine, porcine, etc.), such as a NO-REACT® tissue product, which is available from Shelhigh, Inc. of Union, N.J.

[0050] Implantation of a cardiac prosthesis can be accomplished by several means. For the type of prosthesis illustrated in **FIG. 11**, these means will generally require open heart surgery. For example, the base portion **102** can be sewn to the wall of the valve **54** at the implantation flange **116** to hold the prosthesis in place. The base portion **102** can also include barbs or hooks (not shown) that extend radially from the exterior of the base potion, such as disclosed in the above incorporated Gabbay patent application. These barbs can be pressed into the wall of the valve to directly engage the muscle tissue of the valve.

[0051] The implantation of other types of prostheses can be less invasive. For example, a prosthesis can be designed to be reducible to a smaller cross-sectional dimension for placement via a catheter or a type of implantation. The sizing tool and process used for these non-invasive techniques can vary from those described above, in accordance with additional aspects of the present invention.

[0052] **FIG. 12** illustrates a part of a heart in which a prosthesis **130** is implanted at a mitral valve **132**. For the purpose of example, the implanted prosthesis will be the type of prosthesis **100** illustrated in **FIG. 11**, but in which the removable section **103** of the annular base **102** has been removed. It will be appreciated, however, that the present invention is not limited to use with this prosthesis. A number of other cardiac prostheses are available and suitable for use with the sizing apparatus of the present invention.

[0053] The valve **132** facilitates a unidirectional flow of blood from the left atrium **134** into the left ventricle **136**. The mitral valve **132** includes an anterior leaflet **138** that extends from the valve opening and attaches to muscular tissue in the wall of the left ventricle by fibrous cordae tendinae **140**. A posterior leaflet (not shown) extends from an opposing surface of the valve opening and coapts the anterior leaflet at valve closure. In **FIG. 12**, the posterior leaflet has been substantially removed from the heart, such as by excising it before implanting the prosthesis **130**. It is to be understood and appreciated, however, that the posterior leaflet can remain intact, with a buttress **142** of the prosthesis **130** interposed between the posterior and anterior leaflets.

[0054] The buttress **142** extends from a base **144** of the prosthesis **130** into the ventricle **136** at a position corre-

sponding to the position of the posterior leaflet of the mitral valve **132**. As mentioned above, the buttress **142** extends into the ventricle **136** It is to be appreciated that the buttress **142** can be formed of a generally rigid material that remains substantially stationary (e.g., static) during both the open and closed positions of the valve. Alternatively, the buttress **142** can be a sufficiently flexible- material to permit movement thereof commensurate with the flow of blood from the atrium **136** into the ventricle **136** through the valve **132**.

[**0055**] **FIG. 12** illustrates the anterior leaflet **138** engaging the buttress **142** of the prosthesis **130**, operating as a closed valve. In this way, the buttress **142** of the prosthesis **130** simulates the function of the posterior leaflet at valve closure by providing a surface against which the anterior leaflet **138** coapts. Consequently, the buttress **142** and the anterior leaflet **138** cooperate to inhibit regurgitation of blood from the left ventricle **136** into the left atrium **136**, such as during ventricular contraction.

[**0056**] The buttress **142**, in conjunction with the anterior leaflet **138**, facilitates and promotes unidirectional flow of blood when the valve is open. In particular, when a prosthesis **130** of an appropriate size is implanted, an opening or aperture extends through the implanted prosthesis **130** between the buttress **142** and the anterior leaflet **138**. Advantageously, the movement of the anterior leaflet **138** relative to the buttress **142**, in response to the flow of blood during the contraction of the left atrium **136**, provides a sufficient orifice to permit the substantially free flow of blood from the left atrium into the left ventricle **136**. The buttress **142** also can be formed of a flexible material that is able to move radially relative to the base portion **144** to further facilitate blood flow.

[**0057**] **FIG. 13** illustrates an apparatus **150** in accordance with another aspect of the invention. The apparatus **150** includes a contact member **152**. As is illustrated in **FIG. 13**, the contact member **152** can be capable of assuming multiple configurations having different associated cross-sectional dimensions. The contact member has a curved surface **154** with an associated shape and area varying with the configuration of the contact member **152**. In the example of **FIG. 13**, the cross-sectional width dimension is shown to vary between W1 and W2, where W1>W2. In this way, a given apparatus can accommodate differently sized valves. Additionally, the positioning of the by contact member at the patient's heart valve can be facilitated when the contact member is at a reduced cross-section. In at least one configuration of the contact member **152**, the curved surface **154** is shaped to engage a leaflet within a heart valve.

[**0058**] The contact member **152** can be made from a material having with a natural shape and a tendency to return to that natural shape in the absence of a deforming force and the capacity to be deformed from that natural shape by pressure or some other means. By way of example, the contact member can be formed from a shape memory alloy material, such as Nitinol. Such an alloy can be formed into a particular shape and treated to allow it to "remember" that form. At low temperatures, the material remains pliant, but at higher temperatures, such as those within a patient's body, the material will attempt to revert to the remembered form. The shape memory alloy can be coated with natural or synthetic material, such as a soft plastic, rubber or biological material (e.g., animal pericardium, dura matter, etc.).

[**0059**] For example, the natural shape of the material corresponds to the configuration of the contact member having the largest cross-sectional dimension W1. It will be appreciated, however, that the apparatus may be designed such that the natural shape is the configuration with the smallest cross-sectional dimension W2 or an intermediate cross-sectional dimension, depending on the requirements of a given application.

[**0060**] The illustrated contact member **152** can be deformed into a configuration having a smaller cross-sectional dimension (e.g., less than W1) by one or more control members. In the illustrated embodiment, the control members include one or more elongated restraints **156** and **158**, such as sutures. It will be appreciated that the one or more control members of the device may take a number of forms, and that the illustrated device is merely exemplary.

[**0061**] The restraints are connected at their distal ends to the lateral edges **160** and **162** of the contact member **152** to hold the contact member in a configuration having a reduced cross-sectional dimension. An elongated member **159** extends from the contact member **152** to a proximal end (not shown). One or more apertures (also not shown) extend through the elongated member **159** from its proximal end **162** to a point near the contact surface **154** of the contact member **152**. The restraints **156** and **158** extend through one or more orifices **164** and **166** into the aperture within the elongated member **159** at a point near the contact surface **154**. The restraints **156** and **158** extend through the aperture to a proximal end **162** of the elongated member **160**. At the proximal end, the restraints **156** and **158** can be fastened by their proximal ends to a control device (not shown) to maintain a necessary tension within the restraints **156** and **158** to deform the contact member **152**.

[**0062**] The configuration of the contact member **152** can be controlled by the control device at the proximal end of the elongated member **159**. The control device is operative to increase or decrease the length of the restraints **156** and **158** between the proximal end **162** of the elongated member **159** and the lateral edges **160** and **162** of the contact member **152**. As the portion of the restraints **156** and **158** between the proximal end **162** and the lateral edges **160** and **162** of the contact member **152** is shortened, the restraints operate to pull the lateral edges closer together, reducing the cross-sectional dimension of the contact member (e.g., to less than W1). When the tension on the restraints **156** and **158** is loosened, such as to increase the length of the restraints between the apertures **164** and **166** and the respective lateral edges **160** and **162**, the lateral edges will move apart as the contact member **152** attempting to return to its natural configuration (e.g., W1). The expanded size thus will vary according to the length of the restraints between the apertures **164** and **166** and the respective lateral edges **160** and **162**.

[**0063**] It will be appreciated that the control device can include any of a number of devices useful in controlling the tension on the restraints **156** and **158**. For example, one or more wheels can gather a portion of the restraints **156** and **158** into a coil under manual or mechanical pressure. Alternatively, one or more restraining clips on the exterior of the device can be employed to enable the user to withdraw or release a portion of the restraints manually and clip the

restraints into place at a desired length. Similar examples should be apparent to one skilled in the art in light of the foregoing discussion.

[0064] Regardless of the specific control device used, markings or indicia can be provided on the device, for example, on the device exterior, to directly or indirectly measure the length of the restraints **156** and **158** between the proximal end **162** and the lateral edges **160** and **162** of the contact member **152**. The apparatus **150** can be calibrated such that a particular length of one or more of the restraints **156** and **158** will correspond to a cross-sectional dimension of the contact member **152**, allowing the cross-sectional dimension to be determined from the measurement of the length of the one or more restraints.

[0065] An intended purpose of the apparatus **150** of **FIG. 13** is its use in a minimally invasive sizing process to precede implantation of a valvuloplasty device, such as shown and described in the above-incorporated Gabbay patent application. The illustrated contact member **152** can be deformed to a configuration having a reduced cross-sectional dimension to facilitate placement of the device. The apparatus **150** can be mounted to a catheter, an elongated handle, or another positioning device for insertion into a heart valve. An appropriate vision system can be included with the apparatus **150** to guide the placement of the apparatus **150** and determine if a particular configuration of the contact member provides effective coaptation with any viable leaflets in the valve.

[0066] Where the apparatus **150** is mounted to an elongated handle, a low invasive minithoracotomy can be used to gain access to the heart of the patient and the apparatus **150** can be inserted through the minithoracotomy passage. The contact member **152** is first placed into a configuration having a minimal cross-sectional dimension. The surgeon can then guide the apparatus **150** through the passage using an appropriate vision system to bring the contact member **152** into a desired position for engaging with any viable leaflets of the valve. The cross-sectional dimension of the contact member can then be expanded to the size where it engages with the viable leaflets and the cross-sectional dimension necessary to provide effective coaptation can be recorded. The point where effective coaptation takes place can be determined by the surgeon using the vision system. The cross-sectional dimension of the contact member **152** can then be reduced back to its initial, minimal configuration to facilitate withdrawal of the device. It will be appreciated that such a procedure can be implemented with little or no cardiopulmonary bypass.

[0067] Similarly, where the apparatus **150** is mounted to a catheter, it can be inserted into the heart valve from a remote entry point within the body. When a catheter is used to position the apparatus **150**, an electromechanical mechanism can be used to adjust the length of the restraints **156** and **158** and accordingly, adjust the configuration of the contact member **152**, as the restraints **156** and **158** may not be in a position to be manually adjusted. The cross-sectional dimension of the contact member **152** can be reduced to facilitate passage through blood vessels into the valve, and expanded to measure the size of a prosthetic replacement necessary to provide effective coaptation of any viable leaflets. The cross-sectional dimension of the contact member **152** can then be reduced to allow the apparatus **150** to be removed.

[0068] **FIG. 14** illustrates an apparatus **210** in accordance with another aspect of the invention. The apparatus **210** includes a contact member **212**. As is illustrated in **FIG. 14**, the contact member **212** is capable of assuming a plurality (e.g., at least two) configurations, each having a different associated cross-sectional dimension. Two such dimensions are depicted at **W1** and **W2**, where **W1>W2**. The contact member **212** has a curved surface **214** with an associated shape and area varying with the configuration of the contact member **212**. The size contact member **212** thus is variable to accommodate differently sized heart valves. Additionally, the contact member can be provided in a sufficiently reduce cross-sectional dimension to facilitate its positioning at a patient's heart valve by minimally invasive means according to an aspect of the present invention.

[0069] The contact member **212** (or at least the surface **214** thereof) is formed from a fluid impermeable membrane **241** defining an interior chamber. The outer membrane **241** can be formed from rubber, flexible plastic, or any other elastic, fluid-impermeable substance that is substantially biocompatible. The interior chamber of the member **212** is connected to a fluid source (not shown) that can be located near the proximal end of the elongated member **244** through a conduit **245** or other fluid communicating member. The conduit **245**, for example, can be formed as an aperture extending through the elongated member **244**.

[0070] A control device (not shown) on the fluid source directs a fluid through the aperture **245** to the interior chamber. This mechanism can be a pump, a syringe, a bellows, or any similar device for encouraging the flow of fluid. The fluid itself may be air, water, saline, blood, or any other biocompatible fluid. As the interior chamber fills with fluid, it inflates the outer membrane **241** causing the contact member **212** to assume a configuration having a cross-sectional dimension functionally related to the amount of fluid in the chamber of the member **212**. The cross-sectional dimension of the contact member **212** can be ascertained according to the amount of fluid that is directed into the interior chamber. The apparatus **210** can be calibrated such that a particular fluid level can be translated into an appropriate cross-sectional dimension. A control device can include means for evacuating the fluid within the interior chamber, either back into the fluid source, or into the heart valve.

[0071] An intended purpose of the apparatus **210** illustrated in **FIG. 14** is its use in a minimally invasive sizing process to precede implantation of a valvuloplasty device. In this process, the contact member **212** begins with the outer membrane **241** deflated to provide a reduced cross-sectional dimension that facilitates placement of the device. The apparatus **210** can be mounted to a catheter, an elongated handle, or another positioning device for insertion into a heart valve. The fluid source can connect to the contact member **212** through an aperture **246** in the elongated member **244**. An appropriate vision system can be included with the device to guide the placement of the device and determine if a particular configuration of the contact member **212** provides effective coaptation with any viable leaflets in the valve.

[0072] Where the apparatus **210** is mounted to an elongated handle, a low invasive minithoracotomy can be used to gain access to the heart of the patient, such that the

apparatus **210** can be inserted through the minithoracotomy passage. The contact member **212** is placed in a deflated configuration having a minimal cross-sectional dimension to facilitate positioning of the device. The surgeon can then guide the apparatus **210** through the passage using an appropriate vision system to place the contact member **212** at a desired position for engaging one or more viable leaflets of the valve. The cross-sectional dimension of the contact member **212** can then be selectively expanded through inflation of the outer membrane **241** to the point where the viable leaflets can engage the surface **214** to inhibit flow of fluid through the valve annulus (e.g., simulating operation of competent heart valve). The cross-sectional dimension necessary to provide effective coaptation can be recorded based on the amount of fluid provided to the inner chamber, for example. The coaptation between the contact member and the valve leaflet (or leaflets) can be determined by the surgeon using the vision system. The cross-sectional dimension of the contact member **212** can then be reduced back to its initial, minimal configuration to facilitate withdrawal of the device by evacuating the fluid within the device. It will be appreciated that such a procedure can be implemented with little or no cardiopulmonary bypass.

[**0073**] Similarly, the apparatus **210** can be mounted to a catheter for insertion into the heart valve from a remote entry point of the body. When a catheter is used to position the apparatus **210**, a separate tube can be included to carry fluid to the interior chamber from the fluid source to adjust the configuration of the contact member **212**. The cross-sectional dimension of the contact member **212** is placed in a reduced form to facilitate passage through blood vessels into the valve. The inner chamber of the contact member **212** is then filled at least partially with fluid to expand the contact member **212** to determine a suitable size of a prosthetic device to provide effective coaptation of any viable leaflets. The cross-sectional dimension of the contact member **212** can then be reduced to allow the apparatus **210** to be removed by evacuating the fluid from the inner chamber.

[**0074**] In view of the foregoing, an apparatus according to the present invention provides a useful apparatus for determining the necessary size for a valvuloplasty device intended for implantation into a heart valve. A method for utilizing the apparatus for sizing a heart valve has been described. Embodiments of the apparatus that are useful for a minimally invasive sizing procedure have been provided.

[**0075**] What has been described above are examples of the present invention. It is, of course, not possible to describe every conceivable combination of components or methodologies for purposes of describing the present invention, but one of ordinary skill in the art will recognize that many further combinations and permutations of the present invention are possible. For example, while many of the illustrated examples show the discuss the treatment of a bicuspid (mitral) valve, an apparatus in accordance with the present invention can also be useful in sizing prosthetic devices for other types of heart valves (e.g., a tricuspid valve or other bicuspid valves). Accordingly, the present invention is intended to embrace all such alterations, modifications and variations that fall within the spirit and scope of the appended claims. Furthermore, to the extent that the term "includes" is used in either the detailed description or the claims, such term is intended to be inclusive in a manner similar to the term "comprising."

What is claimed is:

1. A sizing apparatus for a prosthetic device, comprising:

a contact member having a curved surface that is configured to be engaged by at least one functioning leaflet of a heart valve within a patient when the contact member is positioned at the heart valve; and

an elongated member extending from the contact member and terminating in a proximal end.

2. The sizing apparatus of claim 1, further comprising an aperture extending through the elongated member from the proximal end and terminating in an opening end near the contact member to facilitate flow of fluid therethrough.

3. The sizing apparatus of claim 2, the aperture terminating near a surface of the contact member opposite the curved surface.

4. The sizing apparatus of claim 2, further comprising a fluid source operative to supply fluid into the aperture.

5. The sizing apparatus of claim 4, the fluid source further comprising a syringe for providing fluid into the aperture.

6. The sizing apparatus of claim 4, further comprising a conduit interface that extends from the proximal end of the elongated member and terminates in a proximal end portion thereof, the proximal end portion of the conduit interface being adapted to connect to the fluid source.

7. The sizing apparatus of claim 6, the conduit interface further comprising a flexible material.

8. The sizing apparatus of claim 1, the contact member having a first axis substantially parallel with the elongated member and a second axis substantially perpendicular with the elongated member, the contact member being curved along at least one of the first and second axes.

9. The sizing apparatus of claim 1, the contact member being dimensioned and configured to approximate a radially inner surface of at least one leaflet at closure.

10. The sizing apparatus of claim 1, the contact member being configured to provide a cross-sectional dimension that is variable between a reduced cross-sectional dimension to facilitate positioning thereof at the heart valve and an expanded cross-sectional dimension to facilitate determining the size of a desired cardiac prosthesis based on engagement between the contact member and the at least one leaflet.

11. The sizing apparatus of claim 10, the contact member further comprising a fluid impermeable outer membrane having an inner chamber, the outer membrane defining the cross-sectional dimension of the contact member based on an amount of fluid within the inner chamber.

12. The sizing apparatus of claim 10, further comprising a control member operative to adjust the cross-sectional dimension of the contact member to a desired size.

13. The sizing apparatus of claim 10, further comprising a retaining mechanism operative to adjust the cross-sectional dimension of the contact member to a desired size, the contact member being self-expanding from the reduced cross-sectional dimension to the expanded cross-sectional dimension.

14. The sizing apparatus of claim 13, the retaining mechanism further comprising at least one elongated elements having distal ends connected to lateral edges of the contact member and proximal ends that extend from the contact member, the cross-sectional dimension of the contact member, varying as a function of the length of at least one of the connecting elements between the proximal end of the elon-

gated member and the respective lateral edge of the contact member to which the at least one connecting element is connected.

15. The sizing apparatus of claim 10, the contact member comprising a material having shape memory properties so that the contact member is self-expanding from the reduced cross-sectional dimension to the expanded cross-sectional dimension.

16. An apparatus for determining an appropriate size for a prosthetic device, comprising:

means for contacting at least one leaflet of a patient's heart valve, such that the amount of coaptation between the at least one leaflet and the means for contacting is indicative of sizing requirements for a cardiac prosthesis; and

means to facilitate positioning the means for contacting to an appropriate position relative to the at least one leaflet of the patient's heart valve, the means for positioning extending from the means for contacting.

17. An apparatus as set forth in claim 16, including means for urging the at least one viable leaflet toward the means for contacting.

18. A sizing apparatus for a prosthetic device, comprising:

a contact member having a curved surface that is configured to be engaged by at least one functioning leaflet of a heart valve within a patient when the contact member is positioned at the heart valve;

an elongated member extending from the contact member and terminating in a proximal end; and

an aperture extending through the elongated member from the proximal end and terminating in an opening end proximal the contact member to facilitate flow of fluid therethrough.

19. A method to facilitate selecting a cardiac prosthesis for implantation at a patient's heart valve, the method comprising:

positioning a contact member to an appropriate position relative to at least one leaflet of the patient's heart valve;

urging the at least one leaflet of a patient's heart valve toward the contact member, the contact member having a known cross-sectional dimension; and

determining sizing requirements for the cardiac prosthesis based on coaptation between the at least one leaflet and the contact member.

20. The method of claim 19, further comprising:

selecting a cardiac prosthesis based on the determined sizing requirements, the cardiac prosthesis comprising a generally arcuate base and a buttress extending from the base; and

implanting the cardiac prosthesis at the patient's heart valve such that the at least one leaflet is moveable relative to the buttress to provide substantially unidirectional flow of blood through the heart valve.

21. The method of claim 19, wherein the contact member is a first contact member and the method further includes positioning a second contact member having a different cross-sectional dimension than that of the first contact member in place of the first contact member.

22. The method of claim 19, further comprising adjusting the cross-sectional dimension of the contact member.

23. The method of claim 22, wherein the adjusting of the cross-sectional dimension of the contact member includes one of supplying and removing fluid from within the contact member.

24. The method of claim 22, wherein the contact member is self-expanding from a reduced cross-sectional dimension to an expanded cross-sectional dimension, and the adjusting of the cross-sectional dimension of the contact member includes adjusting a length of at least one retaining mechanism that is operatively connected to the contact member.

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