(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 March 2001 (22.03.2001)

PCT

(10) International Publication Number
WO 01/19291 A1

(51) International Patent Classification[7]: A61F 2/24

(21) International Application Number: PCT/US00/25043

(22) International Filing Date:
13 September 2000 (13.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/396,124 14 September 1999 (14.09.1999) US

(71) Applicant: EDWARDS LIFESCIENCES CORPORATION [US/US]; One Edwards Way, Irvine, CA 92614 (US).

(72) Inventor: RHEE, Richard; 24344 Darrin Drive, Diamond Bar, CA 91765 (US).

(74) Agents: CONDINO, Debra, D. et al.; Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 (US).

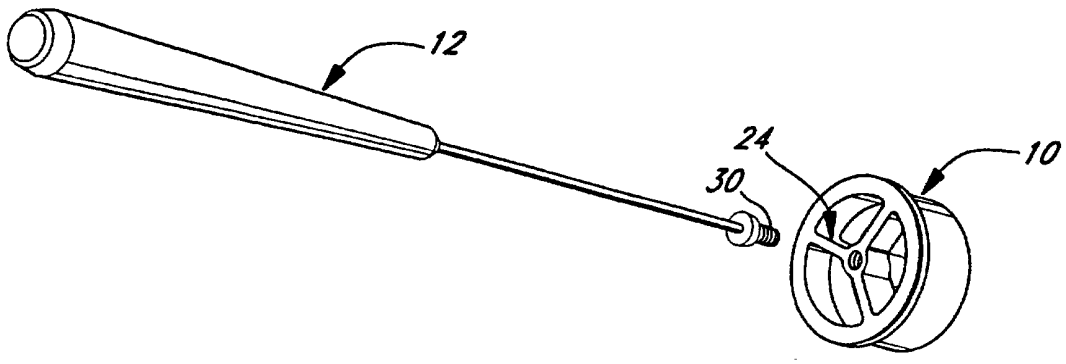
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

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.

(54) Title: METHODS AND APPARATUS FOR MEASURING VALVE ANNULUSES DURING HEART VALVE-REPLACEMENT SURGERY



(57) Abstract: A sizer measures a valve annulus to determine a size of an artificial heart valve to be sewn in the valve annulus during heart-valve replacement surgery. The sizer includes a support member and a resilient member. The support member has a size corresponding to the size of one of a plurality of artificial heart valves. The resilient member is disposed about the support member and has a resiliency substantially equal to the resiliency of a sewing ring of the artificial heart valve. Accordingly, when a surgeon inserts the sizer into a valve annulus, the resilient member conforms to the shape of the valve annulus much like the sewing ring will conform when positioned in the annulus and sewn in place. The surgeon is therefore able to determine more accurately the size of the annulus and, thereafter, to select a properly sized artificial valve.

WO 01/19291 A1

METHODS AND APPARATUS FOR MEASURING VALVE ANNULUSES DURING HEART VALVE-REPLACEMENT SURGERY

Field of the Invention

The present invention is directed to surgical apparatus and associated methods for measuring the size of a valve annulus (that is, the opening resulting from the removal of a diseased natural valve) during heart valve-replacement surgery. Valve annuluses need to be sized in order for a surgeon to select a properly sized replacement artificial valve.

Background of the Invention

The heart has four valves—two on the right (the pulmonic and tricuspid) and two on the left (the aortic and mitral)—that control the flow of blood through the chambers of the heart and out to the body. Although any of these valves may fail to function properly, disease most commonly affects the valves on the left side of the heart. The valves may narrow (called *stenosis*); the valves may not close all the way (causing a backflow of blood called *regurgitation*); or the valves may close incorrectly (called *prolapse*). A *heart murmur* represents the sound that a leaky or narrowed heart valve makes as blood moves through it.

The Aortic and Mitral Valves

Aortic stenosis is a narrowing of the aortic valve, through which blood flows from the left ventricle of the heart to the ascending aorta, the major artery whose branches supply blood to various parts of the body. Sometimes this narrowness is a congenital (i.e., inborn) defect, but more often the valve narrows as a consequence of aging, or of infections, such as rheumatic fever. Aortic stenosis results in the left ventricle having to work harder and harder to push blood out. As this occurs, the muscular walls of the ventricle thicken, increasing their requirement for oxygen. Symptoms of aortic stenosis include chest pain when the oxygen needs exceed the supply from the coronary arteries; fainting (syncope), if the valve becomes very tight; and congestive heart failure, which usually does not occur unless the valve has been narrowed for many years. Valve replacement, either with a mechanical or tissue valve often alleviates these symptoms.

In *mitral stenosis*, the valve opening between the upper and lower chambers on the left side of the heart has become narrowed. The cause is almost always rheumatic fever, which is now rare in most developed countries but is common in many parts of the world. When mitral stenosis occurs, the entry of blood into the left ventricle from the atrium is impeded by the narrow valve. Pressure builds up behind the valve, leading to an elevation of pressure in the lungs. This in turn may lead to shortness or breath (dyspnea), which is one of the major symptoms of mitral stenosis. Often, however, it occurs without any symptoms.

In *aortic regurgitation*, the aortic valve fails to close completely after the heart has pumped blood out into the aorta. Blood leaks back from the aorta into the left ventricle. In *mitral regurgitation*, improper closure causes blood to lead from the left ventricle back into the left atrium. In either case, the valve does not close properly because of a physical change in its shape or its support. This change may be the result of rheumatic fever; an infection (endocarditis), which may leave the valve scarred; or a heart attack, which causes loss of supporting muscle tissue. In the mitral valve, the change may be the result of a heart attack, which causes a loss of muscle tissue, or a spontaneous rupture of one of its muscular chords (chordea tendineae) that normally act as guide wires to keep it in place.

Major symptoms of defective mitral valves include fatigue, shortness of breath, and edema. Medications such as digitalis, diuretics, and angiotensin-converting enzyme (ACE) inhibitors can help alleviate symptoms. Some defective mitral valves can be reconstructed or, failing that, replaced by an artificial valve.

The Pulmonic and Tricuspid Valves

In the pulmonic and tricuspid valves, any narrowing is rare and almost always congenital. Leakage, or regurgitation, is unusual, but may occur when use of illicit intravenous drugs leads to infection that damages the valve. The infection, hallmarked by fever, often settles on these two valves because they are the first ones bacteria come in contact with as they travel through the bloodstream. If the valve becomes leaky, swelling of the abdomen and legs may occur. As with other valves, treatment can include replacement, but this is rare and usually not as effective as it is when the aortic or mitral valve is involved.

Artificial Valves

Valve-replacement surgery is usually recommended when the damage to the valve is severe enough to be potentially life-threatening, as in the case of severe aortic stenosis. The mitral and aortic valves are the heart valves that most often need to be replaced. Artificial valves have been in use since 1952, when Charles Hufnagel successfully replaced a patient's aortic valve with a caged-ball valve.

There are two types of artificial, or prosthetic, valves that can be used to replace the original valves: mechanical and tissue. Mechanical valves are made of synthetic materials, such as metal alloys, carbon, and various plastics. They come in two major designs: a "caged-ball valve" and a "tilting-disk valve." Tissue valves can be composed of animal or human valve tissue. Because of the scarcity of human valves available for transplantation, pig valves, specially processed and sutured into a synthetic cloth, are most often used. These valves are also called *porcine* valves. Pericardial valves make use of leaflets cut from the pericardium sac of a cow. Most tissue valves are well tolerated by the human body and are much less likely to require blood-thinning therapy, but they tend to be less durable: after 10 years, some 60 percent need to be replaced.

Both mechanical and tissue valves include some support structure or stent and a soft peripheral sewing ring. The sewing ring is used to secure the valve into place occluding the annulus, and must provide a good seal around the valve to prevent leakage.

Valve Replacement Surgery

Valve replacement is performed during open-heart surgery. The valves are mounted in an annulus comprising dense fibrous rings attached either directly or indirectly to the atrial and ventricular muscle fibers. In a valve replacement operation, the damaged leaflets are excised and the annulus sculpted to receive a replacement valve. Ideally the annulus presents relatively healthy tissue which can be formed by the surgeon into a uniform ledge projecting into the orifice left by the removed valve. The time and spatial constraints imposed by surgery, however, often dictate that the shape of the resulting annulus is less than perfect for attachment of a sewing ring. Moreover, the annulus may be calcified as well as the leaflets and complete annular debridement, or removal of the hardened tissue, results in a larger orifice and less defined annulus ledge

to which to attach the sewing ring. In short, the contours of the resulting annulus vary widely after the natural valve has been excised.

The annulus is sized with an annulus sizer to determine the proper size of the replacement artificial valve. The artificial valve is then positioned in the opening and the sewing ring is carefully sutured or sewn to the tissue surrounding the valve opening. Given the uneven nature of the annuluses, the match between the valve sewing ring and annulus is a crucial aspect of prosthetic heart valve implantation. The annulus sizer is typically cylindrical, and made of hard plastic with a central threaded tap to which a handle is attached. A number of sizers are at a surgeon's disposal, each having a different size, or diameter. In use the surgeon inserts the sizer into the valve opening, measuring the size of the opening. An artificial valve properly sized for the valve opening is then selected and sewn in place.

Most annulus sizers are made from a biocompatible material and are rigid and inflexible. In contrast, the sewing rings of artificial valves are flexible. When inserted in the valve opening, the sewing ring may compress. The compression may result in the valve being too small for the valve opening. If this happens, the valve needs to be discarded, and a new valve needs to be chosen. As artificial valves are expensive to produce, discarding an artificial valve unnecessarily represents a tremendous waste. Also the time which is wasted in replacing improperly sized valves during the valve replacement surgery is critical to the patient and should avoided. Another possible error in sizing stems from using the rigid circular sizer to measure what is often an irregular annulus.

Accordingly, in view of the foregoing, it is an object of the present invention to provide annulus sizers which eliminate many of the drawbacks associated with conventional sizers.

Summary of the Invention

It is thus an object of the present invention to provide annulus sizers which enable a surgeon to accurately select a properly sized artificial valve.

It is yet another object of the present invention to provide annulus sizers for measuring the size of valve openings which mimic the physical characteristics of an artificial valve sewing ring.

It is still another object of the present invention to provide methodology which enables surgeons to accurately determine the size of valve annuluses which, in turn, enables surgeons to select properly sized replacement artificial valves during valve replacement surgery.

These and other objects are achieved by the surgical apparatus and associated methods of the present invention which enable a surgeon to accurately measure the size of a valve annulus and then to properly selected a replacement artificial valve during valve-replacement surgery.

In accordance with a broad aspect of the invention, a sizer for measuring a valve annulus to determine a size of an artificial heart valve to be sewn in the valve annulus during heart-valve replacement surgery, includes a support member and a resilient member. The support member has a size corresponding to the size of one of a plurality of artificial heart valves. The resilient member is disposed about the support member and has a resiliency substantially equal to the resiliency of a sewing ring of the artificial heart valve. Accordingly, when a surgeon inserts the sizer into a valve annulus, the resilient member conforms to the shape of the valve annulus, analogous to how the sewing ring will conform when positioned in the annulus and sewn in place. The surgeon is therefore able to determine more accurately the size of the annulus and, thereafter, to select a properly sized artificial valve.

In addition to having substantially the same resilience as the sewing ring of an artificial heart valve, the resilient member also preferably is configured substantially the same as the sewing ring of the artificial heart valve. By substantially matching the artificial heart valve configuration, the sizer is able to "mimic" more accurately how the artificial heart valve will be received in the valve annulus for sewing.

The support member of the sizer is preferably releasably attachable to a surgical handle. Accordingly, in the operating theater, a surgeon is able to select a sizer and insert the sizer into the valve annulus to determine the size of the annulus. If the sizer does not fit to the surgeon's satisfaction, the surgeon is able to remove the sizer from the annulus, detach the sizer from the handle, select and attach another sizer of different size, and re-insert the new sizer into the annulus. This process may be repeated until the surgeon has determined the size of the valve annulus.

Other aspects, features, and advantages of the present invention will become apparent to those persons having ordinary skill in the art to which the present invention

pertains from the following description taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

FIG. **1** is a perspective view of an exemplary sizer for measuring valve annuluses during heart valve-replacement surgery in accordance with the present invention, particularly illustrating the sizer in conjunction with a surgical handle;

FIG. **2** is a perspective view of the sizer of FIG. **1**, particularly illustrating a proximal end thereof;

FIG. **3** is a perspective view of the sizer of FIG. **1**, particularly illustrating a distal end thereof;

FIG. **4** is a side view of the sizer of FIG. **1**;

FIG. **5** is a cross-sectional view of the sizer taken along line 5-5 of FIG. **2**;

FIGS. **6A-C** are cross-sectional views of sizers of the present invention with different cross-sectional shaped resilient members;

FIG. **7A** is a perspective view of an artificial mechanical heart valve, particularly a caged-ball valve;

FIG. **7B** is a perspective view of an artificial mechanical heart valve, particularly a tilting-disk valve;

FIG. **7C** is a perspective view of an artificial tissue heart valve for the mitral position;

FIG. **7D** is a perspective view of an artificial tissue heart valve for the aortic position;

FIG. **8** is a side view of a sizer of the present invention having a scalloped groove for receiving a resilient member;

FIG. **9A** is a schematic view of a heart illustrating a step in the methodology of the present invention in which a sizer is inserted into a valve annulus;

FIG. **9B** is a schematic view of a heart illustrating another step in the methodology of the invention in which an artificial valve is sewn into a valve annulus; and

FIG. **10** is an enlarged schematic view of a sizer of the invention inserted into and urged against a valve annulus, particularly illustrating conforming features of a resilient member of the sizer.

Detailed Description of the Invention

Referring to the drawings in more detail, an exemplary embodiment of a valve sizer **10** of the present invention is illustrated in FIG. **1** in conjunction with a surgical handle **12**. With additional reference to FIGS. **2**, **3**, **4**, and **5**, exemplary sizer **10** includes a support member **14** and an annular or resilient member **16**. Exemplary support member **14** has a body **18** and a retainer **20**. The body **18** defines a distal portion of sizer **10**, and the retainer **20** defines a proximal portion of the sizer.

The retainer **20** includes an annular or circumferential recess **22** for receiving and/or retaining resilient member **16**, as particularly shown in FIGS. **4** and **5** (with the resilient member being shown in phantom line in FIG. **4**). The resilient member **16** may be either removable from or integral with the retainer **20**. The resilient member **16** has an outer diameter D_r (FIG. **5**) which is larger than an outer diameter D_b (FIG. **4**) of the body **18**.

Exemplary support member **14** may be substantially tubular or cylindrical in configuration, with an attaching portion **24** disposed therein. As particularly shown in FIGS. **1**, **2**, and **3**, the attaching portion **24** may include a threaded post **26** supported by a plurality of spokes **28**. A threaded end **30** of the handle **12** may then be releasably attached to the threaded post **26** of the sizer **10**.

Exemplary resilient annular member **16** may be substantially ring-like (toroidal) in configuration, for example, similar to an O-ring. The annular recess **22** of the support member **14** is concave with a configuration complementary to the inner shape of the resilient member **16**. Exemplary resilient member **16** is made from resilient material, such as a soft polymer, so as to be compressible and flexible.

Although a toroidal configuration of the resilient member **16** is illustrated, the resilient member **16** may be semi-rectangular, triangular, or elliptical, for example. With reference to FIGS. **6A-6C**, various cross-sections of resilient member **16** are illustrated. FIG. **6A** shows a semi-rectangular shaped resilient member **16a**. To be precise, the member **16a** includes an inner convex side **31**, an outer angled side **32**, a top side **33**, and a bottom side **34** generally parallel with the top side. Because of the angled side **32** the top side **33** is longer than the bottom side **34**. FIG. **6B** illustrates an elliptical resilient member **16b** with a minor axis parallel with the centerline **CL** of the valve and a major axis perpendicular thereto. Finally, FIG. **6C** shows a resilient

member **16c** with a substantially triangular cross-section, except for a convex inner side.

As known in the art of artificial valves, sewing rings are made from a resilient material so as to conform to the valve annulus, that is, the opening resulting from the removal of the diseased natural valve. The resilient sewing ring may then be sutured to the tissue of the valve annulus. Exemplary resilient member **16** of the sizer **10** of the present invention has physical properties, particularly with respect to resilience and flexibility, substantially the same as those of sewing rings **46–50** common to artificial valves **40–44** in use today.

In addition, exemplary resilient member **16** is preferably configured substantially the same as the sewing rings; that is, if the sewing ring of a desired valve is elliptical in configuration, then the resilient member **16** may be substantially elliptical in configuration. In this regard, reference is made to FIGS. **7A-7D** which respectively illustrate a caged-ball mechanical heart valve **40**, a tilting-disk mechanical heart valve **42**, a tissue valve **44** for the mitral annulus, and a tissue valve **46** for the aortic annulus. Each of the valves includes a sewing ring **40a**, **42a**, **44a**, and **46a**, respectively. The first three sewing rings **40a**, **42a**, and **44a** are planar rings, while the sewing ring **46a** for the aortic valve **46** may be scalloped, or undulating, around the periphery.

In order to conform to the shape of the corresponding sewing ring, it should be noted that the resilient members for the annulus sizers of the present invention may be planar rings or rings having a three-dimensional shape, so as to conform to the shape of a scalloped aortic valve sewing ring, for example. Indeed, such a sizer configuration is seen in FIG. **8** with the resilient member removed to exposed the scalloped channel **48**. In this regard, the resilient member may be scalloped also, or may simply conform to the shape of the channel **48**.

Referencing FIGS. **9A** and **9B**, in use the sizer **10** may be attached to the handle **12** as described above. Access is made to the heart, which is referenced by numeral **52**, particularly to a diseased heart valve, which is subsequently removed, as known in the art. Access may be according to conventional sternotomies or, more preferably, in accordance with minimally invasive procedures. When the valve is removed, a valve annulus **54** remains, the size of which is measured by exemplary sizer **10**. A plurality of artificial valves may be provided, each with a sewing ring of

unique size. A plurality of sizers **10** may also be provided. The body **18** and the resilient member **16** of each sizer **10** are configured to corresponding to that of one of the artificial heart valves.

To measure the size of the annulus **54**, a surgeon selects a sizer **10** from the plurality of differently sized sizers. The outer diameters D_b of the sizers may range, for example, from about 18 millimeters (mm) or 19 mm to about 35 mm or more. The distal body **18** of the sizer **10** is inserted into through the valve annulus **54** until the resilient member **16** abuts the valve annulus **54**. The resilient member **16** conforms to the shape of the valve annulus **54**. The valve annulus **54** may be irregular in shape, with portions thereof more hard than other portions due to calcification. Accordingly, the resilient member **16** is able to compress in response to relatively hard portions of the annulus **54**, thereby conforming to the shape of the annulus. More specifically, as particularly shown in FIG **10**, the resilient member **16** is able to compress from a normal position, shown in phantom line, to a compressed positioned when urged against the annulus **54**, as shown by solid line, thereby conforming to the shape of the annulus. This conforming feature of the invention allows a surgeon to determine accurately the size of the annulus and select a properly sized replacement valve.

If the resilient member **16** does not conform to the valve annulus **54** in a desired manner, the surgeon may remove the sizer **10** and replace it with a differently sized diameter, which may then be inserted into the valve annulus **54**. This process may be repeated until the surgeon has determined the size of the annulus **54** to his or her satisfaction. The surgeon may then select a properly sized valve (e.g., valve **44**), position the valve **44** in the annulus **54**, and suture the sewing ring **50** to the annulus, as shown in FIG. **9B**.

With further reference to FIGS. **2–5**, the exemplary embodiment of the sizer **10** of the invention illustrated in the drawings is a two-piece configuration: the support member **14** and the resilient member **16**. The support member **14** may be made from substantially rigid material (i.e., having little resilience when compared to the resilient member **16**) to withstand forces required to insert the sizer **10** into a valve annulus. Alternatively, the sizer **10** may be a one-piece design, with the resilient member **16** permanently attached or integral with the support member **14**. In the one-piece embodiment, the support member **14** may be made from material which is either rigid

or resilient. In a resilient embodiment of the support member **14**, the body **18** is able to conform to a relatively hard and/or calcified annulus. In any case, the resilient member **16** is made from material which is substantially analogous to that of sewing rings of artificial valves commonly used today.

In addition to the substantially cylindrical configuration of the sizer **10**, the support member **14** may be configured in other shapes; for example, the support member **14** may be elliptical, oval, kidney-shaped, and so on.

The handle **12** is preferably bendable to provide the surgeon with an implement that may reach difficult-to-access areas of the heart **52**. In this regard, the handle **12** may be configured in accordance with a handle disclosed in United States Patent Application Serial No. 09/031,789 filed February 27, 1998, the entire disclosure of which is incorporated herein by reference.

The resilient member **16** of the present sizer may be formed integrally with the support member **14**, or may be removable. In the letter case, the resilient member **16** may be provided as a disposable item, while the support member **14** is reusable. The support member **14** is desirably made of a rigid material, such as polypropylene or polycarbonate, that is capable of being sterilized in an autoclave. The resilient member **16** can be used once, and then thrown away. A set of resilient members **16** for any one support member **14** may be provided, or replacement resilient members can be obtained separately. In addition, for any one support member **14**, a number of different shaped resilient members **16** may be supplied. So, for example, a full set of sizers may include a plurality of different sized support members **14**, with toroidal, elliptical, triangular, and irregularly-shaped resilient members **16** for each support member size.

Those skilled in the art will understand that the embodiments of the present invention described above exemplify the principles of the invention and do not limit the scope of the invention to those embodiments of the surgical apparatus specifically illustrated in the drawings and described above. The exemplary embodiments provide a foundation from which numerous alternatives and modifications may be made, which alternatives and modifications are also within the scope of the present invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A sizer for measuring a valve annulus to determine a size of an artificial heart valve to be sewn in the valve annulus during heart-valve replacement surgery, the artificial heart valve including a sewing ring having a resiliency, said sizer comprising:

a support member including having a predetermined size; and

a resilient member disposed about said support member;

said resilient member having a resiliency substantially the same as the resiliency of the sewing ring of the artificial heart valve.

2. A sizer as claimed in claim 1 wherein said support member includes a retainer about which said resilient member is disposed and a body having an outer diameter.

3. A sizer as claimed in claim 1 wherein said support member includes a concave peripheral recess for retaining said resilient member.

4. A sizer as claimed in claim 1 wherein said support member includes an attaching portion for attaching to a handle.

5. A sizer as claimed in claim 1 wherein said resilient member is configured substantially the same as the sewing ring of the artificial heart valve.

6. A sizer as claimed in claim 5 wherein said resilient member is substantially toroidal in configuration.

7. A sizer as claimed in claim 5 wherein said resilient member is three-dimensional in configuration.

8. A sizer as claimed in claim 7 wherein said resilient member is scalloped.

9. A sizer as claimed in claim 5 wherein said resilient member has an elliptical cross-section.

10. A sizer as claimed in claim 5 wherein said resilient member has a triangular cross-section.

11. A sizer for measuring a valve annulus, said sizer comprising:

a support member having a predetermined size; and

an resilient member disposed about a periphery of said support member;

said resilient member being adapted to conform to the shape of the valve annulus when urged thereagainst.

12. A sizer as claimed in claim 11 wherein said support member is attachable to a surgical handle.

13. A sizer as claimed in claim 11 wherein said support member is substantially rigid.

14. A sizer as claimed in claim 11 wherein said support member is resilient.

15. A sizer as claimed in claim 11 wherein said resilient member is integral with said support member.

16. A sizer as claimed in claim 11 wherein said resilient member is removable from said support member.

17. A sizer as claimed in claim 16 wherein said support member includes a peripheral groove for receiving the resilient member.

18. A sizer as claimed in claim 17 wherein said peripheral groove is three-dimensional in configuration.

19. A sizer as claimed in claim 17 wherein said peripheral groove is scalloped.

20. A sizer as claimed in claim 11 wherein said resilient member has an outer diameter larger than that of said support member.

21. A method for measuring a size of a valve annulus to determine a proper size of an artificial valve when replacing a natural heart valve of a heart, said method comprising the steps of:

providing a plurality of artificial heart valves, each of said artificial heart valves having a resilient sewing ring of unique size;

providing a plurality of sizers, each of said sizers including a support member and a resilient disposed about a periphery of said support member, each said resilient member of said sizers having a size corresponding to that of one of said artificial heart valves;

selecting one of said sizers to define a selected sizer;

attaching a handle to said support member of said selected sizer;

inserting said selected sizer into the valve opening;

determining whether said selected sizer approximates the size of the valve annulus; and

selecting an artificial heart valve which has a sewing ring with a size corresponding to that of said attached sizer.

22. A method as claimed in claim 21 wherein the step of providing a plurality of sizers includes providing more than one resilient member for each sizer.

23. A method as claimed in claim 21 wherein the resilient members provided for each sizer have different cross-sectional shapes.

24. A surgical apparatus for measuring a valve opening to determine a proper size of an artificial heart valve during heart-valve replacement surgery, the artificial heart valve including a sewing ring having a resiliency and a configuration, said surgical apparatus comprising:

a handle; and

a sizer including a support member connectable to said handle and a resilient member disposed about a periphery of said support member;

said resilient member having resiliency substantially equivalent to the resiliency of the sewing ring of the artificial heart valve.

25. Surgical apparatus as claimed in claim 24 wherein said resilient member has a cross-sectional shape substantially the same as the configuration of the sewing ring.

26. Surgical apparatus as claimed in claim 24 further comprising a plurality of said sizers, said plurality of said sizers including sizers of different size.

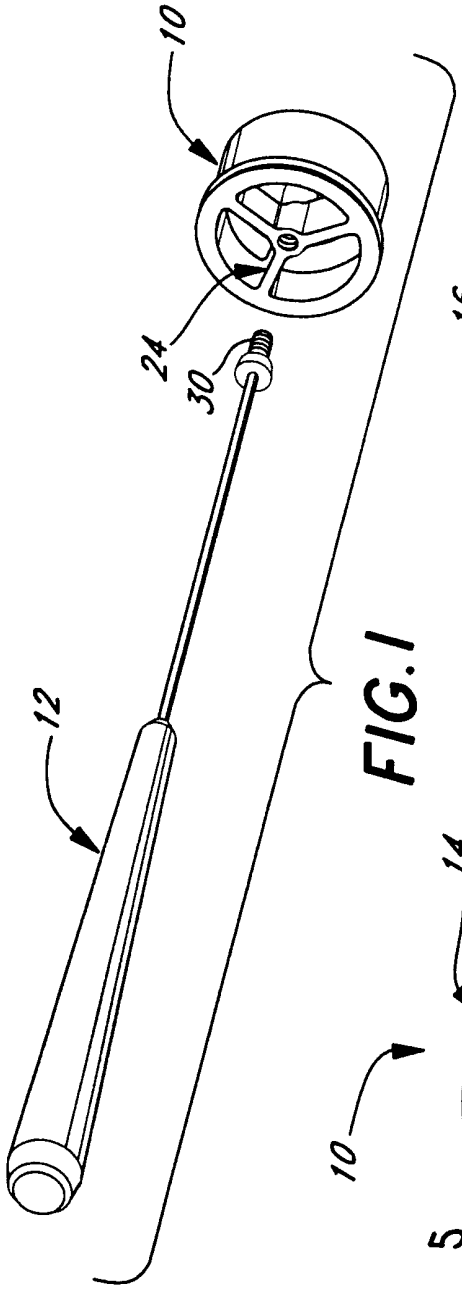


FIG. 1

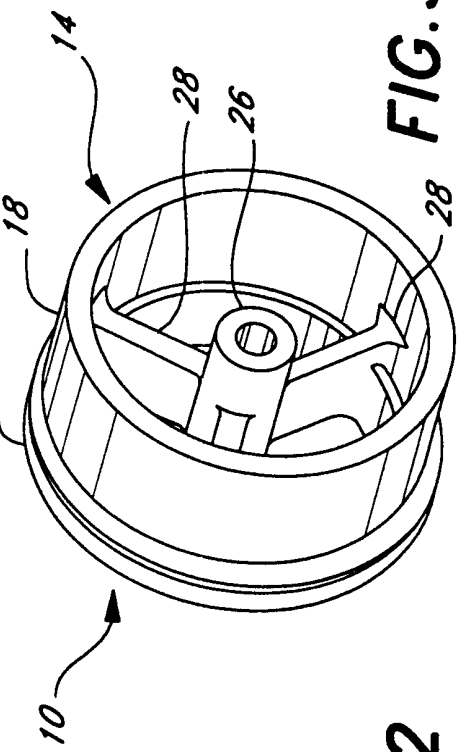


FIG. 3

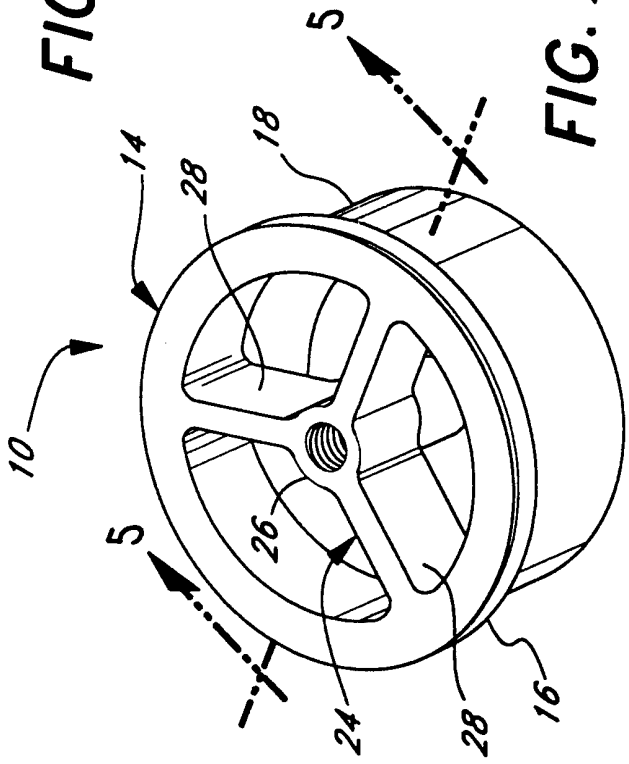


FIG. 2

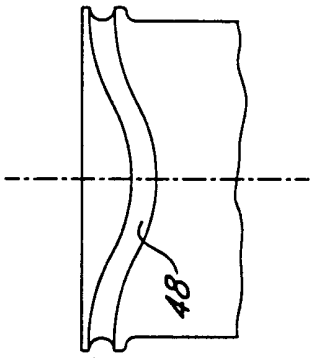


FIG. 8

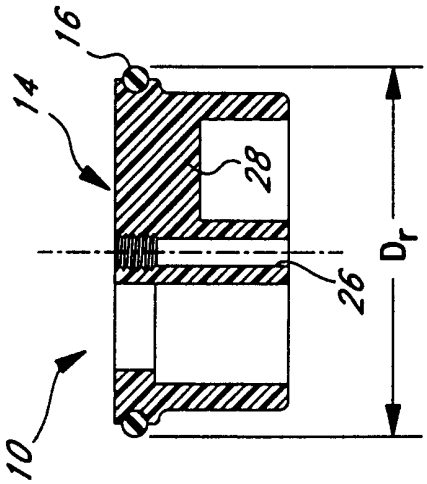


FIG. 5

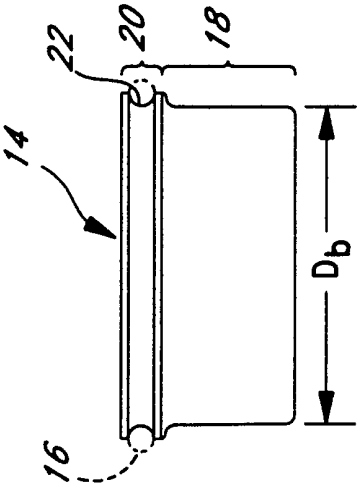


FIG. 4

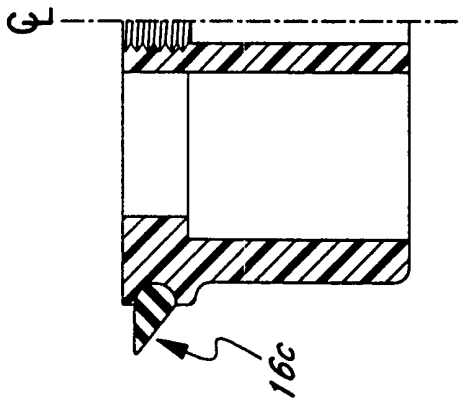


FIG.6C

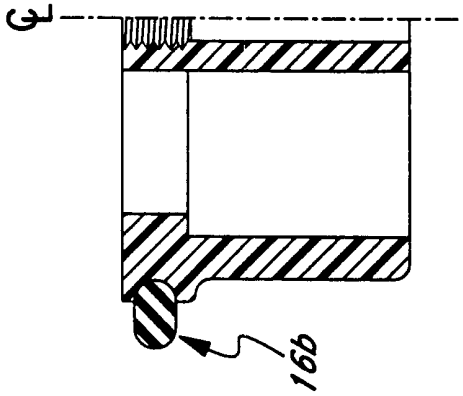


FIG.6B

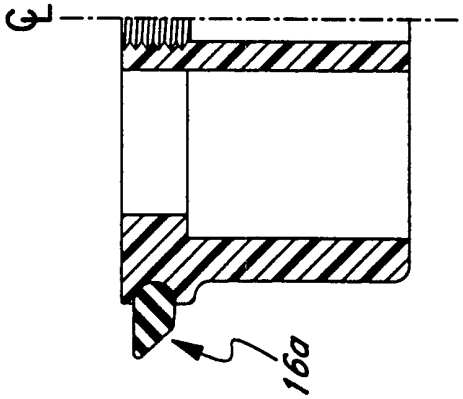


FIG.6A

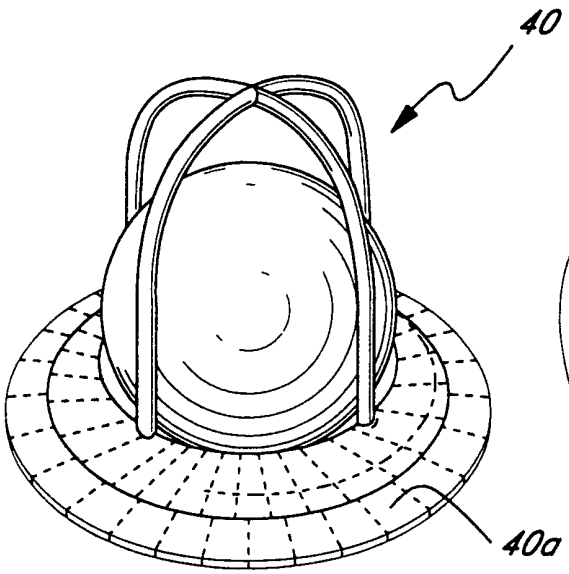


FIG. 7A

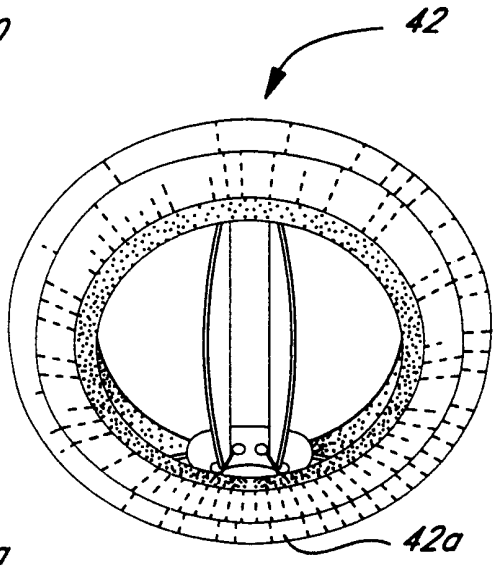


FIG. 7B

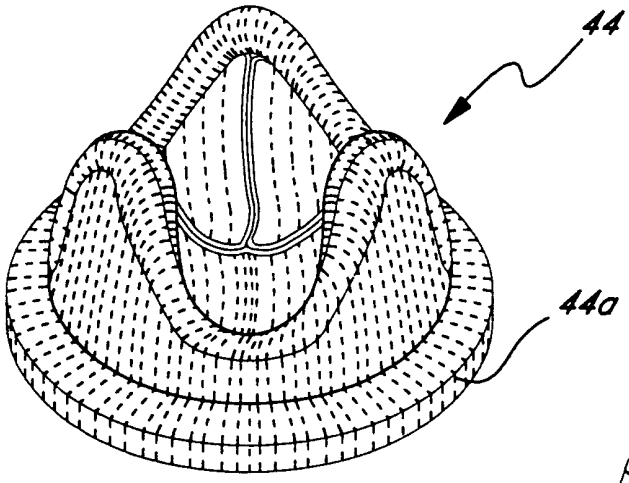


FIG. 7C

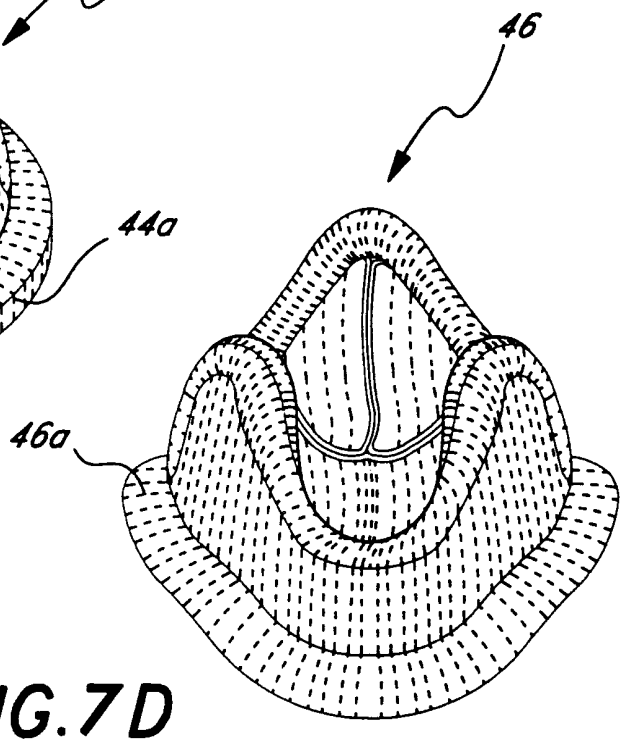


FIG. 7D

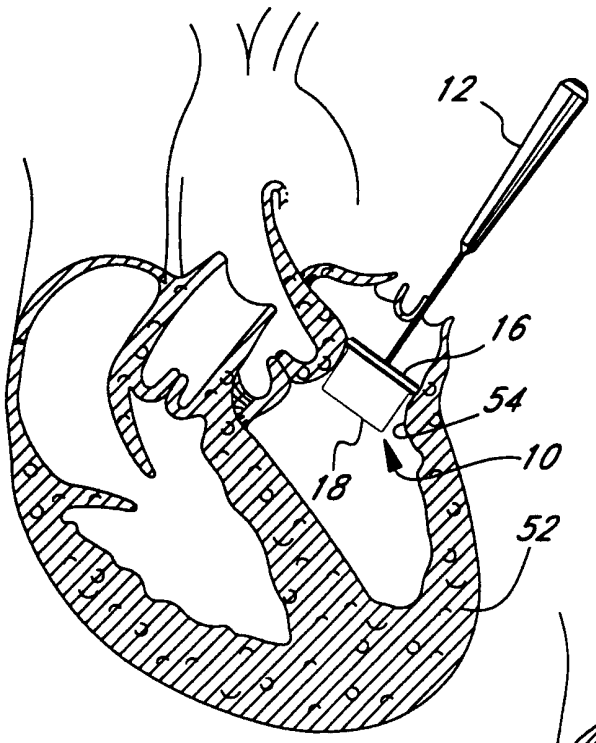


FIG.9A

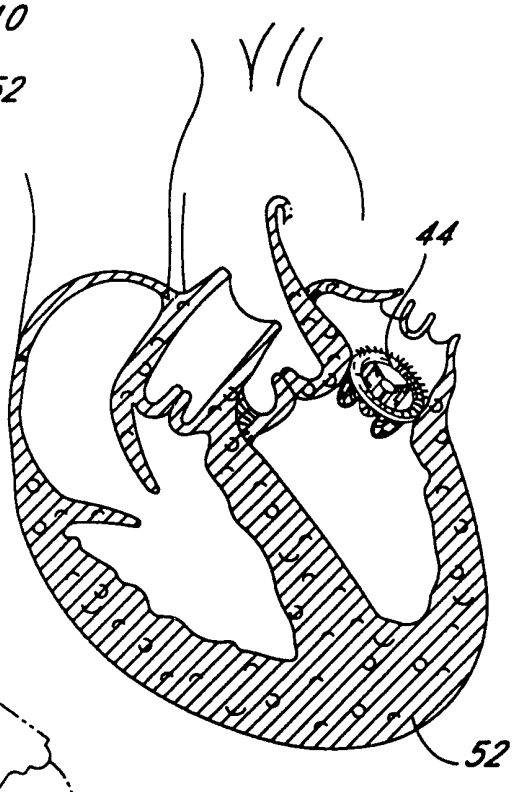


FIG.9B

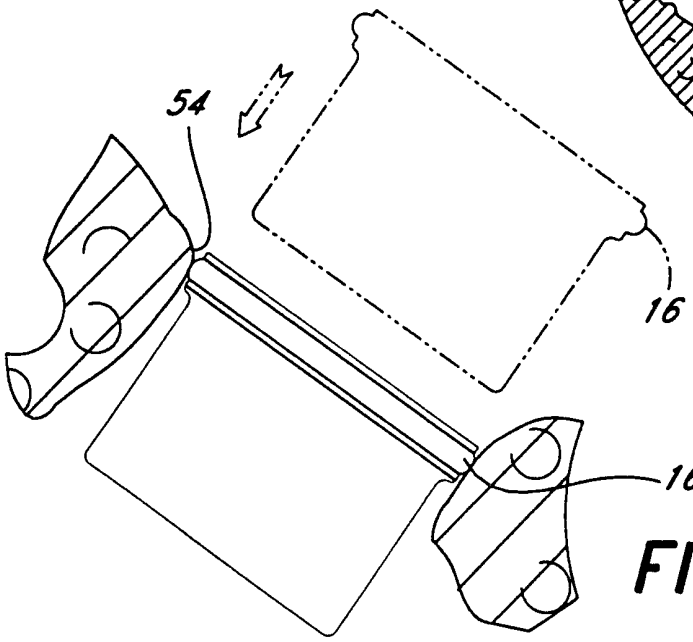


FIG.10

INTERNATIONAL SEARCH REPORT

Inter ɔnal Application No
PCT/US 00/25043

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 814 098 A (HILLYARD ANGELA L ET AL) 29 September 1998 (1998-09-29) column 4, line 35 -column 5, line 3; figures	1,4,11, 12,24
A	WO 97 41801 A (HEARTPORT INC) 13 November 1997 (1997-11-13) page 6, line 6 -page 7, line 20; figures 5-7	1,4,11, 12,24
A	WO 97 25003 A (BAXTER INT) 17 July 1997 (1997-07-17) claim 9; figures	1,4,11, 12,24,26

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 January 2001	11/01/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

1

INTERNATIONAL SEARCH REPORT

.iformation on patent family members

Inter onal Application No
PCT/US 00/25043

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5814098 A	29-09-1998	US 6110200 A	29-08-2000
		AU 6029696 A	30-12-1996
		WO 9640006 A	19-12-1996
WO 9741801 A	13-11-1997	US 5885228 A	23-03-1999
		AU 3061197 A	26-11-1997
		US 6042554 A	28-03-2000
WO 9725003 A	17-07-1997	AU 2241497 A	01-08-1997
		DE 69700302 D	05-08-1999
		DE 69700302 T	23-03-2000
		EP 0873094 A	28-10-1998
		JP 2000502937 T	14-03-2000
		US 5814096 A	29-09-1998