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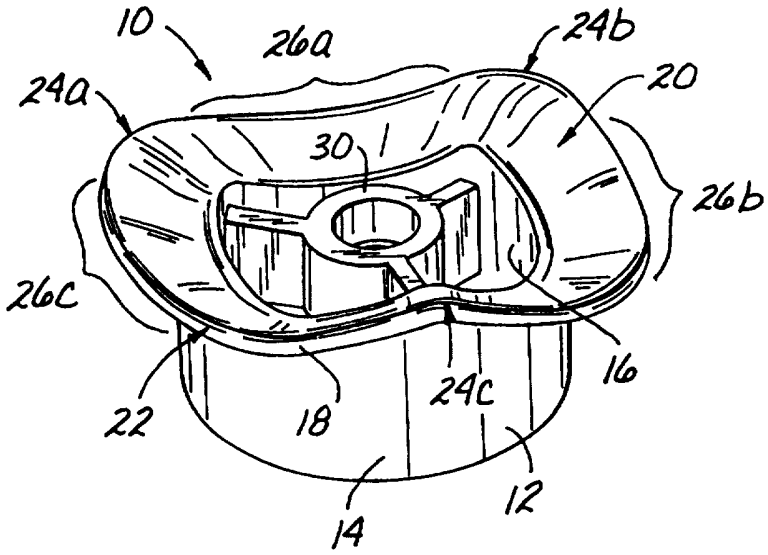
(57) Abstract

An aortic valve sizing obturator apparatus for employment in determining the correct size of an aortic annulus. The apparatus includes a cylindrical obturator body with a flange member formed thereabout. At least the under surface of the flange member is of a non-planar, multi-curvate configuration to thereby be complementary in shape to the annulus of an aortic valve when seated in the annulus during size determination. Within the cylindrical obturator body can be disposed a handle connector to which a handle can be attached during placement of the obturator apparatus within an annulus. The present invention also includes methodology for determining the size of an aortic valve annulus by employing a plurality of differently-sized aortic valve sizing obturators defined above and individually seating them sequentially within the aortic annulus until an obturator that reflects annulus size is located.



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SIZING OBTURATOR FOR PROSTHETIC AORTIC VALVES

Field of the Invention

The present invention pertains generally to medical devices and more particularly to an obturator apparatus insertable into an aortic valve annulus of a human heart following performance of a valvulotomy for the purpose of determining the correct size of a prosthetic valve to be surgically implanted therein.

Background of the Invention

Surgical valvulotomy and prosthetic valve replacement has been performed in human beings for many years. Most frequently, the procedures are utilized to replace mitral or aortic valves in patients who suffer from valvular heart disease.

In particular, surgical replacement of the aortic valve is typically necessitated by a) obstruction (i.e., stenosis) of the aortic heart valve or b) leakage (i.e., regurgitation, incompetence or insufficiency) of blood through the aortic valve. In some patients, symptoms of both obstruction and leakage are present, this being known as "mixed disease" or "combined lesions". Aortic valvular heart disease may be caused by a number of factors, including congenital deformations, infections, degenerative calcification, and certain rheumatological heart disorders.

Surgical replacement of the aortic valve is typically performed under general anesthesia, with full cardiopulmonary bypass. The leaflets of the endogenous aortic valve are removed along with any calcified surrounding tissue. This results in the formation of an annular opening at the site of the endogenous aortic valve. Thereafter, a mechanical or bioprosthetic aortic valve is then selected and sutured into the annular valve

opening, as a prosthetic replacement for the surgically-removed endogenous valve. Examples of mechanical prosthetic aortic valves which have heretofore been utilized, include the Starr-Edwards™ Silastic Ball Valve (Baxter Healthcare Corporation, Edwards CVC Division, 17221 Red Hill Ave., P.O. Box 11150, Santa Ana, California 92711-1150); the St. Jude Bileaflet Heart Valve (St. Jude Medical, Inc., St. Paul, Minnesota) and the Medtronic-Hall Tilting Disk Valve (Medtronic Inc., Minneapolis, Minnesota). Examples of bioprosthetic aortic valves which have heretofore been utilized include the Carpentier-Edwards®, PERIMOUNT™ Pericardial Bioprosthesis (Baxter Healthcare Corporation, Edwards CVS Division, 17221 Red Hill Ave., P.O. Box 11150, Santa Ana, California 92711-1150) as well as the Carpentier-Edwards® Porcine Bioprosthesis (Baxter Healthcare Corporation, Edwards CVC Division, 17221 Red Hill Ave., P.O. Box 11150, Santa Ana, California 92711-1150).

In general, these prosthetic aortic valves comprise a cylindrical valve body having a blood flow passageway extending longitudinally therethrough, and a suture ring formed annularly thereabout. The suture ring comprises suture penetrable material or a series of suture passage apertures, to facilitate anastomosis of the suture ring to the adjacent surgically-prepared aortic annulus. Because of the tricuspid configuration of the endogenous aortic valve, the natural aortic root has a non-planar, multi-curvate configuration. To correspond to such anatomical configuration of the natural aortic root, some or all of the aortic prosthetic valve of the prior art have utilized suture rings which are of a generally non-planar, multi-curvate configuration.

The ultimate success of any aortic valve placement procedure is dependant on a number of factors, including the correct sizing and placement of the prosthetic aortic valve. In this regard, it is common practice to utilize

a sizing obturator to determine the correct size of prosthetic valve for implantation. Such sizing obturators typically comprise a series of different-sized cylindrical members which are independently attachable to a handle, and which are insertable into the surgically-prepared valve annulus to determine the actual size of the annular opening. Such sizing obturators may be color-coded for size identification. Examples of aortic and mitral valve sizing obturators of the prior art include the True-Size™ Aortic Obturator-Model 1161 and the True-Size™ Mitral Obturator-Model 1162, Baxter Healthcare Corporation, Edwards CVS Division, 17221 Red Hill Ave., P.O. Box 1150, Santa Ana, California 92711-1150.

One drawback associated with aortic valve sizing obturators of the prior art is that such obturators typically comprise a generally cylindrical obturator body having a flat annular flange extending therearound. The flat annular flange is typically advanced into abutment with, but does not actually seat or nest within, the non-planar, three-peaked anatomy of the natural aortic root, which defines the superior aspect of the aortic annulus.

In view of the importance of ascertaining the correct size and configuration of the prosthetic aortic valve to be utilized, there exists a need in the art for the development of a new sizing obturator device which has a non-planar, multi-curvate flange configured to directly seat or nest within the three-peaked normal anatomy of the superior aspect of the annular, thereby providing the surgeon with an accurate, preliminary reading of the correct size and configuration of non-planar, multi-curvate suture ring to be utilized.

Accordingly, a primary object of the present invention is to provide a sizing obturator which has a cylindrical body which may be inserted through the annulus. and a flange member which is configured to be

substantially complimentary to the configuration of the superior aspect of the aortic annulus, within which a prosthetic valve is to be subsequently implanted.

Another object of the present invention is to provide such a sizing obturator whose cylindrical body has, disposed therein, a connector member which is connectable to a handle usable during obturator placement.

Yet another object of the present invention is to provide methodology employing the above-defined obturator in a plurality of sizes to thereby accurately reflect aortic annulus size for subsequent prosthetic valve implantation.

These and other objects of the present invention will become apparent throughout the description of the invention which now follows.

Summary of the Invention

The present invention is an aortic valve sizing obturator apparatus for employment in determining the correct size of an aortic annulus so that a correctly sized prosthetic valve can be chosen for subsequent placement within the annulus. The apparatus comprises a cylindrical obturator body having a top end, a bottom end, an inner surface, an outer surface, and a first outer diameter. A flange member is formed about the obturator body and has an upper surface, an under surface, and a second outer diameter which is greater than the first outer diameter of the obturator body. The undersurface of the flange member is of a non-planar, multi-curvate (i.e., having more than one curve formed therein) configuration to thereby be complimentary in shape to the superior aspect of the aortic annulus such that the flange may be seated or nested within the supra-annular anatomy (three peaked configuration of the aortic root during size determination. Within the cylindrical

obturator body, there may be disposed a handle connector apparatus, to which a separate handle can be attached to facilitate insertion and placement of the obturator apparatus during the sizing procedure.

The present invention also includes methodology for determining the size of an aortic valve annulus for subsequent placement therein of a prosthetic aortic valve. This methodology employs a plurality of aortic valve sizing obturators defined above and includes placing of one or more obturators, one at a time, into an aortic valve annulus such that the flange member is seated in a complimentary relationship with the configuration of the annulus. This procedure continues until a properly sized obturator that reflects the size of the aortic annulus, is located.

By employing the present invention in a procedure wherein a prosthetic aortic valve is to be implanted, a surgeon is able to accurately determine the size needed for the replacement valve. Achieving such accuracy is greatly enhanced because of the non-planar, multi-curvate flange member described above which permits seating of the flange in a complimentary relationship with the configuration of the aortic annulus to thereby gain a more accurate reflection of the size of the annulus and of the consequent replacement valve.

Brief Description of the Drawings

Figure 1 is top perspective view of a preferred aortic valve sizing obturator of the present invention.

Figure 2 is a top plan view of the preferred aortic valve sizing obturator of Figure 1.

Figure 3 is a side elevational view of the preferred aortic valve sizing obturator of Figure 1.

Figure 4 is a cross sectional view through line 4-4 of Figure 2.

Figure 5 is a cross sectional view through line 5-5

of Figure 2.

Figure 6a is a perspective view of a prior art handle member which may be utilized in conjunction with the preferred aortic valve sizing obturator of the present invention.

Figure 6b is a perspective view of an alternative, bendable, handle member which may be utilized in conjunction with the aortic valve sizing obturator of the present invention.

Figure 7 is a perspective schematic view of a portion of a human heart, showing the manner in which the preferred aortic valve sizing obturator of the present invention is inserted into the surgically-prepared aortic annulus.

Figure 7a is an enlarged elevational view of a portion of Figure 7.

Detailed Description of the Preferred Embodiment

The following detailed description and the accompanying drawings are provided for the purpose of describing and illustrating a presently preferred embodiment of the invention only, and are not intended to limit the scope of the invention in any way.

With reference to the drawings, the preferred aortic valve sizing obturator 10 of the present invention comprises a cylindrical obturator body 12 having an outer surface 14 and an inner surface 16, and a non-planar, multi-curvate annular flange 18 extending outwardly about one end of the cylindrical obturator body 12. The non-planar, multi-curvate annular flange 18 has an upper surface 20, and a lower surface 22. (As used in this patent application, the term "multi-curvate" means having more than one curve formed therein.)

The end of the cylindrical obturator body 12 upon which the non-planar, multi-curvate flange 18 is positioned, and the configuration of the non-planar,

multi-curvate flange 18 itself, are characterized by the presence of three equally-spaced-apart blunt peaks 24a, 24b, 24c having three generally arcuate depressions 26a, 26b, 26c extending therebetween, as shown.

Three (3) radial strut members 28a, 28b, 28c extend inwardly from the inner surface 16 of the cylindrical obturator body 12 at locations which are immediately below each of the discrete blunt peaks 24a, 24b, 24c formed in the non-planar, multi-curvate flange 18. A cylindrical inner member 30 is positioned coaxially within the central bore 32 of the cylindrical obturator body 12, and is supported and held in fixed position by the strut members 28a, 28b, 28c. A hollow inner bore 34 extends longitudinally through the inner cylindrical member 30, and internal threads 36 are formed on the inner surface of such longitudinal bore 34.

A single longitudinal axis LA as illustrated in Figure 4 is projectable longitudinally through the cylindrical obturator body 12, such that the obturator body 12 and inner cylindrical member 30 are coaxially disposed about such common longitudinal axis LA.

Figure 6a-6b show two prior art stainless steel handles which may be utilized in conjunction with the preferred aortic valve sizing obturator shown in Figures 1-5. Specifically, Figure 6a shows a reusable handle comprising an elongate rigid handle member 40 having an externally threaded distal projection 42 extending from the distal end thereof. The externally threaded projection 42 is insertable into the upper end of the bore 34 of the inner cylindrical member 30 of the preferred aortic valve sizing obturator 10 of the present invention such that the external threads of projection 42 may be rotatably engaged with the internal threads 36 formed within the bore 34 of the inner cylindrical member 30, thereby attaching the elongate handle member 40 to the aortic valve sizing obturator 10. The particular

handle shown in Figure 6a has been commercially available as Handle Model 1108, Baxter Healthcare Corporation, Edwards CVC Division, 17221 Red Hill Ave., P.O. Box 11150, Santa Ana, California 92711-1150.

Figure 6b shows an alternative handle which comprises a segmented rigid handle member 40a having a bendable segment 46 disposed therewithin, and an externally threaded distal projection 42a extending from the distal end thereof. A flanged bushing 44 is formed proximal to the externally threaded distal portion 42a, as shown. The bendable segment 46 of this handle may be manually bent or preformed by the surgeon to a desired configuration to facilitate insertion and positioning of the aortic valve sizing obturator 10. The particular handle shown in Figure 6b has been commercially available as Handle Model 1111, Baxter Healthcare Corporation Edwards CVC Division, 17221 Red Hill Ave., P.O. Box 11150, Santa Ana, California 92711-1150.

The aortic valve sizing obturator 10 may be formed of any suitable material including rigid, autoclavable thermoplastic material such as polysulfonate. The obturators 10 will typically be provided in a kit consisting of a series of different-sized obturators 10, corresponding to the available sizes of the particular prosthetic heart valves for which the obturator 10 is to be employed. For example, the following table shows examples of specific component dimensions (in millimeters) of standard, commercially available sizes of the Carpentier-Edwards® PERIMOUNT™ Pericardial Aortic Bioprosthesis referred to hereabove:

Mounting Diameter (Annulus)	19	21	23	25	27	29
Internal Diameter (Stent I.D.)	18	20	22	24	26	28
Profile Height	13	14	15	16	17	18
External Sewing Ring Diameter	28	31	33	35	38	40

When the sizing obturator 10 of the present invention is to be used for determining the correct size of the Model

2700 Aortic Bioprosthesis to be employed, the manufacturer will typically provide a kit having a series of different-sized obturators 10, which correspond directly to the available sizes of the Model 2700 Aortic Valvular Prosthesis. In this regard, if an obturator 10 having a mounting diameter (i.e., the diameter of the outer surface 14 of the cylindrical obturator body 12) of 19 is found to provide the best fit within the surgically-prepared valve annulus, a Model 2700 prosthetic valve having a mounting diameter of 19 will typically be selected. Also, because the sizing obturator 10 of the present invention is provided with a non-planar, multi-curvate flange 18, such flange may be directly nested or seated within the surgically-prepared natural valve annulus to provide a direct and precise indication of the correct external sewing ring diameter desired.

It will be appreciated that, in most aortic valve replacement surgeries, the prosthetic valve is implanted in a supra-annular position wherein the suture ring of the prosthetic valve is positioned superior to the surgically-prepared valve annulus. Alternatively, however, it may sometimes be desirable to implant the prosthetic valve in an intra-annular position, wherein the entire suture ring of the prosthetic valve is positioned within the surgically-prepared valve annulus and an everting mattress suture technique is employed to anastomose the prosthetic valve in such intra-annular position. In this regard, when it is desired to utilize the typical supra-annular positioning of the prosthetic valve, the sizing obturator 10 will be inserted such that the non-planar, multi-curvate flange 18 is nested or seated in a supra-annular position which is analogous to the intended positioning of the suturing ring of the prosthetic valve. Alternatively, however, if it is intended to implant the prosthetic valve in an intra-

annular position, the sizing obturator 10 of the present invention will be initially placed such that the non-planar, multi-curvate annular flange 18 is located in the desired intra-annular position.

Figures 7-7a provide a schematic illustration of the typical manner in which the aortic valve sizing obturator 10 of the present invention may be utilized to determine the correct prosthetic valve size to be used for supra-annular implantation in a human heart. In the showing of the human heart provided in Figure 7, the major anatomical structures are labeled accordingly to the following legend:

A = Aorta
AA = Aortic Annulus
M = Myocardium
IVS = Interventricular Septum
RV = Right Ventricle
RA = Right Atrium
LV = Left Ventricle
SVC = Superior Vena Cava

As shown, a handle such as that shown in Figure 6b is initially inserted and engaged into the upper end of the hollow bore 34 of the sizing obturator 10, and the threaded distal projection 42a of the handle is rotatably advanced such that its external threads will rotatably engage the internal threads 36 formed within the bore 34 of the obturator 10. In this manner, the handle of the type shown in Figure 6b is firmly attached to the obturator 10, and extends in a longitudinally coaxial fashion from the upper end of the obturator 10, as shown.

The diseased or damaged aortic valve leaflets, and all associated structures deemed necessary, are surgically removed. The surgeon may also remove any calcium from the valve annulus, to ensure proper seating of the suture ring of the prosthetic valve.

After the aortic valve annulus has been surgically prepared, the aortic valve sizing obturator 10 of the

present invention will be inserted such that the cylindrical obturator body 12 passes downwardly through the surgically-prepared valve annulus with little resistance. The obturator 10 is then rotatably reoriented and further advanced until the undersurface 22 of the non-planar, multi-curvate flange becomes nested or seated within the non-planar, multi-curvate anatomical structure of the natural aortic root. In this manner, the surgeon may visually verify that the diameter of the cylindrical obturator body 12 and non-planar, multi-curvate annular flange 18 are correct for that particular patient. Thereafter, the surgeon may select a prosthetic aortic valve which has a mounting (annulus) diameter and external sewing ring diameter the same as that of the obturator 10 which was found to correctly fit within the patient's aortic valve annulus. Thereafter, the obturator 10 and accompanying handle may be extracted and removed, and the selected prosthetic aortic valve may be sutured into place. Following use, the handle may be rotatably detached and removed from the obturator 10, and both the stainless steel handle and the molded plastic obturator may be autoclaved or otherwise sterilized for subsequent reuse.

It will be appreciated that the present invention has been described hereabove with reference to certain presently preferred embodiments only, and no effort has been made to exhaustively describe all possible embodiments in which the invention may take physical form. It will be appreciated by those skilled in the art that various addition, deletions, modifications and alterations may be made to the above-described embodiment without departing from the intended spirit and scope of the present invention. Accordingly, it is intended that all such additions, deletions, modifications and alterations be included within the scope of the following claims.

WHAT IS CLAIMED IS:

1. An aortic valve sizing obturator apparatus comprising:

a cylindrical obturator body having a top end, a bottom end, an inner surface and an outer surface;

said cylindrical obturator body having a first outer diameter;

a flange member formed about said cylindrical obturator body, said flange member having an upper surface, an under surface, and a second outer diameter, said second outer diameter being larger than said first outer diameter; and,

the undersurface of said flange member having a non-planar, multi-curvate configuration.

2. The apparatus of Claim 1 wherein the non-planar, multi-curvate configuration of the undersurface of said flange member comprises:

three spaced-apart peaks with three arcuate depressions, each of said arcuate depressions extending between adjacent ones of said peaks.

3. The apparatus of Claim 2 wherein said peaks are equidistantly spaced apart.

4. The apparatus of Claim 1 wherein the entire annular flange is of said non-linear, multi-curvate configuration.

5. The apparatus of Claim 4 wherein the upper surface of said flange member is coterminous with the upper end of said cylindrical obturator body, and wherein the upper end of said cylindrical obturator body is also of said non-planar, multi-curvate configuration.

6. The apparatus of Claim 1 further comprising:

an inner cylindrical member disposed longitudinally and coaxially within the cylindrical obturator body, said inner cylindrical member being rigidly affixed to said obturator body and incorporating a handle connector apparatus whereby

a separate handle member may be attached to said obturator apparatus.

7. The apparatus of Claim 6 wherein said connector apparatus incorporated within said inner cylindrical member comprises:

a hollow bore extending longitudinally through at least a portion of said inner cylindrical member, and internal threads formed within said hollow bore such that an externally threaded handle may be rotatably engaged therewith.

8. A system for determining the size of a prosthetic aortic heart valve to be used, said system comprising:

a plurality of sizing obturators according to Claim 1, at least the first diameter of each of said sizing obturators being different; and,

an elongate handle member which is alternately attachable to each of said sizing obturators, to facilitate the insertion and subsequent removal of selected ones of said obturators into a surgically-prepared anatomical opening formed within a mammalian heart.

9. A method for determining size of an aortic valve annulus for subsequent placement therein of a prosthetic aortic valve, the method comprising:

a) providing a plurality of aortic valve sizing obturators each having a different diameter and each comprising:

i) a cylindrical obturator body having a top end, a bottom end, an inner surface, an outer surface and a first outer diameter;

ii) a flange member formed about said cylindrical obturator body, said flange member having an upper surface, an under surface, and a second outer diameter, said second outer diameter being larger than said first outer

diameter; and,

iii) the under surface of said flange member being of non-planar, multi-curvate configuration; and

b) selecting from the plurality of obturators a properly sized obturator whose size reflects the size of the aortic valve annulus, such selection performed by individually and sequentially inserting and then removing one or more obturators as necessary within the annulus and seating the flange member in complimentary relationship with the annulus until the properly sized obturator is located.

10. A method as claimed in Claim 9 wherein the non-planar, multi-curvate configuration of the undersurface of said flange member comprises:

three spaced-apart peaks with three arcuate depressions, each of said arcuate depressions extending between adjacent ones of said peaks.

11. A method as claimed in Claim 2 wherein said peaks are equidistantly spaced apart.

12. A method as claimed in Claim 9 wherein the entire annular flange is of said non-linear, multi-curvate configuration.

13. A method as claimed in Claim 12 wherein the upper surface of said flange member is coterminous with the upper end of said cylindrical obturator body, and wherein the upper end of said cylindrical obturator body is also of said non-planar, multi-curvate configuration.

14. A method as claimed in Claim 9 wherein each valve sizing obturator additionally comprises:

an inner cylindrical member disposed longitudinally and coaxially within the cylindrical obturator body, said inner cylindrical member being rigidly affixed to said obturator body and

incorporating a handle connector apparatus whereby a separate handle member may be attached to said obturator apparatus.

15. A method as claimed in Claim 14 wherein said connector apparatus incorporated within said inner cylindrical member comprises:

a hollow bore extending longitudinally through at least a portion of said inner cylindrical member, and internal threads formed within said hollow bore such that an externally threaded handle may be rotatably engaged therewith.

16. In an aortic heart valve sizing obturator of the type comprising a generally cylindrical obturator body having a first diameter and an annular flange which extends generally outward from said cylindrical obturator body, said flange having an undersurface which abuts against a superior aspect of the aortic an annulus when said flange is positioned supra-annularly such that the cylindrical obturator body extends through the aortic annulus, the improvement comprising:

causing the undersurface of said flange to be of non-planar, multi-curvate configuration.

17. The improvement of Claim 16 wherein said non-planar, multi-curvate configuration has three blunt peaks with arcuate depressions extending between said peaks.

18. The improvement of Claim 17 wherein said blunt peaks and arcuate depressions are sized and spaced-apart relative to each other so as to correspond to the anatomical configuration of the superior aspect of the aortic annulus, thereby allowing said flange to nest within the superior aspect of the aortic annulus with the cylindrical obturator body extending through said annulus.

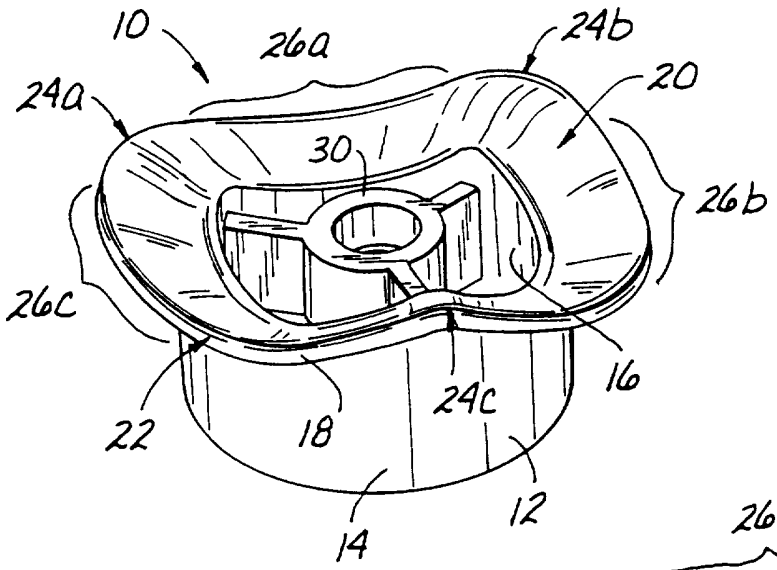


Fig. 1

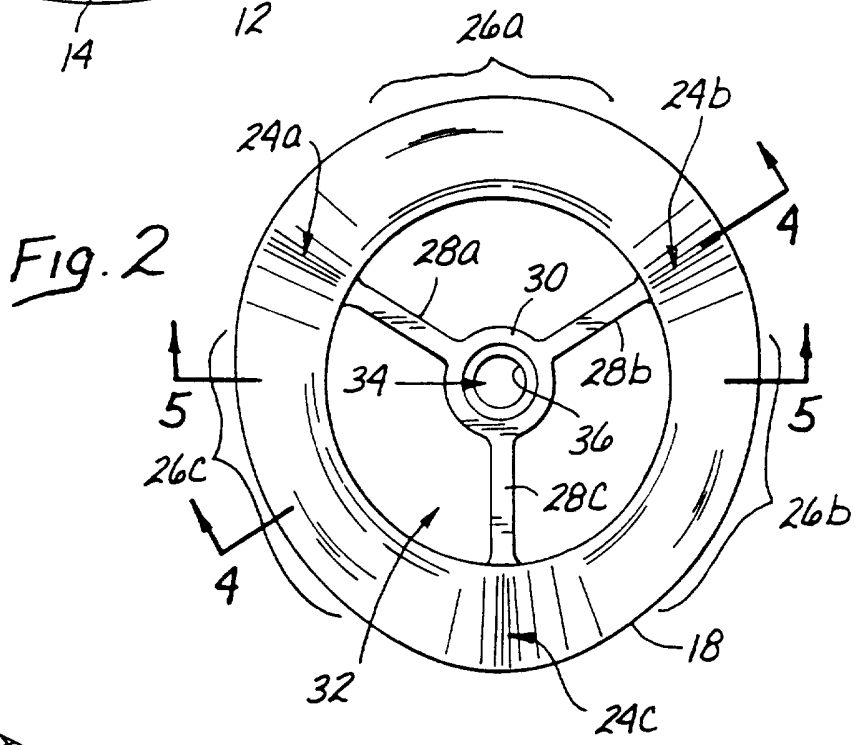


Fig. 2

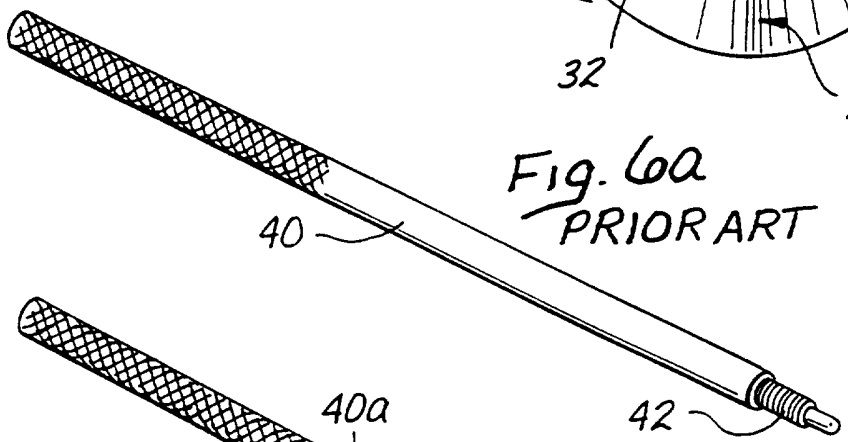


Fig. 6a
PRIOR ART

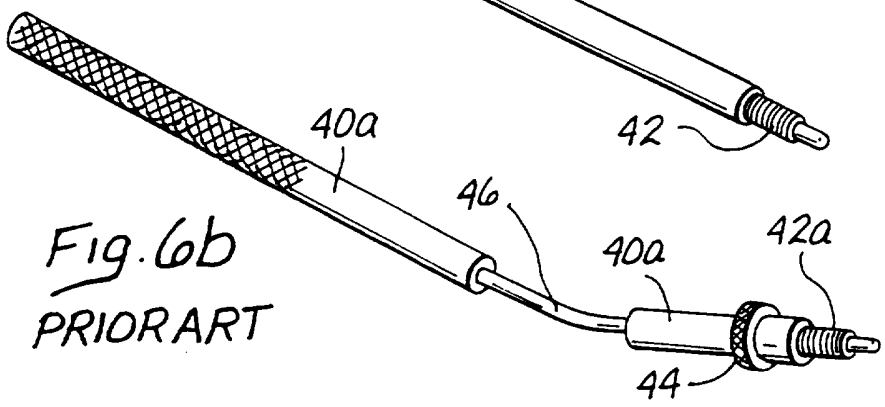


Fig. 6b
PRIOR ART

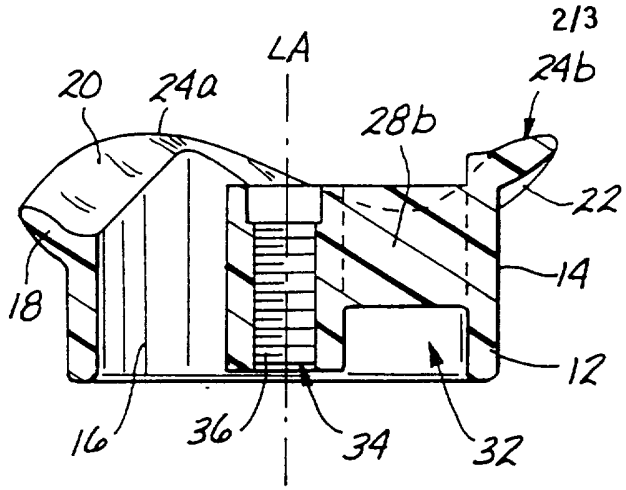
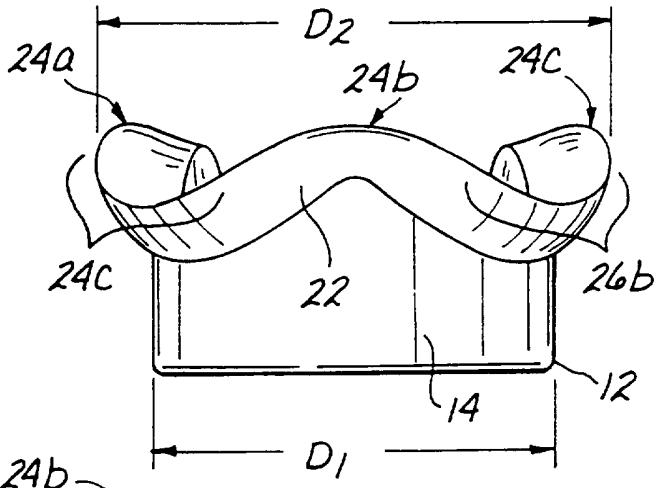


Fig. 4

Fig. 3



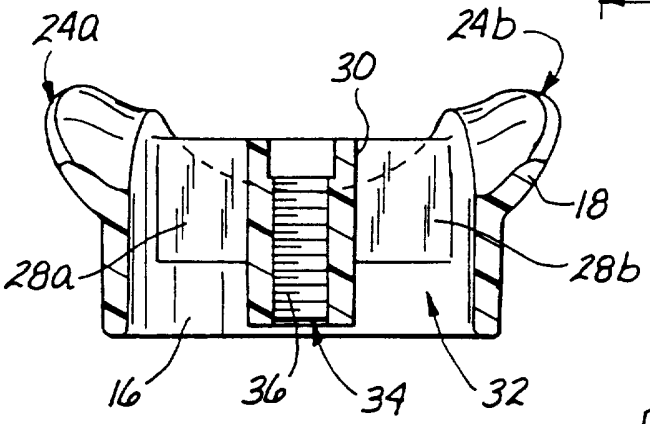


Fig. 5

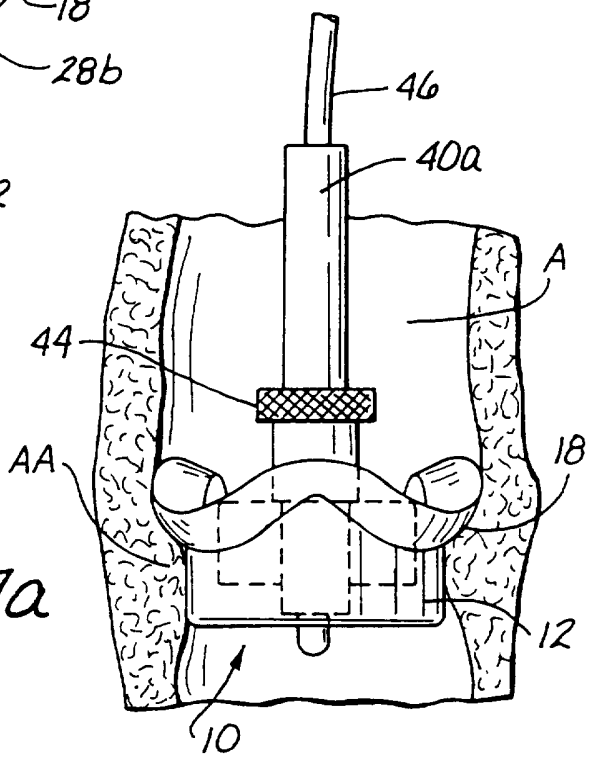


Fig. 7a

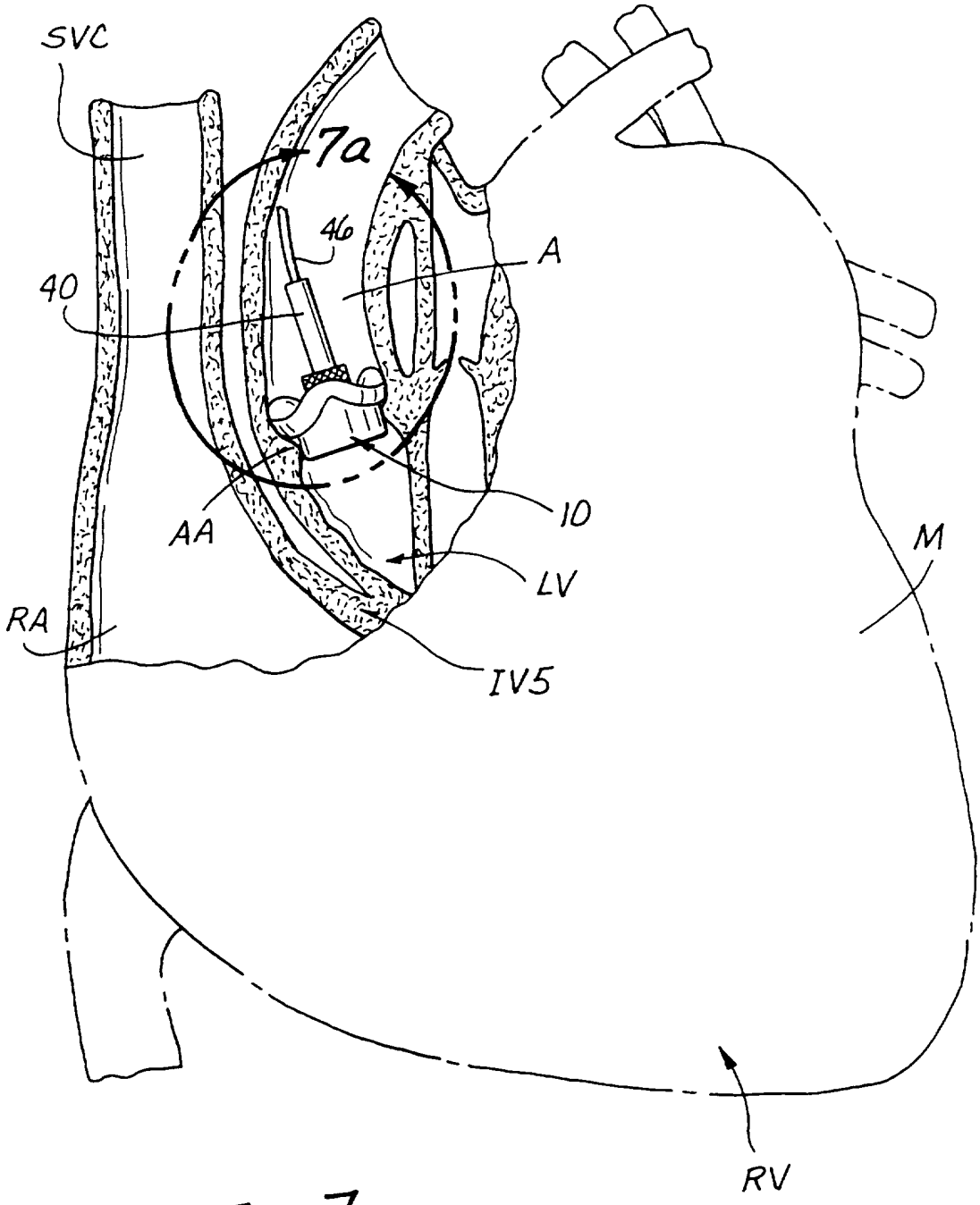


Fig. 7

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 97/00189

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/24 A61B5/107

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 6 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 16410 A (AUTOGENICS) 22 June 1995 see page 3, line 23 - page 5, line 28; figures	1,6,8,16
A	FR 2 418 918 A (KASTEC CORPORATION) 28 September 1979 see the whole document	1,8,16
A	US 5 360 014 A (CARBOMEDICS) 1 November 1994	
A	GB 2 083 362 A (ALBERT EINSZEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY) 24 March 1982	

☐ 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
6 May 1997	15.05.1997

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	Steenbakker, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

.rnational application No.
PCT/US 97/00189

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 9-15
because they relate to subject matter not required to be searched by this Authority, namely:
Please see Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were umely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ..tional Application No
PCT/US 97/00189

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9516410 A	22-06-95	US 5489296 A	06-02-96
FR 2418918 A	28-09-79	US 4211241 A	08-07-80
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