EXHIBIT J

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	**DEMAND FOR JURY TRIAL**
MEDTRONIC, INC., MEDTRONIC COREVALVE, LLC, and MEDTRONIC VASCULAR, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Edwards Lifesciences AG ("Edwards AG") and Edwards Lifesciences LLC ("Edwards LLC") (collectively, "Plaintiffs"), for their Complaint against Defendants Medtronic, Inc. ("Medtronic"), Medtronic CoreValve, LLC ("Medtronic CoreValve"), and Medtronic Vascular, Inc. ("Medtronic Vascular") (collectively, "Defendants"), allege as follows:

JURISDICTION AND VENUE

1. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* This Court has jurisdiction over the subject matter of this action based on 28 U.S.C. §§ 1338(a) and 1331. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE PARTIES

Edwards

2. Plaintiff Edwards AG is a corporation organized and existing under the laws of Switzerland and having its principal executive offices in St.-Prex, Switzerland.

3. Plaintiff Edwards LLC is a limited liability company organized and existing under the laws of the State of Delaware and having its principal executive offices in Irvine, California.

4. Edwards AG is the assignee of the following United States Patent covering pioneering percutaneous heart valve products: U.S. Patent No. 7,618,446 ("the '446 Patent"). The '446 Patent discloses and claims, *inter alia*, collapsible and expandable tissue valve prostheses that replace human heart valves using minimally invasive catheterization procedures.

5. Edwards LLC is the exclusive licensee of the '446 Patent for the field of all cardiovascular applications.

Medtronic

6. Upon information and belief, Defendant Medtronic is a corporation organized and existing under the laws of the State of Minnesota and having its principal place of business in Minneapolis, Minnesota.

7. Upon information and belief, Medtronic is registered to do business in Delaware, and is doing business in Delaware.

8. Upon information and belief, Medtronic and/or its subsidiaries or affiliates have manufactured and currently manufacture in the United States heart valve prostheses, including the ReValving system, that infringe the '446 Patent.

9. Upon information and belief, Medtronic has offered and is currently offering for commercial sale and has commercially sold the ReValving system in Europe and elsewhere outside the United States.

10. Upon information and belief, Medtronic has knowingly and actively induced others to infringe the '446 Patent and continues to do so.

Medtronic CoreValve

11. Upon information and belief, Defendant Medtronic CoreValve is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in Irvine, California.

12. Upon information and belief, Medtronic CoreValve is a wholly owned subsidiary of, and controlled by, Medtronic.

13. Upon information and belief, Medtronic CoreValve has manufactured and currently manufactures in the United States heart valve prostheses, including the ReValving system, that infringe the '446 Patent.

14. Upon information and belief, Medtronic CoreValve has offered and is currently offering for commercial sale and has commercially sold the ReValving system in Europe and elsewhere outside the United States.

15. Upon information and belief, Medtronic CoreValve has knowingly and actively induced others to infringe the '446 Patent and continues to do so.

Medtronic Vascular

16. Upon information and belief, Defendant Medtronic Vascular is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in Santa Rosa, California.

17. Upon information and belief, Medtronic Vascular is a wholly owned subsidiary of, and controlled by, Medtronic.

18. Upon information and belief, Medtronic Vascular and/or its subsidiaries or affiliates have manufactured and currently manufacture in the United States heart valve prostheses, including the ReValving system, that infringe the '446 Patent.

19. Upon information and belief, Medtronic Vascular has knowingly and actively induced others to infringe the '446 Patent and continues to do so.

INFRINGEMENT OF THE '446 PATENT

20. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 19 above.

21. On November 17, 2009, U.S. Patent No. 7,618,446 ("the '446 Patent") (a copy of which obtained from the U.S. Patent and Trademark Office on November 17, 2009 is attached hereto as Exh. 1), entitled "A Valve Prosthesis for Implantation in the Body and a Catheter for Implanting Such Valve Prosthesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '446 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '446 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

22. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '446 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '446 Patent, including products designated as the ReValving system.

23. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '446 Patent, including at least by their knowing and active inducement of the manufacturing,

using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '446 Patent, including products designated as the ReValving system.

24. Defendants' foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

25. Plaintiffs have been damaged and will be irreparably injured by Defendants' past and continuing infringement, for which Plaintiffs have no adequate remedy at law. Defendants' continued infringement will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand judgment as follows:

(a) Finding that Defendants have infringed the '446 Patent;

(b) Finding that Defendants' infringement of the '446 Patent has been willful and deliberate;

(c) Preliminarily and permanently enjoining and restraining Defendants and their officers, agents, servants, employees and attorneys, all parent, subsidiary and affiliate corporations and other related business entities, and all other persons or entities acting in concert, participation or in privity with Defendants, and their successors and assigns, from infringing, contributing to the infringement of, or inducing others to infringe the '446 Patent;

(d) Awarding Plaintiffs damages, in an amount to be determined at trial, together with interest and costs as fixed by the Court;

(e) Awarding Plaintiffs enhanced damages under 35 U.S.C. § 284;

(f) Awarding Plaintiffs their reasonable attorneys' fees and their costs and disbursements in this action, as provided by 35 U.S.C. § 285; and

(g) Granting Plaintiffs such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable in this Complaint.

POTTER ANDERSON & CORROON LLP

By: _____

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Dated: November 17, 2009
937320 / 34927

EXHIBIT 1

US007618446B2

(12) **United States Patent**
Andersen et al.

(10) **Patent No.: US 7,618,446 B2**
(45) **Date of Patent: *Nov. 17, 2009**

(54) **VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS**

(75) Inventors: **Henning Rud Andersen**, Hoejbjerg (DK); **John Michael Hasenkam**, Aarhus (DK); **Lars Lyhne Knudseu**, Aarhus (DK)

(73) Assignee: **Edwards Lifesciences AG**, Nyon (CH)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/268,253**

(22) Filed: **Oct. 10, 2002**

(65) **Prior Publicatiou Data**

US 2003/0036795 A1 Feb. 20, 2003

Related U.S. Application Data

(60) Continuation of application No. 09/514,426, filed on Feb. 28, 2000, now Pat. No. 6,582,462, which is a continuation of application No. 09/026,574, filed on Feb. 20, 1998, now Pat. No. 6,168,614, which is a continuation of application No. 08/955,228, filed on Oct. 21, 1997, now abandoned, which is a division of application No. 08/801,036, filed on Feb. 19, 1997, now Pat. No. 5,840,081, which is a continuation of application No. 08/569,314, filed on Dec. 8, 1995, now abandoned, which is a continuation of application No. 08/352,127, filed on Dec. 1, 1994, now abandoned, which is a division of application No. 08/261,235, filed on Jun. 14, 1994, now Pat. No. 5,411,552, which is a continuation of application No. 07/961,891, filed as application No. PCT/DK91/00134 on May 16, 1991, now abandoned.

(30) **Foreign Application Priority Data**

May 18, 1990 (DK) 1246/90

(51) **Int. Cl.**
A61F 2/24 (2006.01)
A61F 2/90 (2006.01)
A61F 2/88 (2006.01)

(52) **U.S. Cl.** **623/1.26**; 623/2.14

(58) **Field of Classification Search** ..... 623/2.1–2.19, 623/2.38–2.41, 900, 904, 1.24–1.26, FOR. 101, 623/23.68; 604/9

See application file for complete search history.

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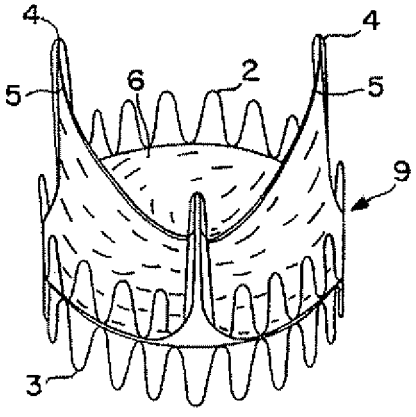
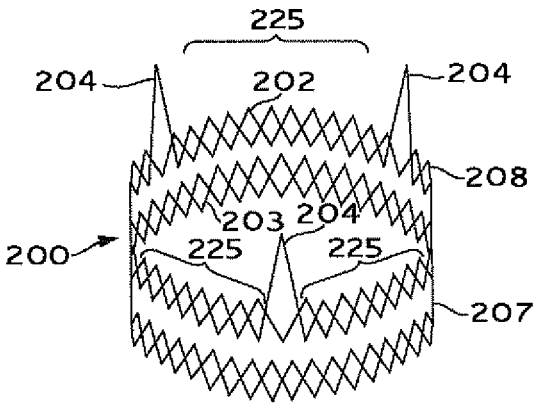
Primary Examiner—David H. Willse
(74) *Attorney, Agent, or Firm*—David L. Hauser

(57) **ABSTRACT**

A valve prosthesis for implantation in the body by use of a catheter includes a stent made from an expandable cylinder-shaped thread structure including several spaced apices. The elastically collapsible valve is mounted on the stent as the commissnral points of the valve are secured to the projecting apices. The valve prosthesis can be compressed around balloons of the balloon catheter and inserted in a channel, for instance, in the aorta. When the valve prosthesis is placed correctly, the balloons are inflated to expand the stent and wedge it against the wall of the aorta. The balloons are provided with beads to ensure a steady fastening of the valve prosthesis on the balloons during insertion and expansion. The valve prosthesis and the balloon catheter make it possible to insert a cardiac valve prosthesis without a surgical operation involving opening the thoracic cavity.

49 Claims, 5 Drawing Sheets





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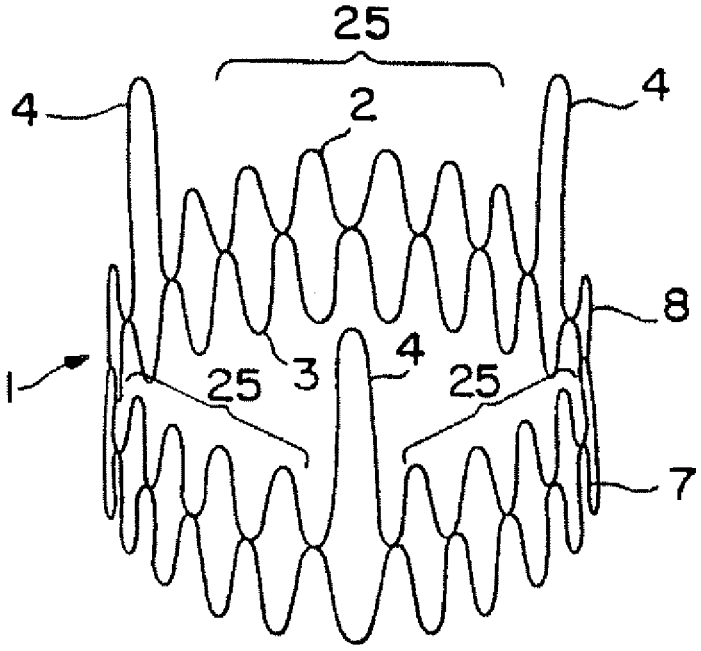


FIG. 1

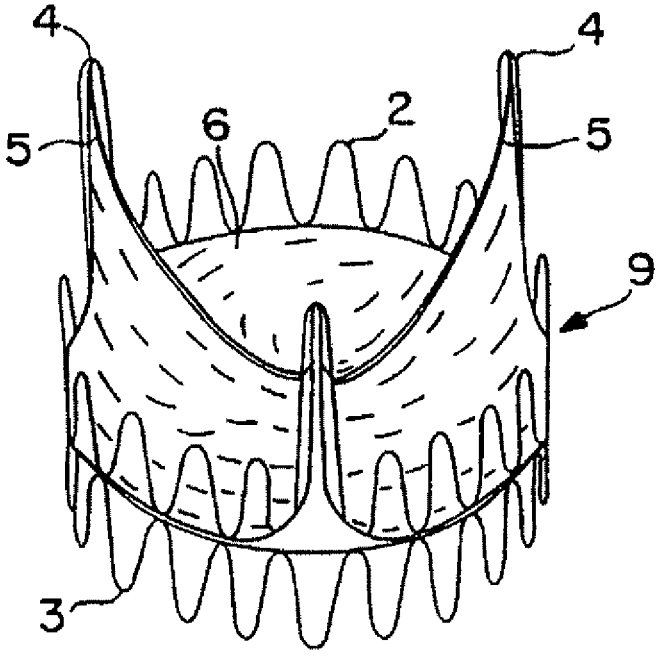
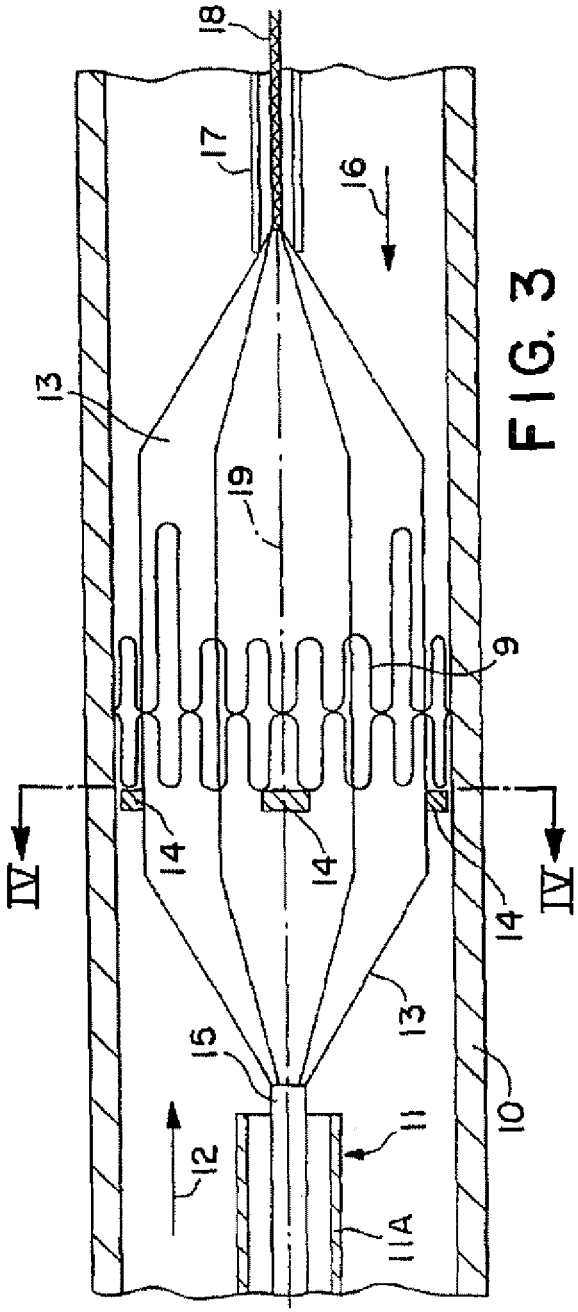


FIG. 2



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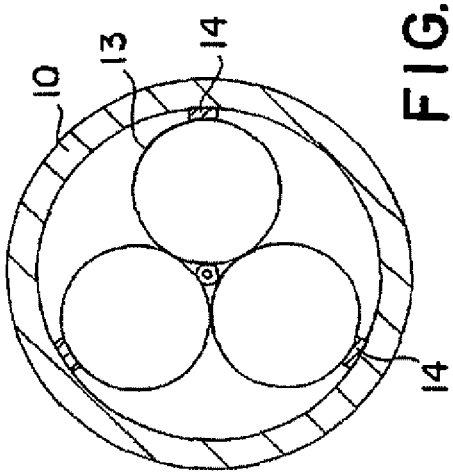
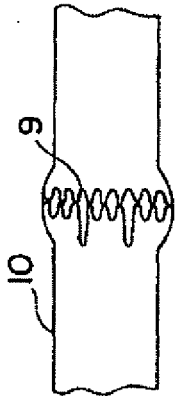


FIG. 4



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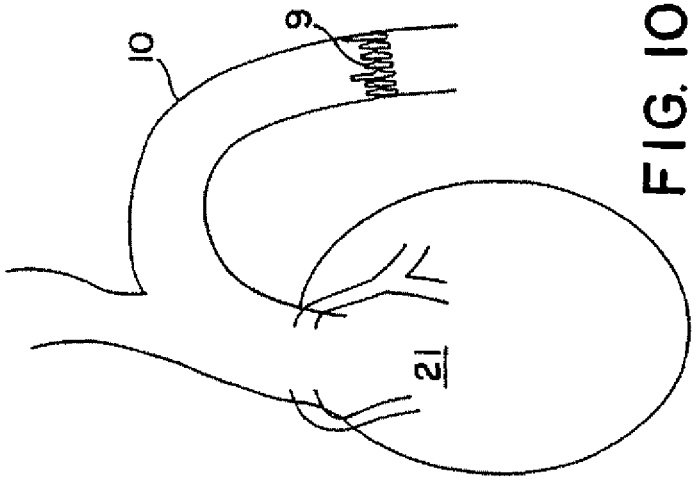

FIG. 10

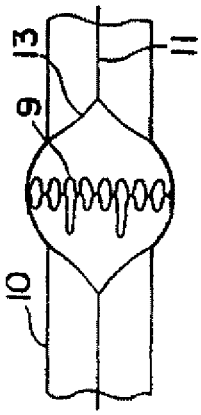

FIG. 6

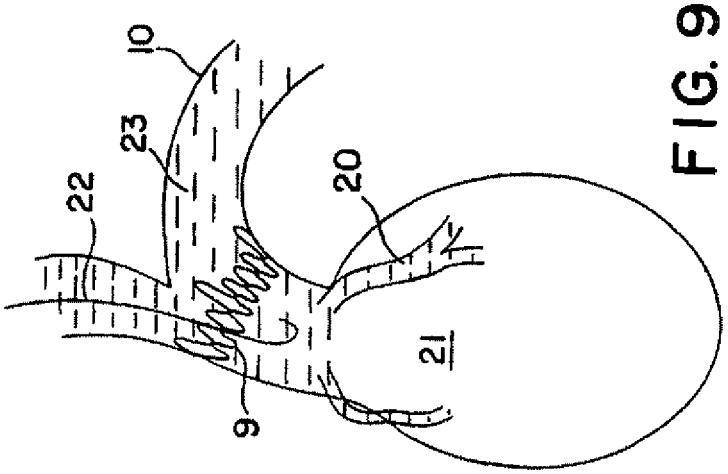

FIG. 9

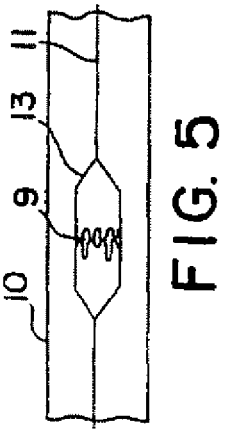

FIG. 5

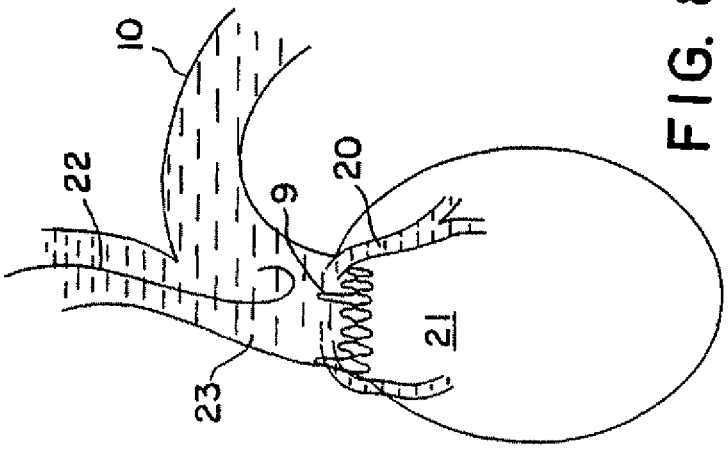

FIG. 8

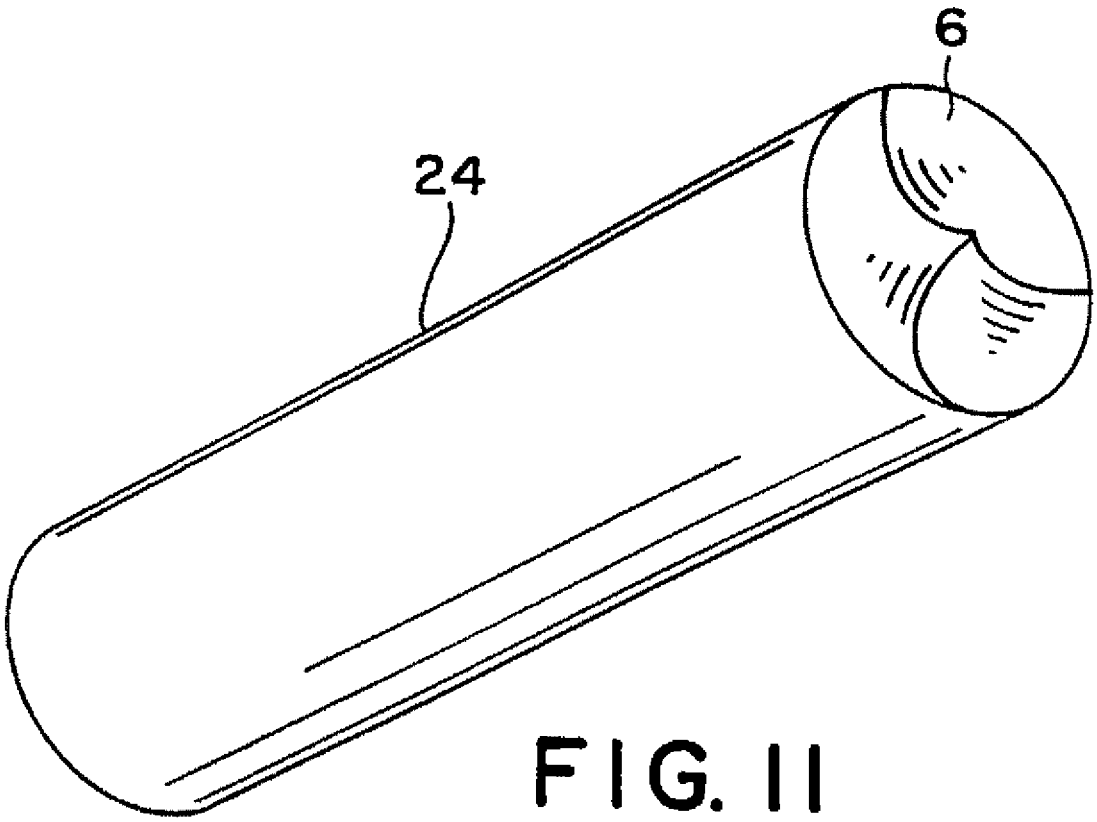

FIG. 11

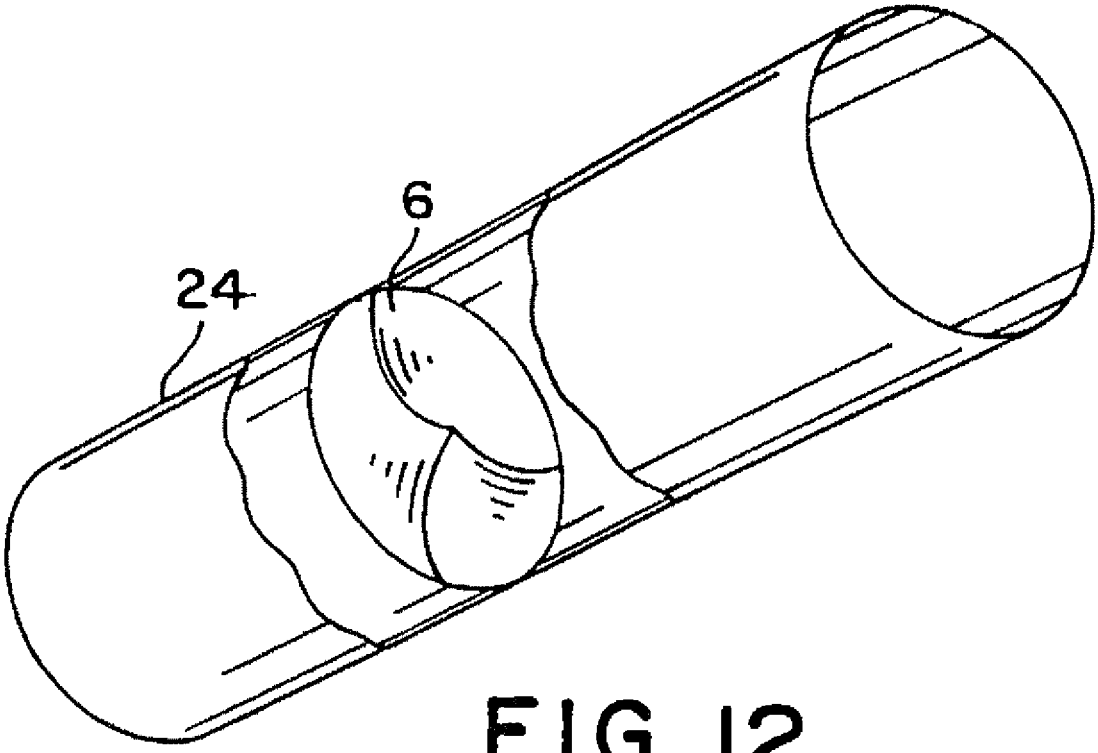

FIG. 12

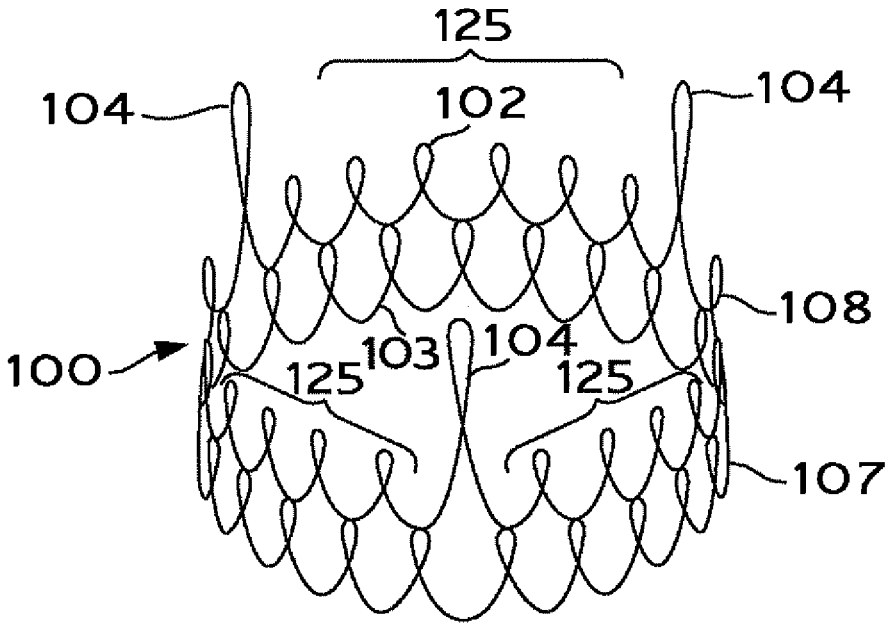
125
104
102
104
108
100
103
104
125
125
107

FIG. 13

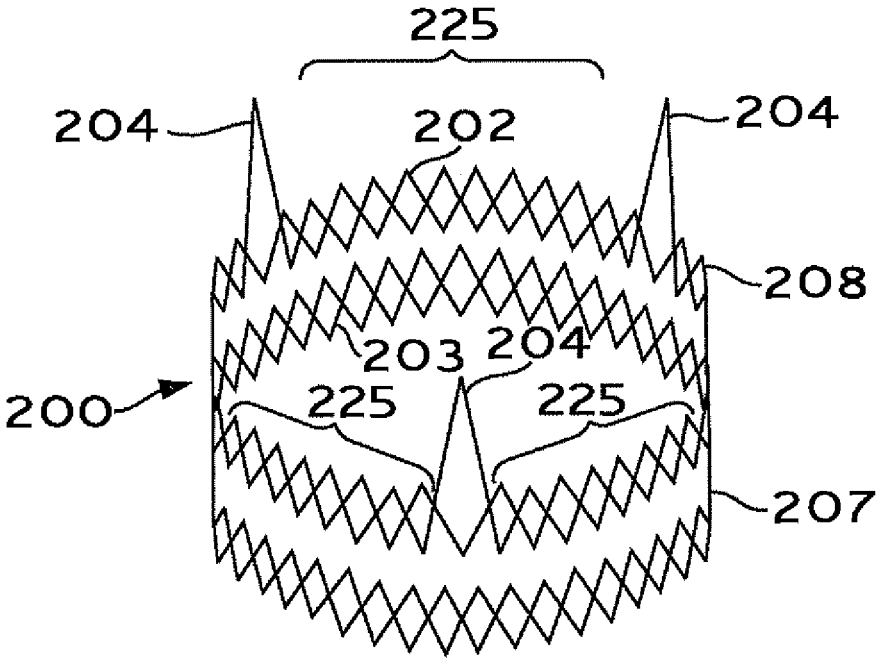
225
204
202
204
208
203
204
200
225
225
207

FIG. 14

VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 09/514,426, filed Feb. 28, 2000, (now U.S. Pat. No. 6,582,462), which is a continuation of U.S. patent application Ser. No. 09/026,574, filed Feb. 20, 1998 (now U.S. Pat. No. 6,168,614), which is a continuation of U.S. patent application Ser. No. 08/955,228, filed Oct. 21, 1997 (abandoned), which is a divisional of U.S. patent application Ser. No. 08/801,036, filed Feb. 19, 1997 (issued as U.S. Pat. No. 5,840,081 on Nov. 24, 1998), which is a continuation of U.S. patent application Ser. No. 08/569,314, filed Dec. 8, 1995 (abandoned), which is a continuation of U.S. patent application Ser. No. 08/352,127, filed Dec. 1, 1994 (abandoned), which is a divisional of U.S. patent application Ser. No. 08/261,235, filed Jun. 14, 1994 (now U.S. Pat. No. 5,411,552), which is a continuation of U.S. patent application Ser. No. 07/961,891, filed Jan. 11, 1993 (abandoned), which is a national stage application of PCT/DK91/00134, filed May 16, 1991 (abandoned).

BACKGROUND OF THE INVENTION

The present invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastic valve which is mounted on an elastic stent wherein the commissural points of the elastic collapsible valve are mounted on the cylinder surface of the elastic stent.

Valve prostheses of this type are usually implanted in one of the channels of the body to replace a natural valve. In the present description the invention will be explained in connection with a cardiac valve prosthesis for implantation in aorta. However, it will be possible to use a valve prosthesis according to the invention in connection with implantation in other channels in the body by using the same technique as the one used for implantation of cardiac valve prosthesis. Such an implantation may, e.g., comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
2. a valve in the esophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

An existing natural valve in the body is traditionally replaced with a valve prosthesis by a surgical implantation. However, a surgical implantation is often an exacting operation. Thus, today the implantation of cardiac valves are solely made by surgical technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

Due to its exacting character, it is impossible to offer such operation to certain people. For instance, this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in U.S. Pat. Nos. 3,671,979 and 4,056,854. However, both of these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

From U.S. Pat. No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prostheses is not designed for implantation in the body by catheterization. Even though this patent contains no detailed explanation, the description indicates that this valve prosthesis is designed for implantation and sewing on by a surgical intervention.

Moreover, from U.S. Pat. Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

The nearest prior art may be that the described in GB-A-2,056,023. This document discloses an elastic stent as described by way of introduction. Thus, the stent described comprises an elastic collapsible valve mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible, it will not be suited for implantation by a catheterization procedure.

SUMMARY OF THE INVENTION

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure, this can for instance be grate shaped, loop shaped or helical . This makes it possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may, e.g., be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon. When using a self-expandable stent, a catheter with an expansion arrangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means, which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small, which makes it possible to introduce the valve prostheses through a channel in the body.

When the valve prosthesis is introduced and placed correctly, the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an outer

dimension which is slightly larger than the channel in which it is placed. As the stent is elastic, a contraction of the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made, the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention to optionally expose the body channel, e.g., a vein, through which the insertion takes place. Thus, patients for whom an operation would be associated with high risk can be offered implantation of, for instance, cardiac valves. After the implantation has taken place, the after-treatment will advantageously be shorter than normal, which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implant the valve prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves. The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the central veins in the center of the leg towards the superficial veins. Among other things, this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in a wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumors, where too much humour is produced. If the humour is able to flow from the cancerous tumor through several channels, it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prosthesis.

When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is possible to mount it in three positions, viz., in the descending part of the aorta in a position between the coronary arteries and the left ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus, the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise, the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who cannot be offered an open heart surgery, the valve prosthesis can also be used for patents in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who cannot be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof, the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.

Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prosthesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries, it is desirable that the valve prosthesis has a greater surface to distribute the outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implanting a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implanting cores in the body are known. For instance, such balloon catheters are known from U.S. Pat. Nos. 4,856,516, 4,733,665 and 4,796,629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvantageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevents a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation, any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for the catheter, X-ray supervision, injection of X-ray traceable liquids, ultrasonic measuring, etc. may be used.

DESCRIPTION OF THE DRAWINGS

The invention will now be explained in detail with reference to the accompanying schematical drawing, wherein

FIG. **1** shows a perspective view of a stent without a valve,

FIG. **2** is a perspective view of a valve prosthesis according to the invention made from the stent shown in FIG. 1 having a biological valve mounted thereon,

FIG. **3** is a partial view through the aorta illustrating a partially inflated balloon catheter,

FIG. **4** is a cross section through the embodiment shown in FIG. **9**,

FIGS. **5-7** are views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,

FIGS. **8-10** are views illustrating three possible positions of a cardiac valve prosthesis,

FIGS. **11-12** are perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall, and

FIGS. **13-14** are perspective views illustrating two further embodiments of a stent without a valve.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** shows a stent **1** made by support means in the form of two 0.55 mm surgical stainless steel wires **2,3**. The wires are folded in 15 loops. Three loops **4** are 14 mm in height and are intended to secure the commissural points **5** (see FIG. **2**) from a biological cardiac valve **6** which is mounted in the stent **1**. The remaining loops have a height of 8 mm. These loops form circumferentially expandable sections **25** between the commissural points **5** forming commissural supports. Each of the two folded wires **2,3** is bent to form rings **7,8** which are closed by welding the ends. The two rings are placed on top of each other as will appear from FIG. **1** and they are mutually secured by means of a number of sutures (not shown). The lower ring is circumferentially expandable at least along sections thereof which correspond to the circumferentially expandable sections **25**. By using a substantially cylindrical thread structure with projecting apices, a reduction in weight is obtained as compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve **6** was removed from a slaughtered pig of 100 kg. The valve was cleaned before mounting in the stent **1**. The cleaned valve has an outer diameter of 25-27 mm and the height of the three commissural points **5** is 8 mm. The valve **6** is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis **9** shown in FIG. **2**. The valve prosthesis produced is used for performing tests in pigs by implantation of cardiac valve prosthesis. However, the cardiac valve prosthesis for use in human beings has a corresponding form.

FIG. **3** shows a partial view through the aorta **10**. A balloon catheter **11** is introduced in the aorta according to the direction of an arrow **12**. In the Figure shown the balloon means **13** of the balloon catheter is led out of the protection cap **11**A and is partly inflated through a fluid channel **15**, which is led to the surface of the patient. The balloon means **13** constitutes a tri-sectional balloon upon which the cardiac valve prosthesis is placed. In the form shown, the cardiac valve prosthesis is expanded exactly to be in contact with the aorta **10**. The balloon means **13** is provided with three projecting beads **14** which are engaged with the one side of the cardiac valve prosthesis **9**. The blood flowing through the aorta according to the direction of an arrow **16** will thus cause the cardiac valve prosthesis **9** to abut on the beads **14** and the valve cannot be displaced in relation to the balloon means **13**. Moreover, the balloon catheter used comprises a central channel **17** to receive a guide wire **18** which is used in a way known per se for supervising the introduction of the catheter through fluoroscopi. In the shown embodiment beads **14** are only used at one side of the valve prosthesis, but, however, it will often be desirable to use the beads in pairs placed along lines parallel to the longitudinal axes **19** through the balloon means **13**. In this case the spacing of the pair of beads **14** will correspond to the height of the loops of the stent. This makes it possible to make an effective fastening of a valve prosthesis on balloon means. Moreover, the fastening on the balloon means may be provided by using balloon means with an indentation in the surface (not shown).

FIG. **4** shows a cross section through the embodiment shown in FIG. **3** illustrating the placing of the beads **14** on the tri-sectional balloon means **13**.

A balloon catheter of the above-described type which was used in tests of implanting of cardiac valve prosthesis **9** in pigs had the following dimensions. Each of the three balloons was 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons was 31 mm and in the balloon catheter used two beads **14** having a height of 3 mm were mounted on each side of the three balloons. The beads had a spacing of 15 mm. The protection cap **11**A of the balloon catheter had an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter was provided with a standard guide wire having a diameter of 0.9 mm and a length 300 cm.

FIGS. **5-7** show the valve prosthesis **9** at different steps in introducing and implanting in the aorta **10** by means of the catheter **11** having the inflatable balloon means **13**. The cardiac valve prosthesis **9** is initially placed above the deflated balloon means **13** and compressed manually around the balloon means (FIG. **5**), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning, the balloon means **13** is inflated (FIG. **6**), thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta, the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter **11** may subsequently be removed from the aorta **10** (FIG. **7**). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter **13**. When the valve prosthesis is mounted as shown in FIG. **7**, the patient will he ahle to resume a substantially normal life after a few days.

FIGS. **8-10** show the positioning of the valve prosthesis **9** as cardiac valve prosthesis in the aorta **10** in three different positions, i.e., in a position between the coronary arteries **20** and the left ventricle of the heart **21** (FIG. **8**), in a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (FIG. **9**), and in a position in the descending part of the aorta **10**. The positioning of the valve prosthesis is chosen in accordance with the diagnosis of the illness of the patient. By placing the cardiac valve prosthesis as shown in FIG. **8**, there is a risk of detachment and/or covering the mouth of the coronary arteries, and therefore it is preferred to use a higher stent which, for instance, comprises several ranges placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. FIGS. **8** and **9** show how a contrast medium **23** is injected by means of a so-called pigtail catheter for registration of tightness of the implanted valve prosthesis **9**.

A specific embodiment for a valve prosthesis and a balloon catheter for implanting the valve prosthesis has been explained above. However, it is obvious that it is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus, the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured folded ring-placed

on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g., polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in FIGS. **11** and **12**. In both Figures the support means of the valve prosthesis is made of an elongated tubular means **24** having a closed cylinder surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against the wall of the channel. In FIG. **11** the valve **6** is mounted at the end of the tubular means **24**. In FIG. **12** an embodiment is shown where the valve **6** is mounted in a central position in the tubular means **24**.

An explanation of a method of implanting a valve prosthesis according to the invention is given below:

- a valve prosthesis **9** made of a stent **1** and a collapsible valve **6**, as described above, is placed on a deflated balloon means and is manually compressed thereon,
- the balloon means **13** and the valve prosthesis are drawn into an insertion cover **11**A,
- a guide wire **18** is inserted into the left ventricle of the heart through the central opening **17** of the balloon catheter under continuous fluoroscopi,
- the insertion cover **11**A conveys the guide wire **18** to a point in the channel in the immediate vicinity of the desired position of the valve prosthesis,
- the balloon means **13** is pushed out of the protection cap **11**A and the valve prosthesis is positioned in the desired position if necessary by use of further registration means to ensure an accurate positioning,
- the balloon means **13** is inflated with a certain overstretching of the channel,
- the balloon means **13** is deflated, and
- the balloon means **13**, the guide wire **18** and the protection cap **11**A are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be closed.

FIGS. **13-14** are perspective view illustrating two further embodiments of a stent without a valve. In FIG. **13**, the stent **100** is made by support means in the form of helical wires **102, 103**, with loops **104** and circumferentially expandable sections **125**. Each of the two helical wires **102, 103** is bent to form rings **107, 108**. In FIG. **14**, the stent **200** is made by support means in the form of gate-shaped wires **202, 203**, with loops **204** and circumferentially expandable sections **225**. Each of the two gate-shaped wires **202, 203** is bent to form rings **207, 208**. The primary difference between prior described embodiments, such as in FIG. **2**, versus those embodiments shown in FIGS. **13** and **14**, for example, is the replacement of the series of loops **4** (FIG. **2**) with the helical wires **102, 103** and loops **104** (FIG. **13**) or the grate-shaped wires **202, 203** and loops **204** (FIG. **14**). As the artisan will readily appreciate, the embodiments of FIGS. **13-14** otherwise include those features shown in prior described embodiments, such as in FIG. **2**, including the commissural points **5** forming commissural supports.

What is claimed is:

1. A valve prosthesis for implantation in a body, comprising:

an elastical stent comprising a cylindrical support having circumferentially expandable sections comprised of a series of loops with commissural supports therebetween and integral therewith; and

an elastical valve, commissural points of which are mounted on a respective one of the commissural supports;

wherein the cylindrical support is radially collapsible for implantation in the body via a catheter.

2. The valve prosthesis according to claim **1** wherein:

the elastical valve comprises a biologically tribolate valve.

3. The valve prosthesis according to claim **1**, wherein:

the elastical valve comprises a cardiac valve.

4. The valve prosthesis according to claim **1**, wherein:

the elastical valve comprises a venous valve.

5. The valve prosthesis according to claim **1**, wherein:

the cylindrical support comprises a metal having a stiffness sufficient to prevent a contraction of the cylindrical support of more than about 10% following expansion.

6. The valve prosthesis according to claim **1**, wherein:

the cylindrical support comprises a thread structure which forms a cylinder surface.

7. A valve prosthesis for implantation in a body, comprising:

an elastical stent comprising a support means having circumferentially expandable sections comprised of a series of loops with commissural supports therebetween and integral therewith; and

an elastical valve, commissural points of which are mounted on a respective one of the commissural supports;

wherein the support means is radially collapsible for implantation in the body via a catheter and the support means extends axially for supporting the elastical valve.

8. The valve prosthesis according to claim **7**, wherein:

the support means is cylindrical.

9. The valve prosthesis according to claim **7**, wherein:

a surface of the support means is cylindrical.

10. The valve prosthesis according to claim **7**, wherein:

the elastical valve is a biologically trilobate valve.

11. The valve prosthesis according to claim **7**, wherein:

the support means is expandable upon removal from the catheter.

12. The valve prosthesis according to claim **7**, wherein:

the elastical valve comprises a cardiac valve.

13. The valve prosthesis according to claim **7**, wherein:

the elastical valve comprises a venous valve.

14. The valve prosthesis according to claim **7**, wherein:

the support means comprises a metal having a stiffness sufficient to prevent a contraction of the support means of more than about 10% following expansion.

15. A valve prosthesis for implantation in a body, comprising:

an elastical stent comprising a cylindrical support having a thread structure cylinder surface; and

an elastical valve, commissural points of which are mounted on the cylinder surface; and

wherein the cylinder surface is radially collapsible for implantation in the body via a catheter,

the thread structure comprises stainless steel wire folded in a plurality of loops, bended according to a circle, and welded to provide at least two closed rings,

the at least two closed rings are mutually connected end to end to form the cylindrical surface.

three loops in an external one of the rings are folded with a greater height than remaining ones of loops to form apices.

16. The valve prosthesis according to claim 15, wherein:

the cylindrical support is expandable upon removal from the catheter;

each of the closed rings comprises a wire having a diameter of 0.55 mm;

a height of the remaining ones of loops is approximately 8 mm;

a height of the three greater height loops is approximately 14 mm; and

the cylindrical support and the elastical valve mounted thereon, when collapsed, have an outer diameter of approximately 10 mm and, when expanded, an outer diameter of approximately 30 mm.

17. The valve prosthesis according to claim 15, wherein:

the stent is made to be fixed, through expansion of the cylindrical support upon removal from the catheter, at one point in a channel in which the valve prosthesis is implanted, which point is different from a point where the elastical valve is mounted on the stent.

18. A valve prosthesis for implantation in a patient's body without requiring open heart surgery, comprising:

a self expandable stent constructed to be radially compressible and re-expandable, the stent having a top end, a bottom end and a metallic outer surface configured to contact native tissue in a body channel; and

a collapsible and re-expandable elastical valve comprising three flaps formed entirely of biological tissue, the elastical valve positioned within an interior portion of the stent for folding and expanding together with the stent, the elastical valve located between the top and bottom ends of the stent, the elastical valve having three commissural points sutured to the self expandable stent, the elastical valve configured to allow blood to flow in one direction such that blood is capable of flowing through the stent from the bottom end toward the top end;

wherein the valve prosthesis is radially compressible from an expanded condition to a compressed condition, the compressed condition having a first outer diameter of 10 mm or less for insertion inside a tubular wall of a cap along a distal end portion of a delivery catheter for advancement through a small inlet opening into the body channel and wherein the valve prosthesis is radially self-expandable upon ejection from the cap to a re-expanded condition comprising a second outer diameter of approximately 27 mm or more such that the second outer diameter of the valve prosthesis is greater than an inner diameter of the body channel for securing the valve prosthesis in the body channel without suturing the valve prosthesis to native tissue and to establish valvular function in the body channel, thereby allowing implantation of the valve prosthesis in the body channel for replacing the function of a natural aortic valve in an adult human being without open heart surgery and wherein the valve prosthesis is detachable from the delivery catheter such that the delivery catheter can be removed from the body channel and the small inlet opening can be closed such that the patient can resume a substantially normal life.

19. The valve prosthesis according to claim 18, wherein:

the self-expandable stent has a height comprising a first range configured to be positioned downstream of the coronary ostia and a second range configured to support the elastical valve between the coronary ostia and the left ventricle.

20. The valve prosthesis according to claim 19, wherein:

the elastical valve is formed entirely of biological tissue from a pig heart.

21. The valve prosthesis according to claim 18, wherein:

the elastical valve comprises a venous valve.

22. The valve prosthesis according to claim 18, wherein:

the stent has a stiffness sufficient to prevent a contraction of more than about 10% following re-expansion.

23. The valve prosthesis according to claim 18, wherein:

the stent comprises a grate shaped structure which forms a cylinder surface.

24. A valve prosthesis configured to be implanted in a body channel without open heart surgery for replacing the function of a natural aortic valve in an adult human being, comprising:

a radially compressible and re-expandable metallic stent having a top end, a bottom end and a metallic outer surface configured to directly contact surrounding native tissue in a body channel with a pressure sufficient to prevent detachment from the body channel; and

a radially collapsible and re-expandable valve positioned within an interior portion of the stent and sutured to the stent for folding and expanding together with the stent, the valve having three flaps formed of biological tissue from a pig, the three flaps positioned between the top and bottom ends of the stent for allowing blood to flow in one direction such that blood is capable of flowing through the stent from the bottom end toward the top end, the valve having three commissural points sutured to the stent;

wherein the valve prosthesis is radially compressible from an expanded condition to a compressed condition, the compressed condition having an outer diameter of less than 12.5 mm to be located inside a tubular wall of a cap along a distal end portion of a catheter for advancement through a small inlet opening into the body channel and wherein the valve prosthesis is radially re-expandable upon ejection from the cap to a re-expanded condition comprising an outer diameter of approximately 27 mm or larger for securing the valve prosthesis to the surrounding native tissue without suturing the valve prosthesis to the surronnding native tissue and wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the body channel and the small inlet opening can be closed and wherein the metallic stent has a sufficient height such that the top end of the stent is capable of being positioned downstream of the coronary ostia while the valve is positioned substantially between coronary ostia and a left ventricle of a heart for replacing the function of the natural aortic valve without open heart surgery.

25. The valve prosthesis according to claim 24, wherein:

at least a portion of the metallic stent is substantially cylindrical.

26. The valve prosthesis according to claim 24, wherein:

the metallic stent is self-expandable upon ejection from the cap and wherein the outer diameter in the re-expanded condition is slightly larger than an inner diameter of the body channel.

27. The valve prosthesis according to claim 24, wherein:

the radially collapsible and re-expandable valve comprises a cardiac valve.

28. The valve prosthesis according to claim 24, wherein:

the radially collapsible and re-expandable valve comprises a venous valve.

29. The valve prosthesis according to claim 24, wherein:
the metallic stent comprises a grate shaped structure having a stiffness sufficient to prevent a contraction of the metallic stent of more than about 10% following re-expansion.

30. A valve prosthesis for replacing the function of a native valve in a patient's body by a technique of catheterization, comprising:
a radially collapsible and re-expandable stent having a top end, a bottom end and a metallic outer surface configured to contact native tissue in a body channel; and
a collapsible and re-expandable valve structure positioned within an interior portion of the stent and sutured to the stent, the valve structure having three flaps formed entirely of biological tissue, the three flaps positioned between the top and bottom ends of the stent, the valve structure having three commissural points sutured to the stent, the valve structure configured to allow blood to flow in one direction such that blood enters through a bottom opening at the bottom end of the stent and exits through a top opening at the top end of the stent;
wherein the valve prosthesis is radially collapsible to an outer diameter of less than 10 mm for introduction by way of a catheter through an inlet opening into the body channel and wherein the outer diameter of the stent is radially re-expandable to a re-expanded dimension sized to engage the native tissue in the body channel with a pressure sufficient for preventing detachment from the body channel and for fixing the valve prosthesis in the body channel without suturing the valve prosthesis to native tissue and wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the patient's body and the inlet opening can be closed while the valve prosthesis remains in the body channel;
wherein the valve structure has an expanded outer diameter in the range of about 25 to 27 mm.

31. A valve prosthesis for replacing the function of a native valve in a patient's body by a technique of catheterization, comprising:
a radially collapsible and re-expandable stent having a top end, a bottom end and a metallic outer surface configured to contact native tissue in a body channel; and
a collapsible and re-expandable valve structure positioned within an interior portion of the stent and sutured to the stent, the valve structure having three flaps formed entirely of biological tissue, the three flaps positioned between the top and bottom ends of the stent, the valve structure having three commissural points sutured to the stent, the valve structure configured to allow blood to flow in one direction such that blood enters through a bottom opening at the bottom end of the stent and exits through a top opening at the top end of the stent;
wherein the valve prosthesis is radially collapsible to an outer diameter of less than 10 mm for introduction by way of a catheter through an inlet opening into the body channel and wherein the outer diameter of the stent is radially re-expandable to a re-expanded dimension sized to engage the native tissue in the body channel with a pressure sufficient for preventing detachment from the body channel and for fixing the valve prosthesis in the body channel without suturing the valve prosthesis to native tissue and wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the patient's body and the inlet opening can be closed while the valve prosthesis remains in the body channel;
wherein the re-expanded dimension has a diameter of about 30 mm.

32. A valve prosthesis for replacing the function of a natural heart valve, comprising:
a radially compressible and re-expandable stent, the stent being compressible from an expanded condition to a compressed condition having an outer diameter suitable for introduction through a small inlet opening into a body channel by way of a delivery catheter and the stent being re-expandable to a re-expanded condition, the stent having a metallic outer surface for contacting surrounding tissue in the body channel, wherein an outer diameter of the stent in the re-expanded condition is at least 2.7 times larger than the outer diameter of the stent in the compressed condition; and
a collapsible and re-expandable valve structure mounted to the stent for folding and expanding together with the stent, the valve structure having three commissural points coupled to the stent, the valve structure having three flaps formed entirely of biological tissue, the valve structure positioned within an interior portion of the stent for preventing blood flow in one direction;
wherein the valve prosthesis is detachable from the delivery catheter after deployment in the body channel such that the delivery catheter can be removed from the body channel and the small inlet opening can be closed and wherein the stent has a stiffness in the expanded condition, the stiffness being sufficient to maintain pressure along surrounding tissue in the body channel for securing the valve prosthesis and preventing detachment from the body channel, thereby allowing the valve prosthesis to be permanently implanted in the body channel by way of catheterization without requiring surgical intervention.

33. The valve prosthesis according to claim 32, wherein:
the stent is balloon expandable.

34. The valve prosthesis according to claim 32, wherein:
the stent is formed of a metallic self-expandable material.

35. The valve prosthesis according to claim 34, wherein:
the self-expandable stent has a height comprising a first range configured for fixation in the ascending aorta downstream of the coronary ostia and a second range configured to position the valve structure substantially between the coronary ostia and the left ventricle after implantation.

36. The valve prosthesis of claim 32, wherein:
the valve structure is formed entirely of biological tissue from a slaughtered pig.

37. The valve prosthesis of claim 32, wherein:
the valve prosthesis is configured to be implanted in the body channel without opening the thoracic cavity.

38. A valve prosthesis configured for implantation without surgical intervention for replacing the function of a defective natural valve in an adult human heart, comprising:
a compressible and re-expandable stent having an inlet end, an outlet end and a metallic outer surface, the stent being radially compressible from an expanded state to a compressed state for introduction through an inlet opening into a body channel by way of a catheter, the stent being re-expandable to a re-expanded state such that the metallic outer surface engages surrounding tissue in the body channel, wherein an outer diameter of the stent in the re-expanded state is at least 2.7 times larger than an outer diameter of the stent in the compressed state; and
a collapsible and re-expandable valve structure mounted within an interior portion of the stent between the inlet and outlet ends of the stent for folding and expanding

together with the stent and configured for preventing blood flow in one direction, the valve structure having movable flaps positioned between the inlet and outlet ends of the stent for allowing blood to flow only from the inlet end toward the outlet end of the stent;

wherein stent stiffness provides the sole means of fixation to surrounding tissue for securing the valve prosthesis to the body channel and wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the body channel after deploying the valve prosthesis in the body channel and the inlet opening can be closed such that the valve prosthesis is permanently implantable in the body channel for replacing the function of a native valve without suturing the valve prosthesis to surrounding native tissue.

39. The valve prosthesis of claim **38**, wherein:

the stent comprises a grate-shaped structure.

40. The valve prosthesis of claim **39**, wherein:

the stent is self expandable.

41. The valve prosthesis of claim **40**, wherein:

the stent further comprises an outlet end portion configured for fixation in the ascending aorta at a location downstream of the coronary ostia and an inlet end portion configured for positioning the valve structure substantially between the coronary ostia and the left ventricle.

42. The valve prosthesis of claim **41**, wherein:

at least the inlet end portion of the stent is substantially cylindrical.

43. The valve prosthesis of claim **38**, wherein:

the valve structure is formed of biological tissue before the valve prosthesis is introduced through the inlet opening into the body channel.

44. The valve prosthesis of claim **43**, wherein the biological tissue forms two or more adjacent flaps, the flaps forming commissural points between adjacent flaps.

45. The valve prosthesis of claim **38**, wherein:

the outer diameter of the stent in the re-expanded state is at least three times larger than the outer diameter of the stent in the compressed state.

46. A valve prosthesis configured for implantation in an adult human being without requiring surgical intervention for replacing the function of a defective natural aortic valve, comprising:

a self expandable metallic stent having an inlet end, an outlet end and a metallic outer surface, the stent being radially compressible to a compressed condition having an outer diameter suitable for insertion into a protection cap and sized for introduction through an inlet opening into a body channel by way of a catheter, the stent configured to self-expand to an expanded condition upon ejection from the protection cap, the stent comprising an outer diameter in the expanded condition at least three times greater than the outer diameter in the compressed condition, the outer diameter being greater than an inner diameter of an ascending aorta such that at least a portion of the metallic outer surface of the stent engages an inner wall of the ascending aorta for counteracting detachment of the valve prosthesis;

a collapsible and expandable elastical valve comprising three flaps formed of biological tissue, the elastical valve positioned within an interior portion of the stent for folding and expanding together with the stent, the elastical valve located between the inlet and outlet ends of the stent, the elastical valve having three commissural points sutured to the self expandable stent, the elastical valve configured to allow blood to flow in one direction such that blood is capable of flowing through the stent from the inlet end toward the outlet end;

wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the body channel after implanting the valve prosthesis and the inlet opening can be closed such that the valve prosthesis is permanently implantable for replacing the function of the defective natural aortic valve without suturing the valve prosthesis to surrounding native tissue.

47. The valve prosthesis according to claim **46**, wherein:

the self-expandable stent comprises an inlet end portion configured to position the elastical valve substantially between the coronary ostia and the left ventricle.

48. The valve prosthesis according to claim **46**, wherein:

the outer diameter of the stent in the compressed condition is 10 mm or less.

49. The valve prosthesis according to claim **48**, wherein:

the outer diameter of the stent in the expanded condition is 30 mm or greater.

* * * * *

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Richard L. Horwitz (#2246)/David E. Moore (#3983) (302) 984-6000
Potter Anderson & Corroon LLP, 1313 N. Market Street Wilmington, Delaware 19801

DEFENDANTS

MEDTRONIC, INC., MEDTRONIC COREVALVE, LLC, and MEDTRONIC VASCULAR, INC.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☑ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☑ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
35 U.S.C. § 1 et seq., 35 U.S.C. §271

Brief description of cause:
Patent Infringement

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Gregory M. Sleet DOCKET NUMBER 08-91 (GMS)

Another case filed today against same

DATE 11/17/2009

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JS 44 Reverse (Rev. 12/07)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

EXHIBIT K

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 09-873 (GMS)
MEDTRONIC, INC., MEDTRONIC COREVALVE, LLC, and MEDTRONIC VASCULAR, INC.	)	**DEMAND FOR JURY TRIAL**
Defendants.	)	

SECOND AMENDED COMPLAINT

Plaintiffs Edwards Lifesciences AG ("Edwards AG") and Edwards Lifesciences LLC ("Edwards LLC") (collectively, "Plaintiffs"), for their Second Amended Complaint ("Complaint") against Defendants Medtronic, Inc. ("Medtronic"), Medtronic CoreValve, LLC ("Medtronic CoreValve"), and Medtronic Vascular, Inc. ("Medtronic Vascular") (collectively, "Defendants"), allege as follows:

JURISDICTION AND VENUE

1. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* This Court has jurisdiction over the subject matter of this action based on 28 U.S.C. §§ 1338(a) and 1331. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

THE PARTIES

Edwards

2. Plaintiff Edwards AG is a corporation organized and existing under the laws of Switzerland and having its principal executive offices in Nyon, Switzerland.

3. Plaintiff Edwards LLC is a limited liability company organized and existing under the laws of the State of Delaware and having its principal executive offices in Irvine, California.

4. Edwards AG is the assignee of the following United States Patents covering pioneering percutaneous heart valve products: U.S. Patent No. 7,618,446 ("the '446 Patent"), U.S. Patent No. 5,411,552 ("the '552 Patent"), and U.S. Patent No. 6,582,462 ("the '462 Patent") (collectively, "the Patents"). The Patents disclose and claim, *inter alia*, collapsible and expandable tissue valve prostheses that replace human heart valves using minimally invasive catheterization procedures.

5. Edwards LLC is the exclusive licensee of the Patents for the field of all cardiovascular applications.

Medtronic

6. Upon information and belief, Defendant Medtronic is a corporation organized and existing under the laws of the State of Minnesota and having its principal place of business in Minneapolis, Minnesota.

7. Upon information and belief, Medtronic is registered to do business in Delaware, and is doing business in Delaware.

8. Upon information and belief, Medtronic has been and is now manufacturing, using, importing, selling and/or offering to sell in the United States heart valve prostheses, including heart valve prostheses known as "Medtronic CoreValve Percutaneous System," "CoreValve transcatheter aortic valve system," and/or the "ReValving" system (hereinafter collectively the "ReValving" system), and/or supplying or causing to be supplied in

or from the United States one or more components of such heart valve prostheses, which activities infringe the '446 Patent, the '552 Patent and the '462 Patent.

9. Upon information and belief, Medtronic has been and is now knowingly and actively inducing others to infringe the '446 Patent, the '552 Patent and the '462 Patent and continues to do so.

Medtronic CoreValve

10. Upon information and belief, Defendant Medtronic CoreValve is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in Irvine, California.

11. Upon information and belief, Medtronic CoreValve is a wholly owned subsidiary of, and controlled by, Medtronic.

12. Upon information and belief, Medtronic CoreValve has been and is now manufacturing, using, importing, selling and/or offering to sell in the United States heart valve prostheses, including heart valve prostheses known as the ReValving system, and/or supplying or causing to be supplied in or from the United States one or more components of such heart valve prostheses, which activities infringe the '446 Patent and the '462 Patent.

13. On April 1, 2010, in *Edwards Lifesciences AG et al.* v. *Medtronic CoreValve, LLC et al.*, C.A. No. 08-91 (D. Del.) (GMS), a jury returned a verdict that Medtronic CoreValve literally and willfully infringed the '552 Patent by manufacturing the ReValving system in the United States.

14. Upon information and belief, Medtronic CoreValve is now supplying or causing to be supplied in or from the United States one or more components of heart valve prostheses, including the ReValving system, which activities infringe the '552 Patent.

15. Upon information and belief, Medtronic CoreValve has been and is now knowingly and actively inducing others to infringe the '446 Patent, the '552 Patent and/or the '462 Patent and continues to do so.

Medtronic Vascular

16. Upon information and belief, Defendant Medtronic Vascular is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in Santa Rosa, California.

17. Upon information and belief, Medtronic Vascular is a wholly owned subsidiary of, and controlled by, Medtronic.

18. Upon information and belief, Medtronic Vascular has been and is now manufacturing, using, importing, selling and/or offering to sell in the United States heart valve prostheses, including heart valve prostheses known the ReValving system, and/or supplying or causing to be supplied in or from the United States one or more components of such heart valve prostheses, which activities infringe the '446 Patent, the '552 Patent and the '462 Patent.

19. Upon information and belief, Medtronic Vascular has been and is now knowingly and actively inducing others to infringe the '446 Patent, the '552 Patent and the '462 Patent and continues to do so.

FIRST CAUSE OF ACTION
(Infringement of the '446 Patent)

20. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 19 above.

21. On November 17, 2009, the '446 Patent (Exhibit 1), entitled "A Valve Prosthesis for Implantation in the Body and a Catheter for Implanting Such Valve Prosthesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars

Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '446 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '446 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

22. Upon information and belief, and in violation of 35 U.S.C. § 271(a), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '446 Patent by manufacturing, using, importing, selling and/or offering to sell heart valve prostheses covered by one or more claims of the '446 Patent, including products designated as the ReValving system.

23. Upon information and belief, and in violation of 35 U.S.C. § 271(b), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '446 Patent, including at least by their knowing and active inducement of the manufacture, use, importation, sale and/or offer to sell of heart valve prostheses covered by one or more claims of the '446 Patent, including products designated as the ReValving system.

24. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(1), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '446 Patent by supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the invention claimed in the '446 Patent, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the '446 Patent if such combination occurred within the United States.

25. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(2), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '446 Patent by

supplying or causing to be supplied in or from the United States one or more components of the invention claimed in the '446 Patent, that is or are especially made or especially adapted for use in the invention claimed in the '446 Patent and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component or components is or are uncombined in whole or in part, knowing that such component or components is or are so made or adapted and intending that such component or components will be combined outside of the United States in a manner that would infringe the '446 Patent if such combination occurred within the United States.

26. Defendants' foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

27. Plaintiffs have been damaged and will be irreparably injured by Defendants' past and continuing infringement, for which Plaintiffs have no adequate remedy at law. Defendants' infringement will continue unless enjoined by this Court.

SECOND CAUSE OF ACTION
(Infringement of the '552 Patent)

28. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 27 above.

29. On May 2, 1995, the '552 Patent (Exhibit 2 hereto), entitled "Valve Prothesis for Implantation in the Body and a Catheter for Implanting such Valve Prothesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '552 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '552 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

30. Upon information and belief, and in violation of 35 U.S.C. § 271(a), Medtronic and Medtronic Vascular have been and are now infringing the '552 Patent by manufacturing, using, importing, selling and/or offering to sell heart valve prostheses covered by one or more claims of the '552 Patent, including products designated as the ReValving system.

31. Upon information and belief, and in violation of 35 U.S.C. § 271(b), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and/or are now infringing the '552 Patent, including at least by their knowing and active inducement of the manufacture, use, importation, sale and/or offer to sell of heart valve prostheses covered by one or more claims of the '552 Patent, including products designated as the ReValving system.

32. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(1), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '552 Patent by supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the invention claimed in the '552 Patent, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the '552 Patent if such combination occurred within the United States.

33. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(2), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '552 Patent by supplying or causing to be supplied in or from the United States one or more components of the invention claimed in the '552 Patent, that is or are especially made or especially adapted for use in the invention claimed in the '552 Patent and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component or components is or are uncombined in whole or in part, knowing that such component or components is or are so made

or adapted and intending that such component or components will be combined outside of the United States in a manner that would infringe the '552 Patent if such combination occurred within the United States.

34. Defendants' foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

35. Plaintiffs have been damaged and will be irreparably injured by Defendants' past and continuing infringement, for which Plaintiffs have no adequate remedy at law. Defendants' infringement will continue unless enjoined by this Court.

THIRD CAUSE OF ACTION
(Infringement of the '462 Patent)

36. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 35 above.

37. On June 24, 2003, the '462 Patent (Exhibit 3 hereto), entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting such Valve Prosthesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '462 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '462 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

38. Upon information and belief, and in violation of 35 U.S.C. § 271(a), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '462 Patent by manufacturing, using, importing, selling and/or offering to sell heart valve prostheses covered by one or more claims of the '462 Patent, including products designated as the ReValving system.

39. Upon information and belief, and in violation of 35 U.S.C. § 271(b), Medtronic, Medtronic CoreValve and Medtronic Vascular have been and are now infringing the '462 Patent, including at least by their knowing and active inducement of the manufacture, use, importation, sale and/or offer to sell of heart valve prostheses covered by one or more claims of the '462 Patent, including products designated as the ReValving system.

40. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(1), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '462 Patent by supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the invention claimed in the '462 Patent, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the '462 Patent if such combination occurred within the United States.

41. Upon information and belief, and in violation of 35 U.S.C. § 271(f)(2), Medtronic, Medtronic CoreValve and Medtronic Vascular are now infringing the '462 Patent by supplying or causing to be supplied in or from the United States one or more components of the invention claimed in the '462 Patent, that is or are especially made or especially adapted for use in the invention claimed in the '462 Patent and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component or components is or are uncombined in whole or in part, knowing that such component or components is or are so made or adapted and intending that such component or components will be combined outside of the United States in a manner that would infringe the '462 Patent if such combination occurred within the United States.

42. Defendants' foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

43. Plaintiffs have been damaged and will be irreparably injured by Defendants' past and continuing infringement, for which Plaintiffs have no adequate remedy at law. Defendants' infringement will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand judgment as follows:

(a) Finding that Defendants have infringed the '446 Patent, the '552 Patent and the '462 Patent;

(b) Finding that Defendants' infringement of the '446 Patent, the '552 Patent and the '462 Patent has been willful and deliberate;

(c) Preliminarily and permanently enjoining and restraining Defendants and their officers, agents, servants, employees and attorneys, all parent, subsidiary and affiliate corporations and other related business entities, and all other persons or entities acting in concert, participation or in privity with Defendants, and their successors and assigns, from infringing, contributing to the infringement of, or inducing others to infringe the '446 Patent, the '552 Patent and the '462 Patent;

(d) Awarding Plaintiffs damages, in an amount to be determined at trial, together with interest and costs as fixed by the Court;

(e) Awarding Plaintiffs enhanced damages under 35 U.S.C. § 284;

(f) Awarding Plaintiffs their reasonable attorneys' fees and their costs and disbursements in this action, as provided by 35 U.S.C. § 285; and

(g) Granting Plaintiffs such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable in this Complaint.

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April 23, 2010

CERTIFICATE OF SERVICE

I hereby certify that on April 23, 2010, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

John W. Shaw, Esquire
Karen E. Keller, Esquire
YOUNG CONAWAY STARGATT & TAYLOR, LLP

I further certify that I caused copies of the foregoing document to be served on April 23, 2010, upon the following in the manner indicated:

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EXHIBIT 1

US007618446B2

(12) **United States Patent**
Andersen et al.

(10) **Patent No.: US 7,618,446 B2**
(45) **Date of Patent: *Nov. 17, 2009**

(54) **VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS**

(75) Inventors: **Henning Rud Andersen**, Hoejbjerg (DK); **John Michael Hasenkam**, Aarhus (DK); **Lars Lyhne Knudsen**, Aarhus (DK)

(73) Assignee: **Edwards Lifesciences AG**, Nyon (CH)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/268,253**

(22) Filed: **Oct. 10, 2002**

(65) **Prior Publication Data**

US 2003/0036795 A1 Feb. 20, 2003

Related U.S. Application Data

(60) Continuation of application No. 09/514,426, filed on Feb. 28, 2000, now Pat. No. 6,582,462, which is a continuation of application No. 09/026,574, filed on Feb. 20, 1998, now Pat. No. 6,168,614, which is a continuation of application No. 08/955,228, filed on Oct. 21, 1997, now abandoned, which is a division of application No. 08/801,036, filed on Feb. 19, 1997, now Pat. No. 5,840,081, which is a continuation of application No. 08/569,314, filed on Dec. 8, 1995, now abandoned, which is a continuation of application No. 08/352,127, filed on Dec. 1, 1994, now abandoned, which is a division of application No. 08/261,235, filed on Jun. 14, 1994, now Pat. No. 5,411,552, which is a continuation of application No. 07/961,891, filed as application No. PCT/DK91/00134 on May 16, 1991, now abandoned.

(30) **Foreign Application Priority Data**

May 18, 1990 (DK) 1246/90

(51) **Int. Cl.**
A61F 2/24 (2006.01)
A61F 2/90 (2006.01)
A61F 2/88 (2006.01)

(52) **U.S. Cl.** **623/1.26**; 623/2.14

(58) **Field of Classification Search** ..... 623/2.1–2.19, 623/2.38–2.41, 900, 904, 1.24–1.26, FOR. 101, 623/23.68; 604/9

See application file for complete search history.

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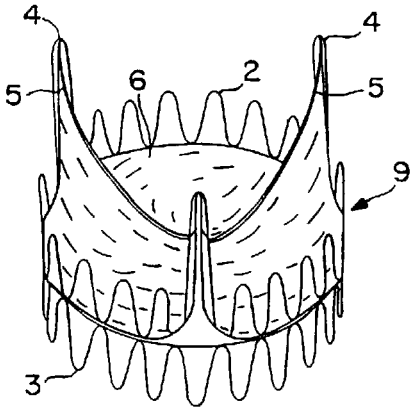
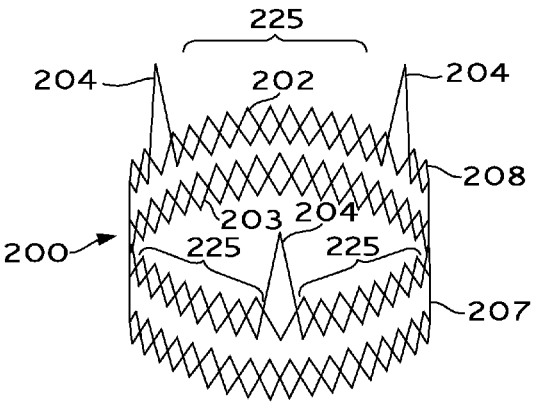
(74) *Attorney, Agent, or Firm*—David L. Hauser

(57) **ABSTRACT**

A valve prosthesis for implantation in the body by use of a catheter includes a stent made from an expandable cylinder-shaped thread structure including several spaced apices. The elastically collapsible valve is mounted on the stent as the commissural points of the valve are secured to the projecting apices. The valve prosthesis can be compressed around balloons of the balloon catheter and inserted in a channel, for instance, in the aorta. When the valve prosthesis is placed correctly, the balloons are inflated to expand the stent and wedge it against the wall of the aorta. The balloons are provided with beads to ensure a steady fastening of the valve prosthesis on the balloons during insertion and expansion. The valve prosthesis and the balloon catheter make it possible to insert a cardiac valve prosthesis without a surgical operation involving opening the thoracic cavity.

49 Claims, 5 Drawing Sheets





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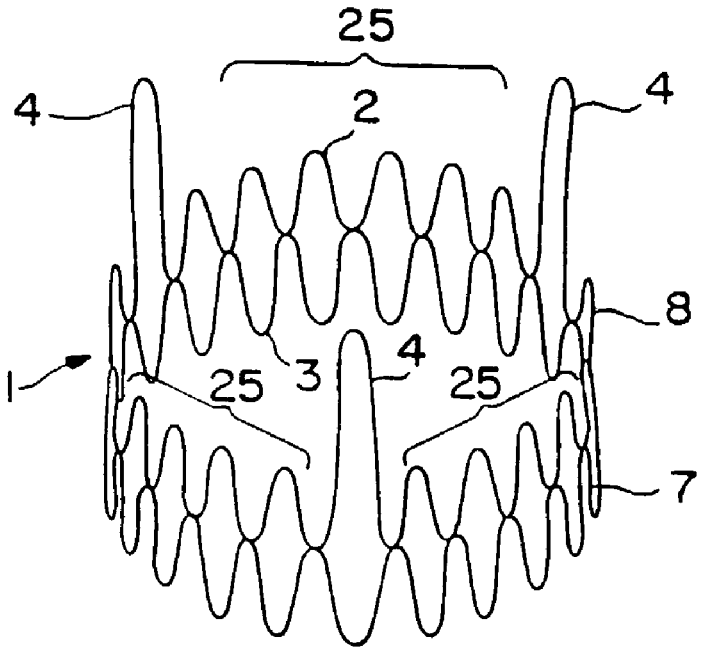

FIG. 1

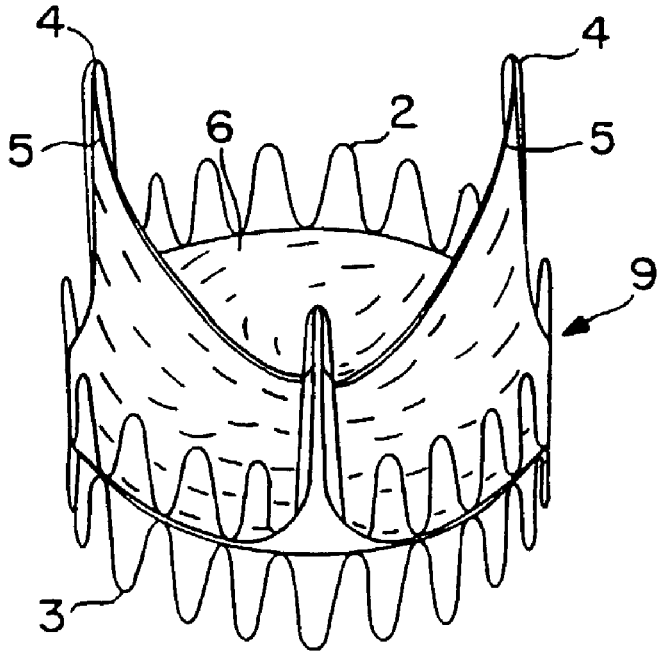

FIG. 2

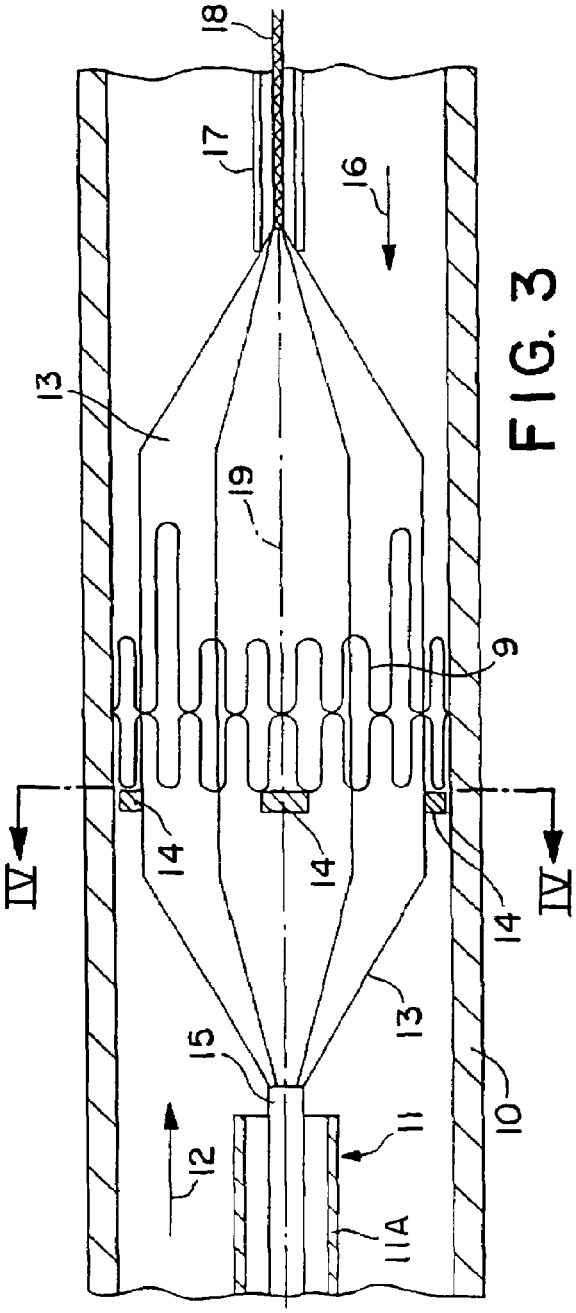

FIG. 3

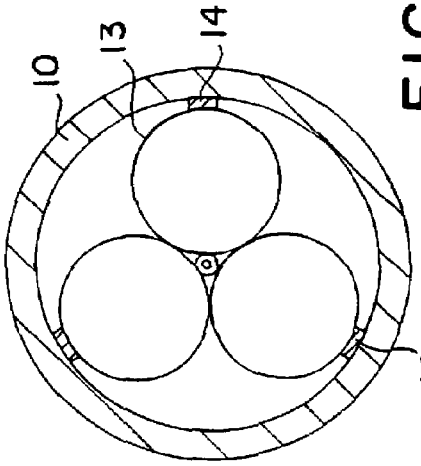

FIG. 4

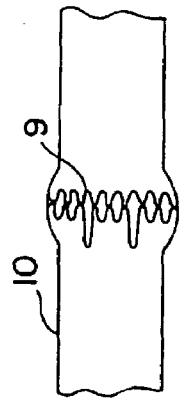

FIG. 7

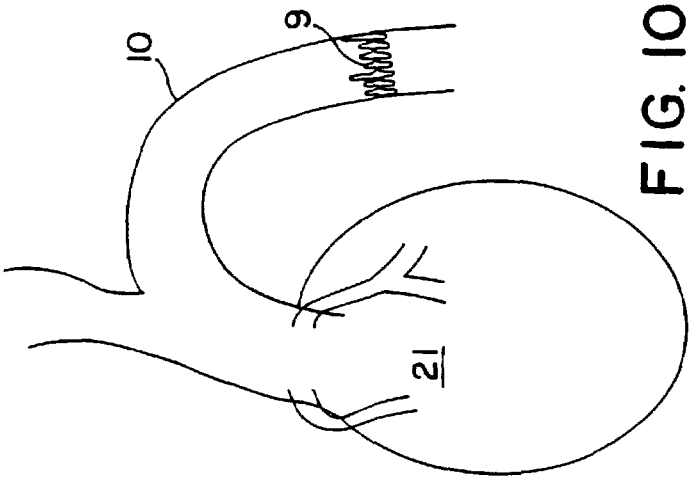

FIG. 10

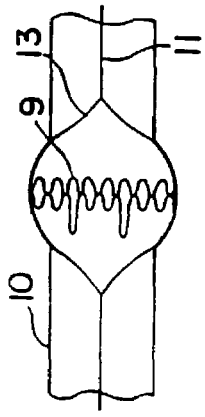

FIG. 6

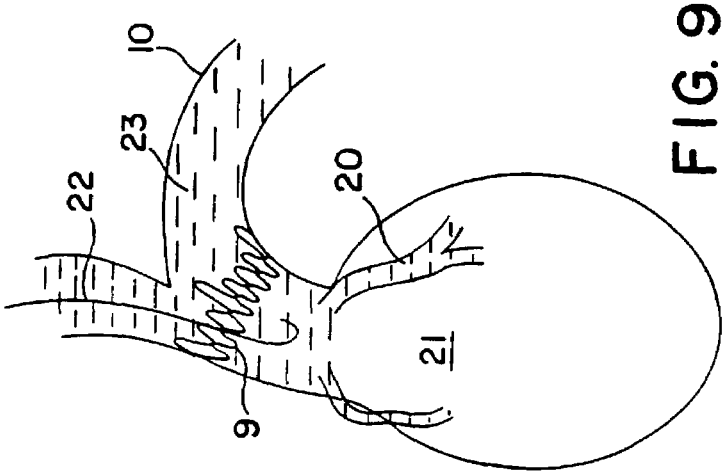

FIG. 9

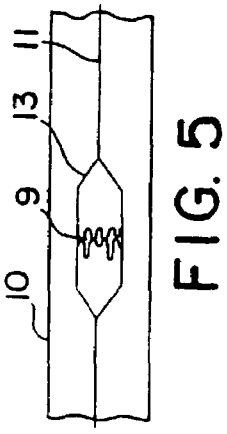

FIG. 5

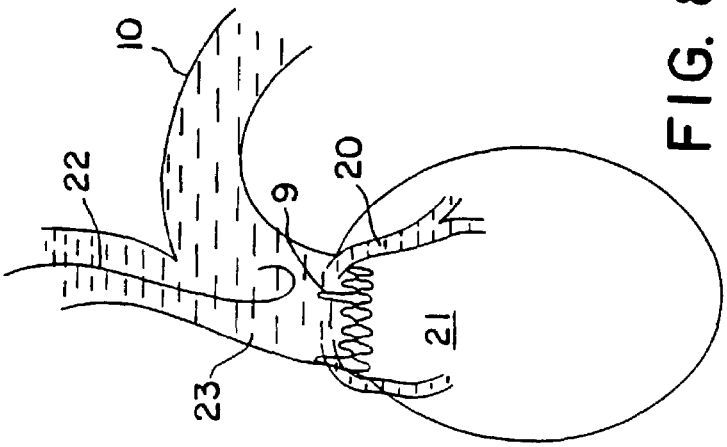

FIG. 8

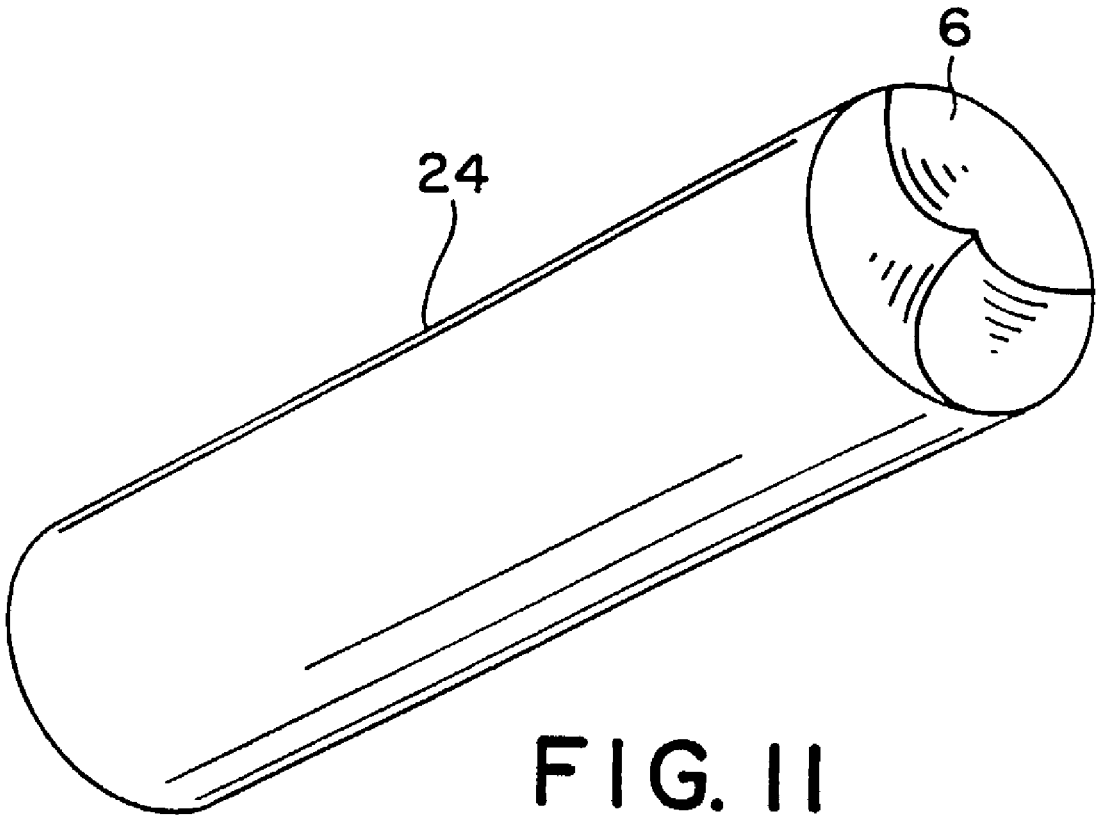

FIG. 11

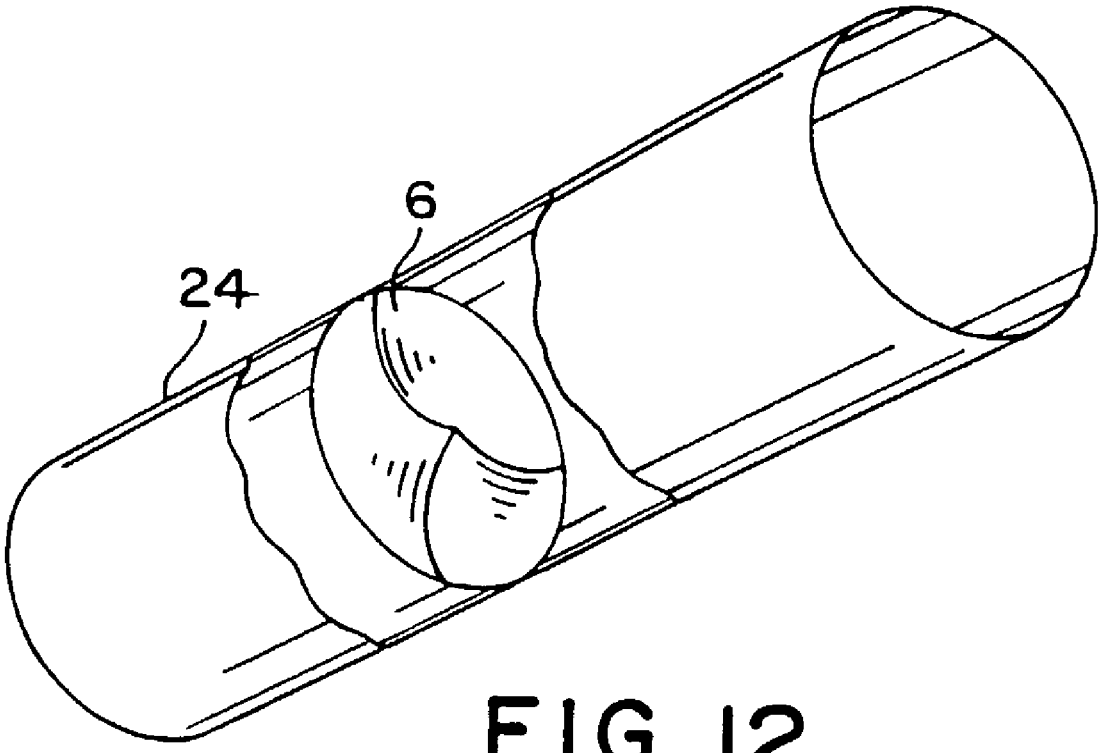

FIG. 12

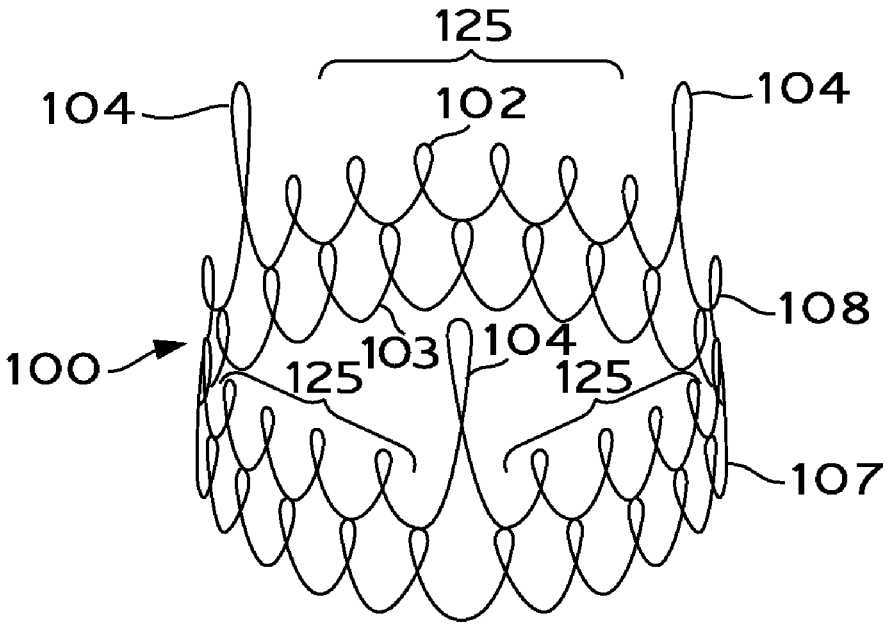
125
104
102
104
108
100
103
104
125
125
107

FIG. 13

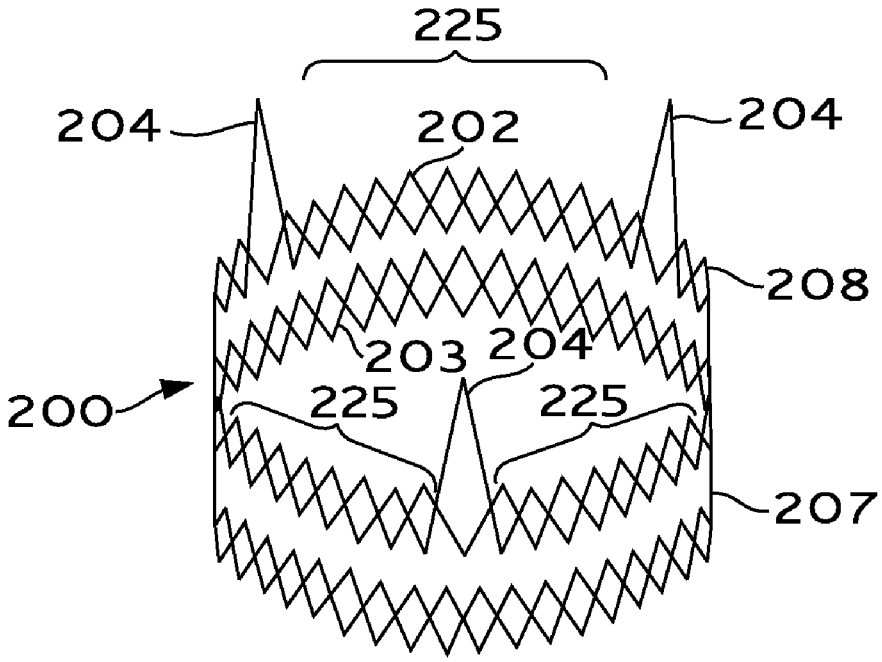
225
204
202
204
208
203
204
200
225
225
207

FIG. 14

VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 09/514,426, filed Feb. 28, 2000, (now U.S. Pat. No. 6,582,462), which is a continuation of U.S. patent application Ser. No. 09/026,574, filed Feb. 20, 1998 (now U.S. Pat. No. 6,168,614), which is a continuation of U.S. patent application Ser. No. 08/955,228, filed Oct. 21, 1997 (abandoned), which is a divisional of U.S. patent application Ser. No. 08/801,036, filed Feb. 19, 1997 (issued as U.S. Pat. No. 5,840,081 on Nov. 24, 1998), which is a continuation of U.S. patent application Ser. No. 08/569,314, filed Dec. 8, 1995 (abandoned), which is a continuation of U.S. patent application Ser. No. 08/352,127, filed Dec. 1, 1994 (abandoned), which is a divisional of U.S. patent application Ser. No. 08/261,235, filed Jun. 14, 1994 (now U.S. Pat. No. 5,411,552), which is a continuation of U.S. patent application Ser. No. 07/961,891, filed Jan. 11, 1993 (abandoned), which is a national stage application of PCT/DK91/00134, filed May 16, 1991 (abandoned).

BACKGROUND OF THE INVENTION

The present invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastic valve which is mounted on an elastic stent wherein the commissural points of the elastic collapsible valve are mounted on the cylinder surface of the elastic stent.

Valve prostheses of this type are usually implanted in one of the channels of the body to replace a natural valve. In the present description the invention will be explained in connection with a cardiac valve prosthesis for implantation in aorta. However, it will be possible to use a valve prosthesis according to the invention in connection with implantation in other channels in the body by using the same technique as the one used for implantation of cardiac valve prosthesis. Such an implantation may, e.g., comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
2. a valve in the esophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

An existing natural valve in the body is traditionally replaced with a valve prosthesis by a surgical implantation. However, a surgical implantation is often an exacting operation. Thus, today the implantation of cardiac valves are solely made by surgical technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

Due to its exacting character, it is impossible to offer such operation to certain people. For instance, this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in U.S. Pat. Nos. 3,671,979 and 4,056,854. However, both of these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

From U.S. Pat. No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prostheses is not designed for implantation in the body by catheterization. Even though this patent contains no detailed explanation, the description indicates that this valve prosthesis is designed for implantation and sewing on by a surgical intervention.

Moreover, from U.S. Pat. Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

The nearest prior art may be that the described in GB-A-2,056,023. This document discloses an elastic stent as described by way of introduction. Thus, the stent described comprises an elastic collapsible valve mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible, it will not be suited for implantation by a catheterization procedure.

SUMMARY OF THE INVENTION

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure, this can for instance be grate shaped, loop shaped or helical . This makes it possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may, e.g., be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon. When using a self-expandable stent, a catheter with an expansion arrangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means, which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small, which makes it possible to introduce the valve prostheses through a channel in the body.

When the valve prosthesis is introduced and placed correctly, the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an outer

dimension which is slightly larger than the channel in which it is placed. As the stent is elastic, a contraction of the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made, the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention to optionally expose the body channel, e.g., a vein, through which the insertion takes place. Thus, patients for whom an operation would be associated with high risk can be offered implantation of, for instance, cardiac valves. After the implantation has taken place, the after-treatment will advantageously be shorter than normal, which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implant the valve prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves. The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the central veins in the center of the leg towards the superficial veins. Among other things, this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in a wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumors, where too much humour is produced. If the humour is able to flow from the cancerous tumor through several channels, it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prosthesis.

When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is possible to mount it in three positions, viz., in the descending part of the aorta in a position between the coronary arteries and the left ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus, the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise, the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who cannot be offered an open heart surgery, the valve prosthesis can also be used for patents in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who cannot be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof, the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.

Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prosthesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries, it is desirable that the valve prosthesis has a greater surface to distribute the outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implanting a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implanting cores in the body are known. For instance, such balloon catheters are known from U.S. Pat. Nos. 4,856,516, 4,733,665 and 4,796,629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvantageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevents a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation, any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for the catheter, X-ray supervision, injection of X-ray traceable liquids, ultrasonic measuring, etc. may be used.

DESCRIPTION OF THE DRAWINGS

The invention will now be explained in detail with reference to the accompanying schematical drawing, wherein

FIG. **1** shows a perspective view of a stent without a valve,

FIG. **2** is a perspective view of a valve prosthesis according to the invention made from the stent shown in FIG. **1** having a biological valve mounted thereon,

FIG. **3** is a partial view through the aorta illustrating a partially inflated balloon catheter,

FIG. **4** is a cross section through the embodiment shown in FIG. **9**,

FIGS. **5-7** are views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,

FIGS. **8-10** are views illustrating three possible positions of a cardiac valve prosthesis,

FIGS. **11-12** are perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall, and

FIGS. **13-14** are perspective views illustrating two further embodiments of a stent without a valve.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** shows a stent **1** made by support means in the form of two 0.55 mm surgical stainless steel wires **2**,**3**. The wires are folded in 15 loops. Three loops **4** are 14 mm in height and are intended to secure the commissural points **5** (see FIG. **2**) from a biological cardiac valve **6** which is mounted in the stent **1**. The remaining loops have a height of 8 mm. These loops form circumferentially expandable sections **25** between the commissural points **5** forming commissural supports. Each of the two folded wires **2**,**3** is bent to form rings **7**,**8** which are closed by welding the ends. The two rings are placed on top of each other as will appear from FIG. **1** and they are mutually secured by means of a number of sutures (not shown). The lower ring is circumferentially expandable at least along sections thereof which correspond to the circumferentially expandable sections **25**. By using a substantially cylindrical thread structure with projecting apices, a reduction in weight is obtained as compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve **6** was removed from a slaughtered pig of 100 kg. The valve was cleaned before mounting in the stent **1**. The cleaned valve has an outer diameter of 25-27 mm and the height of the three commissural points **5** is 8 mm. The valve **6** is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis **9** shown in FIG. **2**. The valve prosthesis produced is used for performing tests in pigs by implantation of cardiac valve prosthesis. However, the cardiac valve prosthesis for use in human beings has a corresponding form.

FIG. **3** shows a partial view through the aorta **10**. A balloon catheter **11** is introduced in the aorta according to the direction of an arrow **12**. In the Figure shown the balloon means **13** of the balloon catheter is led out of the protection cap **11**A and is partly inflated through a fluid channel **15**, which is led to the surface of the patient. The balloon means **13** constitutes a tri-sectional balloon upon which the cardiac valve prosthesis is placed. In the form shown, the cardiac valve prosthesis is expanded exactly to be in contact with the aorta **10**. The balloon means **13** is provided with three projecting beads **14** which are engaged with the one side of the cardiac valve prosthesis **9**. The blood flowing through the aorta according to the direction of an arrow **16** will thus cause the cardiac valve prosthesis **9** to abut on the beads **14** and the valve cannot be displaced in relation to the balloon means **13**. Moreover, the balloon catheter used comprises a central channel **17** to receive a guide wire **18** which is used in a way known per se for supervising the introduction of the catheter through fluoroscopi. In the shown embodiment beads **14** are only used at one side of the valve prosthesis, but, however, it will often be desirable to use the beads in pairs placed along lines parallel to the longitudinal axes **19** through the balloon means **13**. In this case the spacing of the pair of beads **14** will correspond to the height of the loops of the stent. This makes it possible to make an effective fastening of a valve prosthesis on balloon means. Moreover, the fastening on the balloon means may be provided by using balloon means with an indentation in the surface (not shown).

FIG. **4** shows a cross section through the embodiment shown in FIG. **3** illustrating the placing of the beads **14** on the tri-sectional balloon means **13**.

A balloon catheter of the above-described type which was used in tests of implanting of cardiac valve prosthesis **9** in pigs had the following dimensions. Each of the three balloons was 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons was 31 mm and in the balloon catheter used two beads **14** having a height of 3 mm were mounted on each side of the three balloons. The beads had a spacing of 15 mm. The protection cap **11**A of the balloon catheter had an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter was provided with a standard guide wire having a diameter of 0.9 mm and a length 300 cm.

FIGS. **5-7** show the valve prosthesis **9** at different steps in introducing and implanting in the aorta **10** by means of the catheter **11** having the inflatable balloon means **13**. The cardiac valve prosthesis **9** is initially placed above the deflated balloon means **13** and compressed manually around the balloon means (FIG. **5**), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning, the balloon means **13** is inflated (FIG. **6**), thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta, the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter **11** may subsequently be removed from the aorta **10** (FIG. **7**). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter **13**. When the valve prosthesis is mounted as shown in FIG. **7**, the patient will be able to resume a substantially normal life after a few days.

FIGS. **8-10** show the positioning of the valve prosthesis **9** as cardiac valve prosthesis in the aorta **10** in three different positions, i.e., in a position between the coronary arteries **20** and the left ventricle of the heart **21** (FIG. **8**), in a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (FIG. **9**), and in a position in the descending part of the aorta **10**. The positioning of the valve prosthesis is chosen in accordance with the diagnosis of the illness of the patient. By placing the cardiac valve prosthesis as shown in FIG. **8**, there is a risk of detachment and/or covering the mouth of the coronary arteries, and therefore it is preferred to use a higher stent which, for instance, comprises several ranges placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. FIGS. **8** and **9** show how a contrast medium **23** is injected by means of a so-called pigtail catheter for registration of tightness of the implanted valve prosthesis **9**.

A specific embodiment for a valve prosthesis and a balloon catheter for implanting the valve prosthesis has been explained above. However, it is obvious that it is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus, the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed

on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g., polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in FIGS. **11** and **12**. In both Figures the support means of the valve prosthesis is made of an elongated tubular means **24** having a closed cylinder surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against the wall of the channel. In FIG. **11** the valve **6** is mounted at the end of the tubular means **24**. In FIG. **12** an embodiment is shown where the valve **6** is mounted in a central position in the tubular means **24**.

An explanation of a method of implanting a valve prosthesis according to the invention is given below:

- a valve prosthesis **9** made of a stent **1** and a collapsible valve **6**, as described above, is placed on a deflated balloon means and is manually compressed thereon,
- the balloon means **13** and the valve prosthesis are drawn into an insertion cover **11**A,
- a guide wire **18** is inserted into the left ventricle of the heart through the central opening **17** of the balloon catheter under continuous fluoroscopi,
- the insertion cover **11**A conveys the guide wire **18** to a point in the channel in the immediate vicinity of the desired position of the valve prosthesis,
- the balloon means **13** is pushed out of the protection cap **11**A and the valve prosthesis is positioned in the desired position if necessary by use of further registration means to ensure an accurate positioning,
- the balloon means **13** is inflated with a certain overstretching of the channel,
- the balloon means **13** is deflated, and
- the balloon means **13**, the guide wire **18** and the protection cap **11**A are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be closed.

FIGS. **13-14** are perspective view illustrating two further embodiments of a stent without a valve. In FIG. **13**, the stent **100** is made by support means in the form of helical wires **102**, **103**, with loops **104** and circumferentially expandable sections **125**. Each of the two helical wires **102**, **103** is bent to form rings **107**, **108**. In FIG. **14**, the stent **200** is made by support means in the form of gate-shaped wires **202**, **203**, with loops **204** and circumferentially expandable sections **225**. Each of the two gate-shaped wires **202**, **203** is bent to form rings **207**, **208**. The primary difference between prior described embodiments, such as in FIG. **2**, versus those embodiments shown in FIGS. **13** and **14**, for example, is the replacement of the series of loops **4** (FIG. **2**) with the helical wires **102**, **103** and loops **104** (FIG. **13**) or the grate-shaped wires **202**, **203** and loops **204** (FIG. **14**). As the artisan will readily appreciate, the embodiments of FIGS. **13-14** otherwise include those features shown in prior described embodiments, such as in FIG. **2**, including the commissural points **5** forming commissural supports.

What is claimed is:

1. A valve prosthesis for implantation in a body, comprising:

an elastical stent comprising a cylindrical support having circumferentially expandable sections comprised of a series of loops with commissural supports therebetween and integral therewith; and

an elastical valve, commissural points of which are mounted on a respective one of the commissural supports;

wherein the cylindrical support is radially collapsible for implantation in the body via a catheter.

2. The valve prosthesis according to claim **1** wherein:

the elastical valve comprises a biologically tribolate valve.

3. The valve prosthesis according to claim **1**, wherein:

the elastical valve comprises a cardiac valve.

4. The valve prosthesis according to claim **1**, wherein:

the elastical valve comprises a venous valve.

5. The valve prosthesis according to claim **1**, wherein:

the cylindrical support comprises a metal having a stiffness sufficient to prevent a contraction of the cylindrical support of more than about 10% following expansion.

6. The valve prosthesis according to claim **1**, wherein:

the cylindrical support comprises a thread structure which forms a cylinder surface.

7. A valve prosthesis for implantation in a body, comprising:

an elastical stent comprising a support means having circumferentially expandable sections comprised of a series of loops with commissural supports therebetween and integral therewith; and

an elastical valve, commissural points of which are mounted on a respective one of the commissural supports;

wherein the support means is radially collapsible for implantation in the body via a catheter and the support means extends axially for supporting the elastical valve.

8. The valve prosthesis according to claim **7**, wherein:

the support means is cylindrical.

9. The valve prosthesis according to claim **7**, wherein:

a surface of the support means is cylindrical.

10. The valve prosthesis according to claim **7**, wherein:

the elastical valve is a biologically trilobate valve.

11. The valve prosthesis according to claim **7**, wherein:

the support means is expandable upon removal from the catheter.

12. The valve prosthesis according to claim **7**, wherein:

the elastical valve comprises a cardiac valve.

13. The valve prosthesis according to claim **7**, wherein:

the elastical valve comprises a venous valve.

14. The valve prosthesis according to claim **7**, wherein:

the support means comprises a metal having a stiffness sufficient to prevent a contraction of the support means of more than about 10% following expansion.

15. A valve prosthesis for implantation in a body, comprising:

an elastical stent comprising a cylindrical support having a thread structure cylinder surface; and

an elastical valve, commissural points of which are mounted on the cylinder surface; and

wherein the cylinder surface is radially collapsible for implantation in the body via a catheter,

the thread structure comprises stainless steel wire folded in a plurality of loops, bended according to a circle, and welded to provide at least two closed rings,

the at least two closed rings are mutually connected end to end to form the cylindrical support, and

three loops in an external one of the rings are folded with a greater height than remaining ones of loops to form apices.

16. The valve prosthesis according to claim **15**, wherein:

the cylindrical support is expandable upon removal from the catheter;

each of the closed rings comprises a wire having a diameter of 0.55 mm;

a height of the remaining ones of loops is approximately 8 mm;

a height of the three greater height loops is approximately 14 mm; and

the cylindrical support and the elastical valve mounted thereon, when collapsed, have an outer diameter of approximately 10 mm and, when expanded, an outer diameter of approximately 30 mm.

17. The valve prosthesis according to claim **15**, wherein:

the stent is made to be fixed, through expansion of the cylindrical support upon removal from the catheter, at one point in a channel in which the valve prosthesis is implanted, which point is different from a point where the elastical valve is mounted on the stent.

18. A valve prosthesis for implantation in a patient's body without requiring open heart surgery, comprising:

a self expandable stent constructed to be radially compressible and re-expandable, the stent having a top end, a bottom end and a metallic outer surface configured to contact native tissue in a body channel; and

a collapsible and re-expandable elastical valve comprising three flaps formed entirely of biological tissue, the elastical valve positioned within an interior portion of the stent for folding and expanding together with the stent, the elastical valve located between the top and bottom ends of the stent, the elastical valve having three commissural points sutured to the self expandable stent, the elastical valve configured to allow blood to flow in one direction such that blood is capable of flowing through the stent from the bottom end toward the top end;

wherein the valve prosthesis is radially compressible from an expanded condition to a compressed condition, the compressed condition having a first outer diameter of 10 mm or less for insertion inside a tubular wall of a cap along a distal end portion of a delivery catheter for advancement through a small inlet opening into the body channel and wherein the valve prosthesis is radially self-expandable upon ejection from the cap to a re-expanded condition comprising a second outer diameter of approximately 27 mm or more such that the second outer diameter of the valve prosthesis is greater than an inner diameter of the body channel for securing the valve prosthesis in the body channel without suturing the valve prosthesis to native tissue and to establish valvular function in the body channel, thereby allowing implantation of the valve prosthesis in the body channel for replacing the function of a natural aortic valve in an adult human being without open heart surgery and wherein the valve prosthesis is detachable from the delivery catheter such that the delivery catheter can be removed from the body channel and the small inlet opening can be closed such that the patient can resume a substantially normal life.

19. The valve prosthesis according to claim **18**, wherein:

the self-expandable stent has a height comprising a first range configured to be positioned downstream of the coronary ostia and a second range configured to support the elastical valve between the coronary ostia and the left ventricle.

20. The valve prosthesis according to claim **19**, wherein:

the elastical valve is formed entirely of biological tissue from a pig heart.

21. The valve prosthesis according to claim **18**, wherein:

the elastical valve comprises a venous valve.

22. The valve prosthesis according to claim **18**, wherein:

the stent has a stiffness sufficient to prevent a contraction of more than about 10% following re-expansion.

23. The valve prosthesis according to claim **18**, wherein:

the stent comprises a grate shaped structure which forms a cylinder surface.

24. A valve prosthesis configured to be implanted in a body channel without open heart surgery for replacing the function of a natural aortic valve in an adult human being, comprising:

a radially compressible and re-expandable metallic stent having a top end, a bottom end and a metallic outer surface configured to directly contact surrounding native tissue in a body channel with a pressure sufficient to prevent detachment from the body channel; and

a radially collapsible and re-expandable valve positioned within an interior portion of the stent and sutured to the stent for folding and expanding together with the stent, the valve having three flaps formed of biological tissue from a pig, the three flaps positioned between the top and bottom ends of the stent for allowing blood to flow in one direction such that blood is capable of flowing through the stent from the bottom end toward the top end, the valve having three commissural points sutured to the stent;

wherein the valve prosthesis is radially compressible from an expanded condition to a compressed condition, the compressed condition having an outer diameter of less than 12.5 mm to be located inside a tubular wall of a cap along a distal end portion of a catheter for advancement through a small inlet opening into the body channel and wherein the valve prosthesis is radially re-expandable upon ejection from the cap to a re-expanded condition comprising an outer diameter of approximately 27 mm or larger for securing the valve prosthesis to the surrounding native tissue without suturing the valve prosthesis to the surrounding native tissue and wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the body channel and the small inlet opening can be closed and wherein the metallic stent has a sufficient height such that the top end of the stent is capable of being positioned downstream of the coronary ostia while the valve is positioned substantially between coronary ostia and a left ventricle of a heart for replacing the function of the natural aortic valve without open heart surgery.

25. The valve prosthesis according to claim **24**, wherein:

at least a portion of the metallic stent is substantially cylindrical.

26. The valve prosthesis according to claim **24**, wherein:

the metallic stent is self-expandable upon ejection from the cap and wherein the outer diameter in the re-expanded condition is slightly larger than an inner diameter of the body channel.

27. The valve prosthesis according to claim **24**, wherein:

the radially collapsible and re-expandable valve comprises a cardiac valve.

28. The valve prosthesis according to claim **24**, wherein:

the radially collapsible and re-expandable valve comprises a venous valve.

29. The valve prosthesis according to claim **24**, wherein:

the metallic stent comprises a grate shaped structure having a stiffness sufficient to prevent a contraction of the metallic stent of more than about 10% following re-expansion.

30. A valve prosthesis for replacing the function of a native valve in a patient's body by a technique of catheterization, comprising:

a radially collapsible and re-expandable stent having a top end, a bottom end and a metallic outer surface configured to contact native tissue in a body channel; and

a collapsible and re-expandable valve structure positioned within an interior portion of the stent and sutured to the stent, the valve structure having three flaps formed entirely of biological tissue, the three flaps positioned between the top and bottom ends of the stent, the valve structure having three commissural points sutured to the stent, the valve structure configured to allow blood to flow in one direction such that blood enters through a bottom opening at the bottom end of the stent and exits through a top opening at the top end of the stent;

wherein the valve prosthesis is radially collapsible to an outer diameter of less than 10 mm for introduction by way of a catheter through an inlet opening into the body channel and wherein the outer diameter of the stent is radially re-expandable to a re-expanded dimension sized to engage the native tissue in the body channel with a pressure sufficient for preventing detachment from the body channel and for fixing the valve prosthesis in the body channel without suturing the valve prosthesis to native tissue and wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the patient's body and the inlet opening can be closed while the valve prosthesis remains in the body channel;

wherein the valve structure has an expanded outer diameter in the range of about 25 to 27 mm.

31. A valve prosthesis for replacing the function of a native valve in a patient's body by a technique of catheterization, comprising:

a radially collapsible and re-expandable stent having a top end, a bottom end and a metallic outer surface configured to contact native tissue in a body channel; and

a collapsible and re-expandable valve structure positioned within an interior portion of the stent and sutured to the stent, the valve structure having three flaps formed entirely of biological tissue, the three flaps positioned between the top and bottom ends of the stent, the valve structure having three commissural points sutured to the stent, the valve structure configured to allow blood to flow in one direction such that blood enters through a bottom opening at the bottom end of the stent and exits through a top opening at the top end of the stent;

wherein the valve prosthesis is radially collapsible to an outer diameter of less than 10 mm for introduction by way of a catheter through an inlet opening into the body channel and wherein the outer diameter of the stent is radially re-expandable to a re-expanded dimension sized to engage the native tissue in the body channel with a pressure sufficient for preventing detachment from the body channel and for fixing the valve prosthesis in the body channel without suturing the valve prosthesis to native tissue and wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the patient's body and the inlet opening can be closed while the valve prosthesis remains in the body channel;

wherein the re-expanded dimension has a diameter of about 30 mm.

32. A valve prosthesis for replacing the function of a natural heart valve, comprising:

a radially compressible and re-expandable stent, the stent being compressible from an expanded condition to a compressed condition having an outer diameter suitable for introduction through a small inlet opening into a body channel by way of a delivery catheter and the stent being re-expandable to a re-expanded condition, the stent having a metallic outer surface for contacting surrounding tissue in the body channel, wherein an outer diameter of the stent in the re-expanded condition is at least 2.7 times larger than the outer diameter of the stent in the compressed condition; and

a collapsible and re-expandable valve structure mounted to the stent for folding and expanding together with the stent, the valve structure having three commissural points coupled to the stent, the valve structure having three flaps formed entirely of biological tissue, the valve structure positioned within an interior portion of the stent for preventing blood flow in one direction;

wherein the valve prosthesis is detachable from the delivery catheter after deployment in the body channel such that the delivery catheter can be removed from the body channel and the small inlet opening can be closed and wherein the stent has a stiffness in the expanded condition, the stiffness being sufficient to maintain pressure along surrounding tissue in the body channel for securing the valve prosthesis and preventing detachment from the body channel, thereby allowing the valve prosthesis to be permanently implanted in the body channel by way of catheterization without requiring surgical intervention.

33. The valve prosthesis according to claim **32**, wherein:

the stent is balloon expandable.

34. The valve prosthesis according to claim **32**, wherein:

the stent is formed of a metallic self-expandable material.

35. The valve prosthesis according to claim **34**, wherein:

the self-expandable stent has a height comprising a first range configured for fixation in the ascending aorta downstream of the coronary ostia and a second range configured to position the valve structure substantially between the coronary ostia and the left ventricle after implantation.

36. The valve prosthesis of claim **32**, wherein:

the valve structure is formed entirely of biological tissue from a slaughtered pig.

37. The valve prosthesis of claim **32**, wherein:

the valve prosthesis is configured to be implanted in the body channel without opening the thoracic cavity.

38. A valve prosthesis configured for implantation without surgical intervention for replacing the function of a defective natural valve in an adult human heart, comprising:

a compressible and re-expandable stent having an inlet end, an outlet end and a metallic outer surface, the stent being radially compressible from an expanded state to a compressed state for introduction through an inlet opening into a body channel by way of a catheter, the stent being re-expandable to a re-expanded state such that the metallic outer surface engages surrounding tissue in the body channel, wherein an outer diameter of the stent in the re-expanded state is at least 2.7 times larger than an outer diameter of the stent in the compressed state; and

a collapsible and re-expandable valve structure mounted within an interior portion of the stent between the inlet and outlet ends of the stent for folding and expanding

together with the stent and configured for preventing blood flow in one direction, the valve structure having movable flaps positioned between the inlet and outlet ends of the stent for allowing blood to flow only from the inlet end toward the outlet end of the stent;

wherein stent stiffness provides the sole means of fixation to surrounding tissue for securing the valve prosthesis to the body channel and wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the body channel after deploying the valve prosthesis in the body channel and the inlet opening can be closed such that the valve prosthesis is permanently implantable in the body channel for replacing the function of a native valve without suturing the valve prosthesis to surrounding native tissue.

39. The valve prosthesis of claim **38**, wherein:

the stent comprises a grate-shaped structure.

40. The valve prosthesis of claim **39**, wherein:

the stent is self expandable.

41. The valve prosthesis of claim **40**, wherein:

the stent further comprises an outlet end portion configured for fixation in the ascending aorta at a location downstream of the coronary ostia and an inlet end portion configured for positioning the valve structure substantially between the coronary ostia and the left ventricle.

42. The valve prosthesis of claim **41**, wherein:

at least the inlet end portion of the stent is substantially cylindrical.

43. The valve prosthesis of claim **38**, wherein:

the valve structure is formed of biological tissue before the valve prosthesis is introduced through the inlet opening into the body channel.

44. The valve prosthesis of claim **43**, wherein the biological tissue forms two or more adjacent flaps, the flaps forming commissural points between adjacent flaps.

45. The valve prosthesis of claim **38**, wherein:

the outer diameter of the stent in the re-expanded state is at least three times larger than the outer diameter of the stent in the compressed state.

46. A valve prosthesis configured for implantation in an adult human being without requiring surgical intervention for replacing the function of a defective natural aortic valve, comprising:

a self expandable metallic stent having an inlet end, an outlet end and a metallic outer surface, the stent being radially compressible to a compressed condition having an outer diameter suitable for insertion into a protection cap and sized for introduction through an inlet opening into a body channel by way of a catheter, the stent configured to self-expand to an expanded condition upon ejection from the protection cap, the stent comprising an outer diameter in the expanded condition at least three times greater than the outer diameter in the compressed condition, the outer diameter being greater than an inner diameter of an ascending aorta such that at least a portion of the metallic outer surface of the stent engages an inner wall of the ascending aorta for counteracting detachment of the valve prosthesis;

a collapsible and expandable elastical valve comprising three flaps formed of biological tissue, the elastical valve positioned within an interior portion of the stent for folding and expanding together with the stent, the elastical valve located between the inlet and outlet ends of the stent, the elastical valve having three commissural points sutured to the self expandable stent, the elastical valve configured to allow blood to flow in one direction such that blood is capable of flowing through the stent from the inlet end toward the outlet end;

wherein the valve prosthesis is detachable from the catheter such that the catheter can be removed from the body channel after implanting the valve prosthesis and the inlet opening can be closed such that the valve prosthesis is permanently implantable for replacing the function of the defective natural aortic valve without suturing the valve prosthesis to surrounding native tissue.

47. The valve prosthesis according to claim **46**, wherein:

the self-expandable stent comprises an inlet end portion configured to position the elastical valve substantially between the coronary ostia and the left ventricle.

48. The valve prosthesis according to claim **46**, wherein:

the outer diameter of the stent in the compressed condition is 10 mm or less.

49. The valve prosthesis according to claim **48**, wherein:

the outer diameter of the stent in the expanded condition is 30 mm or greater.

* * * * *

EXHIBIT 2

US005411552A

United States Patent [19]

Andersen et al.

[11] **Patent Number: 5,411,552**

[45] **Date of Patent: May 2, 1995**

[54] **VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS**

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[21] Appl. No.: **261,235**

[22] Filed: **Jun. 14, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 961,891, Jan. 11, 1993, abandoned.

[30] **Foreign Application Priority Data**

May 18, 1990 [DK] Denmark 1246/90

[51] **Int. Cl.**[6] **A61F 2/24**

[52] **U.S. Cl.** **623/2;** 623/900; 137/343; 137/844; 251/358

[58] **Field of Search** 623/2, 900; 137/343, 137/844, 316; 251/358; 606/108

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Primary Examiner—David H. Willse
Attorney, Agent, or Firm—Watson, Cole, Grindle & Watson

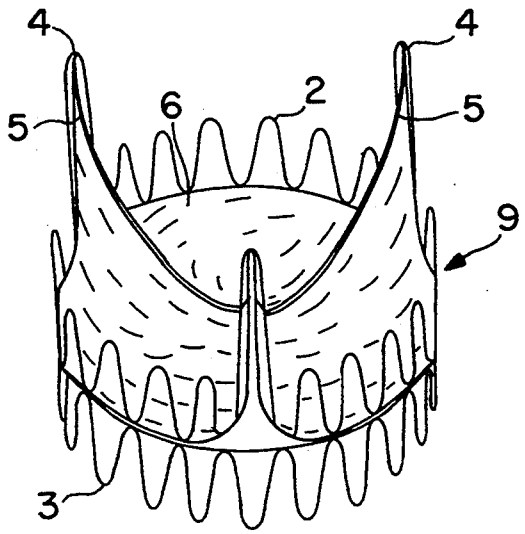
[57] **ABSTRACT**

A valve prosthesis (**9**) for implantation in the body by use of catheter (**11**) comprises a stent made from an expandable cylinder-shaped thread structure (**2,3**) comprising several spaced apices (**4**). The elastically collapsible valve (**4**) is mounted on the stent as the commissural points (**5**) of the valve (**6**) are secured to the projecting apices (**4**).

The valve prosthesis (**9**) can be compressed around the balloon means (**13**) of the balloon catheter (**11**) and be inserted in a channel, for instance in the aorta (**10**). When the valve prosthesis is placed correctly the balloon means (**13**) is inflated thereby expanding the stent and wedging it against the wall of aorta. The balloon means is provided with beads (**14**) to ensure a steady fastening of the valve prosthesis on the balloon means during insertion and expansion.

The valve prosthesis (**9**) and the balloon catheter (**11**) make it possible to insert a cardiac valve prosthesis without a surgical operation comprising opening the thoracic cavity.

8 Claims, 4 Drawing Sheets



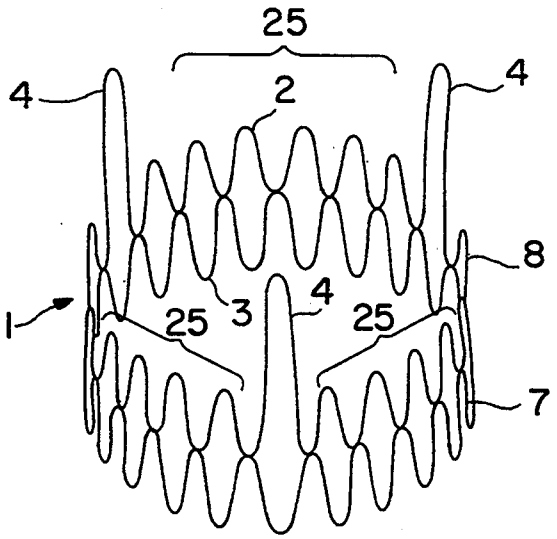


FIG. 1

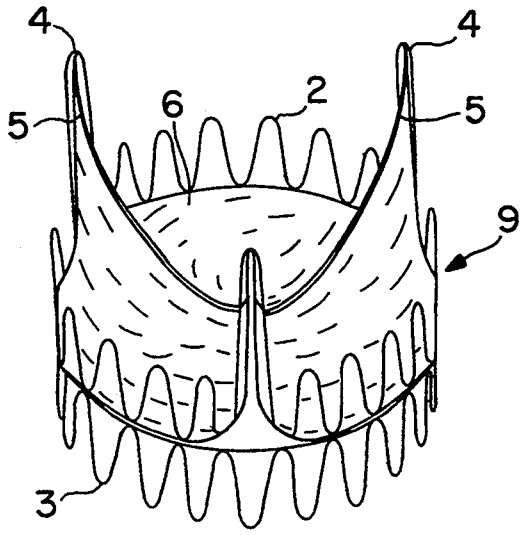


FIG. 2

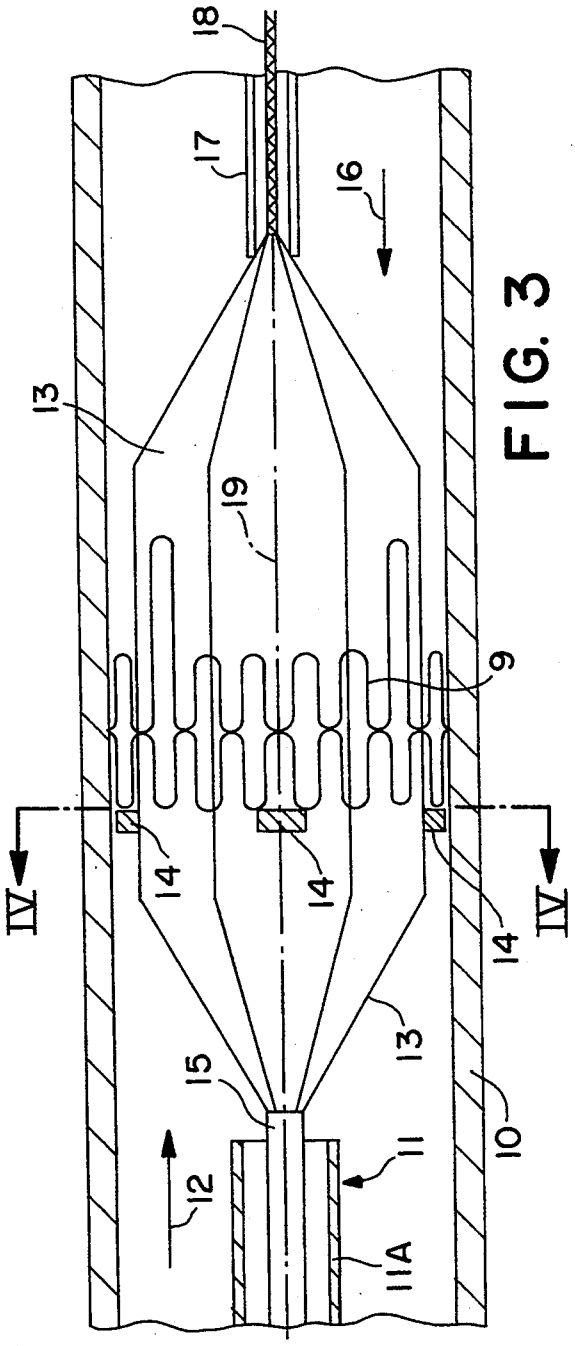


FIG. 3

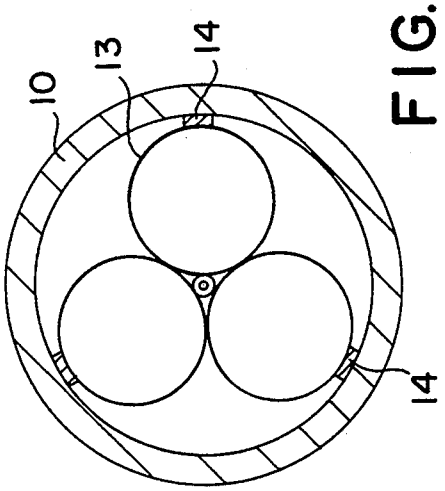


FIG. 4

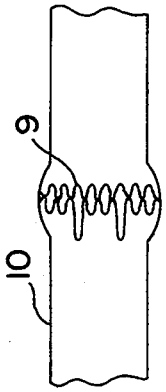


FIG. 7

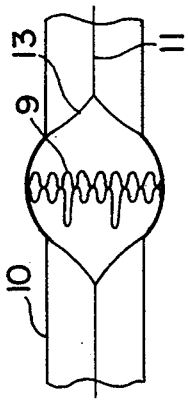


FIG. 6

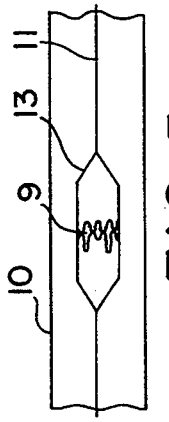


FIG. 5

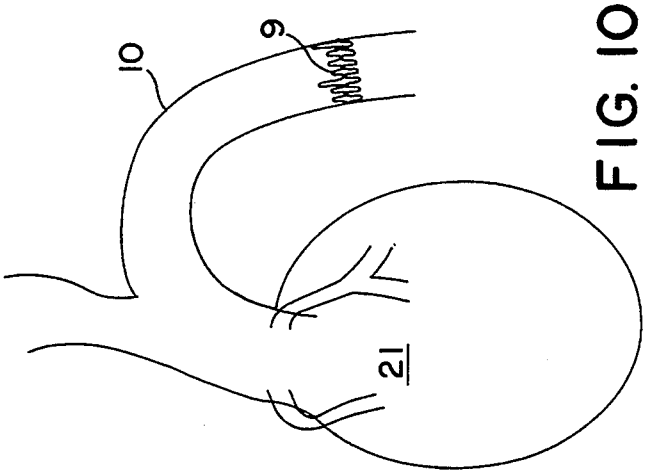


FIG. 10

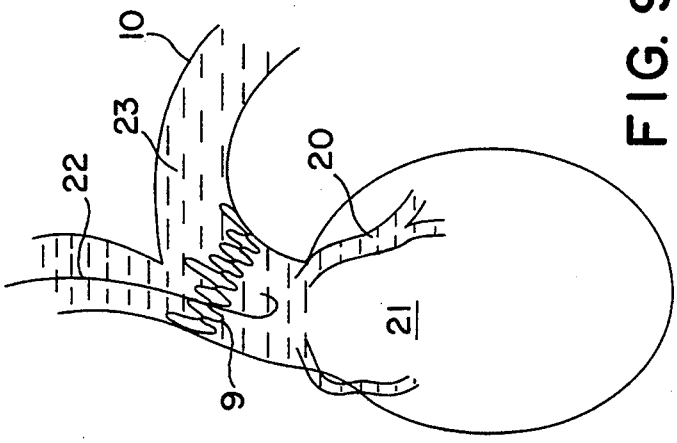


FIG. 9

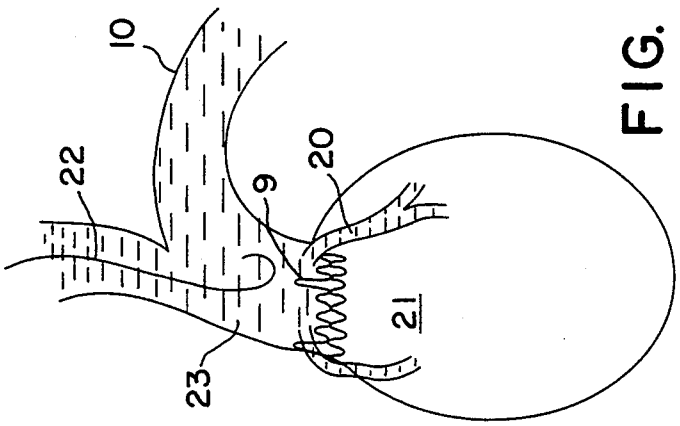


FIG. 8

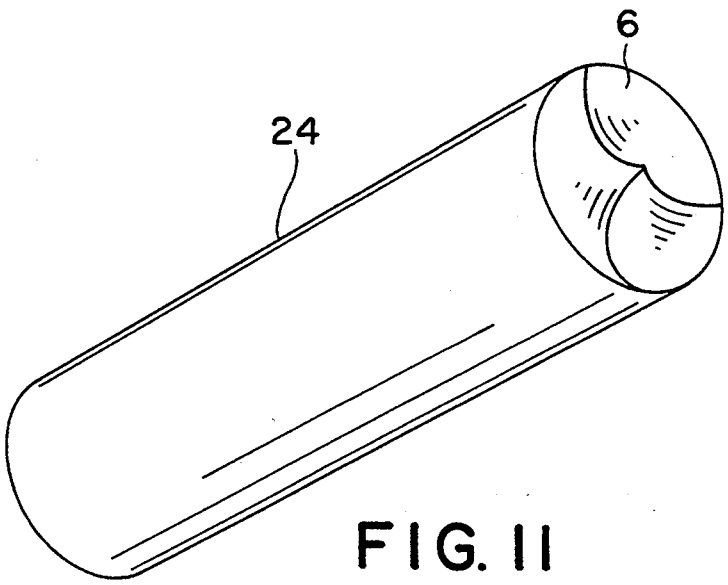


FIG. 11

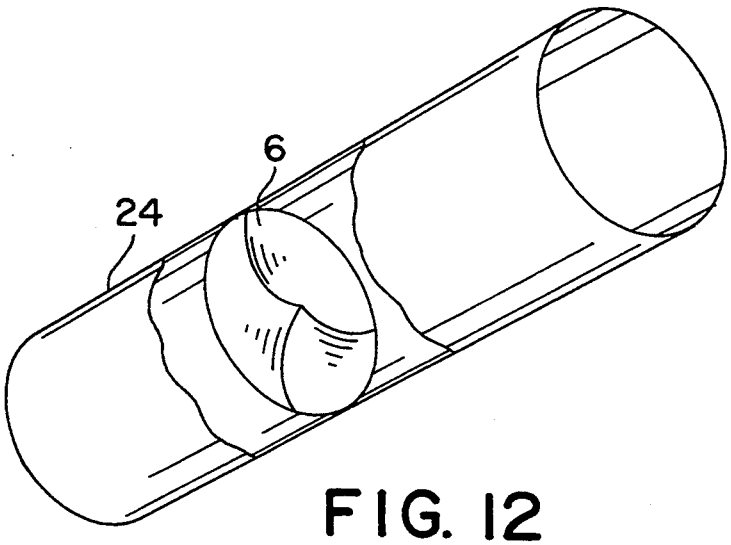


FIG. 12

VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 961,891, filed Jan. 11, 1993, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastical valve which is mounted on an elastical stent wherein the commissural points of the elastical collapsible valve are mounted on the cylinder surface of the elastical stent.

Valve prostheses of this type are usually implanted in one of the channels of the body to replace a natural valve. In the present description the invention will be explained in connection with an cardiac valve prosthesis for implantation in aorta. However, it will be possible to use a valve prosthesis according to the invention in connection with implantation in other channels in the body by using the same technique as the one used for implantation of cardiac valve prosthesis. Such an implantation may, e.g., comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
2. a valve in the oesophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

An existing natural valve in the body is traditionally replaced with a valve prosthesis by a surgical implantation. However, a surgical implantation is often an exacting operation. Thus, today the implantation of cardiac valves are solely made by surgical technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

Due to its exacting character, it is impossible to offer such operation to certain people. For instance, this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in U.S. Pat. Nos. 3,671,979 and 4,056,854. However, both of these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

From U.S. Pat. No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prosthesis is not designed for implantation in the body by catheterization. Even though this patent contains no detailed explanation, the description indicates that this valve prosthesis is designed for implantation and sewering on by a surgical intervention.

Moreover, from U.S. Pat. Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

The nearest prior art may be that described in GB-A-2,056,023. This document discloses an elastic stent as described by way of introduction. Thus, the stent described comprises an elastic collapsible valve mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible, it will not be suited for implantation by a catheterization procedure.

SUMMARY OF THE INVENTION

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure, this can for instance be grate shaped, loop shaped or helical. This makes it possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may, e.g., be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon. When using a self-expandable stent, a catheter with an expansion arrangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means, which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small, which makes it possible to introduce the valve prosthesis through a channel in the body.

When the valve prosthesis is introduced and placed correctly, the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an outer dimension which is slightly larger than the channel in which it is placed. As the stent is elastic, a contraction of the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made, the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention to optionally expose the body channel, e.g., a vein, through which the insertion takes place. Thus, patients for whom an operation would be associated with high risk can be offered implantation of, for instance, cardiac valves. After the implantation has taken place, the after-treatment will advantageously be shorter than normally, which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implantate the valve prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves. The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the central veins in the centre of the leg towards the superficial veins. Among other things, this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in a wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumors, where too much humour is produced. If the humour is able to flow from the cancerous tumor through several channels, it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prosthesis.

When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is possible to mount it in three positions, viz., in the descending part of the aorta, in a position between the coronary arteries and the left ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus, the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise, the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who cannot be offered an open heart surgery, the valve prosthesis can also be used for patients in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who cannot be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof, the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.

Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prothesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries, it is desirable that the valve prothesis has a greater surface to distribute the outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implantating a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with a profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implantating cores in the body are known. For instance, such balloon catheters are known from U.S. Pat. Nos. 4,856,516, 4,733,665 and 4,796,629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvantageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevents a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation, any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for the catheter, X-ray supervision, injection of X-ray traceable liquids, ultrasonic measuring, etc., may be used.

DESCRIPTION OF THE DRAWINGS

The invention will now be explained in detail with reference to the accompanying schematical drawing, wherein

FIG. **1** shows a perspective view of a stent without a valve,

FIG. **2** is a perspective view of a valve prosthesis according to the invention made from the stent shown in FIG. **1** having a biological valve mounted thereon,

FIG. **3** is a partial view through the aorta illustrating a partially inflated balloon catheter,

FIG. **4** is a cross section through the embodiment shown in FIG. **9**,

FIG. **5–7** are views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,

FIG. 8–10 are views illustrating three possible positions of a cardiac valve prosthesis, and

FIG. 11–12 are perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a stent 1 made by support means in the form of two 0.55 mm surgical stainless steel wires 2,3. The wires are folded in 15 loops. Three loops 4 are 14 mm in height and are intended to secure the commissural points 5 (see FIG. 2) from a biological cardiac valve 6 which is mounted in the stent 1. The remaining loops have a height of 8 mm. These loops form circumferentially expandable sections 25 between the commissural points 5 forming commissural supports. Each of the two folded wires 2,3 is bent to form rings 7,8 which are closed by welding the ends. The two rings are placed on top of each other as will appear from FIG. 1 and they are mutually secured by means of a number of sutures (not shown). The lower ring is circumferentially expandable at least along sections thereof which correspond to the circumferentially expandable sections 25. By using a substantially cylindrical thread structure with projecting apices, a reduction in weight is obtained as compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve 6 was removed from a slaughtered pig of 100 kg. The valve was cleaned before mounting in the stent 1. The cleaned valve has an outer diameter of 25–27 mm and the height of the three commissural points 5 is 8 mm. The valve 6 is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis 9 shown in FIG. 2. The valve prosthesis produced is used for performing tests in pigs by implantation of cardiac valve prosthesis. However, the cardiac valve prosthesis for use in human beings has a corresponding form.

FIG. 3 shows a partial view through the aorta 10. A balloon catheter 11 is introduced in the aorta according to the direction of an arrow 12. In the Figure shown the balloon means 13 of the balloon catheter is led out of the protection cap 11A and is partly inflated through a fluid channel 15, which is led to the surface of the patient. The balloon means 13 constitutes a tri-sectional balloon upon which the cardiac valve prosthesis is placed. In the form shown, the cardiac valve prosthesis is expanded exactly to be in contact with the aorta 10. The balloon means 13 is provided with three projecting beads 14 which are engaged with the one side of the cardiac valve prosthesis 9. The blood flowing through the aorta according to the direction of an arrow 16 will thus cause the cardiac valve prosthesis 9 to abut on the beads 14 and the valve cannot be displaced in relation to the balloon means 13. Moreover, the balloon catheter used comprises a central channel 17 to receive a guide wire 18 which is used in a way known per se for supervising the introduction of the catheter through fluoroscopi. In the shown embodiment beads 14 are only used at one side of the valve prosthesis, but, however, it will often be desirable to use the beads in pairs placed along lines parallel to the longitudinal axes 19 through the balloon means 13. In this case the spacing of the pair of beads 14 will correspond to the height of the loops of the stent. This makes it possible to make an effective fastening of a valve prosthesis on balloon means. Moreover, the fastening on the balloon means may be provided by using balloon means with an indentation in the surface (not shown).

FIG. 4 shows a cross section through the embodiment shown in FIG. 3 illustrating the placing of the beads 14 on the tri-sectional balloon means 13.

A balloon catheter of the above-described type which was used in tests of implantating the cardiac valve prosthesis 9 in pigs had the following dimensions. Each of the three balloons was 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons was 31 mm and in the balloon catheter used two beads 14 having a height of 3 mm were mounted on each side of the three balloons. The beads had a spacing of 15 mm. The protection cap 11A of the balloon catheter had an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter was provided with a standard guide wire having a diameter of 0.9 mm and a length of 300 cm.

FIGS. 5–7 show the valve prosthesis 9 at different steps in introducing and implantating in the aorta 10 by means of the catheter 11 having the inflatable balloon means 13. The cardiac valve prosthesis 9 is initially placed above the deflated balloon means 13 and compressed manually around the balloon means (FIG. 5), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning, the balloon means 13 is inflated (FIG. 6), thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta, the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter 11 may subsequently be removed from the aorta 10 (FIG. 7). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter 13. When the valve prosthesis is mounted as shown in FIG. 7, the patient will be able to resume a substantially normal life after a few days.

FIGS. 8–10 show the positioning of the valve prosthesis 9 as cardiac valve prosthesis in the aorta 10 in three different positions, i.e., in a position between the coronary arteries 20 and the left ventricle of the heart 21 (FIG. 8), in a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (FIG. 9), and in a position in the descending part of the aorta 10. The positioning of the valve prosthesis is chosen in accordance with the diagnosis of the illness of the patient. By placing the cardiac valve prosthesis as shown in FIG. 8, there is a risk of detachment and/or covering the mouth of the coronary arteries, and therefore it is preferred to use a higher stent which, for instance, comprises several rings 7,8 placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. FIGS. 8 and 9 show how a contrast medium 23 is injected by means of a so-called pigtail catheter for registration of the tightness of the implantated valve prosthesis 9.

A specific embodiment for a valve prosthesis and a balloon catheter for implantating the valve prosthesis has been explained above. However, it is obvious that it

is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus, the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g., polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in FIGS. **11** and **12**. In both Figures the support means of the valve prosthesis is made of an elongated tubular means **24** having a closed cylinder surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against he wall of the channel. In FIG. **11** the valve **6** is mounted at the end of the tubular means **24**. In FIG. **12** an embodiment is shown where the valve **6** is mounted in a central position in the tubular means **24**.

An explanation of a method of implantating a valve prosthesis according to the invention is given below:

- a valve prosthesis **9** made of a stent **1** and a collapsible valve **6**, as described above, is placed on a deflated balloon means and is manually compressed thereon,
- the balloon means **13** and the valve prosthesis are drawn into an insertion cover **11A**,
- a guide wire **18** is inserted into the left ventricle of the heart through the central opening **17** of the balloon catheter under continuous fluoroscopi,
- the insertion cover **11A** conveys the guide wire **18** to a point in the channel in the immediate vicinity of the desired position of the valve prosthesis,
- the balloon means **13** is pushed out of the protection cap **11A** and the valve prosthesis is positioned in the desired position if necessary by use of further registration means to ensure an accurate positioning,
- the balloon means **13** is inflated with a certain overstretching of the channel,
- the balloon means **13** is deflatated, and
- the balloon means **13**, the guide wire **18** and the protection cap **11A** are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be closed.

We claim:

1. A valve prosthesis for implantation in a body channel, the valve prosthesis comprising a collapsible elastical valve which is mounted on an elastical stent, the elastical valve having a plurality of commissural points, wherein the stent comprises:

cylindrical support means which is radially collapsible for introduction within the body channel and which has a plurality of circumferentially-expandable sections such that the cylindrical support means is radially expandable for being secured within the body channel; and

a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof for supporting the commissural points of the collapsible valve, at least one circumferentially-expandable section of the cylindrical support means lying between each of the commissural supports, such that the collapsible valve may be collapsed and expanded together with the cylindrical support means for implantation in the body channel by means of a technique of catheterization.

2. A valve prosthesis according to claim **1**, wherein the cylindrical support means is made of a thread structure.

3. A valve prosthesis according to claim **2**, wherein the thread structure comprises several spaced apices projecting from the one side of the cylindrical structure and in a direction along the longitudinal axis of the cylinder and that the commissural points of the valve are attached to the projecting apices.

4. A valve prosthesis according to claim **3**, wherein the elastically collapsible valve is a biological trilobate valve.

5. A valve prosthesis to claim **4**, wherein the stent is made from a stainless steel wire folded in a number of loops and bent into a circle and welded to form a closed ring, wherein the stent comprises two or more such closed rings which are mutually connected end to end to form the cylindrical thread structure, and wherein three of the loops in a ring at an end of said stent are folded with a greater height than the remaining loops to form the apices to which the commissural points of the biological valve are attached.

6. A valve prosthesis according to claim **5**, wherein each of the rings of the stent is made from a wire having a diameter of 0.55 mm and a loop height of approximately 8 mm and approximately 14 mm for the three greater loops, and wherein the cylindrical thread structure produced and the collapsible valve mounted thereon in a folded state have an outer diameter of approximately 10 mm and in expanded state an outer diameter of approximately 30 mm.

7. A valve prosthesis according to claim **5**, wherein the stent is made to be fixed through the expansion at one point in the channel wherein the valve prosthesis is inserted, which point is different from the point where the valve is mounted in the stent.

8. A valve prosthesis according to claim **1**, wherein the cylinder surface of the support means is closed to form a tubular element.

* * * * *

EXHIBIT 3

US006582462B1

(12) **United States Patent**
Andersen et al.

(10) **Patent No.: US 6,582,462 B1**
(45) **Date of Patent: *Jun. 24, 2003**

(54) **VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/514,426**

(22) Filed: **Feb. 28, 2000**

Related U.S. Application Data

(63) Continuation of application No. 09/026,574, filed on Feb. 20, 1998, now Pat. No. 6,168,614, which is a continuation of application No. 08/955,228, filed on Oct. 21, 1997, now abandoned, which is a division of application No. 08/801,036, filed on Feb. 19, 1997, now Pat. No. 5,840,081, which is a continuation of application No. 08/569,314, filed on Dec. 8, 1995, now abandoned, which is a continuation of application No. 08/352,127, filed on Dec. 1, 1994, now abandoned, which is a division of application No. 08/261,235, filed on Jun. 14, 1994, now Pat. No. 5,411,552, which is a continuation of application No. 07/961,891, filed as application No. PCT/DK91/00134 on Mar. 16, 1991, now abandoned.

(30) **Foreign Application Priority Data**

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(51) **Int. Cl.**[7] **A61F 2/24**
(52) **U.S. Cl.** **623/1.26**; 623/2.14
(58) **Field of Search** 623/FOR 101, 623/2.1–2.19, 2.38–2.41, 900, 904, 1.24–1.26

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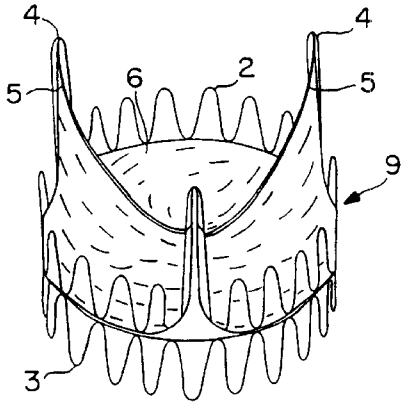
Primary Examiner—David H. Willse

(57) **ABSTRACT**

A valve prosthesis for implantation in the body by use of a catheter includes a stent made from an expandable cylinder-shaped thread structure having several spaced apices. The elastically collapsible valve is mounted on the stent as the commissural points of the valve are secured to the projecting apices.

8 Claims, 4 Drawing Sheets



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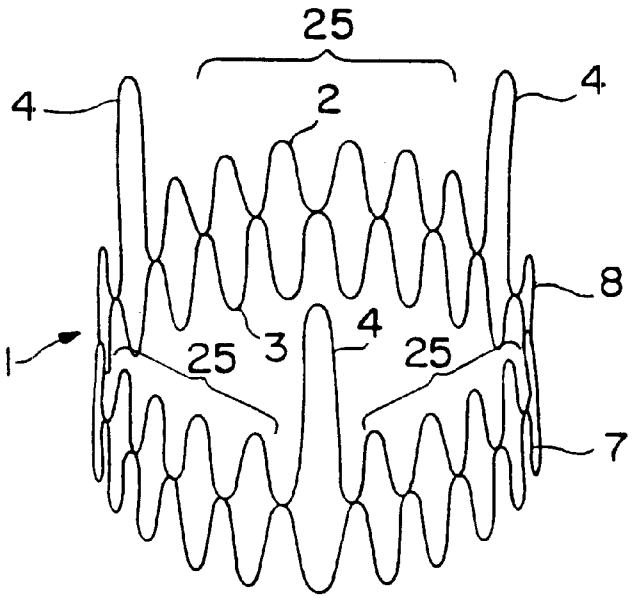

FIG. 1

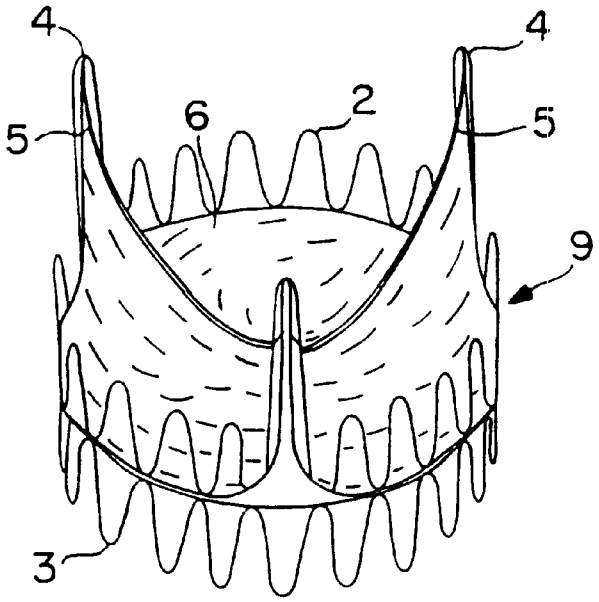

FIG. 2

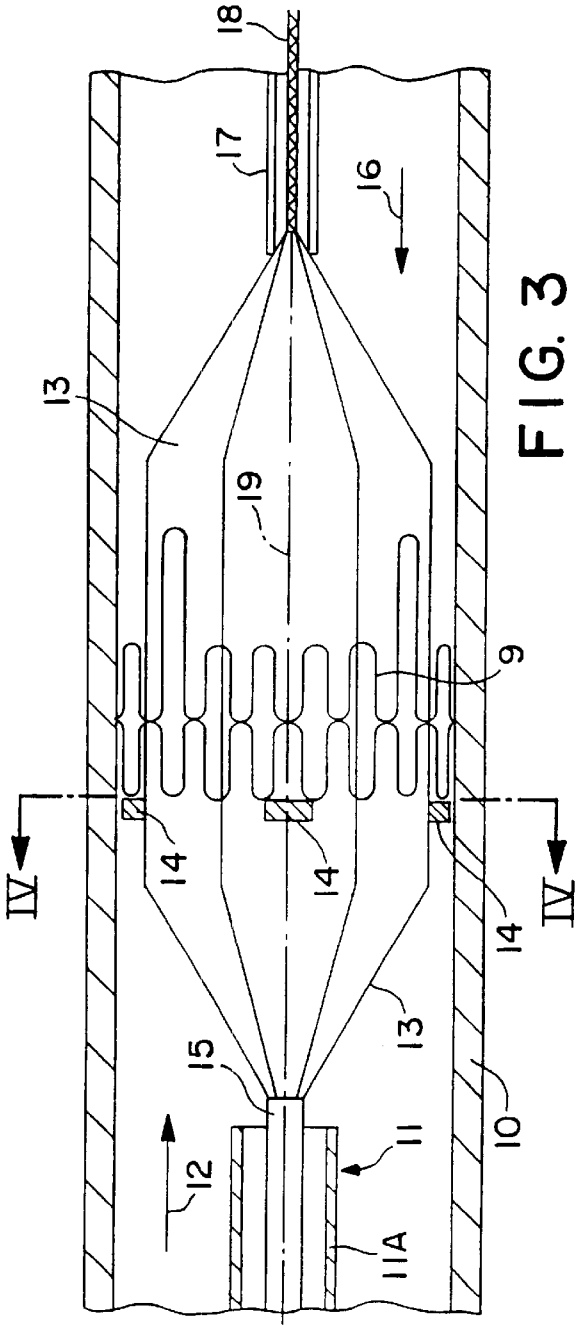

FIG. 3

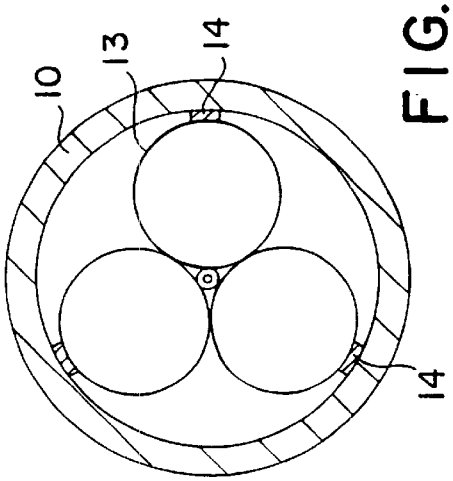

FIG. 4

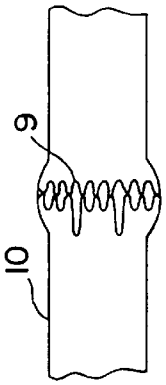

FIG. 7

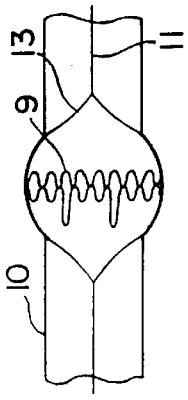

FIG. 6

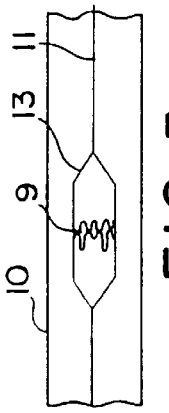

FIG. 5

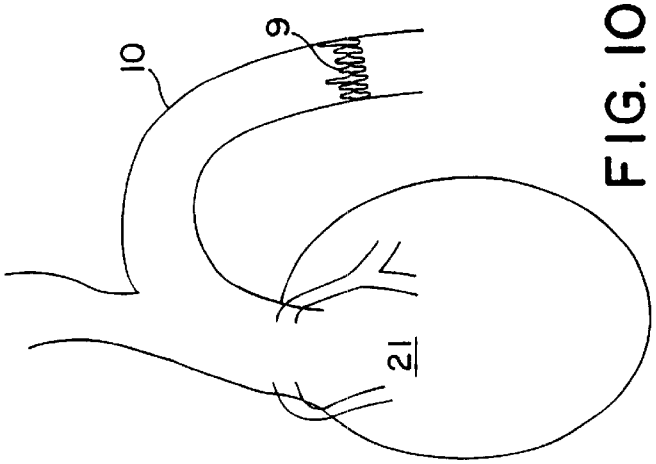

FIG. 10

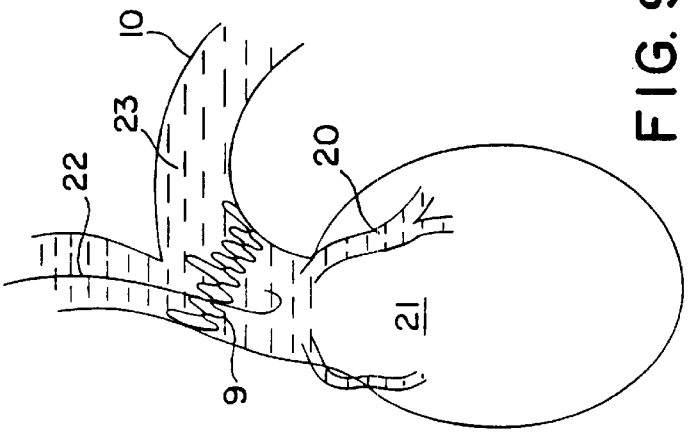

FIG. 9

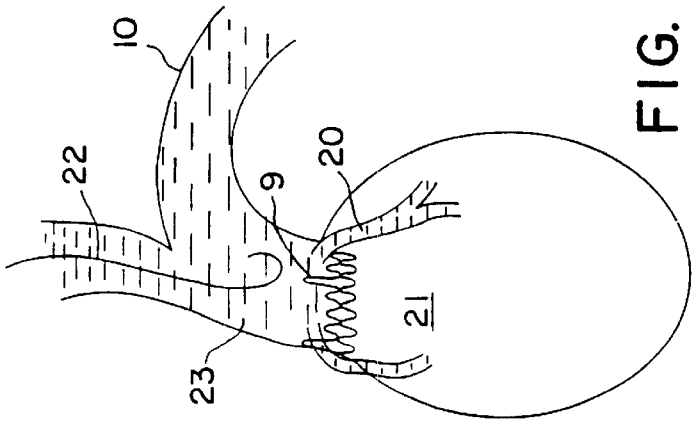

FIG. 8

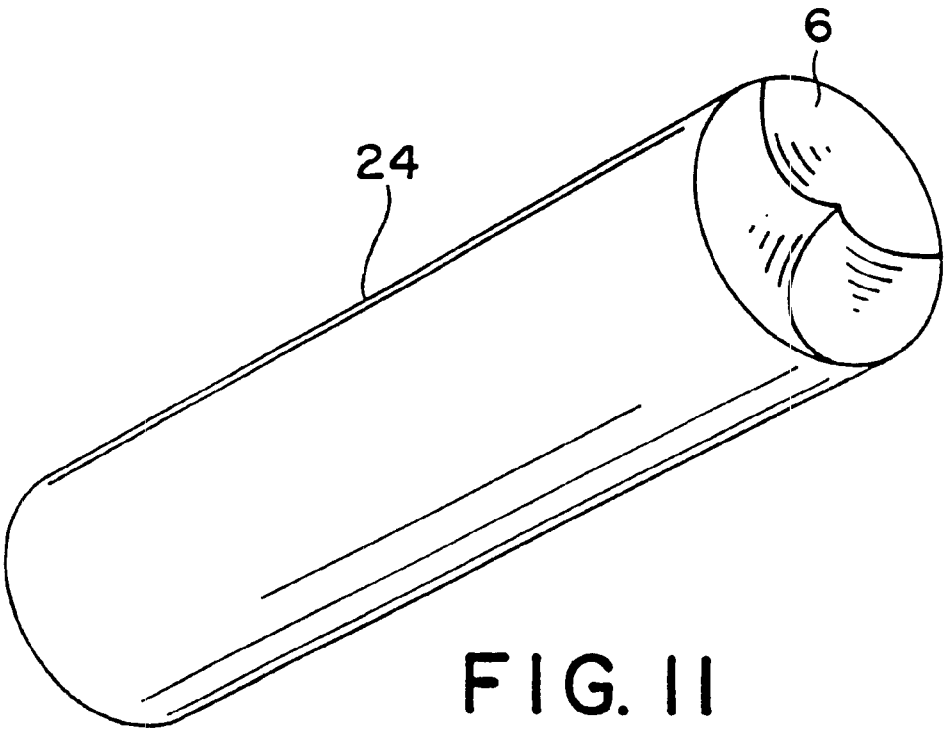

FIG. 11

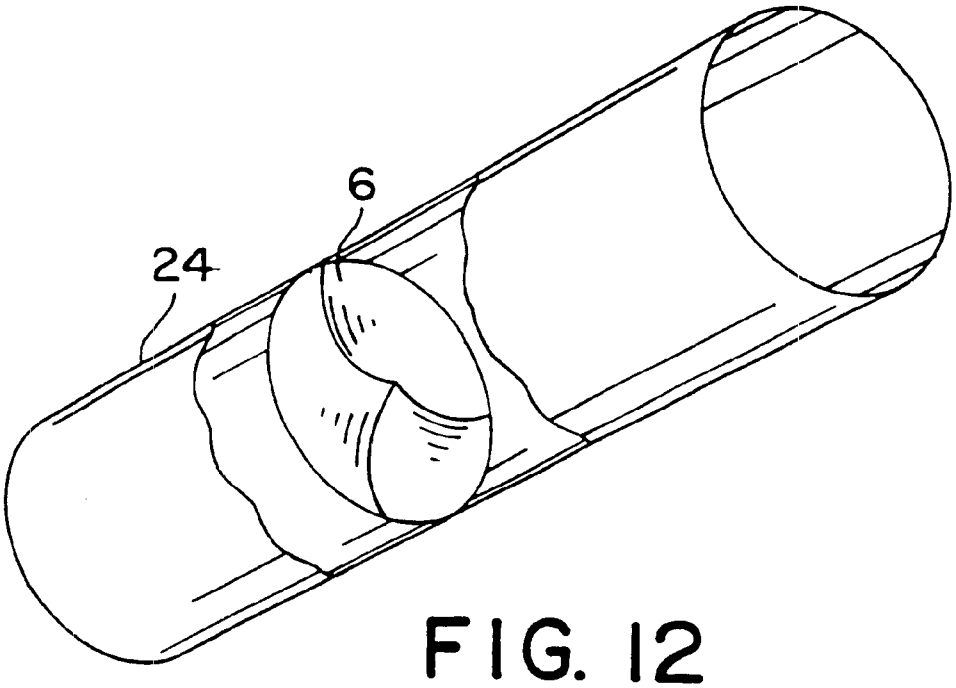

FIG. 12

VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 09/026,574, filed Feb. 20, 1998, now U.S. Pat. No. 6,168,614, which is a continuation of application Ser. No. 08/955,228, filed Oct. 21, 1997, now abandoned, which is a division of application Ser. No. 08/801,036, filed Feb. 19, 1997, now U.S. Pat. No. 5,840,081, which is a continuation of application Ser. No. 08/569,314, filed Dec. 8, 1995, now abandoned, which is a continuation of application Ser. No. 08/352,127, filed Dec. 1, 1994, now abandoned, which is a division of application Ser. No. 08/261,235, filed Jun. 14, 1994, now U.S. Pat. No. 5,411,552, which is a continuation of application Ser. No. 07/961,891, filed Jan. 11, 1993, now abandoned which is based on PCT/DK91/00134, filed Mar. 16, 1991.

BACKGROUND OF THE INVENTION

The present invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastic valve which is mounted on an elastic stent wherein the commissural points of the elastic collapsible valve are mounted on the cylinder surface of the elastic stent.

Valve prostheses of this type are usually implanted in one of the channels of the body to replace a natural valve. In the present description the invention will be explained in connection with a cardiac valve prosthesis for implantation in aorta. However, it will be possible to use a valve prosthesis according to the invention in connection with implantation in other channels in the body by using the same technique as the one used for implantation of cardiac valve prosthesis. Such an implantation may, e.g., comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
2. a valve in the esophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

An existing natural valve in the body is traditionally replaced with a valve prosthesis by a surgical implantation. However, a surgical implantation is often an exacting operation. Thus, today the implantation of cardiac valves are solely made by surgical technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

Due to its exacting character, it is impossible to offer such operation to certain people. For instance, this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in U.S. Pat. Nos. 3,671,979 and 4,056,854. However, both of these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

From U.S. Pat. No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prostheses is not designed for implantation in the body by catheterization. Even though this patent contains no detailed explanation, the description indicates that this valve prosthesis is designed for implantation and sewing on by a surgical intervention.

Moreover, from U.S. Pat. Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

The nearest prior art may be that the described in GB-A-2.056,023. This document discloses an elastic stent as described by way of introduction. Thus, the stent described comprises an elastic collapsible valve mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible, it will not be suited for implantation by a catheterization procedure.

SUMMARY OF THE INVENTION

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure, this can for instance be grate shaped, loop shaped or helical. This makes it possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may, e.g., be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon. When using a self-expandable stent, a catheter with an expansion arrangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means, which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small, which makes it possible to introduce the valve prostheses through a channel in the body.

When the valve prosthesis is introduced and placed correctly, the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an outer dimension which is slightly larger than the channel in which it is placed. As the stent is elastic, a contraction of

the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made, the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention to optionally expose the body channel, e.g., a vein, through which the insertion takes place. Thus, patients for whom an operation would be associated with high risk can be offered implantation of, for instance, cardiac valves. After the implantation has taken place, the after-treatment will advantageously be shorter than normal, which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implant the valve prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves. The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the central veins in the center of the leg towards the superficial veins. Among other things, this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in a wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumors, where too much humour is produced. If the humour is able to flow from the cancerous tumor through several channels, it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prosthesis.

When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is possible to mount it in three positions, viz., in the descending part of the aorta in a position between the coronary arteries and the left ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus, the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise, the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who cannot be offered an open heart surgery, the valve prosthesis can also be used for patents in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who cannot be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof, the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.

Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prosthesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries, it is desirable that the valve prosthesis has a greater surface to distribute the outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implanting a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implanting cores in the body are known. For instance. such balloon catheters are known from U.S. Pat. Nos. 4,856,516, 4,733,665 and 4,796,629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvantageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevents a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation, any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for the catheter, X-ray supervision, injection of X-ray traceable liquids, ultrasonic measuring, etc. may be used.

DESCRIPTION OF THE DRAWINGS

The invention will now be explained in detail with reference to the accompanying schematical drawing, wherein

FIG. **1** shows a perspective view of a stent without a valve,

FIG. **2** is a perspective view of a valve prosthesis according to the invention made from the stent shown in FIG. **1** having a biological valve mounted thereon,

FIG. **3** is a partial view through the aorta illustrating a partially inflated balloon catheter,

FIG. **4** is a cross section through the embodiment shown in FIG. **9**,

FIGS. **5–7** are views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,

FIGS. **8–10** are views illustrating three possible positions of a cardiac valve prosthesis, and

FIGS. **11–12** are perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** shows a stent **1** made by support means in the form of two 0.55 mm surgical stainless steel wires **2,3**. The wires are folded in 15 loops. Three loops **4** are 14 mm in height and are intended to secure the commissural points **5** (see FIG. **2**) from a biological cardiac valve **6** which is mounted in the stent **1**. The remaining loops have a height of 8 mm. These loops form circumferentially expandable sections **25** between the commissural points **5** forming commissural supports. Each of the two folded wires **2,3** is bent to form rings **7,8** which are closed by welding the ends. The two rings are placed on top of each other as will appear from FIG. **1** and they are mutually secured by means of a number of sutures (not shown). The lower ring is circumferentially expandable at least along sections thereof which correspond to the circumferentially expandable sections **25**. By using a substantially cylindrical thread structure with projecting apices. a reduction in weight is obtained as compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve **6** was removed from a slaughtered pig of 100 kg. The valve was cleaned before mounting in the stent **1**. The cleaned valve has an outer diameter of 25–27 mm and the height of the three commissural points **5** is 8 mm. The valve **6** is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis **9** shown in FIG. **2**. The valve prosthesis produced is used for performing tests in pigs by implantation of cardiac valve prosthesis. However, the cardiac valve prosthesis for use in human beings has a corresponding form.

FIG. **3** shows a partial view through the aorta **10**. A balloon catheter **11** is introduced in the aorta according to the direction of an arrow **12**. In the Figure shown the balloon means **13** of the balloon catheter is led out of the protection cap **11**A and is partly inflated through a fluid channel **15**, which is led to the surface of the patient. The balloon means **13** constitutes a tri-sectional balloon upon which the cardiac valve prosthesis is placed. In the form shown, the cardiac valve prosthesis is expanded exactly to be in contact with the aorta **10**. The balloon means **13** is provided with three projecting beads **14** which are engaged with the one side of the cardiac valve prosthesis **9**. The blood flowing through the aorta according to the direction of an arrow **16** will thus cause the cardiac valve prosthesis **9** to abut on the beads **14** and the valve cannot be displaced in relation to the balloon means **13**. Moreover, the balloon catheter used comprises a central channel **17** to receive a guide wire **18** which is used in a way known per se for supervising the introduction of the catheter through fluoroscopi. In the shown embodiment beads **14** are only used at one side of the valve prosthesis, but, however, it will often be desirable to use the beads in pairs placed along lines parallel to the longitudinal axes **19** through the balloon means **13**. In this case the spacing of the pair of beads **14** will correspond to the height of the loops of the stent. This makes it possible to make an effective fastening of a valve prosthesis on balloon means. Moreover, the fastening on the balloon means may be provided by using balloon means with an indentation in the surface (not shown).

FIG. **4** shows a cross section through the embodiment shown in FIG. **3** illustrating the placing of the beads **14** on the tri-sectional balloon means **13**.

A balloon catheter of the above-described type which was used in tests of implanting of cardiac valve prosthesis **9** in pigs had the following dimensions. Each of the three balloons was 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons was 31 mm and in the balloon catheter used two beads **14** having a height of 3 mm were mounted on each side of the three balloons. The beads had a spacing of 15 mm. The protection cap **11**A of the balloon catheter had an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter was provided with a standard guide wire having a diameter of 0.9 mm and a length 300 cm.

FIGS. **5–7** show the valve prosthesis **9** at different steps in introducing and implanting in the aorta **10** by means of the catheter **11** having the inflatable balloon means **13**. The cardiac valve prosthesis **9** is initially placed above the deflated balloon means **13** and compressed manually around the balloon means (FIG. **5**), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning, the balloon means **13** is inflated (FIG. **6**), thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta, the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter **11** may subsequently be removed from the aorta **10** (FIG. **7**). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter **13**. When the valve prosthesis is mounted as shown in FIG. **7**, the patient will be able to resume a substantially normal life after a few days.

FIGS. **8–10** show the positioning of the valve prosthesis **9** as cardiac valve prosthesis in the aorta **10** in three different positions, i.e., in a position between the coronary arteries **20** and the left ventricle of the heart **21** (FIG. **8**), in a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (FIG. **9**), and in a position in the descending part of the aorta **10**. The positioning of the valve prosthesis is chosen in accordance with the diagnosis of the illness of the patient. By placing the cardiac valve prosthesis as shown in FIG. **8**, there is a risk of detachment and/or covering the mouth of the coronary arteries, and therefore it is preferred to use a higher stent which, for instance, comprises several ranges placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. FIGS. **8** and **9** show how a contrast medium **23** is injected by means of a so-called pigtail catheter for registration of tightness of the implanted valve prosthesis **9**.

A specific embodiment for a valve prosthesis and a balloon catheter for implanting the valve prosthesis has been explained above. However, it is obvious that it is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus, the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of

loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g., polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in FIGS. **11** and **12**. In both Figures the support means of the valve prosthesis is made of an elongated tubular means **24** having a closed cylinder surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against the wall of the channel. In FIG. **11** the valve **6** is mounted at the end of the tubular means **24**. In FIG. **12** an embodiment is shown where the valve **6** is mounted in a central position in the tubular means **24**.

An explanation of a method of implanting a valve prosthesis according to the invention is given below:

a valve prosthesis **9** made of a stent **1** and a collapsible valve **6**, as described above, is placed on a deflated balloon means and is manually compressed thereon,

the balloon means **13** and the valve prosthesis are drawn into an insertion cover **11**A,

a guide wire **18** is inserted into the left ventricle of the heart through the central opening **17** of the balloon catheter under continuous fluoroscopi,

the insertion cover **11**A conveys the guide wire **18** to a point in the channel in the immediate vicinity of the desired position of the valve prosthesis,

the balloon means **13** is pushed out of the protection cap **11**A and the valve prosthesis is positioned in the desired position if necessary by use of further registration means to ensure an accurate positioning,

the balloon means **13** is inflated with a certain overstretching of the channel,

the balloon means **13** is deflated, and

the balloon means **13**, the guide wire **18** and the protection cap **11**A are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be closed.

What is claimed is:

1. A valve prosthesis for implantation in a body channel having an inner wall, the prosthesis comprising;

a radially collapsible and expandable cylindrical stent, the stent including a cylindrical support means having a cylinder surface; and

a collapsible and expandable valve having commissural points, the valve mounted to the stent at the commissural points, wherein the stent and valve are configured to be implanted in the body by way of catheterization.

2. The valve prosthesis according to claim **1**, wherein the support means is made of thread structure.

3. The valve prosthesis according to claim **2**, wherein the thread structure comprises several spaced apices that extend from one end of the cylindrical support means in a direction along a longitudinal axis of the cylindrical support means, the commissural points of the valve being attached to the apices.

4. The valve prosthesis according to claim **3**, wherein the collapsible valve is a biologically trilobate valve.

5. The valve prosthesis according to claim **1**, wherein the stent comprises at least two closed rings, each formed from more than three loops, the rings connected one to another, and wherein three of the loops in at least one of the rings has a greater height than the remaining loops.

6. The valve prosthesis according to claim **5**, wherein each of the rings of the stent is made from a wire having a diameter of 0.05 mm and a loop height of approximately 8 mm and approximately 14 mm for the three greater height loops, and that the cylindrical wire structure produced and the collapsible valve mounted thereon in a folded state have an outer diameter of approximately 10 mm and in an expanded state an outer diameter of approximately 30 mm.

7. The valve prosthesis according to claim **5**, wherein three or more mutually attached rings placed on top of each other are used in that the stent is made to be fixed through the expansion at one point in the channel where the valve prosthesis is inserted, which point is different from the point where the valve is mounted in the stent.

8. The valve prosthesis according to claim **1**, wherein the cylinder surface of the support means is closed to form a tubular element.

* * * * *

EXHIBIT L

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MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., and MEDTRONIC VASCULAR GALWAY LTD.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., AND MEDTRONIC VASCULAR GALWAY LTD.,

Plaintiffs,

v.

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES (U.S.) INC.,

Defendants.

Case No. SACV11-00961 JVS(MLGx)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., and Medtronic Vascular Galway, Ltd. (collectively "Medtronic") for their Complaint against Defendants Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc., hereby states and alleges as follows:

I.

INTRODUCTION

1. This is an action for willful infringement by Defendants of a United States patent owned by Medtronic CoreValve LLC.

2. Plaintiff Medtronic CoreValve LLC is a limited liability company organized and existing under the laws of Delaware, with its principal place of business in Irvine, California.

3. Plaintiff Medtronic CV Luxembourg S.a.r.l. is a limited liability company organized and existing under the laws of Luxembourg, with its principal place of business in Luxembourg.

4. Plaintiff Medtronic Vascular Galway Ltd. is a company organized and existing under the laws of Ireland, with its principal place of business in Galway, Ireland.

5. Upon information and belief, Defendant Lifesciences Corporation is a corporation organized and existing under the laws of Delaware with its principal place of business in Irvine, California.

6. Upon information and belief, Defendant Edward Lifesciences LLC is a wholly-owned subsidiary of Edwards Lifesciences Corporation that is organized under the laws of Delaware with its principal place of business in Irvine, California.

7. Upon information and belief, Defendant Edwards Lifesciences (U.S.) Inc. is a wholly-owned subsidiary of Edwards Lifesciences Corporation that is organized under the laws of Delaware with its principal place of business in Irvine, California. Edwards Lifesciences Corporation, Edwards Lifesciences LLC and

Edwards Lifesciences (U.S.) Inc. are collectively hereinafter referred to as "Edwards."

II.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and § 1338(a) in that this action arises under the patent laws of the United States.

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

10. This Court has personal jurisdiction over the Defendants because, upon information and belief, Defendants conduct business within this judicial district, and have their principal places of business within this judicial district. Upon information and belief, Defendants have committed and continue to commit acts of patent infringement within this judicial district.

III.

FACTUAL BACKGROUND

11. Plaintiff Medtronic CoreValve LLC is the lawful owner of United States Patent No. 7,892,281 ("the '281 Patent"), which was duly and legally issued by the United States Patent and Trademark Office on February 22, 2011. The '281 Patent is entitled "Prosthetic Valve for Transluminal Delivery." A copy of the '281 Patent is attached hereto as Exhibit 1.

12. Plaintiff Medtronic CV Luxembourg S.a.r.l. is the exclusive licensee of the '281 Patent.

13. Plaintiff Medtronic Vascular Galway Ltd. holds world wide manufacturing and distribution rights to the '281 Patent.

14. Collectively, the Medtronic Plaintiffs own all rights, title and interests in the '281 Patent.

15. Medtronic has the exclusive right under the patent laws of the United States to exclude others from making, using, offering for sale, selling, or importing its patented invention, including the right to bring this action for injunctive relief, and accounting and damages.

IV.

COUNT I

(Claim for Patent Infringement of U.S. Patent No. 7,892,281)

16. Medtronic hereby restates and re-alleges the allegations set forth in Paragraphs 1 through 15 and incorporates them into this count by reference.

17. Upon information and belief Defendant Edwards manufactures in the Central District of California and elsewhere within the United States devices that infringe, either literally or under the Doctrine of Equivalents, one or more claims of the '281 Patent. Such devices include, but are not limited to, the Sapien Transcatheter Aortic Valve.

18. Upon information and belief, and in violation of 35 U.S.C. § 271, Edwards has been and is now infringing the '281 patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve devices covered by one or more claims of the '281 patent, including without limitation the Sapien Transcatheter Aortic Valve.

19. Edwards' foregoing infringement has been willful, warranting a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285.

20. The unlawful infringing activities by Defendant Edwards are continuing and will continue unless enjoined by this Court.

21. As a result of the infringing acts herein described, Medtronic has sustained damages and will continue to sustain damages in the future, including irreparable harm, unless Defendant Edwards is enjoined from infringing said patent.

V.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Medtronic prays for judgment against Defendants as follows:

1. That Defendants have infringed, either literally or under the Doctrine of Equivalents, one or more claims of the '281 Patent;

2. That Defendants' infringement has been willful and trebling the award of damages;

3. That Defendants, and their respective agents, servants, officers, directors, employees and all persons acting in concert with them, directly or indirectly, be permanently enjoined from infringing the '281 Patent;

4. That Defendants account for and pay to Plaintiff damages adequate to compensate them for Defendants' infringement, in an amount to be proven at trial, together with interest and costs as fixed by the Court;

5. Declaring that this case is exceptional and awarding Plaintiff its costs and attorneys' fees in accordance with 35 U.S.C. § 285; and

6. That Plaintiff be awarded such other and further relief as the Court may deem just and equitable.

Dated: June 24, 2011

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

By: /s/ David Martinez

David Martinez
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Lauren Wood

Attorneys for Plaintiffs MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., and MEDTRONIC VASCULAR GALWAY LTD.

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.
ATTORNEYS AT LAW
LOS ANGELES

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all matters so triable.

Dated: June 24, 2011

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

By: David Martinez / ATTNEY
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Jan Conlin
Stacie Oberts
Lauren Wood

Attorney for Plaintiffs MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., and MEDTRONIC VASCULAR GALWAY LTD.

EXHIBIT 1

US007892281B2

(12) **United States Patent**
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(54) **PROSTHETIC VALVE FOR TRANSLUMINAL DELIVERY**

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See application file for complete search history.

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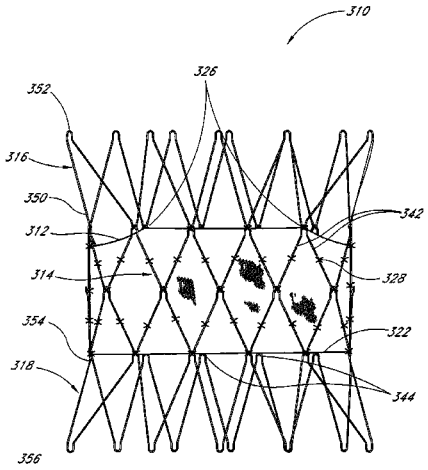
(57) **ABSTRACT**

A prosthetic valve assembly for use in replacing a deficient native valve comprises a replacement valve supported on an expandable valve support. If desired, one or more anchor may be used. The valve support, which entirely supports the valve annulus, valve leaflets, and valve commissure points, is configured to be collapsible for transluminal delivery and expandable to contact the anatomical annulus of the native valve when the assembly is properly positioned. The anchor engages the lumen wall when expanded and prevents substantial migration of the valve assembly when positioned in place. The prosthetic valve assembly is compressible about a catheter, and restrained from expanding by an outer sheath. The catheter may be inserted inside a lumen within the body, such as the femoral artery, and delivered to a desired location, such as the heart. When the outer sheath is retracted, the prosthetic valve assembly expands to an expanded position such that the valve and valve support expand within the deficient native valve, and the anchor engages the lumen wall.

15 Claims, 25 Drawing Sheets



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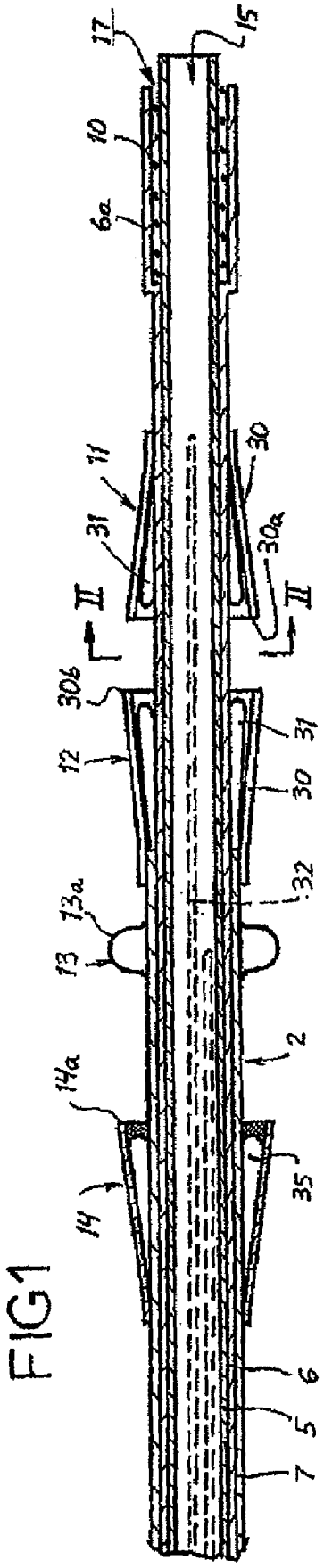


FIG1

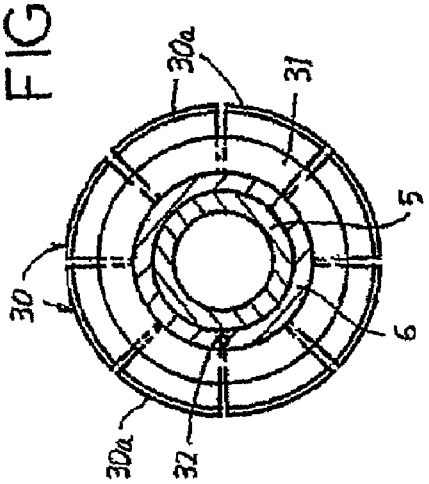


FIG 3

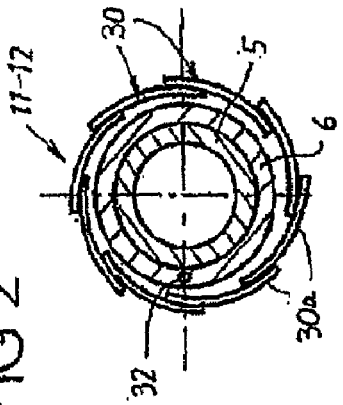


FIG 2

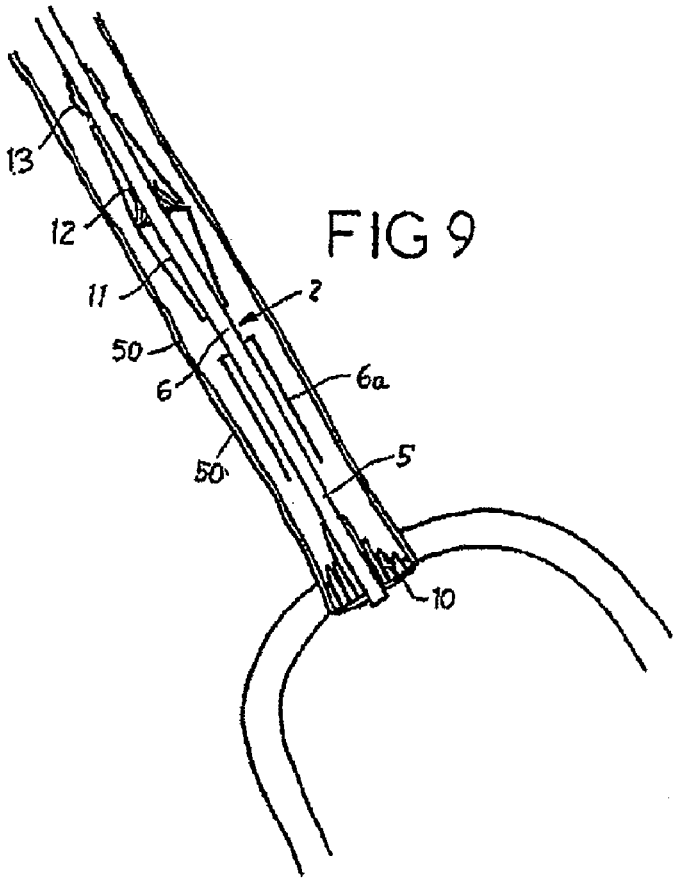


FIG 9

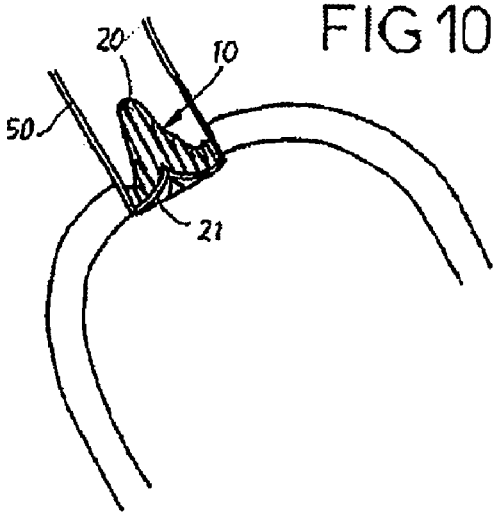
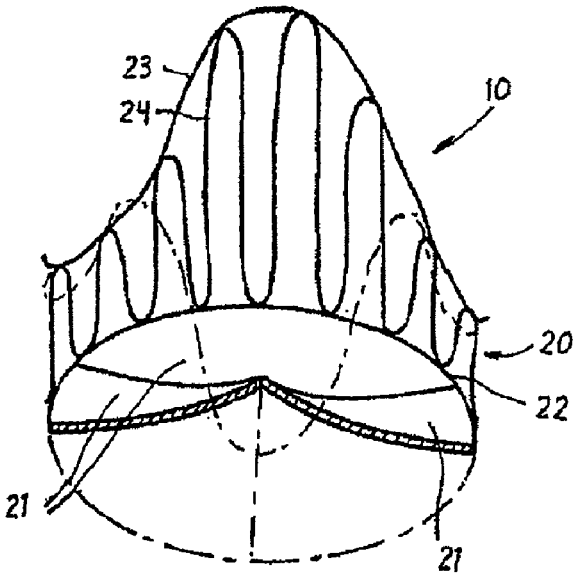


FIG 10

FIG 4



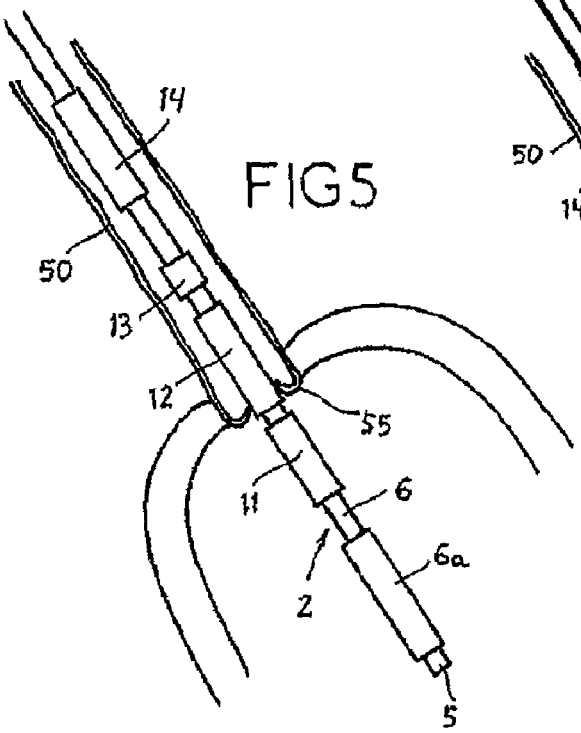


FIG5

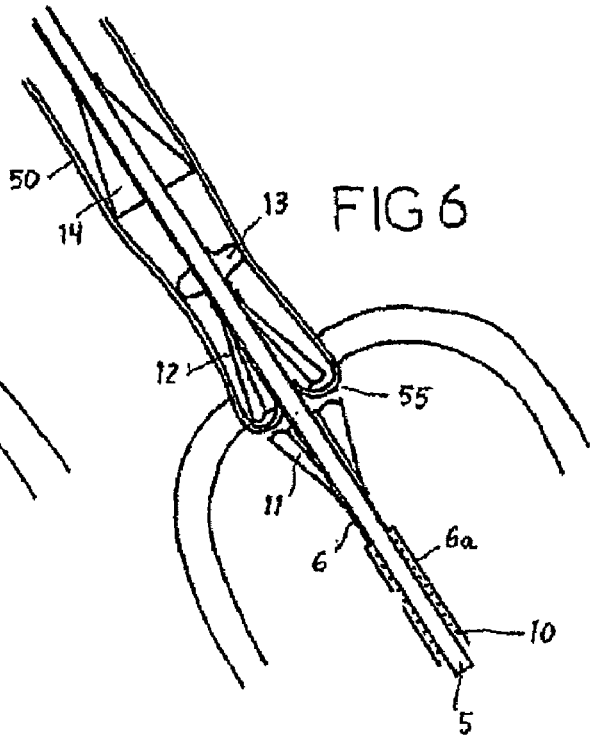


FIG 6

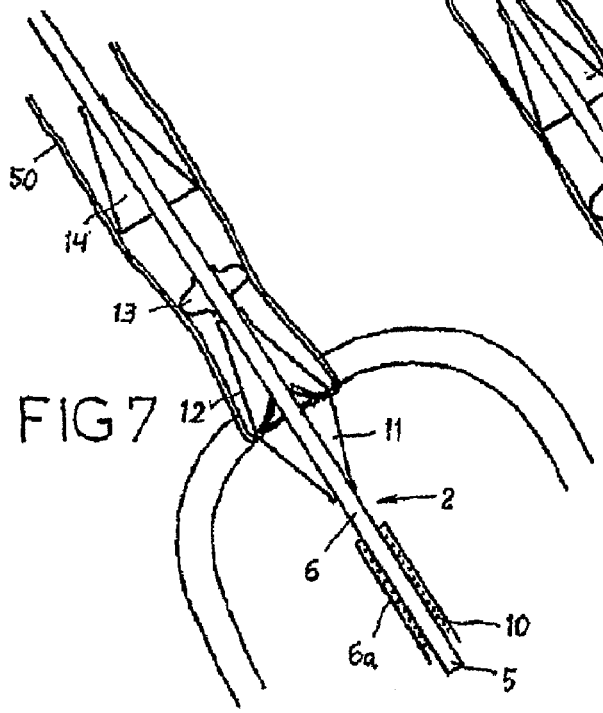


FIG 7

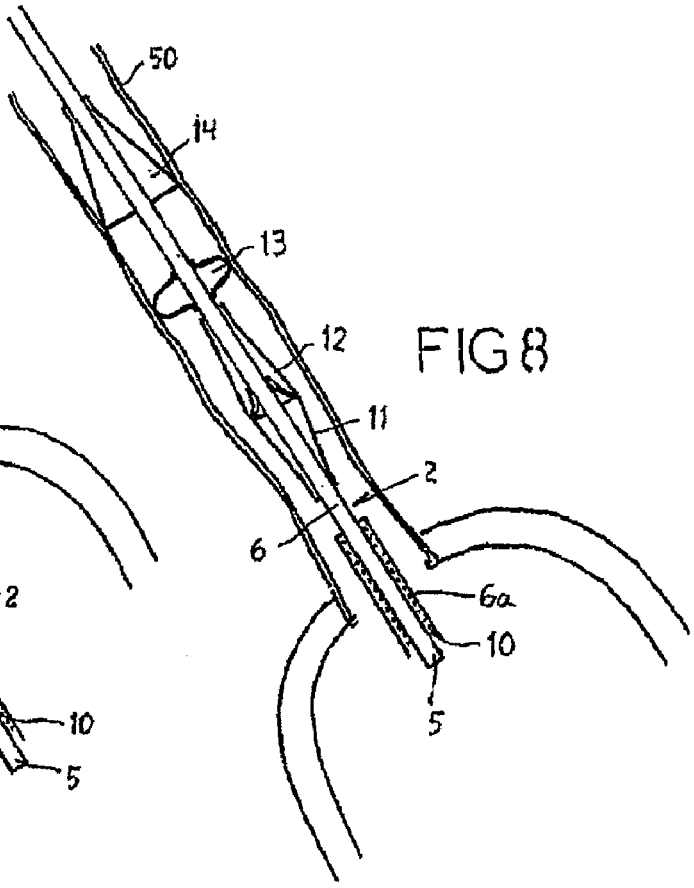


FIG 8

FIG 11

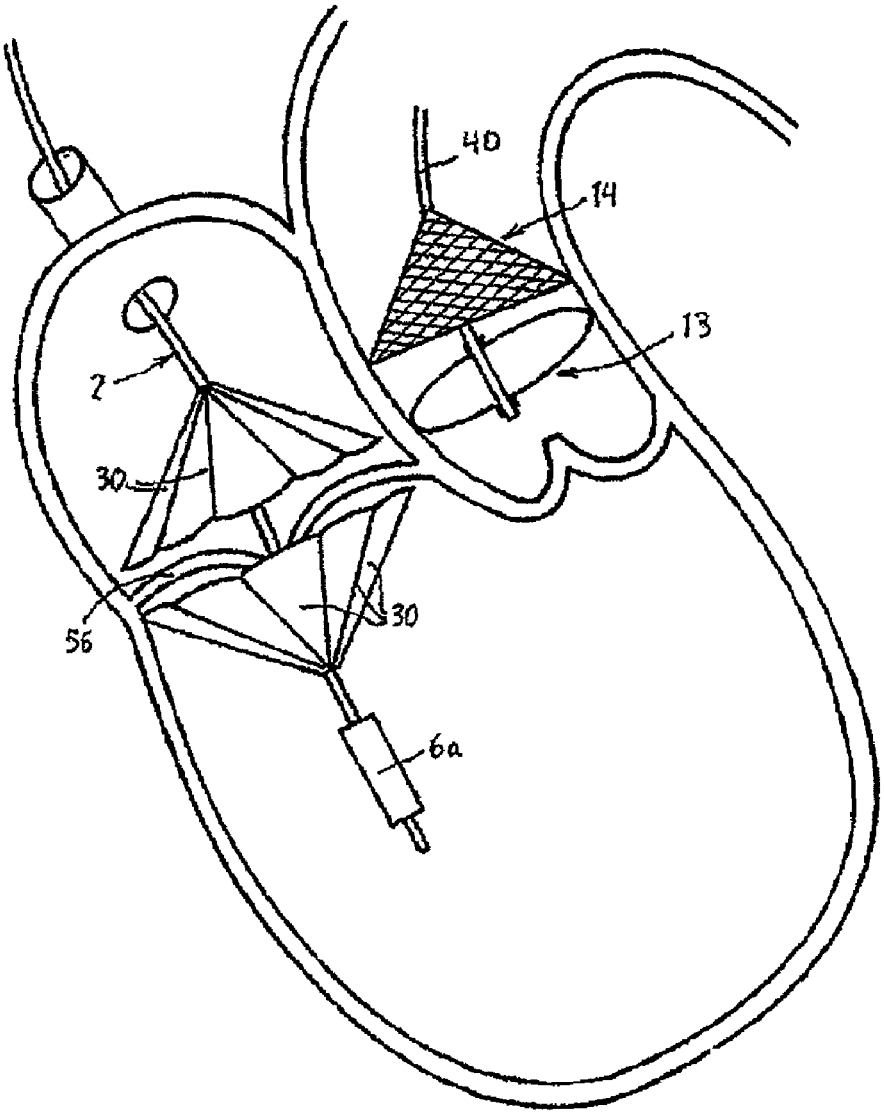
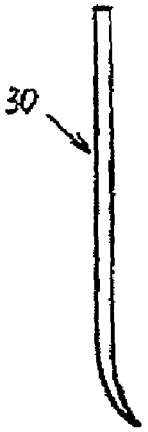


FIG 12



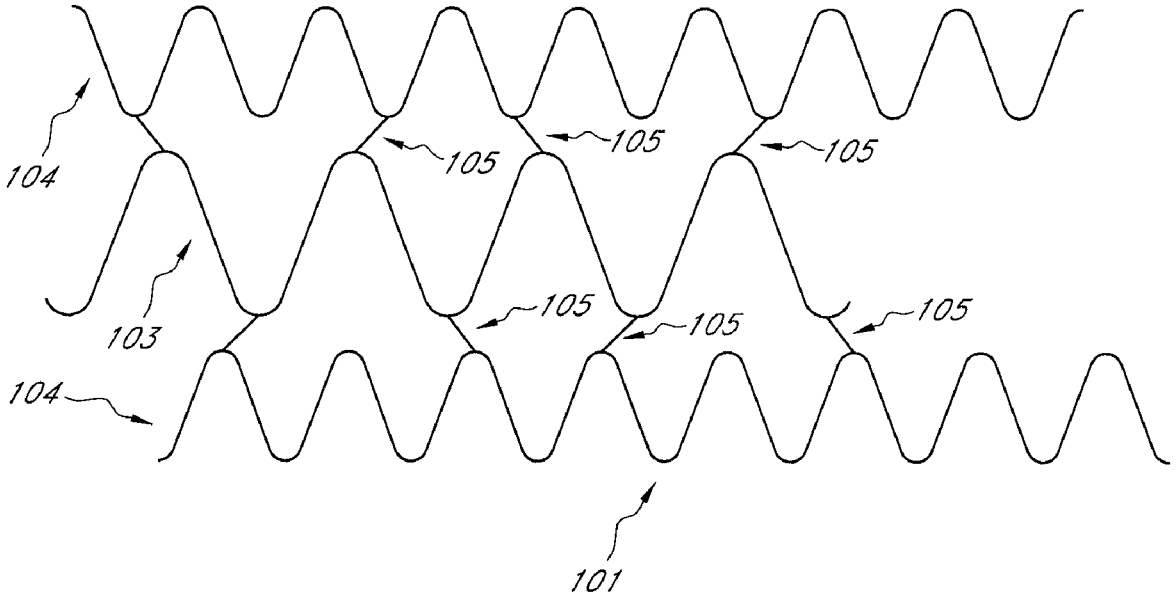

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FIG. 13

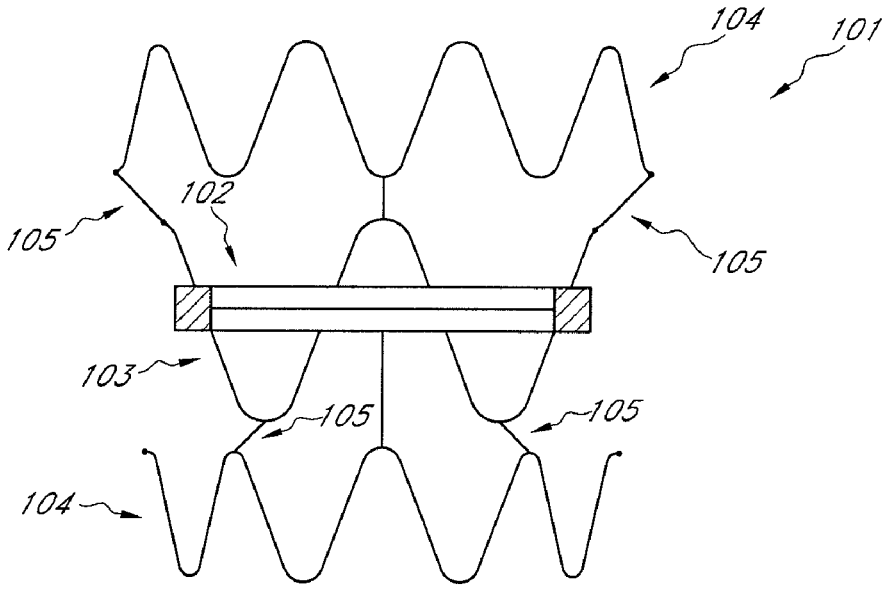
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FIG. 14

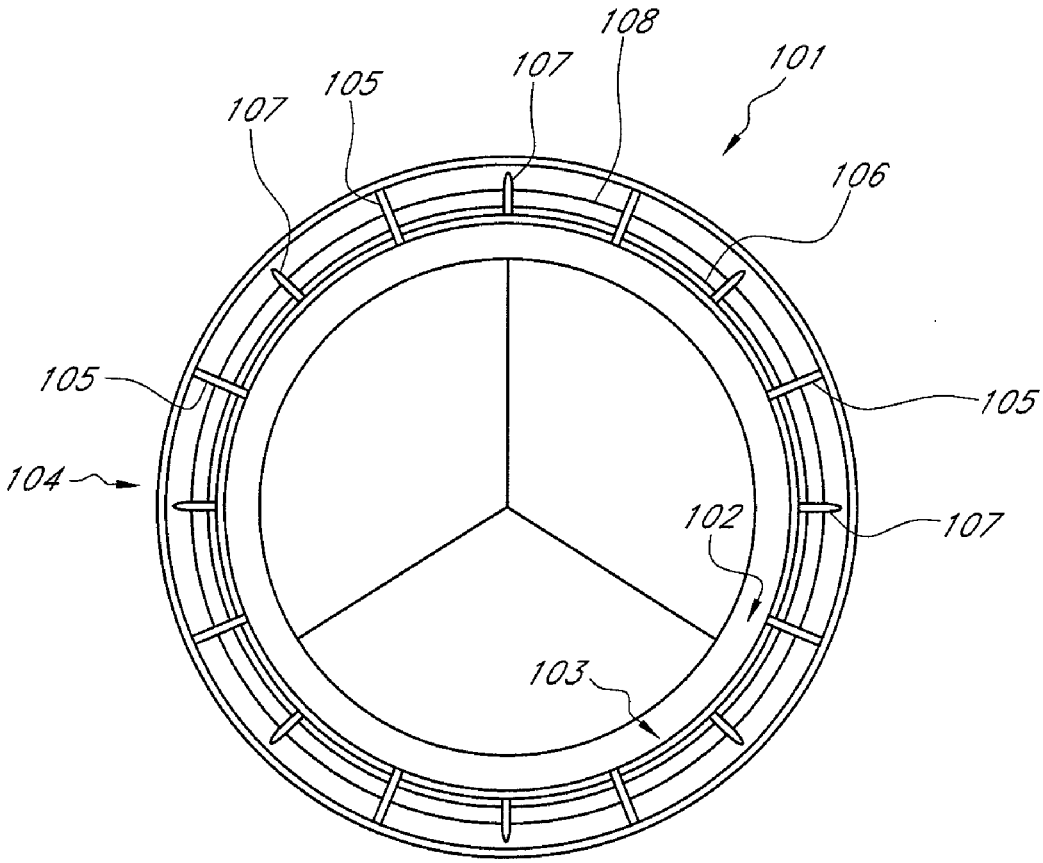
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FIG. 15

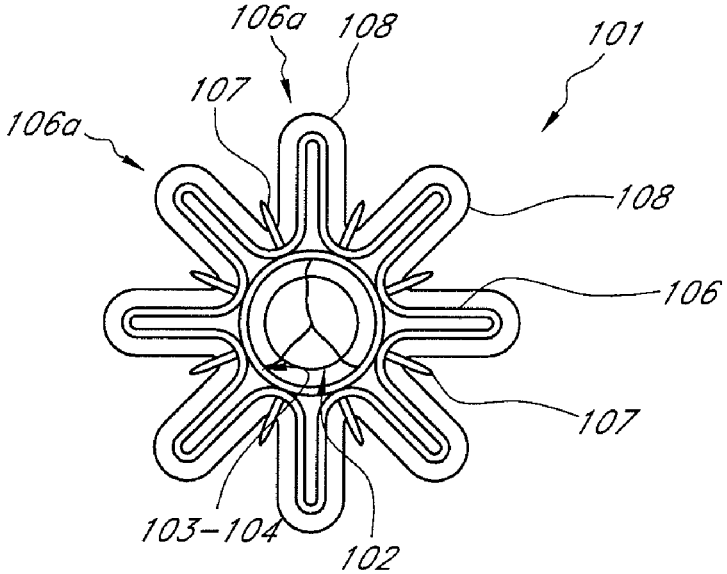
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FIG. 16

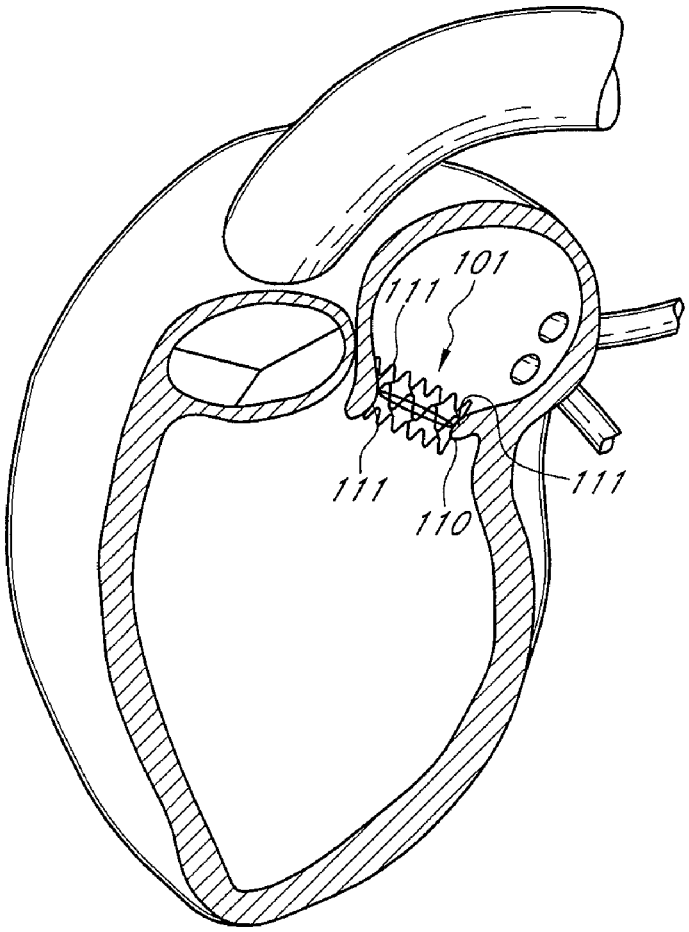

FIG. 17

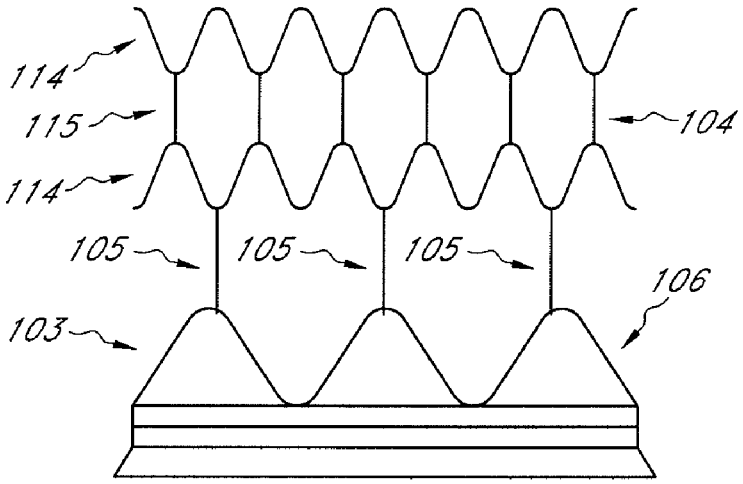

FIG. 18

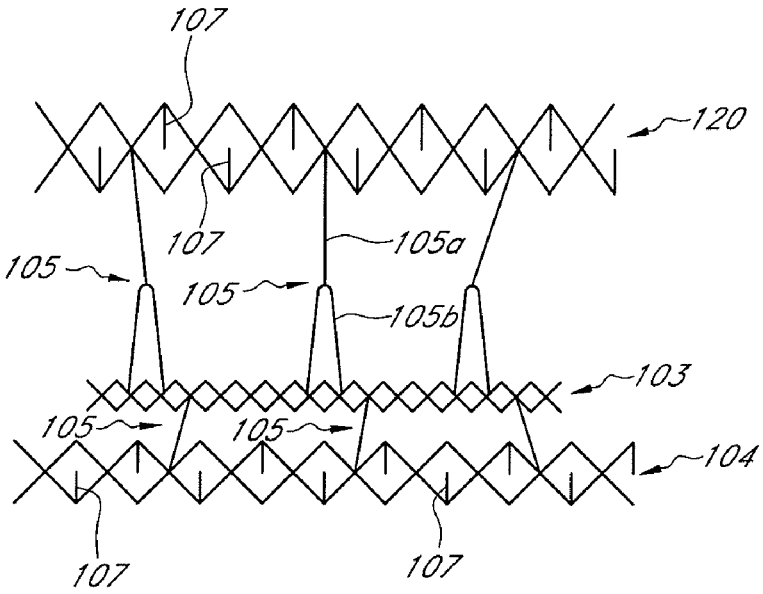
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FIG. 19

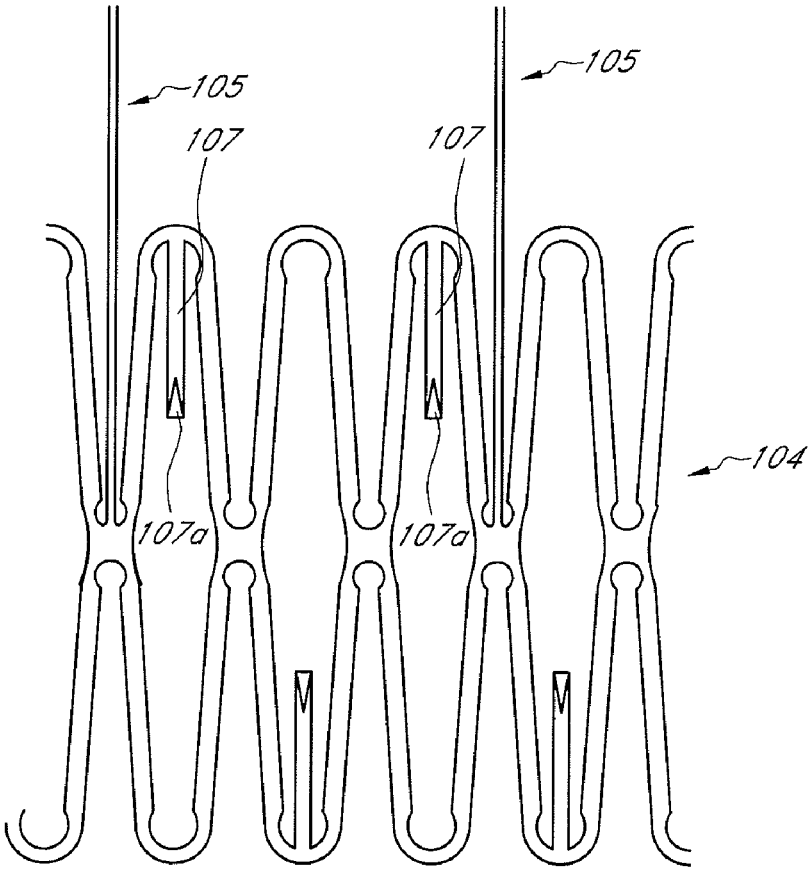
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FIG. 20

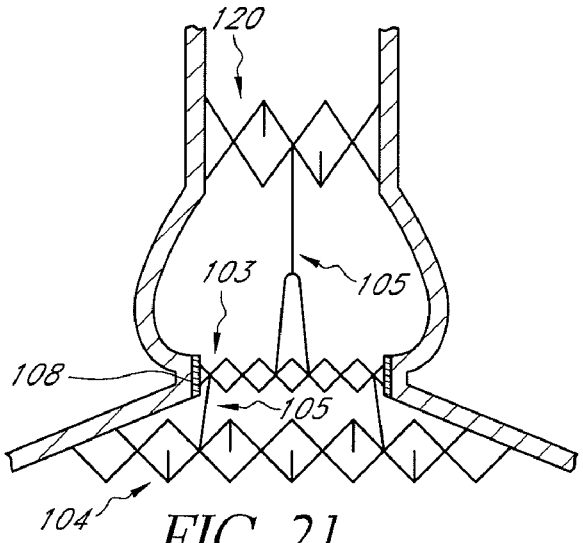
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FIG. 21

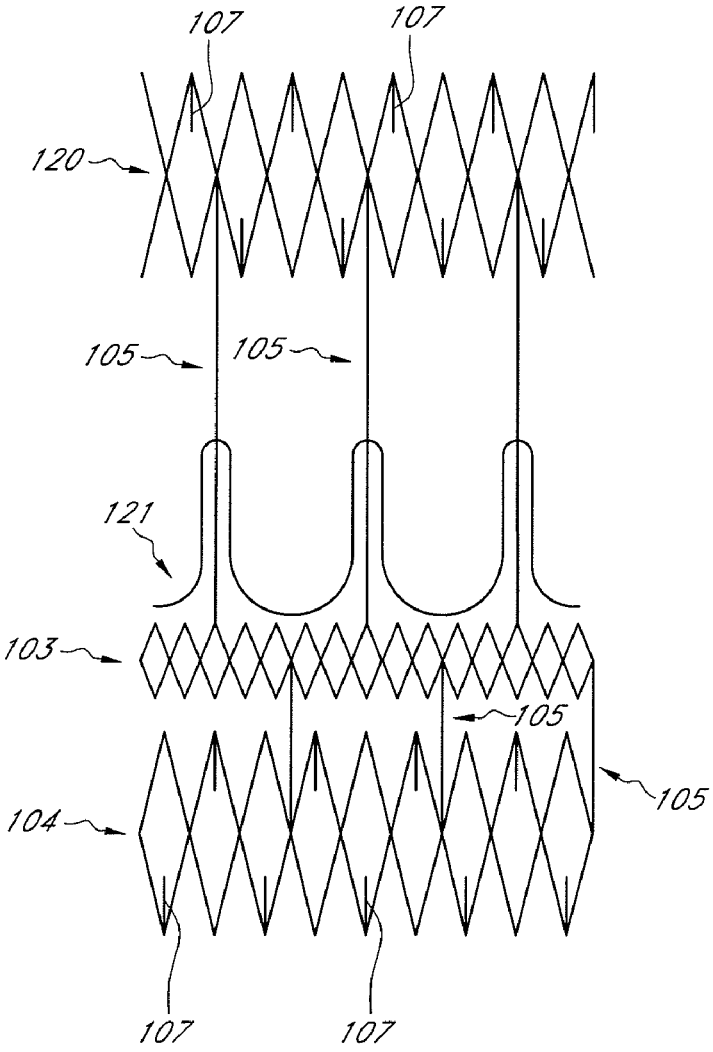
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FIG. 22