EXHIBIT A

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
COREVALVE, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Edwards Lifesciences AG ("Edwards AG") and Edwards Lifesciences LLC ("Edwards LLC") (collectively, "Plaintiffs"), for their Complaint against Defendant CoreValve, Inc. ("CoreValve"), 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), because CoreValve resides in this Judicial District.

THE PARTIES

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 Patents covering pioneering percutaneous heart valve products and methods of their use: U.S. Patent

No. 5,411,552, U.S. Patent No. 6,168,614, and U.S. Patent No. 6,582,462 (collectively, "Patents"). The Patents disclose and claim, *inter alia*, collapsible and expandable tissue valve prostheses and methods for replacing 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.

6. Upon information and belief, Defendant 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.

7. Upon information and belief, CoreValve manufactures in the United States heart valve prostheses known as the "ReValving" system that infringe the Patents.

8. Upon information and belief, CoreValve has obtained European CE mark approval for its ReValving heart valve prostheses, and is currently offering its ReValving system for commercial sale in Europe.

FIRST CAUSE OF ACTION
(For Infringement of the '552 Patent)

9. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 8 above.

10. On May 2, 1995, U.S. Patent No. 5,411,552 ("'552 Patent") (Exh. 1 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.

11. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the '552 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '552 Patent, including without limitation products designated as the ReValving system.

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

13. Plaintiffs have been damaged and will be irreparably injured by CoreValve's continuing infringement, for which Plaintiffs have no adequate remedy at law. CoreValve's infringing activities will continue unless enjoined by this Court.

SECOND CAUSE OF ACTION
(For Infringement of the '614 Patent)

14. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 13 above.

15. On January 2, 2001, U.S. Patent No. 6,168,614 ("'614 Patent") (Exh. 2 hereto), entitled "Valve Prosthesis for Implantation in the Body," 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 '614 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '614 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

16. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the '614 Patent by supplying or causing to be supplied

in or from the United States a component of the invention claimed in the '614 Patent, including without limitation supplying the ReValving system, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the '614 Patent if such combination occurred in the United States.

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

18. Plaintiffs have been damaged and will be irreparably injured by CoreValve's continuing infringement, for which Plaintiffs have no adequate remedy at law. CoreValve's infringing activities will continue unless enjoined by this Court.

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

19. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 18 above.

20. On June 24, 2003, U.S. Patent No. 6,582,462 ("'462 Patent") (Exh. 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 sublicensee 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.

21. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the '462 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '462 Patent, including without limitation products designated as the ReValving system.

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

23. Plaintiffs have been damaged and will be irreparably injured by CoreValve's continuing infringement, for which Plaintiffs have no adequate remedy at law. CoreValve's infringing activities will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand judgment as follows:

(a) Finding that CoreValve has infringed the '552 Patent, the '614 Patent and the '462 Patent;

(b) Finding that CoreValve's infringement has been willful and deliberate;

(c) Preliminarily and permanently enjoining and restraining CoreValve, its 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 one or more of them, and their successors and assigns, from infringing, contributing to the infringement of, or inducing others to infringe the '552 Patent, the '614 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;

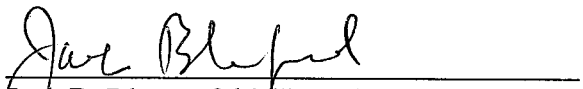
(f) Awarding Plaintiffs their reasonable attorneys' fees and their costs and disbursements in this action, as provided by 35 U.S.C. § 285; and

(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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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February 12, 2008

EXHIBIT 1

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**

[76] Inventors: **Henning R. Andersen**, Dalvangen 37A, DK-8270 Hoejbjerg; **John M. Hasenkam**, Aprilvej 8, DK-8210 Aarhus V; **Lars L. Knudsen**, RudolfWulffsgade 6,4.mf., DK-8000 Aarhus C, all of Denmark

[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

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,671,979	6/1972	Moulopoulos .	
4,038,703	8/1977	Bokros	623/2
4,056,854	11/1977	Boretos et al.	623/2
4,106,129	8/1978	Carpentier et al.	623/2
4,297,749	11/1981	Davis et al.	623/2
4,343,048	8/1982	Ross .	
4,733,665	3/1988	Palmaz	606/108
4,856,516	8/1989	Hillstead	604/194
5,037,434	8/1991	Lane	623/2
5,163,953	11/1992	Vince	623/2

FOREIGN PATENT DOCUMENTS

0357003	3/1990	European Pat. Off.	623/900
1271508	11/1986	U.S.S.R.	623/2
1371701	2/1988	U.S.S.R.	623/2

OTHER PUBLICATIONS

Derwent Abstract No. 87-190867/27 (1987), SU 1271508 (Gorkii Kirov Medical Ins.).

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

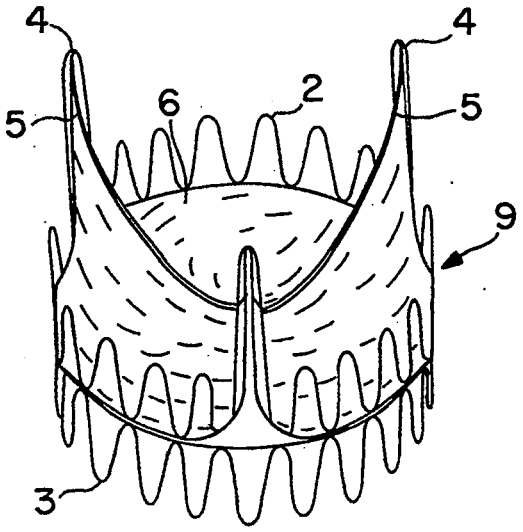
[57] **ABSTRACT**

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



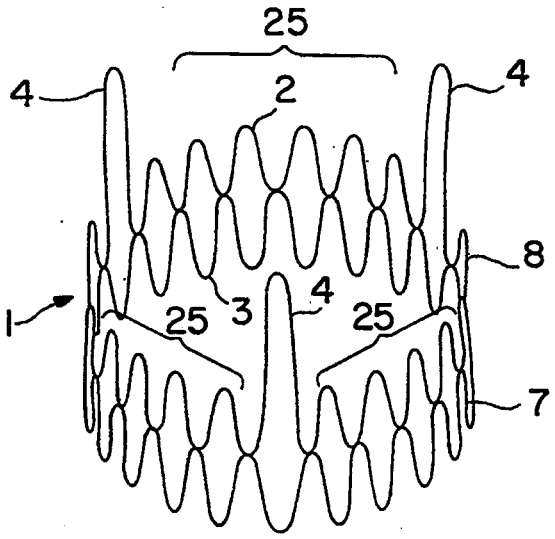


FIG. 1

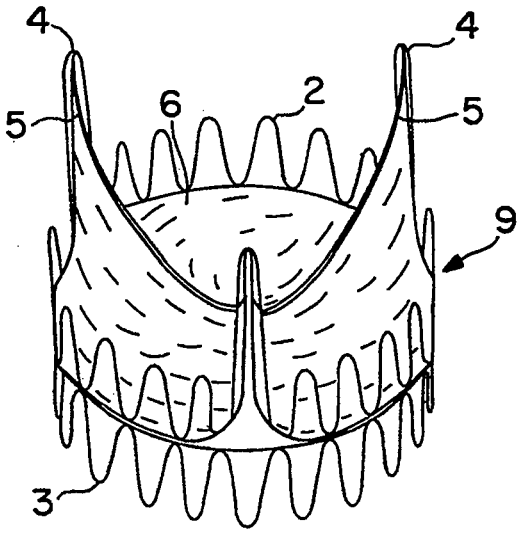


FIG. 2

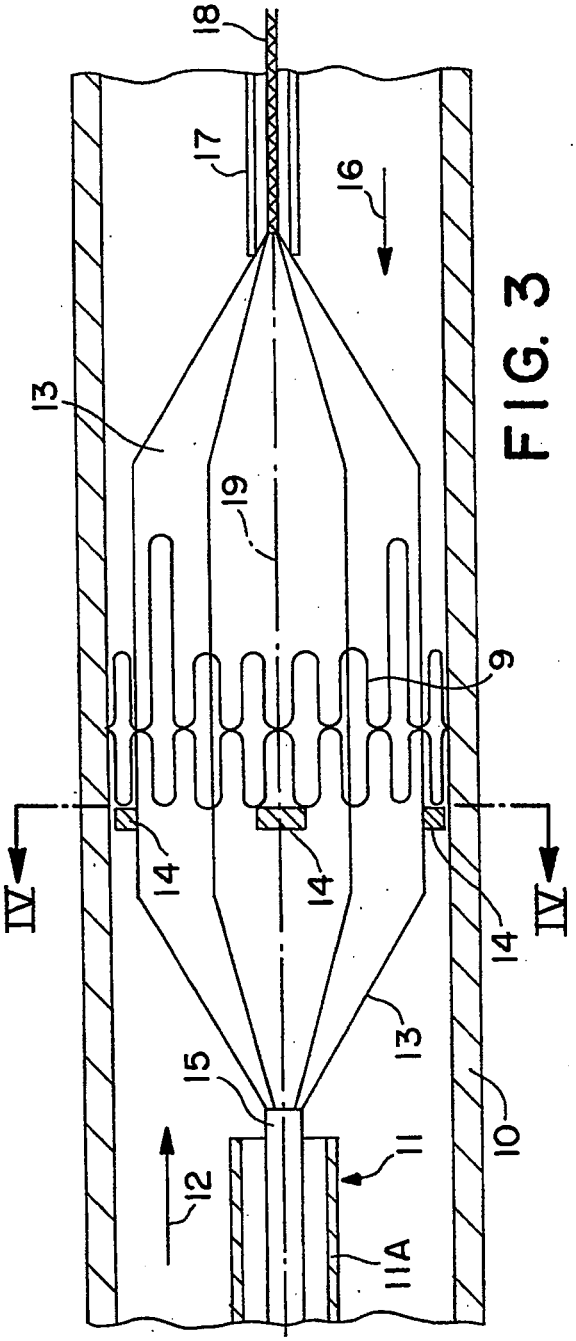


FIG. 3

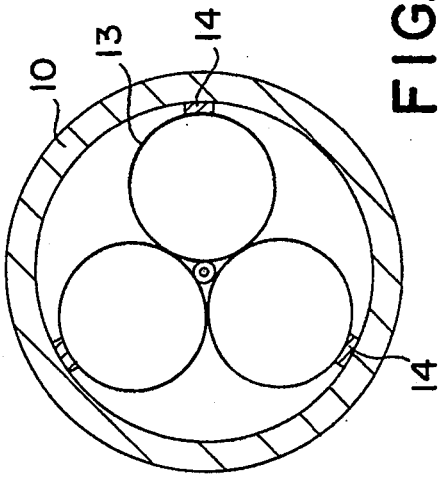


FIG. 4

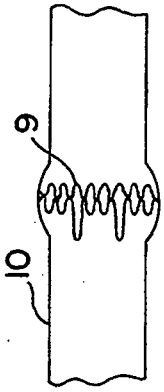


FIG. 7

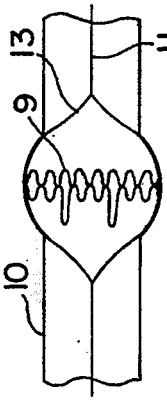


FIG. 6

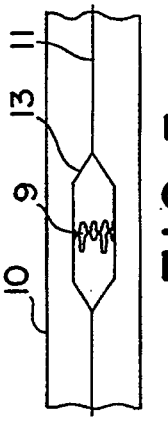


FIG. 5

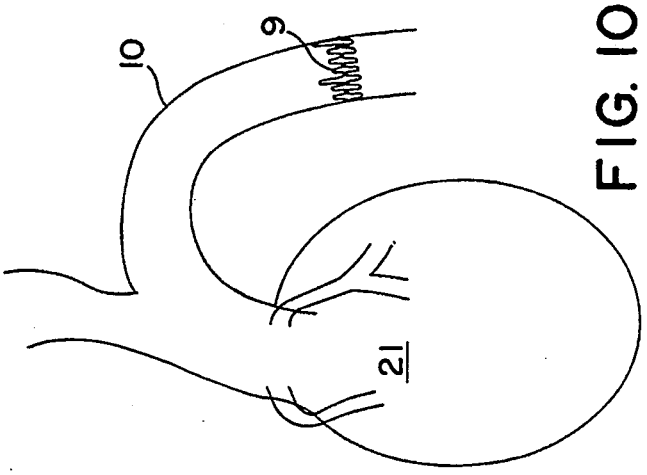


FIG. 10

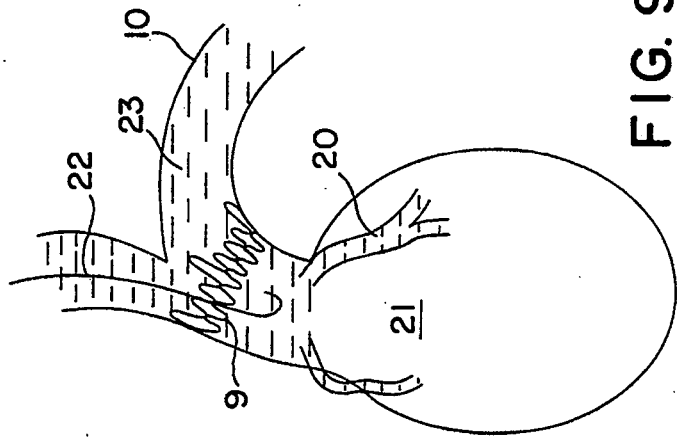


FIG. 9

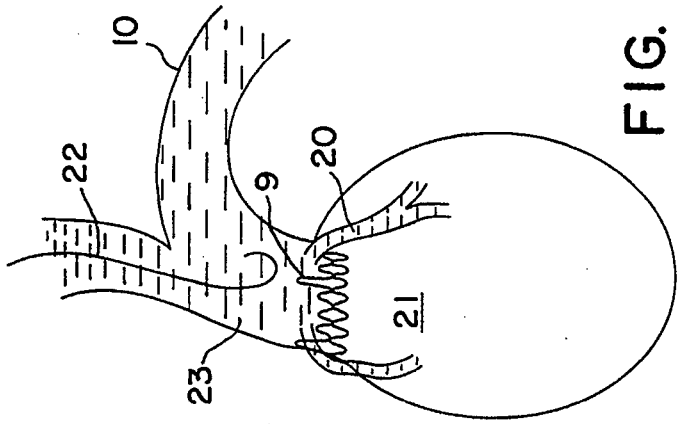


FIG. 8

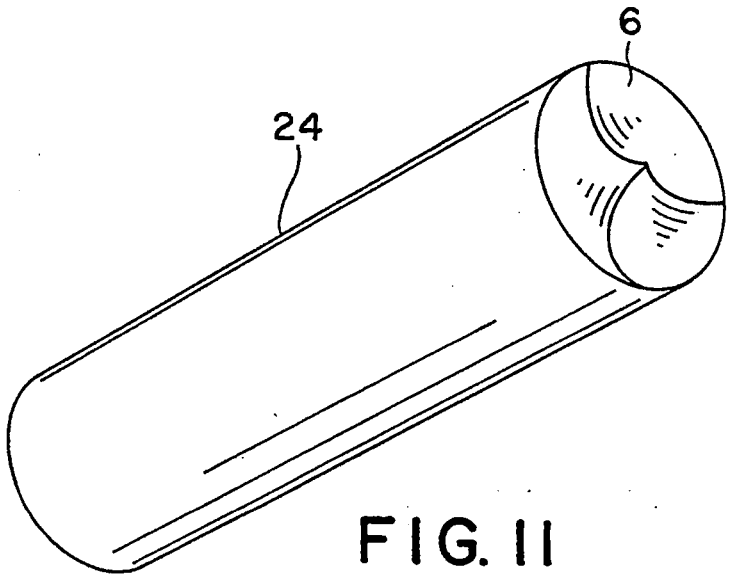


FIG. 11

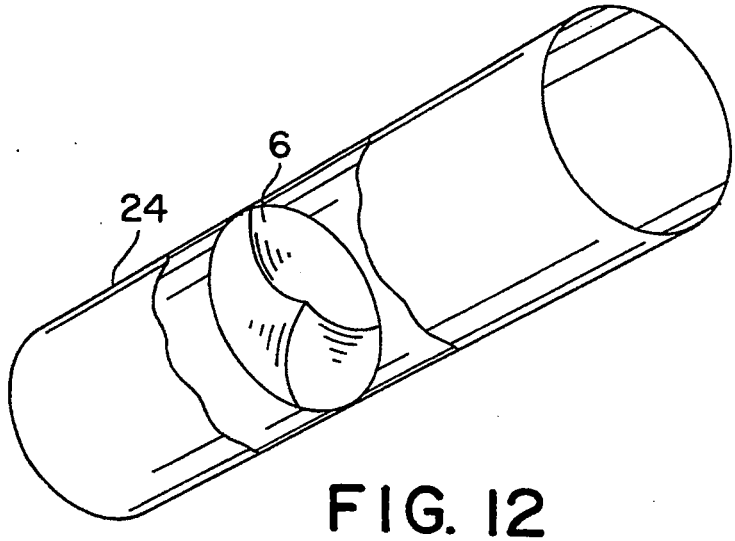


FIG. 12

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 2

US006168614B1

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

(10) **Patent No.: US 6,168,614 B1**
(45) **Date of Patent: *Jan. 2, 2001**

(54) **VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY**

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(73) Assignee: **Heartport, Inc.**, Redwood City, CA (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Under 35 U.S.C. 154(b), the term of this patent shall be extended for 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/026,574**

(22) Filed: **Feb. 20, 1998**

Related U.S. Application Data

(62) 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. 08/352,127, filed on Dec. 1, 1994, now abandoned, which is a division of application No. 08/261,235, filed as application No. PCT/DK91/00134 on May 16, 1991.

(30) **Foreign Application Priority Data**

May 18, 1990 (DK) 1246-90

(51) **Int. Cl.**[7] **A61F 2/06**

(52) **U.S. Cl.** **623/1**; 623/2; 623/12; 623/900

(58) **Field of Search** 623/1, 2, 12, 11, 623/900

(56) **References Cited**

U.S. PATENT DOCUMENTS

Re. 33,258	7/1990	Onik .
3,409,013	11/1968	Berry .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

2246526	3/1973	(DE) .
0103546	3/1984	(EP) .
0350302	1/1990	(EP) .

(List continued on next page.)

OTHER PUBLICATIONS

Yamaguchi, Case Description, "A Case of a Reoperation Using a Ballon Catheter with Blocked Pars Ascendes Aortae," *Kyobu Geka*, 1989;42(11):961–964.

"Valvular Heart Disease," Sixteenth Ed. of *The Merck Manual of Diagnosis and Therapy*, 1992, pp.546–553.

Primary Examiner—Jeffrey A. Smith
(74) *Attorney, Agent, or Firm*—Jens E. Hoekendijk; Michael J. Lynch

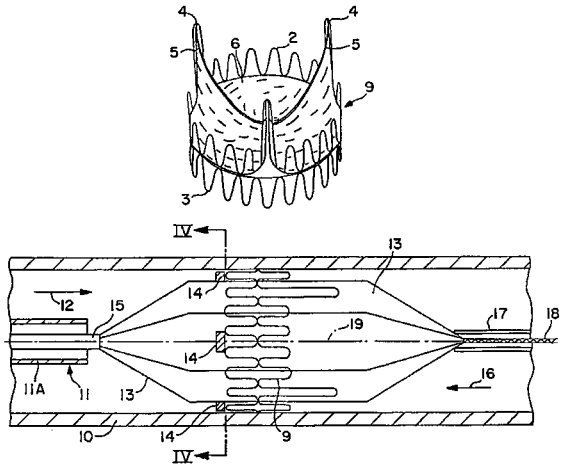
(57) **ABSTRACT**

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 (**6**) is mounted on the stent as the commissural points (**5**) of the valve (**6**) is 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 the 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.

25 Claims, 4 Drawing Sheets



U.S. PATENT DOCUMENTS

3,587,115		6/1971	Shiley .	
3,657,744	*	4/1972	Ersek .	
3,671,979		6/1972	Moulopoulos .	
3,714,671	*	2/1973	Edwards et al.	623/900 X
3,755,823		9/1973	Hancock .	
4,035,849	*	7/1977	Angell et al. .	
4,056,854	*	11/1977	Boretos .	
4,106,129	*	8/1978	Carpentier et al. .	
4,222,126		9/1980	Boretos et al. .	
4,297,749		11/1981	Davis et al. .	
4,339,831	*	7/1982	Johnson .	
4,343,048		8/1982	Ross et al. .	
4,470,157	*	9/1984	Love .	
4,574,803		3/1986	Storz .	
4,592,340		6/1986	Boyles .	
4,612,011		9/1986	Kautzky .	
4,655,771	*	4/1987	Wallsten .	
4,733,665		3/1988	Palmaz .	
4,777,951		10/1988	Cribier et al. .	
4,787,899		11/1988	Lazarus .	
4,787,901		11/1988	Baykut .	
4,796,629		1/1989	Grayzel .	
4,878,495		11/1989	Grayzel .	
4,878,906	*	11/1989	Lindemann et al.	623/1
4,883,458		11/1989	Shiber .	
4,966,604		10/1990	Reiss .	
4,979,939		12/1990	Shiber .	
4,986,830		1/1991	Owens et al. .	
4,994,077		2/1991	Dobben .	
5,007,896		4/1991	Shiber .	
5,026,366		6/1991	Leckrone .	
5,032,128		7/1991	Alonso .	
5,037,434		8/1991	Lane .	
5,047,041		9/1991	Samuels .	
5,059,177		10/1991	Towne et al. .	
5,085,635		2/1992	Cragg .	
5,089,015		2/1992	Ross .	
5,152,771		10/1992	Sabbaghian et al. .	
5,163,953		11/1992	Vince .	
5,167,628		12/1992	Boyles .	
5,295,958		3/1994	Shturman .	
5,397,351		3/1995	Pavcnik et al. .	
5,411,552		5/1995	Andersen et al. .	
5,443,446		8/1995	Shturman .	
5,480,424		1/1996	Cox .	
5,545,209		8/1996	Roberts et al. .	
5,840,081	*	11/1998	Andersen et al.	623/2

FOREIGN PATENT DOCUMENTS

2056023	3/1981	(GB) .
1271508	11/1986	(SU) .
97/17720	11/1991	(WO) .
92/17118	10/1992	(WO) .

* cited by examiner

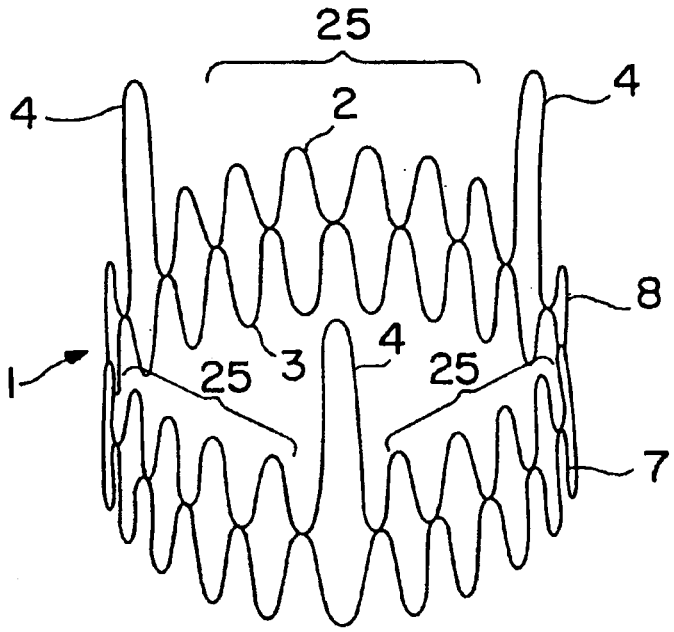


FIG. 1

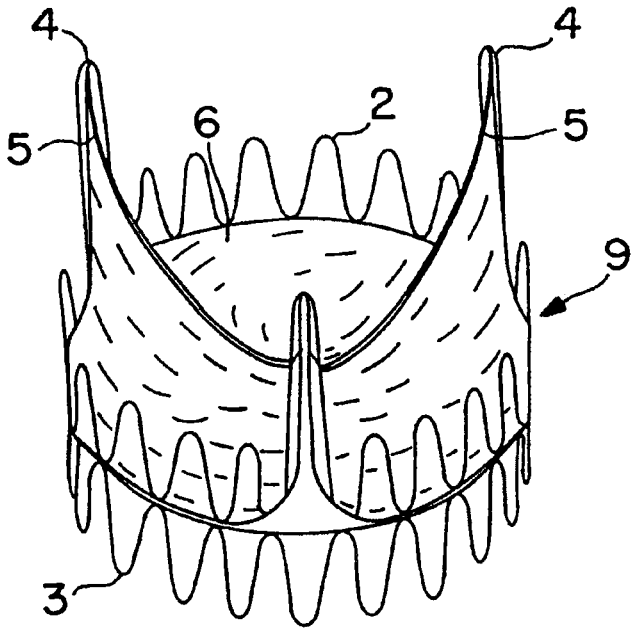


FIG. 2

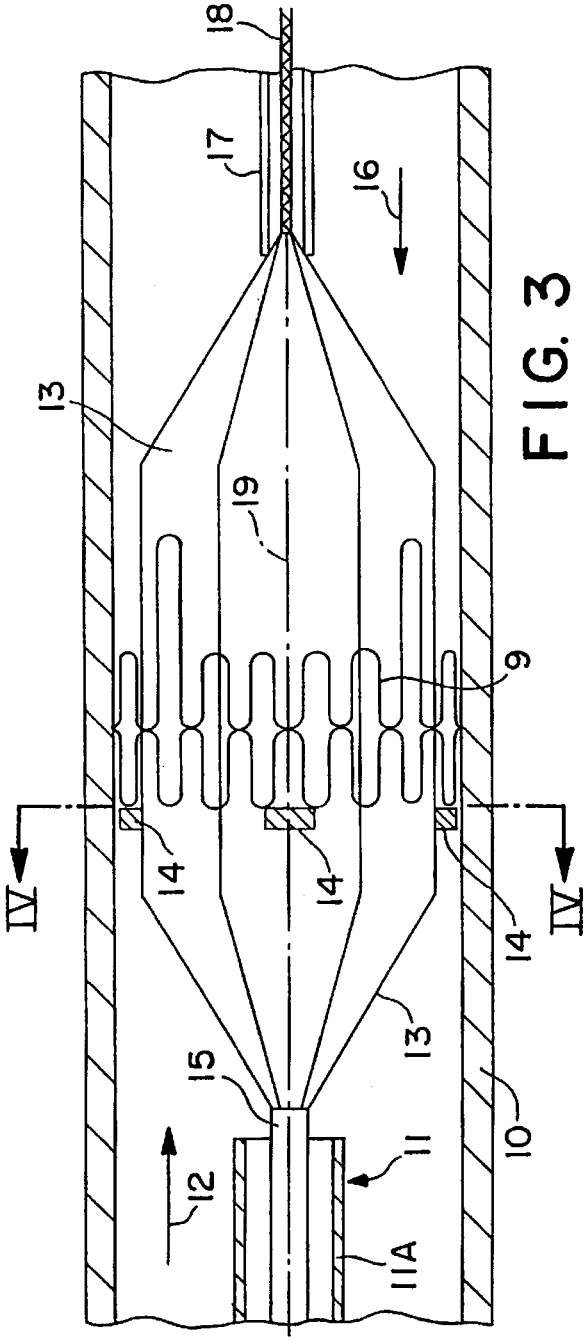


FIG. 3

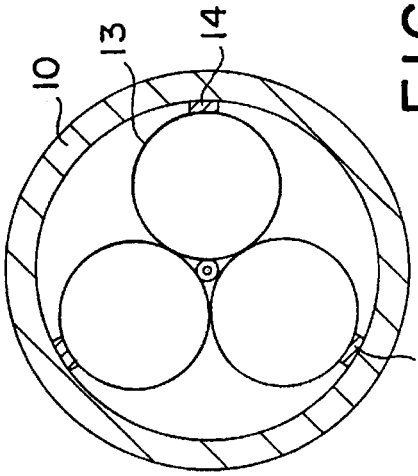


FIG. 4

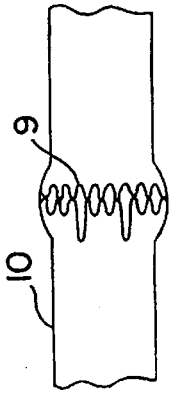


FIG. 7

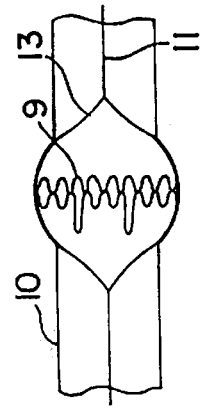


FIG. 6

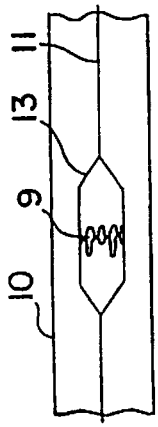


FIG. 5

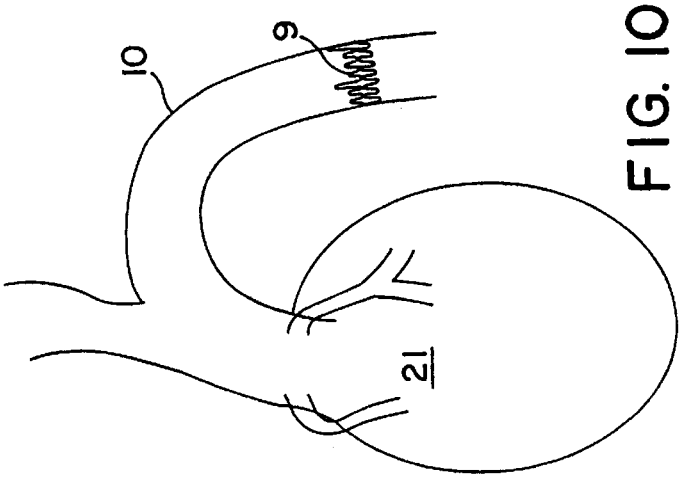


FIG. 10

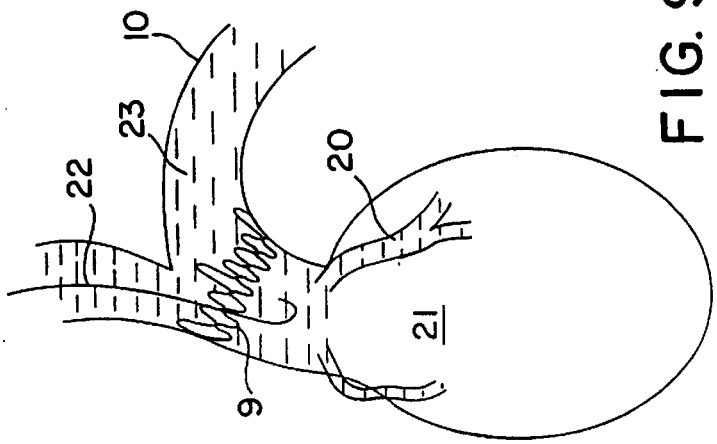


FIG. 9

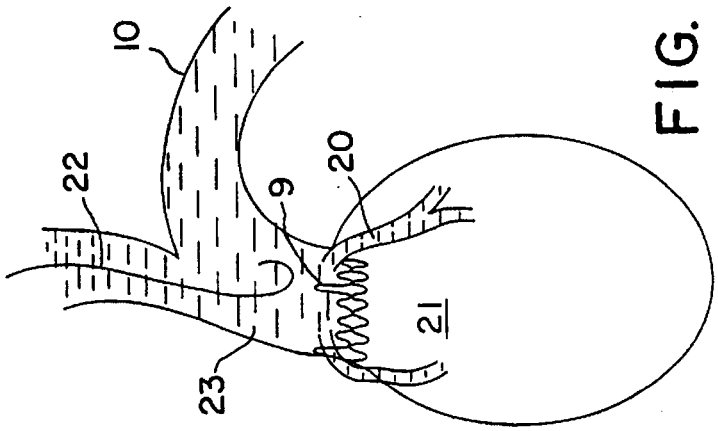


FIG. 8

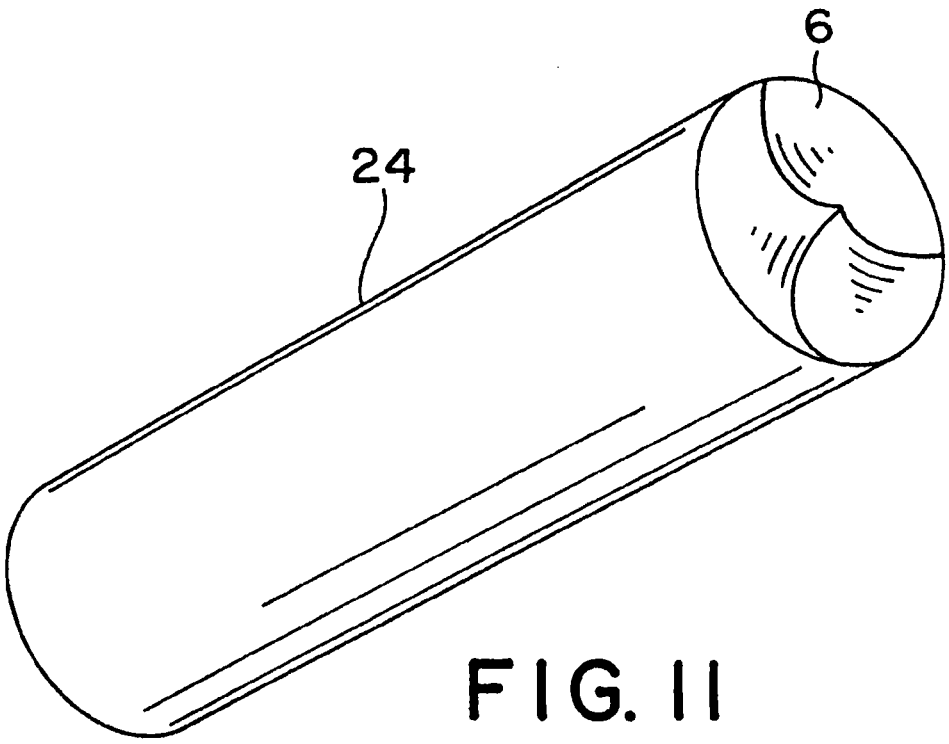


FIG. 11

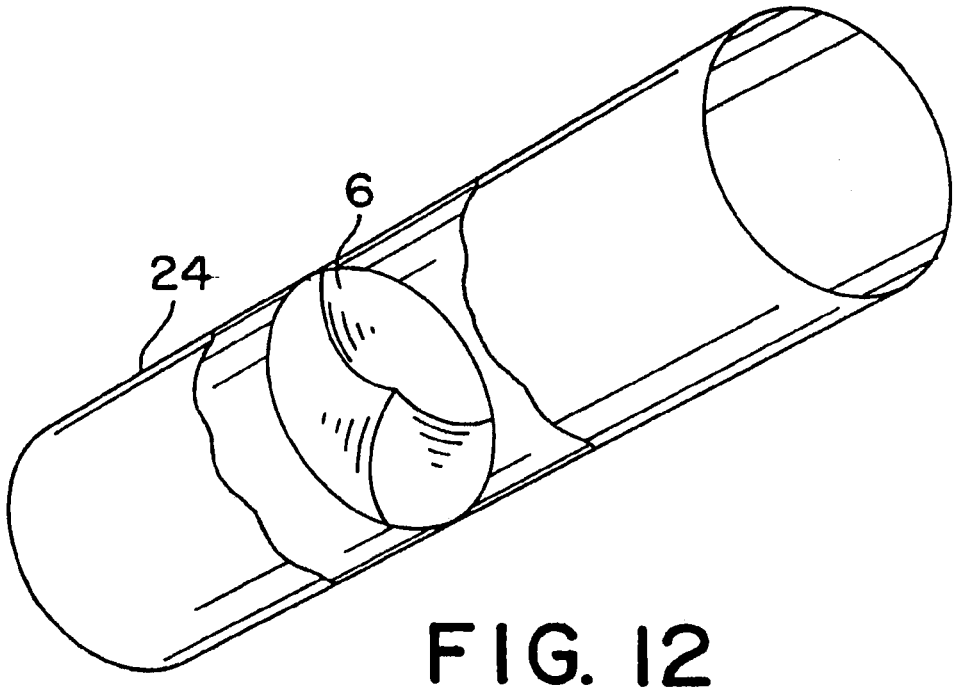


FIG. 12

VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY

CROSS REFERENCE TO RELATED APPLICATION

This application 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. 08/352,127, filed Dec. 1, 1994, now abandoned, which is a divisional of Ser. No. 08/261,235, filed Jun. 14, 1994, now U.S. Pat. No. 5,411,552 which is a 371 of 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 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 **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 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 **22** 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 method of endovascularly delivering a valve through a blood vessel, comprising the step of:

providing a tissue valve and a support structure, the support structure being movable from a collapsed shape to an expanded shape, the tissue valve being configured to permit blood flow in a direction and prevent blood flow in an opposite direction;

connecting the tissue valve to the support structure;

passing the support structure through a blood vessel with the support structure in the collapsed position; and

securing the tissue valve and the support structure to a desired valve location with the support structure in the expanded shape.

2. The method of claim **1**, wherein:

the providing step is carried out with the support structure comprising a ring.

3. The method of claim **2**, wherein:

the providing step is carried out with the ring being a cylinder.

4. The method of claim **2**, wherein:

the providing step is carried out with the support structure having at least one commissure support extending outwardly from the ring.

5. The method of claim **4**, wherein:

the providing step is carried out with the support structure comprising a wire.

6. The method of claim **5**, wherein:

the providing step is carried out with the wire forming a closed loop.

7. The method of claim **5**, wherein:

the providing step is carried out with the wire forming at least one commissure support extending outwardly from the ring.

8. The method of claim **1**, wherein:

the connecting step is carried out before the passing step.

9. The method of claim **1**, further comprising the step of:

expanding the support structure from the collapsed shape to the expanded shape before the securing step.

10. The method of claim **9**, wherein:

the expanding step is carried out by inflating a balloon so that the balloon moves the support structure from the collapsed shape to the expanded shape.

11. The method of claim **1**, wherein:

the passing step is carried out by coupling the support structure to a catheter.

12. The method of claim **1**, wherein:

the providing step is carried out with the tissue valve having three valve leaflets.

13. The method of claim **1**, wherein:

the passing step is carried out with the desired valve location being an artery.

14. The method of claim **13**, wherein:

the passing step is carried out with the desired valve location being the descending aorta.

15. The method of claim **1**, wherein:

the passing step is carried out with the desired valve location being the heart.

16. A method of endovascularly delivering a valve through a blood vessel, comprising the step of:

providing a valve having a support structure movable from a collapsed shape to an expanded shape, the valve being configured to permit blood flow in a direction and prevent blood flow in an opposite direction, the support structure having a ring with at least one commissure support extending from the ring, the commissure support supporting the valve;

passing the support structure through a vessel to a desired valve location with the support structure in the collapsed position;

expanding the support structure to the expanded shape with an expandable device thereby securing the valve to the desired valve location; and

removing the expandable device after the expanding step is completed thereby leaving the valve in the desired valve location.

17. The method of claim **16**, wherein:

the expanding step is carried out with the expandable device being an inflatable balloon.

18. The method of claim **16**, further comprising the step of:

mounting the support structure to the expandable device before the passing step.

19. The method of claim **16**, wherein:

the providing step is carried out with the support structure having a wire.

20. The method of claim **19**, wherein:

the providing step is carried out with the wire forming a closed loop.

21. The method of claim 16, wherein:

the providing step is carried out with the valve having a tissue portion mounted to the support structure.

22. The method of claim 16, wherein:

the expanding step is carried out so that the ring continuously engages the desired valve location.

23. The method of claim 16, wherein:

the passing step is carried out with the desired valve location being an artery.

24. The method of claim 23, wherein:

the passing step is carried out with the desired valve location being the descending aorta.

25. The method of claim 16, wherein:

the passing step is carried out with the desired valve location being the heart.

* * * * *

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

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,055,188 A 4/1934 Wapler et al.
3,409,013 A 11/1968 Berry
3,587,115 A 6/1971 Shiley

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

DE	2246526	3/1973	
EP	0103546 A1	3/1984	
EP	0350302	1/1990	
EP	0357003	3/1990	
EP	0592410 B1	10/1995	
GB	2056023	3/1981	
RU	1258406	9/1986	
RU	1271508	11/1986	
RU	1371701	2/1988	
SU	1271508 A *	11/1986	..... 623/FOR 101
WO	WO9117720	11/1991	
WO	WO9217118	10/1992	

OTHER PUBLICATIONS

Fishman et al., "Prevention of Prothetic Cardiac Valve Detachment", Surgery, vol. 67, No. 5, pp. 867–873, May 1970.*

16th Ediiton of The Merck Manual of Diagnosis and Therapy (1992) "Valvular Heart Disease," pp. 546–553.

Yamaguchi, Case Description "A Case of a Reoperation Using a Balloon Catheter with Blocked Pars Ascendes Aortae" Kyobu Geka, Oct. 1989, 42:11, pp. 961–964.

World Medical Manufacturing Corp., Talent Endovascular Bifurcated Spring Graft System Composite Design brochure, no date.

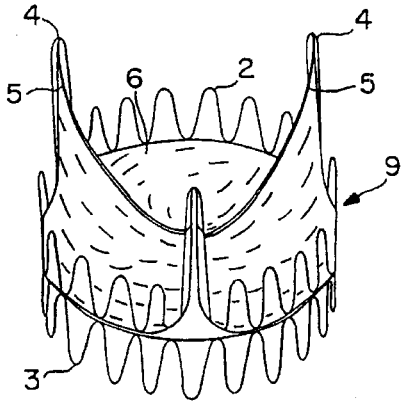
Derwent Abstract No. 87–1980867/27 (1987), SU 1271508 (Gorkii Kirov Medical Ins.).

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



U.S. PATENT DOCUMENTS

3,657,744	A	*	4/1972	Ersek ..... 623/902 X
3,671,979	A		6/1972	Moulopoulos
3,714,671	A		2/1973	Edwards et al.
3,755,823	A		9/1973	Handcodk
3,799,150	A		3/1974	Bonnet
4,035,849	A		7/1977	Angell et al.
4,038,703	A		8/1977	Bokros
4,056,854	A	*	11/1977	Boretos et al. 623/2.18
4,106,129	A		8/1978	Carpentier et al.
4,222,126	A		9/1980	Boretos et al.
4,297,749	A		11/1981	Davis et al.
4,339,831	A		7/1982	Johnson
4,343,048	A		8/1982	Ross
4,391,282	A		7/1983	Ando et al.
4,470,157	A		9/1984	Love
4,574,803	A		3/1986	Storz
4,580,568	A		4/1986	Gianturco
4,592,340	A		6/1986	Boyles
4,612,011	A		9/1986	Kautzky
4,655,771	A		4/1987	Wallsten
4,692,164	A		9/1987	Dzemeshkevich et al.
4,725,274	A		2/1988	Lane et al.
4,731,074	A		3/1988	Rousseau et al.
4,733,665	A		3/1988	Palmaz
4,777,951	A		10/1988	Cribier et al.
4,778,461	A		10/1988	Pietsch et al.
4,787,899	A		11/1988	Lazarus
4,787,901	A		11/1988	Baykut
4,790,843	A		12/1988	Carpentier et al.
4,796,629	A		1/1989	Grayzel
4,830,003	A		5/1989	Wolff et al.
4,851,000	A		7/1989	Gupta
4,856,516	A		8/1989	Hillstead
4,878,495	A		11/1989	Grayzel
4,878,906	A		11/1989	Lindemann et al.
4,883,458	A		11/1989	Shiber
4,892,541	A		1/1990	Alonso
4,917,698	A		4/1990	Carpentier et al.
4,932,965	A		6/1990	Phillips
RE33,258	E		7/1990	Onik
4,966,604	A		10/1990	Reiss
4,979,939	A		12/1990	Shiber
4,986,830	A		1/1991	Owens et al.
4,994,077	A	*	2/1991	Dobben 623/2.2
5,007,896	A		4/1991	Shiber
5,019,102	A		5/1991	Hoene
5,026,366	A		6/1991	Leckrone
5,032,128	A		7/1991	Alonso
5,037,434	A		8/1991	Lane
5,041,130	A		8/1991	Cosgrove et al.
5,047,041	A		9/1991	Samuels
5,059,177	A		10/1991	Towne et al.
5,061,277	A		10/1991	Carpentier et al.
5,085,635	A		2/1992	Cragg
5,089,015	A		2/1992	Ross
5,104,407	A		4/1992	Lam et al.
5,123,919	A		6/1992	Sauter et al.
5,147,391	A		9/1992	Lane
5,152,771	A		10/1992	Sabbaghian et al.
5,163,953	A		11/1992	Vince
5,163,955	A		11/1992	Love et al.
5,167,628	A		12/1992	Boyles
5,201,880	A		4/1993	Wright et al.
5,258,021	A		11/1993	Duran
5,258,023	A		11/1993	Reger
5,295,958	A		3/1994	Shturman
5,306,296	A		4/1994	Wright et al.
5,332,402	A		7/1994	Teitelbaum
5,332,403	A		7/1994	Kolff
5,344,442	A		9/1994	Deac
5,350,420	A		9/1994	Cosgrove et al.
5,376,112	A		12/1994	Duran
5,376,113	A		12/1994	Jansen et al.
5,397,351	A		3/1995	Pavcnik et al.
5,411,552	A		5/1995	Andersen et al.
5,443,446	A		8/1995	Shturman
5,449,384	A		9/1995	Johnson
5,469,868	A		11/1995	Reger
5,480,424	A		1/1996	Cox
5,489,298	A		2/1996	Love et al.
5,545,209	A		8/1996	Roberts et al.
5,609,626	A		3/1997	Quijano et al.
5,755,782	A		5/1998	Love et al.
5,824,061	A		10/1998	Quijano et al.
5,840,081	A		11/1998	Andersen et al.
6,283,993	B1		9/2001	Cosgrove et al.

* cited by examiner

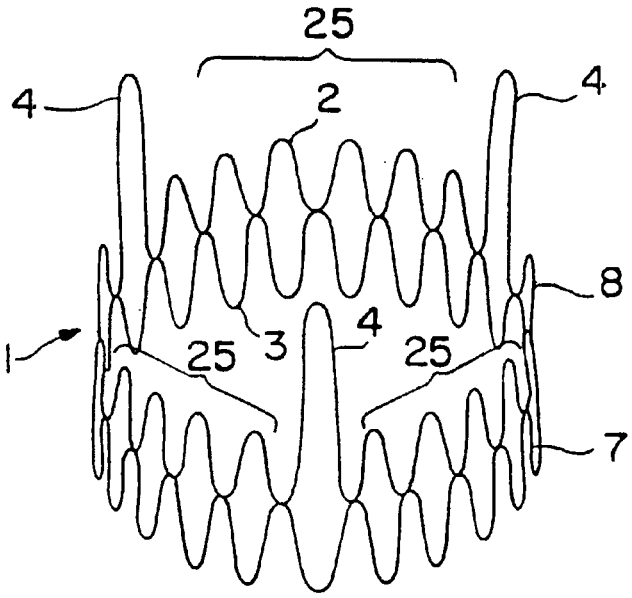


FIG. 1

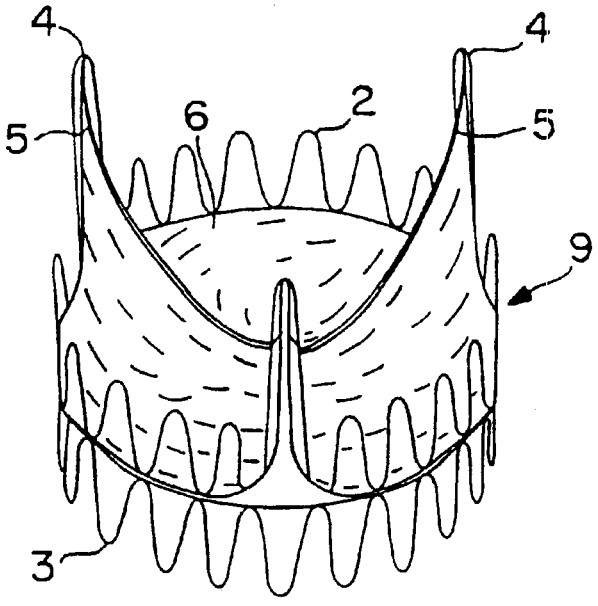


FIG. 2

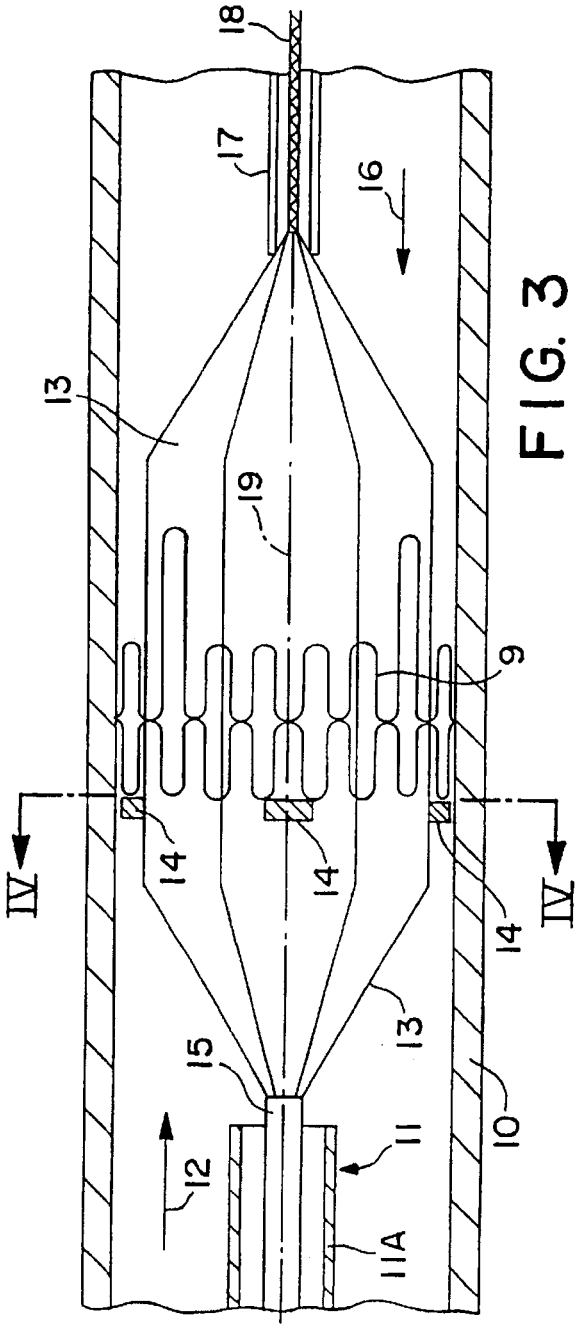


FIG. 3

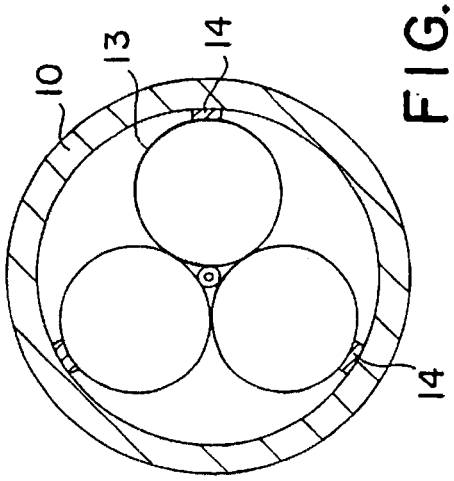


FIG. 4

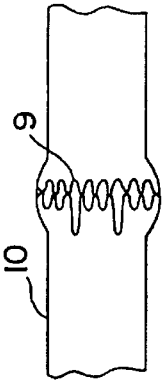


FIG. 7

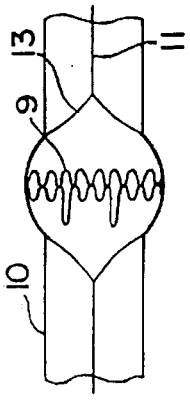


FIG. 6

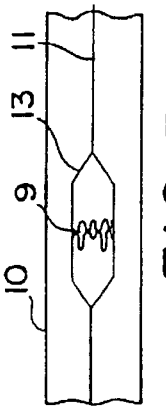


FIG. 5

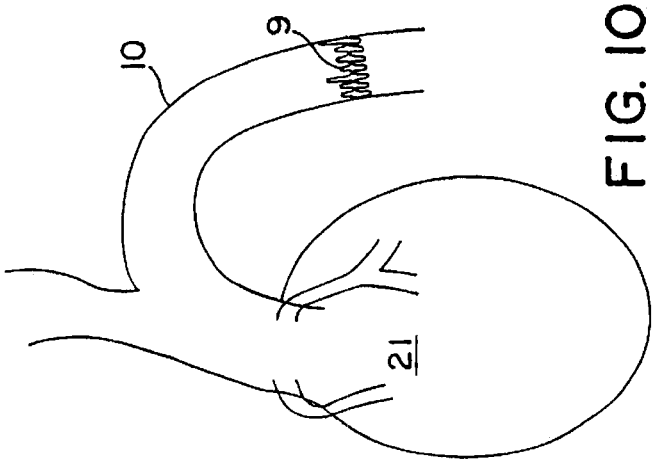


FIG. 10

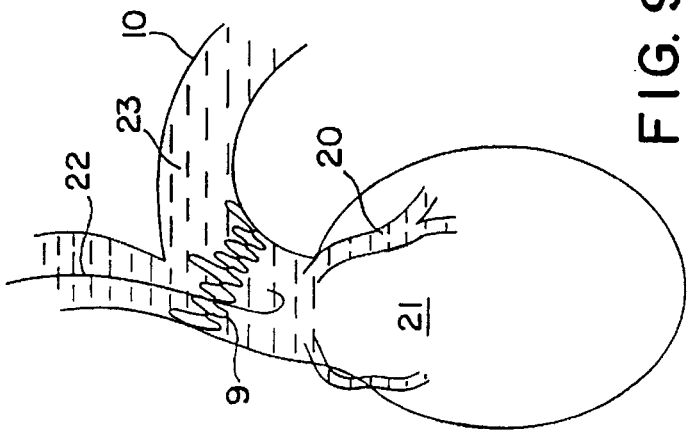


FIG. 9

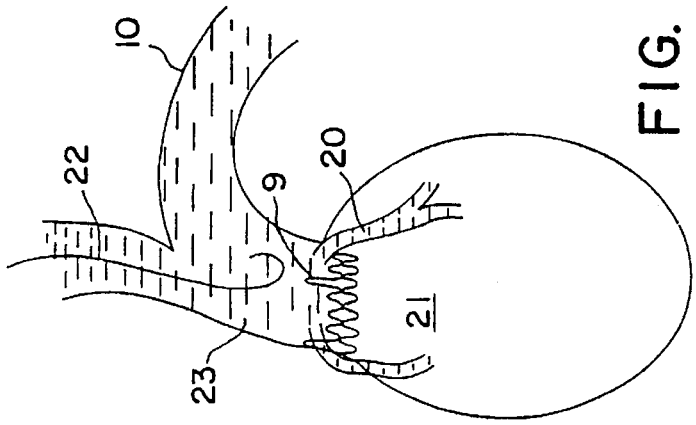


FIG. 8

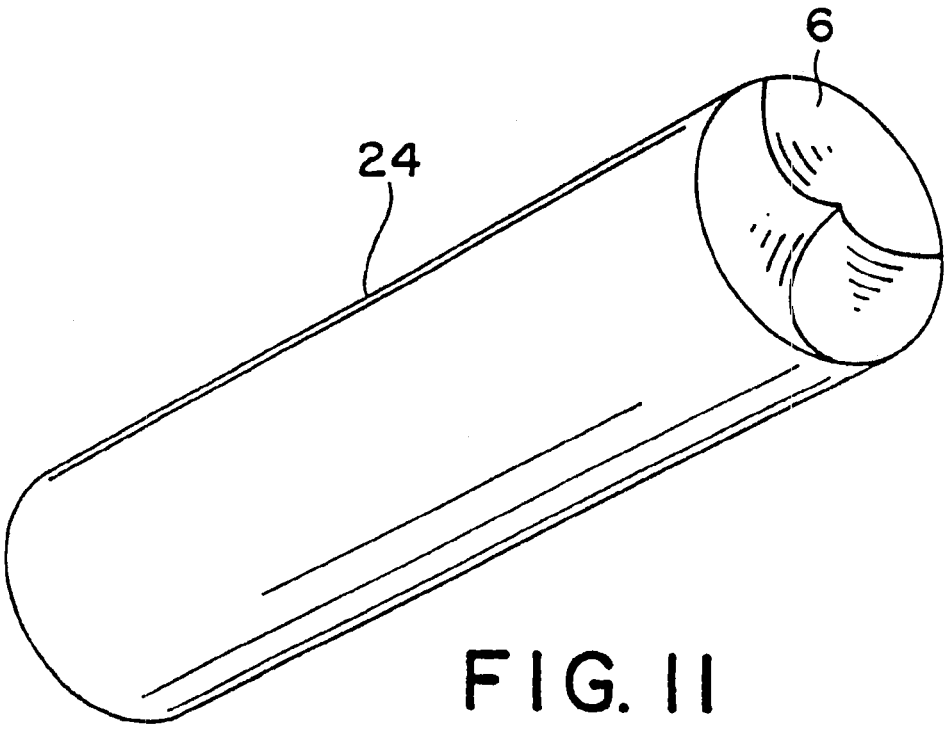


FIG. 11

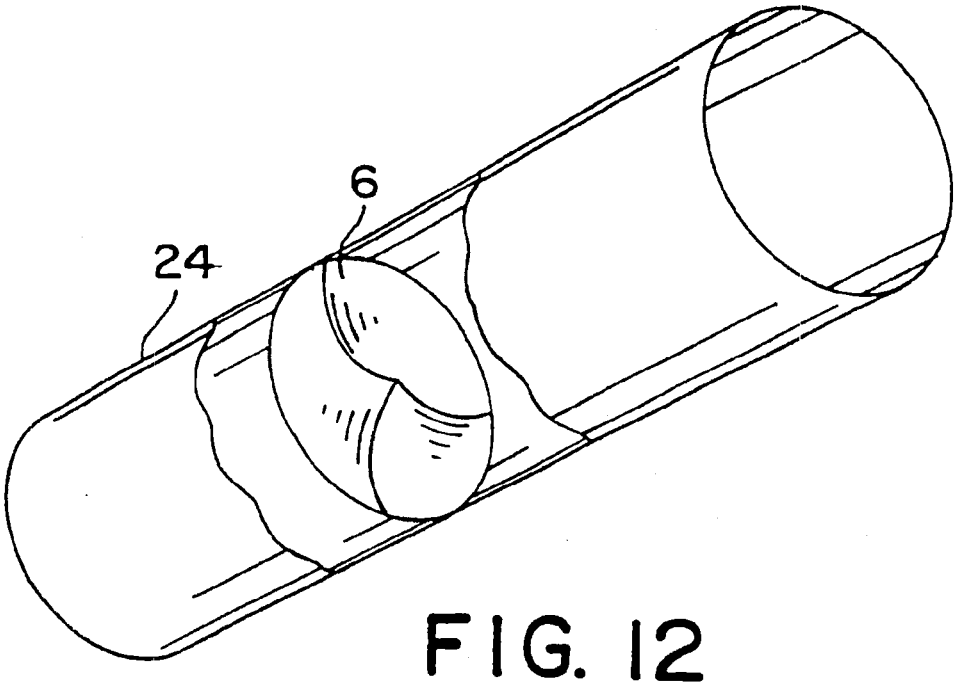


FIG. 12

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 **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 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 **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 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 **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 deflated, 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.

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.

* * * * *

JS 44 (Rev. 11/04)

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

DEFENDANTS
CoreValve, Inc.

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

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.

(c) Attorney's (Firm Name, Address, and Telephone Number)
Jack B. Blumenfeld, MORRIS, NICHOLS, ARSHT & TUNNELL LLP,
1201 North Market Street, P.O. Box 1347,
Wilmington, DE 19899-1347, (302) 658-9200

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

BANKRUPTCY
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- ☐ 423 Withdrawal 28 USC 157

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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 Determinatio 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. § 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 _____ DOCKET NUMBER _____

DATE
Feb. 12, 2008

SIGNATURE OF ATTORNEY OF RECORD
Jack Blumenfeld

FOR OFFICE USE ONLY

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

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 B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
	)	C.A. No. 08-91 (GMS)
v.	)	
COREVALVE, INC.,	)	
Defendant.	)	

MOTION FOR LEAVE TO FILE SUPPLEMENTAL COMPLAINT

Pursuant to Rule 15(d) of the Federal Rules of Civil Procedure, plaintiffs Edwards Lifesciences AG and Edwards Lifesciences LLC (collectively "Edwards") respectively move for leave to file the Supplemental Complaint attached as Exhibit 1. A black-line comparison illustrating the proposed amendments is attached as Exhibit 2. The grounds for this motion are as follows:

1. This action concerns CoreValve Inc.'s ("CoreValve") alleged willful infringement of three U.S. patents that involve medical technology for implanting prosthetic valves using a catheter. The product at issue in this case is CoreValve's ReValving heart valve prosthesis (the "ReValving system").

2. Edwards seeks leave to supplement its Complaint to add two additional parties, both of which are related to the current defendant:

- Medtronic, Inc. (successor in interest to CoreValve)
- Medtronic CoreValve LLC (a wholly owned subsidiary of, and controlled by, Medtronic Inc.)

3. "The standard applicable to motions to amend under *Fed. R. Civ. P. 15(d)* is essentially the same standard that applies to *Fed. R. Civ. P. 15(a)*." *Medeva Pharma Ltd.* v. *American Home Products Corp.*, 201 F.R.D. 103, 104 n. 3 (D. Del. 2001) (citing *Epstein* v. *Township of Whitehall*, 1989 WL 73741, at *2 (E.D. Pa. June 29, 1989)). Rule 15(a)(2) allows a party to amend its complaint by leave of court, and states that "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2); *see also* Fed. R. Civ. P. 21 ("On motion or on its own, the court may at any time, on just terms, add or drop a party."). "Leave to supplement should be granted if it will promote the just disposition of the case, will not cause undue prejudice or delay and will not prejudice the rights of any parties." *Medeva Pharma Ltd.*, 201 F.R.D. at 104. The proposed Supplemental Complaint would promote the just disposition of the case, would not cause undue delay, and does not prejudice the rights of any parties.

4. Edwards seeks leave to supplement its Complaint within a reasonable timeframe following Medtronic, Inc.'s acquisition of CoreValve and Medtronic CoreValve's acquisition of the interest in the ReValving system. Medtronic CoreValve acquired CoreValve's interest in the ReValving system on April 9, 2009. At the same time, Medtronic, Inc. became the successor in interest to CoreValve. Thus, the timing of Medtronic, Inc. and Medtronic CoreValve's acquisitions made it impossible for Edwards to amend its Complaint prior to the January 9, 2009 deadline set forth in the Court's Scheduling Order. (D.I. 31).

5. Edwards requested consent to this motion on July 2, 2009. (Ex. 3.) During a July 15, 2009 telephone conference, CoreValve's counsel advised Edwards' counsel CoreValve would not consent. CoreValve took this position despite the fact that on June 24, 2009, CoreValve's counsel indicated to the Court that CoreValve had produced a redacted version of the merger agreement between CoreValve and Medtronic, Inc. so that Edwards "can

join parties as may be necessary." (Ex. 4.) Further, your Honor ordered CoreValve to produce an unredacted version of the merger agreement just three weeks ago. *See id.*

6. Through its review of the merger agreement, Edwards has learned that Medtronic, Inc. is inducing the infringement of the patents-in-suit. Thus, the Supplemental Complaint would add claims including inducement of infringement based on 35 U.S.C. § 271(b). Edwards however, does not anticipate the need for additional discovery from either Medtronic entity to prove these additional claims. Therefore, adding these parties and claims to the Supplemental Complaint will not result in unreasonable delay or prejudice to any party. Further, inclusion of the Medtronic entities in this matter serves the interests of efficient litigation and judicial economy.

7. Edwards' leave to supplement is sought in good faith on the basis of information learned through the course of discovery. Edwards' motion should therefore be granted. A proposed Order is attached.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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(212) 373-3000

July 17, 2009
3016267

RULE 7.1.1 CERTIFICATE

I hereby certify that the subject of the foregoing motion has been discussed with counsel for the defendant, and that no agreement was reached.

/s/ Maryellen Noreika
Maryellen Noreika (#3208)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	
	)	C.A. No. 08-91 (GMS)
v.	)	
COREVALVE, INC.,	)	
Defendant.	)	

PROPOSED ORDER

Having considered Edwards' Motion for Leave to File a Supplemental Complaint, as well as Defendant's response thereto,

IT IS ORDERED THAT:

1. Edwards' Motion is Granted; and

2. Edwards' Supplemental Complaint is deemed served and filed as of the date of this Order.

_____
J.

CERTIFICATE OF SERVICE

I hereby certify that on July 17, 2009 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Frederick L. Cottrell, III, Esquire
Chad M. Shandler, Esquire
RICHARDS, LAYTON & FINGER, P.A.

I further certify that I caused copies of the foregoing document to be served on July 17, 2009 upon the following in the manner indicated:

Frederick L. Cottrell, III, Esquire
Chad M. Shandler, Esquire
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801

VIA ELECTRONIC MAIL and HAND DELIVERY

J. David Evered, Esquire
Joseph R. Re, Esquire
Joseph S. Cianfrani, Esquire
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street
Fourteenth Floor
Irvine, CA 92614

VIA ELECTRONIC MAIL

/s/ Maryellen Noreika

Maryellen Noreika (#3208)

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	:	
Plaintiffs,	:	C.A. No. 08-91 (GMS)
v.	:	DEMAND FOR JURY TRIAL
COREVALVE, INC., MEDTRONIC COREVALVE LLC and MEDTRONIC, INC.,	:	
Defendants.	:	

SUPPLEMENTAL COMPLAINT

Plaintiffs Edwards Lifesciences AG ("Edwards AG") and Edwards Lifesciences LLC ("Edwards LLC") (collectively, "Plaintiffs"), for their Supplemental Complaint against CoreValve, Inc. ("CoreValve"), Medtronic CoreValve LLC ("Medtronic CoreValve"), and Medtronic, Inc. ("Medtronic") (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), because CoreValve, Medtronic CoreValve and Medtronic reside in this Judicial District.

THE PARTIES

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 Patents covering pioneering percutaneous heart valve products and methods of their use: U.S. Patent No. 5,411,552, U.S. Patent No. 6,168,614, and U.S. Patent No. 6,582,462 (collectively, "Patents"). The Patents disclose and claim, *inter alia*, collapsible and expandable tissue valve prostheses and methods for replacing 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.

6. Upon information and belief, Defendant 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.

7. Upon information and belief, CoreValve has manufactured in the United States heart valve prostheses known as the "ReValving" system that infringe the Patents.

8. Upon information and belief, CoreValve obtained European CE mark approval for its ReValving heart valve prostheses, and has offered for commercial sale and has commercially sold its ReValving system in Europe and elsewhere outside the United States.

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

10. Upon information and belief, on or about April 9, 2009, Medtronic CoreValve acquired CoreValve's interest in the ReValving system that infringes the Patents and thereafter continues to infringe the Patents.

11. Upon information and belief, Medtronic CoreValve manufactures in the United States heart valve prostheses known as the ReValving system that infringe the Patents.

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

13. 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.

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

15. Upon information and belief, on or about April 9, 2009, Medtronic became the successor in interest to CoreValve, and as such is liable for the satisfaction of any judgment against CoreValve for its past infringement of the Patents.

16. Upon information and belief, Medtronic is liable for Medtronic CoreValve's infringement of the Patents because Medtronic CoreValve is the alter ego of Medtronic and Medtronic is directing the activities of Medtronic CoreValve, resulting in a limited agency relationship for the purposes of infringing the Patents.

17. Upon information and belief, Medtronic is knowingly and actively directing and encouraging Medtronic CoreValve to continue manufacturing the ReValving system and to engage in related conduct that infringes the Patents.

18. Upon information and belief, Medtronic is knowingly and actively inducing Medtronic CoreValve's continued infringement of the Patents by encouraging Medtronic CoreValve to engage in conduct that infringes the Patents.

19. Upon information and belief, Medtronic is actively participating in and/or controlling the defense of this litigation on behalf of CoreValve and Medtronic CoreValve.

FIRST CAUSE OF ACTION
(For Infringement of the '552 Patent)

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

21. On May 2, 1995, U.S. Patent No. 5,411,552 ("'552 Patent") (Exh. 1 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.

22. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has willfully and deliberately infringed the '552 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '552 Patent, including without limitation products designated as the ReValving system.

23. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic CoreValve, which acquired CoreValve's interest in the ReValving system, continues to engage in willful and deliberate infringement of the '552 Patent by manufacturing, using,

importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more of claims of the '552 Patent, including without limitation, products designated as the ReValving system.

24. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '552 Patent, including at least by its knowing and active inducement of the continued willful and deliberate infringement of the '552 Patent as the successor in interest to CoreValve.

25. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '552 Patent, including at least by its knowing and active inducement of Medtronic CoreValve's continued willful and deliberate infringement of the '552 Patent.

26. CoreValve's, Medtronic CoreValve's and Medtronic's foregoing infringement and/or active inducement of 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 CoreValve's past infringement and Medtronic CoreValve's and Medtronic's continuing infringement and/or active inducement of infringement, for which Plaintiffs have no adequate remedy at law. Medtronic CoreValve's and Medtronic's continued infringement and/or active inducement of infringement will continue unless enjoined by this Court.

SECOND CAUSE OF ACTION
(For Infringement of the '614 Patent)

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

29. On January 2, 2001, U.S. Patent No. 6,168,614 ("'614 Patent") (Exh. 2 hereto), entitled "Valve Prosthesis for Implantation in the Body," 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 '614 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '614 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, CoreValve has infringed the '614 Patent by supplying or causing to be supplied in or from the United States a component of the invention claimed in the '614 Patent, including without limitation supplying the ReValving system, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the '614 Patent if such combination occurred in the United States.

31. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic CoreValve, which acquired CoreValve's interest in the ReValving system, continues to engage in willful and deliberate infringement of the '614 Patent by supplying or causing to be supplied in or from the United States a component of the invention claimed in the '614 Patent, including without limitation supplying the ReValving system, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, knowing that such component is so made or adapted

and intending that such component will be combined outside of the United States in a manner that would infringe the '614 Patent if such combination occurred in the United States.

32. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '614 Patent, including at least by its knowing and active inducement of the continued willful and deliberate infringement of the '614 Patent as the successor in interest to CoreValve.

33. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '614 Patent, including at least by its knowing and active inducement of Medtronic CoreValve's continued willful and deliberate infringement of the '614 Patent.

34. CoreValve's, Medtronic CoreValve's and Medtronic's foregoing infringement and/or active inducement of 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 CoreValve's past infringement and Medtronic CoreValve's and Medtronic's continuing infringement and/or active inducement of infringement, for which Plaintiffs have no adequate remedy at law. Medtronic CoreValve's and Medtronic's continued infringement and/or active inducement of infringement will continue unless enjoined by this Court.

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

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

37. On June 24, 2003, U.S. Patent No. 6,582,462 ("'462 Patent") (Exh. 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, CoreValve has infringed the '462 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '462 Patent, including without limitation products designated as the ReValving system.

39. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic CoreValve, which acquired CoreValve's interest in the ReValving system, continues to engage in willful and deliberate infringement of the '462 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more of claims of the '462 Patent, including without limitation, products designated as the ReValving system.

40. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '462 Patent, including at least by its knowing and active inducement of the continued willful and deliberate infringement of the '462 Patent as the successor in interest to CoreValve.

41. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '462 Patent, including at least by its

knowing and active inducement of Medtronic CoreValve's continued willful and deliberate infringement of the '462 Patent.

42. CoreValve's, Medtronic CoreValve's and Medtronic's foregoing infringement and/or active inducement of 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 CoreValve's past infringement and Medtronic CoreValve's and Medtronic's continuing infringement and/or active inducement of infringement, for which Plaintiffs have no adequate remedy at law. Medtronic CoreValve's and Medtronic's continued infringement and/or active inducement of infringement will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand judgment as follows:

(a) Finding that CoreValve, Medtronic CoreValve, and Medtronic have infringed the '552 Patent, the '614 Patent and the '462 Patent;

(b) Finding that CoreValve's, Medtronic CoreValve's, and Medtronic's infringement has been willful and deliberate;

(c) Preliminarily and permanently enjoining and restraining CoreValve, Medtronic CoreValve, and Medtronic 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 one or more of them, and their successors and assigns, from infringing, contributing to the infringement of, or inducing others to infringe the '552 Patent, the '614 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, for which Defendants are jointly and severally liable;

(e) Awarding Plaintiffs enhanced damages under 35 U.S.C. § 284, for which Defendants are jointly and severally liable;

(f) Awarding Plaintiffs their reasonable attorneys' fees and their costs and disbursements in this action, as provided by 35 U.S.C. § 285, for which Defendants are jointly and severally liable; 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 Supplemental Complaint.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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(212) 373-3000

July 17, 2009

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	:	
Plaintiffs,	:	C.A. No. 08-91 (GMS)
v.	:	DEMAND FOR JURY TRIAL
COREVALVE, INC., MEDTRONIC COREVALVE LLC and MEDTRONIC, INC.,	:	
Defendants.	:	

~~EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,~~

~~Plaintiffs,~~

~~v.~~

~~COREVALVE, INC.,~~

~~Defendant.~~

~~C.A. No.~~

~~DEMAND FOR JURY TRIAL~~

SUPPLEMENTAL COMPLAINT

Plaintiffs Edwards Lifesciences AG ("Edwards AG") and Edwards Lifesciences LLC ("Edwards LLC") (collectively, "Plaintiffs"), for their Supplemental Complaint against ~~Defendant~~ CoreValve, Inc. ("CoreValve"), Medtronic CoreValve LLC ("Medtronic CoreValve"), and Medtronic, Inc. ("Medtronic") (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), because CoreValve ~~resides~~, Medtronic CoreValve and Medtronic reside in this Judicial District.

THE PARTIES

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 Patents covering pioneering percutaneous heart valve products and methods of their use: U.S. Patent No. 5,411,552, U.S. Patent No. 6,168,614, and U.S. Patent No. 6,582,462 (collectively, "Patents"). The Patents disclose and claim, *inter alia*, collapsible and expandable tissue valve prostheses and methods for replacing 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.

6. Upon information and belief, Defendant 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.

7. Upon information and belief, CoreValve ~~manufactures~~has manufactured in the United States heart valve prostheses known as the "ReValving" system that infringe the Patents.

8. Upon information and belief, CoreValve ~~has~~ obtained European CE mark approval for its ReValving heart valve prostheses, and ~~is currently offering~~has offered for

commercial sale and has commercially sold its ReValving system ~~for commercial sale~~ in Europe and elsewhere outside the United States.

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

10. Upon information and belief, on or about April 9, 2009, Medtronic CoreValve acquired CoreValve's interest in the ReValving system that infringes the Patents and thereafter continues to infringe the Patents.

11. Upon information and belief, Medtronic CoreValve manufactures in the United States heart valve prostheses known as the ReValving system that infringe the Patents.

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

13. 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.

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

15. Upon information and belief, on or about April 9, 2009, Medtronic became the successor in interest to CoreValve, and as such is liable for the satisfaction of any judgment against CoreValve for its past infringement of the Patents.

16. Upon information and belief, Medtronic is liable for Medtronic CoreValve's infringement of the Patents because Medtronic CoreValve is the alter ego of

Medtronic and Medtronic is directing the activities of Medtronic CoreValve, resulting in a limited agency relationship for the purposes of infringing the Patents.

17. Upon information and belief, Medtronic is knowingly and actively directing and encouraging Medtronic CoreValve to continue manufacturing the ReValving system and to engage in related conduct that infringes the Patents.

18. Upon information and belief, Medtronic is knowingly and actively inducing Medtronic CoreValve's continued infringement of the Patents by encouraging Medtronic CoreValve to engage in conduct that infringes the Patents.

19. Upon information and belief, Medtronic is actively participating in and/or controlling the defense of this litigation on behalf of CoreValve and Medtronic CoreValve.

FIRST CAUSE OF ACTION
(For Infringement of the '552 Patent)

20. ~~9.~~ Plaintiffs repeat and reallege the allegations of paragraphs 1 through ~~8~~19 above.

21. ~~10.~~ On May 2, 1995, U.S. Patent No. 5,411,552 ("'552 Patent") (Exh. 1 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.

22. ~~11.~~ Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has ~~been and is now infringing~~willfully and deliberately infringed the '552 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses

covered by one or more claims of the '552 Patent, including without limitation products designated as the ReValving system.

23. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic CoreValve, which acquired CoreValve's interest in the ReValving system, continues to engage in willful and deliberate infringement of the '552 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more of claims of the '552 Patent, including without limitation, products designated as the ReValving system.

24. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '552 Patent, including at least by its knowing and active inducement of the continued willful and deliberate infringement of the '552 Patent as the successor in interest to CoreValve.

25. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '552 Patent, including at least by its knowing and active inducement of Medtronic CoreValve's continued willful and deliberate infringement of the '552 Patent.

26. ~~12.~~ CoreValve's, Medtronic CoreValve's and Medtronic's foregoing infringement and/or active inducement of infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

27. ~~13.~~ Plaintiffs have been damaged and will be irreparably injured by CoreValve's ~~continuing~~past infringement and Medtronic CoreValve's and Medtronic's continuing infringement and/or active inducement of infringement, for which Plaintiffs have no adequate remedy at law. Medtronic CoreValve's ~~infringing activities~~and Medtronic's continued

infringement and/or active inducement of infringement will continue unless enjoined by this Court.

SECOND CAUSE OF ACTION
(For Infringement of the '614 Patent)

28. ~~14.~~ Plaintiffs repeat and reallege the allegations of paragraphs 1 through ~~13~~27 above.

29. ~~15.~~ On January 2, 2001, U.S. Patent No. 6,168,614 ("'614 Patent") (Exh. 2 hereto), entitled "Valve Prosthesis for Implantation in the Body," 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 '614 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '614 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

30. ~~16.~~ Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has ~~been and is now infringing~~infringed the '614 Patent by supplying or causing to be supplied in or from the United States a component of the invention claimed in the '614 Patent, including without limitation supplying the ReValving system, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the '614 Patent if such combination occurred in the United States.

31. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic CoreValve, which acquired CoreValve's interest in the ReValving system, continues to engage in willful and deliberate infringement of the '614 Patent by supplying or causing to be

supplied in or from the United States a component of the invention claimed in the '614 Patent, including without limitation supplying the ReValving system, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the '614 Patent if such combination occurred in the United States.

32. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '614 Patent, including at least by its knowing and active inducement of the continued willful and deliberate infringement of the '614 Patent as the successor in interest to CoreValve.

33. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '614 Patent, including at least by its knowing and active inducement of Medtronic CoreValve's continued willful and deliberate infringement of the '614 Patent.

34. ~~17.~~ CoreValve's, Medtronic CoreValve's and Medtronic's foregoing infringement and/or active inducement of infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

35. ~~18.~~ Plaintiffs have been damaged and will be irreparably injured by CoreValve's ~~continuing~~past infringement and Medtronic CoreValve's and Medtronic's continuing infringement and/or active inducement of infringement, for which Plaintiffs have no adequate remedy at law. Medtronic CoreValve's ~~infringing activities~~and Medtronic's continued infringement and/or active inducement of infringement will continue unless enjoined by this Court.

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

36. ~~19.~~ Plaintiffs repeat and reallege the allegations of paragraphs 1 through ~~18~~35 above.

37. ~~20.~~ On June 24, 2003, U.S. Patent No. 6,582,462 ("'462 Patent") (Exh. 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 ~~sublicensee~~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. ~~21.~~ Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has ~~been and is now infringing~~infringed the '462 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '462 Patent, including without limitation products designated as the ReValving system.

39. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic CoreValve, which acquired CoreValve's interest in the ReValving system, continues to engage in willful and deliberate infringement of the '462 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more of claims of the '462 Patent, including without limitation, products designated as the ReValving system.

40. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '462 Patent, including at least by its knowing and active inducement of the continued willful and deliberate infringement of the '462 Patent as the successor in interest to CoreValve.

41. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic is willfully and deliberately infringing the '462 Patent, including at least by its knowing and active inducement of Medtronic CoreValve's continued willful and deliberate infringement of the '462 Patent.

42. ~~22.~~ CoreValve's, Medtronic CoreValve's and Medtronic's foregoing infringement and/or active inducement of infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

43. ~~23.~~ Plaintiffs have been damaged and will be irreparably injured by CoreValve's ~~continuing~~past infringement and Medtronic CoreValve's and Medtronic's continuing infringement and/or active inducement of infringement, for which Plaintiffs have no adequate remedy at law. Medtronic CoreValve's ~~infringing activities~~and Medtronic's continued infringement and/or active inducement of infringement will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand judgment as follows:

(a) Finding that CoreValve ~~has~~, Medtronic CoreValve, and Medtronic have infringed the '552 Patent, the '614 Patent and the '462 Patent;

(b) Finding that CoreValve's, Medtronic CoreValve's, and Medtronic's infringement has been willful and deliberate;

(c) Preliminarily and permanently enjoining and restraining CoreValve, its Medtronic CoreValve, and Medtronic 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 one or more of them, and their successors and assigns, from infringing, contributing to the infringement of, or inducing others to infringe the '552 Patent, the '614 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, for which Defendants are jointly and severally liable;

(e) Awarding Plaintiffs enhanced damages under 35 U.S.C. § 284284, for which Defendants are jointly and severally liable;

(f) Awarding Plaintiffs their reasonable attorneys' fees and their costs and disbursements in this action, as provided by 35 U.S.C. § 285285, for which Defendants are jointly and severally liable; 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 Supplemental Complaint.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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~~February 12, 2008~~
July 17, 2009

EXHIBIT 3

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July 2, 2009

Via Electronic Mail

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Edwards Lifesciences v. *CoreValve, Inc.*
Civ. A. No. 08-91 (D. Del.) (GMS)

Dear Joe:

Edwards intends to move pursuant to Rule 15(d) for leave to serve the enclosed Supplemental Complaint.

Please advise me promptly if you will consent to this motion.

Sincerely yours,

John E. Nathan

JEN:cjr
Enclosure