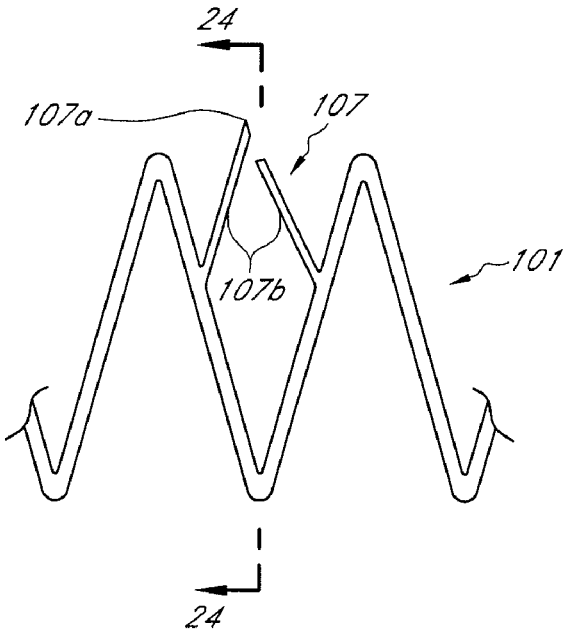

FIG. 23

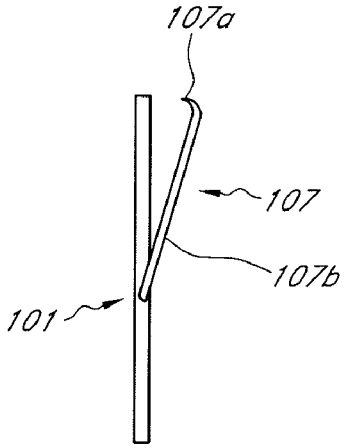

FIG. 24

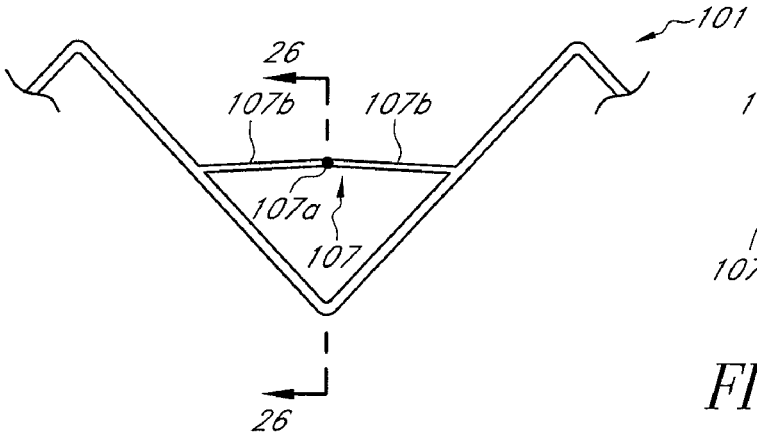

FIG. 25

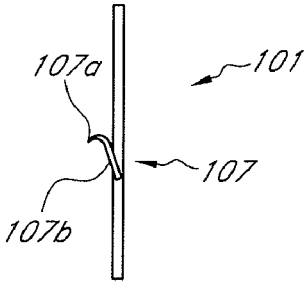

FIG. 26

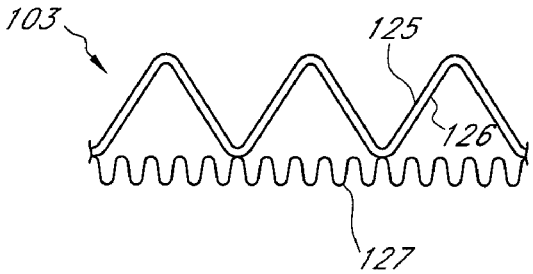

FIG. 27

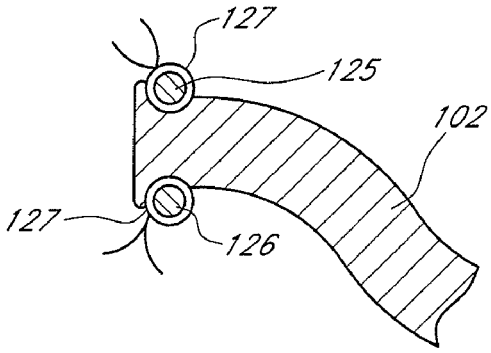

FIG. 28

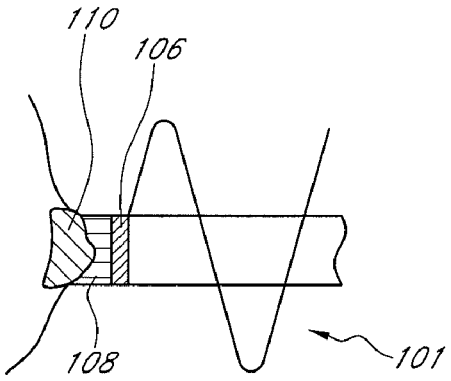

FIG. 29

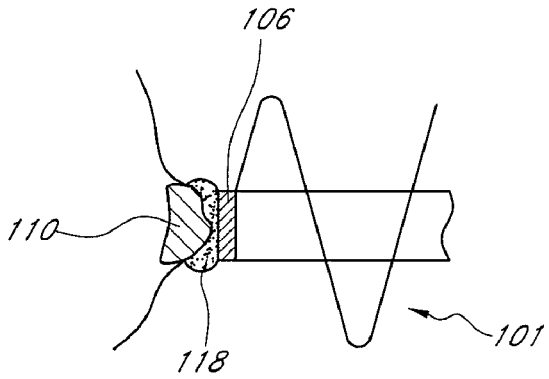

FIG. 30

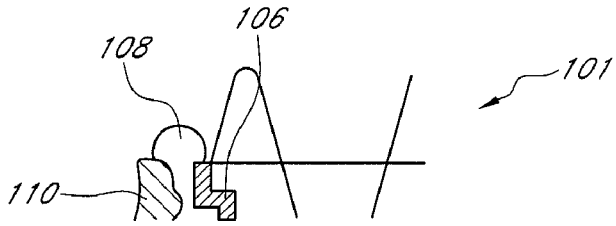

FIG. 31

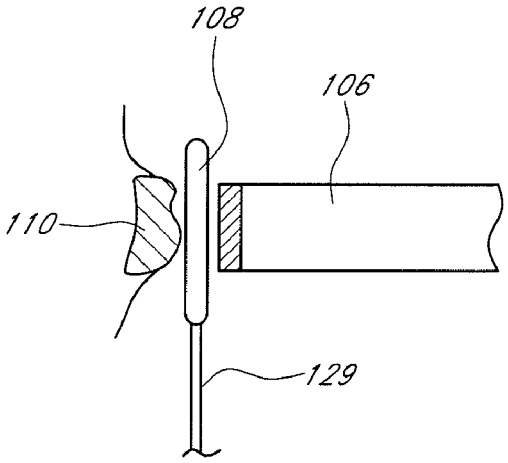

FIG. 32

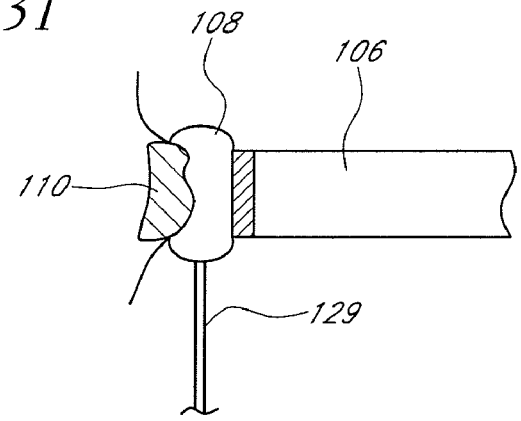

FIG. 33

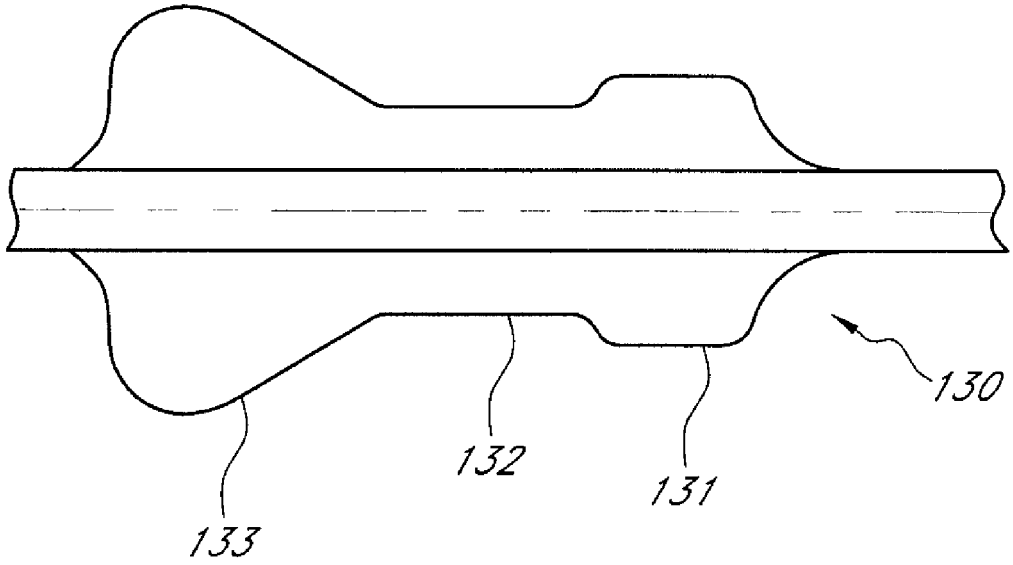

FIG. 34

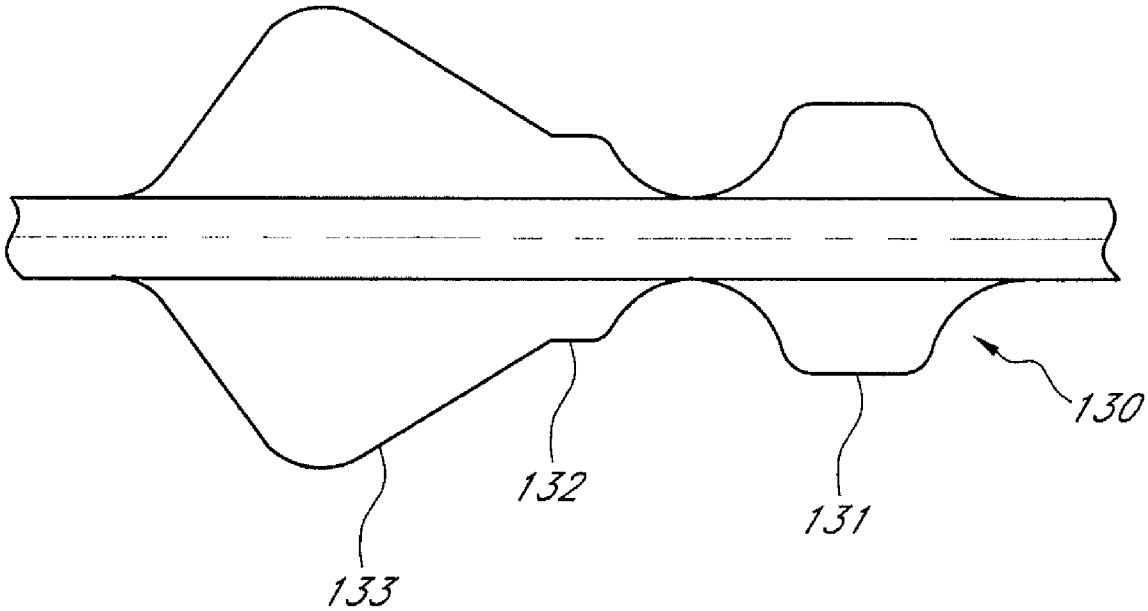

FIG. 35

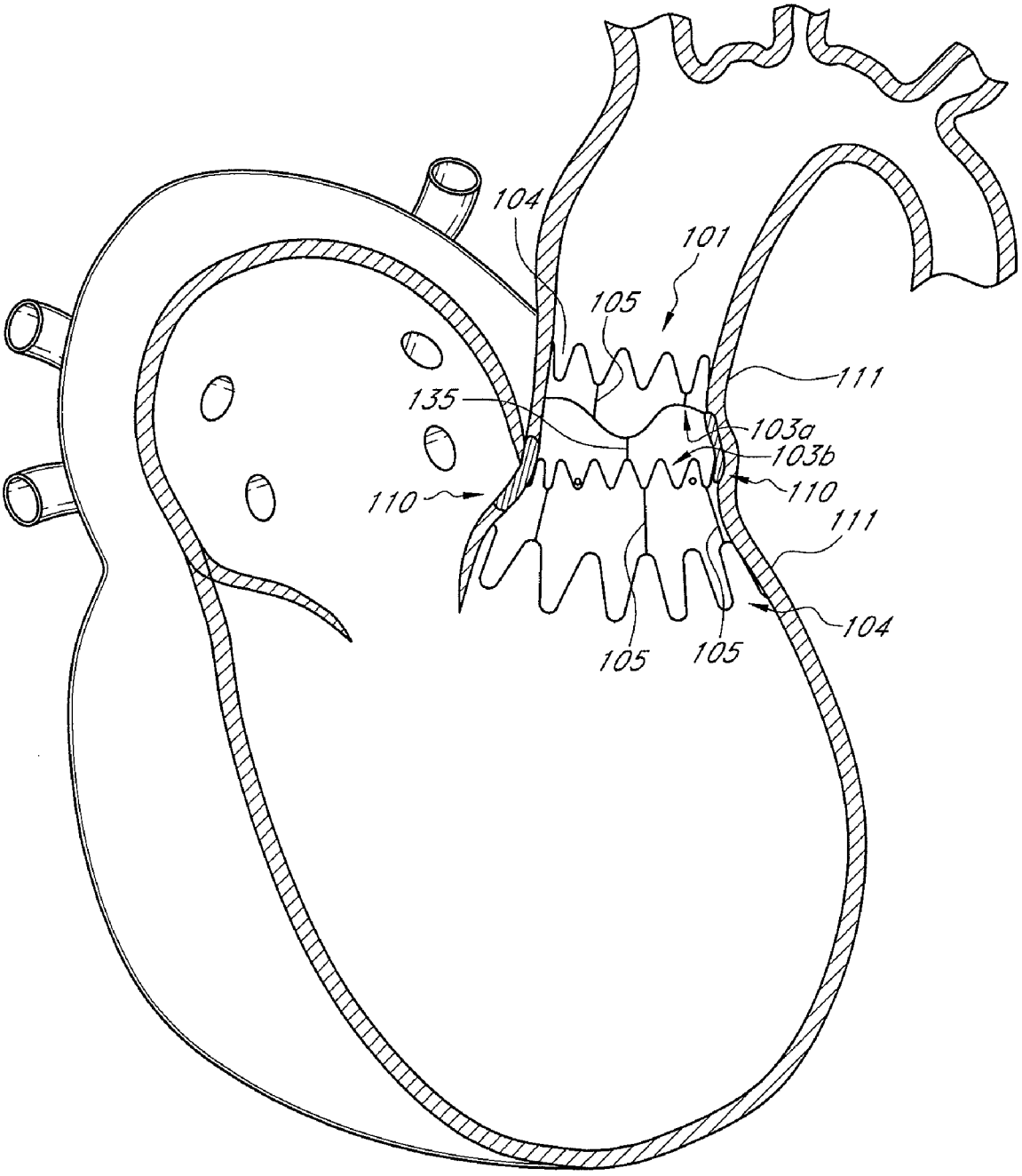

FIG. 36

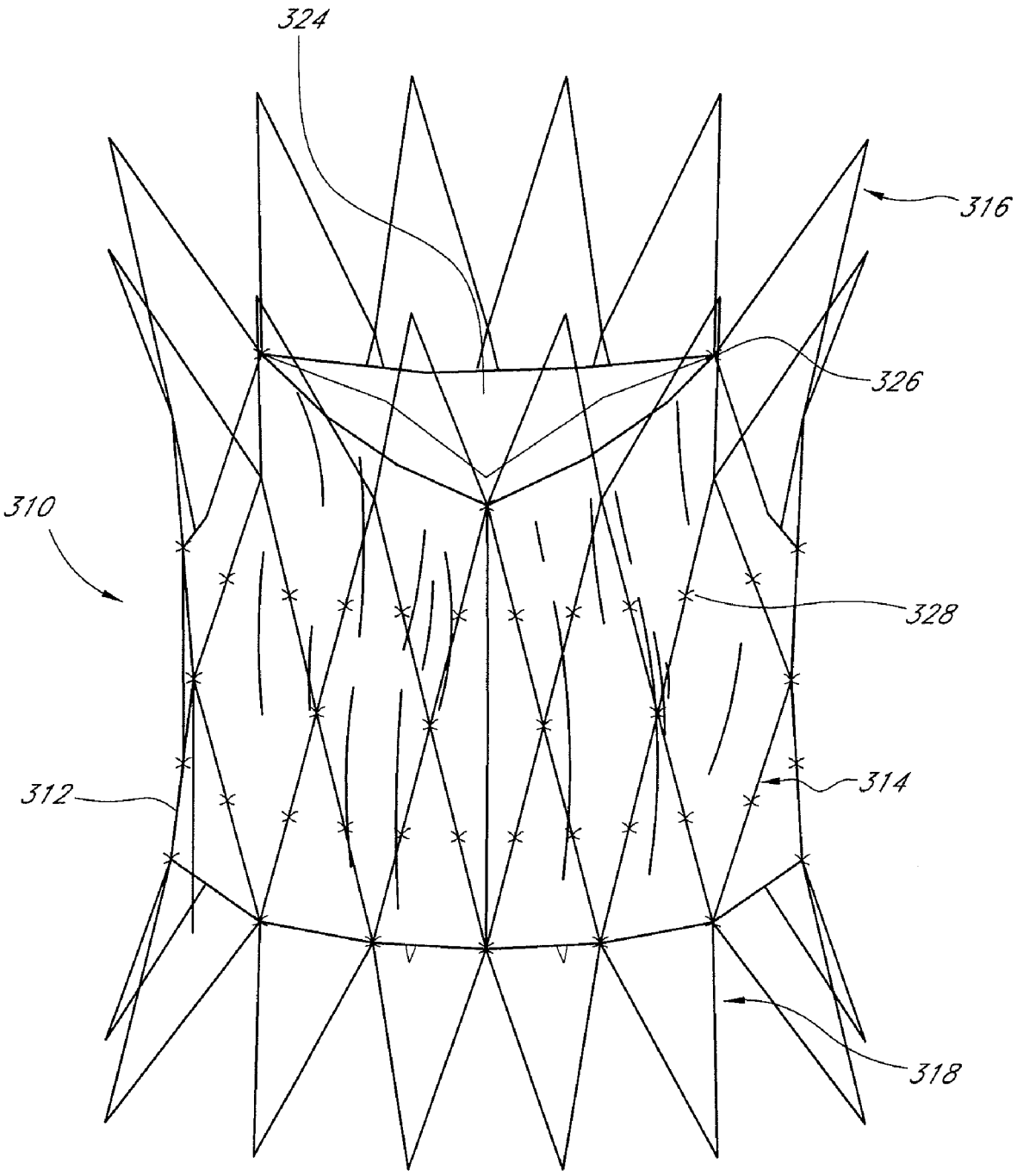

FIG. 37

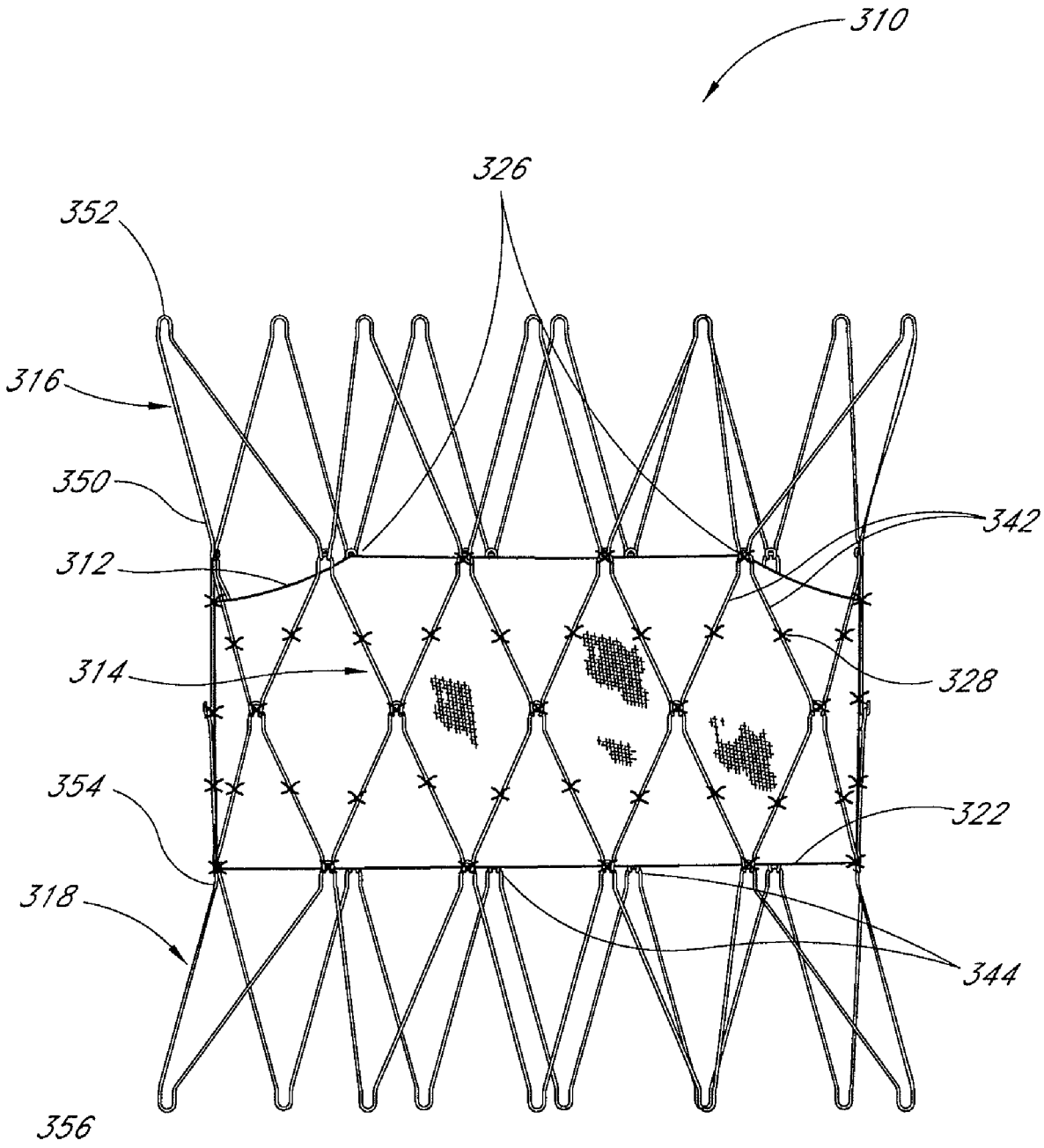

FIG. 38

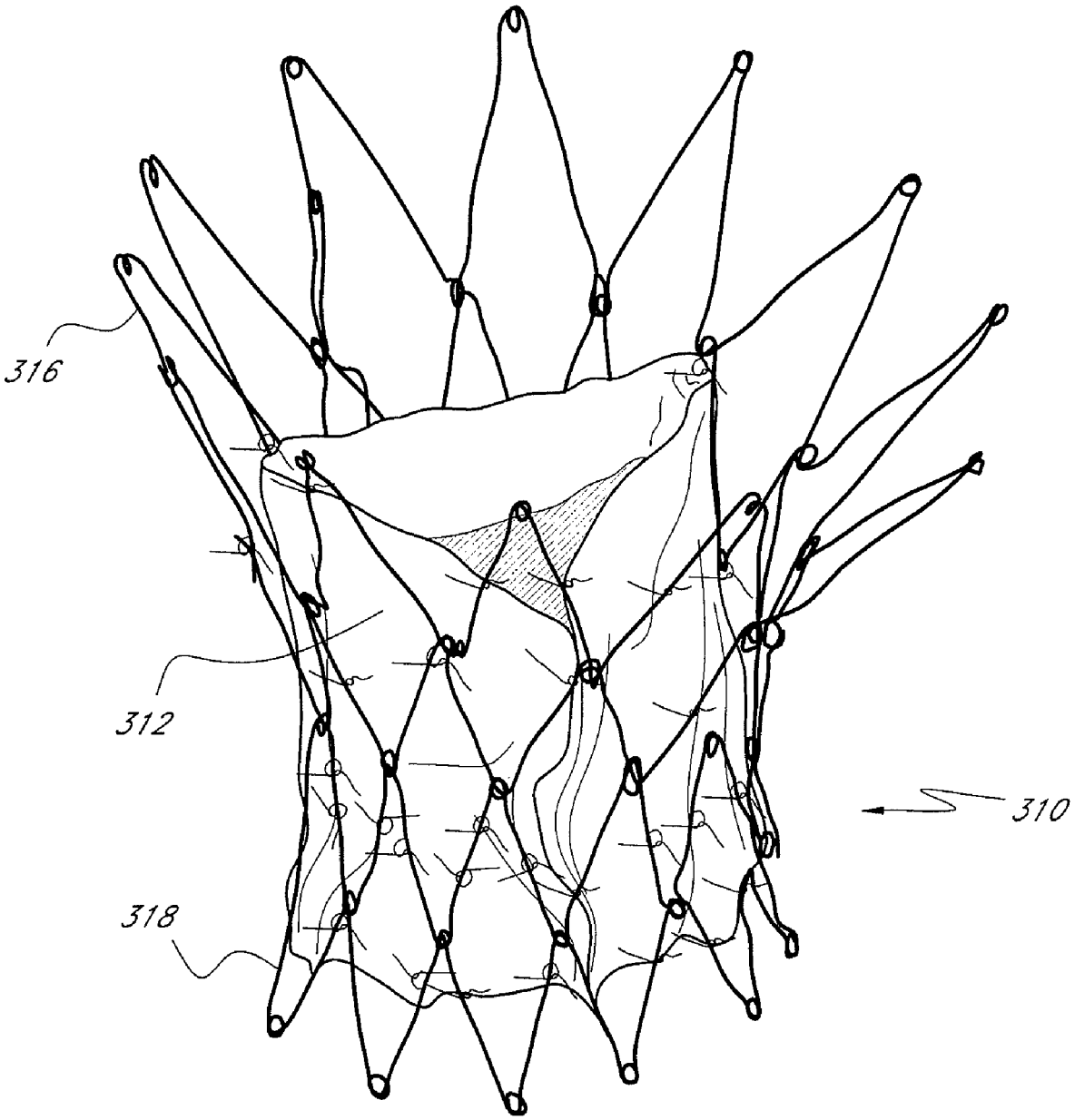

FIG. 39

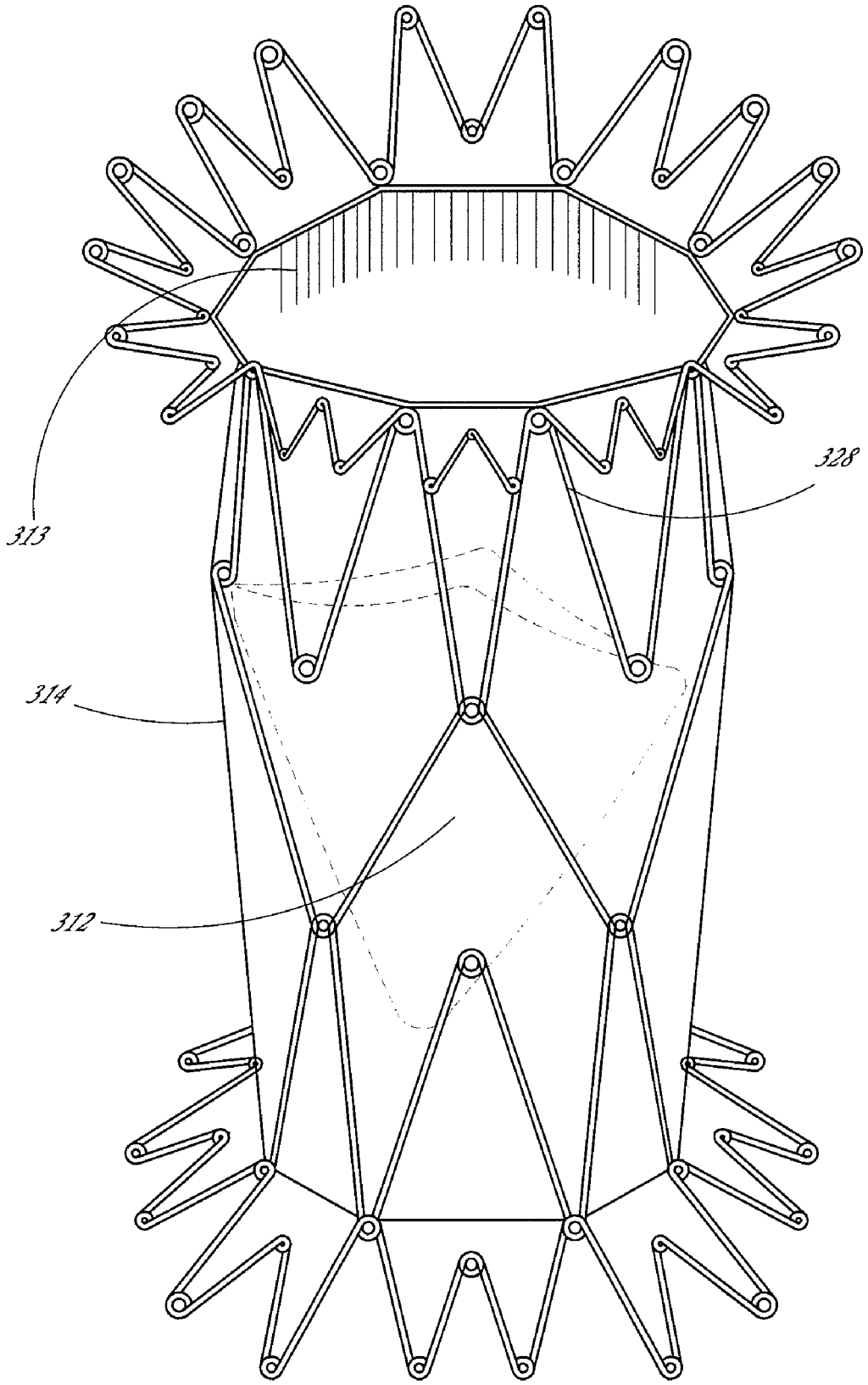

FIG. 40

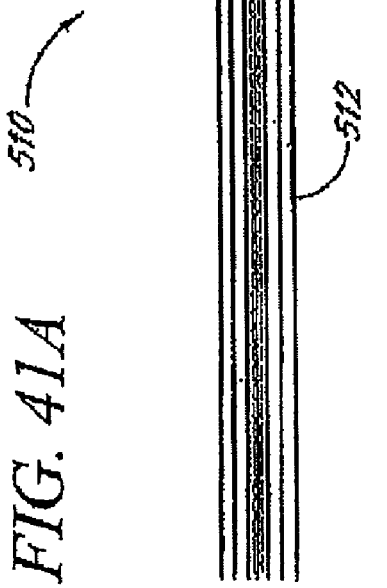

FIG. 41A

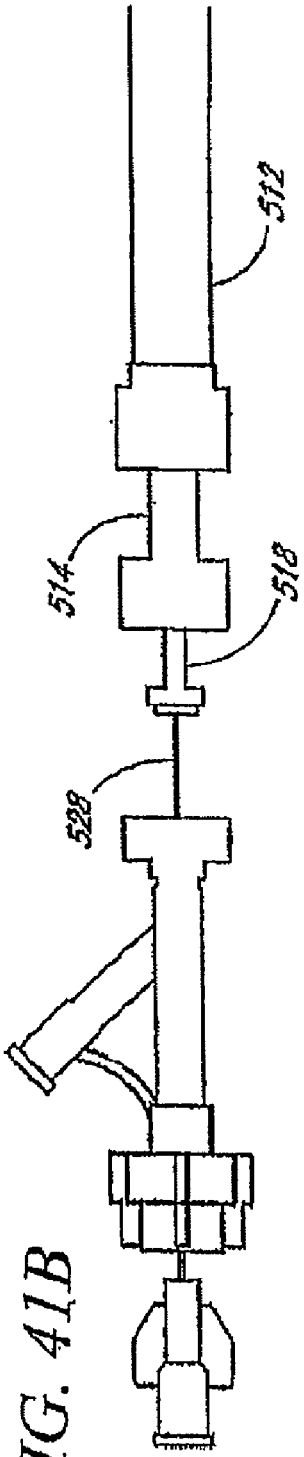

FIG. 41B

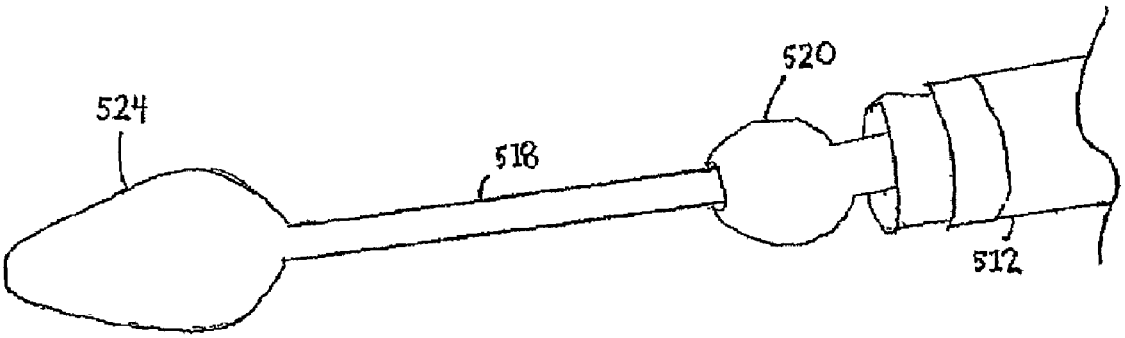

FIG. 42

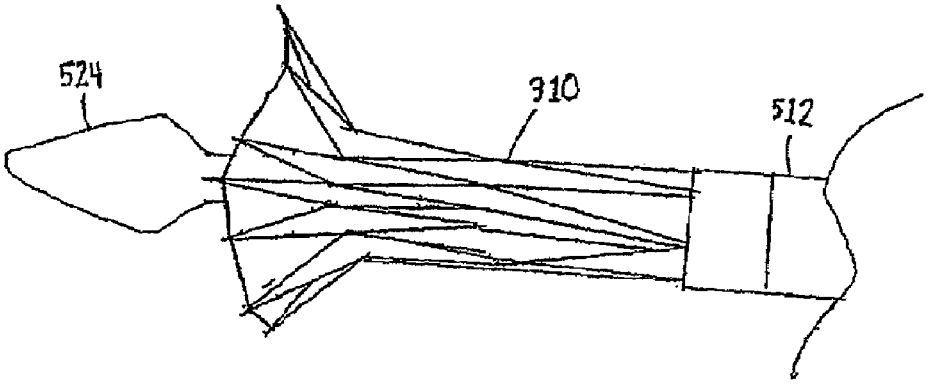

FIG. 43

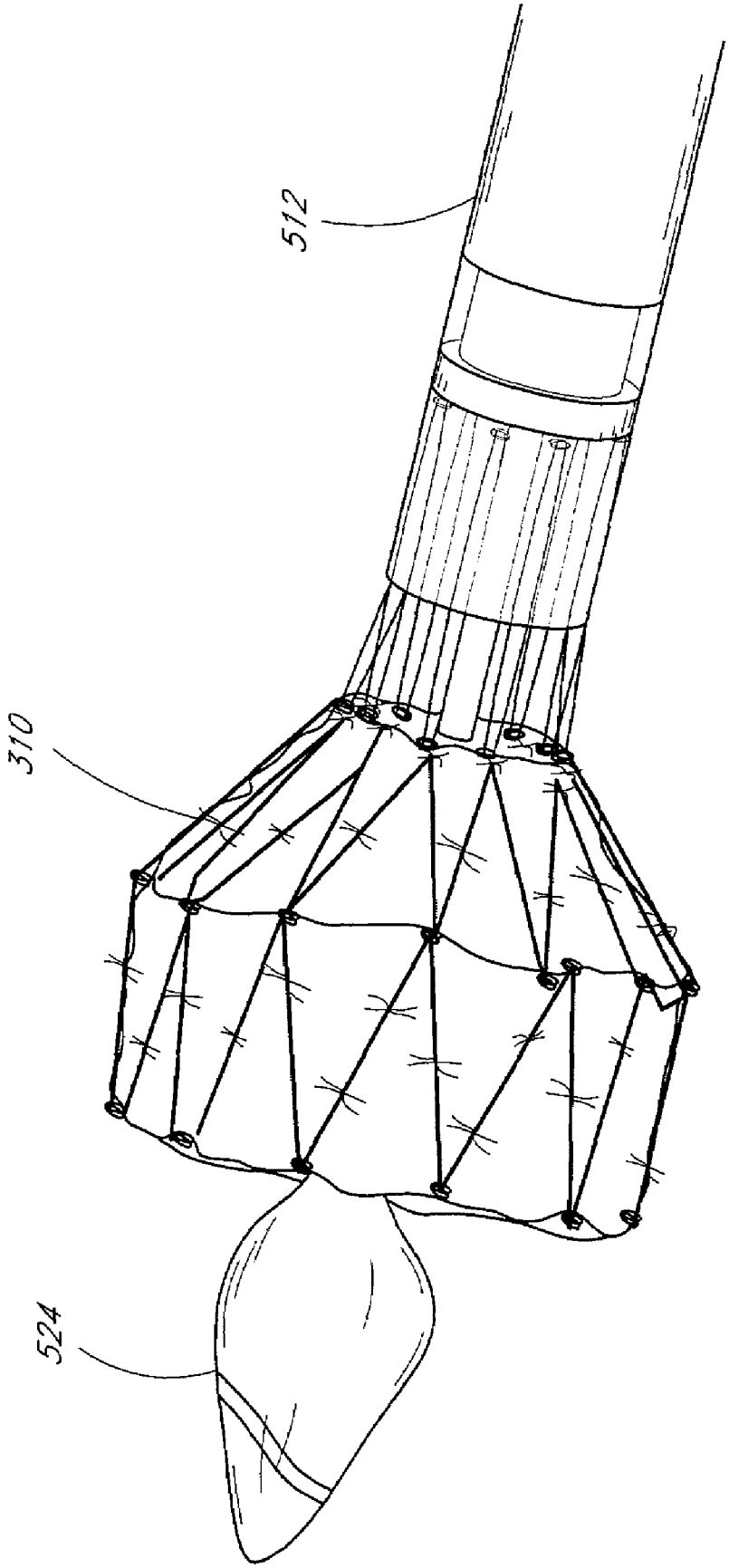

FIG. 44

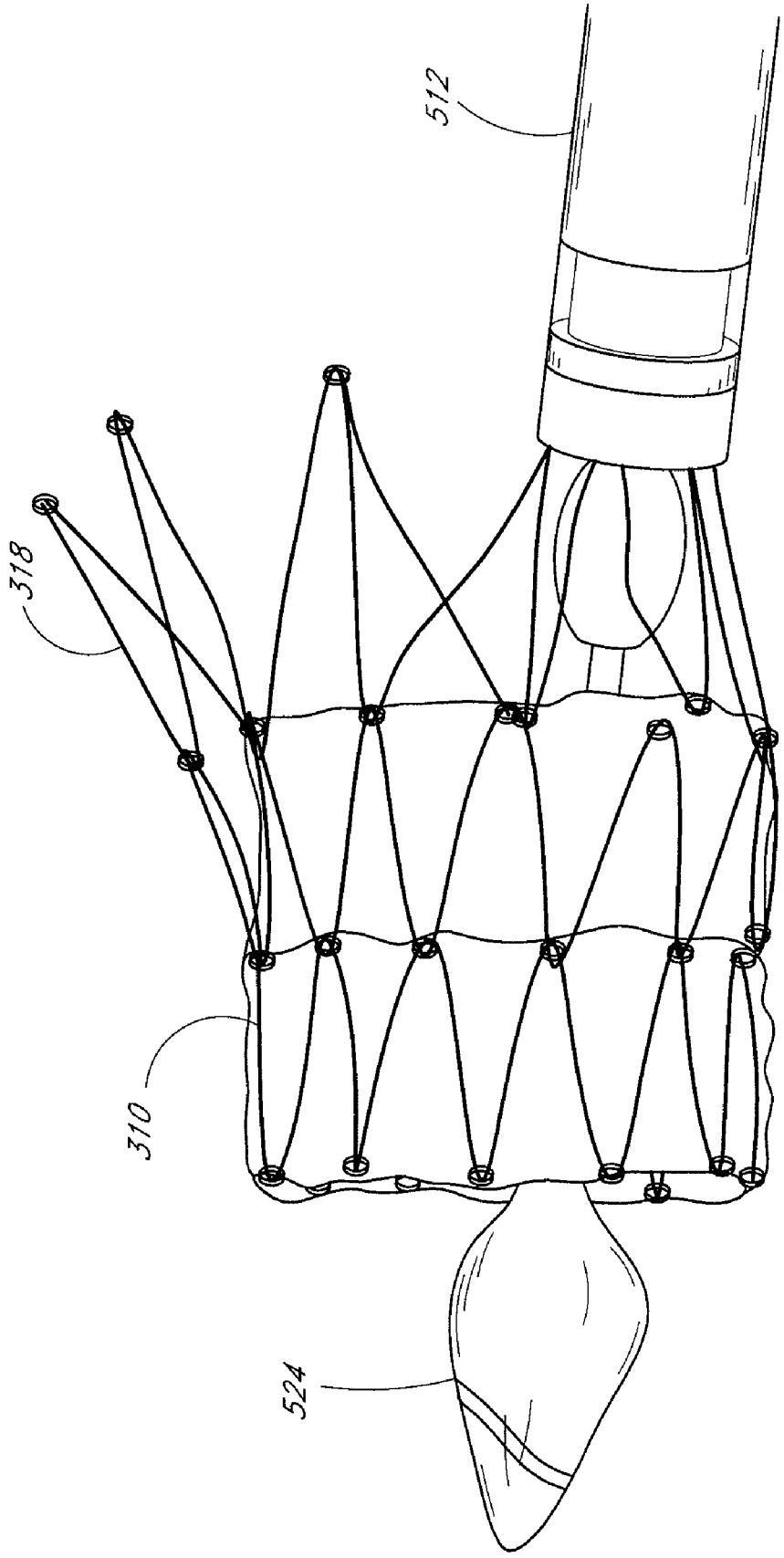

FIG. 45

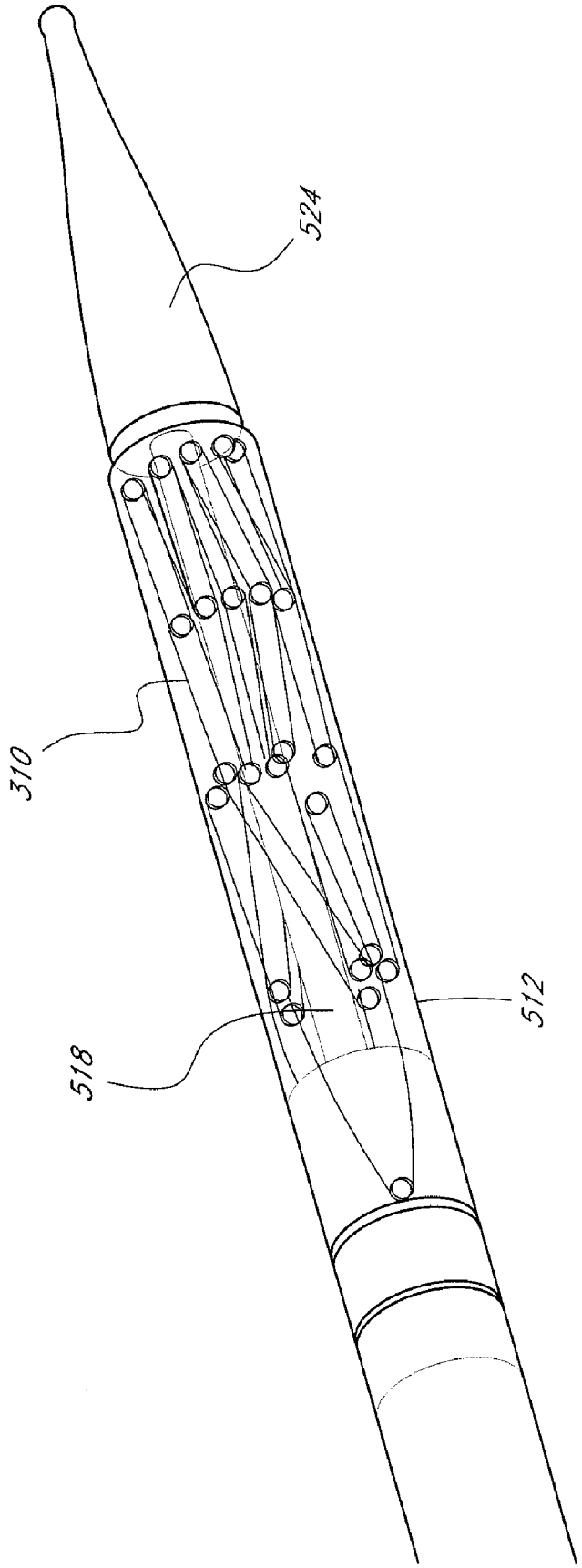

FIG. 46

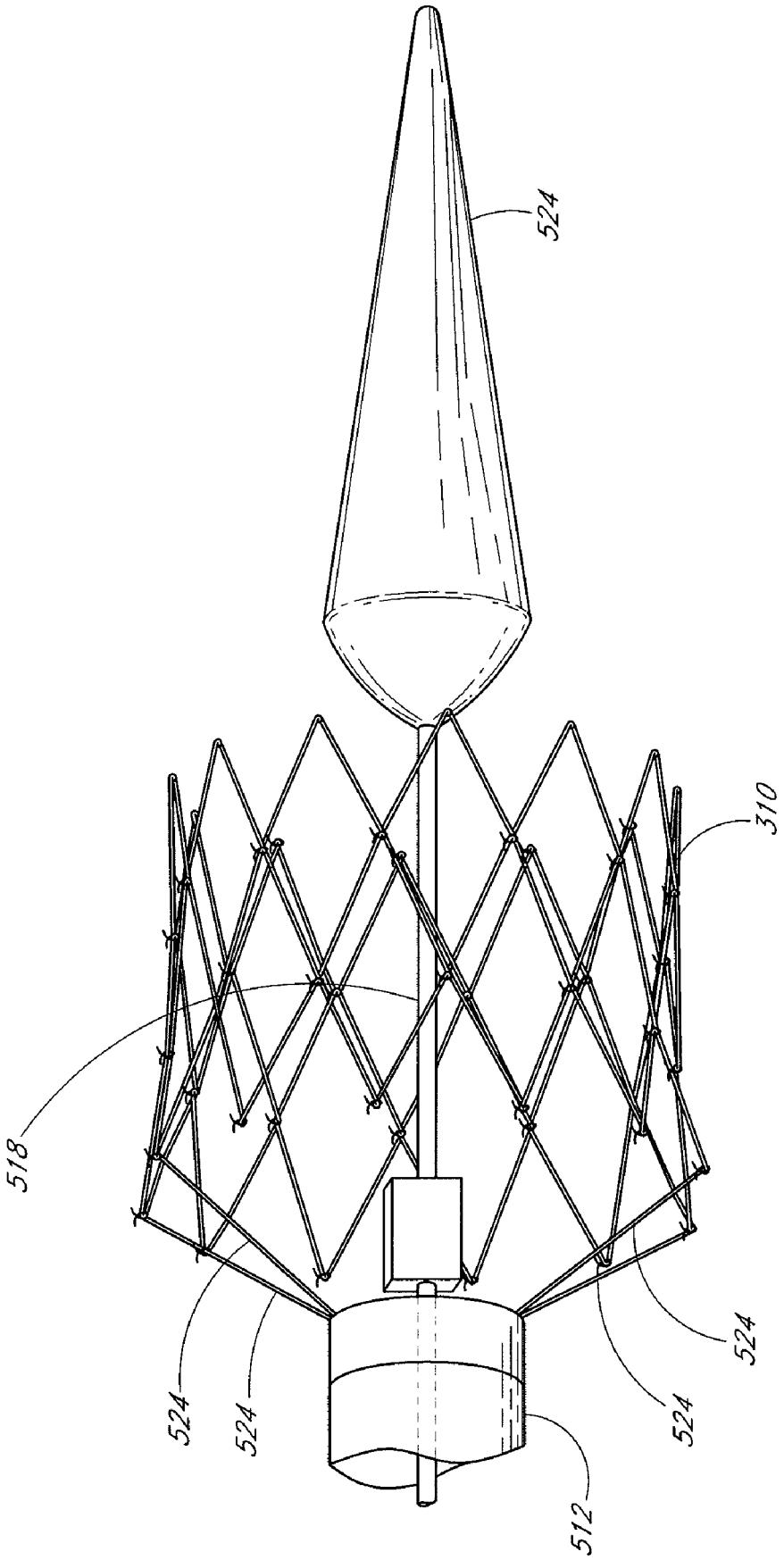

FIG. 47

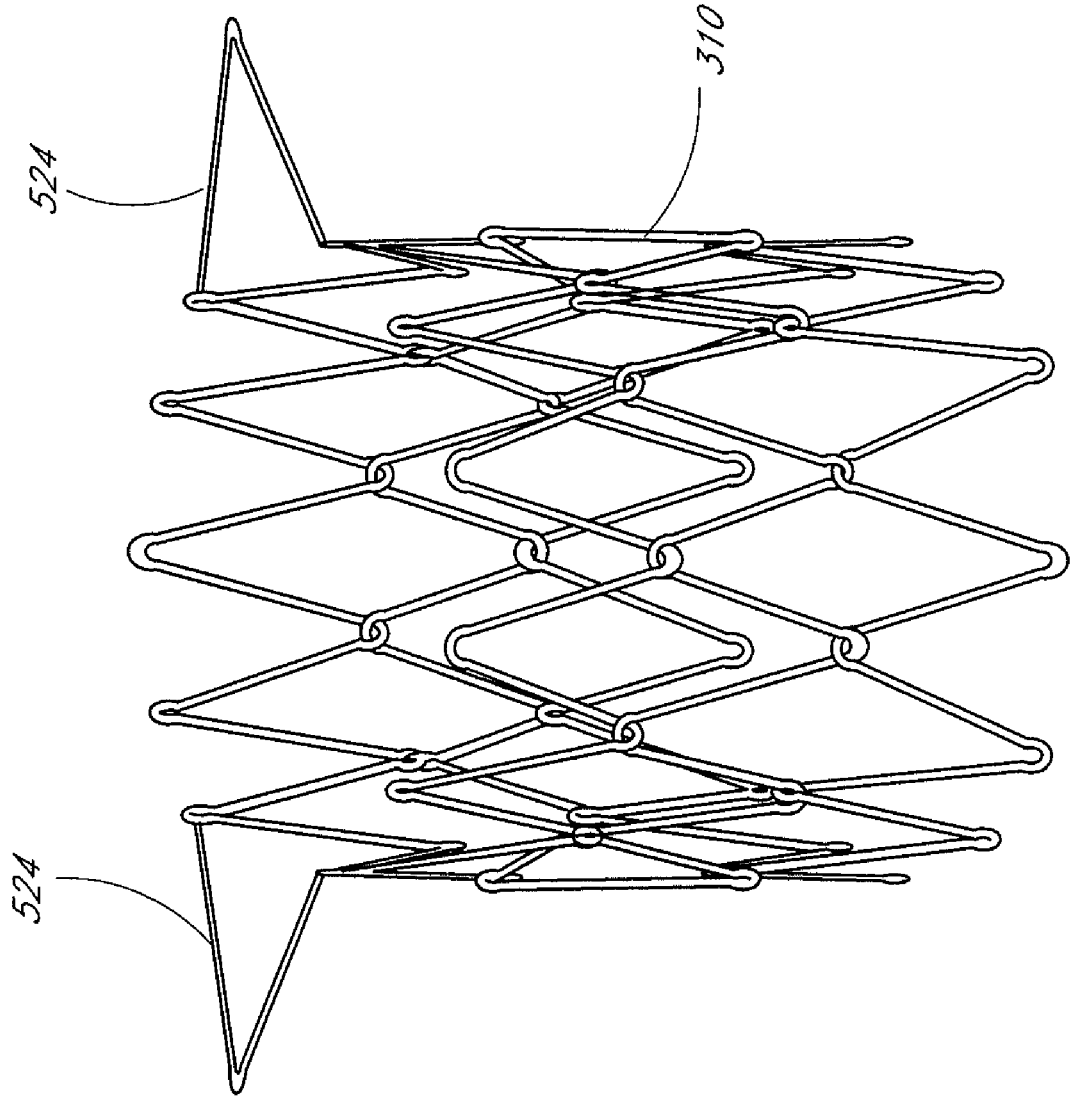

FIG. 48

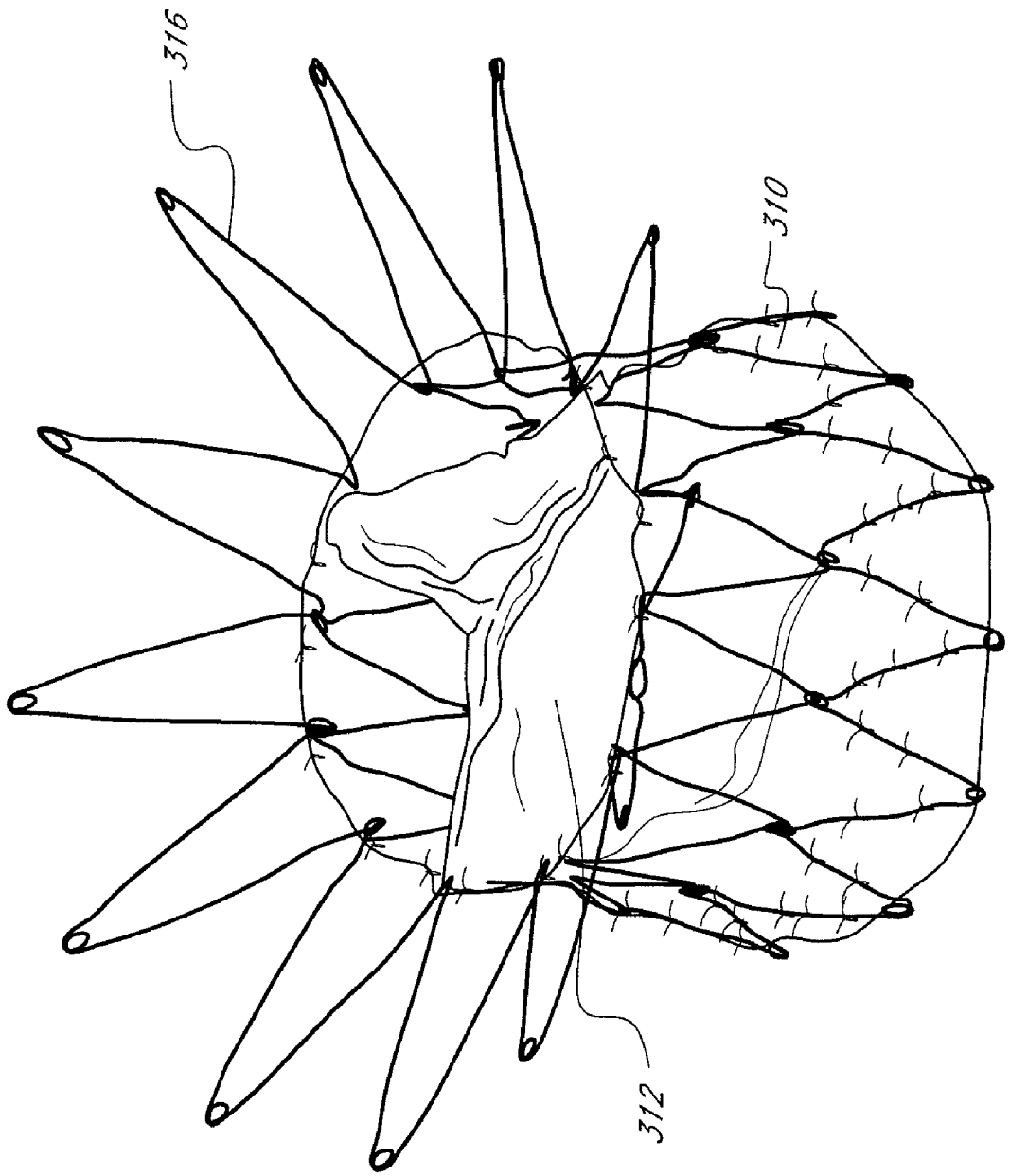

FIG. 49

PROSTHETIC VALVE FOR TRANSLUMINAL DELIVERY

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims priority under 35 U.S.C. §120 as a continuation of U.S. application Ser. No. 12/029,031, filed Feb. 11, 2008, which is a continuation of U.S. application Ser. No. 11/352,614 filed Feb. 13, 2006, now U.S. Pat. No. 7,329,278, which is a continuation of U.S. application Ser. No. 10/412,634 filed Apr. 10, 2003, now U.S. Pat. No. 7,018,406, which is a continuation-in-part of U.S. application Ser. No. 10/130,355, now U.S. Pat. No. 6,830,584, which has a 371(c) date of Nov. 26, 2002 and is the U.S. national phase under §371 of International Application No. PCT/FR00/03176, filed on Nov. 15, 2000, which was published in a language other than English and which claims priority from French Application No. 99/14462 filed on Nov. 17, 1999, now French Patent No. 2,800,984; application Ser. No. 10/412,634is also a continuation-in-part of International Application No. PCT/FR01/03258 filed on Oct. 19, 2001, which was published in a language other than English and which claims priority from French Application No. 00/14028 filed on Oct. 31, 2000, now French Patent No. 2,815,844. The present application also claims priority under 35 U.S.C. §120 as a continuation of U.S. application Ser. No. 11/434,506 filed May 15, 2006,which is a continuation-in-part of U.S. application Ser. No. 10/772,101 filed Feb. 4, 2004, which is a continuation-in-part of U.S. application Ser. No. 10/412,634 filed Apr. 10, 2003, now U.S. Pat. No. 7,018,406, which is a continuation-in-part of U.S. application Ser. No. 10/130,355, now U.S. Pat. No. 6,830,584, which has a 371(c) date of Nov. 26, 2002 and is the U.S. national phase under §371 of International Application No. PCT/FR00/03176, filed on Nov. 15, 2000, which was published in a language other than English and which claims priority from French Application No. 99/14462 filed on Nov. 17, 1999, now French Patent No. 2,800,984; application Ser. No. 10/412,634 is also a continuation-in-part of International Application No. PCT/FR01/03258 filed on Oct. 19, 2001, which was published in a language other than English and which claims priority from French Application No. 00/14028 filed Oct. 31, 2000, now French Patent No. 2,815,844.

FIELD OF THE INVENTION

The present invention relates to a prosthetic cardiac valve and related deployment system that can be delivered percutaneously through the vasculature, and a method for delivering same.

BACKGROUND OF THE INVENTION

Currently, the replacement of a deficient cardiac valve is often performed by opening the thorax, placing the patient under extracorporeal circulation, temporarily stopping the heart, surgically opening the heart, excising the deficient valve, and then implanting a prosthetic valve in its place. U.S. Pat. No. 4,106,129 to Carpentier describes a bioprosthetic heart valve with compliant orifice ring for surgical implantation. This procedure generally requires prolonged patient hospitalization, as well as extensive and often painful recovery. It also presents advanced complexities and significant costs.

To address the risks associated with open heart implantation, devices and methods for replacing a cardiac valve by a less invasive means have been contemplated. For example, French Patent Application No. 99 14462 illustrates a technique and a device for the ablation of a deficient heart valve by percutaneous route, with a peripheral valvular approach. International Application (PCT) Nos. WO 93/01768 and WO 97/28807, as well as U.S. Pat. Nos. 5,814,097 to Sterman et al., U.S. Pat. No. 5,370,685 to Stevens, and U.S. Pat. No. 5,545,214 to Stevens illustrate techniques that are not very invasive as well as instruments for implementation of these techniques.

U.S. Pat. No. 3,671,979 to Moulopoulos and U.S. Pat. No. 4,056,854 to Boretos describe a catheter mounted artificial heart valve for implantation in close proximity to a defective heart valve. Both of these prostheses are temporary in nature and require continued connection to the catheter for subsequent repositioning or removal of the valve prosthesis, or for subsequent valve activation.

With regard to the positioning of a replacement heart valve, attaching this valve on a support with a structure in the form of a wire or network of wires, currently called a stent, has been proposed. This stent support can be contracted radially in such a way that it can be introduced into the body of the patient percutaneously by means of a catheter, and it can be deployed so as to be radially expanded once it is positioned at the desired target site. U.S. Pat. No. 3,657,744 to Ersek discloses a cylindrical, stent-supported, tri-leaflet, tissue, heart valve that can be delivered through a portion of the vasculature using an elongate tool. The stent is mounted onto the expansion tool prior to delivery to the target location where the stent and valve is expanded into place. More recently, U.S. Pat. No. 5,411,552 to Andersen also illustrates a technique of this type. In the Andersen patent, a stent-supported tissue valve is deliverable percutaneously to the native heart valve site for deployment using a balloon or other expanding device. Efforts have been made to develop a stent supported valve that is self-expandable, using memory materials such as Nitinol.

The stent supported systems designed for the positioning of a heart valve introduce uncertainties of varying degree with regard to minimizing migration from the target valve site. A cardiac valve that is not adequately anchored in place to resist the forces of the constantly changing vessel wall diameter, and turbulent blood flow therethrough, may dislodge itself, or otherwise become ineffective. In particular, the known stents do not appear to be suited to sites in which the cardiac wall widens on either proximally and/or distally of the valve annulus situs. Furthermore, the native cardiac ring remaining after ablation of the native valve can hinder the positioning of these stents. These known systems also in certain cases create problems related to the sealing quality of the replacement valve. In effect, the existing cardiac ring can have a surface that is to varying degrees irregular and calcified, which not only lessens the quality of the support of the stent against this ring but also acts as the source of leaks between the valve and this ring. Also, these systems can no longer be moved at all after deployment of the support, even if their position is not optimal.

Also, the existing techniques are, however, considered not completely satisfactory and capable of being improved. In particular, some of these techniques have the problem of involving, in any case, putting the patient under extracorporeal circulation and temporarily stopping of the heart; they are difficult to put into practice; they do not allow precise control of the diameter according to which the natural valve is cut, in view of the later calibration of the prosthetic valve; they lead to risks of diffusion of natural valve fragments, often calcified, into the organism, which can lead to [illegible]

well as to risks of perforation of the aortic or cardiac wall; they, moreover, induce risks of acute reflux of blood during ablation of the natural valve and risks of obstruction of blood flow during implantation of the device with a balloon expandable stent for example.

SUMMARY OF THE INVENTION

The object of the present invention is to transluminally provide a prosthetic valve assembly that includes features for preventing substantial migration of the prosthetic valve assembly once delivered to a desired location within a body. The present invention aims to remedy these significant problems. Another objective of the invention is to provide a support at the time of positioning of the replacement valve that makes it possible to eliminate the problem caused by the native valve sheets, which are naturally calcified, thickened and indurated, or by the residues of the valve sheets after valve resection. Yet another objective of the invention is to provide a support making possible complete sealing of the replacement valve, even in case of an existing cardiac ring which has a surface which is to varying degrees irregular and/or to varying degrees calcified. Another objective of the invention is to have a device that can adapt itself to the local anatomy (i.e. varying diameters of the ring, the subannular zone, the sino-tubular junction) and maintain a known diameter of the valve prosthesis to optimize function and durability. The invention also has the objective of providing a support whose position can be adapted and/or corrected if necessary at the time of implantation.

The present invention is a prosthesis comprising a tissue valve supported on a self-expandable stent in the form of a wire or a plurality of wires that can be contracted radially in order to make possible the introduction of the support-valve assembly into the body of the patient by means of a catheter, and which can be deployed in order to allow this structure to engage the wall of the site where the valve is to be deployed. In one embodiment, the valve is supported entirely within a central, self-expandable, band. The prosthetic valve assembly also includes proximal and distal anchors. In one embodiment, the anchors comprise discrete self-expandable bands connected to the central band so that the entire assembly expands in unison into place to conform more naturally to the anatomy. The valve can be made from a biological material, such as an animal or human valve or tissue, or from a synthetic material, such as a polymer, and includes an annulus, leaflets, and commissure points. The valve is attached to the valve support band with, for example, a suture. The suture can be a biologically compatible thread, plastic, metal, or adhesive, such as cyanoacrylate.

In one embodiment, the valve support band is made from a single wire bent in a zigzag manner to form a cylinder. Alternatively, the valve support band can be made from a plurality of wires interwoven with one another. The wire can be made from stainless steel, silver, tantalum, gold, titanium, or any suitable tissue or biologically compatible plastic, such as ePTFE or Teflon. The valve support band may have a loop at its ends so that the valve support band can be attached to an upper anchor band at its upper end, and a lower anchor band at its lower end. The link can be made from, for example, stainless steel, silver, tantalum, gold, titanium, any suitable plastic material, or suture.

The prosthetic valve assembly is compressible about its center axis such that its diameter can be decreased from an expanded position to a compressed position. The prosthetic valve assembly may be loaded onto a catheter in its compressed position, and so held in place. Once loaded onto the catheter and secured in the compressed position, the prosthetic valve assembly can be transluminally delivered to a desired location within a body, such as a deficient valve within the heart. Once properly positioned within the body, the catheter can be manipulated to release the prosthetic valve assembly and expand it into its expanded position. In one embodiment, the catheter includes adjustment hooks such that the prosthetic valve assembly may be partially released and expanded within the body and moved or otherwise adjusted to a final desired location. At the final desired location, the prosthetic valve assembly may be totally released from the catheter and expanded to its full expanded position. Once the prosthetic valve assembly is totally released from the catheter and expanded, the catheter may be removed from the body.

Other embodiments are contemplated. In one such alternative embodiment, this structure comprises an axial valve support portion, which has a structure in the form of a wire or in the form of a network of wires suitable for receiving the replacement valve mounted on it, and suitable for supporting the cardiac ring remaining after the removal of the deficient native valve; at least one axial wedging portion, which has a structure in the form of a wire or in the form of a network of wires that is distinct from the structure of said axial valve support portion, and of which at least a part has, when deployed a diameter greater or smaller than that of said deployed axial valve support portion, such that this axial wedging portion is suitable for supporting the wall bordering said existing cardiac ring; and at least a wire for connecting said portions, this wire or these wires being connected at points to these portions in such a way as not to obstruct the deployment of said axial portions according to their respective diameters. The embodiment thus provides a support in the form of at least two axial portions that are individualized with respect to one another with regard to their structure, which are connected in a localized manner by at least one wire; where this wire or these wires do not obstruct the variable deployment of the axial portion with the valve and of the axial wedging portion(s).

The presence of a structure in the form of a wire or in the form of a network of wires in the axial valve support portion makes possible a perfect assembly of this valve with this structure, and the shape as well as the diameter of this axial portion can be adapted for supporting the existing cardiac ring under the best conditions. In particular, this axial valve support portion can have a radial force of expansion such that it pushes back ("impacts") the valve sheets that are naturally calcified or the residues of the valve sheets after valve resection onto or into the underlying tissues, so that these elements do not constitute a hindrance to the positioning of the replacement valve. This structure also makes it possible to support possible anchoring means for the support and/or possible sealing means for the space existing between the existing cardiac ring and the replacement valve, as indicated below.

The form and/or diameter of each axial wedging portion can be adapted for supporting the cardiac wall situated at the approach to the existing cardiac ring under the best conditions. In particular, this axial wedging portion can have a tubular shape with a constant diameter greater than that of the axial valve support portion, or the form of a truncated cone whose diameter increases with distance from the axial valve support portion.

Preferably, the tubular support has an axial valve support portion in the form of at least two parts, of which at least one is suitable for supporting the valve and of which at least another is suitable for pushing back the native valve sheets or the residues of the native valve sheets [illegible] retaining.

into or onto the adjacent tissue in order to make this region able to receive the tubular support. This axial valve support portion eliminates the problem generated by these valve or cardiac ring elements at the time of positioning of the replacement valve. The radial force of this axial valve support portion, by impacting all or part of the valvular tissue or in the wall or its vicinity in effect ensures a more regular surface more capable of receiving the valve support axis. It also ensures a better connection with the wall while reducing the risk of peri-prosthetic leakage. Furthermore, such a structure permits the valve to maintain a diameter within a preset range to ensure substantial coaptivity and avoid significant leakage.

Specifically, in order to support the valve, the axial valve support portion can have a part in the form of an undulating wire with large-amplitude undulations, and a part in the form of an undulating wire with small-amplitude undulations, adjacent to said part with large amplitude undulations, having a relatively great radial force in order to make it possible to push said valvular tissue against or into the wall of the passage. Preferably, the support according to one embodiment of the present invention has two axial wedging portions, one connected to an axial end of said valve support portion and the other to the other axial end of this same valve support portion. These two axial wedging portions thus make it possible to wedge the support on both sides of the existing cardiac ring, and consequently make possible complete wedging of the support in two opposite directions with respect to the treated site. If necessary, for example, in the case in which the passage with the valve has an aneurysm, the support according to the invention has: an axial holding portion, suitable for supporting in the deployed state the wall of the passage, and connecting wires such as the aforementioned connecting wires, connecting said axial valve support portion and said axial holding portion, these wires having a length such that the axial holding portion is situated after implantation a distance away from the axial valve support portion. This distance allows said axial holding portion to rest against a region of the wall of the passage not related to a possible defect which may be present at the approach to the valve, particularly an aneurysm. The length of the connecting wires can also be calculated in order to prevent the axial holding portion from coming into contact with the ostia of the coronary arteries. The aforementioned axial portions (valve support, wedging, holding portions) can have a structure in the form of an undulating wire, in zigzag form, or preferably a structure in diamond-shaped mesh form, the mesh parts being juxtaposed in the direction of the circumference of these portions. This last structure allows a suitable radial force making it possible to ensure complete resting of said portions against the wall which receives them.

The support according to the invention can be produced from a metal that can be plastically deformed. The instrument for positioning of the support then includes a balloon which has an axial portion with a predetermined diameter, adapted for realizing the deployment of said axial valve support portion, and at least one axial portion shaped so as to have, in the inflated state, a greater cross section than that of the passage to be treated, in such a way as to produce the expansion of the axial wedging portion placed on it until this axial wedging portion encounters the wall which it is intended to engage. The support according to this embodiment of the present invention can also be produced from a material that can be elastically deformed or even a material with shape memory, such as the nickel-titanium alloy of the type known as "Nitinol," which can be contracted radially at a temperature different from that of the body of the patient and which regains its original shape when its temperature approaches or reaches that of the body of the patient.

According to another possibility, the support is produced from a material with shape memory but that can be plastically deformed, or has parts made from a material with shape memory and parts made from a material that can be plastically deformed, and is formed in such a way that it can be brought, by shape memory or plastic deformation, from a state of contraction to a stable intermediate state of deployment between the state of contraction and the state of total deployment, and then by plastic deformation or shape memory respectively, from said intermediate state of deployment to said state of total deployment; in said intermediate state of deployment, the support has dimensions such that it remains mobile with respect to the site to be treated. The support is thus brought to the site to be treated and then is deployed from its intermediate state; its position can then possibly be adapted and/or corrected, and then the support is brought to its state of total deployment. Specifically, the aforementioned material may have shape memory but that can be plastically deformed, such as a nickel-titanium alloy of the type called "martensitic Nitinol" that can undergo plastic deformation by means of a balloon.

Advantageously, the support according to the invention has some anchoring means suitable for insertion into the wall of the site to be treated, and is shaped in such a way as to be mobile between an inactive position, in which it does not obstruct the introduction of the support into the body of the patient, and an active position, in which it is inserted into the wall of the site to be treated. Substantially complete immobilization of the support at the site is thus obtained. In particular, this anchoring means can be in the form of needles and can be mounted on the support between retracted positions and radially projected positions. Advantageously, the axial valve support portion has, at the site of its exterior surface, a sealing means shaped in such a way as to absorb the surface irregularities that might exist at or near the existing cardiac ring. This sealing means can consist of a peripheral shell made from a compressible material such as polyester or tissue identical to the valve or a peripheral shell delimiting a chamber and having a radially expandable structure, this chamber being capable of receiving an inflating fluid suitable for solidifying after a predetermined delay following the introduction into said chamber. This sealing means can also include a material that can be applied between the existing cardiac ring and the axial valve support portion, this material being capable of solidifying after a predetermined delay following this application. Specifically, in this case, this material is capable of heat activation, for example, by means of a laser, through the balloon, or capable of activation by emission of light of predetermined frequency, for example, by means of an ultraviolet laser, through the balloon. Said sealing means can also be present in the form of an inflatable insert with a spool-shaped cross section in the inflated state, which can be inserted between the existing cardiac ring and the axial valve support portion, Said spool shape allows this insert to conform to the best extent possible to the adjacent irregular structures and to provide a better seal.

An assembly and method for removing the native valve is also contemplated. In particular, the invention has the objective of providing a device which gives complete satisfaction with regard to the exeresis and replacement of the valve, while allowing one to operate without opening of the thorax, stopping of the heart and/or opening of the heart, and preventing any diffusion into the circulatory system of fragments of the removed valve. In one embodiment, the device comprises: an elongated support element; a first series of [illegible]

arranged around the circumference of said elongated element; these blades are connected in a pivoting manner to the elongated element at the site of their proximal longitudinal ends and each has a sharp edge at the site of its distal longitudinal end; these blades can pivot with respect to the elongated element between a folded up position, in which they are near the wall of the elongated element in such a way that they do not stand in the way of the introduction and sliding of the device in the body channel in which the valve is located, in particular in the aorta, and an opened out position, in which these blades are spread out in the form of a corolla in such a way that their sharp edges are placed in extension of one another and thus constitute a sharp circular edge; a second series of blades, arranged consecutively to said first series of blades in the distal direction; the blades of this second series of blades have a structure identical to that of the blades of said first series of blades, except that these blades of this second series are connected to the elongated element by their distal longitudinal ends and each has a sharp edge at the site of its proximal longitudinal end; means making it possible to bring the blades of said first and second series of blades from their folded up position to their opened out position; means making it possible to move said series of blades axially in the direction of one another, between a position of mutual distancing of these series of blades, in which one series of blades can be placed axially on one side of the natural valve while the other series of blades is placed axially on the other side of this valve, and a close together position, in which the sharp circular edges of these two series of blades are brought in mutual contact and thus cut off the natural valve, making it possible to position each of the two aforementioned series of blades on one side of this valve.

The device according to the invention can be introduced percutaneously into said body channel and can be slid in this channel until each of the aforementioned series of blades is placed on one side of the valve. This position is identified using said means of identification. A system of peripheral perfusion or extracorporeal circulation or a blood pump through the center of the delivery system pumping blood from the left ventricle (proximal to the aortic valve) to the aorta (distal to the aortic valve) can be put in place in order to facilitate the flow of the blood, for the purpose of preventing stagnation of the blood in the heart. After the aforementioned positioning of the device, the blades of the two series of blades are spread out; then these two series are brought closer together until the valve is cut off. The configuration of these blades makes it possible to execute this cutting in a single operation, therefore without generating fragments which can be diffused into the circulatory system, or at the very least generating only very few such fragments; this configuration moreover makes possible precise control of the diameter according to which the natural valve is cut, in view of later calibration of the prosthetic valve. The blades are then brought back to the folded up position. The prosthetic valve is then put in place.

This valve can be separate from the device, in which case the latter is removed and then the prosthetic valve is introduced and positioned in said body channel by means of a separate device. Preferably however, the device according to the invention includes a proximal prosthetic valve, with a structure which can be spread out radially, with it possible for this prosthetic valve to occupy a folded up position, in which it is near the wall of said elongated element and does not sand in the way of the introduction and siding of the device in said body channel, and an opened out position, in which it rests against the wall of this channel and is capable of replacing the natural cardiac valve.

The device thus makes it possible to introduce and to position the prosthetic valve at the appropriate place in the body channel, by the same action as that making it possible to cut off the natural valve. After cutting off of the latter, the device is slid axially in the distal direction in order to bring the prosthetic valve to the appropriate site in this channel, after which this prosthetic valve is spread out. The device is then withdrawn, and the cut off natural valve is recovered.

Preferably, said elongated support element is a tubular catheter. This catheter thus allows the blood to flow through it during the exeresis of the natural valve. The cross section of the channel of this catheter can be sufficient to allow the blood to flow through this channel with or without the help of a pump, which limits or prevents resorting to putting the patient in extracorporeal circulation. The catheter can also have a small diameter, which facilitates the introduction and sliding of the device in the body channel, but it is then necessary to provide peripheral circulation by an external assistance system such as an extracorporeal circulation system. The catheter has a lateral distal opening in order to allow the blood to rejoin the body channel, for example, the ascending aorta, this opening being arranged in such a way that the length of catheter passed through the blood is as short as possible.

Preferably, the device has a distal inflatable balloon, placed at the site of the exterior surface of said elongated element; this balloon is configured so as to occupy a folded up position, in which it has a cross section such that it does not stand in the way of the introduction and to the sliding of the device in said body channel, and an opened out position, in which it occupies he whole space existing between the exterior surface of said elongated element and the wall of said body channel and rests, by a peripheral edge which it has, against this wall. The balloon is inflated after the positioning of the series of blades on both sides of the natural valve, in order to prevent reflux of the blood during the ablation of the natural valve. If said elongated element is a catheter, this balloon moreover makes it possible to case this blood to flow only through the catheter. Once the prosthetic valve is positioned, the balloon is brought back to a folded up position so as to re-establish the blood flow through the body channel.

Preferably, the device has a distal filter made of flexible material, placed in the site of the exterior surface of said elongated element; this filter is configured so that it can occupy a folded up position, in which it has a cross section such that it does not stand in the way of the introduction and sliding of the device in said body channel, and an opened out position, in which it occupies the whole space existing between the exterior surface of said elongated element and the wall of the channel and rests, by a peripheral edge which it has, against this wall. This filter makes it possible to catch possible fragments generated by the exeresis of the valve and to retain them so that they are removed from the blood circulation. The device can have some means making it possible to move said series of blades in the axial direction independently from said balloon and/or from said filter. Once opened out, this or these means do not have to be moved axially in the body channel during the aforementioned axial movement of the series of blades.

Said balloon and/or said filter can also be separate from the device, being mounted on an elongated support element which belongs to them. In case of operation on a mitral valve, this balloon and/or this filter is/are introduced into the aorta by a peripheral artery route, and the device is itself introduced into the heart by the peripheral venous system, up to the right atrium and then into the left atrium through the interatrial septum, up to the site of the mitral valve. The prosthetic valve can advantageously have a frame made of material with a

shape memory, particularly a nickel-titanium alloy known as "Nitinol." This same valve can have valves made of biological material (preserved animal or human valves) or valves made of synthetic material such as a polymer. When replacing an aortic valve the device may be alternatively introduced in a retrograde manner through a peripheral artery (femoral artery) or through a venous approach and trans-septally (antegrade).

The above embodiments and methods of use are explained in more detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross-sectional side view of one embodiment of an assembly of the present invention for removing and replacing a native heart valve percutaneously;

FIG. **2** is a cross-section axial view of the assembly of FIG. **1** taken at line II-II, shown in a closed condition;

FIG. **3** is a cross-section axial view of the assembly of FIG. **1** taken at line II-II, shown in an opened condition;

FIG. **4** is a perspective schematic view of one embodiment of a prosthetic valve of the present invention;

FIGS. **5** to **9** are schematic views of the assembly of the present invention positioned in a heart, at the site of the valve that is to be treated, during the various successive operations by means of which this valve is cut out and the prosthetic valve shown in FIG. **4** deployed;

FIG. **10** is a schematic view of the prosthetic valve shown of FIG. **4** shown in a deployed state;

FIG. **11** is a schematic view of an alternative embodiment of the assembly of the present invention shown treating a mitral valve;

FIG. **12** is a cross-sectional view of a section of a blade used in excising the native valve;

FIG. **13** is a schematic view of one embodiment of the support structure of the prosthesis assembly of the present invention;

FIG. **14** is a cross-sectional view of the support of FIG. **13** showing a heart valve supported by the central portion of the support;

FIG. **15** is an end view of the support of FIGS. **13** and **14** in the deployed state;

FIG. **16** is an end view of the support of FIGS. **13** and **14** in the contracted state;

FIG. **17** is a schematic view of a heart with an embodiment of the present inventive prosthesis shown deployed in place;

FIG. **18** is a schematic view of an alternative embodiment of the present invention;

FIG. **19** is schematic view of an alternative embodiment of the present invention;

FIG. **20** is a detail view of a part of the support structure of one embodiment of the present invention;

FIG. **21** is a schematic view of the support of FIG. **19** shown in a deployed state;

FIG. **22** is schematic view of an alternative embodiment of the present invention;

FIG. **23** is a detail view of the support of FIG. **22** shown in the contracted state;

FIG. **24** is a detail view of the support of FIG. **23** taken along line **23-23**;

FIG. **25** is a detail view of the support of FIG. **22** shown in the expanded state;

FIG. **26** is a detail view of the support of FIG. **25** taken along line **25-25**;

FIG. **27** is a schematic view of an alternative embodiment of the present invention;

FIG. **28** is a detailed cross section view of the support of FIG. **27**;

FIG. **29** is a partial schematic view in longitudinal section of the support of the present invention and of a calcified cardiac ring;

FIG. **30** is a schematic view of an alternative to the support of FIG. **29**;

FIG. **31** is a schematic view of an alternative to the support of FIG. **29**;

FIGS. **32** and **33** are schematic views of an alternative to the support of FIG. **29**;

FIG. **34** is a schematic cross-sectional view of a balloon corresponding to the support structure of FIGS. **19** to **21**;

FIG. **35** is a schematic longitudinal sectional view of an alternative embodiment of the balloon of FIG. **34**;

FIG. **36** is a schematic view of a heart with an embodiment of the present inventive prosthesis shown deployed in place;

FIG. **37** is a perspective view of one embodiment of a prosthetic valve assembly of the present invention;

FIG. **38** is a side view of the prosthetic valve assembly of FIG. **37**;

FIG. **39** is a photograph of one embodiment of the prosthetic valve assembly of FIG. **37**;

FIG. **40** is a photograph of an alternative embodiment of the prosthetic valve assembly with a sheath around the valve;

FIG. **41**A is a perspective view of a distal portion of a catheter assembly for use in deploying the prosthetic valve assembly described herein;

FIG. **41**B is a perspective view of a proximal portion of the catheter assembly of FIG. **41**A;

FIG. **42** is a photograph of the distal portion of the catheter assembly of FIG. **41**A;

FIGS. **43** through **45** are photographs of the catheter assembly of FIG. **40**A showing deployment of a prosthesis assembly in sequence;

FIGS. **46** and **47** are photographs of the catheter assembly of FIG. **41**A showing deployment of an alternative prosthesis assembly;

FIG. **48** is a photograph of the alternative prosthesis assembly shown in FIGS. **46** and **47**.

FIG. **49** is a photograph of an alternative embodiment of the prosthetic valve assembly of FIG. **37** showing only a distal anchor;

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Reference is now made to the figures wherein like parts are designated with like numerals throughout. FIGS. **1** to **3** represent a device **1** for replacing a heart valve by a percutaneous route. This device comprises a tubular catheter **2** formed from three tubes **5**, **6**, **7** engaged one inside the other and on which there are placed, from the proximal end to the distal end (considered with respect to the flow of blood, that is to say from right to left in FIG. **1**), a prosthetic valve **10**, two series of blades **11**, **12**, a balloon **13** and a filter **14**. The three tubes **5**, **6**, **7** are mounted so that they can slide one inside the other. The interior tube **5** delimits a passage **15**, the cross section of which is large enough to allow blood to flow through it. At the proximal end, the intermediate tube **6** forms a bell housing **6***a* delimiting, with the interior tube **5**, an annular cavity **17** in which the prosthetic valve **10** is contained in the furled condition.

FIG. **4** shows that this valve **10** comprises an armature **20** and valve leaflets **21** mounted so that they are functionally mobile on this armature **20**. The armature consists of a collection of wires **22**, **23**, **24** made of shape memory material.

particularly of nickel-titanium alloy known by the name of "NITINOL;" namely, (i) a proximal end wire **22** which, when the valve **10** is in the deployed state, has a roughly circular shape; (ii) a distal end wire **23** forming three corrugations in the axial direction, these corrugations being distributed uniformly around the circumference of the valve **10**, and (iii) an intermediate wire **24** forming longitudinal corrugations between the wires **22** and **23**, this wire **24** being connected to the latter ones via the ends of each of these corrugations. The valve leaflets **21** for their part are made of biological material (preserved human or animal valve leaflets) or of synthetic material, such as a polymer. The armature **20** may, when its material is cooled, be radially contracted so that the valve **10** can enter the cavity **17**. When this material is heated to body temperature, this armature **20** returns to its original shape, depicted in FIG. **4**, in which it has a diameter matched to that of a bodily vessel, particularly the aorta, in which the native valve that is to be treated lies. This diameter of the armature **20** is such that the valve **10** bears against the wall of the bodily vessel and is immobilized in the axial direction with respect to that vessel.

Each series of blades **11**, **12** comprises metal elongate blades **30** and an inflatable balloon **31** situated between the catheter **2** and these blades **30**. The blades **30** have a curved profile and are arranged on the circumference of the catheter **2**, as shown in FIGS. **2** and **3**. The blades **30** of the proximal series **11** are connected pivotably to the tube **6** by their proximal ends and comprise a cutting distal edge **30***a*, while the blades **30** of the distal series **12** are connected pivotably to the exterior tube **7** by their distal ends and comprise a cutting proximal edge **30***b*. The connection between the blades **30** and the respective tubes **6** and **7** is achieved by welding the ends of the blades **30** together to form a ring, this ring being fixed axially to the corresponding tube **6**, **7** by crimping this ring onto this tube **6**, **7**, the pivoting of the blades **30** being achieved by simple elastic deformation of these blades **30**. This pivoting can take place between a position in which the blades **30** are furled, radially internally with respect to the catheter **2** and shown in FIGS. **1** and **2**, and a position in which these blades **30** are unfurled, radially externally with respect to this catheter **2** and shown in FIG. **3**. In the furled position, the blades **30** lie close to the wall of the tube **6** and partially overlap each other so that they do not impede the introduction and the sliding of the device **1** into and in the bodily vessel in which the native valve that is to be treated lies; in said unfurled position, the blades **30** are deployed in a corolla so that their cutting edges **30***a*, **30***b* are placed in the continuation of one another and thus constitute a circular cutting edge visible in FIG. **3**.

Each balloon **31**, placed between the tube **3** and the blades **30**, may be inflated from the end of the catheter **2** which emerges from the patient, via a passage **32** formed in the tube **6**. It thus, when inflated, allows the blades **30** to be brought from their furled position into their unfurled position, and performs the reverse effect when deflated. The axial sliding of the tube **6** with respect to the tube **7** allows the series of blades **11**, **12** to be moved axially toward one another, between a spaced-apart position shown in FIG. **1**, and a close-together position. In the former of these positions, one series of blades **11** may be placed axially on one side of the native valve while the other series of blades **12** is placed axially on the other side of this valve, whereas in the latter of these positions, the circular cutting edges of these two series of blades **11**, **12** are brought into mutual contact and thus cut through the native valve in such a way as to detach it from said bodily vessel. The tubes **5** to **7** further comprise marks (not visible in the figures) in barium sulfate allowing the axial position of the device **1** with respect to the native valve to be identified percutaneously so that each of the two series of blades **11**, **12** can be placed on one axial side of this valve. These tubes **5** to **7** also comprise lateral distal openings (not depicted) to allow the blood to reach the bodily vessel, these openings being formed in such a way that the length of catheter **2** through which the blood flows is as short as possible, that is to say immediately after the filter **14**, in the distal direction.

The balloon **13** is placed on the exterior face of the tube **7**, distally with respect to the series **12**. This balloon **13** has an annular shape and is shaped to be able to occupy a furled position in which it has a cross section such that it does not impede the introduction and sliding of the device **1** into and in said bodily vessel, and an unfurled position, in which it occupies all of the space between the exterior face of the tube **7** and the wall of said bodily vessel and, via a peripheral edge **13***a* which it comprises, bears against this wall.

The filter **14** is placed distally with respect to the balloon **13**, on the tube **7**, to which it is axially fixed. This filter **14** is made of flexible material, for example polyester netting, and is shaped to be able to occupy a furled position in which it has a cross section such that it does not impede the introduction and sliding of the device **1** into and in said bodily vessel, and an unfurled position in which it occupies all of the space between the exterior face of the catheter **2** and the wall of this vessel and, via a peripheral edge **14***a* which it comprises, bears against this wall.

An inflatable balloon **35** is placed between the tube **7** and the filter **14** so as, depending on whether it is inflated or deflated, to bring the filter **14** into its respective unfurled and furled positions. In practice, as shown by FIGS. **5** to **9**, the device **1** is introduced into said bodily vessel **50** by a percutaneous route and is slid along inside this vessel **50** until each of the series **11**, **12** of blades is placed on one side of the native valve **55** that is to be treated (FIG. **5**). This position is identified using the aforementioned marks. When the device is in this position, the proximal part of the catheter **2** is situated in the heart, preferably in the left ventricle, while the aforementioned distal lateral openings are placed in a peripheral arterial vessel, preferably in the ascending aorta. The balloons **13** and **35** are inflated in such a way as to cause blood to flow only through the passage **15** and prevent blood reflux during the ablation of the valve **55**. A peripheral perfusion system is set in place to facilitate this flow. The blades **30** of the two series **11**, **12** are then deployed (FIG. **6**) by inflating the balloons **31**, then these two series **11**, **12** are moved closer together by sliding the tube **6** with respect to the tube **7**, until the valve **55** is cut through (FIG. **7**). The blades **30** are then returned to their furled position by deflating the balloons **31** while at the same time remaining in their close-together position, which allows the cut-out valve **55** to be held between them. The device **1** is then slid axially in the distal direction so as to bring the bell housing **6***a* to the appropriate position in the vessel **50** (FIG. **8**), after which the valve **10** is deployed by sliding the tube **6** with respect to the tube **5** (FIG. **9**). The balloons **13** and **35** are deflated then the device **1** is withdrawn and the cut-out valve **55** is recovered (FIG. **10**).

FIG. **11** shows a second embodiment of the device **1**, allowing operation on a mitral valve **56**. The same reference numerals are used to denote the same elements or parts as the aforementioned, as long as these elements or parts are identical or similar in both embodiments. In this case, the tubular catheter is replaced by a support wire **2**, on which one of the series of blades is mounted and by a tube engaged over and able to slide along this wire, on which tube the other series of blades is mounted; the passages for inflating the balloons **31** run along this support wire and this tube. The balloon is used

the filter **14** are separate from the device **1** and are introduced into the aorta via a peripheral arterial route, by means of a support wire **40** along which the passages for inflating the balloons **13** and **35** run. The device **1**, devoid of balloon **13** and the filter **14**, is for its part introduced into the heart through the peripheral venous system, as far as the right atrium then into the left atrium through the inter-auricular septum, as far as the valve **56**. For the remainder, the device **1** operates in the same way as was mentioned earlier. The invention thus provides a device for replacing a heart valve by a percutaneous route, making it possible to overcome the drawbacks of the prior techniques. Indeed the device **1** is entirely satisfactory as regards the cutting-away of the valve **55**, **56**, making it possible to operate without stopping the heart and making it possible, by virtue of the filter **14**, to prevent any dispersion of valve fragments **55**, **56** into the circulatory system.

The above device may comprise a fourth tube, engaged on and able to slide along the tube **7**, this fourth tube comprising the balloon and the filter mounted on it and allowing said series of blades to be moved in the axial direction independently of said balloon and/or of said filter; the blades may be straight as depicted in the drawing or may be curved toward the axis of the device at their end which has the cutting edge, so as to eliminate any risk of lesion in the wall of the bodily vessel, as shown in FIG. **12**; the filter **14** may be of the self-expanding type and normally kept in the contracted position by a sliding tube, which covers it, making the balloon **35** unnecessary.

FIGS. **13** to **16** represent tubular support **101** for positioning, by percutaneous route, of replacement heart valve **102**. The support structure **101** includes median portion **103**, which contains valve **102**, two extreme wedging portions **104** and wires **105** for connecting these portions **103** and **104**, Median portion **103** also includes peripheral shell **106** provided with anchoring needles **107** and shell **108** made of compressible material. As is particularly apparent from FIG. **13**, each of portions **103** and **104** is formed with an undulating wire, and wires **105** connect pointwise the ends of the undulations of portion **103** to the end of an adjacent wave of portion **104**. Portions **104**, seen in expanded form, have lengths greater than the length of portion **103**, so that when the ends of the wires respectively forming portions **103** and **104** are connected in order to form the tubular support structure **101**, the diameter of portion **103** is smaller than the diameter of portions **104**.

The diameter of portion **103** is such that portion **103** can, as shown by FIG. **17**, support cardiac ring **110** that remains after removal of the deficient native valve, while portions **104** cart support walls **111** bordering ring **110**. These respective diameters are preferably such that said supporting operations take place with slight radial restraint of ring **110** and walls **111**. Portion **103** presents in the deployed state a constant diameter. Portions **104** can have a constant diameter in the form of a truncated cone whose diameter increases away from portion **103**. The entire support structure **101** can be made from a material with shape memory, such as the nickel-titanium alloy known as "Nitinol." This material allows the structure to be contracted radially, as shown in FIG. **16**, at a temperature different form that of the body of the patient and to regain the original shape shown in FIGS. **14** and **15** when its temperature approaches or reaches that of the body of the patient. The entire support structure **101** can also be made from a material that can be expanded using a balloon, such as from medical stainless steel (steel 316 L). Valve **102** can be made of biological or synthetic tissue. It is connected to portion **103** by sutures or by any other appropriate means of attachment. It can also be molded on portion **103**. Shell **106** may be made of "Nitinol." It is connected to the undulations of portion **103** at mid-amplitude, and has needles **107** at the site of its regions connected to these undulations. Needles **107** consist of strands of metallic wire pointed at their free ends, which project radially towards the exterior of shell **106**.

This shell can take on the undulating form which can be seen in FIG. **16** in the contracted state of support **101** and the circular form which can be seen in FIG. **4** in the deployed state of this support **101**. In its undulating form, shell **106** forms undulations **106***a* projecting radially on the outside of support **101**, beyond needles **107**, so that these needles **107**, in the retracted position, do not obstruct the introduction of support **101** in a catheter or, once support **101** has been introduced into the heart using this catheter, do not obstruct the deployment out of this support **1**. The return of shell **6** to its circular form brings needles **107** to a position of deployment, allowing them to be inserted in ring **110** in order to complete the anchoring of support **101**. Shell **108** is attached on shell **106**. Its compressible material allows it to absorb the surface irregularities which might exist at or near ring **110** and thus to ensure complete sealing of valve **102**.

FIG. **18** shows a support structure **101** having a single portion **104** connected to portion **103** by wires **105**. This portion **104** is formed by two undulating wires **114** connected together by wires **115**. FIG. **19** shows a support structure **101** which has portion **103** and portion **104** connected by connecting wires **105**. These portions **103** and **104** have diamond-shaped mesh structures, these mesh parts being juxtaposed in the direction of the circumference of these portions and connected together at the site of two of their opposite angles in the direction of the circumference of these portions **103** and **104**. Wires **105** are connected to these structures at the site of the region of junction of two consecutive mesh parts. These mesh parts also have anchoring hooks **107** extending through them from one of their angles situated in the longitudinal direction of support **101**.

FIG. **20** illustrates, in an enlarged scale, the structure of this portion **104** and of a part of wires **105**, as cut, for example, with a laser from a cylinder of stainless steel, and after bending of sharp ends **107***a* of hooks **107**. These hooks, in a profile view, can have the shape as shown in FIG. **4** or **26**. The structure represented in FIG. **19** also has axial holding portion **120**, which has a structure identical to that of portion **104** but with a coarser mesh size, and three wires **105** of significant length connecting this portion **120** to portion **103**. These wires **105**, on the side of portion **120**, have a single link **105***a* and on the side of portion **103**, a double link **105***b*. Their number corresponds to the three junctions formed by the three valves of valve **102**, which facilitates mounting of valve **102** on support **101** thus formed. The support according to FIG. **19** is intended to be used, as appears in FIG. **21**, when the body passage with the valve to be replaced, in particular the aorta, has a variation in diameter at the approach to the valve. The length of wires **105** connecting portions **103** and **120** is provided so that after implantation, portion **120** is situated in a non-dilated region of said body passage, and this portion **120** is provided so as to engage the wall of the passage.

FIG. **22** shows a structure similar to that of FIG. **19** but unexpanded, except that the three wires **105** have a single wire structure but have an undulating wire **121** ensuring additional support near portion **103**. This wire **121** is designed to support valve **102** with three valve leaflets. FIGS. **23** to **26** show an embodiment variant of the structure of portions **103**, **104** or **120**, when this structure is equipped with hooks **107**. In this case, the structure has a zigzagged form, and each hook **107** has two arms **107***b*; each of these arms **107***b* is connected

to the other arm **107***b* at one end and to an arm of structure **101** at its other end. The region of junction of the two arms **107***b* has bent hooking pin **107***a*.

FIG. **27** shows portion **103** which has two undulating wires **125**, **126** extending in the vicinity of one another and secondary undulating wire **127**. As represented in FIG. **28**, wires **125**, **126** can be used to execute the insertion of valve **102** made of biological material between them and the attachment of this valve **102** to them by means of sutures **127**. FIG. **29** shows a part of support **101** according to FIGS. **13** to **17** and the way in which the compressible material constituting shell **108** can absorb the surface irregularities possibly existing at or near ring **110**, which result from calcifications. FIG. **30** shows support **101** whose shell **106** has no compressible shell. A material can then be applied, by means of an appropriate cannula (not represented), between ring **110** and this shell **106**, this material being able to solidify after a predetermined delay following application.

FIG. **31** shows support **101** whose shell **106** has a cross section in the form of a broken line, delimiting, on the exterior radial side, a lower shoulder. Housed in the step formed by this shoulder and the adjacent circumferential wall is peripheral shell **108** which can be inflated by means of a catheter (not represented). This shell **108** delimits a chamber and has a radially expandable structure, such that it has in cross section, in the inflated state, two widened ends projecting on both sides of shell **106**. This chamber can receive an inflating fluid that can solidify in a predetermined delay following its introduction into said chamber. Once this material has solidified, the inflating catheter is cut off.

FIGS. **32** and **33** show support **101** whose shell **106** receives inflatable insert **108** which has a spool-shaped cross section in the inflated state; this insert **108** can be inflated by means of catheter **129**. Insert **108** is positioned in the uninflated state (FIG. **32**) at the sites in which a space exists between shell **106** and existing cardiac ring **110**. Its spool shape allows this insert (cf. FIG. **33**) to conform as much as possible to the adjacent irregular structures and to ensure a better seal.

FIG. **34** shows balloon **130** making it possible to deploy support **101** according to FIGS. **19** to **21**. This balloon **130** has cylindrical portion **131** whose diameter in the inflated state makes possible the expansion of holding portion **120**, a cylindrical portion **132** of lesser diameter, suitable for producing the expansion of portion **103**, and portion **133** in the form of a truncated cone, makes possible the expansion of portion **104**. As shown by FIG. **35**, portion **132** can be limited to what is strictly necessary for deploying portion **103**, which makes it possible to produce balloon **130** in two parts instead of a single part, thus limiting the volume of this balloon **130**.

FIG. **36** shows support **101** whose median portion **103** is in two parts **103***a*, **103***b*. Part **103***a* is made of undulating wire with large-amplitude undulations, in order to support valve **102**, and part **103***b*, adjacent to said part **103***a* and connected to it by bridges **135**, is made of undulating wire with small-amplitude undulations. Due to its structure, this part **103***b* presents a relatively high radial force of expansion and is intended to be placed opposite ring **110** in order to push back: the native valve sheets which are naturally calcified, thickened and indurated, or the residues of the valve sheets after valve resection against or into the wall of the passage. This axial portion **103***a*, **103***b* thus eliminates the problem induced by these sheets or residual sheets at the time of positioning of valve **102**.

It is apparent from the preceding that one embodiment of the invention provides a tubular support for positioning, by percutaneous route, of a replacement heart valve, which provides, due to its portions **103** and **104**, complete certitude as to its maintenance of position after implantation. This support also makes possible a complete sealing of the replacement valve, even in case of a cardiac ring with a surface that is to varying degrees irregular and/or calcified, and its position can be adapted and/or corrected as necessary at the time of implantation.

Referring to FIGS. **37** and **38**, the present invention also comprises an alternative prosthetic valve assembly **310**, which further comprises a prosthetic valve **312**, a valve support band **314**, distal anchor **316**, and a proximal anchor **318**. Valve **312** can be made from a biological material, such as one originating from an animal or human, or from a synthetic material, such as a polymer. Depending upon the native valve to be replaced, the prosthetic valve **312** comprises an annulus **322**, a plurality of leaflets **324**, and a plurality of commissure points **326**. The leaflets **324** permit the flow of blood through the valve **312** in only one direction. In the preferred embodiment, the valve annulus **322** and the commissure points **326** are all entirely supported within the central support band **314**. Valve **312** is attached to the valve support band **314** with a plurality of sutures **328**, which can be a biologically compatible thread. The valve could also be supported on band **314** with adhesive, such as cyanoacrylate.

In one embodiment, valve **312** can be attached to, or may integral with, a sleeve or sheath (not shown). The sheath is secured to the valve support band **314** such that the outer surface of the sheath is substantially in contact with the inner surface of the valve support band **314**. In such embodiment, the sheath can be attached to the valve support band **314** with sutures **328**. FIG. **40** is a photograph of the concept of this alternative embodiment. If desired, the sheath can be secured to the outside of valve support band **314** (not shown).

Referring to FIGS. **37** and **38**, in one embodiment, valve support band **314** is made from a single wire **342** configured in a zigzag manner to form a cylinder. Alternatively, valve support band **314** can be made from a plurality of wires **342** attached to one another. In either case, the band may comprise one or more tiers, each of which may comprise one or more wires arranged in a zigzag manner, for structural stability or manufacturing ease, or as anatomical constraints may dictate. If desired, even where the central valve support **314** is manufactured having more than one tier, the entire valve support **314** may comprise a single wire. Wire **342** can be made from, for example, stainless steel, silver, tantalum, gold, titanium, or any suitable plastic material. Valve support band **314** may comprise a plurality of loops **344** at opposing ends to permit attachment to valve support band **314** of anchors **316** and/or **318** with a link. Loops **344** can be formed by twisting or bending the wire **342** into a circular shape. Alternatively, valve support band **314** and loops **344** can be formed from a single wire **342** bent in a zigzag manner, and twisted or bent into a circular shape at each bend. The links can be made from, for example, stainless steel, silver, tantalum, gold, titanium, any suitable plastic material, solder, thread, or suture. The ends of wire **342** can be joined together by any suitable method, including welding, gluing or crimping.

Still referring to FIGS. **37** and **38**, in one embodiment, distal anchor **316** and proximal anchor **318** each comprise a discrete expandable band made from one or more wires **342** bent in a zigzag manner similar to the central band. Distal anchor band **316** and proximal anchor band **318** may comprise a plurality of loops **344** located at an end of wire **342** so that distal anchor band **316** and proximal anchor band **318** can each be attached to valve support band **314** with a link. Loop **344** can be formed by twisting or bending the wire **342** into a circular shape. As desired, distal and proximal anchors

316, 318 may comprise one or more tiers, as explained before with the valve support 314. Likewise, each anchor may comprise one or more wires, regardless of the number of tiers. As explained above in regard to other embodiments, the distal anchor may be attached to the central valve support band 314 directly, as in FIG. 37, or spaced distally from the distal end of the valve support 314, as shown above schematically in FIGS. 18, 19, 21 and 22. In the later instance, one or more struts may be used to link the distal anchor band to the valve support band, as described above.

Distal anchor band 316 has a first end 350 attached to the central valve band 314, and a second end 352. Similarly, proximal anchor band 318 has first attached end 354 and a second end 356. The unattached ends 352, 356 of the anchors 316, 318, respectively are free to expand in a flared manner to conform to the local anatomy. In such embodiment the distal and proximal anchor bands 316, 318 are configured to exert sufficient radial force against the inside wall of a vessel in which it can be inserted. Applying such radial forces provides mechanical fixation of the prosthetic valve assembly 310, reducing migration of the prosthetic valve assembly 310 once deployed. It is contemplated, however, that the radial forces exerted by the valve support 314 may be sufficient to resist more than a minimal amount of migration, thus avoiding the need for any type of anchor.

In an alternative embodiment, distal and proximal anchors may comprise a fixation device, including barbs, hooks, or pins (not shown). Such devices may alternatively or in addition be placed on the valve support 314. If so desired, the prosthetic valve assembly 310 may comprise an adhesive on the exterior thereof to adhere to the internal anatomical lumen.

Prosthetic valve assembly 310 is compressible about its center axis such that its diameter may be decreased from an expanded position to a compressed position. When placed into the compressed position, valve assembly 310 may be loaded onto a catheter and transluminally delivered to a desired location within a body, such as a blood vessel, or a defective, native heart valve. Once properly positioned within the body the valve assembly 310 can be deployed from the compressed position to the expanded position. FIG. 39 is a photograph of one embodiment of the prosthetic valve assembly described with both distal and proximal anchor bands while FIG. 49 is a photograph showing only a distal anchor.

In the preferred embodiment, the prosthetic valve assembly 310 is made of self-expanding material, such as Nitinol. In an alternative embodiment, the valve assembly 310 requires active expansion to deploy it into place. Active expansion may be provided by an expansion device such as a balloon.

As referred to above in association with other embodiments, the prosthetic valve assembly of the present invention is intended to be percutaneously inserted and deployed using a catheter assembly. Referring to FIG. 41A, the catheter assembly 510 comprises an outer sheath 512, an elongate pusher tube 514, and a central tube 518, each of which are concentrically aligned and permit relative movement with respect to each other. At a distal end of the pusher tube 514 is a pusher tip 520 and one or more deployment hooks 522 for retaining the prosthesis assembly (not shown). The pusher tip 520 is sufficiently large so that a contracted prosthesis assembly engages the pusher tip 520 in a frictional fit arrangement. Advancement of the pusher tube 514 (within the outer sheath 512) in a distal direction serves to advance the prosthesis relative to the outer sheath 512 for deployment purposes.

At a distal end of the central tube 518 is an atraumatic tip 524 for facilitating the advancement of the catheter assembly 510 through the patient's skin and vasculature. The central tube 518 comprises a central lumen (shown in phantom) that can accommodate a guide wire 528. In one embodiment, the central lumen is sufficiently large to accommodate a guide wire 528 that is 0.038 inch in diameter. The guide wire can slide through the total length of the catheter form tip to handle ('over the wire' catheter) or the outer sheath 512 can be conformed so as to allow for the guide wire to leave the catheter before reaching its proximal end ('rapid exchange' catheter). The space between the pusher tube 514 and the outer sheath 512 forms a space within which a prosthetic valve assembly may be mounted.

Hooks 522 on the distal end of the pusher tube 514 may be configured in any desired arrangement, depending upon the specific features of the prosthetic assembly. With regard to the prosthesis assembly of FIGS. 37 and 38, the hooks 522 preferably comprise an L-shaped arrangement to retain the prosthesis assembly axially, but not radially. With a self-expanding assembly, as the prosthesis assembly is advanced distally beyond the distal end of the outer sheath 512, the exposed portions of the prosthesis assembly expand while the hooks 522 still retain the portion of the prosthesis still housed within the outer sheath. When the entire prosthesis assembly is advanced beyond the distal end of the outer sheath, the entire prosthesis assembly is permitted to expand, releasing the assembly from the hooks. FIGS. 42 through 45 show the distal end of one embodiment of the catheter assembly, three of which show sequenced deployment of a valve prosthesis.

In an alternative embodiment of the valve prosthesis, loop elements extend axially from one end of the prosthesis, where the loop elements can be retained by the hooks 522 during deployment. This alternative embodiment is shown in the photograph of FIG. 48, where the photographs of FIGS. 46 and 47 show a catheter assembly used for deploying the alternative prosthesis assembly. By adding loop elements to the prosthesis, the prosthesis may be positioned with its support and anchors fully expanded in place while permitting axial adjustment into final placement before releasing the prosthesis entirely from the catheter.

FIG. 41B shows the proximal end of the catheter assembly 510, which to a greater extent has many conventional features. At the distal end of the pusher tube 514 is a plunger 530 for advancing and retreating the pusher tube 514 as deployment of the prosthesis assembly is desired. As desired, valves and flush ports proximal and distal to the valve prosthesis may be provided to permit effective and safe utilization of the catheter assembly 510 to deploy a prosthesis assembly.

In one embodiment, prosthetic valve assembly 310 (not shown) is mounted onto catheter 510 so that the valve assembly 310 may be delivered to a desired location inside of a body. In such embodiment, prosthetic valve assembly 310 is placed around pusher tip 520 and compressed radially around the tip 520. The distal end of prosthetic valve assembly 310 is positioned on the hooks 522. While in the compressed position, outer sheath 512 is slid toward the atraumatic tip 524 until it substantially covers prosthetic valve assembly 310.

To deliver prosthetic valve assembly 310 to a desired location within the body, a guide wire 528 is inserted into a suitable lumen of the body, such as the femoral artery or vein to the right atrium, then to the left atrium through a transseptal approach, and maneuvered, utilizing conventional techniques, until the distal end of the guide wire 528 reaches the desired location. The catheter assembly 510 is inserted into the body over the guide wire 528 to the desired position. Atraumatic tip 524 facilitates advancement of the catheter assembly 510 into the body. Once the desired location is reached, the outer sheath 512 is retracted permitting the valve prosthesis to be released from within [illegible]

and expand to conform to the anatomy. In this partially released state, the position of prosthetic valve **310** may be axially adjusted by moving catheter assembly **510** in the proximal or distal direction.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, and not restrictive and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A prosthetic valve assembly for use in replacing a deficient native valve, the valve assembly comprising:

a valve having a plurality of leaflets, a base, and a plurality of commissure points;

a valve support comprising a generally cylindrical band comprising a plurality of expandable cells, the valve support configured to be collapsible for transluminal delivery and expandable to contact the anatomical annulus of the native valve when the assembly is positioned in situ, said generally cylindrical band of the valve support supporting the base and the commissure points of the valve; and

an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment:

wherein the anchor comprises one or more hooks extending radially outward from the valve support.

2. The valve assembly of claim **1**, wherein the valve support comprises nickel titanium.

3. A method of replacing a deficient native valve comprising the steps of:

providing a prosthetic valve assembly, the assembly comprising a valve, a valve support comprising a plurality of expandable cells and having the base and the commissures of the valve positioned and secured at or adjacent the expandable cells, the valve support further comprising an anchor;

collapsing the valve support and anchor to fit on a distal portion of a catheter;

advancing the catheter to the deficient native valve to a position within adjacent the leaflets and within the annulus of the deficient native valve;

deploying the valve assembly within the deficient native valve, whereby the valve support expands against the leaflets of the deficient native valve; and

withdrawing the catheter, leaving the valve assembly to function in place of the deficient native valve.

4. The method of claim **3**, further comprising the step of positioning the valve support and anchor within a generally tubular sheath extending around the distal portion of the catheter.

5. The method of claim **3**, wherein the anchor is self-expanding.

6. The method of claim **3**, wherein the valve support is self-expanding.

7. The method of claim **3**, wherein the valve support is balloon-expandable.

8. The method of claim **3**, further comprising the step of securing a portion of the valve support to the catheter.

9. The method of claim **3**, wherein deploying the valve assembly comprises the step of crushing the native valve leaflets against the native valve annulus.

10. The method of claim **3**, wherein the prosthetic valve assembly further comprises an anchor for engaging a lumen wall for preventing substantial migration of the valve assembly when positioned in place.

11. The method of claim **10**, wherein the anchor is spaced from the valve support.

12. A prosthetic valve assembly for use in replacing a deficient native valve, the valve assembly comprising:

a valve having a base, a plurality of leaflets and commissure points;

a valve support comprising a plurality of expandable cells and a plurality of longitudinal bars, the valve support configured to be collapsible for transluminal delivery and expandable to contact the anatomical annulus of the native valve when the assembly is positioned in situ, said valve support supporting the base, wherein the commissure points of the valve are secured at the longitudinal bars and adjacent one or more of the expandable cells, and wherein the longitudinal bars of the valve support further comprise a plurality of holes, wherein the plurality of leaflets are secured to the longitudinal bars via suture lines passing through the plurality of holes.

13. The valve assembly of claim **12**, wherein the valve support is self-expanding.

14. The valve assembly of claim **12**, wherein the valve support is balloon expandable.

15. The valve assembly of claim **12**, wherein the valve support is configured to press radially against the native valve leaflets to hold the native valve leaflets against walls of the native valve annulus and/or against walls of an adjacent lumen to thereby prevent the native valve leaflets from obstructing the native valve annulus.

* * * * *

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge James V. Selna and the assigned discovery Magistrate Judge is Marc Goldman.

The case number on all documents filed with the Court should read as follows:

SACV11- 961 JVS (MLGx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

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NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[ ] **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

[X] **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

[ ] **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

CENTRAL DISTRICT OF CALIFORNIA

Medtronic CoreValve LLC, Medtronic CV Luxembourg S.A.R.L., and Medtronic Vascular Galway Ltd.

Plaintiff

v.

Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.), Inc.

Defendant

Civil Action No. SACV11-00961 JVS (MLGx)

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Edwards Lifesciences Corporation, Edwards Lifesciences LLC,
Edwards Lifesciences (U.S.) Inc.
One Edwards Way
Irvine, CA 92614

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

David Martinez, Esq.
Robins, Kaplan, Miller & Ciresi L.L.P.
2049 Century Park East, Suite 3400,
Los Angeles, CA 90067-3208

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: JUN 27 2011

Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)
MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L. AND MEDTRONIC VASCULAR GALWAY LTD

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

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)
David Martinez (310) 552-0130
ROBINS, KAPLAN, MILLER & CIRESI L.L.P.
2049 Century Park East, Suite 3400, Los Angeles, CA 90037-3208

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 - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.)

	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. 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 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☑ Yes ☐ No (Check 'Yes' only if demanded in complaint.)
CLASS ACTION under F.R.C.P. 23: ☐ Yes ☑ No **☐ MONEY DEMANDED IN COMPLAINT: $**

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
Action for patent infringement (Violation of 35 U.S.C. § 271)

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/etc.
☐ 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 Act
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Info. Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes

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 Loan (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 Fed. Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
☐ 362 Personal Injury-Med Malpractice
☐ 365 Personal Injury-Product Liability
☐ 368 Asbestos Personal Injury Product Liability

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

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

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

CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/Accommodations
☐ 444 Welfare
☐ 445 American with Disabilities - Employment
☐ 446 American with 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

PROPERTY RIGHTS
☐ 820 Copyrights
☑ 830 Patent
☐ 840 Trademark

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

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

FOR OFFICE USE ONLY: Case Number: SACV11-00961

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☑ No ☐ Yes
If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☑ No ☐ Yes
If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:
(Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Medtronic Corevalve LLC: Orange County	Medtronic CV Luxembourg S.a.r.l.: Luxembourg Medtronic Vascular Galway Ltd.: Galway, Ireland

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc.: Orange County	

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange County	

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**
Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): _____ Date June 24, 2011
David Martinez

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Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

EXHIBIT M

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, SANTA ANA

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

Plaintiffs,

v.

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

Defendants.

CASE NO. SACV11-00961 JVS (MLGx)
Hon. Joseph V. Selna
Magistrate Judge Marc L. Goldman

ANSWER AND COUNTERCLAIMS

DEMAND FOR JURY TRIAL

COMPLAINT FILED: June 27, 2011

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

Counterclaim-Plaintiffs,

v.

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

Counterclaim-Defendants

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Defendants and Counterclaim-Plaintiffs Edwards Lifesciences Corporation, Edwards Lifesciences LLC ("Edwards LLC") and Edwards Lifesciences (U.S.) Inc. (collectively, "Edwards"), file this Answer and Counterclaims Counts I and II in response to Plaintiffs Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l. and Medtronic Vascular Galway Ltd. (collectively, "Medtronic Plaintiffs") Complaint for Patent Infringement (hereinafter, "the Complaint"), and Counterclaim-Plaintiffs Edwards LLC and Edwards Lifesciences PVT, Inc. ("Edwards PVT") file Counterclaim Count III for infringement of United States Patent No. 8,002,825 by the Medtronic entities as hereinafter stated.

ANSWER

INTRODUCTION

1. Edwards admits only that the Complaint purports to bring an action for patent infringement.

2. Edwards is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 of the Complaint, and

accordingly those allegations are denied.

3. Edwards is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 of the Complaint, and accordingly those allegations are denied.

4. Edwards is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4 of the Complaint, and accordingly those allegations are denied.

5. Edwards admits the allegations of Paragraph 5 of the Complaint.

6. Edwards admits the allegations of Paragraph 6 of the Complaint.

7. Edwards admits the allegations of Paragraph 7 of the Complaint.

JURISDICTION AND VENUE

8. Edwards admits only that the Medtronic Plaintiffs purport to invoke the jurisdiction of this Court pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Edwards admits only that venue in this District is proper.

10. Edwards admits only that this Court has personal jurisdiction over each of the named Defendants. Edwards denies every other allegation of Paragraph 10.

FACTUAL BACKGROUND

11. Edwards admits that United States Patent No. 7,892,281 ("the Seguin '281 patent") was issued on February 22, 2011, is entitled "Prosthetic Valve for Transluminal Delivery," and that a copy of the Seguin '281 patent is attached to the Complaint as "Exhibit 1." Edwards denies the remaining allegations of Paragraph 11 of the Complaint.

12. Edwards is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 12 of the Complaint, and accordingly those allegations are denied.

13. Edwards is without knowledge or information sufficient to form a

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belief as to the truth of the allegations of Paragraph 13 of the Complaint, and accordingly those allegations are denied.

14. Edwards is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 14 of the Complaint, and accordingly those allegations are denied.

15. Edwards is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 15 of the Complaint, and accordingly those allegations are denied.

COUNT 1

16. Edwards restates, realleges and incorporates by reference its responses to the allegations set forth in Paragraphs 1 through 15.

17. Edwards denies the allegations of Paragraph 17 of the Complaint.

18. Edwards denies the allegations of Paragraph 18 of the Complaint.

19. Edwards denies the allegations of Paragraph 19 of the Complaint.

20. Edwards denies the allegations of Paragraph 20 of the Complaint.

21. Edwards denies the allegations of Paragraph 21 of the Complaint.

AFFIRMATIVE DEFENSES

First Affirmative Defense (Failure to State a Claim)

22. Medtronic Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

Second Affirmative Defense (Noninfringement)

23. Edwards has not infringed, contributorily infringed or actively induced the infringement of any valid claim of the Seguin '281 patent, either literally or under the doctrine of equivalents, and does not do so now.

Third Affirmative Defense (Invalidity)

24. Edwards is informed and believes, and thereupon alleges, that the Seguin '281 patent is invalid for failure to meet one or more of the requirements of

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patentability under United States Code Title 35, including, without limitation, one or more of the requirements of 35 U.S.C. §§ 102, 103 and/or 112.

Additional Affirmative Defenses

25. Edwards expressly reserves the right to assert and pursue additional defenses resulting from discovery and/or Edwards' ongoing investigations.

PRAYER FOR RELIEF

WHEREFORE, Edwards prays for relief as follows:

A. That the Court enter judgment in favor of Edwards, and against Medtronic Plaintiffs;

B. That the Court enter judgment that Edwards has not infringed the Seguin '281 patent, either literally or under the doctrine of equivalents;

C. That the Court enter judgment that the Seguin '281 patent is invalid;

D. That the Court deny any and all of Medtronic Plaintiffs' requests for injunctive relief;

E. That the Court dismiss Medtronic Plaintiffs' Complaint in its entirety, with prejudice;

F. That the Court find this case exceptional under 35 U.S.C. § 285, and award Edwards its reasonable attorneys' fees, costs and disbursements; and

G. That the Court grant Edwards such other relief as the Court deems just and proper.

JURY DEMAND

Edwards demands a trial by jury on all issues so triable in the Complaint.

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COUNTERCLAIMS

INTRODUCTION

1. These Counterclaims are for declaratory relief with respect to the Seguin '281 patent (Counts I and II), and for willful infringement of United States Patent 8,002,825 ("the Cribier '825 patent") owned and licensed by Edwards PVT and Edwards LLC as hereinafter stated (Count III). These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 101 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

JURISDICTION AND VENUE

2. The Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, and 1367.

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

4. Counterclaim-Plaintiffs Edwards Lifesciences Corporation, Edwards LLC, Edwards Lifesciences (U.S.) Inc. and Edwards PVT are each organized and existing under the laws of Delaware, with their principal places of business in Irvine, California.

5. Upon information and belief, Counterclaim-Defendant Medtronic CoreValve LLC is a limited liability corporation organized and existing under the laws of Delaware, with its principal place of business in Irvine, California.

6. Upon information and belief, Counterclaim-Defendant Medtronic CV Luxembourg S.a.r.l. is a limited liability company organized and existing under the laws of Luxembourg, with its principal place of business in Luxembourg. Upon information and belief, Medtronic CV Luxembourg S.a.r.l. is subject to the jurisdiction of this Court, *inter alia*, by virtue of invoking the jurisdiction of this Court by filing this action, and by doing business in this District.

7. Upon information and belief, Counterclaim-Defendant Medtronic

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Vascular Galway Ltd. is a company organized and existing under the laws of Ireland, with its principal place of business in Galway, Ireland. Upon information and belief, Medtronic Vascular is subject to the jurisdiction of this Court, *inter alia*, by virtue of invoking the jurisdiction of this Court by filing this action, and by doing business in this District.

8. Upon information and belief, Counterclaim-Defendant Medtronic, Inc. is a corporation organized and existing under the laws of the state of Minnesota and having its principal place of business in Minneapolis, Minnesota. Upon information and belief, Medtronic, Inc. is subject to the jurisdiction of this Court, *inter alia*, by doing business in this District.

9. Upon information and belief, Counterclaim-Defendant Medtronic Vascular, Inc. is a corporation organized and existing under the laws of the state of Delaware and having its principal place of business in Santa Rosa, California. Upon information and belief, Medtronic Vascular, Inc. is subject to the jurisdiction of this Court, *inter alia*, by doing business in this District.

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COUNT I

DECLARATORY JUDGMENT OF

NONINFRINGEMENT OF THE SEGUIN '281 PATENT

10. Edwards restates, realleges and incorporates by reference the allegations made in the Affirmative Defenses and in Paragraphs 1-9 of the Counterclaims above.

11. An actual controversy exists between Edwards and Counter-Defendants Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l. and Medtronic Vascular Galway Ltd. over the alleged infringement of the Seguin '281 patent.

12. Edwards has not infringed, contributorily infringed or actively induced the infringement of any valid claim of the Seguin '281 patent, either literally or

under the doctrine of equivalents.

13. Edwards has not willfully infringed, contributorily infringed or actively induced the infringement of any valid claim of the Seguin '281 patent, either literally or under the doctrine of equivalents.

COUNT II

DECLARATORY JUDGMENT OF

INVALIDITY OF THE SEGUIN '281 PATENT

14. Edwards restates, realleges and incorporates by reference the allegations made in its Affirmative Defenses and in Paragraphs 1-13 of Edwards' Counterclaims above.

15. An actual controversy exists between Edwards and Counterclaim-Defendants Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l. and Medtronic Vascular Galway Ltd. over the invalidity of the Seguin '281 patent.

16. All claims of the Seguin '281 patent are invalid because they fail to comply with one or more requirements of United States Code Title 35, including, without limitation, one or more requirements of 35 U.S.C. §§ 102, 103 and/or 112.

COUNT III

INFRINGEMENT OF THE CRIBIER '825 PATENT

17. Counterclaim-Plaintiffs Edwards LLC and Edwards PVT restate, reallege and incorporate by reference the allegations of Paragraphs 1-16 above.

18. On August 23, 2011, the Cribier '825 patent (Exhibit A hereto), entitled "Implantable Prosthetic Valve for Treating Aortic Stenosis," was duly and legally issued and names Alain Cribier and Brice Letac as inventors. Counterclaim-Plaintiff Edwards PVT is the assignee of the Cribier '825 patent, and Counterclaim-Plaintiff Edwards LLC is the exclusive licensee of the Cribier '825 patent for the field of all cardiovascular applications, including the right to sue and recover for any and all past infringement thereof in the field of all cardiovascular applications.

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19. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., Medtronic Vascular Galway Ltd., Medtronic, Inc. and/or Medtronic Vascular, Inc. have been and are now infringing the Cribier '825 patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one of more claims of the Cribier '825 patent, including without limitation products designated as the Generation 3 ReValving system.

20. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic CV Luxembourg S.a.r.l., Medtronic Vascular Galway Ltd., Medtronic, Inc. and/or Medtronic Vascular, Inc. had knowledge of the Cribier '825 patent, and have acted with specific intent to actively induce Medtronic CoreValve LLC to directly infringe the Cribier '825 patent by, *inter alia*, manufacturing the Generation 3 ReValving system.

21. Upon information and belief, and in violation of 35 U.S.C. § 271, Medtronic CV Luxembourg S.a.r.l., Medtronic Vascular Galway Ltd., Medtronic, Inc., and/or Medtronic Vascular, Inc. have contributorily infringed the Cribier '825 patent by supplying components constituting a material part of the invention claimed in the Cribier '825 patent, knowing the same to be especially made or especially adapted for infringement of the Cribier '825 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, including without limitation infringement by virtue of Medtronic CoreValve LLC's manufacture of the Generation 3 ReValving system.

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

23. Counterclaim-Plaintiffs Edwards PVT and Edwards LLC have been damaged and will be irreparably injured by the foregoing continuing infringement, for which Edwards PVT and Edwards LLC have no adequate remedy at law. These

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infringing activities will continue unless enjoined by this Court.

ADDITIONAL COUNTERCLAIMS

Each and all of the Counterclaim-Plaintiffs reserve the right to assert and pursue additional counterclaims resulting from discovery and the Counterclaim-Plaintiffs' ongoing investigations.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs Edwards and Edwards PVT pray for relief as follows:

A. That the Court enter judgment that Edwards has not infringed the Seguin'281 patent, either literally or under the doctrines of equivalents;

B. That the Court enter judgment that the Seguin '281 patent is invalid;

C. That the Court enter judgment that Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., Medtronic Vascular Galway Ltd., Medtronic, Inc. and Medtronic Vascular, Inc. have infringed, contributorily infringed and/or actively induced the infringement of the Cribier '825 patent;

D. That the Court enter judgment that the foregoing infringement by Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., Medtronic Vascular Galway Ltd., Medtronic, Inc. and Medtronic Vascular, Inc. has been willful and deliberate;

E. That the Court enter an order permanently enjoining and restraining Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., Medtronic Vascular Galway Ltd., Medtronic, Inc. and Medtronic Vascular, Inc., 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 actively inducing others to infringe the Cribier '825 patent;

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F. That the Court award Edwards PVT and Edwards LLC damages, in an amount to be determined at trial, together with interest and costs as fixed by the Court;

G. That the Court award Edwards PVT and Edwards LLC enhanced damages under 35 U.S.C. § 284;

H. That the Court award Edwards and Edwards PVT their reasonable attorneys' fees and their costs and disbursements in this action, as provided by 35 U.S.C. § 285; and

I. That the Court grant Edwards and Edwards PVT such other relief as the Court deems just and proper.

JURY DEMAND

Edwards and Edwards PVT demand a trial by jury on all issues so triable in its Counterclaims.

Dated: September 19, 2011

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Exhibit A

US008002825B2

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

(10) **Patent No.: US 8,002,825 B2**
(45) **Date of Patent: *Aug. 23, 2011**

(54) **IMPLANTABLE PROSTHETIC VALVE FOR TREATING AORTIC STENOSIS**

(75) Inventors: **Brice Letac**, Mont-Saint-Aigan (FR); **Alain Cribier**, Pavilly (FR)

(73) Assignee: **Edwards Lifesciences PVT, Inc.**, Irvine, CA (US)

(*) 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.: **12/915,538**

(22) Filed: **Oct. 29, 2010**

(65) **Prior Publication Data**

US 2011/0040375 A1 Feb. 17, 2011

Related U.S. Application Data

(63) Continuation of application No. 11/942,690, filed on Nov. 19, 2007, now Pat. No. 7,846,204, which is a continuation of application No. 11/110,402, filed on Apr. 20, 2005, now abandoned, which is a continuation of application No. 10/139,741, filed on May 2, 2002, now Pat. No. 6,908,481, which is a continuation of application No. 09/795,803, filed on Feb. 28, 2001, now abandoned, which is a continuation of application No. 09/345,824, filed on Jun. 30, 1999, now abandoned, which is a continuation of application No. PCT/EP97/07337, filed on Dec. 13, 1997.

(30) **Foreign Application Priority Data**

Dec. 31, 1996 (EP) 96402929

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

(52) **U.S. Cl.** **623/2.14**; 623/2.17; 623/900

(58) **Field of Classification Search** 623/2.14, 623/2.17, 900, 1.26, 2.12
See application file for complete search history.

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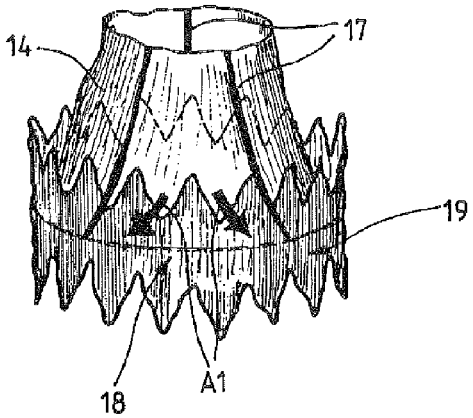
Primary Examiner — Brian Pellegrino
(74) *Attorney, Agent, or Firm* David L. Hauser

(57) **ABSTRACT**

A prosthetic valve for implantation in a stenosed aortic valve. The prosthetic valve includes a compressible and expandable frame formed with intersecting metallic bars and a valvular structure made with pericardial tissue. The frame is compressible for delivery into a patient's vasculature through an 18 F (5.7 mm) arterial introducer using a catheterization technique. The bars of the frame preferably have a diameter in the range of 0.1 to 0.6 mm for providing the frame with sufficient radial strength to resist the recoil force exerted by the stenosed aortic valve after implantation. The prosthetic valve includes an internal cover made with pericardial tissue. The internal cover is fastened to an internal surface of the frame between an inlet end of the frame and the valvular structure for preventing regurgitation.

20 Claims, 18 Drawing Sheets



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Amendments to claims 33-49 from U.S. Appl. No. 09/795,803, filed Apr. 15, 2002 (pp. 1-3).

Claims 1-32 form U.S. Appl. No. 09/345,824, filed Jun. 30, 1999, (pp. 39-43).

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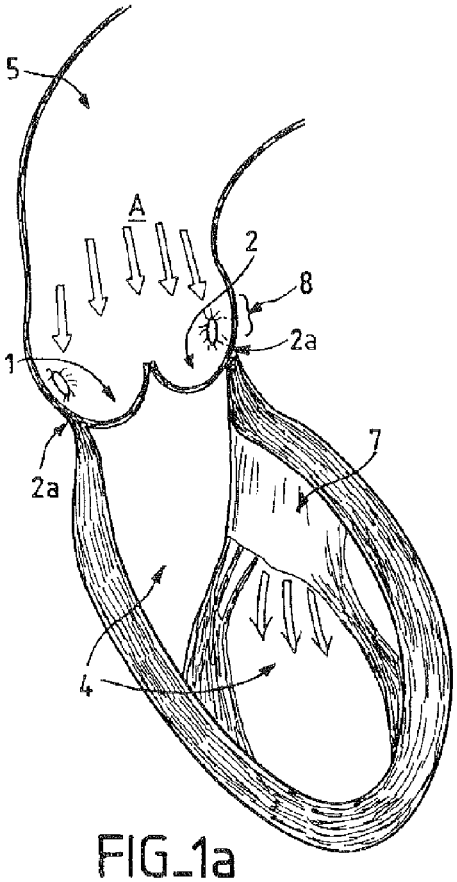
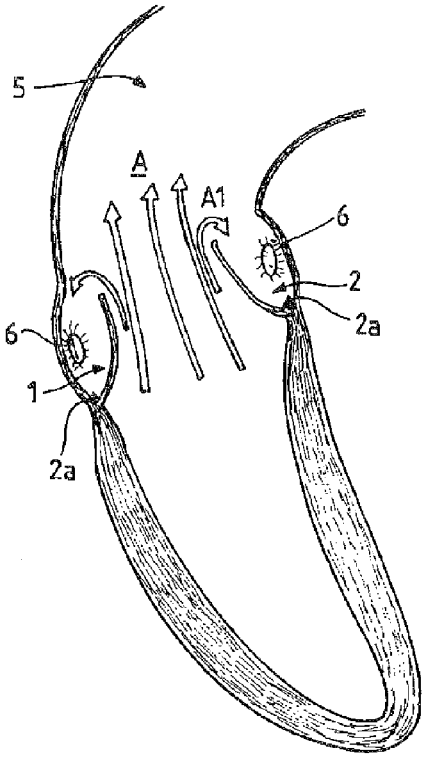


FIG_1a



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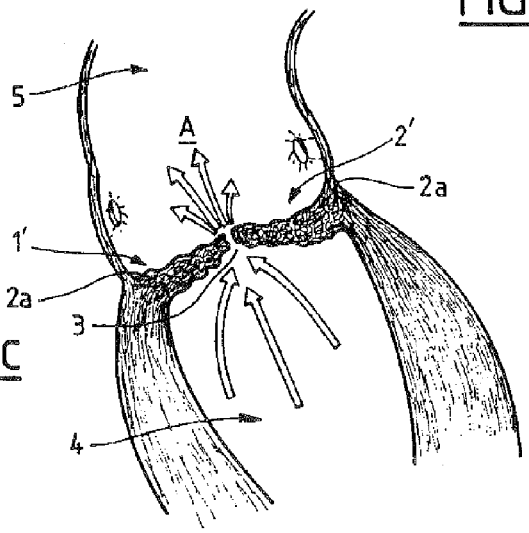


FIG_1c

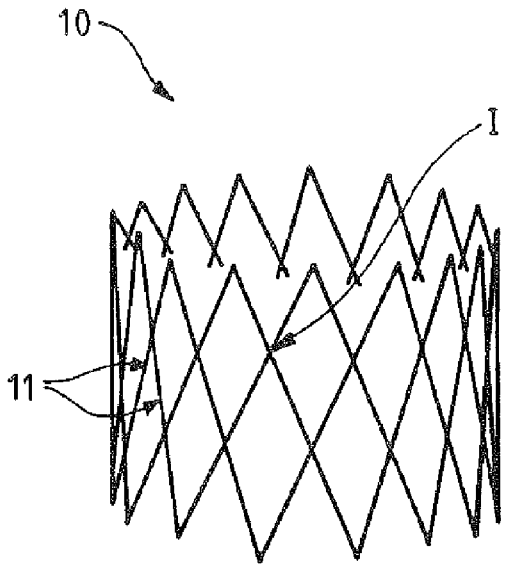


FIG_2a

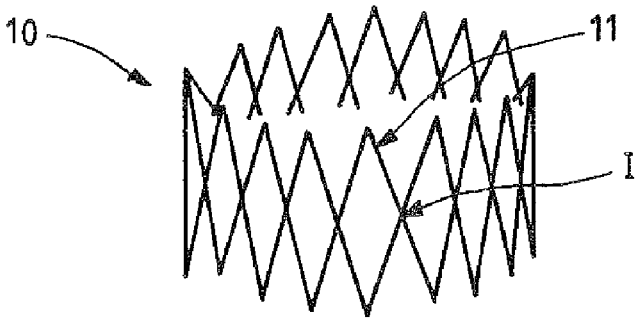


FIG_2b

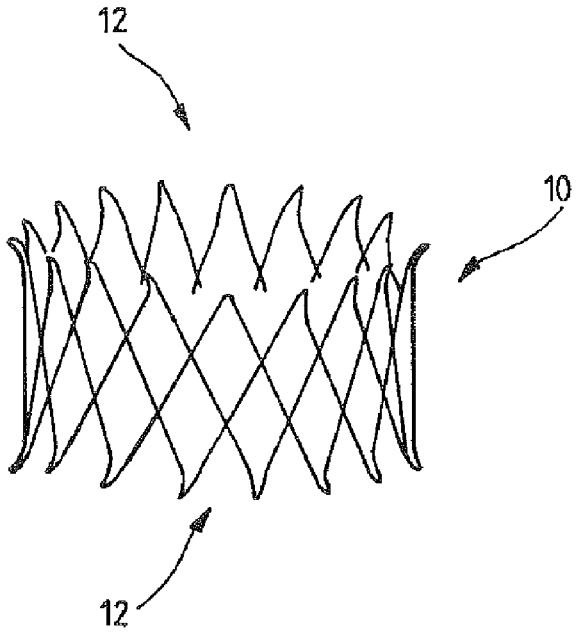


FIG_3a

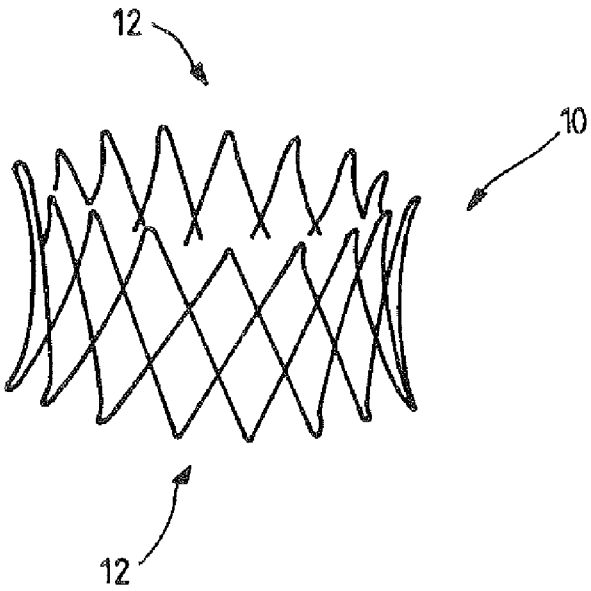
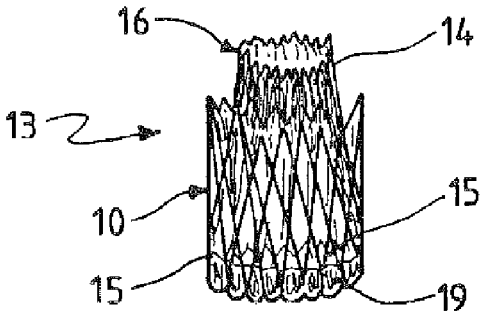


FIG_3b



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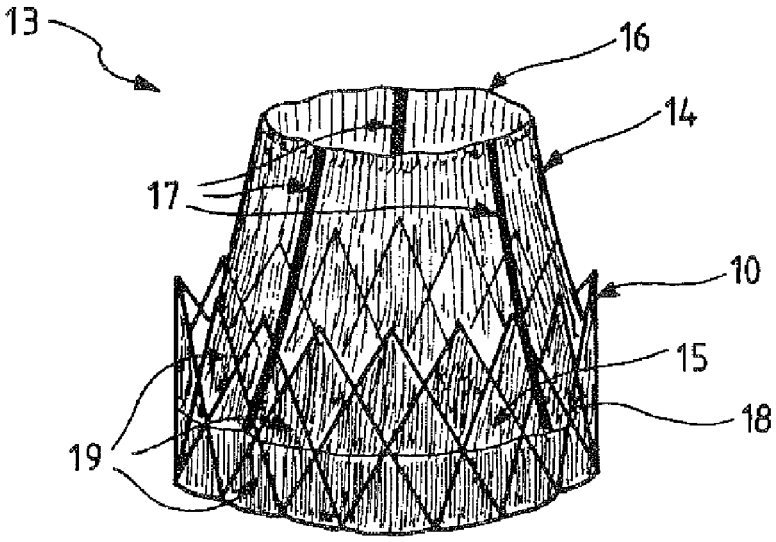


FIG_4b

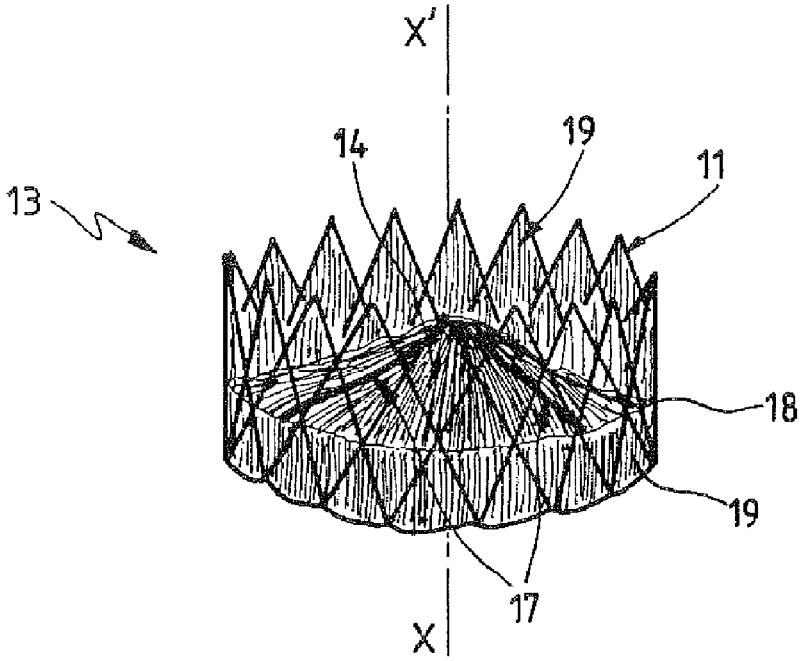


FIG_5a

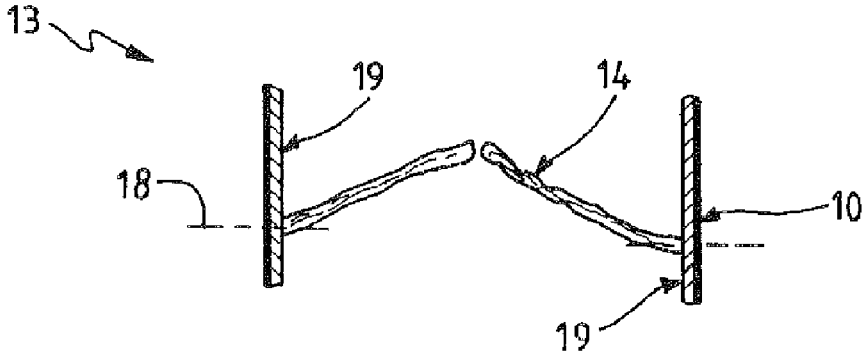


FIG_5b

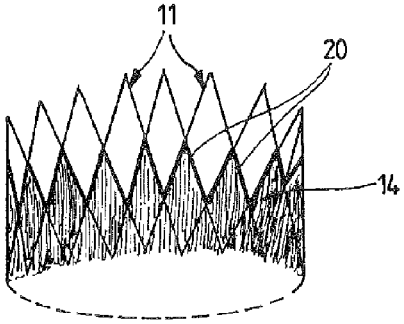


FIG_7

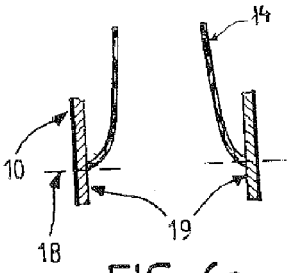


FIG_6a

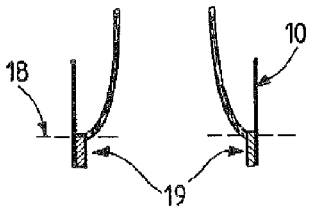


FIG_6b

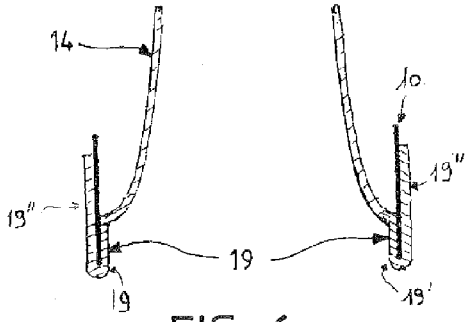


FIG_6d

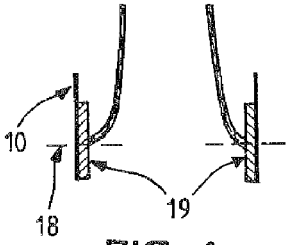


FIG_6c

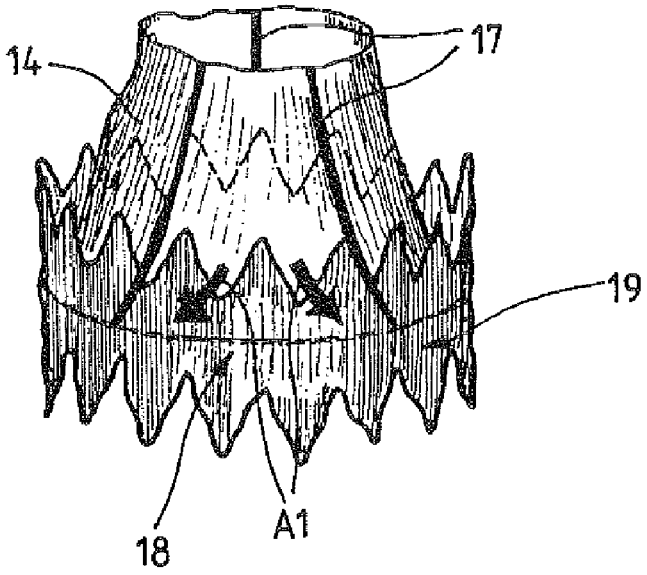


FIG_8a

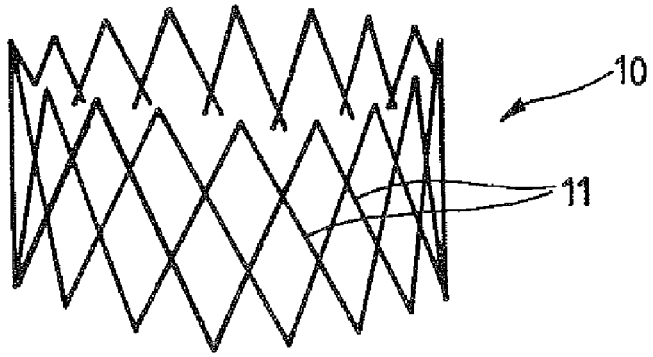


FIG_8b

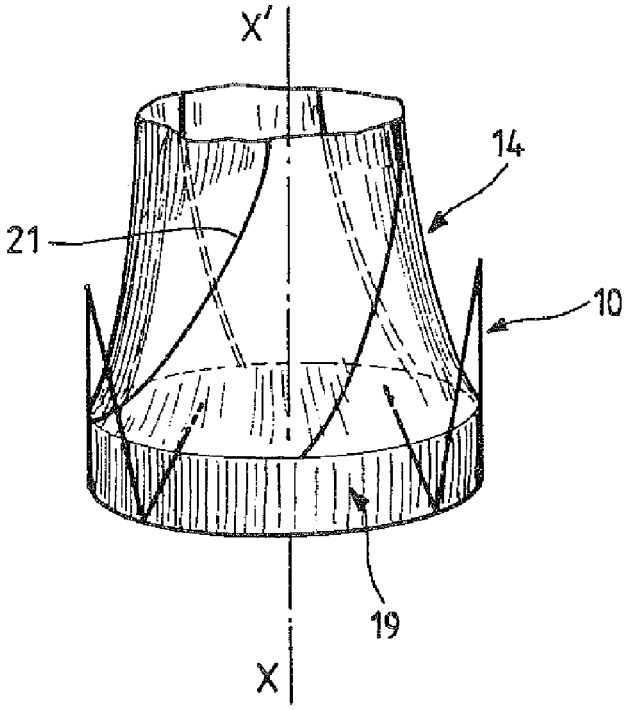


FIG_9a

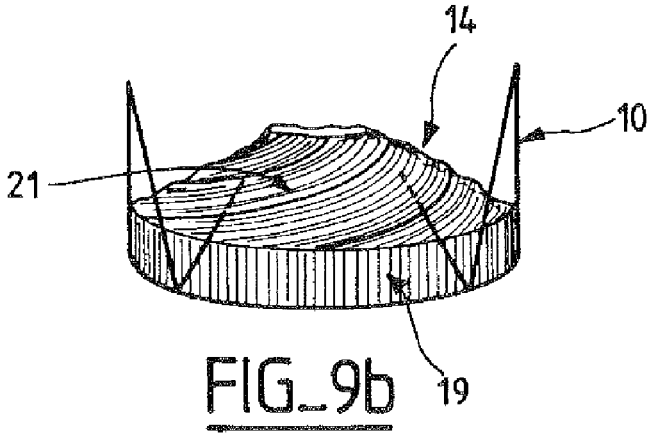


FIG_9b

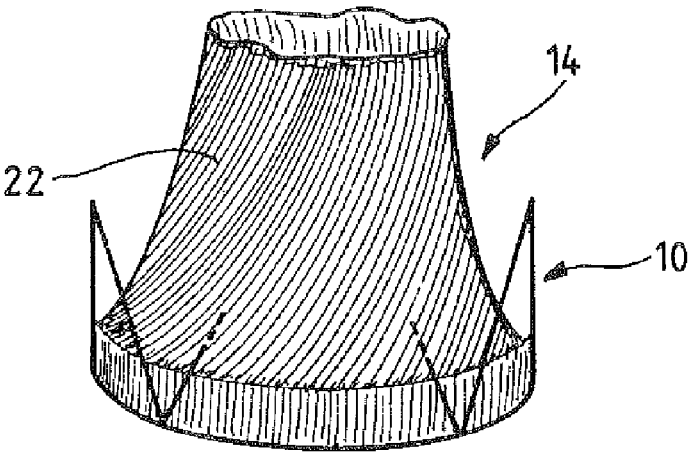


FIG_10a

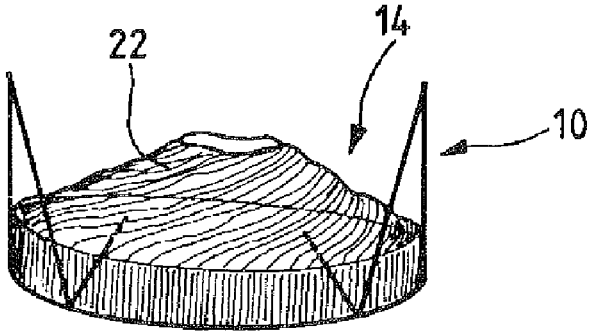


FIG_10b

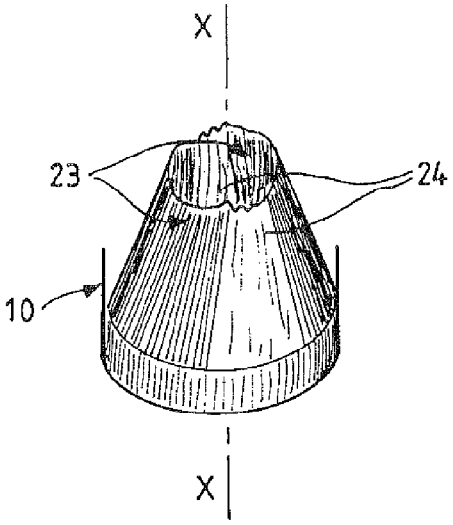


FIG_11a

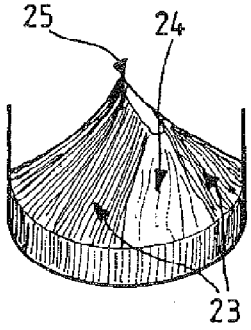


FIG_11b

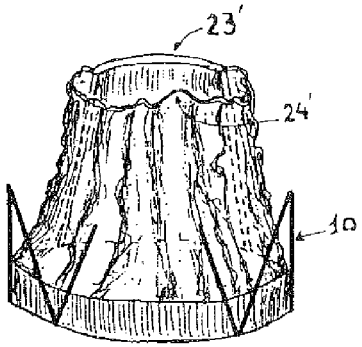


FIG_11c

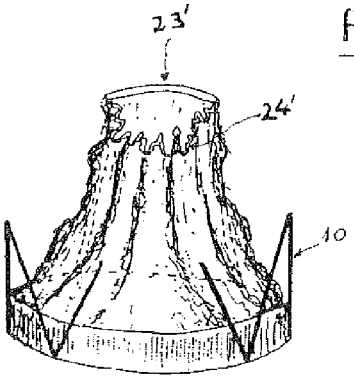


FIG_11d

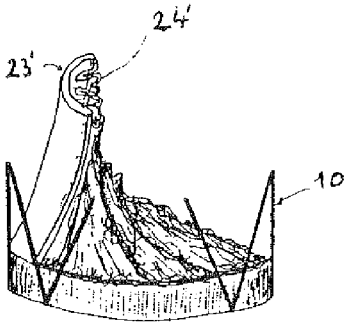


FIG_11e

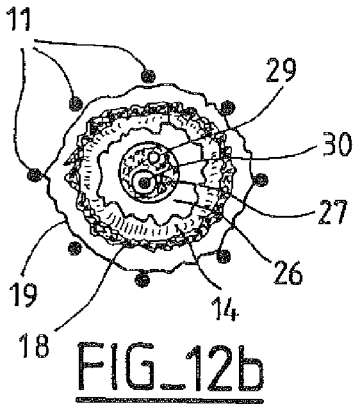


FIG_12b

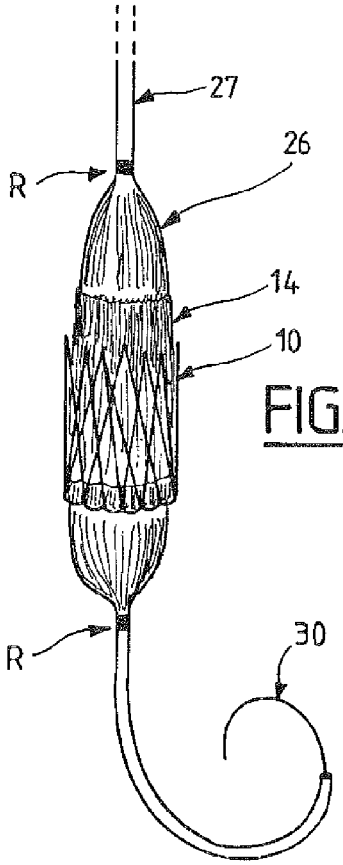


FIG_12a

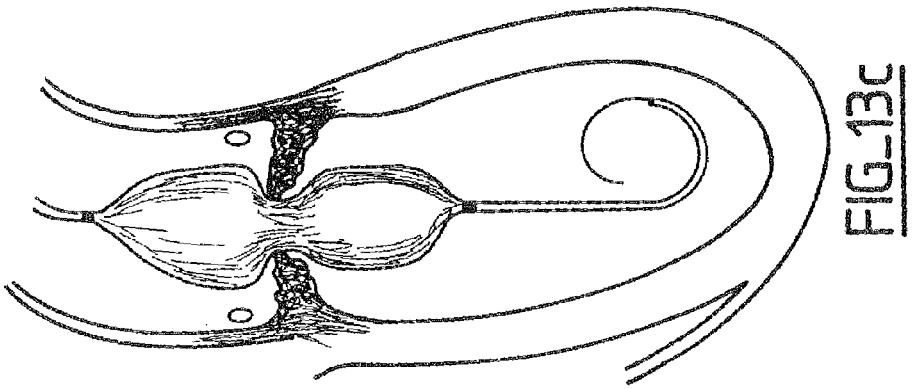


FIG_13c

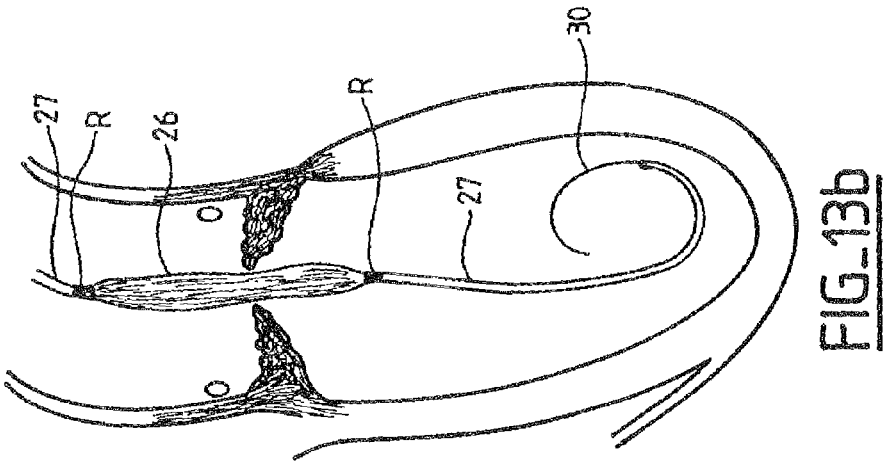


FIG_13b

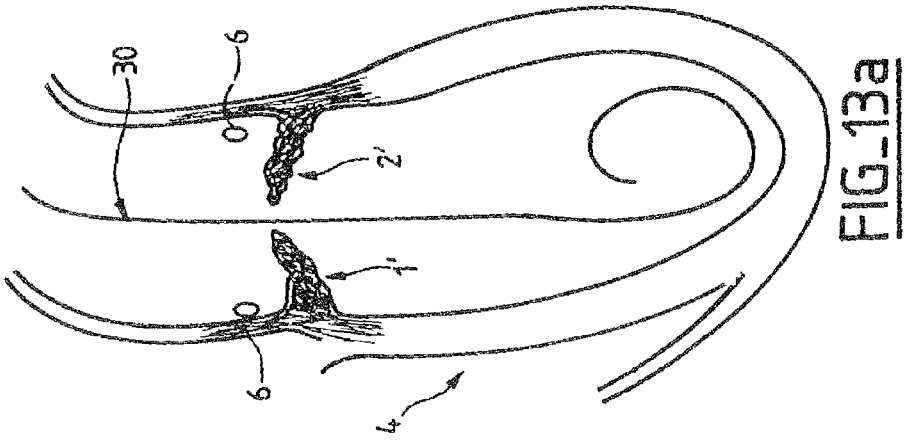


FIG_13a

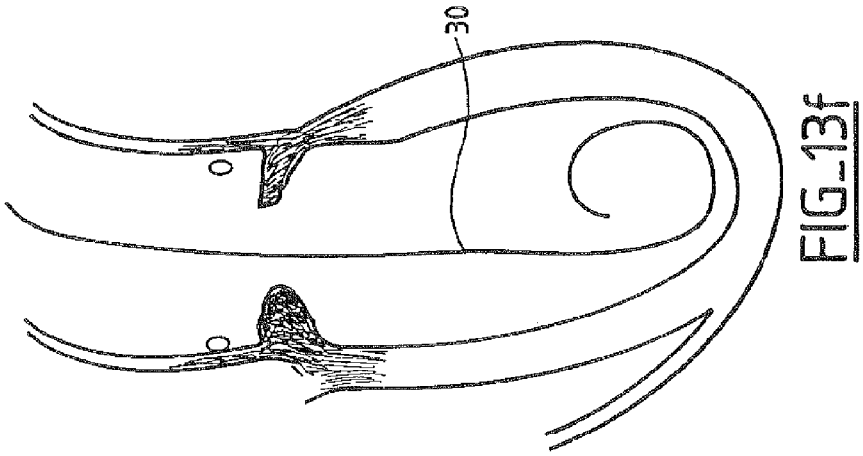


FIG_13f

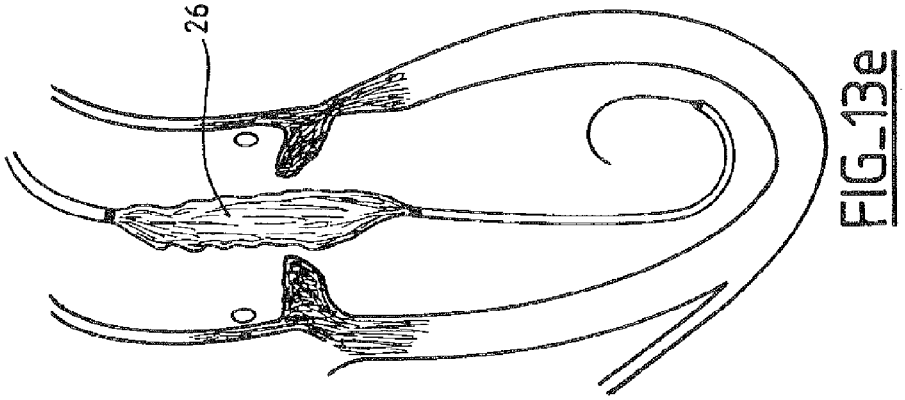


FIG_13e

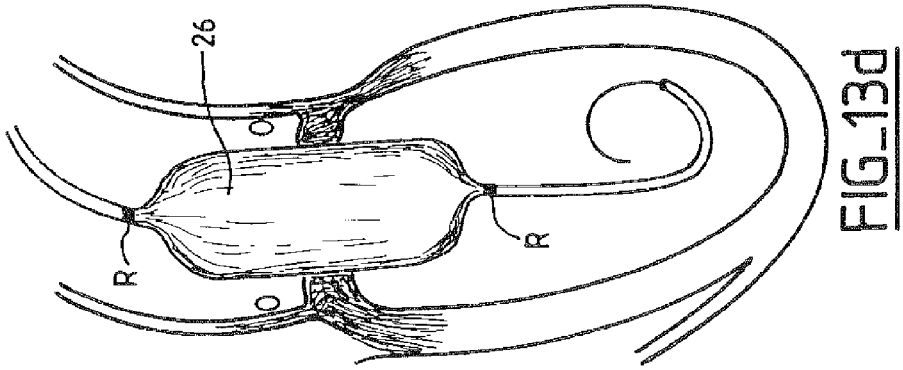


FIG_13d

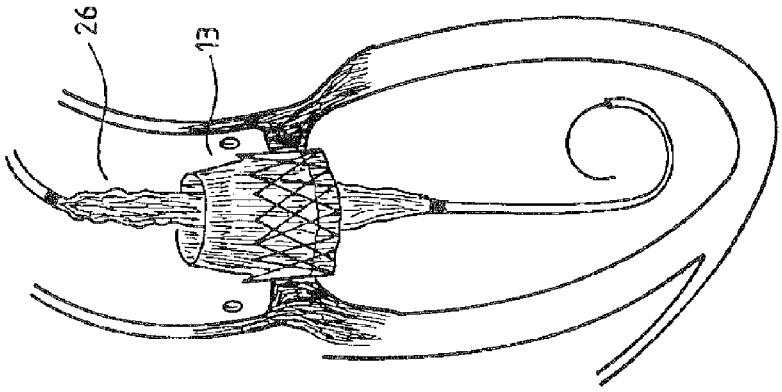


FIG_13i

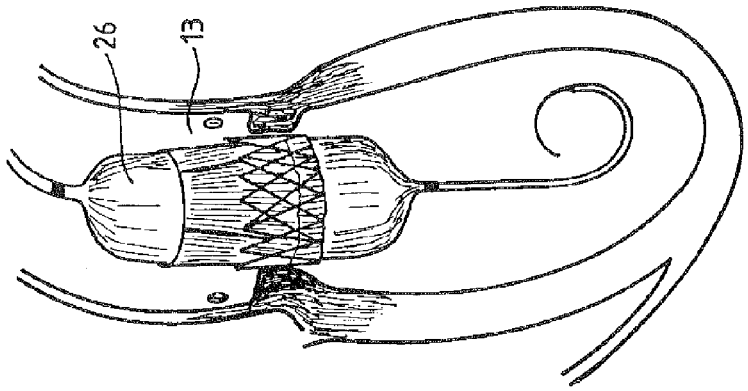


FIG_13h

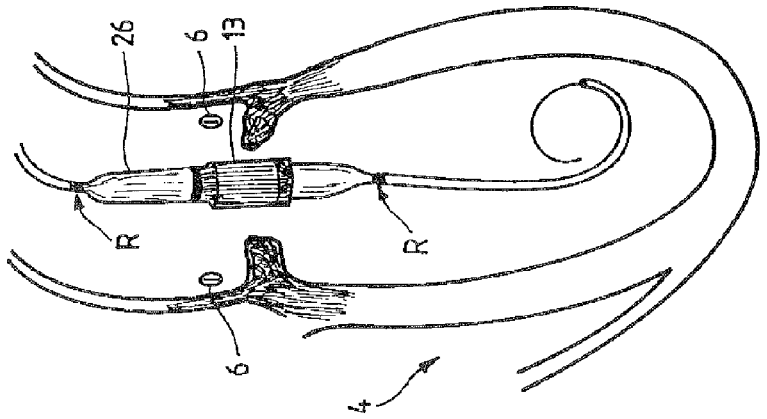


FIG_13g

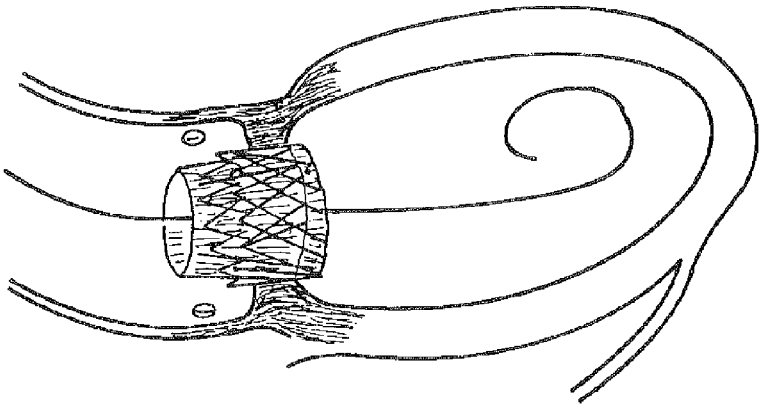


FIG_13I

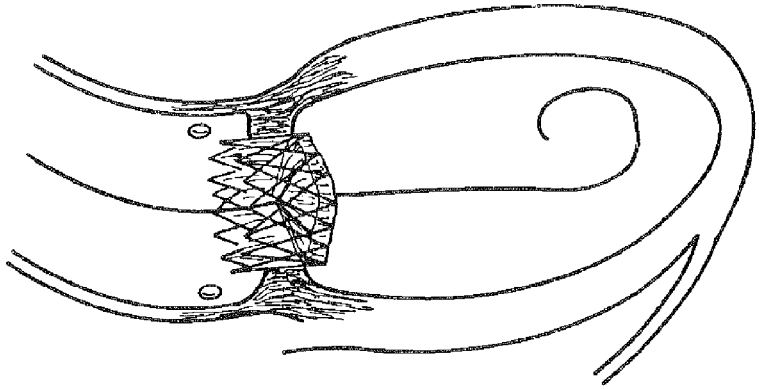


FIG_13K

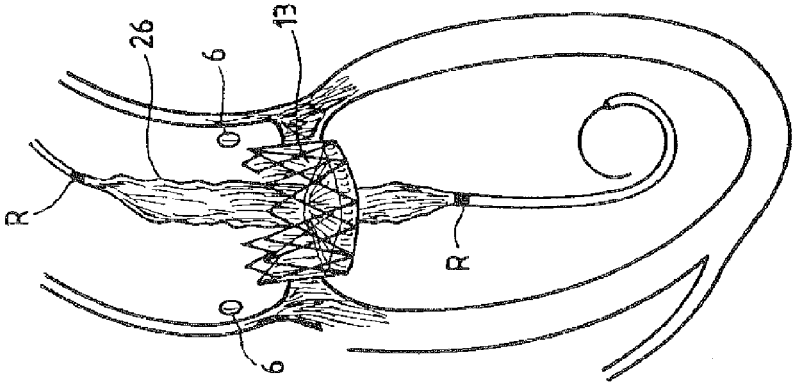
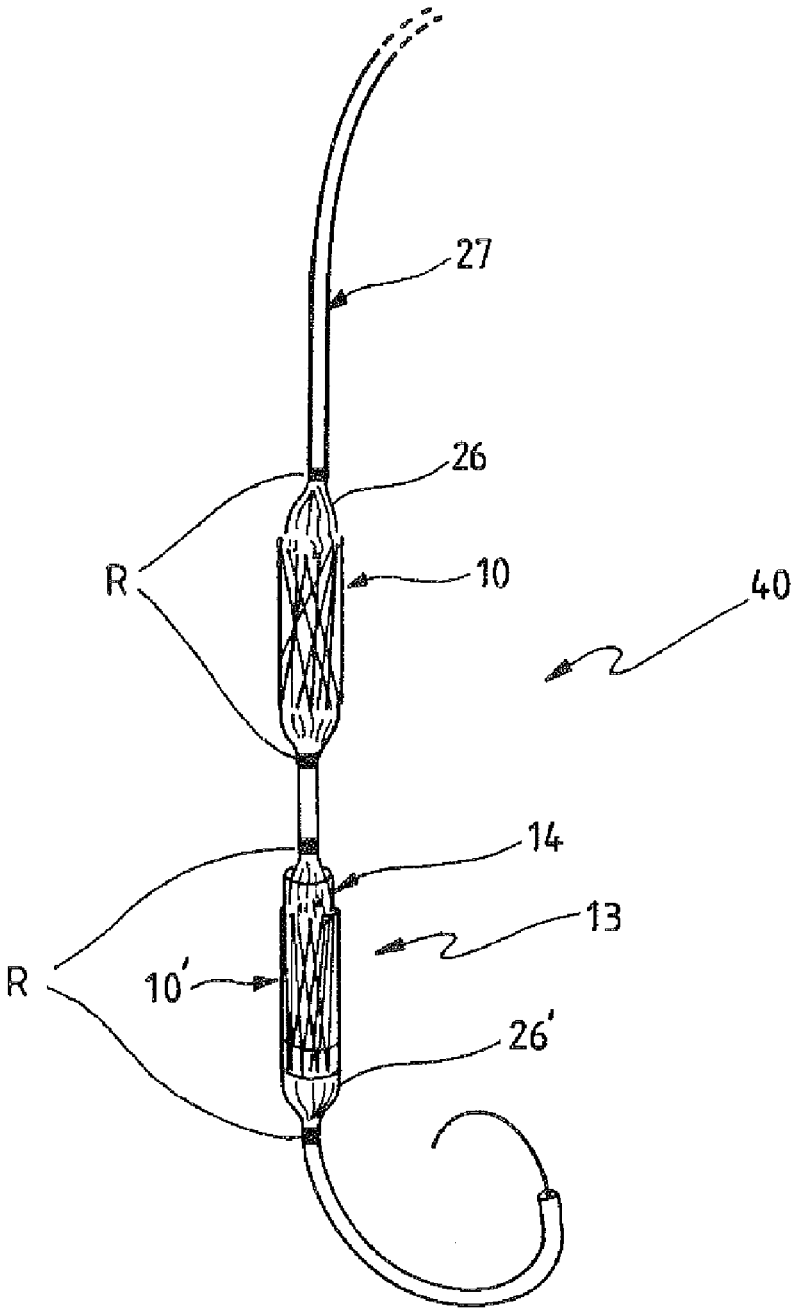


FIG_13J

FIG_14



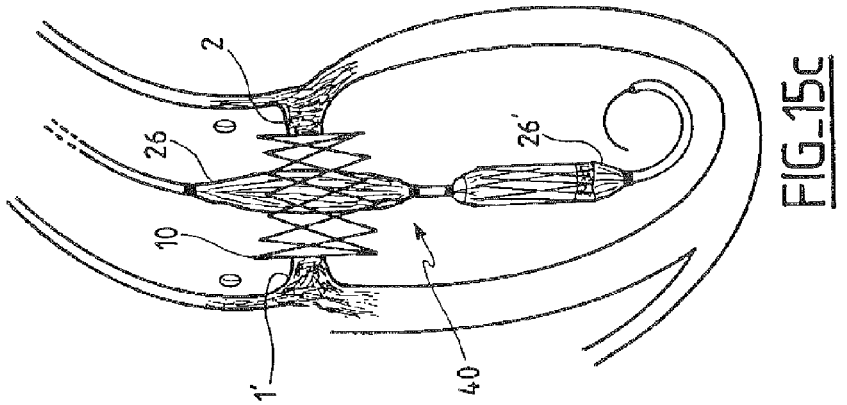


FIG_15c

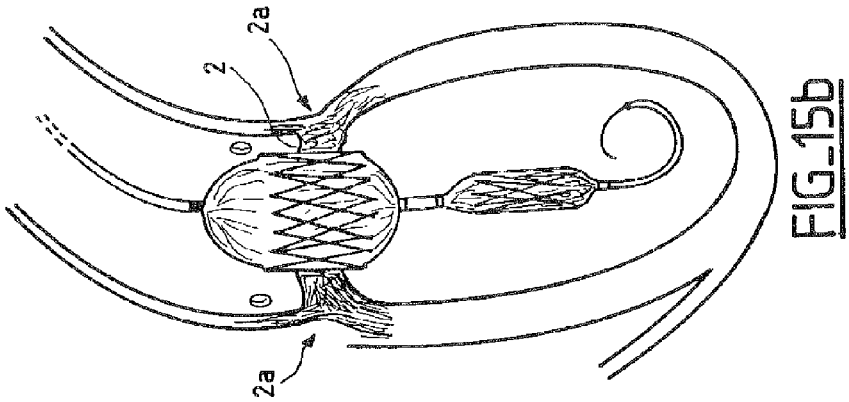


FIG_15b

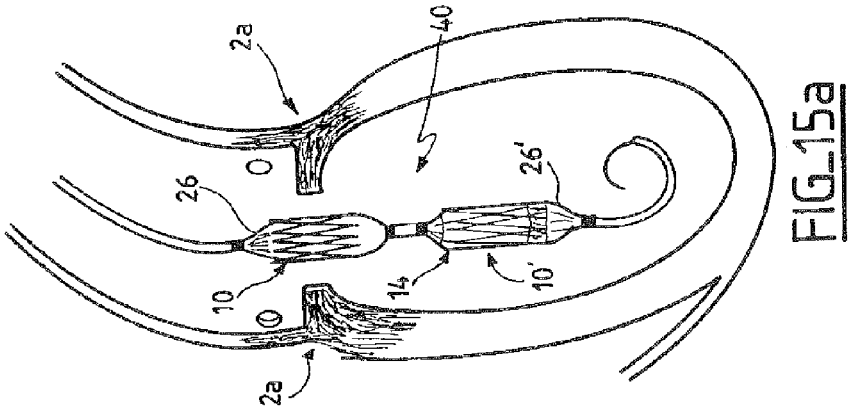


FIG_15a

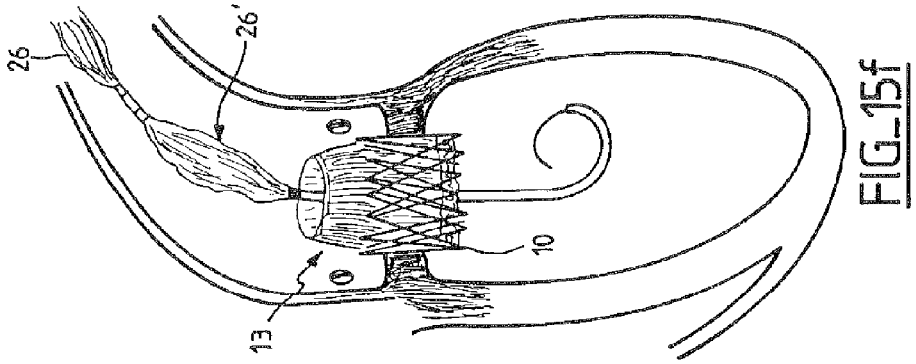


FIG_15f

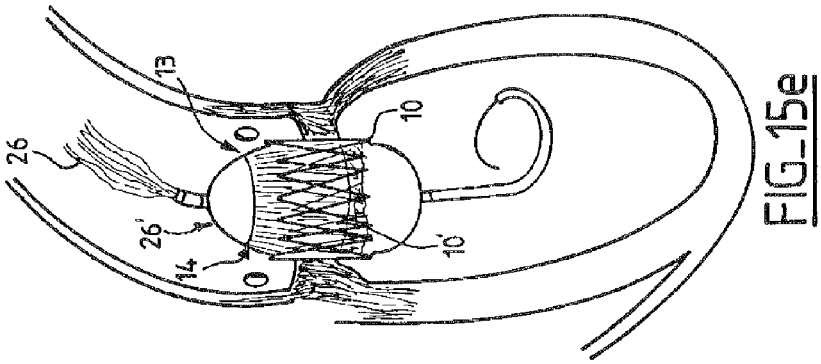


FIG_15e

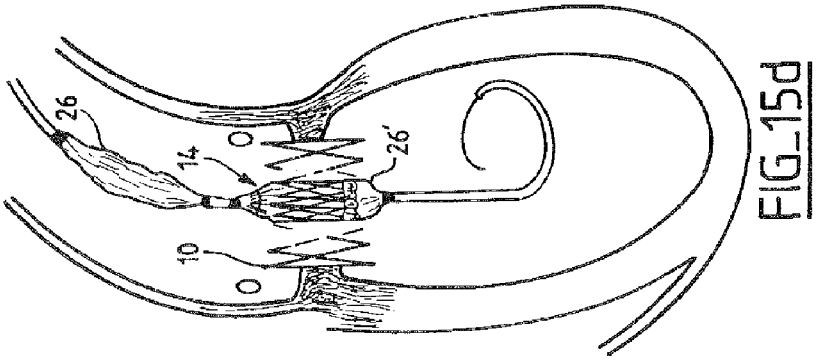


FIG_15d

IMPLANTABLE PROSTHETIC VALVE FOR TREATING AORTIC STENOSIS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 11/942,690, filed Nov. 19, 2007, now U.S. Pat. No. 7,846,204, which is a continuation of U.S. patent application Ser. No. 11/110,402, filed Apr. 20, 2005, now abandoned, which is a continuation of U.S. patent application Ser. No. 10/139,741, filed May 2, 2002, now U.S. Pat. No. 6,908,481, which is a continuation of U.S. patent application Ser. No. 09/795,803, filed Feb. 28, 2001, now abandoned, which in turn is a continuation of U.S. patent application Ser. No. 09/345,824, filed Jun. 30, 1999, now abandoned, which is a continuation of International application No. PCT/EP 97/07337, filed Dec. 31, 1997, which designates the United States and was published in English by the International Bureau on Jul. 9, 1998 as WO 98/29057, which claims priority to European application No. 96402929.2, filed Dec. 31, 1996, all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to a valve prosthesis for implantation in body channels, more particularly but not only to, cardiac valve prosthesis to be implanted by a transcutaneous catheterization technique.

The valve prosthesis can be also applied to other body channels provided with native valves, such as veins or in organs (liver, intestine, urethra . . .).

The present invention also relates to a method for implanting a valve prosthesis, such as the valve according to the present invention.

Implantable valves, which will be indifferently designated hereafter as "IV", "valve prosthesis" or "prosthetic valve", permits the reparation of a valvular defect by a less invasive technique in place of the usual surgical valve implantation which, in the case of valvular heart diseases, requires thoracotomy and extracorporeal circulation. A particular use for the IV concerns patients who cannot be operated on because of an associated disease or because of very old age or also patients who could be operated on but only at a very high risk.

Although the IV of the present invention and the process for implanting said IV can be used in various heart valve diseases, the following description will first concern the aortic orifice in aortic stenosis, more particularly in its degenerative form in elderly patients.

Aortic stenosis is a disease of the aortic valve in the left ventricle of the heart. The aortic valvular orifice is normally capable of opening during systole up to 4 to 6 cm^2, therefore allowing free ejection of the ventricular blood volume into the aorta. This aortic valvular orifice can become tightly stenosed, and therefore the blood cannot anymore be freely ejected from the left ventricle. In fact, only a reduced amount of blood can be ejected by the left ventricle which has to markedly increase the intra-cavitary pressure to force the stenosed aortic orifice. In such aortic diseases, the patients can have syncope, chest pain, and mainly difficulty in breathing. The evolution of such a disease is disastrous when symptoms of cardiac failure appear, since 50% of the patients die in the year following the first symptoms of the disease.

The only commonly available treatment is the replacement of the stenosed aortic valve by a prosthetic valve via surgery: this treatment moreover providing excellent results. If surgery is impossible to perform, i.e., if the patient is deemed

inoperable or operable only at a too high surgical risk, an alternative possibility is to dilate the valve with a balloon catheter to enlarge the aortic orifice. Unfortunately, a good result is obtained only in about half of the cases and there is a high restenosis rate, i.e., about 80% after one year.

Aortic stenosis is a very common disease in people above seventy years old and occurs more and more frequently as the subject gets older. As evidenced, the present tendency of the general evolution of the population is becoming older and older. Also, it can be evaluated, as a crude estimation, that about 30 to 50% of the subjects who are older than 80 years and have a tight aortic stenosis, either cannot be operated on for aortic valve replacement with a reasonable surgical risk or even cannot be considered at all for surgery.

It can be estimated that, about 30 to 40 persons out of a million per year, could benefit from an implantable aortic valve positioned by a catheterization technique. Until now, the implantation of a valve prosthesis for the treatment of aortic stenosis is considered unrealistic to perform since it is deemed difficult to superpose another valve such an implantable valve on the distorted stenosed native valve without excising the latter.

From 1985, the technique of aortic valvuloplasty with a balloon catheter has been introduced for the treatment of subjects in whom surgery cannot be performed at all or which could be performed only with a prohibitive surgical risk. Despite the considerable deformation of the stenosed aortic valve, commonly with marked calcification, it is often possible to enlarge significantly the aortic orifice by balloon inflation, a procedure which is considered as low risk.

However, this technique has been abandoned by most physicians because of the very high restenosis rate which occurs in about 80% of the patients within 10 to 12 months. Indeed, immediately after deflation of the balloon, a strong recoil phenomenon often produces a loss of half or even two thirds of the opening area obtained by the inflated balloon. For instance, inflation of a 20 mm diameter balloon in a stenosed aortic orifice of 0.5 cm^2 area gives, when forcefully and fully inflated, an opening area equal to the cross sectional area of the maximally inflated balloon, i.e., about 3 cm^2. However, measurements performed a few minutes after deflation and removal of the balloon have only an area around 1 cm^2 to 1.2 cm^2. This is due to the considerable recoil of the fibrous tissue of the diseased valve. The drawback in this procedure has also been clearly shown on fresh post mortem specimens.

However, it is important to note that whereas the natural normal aortic valve is able to open with an orifice of about 5 to 6 cm^2 and to accommodate a blood flow of more that 15 l/min during heavy exercise for instance, an opening area of about 1.5 to 2 cm^2 can accept a 6 to 8 l/min blood flow without a significant pressure gradient. Such a flow corresponds to the cardiac output of the elderly subject with limited physical activity.

Therefore, an IV would not have to produce a large opening of the aortic orifice since an opening about 2 cm^2 would be sufficient in most subjects, in particular in elderly subjects, whose cardiac output probably does not reach more than 6 to 8 l/min during normal physical activity. For instance, the surgically implanted mechanical valves have an opening area which is far from the natural valve opening that ranges from 2 to 2.5 cm^2, mainly because of the room taken by the large circular structure supporting the valvular part of the device.

The prior art describes examples of cardiac valves prosthesis that are aimed at being implanted without surgical intervention by way of catheterization. For instance, U.S. Pat. No. 5,411,552 describes a collapsible valve able to be introduced

in the body in a compressed presentation and expanded in the right position by balloon inflation.

Such valves, with a semi-lunar leaflet design, tend to imitate the natural valve. However, this type of design is inherently fragile, and such structures are not strong enough to be used in the case of aortic stenosis because of the strong recoil that will distort this weak structure and because they would not be able to resist the balloon inflation performed to position the implantable valve. Furthermore, this valvular structure is attached to a metallic frame of thin wires that will not be able to be tightly secured against the valve annulus. The metallic frame of this implantable valve is made of thin wires like in stents, which are implanted in vessels after balloon dilatation. Such a light stent structure is too weak to allow the implantable valve to be forcefully embedded into the aortic annulus. Moreover, there is a high risk of massive regurgitation (during the diastolic phase) through the spaces between the frame wires which is another prohibitive risk that would make this implantable valve impossible to use in clinical practice.

Furthermore, an important point in view of the development of the IV is that it is possible to maximally inflate a balloon placed inside the compressed implantable valve to expand it and insert it in the stenosed aortic valve up to about 20 to 23 mm in diameter. At the time of maximum balloon inflation, the balloon is absolutely stiff and cylindrical without any waist. At that moment, the implantable valve is squeezed and crushed between the strong aortic annulus and the rigid balloon with the risk of causing irreversible damage to the valvular structure of the implantable valve.

SUMMARY OF THE INVENTION

The invention is aimed to overcome these drawbacks and to implant an IV which will remain reliable for years.

A particular aim of the present invention is to provide an IV, especially aimed at being used in case of aortic stenosis, which structure is capable of resisting the powerful recoil force and to stand the forceful balloon inflation performed to deploy the IV and to embed it in the aortic annulus.

Another aim of the present invention is to provide an efficient prosthesis valve which can be implanted by a catheterization technique, in particular in a stenosed aortic orifice, taking advantage of the strong structure made of the distorted stenosed valve and of the large opening area produced by preliminary balloon inflation, performed as an initial step of the procedure.

A further aim of the present invention is to provide an implantable valve which would not produce any risk of fluid regurgitation.

A further aim of the present invention is to provide a valve prosthesis implantation technique using a two-balloon catheter and a two-frame device.

These aims are achieved according to the present invention which provides a valve prosthesis of the type mentioned in the introductory part and wherein said valve prosthesis comprises a collapsible continuous structure with guiding means providing stiffness and a frame to which said structure is fastened, said frame being strong enough to resist the recoil phenomenon of the fibrous tissue of the diseased valve.

The IV, which is strongly embedded, enables the implantable valve to be maintained in the right position without any risk of further displacement, which would be a catastrophic event.

More precisely, this valvular structure comprises a valvular tissue compatible with the human body and blood, which is supple and resistant to allow said valvular structure to pass from a closed state to an open state to allow a body fluid, more particularly the blood, exerting pressure on said valvular structure, to flow. The valvular tissue forms a continuous surface and is provided with guiding means formed or incorporated within, creating stiffened zones which induce the valvular structure to follow a patterned movement from its open position to its closed state and vice-versa, providing therefore a structure sufficiently rigid to prevent diversion, in particular into the left ventricle and thus preventing any regurgitation of blood into the left ventricle in case of aortic implantation.

Moreover, the guided structure of the IV of the invention allows the tissue of this structure to open and close with the same patterned movement while occupying as little space as possible in the closed state of the valve. Therefore, owing to these guiding means, the valvular structure withstands the unceasing movements under blood pressure changes during the heart beats.

More preferably, the valvular structure has a substantially truncated hyperboloidal shape in its expanded position, with a larger base and a growing closer neck, ending in a smaller extremity forming the upper part of the valvular structure. The valvular structure has a curvature at its surface that is concave towards the aortic wall. Such a shape produces a strong and efficient structure in view of the systolo-diastolic movement of the valvular tissue. Such a valvular structure with its simple and regular shape also lowers the risk of being damaged by forceful balloon inflation at the time of IV deployment.

A trunco-hyperboloidal shape with a small diameter at the upper extremity facilitates the closure of the valve at the beginning of diastole in initiating the starting of the reverse movement of the valvular tissue towards its base. Another advantage of this truncated hyperboloidal shape is that the upper extremity of the valvular structure, because of its smaller diameter, remains at a distance from the coronary ostia during systole as well as during diastole, thus offering an additional security to ensure not to impede at all the passage of blood from the aorta to the coronary ostia.

As another advantageous embodiment of the invention, the guiding means of the valvular structure are inclined strips from the base to the upper extremity of the valvular structure with regard to the central axis of the valvular structure. This inclination initiates and imparts a general helicoidal movement of the valvular structure around said central axis at the time of closure or opening of said structure, such a movement enabling to help initiate and finalize the closure of the valvular structure. In particular, this movement improves the collapse of the valvular structure towards its base at the time of diastole and during the reversal of flow at the very beginning of diastole. During diastole, the valvular structure thus fails down, folding on itself and collapses on its base, therefore closing the aortic orifice. The strips can be pleats, strengthening struts or thickened zones.

In other embodiments, said guiding means are rectilinear strips from the base to the upper extremity of the valvular structure. In this case, the guiding means can comprise pleats, struts or thickened zones. In a particular embodiment, the stiffened zones then created can be advantageously two main portions, trapezoidal in shape, formed symmetrically one to each other with regard to the central axis of the valvular structure, and two less rigid portions separating said two main portions to lead to a tight closeness in shape of a closed slot at the time of closure of the upper extremities of the main portions of the valvular structure. The thickened zones can be extended up to form the stiffened zones.

More particularly, each of said main slightly rigid portions occupy approximately one third of the circumference of the

valvular structure when this latter is in its open position. The slightly rigid portions maintain the valvular structure closed during diastole by firmly applying themselves on each other. The closure of the valvular structure at the time of diastole thus does not have any tendency to collapse too much towards the aortic annulus.

Preferably, the guiding means are a number of pleats formed within the tissue by folding, or formed by recesses or grooves made in the tissue. The shape of the pleats is adapted to achieve a global shape of the desired type for said position.

Alternatively, the guiding means are made of strengthening struts, preferably at least three, incorporated in the tissue in combination or not with said pleats.

The guiding means and, in particular, the strengthening struts, help to prevent the valvular tissue from collapsing back too much and to reverse inside the left ventricle through the base of the frame, preventing the risk of blood regurgitation.

In a preferred prosthetic valve of the invention, said valvular tissue is made of synthetic biocompatible material such as TEFLON® or DACRON®, polyethylene, polyamide, or made of biological material such as pericardium, porcine leaflets and the like. These materials are commonly used in cardiac surgery and are quite resistant, particularly to folding movements due to the increasing systolo-diastolic movements of the valvular tissue and particularly at the junction with the frame of the implantable valve.

The valvular structure is fastened along a substantial portion of an expandable frame, by sewing, by molding or by gluing to exhibit a tightness sufficiently hermetical to prevent any regurgitation of said body fluid between the frame and the valvular structure.

Preferably, an internal cover is coupled or is integral to the valvular structure and placed between said valvular structure and the internal wall of the frame to prevent any passage of the body fluid through said frame. Therefore, there is no regurgitation of blood as it would be the case if there were any space between the valvular structure fastened on the frame and the zone of application of the frame on the aortic annulus. The internal cover makes a sort of "sleeve" at least below the fastening of the valvular structure covering the internal surface of the frame and thus prevents any regurgitation of blood through the frame.

In the present invention, the frame is a substantially cylindrical structure capable of maintaining said body channel open in its expanded state and supporting said collapsible valvular structure.

In a preferred embodiment of the invention, the frame is made of a material which is distinguishable from biological tissue to be easily visible by non invasive imaging techniques.

Preferably, said frame is a stainless metal structure or a foldable plastic material, made of intercrossing, preferably with rounded and smooth linear bars. This frame is strong enough to resist the recoil phenomenon of the fibrous tissue of the diseased valve. The size of the bars and their number are determined to give both the maximal rigidity when said frame is expanded and the smallest volume when the frame is compressed.

More preferably, the frame has projecting curved extremities and presents a concave shape. This is aimed at reinforcing the embedding and the locking of the implantable valve in the distorted aortic orifice.

In a preferred embodiment of the present invention, the IV is made in two parts, a first reinforced frame coupled with a second frame which is made of thinner bars than said first frame and which is embedded inside the second frame. This second frame to which the valvular structure is fastened as described above, is preferably less bulky than the first frame to occupy as little space as possible and to be easily expanded using low pressure balloon inflation.

The present invention also relates to a double balloon catheter to separately position the first frame in the dilated stenosed aortic valve and place the second frame that comprises the valvular structure. This catheter comprises two balloons fixed on a catheter shaft and separated by few centimeters.

The first balloon is of the type sufficiently strong to avoid bursting even at a very high pressure inflation and is aimed at carrying, in its deflated state, a strong frame aimed at scaffolding the previously dilated stenosed aortic valve. The second balloon is aimed at carrying the second frame with the valvular structure.

An advantage of this double balloon catheter is that each balloon has an external diameter which is smaller than known balloons since each element to be expanded is smaller.

Moreover, such a double balloon catheter allows to enlarge the choice for making an efficient valvular structure enabling to overcome the following two contradictory conditions:

1) having a soft and mobile valvular structure capable of opening and closing freely in the blood stream, without risk of being damaged by balloon inflation; and
2) needing a very strong structure able to resist the recoil force of the stenosed valve and capable of resisting, without any damage, a strong pressure inflation of the expanding balloon.

Furthermore, the shaft of said double balloon catheter comprises two lumens for successive and separate inflation of each balloon. Of note, an additional lumen capable of allowing a rapid inflation takes additional room in the shaft.

The invention also relates to a method of using a two-balloon catheter with a first frame and second frame to which a valve prosthesis of the type previously described is fastened.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be explained and other advantages and features will appear with reference to the accompanying schematical drawings wherein:

FIGS. **1***a*, **1***b* and **1***c* illustrate, in section views, respectively, the normal aortic valve in systole, in diastole and a stenosed aortic valve;

FIGS. **2***a* and **2***b* illustrate two examples of a metallic frame which are combined to a valvular structure according to the present invention;

FIGS. **3***a* and **3***b* illustrate a frame according to the invention in its expanded position with an opening out of the extremities, respectively, with a cylindrical and a concave shape;

FIGS. **4***a* and **4***b* illustrate an IV of the invention respectively in its compressed position and in its expanded position in an open position as in systole;

FIGS. **5***a* and **5***b* illustrate respectively an IV of the invention in its closed position and a sectional view according to the central axis of such a valvular structure which is closed as in diastole;

FIGS. **6***a* to **6***d* illustrate a sectional view according to the central axis of an IV according to the present invention and showing the internal cover and the external cover of the valvular structure overlapping partially or non overlapping the frame bars;

FIG. **7** illustrates the frontal zig-zag fastening line of the valvular tissue on the frame;

FIGS. **8***a* and **8***b* illustrate, respectively, a perspective view of a valvular structure and an internal cover made all of one

piece and a perspective view of the corresponding frame into which they will be inserted and fastened;

FIGS. **9***a* and **9***b* illustrate inclined strengthening struts, an example of a valvular structure according to the invention, respectively in the open position and in the closed position;

FIGS. **10***a* and **10***b* illustrate an example of a valvular structure comprising pleats, respectively in the open and in the closed position;

FIGS. **11***a* and **11***b* illustrate a valvular structure comprising two trapezoidal slightly rigid portions, respectively in the open and in the closed position;

FIGS. **11***c* to **11***e* illustrate a valvular structure comprising a rectangular stiffened zone, respectively in the open, intermediate and closed position;

FIGS. **12***a* and **12***b* illustrate, respectively, a perspective and cross sectional views of an implantable valve in its compressed presentation squeezed on a balloon catheter;

FIGS. **13***a* to **13***l* illustrate views of the successive procedure steps for the IV implantation in a stenosed aortic orifice;

FIG. **14** illustrates an implantable valve made in two parts in its compressed presentation squeezed on a two-balloon catheter with a reinforced frame on a first balloon and with the implantable valve on the second balloon; and

FIGS. **15***a* to **15***f* illustrate the successive steps of the implantation of the implantation valve in two parts with a two-balloon catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the diastole and systole illustrations of section views of FIGS. **1***a* and **1***b*, the arrows A indicates the general direction of the blood flow. The semi-lunar leaflets **1** and **2** of a native aortic valve (with only two out of three shown here) are thin, supple and move easily from the completely open position (systole) to the closed position (diastole). The leaflets originate from an aortic annulus **2***a*.

The leaflets **1'** and **2'** of a stenosed valve as illustrated in FIG. **1***c*, are thickened, distorted, calcified and more or less fused, leaving only a small hole or a narrow slit **3**, which makes the ejection of blood from the left ventricle cavity **4** into the aorta **5** difficult and limited. FIGS. **1***a* to **1***c* show also the coronary artery ostium **6***a* and **6***b* and FIG. **1***a* shows, in particular, the mitral valve **7** of the left ventricle cavity **4**.

An implantable valve according to the invention essentially comprises a supple valvular structure supported by a strong frame. The positioning of the implantable valve is an important point since the expanded frame has to be positioned exactly at the level of the native valvular leaflets **1**, **2** of the native valve, the structures of which are pushed aside by the inflated balloon.

Ideally, the implantable valve is positioned with the fastening line of the valvular structure on the frame exactly on the remains of the crushed stenosed valve to prevent any regurgitation of blood. In practice, it is difficult to position the implantable valve within less than 2 or 3 mm. However, any risk of regurgitation of blood is eliminated with the presence of an internal cover, as will be described below.

The upper limit of the frame should be placed below the opening of the coronary arteries, i.e., the coronary ostia **6**, or at their level so that the frame does not impede free blood flow in the coronary arteries. This point is a delicate part of positioning an IV since the distance between the superior limit of the leaflets of the natural valve and the coronary ostia **6** is only about 5 to 6 mm. However, the ostia are located in the Valsalva sinus **8** which constitutes a hollow that are located a little out of the way. This helps to prevent from impeding the coronary blood flow by the IV.

At the time of implantation, the operator evaluates the exact positioning of the coronary ostia by looking at the image produced by a sub-valvular angiogram with contrast injection performed before the implantation procedure. This image will be fixed in the same projection on a satellite TV screen and will permit the evaluation of the level of the origin of the right and left coronary arteries. Possibly, in case the ostia are not clearly seen by sub-valvular angiography, a thin guide wire, as those used in coronary angioplasty, is positioned in each of the coronary arteries to serve as a marker of the coronary ostia.

The lower part of the frame of the IV preferably extends by 2 or 3 mm inside the left ventricle **4**, below the aortic annulus **2***a*. However, this part of the frame should not reach the insertion of the septal leaflet of the mitral valve **7**, so that it does not interfere with its movements, particularly during diastole.

FIGS. **2***a* and **2***b* show respectively an example of a cylindrical frame or stent **10** comprising intercrossing linear bars **11**, with two intersections I by bar **11**, the bars **11** being soldered or provided from a folded wire to constitute the frame, with for instance a 20 mm, 15 mm or 12 mm height, and an example with only one intersection of bars **11**. Preferably, such a frame is expandable from a size of about 4 to 5 millimeters to a size of about 20 to 25 mm in diameter, or even to about 30-35 mm (or more) in particular cases, for instance for the mitral valve. Moreover, said frame, in its fully expanded state, has a height of approximately between 10 and 15 mm and in its fully compressed frame, a height of approximately 20 mm. The number and the size of the bars are adapted to be sufficiently strong and rigid when the frame is fully open in the aortic orifice to resist the strong recoil force exerted by the distorted stenosed aortic orifice after deflation' of the balloon used in the catheterization technique which has been previously maximally inflated to enlarge the stenosed valve orifice.

The frame may have several configurations according to the number of bars **11** and intersections. This number, as well as the size and the strength of the bars **11**, are calculated taking into account all the requirements described, i.e., a small size in its compressed form, its capacity to be enlarged up to at least 20 mm in diameter and being strong when positioned in the aortic orifice to be able to be forcefully embedded in the remains of the diseased aortic valve and to resist the recoil force of the aortic annulus. The diameter of the bars is chosen, for instance, in the range of 0.1-0.6 mm.

A frame particularly advantageous presents, when deployed in its expanded state, an opening out **12** at both extremities as shown in FIGS. **3***a* and **3***b*, the frame having a linear profile (FIG. **3***a*) or a concave shape profile (FIG. **3***b*). This is aimed at reinforcing the embedding of the IV in the aortic orifice. However, the free extremities of the openings **12** are rounded and very smooth to avoid any traumatism of the aorta or of the myocardium.

The structure of a preferred frame used in the present invention both maintains the aortic orifice fully open once dilated and produces a support for the valvular structure. The frame is also foldable. When folded by compression, the diameter of said frame is about 4 to 5 millimeters, in view of its transcutaneous introduction in the femoral artery through an arterial sheath of 14 to 16 F (F means French, a unit usually used in cardiology field) i.e., about 4.5 to 5.1 mm. Also, as described below, when positioned in the aortic orifice, the

frame is able to expand under the force of an inflated balloon up to a size of 20 to 23 mm in diameter.

The frame is preferably a metallic frame, preferably made of steel. It constitutes a frame with a grate type design able to support the valvular structure and to behave as a strong scaffold for the open stenosed aortic orifice.

When the frame is fully expanded, its intercrossing bars push against the remains of the native stenosed valve that has been crushed aside against the aortic annulus by the inflated balloon. This produces a penetration and embeds the bars within the remains of the stenosed valve, in particular owing to a concave profile of the frame provided with an opening out, as illustrated in FIG. **3***b*. This embedding of the frame on the aortic annulus, or more precisely on the remains of the crushed distorted aortic valve, will be determinant for the strong fixation of the IV in the right position, without any risk of displacement.

Moreover, the fact that the valve leaflets in degenerative aortic stenosis are grossly distorted and calcified, sometimes leaving only a small hole or a small slit in the middle of the orifice, has to be considered an advantage for the implantation of the valve and for its stable positioning without risk of later mobilization. The fibrous and calcified structure of the distorted valve provides a strong base for the frame of the IV and the powerful recoil phenomenon that results from elasticity of the tissues contribute to the fixation of the metallic frame.

The height of the fully expanded frame of the illustrated frames **10** is preferably between 10 and 15 mm. Indeed, since the passage from the compressed state to the expanded state results in a shortening of the metallic structure, the structure in its compressed form is a little longer, i.e., preferably about 20 mm length. This does not constitute a drawback for its transcutaneous introduction and its positioning in the aortic orifice.

As mentioned above, the frame is strong enough to be able to oppose the powerful recoil force of the distended valve and of the aortic annulus **2***a*. Preferably it does not possess any flexible properties. When the frame has reached its maximal expanded shape under the push of a forcefully inflated balloon, it remains substantially without any decrease in size and without any change of shape. The size of the bars that are the basic elements of the frame is calculated in such a way to provide a substantial rigidity when the frame is fully expanded. The size of the bars and their number are calculated to give both maximal rigidity when expanded and the smallest volume when the metallic frame is its compressed position.

At the time of making the IV, the frame is expanded by dilatation to its broadest dimension, i.e., between 20 mm and 25 mm in diameter, so as to be able to fasten the valvular structure on the inside side of its surface. This fastening is performed using the techniques in current use for the making of products such as other prosthetic heart valves or multipolars catheters etc. Afterwards, it is compressed in its minimal size, i.e., 4 or 5 mm, in diameter in view of its introduction in the femoral artery. At time of the IV positioning, the frame is expanded again by balloon inflation to its maximal size in the aortic orifice.

If the frame is built in an expanded position, it will be compressed, after fastening the valvular structure, by exerting a circular force on its periphery and/or on its total height until obtaining the smallest compressed position. If the frame is built in its compressed position, it will be first dilated, for instance, by inflation of a balloon and then compressed again as described above.

To help localizing the IV, the frame being the only visible component of the valve, the shaft of the balloon catheter on which will be mounted the IV before introduction in the body (see below) possesses preferentially metallic reference marks easily seen on fluoroscopy. One mark will be at level of the upper border of the frame and the other at the level of the lower border. The IV, when mounted on the catheter shaft and crimpled on it, is exactly positioned taking into account these reference marks on the shaft.

Accordingly, the frame is visible during fluoroscopy when introduced in the patient's body. When the frame is positioned at the level of the aortic annulus, the upper border of the frame is placed below the coronary ostia. Furthermore, the implanting process during which the balloon inflation completely obstructs the aortic orifice, as seen below, is performed within a very short time, i.e., around 10 to 15 seconds. This also explains why the frame is clearly and easily seen, without spending time to localize it. More particularly, its upper and lower borders are clearly delineated.

FIGS. **4***a* and **4***b* show an example of a preferred IV **13** of the present invention, respectively in its compressed position, in view of its introduction and positioning in the aortic orifice, and in its expanded and opened (systole) position. FIGS. **5***a* and **5***b* show the expanded position of this example closed in diastole, respectively in perspective and in a crossed section view along the central axis XX of the valve prosthesis.

The valvular structure **14** is compressed inside the frame **10** when this is in its compressed position (FIG. **4***a*), i.e., it fits into a 4 to 5 mm diameter space. On the other hand, the valvular structure can expand (FIG. **4***b*) and follow the frame expansion produced by the inflated balloon. It will have to be able to reach the size of the inside of the fully deployed frame.

The illustrated IV **13** is made of a combination of two main parts:

1) the expandable but substantially rigid structure made of the frame **10**, a metallic frame in the example; and
2) a soft and mobile tissue constituting the valvular structure **14** exhibiting a continuous surface truncated between a base **15** and an upper extremity **16**; the tissue is fastened to the bars **11** of the frame at its base **16** and is able to open in systole and to close in diastole at its extremity **16**, as the blood flows in a pulsatile way from the left ventricle towards the aorta.

The tissue has rectilinear struts **17** incorporated in it in plane including the central axis XX, in order to strengthen it, in particular, in its closed state with a minimal occupation of the space, and to induce a patterned movement between its open and closed state. Other examples of strengthening struts are described below. They are formed from thicker zones of the tissue or from strips of stiffening material incorporated in the tissue; they can also be glued or soldered on the valvular tissue.

These strengthening struts help to prevent the valvular tissue from collapsing back too much and to evert inside the left ventricle through the base of the frame. These reinforcements of the valvular tissue help maintain the folded tissue above the level of the orifice during diastole, prevent too much folding back and risk of inversion of the valvular structure inside the left ventricle. By also preventing too much folding, a decrease of the risk of thrombi formation can also be expected by reducing the number of folds.

The truncated shape forming a continuous surface enables to obtain a strong structure and is more efficient for the systolo-diastolic movements of the valvular tissue during heart beats. The truncoidal shape facilitates the closure of the valve structure at the beginning of diastole in facilitating the start of the reverse movement of the valvular tissue towards its base at the time of diastole, i.e., at the time of flow reversal at the very beginning of diastole. During diastole, the valvular structure **14** thus fails down, folding on itself, thereby col-

lapsing on its base, and therefore closing the aortic orifice. In fact, the valvular structure has preferably, as illustrated, an hyperboloid shape, with a curvature on its surface concave towards the aortic wall that will contribute to initiating its closure.

Moreover, the basis of the truncated hyperboloid is fixed on the lower part of a frame and the smallest extremity of the truncated hyperboloid is free in the blood stream, during the respected closing and opening phases.

An important advantage of this hyperboloidal shape is that the upper extremity **16** of the valvular structure **14** can remain at a distance from the coronary ostia during systole as well as during diastole, because of its smaller diameter, thus offering an additional security to make certain that the passage of blood from aorta to the coronary ostia is not impeded.

The base **15** of the truncated tissue is attached on the frame **10** along a line of coupling **18** disposed between the inferior fourth and the third fourth of the frame in the example. The upper extremity **16**, with the smaller diameter, overpasses the upper part of the frame by a few millimeters; 6 to 8 mm, for instance. This gives the valvular structure a total height of about 12 to 15 mm.

The upper extremity **16** of the truncated tissue, i.e., the smaller diameter of the hyperboloidal structure **14**, is about 17 to 18 mm in diameter (producing a 2.3 to 2.5 cm^2 area opening) for a 20 mm diameter base of the truncated structure, or 19 to 20 mm in diameter (producing a 2.8 or a 3 cm^2 area opening) for a 23 mm diameter base. An opening area around 2 cm^2 or slightly above, gives satisfactory results, particularly in elderly patients who would not reasonably need to exert high cardiac output.

For instance, in the present example, the line of fastening of the base of the truncated tissue on the frame will have to expand from a 12.5 mm perimeter (for a 4 mm external diameter of the compressed IV) to a 63 mm perimeter (for a 20 mm external diameter of the expanded IV), or to a 72 mm perimeter (for a 23 mm external diameter, in case a 23 mm balloon is used).

Another advantage of this truncated continuous shape is that it is stronger and has less risk of being destroyed or distorted by the forceful balloon inflation at the time of IV deployment. Also, if the truncated hyperboloidal shape is marked, for instance, with a 16 or 17 mm diameter of the upper extremity as compared to a 20 mm diameter of the base (or 18 to 20 mm for 23 mm), the smaller upper part is compliant during balloon inflation in order to enable the balloon to expand cylindrically to its maximal mm diameter (or 23 mm). This is made possible by using a material with some elastic or compliant properties.

The valvular structure of the invention, as shown in the illustrated example, includes advantageously a third part, i.e., the internal cover **19** to be fixed on the internal wall of the frame **10**. This internal cover prevents any passage of blood through the spaces between the bars **11** of the frame in case the implantable valve would be positioned with the fastening line of the valvular structure on the frame not exactly on the remains of the dilated aortic valve, i.e., either above or below. It also strengthens the fastening of the valvular structure **14** to the frame **10**.

In the different sectional views of the different examples of IV according to the invention, as illustrated at FIGS. **6***a* to **6***c*, the internal cover **19** covers the totality of the internal side of the frame **10** (FIG. **6***a*), only the lower part of the frame **10** (FIG. **6***b*), or it can additionally cover partially 3 to 5 mm as shown in the passage of blood from aorta to the coronary ostia FIG. **6***c*, the upper part defined above the coupling line **18** of the valvular structure.

For instance, such an extension of the internal cover **19** above the fastening line **18** of the valvular structure will give another security to avoid any risk of regurgitation through the spaces between the bars **11** in case the IV would be positioned too low with respect to the border of the native aortic valve.

The internal cover can also be molded to the valvular structure or casted to it which therefore constitutes an integral structure. The valvular structure and the internal cover are therefore strongly locked together with minimum risk of detachment of the valvular structure which is unceasingly in motion during systole and diastole. In that case, only the internal cover has to be fastened on the internal surface of the frame which renders the making of the IV easier and makes the complete device stronger and more resistant. In particular, the junction of the mobile part of the valvular structure and the fixed part being molded as one piece is stronger and capable to face the increasing movements during the systolo-diastolic displacements without any risk of detachment.

The presence of the internal cover makes an additional layer of plastic material that occupies the inside of the frame and increases the final size of the IV. Therefore, in the case in which the internal cover is limited to the inferior part of the frame (that is, below the fastening line of the valvular structure), it does not occupy any additional space inside the frame. Here also, it is more convenient and safer to make the valvular structure and this limited internal cover in one piece.

In other aspects, to prevent any regurgitation of blood from the aorta towards the left ventricle during diastole, the base of the valvular structure is preferably positioned exactly at the level of the aortic annulus against the remains of distorted stenosed valve pushed apart by the inflated balloon. Therefore, there is no possibility of blood passage through the spaces between the metallic frame bars **11** below the attachment of the valvular structure.

However, to avoid any risk of leaks, the part of the frame below the fastening of the valvular structure (about 3 to 5 mm) is preferably covered by an internal cover which is preferably made with the same tissue as the valvular structure. Thus, there would be no regurgitation of blood which is a possibility when there is any space between the valvular structure fastened on the metallic frame and the line of application of the frame on the aortic annulus. The internal cover makes a sort of "sleeve" below the fastening of the valvular structure on the internal surface of the frame, covering the spaces between the frame bars of the frame at this level, thus preventing any regurgitation of blood through these spaces.

The internal cover can also have another function, i.e., it can be used to fasten the valvular structure inside the frame, as described below.

At FIG. **6***d*, the internal cover **19** is extended at its lower end **19'** to an external cover **19'** which is rolled up to be applied on the external wall of the stent **10**. The internal and external cover are molded, glued or soldered to the bars of the stent **10**.

The coupling process of the valvular structure on the frame is of importance since it has to be very strong without any risk of detachment of the valvular structure from the frame during millions of heart beats with pulsatile blood flow alternatively opening and closing the valvular structure.

The valvular structure of the invention folds to a very small size inside the frame in the compressed position of the valve and is expandable up to 20 to 23 mm diameter. Also, the valvular structure can resist the strong force exerted by the maximally inflated balloon that will powerfully squeeze it against the bars of the frame or against the internal cover, this one being squeezed directly against the bars of the frame. The junction zone is also particularly subjected to very strong pressure exerted by the inflated balloon. Furthermore, this

junction zone must not tear or break off during expansion of the balloon. At this time, each part of the junction zone is squeezed against the bars but nonetheless follows the expansion of the frame.

As shown in FIG. **7**, the junction zone is, for example, a fastening line **20** which follows the design of a "zig-zag" line drawn by the intercrossing bars **11** of the frame on the internal cover **19**.

The fastening of the valvular structure to the frame can be made by sewing the internal and/or the external cover to the bars. To prevent any leakage of blood, stitches are preferably numerous and very close to each other, either as separated stitches or as a continuous suture line. Also, the stitches are made directly around the bars **11**. Furthermore, since the valvular structure is expanded together with the metallic frame, the stitches, if made as a continuous suture line, are also able to expand at the same time.

The fastening process can also be made by molding the base of the valvular structure on the frame. At this level, the bars **11** are imbedded in the coupling line of the valvular structure **14**. This mold way also concerns the internal cover **19**, when it goes below the coupling line **14** on the frame over few millimeters, for example, 2 to 4 mm. As mentioned above, this is intended in order to prevent any regurgitation of blood just below the lower part of the valvular structure **14** in case the frame **10** would not be exactly positioned on the aortic annulus but at few millimeters away.

The fastening process can further be made by gluing or soldering the valvular structure on the bars with sufficiently powerful biocompatible glues. The same remark can be made concerning the internal cover of the frame below the coupling line of the valvular structure.

Also, this allows the coupling line to follow the frame changes from the compressed position to its expanded one.

The valvular structure can also be fastened on the internal cover previously fixed at the total length of the internal surface of the metallic frame. The internal cover constitutes therefore a surface on which any type of valvular structure be more easily sewed, molded or glued. Because it is a structure with a large surface and is not involved in the movements of the valvular tissue during systole and diastole, the internal cover is more easily fastened to the internal surface of the frame.

In the particular embodiment shown in FIGS. **8***a* and **8***b*, the internal cover **19** is fastened, after introduction (indicated by the arrow B), at the upper and lower extremities of the frame **10** on the upper and lower zig-zag lines of the intercrossing bars **11**. In fact, the fastening of the internal cover **19** on the zig-zag lines made by the intercrossing bars **11** of the frame allows an easier passage of blood from the aorta above the IV towards the coronary ostia. Indeed, the blood can find more space to flow into the coronary ostia by passing through the lowest point of each triangular space made by two intercrossing bars **11**, as indicated by the arrows A**1** (see also FIG. **1***b*).

The fastening of the internal cover **19** on the extremities can be reinforced by various points of attachment on various parts of the internal surface of the frame **10**. The internal cover **19** can be fastened by sewing, molding or gluing the bars **11** onto the frame.

Fastening the valvular tissue (and the cover tissue below) on the inside of the frame, requires work on the frame in its expanded position to have access to the inside of this cylindric frame. In a preferred embodiment the frame is expanded a first time for fastening the valvular tissue on its bars, then compressed back to a smaller size to be able to be introduced via arterial introducer and finally expanded again by the balloon inflation.

Since it is aimed at being positioned in the heart after having been introduced by a catheterization technique by a transcutaneous route in a peripheral artery, mainly the femoral artery, the IV should preferably have the smallest possible external diameter. Ideally, it should be able to be introduced in the femoral artery through a 14 F (4.5 mm) size arterial introducer which is the size of the arterial introducer commonly used to perform an aortic dilatation. However, a 16 F (5.1 mm) or even a 18 F (5.7 mm) introducer would also be acceptable.

Above this size, the introduction of the IV in the femoral artery should probably be done by a surgical technique. This is still quite acceptable since the surgical procedure would be a very light procedure which could be done by a surgeon with a simple local anaesthesia. It has to be recalled that this technique is used to position big metallic frames, about 24 F in size (7.64 mm in diameter), in the abdominal aorta for the treatment of aneurysms of the abdominal aorta. In that situation, this necessitates surgical repair of the artery after withdrawal of the sheath (M. D. Dake, New Engl. J. Med. 1994; 331:1729-34).

Ideally, an IV should be able to last several tenths of life years without defect, like the mechanical prosthetic valves which are currently implanted by the surgeons. Nevertheless, an implantable valve that would last at least ten years without risk of deterioration would be effective for the treatment of elderly patients.

A valvular structure according to the invention is made of a supple and reinforced tissue which has a thickness to be thin enough to occupy as less as possible space in the compressed form of the valve, is pliable, and also strong enough to stand the unceasing movements under the blood pressure changes during heart beats. The valvular structure is capable of moving from its closed position to its open position under the action of the force exerted by the movements of the blood during systole and diastole, without having any significant resistance to blood displacements.

The material used for the tissue, which exhibits the above mentioned requirements, may be TEFLON® or DACRON®, which are quite resistant to folding movements, at least when they are used to repair cardiac defects such as inter-atrial or interventricular defects or when they are used to repair a valve such as the mitral valve which is subjected to high pressure changes and movements during heart beats. Also, a main point is the increasing systolo-diastolic movements of the valvular tissue, particularly at its junction with the rigid part of the IV, and it is therefore necessary to find the most possible resistant material tissue.

As mentioned previously, the valvular structure can also possibly be made with biological tissue such as the pericardium, or with porcine leaflets, which are commonly used in bioprosthetic surgically implanted valves.

Moreover, the valvular prosthesis of the present invention does not induce any significant thrombosis phenomenon during its stay in the blood flow and is biologically neutral.

To prevent the risk of thrombus formation and of emboli caused by clots, a substance with anti-thrombic properties could be used, such as heparine, ticlopidine, phosphorylcholine, etc., either as a coating material or it can be incorporated into the material used for the implantable valve, in particular, for the valvular structure and/or for the internal cover.

The valvular structure of the invention can have several types of designs and shapes. Besides the example illustrated in FIGS. **4** and **5**, examples of strengthened valvular struc-

tures according to the invention are shown in FIGS. **9** to **11**, respectively in the closed (FIGS. **9***a*, **10***a*, **11***a*) and in the open state (FIGS. **9***b*, **10***b*, **11***b*) to form a prosthetic valve according to the present invention. In those figures, the frame line is simplified to clarify the drawings.

To help initiate and finalize the closure of the valvular structure, four strengthening struts **14***a* are slightly inclined from the base to the upper part as compared to the central axis XX of the structure, as shown in FIGS. **9***a* and **9***b*. Accordingly, a patterned movement of the valvular structure, during the closing and the opening phases, is initiated. This patterned movement is, in the present case, a helicoidal-type one, as suggested in FIGS. **9***b* and **10***b* by the circular arrow **21**.

FIGS. **10***a* and **10***b* illustrate another embodiment to help the closing of the valvular structure and which also involves a helicoidal movement. Represented by lines **22**, inclined pleats are formed in the tissue to impart such a movement. As illustrated, these lines have an inclination from the base to the upper part of the valvular structure tissue **14**. Pleats are formed by folding the tissue or by alternating thinner and thicker portions. The width and the number of those pleats are variable, and depend particularly on the type of material used. According to another example, these pleats **22** are combined with the above described inclined strengthening struts.

These reinforcing pleats and/or struts, rectilinear or inclined, have the advantage to impart a reproducible movement and, accordingly, to avoid the valvular structure from closing to a nonstructurized collapse on the frame base.

Another shape of the valvular structure comprises two portions: one portion being flexible but with some rigidity, having a rectangular shape, occupying about one third of the circumference of the valvular structure, and the other portion being more supple, flexible and foldable occupying the rest of the circumference at its base as well as at its upper, free border. According to FIG. **11***c*, this valve is opened, during the ejection of blood, i.e., during systol. In FIG. **11***d*, a front view of the valve is closed, during an intermediate diastole, and in FIG. **11***e* the same closed valve during diastole is shown from a side view. The semi-rigid part **24'** moves little during systole and during diastole. The foldable part **23'** moves away from the rigid part during systole to let the blood flow through the orifice thus made. This orifice, due to the diameter of the upper part which is the same as that of the open stent, is large, generally as large as that of the open stent. At the time of diastole, due to the reverse of pressure, the foldable part moves back towards the semi-rigid part and presses on it, and thus closes the orifice and prevents any regurgitation of blood.

The advantage of such a valve design is to allow a large opening of the upper part of the valvular structure, not only to permit more blood flow at time of systole after the valve has been implanted, but also at the very time of implantation, when the balloon is maximally inflated to expand the valve to imbed it in the valvular annulus. The diameter of the upper part of the valvular structure could be the same size as the balloon, so that there would be no distension of the valvular part of the valve at the time of implantation, and therefore no risk of deterioration of the valvular structure by the inflated balloon.

The foldable part of the valve could be reinforced by strengthening struts to prevent an eversion of the valve towards the left ventricle during diastole.

Another shape of the valvular structure, as illustrated in FIGS. **11***a* and **11***b* comprise four portions, alternatively a main portion **23** and a more narrow portion **24**. The main and the narrow portions are facing each other. Each portion has an isosceles trapezoidal shape. The main portions **23** are flexible but with some slight rigidity and the more narrow portions **24** are compliant, more supple and foldable. In this type of design, the two slightly rigid main portions **23** maintain the valvular structure closed during diastole by firmly applying on each other in their upper extremities, thus forming a slot-like closure **25**. This particular embodiment needs less foldable tissue than in the previous embodiments and the closure of the valvular structure at the time of early diastole does not have any tendency to collapse towards the aortic annulus.

Another design for the valvular structure is a combination of a cylindrical shape followed by a truncated shape.

This type of valvular structure is longer that the hyperboloidal type, for instance, 25 or 30 mm long, therefore exceeding out of the upper part of the metallic frame, by 10 to 20 mm. The cylindrical part corresponds to the I0 metallic frame and remains inside it. The truncated conic shape is the upper part of the valvular structure, totally exceeding out of the upper extremity of the metallic frame. An advantage of such a design is that the balloon can be inflated only in the cylindrical part of the valvular structure, therefore without risk of stretching the truncated conical part of the upper diameter which is smaller than that of the inflated balloon.

When the upper extremity of the cylindrical part has the same size as the lower extremity, there is no difference during balloon inflation in the degree of force exerted by the balloon on the lower and on the upper extremity of the valvular structure. Preferably, rectilinear reinforcing struts are used in this embodiment, to strengthen the valve structure and aid in its shutting without collapsing and inverting inside the left ventricle through the aortic annulus under the force of the diastolic pressure.

Two different processes for implanting a valve according to the present invention are shown respectively in FIGS. **13***a* to **13***l* with a unique balloon catheter, as illustrated in FIGS. **12***a* and **12***b* and in FIGS. **15***a* to **15***f*, with a two-balloon catheter, as illustrated in FIG. **14**.

The IV positioning in the aortic orifice and its expansion can be performed with the help of a unique substantially cylindrical balloon catheter **26** in the so-called unique-balloon catheterization technique.

Preparing for its introduction by transcutaneous route in the femoral artery, the IV **13** is, as illustrated in the perspective view of FIG. **10***a* in a compressed form crimpled on the balloon catheter **26**. A central sectional view of the mounted IV **13** on the complete balloon catheter **26** is shown in FIG. **12***b*.

The shaft **27***f* of the balloon dilatation catheter **26** is as small as possible, i.e., a 7 F (2.2 mm) or a 6 F (1.9 mm) size. The balloon **26** is mounted on the shaft **27** between two rings R. Moreover, the shaft **27** comprises a lumen **28** (FIG. **12***b*) as large as possible for inflation of the balloon **26** with diluted contrast to allow simple and fast inflation and deflation. It has also another lumen **29** able to accept a stiff guide wire **30**, for example 0.036 to 0.038 inches (0.97 mm), to help position the implantable valve with precision.

The balloon **26** has, for example, a 3 to 4 cm length in its cylindrical part and the smallest possible size when completely deflated so that it will be able to be placed inside the folded valve having an outside diameter which ranges between about 4 and 5 mm. Therefore, the folded balloon preferably has at the most a section diameter of about 2.5 to 3 mm.

The balloon is therefore made of a very thin plastic material. It is inflated with saline containing a small amount of contrast dye in such a way to remain very fluid and visible when using X-ray.

However, the balloon **26** has to be sufficiently strong to resist the high pressure that it has to withstand to be capable of expanding the folded valvular structure **14** and the compressed frame in the stenosed aortic orifice considering that, although pre-dilated, the aortic orifice still exerts a quite strong resistance to expansion because of the recoil phenomenon.

This procedure is shown in FIGS. **13***a* to **13***e*.

In contrast to the technique used when performing the usual aortic dilatation (without valve implantation), i.e., inflating the balloon maximally markedly above the nominal pressure, if possible, up to the bursting point (which occurs always with a longitudinal tear, without deleterious consequence, and with the advantage of both exerting a maximal dilating force and restoring blood ejection instantaneously), the balloon inflated for expansion of an implantable valve should not burst in any case. Indeed, bursting of the balloon would involve a risk of incomplete valve expansion and wrong positioning. Therefore, the balloon should be very resistant to a very high pressure inflation. Furthermore, the balloon is inflated only up to the nominal pressure indicated by the maker and the pressure is controlled during inflation by using a manometer. Such relatively low pressure should be sufficient since prior to positioning the IV, an efficacious dilatation of the stenosed aortic valve according to the usual technique with a maximally inflated balloon for example 20 mm or 25 mm in size in such a way to soften the distorted valvular tissue and facilitate the enlargement of the opening of the valve at time of IV implantation is performed.

The implantation of the aortic valve **20** can be made in two steps, as described as follows.

The first step, as shown in FIGS. **13***a* to **13***f*, consists in introducing the shaft **27** and balloon catheter **26** along the guide wire previously positioned in the ventricle **4** (FIGS. **13***a*-**13***b*). The dilatation of the stenosed aortic valve **1'**, **2'** using a regular balloon catheter, according to the commonly performed procedure, i.e., with the guide wire **30** introduced in the ventricle **4** (FIG. **13***a*) and with maximal inflation of the balloon **26** (FIGS. **13***c* to **13***d*) up to the bursting point. Dilatation is performed at least with a balloon having about 20 mm diameter, but it can be performed with a balloon having about 23 mm diameter so as to increase maximally the aortic orifice opening before implantation of the valve although the implantable valve is about 20 mm in diameter. This preliminary dilatation of the aortic orifice helps in limiting the force required to inflate the balloon used to expand the implantable valve and position it in the aortic orifice, and also in limiting the recoil of the aortic valve that occurs immediately after balloon deflation. The balloon is deflated (FIG. **13***a*) and pulled back on the wire guide **30** left inside the ventricle.

Owing to the marked recoil of the stenosed valve and also of the strong aortic annulus, the 20 mm diameter valve is forcefully maintained against the valvular remains at the level of the aortic annulus. Preliminary dilatation has another advantage in that it permits an easier expansion of the IV, having a lower pressure balloon inflation which helps prevent damage of the valvular structure of the IV. This also facilitates the accurate positioning of the prosthetic valve.

The second step corresponds to the implantation of the valve **13** is shown in FIGS. **13***g* to **13***l*. The positioning of the IV needs to be precise at a near 2 or 3 mm, since the coronary ostia **6** has to remain absolutely free of any obstruction by the valve **13** (FIGS. **13***k* and **13***l*). As mentioned above, this is, for example, performed with the help of the image of the subvalvular angiogram in the same projection fixed on an adjacent TV screen. The expansion and the positioning of the valve prosthesis **13** is performed within a few seconds (15 to 20 among at most) since during the maximal balloon inflation (which has to be maintained only a very few seconds, 3, 4) the aortic orifice is obstructed by the inflated balloon **31** and the cardiac output is zero (FIG. **13***h*). As for the pre-dilatation act itself, the balloon **26** is immediately deflated within less than 5 or 6 seconds (FIG. **13***j*) and, as soon as the deflation has clearly begun, the closing and opening states of the IV are active whereas the balloon is pulled back briskly in the aorta (FIGS. **13***j* to **13***l*). In case the IV is not maximally expanded by the first inflation, it is possible to replace the balloon inside the IV and to reinflate it so as to reinforce the expansion of the IV.

The IV **13** can also be used in aortic regurgitation. This concerns more often younger patients rather than those with aortic stenosis. The contraindication to surgical valve replacement is often not due to the old age of the patients, but stems mainly from particular cases where the general status of the patient is too weak to allow surgery, or because of associated pathological conditions. Apart from the fact that there is no need for a preliminary dilatation, the procedure of the valve implantation remains approximately the same. The balloon inflation inside the IV is chosen accordingly, taking also into account the fact that it is necessary to overdilate the aortic annulus to obtain a recoil phenomenon of the annulus after balloon deflation to help maintain the IV in position without any risk of displacement.

However, the size of the expanded implantable valve is around 25 to 30 mm in diameter, or even bigger, because the aortic annulus is usually enlarged. A preliminary measurement of the annulus will have to be performed on the subvalvular angiography and by echocardiography to determine the optimal size to choose.

The IV can be used in the mitral position, mainly in case of mitral regurgitation, but also in case of mitral stenosis. Here again, the IV **20** is only described when used only in cases of contraindication to surgical valve repair or replacement. The procedure is based on the same general principles though the route for the valve positioning is different, using the transseptal route, like the commonly performed mitral dilatation procedure in mitral stenosis. The IV size is quite larger than for the aortic localization (about 30 to 35 mm in diameter when expanded or clearly above in case of a large mitral annulus, a frequent occurrence in mitral insufficiency), to be capable of occupying the mitral area. A preliminary measurement of the mitral annulus is performed to determine the optimal implantable valve size to choose. Since the introduction of the IV is performed through a venous route, almost always through the femoral vein which is quite large and distensable, the bigger the size of the IV in its compressed position is not a drawback even if the diameter size is about 6 or 7 mm. Moreover, the problem of protection of the coronary ostia as encountered in the aortic position does not exist here which therefore makes the procedure easier to be performed.

Finally, the IV can be used to replace the tricuspid valve in patients with a tricuspid insufficiency. This procedure is simple to perform since the positioning of the IV is made by the venous route, using the shortest way to place in the right position at the level of the tricuspid orifice practically without any danger from clot migration during the procedure. A large implantable valve is used, with a diameter of about 40 mm or even larger because the tricuspid annulus is often markedly dilated in tricuspid insufficiency. Here also, as in the mitral position, the compressed IV and the catheter used can be without inconvenience, quite larger than that for the aortic position because of the venous route used.

Furthermore, it has to be noted that the IV can be used also as a first step in the treatment of patients who have contrain-

dication to surgery, when they are examined for the first time, but who could improve later on after correction of the initial hemodynamic failure. The IV procedure can be used as a bridge towards surgery for patients in a weak general condition which are expected to improve within the following weeks or months after the IV procedure in such a way that they can be treated by open heart surgery later on. In the same vein, the IV procedure can be used as a bridge towards surgical valve replacement or repair in patients with a profoundly altered cardiac function that can improve secondarily owing to the hemodynamic improvement resulting from the correction of the initial valvular disease by the IV implantation.

Another technique for implantation of an aortic valve by transcutaneous catheterization uses a two-balloon catheter.

An example of this technique using the two parts IV with a two-balloon catheter **40** is shown in FIG. **14**.

Two-balloons **26** and **26'** are fixed on a unique catheter shaft **27**, said balloons being separated by a few millimeters. The two balloons are preferably short, i.e., about 2 to 2.5 cm long in their cylindrical part. The first balloon **26** to be used, carries a first frame **10** aimed at scaffolding the stenosed aortic orifice after initial dilatation. This first balloon **26** is positioned on the aorta side, above the second balloon **26'** which is positioned on the left ventricle side. The second balloon **26'** carries the expandable valve **13** which is of the type described above made of a second frame **10'** and a valvular structure **14** attached to said frame **10'**. The difference is that the second frame does not need to be as strong as the first frame and is easier to expand with low balloon pressure inflation which does not risk damaging the valvular structure **14**.

This enlarges the choice for making a valvular structure without having to face two contradictory conditions:

- having a soft and mobile valvular structure **14** capable of opening and closing freely in the blood stream without risk of being damaged by a balloon inflation; and
- needing a reinforced frame strong enough to be capable of resisting without any damage, a strong pressure inflation of the expanding balloon.

The shaft **27** of this successive two-balloon catheter **40** comprises two lumens for successive and separate inflation of each balloon. Indeed, an additional lumen capable of allowing a fast inflation occupies space in the shaft and therefore an enlargement of the shaft is necessary. However, this enlargement of the shaft stops at the level of the first balloon **26** since, further to said first balloon, only one lumen is necessary to inflate the second balloon **2**C, at the level of the IV which is the biggest part of the device.

Another advantage of this two part IV with a two-balloon catheter is that each set of implantable valve and balloon has a smaller external diameter since each element to be expanded, considered separately, is smaller than in combination. This allows obtaining more easily a final device with an external diameter 14 F.

The first balloon is sufficiently strong to avoid bursting even at a very high pressure inflation. This first balloon is mounted in the frame in its deflated position, prior to its introduction by the strong frame which is aimed to scaffold the dilated stenosed aortic valve. The size and shape of said frame is comparable to what has been described previously but said frame is calculated (in particular the material, the number and diameter of its bars are chosen by the person skilled in the art) to make sure that it will resist the recoil of the dilated valve and that it will be securely embedded in the remains of the native aortic valve.

The second balloon does not need to be as strong as the first one and, therefore, can be thinner, occupying less space and being easier to expand with a lower pressure for balloon inflation. This second balloon **26'** is mounted in the valve itself which, as in the preceding description, comprises a frame to support the valvular structure and said valvular structure.

Also, the second frame **10'** does not need to be as strong as the first one. This frame can be slightly shorter, 10 mm instead of 12 mm, and its bars can be thinner. This frame can have an external surface which is a bit rough to allow better fixation on the first frame when expanded. The bars may also have some hooks to fasten to the first frame.

The valvular structure is attached on said second frame and expanded by relatively low pressure in the second balloon called hereafter the IV balloon. It does not need to be as strong as in the preceding case (IV in one part and unique balloon catheter technique) and, therefore, it occupies less space and has less risk to be damaged at the time of expansion.

This technique is shown in FIGS. **15***a* to **15***f*.

One of the problems relevant to the IV implantation procedure as described above, with the IV in one part, is the expansion at the same time by the same balloon inflation of both the frame and the valvular structure. Indeed, the frame is a solid element and the valvular structure is a relative weak one that could be damaged when squeezed by the inflated balloon.

Therefore, the valve implantation can be performed in two immediately successive steps. The first step (FIGS. **15***a*-**15***b*) corresponds to the expansion and the positioning of the first frame with the first balloon **26** wherein inflation is performed at a high pressure. The second step (FIGS. **15***d*-**15***e*) corresponds to the expansion and the positioning of the valvular structure **14** inside the frame **10'** using the second balloon **2**C. This second step follows the first one within a few seconds because, in the time interval between the two steps, there is a total aortic regurgitation towards the left ventricle which is an hemodynamic condition that cannot be maintained for more than a few heart beats, i.e., a few seconds, without inducing a massive pulmonary edema and a drop to zero of the cardiac output.

In another embodiment, the first frame to be introduced comprises the valvular structure and the second frame being stronger than the first one to scaffold the previously deleted stenosed aortic valve.

The advantage of this two step procedure would be to allow expansion and positioning of the frame part **10'** of the R **13** using strong pressure inflation of the balloon **26'** without the risk of damaging the valvular structure **14** which, for its own expansion, would need only light pressure inflation.

The method is schematically detailed in FIGS. **15***a* to **15***f*. A previous dilatation of the stenosed aortic valve is performed as an initial step of the procedure to prepare the distorted valve to facilitate the following steps:

1/ positioning the double balloon catheter **40** with the first balloon **26** with the frame at the level of the aortic annulus **2***a*, the second IV balloon **26'** being inside the left ventricle beyond the aortic annulus **2***a* (FIG. **15***a*);

2/ compression of the stenosed aortic valve **1'**, **2'** with the first balloon **26** having a 20 mm, preferably with a 23 mm diameter, the balloon being inflated maximally up to

the bursting point, to prepare the IV insertion (FIG. **15***b*). Inflation lasts a few seconds (preferably 10 seconds at most) with powerful pressure being used to expand the frame and forcefully embed said frame in the remains of the dilated valve;

3/ an immediate speedy deflation of said first balloon **26** follows (FIG. **15***c*); as soon as the balloon **26** is beginning to clearly deflate, the first frame **10** remaining attached to the stenosed valve **1'**, **2'**, the catheter is withdrawn to position the IV balloon **26'** inside the previously expanded frame **26** (FIG. **15***c* in which the frame **10'** is partially drawn for clarity purpose); and

4/ immediately after being well positioned, the IV balloon **26'** is promptly inflated, to expand the IV **13** (FIG. **15***c*); and/when the IV **13** is blocked inside the first frame **10**, the IV balloon **26'** is deflated (FIG. **18***f*).

Finally, the whole device has to be withdrawn to allow homeostasis of the femoral artery puncture hole.

The total duration of the successive steps, particularly the time during which the balloons are inflated, and the time during which the frame is expanded whereas the valve has not yet been positioned and expanded, is about 20 to 30 seconds. This is feasible if the balloons are inflated and deflated within very a few seconds, 6 to 8, for instance. This is permitted if the lumen of the shaft can be sufficiently large, taking into account the inescapable small diameter size of the shaft. This can also be facilitated by a device producing instantaneously a strong inflation or deflation pressure.

What is claimed is:

1. A prosthetic valve for implantation in a stenosed aortic valve, comprising:

a metallic frame having intersecting bars, the frame being compressible to a compressed external diameter capable of being introduced through an 18 French arterial introducer and into a patient's vasculature using a catheterization technique, the frame being expandable for implantation in the stenosed aortic valve, the intersecting bars of the frame having a diameter in the range of 0.1 to 0.6 mm for providing the frame with sufficient radial strength to resist the recoil force exerted by the stenosed aortic valve, the frame having an upper extremity formed with a zig-zag shape and a lower extremity formed with a zig-zag shape;

a flexible valvular structure made with pericardial tissue, the valvular structure sewn to the frame with stitches made directly around the bars of the frame, the valvular structure positioned entirely between the upper and lower extremities of the frame when in a closed position; and

an internal cover made with pericardial tissue and sewn to the frame, the internal cover fastened on an internal surface of the frame for preventing a passage of blood through spaces between the bars of the frame, the internal cover having an inlet end sewn to the lower extremity of the frame along a zig-zag line, the internal cover having an outlet end sewn to the valvular structure;

wherein the internal cover extends between the lower extremity of the frame and the valvular structure and wherein blood is permitted to pass through spaces in the frame between the valvular structure and the upper extremity of the frame.

2. The prosthetic valve of claim **1**, wherein the internal cover strengthens the fastening of the valvular structure to the frame.

3. The prosthetic valve of claim **1**, wherein the frame comprises a concave shape profile.

4. The prosthetic valve of claim **1**, wherein the valvular structure forms a continuous surface and is provided with guiding means.

5. The prosthetic valve of claim **4**, wherein the guiding means create stiffened zones which induce the valvular structure to follow a patterned movement when moving from the closed position to the open position.

6. The prosthetic valve of claim **5**, wherein the guiding means are further configured to prevent eversion of the valvular structure.

7. The prosthetic valve of claim **1**, wherein the frame is configured to be expanded by a balloon.

8. The prosthetic valve of claim **1**, wherein the frame is further compressible to a compressed external diameter capable of being introduced through a 16 French arterial introducer.

9. The prosthetic valve of claim **1**, wherein the frame is further compressible to a compressed external diameter capable of being introduced through a 14 French arterial introducer.

10. The prosthetic valve of claim **1**, wherein a substance with anti-thrombotic properties is incorporated into the valvular structure.

11. The prosthetic valve of claim **1**, wherein the frame constitutes a grate type structure.

12. The prosthetic valve of claim **1**, wherein the upper and lower extremities of the frame are rounded and smooth.

13. The prosthetic valve of claim **1**, wherein the frame comprises an expanded external diameter of about 20 to 25 millimeters for contacting the stenosed aortic valve after the prosthetic valve is implanted.

14. A prosthetic valve for implantation in a stenosed aortic valve by a catheterization technique, comprising:

a compressible and expandable frame made with intersecting metallic bars, the frame having a compressed external diameter capable of being introduced into a patient's vasculature through an 18 French arterial introducer using a catheterization technique, the intersecting metallic bars of the frame having a diameter in the range of 0.1 to 0.6 mm for providing the frame with sufficient radial strength to resist the recoil force exerted by the stenosed aortic valve, the frame being expandable to a shape comprising a concave profile and having an upper extremity formed with a zig-zag shape and a lower extremity formed with a zig-zag shape;

a flexible valvular structure having open and closed states, the valvular structure sewn directly to the frame between the upper and lower extremities of the frame, the valvular structure made with pericardial tissue and positioned entirely between the upper and lower extremities of the frame when in the closed position; and

an internal cover made with pericardial tissue and sewn to the frame, the internal cover fastened on an internal surface of the frame for preventing a passage of blood through spaces between the bars of the frame, the internal cover having an inlet end sewn to the lower extremity of the frame along a zig-zag line, the internal cover having an outlet end sewn to the valvular structure;

wherein the internal cover extends only between the lower extremity of the frame and the valvular structure.

15. The prosthetic valve of claim **14**, wherein the frame is further compressible to a compressed external diameter capable of being introduced through a 16 French arterial introducer.

16. The prosthetic valve of claim **14**, wherein the upper and lower extremities of the frame are rounded and smooth.

17. The prosthetic valve of claim **14**, wherein the internal cover strengthens the fastening of the valvular structure to the frame.

18. The prosthetic valve of claim **14**, wherein the frame is configured to be expanded by a balloon.

19. The prosthetic valve of claim **14**, wherein a substance with anti-thrombotic properties is incorporated into the valvular structure.

20. The prosthetic valve of claim **14**, wherein the frame constitutes a grate type structure.

* * * * *

Medtronic Corevalve LLC, etc., et al. vs. Edwards Lifesciences Corporation, et al.
US District Court, Central District of California, Case No. SA CV 11-00961 JVS (MLGx)

CERTIFICATE OF SERVICE

I hereby certify that on September 19, 2011, I electronically filed the document described as **Answer and Counterclaims – Demand for Jury Trial** with the Clerk of the Court using the CM/ECF System which will send notification of such filing to the following:

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EXHIBIT N

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	:	Civil Action
Plaintiffs,	:	
v.	:	
COREVALVE, INC.,	:	
Defendant.	:	No. 08-91(GMS)

- - -

Wilmington, Delaware
Tuesday, March 23, 2010
9:00 a.m.
Day 1 of Trial

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge

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THE COURT: Good morning, counsel. Please take your seats.

Mr. Nathan, I understand you have an issue or two.

MR. NATHAN: Not an issue, Your Honor. But a report of a significant development in the case.

Last night I believe after 9:00 we were informed that CoreValve has dropped all their anticipation defenses, all their obviousness defenses, and all their written description defenses. So we are left with infringement, willful infringement, lack of enablement, and damages.

We scrambled last night to redo the preliminary instructions. We have redone the voir dire, and also to take into account Your Honor's ruling yesterday that this is a one-patent case. I believe those papers are in order. I felt obligated to tell you that the contours of the case

The valve is inside that frame and supported.

It's also important to see that the valve is supported at a 30-degree angle.

Your Honor, if I could approach the board one more time.

THE COURT: You may.

MR. VAN NEST: Notice that the valve is supported at a 30-degree angle. That is not an accident. That is not a mistake. That is the idea of the inventors, which was you are stronger if your front leg is forward, just like you would be in a tug of war, you would have more stability if you were attached at an angle.

By attaching each of these -- this one is facing us so it is harder to see, this one is right by your side -- by attaching these at a 30-degree angle to the base, they got a lot more strength out of this valve and it meant that it was much less likely for the valve tissue to tear as it might.

You can imagine the pounding of the blood against that valve when it's closed, it could tear it off. But by attaching it at this angle, and by using the entire frame to support the valve, Dr. Seguin and his colleagues built something that was stronger, more durable, more safe, and became the first approved for use anywhere in the world.

We are showing here the little guy in the tug of

war strong enough to support.

If we can have the next slide.

Dr. Seguin and Mr. Bortlien received patents on their devices.

Here is the patent on the device you are looking at, the '682, applied for by Dr. Seguin, and Dr. Seguin alone. Notice, it is not perfect, but you can see in the drawing the basic nuts and bolts of his idea, the top that is flared so that it will attach high up in the aorta. The bottom that is conical there by Point 10, so that it will migrate.

So this is the top. It goes into the aorta there. This is the conical bottom. It's a long, tall device. And reading through it, reading through it, one understands what it is that Dr. Seguin had in mind.

By the way, when the Patent Office issued this patent, they knew about the Andersen patents. Dr. Seguin explained to the Patent Office that Andersen had an earlier patent and he said mine is better, mine is different, the Andersen patent doesn't get the job done. Mine does. It's different. And the Patent Office awarded Dr. Seguin not only one but two patents.

There is a second patent, the '406. We have a picture of that as well. It looks a little different. But it's really the same idea.

It's a taller prototype. And we will actually show you this prototype when Mr. Bortlien is here, supporting the valve within the frame as it does.

Let's go back.

So this patent also disclosed that Dr. Andersen had a patent, too. So the Patent Office, when it issued both of these patents, was aware of Dr. Andersen's patents.

Now, our next slide simply shows the approval in Europe. The Commissioner of Ireland approved the use of this in humans. It was issued for use, approved for use. As our next slide shows, it's been used and used and used.

29 countries, 200 cardiologists have now been trained on this, 7,000 patients have now been treated. It's been an enormous success, and it's been a huge benefit for patients around the world.

Okay. Let's look at our next slide.

This device, this product, does not rely on or use the Andersen patents. That is an important point that you will be asked to resolve for us at the end of the case.

I want to start with the next slide showing that Dr. Andersen is not claiming that he invented the idea of putting a valve inside a catheter. You can see on the slide here -- we will go into this in more detail.

Actually, let me take a moment and introduce a man that is going to help us present this evidence to you, a

cardiologist from the U.K. his name is Dr. Martin Rothman.

Dr. Rothman, if you would stand please, for a moment.

Dr. Rothman was the first cardiologist to put a stent in a patient in England. He was the very first.

So he is also one of the pioneers in this field. And he has evaluated this case and this evidence on behalf of CoreValve.

He will talk a little bit about this. There are a number of examples of inventors that patented designs on valves inside catheters, and you see a list of them there.

The next slide shows that Dr. Andersen acknowledged this, his patent, the '552, says others have been out there doing this, but I have got a new and better way: Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization.

So he is acknowledging that there were others before him, and that he didn't come up with this idea. What he came up with in his mind, in his patent, is a particular way of doing this, a particular design.

So now I want to look at the design that he came up with and compare that to the CoreValve product. That's what infringement is all about.

So here are the three key elements of his

design.

You heard from Mr. Nathan about cylindrical support means. That's a stent that supports the valve, a plurality of commissural supports projecting from one side. That is critical language, projecting from one side, and those commissural supports have to project in a direction generally parallel to longitudinal axis.

Let's focus in on these commissural supports. By the way, I am going go to let you decide whether you think this is cylindrical or not. People will be presenting all sorts of testimony. But you can look at this device at the end of the day and decide for yourselves whether that is cylindrical or not and how close it is to a cylinder from far away.

I want to talk about these commissural supports.

What is a commissural point?

Every valve has leaflets, even our little model. Every valve has leaflets. These leaflets open and close. That's how the valve works. They snap open, you can't quite get them open all the way with my finger, but they snap open to let the blood through and they snap shut when the pressure is on. So they open and shut.

Where the leaflets join, that is called a commissural point. Every valve has commissural points, way back to the surgical valve, that is the Hancock surgical

valve at the bottom.

Every valve has commissural points. You have to support them some way. You have to hold them up or the leaflets won't work. So there has to be some way of supporting them.

Notice Hancock looks a lot like Andersen's patent. And Andersen has said that he got his inspiration from the old surgical valves. He was trying to replicate an old surgical valve that went in your annulus there and turn it into a catheter version.

Let's go to the next slide.

Those commissural supports in the Andersen patent have to operate a certain way. They have to project from one side.

You can see there, he describes them in his Figure 1 example as projecting from the side. They are those yellow points that project up from the side. And the inventors, Dr. Knudsen actually referred to these as towers.

Actually, let's go to the next slide. So I just want to explain that these are both figures from the patent, and they show that here on the left you have got these commissural supports that project up. Mr. Nathan said they stick up. Well, I would agree with that. They stick up from the side. And here you see in Figure 2 the valve is suspended from these three points. Here is one point. Here

is one point. Here is one point. There are three points. They are suspended from these commissural supports.

Next slide, please.

You see that Dr. Knudsen is one of the other inventors. He is one of the three inventors of the Andersen patent. We took testimony from him in this case. He calls this a tower. He drew it actually at his deposition this way. This, he said, was the very first prototype that they built, so he calls it a tower.

Next slide, please.

Well, the ReValve device does not have any such towers or projecting points. You can see on the left, the valve is supported by those projections that stick up. On the right, there are no projections.

If I can approach the board, Your Honor.

There are no projections in CoreValve's product. That is the whole point. There is nothing sticking up above the top.

By the way, this little tab is there for the purpose of allowing the cardiologist to get this device hooked into the catheter. So it has no role in supporting the valve. It's just a tab, and that's agreed by both parties.

So in this device, unlike Andersen, the valve itself, the tissue that opens and closes, is supported

entirely within the frame, not on a post, not on a pole, not on a projection, as you see with Andersen. And it is the entirety of the frame that supports this. If you take out metal from this frame, it will not work. Dr. Andersen's whole point was, take the metal out between the posts, because then the frame will be lighter. He actually says in the patent, mine is better because I am taking metal out between these. And therefore, I am lightening my device.

That is not what CoreValve did. Seguin went a whole different direction. He wanted something bid, anchored in two points, and he wanted to support the valve entirely within the frame.

So that is one way in which this differs from the claim.

May I see the next slide, please.

There is another important distinction. It relates to that 30-degree angle that I mentioned.

In the Andersen design, the commissural supports have to project in a direction generally parallel, and this is what was shown and Mr. Nathan showed this same thing. These points have to be generally parallel to the sides of the frame. They have to stick up straight or almost straight. It doesn't have to be perfectly parallel. But it has to be generally parallel.

In the CoreValve frame, these commissural points

are not supported in a parallel way. They are supported at a 30-degree angle. Why? Again, because the designers wanted to have more strength. They wanted to spread the stress from this commissural point across the whole tissue. And that was a big deal.

You are going to hear testimony from Mr. Michiels that this was something that they studied and studied and they evaluated and they tried different angles, more than 30, less than 30, until they could get an angle that did this right.

You can see the difference on the left, it's parallel, generally so. On the right, they are attached at a 30-degree angle.

That leads to a third key difference. A third key difference between these is that the CoreValve valve is safer because it has no moving parts. Moving parts in a valve inside your body, not a good thing.

Let's look at the next slide.

You will hear testimony from the Edwards side, Dr. Buller, their expert, that one of the principles of Andersen was that those commissural points, you see the little yellow arrows I had at the top there, those aren't in the patent.

This is a figure from the patent, but these arrows -- and this word is not in the patent -- because the

patent makes clear that these towers have to be elastic. They have to move. Why?

Because if you are supporting the tissue on a tower, and the pressure is hitting that valve over and over, if you don't put some give in that thing, the tissue is going to tear.

If you don't have some give in your tower, the tissue will tear away from this. It will pull away, and your valve won't function anymore. So if you don't have movement here, it doesn't work.

There is no movement here. The whole idea of this device is to be rigid, a rigid frame. And the way the designers, Dr. Seguin and Bortlien, Mr. Michiels and his team, Taun Nguyen, they built a device that was rigid, no movement, very, very different from what is claimed or called for in the Andersen device.

So just to sum this up, why is CoreValve different? Totally different shape. No projecting supports to hold the valve. Valve is supported at a 30-degree angle, not generally parallel and no moving parts. Those are all big differences between the way the patent set forth the invention and the way Dr. Seguin and his team did it.

Now, I will pause just a minute to say that Dr. Seguin will be here live. Georg Bortlien will be here live. Rob Michiels is here and will be here live. And

they'll all testify that they believed there was no way they were infringing this Andersen patent for the reasons I have just given.

No. 1, they went in a different direction from Andersen. They did not want to duplicate what Andersen laid out because they felt Andersen was not going to work. No. 1.

No. 2, they had patents on their own device. And those patents were obtained only after they told the Patent Office, hey, Dr. Andersen has a patent, too. We don't think his will work properly. We think ours is better, and we think ours is different. And so they got patents on the CoreValve designs, too.

So I want to turn to my last topic. If we could put up the next slide.

Oh. Why is this important, these differences we're talking about? Well, because, as the Court will advise, and you got a little bit of an idea this morning, in order to infringe someone's patent, you have to practice every element of the claim. So if I have a patent, for example, on a soccer ball. Let's say I'm lucky enough to have a patent. My elements are made of leather, stitched together, filled with air, and round. That is what my invention is.

Well, your football can't infringe that even though it is made of leather, stitched together and filled

with air. It's oblong, so it's different. In order to find infringement, every single element has to be present.

So let's look at the next slide.

You can see that's true for medical devices, too. If there are no projecting commissural supports or the valve is supported at something other than a parallel way, there is no infringement. That is just the way the rules work.

That is because the only property that Dr. Andersen is entitled to own is the property he claimed. What is within his deed? If I have property next door, down the street or another block away where CoreValve is, I'm not trespassing on Andersen's property. I have my own property, and I have my own patents to protect my device, too.

Next slide.

Okay. You might wonder if CoreValve doesn't infringe the patent, why do we need to talk about validity? And I would agree normally that we don't need just another defense. We have plenty to do. We know how hard you're working, but CoreValve is going to be in this market for years to come.

CoreValve has the right to ask a jury, as part of the patent system, to look at evidence the Patent Office never saw. You shouldn't have to keep contending with the same patent over and over as we develop new products. And

so while we don't need this defense in this case particularly because we don't infringe, it's important to us that you take your opportunity to look at the evidence the Patent Office never saw.

As you saw in the patent video, the Patent Office operates only based on what the inventors give it and what it can find on its own. The Patent Office is not like the FDA. They don't test anything. They don't test devices and that sort of thing. And no one else is participating.

So the point of this last little segment is we want to outline evidence for you that the Patent Office never saw.

So why is that relevant? To get a patent, as you heard His Honor explain, and the patent video, you have enable someone to make it and use it.

Da Vinci had a beautiful drawing of a flying machine in the 15th Century. You could build just like that but it would never fly. That is not an enabled device.

On the other hand, in 1906, the Wright Brothers did patent the first flying machine. And that flew at Kitty Hawk, North Carolina. You could build it and fly it.

That is the difference between enablement and nonenablement. And the next slide shows us the rule.

The patent is invalid if the description of the invention would not have enabled one of skilled in the

field -- that is someone that had skill in the making of these products -- to make and use the invention without undue experimentation -- to make and use the invention without undue experimentation.

It's not that people couldn't figure out how to build what Andersen was describing. They could. But they couldn't get it to work. And that is why Edwards spent so much time talking about these 12 years.

I'll up the ante because the evidence I'm going to review with you now for just a moment before we finish shows that in the 18 years, 18 years since the patent was made public, nobody, anywhere in the world, has ever used it to build a working product. The inventors didn't do it. Heartport didn't do it. Edwards didn't do it. Lots of companies had an opportunity to do it. No one could make it work. It's not an enabled invention.

This is a statement from Dr. Knudsen, who unfortunately won't be here live but we'll see his testimony on videotape. He wrote this thesis two years after he applied for a patent. You saw their patent application date in '90. Two years later, he said: Our experiments, the experiments undertaken are of the nature of a preliminary technical investigation, and many important questions still remain open ... there may be some risk of detachment and distal migration.

So he is pointing out the problems, not the solution.

And he and his colleagues spent three years trying to get this thing to work in laboratory pigs.

Slide next, please.

They never did. No. 1, these experiments went on for about three years. And you will hear some testimony about that from some of the inventors and from Dr. Rothman.

The device was not small enough to put into a catheter. The Andersen device they had, they couldn't get into a catheter like this, so they had to cut the pig open in the stomach to try to get it in. They had to do it the old-fashioned way, surgically. They never implanted it using a catheter or anything like a catheter, No. 1.

No. 2, they couldn't get it to stay in the annulus where it has to go. They couldn't get it to stay in the annulus. It went all over the place.

No pig lived for more than one hour. No pig lived for more than one hour after this device was implanted. Most of the time, death was almost immediate, because they couldn't get the thing in. It didn't work right. You couldn't get it to stay.

And it turns out they weren't alone.

Let's go back a minute. Let's go back just a minute.

All right. So here is the history. The history is the inventors didn't get it to work.

Heartport, which is down out at Stanford, south of San Francisco, they got a license. They couldn't develop it. The testimony there will be that for about a year and-a-half, they tried to figure out how to use the Andersen device, and they just, they couldn't get it done. They went on to things that were easier and had more prospect of success.

Okay. Now, Stan Rowe also will not be here live. He is an Edward employee coming by videotape. He was at PVT. You heard about PVT. That's the company that Edwards bought.

Well, Stan Rowe's opinion of Andersen was it's not strong enough and it's way too big. It will never work. That was Stan Rowe's opinion.

PVT's first prototype didn't use Andersen. They used good ol' Palmaz-Schatz stent. This is one of the early stent designs. So they didn't use Andersen, they used something already on the market and stuck the valve inside it as their point of departure.

They actually -- and you will see this in a minute. PVT built a prototype using the Andersen patent and tested it in a lab and it failed. It failed. Those commissural supports were too weak to support the valve. So

they never even took it beyond that stage. They never put it in a person. They never did clinical trials with it. It failed in the lab, on the bench.

And then when Cribier -- You heard about -- maybe you didn't hear about Cribier. Alain Cribier worked for PVT, and he was a colleague of Dr. Seguin in France. Another French cardiologist, and a notable one. He was one of the people working in this field that was very well known. And Cribier actually holds the patent on the Edwards device.

They actually called the device originally the Cribier-Edwards device. Not the Andersen-Edwards device, the Cribier-Edwards device. Their sapient product was originally Cribier-Edwards. And Cribier wrote a patent in which he said Andersen will never work. So Cribier and Stan Rowe and all these people that are PVT are now employed by Edwards.

So let's review a brief bit of the evidence, and we'll give it a rest.

This is from Cribier's patent.

He is referring to Andersen. He is talking about the Andersen patent, the '552 that you are evaluating in this trial.

Such a light stent structure is too weak to allow the implantable valve to be forcefully embedded.