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(54) **DEVICE FOR IN SITU AXIAL AND RADIAL POSITIONING OF CARDIAC VALVE PROSTHESES**

(75) Inventors: **Laura Ghione**, Torino (IT); **Giovanni Righini**, Chivasso-Torino (IT); **Eric Manasse**, Milano (IT); **Giovanni Rolando**, Chavasso-Torino (IT); **Paolo Gaschino**, Castagneto Po-Torino (IT); **Dong Ik Shin**, Poway, CA (US)

Correspondence Address:
FAEGRE & BENSON LLP
PATENT DOCKETING
2200 WELLS FARGO CENTER, 90 SOUTH SEVENTH STREET
MINNEAPOLIS, MN 55402-3901

(73) Assignee: **Sorin Biomedica Cardio S.r.l.**, Saluggia (Vercelli) (IT)

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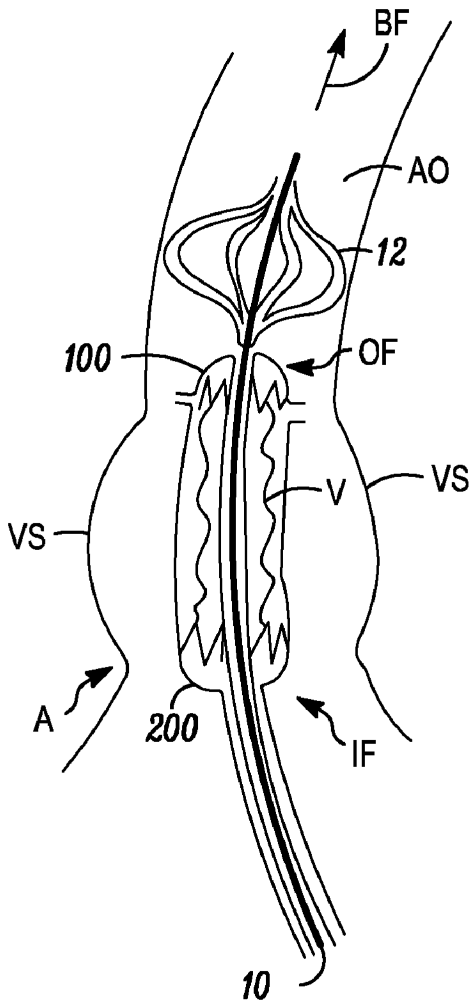
(57) **ABSTRACT**

An instrument for positioning a cardiac valve prosthesis in a vessel includes a wire element to slidingly guide the valve prosthesis towards an implantation site and an expandable element coupled to the wire element. The expandable element is expandable in the vessel to position the wire element in association with the implantation site. A method for positioning a cardiac valve prosthesis includes securing a delivery instrument at an appropriate location at the implantation site and delivering the valve prosthesis to the implantation site using the delivery instrument.



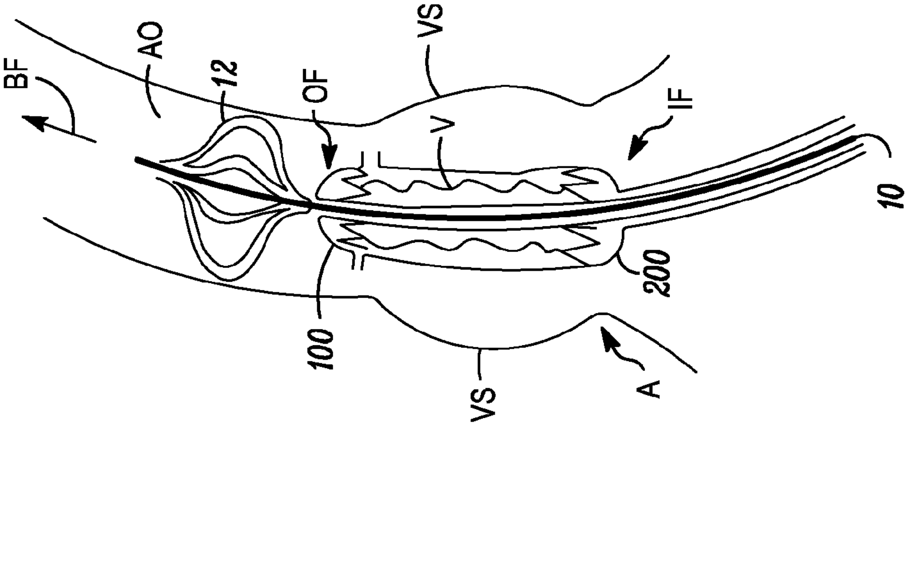


FIG. 1

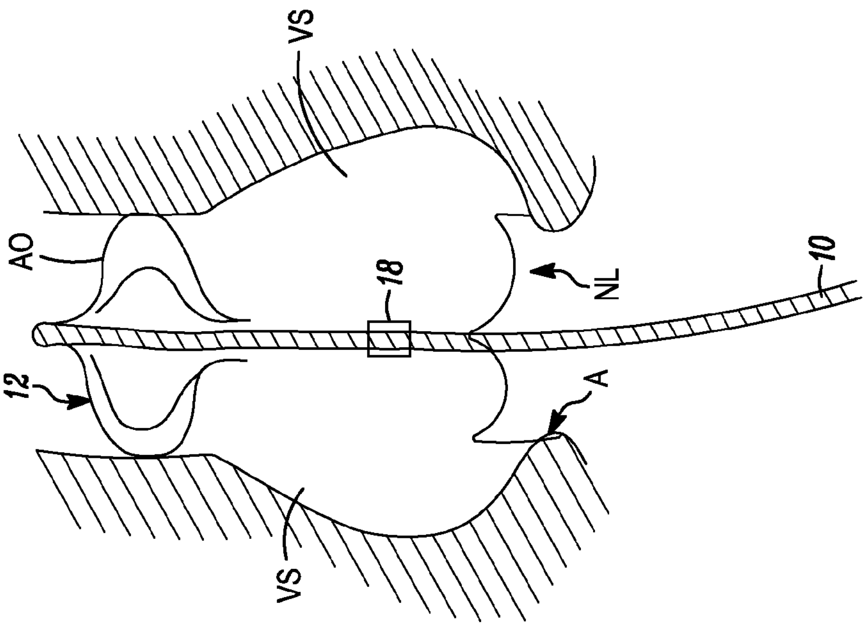


FIG. 2

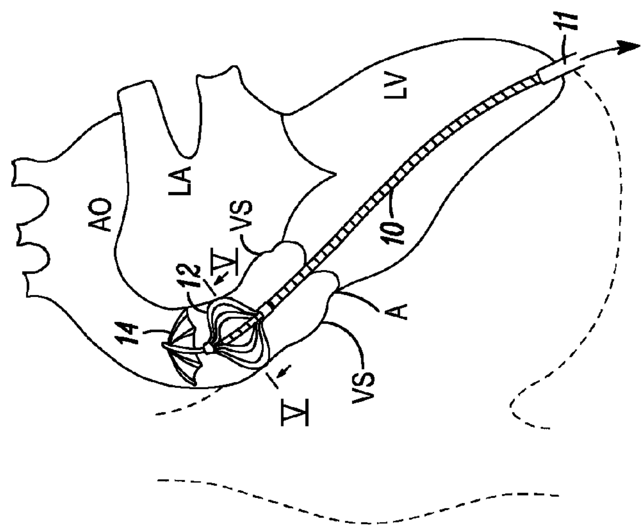


FIG. 4

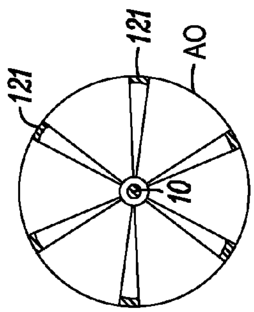


FIG. 5

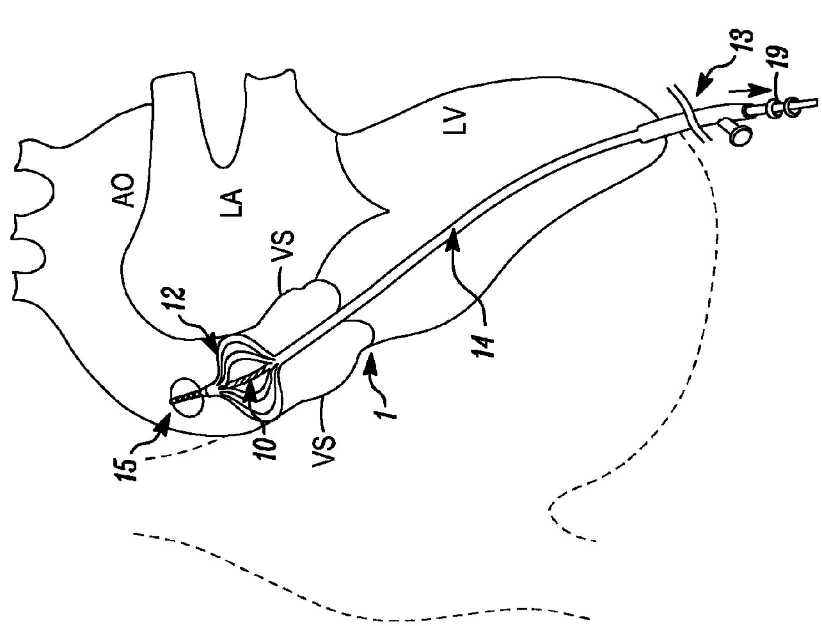


FIG. 3

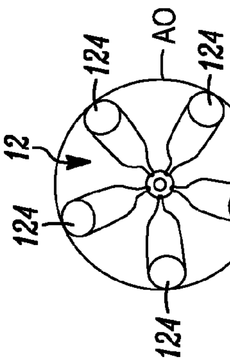


FIG. 9

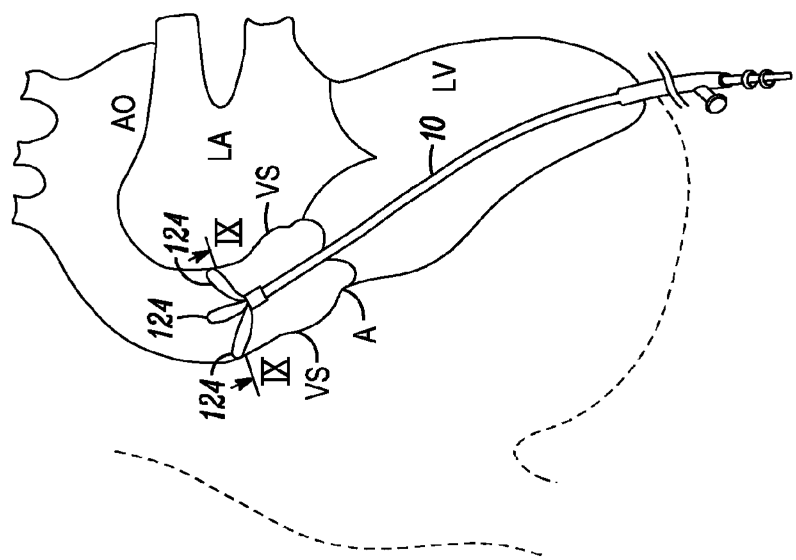


FIG. 8

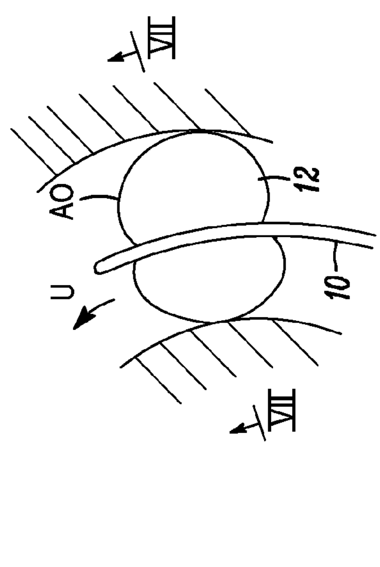


FIG. 6

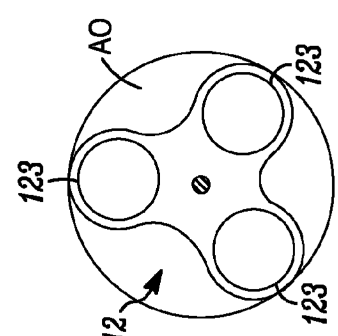


FIG. 7

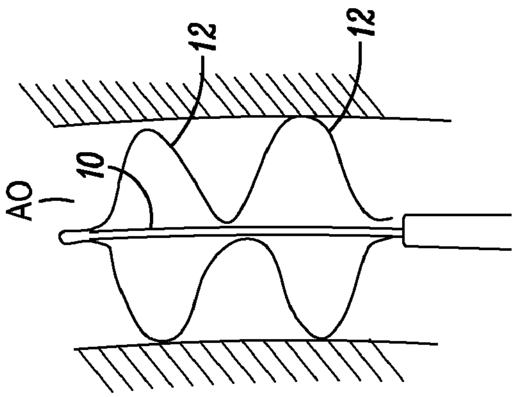


FIG. 12

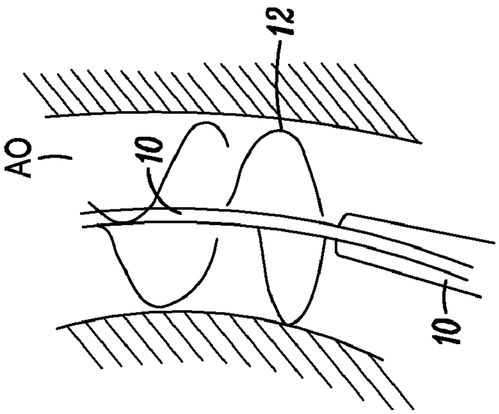


FIG. 11

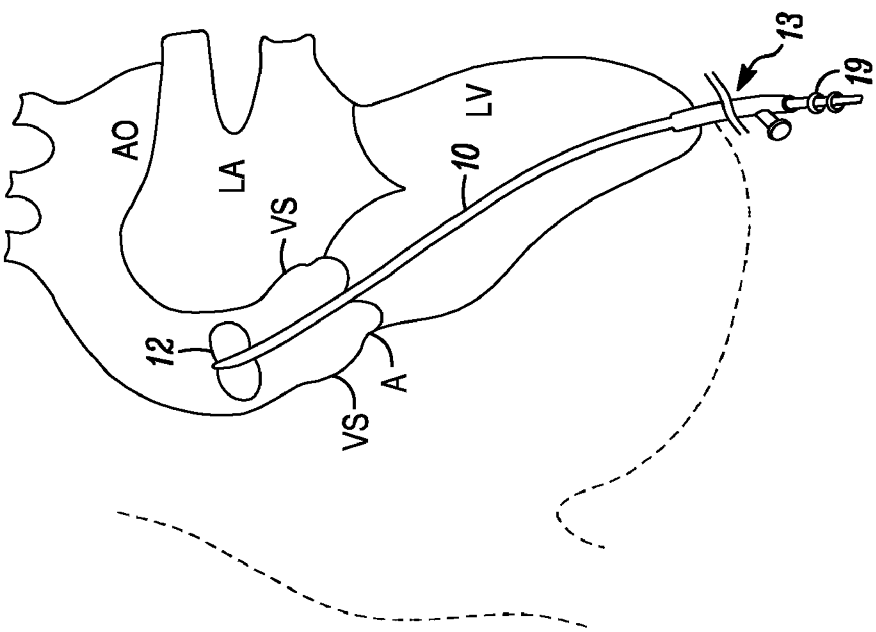


FIG. 10

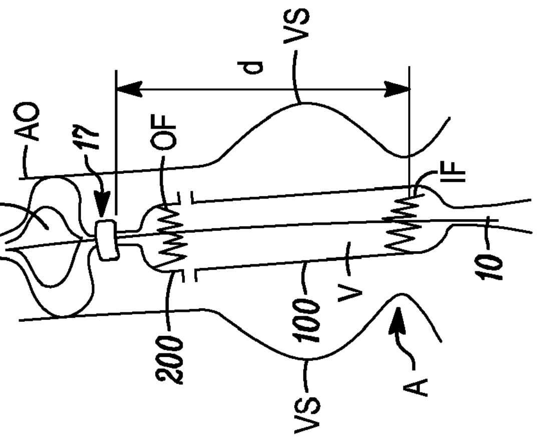


FIG. 15

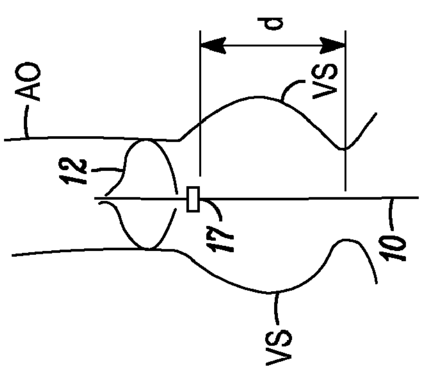


FIG. 14

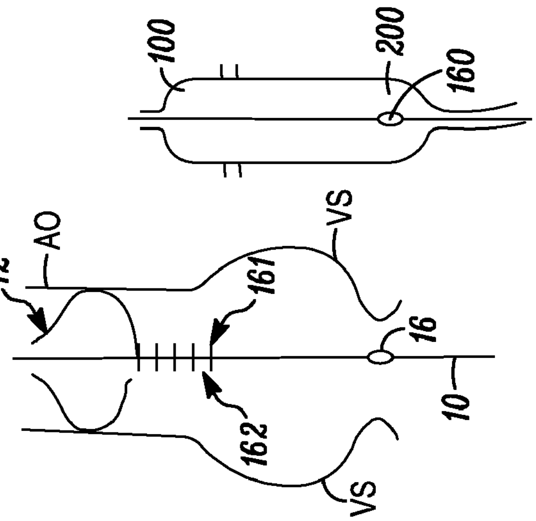


FIG. 13

DEVICE FOR IN SITU AXIAL AND RADIAL POSITIONING OF CARDIAC VALVE PROSTHESES

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is related to co-pending U.S. application Ser. No. XX/YYY,YYY, entitled "Instrument and Method for In Situ Deployment of Cardiac Valve Prostheses," U.S. application Ser. No. XX/YYY,YYY, entitled "System for In Situ Positioning of Cardiac Valve Prostheses without Occluding Blood Flow," and U.S. application Ser. No. XX/YYY,YYY, entitled "Device for In Situ Positioning of Cardiac Valve Prostheses," all of which were filed on even date herewith and are hereby incorporated by reference.

TECHNICAL FIELD

[0002] The present invention relates to instruments for the in situ positioning of implantable devices. In particular, the invention relates to the in situ positioning of expandable prosthetic cardiac valves.

BACKGROUND

[0003] Recently, there has been increasing consideration given to the possibility of using, as an alternative to traditional cardiac-valve prostheses, valves designed to be implanted using minimally-invasive surgical techniques or endovascular delivery (so-called "percutaneous valves"). Implantation of a percutaneous valve (or implantation using thoracic-microsurgery techniques) is a far less invasive act than the surgical operation required for implanting traditional cardiac-valve prostheses.

[0004] These expandable prosthetic valves typically include an anchoring structure or armature, which is able to support and fix the valve prosthesis in the implantation position, and prosthetic valve elements, generally in the form of leaflets or flaps, which are stably connected to the anchoring structure and are able to regulate blood flow. One exemplary expandable prosthetic valve is disclosed in U.S. Publication 2006/0178740 A1, which is incorporated herein by reference in its entirety.

[0005] An advantage of these expandable prosthetic valves is that they enable implantation using various minimally invasive or sutureless techniques. One non-limiting exemplary application for such an expandable valve prosthesis is for aortic valve replacement. Various techniques are generally known for implanting such an aortic valve prosthesis and include percutaneous implantation (e.g., transvascular delivery through a catheter), dissection of the ascending aorta using minimally invasive thoracic access (e.g., mini-thoracotomy), and transapical delivery wherein the aortic valve annulus is accessed directly through an opening near the apex of the left ventricle. Note that the percutaneous and thoracic access approaches involve delivering the prosthesis in a direction opposing blood flow (i.e., retrograde), whereas the transapical approach involves delivering the prosthesis in the same direction as blood flow (i.e., antegrade) Similar techniques may also be applied to implant such a cardiac valve prosthesis at other locations (e.g., a pulmonary valve annulus).

[0006] For the implantation of cardiac valve prostheses, it is important to check in a precise way the positioning of the various parts of the valve prosthesis. This applies to both axial positioning, to ensure that the prosthetic valve is positioned properly with respect to the valve annulus, and angular positioning, to ensure that the prosthesis may optimally engage the Valsalva sinuses, thus ensuring that the prosthetic valve leaflets are located with respect to the valve annulus at positions essentially corresponding to the positions of the natural valve leaflets.

[0007] There is a need in the art for delivery and implantation instruments capable of delivering an expandable prosthetic valve to a precise location associated with a corresponding valve annulus. There is a further need for instruments adapted to carefully control expansion of the valve to prevent the valve from misaligning during valve expansion.

SUMMARY

[0008] The present invention, according to one embodiment, is a device for use in positioning a cardiac valve prosthesis in a vessel. The device comprises a wire element to facilitate advancement of the valve prosthesis, the wire element including an abutment element configured to limit advancement of the prosthesis and an expandable element coupled to the wire element, the expandable element including an expanded configuration operable to axially secure the wire element with respect to an implantation site in the vessel, while not occluding blood flow through the vessel. The expandable element is disposed in a symmetrical fashion about the wire element, such that at least a portion of the wire element is generally positioned along a central longitudinal axis of the vessel.

[0009] The present invention, according to another embodiment, is a method of implanting a replacement aortic valve prosthesis at an implantation site. The method includes advancing a positioning instrument having an expandable element and a wire element through an aortic annulus to an anchoring position distal to the Valsalva sinuses, deploying the expandable element to secure the positioning instrument to the aortic wall, while not occluding blood flow through the aortic arch, advancing the aortic valve prosthesis over the wire element to a reference point coupled to the wire element, such that the prosthesis is in a desired position with respect to the aortic annulus, and expanding the aortic valve prosthesis, such that the prosthesis anchors to the aortic annulus and the Valsalva sinuses.

[0010] While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. As will be realized, the invention is capable of modifications in various obvious aspects, all without departing from the spirit and scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. **1** is a schematic view showing the implantation of a cardiac valve prosthesis using an instrument described herein, according to one embodiment of the present invention.

[0012] FIG. **2** is a schematic view showing the basic structure and principle of operation of a deployment instrument, according to one embodiment of the present invention.

[0013] FIGS. **3-12** (FIGS. **5**, **7** and **9** being cross-sectional views according to the lines V-V, VII-VII and IX-IX of FIGS. **4**, **6** and **8**, respectively) show deployment instruments, according to various alternative embodiments of the present invention.

[0014] FIGS. **13-15** are schematic view showing further details of the instrument, according to various embodiments of the present invention.

[0015] While the invention is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

[0016] Without limiting the scope of the invention, the description that follows makes reference to an instrument employed for the implantation of a cardiac valve prosthesis destined to replace an aortic valve. It will be apparent that the instrument of the present invention may likewise be employed in connection with implantation of valve prostheses at different locations (e.g., pulmonary valve or mitral valve).

[0017] FIG. **1** is a schematic view showing the implantation of a valve prosthesis at the aortic valve location. The prosthesis V may be any of a variety of minimally-invasive or expandable cardiac valve prostheses known in the art. The prosthesis V, for example, could be of the type described in U.S. Publication 2006/0178740 A1. As shown in FIG. **1**, the valve prosthesis V includes two radially expandable annular end portions, namely an inflow portion IF and an outflow portion OF. The terms "inflow" and "outflow" refer to the pulsated blood flow through the prosthesis V.

[0018] The prosthesis V is configured to be positioned with the annular inflow portion IF in correspondence with the aortic annulus A and the annular outflow portion OF located in the ascending line of the aorta AO, in a fluidodynamically distal position with respect to the Valsalva sinuses VS. The prosthesis V is provided with anchoring formations (not shown) that connect in a bridge-like fashion the annular end portions IF, OF. The anchoring formations are configured to extend into the Valsalva sinuses to anchor the valve prosthesis V in the implant position, thus helping to longitudinally secure the prosthesis V. By extending into the sinuses of Valsalva VS, which form a three-lobed cavity downstream the valve annulus, the anchoring formations (e.g., three formations disposed at roughly 120° angles from each other over about the circumference of the prosthesis V) also ensure the appropriate angular positioning of the valve prosthesis V, so that the prosthetic valve leaflets will be at angular positions corresponding to the angular positions of the natural valve leaflets with respect to the valve annulus. FIGS. **2-4**, **8**, and **10** schematically show the natural valve leaflets in correspondence with the valve annulus. These figures show that the instrument of the invention can be located at the implantation site before the possible ablation of the natural valve leaflets.

[0019] The prosthesis V shown in FIG. **1** is contained in a carrier portion of an instrument used for positioning and deploying the valve prosthesis V in situ. This carrier portion includes a capsule having two deployment elements **100**, **200** each in the form of a collar, sheath, or cap that constrains the prosthesis V in a radially contracted position. Once the implantation site is reached, the two deployment elements **100**, **200** can be displaced longitudinally so as to uncover the prosthesis V. In an embodiment wherein the prosthesis V is formed from a superelastic material, the prosthesis V is then able to radially expand upon release from the deployment elements **100**, **200**. One exemplary embodiment of such a deployment instrument is disclosed in co-pending, commonly-assigned U.S. application Ser. No. XX/YYY,YYY, entitled "Instrument and Method for In Situ Deployment of Cardiac Valve Prosthesis," which was filed on even date herewith. In one embodiment, the prosthesis V and the deployment instrument include an axial lumen configured to accept a guide wire, such that the instrument may be advanced through a patient's vasculature over such guide wire.

[0020] As shown in FIG. **1**, the instrument of the present invention includes a stylet or guide wire **10** and an expandable element **12** mounted on a distal portion thereof. As more clearly illustrated in FIG. **2**, the expandable element **12** is configured to be located and expanded in the ascending portion of the aorta AO at a fluidodynamically distal position with respect to the Valsalva sinuses SV. Accordingly, the distal portion of the wire **10** can be positioned precisely with respect to the implantation site of the valve prosthesis V, in both the axial and the radial direction, with the wire **10** extending in a precise radial position (e.g. substantially central) with respect to the implantation lumen, which in the exemplary case considered herein is the aorta AO. In one embodiment, the expandable element **12** is configured to be able to expand or to swell with respect to the guide wire **10** under conditions of substantial rotational symmetry, so that, with the element **12** in an expanded condition, the distal part of the wire **10** is in a substantially central position with respect to the aortic lumen.

[0021] With respect to axial positioning, once the element **12** is disposed at a given axial position along the ascending line of the aorta, and thus at a given position with respect to the aortic annulus, the expandable element **12** serves as a reference point. The prosthesis V may thus travel along the guide wire **10** to locate it at a desired axial position, before it is anchored at the desired location with respect to the valve annulus. The present invention thus allows for precise positioning of a prosthesis V, by providing a guide for advancing the prosthesis to the implantation site.

[0022] Several variations of the expandable element **12** are contemplated. In one embodiment, once expanded, the element **12** does not undesirably obstruct blood flow (represented by the arrow designated BF in FIG. **1**). In this embodiment, blood flow will not be impeded, and blood will be able to keep on flowing from the ventricle (designated LV in FIGS. **3**, **4**, **8** and **10**) towards the aorta AO in the pulsating fashion determined by the alternate phases of systole and diastole. Accordingly, the instrument of the present invention can be used without recourse to extracorporeal circulation, with the further effect of facilitating the sequence of positioning, deployment and implantation of the prosthesis V without time constraints, which would inevitably apply if the expandable element completely obstructed the cross section of the aorta (or, in general, of the treated lumen).

[0023] In one exemplary embodiment, the expandable element **12** is a completely "apertured" structure, namely a structure that in its expanded position is traversed by passageways through which blood can readily flow. Alternatively, the non-obstructive effect can be achieved by ensuring that the element **12** has an expansion cross-sectional radius which is smaller than the cross-sectional radius of the treated lumen. In this embodiment, general centering the guide wire **10** with respect to the implantation lumen will be accomplished by the element **12** "floating" in the blood flow and will not require the expandable element **12** to apply any radial pressure against the lumen wall. This embodiment may be helpful in at least some patients suffering from degenerative diseases, as the lumen wall may be fragile and therefore susceptible to be damaged by pressure.

[0024] In one embodiment, the guide wire **10** has a stiffness sufficient to cause its length extending from the expandable element **12** towards the valve annulus to remain approximately in the center of the body lumen throughout. A distal portion of the guide wire **10**, for example, has a stiffness sufficient to hold and retain its shape.

[0025] The embodiments of FIGS. **3** and **4** the expandable element **12** having a general cage-like structure. In this embodiment, the expandable element **12** includes a plurality of wire-like elements that are operable between a first position co-extensive with the guide wire **10** and a second position projecting outwardly from the guide wire. FIG. **3** shows an embodiment wherein the cage-like structure includes a portion of a tubular element (for instance of a metal tube) having a distal end fixed to the distal end of the guide wire **10** and a proximal end fixed to a sheath **11** slidably arranged over the guide wire **10**.

[0026] In this embodiment, the wall of the tubular element includes a plurality of slits extending in a substantially longitudinal direction defining therebetween wire-like or band-like portions of the tube wall. According to one embodiment, these longitudinal slits are formed from a microtube using a laser cutting technique. The microtube can be of the type normally used for producing angioplasty stents (e.g., a hypotube).

[0027] These band-like expandable elements **12** may be deployed, for example, by manipulating a proximal control means **13**, of a known type in the catheter art, to effect a relative movement of the guide wire **10** and the sheath **11**. The sheath **11** may be advanced distally towards the expandable elements **12** to reduce the distance between the distal end of the sheath **11** and the distal end of the guide wire **10**, thereby deforming the tubular elements and causing the wire-like or band-like wall elements between the slits to protrude outwardly of the guide wire **10** to form a radially expanded element **12** as desired. The further that the sheath **11** is advanced towards the distal end of the guide wire, the further that the tubular elements protrude radially.

[0028] The tubular element can be comprised of any metal material approved for use in the biomedical field, such as for instance steel, and in that case the expansion to form the expanded element **12** is positively determined by sliding the sheath **11** over the guide wire **10**. The tubular elements may also be formed for example of any known polymer material approved for human implantation.

[0029] FIG. **4** shows an embodiment wherein the expandable element **12** is comprised of a cage-like structure of wires or bands **121** made from a superelastic material (for instance, Nitinol). In a "rest" condition, namely in the absence of constraints applied thereto, the wires or bands **121** will naturally assume the desired cage-like configuration of the element **12** in the expanded condition. In this embodiment, the sheath **11** extends initially to the distal end of the guide wire **10** in order to constrain to the Nitinol wires or bands **121** in a radially contracted position. When retracted along the guide wire **10** (see bottom of FIG. **4**), the sheath **11** will uncover and release the wires or bands **121**, which will then be free to return, because of their superelastic characteristics, to the radially expanded position, which corresponds to the desired expansion of the element **12**.

[0030] The cage-like structure constituting the expandable element **12** is shown FIGS. **3** and **4** in an "onion-like" configuration, with the wire-like or band-like elements forming the cage connected at both the proximal and distal ends of the cage. In an alternative embodiment, the expandable element **12** could be configured in an "artichoke-like" shape, with the wire-like or band-like elements forming the cage spreading from the proximal extremity of the cage according to a general wine glass configuration without any connection at their distal ends.

[0031] According to one embodiment, the cage-like structure includes at least three such elements. In other embodiments, the cage-like structure includes at least five or six such elements. FIG. **5**, for example, shows a one such configuration including six elements. More elements may provide more precise positioning of the guide wire **10** at the center of the treated lumen (e.g., the aorta AO). The number of elements forming the cage-like structure, as well as the choice of the constituent material and the manner of expanding the structure, are influenced by the fact that, in order to reach the desired expanded position shown in FIG. **2**, the expandable element **12** must pass through the site of the aortic valve. In some situations, wherein the natural valve leaflets NL were not removed, the natural valve leaflets may be extensively calcified and thus resist penetration. Accordingly, in some situations, it is important that the expandable element **12** have an unexpanded cross sectional profile that is as small as possible, to facilitate penetration through the calcified valve leaflets.

[0032] According to one exemplary embodiment, as shown in FIG. **4**, the instrument further includes a filtering element **14**, which is typically located in a fluidodynamically distal position with respect to the expandable element **12**. This filtering element **14**, which can also be integrated into the expandable element **12**, may be expanded along with the expandable element **12** to form a net that is permeable to the blood flow BF in the aorta, but will entrap and thus retain fragments of calcified formation (e.g., possibly released during the intervention), air and clots, thereby preventing these materials from flowing into the aorta.

[0033] FIG. **3** also shows an embodiment wherein the distal end portion of the guide wire **10** includes a balloon **15**. The balloon **15** is typically of the inflatable type and is intended to act as a fluidodynamic dragging element, according to the principles of operation of those balloons generally known in the art as Swan-Ganz balloons. As indicated, the instrument described herein is primarily intended to be used in transapical insertion procedures, wherein the instrument is introduced in the ventricle cavity and advanced towards the aortic valve site. Once the instrument is inserted in the ventricle, the Swan-Ganz balloon **15** at the distal end portion will be carried by the blood flow during the ventricle systole and drawn to the aorta. In this way, the distal end of the instrument will be automatically drawn toward the aortic valve by the blood flow. The blood flow will then further draw the Swan-Ganz balloon **15** and the distal end of the instrument through the aortic annulus and on through the Valsalva sinuses to the ascending line of the aorta where the expandable element **12**

is to be positioned. In one embodiment, the Swan-Ganz balloon **15** is configured to be selectively deflated, for instance to allow passage through heavily calcified natural valve leaflets before ablation. The entrapment element **14** and/or the Swan-Ganz balloon **15** can be optionally included with any of the embodiments disclosed herein.

[0034] FIGS. **6-9** show expandable elements **12** in the form of inflatable balloons. Specifically, FIGS. **6** and **7** show an expandable element **12** comprising an inflatable balloons with a multi-lobed structure. In one exemplary embodiment, a balloon comprising three expandable sections **123** angularly spaced at 120° intervals about the circumference. Such a multi-lobed balloon structure, and a related manufacturing process, is described in detail in EP-A-0 512 359. In this embodiment, the various lobes **123** of the balloon, once expanded, do not obstruct the treated lumen (e.g., the aorta AO). In an alternative embodiment, shown in FIGS. **8** and **9**, the expandable element **12** includes a bundle of expandable bar-like balloons **124** of the type used, for instance, for implanting angioplasty stents. Both in the case of an expandable element comprised of a multi-lobed balloon (FIGS. **6** and **7**) and in the case of an expandable element including a bundle of bar-like balloons (FIGS. **8** and **9**), the action of inflation (and deflation) of the expandable element **12** can be accomplished by injecting (and withdrawing) fluid through a lumen.

[0035] FIG. **10** shows an alternative embodiment including a single balloon. In this embodiment, the expandable element **12** can be expanded so as to occupy only part of the net cross section of the implantation lumen (e.g., the aorta AO). According to one embodiment, a substantially non-obstructive effect of the free flow of the blood in the treated lumen, which allows the expandable element **12** to remain in an expanded condition long enough to permit the implantation of a valve prosthesis V without the duration of the intervention becoming a critical parameter, is achieved if the expandable element **12**, when expanded, occupies less than about 90 to 95% of the net cross sectional area of the lumen or (for elements **12** having an apertured structure with passageways for blood therethrough) the area of the circle whose radius is equal to the expansion radius of the element **12** with respect to the guide wire **10**. In another embodiment, the expandable element **12** occupies less than about 75% of the net cross sectional area of the lumen.

[0036] As illustrated in FIG. **10**, this non-obstructive effect on blood flow can be also achieved by an element **12** having a structure not of an apertured type by ensuring that, when expanded, the element **12** has an expansion radius smaller that than the radius of the lumen (the radius of the aorta, in the exemplary case considered herein) at the location where the element is expanded. In this way, while being still centered in a radial sense with respect to the lumen, due to fluidodynamic actions of blood flowing around it, the expandable element **12** will not exert any appreciable pressure on the lumen walls which, at least in some patients affected by particular pathologies, may be particularly sensitive and fragile.

[0037] FIGS. **11** and **12** schematically show still other possible embodiments of the expandable element **12**. FIG. **11**, for instance, shows an expandable element **12** wherein the elements of the cage-like or shape similar to an onion-like structure do not extend along the "meridians" of the expandable structure (as is the case of FIGS. **3** and **4**), but rather follow approximately helical trajectories. This solution may be advantageously used in conjunction with both self-expandable elements (e.g., Nitinol) and with elements whose expansions is obtained by a positive action (e.g., inflating a balloon or sliding a sheath **11** over the guide wire **10**). According to the embodiment of FIG. **12**, the guide wire **10** includes a plurality of expandable elements **12** (e.g., onion-like cage structures) arranged in a cascaded configuration and adapted to be selectively expandable in a coordinated manner.

[0038] FIGS. **13-15** show how the instrument described herein may ensure the correct axial positioning of the valve prosthesis V with respect to a valve site (e.g., an aortic valve annulus). In the illustrated embodiment, the instrument is employed to ensure that the annular inflow portion IF is positioned to be deployed in appropriate correspondence with the valve annulus A.

[0039] FIG. **13** shows a solution wherein at least one opaque marker **16** is provided on the guide wire **10** (or the expandable element **12**). The designation "opaque" (e.g., radiopaque) denotes any marker which is visible and can be observed to identify its position in the patient body by resorting to current imaging techniques (e.g., radioscopy and nuclear magnetic resonance). The marker **16** assists the operator to advance the instrument (the guide wire **10** and expandable element **12**) through the valve annulus A so as to locate the expandable element **12** in the aorta distally with respect to the Valsalva sinuses. Specifically, the operator will be able to verify that the marker **16** has reached a clearly identified position, for instance by positioning it in the plane of the valve annulus A, about the center of the annulus.

[0040] The expandable element **12** is then expanded so that the marker **16**, and thus the guide wire **10**, substantially maintain the desired axial position. In the embodiment shown in FIG. **14**, the axial position of the guide wire **10** can be further secured at a desired position by blocking (by means of a blocking device **19** of a known type) the proximal end of the guide wire **10** that is located outside the patient's body. This further inhibits axial movement of the guide wire **10**, even in the case where the expandable element **12** is free or slightly "floating" in radial sense with respect to the aorta wall.

[0041] Positioning and securing the expandable element **12** and the guide wire **10** facilitates positioning the valve prosthesis V at the desired position with respect to the implantation site (e.g., aortic valve annulus). The results in terms of accuracy already achieved in positioning of the instrument will thus be exploited for the purpose of positioning of the valve prosthesis V.

[0042] During an implantation procedure, the valve prosthesis V is advanced longitudinally over the guide wire **10** (see FIGS. **1** and **13**) until an opaque marker **160** positioned, e.g. at the inflow end IF of the valve prosthesis V aligns (e.g., overlaps) with the marker **16** on the guide wire **10**, to thus ensure that the prosthesis V is in the desired position for implantation, with the inflow end IF in the plane of the valve annulus A. This technique lends itself to further refinement, both regarding the positioning of the instrument **10**, **12** and the relative positioning of the valve prosthesis V with respect to the instrument previously positioned.

[0043] For instance, instead of a single marker **16**, the guide wire **10** may include multiple markers **161**, **162**, etc. defining a graduated scale along the guide wire **10**. The operator will thus be able to position the marker **160** on the valve prosthesis V in alignment with one particular marker in the scale, in view of specific requirements arising at the time of implantation.

[0044] In a complementary and dual manner, it is possible to provide multiple markers on the prosthetic valve V. These markers can be provided, rather than on the cardiac valve prosthesis V, on the respective deployment instrument, for instance on either or both the deployment elements **100**, **200** mentioned above. Providing the markers on the prosthesis V allows the operator to check over time the positioning of the valve prosthesis V.

[0045] FIGS. **14** and **15** show exemplary embodiments including an abutment formation **17**, which may, for instance, have the form of a collar-like member mounted on the guide wire **10** (or on the expandable element **12**). The formation **17** is arranged for mechanical co-operation with the prosthesis V and/or with the distal part of the relative deployment instrument (for instance with the deployment element **200**) in order to stop the sliding movement of the prosthesis V over the guide wire **10**.

[0046] FIGS. **14** and **15** specifically illustrate a situation where the distal border of the deployment element **200** must be at a distance d with respect to the plane of the aortic annulus A, in order to properly locate the prosthesis V at the implant site. The guide wire **10** or expandable element **12** is thus positioned in such way that the stop element **17** is exactly located at a distance d with respect to the plane of the aortic annulus A. In this embodiment, the correct axial positioning of the prosthesis V will be easily achieved by sliding the prosthesis V over the guide wire **10** up to the point where, as schematically illustrated in FIG. **15**, the distal border of the deployment element **200** abuts against the element **17** provided on the guide wire **10** (or, possibly, on the expandable element **12**).

[0047] At this point, by realizing that the prosthesis V can no longer be advanced over the guide wire **10** because of the mechanical co-operation of deployment element **200** against the abutment element **17**, the operator will know that the prosthesis V has reached the desired position. The operator can thus proceed to deploy the annular inflow and outflow portions IF, OF of the prosthesis V without having to worry about the axial (and radial) positioning of the prosthetic valve. The operator will thus be able to concentrate on other issues related to implanting the prosthesis, such as the appropriate angular positioning of the prosthesis V, by making sure that the protruding parts of the prosthesis V are angularly positioned in correspondence with the Valsalva sinuses and correctly extend into the Valsalva sinuses the prosthesis V is deployed.

[0048] A micrometric adjustment mechanism (of a type known by itself) actuatable from the proximal extremity of the instrument can be associated to the abutment element **17** for regulating in a precise way, if necessary, the position of the element **17** with respect to the guide wire **10** and/or the expandable element **12**. This adjustment feature may turn out to be advantageous in certain situations where the expandable element **12** must be expanded and thus deployed in a different position with respect to the originally anticipated position. In this case, adjusting the position of the abutment element **17** makes it possible to position that element at the position where it would be disposed had the expandable element **12** been positioned in the anticipated way.

[0049] FIG. **2** refers to an exemplary embodiment that includes a pressure sensor **18** (e.g., piezoelectric pressure sensor). The pressure signal generated by the sensor **18** is transmitted to the outside of the body of the patient (for instance through wires that extend along the guide wire **10**) and makes it possible to detect if the point where the pressure sensor **18** is located is momentarily upstream or downstream of the valve annulus A. Having such information available is a further aid to the operator in achieving the correct positioning of the instrument and, accordingly, of the valve prosthesis V. In yet another embodiment, the instrument further includes a lumen adapted to inject contrast fluid. In this embodiment, the contrast fluid may be used by the operator to obtain an image of the implantation site.

[0050] Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. Accordingly, the scope of the present invention is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof. This is particularly true as regards the possible combination, within a single implantation kit, of the instrument described herein with a deployment instrument described in the co-pending patent application already referred to in the foregoing.

We claim:

1. A device for use in positioning an expandable aortic valve prosthesis in the aorta, the device comprising a wire coupled to an expandable support, wherein the expandable support is operable to locate at least a portion of the wire generally in a center of the aorta.

2. A cardiac valve prosthesis implantation device, comprising: a axial positioning element and a radial positioning element.

3. The device of claim **2** in which said radial positioning element is structured to permit location of said prosthesis with respect to a valve annulus at a position substantially corresponding to a position of natural valve leaflets without interference of a structural component of said prosthesis with naturally occurring blood flow.

4. The device of claim **2** in which said radially positioning element is variably adjustable.

5. An improved device for delivering an expandable cardiac valve prosthesis to a desired position in a vessel, the improvement comprising: a guide wire or wire-like element having an axial and radial positioning element.

6. The improved device of claim **5** in which said axial and radial position element is sized and dimensioned to permit the flow of blood therethrough.

7. The improved device of claim **5** in which said axial and radial positioning element comprises: an axial positioning element and a radial positioning element.

8. The improved device of claim **7** in which one or both of said axial positioning element or said radial positioning element is variably adjustable.

9. The improved device of claim **5** further comprising an abutment element.

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