(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 May 2016 (19.05.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/075615 A2

(51) International Patent Classification:
A61F 2/07 (2013.01)

(21) International Application Number:
PCT/IB2015/058662

(22) International Filing Date:
10 November 2015 (10.11.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
RM2014A000659 10 November 2014 (10.11.2014) IT

(72) Inventor; and
(71) Applicant : **MELISSANO, Germano Carlo Giuseppe** [IT/IT]; Via San Giulio 22, I-20021 Bollate MI (IT).

(74) Agents: **PAPA, Elisabetta** et al.; c/o SOCIETA' ITALIANA BREVETTI S.p.A., Piazza di Pietra, 39, I-00186 Rome (IT).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) Title: VASCULAR ENDOPROSTHESIS FOR ANEURYSM AND DISSECTION OF THE AORTIC ARCH

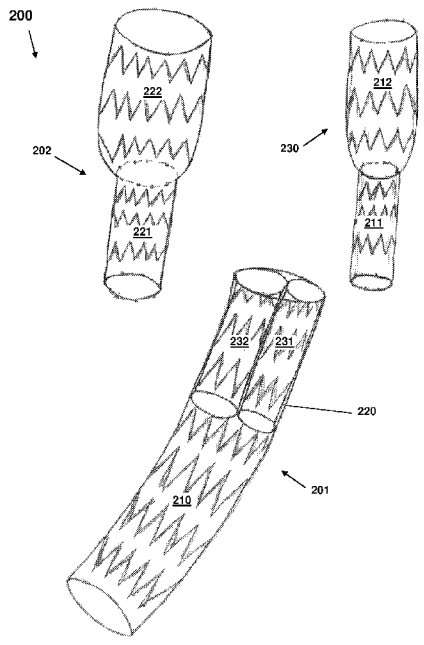

FIG. 13

(57) Abstract: A vascular endoprosthetic device (200) configured for placement inside the aortic arch, in particular for treating aneurysms and/or dissections, which device (200) has a tubular structure and a construction allowing a modular insertion and deployment, which device (200) comprises: - a distal component (201) configured to be placed in the distal part of the aortic arch or in the descending thoracic aorta, which distal component (201) has a main body portion (210) with an internal lumen and comprises a first and a second docking branches (231, 232) housed inside said lumen at a proximal end part thereof, which first and second docking branches (231, 232) are integral to, or fixed to with, said main body portion (210); - a first proximal component (230), configured to be placed in the innominate artery; - a second proximal component (202), configured to be placed in the ascending aorta, wherein said distal (201), first proximal (230) and second proximal (202) components are provided as distinct elements and are apt to be assembled in the aortic arch during an insertion and deployment procedure, wherein each of said first (211) and second (202) proximal components has a respective proximal portion (212, 222) and a respective distal portion (211, 221), such distal portion (211, 221) having a reduced cross-section with respect to the respective proximal portion (212, 222), wherein each of said distal portions (211, 221) of said first (230) and second (202) proximal components is configured so that, once the device (200) is deployed in situ, such distal portion is received in a respective first (231) or second (232) docking branch of said distal component (201), so that said docking branch (231, 232) acts as a docking site for the respective first (230) or second (202) proximal component, wherein said second proximal component (202) has a diameter configured to accommodate the whole cardiac output, and wherein the endoprosthetic device is configured so that, once deployed in situ, blood flows from the heart through said second proximal component (202) and into said second docking branch (232) of said distal component (201), and from the latter into said proximal portion (211) of said first proximal component (230) and from that retrogradely into said distal portion (212) of said first proximal component (230).

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VASCULAR ENDOPROSTHESIS
FOR ANEURYSM AND DISSECTION OF THE AORTIC ARCH
DESCRIPTION

Field of the invention

The present invention relates to a vascular endoprosthesis (or vascular endograft or stent-graft), specifically configured for insertion in the aortic arch.

In particular, the endoprosthesis of the invention is suitable for treating aneurysmal and/or dissecting disease of the aortic arch.

Background of the invention

A traditional approach for the treatment of aneurysms or dissections of the aortic arch is based entirely upon open-surgical repair. Over the past fifteen years, such traditional approach has been increasingly integrated by endovascular procedures, giving rise to a so-called "hybrid" approach. Two main types of hybrid approach are known, namely:

- an approach based upon "de-branching" of the aortic arch, which allows brain perfusion through a deviation of the blood flow by means of either anatomic (intrathoracic) or extra-anatomic (at the neck) by-passes; and
- an approach requiring sternotomy or thoracotomy and extra-corporeal circulation (with or without hypothermic circulatory arrest), which, of course, is highly-invasive.

Although many types of vascular endoprostheses and associated surgical procedures have been proposed in recent years under the hybrid approach mentioned above, there are still high risks of complications, mostly associated with cerebral embolism and/or hypo-perfusion, as well as the cardiac and general morbidity of the more invasive procedures. For this reason, simplifying the whole procedure and minimising the time needed to perform it - in both its purely surgical steps and endoprosthesis insertion - is essential in order to avoid the above mentioned complications.

On the other hand, both the timing of the intervention and the endoprosthesis configuration should be suitable to achieve a precise and stable positioning of the prosthesis and avoid its possible subsequent displacement.

The accomplishment of the above goals is also strictly related to the easiness

with which the endoprosthesis can be positioned *in situ*. With respect to this latter issue, it is to be noted that, generally speaking, the current vascular endoprostheses for the arch allow little, if any, tolerance for adapting to different dimensional or positioning needs that arise when performing a specific procedure. Moreover they require a great deal of endovascular manipulation of the aortic arch and supra-aortic trunks which cause embolism.

In summary, the treatment of aneurysmal and/or dissecting disease of the aortic arch is still a very challenging issue, which still requires optimisation at the level of both the endoprosthesis structure and the associated surgical procedure.

US 6,099,558 discloses a vascular endoprosthesis having a bifurcated component, which prosthesis is configured and dimensioned for insertion in the abdominal portion of the aorta and into the iliac arteries.

WO 2005/027784 discloses a vascular endoprosthesis to be used in the aortic arch. In one embodiment, the endoprosthesis has a bifurcated component configured and dimensioned to be inserted proximally to the heart and a distal component configured and dimensioned to be introduced distally in the aortic arch. The endoprosthesis requires an insertion procedure through the carotid artery, thereby being at risk of inducing complications for the patient.

Summary of the invention

The technical problem underlying the present invention is therefore that of overcoming the drawbacks mentioned above with reference to the state of the art.

Such problem is solved by a vascular endoprosthetic device according to claim 1, 4 or 6.

The invention also provides a procedure for the treatment of diseases of the aortic arch, in particular aneurysms and/or dissections, based upon implantation of said vascular endoprosthesis. Such procedure may be a surgical procedure, preferably falling under the aforementioned hybrid approach.

Preferred features of the invention are object of the dependent claims.

The vascular endoprosthesis of the invention has a construction allowing a modular deployment, being made of two or more components configured to be deployed in sequence during an implantation procedure.

In particular, according to a first preferred embodiment of the invention, the components are provided as distinct elements and are configured so that they can be assembled and interconnected *in situ* during the implantation procedure.

According to another preferred embodiment, particularly suitable for open-surgery, the components of the device are housed one inside the other during insertion.

The modularly-deployable construction simplifies insertion of the device and allows its precise positioning during the procedure.

Such construction can also provide a good longitudinal tolerance in the relative positioning of the components of the endoprosthesis.

The aforementioned components of the endoprosthesis of the invention are a first, distal (with respect to the heart) component and one or two proximal components.

The distal component comprises, or is associated with, a first proximal branch or component and a second proximal branch or component, configured to be inserted in the innominate artery and in the ascending aorta, respectively. The overall construction and configuration is such that blood flow in the Innominate Artery and in all cerebral vessels is assured by way of retrograde perfusion through the first proximal branch or component.

Moreover, the second proximal branch or component is configured so as to be able to withstand substantially the whole cardiac output flow (eventually minus the coronary flow which is more proximal).

Brief description of the drawings

Reference will be made to the figures of the annexed drawings, wherein:

- Figure 1 shows schematically a vascular endoprosthesis suitable to be placed in the aortic arch and the innominate artery according to a preferred embodiment of the present invention;
- Figure 2A depicts schematically a so-called “Zone 0” aortic arch aneurysm which can be treated by the endoprosthesis of Figure 1;
- Figure 2B depicts schematically an extra-anatomic supra-aortic vessels revascularisation performed by means of right carotid – left carotid – left subclavian bypass through two small cervicotomies, as a preferred surgical step preparatory to the implantation of the endoprosthesis of Figure 1;
- Figure 2C depicts schematically another preferred preparatory step,

subsequent to that of Figure 2B and consisting in ligating the left common carotid artery proximal to the bypass and in placing a plug at the origin of the left subclavian artery;

- Figure 2D depicts schematically a further preferred preparatory step consisting in placing a filter in the right common carotid artery, the latter now supplying also the left carotid artery and the left subclavian artery and therefore also left vertebral artery;
- Figure 3A depicts schematically a step of inserting a wire from a common femoral artery and into an introducer sheath placed in the right humeral or axillary artery (through-and-through technique), as a preferred step preliminary to introduction of a first component of the endoprosthesis of Figure 1;
- Figure 3B depicts schematically a preferred first step of inserting the first component of the endoprosthesis in the aortic arch by means of an introducer device, the latter being positioned up to the innominate artery with a tip well into the right subclavian artery;
- Figure 4A depicts schematically a preferred subsequent step of initial unsheathing the first component of the endoprosthesis by a pull-back manoeuvre;
- Figure 4B depicts schematically as the unsheathing proceeds distally with deployment of a central part of the first component of the endoprosthesis;
- Figure 4C depicts schematically the first component of Figure 1 fully unsheathed;
- Figure 5A depicts schematically a step subsequent to that of Figure 4C, wherein a wire is introduced in a branch of the endoprosthesis of Figure 1, as a preferred preparatory step to the introduction of a second component of such endoprosthesis and the introducer device containing the second component is positioned in the ascending aorta;
- Figure 5B depicts schematically a first preferred step of unsheathing the second component by a pull-back manoeuvre;
- Figure 5C depicts schematically the second component fully unsheathed;
- Figure 5D depicts schematically a final appearance of the endoprosthesis of Figure 1, that is fully deployed *in situ* in a desired position;
- Figure 6 depicts schematically another preferred surgical step preparatory to the implantation of the endoprosthesis of Figure 1 and alternative to the steps of Figures 2B and 2C;
- Figure 7 depicts schematically still another preferred surgical step preparatory to the implantation of the endoprosthesis of Figure 1 and alternative to the steps of Figures 2B and 2C or of Figure 6;
- Figures 8A and 8B each show schematically a vascular endoprosthesis

suitable to be placed in the aortic arch and the innominate artery according to another preferred embodiment of the present invention, each in a respective deployment configuration;

- Figure 9 depicts schematically a case of aortic arch aneurysm/dissection with aortic valve incompetence that requires surgical repair;
- Figure 10 depicts schematically the endoprosthesis of Figures 8A, 8B in place, after insertion and before full deployment of its components;
- Figure 11 depicts schematically the endoprosthesis of Figures 8A, 8B in place, after full deployment of its components, wherein in particular an unsupported segment of the endoprosthesis is unfolded and clamped;
- Figure 12 depicts schematically a final view of the aortic arch replacement with the endoprosthesis of Figures 8A, 8B;
- Figure 13 shows schematically a vascular endoprosthesis suitable to be placed in the aortic arch and the innominate artery according to a further preferred embodiment of the present invention, in a disassembled configuration;
- Figures 14A to 14K show each a respective step of a surgical procedure for inserting the endoprosthesis of Figure 13 into the aortic arch and Innominate Artery.

Detailed description of preferred embodiments of the invention

With reference initially to Figure 1, there is shown a vascular endoprosthetic device according to a preferred embodiment of the present invention. Such device is globally denoted by 100 in the drawings and may also be referred to as an endoprosthesis, a graft, an endograft, a stent-graft or the like.

Device 100 is specifically configured for placement inside the aortic arch and the innominate artery (or so-called brachio-cephalic trunk). In particular, implantation of device 100 is especially provided for treating an aneurysm and/or a dissection of the aortic arch.

Device 100 has a modular construction which allows a modular deployment, being made of a first distal component 1 and a second proximal component 2. Thus, components 1 and 2 are provided as distinct, i.e. separate, elements and are assembled in the aortic arch during a deployment procedure of device 100. In the present example, a preferred deployment procedure is a surgical intervention.

In the present context - and as commonplace in the relevant field - the terms “proximal” and “distal” are used with reference to the proximity to the heart.

Device 100 and its components 1 and 2 have a tubular construction suitable to allow blood flow therein and, preferably, a substantially cylindrical or tapered geometry.

Distal component 1 (which – as explained later on - is deployed first) has a substantially bifurcated, or “Y”-shaped, configuration. In particular, the main arm of the “Y” is made by a distal branch 10 suitable to be placed in the distal part of the aortic arch or in the descending aorta. The two bifurcating arms of the “Y” are made by a first longer proximal branch 11 and a second shorter proximal branch 12, respectively, both originating from distal branch 10.

First longer proximal branch 11 has an intermediate portion 111 which, in use, is placed in the aortic arch, and a distal portion 112 which, in use, is placed in the innominate artery.

In use, second shorter proximal branch 12 is placed in the aortic arch, proximally with respect to distal branch 10. Second proximal branch 12 has a cross-section, in particular a diameter, configured to accommodate substantially the whole cardiac output. Therefore, preferably it has a diameter larger than that of first proximal branch.

Proximal component 2 has, as well, a cross-section configured to accommodate substantially the whole cardiac output.

Second proximal branch 12, or a more proximal portion thereof, defines a proximal engagement seat 120 for second component 2, as will be explained below. For this reason, second branch 12 may also be defined as a “docking” branch or portion for second component 2.

Proximal component 2 (which – as explained later on - is deployed second) comprises a distal portion 21 and a proximal portion 22. Distal portion 21 may have a different cross-section with respect to proximal portion 22 and, in use, is received into the engagement seat 120 of the second proximal branch 12. In the present embodiment, both seat 120 and distal portion 21 introduced therein have a substantially cylindrical configuration. Distal portion 21 is of a larger diameter than second proximal branch 12 of distal component 1 in order to ensure a safe interconnection of the two components in the overlapping area.

The degree of overlapping of the two components can be regulated, i.e. changed, by sliding them one into the other, thus providing tolerance. In particular, distal portion 21 of second component 2 may have a longitudinal dimension, i.e. a length, in particular a dimension in a direction generally

orthogonal to its cross-section, greater than a corresponding longitudinal dimension of second proximal branch 12 of first component 1. Such longitudinal dimensions are depicted schematically in Figure 1 and denoted by L2 and L1, respectively.

In other words, a longitudinal adjustment of the position of the second component several cm proximally or distally (degree of overlap) may be allowed.

As said above, device 100 is specifically configured for implantation in the aortic arch and innominate artery according to an implanted position that will be described in detail later on. Due to such specific configuration and positioning *in situ*, device 100 has most preferred specific dimensions that will be now indicated.

Total length of distal component 1 along its longitudinal extension, from its most distal section to the most proximal section of second proximal branch 12 is preferably comprised in a range of 15-25 cm.

Total length of first proximal branch 11 is preferably about 7-14 cm.

Total length of second proximal branch 12 is preferably about 7-8 cm.

According to a preferred variant embodiment, diameter of distal branch 10 is included in a range of about 30-46 mm.

Preferably, diameter of first proximal branch 11 is included in a range of about 10-20 mm.

Advantageously, diameter of second proximal branch 12 is included in a range of about 20-26 mm.

Distal portion 21 of proximal component 2 has preferably a length of about 7-8 cm.

Proximal portion 22 of proximal component 2 has preferably a length of about 5-10 cm.

Preferably, diameter of distal portion 21 is about 15-20% larger than that of proximal branch 12.

Advantageously, diameter of proximal portion 22 is included in a range of about 30-46 mm.

According to a technology which is well-known in the art, device 100 has self-expanding stents 3 all over its external or internal surface/walls.

Stents 3 allow or help the retaining *in situ* of device 100 by exerting a radial compression force towards the vascular walls. This is obtained by oversizing the cross-section of device 100, and in particular of its components and branches, and more specifically by oversizing the relevant diameters, with respect to the anatomical vessel(s).

In order to facilitate retention, device 100 may be provided (especially at distal portion 112 and/or at proximal portion 22) with one or more means of active fixation 4 such as barbs or barbed regions, bare metal stents or other (not depicted).

In the present embodiment, a barbed region is provided at least at a terminal proximal end of first proximal branch 11, in order to allow/help retention in the innominate artery.

In the present example, no barbs are provided at second proximal branch 12 of first component 1 so as to allow a positioning tolerance, i.e. small movements of the endoprosthesis after implantation. Such small movements allow adaptation of the device 100 to vascular aging, which may entail changes in anatomical dimensions and/or configuration while maintaining an effective sealing of the aneurysm.

Alternative embodiments may provide a different stents and/or barbs distribution onto the device external or internal surface and/or different retaining means.

In order to facilitate its insertion and deployment *in situ*, in the present embodiment device 100 has marking means, in particular a plurality of radio-opaque markers, one of which denoted by way of example by 5.

Preferably, markers 5 are arranged at one or more terminal ends of device 100. In the present embodiment, one or more markers 5 may be located at any of the proximal and/or distal end portions of first component 1, second component 2, and/or any of branches 10, 11 and 12. Most preferably, markers 5 are located at: the proximal terminal region of first proximal branch 11 into the innominate artery; the distal end region of distal component 1, in particular of its distal branch 10; the proximal and distal end regions of second proximal branch 12; the proximal and distal end regions of second component 2 and a transition region between first and second portions 21 and 22.

Preferably, and as shown in Figure 1, markers 5 are arranged in line along a circumferential extension of device 100.

Variant embodiments may provide a different placement of distribution of the markers.

* * *

A preferred implantation procedure for endoprosthesis 100 will now be described.

It will be appreciated that the invention relates also to such surgical procedure for treating aneurysms and/or dissections inside the aortic arch, which procedure provides the implantation of a vascular endoprosthetic device 100 as described above and as defined in the claims.

Figure 2A shows schematically a so-called “Zone 0” aortic arch aneurysm A0, i.e. a disease involving the whole aortic arch and the origin of all supra-aortic trunks, including the innominate artery. In such figure, for ease of reference the aortic arch is denoted by AA, the right common carotid artery by RC, the left common carotid artery by LC, the left subclavian artery by LS, the right subclavian artery by RS and the innominate artery by IA. These abbreviations may be used also in the following.

Figure 2B depicts schematically a preferred preliminary open surgical procedure which needs to be performed before the implantation of endoprosthesis 100. In particular, an extra-anatomic supra-aortic vessels revascularisation is performed by means of RC – LC – LS bypass executed through two small cervicotomies. The bypass can be obtained by means of a standard prosthetic body 71, in particular a commercially-available tubular, straight synthetic vascular graft preferably of a diameter comprised in a range of about 6 to 8 mm. The bypass can be executed by conventional open surgery.

As a consequence of the bypass, the RC artery supplies also the LC and LS and therefore also the left vertebral artery.

Figure 2C depicts schematically a preferred preparatory step subsequent to that of Figure 2B. In such subsequent step, the left common carotid artery is ligated by an element, or ligation or tie or suture, 72 at a position PL proximal to the bypass. Such ligation produces an obstruction of the LC, avoiding ri-perfusion of the aneurysm.

Moreover, before, after or substantially at the same time with the ligation, a plug 73 is placed at the origin of the LS proximal to the origin of the left vertebral artery. Plug 73 is apt to interrupt blood flow in the LS and may be of a conventional type commercially available.

In a variant embodiment, plug 73 may be replaced by a ligation. However, use of plug 73 may be preferred to avoid interferences with the perfusion of other vessels originating in the proximity of the LS or with other adjacent anatomical structures.

Figure 2D depicts schematically a further preferred preparatory step, which may

be performed immediately before the deployment procedure of the endograft. A filter 74 is placed in the RC. Filter 74 is mainly intended to avoid propagation of possible embolic material of different kind (blood clots, platelets aggregates, atherosclerotic debris). Since RC also supply LC and LS, embolic protection is thus offered to most of the cerebral circulation. Also filter 74 may be of a conventional type commercially available.

An additional protection device may be used also for the right vertebral artery (not shown).

Figure 3A depicts schematically a step subsequent to the ones mentioned above. The step of Figure 3A provides the introduction of a wire or guide-wire 81, preferably a metallic wire and most preferably a stiff one, from a common femoral artery into the aortic arch, through the IA and RS and down to the right humeral or axillary artery by a so-called “through-and-through” technique. Wire 81 – or an element equivalent thereto - is snared and passed through a sheath 82 inserted through the right humeral or axillary artery and into the RS. Sheath 82 - or an equivalent cannula, channel, catheter or other element - may be used also for imaging purposes, in particular for injecting a contrast medium into the relevant body districts.

Wire 81 acts as a guide for the subsequent steps achieving a deployment *in situ* of device 100.

Figure 3B depicts schematically a first step of introducing endoprosthesis 100 in the aortic arch by means of a second sheath 83, it too part of, or associated with, the aforementioned introducer device made of wire 81 and first sheath 82 (or equivalent elements) and guided onto wire 81. Also sheath 83 may be replaced by an equivalent cannula, channel or catheter or other element.

Sheath 83 encloses endoprosthesis 100, the latter in a minimal-encumbrance configuration, and is positioned up to the innominate artery.

As better seen in Figure 4A, inside sheath 83 and endoprosthesis 100 it is passed an inner cannula or equivalent element 85. Cannula 85 protrudes out of branch 11 into the RS and carries at its end a tip 84, preferably a tapered tip, which allows navigation of the introducer device, and/or of its associated elements, into the relevant vessels.

Also cannula 85 and/or tip 84 may be part of the introducer device.

From here on the deployment procedure may be preferably carried out under controlled hypotension (i.e. rapid cardiac pacing).

Figure 4A depicts schematically a step of initial unsheathing of endoprosthesis 100 by a pull-back manoeuvre, according to a first, simplified variant of the insertion and deployment procedure. In particular, first proximal branch 11 of first component 1 deploys first, and its barbs 4 open automatically towards the

vessel's walls by virtue of their intrinsic elasticity.

Variant embodiments may provide a different unsheathing procedure than the pull-back one mentioned above.

Figure 4B depicts schematically as the unsheathing proceeds distally by the pull-back manoeuvre, so that also second proximal branch 12 of first component 1 is exposed.

Figure 4C depicts schematically first component 1 of endoprosthesis 100 fully unsheathed and deployed. As shown in Figure 4C, first component 1 engages with the walls of the innominate artery proximally and with those of the descending thoracic aorta distally.

In the configuration of Figure 4C, cerebral circulation is jeopardized by the controlled hypotension and presence of the partially opened first component 1 in the innominate artery. The procedure being described and the endoprosthesis structure allow keeping the time of such jeopardized circulation at a minimum (in particular, < 1 min').

Figure 5A depicts schematically a preferred step for deploying *in situ* second component 2, i.e. in the docking site made by second proximal branch 12 in the aortic arch.

A wire 95, or an equivalent element, is introduced through the femoral artery, inside cannula 83, through first component 1 in the aortic arch and out of second proximal branch 12. Wire 95 is looped at the level of the aortic valve plan. At this position, wire 95 forms a blunt curled shape 96.

Alternatively, wire 95 may be allowed to cross the aortic valve and rest into the left ventricle.

Wire 95 is introduced before a further outer sheath 97 (or cannula, channel, catheter or equivalent element). Sheath 97 encloses second component 2 in a configuration of minimal encumbrance.

The introducer 97 of the second component 2 comes preferably with a blunt tip 98. The blunt tip is not apt to navigate up the arterial system, however this is not necessary because the introducer 97 is advanced within the sheath 83 (left *in situ*) up to the descending thoracic aorta. The blunt tip 98 avoids possible injuries to the aortic valve or to other cardiac structures by a tapered tip. Blunt tip 98 may house retention means for the proximal terminal end of proximal component 2 and is intended to be adequate length so that when it sits in the aortic valve, the proximal terminal end of proximal component 2 on opening may not inadvertently cover the coronary ostia or the aortic valve cusps.

Figure 5B depicts schematically a simple step of initial unsheathing of second

component 2 by a pull-back manoeuvre. Second component 2 is allowed to open in the desired position proximally in the ascending aorta and distally in docking branch 12 of first component 1.

Also this step may be performed under rapid cardiac pacing for controlled hypotension.

A retaining wire or tie (not shown) could also keep component 2 fixed to an inner cannula or partially open, until its complete release, for additional stability and safety during deployment and for deployment orthogonal to the ascending aorta.

Figure 5C depicts schematically the final configuration of device 100, with a few components of the introducer device still in place.

At this stage, touch up with a moulding balloon is optional and could be performed particularly at the level of the overlapping of the two components and at the end of the two components (not shown in the figure) and should be performed with caution under rapid pacing. Generally, speaking, ballooning at the overlapping may be recommended.

Figure 5D depicts schematically final appearance of endoprosthesis 100 that is fully deployed in a desired position, without the introducer device or other manoeuvring elements.

In the conditions of Figures 5C and 5D, the aneurysm is no longer perfused.

As can be appreciated from Figure 5D, once the prosthesis is deployed *in situ*, blood flows from the heart through proximal component 2 and into second proximal branch 12. From such proximal branch 12, blood flows into intermediate portion 111 of first proximal branch 11 and from that into distal portion 112. Therefore, the flow into the Innominate Artery is retrograde, in that such flow is directed first from the heart towards the descending aorta and, at the bifurcation of distal component 1, part of the flow enters first proximal branch 11 at least for a portion of the cardiac cycle.

Therefore, blood flow in the Innominate Artery and in all cerebral vessels is assured by way of retrograde perfusion by first proximal branch 11.

As said above, second proximal branch 12 is configured so as to be able to withstand the whole cardiac output flow (minus the coronary flow which is more proximal).

The above retrograde perfusion modes are shown by way of example through arrows in Fig. 5D.

It will be appreciated that the prosthetic device and associated implantation technique described above do not require an access through the carotid artery or other supra-aortic vessels.

Figure 6 depicts schematically an alternative preparatory step of the surgical procedure, to be used instead of the step depicted in Figures 2B and 2C. In such variant, supra-aortic vessels de-branching is performed with a latero-terminal anastomosis of the by-pass to the LC (inverted T shape).

Figure 7 depicts schematically a further alterative, wherein left subclavian–carotid transposition (instead of by pass) is performed and the LS is ligated proximally to the origin of the left vertebral artery.

Therefore, in a general definition the surgical procedure provided by the invention provides the steps summarised below.

A first preferred, preliminary, open surgery step provides for extra-anatomic supra-aortic vessels revascularisation by means of a RC – LC – LS bypass. In particular, such step is executed through two small cervicotomies. Preferably, the bypass is obtained by means of a tubular prosthetic body, in particular a straight synthetic vascular graft preferably of a diameter comprised in a range of about 6 to 8 mm. Through the bypass, the RC artery supplies also the LC and LS and therefore also the left vertebral artery.

A second preferred preparatory step, eventually subsequent to the aforementioned first step, provides for the left common carotid artery be ligated by an element, or ligation or tie or suture, at a position proximal to the bypass. Such ligation produces an obstruction of the LC, avoiding ri-perfusion of the aneurysm. Preferably, before, after or substantially at the same time with the ligation, a plug may be placed at the origin of the LS proximal to the origin of the left vertebral artery. Such plug is implanted so as to interrupt blood flow in the LS. In a variant embodiment, said plug is replaced by a ligation.

A further preferred preparatory step provides for a filter be placed in the RC. Such filter is mainly intended to avoid propagation of possible embolic material of different kind (blood clots, platelets aggregates, atherosclerotic debris). An additional protection device might be used also for the right vertebral artery.

Another preferred step provides the introduction of a wire, or guide-wire, or an equivalent element from a common femoral artery into the aortic arch, through the IA and RS and down to the right humeral or axillary artery by a so-called “through-and-through” technique. Said wire – or the element equivalent thereto - is snared and passed through a sheath inserted through the right humeral or axillary artery and into the RS. Such sheath - or an equivalent cannula, channel, catheter or other element - may be used also for imaging purposes, for example for injecting a contrast medium into the relevant body districts.

The wire or equivalent element acts as a guide for the subsequent steps achieving a deployment *in situ* of the endoprosthesis.

A further step provides introducing the endoprosthesis in the aortic arch by

means of a second sheath. Also the second sheath may be replaced by an equivalent cannula, channel or catheter or other element.

The second sheath encloses the distal component of the endoprosthesis, the latter in a minimal-encumbrance configuration, and is positioned up to the innominate artery.

Therefore, a fundamental step of the procedure provides introduction of the endoprosthesis through a sheath, or other introducer element, inserted in the body through a common femoral artery and from there into the aortic arch.

Inside second sheath and endoprosthesis it might be passed an inner cannula or equivalent element. The latter protrudes out of first proximal branch into the RS and may carry at its end a tip, preferably a tapered tip, which allows navigation of the introducer device, and/or of its associated elements, into the relevant vessels.

From here on the deployment procedure may be preferably carried out under controlled hypotension (i.e. rapid cardiac pacing).

A subsequent step provides initial unsheathing of endoprosthesis, preferably by a pull-back manoeuvre, according to a first, simplified variant of the insertion and deployment procedure. In particular, the first proximal branch of first component deploys first, and preferably its barbs open automatically towards the vessel's walls, for example by virtue of their intrinsic elasticity.

As the unsheathing proceeds distally, also the second proximal branch of first component is exposed.

Once fully unsheathed and deployed, the distal component engages with the walls of the innominate artery proximally and with those of the descending thoracic aorta distally.

When two-part prosthesis 100 is used, the proximal component is now inserted in the body and subsequently deployed.

Preferably, such insertion step uses a wire, or an equivalent element, which is introduced through the femoral artery, preferably inside said second cannula, through first component in the aortic arch and out of the second proximal branch. Said wire is preferably looped at the level of the aortic valve plan. At this position, wire preferably forms a blunt curled shape. Alternatively, said wire may be allowed to cross the aortic valve and rest into the left ventricle.

In a subsequent step, a further outer sheath (or cannula, channel, catheter or equivalent element), enclosing the proximal component in a configuration of minimal encumbrance, is passed over said wire.

In a further preferred step, the proximal component is unsheathed, for example by a pull-back manoeuvre and it is allowed to open in a position proximally in the ascending aorta and distally in the docking branch of distal component.

Also this step may be performed under rapid cardiac pacing for controlled hypotension.

Optionally, a retaining wire or tie could also keep proximal component fixed to an inner cannula or partially open, until its complete release, for additional stability and safety during deployment and for deployment orthogonal to the ascending aorta.

It may be appreciated that intermediate steps for a more modular, or gradual, deployment of the prosthesis may be applied. For example, two or more components or branches of the prosthesis may be kept together by ties or similar elements during the deployment procedure.

* * *

Figures 8A and 8B show another embodiment of the vascular endoprosthetic device according to the invention, in this case denoted by 100'.

Device 100' will be described only with reference to its differences with device 100 already disclosed. Accordingly, similar or identical components will be denoted by the same reference number already used above.

Device 100' is made of a first distal component 101 and a second proximal component 102 connected one to the other at respective end portions, so as to form a single body or element. Second proximal component 2 is unsupported, i.e. preferably it has no stents at its external or internal surface/walls. Therefore, preferably component 102 is entirely made of fabric.

Device 100' is configured to assume two deployment configurations, namely:

- an insertion configuration (shown in Figure 8A), wherein proximal component 102 is infolded, or housed, inside second proximal branch 12 of first component 101,
- an operative configuration (shown in Figure 8B), wherein proximal component 102 is extracted from second proximal branch 12 and extends freely in the operating field – in other words, the second component 102 is telescopically extracted from the first component 101.

Device 100' is preferred in all cases in which some form of open repair of the aortic valve, sinuses of Valsalva, coronary ostia, aortic root and/or ascending aorta is mandatory or highly recommended. In particular, in some instances of aneurysmal and especially dissecting disease the hybrid procedure described above may not be employed - also but not necessarily only - for one or more of the following reasons:

- aortic valve insufficiency requiring replacement or repair,
- sinuses of Valsalva / aortic root dilatation,
- coronary ostia aneurysm, dissection, stenosis,
- ascending aortic dilatation > 40 mm,
- type A aortic dissection with intimal tear in the proximity of the Sinuses of Valsalva.

Open repair needs to be performed through sternotomy or thoracotomy with the use of extra corporeal circulation (Cardio-Pulmonary By-Pass, CPBP). However, if the disease (aneurysm or dissection) is extended into the aortic arch, the distal part of the operative procedure, involving the arch at the level of the supra-aortic trunks (whether with the standard technique or with the "frozen elephant trunk" technique), would require hypothermic circulatory arrest in addition to CPBP. This makes the procedure much more invasive, it contra-indicates it in unfit patients and increases the percentage of postoperative complications, particularly neurologic ones. In these cases, device 100' is suitable to be used to treat the aortic arch, avoiding the need for circulatory arrest.

A preferred operative procedure for implanting device 100' is disclosed below. It will be appreciated that the invention relates to such procedure as well.

Figure 9 depicts a case of aortic arch aneurysm/dissection with aortic valve incompetence that requires open surgical repair. The patient undergoes supra-aortic trunks de-branching (i.e. carotid-carotid-subclavian by-pass, as in the procedure described previously). Through median sternotomy, the patient undergoes CPBP with perfusion through a right subclavian artery conduit (not shown), and aortic clamping of the ascending aorta just proximal to the innominate artery. Patient undergoes aortic valve/aortic root procedure as required.

Figure 10 depicts a filter in place in the right common carotid artery, as in the previously-disclosed procedure, and device 100' in place as well, after a standard insertion procedure. In such configuration, proximal component 102 is received inside proximal branch 12, i.e. infolded within such proximal branch 12.

In the step of Figure 10, CPBP is stopped for just a few seconds, the clamp is temporarily removed, and the infolded unsupported segment, i.e. proximal component 102, of device 100' is captured with a forceps (not shown), brought out of the distal component 101 and clamped as shown in Figure 11 after de-airing. CPBP is resumed and the patient is rewarmed, while the proximal anastomosis between the unsupported graft - cut to the appropriate measure, not shown - and the aortic root is completed.

Figure 12 shows a final view of the aortic arch replacement with device 100' and

the aortic valve repaired in a customary fashion. Patient is weaned from CPBP and closed in a customary fashion.

It will be appreciated that, in an alternative application and procedure to the one just disclosed, the insertion and deployment steps of endoprostheis 100' may be the same as those of endoprosthesis 100, wherein deployment of proximal component 2 is substituted by telescopic extraction of proximal component 102.

* * *

Figure 13 shows a further, most preferred embodiment of the vascular endoprosthetic device according to the invention, in this case denoted by 200.

Device 200 will be described only with reference to its differences with device 100 already disclosed. Accordingly, similar or identical components will be denoted by the same name.

Device 200 has a modular construction which allows a modular deployment, being made of a distal component, here denoted by 201, a first proximal component denoted by 230, and a second proximal component, the latter here denoted by 202.

Preferably, components 201, 202 and 230 are provided as distinct, i.e. separate, elements and are assembled in the aortic arch during a deployment procedure of device 200.

Device 200 and its components 201, 202 and 230 have each a tubular construction suitable to allow blood flow therein, and, preferably, a substantially cylindrical or tapered geometry.

Distal component 201 (which – as explained later on - is deployed first) is configured to be placed in the distal part of the aortic arch or in the descending aorta. First component 201 has a distal body portion 210 and a proximal body portion 220. This latter portion 220 houses two tubular docking branches 231 and 232 placed one adjacent to the other along a longitudinal extension of distal component 201. The two docking branches 231 and 232 substantially occupy the whole internal lumen of proximal portion 220. Such branches 231 and 232 can be obtained as tubular sockets housed inside, and occupying substantially the whole, proximal body portion 220 of distal component 201.

Docking branches 231 and 232 are configured to receive, each as a "docking station", first and second proximal components 230 and 202, respectively. In other words, docking branches 231 and 232, or more proximal portions thereof,

each define a distal engagement seat for first and second proximal component 230 and 202, respectively. Docking branches 231 and 232 are provided integral to, or fixed with, distal component 201.

First proximal component 230 (which – as explained later on - is deployed after first component 201) has a distal portion 211 which, in use, is totally or partially housed inside docking branch 232 and placed in the aortic arch. First proximal component 230 has a distal portion 212 which, in use, is received in the Innominate Artery.

Second proximal component 202 (which – as explained later on - is deployed after first component 201) has a distal portion 221 which, in use, is totally or partially housed inside docking branch 231 and placed in the aortic arch, proximally with respect to first proximal component 230. Second proximal component 202 has also a distal portion 222 which, in use, is placed in the proximal aortic arch. Second proximal component 202 has a cross-section, in particular a diameter, configured to accommodate the whole cardiac output. Also second docking branch 232 has a cross-section, in particular a diameter, configured to accommodate the whole cardiac output.

Therefore, preferably it has a diameter larger than that of first proximal component 230. Similarly, second docking branch 232 may have a greater cross-section, in particular a diameter, than first docking branch 231.

Similarly to proximal component 2 of the embodiment of Figure 1, the distal portions 211, 221 of each of first and second proximal components 230 and 202 may be of a larger diameter than the respective docking branches 231, 232 in order to ensure a safe interconnection of components in the overlapping area.

The degree of overlapping of each proximal component inside the respective docking branch can be regulated, i.e. changed, by sliding them one into the other, thus providing tolerance in the longitudinal measurement, analogously to the modes already described in conjunction with the embodiment of Figure 1.

Each distal portion 211, 221, in the present example, has a lower cross-section (in particular diameter) than the respective proximal portion 212, 222.

Each of the elements described above may incorporate stents, markers or other means or devices already disclosed in conjunction with the previous embodiments.

A variant embodiment may provide for one or both the proximal components be

connected each to respective end portions of distal component, similarly to the embodiment disclosed with reference to Figure 8A and 8B in conjunction with component 102. In this case, second and third component can assume each two deployment configurations, in full analogy to the aforementioned embodiment of Figures 8A and 8B, namely:

- an insertion configuration, wherein said two proximal components are infolded, or housed, inside first component,
- an operative configuration, wherein each proximal component is extracted from the distal component and extends freely in the operating field – in other words, the second and third components are each telescopically extracted from the first component.

A preferred implantation procedure for endoprosthesis 200 will now be described, only in conjunction with the differences with respect to the procedure already illustrated above for endoprosthesis 100 of Figure 1.

As shown in Figure 14A, in a first preferred step a principal guide wire 800 is inserted through the common femoral artery up to the ascending aorta.

In a second preferred step shown in Figure 14B, a delivery system 900, or introducer device, analogous to that already described is inserted over the principal wire 800 up to the desired position in the aortic arch.

As shown in Figure 14C, an ancillary wire 801 passing through the first docking branch 231 of endoprosthesis 200 is advanced into the innominate and right subclavian artery.

According to the present embodiment as shown in Figure 14D, the distal component 201, i.e. the common body of the endoprosthesis 200, is released from the delivery system 900.

As shown in Figure 14E, the fully opened distal component 201 is landed in the desired position.

With reference to Figure 14F, preferably second proximal component 202, i.e. the larger secondary module of endoprosthesis 200, is advanced, in a minimally-encumbrance configuration, over the principal wire 800 through the body of distal component 201 and through the larger inner docking branch 232 up to the ascending aorta.

As shown in Figure 14G, preferably second proximal component 202 is released proximally in the desired position in the ascending aorta. Figure 14H shows second proximal component 202 that is allowed to dock distally in the larger inner docking branch 232.

According to a preferred subsequent step shown in Figure 14I, first proximal component 230, i.e. the lesser secondary module of endoprosthesis 200, is advanced, in a minimally-encumbrance configuration, over ancillary wire 900

through the body of distal component 201 and through the lesser inner docking branch 231 up to the Innominate Artery.

As shown in Figure 14J, first proximal component 230 is released proximally in the desired position in the Innominate Artery. Figure 14K shows component 230 that is allowed to dock distally in docking branch 231.

Touch up with a moulding balloon is an optional (not depicted) step of the procedure. The final configuration of the assembled tri-modular version of the implant is shown in Figure 14K.

* * *

It will be understood that, in specific procedures, the treatment may be completed by additional graft components already available in the art. Such additional components might be, for example endoprostheses to be placed at the distal aortic arch or descending thoracic aorta, proximally or distally, or at the innominate artery.

At this stage it will be better appreciated that the device of the invention allows achieving any of the following advantages:

- simple deployment procedure,
- reduced endovascular wires and devices manipulation,
- embolic cerebral protection,
- device available off the shelf,
- immediate availability for emergency cases,
- limited stock would serve most cases,
- cheaper than totally endovascular branched systems,
- no additional covered stents required for bridging target arteries,
- less invasive than open arch repair,
- less invasive than “frozen elephant trunk” technique,
- less invasive then hybrid repair of Zone 0 aneurysm with sternotomy.

The present invention has been described so far with reference to preferred embodiments. It is intended that there may be other embodiments which refer to the same inventive concept and fall within the scope of the appended claims.

CLAIMS

1. A vascular endoprosthetic device (200) configured for placement inside the aortic arch, in particular for treating aneurysms and/or dissections,

which device (200) has a tubular structure and a construction allowing a modular insertion and deployment,

which device (200) comprises:

- a distal component (201) configured to be placed in the distal part of the aortic arch or in the descending thoracic aorta,

  which distal component (201) has a main body portion (210) with an internal lumen

  and comprises a first and a second docking branch (231, 232) housed inside said lumen at a proximal end part (220) thereof, which first and second docking branches (231, 232) are integral to, or fixed to with, said main body portion (210) and are each in form of a tubular socket;
- a first proximal component (230), configured to be placed in the innominate artery;
- a second proximal component (202), configured to be placed in the ascending aorta and having a cross-section configured to accommodate the whole cardiac output,

wherein said distal (201), first proximal (230) and second proximal (202) components are configured to be deployed in the aortic arch during an insertion procedure,

wherein each of said first (230) and second (202) proximal components has a respective proximal portion (212, 222) and a respective distal portion (211, 221), wherein each of said distal portions (211, 221) of said first (230) and second (202) proximal components is configured so that, once the device (200) is deployed *in situ*, such distal portion is received in a respective first (231) or second (232) docking branch of said distal component (201), so that said docking branch (231, 232) acts as a docking site for the respective first (230) or second (202) proximal component,

and wherein the endoprosthetic device (200) is configured so that, once deployed *in situ*, blood flows from the heart through said second proximal component (202) and into said second docking branch (232) of said distal component (201), and from the latter into said proximal portion (211) of said first proximal component (230) and from that retrogradely into said distal portion (212) of said first proximal component (230).

2. The device (200) according to claim 1, wherein each of said distal portions (211, 221) of said first (230) and second (202) proximal components has a reduced cross-section with respect to the respective proximal portion (212, 222).

3. The device (200) according to claim 1 or 2, wherein said distal (201), first proximal (230) and second proximal (202) components are provided as distinct elements and are apt to be assembled in the aortic arch during the insertion procedure.

4. A vascular endoprosthetic device (100) configured for placement inside the aortic arch, in particular for treating aneurysms and/or dissections,

which device (100) has a tubular structure and a construction allowing a modular insertion and deployment,

which device (100) comprises:

- a distal component (1) having a substantially bifurcated, or "Y"-shaped, configuration and comprising:
  - a distal branch (10), configured to be placed in the distal part of the aortic arch or in the descending thoracic aorta;
  - a first proximal branch (11), originating from said distal branch (10) and having an intermediate portion (111) configured to be placed in the aortic arch and a distal portion (112) configured to be placed in the innominate artery;
  - a second proximal branch (12), originating from said distal branch (10), configured to be placed in the aortic arch and defining a proximal engagement seat (120); and
- a proximal component (2), configured to be placed in the ascending aorta and having a cross-section configured to accommodate the whole cardiac output, which proximal component (2) comprises a distal portion (21) and a proximal portion (22), and, once the device (100) is deployed *in situ*, is configured to be received in said engagement seat (120) of said second proximal branch (12) of said distal component (1), so that said second proximal branch (12) acts as a docking site for said proximal component (2),

wherein said distal (1) and proximal (2) components are provided as distinct elements and are configured to be assembled in the aortic arch during an insertion and deployment procedure,

and wherein the endoprosthetic device is configured so that, once deployed *in situ*, blood flows from the heart through said proximal component (2) and into

said second proximal branch (12), and from such proximal branch (12) into said intermediate portion (111) of said first proximal branch (11) and from that retrogradely into said distal portion (112) of said first proximal branch (11).

5. The device (100) according to claim 4, wherein said distal portion (21) of said proximal component (2) has a lower cross-section with respect to said proximal portion (22) of said proximal component (2).

6. A vascular endoprosthetic device (100') configured for placement inside the aortic arch, in particular for treating aneurysms and/or dissections,

which device (100') has a tubular structure and a construction allowing a modular deployment,

which device (100') comprises:

- a distal component (101) having a substantially bifurcated, or "Y"-shaped, configuration comprising:
  - a distal branch (10), configured to be placed in the distal part of the aortic arch or in the descending thoracic aorta;
  - a first proximal branch (11), originating from said distal branch (10) and having an intermediate portion (111) configured to be placed in the aortic arch and a distal portion (112) suitable to be placed in the innominate artery;
  - a second proximal branch (12), originating from said distal branch (10), configured to be placed in the aortic arch and defining a proximal engagement seat (120); and
- a proximal component (102), configured to be placed in the proximal part of the aortic arch and having a cross-section configured to accommodate the whole cardiac output,

wherein said proximal component (102) and said second proximal branch (12) of said distal component (101) are connected at respective terminal ends so as to form a single body or element, and wherein said proximal component (102) is configured to be housed infolded inside said second proximal branch (12) during insertion of the device (100')

and wherein the endoprosthetic device is configured so that, once deployed *in situ*, blood flows from the heart through said proximal component (102) and into said second proximal branch (12), and from such proximal branch (12) into said intermediate portion (111) of said first proximal branch (11) and from that retrogradely into said distal portion (112) of said first proximal branch (11).

7. The device (100) according to any of the preceding claims, comprising supporting means, in particular one or more stents (3).

8. The device (100') according to claim 6, wherein said proximal component (102) is unsupported, not being provided with stents or equivalent supporting means.

9. The device (100) according to any of the preceding claims, comprising retaining means for holding it *in situ*, in particular one or more stents (3) and/or one or more barbs or barbed regions (4).

10. The device (100) according to any of the preceding claims, comprising marking means (5), in particular one or more radio-opaque markers.

11. The device (100) according to claim 9 or 10, wherein said retaining means (4) and/or said marking means (5) is preferably arranged at one or more terminal ends of any of said components (1; 201; 230), branches (10, 11) or portions.

12. The device (100) according to any of the preceding claims, wherein a total length of said distal component (1) from its most distal section to a most proximal section thereof is comprised in a range of about 15-25 cm.

13. The device (100) according to any of the preceding claims, wherein the diameter of said distal branch (10) or main body portion (210) is included in a range of about 30-46 mm.

14. A surgical procedure for treating an aneurysm of the aortic arch, which procedures provides for implantation of an endoprosthetic device according to claim 1, 4 or 6, which procedure comprises a step of inserting said distal component and subsequently said or each proximal component of said endoprosthetic device through a common femoral artery and from there into the aortic arch.

15. A surgical procedure for replacing part of the aortic arch, which procedures provides for implantation of an endoprosthetic device according to claim 6, which procedure comprises a step of inserting said distal component and subsequently said proximal component of said endoprosthetic device through a common femoral artery and from there into the aortic arch.

16. The surgical procedure of claim 14 or 15, wherein said step of inserting uses an introducer element, preferably a sheath and/or a guide wire.

17. The surgical procedure of any of claims 14 to 16, wherein said step of inserting provides that the distal component and/or the or each proximal component of the endoprosthetic device is introduced in a minimal encumbrance configuration and subsequently deployed *in situ*.

18. The surgical procedure of any of claims 14 to 17, further comprising a step of unsheathing said distal component and/or said or each proximal component.

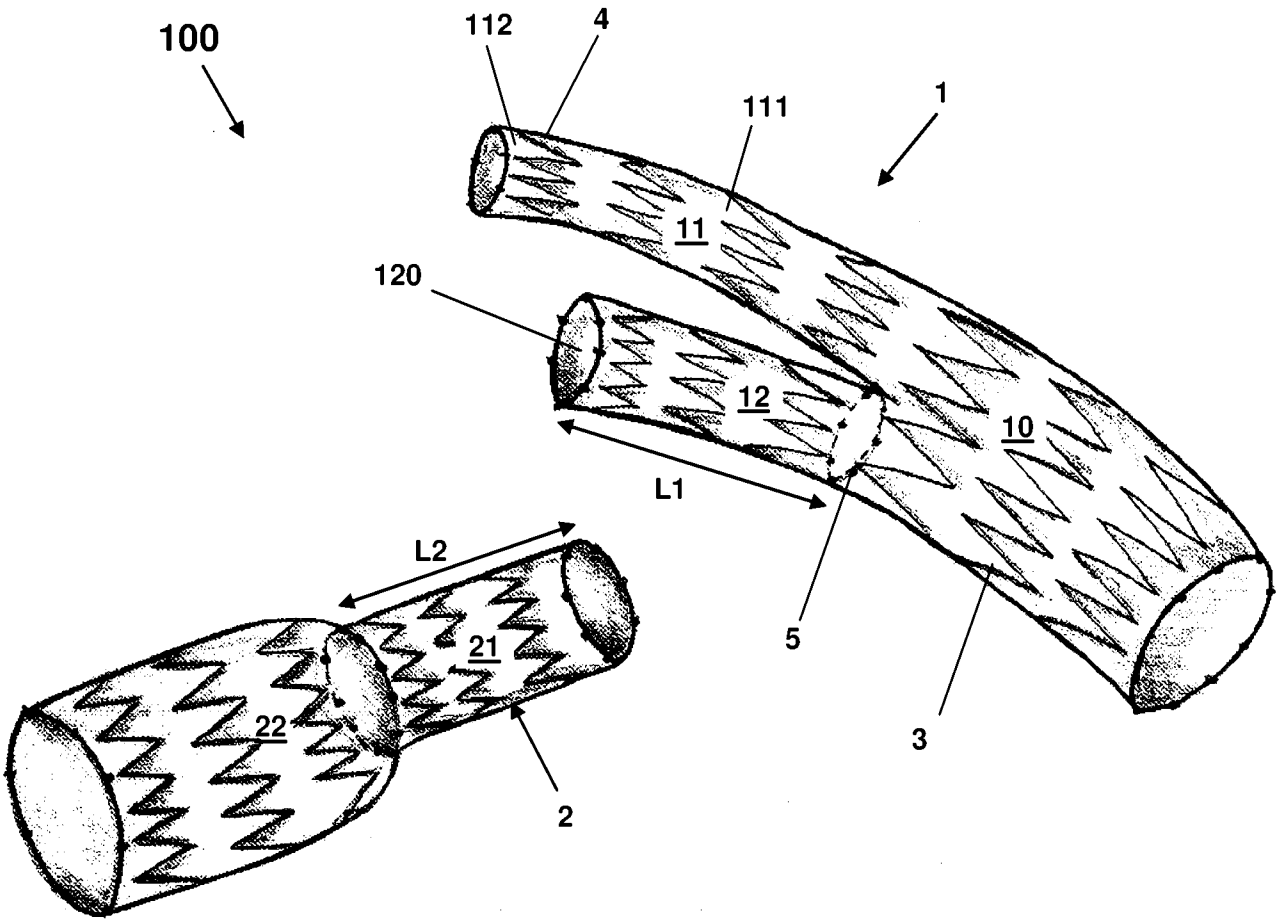

FIG. 1

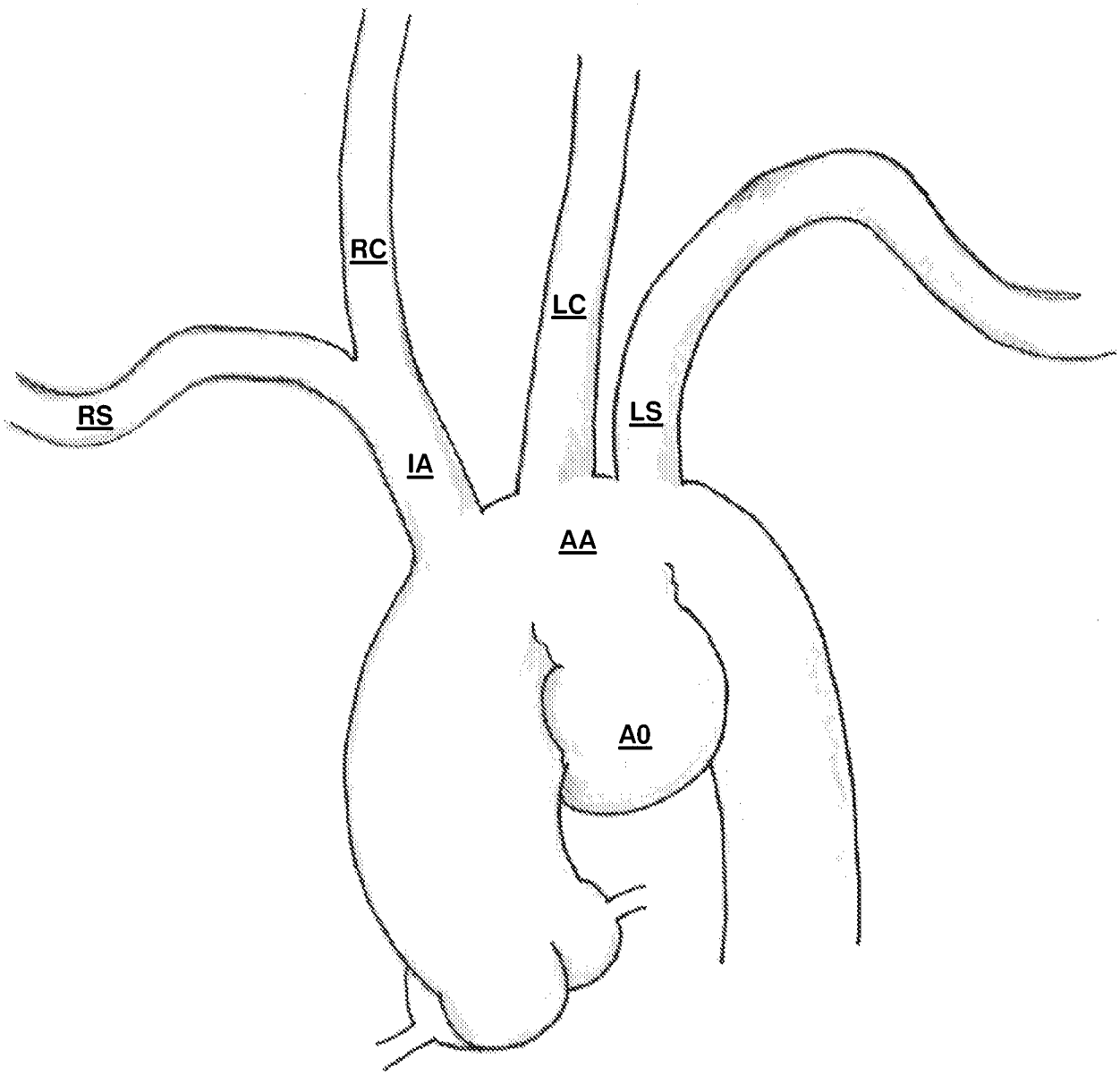

FIG. 2A

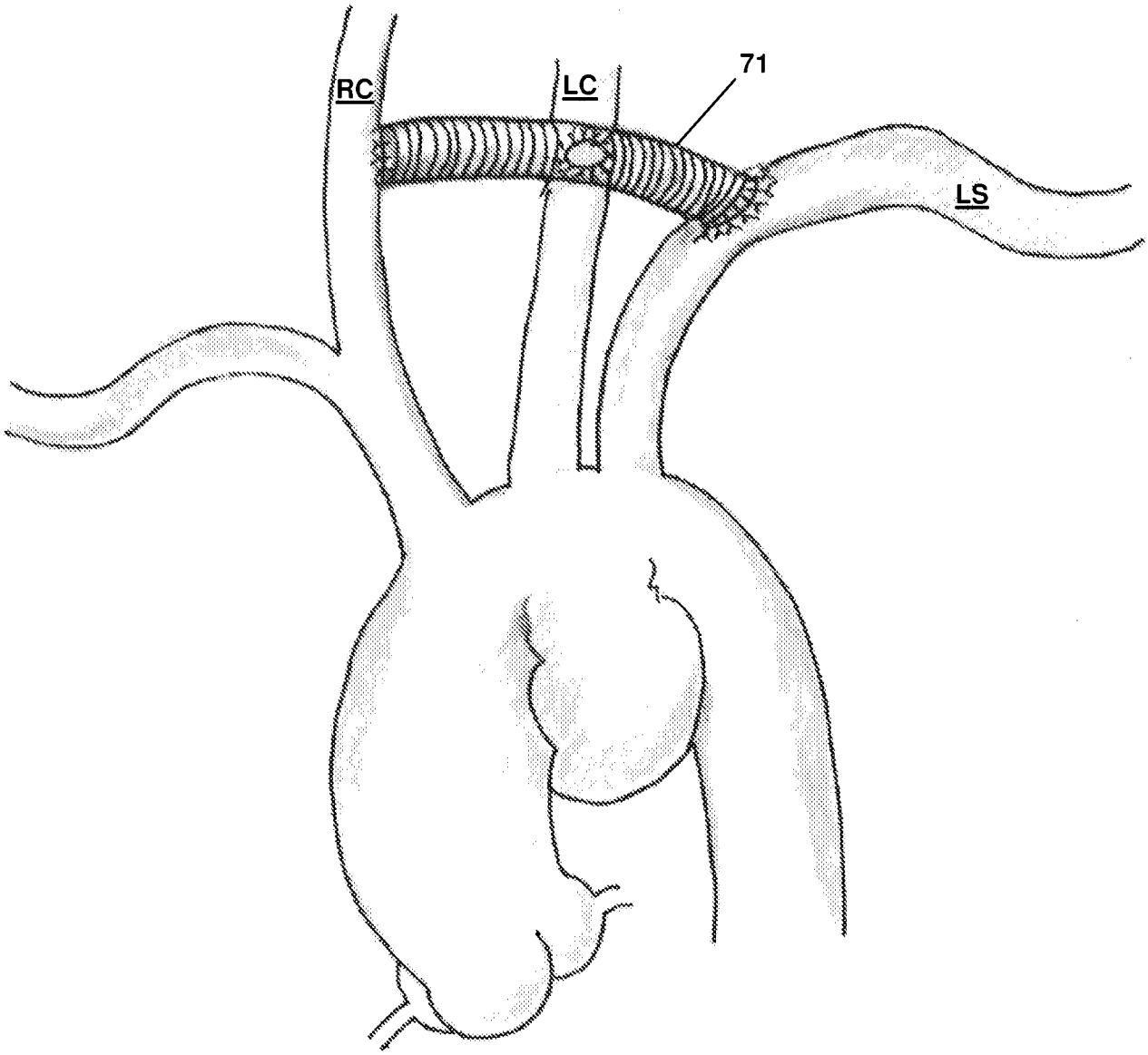

FIG. 2B

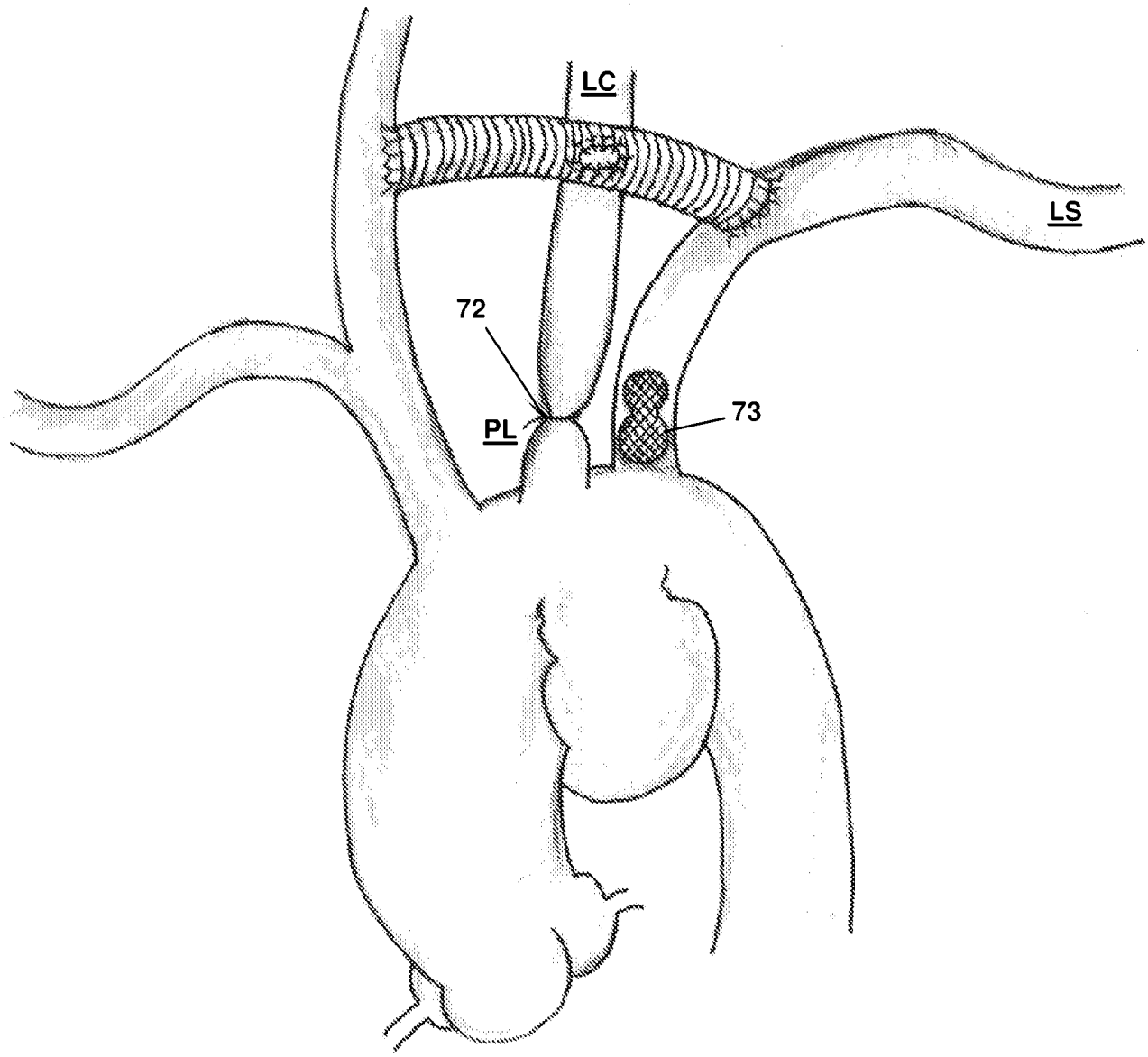

FIG. 2C

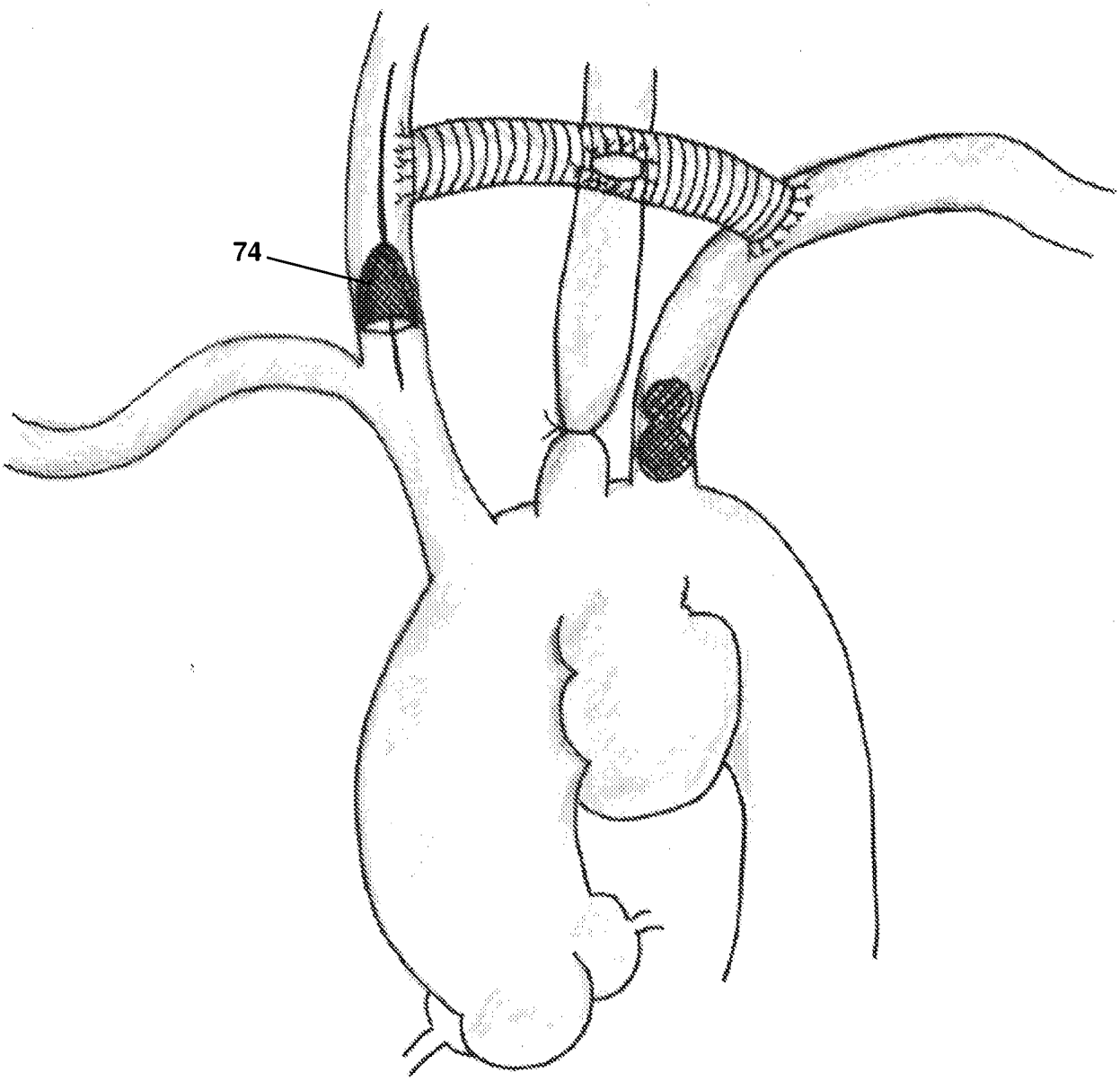

FIG. 2D

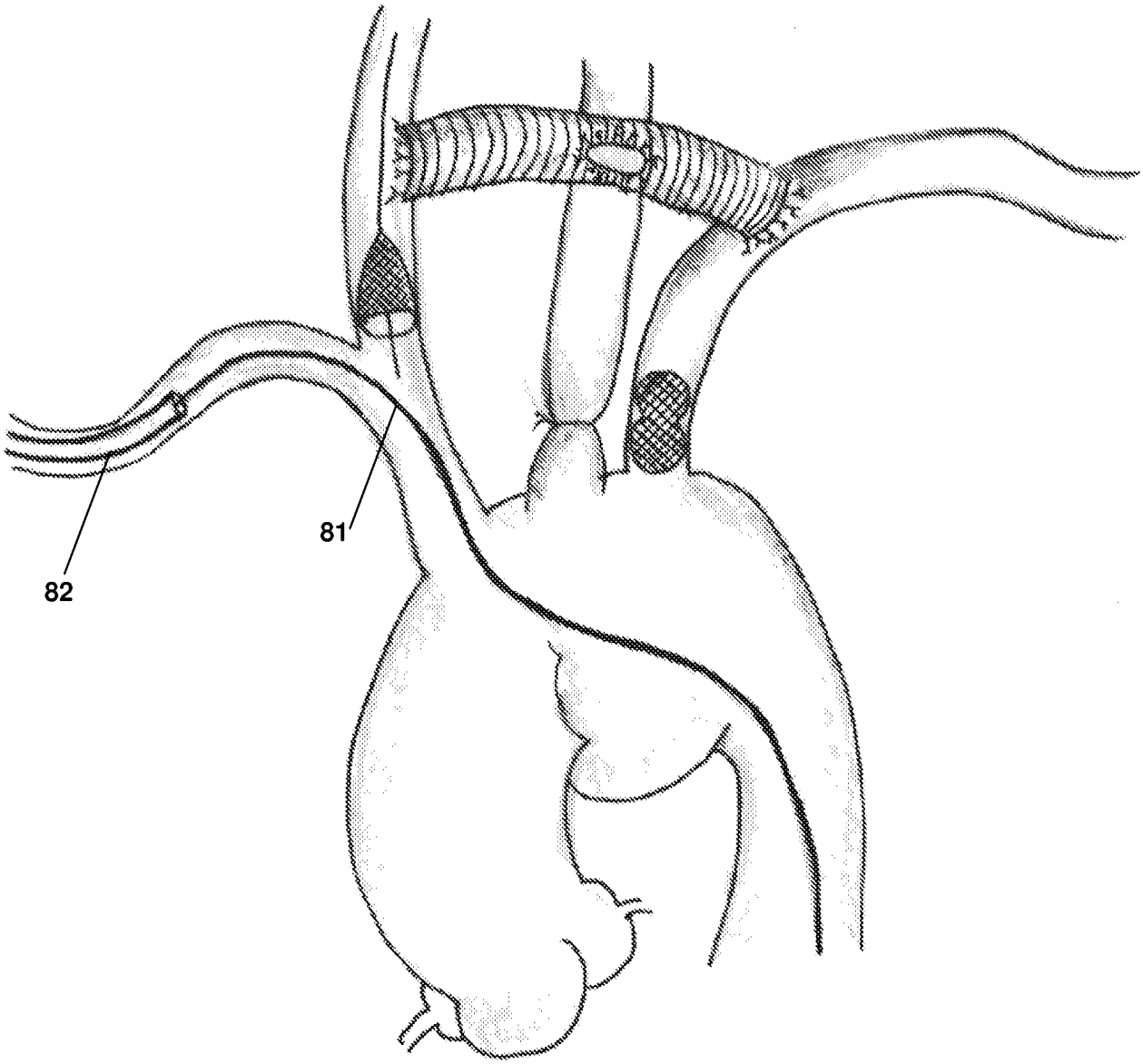

FIG. 3A

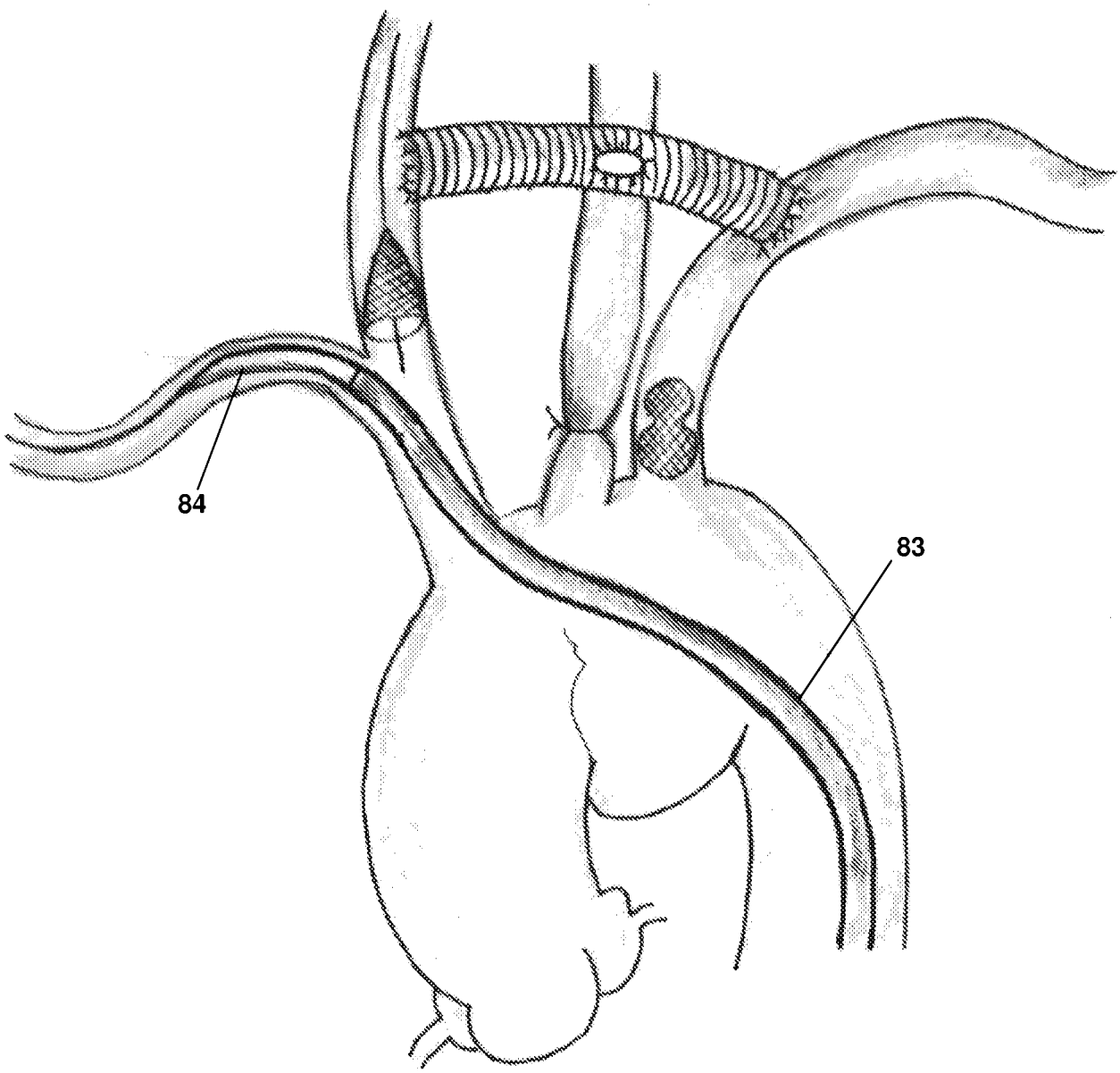

FIG. 3B

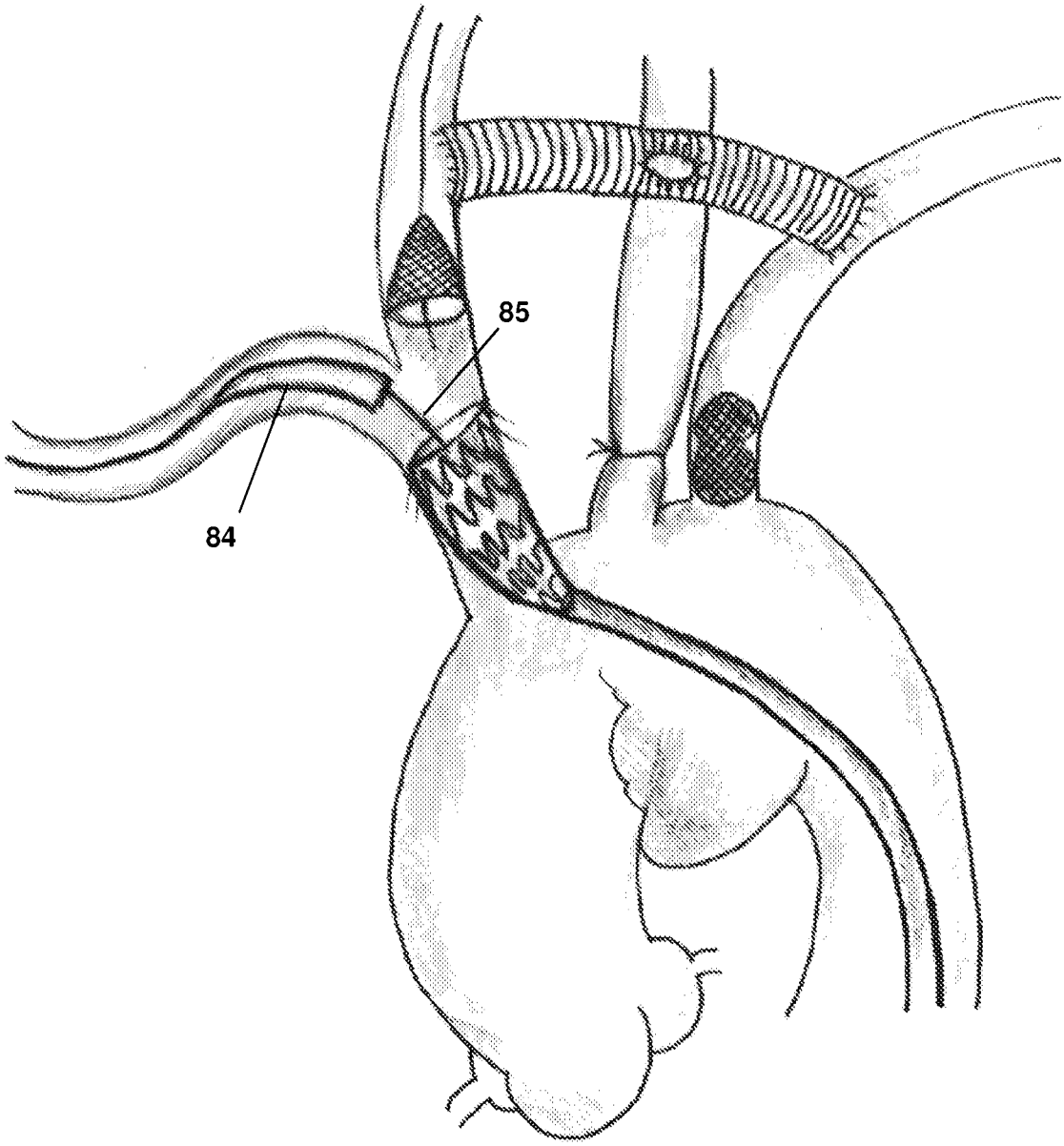

FIG. 4A

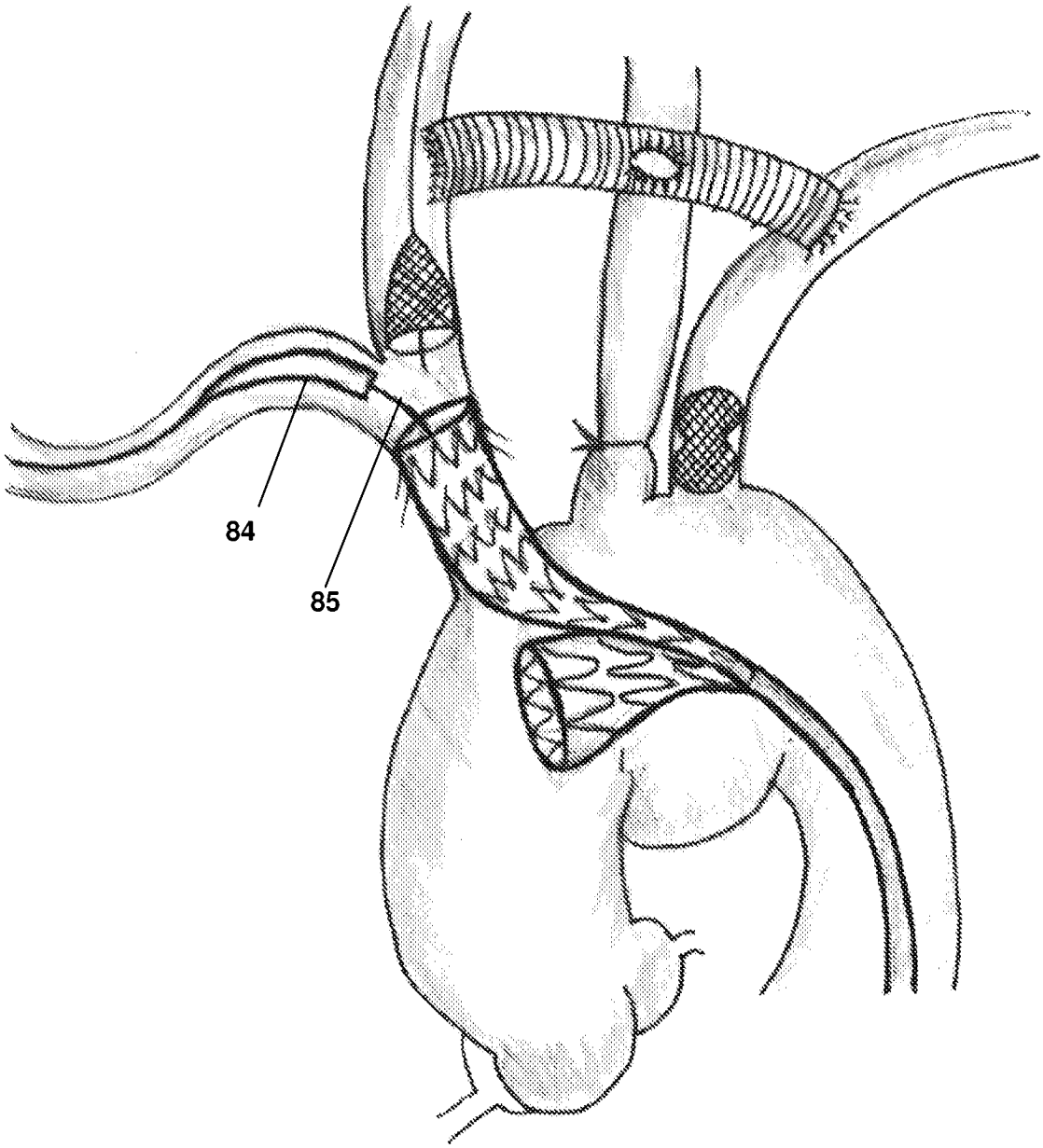

FIG. 4B

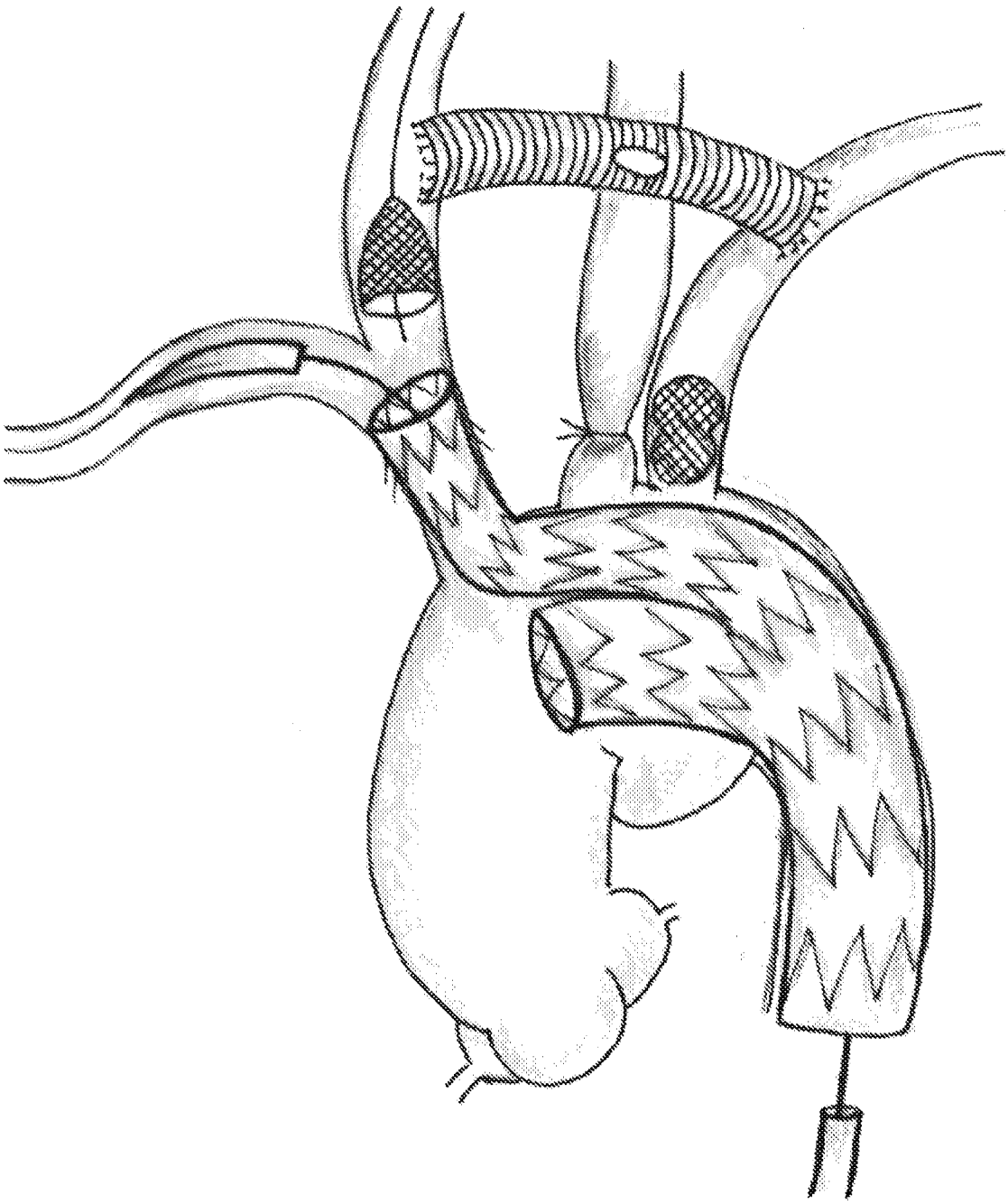

FIG. 4C

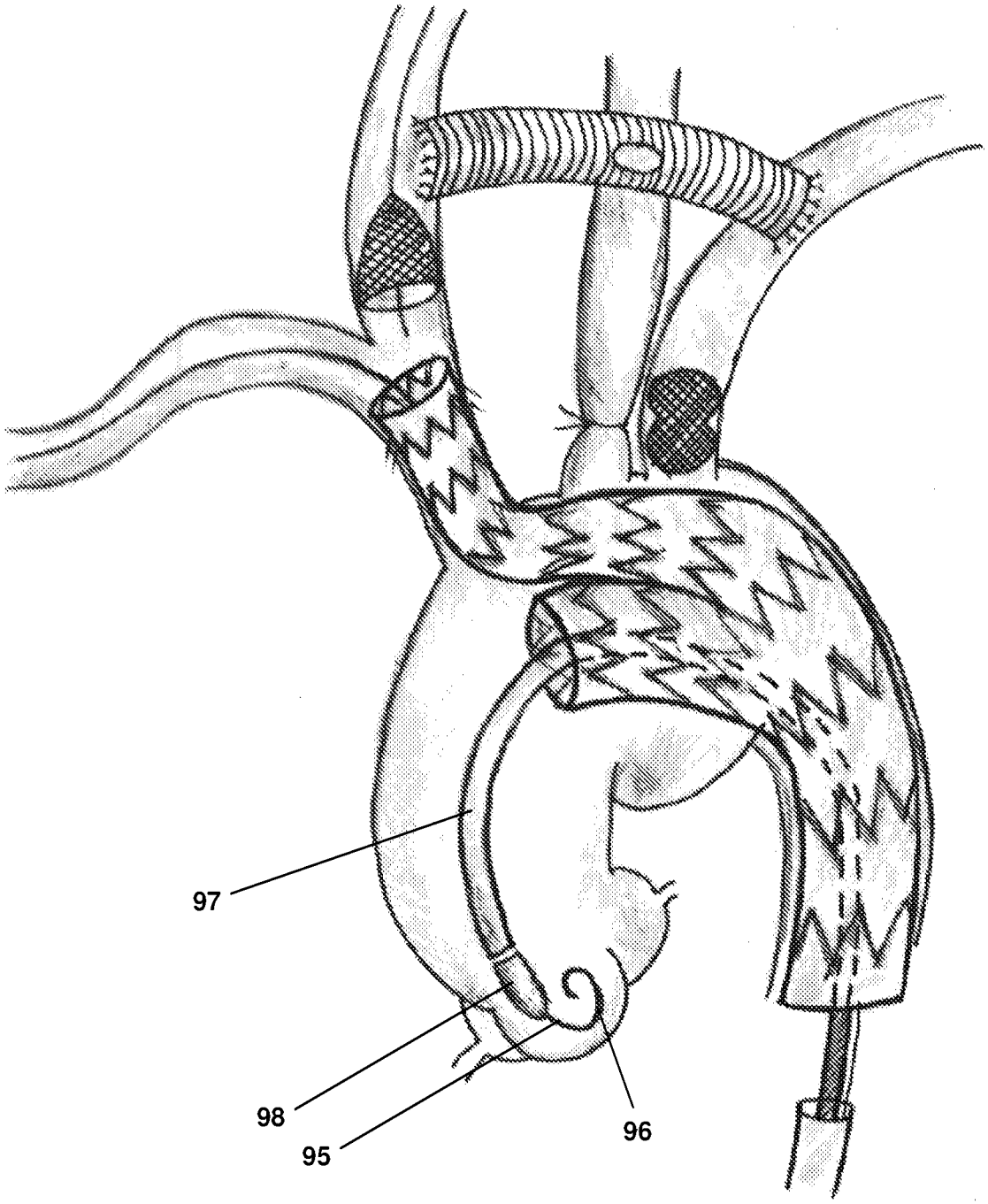

FIG. 5A

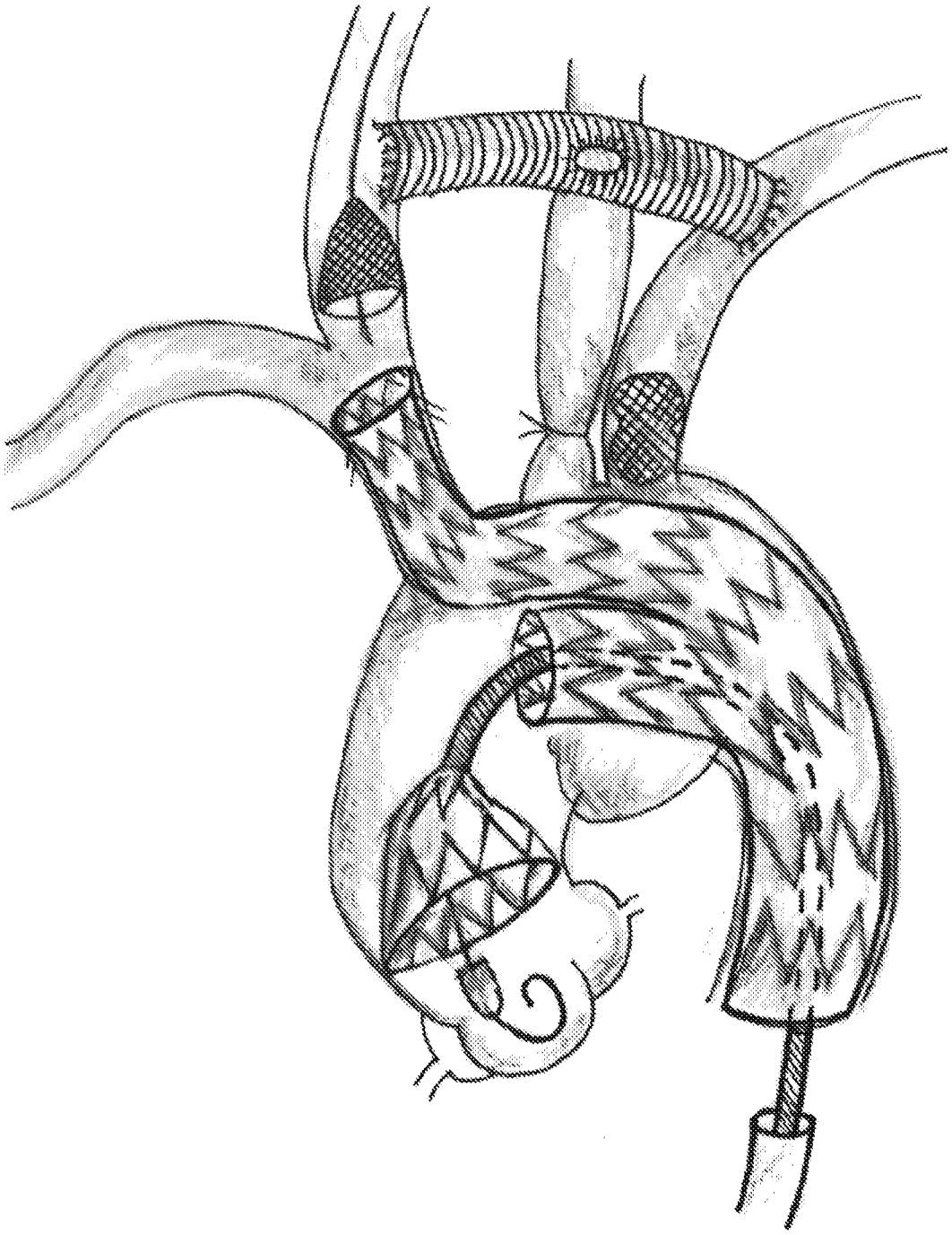

FIG. 5B

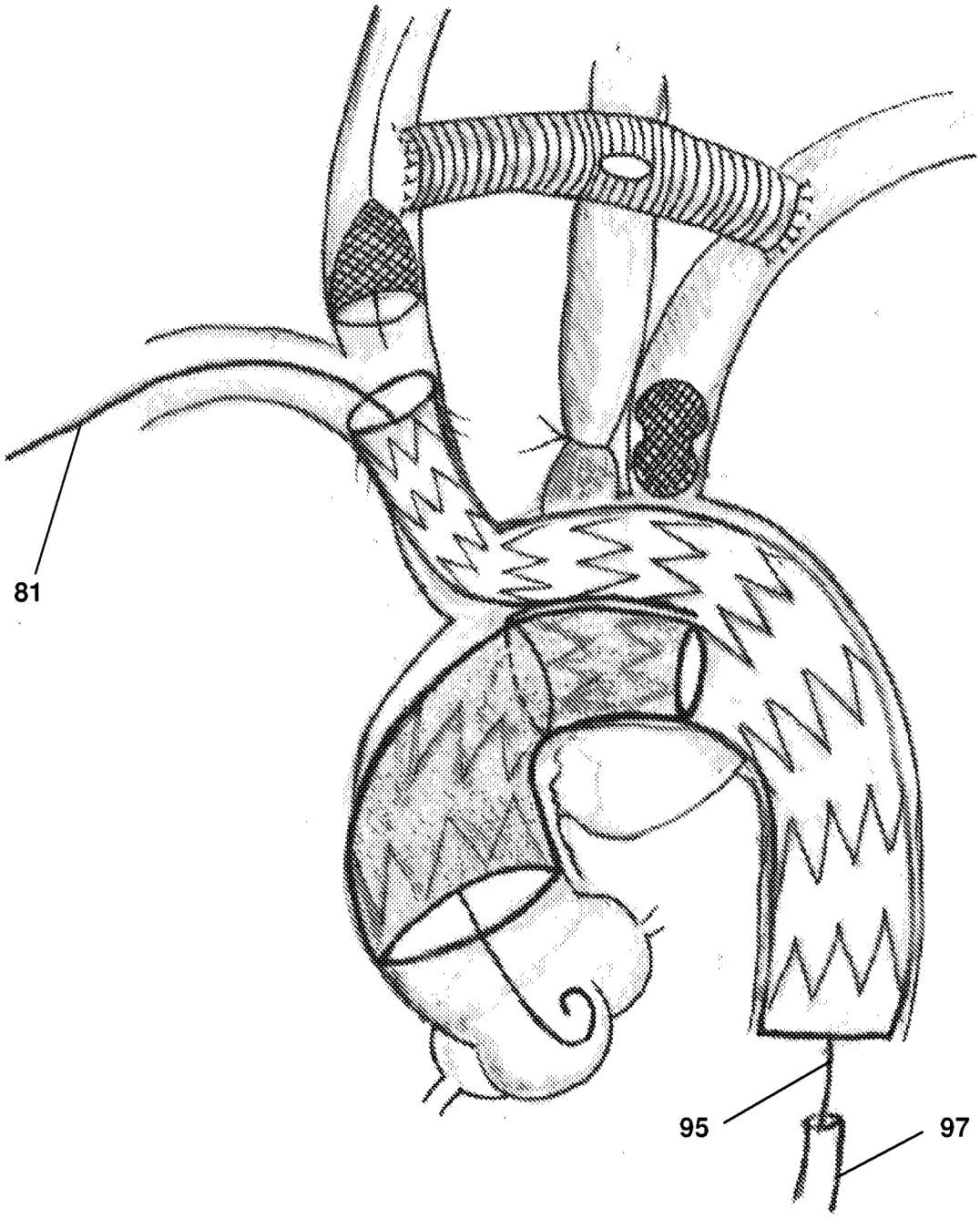

FIG. 5C

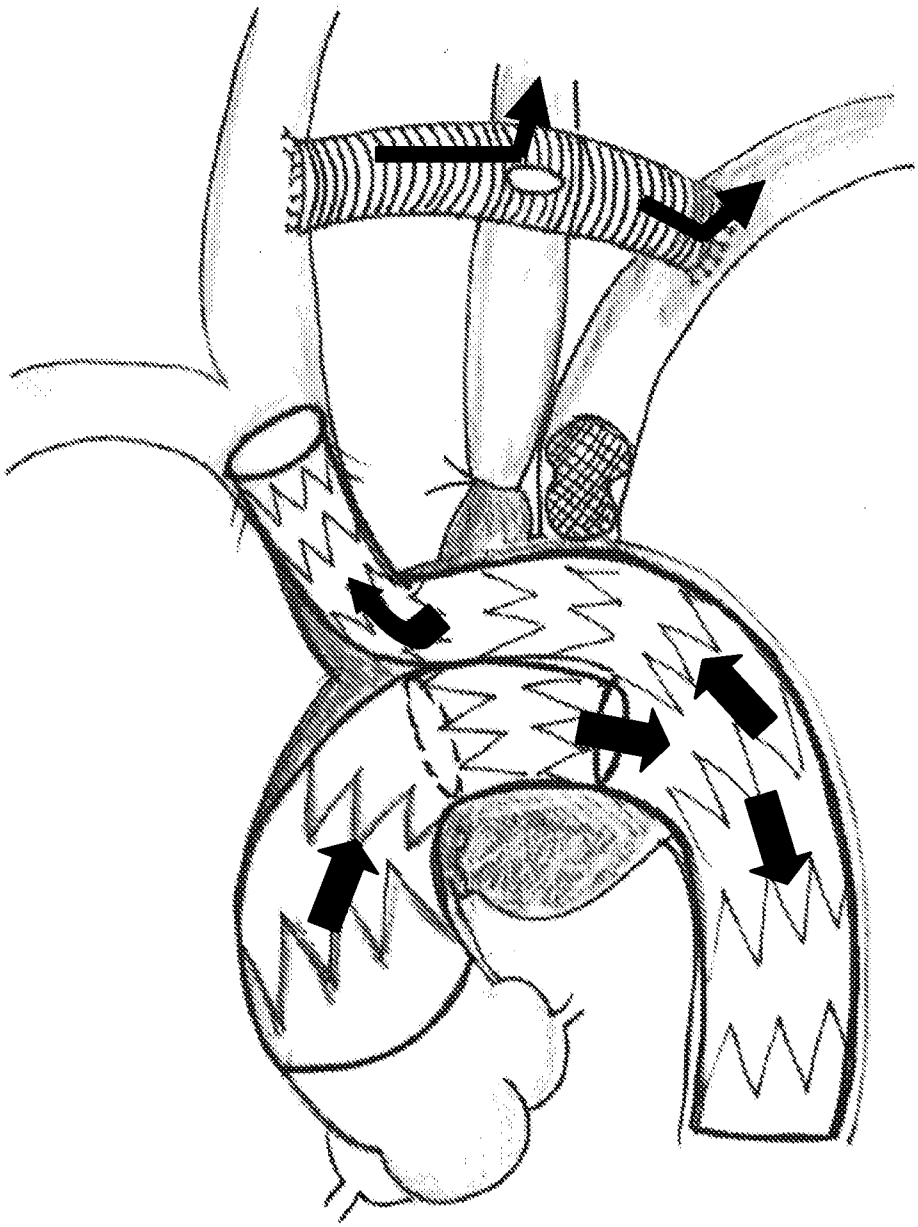

FIG. 5D

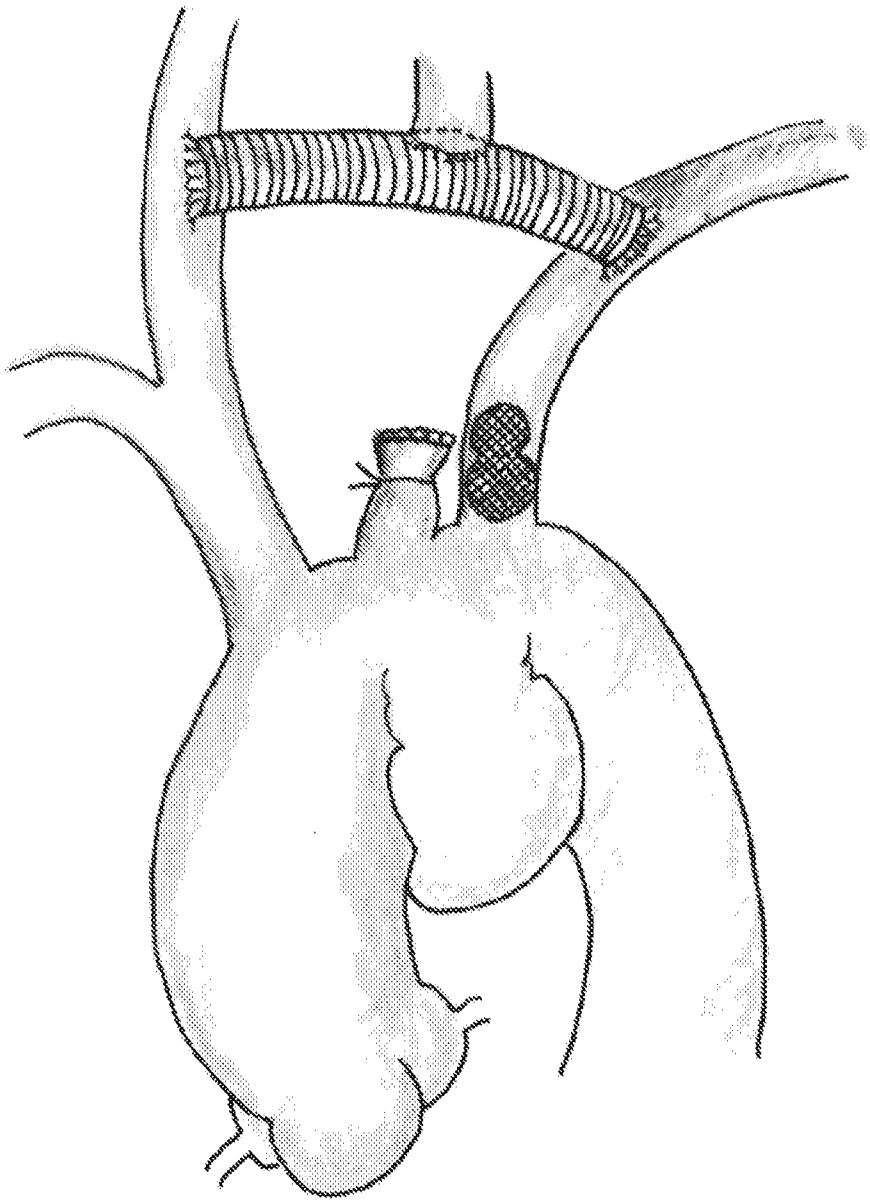

FIG. 6

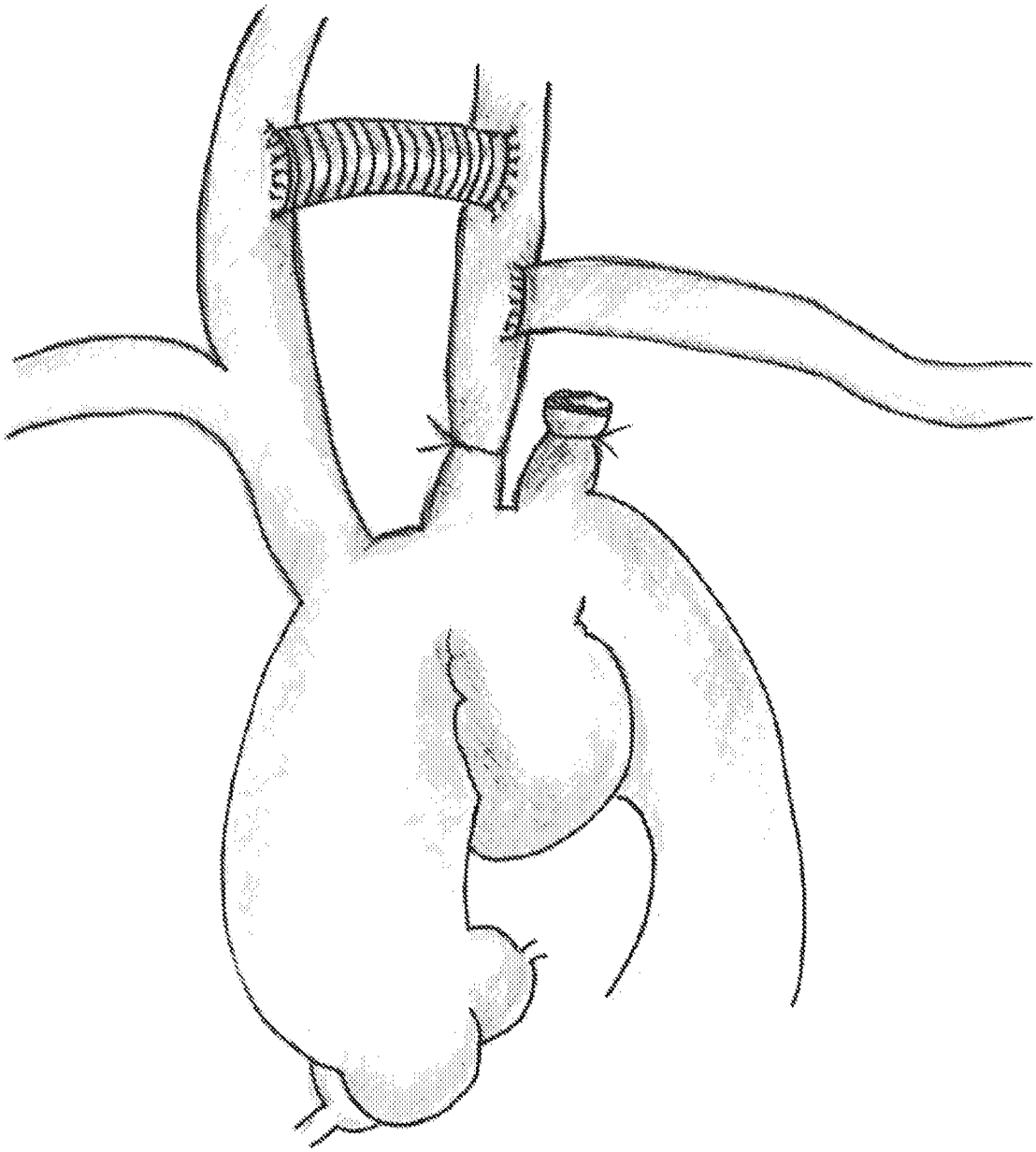

FIG. 7

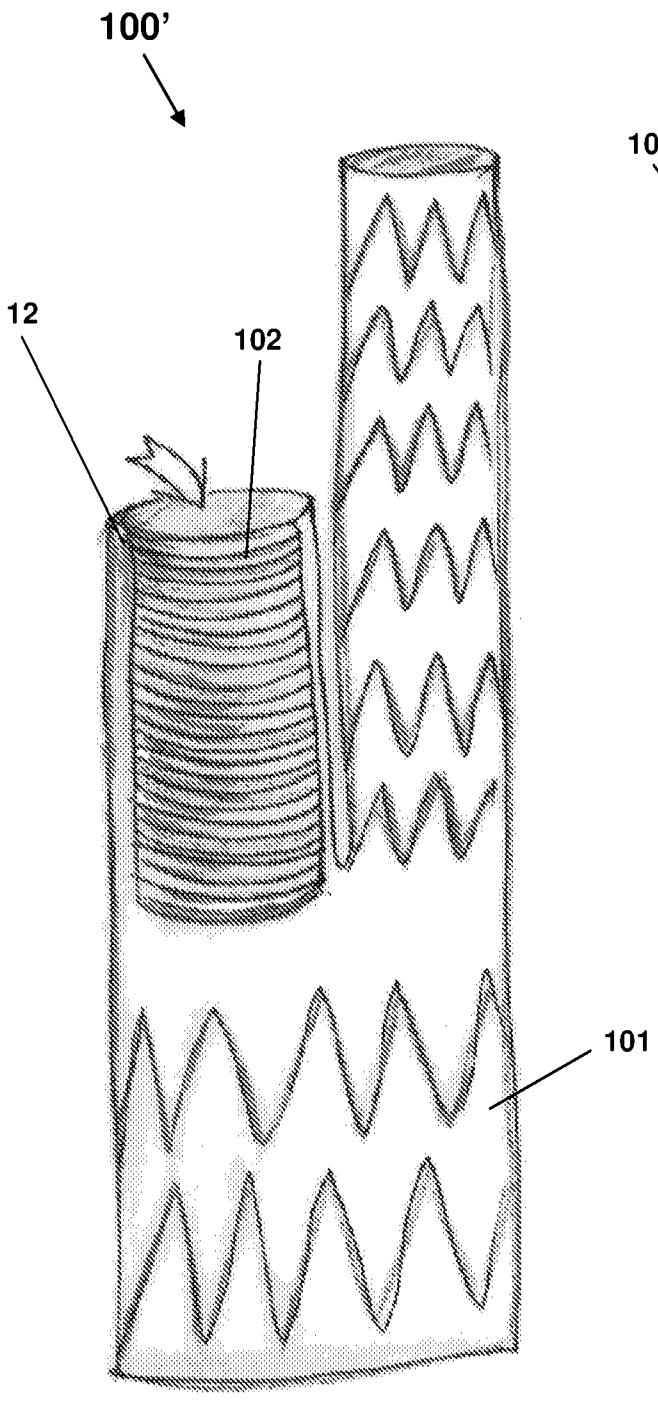

FIG. 8A

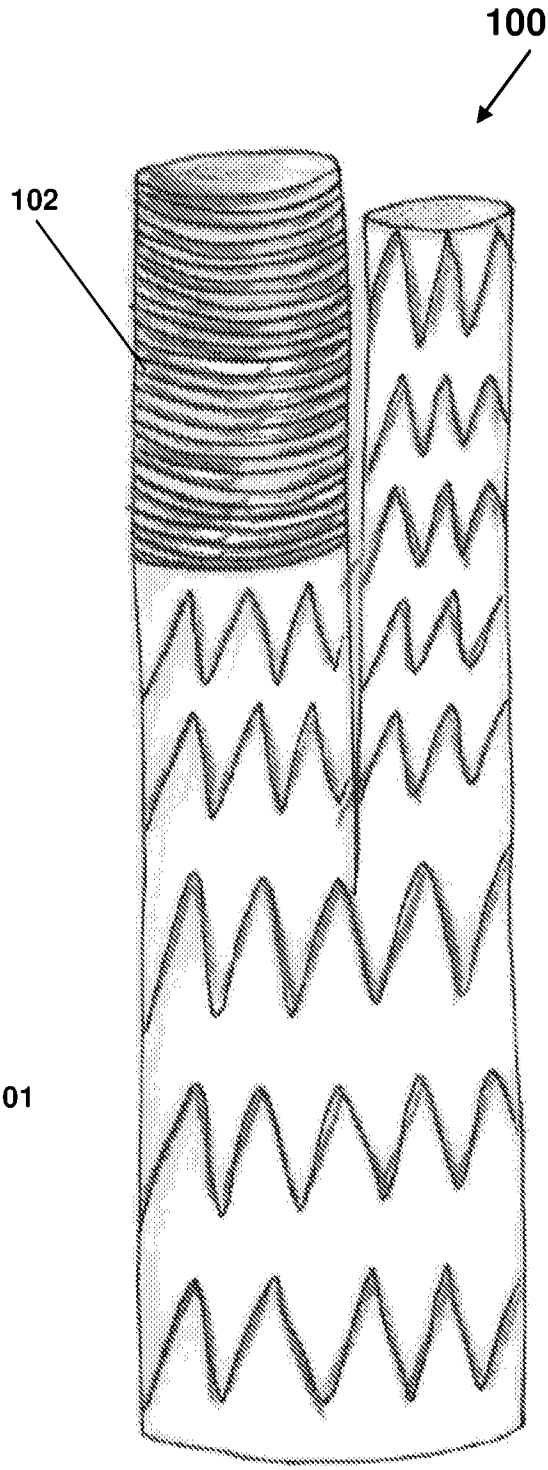

FIG. 8B

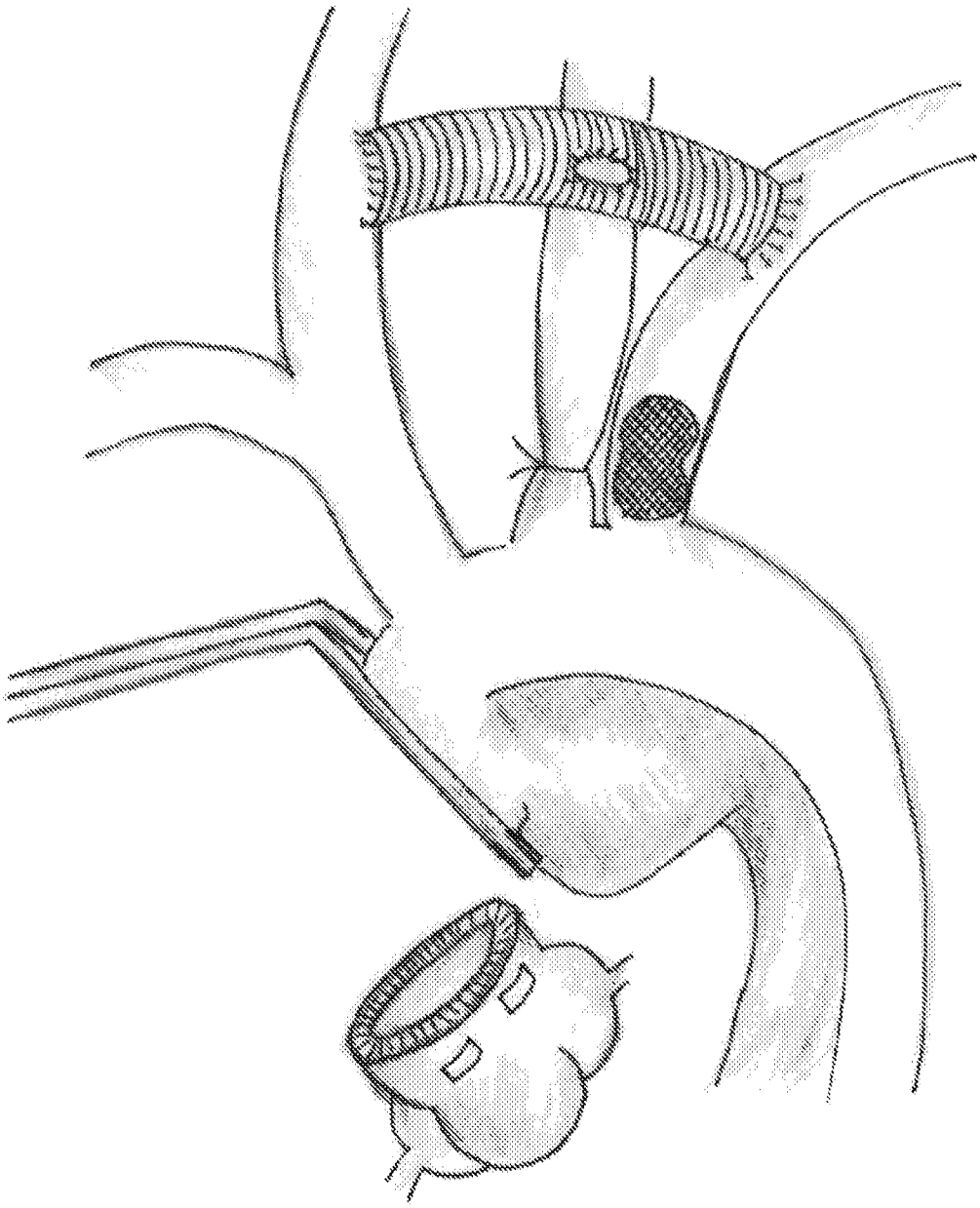

FIG. 9

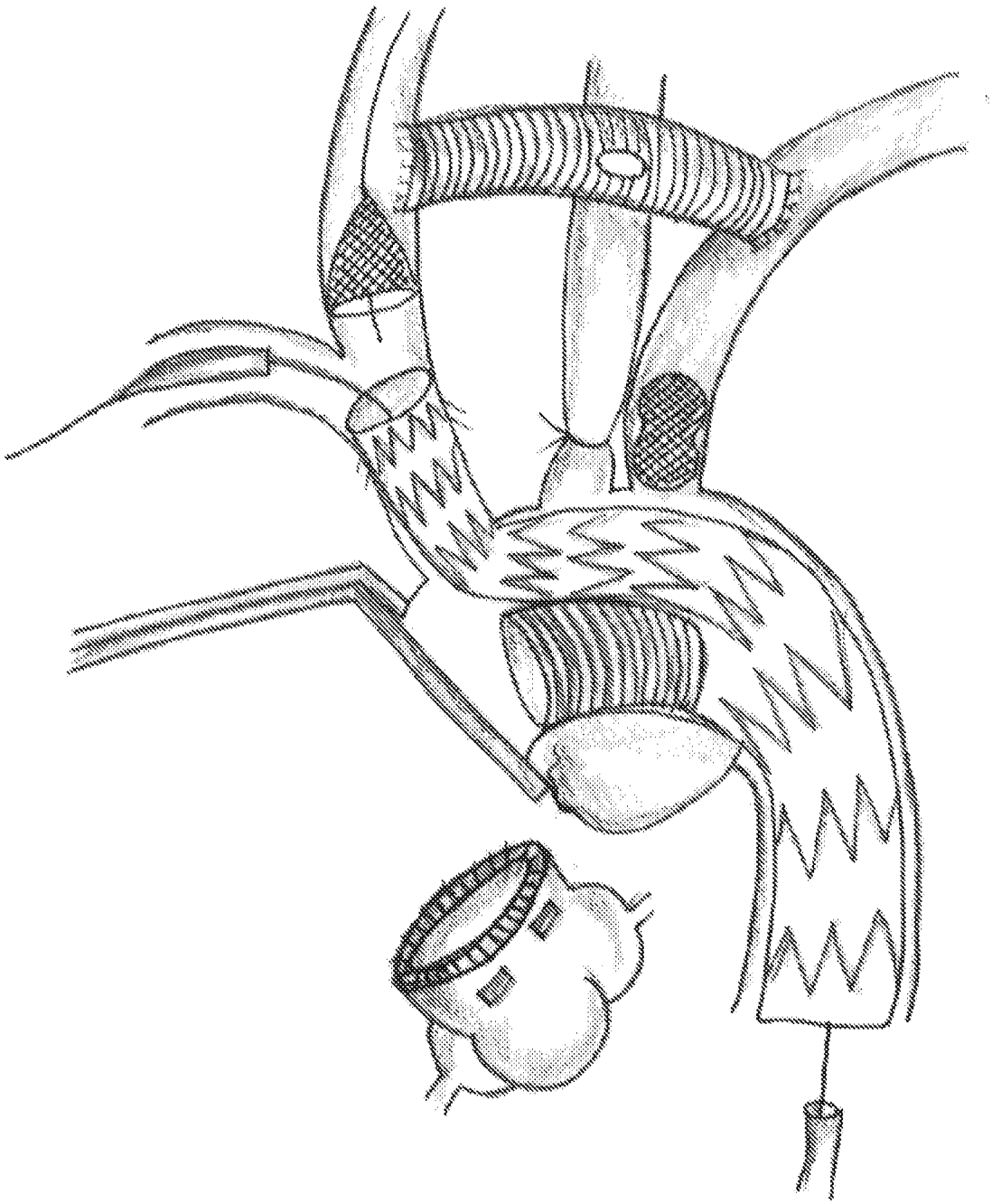

FIG. 10

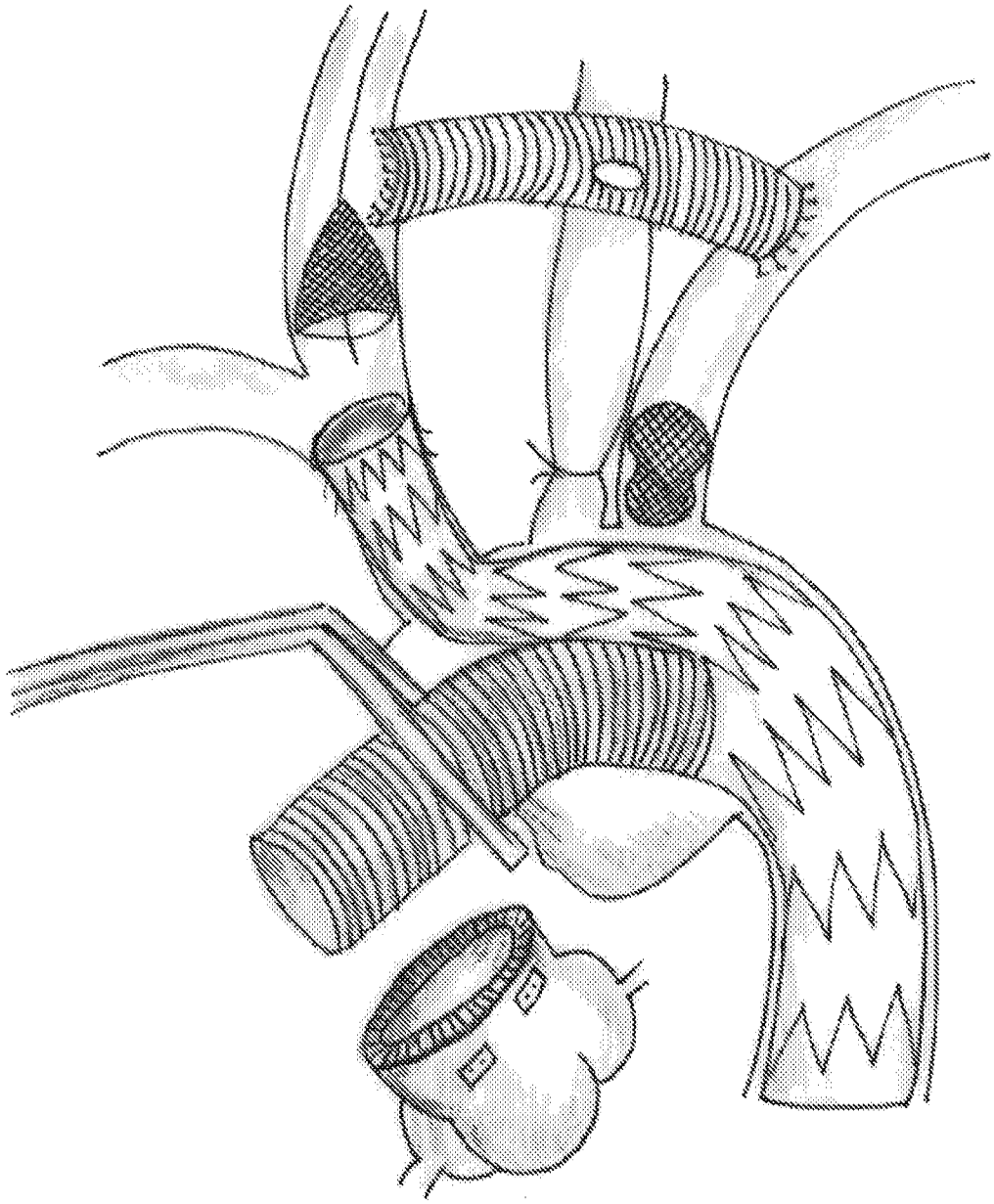

FIG. 11

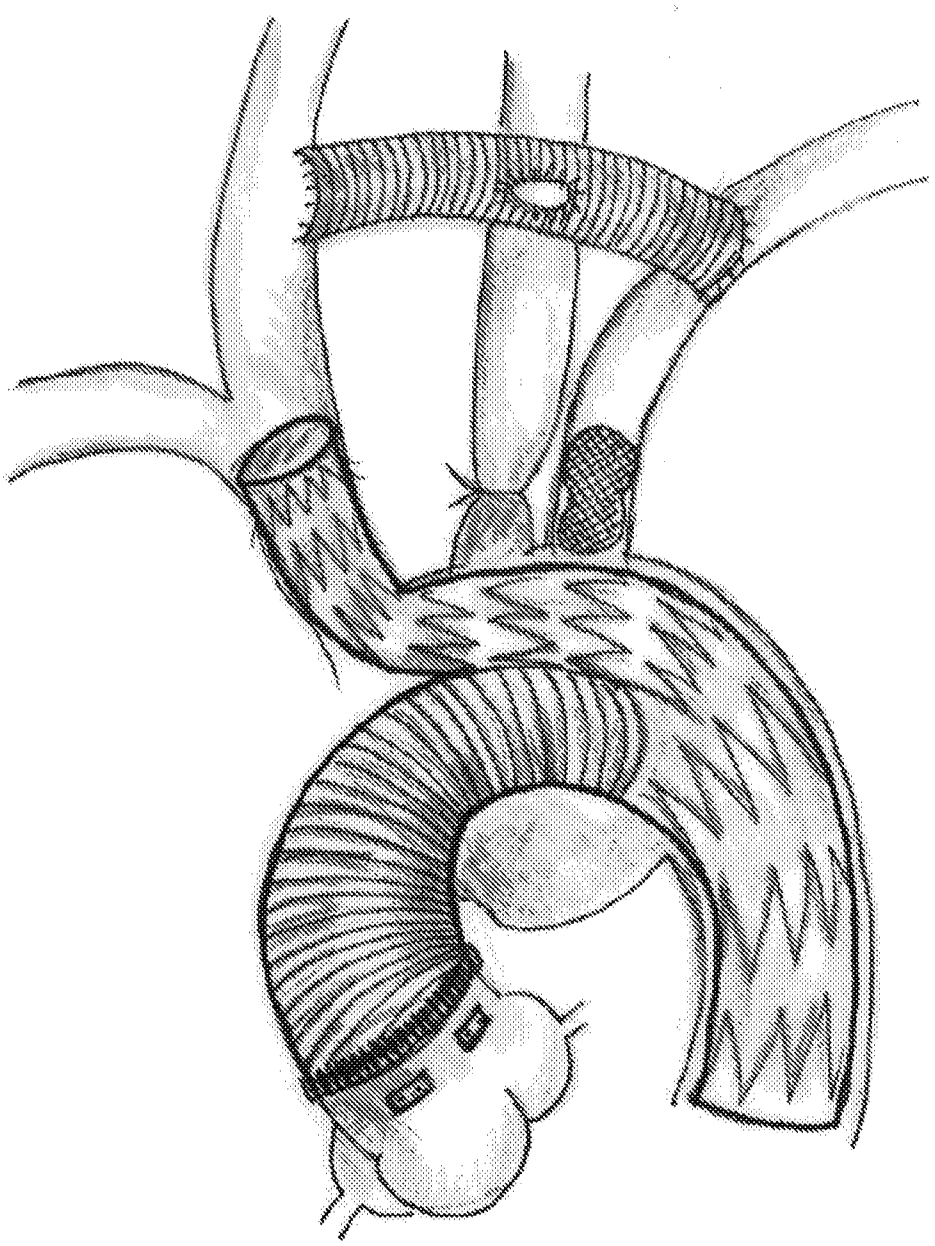

FIG. 12

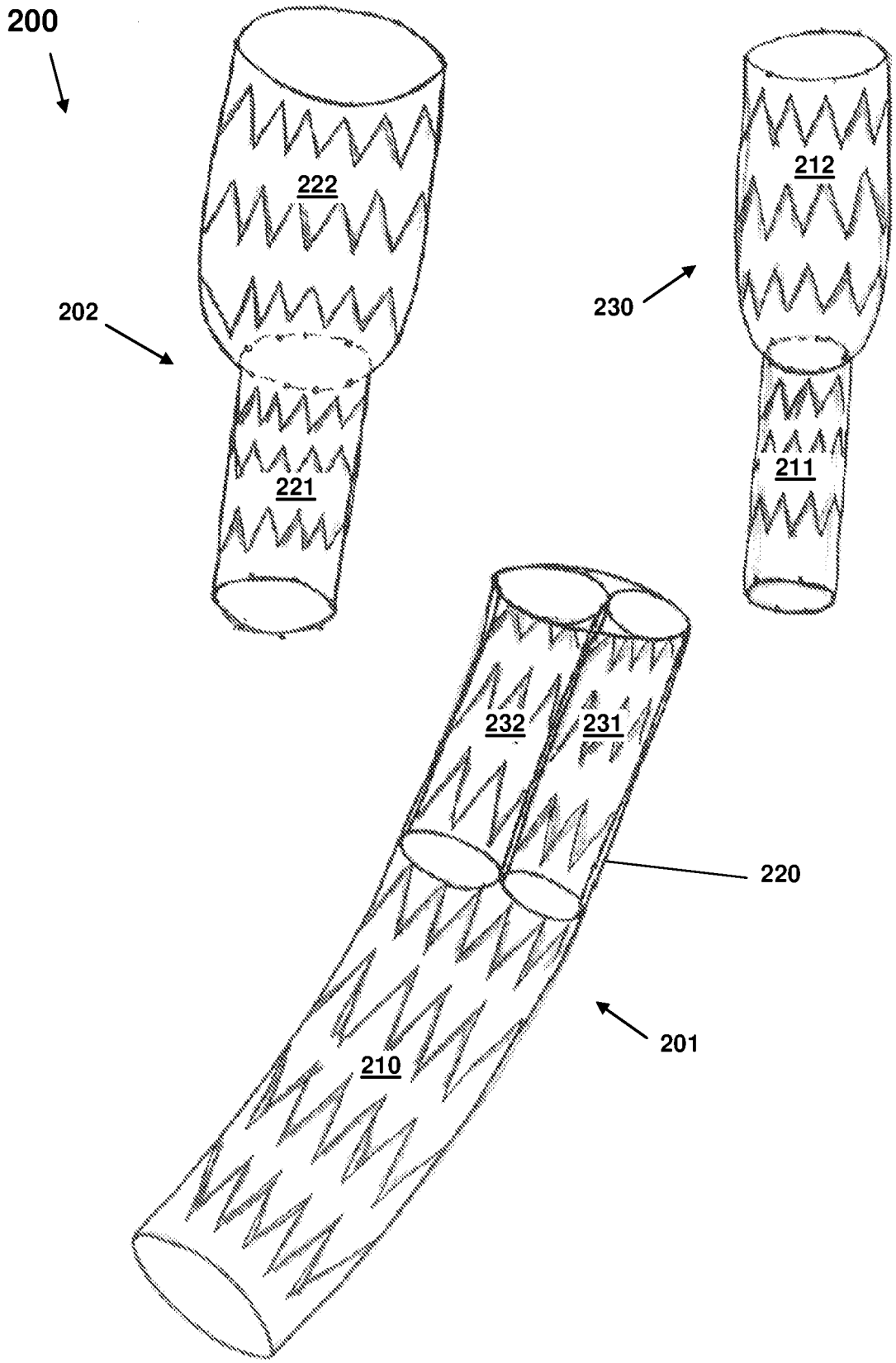

FIG. 13

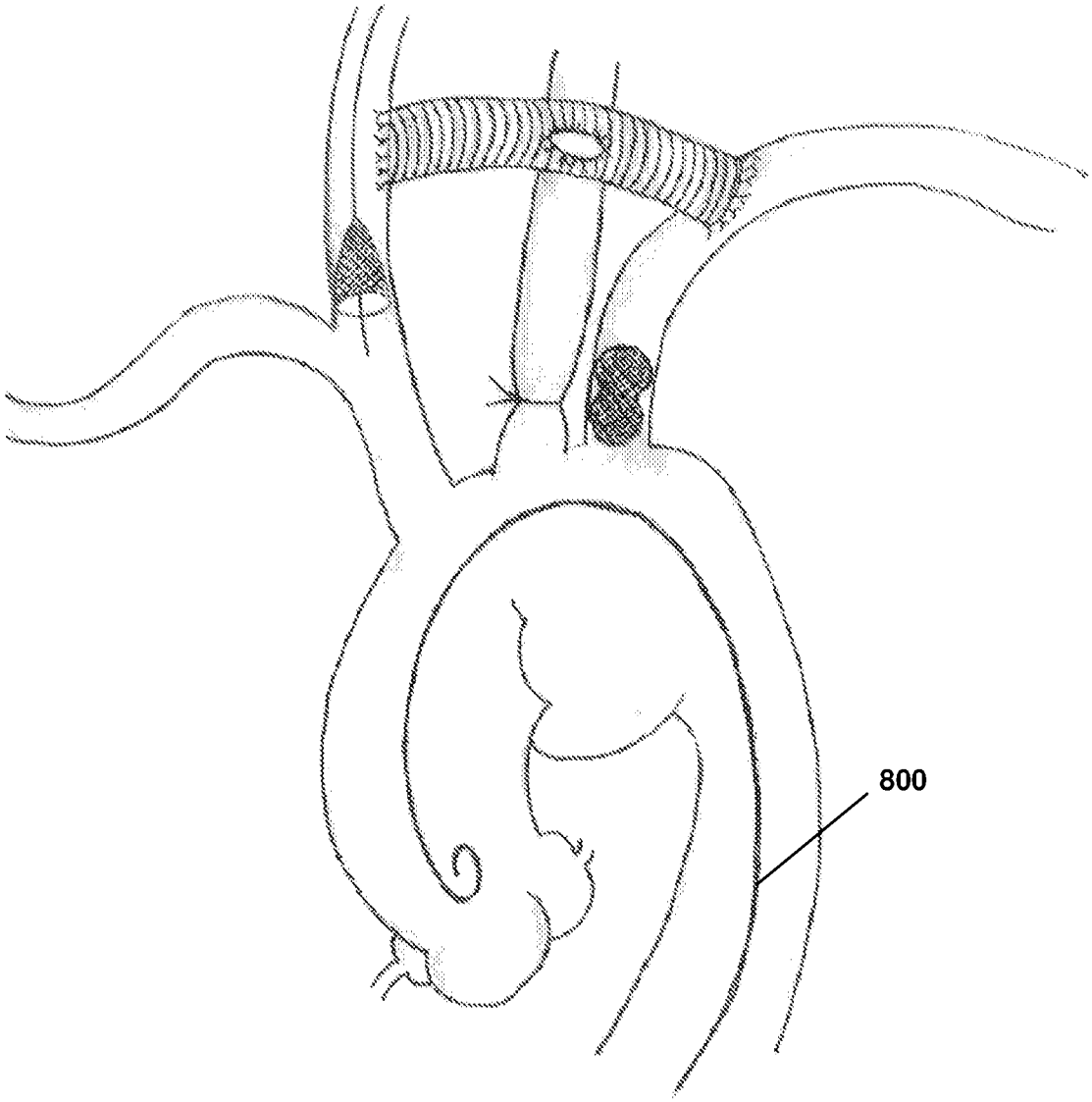

FIG. 14A

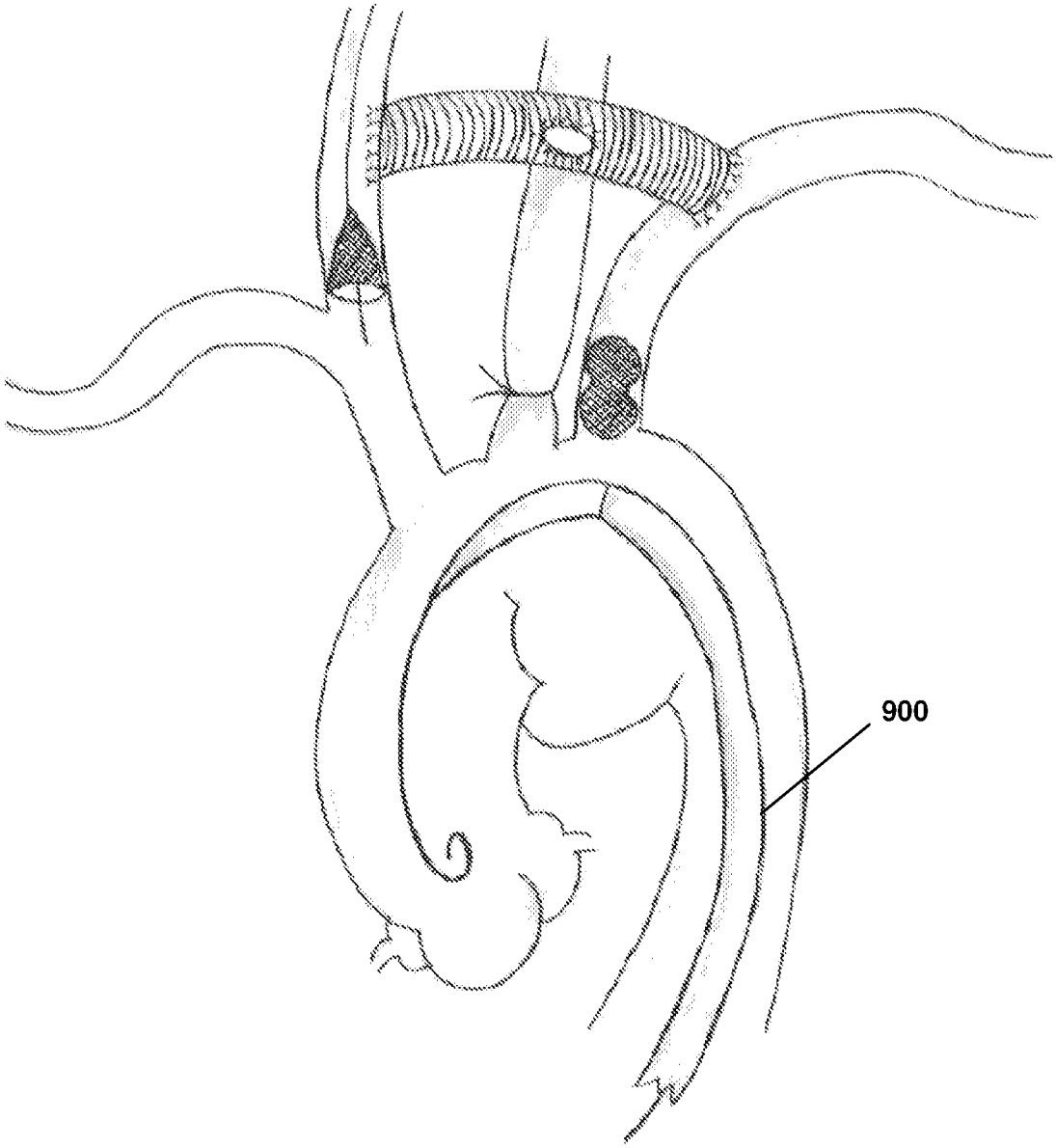

FIG. 14B

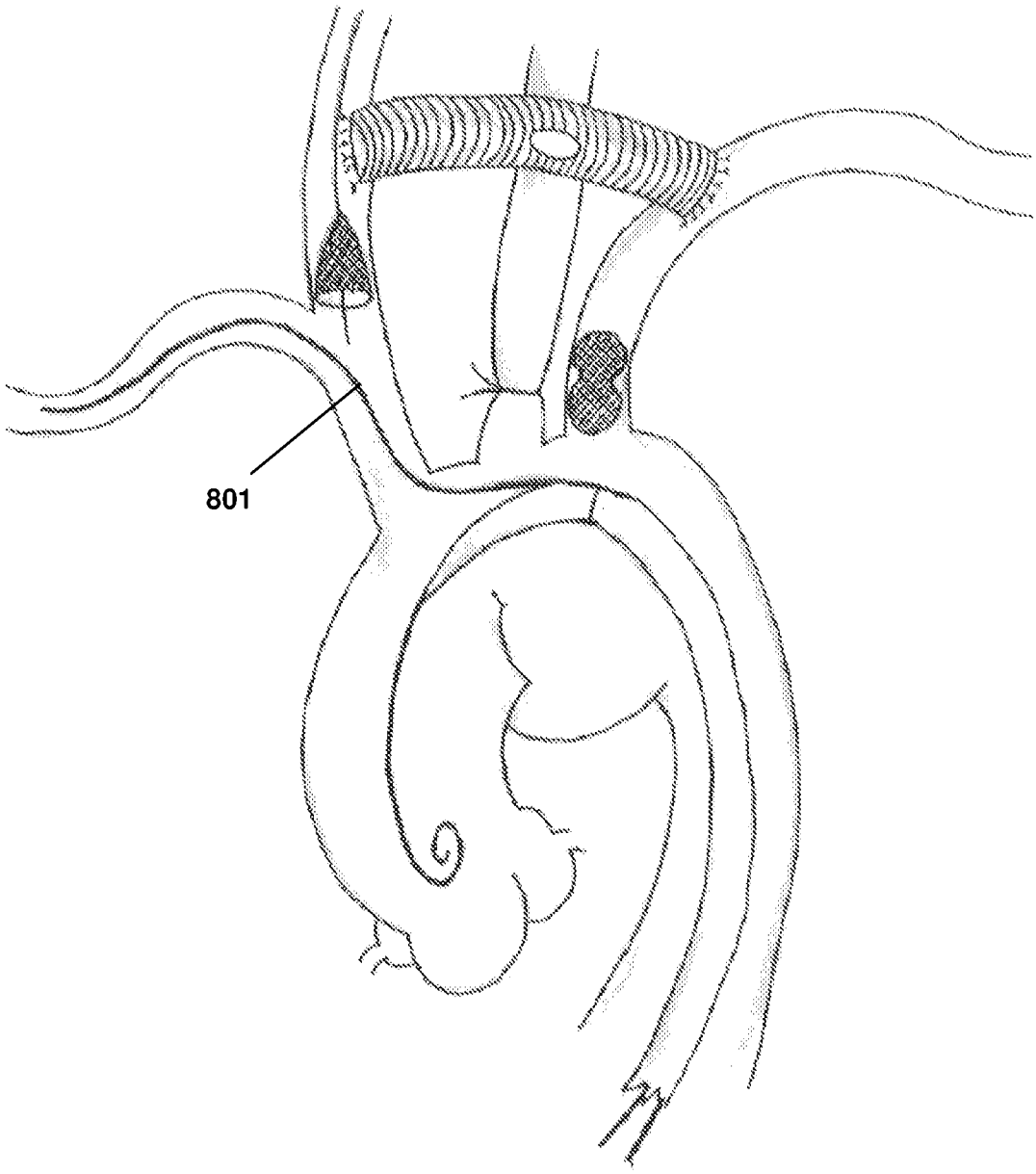

FIG. 14C

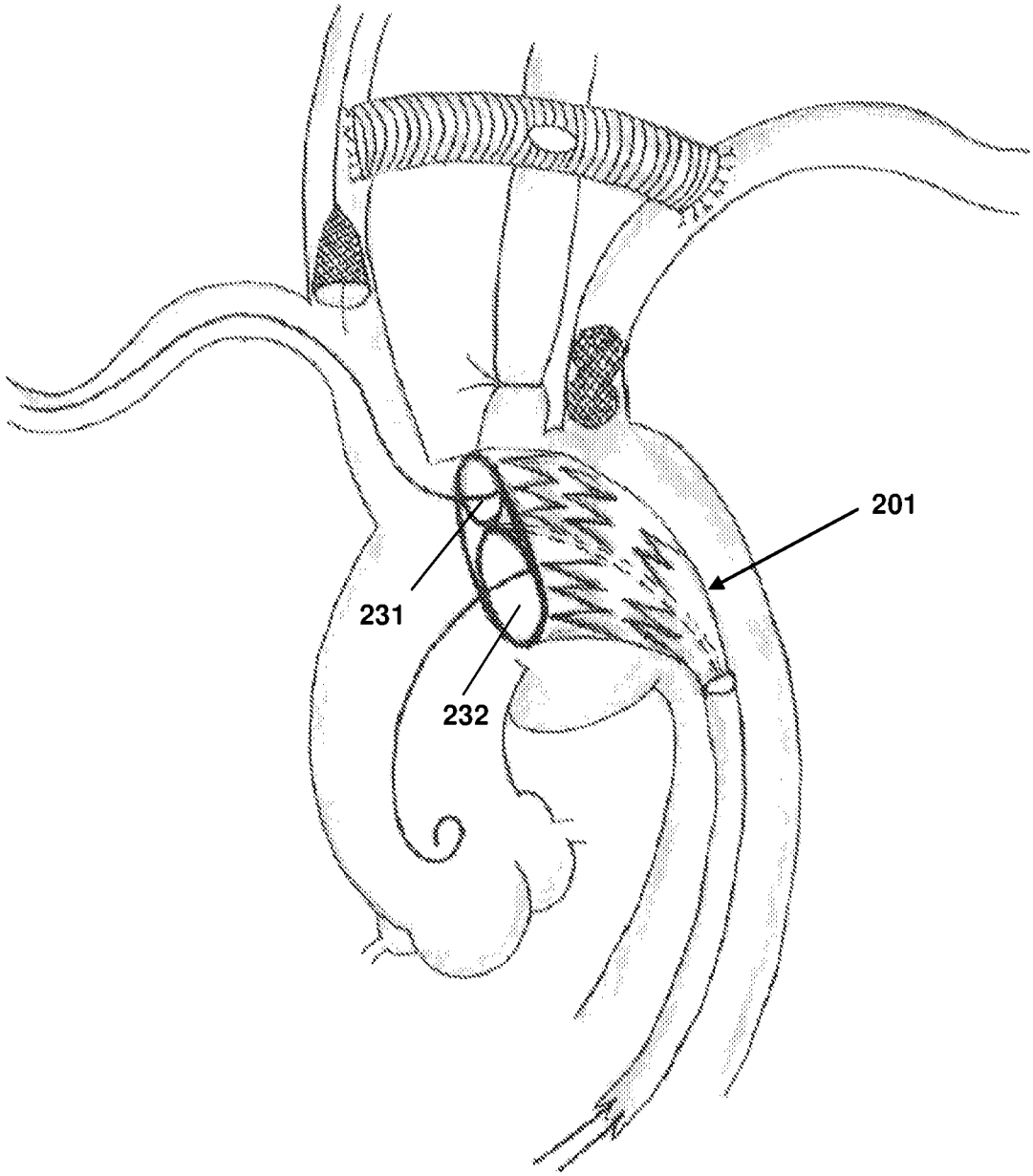

FIG. 14D

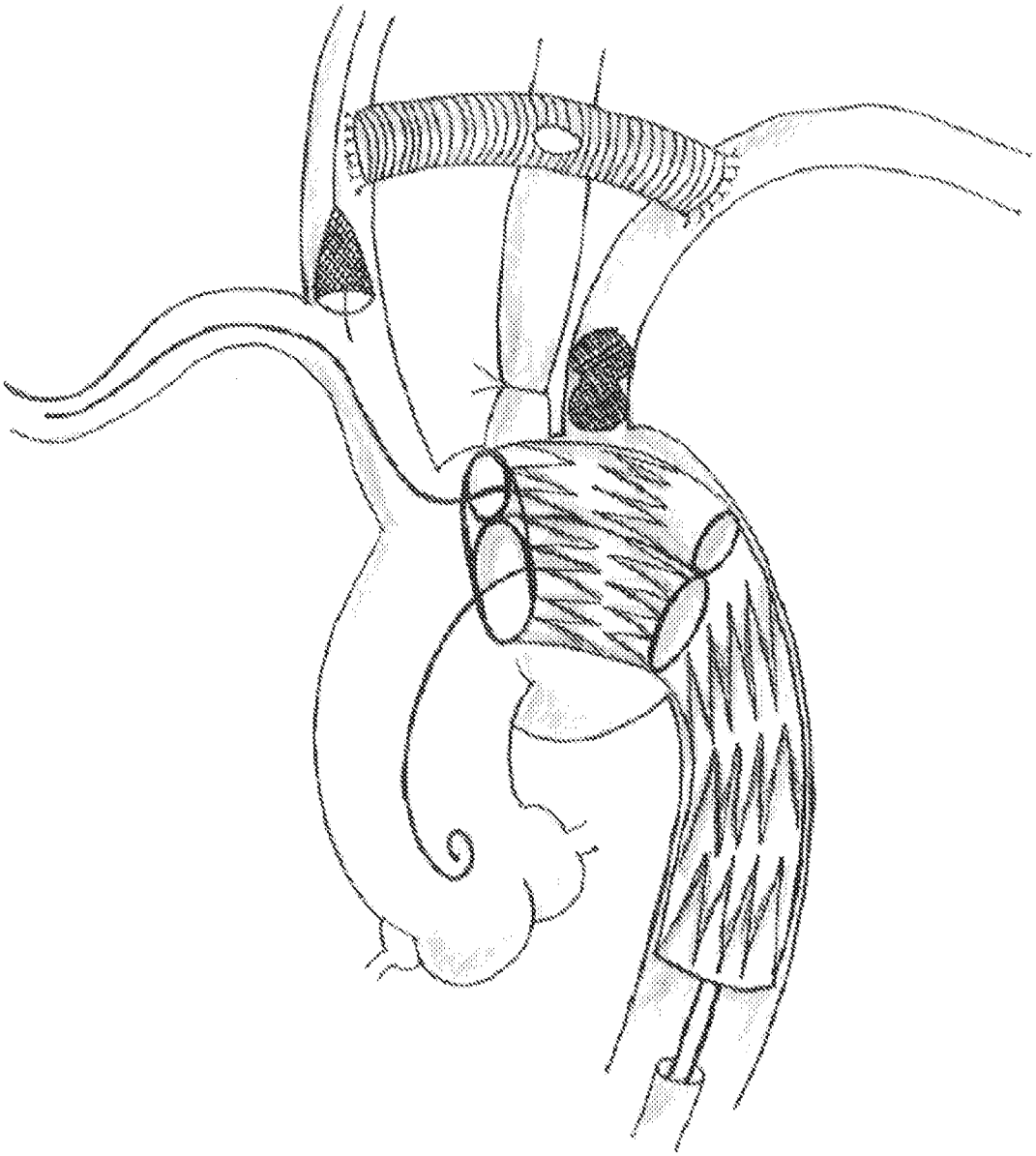

FIG. 14E

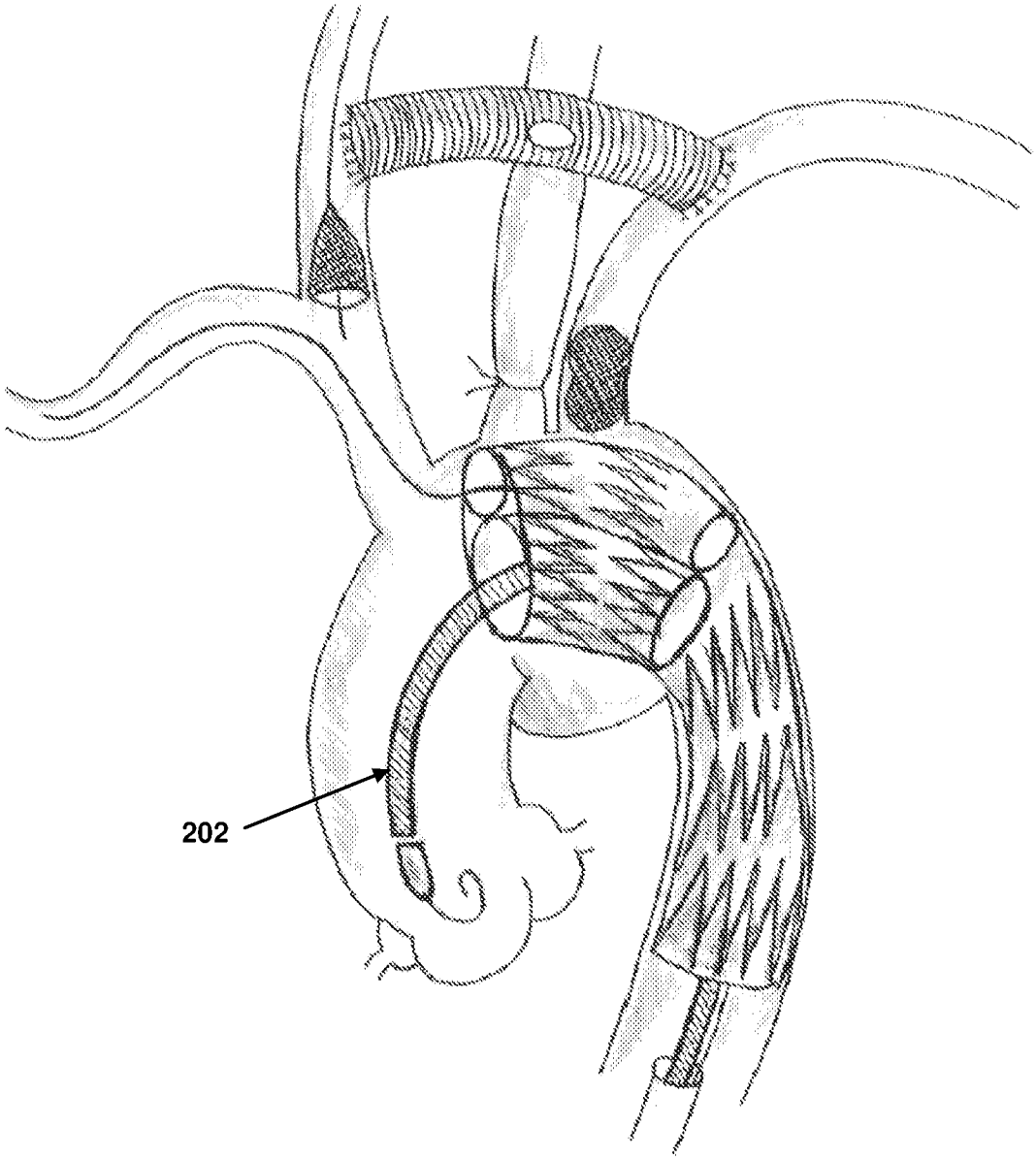

FIG. 14F

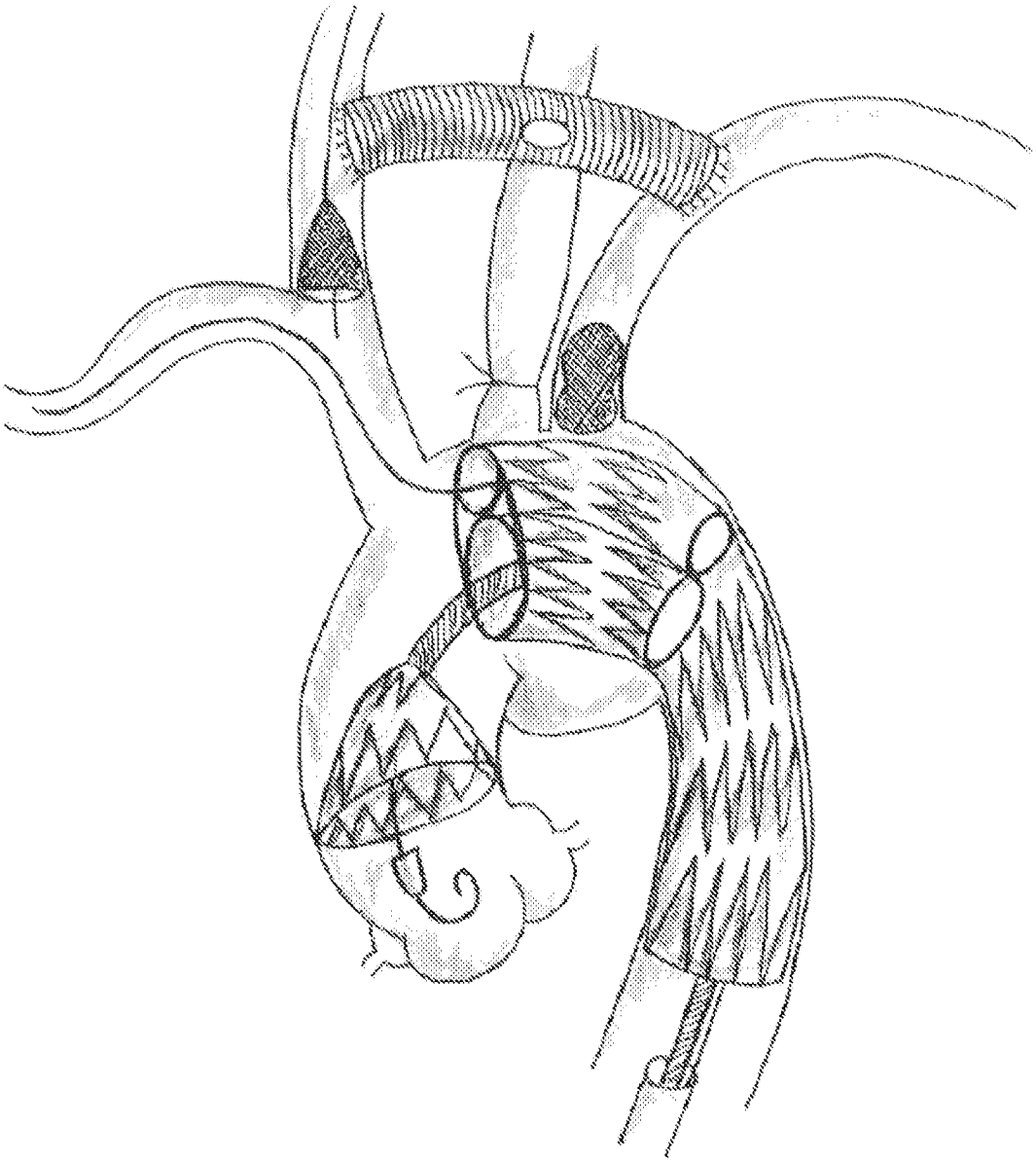

FIG. 14G

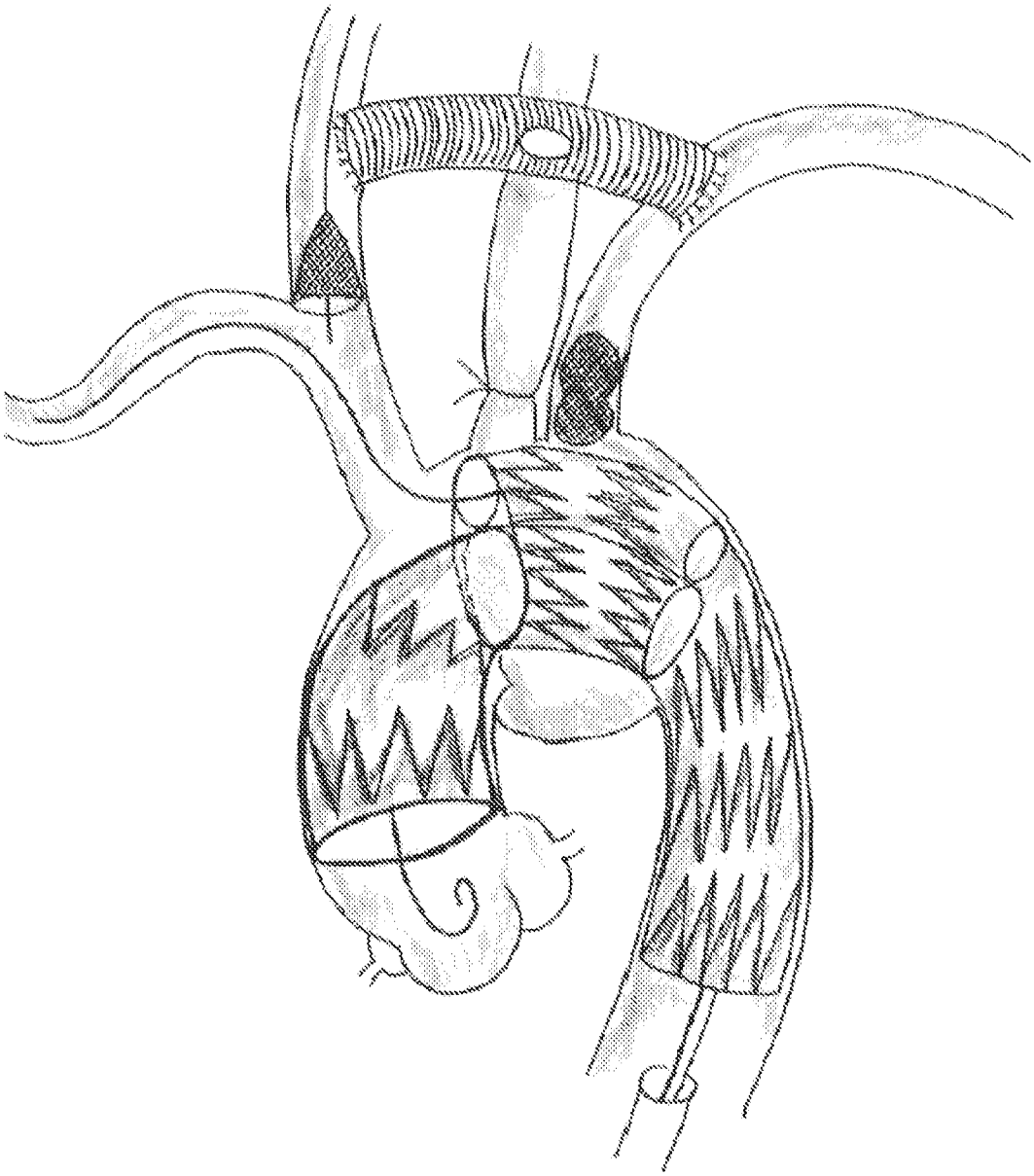

FIG. 14H

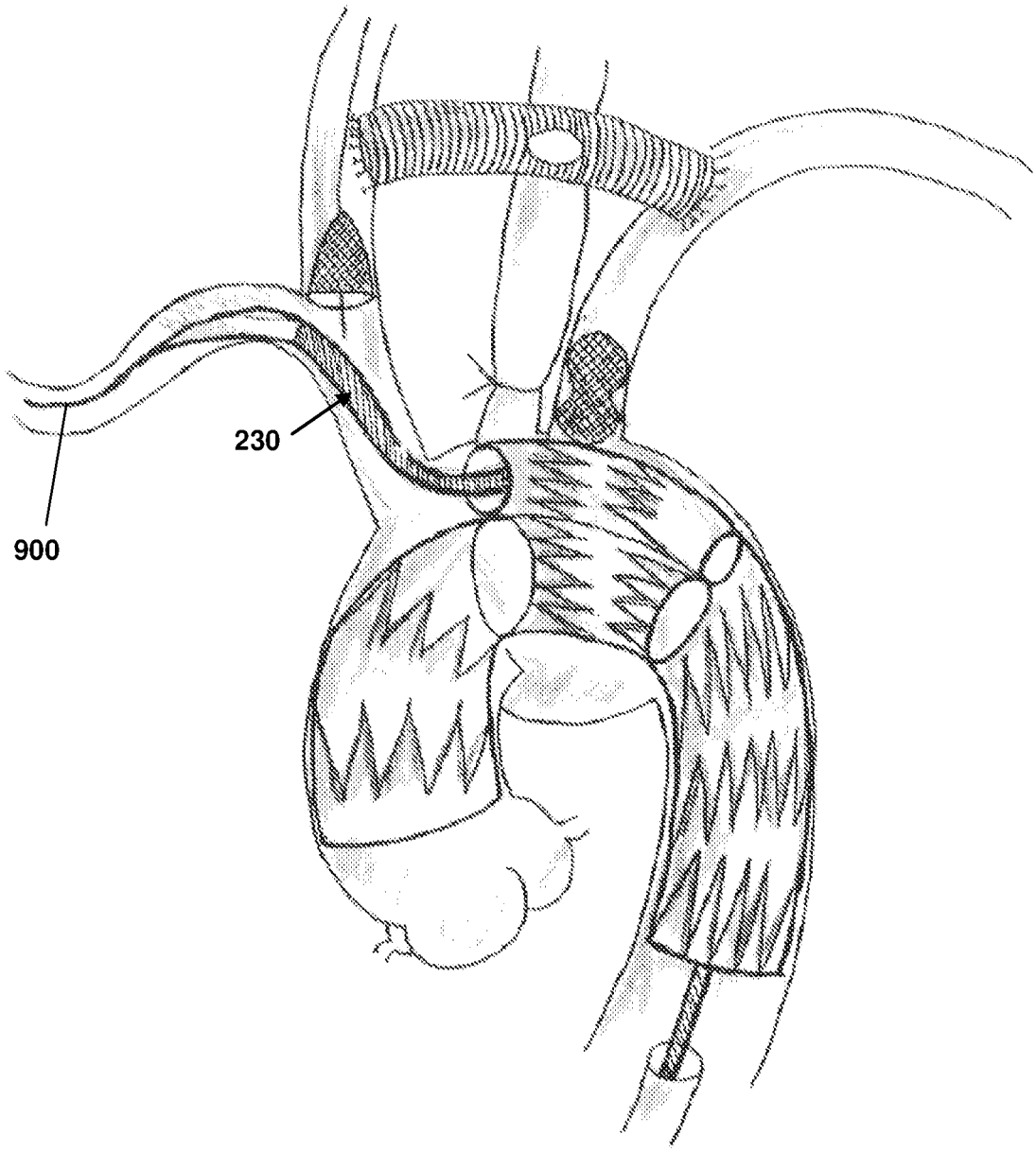

FIG. 14I

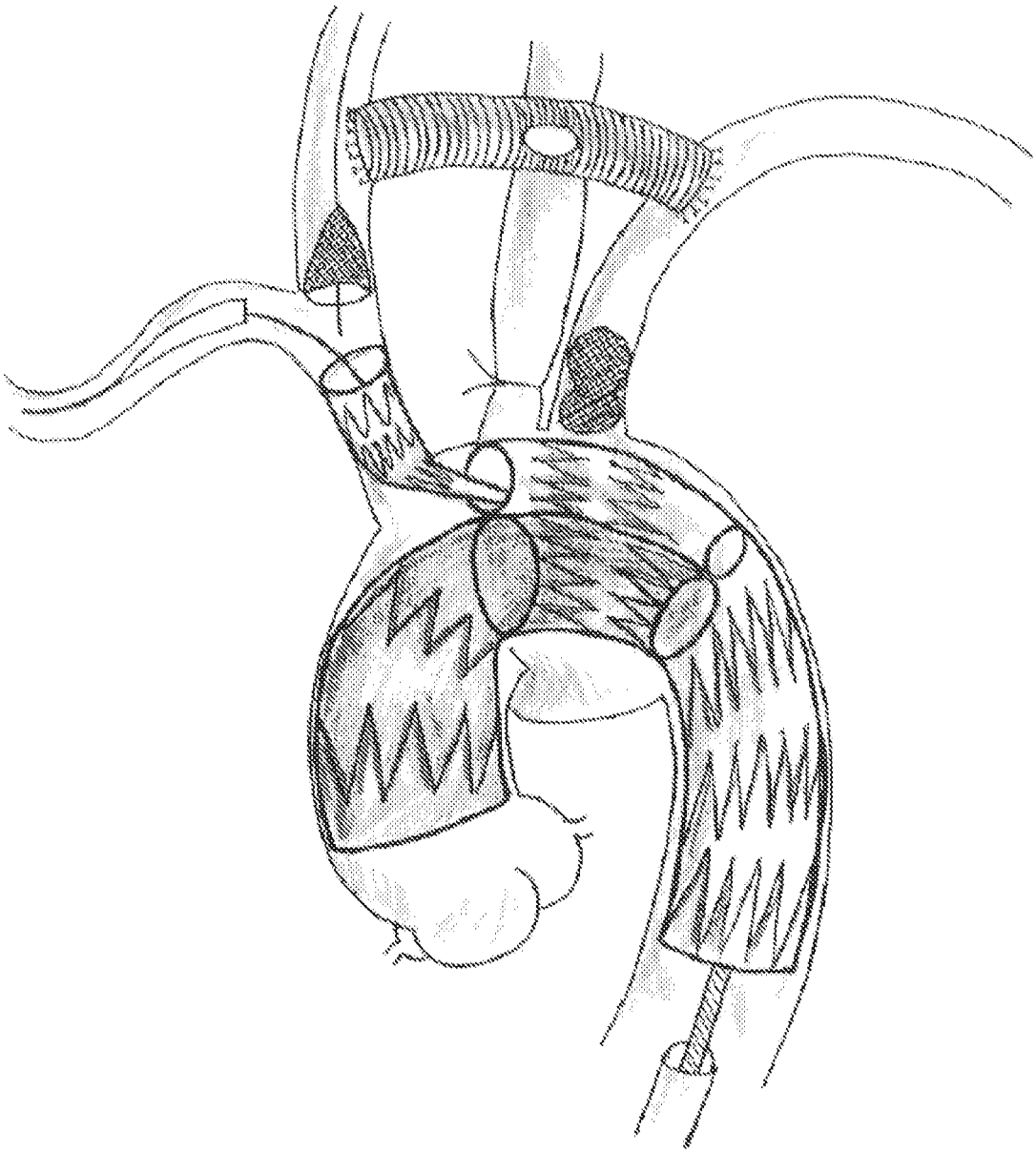

FIG. 14J

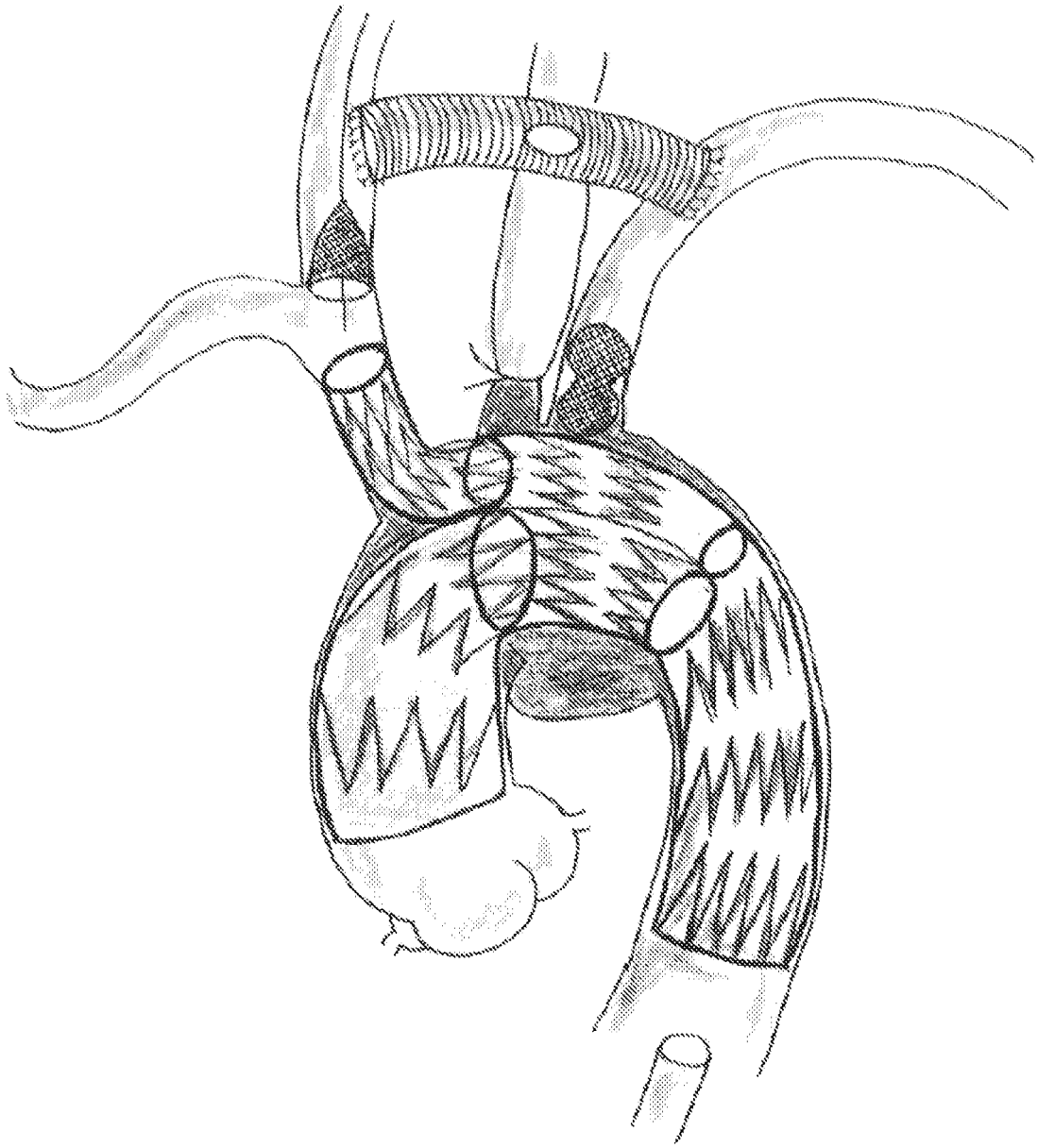

FIG. 14K