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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 May 2007 (24.05.2007)

PCT

(10) International Publication Number
WO 2007/057739 A1

(51) International Patent Classification:
A61B 5/00 (2006.01) *A61B 5/0215* (2006.01)

(21) International Application Number:
PCT/IB2006/003183

(22) International Filing Date:
14 November 2006 (14.11.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/737,131 15 November 2005 (15.11.2005) US

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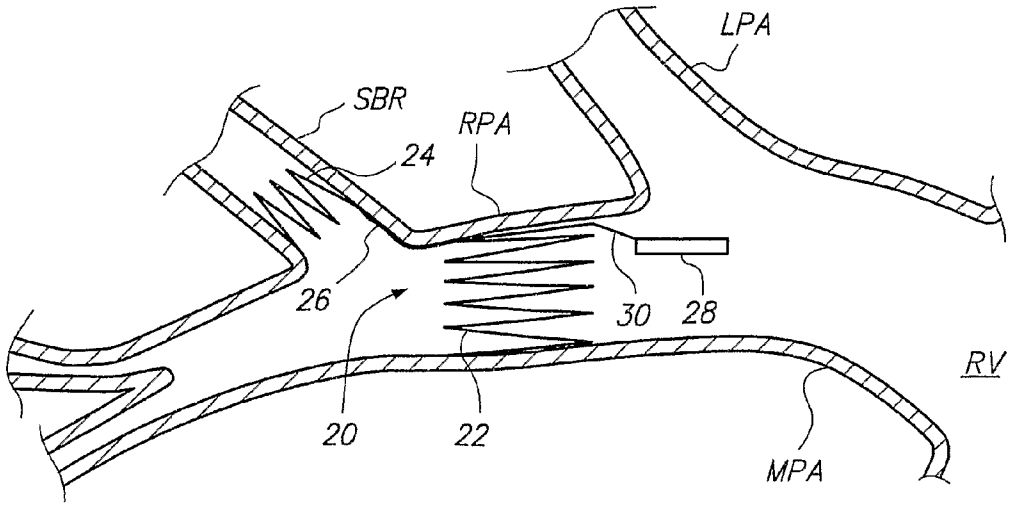
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** IMPLANT DEVICE FOR FIXING A SENSOR IN A BODY LUMEN



(57) **Abstract:** An implant for sensing parameters within an anatomical vessel network of a patient includes a first fixation element having an expanded geometry for firmly engaging a wall of the vessel network at a first longitudinal location, a second fixation element having an expanded geometry for firmly engaging the wall of vessel network at a second longitudinal location, a connecting element mechanically coupling the first and second fixation elements together in an articulating manner, and a sensing element mechanically coupled to the first fixation element opposite the connecting element.

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IMPLANT DEVICE FOR FIXING A SENSOR IN A BODY LUMEN

FIELD OF THE INVENTION

The invention relates to the field of implantable medical devices, and in particular, to implantable devices for positioning a sensor within a body lumen, such as the lumen of a blood vessel.

BACKGROUND OF THE INVENTION

The use of sensing devices in anatomical lumens is well known. For example, U.S. Patent No. 4,485,813 describes a cardiac pacemaker sensor that can be permanently implanted in a specific location within a patient's body. U.S. Patent Nos. 6,645,143, 6,053,873, and 6,442,413 and U.S. Patent Publication No. 2002/0188207 describe medical monitoring sensors designed to be permanently implanted in blood vessels and capable of sensing and transmitting via a telemetry link to an external monitor. The implanted sensing devices are utilized for monitoring physiological parameters within the patient's body.

Because the force created by the blood flow and/or heart movement, which may act on an implanted sensing device like a sail, tends to drag the sensing device longitudinally along the vessel, or rotate it in the case where the sensing device is implanted adjacent a bifurcation of a vessel branch, it is critical that the anchoring force created between the sensing device and the wall of the blood vessel be as great as possible. However, high local or radial force on the relative weak pulmonary artery vessel wall may cause perforation or aneurysm. Many of the vascular implantation techniques assume that the segment of the blood vessel in which the sensing device is intended to be implanted is straight (i.e., it has no branches). In some cases, however, the

vessel segment may be branched. If the vessel segment adjacent the branch is long enough to accommodate the entire length of the sensing device, the sensing device may be implanted within the blood vessel without regard to the branch. If, however, the length of the vessel segment is limited, the sensing device may not be adequately implanted within the vessel segment without crossing the branch. In this case, the implanted sensing device may block future access to the vessel branch, e.g., during catheterization, may be unstable due to the transverse blood flow through the branch, and worse yet, may cause blood clots that may potentially result in an embolism. As a result, the length of the sensing device sufficient for affixation to the wall of the blood vessel may have to be reduced in order to accommodate the branched vessel. In addition, the diameters of many blood vessels are not uniform, and may even be conical, thereby presenting further challenges to lengthening the sensing device.

The right pulmonary artery, which is frequently the target of sensor implantation, such as for the purpose of monitoring hemodynamic parameters indicative of the efficiency of the heart or measure the glucose level of the blood, is both branched and non-uniform. For example, referring to Fig. 1, an implantable sensing device 10, which generally includes a fixation element 12 (e.g., a stent) and a sensing element 14 coupled to the fixation element 12, is shown implanted within the right pulmonary artery RPA of a patient. As shown by the arrows, blood flows from the right ventricle RV of the heart, out through the main pulmonary artery MPA, which branches into the right pulmonary artery RPA and a left pulmonary artery LPA. The sensing element

14, once implanted, may thus be capable of monitoring, e.g., the hemodynamic parameters of the blood flowing from the right ventricle RV.

As can be seen in Fig. 1, the right pulmonary artery RPA branches into various side branches SBR, none of which is crossed by the sensing device 10 to prevent the afore-mentioned problems from occurring. However, because the length of the implantable segment of the right pulmonary artery RPA (i.e., the segment between the point at which the right pulmonary artery RPA begins and the point at which the first side branch SBR, known anatomically as "Truncus anterior", begins) is relatively short (on average, about 40mm), the length of the fixation element 12 must be relative short in order to accommodate the side branch SBR.

Because the length of the fixation element 12 must be relatively short, the stability of the sensing device 10 may be compromised. In addition, as can be seen from Fig. 1, the diameter of the right pulmonary artery RPA substantially decreases in the distal direction (i.e., from right to left), which causes the proximal end of the fixation element 12 to engage the vessel wall less firmly than the distal end of the fixation element 12 engages the vessel wall, thereby further compromising the stability of the sensing device 10.

There, thus, is a need to provide an improved technique for implanting a sensing device in a non-uniform and branched anatomical vessel.

SUMMARY OF THE INVENTION

In accordance with one embodiment of the invention, an implant for sensing parameters within an anatomical vessel network (e.g., the blood vessel network) of a patient is provided. The implant comprises a first fixation element having an expanded geometry for firmly engaging a wall of the vessel

network at a first longitudinal location, and a second fixation element having an expanded geometry for firmly engaging the wall of vessel network at a second longitudinal location. The fixation elements can take the form of any suitable element, such as, e.g., a stent or a coil. The first and second longitudinal locations may be, e.g., in a single anatomical vessel, or respectively in a main anatomical vessel and an anatomical vessel branch of the main anatomical vessel. In one method, the vessel network has substantially differing diameters at the first and second longitudinal locations.

The implant further comprises a connecting element mechanically coupling the first and second fixation elements together in an articulating manner. The implant can optionally comprise a third fixation element having an expanded geometry for firmly engaging the wall of vessel network at a third longitudinal location, and another connecting element mechanically coupling the second and third fixation elements together in an articulating manner. Articulation of the fixation elements allows them to expand and move relative to each other, so that, e.g., they can be implanted within misaligned vessel segments (e.g., a main anatomical vessel and a branch of the anatomical vessel) or vessel segments with non-uniform diameters.

The implant further comprises a sensing element mechanically coupled to the first fixation element opposite the connecting element. The sensing element can be, e.g., one or more of a pressure sensor, an accelerometer, a position sensor, a wall motion sensor, a flow sensor, a temperature sensor, an oxygen sensor, a calcium sensor, a potassium sensor, a glucose sensor, a coagulation sensor, an electrical activity sensor, and a pH sensor. In an optional embodiment, the implant further comprises a transmitter configured

for wirelessly transmitting information sensed by the sensing element to a remote receiver.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate the design and utility of embodiments of the invention, in which similar elements are referred to by common reference numerals, and in which:

Fig. 1 is a side view of a prior art sensing device arrangement within a pulmonary arterial network of a patient;

Fig. 2 is a side view of a first sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 3 is a side view of a second sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 4 is a side view of a third sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 5 is a side view of a fourth sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 6 is a side view of a fifth sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 7 is a side view of a sixth sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 8 is a side view of a seventh sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 9 is a side view of an eighth sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 10 is a side view of a ninth sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 11 is a side view of a tenth sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 12 is a side view of an eleventh sensing device arrangement within the pulmonary arterial network in accordance with the invention;

Fig. 13 is a side view of an alternative embodiment of a fixation element used in the eleventh sensing device arrangement of Fig. 12;

Fig. 14 is a side view of another alternative embodiment of fixation element used in the eleventh sensing device arrangement of Fig. 12;

Fig. 15 is a side view of a still another alternative embodiment of a fixation element used in the eleventh sensing device arrangement of Fig. 12;

Fig. 16 is a side view of yet another alternative embodiment of fixation element used in the eleventh sensing device arrangement of Fig. 12;

Fig. 17 is a side view of yet another alternative embodiment of fixation element used in the eleventh sensing device arrangement of Fig. 12;

Figs. 18A-18D are side views illustrating one method of implanting a sensing device using embodiments of the invention, for purposes of better understanding the invention; and

Figs. 19A-19H are side views illustrating other methods of implanting a sensing device using embodiments of the invention, for purposes of better understanding the invention.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Referring to Fig. 2, an implantable sensing device 20 constructed in accordance with the invention will now be described. The sensing device 20 is shown implanted within an anatomical vessel network, and in particular, the pulmonary arterial network of a patient. As previously described, blood flows from the right ventricle RV of the heart H, out through the main pulmonary artery MPA, which branches into the right pulmonary artery RPA and a left pulmonary artery LPA. The blood from the right pulmonary artery RPA further flows into various pulmonary artery branches PBR of the right pulmonary artery RPA.

The sensing device 20 generally comprises a proximal fixation element 22, a distal fixation element 24, a connecting element 26 mechanically coupling the proximal fixation element 22 to the distal fixation element 24, and a sensing element 28 mechanically coupled to the proximal fixation element 22 via another connecting element 30 opposite the connecting element 26 (i.e., the proximal fixation element 22 is between the connecting elements 26, 30). As shown in Fig. 2, the proximal fixation element 22 is firmly engaged with the wall of the right pulmonary artery RPA at a longitudinal location proximal to a side branch SBR, while the distal fixation element 24 is firmly engaged with the wall of the side branch SBR.

It can be appreciated that the use of two fixation elements 22, 24 effectively increases the anchoring force between the sensing device 20 and

the vessel wall of the pulmonary arterial network in the longitudinal direction, thereby minimizing the chance that the sensing device 20 will migrate within the right pulmonary artery RPA after implantation. In addition, because the distal fixation element 24 is disposed in the side branch SBR transverse to the lumen of the right pulmonary artery RPA, the anchoring force between the sensing device 20 and the vessel wall of the pulmonary arterial network is also increased in a rotational direction about the longitudinal axis of the right pulmonary artery RPA.

Advantageously, the connecting element 26 allows the fixation elements 22, 24 to articulate relative to each other, so that the distal fixation element 24 can be more easily disposed within the pulmonary branch BR, while the proximal fixation element 22 is disposed within the right pulmonary artery RPA. Also, the only portion of the sensing device 20 that is within the bifurcation between the right pulmonary artery RPA and the side branch SBR is the relatively low profile connecting element 26. As a result, very little force will be applied to the sensing device 20 by the blood flowing into the side branch SBR from the right pulmonary artery RPA, thereby increasing the stability of the sensing device 20 within the right pulmonary artery RPA, as well as decreasing the chance of embolism that may otherwise result from clots formed by the obstructed blood flow. In addition, because the connecting element 26 has a low profile, future access to the side branch SBR is not significantly hindered, thereby preserving the capability of catheterizing the side branch SBR if necessary or desired.

The other connecting element 30 may be rigid, so as to maintain the sensing element 28 at a constant position, or can be flexible, so as to enable

movement of the sensing element 28 within the vessel lumen. In the illustrated embodiment, the other connecting element 30 maintains the sensing element 28 between the vessel wall and the center of the vessel lumen, e.g., between 0.05mm and 0.8r, where r is the radius of the vessel lumen. For example, for a lumen having a radius of r=10mm, the sensing element 28 can be positioned at a distance between 0.05mm and 8mm from the vessel wall. In alternative embodiments, the sensing element 28 can be located either in contact with the vessel wall, at the vicinity of the vessel wall, or in any other convenient location within the vessel lumen. In these cases, the sensing element 28 may be connected directly to the proximal fixation element 22.

As illustrated in Fig. 2, each of the fixation elements 22, 24 has an expandable stent-like configuration having one or more struts coupled together to provide an outwardly urging radial force against the vessel wall. In the illustrated embodiment, the resilient struts are in an open radial zigzag configuration. Alternatively, the resilient struts may be in a closed radial zigzag configuration, as illustrated in Fig. 3. In either case, the expanded sizes, and in particular the diameters, of the fixation elements 22, 24 are individually selected to provide the necessary anchoring force within the respective vessel segments in which they are intended to be disposed; in this case, within the right pulmonary artery RPA and the side branch SBR, so that the expanded diameter of the proximal fixation element 22 will be greater than the expanded diameter of the distal fixation element 24.

In the illustrated embodiment, the struts of the fixation elements 22, 24 are composed of a suitable material that allows the fixation elements 22, 24 to

self-expand radially outward in the absence of a compressive force. To this end, the fixation elements 22, 24 may be manufactured from a wire, a laser cut tube, or a chemical etched tube or metal sheet composed of a suitable biocompatible material, such as nickel-titanium alloy, stainless steel, titanium, or cobalt-based alloy, or to enhance the radio-opacity of the sensing device, tantalum, gold, platinum, or platinum-iridium. The fixation elements 22, 24 may alternatively be composed of a polymer, including a shape memory polymer with or without the addition of radio-opaque material (e.g., barium sulfate). The cross-section of the struts may be, e.g., round, oval, rectangular, or any convenient shape. The thickness of the struts may be in the range of 0.05-0.5mm. The struts may optionally include ridges, barbs, or hooks for preventing migration of the sensing device 20 within the vessel lumen.

Each of the connecting elements 26, 30 may be composed of a suitable biocompatible material, such as nickel-titanium alloy, stainless steel, titanium, or cobalt-based alloy, or to enhance the radio-opacity of the sensing device, tantalum, gold, platinum, or platinum-iridium. The connecting elements 26, 30 may alternatively be composed of a polymer, including a shape memory polymer with or without the addition of radio-opaque material (e.g., barium sulfate).

In the illustrated embodiment, the sensing element 28 is a pressure sensor for monitoring blood pressure within the blood vessel. However, any known sensor can be used, including, but not limited to, an accelerometer, a wall motion sensor, a flow sensor, temperature sensor, oxygen sensor, glucose sensor, coagulation sensor, an electrical activity sensor, and pH

sensor. In alternative embodiments, another operative element can be located either in contact with the vessel wall, at the vicinity of the vessel wall, or in any other convenient location within the vessel lumen. The operative element may be another sensing element different from the sensing element 28, or an energy source, such as a battery. For example, using an isolated electrical wire, the sensing element 28 can be electrically connected to a battery for enabling energy transfer from the battery to the sensing element 28. Further details describing the structure and function of implantable sensing elements are disclosed in U.S. Patent Nos. 6,764,446 and 7,024,248.

Referring now to Fig. 4, the sensing device 20 is shown implanted within the vessel network in a different configuration. In particular, the proximal fixation element 22 is firmly engaged with the wall of the right pulmonary artery RPA at a longitudinal location proximal to the side branch SBR, while the distal fixation element 24 is firmly engaged with the wall of the right pulmonary artery RPA at a longitudinal location distal to the side branch SBR.

As previously described with respect to Fig. 2, the use of two fixation elements 22, 24 effectively increases the anchoring force between the sensing device 20 and the vessel wall of the pulmonary arterial network in the longitudinal direction, thereby minimizing the chance that the sensing device 20 will migrate within the right pulmonary artery RPA after implantation. In addition, because the fixation elements 22, 24 articulate relative to each other, the non-uniformity of the diameter along the right pulmonary artery RPA does not significantly diminish the anchoring capability of the sensing device 20. While the configuration shown in Fig. 4 does not use the side branch SBR as

an anchoring mechanism, it does accommodate the side branch SBR by only locating the low-profile connecting element 26 at the bifurcation. The connecting element 26 may either cross the side branch SBR, or may even be offset from the side branch SBR to maintain the side branch SBR totally patent without crossing it.

Referring to Fig. 5, another implantable sensing device 40 constructed in accordance with the invention will now be described. The sensing device 40 is similar to the previously sensing device 40, with the exception that the sensing element 28 is coupled between the fixation elements 22, 24. As can be seen, the sensing element 28 is suspended in the lumen of the right pulmonary artery RPA at the bifurcation. Preferably, the sensing element 28 is located as remotely as possible from the bifurcation to minimize blockage of the side branch SBR, which may otherwise increase the chances of migration and/or embolism. An optional connecting element 34 may be mechanically coupled between the fixation elements 22, 24 to provide additional support, and thus, anchoring force to the sensing device 40.

Referring to Fig. 6, another implantable sensing device 50 constructed in accordance with the invention will now be described. The sensing device 50 is similar to the previously described sensing device 20, with the exception that the sensing element 28 is mounted to the connecting element 26 between the fixation elements 22, 24. As shown, the fixation element 22 is firmly engaged with the wall of the right pulmonary artery RPA at a longitudinal location distal to a side branch SBR, while the fixation element 24 is firmly engaged with the wall of the side branch SBR. As can be seen, the sensing element 28 is suspended in the lumen of the right pulmonary artery

RPA at the bifurcation. Preferably, the sensing element 28 is located as remotely as possible from the bifurcation to minimize blockage of the side branch SBR, which may otherwise increase the chances of migration and/or embolism.

While the implantable sensing devices 20, 40, and 50 have been described as having only two fixation elements and only one sensing element, an implantable sensing device constructed in accordance with the invention can have more than two fixation elements and more than one sensing element. For example, referring to Fig. 7, an implantable sensing device 60 generally comprises a proximal fixation element 62, a medial fixation element 64, a distal fixation element 66, a first connecting element 68 mechanically coupling the proximal fixation element 62 to the medical fixation element 64, a second connecting element 70 mechanically coupling the distal fixation element 66 to the medical fixation element 64, and three sensing elements 72, 74, 76 mechanically coupled to the respective fixation elements 62, 64, 66 via three connecting elements 78, 80, 82. The fixation elements 62, 64, 66 connecting elements 78, 80, 82, and sensing elements 72, 74, 76 can be similarly constructed and function in the same manner as the same-named components described above.

As shown in Fig. 7, the proximal fixation element 62 is firmly engaged with the wall of the right pulmonary artery RPA at a longitudinal location proximal to the side branch SBR, the medial fixation element 64 is firmly engaged with the wall of the side branch SBR, and the distal fixation element 66 is firmly engaged with the wall of the right pulmonary artery RPA at a longitudinal location distal to the side branch SBR. Thus, it can be

appreciated that the use of three fixation elements, one of which is disposed in the side branch SBR, further increases the anchoring force between the sensing device 60 and the vessel wall of the pulmonary arterial network in the longitudinal and rotational directions, thereby further minimizing the chance that the sensing device 20 will migrate within the right pulmonary artery RPA after implantation. In addition, the use of three sensing elements increases the volume and/or types of information sensed within the right pulmonary artery RPA.

While the fixation elements have thus far been described as having stent-like configurations, the fixation elements can have other configurations (which may be different between fixation elements of the same device) suitable for firmly engaging the walls of an anatomical vessel. For example, referring to Fig. 8, an implantable sensing device 90 is similar to the sensing device 20 illustrated in Fig. 2, with the exception that, instead of having a distal fixation element 24 in a stent-like configuration, it comprises two distal fixation elements 92, 94 in coil-like configurations, which are mechanically coupled to the proximal fixation element 22 via respective connecting elements 96, 98. Each of the coiled fixation elements 92, 94 comprises a single wire, which can have the same cross-section and be composed of the same material as the struts of the fixation elements 22, 24 described above with respect to Fig. 2. As shown, the fixation element 92 is firmly engaged with the wall of the right pulmonary artery RPA at a location distal to the side branch SBR, and the fixation element 94 is firmly engaged with the wall of the side branch SBR, thereby providing the same anchoring advantages as the implantable sensing device 20 of Fig. 6.

Implantable sensing devices constructed in accordance with the invention can have stabilization elements other than fixation elements. For example, referring to Fig. 9, an implantable sensing device 100 is similar to the sensing device 20 illustrated in Fig. 2, with the exception that, instead of a distal fixation element 24, a stabilization element in the form of a flange 102 is mechanically coupled to the proximal fixation element 22. In the illustrated embodiment, the flange 102 is formed by looping a strut of the fixation element 22 back onto itself. The flange 102 is pre-shaped (e.g., by an appropriate thermal treatment of a nickel-titanium alloy), such that it extends at an angle from the fixation element 22 (i.e., transversely or obliquely to the longitudinal axis of the fixation element 22) into contact with the wall of the side branch SBR, thereby increasing the anchoring force between the sensing device 20 and the pulmonary arterial network in both the longitudinal and rotational directions. Preferably, the flange 102 is composed of a material rigid enough to provide the necessary stability to the sensing device 100.

Referring now to Fig. 10, another implantable sensing device 110 will be described. The sensing device 110 is similar to the previously described sensing device 100 of Fig. 9, with the exception that, instead of a proximal fixation element 22, it includes the distal fixation element 24 configured to firmly engage the wall of the right pulmonary artery RPA at a location distal to the side branch SBR. As with the sensing device 100, the sensing device 110 comprises a flange 112 mechanically coupled to the distal fixation element 24 and shaped, such that it extends at an angle from the fixation element 24 into contact with the wall of the side branch SBR, thereby increasing the anchoring force between the sensing device 100 and the pulmonary arterial network in

both the longitudinal and rotational directions. The flange 112 may be formed by looping a strut of the fixation element 24 back onto itself, and is preferably composed of a material rigid enough to provide the necessary stability to the sensing device 110.

Referring now to Fig. 11, still another implantable sensing device 120 will be described. The sensing device 120 is similar to the previously described sensing device 110 of Fig. 10, with the exception that it includes a flange 122 that is not pre-shaped to extend within the side branch SBR. Rather, the flange 122 is relatively straight, so that it remains within the lumen of the right pulmonary artery RPA. In addition, the sensing element 28 is mechanically coupled between the distal fixation element 24 and the flange 122. Although the flange 122 is not designed to extend within the side branch SBR, and thus, does not significantly increase the anchoring force in a rotational direction about the longitudinal axis of the right pulmonary artery RPA, the flange 122 abuts the wall of the right pulmonary artery RPA, thereby preventing the sensing element 28 from hinging into the side branch SBR in response to the flow of blood from the right pulmonary artery RPA into the side branch SBR.

Referring to Fig. 12, yet another implantable sensing device 130 constructed in accordance with the invention will now be described. The sensing device 130 comprises a single fixation element 132 and the previously described sensing element 28 mechanically coupled to the fixation element 132. The fixation element 132 is similar to either of the previously described fixation elements 22, 24 in Fig. 2, with the exception that the length of the fixation element 132 is increased to allow it to cross the side branch

SBR. For example, the length of the fixation element 132 may be equal to or greater than 35mm. The increased length of the fixation element 132 increases the anchoring force between the sensing device 130 and the vessel wall of the pulmonary arterial network. To further increase the anchoring capability of the fixation element 132, the proximal and distal edges of the fixation element 132 may be curved radially outward, as illustrated in Fig. 13, to provide a gripping force against the vessel wall that decreases longitudinal migration of the sensing device 130. Alternatively, the proximal and distal edges of the fixation element 132 may be curved radially inward, as illustrated in Fig. 14. In this manner, the resilient spring force of the fixation element 132 can be increased, thereby increasing its anchoring capability, without concern that the edges of the fixation element 132 will damage or otherwise irritate the wall of the right pulmonary artery RPA.

Notably, if the fixation element 132 is relatively uniform diameter along its length, its implantation into a conically shaped vessel may induce a spring forces that tends to push the sensing device 130 in the proximal direction. To address this, the fixation element 132 may be pre-shaped to have a conical geometry similar to the conical shape of the vessel (e.g., conical angle of 0-40° and length of 10-35 mm), as illustrated in Fig. 15. In this case, the fixation element 132 will be arranged in the vessel, such that the larger diameter of the fixation element 132 coincides with the large diameter of the vessel, and the small diameter of the fixation element 132 coincides with the small diameter of the vessel. Thus, the non-loaded fixation element 132 will have less of a tendency to move from its intended position. Alternatively, the fixation element 132 may be arranged as a mirror image of the vessel, as

illustrated in Fig. 16. That is, the large diameter of the fixation element 132 coincides with the small diameter of the vessel, and the small diameter of the fixation element 132 coincides with the large diameter of the vessel. In this case, the shape and configuration of the fixation element 132 will straighten out the vessel, so that it is no longer conically shaped. Alternatively, as illustrated in Fig. 17, the distal edges of the fixation element 132 may be curved radially outward to provide a gripping force against the vessel wall that decreases longitudinal migration of the sensing device 130. Notably, these conical fixation element concepts can be applied to any of the previous embodiments.

The afore-described sensing devices can be delivered and implanted within the pulmonary arterial network of the patient using any suitable means, such as, e.g., a deliver catheter. For example, referring to Figs. 18A-18D, a method of delivering the sensing device 20 within the pulmonary arterial network of a patient will now be described, for purposes of better understanding the invention. The delivery system 150 includes a flexible catheter 152 configured for being delivered through the vasculature of a patient, and a pusher element 154 slidably disposed within the lumen of the catheter 152. The sensing device 20, and in particular, the sensing element 28, is detachably coupled to the distal end of the pusher element 154 using suitable means, such as a mechanical interference or electrolytic arrangement.

In the illustrated embodiment, the pusher element 154 is capable of being rotated relative to the catheter 152, so that the sensing device 20 can be implanted within the pulmonary arterial network in a specific circumferential

location. That is, it may be desirable for the sensing element 28 to be located at the top of the vessel wall or at the bottom of the vessel wall. It may also be desirable to maintain the rotational orientation of the fixation elements 22, 24 relative to each other, so that the connecting element 26 runs along one side of the vessel wall—instead of traversing the lumen of the vessel in the case where the one of the fixation elements 22, 24 is rotationally misaligned by 180 degrees.

To this end, a radio-opaque marker 156 is disposed on the sensing device 20 in a manner that allows the orientation of the sensing device 20 to be determined via fluoroscopic imaging. The radio-opaque marker 156 may take the form of a material (e.g., platinum, gold, tantalum, or other commonly used radio-opaque material) coated on the sensing element 28 (as shown in the figures), or may take the form of a wire composed of the same material, which may, e.g., be crimped onto one or both of the fixation element 22, 24, or may even take the form of the connecting element 26 itself.

In the illustrated method, the sensing device 20 will be delivered into the pulmonary arterial network in the configuration illustrated in Fig. 2; i.e., with the distal fixation element 24 disposed within the side branch SBR and the proximal fixation element 24 disposed in the right pulmonary artery RPA at a longitudinal location proximal to the side branch SBR. As shown in Fig. 18A, the catheter 152 is advanced from the right ventricle RV of the heart, through the main pulmonary artery MPA, and into the lumen of the right pulmonary artery RPA. As can be seen, the sensing device 20 is loaded into the delivery catheter 152, such that the distal fixation element 24 will be deployed prior to the proximal fixation element.

As shown in Fig. 18B, the distal end of the catheter 152 is advanced into the side branch SBR (or alternatively, at the bifurcation within the right pulmonary artery RPA, but deflected towards the opening of the side branch SBR), and the pusher element 154 is distally advanced to push the distal fixation element 24 out from the catheter 152 and into the lumen of the side branch SBR. As previously discussed, the distal fixation element 24 is composed of a resilient material that causes it to self-expand in the absence of a compressive force. As a result, the distal fixation element 24 will automatically expand radially outward into firm contact with the wall of the side branch SBR once it is deployed from the catheter 152. Alternatively, if the distal fixation element 24 is not capable of self-expanding, a balloon can be used to radially expand the distal fixation element 24 into firm contact with the vessel wall.

As shown in Fig. 18C, the catheter 152 is then pulled in the proximal direction, so that the distal end of the catheter 152 is located within the right pulmonary artery RPA, and the pusher element 154 is distally advanced to push the proximal fixation element 24 out from the catheter 152 into the lumen of the right pulmonary artery RPA, where it automatically expands radially outward (or alternatively radially expands with the aid of a balloon) into firm contact with the wall of the right pulmonary artery RPA. As shown in Fig. 18D, the pusher element 154 is distally advanced further to push the sensing element 28 out from the catheter 152 into the lumen of the right pulmonary artery RPA, and the pusher element 154 is detached from the sensor element 28.

Similar delivery techniques can be used to form the configurations within the pulmonary arterial network illustrated in Figs. 3-8. With respect to the configurations illustrated in Figs. 9 and 10, the sensing devices can be implanted in the pulmonary arterial network by dragging the flange of the sensing device proximally or distally within the right pulmonary artery RPA until the flange locates itself into the side branch SBR, as illustrated in Figs. 19A-19H.

For example, as shown in Fig. 19A, the sensing device 100 is loaded into the delivery catheter 152, such that the flange 102 will be deployed prior to the fixation element 22. As shown in Fig. 19B, the distal end of the catheter 152 is advanced to a location in the right pulmonary artery RPA distal to the side branch SBR, and the pusher element 154 is distally advanced to push the flange 102 out from the catheter 152 and into contact with the wall of the right pulmonary artery RPA. As shown in Fig. 19C, the catheter 152 is pulled in the proximal direction until the flange 102 catches within the side branch SBR.

As an alternative to the steps illustrated in Figs. 19B and 19C, the distal end of the catheter 152 can be advanced to a location in the right pulmonary artery RPA proximal to the side branch SBR, and the pusher element 154 is distally advanced to push the flange 102 out from the catheter 152 and into contact with the wall of the right pulmonary artery RPA, as illustrated in Fig. 19D, after which the catheter 152 is pushed in the distal direction until the flange 102 catches within the side branch SBR.

In any event, once the flange 102 is located within the side branch SBR, the pusher element 154 is distally advanced to push the fixation element

22 out from the catheter 152 into the lumen of the right pulmonary artery RPA, where it automatically expands radially outward into firm contact with the wall of the right pulmonary artery RPA, as shown in Fig. 19E. The pusher element 154 is distally advanced further to push the sensing element 28 out from the catheter 152 into the lumen of the right pulmonary artery RPA, and the pusher element 154 is detached from the sensor element 28, as illustrated in Fig. 19F.

A similar method can be utilized to implant the sensing device 110 of Fig. 10, with the exception that the fixation element 24 will need to be deployed out from the catheter 152 before the flange 112, as illustrated in Fig. 19G, for purposes of better understanding the invention. In this case, before the sensing element 28 is detached from the pusher element 154, the catheter 152 is pulled in the proximal direction, thereby displacing the entire sensing device 110, including the expanded fixation element 24, within the right pulmonary artery RPA until the flange 112 is located within the side branch SBR, as illustrated in Fig. 19H. After the sensing device 110 is properly located, the pusher element 154 is detached from the sensor element 28.

The sensing device 120 illustrated in Fig. 11 can be implanted within the pulmonary arterial network simply by deploying the fixation element 24 in the right pulmonary artery RPA at a location distal to the side branch SBR, pulling the catheter 152 in the proximal direction to deploy the sensor 28 and flange 122 within the right pulmonary artery RPA, and detaching the pusher element 154 from the sensor element 28. The sensing device 130 illustrated in Fig. 12 can be implanted within the pulmonary arterial network simply by

deploying the fixation element 24 in the right pulmonary artery RPA at a location at the side branch SBR, pulling the catheter 152 in the proximal direction to deploy the sensor 28 within the right pulmonary artery RPA, and detaching the pusher element 154 from the sensor element 28.

As previously discussed, the distal fixation element 24 is composed of a resilient material that causes it to self-expand in the absence of a compressive force. As a result, the distal fixation element 24 will automatically expand radially outward into firm contact with the wall of the side branch SBR once it is deployed from the catheter 152. Alternatively, if the distal fixation element 24 is not capable of self-expanding, a balloon can be used to radially expand the distal fixation element 24 into firm contact with the vessel wall.

While the sensing devices have been illustrated and described as being implanted within the pulmonary artery PA, it should be appreciated that the sensing devices can be implanted in other blood vessels of the patient's body, e.g., the vena cava, pulmonary vein, coronary sinus, aorta, sub-clavian artery, iliac artery, and carotid artery.

CLAIMS

1. An implant for sensing parameters within an anatomical vessel network of a patient, comprising:

a first fixation element having an expanded geometry for firmly engaging a wall of the vessel network at a first longitudinal location;

a second fixation element having an expanded geometry for firmly engaging the wall of vessel network at a second longitudinal location;

a connecting element mechanically coupling the first and second fixation elements together in an articulating manner; and

a sensing element mechanically coupled to the first fixation element opposite the connecting element.

2. The implant of claim 1, wherein the vessel network is a blood vessel network.

3. The implant of claims 1 or 2, wherein at least one of the first and second longitudinal locations is in a right pulmonary artery.

4. The implant of any of claims 1 – 3, wherein the vessel network has substantially differing diameters at the first and second longitudinal locations.

5. The implant of any of claims 1 – 4, wherein the first and second longitudinal locations are in a single anatomical vessel.

6. The implant any of claims 1 – 4, wherein the first longitudinal location is in a main anatomical vessel, and the second longitudinal location is in an anatomical vessel branch of the main anatomical vessel.

7. The implant of any of claims 1 – 6, wherein each of the first and second fixation elements is selected from the group consisting of a stent and a coil.

8. The implant of any of claims 1 – 7, wherein the sensing element comprises one or more of a pressure sensor, an accelerometer, a wall motion sensor, a flow sensor, a temperature sensor, an oxygen sensor, a glucose sensor, a coagulation sensor, an electrical activity sensor, and a pH sensor.

9. The implant of any of claims 1 – 8, further comprising:

a third fixation element having an expanded geometry for firmly engaging the wall of vessel network at a third longitudinal location; and

another connecting element mechanically coupling the second and third fixation elements together in an articulating manner.

10. The implant of any of claims 1 – 9, further comprising a transmitter configured for wirelessly transmitting information sensed by the sensing element to a remote receiver.

FIG. 1

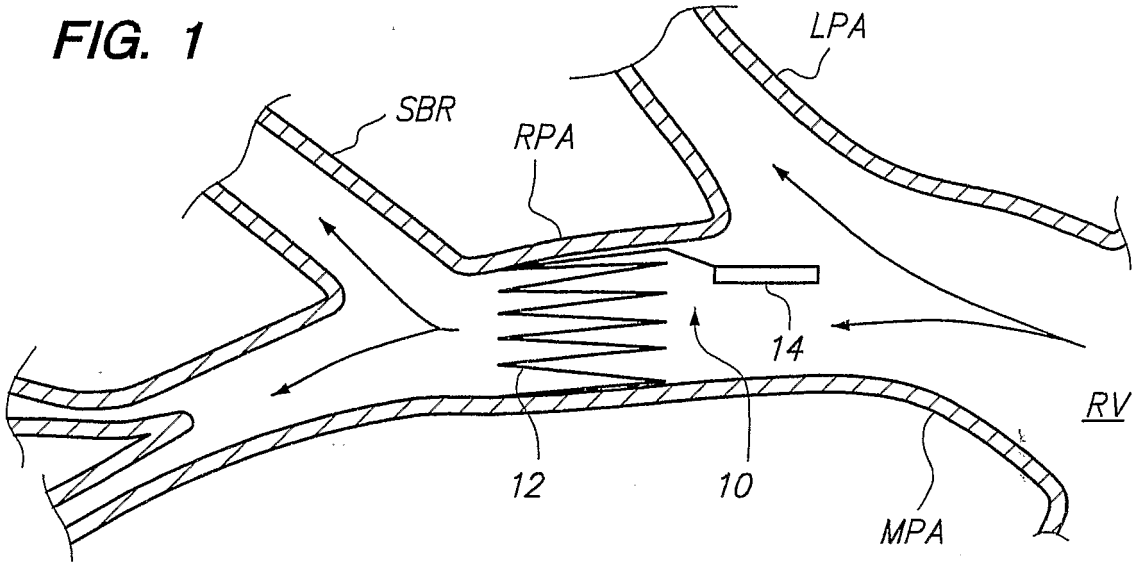


FIG. 2

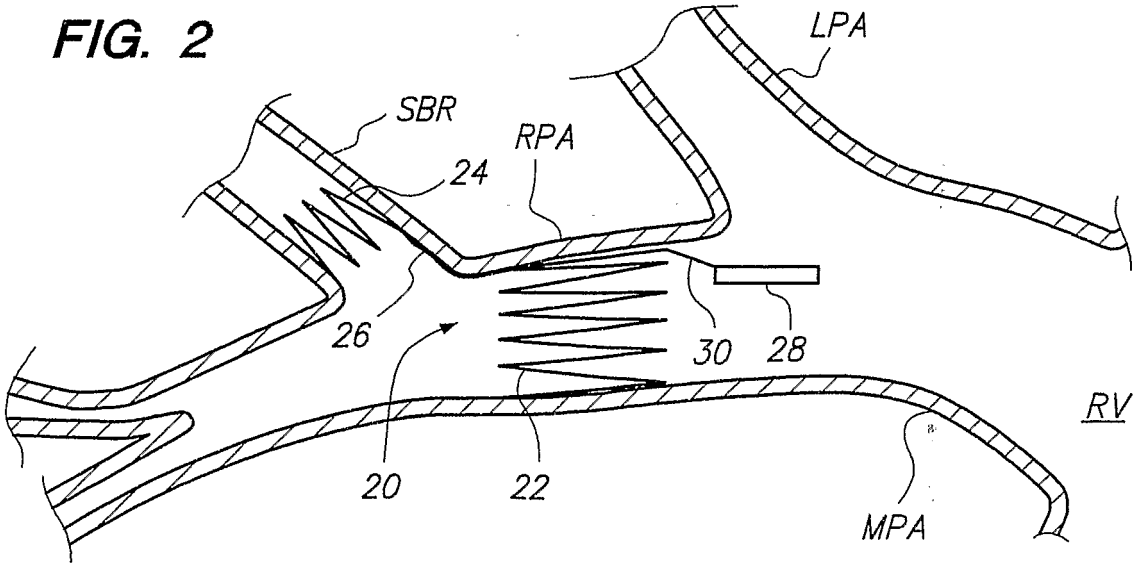


FIG. 3

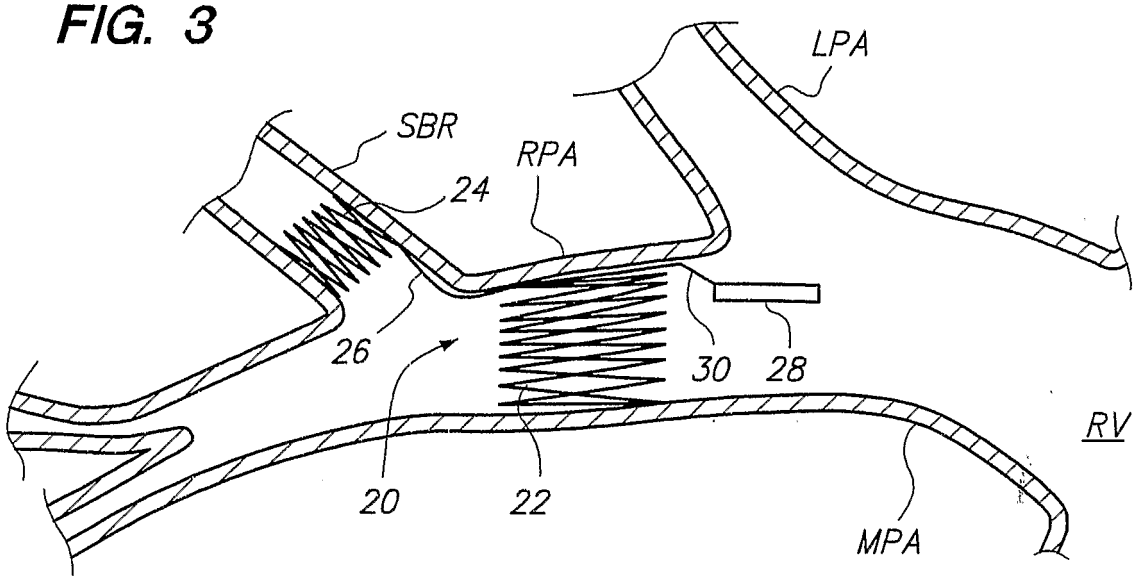

LPA
SBR
RPA
24
26
30
28
RV
20
22
MPA

FIG. 4

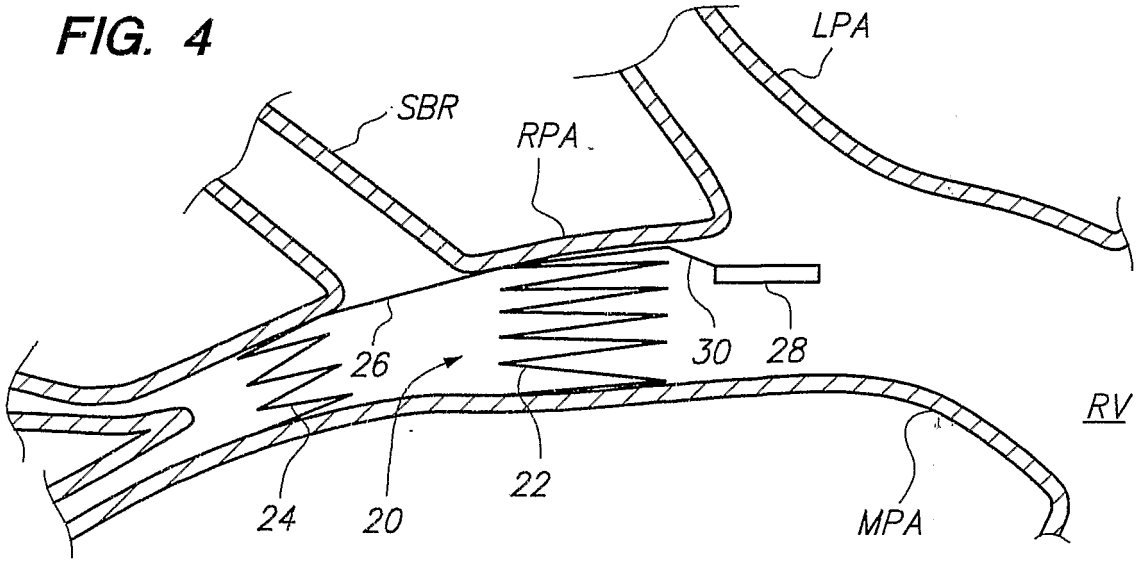

LPA
SBR
RPA
26
30
28
RV
24
20
22
MPA

FIG. 5

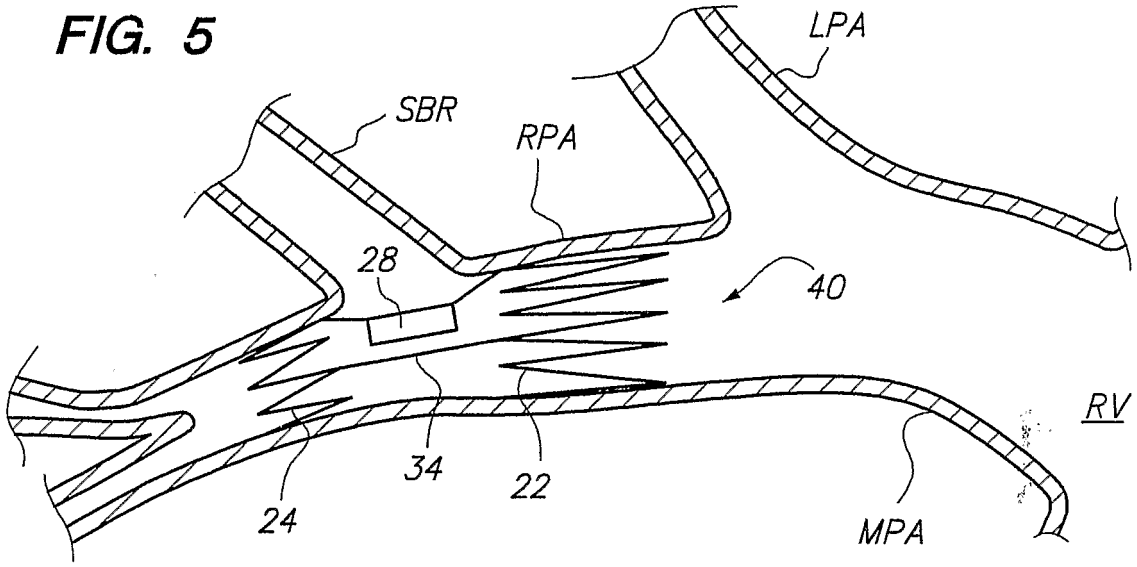


FIG. 6

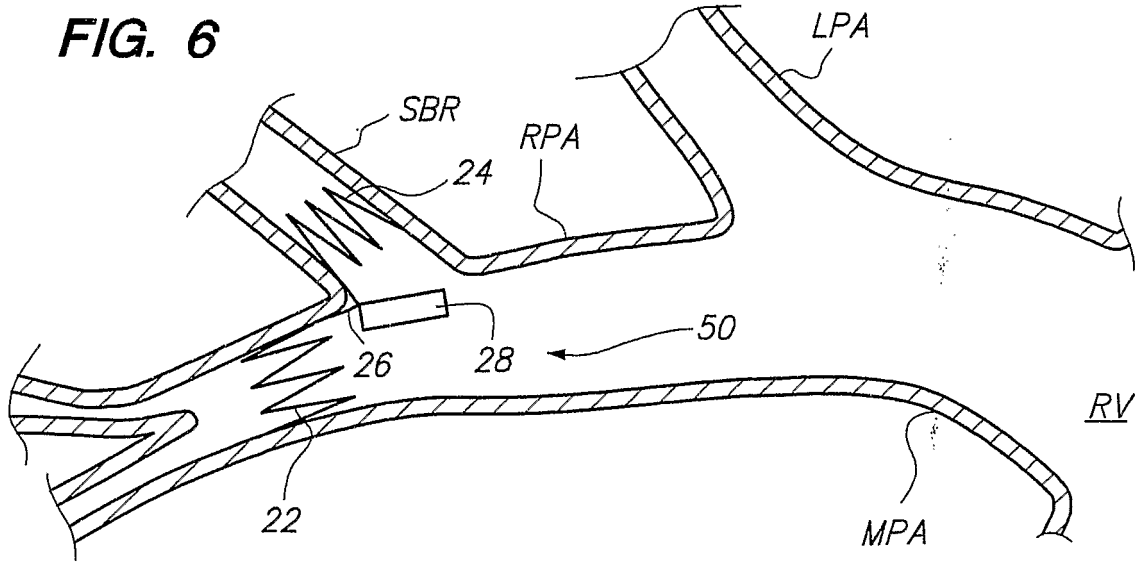


FIG. 7

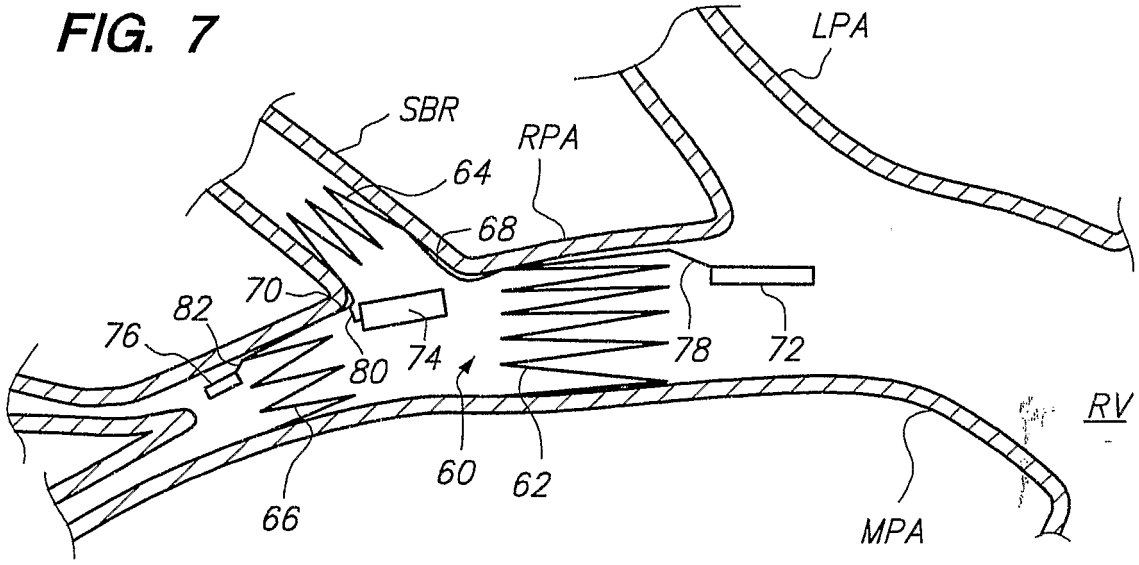

LPA
SBR
RPA
64
68
70
82
76
74
80
78
72
RV
60
62
66
MPA

FIG. 8

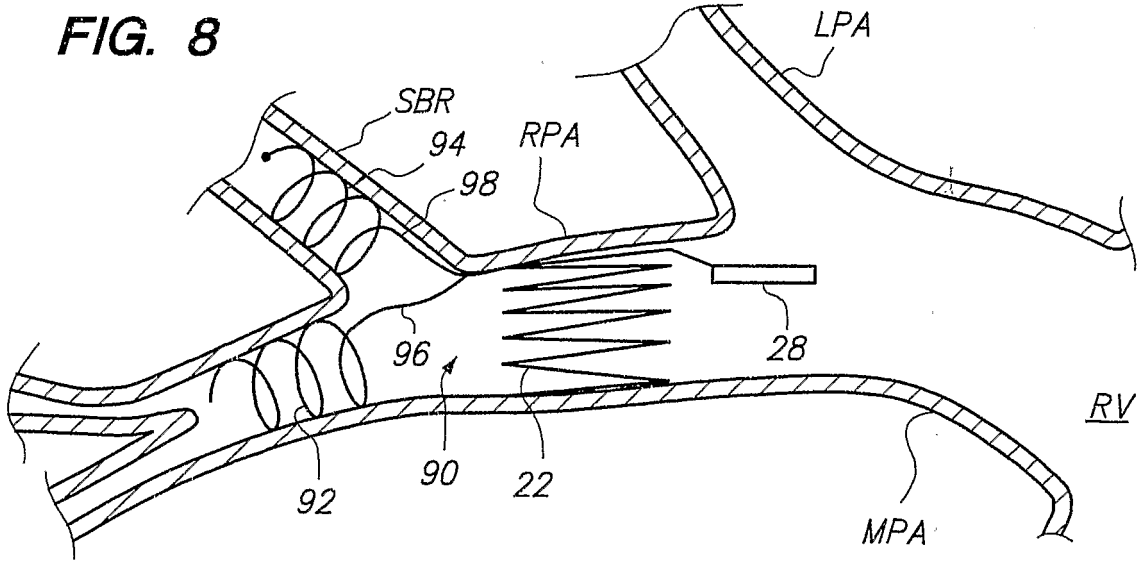

LPA
SBR
94
RPA
98
96
28
RV
90
22
92
MPA

FIG. 9

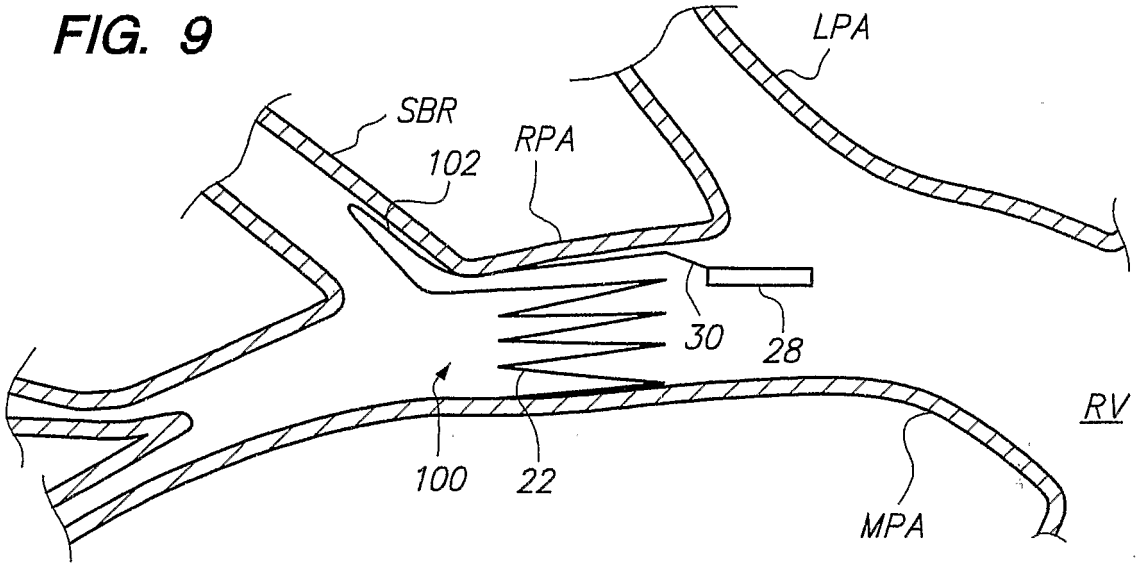

LPA
SBR
RPA
102
30
28
RV
100
22
MPA

FIG. 10

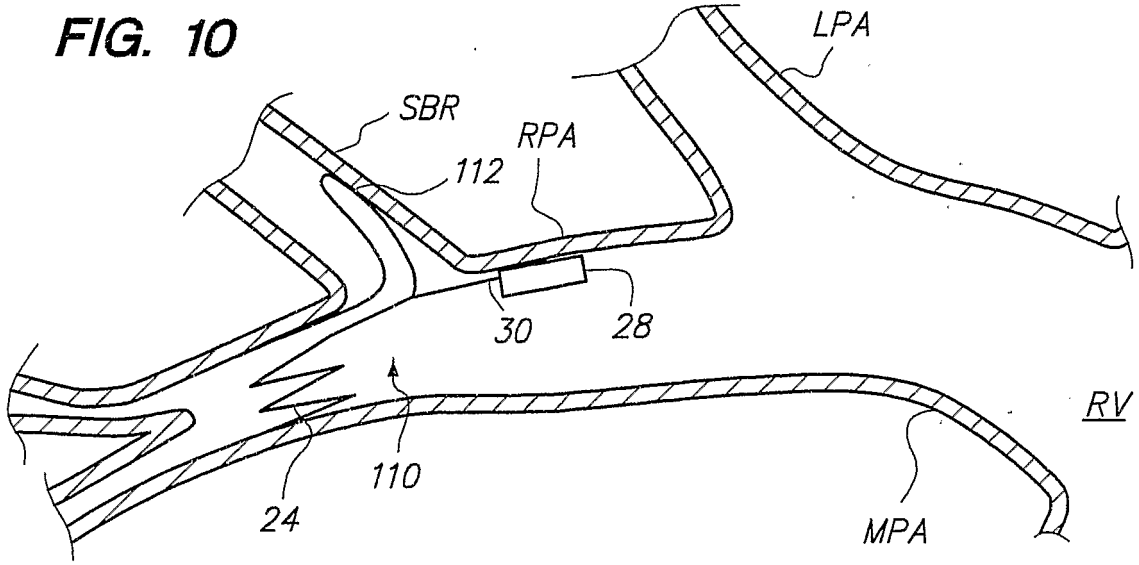

LPA
SBR
RPA
112
30
28
RV
110
24
MPA

FIG. 11

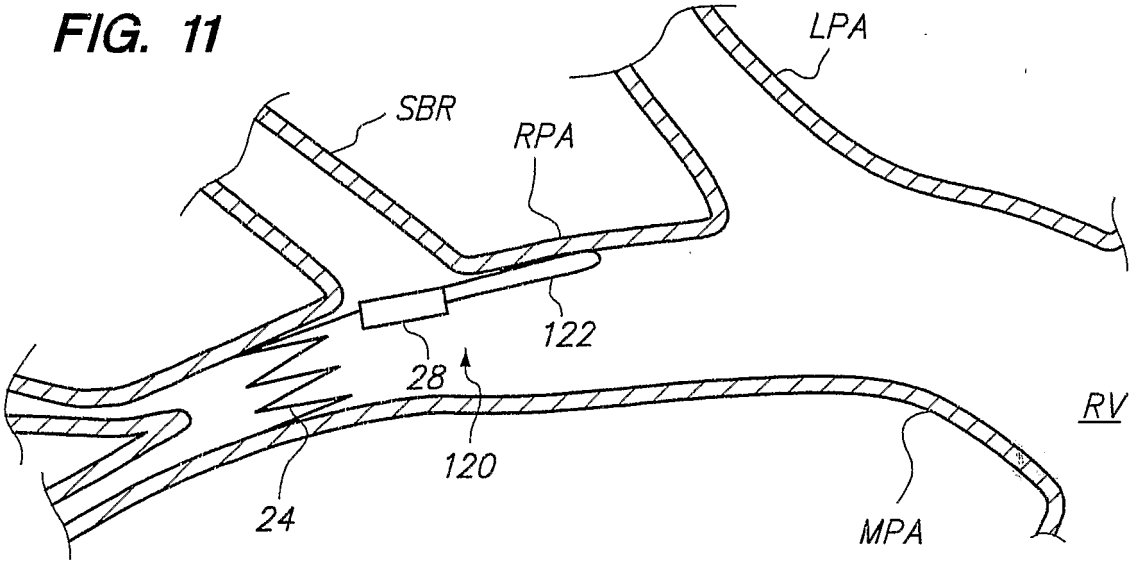


FIG. 12

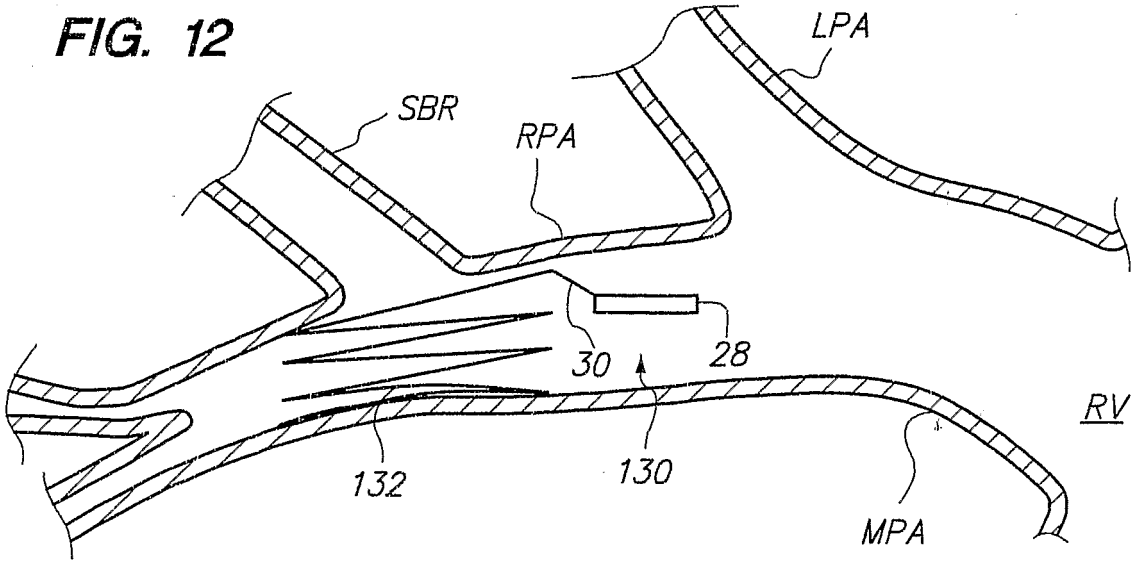


FIG. 13

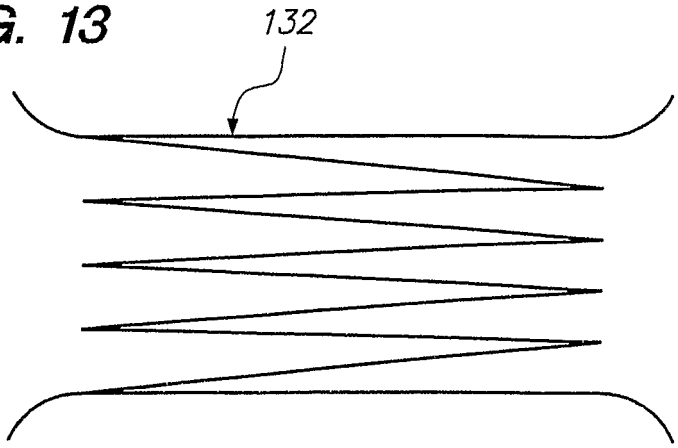


FIG. 14

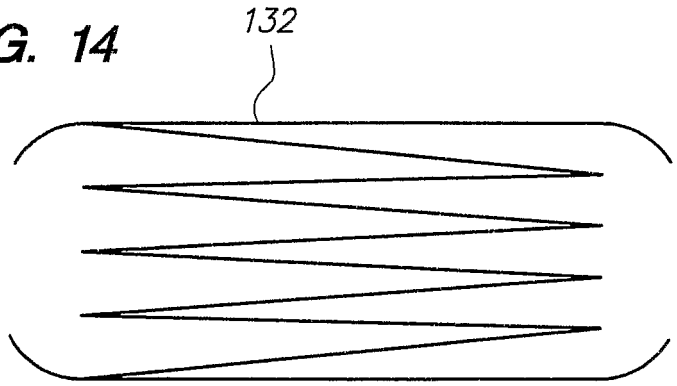


FIG. 15

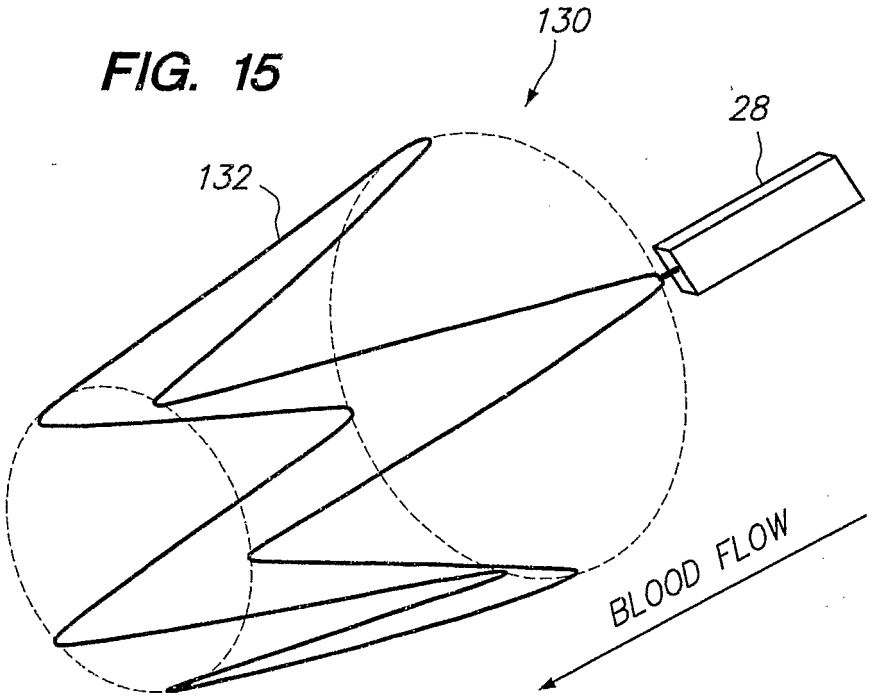


FIG. 16

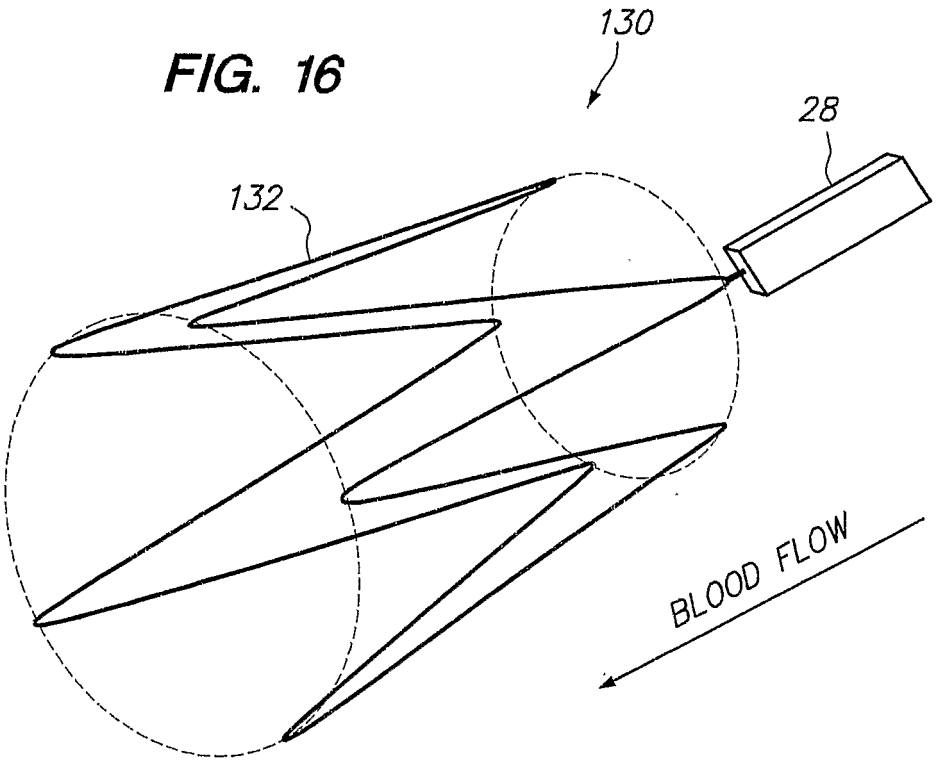


FIG. 17

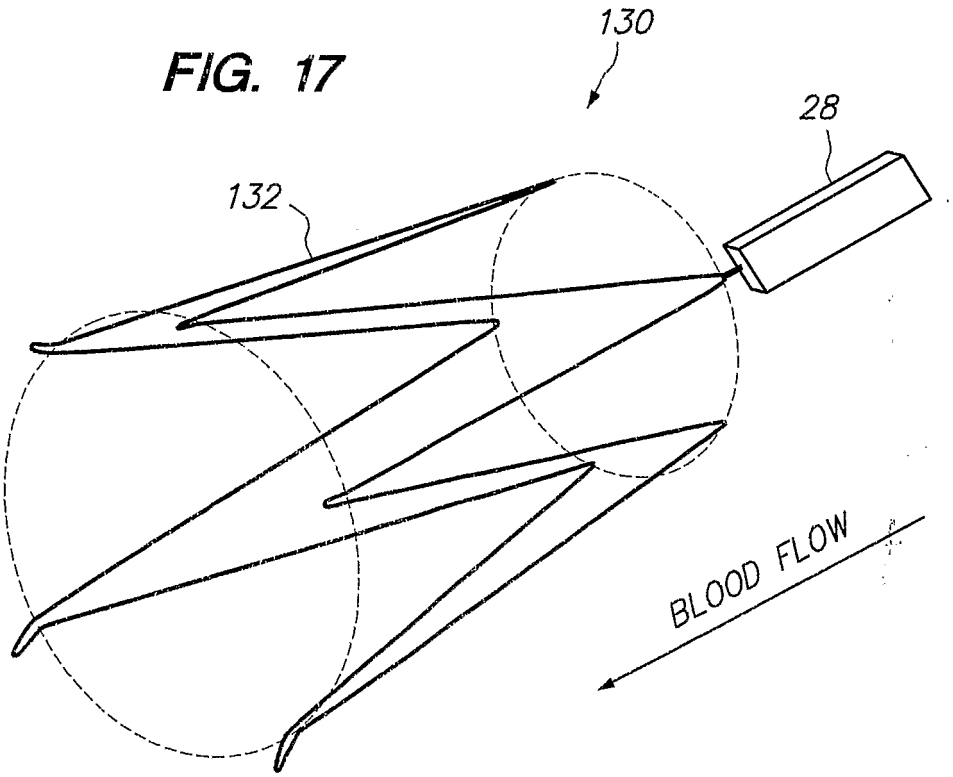


FIG. 18A

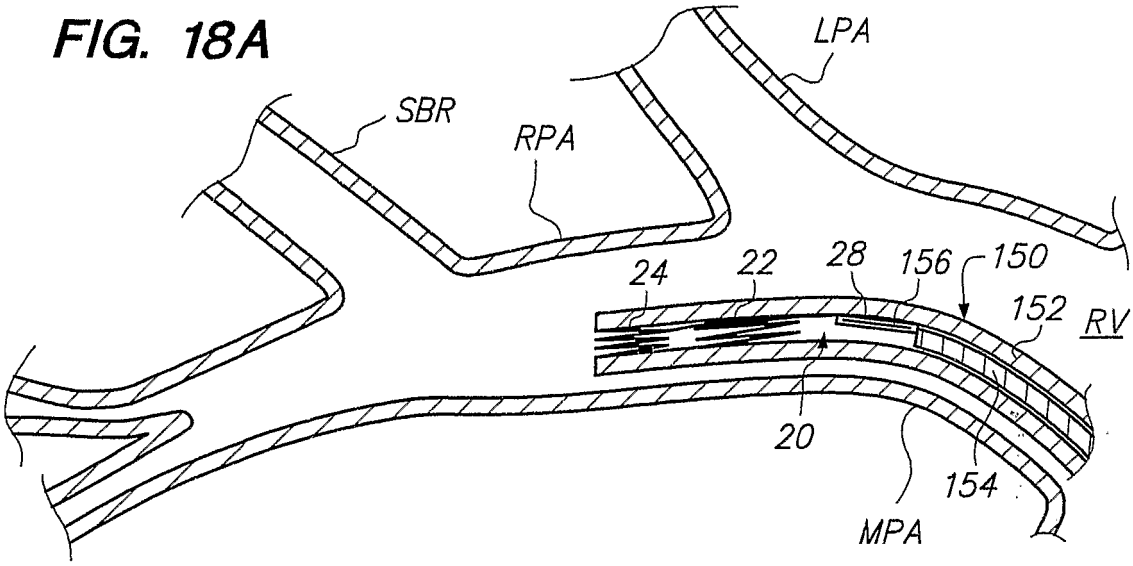


FIG. 18B

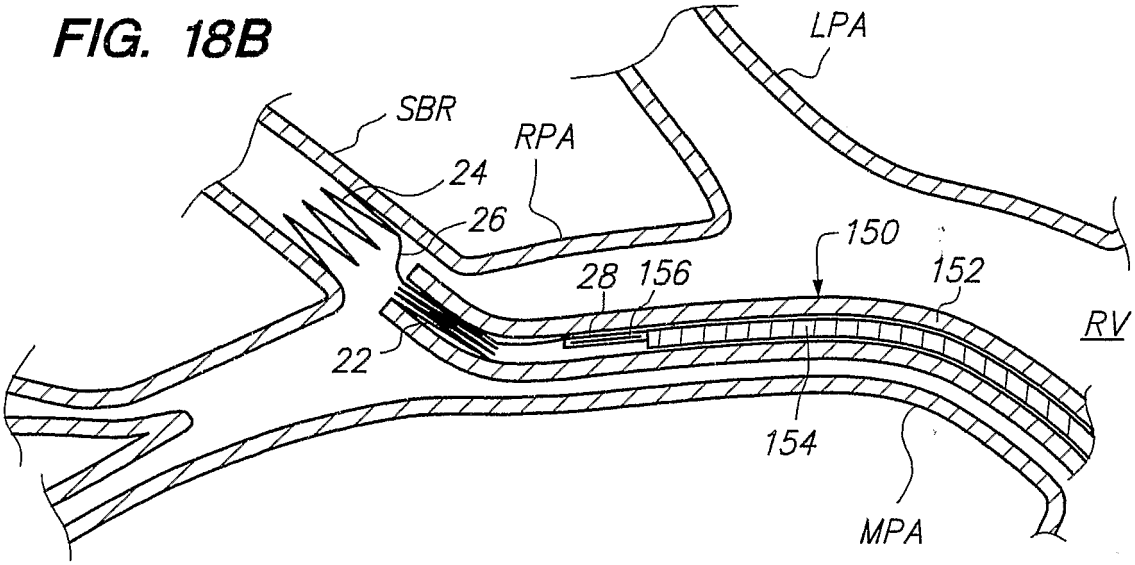


FIG. 18C

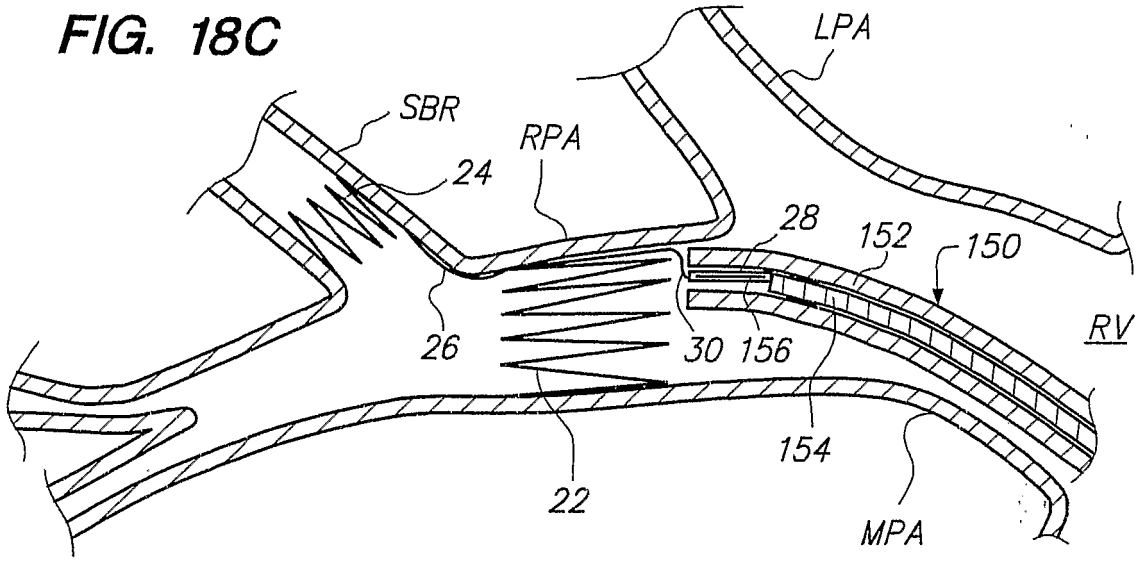


FIG. 18D

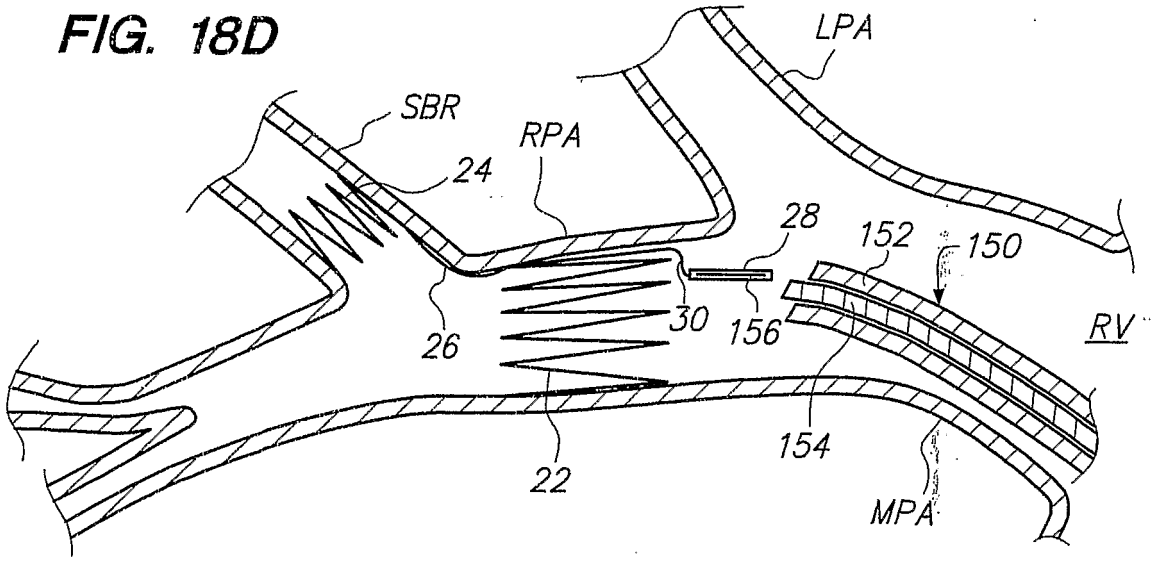


FIG. 19A

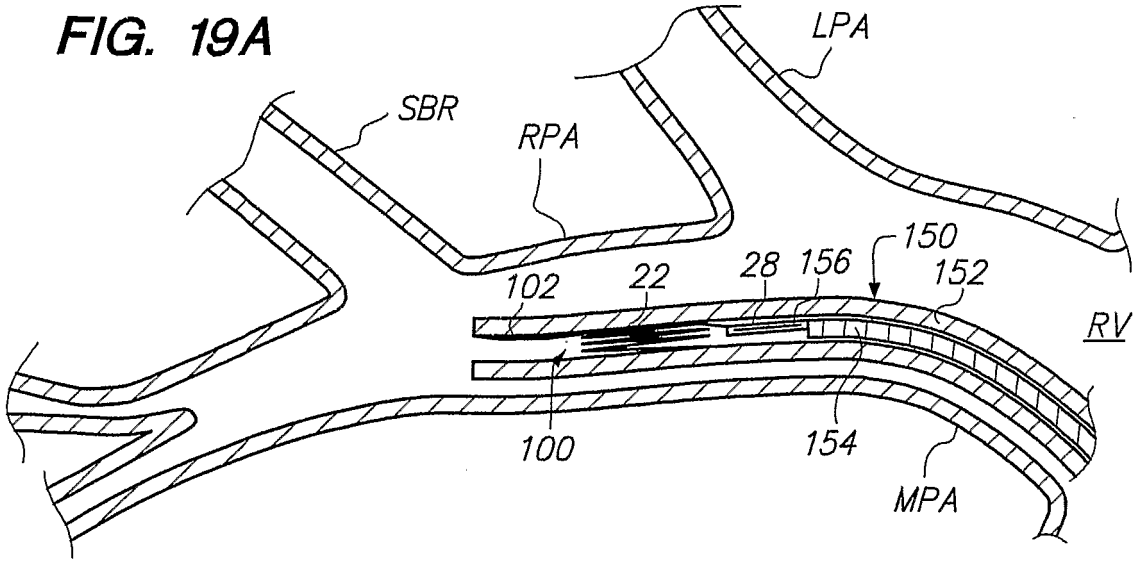


FIG. 19B

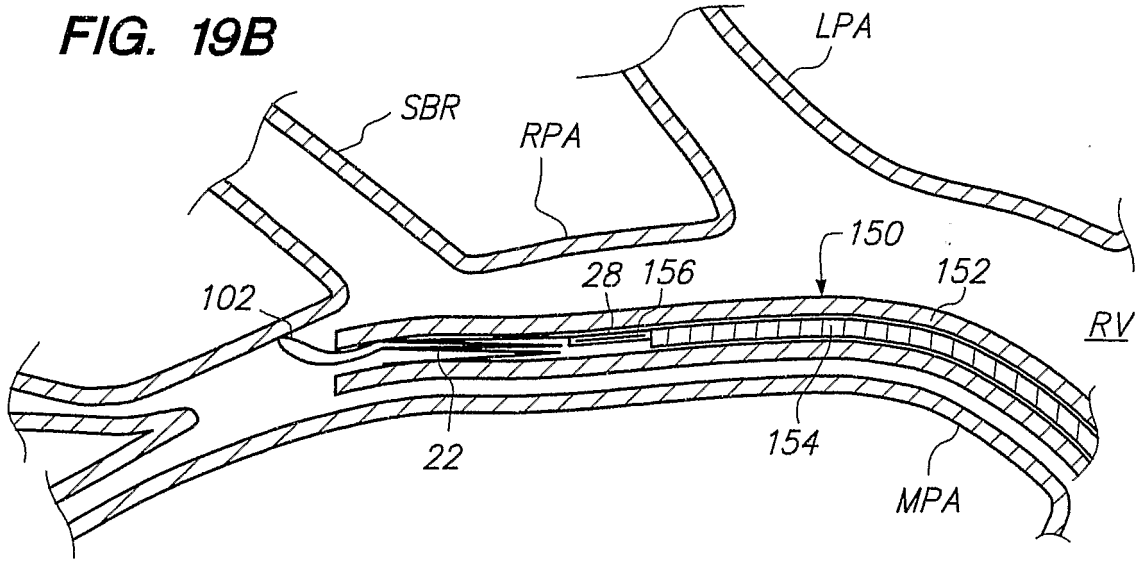


FIG. 19C

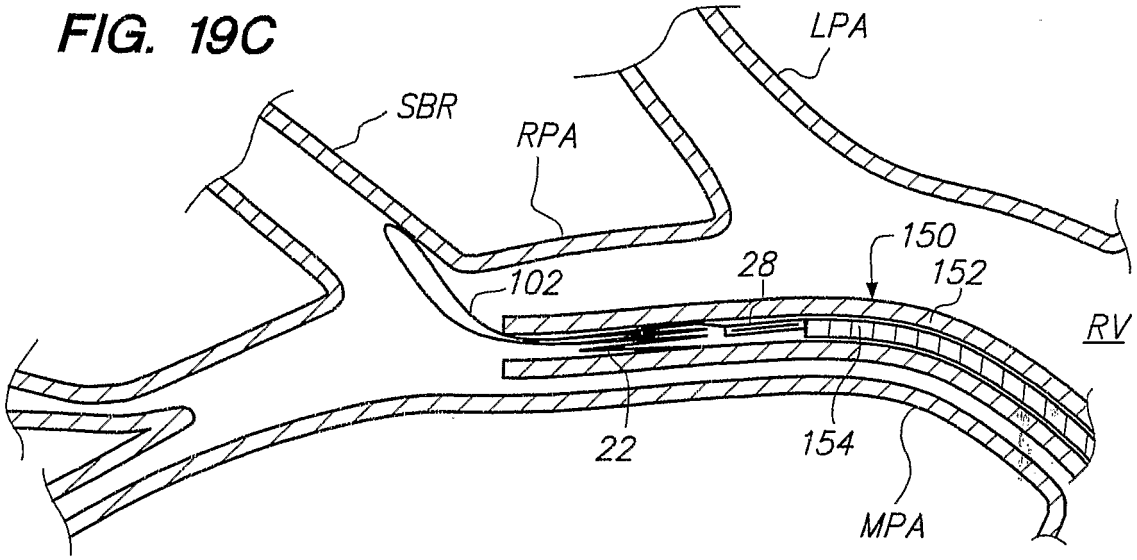


FIG. 19D

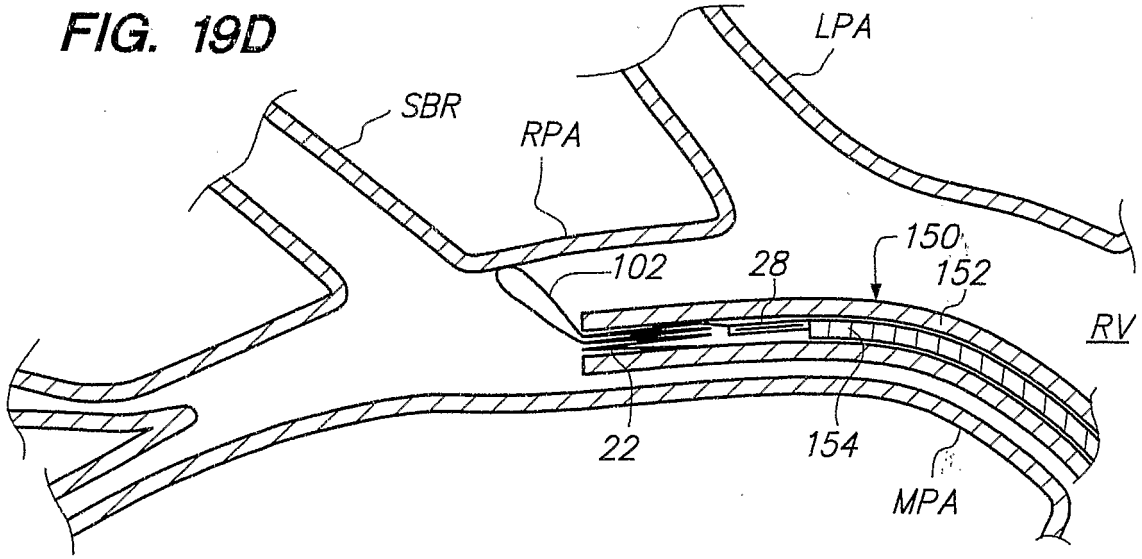


FIG. 19E

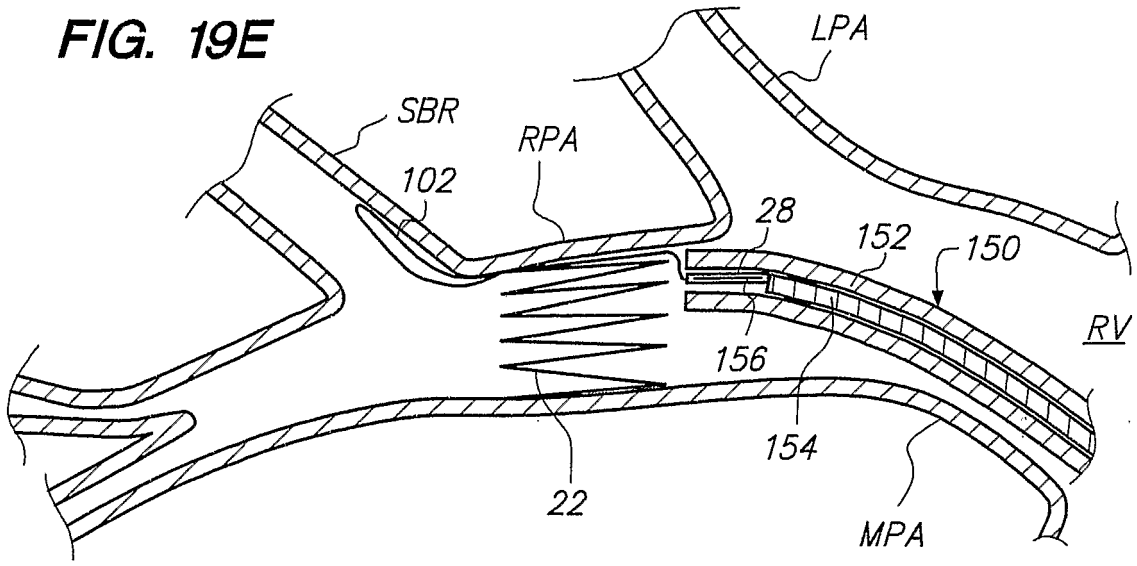


FIG. 19F

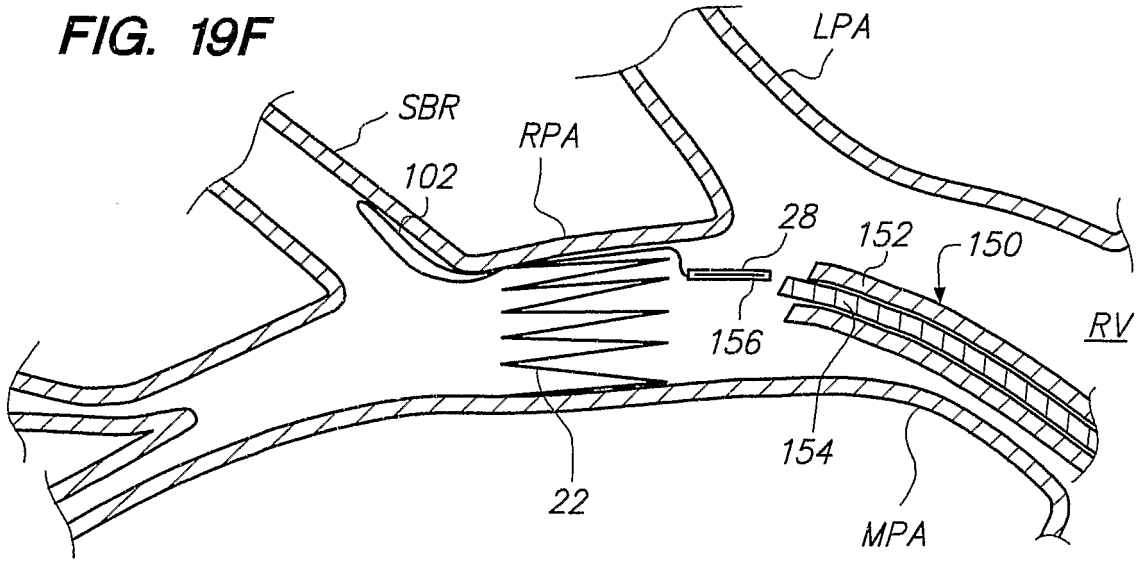


FIG. 19G

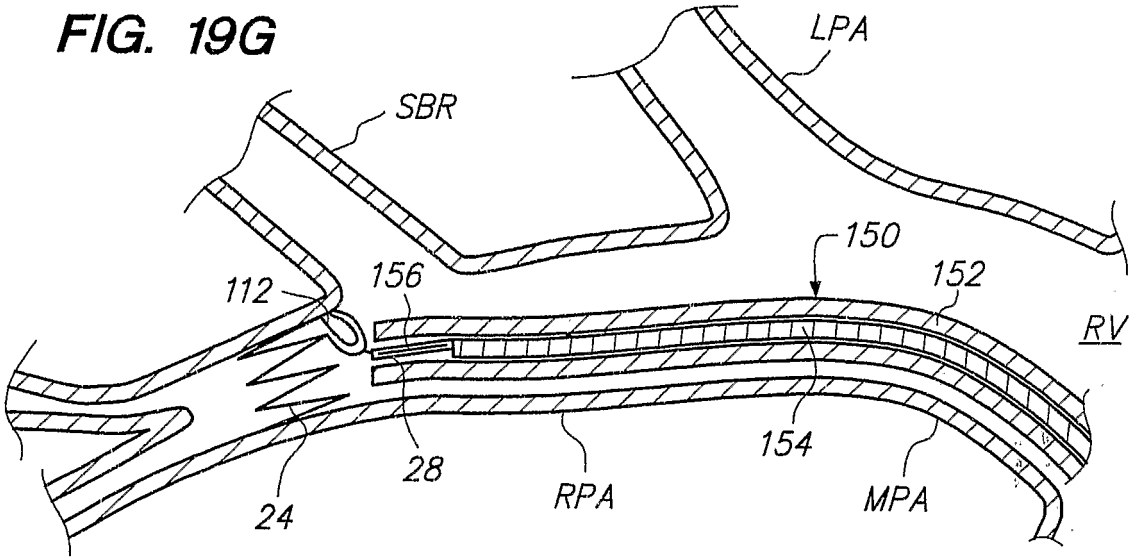
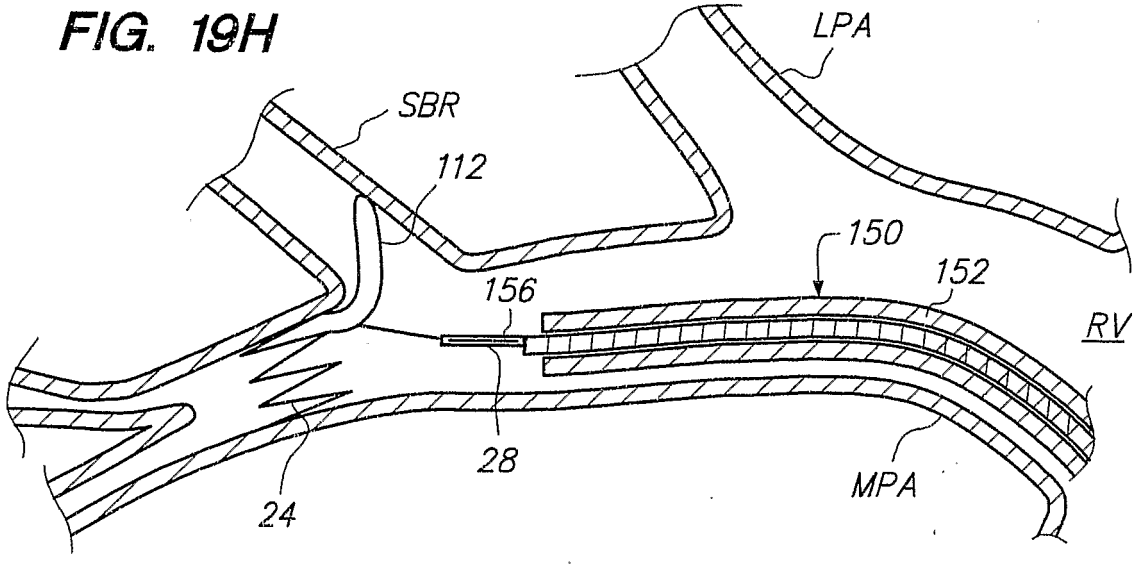


FIG. 19H



INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/003183

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/0215

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/176672 A1 (SILVER JAMES H [US] ET AL) 9 September 2004 (2004-09-09) paragraphs [0050] - [0065] paragraphs [0204] - [0206] figures 10,11	1-10
A	US 2005/154321 A1 (WOLINSKY LONE [IL] ET AL) 14 July 2005 (2005-07-14) the whole document	1
A	EP 0 928 598 A2 (MICROSENSE CARDIOVASCULAR SYST [IL] MICROSENSE CARDIOVASCULAR [IL]) 14 July 1999 (1999-07-14) paragraphs [0005] - [0015] figures 1-9	1
	-/--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 February 2007	02/03/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Abraham, Volkhard

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2006/003183

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/151816 A1 (RICH COLLIN A [US] ET AL) 17 October 2002 (2002-10-17) paragraphs [0019] - [0025] figures 15-19	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2006/003183

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004176672 A1	09-09-2004	NONE	
US 2005154321 A1	14-07-2005	NONE	
EP 0928598 A2	14-07-1999	AU 1888499 A	26-07-1999
		AU 9704698 A	29-07-1999
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		SG 71881 A1	18-04-2000
		SK 1699 A3	12-07-1999
		US 6331163 B1	18-12-2001
US 2002151816 A1	17-10-2002	NONE	

专利名称(译)	用于将传感器固定在体腔中的植入装置		
公开(公告)号	EP1948007A1	公开(公告)日	2008-07-30
申请号	EP2006809209	申请日	2006-11-14
[标]申请(专利权)人(译)	REMON医疗TECH		
申请(专利权)人(译)	REMON MEDICAL TECHNOLOGIES LTD.		
当前申请(专利权)人(译)	REMON MEDICAL TECHNOLOGIES LTD.		
[标]发明人	PENNER ABRAHAM		
发明人	PENNER, ABRAHAM		
IPC分类号	A61B5/00 A61B5/0215		
CPC分类号	A61B5/6862 A61B5/0031 A61B5/0215 A61B5/6876 A61B5/6882		
优先权	60/737131 2005-11-15 US		
外部链接	Espacenet		

摘要(译)

用于感测患者的解剖血管网络内的参数的植入物包括具有扩展几何形状的第一固定元件，用于在第一纵向位置处牢固地接合血管网络的壁，具有扩展几何形状的第二固定元件用于牢固地接合所述壁在第二纵向位置处的容器网络的连接元件，以铰接方式将第一和第二固定元件机械地连接在一起的连接元件，以及与连接元件相对地机械连接到第一固定元件的传感元件。