

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
20 March 2008 (20.03.2008)

PCT

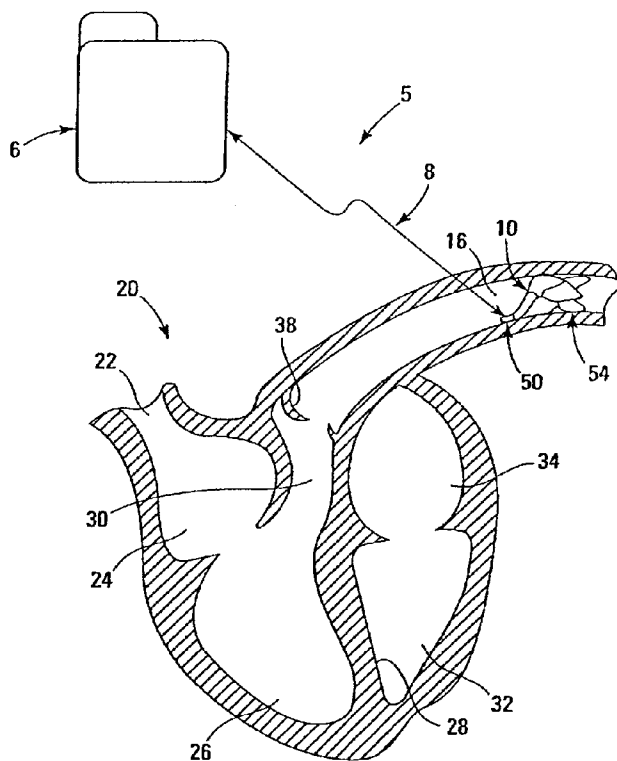
(10) International Publication Number
WO 2008/034077 A2

- (51) International Patent Classification:
A61B 5/0215 (2006.01)
- (21) International Application Number:
PCT/US2007/078525
- (22) International Filing Date:
14 September 2007 (14.09.2007)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/844,821 15 September 2006 (15.09.2006) 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, BH, BR, BW, BY, BZ, CA, CH, 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, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK,

[Continued on next page]

(54) Title: ANCHOR FOR AN IMPLANTABLE SENSOR



(57) Abstract: An anchor for an implantable medical device, for example, and implantable physiologic sensor, includes a proximal hub portion, an intermediate portion extending radially and distally from the hub portion, and a distal portion extending distally from the proximal portion and adapted to engage an inner surface of a target vessel for securing the implantable medical device therein. The anchor can assume a collapsed configuration for delivery through a catheter, and an expanded configuration for fixation within the vessel once deployed. The intermediate portion extends from the proximal portion at an oblique angle, allowing the anchor to be retracted and re-collapsed within the delivery catheter after initial deployment, if re-positioning or removal of the implantable medical device is necessary or desired.

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LR, LS, LT, LU, LY, MA, MD, ME, 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.

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, MT, 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).

(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,

Published:

— *without international search report and to be republished upon receipt of that report*

ANCHOR FOR AN IMPLANTABLE SENSOR

CROSS REFERENCE TO RELATED APPLICATION

[001] The present invention claims priority under 35 U.S.C. § 119 to U.S. Provisional Application No. 60/844,821, filed September 15, 2006, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[002] The present invention relates to medical devices and methods for anchoring implantable medical devices in the body. In particular, the present invention relates to anchoring devices and methods for anchoring implantable physiologic sensors and other implantable medical devices within a patient's cardiovascular system.

BACKGROUND

[003] Medical devices that can be implanted within a patient's body for monitoring one or more physiological parameters and/or to provide therapeutic functions are known. For example, sensors or transducers can be placed in the body for monitoring a variety of properties, such as temperature, blood pressure, strain, fluid flow, chemical properties, electrical properties, magnetic properties, and the like. In addition, medical devices can be implanted that perform one or more therapeutic functions, such as drug delivery, cardiac pacing, defibrillation, electrical stimulation, and the like.

[004] One parameter of particular interest is blood pressure. One or more implantable pressure sensing modules can be used in conjunction with cardiac rhythm management (CRM) devices to facilitate optimization of CRM device settings. In such systems, the pressure sensing module is delivered transvenously to a target vessel (e.g., the pulmonary artery), and anchored in the vessel using various fixation techniques. Accurate placement of the sensing module is an important factor in accurately and reliably measuring the desired parameter. Additionally, under some circumstances, it becomes

necessary to re-position an implantable sensor module after initial deployment, or alternatively, to remove the sensor from the patient entirely.

[005] Thus, a need exists for an apparatus and methods for placing and anchoring implantable medical devices within a patient's body. In particular, there is a need for an anchoring system that can be accurately re-positioned and re-deployed, or in the alternative, removed from the patient's vasculature, after an initial deployment.

SUMMARY

[006] The present invention, in one embodiment, is an implantable sensor assembly configured for delivery through a delivery catheter, the sensor assembly comprising an implantable sensor and an anchor coupled to the sensor and adapted to assume a collapsed configuration within the delivery catheter and an expanded configuration external to the delivery catheter. The anchor includes a proximal hub portion, an intermediate portion hingedly coupled to and extending distally and radially from the hub portion, the intermediate portion configured to assume a generally oblique angle with respect to the hub portion when the anchor is in the expanded configuration, and a distal portion extending distally from the intermediate portion and adapted to engage an inner surface of a vessel when the anchor is in the expanded configuration. The intermediate portion is configured to allow the anchor to be retracted within the delivery catheter and to assume the collapsed configuration after assuming the expanded configuration.

[007] The present invention, in another embodiment, is an implantable sensor assembly comprising a sensor including a housing hermetically enclosing a sensor element, an anchor. The anchor includes a proximal sensor attachment portion coupled to the housing, and radially expandable means extending from the sensor attachment portion for engaging an inner surface of a vessel.

[008] In yet another embodiment, the present invention is a method of deploying an implantable sensor assembly. In one embodiment, the method comprises positioning a distal end of a delivery catheter at a first location within a body lumen. Next, the method includes deploying an anchor portion of the sensor assembly from the distal end of the delivery catheter such that the anchor portion assumes an expanded configuration. The method further includes, in one embodiment, retracting the anchor portion into the delivery catheter such that the anchor portion assumes a collapsed configuration, repositioning the distal end of the delivery catheter at a second location within the body lumen, and re-deploying the anchor portion of the sensor assembly from the distal end of the delivery catheter such that the anchor portion re-assumes the expanded configuration.

[009] While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[010] FIG. 1 is a schematic view of a cardiac rhythm management system including a pulse generator and an implantable sensor module implanted within a pulmonary artery of a heart according to one embodiment of the present invention.

[011] FIGS. 2A and 2B are side and proximal end views, respectively, of the sensor assembly shown implanted in FIG. 1.

[012] FIGS. 3A and 3B are side and proximal end views, respectively, of a sensor assembly according to another embodiment of the present invention.

[013] FIG. 4 is a side view of a sensor assembly according to another embodiment of the present invention.

[014] FIGS. 5A-5D are side views of the sensor assembly of FIGS. 3A-3B being deployed from a delivery catheter according to one embodiment of the present invention.

[015] FIGS. 6A – 6D are perspective, side, top, and distal end views, respectively, of an anchor for a sensor assembly or other implantable medical device according to another embodiment of the present invention.

[016] FIGS. 7-10 are schematic perspective views of alternative anchors for a sensor assembly or other implantable medical device according to other embodiments of the present invention.

[017] FIG. 11 is a flow chart illustrating a method of deploying an implantable sensor assembly according to one embodiment of the present invention.

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

DETAILED DESCRIPTION

[019] FIG. 1 is a schematic view of a cardiac rhythm management system 5 including a pulse generator 6, a communication link 8, and an implantable sensor assembly 10 implanted within a pulmonary artery 16 of a heart 20 according to one embodiment of the present invention. As is known in the art, the pulse generator 6 is typically implanted subcutaneously at an implantation location in the patient's chest or abdomen. As shown, the heart 20 generally includes a superior vena cava 22, a right atrium 24, a right ventricle 26, a ventricular septum 28, a right ventricular outflow tract 30, a left ventricle 32 and a left atrium 34. As shown, the right ventricular outflow tract 30 leads to the

pulmonary artery 16, which is separated from the right ventricle by a pulmonary artery valve 38.

[020] The pulse generator 6 may be any implantable medical device known in the art or later developed, delivering an electrical therapeutic stimulus to the patient. In one embodiment, the pulse generator 6 is a pacemaker. In another embodiment, the pulse generator is an implantable cardiac defibrillator. In still other exemplary embodiments, the pulse generator 6 includes both pacing and defibrillation capabilities. In the illustrated embodiment, the pulse generator 6 and the implantable sensor assembly 10 are communicably coupled by the communication link 8, which may be a wired or wireless communication link.

[021] As shown in FIG. 1, the sensor assembly 10 includes an implantable sensor 50 and an anchor 54 coupled to the sensor 50. As will be discussed in detail below, the anchor 54 is an expandable structure configured to assume a collapsed configuration for transvenous delivery of the sensor assembly 10 to the desired implantation location (e.g., via a delivery catheter), and an expanded configuration, illustrated in FIG. 1, in which the anchor 54 engages an inner surface of the pulmonary artery 16. The anchor 54 is further advantageously configured to facilitate retraction of the anchor 54 back within the delivery catheter after initial deployment so that the sensor assembly 10 can be repositioned within the same or a different vessel, or alternatively, removed from the patient altogether.

[022] In the embodiment illustrated in FIG. 1, the sensor assembly 10 is implanted in the patient's main pulmonary artery 16. In other embodiments, the sensor assembly 10 may be implanted in a branch of the pulmonary artery 16 (e.g., the right or left pulmonary artery). In other embodiments, the sensor assembly 10 may be implanted in other regions of the patient's vasculature or in other body lumens.

[023] The sensor 50 is configured to communicate with the pulse generator 6 via the communication link 8, which may be wired or wireless. Various types of wireless communication circuitry are well

known in the art, and the specific type and/or style of wireless communication that can be used is not limited. For example, ultrasonic waves, acoustic communications, radio frequency communications, and the like may be used. In one embodiment, the sensor 50 includes an acoustic transmitter/receiver configured for acoustic telemetry, which transmitter/receiver is configured to transmit and/or receive ultrasonic signals to/from the pulse generator 6. In some embodiments, the sensor 50 may be configured to communicate with one or more other implantable medical devices (e.g., another pulse generator or other therapeutic device such as a drug delivery device) via other wired or wireless communication links. In still other embodiments, the sensor 50 is configured to communicate with devices external to the patient's body via wireless communication links.

[024] The sensor 50 may be configured to perform one or more designated functions, which may include taking one or more physiological measurements. The sensor 50 may be configured to measure any known physiologic parameters such as, for example, blood pressure, temperature, blood or fluid flow, strain, electrical, chemical, or magnetic properties within the body. The specific parameters to be measured, and thus the implantation site for the sensor assembly 10, are determined based on the particular therapeutic needs of the patient. In one exemplary embodiment, the sensor 50 may be configured to measure blood pressure in the pulmonary artery 16 (e.g., as illustrated in FIG. 1). In the illustrated embodiment, the sensor 50 is adapted to store and/or transmit blood pressure data to the pulse generator 6 or a device (e.g., a monitor or programmer) located external to the patient's body.

[025] FIGS. 2A and 2B are side and proximal end views, respectively, of the sensor assembly 10 in its expanded configuration according to one embodiment of the present invention. As shown in FIGS. 2A-2B, the sensor 50 includes a housing 60 defining a proximal end 64, and the anchor 54 includes a proximal hub portion 68, an intermediate portion 72, and a distal portion 76. In the illustrated embodiment, the

hub portion 68 is coupled to the sensor housing 60. In other embodiments, the sensor 50 may be coupled to other portions of the anchor 54 (e.g., near the distal end of the distal portion 76).

[026] As shown, the intermediate portion 72 extends both distally and radially from the hub portion 68, and the distal portion 76 extends distally from the intermediate portion 72, forming a continuous transition from the intermediate portion 72 to the distal portion 76. In the illustrated embodiment, the intermediate portion 72 is formed from a plurality of elongated struts 82 extending distally and radially from the hub portion 68. In this configuration, the struts 82 are effectively hingedly connected to the hub portion 68, which permits the anchor 54 to be collapsed upon being retracted into a delivery catheter. As further shown, the distal portion 76 extends distally from the intermediate portion 72, and includes a plurality of elongate, arcuate members interconnected at approximately their mid-sections to form a generally tubular stent-like structure defining a lumen 77 for the flow of body fluids (e.g., blood) through the vessel (e.g., the pulmonary artery) in which the sensor assembly 10 is implanted. When in the expanded configuration as illustrated, at least the stent-like distal portion 76, and in some embodiments, at least portions of the struts 82 making up the intermediate portion 72, are adapted to direct a radial force against and engage the inner surface of the pulmonary artery (or other vessel) to fixate the sensor assembly 10 therein.

[027] As shown, the proximal hub portion 68, and thus the sensor 50 attached thereto, is radially positioned at or proximate an outer periphery 84 of the anchor 54. Thus, in the illustrated embodiment, the sensor 50 will be located at or very near the wall of the vessel (e.g., the pulmonary artery) in which the sensor assembly 10 is implanted. Thus, as can perhaps be best seen in FIG. 2B, the lumen 77 formed by the anchor 54 is substantially unobstructed by other portions of the anchor assembly 10, and thus the lumen 77 provides a substantially unobstructed conduit for blood flow, passage of other medical devices (e.g., catheters, electrical leads), and the like.

[028] In the illustrated embodiment, the proximal hub portion 68 is a generally annular structure and extends circumferentially around the housing 60 of the sensor 50. In other embodiments, the hub portion 68 may not extend completely around the sensor housing 60. In still other embodiments, the annular structure may be omitted from the hub portion 68. For example, the hub portion 68 may include generally linear members joined at or near the proximal end of the anchor 54, which members may diverge to form the intermediate portion of the anchor 54.

[029] The anchor 54 may be coupled to the sensor 50 by any methods known in the art. For example, the anchor may be welded, brazed, soldered, adhesively bonded, or attached to the sensor housing 60 by crimping or using a mechanical fastening structure such as a snap-fit ring. Alternatively, the sensor housing 60 may be formed integrally with the anchor 54, or portions thereof. In short, the present invention does not require any particular method of coupling the sensor 50 and the anchor 54. Furthermore, in some embodiments, the sensor 50 may be frictionally coupled to the anchor (e.g., by designing an interference fit between the sensor 50 partially and the annular hub portion 68 as illustrated in FIGS. 2A-2B). Such embodiments may facilitate removing and/or replacing the sensor 50 while leaving the anchor 54 in its implanted location in a patient's vasculature.

[030] As further shown in FIG. 2A, in the expanded configuration of the anchor 54, the struts 82 of the intermediate portion 72 radiate distally and outwardly with respect to the hub portion 68, such that at least the portion of the intermediate portion 72 nearest the hub portion 68 forms a generally oblique angle α with respect to an axis A_{10} extending longitudinally through the hub portion 68. As will be explained in more detail below, the sloped orientation of the intermediate portion 72 with respect to the axis A_{10} advantageously facilitates retracting the anchor 54 within a delivery sheath after deployment, such that the sensor assembly 10 can be repositioned and/or removed from the body entirely, if desired, after an initial

deployment. For example, a specialized stylet or other retaining element can be releasably coupled to the proximal end 64 of the sensor 50 (or to the proximal hub portion 68 of the anchor 54), providing a means for retracting the anchor 54 back within a delivery catheter after deployment.

[031] The specific dimensions of the anchor 54 will vary depending on the particular implantation location and the required fixation strength. In general, the anchor 54 has an expanded outer distal portion diameter D_{10} and a length L_{10} selected to impart a radial force on and to frictionally engage the inner surface of the target vessel in which the sensor assembly 10 is implanted. For example, as discussed above, in one embodiment, the sensor assembly 10 is configured for implantation in the pulmonary artery 16. In various exemplary embodiments, the anchor 54 has a length L_{10} of from about 20 millimeters to about 60 millimeters and an expanded diameter D_{10} of from about 16 millimeters to about 50 millimeters. In one embodiment, the length L_{10} is about 50 millimeters and the expanded diameter D_{10} is about 38 millimeters. In one embodiment, the length L_{10} is about 50 millimeters and the expanded diameter D_{10} is about 32 millimeters. It is emphasized, however, that these examples are illustrative only, and that particular implantation locations may call for other anchor lengths L_{10} and expanded diameters D_{10} .

[032] FIGS. 3A and 3B are side and proximal end views, respectively, of a sensor assembly 110 according to another embodiment of the present invention. As shown in FIGS. 3A-3B, the sensor assembly 110 includes a sensor 150 and an anchor 154, which like the anchor 54 described above, includes a housing 160 and a proximal end 164, and the anchor 154 includes a proximal hub portion 168, an intermediate portion 172, and a distal portion 176. In the illustrated embodiment, the hub portion 168 is coupled to the sensor housing 160. In other embodiments, the sensor 150 may be coupled to other portions of the anchor 154. The distal portion 176 includes a plurality of interconnected, undulating members arranged to form a generally

tubular stent-like structure providing a lumen 177 for the flow of body fluids (e.g., blood) through the vessel (e.g., the pulmonary artery) in which the sensor assembly 110 is implanted.

[033] The sensor assembly 110 is in many respects similar to the sensor assembly 10 described above, with the primary exception being that in the sensor assembly 110, the hub portion 168 is radially located within the lumen 177 formed by the distal portion 176, and the intermediate portion 172 includes a plurality of struts 182 extending distally and radially from the hub portion 168 in a manner similar to spokes on a wheel. In the illustrated embodiment, the hub portion 168 is substantially centrally located in the lumen 177. In other embodiments, the hub portion 168 may be offset from the radial center of the lumen 177.

[034] Similar to the anchor 54, in the expanded configuration shown in FIGS. 3A and 3B, the struts 182 of the anchor intermediate portion 172 of the anchor 154 radiates distally and outwardly, such that the intermediate portion 172 generally forms an oblique angle α with respect to an axis A_{110} extending longitudinally through the hub portion 168. Thus, as with the anchor 54, the sloped orientation of the intermediate portion 172 with respect to the axis A_{110} advantageously facilitates retracting the anchor 154 within a delivery sheath after deployment.

[035] As with the anchor 54 described above, the anchor 154 has an expanded outer distal portion diameter D_{110} and a length L_{110} selected to impart a radial force on and to frictionally engage the inner surface of the target vessel in which the sensor assembly 10 is implanted. In one embodiment, the sensor assembly 110 is configured for implantation in the pulmonary artery 16, and the anchor 154 has a length L_{110} of from about 20 millimeters to about 60 millimeters and an expanded diameter D_{110} of from about 16 millimeters to about 50 millimeters. In one embodiment, the length L_{110} is about 50 millimeters and the expanded diameter D_{110} is about 38 millimeters. In one embodiment, the length L_{110} is about 50 millimeters and the expanded diameter D_{110} is about

32 millimeters. It is emphasized, however, that these examples are illustrative only, and that particular implantation locations may call for other anchor lengths L_{110} and expanded diameters D_{110} .

[036] FIG. 4 is a side view of a sensor assembly 210 according to another embodiment of the present invention. As shown in FIG. 4, the sensor assembly 210 includes a sensor 250 and an anchor 254. The sensor 250 includes a housing 260 and a proximal end 164, and the anchor 254 includes a proximal hub portion 268, an intermediate portion 272, and a distal portion 276. In the illustrated embodiment, the hub portion 268 is coupled to the sensor housing 260, although in other embodiments, the sensor 250 may be coupled to the anchor 254 at other locations.

[037] As can be seen in FIG. 4, the sensor assembly 210 is configured in a manner substantially similar to the sensor assembly 10 described above, with the primary difference being the elongated distal portion 276 of the anchor 254 as compared to the anchor 54. The elongated distal portion 276 provides an increased fixation strength due to the increased surface area for engaging the vessel inner surface, as compared to the distal portion 76 of the anchor 54. In one embodiment of the sensor assembly 210 configured for implantation in the patient's pulmonary artery, the anchor 254 has a length L_{210} of from about 70 to about 90 millimeters. In one embodiment, the length L_{210} is about 80 millimeters.

[038] Thus, when in their expanded configurations as illustrated in the respective figures, the intermediate portions and the stent-like distal portions of the anchors 54, 154, and 254 form radially expandable means for engaging the inner surface of the vessel (e.g., the pulmonary artery) to fixate the respective sensor assembly 10 therein.

[039] The respective sensors and anchors of the sensor assemblies 10, 110, 210 described above can be made of any biocompatible materials suitable for similar implantable medical devices, whether now known or later developed. For example, in various embodiments, any or all of the sensor housings 60, 160, and/or 260 may be made of any

biocompatible materials suitable for use for hermetic housings for other implantable medical devices. Such materials include, without limitation, titanium, stainless steel, biocompatible polymers, and the like. It will be appreciated that the particular design requirements of the implantable medical device and the associated anchor will primarily dictate the material selected.

[040] The stent-like anchors 54, 154, and/or 254 described above can be self-expanding or balloon expandable, and can be made from any materials, whether now known or later developed, suitable for use in cardiovascular stents or similar implantable devices. By way of example only, suitable materials include stainless steel and a wide variety of alloys and polymers. For self-expanding embodiments, the anchors 54, 154, 254 are made at least partially from materials having desirable shape memory and/or superelastic properties. Exemplary materials exhibiting suitable shape memory and superelasticity include shape memory polymers and nickel-titanium shape memory alloys such as nitinol. In some embodiments, the anchors 54, 154, and/or 254 are laser cut from a nitinol tube. In other embodiments, the anchors 54, 154, and/or 254 may be formed substantially from wire stock. Other suitable materials will be ascertained by those skilled in the art based on the foregoing.

[041] For all of various embodiments of the present invention, the size of the anchor structure, in both the collapsed and expanded configurations, will generally be determined based on the particular patient anatomy. In some embodiments, the anchors 54, 154, and/or 254 are designed and sized to frictionally engage the inner surface of the vessel wall upon expansion. In one embodiment, e.g., where the anchoring structures are designed to be secured in the pulmonary artery 16, which branches and tapers as it flows toward the lungs, the anchoring structure can be placed in the pulmonary artery, and then allowed to flow with blood stream until the anchoring structure lodges in a desired location. Once secured, the sensor can collect the desired data measurements. Of course, as one skilled in the art will

appreciate, the anchoring structure can be placed in other blood vessels, or other bodily lumens.

[042] FIGS. 5A-5D are side views illustrating, schematically, the sensor assembly 110 being deployed from a delivery catheter 300. As shown in FIG. 5A, the sensor assembly 110 is initially retained within the delivery catheter 300 with the anchor 154 in a collapsed configuration and a tether 302 releasably coupled to the proximal end 164 of the sensor 150. The tether 302 can be a stilet, guidewire, or similar structure having a distal mechanism adapted to releasably engage the sensor 150 (or the hub portion 168) as the sensor assembly 110 is deployed through the catheter 300. For example, the tether 302 may include any of the structures disclosed in the co-pending and commonly assigned U.S. Provisional Patent Applications 60/844,953 titled "DELIVERY SYSTEM FOR AN IMPLANTABLE PHYSIOLOGIC SENSOR" filed September 15, 2006, and 60/844,948 titled "MECHANISM FOR RELEASABLY ENGAGING AN IMPLANTABLE MEDICAL DEVICE FOR IMPLANTATION" filed September 15, 2006, the contents of which are incorporated herein by reference for all purposes.

[043] The tether 302 allows the user (e.g., a physician or other medical professional) to control the position of the sensor assembly 110 with respect to the catheter 300. For example, the tether 302 can be pushed distally relative to the catheter 300 to advance the anchor 154 beyond a distal end 304 of the catheter 300. Alternatively, the catheter 300 can be retracted in a proximal direction while the tether 302 is held in place. In either approach, in the illustrated embodiment, the anchor 154 self-expands to its expanded configuration upon being extended beyond the distal end 304 of the catheter 300.

[044] FIG. 5B illustrates the sensor assembly 110 with the anchor 154 partially deployed from the distal end 304 of the catheter 300. In the embodiment of FIG. 5B, the anchor 154 is self-expanding, and in that respect is similar to cardiovascular stents as are known in the art. FIG. 5C illustrates the sensor assembly 110 fully deployed from the distal

end 304 of the catheter 300, with the tether 302 still coupled to the proximal end 164 of the sensor 150. As shown in FIG. 5C, the anchor 154 is fully expanded to its expanded configuration such that it can engage an inner surface of a vessel (e.g., the pulmonary artery) to secure the sensor assembly 110 therein. FIG. 5C further illustrates the sloped configuration of the intermediate portion 172 with respect to the sensor 150 and the longitudinal axis A_{110} extending through the proximal portion 168 (see FIG. 3A), and in turn, the delivery catheter 300.

[045] FIG. 5D illustrates the sensor assembly 110 partially retracted within the catheter 300. As shown in FIG. 5D, the anchor 154 can re-assume its collapsed configuration and be retracted back into the catheter 300 after being fully deployed as shown in FIG. 5C. This retractability is enabled by the configuration of the intermediate portion 172 of the anchor 154, and more particularly, the oblique angle of the intermediate portion 172 with respect to the longitudinal axis A_{110} extending through the proximal hub portion 168 (see FIG. 3A). The illustrated configuration of the hub portion 168 and the intermediate portion 172 in effect hingedly connects the members making up the intermediate portion 172 to the hub portion 168, allowing the anchor 154 to be collapsed as it is withdrawn back into the catheter 300. It will be appreciated that the anchor 154 can subsequently be re-deployed at this or a different location within the vasculature, if desired.

[046] FIGS. 6A through 6D are perspective, side, top, and distal end views, respectively, of an anchor 354 according to another embodiment of the present invention. As shown in FIGS. 6A-6D, the anchor 354 includes a proximal hub portion 368, an intermediate portion 372, and a distal portion 376. As with the anchors described above, the intermediate portion 372 extends distally from the hub portion 368, and the distal portion 376 extends distally from the intermediate portion 372. In the illustrated embodiment, the hub portion 368 includes an annular ring 379 adapted to be coupled to an implantable medical device (e.g., an implantable physiologic sensor such as the sensors 50,

150, 250 described above). As shown, the hub portion 368 further includes a plurality (in this case, two) shank members 380, 382 extending distally from the annular ring 379. As with the anchor embodiments described above, the annular ring 379 may, in some embodiments, be omitted. Alternatively, the hub portion 368 may include an alternative structure adapted for coupling the anchor 354 to the respective implantable medical device.

[047] As shown, the intermediate portion 372 includes a pair of hinge elements 384, 386 extending distally from the shank members 380, 382, respectively. As further shown, the hinge element 384 includes a pair of diverging arms 388, 389 hingedly connected at the distal end of the shank member 380, and the hinge element 386 includes a pair of diverging arms 390, 391 hingedly connected at the distal end of the shank member 382.

[048] The distal portion 376 includes a pair of vessel engaging structures 400, 402 which as illustrated are in the form of nested jaw structures extending from the distal ends of the diverging arms 388, 390 and 389, 391, respectively. The jaw structures further include peripheral surfaces 404, 406 adapted to frictionally engage the inner surfaces of the target vessel when the anchor is in its expanded configuration as shown in FIGS. 6A-6C. Thus, when in its expanded configuration as illustrated, in the respective figures, the intermediate portion 372 and the distal portion 376 form radially expandable means for engaging the inner surface of the vessel (e.g., the pulmonary artery) to fixate the sensor assembly therein.

[049] The hinged configuration of the anchor 354 and the design of the distal portion 376 allows the intermediate and distal portions 372, 376 to be collapsed inwardly, as indicated by the arrows R in FIGS. 6A and 6C, for delivery of the anchor 354 through a catheter or similar device. Additionally, the anchor 354 is adapted to self-expand to the expanded configuration illustrated in FIGS. 6A-6C for securing an implantable medical device (not shown) attached to the hub portion 368 within a target vessel. Still additionally, similarly to the anchors 54,

154, and 254 (see FIGS. 5A-5D) described above, the hinged configuration of the intermediate portion 372 and the oblique orientation of the intermediate portion 372 relative to the proximal portion 368 allows the anchor 354 to be collapsed when retracted back within a delivery catheter after initial deployment.

[050] The anchor 354 may be made from any of the materials described above in connection with the anchors 54, 154, and 254. Additionally, as will be appreciated, the anchor 354 may be formed by any methods known in the art or later developed for manufacturing expandable implantable medical device anchors and the like.

[051] FIG. 7 is a schematic perspective view of a re-positionable anchor 454 in an expanded configuration according to another embodiment of the present invention. As shown in FIG. 7, the anchor 454 generally takes the form of a teardrop-shaped loop when in the expanded configuration, and includes a proximal hub portion 468, an intermediate portion 472, and a distal portion 476. As with the anchors described above, the intermediate portion 472 extends distally from the hub portion 468, and the distal portion 476 extends distally from the intermediate portion 472. In the illustrated embodiment, the hub portion 468 includes an annular ring 478 forming an attachment structure (such as the annular rings shown in FIGS. 2A and 6A-6C) adapted for coupling to the anchor 454 to an implantable medical device (e.g., an implantable physiologic sensor such as the sensors 50, 150, 250 described above).

[052] As is apparent from FIG. 7, the anchor 454 transitions gradually from the hub portion 468 to the intermediate portion 472, which forms an oblique angle α with respect to the hub portion 468, which itself is desirably oriented generally parallel to the target vessel (e.g., the pulmonary artery 16, see FIG. 1) in which the anchor 454 is implanted. This configuration, and the loop shape of the anchor 454 in general, permit the anchor 454 to be collapsed radially and longitudinally (as indicated by the arrows R and L in FIG. 7) when retracted back within a delivery catheter or sheath after initial deployment. Thus, as with the

anchors 54, 154, 254, and 354 described above, the anchor 454 allows an implantable medical device (e.g., an implantable sensor) to be repositioned within a patient's vasculature after initial deployment from the delivery catheter.

[053] FIG. 8 is a schematic perspective view of a repositionable anchor 554 in an expanded configuration according to another embodiment of the present invention. As shown in FIG. 8, the anchor 554 includes a pair of loops 556, 557 arranged back-to-back and connected at a connection location 558 at or near the vertices of the anchor 454 and the loop loops 556, 557. As can be seen in FIG. 8, at least the loop 556 is substantially similar in form and construction as the anchor 454 described above, and includes a proximal hub portion 564, an intermediate portion 572, and a distal portion 576, which portions are configured substantially similar or identical to the corresponding portions of the anchor 454 described above. In the illustrated embodiment, the hub portion 568 includes an annular ring 578 for coupling to the anchor 554 to an implantable medical device as described above. As can be further seen, the loop 557 is, in the illustrated embodiment, essentially a mirror image of the loop 556 and includes a distal end portion 582. The anchor 554 further includes coil-shaped connecting members 586, 588 extending between and connecting the loops 556, 557.

[054] The loops 556, 557 of the anchor 554 are configured to operate in substantially the same manner as the anchor 454 above. In particular, the loops 556, 557 permit the anchor 554 to be collapsed radially and longitudinally when retracted back within a delivery catheter or sheath after initial deployment. Additionally, in some embodiments, the distal end portion 582 may provide a structure for the attachment of an implantable sensor or other implantable medical device. Thus, the embodiment of FIG. 9 advantageously permits the attachment of multiple implantable sensors, if desired. Alternatively, an implantable sensor may be attached to the distal end portion 582 and not to the proximal hub portion 568, which may be used for other

purposes (e.g., for coupling the anchor 554 to a tether or retaining element for deployment of the anchor and implantable medical device attached thereto).

[055] FIG. 9 is a schematic perspective view of a repositionable anchor 654 in an expanded configuration according to another embodiment of the present invention. As can be seen in FIG. 9, the anchor 654 is another variation of the anchor 454, and includes a pair of loops 656, 657 longitudinally spaced and connected by an elongate connecting element 658. As shown, at least the loop 656 is substantially similar in form and construction as the anchor 454 described above, and includes a proximal hub portion 664, an intermediate portion 672, and a distal portion 676, which portions are configured substantially similar or identical to the corresponding portions of the anchor 454 described above. As further shown, the proximal hub portion 668 includes an annular ring 678 for coupling to the anchor 654 to an implantable medical device as described above.

[056] FIG. 10 is a schematic perspective view of a repositionable anchor 754 in an expanded configuration according to another embodiment of the present invention. As can be seen in FIG. 10, the anchor 754 is another variation of the anchor 454, and includes a pair of loops 756, 757 longitudinally spaced and connected by elongate connecting elements 758, 759 disposed along the periphery of the anchor with the loops 756, 757 in their expanded configurations. At least the loop 756 is substantially similar in form and construction as the anchor 454 described above, and includes a proximal hub portion 768, an intermediate portion 772, and a distal portion 776, which portions are configured substantially similar or identical to the corresponding portions of the anchor 454 described above. In the illustrated embodiment, the hub portion 768 includes an annular ring 778 for coupling to the anchor 754 to an implantable medical device as described above. As further shown, the distal portion 776 of the loop 756 is directly attached to the loop 757 at an attachment location 788.

[057] Any of the loop-shaped anchors 454, 554, 654, and 754 are configured to operate in substantially the same or an identical manner as the anchors 54, 154, 254, and 354 described above. In particular, all of the foregoing anchors are configured such that they can be collapsed radially and longitudinally (such as indicated by the arrows R and L in FIG. 7) when retracted back within a delivery catheter or sheath after initial deployment. Thus, as with the anchors 54, 154, 254, and 354 described above, these anchors allow an implantable medical device (e.g., an implantable sensor) to be repositioned within a patient's vasculature after initial deployment from the delivery catheter. Thus, when in their expanded configurations as illustrated in the respective figures, the intermediate portions and the distal portions of the anchors 454, 554, 654, and 754 form radially expandable means for engaging the inner surface of the vessel (e.g., the pulmonary artery) to fixate the respective sensor assembly therein.

[058] The anchoring structures described above allow the sensor, or other implantable medical device, to be anchored and secured in any part of the vascular system. In one particular embodiment, assembly can be delivered to the target implantation site within the vascular system using known catheterization techniques.

[059] FIG. 11 is a flow chart illustrating a method of deploying an implantable sensor assembly (e.g., the assembly 10, 110, 210, or an assembly utilizing one of the anchors 354, 454, 554, 654, 754) according to one embodiment of the present invention. In one exemplary embodiment, the sensor assembly is implanted in the pulmonary artery 16 (see FIG. 1) or a branch thereof. As shown in FIG. 11, a guide catheter is transvenously advanced, using methods known in the art, until its distal end is positioned proximate an implantation site within the pulmonary artery 16. (Block 810) For example, in one embodiment, a Swan Ganz catheter, which includes a balloon at or near its distal end, may be inserted into the venous system and floated with the blood flow into and through the heart 20 out to the pulmonary artery 16. The balloon catheter can then be used

to locate a guide wire and subsequently, a second guide catheter partially within the pulmonary artery 16. It is emphasized, however, that any catheterization techniques, whether now known or later developed, can be used to position the sensor assembly within the pulmonary artery 16 (or other region of the vasculature system, as appropriate).

[060] If desired by the clinician, the sensor assembly, with a tether or other retaining structure releasably attached, can be pre-loaded into the guide catheter lumen prior to catheterization. Alternatively, the guide catheter can be positioned as desired in the patient's vasculature system, and the sensor assembly and tether can be advanced through the catheter lumen to a location proximate the distal opening of the catheter. (Block 812)

[061] The sensor assembly, or at least the anchor, can then be deployed, with the tether still attached, from the distal end of the guide catheter. (Block 814) For example, the sensor assembly can be deployed by retracting the guide catheter while holding the tether, and thus the sensor assembly, in position, or by pushing the tether and sensor assembly distally out the distal end of the catheter. Once released from the guide catheter, the anchor may self-expand to assume its expanded configuration and engage the inner surface of the pulmonary artery 16. Alternatively, where a balloon-expandable anchor is used, the anchor can be expanded by inflating a balloon, as is known in the art for, example, expanding balloon-expandable vascular stents.

[062] If desired, the tether can then be released from the sensor assembly, and the tether and guide catheter can be retracted from the patient. Alternatively, if the physician determines that the sensor assembly should be removed or repositioned, the physician can retract the sensor assembly, including the anchor, back within the guide catheter by pulling the tether distally with respect to the guide catheter. (Block 816) As illustrated in FIG. 5D, the anchor will collapse as it is retracted back within the guide catheter so as to re-assume its

collapsed configuration within the guide catheter. The catheter can then be re-positioned in the pulmonary artery or relocated to another area of the patient's vasculature. The anchor and/or the sensor assembly in its entirety can then be re-deployed from the guide catheter. Alternatively, the sensor assembly can be removed from the body entirely (e.g., if the sensor is determined to be not functioning as desired, or if the anchor is incorrectly sized or configured for the particular patient anatomy).

[063] Of course, it will be appreciated that the anchor structures described above may be utilized to secure physiologic sensors and/or other implantable medical devices in any area of a patient's cardiovascular system, or in some embodiments, in other bodily lumens. That is, the anchors described above may effectively secure sensors and other devices in vessels other than the pulmonary artery and its branches.

[064] Additionally, in some embodiments, the anchors described above may be utilized to secure therapy delivery devices (e.g., drug delivery devices, stimulation electrodes) in addition to, or in lieu of, implantable physiologic sensors. In such embodiments, the therapeutic functions are not limited to any particular type and can include, for example, ultrasound or drug delivery therapy, or any other therapy capable of being administered with an implantable medical device currently known or later developed. In some embodiments, anchoring structures may be used to place a plurality of sensors, actuators, or a combination of sensors and actuators. Placement of multiple sensors and/or actuating devices throughout the body can allow for a more comprehensive therapeutic and diagnostic system, but multiple sensors and/or actuating devices are not required.

[065] Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. For example, while the embodiments described above refer to particular features, the scope of this invention also includes embodiments having different combinations of features and

embodiments that do not include all of the described features. Accordingly, the scope of the present invention is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

CLAIMS

We claim:

1. An implantable sensor assembly configured for delivery through a delivery catheter, the sensor assembly comprising:

an implantable sensor;

an anchor coupled to the sensor and adapted to assume a collapsed configuration within the delivery catheter and an expanded configuration external to the delivery catheter, the anchor including:

a proximal hub portion;

an intermediate portion hingedly coupled to and extending distally and radially from the hub portion, the intermediate portion configured to assume a generally oblique angle with respect to the hub portion when the anchor is in the expanded configuration; and

a distal portion extending distally from the intermediate portion and adapted to engage an inner surface of a vessel when the anchor is in the expanded configuration,

wherein the intermediate portion is configured to allow the anchor to be retracted within the delivery catheter and to assume the collapsed configuration after assuming the expanded configuration.

2. The assembly of claim 1 wherein the anchor is coupled to the sensor at the hub portion.

3. The assembly of claim 2 wherein the sensor includes a housing, and wherein the hub portion is generally annular and is adapted to extend circumferentially around at least a portion of the sensor housing.

4. The assembly of claim 1 wherein at least the distal portion is adapted to engage an inner surface of a pulmonary artery of a patient.
5. The assembly of claim 1 wherein the sensor includes a pressure sensor.
6. The assembly of claim 5 wherein the pressure sensor is adapted to measure a pulmonary arterial blood pressure.
7. The assembly of claim 1 wherein the sensor is located at approximately a radial center of the anchor when the anchor is in the expanded configuration.
8. The assembly of claim 1 wherein the sensor is positioned proximate a periphery of the anchor when the anchor is in the expanded configuration.
9. The assembly of claim 1 wherein the anchor is balloon-expandable.
10. The assembly of claim 1 wherein the anchor is self-expanding.
11. The assembly of claim 1 wherein the anchor is made substantially from a shape memory material.
12. The assembly of claim 11 wherein the anchor is made substantially from a shape memory nickel-titanium alloy.
13. An implantable sensor assembly comprising:
 - a sensor including a housing hermetically enclosing a sensor element; and
 - an anchor including:
 - a proximal sensor attachment portion coupled to the housing;
 - and

radially expandable means extending from the sensor attachment portion for engaging an inner surface of a vessel.

14. The assembly of claim 13 wherein the radially expandable means for engaging an inner surface of a vessel are configured to assume a collapsed configuration for delivery within a catheter and an expanded configuration external to the catheter.

15. The assembly of claim 14 wherein the radially expandable means for engaging an inner surface of a vessel include:

a plurality of first elongate members extending distally and radially from the sensor attachment portion at an oblique angle with respect to the sensor attachment portion when in the expanded configuration; and

a plurality of second elongate members each extending distally from at least one of the first elongate members,

wherein at least the second elongate members are adapted to engage the inner surface of the vessel when in the expanded configuration.

16. The apparatus of claim 15 wherein the second elongate members each include at least one arcuate segment, wherein adjacent second elongate members are attached to each other at approximately a middle portion of each arcuate segment.

17. The apparatus of claim 16 wherein the sensor attachment portion is generally annular and is adapted to extend circumferentially surround at least a portion of the sensor housing.

18. A method of deploying an implantable sensor assembly, the method comprising:

positioning a distal end of a delivery catheter at a first location within a body lumen;

deploying an anchor portion of the sensor assembly from the distal end of the delivery catheter such that the anchor portion assumes an expanded configuration;

retracting the anchor portion into the delivery catheter such that the anchor portion assumes a collapsed configuration;

repositioning the distal end of the delivery catheter at a second location within the body lumen; and

re-deploying the anchor portion of the sensor assembly from the distal end of the delivery catheter such that the anchor portion re-assumes the expanded configuration.

19. The method of claim 18 for deploying an implantable pressure sensor assembly.

20. The method of claim 19 wherein positioning a distal end of a delivery catheter includes transvenously advancing the delivery catheter to locate the distal end in a pulmonary artery.

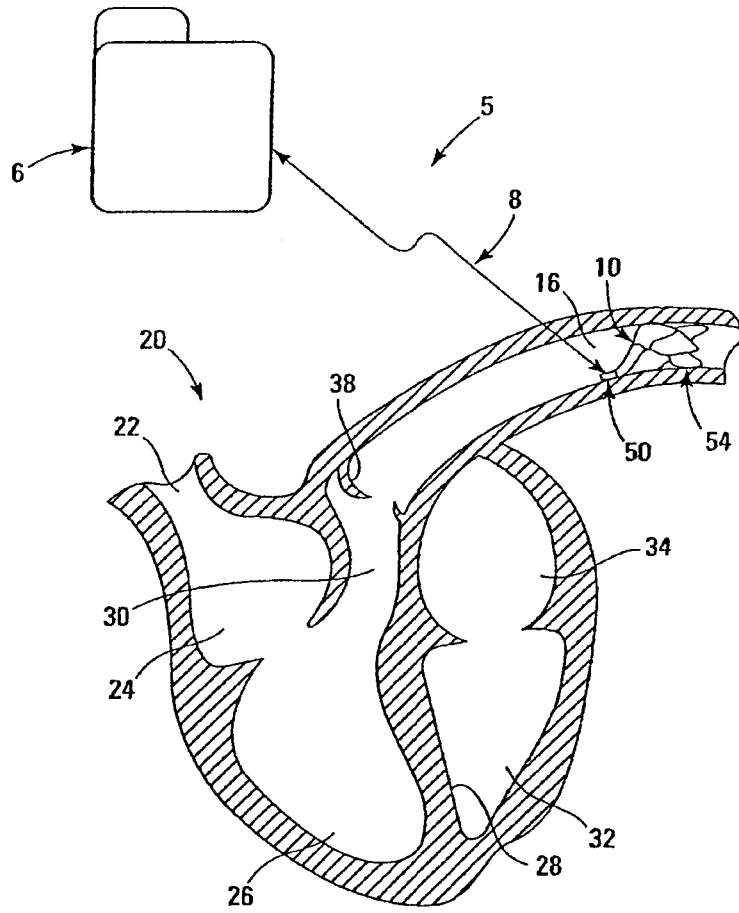


Fig. 1

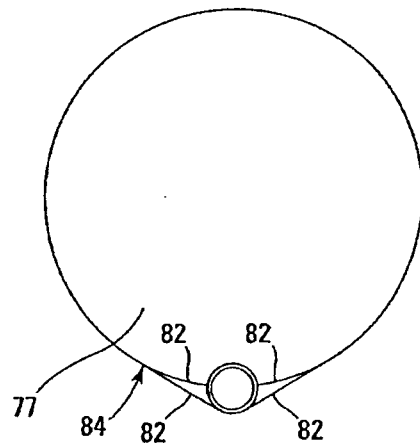
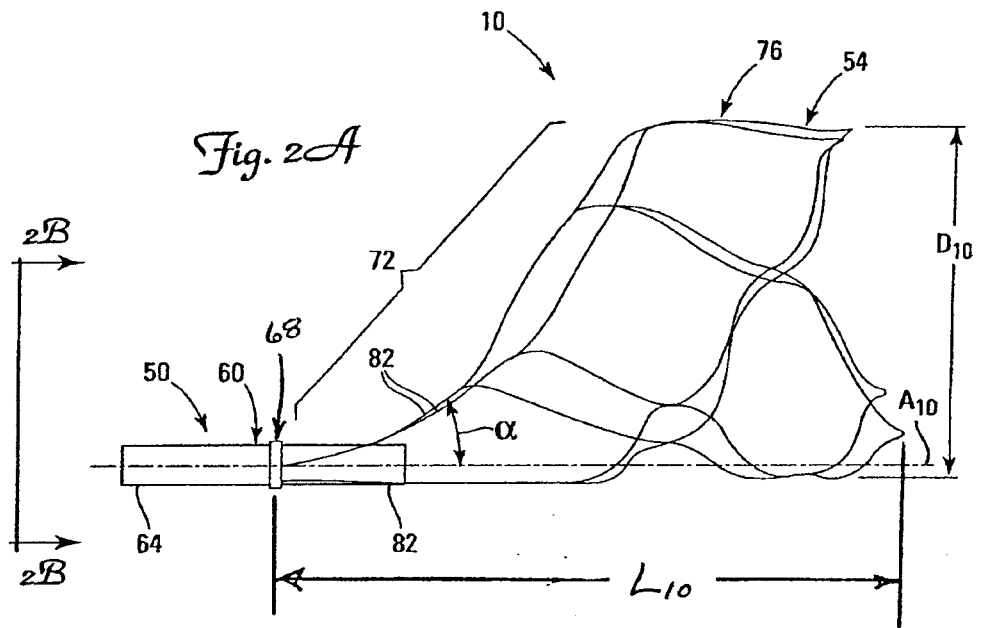


Fig. 2B

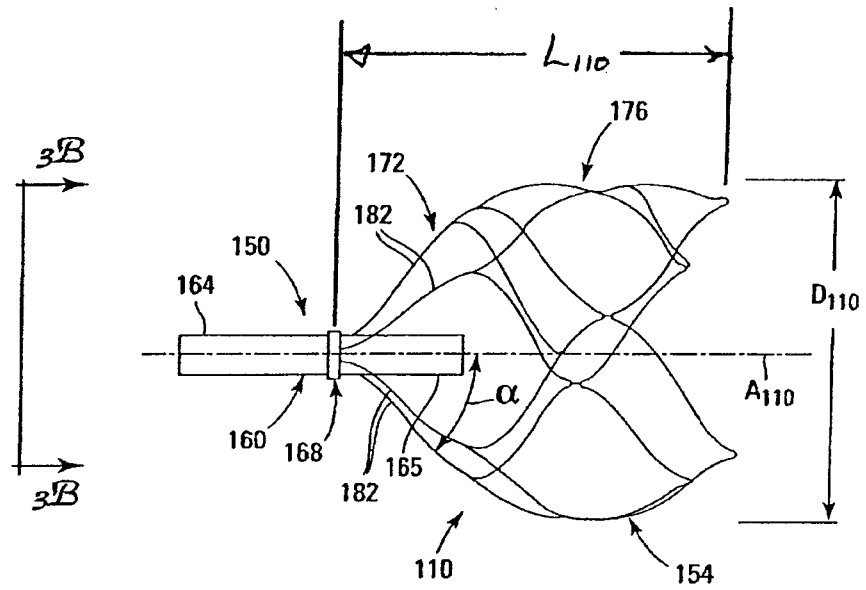


Fig. 3A

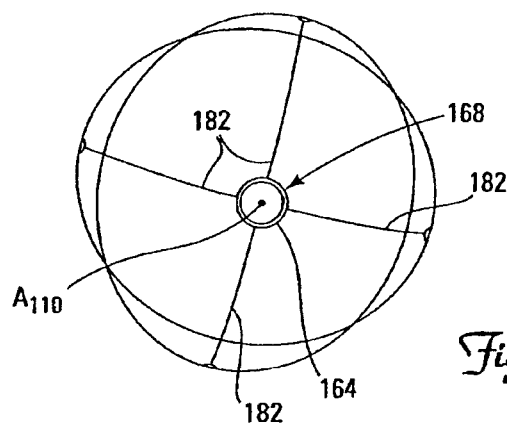


Fig. 3B

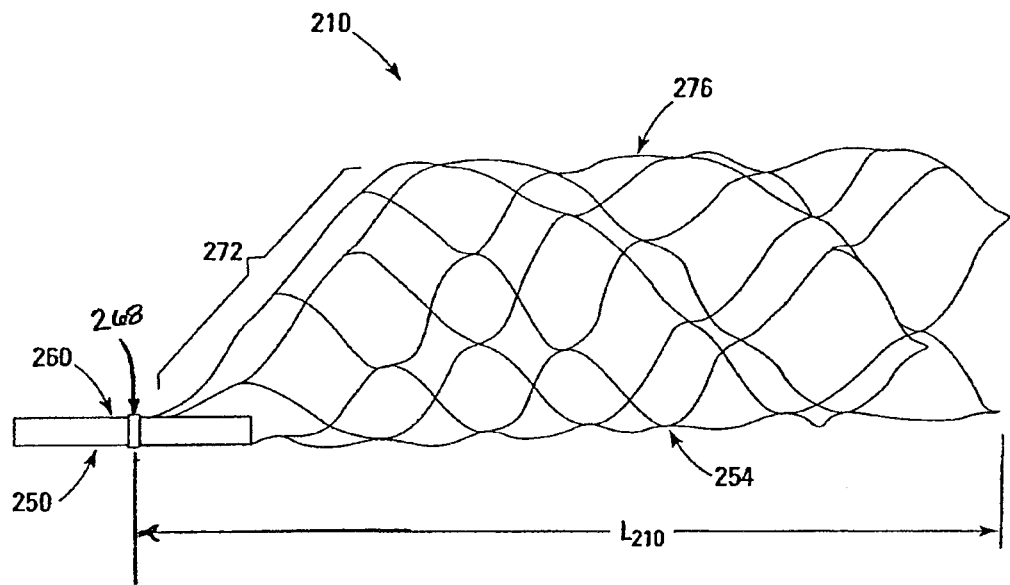


Fig. 4

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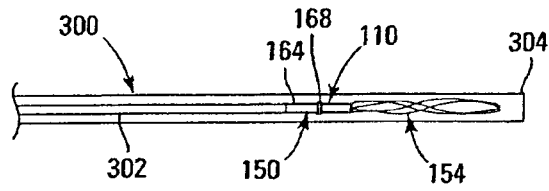


Fig. 5A

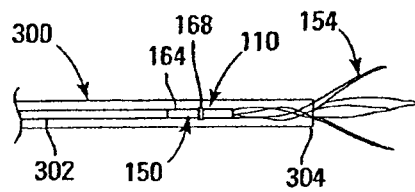


Fig. 5B

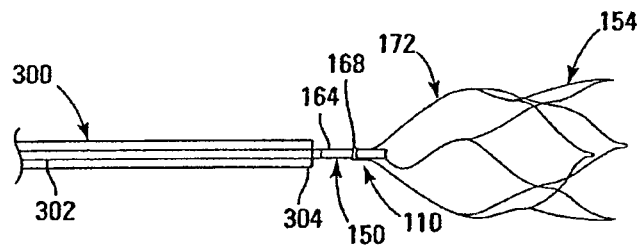


Fig. 5C

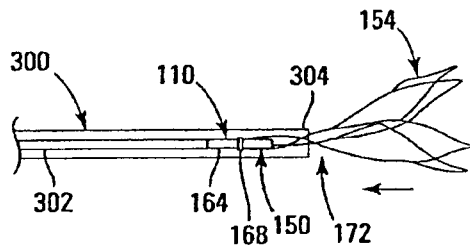


Fig. 5D

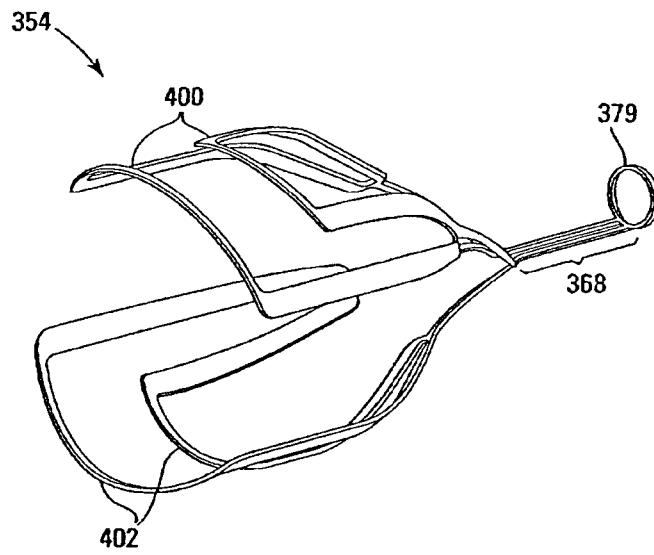


Fig. 6A

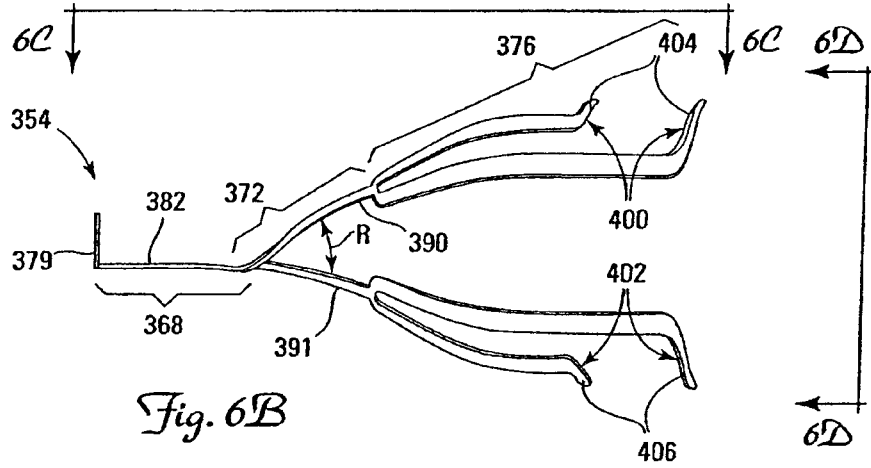


Fig. 6B

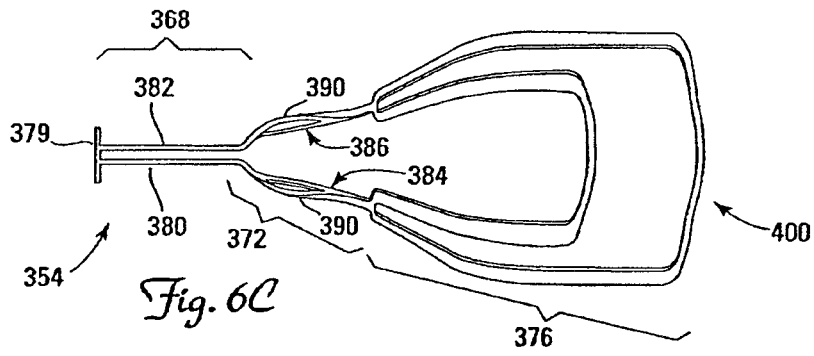


Fig. 6C

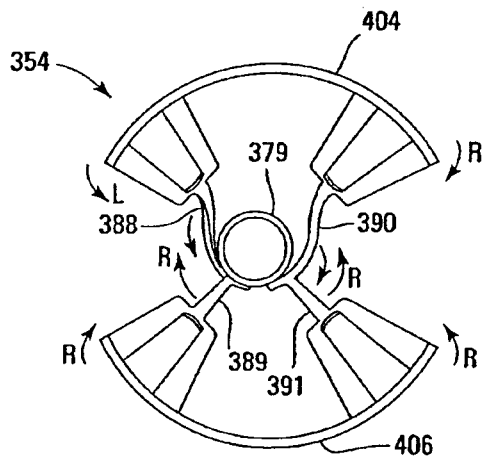
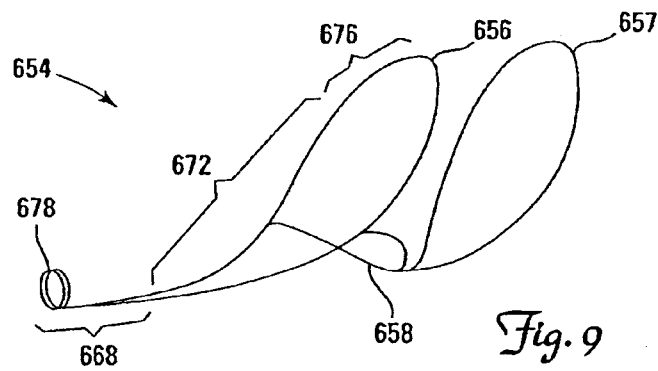
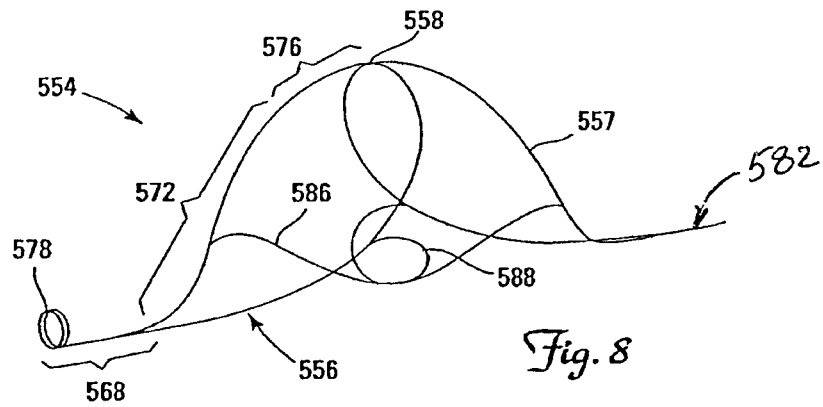
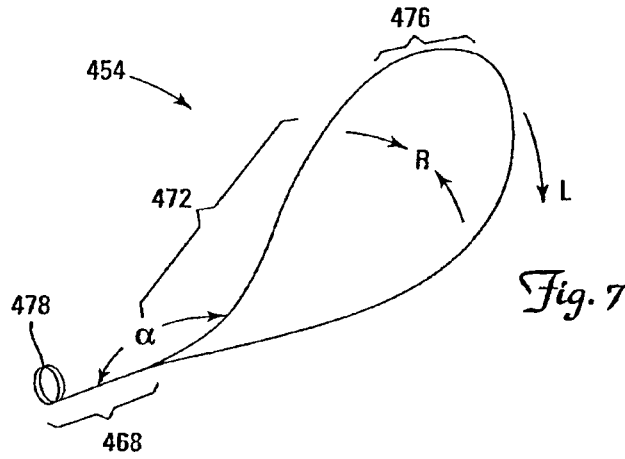


Fig. 6D



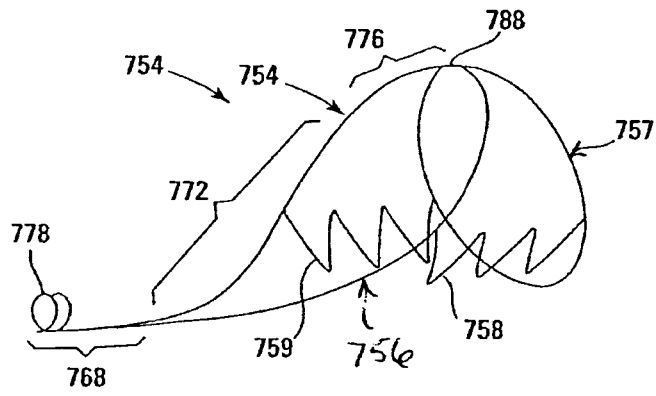


Fig. 10

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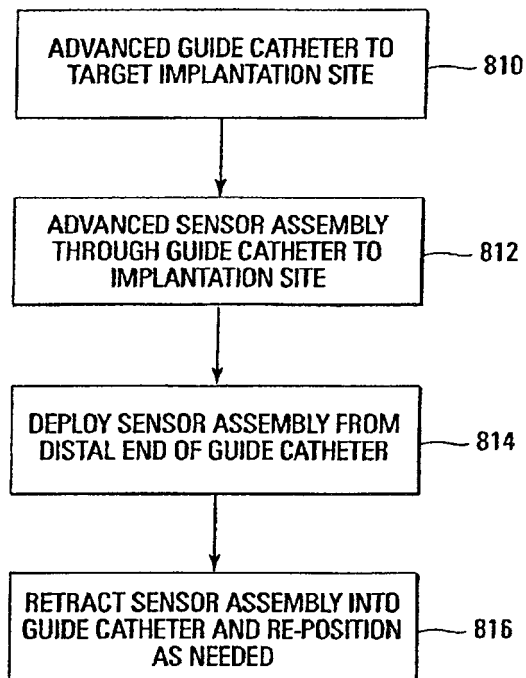


Fig. 11

专利名称(译)	锚固植入式传感器		
公开(公告)号	EP2061373A2	公开(公告)日	2009-05-27
申请号	EP2007842532	申请日	2007-09-14
[标]申请(专利权)人(译)	心脏起搏器股份公司		
申请(专利权)人(译)	心脏起搏器, INC.		
当前申请(专利权)人(译)	心脏起搏器, INC.		
[标]发明人	GREENLAND JOHN S DAQUANNI PETER J CHIN WILLIAM S PETERSON CHUCK MAGRINI KEVIN M DELGADO JESSIE FRULAND BENJAMIN R		
发明人	GREENLAND, JOHN S. D'AQUANNI, PETER J. CHIN, WILLIAM S. PETERSON, CHUCK MAGRINI, KEVIN M. DELGADO, JESSIE FRULAND, BENJAMIN R.		
IPC分类号	A61B5/0215 A61B5/07 A61B5/00		
CPC分类号	A61B5/0031 A61B5/0215 A61B5/076 A61B5/6882 A61B5/6885 A61B2018/00279 A61N1/36564 A61N1/37288 A61N1/39622		
优先权	60/844821 2006-09-15 US		
其他公开文献	EP2061373B1		
外部链接	Espacenet		

摘要(译)

例如,可植入医疗装置和可植入生理传感器的锚包括近端鞍部分,从鞍部分径向和远端延伸的中间部分,以及从近端部分向远侧延伸并适于接合内部的远端部分。用于将可植入医疗装置固定在其中的目标血管的表面。锚可以呈现用于通过导管递送的收缩构造,以及用于在展开后固定在血管内的扩张构型。中间部分以倾斜角度从近端部分延伸,如果需要或期望重新定位或移除可植入医疗装置,则允许锚定件在初始展开之后缩回并在输送导管内再次塌陷。