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(54) **METHOD AND APPARATUS FOR FIXATING A PACING LEAD OF AN IMPLANTABLE MEDICAL DEVICE**

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(76) Inventors: **Vicki L. Bjorklund**, Maple Grove, MN (US); **Douglas S. Hine**, White Bear Lake, MN (US); **John L. Sommer**, Coon Rapids, MN (US); **Douglas N. Hess**, Maple Grove, MN (US); **Richard D. Sandstrom**, Scandia, MN (US); **Wayne R. Bass**, Coon Rapids, MN (US); **Mary M. Morris**, Mounds View, MN (US); **Nicolaas M. Lokhoff**, Kerkrade (NL)

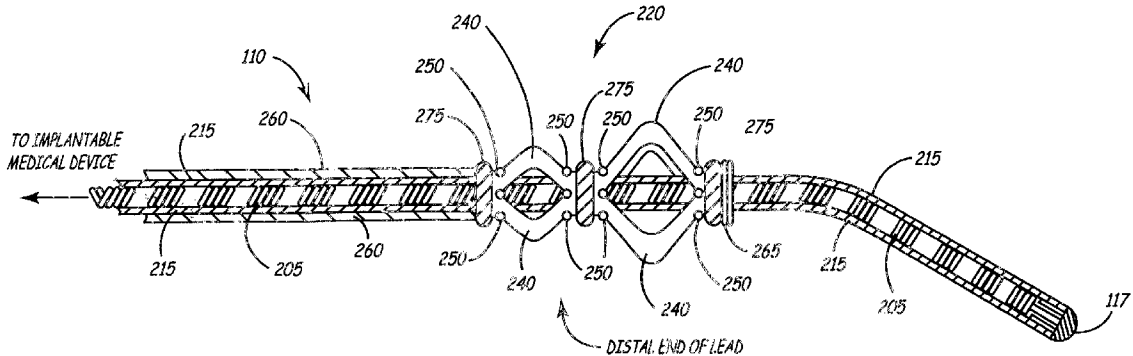
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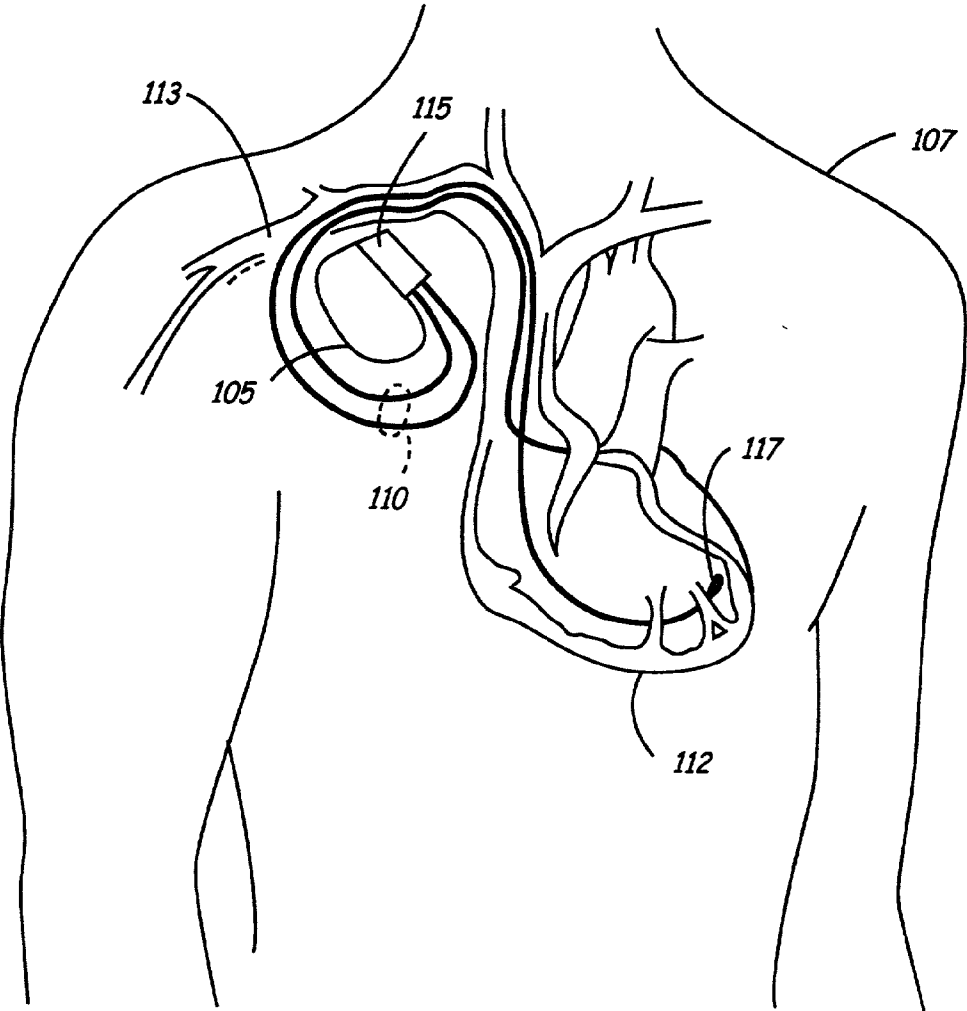
(57) **ABSTRACT**

A method and apparatus for dynamically fixating and removing a lead in a vasculature of a body. At least one segmenting means such as a collar is disposed at a distal end of the lead forming a deployable actuatable segment adapted to dynamically assume an engaging and retracted position. In an engaging position, the actuatable segment dynamically and varyingly adapts into a shape or shapes to engage a vessel. In a retracted position the shape or shapes collapse thus maintaining the original geometry of the lead in the vasculature. The actuatable segment assumes a deployed or retracted position based on the flexural condition of the segment, respectively.

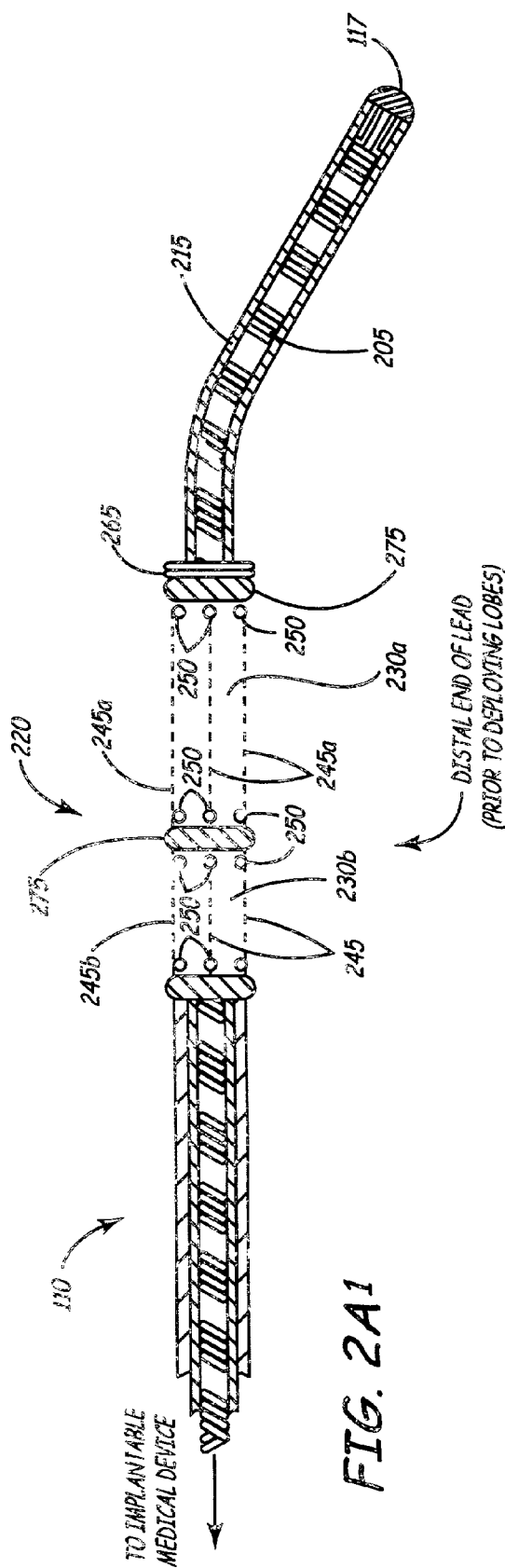
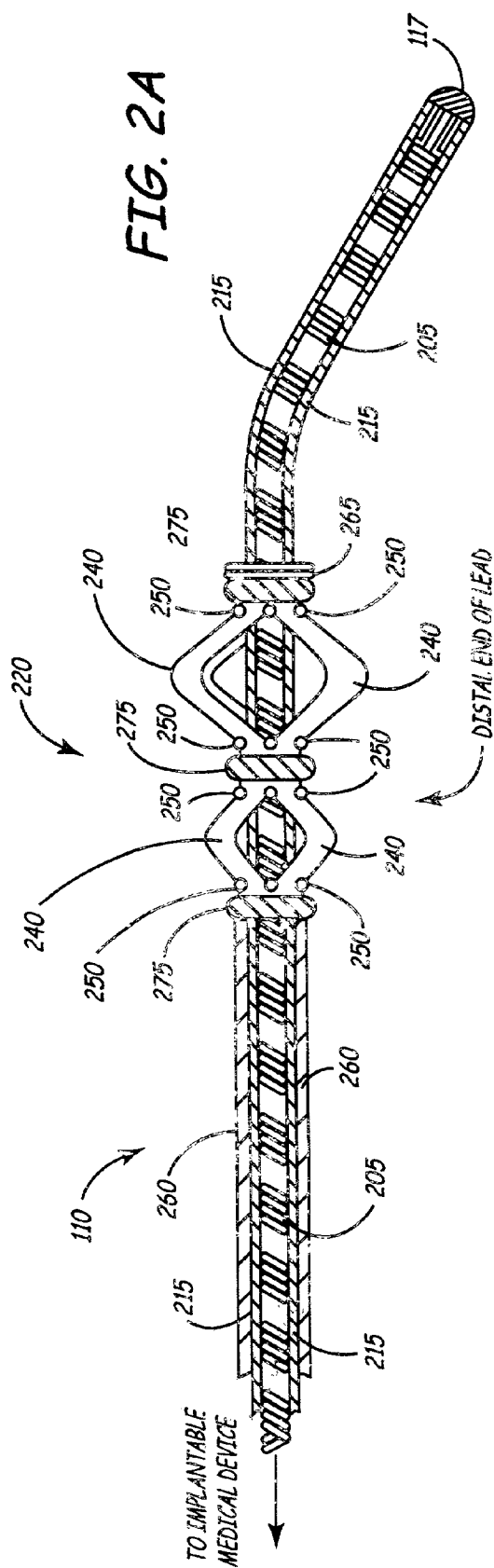
Correspondence Address:  
**MEDTRONIC, INC.**  
**710 MEDTRONIC PARKWAY NE**  
**MS-LC340**  
**MINNEAPOLIS, MN 55432-5604 (US)**

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*FIG. 1*



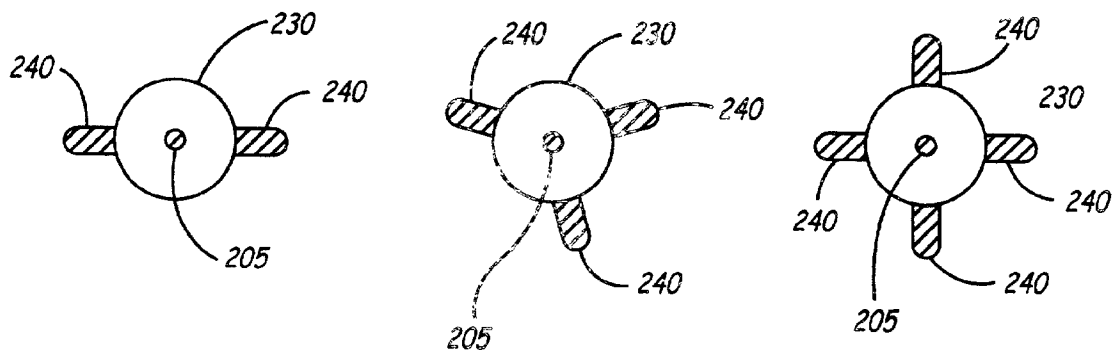


FIG. 2B

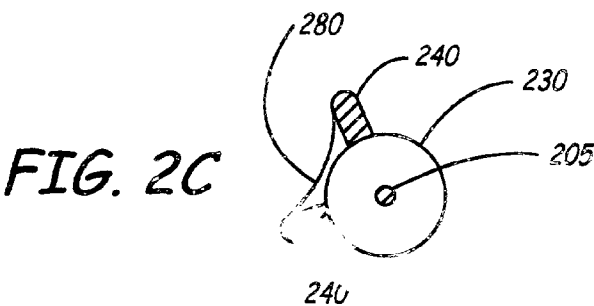


FIG. 2C

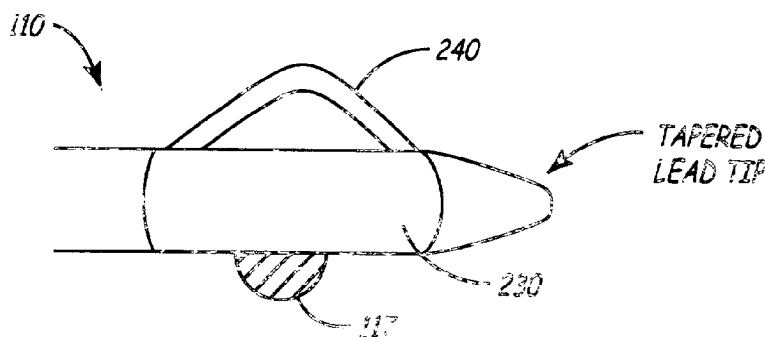
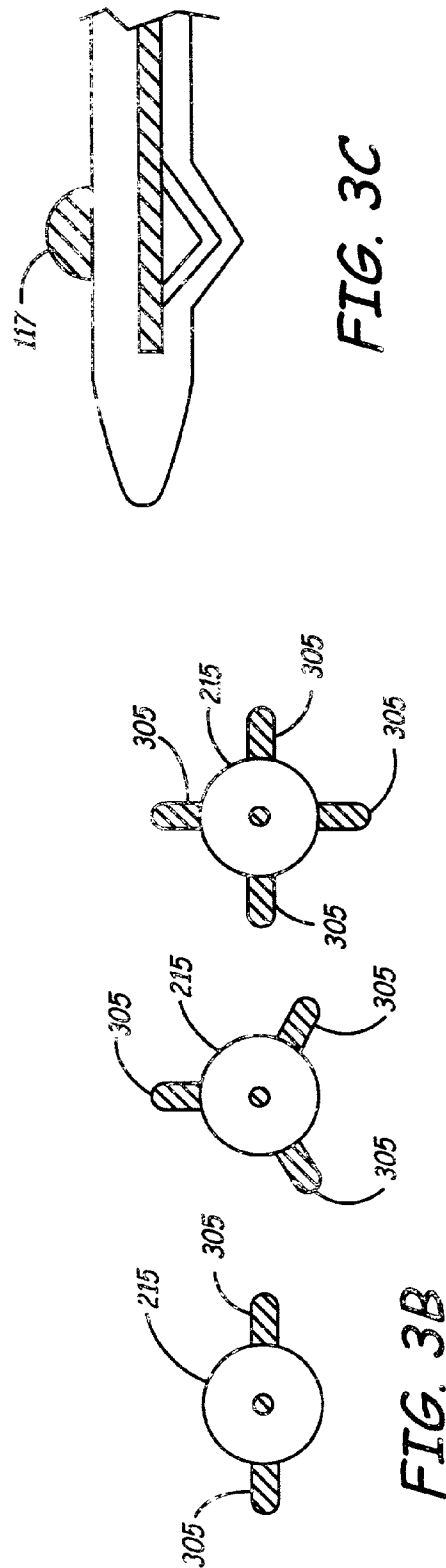
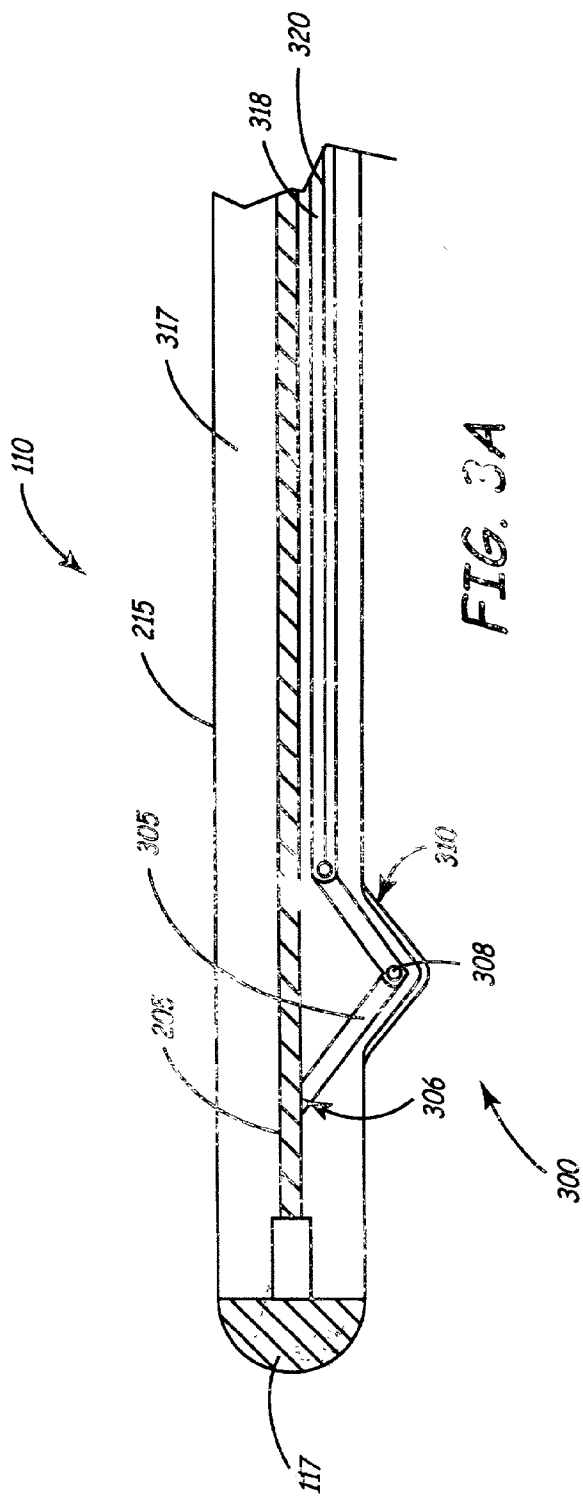
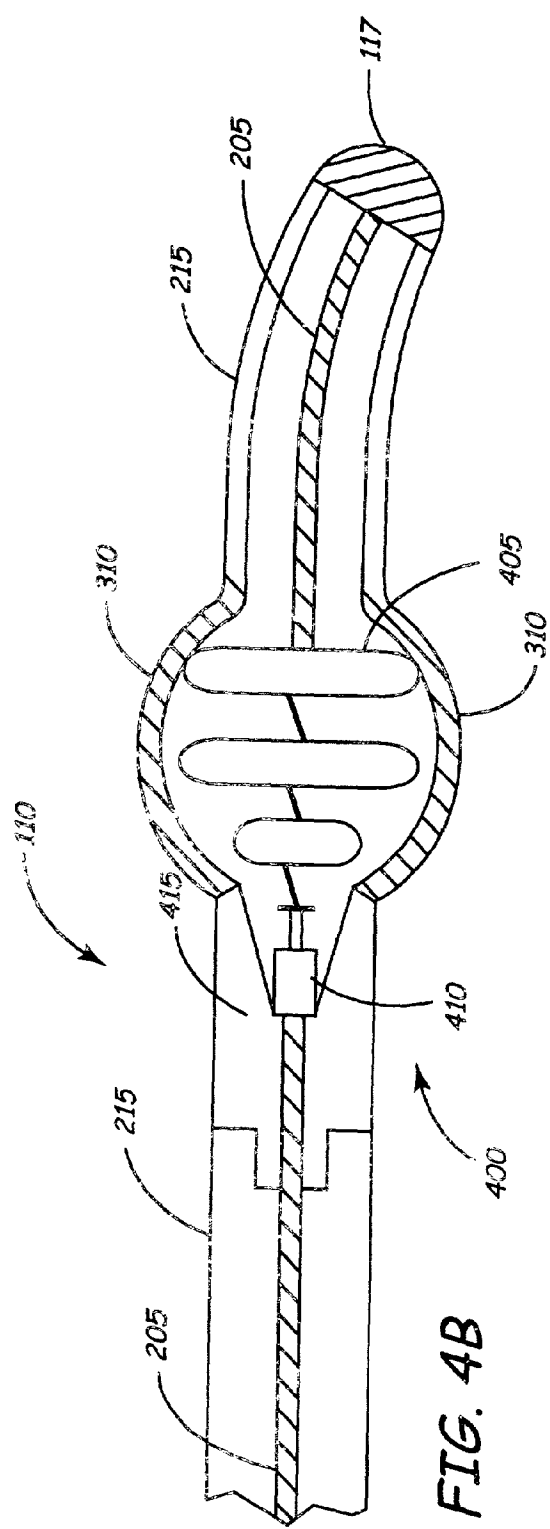
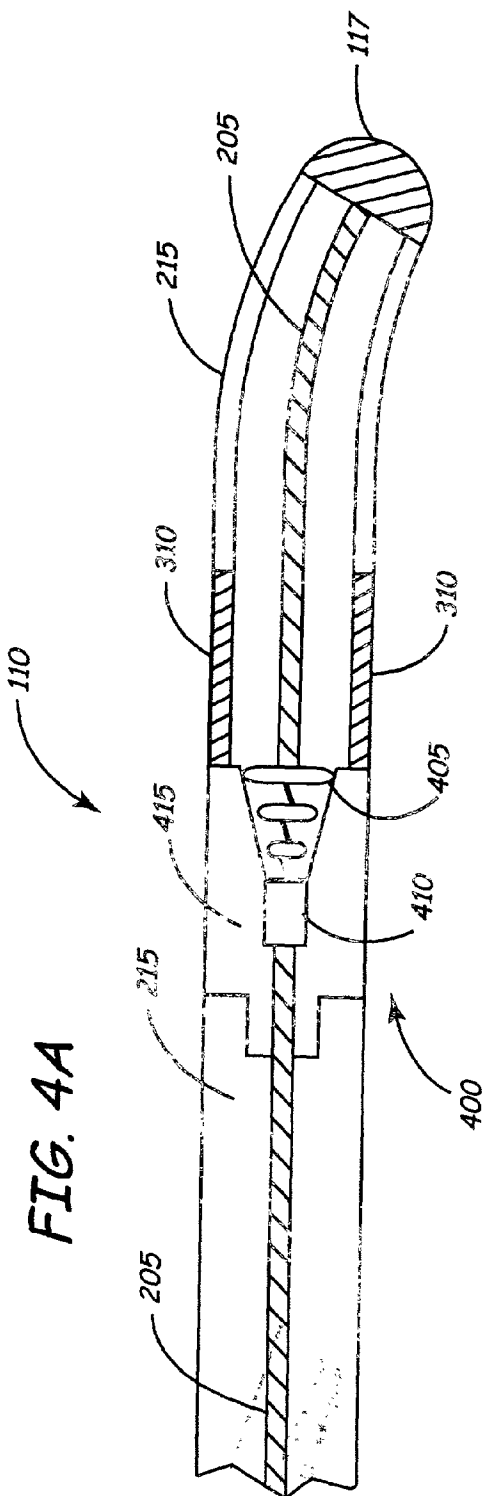


FIG. 2D





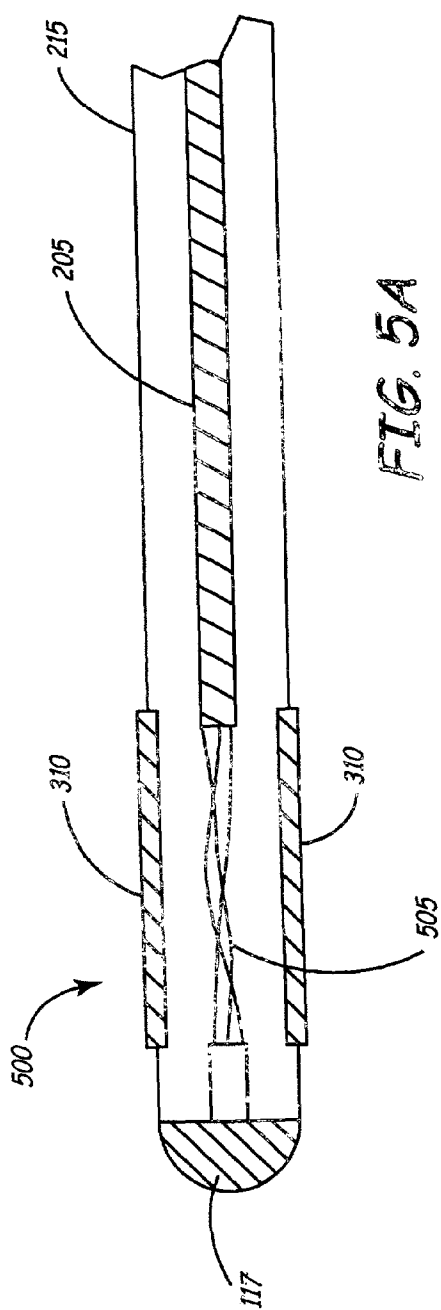


FIG. 5A

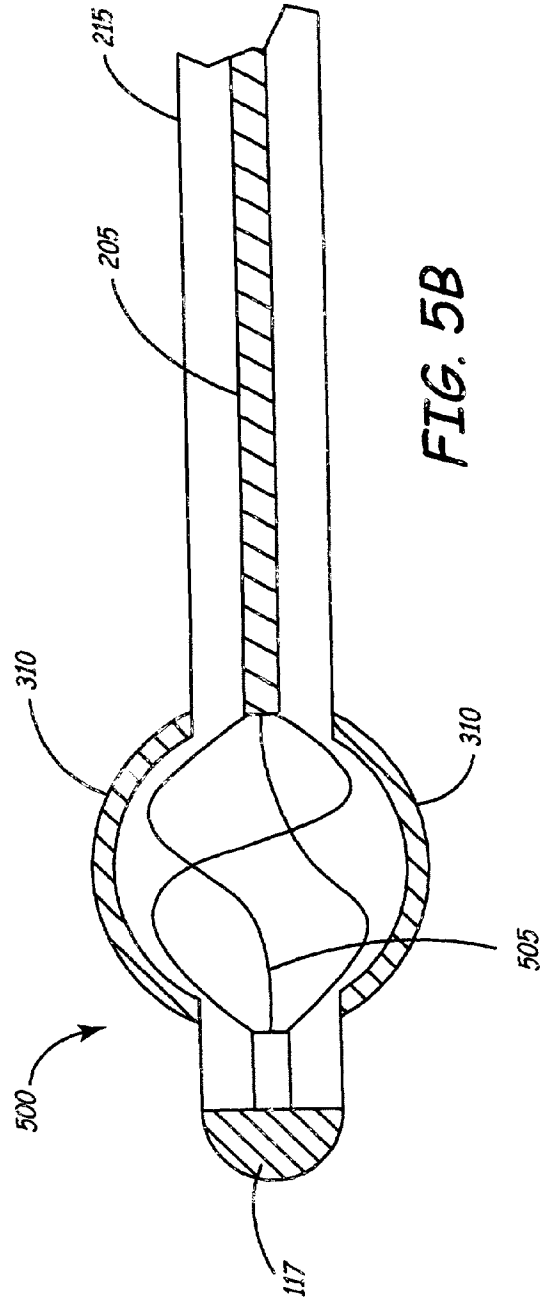
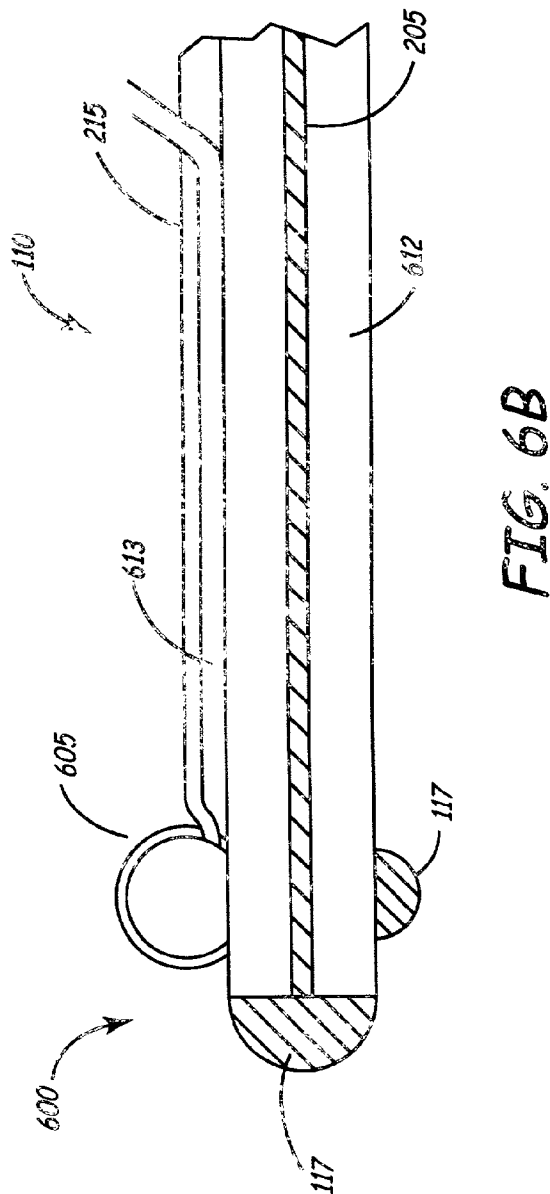
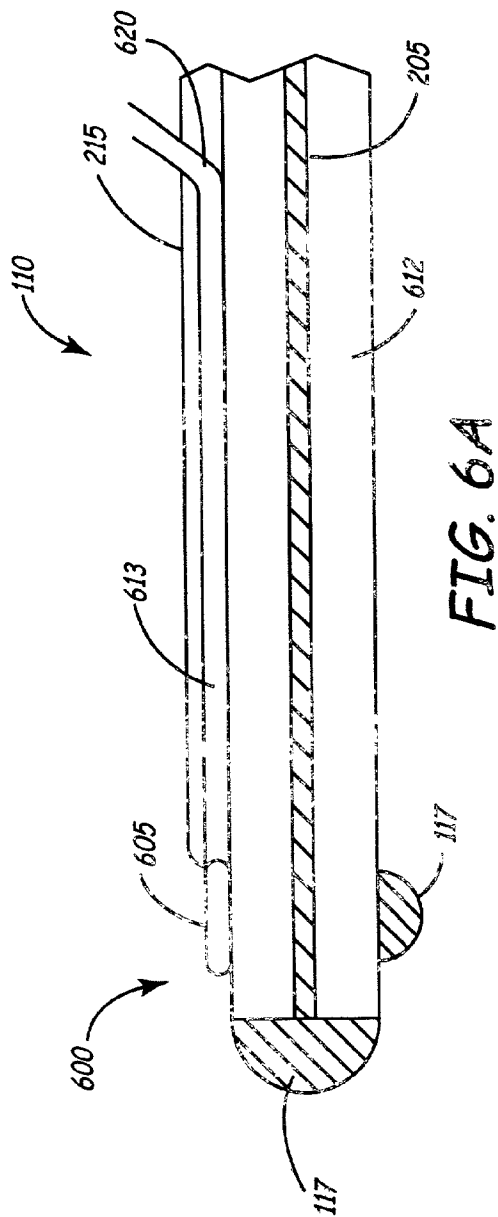


FIG. 5B





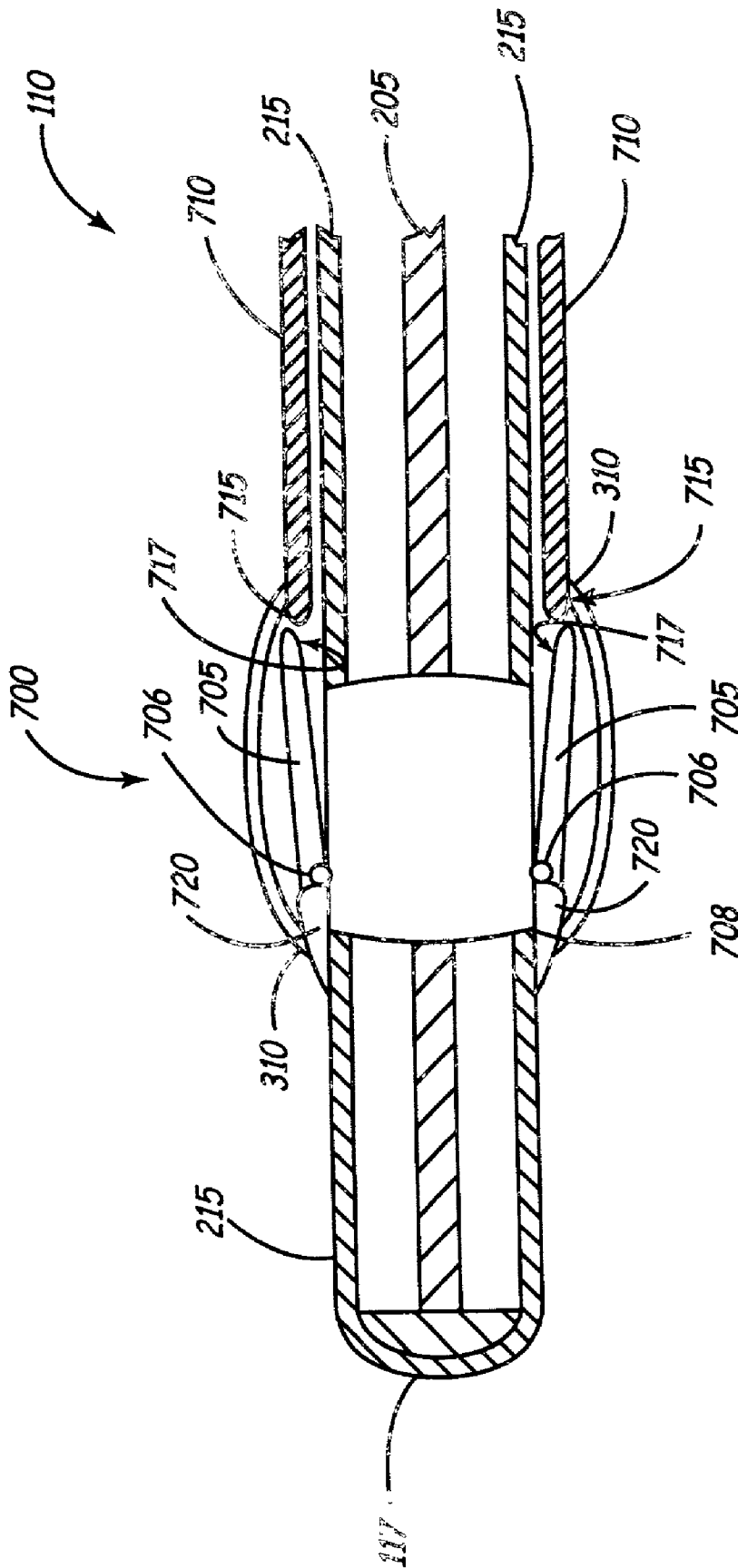
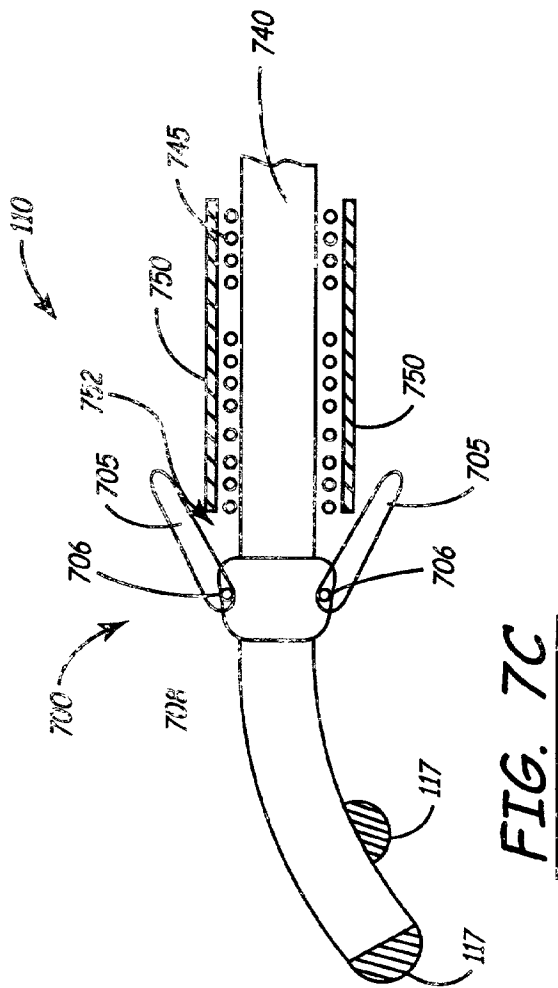
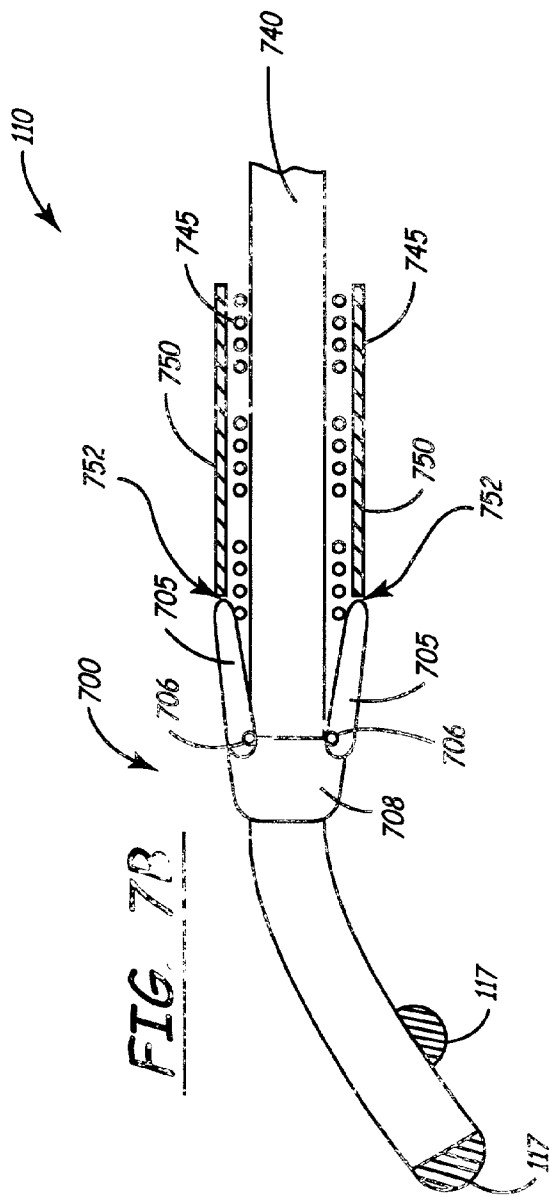
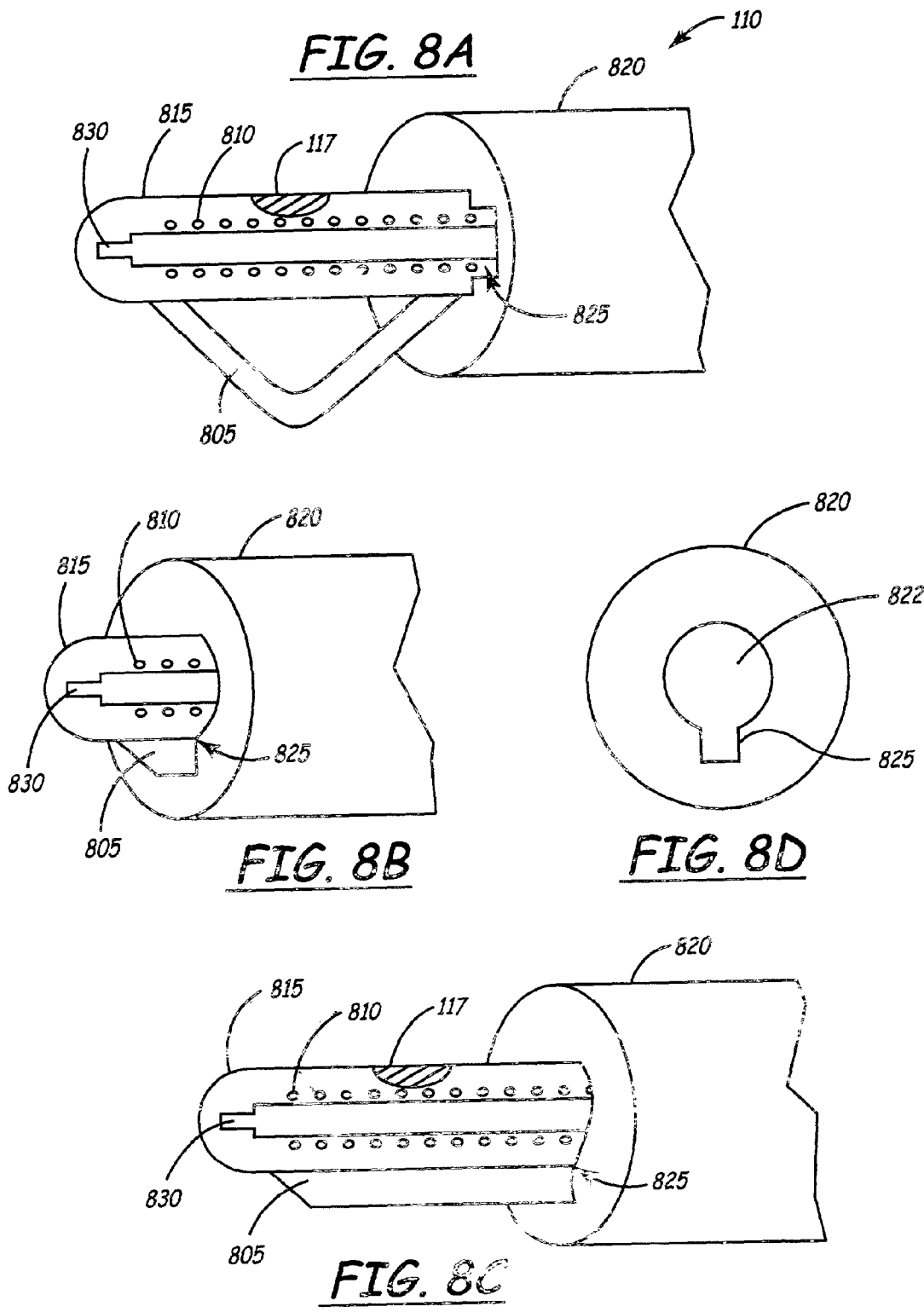


FIG. 7A





## METHOD AND APPARATUS FOR FIXATING A PACING LEAD OF AN IMPLANTABLE MEDICAL DEVICE

### FIELD OF THE INVENTION

[0001] This invention relates generally to implantable medical devices, and, more particularly, to a fixation mechanism for securing a lead of the implantable medical device within a cardiac vessel of a patient.

### DESCRIPTION OF THE RELATED ART

[0002] Since their earliest inception some forty years ago, there has been a significant advancement in body-implantable electronic medical devices. Today, these implantable devices include therapeutic and diagnostic devices, such as pacemakers, cardioverters, defibrillators, neural stimulators, drug administering devices, among others for alleviating the adverse effects of various health ailments. Today's implantable medical devices are also vastly more sophisticated and complex than their predecessors, and are therefore capable of performing considerably more complex tasks for reducing the effects of these health ailments.

[0003] The implantable medical device is generally implanted within the patient's body and a lead couples the implantable device to a portion of the patient's body, such as the patient's heart, for example. Typically, an electrode is provided at the distal end of the lead, and it is adapted to be disposed at a desired site within a cardiac vessel of the heart, such as a vein. The electrodes typically sense cardiac activity and deliver electrical pacing stimuli (i.e., therapeutic signals) to the patient's heart depending on the sensed cardiac activity.

[0004] The pacing leads are commonly implanted within the cardiac vessel with the aid of a stylet that is positioned within a lumen in the lead. If the electrode residing on the distal end of the pacing lead becomes dislodged after implantation within the cardiac vessel, the electrode may not be able to properly sense the cardiac activity of the patient and deliver the electrical pulsing stimuli to the desired area of the patient's heart. If the electrode becomes dislodged from the desired location within the patient's cardiac vessel, a significant amount of time and expense may occur to have the dislodged electrode replanted within the desired site of the cardiac vessel. Moreover, upon dislodgment of the electrode, the patient may be subjected to serious health risks as a result of the electrode not being able to properly sense cardiac activity of the patient and/or deliver a proper therapy to the desired site within the patient's heart.

[0005] The present invention is directed to overcoming, or at least reducing the effects of, one or more of the problems set forth above.

### SUMMARY OF THE INVENTION

[0006] In one aspect of the present invention, an apparatus for fixating a lead disposed within a vessel is provided. The apparatus comprises a fixation segment of the lead at a distal end thereof, and at least one deployable lobe situated on the fixation segment. The deployable lobe is adapted to assume a retracted position and an engaging position, where the engaging position engages the at least one deployable lobe with the vessel. The at least one deployable lobe assumes the

engaging position in response to the fixation segment being compressed and assumes the retracted position when the fixation segment is not compressed.

[0007] In another aspect of the invention, an apparatus for fixating a lead disposed within a vessel is provided. The apparatus comprises at least one deployable lobe situated on a distal portion of the lead. The deployable lobe is adapted to assume a retracted position and an engaging position, where the engaging position engages the at least one deployable lobe with the vessel. The apparatus further comprises a flexible material covering a portion of an outer surface of the lead. The at least one deployable lobe assumes the engaging position by extending outwardly from the lead at the portion of the outer surface by stretching the flexible material.

[0008] In another aspect of the invention, an apparatus for fixating a lead disposed within a vessel is provided. The apparatus comprises at least one deployable lobe situated on a distal portion of the lead. The deployable lobe is adapted to assume a retracted position and an engaging position, where the engaging position engages the at least one deployable lobe with the vessel. A lumen is coupled to the deployable lobe and is adapted to extend the deployable lobe to the engaging position. The at least one deployable lobe assumes the engaging position by extending outwardly from an outer surface of the lead.

[0009] In another aspect of the invention, an apparatus for fixating a lead disposed within a vessel is provided. The lead includes an electrical conductor surrounded by a conductor tubing, and an outer tubing that is slideably received over the conductor tubing. The apparatus comprises at least one deployable lobe situated on a distal portion of an outer surface of the conductor tubing of the lead, the deployable lobe adapted to assume a retracted position and an engaging position, the engaging position engaging the at least one deployable lobe with the vessel. A recessed slot is formed lengthwise within an inner surface of the outer tubing. The at least one deployable lobe assumes the retracted position when the recessed slot formed within the outer tubing is in alignment with the deployable lobe and is slideably received within the recessed slot, and assumes an engaging position by extending outwardly from the outer surface of the conductor tubing when the deployable lobe is not in alignment with the recessed slot.

[0010] In another aspect of the invention a method for fixating a lead disposed within a vessel is provided. The method includes providing a fixation segment surrounding the lead at a distal end thereof, and providing at least one deployable lobe situated on the fixation segment. The deployable lobe is adapted to assume a retracted position and an engaging position, where the engaging position engages the at least one deployable lobe with the vessel. The fixation segment is compressed to have the at least one deployable lobe assume the engaging position.

[0011] In another aspect of the present invention a method for fixating a lead disposed within a vessel is provided. The method includes providing at least one deployable lobe situated on a distal portion of the lead. The deployable lobe is adapted to assume a retracted position and an engaging position, where the engaging position engages the at least one deployable lobe with the vessel. A flexible material is provided to cover a portion of an outer surface of the lead.

The flexible material is extended outwardly from the lead at the portion of the outer surface when the at least one deployable lobe assumes the engaging position.

**[0012]** In another aspect of the present invention, a method for fixating a lead disposed within a vessel is provided. The method includes providing at least one deployable lobe situated on a distal portion of the lead. The deployable lobe is adapted to assume a retracted position and an engaging position, where the engaging position engages the at least one deployable lobe with the vessel. The method further includes providing a lumen coupled to the deployable lobe, and adapted to extend the deployable lobe to the engaging position by extending outwardly from an outer surface of the lead.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0013]** The invention may be understood by reference to the following description taken in conjunction with the accompanying drawings, in which the leftmost significant digit(s) in the reference numerals denote(s) the first figure in which the respective reference numerals appear, and in which:

**[0014]** **FIG. 1** schematically illustrates an implantable medical device, in the form of a pacemaker, according to one embodiment of the present invention;

**[0015]** **FIGS. 2A, 2A', 2B-D** show perspective views of a distal portion of a lead having a deployable lobe for fixating the lead to a vessel according to one embodiment of the present invention;

**[0016]** **FIGS. 3A-C** show perspective views of the distal portion of the lead having a deployable lobe for fixating the lead to the vessel in accordance with another embodiment of the present invention;

**[0017]** **FIGS. 4A-B** show a side view perspective of the distal portion of the lead employing an expandable spring for fixating the lead to the vessel in accordance with another embodiment of the present invention;

**[0018]** **FIGS. 5A-B** show a side view perspective of the distal portion of the lead employing a stent for fixating the lead to the vessel in accordance with another embodiment of the present invention;

**[0019]** **FIGS. 6A-B** show a side view perspective of the distal portion of the lead employing a balloon for fixating the lead to the vessel in accordance with another embodiment of the present invention;

**[0020]** **FIGS. 7A-C** show a side view perspective of the distal portion of the lead employing a pair of flanges for fixating the lead to the vessel in accordance with another embodiment of the present invention; and

**[0021]** **FIGS. 8A-D** show perspective views of a distal portion of a lead having a deployable lobe for fixating the lead to a vessel according to another embodiment of the present invention.

**[0022]** While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and are herein described in detail. It should be understood, however, that the description herein of specific embodiments is not intended to limit the invention to the particular forms

disclosed, but, on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

#### DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

**[0023]** Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure.

**[0024]** Turning now to the drawings, and specifically referring to **FIG. 1**, an implantable medical device (IMD) system **100** is shown in accordance with one embodiment of the present invention. The IMD system **100** includes an implantable medical device **105** that has been implanted in a patient **107**. In accordance with the illustrated embodiment of the present invention, the implantable device **105** takes the form of a pacemaker for regulating the patient's heart rhythm. Although the implantable device **105** will be discussed in the form of a pacemaker, it will be appreciated that the implantable device **105** may alternatively take the form of a cardioverter, defibrillator, neural stimulator, drug administering device, and the like without departing from the spirit and scope of the present invention.

**[0025]** The implantable device **105** is housed within a hermetically sealed, biologically inert outer housing or container, which may itself be conductive so as to serve as an electrode in the pacemaker's pacing/sensing circuit. One or more pacemaker leads, which are collectively identified by reference numeral **110**, are electrically coupled to the implantable device **105** and extend into the patient's heart **112** through a vessel **113**, such as a vein. The leads **110** are coupled to the implantable medical device **105** via a connector block assembly **115**. Disposed generally near a distal end of the leads **110** are one or more exposed conductive electrodes **117** for sensing cardiac activity and/or delivering electrical pacing stimuli (i.e., therapeutic signals) to the heart **112**. The distal end of the lead **110** may be deployed in the ventricle, atrium, coronary sinus, or a cardiac vessel of the heart **112**.

**[0026]** Turning now to **FIGS. 2A** and **2A'**, a more detailed representation of the distal end of the lead **110** is shown in accordance with one embodiment of the present invention. The lead **110** comprises a flexible electrical conductor **205** for sending diagnostic signals received via the electrode **117** (that may be mounted on the terminal end of the lead **110**) to the implantable device **105**, and/or for delivering therapeutic signals to the patient via the electrode **117**. In one embodiment, the electrical conductor **205** may include tightly coiled stainless steel or a platinum filament. It will be appreciated, however, that the electrical conductor **205** may be constructed from various other suitable materials without departing from the spirit and scope of the present invention.

[0027] In accordance with one embodiment of the present invention, the electrical conductor **205** is covered by an electrically insulated sheath or conductor tubing **215** to protect the electrical conductor **205** from bodily fluids of the patient, and to electrically insulate the conductor **205**. In one embodiment, the conductor tubing **215** may be constructed from polyurethane. It will be appreciated, however, that the conductor tubing **215** may be constructed from various other materials, such as silicone, for example, without departing from the spirit and scope of the present invention.

[0028] In accordance with the illustrated embodiment, a fixation mechanism **220** is provided on the mid or distal portion of the lead **110** to hold the lead **110** substantially stationary within the cardiac vessel of the patient when disposed therein. According to one embodiment, the fixation mechanism **220** comprises a fixation segment **230** that engages and surrounds the conductor tubing **215** of the lead **110**. In accordance with the illustrated embodiment, the fixation segment **230** may be constructed of silicone, polyurethane, or the like.

[0029] In accordance with one embodiment of the present invention, the fixation segment **230** comprises one or more deployable lobes **240** that are formed lengthwise on the segment **230** by a pair of elongated, parallel cuts or slits **245** made within the fixation segment **230**. That is, the deployable lobe **240** is formed between the elongated, substantially parallel slits **245** made within the fixation segment **230** that surrounds the conductor tubing **215**. The spacing between the two parallel slits **245** formed within the fixation segment **230** generally defines the width of the deployable lobe **240** formed therebetween. Accordingly, the rigidity of the deployable lobe **240** may be increased by increasing the width of the deployable lobe **240** (i.e., increasing the distance between the parallel slits **245**). Additionally, the rigidity of the lobe **240** may be increased by increasing the thickness of the fixation segment **230** that surrounds the conductor tubing **215**. Furthermore, the rigidity of the lobe **240** may be altered by using different types of materials for the fixation segment **230**. In one embodiment, the end portions of the pair of parallel slits **245** formed within the fixation segment **230** may be joined by a circular cut **250** (within the segment **230**) so as to reduce the likelihood of the slits **245** from spreading or expanding along the fixation segment **230**.

[0030] In accordance with one embodiment of the present invention, push tubing **260** is disposed around the conductor tubing **215** of the lead **110**, and is attached to the fixation segment **230** at one end thereof. At the other end of the fixation segment **230**, an anchor member **265** is affixed to the conductor tubing **215** to substantially prevent movement of the fixation segment **230** beyond the anchor member **265** (i.e., the anchor member **265** substantially prevents the fixation segment **230** from sliding further down the distal end of the lead **110**). In one embodiment, the push tubing **260** may be used to apply compression of the fixation segment **230** against the anchor member **265**, by advancing the push tubing **260** toward the distal end of the lead **110**. The pushing action on the fixation segment **230** causes the segment **230** to become compressed, thus causing the extension of the deployable lobe **240** outwardly from the outer surface of the fixation segment **230**. In an alternative embodiment, the push tubing **260** may be held stationary while the compression of the fixation segment **230** is accom-

plished by withdrawing the conductor tubing **215** toward the proximal end of the lead **110**.

[0031] Prior to the lead **110** being placed within a cardiac vessel of the patient, the deployable lobe **240** assumes a retracted position when there is substantially no compression on the fixation segment **230** by the push tubing **260**. In the retracted position, the deployable lobe **240** is substantially flat (i.e., not extended outwardly) along the surface of the fixation segment **230**. When the lead **110** is placed within the desired site within the cardiac vessel of the patient, the push tubing **260** is pushed toward the distal end of the lead **110**. The pushing of the push tubing **260** causes compression of the fixation segment **230** against the anchor member **265**, thereby causing the deployable lobe **240** to extend outwardly or protrude from the surface of the fixation segment **230** by assuming an angular flexure or “boomerang” shape (as illustrated in FIG. 2A). In one embodiment, the push tubing **260** may be held in place by using a clip mechanism (not shown) on the proximal end of the lead **110**, thereby causing constant compression of the fixation segment **230** by push tubing **260** until the clip mechanism is removed. The deploying of the lobe **240** secures lead **110** within the cardiac vessel and, thus, substantially prevents any movement of the lead **110** within the cardiac vessel.

[0032] In an alternative embodiment, lead **110** may have lobe **240** extended outwardly. In other words, in the resting state, lobes **240** would be deployed and during implant the tube is retracted or withdrawn to flatten lobes **240** and relieve all the tension to deploy the lead. When the lead is in a desired position the tubing is pushed to dynamically shape lobes **240** forming an engaging surface thereof. Further, multiple sets of lobes **240** may be located on segments lead **110**. In this embodiment, the lengths of segments **245** and the number of slits can vary from subsequent segments of lead **110** on which a series of segments having lobes **240** are located. In yet another embodiment, once the lead is deployed and lobes **240** are in an engaged position, a temporary snap-on clip or an anchoring sleeve may be used for chronic implant. Further, the thickness “t” of lobes **240** could be varied between segments to enable variability in rigidity and resistance at different segments of lead **110** such that each lobe **240** provides varying degrees of flexure.

[0033] In accordance with another embodiment of the present invention, more than one deployable lobe **240** may be provided around the circumference of the fixation segment **230** to further secure the lead **110** within the cardiac vessel of the patient (as shown in FIG. 2B). For example, two deployable lobes **240** may be provided on opposite sides of the fixation segment **230**, three deployable lobes **240** may be provided at 120-degree separation points around the circumference of the fixation segment **230**, or four deployable lobes **240** may be provided at 90-degree separation points around the circumference of the fixation segment **230**. It will be appreciated that any number of deployable lobes **240** may be placed around the circumference of the fixation segment **230** to aid in securing the lead **110** within the cardiac vessel. Furthermore, the spacing (i.e., the degree of separation) between the deployable lobes **240** around the circumference of the fixation segment **230** may vary as well. Additionally, the spacing between the deployable lobes **240** around the circumference of the fixation segment **230** need not necessarily be uniform, but may be placed at varying positions around the circumference of the fixation segment

**230.** It will be further appreciated that the lead **110** may also include two or more fixation segments **230** that are disposed along the distal portion of the lead **110** in series. Accordingly, in this embodiment, each fixation segment **230** will have its own set of deployable lobes **240**.

**[0034]** According to the illustrated embodiment, the fixation mechanism **220** may be further configured with a pair of platinum rings **275** (**FIG. 2A** and **2A'**), with each ring **275** disposed around each end of the fixation segment **230** to indicate the degree with which the deployable lobes **240** have been extended outwardly from the surface of the fixation segment **230** under an x-ray examination, for example. Accordingly, if the distance between the platinum rings **275** is minimal, it will indicate that the lobes **240** are deployed (extend outwardly from the surface of the fixation segment **230**). In another embodiment, it will be appreciated that the deployable lobes **240** of the fixation segment **230** may be constructed with a radiopaque material, such as barium, platinum or tantalum loaded rubber or polymer, so as to indicate the degree in which the lobes **240** are deployed (in lieu of the platinum rings **275**) without departing from the spirit and scope of the present invention.

**[0035]** In accordance with one embodiment of the present invention, a webbing material **280** may be attached between two consecutively spaced lobes **240**, and deployed when the lobes **240** extend outwardly from the surface of the fixation segment **230** (as shown in **FIG. 2C**). In another embodiment of the present invention, the electrode **117** may be disposed on the surface of the fixation segment **230** on a side opposite of the deployable lobe **240** (**FIG. 2D**). In yet another embodiment of the present invention, the terminal end of the lead **110** may be tapered and/or angled to aid in cardiac vessel selection when the electrode **117** is disposed on the surface of the fixation segment **230**.

**[0036]** In accordance with another embodiment, a slip coating or clot resistant slip coating may be applied to the inner surface of the push tubing **260** or to the outer surface of the conductor tubing **215** to facilitate the sliding of the push tubing **260** over the conductor tubing **215**. According to one embodiment, the slip coating may take the form of polyacrylamide PVP, or heparin polyacrylamide hydrophilic coating, or polytetrafluoroethylene (PTFE); however, it will be appreciated that the slip coating or slip and anti-coagulant combination coating may include various other equivalent materials without departing from the scope of the present invention.

**[0037]** Turning now to **FIG. 3A**, a fixation mechanism **300** for the lead **110** is shown in accordance with another embodiment of the present invention. In this particular embodiment, the distal end of the lead **110** is configured with at least one deployable lobe **305** that may extend outwardly so as to protrude from the surface of the conductor tubing **215**. In one embodiment, the portion of the conductor tubing **215** that covers the deployable lobe **305** comprises a flexible material **310**. In accordance with one embodiment, the flexible material **310** is provided in the form of a balloon-like material (such as polyisoprene, polyurethane, or silicone, for example) that may stretch when the deployable lobe **305** is extended outwardly from the surface of the conductor tubing **215**. In one embodiment, the deployable lobe **305** may be fixedly attached to the electrical conductor **205** at a point **306**, and provided with a joint **308** to permit

the deployable lobe **305** to be substantially parallel with the conductor tubing **215** when assuming a retracted position or to extend outwardly or protrude from the surface of the conductor tubing **215** by assuming an angular or "boomerang" shape (as depicted in **FIG. 3A**). Alternatively, the deployable lobe **305** at the point **306** may be fixedly attached to a "stopper" mechanism (not shown) disposed within the conductor tubing **215**, as opposed to be attached to the electrical conductor **205** (as shown in **FIG. 3A**), without departing from the spirit and scope of the present invention. It will further be appreciated, in another embodiment, that the flexible material **310** may be omitted from covering the deployable lobe **305** providing that the electrical conductor **205** is covered with an insulating material to protect the conductor **205** from bodily fluids of the patient.

**[0038]** In accordance with the illustrated embodiment, the conductor tubing **215** comprises a bitumen tubing, with a first lumen **317** accommodating the electrical conductor **205** and a second lumen **318** for accommodating a push-pull wire **320** for actuating the deployable lobe **305**. Prior to the lead **110** being placed within a cardiac vessel of the patient, the deployable lobe **305** is retracted by pulling the push-pull wire **320** within the lumen **318**. In the retracted position, the deployable lobe **305** assumes a substantially linear (or straightened) position, where the flexible material **310** is not extended outwardly from the conductor tubing **215** of the lead **110**. When the lead **110** is placed at the desired site within the cardiac vessel, the push-pull wire **320** is pushed within the lumen **318** toward the deployable lobe **305**. The pushing of the push-pull wire **320** within the lumen **318** causes the deployable lobe **305** to extend outwardly or protrude from the surface of the conductor tubing **215** by assuming an angular or "boomerang" shape. As the deployable lobe **305** extends outwardly or protrudes from the surface of the conductor tubing **215**, the deployable lobe **305** stretches the flexible material **310** resting thereon. The push-pull wire **320** is pushed within the lumen **318** until the apex of the deployable lobe **305** engages the cardiac vessel, thereby securing the lead **110** within the cardiac vessel and, thus, substantially preventing any movement of the lead **110** therein.

**[0039]** It will be appreciated that more than one deployable lobe **305** may be provided for the lead **110** to further secure the lead **110** within the cardiac vessel (as shown in **FIG. 3B**). For example, two deployable lobes **305** may be provided on opposite sides of the lead **110**, three deployable lobes **305** may be provided at 120-degree separation points around the circumference of the lead **110**, or four deployable lobes **305** may be provided at 90-degree separation points around the circumference of the lead **110**. It will further be appreciated that any number of deployable lobes **305** may be placed around the circumference of the lead **110** to aid in securing the lead **110** within the cardiac vessel. Furthermore, the spacing (i.e., the degree of separation) between the deployable lobes **305** around the circumference of the lead **110** may vary as well. Additionally, the rigidity of the deployable lobe **305** may be altered by increasing or decreasing the width of the deployable lobe **305**.

**[0040]** In accordance with one embodiment of the present invention, the electrode **117** may be placed on the terminal end of the lead **110**. In another embodiment, the electrode **117** may be placed on a side of the lead **110** opposite from

the side the deployable lobe **305** (in the case where one deployable lobe **305** is utilized) for the fixation mechanism **300** (as shown in FIG. 3C).

[0041] Turning now to FIG. 4A, a fixation mechanism **400** for the lead **110** is shown in accordance with another embodiment of the present invention. In this particular embodiment, the distal end of the lead **110** is configured with an expandable spring **405** that encircles the electrical conductor **205** and is attached thereto by a crimp bus **410**. In accordance with the illustrated embodiment, the expandable spring **405** is housed within a sleeve head **415** when the expandable spring **405** assumes a retracted position. A portion of the conductor tubing **215** includes the flexible material **310**, such as a stretchable balloon-like material, for example, which is capable of expanding beyond the diameter of the conductor tubing **215** when the expandable spring **405** is pushed out from the sleeve head **415**.

[0042] Prior to the lead **110** being placed within a cardiac vessel of the patient, the expandable spring **405** is retracted within the sleeve head **415** by rotating the electrical conductor **205** in one direction (e.g., counter-clockwise). In the retracted position, the expandable spring **405** is compressed by the sleeve head **415**, and the flexible material **310** attached to the conductor tubing **215** is not extended outwardly from the conductor tubing **215** of the lead **110** (i.e., the flexible material **310** has substantially the same diameter as the conductor tubing **215**). When the lead **110** is placed at the desired site within the cardiac vessel, the electrical conductor **205** is rotated in the other direction (e.g., clockwise), which causes the expandable spring **405** to be ejected from the sleeve head **415**, and causes the spring **405** to expand the flexible material **310** outwardly or protrude from the surface of the conductor tubing **215** (as shown in FIG. 4B). As the expandable spring **405** extends outwardly from the surface of the conductor tubing **215**, the spring **405** stretches the flexible material **310** resting thereon. The electrical conductor **205** is rotated until the flexible material **310** engages the cardiac vessel, thereby securing the lead **110** within the cardiac vessel **113** and, thus, substantially preventing any movement of the lead **110** therein. In another embodiment of the present invention, it will be appreciated that the flexible material **310** may be placed underneath the expandable spring **405** and the exposed spring **405** may be further used as an electrode.

[0043] Turning now to FIG. 5A, a fixation mechanism **500** is shown in accordance with another embodiment of the present invention. In this particular embodiment, the distal end of the lead **110** is configured with a stent **505** that may be expanded so as to protrude from the surface of the conductor tubing **215** (as shown in FIG. 5B). In one embodiment, the portion of the conductor tubing **215** that covers the stent **505** comprises a flexible material **310**. In accordance with the illustrated embodiment, the flexible material **310** is provided in the form of a balloon-like material that may stretch when the stent **505** is expanded outwardly from the surface of the conductor tubing **215**. In one embodiment of the present invention, the stent **505** may take the form of a spring or coil. In another embodiment, the stent **505** may be placed around the conductor tubing **215** as opposed to being located within the conductor tubing **215**.

[0044] Prior to the lead **110** being placed within a cardiac vessel of the patient, the stent **505** assumes an unexpanded

state by rotating the electrical conductor **205** in one direction (e.g., in a counter-clockwise direction). In the unexpanded state, the diameter of the stent **505** substantially matches the diameter of the conductor tubing **215** of the lead **110**, where the flexible material **310** is not stretched or expanded outwardly therefrom. When the lead **110** is placed within the cardiac vessel at the desired site, the electrical conductor **205** is rotated in the opposite direction (e.g., a clockwise direction), which causes the stent **505** to expand in diameter. When the diameter of the stent **505** is expanded so as to exceed the diameter of the conductor tubing **205**, the flexible material **310** resting thereon expands outwardly from the surface of the conductor tubing **215**. As the stent **505** expands or protrudes from the surface of the conductor tubing **215**, the stent **505** stretches the flexible material **310** resting thereon. The electrical conductor **205** is rotated until the stent **505** and the flexible material **310** resting thereon engages the cardiac vessel, thereby securing the lead **110** within the cardiac vessel and substantially preventing any movement of the lead **110** therein.

[0045] Turning now to FIG. 6A, a fixation mechanism **600** is shown in accordance with another embodiment of the present invention. In this particular embodiment, the distal end of the lead **110** is configured with a deployable lobe **605** that may be expanded so as to protrude from the outer surface of the conductor tubing **215**. In one embodiment, the deployable lobe **605** takes the form of a balloon that resides on a side surface of the conductor tubing **215** of the lead **110**. In an alternative embodiment, the deployable lobe **605** may be configured so as to surround the circumference of the lead **110**. In the illustrated embodiment, the conductor tubing **215** comprises a bilumen tubing with a first lumen **612** accommodating the electrical conductor **205** and a second lumen **613** with a port **620** used for injecting a gas or liquid solution within the second lumen **613** to expand the deployable lobe **605**.

[0046] In accordance with one embodiment of the present invention, prior to the lead **110** being placed within a cardiac vessel of the patient, the deployable lobe **605** remains deflated on the side-surface of the conductor tubing **215** of the lead **110** (as shown in FIG. 6A). When the lead **110** is placed at a desired site within the cardiac vessel, a liquid solution or gas is injected into the lumen **613** via the port **620**. In accordance with one embodiment, the liquid solution may include saline and the gas may include carbon dioxide. It will be appreciated, however, that various other liquid solutions or gases may be used in lieu of the examples provided without departing from the spirit and scope of the present invention.

[0047] The injecting of the solution or gas within the lumen **613** causes the deployable lobe **605** to expand by filling the lobe **605** with the solution or gas and, thus, protrude or expand outwardly from the outer surface of the conductor tubing **215** (as shown in FIG. 6B). The solution or gas is injected through the port **620** until the deployable lobe **605** engages the cardiac vessel, thereby securing the lead **110** within the cardiac vessel and, thus, substantially preventing any movement of the lead **110** therein. Subsequent to filling the deployable lobe **605** with the desired amount of solution or gas, the port **620** may be removed, and the lumen **613** may be sealed at the opening formed by the port **620** with an adhesive or a self-sealing rubber grommet, for example, so as to prevent any leakage of the solution or



gas from the lumen 613 (and, thus, preventing the deployable lobe 605 from deflating). In accordance with another embodiment, the conductor tubing 215 may be provided as a single lumen, and the deployable lobe 605 may be provided with an opening (not shown) therein to inject a gas or solution to inflate the deployable lobe 605. In this particular embodiment, the opening within the deployable lobe 605 may then be sealed to prevent any leakage of the gas or solution injected therein, and, thus, substantially prevent deflation of the deployable lobe 605.

[0048] In accordance with one embodiment, the electrode 117 may be placed on the terminal end of the lead 110. In another embodiment, the electrode 117 may be placed on a side of the lead 110 opposite from the side the deployable lobe 605 on the lead 110.

[0049] Turning now to FIG. 7A, a fixation mechanism 700 for the lead 110 is shown in accordance with another embodiment of the present invention. In this particular embodiment, the distal end of the lead 110 is configured with a pair of deployable lobes 705 that may extend outwardly so as to protrude from the surface of the conductor tubing 215. Although two deployable lobes 705 are shown in FIG. 7A, it will be appreciated that only one or more than two deployable lobes 705 may be disposed around the circumference of the conductor tubing 215 without departing from the spirit and scope of the present invention.

[0050] In one embodiment, the deployable lobe 705 may take the form of a flange, and may be fixedly attached to a fixation segment 708 that is engaged with and encircles the conductor tubing 215. In one embodiment, the deployable lobe 705 may be constructed out of a plastic (e.g., silicon or some other polymer) or may be constructed out of a metal. The deployable lobe 705 may be fixedly attached to the fixation segment 708 at a pivot point 706 to allow the deployable lobe 705 to be substantially parallel to the surface of the conductor tubing 215 when assuming a retracted position or to extend outwardly or protrude from the surface of the conductor tubing 215 when the deployable lobe 705 is extended outwardly from the surface of the conductor tubing 215 (i.e., when the deployable lobe 705 rotates about the pivot point 706). Push tubing 710 surrounds the conductor tubing 215, and an end portion 715 of the push tubing 710 engages an inner edge 717 of the deployable lobe 705.

[0051] In the illustrated embodiment, the inner edge 717 of the deployable lobe 705 is sloped or tapered so as to cause the deployable lobe 705 to eject outwardly when the end portion 715 of the push tubing 710 slides between the outer surface of the conductor tubing 215 and the inner edge 717 of the deployable lobe 705. That is, when the push tubing 710 is pushed towards the distal end of the lead 110, the end portion 715 of the push tubing 710 slides between the outer surface of the conductor tubing 215 and the inner edge 717 of the deployable lobe 705, thereby causing the lobe 705 to rotate about the pivot point 706 and extend outwardly from the outer surface of the conductor tubing 215.

[0052] When the push tubing 710 is pulled away from the distal end of the lead 110, the deployable lobe 705 will retract until the deployable lobe 705 is substantially parallel to the outer surface of the conductor tubing 215. A slip coating may be applied to the inner surface of the push tubing 710 or to the outer surface of the conductor tubing

215 to facilitate the sliding of the push tubing 710 over the conductor tubing 215. According to one embodiment, the slip coating may take the form of polyacrylamide or polytetrafluoroethylene (PrFE); however, it will be appreciated that the slip coating may include various other materials. In the illustrated embodiment, a molded transitional piece 720 is provided between the deployable lobe 705 and the outer surface of the conductor tubing 215 to provide a gradual transition between the outer surface of the conductor tubing 215 and the deployable lobe 705.

[0053] In one embodiment, the end portion 715 of the push tubing 710 is tapered so as to facilitate the passage of the end portion 715 of the push tubing 710 underneath the deployable lobe 705. Furthermore, the distal tip of the deployable lobe 705, which engages the cardiac vessel when the lobe 705 is extended outwardly, may be rounded to prevent damage to the cardiac vessel when engaged therewith.

[0054] In one embodiment of the present invention, the deployable lobe 705 may be covered by flexible material 310 that is attached to the molded transition piece 720 and the push tubing 710 to reduce the likelihood of tissue engrowth or bodily fluids of the patient from ingressing underneath the push tubing 215. In accordance with one embodiment, the flexible material 310 is provided in the form of a balloon-like material (such as polyisoprene, polyurethane, or silicone, for example) that may stretch when the deployable lobe 705 is extended outwardly from the surface of the conductor tubing 215. In accordance with an alternative embodiment, it will be appreciated that the flexible material 310 may be omitted, if so desired.

[0055] Prior to the lead 110 being placed within a cardiac vessel of the patient, the deployable lobes 705 are retracted by pulling the push tubing 710 away from the distal end of the lead 110. In the retracted position, the deployable lobe 705 assumes a substantially parallel position relative to the outer surface of the conductor tubing 215, where the deployable lobe 705 is not extended outwardly from the conductor tubing 215 of the lead 110. When the lead 110 is placed at the desired site within the cardiac vessel, the push tubing 710 is pushed toward the distal end of the lead 110. This pushing action will cause the end portion 715 of the push tubing 710 to slide under the deployable lobe 705, which will cause the deployable lobe 705 to extend outwardly or protrude from the surface of the conductor tubing 215 rotating outwardly about the pivot point 706. As the deployable lobe 705 extends outwardly or protrudes from the surface of the conductor tubing 215, the deployable lobe 705 stretches the flexible material 310 resting thereon. The pushing action of the push tubing 710 resumes until the distal tip of the deployable lobe 705 engages the cardiac vessel, thereby securing the lead 110 within the cardiac vessel. It will be appreciated that the push tubing 710 may be held in place with a clip mechanism (not shown), as discussed previously.

[0056] Turning now to FIG. 7B, the fixation mechanism 700 is shown in accordance with another embodiment of the present invention. In this particular embodiment, a unipolar lead 740 is surrounded by an outer coil 745, and an outer tubing 750 surrounds the outer coil 745. By rotating the outer coil 745 in one direction (i.e., clockwise, for example), it will cause the end portion 752 of the outer tubing 750 to go under the deployable lobe 705 and cause the lobe 705 to

extend outwardly from the outer tubing 750 when the lobe 705 rotates about the pivot point 706 as illustrated in FIG. 7C. When it is desired to retract the lobe 705 such that it becomes substantially parallel with the surface of the outer tubing 750, the outer coil 745 may be rotated in the opposite direction (i.e., counter-clockwise, for example) to cause the outer tubing 750 to disengage from underneath the deployable lobe 705, and thus cause the lobe 705 to retract and become substantially parallel in relation to the surface of the outer tubing 750.

[0057] Turning now to FIG. 8A, a fixation mechanism 800 for the lead 110 is shown in accordance with another embodiment of the present invention. In this particular embodiment, the distal end of the lead 110 is configured with at least one deployable lobe 805 that may extend outwardly so as to protrude from the surface of a conductor tubing 815 that surrounds an electrical conductor 810. In one embodiment, the deployable lobe 805 takes the form of a polyurethane strip material that may be fixedly attached to the outer surface of the conductor tubing 815 at each end of the lobe 805. It will be appreciated that the deployable lobe 805, as opposed to being provided in the form of a polyurethane strip, may be constructed out of various other materials, such as silicone, for example, without departing from the spirit and scope of the present invention.

[0058] In accordance with the illustrated embodiment, the electrical conductor 810 is slideably received within an opening of an outer tubing 820 that surrounds the electrical conductor 810. Referring to FIG. 8B, the deployable lobe 805 is shown in the retracted position, where the lobe 805 is received within a recessed slot 825 formed within the opening of the outer tubing 820. FIG. 8D illustrates a cross-sectional view of the outer tubing 820 with the opening 822 in which the electrical conductor 810 is slideably received and the recessed slot 825 formed within the opening 822 for receiving the deployable lobe 805.

[0059] Typically, the electrical conductor 810 will have a natural tendency to remain retracted within the opening 822 of the outer tubing 820. A stylet (not shown) is utilized to push out the electrical conductor 810 from the opening 822 of the outer tubing 820, as is conventional in the art. FIG. 8C shows the electrical conductor 810 extended from the opening 822 of the outer tubing 820. When the electrical conductor 810 is extended from the opening 822 of the outer tubing 820 using the stylet, the deployable lobe 805 on the outer surface of the conductor tubing 815 is exposed. Once the deployable lobe 805 is exposed, the electrical conductor 810 may then be rotated either clockwise or counter-clockwise using the stylet (not shown) within a recessed opening 830 of the electrical conductor 810. By rotating the electrical conductor 810, the deployable lobe 805 is no longer in alignment with the recessed slot 825, and, therefore, may not be received within the slot. Subsequent to rotation by the stylet, the electrical conductor 810 will attempt to retract within the opening 822 of the outer tubing 820, and because the deployable lobe 805 is not in alignment with the recessed slot 825, will cause the deployable lobe 805 to extend outwardly (or "buckle") from the outer surface of the conductor tubing 815 (as illustrated in FIG. 8A).

[0060] Prior to the lead 110 being placed within a cardiac vessel of the patient, the deployable lobe 805 assumes a retracted position within the recessed slot 825 of the outer

tubing 820 as illustrated in FIG. 8B. In the retracted position, the deployable lobe 805 assumes a substantially parallel position relative to the outer surface of the conductor tubing 815, where the deployable lobe 805 is not extended outwardly from the surface of the conductor tubing 815 of the lead 110. When the lead 110 is placed at the desired site within the cardiac vessel, a stylet (not shown) is used to push out the electrical conductor 810 from the opening 822 of the outer tubing 820 until the deployable lobe 805 is exposed (as illustrated in FIG. 8C). The stylet is then used to rotate the electrical conductor 810 either clockwise or counter-clockwise until the deployable lobe 805 is no longer in alignment with the recessed slot 825 formed within the opening 822 of the outer tubing 820. When the stylet is removed, the electrical conductor 810 will naturally attempt to retract within the opening 822 of the outer tubing 820. Because the deployable lobe 805 is not in alignment with the recessed slot 825 of the opening 822 of the outer tubing 820, the deployable lobe 805 will extend outwardly from the outer surface of the conductor tubing 815 (as illustrated in FIG. 8A), thereby causing the apex of the lobe 805 to engage the side of the cardiac vessel and fixedly secure the lead 110 therein.

[0061] The particular embodiments disclosed above are illustrative only, as the invention may be modified and practiced in different but equivalent manners apparent to those skilled in the art having the benefit of the teachings herein. Furthermore, no limitations are intended to the details of construction or design herein shown, other than as described in the claims below. It is therefore evident that the particular embodiments disclosed above may be altered or modified and all such variations are considered within the scope and spirit of the invention. Accordingly, the protection sought herein is as set forth in the claims below.

What is claimed:

1. An apparatus for fixating a lead disposed within a vessel, comprising:

a segment at a distal end of the lead;

at least one deployable lobe situated at the segment, the deployable lobe adapted to assume a retracted position and an engaging position, the engaging position engaging the at least one deployable lobe with the vessel; and

wherein the at least one deployable lobe assumes the engaging position in response to the segment being compressed and assumes the retracted position when the fixation segment is not compressed.

2. The apparatus of claim 1, wherein the at least one deployable lobe is formed between a pair of elongated, substantially parallel slits in the segment.

3. The apparatus of claim 1, wherein the compression of the segment causes the deployable lobe to extend outwardly from an outer surface of the segment.

4. The apparatus of claim 1, wherein by not compressing the segment causes the deployable lobe to retract and become substantially parallel to an outer surface of the fixation segment.

5. The apparatus of claim 3, wherein compression of the segment causes the deployable lobe to extend outwardly from the outer surface of the fixation segment and form an angular shape having an apex.

6. The apparatus of claim 5, wherein the apex of the angular shape formed by the deployable lobe engages the vessel, thereby substantially fixating the lead within the vessel.

7. The apparatus of claim 1, further comprising:

push tubing surrounding the lead and secured to the segment at one end thereof; and

an anchor member for securing an opposite end of the segment to the lead; and

wherein pushing of the push tubing toward the segment causes compression of the segment against the anchor member.

8. An apparatus for fixating a lead disposed within a vessel, comprising:

at least one deployable lobe situated on a distal portion of the lead, the deployable lobe adapted to assume a retracted position and an engaging position, the engaging position engaging the at least one deployable lobe with the vessel;

a flexible material covering a portion of an outer surface of the lead; and

wherein the at least one deployable lobe assumes the engaging position by deforming of the flexible material a segment from the lead at the portion of the outer surface and assumes the retracted position by rectifying said deforming of the segment.

9. The apparatus of claim 8, wherein the at least one deployable lobe comprises an expandable spring within the lead, and wherein the spring stretches the flexible material outwardly from the lead when the spring assumes the engaging position.

10. The apparatus of claim 9, wherein the expandable spring is expanded to stretch the flexible material by rotating a conductor that is disposed within the lead.

11. The apparatus of claim 9, wherein the expandable spring and flexible material engage the vessel when assuming the engaging position, thereby substantially fixating the lead within the vessel.

12. The apparatus of claim 8, wherein the flexible material comprises at least one of polyisoprene, polyurethane, and silicone.

13. The apparatus of claim 8, wherein the at least one deployable lobe comprises a stent within the lead, and wherein the stent stretches the flexible material outwardly from the lead when the stent assumes the engaging position.

14. The apparatus of claim 13, wherein the stent and flexible material engage the vessel when assuming the engaging position, thereby substantially fixating the lead within the vessel.

15. The apparatus of claim 13, wherein the stent is expanded to stretch the flexible material by rotating a conductor that is disposed within the lead.

16. The apparatus of claim 8, wherein the at least one deployable lobe comprises a flange within the lead, and wherein the flange bends to form an angular shape that stretches the flexible material outwardly from the lead when the flange assumes the engaging position.

17. The apparatus of claim 16, wherein the flange bends to form the angular shape by pushing a wire attached to one end thereof.

18. The apparatus of claim 16, wherein the flange and flexible material engage the vessel when assuming the engaging position, thereby substantially fixating the lead within the vessel.

19. The apparatus of claim 8, wherein the at least one deployable lobe comprises a flange that is attached to the lead at one end thereof by a hinge member, and wherein the flange rotates outwardly about the hinge member and stretches the flexible material outwardly from the lead when the flange assumes the engaging position.

20. The apparatus of claim 19, wherein the flange rotates outwardly about the hinge member by pushing an outer tubing that surrounds the lead underneath the flange.

21. The apparatus of claim 20, wherein an inner edge of the flange is sloped to facilitate the outward rotation of the flange when the outer tubing is engaged therewith.

22. An apparatus for fixating a lead disposed within a vessel, comprising:

at least one deployable lobe situated on a distal portion of the lead, the deployable lobe adapted to assume a retracted position and an engaging position, the engaging position engaging the at least one deployable lobe with the vessel;

a lumen coupled to the deployable lobe, and adapted to extend the deployable lobe to the engaging position; and

wherein the at least one deployable lobe assumes the engaging position by extending outwardly from an outer surface of the lead.

23. The apparatus of claim 22, wherein the deployable lobe takes the form of a balloon-like material.

24. The apparatus of claim 22, wherein the deployable lobe is extended outwardly from the outer surface of the lead by inflation of the lobe via the lumen.

25. The apparatus of claim 24, wherein the deployable lobe is extended outwardly from the outer surface of the lead by inflation of the lobe by injecting a gas or liquid into the lumen.

26. The apparatus of claim 22, wherein the deployable lobe engages the vessel when assuming the engaging position, thereby substantially fixating the lead within the vessel.

27. An apparatus for fixating a lead disposed within a vessel, the lead including an electrical conductor surrounded by a conductor tubing and an outer tubing that is slideably received over the conductor tubing, the apparatus comprising:

at least one deployable lobe situated on a distal portion of an outer surface of the conductor tubing of the lead, the deployable lobe adapted to assume a retracted position and an engaging position, the engaging position engaging the at least one deployable lobe with the vessel;

a recessed slot formed lengthwise within an inner surface of the outer tubing; and

wherein the at least one deployable lobe assumes the retracted position when the recessed slot formed within the outer tubing is in alignment with the deployable lobe and is slideably received within the recessed slot, and assumes an engaging position by extending outwardly from the outer surface of the conductor tubing when the deployable lobe is not in alignment with the recessed slot.

**28.** The apparatus of claim 27, wherein the deployable lobe comprises a flexible strip, and wherein each end of the flexible strip is fixedly attached to the outer surface of the conductor tubing.

**29.** The apparatus of claim 27, wherein the electrical conductor is rotated within the outer tubing to align or unalign the deployable lobe with the recessed slot formed lengthwise within the inner surface of the outer tubing.

**30.** The apparatus of claim 27, wherein the engaging position of the deployable lobe is achieved by pushing the electrical conductor out from the outer tubing until the deployable lobe is exposed from the recessed slot, and rotating the electrical conductor until the deployable lobe is not in alignment with the recessed slot formed within the outer tubing.

**31.** The apparatus of claim 27, wherein the retracted position of the deployable lobe is achieved by rotating the electrical conductor until the deployable lobe is in alignment with the recessed slot formed within the outer tubing and the deployable lobe is slideably received within the recessed slot.

**32.** A method for fixating a lead disposed within a vessel, comprising:

providing a fixation segment surrounding the lead at a distal end thereof;

providing at least one deployable lobe situated on the fixation segment, the deployable lobe adapted to assume a retracted position and an engaging position, the engaging position engaging the at least one deployable lobe with the vessel; and

compressing the fixation segment to have the at least one deployable lobe assume the engaging position.

**33.** A method for fixating a lead disposed within a vessel, comprising:

providing at least one deployable lobe situated on a distal portion of the lead, the deployable lobe adapted to assume a retracted position and an engaging position, the engaging position engaging the at least one deployable lobe with the vessel;

providing a flexible material covering a portion of an outer surface of the lead; and

extending the flexible material outwardly from the lead at the portion of the outer surface when the at least one deployable lobe assumes the engaging position.

**34.** A method for fixating a lead disposed within a vessel, comprising:

providing at least one deployable lobe situated on a distal portion of the lead, the deployable lobe adapted to assume a retracted position and an engaging position, the engaging position engaging the at least one deployable lobe with the vessel; and

providing a lumen coupled to the deployable lobe, and adapted to extend the deployable lobe to the engaging position by extending outwardly from an outer surface of the lead.

**35.** A method for fixating a lead disposed within a vessel, the lead including an electrical conductor surrounded by a conductor tubing and an outer tubing that is slideably received over the conductor tubing, the method comprising:

providing at least one deployable lobe situated on a distal portion of an outer surface of the conductor tubing of the lead, the deployable lobe adapted to assume a retracted position and an engaging position, the engaging position engaging the at least one deployable lobe with the vessel;

forming a recessed slot lengthwise within an inner surface of the outer tubing; and

retracting the deployable lobe when the recessed slot formed within the outer tubing is in alignment with the deployable lobe and is slideably received within the recessed slot, thereby assuming the retracted position; and

extending the deployable lobe outwardly from the outer surface of the conductor tubing when the deployable lobe is not in alignment with the recessed slot and is withdrawn therefrom, thereby assuming the engaging position.

**36.** The method of claim 35 wherein a slip anti-coagulant (heparin) coating is used on the conductor tubing.

**37.** The method of claim 35 wherein the lobes are annealed to enable deployment in an engaging position.

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