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(54) LEAD STABILIZATION DEVICES AND METHODS

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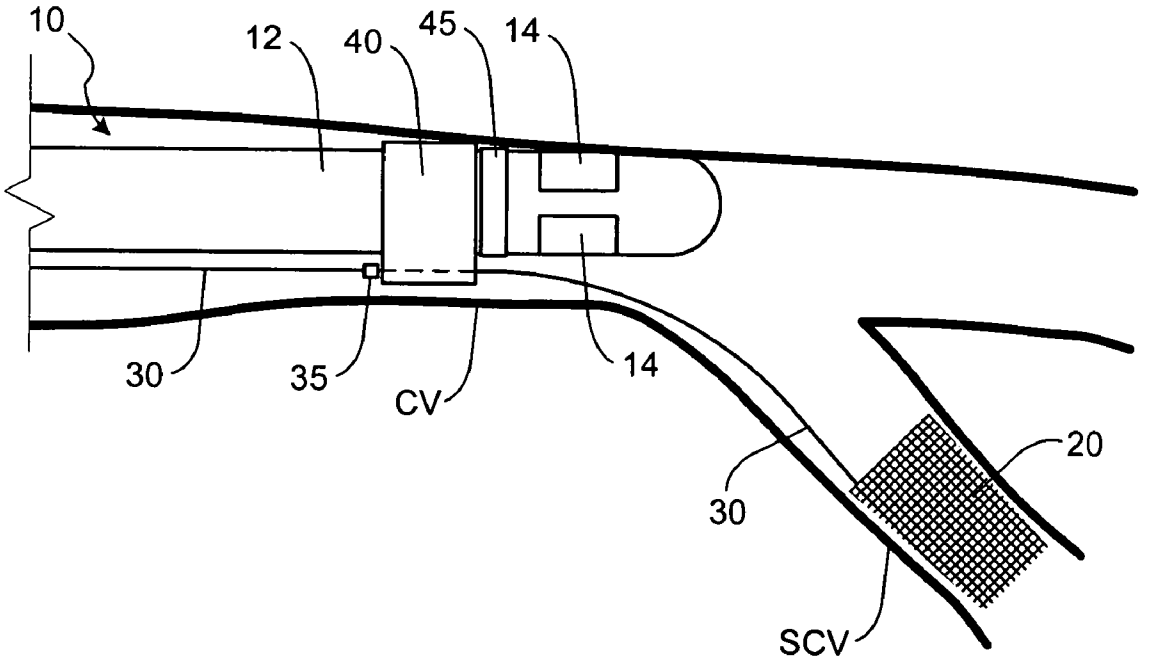
(52) **U.S. Cl.** **607/126**

(57) **ABSTRACT**

Devices and methods for stabilizing a lead in a cardiac vein.



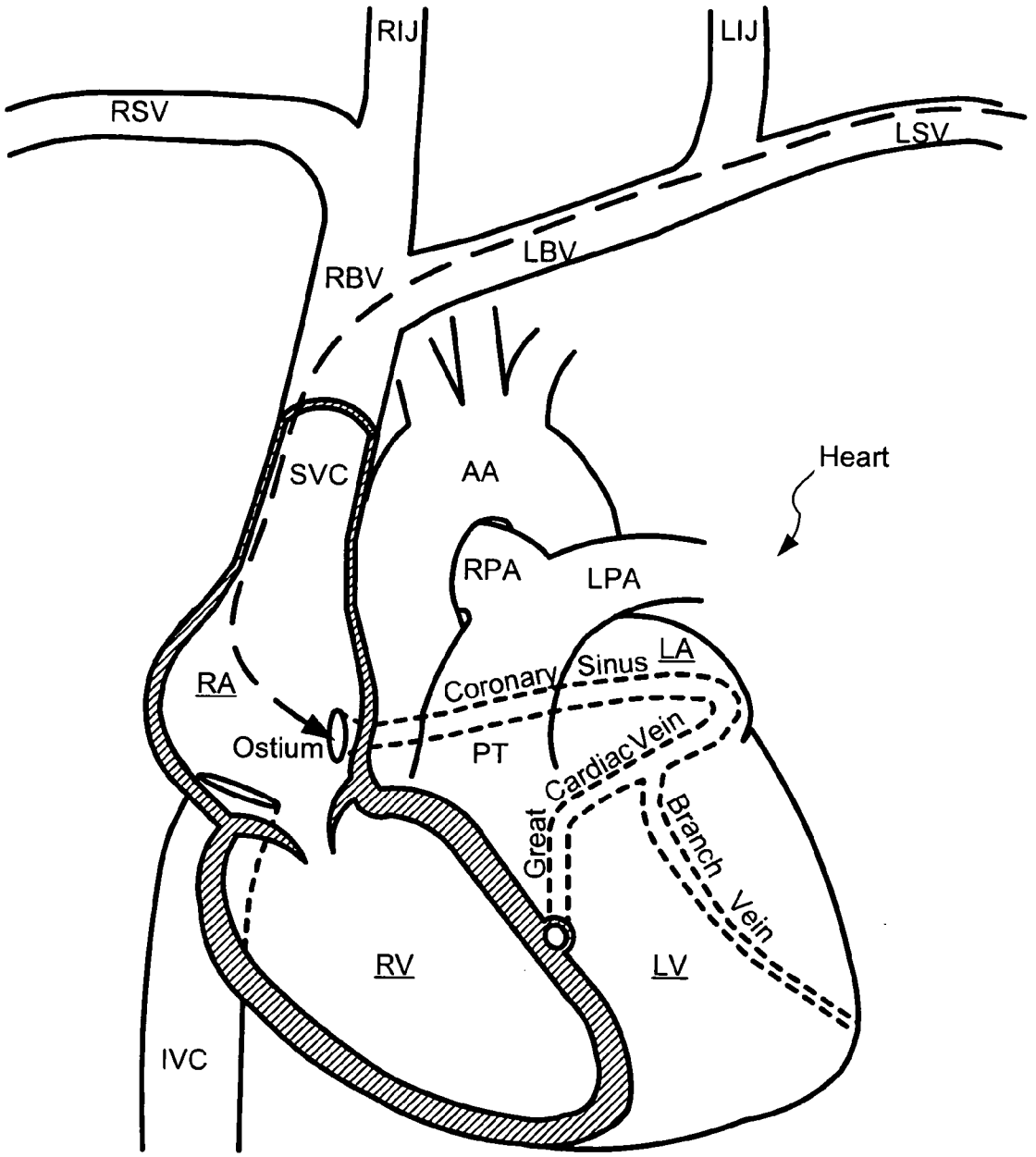

RIJ
LIJ
RSV
LSV
LBV
RBV
SVC
AA
Heart
RPA
LPA
RA
Coronary Sinus
LA
Ostium
PT
Cardiac Vein
Great
Branch Vein
RV
LV
IVC

FIG. 1

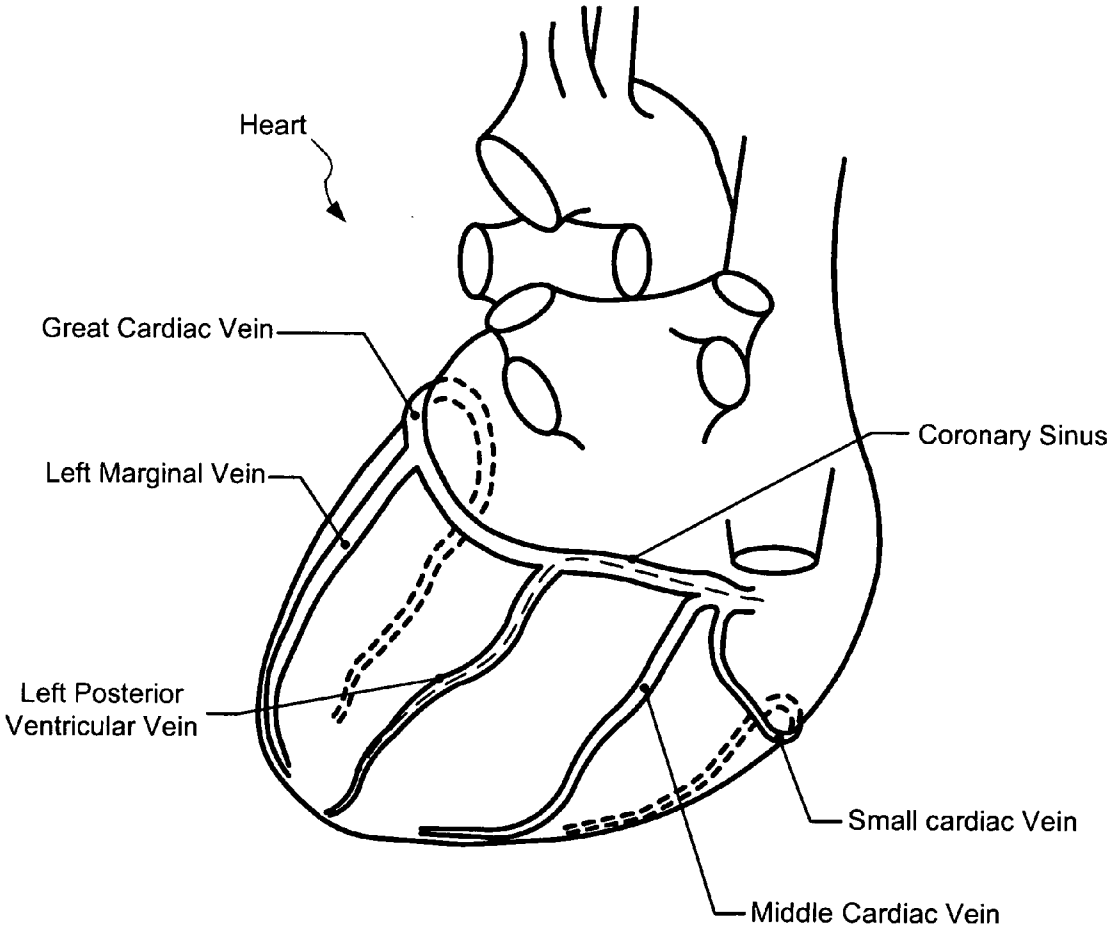

Heart
Great Cardiac Vein
Left Marginal Vein
Left Posterior
Ventricular Vein
Coronary Sinus
Small cardiac Vein
Middle Cardiac Vein

FIG. 2

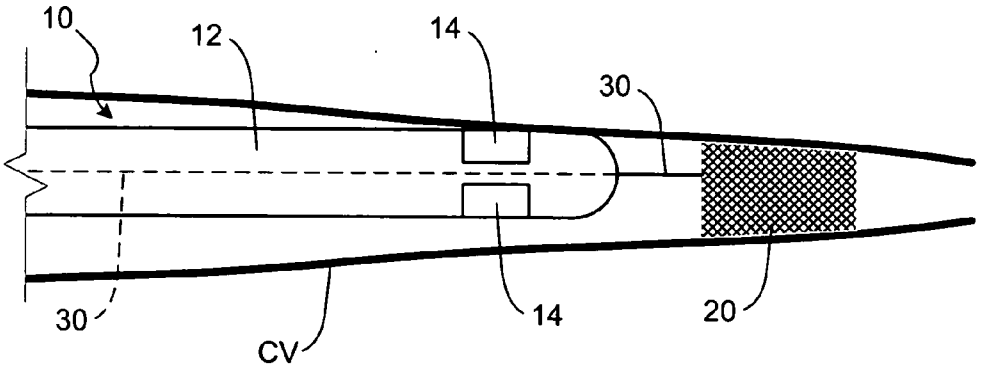


FIG. 3

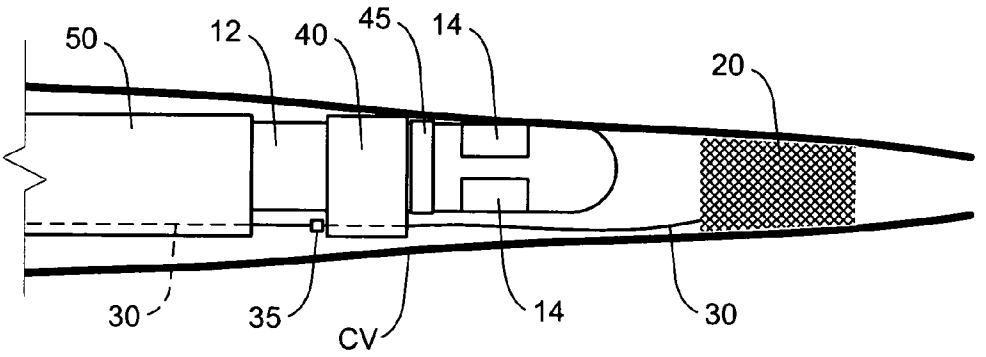


FIG. 4

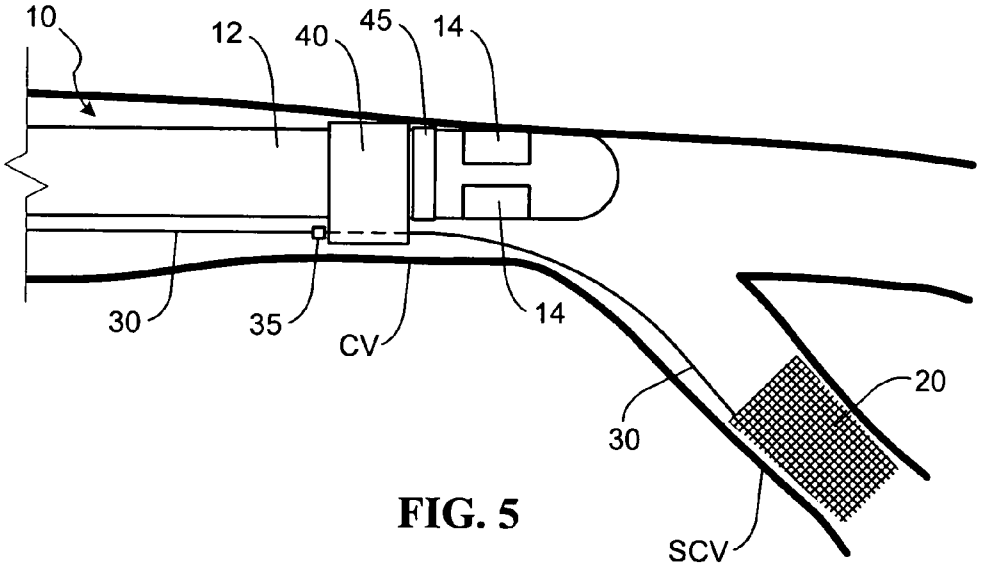


FIG. 5

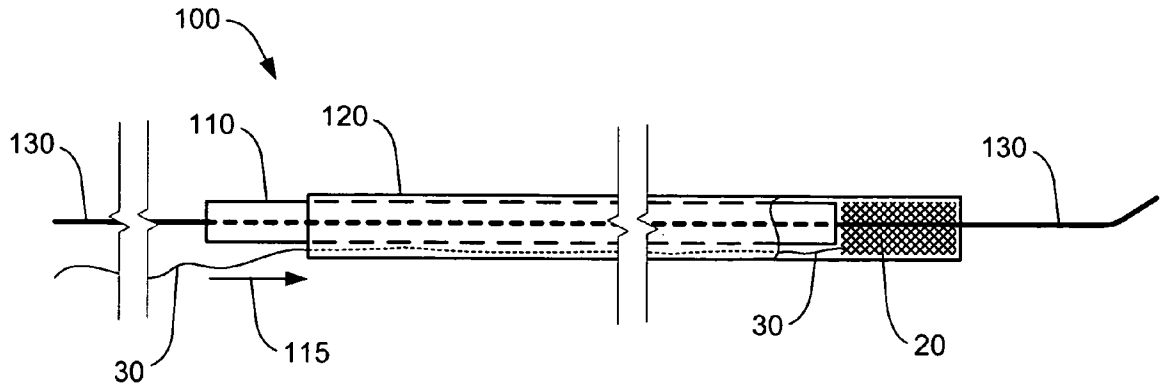


FIG. 6

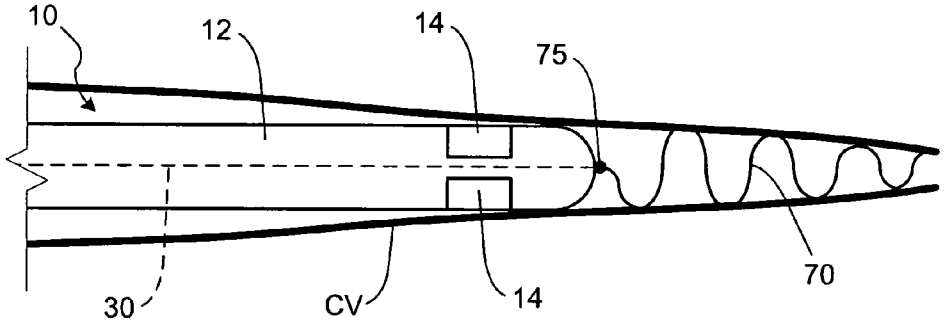


FIG. 7

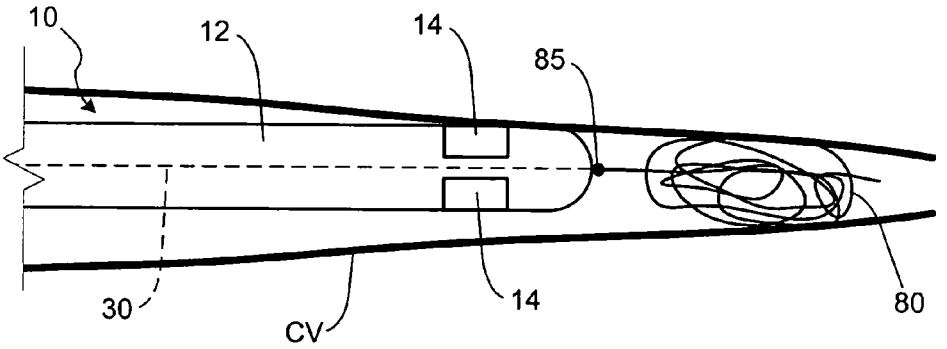


FIG. 8

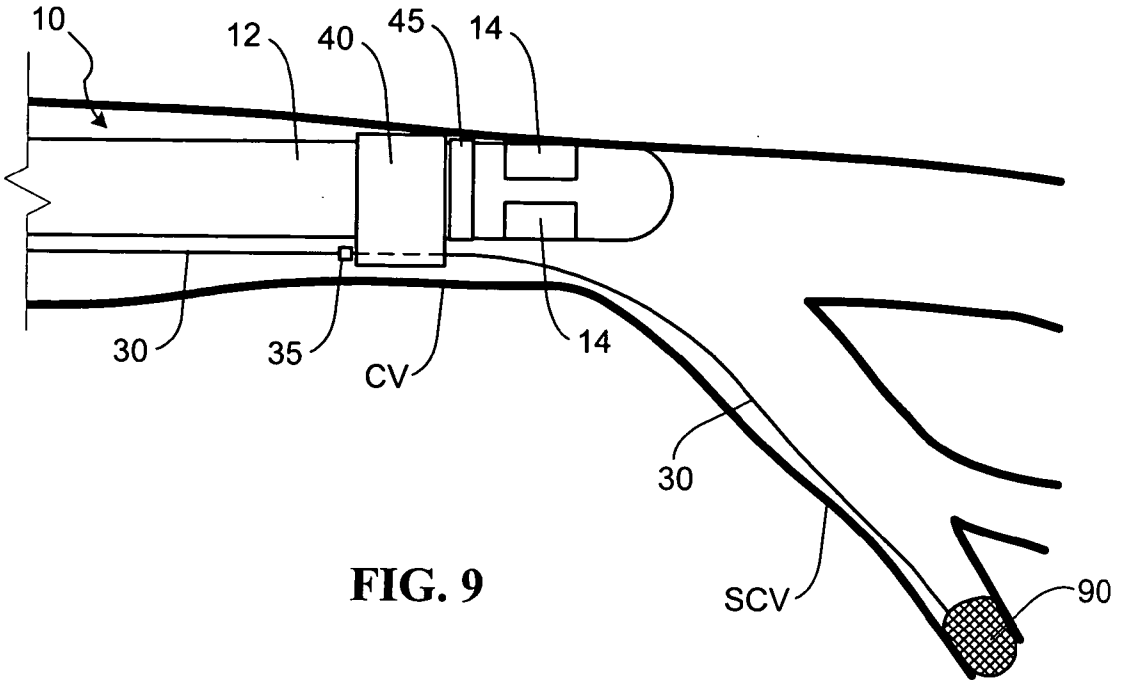


FIG. 9

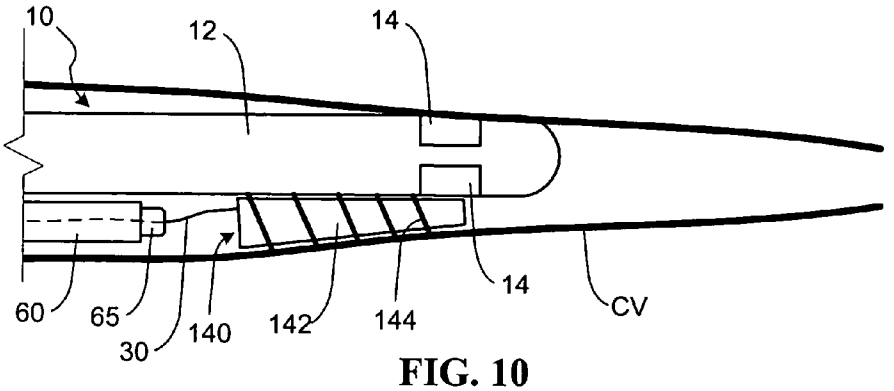


FIG. 10

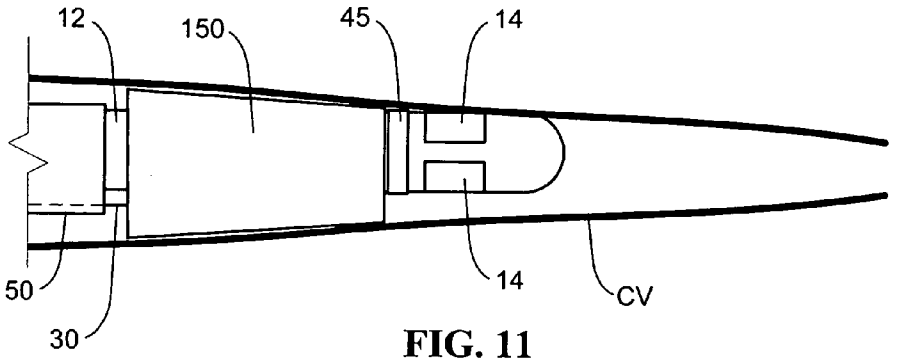


FIG. 11

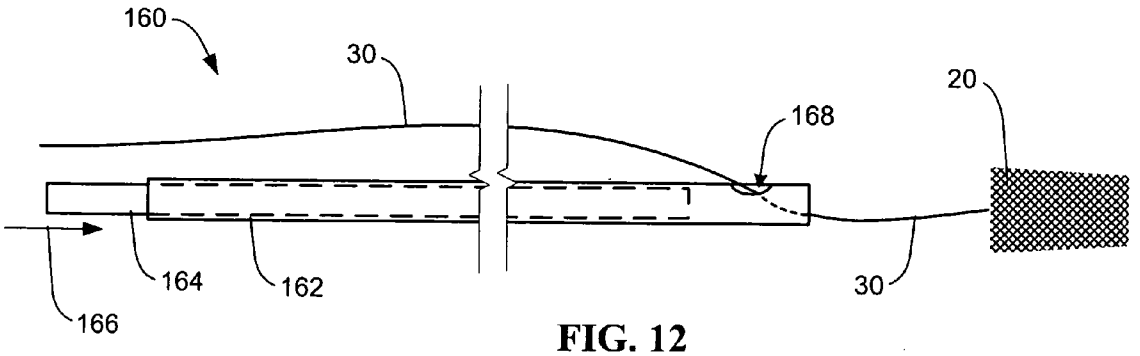


FIG. 12

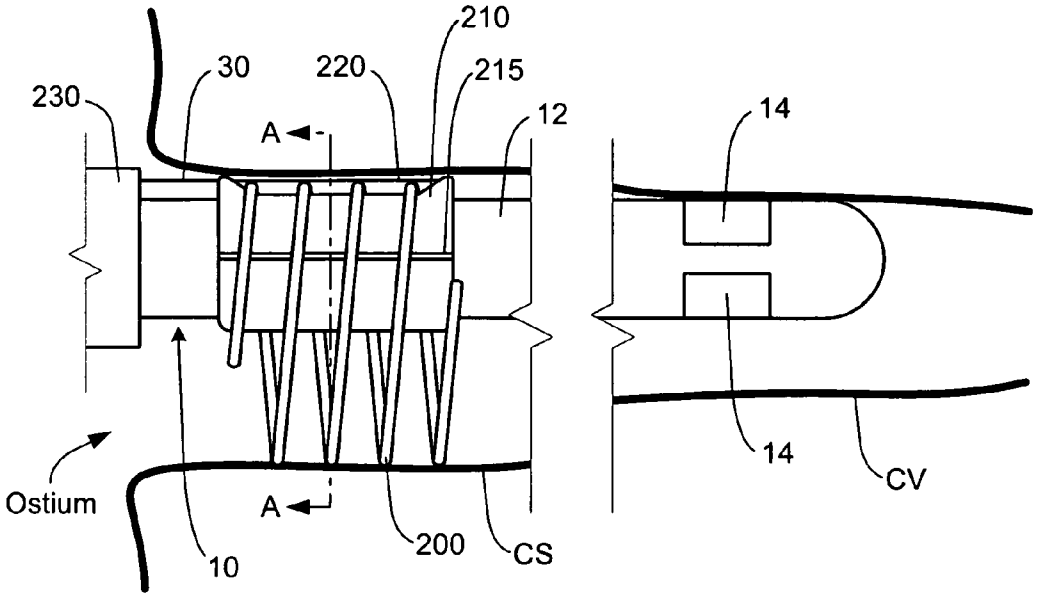


FIG. 13

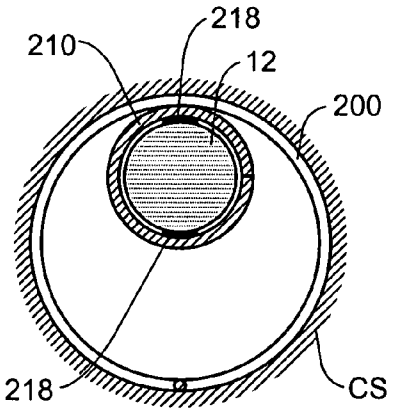


FIG. 13A

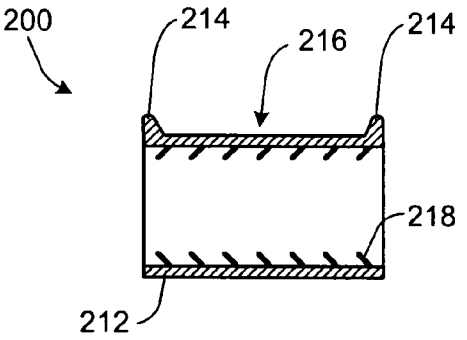


FIG. 13B

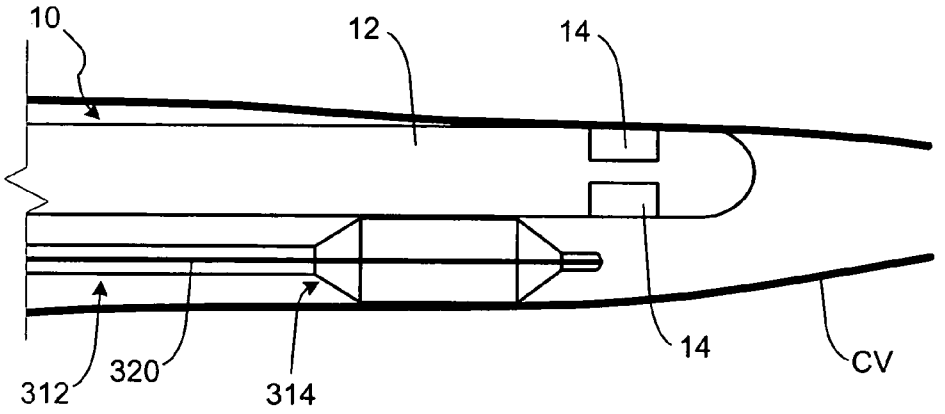


FIG. 14

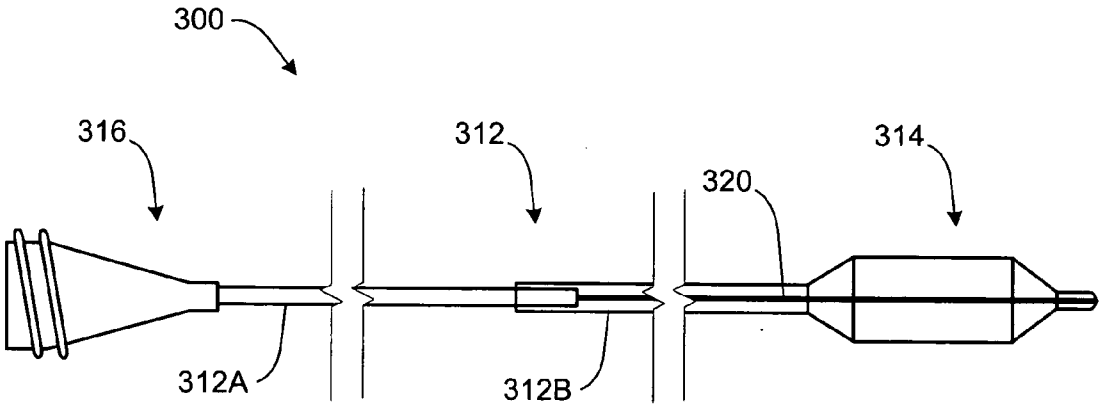


FIG. 15

LEAD STABILIZATION DEVICES AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 60/510,663, filed Oct. 10, 2003, entitled LEAD STABILIZATION DEVICES AND METHODS to Atkinson et al., the entire disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention generally relates to medical devices and methods. More specifically, the present invention relates to medical devices and methods for stabilizing leads in cardiac vasculature.

BACKGROUND OF THE INVENTION

[0003] Heart failure is an increasingly common condition worldwide. Cardiac resynchronization therapy (CRT) has shown great promise as a treatment for a large percentage of patients in various stages of heart failure. CRT involves cardiac pacing of both the left and right ventricles of the heart (biventricular pacing), which causes both ventricles to beat simultaneously, greatly improving the pumping efficiency of the heart. Typically, the lead that stimulates the left ventricle is positioned via the coronary sinus into a cardiac vein along the free wall of the left ventricle.

[0004] There are numerous challenges in successfully positioning the left ventricular lead, including accessing the coronary sinus and veins, advancing the leads to a position which yields proper stimulation, and preventing subsequent lead dislodgement during removal of delivery devices. Post procedural challenges related to the left ventricular lead include lead dislodgement prior to fibrosis, loss of stimulation capture, and lead removal necessitated by infection.

[0005] Currently available left ventricular leads have generally been designed to facilitate effective delivery and provide fatigue resistance, and are particularly susceptible to dislodgement both intra-procedurally and post-procedurally. Efforts to incorporate more aggressive anchoring into the lead body have generally been insufficient for preventing dislodgment, and/or have compromised effective delivery, fatigue resistance and subsequent lead removal.

SUMMARY OF THE INVENTION

[0006] Therefore, a need exists to enable effective lead stabilization without compromising lead delivery, resistance to lead fatigue, or lead removal. To address this need, various exemplary non-limiting embodiments are described herein which provide devices and methods for acute and/or chronic lead stabilization. By way of example, not limitation, the lead stabilization mechanisms described herein may be separate from but cooperative with the lead, thus allowing independent delivery and function. To this end, the lead may be designed for effective delivery and fatigue resistance, and the stabilization mechanism may be designed for effective acute and/or chronic anchoring to prevent lead dislodgement. In addition, the stabilization mechanisms described herein may be separable from the lead to permit subsequent lead removal.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] **FIG. 1** is an anterior view of a human heart and associated vasculature;

[0008] **FIG. 2** is a posterior view of a human heart and associated cardiac venous vasculature;

[0009] **FIG. 3** is a schematic side view of a lead and an anchor device in the form of a stent disposed in a cardiac vein;

[0010] **FIG. 4** is a schematic side view of a lead and an alternative anchor device in the form of a stent disposed in a cardiac vein;

[0011] **FIG. 5** is a schematic side view of a lead disposed in a coronary vein and an alternative anchor device in the form of a stent disposed in a secondary cardiac vein;

[0012] **FIG. 6** is a schematic side view of an anchor delivery device for use in delivering the anchor devices illustrated in **FIGS. 3-5**;

[0013] **FIG. 7** is a schematic side view of a lead and an alternative anchor device in the form of a coil disposed in a cardiac vein;

[0014] **FIG. 8** is a schematic side view of a lead and an alternative anchor device in the form of a bundle disposed in a cardiac vein;

[0015] **FIG. 9** is a schematic side view of a lead disposed in a cardiac vein and an alternative anchor device in the form of a plug disposed in a secondary cardiac vein;

[0016] **FIGS. 10 and 11** are schematic side views of a lead and alternative anchor devices in the form of wedges disposed in a cardiac vein;

[0017] **FIG. 12** is a schematic illustration of a release mechanism in the form of a connector cutter;

[0018] **FIG. 13** is a schematic side view of a lead disposed in a cardiac vein and an anchor device in the form of a coiled stent disposed near the ostium of the coronary sinus;

[0019] **FIG. 13A** is a cross sectional view taken along line A-A in **FIG. 13**;

[0020] **FIG. 13B** is side sectional view of the fastener illustrated in **FIG. 13**;

[0021] **FIG. 14** is a schematic side view of a lead disposed in a cardiac vein and an anchor device in the form an anchor catheter; and

[0022] **FIG. 15** is a detailed schematic view of the anchor catheter illustrated in **FIG. 14**.

DETAILED DESCRIPTION OF THE INVENTION

[0023] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

[0024] With reference to **FIGS. 1 and 2**, the anatomy of a human heart (H) is illustrated. **FIG. 1** shows the heart from the anterior side, with the right chambers of the heart shown

in section. **FIG. 2** shows the heart from the posterior side, and illustrates the cardiac veins, including the coronary sinus (CS) and its associated venous branches (great cardiac vein, left marginal vein, left posterior ventricular vein, middle cardiac vein, and small cardiac vein). The CS carries the primary venous return for the cardiac circulation, with the venous branches distributed about the heart and draining into the CS. The CS circumnavigates the left side of the heart, generally between the left atrium (LA) and the left ventricle (LV). The CS drains into the right atrium (RA) at the ostium.

[**0025**] Left ventricular leads are typically implanted with the proximal end connected to a pulse generator in a subcutaneous or submuscular pocket, and the distal end (electrode(s)) disposed in one of the cardiac veins to stimulate the left ventricle. The lead body typically extends from the pulse generator in the subcutaneous or submuscular pocket, through the vein wall and into the left subclavian vein (LSV), through the left brachio-cephalic vein (LBV), down the superior vena cava (SVC) and into the right atrium (RA), into the CS and into the target cardiac vein. The venous circulation is usually accessed by introducing delivery catheters (called guide catheters or guide sheaths) from a venous arteriotomy in the LSV to the CS ostium, following the dashed line shown in **FIG. 1**. Once the CS is cannulated by a delivery catheter, a coronary venogram is obtained to visualize the cardiac veins. The lead is advanced into the CS and the desired cardiac vein, following an exemplary path indicated by the dashed line shown in **FIG. 2**.

[**0026**] There are generally two categories of LV leads, over-the-wire (OTW) leads and stylet-delivered leads. OTW leads incorporate a guide wire lumen which extends through the entire lead body, emerging at the tip of the lead. Navigation within the CS and cardiac veins is performed by advancing a steerable guide wire to a desired location in a cardiac vein, and the lead is then advanced over the guide wire. Stylet delivered leads have a stylet lumen which extends through the lead body, but typically terminates proximal of the distal tip. A shaped styled is positioned in the stylet lumen and the lead and stylet are advanced together to navigate the lead to a desired location in a cardiac vein.

[**0027**] Once the lead is positioned in a location that yields acceptable stimulation (capture), the delivery catheter is removed. Depending on the particular lead, and the type of electrical connector utilized, removal is accomplished either by withdrawing the delivery catheter over the proximal end of the lead, or by splitting the delivery catheter as it is removed over the proximal end of the lead. In some situations, removal of the delivery catheter may dislodge the lead, as the stability of the lead position is often quite tenuous. Even if the lead is not dislodged during removal of the delivery catheter, the beating of the heart and other patient activities can cause lead movement or dislodgement, leading to potential loss of capture (effective pacing of the LV).

[**0028**] With reference to **FIG. 3**, a pacing lead **10** and an anchor device in the form of a stent **20** are schematically shown disposed in a cardiac vein CV. Generally, the CV generically refers to venous braches of the coronary sinus such as the great cardiac vein, left posterior ventricular vein, middle cardiac vein, small cardiac vein, or other cardiac vein that leads to the left ventricle, and preferably that leads to the apex of the left ventricular free wall or that otherwise provides for effective pacing of the left ventricle. Those skilled in the art will recognize that because of anatomic variation, the precise name and position of the CV will vary.

[**0029**] Lead **10** may comprises a conventional pacing lead having an elongate body or shaft **12** and one or more electrodes **14** connected to a pulse generator (not shown) by corresponding wires or traces inside the lead body **12**. Lead **10** is generally designed to be very flexible and fatigue resistant to permit free cardiac movement, to minimize tissue trauma, and to withstand repeated flexure primarily caused by the beating heart. The electrodes **14** are typically positioned on or near the wall of the vein facing the heart to establish effective conduction into the heart wall.

[**0030**] Stent **20** may be self-expandable or balloon expandable, for example, and may be formed of a biocompatible metal material such as stainless steel, Nitinol, Elgiloy, or MP35N. Alternatively, stent **20** may be formed of a biodegradable polymeric material such as poly-L-lactic acid, polyglycolic acid, or polycaprolactone, or other biodegradable materials such as those used for biodegradable sutures. In the case of polymeric materials used for stent **20**, the polymer may be loaded with a radiopaque agent such as barium, bismuth subcarbonate, etc. to facilitate x-ray visualization. Generally speaking, all of the anchors of the anchor devices described herein may be formed of the aforementioned materials and may be radiopaque.

[**0031**] Stent **20** may be connected to lead **10** by an elongate connector **30**. Elongate connector **30** may comprise a tether that is flexible and fatigue resistant such as a braided cord of a high strength biocompatible polymer such as polyester, polypropylene, or polyethylene (e.g., Spectra brand), and may be partially or fully covered or coated with a material that promotes tissue in-growth such as ePTFE. The tissue in-growth promoting material may serve to secure the elongate member **30** to the lead **10** and/or prevent bacteria migration along the elongate member **30**.

[**0032**] In the embodiment illustrated in **FIG. 3**, the elongate member or tether **30** extends through the lumen (e.g., guide wire lumen) of the lead **10**. This embodiment is particularly suitable for OTW leads that typically have a guide wire lumen extending therethrough. The proximal end of the tether **30** may extend out the proximal end of the lumen of the lead **10**, and may be connected to the lead **10** by tying a knot that is larger than the diameter of the lumen, for example. Alternatively, the proximal end of the tether **30** may be connected to the proximal end of the lead **10** by trapping the tether **30** in the lumen of the lead **10** with a wedge or pinching it between the electrical connector of the lead **10** and the socket of the pulse generator. The distal end of the tether **30** may be connected to the stent **20** by tying the tether **30** in a knot around a strut of the stent **20**, or swaging and end of the tether **30** between struts of the stent **20**, for example.

[**0033**] In this embodiment, the stent **20** and tether **30** may be deployed before the lead **10** is delivered. The stent **20** may be deployed in a distal portion of the target CV with a delivery device as described in more detail with reference to **FIG. 6**. Once deployed, the proximal end of the tether **30** may be inserted into the distal end of the lumen extending through the lead **10**, and the lead **10** may then be advanced over the tether **30** and into the CV to the desired position,

and pacing tests may be performed to ascertain LV pacing capture. Once the lead **10** is in the desired position, the proximal end of the tether **30** may be secured to the proximal end of the lead **10** as described previously.

[**0034**] If it is necessary or desired to remove or reposition the lead **10**, the lead **10** may be removed from the CV by disconnecting the tether **30** from the lead **10** (e.g., by cutting the knot in the tether **30** at the proximal end of the lead **10**), the tether **30** may be removed from the CV by disconnecting the tether **30** from the stent **20** (e.g., by using a cutting device as described in more detail with reference to **FIG. 12**), and the stent **20** may be left in place in the CV without compromising blood flow through the CV.

[**0035**] With reference to **FIG. 4**, an alternative anchor device arrangement is shown schematically. In this embodiment, rather than extending through the lumen of the lead **10**, the tether **30** extends along side the lead **10**. This embodiment is particularly suitable for stylet-delivered leads that typically do not have a lumen extending therethrough, but may be used with either stylet-delivered or OTW leads. This embodiment also allows for the delivery of the anchor device either before or after lead **10** placement.

[**0036**] The tether **30** may be connected to the lead **10** by a fastener such as collar **40**. Collar **40** may comprise a short dual lumen tube including a relatively large lumen to accommodate the lead **10** therethrough and a relatively small lumen to accommodate the tether **30** therethrough. Collar **40** may be fixedly connected to the lead **10** if the anchor device is delivered prior to the lead **10** by swaging, adhesive, etc. To facilitate delivery of the lead after placement of the lead **10**, the collar **40** may be slidable over the lead **10** and lock in place adjacent the distal potion of the lead **10** using a mating geometry such as a detent on the outer surface of the lead **10** that receives a protrusion extending from the inside surface of the collar **40**. Alternatively, the outer surface of the lead **10** may include a protrusion such as a stepped ridge **45** that abuts the distal end of the collar **40** as the collar **40** is advanced over the lead **10** in order to prevent proximal movement of the lead **10** relative to the collar **40**. With this alternative, the stepped ridge **45** may be an integral extension of the outer surface of the lead **10** or a separate component fixedly connected to the lead **10**.

[**0037**] The tether **30** may be effectively connected to the collar **40** to prevent proximal movement of the collar **40** relative to the tether **30** by utilizing a knot or stop **35** that is slid down the length of the tether **30**. A knot may be made in the tether at its proximal end and advanced distally to the collar **40** using a conventional knot pusher. A stop **35** may be used and configured to readily advance distally over the tether **30** and resist retraction proximally. For example, stop **35** may comprise a short tubular segment having proximal facing flanges extending from the inside surface that selectively engage the tether **30** only when the stop **35** is advanced in the proximal direction relative to the tether **30**. To facilitate removal of the lead **10**, the stop **35** may be cut or the tether **30** may be cut between the stop **35** and the collar **40** using the cutting device described with reference to **FIG. 12**.

[**0038**] To facilitate advancement of the collar **40** over the lead **10** and to facilitate advancement of the stop **35** over the tether **35**, a dual lumen advancement sheath **50** may be slid (pushed) over the lead **10** and tether **30**. Sheath **50** may comprise an elongate dual lumen tube having a length sufficient to extend over the lead **10**, through the venous vasculature, and out the venous access site, with one lumen to accommodate the lead **10** and another lumen to accommodate the tether **30**. Sheath **50** may include a slit (not shown) along the length thereof to facilitate peeling over the lead **10**. Sheath **50** may be removed over the lead **10** and tether **30** after advancement of the collar **40** and stop **35**, or it may be left implanted to contain the tether **30** relative to the lead **10**.

[**0039**] With reference to **FIG. 5**, an alternative anchor device arrangement is shown schematically. In this embodiment, the stent **20** is deployed in a secondary cardiac vein (SCV) and connected via tether **30** and collar **40** to lead **10** as described with reference to **FIG. 4**. Positioning the stent **20** in a SCV enhances the anchoring effect and, because of collateral venous circulation, reduces the possibility of adverse effects if the stent **20** were to become occluded.

[**0040**] With reference to **FIG. 6**, a schematic side view of an anchor delivery catheter device **100** for use in delivering anchor devices such as stent **20** as described in connection with the embodiments of **FIGS. 3-5**. In this embodiment, the delivery device **100** is configured to deliver an elastically expandable (self-expanding) stent, but a balloon catheter type delivery device may alternatively be utilized to deliver a plastically deformable (balloon expandable) stent. In the illustrated embodiment, the delivery catheter **100** may include an inner tube **110** coaxially disposed in an outer tube **120**. The stent **20** may be pre-loaded inside the outer tube **120**, near its distal end. The distal end of the inner tube **110** abuts the proximal end of the stent **20**, and may be advanced distally with respect to the outer tube **120** as indicated by arrow **115** to advance stent **20** out of the distal end of the outer tube **120**. The tether **30** may be disposed between the inner tube **110** and the outer tube **120**.

[**0041**] To facilitate delivery, a guide wire **130** may be used to initially navigate the CV. Once the guide wire **130** is in the desired position, the delivery catheter **100** with the pre-loaded stent **20** therein may then be advanced over the proximal end of the guide wire **130** and advanced thereover to the desired deployment position. The inner tube **110** may be advanced in the distal direction with respect to the outer tube **120** as indicated by arrow **115** to deploy the stent **20** in the CV. Once the stent **20** is deployed, the delivery catheter **100** may be removed.

[**0042**] With reference to **FIG. 7**, an alternative anchor device arrangement is shown schematically. In this embodiment, a coil **70** is deployed distal of the lead **10** and connected via tether **30** to lead **10** as described with reference to **FIG. 3**. The proximal end of the coil **70** may be connected to the distal end of the tether **30** at connection **75**, and the coil **70** may comprise a resilient structure such as a metal wire formed of any of the materials described with reference to stent **20**. Coil **70** may be delivered via a lumen (e.g. guide wire lumen) extending through the lead **10** and is particularly suitable for an OTW lead. The coil **70** may be advanced through the lumen of the lead **10** using a push tube (not shown) having sufficient column strength disposed over the tether **30** that abuts the connection **75** between the coil **70** and the tether **30**.

[**0043**] To accommodate delivery through the lumen extending through the lead **10**, the coil **70** may have a

delivery configuration wherein the coil **70** is elongated to have a reduced profile sufficiently small to fit into the lumen, and a deployed configuration wherein the coil **70** is radially expanded to have an expanded profile sufficiently large to frictionally engage the wall of the CV. The coil **70** may be highly elastic such that it assumes the deployed configuration automatically upon advancement out of the distal end of the lead **10**, or the coil may be actuated (e.g., thermally) upon advancement out of the distal end of the lead **10** to assume the deployed configuration.

[**0044**] With reference to **FIG. 8**, an alternative anchor device arrangement is shown schematically. In this embodiment, a bundle **80** is deployed distal of the lead **10** and connected via tether **30** to lead **10** as described with reference to **FIG. 3**. The proximal end of the bundle **80** may be connected to the distal end of the tether **30** at connection **85**, and the bundle **80** may comprise a resilient structure such as a metal wire formed of any of the materials described with reference to stent **20**. Bundle **80** may be delivered in the same manner as and may have the same or similar characteristics as coil **70** described with reference to **FIG. 7**. Bundle **80**, as opposed to coil **70**, may have an occlusive effect, and therefore may be particularly suitable for a SCV to take advantage of collateral venous circulation.

[**0045**] With reference to **FIG. 9**, an alternative anchor device arrangement is shown schematically. This embodiment is similar to the embodiment illustrated in **FIG. 5**, except that a plug **90** is used in place of stent **20**. The plug **90** may comprise a curable adhesive (e.g., cyanoacrylate, EVA in a DSMO solvent) or an embolic coil, for example, such as those conventionally used in occluding blood vessels and aneurisms. Plug **90** may be deployed in a SCV using a conventional embolic delivery system and connected via tether **30** and collar **40** to lead **10** as described with reference to **FIG. 4**. Positioning the plug **90** in a SCV enhances the anchoring effect, and despite the occlusive effect of the plug **90**, the possibility of adverse effects are reduced if not eliminated due to collateral venous circulation.

[**0046**] With reference to **FIGS. 10 and 11**, alternative anchor device arrangements are shown schematically. In these embodiments, a wedge **140** or **150** is deployed adjacent the distal portion of the lead **10**, such as proximal of electrodes **14**. Wedges **140** and **150** frictionally engage the lead body **12** and the wall of the CV, to lodge the lead **10** in the desired position in the CV. The wedges **140** and **150** may be connected to tether **30** to facilitate subsequent removal. Wedges **140** and **150** may comprise any of the materials discussed with reference to stent **20**. Wedges **140** and **150** are particularly suitable for deployment after the lead **10** has been delivered to the desired position.

[**0047**] With specific reference to **FIG. 10**, wedge **140** includes a body portion **142** and optional threads **144**. Body portion **142** may include a perfusion lumen extending therethrough to permit blood perfusion from the distal end to the proximal end of the wedge **140**. The wedge body **142** (or the wedge threads **144** if used) may have a diameter slightly greater than the diameter of the lumen of the CV less the diameter of the lead **10** in order to provide a snug frictional fit therebetween. Wedge **140** may be delivered into the desired position utilizing a push tube **60** advanced over a guide wire (not shown), for example, wherein the push tube **60** has sufficient column strength to push the wedge **140** alongside the lead **10** with the distal end **65** of the push tube abutting the proximal end of the wedge **140** and the tether **30** extending through the push tube. The push tube may also have sufficient torsional strength with a distal end **65** that mates with the proximal inside diameter of the wedge **140** such that the wedge **140** may be rotated to engage or disengage the threads **144** with the lead **10** and the wall of the CV.

[**0048**] With specific reference to **FIG. 11**, wedge **150** comprises a short dual lumen having one lumen to accommodate the lead **10** and another (crescent shaped) lumen to permit blood perfusion from the distal end to the proximal end of the wedge **150**. The wedge **150** may be tapered and may have a diameter slightly greater than the diameter of the lumen of the CV less the diameter of the lead **10** in order to provide a snug frictional fit therebetween. Stepped ridge **45** prevents proximal movement of the lead **10** relative to wedge **150** as described previously. Wedge **150** may be delivered into the desired position utilizing a push tube **50** advanced over the lead **10**, as described previously.

[**0049**] With reference to **FIG. 12**, a cutting device **160** is shown schematically. Cutting device **160** may be used to cut tether **30** and/or stop **35** in order to disconnect the tether **30** from the anchor device, such as stent **20**. Cutting device **160** is merely an example of a variety of cutting mechanisms that may be used to sever the connection of the tether **30** from the anchor device. For example, the tether **30** may be equipped with two internal wires connected to a distal electrolytic fuse that separates (melts) upon the application of electrical current, such as those used for detachable embolic coils.

[**0050**] In this exemplary embodiment, cutting device **160** includes an outer tube **162** and an inner tube **164** coaxially disposed and movable therein. The outer and inner tubes **162** and **164** may have a length sufficient to extend from outside the vascular access site to the anchor device, and may be configured for intravascular navigation and advancement over tether **30**. The distal end of the inner tube **164** may have a sharpened edge and may be formed of a material that retains a cutting edge (e.g., metal). A cutting hole **168** is provided adjacent the distal end of the outer tube **162** through which the tether **30** may be threaded. The distal circumference of the cutting hole **168** may be sharpened and may be formed of a material that retains a cutting edge (e.g., metal) After the cutting device is advanced over the tether **30** to the desired cutting site, the inner tube **164** may be advanced distally as indicated by arrow **166**, with the sharpened distal end of the inner tube **164** and the sharpened cutting hole **168** acting as shears to cut the tether **30** at the cutting hole **168**.

[**0051**] With reference to **FIG. 13**, a lead **10** is shown disposed in a CV, with an anchor device in the form of a coiled stent **200** disposed near the ostium of the CS. The coiled stent **200** may be positioned near the ostium of the CS, where the vessel diameter is large enough to resist becoming occluded by the presence of the coiled stent **200** next to the lead **10**. However, it is contemplated that the coiled stent **200** may be placed elsewhere within the CS or CV in which the lead is positioned. As seen in **FIG. 13A**, the lead **10** is eccentrically disposed in the lumen of the CS to define a relatively large crescent shaped blood perfusion lumen.

[**0052**] Coil stent **200** may be formed of a resilient material such as Nitinol, Elgiloy, MP35N, or stainless steel. Coiled

stent **200** could also be formed of degradable materials such as those described in reference to stent **20** above. Coiled stent **200** may be releasably attached to the lead **10** utilizing collar **210**, and collar **210** may frictionally engage the body **12** of lead **10**, thus facilitating anchoring of the lead within the coronary sinus or cardiac vein.

[**0053**] With reference to **FIG. 13B**, the collar **210** may comprise a relatively short tube **212**, and may include one or more proximally oriented grips **218**. Grips **218** may be in the shape of finger-like projections, or circular ribs either partially or completely extending circumferentially around the inside of tube **212**. Grips **218** facilitate the advancement of the collar **210** in a distal direction for delivery over lead **10**, but resist proximal movement once the collar **210** is positioned in a desired anchoring location. Grips **218** may be formed of a soft resilient material such as silicone, polyurethane, polyether-block-amide, or the like.

[**0054**] To facilitate subsequent removal of the lead **10**, the coiled stent **200** may be connected to the collar **210** in a detachable manner. For example, the coiled stent **200** may be connected to the collar **210** utilizing a biodegradable adhesive connecting adjacent portions of the coil **200** to the collar **210**. Such an adhesive may degrade after the lead **10** has chronically anchored to the wall of the CS by normal tissue encapsulation. After the adhesive has degraded, the lead **10** (along with collar **210**) may be removed utilizing standard techniques, with the coiled stent **200** remaining in the CS.

[**0055**] Alternatively, the coiled stent **200** may be secured to the collar **210** utilizing a retractable pin **220**. In this alternative embodiment, collar **210** may include two angled flanges **214** collectively defining a recess **216** in which stent coil **200** may reside. Pin **220** may span the length of the recess **216** between the flanges **214**, extending over the coiled stent **200** to retain the coil stent **200** in the recess **216**, thus providing a connection between the stent coil **200** and the collar **214**. Subsequent release of the stent coil **200** from the lead **10** may be accomplished by removing pin **220** using tether **30** which extends from the proximal end of the lead **10** to the pin **220**. The proximal end of the pin **220** is connected to the distal end of the tether **30**, and the pin **220** may be removed by pulling the tether **30** proximally. After the pin **220** is removed, the lead **10** and collar **210** are free from the stent coil **200** and may be removed with standard techniques, leaving stent coil **200** in the CS.

[**0056**] Delivery and deployment of the stent coil **200** and collar **210** may be facilitated by deployment sheath **230**. The deployment sheath **230** may comprise a tubular catheter, having a lumen extending therethrough to accommodate the lead **10** and the stent coil **200**. Alternatively, the lumen in the deployment sheath **230** may extend from a distal opening to a mid-shaft opening as used in conventional monorail style balloon catheters. After lead **10** has been positioned by standard techniques to a desired position, the stent coil **200** and collar **210** may be loaded on the proximal end of the lead **10**. Coil **200** may be initially in a compressed condition, and loaded in the inside of the deployment sheath **230**. If the lead **10** has a large diameter proximal connector, an optional slit **215** may be provided in the collar **220** to facilitate loading over the large diameter connector. In this case, the collar **210** and coil **200** may be positioned on the lead body **12** before the coil **200** is loaded into the deployment sheath **230**. The deployment sheath **230** may be advanced distally down the body **12** of the lead **10** until the stent coil **200** and collar **210** are in the desirable location. The deployment sheath **230** may then be withdrawn proximally, with the collar **210** and stent coil **200** remaining in position on the lead **10** due to grips **218** on collar **210**. As the stent coil **200** emerges from the deployment sheath **230**, it expands to engage the wall of the CS. The deployment sheath **230** can then be removed from the lead **10**.

[**0057**] **FIGS. 14 and 15** illustrate an anchor device in the form of an anchoring catheter **300**, which may be utilized to secure the position of lead **10**, particularly during the removal of the guide sheath (guide catheter) used in the delivery of the lead **10**. As described above, the lead stability is particularly vulnerable during the removal of the guide sheath.

[**0058**] In use, the anchoring catheter **300** is positioned next to the lead **10** after lead **10** has been positioned in a desired location. Anchoring catheter **300** may be advanced within the guide sheath (not shown), generally parallel to the lead body **12**, or may be advanced outside the guide sheath. An expandable member such as a balloon **314** is inflated to frictionally secure lead **10** against the wall of the blood vessel. The guide sheath can then be removed without inadvertent dislodgement of the lead **10**. The anchoring catheter **300** can then be removed. Since anchoring catheter **300** is next to and not surrounding the lead body **12**, removal of the anchoring catheter **300** does not pose a risk of dislodging lead **10**.

[**0059**] With particular reference to **FIG. 15**, anchoring catheter **300** is shown in more detail. Shaft **312** may comprise a proximal shaft portion **312**A connected by adhesive, for example, to a distal shaft portion **312**B. A luer adaptor **316** may be connected to the proximal end of the proximal shaft portion **312**A for connection to an inflation apparatus (not shown) such as a syringe. An inflatable balloon **314** may be connected to the distal end of the distal shaft portion **312**B, and may be formed of elastomeric material or a molded inelastic material.

[**0060**] Proximal shaft portion **312**A may be relatively stiff and may be formed of a metallic tube such as a stainless steel hypotube. Distal shaft portion **312**B may be relatively flexible and may be formed of a polymeric tube, for example. To facilitate advancement of the flexible distal shaft portion **312**B and the balloon **314**, a core wire may be connected to and extend from the distal end of the proximal shaft portion **312**A. The core wire **320** may comprise a metal wire such as a tapered stainless steel mandrel.

[**0061**] Core wire **320** extends to the distal end of the balloon **314**, and may extend beyond with an atraumatic spring tip, for example. The distal end of the balloon **314** may be bonded to the core wire **320**, and the proximal end of the balloon **314** may be bonded to the distal end of the distal shaft portion **312**B. Within the shaft **312** is a lumen through which inflation medium is infused to inflate balloon **314**.

[**0062**] Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

1-28. (canceled)

29. A system for stabilizing an electrical lead in a coronary vessel, comprising:

an electrical lead having a proximal portion and a distal portion with a lumen extending therethrough; and

an intravascular anchoring device including an anchor and an elongate tether, the tether detachably connected to the anchor and extending proximally from the anchor, the tether extending through the lumen of the lead with the anchor disposed distally of the lead, wherein the lead is longitudinally movable with respect to the anchoring device.

30. A system as in claim 29, further comprising a connector for limiting longitudinal movement between the lead and the anchoring device, wherein the connector is insertable into the lumen of the lead adjacent the tether.

31. A system as in claim 29, wherein the tether in nonelectrically conductive.

32. A system as in claim 29, wherein the tether comprises a braid.

33. A system as in claim 29, wherein the tether comprises a polymeric braid.

34. A system as in claim 29, wherein the anchor comprises a self-expanding structure.

35. A system for stabilizing an electrical lead in a coronary vessel, comprising:

an electrical lead having a proximal portion and a distal portion with a lumen extending therethrough; and

an intravascular anchoring device including a self-expanding anchor and an elongate tether, the tether connected to the anchor and extending proximally from the anchor, the tether extending through the lumen of the lead with the anchor disposed distally of the lead, wherein the lead is longitudinally movable with respect to the anchoring device.

36. A system as in claim 35, further comprising a connector for limiting longitudinal movement between the lead and the anchoring device, wherein the connector is insertable into the lumen of the lead adjacent the tether.

37. A system as in claim 35, wherein the tether in non-electrically conductive.

38. A system as in claim 35, wherein the tether comprises a braid.

39. A system as in claim 35, wherein the tether comprises a polymeric braid.

40. A system as in claim 35, wherein the tether is detachable from the anchor.

41. A system for stabilizing an electrical lead in a coronary vessel, comprising:

an electrical lead having a proximal portion and a distal portion with a lumen extending therethrough; and

an intravascular anchoring device including an anchor and an elongate non-electrically conductive tether, the tether connected to the anchor and extending proximally from the anchor, the tether extending through the lumen of the lead with the anchor disposed distally of the lead, wherein the connector is insertable into the lumen of the lead adjacent the tether.

42. A system as in claim 41, further comprising a connector for limiting longitudinal movement between the lead and the anchoring device, wherein the connector is insertable into the lumen of the lead adjacent the tether.

43. A system as in claim 41, wherein the anchor comprises a self-expanding structure.

44. A system as in claim 41, wherein the tether comprises a braid.

45. A system as in claim 41, wherein the tether comprises a polymeric braid.

46. A system as in claim 41, wherein the tether is detachable from the anchor.

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