

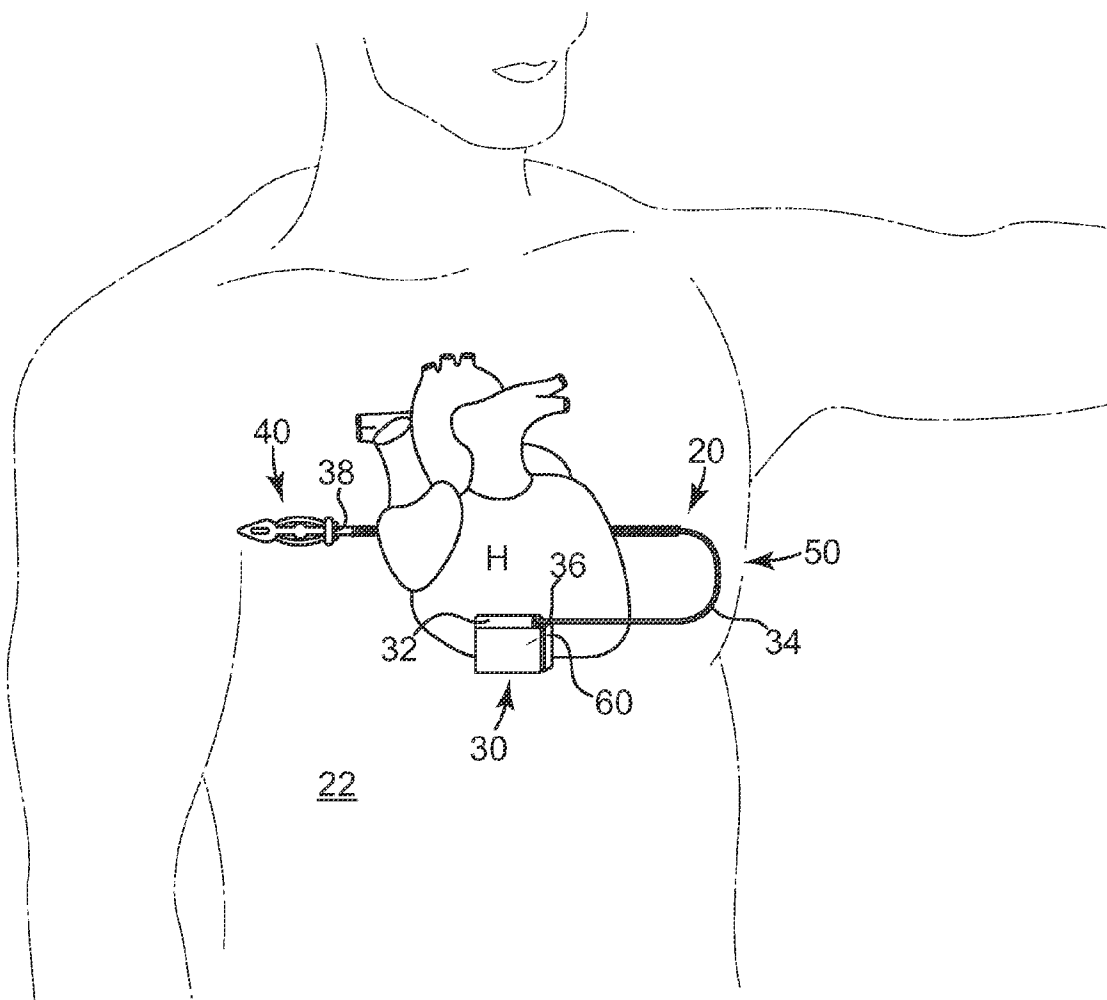


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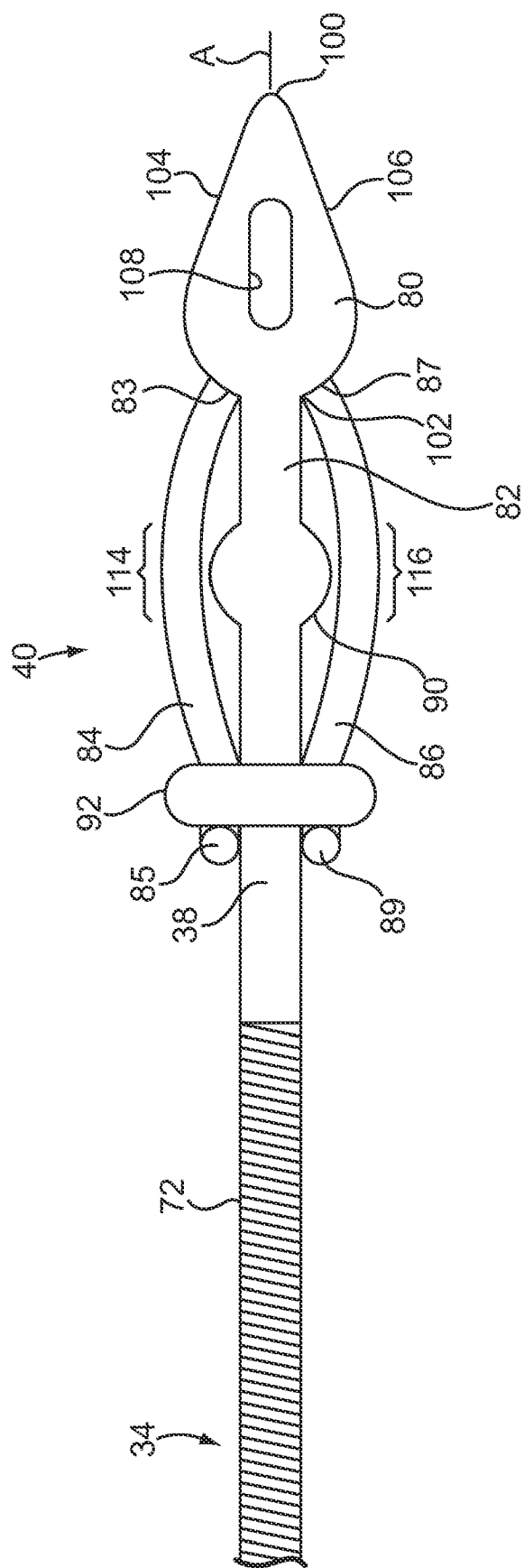
(19) **United States**(12) **Patent Application Publication**
Lazeroms et al.(10) **Pub. No.: US 2010/0030311 A1**(43) **Pub. Date: Feb. 4, 2010**(54) **SUBCUTANEOUSLY IMPLANTABLE LEAD
INCLUDING DISTAL FIXATION
MECHANISM**(22) Filed: **Jul. 31, 2008****Publication Classification**(76) Inventors: **Markus J.C. Lazeroms,**
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J.G. Rutten, Bocholtz (NL); **Karel**
F.A.A. Smits, Munstergeleen (NL)(51) **Int. Cl.**
A61N 1/05 (2006.01)(52) **U.S. Cl.** **607/119; 607/116**(57) **ABSTRACT**

A subcutaneously implantable lead includes a coil disposed along a portion of the lead, and a lead tip coupled to a distal end of the lead. The lead tip includes at least one component that is movable relative to the distal end of the lead and configured to anchor the lead tip in subcutaneous tissue.

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100



200

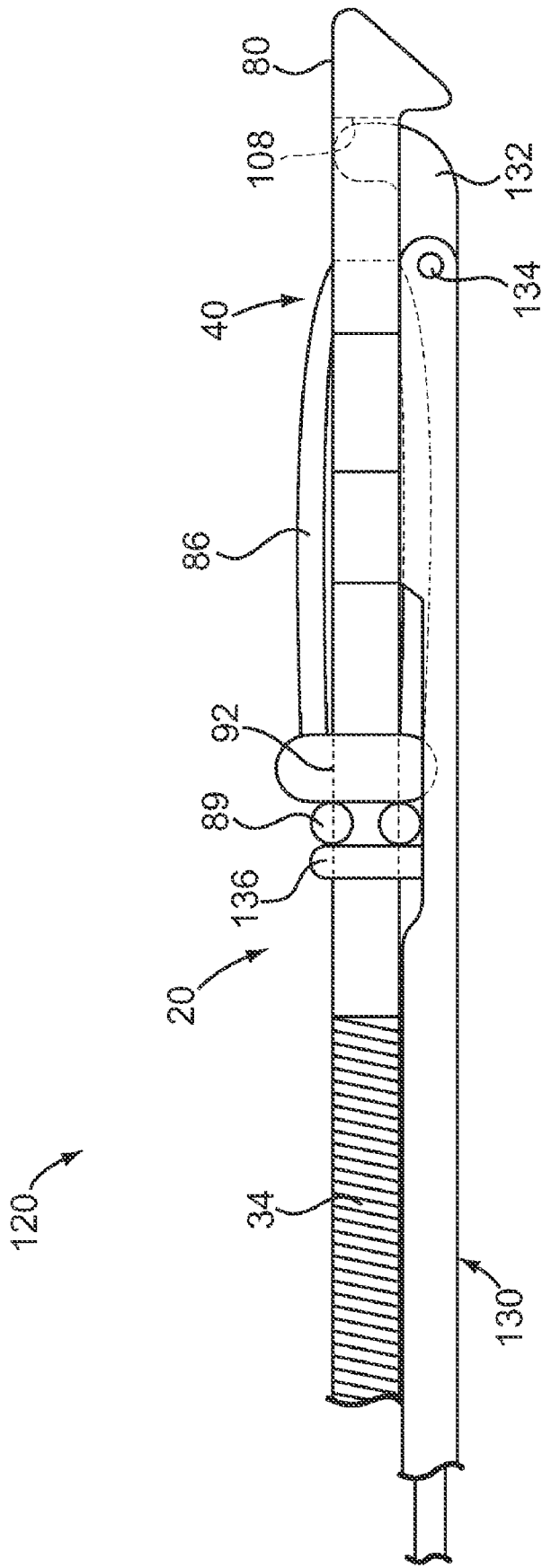


Fig. 3

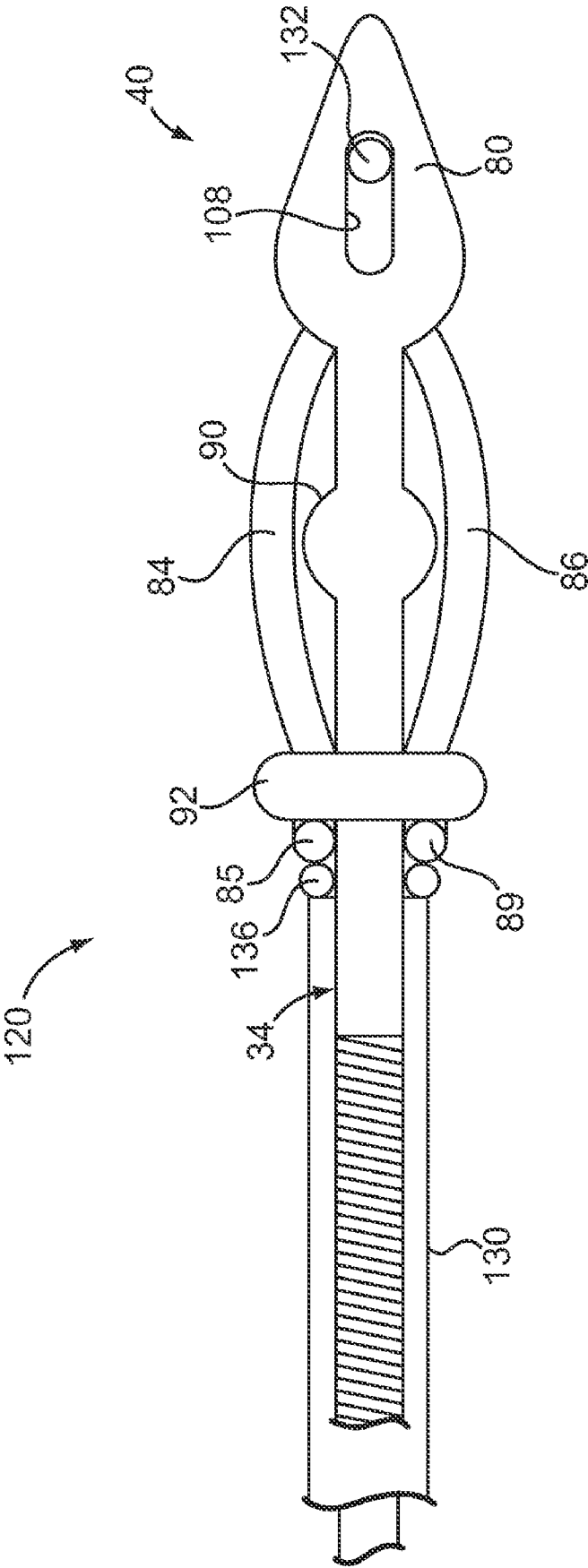


Fig. 4

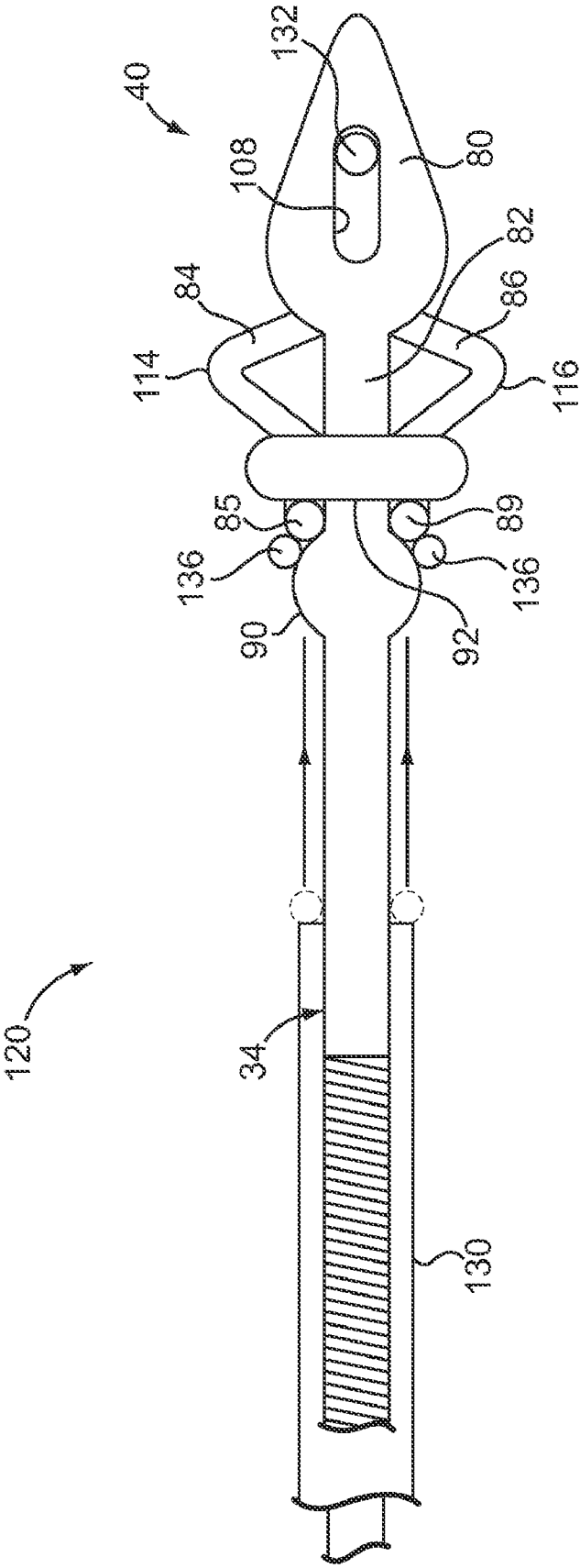


Fig. 5

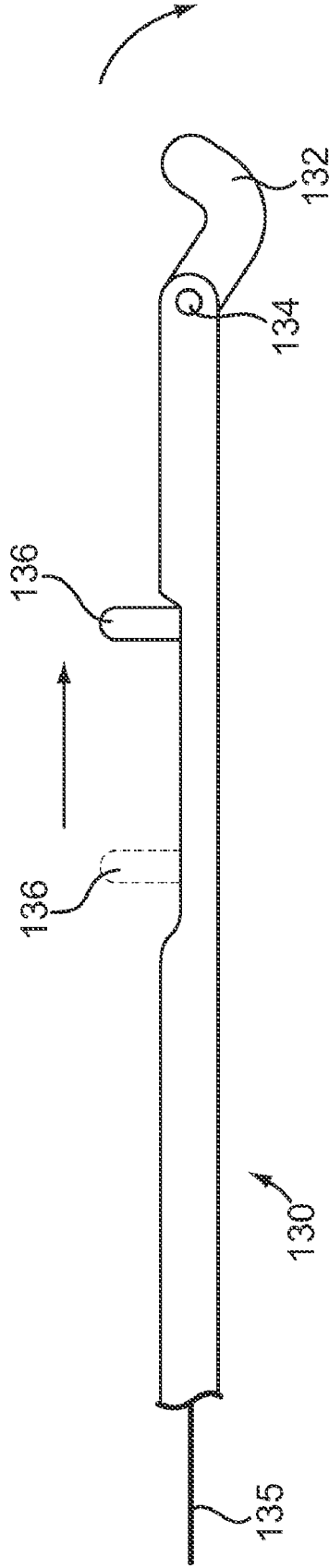


Fig. 6

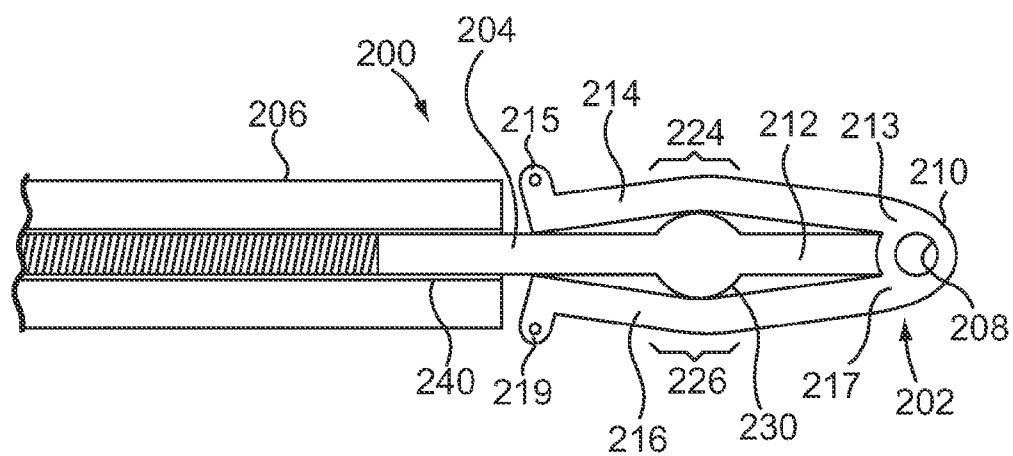


Fig. 7A

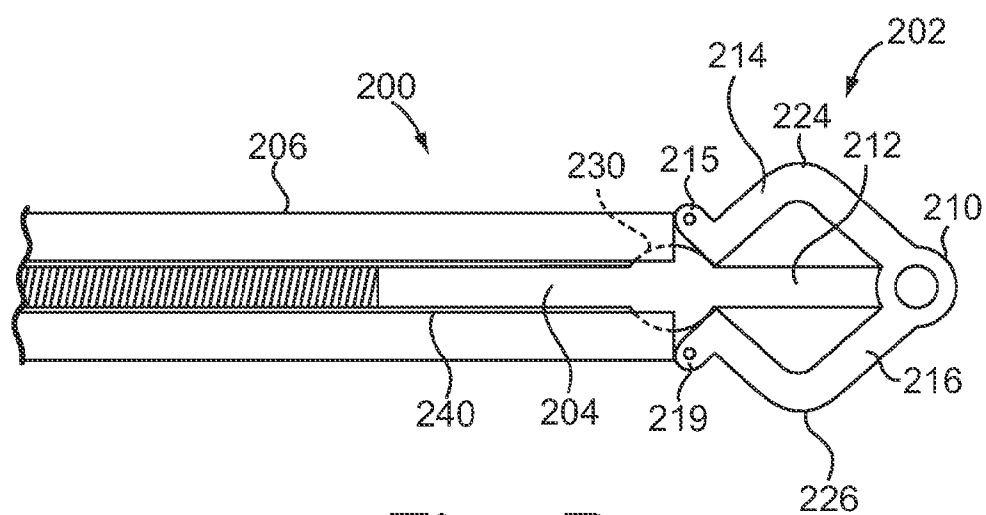


Fig. 7B

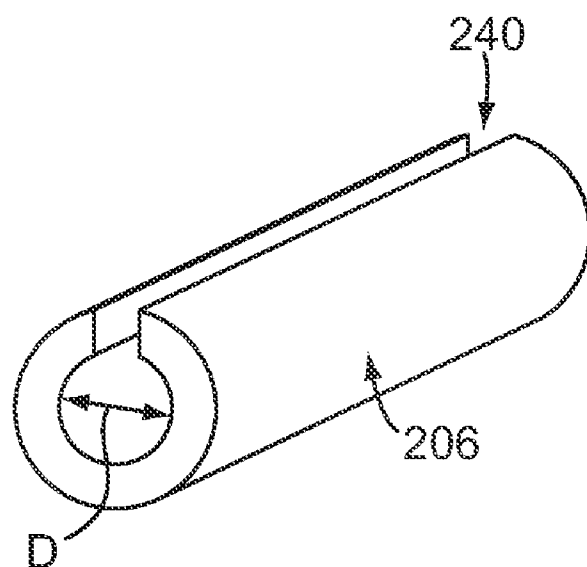


Fig. 7C

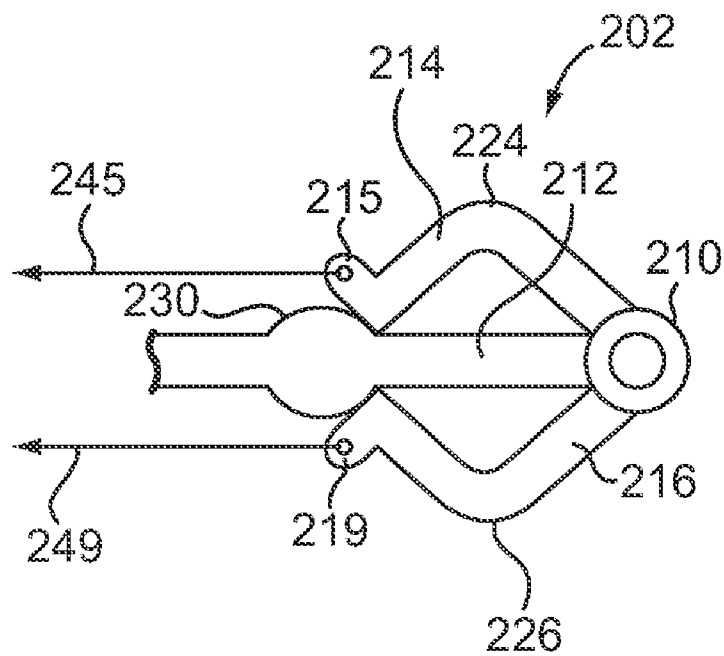


Fig. 8

SUBCUTANEOUSLY IMPLANTABLE LEAD INCLUDING DISTAL FIXATION MECHANISM

FIELD OF THE INVENTION

[0001] The present invention relates generally to subcutaneously implantable leads, and more particularly, to a lead tip having an active distal fixation mechanism employable to subcutaneously secure an implanted lead.

BACKGROUND OF THE INVENTION

[0002] Many types of implantable medical devices have been clinically implanted into patient's bodies over the last twenty years that deliver relatively high-energy cardioversion and/or defibrillation shocks to a patient's heart when a malignant tachyarrhythmia, e.g., atrial or ventricular fibrillation, is detected. Cardioversion shocks are delivered in synchrony with a detected R-wave when fibrillation detection criteria are met, whereas defibrillation shocks are delivered when fibrillation criteria are met and an R-wave cannot be discerned from the electrocardiogram. The earliest clinically released automatic implantable defibrillators (AIDs) that were implanted in human patients provided a high energy defibrillation shock developed by an AID implantable pulse generator (IPG) through a pair of epicardial electrodes applied directly to the epicardium of the heart exposed through a thoracotomy when high heart rate detection criteria were met. Later developed and clinically implanted implantable cardio-defibrillators (ICDs), originally referred to as pacemaker/cardioverter/defibrillators (PCDs), possessed more sophisticated detection algorithms and provided defibrillation, R-wave synchronized cardioversion, and pacing therapies to treat a variety of malignant tachyarrhythmias ranging from fibrillation to fast tachycardias. Current ICDs typically additionally possess single or dual chamber bradycardia pacing capabilities for treating specified chronic or episodic atrial and/or ventricular bradycardia and tachycardia. The most current clinically released ICDs also include right and left heart chamber pacing capabilities for improving the cardiac output of patient's hearts that are in heart failure. Unless otherwise indicated, all of the above-described implantable devices are referred to herein as ICDs.

[0003] It was postulated early in the development of ICDs that cardioversion/defibrillation shocks could be delivered between large surface area patch electrodes implanted subcutaneously over the rib cage on either side of the heart as indicated in the article by Schuder et al. entitled "Experimental Ventricular Defibrillation with an Automatic and Completely Implanted System", Transactions American Society for Artificial Internal Organs, 16:207, 1970.

[0004] Subcutaneous leads are implanted between the patient's skin and rib cage with a tunneling tool. Conventional subcutaneous implantable leads are implanted by first forming a subcutaneous channel with a tunneling tool that is coaxial with a sheath. After the channel is formed, the tool is removed leaving the sheath disposed in the channel. The lead is subsequently threaded down the sheath into a desired subcutaneous position. The sheath is thereafter removed by withdrawing and slitting the sheath to bring the sheath over a proximal end of the lead. Withdrawing the sheath from the channel can undesirably snag the lead and move it from its desired subcutaneous position.

[0005] It is desirable to provide implantable leads for use with ICDs that are simpler to place subcutaneously.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. 1 is a schematic perspective view of an implanted implantable cardio-defibrillator (ICD) including a lead attached to a lead tip according to one embodiment;

[0007] FIG. 2 is a top view of the lead and the lead tip of FIG. 1;

[0008] FIG. 3 is a side view of a subcutaneous implantable lead system including a tunneling tool engaged with the lead tip illustrated in FIG. 2 according to one embodiment;

[0009] FIG. 4 is a top view of the lead system illustrated in FIG. 3 showing the lead tip in an implantation configuration where arms of the lead tip are relaxed alongside a body of the lead tip;

[0010] FIG. 5 is a top view of the lead system illustrated in FIG. 3 showing the arms deployed proximally via the tunneling tool to a distal fixation configuration according to one embodiment;

[0011] FIG. 6 is a side view of the tunneling tool disengaged from the lead tip according to one embodiment;

[0012] FIG. 7A is a top view of a subcutaneous implantable lead system including a lead tip and push tubing according to one embodiment;

[0013] FIG. 7B is a top view of the lead system illustrated in FIG. 7A showing the push tubing employed to distally fix the lead tip in an expanded state according to one embodiment;

[0014] FIG. 7C is a perspective view of the push tubing illustrated in FIG. 7B; and

[0015] FIG. 8 is a top view of a lead tip for a subcutaneous implantable lead including pull wires configured to remove the lead tip according to one embodiment.

DETAILED DESCRIPTION OF THE INVENTION

[0016] According to an embodiment of the present invention, a subcutaneously implantable lead is provided that includes a coil disposed along a portion of the lead, and a lead tip coupled to a distal end of the lead. The lead tip includes at least one component that is movable relative to the distal end of the lead and configured to anchor the lead tip in subcutaneous tissue.

[0017] According to an embodiment of the present invention, a method of implanting a lead in a patient, where the lead is attachable to an implantable cardio-defibrillator (ICD), includes subcutaneously advancing a lead tip attached to a distal end of the lead through a surgical incision formed in the patient's skin with a tunneling tool that is removably attached to the lead tip; and activating a movable portion of the lead tip from a proximal end of the lead to fix the distal end of the lead in subcutaneous tissue.

[0018] In this specification, "anchor" means to fix a position of an object relative to tissue to minimize movement of the object relative to the tissue. Thus, although there may be small movements of the object relative to the tissue, arising for example from body movements of the patient that give rise to small deflections of the object within the tissue, the object is nevertheless "anchored" subcutaneously in the tissue.

[0019] It is to be understood that features of the various exemplary embodiments described herein may be combined with each other, unless specifically noted otherwise.

[0020] FIG. 1 is a schematic illustration of an implantable cardio-defibrillator (ICD) 20 subcutaneously implanted in a

patient 22 according to one embodiment. ICD 20 includes a housing 30 including a header 32, a lead 34 including a proximal end 36 coupled to header 32 and a distal end 38 coupled to a lead tip 40. In one embodiment, lead tip 40 is tunneled subcutaneously through an incision 50 to place lead 34 between the patient's 22 skin and rib cage in the region of the heart H. Thereafter, proximal end 36 of lead 34 is connected to header 32 and housing 30 is subcutaneously implanted pectorally within patient 22 between the skin and rib cage.

[0021] ICD 20 is implanted subcutaneously outside the thorax and inside the skin. Suitable implantation sites include a posterior region of the patient's rib cage, a paraspinal region of the patient, a parascapular region of the patient, or approximately posterior to a midaxillary line of the patient. In one embodiment, ICD 20 provides subcutaneous defibrillation and pacing without implanted venous epicardial leads. In one embodiment, ICD 20 provides subcutaneous defibrillation and pacing in addition to one or more implanted venous epicardial leads that connect to circuitry within housing 30.

[0022] In one embodiment, housing 30 is hermetically sealed to enclose electronic sensing, pacing, and cardioversion/defibrillation circuitry, including high voltage capacitors that are charged and discharged to deliver cardioversion/defibrillation shocks, and a low voltage battery employed for powering the circuitry and delivering pacing pulses.

[0023] In one embodiment, housing 30 includes a first electrode 60 formed on a major surface of housing 30. In one embodiment, first electrode 60 is sized between about 100 mm² and 1,000 mm², for example, and is formed of a solid conductive sheet or a conductive mesh formed of a biocompatible electrode material, e.g., titanium, nickel alloys, stainless steel alloys, platinum, platinum iridium alloy, and mixtures thereof. When positioned, tissue adhesive may be employed to secure housing 30 at the desired subcutaneous site and prevent migration. Alternatively, the site is exposed through a minimally invasive surgical procedure and housing 30 is sutured at the site to prevent device migration. The resulting cosmetic appearance can be improved by forming the housing 30 to be as thin as possible, minimizing the bulk of header 32 and curving the major housing surfaces to conform well to the curvature of the thorax at the recommended posterior and anterior or other implantation sites.

[0024] In one embodiment, header 32 is configured for permanent connection to proximal end 36 of lead 34. In one embodiment, header 32 is configured for removable connection with proximal end 36 of lead 34.

[0025] FIG. 2 is a top view of lead tip 40 attached to lead 34 and oriented along a central longitudinal axis A. In one embodiment, lead tip 40 includes a head 80, a body 82 extending between head 80 and lead 34, a first movable arm 84 including a first end 83 attached to head 80 and a second end 85 movable relative to head 80, and a second movable arm 86 including a first end 87 attached to head 80 and a second end 89 movable relative to head 80. In one embodiment, at least two laterally movable arms are provided. In one embodiment, multiple movable arms are provided that move radially away from body 82 laterally and in the plane of the printed image as illustrated.

[0026] In one embodiment, body 82 includes a waist 90 defined by a bulge extending radially from body 82. Second ends 85, 89 of movable arms 84, 86, respectively, are configured to slide along body 82 and engage with waist 90 in a manner that laterally extends arms 84, 86 for fixation into

tissue of the patient. In one embodiment, an elastic ring 92 is provided to compress second ends 85, 87 into engagement with waist 90 to selectively retain movable arms 84, 86 in the deployed position.

[0027] In one embodiment, head 80 includes a leading end 100 opposite a trailing end 102, and first and second non-parallel sides 104, 106 that taper down and converge with leading end 100. Trailing end 102 couples with body 82 and lead 34. First and second non-parallel sides 104, 106 that taper to an apex formed by leading end 100 such that head 80 is arrow-shaped or triangular in longitudinal cross-section. At least the apex of head 80 is configured to part subcutaneous tissue without cutting through the skin or the thorax. In one embodiment, head 80 is formed to define an opening 108 between leading end 100 and trailing end 102, where opening 108 is configured for engagement with a tunneling tool that is employed to subcutaneously place lead 34.

[0028] In one embodiment, each arm 84, 86 includes a central portion 114, 116, respectively, that is configured to diverge laterally away from axis A when second ends 85, 89, respectively, are moved axially toward head 80. In this regard, central portions 114, 116 lie adjacent to body 82 when in a tunneling state and are configured to expand laterally away from central axis A into a deployed state in which central portions 114, 116 are offset away from body 82. In one embodiment, lead tip 40 has a cross-sectional lateral dimension of about 3.5 mm when in the tunneling state, and is deployed to have a cross-sectional lateral dimension of between about 10-25 mm when in the deployed, fixed state.

[0029] Suitable materials for fabrication of lead tip 40 include plastic or metal. In one embodiment, at least movable arms 84, 86 are formed of a flexible plastic such as silicone, silicone rubber, or polyurethane. In one embodiment, the entire lead tip 40 including head 80, body 82 and movable arms 84, 86 are integrally formed of a plastic. In another embodiment, movable arms 84, 86 are formed of a plastic and at least a portion of lead tip 40 (e.g., head 80 or body 82) is formed to include an electrically conductive material. In one embodiment, elastic ring 92 is formed of a silicone rubber that is configured to stretch to enable second ends 85, 89 to clear waist 90 as second ends 85, 89 axially traverse body 82.

[0030] FIG. 3 is a side view and FIG. 4 is a top view of a subcutaneous implantable lead system 120 according to one embodiment. System 120 includes a tunneling tool 130 having a finger 132 that is configured to engage with opening 108 formed in head 80 of lead tip 40. In one embodiment, tunneling tool 130 includes a hinge 134 and a movable flange 136 that are configured to be activated by wires extending between hinge 134/flange 136 and a handle on a proximate end of tunneling tool 130.

[0031] Activating hinge 134 (from the proximal end of tunneling tool 130) moves finger 132 into engagement with opening 108 and out of engagement with opening 108. Finger 132 is engaged with opening 108 to couple tunneling tool 130 to lead tip 40 prior to subcutaneously advancing lead tip 40. After advancing lead 34, flange 136 is activated from the proximal end of tunneling tool 130 to push second ends 85, 89, toward head 80 and fix arms 84, 86 into tissue. Thereafter, finger 132 is removed from opening 108 to disengage tunneling tool 130 from lead tip 40 after subcutaneously advancing and distally fixing lead tip 40 in place. In one embodiment, movable arms 84, 86 are co-planar and aligned alongside body 82, where the co-planar plane may be either a vertical or lateral plane. In one embodiment, movable arms

84, 86 are aligned alongside body **82** with movable arm **84** offset above, and not co-planar, with movable arm **86**.

[0032] FIG. 5 is a top view of flange **136** advanced distally to slide second ends **85, 89** over waist **90** and laterally displace central portions **114, 116** of arms **84, 86** into their deployed positions. When deployed, central portions **114, 116** of movable arms **84, 86** extend from body **82** to fix and anchor lead tip **40** into tissue (i.e., fat tissue). Flexible ring **92** constricts ends **85, 89** into position on a distal side of waist **90**. In this manner, lead tip **40** is tunneled into position with tunneling tool **130** and distally activated by manipulating a proximal end of tunneling tool **130** to expand arms **114, 116** and anchor lead tip **40** subcutaneously.

[0033] FIG. 6 is a side view of tunneling tool **130** having finger **132** rotated out of engagement with opening **108** (FIG. 5). A wire **135** is located coaxially within tunneling tool **130** and communicates with hinge **134**. Activating wire **135** proximally (for example by pulling) rotates finger **132** downward to unlock tunneling tool from lead tip **40** (FIG. 5). In one embodiment, a wire similar to wire **135** is employed to displace flange **136** distally to deploy lead tip **40** (FIG. 5) into its expanded state. Other deployment mechanisms apart from wires, such as pneumatic activation, direct connection via rods, etc are also acceptable for proximally activating the distal deployment mechanisms.

[0034] FIG. 7A is a top view of another subcutaneous implantable system **200** according to one embodiment. System **200** includes a lead tip **202** coupled to a lead **204** and a tubular member **206** configured to activate and anchor lead tip **202** in subcutaneous tissue.

[0035] In one embodiment, lead tip **202** includes a head **210**, a body **212** extending between head **210** and lead **204**, a first arm **214** including a first end **213** attached to head **210** and a second end **215** that is movable relative to head **210**, and a second arm **216** including a first end **217** attached to head **210** and a second end **219** that is movable relative to head **210**. Similar to lead tip **40** described in FIG. 2 above, arms **214, 216** are configured to move axially along body **212** to move central portions **224, 226** laterally away from body **212**. In one embodiment, body **212** includes a waist **230** extending radially away from body **212** to form a bulge that is configured to engage with second ends **215, 219**. Although not shown for ease of illustration, in one embodiment an elastic ring is provided to compress second ends **215, 219** into engagement with waist **230** to selectively retain movable arms **214, 216** in the deployed position.

[0036] In one embodiment, head **210** is formed to define an opening **208** configured to receive finger **132** of tunneling tool **130** (FIG. 6). In one embodiment, head **210** is formed to be substantially circular in lateral cross-section to provide a blunt distal leading end that is configured to part subcutaneous tissue without cutting through the skin or the thorax. Other suitable shapes for head **210** are also acceptable, including arrow-shapes and wedge-shapes.

[0037] FIG. 7B is a top view of tubular member **206** moving second ends **215, 219** distally toward head **210**. In one embodiment, lead tip **202** and lead **204** are delivered subcutaneously by a tunneling tool, such as tunneling tool **130** (FIG. 6). Lead **204** and tunneling tool **130** are disposed coaxially within tubular member **206** as lead **204** is delivered subcutaneously.

[0038] Tubular member **206** is manipulated from a proximal end exterior to the patient **22** (FIG. 1) to distally activate movable arms **214, 216** into engagement with subcutaneous

tissue. In one embodiment, tubular member **206** pushes second ends **215, 219** over waist **230**, second ends **215, 219** engage with a distal side of waist **230**, and central portions **224, 226** of arms **214, 216** move laterally away from body **212**. In this manner, arms **214, 216** are expanded to a deployed state characterized by an increased cross-sectional area of lead tip **202**.

[0039] FIG. 7C is a perspective view of tubular member **206** according to one embodiment. In one embodiment, tubular member **206** is formed to include a full-length axial channel **240** that is sized to enable tubular member **206** to disengage from tool **130** (FIG. 6) and lead **204** after placement of lead tip **202**. In one embodiment, tubular member **206** includes an internal diameter **D** of approximately 1-3 mm that is sized to coaxially receive lead **204** and tunneling tool **130**. In one deployment methodology, tunneling tool **130** is employed to subcutaneously implant lead tip **202**, after which tunneling tool **130** is retrieved through tubular member **206**. Thereafter, tubular member **206** is disengaged from lead **204** by sliding lead **204** through axial channel **240**.

[0040] FIG. 8 is a top view of lead tip **202** including optional pull wires **245, 249** according to one embodiment. Lead tip **202** is illustrated in its deployed state having central portions **224, 226** laterally offset from body **212**. Occasionally, it is desirable to remove lead **204** and lead tip **202** when managing the implantation site. Pull wires **245, 249** are provided and attached to lead tip **202** to enable collapsing movable arms **214, 216** along side body **212** prior to retrieving lead tip **202** from patient **22** (FIG. 1).

[0041] Pull wire **245** is coupled to second end **215** of movable arm **214**, and pull wire **249** is coupled to second end **219** of movable arm **216**. In one embodiment, pull wires **245, 249** are formed of an electrically non-conducting material and are implanted alongside lead **204** when lead tip **202** is subcutaneously implanted. To remove lead tip **202**, pull wires **245, 249** are pulled proximally and second ends **215, 219**, respectively, are displaced in a proximal direction over waist **230** such that arms **214, 216** collapses alongside body **212**. In this manner, lead tip **202** is collapsed to have a cross-sectional dimension of about 3.5 mm to enable retrieval of lead tip **202** from the subcutaneous implantation site.

What is claimed is:

1. A subcutaneous implantable lead comprising:
 - a coil disposed along a portion of the lead; and
 - a lead tip coupled to a distal end of the lead and comprising at least one component that is movable relative to the distal end of the lead and configured to anchor the lead tip in subcutaneous tissue.
2. The subcutaneous implantable lead of claim 1, wherein the lead tip comprises:
 - a head defining a leading end opposite a trailing end that is coupled to the distal end of the lead; and
 - at least one arm coupled to the head and comprising a first end attached to the head and a second end that is movable relative to the head.
3. The subcutaneous implantable lead of claim 2, wherein when the second end of the arm is moved axially toward the head a central portion of the arm moves laterally relative to the head to secure the implantable lead within subcutaneous tissue.
4. The subcutaneous implantable lead of claim 2, wherein the lead tip comprises a body coupled to the head, the body disposed along a central longitudinal axis of the head, the second end movable along the body relative to the head.

5. The subcutaneous implantable lead of claim 4, wherein the body comprises a waist defined by a bulge extending radially from the body, the second end of the arm configured to engage the waist and move an elbow portion of the arm laterally away from the body to anchor the lead tip in subcutaneous tissue.

6. The subcutaneous implantable lead of claim 5, comprising two arms coupled to the head, each arm comprising a first end attached to the head and a second end that is movable relative to the head and configured to engage the waist and move an elbow portion of the arm laterally away from the body.

7. The subcutaneous implantable lead of claim 5, further comprising:

an elastic ring coupled to the second ends of the lead tip, the ring configured to compress the second ends into engagement with the waist.

8. The subcutaneous implantable lead of claim 6, further comprising:

a wire coupled to each of the second ends of the arms, the wire configured to pull each second end of the arm toward a proximal end of the lead, disengage the second end of the arm from the waist, and move the elbow portion of the arm laterally toward the body for removal of the lead tip from the subcutaneous tissue.

9. The subcutaneous implantable lead of claim 2, wherein the head comprises an opening formed in the head located between the leading end and the trailing end, the opening configured for engagement with a tunneling tool.

10. The subcutaneous implantable lead of claim 2, wherein the head comprises first and second sides that extend from the trailing end and converge to an apex at the leading end to define a substantially triangular shape.

11. The subcutaneous implantable lead of claim 1, wherein the lead tip is formed from a polymer.

12. The subcutaneous implantable lead of claim 2, wherein the head and the at least one arm are integrally formed as a single piece.

13. The subcutaneous implantable lead of claim 1, wherein at least a portion of the lead tip is electrically conductive.

14. The subcutaneous implantable lead of claim 1, wherein the coil comprises a first electrode and a proximal end of the lead is coupled to an implantable cardioverter/defibrillator that comprises a second electrode.

15. A subcutaneous implantable lead system comprising:

a lead comprising a defibrillation electrode;
a lead tip coupled to a distal end of the lead and comprising at least one arm that is movable relative to a central axis of the lead tip;

a tunneling tool configured to removably couple with the lead tip and advance the lead tip subcutaneously; and

a tubular member movable axially along the tunneling tool to displace a portion of the arm laterally away from the central axis of the lead tip and anchor the lead tip in subcutaneous tissue.

16. The system of claim 15, wherein the lead tip comprises a head defining a leading end opposite a trailing end that is coupled to the distal end of the lead, a recess formed in the head, and a distal end of the tunneling tool comprises a prong configured to engage with the recess formed in the head.

17. The system of claim 15, wherein the tubular member comprises a channel opening formed in a wall of the tubular member between a proximal end and a distal end of the tubular member, the channel opening configured to enable removal of the tubular member from the subcutaneously implanted lead.

18. A method of implanting a lead in a patient, the lead attachable to an implantable cardioverter/defibrillator (ICD), the method comprising:

subcutaneously advancing a lead tip attached to a distal end of the lead through a surgical incision formed in the patient's skin with a tunneling tool that is removably attached to the lead tip; and

activating a movable portion of the lead tip from a proximal end of the lead to fix the distal end of the lead in subcutaneous tissue.

19. The method of claim 18, wherein subcutaneously advancing a lead tip attached to a distal end of the lead comprises subcutaneously advancing a lead tip comprising a head defining a leading end aligned axially with a trailing end that is coupled to the distal end of the lead, and a movable arm coupled to the head that is movable radially away from the head.

20. The method of claim 19, wherein activating a movable portion of the lead tip comprises moving a proximal end of the movable arm axially toward the leading end of the head and displacing a central portion of the movable arm radially away from the head.

21. The method of claim 20, wherein activating a movable portion of the lead tip comprises coaxially moving a push tubing along the lead and engaging a proximal end of the push tubing with the proximal end of the movable arm.

22. The method of claim 21, wherein the lead tip comprises a body extending from the head, and moving a proximal end of the movable arm axially toward the leading end of the head comprises fixably engaging the proximal end of the movable arm over a waist formed in the body of the lead tip.

23. The method of claim 22, further comprising:

removing the lead and the lead tip from the patient by collapsing the movable arm alongside the body and retrieving the lead tip.

24. The method of claim 23, wherein collapsing the movable arm alongside the body comprises pulling a wire coupled to the proximal end of the movable arm and moving the proximal end of the movable arm axially toward the proximal end of the lead.

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