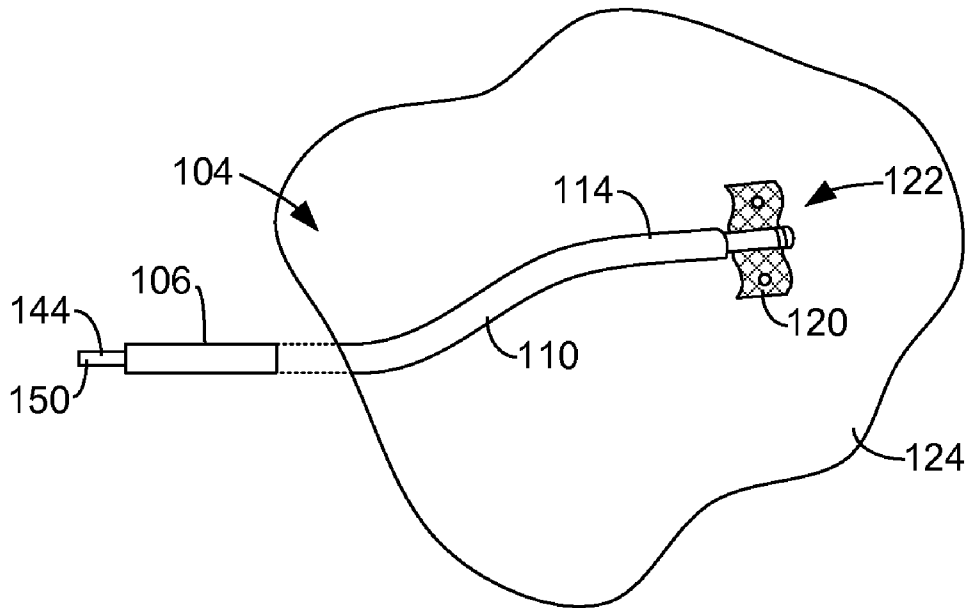




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Finlay et al.(10) **Pub. No.: US 2016/0089531 A1**(43) **Pub. Date: Mar. 31, 2016**(54) **ELECTRODE LEAD INCLUDING A
DEPLOYABLE TISSUE ANCHOR****Publication Classification**(71) Applicant: **Astora Women's Health, LLC**, Eden
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A61N 1/05 (2006.01)(72) Inventors: **Matthew S. Finlay**, Eindhoven (NL);
William J. Rissmann, Deephaven, MN
(US)(52) **U.S. Cl.**
CPC **A61N 1/05** (2013.01)(21) Appl. No.: **14/947,502**(57) **ABSTRACT**(22) Filed: **Nov. 20, 2015**

In a method, an electrode lead is provided that includes a tubular lead body, an electrode supported by the lead body, a rotatable member, a deployable member and a deployment mechanism. The rotatable member is contained within a distal end of the tubular lead body. The deployable member is attached to the rotatable member and comprises a tissue anchor that includes mesh. Also in the method, the distal end of the tubular lead body is positioned proximate target tissue of a patient. The rotatable member is rotated relative to the tubular lead body. The deployable member is driven along the central axis, out the distal end of the tubular lead body, and into the target tissue using the deployment mechanism responsive to the rotation of the rotatable member. The deployment member does not rotate about the central axis with the rotation of the rotatable member.

Related U.S. Application Data(62) Division of application No. 13/490,600, filed on Jun. 7,
2012, now Pat. No. 9,220,887.(60) Provisional application No. 61/494,950, filed on Jun.
9, 2011.

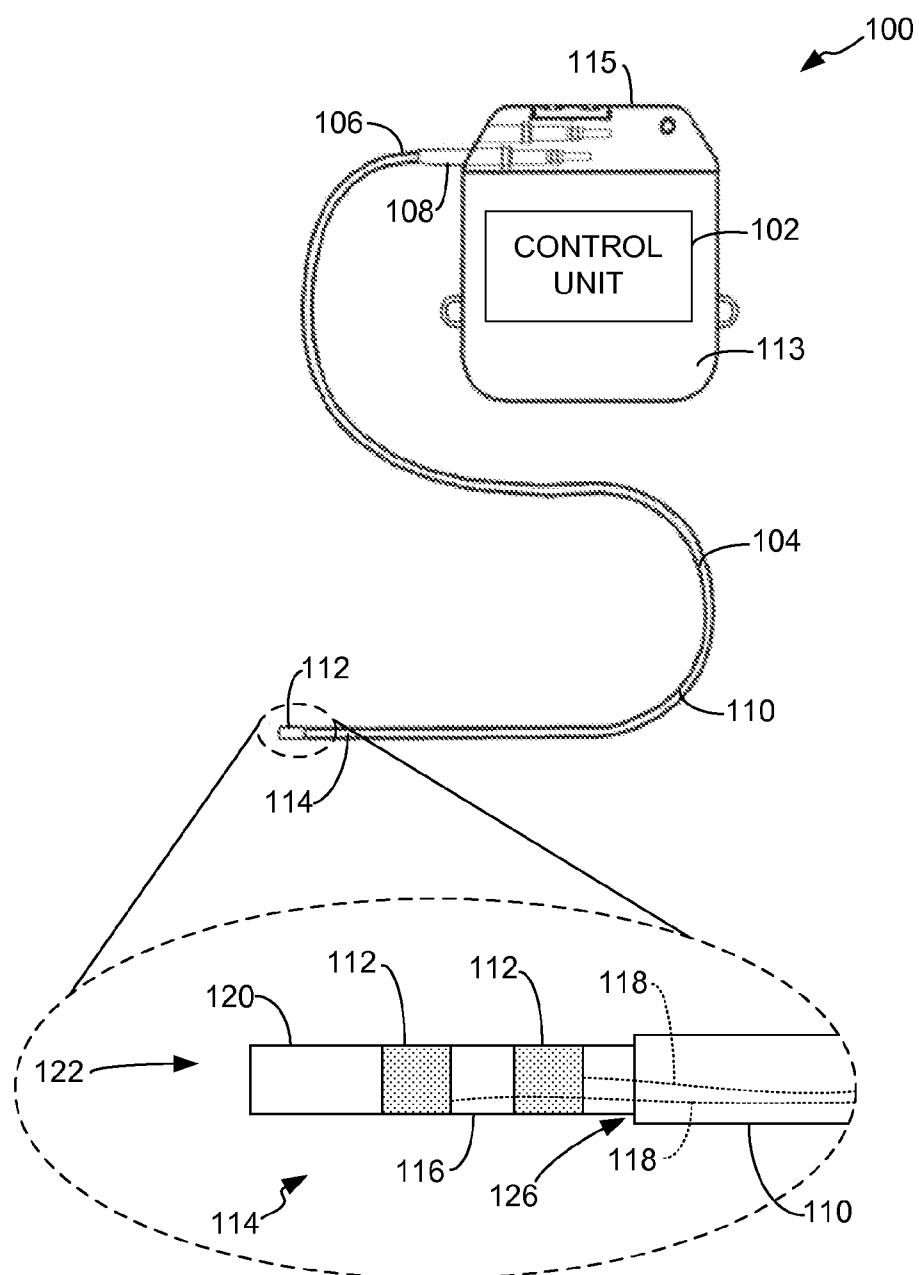


FIG. 1

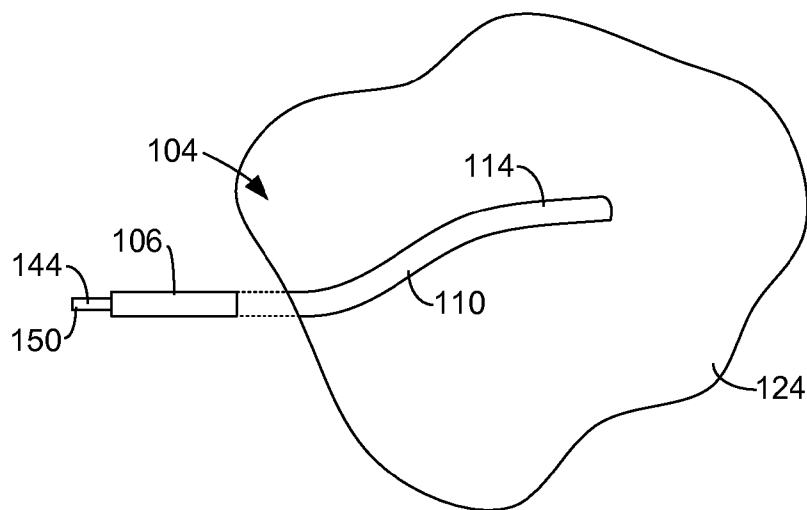


FIG. 2

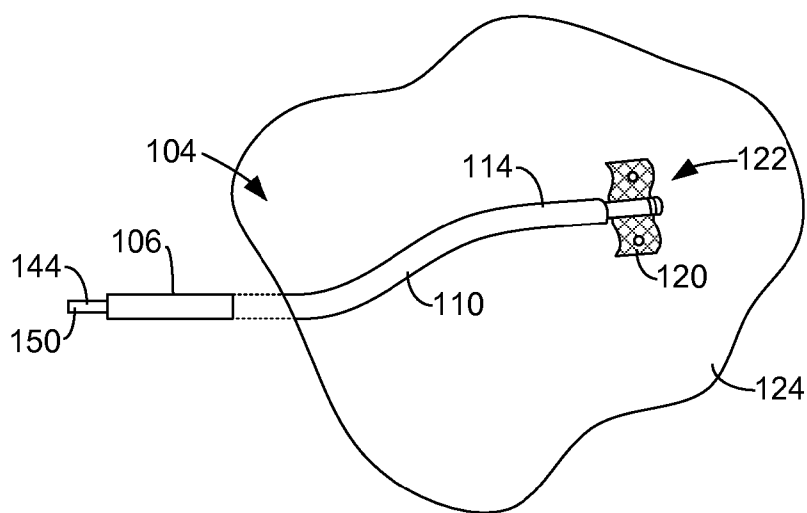


FIG. 3

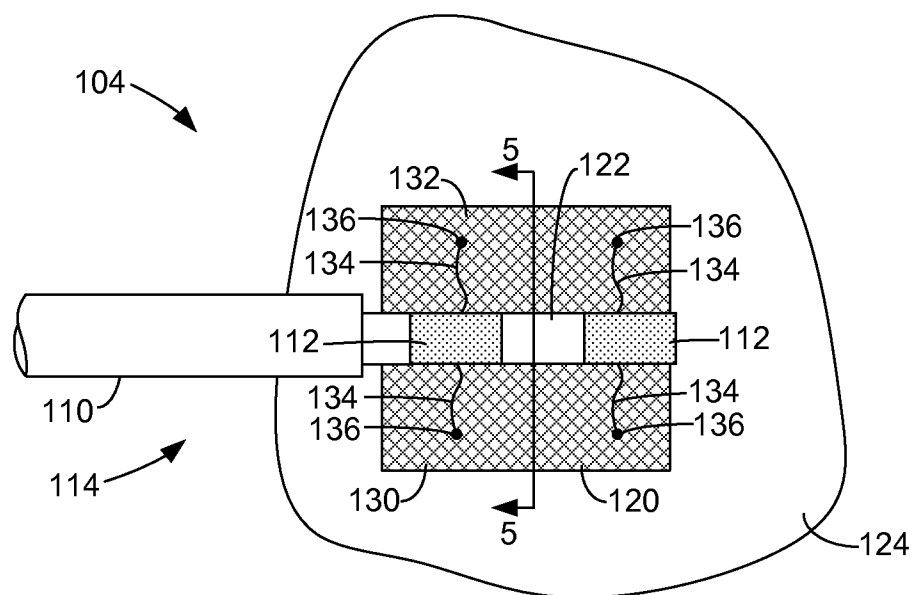


FIG. 4

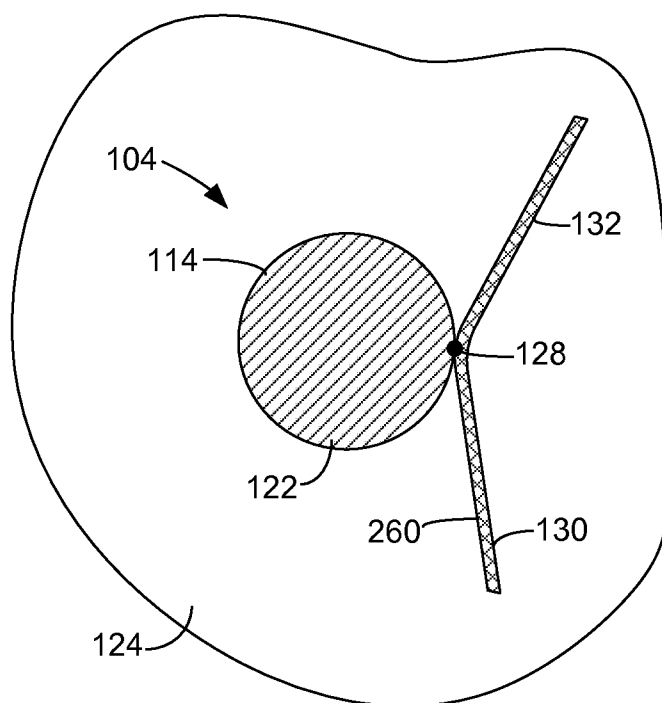


FIG. 5

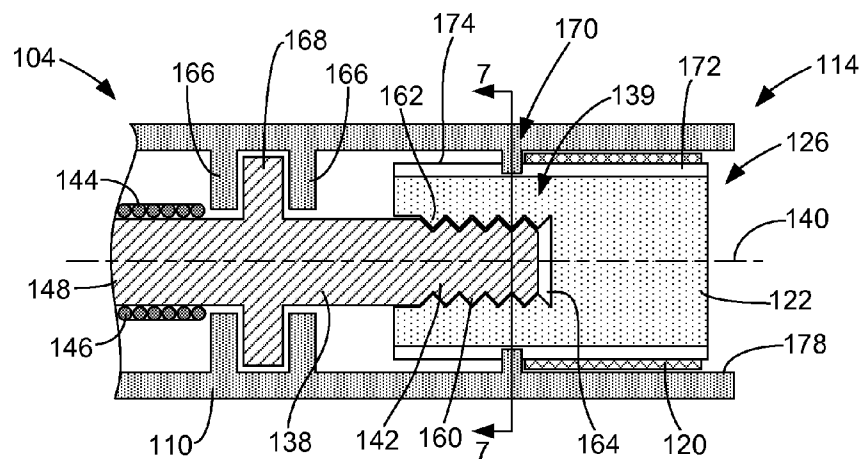


FIG. 6

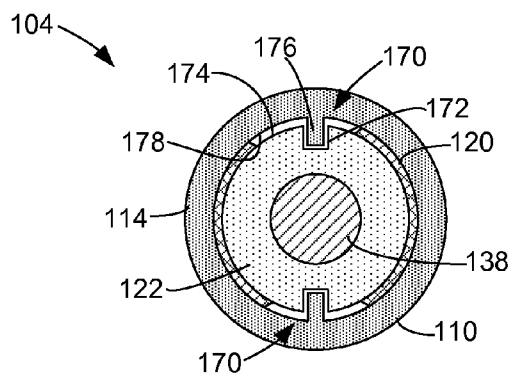


FIG. 7

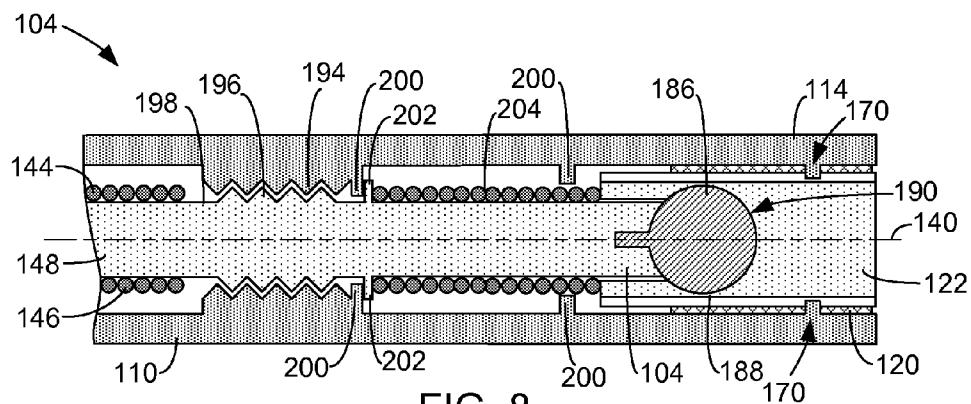


FIG. 8

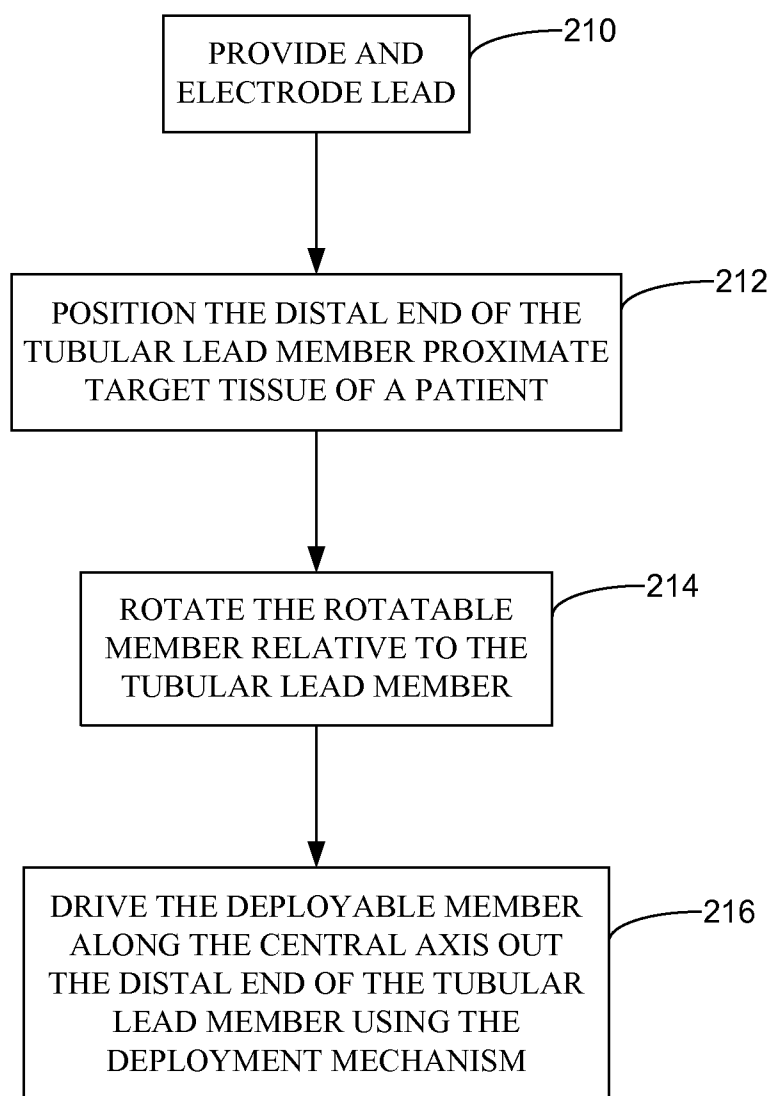


FIG. 9

ELECTRODE LEAD INCLUDING A DEPLOYABLE TISSUE ANCHOR

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. provisional patent application Ser. No. 61/494,950 filed Jun. 9, 2011, the content of which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] Embodiments of the present invention generally relate to an anchor that facilitates securing devices or components to internal tissue of a patient and preventing migration of the devices or components from their intended location relative to the tissue of the patient.

BACKGROUND OF THE INVENTION

[0003] Implantable electronic stimulator devices, such as neuromuscular stimulation devices, have been disclosed for use in the treatment of various pelvic conditions, such as urinary incontinence, fecal incontinence and sexual dysfunction. Such devices generally include one or more electrodes that are coupled to a control unit by electrode leads. Electrical signals are applied to the desired pelvic tissue of the patient through the electrode leads in order to treat the condition of the patient. Exemplary implantable electronic stimulator devices and uses of the devices are disclosed in U.S. Pat. Nos. 6,354,991, 6,652,449, 6,712,772 and 6,862,480, each of which is hereby incorporated by reference in its entirety.

[0004] Electrical leads utilize anchors to secure the one or more electrodes in tissue of the patient. Exemplary anchors include helical coils and mesh, such as that disclosed in (A92.12-0136), which is incorporated herein by reference in its entirety. It is desirable, for example, that such anchors prevent relative movement between the anchor and the tissue in which the anchor is embedded, are easy to install in the tissue, avoid damaging the tissue during the implantation procedure, can be removed without significantly damaging the tissue, and/or have other features or benefits recognized by those skilled in the art.

SUMMARY

[0005] Embodiments of the invention are directed to an implantable electrode lead. In some embodiments, the electrode lead comprises a tubular lead body, an electrode supported by the lead body, a rotatable member, a deployable member and a deployment mechanism. The rotatable member is contained within a distal end of the tubular lead body. The deployable member is attached to the rotatable member and comprises a tissue anchor. The deployment mechanism is configured to drive the deployable member along a central axis and out the distal end of the tubular lead body responsive to rotation of the rotatable member about the central axis. In one embodiment, the deployable member does not rotate about the central axis with the rotation of the rotatable member.

[0006] Another embodiment is directed to a method, in which an electrode lead is provided. The electrode lead comprises a tubular lead body, an electrode supported by the lead body, a rotatable member, a deployable member and a deployment mechanism. The rotatable member is contained within a distal end of the tubular lead body. The deployable member is

attached to the rotatable member and comprises a tissue anchor. Also in the method, the distal end of the tubular lead body is positioned proximate target tissue of a patient. The rotatable member is rotated relative to the tubular lead body. The deployable member is driven along the central axis, out the distal end of the tubular lead body, and into the target tissue using the deployment mechanism responsive to the rotation of the rotatable member. In one embodiment, the deployable member does not rotate about the central axis with the rotation of the rotatable member.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 is a side plan view of an exemplary electronic stimulator device, in accordance with embodiments of the invention.

[0008] FIGS. 2 and 3 are simplified views of an electrode lead formed in accordance with embodiments of the invention positioned within tissue of a patient.

[0009] FIG. 4 is a simplified side view of a distal end of an electrode lead having a mesh anchor in a deployed position, in accordance with embodiments of the invention.

[0010] FIG. 5 is a cross-sectional view of the portion of the lead of FIG. 4 taken generally along line 5-5.

[0011] FIG. 6 is a simplified side cross-sectional view of a distal end of an electrode lead, in accordance with embodiments of the invention.

[0012] FIG. 7 is a cross-sectional view of the electrode lead of FIG. 6 taken generally along line 7-7.

[0013] FIG. 8 is a simplified side cross-sectional view of a distal end of an electrode lead, in accordance with embodiments of the invention.

[0014] FIG. 9 is a flowchart illustrating a method of using the electrode lead formed in accordance with one or more embodiments of the invention.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0015] Embodiments of the invention are described more fully hereinafter with reference to the accompanying drawings. The various embodiments of the invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Elements that are identified using the same or similar reference characters refer to the same or similar elements.

[0016] FIG. 1 is a side plan view of an exemplary electronic stimulator device **100**, in accordance with embodiments of the invention. The stimulator device **100** is configured for implantation into a pelvic region of a patient to provide muscle and/or nerve stimulation that is used to control and/or treat a pelvic condition of the patient, such as pelvic pain, urinary incontinence, fecal incontinence, erectile dysfunction or other pelvic condition that may be treated through electrical stimulation.

[0017] In one embodiment, the device **100** comprises a control unit **102** and one or more electrode leads **104**, a proximal end **106** of which is electrically coupled to the control unit **102** via a connector **108**. In one embodiment, the electrode lead **104** comprises a tubular lead body **110** and one or more stimulation elements or electrodes **112** supported at a distal end **114** by the lead body **110**. In one embodiment, the

electrodes **112** are separated from each other by an insulative portion or element **116**. The lead body **110** insulates electrical wires **118** or other conductor that connects the control unit **102** to the electrodes **112**. The lead body **110** can be in the form of an insulating jacket typically comprising silicone, polyurethane or other flexible, biocompatible electrically insulating material. Additional electrode leads **104** or physiological sensors may be coupled to the control unit **102**.

[0018] In one embodiment, the control unit **102** comprises circuitry including at least one processor for processing electrical signals received from the one or more electrodes **112** or physiological sensors (not shown). In one embodiment, the control unit **102** is also configured to apply an electrical current or waveform to the tissue of the patient through the one or more electrodes **112** that are in contact with the tissue. In one embodiment, the control unit **102** receives power from an internal battery (not shown).

[0019] In one embodiment, the control unit **102** is enclosed within a hermetically sealed metal housing **113** commonly referred to as a “can.” The can **113** generally comprises first and second halves that are joined together in a laser-welding operation about their perimeters after the battery power supply and electronic circuitry are inserted in the space defined by the two halves of the can.

[0020] A header **115** includes a connector block that may be molded in the header or inserted after the header has been molded. Feed-through conductors from the electronic circuitry within the can are coupled to electrical contacts of the connector block. The connector block includes one or more ports, each of which receives the connector **108** of each lead **104** and electrically couples the connector **108** to the electronic circuitry or control unit **102** contained within the can **113** via the feed-through conductors.

[0021] The distal end **114** of the electrode lead **104** can be anchored to pelvic tissue of the patient (e.g., urinary sphincter muscle, anal sphincter muscle, etc.) by means of a tissue anchor **120**, in accordance with embodiments of the invention. Embodiments of the anchor include a helical coil, mesh and other suitable components. The anchor **120** operates to secure the position of the electrodes **112** in the desired tissue of the patient.

[0022] In one embodiment, the anchor **120** is attached to a deployable member **122** that may be deployed from within the tubular lead body, as illustrated in FIG. 1. In one embodiment, the deployable member **122** includes the one or more electrodes **112**, as shown in FIG. 1.

[0023] In one embodiment, the deployable member **122** has a retracted position, in which the deployable member **122** is received within the tubular lead body **110**, as shown in the simplified side view of FIG. 2. While in this retracted position, the distal end **114** of the electrode lead **104** may be implanted in tissue **124** of a patient, as shown in the simplified side view of FIG. 3. The implantation of the distal end **114** of the electrode lead **104** may be accomplished using conventional techniques, such as with an introducer needle. Once the distal end **114** of the electrode lead **104** is positioned as desired within the tissue **124**, the physician may use a deployment mechanism to move the deployable member **122** out an opening **126** of the tubular lead member **110**, as illustrated in FIGS. 1 and 3.

[0024] In one embodiment, the tissue anchor **120** is attached to the deployable member **122** and comprises mesh, as illustrated in FIG. 3. FIG. 4 is a simplified side view of the distal end **114** of the electrode lead **104** with the deployable

member **122** having the mesh anchor **120** in the deployed position within tissue **124** of a patient. FIG. 5 is a cross-sectional view of the deployable member **122** taken generally along line 5-5 of FIG. 4 and illustrates the implantation of the distal end **114** of the electrode lead **104**. In one embodiment, the mesh anchor **120** is preferably a bio-compatible open matrix mesh, such as a mesh constructed of polypropylene monofilament. A portion of the mesh anchor **120** is attached to the deployable member **122** at a location **128**. Exemplary means for attaching the mesh anchor **120** to the deployable member **122** include sutures, glue, anchors, or other suitable bio-compatible methods. In one embodiment, the mesh anchor **120** comprises one or more mesh sections or wings, such as wings **130** and **132**.

[0025] In one embodiment, the mesh anchor **120** has a compact state and an expanded state. The mesh anchor **120** is placed in the compact state when retracted within the tubular lead **110** (FIG. 2). When the deployable member **122** is moved through the opening **126**, the mesh anchor **120** expands, as shown in FIGS. 3-5, to promote tissue ingrowth through the mesh and anchor the deployable member **122** and the distal end **114** of the electrode lead **104** in place within the tissue **124**. In general, at least a portion of the mesh anchor **120** is displaced a greater distance from the deployable member **122** when in the expanded state than when in the compact state.

[0026] In one embodiment, the mesh anchor **120** has a shape memory that drives the mesh to a preset expanded, quiescent shape, in which at least a portion of the mesh anchor **120** extends away from the deployable member **122** and into the surrounding tissue **124**. As used herein, the “quiescent shape” of the mesh anchor **120** is one in which the mesh will naturally return to after being deformed, such as when compressed into a compact state. In one embodiment, the expanded state of the mesh wings **130** and **132** is one in which the wings **130** and **132** are displaced from each other, such as illustrated FIG. 5. In one embodiment, a nitinol structure is secured to the mesh and promotes the expansion of the mesh. Thus, one embodiment of the mesh anchor **120** has a shape memory that encourages separation of the one or more wings, such as wings **130** and **132**, within the tissue **124**.

[0027] In one embodiment, the mesh anchor **120** comprises the one or more electrodes **112** that are used to deliver electrical signals to the tissue **124**. In one embodiment, one or more conductive fibers **134** are attached to the mesh anchor **120** and conduct electrical signals from the deployable member **122**, such as electrodes **112** on the deployable member **122**, to the tissue **124**, as shown in FIG. 4. In one embodiment, the conductive fibers **134** are electrically insulated from the tissue **124** and conduct the electrical signals to one or more electrically conductive nodes or electrodes **136** that are attached to the mesh anchor **120** and deliver the electrical signals to the tissue **124**.

[0028] FIG. 6 is a simplified side cross-sectional view of a distal end **114** of an electrode lead **104** in accordance with embodiments of the invention. FIG. 7 is a cross-sectional view of the electrode lead **104** of FIG. 6 taken generally along line 7-7. In one embodiment, the lead **104** comprises the tubular lead body **110**, a rotatable member **138** within the distal end **114** of the tubular lead body **110**, the deployable member **122**, and a deployment mechanism **139**. In one embodiment, electrode lead **104** includes one or more electrodes **112** that are supported by the lead body **110**, such as through the attachment of the electrodes **112** to the lead body

110, or to the deployable member 122, for example. The electrodes 112 are not illustrated in FIG. 6 or 7 in order to simplify the drawings.

[0029] In one embodiment, the rotatable member 138 is configured to rotate about a central axis 140, which is generally aligned with the longitudinal axis of the tubular lead body 110. In one embodiment, a distal end 142 of the rotatable member 138 is attached to the deployable member 122. In one embodiment, the electrode lead 104 includes an extension member 144 having a distal end 146 that is attached to a proximal end 148 of the rotatable member 138, as shown in FIG. 6. In one embodiment, the extension member 144 has a proximal end 150 that extends to the proximal end 106 of the tubular lead body 104, as shown in FIG. 2. A physician may rotate the proximal end 150 of the extension member 144 by hand to drive the rotation of the rotatable member 138 about the central axis 140. Alternatively, a motorized device or other tool may be used to drive the rotation of the proximal end 150. In one embodiment, the extension member 144 comprises a coil, as illustrated in FIG. 6.

[0030] In one embodiment, at least one electrical conductor extends through the tubular lead body 110 and is electrically coupled to the one or more electrodes 112. In one embodiment, when the one or more electrodes 112 are disposed in or on the deployable member 122, or are otherwise electrically coupled to the deployable member 122, the rotatable member 138 is formed of or includes an electrically conductive material that conducts electrical signals to the one or more electrodes 112 through the deployable member 122. In one embodiment, the extension member 144 is used to conduct the electrical signals to the rotatable member 138. Alternatively, separate electrical conductors, such as wires 118 (FIG. 1) may extend through the lead body 110 to the rotatable member 138. Other configurations are also possible.

[0031] One embodiment of the deployment mechanism 139 is configured to drive the deployable member 122 along the central axis 140 responsive to the rotation of the rotatable member 138 about the central axis 140 to move the deployable member 122 between the retracted position (FIG. 2) and the deployed position (FIGS. 1 and 3). In one embodiment, the deployment mechanism 139 comprises a threaded section 160 of the rotatable member 138 and a threaded section 162 of the deployable member 122, as shown in FIG. 6. In one embodiment, the threaded section 160 of the rotatable member 138 is located on an exterior surface of the rotatable member 138, and the threaded section 162 is located on an interior surface of a bore 164 of the deployable member 122. However, it is understood that this arrangement may be reversed by placing the threaded section 160 of the rotatable member 138 on an interior surface of a bore, and arranging the threaded section 162 of the deployable member 122 on an exterior surface that is received within the bore of the rotatable member 138.

[0032] In one embodiment, the threaded sections 160 and 162 intermesh and the rotation of the rotatable member 138 about the central axis 140 relative to the deployable member 122 drives the deployable member 122 along the central axis 140 relative to the rotatable member 138 and the tubular lead body 110. This allows the deployable member 122 to be deployed from within the tubular lead body 110 through the opening 126, or retracted into the tubular lead body 110, through the rotation of the rotatable member 138, which is driven, for example, by the rotation of the extension portion 144.

[0033] In one embodiment, the position of the rotatable member 138 along the central axis 140 is fixed relative to the tubular lead body 110. In one embodiment, this is accomplished using one or more stop members 166 of the lead body 110 that engage a member 168 of the rotatable member 138, as shown in FIG. 6.

[0034] In one embodiment, the electrode lead 104 includes a guide 170 that is configured to prevent the deployable member 122 from rotating about the central axis 140 relative to the lead body 110. In one embodiment, the guide 170 comprises a slot 172 in an exterior wall 174 of the deployable member 122, and a protrusion 176 extending from an interior wall 178 of the lead body 110, as shown in FIGS. 6 and 7. As the deployable member 122 is moved along the central axis 140 relative to the lead body 110 responsive to the rotation of the rotatable member 138, the protrusion 176 slides within the slot 172 and prevents the deployable member 122 from rotating about the central axis 140 relative to the lead body 110. As a result, the deployable member 122 does not rotate about the central axis 140 with the rotation of the rotatable member 138. In one embodiment, the electrode lead 104 includes a pair of the guides 170, as shown in FIGS. 6 and 7. Additional guides may also be used as necessary.

[0035] FIG. 8 is a simplified side cross-sectional view of a distal end 114 of electrode lead 104 in accordance with embodiments of the invention. In one embodiment, the deployable member 122 is coupled to the distal end 142 through a suitable mechanical connection. In one embodiment, the mechanical connection allows the deployable member 122 to remain in a fixed angular position about the central axis 140 as the rotatable member 138 rotates about the axis 140. The mechanical coupling between the deployable member 122 and the rotatable member 138 can take on many different forms while providing the desired function described above.

[0036] In one exemplary embodiment, the mechanical coupling comprises a ball member 186 coupled to the rotatable member 138, and a socket member 188 coupled to the deployable member 122. The ball member 186 is received within the socket member 188 and is able to rotate within the socket member 188. In one embodiment, a low friction interface 190 is formed between the exterior surface of the ball member 186 and the interior surface of the socket member 188. The low friction interface 190 may be formed using a suitable lubricant, an insert covering the exterior of the ball member 186, an insert covering the interior surface of the socket member 188, and/or other suitable techniques for forming a low friction interface.

[0037] In one embodiment, the deployable member 122 is restricted from rotating about the axis 140 relative to the lead body 110. In one embodiment, the lead 104 includes one or more of the guides 170 described above, as shown in FIG. 8.

[0038] Another embodiment of the deployment mechanism 139, illustrated in FIG. 8, comprises a threaded section 194 on the interior wall 178 of the tubular lead member 110, and a threaded section 196 on the exterior surface 198 of the rotatable member 138. The threaded sections 194 and 196 are positioned to intermesh with each other. Rotation of the rotatable member 138 about the axis 140 drives movement of the rotatable member 138 along the axis 140 relative to the lead body 110. Due to the mechanical coupling between the distal end 142 of the rotatable member 138 and the deployable member 122, the rotation of the rotatable member 138 about the axis 140 also drives movement of the deployable member

122 along the axis 140. Thus, the deployment mechanism 139 drives movement of the deployable member 122 along the axis 140 relative to the lead body 110 through the rotation of the rotatable member 138, and it may be used to deploy the deployable member 122 from within the lead body 110 through the opening 126 into desired tissue of a patient, and retract the deployable member 122 back into the lead body 110 through the opening 126, as described above.

[0039] In one embodiment, the movement of the rotatable member 138 along the central axis 140 is restricted by one or more stops 200 projecting from the interior wall 178 of the lead body 110 and stops 202 extending radially from the rotatable member 138. The stops 200 of the lead body 110 engage the stops 202 to limit the distance the rotatable member 138 may travel along the central axis 140 and, thus, the distance the deployable member 122 may travel along the axis 140 relative to the tubular lead member 110.

[0040] As discussed above, the deployable member 122 and/or the connected anchor 120 may include the one or more electrodes or stimulation elements 112. As discussed above, electrical signals are delivered to the one or more electrodes 112 on the deployable member 122 through an electrical conductive path that extends to the proximal end 106 of the tubular lead body 110. In one embodiment, the electrical signals are conducted to the rotatable member 138 using, for example, the extension member 144, or other suitable conductor. In one embodiment, an electrical connection is formed between the rotatable member 138 and the deployable member 122 such that electrical signals conducted to the rotatable member 138 may be delivered to the one or more electrodes 112 that are connected to the deployable member 122. In one embodiment, the electrical connection comprises a coil 204 or other suitable component that rotates about the central axis 140 with the rotation of the rotatable member 138. The coil 204 or other suitable component is placed in sliding contact with the deployable member 122 to conduct electrical signals from the rotatable member 138 to the deployable member 122. The electrical connection allows electrical signals to be delivered to the one or more electrodes 112 through the deployable member 122 while maintaining the ability to rotate the rotatable member 138 relative to the deployable member 122. In accordance with another embodiment, the electrical connection is formed between the ball member 186 and the socket member 188.

[0041] FIG. 9 is a flowchart illustrating a method of using the electrode lead 104 formed in accordance with one or more embodiments described above. At 210, an electrode lead 104 formed in accordance with one or more of the embodiments described above is provided. At 212, the distal end 114 of the tubular lead member 110 is positioned approximate target tissue 124 of a patient, as shown in FIG. 2. At 214, the rotatable member 138 is rotated relative to the tubular lead member 110. As discussed above, this may be accomplished through the rotation of the proximal end 143 of the extension member 138 by the physician. At 216, the deployable member 122 is driven along the central axis 140 and out the opening 146 at the distal end 114 of the tubular lead member 110 using the deployment mechanism 139, as shown in FIG. 3.

[0042] Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

1-14. (canceled)

15. A method comprising:

providing an electrode lead comprising:

- a tubular lead body;
- an electrode supported by the lead body;
- a rotatable member within a distal end of the tubular lead body;
- a deployable member attached to the rotatable member and comprising a tissue anchor, the tissue anchor comprising mesh; and
- a deployment mechanism;

positioning the distal end of the tubular lead body proximate target tissue of a patient;

rotating the rotatable member relative to the tubular lead body; and

driving the deployable member along the central axis out the distal end of the tubular lead body and into the target tissue using the deployment mechanism responsive to rotating the rotatable member;

wherein the deployable member does not rotate about the central axis with the rotation of the rotatable member.

16. The method of claim 15, further comprising driving the anchor into the target tissue responsive to driving the deployable member along the central axis.

17. (canceled)

18. The method of claim 15, wherein the deployable member includes the electrode.

19. The method of claim 15, wherein:

the deployment mechanism comprises:

- a first threaded section attached to the rotatable member; and
- a second threaded section attached to the deployable member that intermeshes with the first threaded section; and

driving the deployable member along the central axis comprises intermeshing the first and second threaded sections during rotation of the rotatable member.

20. The method of claim 15, wherein:

the deployment mechanism comprises:

- a first threaded section on an interior wall of the tubular lead body; and
- a second threaded section on an exterior wall of the rotatable member that intermeshes with the first threaded section;

driving the deployable member along the central axis comprises intermeshing the first and second threaded sections during rotation of the rotatable member.

21. The method of claim 15, wherein:

the electrode is attached to the mesh; and

the method comprises delivering electrical signals to the electrode.

* * * * *