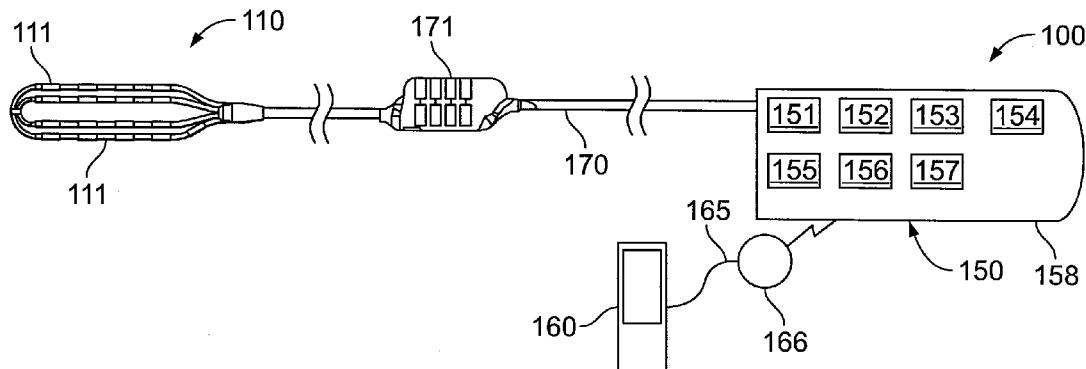




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De La Rama(10) **Pub. No.: US 2014/0200639 A1**(43) **Pub. Date: Jul. 17, 2014**(54) **SELF-EXPANDING NEUROSTIMULATION
LEADS HAVING BROAD
MULTI-ELECTRODE ARRAYS****Publication Classification**(51) **Int. Cl.**
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USPC **607/116**(71) Applicant: **Advanced Neuromodulation Systems,
Inc., Plano, TX (US)**(72) Inventor: **Alan De La Rama, Cerritos, CA (US)**(73) Assignee: **Advanced Neuromodulation Systems,
Inc., Plano, TX (US)**(21) Appl. No.: **14/048,352**(22) Filed: **Oct. 8, 2013****Related U.S. Application Data**(60) Provisional application No. 61/753,429, filed on Jan.
16, 2013.(57) **ABSTRACT**

Self-expanding lead including a lead body having a distal body end, a proximal body end, and a central axis extending therebetween. The lead body includes first and second outer arms and an inner arm disposed between the first and second outer arms. The first and second outer arms and the inner arm extend lengthwise between the proximal body end and the distal body end. The lead also includes an array of electrodes that are configured to apply a neurostimulation therapy within an epidural space of a patient. At least some of the electrodes are positioned along the first and second outer arms. Each of the first and second outer arms includes a resilient member that is biased to flex the corresponding first and second outer arms from a collapsed condition to an expanded condition in a lateral direction away from the inner arm.



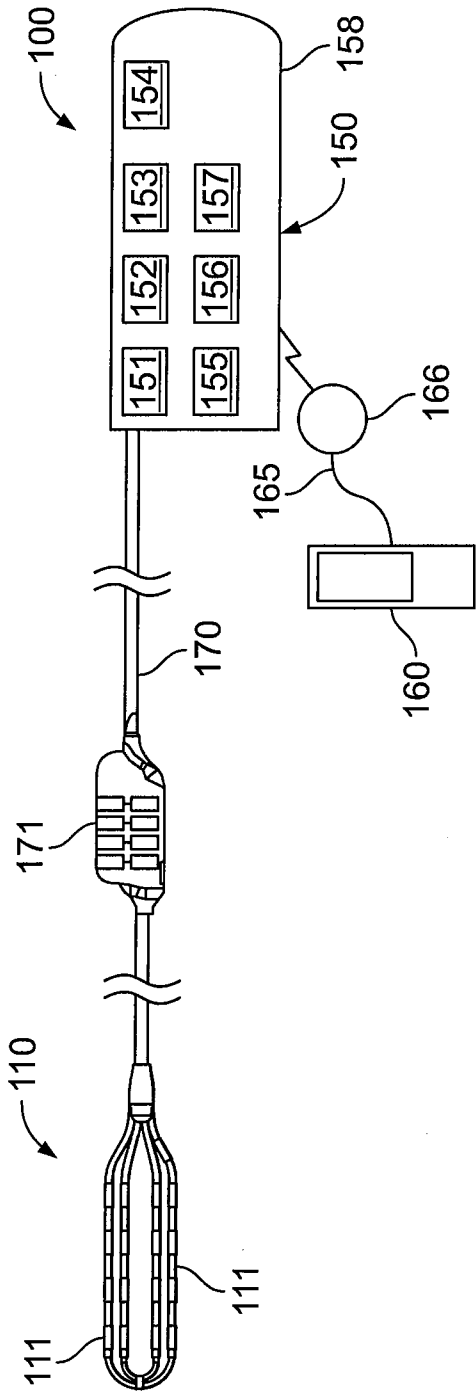


FIG. 1

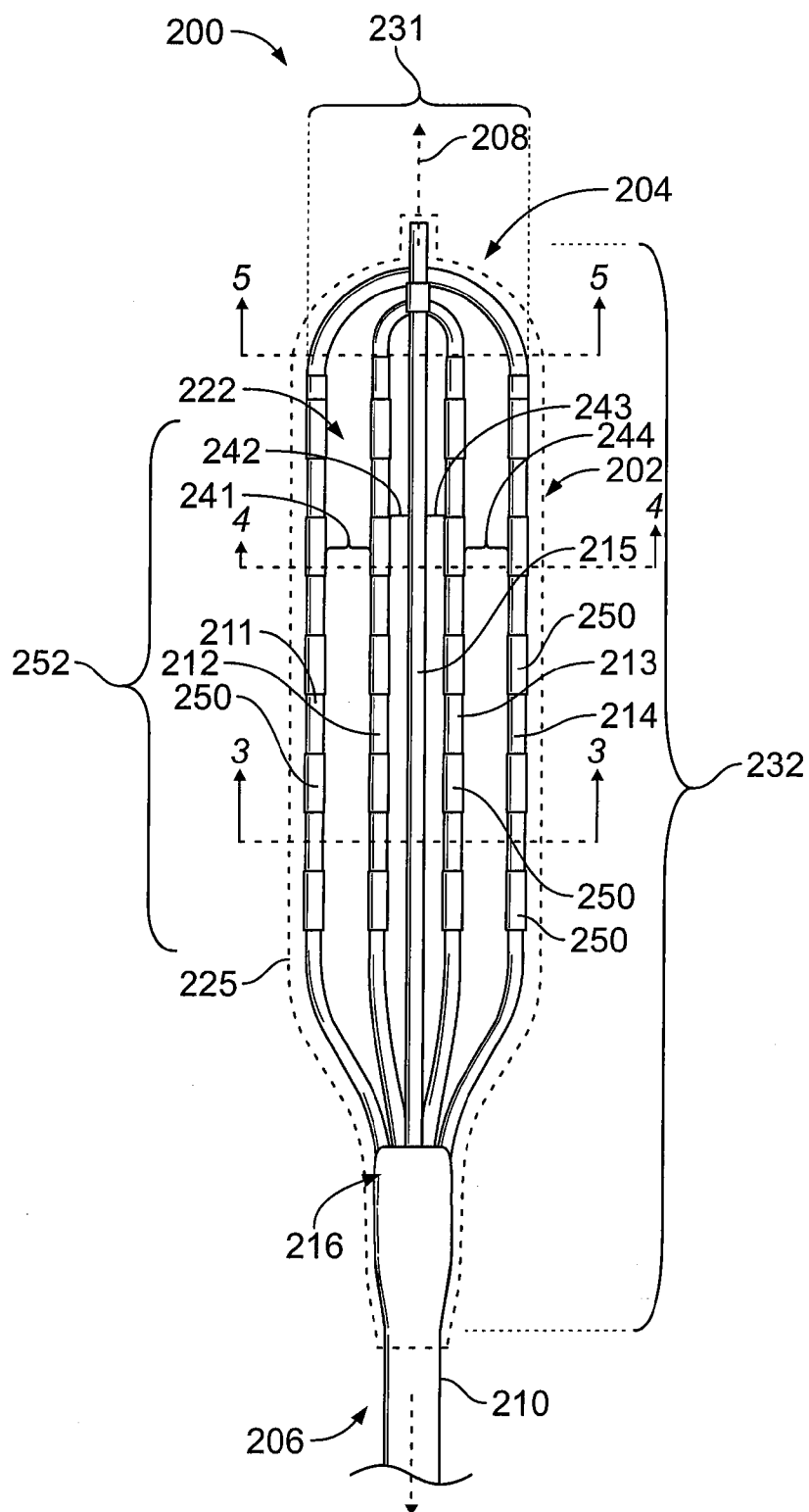


FIG. 2A

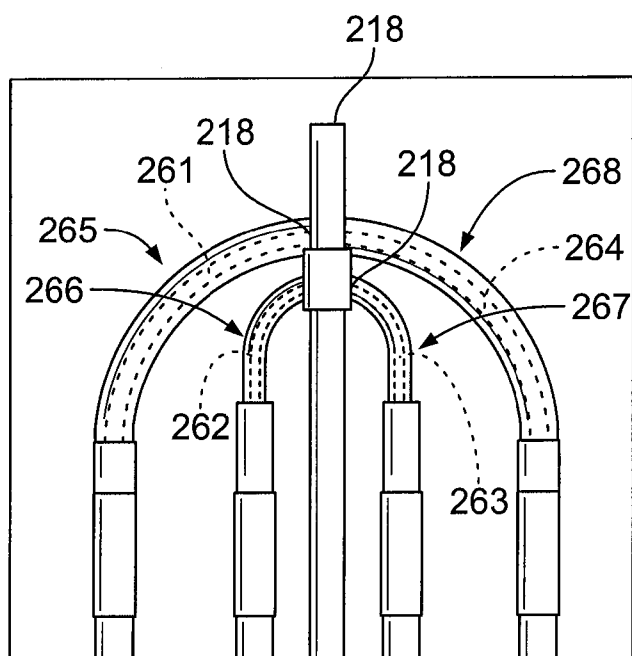


FIG. 2B

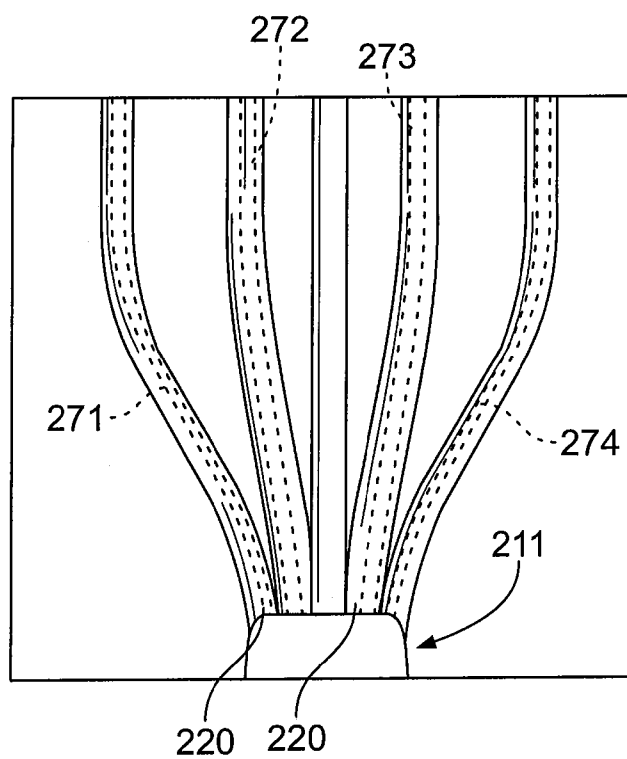


FIG. 2C

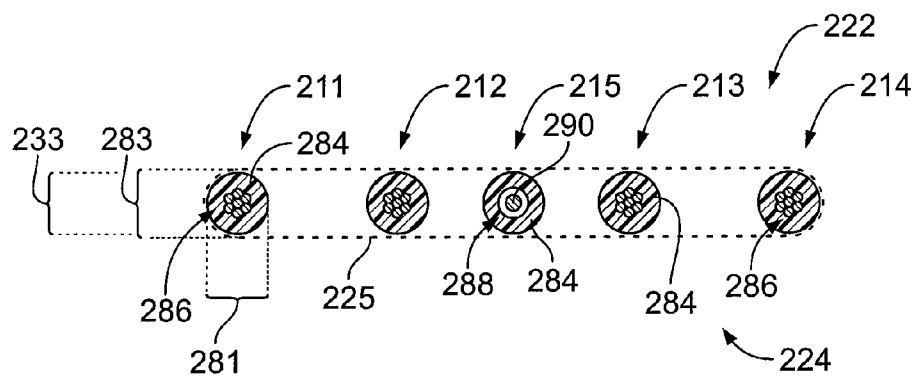


FIG. 3

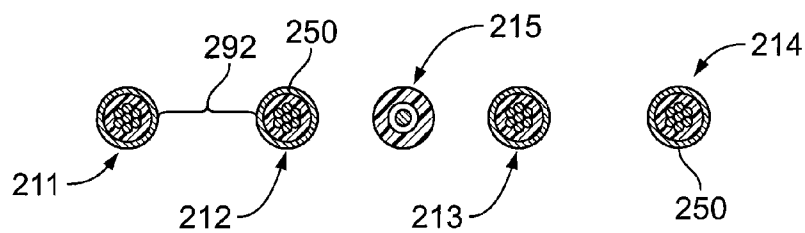


FIG. 4

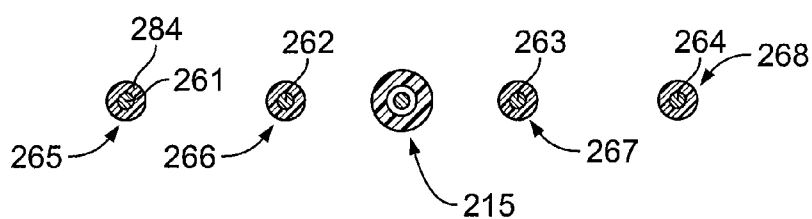


FIG. 5

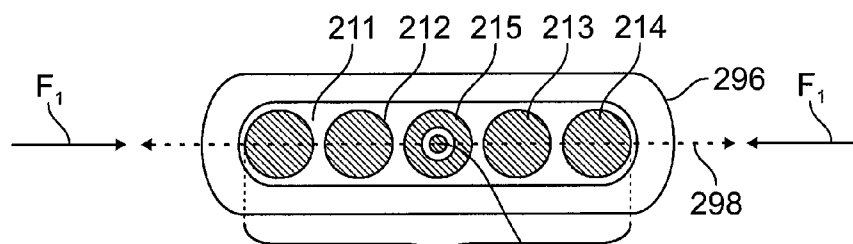


FIG. 6

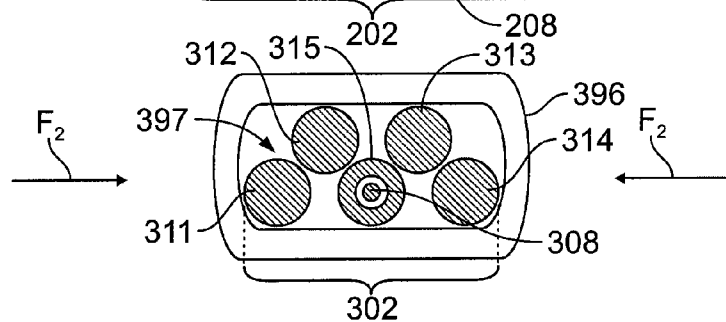


FIG. 7

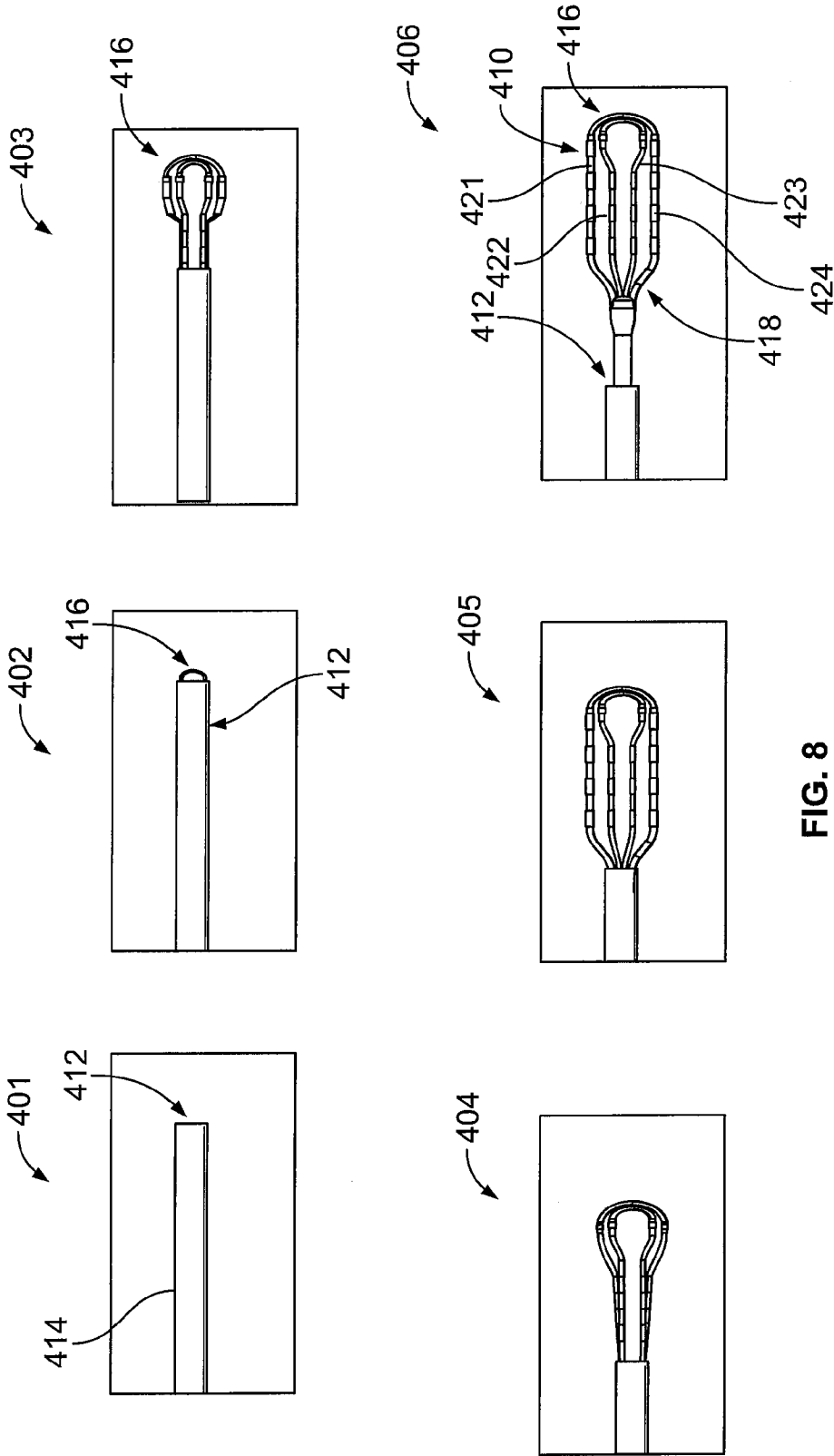


FIG. 8

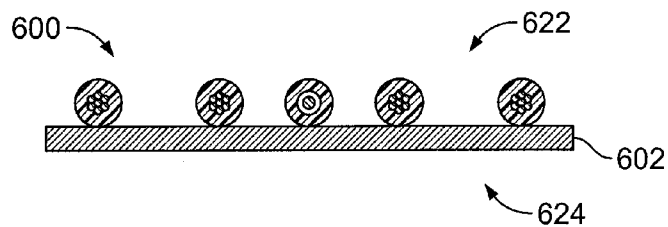
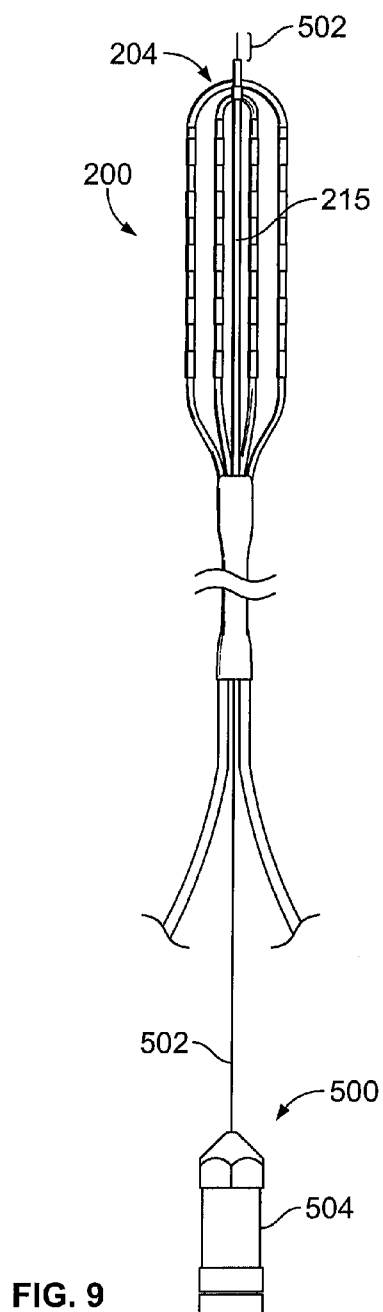


FIG. 11

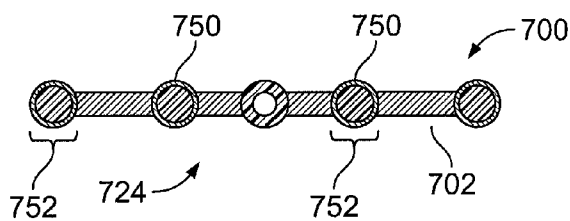


FIG. 12

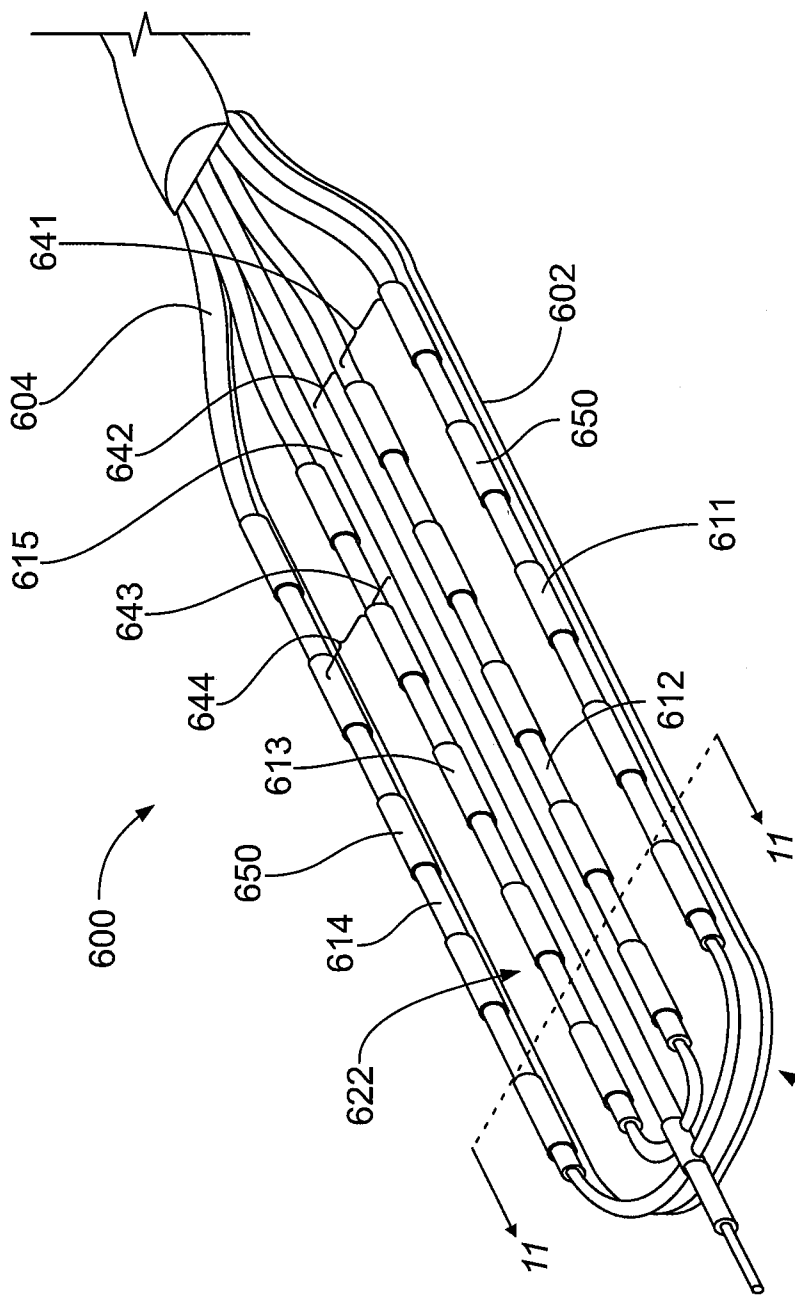


FIG. 10

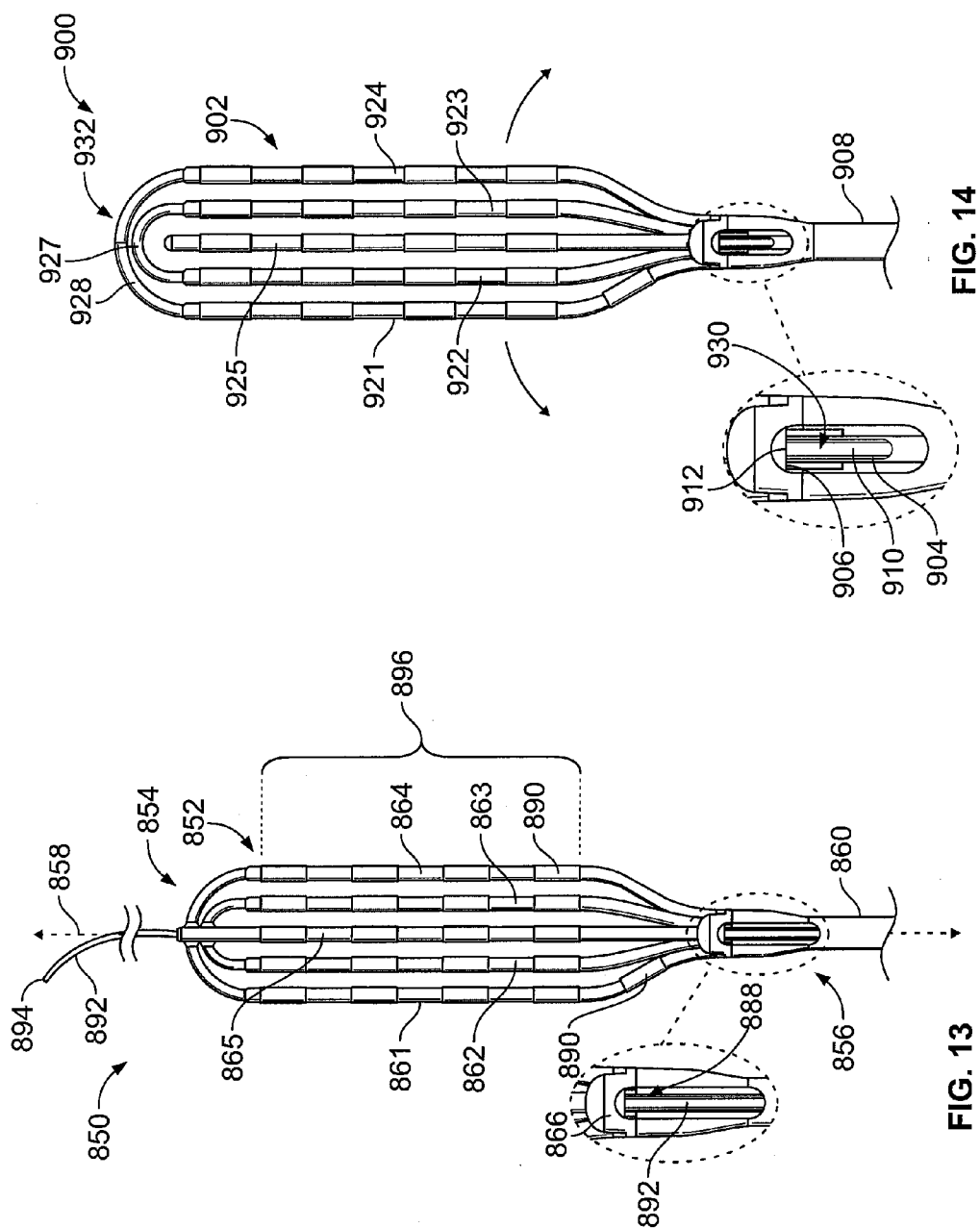
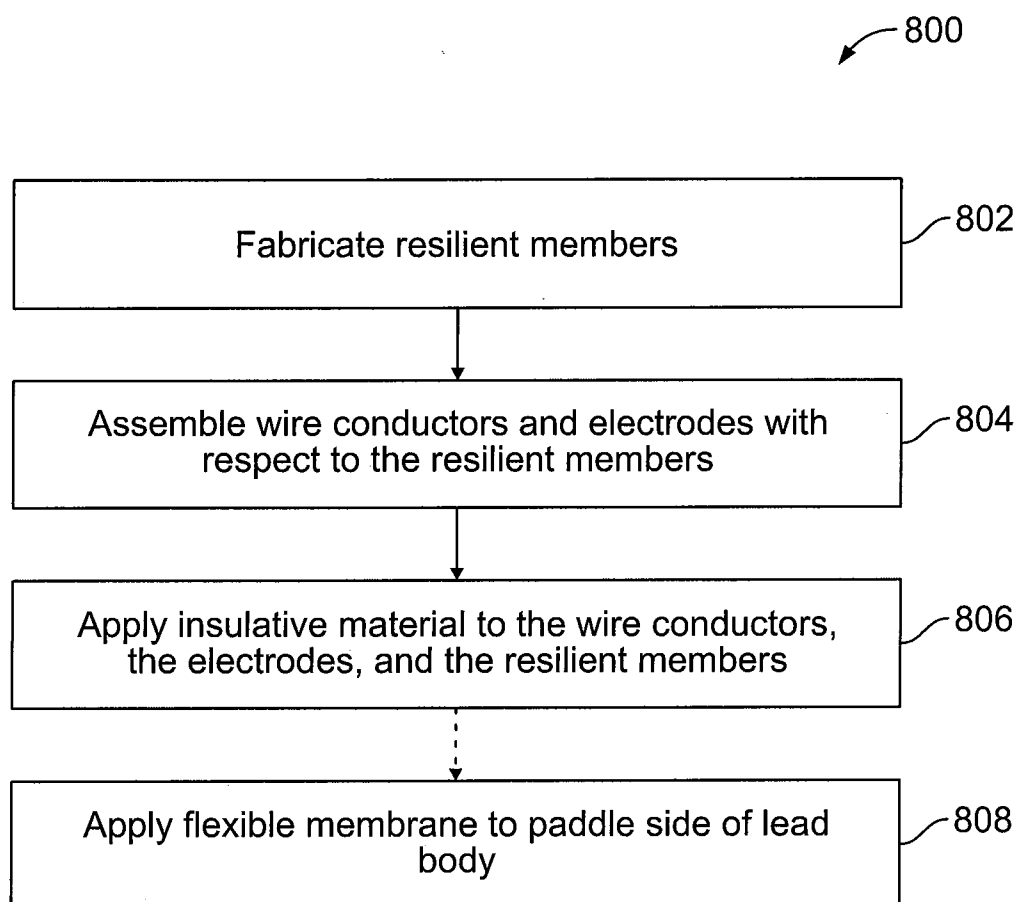


FIG. 14

FIG. 13

**FIG. 15**

SELF-EXPANDING NEUROSTIMULATION LEADS HAVING BROAD MULTI-ELECTRODE ARRAYS

RELATED APPLICATION

[0001] The present application claims the benefit of U.S. Provisional Application No. 61/753,429, filed on 16 Jan. 2013, which is incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] One or more embodiments of the subject matter described herein generally relate to systems having leads for generating electric fields proximate to nerve tissue.

BACKGROUND

[0003] Neurostimulation systems (NS) include devices that generate electrical pulses and deliver the pulses to nerve tissue to treat a variety of disorders. Spinal cord stimulation (SCS) is a common type of neurostimulation. In SCS, electrical pulses are delivered to nerve tissue in the spine typically for the purpose of chronic pain control. While a precise understanding of the interaction between the applied electrical energy and the nerve tissue is not fully appreciated, it is known that application of an electric field to spinal nerve tissue can effectively mask or alleviate certain types of pain transmitted from regions of the body associated with the stimulated nerve tissue. SCS may have applications other than pain alleviation as well.

[0004] NS and SCS systems generally include a pulse generator and one or more leads electrically coupled to the pulse generator. A lead includes an elongated body of insulative material. A stimulating end portion of the lead includes multiple electrodes that are electrically coupled to the pulse generator through wire conductors. The stimulating end portion of a lead is implanted proximate to nerve tissue (e.g., within epidural space of a spinal cord) to deliver the electrical pulses. A trailing end portion of the lead body includes multiple terminal contacts, which are also electrically coupled to the wire conductors. The terminal contacts, in turn, are electrically coupled to the pulse generator. The terminal contacts receive electrical pulses from the pulse generator that are then delivered to the electrodes through the wire conductors to generate the electric fields. The pulse generator is typically implanted within the individual and may be programmed (and re-programmed) to provide the electrical pulses in accordance with a designated sequence.

[0005] Typically, one of two types of leads is used. The first type is a percutaneous lead, which has a rod-like shape and includes electrodes spaced apart from each other along a single axis. The second type of lead is a laminectomy or laminotomy lead (hereinafter referred to as a paddle lead). A paddle lead has an elongated planar body with a thin rectangular shape (i.e., paddle-like shape). Although the paddle lead may include only one row or column of electrodes, the paddle lead typically includes an array of electrodes that are spaced apart from each other along a substantially common plane. The number of electrodes may be, for example, two, four, eight, or sixteen.

[0006] A single paddle lead enables more coverage of the nerve tissue relative to a single percutaneous lead. However, due to their dimensions and physical characteristics, paddle leads require a surgical procedure (e.g. a partial laminectomy) to implant the lead. The paddle lead is typically positioned

within the epidural space adjacent to the dura of the spinal cord. Conventional percutaneous leads are inserted into the body through a narrow introducer. Compared to paddle leads, the percutaneous leads have dimensions that may enable an easier insertion into the spinal cord and/or may cause less trauma to the insertion site of the spinal cord.

[0007] Therefore, a need remains for implantable leads that may be inserted into the spinal cord with a simpler insertion procedure than conventional paddle leads and also have electrode coverage of the nerve tissue that is broader than conventional percutaneous leads.

BRIEF SUMMARY

[0008] In accordance with an embodiment, a self-expanding lead is provided that includes a lead body having a distal body end, a proximal body end, and a central axis extending therebetween. The lead body includes first and second outer arms and an inner arm disposed between the first and second outer arms. The first and second outer arms and the inner arm extend lengthwise between the proximal body end and the distal body end. The lead also includes an array of electrodes that are configured to apply a neurostimulation therapy within an epidural space of a patient. At least some of the electrodes are positioned along the first and second outer arms. Each of the first and second outer arms includes a resilient member that is biased to flex the respective outer arm from a collapsed condition to an expanded condition in a direction that is away from the inner arm. The resilient member permits the respective outer arm to flex toward the inner arm from the expanded condition to the collapsed condition when a force is applied.

[0009] In accordance with another embodiment, a self-expanding lead is provided that includes first and second outer arms extending between respective proximal and distal arm ends. Each of the first and second outer arms includes electrodes that are positioned along a length of the respective outer arm. The lead also includes an inner arm that is disposed between the first and second outer arms. The inner arm extends between a respective base end and a respective distal arm end. The proximal ends of the inner arm and the first and second outer arms are coupled to each other proximate to a proximal body end of the self-expanding lead. The lead also includes a multi-electrode array having the electrodes of the first and second arms. The multi-electrode array is configured to apply a neurostimulation therapy within an epidural space of a patient. Each of the first and second outer arms includes a resilient member that is biased to flex the respective outer arm from a collapsed condition to an expanded condition in a direction that is away from the inner arm. The resilient member permits the respective outer arm to flex toward the inner arm from the expanded condition to the collapsed condition when a force is applied.

[0010] While multiple embodiments are described, still other embodiments of the described subject matter will become apparent to those skilled in the art from the following detailed description and drawings, which show and describe illustrative embodiments of disclosed inventive subject matter. As will be realized, the inventive subject matter is capable of modifications in various aspects, all without departing from the spirit and scope of the described subject matter. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 is a schematic view of one embodiment of a neurostimulating (NS) system in accordance with one embodiment.

[0012] FIG. 2A illustrates a plan view of a self-expanding lead that is in an expanded or relaxed state in accordance with one embodiment.

[0013] FIG. 2B is an enlarged view of a distal portion of the self-expanding lead shown in FIG. 2A.

[0014] FIG. 2C is an enlarged view of a proximal portion of the self-expanding lead shown in FIG. 2A.

[0015] FIG. 3 is a cross-section of the self-expanding lead taken along the line 3-3 in FIG. 2A while in the expanded state.

[0016] FIG. 4 is a cross-section of the self-expanding lead taken along the line 4-4 in FIG. 2A while in the expanded state.

[0017] FIG. 5 is a cross-section of the self-expanding lead taken along the line 5-5 in FIG. 2A while in the expanded state.

[0018] FIG. 6 is a cross-section of the self-expanding lead in a collapsed state while within an insertion tool in accordance with one embodiment.

[0019] FIG. 7 is a cross-section of a self-expanding lead in accordance with one embodiment while the lead is in a collapsed state within an insertion tool.

[0020] FIG. 8 illustrates a series of stages during an insertion process in which a self-expanding lead clears an insertion tool.

[0021] FIG. 9 illustrates a guide wire device that may be used to direct a self-expanding lead into an anatomical space of a patient in accordance with one embodiment.

[0022] FIG. 10 is a perspective view of a self-expanding lead in accordance with one embodiment that utilizes a flexible membrane.

[0023] FIG. 11 is a cross-section of a self-expanding lead having a flexible membrane in accordance with one embodiment.

[0024] FIG. 12 is a cross-section of a self-expanding lead having a flexible membrane in accordance with one embodiment.

[0025] FIG. 13 illustrates a plan view of a self-expanding lead that is in an expanded state in accordance with one embodiment.

[0026] FIG. 14 illustrates a plan view of a self-expanding lead that is in an expanded state in accordance with one embodiment.

[0027] FIG. 15 is a block diagram illustrating a method of manufacturing a self-expandable lead in accordance with one embodiment.

DETAILED DESCRIPTION

[0028] Embodiments described herein include self-expanding leads that are capable of flexing into an operative shape or configuration as the self-expanding lead is inserted into the epidural space. For example, the self-expanding lead may include one or more resilient members that are biased to expand the self-expanding lead when the self-expanding lead is permitted to expand (e.g., when a force is removed). The self-expanding lead may include a plurality of arms, at least one of which may be capable of flexing into an expanded condition. The individual arms may reduce the amount of

pressure along the spinal nerves within the epidural space relative to conventional paddle leads.

[0029] The individual arms of the lead may include one or more electrodes. Collectively, the electrodes of the individual arms may form a multi-electrode array (e.g., two-dimensional array) that provides electrode coverage comparable to conventional paddle leads. For instance, the multi-electrode array may be configured to have a coverage similar to Penta™ paddle leads distributed by St. Jude. In addition to the broad electrode coverage, the expandable/collapsible lead may enable delivery of the lead through introducers that are typically used for inserting percutaneous leads. As such, incisions for inserting the lead into the patient may be smaller than those used for inserting paddle leads, which may reduce recovery and clinical cost.

[0030] FIG. 1 depicts a neurostimulation (NS) system 100 that generates electrical pulses for application to tissue, such as spinal cord tissue, of a patient according to one embodiment. For embodiments that stimulate spinal cord tissue, the nerve tissue may include dorsal column (DC) fibers and/or dorsal root (DR) fibers. The NS system 100 includes an NS device (or pulse generator) 150 that is adapted to generate electrical pulses in order to apply electric fields to the tissue. The NS device 150 is typically implantable within an individual (e.g., patient) and, as such, may be referred to as an implantable pulse generator (IPG). The implantable NS device 150 typically comprises a housing 158 that encloses a controller 151, which may include or be operably coupled to a pulse generating circuit module 152, a charging coil 153, a battery 154, a far-field and/or near field communication circuit module 155, a battery charging circuit module 156, a switching circuit module 157, etc. of the device. The controller 151 may include a processor or other logic-based device for controlling the various other components of the NS device 150. Software code is typically stored in memory of the NS device 150 for execution by the NS device 150 to control the various components of the device.

[0031] The controller 151 may be a programmable controller that controls the various modes of stimulation therapy for the NS device 150. The controller 151 may include a microprocessor, or equivalent control circuitry, designed specifically for controlling delivery of stimulation therapy and may further include RAM or ROM memory, logic and timing circuitry, state machine circuitry, and I/O circuitry. The microcontroller 151 may have the ability to process or monitor input signals (data) as controlled by a program code stored in memory. The details of the design and operation of the microcontroller 151 are not critical to the present invention. Rather, any suitable microcontroller 151 may be used.

[0032] FIG. 1 illustrates various blocks in which some of the blocks are referred to as a “circuit module.” It is to be understood that the circuit modules that may be implemented as hardware with associated instructions (e.g., software stored on a tangible and non-transitory computer readable storage medium, such as a computer hard drive, ROM, RAM, or the like) that perform the operations described herein. The hardware may include state machine circuitry hard wired to perform the functions described herein. Optionally, the hardware may include electronic circuits that include and/or are connected to one or more logic-based devices, such as microprocessors, processors, controllers, or the like. Optionally, the circuit modules may represent processing circuitry such as one or more field programmable gate array (FPGA), application specific integrated circuit (ASIC), or microprocessor.

The circuit modules in various embodiments may be configured to execute one or more algorithms to perform functions described herein. The one or more algorithms may include aspects of embodiments disclosed herein, whether or not expressly identified in a flowchart or a method.

[0033] The NS device **150** may comprise a separate or an attached extension component **170**. If the extension component **170** is a separate component, the extension component **170** may connect with the “header” portion of the NS device **150** as is known in the art. If the extension component **170** is integrated with the NS device **150**, internal electrical connections may be made through respective conductive components. Within the NS device **150**, electrical pulses are generated by the pulse generating circuit module **152** and are provided to the switching circuit module **157**. The switching circuit module **157** connects to outputs of the NS device **150**. Electrical connectors (e.g., “Bal-Seal” connectors) within a connector portion **171** of the extension component **170** or within the header portion may be employed to conduct the electrical pulses. Terminal contacts (not shown) of one or more neurostimulator leads **110** are inserted within the connector portion **171** or within the header for electrical connection with respective connectors. Thereby, the pulses originating from NS device **150** are provided to the neurostimulator lead **110**. The pulses are then conducted through wire conductors of the lead **110** and applied to tissue of an individual via electrodes **111**. In the illustrated embodiment, the neurostimulator lead is a lead configured for insertion after a laminectomy or a laminotomy. The neurostimulator lead **110** is hereinafter referred to as a “self-expanding lead.”

[0034] For implementation of the components within NS device **150**, a processor and associated charge control circuitry for an implantable pulse generator is described in U.S. Patent Application Publication No. 2006/0259098, entitled “SYSTEMS AND METHODS FOR USE IN PULSE GENERATION,” which is incorporated herein by reference in its entirety. Circuitry for recharging a rechargeable battery of an implantable pulse generator using inductive coupling and external charging circuits are described in U.S. Pat. No. 7,212,110, entitled “IMPLANTABLE DEVICE AND SYSTEM FOR WIRELESS COMMUNICATION,” which is incorporated herein by reference in its entirety. One or more NS devices and one or more paddle leads that may be used with embodiments described herein are described in U.S. Patent Application Publication No. US 2013/0006341 in its entirety.

[0035] An example and discussion of “constant current” pulse generating circuitry is provided in U.S. Patent Application Publication No. 2006/0170486 entitled “PULSE GENERATOR HAVING AN EFFICIENT FRACTIONAL VOLTAGE CONVERTER AND METHOD OF USE,” which is incorporated herein by reference in its entirety. One or multiple sets of such circuitry may be provided within the NS device **150**. Different pulses on different electrodes may be generated using a single set of pulse generating circuitry using consecutively generated pulses according to a “multi-stimset program.” Complex pulse parameters may be employed such as those described in U.S. Pat. No. 7,228,179, entitled “METHOD AND APPARATUS FOR PROVIDING COMPLEX TISSUE STIMULATION PATTERNS,” and International Patent Publication No. WO 2001/093953 A1, entitled “NEUROMODULATION THERAPY SYSTEM,” each of which is incorporated herein by reference in its entirety. Alternatively, multiple sets of such circuitry may be

employed to provide pulse patterns that include simultaneously generated and delivered stimulation pulses through various electrodes of one or more stimulation leads as is also known in the art. Various sets of parameters may define the pulse characteristics and pulse timing for the pulses applied to various electrodes as is known in the art. Although constant current pulse generating circuitry is contemplated for some embodiments, any other suitable type of pulse generating circuitry may be employed such as constant voltage pulse generating circuitry.

[0036] In some embodiments, a controller device **160** may be implemented to recharge battery **154** of the NS device **150**. For example, a wand **165** may be electrically connected to the controller device **160** through suitable electrical connectors (not shown). The electrical connectors may be electrically connected to a primary coil **166** at the distal end of wand **165** through respective wires (not shown). The primary coil **166** may be placed against the patient’s body immediately above the charging coil (or secondary coil) **153** of the NS device **150**. The controller device **160** may generate an AC-signal to drive current through the primary coil **166**. Current may be induced in the secondary coil **153** to recharge the battery **154**.

[0037] In some embodiments, the controller device **160** preferably provides one or more user interfaces to allow the user to the NS device **150** according to one or more stimulation programs to treat the patient’s disorder(s). Each stimulation program may include one or more sets of stimulation parameters including pulse amplitude, pulse width, pulse frequency or inter-pulse period, pulse repetition parameter (e.g., number of times for a given pulse to be repeated for respective stimset during execution of program), etc. The NS device **150** modifies its internal parameters in response to the control signals from controller device **160** to vary the stimulation characteristics of stimulation pulses transmitted through stimulation lead **110** to the tissue of the patient. Neurostimulation systems, stimsets, and multi-stimset programs are discussed in PCT Publication No. WO 01/93953, entitled “NEUROMODULATION THERAPY SYSTEM,” and U.S. Pat. No. 7,228,179, entitled “METHOD AND APPARATUS FOR PROVIDING COMPLEX TISSUE STIMULATION PATTERNS,” which are incorporated herein by reference.

[0038] FIG. 2A is a plan view of a self-expandable lead **200** and includes two isolated, enlarged views of the lead **200**. The lead **200** may be similar or identical to the lead **110** (FIG. 1) and may be used with an NS system, such as the NS system **100** (FIG. 1). The lead **200** includes a lead body **202** having a distal body end **204**, a proximal body end **206**, and a central axis **208** extending therebetween. A portion of the lead body **202** near the distal body end **204** is shown in greater detail in FIG. 2B, and a portion of the lead body **202** near the proximal body end **206** is shown in greater detail in FIG. 2C. With respect to FIG. 2A, the central axis **208** extends generally along a geometric center of a cross-section of the lead **200**. As shown, the lead body **202** includes a plurality of arms or splines **211-215** that extend lengthwise between the distal body end **204** and the proximal body end **206** of the lead body **202**.

[0039] In the illustrated embodiment, the arms **211-215** include first and second outer arms **211, 214**, first and second inner arms **212, 213**, and a center inner arm **215**. The inner arms **212, 213, 215** are disposed between the outer arms **211, 214**, and the center inner arm **215** is disposed between the first and second inner arms **212, 213**. In some embodiments, the inner arms **212, 213** may be described or characterized inter-

mediate arms **212**, **213**. Each of the arms **211-215** extends lengthwise between a respective distal arm end **218** (shown in FIG. 2B) and a respective proximal arm end **220** (shown in FIG. 2C). The distal arm ends **218** are located proximate to the distal body end **204**, and the proximal arm ends **220** are located proximate to the proximal body end **206**. The proximal body end **206** may include an end **216** (or cable end) of a lead cable **210**. The lead body **202** also includes a first paddle side **222**, which is shown in FIG. 2, and a second paddle side **224** (shown in FIG. 3). The first and second paddle sides **222**, **224** face in opposite directions and extend lengthwise between the distal body end **204** and the proximal body end **206**.

[0040] In the illustrated embodiment, the lead body **202** has a lead profile or footprint **225** that constitutes a spatial volume defined by exterior surfaces of the lead body **202** when the lead body **202** is in a relaxed state. In FIG. 2, the lead profile **225** is represented by a dashed line that extends alongside a perimeter of the lead body **202**. For illustrative purposes, the dashed line is spaced apart from the exterior surfaces of the lead body **202** that define the lead profile **225**. By way of example, the lead body **202** may have a first dimension or width **231** that extends between exterior surfaces of the outer arms **211**, **214** and which face in opposite directions. The lead body **202** also has a second dimension or length **232** that extends between an exterior surface of the distal body end **204** and a location where the proximal body end **206** joins the lead cable **210**. The lead body **202** may also have a third dimension or thickness **233** (shown in FIG. 3) that extends between paddle sides **222**, **224**. Each of the width **231**, the length **232**, and the thickness **233** may have a varying or non-uniform value as the lead body **202** extends along the dimensions. For instance, the length **232** is greatest when measured along the central axis **208**.

[0041] As shown, the lead profile **225** may include elongated windows or openings **241-244** that are defined between adjacent arms. More specifically, with respect to the illustrated embodiment, the lead body **202** defines the elongated window **241** between the outer arm **211** and the inner arm **212**, the elongated window **242** between the inner arm **212** and the inner arm **215**, the elongated window **243** between the inner arm **215** and the inner arm **213**, and the elongated window **244** between the inner arm **213** and the outer arm **214**. The elongated windows **241** extend lengthwise along the central axis **208** and widthwise between the adjacent arms. The elongated windows **241-244** reduce or shrink when the lead **200** is in a collapsed state.

[0042] When the lead **200** is in a relaxed state prior to insertion as shown in FIG. 2, the lead profile **225** of the lead body **202** may be substantially planar widthwise and lengthwise. For example, the arms **211-215** may be substantially coplanar (e.g., substantially coincide along a common plane). In other embodiments, the lead profile **225** may have a curved contour when the lead body **202** is in a relaxed state. For example, the lead profile **225** may curve as the lead body **202** extends along the length **232** (e.g., such that the central axis **208** is not linear and has a curved or bent shape) and/or as the lead body **202** extends along the width **231** (e.g., the lead body **202** may be C-shaped as viewed along the central axis **208**). The contours may be predetermined by the manufacturing process of the lead **200**. For example, the contours may be predetermined to complement the anatomical structure that the lead **200** will interface.

[0043] During an implantation procedure, the distal body end **204** is typically the first end that is inserted through an incision and into the spinal column. As shown, the lead cable **210** extends away from the lead body **202** from the proximal body end **206**. The lead cable **210** may include conductive pathways **286** (shown in FIG. 3), such as wire conductors, which extend from the lead body **202** to an NS device or pulse generator (not shown), such as the NS device **150** (FIG. 1). The conductive pathways **286** also extend lengthwise along the arms **211-215** to electrically couple the corresponding electrodes **250** to the pulse generator.

[0044] As shown in FIG. 2, the lead **200** also includes a plurality of electrodes **250** that are disposed along the outer arms **211**, **214** and the inner arms **212**, **213**, but not the inner arm **215**. In other embodiments, the inner arm **215** may include one or more of the electrodes **250**. The electrodes **250** may comprise Platinum-Iridium (Pt—Ir) or other equivalent material. As one specific example only, the electrodes may be 90-10 Pt—Ir (i.e., 90% Platinum, 10% Iridium). The electrodes **250** may be positioned relative to each other to form a multi-electrode array **252**. The multi-electrode array **252** is a two-dimensional array in the illustrated embodiment. The electrodes **250** and/or the multi-electrode array **252** may be configured to provide a neurostimulation therapy in an epidural space of a patient. For example, electrical pulses transmitted from the NS device **150** may be provided at a predetermined schedule or frequency to provide therapy to the patient. It is noted that the FIG. 2 illustrates only one arrangement of the electrodes **250**. However, in other embodiments, the electrodes **250** may have any one of a variety of arrangements.

[0045] When the lead **200** is disposed in the epidural space, one of the paddle sides may interface with nerve tissue and the other paddle side may interface with an anatomical structure (e.g., bone, ligament, or other portions of the spine). In some embodiments, the electrodes **250** may be exposed along each of the paddle sides **222**, **224**. In other embodiments, the electrodes **250** may be exposed only along one of the paddle sides, such as the paddle side **222** shown in FIG. 2, and not the other paddle side.

[0046] In the illustrated embodiment, each of the outer arms **211**, **214** and each of the inner arms **212**, **213** include a series or column of electrodes **250** that are spaced apart from each other along a length of the respective arm. When in an operative state (e.g., an expanded state), the arms are spaced apart from each other thereby laterally separating the electrodes **250** of adjacent arms. To form the multi-electrode array **252** with a predetermined configuration, the electrodes **250** may be disposed along the lengths of the respective arms at designated locations and the arms **211-215** may be configured to have a designated separation when in the expanded state so that the electrodes **250** form the multi-electrode array **252**.

[0047] In the illustrated embodiment, multi-electrode array **252** includes a 4×5 grid of electrodes **250** in which the electrodes **250** are substantially evenly distributed along (e.g. parallel to) the central axis **208**. In alternative embodiments, the electrodes **250** may form a single row or column that extends along the central axis **208** and are spaced apart from each other. In other embodiments, the multi-electrode array **252** may have a 4×4 grid of electrodes **250** or a 4×8 grid of electrodes **250**. In particular embodiments, the multi-electrode array **252** may be configured to have a coverage similar to Penta™ paddle leads distributed by St. Jude.

[0048] To this end, the lead body 202 may include a plurality of resilient members 261-264 (shown in FIG. 2B) proximate to the distal body end 204 and a plurality of resilient members 271-274 (shown in FIG. 2C) proximate to the proximal body end 206. In the illustrated embodiment, the resilient members 261-264 are located within the arms 211-214, respectively, and the resilient members 271-274 are located within the arms 211-214, respectively. In an exemplary embodiment, the resilient members 261-264 and 271-274 include a resilient material that is capable of being collapsed when a force is applied and biased to flex back to a designated shape when the force is removed. In certain embodiments, the resilient material is a metal or metal alloy. The resilient material may have shape memory. In particular embodiments, the resilient material includes nitinol, which is a metal alloy of nickel and titanium. However, other materials, including combinations of materials, may be used.

[0049] FIGS. 2A-2C show the lead 200 in a relaxed or expanded state. The resilient members are biased to flex the respective arm from a collapsed condition to an expanded condition in a direction that is away from the central axis 208 (or the center inner arm 215). The resilient members also permit the respective arm to flex toward the central axis 208 (or the center inner arm 215) from the expanded condition to the collapsed condition when a force is applied.

[0050] FIGS. 3-5 illustrate different cross-sections of the lead 200 as shown in FIG. 2A. FIG. 3 is taken along the line 3-3 in FIG. 2A and illustrates cross-section of the arms 211-215 in greater detail. For illustrative purposes, the lead profile 225 is shown. The lead body 202 includes the paddle sides 222 and 224. Each of the arms 211-215 has a cross-section that includes an arm width 281 and an arm height 283. In some embodiments, the arm height 283 may be substantially equal to the thickness 233 of the lead body 202 or the lead profile 225 at the cross-section shown in FIG. 3. In particular embodiments, the arms 211-215 are narrow, elongated splines or beams in which the arm width 281 and the arm height 283 are approximately equal. For example, the arm width 281 and the arm height 283 may differ by at most 50% of the greater of the arm width 281 and the arm height 283. For example, if the arm width 281 were about 1.5 mm, the arm height 283 may be about 0.75 mm. If the arm height 283 is larger and is, for example, about 1.0 mm, the arm width 281 may be about 0.75 mm. In other embodiments, the arm width 281 and the arm height 283 may differ by at most 25% of the greater of the arm width 281 and the arm height 283 or, more particularly, by at most 10% of the greater of the arm width 281 and the arm height 283.

[0051] In the illustrated embodiment, the cross-section of the arms 211-215 have a substantially circular shape or substantially square shape such that the arm width 281 and the arm height 283 are substantially equal. In other embodiments, the arms 211-215 may have a substantially rectangular shape. For example, the arm width 281 may be about 2.25 mm and the arm height 283 may be about 1.0 mm.

[0052] As shown, the arms 211-215 comprise an insulative material 284 that may include the exterior surfaces of the arms 211-215. In FIG. 3, the arms 211-214 also include conductive pathways 286 (e.g., wire conductors). The conductive pathways 286 comprise a conductive material, such as copper, and are configured to transmit electrical signals (e.g., current) to corresponding electrodes 250 (FIG. 2A). The conductive pathways 286 are electrically coupled to the pulse generator of the NS system 100. As described above, a des-

ignated frequency may be transmitted to the electrodes 250 in order to provide therapy to a patient. In an exemplary embodiment, the conductive pathways 286 may include jackets that insulate the conductive pathways 286 from each other.

[0053] The inner arm 215 includes a steering lumen 288. The steering lumen 288 may be defined by an interior surface of the insulative material 284. The steering lumen 288 may extend lengthwise through the inner arm 215 from the proximal body end 206 (FIGS. 2A and 2C) to and, optionally, through the distal body end 204 (FIGS. 2A and 2B). The steering lumen 288 is sized and shaped to receive an elongated tool 290, such as a guide wire. The elongated tool 290 may be used during the insertion process to guide the lead 200 (FIG. 2A).

[0054] The insulative material 284 may include one or more biocompatible materials. Non-limiting examples of such materials include polyimide, polyetheretherketone (PEEK), polyethylene terephthalate (PET) film (also known as polyester or Mylar), polytetrafluoroethylene (PTFE) (e.g., Teflon), or parylene coating, polyether bloc amides, polyurethane. In some embodiments, the material of the lead body 202 that surrounds the metal components (e.g., electrodes 250 and the conductive pathways 286 that couple to the electrodes 250) includes at least one of polyimide, polyetheretherketone (PEEK), polyethylene terephthalate (PET) film, polytetrafluoroethylene (PTFE), parylene, polyether bloc amides, or polyurethane.

[0055] FIG. 4 shows cross-sections of the arms 211-215 taken along the line 4-4 of FIG. 2A. In FIG. 4, each of the arms 211-214 includes one of the electrodes 250. The electrode 250 is configured to be exposed along an outer surface of the respective arm so that the electrode 250 may interface with an anatomical structure, such as nerve tissue. In FIG. 4, the electrodes 250 are completely exposed along the outer surface. In other embodiments, one or more portions of the electrodes 250 may be covered such that the corresponding portion(s) is not exposed. For instance, the insulative material 284 may cover the one or more portions of the electrodes 250. As shown in FIG. 4, the electrode 250 may be separated from an adjacent electrode 250 by a gap 292. The gaps 292 may be part of the elongated windows 241-244.

[0056] FIG. 5 shows cross-sections of the joints 265-268 of the respective arms 211-215 (FIG. 2A) taken along the line 5-5 in FIG. 2A. As shown, each of the joints 265-268 includes the respective resilient member 261-264 that is at least partially surrounded by the insulative material 284. The resilient members 261-264 of the respective joints 265-268 are dimensioned and shaped to function as described herein. For example, the resilient members 261-264 may be etched, creased, and/or have varying dimensions in order to provide sufficient resiliency for returning the arms 211-214 to the expanded state when the force is removed. In some embodiments, the resilient members 261-264 may be etched (e.g., laser-cut) to provide the designated shape.

[0057] FIG. 6 shows a cross-section of the lead body 202 when each of the arms 211-214 is in a collapsed condition within an insertion tool 296, which may also be referenced as an introducer. The resilient members 261-264, 271-274 (FIGS. 2B and 2C, respectively) may be configured such that the arms 211-214 collapse in a designated manner. For example, the resilient members 261-264, 271-274 may be shaped such that when a laterally-inward force F_1 (indicated by the inwardly pointing arrows) is provided, the arms 211-214 collapse toward (e.g., move toward) the inner arm 215

and/or the central axis **208**. The laterally-inward force F_1 may be applied when the lead body **202** is drawn into or advanced into a cavity of an insertion tool. The cavity may be defined by interior surfaces of the insertion tool. The lead body **202** may slide through the insertion tool when a linear force is applied. The linear force may be translated into the laterally-inward force F_1 as the unyielding interior surface of the insertion tool collapses the arms **211-214**.

[0058] In the illustrated embodiment, when the lead body **202** is in an expanded state, each of the arms **211-214** coincides with a body plane **298** prior to the arms **211-214** collapsing. As the arms **211-214** collapse, the arms **211-214** move along the body plane **298** in an inward direction toward the inner arm **215** and/or toward the central axis **208**. When the arms **211-214** are in the collapsed conditions as shown in FIG. 6, the arms **211-214** may be co-planar with one another such that the arms **211-214** coincide with the body plane **298**.

[0059] FIG. 7 shows a cross-section of a lead body **302** when the lead body **302** is located within an insertion tool **396**. The lead body **302** may be similar or identical to the lead body **202** (FIG. 2A). For example, the lead body **302** includes arms **311-315**. As shown in FIG. 7, each of the arms **311-314** is in a collapsed condition within a cavity **397** of the insertion tool **396**. The cavity **397** is defined by one or more interior surfaces of the insertion tool **396**. Although not shown, the arms **311-314** may include resilient members, such as the resilient members **261-264**, **271-274** (FIGS. 2B and 2C, respectively), which may be configured to expand the arms **311-314** in a designated manner and permit the arms **311-314** to collapse in a designated manner. For instance, the resilient members may be shaped such that when an inward force F_2 (indicated by arrows) is provided, the arms **311-314** collapse toward the inner arm **315** and/or a central axis **308** of the lead body **302**. However, the resilient members of the arms **311-314** may be biased such that the arms **311-314** move toward the inner arm **315** or the central axis **308** in a different manner than the arms **211-214** shown in FIG. 6. For instance, the inner arms **312**, **313** may move above or below the inner arm **315** and the inner arms **311**, **314** may move below or above the inner arms **312**, **313**, respectively. As such, the inner arms **311-315** may have a substantially stacked or overlapping configuration as shown in FIG. 7. In other embodiments, the stacked configuration may include the inner arms **311-314** forming a square perimeter that surrounds the inner arm **315** within a center of the stacked configuration.

[0060] FIG. 8 illustrates a series of stages **401-406** during an insertion process in which a self-expanding lead **410** clears an end opening **412** of an insertion tool **414** (e.g., an introducer). The lead **410** may be similar or identical to other self-expanding leads described herein and have a distal body end **416** and a proximal body end **418** (shown with respect to the stage **406**). The lead **410** may include arms **421-424** that have resilient members (not shown) that enable the arms **421-424** to flex between collapsed and expanded conditions. Unlike other self-expandable leads described herein, the lead **410** does not include a central inner arm through which a steering lumen extends. In alternative embodiments, the lead **410** may include such an inner arm.

[0061] At stage **401**, the lead **410** is disposed within a cavity, such as the cavity **397** (FIG. 7), of the insertion tool **414**. As described above, the relaxed state of the lead **410** may be the expanded state. When the lead **410** is advanced into the cavity **397**, interior surfaces of the insertion tool **414** that define the cavity may engage one or more of the arms, such as

the arms **421** and **424**. The insertion tool **414** may resist lateral deformation such that the insertion tool **414** pushes the arms **421** and **424** and, consequently, the arms **422**, **423** laterally-inward as the lead **410** is advanced into the cavity. Thus, the linear insertion force that is applied to the lead **410** may be translated by the interior surface(s) of the insertion tool **414** into a laterally-inward force that collapses the arms **211-214**.

[0062] Before or after the lead **410** has been disposed within the insertion tool **414**, the insertion tool **414** may be advanced into a patient (not shown) through one or more incisions. For example, the insertion tool **414** may be advanced through one or more incisions that provide access to the spinal cord (not shown). In some embodiments, the insertion tool **414** may be identical to the introducers that are used to insert percutaneous leads into the spinal cord. In other embodiments, the insertion tool **414** may not be identical, but may have dimensions that are approximate to or similar to the dimensions of conventional percutaneous introducers.

[0063] At stage **402**, the distal body end **416** clears the end opening **412** of the insertion tool **414**. As the lead **410** transitions to stage **403**, the distal body end **416** may expand to have a larger lead profile. At this time, the distal body end **416** may engage tissue within the anatomical space (not shown). Geometries of the anatomical space, including the epidural space, vary from patient to patient. In some cases, it may be desirable for the lead **410** to be capable of moving around obstructions, such as bone or tissue, and/or to be capable for moving tissue without causing significant trauma to the patient. In accordance with some embodiments, the resiliency of the arms **421-424** at the distal body end **416** may be configured such that the distal body end **416** is capable of engaging and flexing to slide around tissue and/or is capable of engaging and moving tissue within the anatomical space.

[0064] At stage **404**, the distal body end **416** has cleared the end opening **412** of the insertion tool **414** and a majority of a length of the lead **410** has advanced into the anatomical space. At stages **405** and **406**, the proximal body end **418** has expanded such that the arms **421-424** are fully expanded and the lead **410** has a maximum lead profile. Before or after the lead **410** is properly positioned within the epidural space, the tool **414** may be withdrawn through the one or more incision sites.

[0065] FIG. 9 illustrates a guiding device **500** that may be used to direct the self-expanding lead **200** into an anatomical space of a patient. As shown, the guiding device **500** includes a guide wire **502** that is operably coupled to a handle **504** that is configured to be gripped by an individual (e.g., doctor). In FIG. 9, the guide wire **502** is inserted entirely through the steering lumen **288** (FIG. 3) of the inner arm **215** such that the guide wire **502** extends beyond the distal body end **204** of the lead **200**.

[0066] The insertion process with respect to the lead **200** may be similar to the insertion process described with respect to FIG. 8. However, before or after the lead **200** is loaded into the insertion tool (not shown), the guide wire **502** of the guiding device **500** may be inserted through the steering lumen **288** of the inner arm **215**. After the insertion tool has been advanced through the incision site and positioned proximate to the designated anatomical space as described above, the guide wire **502** may be moved into the anatomical space before the lead **200** clears the end opening (not shown) of the insertion tool. With the guide wire **502** located within the anatomical space, the lead **200** may be advanced into the anatomical space with the guide wire **502** directing or guiding

the lead 200. As the lead 200 is advanced into the anatomical space, the distal body end 204 of the lead 200 expands. In some embodiments, the expanding of the lead 200 may displace tissue or other obstructions thereby permitting the guide wire 502 to advance. After the lead 200 has partially expanded, the lead 200 may then be further advanced into the anatomical space.

[0067] FIGS. 10-13 illustrate self-expandable leads having flexible membranes. For some applications, it may be desirable to have a flexible membrane extend across the width of the lead and join the arms of the lead body. The flexible membranes may impede growth of tissue around the arms which may enable a simpler process for withdrawing the lead with a decreased likelihood of trauma or injury to the patient. For example, FIG. 10 is a perspective view of a self-expanding lead 600 that utilizes a flexible membrane 602 in accordance with one embodiment. Other than the flexible membrane 602, the lead 600 may be identical to the lead 200 (FIG. 2A). For example, the lead 200 may include a lead body 604 having arms 611-615. In the, expanded state shown in FIG. 10, the lead body 604 has first and second paddle sides 622, 624. Also shown, the lead 600 includes elongated windows or openings 641-644 that are defined between adjacent arms. The flexible membrane 602 extends along the paddles side 624 and covers the elongated windows 641-644.

[0068] FIG. 11 is a cross-section of the lead 600 taken along the line 11-11 in FIG. 10. The flexible membrane 602 may be attached to the arms 611-615 along the paddle side 624 in one or more manners. For example, the flexible membrane 602 may comprise a biocompatible material, which may be the same as or similar to the insulative material 284, that is attached by selectively applying heat to the flexible membrane 602. In other embodiments, an adhesive may be applied to the flexible membrane 602, which may then be attached to the arms 611-614.

[0069] In the embodiment of FIG. 11, the lead 600 has a uni-directional configuration. More specifically, the flexible membrane 602 may extend along the paddle side 624 such that electrodes 650 (FIG. 10) of the lead 600 are covered by the flexible membrane 602 and are only exposed along the paddle side 622. In such embodiments, it may be necessary to orient the lead 600 so that a predetermined paddle side interfaces with the nerve tissue.

[0070] FIG. 12 is a cross-section of a self-expanding lead 700 having a flexible membrane 702 in accordance with one embodiment. Other than the flexible membrane 702, the lead 700 may be identical to the lead 200 (FIG. 2A). In the embodiment of FIG. 12, the flexible membrane 702 is applied to a paddle side 724 of the lead 700. The flexible membrane 702 may have electrode openings 752 that expose the electrodes 750 along the paddle side 724. The electrode openings 752 may be fabricated by etching the flexible membrane 702 material after the flexible membrane 702 has been applied to the paddle side 724. In some embodiments, the flexible membrane 702 may be applied through an injection molding process. With injection molding, the lead 700 may be positioned within a mold that covers portions of the electrodes 750 so that molten membrane material cures at designated portions thereby forming the electrode openings 752.

[0071] Accordingly, embodiments described herein may have a flexible membrane along one or both paddle sides. The flexible membrane may limit adhesion of the self-expanding lead to the patient by limiting growth of tissue or other material within the epidural space around the arms of the lead. In

such embodiments that utilize a flexible membrane, the flexible membrane may be capable of folding over within the cavity of the insertion tool, such as the insertion tool 414, thereby permitting the expanding/collapsing abilities of the leads described herein.

[0072] FIG. 13 illustrates a plan view of a self-expanding lead 850 in an expanded state. The lead 850 may be similar to other leads described herein, such as the lead 200 (FIG. 2A). For example, the lead 850 includes a lead body 852 having a distal body end 854, a proximal body end 856, and a central axis 858 extending therebetween. The proximal body end 856 may include an end 866 (or cable end) of a lead cable 860. As shown, the lead body 852 includes a plurality of arms or splines 861-865 that extend lengthwise between the distal body end 854 and the proximal body end 856 along the central axis 858. In the illustrated embodiment, the arms 861-865 include first and second outer arms 861, 864, first and second inner arms 862, 863, and a center inner arm 865. The inner arms 862, 863, 865 are disposed between the outer arms 861, 864, and the center inner arm 865 is disposed between the first and second inner arms 862, 863.

[0073] The lead cable 860 may include conductive pathways (not shown), such as wire conductors, which extend from the lead body 852 to an NS device or pulse generator (not shown), such as the NS device 150 (FIG. 1). The conductive pathways also extend lengthwise along the arms 861-865 to electrically couple corresponding electrodes 890 to the pulse generator. As shown, the corresponding electrodes 890 are disposed along each of the arms 861-865, including the inner arm 865. The electrodes 890 may be positioned relative to each other to form a multi-electrode array 896.

[0074] Although not shown, the lead body 852 may include a plurality of resilient members proximate to the distal body end 854 and a plurality of resilient members proximate to the proximal body end 856. The resilient members may be similar to the resilient members 261-264 and 271-274 (FIGS. 2B and 2C, respectively) described with respect to the lead 200 and located within the arms. The resilient members may include a resilient material that is capable of being collapsed when a force is applied and biased to flex back to a designated shape when the force is removed.

[0075] In the illustrated embodiment, the inner arm 865 includes a steering lumen 888. The steering lumen 888 extends through the lead cable 860 into the inner arm 865. The steering lumen 888 may be defined by an interior surface of an insulative material of the lead cable 860 and the inner arm 865. As shown, the steering lumen 888 extends lengthwise through the inner arm 865 from the proximal body end 856 and through the distal body end 854. The steering lumen 888 is sized and shaped to receive an elongated tool, which is illustrated as a guide wire 892 in FIG. 13. The guide wire 892 may be used during the insertion process to guide the lead 850 to a designated position in the epidural space (not shown). More specifically, the distal body end 854 may have an opening that permits a wire end 894 of the guide wire 892 to clear the distal body end 854 and be positioned within the epidural. With the wire end 894 located within the epidural space, the lead 850 may then be directed along the guide wire 892 and delivered to the epidural space. The path taken by the lead 850 is determined by the shape of the guide wire 892.

[0076] In some embodiments, the center inner arm 865 may not include resilient material for flexing between different positions. For example, in particular embodiments, the center inner arm 865 may not include such resilient material and,

instead, may include a more rigid material. The rigid material may be more suitable for receiving a tool, such as the guide wire **892**.

[0077] FIG. **14** illustrates a plan view of a self-expanding lead **900** in an expanded state. The lead **900** may have a lead body **902** that is similar in shape as the lead body **852**. However, as shown in FIG. **14**, a center inner arm **925** of the lead body **902** may not have a steering lumen that extends entirely through the lead body **902**. Instead, the center inner arm **925** may end short of a distal body end **932** and permit inner arms **922** and **923** to be directly coupled by a joint **927** and outer arms **921** and **924** to be directly coupled by a joint **928**.

[0078] However, the lead body **902** may have a steering lumen **904** that extends to and ends at a cable end **906** of a lead cable **908**. As shown, a guide wire **910** may be inserted into the steering lumen **904** until a wire end **912** of the guide wire **910** engages the cable end **906** of the lead body **902**. The guide wire **910** may be operated to move the lead body **902** into a designated orientation. For example, when the lead body **902** is inserted into the epidural space (not shown), the lead body **902** may be moved to into a designated orientation by the guide wire **910**. More specifically, the lead body **902** may pivot (as indicated by the arrows) about a point **930** located within the cable end **906**.

[0079] FIG. **15** is a block diagram illustrating a method **800** of manufacturing a self-expandable lead in accordance with one embodiment. The lead may be similar to the leads shown and described in the present application. The method **800** includes fabricating (at **802**) resilient members. The resilient members may be fabricated (at **802**) by etching a sheet of resilient material (e.g., metal alloy or plastic). In particular embodiments, the sheet of resilient material includes nitinol. The etching may include laser-cutting the sheet material. The resilient members may be elongated structures that extend along curved paths. For instance, in a relaxed state, the resilient members may extend along curved paths that have similar shapes as the arms that the resilient members will be located within. As one example, the resilient members may be shaped similar to the resilient members **261-264** and **271-274** shown in FIGS. **2B** and **2C**, respectively.

[0080] The method **800** also includes assembling (at **804**) wire conductors and electrodes of the lead. The assembling (at **804**) may include positioning the resilient members relative to the wire conductors and the electrodes. At **806**, an insulative material may be applied (e.g., molded) to the assembly of wire conductors, electrodes, and resilient members. The insulative material may be a biocompatible material, such as the materials described herein. The insulative material may completely cover or insulate the wire conductors and at least partially cover the electrodes. The resilient members may be at least partially covered by the insulative material.

[0081] A lead body may be formed upon applying the insulative material at **806**. The lead body may be similar to other leads or lead bodies described herein, such as the lead body **200**. In particular, the lead body may include a plurality of arms that extend between a distal body end and a proximal body end of the lead body. For example, the arms may include first and second outer arms and an inner arm generally disposed between the first and second outer arms. The first and second outer arms and the inner arm may extend lengthwise between the proximal body end and the distal body end.

[0082] The electrodes may form a multi-electrode array that is configured to apply a neurostimulation therapy. Some

or all of the electrodes may be positioned along the first and second outer arms. Each of the first and second outer arms may include at least one of the resilient members. The resilient members may bias the respective outer arm to flex from a collapsed condition to an expanded condition in a laterally-outward direction. The resilient members may also permit the respective outer arm to flex laterally-inward from the expanded condition to the collapsed condition when a force is applied.

[0083] Optionally, at **808**, a flexible membrane may be applied to a paddle side of the lead body. The flexible membrane may be similar to the flexible membranes **602** or **702** (FIGS. **10** and **12**, respectively). In some embodiments, the flexible membrane may be applied (at **808**) after the lead body is formed. In other embodiments, the flexible membrane may be applied as the lead body is formed. For example, the flexible membrane may be molded with the arms of the lead body. In some embodiments, a flexible membrane may be applied on each of the paddle sides.

[0084] It is to be understood that the subject matter described herein is not limited in its application to the details of construction and the arrangement of components set forth in the description herein or illustrated in the drawings hereof. The subject matter described herein is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of “including,” “comprising,” or “having” and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

[0085] Unless specified or limited otherwise, the terms “mounted,” “connected,” “supported,” and “coupled” and variations thereof are used broadly and encompass both direct and indirect mountings, connections, supports, and couplings. Further, “connected” and “coupled” are not restricted to physical or mechanical connections or couplings. Also, it is to be understood that phraseology and terminology used herein with reference to device or element orientation (such as, for example, terms like “central,” “upper,” “lower,” “front,” “rear,” “distal,” “proximal,” and the like) are only used to simplify description of one or more embodiments described herein, and do not alone indicate or imply that the device or element referred to must have a particular orientation. In addition, terms such as “outer” and “inner” are used herein for purposes of description and are not intended to indicate or imply relative importance or significance.

[0086] It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described embodiments (and/or aspects thereof) may be used in combination with each other. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the presently described subject matter without departing from its scope. While the dimensions, types of materials and coatings described herein are intended to define the parameters of the disclosed subject matter, they are by no means limiting and are exemplary embodiments. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the inventive subject matter should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms “including” and “in which” are used as the plain-English equivalents of the respective

terms “comprising” and “wherein.” Moreover, in the following claims, the terms “first,” “second,” and “third,” etc. are used merely as labels, and are not intended to impose numerical requirements on their objects. Further, the limitations of the following claims are not written in means-plus-function format and are not intended to be interpreted based on 35 U.S.C. §112, sixth paragraph, unless and until such claim limitations expressly use the phrase “means for” followed by a statement of function void of further structure.

[0087] The following claims recite aspects of certain embodiments of the inventive subject matter and are considered to be part of the above disclosure.

What is claimed is:

1. A self-expanding lead comprising:
 - a lead body having a distal body end, a proximal body end, and a central axis extending therebetween, the lead body comprising first and second outer arms and an inner arm disposed generally between the first and second outer arms, the first and second outer arms and the inner arm extending lengthwise between the proximal body end and the distal body end; and
 - an array of electrodes configured to apply a neurostimulation therapy within an epidural space of a patient, at least some of the electrodes being positioned along the first and second outer arms;
 wherein each of the first and second outer arms includes a resilient member that is biased to flex the corresponding first and second outer arms from a collapsed condition to an expanded condition in a lateral direction away from the inner arm, the resilient members permitting the corresponding first and second outer arms to flex toward the inner arm from the expanded condition to the collapsed condition when a force is applied.
2. The self-expanding lead of claim 1, wherein the inner arm includes a steering lumen at the distal body end, the steering lumen sized and shaped to receive an elongated tool for directing the lead body during an insertion process.
3. The self-expanding lead of claim 2, wherein the steering lumen extends through the proximal body end to the distal body end.
4. The self-expanding lead of claim 1, wherein the inner arm includes at least some of the electrodes from the array of electrodes.
5. The self-expanding lead of claim 4, wherein the inner arm includes a respective resilient member that biases the inner arm to flex from a corresponding collapsed condition to a corresponding expanded condition, the resilient member of the inner arm permitting the inner arm to be flexed to the collapsed condition when the force is applied.
6. The self-expanding lead of claim 1, wherein the inner arm is a first inner arm and the lead body includes a second inner arm, each of the first and second inner arms including at least some of the electrodes of the array.
7. The self-expanding lead of claim 1, wherein the first and second outer arms partially define first and second elongated windows, respectively, the first and second elongated windows extending between the proximal body end and distal body end and between the respective outer arm and the inner arm.
8. The self-expanding lead of claim 7, further comprising a flexible membrane that is coupled to the lead body and covers at least one of the first and second elongated windows.
9. The self-expanding lead of claim 7, wherein the lead body has opposite paddle sides when the first and second arms

are in the expanded conditions, the self-expanding lead further comprising a flexible membrane that is coupled to the lead body and covers at least one of the paddle sides.

10. The self-expanding lead of claim 1, wherein each of the first and second arms has an arm cross-section that includes first and second dimensions, the first and second dimensions being perpendicular with respect to each other and differing by at most 50%.

11. A self-expanding lead comprising:

first and second outer arms extending between respective base and distal arm ends;

an inner arm disposed generally between the first and second outer arms, the inner arm extending between a respective base end and a respective distal arm end, the base ends of the inner arm and the first and second outer arms being coupled to each other proximate to a proximal body end of the self-expanding lead; and

a multi-electrode array including a plurality of electrodes, the first and second arms including at least one electrode of the multi-electrode array, wherein each of the first and second outer arms includes a resilient member that is biased to flex the corresponding first and second outer arms from a collapsed condition to an expanded condition in a laterally-outward direction, the resilient members permitting the corresponding first and second outer arms to flex in a laterally-inward direction from the expanded condition to the collapsed condition when a force is applied;

wherein the electrodes of the multi-electrode array are configured to have predetermined positions with respect to one another when the first and second outer arms are in the expanded conditions in order to apply a neurostimulation therapy within an epidural space of a patient.

12. The self-expanding lead of claim 11, wherein the distal arm ends of the inner arm and the first and second outer arms are coupled to each other proximate to a distal body end of the self-expanding lead.

13. The self-expanding lead of claim 11, wherein the inner arm includes a steering lumen, the steering lumen sized and shaped to receive an elongated tool for directing the lead body during an insertion process.

14. The self-expanding lead of claim 11, wherein the inner arm includes electrodes positioned along a length of the inner arm, the electrodes of the inner arm being part of the multi-electrode array.

15. The self-expanding lead of claim 11, wherein the inner arm is a first inner arm and the self-expandable lead also includes a second inner arm, each of the first and second inner arms including electrodes that form part of the multi-electrode array.

16. The self-expanding lead of claim 15, wherein the first outer arm and the first inner arm are adjacent to each other and the second outer arm and the second inner arm are adjacent to each other, the first outer arm and inner arm moving in a common direction toward the second outer arm and the second inner arm when the lead is collapsed.

17. The self-expanding lead of claim 11, wherein the self-expandable lead has opposite paddle sides when the first and second arms are in the expanded conditions, the self-expandable lead further comprising a flexible membrane that is coupled to the lead body and covers at least one of the paddle sides.

18. The self-expandable lead of claim **16**, wherein the flexible membrane extends along only one of the paddle sides.

19. The self-expanding lead of claim **16**, wherein the flexible membrane has electrode openings that expose portions of the electrodes along the at least one paddle side.

20. The self-expanding lead of claim **11**, wherein each of the first and second arms has an arm cross-section that includes first and second dimensions, the first and second dimensions being perpendicular with respect to each other and differing by at most 50%.

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