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(54) ELECTRODE LEADS HAVING NERVE CUFFS WITH INFLATABLE NERVE CUFF STRAIGHTENERS

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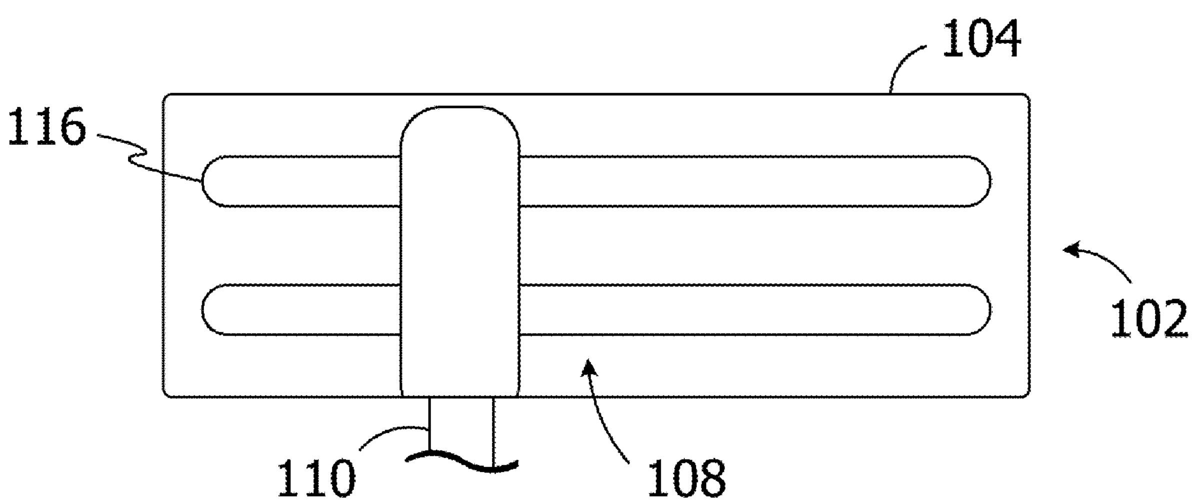
CPC ***A61N 1/0558*** (2013.01); ***A61N 1/0556*** (2013.01)

(57) **ABSTRACT**

An electrode lead comprising an elongate lead body having a proximal end, a distal end and a plurality of electrical conductors, a biologically compatible, elastic, electrically insulative nerve cuff body that is associated with the distal end of the lead body, is configured to be circumferentially disposed around a nerve, has a pre-set furled state that defines an inner lumen and is movable to an unfurled state, a plurality of electrically conductive contacts carried by the nerve cuff body and electrically associated with the electrical conductors, and an inflatable nerve cuff straightener associated with the nerve cuff body and configured to at least substantially straighten the nerve cuff body when in a fully inflated state.



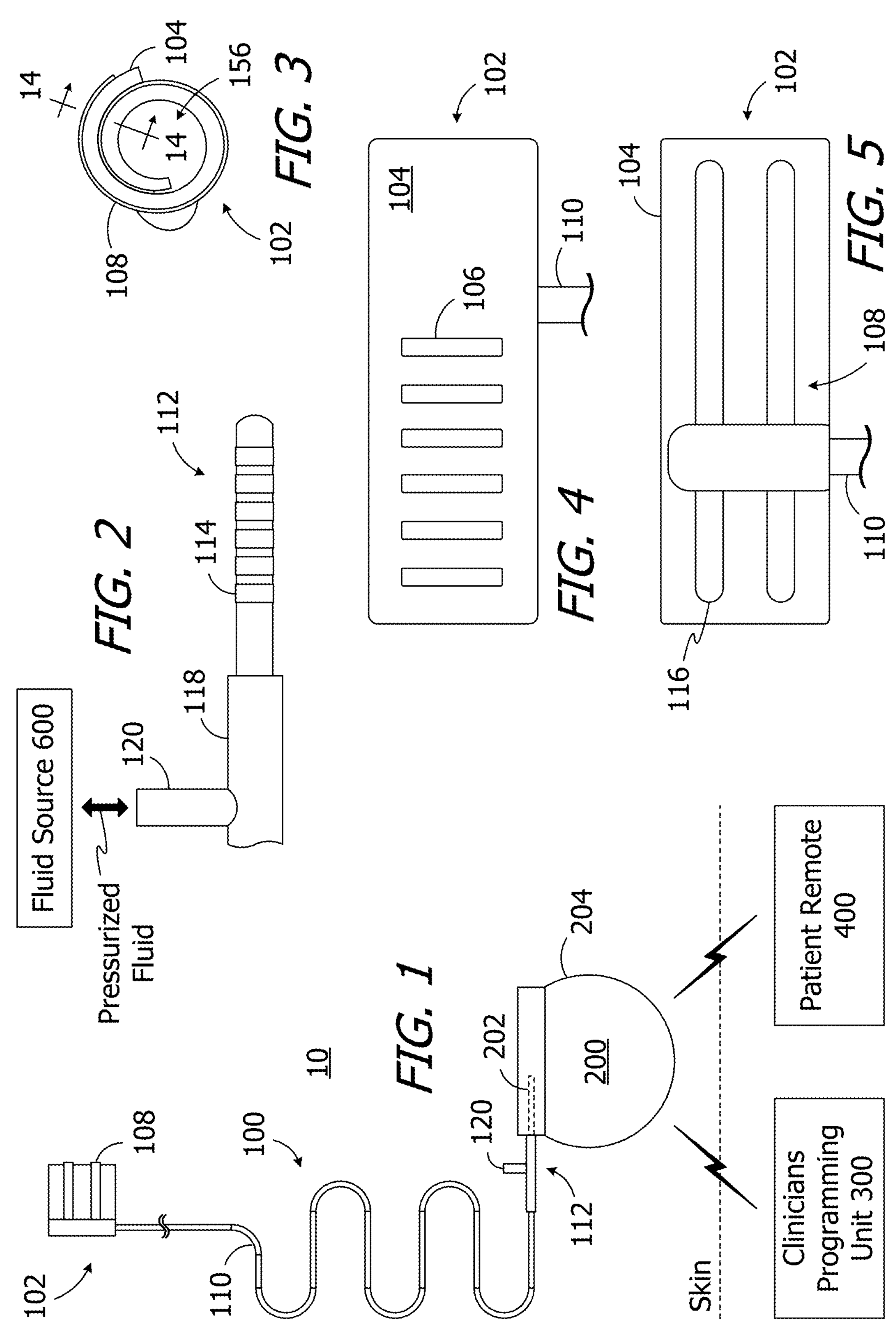


FIG. 1
FIG. 2
FIG. 3
FIG. 4
FIG. 5
Fluid Source 600
Pressurized Fluid
Skin
Clinicians Programming Unit 300
Patient Remote 400
10
100
102
104
106
108
110
112
114
116
118
120
14
156
200
202
204

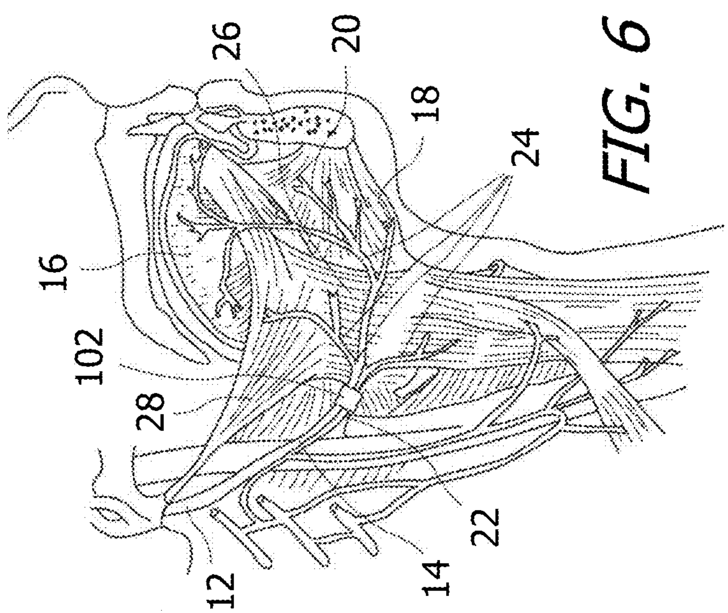


FIG. 6

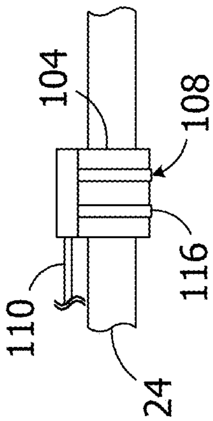


FIG. 7

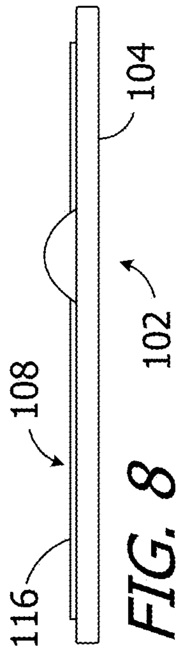


FIG. 8

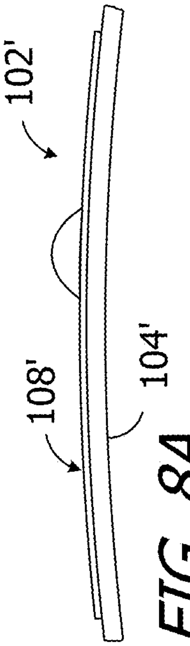


FIG. 8A

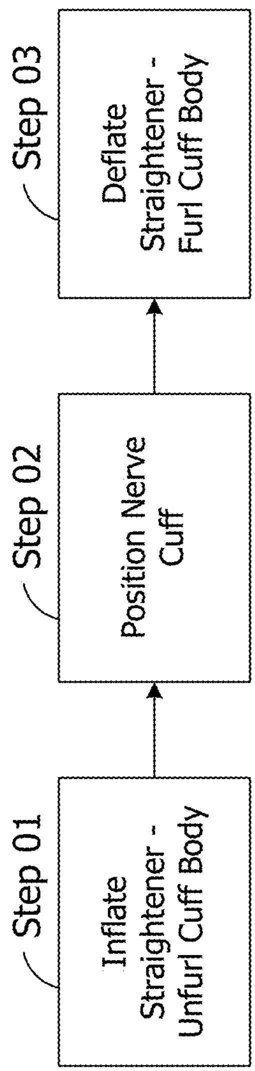


FIG. 9

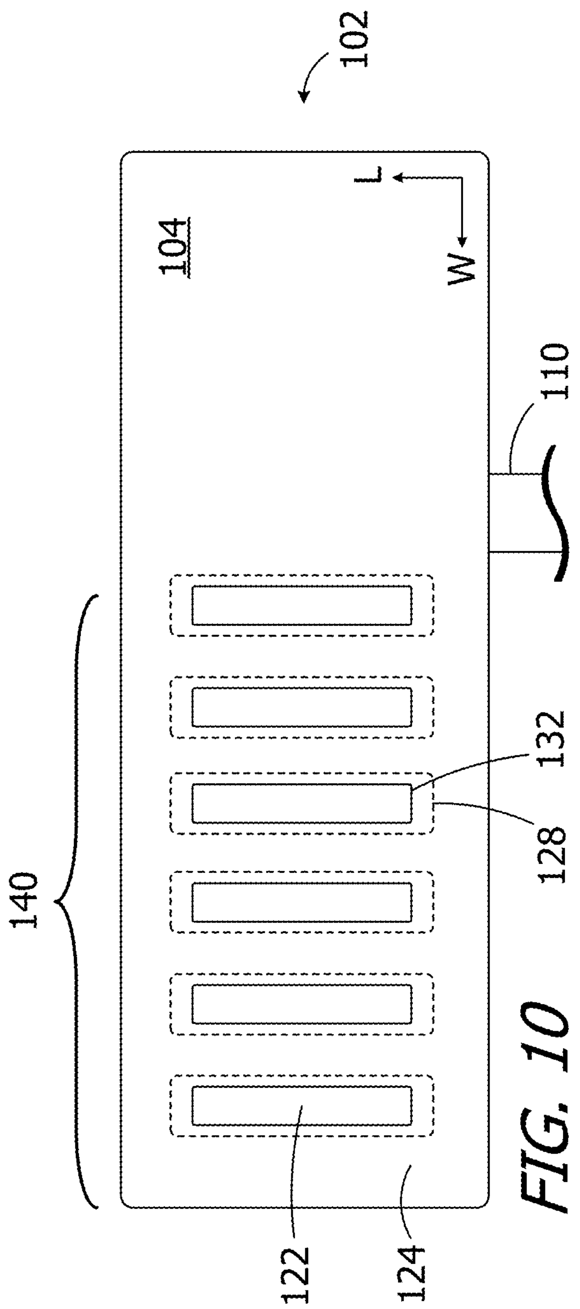

102
104
L
W
110
140
132
128
122
124

FIG. 10

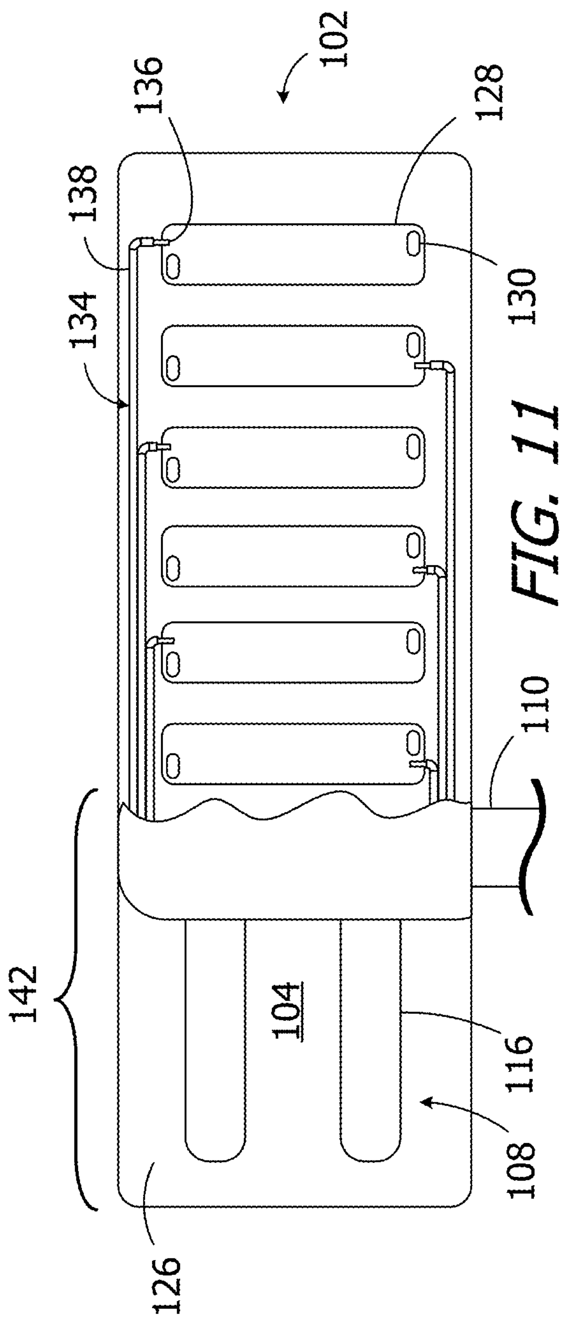

102
136
128
138
134
130
110
142
104
116
108
126

FIG. 11

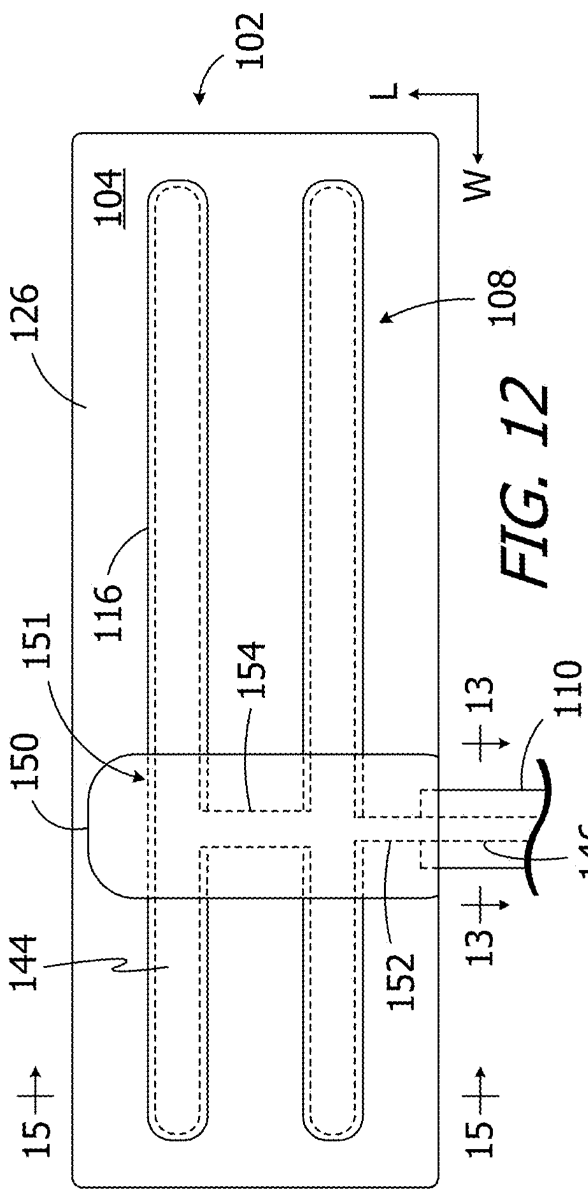


FIG. 12

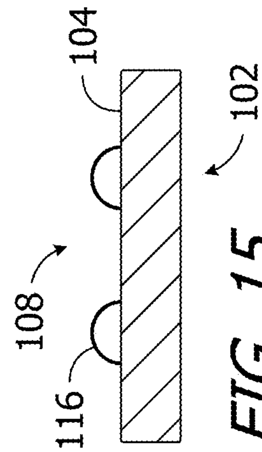


FIG. 15

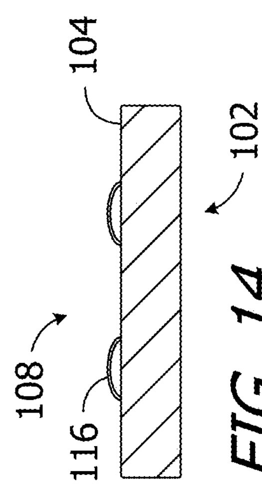


FIG. 14

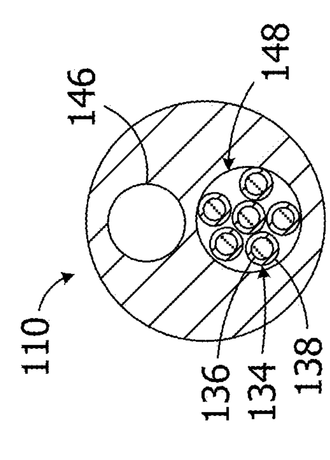


FIG. 13

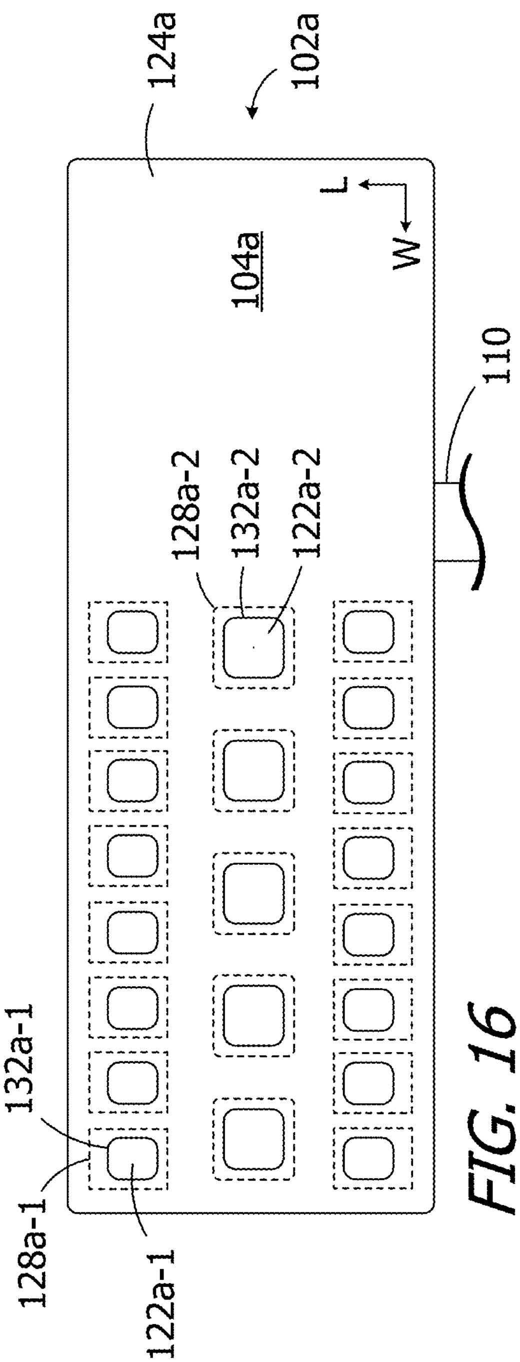

124a
102a
104a
L
W
110
128a-2
132a-2
122a-2
132a-1
128a-1
122a-1

FIG. 16

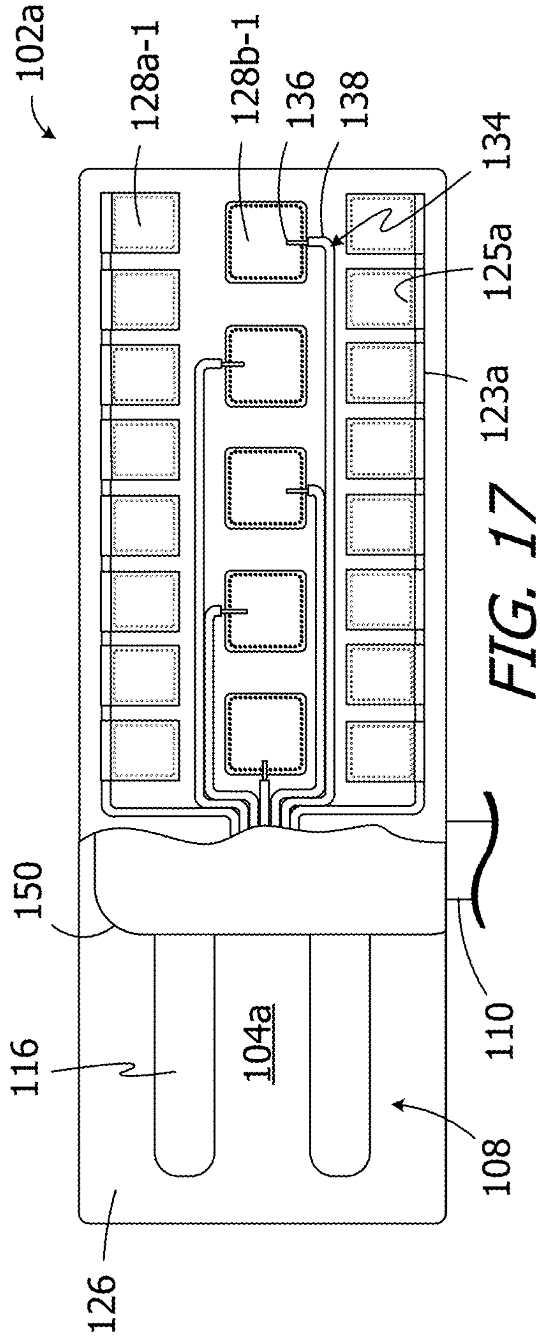

102a
128a-1
128b-1
136
138
134
125a
123a
150
116
104a
110
108
126

FIG. 17

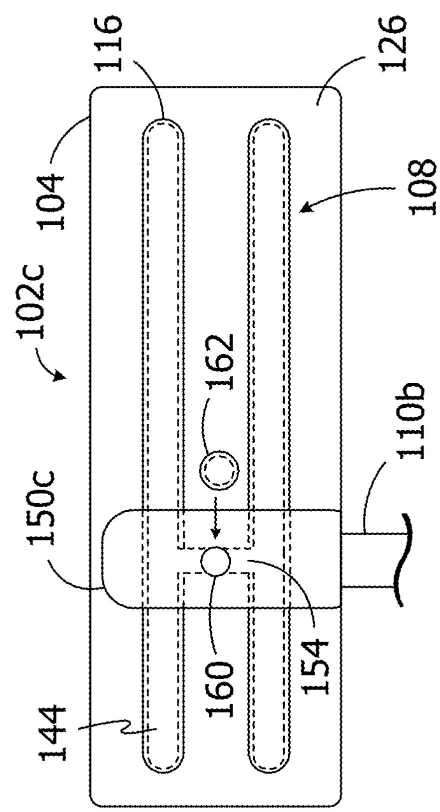


FIG. 19

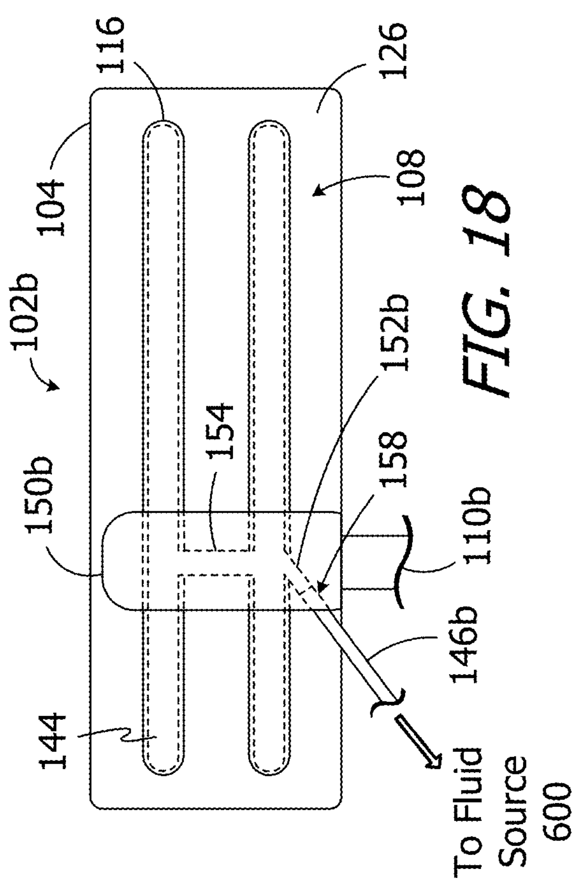


FIG. 18

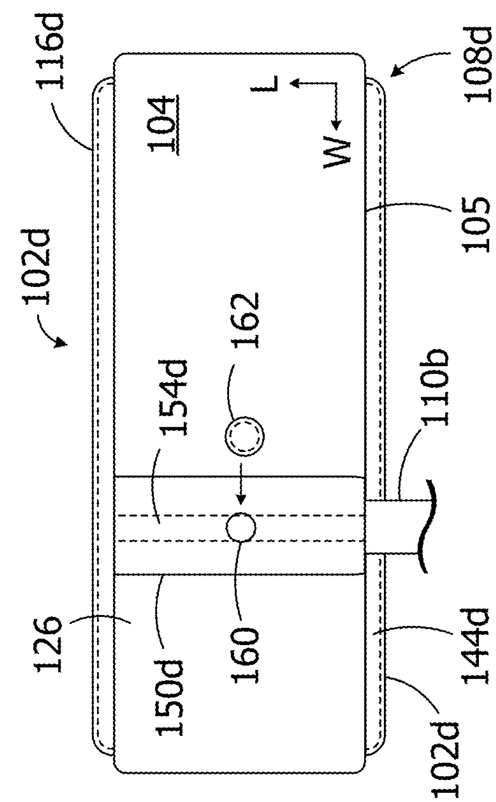


FIG. 20

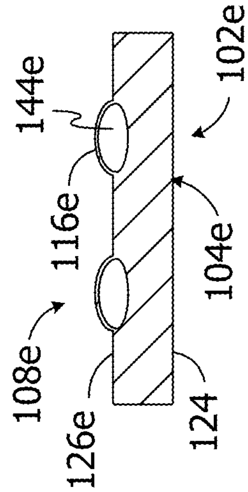


FIG. 24

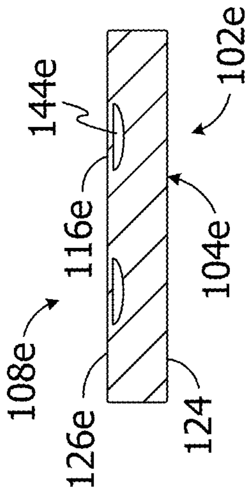


FIG. 22

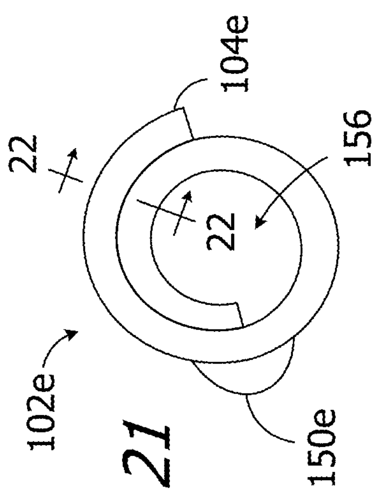


FIG. 21

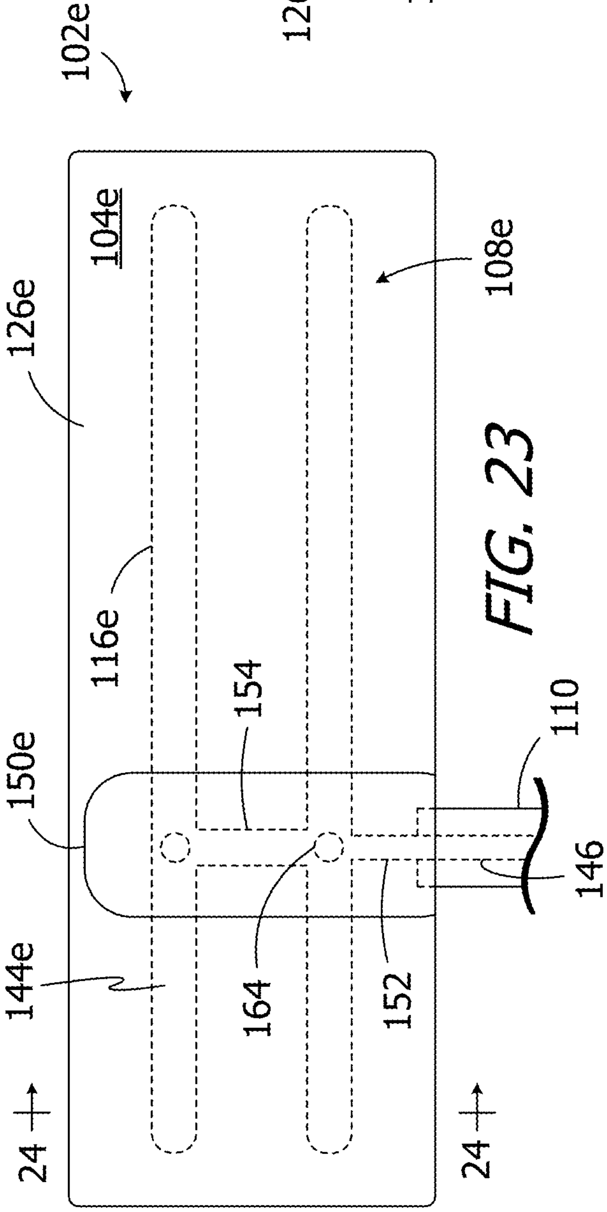


FIG. 23

ELECTRODE LEADS HAVING NERVE CUFFS WITH INFLATABLE NERVE CUFF STRAIGHTENERS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 63/552,445, filed Feb. 12, 2024, and entitled "Inflatable Nerve Cuffs," which is incorporated herein by reference.

BACKGROUND OF THE INVENTIONS

1. Field of Inventions

[0002] The present inventions relate generally to the treatment of obstructive sleep apnea by stimulating the hypoglossal nerve.

2. Description of the Related Art

[0003] Obstructive sleep apnea (OSA) is a highly prevalent sleep disorder that is caused by the collapse of or increase in the resistance of the pharyngeal airway, often resulting from tongue obstruction. The obstruction of the upper airway is mainly caused by reduced genioglossus muscle activity during the deeper states of non-rapid eye movement (NREM) sleep. In some OSA patients, obstruction occurs predominantly during rapid eye movement (REM) sleep. This is known as REM OSA and has different cardiometabolic and neurocognitive risks. Obstruction of the upper airway causes breathing to pause during sleep. Cessation of breathing, in turn, causes a decrease in the blood oxygen saturation level, which is eventually corrected when the person wakes up and resumes breathing. The long-term effects of OSA include, but are not limited to, high blood pressure, heart failure, strokes, diabetes, headaches, and general daytime sleepiness and memory loss.

[0004] Some proposed methods of alleviating apneic events involve the use of neurostimulators to open the upper airway. Such therapy involves stimulating the nerve fascicles of the hypoglossal nerve (HGN) that innervate the intrinsic and extrinsic muscles of the tongue in a manner that prevents retraction of the tongue, which would otherwise close the upper airway during the inspiration portion of the respiratory cycle. In some instances, the trunk of the HGN is stimulated with a nerve cuff, including a cuff body and a plurality of electrically conductive contacts (sometimes referred to as "electrodes") on the cuff body, that is positioned around the HGN trunk. To that end, some nerve cuffs are pre-shaped to a furled state, may assume slightly less furled states, and may be unfurled to a flattened state. The HGN trunk nerve cuff may be configured in such a manner that it can be used to selectively stimulate nerve fascicles which innervate muscles that extend the tongue, while avoiding other nerve fascicles, with what is predominantly radial vector stimulation. HGN branches may also be stimulated. For example, an HGN GM branch may be stimulated with what is predominantly axial vector stimulation.

[0005] Exemplary nerve cuffs are illustrated and described in U.S. Pat. Pub. Nos. 2018/0318577A1, 2018/0318578A1, 2019/0060646A1, 2019/0282805A1, 2022/0062629A1, 2022/0313987A1, 2023/0010510A1, 2023/0241394A1, 2024/0009452A1, and 2024/0108883A1, which are incorporated herein by reference in their entirety.

SUMMARY

[0006] The present inventors have determined that nerve cuffs are susceptible to improvement. In particular, at least some nerve cuffs are pre-set (or "pre-shaped") to a furled (or "curled") state that causes the nerve cuff to self-wrap around the associated nerve. The present inventors have determined that nerve cuffs which are pre-set to a furled state are advantageous because, for example, they do not require the physician to manually wrap the cuff around the nerve and do not require sutures, or specialty clips or clamps, to hold the cuff is place, as do flat nerve cuffs. The present inventors have, nevertheless, determined that conventional nerve cuffs which are pre-set to a furled state are susceptible to improvement. For example, the present inventors have determined that the process of straightening the nerve cuff so that it may be placed around the nerve can be difficult, can damage the nerve cuff, can make it difficult to accurately place the nerve cuff, and can increase the duration of the surgical procedure.

[0007] An electrode lead in accordance with at least one of the present inventions includes an elongate lead body having a proximal end, a distal end and a plurality of electrical conductors, a biologically compatible, elastic, electrically insulative nerve cuff body that is associated with the distal end of the lead body, is configured to be circumferentially disposed around a nerve, has a pre-set furled state that defines an inner lumen and is movable to an unfurled state, a plurality of electrically conductive contacts carried by the nerve cuff body and electrically associated with the electrical conductors, and an inflatable nerve cuff straightener associated with the nerve cuff body and configured to at least substantially straighten the nerve cuff body when in a fully inflated state. The present inventions also include systems with an implantable pulse generator or other implantable stimulation device in combination with such an electrode lead.

[0008] A method in accordance with at least one of the present inventions includes at least partially unfurling a nerve cuff, having a pre-set furled state that defines an inner lumen, by supplying pressurized fluid (i.e., liquid or gas) to the nerve cuff, positioning the at least partially unfurled nerve cuff adjacent to a nerve, and allowing the at least partially unfurled nerve cuff to return to the pre-set furled state, with the nerve located within the inner lumen, by removing at least some of the pressurized fluid from the nerve cuff.

[0009] There are several advantages associated with the present electrode leads and methods. Byway of example, but not limitation, the present electrode leads and methods simplify the process of straightening the nerve cuff so that it may be placed around the nerve. The physician can also selectively adjust the curvature of the nerve cuff by varying the pressure within the inflatable cuff straightener as the nerve cuff is being positioned around the HGN trunk or HGN GM branch. The nerve cuff will return to the pre-shaped furled state around the nerve when the pressurized fluid is removed therefrom. The ability to selectively unstraighten portions of the nerve cuff and adjust the curvature with the movable cuff straightener reduces the difficulty, duration and likelihood of cuff damage associated with the implantation process.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Detailed descriptions of exemplary embodiments will be made with reference to the accompanying drawings.

[0011] FIG. **1** is a plan view of a stimulation system including an electrode lead in accordance with one embodiment of a present invention.

[0012] FIG. **2** is a side view of a portion of the stimulation system illustrated in FIG. **1**.

[0013] FIG. **3** is a side view showing the nerve cuff illustrated in FIG. **1** in a pre-shaped furled and uninflated state.

[0014] FIG. **4** is a front view of the nerve cuff illustrated in FIG. **1** in an unfurled and inflated state.

[0015] FIG. **5** is a rear view of the nerve cuff illustrated in FIG. **1** in an unfurled and inflated state.

[0016] FIG. **6** is a cut-away anatomical drawing of the head and neck area illustrating the muscles that control movement of the tongue, the HGN and its branches that innervate these muscles, and the nerve cuff illustrated in FIG. **1** on the HGN trunk.

[0017] FIG. **7** is a side view showing the nerve cuff illustrated in FIG. **1** in a pre-shaped furled state around an HGN branch.

[0018] FIG. **8** is a side view of the nerve cuff illustrated in FIG. **1** in an unfurled and inflated state.

[0019] FIG. **8**A is a side view of a nerve cuff in accordance with one embodiment of a present invention in an unfurled and inflated state.

[0020] FIG. **9** is a flow chart showing a method in accordance with one embodiment of a present invention.

[0021] FIG. **10** is a front view of the nerve cuff illustrated in FIG. **1** in an unfurled and inflated state.

[0022] FIG. **11** is a rear, cutaway view of the nerve cuff illustrated in FIG. **1** in an unfurled and inflated state.

[0023] FIG. **12** is a rear view of the nerve cuff illustrated in FIG. **1** in an unfurled and inflated state.

[0024] FIG. **13** is a section view taken along line **13-13** in FIG. **12**.

[0025] FIG. **14** is a section view taken along line **14-14** in FIG. **3**.

[0026] FIG. **15** is a section view taken along line **15-15** in FIG. **12**.

[0027] FIG. **16** is a front view of a nerve cuff in accordance with one embodiment of a present invention in an unfurled and inflated state.

[0028] FIG. **17** is a rear, cutaway view of the nerve cuff illustrated in FIG. **16** in an unfurled and inflated state.

[0029] FIG. **18** is a rear view of a nerve cuff in accordance with one embodiment of a present invention in an unfurled and inflated state.

[0030] FIG. **19** is a rear view of a nerve cuff in accordance with one embodiment of a present invention in an unfurled and inflated state.

[0031] FIG. **20** is a rear view of a nerve cuff in accordance with one embodiment of a present invention in an unfurled and inflated state.

[0032] FIG. **21** is a side view showing a nerve cuff in accordance with one embodiment of a present invention in a pre-shaped furled and uninflated state.

[0033] FIG. **22** is a section view taken along line **22-22** in FIG. **21**.

[0034] FIG. **23** is a rear view of the nerve cuff illustrated in FIG. **21** in an unfurled and inflated state.

[0035] FIG. **24** is a section view taken along line **24-24** in FIG. **23**.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

[0036] The following is a detailed description of the best presently known modes of carrying out the inventions. This description is not to be taken in a limiting sense but is made merely for the purpose of illustrating the general principles of the inventions.

[0037] Referring to FIGS. **1-5**, a stimulation system **10** in accordance with one embodiment of a present invention includes an electrode lead **100** and an implantable stimulator such as the implantable pulse generator ("IPG") **200**. A clinician's programming unit **300**, a patient remote **400** and an IPG charger (not shown) may also be provided in some instances. The exemplary electrode lead **100** includes a nerve cuff **102**, with a cuff body **104**, electrically conductive contacts (or "electrodes") **106** and an inflatable cuff straightener **108**, and a lead body **110**. The lead body **110** couples the nerve cuff **102** to the IPG **200** by way of a lead connector **112** with contacts **114** on the proximal end of the lead body **110** and a corresponding connector receptacle **202** on the IPG **200**. The exemplary cuff body **104** and electrically conductive contacts **106** are discussed in greater detail below with reference to FIGS. **10** and **11**. The inflatable cuff straightener **108** may be used to straighten cuff body **104** (and the nerve cuff **102**) to facilitate placement onto and around a nerve. For example, the cuff body **104** (and nerve cuff **102**) may be pre-set (or "pre-shaped") to the furled (or "curled") state illustrated in FIG. **3**, where the inflatable cuff straightener **108** is in an uninflated state, which allows the cuff body **104** to be circumferentially disposed around either the HGN trunk or a HGN branch (e.g., the HGN GM branch), as is described below with reference to FIGS. **6** and **7**. The inflatable cuff straightener **108** may be inflated with a pressurized fluid to such an extent that the inflatable cuff straightener **108** straightens, thereby overcoming the stiffness of the cuff body **104** and straightening the cuff **102** in the manner illustrated in FIGS. **4** and **5**.

[0038] The exemplary inflatable cuff straightener **108** includes two inflatable members **116**, although the number of inflatable members may be increased or decreased. Any suitable pressurized fluid (liquid or gas) may be supplied to and used to inflate the inflatable members **116**, which are described in greater detail below with reference to FIGS. **12-15**. The pressurized fluid may be supplied by a fluid source **600**, as is described below. To that end, in some implementations, the lead connector **112** includes a grip zone **118** with a fluid port **120**. The fluid port **120**, which is configured to be connected to the fluid source **600**, is in fluid communication with a fluid lumen **146** (FIG. **13**) within the lead body **110** that extends to the nerve cuff where it is fluidically coupled to the inflatable members **116**. Fluid may be supplied to inflatable cuff straighteners in other ways, as is discussed below with reference to FIGS. **18** and **19**.

[0039] The exemplary lead body **110** may also include one or more S-shaped sections (FIG. **1**) to provide strain relief (as shown) or may be straight. The S-shaped sections accommodate body movement at the location within the neck where the lead body **110** is implanted, thereby reducing the likelihood that the HGN will be damaged due to unavoidable pulling of the electrode lead **100** that may result from neck movements. The accommodation provided by the S-shaped sections also reduces the likelihood of fatigue damage. Additionally, although the exemplary system **10** includes a single electrode lead **100**, other embodiments may include a pair of electrode leads **100** for bilateral HGN stimulation and an IPG (not shown) with two connector receptacles.

[0040] Turning to FIG. **6**, and as alluded to above, the nerve cuff **102** may be positioned around the trunk **14** of the HGN **12** and used to stimulate the muscles that anteriorly move the tongue **16** and, in particular, the fascicles of the HGN **12** that innervate the tongue protrusor muscles, such as the genioglossus **18** and/or the geniohyoid muscles **20**. The nerve cuff **102** is positioned on the HGN trunk **14** at a position **22** proximal to the HGN branches **24**. Although there are advantages to implanting the nerve cuff **102** at this proximal position **22**, i.e., reduced surgical time and effort as well as reduced risk and trauma to the patient, it introduces the problem of inadvertently stimulating other fascicles of the HGN trunk **14** that innervate muscles in opposition to the genioglossus **18** and/or the geniohyoid muscles **20**, i.e., the tongue retractor muscles, e.g., the hyoglossus **26** and styloglossus muscles **28**, as well as the intrinsic muscles of the tongue **16**. Accordingly, while some clinicians may desire to stimulate the HGN **12** at the HGN trunk **14**, others may desire to stimulate the HGN at the GM branch **24**. As illustrated in FIG. **7**, the nerve cuff **102** is configured in such a manner that it may be positioned the HGN GM branch **24** as well as the trunk **14** in various furled states. In the illustrated implementation, the nerve cuff **102** is pre-set (or "pre-shaped") to the furled (or "curled") state illustrated in FIG. **7**.

[0041] In one exemplary method of using the inflatable cuff straightener **108** to facilitate positioning of the nerve cuff **102** of the electrode lead **100** (as well as the other inflatable cuff straighteners and nerves cuffs described herein) around the HGN trunk **14** or HGN GM branch **24**, pressurized fluid is supplied by a fluid source **600** to the inflatable members **116**. Full pressurization will result in the nerve cuff transitioning from the furled state to an at least substantially straightened state, i.e., either a straightened state or slightly curved state depending on the characteristics of the various aspects of the nerve cuff and pressure of the supplied fluid. The respective characteristics of the cuff body **104** and the inflatable cuff straightener **108** result in the nerve cuff **102** transitioning to a straightened state illustrated in FIG. **8** at full pressurization. In other instances, the respective characteristics of the cuff body **104'** and the inflatable cuff straightener **108'** result in the nerve cuff **102'** transitioning to a slightly curved, at least substantially straightened state such as that illustrated in FIG. **8**A at full pressure.

[0042] One exemplary method of positioning the present nerve cuffs is summarized in the flow chart illustrated in FIG. **9** and is described in the exemplary context of nerve cuff **102**. The illustrated method is also applicable to the other nerve cuffs described herein. First, the inflatable members **116** of the cuff straightener **108** are inflated to unfurl and at least substantially straighten the cuff body **104** (Step **01**). The inflation may be performed at the time of the implantation surgery or at any other appropriate time. The pressure may be modulated as the nerve cuff is being positioned around the HGN trunk or HGN GM branch (Step **02**) to selectively adjust the curvature of the cuff body **104** (and nerve cuff **102**). Removal of the fluid, e.g., by applying suction with the fluid source **600** or by allowing the structural biasing force that pre-shapes the cuff body **104** to drive the fluid out, deflates the inflatable members **116** (Step **03**) and returns the cuff body **104** to a furled state, such as that illustrated in FIGS. **3**, **6** and **7**, with the nerve cuff **102** wrapped around the HGN trunk or HGN GM branch. The fluid source **600** may also be disconnected from the nerve cuff after depressurization.

[0043] The present electrode leads may include any suitable nerve cuff configuration. As illustrated for example in FIGS. **10** and **11**, the exemplary nerve cuff **102** includes the cuff body **104**, which defines a length L and a width W that is greater than the length in the unfurled state, and a plurality of electrically conductive contacts (or "contacts") **122** on the cuff body **104**. Such contacts may also be referred to as "electrodes." Although the present inventions are not so limited, the contacts **122** are relatively narrow contacts, i.e., are contacts with a greater length than width, and are spaced from one another in the width direction. Although the number may increase or decrease in the context of other nerve applications, there are six contacts **122** in the illustrated embodiment. With respect to shape, and although the present inventions are not so limited, the contacts **122** are the same shape, i.e., rectangles with rounded corners. The contacts **122** are also the same size. In other implementations, the contacts within a particular nerve cuff may differ in shape, size, and/or orientation. Other exemplary contact shapes include, but are not limited to, rounded rectangles, circles, ovals, and squares. Some or all of the contacts may also be relatively wide, as is discussed below with reference to FIGS. **16** and **17**.

[0044] The cuff body **104** and contacts **122** may be of any suitable construction. In the illustrated implementation, the cuff body **104** includes a front layer **124** that will face the HGN trunk or branch (and defines the front surface) and a rear layer **126** that will face away from the HGN trunk or branch (and defines the rear surface). Conductive members **128** are located between the front layer **124** and rear layer **126** and may also include apertures **130** that, in conjunction with the material that forms the front and rear layers and enters the apertures, anchor the conductive members in their intended locations. The conductive members **128** are each exposed by way of respective openings **132** in the cuff body front layer **124**. The openings **132** are located inwardly of the outer perimeter of the conductive members **128**, which are shown in dashed lines in FIG. **10**. Referring to FIG. **11**, the contacts **122** in the illustrated embodiment may be individually electrically connected to the plurality contacts **114** on the lead connector **112** (FIG. **2**) by wires **134** that extend through the lead body **110**. Each wire **134** includes a conductor **136** and an insulator **138**. The conductors **136** may be connected to the rear side of the conductive members **128** by welding or other suitable processes. The cables or other electrical conductors may be employed in place of the wires **134** in other implementations.

[0045] With respect to the location of the contacts **122** in the exemplary nerve cuff **102**, the cuff body **104** includes a stimulation region **140** and a compression region **142**. The contacts **122** are located within the stimulation region **140**. There are no contacts located within the compression region **142**. The compression region **142** wraps around at least a portion of the stimulation region **140** when the nerve cuff **102** is in the pre-shaped furled state and slightly larger, expanded and less tightly furled states, thereby resisting (but not preventing) expansion of the stimulation region and improving the electrical connection between the contacts **122** and the HGN.

[0046] Turning to FIGS. **12-15**, and as alluded to above, the exemplary inflatable cuff straightener **108** includes two inflatable members **116** that are located on the rear surface of the cuff body **104**. The inflatable members **116** define internal pressure chambers **144** that are connected to the fluid source **600** by way of the exemplary lead body **110**. To that end, the exemplary lead body **110** may include an internal fluid lumen **146** and an internal wire lumen **148**, and the nerve cuff **102** may include a manifold **150** that is secured to rear layer **126** of the cuff body **104**, with lumens **152** and **154**, to anchor the lead body **110** to the rear layer **126** of the cuff body **104**. Lumen **152** fluidically connects the fluid lumen **146** to one of the pressure chambers **144**, and lumen **154** connects the pressure chambers **144** to one another. The manifold **150** also functions as a strain relief and provides passage for the wires **134**.

[0047] In the illustrated implementation, the manifold **150** defines passages **151** that the inflatable members **116** extend through. The size and shape of the passages corresponds to the size and shape of the inflatable members **116** in their deflated states. To that end, it should be noted that the exemplary inflatable members **116** may be elastomeric and expand linearly with pressure when the inflated, or may simply be flexible but not elastomeric. An elastomeric inflatable member **116** may in some instances bulge, and slightly re-furl the nerve cuff **102**, if it is inflated to such an extent that it elongates. A non-elastomeric inflatable member **116** will not bulge if overinflated. It will simply straighten the cuff and will collapse to a relatively thin or small profile when deflated.

[0048] The inflatable members **116** of the exemplary cuff straightener **108**, which are shown in a deflated state in FIGS. **3** and **14** and in an inflated state in FIGS. **12** and **15**, may be separately formed structures that are secured to the rear side of the cuff body **104** or may be an integral part of the rear layer **126**. Other configurations are described below with reference to FIGS. **20-24**. In any case, the configuration of the inflatable members **116** and the degree of pressurization provided by the fluid source **600** are sufficient to hold cuff body in the unfurled state illustrated in in FIGS. **12** and **15**.

[0049] In the illustrated implementation, the inflatable members **116** (and inflatable cuff straightener **108**) define a length and a width that is greater than the length. The width of the inflatable members **116** (and inflatable cuff straightener **108**) is slightly less, i.e., about 10% less, than the width of the cuff body in the embodiment illustrated in FIG. **12**. The width of the inflatable members **116** (and inflatable cuff straightener **108**) may range from about 60% to about 100% of the width of the cuff body **104**. As used herein in the context of percentages, the word "about" means±10-20%, although the width of the inflatable members **116** (and inflatable cuff straightener **108**) will typically not be greater than the width of the cuff body **104**.

[0050] The pressurized fluid supplied by the fluid source **600** may be a gaseous fluid, such as air or helium, a liquid fluid such as water or saline, any other sufficiently compliant media, and combinations thereof. The fluid source **600** may be configured to create both positive and negative fluid pressures in order to inflate and deflate the inflatable members **116** of the inflatable cuff straightener **108**. Suitable fluid sources include, but are not limited to, pumps and syringes, and may include a coupling (not shown) that is configured to connect to the fluid port **120** (FIGS. **1** and **2**).

[0051] In some instances, one of more valves (not shown) that regulated the flow of pressurized fluid, prevent overinflation, and/or prevent pressurized fluid from escaping prematurely may be provided. The valve(s) may, for example, be associated with the fluid port **120** (FIG. **2**), the port **160** (FIGS. **19** and **20**), and/or the fluid source **600** (FIG. **2**).

[0052] With respect to materials and dimensions, the exemplary cuff body **104** may be formed from any suitable material. Such materials may be biologically compatible, electrically insulative, elastic and capable of functioning in the manner described herein. By way of example, but not limitation, suitable cuff body materials include silicone, polyurethane and styrene-isobutylen-styrene (SIBS) elastomers. Suitable materials for the contacts **122** include, but are not limited to, platinum-iridium and palladium. The cuff materials should be pliable enough to allow inflatable cuff straightener **108** or a clinician to hold the cuff body **104** (and nerve cuff **102**) in an unfurled state when the nerve cuff **102** is being placed around the HGN trunk (or HGN GM branch). The exemplary materials are also resilient enough to cause the nerve cuff return **102** to the pre-shaped furled state illustrated in FIG. **3** when the inflatable members **116** are deflated, yet flexible enough to allow the cuff body **104** (and nerve cuff **102**) to instead assume the slightly larger, expanded and less tightly furled, furled states. For example, the inner lumen **156** defined by the cuff body **104** (and nerve cuff **102**) in FIG. **3** is sized to accommodate an HGN structure that has a diameter of about 2.5 mm (e.g., the HGN GM branch **24**). The cuff body **104** (and nerve cuff **102**) is also cable of assuming less furled states that are less tightly furled to, for example, accommodate an HGN structure that has a diameter of about 3.0 mm (e.g., the HGN GM branch **24** in a swollen state) and an HGN structure that has a diameter of about 4.0 mm (e.g., the HGN trunk **14**). The ability to assume slightly larger, expanded and less tightly furled states, in addition to the smaller fully furled state, allows the same nerve Cuff **102** to accommodate either of the larger HGN trunk **14** or a smaller HGN branch **24**. The ability to assume slightly larger, expanded furled states also allows the nerve cuff to accommodate nerve swelling that may occur post-surgery and to self-adjust to a smaller state when the swelling subsides. It should also be noted here that the width of the stimulation region **140** is such that it extends completely around the inner lumen **156**, i.e., 360° or more around the longitudinal axis of the inner lumen, when the cuff body **104** is in the fully furled state illustrated in FIG. **3** that accommodates an HGN structure having a diameter of about 2.5 mm. The stimulation region **140** also extends substantially around the inner lumen **156**, i.e., at least 288° in some examples and 360° or more in other examples, when the cuff body **104** is in an expanded and less tightly furled state that accommodates an HGN structure having a diameter of about 4.0 mm. The dimensions of the present nerve cuffs, including the various elements thereof, may by any dimensions that result in the nerve cuffs functioning as intended. With respect to the dimensions of the cuff body **104** of the exemplary nerve cuff **104**, and referring to FIGS. **10** and **11**, the cuff body is about 1.1 inches wide and about 0.34 inches long. As used herein in the context of dimensions, the word "about" means±10-20%. The width of the stimulation region **140** is about 0.6 inches, while the width of the compression region **142** is about 0.5 inches.

[0053] Turning to the inflatable members **116**, the inflatable members may be formed from any suitable material that can accommodate elastic pressurization during inflation. Pliable, elastic, and biocompatible materials such as silicone, nylon, Urethane, vinyl, latex rubber, PET and polyolefins or combinations thereof, may be employed. Non-biocompatible materials may be coated with a layer of biocompatible material and sufficiently sealed within the interior of the cuff body.

[0054] The embodiments described above are susceptible to a wide variety of modifications. For example, the present inventions are not limited to any particular cuff body or contact configuration. Nerve cuffs with helical cuff bodies and/or nerve cuffs with coil contacts may include any of the inflatable cuff straighteners described herein. One exemplary alternative contact configuration is illustrated in FIGS. **16** and **17** in the context of exemplary nerve cuff **102***a*. Nerve cuff **102***a* is substantially similar to nerve cuff **102** and similar elements are represented by similar reference numerals. Here, however, the nerve cuff **102***a* includes first and second pluralities of electrically conductive contacts **122***a***-1** on the cuff body **104***a*, and a plurality of electrically conductive contacts **122***a***-2** between the first and second pluralities of electrically conductive contacts **122***a***-1**. The contacts **122***a***-1** in are spaced from one another in the width direction, as are the contacts **122***a***-2**, and the contacts may also be referred to as "electrodes." The contacts **122***a***-1** within each plurality are connected to one another in series and function as a single relatively wide contact. To that end, the contacts **122***a***-1** within each plurality are connected to a single wire **134** with crimp regions **123***a*. The contacts **122***a***-2** are not connected to one another in series and are instead each connected to a separate wire **134**. Additionally, as compared to the each of the pluralities of contacts **122***a***-1**, the contacts **122***a***-2** are relatively narrow. The contacts **122***a***-1** and **122***a***-2** are formed by conductive members **128***a***-1** and **128***a***-2**, which are located between the front layer **124***a* and the rear layer **126** and are exposed by way of windows **132***a***-1** and **132***a***-2** in the cuff body front layer **124***a*. In some instances, the conductive members **128***a***-1** and **128***a***-2** may include a plurality of holes **125***a* that extend completely through the conductive members **128***a***-1** and **128***a***-2** and through which the cuff body material extends, thereby forming anchors that reduce the likelihood of delamination and/or conductive member dislodgement.

[0055] Other exemplary cuff body and contact configurations that may be employed in either instance include, but are not limited to, those illustrated and described in U.S. Pat. Pub. Nos. 2018/0318577A1, 2018/0318578A1, 2019/0060646A1, 2019/0282805A1, 2022/0062629A1, 2022/0313987A1, 2023/0010510A1, 2023/0241394A1, 2024/0009452A1, and 2024/0108883A1.

[0056] Turning to non-limiting examples of other inflatable cuff straighteners, the exemplary nerve cuff **102***b* illustrated in FIG. **18** is substantially similar to nerve cuff **102** and similar elements are represented by similar reference numerals. Here, however, the lead body **110***b* does not include a fluid lumen and the manifold **150***b* is connected to the fluid source **600** by way of a separate fluid tube **146***b*. The exemplary fluid tube **146***b* is permanently connected to the manifold lumen **152***b* at a port **158**. After the inflatable cuff straightener **108** has been inflated and deflated and the nerve cuff **102***b* is positioned on a nerve, the fluid tube **146***b* may be severed and in some instances sealed (e.g., with a clip or heat). Alternatively, as shown in FIG. **19**, the nerve cuff **102***c* includes a manifold **150***c* with a port **160** that is configured to receive a coupling (not shown) at the end of a tube that is connected to the fluid source **600**. A plug **162** may be used to seal the port **160**.

[0057] The location of the inflatable cuff straightener is not limited to the rear side of the cuff body. By way of example, but not limitation, inflatable members may be located on the side edges of a cuff body. To that end, and referring to FIG. **20**, the exemplary nerve cuff **102***d* is substantially similar to nerve cuff **102** and similar elements are represented by similar reference numerals. Here, however, the inflatable cuff straightener **108***d* includes a pair of inflatable members **116***d*, with internal pressure chambers **144***d*, that extend in the width direction along the side edges **105** of the cuff body **104**. The inflatable members **116***d* may be only on the side edges **105** (as shown), or may have small portions than extend onto the front and/or rear surfaces **124** and **126** of the cuff body **104**. The nerve cuff **102***d* also includes a manifold **150***d* with a lumen **154***d* that is fluidically connected to both of the pressure chambers **144***d*. Pressurized fluid may pass in and out of the manifold **150***d* by way of a port **160** that is configured to receive a coupling (not shown) at the end of a tube that is connected to the fluid source **600**. Here too, a plug **162** may be used to seal the port **160**.

[0058] Inflatable cuff straighteners may also be located within nerve cuff bodies. For example, the nerve cuff **102***e* illustrated in FIGS. **21-24** is substantially similar to nerve cuff **102** and similar elements are represented by similar reference numerals. Here, however, the inflatable cuff straightener **108***e* is located within, and is formed by, portions of the cuff body **104***e*. In particular, the exemplary cuff straightener **108***e* includes a pair of inflatable members **116***e*, with internal pressure chambers **144***e*, that are located under the rear surface (i.e., are located between the front and rear surfaces) and are formed at least in part by the rear layer **126***e*. The internal pressure chambers **144***e* are connected to the lumen **154** within manifold **150***e* by apertures **164**. Supplying pressurized fluid to the pressure chambers **144***e* (e.g., with the fluid source **600**), thereby pressurizing and straightening the inflatable members **116***e*, distends and straightens the inflatable members **116***e*, thereby driving the cuff body **104***e* from the furled state illustrated in FIGS. **21** and **22** to the unfurled state illustrated in FIGS. **23** and **24**. The cuff body **104***e* will return to the furled state when the pressurized fluid is removed.

[0059] Although the inventions disclosed herein have been described in terms of the preferred embodiments above, numerous modifications and/or additions to the above-described preferred embodiments would be readily apparent to one skilled in the art.

[0060] By way of example, although the exemplary cuff straighteners described above include two fluidically connected inflatable members, the present inventions are not so limited. Other embodiments may include a single inflatable member, more than two inflatable members, and/or multiple inflatable members that are fluidically isolated from one another and are separately inflatable.

[0061] It is intended that the scope of the present inventions extend to all such modifications and/or additions. The inventions include any and all combinations of the elements from the various embodiments disclosed in the specification. The scope of the present inventions is limited solely by the claims set forth below.

1. An electrode lead, comprising:
an elongate lead body having a proximal end, a distal end and a plurality of electrical conductors;
a biologically compatible, elastic, electrically insulative nerve cuff body that is associated with the distal end of the lead body, is configured to be circumferentially disposed around a nerve, has a pre-set furled state that defines an inner lumen and is movable to an unfurled state;
a plurality of electrically conductive contacts carried by the nerve cuff body and electrically associated with the electrical conductors; and
an inflatable nerve cuff straightener associated with the nerve cuff body and configured to at least substantially straighten the nerve cuff body when in a fully inflated state.

2. The electrode lead claimed in claim **1**, wherein
the nerve cuff body defines a front surface and a rear surface; and
the inflatable nerve cuff straightener is located on the rear surface.

3. The electrode lead claimed in claim **1**, wherein
the nerve cuff body defines a front surface and a rear surface; and
the inflatable nerve cuff straightener is located between the front surface and the rear surface.

4. The electrode lead claimed in claim **1**, wherein
the nerve cuff body defines a front surface, a rear surface and side surfaces; and
the inflatable nerve cuff straightener is located on at least one of the side surfaces.

5. The electrode lead claimed in claim **1**, wherein
the elongate lead body includes a fluid lumen that is in fluid communication with the inflatable nerve cuff straightener.

6. The electrode lead claimed in claim **1**, wherein
the elongate lead body does not include a fluid lumen.

7. The electrode lead claimed in claim **5**, further comprising:
a manifold on the nerve cuff body that is in fluid communication with the inflatable nerve cuff straightener.

8. The electrode lead claimed claim **1**, wherein,
inflatable nerve cuff straightener comprises at least one inflatable member.

9. The electrode lead claimed in claim **8**, wherein,
inflatable nerve cuff straightener comprises a plurality of inflatable members.

10. The electrode lead claimed in claim **1**, wherein,
the nerve cuff body defines a length, a width in the unfurled state that is greater than the length, and a width direction; and
the inflatable nerve cuff straightener defines a length and a width in the unfurled state that is greater than the length and that is at least 60% of the width of the nerve cuff body.

11. The electrode lead claimed in claim **1**, wherein,
the nerve cuff body defines a length, a width in the unfurled state that is greater than the length, and a width direction; and
the electrically conductive contacts each define a length and a width that is less than the length;
the electrically conductive contacts are spaced from one another in the width direction of the nerve cuff body.

12. The electrode lead claimed in claim **1**, wherein,
the nerve cuff body defines a length, a length direction, a width in the unfurled state that is greater than the length, and a width direction; and
the electrically conductive contacts comprise first and second relatively wide electrically conductive contacts that are spaced from one another in the length direction and extend in the width direction to such an extent that they extend completely around the cuff body inner lumen when the cuff body is in the pre-set furled state and a plurality of relatively narrow electrically conductive contacts that are spaced from one another in the width direction and are located between the first and second relatively wide electrically conductive contacts.

13. A method, comprising:
at least partially unfurling a nerve cuff, having a pre-set furled state that defines an inner lumen, by supplying pressurized fluid to the nerve cuff;
positioning the at least partially unfurled nerve cuff adjacent to a nerve; and
allowing the at least partially unfurled nerve cuff to return to the pre-set furled state, with the nerve located within the inner lumen, by removing at least some of the pressurized fluid from the nerve cuff.

14. The method according to claim **13**, wherein
the nerve cuff includes a nerve cuff body, a plurality of electrically conductive contacts carried by the nerve cuff body, and an inflatable nerve cuff straightener associated with the nerve cuff body and configured to at least substantially straighten the nerve cuff body when in a fully inflated state in response to receipt of the pressurized fluid.

15. The method according to claim **14**, wherein
the nerve cuff is connected to an elongate lead body having a proximal end, a distal end a plurality of electrical conductors electrically associated with the electrically conductive contacts;
the pressurized fluid is supplied to the nerve cuff by way of the elongate lead body.

16. The method according to claim **14**, wherein
the nerve cuff is connected to an elongate lead body having a proximal end, a distal end a plurality of electrical conductors electrically associated with the electrically conductive contacts;
the pressurized fluid is not supplied to the nerve cuff by way of the elongate lead body.

17. The method according to claim **13**, wherein
the pressurized fluid is supplied by a fluid source.

18. The method according to claim **17**, wherein
the pressurized fluid is removed with the fluid source.

19. The method according to claim **13**, further comprising:
varying the fluid pressure within the nerve cuff while positioning the nerve cuff adjacent to the nerve and/or allowing the nerve cuff to return to the pre-set furled state,

20. The method according to claim **13**, wherein
at least partially unfurling a nerve cuff comprises fully unfurling the nerve cuff.

21. The method according to claim **20**, wherein
the fully unfurled nerve cuff is in an at least substantially straightened state.

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