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(54) **MEDICAL ELECTRODE AND TOOL FOR DELIVERING THE ELECTRODE**

(75) Inventors: **Walter D. Gillespie**, San Diego, CA (US); **David G. Matsuura**, Encinitas, CA (US); **Gary R. Dulak**, Valencia, CA (US)

(73) Assignee: **Pacesetter, Inc.**, Sylmar, CA (US)

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A61N 1/00 (2006.01)

(52) **U.S. Cl.** **607/116**

(58) **Field of Classification Search** 607/115, 607/116, 117, 118, 126, 127, 128, 130; 81/177.7-177.75

See application file for complete search history.

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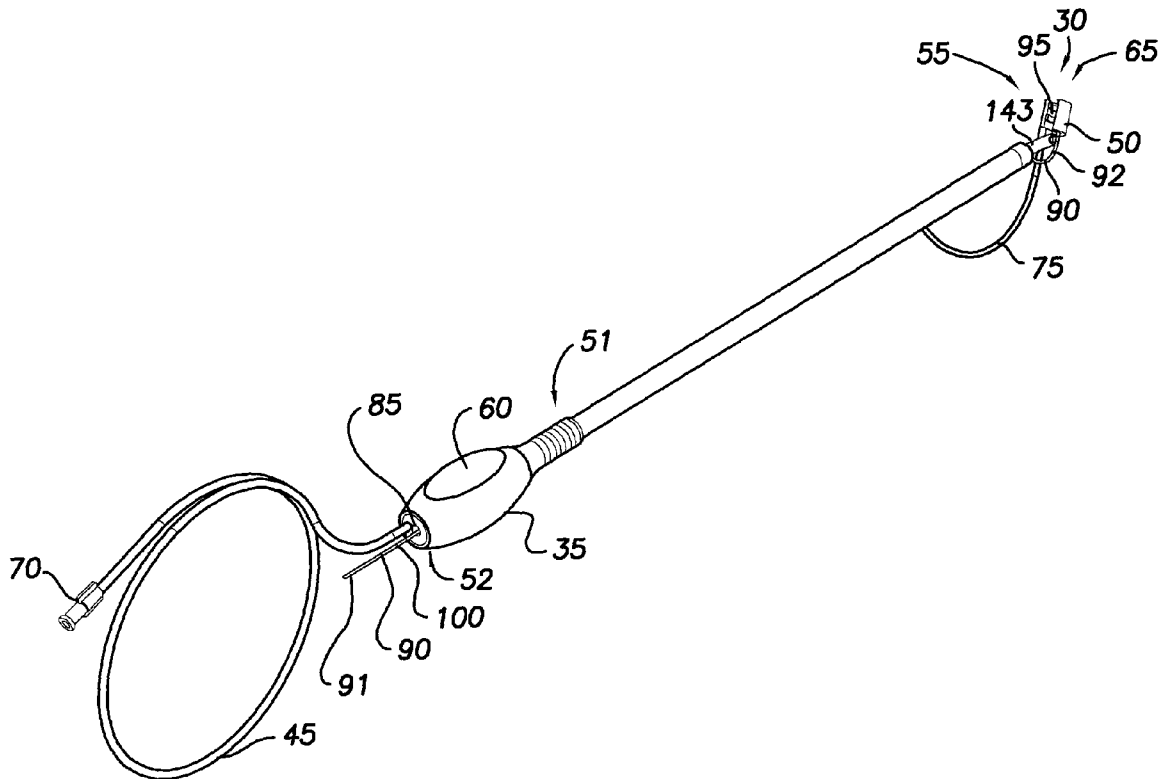
Primary Examiner — Mark W Bockelman

Assistant Examiner — Elizabeth K So

(57) **ABSTRACT**

Disclosed herein is a tool for delivering an implantable electrode about a body structure of a patient. In one embodiment, the tool includes a shaft and an electrode tray. The shaft includes a proximal end and a distal end. The electrode tray is articulatably coupled to the distal end and configured to maintain the electrode in an open configuration until the electrode is delivered about the body structure.

11 Claims, 12 Drawing Sheets



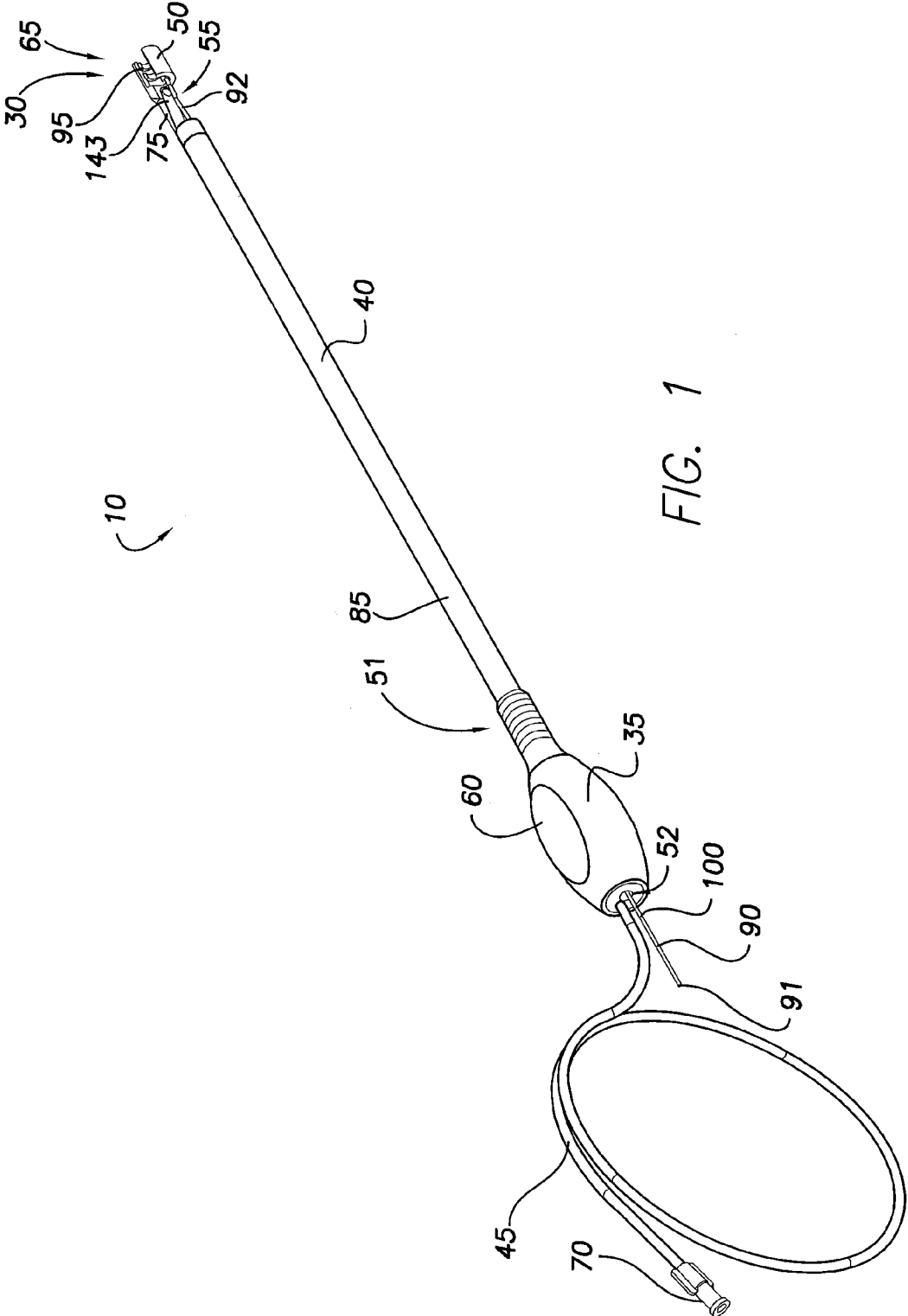


FIG. 1

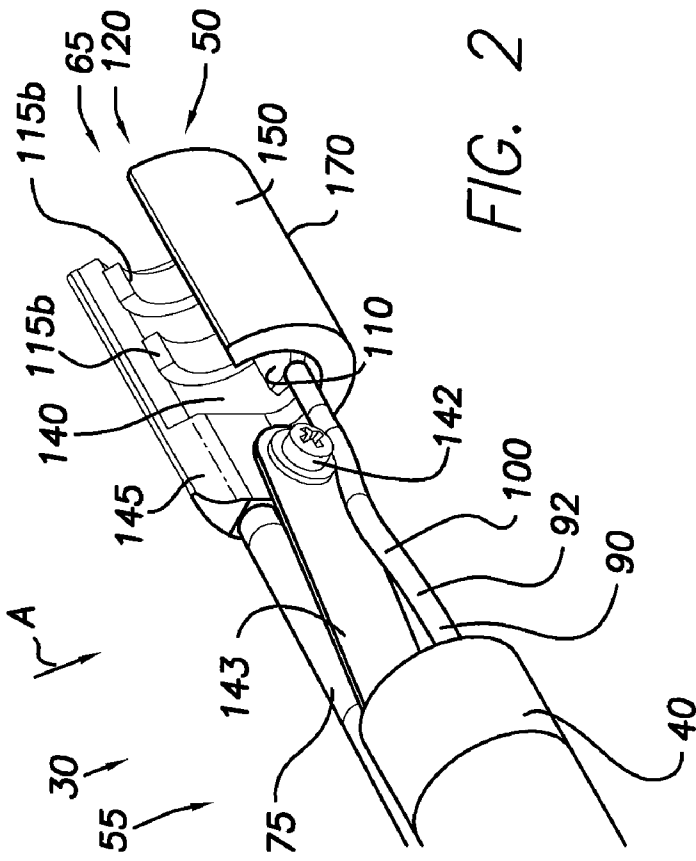


FIG. 2

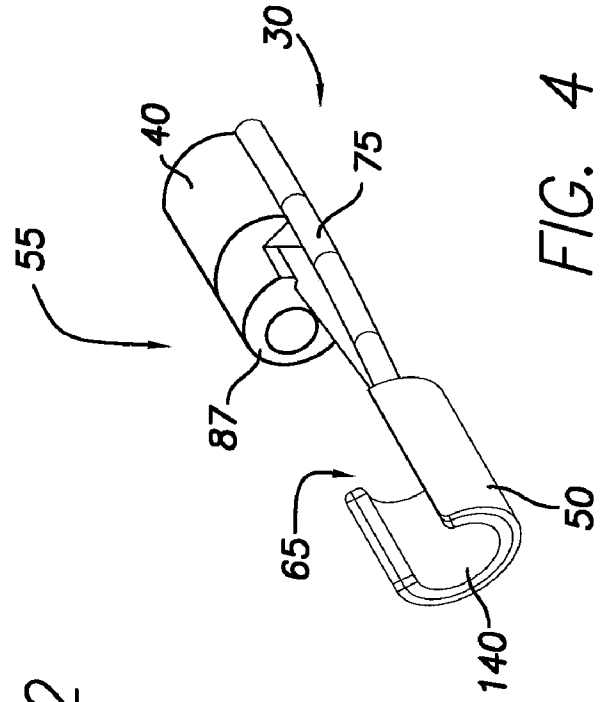
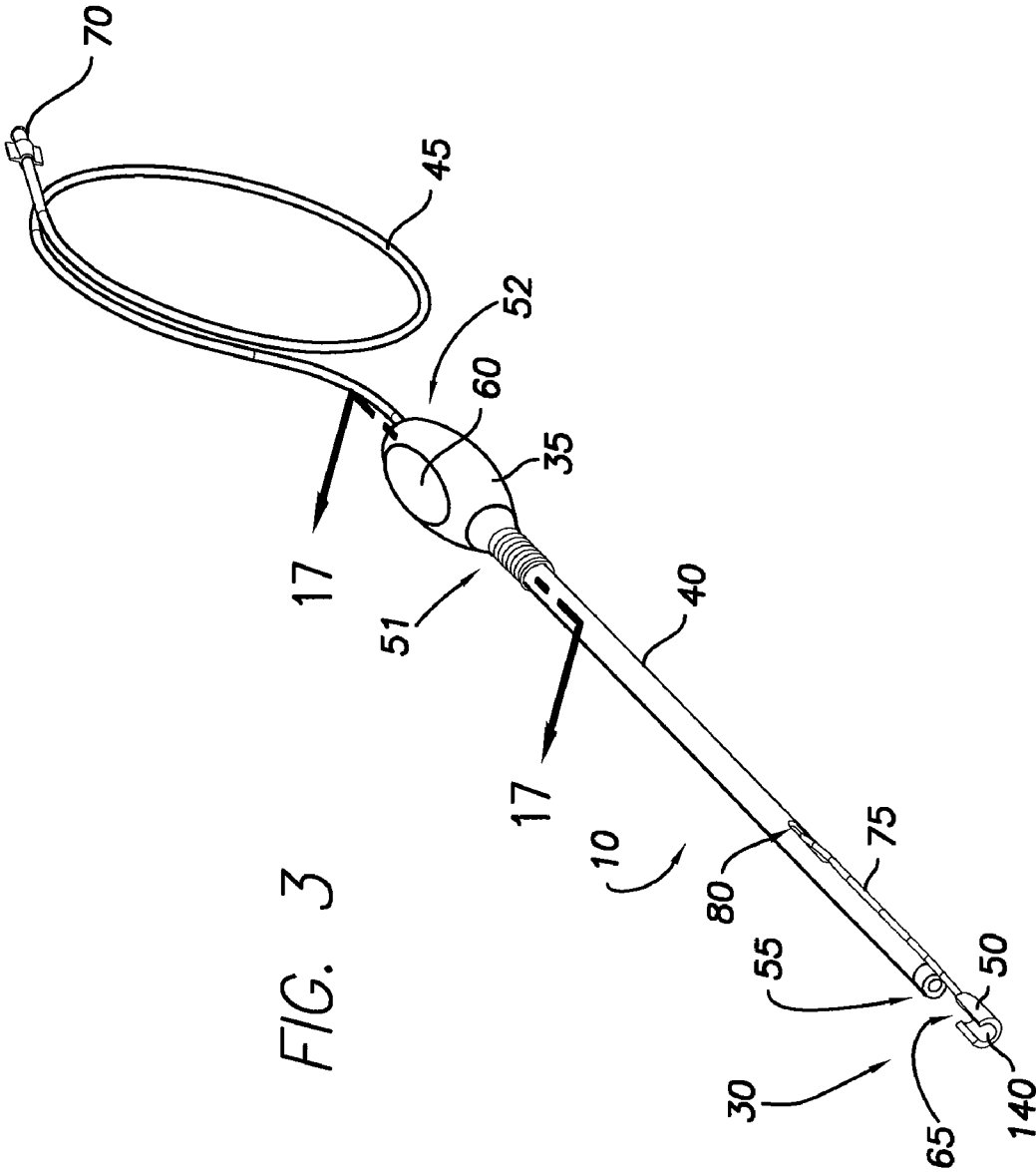


FIG. 4



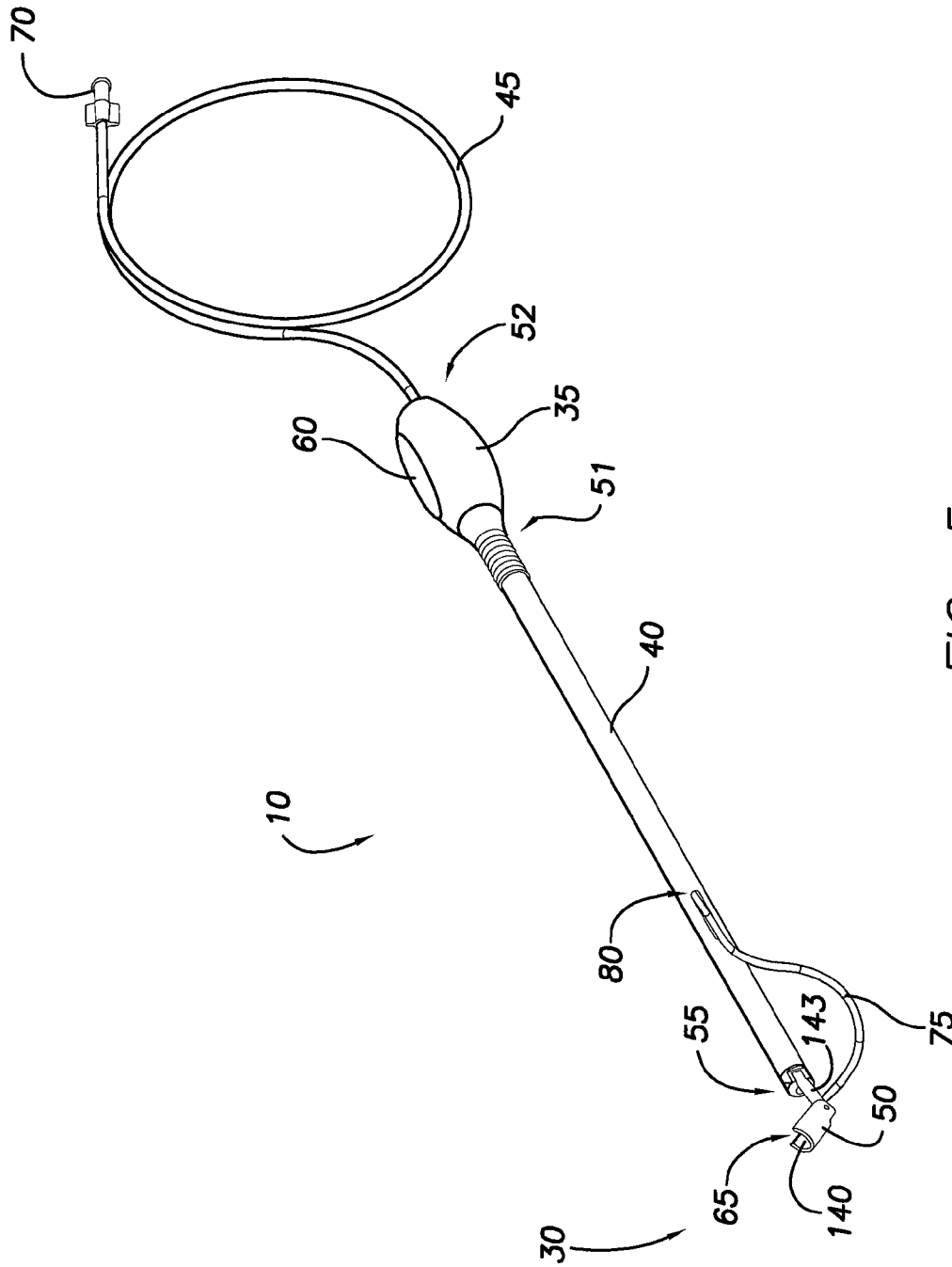


FIG. 5

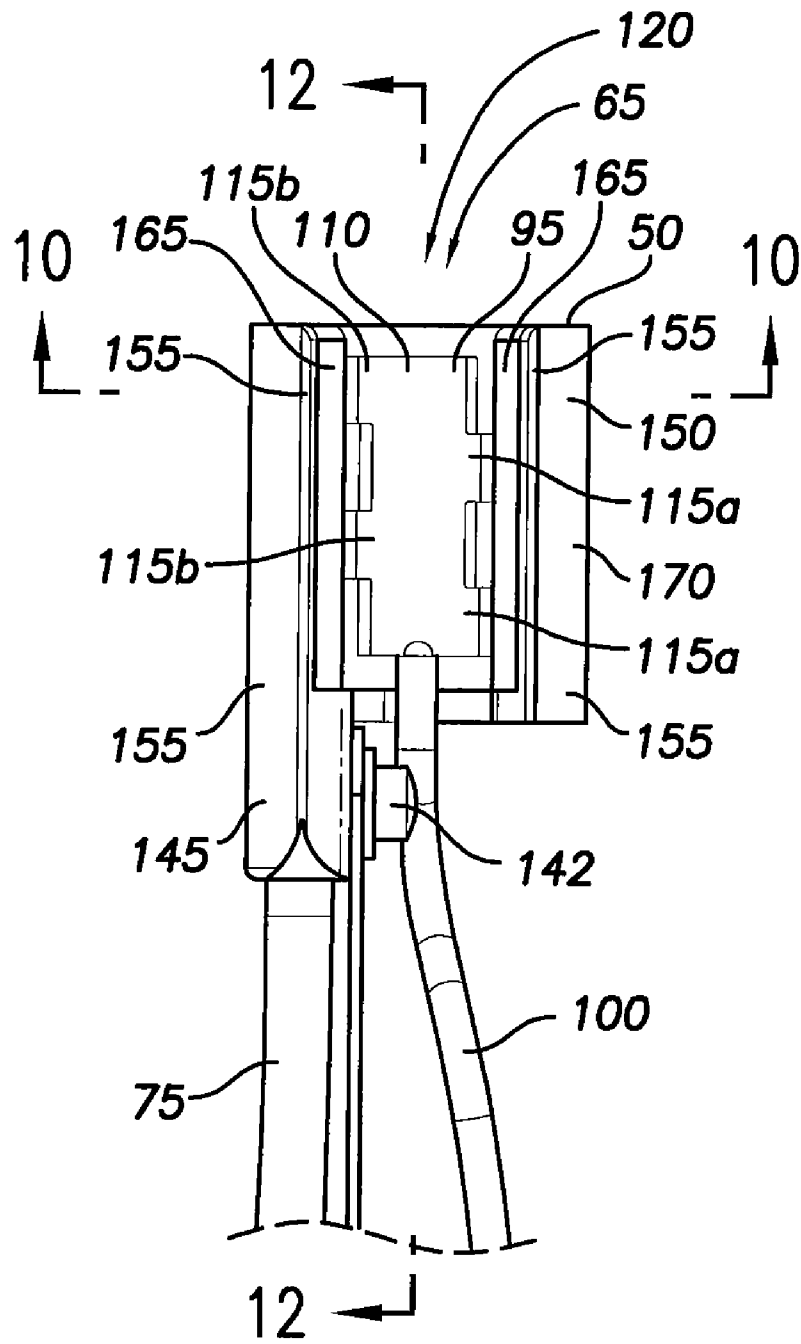


FIG. 9

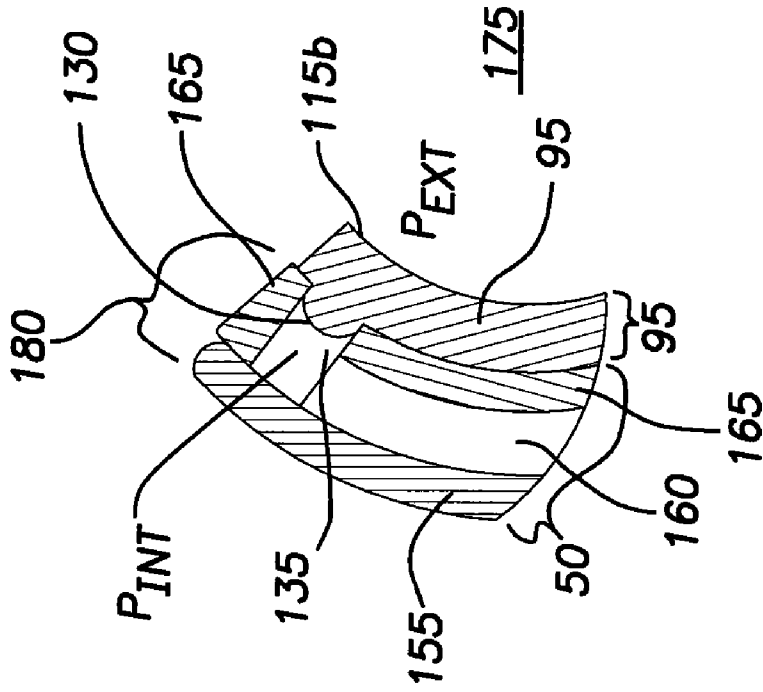


FIG. 10

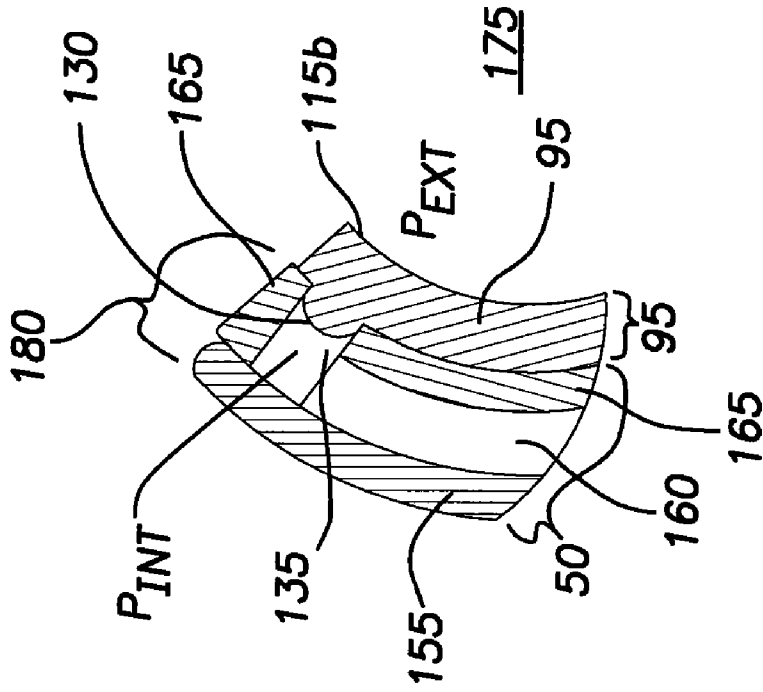


FIG. 11

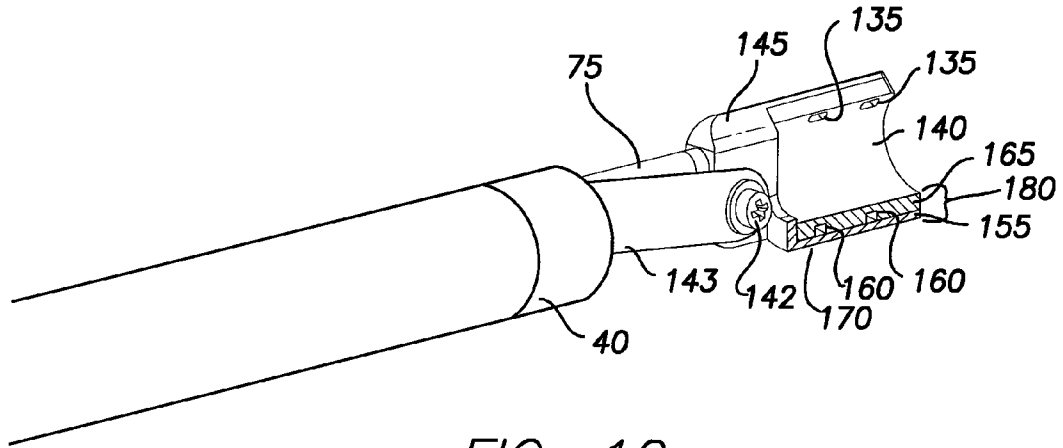


FIG. 12

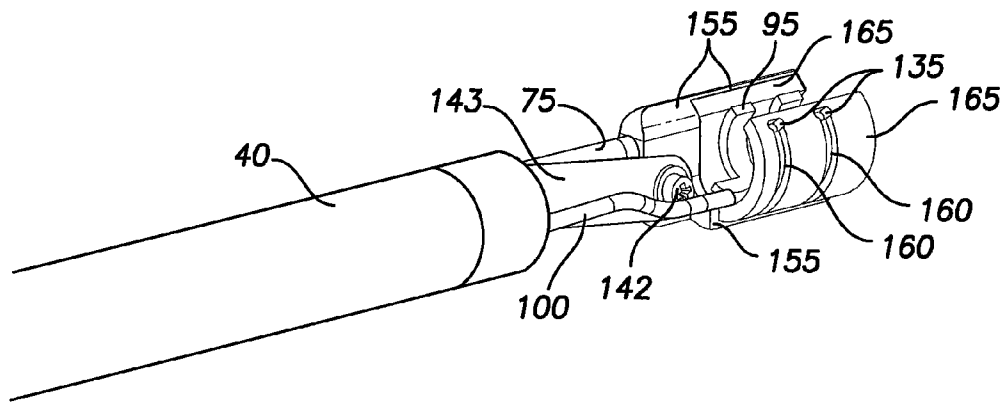
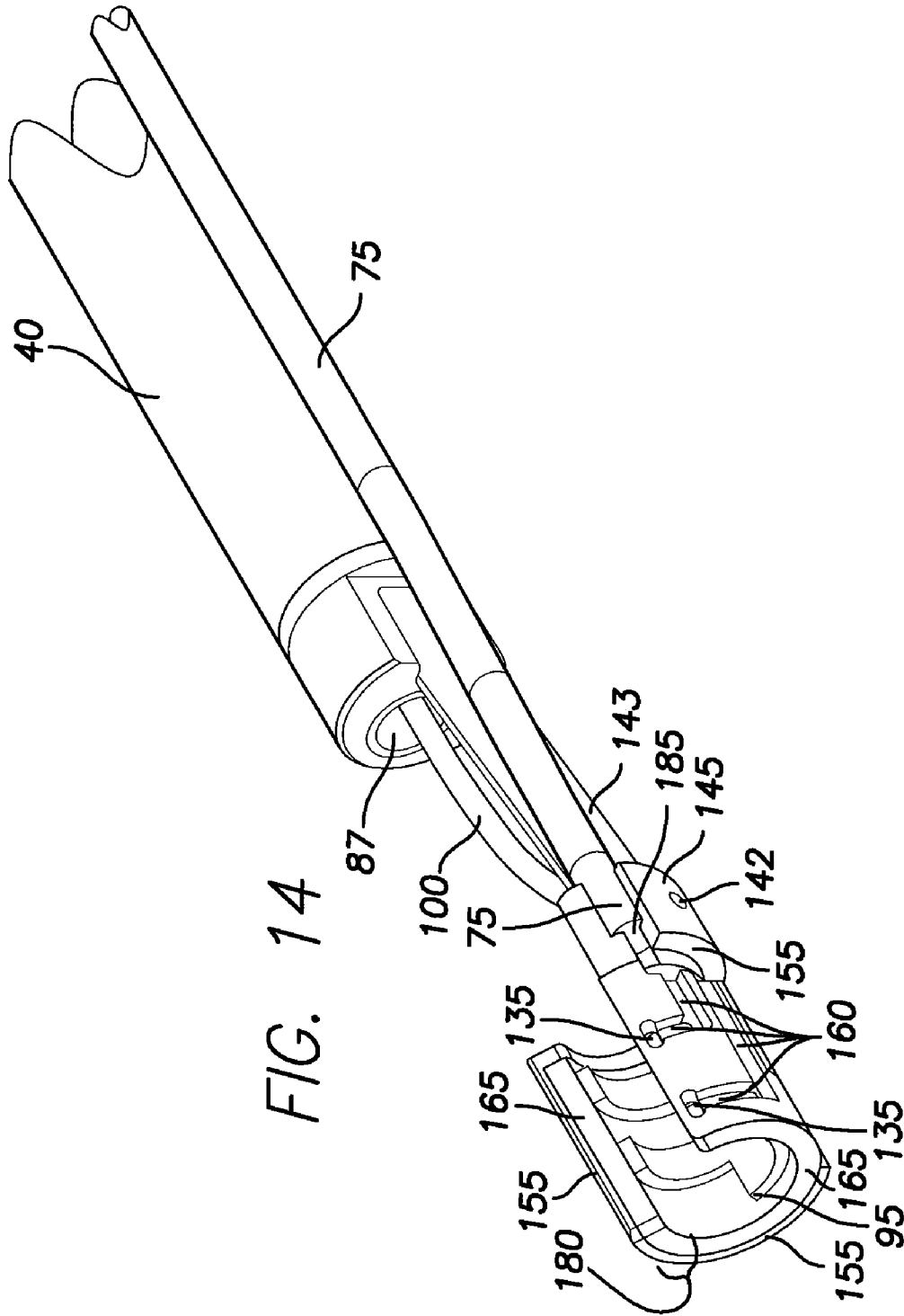
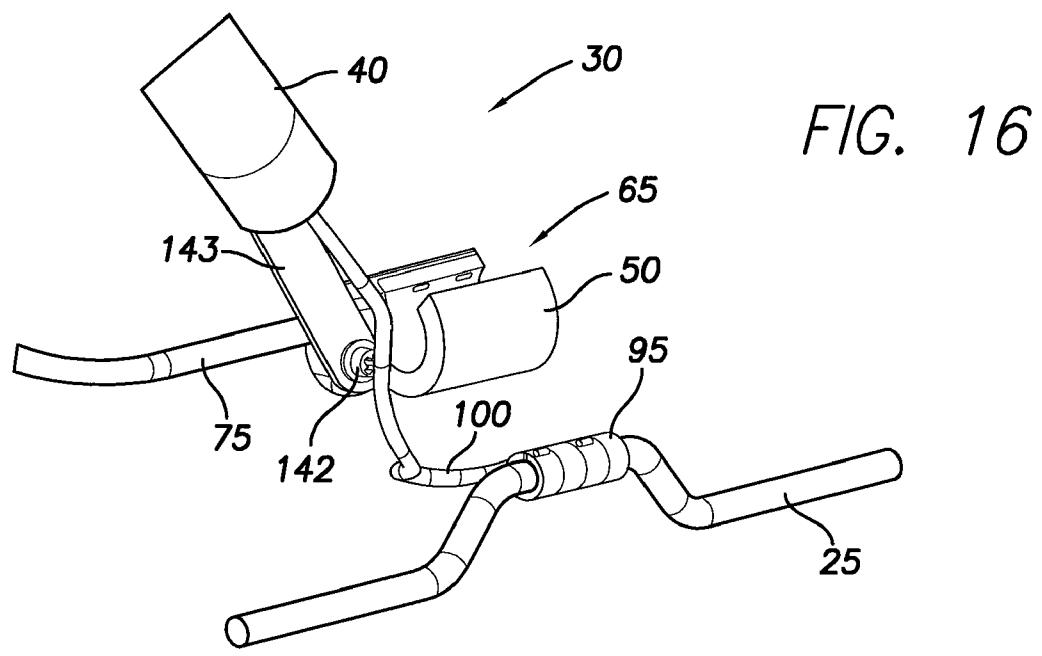
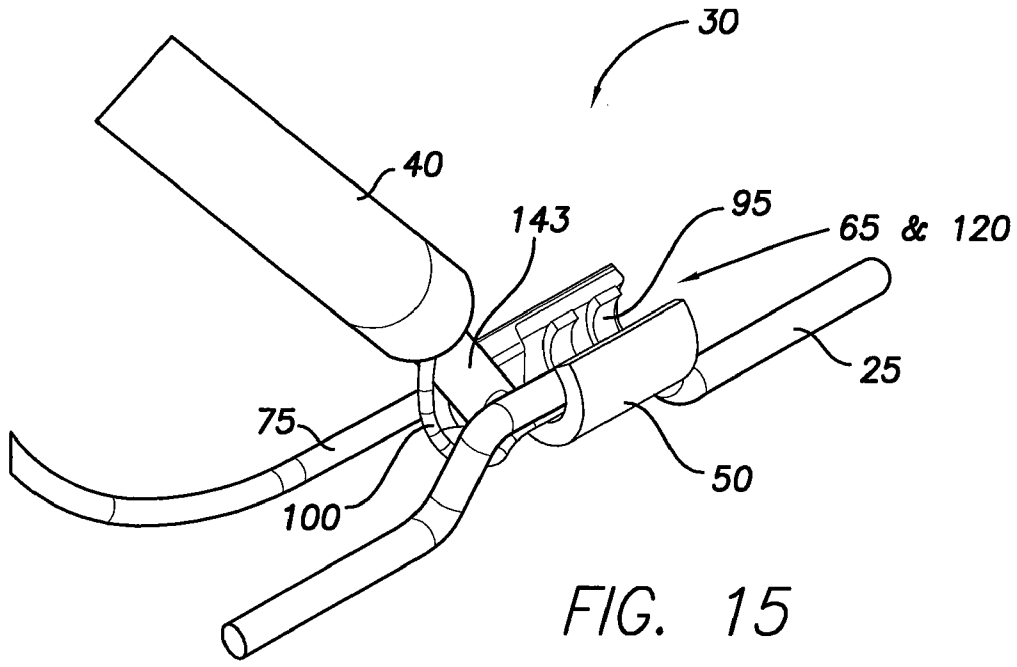


FIG. 13





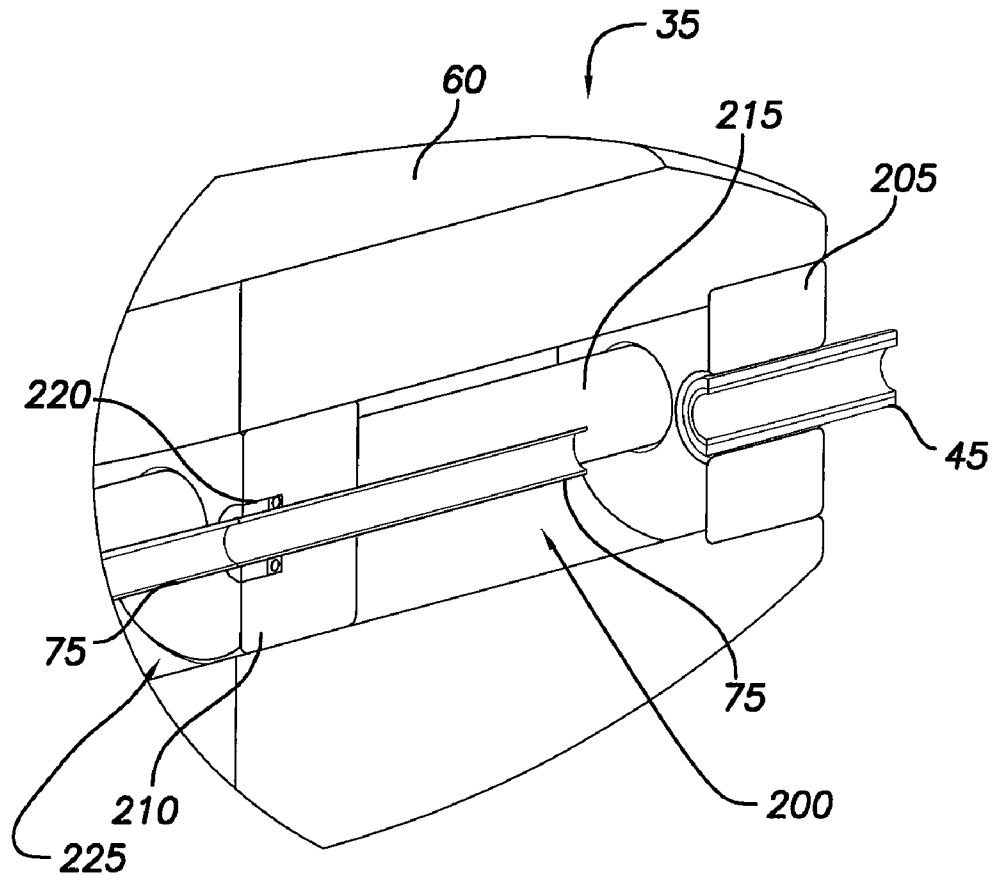


FIG. 17

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MEDICAL ELECTRODE AND TOOL FOR DELIVERING THE ELECTRODE

FIELD OF THE INVENTION

The present invention relates to methods and apparatus for the delivery and implantation of an implantable medical lead within an animal or human. More specifically, the present invention relates to methods and apparatus for the delivery and attachment of an electrode of an implantable medical lead to an anatomical structure of an animal or human.

BACKGROUND OF THE INVENTION

Many medical disorders can be treated by the attachment of an electrode of an implantable medical lead to a body structure, such as a nerve or nerve bundle. Such electrodes can provide therapeutic electrical stimulation to the body structure and/or take direct measurement of local electrical activity.

Attaching an electrode to a fragile body structure such as a nerve or nerve bundle is difficult and presents significant risks of damage to the body structure.

There is a need in the art for an electrode and electrode delivery tool that reduces the difficulty and risk associated with attaching an electrode to a fragile body structure. There is also a need in the art for a method of attaching an electrode to a fragile body structure, the method having a reduced level of difficulty and risk.

SUMMARY

Disclosed herein is a tool for delivering an implantable electrode about a body structure of a patient. In one embodiment, the tool includes a shaft and an electrode tray. The shaft includes a proximal end and a distal end. The electrode tray is articulatably coupled to the distal end and configured to maintain the electrode in an open configuration until the electrode is delivered about the body structure.

Disclosed herein is a medical system for administering electrotherapy to a body structure. In one embodiment the system includes a lead and a tool. The lead includes a longitudinally extending body and an electrode coupled to a distal end of the body. The electrode includes a generally cylindrical body having a gap defined therein when the electrode is in an open configuration. The tool is for delivering the electrode about the body and includes a shaft and a tray articulatably coupled to a distal end of the shaft. The tray is generally cylindrical and includes a gap defined therein. The electrode gap and tray gap align to allow the body structure to enter the electrode when the electrode is held in an open configuration within the tray.

Disclosed herein is an implantable electrode for attachment to a body structure. In one embodiment, the electrode includes a spine, a first pair of spaced apart ribs extending from a first side of the spine, and a second pair of spaced apart ribs extending from a second side of the spine. The first and second pair of ribs oppose each other and are staggered relative to each other such that the ribs of the first pair mesh in alternating fashion with the ribs of the second pair when the electrode is in a closed configuration.

While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. As will be realized, the invention is capable of modifications in various aspects, all without departing from

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the spirit and scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a rear isometric view of the tool.

FIG. 2 is an enlarged view of the distal end of the tool as depicted in FIG. 1.

FIG. 3 is a front isometric view of the tool.

FIG. 4 is an enlarged view of the distal end of the tool as depicted in FIG. 3.

FIG. 5 is a view similar to that depicted in FIG. 3, except the distal end of the tool is in a deflected state.

FIG. 6 is a view similar to that depicted in FIG. 1, except the distal end of the tool is in a deflected state.

FIG. 7 is an enlarged view of the distal end of the tool as depicted in FIG. 6.

FIGS. 8A and 8B are a distal isometric view of the lead with its electrode in an open state.

FIG. 9 is a plan view of the tray with the electrode therein, as viewed from the direction of arrow A in FIG. 2.

FIG. 10 is a transverse cross section through the electrode and tray, as taken along section line 10-10 in FIG. 9.

FIG. 11 is an enlarged view of a portion of the cross section depicted in FIG. 10.

FIG. 12 is an isometric view of a longitudinal cross section of the tray without the electrode and as taken along section line 12-12 in FIG. 9.

FIG. 13 is a view of the tray and electrode therein similar to that depicted in FIG. 2, except a portion of the outer jacket of the tray is removed to show the air/vacuum channels defined in the inner jacket of the tray.

FIG. 14 is a view similar to FIG. 13, except of the opposite side of the tray.

FIG. 15 is an isometric view of the tool distal end with the electrode contained within the pivoted tray, which is maintaining the electrode in the open configuration, the nerve bundle being located within the electrode.

FIG. 16 is the same view depicted in FIG. 15, except the electrode is engaged about the nerve bundle and the electrode has been released from the tray.

FIG. 17 is an isometric cross section view through the handle 35 as taken along section line 17-17 in FIG. 3.

DETAILED DESCRIPTION

Disclosed herein is a delivery tool 10 for, and method of, delivering and attaching an electrode of an implantable medical lead to a structure in the body of an animal or human. In one embodiment, the delivery tool 10 is used to place the electrode in circumferential contact with a nerve bundle or other similar body structure. The delivery tool 10 is then removed, leaving the electrode attached to the nerve bundle.

For a discussion of the overall configuration of the tool 10, reference is made to FIGS. 1-7. FIG. 1 is a rear isometric view of the tool 10. FIG. 2 is an enlarged view of the distal end 30 of the tool 10 as depicted in FIG. 1. FIG. 3 is a front isometric view of the tool 10. FIG. 4 is an enlarged view of the distal end 30 of the tool 10 as depicted in FIG. 3. FIG. 5 is a view similar to that depicted in FIG. 3, except the distal end 30 of the tool 10 is in a deflected state. FIG. 6 is a view similar to that depicted in FIG. 1, except the distal end 30 of the tool 10 is in a deflected state. FIG. 7 is an enlarged view of the distal end 30 of the tool 10 as depicted in FIG. 7.

As illustrated in FIGS. 1, 3, 5 and 6, in one embodiment, the tool 10 includes a handle 35, a tubular body or shaft 40, an

air/vacuum line **45**, and an electrode capture or retention tray **50**. The handle **35** is mounted on a proximal end **52** of the shaft **40**, which extends distally from the handle **35**. The air/vacuum line **45** extends proximally from the shaft proximal end **52**. As can be understood from FIGS. 1-7, in one embodiment, the tray **50** is pivotally coupled to a distal end **55** of the shaft **40**.

As indicated in FIGS. 1, 3, 5 and 6, in one embodiment, the handle **35** is bulb-shaped with a flattened region **60**, and the tray **50** is generally cylindrically shaped with a slot **65** longitudinally extending through a side of the tray **50**. In one embodiment, the slot **65** and flattened region **60** are generally aligned with each other to indicate to a physician using the tool **10** the orientation of the tray **50** when the tool distal end **30** is located within a patient during an implantation procedure. In one embodiment, the handle **35** includes a multiplicity of annular grooves **51** near the distal extent of the handle **35** to give the user additional longitudinal grip.

As depicted in FIGS. 1 and 6, the air/vacuum line **45** is connected to the shaft distal end **52**. In one embodiment, the connection between the line **45** and the shaft distal end **52** is permanent. In one embodiment, the line **45** terminates at its proximal end with a female luer **70**, thereby allowing the line to be securely connected to a vacuum or air source.

As shown in FIGS. 3-7, a distal air/vacuum line **75** extends from an opening **80** in the outer circumferential wall of the shaft **40** proximal of the shaft distal end **55**. The distal air/vacuum line **75** is in fluid communication with the proximal air/vacuum line **45**. In one embodiment as indicated in later discussed FIG. 17, the lines **45**, **75** are individual pieces fluidly coupled to each other via a fluid/vacuum chamber **200** defined in the handle **35**. In one embodiment, the lines **45**, **75** are simply proximal and distal portions of a continuous air/vacuum line longitudinally routed through the shaft **40**. The air/vacuum lines **45**, **75** fluidly couple the electrode retention tray **50** to the air/vacuum source coupled to the luer **70**.

As can be understood from FIGS. 1, 3, 4 and 6, a lead receiving lumen longitudinally extends through the shaft **40** and daylights at the shaft proximal and distal ends **52**, **55** as proximal and distal lead port **85**, **87**. As shown in FIGS. 1, 2, 6 and 7, when a lead **90** is located within the lead receiving lumen, a proximal end **91** of the lead **90** will extend from the proximal port **85**, and a distal end **92** of the lead **90** will extend from the distal port **87**.

In one embodiment, the shaft **40** is made of a biocompatible metal or rigid plastic such as stainless steel or polycarbonate, etc. The handle **35** may be made of polycarbonate, etc. The air/vacuum line **45**, **75** may be made of polyethylene or some other common flexible tubing that is biocompatible. The lead receiving lumen **85**, **87** may be made of polycarbonate or Ultem, etc. In one embodiment, the shaft **40** is molded, extruded or otherwise formed via a thermoforming process. The line **45**, **47** and/or lumen **85**, **87** are defined in the shaft **40** during the process, or the shaft **40** is formed about the line **45**, **47** and/or lumen **85**, **87** during the process. Subsequent to the formation of the shaft **40**, the handle **35** is formed about the shaft **40** via an injection molding process.

In one embodiment, the shaft **40** has an outer diameter of between approximately 0.15" and approximately 0.25". In one embodiment, the lead receiving lumen **85**, **87** has an inner diameter of between approximately 0.05" and approximately 0.2". In one embodiment, the lumen of the air/vacuum line **45**, **75** has a diameter of between approximately 0.025" and approximately 0.1".

For a discussion of an embodiment of a lead **90** for use with the tool **10** described herein, reference is made to FIGS. 8A and 8B, which are distal isometric views of the lead **90** with its

electrode **95** in an open state. As shown in FIGS. 8A and 8B, the lead **90** includes proximal and distal ends **91**, **92**, an electrode **95**, a lead body **100** with a cable conductor extending there through or a conductor cable **100** that generally forms a lead body itself, and a connective end **105**. The electrode **95** is located at the distal end **92**, and the connective end **105** is located at the proximal end **91**. In one embodiment, the connective end **105** is adapted to electrically couple with a pulse generator such as a pacemaker, defibrillator, implantable cardioverter defibrillator ("ICD"), etc. The conductor cable **100** extends between and electrically couples the electrode **95** and connective end **105**.

In one embodiment, the body or conductor cable **100** is an electrically conductive core surrounded by an electrically insulating jacket. In one embodiment, the electrically conductive core is formed of a metal or alloy material such as platinum, platinum-iridium, stainless steel, etc., and the electrically insulating jacket is formed of PTFE, ETFE, polyimide or other common insulative materials. In one embodiment, the body or conductor cable **100** has a diameter of between approximately 0.002" and approximately 0.007".

As depicted in FIGS. 8A and 8B, in one embodiment, the electrode **95** is generally cylindrical and includes an arcuate spine **110** and pairs of spaced-apart arcuate ribs **115a** and **115b** transversely extending from each side of the spine **110**. As shown in FIGS. 8A and 8B, when the electrode **95** is in an open state, a longitudinally extending slot or opening **120** is defined between the free ends of the ribs **115a** and **115b** to extend from the outer circumferential surface **121** of the electrode **95** to the inner circumferential surface **122** of the electrode **95**. The opening **120** allows a body structure **25** such as a nerve bundle **25** to enter into the space defined by inner circumferential surface **122** of the electrode capture/retention tray **50**.

As indicated in FIGS. 8A and 8B, in one embodiment, each side of the electrode **95**, or more specifically the spine **110**, will have two ribs **115** spaced-apart or separated by a gap **125a** and **125b**. However, in other embodiments, each side of the electrode **95** will have a greater or lesser number of ribs **115** and gaps **125a** and **125b**.

As illustrated in FIGS. 8A and 8B, in one embodiment, the first side's spaced-apart ribs **115a** are longitudinally offset from the second side's spaced-apart ribs **115b**. As a result and as indicated in FIG. 16 discussed later in this Detailed Discussion, when the electrode **95** is in a closed state to encircle or enclose a body structure **25** such as a nerve bundle **25**, the offset relationship between the ribs **115** of the two sides allows the first side ribs **115a** to be received between the gaps **125b** separating the second side ribs **115b** and the second side ribs **115b** to be received between the gaps **125a** separating the first side ribs **115a**.

In one embodiment, one or more ribs **115** will extend from a single side of the electrode **95**, or more specifically the spine **110**. In such an embodiment, the one or more ribs **115** may or may not be space-apart or separated from each other.

As indicated in FIGS. 8A and 8B, in one embodiment, one or more protrusions **130** project from the outer circumferential surface **121** of the ribs **115a**, **115b**. In one embodiment, the protrusions **130** are located near the free ends of the ribs **115a**, **115b**. In other embodiments, the protrusions **130** are located at other locations on the outer circumferential surface **121** of the ribs **115a**, **115b**. In one embodiment, one or more protrusions **130** are located on the outer circumferential surface **121** of the spine **110**. As illustrated in later discussed FIGS. 11 and 12, the protrusions **130** are received in air/vacuum ports **135** in the inner circumferential surface **140** of

the of the electrode retention tray **50** when the electrode **95** resides in the tray **50** as depicted FIGS. **1**, **2**, **6** and **7**.

In one embodiment, the electrode **95** or at least a portion of the inner circumferential surface **122** is made of an electrically conductive metal or alloy such as platinum, platinum-iridium, stainless steel, etc. In one embodiment, where the cylindrical wall of the electrode **95** is a sandwich configuration having an insulating outer circumferential layer forming the outer circumferential layer **121** and an electrically conductive inner circumferential layer forming the inner circumferential layer **122**, the outer insulating layer will be made of a material such as silicone, PTFE or other insulative polymers and the inner conductive layer will be formed of silicone, PTFE or other insulative polymers.

In one embodiment, the electrode **95** is molded or otherwise formed via a thermoforming process. In one embodiment, where the electrode **95** has the above-described sandwich configuration, the inner circumferential layer is formed via a molding process and then the outer circumferential layer is formed over the inner circumferential layer via an over-molding process. Alternatively, in one embodiment, the inner and outer circumferential layers forming the electrode **95** are formed via a co-extrusion process.

As can be understood from FIGS. **8A** and **8B**, in one embodiment, the inner cylindrical volume defined by the inner circumferential surface **122** has a diameter of between approximately 1 mm and approximately 7 mm when the electrode **95** is in a closed configuration as depicted in later discussed FIG. **16**. In one embodiment, the inner cylindrical volume has a longitudinally extending length of between approximately 2 mm and approximately 20 mm. In one embodiment, the cylindrical wall of the electrode **95** has a radial thickness of between the inner and outer circumferential surfaces **121**, **122** of between approximately 0.5 mm and approximately 4 mm. In one embodiment, the slot/opening **120** has a circumferentially extending width of between approximately 0.5 mm and approximately 8 mm when the electrode **95** is held in a fully open state as depicted in FIG. **2**.

In FIGS. **8A** and **8B**, the electrode **95** is depicted in an open configuration. However, in one embodiment, the electrode **95** must be maintained in the open configuration by being held in tray **50** as illustrated in FIG. **2**. In such an embodiment, the electrode **95** is biased to assume a closed configuration (as depicted in later discussed FIG. **16**) when not maintained in an open configuration (as depicted in FIG. **2**). Thus, when electrode **95** is released from the tray **50**, the electrode biases to the closed configuration illustrated in FIG. **16**.

As indicated in FIGS. **2** and **7**, in one embodiment, the electrode tray **50** includes an arm **145** and a cylindrical portion **150**. The arm **145** extends proximally from the cylindrical portion **150**. A shaft arm **143** extends distally from the shaft distal end **55**. A pin, screw or bolt **142** transversely extends through both the shaft arm **143** and the tray arm **145** to pivotally couple the tray **50** to the shaft arm **143**.

As can be understood from a comparison of FIGS. **1-2** to FIGS. **5-7**, the tray **50** can pivotally displace relative to the shaft distal end **55** and, more specifically, the shaft arm **143**. To pivotally displace the tray **50**, the lead cable conductor **100** is fed distally through the lead receiving lumen of the tool shaft **40** while the lead electrode **95** is securely received in the electrode tray **50**. Because the lead cable conductor **100** intersects the combined electrode **95** and tray **50** at a location offset from the pivot axis created by the longitudinal axis of the bolt **142**, the combined electrode **95** and tray **50** are caused to pivot about the bolt **142** from the straight forward orientation depicted in FIGS. **1-2** to the angled orientation depicted FIGS. **5-7**.

In one embodiment, the force required to cause the tray **50** to pivot about the pivot axis **142** can be predetermined at the time of assembly by regulating the amount of torque used to tighten the bolt **142**. The force required to cause the tray **50** to pivot about the pivot axis **142** can also be predetermined at the time of assembly by selecting a tube with a proper stiffness for the air/vacuum line **75** extending between the tray **50** and the shaft distal end **55**.

As shown in FIGS. **5** and **6**, the distal air/vacuum line **75** has sufficient slack such that the line **75** does not prevent the tray **50** from pivoting about the pivot axis **142**. The slack and flexibility of the air/vacuum line **75** accommodates the articulation of the tray **50** to prevent kinking of the air/vacuum line **75** and to reduce the amount of effort required to articulate the tray **50**. Similarly, the lead body **100** bends to accommodate the articulation of the tray **50** when the electrode **95** is held within the tray **50**.

In one embodiment, the tray **50** is capable of being pivoted about the pivot axis **142** from an orientation generally axially aligned with a longitudinal axis of the tool shaft **40** (see FIGS. **1-2**) to an orientation that is between approximately 45 degrees to approximately 90 from being aligned with the longitudinal axis of the tool shaft **40** (see FIGS. **5-7**).

As can be understood from FIGS. **1** and **6**, by grasping the lead proximal end **91** protruding from the proximal port **85** and displacing the lead **90** distally or proximally relative to the tool handle **35**, the pivot angle of the tray **50** relative to the tool shaft distal end **55** can be adjusted to further increase the pivot or reduce the pivot.

While in one embodiment the tray **50** is pivotally coupled to the shaft distal end **55**, other embodiments will employ other configurations for attaching the tray **50** to the shaft distal end **55** and allowing the tray **50** to displace relative to the shaft distal end **55**. For example, as can be understood from FIGS. **2** and **7**, in one embodiment, the shaft arm **143** is thin and flexible such that longitudinal displacement of the lead body **100** through the shaft **40** causes the tray **50** with the electrode **95** therein to articulate or otherwise displace relative to the shaft distal end **55**. In another embodiment, the shaft arm **143** is thin and malleable, and the electrode tray **50** contacting a body structure can cause the tray **50** to deflect in any desired plane and angle.

For a discussion regarding the configuration of the electrode tray **50** and the connective relationship between the tray **50** and the lead electrode **95**, reference is made to FIGS. **2** and **9-14**. FIG. **9** is a plan view of the tray **50** with the electrode therein, as viewed from the direction of arrow A in FIG. **2**. FIG. **10** is a transverse cross section through the electrode **95** and tray **50**, as taken along section line **10-10** in FIG. **9**. FIG. **11** is an enlarged view of a portion of the cross section depicted in FIG. **10**. FIG. **12** is an isometric view of a longitudinal cross section of the tray **50** without the electrode **95** and as taken along section line **12-12** in FIG. **9**. FIG. **13** is a view of the tray **50** and electrode **95** therein similar to that depicted in FIG. **2**, except a portion of the outer jacket **155** of the tray **50** is removed to show the air/vacuum channels **160** defined in the inner jacket **165** of the tray **50**. FIG. **14** is a view similar to FIG. **13**, except of the opposite side of the tray **50**.

As best understood from FIGS. **2**, **3**, **9** and **10**, the electrode retention tray **50** is generally cylindrical with a cylindrical wall **180** having an outer circumferential surface **170** defining the cylindrical outer surface of the tray **50** and an inner circumferential surface **140**. The inner circumferential surface **140** defines an inner cylindrical volume **175** for receiving the electrode **95** therein and provides a circumferential surface for matingly contacting the outer circumferential surface **121** of the electrode **95**.

A longitudinally extending slot or gap **65** extends through the cylindrical wall **180** between the outer and inner circumferential surfaces **170**, **140** of the cylindrical wall **180**. As best understood from later discussed FIGS. **15** and **16**, the slot **65** provides an avenue for a body structure **25** to enter an open electrode **95** held in the inner cylindrical volume **175**. The slot **65** also provides an avenue for the body structure **25**, with the electrode **95** closed about at least a portion of the body structure **25**, to exit the volume **175**.

As indicated in FIGS. **10-12**, the cylindrical wall **180** includes an outer jacket or layer **155** and an inner jacket or layer **165**. The exposed surface of the outer jacket **155** is the outer circumferential surface **170** of the wall **180**, and the exposed surface of the inner jacket **165** is the inner circumferential surface **140** of the wall **180**.

As shown in FIGS. **2**, **9**, **13** and **14**, in one embodiment, the tray pivot arm **145** is an extension of the outer jacket **155**. In other embodiments, the tray pivot arm **145** is an extension of the inner jacket **165** or an extension of both jackets **155**, **165**.

In one embodiment, the outer jacket **155** is made of Ultem, polycarbonate, a rigid, biocompatible polymer, etc., and the inner jacket **165** is made of Ultem, polycarbonate, a rigid, biocompatible polymer, etc. In one embodiment, the inner jacket **165** is molded or otherwise formed via a molding and/or machining process and then the outer jacket **155** is formed about the inner jacket **165** via a molding and/or machining process.

As can be understood from FIGS. **9** and **10**, in one embodiment, the inner cylindrical volume **175** has a diameter of between approximately 1 mm and approximately 8 mm. In one embodiment, the inner cylindrical volume **175** has a longitudinally extending length of between approximately 2 mm and approximately 20 mm. In one embodiment, the cylindrical wall **180** has a radial thickness of between approximately 0.5 mm and approximately 4 mm. In one embodiment, the gap **65** has a circumferentially extending width of between approximately 1 mm and approximately 9 mm.

As indicated in FIGS. **10-14**, air/vacuum ports **135** are defined in the inner jacket **165** and inner circumferential surface **135**. Air/vacuum channels **160** are defined in the inner jacket **165**. The outer jacket **155** extends over the channels **160** as the outer jacket **155** extends over the outer circumferential surface of the inner jacket **165**, thereby capping/covering the channels **160** to form sealed air/vacuum conveying pathways defined in the interior of the cylindrical wall **180** of the tray **50**.

As shown in FIG. **14**, the channels **160** are in a manifold configuration. The channels **160** lead to the air/vacuum ports **135** from the distal lumen opening **185** in the air/vacuum line **75**, thereby placing the air/vacuum ports **135** in the fluid communication with the air/vacuum source coupled to the luer **70** at the proximal end of the air/vacuum line **45** (see FIG. **1**).

As indicated in FIGS. **12-14**, in one embodiment, a pair of air/vacuum ports **135** is defined in the inner circumferential surface **140** near each longitudinally extending edge of the gap **65**. In other embodiments, there will be a greater or lesser number of ports **135** and/or the ports will be defined in other regions of the inner circumferential surface **140**.

As indicated in FIGS. **10** and **11**, when the electrode **95** is held in the open configuration by the tray **50**, the outer circumferential surface **121** of the electrode **95** circumferentially abuts against the inner circumferential surface **140** of the tray **50** and the protrusions **130** are received in the air/vacuum ports **135**. The gaps **65**, **120** of the tray **50** and electrode **95** are aligned to allow the passage of a body struc-

ture **25** into the space within the electrode **95** defined by the inner circumferential surface **122**.

In one embodiment, protrusions **130** are held in the ports **135** via a friction or interference fit resulting between protrusions **130** and ports **135**. In such an embodiment, as can be understood from FIGS. **11** and **14**, the protrusions **130** are freed from the ports **135** by providing pressurized fluid (e.g., air, nitrogen, saline, CO₂, etc.) through the fluid pathway **45**, **75**, **160** leading to the ports **135** from a fluid supply coupled to the luer **70**. The application of the pressurized fluid increases the interior pressure P_{INT} (i.e., the pressure in the ports **135**) over the exterior pressure P_{EXT} (i.e., the ambient pressure in the cylindrical volume **175** of the tray **50**). The resulting force created by the pressure differential overcomes the friction or interference fit, releasing the electrode **95** to bias into its closed configuration.

In one embodiment, the outer circumferential surface **121** of the electrode **95** is maintained against the inner circumferential surface **140** of the tray **50** to maintain the electrode **95** in the open configuration by the presence of an adhesive located between the two circumferential surfaces **121**, **140**. In one embodiment, the adhesive is cyanoacrylate or other common adhesives for medical device assembly. As with the above-described friction or interference fit embodiment, application of the pressurized fluid in the fluid pathway **45**, **75**, **160** creates a pressure differential resulting in a force sufficient to overcome the adhesive and allow the electrode **95** to bias into its closed configuration.

In one embodiment, mechanical graspers are located on the tray **50** and/or electrode **95** for coupling the electrode **95** to the tray **50** in the open configuration. Application of pressurized fluid in the fluid pathway **45**, **75**, **160** creates a pressure differential resulting in a force sufficient to overcome the mechanical graspers and allow the electrode to bias into its closed configuration.

As can be understood from FIGS. **11** and **14**, in one embodiment, protrusions **130** are held in the ports **135** via a force created by a pressure differential resulting from the exterior pressure P_{EXT} (i.e., the ambient pressure in the cylindrical volume **175** of the tray **50**) exceeding the internal pressure P_{INT} (i.e., the pressure in the ports **135**). Such a pressure differential is created and maintained by placing the fluid pathway **45**, **75**, **160** in a vacuum condition caused by a vacuum generator coupled to the luer **70**. As long as the vacuum condition is maintained in the fluid pathway **45**, **75**, **160**, the electrode **95** is held in the open configuration in the tray **50**. Upon termination of the vacuum condition, the protrusions **130** are freed from the ports **135** and the electrode **95** can bias into the closed configuration.

As shown in FIG. **17**, which is an isometric cross section view through the handle **35** as taken along section line **17-17** in FIG. **3**, in one embodiment, the handle **35** has defined therein a fluid/vacuum chamber **200**. The chamber **200** is a cylindrical channel generally running the length of the handle **35** between proximal and distal bulkheads **205**, **210**.

The proximal fluid/vacuum line **45** and the distal fluid/vacuum line **75** both open into the chamber **200**. The lead receiving lumen or channel **215** extends through the chamber **200** as the lumen **215** extends between the proximal and distal ports **85**, **87** of the lumen **215**. However, the lead receiving lumen **215** does not open into the chamber **200**.

As indicated in FIG. **17**, a seal is formed between the distal bulkhead **210** and the distal fluid/vacuum line **75** by an o-ring **220**. This o-ring **220** allows the distal fluid/vacuum line **75** to translate longitudinally within the distal bulkhead **210** as required to have enough play or slack in the distal line **75** to accommodate rotation of the electrode capture tray **50** rela-

tive to the shaft 40, as indicated by a comparison of FIGS. 2 and 7. To facilitate the longitudinal translation of the line 75 within the shaft 40, the line 75 extends through, and is replaceable within, a lumen 225 defined in the shaft 40 distal of the distal bulkhead 210 and extending nearly the length of the shaft 40 to daylight as the shaft opening 80 near the distal end of the shaft 40 (see FIG. 5). To prevent the line 75 from pulling through the seal 75, the line 75 extends substantially proximally into the chamber 200 before terminating.

For a discussion of a method of using the tool 10 to deploy the electrode 95 about a target structure (e.g., nerve bundle 25), reference is made to FIGS. 15 and 16. FIG. 15 is an isometric view of the tool distal end 30 with the electrode 95 contained within the pivoted tray 50, which is maintaining the electrode 25 in the open configuration, the nerve bundle 25 being located within the electrode 95 FIG. 16 is the same view depicted in FIG. 15, except the electrode 95 is engaged about the nerve bundle 25 and the electrode 95 has been released from the tray 50.

In one embodiment, the delivery tool 10 and lead 90 carried by the tool are introduced into the body via a minimally invasive procedure. For example, the tool and lead can be introduced via a percutaneous puncture via an introducer sheath. Similarly, the tool and lead can be introduced via a laparoscopic access cannula.

As can be understood from FIG. 15, the tool distal end 30, with its tray 50 articulated relative to the shaft 40, is maneuvered into position adjacent the nerve 25. The tray 50 holds the electrode in the open configuration such that the electrode 95 and tray gaps 120, 65 coincide to allow the nerve 25 to enter the electrode 95. The nerve 25 is received in the open electrode 95 to appear as depicted in FIG. 15.

As discussed above, in one embodiment, the electrode 95 is maintained in the open configuration via an adhesive between the electrode 95 and tray 50. Upon the nerve 25 being received in the open electrode 95, pressurized fluid, which is supplied to the tray 50 via the line 75, is applied against the electrode 95 to separate the electrode 95 from the tray 50. Upon separation of the electrode from the tray, the electrode is free to bias into the closed configuration, thereby enclosing the nerve 25 within the electrode 95, as depicted in FIG. 16.

As discussed above, in one embodiment, the electrode 95 is maintained in the open configuration via a friction or interference fit between the electrode 95 and tray 50. Upon the nerve 25 being received in the open electrode 95, pressurized fluid, which is supplied to the tray 50 via the line 75, is applied against the electrode 95 to separate the electrode 95 from the tray 50. Upon separation of the electrode from the tray, the electrode is free to bias into the closed configuration, thereby enclosing the nerve 25 within the electrode 95, as depicted in FIG. 16.

As discussed above, in one embodiment, the electrode 95 is maintained in the open configuration via a vacuum condition established between the electrode 95 and tray 50. The vacuum condition is transmitted from a vacuum generator to the tray 50 via the line 75. Upon the nerve 25 being received in the open electrode 95, the vacuum condition is terminated, thereby freeing the electrode 95 to separate from the tray 50. Upon separation of the electrode from the tray, the electrode is free to bias into the closed configuration, thereby enclosing the nerve 25 within the electrode 95, as depicted in FIG. 16.

In each of the three aforementioned embodiments, upon the electrode 95 attaching to the nerve 25, the tool 10 can be retracted from the electrode 95. As the tool 10 is retracted, the lead body 100 slides through the shaft 40 until the lead distal

end exits the shaft 40. The lead connective end 105 can then be electrically coupled to a pulse generator or other energy source.

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

What is claimed is:

1. A tool for delivering an implantable electrode about a nerve or nerve bundle of a patient, the implantable electrode including a generally cylindrical body having a gap defined therein, the tool comprising:

a shaft defining a proximal end and a distal end; and
an electrode tray articulatably coupled to the distal end and configured to maintain the electrode in an open configuration until the electrode is delivered about the nerve or nerve bundle;

wherein the tray is generally cylindrical in shape and extends longitudinally from a proximal end to a distal end, wherein a slot longitudinally extends through an entire side of the tray from the distal end to the proximal end, and wherein the electrode gap and the tray slot align to allow the nerve or nerve bundle to enter the electrode and tray slot when the electrode is held in an open configuration within the tray and to allow the nerve or nerve bundle to exit the electrode and tray slot when the electrode is held in an open configuration; and
wherein the tray is articulatably coupled to the distal end via a pivot axis, the pivot axis being substantially perpendicular to a longitudinal axis of the shaft.

2. The tool of claim 1, further comprising a friction or interference fit between a feature of the electrode and a feature of the tray to maintain the electrode in an open configuration.

3. The tool of claim 1, further comprising a mechanical arrangement between the electrode and tray adapted to maintain the electrode in an open configuration.

4. The tool of claim 1, further comprising an adhesive between the electrode and tray adapted to maintain the electrode in an open configuration.

5. The tool of claim 1, further comprising a vacuum condition existing between the electrode and tray adapted to maintain the electrode in an open configuration.

6. The tool of claim 1, further comprising a fluid or vacuum pathway extending from the distal end to the tray.

7. The tool of claim 1, wherein longitudinal displacement within the shaft of a lead body extending from the electrode causes the tray to articulate relative to the shaft when the electrode is located within the tray.

8. A medical system for administering electrotherapy to a nerve or nerve bundle, the system comprising: a lead including a longitudinally extending body and an electrode coupled to a distal end of the body, the electrode including a generally cylindrical body having a gap defined therein when the electrode is in an open configuration; and a tool for delivering the electrode about the body and including a shaft and a tray articulatably coupled to a distal end of the shaft, wherein the tray is generally cylindrical and extends longitudinally from a proximal end to a distal end, and wherein a slot longitudinally extends through an entire side of the tray from the distal end to the proximal end, wherein the electrode gap and tray slot align to allow the nerve or nerve bundle to enter the electrode when the electrode is held in an open configuration within the tray, wherein the tray is articulatably coupled to the distal end via a pivot axis, and wherein the pivot axis is substantially perpendicular to a longitudinal axis of the shaft.

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9. The system of claim 8, wherein the electrode is maintained in the open configuration by an adhesive between the electrode and tray.

10. The system of claim 8, wherein the electrode is maintained in the open configuration by an interference or friction fit between features of the electrode and features of the tray. 5

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11. The system of claim 8, wherein the electrode is maintained in the open configuration by maintaining a vacuum state between the electrode and tray.

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