



(51) International Patent Classification:

A61N 1/375 (2006.01) H01R 13/64 (2006.01)
A61N 1/05 (2006.01) H01R 43/26 (2006.01)
H01R 13/52 (2006.01) H01R 24/58 (2011.01)
H01R 13/629 (2006.01)

(21) International Application Number:

PCT/US2016/026044

(22) International Filing Date:

5 April 2016 (05.04.2016)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/146,017 10 April 2015 (10.04.2015) US

(71) Applicant: BOSTON SCIENTIFIC NEUROMODULATION CORPORATION [US/US]; 25155 Rye Canyon Loop, Valencia, CA 91355 (US).

(72) Inventors: GOVEA, Michael, X.; 1137 N Lousie St., #5, Glendale, CA 91207 (US). HOWARD, Joshua, Dale; 3441 38th Street, Sacramento, CA 95817 (US).

(74) Agent: BLACK, Bruce, E.; Lowe Graham Jones PLLC, 701 5th Ave., Suite 4800, Seattle, WA 98104 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: SYSTEMS AND METHODS FOR MAKING AND USING IMPROVED CONTACT ARRAYS FOR ELECTRICAL STIMULATION SYSTEMS

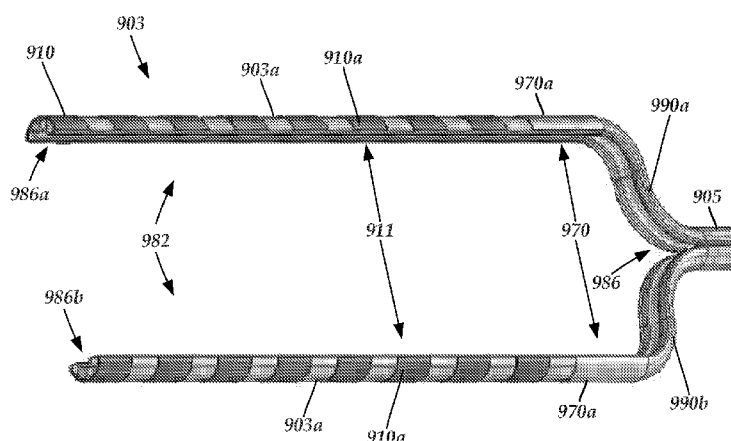


Fig. 9A

(57) Abstract: An electrical stimulation lead or lead extension includes a body having an outer surface, a proximal end, a proximal portion, at least one distal portion, an outer surface, a perimeter, and a longitudinal length, the body defining an alignment slit extending distally from the proximal end of the body and splitting the proximal portion of the body into two transversely space-apart sections; first contacts disposed along the distal portion of the body; segmented second contacts disposed along the proximal portion of the body, where each segmented second contact extends around less than the entire perimeter of the body and is separated from all other segmented second contacts by portions of the body or the alignment slit; and conductors electrically coupling the first contacts to the second contacts.



SYSTEMS AND METHODS FOR MAKING AND USING IMPROVED CONTACT ARRAYS FOR ELECTRICAL STIMULATION SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Serial No. 62/146,017, filed April 10, 2015, which is incorporated herein by reference.

FIELD

10 The present invention is directed to the area of implantable electrical stimulation systems and methods of making and using the systems. The present invention is also directed to implantable electrical stimulation systems having elongated members with improved contact arrays, as well as methods of making and using the elongated devices, contact arrays, and electrical stimulation systems.

BACKGROUND

15 Implantable electrical stimulation systems have proven therapeutic in a variety of diseases and disorders. For example, spinal cord stimulation systems have been used as a therapeutic modality for the treatment of chronic pain syndromes. Peripheral nerve stimulation has been used to treat incontinence, as well as a number of other applications under investigation. Functional electrical stimulation systems have been applied to
20 restore some functionality to paralyzed extremities in spinal cord injury patients.

 Stimulators have been developed to provide therapy for a variety of treatments. A stimulator can include a control module (with a pulse generator), one or more leads, and an array of stimulator electrodes on each lead. The stimulator electrodes are in contact with or near the nerves, muscles, or other tissue to be stimulated. The pulse generator in
25 the control module generates electrical pulses that are delivered by the electrodes to body tissue.

BRIEF SUMMARY

 One embodiment is an electrical stimulation lead or lead extension that includes a body having an outer surface, a proximal end, a proximal portion, at least one distal
30 portion, an outer surface, a perimeter, and a longitudinal length, the body defining an alignment slit extending distally from the proximal end of the body and splitting the

proximal portion of the body into two transversely space-apart sections; first contacts disposed along the distal portion of the body; segmented second contacts disposed along the proximal portion of the body, where each segmented second contact extends around less than the entire perimeter of the body and is separated from all other segmented
5 second contacts by portions of the body or the alignment slit; and conductors electrically coupling the first contacts to the second contacts.

In at least some embodiments, the segmented second contacts are arranged in sets of segmented second contacts, where each set of segmented second contacts includes at least two of the segmented second contacts disposed in a circumferential arrangement at a
10 same longitudinal position of the lead. In at least some embodiments, the alignment slit extends between at least two of the segmented second contacts of each of the sets of segmented second contacts. In at least some embodiments, each of the sets of segmented second contacts contains exactly two segmented second contacts.

In at least some embodiments, the electrical stimulation lead or lead extension
15 further includes a retention sleeve disposed distal of all of the segmented second contacts. In at least some embodiments, the alignment slit separates the retention sleeve into two laterally spaced-apart pieces. In at least some embodiments, the alignment slit terminates proximal to the retention sleeve.

In at least some embodiments, the alignment slit separates the proximal portion of
20 the body into two branches, where each branch further defines a bendable portion distal to all of the segmented second contacts and the bendable portions of the two branches allow the branches to be sufficiently separated so that the branches can be inserted into different connectors. In at least some embodiments, the first and second branches each have a hemispherical lateral cross-sectional shape.

25 In at least some embodiments, the first contacts are electrodes and the segmented second contacts are segmented terminals and the electrical stimulation lead or lead extension is an electrical stimulation lead. In at least some embodiments, the first contacts are connector contacts and the segmented second contacts are segmented terminals and the electrical stimulation lead or lead extension is a lead extension.

Another embodiment is an electrical stimulation system that includes any of the electrical stimulation leads or lead extensions described above; and a first connector defining a connector lumen to receive at least a portion of the proximal end of the electrical stimulation lead or lead extension. The first connector includes segmented
5 connector contacts disposed along the connector lumen.

In at least some embodiments, the electrical stimulation system further includes a control module that includes the connector, a housing, and an electrical subassembly disposed in the housing and electrical coupled to the connector contacts of the connector. In at least some embodiments, the electrical stimulation system further includes a lead
10 extension that includes the connector.

In at least some embodiments, the connector contacts of the first connector are arranged in sets of segmented connector contacts, where each set of segmented connector contacts includes at least two of the segmented connector contacts disposed in a circumferential arrangement at a same longitudinal position along the connector lumen.
15 In at least some embodiments, the connector further includes a connector housing containing the connector lumen and defining an opening into the connector lumen, and an alignment structure extending across the connector lumen and configured and arranged to mate with the alignment slit of the electrical stimulation lead or lead extension.

In at least some embodiments, the electrical stimulation system further includes a
20 second connector defining a connector lumen to receive the proximal end of the electrical stimulation lead or lead extension, where the second connector includes a plurality of segmented connector contacts disposed along the connector lumen. The electrical stimulation lead or lead extension is configured and arranged so that the alignment slit separates the proximal portion of the body into a first branch and a second branch, where
25 each of the first and second branched further defines a bendable portion distal to all of the segmented second contacts, and the bendable portions of the first and second branches allow the first and second branches to be sufficiently separated so that the first and second branches can be separately inserted into the first and second connectors, respectively. In at least some embodiments, the first and second branches each have a hemispherical
30 lateral cross-sectional shape.

A further embodiment is a control module for an electrical stimulation system that includes a housing; an electrical subassembly disposed in the housing; and a connector disposed in the housing, defining at least one connector lumen, and including conductive contacts disposed around the at least one connector lumen and an alignment structure
5 extending across the connector lumen and configured and arranged to mate with an alignment slit of an electrical stimulation lead or lead extension.

Yet another embodiment is a control module for an electrical stimulation system that includes a housing; an electrical subassembly disposed in the housing; and at least two connectors disposed in the housing, each connector defining a connector lumen, and
10 including conductive contacts disposed around the connector lumen. The connector lumen has a hemispherical lateral cross-sectional shape and is configured and arranged to receive a proximal portion of a lead or lead extension.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting and non-exhaustive embodiments of the present invention are
15 described with reference to the following drawings. In the drawings, like reference numerals refer to like parts throughout the various figures unless otherwise specified.

For a better understanding of the present invention, reference will be made to the following Detailed Description, which is to be read in association with the accompanying drawings, wherein:

20 FIG. 1 is a schematic view of one embodiment of an implantable medical device that includes a paddle body coupled to a control module via lead bodies, according to the invention;

FIG. 2 is a schematic view of another embodiment of an implantable medical device that includes a percutaneous lead body coupled to a control module via a lead
25 body, according to the invention;

FIG. 3A is a schematic view of one embodiment of a plurality of connectors disposed in the control module of FIG. 1, the connectors configured and arranged to receive the proximal portions of the lead bodies of FIG. 1, according to the invention;

FIG. 3B is a schematic view of one embodiment of a connector disposed in the control module of FIG. 2, the connector configured and arranged to receive the proximal portion of one of the lead body of FIG. 2, according to the invention;

5 FIG. 3C is a schematic view of one embodiment of a proximal portion of the lead body of FIG. 2, a lead extension, and the control module of FIG. 2, the lead extension configured and arranged to couple the lead body to the control module, according to the invention;

FIG. 4 is a schematic side view of yet another embodiment of an implantable medical device for brain stimulation, according to the invention;

10 FIG. 5A is a schematic perspective view of one embodiment of a distal end of a lead containing segmented electrodes, according to the invention;

FIG. 5B is a schematic perspective view of a second embodiment of a distal end of a lead containing segmented electrodes, according to the invention;

15 FIG. 5C is a schematic perspective view of a third embodiment of a distal end of a lead containing segmented electrodes, according to the invention;

FIG. 5D is a schematic perspective view of a fourth embodiment of a distal end of a lead containing segmented electrodes, according to the invention;

FIG. 5E is a schematic perspective view of a fifth embodiment of a distal end of a lead containing segmented electrodes, according to the invention;

20 FIG. 5F is a schematic perspective view of a sixth embodiment of a distal end of a lead containing segmented electrodes, according to the invention;

FIG. 5G is a schematic perspective view of a seventh embodiment of a distal end of a lead containing segmented electrodes, according to the invention;

25 FIG. 6A is a schematic side view of one embodiment of a proximal end of a lead containing segmented terminals and an alignment slit, according to the invention;

FIG. 6B is a schematic side view of a second embodiment of a proximal end of a lead containing segmented terminals and an alignment slit, according to the invention;

FIG. 6C is a schematic side view of a third embodiment of a proximal end of a lead containing segmented terminals and an alignment slit, according to the invention;

FIG. 6D is a schematic side view of a fourth embodiment of a proximal end of a lead containing segmented terminals and an alignment slit, according to the invention;

5 FIG. 6E is a schematic side view of a fifth embodiment of a proximal end of a lead containing segmented terminals and an alignment slit, according to the invention;

FIG. 6F is a schematic cross-sectional view of any one of the leads of FIGS. 6A-6E, according to the invention;

10 FIG. 7A is schematic end view of one embodiment of a connector for receiving a lead containing segmented terminals, according to the invention;

FIG. 7B is schematic side view of one embodiment of a connector for receiving a lead containing segmented terminals, according to the invention;

FIG. 7C is schematic side view of a second embodiment of a connector for receiving a lead containing segmented terminals, according to the invention;

15 FIG. 7D is schematic side view of a third embodiment of a connector for receiving a lead containing segmented terminals, according to the invention;

FIG. 8A is a schematic cross-sectional view of one embodiment of segmented connector contacts and a connector lumen, according to the invention;

20 FIG. 8B is a schematic cross-sectional view of a second embodiment of segmented connector contacts and a connector lumen, according to the invention;

FIG. 8C is a schematic cross-sectional view of a third embodiment of segmented connector contacts and a connector lumen, according to the invention;

FIG. 8D is a schematic cross-sectional view of a fourth embodiment of segmented connector contacts and a connector lumen, according to the invention;

FIG. 9A is a schematic perspective side view of a sixth embodiment of a proximal end of a lead containing segmented terminals and an alignment slit, according to the invention;

FIG. 9B is a schematic side view of the proximal end of the lead of FIG. 9A
5 inserted into two connectors, according to the invention;

FIG. 10A is a schematic perspective view of a distal portion of a connector for receiving a portion of the proximal end of the lead of FIG. 9A with the body rendered translucent to illustrated inner components of the connector, according to the invention;

FIG. 10B is a schematic side view of the proximal end of the lead of FIG. 9A
10 inserted into two connectors with the bodies of the connectors rendered translucent to illustrated inner components of the connectors, according to the invention; and

FIG. 11 is a schematic overview of one embodiment of components of an electrical stimulation system, according to the invention.

DETAILED DESCRIPTION

15 The present invention is directed to the area of implantable electrical stimulation systems and methods of making and using the systems. The present invention is also directed to implantable electrical stimulation systems having elongated members with improved contact arrays, as well as methods of making and using the elongated devices, contact arrays, and electrical stimulation systems.

20 Suitable implantable electrical stimulation systems include, but are not limited to, an electrode lead ("lead") with one or more electrodes disposed on a distal end of the lead and one or more terminals disposed on one or more proximal ends of the lead. Leads include, for example, deep brain stimulation leads, percutaneous leads, paddle leads, and cuff leads. Examples of electrical stimulation systems with leads are found in, for
25 example, U.S. Patents Nos. 6,181,969; 6,516,227; 6,609,029; 6,609,032; 6,741,892; 7,244,150; 7,450,997; 7,672,734; 7,761,165; 7,783,359; 7,792,590; 7,809,446; 7,949,395; 7,974,706; 6,175,710; 6,224,450; 6,271,094; 6,295,944; 6,364,278; and 6,391,985; U.S. Patent Applications Publication Nos. 2007/0150036; 2009/0187222; 2009/0276021; 2010/0076535; 2010/0268298; 2011/0004267; 2011/0078900; 2011/0130817;
30 2011/0130818; 2011/0238129; 2011/0313500; 2012/0016378; 2012/0046710;

2012/0071949; 2012/0165911; 2012/0197375; 2012/0203316; 2012/0203320; 2012/0203321; 2012/0316615; and 2013/0105071; and U.S. Patent Applications Serial Nos. 12/177,823 and 13/750,725, all of which are incorporated by reference.

Figure 1 illustrates schematically one embodiment of an electrical stimulation
5 system 100. The electrical stimulation system includes a control module (*e.g.*, a stimulator or pulse generator) 102 and a lead 103. The lead 103 including a paddle body 104 and one or more lead bodies 106 coupling the control module 102 to the paddle body 104. The paddle body 104 and the one or more lead bodies 106 form the lead 103. The paddle body 104 typically includes a plurality of electrodes 134 that form an array of
10 electrodes 133. The control module 102 typically includes an electronic subassembly 110 and an optional power source 120 disposed in a sealed housing 114. In Figure 1, two lead bodies 106 are shown coupled to the control module 102.

The control module 102 typically includes one or more connectors 144 into which the proximal end of the one or more lead bodies 106 can be plugged to make an electrical
15 connection via connector contacts (*e.g.*, 316 in Figure 3A) disposed in the connector 144 and terminals (*e.g.*, 310 in Figure 3A) on each of the one or more lead bodies 106. The connector contacts are coupled to the electronic subassembly 110 and the terminals are coupled to the electrodes 134. In Figure 1, two connectors 144 are shown.

The one or more connectors 144 may be disposed in a header 150. The header
20 150 provides a protective covering over the one or more connectors 144. The header 150 may be formed using any suitable process including, for example, casting, molding (including injection molding), and the like. In addition, one or more lead extensions 324 (see Figure 3C) can be disposed between the one or more lead bodies 106 and the control module 102 to extend the distance between the one or more lead bodies 106 and the
25 control module 102.

It will be understood that the electrical stimulation system can include more, fewer, or different components and can have a variety of different configurations including those configurations disclosed in the electrical stimulation system references cited herein. For example, instead of a paddle body 104, the electrodes 134 can be
30 disposed in an array at or near the distal end of a lead body 106' forming a percutaneous lead 103, as illustrated in Figure 2. The percutaneous lead may be isodiametric along the

length of the lead body 106". The lead body 106' can be coupled with a control module 102' with a single connector 144.

The electrical stimulation system or components of the electrical stimulation system, including one or more of the lead bodies 106, the control module 102, and, in the case of a paddle lead, the paddle body 104, are typically implanted into the body of a patient. The electrical stimulation system can be used for a variety of applications including, but not limited to, spinal cord stimulation, brain stimulation, neural stimulation, muscle activation via stimulation of nerves innervating muscle, and the like.

The electrodes 134 can be formed using any conductive, biocompatible material. Examples of suitable materials include metals, alloys, conductive polymers, conductive carbon, and the like, as well as combinations thereof. In at least some embodiments, one or more of the electrodes 134 are formed from one or more of: platinum, platinum iridium, palladium, titanium, or rhenium.

The number of electrodes 134 in the array of electrodes 133 may vary. For example, there can be two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, or more electrodes 134. As will be recognized, other numbers of electrodes 134 may also be used. In Figure 1, sixteen electrodes 134 are shown. The electrodes 134 can be formed in any suitable shape including, for example, round, oval, triangular, rectangular, pentagonal, hexagonal, heptagonal, octagonal, or the like.

The electrodes of the paddle body 104 or one or more lead bodies 106 are typically disposed in, or separated by, a non-conductive, biocompatible material including, for example, silicone, polyurethane, and the like or combinations thereof. The paddle body 104 and one or more lead bodies 106 may be formed in the desired shape by any process including, for example, molding (including injection molding), casting, and the like. Electrodes and connecting wires can be disposed onto or within a paddle body either prior to or subsequent to a molding or casting process. The non-conductive material typically extends from the distal end of the lead 103 to the proximal end of each of the one or more lead bodies 106. The non-conductive, biocompatible material of the paddle body 104 and the one or more lead bodies 106 may be the same or different. The

paddle body 104 and the one or more lead bodies 106 may be a unitary structure or can be formed as two separate structures that are permanently or detachably coupled together.

Terminals (*e.g.*, 310 in Figure 3A) are typically disposed at the proximal end of the one or more lead bodies 106 for connection to corresponding conductive contacts (*e.g.*, 316 in Figure 3A) in connectors (*e.g.*, 144 in Figure 1) disposed on, for example, the control module 102 (or to other devices, such as conductive contacts on a lead extension, an operating room cable, a splitter, an adaptor, or the like).

Conductive wires (not shown) extend from the terminals (*e.g.*, 310 in Figure 3A) to the electrodes 134. Typically, one or more electrodes 134 are electrically coupled to a terminal (*e.g.*, 310 in Figure 3A). In some embodiments, each terminal (*e.g.*, 310 in Figure 3A) is only coupled to one electrode 134.

The conductive wires may be embedded in the non-conductive material of the lead or can be disposed in one or more lumens (not shown) extending along the lead. In some embodiments, there is an individual lumen for each conductive wire. In other embodiments, two or more conductive wires may extend through a lumen. There may also be one or more lumens (not shown) that open at, or near, the proximal end of the lead, for example, for inserting a stylet rod to facilitate placement of the lead within a body of a patient. Additionally, there may also be one or more lumens (not shown) that open at, or near, the distal end of the lead, for example, for infusion of drugs or medication into the site of implantation of the paddle body 104. The one or more lumens may, optionally, be flushed continually, or on a regular basis, with saline, epidural fluid, or the like. The one or more lumens can be permanently or removably sealable at the distal end.

As discussed above, the one or more lead bodies 106 may be coupled to the one or more connectors 144 disposed on the control module 102. The control module 102 can include any suitable number of connectors 144 including, for example, two three, four, five, six, seven, eight, or more connectors 144. It will be understood that other numbers of connectors 144 may be used instead. In Figure 1, each of the two lead bodies 106 includes eight terminals that are shown coupled with eight conductive contacts disposed in a different one of two different connectors 144.

Figure 3A is a schematic side view of one embodiment of a plurality of connectors 144 disposed on the control module 102. In at least some embodiments, the control module 102 includes two connectors 144. In at least some embodiments, the control module 102 includes four connectors 144. In Figure 3A, proximal ends 306 of the plurality of lead bodies 106 are shown configured and arranged for insertion to the control module 102. Figure 3B is a schematic side view of one embodiment of a single connector 144 disposed on the control module 102'. In Figure 3B, the proximal end 306 of the single lead body 106' is shown configured and arranged for insertion to the control module 102'.

In Figures 3A and 3B, the one or more connectors 144 are disposed in the header 150. In at least some embodiments, the header 150 defines one or more lumens 304 into which the proximal end(s) 306 of the one or more lead bodies 106/106' with terminals 310 can be inserted, as shown by directional arrows 312, in order to gain access to the connector contacts disposed in the one or more connectors 144.

The one or more connectors 144 each include a connector housing 314 and a plurality of connector contacts 316 disposed therein. Typically, the connector housing 314 provides access to the plurality of connector contacts 316 via the lumen 304. In at least some embodiments, one or more of the connectors 144 further includes a retaining element 318 configured and arranged to fasten the corresponding lead body 106/106' to the connector 144 when the lead body 106/106' is inserted into the connector 144 to prevent undesired detachment of the lead body 106/106' from the connector 144. For example, the retaining element 318 may include an aperture 320 through which a fastener (*e.g.*, a set screw, pin, or the like) may be inserted and secured against an inserted lead body 106/106'.

When the one or more lead bodies 106/106' are inserted into the one or more lumens 304, the connector contacts 316 can be aligned with the terminals 310 disposed on the one or more lead bodies 106/106' to electrically couple the control module 102 to the electrodes (134 of Figure 1) disposed at a distal end of the one or more lead bodies 106. Examples of connectors in control modules are found in, for example, U.S. Patents Nos. 7,244,150 and 6,224,450, which are incorporated by reference.

In at least some embodiments, the electrical stimulation system includes one or more lead extensions. The one or more lead bodies 106/106' can be coupled to one or more lead extensions which, in turn, are coupled to the control module 102/102'. In Figure 3C, a lead extension connector 322 is disposed on a lead extension 324. The lead extension connector 322 is shown disposed at a distal end 326 of the lead extension 324. The lead extension connector 322 includes a connector housing 344. The connector housing 344 defines at least one lumen 330 into which a proximal end 306 of the lead body 106' with terminals 310 can be inserted, as shown by directional arrow 338. The lead extension connector 322 also includes a plurality of connector contacts 340. When the lead body 106' is inserted into the lumen 330, the connector contacts 340 disposed in the connector housing 344 can be aligned with the terminals 310 on the lead body 106 to electrically couple the lead extension 324 to the electrodes (134 of Figure 1) disposed at a distal end (not shown) of the lead body 106'.

The proximal end of a lead extension can be similarly configured and arranged as a proximal end of a lead body. The lead extension 324 may include a plurality of conductive wires (not shown) that electrically couple the connector contacts 340 to terminal on a proximal end 348 of the lead extension 324. The conductive wires disposed in the lead extension 324 can be electrically coupled to a plurality of terminals (not shown) disposed on the proximal end 348 of the lead extension 324. In at least some embodiments, the proximal end 348 of the lead extension 324 is configured and arranged for insertion into a lead extension connector disposed in another lead extension. In other embodiments (as shown in Figure 3C), the proximal end 348 of the lead extension 324 is configured and arranged for insertion into the connector 144 disposed on the control module 102'.

It will be understood that the control modules 102/102' can receive either lead bodies 106/106' or lead extensions 324. It will also be understood that the electrical stimulation system 100 can include a plurality of lead extensions 324. For example, each of the lead bodies 106 shown in Figures 1 and 3A can, alternatively, be coupled to a different lead extension 324 which, in turn, are each coupled to different ports of a two-port control module, such as the control module 102 of Figures 1 and 3A.

Turning to Figure 4, in the case of deep brain stimulation, the lead may include stimulation electrodes, recording electrodes, or a combination of both. At least some of

the stimulation electrodes, recording electrodes, or both are provided in the form of segmented electrodes that extend only partially around the perimeter (for example, the circumference) of the lead. These segmented electrodes can be provided in sets of electrodes, with each set having electrodes circumferentially distributed about the lead at
5 a particular longitudinal position.

In at least some embodiments, a practitioner may determine the position of the target neurons using recording electrode(s) and then position the stimulation electrode(s) accordingly. In some embodiments, the same electrodes can be used for both recording and stimulation. In some embodiments, separate leads can be used; one with recording
10 electrodes which identify target neurons, and a second lead with stimulation electrodes that replaces the first after target neuron identification. In some embodiments, the same lead may include both recording electrodes and stimulation electrodes or electrodes may be used for both recording and stimulation.

Figure 4 illustrates one embodiment of a device 400 for brain stimulation. The device includes a lead 410, a plurality of electrodes 425 disposed at least partially about a
15 perimeter of the lead 410, a plurality of terminals 435, a connector 444 for connection of the electrodes to a control unit, and a stylet 440 for assisting in insertion and positioning of the lead in the patient's brain. The stylet 440 can be made of a rigid material. Examples of suitable materials for the stylet include, but are not limited to, tungsten,
20 stainless steel, and plastic. The stylet 440 may have a handle 450 to assist insertion into the lead 410, as well as rotation of the stylet 440 and lead 410. The connector 444 fits over a proximal end of the lead 410, preferably after removal of the stylet 440.

In Figure 4, the electrodes 425 are shown as including both ring electrodes, such as ring electrode 420, and segmented electrodes, such as segmented electrodes 430. In
25 some embodiments, the electrodes 425 are all segmented. In other embodiments, the electrodes 425 are all ring-shaped. In Figure 4, each of the terminals 435 is shown as being ring-shaped. The segmented electrodes of Figure 4 are shown in sets of two, where the two segmented electrodes of a particular set are electrically isolated from one another and are circumferentially-offset along the lead 410. Any suitable number of segmented
30 electrodes can be formed into a set including, for example, two, three, four, or more segmented electrodes.

Segmented electrodes can be used to direct stimulus current to one side, or even a portion of one side, of the lead. When segmented electrodes are used in conjunction with an implantable pulse generator that delivers current stimulus, current steering can be achieved to more precisely deliver the stimulus to a position around an axis of the lead (i.e., radial positioning around the axis of the lead). Segmented electrodes may provide for superior current steering than ring electrodes because target structures in deep brain stimulation are not typically symmetric about the axis of the distal electrode array. Instead, a target may be located on one side of a plane running through the axis of the lead. Through the use of a segmented electrode array, current steering can be performed not only along a length of the lead but also around a perimeter of the lead. This provides precise three-dimensional targeting and delivery of the current stimulus to neural target tissue, while potentially avoiding stimulation of other tissue. Examples of leads with segmented electrodes include U.S. Patent Nos. 6,295,944; and 6,391,985; and U.S. Patent Applications Publication Nos. 2011/0005069; 2010/0268298; 2011/0130817; 2011/0130818; 2011/0078900; 2011/0238129; 2011/0313500; 2012/0016378; 2012/0046710; 2012/0165911; 2012/0197375; 2012/0203316; 2012/0203320; and 2012/0203321, all of which are incorporated herein by reference.

Figures 5A-5H illustrate leads 500 with segmented electrodes 550, optional ring electrodes 520 or tip electrodes 520a, and a lead body 510. The sets of segmented electrodes 550 each include either two (Figure 5B), three (Figures 5E-5H), or four (Figures 5A, 5C, and 5D) or any other number of segmented electrodes including, for example, three, five, six, or more. The sets of segmented electrodes 550 can be aligned with each other (Figures 5A-5G) or staggered (Figure 5H).

When the lead 500 includes both ring electrodes 520 and segmented electrodes 550, the ring electrodes 520 and the segmented electrodes 550 may be arranged in any suitable configuration. For example, when the lead 500 includes two ring electrodes 520 and two sets of segmented electrodes 550, the ring electrodes 520 can flank the two sets of segmented electrodes 550 (see *e.g.*, Figures 1, 5A, and 5E-5H). Alternately, the two sets of ring electrodes 520 can be disposed proximal to the two sets of segmented electrodes 550 (see *e.g.*, Figure 5C), or the two sets of ring electrodes 520 can be disposed distal to the two sets of segmented electrodes 550 (see *e.g.*, Figure 5D). One of the ring electrodes can be a tip electrode (see, tip electrode 520a of Figures 5E and 5G). It will

be understood that other configurations are possible as well (*e.g.*, alternating ring and segmented electrodes, or the like).

By varying the location of the segmented electrodes 550, different coverage of the target neurons may be selected. For example, the electrode arrangement of Figure 5C
5 may be useful if the physician anticipates that the neural target will be closer to a distal tip of the lead body 510, while the electrode arrangement of Figure 5D may be useful if the physician anticipates that the neural target will be closer to a proximal end of the lead body 510.

Any combination of ring electrodes 520 and segmented electrodes 550 may be
10 disposed on the lead 500. For example, the lead may include a first ring electrode 520, two sets of segmented electrodes; each set formed of four segmented electrodes 550, and a final ring electrode 520 at the end of the lead. This configuration may simply be referred to as a 1-4-4-1 configuration (Figures 5A and 5E – ring electrodes 520 and segmented electrode 550). It may be useful to refer to the electrodes with this shorthand
15 notation. Thus, the embodiment of Figure 5C may be referred to as a 1-1-4-4 configuration, while the embodiment of Figure 5D may be referred to as a 4-4-1-1 configuration. The embodiments of Figures 5F, 5G, and 5H can be referred to as a 1-3-3-1 configuration. Other electrode configurations include, for example, a 2-2-2-2 configuration, where four sets of segmented electrodes are disposed on the lead, and a 4-4
20 configuration, where two sets of segmented electrodes, each having four segmented electrodes 550 are disposed on the lead. The 1-3-3-1 electrode configuration of Figures 5F, 5G, and 5H has two sets of segmented electrodes, each set containing three electrodes disposed around the perimeter of the lead, flanked by two ring electrodes (Figures 5F and 5H) or a ring electrode and a tip electrode (Figure 5G). In some embodiments, the lead
25 includes 16 electrodes. Possible configurations for a 16-electrode lead include, but are not limited to 4-4-4-4; 6-8; 5-3-3-3-3-1 (and all rearrangements of this configuration); and 2-2-2-2-2-2-2-2. Any other suitable segmented electrode arrangements (with or without ring electrodes) can be used including, but not limited to, those disclosed in U.S. Provisional Patent Application Serial No. 62/113,291 and U.S. Patent Applications
30 Publication Nos. 2012/0197375 and 2015/0045864, all of which are incorporated herein by reference.

In at least some embodiments, a lead with 16 electrodes also includes 16 terminals. Many conventional control modules and connectors are designed to accept a proximal end of a lead or lead extension with an array of eight terminals. To instead have 16 terminals could extend the length of the proximal end of the lead or lead extension and
5 a consequent increase in the size of connector or control module.

Instead, in at least some embodiments it may be advantageous to design an elongate member (*e.g.*, a lead, lead extension, splitter, adaptor, or the like) with segmented terminals. In at least some embodiments, the elongate member also includes segmented electrodes. Utilizing segmented terminals may reduce the physical size of the
10 terminal array when compared to conventional terminal arrays with ring-shaped terminals. Consequently, the portion of the elongate member that is inserted into a connector to make electrical contact with the pulse generator can be reduced, as compared to conventional electrical stimulation systems. Alternately, the number of terminals that can be disposed along a proximal portion of an elongate member and that can be inserted
15 into a conventionally-sized connector may be increased from conventional electrical stimulation systems. Some examples of such arrangements are found in, for example, U.S. Provisional Patent Application Serial No. 62/113,291, incorporated herein by reference.

Although the embodiments described below are presented as leads, it will be
20 understood that the arrangement of segmented terminals, a retention sleeve, and an alignment slit, described below, can also be applied to a lead extension or other elongate member having terminals. In general, any elongate member can have first contacts (for example, electrode for a lead or conductive contacts for a lead extension) disposed along a distal portion of the elongate member and second segmented contacts (for example,
25 segmented terminals) disposed along a proximal portion of the elongate member.

Figure 6A illustrates one embodiment of a proximal portion of a lead 603 (or other elongate member) with an array of segmented terminals 610 and an optional retention sleeve 670. To ensure proper alignment between of the lead 603 (or other elongate member) in a connector 644 (Figures 7A-7D) so that each terminal is electrically
30 connected to a single connector contact, the lead includes an alignment slit 682 formed along a portion of the proximal end of the lead. The alignment slit 682 extends completely through the lead 603 and intersects a central lumen 686 (or stylet lumen) of

the lead, as shown in Figure 6F. The alignment slit 682 separates the proximal portion of the lead into at least two sections 603a, 603b that are laterally spaced-apart and separated by the alignment slit.

5 The segmented terminals 610 can be formed in sets of two or more terminals at a same position along the longitudinal axis of the lead. Each of the segmented terminals of a particular set extends around less than (for example, no more than 45%, 40%, 33%, 30%, or 25% of) the entire perimeter of the elongate member. The segmented terminals of the set are not in electrical contact with one another and are circumferentially-offset from one another along the elongate member. In at least some embodiments, the terminal
10 array includes at least one segmented terminal set, such as segmented terminal set 611 which, in turn, includes multiple segmented terminals 610, such as segmented terminals 610a and 610b. In some embodiments, a set of segmented terminals can have two, three, four, or more segmented terminals disposed at the same position along the longitudinal axis of the elongate member, but circumferentially offset from each other. In at least
15 some embodiments, the alignment slit 682 extends between at least two of the segmented terminals of one or more (or even each) of the sets of segmented terminals. In at least some of these embodiments, each set includes exactly two segmented terminals.

In some embodiments, the terminal array is formed exclusively from segmented terminals. In other embodiments, the terminal array includes a combination of one or
20 more ring-shaped terminals and one or more segmented terminal sets.

The terminal array can include any suitable number of segmented terminal sets 611 including, for example, one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, or more segmented-terminal sets. In Figure 6A, eight segmented terminal sets 611 are shown disposed along the lead 603.

25 In at least some embodiments, the elongate member includes a single proximal portion and multiple distal portions. One advantage of implementing segmented terminals is that it may increase the number of terminals disposed along a lead from conventional leads. The increased number of terminals may enable the lead to be designed with multiple distal portions, where a different electrode array is disposed along
30 each of the distal portions, and where electrodes of each of the multiple electrode arrays are coupled to terminals disposed along a single proximal portion. Such a design may be

useful, for example, in deep brain stimulation where bilateral stimulation may be desirable.

When the lead has multiple distal portions and a single proximal portion with segmented terminals, the single proximal portion can be received by a single connector port. Such an arrangement enables each of multiple electrode arrays disposed along
5 different distal portions to be operated by a single control module. Additionally, such a design enables multiple electrode arrays to be controlled by a single control module via a single connector with a single lead-receiving port.

In Figure 6A, the alignment slit 682 extends from the proximal end of the lead to a
10 point beyond the retention sleeve 670. The alignment slit 682 separates the terminals 610a, 610b in each set 611 and divides the retention sleeve 670 into two parts that are laterally spaced-apart and separated from each other by the alignment slit. Figures 6B, 6C, 6D, and 6E illustrate alternative embodiments of the lead 603 and the alignment slit 682. In the embodiments of Figures 6B, 6D, and 6E, the alignment slit 682 terminates
15 distal to all of the terminals 610, but proximal to the retention sleeve 670. In the embodiment of Figure 6C, the alignment slit 682 terminates proximal to all of the terminals 610. It will be understood that in other embodiments, the alignment slit can terminate anywhere along the array of terminals 610.

In Figures 6A-6C, the terminal 610 of each set are aligned with each other to form
20 longitudinal columns (i.e., columns parallel to the longitudinal axis of the lead) of terminals that are aligned. Figures 6D and 6E illustrate arrangements of segmented terminals 610 in longitudinal columns that are longitudinally offset from each other (for example, the terminals on the left of Figures 6D and 6E are longitudinally offset from those on the right). In Figure 6D the terminals of different longitudinal columns do not
25 overlap and in Figure 6E the terminals of different longitudinal columns do overlap. It will be recognized that other arrangements of segmented terminals, including any of those arrangements described above with respect to arrangements of segmented terminals, can be used.

Turning to Figures 7A and 7B, the proximal portion of the elongate member, such
30 as the lead 603 (Figures 6A-6F), is typically inserted into a connector 644 disposed on or along a lead extension, control module, adaptor, splitter, or the like. The connector 644

includes segmented connector contacts 640 suitable for coupling with the segmented terminals. The connector 644 includes an elongated connector housing 660 that defines a connector lumen 662 suitable for receiving a portion of an elongate member, such as the lead 603 (Figure 6A-6F); a lead extension (*e.g.*, 324 in Figure 3C); or the like. The connector 644 also include an alignment structure 680 (Figure 6C - for example, a pin, blade, seal, wall, rod, or rail) that extends into the connector lumen 662 (and, in at least some embodiments, across the entire diameter of the connector lumen) and can be used to align the lead with the connector by mating with the alignment slit 682 of the lead. Although the illustrated connector lumen has a circular cross-section, it will be understood that lumens with other cross-sections (and leads with non-circular cross-sections) can also be used including, but not limited to, oval, square, rectangular, triangular, pentagonal, hexagonal, octagonal, cruciform, or any other suitable regular or irregular cross-sectional shape.

Multiple connector contacts 640 are disposed in a spaced-apart relationship along the longitudinal length of the connector housing 660 such that the connector contacts are exposed to the connector lumen 662 (Figure 7A) and individually attached to an array of conductive members (for example, wires, pins, traces, terminals, or the like) that couple the connector contacts to other components. When, for example, the connector 644 is disposed on a lead extension (*e.g.*, 324 in Figure 3C), the conductive members (for example, wires or other conductors) may couple the connector contacts to lead extension terminals. When, for example, the connector 644 is disposed on a control module, the conductive members (for example, wires, traces, pins, or the like) may couple the connector contacts 640 to the electronic subassembly (110 in Figure 1). In at least some embodiments, the conductive members 664 couple the connector contacts 640 to the electronic subassembly (110 in Figure 1) via feedthrough pins extending through the sealed housing (114 in Figure 1).

In at least some embodiments, the segmented connector contacts 640 can be formed in sets of two or more terminals at a same position along the longitudinal axis of the connector lumen 662. Each of the segmented connector contacts of a particular set extends around less than (for example, no more than 45%, 40%, 33%, 30%, or 25% of) the entire perimeter of the connector lumen. The segmented connector contacts of the set are not in electrical contact with one another and are circumferentially offset from one

another along the connector lumen. In at least some embodiments, the connector contact array includes at least one segmented connector contacts set, such as segmented connector contacts set 641 which, in turn, includes multiple segmented connector contacts 640, such as segmented terminals 640a and 640b. In some embodiments, a set of segmented connector contacts can have two, three, four, or more segmented connector contacts disposed at the same position along the longitudinal axis of the connector lumen, but circumferentially offset from each other.

Optionally, a retention block 666 is disposed along the connector 644. The retention block 666 can be used to facilitate retention of an elongate member when the elongate member is inserted into the connector lumen 662. In at least some embodiments, the retention block 666 defines a fastening aperture 668 configured to receive a fastener (*e.g.*, a set screw, pin, or the like) which can engage the optional retention sleeve 670 (Figure 6A) of the lead. In at least some embodiments, the fastener, when received by the fastener aperture 668, is configured to tighten against a portion of the elongate member (*e.g.*, a retention sleeve) when the elongate member is inserted into the connector lumen 662.

The connector 644 includes an alignment structure 680 that mates with or fits within the alignment slit 682 of the lead 603. Engagement of the alignment structure 680 of the connector 644 with the alignment slit 682 of the lead 603 ensures that the lead and connector have the proper rotational alignment for correctly coupling the segmented terminals 610 of the lead 603 with the connector contacts 640 of the connector 644.

In the embodiment of Figure 7B, the alignment structure 680 is disposed in the retention block 666. This particular arrangement is useful with the lead 603 of Figure 6A where the alignment slit 670 extends through the retention sleeve 670. The alignment structure 680 can be placed elsewhere in the connector 644. For example, in the embodiment illustrated in Figure 7C, the alignment structure 680 is placed outside the retention block 666. This arrangement can be used with any of the leads illustrated in Figure 6A, 6B, 6D, and 6E. In the embodiment illustrated in Figure 7D, the alignment structure 680 extends between all of the connector contacts 640 and can be used with any of the leads illustrated in Figures 6A, 6B, 6D, and 6E. In other embodiments, the alignment structure 680 may extend between fewer than all of the connector contacts 640. The alignment structure 680 can be placed in other portions of the connector lumen 662,

such as near the end of the connector lumen, which would be required for use with the lead illustrated in Figure 6C.

Any suitable type of connector contact 640 can be used in connector 644. Examples of suitable connector contacts and connectors can be found in, for example, U.S. Provisional Patent Applications Serial Nos. 62/077,762; 62/077,784; and 62/113,291, all of which are incorporated herein by reference.

Figures 8A-8D illustrate, in cross-section, embodiments of connector contacts 840 (two connector contacts are illustrated in each Figure) for use in a connector (such as connector 644 of Figures 7A-7D) having a connector wall 861 that defines the connector lumen 862 and an alignment structure 880. If Figures 8A and 8B, the connector contacts 840 are arced metal contacts. These connector contacts form an arc ranging from, for example, 90 to 175 degrees or 100 to 160 degrees.

In Figure 8C, the connector contacts 840 are leaf springs 890 disposed within the connector lumen 862 with one or more legs 892 that extend through the connector wall 861 to make electrical connection (for example, by welding, soldering, or the like) with other portions (for example, conductive members 664 of Figure 6C) of the connector. In Figure 8D, the connector contacts 840 are coiled leaf springs 891 disposed within the connector lumen 862 with one or more legs 892 that extend through the connector wall 861 to make electrical connection with other portions of the connector.

Figures 9A illustrates the proximal end portion of another embodiment of lead 903 with an array of segmented terminals 910, an optional retention sleeve 970, and an alignment slit 982. The proximal end portion of the lead 903 is divided into two branches 903a, 903b by the alignment slit 982 with terminals 910a, 910b disposed on each branch and, optionally, a portion 970a, 970b of the retention sleeve. Each branch 903a, 903b includes a bendable section 990a, 990b distal to all of the terminals 910 and the optional retention sleeve 970. The bendable sections 990a, 990b can allow the two branches 903a, 930b to be inserted into two different connectors. The two branches 903a, 903b join together to form a joined portion 905 of the lead 903. The lead 903 can also include a central lumen 986 with separate channels 986a, 986b form in the respective branches 903a, 903b. In at least some embodiments, the two branches 903a, 903b have a

hemispherical lateral cross-sectional shape which could be considered an arc-shaped lateral cross-sectional shape if the central lumen 986 is ignored.

Each branch 903a, 903b can fit into a different connector 944a, 944b, as illustrated in Figure 9B. The two different connectors 944a, 944b can be two connectors formed as part of control module (for example, control module 902) or two connectors of a single lead extension or connectors on two different lead extensions (see, for example, lead extension 324 of Figure 3C). In at least some embodiments, the connector lumens of the two connectors 944a, 944b that receive the branches 903a, 903b can have a hemispherical or arc-shaped lateral cross-sectional shape.

The segmented terminals 910 can be formed in sets of two or more terminals at a same position along the longitudinal axis of the lead. The segmented terminals of the set are not in electrical contact with one another and are circumferentially-offset from one another along the elongate member. In at least some embodiments, the terminal array includes at least one segmented terminal set, such as segmented terminal set 911 which, in turn, includes multiple segmented terminals 910, such as segmented terminals 910a and 910b. In some embodiments, a set of segmented terminals can have two, three, four, or more segmented terminals disposed at the same position along the longitudinal axis of the elongate member, but circumferentially offset from each other.

The terminal array can include any suitable number of segmented terminal sets 911 including, for example, one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, or more segmented-terminal sets. In Figure 9A, eight segmented terminal sets 911 are shown disposed along the lead 903.

In at least some embodiments, the bendable sections 990a, 990b are permanently bent in the desired configuration. In other embodiments, the bendable sections 990a, 990b are sufficiently flexible to allow a practitioner to modify the bends in the bendable sections, but still maintain the modified bends when the branch is released by the practitioner. In yet other embodiments, the bendable sections 990a, 990b are sufficiently flexible to be bent by the practitioner, but do not maintain the bends when the branch is released by the practitioner.

Figures 10A and 10B illustrate one embodiment of connectors 1044a, 1044b where the body 1060 of the connectors is translucent to facilitate a view of the interior components of the connectors. Each connector 1044a, 1044b has a connector lumen 1062a, 1062b that, in at least some embodiments, has a shape similar to the branch 903a, 903b of the lead 903 (for example, a hemispherical shape.) Each connector 1044, 1044a includes connector contacts 1040 suitable for coupling with the segmented terminals. Optionally, a retention block 1066 is disposed along each connector 1044a, 1044b. The retention block 1066 can be used to facilitate retention of an elongate member when the elongate member is inserted into the connector lumen 1062a, 1062b. In at least some embodiments, the retention block 1066 defines a fastening aperture 1068 configured to receive a fastener (*e.g.*, a set screw, pin, or the like) which can engage the optional retention sleeve 1070 of the lead. In at least some embodiments, the fastener, when received by the fastener aperture 1068, is configured to tighten against a portion of the elongate member (*e.g.*, a retention sleeve) when the elongate member is inserted into the connector lumen 1062a, 1062b. Each connector can also optionally include a stop 1096 which provides a back stop for insertion of the lead or lead extension into the connector

In the illustrated embodiment, the connector contacts 1040 are formed as circular arcs of 180 degrees or less, but it will be understood that a full cylinder (or circular arc of greater than 180 degrees) can be used for the connector contact. In addition, any of the connector contacts illustrated in Figures 8A-8D can be used but with only a single connector contact at each position along the connector, instead of two connector contacts as illustrated in Figures 8A-8D.

With respect to leads with the terminal arrays illustrated in Figures 6A-6E and 9A, the corresponding electrodes can be segmented electrodes, ring electrodes, other electrodes disclosed herein, or any other suitable electrode, or any combination thereof. In particular, although the terminals of a lead may be all or part segmented terminals, the corresponding electrodes may be segmented electrodes, non-segmented electrodes, or any combination thereof.

Figure 11 is a schematic overview of one embodiment of components of an electrical stimulation system 1100 including an electronic subassembly 1110 disposed within a control module. It will be understood that the electrical stimulation system can include more, fewer, or different components and can have a variety of different

configurations including those configurations disclosed in the stimulator references cited herein.

Some of the components (for example, power source 1112, antenna 1118, receiver 1102, and processor 1104) of the electrical stimulation system can be positioned on one or more circuit boards or similar carriers within a sealed housing of an implantable pulse generator, if desired. Any power source 1112 can be used including, for example, a battery such as a primary battery or a rechargeable battery. Examples of other power sources include super capacitors, nuclear or atomic batteries, mechanical resonators, infrared collectors, thermally-powered energy sources, flexural powered energy sources, bioenergy power sources, fuel cells, bioelectric cells, osmotic pressure pumps, and the like including the power sources described in U.S. Patent No. 7,437,193, incorporated herein by reference.

As another alternative, power can be supplied by an external power source through inductive coupling via the optional antenna 1118 or a secondary antenna. The external power source can be in a device that is mounted on the skin of the user or in a unit that is provided near the user on a permanent or periodic basis.

If the power source 1112 is a rechargeable battery, the battery may be recharged using the optional antenna 1118, if desired. Power can be provided to the battery for recharging by inductively coupling the battery through the antenna to a recharging unit 1116 external to the user. Examples of such arrangements can be found in the references identified above.

In one embodiment, electrical current is emitted by the electrodes 134 on the paddle or lead body to stimulate nerve fibers, muscle fibers, or other body tissues near the electrical stimulation system. A processor 1104 is generally included to control the timing and electrical characteristics of the electrical stimulation system. For example, the processor 1104 can, if desired, control one or more of the timing, frequency, strength, duration, and waveform of the pulses. In addition, the processor 1104 can select which electrodes can be used to provide stimulation, if desired. In some embodiments, the processor 1104 may select which electrode(s) are cathodes and which electrode(s) are anodes. In some embodiments, the processor 1104 may be used to identify which electrodes provide the most useful stimulation of the desired tissue.

Any processor can be used and can be as simple as an electronic device that, for example, produces pulses at a regular interval or the processor can be capable of receiving and interpreting instructions from an external programming unit 1108 that, for example, allows modification of pulse characteristics. In the illustrated embodiment, the processor 1104 is coupled to a receiver 1102 which, in turn, is coupled to the optional antenna 1118. This allows the processor 1104 to receive instructions from an external source to, for example, direct the pulse characteristics and the selection of electrodes, if desired.

In one embodiment, the antenna 1118 is capable of receiving signals (*e.g.*, RF signals) from an external telemetry unit 1106 which is programmed by a programming unit 1108. The programming unit 1108 can be external to, or part of, the telemetry unit 1106. The telemetry unit 1106 can be a device that is worn on the skin of the user or can be carried by the user and can have a form similar to a pager, cellular phone, or remote control, if desired. As another alternative, the telemetry unit 1106 may not be worn or carried by the user but may only be available at a home station or at a clinician's office. The programming unit 1108 can be any unit that can provide information to the telemetry unit 1106 for transmission to the electrical stimulation system 1100. The programming unit 1108 can be part of the telemetry unit 1106 or can provide signals or information to the telemetry unit 1106 via a wireless or wired connection. One example of a suitable programming unit is a computer operated by the user or clinician to send signals to the telemetry unit 1106.

The signals sent to the processor 1104 via the antenna 1118 and receiver 1102 can be used to modify or otherwise direct the operation of the electrical stimulation system. For example, the signals may be used to modify the pulses of the electrical stimulation system such as modifying one or more of pulse duration, pulse frequency, pulse waveform, and pulse strength. The signals may also direct the electrical stimulation system 1100 to cease operation, to start operation, to start charging the battery, or to stop charging the battery. In other embodiments, the stimulation system does not include an antenna 1118 or receiver 1102 and the processor 1104 operates as programmed.

Optionally, the electrical stimulation system 1100 may include a transmitter (not shown) coupled to the processor 1104 and the antenna 1118 for transmitting signals back to the telemetry unit 1106 or another unit capable of receiving the signals. For example,

the electrical stimulation system 1100 may transmit signals indicating whether the electrical stimulation system 1100 is operating properly or not or indicating when the battery needs to be charged or the level of charge remaining in the battery. The processor 1104 may also be capable of transmitting information about the pulse characteristics so
5 that a user or clinician can determine or verify the characteristics.

The above specification, examples and data provide a description of the manufacture and use of the composition of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention also resides in the claims hereinafter appended.

10

CLAIMS

What is claimed as new and desired to be protected by Letters Patent of the United States is:

1. An electrical stimulation lead or lead extension, comprising:
 - a body having an outer surface, a proximal end, a proximal portion, at least one distal portion, an outer surface, a perimeter, and a longitudinal length, the body defining an alignment slit extending distally from the proximal end of the body and splitting the proximal portion of the body into two transversely space-apart sections;
 - a plurality of first contacts disposed along the distal portion of the body;
 - a plurality of segmented second contacts disposed along the proximal portion of the body, wherein each segmented second contact extends around less than the entire perimeter of the body and is separated from all other segmented second contacts by portions of the body or the alignment slit; and
 - a plurality of conductors electrically coupling the plurality of first contacts to the plurality of second contacts.
2. The electrical stimulation lead or lead extension of claim 1, wherein the segmented second contacts are arranged in a plurality of sets of segmented second contacts, wherein each set of segmented second contacts comprises at least two of the segmented second contacts disposed in a circumferential arrangement at a same longitudinal position of the lead.
3. The electrical stimulation lead or lead extension of claim 2, wherein the alignment slit extends between at least two of the segmented second contacts of each of the sets of segmented second contacts.
4. The electrical stimulation lead or lead extension of any one of claims 2 or 3, wherein each of the sets of segmented second contacts contains exactly two segmented second contacts.

5. The electrical stimulation lead or lead extension of any one of claims 1-4, further comprising a retention sleeve disposed distal of all of the segmented second contacts.

6. The electrical stimulation lead or lead extension of claim 5, wherein the alignment slit separates the retention sleeve into two laterally spaced-apart pieces.

7. The electrical stimulation lead or lead extension of any one of claims 1-6, wherein the alignment slit separates the proximal portion of the body into two branches, wherein each branch further defines a bendable portion distal to all of the segmented second contacts, wherein the bendable portions of the two branches allow the branches to be sufficiently separated so that the branches can be inserted into different connectors.

8. The electrical stimulation lead or lead extension of any one of claims 1-7, wherein the first contacts are electrodes and the segmented second contacts are segmented terminals and the electrical stimulation lead or lead extension is an electrical stimulation lead.

9. The electrical stimulation lead or lead extension of any one of claims 1-7, wherein the first contacts are connector contacts and the segmented second contacts are segmented terminals and the electrical stimulation lead or lead extension is a lead extension.

10. An electrical stimulation system comprising:
the electrical stimulation lead or lead extension of any one of claims 1-9; and
a first connector defining a connector lumen configured and arranged to receive at least a portion of the proximal end of the electrical stimulation lead or lead extension, wherein the first connector comprises a plurality of segmented connector contacts disposed along the connector lumen.

11. The electrical stimulation system of claim 10, further comprising a control module, wherein the control module comprises the connector, a housing, and an electrical subassembly disposed in the housing and electrical coupled to the connector contacts of the connector.

12. The electrical stimulation system of claim 10, further comprising a lead extension, wherein the lead extension comprises the connector.

13. The electrical stimulation system of any one of claims 10-12, wherein the connector contacts of the first connector are arranged in a plurality of sets of segmented connector contacts, wherein each set of segmented connector contacts comprises at least two of the segmented connector contacts disposed in a circumferential arrangement at a same longitudinal position along the connector lumen.

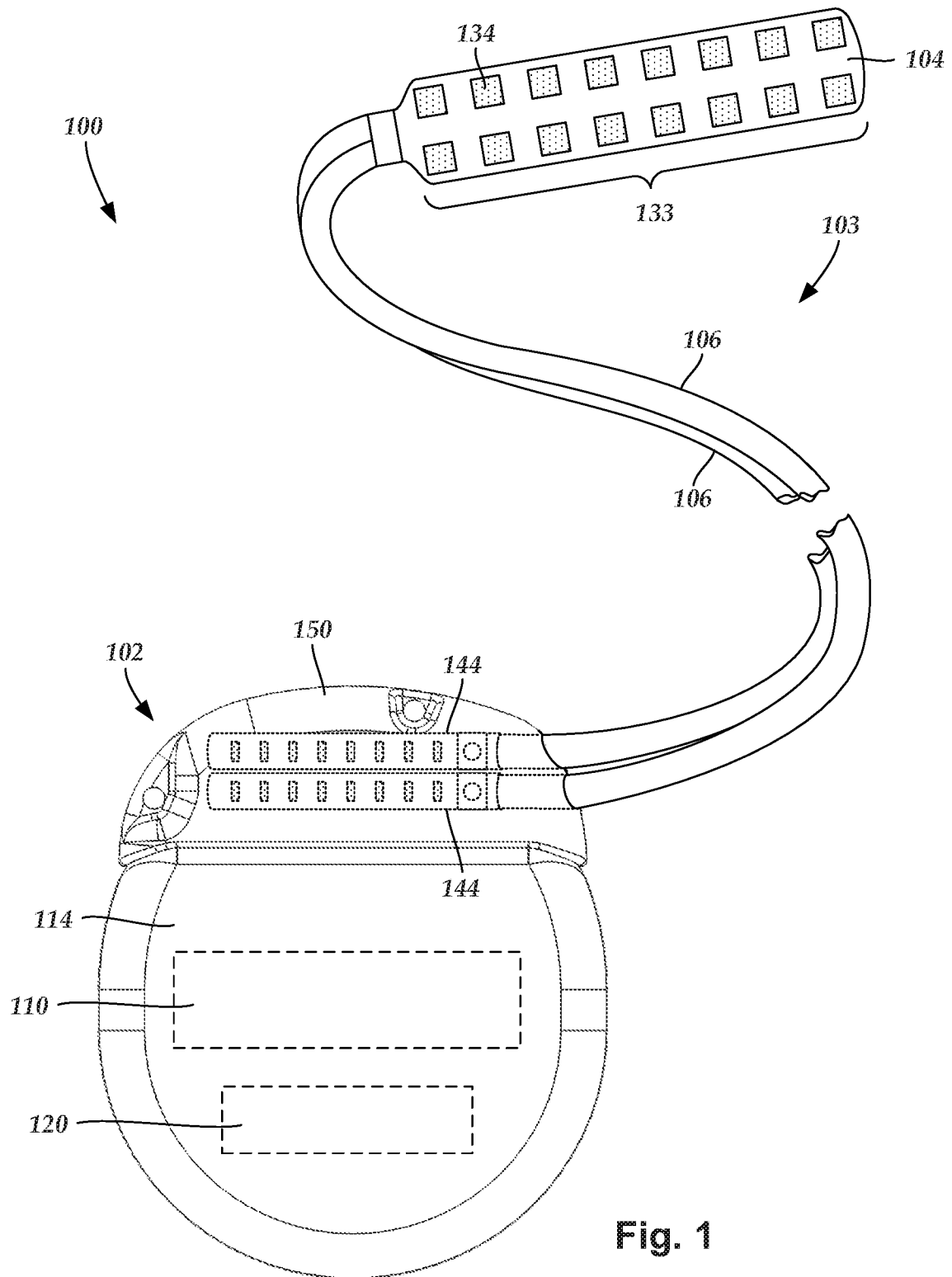
14. The electrical stimulation system of any one of claims 10-13, wherein the connector further comprises a connector housing containing the connector lumen and defining an opening into the connector lumen, and

an alignment structure extending across the connector lumen and configured and arranged to mate with the alignment slit of the electrical stimulation lead or lead extension.

15. The electrical stimulation system of any one of claims 10-12, further comprising a second connector defining a connector lumen configured and arranged to receive the proximal end of the electrical stimulation lead or lead extension, wherein the second connector comprises a plurality of segmented connector contacts disposed along the connector lumen,

wherein the electrical stimulation lead or lead extension is configured and arranged so that the alignment slit separates the proximal portion of the body into a first branch and a second branch, wherein each of the first and second branched further defines a bendable portion distal to all of the segmented second contacts, wherein the bendable portions of the first and second branches allow the first and second branches to be

sufficiently separated so that the first and second branches can be separately inserted into the first and second connectors, respectively.



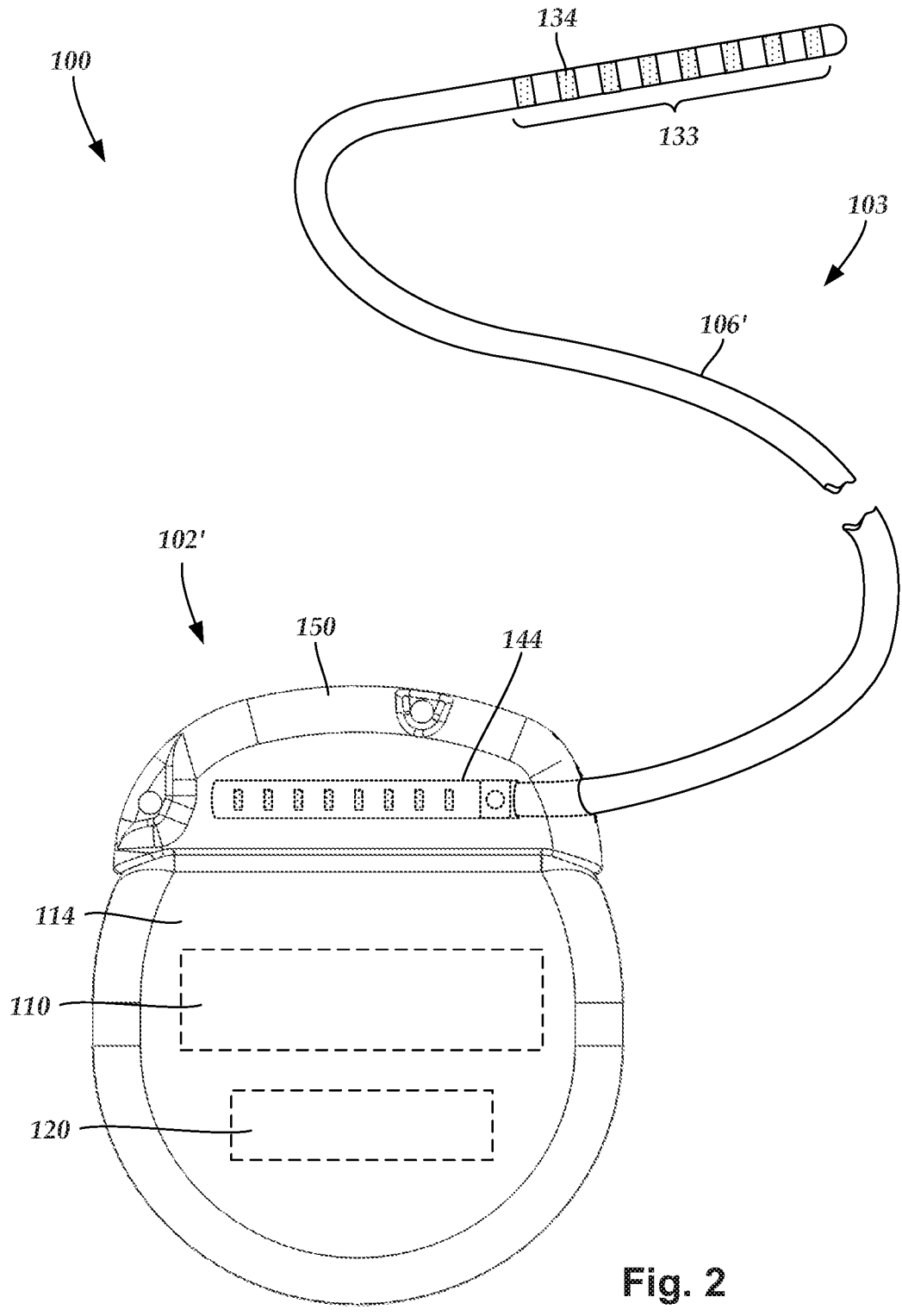


Fig. 2

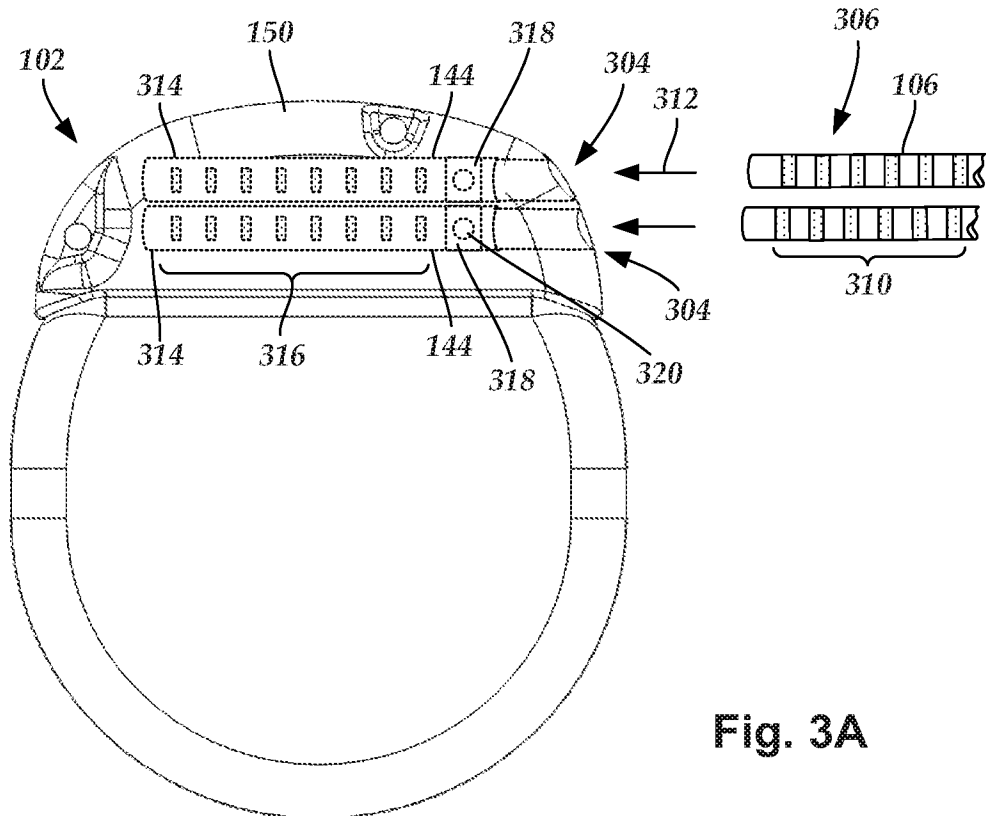


Fig. 3A

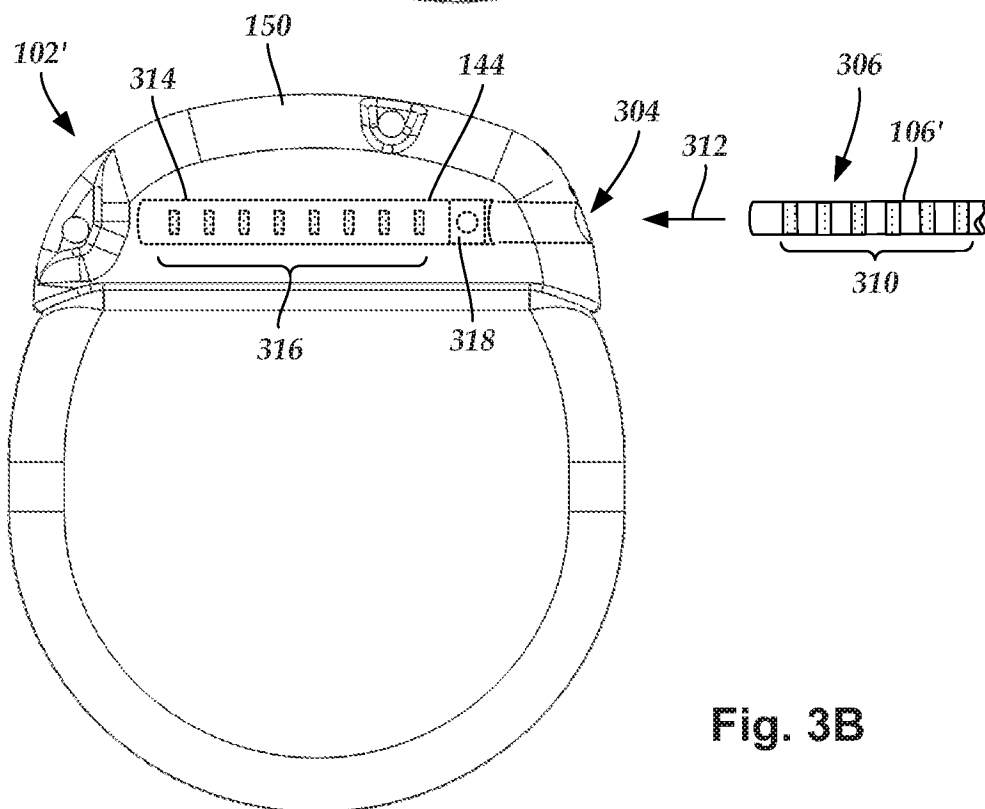
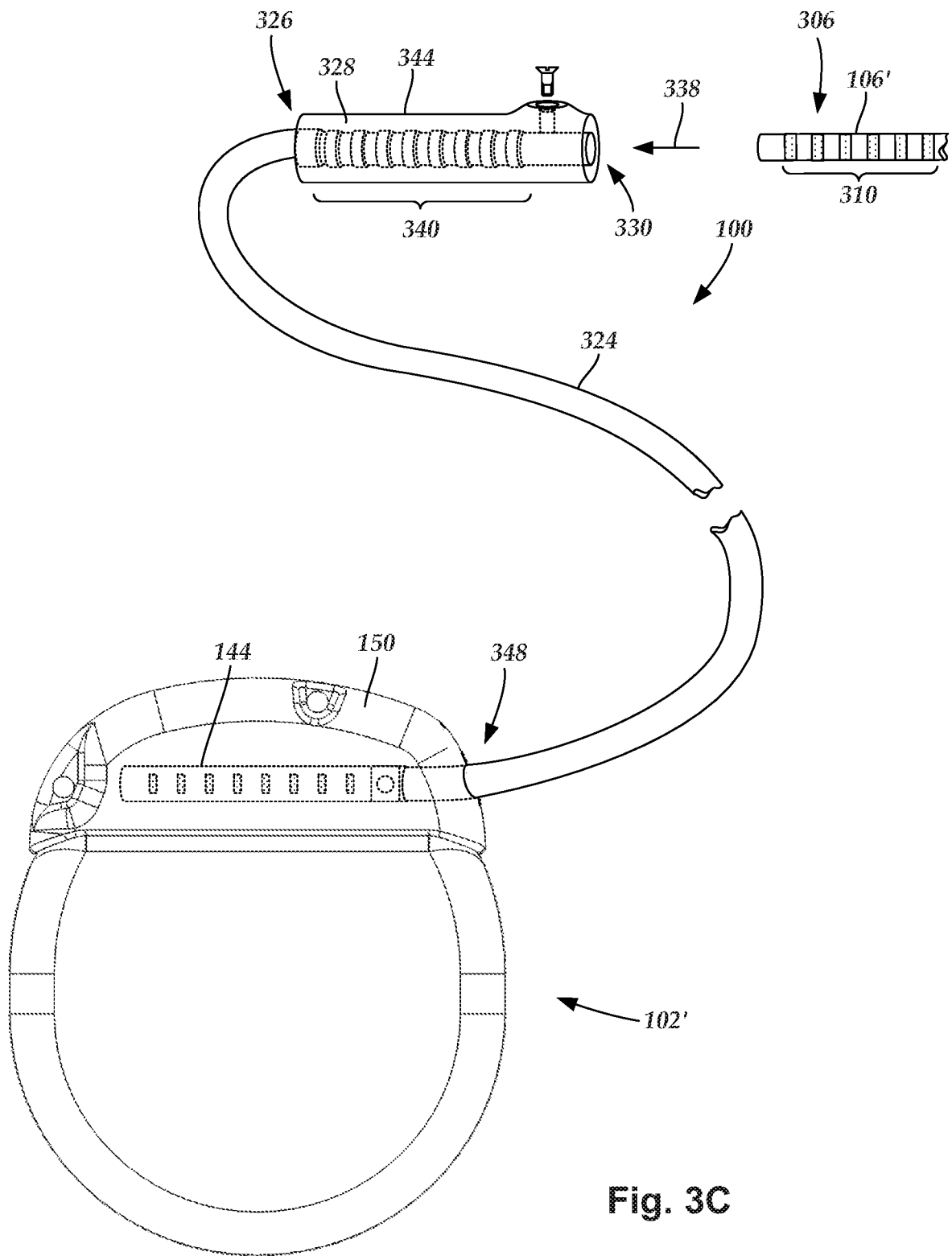


Fig. 3B



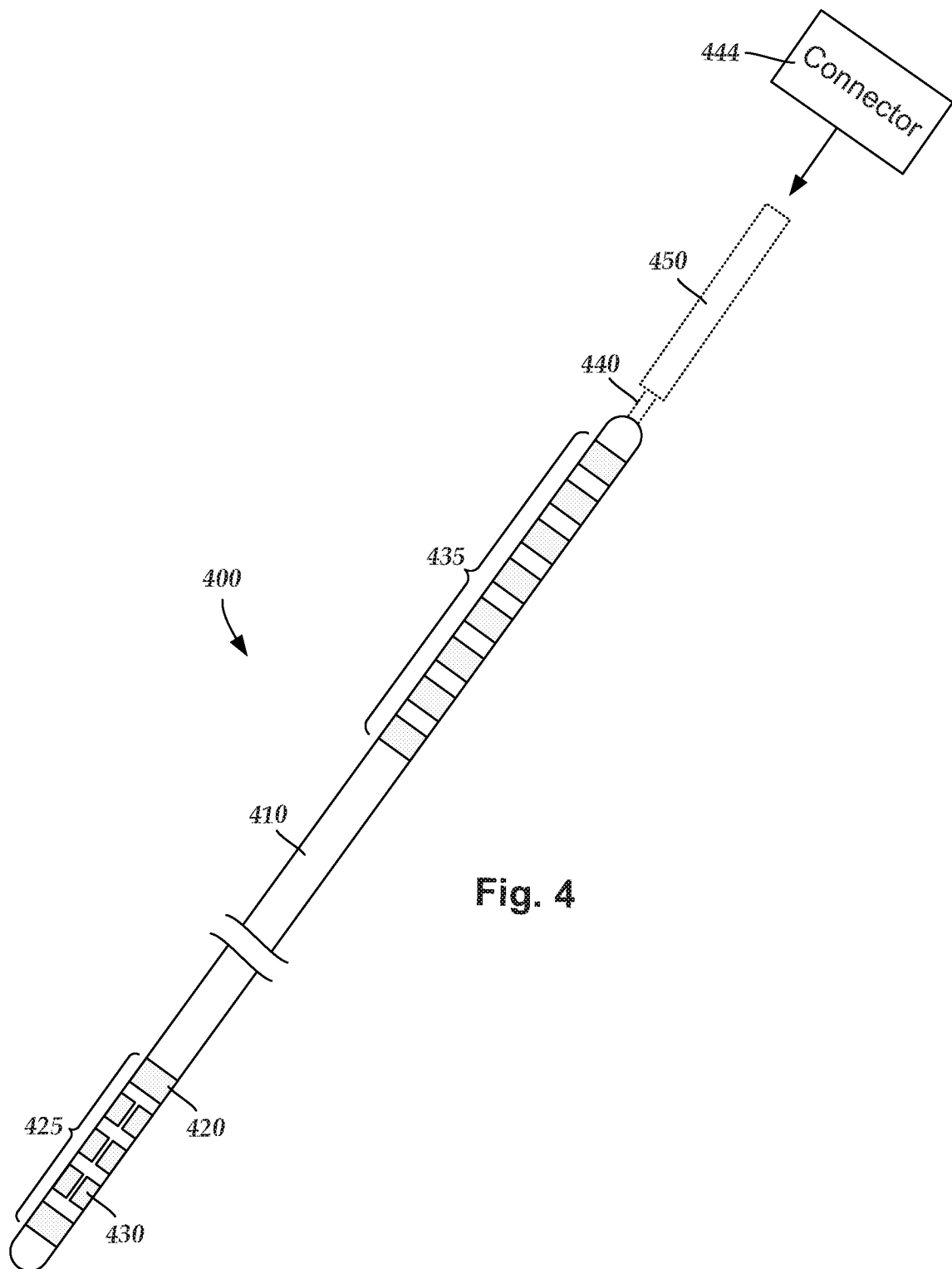
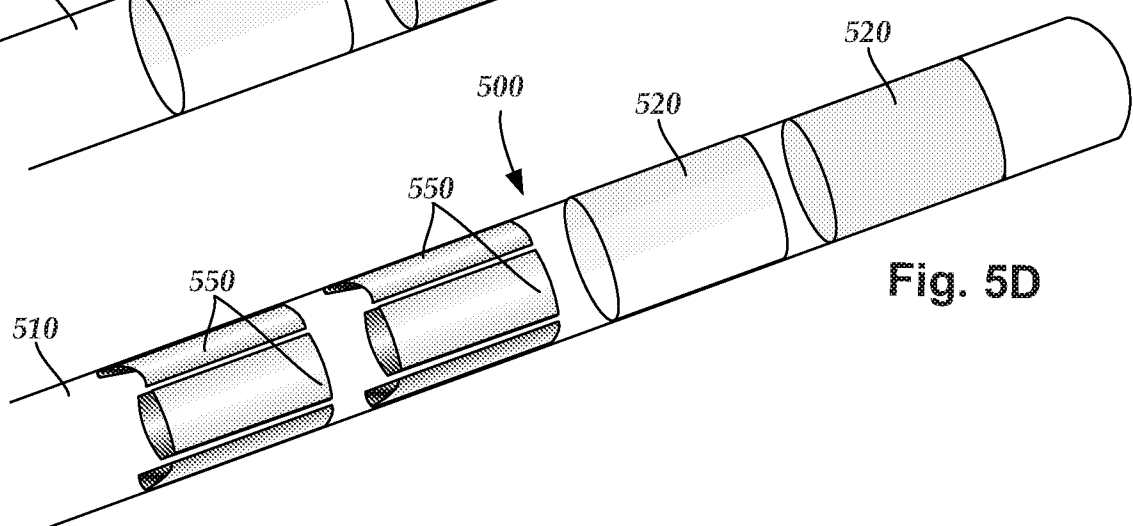
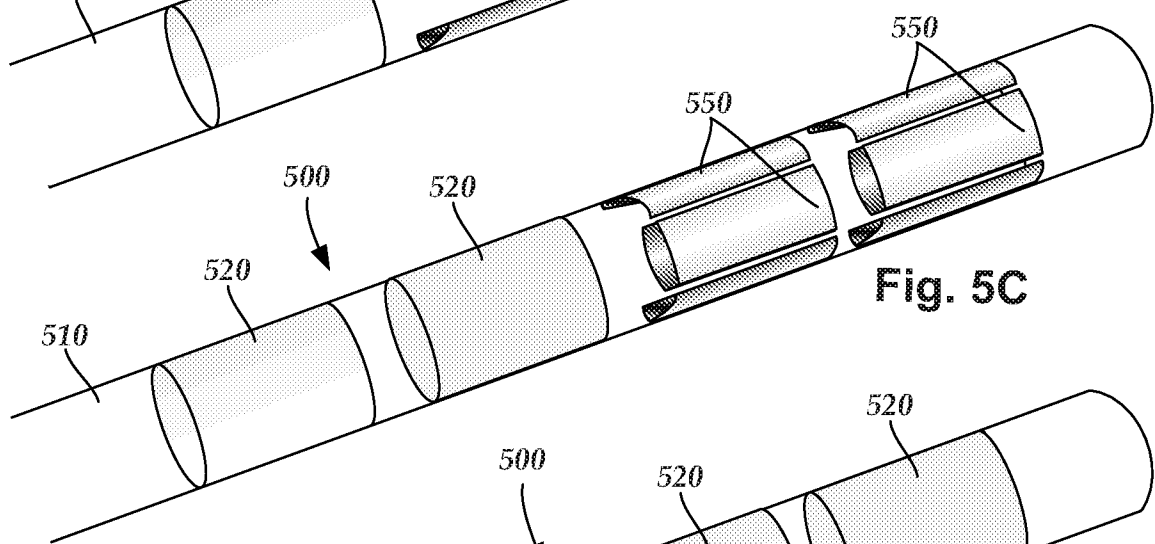
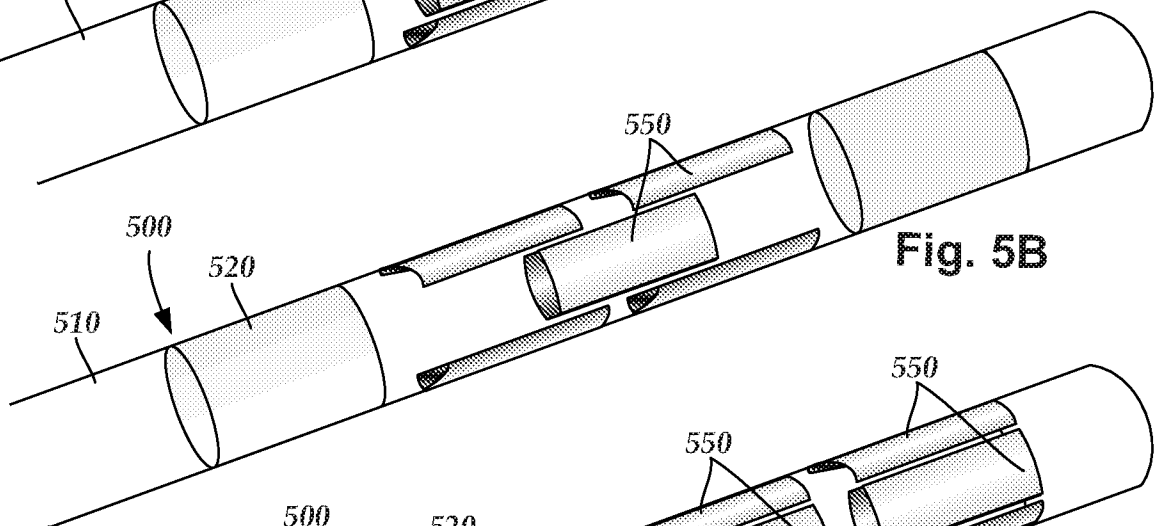
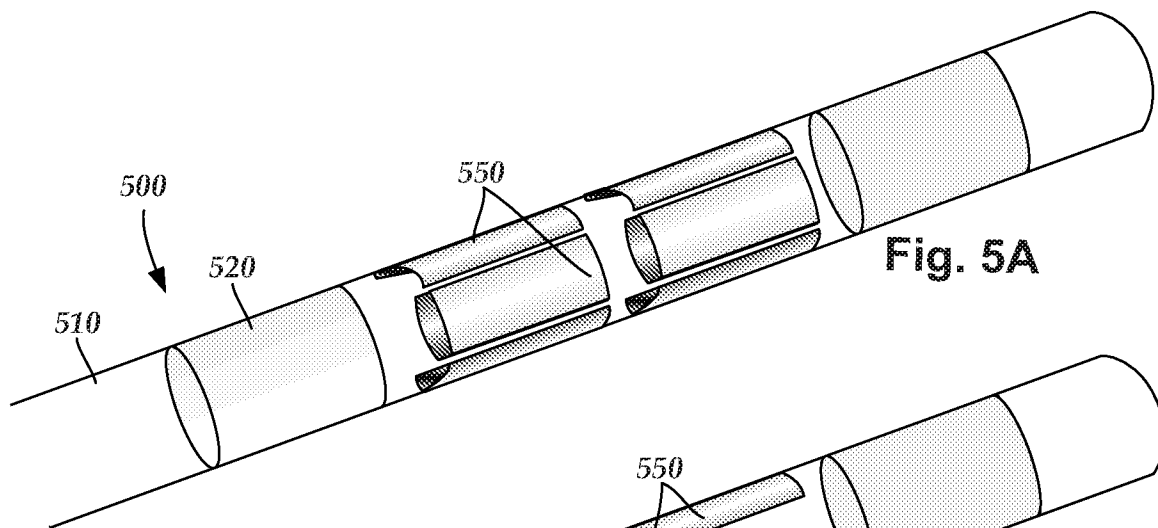
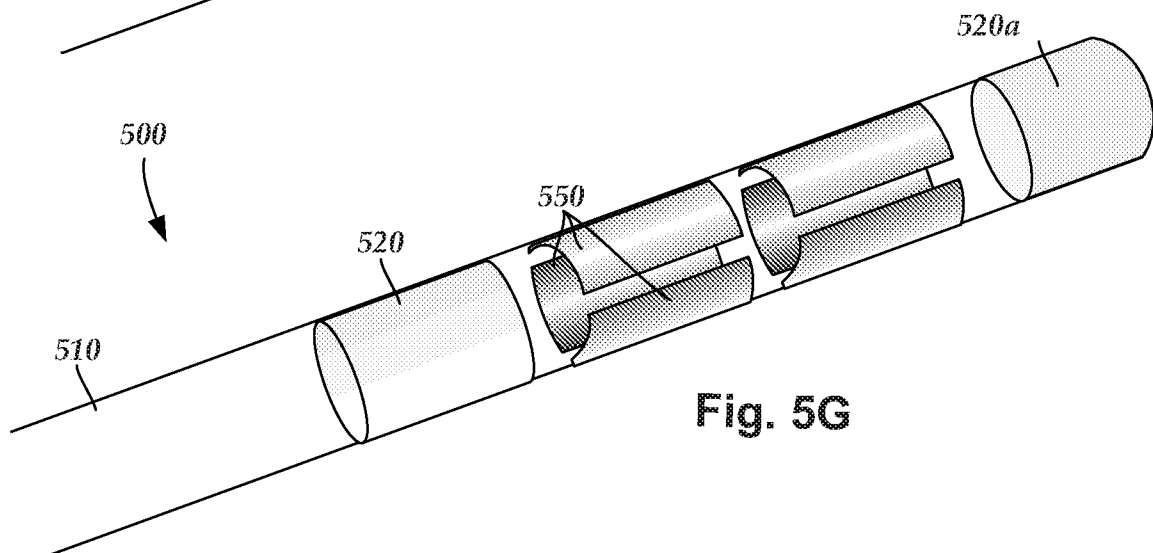
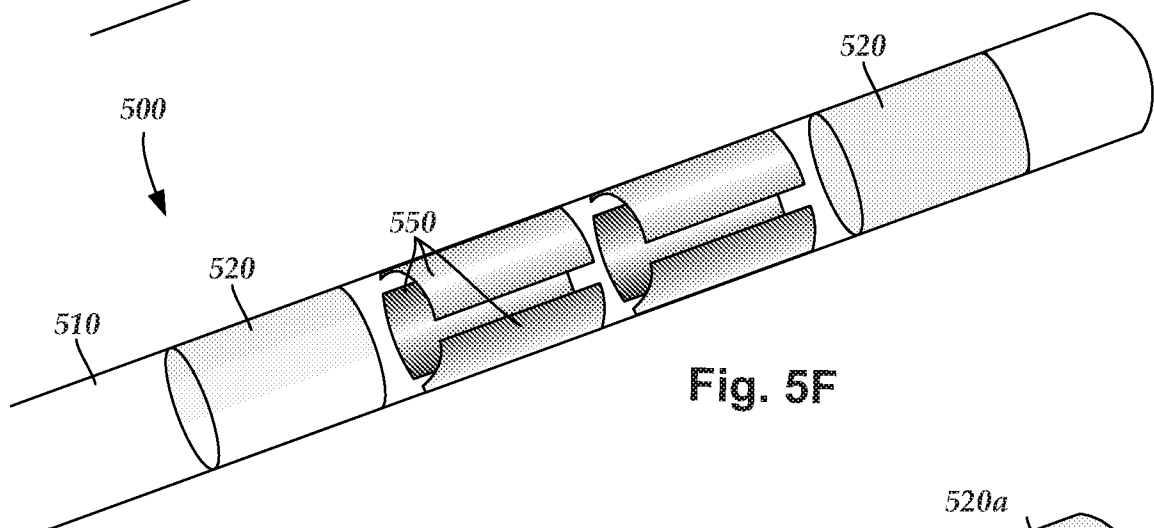
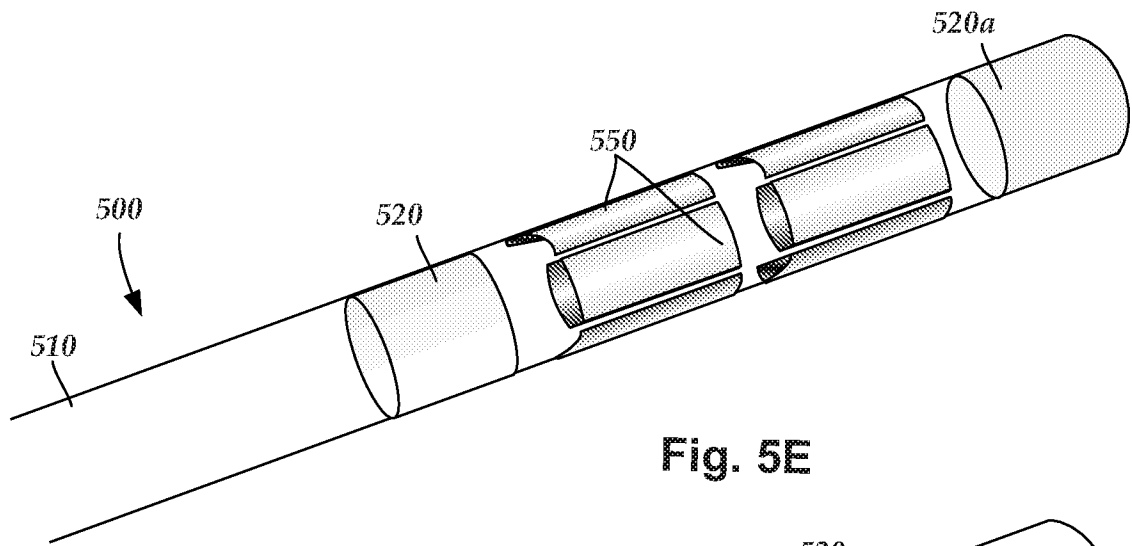
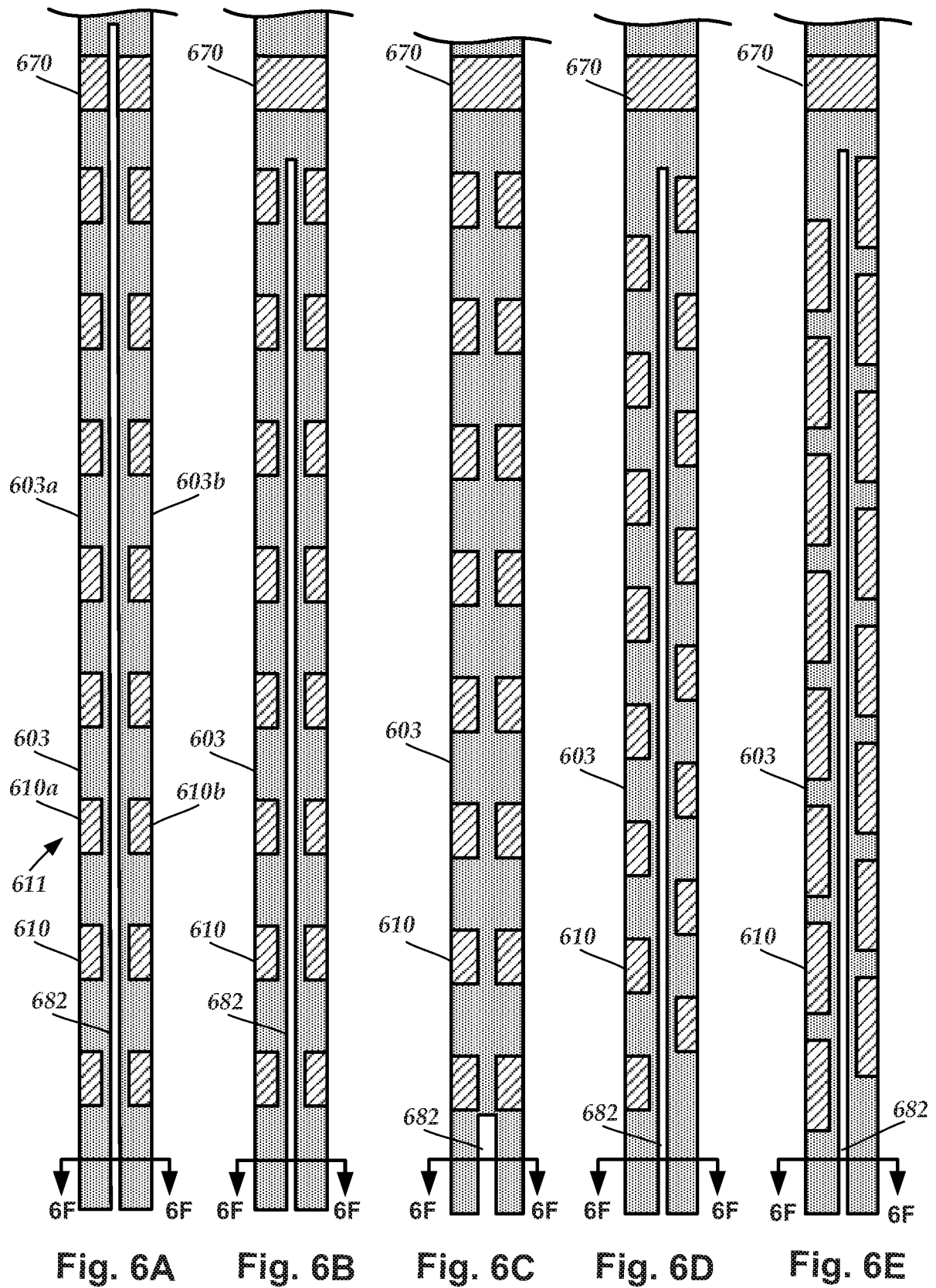


Fig. 4







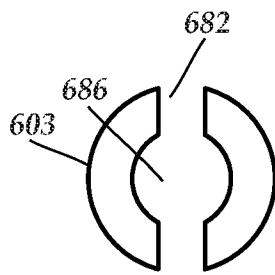


Fig. 6F

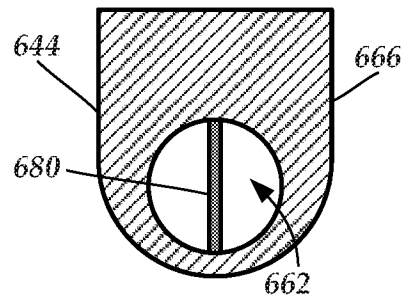


Fig. 7A

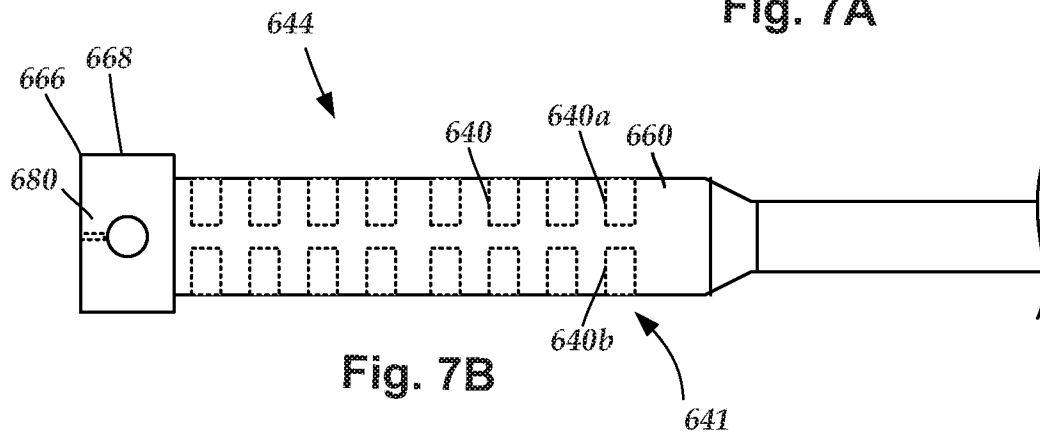


Fig. 7B

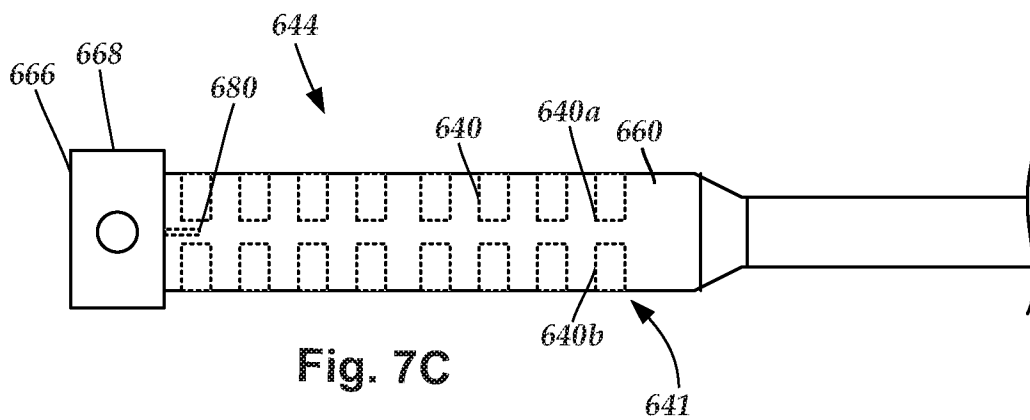


Fig. 7C

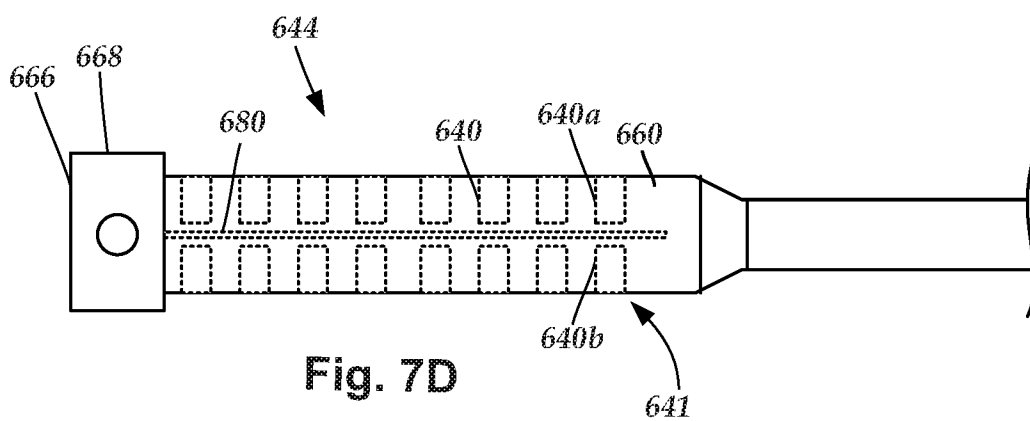


Fig. 7D

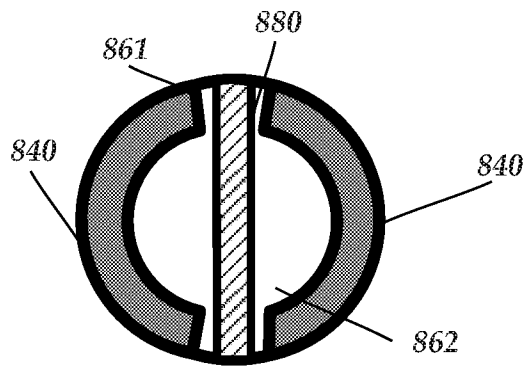


Fig. 8A

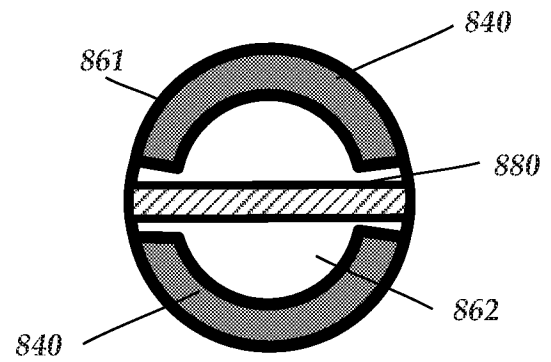


Fig. 8B

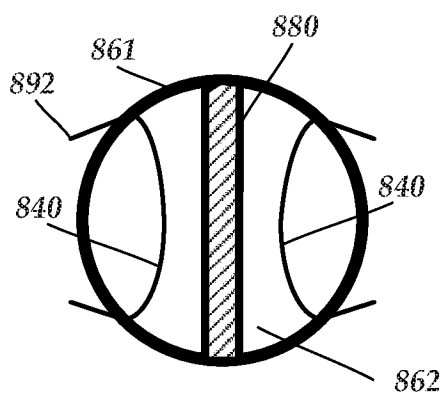


Fig. 8C

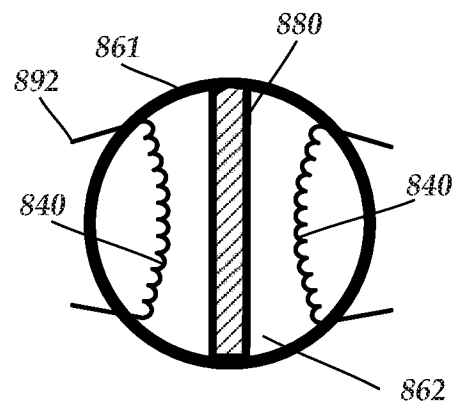


Fig. 8D

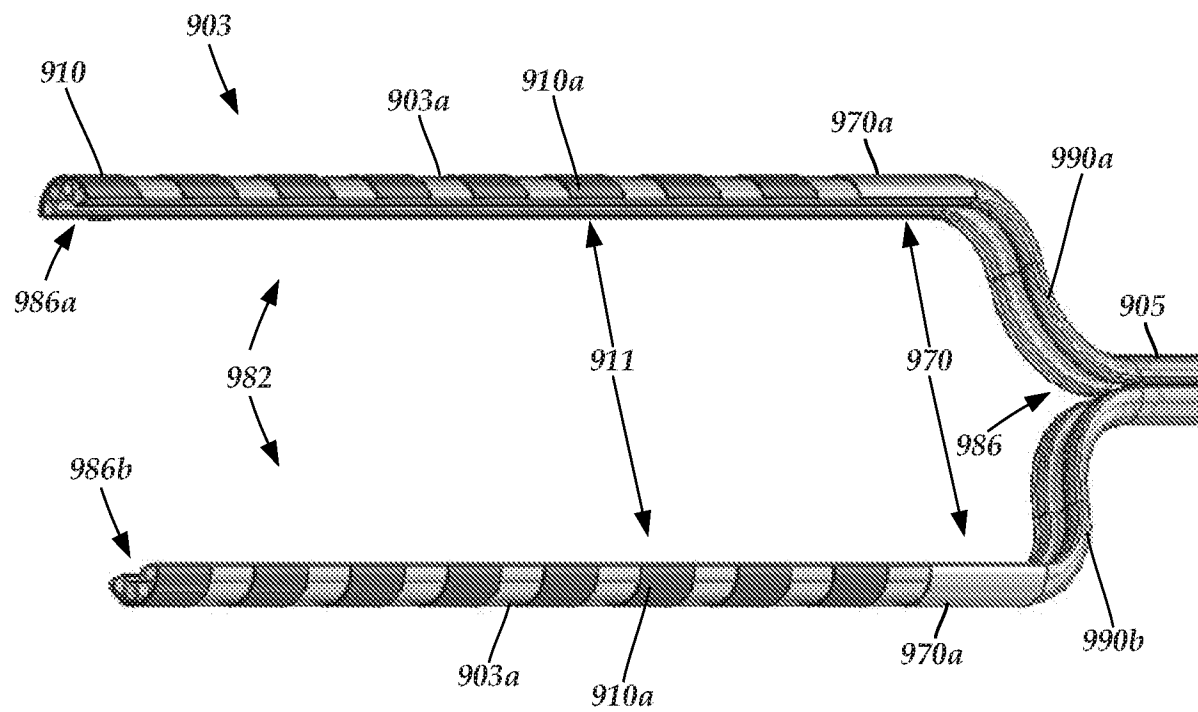


Fig. 9A

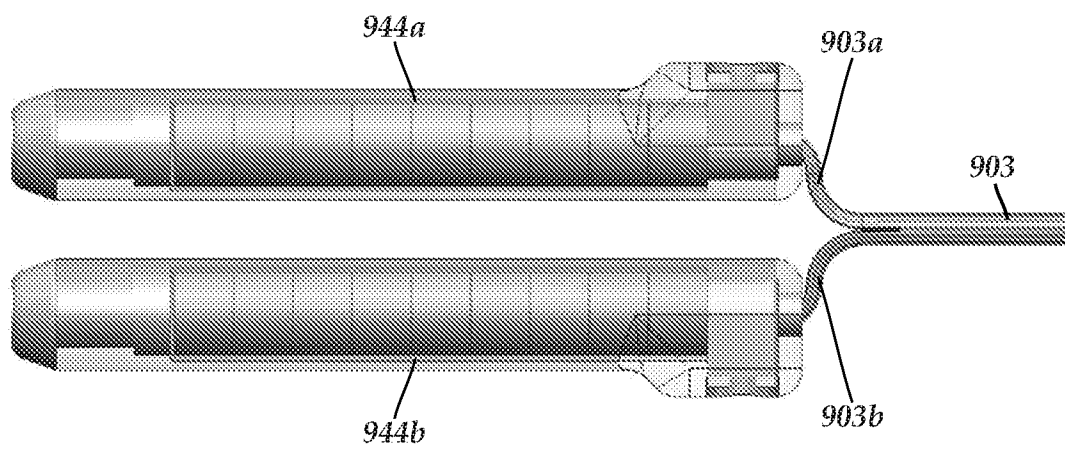


Fig. 9B

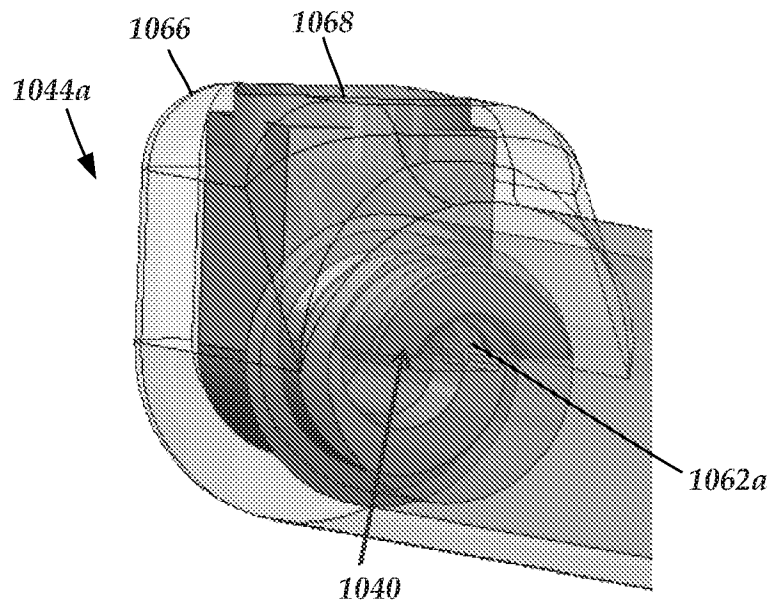


Fig. 10A

640a

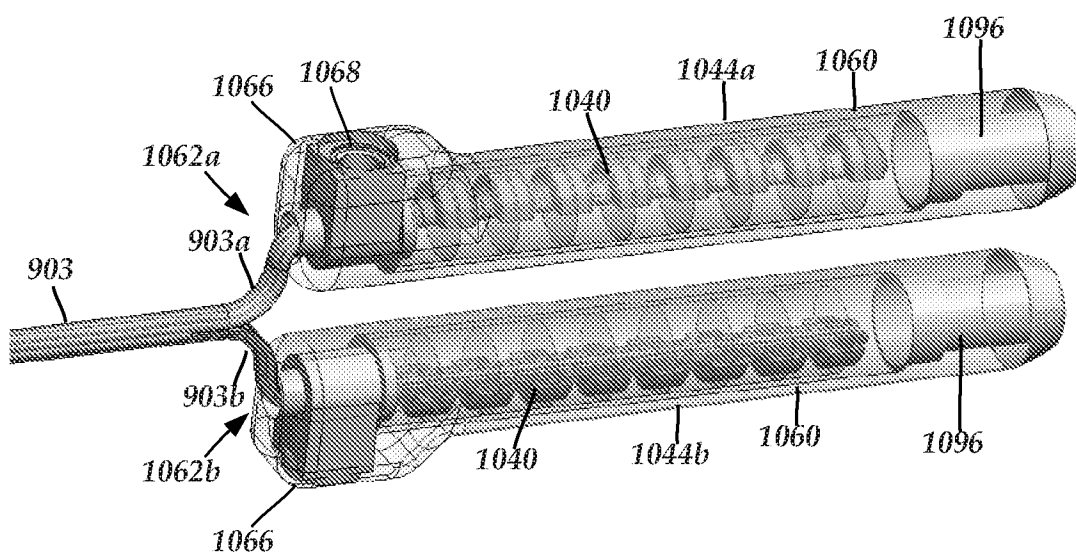


Fig. 10B

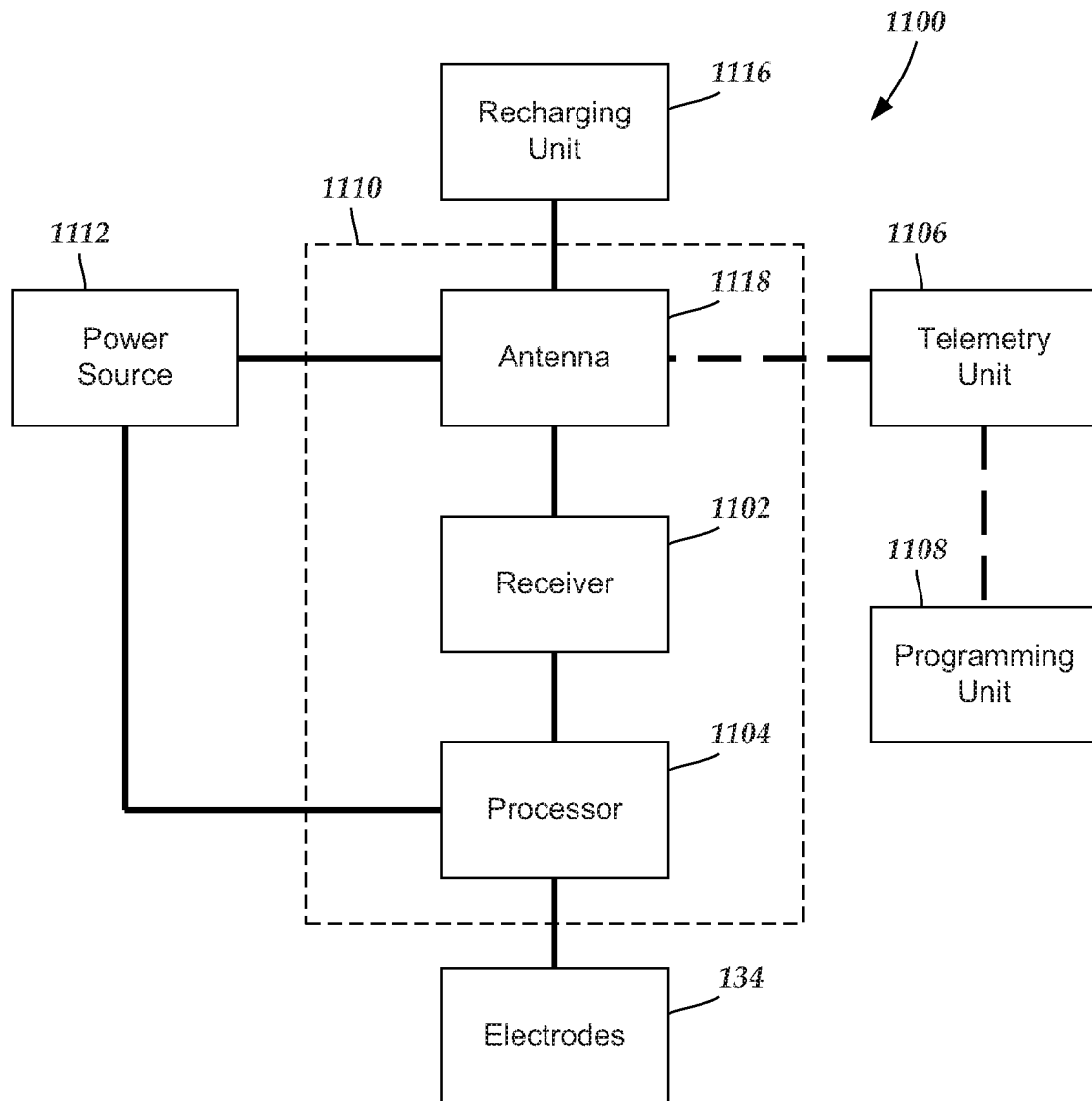


Fig. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/026044

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61N1/375 A61N1/05 H01R13/52 H01R13/629 H01R13/64
H01R43/26 H01R24/58

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N H01R

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/057176 A1 (BARKER JOHN MICHAEL [US]) 4 March 2010 (2010-03-04) abstract; figures 1-8, 15 paragraphs [0032] - [0080] -----	1-15
Y	WO 2009/148939 A1 (MEDTRONIC INC [US]; KAST JOHN [US]; ZIMMERMAN JAMES A [US]; PILARSKI C) 10 December 2009 (2009-12-10) abstract; figures 1-8 paragraphs [0030] - [0049] -----	1-15
A	US 2012/203302 A1 (MOFFITT MICHAEL ADAM [US] ET AL) 9 August 2012 (2012-08-09) abstract; figures 1-8 paragraphs [0033] - [0066] ----- -/-	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

14 June 2016

Date of mailing of the international search report

22/06/2016

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Mendelevitch, L

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2016/026044

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2012/259386 A1 (DEROHAN ROBERT [US] ET AL) 11 October 2012 (2012-10-11) abstract; figures 1-12 paragraphs [0032] - [0096] -----	1-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/026044

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010057176 A1	04-03-2010	AU 2009288344 A1	11-03-2010
		CA 2734668 A1	11-03-2010
		EP 2355892 A2	17-08-2011
		US 2010057176 A1	04-03-2010
		WO 2010027787 A2	11-03-2010

WO 2009148939 A1	10-12-2009	EP 2320995 A1	18-05-2011
		US 2011082516 A1	07-04-2011
		US 2014200642 A1	17-07-2014
		WO 2009148939 A1	10-12-2009

US 2012203302 A1	09-08-2012	NONE	

US 2012259386 A1	11-10-2012	US 2012259386 A1	11-10-2012
		US 2014148885 A1	29-05-2014
