(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 July 2009 (30.07.2009)

PCT

(10) International Publication Number
WO 2009/094315 A2

(51) International Patent Classification:
A61N 1/05 (2006.01)

(21) International Application Number:
PCT/US2009/031383

(22) International Filing Date: 19 January 2009 (19.01.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
12/020,479 25 January 2008 (25.01.2008) US

(71) Applicant *(for all designated States except US)*: **MEDTRONIC, INC.** [US/US]; 710 Medtronic Parkway MS LC340, Minneapolis, Minnesota 55432 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SEIFERT, Kevin R.** [US/US]; 21927 Iden Avenue Circle North, Forest Lake, Minnesota 55025 (US). **BOSER, Gregory A.** [US/US]; 7313 Emerson Avenue South, Richfield, Minnesota 55423 (US).

(74) Agent: **BARRY, Carol F._**; 710 Medtronic Parkway MS LC340, Minneapolis, Minnesota 55432 (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, BR, BW, BY, BZ, CA, CH, 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, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, SE, SI, SK, TR), OAPI (BF, BJ,

[Continued on next page]

(54) Title: MEDICAL ELECTRICAL LEAD

(57) Abstract: A medical device lead is presented. One embodiment of the claimed invention includes a lead body, a conductor, and a flexible component. The lead body includes a proximal end and a distal end. The conductor is coupled to the lead body. A sleeve is coupled to the distal end of the lead body. The flexible component is coupled to the distal end of the sleeve. The distal end of the flexible component includes an outer diameter that is greater than the outer diameter of the proximal end.

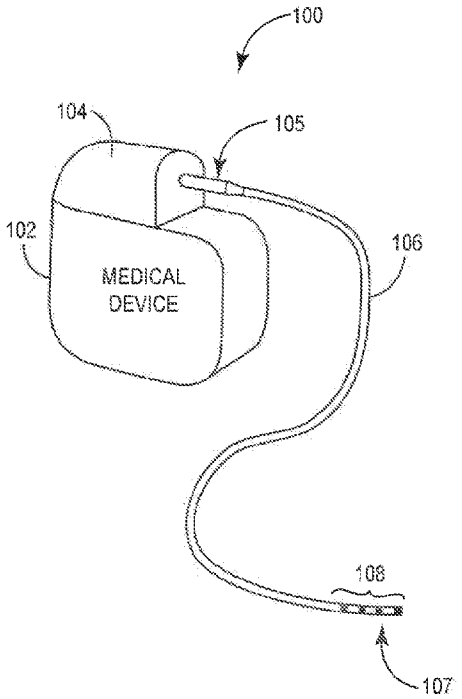

Fig. 1

WO 2009/094315 A2

CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

MEDICAL ELECTRICAL LEAD

TECHNICAL FIELD

The present invention relates to implantable medical devices and, more particularly, to implantable medical leads.

BACKGROUND

Implantable medical devices (IMDs) detect and deliver therapy through a lead. Typically, a stimulation electrode at the distal end of a lead is positioned near or in tissue so that electrical stimuli may be delivered. To reduce or prevent inflammation of the tissue in response to the stimulation lectrode, the distal end of the lead includes a monolithic controlled release device that releases an anti-inflammatory agent such as a steroid. It is desirable to develop devices that are able to chronically release anti-inflammatory agents in the vicinity of a stimulation electrode.

BRIEF DESCRIPTION OF DRAWINGS

Aspects and features of the present invention will be appreciated as the same becomes better understood by reference to the following detailed description of the embodiments of the invention when considered in connection with the accompanying drawings, wherein:

FIG. 1 is a conceptual schematic view of an implantable medical device coupled to a medical electrical lead;

FIG. 2 is a schematic view of a medical electrical lead;

FIG. 3 is a schematic view of an exemplary distal end of the lead depicted in **FIG. 2**;

FIG. 4 is a schematic view of a flexible component at the distal end of the lead depicted in **FIG. 3**;

FIG. 5 is a schematic end view of the flexible component depicted in **FIG. 4**;

FIG. 6 is a cross-sectional view of the flexible component depicted in **FIG. 5**;

FIG. 7A depicts a schematic side view of a distal end of a lead in which the flexible component is compressed inside a lumen of an introducer before the lead is extended out of the introducer and placed near targeted tissue of a patient;

FIG. 7B depicts the flexible component of **FIG. 7A** that expands after extending in a distal direction away from the distal end of the introducer;

FIG. 7C depicts a distal end of the lead depicted in **FIG. 7B** in which the CRD is compressed inside a lumen of an introducer after the lead is being repositioned or removed from a body lumen of a patient;

FIG. 8A depicts a schematic cross-sectional view of a flexible component mechanically connected to a sleeve;

FIG. 8B depicts a schematic cross-sectional view of a flexible component mechanically connected to a sleeve;

FIG. 8C depicts a schematic cross-sectional view of a flexible component mechanically connected to a sleeve;

FIG. 9 is a schematic view of another flexible component in the shape of a flange; and

FIG. 10 depicts a schematic cross-sectional view of a helical tip electrode passing through the flexible component.

DETAILED DESCRIPTION

One embodiment of the present invention is directed to a flexible controlled release device (CRD) that is located at a distal end of a medical electrical lead. The CRD comprises a substantially cylindrical body with a distal end that has an outer diameter greater than the outer diameter at the proximal end. By increasing the outer diameter of the distal end of the CRD, agent elution (e.g. anti-inflammatory drug or agent, anti-arrhythmic agent etc.) of the CRD is increased. Additionally, the larger outer diameter of the distal end of the CRD substantially increases the effective tip area. Effective tip area includes the surface area of the distal end of the CRD and/or the outer diameter of the distal end of the CRD. In effect, the larger outer diameter of the distal end of the CRD

allows the diameter of a lead body to be reduced while maintaining or lowering the effective tip pressure. Tip pressure is the amount of force per unit area applied against the distal end of the CRD against an opposing surface such as tissue. The claimed invention has substantially reduced tip pressure by up to 50 percent (%) relative to the smaller sized diameter lead body.

Another embodiment of the claimed invention relates to a flexible component without a steroid. The flexible component comprises a substantially cylindrical body with a distal end that has an outer diameter greater than the outer diameter at the proximal end. **FIG. 1** depicts a medical device system **100**. Medical device system **100** includes a medical device housing **102** having a connector module **104** (e.g. IS-1, DF-1, IS-4 etc.) that electrically couples various internal electrical components of medical device housing **102** to a proximal end **105** of a medical lead **106**. A medical device system **100** may comprise any of a wide variety of medical devices that include one or more medical lead(s) **106** such as pacing and/or defibrillation leads and circuitry coupled to the medical lead(s) **106**. An exemplary medical device system **100** may take the form of an implantable cardiac pacemaker, an implantable cardioverter, an implantable defibrillator, an implantable cardiac pacemaker-cardioverter-defibrillator (PCD), a neurostimulator, a sensing lead (e.g. oxygen sensor, pressure sensor, chemical sensors etc.), a tissue or muscle stimulator and/or combinations thereof. Medical device system **100** may deliver, for example, pacing, cardioversion or defibrillation pulses to a patient via electrodes **108** disposed on distal end **107** of one or more lead(s) **106**.

FIG. 2 depicts lead **106** as including an elongated lead body **117** (e.g. pacing and/or defibrillation lead bodies etc.) extending from proximal end **105** to a distal end **107**. Lead **106** includes one or more insulated conductive elements **112a-c** (coils, wires, coil wound around a filament, cables, conductors etc.) that are directly connected to medical device **100** through connectors (e.g. set screws etc.). One or more conductive elements **112 a,b** are defibrillation electrodes that extend from proximal end **105** through a portion of lead body **117**. Lead **106** also includes a conductive element **112c** that extends from the proximal end **105** to ring electrode **118** and another conductive element **112c** that extends from proximal end **105** to tip electrode **120**.

FIG. 3 depicts details of a distal end **107** of a medical lead **106**. Distal end **107** of a medical lead **106** includes a ring electrode **118**, a tip electrode **120**, a sleeve member **215** (also referred to as a sleeve head, or sleeve), and a soft distal flexible component **213** that optionally includes an agent (e.g. antiarryhymic, anti-inflammatory etc.). Sleeve member **215** supports deployment of tip electrode **120** and, in one embodiment, separates ring electrode **118** from tip electrode **120**. Sharpened distal tip electrode **120**, which facilitates fixation of distal end **107** of lead **106** into tissue of a patient, passes through a lumen formed by an inner diameter of flexible component **213**. Flexible component **213**, depicted in greater detail in **FIGs. 4-6**, optionally provides chronic agent (e.g. antiarryhymic, anti-inflammatory etc.) elution in the vicinity of tip electrode **120**. The agent (e.g. sodium dexamethasone phosphate etc.) enters body fluid and then contacts the tissue adjacent to the helical tip electrode **120**.

Flexible component **213** is directly coupled to sleeve member **215** through mechanical means and/or an adhesive bond. Referring briefly to **FIGs. 8A-8C**, flexible component **300** is shown to be mechanically connected to sleeve member **215** through one or more grooves **302,** formed for a female member while sleeve member **215** includes one or more protruding male member(s). In another embodiment, sleeve member **215** may be configured to include one or more grooves for a male member whereas flexible component **213** would be configured to include corresponding female groove members. Alternatively, the grooves could be located solely in the male member with a recessed region that is configured to receive an adhesive to form an interlock between the male and female members. In still yet another embodiment, the surface of the outer diameter (D2) of proximal end **219** of flexible component **213** is directly connected to sleeve member **215,** through, for example, an adhesive bond. Exemplary adhesive bonds include silicone adhesive (e.g. Nusil 1137 commercially available from Nusil located in Carpinteria, CA etc) an urethane adhesive, or other suitable adhesives.

Flexible component **213** is substantially cylindrical or concentric in shape. Substantially cylindrical is defined as a cylinder within ten percent of the shape of a standard cylinder shape. Flexible component **213** extends a total length of L1 and includes a flared distal end **217** and a proximal end **219** with a lumen therebetween. The stepped inner diameter includes a first inner diameter (D1) that extends a length of about **L3** from

the distal end **217** and a second inner diameter (D2) that extends a length of about **L2**. In alternative embodiments, the inner diameter of flexible component **213** may be tapered or straight. Flexible component **213** also includes an outer diameter D3 at the proximal end **219** and outer diameter D4 at the flared distal end **217**. Distal end **217** of flexible component **213** begins to flare at a length of L4 from proximal end **219** of flexible component **213**. In yet another embodiment, first inner diameter D1 is shifted or offset from second inner diameter D2 to align with entry point of helix 120. In this embodiment the diameter D1 is reduced a near the helix diameter and such that it substantially occludes or covers the distal face 232 of the flexible component 213.

Flexible component **213** includes reinforcing segments **234,** one or more recessed regions **230** (also referred to as first recessed regions) along the outer surface (outer diameter D4) of the body of flexible component **213**, and recessed regions **230** (also referred to as second recessed regions) along the distal end **217**. Reinforcing segments **234** are proximal to surface or distal face 232 and prevent the distal end of flexible component **213** from folding back onto its proximal end. Reinforcing segments **234** may be tapered or rounded to smoothly align with diameter D3.

Optionally, recessed regions **230** are employed to prevent a seal from forming between the outer surface of flexible component **213** and an introducer (not shown) or guide catheter. Specifically, recessed regions **230** allows fluid (e.g. saline solution, air etc.) to pass between the outer surface of flexible component **213** and the inner diameter of an introducer while the introducer is being passed through a lumen of the body. Specifically, recessed regions **230** prevent the distal tip from fully occluding the introducer during advancement of lead **106**. While recessed regions **230** are depicted as substantially triangular in shape, other suitable shapes (e.g. substantially cylindrical, rectangular, other shapes that include at least one triangle (e.g. hexagon etc.), nonshapes etc.) may also be used.

Recessed regions **260** are located along an end surface **232** of outer diameter D4 of flexible component **213.** Recessed regions **260** increase the flexibility of flexible component **213.** For example, the sides **262a,b** of recessed regions **260** are closer together when flexible component **213** is in the introducer. However, once flexible component **213**

passes through the introducer, the sides **262a,b** of recessed regions **260** are further apart from one another. Accordingly, recessed regions **260** adds flexibility to component **213** that more easily allows component **213** to compress in an introducer as component **213** passes through the introducer and then expands after flexible component **213** exits the distal end of the introducer. Exemplary recessed region **260** may be substantially triangular in shape in which angle θ is formed by a first and second side **260** and having a depth of about L5 from end surface **232**. While recessed regions **260** are depicted as substantially triangular in shape, other suitable shapes (e.g. substantially cylindrical, rectangular etc.) may also be used.

Component **213** is flexible such that distal end **217** is able to contract or expand. Flexibility of component **213** may be due, at least in part, to component **213** being comprised of a polymer. Exemplary polymers include silicone (e.g. silastic MDX4-4210, silastic ETR, Q7-4735 and/or Q7-4765 commercially available from Dow Corning located in Midland, MI), polyurethane, polyurea and/or polyurethane-polyurea, polyurethane/silicone blends etc.). The polymer may be molded or formed into its depicted shape through conventional techniques.

FIGs. 7A-7C depicts flexible component **213** moving from a contracted to expanded positions. Flexible component **213** is initially in a contracted position (**FIG. 7A**) while disposed in a lumen formed by the inner walls of an introducer **225**. Flexible component **213** fully expands (**FIG. 7B**) once component **213** passes through introducer **225**. The physician passes component **213** through the introducer once lead **106** is properly positioned in a patient's tissue. **FIG. 7C** depicts flexible component **213** in a contracted position after the physician causes component **213** to move in a proximal direction **105** of lead **106**.

Table 1 lists exemplary dimensions for one embodiment of flexible component **213**; however, other dimensions may be used to create flexible component **213**. For D4, a 0.060 inch diameter lead body typically could have a range of about 0.065 inches (5 French) to about 0.080 inches (6.2 French).

Table 1—Exemplary dimensions for the flexible component

Element	Dimension (inches)
D1	0.038
D2	0.048
D3	0.060
D4	0.070
L1	0.035
L2	0.025
L3	0.010
L4	0.016
L5	0.000-0.005

Table 2 relates to numerous embodiments in which the outer diameter at the distal end **217** is greater than the proximal end **219** of the flexible component **213**. For example, the first embodiment includes flexible component **213** in which the outer diameter at the distal end is 3% or greater than the outer diameter at the proximal end for flexible component **213**. Depending on the lead body size or outer diameter at the proximal end **219**, the introduction size for which lead **106** is targeted and the targeted interference of distal diameter with introducer, flexible component **213** can have many embodiments that increase the effective distal diameter of the flexible component **213**. For example, effective distal diameter of the flexible component **213** can increase from about 10% to about 50%.

Table 2—embodiments of flexible component

Embodiment	The outer diameter at the distal end is greater than the outer diameter at the proximal end for the flexible component	The range that the outer diameter at the distal end is greater than the outer diameter at the proximal end for the flexible component
1	3%	3% or more
2	4%	4% or more
3	5%	5% or more
4	10%	10% or more
5	15%	15% or more
6	20%	20% or more
7	25%	25% or more
8	30%	30% or more
9	35%	35% or more
10	40%	40% or more
11	45%	45% or more
12	50%	50% or more

As described, the flexible softer distal tip **217** of flexible component **213** helps to prevent a physician from inadvertently puncturing non-targeted tissue. The distal tip **217** can be enlarged but still be compatible with an introducer. The softer flared distal end of flexible component **213** opens and becomes larger when pressed against an object (i.e. tissue). Additionally, as shown in the Table I embodiment, the flared distal end **217** increases the overall tip outer diameter from about 0.060 to an upper limit of about 0.065-0.080 inches, which decreases the lead tip pressure by about 14% to about 38% compared to conventional CRDs for a lead.

Alternative embodiments may also be used to implement the claimed invention. For example, the CRD or nonCRD component can be molded into outer tubing/insulation via reflowing or other tipping operations, as described in US patent no. 4,904,433 issued to Williamitis on February 27, 1990. In one embodiment, flexible component **213** and sleeve **215** is formed as a single piece. Molding flexible component **213** onto sleeve **215** is one way of forming flexible component **213** and sleeve **215** as a single piece. In another embodiment, an outer diameter of flexible component **213** lacks the recessed regions **230** depicted in **FIGs. 4-6.** In still yet another embodiment, **FIG. 9** depicts a flanged flexible component with one or more recessed regions alongside an elongated portion of the flange. In the embodiment depicted in **FIG. 9**, the flanged distal portion of the flexible component can be geometrically incorporated directly into the outer tubing and/or insulation of lead **106**. For example, the flange can be molded into the sleeve or outer lead body tubing. In other embodiments, the principles described herein apply to all sizes of leads. For example, the claimed CRD or nonCRD component can be used in a 11 French sized lead or less. Exemplary sized French sized leads include 2, 2.6, 3.5, 4, 4.5, 4.6, 5, 6 etc. While exemplary values are provided for the CRD dimensions, other numerical values may also be used.

In one embodiment, as depicted in **FIG. 10**, a fixation mechanism such as a helical tip electrode passes through the flexible component. As shown, the distal face of the flexible component substantially covers the opening **340** on the face of the flexible component. Any such hole or opening **340** is sized and offset to allow translation or movement of the fixation mechanism. Specifically, the fixation mechanism is allowed to translate and rotate through the hole. In still yet another embodiment, the helix is fixed such that no movement or translation is required. In yet another embodiment, the principles described herein also apply to leads configured for passive fixation such as leads without a helix tip.

The description of the invention is merely exemplary in nature and, thus, variations that do not depart from the gist of the invention are intended to be within the scope of the invention. Such variations are not to be regarded as a departure from the spirit and scope of the invention.

CLAIMS:

1. An implantable medical electrical lead comprising:
an insulative lead body that includes a proximal end and a distal end with a lumen extending therebetween;
at least one conductive element disposed in the lumen;
a sleeve coupled to the distal end of the lead body; and
a flexible component that includes a proximal end and a distal end, the proximal end of the flexible component being coupled to the sleeve, each having an outer diameter, the distal end of the flexible component including an outer diameter greater than the outer diameter of the proximal end of the flexible component.

2. The lead of claim 1 wherein the flexible component comprises a polymer.

3. The lead of claim 2 wherein the flexible component comprises at least one of silicone, polyurethane, polyurea, polyurethane-silicone, and polyurethane-polyurea.

4. The lead of claim 1 wherein the flexible component outer diameter at the distal end is 10 percent (%) or greater than the outer diameter at the proximal end of the flexible component.

5. The lead of claim 1 wherein the flexible component outer diameter of the distal end is 20% or greater than the outer diameter of the proximal end of the flexible component.

6. The lead of claim 1 wherein the flexible component outer diameter of the distal end is 30% or greater than the outer diameter of the proximal end of the flexible component.

7. The lead of claim 1 wherein the flexible component includes an inner surface and an outer surface, one or more recessed regions are disposed in the outer surface of the flexible component.

8. The lead of claim 1 wherein the one or more recessed regions disposed in the outer surface of the flexible component prevents occluding of an introducer during advancement of a lead through a body lumen.

9. The lead of claim 1 wherein the distal end of the flexible component is flared.

10. The lead of claim 8 wherein the flared distal end of the flexible component has an outer diameter that is greater than the proximal end of the flexible component by about 10 to 35%.

11. The lead of claim 1 wherein the flexible component is a flexible controlled release device (CRD) that includes an agent.

12. The lead of claim 12 wherein the agent is an anti-inflammatory drug or an anti-arrhythmic agent.

13. The lead of claim 1 wherein the flexible component includes at least one reinforcing segment.

14. A medical device comprising:

an implantable medical electrical lead that comprises:

(a) an insulative lead body that includes a proximal end and a distal end;

(b) at least one conductor disposed in the lead body; and

(c) a flexible component that includes a proximal end and a flared distal end, each having an outer diameter, the proximal end of the flexible component being coupled to the distal end of the lead body, the distal end of the flexible component includes an outer

diameter that is 10% greater than the outer diameter of the proximal end of the flexible component; and

an introducer coupled to the lead,

wherein the distal end of the flexible component flexibly expands once the flexible component extends beyond a distal end of the introducer.

15. The lead according to claim 14 wherein the polymer comprises one of a silicone, polyurethane, polyurea, polyurethane-polyurea, and polyurethane-silicone.

16. A controlled release device (CRD) for a medical electrical lead comprising:

a substantially cylindrical body that includes a distal end and a proximal end, the distal end having an outer diameter greater than the outer diameter at the proximal end.

17. The CRD of claim 16, wherein the outer diameter of the distal end is 20% or greater than the outer diameter of the proximal end of the CRD.

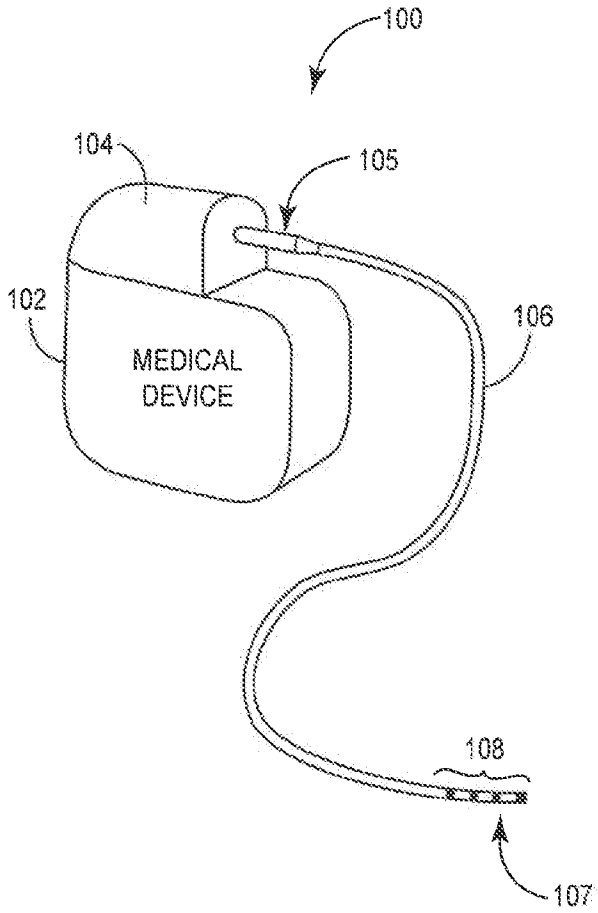

Fig. 1

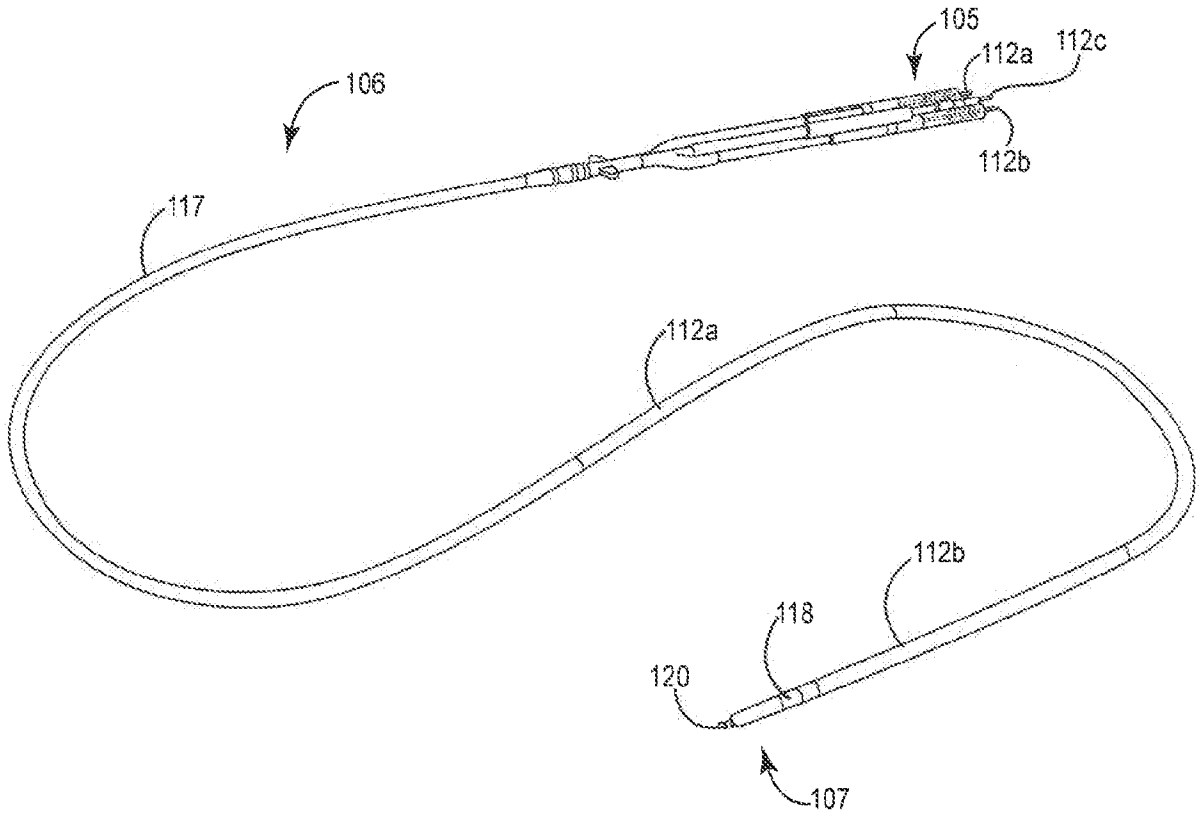

Fig. 2

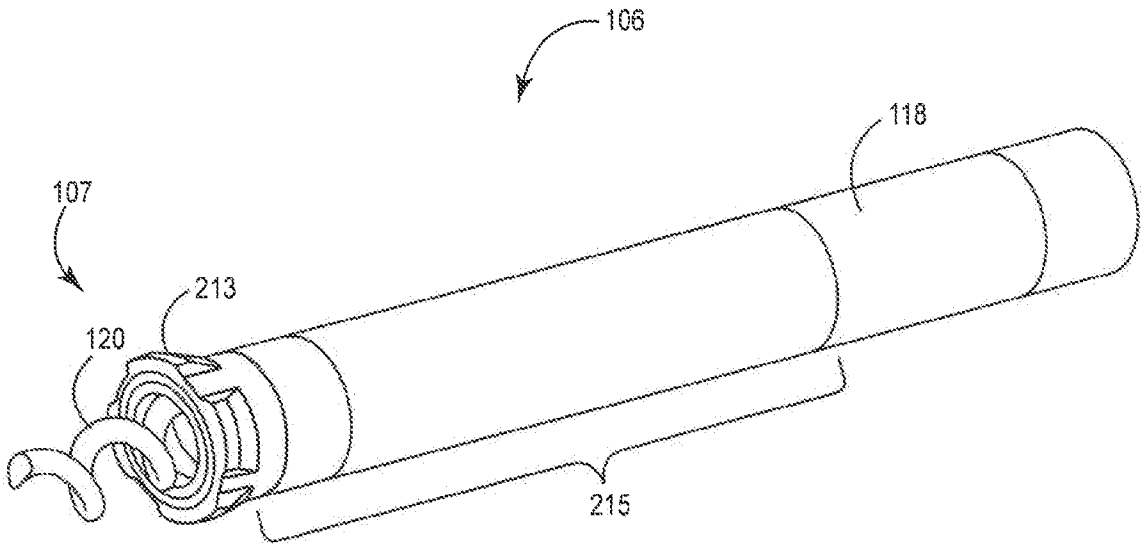

Fig. 3

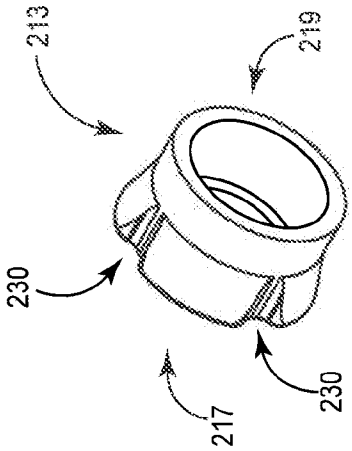

Fig. 4

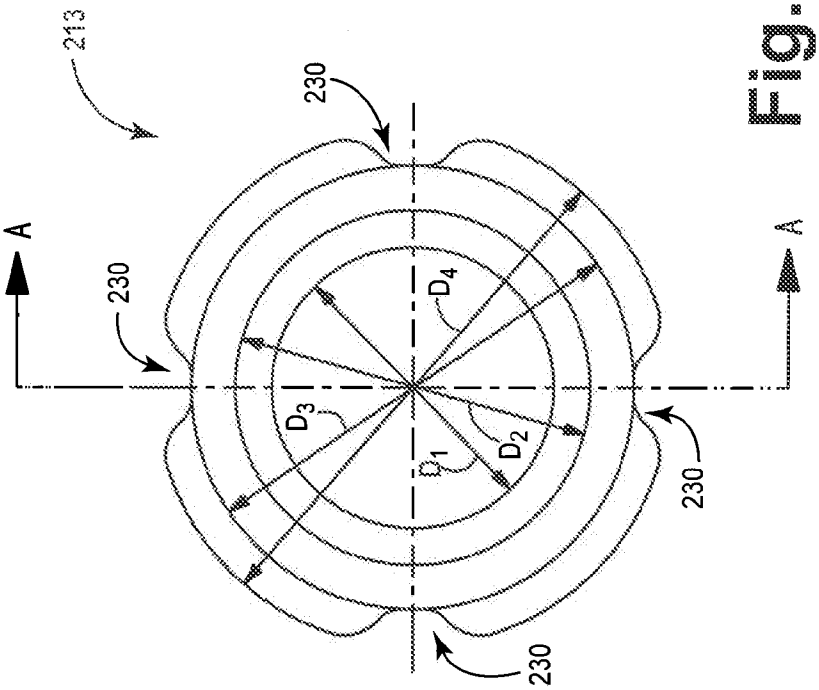

Fig. 5

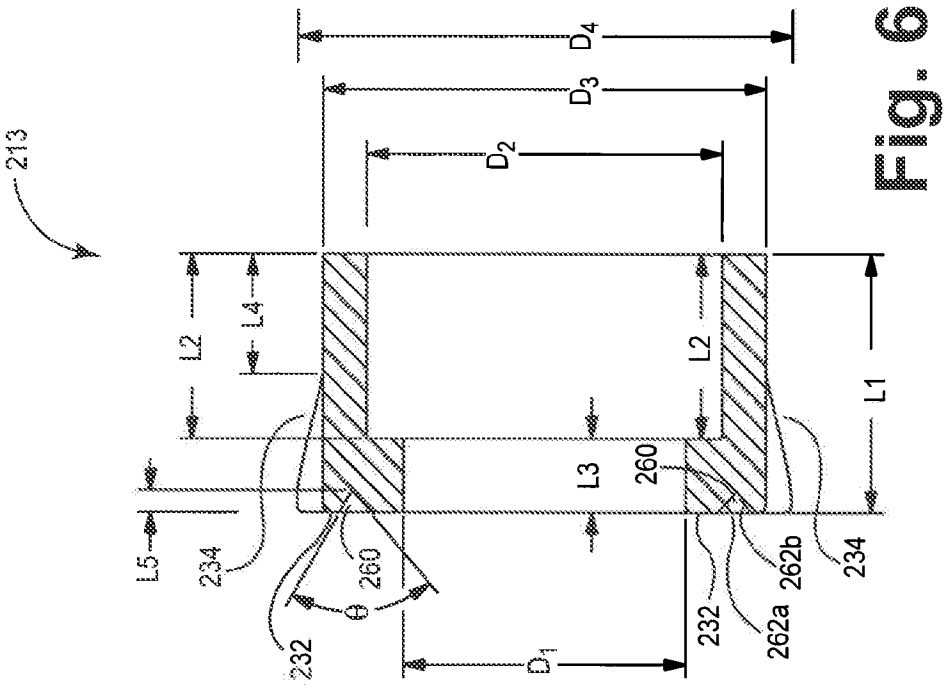

Fig. 6

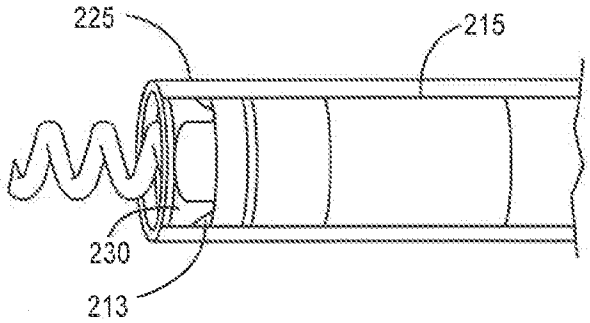

Fig. 7A

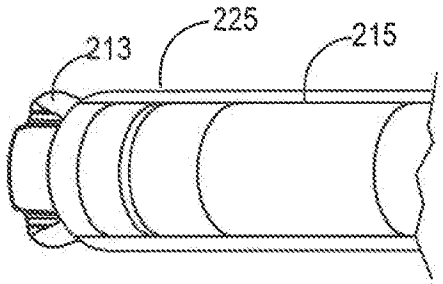

Fig. 7B

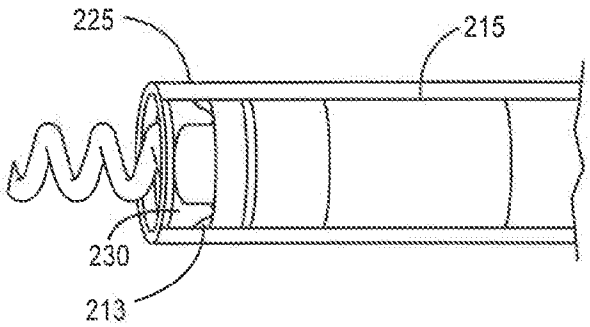

Fig. 7C

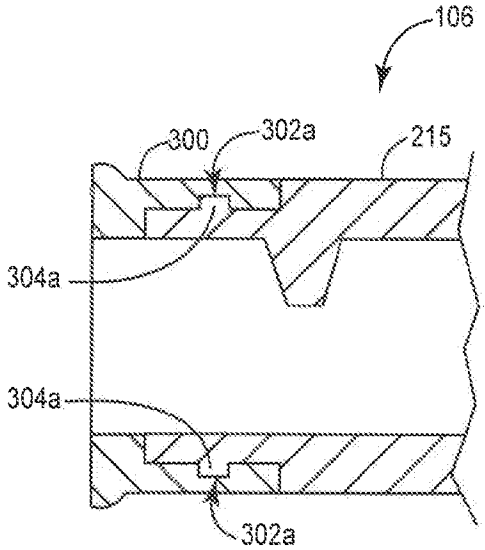

Fig. 8A

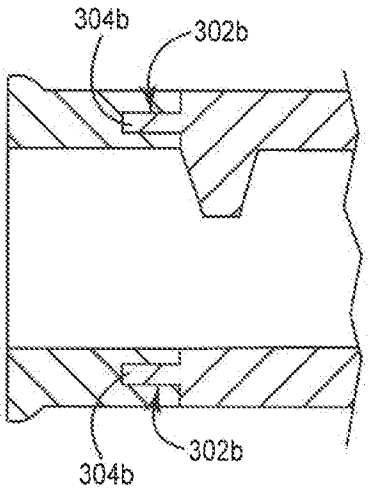

Fig. 8B

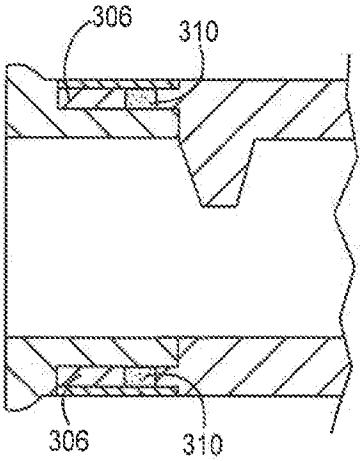

Fig. 8C

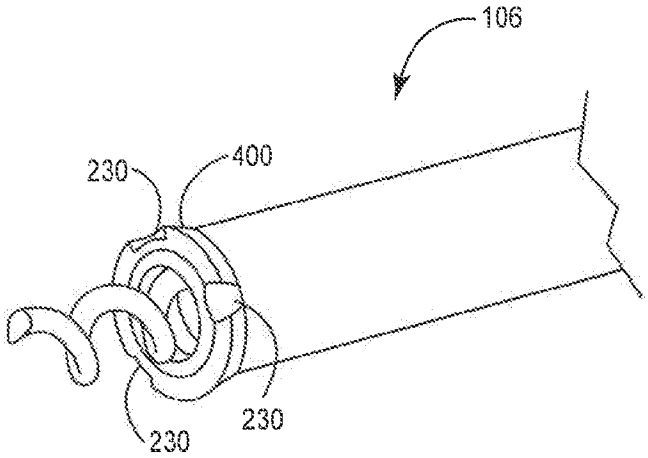

Fig. 9

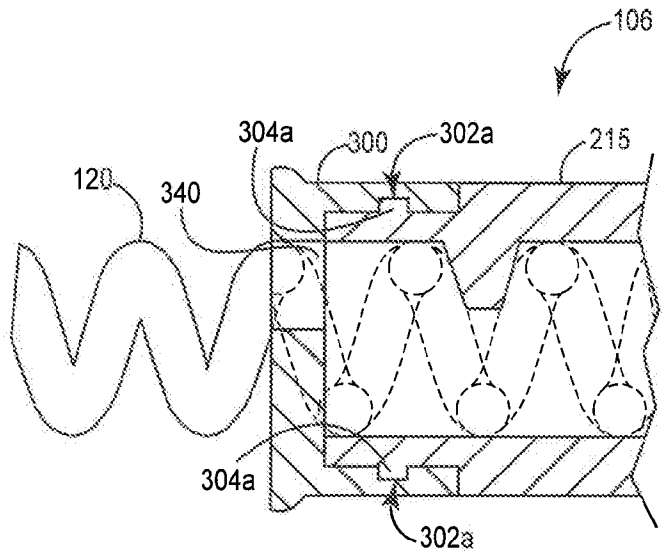

Fig. 10