Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2577094 A1 2006/03/02

(21) 2 577 094

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 2005/08/10
(87) Date publication PCT/PCT Publication Date: 2006/03/02
(85) Entrée phase nationale/National Entry: 2007/02/13
(86) N° demande PCT/PCT Application No.: US 2005/028395
(87) N° publication PCT/PCT Publication No.: 2006/023343
(30) Priorité/Priority: 2004/08/19 (US10/922,210)

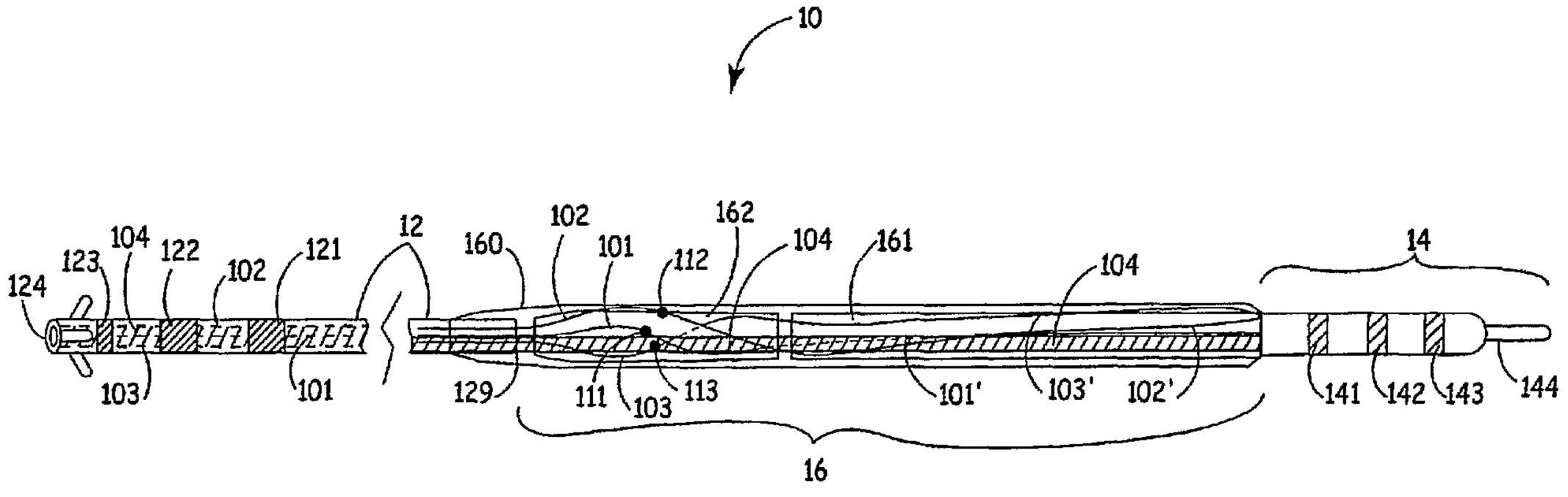
(51) Cl.Int./Int.Cl. *A61N 1/05* (2006.01)

(71) Demandeur/Applicant:
MEDTRONIC, INC., US

(72) Inventeurs/Inventors:
MEHDIZADEH, BRUCE R., US;
VIKTORA, SANDRA F., US;
LUNDBERG, CATHERINE A., US;
WILLIAMS, DINA L., US

(74) Agent: SMART & BIGGAR

(54) Titre : NOUVELLE ZONE DE TRANSITION POUR CORPS CONDUCTEUR-A-CONNECTEUR
(54) Title: NOVEL LEAD BODY-TO-CONNECTOR TRANSITION ZONE




(57) Abrégé/Abstract:
A medical electrical lead includes a lead body and a connector terminal. A conductor extends from the lead body to the connector terminal along a helical path through a transition zone.

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 March 2006 (02.03.2006)

PCT

(10) International Publication Number
WO 2006/023343 A3

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

(21) International Application Number:
PCT/US2005/028395

(22) International Filing Date: 10 August 2005 (10.08.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/922,210 19 August 2004 (19.08.2004) US

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

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MEHDIZADEH, Bruce, R.** [US/US]; 14582 Joppa Avenue South, Savage, MN 55378 (US). **VIKTORA, Sandra, F.** [US/US]; 10685-106th Quince Street Northwest, Coon Rapids, MN 55433 (US). **LUNDBERG, Catherine, A.** [US/US]; 9404 Tyler Street Northeast, Blaine, MN 55434 (US). **WILLIAMS, Dina, L.** [US/US]; 14577 Ibis Street Northwest, Andover, MN 55304 (US).

(74) Agents: **SOLDNER, Michael** et al.; MS LC340, 710 Medtronic Parkway, Minneapolis, MN 55432 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, 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, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

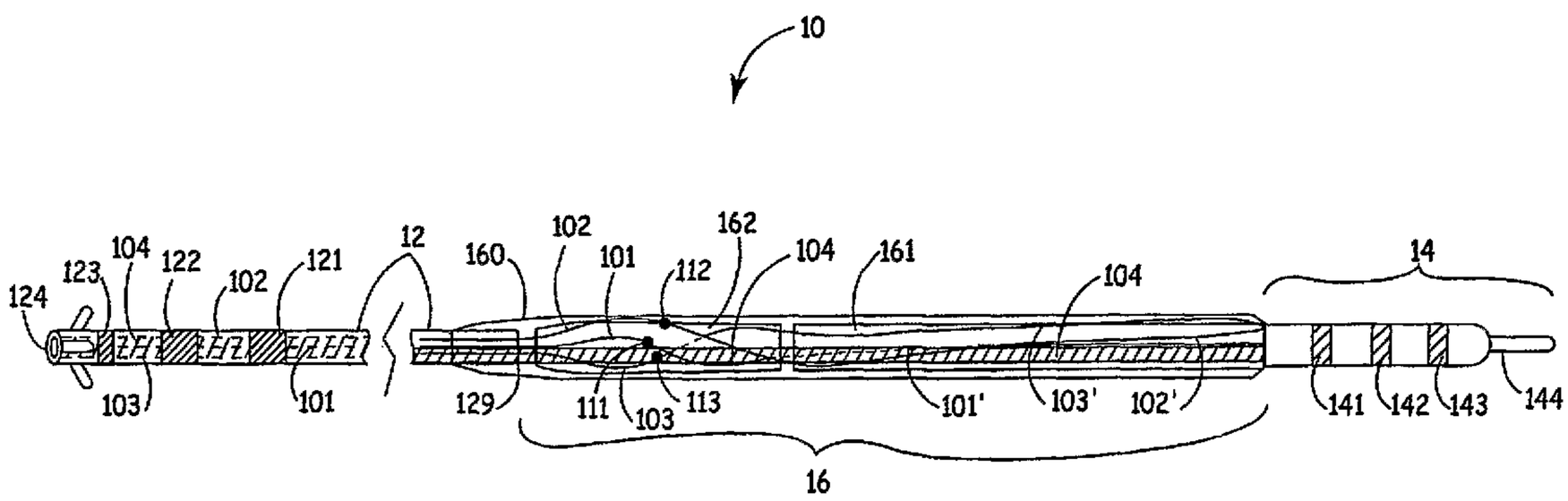
**Declarations under Rule 4.17:**
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

**Published:**
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
6 July 2006

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: NOVEL LEAD BODY-TO-CONNECTOR TRANSITION ZONE




(57) Abstract: A medical electrical lead includes a lead body and a connector terminal. A conductor extends from the lead body to the connector terminal along a helical path through a transition zone.

WO 2006/023343 A3

# NOVEL LEAD BODY-TO-CONNECTOR TRANSITION ZONE

The present invention relates to medical electrical leads and more particularly to lead body-to-connector terminal transition zones.

A host of medical devices include a connector bore into which a connector terminal of an electrical lead, or catheter, is inserted in order to make electrical connection with the device so as to form a medical system. Each insulated conductor, extending within a body of the lead, couples a lead electrode and or other electrically activated sensor to an electrical contact element formed on the connector terminal, and each contact element is engaged by a contact within the device connector bore when the connector is fully inserted within the bore. When the connector terminal of a lead is thus coupled to a device and the resulting system implanted within a body of a patient, certain stresses and strains may develop in a transition zone between the body of the lead and the connector terminal; these stresses and strains may lead to conductor failures within the transition zone. Thus, a transition zone designed to mitigate such stresses and strains is needed.

The following drawings are illustrative of particular embodiments of the invention and therefore do not limit its scope, but are presented to assist in providing a proper understanding of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. The present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements, and:

Figure 1 is a plan view of an exemplary medical lead including an embodiment of the present invention;

Figures 2A-B are a perspective view and a schematic, respectively, of a multi-lumen tube according to some embodiments of the present invention;

Figures 3A-B are a perspective view and schematic, respectively, of another multi-lumen tube according to some embodiments of the present invention;

Figures 4A-B are plan views illustrating assembly steps according to some methods of the present invention; and

Figure 4C is a perspective view according to one method of the present invention.

The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides a practical illustration for implementing exemplary embodiments of the invention.

Figure 1 is a plan view of an exemplary medical lead 10 including an embodiment of the present invention. Figure 1 illustrates lead 10 including a lead body 12 and a lead connector terminal 14 joined to lead body 12 in a transition zone 16 that extends between a proximal end 129 of body 12 and connector terminal 14; a plurality of electrodes 121, 122, 123 and 124 coupled to a distal portion of body 12 are electrically coupled to corresponding connector contacts 141, 142, 143 and 144, respectively, via elongate conductors 101/101′, 102/102′, 103/103′ and 104. According to the illustrated embodiment, lead body 12 includes a multi-lumen tubing through which conductors 101, 102, 103 and 104 extend; conductors 101, 102, 103 and 104 exit from proximal end 129 to meet with corresponding conductors 101′, 102′ and 103′ in transition zone 16 where ends of each are spliced together at junctions 111, 112 and 113, respectively. Conductors 101/101′, 102/102′, 103/103 may be in the form of cables and conductor 104 in the form of a coil; such cabled and coiled conductor configurations may be formed of one or more conductor wires made of MP35N alloy according to configurations well known to those skilled in the art. It should be noted that embodiments of the present invention also include those without splice junctions 111, 112 and 113 wherein conductors are continuous from lead body 12 to connector 14.

Figure 1 further illustrates transition zone 16 contained within a connector sleeve 160 and including a first multi-lumen tube 161, positioned adjacent connector 14, and a second multi-lumen tube 162, positioned adjacent proximal end 129 of lead body 12; each lumen of first second multi-lumen tubes 161 and 162 serves to route each one of conductors 101/101′, 102/102′, 103/103′ and 104 from lead body 12 to connector 14. According to embodiments of the present invention, conductors 101/101′, 102/102′ and 103/103′ are routed in a helical path within transition zone 16 so that stresses and strains may be alleviated. Although Figure 1 illustrates transition zone 16 including two tubes 161 and 162, alternate embodiments of the present invention can employ a single tube

within zone 16 to provide the helical routing. According to some of these alternate single tube embodiments, helical routing has a constant pitch along a length of transition zone 16, while according to others of these embodiments helical routing has a variable pitch along a length of transition zone 16, for example as illustrated in Figure 1.

Figures 2A-B are a perspective view and a schematic, respectively, of multi-lumen tube 161 according to some embodiments of the present invention. Figures 2A-B illustrate tube 161 including a central lumen 22 and three peripheral lumens 21 each extending from a first end 205 to a second end 207 of tube 161; peripheral lumens 21 each extend along a helical path about central lumen 22, for example as illustrated by a bold line 201. According to the illustrated embodiment, peripheral lumens 21 twist about central lumen 22 from first end 205 to second end 207 in an angle T, which is approximately 90 degrees, but may be as great as approximately 180 degrees; thus, a pitch of the helical path of lumens 21 is greater than a length of tube 161 from first end 205 to second end 207, which length is between approximately 1.25 inches and 1.5 inches.

Figures 2A-B further illustrate lumens 21 each having a ellipsoid cross-section and offset about a periphery of central lumen 22 at an angle X between adjacent edges of lumens, angle X being approximately 45 degrees according to the illustrated embodiment. According to one embodiment of the present invention, the ellipsoid cross-section of lumens 21 provides a loose fit of conductors 101′, 102′ and 103′, having a generally circular cross-section, therein, thus allowing movement of the conductors for stress relief and further providing some slack so that an orientation of first multi-lumen tube 161 with respect to second multi-lumen tube 162 is not as critical.

According to an exemplary embodiment of the present invention, first multi-lumen tube 161 is made of polyurethane; tube 161 would have been extruded so that a center axis of lumens 21 is approximately straight extending parallel to a central axis of central lumen 22 and then taken through a secondary process to create the twisted configuration illustrated in Figures 2A-B. The secondary process, according to one embodiment, includes clamping first end 205 to a fixture plate and then rotating or twisting, through angle T, second end 207 with respect to first end 205; second end 207 is then secured or clamped to the plate and tube 161 is held at a temperature of approximately 150° Celsius (+/- 5°) for approximately 15 minutes (+/- 5 minutes) to heat set tube 161 in the twisted

configuration. According to an alternate embodiment, tube 161 is extruded or molded into the illustrated configuration without need for such a secondary process.

Figures 3A-B are a perspective view and schematic, respectively, of second multi-lumen tube 162 according to some embodiments of the present invention. Figures 3A-B illustrate tube 162 including a central lumen 32 and three peripheral lumens 31 each extending from a first end 305 to a second end 307 of tube 162; peripheral lumens 31 each extend along a helical path about central lumen 32, a trajectory of which may be seen in Figures 3A-B, more clearly illustrated in Figure 3B by path 301. According to the illustrated embodiment, peripheral lumens 31 twist about central lumen 32 from first end 305 to second end 307 in an angle, which is approximately 360 degrees, but may be as great as approximately 400 degrees; a length of tube 162 from first end 305 to second end 307 is between approximately 0.5 inch and 1 inch.

According to an exemplary embodiment of the present invention, second multi-lumen tube 162 is made of silicone which may either have been extruded or molded into the twisted configuration illustrated in Figures 3A-B. According to an alternate embodiment, second tube 162 may have been extruded from polyurethane and set in the twisted configuration via the process previously described for first tube 161.

Figures 4A-B are plan views illustrating assembly steps according to some methods of the present invention. Figure 4A illustrates a partial connector assembly 44 wherein connector contacts 141, 142 and 143 are mounted on an internal strut, whose distal end 450 is shown; contacts 141, 142 and 143 are each coupled to conductors 101′, 102′ and 103′, respectively, shown extending from a distal end of assembly 44, and alternate with insulative spacers 140, 145, 146 and 147, which are also mounted on the strut. Such a connector assembly is described in co-pending and commonly assigned patent application serial number 10/812,796 (Attorney Docket P-11476.00), which is incorporated by reference in its entirety herein.

According to one method of the present invention illustrated in Figure 4A, an initial transition zone assembly step includes positioning first multi-lumen tube 161 adjacent connector assembly 44 per arrow A while inserting each of conductors 101′, 102′ and 103′ into a respective peripheral lumen 21 of first tube 161; first end 205 of tube 161 is coupled to connector assembly 44 by inserting strut distal end 450 into central lumen 22 according to one embodiment. Once first tube 161 is positioned, distal ends of conductors

101′, 102′ and 103′ extend distally from second end 207 of tube 161 as illustrated in Figure 4B.

According to the embodiments described in conjunction with Figures 2A-B, a polyurethane material forming first tube 161, preferably having a hardness or durometer of about 55 on a Shore D scale, the length of first tube 161, and the twist, according to angle T, of peripheral lumens 21 can all facilitate insertion of each of conductors 101′, 102′ and 103′ into respective lumens 21 without kinking of conductors 101′, 102′ and 103′. Furthermore, according to these embodiments, the polyurethane lends a stiffness to transition zone 10 that can facilitate insertion of connector 14 (Figure 1) into a device connector bore when transition zone 16 is grasped for such insertion.

Figure 4B illustrates a series of steps subsequent to that illustrated in Figure 4A, according to some methods of the present invention. According to the illustrated embodiment, lead body 12, having conductors 101, 102, 103 and 104 extending proximally therefrom, is positioned in proximity to first tube 161, having conductors 101′, 102′ and 103′ extending distally therefrom, and is advanced per arrow B such that conductor 104 is inserted through central lumen 22 of first tube 161 and through connector assembly 44. As illustrated in Figure 4B, proximal ends of conductors 101, 102 and 103 and distal ends of conductors 101′, 102′ and 103′ are brought together per arrows 41, 42 and 43, respectively to form splice junctions 111, 112 and 113 (Figure 1), while a proximal end of conductor 104 is extended from a proximal end of connector assembly 44 to be coupled with connector contact pin 144. Splice junctions 111, 112 and 113 may be formed with or without additional components using methods, for example welding and crimping, known to those skilled in the art.

Figure 4B further illustrates second multi-lumen tube 162 directed per arrow C in order to position second tube 162 between first tube 161 and lead body 12 and to position conductor 104 within central lumen 32 and each conductors 101/101′, 102/102′ and 103/103′ within respective peripheral lumens 31. According to the illustrated embodiment, a slit 432 extending from an exterior surface of second tube 162 to central lumen 32 allows for positioning, per arrow C, of conductor 104 within central lumen 32, and slits 431 extending from the exterior surface to peripheral lumens 31 likewise allow positioning of conductors 101/101′, 102/102′ and 103/103′ within peripheral lumens 31.

Splice junctions 111, 112 and 113 may be formed either before or after positioning of second tube 162.

According to embodiments described in conjunction with Figures 3A-B, the shorter pitch of the helical path taken by peripheral lumens 31, of second tube 162, than the pitch of the helical path of peripheral lumens 21, of first tube 161, provide enhanced strain relief to the transition of conductors 101/101′, 102/102′ and 103/103′; furthermore the softer silicone material, preferably having a hardness or durometer of about 50-60 on a shore A scale, facilitates the slitting of tube 162 and positioning of conductors 101/101′, 102/102′, 103/103′ and 104 according to the illustrated assembly method.

Figure 4C is a perspective view according to one method of the present invention wherein a straightening fixture 400 is employed for forming slit 432 in second multi-lumen tube 162. Figure 4C illustrates second tube 162 mounted on straightening fixture 400 such that each of mandrels 401 extending from a base 405 of fixture 400 are inserted within a respective peripheral lumen 31; mandrels 401 thus straighten peripheral lumens 31 so that slit 432 may be formed, for example with a cutting blade, without undue risk of cutting into peripheral lumens 31.

Returning now to Figure 1, a final assembly step according to one method of the present invention includes positioning connector sleeve 160 to couple lead body 12 to connector terminal 14 and to encompass conductors 101/101′, 102/102′, 103/103′ and 104 passing through transition zone 16. A silicone medical adhesive may be injected beneath connector sleeve 160 to fill in voids within transition zone 16; when both connector sleeve 160 and second multi-lumen tube 162 are formed of silicone, the silicone adhesive provides very good isolation of conductors 101/101′, 102/102′, 103/103′ and 104 via a common material adhesion between adhesive, tube 162 and sleeve 160. Embodiments incorporating silicone adhesive backfill and silicone forming connector sleeve 160 and second tubing 162 also give transition zone 16 a flexibility facilitating bending of transition zone 16, distal to a point where zone 16 exits a device connector bore, when connector 14 is fully inserted in the bore and the proximal portion of lead body 12 is wrapped about the device according to methods known to those skilled in the art.

In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention

as set forth in the appended claims. For example, although peripheral lumens of multi-lumen tubes have been illustrated as generally closed with respect to outer longitudinal surfaces of the tubes, tubes having peripheral lumens formed as open channels or grooves to route conductors are within the scope of the present invention and the term 'lumen' used herein is intended to broadly cover such a configuration.

What is claimed is:

1. A medical electrical lead, comprising:

a lead body;

a connector terminal coupled to the lead body;

a lead body-to-connector transition zone comprising a first multi-lumen tube including a proximal end, a distal end, a central lumen extending from the proximal end to the distal end and a peripheral lumen extending from the proximal end to the distal end in a helical path about the central lumen; and

a conductor extending from the lead body to the connector terminal through the peripheral lumen of the first multi-lumen tube.

2. The lead of claim 1, wherein the peripheral lumen includes an ellipsoidal cross-section.

3. The lead of claim 1, wherein the conductor fits loosely within the peripheral lumen.

4. The lead of claim 1, wherein a pitch of the helical path is greater than a length of the first multi-lumen tube.

5. The lead of claim 1, wherein the first multi-lumen tube has a length between approximately 1.25 inches and approximately 1.5 inches and the helical path twists about the central lumen, from the proximal end to the distal end, approximately 90 degrees to approximately 180 degrees.

6. The lead of claim 1, wherein the peripheral lumen includes a plurality of peripheral lumens offset from one another about a circumference of the central lumen.

7. The lead of claim 6, wherein the offset is approximately 45 degrees from an edge of one of the plurality of lumens to an adjacent edge of another of the plurality of lumens.

8. The lead of claim 6, wherein the conductor comprises a plurality of conductors, each of the plurality of conductors extending through each of the plurality of peripheral lumens.

9. The lead of claim 1, wherein the conductor comprises a first conductor spliced to a second conductor, the first conductor extending from the lead body and the second conductor extending into the connector terminal.

10. The lead of claim 1, wherein:
the connector terminal includes a central strut; and
the central lumen at the proximal end of the first multi-lumen tube is mounted about a distal surface of the central strut.

11. The lead of claim 1, wherein:
the lead body-to-connector transition zone further comprises a second multi-lumen tube extending between the lead body and the distal end of the first multi-lumen tube;
the second multi-lumen tube includes a proximal end, a distal end, a second central lumen extending from the proximal end to the distal end, and a second peripheral lumen extending in a second helical path from the proximal end to the distal end;
the second helical path includes a pitch that is less than a pitch of the helical path of the first peripheral lumen; and
the conductor extends through the second peripheral lumen from the lead body to the first multi-lumen tube.

12. The lead of claim 11, wherein the second multi-lumen tube has a length between approximately 0.5 inch and approximately 1 inch and the second helical path twists about the second central lumen, from the proximal end of the second tube to the distal end of the second tube, approximately 360 degrees to approximately 400 degrees.

13. The lead of claim 11, wherein the second peripheral lumen includes a plurality of peripheral lumens offset about a circumference of the second central lumen.

14. The lead of claim 13, wherein the offset is approximately 120 degrees from a center of one of the plurality of lumens to a center of an adjacent lumen of the plurality of lumens.

15. The lead of claim 13, wherein the conductor comprises a plurality of conductors, each of the plurality of conductors extending through each of the plurality of peripheral lumens.

16. The lead of claim 11, wherein the conductor comprises a first conductor spliced to a second conductor at a junction, the first conductor extending from the lead body and the second conductor extending into the connector terminal and the junction being located within the second peripheral lumen.

17. The lead of claim 11, wherein a pitch of the helical path of the first peripheral lumen is greater than a length of the first multi-lumen tube.

18. The lead of claim 11, wherein the first multi-lumen tube has a length between approximately 1.25 inches and approximately 1.5 inches and the helical path thereof twists about the central lumen, from the proximal end of the first tube to the distal end of the first tube, approximately 90 degrees to approximately 180 degrees.

19. A method for assembling a transition zone between a medical electrical lead body and a lead connector assembly, the method comprising the steps of:

forming a multi-lumen tube having a peripheral lumen extending from a first end to a second end of the tube in a helical path about a central lumen of the tube;

positioning the multi-lumen tube adjacent the connector assembly; and

positioning a medical electrical lead conductor within the peripheral lumen.

20. The method of claim 19, wherein the multi-lumen tube is formed of a polyurethane material and the step of forming the multi-lumen tube comprises:

molding or extruding the tube such that the peripheral lumen extends from the first end to the second end approximately aligned with a central axis of the central lumen;

twisting the first end of the tube with respect to the second end of the tube such that the peripheral lumen extends in the helical path;

securing the first end and the second end in the twisted configuration; and

holding the ends at a temperature between approximately 145° C and 155° C for a time between approximately 10 minutes and 20 minutes.

21. The method of claim 19, wherein the step of forming the multi-lumen tube comprises molding.

22. The method of claim 19, wherein the conductor has been coupled to the connector assembly and the step of positioning the conductor comprises inserting the conductor into the first end of the peripheral lumen.

23. The method of claim 19, wherein the conductor has been coupled to the lead body and the step of positioning the conductor comprises inserting the conductor into the distal end of the peripheral lumen.

24. The method of claim 19, further comprising the step of forming the conductor from a first conductor, which is coupled to the lead body, and a second conductor, which is coupled to the connector assembly, by splicing a proximal end of the first conductor, which extends proximally from the lead body, to a distal end of the second conductor, which extends distally from the connector assembly.

25. The method of claim 19, wherein the step of positioning the conductor comprises pressing the conductor from a longitudinal exterior surface of the tube into the peripheral lumen.

26. The method of claim 24, wherein the step of positioning the conductor comprises pressing the spliced portion of the conductor from a longitudinal exterior surface of the tube into the peripheral lumen.

27. The method of claim 19, further comprising the step of positioning a second medical electrical lead conductor within the central lumen of the multi-lumen tube.

28. The method of claim 27, wherein the second medical electrical lead conductor is coupled to the lead body and extends proximally therefrom.

29. The method of claim 27, wherein the second conductor has been coupled to the connector assembly and the step of positioning the second conductor comprises inserting the second conductor into the first end of the central lumen.

30. The method of claim 27, wherein the second conductor has been coupled to the lead body and the step of positioning the second conductor comprises inserting the second conductor into the distal end of the central lumen.

31. The method of claim 27, wherein the step of positioning the second conductor comprises pressing the conductor from a longitudinal exterior surface of the tube into the central lumen.

32. The method of claim 19, further comprising the step of coupling the multi-lumen tube to the connector assembly.

33. The method of claim 22, further comprising the step of coupling a distal end the conductor, which extends distally from the peripheral lumen of the multi-lumen tube, to another conductor extending proximally from the lead body to form a conductor splice.

34. The method of claim 22, further comprising the steps of;

forming a second multi-lumen tube having a second peripheral lumen extending from a first end of the second tube to a second end of the second tube in a helical path about a central lumen of the second tube;
positioning the second tube between the multi-lumen tube and the lead body; and
positioning the conductor within the second peripheral lumen.

35. The method of claim 34, wherein the step of positioning the conductor comprises pressing the conductor from a longitudinal exterior surface of the second tube into the second peripheral lumen.

36. The method of claim 28, further comprising the steps of:
forming a second multi-lumen tube having a second peripheral lumen extending from a first end of the second tube to a second end of the second tube in a helical path about a central lumen of the second tube;
positioning the second tube between the multi-lumen tube and the lead body; and
positioning the conductor within the second peripheral lumen.

37. The method of claim 36, further comprising the step of positioning the second conductor within the central lumen of the second tube.

38. The method of claim 37, wherein the step of positioning the second conductor comprises pressing the second conductor from a longitudinal exterior surface of the second tube into the central lumen.

39. The method of claim 33, further comprising the steps of:
forming a second multi-lumen tube having a second peripheral lumen extending from a first end of the second tube to a second end of the second tube in a helical path about a central lumen of the second tube;
positioning the second tube between the multi-lumen tube and the lead body; and

positioning the conductor splice within the second peripheral lumen.

40. The method of claim 39, wherein the step of positioning the splice of the conductors comprises pressing the splice from a longitudinal exterior surface of the second tube into the second peripheral lumen.

41. A medical electrical lead, comprising:

a lead body;

a connector terminal coupled to the lead body;

a lead body-to-connector transition zone extending between the lead body and the connector terminal; and

a conductor extending from the lead body to the connector terminal through the transition zone in a helical path, the helical path including a distal part having a first pitch and a proximal part having a second pitch, the second pitch being greater than the first pitch.

42. The lead of claim 41, wherein the conductor comprises a plurality of conductors, each of the plurality of conductors extending through the helical path and being offset from one another about a circumference of the transition zone.

43. The lead of claim 41, wherein the conductor comprises a first conductor spliced to a second conductor, the first conductor extending from the lead body and the second conductor extending into the connector terminal.

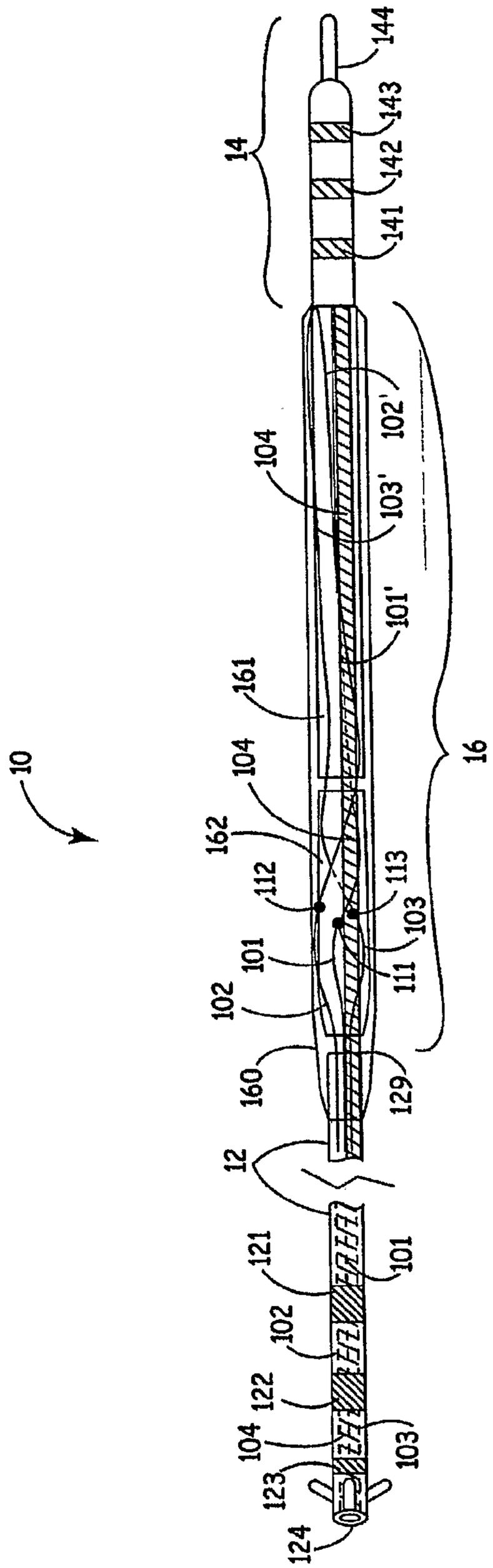

144
143
142
141
14
10
104
161
162
112
113
103
102
101
111
160
129
12
121
122
123
124
16
102'
103'
101'

Figure 1

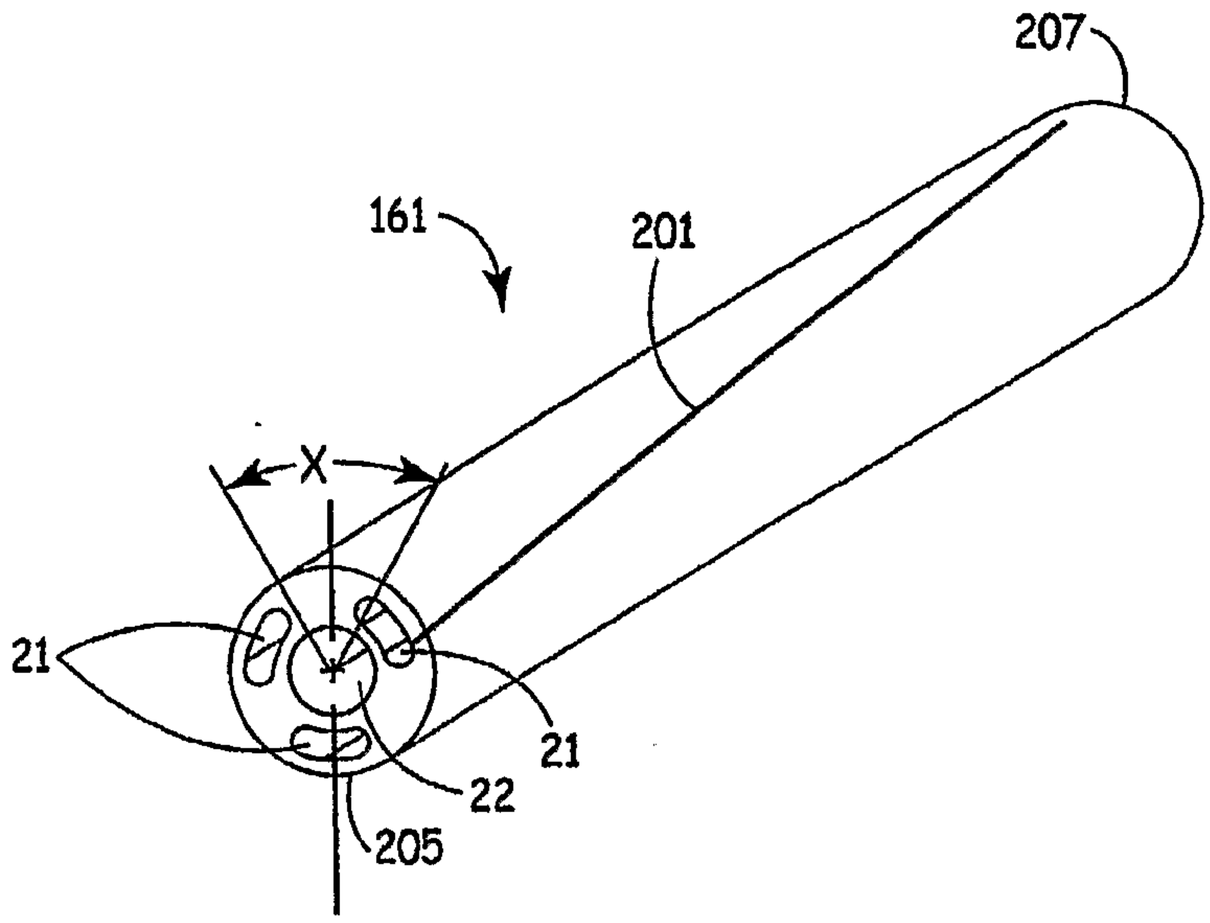



Figure 2A

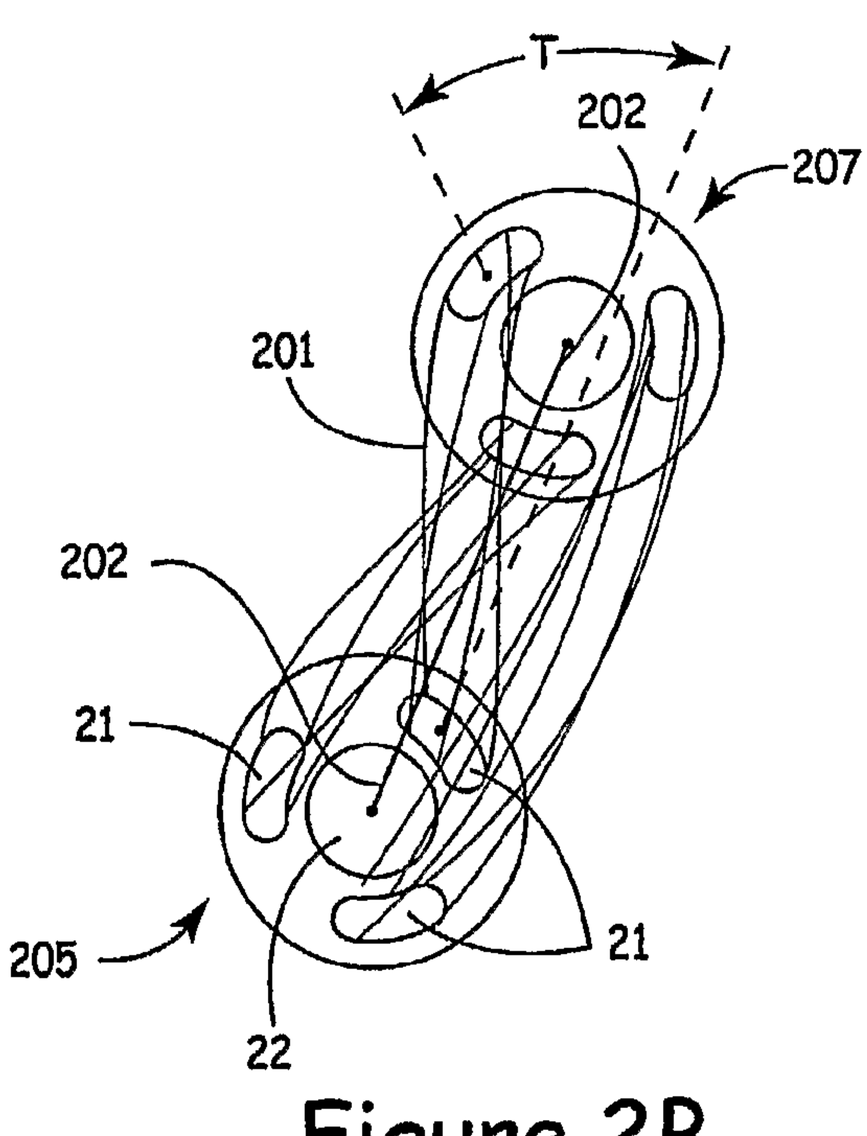



Figure 2B

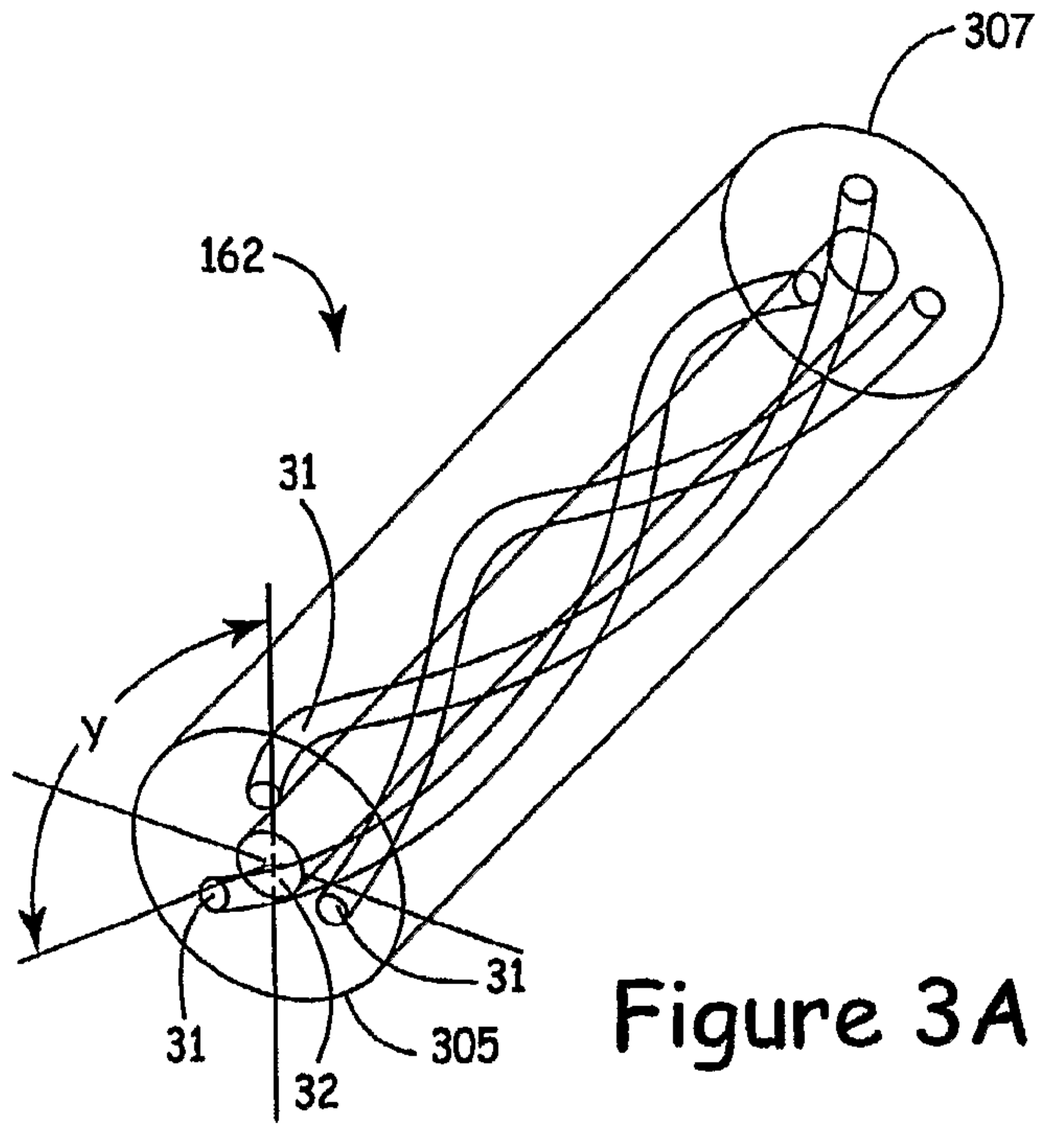



Figure 3A

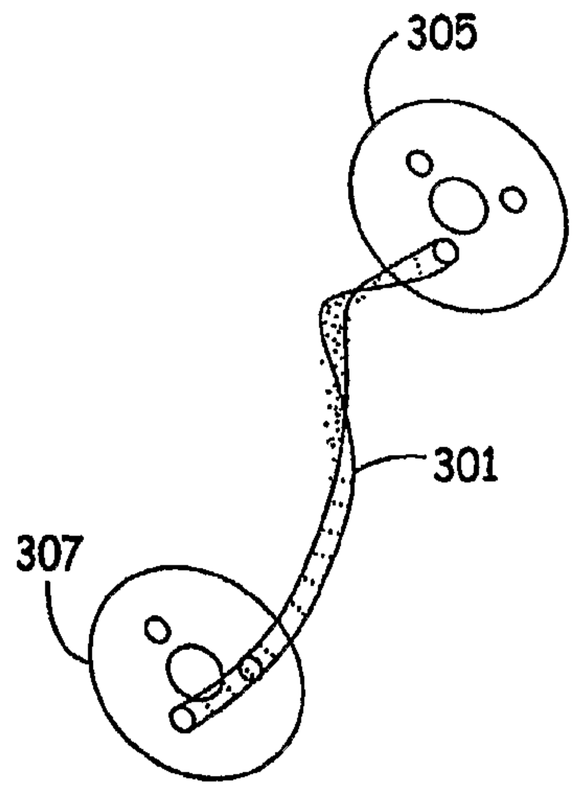



Figure 3B

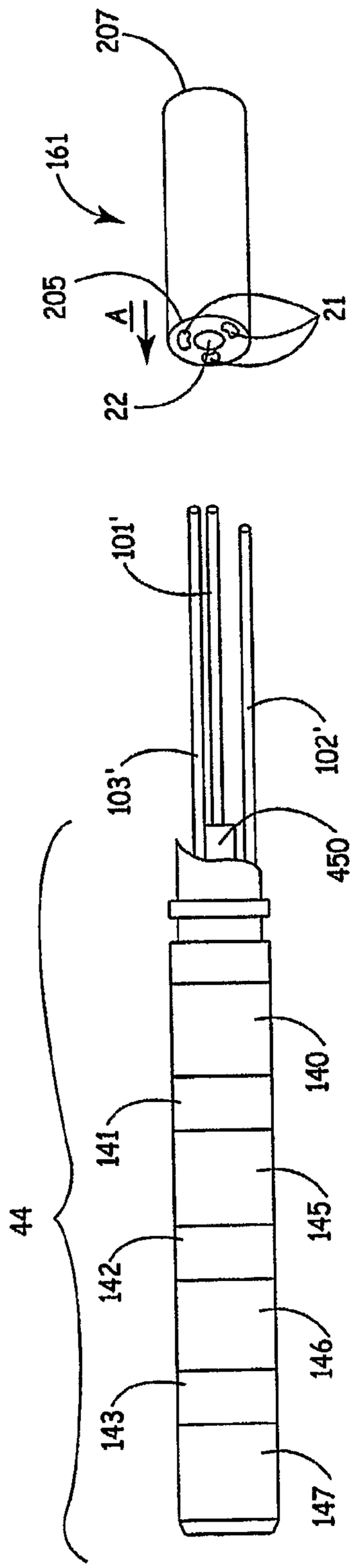



Figure 4A

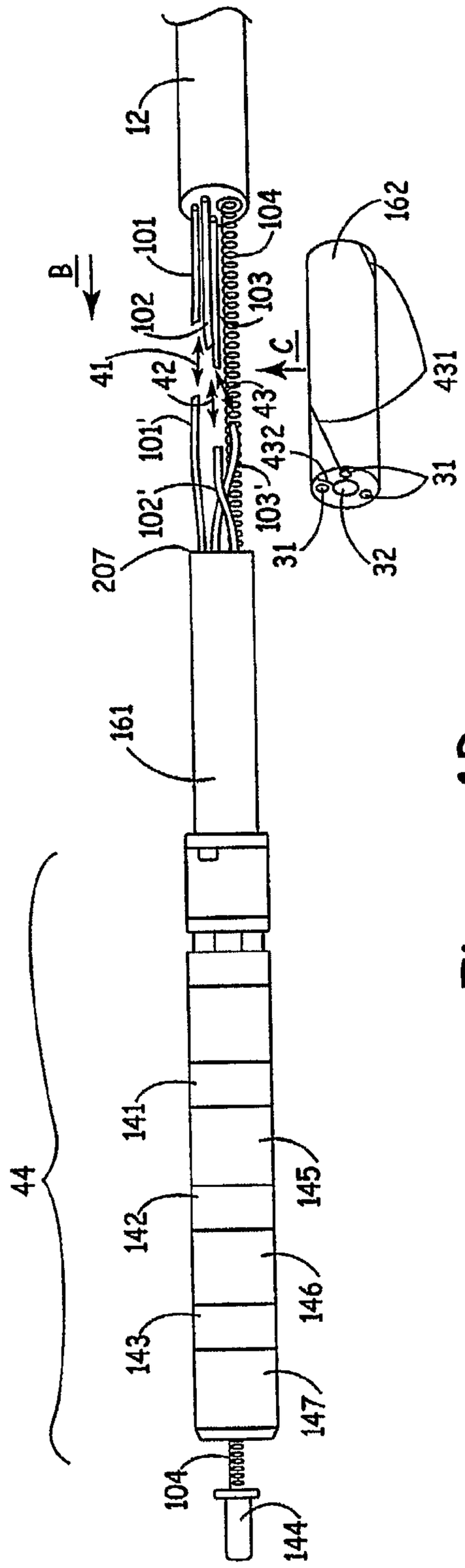

12
101
104
162
B
102
103
C
41
42
43'
431
101'
432
31
102'
103'
31
207
32
161
44
141
145
142
146
143
147
104
144

Figure 4B

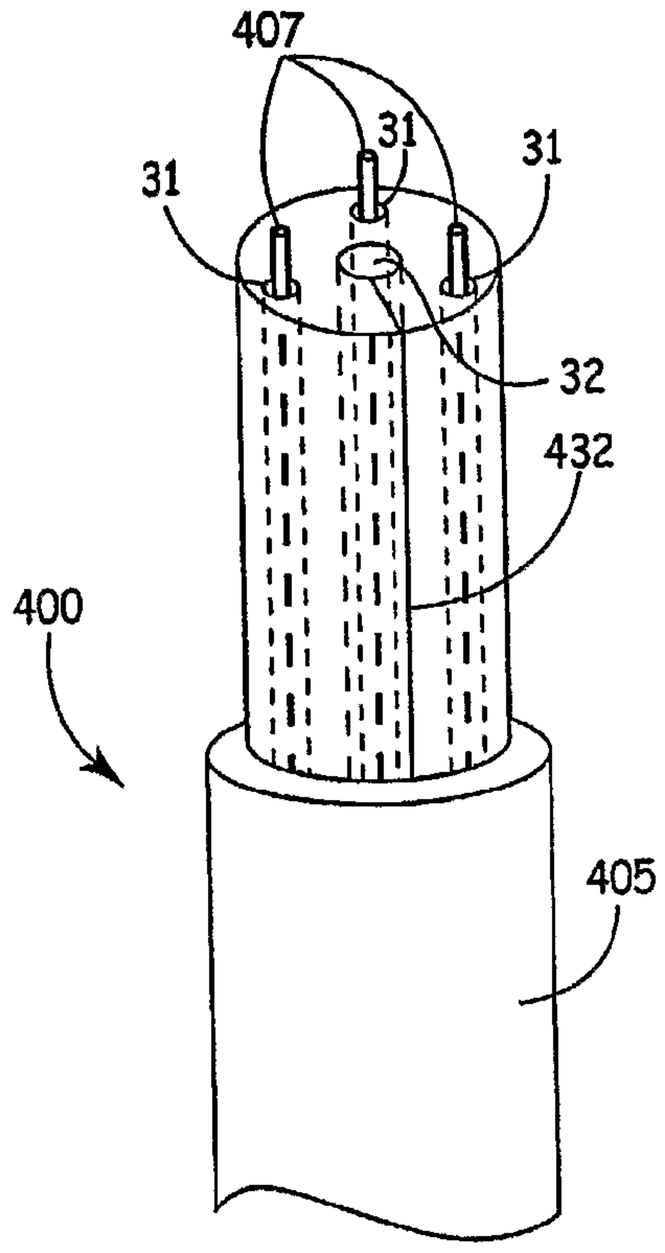
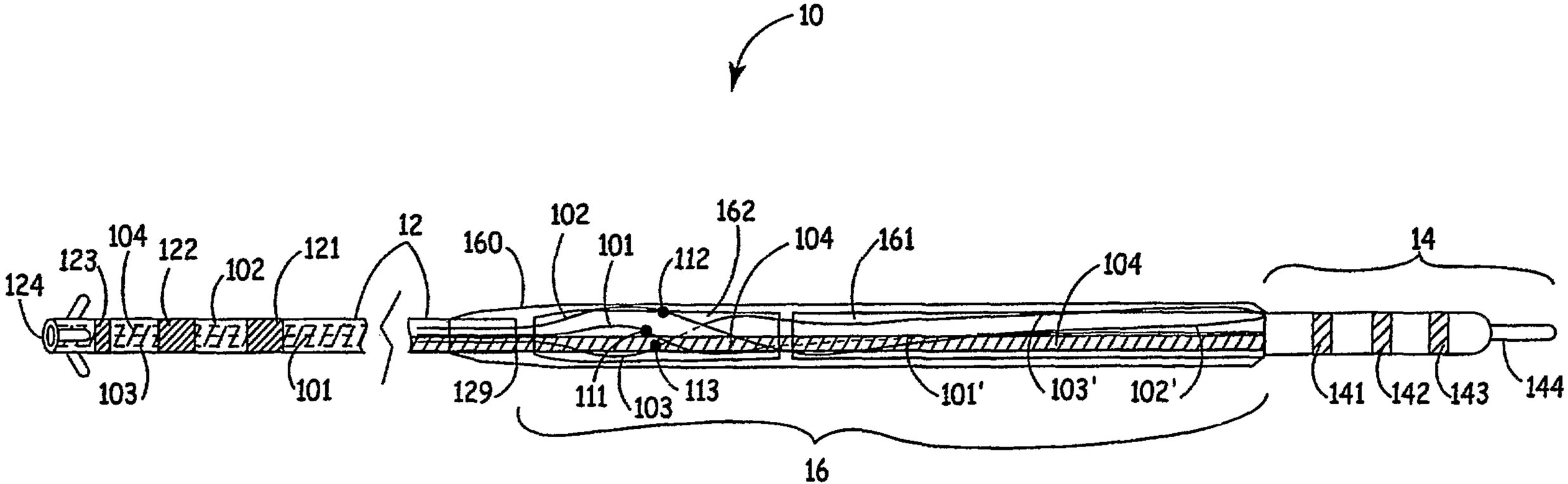



Figure 4C


10
12
14
16
101
101'
102
102'
103
103'
104
111
112
113
121
122
123
124
129
141
142
143
144
160
161
162