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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 May 2008 (08.05.2008)

PCT

(10) International Publication Number
WO 2008/055025 A1

(51) International Patent Classification:
A61N 1/05 (2006.01) *A61M 25/01* (2006.01)
A61M 25/09 (2006.01)

(21) International Application Number:
PCT/US2007/082080

(22) International Filing Date: 22 October 2007 (22.10.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/555,004 31 October 2006 (31.10.2006) US

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

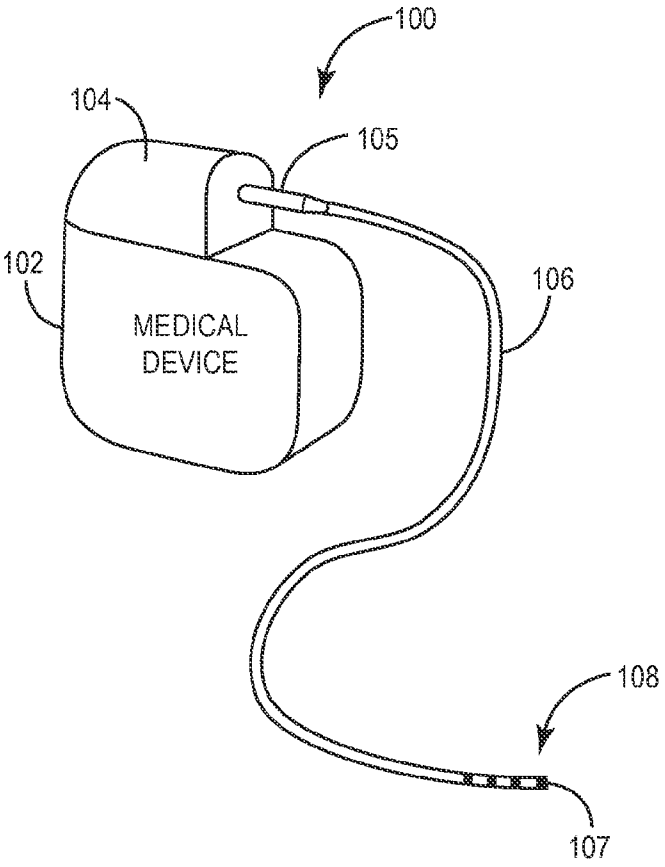
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BAUER, Ryan T.** [US/US]; 12700 50th Avenue North, Plymouth, MN 55442 (US). **MEREGOTTE, Pedro A.** [US/US]; 424 Vadnais Lake Drive, Vadnais Heights, MN 55127 (US). **SOMMER, John L.** [US/US]; 12788 Ibis Street Northwest, Coon Rapids, MN 55448 (US). **SENARITH, Patrick P.** [US/US]; 33 Village Parkway, Unit 421, Circle Pines, MN 55014 (US). **STEINGISSER, H. Allan** [US/US]; 18 Rockland Street, Number 2, Melrose, MA 02176 (US). **HORRIGAN, John B.** [US/US]; 33 Berrywood lane, Beverly, MA 01915 (US).

(74) Agents: **BARRY, Carol F.** et al.; 710 Medtronic Parkway MS LC340, 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, 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,

[Continued on next page]

(54) Title: MEDICAL LEAD DELIVERY DEVICE



(57) Abstract: The medical lead delivery device combines features of a guidewire and a stylet in order to more easily and quickly deliver a lead to the left ventricle of a patient's heart. The medical lead delivery device includes an elongated body, a controller, a first and second spring, and a sleeve. The elongated body includes a proximal end and a distal end. The controller is disposed at the proximal end and provides enhanced control of the distal tip of the elongated body.

WO 2008/055025 A1

PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, 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, HU, IE, IS, IT, LT, LU, LV, MC, MT, 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).

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*

MEDICAL LEAD DELIVERY DEVICE

TECHNICAL FIELD

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

BACKGROUND

Most commercially available cardiac pacing and defibrillation leads are placed by means of a stylet which is inserted into a central lumen through the lead, and is used to assist in pushing the lead through the vascular system and guiding it to a desired location. Leads may also be placed by a guidewire extending entirely through the lead and out its distal end. This basic approach has been adapted to cardiac pacing leads and cardioversion leads as well, as disclosed in U.S. Pat. No. 5,003,990 issued to Osypka, U.S. Pat. No. 5,755,765 issued to Hyde et al, U.S. Pat. No. 5,381,790 issued to Kenasaka and U.S. Pat. No. 5,304,218 issued to Alferness.

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 block diagram of an implantable medical device;

FIG. 2 is a block diagram of a delivery device in a medical lead;

FIG. 3 is a cross-sectional view of a delivery device of Figure 2;

FIG. 4 is an enlarged view of a proximal joint of the delivery device depicted in FIG. 3;

FIG. 5 is an enlarged view of a distal joint of the delivery device depicted in FIG. 3; and

FIG. 6 is an enlarged view of a tip joint of the delivery device depicted in FIG. 3.

DETAILED DESCRIPTION

The present invention is directed to a delivery device that assists in placement of a medical lead in the left heart of a patient. The delivery device is a hybrid of a guidewire and a stylet. The medical lead delivery device includes an elongated body, a controller, a first and second spring, and a sleeve. The elongated body includes a proximal end and a distal end. The controller is disposed at the proximal end and provides enhanced control of the distal tip of the elongated body. In particular, the delivery device can be advanced beyond the tip of the lead to provide a "rail" for the medical lead to track. The first and second springs are coupled to the distal end of the elongated body. A sleeve is coupled to the elongated body and to the first and second springs through first, second and third solder elements. The delivery device eases delivery of a medical lead to the left ventricle of the heart. Additionally, a lower manufacturing cost exists to produce the delivery device.

FIG. 1 depicts a medical device system 100. A medical device system 100 includes a medical device housing 102 having a connector module 104 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 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, or a muscle stimulator. 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. In other words, lead 106 may position one or more electrodes 108 with respect to various tissue (e.g. cardiac tissue etc.) locations so that medical device system 100 can deliver pulses to the appropriate locations.

Lead 106 is provided with an elongated insulative lead body (e.g. insulative polymeric tube etc.), which carries a coiled conductor therein. Other lead body types may be substituted within the context of the present invention, including lead bodies employing multiple lumen tubes and/or stranded or braided conductors as disclosed in U.S. Pat. No. 5,584,873 issued to Shoberg et al, and incorporated herein by reference in its entirety.

Alternatively, the lead may include additional conductors arranged either within a multi-lumen lead body or concentrically, as disclosed in U.S. Pat. No. 4,355,646 issued to Kallok et al and incorporated herein by reference in its entirety. Additional pacing electrodes, sensors, or defibrillation electrodes, may of course be added to the lead body and coupled to additional conductors.

At the proximal end of the lead body is a connector assembly (e.g. IS1, IS-4 connector assemblies etc.) used in commercially available cardiac pacing leads. The connector assembly includes a conductive connector pin which is coupled by means of the conductor within the lead body to a tip electrode located at the distal tip of lead 106.

FIGs. 2-6 depict details of a delivery device 200 (or delivery wire) used to place lead 106 in a patient's body (e.g. left heart etc.). Delivery device 200 has a proximal end 204 and a distal end 206. Delivery device 200 comprises a controller 208, an elongated member 202, a sleeve 216, springs (or coils) 218, 220 and solder coupled to springs 218, 220 and to sleeve 216. Elongated member 202 comprises a conductive material (e.g. stainless steel, NiTiNOL (i.e. a family of Ni - Ti Alloys etc.)) with a length up to L1 and a diameter that ranges from D1 to D4. At proximal end 204 is controller 208. Controller 208 is an ergonomic knob configured to allow more control of the distal tip to elongated member 202 relative to lead 106. In particular, controller 10 assists in advancing delivery device 200 beyond the distal tip of lead 106 to provide a "rail" for the medical lead to track. In one embodiment, controller 208 is permanently attached to elongated member 202. In another embodiment, controller 208 is temporarily coupled to elongated member 202 to allow controller 208 to be removed from elongated member 202. For example, controller 208 may be screwed onto the proximal end 204 of elongated member 202.

In one embodiment, controller 208 comprises a gripping member 210 and a tapered distal end 211 with a length of about L2. Gripping member 210 is cylindrically shaped and includes a diameter that of about D1 and a length that extends L3. During insertion of a lead into a patient, gripping member 210 is held between the thumb and the forefinger of the person attempting to place the lead in the left heart. In one embodiment, gripping member 210 includes elongated recessed regions 212 to enhance the person's ability to hold gripping member 210. At the distal end of gripping member 210 is a tapered distal end 211. Tapered distal end 211 includes a diameter D4, a length L4, and angle θ formed by first and second sides 236, 238. Tapered distal end 211 of controller 208 is configured

to receive the proximal end of elongated member 202. The proximal end of elongated member 202 includes a D13.

A distal portion of elongated member 202 is surrounded by cylindrical sleeve 216 with spring 218 disposed between an inner wall of sleeve 216 and elongated member 202. Sleeve 216 provides lubricity for moving within a lead body and coil alignment between springs 218, 220. Sleeve 216 extends a length of L5 and includes an inner diameter of D_{sleeve}. Solder 224 (also referred to as a second solder element) connects sleeve 216 to elongated member 202, and to springs 218, 220. Solder 224 is introduced over spring 218 and sleeve 216 at a high temperature.

Elongated member 202 extends a length of L6, which is comprised of regions defined by lengths L7, L8, and L9. The L7 region includes a diameter D13 whereas the L8 region is tapered at its distal end and contacts sleeve 216. The L8 region has a diameter that ranges from about $D8_{small}$ to about $D8_{large}$. The L9 region is tapered and includes regions L10, L11, L12, and L13. The L10 region includes a tapered section of elongated member 202 defined by a diameter that ranges from about $D10_{small}$ to about $D10_{large}$. At the distal end of the L10 region is solder element 222. Solder element 222, also referred to as a third solder element, connects sleeve 216 with spring 218 and elongated member 202. Region L11 depicts spring 218 around elongated member 202. Region L11 includes a tapered section of elongated member 202 defined by a diameter that ranges from about $D11_{small}$ to about $D11_{large}$. The L12 region extends from solder elements 224 and 214. The distal tip of elongated member 202 extends into solder 214 which increases isodymetry and body (or stiffness) to elongated member 200. Solder 214 has a diameter of D5 and is also referred to as the first solder element.

Springs 218, 220 are formed from any desired conductive material, selected based on the application of the elongated member being manufactured. Conductive material includes conductive metals or alloys, and/or conductive polymers. For example, springs 218, 220 may be formed from silver, platinum, gold, copper, a conductive alloy, or any other conductive material suitable for use in a medical lead.

Provided in Table 1 are the general dimensions for a delivery device 200 made to deliver 4 and 6 French leads.

Table 1—Dimensions of a delivery device.

Element designation	Dimension of a 4 French delivery device	Dimension of a 6 French delivery device
L1	43.01 inches	43.01 inches
L2	0.49 inches	0.49 inches
L3		
L4		
L5	9.45 inches	9.45 inches
L6	42.52 inches	42.52 inches
L7		
L8		
L9		
L10		
L11		
L12	2.36 inches	2.36 inches
L13		
D1	0.19 inches	0.19 inches
D2	0.0024 inches	0.0024 inches
D3	0.009 inches	0.012 inches
D4		
D5	0.012 inches	0.012 inches
D13	0.014 inches	0.014 inches

Another embodiment of length of L1 is about 34 inches. Another embodiment of length of L1 is about 51 inches. L1 can range from about 34 inches to about 51 inches. Various embodiments of the invention have been described. These and other embodiments are within the scope of the following claims. Presented below are additional embodiments related to delivery device 200. For example, a slideable torque tool may be employed. This embodiment is implemented through the following: side loading occurs and/or a torque-limiting (or slip clutch mechanism) – engage with lead via a connector. In another embodiment, for ease of torquing delivery device 200, proximal end is configured

with square (or on-rounded) cross-section or segmented round to non-round. In yet another embodiment, the delivery device is configured with alternating floppy and stiff areas. In still yet another embodiment, a coupling and decoupling via a lead and wire mechanism. In yet another embodiment, infusion wire with injection lumen and sideport – are able to inject contrast through the lumen. In yet another embodiment, a mechanism is employed for using a temperature sensitive alloy for lead fixation. In yet another embodiment, pacing wire may be unipolar and bi-polar configuration. This may include the following: a cathode range: 1.5 mm2 to 15 mm2 – 5 mm2 nominal and/or an anode range: 5 mm2 to 30 mm2 – 10 mm2 nominal. In yet another embodiment, a telescoping delivery device is employed. In yet another embodiment, delivery device includes a centering/loading tool.

CLAIMS:

1. A medical lead delivery device comprising:
an elongated body that includes a proximal end and a distal end;
a controller disposed at the proximal end;
a first and second spring coupled to the distal end of the elongated body; and
a sleeve coupled to the elongated body and to the first and second springs.

2. The medical lead delivery device of claim 1, wherein the controller configured to provide increased control over the distal tip of the elongated member.

3. The medical lead delivery device of claim 1, wherein the sleeve coupled to the elongated body and to the first and second springs through a first solder element.

4. The medical lead delivery device of claim 2, the sleeve coupled to the elongated body and to the first spring through a second solder element.

5. The medical lead delivery device of claim 3, the sleeve coupled to the elongated body and to the first spring through a third solder element.

6. The medical lead delivery device of claim 1, wherein the elongated body ranges in length from about 34 inches to about 51 inches.

7. The medical lead delivery device of claim 1, wherein the elongated body being about 34 inches.

8. The medical lead delivery device of claim 1 being a hybrid stylet and guidewire.

9. A medical lead delivery device comprising:
an elongated body that includes a proximal end and a distal end;
a controller disposed at the proximal end;

a first and second coil coupled to the distal end of the elongated body; and
a sleeve coupled to the elongated body and to the first and second coils,
wherein the controller configured to provide increased control over the distal tip of the elongated member.

10. The medical lead delivery device of claim 9, wherein the sleeve coupled to the elongated body and to the first and second coils through a first solder element.

11. The medical lead delivery device of claim 10, the sleeve coupled to the elongated body and to the first coil through a second solder element.

12. The medical lead delivery device of claim 10, the sleeve coupled to the elongated body and to the first coil through a third solder element.

13. The medical lead delivery device of claim 9, wherein the elongated body ranges in length from about 34 inches to about 51 inches.

14. The medical lead delivery device of claim 9, wherein the elongated body being about 34 inches.

15. The medical lead delivery device of claim 9 being a hybrid stylet and guidewire.

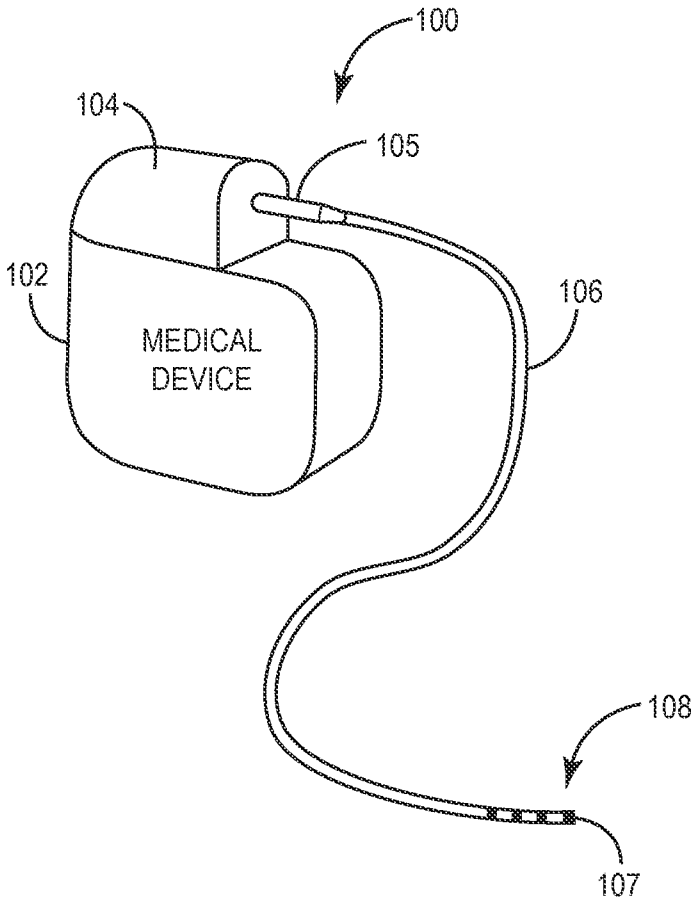


Fig. 1

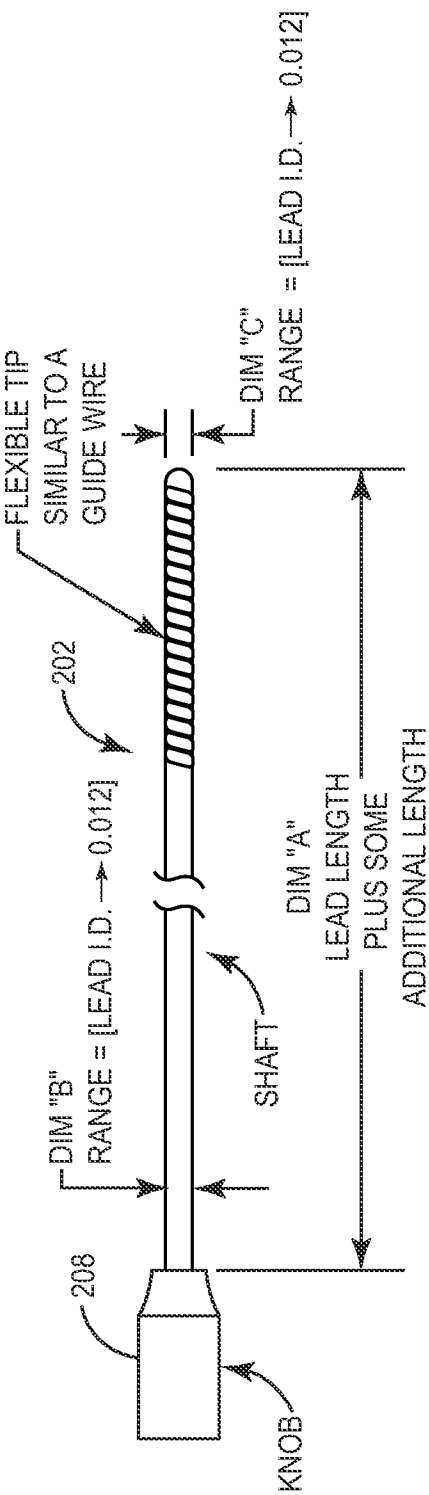

FLEXIBLE TIP
SIMILAR TO A
GUIDE WIRE
DIM "C"
RANGE = [LEAD I.D. → 0.012]
202
DIM "B"
RANGE = [LEAD I.D. → 0.012]
SHAFT
DIM "A"
LEAD LENGTH
PLUS SOME
ADDITIONAL LENGTH
208
KNOB

Fig. 2

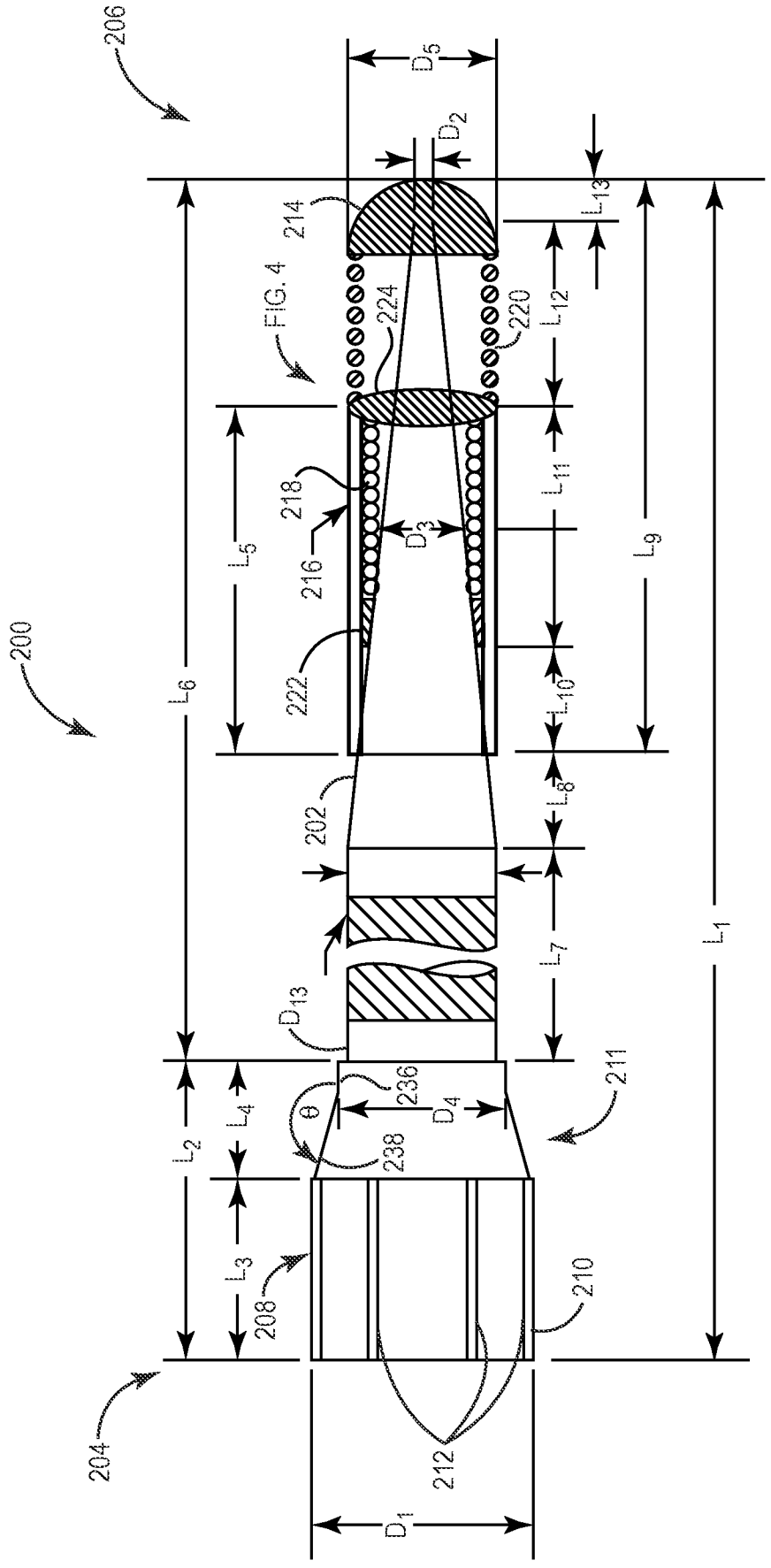

206
200
204
214
224
220
218
216
222
202
211
210
208
212
236
238
θ
D_5
D_2
D_3
D_{13}
D_4
D_1
L_{13}
L_{12}
L_{11}
L_{10}
L_9
L_8
L_7
L_6
L_5
L_4
L_3
L_2
L_1

FIG. 4

Fig. 3

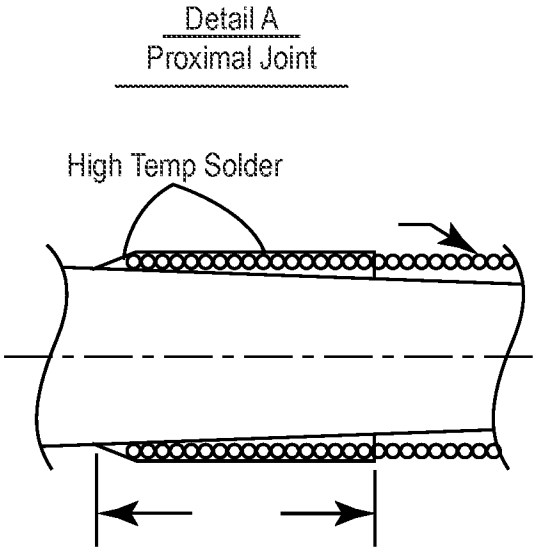


Fig. 4

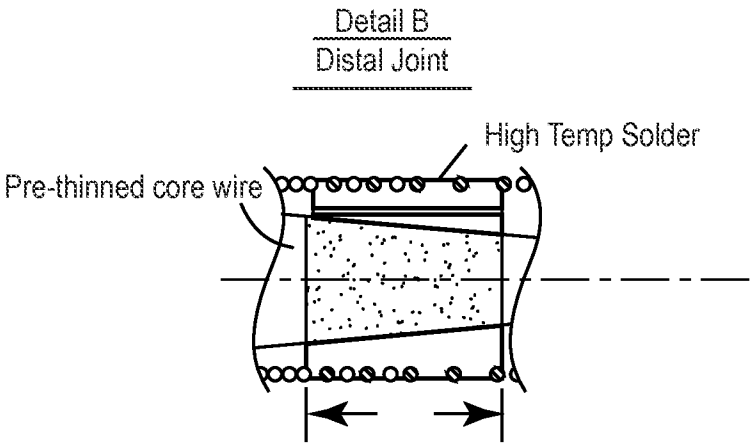

Detail B
Distal Joint
High Temp Solder
Pre-thinned core wire

Fig. 5

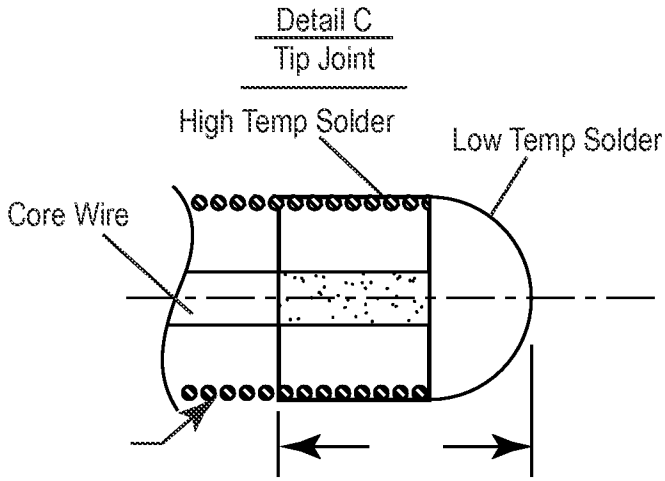

Detail C
Tip Joint
High Temp Solder
Low Temp Solder
Core Wire

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/082080

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05 A61M25/09 A61M25/01

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 A61M

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 practical, 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 4 763 647 A (GAMBALE RICHARD A [US]) 16 August 1988 (1988-08-16) column 1, lines 16-18 column 2, lines 4-27 column 3, lines 9-26 figures 1,2	1-15
Y	US 4 545 390 A (LEARY JAMES J [US]) 8 October 1985 (1985-10-08) column 6, lines 38-40	1-15
X	US 2005/113862 A1 (BESSELINK PETRUS A [NL] ET AL) 26 May 2005 (2005-05-26) paragraphs [0050], [0060] figures 2,4,10	9-11,15
Y		1-15

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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 document 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	Date of mailing of the international search report
13 March 2008	28/03/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Aronsson, Fredrik

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/082080

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 2007/233215 A1 (SOMMER JOHN L [US] ET AL) 4 October 2007 (2007-10-04) paragraphs [0021], [0027], [0028], [0030], [0031]; figure 3	1-15
P,X	US 2007/185415 A1 (RESSEMANN THOMAS V [US] ET AL) 9 August 2007 (2007-08-09) paragraphs [0071], [0072]; figure 8	1-15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/082080

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: -
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: -

For the purpose of the search, the subject-matter of claims 3-5 and 10-12 has been interpreted as described on page 4 of the description and in fig. 3, i.e.:
the elongated body (202) is coupled to the first spring/coil (220) through a first solder element (214),
the elongated body (202) is coupled to the sleeve (216) and to the first and second springs/coils (220, 218) through a second solder element (224),
the elongated body (202) is coupled to the sleeve (216) and to the second spring/coil (218) through a third solder element (222).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2)PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/082080

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4763647 A	16-08-1988	CA 1289837 C	01-10-1991
		DE 3873356 D1	10-09-1992
		DE 3873356 T2	10-12-1992
		EP 0274412 A2	13-07-1988
		JP 63181774 A	26-07-1988
US 4545390 A	08-10-1985	AR 231925 A1	30-04-1985
		CA 1208096 A1	22-07-1986
		DE 3334174 A1	22-03-1984
		FR 2533130 A1	23-03-1984
		GB 2127294 A	11-04-1984
		JP 4005467 B	31-01-1992
		JP 59077866 A	04-05-1984
		MX 153522 A	10-11-1986
US 2005113862 A1	26-05-2005	NONE	
US 2007233215 A1	04-10-2007	NONE	
US 2007185415 A1	09-08-2007	US 2007010762 A1	11-01-2007