

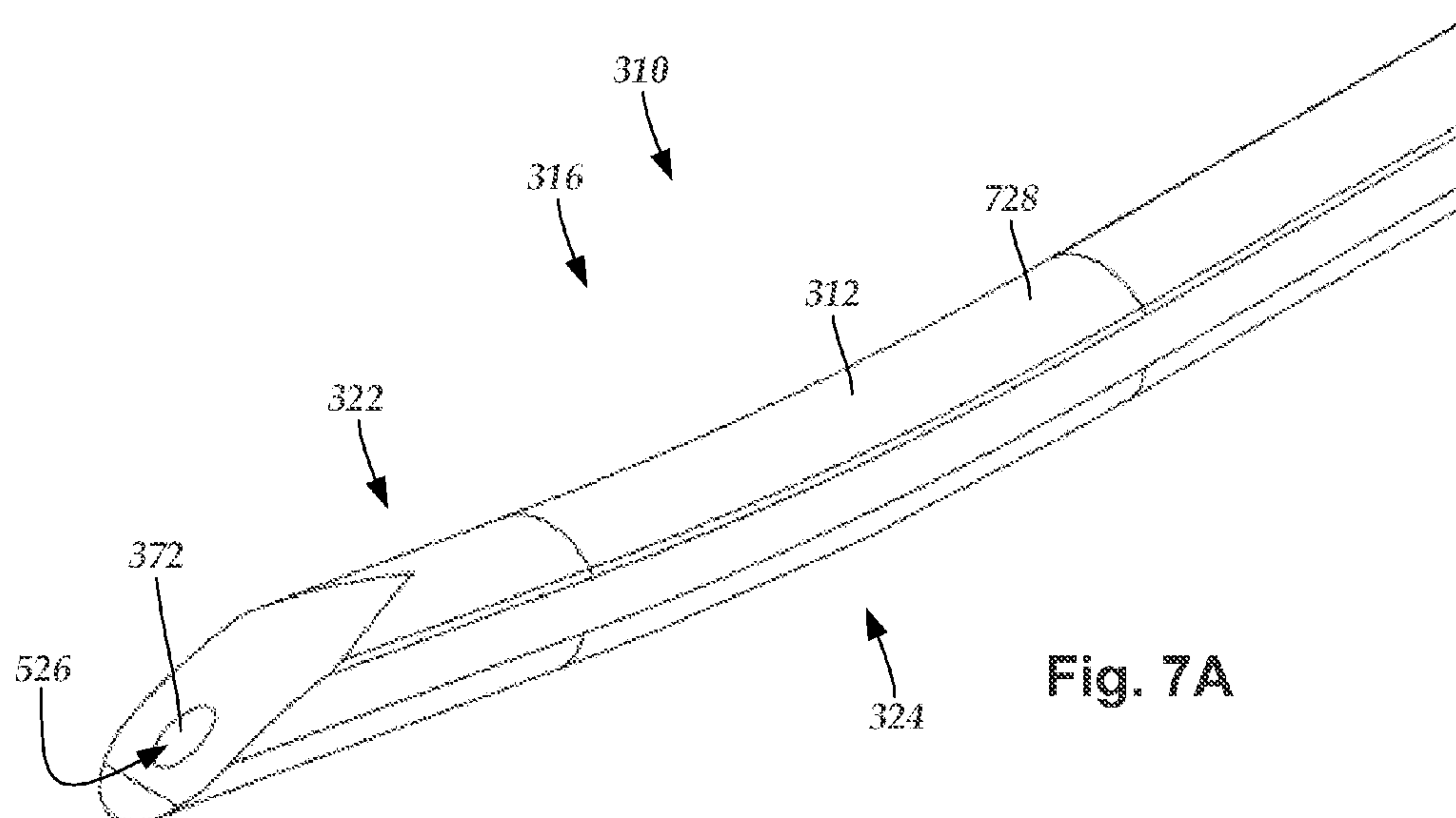


(86) Date de dépôt PCT/PCT Filing Date: 2014/09/02
(87) Date publication PCT/PCT Publication Date: 2015/03/12
(85) Entrée phase nationale/National Entry: 2016/02/10
(86) N° demande PCT/PCT Application No.: US 2014/053751
(87) N° publication PCT/PCT Publication No.: 2015/034842
(30) Priorité/Priority: 2013/09/06 (US61/874,730)

(51) Cl.Int./Int.Cl. *A61N 1/05* (2006.01),
A61B 17/34 (2006.01), *A61M 25/06* (2006.01)
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(54) Titre : DISPOSITIF D'INTRODUCTION DE CABLE POUR SYSTEME DE STIMULATION ELECTRIQUE
IMPLANTABLE

(54) Title: LEAD INTRODUCER FOR AN IMPLANTABLE ELECTRICAL STIMULATION SYSTEM



(57) Abrégé/Abstract:

A lead introducer includes an outer needle with an outer-needle body. The outer needle body includes a bend of at least 5° permanently formed along a distal end portion outer-needle body. The bend facilitates insertion of the lead introducer into an epidural space of a patient. The outer-needle body defines an open channel extending along an entire length of the outer-needle body. An inner needle is slidable along the open channel of the outer needle. The inner needle includes an inner-needle body that defines a lumen extending along an entire length of the inner-needle body. A splittable member is disposable over the outer needle when the inner needle is disposed in the open channel of the outer needle. The splittable member is separable from the inner and outer needles along at least one perforated region.



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

(19) World Intellectual Property
Organization
International Bureau(43) International Publication Date
12 March 2015 (12.03.2015)(10) International Publication Number
WO 2015/034842 A1

(51) International Patent Classification:

A61N 1/05 (2006.01) *A61M 25/06* (2006.01)
A61B 17/34 (2006.01)

(21) International Application Number:

PCT/US2014/053751

(22) International Filing Date:

2 September 2014 (02.09.2014)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/874,730 6 September 2013 (06.09.2013) US

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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, LT, 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: LEAD INTRODUCER FOR AN IMPLANTABLE ELECTRICAL STIMULATION SYSTEM

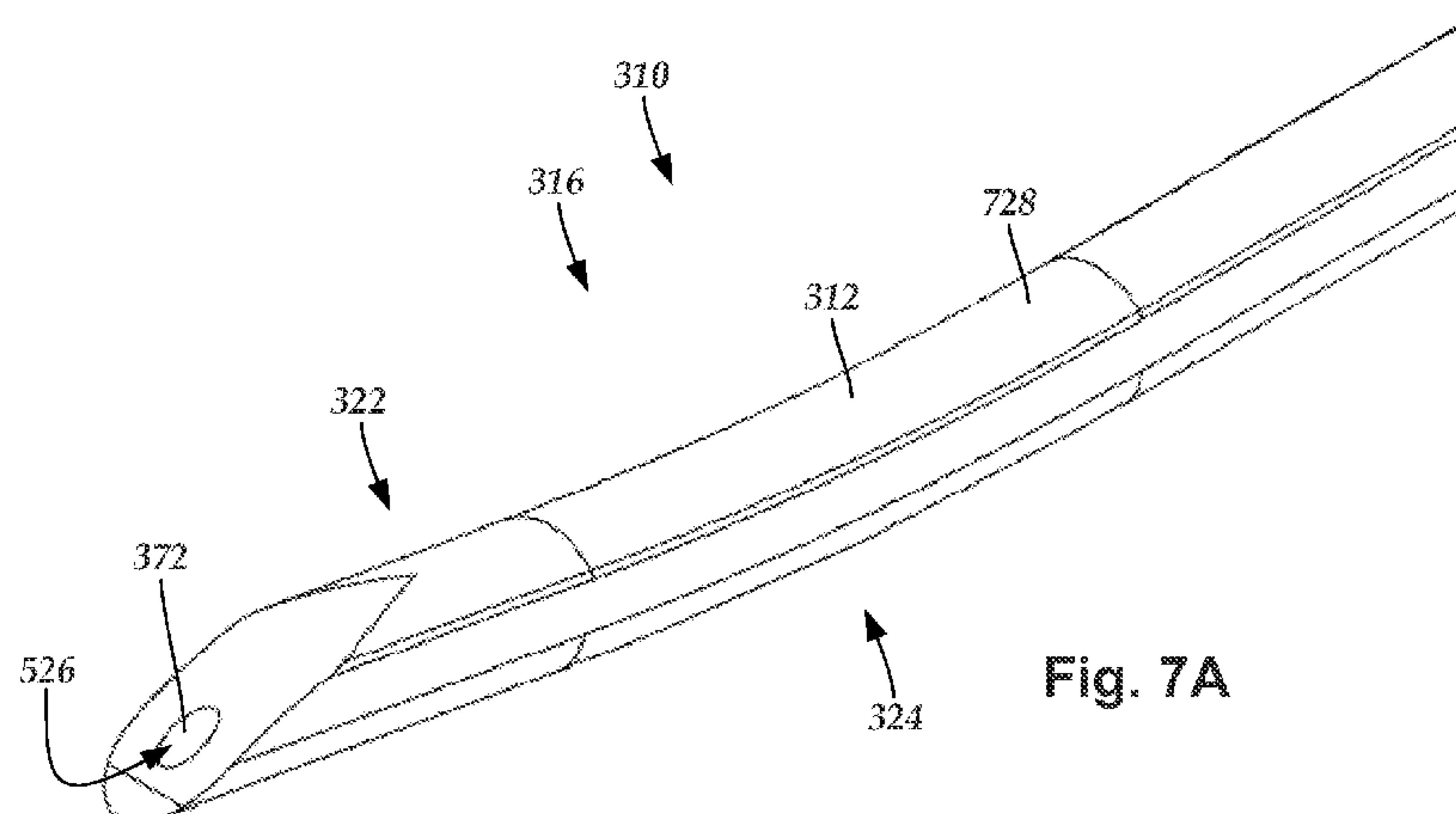


Fig. 7A

(57) Abstract: A lead introducer includes an outer needle with an outer-needle body. The outer needle body includes a bend of at least 5° permanently formed along a distal end portion outer-needle body. The bend facilitates insertion of the lead introducer into an epidural space of a patient. The outer-needle body defines an open channel extending along an entire length of the outer-needle body. An inner needle is slidable along the open channel of the outer needle. The inner needle includes an inner-needle body that defines a lumen extending along an entire length of the inner-needle body. A splittable member is disposable over the outer needle when the inner needle is disposed in the open channel of the outer needle. The splittable member is separable from the inner and outer needles along at least one perforated region.



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LEAD INTRODUCER FOR AN IMPLANTABLE ELECTRICAL STIMULATION SYSTEM

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. 61/874,730, filed September 6, 2013, 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 a lead introducer for facilitating insertion of implantable electrical stimulation leads having non-isodiametric lead bodies into patients, as well as methods of making and using the lead introducers and electrical stimulation leads.

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 chronic pain syndrome and incontinence, with a number of other applications under investigation. Functional electrical stimulation systems have
20 been applied to 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
25 with or near the nerves, muscles, or other tissue to be stimulated. The pulse generator in the control module generates electrical pulses that are delivered by the electrodes to body tissue.

BRIEF SUMMARY

30 In one embodiment, a lead introducer includes an outer needle with an outer-needle body. The outer-needle body has a proximal end portion, a distal end portion, and a longitudinal length. The outer-needle body includes a bend of at least 5° permanently

formed along the distal end portion of the outer-needle body. The bend is configured and arranged for facilitating insertion of the lead introducer into an epidural space of a patient. The outer-needle body defines an open channel extending along the entire longitudinal length of the outer-needle body. An inner needle is configured and arranged for sliding
5 along the open channel of the outer needle. The inner needle includes an inner-needle body. The inner-needle body has a proximal end portion, a distal end portion, and a longitudinal length. The inner-needle body defines a lumen extending along the entire longitudinal length of the inner-needle body. A splittable member has at least one perforated region extending along a longitudinal length of the splittable member. The
10 splittable member is configured and arranged for disposing over the outer-needle body and the inner-needle body when the inner-needle body is disposed in the open channel of the outer-needle body and for separating from the outer-needle body and the inner-needle body by separating along the at least one perforated region.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting and non-exhaustive embodiments of the present invention are 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
20 following Detailed Description, which is to be read in association with the accompanying drawings, wherein:

FIG. 1 is a schematic view of one embodiment of an electrical stimulation system, according to the invention;

FIG. 2A is a schematic view of one embodiment of a proximal portion of a lead
25 and a control module of an electrical stimulation system, according to the invention;

FIG. 2B is a schematic view of one embodiment of a proximal portion of a lead and a lead extension of an electrical stimulation system, according to the invention;

FIG. 3A is a schematic perspective exploded view of one embodiment of a lead introducer configured and arranged for facilitating implantation of a lead of an electrical
30 stimulation system into a patient, the lead introducer including a multi-piece insertion needle and a splittable member, according to the invention;

FIG. 3B is a schematic perspective exploded view of one embodiment of the lead introducer of FIG. 3A with an optional stylet and an optional Luer lock collar, according to the invention;

5 FIG. 4 is a schematic perspective view of one embodiment of the lead introducer of FIG. 3A with the multi-piece insertion needle of the lead introducer nested in the splittable member of the lead introducer and with the Luer lock collar of FIG. 3B locking together the multi-piece insertion needle and the splittable member, according to the invention;

10 FIG. 5 is a schematic perspective close-up view of one embodiment of a distal end portion of the lead introducer of FIG. 4, according to the invention;

FIG. 6A is a schematic perspective view of one embodiment of a distal end portion of a lead and a portion of an outer needle of the lead introducer of FIG. 3A, the outer needle defining an open channel extending along a length of the outer needle, the open channel suitable for receiving the lead, according to the invention;

15 FIG. 6B is a schematic perspective view of one embodiment of a distal end portion of the outer needle of FIG. 6A, according to the invention;

FIG. 6C is a schematic side view of one embodiment of a distal end portion of the outer needle of FIG. 6A, according to the invention;

20 FIG. 7A is a schematic perspective view of one embodiment of a distal end portion of an inner needle of the lead introducer of FIG. 3A, according to the invention;

FIG. 7B is a schematic perspective view of another embodiment of a distal end portion of an inner needle of the lead introducer of FIG. 3A, according to the invention;

FIG. 8 is a schematic perspective view of one embodiment of the lead introducer of FIG. 4 partially inserted into a patient, according to the invention;

25 FIG. 9 is a schematic perspective view of one embodiment of a Luer lock collar and an inner needle removed from the lead introducer of FIG. 8 and the lead of FIG. 6A aligned for insertion into an outer needle of the lead introducer, according to the invention;

FIG. 10 is a schematic perspective view of one embodiment of the outer needle removed from the lead introducer of FIG. 9 and a splittable member of the lead introducer of FIG. 9 being split apart to remove the splittable member from the lead of FIG. 9, according to the invention;

5 FIG. 11A is a schematic perspective view of one embodiment of the Luer lock collar of FIG. 3B disposed over a proximal hub of the inner needle of FIG. 11A, the Luer lock collar locking the multi-piece insertion needle and the splittable member of the lead introducer of FIG. 3A in place relative to each other, according to the invention;

10 FIG. 11B is a schematic perspective view of one embodiment of the Luer lock collar of FIG. 11A disposed over a proximal hub of the inner needle of FIG. 11A, the Luer lock collar shown partially cut away for clarity of illustration, according to the invention; and

15 FIG. 12 is a schematic overview of one embodiment of components of a stimulation system, including an electronic subassembly disposed within a control module, according to the invention.

DETAILED DESCRIPTION

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
20 directed to a lead introducer for facilitating insertion of implantable electrical stimulation leads having non-isodiametric lead bodies into patients, as well as methods of making and using the lead introducers and electrical stimulation leads.

Suitable implantable electrical stimulation systems include, but are not limited to, a least one lead with one or more electrodes disposed along a distal end of the lead and
25 one or more terminals disposed along the one or more proximal ends of the lead. Leads include, for example, percutaneous leads, paddle leads, and cuff leads. Examples of electrical stimulation systems with leads are found in, for example, U.S. Patents Nos. 6,181,969; 6,516,227; 6,609,029; 6,609,032; 6,741,892; 7,949,395; 7,244,150; 7,672,734; 7,761,165; 7,974,706; 8,175,710; 8,224,450; and 8,364,278; and U.S. Patent Application
30 Publication No. 2007/0150036, all of which are incorporated by reference.

Figure 1 illustrates schematically one embodiment of an electrical stimulation system 100. The electrical stimulation system includes a control module (*e.g.*, a stimulator or pulse generator) 102 and a lead 103 coupleable to the control module 102. The lead 103 includes one or more lead bodies 106, an array of electrodes 133, such as electrode 134, and an array of terminals (*e.g.*, 210 in Figure 2A-2B) disposed along the one or more lead bodies 106. In at least some embodiments, the lead is isodiametric along a longitudinal length of the lead body 106. In Figure 1, the electrical stimulation system 100 is shown having a junction 108 configured to couple to distal portion of the lead 103 to one or more proximal portions 109a and 109b.

The lead 103 can be coupled to the control module 102 in any suitable manner. In at least some embodiments, the lead 103 couples directly to the control module 102. In at least some other embodiments, the lead 103 couples to the control module 102 via one or more intermediate devices (200 in Figures 2A-2B). For example, in at least some embodiments one or more lead extensions 224 (*see e.g.*, Figure 2B) can be disposed between the lead 103 and the control module 102 to extend the distance between the lead 103 and the control module 102. Other intermediate devices may be used in addition to, or in lieu of, one or more lead extensions including, for example, a splitter, an adaptor, or the like or combinations thereof. It will be understood that, in the case where the electrical stimulation system 100 includes multiple elongated devices disposed between the lead 103 and the control module 102, the intermediate devices may be configured into any suitable arrangement.

The control module 102 typically includes a connector housing 112 and a sealed electronics housing 114. An electronic subassembly 110 and an optional power source 120 are disposed in the electronics housing 114. A control module connector 144 is disposed in the connector housing 112. The control module connector 144 is configured and arranged to make an electrical connection between the lead 103 and the electronic subassembly 110 of the control module 102.

The electrical stimulation system or components of the electrical stimulation system, including one or more of the lead bodies 106 and the control module 102, 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, brain stimulation, neural stimulation, spinal cord stimulation, muscle stimulation, 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, palladium rhodium, or titanium. The number of electrodes 134 in each array 133 may vary. For example, there can be two, four, six, eight, ten, twelve, fourteen, sixteen, or more electrodes 134. As will be recognized, other numbers of electrodes 134 may also be used.

The electrodes of the one or more lead bodies 106 are typically disposed in, or separated by, a non-conductive, biocompatible material such as, for example, silicone, polyurethane, polyetheretherketone (“PEEK”), epoxy, and the like or combinations thereof. The lead bodies 106 may be formed in the desired shape by any process including, for example, molding (including injection molding), casting, and the like. The non-conductive material typically extends from the distal end of the one or more lead bodies 106 to the proximal end of each of the one or more lead bodies 106.

Terminals (*e.g.*, 210 in Figures 2A-2B) are typically disposed along the proximal end of the one or more proximal portions of the electrical stimulation system 100 (as well as any splitters, lead extensions, adaptors, or the like) for electrical connection to corresponding connector contacts (*e.g.*, 214 in Figures 2A-2B; and 240 in Figure 2B). The connector contacts are disposed in connectors (*e.g.*, 144 in Figures 1-2B; and 222 in Figure 2B) which, in turn, are disposed on, for example, the control module 102 (or a lead extension, a splitter, an adaptor, or the like). Electrically conductive wires, cables, or the like (not shown) extend from the terminals to the electrodes 134. Typically, one or more electrodes 134 are electrically coupled to each terminal. In at least some embodiments, each terminal is only connected to one electrode 134.

The electrically conductive wires (“conductors”) may be embedded in the non-conductive material of the lead body 106 or can be disposed in one or more lumens (not shown) extending along the lead body 106. In some embodiments, there is an individual lumen for each conductor. In other embodiments, two or more conductors 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 body 106, for example, for inserting a stylet to facilitate placement of the lead body 106 within a body of a patient. Additionally, there may be one or more lumens (not shown) that open at, or near, the distal end of the lead body 106, for example, for infusion of drugs or medication into the site of implantation of the one or more lead bodies 106. In at least one embodiment, the one or more lumens are flushed continually, or on a regular basis, with saline, epidural fluid, or the like. In at least some embodiments, the one or more lumens are permanently or removably sealable at the distal end.

Figure 2A is a schematic side view of one embodiment of a proximal end of one or more elongated devices 200 configured and arranged for coupling to one embodiment of the control module connector 144. The one or more elongated devices may include, for example, the lead body 106, one or more intermediate devices (*e.g.*, a splitter, the lead extension 224 of Figure 2B, an adaptor, or the like or combinations thereof), or a combination thereof.

The control module connector 144 defines at least one port into which a proximal end of the elongated device 200 can be inserted, as shown by directional arrows 212a and 212b. In Figure 2A (and in other figures), the connector housing 112 is shown having two ports 204a and 204b. The connector housing 112 can define any suitable number of ports including, for example, one, two, three, four, five, six, seven, eight, or more ports.

The control module connector 144 also includes a plurality of connector contacts, such as connector contact 214, disposed within each port 204a and 204b. When the elongated device 200 is inserted into the ports 204a and 204b, the connector contacts 214 can be aligned with a plurality of terminals 210 disposed along the proximal end(s) of the elongated device(s) 200 to electrically couple the control module 102 to the electrodes (134 of Figure 1) disposed at a distal end of the lead 103. Examples of connectors in control modules are found in, for example, U.S. Patent No. 7,244,150 and 8,224,450, which are incorporated by reference.

Figure 2B is a schematic side view of another embodiment of the electrical stimulation system 100. The electrical stimulation system 100 includes a lead extension 224 that is configured and arranged to couple one or more elongated devices 200 (*e.g.*, the

lead body 106, a splitter, an adaptor, another lead extension, or the like or combinations thereof) to the control module 102. In Figure 2B, the lead extension 224 is shown coupled to a single port 204 defined in the control module connector 144. Additionally, the lead extension 224 is shown configured and arranged to couple to a single elongated
5 device 200. In alternate embodiments, the lead extension 224 is configured and arranged to couple to multiple ports 204 defined in the control module connector 144, or to receive multiple elongated devices 200, or both.

A lead extension connector 222 is disposed on the lead extension 224. In Figure 2B, the lead extension connector 222 is shown disposed at a distal end 226 of the lead
10 extension 224. The lead extension connector 222 includes a connector housing 228. The connector housing 228 defines at least one port 230 into which terminals 210 of the elongated device 200 can be inserted, as shown by directional arrow 238. The connector housing 228 also includes a plurality of connector contacts, such as connector contact
15 240. When the elongated device 200 is inserted into the port 230, the connector contacts 240 disposed in the connector housing 228 can be aligned with the terminals 210 of the elongated device 200 to electrically couple the lead extension 224 to the electrodes (134 of Figure 1) disposed along the lead (103 in Figure 1).

In at least some embodiments, the proximal end of the lead extension 224 is similarly configured and arranged as a proximal end of the lead 103 (or other elongated
20 device 200). The lead extension 224 may include a plurality of electrically conductive wires (not shown) that electrically couple the connector contacts 240 to a proximal end 248 of the lead extension 224 that is opposite to the distal end 226. In at least some embodiments, the conductive wires disposed in the lead extension 224 can be electrically coupled to a plurality of terminals (not shown) disposed along the proximal end 248 of
25 the lead extension 224. In at least some embodiments, the proximal end 248 of the lead extension 224 is configured and arranged for insertion into a connector disposed in another lead extension (or another intermediate device). In other embodiments (and as shown in Figure 2B), the proximal end 248 of the lead extension 224 is configured and arranged for insertion into the control module connector 144.

30 Turning to Figure 3A, some conventional percutaneous implantation techniques involve inserting a lead introducer, such as an epidural needle, into a patient. Once the

lead introducer is inserted into the patient, a lead is inserted into the lead introducer and the lead introducer is positioned at a target stimulation location. Once the lead is positioned at the target stimulation location, the lead introducer is removed from the patient, leaving the lead in place. Typically, the lead introducer is removed from the patient by sliding the lead introducer off the proximal end of the lead.

Unfortunately, when a lead has a body that is not isodiametric (such as the bifurcated lead shown in Figure 1), it may be difficult to slide the lead introducer off the proximal end of the lead. For example, when a proximal end of a lead body has a diameter that is larger than a distal end of the lead body, or when an oversized junction or adapter is disposed along the length of the lead body, the varying diameters along the length of the lead body may hinder, or even prevent, the lead introducer from sliding off the proximal end of the lead.

A lateral-release lead introducer ("lead introducer") uses a multi-piece insertion needle that enables a lead to be laterally separated from the multi-piece insertion needle. An example of a lateral-release lead introducer is found in, for example, U.S. Patent Application Publication No. 2011/0224680, which is incorporated by reference.

The lead introducer enables the lead to laterally separate from the multi-piece insertion needle without sliding the multi-piece insertion needle off the proximal end of the lead. In at least some embodiments, the lead laterally separates from the multi-piece insertion needle by passing the lead through an open channel defined along a length of the multi-piece insertion needle. In at least some embodiments, during implantation of the lead the multi-piece insertion needle is disposed in a splittable member that separates from the lead by splitting apart along a length of the splittable member.

As herein described, a lead introducer includes a multi-piece insertion needle with a rigid bend formed along a distal end portion of the multi-piece insertion needle. The bend is designed to improve insertion of the lead into an epidural space of a patient. The bend improves lead insertion by reducing the angle formed between the distal end portion of the multi-piece insertion needle and the patient's spinal cord, as compared to a straight insertion needle, during a lead-implantation procedure. Reducing the angle between the distal end portion of the multi-piece insertion needle and the patient's spinal cord may facilitate access of the lead introducer into the epidural space, thereby potentially

simplifying the lead-implantation procedure, reducing procedure time, and providing greater patient safety.

Figure 3A is a schematic perspective exploded view of one embodiment of a lead introducer 302 configured and arranged to facilitate implantation of an electrical stimulation system into a patient. The lead introducer 302 includes a multi-piece insertion needle 308 and a splittable member 350. The multi-piece insertion needle 308 includes an inner needle 310 that is insertable into an outer needle 330.

The inner needle 310 has a body 312 with a proximal end portion 314, a distal end portion 316, and a longitudinal length 318. The inner needle 310 includes a proximal hub 320 disposed along the proximal end portion 314 of the body 312 and a distal tip section 322 disposed along the distal end portion 316 of the body 312. In at least some embodiments, a bend 324 is formed along the distal end portion 314 proximal to the distal tip section 322. The optional bend 324 is discussed in more detail below, with reference to Figures 7A-7B. The inner needle 310 defines a lumen (526 in Figure 5) extending along the longitudinal length 318 of the inner needle 310. The lumen is described in more detail below, with reference to Figures 3B and 5.

The outer needle 330 has a body 332 with a proximal end portion 334, a distal end portion 336, and a longitudinal length 338. The outer needle 330 includes a proximal hub 340 disposed along the proximal end portion 334 of the body 332 and a distal tip section 342 disposed along the distal end portion 336 of the body 332. A bend 344 is formed along the distal end portion 334 of the body 332 proximal to the distal tip section 342. The bend 344 is described in more detail below, with reference to Figure 6B. The outer needle 330 defines an open channel (604 in Figures 6A-6B) extending along the longitudinal length 338 of the outer needle 330 and the proximal hub 340. The open channel is discussed in more detail below, with reference to Figures 6A-6B.

The splittable member 350 has a proximal end portion 354, a distal end portion 356, and a longitudinal length 358. A proximal hub 360 is disposed along the proximal end portion 354. A lumen (not shown) extends along the longitudinal length 356 of the splittable member 350 from the proximal hub 360.

The lead introducer 302 may additionally include one or more optional components. Figure 3B is a schematic perspective exploded view of another embodiment of the lead introducer 302 that further includes an optional stylet 370. The stylet 370 is insertable into the lumen (526 in Figure 5) of the inner needle 310. The stylet 370 has a
5 body 372 with a proximal end portion 374 and an opposing distal end portion 376. A proximal hub 380 is disposed along the proximal end portion 374 of the body 372. In at least some embodiments, a distal tip of the distal end portion 376 of the stylet 370 is blunt to prevent coring of patient tissue during insertion of the lead introducer 302 into a patient. In at least some embodiments, a distal tip of the distal end portion 376 of the
10 stylet 370 is slanted to conform to a beveled distal tip of the inner needle, the outer needle, or both.

In at least some other embodiments, the lead introducer 302 is suitable for use without the stylet 370. For example, in at least some embodiments the lumen (526 in Figure 5) of the inner needle 310 has a diameter that is small enough to prevent coring of
15 patient tissue without the use of the stylet 370. Tissue coring is typically undesirable. In addition to causing patient trauma, tissue plugged in the lumen of the inner needle may prevent a medical practitioner from being able to perform a loss-of-resistance technique to confirm epidural access.

The stylet 370 is formed from any suitable material including, for example, a
20 flexible plastic resin (*e.g.*, nylon, polyester, polyurethane, or the like), stainless steel, or the like. The stylet 370 is designed to be sufficiently rigid to be insertable through the lumen (526 in Figure 5) of the inner needle 310, yet sufficiently flexible to navigate across the bend in the inner needle 310 when the inner needle 310 is nested with the outer needle 330. In at least some embodiments, the stylet 370 is configured to engage with the
25 inner needle 310 to circumferentially align the distal tip of the stylet with the distal tip of the inner needle. For example, in at least some embodiments the proximal hub of either the stylet or the inner needle has a male feature that can be aligned with a female feature of the other of the stylet or inner needle by rotating either relative to the other. It may be advantageous to circumferentially align the stylet with the inner needle in order to align
30 the beveled distal tip of the stylet with the beveled distal tip of the inner needle.

Alternately or additionally, the lumen (526 in Figure 5) of the inner needle 310 can be used to check for precise positioning of the lead introducer 302 during, for example, a loss-of-resistance test. In at least some embodiments, the proximal hub 320 of the inner needle 310 is suitable for receiving a syringe. In at least some embodiments, fluid (*e.g.*, saline solution, air, or the like) may be introduced to, or removed from, the patient, via the lumen, to check for precise positioning of the lead introducer 302, for example, whether or not the epidural space has been entered.

Optionally, the lead introducer 302 includes a Luer lock collar 390 for locking together two or more of the proximal hubs 320, 340, and 360. The Luer lock collar 390 is described in more detail below, with reference to Figures 11A-11B.

Turning to Figure 4, in at least some embodiments the inner needle 310, the outer needle 330, and the splittable member 350 are coupleable to one another such that the inner needle 310, the outer needle 330, and the splittable member 350 form a nested arrangement. In at least some embodiments, the stylet 370 is insertable into the lumen (526 in Figure 5) of the inner needle 310 to form a nested arrangement along with the outer needle 330, and the splittable member 350.

Figure 4 is a schematic perspective view of one embodiment of the inner needle 310 disposed in the outer needle 330 which, in turn is disposed in the splittable member 350. As discussed in more detail below with reference to Figure 6A-6B, the inner needle 310 is disposed in the open channel of the outer needle. In at least some embodiments, the separation between the opposing edges of the open channel of the outer needle 330 is smaller than an outside diameter of the inner needle 310. In which case, the inner needle 310 does not separate laterally from the open channel of the outer needle 330, even when the outer needle 330 is not retained by the splittable member 350. Alternately, the inner needle 310 can be formed to separate from the outer needle 330 when not retained in the open channel of the outer needle 330 by the splittable member 350.

In Figure 4, the inner needle 310, the outer needle 330, and the splittable member 350 are shown nested such that the proximal hubs 320, 340, and 360 of the inner needle 310, the outer needle 330, and the splittable member 350, respectively, align axially to one another. In at least some embodiments the proximal hub 380 of the stylet 370 also aligns axially with the other hubs 320, 340, and 360 when nested with the other

components of the lead introducer 302. In at least some embodiments the proximal hub 380 of the stylet 370 aligns circumferentially with the inner needle 310, the outer needle 330, and the splittable member 350, when nested with the other components of the lead introducer 302.

5 In Figure 4, the Luer lock collar 390 is shown disposed over the proximal hub 340 of the outer needle 330 and portions of each of the proximal hub 320 of the inner needle 310 and the proximal hub 360 of the splittable member 350. In at least some embodiments, the Luer lock collar 390 is snap-fit onto the inner needle and is rotatable to tighten the Luer lock collar 390 onto lock tabs (or external screw threads) disposed on the
10 sheath hub 360.

Figure 5 is a schematic perspective close-up view of one embodiment of a distal end portion of the lead introducer 302. In at least some embodiments, the inner needle 310, the outer needle 330, and the splittable member 350 are coupleable to one another such that the distal end portions 316 and 336 of the inner needle 310 and the outer needle
15 330, respectively, extend distally beyond the distal end portion 356 of the splittable member 350.

In at least some embodiments, the stylet 370 is coupleable to the inner needle 310, the outer needle 330, and the splittable member 350 such that the distal end portion 376 of the stylet 370 also extends distally beyond the distal end portion 356 of the splittable
20 member 350. In Figure 5, the distal end portion of the stylet 370 is shown disposed in a lumen 526 defined along the longitudinal length 338 of the inner needle 310.

The distal tip sections 322 and 342 of the inner needle 310 and the outer needle 330, respectively, may have slanted faces with sharpened ends suitable for piercing patient tissue during insertion of the lead introducer 302 into the patient. In at least some
25 embodiments, the slanted faces of the distal tip sections 322 and 342 of the inner needle 310 and the outer needle 330, respectively, are ground down with the inner needle 310 nested with the outer needle 330 to form a matched set. In embodiments of the lead introducer that include the stylet, the stylet may also be ground down with the stylet nested within the inner needle 310 and the outer needle 330 to form a matched set.

Turning to Figures 6A-6B, the outer needle is designed to sequentially receive the inner needle and a lead during a lead-implantation procedure. The inner needle and the lead are received by an open channel extending along the longitudinal length of the outer needle.

5 Figure 6A illustrates, in perspective view, one embodiment of a distal end portion of a lead 602 and a portion of the outer needle 330. An open channel 604 is defined along the longitudinal length 338 of the outer needle 310. As shown in Figure 6A, the open channel 604 also extends along an entire length of the proximal hub 340 of the outer needle 330.

10 In some embodiments, the lead 602 has an isodiametric lead body. In other embodiments, the lead 602 has a non-isodiametric lead body. In at least some embodiments, the lead 602 includes one or more elements (*e.g.*, a junction, adaptor, or the like) disposed along the length of the lead 602 which has a transverse cross-sectional shape or size that is different from the distal end portion of the lead 602. In at least some
15 embodiments, the distal end portion of the lead 602 has a transverse cross-sectional shape that is similar to a cross-sectional shape of the inner needle 310. In at least some embodiments, the one or more elements of the lead 602 having a different transverse cross-sectional shape or size from the distal end portion of the lead 602 are disposed along a proximal end portion of the lead 602.

20 In at least some embodiments, the inner needle 310 is shaped such that the inner needle 310 does not separate laterally from the open channel 604 when the inner needle 310 is received by the outer needle 330. In alternate embodiments, the inner needle 310 is free to separate laterally from the open channel 604 of the outer needle 330 when the inner needle 310 is received by the outer needle 330. In at least some embodiments, the
25 inner needle 310 is insertable into, and removable from, the open channel 604 of the outer needle 330 solely by sliding the inner needle 310 axially along the open channel 604. In at least some embodiments, the inner needle 310 is configured and arranged to at least substantially fill the open channel 604 when the inner needle 310 is disposed in the open channel 604.

30 The open channel 604 is configured and arranged to receive the lead 602 when the inner needle 310 is not disposed in the open channel 604. In at least some embodiments,

the lead 602 is free to separate laterally from the open channel 604 of the outer needle 330 when the inner needle 310 is received by the outer needle 330. In at least some embodiments, the lead 602 is insertable into, and removable from, the open channel 604 of the outer needle 330 by sliding the lead 602 axially along the open channel 604.

5 In at least some embodiments, the open channel 604 is configured and arranged to receive the lead 602 such that the lead 602 is separatable from the open channel 604 without moving the lead 602 axially relative to the outer needle 330. In at least some embodiments, the open channel 604 has a width that is no less than a diameter of the lead 602.

10 In at least some embodiments, the lead 602 has a diameter that is larger than the space between the two opposing edges of the open channel 604 of the outer needle 330. In which case, the lead 602 typically does not pass laterally through the open channel 604 due solely to the force of gravity. The body of the lead 602 is typically formed from a deformable material. In at least some embodiments, the lead 602 is removable from the
15 open channel 604 by applying enough lateral force to at least one of the lead 602 or the outer needle 330 to deform the lead enough to enable the lead 602 to be passed laterally out through the open channel 604.

The open channel 604 can have any transverse cross-sectional shape suitable for sequentially retaining the inner needle 310 and the lead 602. In at least some
20 embodiments, the open channel 604 has a transverse cross-sectional shape that is U-shaped 710. Alternately, the open channel 604 can have a transverse cross-section that is horseshoe-shaped, C-shaped, or the like.

Figure 6B illustrates, in perspective view, one embodiment of the distal end portion 336 of the outer needle 330. Figure 6C illustrates, in side view, one embodiment
25 of the distal end portion 336 of the outer needle 330. The bend 344 is formed along the distal end portion 336 of the outer needle 330. In at least some embodiments, the bend 344 is formed with the open channel 604 extending along the concave portion of the bend 344.

In at least some embodiments, the bend 344 has an angle 606 that is at least 5°,
30 10°, 15°, or 20°. In at least some embodiments, the bend 344 has an angle 606 that is no

greater than 20°, 15°, or 10°. In at least some embodiments, the bend 344 has an angle 606 that is at least 5° and no greater than 20°. In at least some embodiments, the bend 344 has an angle 606 that is at least 10° and no greater than 15°.

In at least some embodiments, the outer needle 330 is rigid. In at least some
 5 embodiments, the outer needle 330 is designed so that the bend 344 maintains a particular shape throughout a lead-implantation procedure. The outer needle 330 can have any suitable bend radius 608 (*i.e.*, the minimum radius that the outer needle 330 can be bent without kinking). In at least some embodiments, the outer needle 330 has a bend radius 608 of at least 0.25 inches (0.6 cm), 0.5 inches (1.3 cm), 0.75 inches (1.9 cm), 1 inch (2.5
 10 cm), 1.25 inches (3.2 cm), 1.5 inches (3.8 cm), or 1.75 inches (4.4 cm). In at least some embodiments, the outer needle 330 has a bend radius 608 that is no greater than 2 inches (5.1 cm), 1.75 inches (4.4 cm), 1.5 inches (3.8 cm), 1.25 inches (3.2 cm), 1 inch (2.5 cm), 0.75 inches (1.9 cm), or 0.5 inches (1.3 cm). In at least some embodiments, the outer needle 330 has a bend radius 608 that is at least 0.25 inches (0.6 cm) and no greater than
 15 2 inches (5.1 cm).

The outer needle 330 is formed from a rigid material suitable for patient insertion, such as stainless steel. In at least some embodiments, the body 332 of the outer needle 330 is straight (or substantially straight) except for along the bend 344. The outer needle 330 can be formed in any suitable manner including, for example, shape
 20 extrusion/drawing, fabricating from a hypodermic needle tubing and forming the open channel via electrical discharge machining (*e.g.*, wire or sinker), slot milling, or the like. The body 332 of the outer needle 330 can be attached to the proximal hub 340 in any suitable manner including, for example, laser welding. In at least some embodiments, the lateral circumference of the outer needle 330 is no greater than sixteen-gauge, fifteen-
 25 gauge, fourteen-gauge, thirteen-gauge, twelve-gauge, eleven-gauge, ten-gauge, nine-gauge, or eight-gauge.

Figure 7A illustrates, in perspective view, one embodiment of the distal end portion 316 of the inner needle 310. The inner needle 310 is formed from a material that is sufficiently flexible to be insertable across the bend 344 of the outer needle 330 when
 30 the inner needle 310 is extended along the open channel 604 of the outer needle 330. The inner needle 310 is also sufficiently flexible to be removed from the open channel 604

when the outer needle 330 is received by the splittable member 350. The inner needle 310 is also rigid enough to be insertable through the open channel 604 of the outer needle 330, either with or without the aid of the stylet 370 inserted into the lumen 526 of the inner needle 310.

5 The inner needle 310 is formed from any suitable material including, for example, a flexible plastic resin (*e.g.*, nylon, polyester, polyurethane, or the like), or the like. Alternately, the inner needle 310 can be formed from stainless steel. In at least some embodiments, the inner needle 310 is formed from the same material as the outer needle 330. In at least some embodiments, the inner needle 310 is formed from a material that is
10 more flexible than the outer needle 330. In at least some embodiments, the outer needle 330 is formed from a material that is more rigid than the splittable member 350. In at least some embodiments, the outer needle 330 is formed from a material that is rigid enough to enable the outer needle 330 to be used to guide (*e.g.*, enable lateral steering) the splittable member 350 within a patient when the outer needle 330 is disposed in the
15 splittable member 350.

 The inner needle 310 can be formed in any suitable manner including, for example, extruding. The body 312 of the inner needle 310 can be attached to the proximal hub 320 in any suitable manner including, for example, adhesive bonding, crimping, or insertion molding to a plastic or metal Luer inner needle hub. In at least
20 some embodiments, the lateral circumference of the inner needle 310 is no greater than seventeen-gauge, sixteen-gauge, fifteen-gauge, fourteen-gauge, or thirteen-gauge.

 In some embodiments, the inner needle 310 includes the bend 324, formed during manufacture, along the distal end portion 316 of the inner needle 310. In other embodiments, the inner needle 310 does not include the preformed bend 324, yet is
25 sufficiently flexible to bend along the bend 344 of the outer needle when inserted into the open channel 604 of the outer needle 330.

 The inner needle 310 can have any transverse cross-sectional shape suitable for extending along the open channel 604 of the outer needle 330. In at least some embodiments, the inner needle 310 has a transverse cross-sectional shape that is oval,
30 oblong, round, or the like.

In at least some embodiments, the body 312 of the inner needle 310 is shaped and sized to slide freely within the open channel 604 of the outer needle 330 with the inner needle 310 only when in a particular circumferential orientation relative to the outer needle 330. In at least some embodiments, a single key rib 728 is disposed along the
5 body 312 of the inner needle 310. In at least some embodiments, the single key rib 728 extends along the entire longitudinal length 318 of the body 312 of the inner needle 310. Alternately, the single key rib 728 extends along less than the entire longitudinal length 318 of the body 312 of the inner needle 310.

The key rib 728 engages the open channel 604 of the outer needle 330 to facilitate
10 sliding of the inner needle 310 relative to the open channel 604. The key rib 728 extends along a particular circumferential portion of the inner needle 310 such that, in at least some embodiments, when the inner needle 310 is extended along the open channel 604, the key rib 728 is disposed directly between opposing edges of the open channel 604 (*i.e.*, the key rib 728 is circumferentially opposed to a trough portion of a transverse cross-
15 section of the open channel 604).

In at least some embodiments, the inner needle includes an axial region of increased flexibility from other axial regions of the inner needle. Figure 7B illustrates, in perspective view, another embodiment of the distal end portion 316 of the inner needle 310. The distal end portion 316 includes a region with increased flexibility 702 relative
20 to adjacent regions of the inner needle 310.

It may be advantageous to position the region of increased flexibility 702 at a location such that the region of increased flexibility 702 is axially-aligned with the bend 344 of the outer needle 330 when the inner needle 310 is received by the outer needle 330. It may also be advantageous to form the region of increased flexibility 702 along the
25 inner needle 310 when the inner needle 310 is formed from a material with a rigidity that may otherwise hinder, or even preclude, the inner needle 310 from bending along the bend 344 when inserted into the open channel 604 of the outer needle 330 under normal operating conditions. Such a rigid material may include, for example, stainless steel.

In Figure 7B, the region of increased flexibility 702 is formed as one or more
30 circumferential grooves 729 defined along an outer surface of at least a portion of the distal tip section 322 of the inner needle 310. In at least some embodiments, at least one

of the circumferential grooves 729 extends more than one revolution around the body 312 of the inner needle 310. In at least some embodiments, at least one of the circumferential grooves 729 extends less than one revolution around the body 312 of the inner needle 310. In at least some embodiments, the one or more circumferential grooves 720 extend
5 the entire longitudinal length of the inner needle 310, either in a stable pitch or in a variable pitch. Alternately or additionally, in at least some embodiments the region of increased flexibility 702 is formed as one or more coiled springs.

In at least some embodiments, a watertight liner lines walls of the lumen 526. The watertight liner can be used to prevent fluid leakage when fluid (*e.g.*, saline solution, air,
10 or the like) is introduced to, or removed from, the patient, via the lumen 526, to check for precise positioning of the lead introducer 302 during a lead-implantation procedure. It may be advantageous to use the watertight liner in embodiments that include the one or more circumferential grooves (or coiled spring) 729 which may otherwise enable fluid to readily pass through walls of the inner needle 310.

15 In at least some embodiments, the key rib 728 extends along less than the entire longitudinal length 318 of the body 312 of the inner needle 310. In at least some embodiments, the key rib 728 is disposed along the distal tip section 322 of the inner needle 310. In at least some embodiments, multiple key ribs 728 are disposed along the inner needle 310. The multiple key ribs 728 may be axially-spaced-apart from one
20 another along the longitudinal length 318 of the body 312 of the inner needle 310. The multiple key ribs 728 may be circumferentially aligned with one another along the body 312 of the inner needle 310. In at least some embodiments, at least one of the multiple key ribs is disposed along the proximal end portion 314 of the body 312 of the inner needle 310.

25 Turning to Figure 8, one embodiment of a lead-implantation procedure is described using the lead introducer 302 to implant the lead 602 at a target stimulation location. The inner needle 310 is inserted into the open channel 604 of the outer needle 330, and the outer needle 330 is inserted into the splittable member 350, as shown in Figure 4 and Figure 5. In at least some embodiments, the stylet 370 is inserted into the
30 lumen of the inner needle 310. It will be understood that, in some embodiments, the lead introducer 302 is pre-assembled during manufacture.

The assembled lead introducer 302 is inserted into a patient and guided in proximity to the target stimulation location (*e.g.*, several vertebrae levels above or below the target stimulation location). In at least some embodiments, once the lead introducer 302 is in proximity to a target stimulation location fluid is introduced or removed through
5 inner needle 310 to check for precise positioning of the lead introducer 302, for example, in an epidural space of the patient. In at least some embodiments, the stylet 370 is removed prior to introducing fluid into the patient via the lumen 526 of the inner needle 310.

Figure 8 is a schematic perspective view of one embodiment of the inner needle
10 310 inserted into the open channel 604 of the outer needle 330 which, in turn, is inserted into the splittable member 350. In Figure 8, the inner needle 310, the outer needle 330, and the splittable member 350 are partially disposed in a patient, as shown by a dotted line 802. The distal end portions of the inner needle 310, the outer needle 330, and the splittable member 350 are advanced to a location in proximity to the target stimulation
15 location.

Turning to Figure 9, once the lead introducer 302 is positioned in the epidural space in proximity to the target stimulation location, the inner needle 310 may be removed and the distal end portion of the lead 602 may be inserted into the open channel 604 of the outer needle 330 and the proximal opening of the sheath 350. Figure 9 is a
20 schematic perspective view of one embodiment of the distal end portion of the lead 602 inserted into the open channel 604 of the outer needle 330 via the proximal hub 320. Once the distal end portion of the lead 602 is inserted into the open channel 604 of the outer needle 330, the distal end portion of the lead 602 may be guided more closely to the target stimulation region. In at least some embodiments, the distal end portion of the lead
25 602 is guided to the target stimulation region by the comparably-rigid outer needle 330.

It may be advantageous to guide the lead 602 within the patient while the lead 602 is disposed in the outer needle 330 and the splittable member 350. The outer needle 330 and the splittable member 350 may provide the medical practitioner with the ability to steer the lead introducer 302 by applying a lateral force of the lead introducer 302 to
30 direct the trajectory of the lead 602. When the outer needle 330 is removed from the lead 602 prior to insertion, then the splittable member 350 may be too flexible to provide this

steering ability. The outer needle 330 can also steer the lead 602 by circumferentially rotating the outer needle 330 and the sheath 350, thereby adjusting the orientation of the distal bend 344 of the outer needle 330 within the epidural space. Such rotation directs the lead 602 towards the right or the left as the lead 602 exits the outer needle/ sheath
5 distal opening.

Once the distal end portion of the lead 602 has been guided to the target stimulation location, the splittable member 350 and the outer needle 330 may be separated from the lead 602 and removed from the patient. It will be understood that the splittable member 350 may be separated from the lead 602 either before or after the outer
10 needle 330 is separated from the lead 602. It will also be understood that the splittable member 350 may be removed from the patient either before or after the outer needle 330 is removed from the patient. In some embodiments, the outer needle 330 is separated from the lead 602 prior to the splittable member 350 being separated from the lead 602. In other embodiments, the splittable member 350 is separated from the lead 602 prior to
15 the outer needle 330 being separated from the lead 602. In some embodiments, the outer needle 330 is removed from the patient prior to removal of the splittable member 350. In other embodiments, the splittable member 350 is removed from the patient prior to removal of the outer needle 330.

In at least some embodiments, the lead 602 is guided to the target stimulation
20 location while disposed in the outer needle 330 and the splittable member 350. The outer needle 330 is removed from the lead 602 (and from the patient). The splittable member 350 is then split apart from the lead 602 and removed from the patient.

Figure 10 is a schematic perspective view of one embodiment of the splittable member 350 being split apart to remove the splittable member 350 from the lead 602. The
25 proximal hub 360 of the splittable member 350 includes at least two pull-apart tabs 1002 and 1004 suitable for facilitating splitting of the splittable member 350.

In at least some embodiments, the splittable member 350 is formed from a flexible material suitable for implantation into the patient 802 including, for example, fluorinated ethylene propylene, polytetrafluoroethylene, high-density polyethylene,
30 polyetheretherketone, and the like or combinations thereof. Additionally, one or more radiopaque materials may be added including, for example, barium sulfate and bismuth

subcarbonate, and the like or combinations thereof to facilitate implantation of the introducer sheath through the use of one or more medical imaging techniques, such as fluoroscopy.

In at least some embodiments, the splitable member includes one or more perforated (or scored, or the like) regions 1006 extending along at least a portion of the longitudinal length 358 of the splitable member 350 from between the at least two pull-apart tabs 1002 and 1004. In at least some embodiments, when the at least two pull-apart tabs 1002 and 1004 are separated from one another, for example, by pulling each pull-apart tab laterally (*i.e.*, away from the other pull-apart tab(s) in directions approximately orthogonal to the splitable member 350), the splitable member 350 separates along the one or more perforated regions 1006.

In at least some embodiments, the splitable member 350 is separated into multiple longitudinal strips while pulling the splitable member 350 proximally along the lead 602. As the splitable member 350 splits apart, the distal end portion 356 of the splitable member 350 (not shown in Figure 10) moves proximally along the lead 602 (as shown by arrow 1008), with an increasing amount of the lead 602 extending through the distal end portion 356 of the splitable member 350. In at least some embodiments, an undersurface of the splitable member 350 includes a lubricious coating to facilitate the proximal movement of the splitable member 350.

Eventually, the splitable member 350 may be completely separated into two or more longitudinal strips, thereby separating completely from the lead 602 and also from the patient. In at least some embodiments, the distal end portions of the splitable member 350 are extracted from the patient as the splitable member 350 is split apart. In at least some embodiments, the splitable member 350 is split apart without causing the lead 602 to move.

Once the lead 602 is positioned at the target stimulation location, the lead 602 may be coupled to a control module (*e.g.*, 102 of Figure 1) and implanted using well-known techniques, for example, using one or more tunneling straws placed in passageways underneath patient skin with bores that are sized large enough to receive the lead 602. In at least some embodiments, the lead 602 is coupled directly to a connector of a control module, as shown in Figure 3. In other embodiments, the lead 602 is coupled to

the control module via one or more other devices, including an adaptor, a lead extension, an operating room cable, or the like or combinations thereof.

In at least some embodiments, a Luer lock collar may be disposed on the proximal hub 320 of the inner needle 310 to lock the inner needle 310, the outer needle 330, and the splittable member 350 all together such that the multi-piece insertion needle 308 and the splittable member 350 do not undesirably rotate relative to each other. Figure 11A is a schematic perspective view of one embodiment of a Luer lock collar 390 disposed over the proximal hub 320 of the inner needle 310. The Luer lock collar 390 is configured and arranged to lock the multi-piece insertion needle 308 and the splittable member 350 all together during insertion of the lead introducer 302 into the patient. Figure 11B is a schematic perspective view of one embodiment of a Luer lock collar 390 disposed over the proximal hub 320 of the inner needle 310. In Figure 11B, the Luer lock collar 390 is shown partially cut away for clarity of illustration.

In Figures 11A-11B, a Luer fitting 1104 is shown coupled to the proximal hub 320 of the inner needle 310. The Luer fitting 1104 is suitable for receiving a syringe. In at least some embodiments, fluid (*e.g.*, saline solution, air, or the like) may be introduced or removed through the Luer fitting 1104 to check for precise positioning of the lead introducer 302, for example, checking whether or not the epidural space has been entered.

Figure 12 is a schematic overview of one embodiment of components of an electrical stimulation system 1200 including an electronic subassembly 1210 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, a power source 1212, an antenna 1218, a receiver 1202, and a processor 1204) 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 1212 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.

5 As another alternative, power can be supplied by an external power source through inductive coupling via the optional antenna 1218 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.

10 If the power source 1212 is a rechargeable battery, the battery may be recharged using the optional antenna 1218, if desired. Power can be provided to the battery for recharging by inductively coupling the battery through the antenna to a recharging unit 1216 external to the user. Examples of such arrangements can be found in the references identified above.

15 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. The processor 1204 is generally included to control the timing and electrical characteristics of the electrical stimulation system. For example, the processor 1204 can, if desired, control one or more of the timing, frequency, strength, duration, and waveform of the pulses. In addition, the processor 1204 can select which electrodes can be used to provide stimulation, if desired. In some embodiments, the
20 processor 1204 selects which electrode(s) are cathodes and which electrode(s) are anodes. In some embodiments, the processor 1204 is 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
25 receiving and interpreting instructions from an external programming unit 1208 that, for example, allows modification of pulse characteristics. In the illustrated embodiment, the processor 1204 is coupled to a receiver 1202 which, in turn, is coupled to the optional antenna 1218. This allows the processor 1204 to receive instructions from an external source to, for example, direct the pulse characteristics and the selection of electrodes, if
30 desired.

In one embodiment, the antenna 1218 is capable of receiving signals (*e.g.*, RF signals) from an external telemetry unit 1206 which is programmed by the programming unit 1208. The programming unit 1208 can be external to, or part of, the telemetry unit 1206. The telemetry unit 1206 can be a device that is worn on the skin of the user or can
5 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 1206 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 1208 can be any unit that can provide information to the telemetry unit 1206 for transmission to the electrical stimulation system 1200. The programming
10 unit 1208 can be part of the telemetry unit 1206 or can provide signals or information to the telemetry unit 1206 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 1206.

The signals sent to the processor 1204 via the antenna 1218 and the receiver 1202
15 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 1200 to cease operation, to start operation, to start charging the battery, or to stop
20 charging the battery. In other embodiments, the stimulation system does not include the antenna 1218 or receiver 1202 and the processor 1204 operates as programmed.

Optionally, the electrical stimulation system 1200 may include a transmitter (not shown) coupled to the processor 1204 and the antenna 1218 for transmitting signals back to the telemetry unit 1206 or another unit capable of receiving the signals. For example,
25 the electrical stimulation system 1200 may transmit signals indicating whether the electrical stimulation system 1200 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 1204 may also be capable of transmitting information about the pulse characteristics so that a user or clinician can determine or verify the characteristics.

30 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.

CLAIMS

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

1. A lead introducer comprising:
an outer needle comprising an outer-needle body having a proximal end portion, a distal end portion, and a longitudinal length, the outer-needle body comprising a bend of at least 5° permanently formed along the distal end portion of the outer-needle body, the bend configured and arranged for facilitating insertion of the lead introducer into an epidural space of a patient, the outer-needle body defining an open channel extending along the entire longitudinal length of the outer-needle body, and
an inner needle configured and arranged for sliding along the open channel of the outer needle, the inner needle comprising an inner-needle body having a proximal end portion, a distal end portion, and a longitudinal length, the inner-needle body defining a lumen extending along the entire longitudinal length of the inner-needle body; and
a splittable member having at least one perforated region extending along a longitudinal length of the splittable member, the splittable member configured and arranged for disposing over the outer-needle body and the inner-needle body when the inner-needle body is disposed in the open channel of the outer-needle body and for separating from the outer-needle body and the inner-needle body by separating along the at least one perforated region.
2. The lead introducer of claim 1, wherein the open channel of the outer needle extends along a concave side of the bend of the outer needle.
3. The lead introducer of claim 1, wherein the bend of the outer needle is no greater than 20 degrees.
4. The lead introducer of claim 1, wherein the outer-needle body has a bend radius that is no greater than 5 cm.

5. The lead introducer of claim 1, wherein the outer-needle body has a bend radius of at least 1 cm.
6. The lead introducer of claim 1, further comprising at least one key rib disposed along the inner needle, the at least one key rib configured and arranged for orienting the inner needle circumferentially relative to the open channel of the outer needle.
7. The lead introducer of claim 6, wherein the key rib extends along the entire longitudinal length of the inner needle.
8. The lead introducer of claim 1, further comprising a watertight liner extending along longitudinal surfaces of the lumen of the inner needle.
9. The lead introducer of claim 1, wherein the inner-needle body comprises a first region having increased flexibility relative to adjacent portions of the inner-needle body, the first region disposed along the distal end portion of the inner-needle body.
10. The lead introducer of claim 9, wherein the first region comprises at least one circumferential groove defined along an outer surface of the distal end portion of the inner-needle body.
11. The lead introducer of claim 9, wherein the first region comprises a coiled spring disposed along the distal end portion of the inner-needle body.
12. The lead introducer of claim 1, further comprising a stylet configured and arranged for insertion into the lumen of the inner needle.
13. An insertion kit comprising:
the lead introducer of claim 1;

a neurostimulation lead configured and arranged for implantation into a patient, the neurostimulation lead comprising

- a lead body having a distal end portion and a proximal end portion,
- a plurality of electrodes disposed at the distal end portion of the lead body,
- a plurality of terminals disposed at the proximal end portion of the lead body, and

- a plurality of conductive wires coupling the plurality of electrodes electrically to the plurality of terminals; and

wherein the open channel of the outer needle is configured and arranged such that, when the inner needle of the lead introducer is not inserted in the open channel, the distal end portion of the lead body is insertable into the open channel with the lead body being laterally separatable from the outer needle of the lead introducer through the open channel of the outer needle.

14. The insertion kit of claim 13, wherein the lead body is laterally separatable from the outer needle through the open channel without moving the lead body axially along the longitudinal length of the outer needle during separation.

15. The insertion kit of claim 13, wherein the neurostimulation lead further comprises one or more elements disposed along a length of the lead body that has a transverse cross-sectional shape or size that is different from the transverse cross-sectional shape or size of the lead body.

16. An electrical stimulation system comprising:
the insertion kit of claim 13;
a control module configured and arranged to electrically couple to the neurostimulation lead of the insertion kit, the control module comprising
a housing, and
an electronic subassembly disposed in the housing; and
a connector for receiving the neurostimulation lead, the connector comprising

a connector housing defining a port for receiving the proximal end portion of the lead body, and

a plurality of connector contacts disposed in the connector housing, the connector contacts configured and arranged to couple to the plurality of terminals of the neurostimulation lead when the proximal end portion of the neurostimulation lead is received by the connector housing.

17. A method for implanting a neurostimulation lead into a patient, the method comprising:

advancing the lead introducer of claim 1 into the patient;

removing the inner needle of the lead introducer from the patient, leaving the outer needle and splittable member of the lead introducer within the patient;

inserting into the open channel of the outer needle a distal end portion of a neurostimulation lead, the neurostimulation lead comprising a plurality of electrodes disposed along the distal end portion of the neurostimulation lead and a plurality of terminals disposed along a proximal end portion of the neurostimulation lead;

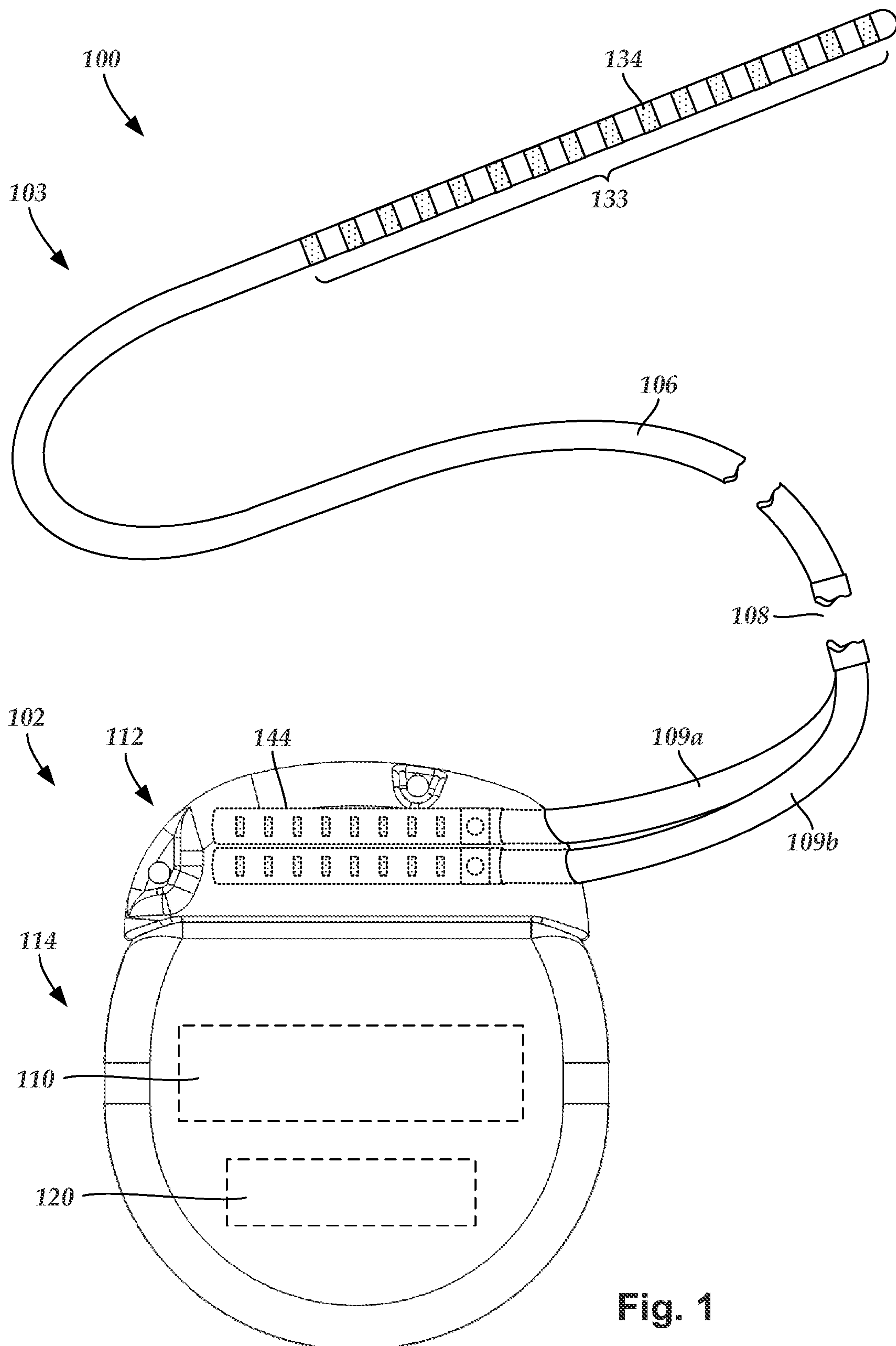
separating the splittable member into at least two parts along the length of the lumen of the splittable member;

removing the outer needle and the splittable member from the patient, leaving the neurostimulation lead implanted in the patient at the target stimulation location.

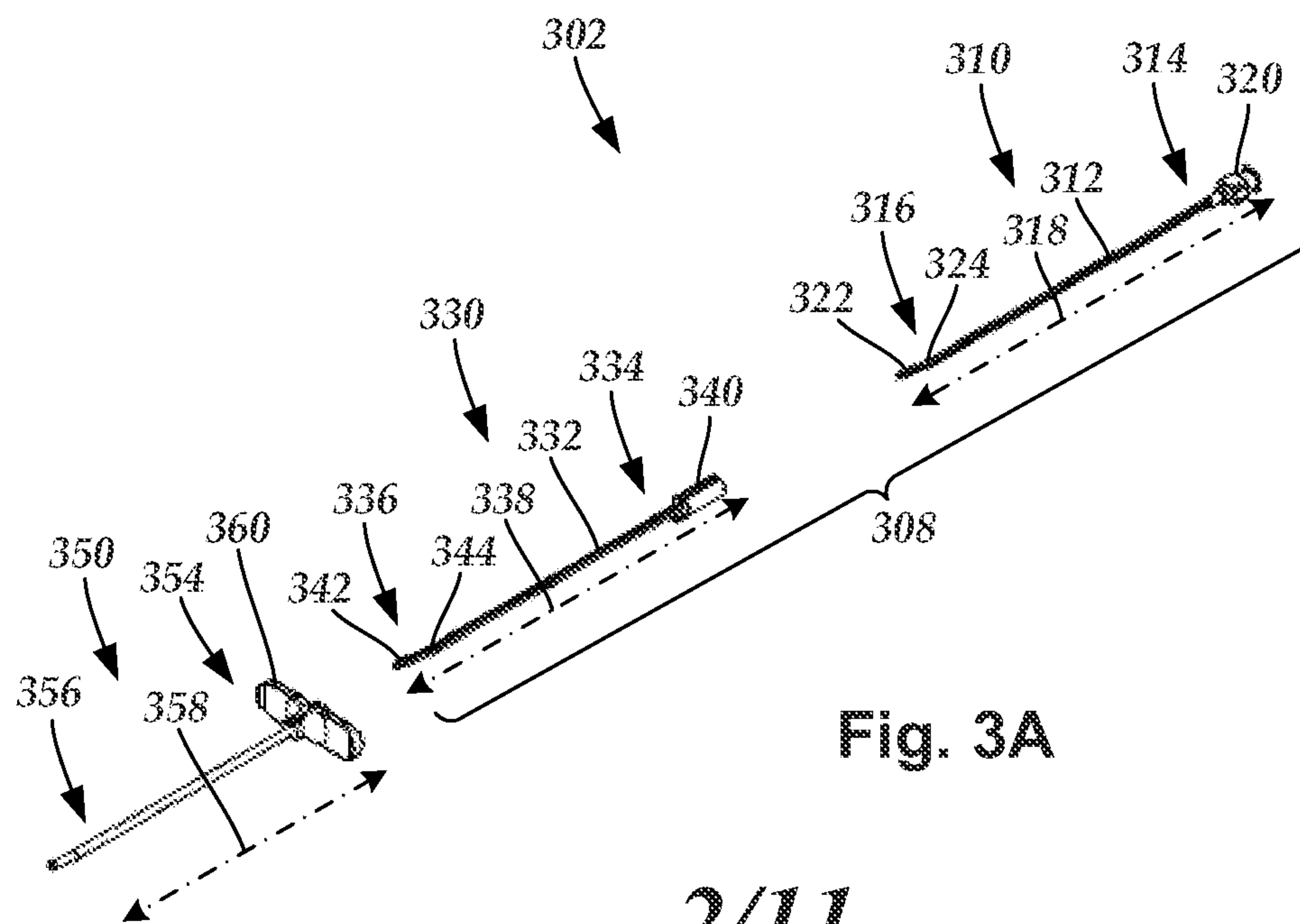
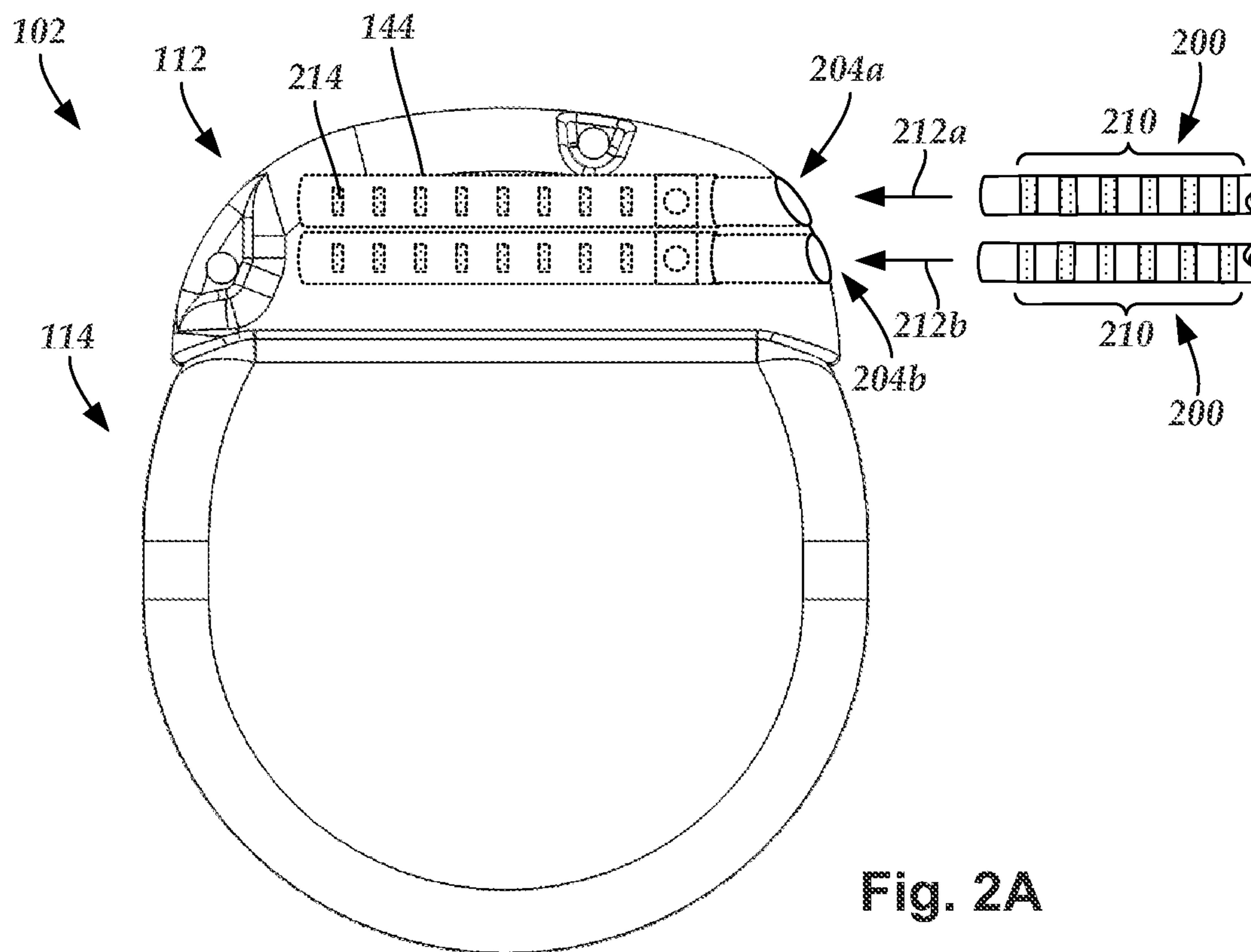
18. The method of claim 17, wherein removing the outer needle and the splittable member from the patient comprises removing the outer needle from the patient prior to removing the splittable member from the patient.

19. The method of claim 17, wherein removing the outer needle and the splittable member from the patient comprises removing the outer needle from the patient prior to separating the splittable member into at least two parts along the length of the lumen of the splittable member.

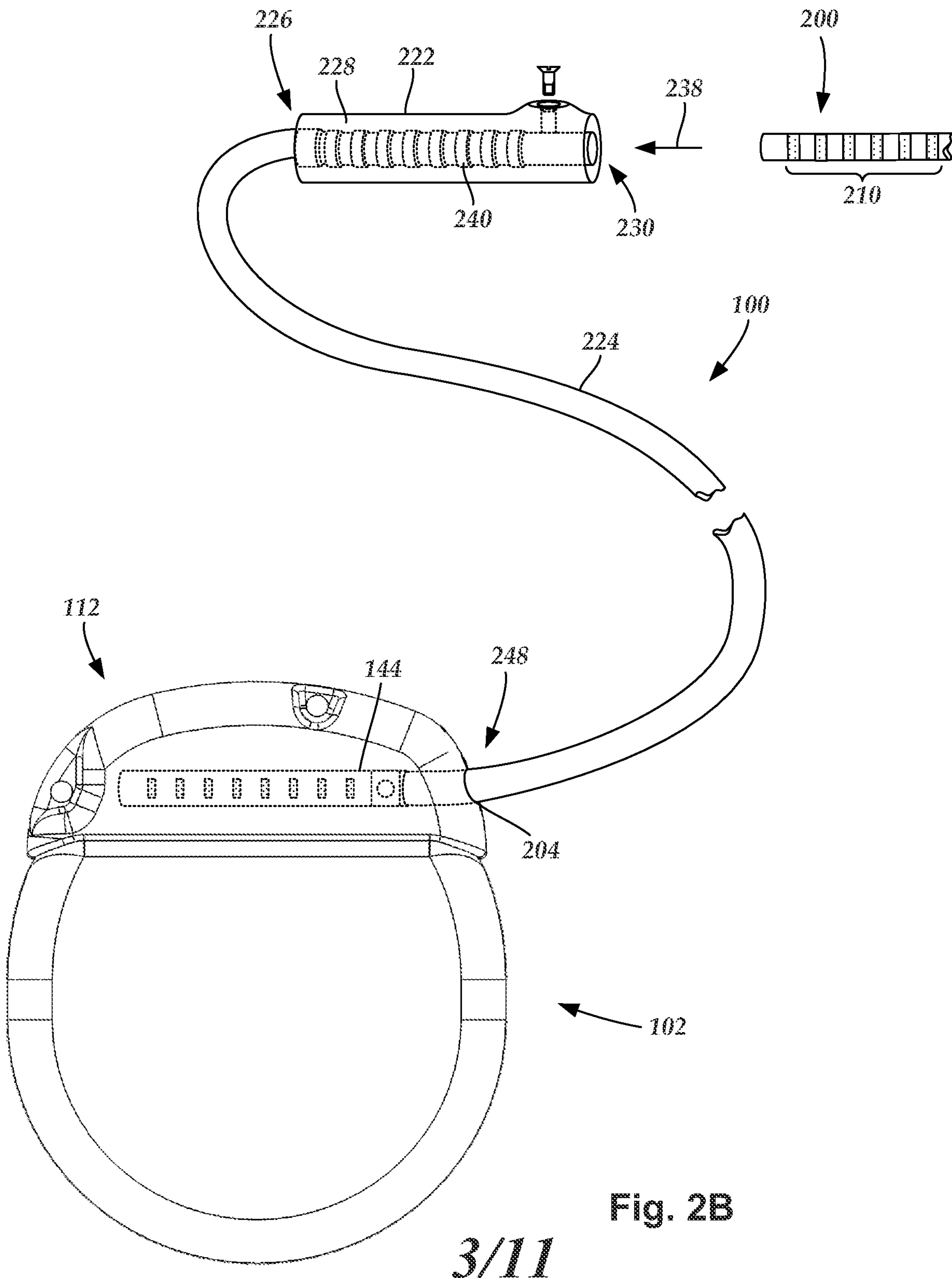
20. The method of claim 17, further comprising disposing a stylet into the inner needle of the lead introducer prior to advancing the lead introducer into the patient.



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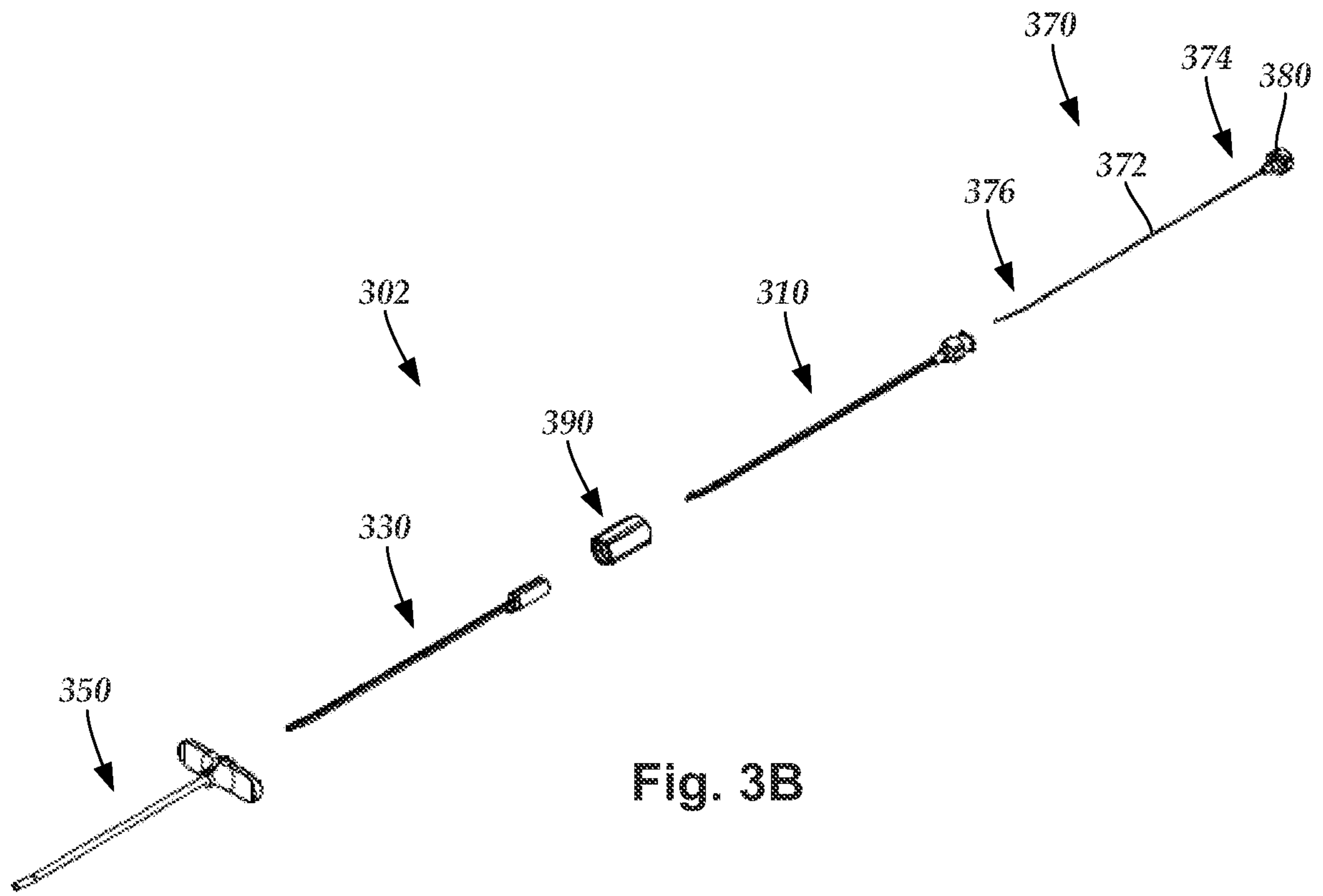


Fig. 3B

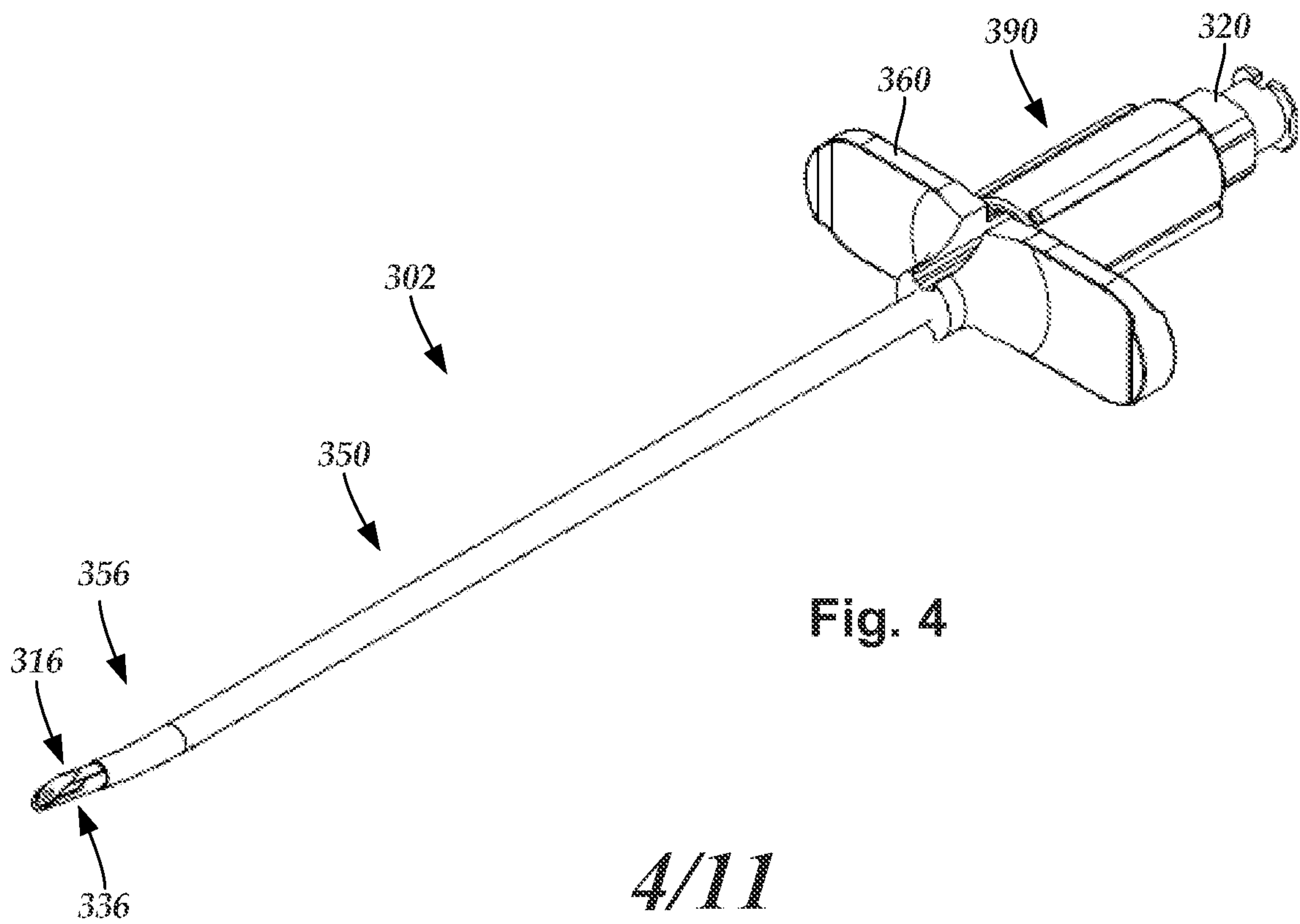
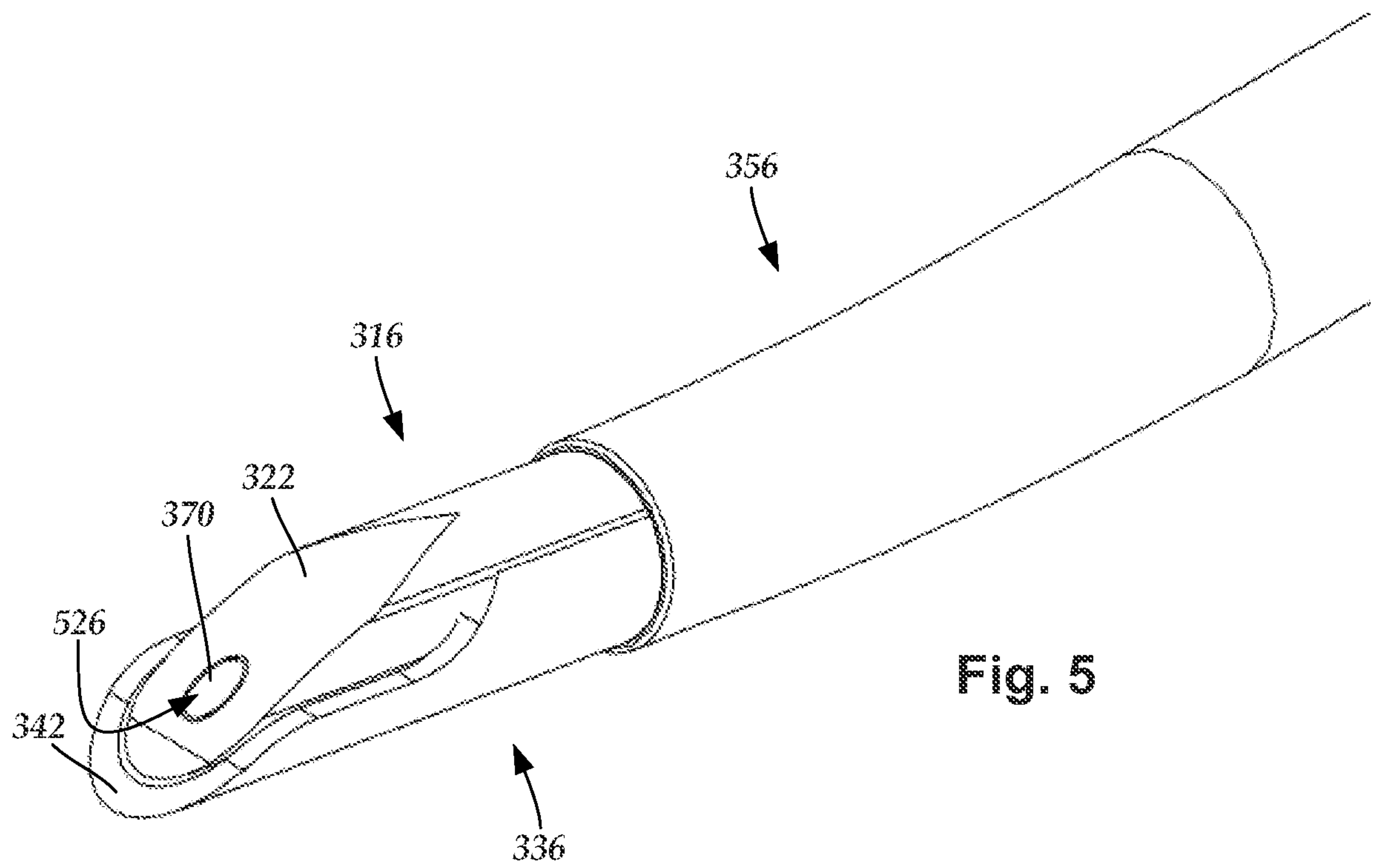


Fig. 4

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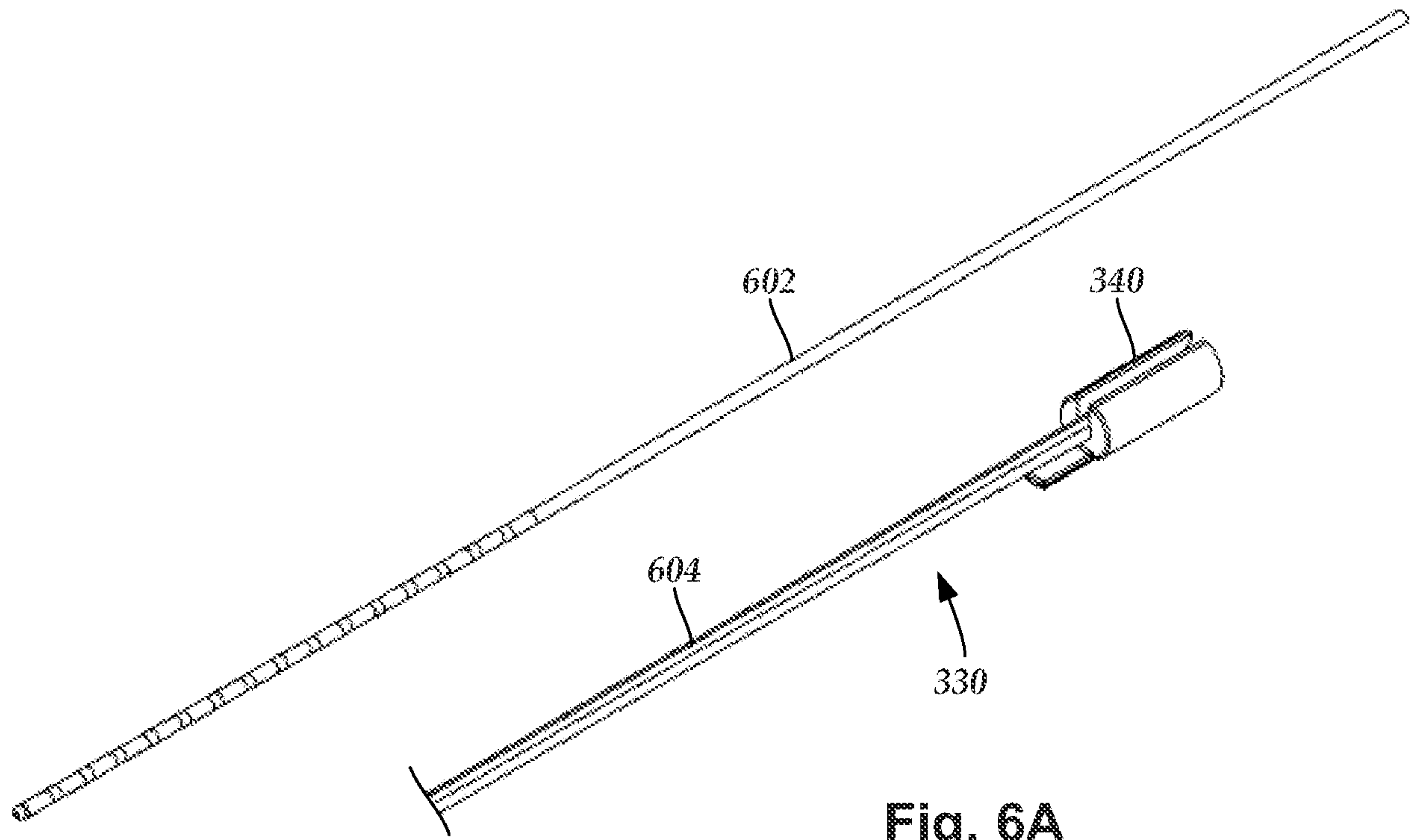


Fig. 6A

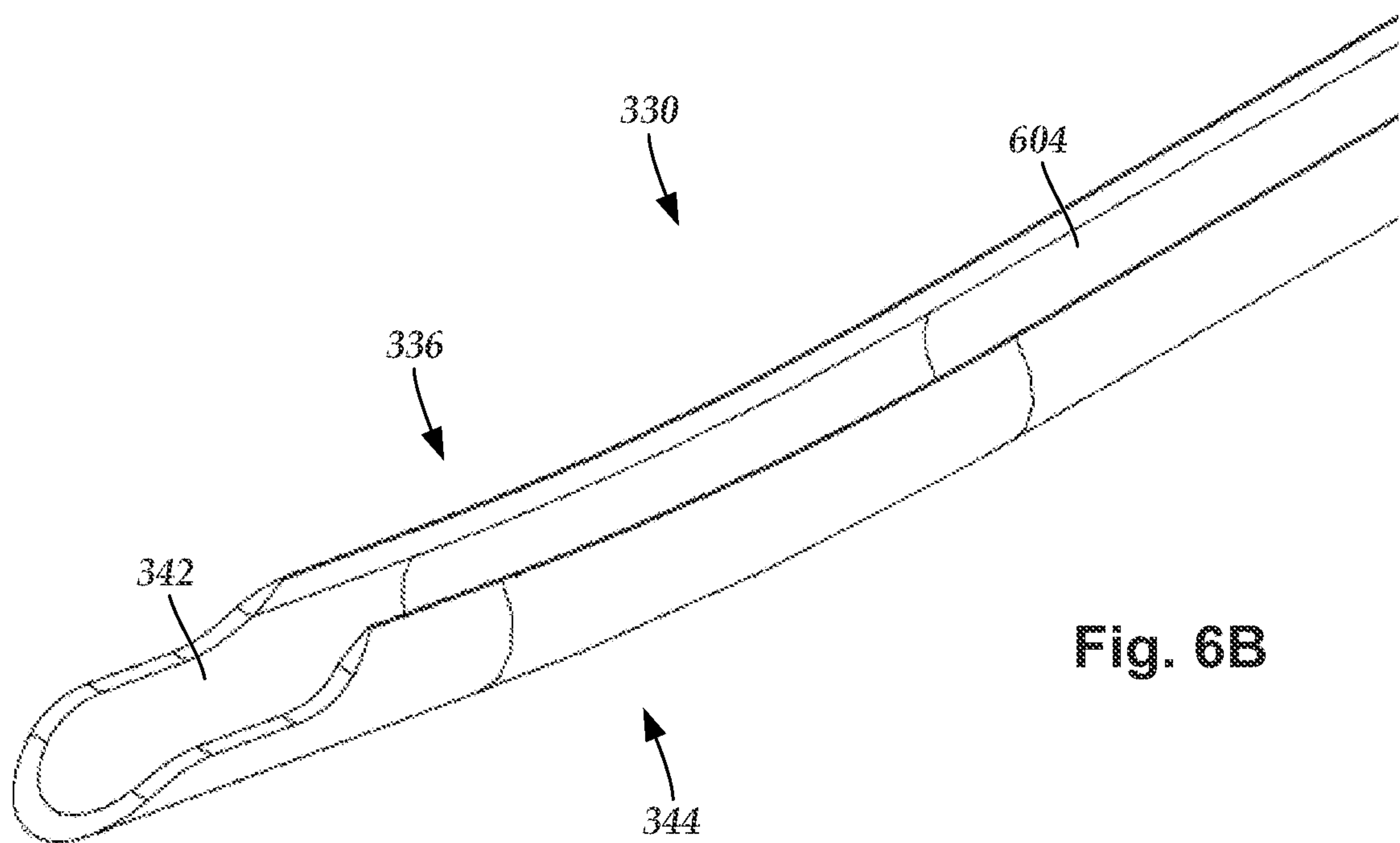


Fig. 6B

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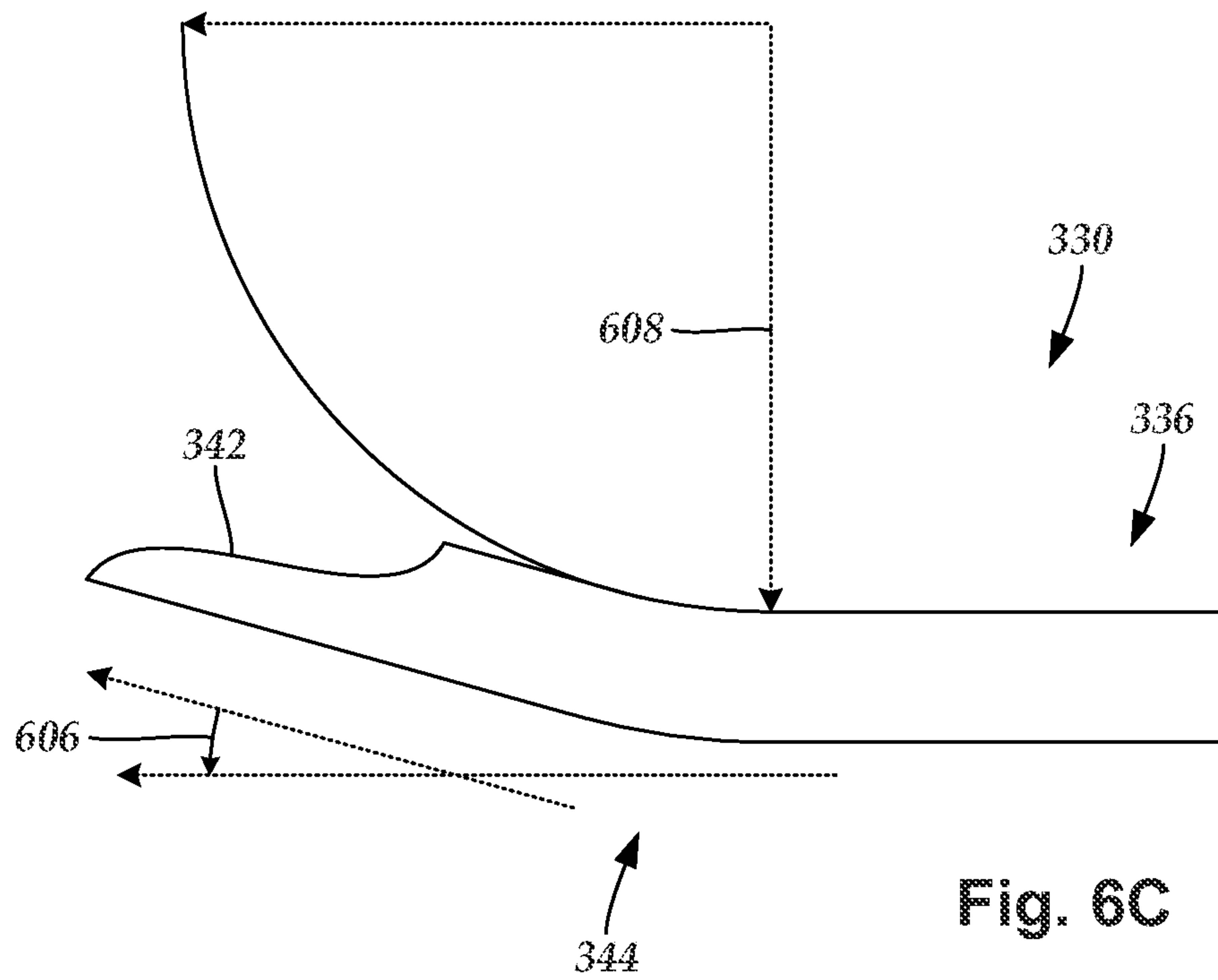
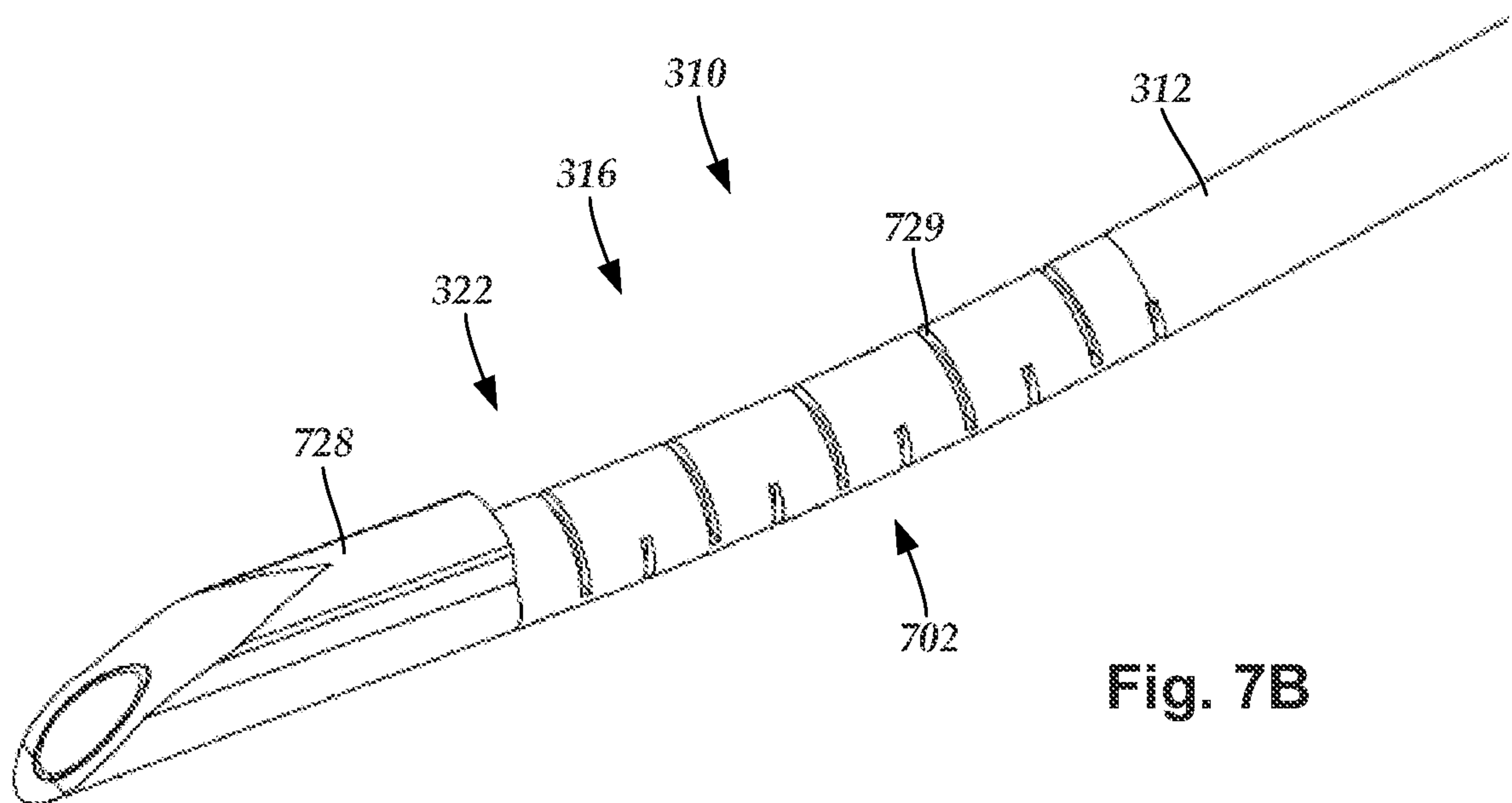
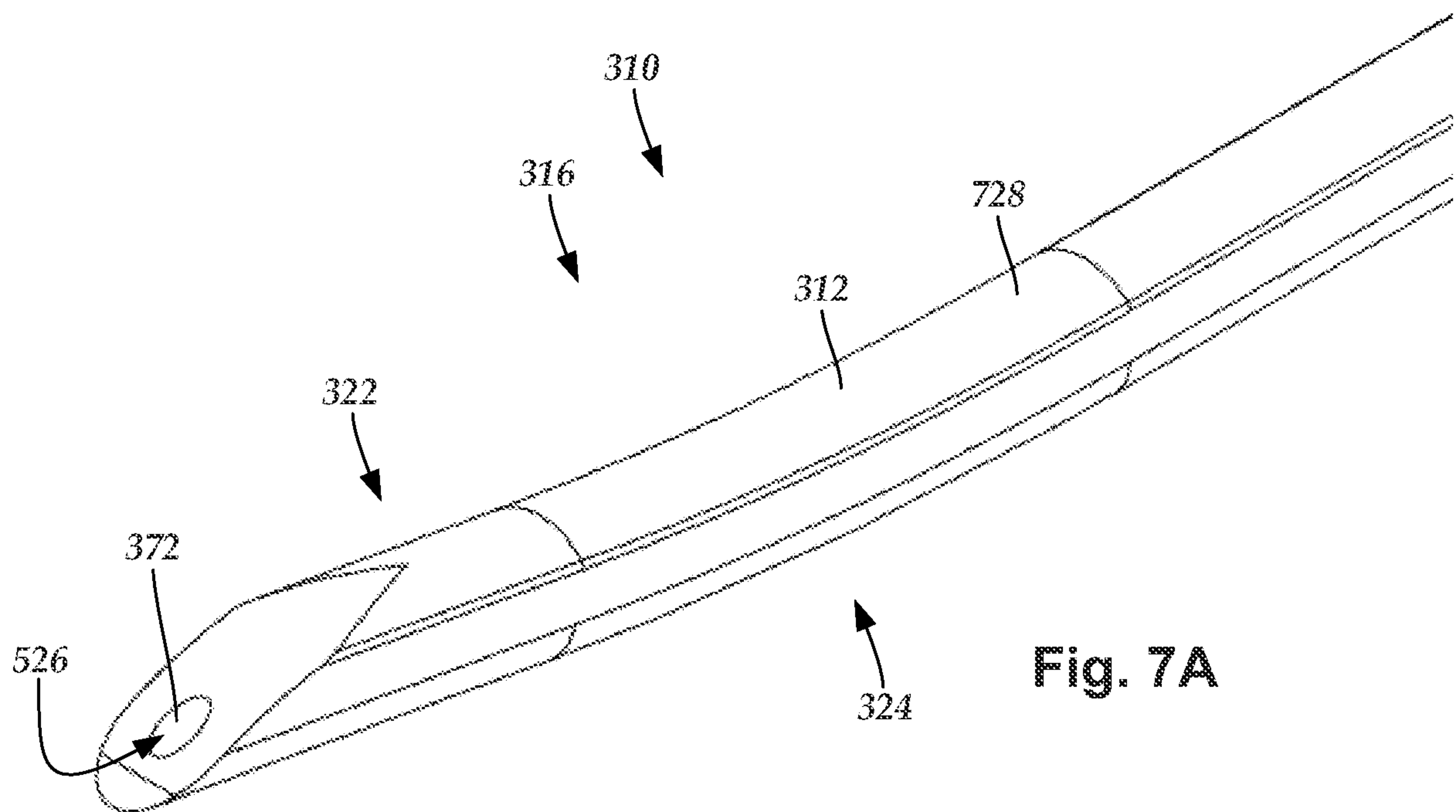
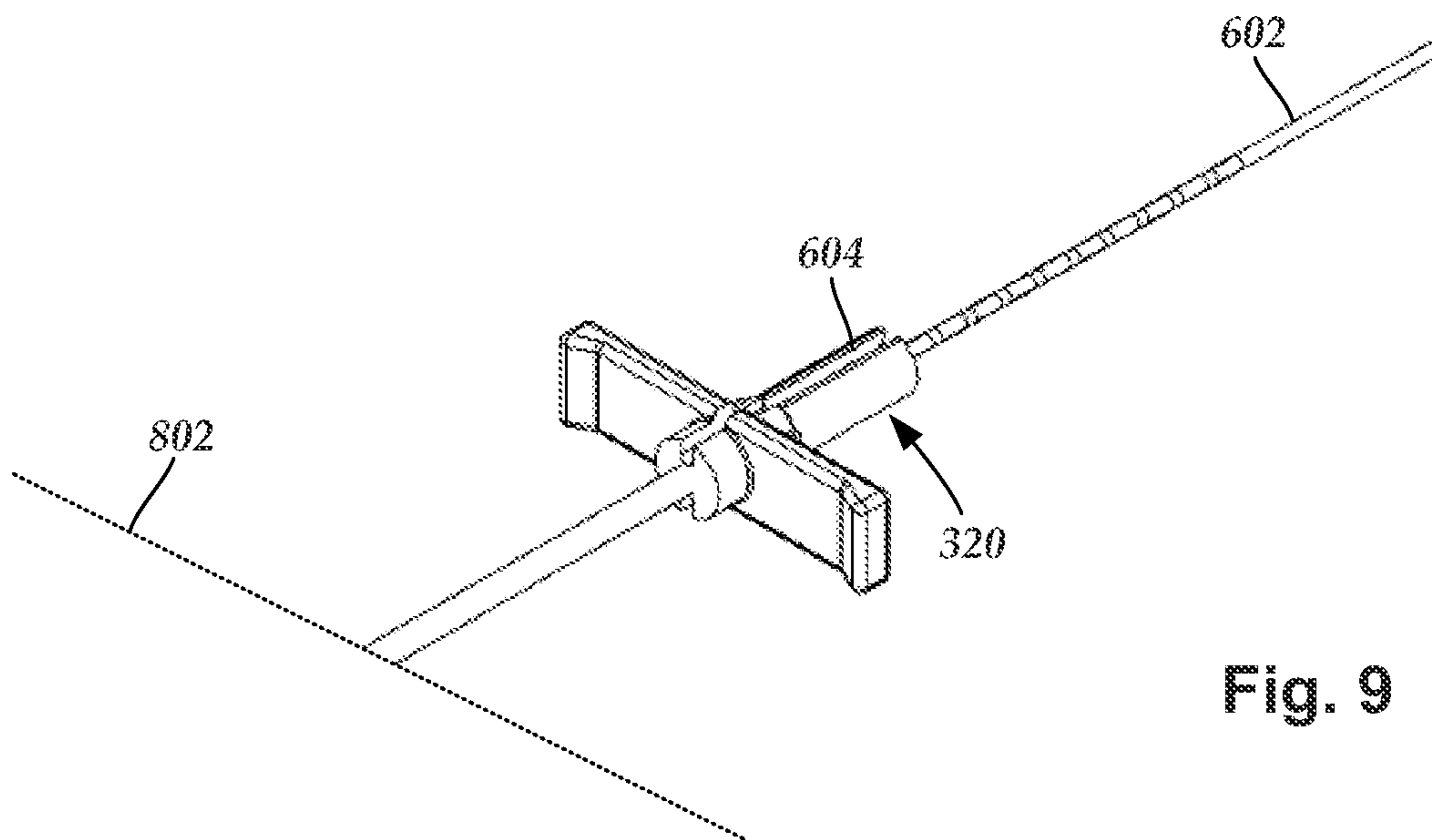
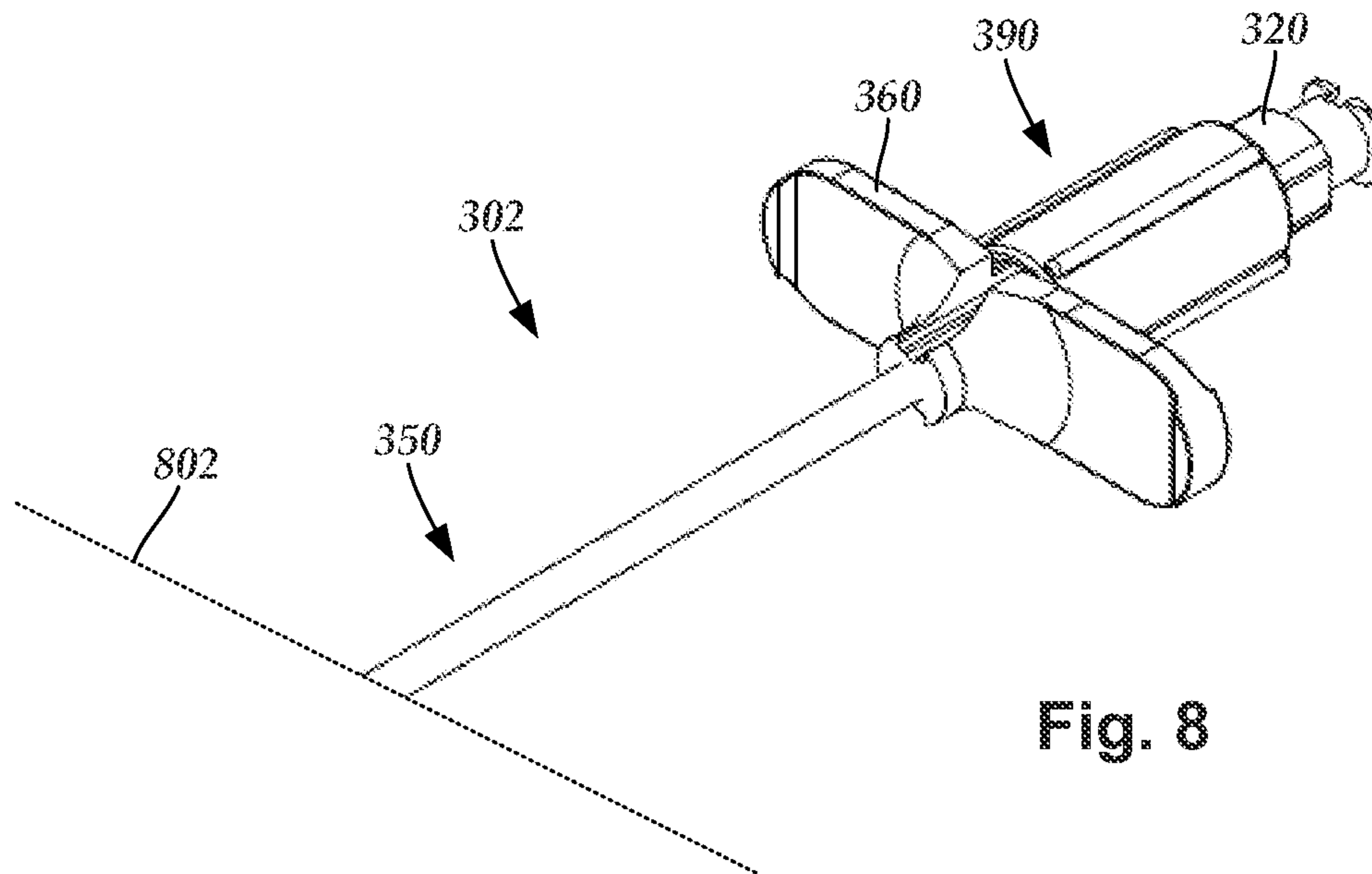
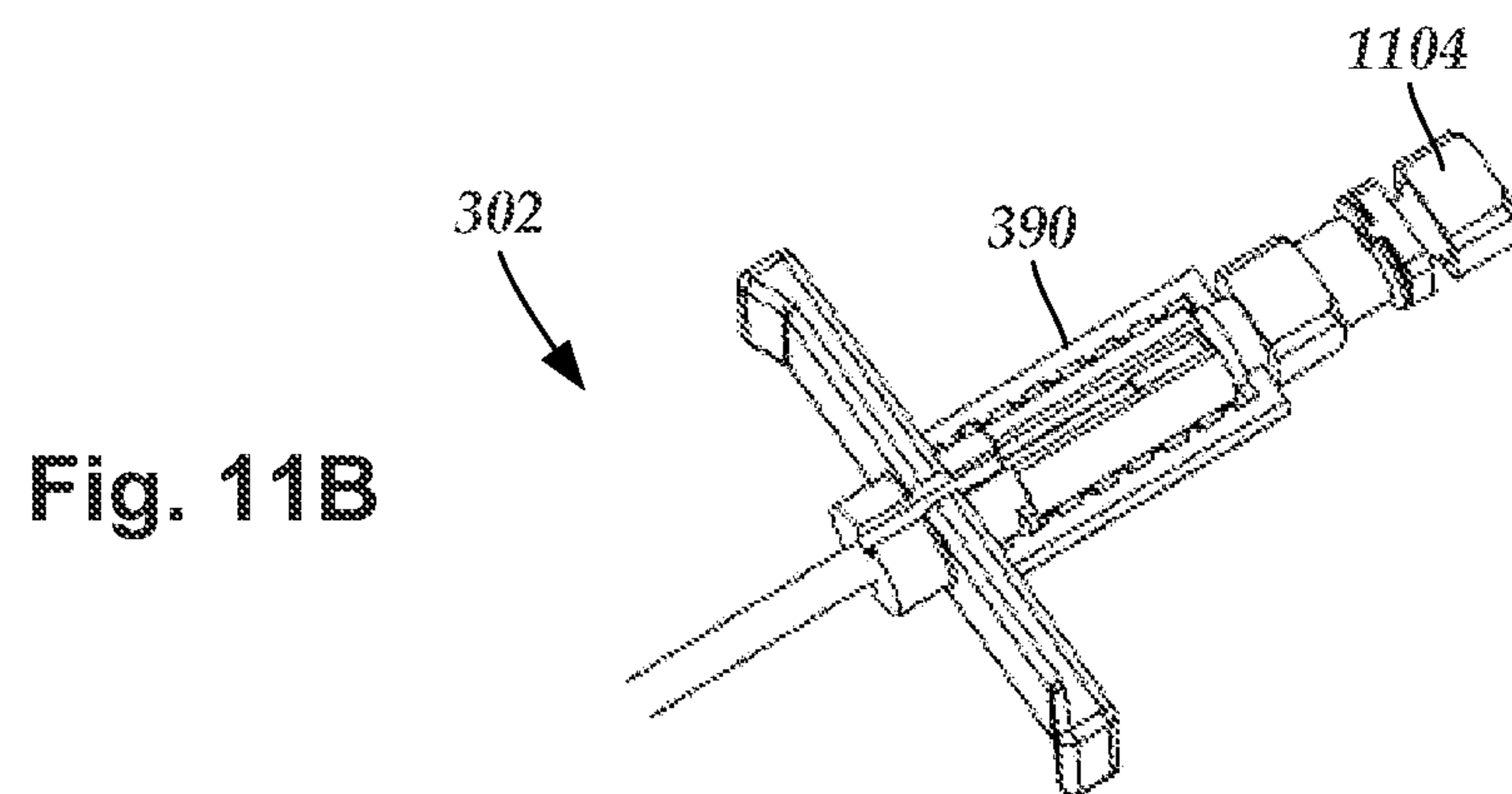
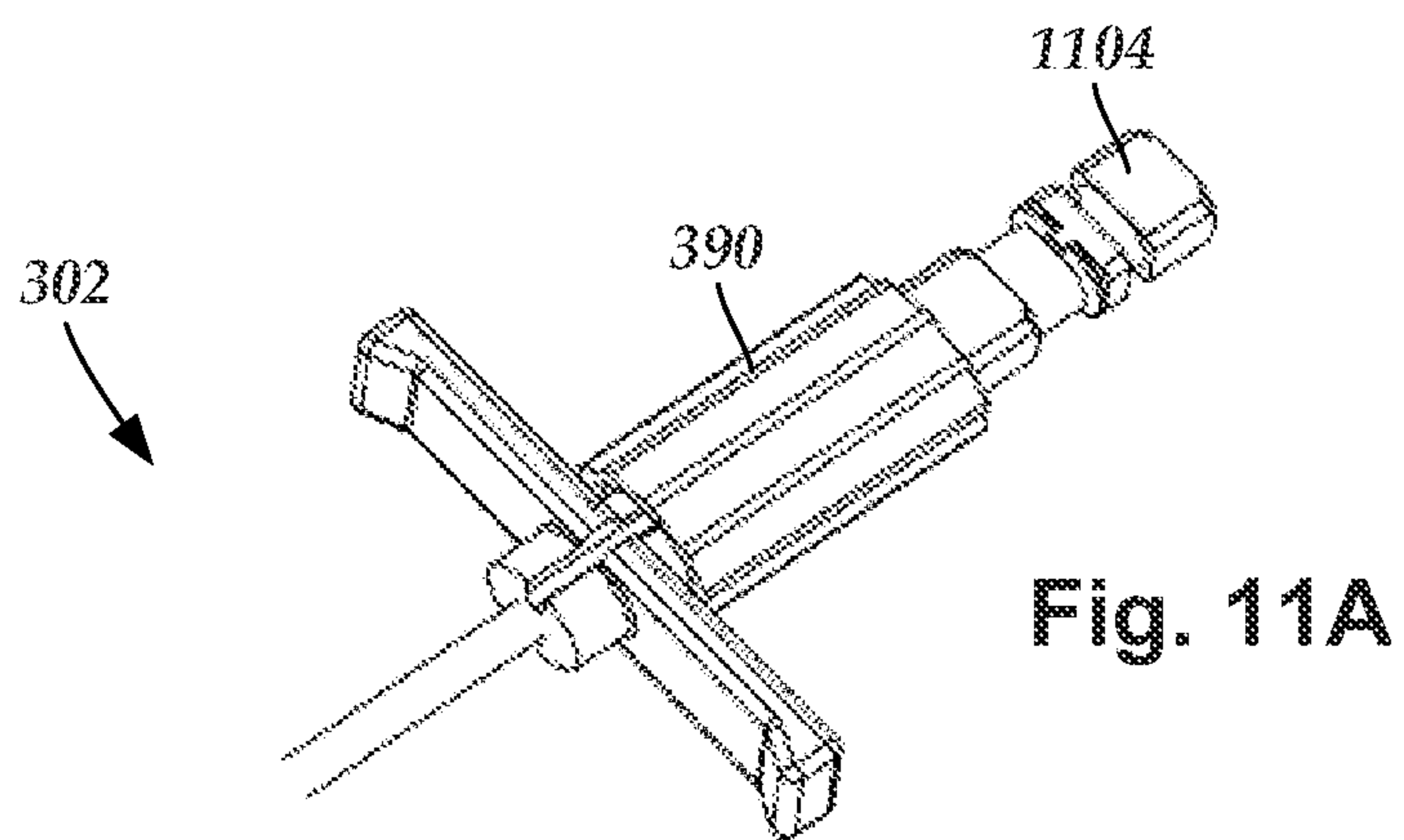
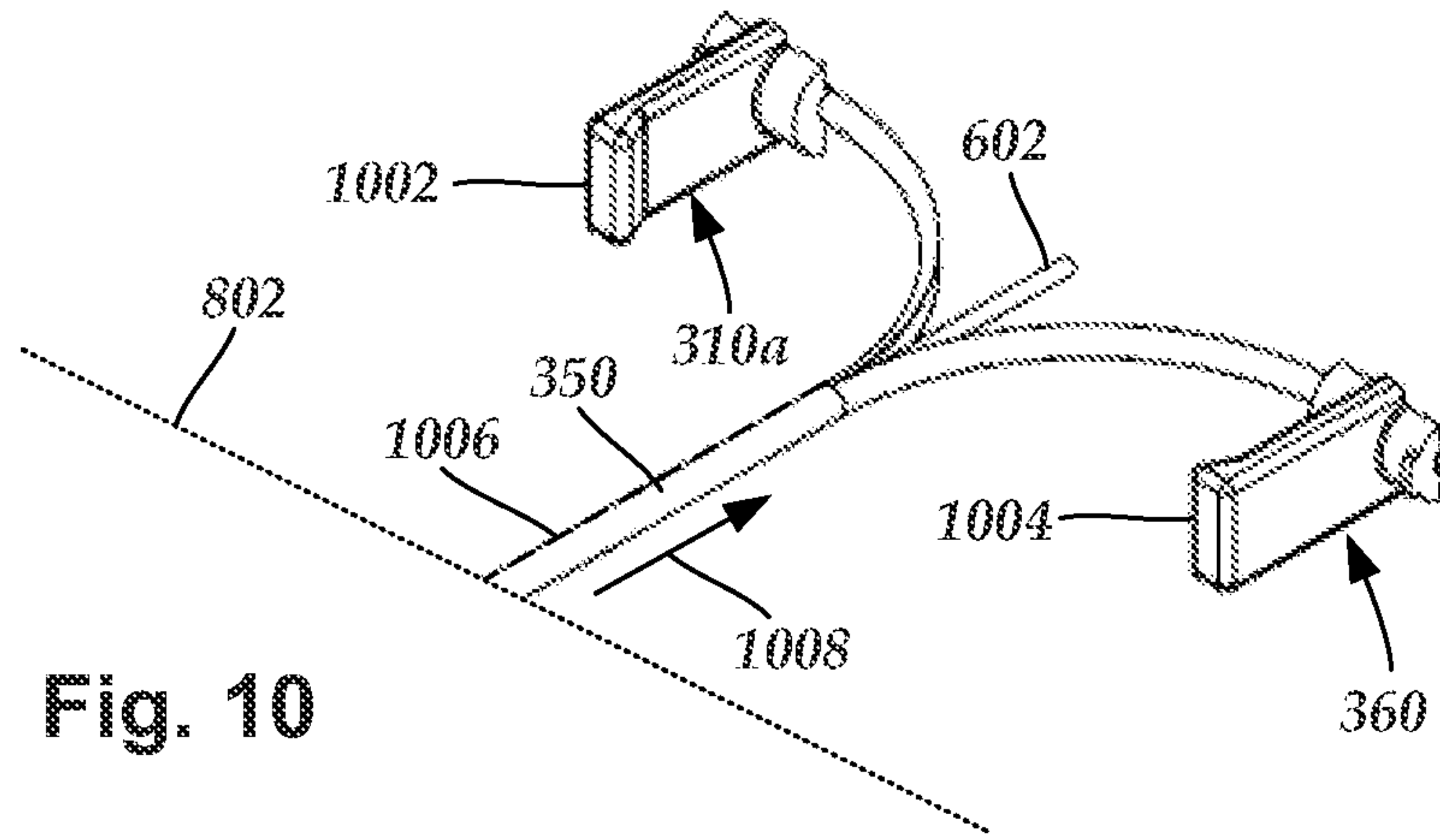


Fig. 6C





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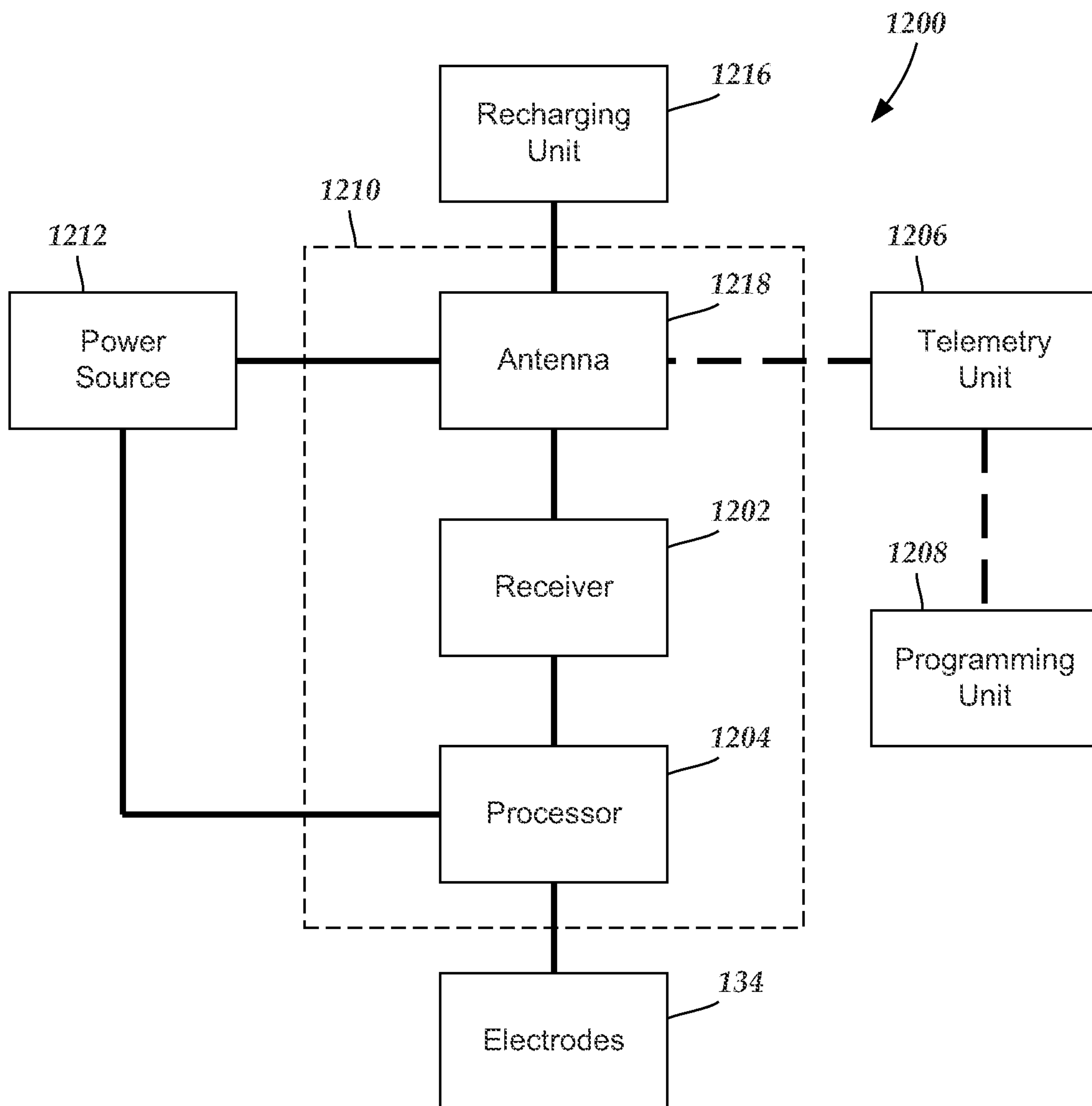


Fig. 12

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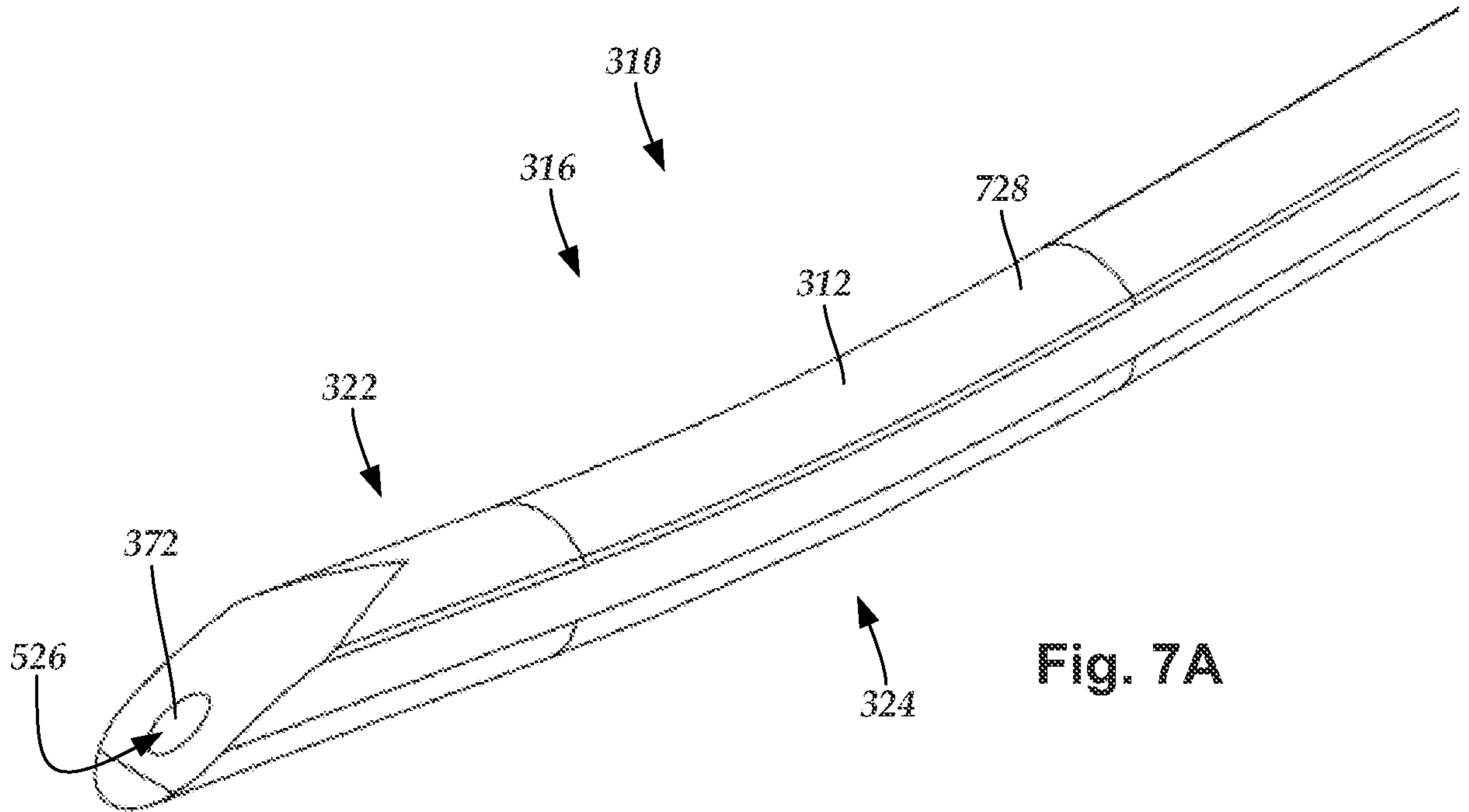


Fig. 7A