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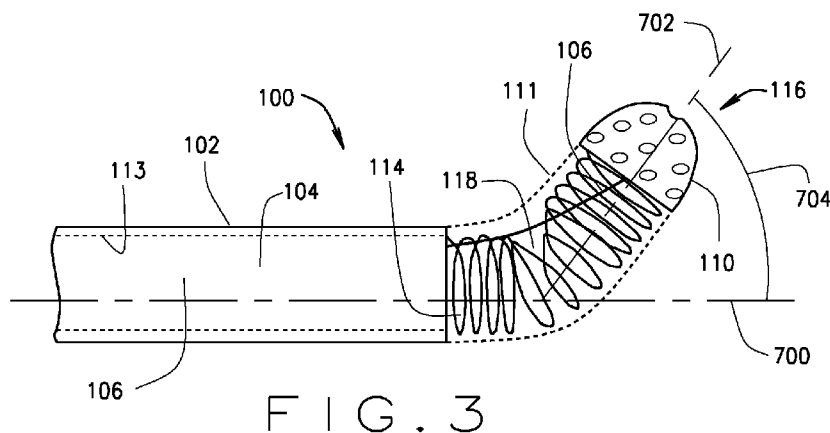
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(54) Title: STEERABLE EPIDURAL CATHETER



(57) Abstract: A steerable catheter device which can be steered to locations within the epidural space, as well as methods of use and manufacture are disclosed. The steerable catheter provides a site-specific drug delivery system for accessing the epidural space. The catheter devices includes a steerable wire or a liner extending from a proximal end of the catheter to the catheter's distal end. Forces applied to the wire or the liner cause the distal end to deflect and/or rotate to reach a targeted epidural site.

STEERABLE EPIDURAL CATHETER

FIELD

[0001] The present application relates to surgical devices and more particularly to a steerable catheter that can be guided to site-specific locations.

BACKGROUND

[0002] The most common interventional pain management procedures are used to manage chronic neck and/or back pain, as well as pain associated with labor and delivery. These procedures typically involve epidural injections to deliver pain reducing medicines to the epidural space. Epidural injections may be made using a direct needle injection at the site of pain (transforaminal approach) or using a catheter maneuvered into the epidural space (interlaminar approach). Although, the transforaminal approach may be more diagnostic and provide greater long term pain management than the interlaminar approach, it carries an increased risk of complications, such as inadvertent vascular or nerve injury, spinal cord injury and death.

[0003] Guided catheters have been employed to manage pain using the interlaminar approach. These types of catheters are typically designed for intravascular areas and are not optimized for epidural procedures. Vascular-type guided catheters often rely on the use of a guide wire to position the catheter within the vascular system. After positioning the guide wire near the treatment site, a separate, hollow catheter may then be threaded over the guide wire and maneuvered to the desired location. The guide wire is then withdrawn and the catheter left in place. After the procedure is completed, the guide wire must be re-inserted into the inner lumen of the catheter and the catheter and guide wire collectively withdrawn. However, this process can be cumbersome, time-consuming, and potentially increase the risk of injury to the patient.

SUMMARY

[0004] In one embodiment, a steerable catheter device may include an elongated catheter body defining a proximal portion and a distal portion and a lumen

formed along the elongated catheter body. The lumen defines a proximal end and a distal end with a reinforcing coil disposed within the lumen for supporting the elongated catheter body. A steerable wire extends proximate or within the lumen from the proximal end of the lumen to a distal tip defined at the distal end of the elongated catheter body, wherein the steerable wire is affixed to the distal tip. Actuation of the steerable wire at the proximal end of the elongated catheter body causes at least one of a rotation and a deflection of the distal tip.

[0005] In another embodiment, a steerable catheter device may include an elongated catheter body defining a proximal portion and a distal portion and a lumen formed along the elongated catheter body. The lumen defines a proximal end and a distal end with a reinforcing coil disposed within the lumen for supporting the elongated catheter body. A steerable liner extends proximate or within the lumen from the proximal end of the lumen to a distal tip defined at the distal end of the elongated catheter body, wherein the steerable liner is affixed to the distal tip. Actuation of the steerable liner at the proximal end of the elongated catheter body causes at least one of a rotation and a deflection of the distal tip.

[0006] In yet another embodiment, a method for delivering a drug to an epidural space may include:

- accessing an area adjacent to the epidural space using a steerable catheter comprising:

- an elongated catheter body defining a proximal portion and a distal portion and a lumen along the elongated catheter body, the lumen having a proximal end and a distal end with a reinforcing coil disposed within the lumen for supporting the elongated catheter body, the lumen containing a steerable wire extending proximate or within the lumen from the proximal end of the lumen to a distal tip defined at the distal end of the elongated catheter body, wherein the steerable wire is affixed to the distal tip, wherein actuation of the steerable wire at the proximal end of the elongated

catheter body causes at least one of a rotation and a deflection of the distal tip;
applying a force to the steering mechanism to at least one of a deflection and a rotation of the distal end into the epidural space;
providing a liquid through the lumen of the catheter;
transmitting the liquid from the proximal end of the lumen to the distal end of the lumen positioned within the epidural space; and
removing the elongated catheter body.

[0007] In an embodiment, a method for manufacturing a steerable catheter device may include:

forming an elongated catheter body defining a distal portion and a proximal portion, the elongated catheter body defining a lumen having a proximal end and a distal end, wherein the distal portion of the elongated catheter body defining a distal tip; and
inserting a steerable wire along the lumen from the proximal portion of the elongated catheter body to the distal tip, wherein actuating the steerable wire causes at least one of a rotation and a deflection of the distal tip; and
affixing an end of the steerable wire to the distal tip.

[0008] In another embodiment, a method for manufacturing a steerable catheter device may include:

forming an elongated catheter body defining a distal portion and a proximal portion, the elongated catheter body defining a lumen having a proximal end and a distal end, wherein the distal portion of the elongated body defining a distal tip; and
inserting a steerable wire along the lumen from the proximal portion of the elongated catheter body to the distal tip, wherein actuating the steerable wire causes at least one of a rotation and a deflection of the distal tip; and
affixing an end of the steerable line to the distal tip.

[0009] Additional objectives, advantages, and novel features will be set forth in the description which follows or will become apparent to those skilled in the art upon examination of the drawings and detailed description which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is an illustration of a prior art epidural site treatment system;

[0011] FIG. 2 is a partial cross-sectional side view showing one embodiment of a steerable catheter;

[0012] FIG. 3 is a side view illustrating the distal end of the steerable catheter;

[0013] FIGS. 4A and 4B are side views the deflection action of the steerable catheter;

[0014] FIG. 5 is a side view showing the collar of the steerable catheter;

[0015] FIG. 6 is a side view of another embodiment of the steerable catheter engaged to a steering mechanism;

[0016] FIG. 7 is a view of a steering mechanism of the steerable catheter; and

[0017] FIG. 8 is a cross-sectional view of tension device of the steerable catheter.

[0018] Corresponding reference characters indicate corresponding elements among the view of the drawings. The headings used in the figures should not be interpreted to limit the scope of the claims.

DETAILED DESCRIPTION

[0019] Aspects of the present disclosure include devices and methods for a steerable catheter. In particular, the steerable catheter includes a steerable wire or a bent liner incorporated proximate or within the lumen of the steerable catheter to maneuver the steerable catheter by deflection and/or rotation of the distal tip defined at a distal end of the steerable catheter. The steerable catheter functions without a removable guide wire for positioning and removing the steerable catheter

[0020] Referring to the drawings, a prior art system **10** to access an epidural site **12** of a mammalian body is illustrated and generally indicated as **10** in FIG. 1. The prior art system **10** includes an epidural needle **14** that is used to puncture the skin and access the epidural treatment site **12**. A guide wire (not shown) and a catheter **16** are collectively inserted through the lumen of the needle **14** which deploys the catheter **16** at the treatment site **12**. However, the use of the guide wire to maneuver the catheter **16** through the needle **14** can increase the risk of injury to surrounding tissue and may also require additional equipment to properly manipulate the guide wire and catheter **16**.

[0021] Referring to FIG. 2, one embodiment of a steerable catheter generally indicated as **100** is illustrated which overcomes the issues related to the prior art system **10**. The steerable catheter **100** includes an elongated catheter body **102** having a proximal portion **109** defining an opening **107** and a distal portion **111** defining a distal tip **108**. In addition, the opening **107** is in fluid flow communication with a lumen **104** (shown in phantom lines) that extends longitudinally along the elongated catheter body **102**. In addition, the lumen **104** has a proximal end **112** in communication with the opening **107** and a distal end **110** that communicates with the distal tip **108**. The elongated catheter body **102** may have a diameter between in 1mm and 5mm. In one embodiment, the elongated body **102** has a diameter equal to or less than 1.5 mm.

[0022] A steerable wire **106** may be disposed within the lumen **104** having a proximal end **130** that extends outwardly from the opening **107** and a distal end **132** that is positioned proximate or within the distal tip **108**. In one embodiment, the steerable wire **106** may be manipulated to deflect and/or rotate the distal tip **108** of the elongated catheter body **102** as shall be discussed in greater detail below. In other embodiments, the steerable wire **106** may be made from a malleable metal material, a bendable plastic material, or a metal material having memory retention characteristics. As shown, the steerable wire **106** may extend from the distal end **110** to a proximal end **112** of the elongated catheter body **102** in parallel orientation relative to the longitudinal axis **700** of the elongated catheter body **102**. The lumen **104** also provides fluid flow communication between the proximal end **112** and distal end **110** of the elongated catheter body **102** such that a medicinal or therapeutic agent, for example a

pharmaceutical drug, may be injected at the proximal end **112** and then discharged at the distal end **110** of the lumen **104**. In some embodiments, a reinforced coil **114** may be disposed along a portion or entire length of the lumen **104** to provide a reinforcing structure to the elongated catheter body **102**. In one embodiment, the steerable wire **106** may be disposed longitudinally through the reinforcing coil **114**; however, in other embodiments, the steerable wire **106** may be disposed freely within the lumen **104**, attached along the inner surface **113** of the lumen **104** or embedded under the inner surface **113** within the elongated catheter body **102**. The reinforcing coil **114** also serves to structurally connect the distal tip **108** with distal portion **132** of the elongated catheter body **102**. In one embodiment, the reinforcing coil **114** may be a variable tension coiled spring. In other embodiments, the reinforcing coil **114** may be a woven, helical, or braided reinforcement structure within the elongated catheter body **102**.

[0023] As further shown, the distal tip **108** includes a plurality of holes **116** that are in fluid flow communication with the lumen **104** such that a liquid, for example a therapeutic agent, injected through the opening **107** of the lumen **104** may pass through the plurality of holes **116** and into the epidural space or other body cavity. The plurality of holes **116** also reduces the probability of any debris or obstruction from completely preventing fluid flow communication through the plurality of holes **116**. In some embodiments, the distal tip **108** may be rounded and have a generally hemispherical configuration. This generally hemispherical configuration of the distal tip **108** also minimizes injuries to the tissue at and around the epidural site **12**.

[0024] As noted above, the proximal end **130** of the steerable wire **106** may be manually manipulated to cause the distal tip **108** to rotate and/or deflect away relative to a longitudinal axis **700** of the elongated catheter body **102**. In particular, distal tip **108** may be deflected such that a center axis **702** of the distal tip **108** is deflected at an angle **704** relative to the longitudinal axis **700**. In some embodiments, the angle **704** of deflection may be between zero to ninety degrees, although in some embodiments the angle **704** of deflection may be between twenty to forty five degrees. The manipulation of the steerable wire **106** may include the application of a tensile force, a compressive force, a rotational torque, or a force perpendicular applied along the longitudinal axis **700**.

[0025] In various aspects, a combination of manipulative forces may be used to manipulate the steerable wire **106**. For example, a first force may deflect the center axis **702** of distal tip **108** from the longitudinal axis **700** at a deflection angle **704** and a second force, such as a rotational force may be applied to rotate the distal tip **108** about the center axis **702**. In some embodiments, the first and second forces may be applied sequentially or concurrently to deflect and rotate the distal tip **108**.

[0026] Referring to FIG. 3, the steerable catheter **100** may include a reinforcing coil **114** defining a structural defect **118**. For example, the structural defect **118** may be generally a wedge-shaped formation defined by one or more loops of the reinforcing coil **114**, which may be formed by the intentional strengthening of one or more loops of the reinforcing coil, or the fusion of two or more loops of the reinforcing coil **114**. The structural defect **118** facilitates the deflection and/or rotation of the distal tip **108** when the steerable wire **106** is manipulated. In one aspect, the structural defect **118** reduces the strength of the reinforcing coil **114** at the formation of the structural defect **118** along the reinforcing coil **114**, and therefore makes the elongated catheter body **102** more flexible at the distal portion **111** and susceptible to the rotation and/or deflection caused by manipulation of the steerable wire **206**. Although the structural defect **118** may be wedge-shaped, the structural defect **118** may have other shapes, such as a symmetrical shape, an asymmetrical shape, a rectangular shape, a square shape or combination of above shapes.

[0027] Referring to FIGS. 4A and 4B, the steerable catheter, designated **200**, has substantially the same configuration as the steerable catheter **100** having an elongated catheter body **202** that defines a lumen **204** having a reinforcing coil **214** and a steerable wire **206** disposed longitudinally proximate or within the lumen **204**. The lumen **204** is in fluid flow communication with a plurality of holes **208** and extends substantially along longitudinal axis **700** when the distal portion **211** is in a straight configuration. In this particular embodiment, the elongated catheter body **202** defines a structural defect **218** for facilitating the deflection and/or rotation of the distal tip **208** rather than the reinforcing coil **214** having the structural defect. In some embodiments, the structural defect **218** may have a wedge-shape configuration defined along the elongated catheter body **202**, one or more pleats incorporated into the elongated

catheter body, or the structural defect **218** may constitute the partial removal of a localized portion of the external or internal surface of the elongated catheter body **202**. In one aspect, the structural defect **218** reduces the strength of the elongated catheter body **302** at the location of the structural defect **218**, and therefore makes the distal portion **211** of the elongated catheter body **202** more flexible and susceptible to the rotation and/or deflection caused by manipulation of the steerable wire **206**. As shown in FIG. **4A**, manipulation of the steerable wire **206** causes center axis **702** of the distal tip **208** to deflect at an angle **705** relative to the longitudinal axis **700**, thereby bringing the opposing sides **218A** and **218B** of the structural defect **218** toward each other. Referring to FIG. **4B**, further manipulation of the steerable wire **206** causes an increase in the deflection angle **706** between the center axis **702** and the longitudinal axis **700** and brings the opposing sides **218A** and **218B** of the structural defect **218** closer together to facilitate the deflection of the distal tip **208**.

[0028] Referring now to FIG. **5**, another embodiment of the steerable catheter, designated **300**, is illustrated. In this embodiment, the steerable catheter **300** includes an elongated catheter body **302** defining a lumen **304** configured to receive a steerable liner **306** therein. The steerable liner **306** defines a proximal portion **312** and a distal portion **314** that extends substantially the length of the elongated catheter body **302** such that manipulation of the proximal portion **312** of the steerable liner **306** causes the distal portion **314** to deflect and/or rotate the distal tip **308**. The steerable liner **306** is a substantially rigid tubular structure, such as a hollow stylette, having a diameter less than the diameter of the lumen **304**. The steerable liner **306** has a generally angled configuration, where the distal portion **314** of the steerable liner **306** may be angled relative to the proximal end **312** of the steerable liner **306**. In some embodiments, the distal portion **314** of the steerable liner **306** may be angled in a range between zero degrees to ninety degrees relative to the longitudinal axis **700**. In one aspect, the steerable liner **306** is threaded through the lumen **304** of the elongated catheter body **302**, such that the center axis **707** of distal tip **308** of the elongated catheter body **302** is deflected from the longitudinal axis **700** by an angle **709** that is substantially equal to the deflection of the distal portion **314** of the steerable liner **306**. In some embodiments, the steerable catheter **300** may also include a steering collar **320** engaged to the proximal

portion **312** of the steerable liner **302** to articulate the distal portion **314** of the steerable liner **306**. In one embodiment, the steering collar **320** is mechanically engaged with the steerable liner **306** to impart a force upon the steerable liner **306**. The steerable liner **306** may be subjected to tensile force, a compressive force, a rotational torque, or a perpendicular force along the longitudinal axis **700** of the steerable catheter **300**.

[0029] Referring now to FIGS. **6-8**, the steerable catheter **100** may be operatively engaged to a steering mechanism, generally indicated as **400**, for articulating the steering wire **106**. In particular, operation of the steering mechanism **400** imparts a force that manipulates the steerable wire **106** and causes the deflection and/or rotation of the distal tip **108** as described above. The steering mechanism **400** may include a tension device **402** and a rotational steering device **404**. The tension device **402** may be used to impart and maintain constant tensile and compressive forces on the steerable wire **106**, while the rotational steering device **404** is used to impart a rotational force on the steerable wire **106**. In one aspect, the functionality of the tension device **402** and a rotational steering device **404** may be incorporated into single steering device that manipulates the steerable wire **106**.

[0030] As shown in FIG. **8**, the tension device **402** may also incorporate locking features **406** to maintain a constant force to the steerable wire **106**. Referring to FIGS. **7** and **8**, the steering mechanism **400** may include a plurality of ratchet teeth **408** that are mechanically engaged to locking features **406** of the tension device **402** to prevent undesired motion of the tension device. For example, the locking features **406** may be a series of pawls or other projections to slidably engage with the plurality of ratchet teeth **408** and prevent undesired retrograde motion of the tension device **402**.

[0031] In various other embodiments, the steering mechanism **400** may also include an injection port, **410** and a handle **412**. The injection port **410** may be used to deliver medications to the epidural site **12** through the lumen **104** of the elongated catheter body **102**, while the handle **412** provides a means to operate the steering mechanism **400**. The steering mechanism **400** may include a plurality of ratchet teeth **404** that are mechanically engaged by the tension device **402** to prevent undesired motion of the steering mechanism **400** and the steerable wire **106**. In another embodiment, the steering mechanism **400** may be mechanically engaged to the steerable

catheter **100**. The steering mechanism **400** may be used to impart and maintain constant tensile and compressive forces on the steerable liner **406** through the tension device **402** and the rotational steering device **404**.

[0032] It is believed that the present disclosure and many of its attendant advantages will be understood by the foregoing description, and it will be apparent that various changes may be made in the form, construction, and arrangement of the components without departing from the disclosed subject matter or without sacrificing all of its material advantages. The form described is merely explanatory, and it is the intention of the following claims to encompass and include such changes.

[0033] While the present disclosure has been described with reference to various embodiments, it will be understood that these embodiments are illustrative and that the scope of the disclosure is not limited to them. Many variations, modifications, additions, and improvements are possible. More generally, embodiments in accordance with the present disclosure have been described in the context of particular implementations. Functionality may be separated or combined in blocks differently in various embodiments of the disclosure or described with different terminology. These and other variations, modifications, additions, and improvements may fall within the scope of the disclosure as defined in the claims that follow.

[0034] Those skilled in the art will appreciate that variations from the specific embodiments disclosed above are contemplated by the invention. The following invention should not be restricted to the above embodiments, but should be measured by the following claims.

CLAIMS

What is claimed is:

1. A steerable catheter device comprising:
 - an elongated catheter body defining a proximal portion and a distal portion and a lumen along the elongated catheter body, the lumen having a proximal end and a distal end with a reinforcing coil disposed within the lumen for supporting the elongated catheter body, the lumen containing a steerable wire extending proximate or within the lumen from the proximal end of the lumen to a distal tip defined at the distal end of the elongated catheter body, wherein the steerable wire is affixed to the distal tip, and wherein actuation of the steerable wire at the proximal end of the elongated catheter body causes at least one of a rotation and a deflection of the distal tip.
2. The device of claim 1 further comprising:
 - a structural defect located at the distal end of the elongated catheter body, wherein the structural defect aids in the rotation and the deflection of the distal tip.
3. The device of claim 2 wherein the distal tip deflects between zero to ninety degrees.
4. The device of claim 3 wherein the distal tip deflects between twenty to forty-five degrees.
5. The device of claim 1 wherein the elongated catheter body has a diameter of less than 1.5 mm.
6. The device of claim 1 wherein the elongated catheter body has a diameter between 1 mm to 5 mm.
7. The device of claim 1 wherein the distal tip has generally hemispherical configuration.

8. The device of claim 1 wherein the distal tip further comprises a plurality of holes.
9. The device of claim 1 further comprising:
 - a steering mechanism directly engaged with the steerable wire, the steering mechanism to actuate the steerable wire to rotate and deflect the distal tip.
10. The device of claim 9 wherein the steering mechanism further comprises a locking mechanism mechanically engaged with the steerable wire to maintain a constant tension on the steerable wire.
11. The device of claim 1 wherein actuation of the steerable wire at the proximal end of the elongated catheter body causes the distal tip to deflect from a longitudinal axis of the catheter.
12. The device of claim 1 wherein actuation of the steerable wire at the proximal end of the elongated catheter body causes the distal tip rotate about a longitudinal axis of the catheter.
13. A steerable catheter for delivering a drug to an epidural cavity comprising:
 - an elongated catheter body defining a proximal portion and a distal portion and a lumen along the elongated catheter body, the lumen having a proximal end and a distal end with a reinforcing coil disposed within the lumen for supporting the elongated catheter body, the lumen containing a steerable liner extending proximate or within the lumen from the proximal end of the lumen to a distal tip defined at the distal end of the elongated catheter body, wherein the steerable liner is affixed to the distal tip, and wherein actuation of the steerable liner at the proximal end of the elongated catheter body causes at least one of a rotation and a deflection of the distal tip.

14. The device of claim 13 further comprising:
a structural defect at the distal end of the elongated catheter body,
wherein the structural defect aids in the rotation and the deflection
of the distal tip.
15. The device of claim 14 wherein the distal tip deflects between zero to ninety
degrees.
16. The device of claim 15 wherein the distal tip deflects between twenty to forty-five
degrees.
17. The device of claim 13 wherein the elongated catheter body has a diameter of
less than 1.5 mm.
18. The device of claim 13 wherein the elongated catheter body has a diameter
between 1 mm to 5 mm.
19. The device of claim 13 wherein the distal tip has a generally hemispherical
configuration.
20. The device of claim 13 wherein the distal tip further comprises a plurality of
holes.
21. The device of claim 13 further comprising:
a steering mechanism directly engaged with the steerable liner, the
steering mechanism to actuate the steerable liner to rotate and
deflect the distal tip.
22. The device of claim 21 wherein the steering mechanism further comprises a
locking mechanism mechanically engaged with the steerable liner to maintain a
constant tension on the steerable liner.
23. The device of claim 13 wherein the steerable liner has a generally tubular
configuration.
24. The device of claim 13 wherein the steerable liner has a solid surface.

25. The device of claim 13 wherein the steerable liner has a generally tubular configuration.
26. The device of claim 13 wherein actuation of the steerable liner at the proximal end of the elongated catheter body causes the distal tip to deflect from a longitudinal axis of the catheter.
27. The device of claim 13 wherein actuation of the steerable liner at the proximal end of the elongated catheter body causes the distal tip to deflect from a longitudinal axis of the catheter.
28. The device of claim 13 wherein actuation of the steerable liner at the proximal end of the elongated catheter body causes the distal tip rotate about a longitudinal axis of the catheter.
29. A method for delivering a drug to an epidural space comprising:
 - accessing an area adjacent to the epidural space using a steerable catheter comprising:
 - an elongated catheter body defining a proximal portion and a distal portion and a lumen along the elongated catheter body, the lumen having a proximal end and a distal end with a reinforcing coil disposed within the lumen for supporting the elongated catheter body, the lumen containing a steerable wire extending proximate or within the lumen from the proximal end of the lumen to a distal tip defined at the distal end of the elongated catheter body, wherein the steerable wire is affixed to the distal tip, wherein actuation of the steerable wire at the proximal end of the elongated catheter body causes at least one of a rotation and a deflection of the distal tip;
 - applying a force to the steering mechanism to at least one of a deflection and a rotation of the distal end into the epidural space;

providing a liquid through the lumen of the catheter;
transmitting the liquid from the proximal end of the lumen to the distal end
of the lumen positioned within the epidural space; and
removing the elongated catheter body.

30. A method for manufacturing a steerable catheter device comprising:
forming an elongated catheter body defining a distal portion and a
proximal portion, the elongated catheter body defining a lumen
having a proximal end and a distal end, wherein the distal portion of
the elongated catheter body defining a distal tip; and
inserting a steerable wire along the lumen from the proximal portion of the
elongated catheter body to the distal tip, wherein actuating the
steerable wire causes at least one of a rotation and a deflection of
the distal tip; and
affixing an end of the steerable wire to the distal tip.
31. A method for manufacturing a steerable catheter device comprising:
forming an elongated catheter body defining a distal portion and a
proximal portion, the elongated catheter body defining a lumen
having a proximal end and a distal end, wherein the distal portion of
the elongated body defining a distal tip; and
inserting a steerable wire along the lumen from the proximal portion of the
elongated catheter body to the distal tip, wherein actuating the
steerable wire causes at least one of a rotation and a deflection of
the distal tip; and
affixing an end of the steerable line to the distal tip.

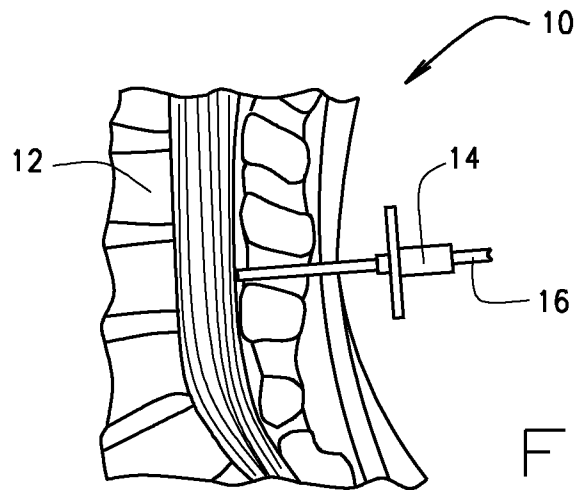


FIG. 1
PRIOR ART

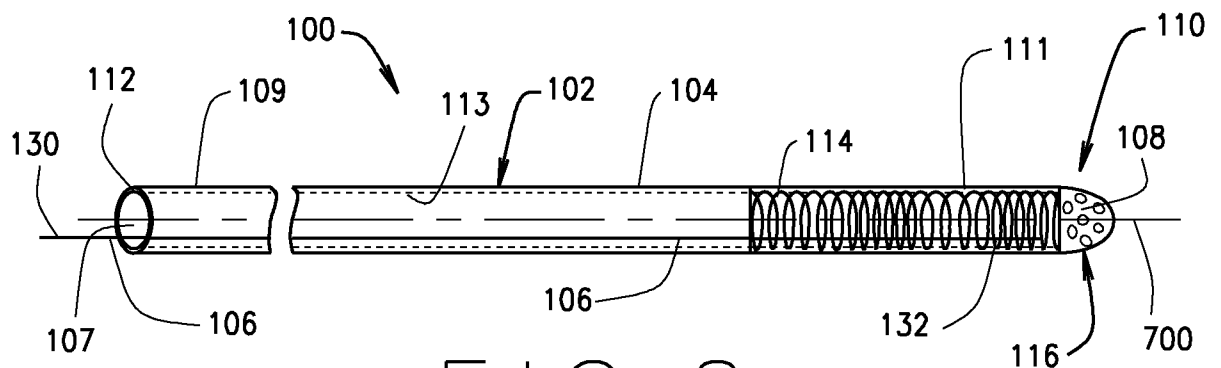


FIG. 2

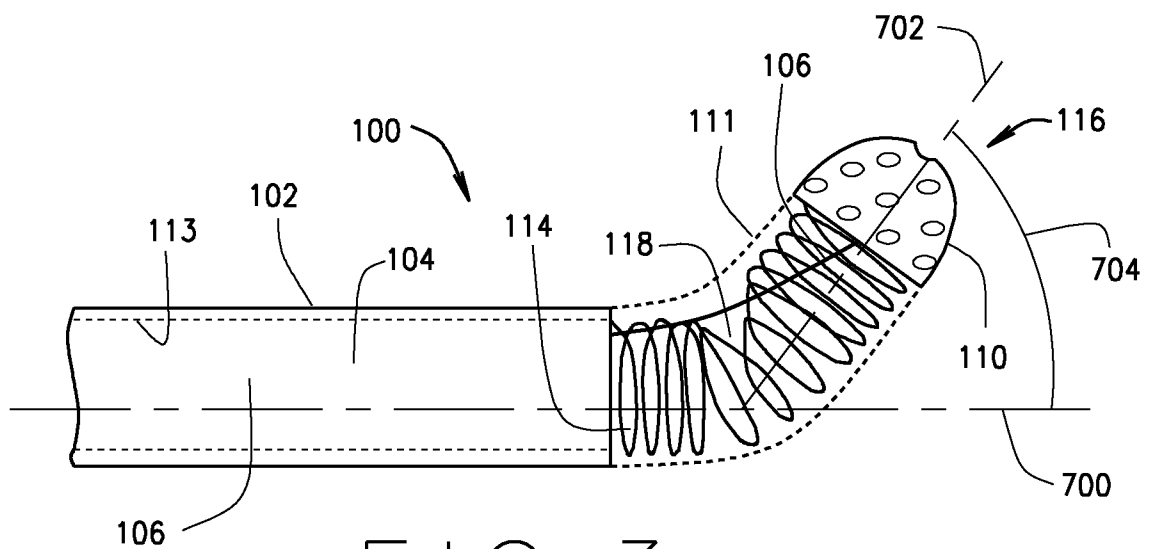


FIG. 3

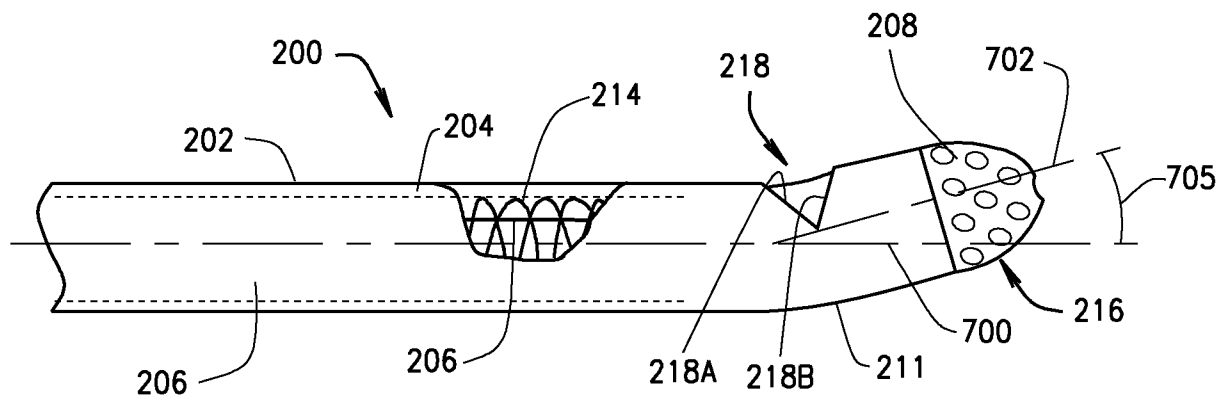


FIG. 4A

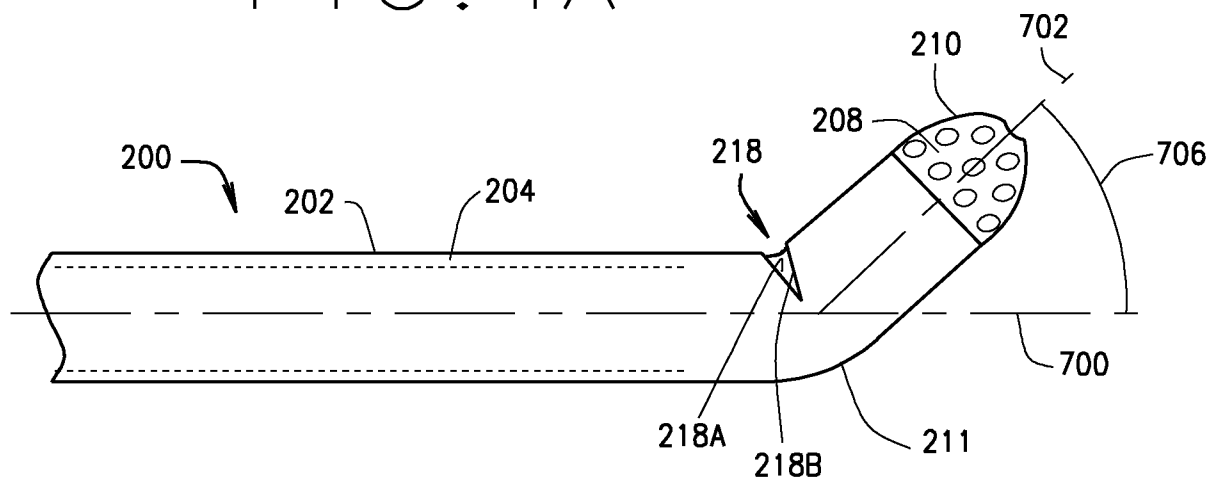


FIG. 4B

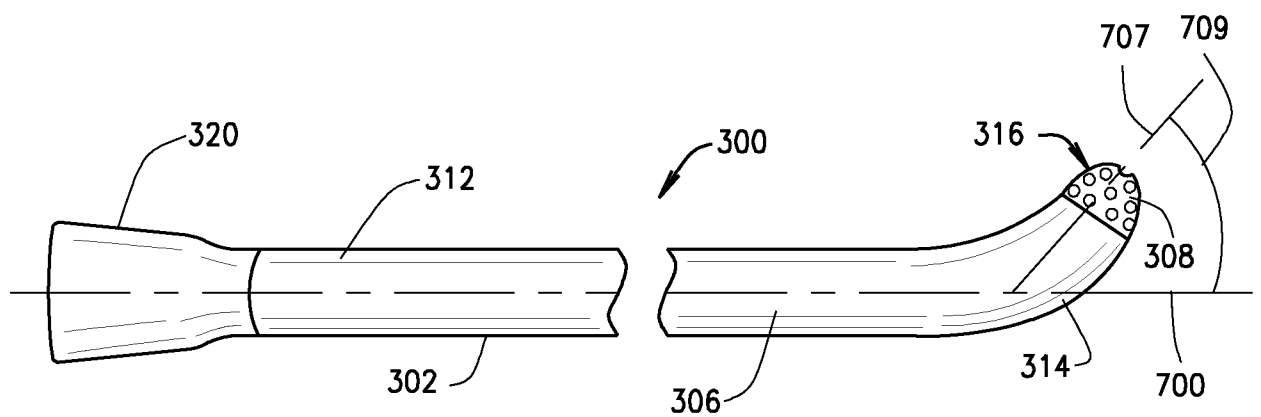
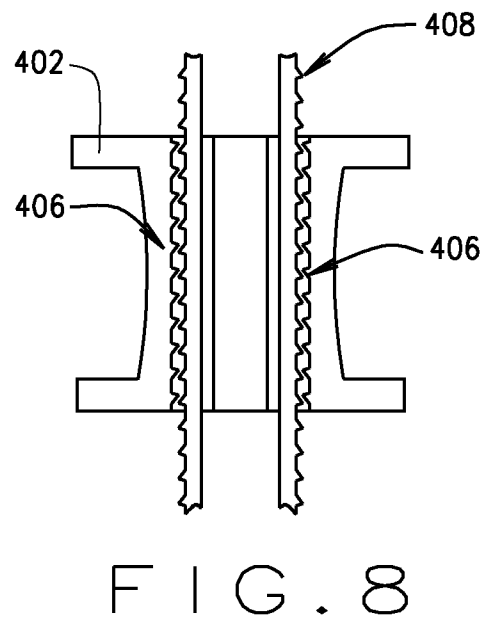
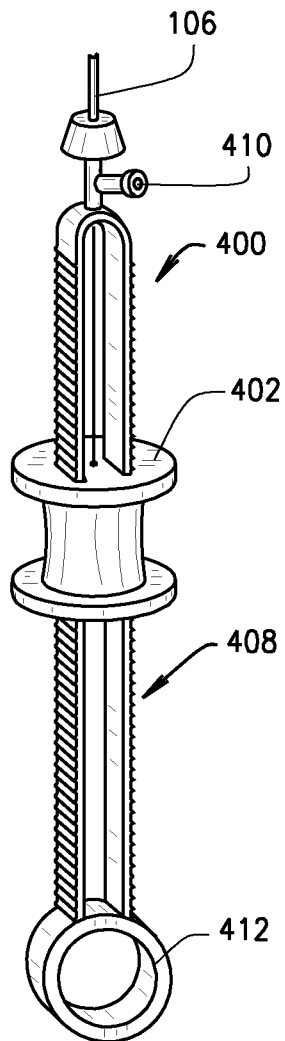
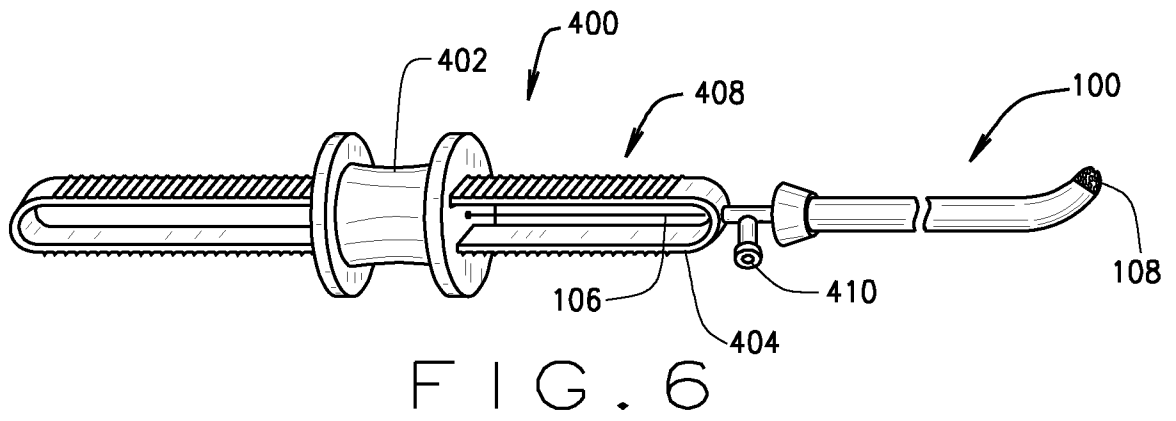


FIG. 5



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2011/041093

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/088 (2011.01)

USPC - 604/524

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)

IPC(8) - A61B 18/18; A61M 5/178, 25/00, 25/01, 25/088, 25/09, 25/092, 31/00, 35/00, 37/00 (2011.01)

USPC - 604/95.02, 95.03, 95.04, 158, 164.01, 506, 512, 523, 524, 528, 532; 606/15; 607/6, 89

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

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

PatBase, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,554,794 B1 (MUELLER et al) 29 April 2003 (29.04.2003) entire document	1-12, 30, 31
-		
Y		13-29
Y	US 7,022,109 B1 (DITTO) 04 April 2006 (04.04.2006) entire document	13-29
A	US 6,402,719 B1 (PONZI et al) 11 June 2002 (11.06.2002) entire document	1-31
A	US 2007/0203474 A1 (RYAN et al) 30 August 2007 (30.08.2007) entire document	1-31
A	US 2009/0177152 A1 (ALTMAN) 09 July 2009 (09.07.2009) entire document	1-31

☐ Further documents are listed in the continuation of Box C.


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

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"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

04 October 2011

Date of mailing of the international search report

14 OCT 2011

Name and mailing address of the ISA/US

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