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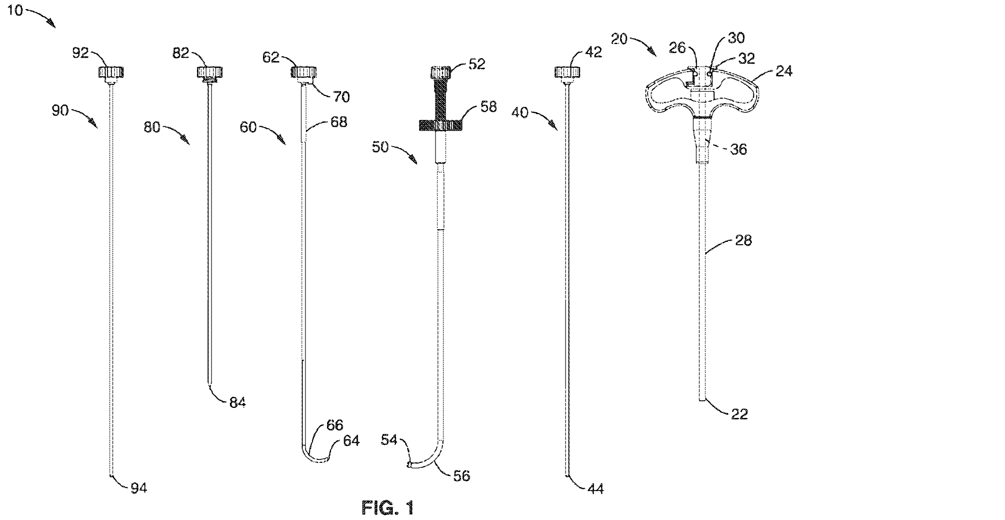

FIG. 1

(57) Abstract: System and methods are shown having a tube-within-tube assembly with a deployable curved deflectable tube or cannula that deploys from a straight cannula or trocar. The curved cannula has pre-curved distal end to create an angular range of 0° to 180° when fully deployed from the straight trocar. The curve is configured such that the flexible element carrying a treatment device can navigate through the angular range of deployment of the curved cannula. The curved cannula allows the flexible element to navigate through a curve within bone without veering off towards an unintended direction.

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SYSTEMS AND METHODS FOR NAVIGATING AN INSTRUMENT THROUGH BONE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. provisional application serial number 61/100,553 filed on September 26, 2008, incorporated herein by reference in its entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable

INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC

[0003] Not Applicable

NOTICE OF MATERIAL SUBJECT TO COPYRIGHT PROTECTION

BACKGROUND OF THE INVENTION

1. <u>Field of the Invention</u>

[0005] This invention pertains generally to generating passageways through tissue, and more particularly to creating curved paths in bone.

2. Description of Related Art

[0006] Recently, the technique of accessing the vertebral body through minimally invasive means has been developed through the surgical techniques used in vertebroplasty and kyphoplasty. Although accessing the vertebral segments of the spine through the pedicle and into the lateral / anterior section of the body of the vertebra is the primary method of placing a treatment device (e.g. a bone cement delivery device and/or an RF probe) into the vertebra, it is difficult to place a probe in the posterior midline section of the vertebra. Furthermore, accessing the posterior midline section of the S1 segment of the spine is difficult with a straight linear access route. A probe preferably needs to be capable of navigating to the posterior section of the S1 vertebral body as well as the same target area within a lumbar vertebral segment. In addition, it is contemplated that spinal segments in the cervical and thoracic spine may also be targeted.

[0007] In order to accurately and predictably place a treatment device in the posterior midline section of a lumbar vertebral body or S1 vertebral body, the device or probe needs to navigate to said area through varying densities of bone. However due to the varying densities of bone, it is difficult to navigate a probe in bone and ensure its positioning will be in the posterior midline section of the vertebral body.

[0008] Current techniques for tissue aspirations require a coaxial needle system that allows taking several aspirates through a guide needle without repositioning the guide needle. However the problem with this system is that after the first pass of the inner needle in to the lesion, subsequent passes tend of follow the same path within the mass, yielding only blood not diagnostic cells.

[0009] A scientific paper written by Kopecky et al., entitled “Side-Exiting Coaxial Needle for Aspiration Biopsy,” describes the use of a side exiting coaxial needle to allow for several aspiration biopsies. The guide needle has a side hole 1cm from the distal tip. When a smaller needle is advanced through this new guide needle, the smaller needle is deflected by a ramp inside the guide, causing the smaller needle to exit through the side hole. Although this side exiting needle is able to deflect a bone aspiration needle, it does not guarantee that the needle exits the side hole in a linear direction into the tissue site. Once the tissue aspiration needle exits the needle, it will deviate from a linear path depending on the density of the tissue and inherent material strength of the needle. This is an inherent problem the device is unable to overcome.

[0010] Accordingly, an object of the present invention is a system and method for generating a path in bone that predictably follows a predetermined curved path.

BRIEF SUMMARY OF THE INVENTION

[0011] The present invention is directed to systems and methods to deploy and navigate a flexible treatment instrument, such as an RF bipolar probe, within bone. Although the systems and methods described below are primarily directed to navigating bone through a vertebral member of the spine, and particularly to treat the BVN of a vertebral member, it is appreciated that the novel aspects of the present invention may be applied to any tissue segment of the body.

[0012] The first novel principle of this invention is the ability to navigate a curve or angle within varying densities of cancellous bone and create a straight channel at the end of the navigated curve or angle. Several systems are described.

[0013] One aspect is a method of therapeutically treating a vertebral body having an outer cortical bone region and an inner cancellous bone region, and a BVN having a trunk extending from the outer cortical bone region into the inner cancellous region and a branches extending from the trunk to define a BVN junction, comprising the steps of: a) inserting an energy device into the vertebral body, and b) exclusively depositing energy within the inner cancellous bone region of the vertebral body between, but exclusive of the BVN junction and the outer cortical bone region, to denervate the BVN.

[0014] In another aspect of the present invention, a tube-within-tube embodiment has a deployable curved Nitinol tube that deploys from a straight cannula. The Nitinol tube is pre-curved to create an angular range of approximately 0° to approximately180°, but more specifically from approximately 45° to approximately110°, when fully deployed from the straight cannula. The design of the curve is such that the flexible element (carrying the treatment device) can navigate through the angular range of deployment of the nitinol tube. The curved nitinol tube allows the flexible element to navigate through a curve within bone without veering off towards an unintended direction. Cancellous bone density varies from person to person. Therefore, creating a curved channel within varying density cancellous bone will generally not predictably or accurately support and contain the treatment device as it tries to navigate the curved channel. With the present invention, the flexible element is deployed into the bone through the curved Nitinol tube, which supports the element as it traverses through the curve. When it departs from the tube, it will do so in a linear direction towards the target zone. This design allows the user to predictably and accurately deploy the flexible element towards the target zone regardless of the density of the cancellous bone.

[0015] An aspect of the invention is a system for channeling a path into bone. The system comprises a trocar having a central channel and opening at its distal tip, and a cannula sized to be received in said central channel and delivered to said distal opening. The cannula has a deflectable tip with a preformed curve such that the tip straightens while being delivered through the trocar and regains its preformed curve upon exiting and extending past the distal opening of the trocar to generate a curved path in the bone corresponding to the preformed curve of the deflectable tip. The cannula comprises a central passageway having a diameter configured allow a treatment device to be delivered through the central passageway to a location beyond the curved path.

[0016] In one embodiment, the system further includes a straight stylet configured to be installed in the trocar, wherein the straight stylet comprises a sharp distal tip that is configured to extend beyond the distal opening of the trocar to pierce the bone as the trocar is being delivered to a treatment location within the bone.

[0017] The system may further include a straightening stylet configured to be installed in the cannula, wherein the straightening stylet comprising a rigid construction configured to straighten the distal tip of the cannula when positioned in the trocar.

[0018] In an alternative embodiment, the straightening stylet further comprises a sharp distal end to pierce the bone, and the straightening stylet and cannula are installed in the trocar in place of the straight stylet as the trocar is delivered into the bone.

[0019] In a preferred embodiment, the system further includes a curved stylet having an outer radius sized to fit within the central passageway of the curved cannula. The curved stylet is configured to be installed in the curved cannula while the curved cannula is extended past the distal opening of the trocar, the curved stylet configured to block the distal opening of the curved cannula while being delivered into the bone. Preferably, the curved stylet has a curved distal end corresponding to the curve of the curved cannula.

[0020] The curved stylet also has a sharp distal tip configured to extend past the curved cannula to pierce the bone as the cannula is delivered past the distal opening of the trocar. The curved stylet also preferably comprises an angled distal tip configured to further support and maintain the curved stylet radius as it is delivered past the distal opening of the trocar and into bone.

[0021] Preferably, the curved stylet and the curved cannula have mating proximal ends that align the curve of the curved stylet with the curve of the curved cannula.

[0022] In one embodiment, the system further includes a straight channeling stylet configured to be installed in the cannula after removing the curved stylet, wherein the straight channeling stylet is flexibly deformable to navigate the curved cannula yet retain a straight form upon exiting the curve cannula, and wherein straight channeling stylet has a length longer than the curved cannula such that it creates a linear path beyond the distal end of the curved cannula when fully extended.

[0023] Another aspect is method for channeling a path into bone to a treatment location in the body of a patient. The method includes the steps of inserting a trocar having a central channel and opening at its distal tip into a region of bone at or near the treatment location, and delivering a cannula through said central channel and to said distal opening, wherein the cannula comprises a deflectable tip with a preformed curve such that the tip straightens while being delivered through the trocar and regains its preformed curve upon exiting the trocar, and extending the cannula past the distal opening of the trocar to generate a curved path in the bone corresponding to the preformed curve of the deflectable tip. Finally, a treatment device is delivered through a central passageway in said cannula having to the treatment location beyond the curved path.

[0024] In one embodiment, inserting a trocar into a region of bone comprises inserting a stylet into the trocar such that the stylet extends beyond the distal opening of the trocar, and inserting the stylet and trocar simultaneously into the region of bone such that the stylet pierces the bone as the trocar is being delivered to a treatment location.

[0025] In another embodiment, delivering a cannula through the central channel comprises inserting a straightening stylet into the central passageway of the cannula, wherein the straightening stylet comprises a rigid construction configured to straighten the curved distal tip of the cannula, and inserting the straightening stylet and straightened cannula simultaneously into the trocar.

[0026] In an alternative embodiment, the straightening stylet further comprises a sharp distal end to pierce the bone, wherein the straightening stylet and cannula are installed simultaneously along with the trocar as the trocar is delivered into the bone.

[0027] In yet another embodiment, extending the cannula past the distal opening is done by inserting a curved stylet into the central passageway of the curved cannula such that a distal tip of the curved stylet extends to at least the distal opening of the curved cannula, and simultaneously extending the curved cannula and curved stylet from the distal end of the trocar such that the curved stylet blocks the distal opening of the curved cannula while being delivered into the bone.

[0028] In a preferred embodiment, the curved stylet has a curved distal end corresponding to the curve of the curved cannula, and wherein the curved stylet reinforces the curved shape of the curved cannula as the curved cannula is extended past the distal opening of the trocar. The curved stylet has a sharp distal tip such that it is advanced within the central passageway so that the curved stylet extends past the distal opening of the curved cannula such that the curved stylet pierces the bone as the cannula is delivered past the distal opening of the trocar.

[0029] In a further step, the curved stylet is removed from the curved cannula, and a straight channeling stylet is inserted into the curved distal end of the cannula. The straight channeling stylet is flexibly deformable to navigate the curved cannula, yet retain a straight form upon exiting the curved cannula. The straight channeling stylet is longer than the curved cannula to create a linear channel beyond the distal tip of the curved cannula.

[0030] In a preferred embodiment, the trocar is inserted through a cortical bone region and into a cancellous bone region of a vertebrae, and the curved cannula is extended though at least a portion of the cancellous bone region to a location at or near the treatment location. A preferred treatment location comprises a BVN of the vertebrae, and treatment is delivered to the treatment location to denervate at least a portion of the BVN. In one embodiment, a portion of the BVN is denervated by delivering focused, therapeutic heating to an isolated region of the BVN. In another embodiment, a portion of the BVN comprises is denervated delivering an agent to the treatment region to isolate treatment to that region. Preferably, the treatment is focused on a location of the BVN that is downstream of one or more branches of the BVN.

[0031] Another aspect is a kit for channeling a path into bone. The kit includes a trocar having a central channel and opening at its distal tip, and a cannula selected from a set of cannulas sized to be received in said central channel and delivered to said distal opening. The cannula has a deflectable distal tip with a preformed curve such that the tip straightens while being delivered through the trocar and regains its preformed curve upon exiting and extending past the distal opening of the trocar to generate a curved path in the bone corresponding to the preformed curve of the deflectable tip. The cannula comprises a central passageway having a diameter configured allow a treatment device to be delivered through the central passageway to a location beyond the curved path, wherein the set of cannulas comprises one or more cannulas that have varying preformed curvatures at the distal tip.

[0032] In a preferred embodiment, the one or more cannulas have a varying preformed radius at the distal tip. In addition, the one or more cannulas each have distal tips that terminate at varying angles with respect to the central channel of the trocar. The length of the distal tips may also be varied. The angle of the distal with respect to the central channel of the trocar may vary from 0 degrees to 180 degrees.

[0033] The kit may further include a straight stylet configured to be installed in the trocar, the straight stylet comprising a sharp distal tip that is configured to extend beyond the distal opening of the trocar to pierce the bone as the trocar is being delivered to a treatment location within the bone.

[0034] In a preferred embodiment, the kit includes a set of curved stylets having an outer radius sized to fit within the central passageway of the curved cannula, wherein each curved stylet is configured to be installed in the curved cannula while the curved cannula is extended past the distal opening of the trocar. The curved stylet is configured to block the distal opening of the curved cannula while being delivered into the bone. Each curved stylet has a varying curved distal end corresponding to the curve of a matching curved cannula in the set of curved cannulas. The curved stylet has a sharp distal tip configured to extend past the curved cannula to pierce the bone as the cannula is delivered past the distal opening of the trocar.

[0035] In another embodiment, the kit includes a set of straight channeling stylets wherein one of the set of stylets is configured to be installed in the cannula after removing the curved stylet. The straight channeling stylet is flexibly deformable to navigate the curved cannula yet retain a straight form upon exiting the curve cannula. Each of the straight channeling stylets has a varying length longer than the curved cannula such that the straight channeling stylet creates a predetermined-length linear path beyond the distal end of the curved cannula when fully extended.

[0035A] In another aspect, there is provided a system for generating a path to a target treatment site within a vertebral body, the system comprising:

an introducer assembly comprising an introducer having a lumen and a first straight stylet;

a curved cannula assembly comprising a cannula and a curved stylet;

a second straight stylet; and

a bipolar radiofrequency ("RF") energy delivery device having two electrodes configured to deliver energy to the target treatment site,

wherein the first straight stylet is configured for insertion into the lumen of the introducer such that a distal tip of the first straight stylet extends beyond an open distal tip of the introducer,

wherein the cannula comprises an internal passageway and a first alignment member at a proximal portion of the cannula,

wherein the cannula is configured to be inserted within the lumen of the introducer upon removal of the first straight stylet,

wherein a distal portion of the cannula is configured to curve to correspond to a curved distal portion of the curved stylet upon insertion of the curved stylet within the internal passageway of the cannula and advancement of a distal tip of the curved stylet to an open distal tip of the cannula,

wherein the curved stylet comprises a second alignment member configured to be aligned with the first alignment member of the cannula to facilitate proper alignment of corresponding curved distal portions of the cannula and the curved stylet,

wherein the curved cannula assembly is configured to form a curved path toward the target treatment site within an inner cancellous bone region of the vertebral body;

wherein the second straight stylet comprises a flexible channeling stylet configured to be inserted within the internal passageway of the cannula upon removal of the curved stylet, wherein a distal portion of the second straight stylet is configured to be advanced out of the open distal tip of the cannula to form a linear path beyond the curved path,

wherein the bipolar RF energy delivery device is configured to be inserted within the internal passageway of the cannula upon removal of the second straight stylet, and

wherein the energy delivered by the bipolar RF energy delivery device is configured to heat the target treatment site sufficient to denervate a basivertebral nerve at the target treatment site.

[0035B] In a further aspect, there is provided a system for generating a path to a target treatment location within a vertebral body, the system comprising:

an energy delivery device configured to deliver energy to heat the target treatment location;

a cannula having an internal passageway and an opening at a distal tip of the cannula,

wherein a portion of the cannula is curved off axis, thereby facilitating formation of a curved path within the vertebral body toward the target treatment location by a curved stylet inserted through the internal passageway of the cannula;

a straight channeling stylet configured to be inserted through the internal passageway of the cannula after removal of the curved stylet and advanced out of the opening at the distal tip of the cannula to form a linear path to the target treatment location beyond the curved path,

wherein the diameter of the internal passageway of the cannula is configured to receive the energy delivery device,

wherein the cannula has a length sufficient to provide access to the target treatment location within the vertebral body by the energy delivery device,

wherein the target treatment location is within an inner cancellous bone region of the vertebral body, and

wherein the energy is configured to heat the target treatment location sufficient to modulate a basivertebral nerve at the target treatment location.

[0035C] In another aspect, there is provided a system for generating a path to a target region within bone, the system comprising

a curved cannula assembly comprising a cannula and a curved stylet; and

a straight channeling stylet,

wherein the cannula comprises an internal passageway and a first alignment member at a proximal portion of the cannula,

wherein the cannula comprises a curved distal portion,

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wherein the curved stylet comprises a curved distal portion corresponding to the curved distal portion of the cannula,

wherein the curved stylet comprises a second alignment member configured to be aligned with the first alignment member of the cannula to facilitate proper alignment of the corresponding curved distal portions of the cannula and the curved stylet,

wherein the curved cannula assembly is configured to form a curved channel toward the target region within the bone;

wherein the straight channeling stylet is configured to be inserted within the internal passageway of the cannula upon removal of the curved stylet, and

wherein a distal tip of the straight channeling stylet is configured to be advanced out of an open distal tip of the cannula to form a linear channel beyond the curved channel.

[0035D] In a still further aspect, there is provided a method of denervating a nerve within a vertebral body, comprising:

inserting a curved stylet within a lumen of a curved cannula;

inserting the curved cannula and the curved stylet together within an inner cancellous bone region of the vertebral body through an introducer;

forming a curved path toward a treatment location within the inner cancellous bone region by advancing the curved cannula and the curved stylet together toward the treatment location;

removing the curved stylet from the curved cannula;

inserting a straight channeling stylet within the lumen of the curved cannula,

advancing a distal end of the straight channeling stylet out of an open distal end of the curved cannula and beyond an end of the curved path to form a linear working channel at the treatment location;

removing the straight channeling stylet;

inserting a treatment device through the curved cannula and positioning a distal end of the treatment device within the linear working channel, and

denervating at least a portion of a basivertebral nerve using the treatment device.

[0035E] In another aspect, there is provided method of energy delivery to a nerve within a bone of the spine, comprising:

identifying a target heating zone within an inner cancellous bone portion of the bone corresponding to a likely location of a portion of the nerve,

inserting a cannula and a first stylet together within the inner cancellous bone portion of the bone, the first stylet being slidably received within a passageway of the cannula, wherein a distal portion of the cannula and a distal portion of the first stylet are curved,

wherein the first stylet and the cannula each have mating proximal ends that align the curve of the distal portion of the first stylet with the curve of the distal portion of the curved cannula;

advancing a distal end of the first stylet and a distal end of the cannula together toward the target heating zone, thereby forming a curved path;

removing the first stylet from the cannula;

inserting a channeling stylet within the passageway of the cannula and advancing a distal end of the channeling stylet beyond the distal end of the cannula,

wherein the channeling stylet is flexibly deformable so as to navigate the cannula yet rigid enough to retain a straight form upon exiting the distal end of the cannula,

forming a linear path beyond the curved path to the target heating zone by advancing the distal end of the channeling stylet beyond the curved path;

removing the channeling stylet from the cannula;

inserting a heat-generating device through the passageway of the cannula to the target heating zone; and

generating heat within the target heating zone using the heat-generating device.

[0036] Further aspects of the invention will be brought out in the following portions of the specification, wherein the detailed description is for the purpose of fully disclosing preferred embodiments of the invention without placing limitations thereon.

[0036A] Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present disclosure as it existed before the priority date of each claim of this application.

[0036B] Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0037] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

[0038] FIG. 1 is a system for generating a curved path in bone according to the present invention.

[0039] FIG. 2 is a sectional view of the system of FIG. 1.

[0040] FIG. 3 illustrates a sectioned view of a vertebral body with a path bored through the cortical shell.

[0041] FIGS. 4A-F illustrate a method for accessing the BVN with the system of the present invention.

[0042] FIG. 5 shows an alternative system for generating a curved path in bone according to the present invention.

[0043] FIG. 6 shows the system of FIG. 5 being installed in a vertebral body.

[0044] FIGS. 7A-7B show a curved stylet in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0045] Referring more specifically to the drawings, for illustrative purposes the present invention is embodied in the apparatus generally shown in FIG. 1 through FIG. 7B. It will be appreciated that the apparatus may vary as to configuration and as to details of the parts, and that the method may vary as to the specific steps and sequence, without departing from the basic concepts as disclosed herein.

[0046] FIGS. 1 and 2 illustrate a first embodiment of the present invention comprising a system or kit 10 for forming a path through bone. The system comprises a having a needle trocar 20 (the main body of the instrument set). The trocar 20 comprises an elongate shaft 28 having a handle 24 at its proximal end 32 and a central lumen 36 passing through to the distal end 22 of the trocar 20. The central lumen 36 is generally sized to allow the other instruments in the system 10 to be slideably introduced into the patient to a treatment region. System 10 further comprises a straight stylet 80 having a sharp-tipped needle 84 at its distal end that is used with the needle trocar 20 to create the initial path through the soft tissue and cortical shell to allow access to the cancellous bone, a curved cannula 50 that is used to create/maintain the curved path within the bone/tissue. A straightening stylet 40 is used to straighten out the curve and load the curved cannula 50 into the needle trocar 20. A curved stylet 60 is used in conjunction with the curved cannula 50 to create the curved path within the bone/tissue, and a channeling stylet 90 is used to create a working channel for a treatment device (such as RF probe 100) beyond the end of the curved path created by the curved cannula 50.

[0047] The surgical devices and surgical systems described may be used to deliver numerous types of treatment devices to varying regions of the body. Although the devices and systems of the present invention are particularly useful in navigating through bone, it is appreciated that they may also be used to navigate through soft tissue, or through channels or lumens in the body, particularly where one lumen may branch from another lumen.

[0048] The following examples illustrate the system 10 applied to generating a curve bone path in the vertebral body, and more particularly for creating a bone path via a transpedicular approach to access targeted regions in the spine. In particular, the system 10 may be used to deliver a treatment device to treat or ablate intraosseous nerves, and in particular that basivertebral nerve (BVN). Although the system and methods provide significant benefit in accessing the BVN, it is appreciated that the system 10 of the present invention may similarly be used to create a bone path in any part of the body.

[0049] FIG. 3 illustrates a cross-sectional view of a vertebra 120. Recently, the existence of substantial intraosseous nerves 122 and nerve branches 130 within human vertebral bodies ("basivertebral nerves") have been identified. The nerve basivertebral 122 has at least one exit 142 point at a location along the nerve 122 where the nerve 122 exits the vertebral body 126 into the vertebral foramen 132.

[0050] Preferably, the basivertebral nerves are at, or in close proximity to, the exit point 142. Thus, the target region of the BVN 122 is located within the cancellous portion 124 of the bone (i.e., to the interior of the outer cortical bone region 128), and proximal to the junction J of the BVN 122 having a plurality of branches 130 (e.g. between points A and B along nerve 122). Treatment in this region is advantageous because only a single portion of the BVN 122 need be effectively treated to denervate or affect the entire system. Typically, treatment in accordance with this embodiment can be effectuated by focusing in the region of the vertebral body located between 60% (point A) and 90% (point B) of the distance between the anterior and posterior ends of the vertebral body. In contrast, treatment of the BVN 122 in locations more downstream than the junction J require the denervation of each branch 130.

[0051] In one approach for accessing the BVN, the patient's skin is penetrated with a surgical instrument which is then used to access the desired basivertebral nerves, i.e., percutaneously. In one embodiment, a transpedicular approach is used for penetrating the vertebral cortex to access the BVN 122. A passageway 140 is created between the transverse process 134 and spinous process 136 through the pedicle138 into the cancellous bone region 124 of the vertebral body 126 to access a region at or near the base of the nerve 122. It is appreciated that a postereolateral approach (not shown) may also be used for accessing the nerve.

[0052] FIGS. 4A-F illustrate a preferred method for accessing the BVN with the system 10 of the present invention. First, the straight stylet 80 is inserted in aperture 26 at the proximal end 32 of needle trocar 20. The straight stylet 80 is advanced down the central lumen 36 (see FIG. 2) of the trocar 20 until the proximal stop 82 abuts against handle 24 of the trocar 20, at which point the distal tip 84 of straight stylet protrudes out of the distal end 22 of the trocar 20. The tip 84 of the straight stylet 80 preferably comprises a sharp tip for piercing soft tissue and bone.

[0053] Referring now to FIG. 4A, the assembly (trocar 20 and straight stylus 80) is advanced through soft tissue to the surface of the bone. Once the proper alignment is determined, the assembly is advanced through the cortical shell of pedicle 138 and into the cancellous interior 124 of the bone.

[0054] After the proper depth is achieved, the straight stylet 80 is removed from the trocar 20, while the trocar 20 remains stationary within the vertebrae 120. The straightening stylet 40 is inserted into proximal aperture 52 (see FIG. 2)of the curved cannula 50 and advanced along the central lumen of the curved cannula 50 until the stop 42 of the stylet 40 abuts up to the proximal end of the curved cannula. This forces the distal tip of the straight stylet through the curved section 56 of the curved cannula 50 to straighten out the curve 56. It is contemplated that the straight stylet comprise a hard, non-compliant material and the distal end 56 of the curved cannula 50 a compliant, yet memory retaining material (e.g. Nitinol, formed PEEK, etc.) such that the curved 56 section yields to the rigidity of the straightening stylet 40 when installed, yet retains its original curved shape when the stylet 40 is removed.

[0055] As shown in FIG. 4B, once the straightening stylet 40 is secure and the curved cannula 50 is straight, they are inserted into the needle trocar 20 and secured. Proper alignment (e.g. prevent rotation, orient curve direction during deployment) is maintained by aligning a flat on the upper portion 58 of the curved cannula 50 to an alignment pin secured perpendicularly into the needle trocar 20 handle 24. Once the curved cannula 50 is secure, the straightening stylet 40 is removed, while the curved cannula 50 remains stationary within the trocar 20.

[0056] Referring to FIG. 4C, the curved stylet 60 is then straightened out by sliding the small tube 68 proximally to distally on its shaft towards the distal tip 64 or from the distal tip 64 proximally on its shaft towards the proximal end 62. Once the curved distal tip 66 is straightened out and fully retracted inside the small tube 68, the curved stylet 60 is inserted into the proximal aperture 52 of the curved cannula 50, which still resides inside the needle trocar 20. As the curved stylet 60 is advanced into the curved cannula 50, the small tube 68 is met by a stop 55 (see FIG. 4C). As the curved stylet 60 continues to advance the small tube 68 is held inside the handle of the curved cannula 50. This allows the curve of the stylet 60 to be exposed inside the curved cannula 50. To create the maximum force the curve of the two parts (50 & 60) must be aligned. To ensure alignment the cap on the curved stylet 60 has an alignment pin 70 which engages with alignment notch 52 on the proximal end of the curved cannula 50.

[0057] Once the stylet 60 is fully seated and aligned with the curved cannula 50 the tip of the curved stylet 60 will protrude from the tip of the curved cannula 50 by about 1/16 to 3/16 inches. This protrusion will help to drive the curve in the direction of its orientation during deployment.

[0058] Referring now to FIG. 4D, with the curved stylet 60 and the curved cannula 50 engaged, the locking nut 58 at the top of the curved cannula 50 is rotated counter clockwise to allow the cannula 50 and stylet 60 to be advanced with relation to the needle trocar 20 such that the proximal end 52 about against 58, advancing the curved cannula 50 and stylet 60 beyond the distal opening of trocar 20 to generate a curved path in the cancellous bone region 124. As the curved cannula 50 and stylet 60 are advanced they will preferably curve at a radius of 0.4 to 1.0 inches through cancellous bone and arc to an angle between 5 and 110 degrees. Once the curved cannula 50 and stylet 60 are deployed to the intended angle, the locking nut at the top of the curved cannula 50 is engaged with the needle trocar 20 to stop any additional advancement of the curved stylet cannula assembly.

[0059] Referring to FIGS. 7A-7B illustrate the tip of the curvet stylet 60, which has been formed with two angles. To help the curve deployment in the proper direction the curve 66 of the curved stylet 60 is shaped in a predetermined orientation. The angle on the inside of the curve 72 is less than the angle on the outside of the curve 74. This disparity in angle helps the stylet cannula assembly 50 & 60 curve in the bone as bone pushes against outside curve face 74 ensuring the curve radius is maintained during deployment.

[0060] Referring now to FIG. 4E, the curved stylet 60 is then removed and replaced by the channeling stylet 90. The tip 94 of the channeling stylet 90 is advanced beyond the end 54 of the curved cannula 50 towards the intended target treatment zone.

[0061] Referring now to FIG. 4F, once the channeling stylet 90 reaches the target treatment zone, it is removed creating a working channel 146. Channel 140 will generally have a first section 142 that crosses the cortical bone of the pedicle 138, followed by a curved path 144. These sections are occupied by curved cannula 50 such that a treatment device fed through the cannula 50 will have to follow the curve of the cannula 50 and not veer off in another direction. The channel may further comprise the linear extension 146 in the cancellous bone 124 to further advance the treatment device toward the treatment site T.

[0062] With the trocar 20 and curved cannula 50 still in place, a treatment device (e.g. treatment probe 100 shown in FIG. 2, with an active element 102 on the distal end 104 of elongate flexible catheter 110 is delivered to the target treatment location T to perform a localized treatment.

[0063] In a preferred embodiment, the active element 102 is delivered to the treatment site and activated to delivery therapeutic treatment energy. The treatment probe may comprise an RF delivery probe having bipolar electrodes 106 and 108 that deliver a therapeutic level of heating to stimulate or ablate the nerve 122.

[0064] It is appreciated that any number of treatment modalities may be delivered to the treatment site for therapeutic treatment. For example, treatment may be affected by monopolar or tripolar RF, ultrasound, radiation, steam, microwave, laser, or other heating means. Additionally, the treatment device may comprise a fluid delivery catheter that deposits an agent, e.g. bone cement, or other therapeutic agent, to the treatment site T. Alternatively, cryogenic cooling may be delivered for localized treatment of the BVN. Furthermore, treatment may be affected by any mechanical destruction and or removal means capable of severing or denervating the BVN. For example, a cutting blade, bur or mechanically actuated cutter typically used in the art of orthoscopic surgery may be used to affect denervation of the BVN.

[0065] In addition to or separate from treating the BVN, a sensor may be delivered to the region to preoperatively or postoperatively measure nerve conduction at the treatment region. In this configuration, the sensor may be delivered on a distal tip of a flexible probe that may or may not have treatment elements as well.

[0066] The goal of the treatment may be ablation, or necrosis of the target nerve or tissue, or some lesser degree of treatment to denervate the BVN. For example, the treatment energy or frequency may be just sufficient to stimulate the nerve to block the nerve from transmitting signal (e.g. signals indicating pain).

[0067] Once the treatment is complete, the probe 100 is withdrawn. The curved cannula 50 is then withdrawn into the needle trocar 20. The needle trocar 20 with the curved cannula 50 is then removed and the access site is closed as prescribed by the physician.

[0068] In the above system 10, the design of the curves 56 and 66 of the curved cannula 50 and curved stylet 60 is such that the flexible element (e.g. carrying the treatment device) can navigate through the angular range of deployment of the Nitinol tube of the curved cannula 50. The curved nitinol tube 50 allows the flexible element to navigate through a curve within bone without veering off towards an unintended direction. Cancellous bone density varies from person to person. Therefore, creating a curved channel within varying density cancellous bone 124 will generally not predictably or accurately support and contain the treatment device as it tries to navigate the curved channel.

[0069] With the system 10 of the present invention, the treatment device 100 is deployed into the bone through the curved Nitinol tube of the curved cannula 50, which supports the element as it traverses through the curve. When it departs from the tube, it will do so in a linear direction along path 146 towards the target zone. This allows the user to predictably and accurately deploy the treatment device towards the target zone T regardless of the density of the cancellous bone.

[0070] In some embodiments, a radius of curvature that is smaller than that which can be achieved with a large diameter Nitinol tube may be advantageous. To achieve this, the curved tube of the curved cannula 50 may take one of several forms. In one embodiment, the tube 50 is formed from a rigid polymer that can be heat set in a particular curve. If the polymer was unable to hold the desired curve, an additional stylet (e.g. curved stylet 60) of Nitinol, or other appropriate material, may also be used in conjunction with the polymer tube to achieve the desired curve. This proposed combination of material may encompass and number or variety of materials in multiple different diameters to achieve the desired curve. These combinations only need to ensure that the final outside element (e.g. trocar 20) be “disengageable” from the internal elements and have an inner diameter sufficient to allow the desired treatment device 100 to pass to the treatment region T.

[0071] In an alternative embodiment, of the curved cannula 50 may comprise a Nitinol tube having a pattern of reliefs or cuts (not shown) in the wall of the tube (particularly on the outer radius of the bend). The pattern of cuts or reliefs would allow the tube to bend into a radius tighter than a solid tube could without compromising the integrity of the tubing wall.

[0072] FIG. 5 illustrates a second embodiment of the system or kit 200 of the present invention that may be used to reduce the number of steps required for the procedure. The second embodiment includes a needle trocar 20, straightening stylet 40, used with the needle trocar 20 and the curved cannula 50 to create the initial path through the soft tissue and cortical shell to allow access to the cancellous bone, curved stylet 60 used in conjunction with the curved cannula 50 to create the curved path within the bone/tissue, and channeling stylet 90 used to create a working channel for the probe beyond the end of the curved path created by the curved stylet.

[0073] In one method according to the present invention, the straightening stylet 40 is inserted into the curved cannula 50 and secured. In this embodiment, the straightening stylet 40 has a sharp tip 46 designed to penetrate bone. Once the straightening stylet 40 is secure and the curved cannula 50 is straight, they are inserted into the needle trocar 20 and secured. In this embodiment, the curved cannula 50 and straightening stylet 40 are inserted into the shaft 28 of the trocar 20 only as far as to have sharp tip 46 of the straightening stylet 40 protrude from the distal end 22 of the trocar 20. Proper alignment is maintained by aligning a flat on the upper portion of the curved cannula 50 with a pin secured perpendicularly into the needle trocar 20 handle.

[0074] Referring now to FIG. 6, once the curved cannula 50 is secure, the assembly (trocar 20, curved cannula 50, and straightening stylet 40) is advanced through soft tissue to the surface of the bone. After finding the proper alignment at the pedicle 138 of vertebrae 120, the assembly (trocar 20, curved cannula 50, and straightening stylet 40) is advanced through the cortical shell 128 and into the cancellous interior 124 of the bone.

[0075] After the proper depth is achieved, the straightening stylet 40 is removed. The curved stylet 60 is then straightened out by sliding the small tube 68 on its shaft towards the distal tip 64. The curved distal tip 66 is straightened out and fully retracted inside the small tube 68, and then the curved stylet 60 is inserted into the curved cannula 50 which still resides inside the needle trocar 20. Once the curved stylet 60 is inserted into the curved cannula 50, the small tube 68 is met by a stop 55 (see FIG. 4C). As the curved stylet 60 continues to advance, the small tube 68 is held inside the handle of the curved cannula 50. This allows the curve of the stylet 60 to be exposed inside the curved cannula 50.

[0076] To create the maximum force, it is preferred that the curve of the two parts (50 & 60) are aligned. To ensure alignment the cap on the curved stylet 60 has an alignment pin, which engages with a notch on the top of the curved cannula 50.

[0077] When the stylet 60 is fully seated and aligned with the curved cannula 50, the tip of the curved stylet 60 will protrude from the tip of the curved cannula 50 by about 1/16 to 3/16 inches. This protrusion will help to drive the curved cannula 50 in the direction of its orientation during deployment. Once the curved stylet 60 and the curved cannula 50 are engaged, the lock nut at the top of the curved cannula 50 is rotated counter clockwise to allow the cannula 50 and stylet 60 to be advanced with relation to the needle trocar 20 (as shown in FIG. 4D). As the curved cannula and stylet are advanced they generate a curved path toward the treatment location T. Once the curved cannula 50 and stylet 60 are deployed to the intended angle, the lock nut at the top of the curved cannula 50 is engaged with the needle trocar 20 to stop any additional advancement of the curved stylet cannula assembly.

[0078] The curved stylet 60 is then removed and replaced by the channeling stylet 90. The channeling stylet 90 is advanced beyond the end of the curved cannula 50 (see FIG. 4E) towards the intended target treatment zone creating a working channel for the active element to be inserted. Once the channeling stylet 80 reached the target treatment zone it is removed and replaced by the treatment device 100, which is delivered to the treatment site T and activated.

[0079] Once the treatment is complete, the treatment device 100 is withdrawn. The curved cannula 50 is then withdrawn into the needle trocar 20. The needle trocar 20 with the curved cannula 50 is then removed and the access site is closed as prescribed by the physician.

[0080] FIGS.7A and 7B illustrate detail views of a Nitinol wire for the curved stylet 60 (proximal end not shown). The wire comprises a shaft 78 having constant diameter D and a length L_s that may vary according to the application and desired depth to the treatment location. The wire has a preformed distal tip that is curved to have a radius r that redirects the distal tip 64 at an angle Θ with the shaft. As shown in FIG. 7A, angle Θ is shown to be approximately 110˚. However, it is appreciated that the preformed tip may have an angle ranging from a few degrees (slight deflection off axis), to up to 180˚ (e.g. directing back toward the proximal end).

[0081] As shown in FIG. 7B detailing the distal tip 64, the tip may have a distal extension L_T that extends away from the shaft 78. To promote channeling along a path that follows radius r, the distal tip 64 is configured with a dual-plane bevels 74 and 72. Plane 74 is offset at angle β, and plane 72 is offset at angle α. This configuration of the leading- allows for the stylet and/or curved cannula to travel through bone in a path correlating to the specified curve in the stylet and/or cannula.

[0082] In the example illustrated in FIGS. 7A and 7B, the curved stylet 60 has a shaft length L_s of approximately 3.6 in., diameter D of approximately 0.040 in., and a distal tip length L_T of 0.125 in., radius r of 0.40 in., and angle β =35˚ and angle α= 31˚. It should be noted that the above dimensions are for illustration only, and may vary depending on the anatomy an tissue type.

[0083] It is appreciated that all the above embodiments may be provided as a kit of instruments to treat different regions of the body. For example, the location, orientation and angle of the treatment device with respect to the trocar 20 may be varied by providing a set of instruments at varying increments. This may be achieved by varying the curvature (56, 66) in the curved cannula 50 and curved stylet 60. The curvature may be varied by varying the radius of curvature r, the insertion depth (shaft length L_s and tip length L_T, and/or the final exit angle Θ with respect to the trocar 20 central bore. Thus, the physician may select a different kit for treating a lumber spine segment as opposed to a cervical spine segment, as the anatomy will dictate the path that needs to be channeled.

[0084] Thus, when treating different spine segments, a set out of the kit may be selected to match the vertebra (or other region being treated). For example, delivering the treatment device at or near the BVN junction for a lumbar vertebra may have a different angle than for a cervical vertebra, and may vary from patient to patient. The set may be selected from the kit intra-operatively, or from a pre-surgery diagnostic evaluation (e.g. radiographic imaging of the target region).

[0085] It is appreciated that each of the instruments in the embodiments 100 and 200 detailed above may have any length, shape, or diameter desired or required to provide access to the treatment region (e.g. intraosseous nerve trunk) thereby facilitating effective treatment of the target region. For example, the size of the intraosseous nerve to be treated, the size of the passageway in the bone (e.g. pedicle 138) for accessing the intraosseous nerve, and the location of the bone, and thus the intraosseous nerve, are factors that that may assist in determining the desired size and shape of the individual instruments.

[0086] The systems 100, 200 described above may be used with a number of different treatment modalities for therapeutic treatment of the target region. For example, in one embodiment, it is desirable to operate the treatment device 100 in a manner that ablates the tissue of the target region (e.g. BVN) to produce as described in U.S. Patent No. 6,699,242, herein incorporated by reference in its entirety.

[0087] In another embodiment, the treatment device is configured to deliver therapeutic treatment that is targeted to block nerve conduction without ablating the nerve, i.e. thermal treatment is delivered to the nerve (e.g. via thermal therapy, agent or the like) that results in denervation of the BVN without necrosis of tissue. This may be achieved via delivery of a lesser amount of energy or agent to the tissue site (either in the form of less exposure time, concentration, intensity, etc.) than is required for ablation, but an amount sufficient to achieve some amount of temporary or permanent denervation.

[0088] As can be seen, therefore, the present invention includes the following inventive embodiments among others:

[0089] 1. A system for channeling a path into bone, comprising: a trocar having a central channel and opening at its distal tip; and a curved cannula sized to be received in said central channel and delivered to said distal opening; the curved cannula having a deflectable tip with a preformed curve such that the tip straightens while being delivered through the trocar and regains its preformed curve upon exiting and extending past the distal opening of the trocar to generate a curved path in the bone corresponding to the preformed curve of the deflectable tip; wherein the curved cannula comprises a central passageway having a diameter configured allow a treatment device to be delivered through the central passageway to a location beyond the curved path.

[0090] 2. A system as recited in embodiment 2, further comprising: a straight stylet configured to be installed in the trocar; the straight stylet comprising a sharp distal tip that is configured to extend beyond the distal opening of the trocar to pierce the bone as the trocar is being delivered to a treatment location within the bone.

[0091] 3. A system as recited in embodiment 2, further comprising: a straightening stylet configured to be installed in the curved cannula; the straightening stylet comprising a rigid construction configured to straighten the distal tip of the curved cannula when positioned in the trocar.

[0092] 4. A system as recited in embodiment 3, wherein the straightening stylet further comprises a sharp distal end to pierce the bone; and wherein the straightening stylet and curved cannula are configured to be installed in the trocar in place of the straight stylet as the trocar is delivered into the bone.

[0093] 5. A system as recited in embodiment 1, further comprising: a curved stylet having an outer radius sized to fit within the central passageway of the curved cannula; wherein the curved stylet is configured to be installed in the curved cannula while the curved cannula is extended past the distal opening of the trocar, the curved stylet configured to block the distal opening of the curved cannula while being delivered into the bone.

[0094] 6. A system as recited in embodiment 5, wherein the curved stylet has a curved distal end corresponding to the curve of the curved cannula.

[0095] 7. A system as recited in embodiment 5, wherein the curved stylet has a sharp distal tip configured to extend past the curved cannula to pierce the bone as the cannula is delivered past the distal opening of the trocar.

[0096] 8. A system as recited in embodiment 7, wherein the curved stylet and the curved cannula have mating proximal ends that align the curve of the curved stylet with the curve of the curved cannula.

[0097] 9. A system as recited in embodiment 5, further comprising a straight channeling stylet configured to be installed in the cannula after removing the curved stylet; wherein the straight channeling stylet is flexibly deformable to navigate the curved cannula yet retain a straight form upon exiting the curve cannula; wherein straight channeling stylet has a length longer than the curved cannula such that it creates a linear path beyond the distal end of the curved cannula when fully extended.

[0098] 10. A method for channeling a path into bone to a treatment location in the body of a patient, comprising: inserting a trocar into a region of bone near the treatment location; the trocar having a central channel and opening at its distal tip; and delivering a cannula through said central channel and to said distal opening; wherein the cannula comprises a deflectable tip with a preformed curve such that the tip straightens while being delivered through the trocar and regains its preformed curve upon exiting the trocar; extending the cannula past the distal opening of the trocar to generate a curved path in the bone corresponding to the preformed curve of the deflectable tip; delivering a treatment device through a central passageway in said cannula having to the treatment location beyond the curved path.

[0099] 11. A method as recited in embodiment 10, wherein inserting a trocar into a region of bone comprises inserting a stylet into the trocar such that the stylet extends beyond the distal opening of the trocar; and inserting the stylet and trocar simultaneously into the region of bone such that the stylet pierces the bone as the trocar is being delivered to a treatment location.

[00100] 12. A method as recited in embodiment 10, wherein delivering a

cannula through the central channel comprises: inserting a straightening stylet into the central passageway of the cannula; the straightening stylet comprising a rigid construction configured to straighten the curved distal tip of the cannula; and inserting the straightening stylet and straightened cannula simultaneously into the trocar.

[00101] 13. A method as recited in embodiment 12, wherein the straightening stylet further comprises a sharp distal end to pierce the bone; and wherein the straightening stylet and cannula are installed simultaneously along with the trocar as the trocar is delivered into the bone.

[00102] 14. A method as recited in embodiment 10, wherein extending the cannula past the distal opening comprises: inserting a curved stylet into the central passageway of the curved cannula such that a distal tip of the curved stylet extends to at least the distal opening of the curved cannula; simultaneously extending the curved cannula and curved stylet from the distal end of the trocar such that the curved stylet blocks the distal opening of the curved cannula while being delivered into the bone.

[00103] 15. A method as recited in embodiment 14, wherein the curved stylet has a curved distal end corresponding to the curve of the curved cannula; and wherein the curved stylet reinforces the curved shape of the curved cannula as the curved cannula is extended past the distal opening of the trocar.

[00104] 16. A method as recited in embodiment 14, wherein the curved stylet has a sharp distal tip; wherein curved stylet is advanced within the central passageway so that the curved stylet extends past the distal opening of the curved cannula such that the curved stylet pierces the bone as the cannula is delivered past the distal opening of the trocar.

[00105] 17. A method as recited in embodiment 14, further comprising: removing the curved stylet from the curved cannula; inserting a straight channeling stylet into the curved distal end of the cannula; wherein the straight channeling stylet is flexibly deformable to navigate the curved cannula yet retain a straight form upon exiting the curved cannula; wherein the straight channeling stylet is longer than the curved cannula to create a linear channel beyond the distal tip of the curved cannula.

[00106] 18. A method as recited in embodiment 10, wherein the trocar is inserted through a cortical bone region and into a cancellous bone region of a vertebrae, and wherein the curved cannula is extended though at least a portion of the cancellous bone region to a location at or near the treatment location.

[00107] 19. A method as recited in embodiment 18, wherein the treatment location comprises a BVN of the vertebrae, the method further comprising: delivering treatment to the treatment location to denervate at least a portion of the BVN.

[00108] 20. A method as recited in embodiment 19, wherein denervating a portion of the BVN comprises delivering focused, therapeutic heating to an isolated region of the BVN.

[00109] 21. A method as recited in embodiment 19, wherein denervating a portion of the BVN comprises delivering an agent to the treatment region to isolate treatment to that region.

[00110] 22. A method as recited in embodiment 19, wherein the treatment is focused on a location of the BVN that is downstream of one or more branches of the BVN.

[00111] 23. A kit for channeling a path into bone, comprising: a trocar having a central channel and opening at its distal tip; and a cannula selected from a set of cannulas sized to be received in said central channel and delivered to said distal opening; the cannula having a deflectable distal tip with a preformed curve such that the tip straightens while being delivered through the trocar and regains its preformed curve upon exiting and extending past the distal opening of the trocar to generate a curved path in the bone corresponding to the preformed curve of the deflectable tip; wherein the cannula comprises a central passageway having a diameter configured allow a treatment device to be delivered through the central passageway to a location beyond the curved path; wherein the set of cannulas comprises one or more cannulas that have varying preformed curvatures at the distal tip.

[00112] 24. A kit as recited in embodiment 23, wherein the one or more cannulas have a varying preformed radius at the distal tip.

[00113] 25. A kit as recited in embodiment 23, wherein the one or more cannulas each have distal tips that terminate at varying angles with respect to the central channel of the trocar.

[00114] 26. A kit as recited in embodiment 25, wherein the angle of the distal tip with respect to the central channel of the trocar varies from approximately 45° to approximately 110°.

[00115] 27. A kit as recited in embodiment 23, further comprising: a straight stylet configured to be installed in the trocar; the straight stylet comprising a sharp distal tip that is configured to extend beyond the distal opening of the trocar to pierce the bone as the trocar is being delivered to a treatment location within the bone.

[00116] 28. A kit as recited in embodiment 23, further comprising: a set of curved stylets having an outer radius sized to fit within the central passageway of the curved cannula; wherein each curved stylet is configured to be installed in the curved cannula while the curved cannula is extended past the distal opening of the trocar; wherein the curved stylet configured to block the distal opening of the curved cannula while being delivered into the bone; and wherein each curved stylet has a varying a curved distal end corresponding to the curve of a matching curved cannula in the set of curved cannulas.

[00117] 29. A kit as recited in embodiment 28, wherein the curved stylet has a sharp distal tip configured to extend past the curved cannula to pierce the bone as the cannula is delivered past the distal opening of the trocar.

[00118] 30. A kit as recited in embodiment 28, wherein the curved stylet and the curved cannula have mating proximal ends that align the curve of the curved stylet with the curve of the curved cannula.

[00119] 31. A kit as recited in embodiment 28, further comprising a set of straight channeling stylets; wherein one of the set of stylets is configured to be installed in the cannula after removing the curved stylet; wherein the straight channeling stylet is flexibly deformable to navigate the curved cannula yet retain a straight form upon exiting the curve cannula; wherein each of the straight channeling stylets has a varying length longer than the curved cannula such that the straight channeling stylet creates a predetermined-length linear path beyond the distal end of the curved cannula when fully extended.

[00120] Although the description above contains many details, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. Therefore, it will be appreciated that the scope of the present invention fully encompasses other embodiments which may become obvious to those skilled in the art, and that the scope of the present invention is accordingly to be limited by nothing other than the appended claims, in which reference to an element in the singular is not intended to mean "one and only one" unless explicitly so stated, but rather "one or more." All structural, chemical, and functional equivalents to the elements of the above-described preferred embodiment that are known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the present claims. Moreover, it is not necessary for a device or method to address each and every problem sought to be solved by the present invention, for it to be encompassed by the present claims. Furthermore, no element, component, or method step in the present disclosure is intended to be dedicated to the public regardless of whether the element, component, or method step is explicitly recited in the claims. No claim element herein is to be construed under the provisions of 35 U.S.C. 112, sixth paragraph, unless the element is expressly recited using the phrase "means for."

CLAIMS

1. A system for generating a path to a target treatment site within a vertebral body, the system comprising:

an introducer assembly comprising an introducer having a lumen and a first straight stylet;

a curved cannula assembly comprising a cannula and a curved stylet;

a second straight stylet; and

a bipolar radiofrequency ("RF") energy delivery device having two electrodes configured to deliver energy to the target treatment site,

wherein the first straight stylet is configured for insertion into the lumen of the introducer such that a distal tip of the first straight stylet extends beyond an open distal tip of the introducer,

wherein the cannula comprises an internal passageway and a first alignment member at a proximal portion of the cannula,

wherein the cannula is configured to be inserted within the lumen of the introducer upon removal of the first straight stylet,

wherein a distal portion of the cannula is configured to curve to correspond to a curved distal portion of the curved stylet upon insertion of the curved stylet within the internal passageway of the cannula and advancement of a distal tip of the curved stylet to an open distal tip of the cannula,

wherein the curved stylet comprises a second alignment member configured to be aligned with the first alignment member of the cannula to facilitate proper alignment of corresponding curved distal portions of the cannula and the curved stylet,

wherein the curved cannula assembly is configured to form a curved path toward the target treatment site within an inner cancellous bone region of the vertebral body;

wherein the second straight stylet comprises a flexible channeling stylet configured to be inserted within the internal passageway of the cannula upon removal of the curved stylet,

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wherein a distal portion of the second straight stylet is configured to be advanced out of the open distal tip of the cannula to form a linear path beyond the curved path,

wherein the bipolar RF energy delivery device is configured to be inserted within the internal passageway of the cannula upon removal of the second straight stylet, and

wherein the energy delivered by the bipolar RF energy delivery device is configured to heat the target treatment site sufficient to denervate a basivertebral nerve at the target treatment site.

2. The system of Claim 1, wherein the delivered energy is configured to heat the target treatment site sufficient to ablate the basivertebral nerve.

3. The system of Claim 1 or Claim 2, wherein the delivered energy is configured to heat the target treatment site sufficient to denervate the basivertebral nerve without necrosis of tissue.

4. The system of any one of the preceding Claims, wherein the target treatment site is proximal to a junction of the basivertebral nerve.

5. The system of any one of the preceding Claims, wherein the first alignment member of the cannula comprises a notch and wherein the second alignment member of the curved stylet comprises an alignment pin.

6. The system of any one of the preceding Claims, wherein the curved distal portion of the cannula is pre-curved.

7. The system of any one of the preceding Claims, wherein the distal tip of the first straight stylet is sufficiently sharp to pierce bone tissue.

8. A system for generating a path to a target treatment location within a vertebral body, the system comprising:

an energy delivery device configured to deliver energy to heat the target treatment location;

a cannula having an internal passageway and an opening at a distal tip of the cannula,

wherein a portion of the cannula is curved off axis, thereby facilitating formation of a curved path within the vertebral body toward the target treatment location by a curved stylet inserted through the internal passageway of the cannula;

a straight channeling stylet configured to be inserted through the internal passageway of the cannula after removal of the curved stylet and advanced out of the opening at the distal tip of the cannula to form a linear path to the target treatment location beyond the curved path,

wherein the diameter of the internal passageway of the cannula is configured to receive the energy delivery device,

wherein the cannula has a length sufficient to provide access to the target treatment location within the vertebral body by the energy delivery device,

wherein the target treatment location is within an inner cancellous bone region of the vertebral body, and

wherein the energy is configured to heat the target treatment location sufficient to modulate a basivertebral nerve at the target treatment location.

9. The system of Claim 8, wherein the energy is configured to heat the target treatment location sufficient to ablate the basivertebral nerve.

10. The system of Claim 8 or Claim 9, wherein the energy is configured to heat the target treatment location sufficient to denervate the basivertebral nerve without necrosis of tissue.

11. The system of any one of Claims 8 to 10, wherein the energy delivery device comprises a bipolar radiofrequency probe comprising two electrodes.

12. The system of any one of Claims 8 to 10, wherein the energy delivery device comprises an ultrasound energy delivery device.

13. A system for generating a path to a target region within bone, the system comprising

a curved cannula assembly comprising a cannula and a curved stylet; and

a straight channeling stylet,

wherein the cannula comprises an internal passageway and a first alignment member at a proximal portion of the cannula,

wherein the cannula comprises a curved distal portion,

wherein the curved stylet comprises a curved distal portion corresponding to the curved distal portion of the cannula,

wherein the curved stylet comprises a second alignment member configured to be aligned with the first alignment member of the cannula to facilitate proper alignment of the corresponding curved distal portions of the cannula and the curved stylet,

wherein the curved cannula assembly is configured to form a curved channel toward the target region within the bone;

wherein the straight channeling stylet is configured to be inserted within the internal passageway of the cannula upon removal of the curved stylet, and

wherein a distal tip of the straight channeling stylet is configured to be advanced out of an open distal tip of the cannula to form a linear channel beyond the curved channel.

14. The system of Claim 13, wherein the curved distal portion of the cannula is pre-curved.

15. The system of Claim 13 or Claim 14, further comprising an introducer assembly comprising an introducer having a lumen and a straight sharpened stylet,

wherein the straight sharpened stylet is configured for insertion into the lumen of the introducer such that a distal tip of the straight sharpened stylet extends beyond an open distal tip of the introducer,

wherein the distal tip of the straight sharpened stylet is sufficiently sharp to pierce bone tissue, and wherein the curved cannula assembly is configured to be delivered to the target region through the lumen of the introducer upon removal of the straight sharpened stylet.

16. The system of Claim 13, further comprising a flexible bipolar radiofrequency energy delivery device having two electrodes configured to deliver energy to the target region,

wherein the energy delivery device is configured to be inserted through the internal passageway of the cannula upon removal of the straight channeling stylet, and

wherein the energy is configured to heat the target region sufficient to ablate an intraosseous nerve within the target region.

17. A method of denervating a nerve within a vertebral body, comprising:

inserting a curved stylet within a lumen of a curved cannula;

inserting the curved cannula and the curved stylet together within an inner cancellous bone region of the vertebral body through an introducer;

forming a curved path toward a treatment location within the inner cancellous bone region by advancing the curved cannula and the curved stylet together toward the treatment location;

removing the curved stylet from the curved cannula;

inserting a straight channeling stylet within the lumen of the curved cannula,

advancing a distal end of the straight channeling stylet out of an open distal end of the curved cannula and beyond an end of the curved path to form a linear working channel at the treatment location;

removing the straight channeling stylet;

inserting a treatment device through the curved cannula and positioning a distal end of the treatment device within the linear working channel, and

denervating at least a portion of a basivertebral nerve using the treatment device.

18. The method of Claim 17, further comprising inserting a distal end of the introducer through cortical bone of the vertebral body to the inner cancellous bone region.

19. The method of Claim 17 or Claim 18, wherein the treatment device comprises an energy delivery device.

20. The method of Claim 19, wherein the energy delivery device comprises a bipolar radiofrequency energy delivery probe having two electrodes configured to generate a current to heat tissue disposed between the two electrodes.

21. The method of Claim 19, wherein the energy delivery device is configured to deliver ultrasound energy.

22. The method of Claim 19, wherein the energy delivery device is configured to deliver laser energy.

23. The method of any one of Claims 17 to 22, wherein the treatment device comprises a fluid delivery device.

24. The method of any one of Claims 17 to 23, further comprising performing a diagnostic evaluation of the treatment location.

25. A method of energy delivery to a nerve within a bone of the spine, comprising:

identifying a target heating zone within an inner cancellous bone portion of the bone corresponding to a likely location of a portion of the nerve,

inserting a cannula and a first stylet together within the inner cancellous bone portion of the bone, the first stylet being slidably received within a passageway of the cannula, wherein a distal portion of the cannula and a distal portion of the first stylet are curved,

wherein the first stylet and the cannula each have mating proximal ends that align the curve of the distal portion of the first stylet with the curve of the distal portion of the curved cannula;

advancing a distal end of the first stylet and a distal end of the cannula together toward the target heating zone, thereby forming a curved path;

removing the first stylet from the cannula;

inserting a channeling stylet within the passageway of the cannula and advancing a distal end of the channeling stylet beyond the distal end of the cannula,

wherein the channeling stylet is flexibly deformable so as to navigate the cannula yet rigid enough to retain a straight form upon exiting the distal end of the cannula,

forming a linear path beyond the curved path to the target heating zone by advancing the distal end of the channeling stylet beyond the curved path;

removing the channeling stylet from the cannula;

inserting a heat-generating device through the passageway of the cannula to the target heating zone; and

generating heat within the target heating zone using the heat-generating device.

26. The method of Claim 25, wherein the heat-generating device comprises a radiofrequency probe configured to deliver radiofrequency energy to generate heat within the target heating zone.

27. The method of Claim 25, wherein the heat-generating device comprises a fluidic heating device.

28. The method of Claim 25, wherein the heat-generating device comprises a laser energy device.

29. The method of Claim 25, wherein the heat-generating device comprises an ultrasound device.

30. The method of any one of Claims 25 to 29, wherein the heat-generating device is configured to generate heat within the target heating zone sufficient to ablate a nerve within the target heating zone.

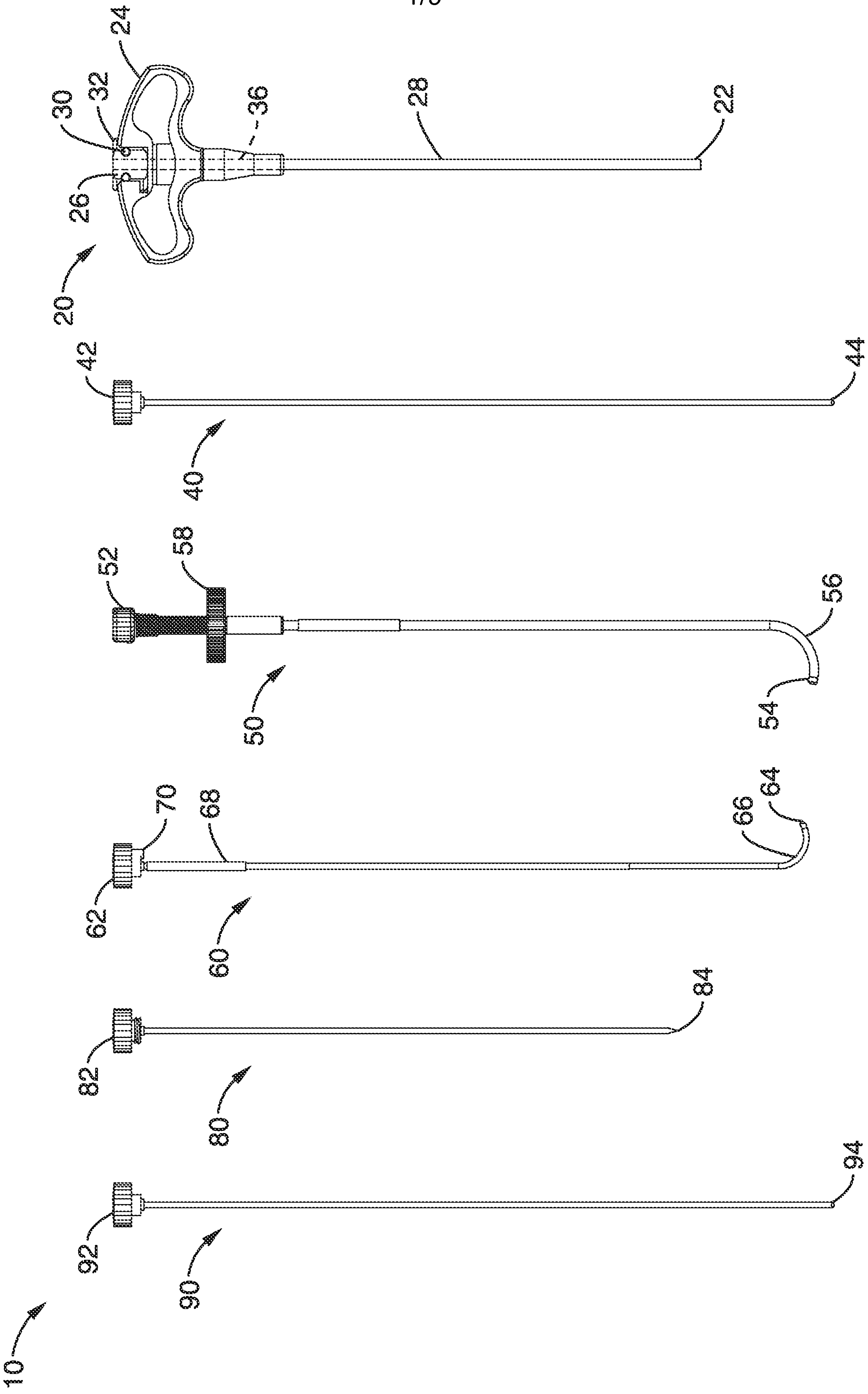
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FIG. 1

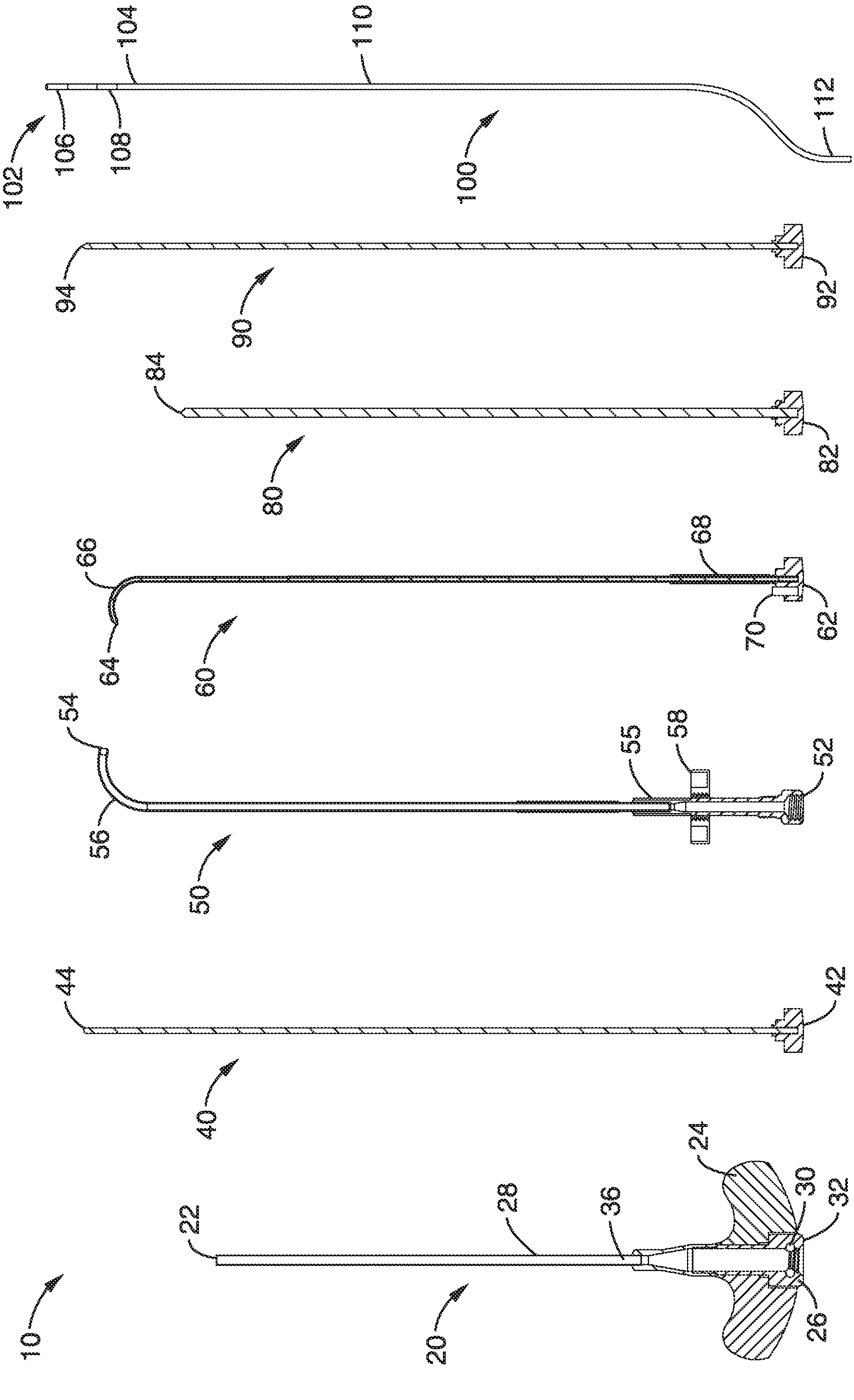
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FIG. 2

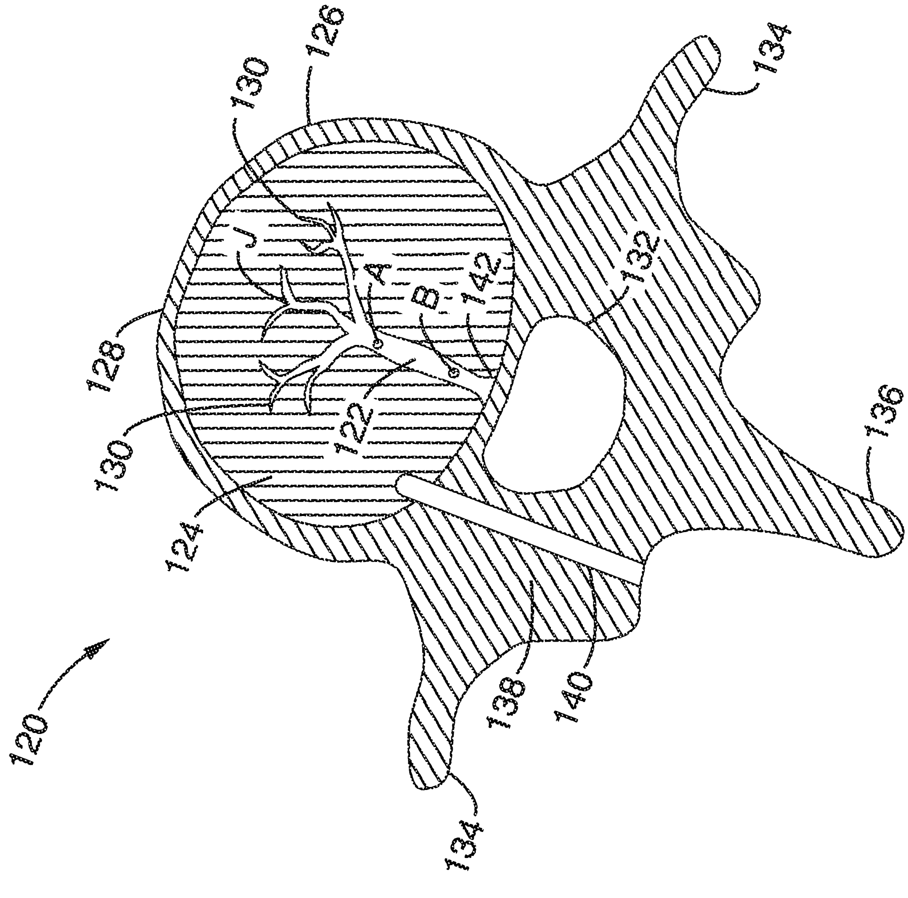

FIG. 3

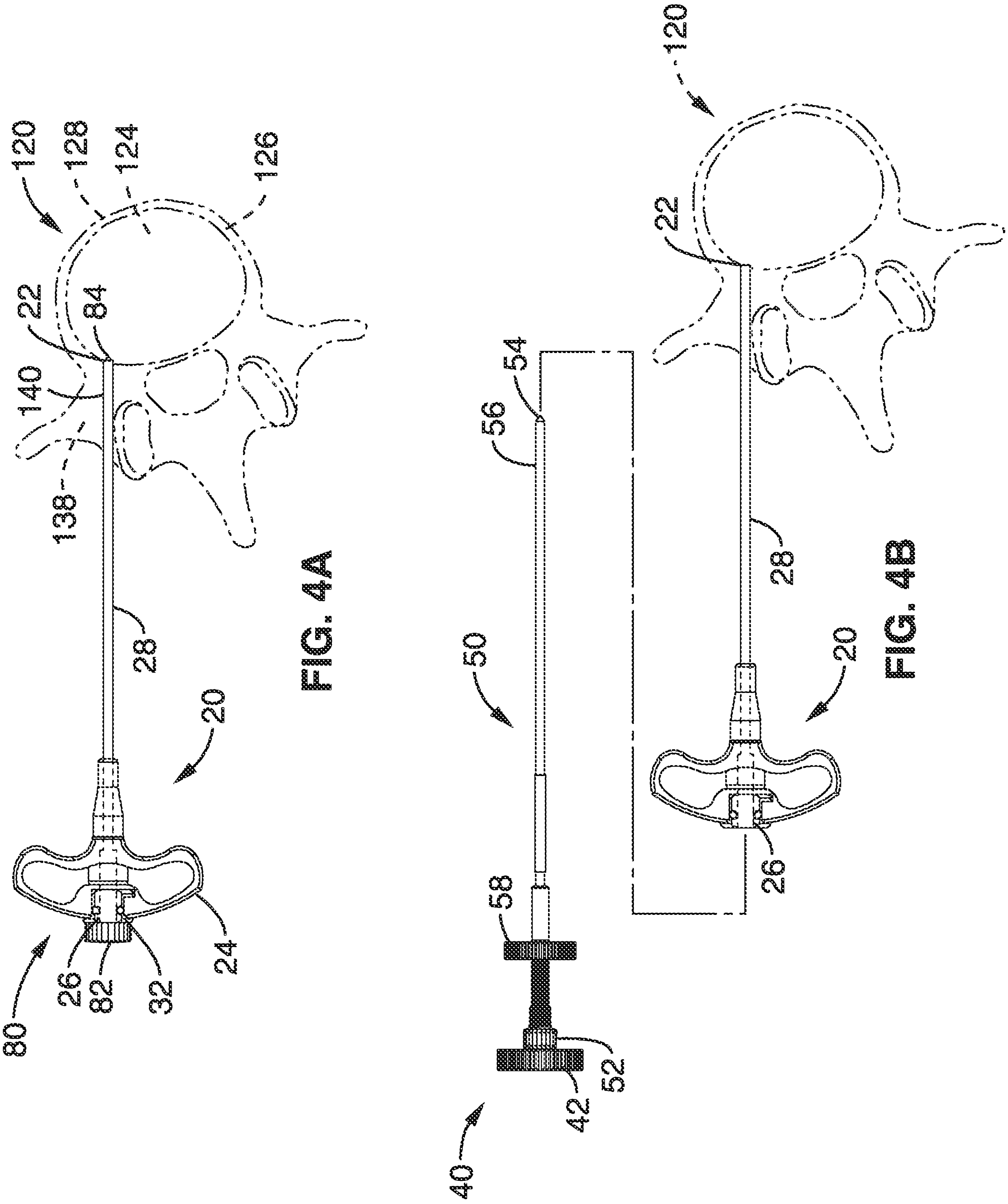
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FIG. 4A

FIG. 4B

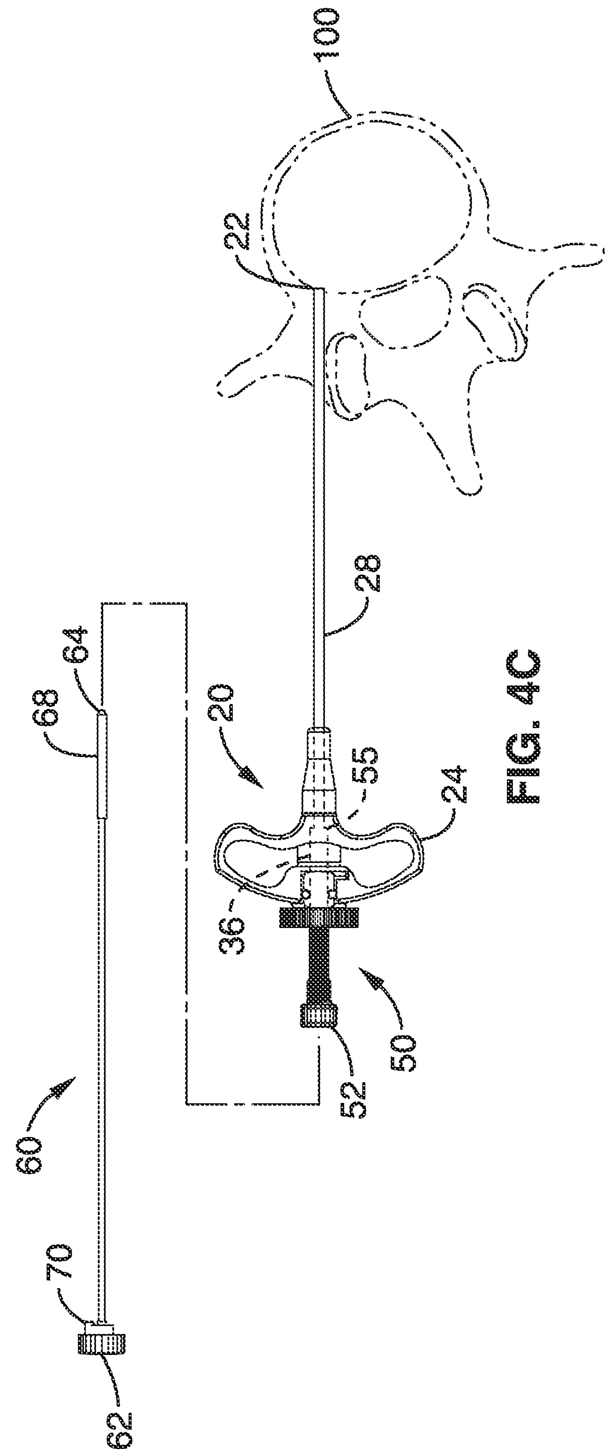
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FIG. 4C

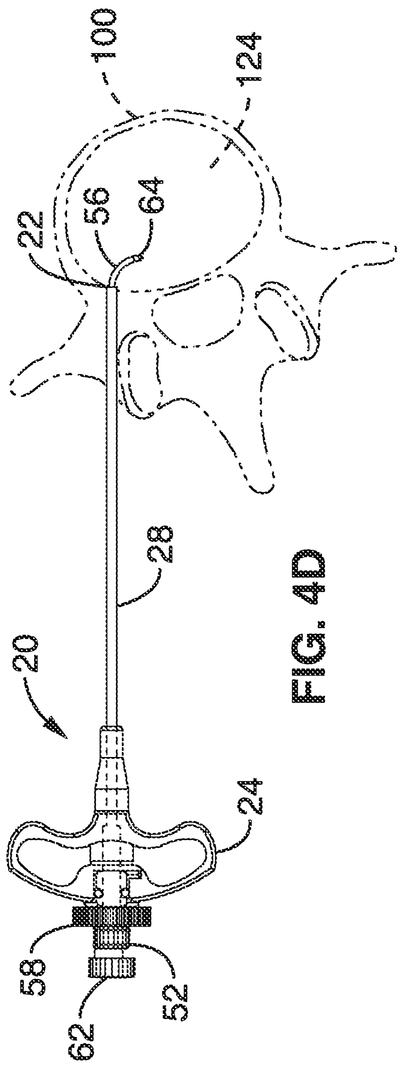
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FIG. 4D

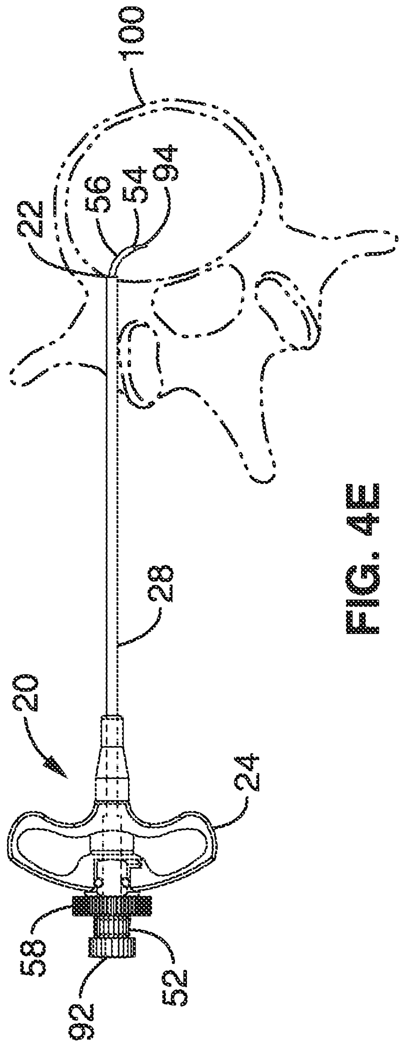
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FIG. 4E

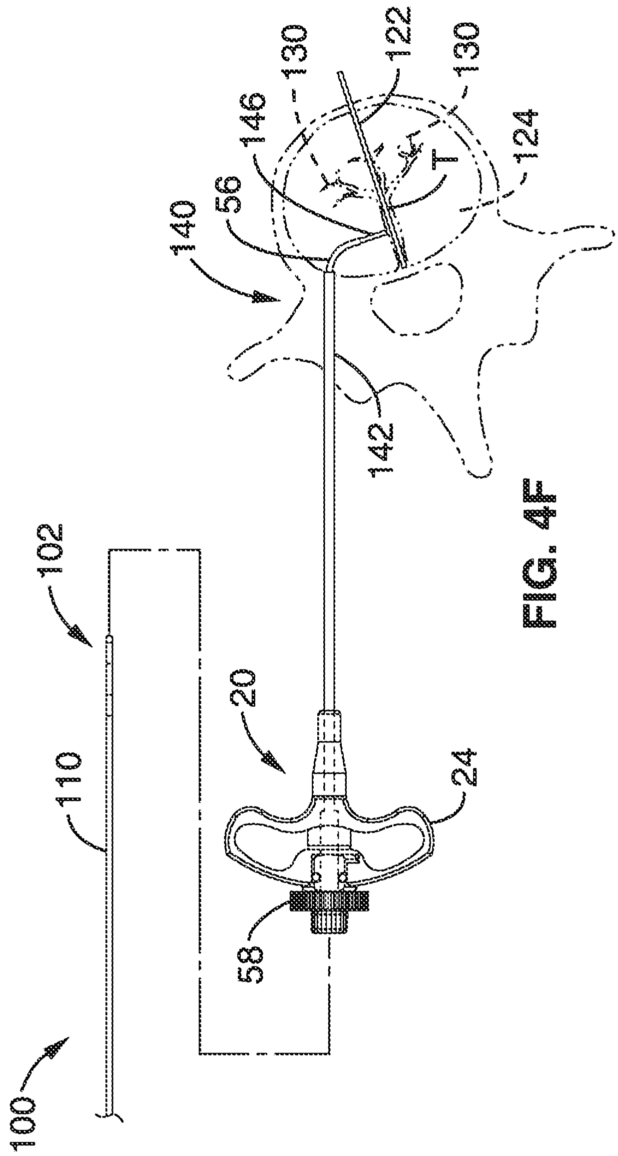
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FIG. 4F

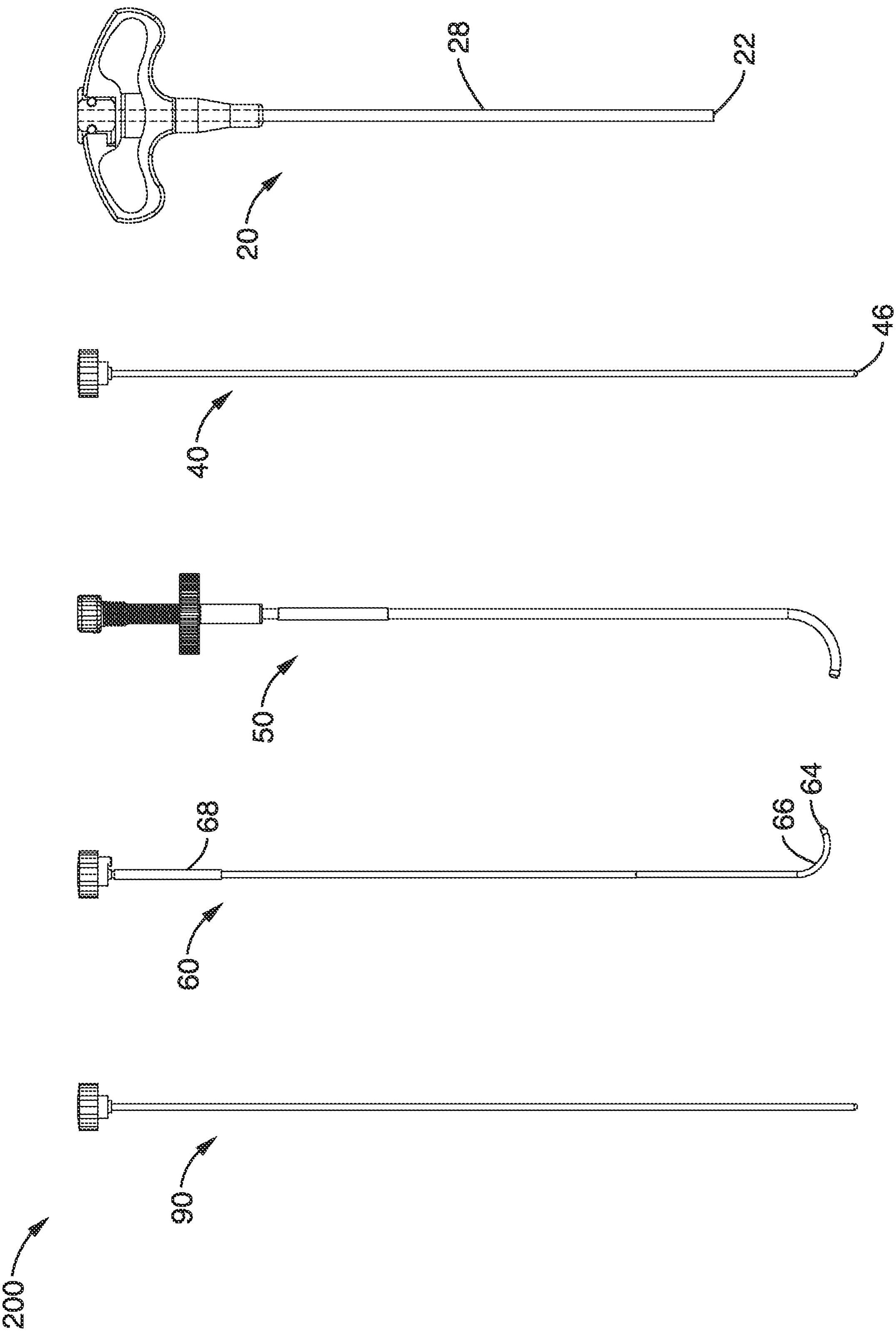

FIG. 5

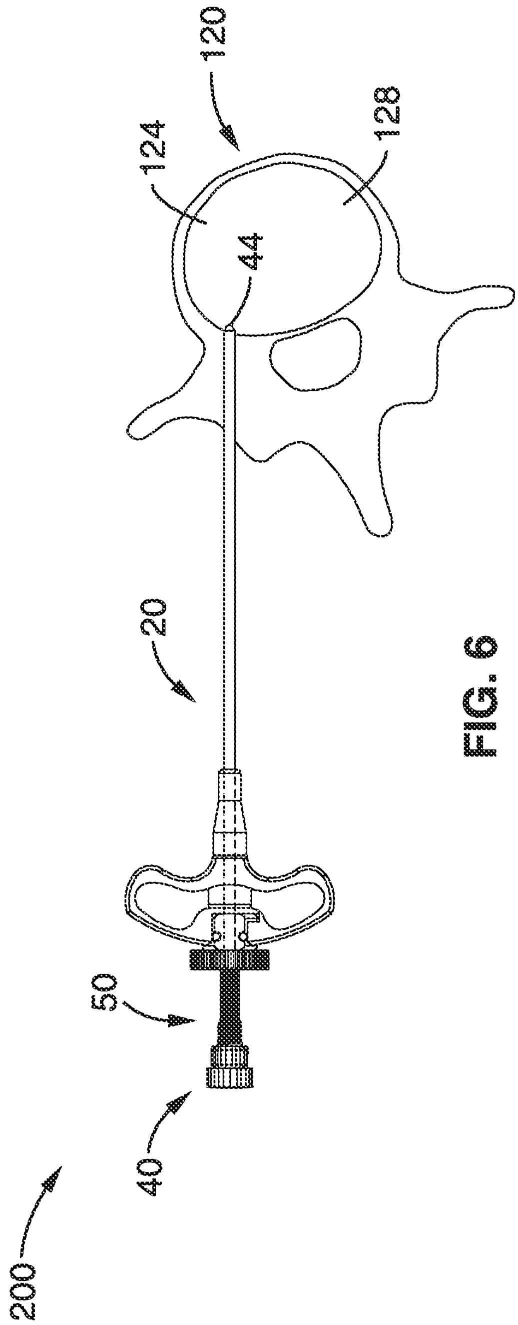

FIG. 6

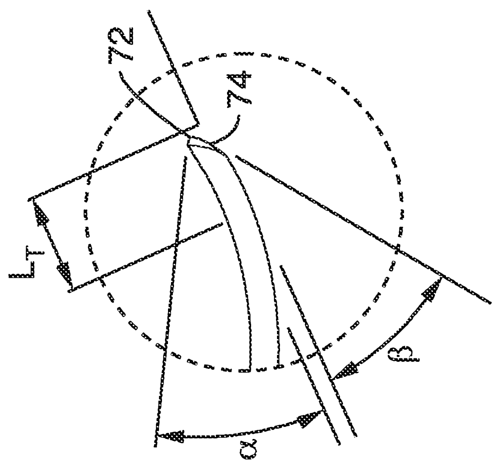

FIG. 7B

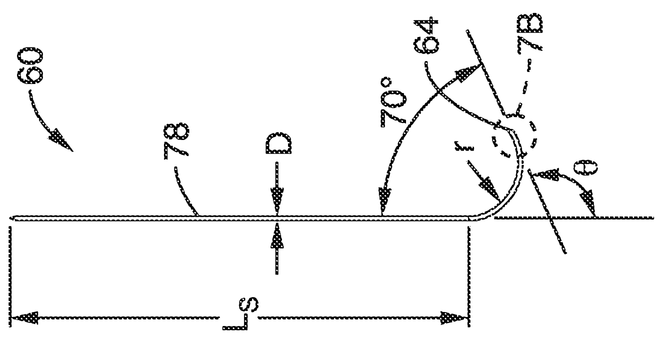

FIG. 7A