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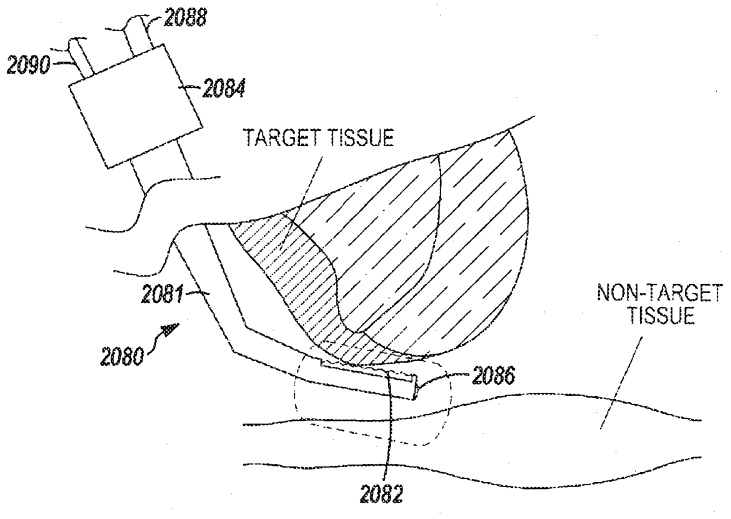
(54) Title: METHODS AND APPARATUS FOR TISSUE MODIFICATION



(57) Abstract: Apparatus for modifying tissue in a patient may include: an elongate, at least partially flexible body having a proximal portion and a distal portion; a tissue modifying member disposed along one side of the body; an atraumatic surface located adjacent the tissue modifying member; an actuator coupled with the tissue modifying member and extending to the proximal portion of the body; and means at or near the proximal and distal portions of the elongate body for facilitating application of tensioning and/or anchoring force to urge the tissue modifying member against the target tissue. In some embodiments, a flexible portion of the elongate body may be configured to extend through an intervertebral foramen of the patient's spine while the proximal and distal portions of the device extend out of the patient, and the tissue modifying member may be configured to remove soft tissue and/or bone to treat or alleviate spinal stenosis.

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METHODS AND APPARATUS FOR TISSUE MODIFICATION

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Patent Application Serial Nos.: 11/375,265 (Attorney Docket No. 026445-000700US), titled "Methods and Apparatus for Tissue Modification," filed March 13, 2006; 11/405,848 (Attorney Docket No. 026445-000720US), titled "Mechanical Tissue Modification Devices and Methods," filed April 17, 2006; 11/406,486 (Attorney Docket No. 026445-000721US), titled "Powered Tissue Modification Devices and Methods," filed April 17, 2006; 11/405,859 (Attorney Docket No. 026445-000722), titled "Tissue Modification Barrier Devices and Methods," filed April 17, 2006; and 11/429,377 (Attorney Docket No. 026445-000723US), titled "Flexible Tissue Rasp," filed May 4, 2006. The full disclosures of all the above-cited references are hereby incorporated by reference.

STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] NOT APPLICABLE

REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK.

[0003] NOT APPLICABLE

BACKGROUND OF THE INVENTION

[0004] Field of the Invention. The present invention relates to methods and apparatus for modifying tissue in a patient.

[0005] Many pathological conditions in the human body may be caused by enlargement, movement, displacement and/or a variety of other changes of bodily tissue, causing the tissue to press against (or "impinge on") one or more otherwise normal tissues or organs. For example, a cancerous tumor may press against an adjacent organ and adversely affect the functioning and/or the health of that organ. In other cases, bony growths (or "bone spurs"), arthritic changes in bone and/or soft tissue, redundant soft tissue, or other hypertrophic bone

or soft tissue conditions may impinge on nearby nerve and/or vascular tissues and compromise functioning of one or more nerves, reduce blood flow through a blood vessel, or both. Other examples of tissues which may grow or move to press against adjacent tissues include ligaments, tendons, cysts, cartilage, scar tissue, blood vessels, adipose tissue, tumor, hematoma, and inflammatory tissue.

[0006] One specific example of a condition caused by tissue impingement is spinal stenosis. Spinal stenosis occurs when neural tissue and/or vascular tissue in the spine become impinged by one or more structures pressing against them ("neural and/or neurovascular impingement"), causing one or more symptoms. This impingement of tissue may occur in one or more of several different areas in the spine, such as in the central spinal canal (the vertical passage through which the spinal cord and cauda equina extends), the lateral recesses of the spinal canal, or one or more intervertebral foramina (the openings through which nerve roots branching from the spinal cord pass).

[0007] For explanatory purposes, Fig. 1 is offered to show an approximate top view of a vertebra (one of the bones of the spinal column) with the cauda equina (the horsetail-shaped bundle of nerves that extends from the base of the spinal cord through the central spinal canal) shown in cross section and two nerve roots exiting the central spinal canal and extending through intervertebral foramina on either side of the vertebra. (Fig. 1 is not drawn to exact scale and is intended for exemplary purposes only. It should be emphasized here that the drawing figures appended to this application are not intended to be precisely anatomically correct and are provided for exemplary purposes to facilitate description.) The spinal cord and cauda equina run vertically along the spine through the central spinal canal, while nerve roots branch off of the spinal cord and cauda equina between adjacent vertebrae and extend through the intervertebral foramina.

[0008] One common cause of spinal stenosis is buckling and thickening of the ligamentum flavum (one of the ligaments attached to and connecting the vertebrae), as shown in Fig. 1. Buckling or thickening of the ligamentum flavum may impinge on one or more neurovascular structures, dorsal root ganglia, nerve roots and/or the spinal cord itself. Another common cause of neural and neurovascular compression within the spine is disease of one or more of the intervertebral discs (the malleable discs between adjacent vertebrae), which may lead to collapse, bulging or herniation of the disc. In Fig. 1, an intervertebral disc is shown with three solid-tipped arrows demonstrating how the disc might bulge or herniate into the central

spinal canal to impinge upon the spinal cord, cauda equina and/or individual nerve roots. Other causes of neural and neurovascular impingement in the spine include: hypertrophy of one or more facet joints (also known as zygopophaseal joints, facet joints provide articulation between adjacent vertebrae--two vertebral facet superior articular processes are shown in Fig. 1); formation of osteophytes (bony growths or "bone spurs") on vertebrae; spondylolisthesis (sliding of one vertebra relative to an adjacent vertebra); and (facet joint) synovial cysts. Disc, bone, ligament or other tissue may impinge on the spinal cord, the cauda equina, branching spinal nerves and/or blood vessels in the spine to cause loss of function, ischemia (shortage of blood supply) and even permanent damage of neural or neurovascular tissue. In a patient, this may manifest as pain, impaired sensation and/or loss of strength or mobility.

[0009] In the United States, spinal stenosis occurs with an incidence of between 4% and 6% of adults aged 50 and older and is the most frequent reason cited for back surgery in patients aged 60 and older. Conservative approaches to the treatment of symptoms of spinal stensosis include systemic medications and physical therapy. Epidural steroid injections may also be utilized, but they do not provide ling lasting benefits. When these approaches are inadequate, current treatment for spinal stenosis is generally limited to invasive surgical procedures to remove vertebral ligament, cartilage, bone spurs, synovial cysts, cartilage, and bone to provide increased room for neural and neurovascular tissue. The standard surgical procedure for spinal stenosis treatment includes laminectomy (complete removal of the lamina (see Fig. 1) of one or more vertebrae) or laminotomy (partial removal of the lamina), followed by removal (or "resection") of the ligamentum flavum. In addition, the surgery often includes partial or occasionally complete facetectomy (removal of all or part of one or more facet joints between vertebrae). In cases where a bulging intervertebral disc contributes to neural impingement, disc material may be removed surgically in a discectomy procedure.

[0010] Removal of vertebral bone, as occurs in laminectomy and facetectomy, often leaves the effected area of the spine very unstable, leading to a need for an additional highly invasive fusion procedure that puts extra demands on the patient's vertebrae and limits the patient's ability to move. In a spinal fusion procedure, the vertebrae are attached together with some kind of support mechanism to prevent them from moving relative to one another and to allow adjacent vertebral bones to fuse together. Unfortunately, a surgical spine fusion results in a loss of ability to move the fused section of the back, diminishing the patient's range of motion and causing stress on the discs and facet joints of adjacent vertebral segments.

[0011] While laminectomy, facetectomy, discectomy, and spinal fusion frequently improve symptoms of neural and neurovascular impingement in the short term, these procedures are highly invasive, diminish spinal function, drastically disrupt normal anatomy, and increase long-term morbidity above levels seen in untreated patients.

[0012] Therefore, it would be desirable to have less invasive methods and devices for addressing neural and neurovascular impingement in a spine. Ideally, methods and devices for addressing impingement in spine would treat one or more target tissues while preventing unwanted effects on adjacent or nearby non-target tissues. Also ideally, such methods and devices would be minimally invasive and reduce impingement without removing significant amounts of vertebral bone, joint, or other spinal support structures, thereby avoiding the need for spinal fusion and, ideally, reducing the long-term morbidity levels resulting from currently available surgical treatments. It may also be advantageous to have less invasive methods and devices for modifying target tissues in parts of the body other than the spine while preventing modification of non-target tissues. At least some of these objectives will be met by the present invention.

[0013] Description of Background Art. Flexible wire saws and chain saws, such as threadwire saws (T-saws) and Gigli saws, have been used since the late 1800s to saw through bone and other tissue in the human body. See, for example, Brunori A et al., "Celebrating the Centenial (1894-1994): Leonardo Gigli and His Wire Saw," J Neurosurg 82:1086-1090, 1995. An example of one such saw is described in U.S. Patent No. 8250, issued to P. A. Stohlmann on November 28, 1876. A description of using a T-saw to cut vertebral bone is provided in Kawahara N et al., "Recapping T-Saw Laminoplasty for Spinal Cord Tumors," SPINE Volume 24, Number 13, pp. 1363-1370.

[0014] Methods and apparatus for treating spinal stenosis are described, for example, in U.S. Patent Application Publication Nos. 2006/0264994 and 2004/0122459 and in PCT Patent Application Pub. No. WO 01/08571. A surgical instrument for removing cartilage from a knee cavity is described in U.S. Patent No. 3,835,859.

BRIEF SUMMARY OF THE INVENTION

[0015] In various embodiments, the present invention provides methods, apparatus and systems for modifying tissue in a patient. Generally, the methods, apparatus and systems may involve using an elongate, at least partially flexible tissue modification device having

one or more tissue modification members to modify one or more target tissues. The tissue modification device may be configured such that when the tissue modification member (or members) is in a position for modifying target tissue, one or more sides, surfaces or portions of the tissue modification device configured to avoid or prevent damage to non-target tissue will face non-target tissue. In various embodiments, during a tissue modification procedure, an anchoring and/or tensioning force may be applied at or near either a distal portion or a proximal portion of the tissue modification device, either inside or outside the patient. Pulling or tensioning force may also be applied to the opposite end of the device to urge the tissue modifying member(s) against target tissue. The tissue modifying members may then be activated to modify tissue while being prevented from extending significantly beyond the target tissue in a proximal or distal direction. In some embodiments, the tissue modifying members may be generally disposed along a length of the tissue modification device that approximates a length of target tissue to be modified.

[0016] By "applying an anchoring force," it is meant that a force is applied to maintain a portion of a device, or the device as a whole, substantially stable or motion-free. Applying an anchoring force is, therefore, not limited to preventing all movement of a device, and in fact, a device to which an anchoring force is applied may actually move in one or more directions in some embodiments. In other embodiments, an anchoring force is applied to maintain a portion of a device substantially stable, while another portion of the device is allowed to move more freely. As will be described in further detail below, applying an anchoring force in one embodiment involves a user of a device grasping the device at or near one of its ends. In other embodiments, devices may use one or more anchoring members to apply an anchoring force. In a number of embodiments, an anchoring force may be applied with or against one or more tissues of a patient's body, and the tissue(s) may often move even as they apply (or help apply) the force. Thus, again, applying an anchoring force to a device does not necessarily mean that all motion of the device is eliminated. Of course, in some embodiments, it may be possible and desirable to eliminate all movement or substantially all movement of a device (or portion of a device), and in some embodiments anchoring force may be used to do so.

[0017] Methods, apparatus and systems of aspects of the present invention generally provide for tissue modification while preventing unwanted modification of, or damage to, surrounding tissues. Tensioning the tissue modification device by applying anchoring force at or near one end and applying tensioning or pulling force at or near the opposite end may

enhance the ability of tissue modification members of the device to work effectively within a limited treatment space. Applying tensioning force to a predominantly flexible device may also allow the device to have a relatively small profile, thus facilitating its use in less invasive procedures and in other procedures in which alternative approaches to target tissue may be advantageous.

[0018] In the present application, "modifying tissue" or "tissue modification" may include any suitable modification to tissue, such as but not limited to cutting, removing, abrading, shrinking, burning, ablating, melting, cooling, heating, freezing, administering medication to, polishing, stenting or moving tissue. In some embodiments, the described methods, apparatus and systems may be used to modify tissue in a spine, such as for treating neural impingement, neurovascular impingement and/or spinal stenosis. In alternative embodiments, target tissues in other parts of the body may be modified.

[0019] In one aspect of the present invention, apparatus for modifying one or more tissues in a patient may include: an elongate, at least partially flexible body having a proximal portion and a distal portion; a tissue modifying member disposed along one side of the body for a limited length approximating a length of a target tissue to be treated; an atraumatic surface located adjacent the tissue modifying member to face non-target tissue; an actuator coupled with the tissue modifying member and extending to the proximal portion of the body to activate the tissue modifying member without significantly translating the elongate body proximally or distally; and means at or near the proximal and distal portions of the elongate body for facilitating application of at least one of tensioning or anchoring force to urge the tissue modifying member against the target tissue. In some embodiments, a flexible portion of the elongate body may be configured to extend through an intervertebral foramen of the patient's spine while the proximal and distal portions of the device extend out of the patient, and the tissue modifying member may be configured to remove soft tissue and/or bone to treat or alleviate spinal stenosis.

[0020] In some embodiments, the elongate body may have a width of not more than 5 mm at any point along its length. In some embodiments, the elongate body may include at least one of a guidewire connector, a guidewire lumen, a rail, a track, or a lengthwise impression along which the device may be passed over or pulled behind a delivery device. In some embodiments, the tissue modifying member may be disposed along a length of the body measuring no longer than 3 cm.

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[0021] Examples of tissue modifying members that may be included in the device include but are not limited to a rongeur, a curette, a scalpel, one or more cutting blades, a scissors, a forceps, a probe, a rasp, a file, an abrasive element, one or more small planes, an electrosurgical device, a bipolar electrode, a unipolar electrode, a thermal electrode, a rotary powered mechanical shaver, a reciprocating powered mechanical shaver, a powered mechanical burr, a laser, an ultrasound crystal, a cryogenic probe, and a pressurized water jet. In one embodiment, the tissue modifying member may comprise two opposing blades, at least one of which may be moved to bring the blades together to cut target tissue. In some embodiments, the tissue modifying member may be mobile relative to the elongate body, while in alternative embodiments, the tissue modifying member may be predominantly static relative to the elongate body. In some embodiments, the tissue modifying member may be deployable out of a window on the elongate body.

[0022] In some embodiments, the force application means may comprise proximal and distal handles configured to facilitate application of force from outside the patient, and at least one of the proximal or distal handles may be removably attachable to the elongate body. Some embodiments may optionally further include at least one shield member removably couplable with the elongate body to protect the non-target tissue from damage during a tissue modification procedure. Some embodiments may optionally further include a tissue collection chamber housed in or coupled with the elongate body.

[0023] In another aspect of the present invention, a device for modifying tissue in a spine may include: a shaft having a proximal portion and a distal portion, the distal portion having dimensions which allow it to be passed into an epidural space of the spine and between target and non-target tissues; a distal force application member extending from the distal portion of the shaft and configured to facilitate application of at least one of anchoring force or tensioning force to the shaft; a movable tissue modifying member coupled with the shaft at or near its distal portion; a drive member coupled with the tissue modifying member; and a power transmission member coupled with the drive member. In some embodiments, a flexible portion of the distal portion of the shaft may be configured to extend through an intervertebral foramen of the patient's spine while the proximal portion of the shaft and the distal force application member extend out of the patient. Also in some embodiments, the tissue modifying member is configured to remove at least one of soft tissue or bone to treat or alleviate spinal stenosis

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[0024] Some embodiments may further include a proximal force application member coupled with the shaft at or near the proximal portion and configured to facilitate application of at least one of anchoring or tensioning force to the shaft. In some embodiments, for example, the proximal force application member may comprise a handle. Such an embodiment may optionally further include an actuator coupled with the handle for activating the at least one drive member.

[0025] In some embodiments, the distal portion of the shaft may have a width of not more than 7 mm. In some embodiments, the distal portion of the shaft may have a height of not more than 2 mm. In some embodiments, the distal force application member may comprise a distal extension of the shaft. Optionally, the distal force application member may further comprise a removable distal handle.

[0026] In some embodiments, the shaft may further comprise a window on the distal portion, and the tissue modifying member may modify tissue through the window. Some embodiments may optionally include a visualization member disposed at or near the distal portion of the shaft for facilitating visualization of a tissue to be modified. Some embodiments may further include at least one lumen extending through the shaft, such as but not limited to an irrigation fluid lumen, a suction lumen, a combined irrigation/suction lumen, a guidewire lumen, a fiber optic lumen, a lumen for passage of one or more visualization devices, a lumen for passage of the power transmission member(s) and/or a lumen for passage of one or more steering members.

[0027] In various alternative embodiments, the power transmission member may comprise one or more radiofrequency, ultrasound, laser, microwave, water, thermal and/or cryogenic power transmission members. In some embodiments, the distal portion of the shaft may include a tissue protective surface disposed adjacent the tissue modifying member for preventing unwanted damage to non-target tissue during a tissue modification procedure. Some embodiments may further include at least one barrier device slidably coupled with the shaft for preventing unwanted damage to non-target tissue during a tissue modification procedure. Additionally, some embodiments may include at least one electrode coupled with the tissue protective surface or the barrier device to stimulate tissue in contact with the tissue

protective surface or the barrier device. In some embodiments, the shaft may inlcude a hollow chamber at or near its distal end for collecting removed tissue.

[0028] In another aspect of the present invention, a device for modifying tissue in a patient may include: an elongate, at least partially flexible body having a proximal portion and a distal portion, the distal portion having dimensions which allow it to be passed between target and non-target tissues in the patient; proximal and distal force application members coupled with the proximal and distal portions of the elongate body and configured to facilitate application of at least one of anchoring force and tensioning force to the elongate body; a movable tissue modifying member coupled with the elongate body; a drive member coupled with the tissue modifying member; and a power transmission member coupled with the drive member. In some embodiments, the dimensions of the elongate body may allow a flexible portion of the body to extend through an intervertebral foramen of the patient's spine while the proximal and distal portions of the device extend out of the patient. Also in some embodiments, the tissue modifying member may be configured to remove at least one of soft tissue or bone to treat or alleviate spinal stenosis.

[0029] In some embodiments, the proximal and distal force application members may each comprise a handle, and at least one of the handles may be removable. Some embodiments may further include an actuator coupled with one of the handles for activating the drive member. In some embodiments, the dimensions of the elongate body allow at least part of the body to be passed through an intervertebral foramen of the patient's spine.

[0030] In another aspect of the present invention, a barrier device for preventing unwanted damage to tissue of a patient during a tissue modification procedure may include: at least one shape changing portion changeable from a collapsed configuration, to facilitate passage into the patient, to an expanded configuration, to facilitate protection of non-target tissue; at least one elongate portion extending from the shape changing portion and having a low profile to facilitate passage of the barrier device into the patient and a length sufficient to extend from an opening on the patient's skin to an area at or near target and non-target tissues; and at least one guide feature extending along at least a portion of the barrier to allow the barrier to be passed into the patient over at least one guide member. Generally, the barrier device may have an overall length sufficient to pass from a first opening on the patient's skin and between the target and non-target tissues.

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[0031] In some embodiments, the device may have an overall length, size and configuration to allow it to extend from the first opening on the patient's skin, into an epidural space of the patient's spine, and between target and non-target tissues in the spine. In some embodiments, the overall length of the device may be sufficient to allow it to further extend from outside the patient, through the first opening, between the target and non-target tissues, and out the patient through a second opening on the patient's skin.

[0032] In some embodiments, the at least one elongate portion may include a proximal elongate portion extending from a proximal end of the shape changing portion and a distal elongate portion extending from a distal end of the shape changing portion. In some embodiments, the device may further include a barrier delivery sheath through which the barrier device may be passed into the patient. In some embodiments, the shape changing portion may change shape automatically when released from the barrier delivery device. In other embodiments, the device may further include at least one actuator coupled with the shape changing portion to change it from its collapsed to its expanded configuration.

[0033] In some embodiments, the at least one guide feature is selected from the group consisting of guidewire lumens, split lumens, rails, tracks and lengthwise impressions. In some embodiments, at least one guide feature is configured to facilitate guidance of one or more tissue modification devices along the barrier member. Some embodiments may further include at least one conductive electrode coupled with the barrier device for delivering electric current to at least one of the target tissue or non-target tissue. The device may optionally further include at least one monitoring device for monitoring an effect of the electric current on the tissue, the monitoring device selected from the group consisting of electromyography (EMG) monitoring devices and somatosensory evoked potential (SSEP) monitoring devices.

[0034] In some embodiments, the shape changing portion of the barrier device may include a front surface for facing a tissue modification device for performing a procedure in the spine and a back surface for facing non-target tissue. In some embodiments, the shape changing portion may be selected from the group consisting of an expandable scaffold, a hydrogel material, a wire mesh, an expandable stent and an inflatable bladder.

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[0035] In another aspect of the present invention, a device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis may include: an elongate, at least partially flexible body having a proximal portion and a distal portion; an abrasive surface disposed along a portion of one side of the elongate body; a non-abrasive surface located adjacent the abrasive surface so as to face non-target tissue when the abrasive surface is positioned to face target tissue; a proximal tensioning member coupled with the elongate body at or near the proximal portion for facilitating application of tensioning force to, and translation of, the elongate body; and a distal tensioning member, coupled with the elongate body at or near the distal portion and not directly connected to the proximal tensioning member, for facilitating application of tensioning force to, and translation of, the elongate body.

[0036] In one embodiment, the elongate body may have a width of not more than 5 mm and a height of not more than 2 mm. In some embodiments, the elongate body may include a guidewire connector, a guidewire lumen, a rail, a track, and/or a lengthwise impression along which the device may be passed over or pulled behind a delivery device. In some embodiments, each of the proximal and distal tensioning members may comprise a handle, and at least one of the handles may be removably attachable to the elongate body. In another embodiment, at least one of the proximal and distal tensioning members may be deployable from within the elongate body.

[0037] Some embodiments may further include at least one shield member coupled with the elongate body to protect the non-target tissue from damage during a tissue modification procedure. In some embodiments, the shield member may include at least one anchor for anchoring the shield member outside the patient. In some embodiments, the anchor may include proximal and distal anchors that may be removably couplable with the shield member at or near proximal and distal portions thereof. In some embodiments, the shield member may include at least one window along its length, through which the abrasive surface may be exposed to modify target tissue. Some embodiments may optionally further include at least one electrode coupled with the shield member for testing positioning of the shield member. Optionally, some embodiments may also include at least one electrode coupled with the tissue modifying device at or near at least one of the abrasive surface and the non-abrasive surface for testing positioning of the device. In some embodiments, the device may also include at least one lumen in the elongate body for providing at least one of suction and irrigation.

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[0038] In another aspect of the present invention, a device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis may include: an elongate, at least partially flexible shield member having a proximal portion, a distal portion and at least one opening along its length; an elongate, at least partially flexible tissue modification member disposed at least partly within the shield member, the tissue modification member having a proximal portion, a distal portion, and at least one abrasive surface; at least one proximal tensioning member at or near the proximal portion of at least one of the shield member and the tissue modification member for facilitating application of tensioning force in a first direction; and at least one distal tensioning member at or near the distal portion of at least one of the shield member and the tissue modification member and not directly connected to the proximal tensioning member, for facilitating application of tensioning force in a second direction.

[0039] In another aspect of the present invention, a method for modifying tissue in a patient may involve: advancing an elongate, at least partially flexible tissue modification device into a patient and between target tissue and non-target tissues; positioning a tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member faces the target tissue and does not face the non-target tissue; applying tensioning forces to the tissue modification device at or near distal and proximal portions of the device, to urge the tissue modifying member against the target tissue; and modifying the target tissue, using the tissue modifying member, while preventing the tissue modifying member from extending significantly beyond the target tissue toward the proximal or distal portion of the tissue modification device during tissue modification.

[0040] In some embodiments, advancing the tissue modification device may involve advancing a flexible portion of the device into an epidural space and through a spinal channel of the patient's spine, such that the proximal and distal portions of the device extend outside the patient. In some embodiments, advancing the tissue modification device may involve advancing the flexible portion along a curved path through an intervertebral foramen. In some embodiments, modifying the target tissue may involve removing soft tissue and/or bone in the spine to treat or alleviate spinal stenosis.

[0041] In another aspect of the present invention, a device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis is provided, the device comprising: an elongate,

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at least partially flexible body having a proximal portion and a distal portion; an abrasive surface disposed along a portion of one side of the elongate body; a non-abrasive surface located adjacent the abrasive surface so as to face non-target tissue when the abrasive surface is positioned to face target tissue; a proximal tensioning member coupled with the elongate body at or near the proximal portion for facilitating application of tensioning force to, and translation of, the elongate body; and, at least one coupler at or near the distal portion of the elongate body for coupling a distal tensioning member to the elongate body such that it is not directly connected to the proximal tensioning member, wherein the distal tensioning member facilitates an application of a tensioning force to, and translation of, the elongate body.

[0042] In some embodiments of the present invention, a device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis is provided, the device comprising: an elongate, at least partially flexible body having a proximal portion and a distal portion; at least one abrasive surface disposed along a portion of one side of the elongate body; at least one non-abrasive surface located adjacent the at least one abrasive surface so as to face non-target tissue when the abrasive surface is positioned to face target tissue; at least one proximal tensioning member coupled with the elongate body at or near the proximal portion for facilitating application of tensioning force to, and translation of, the elongate body; and, at least one distal tensioning member, coupled with the elongate body by at least one coupler provided at or near the distal portion such that the distal tensioning member is not directly connected to the proximal tensioning member, for facilitating application of tensioning force to, and translation of, the elongate body.

[0043] In some embodiments of the present invention, a device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis is provided, the device comprising: an elongate, at least partially flexible shield member having a proximal portion, a distal portion and at least one opening along its length; an elongate, at least partially flexible tissue modification member disposed at least partly within the shield member, the tissue modification member having a proximal portion, a distal portion, and at least one abrasive surface; at least one proximal tensioning member at or near the proximal portion of at least one of the shield member and the tissue modification member for facilitating application of tensioning force in a first direction; and, at least one distal tensioning member coupled to at least one of the shield member and the tissue modification member by at least one coupler

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provided at or near the distal portion of at least one of the shield member and the tissue modification member such that the distal tensioning member is not directly connected to the proximal tensioning member, for facilitating application of tensioning force in a second direction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0044] FIG. 1 is cross-sectional view of a spine, showing a top view of a lumbar vertebra, a cross-sectional view of the cauda equina, and two exiting nerve roots;

[0045] FIG. 2 is a cross-sectional view of a portion of a patient's back and spine, showing part of a vertebra and apparatus in place for modifying tissue according to one embodiment of the present invention;

[0046] FIG. 3A is a perspective view of a tissue modification device according to one embodiment of the present invention;

[0047] FIG. 3B is a perspective view of a portion of the tissue modification device of FIG. 3A;

[0048] FIG. 3C is a top view of the portion shown in FIG. 3B;

[0049] FIG. 3D is a side view of the portion shown in FIGS. 3B and 3C;

[0050] FIGS. 3E and 3F are cross-sectional views of a portion of the tissue modification device taken through lines A-A and B-B, respectively, shown in FIG. 3C;

[0051] FIG. 3G is a perspective view of a portion of the tissue modification device of FIGS. 3B-3F, shown with a blade of the device in a closed position according to one embodiment of the present invention;

[0052] FIG. 3H is a top view of the portion shown in FIG. 3G;

[0053] FIG. 3I is a side view of the portion shown in FIGS. 3G and 3H;

[0054] FIG. 4A is a perspective view of a tissue modification device according to one embodiment of the present invention;

[0055] FIG. 4B is a perspective view of a portion of the tissue modification device of FIG. 4A;

[0056] FIG. 4C is a close-up, perspective view of a portion of the tissue modification device of FIGS. 4A and 4B, showing a tissue modifying member according to one embodiment of the present invention;

[0057] FIGS. 5A-5D are cross-sectional views of a spine and demonstrate a method for using a tissue modification device according to one embodiment of the present invention;

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[0058] FIG. 6A is a cross-sectional view of a portion of a patient's spine and back, with apparatus for modifying tissue in position for modifying spinal tissue and with a distal portion of the apparatus anchored outside the patient according to one embodiment of the present invention;

[0059] FIG. 6B is a cross-sectional view of a portion of a patient's spine and back, with apparatus for modifying tissue in position for modifying spinal tissue and with a distal portion of the apparatus anchored inside the patient according to one embodiment of the present invention;

[0060] FIGS. 7A-7O are cross-sectional views of a portion of a patient's spine and back, demonstrating a method for introducing apparatus for modifying spinal tissue to an area in the spine for performing the tissue modification according to one embodiment of the present invention;

[0061] FIGS. 8A-8F are cross-sectional views of a portion of a patient's spine and back, demonstrating a method for introducing apparatus for modifying spinal tissue to an area in the spine for performing the tissue modification according to an alternative embodiment of the present invention;

[0062] FIGS. 9A-9B are cross-sectional views of a portion of a patient's spine and back, demonstrating a method for introducing apparatus for modifying spinal tissue to an area in the spine for performing the tissue modification according to an alternative embodiment of the present invention;

[0063] FIG. 10A is a perspective view of a distal portion of an introducer sheath according to one embodiment of the present invention;

[0064] FIGS. 10B and 10C are perspective and cross-sectional views, respectively, of a tissue shield device according to one embodiment of the present invention; and

[0065] FIGS. 10D and 10E are perspective and cross-sectional views, respectively, of a tissue shield device according to an alternative embodiment of the present invention.

[0066] FIGS. 11A and 11B are cross-sectional views of a spine with a tissue modification device in position for modifying tissue according to various embodiments of the present invention.

[0067] FIG. 12 is a cross-sectional view of a portion of a spine with a tissue modification device in position for modifying tissue according to an alternative embodiment of the present invention.

[0068] FIGS. 13A-13E are cross-sectional views of a portion of a spine with a tissue modification device in position for modifying tissue according to various alternative embodiments of the present invention.

[0069] FIGS. 13F and 13G are cross-sectional views of a portion of the tissue modification device of FIG. 13E, through line C-C on FIG. 13E, in various configurations according to one embodiment of the present invention.

[0070] FIG. 14 is a cross-sectional view of a portion of a spine with a tissue modification device having a steerable distal portion in position for modifying tissue according to one embodiment of the present invention.

[0071] FIG. 15A is a cross-sectional view of a portion of a spine with a tissue modification device in position for modifying tissue according to one embodiment of the present invention.

[0072] FIG. 15B is a close-up of portion D-D of FIG. 15A.

[0073] FIG. 16 is a cross-sectional view of a portion of a spine with a tissue modification device in position for modifying tissue according to one embodiment of the present invention.

[0074] FIGS. 17A-17E are cross-sectional views taken through line A-A of FIG. 16 according to various alternative embodiments of the present invention.

[0075] FIG. 18 is a cross-sectional view taken through line B-B of FIG. 16 according to one embodiment of the present invention.

[0076] FIGS. 19A-22 are perspective or side views of a distal portion of a tissue modification device according to various alternative embodiments of the present invention.

[0077] FIGS. 23A and 23B are perspective views of a distal portion of a tissue modification device according to alternative embodiments of the present invention.

[0078] FIGS. 24A and 24B are side views of a distal portion of a tissue modification device according to one embodiment of the present invention.

[0079] FIG. 25A is a perspective view of a mesh-type barrier device deploying from a sheath according to one embodiment of the present invention.

[0080] FIG. 25B is a top view of the mesh-type barrier device of Fig. 25A in its free state, prior to loading in a sheath.

[0081] FIG. 25C is a perspective view of a flexible tab-type barrier device deploying from a sheath according to an alternative embodiment of the present invention.

[0082] FIG. 25D is a top view of the flexible tab-type barrier device of Fig. 25C in its free state, prior to loading in a sheath.

[0083] FIG. 25E is a perspective view of a slit-type barrier device deploying from a sheath according to an alternative embodiment of the present invention.

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[0084] FIG. 25F is a top view of the slit-type barrier device of Fig. 25E in its free state, prior to loading in a sheath.

[0085] FIG. 25G is a perspective view of a rib-type barrier device deploying from a sheath according to an alternative embodiment of the present invention.

[0086] FIG. 25H is a top view of the rib-type barrier device of Fig. 25G in its free state, prior to loading in a sheath.

[0087] FIG. 25I is a perspective view of a sheet-type barrier device deploying from a sheath according to an alternative embodiment of the present invention.

[0088] FIG. 25J is a top view of the sheet-type barrier device of Fig. 25I in its free state, prior to loading in a sheath.

[0089] FIG. 25K is a perspective view of a bar-type barrier device deploying from a sheath according to an alternative embodiment of the present invention.

[0090] FIG. 25L is a top view of the bar-type barrier device of Fig. 25K in its free state, prior to loading in a sheath.

[0091] FIGS. 26A and 26B are perspective views of a woven tube barrier device in low-profile and expanded states, respectively, according to one embodiment of the present invention.

[0092] FIGS. 27A and 27B are perspective views of a flat woven barrier device in low-profile and expanded states, respectively, according to one embodiment of the present invention.

[0093] FIGS. 28A and 28B are perspective views of a barrier device with a pull-mechanism in low-profile and expanded states, respectively, according to one embodiment of the present invention.

[0094] FIG. 29A is a perspective view of a cylindrical housing for a barrier device in an un-
25 deployed state according to one embodiment of the present invention.

[0095] FIG. 29B is a perspective view of the cylindrical housing of Fig. 29A and a barrier device deployed from the housing according to one embodiment of the present invention.

[0096] FIGS. 30A-30C are perspective views of a hydrogel material barrier device in the process of unrolling/expanding after exposure to a fluid according to one embodiment of the
30 present invention.

[0097] FIGS. 31A-31C are perspective and side views of a barrier device made from a plurality of curved elements according to one embodiment of the present invention.

[0098] FIGS. 32A and 32B are perspective views of a barrier device and a tissue modification device according to one embodiment of the present invention.

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[0099] FIGS. 33A and 33B are perspective views of a barrier device and a tissue modification device according to an alternative embodiment of the present invention.

[0100] FIG. 34 is a perspective view of a barrier device and a tissue modification device according to an alternative embodiment of the present invention.

[0101] FIG. 35 is a perspective view of a barrier device and a tissue modification device according to an alternative embodiment of the present invention.

[0102] FIGS. 36A and 36B are end-on views of a barrier device according to alternative embodiments of the present invention.

[0103] FIGS. 37A and 37B are end-on views of a barrier device according to alternative embodiments of the present invention.

[0104] FIG. 38 is an end-on view of a barrier device and delivery device according to one embodiment of the present invention.

[0105] FIG. 39 is a side view of a tissue modification rasp device, shown with a cross-sectional view of a spine according to one embodiment of the present invention.

[0106] FIGS. 40A-40D are perspective views of various abrasive, tissue modifying portions of tissue modification rasp devices, according to various embodiments of the present invention.

[0107] FIG. 41 is a side view of a tissue modification rasp device including a barrier member according to one embodiment of the present invention.

[0108] FIGS. 42A and 42B are perspective and partial side views, respectively, of a tissue modification rasp device according to an alternative embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0109] Methods, apparatus and systems for modifying tissue in a patient are provided. Although the following description and accompanying drawing figures generally focus on tissue modification in spine, in various alternative embodiments any of a number of tissues in any of a number of anatomical locations in a patient may be modified.

[0110] Referring to Fig. 2, in one embodiment a tissue modification device 102 may include an elongate body 108 having a proximal portion 107 and a distal portion 109, a handle 104 with an actuator 106 coupled with proximal portion 107, one or more tissue modifying members 110, and one or more protective surfaces 112. In various embodiments, some of which are described further below, modification device 102 may be introduced into an area for performing a treatment, such as a spine, using any of a number of different introduction methods, devices and systems. In Fig. 2, for example, modification device 102

extends through an introducer device 114 placed through a first incision 240 on the patient's back and into the central spinal canal. Modification device 102 is advanced along a guide member 116, which extends through introducer member 114, through the intervertebral foramen between two adjacent vertebrae (only part of one vertebra is shown in Fig. 2), and out a second (or "distal") incision 242 on the back. In some embodiments, as shown, guide member has a beveled distal tip 117 for facilitating advancement of guide member 116 through tissue.

[0111] Generally, tissue modification device 102 may be advanced to a position in the spine such that tissue modifying member 110 faces target tissue to be modified, such as buckled, thickened or otherwise impinging ligamentum flavum tissue as shown in Fig. 2. Modification device 102 is configured such that when tissue modifying member 110 faces the target tissue, protective surface(s) 112 face non-target tissue. Protective surface 112 may be simply a length of elongate body 108 or may have one or more protective features, such as a widened diameter, protective or lubricious coating, extendable barrier, drug-eluting coating or ports, or the like. In some instances, protective surface(s) 112 may act as "non-tissue-modifying" surfaces, in that they may not substantially modify the non-target tissue. In alternative embodiments, protective surface(s) 112 may affect non-target tissue by protecting it in some active way, such as by administering one or more protective drugs, applying one or more forms of energy, providing a physical barrier, or the like.

[0112] In some embodiments, once tissue modification device 102 is positioned such that tissue modifying member 110 faces target tissue and protective surface 112 faces non-target tissue, an anchoring force may be applied at or near distal portion 109 of elongate body 108, either inside or outside the patient's body. A tensioning force may also be applied at or near proximal portion 107 of elongate body 108, such as by pulling on handle 104 (one-directional arrows), and actuator 106 may be used (two-headed arrow) to activate tissue modifying member(s) 110 to modify target tissue. In the example shown, anchoring force is applied near distal portion 109 by a user's hand 244, and handle 104 is pulled proximally (arrows) to apply tensioning force. In an alternative embodiment, hand 244 may grasp guide member 116 at or near its distal portion 117 and thus apply anchoring force to it, thus also applying anchoring force to elongate body 108. In one variation of such an embodiment, elongate body 108 or handle 104 may optionally be adjustably clamped to guide member 116 to further enhance or facilitate application of anchoring force to elongate body 108. Tissue modification via tissue modifying members 110 may include cutting, ablating, dissecting,

repairing, reducing blood flow in, shrinking, shaving, burring, biting, remodeling, biopsying, debriding, lysing, debulking, sanding, filing, planing, heating, cooling, vaporizing, delivering a drug to, and/or retracting the target tissue. Once tissue has been modified, tissue modification device 102 and any introducer devices 114, guide members 116 or other devices may be removed from the patient.

[0113] In various embodiments of the apparatus, tissue modifying member(s) 110 may be disposed along any suitable length of body 108. In one embodiment, for example, such as an embodiment of the device to be used in a spinal treatment, tissue modifying members 110 may be disposed along a length of the device measuring no longer than 10 cm, and preferably no more than 6 cm, and even more preferably no more than 3 cm. In various embodiments, tissue modifying member(s) 110 may include a rongeur, a curette, a scalpel, one or more cutting blades, a scissors, a forceps, a probe, a rasp, a file, an abrasive element, one or more small planes, an electrosurgical device, a bipolar electrode, a unipolar electrode, a thermal electrode, a rotary powered mechanical shaver, a reciprocating powered mechanical shaver, a powered mechanical burr, a laser, an ultrasound crystal, a cryogenic probe, a pressurized water jet, a drug dispensing element, a needle, a needle electrode, or some combination thereof. In various embodiments, all tissue modifying members 110 may be mobile relative to the elongate body, all may be static, or some may be mobile and some may be static. These and other aspects and embodiments are described further below.

[0114] Turning now to Fig. 3A-3I, more detailed figures of one embodiment of tissue modification device 102 are shown. Referring to Fig. 3A, tissue modification device 102 may include elongate body 108 having proximal portion 107 and distal portion 109, a window 111 disposed along elongate body 108, two tissue modifying blades 110 exposed through window 111, and handle 104 with actuator 106 coupled with proximal portion 107. In the embodiment shown, the tissue modifying members comprise blades 110, although in alternative embodiments other tissue modifying members may be added or substituted.

[0115] In various embodiments, elongate body 108 may have any number of dimensions, shapes, profiles and amounts of flexibility. For example, distal portion 109 is shown having a curved shape to demonstrate that at least a portion of elongate body 108 may be flexible. In various embodiments, elongate body 108 may have one or more of a round, ovoid, ellipsoid, flat, cambered flat, rectangular, square, triangular, symmetric or asymmetric cross-sectional shape. As shown in Figs. 3C and 3D, in the pictured embodiment, elongate body 108 has a

relatively flat configuration, which may facilitate placement of body 108 between target and non-target tissues. Distal portion 109 of body 108 may be tapered, to facilitate its passage into or through narrow spaces as well as through small incisions on a patient's skin. Body 108 may also include a slightly widened portion around the area of window 111 and blades. In one embodiment, such as an embodiment used for modifying tissue in a spine, body 108 may have a small profile, such as having a height of not more than 10 mm at any point along its length and a width of not more than 20 mm at any point along its length, or more preferably a height not more than 5 mm at any point along its length and a width of not more than 10 mm at any point along its length, or even more preferably a height not more than 2 mm at any point along its length and a width of not more than 4 mm at any point along its length. Body 108 may be long enough to extend through a first incision on a patient, between target and non-target tissue, and out a second incision on a patient. Alternatively, body 108 may be long enough to extend through a first incision, between the target and non-target tissue, and to an anchoring location within the patient. In another alternative embodiment, body 108 may be long enough to extend through a first incision, between the target and non-target tissue, to a location nearby but distal to the target tissue within the patient, with some portion of tissue modification device 102 anchored to guide member 116. In some embodiments, elongate body 108 includes at least one feature for allowing passage of the body over a guidewire or other guide member or to allow passage of one or more guide members over or through body 108. For example, in various embodiments body 108 may include one or more guidewire lumens, rails, tracks, lengthwise impressions or some combination thereof.

[0116] In one embodiment, elongate body 108 is predominantly flexible along its length and comprises any suitable flexible material, such as thin, flexible metals, plastics, fabrics or the like. In some embodiments, it may be advantageous to include one or more rigid sections in elongate body 108, such as to impart pushability to a portion of body 108 or to facilitate application of force to tissue modification members 110 without causing unwanted bending or kinking of elongate body 108. In such embodiments, rigidity may be conferred by using additional materials in body 108 or by making the rigid portions thicker or wider or of a different shape.

[0117] Handle 104 may have any suitable configuration according to various embodiments. Similarly, actuator 106 may include any of a number of actuation devices in various embodiments. In the embodiment shown in Fig. 3A, actuator 106 comprises a trigger or

moving handle portion, which is grasped by a user and pulled or squeezed toward handle 104 to bring blades 110 together to cut tissue. In an alternative embodiment, actuator 106 instead may include a switch or button for activating a radiofrequency surgical ablation tissue modifying member. In yet another embodiment, actuator 106 may include a combination trigger and switch, one or more pull wires, any suitable form of lever and/or some combination thereof.

[0118] Figs. 3B-3D show in greater detail a portion of tissue modification device 102. In these figures, window 111 and blades 110 are more clearly seen. In one embodiment, at least a portion of elongate body 108 and blades 110 may have a slightly curved configuration. In alternative embodiments, at least a portion of elongate body 108 and blades 110 may be flat. In other alternative embodiments, tissue modification members such as blades 110 may be proud to elongate body 108.

[0119] Blades 110 include a distal 110a and a proximal blade 110b that reside at the distal and proximal edges, respectively, of window 111 of elongate body 108. Window 111 of body 108 may accommodate both soft and hard tissue when the device is forcibly applied to the surface of a target tissue site. The top view of the distal portion of elongate body 108, shown in Fig. 3C, depicts the angled edges of distal blade 110a and proximal blade 110b, which facilitate shearing of target tissue. In alternative embodiments, blades 110 may have any of a number of alternative shapes and configurations. The distal portion of body 108 may have a very low profile (height compared to width), as shown in side view Fig. 3D, where only blades 110 protrude from the top surface of the elongate body 108. In one embodiment, also as shown in Fig. 3D, a guidewire tube 120 (or lumen) may extend from (or be coupled with) a lower surface of elongate body 108. The lower surface of elongate body 108 is an example of a protective or non-tissue-modifying surface.

[0120] In one embodiment, distal blade 110a is coupled with two pull-wires 118, as seen in Figs. 3C, 3E and 3F. Pull-wires 118 coupled to and translated by actuator 106 on handle 104 may be used to drive distal blade 110a proximally to contact the cutting edge of proximal blade 110b, thus cutting tissue. Other alternative mechanisms for driving blades 110, such as gears, ribbons or belts, magnets, electrically powered, shape memory alloy, electro magnetic solenoids and/or the like, coupled to suitable actuators, may be used in alternative embodiments. As mentioned, in one embodiment distal blade 110a and/or proximal blade 110b may have an outwardly curvilinear shape along its cutting edge. Alternatively, distal

blade 110a may have a different blade shape, including flat, rectilinear, v-shaped, and inwardly curvilinear (concave vs. convex). The cutting edge of either blade 110 may have a sharp edge formed by a simple bevel or chamfer. Alternatively or in addition, a cutting edge may have tooth-like elements that interlock with a cutting edge of an opposing blade, or may have corrugated ridges, serrations, rasp-like features, or the like. In various embodiments, both blades 110 may be of equal sharpness, or alternatively one blade 110 may be sharp and the other substantially flat to provide a surface against which the sharp blade 110 may cut. Alternately or in addition, both cutting edges may be equally hard, or a first cutting edge may be harder than a second, the latter of which deflects under force from the first harder edge to facilitate shearing of the target tissue.

[0121] Figs. 3E and 3F show cross-sectional views through elongate body at lines A-A and B-B, respectively, of Fig. 3C. In some embodiments, all or a portion of elongate body 108, such as the lower surface shown in Fig. 3E, may include a lubricious surface for facilitating manipulation of the tool in the surgical space and at the anatomical site. The lubricious lower surface also provides a barrier between blades 110 and non-target tissue in the surgical space. The lower surface may include a guide member lumen 120 to accommodate a guidewire or other access device or rail. Fig. 3E shows distal blade 110 coupled with pull wires 118. Fig. 3F shows proximal blade 110b, which is not coupled with pull wires 118 but rather fixed to body 108. In various alternative embodiments, proximal blade 110b may be movable distally while distal blade 110a is static, both blades may be moved toward one another, or a different number of blades may be used, such as one blade drawn toward a backstop or more than two blades, one or more of which may be mobile. In various alternative embodiments, guide member lumen 120 may be accommodated on a side surface or more centrally within elongate body 108. In further alternative embodiments, the one or more guide member lumens 120 may comprise one or more various cross sectional shapes, for example substantially round, substantially oval, or substantially rectabular, to accommodate alternative guide members, for example flat or rectangular guidewires, needles or rails. In still other alternative embodiments guide member lumen 120 may be adjustably coupled with the elongate body 108 to enable manipulation of the location of the elongate body 108 and therefore the tissue modifying members 110 relative to the guiding member.

[0122] Referring now to Figs. 3G-3I, blades 110 are shown in their closed position. In one embodiment, when distal blade 110a is drawn proximally to cut tissue, at least some of the cut tissue is captured in a hollow interior portion of elongate body 108. Various

embodiments may further include a cover, a cut tissue housing portion and/or the like for collecting cut tissue and/or other tissue debris. Such collected tissue and debris may then be removed from the patient during or after a tissue modification procedure. During a given tissue modification procedure, distal blade 110a may be drawn proximally to cut tissue, allowed to retract distally, and drawn proximally again to further cut tissue as many times as desired to achieve a desired amount of tissue cutting.

[0123] Blades 110 may be made from any suitable metal, polymer, ceramic, or combination thereof. Suitable metals, for example, may include but are not limited to stainless steel (303, 304, 316, 316L), nickel-titanium alloy, tungsten carbide alloy, or cobalt-chromium alloy, for example, Elgiloy® (Elgin Specialty Metals, Elgin, IL, USA), Conichrome® (Carpenter Technology, Reading, PA,USA), or Phynox® (Imphy SA, Paris, France). In some embodiments, materials for the blades or for portions or coatings of the blades may be chosen for their electrically conductive or thermally resistive properties. Suitable polymers include but are not limited to nylon, polyester, Dacron®, polyethylene, acetal, Delrin® (DuPont, Wilmington, DE), polycarbonate, nylon, polyetheretherketone (PEEK), and polyetherketoneketone (PEKK). In some embodiments, polymers may be glass-filled to add strength and stiffness. Ceramics may include but are not limited to aluminas, zirconias, and carbides. In various embodiments, blades 110 may be manufactured using metal injection molding (MIM), CNC machining, injection molding, grinding and/or the like. Pull wires 118 be made from metal or polymer and may have circular, oval, rectangular, square or braided cross-sections. In some embodiments, a diameter of a pull wire 118 may range from about .001" - .050", and more preferably from about .010"-.020".

[0124] Depending on the tissue to be treated or modified, activating blades 110 (or other tissue modifying members in alternative embodiments) may cause them to modify target tissue along an area having any of a number of suitable lengths. In use, it may also be advantageous to limit the extent of action of blades 110 or other tissue modifying members to a desired length of tissue, thus not allowing blades 110 to affect tissue beyond that length. In so limiting the effect of blades, unwanted modification of, or damage to, surrounding tissues and structures may be limited or even eliminated. In one embodiment, for example, where the tissue modification device is used to modify tissue in a spine, blades 110 may operate along a length of target tissue of no more than 10 cm, and preferably no more than 6 cm, and even more preferably no more than 3 cm. Of course, in other parts of the body and to address other tissues, different tissue modification devices may be used and tissue modifying

members may have many different lengths of activity. In one embodiment, to facilitate proper location of tissue modifying members, such as blades 110, relative to target tissue, the tissue modifying members and/or the elongate body and/or one or more additional features intended for just such a purpose may be composed of a material readily identifiable via x-ray, fluoroscopic, magnetic resonance or ultrasound imaging techniques.

[0125] In various embodiments, a number of different techniques may be used to prevent blades 110 (or other tissue modifying members) from extending significantly beyond the target tissue. In one embodiment, for example, preventing blades 110 from extending significantly beyond the target tissue involves holding tissue modification device 102 as a whole predominantly stable to prevent device 102 from translating in a direction toward its proximal portion or toward its distal portion while activating blades 110. Holding device 102 stable is achieved by anchoring one end of the device and applying tensioning force at or near the other end, as described further below.

[0126] In the embodiment shown in Figs. 3A-3I, pull wires 118 are retracted proximally by squeezing actuator 106 proximally. In an alternative embodiment, squeezing actuator 106 may cause both blades 110 to translate inward so that they meet approximately in the middle of window 111. In a further embodiment, distal blade 110a may be returned to it's starting position by a pulling force generated from the distal end of device 102, for example by using a distal actuator that is attached to distal wires, or by pulling on the distal guide member which is attached to distal blade 110a. In yet another alternative embodiment, proximal blade 110b may be moved to cut by a pulling force generated from the distal end of device 102, for example by using a distal actuator that is attached to distal wires, or by pulling on the distal guide member which is attached to proximal blade 110b. In yet another embodiment, squeezing actuator 106 may cause proximal blade 110b to move distally while distal blade 110a stays fixed. In other alternative embodiments, one or more blades 110 may move side-to-side, one or more blades 110 may pop, slide or bow up out of window 111 when activated, or one or more blades 110 may expand through window. In another embodiment, one or more blades 110 and/or other tissue modifying members of device 102 may be powered devices configured to cut, shave, grind, abrade and/or resect target tissue. In other embodiments, one or more blades may be coupled with an energy transmission device, such as a radiofrequency (RF) or thermal resistive device, to provide energy to blade(s) 110 for cutting, ablating, shrinking, dissecting, coagulating or heating and thus enhancing tissue modification. In another embodiment, a rasp or file may be used in conjunction with or coupled with one or

more blades. In any of these embodiments, use of actuator 106 and one or more moving blades 110 provides for tissue modification with relatively little overall translation or other movement of tissue modification device 102. Thus, target tissue may be modified without extending blades 110 or other tissue modification members significantly beyond an area of target tissue to be treated.

[0127] Referring now to Figs. 4A-4C, in an alternative embodiment, a tissue modification device 202 may include an elongate body 208 having a proximal portion and a distal portion 209, a handle 204 and actuator 206 coupled with proximal portion, and a window 211 and tissue modifying member 210 disposed near distal portion 209. As seen more clearly in Figs. 4B and 4C, in the embodiment shown, tissue modifying member 210 comprises an RF electrode wire loop. Wire loop 210 may comprise any suitable RF electrode, such as those commonly used and known in the electrosurgical arts, and may be powered by an internal or external RF generator, such as the RF generators provided by Gyrus Medical, Inc. (Maple Grove, MN). Any of a number of different ranges of radio frequency may be used, according to various embodiments. For example, some embodiments may use RF energy in a range of between about 70 hertz and about 5 megahertz. In some embodiments, the power range for RF energy may be between about 0.5 Watts and about 200 Watts. Additionally, in various embodiments, RF current may be delivered directly into conductive tissue or may be delivered to a conductive medium, such as saline or Lactate Ringers solution, which may in some embodiments be heated or vaporized or converted to plasma that in turn modifies target tissue. Distal portion 209 includes a tapered tip, similar to that described above, to facilitate passage of elongate body 208 into narrow anatomical sites. Handle 204 and actuator 206 are similar to those described above, although in the embodiment of Figs. 4A-4C, actuator 206 may be used to change the diameter of the wire loop 210. Using actuator 206, wire loop 210 may be caused to extend out of window 211, expand, retract, translate and/or the like. Some embodiments may optionally include a second actuator (not shown), such as a foot switch for activating an RF generator to delivery RF current to an electrode.

[0128] Elongate body 208 may be fabricated from any suitable material and have any of a number of configurations. In one embodiment, body 208 comprises a metal tube with a full-thickness slit (to unfold the tube into a flat form--not shown) or stiffening element (not shown). The split tube provides for a simple manufacturing process as well as a conductive pathway for bi-polar RF operation.

[0129] Referring to Fig. 4C, insulators 222 may be disposed around a portion of wire loop 210 so that only a desired portion of wire loop 210 may transfer RF current into the tissue for tissue modifying capability. Wire loop 210, covered with insulators 222 may extend proximally into support tubes 218. In various alternative embodiments, an electrode tissue modifying member (of which wire loop 210 is but one example) may be bipolar or monopolar. For example, as shown in Fig. 4C, a sleeve 224 housed toward the distal portion of window 211 may act as a return electrode for wire loop 210 in a bipolar device. Wire loop electrodes 210 may be made from various conductive metals such as stainless steel alloys, nickel titanium alloys, titanium alloys, tungsten alloys and the like. Insulators 222 may be made from a thermally and electrically stable polymer, such as polyimide, polyetheretherketone (PEEK), polytetrafluoroethylene (PTFE), polyamide-imide, or the like, and may optionally be fiber reinforced or contain a braid for additional stiffness and strength. In alternative embodiments, insulators 222 may be composed of a ceramic-based material.

[0130] In one embodiment, wire loop 210 may be housed within elongate body 208 during delivery of tissue modification device 202 into a patient, and then caused to extend up out of window 211, relative to the rest of body 208, to remove tissue. Wire loop 210 may also be flexible so that it may pop or bow up out of window 211 and may deflect when it encounters hard tissue surfaces. Wire loop 210 may have any of a number of shapes, such as curved, flat, spiral or ridged. Wire loop 210 may have a diameter similar to the width of body 208, while in alternative embodiments it may expand when extended out of window 211 to have a smaller or larger diameter than that of body 208. Pull wires (not shown) may be retracted proximally, in a manner similar to that described above, in order to collapse wire loop 210, decrease the diameter and lower the profile of the wire loop 210, and/or pull wire loop 210 proximally to remove tissue or be housed within body 208. The low profile of the collapsed wire loop 210, facilitates insertion and removal of tissue modification device 202 prior to and after tissue modification. As the wire loop 210 diameter is reduced, support tubes 218 deflect toward the center of elongate body 208.

[0131] In an alternative embodiment (not shown), tissue modification device 202 may include multiple RF wire loops 210 or other RF members. In another embodiment, device 202 may include one or more blades as well as RF wire loop 210. In such an embodiment, wire loop 210 may be used to remove or otherwise modify soft tissues, such as ligamentum flavum, or to provide hemostasis, and blades may be used to modify hard tissues, such as bone. In other embodiments, as described further below, two separate tissue modification

devices (or more than two devices) may be used in one procedure to modify different types of tissue, enhance modification of one type of tissue or the like.

[0132] In other alternative embodiments, tissue modification devices 202 may include tissue modifying members such as a rongeur, a curette, a scalpel, a scissors, a forceps, a probe, a rasp, a file, an abrasive element, one or more small planes, a rotary powered mechanical shaver, a reciprocating powered mechanical shaver, a powered mechanical burr, a laser, an ultrasound crystal a cryogenic probe, a pressurized water jet, a drug dispensing element, a needle, a needle electrode, or some combination thereof. In some embodiments, for example, it may be advantageous to have one or more tissue modifying members that stabilize target tissue, such as by grasping the tissue or using tissue restraints such as barbs, hooks, compressive members or the like. In one embodiment, soft tissue may be stabilized by applying a contained, low-temperature substance (for example, in the cryo-range of temperatures) that hardens the tissue, thus facilitating resection of the tissue by a blade, rasp or other device. In another embodiment, one or more stiffening substances or members may be applied to tissue, such as bioabsorbable rods.

[0133] Referring now to Figs. 5A-5D, one embodiment of a method for modifying tissue in a spine is demonstrated in simplified, diagrammatic, cross-sectional views of a portion of a patient's back and spine. Fig. 5A shows a portion of the patient's back in cross section, with a portion of a vertebra, the spinal cord with branching nerve roots, and target tissue, which in this illustration is the ligamentum flavum and possibly a portion of the facet capsule. The target tissue is typically impinging directly on one or more of the group including nerve roots, neurovascular structures, dorsal root ganglia, cauda equina, or individual nerves.

[0134] In Fig. 5B, tissue modification device 102 has been positioned in the patient's back to perform a tissue modification procedure. Various methods, devices and systems for introducing device 102 into the patient and advancing it to the position for modifying tissue are described in further detail below. Generally, device 102 may be positioned via a percutaneous or open surgical procedure, according to various embodiments. In one embodiment, device 102 may be inserted into the patient through a first incision 240, advanced into the spine and between target tissue and non-target tissue (such as spinal cord, nerve roots, nerves and/or neurovascular tissue), and further advanced so a distal portion of elongate body 108 exits a second (or distal) incision 242 to reside outside the patient. In positioning device 102, one or more tissue modifying members (not shown) are positioned to

face the target tissue, while one or more protective portions of elongate body 108 face non-target tissue.

[0135] Referring to Fig. 5C, once device 102 is positioned in a desired location, anchoring force may be applied at or near the distal portion of elongate body 108. In one embodiment, applying anchoring force involves a user 244 grasping body 108 at or near its distal portion. In alternative embodiments, as described further below, anchoring force may be applied by deploying one or more anchor members disposed at or near the distal portion of body 108, or by grasping a guidewire or other guide member extending through at least part of body 108. Once the anchoring force is applied, proximally-directed tensioning force may be applied to device 102, such as by pulling proximally on handle 104 (one-directional, diagonal arrows). This tensioning force, when applied to the substantially anchored device 102, may help urge the tissue modifying member(s) against the target tissue (one-directional, vertical arrows near target tissue), thus enhancing contact with the target tissue and facilitating its modification. With the tissue modifying member(s) contacting the target tissue, actuator 106 may be squeezed or pulled (two-headed arrow) to cause the tissue modifying member(s) to modify tissue. (Alternative actuators may be activated in different ways in alternative embodiments.)

[0136] In various alternative embodiments, certain of the above-described steps may be carried out in different order. For example, in one embodiment the distal portion of elongate body 108 may be anchored within or outside the patient before the tissue modifying members are positioned adjacent the target tissue. In another alternative embodiment, the proximal portion of device 102 may be anchored, and the tensioning force may be applied to the distal portion of device 102. In yet another embodiment, tensioning force may be applied to both ends of the device. In yet another embodiment, a second handle and actuator may be coupled with the distal end of body 108 after it exits the patient's back, allowing tensioning forces as well as tissue modifying actuation to occur at both the proximal and distal portions of device 102. By anchoring one end of device 102 and applying tensioning force to the opposite end, contact of the tissue modifying members with the target tissue is enhanced, thus reducing or eliminating the need for translating or otherwise moving device 102 as a whole and reducing the overall profile and the resulting access pathway required to position the device. Reducing movement and profile of device 102 and using tissue modifying members confined to a relatively small area of device 102 helps facilitate target tissue modification while minimizing or eliminating damage to surrounding tissues or structures.

[0137] As mentioned above, tissue may be modified using one tissue modification device or multiple devices, according to various embodiments. In one embodiment, for example, an RF electrosurgical tissue modification device may be used in the patient to remove soft tissue such as ligament, and a bladed tissue modification device such as a rongeur may then be used to remove additional soft tissue, calcified soft tissue, or hard tissue such as bone. In some embodiments, such multiple devices may be inserted, used and removed serially, while in alternative embodiments such devices may be inserted into the patient at the same time to be used in combination.

[0138] Referring to Fig. 5D, using one or more tissue modification devices 102, a desired amount of target tissue may be removed from more than one area in the spine. Figs. 5A-5C demonstrate removal of target tissue on one side of the spine, and that method or a similar method may also be used to remove target tissue on an opposite side of the spine, as shown in Fig. 5D, where target tissue has been removed from both sides. That the desired amount of tissue has been removed may be confirmed by tactile feedback from the device or from a separate device, by testing nerve conduction through one or more previously impinged nerves, by testing blood flow through one or more previously impinged blood vessels, by passing (independently or over the guide member) a measurement probe or sound through the treated portion, through one or more radiographic tests, through some combination thereof, or by any other reasonable means.

[0139] Referring now to Fig. 6A, tissue modification device 102 is shown with one embodiment of a distal anchoring member 250 deployed at the patient's skin. In various embodiments, anchoring members may include but are not limited to one or more handles, barbs, hooks, screws, toggle bolts, needles, inflatable balloons, meshes, stents, wires, lassos, backstops or the like. In some embodiments, anchoring members 250 may be disposed at the extreme distal portion 109 of elongate body 108, while in other embodiments anchoring members 250 may be located more proximally. In the embodiment shown, anchoring members 250 are deployed at the patient's skin. In an alternative embodiment, anchoring may be achieved outside the patient by deploying one or more anchoring members 250 above the skin and having a user grasp the anchoring members 250. In an alternative embodiment, anchoring may be achieved outside the patient by deploying one or more anchoring members 250 above the skin and having a user grasp anchoring members 250, after tissue modification device 102 has been anchored to the guide member. In another alternative embodiment, anchoring may be achieved outside the patient by attaching anchoring member 250 to an

external device, for example one that is mounted on the patient or on the procedure table. In a further alternative embodiment, anchoring may be achieved outside the patient by attaching the guide member to an external device, for example one that is mounted to on the patient or on the procedure table, after tissue modification device 102 has been anchored to the guide member. Anchoring members 250 generally are deployable from a first, contracted configuration to facilitate delivery of device 102, to a second, expanded configuration to facilitate anchoring. This change in configuration may be achieved, for example, by using shape memory or super-elastic materials, by spring loading anchoring members 250 into body 108 or the like. In most embodiments, anchoring members 250 may also be collapsed down into the first, contracted configuration after a tissue modification procedure has been performed, to facilitate withdrawal of device 102 from the patient. In an alternative embodiment, anchoring members 250 may detach from body 108 and may be easily removable from the patient's skin.

[0140] Fig. 6B shows tissue modification device 102 with an alternative embodiment of a distal anchoring member 260. Here, distal anchoring member 260 includes multiple hooks or barbs extended out the distal portion 109 of elongate body 108 within the patient's back. In using such an embodiment, it may not be necessary to pass guide member 117 through a second, distal incision on the patient, although in some embodiments guide member 117 may extend significantly beyond distal portion 109. Anchoring member(s) 260, according to various embodiments, may be deployed so as to anchor to bone, ligament, tendon, capsule, cartilage, muscle, or any other suitable tissue of the patient. They may be deployed into vertebral bone or other suitable tissue immediately adjacent an intervertebral foramen or at a location more distant from the intervertebral foramen. When a tissue modification procedure is complete, anchoring members 260 are retracted within elongate body for removal of device 102 from the patient.

[0141] Referring now to Figs. 7A-7O, a system and method for introducing a tissue modification device into a spine is demonstrated. This system and method may be referred to as an "access system" or "access method," in that they provide or facilitate gaining access to a target tissue to be modified. Of course, the embodiment shown is merely one exemplary embodiment, and any of a number of other suitable methods, devices or systems may be used to introduce one or more devices for modifying tissue in spine. For example, in one alternative embodiment a spinal tissue modification procedure may be carried out through an open surgical approach. Therefore, the following description is provided primarily for

exemplary purposes and should not be interpreted to limit the scope of the invention as it is defined in the claims.

[0142] Referring to Fig. 7A, in one embodiment a device delivery method first involves advancing a loss of resistance syringe 304 including a plunger 310, barrel 308 and fluid and/or air 306, coupled with the proximal portion of a needle 300 (or cannula) into the patient's back. The distal portion of cannula 300 is advanced through the ligamentum flavum until it enters the central spinal canal where a loss of resistance to pressure placed on plunger 310 is encountered, and fluid and/or air 306 is injected into central spinal canal to confirm correct placement of cannula 300 as shown in fig. 7B. Syringe 304 is then removed, as in Fig. 7C, and a guidewire 312 with a non-rigid, atraumatic tip is advanced through cannula 300 into the central spinal canal, as in Fig. 7D. Next, cannula 300 is removed, as in Fig. 7E, leaving behind guidewire 312. As shown in Figs. 7F and 7G, an introducer sheath 114, coupled with a dilator 314, is then advanced over guidewire 312 to position a distal portion of sheath 114 at a desired location within the spine. Dilator 314 and guidewire 312 are then removed, as in Fig. 7H.

[0143] Once introducer sheath 114 is in place, one or more curved or steerable guide devices 318 may be advanced through it to desired positions in and/or through the spine, as shown in Figs. 7I and 7J. One or more guide members 116, may then be advanced through the guide device 318, as shown in Figs. 7J-7L. Finally, guide device 318 may be removed, as in Fig. 7M, and elongate body 108 of tissue modification device 102 may be advanced over guide member 116 and through introducer sheath 114 to a desired position in the spine, as in Fig. 7N. As shown in Fig. 7O, elongate body 108 may be tensioned to urge tissue modifying members 110 against target tissue, as shown with arrows at opposite ends of device 102, while distal portion 109 is anchored, in this case by hand 244. In an alternative embodiment, guide member 116 may be tensioned to urge tissue modifying members 110 against target tissue as shown in Fig. 7N.

[0144] Once tissue modification device 102 is in a desired position, tissues which may be modified in various embodiments include, but are not limited to, ligament, tendon, tumor, cyst, cartilage, scar, "bone spurs," inflammatory and bone tissue. In some embodiments, modifying the target tissue reduces impingement of the tissue on a spinal cord, a branching nerve or nerve root, a dorsal root ganglia, and/or vascular tissue in the spine. Actuator 106 on handle 104 is activated to modify target tissue using tissue modification member(s) 110,

while elongate body 108 is held relatively stable by hand 244 and by tension force applied to handle 104.

[0145] In various embodiments, the system and method described immediately above may include additional features or steps, may have fewer features or steps, may have an alternate order of implementation of steps, or may have different features or steps. For example, in some embodiments placement of device 102 will be performed in a medial-to-lateral direction (relative to the patient), while in alternative embodiments device placement will be performed lateral-to-medial. In some embodiments, one or more components of the system described may be anchored to the patient, such as guide member 116 or introducer sheath 114. In various embodiments, one or more guide members 116 may include one or more wires, rails or tracks and may be inserted through guide device 318, introducer sheath 114 without guide device 318, cannula 300, an epidural needle, a lumen of an endoscope, a lumen of a tissue shield or barrier device, a curved guide device 318 placed through a lumen of an endoscope, or the like. In other embodiments, for example, guide device 318 may be placed through introducer cannula 300 and then introducer sheath 114 may be passed over guide device 318. Tissue modification device 102 may similarly be inserted with or without using any of these devices or components in various combinations. Various guidewires 312, guide devices 318 and/or guide members 116 may be pre-shaped to have one or more curves, may be steerable, and/or may include one or more rails, tracks, grooves, lumens, slots, partial lumens, or some combination thereof.

[0146] In some embodiments, tissue modification device 102 is inserted through one or more hollow devices as described above (such as introducer sheath 114, as shown, or cannula 300 in an alternative embodiment) in such a way that device 102 expands upon extending out of a distal portion of the hollow delivery device thereby assuming a wider profile for modifying a greater amount of target tissue from a single location. In an alternative embodiment, device 102 retains the same overall profile during insertion and during use. In some embodiments, one or more delivery devices will remain in the patient during use of tissue modification device 102, while in alternative embodiments all delivery devices are removed from the patient when tissue modification device 102 is operating. In some embodiments, tissue modification device 102 may be slidably coupled with one or more delivery devices during delivery and/or during use. In one embodiment, tissue modification device 102 is advanced through introducer sheath 114 and sheath 114 is used as an irrigation and evacuation lumen to irrigate the area of the target tissue and evacuate removed tissue and

other debris, typically by applying a vacuum. In alternative embodiments, tissue modification device 102 may include an irrigation and/or evacuation lumen to irrigate an area of the target tissue and evacuate removed tissue and other debris.

[0147] Some embodiments of an access system for facilitating tissue modification may further include one or more visualization devices (not shown). Such devices may be used to facilitate placement of the access system for introducing the tissue modification device, to facilitate tissue modification itself, or any combination of these functions. Examples of visualization devices that may be used include flexible, partially flexible, or rigid fiber optic scopes, rigid rod and lens endoscopes, CCD or CMOS chips at the distal portion of rigid or flexible probes, LED illumination, fibers or transmission of an external light source for illumination or the like. Such devices may be slidably couplable with one or more components of an access system or may be slidably or fixedly coupled with a tissue modification device. In other embodiments, additional or alternative devices for helping position, use or assess the effect of a tissue modification device may be included. Examples of other such devices may include one or more neural stimulation electrodes with EMG or SSEP monitoring, ultrasound imaging transducers external or internal to the patient, a computed tomography (CT) scanner, a magnetic resonance imaging (MRI) scanner, a reflectance spectrophotometry device, and a tissue impedance monitor disposed across a bipolar electrode tissue modification member or disposed elsewhere on a tissue modification device or disposed on the access system.

[0148] Referring now to Figs. 8A-8E, in an alternative embodiment, a tissue modification device and optionally one or more introduction/access devices may be positioned in a patient using an open surgical technique. As shown in Fig. 8A, for example, in one embodiment an open surgical incision is made on a patient's back, and two retractors 402 are used to expose a portion of the patient's vertebra. As shown in Fig. 8B, an introducer sheath 414 may then be inserted through the incision, between retractors 402. As in Fig. 8C, a curved guide device 418 may then be inserted through introducer sheath 414. Guide device 418 extends into the epidural space and through the intervertebral foramen as shown in Fig. 8D.

[0149] In some embodiments, a curved and cannulated thin, blunt probe may be placed directly through the open incision into the epidural space of the spine, or alternatively may be placed through introducer sheath 414. The probe tip may be advanced to or through a neural foramen. Such a probe may be similar in shape, for example, to a Woodson elevator,

Penfield 3, hockey stick probe, ball tipped probe, or the like. In alternative embodiments, probes that may be manually bent to change their shapes, or probes with articulating tips, or probes with shape lock portions, and/or probes having grooves instead of cannulas may be used.

[0150] As shown in Figs. 8D-8E, a substantially straight, flexible guidewire 420 with a sharp tip 422 may then be inserted through curved guide device 418 and advanced so that its distal portion with sharp tip 422 extends outside the patient's back at a location separate from the open incision (Fig. 8E). Guide device 418 may then be removed, as in Fig. 8F, and in subsequent steps a tissue modification device may be inserted over guide wire 420 and through introducer sheath 414 and used to modify tissue as described in more detail above. In an alternative embodiment, a curved, flexible cannula may be inserted through the curved guide device, until it extends lateral to the neural foramen, after which a substantially straight, flexible guidewire with a sharp tip may then be inserted through curved cannula and advanced so that its distal portion with sharp tip extends outside the patient's back.

[0151] Referring now to Figs. 9A and 9B, another alternative open surgical access method is shown. In Fig. 9A, a curved guide device 446 is shown in place through the epidural space and intervertebral foramen, and a guidewire 440 with a beveled distal tip 442 is about to be advanced through guide device 446. As shown in Fig. 9B, in this embodiment, guidewire 440 is directed by guide device 446 back through the open incision through which the various access devices are introduced. In such an embodiment, then, only one incision is created and the proximal and distal portions of one or more devices extend out of the patient's back through the same incision.

[0152] In various alternative embodiments, open surgical access may be through exposure down to a vertebral lamina, through ligamentum flavum without lamina removal, through ligamentum flavum with partial or complete lamina removal, through ligamentum flavum with or without lamina removal with partial or complete medial facet joint removal, through open exposure and out through skin laterally, through open exposure and back out through the open exposure, or through a lateral open exposure that accesses the neural foramen from the lateral side. One or more visualization devices may be used with open surgical access procedures as well as with percutaneous or other less invasive procedures. In another alternative embodiment (not shown), a tissue modification device may be placed in the patient directly, without any introduction devices.

[0153] Referring now to Figs. 10A-10E, in the embodiments described above, the tissue modification devices 102, 202 include at least one non-tissue-modifying (or "protective") portion, side or surface. The non-tissue-modifying portion is located on tissue modification device 102, 202 so as to be positioned adjacent non-target tissue when tissue modifying members 110, 210 are facing the target tissue. The non-tissue-modification surface of the device is configured so as to not modify or damage tissue, and thus the non-target tissue is protected from unwanted modification or damage during a tissue modification procedure.

[0154] Optionally, in some embodiments, tissue modification devices or systems may further include one or more tissue shields or barriers for further protecting non-target tissues. Such shields may be slidably coupled with, fixedly coupled with, or separate from the tissue modification devices with which they are used. In various embodiments, a shield may be delivered between target and non-target tissues before delivering the tissue modification device, may be delivered along with the tissue modification device, or may be delivered after delivery of the tissue modification device but before the device is activated. Generally, a shield will be interposed between the non-target tissue and the tissue modification device.

[0155] Fig. 10A shows a distal portion of an introducer device 514 through which a shield may be introduced. Figs. 10B and 10C show one embodiment of a shield device 500 partially deployed and in cross-section, respectively. Typically, shield 500 will have a first, small-profile configuration for delivery to an area near non-target tissue and a second, expanded configuration for protecting the non target tissue. Shield itself may be configured as one piece of super-elastic or shape-memory material, as a scaffold with material draped between the scaffolding, as a series of expandable wires or tubes, as a semicircular stent-like device, as one or more expandable balloons or bladders, as a fan or spring-loaded device, or as any of a number of different devices configured to expand upon release from a delivery device to protect tissue. As shown in Figs. 10B and 10C, shield 500 may comprise a sheet of material disposed with a first end 502a abutting a second end 502b within introducer device 514 and unfurling upon delivery. In an alternative embodiment, as shown in Figs. 10D and 10E, opposite ends 522a and 522b of a shield device 520 may overlap in introducer device 514. Generally, shield 500, 520 may be introduced via introducer device 514 in one embodiment or, alternatively, may be introduced via any of the various means for introducing the tissue modification device, such as those described in conjunction with Figs. 7A-7S, 8A-8F and 9A-9B. In some embodiments, shield 500, 520 may be fixedly coupled with or an extension of a tissue modification device. Shield 500, 520 may also include one or more lumens, rails,

passages or the like for passing a guidewire or other guide member, for introducing, removing or exchanging any of a variety of tissue modification, drug delivery, or diagnostic devices, for passing a visualization device, for providing irrigation fluid at the tissue modification site, and or the like. In some embodiments, shield 500, 520 is advanced over multiple guidewires and the guidewires remain in place during a tissue modification procedure to enhance the stability and/or maintain positioning of shield. 300, 320.

[0156] Referring now to Figs. 11A and 11B, in an alternative embodiment, a powered tissue modification device 2000 suitably includes an elongate shaft 2001 having a proximal portion 2002, a distal portion 2003 and a longitudinal axis 2008, one or more tissue modifying members 2004 coupled with shaft 2001 at or near distal portion 2003, and a handle 2006 coupled with shaft 2001 at or near proximal portion 2002. Optionally, some embodiments may also include one or more power connectors 2010 for connecting device 2000 with one or more power sources. In some embodiments, shaft 2001 has a size and shape that facilitate passage of at least distal portion 2003 into an epidural space of the spine and between target tissue, such as ligamentum flavum, and non-target tissue, such as neural and/or neurovascular tissue. In some embodiments, shaft 2001 may include one or more bends or curves at or near its distal portion 2003 to further facilitate passage and positioning of device 2000. In some embodiments, for example, a bend or curve may facilitate passage of at least part of distal portion 2003 at least partway into an intervertebral foramen.

[0157] In some embodiments, as shown in Fig. 11A, distal portion 2003 of device 2000 may be advanced through the skin of the back of a patient, adjacent a spinous process. Distal portion 2003 may then be advanced between the lamina of adjacent vertebral bodies, into the epidural space, and between target and non-target tissues to position tissue modifying member(s) 2004 in a desired location for modifying target tissue. Power may then be provided to activate tissue modifying member(s) 2004 and thus to modify target tissue. A portion of device 2000 adjacent tissue modifying member(s) 2004 may be configured to face non-target tissue while tissue modifying member(s) 2004 face the target tissue, thus preventing unwanted damage or modification of the non-target tissue. In some embodiments, as described more fully above, the portion of device 2000 facing the non-target tissue may be configured to modify the non-target tissue in some way, such as to protect the tissue with a delivered substance, and/or to test the non-target tissue to confirm that it is non-target tissue.

[0158] In various embodiments, handle 2006 may have any suitable configuration and features. In some embodiments, handle 2006 includes one or more actuators for activating tissue modifying member(s) 2004. Power connector 2010 may have any suitable configuration and may deliver any suitable type of energy from an external power source (not shown) to device 2000 in various embodiments, such as but not limited to electric, radiofrequency, ultrasound, laser or conductive energy. In alternative embodiments, device 2000 may be battery operated or use any other suitable source of internal power or energy, and such internal energy source may be housed in handle 2006, for example. From whatever source, power is typically transmitted to tissue modifying member(s) 2004 to activate them and thus modify tissue.

[0159] With reference now to Fig. 11B, in various embodiments, tissue modification device 2000 may be advanced into a patient using any of a number of suitable techniques and approaches, some of which have been described previously. Fig. 11A illustrates one approach to advancing distal portion 2003 of device 2000 to a position between target and non-target tissue from a contralateral approach, while Fig. 11B illustrates an ipsilateral approach. As shown in Fig. 11B, distal portion 2003 may include two or more bends and/or may be at least partially flexible or steerable to facilitate a desired approach angle, according to various embodiments.

[0160] Turning to Fig. 12, in another embodiment a tissue modification device 2020 includes an elongate shaft 2011 having a proximal portion 2012 and a distal portion 2013, one or more tissue modification member(s) 2014, a conductive electrode 2015 coupled with shaft 2011, a handle 2016, a power connector 2030, and multiple additional connection members 2032, 2033. Electrode 2015 may be configured to deliver a non-target frequency and non-target amplitude of electrical current to non-target tissue. The non-target frequency and non-target amplitude may stimulate a response from a neural tissue. In one embodiment, a first connection member 2032 may provide power to electrode 2015, and if non-target-tissue is stimulated by current from the electrode, the observation of this stimulation, as measured by EMG, SSEP or watching for muscular activation, provides evidence that electrode 2015 is adjacent the non-target tissue. A target stimulating electric current may also be delivered through second connection member 2033 to tissue modifying member(s) 2014 (e.g., composed of electrically conductive material) and/or to a target stimulating electrode located adjacent and on the same side of device 2020 as tissue modifying member(s) 2014. For example, if the target simulating electric current is configured with a

frequency and amplitude to stimulate a response from neural tissue, the type (e.g., neural, non-neural) of the tissue immediately adjacent tissue modifying member(s) 2014 may be determined based on the tissue response or lack thereof. In one embodiment, device 2020 may be configured to allow for control of the target stimulating electric current and the non-target stimulating electric current. For example, the target stimulating electric current and the non-target stimulating electric current may be sequentially delivered to distal portion 2013 of device 2020 to determine the location of neural tissue prior to activation of tissue modifying member(s) 2014, for example, to help ensure that tissue modifying member(s) 2014 do not damage neural tissue.

[0161] In various embodiments, tissue modifying member(s) 2014 may include one or more of a rongeur, a curette, a scalpel, one or more cutting blades, a scissors, a forceps, a probe, a rasp, a file, an abrasive element, one or more small planes, an electrosurgical device, a bipolar electrode, a unipolar electrode, a thermal electrode, a rotary powered mechanical shaver, a reciprocating powered mechanical shaver, a powered mechanical burr, a laser, an ultrasound crystal, a cryogenic probe, a pressurized water jet, or some combination thereof. Some embodiments include one tissue modifying member 2014, while others include multiple tissue modifying members 2014. As is described further below, tissue modifying member(s) 2014 may have any of a number of suitable sizes, shapes and configurations and may move or actuate in any suitable way.

[0162] Referring now to Fig. 13A, in an alternative embodiment, a tissue modification device 2040 includes an elongate shaft 2041, one or more tissue modifying member(s) 2044, a handle 2046 and a power connector 2050. Additionally, device 2040 may include a guidewire lumen (not shown) extending through all or part of shaft 2041, which may allow passage of a guidewire 2048 having proximal 2049 and distal 2047 ends therethrough. In one embodiment, for example, guidewire 2048 may extend from a proximal end of shaft 2041 through a distal end of shaft 2041 and out the patient. In some embodiments, as described previously above, anchoring and/or tensioning force may be applied at or near distal end 2047 and/or proximal end 2049 to help urge tissue modifying member(s) 2044 against target tissue.

[0163] In the embodiment shown in Fig. 13A, tissue modifying member 2044 is shown having relatively flat configuration. In many of the subsequent embodiments described herein, various embodiments of tissue modifying members are also shown as having flat

configurations, primarily for ease of description. In alternative embodiments, however, and with reference now to Fig. 13B, tissue modification device may include a curved and/or flexible tissue modifying member 2045 (or multiple curved and/or flexible members), having a curved/flexible surface for contacting target tissue. Device 2040 may also include a curved and/or flexible shaft 2042. Such curved and/or flexible tissue modifying members 2045 (or tissue modifying surfaces) and shafts 2042 may facilitate tissue modification in some embodiments, in that tissue modifying members 2045 may more readily conform to target tissue. In alternative embodiments, many if not all of the devices described in the present application may have such curved and/or flexible tissue modifying member(s).

[0164] Referring now to Figs. 13C-13E, several alternative embodiments of anchoring members for use with a tissue modification device are shown. Fig. 13C, for example, shows tissue modification device 2040 including a wire anchor 2060 coupled with guidewire 2048. In various embodiments, wire anchor 2060 may be either removably or permanently attached to guidewire 2048 at or near its distal end 2047 to provide anchoring force against the patient's back from outside the patient. Wire anchor 2060 may minimize or prevent guidewire 2048 from moving through the patient's back towards proximal end 2049. In alternative embodiments, additional anchoring and/or tensioning force may be applied to distal end 2047, such as by holding and/or pulling distal end 2047 by hand.

[0165] In an alternative embodiment, as shown in Fig. 13D, distal end 2047 of guidewire 2048 may include one or more deployable anchoring members 2062, which may be deployed within the patient to anchor into tissue of the patient's back, such as muscle, bone, ligament or the like. In one embodiment, for example, guidewire 2048 may have one or more lumens (not shown), and anchoring members 2062 may be translated through the lumen(s) to extend out of distal end 2047. When a tissue modification procedure is complete, anchoring members 2062 may be retracted within the lumen(s) so that guidewire 2048 may be more easily removed from the patient.

[0166] Referring to Fig. 13E, in another embodiment tissue removal device 2040 may also include one or more proximal shaft anchoring members 2066 and/or one or more proximal guidewire anchoring members 2064. Shaft anchoring member 2066 may, in alternative embodiments, either be coupled with or removably couplable with shaft 2041 to facilitate application of anchoring force. For example, in one embodiment, shaft anchoring member 2066 may abut the patient's back to resist translation of shaft 2041 into the patient.

[0167] Proximal guidewire anchoring member 2064 may be included in handle 2046, as shown, or in other embodiments may be located proximal or distal to handle 2046. Guidewire anchoring member 2064 may be used to lock or anchor guidewire 2048 to prevent or minimize its translation into or out of device 2040. This may help facilitate application of tensioning and/or anchoring force via guidewire 2048.

[0168] Figs. 13F and 13G show cross-sectional views of handle 2046 and proximal guidewire anchoring member 2064 taken through line C-C on Fig. 13D. In one embodiment, handle 2046 may include proximal guidewire anchoring member 2064, a tissue modifying drive 2068 in a first lumen, a guidewire 2048 in a guidewire lumen 2070, multiple guiding slots 2074 with corresponding guiding tabs 2075, and one or more lobes 2072. As shown in Fig. 13F, when guidewire anchoring member 2064 is disengaged, guidewire 2048 may freely translate within guidewire lumen 2070, because lobe 2072 does not interfere. As shown in Fig. 13G, when guidewire anchoring member 2064 is engaged, for example by translating and/or rotating guidewire anchoring member 2064 with respect to handle 2046, guidewire 2048 may friction fit (e.g., clamp, pinch) between lobe 2072 of guidewire anchoring member 2064 and the wall of guide wire lumen 2070. Guidewire anchoring member 2064 may then be translated and/or rotated back to the original position (Fig. 13F) to disengage guidewire 2048.

[0169] Referring now to Fig. 14, in some embodiments a tissue removal device 2100 may include an elongate shaft 2104 having proximal 2106 and distal 2105 portions, one or more tissue modifying members 2108, a movable handle 2103 coupled with proximal portion 2106, and a power connector 2107. In the embodiment shown, distal portion 2105 is at least partially steerable (shown in Fig. 14 as two, overlapping distal portions), and movable handle 2103 may be used (two-headed, straight arrow) to steer distal portion 2105 while holding shaft 2104 relatively stationary. A steerable distal portion 2105 may enhance the ability of tissue modifying members 2108 to contact and apply force against target tissue. In some embodiments, the location of tissue modifying members 2108 may be adjusted, using steerable distal portion 2105, without significantly moving shaft 2104. In some embodiments, steerable distal portion 2105 may move in multiple directions, such as laterally and up-and-down, relative to the longitudinal axis of shaft 2104. Movable handle 2103 may operate with a piston-like motion, in one embodiment, where a distal portion of handle 2102 is attached to the shaft and a proximal portion handle 2103 is attached to a tensioning member. The tensioning member may translate tension to steerable distal end 2105 when

handle 2103 is actuated, which in turn deflects distal end 2105. In various alternative embodiments, any other handle steering mechanisms and/or other steering mechanisms, many of which are known in the art, may be used.

[0170] Figs. 15A and 15B show one embodiment of a tissue modification device 2080, which includes an elongate shaft 2081, one or more tissue modifying members 2082, a handle 2084, a visualization device 2086, an optical cable 2090 and a power connector 2088. Visualization device 2086 may include any suitable device, such as but not limited to an endoscope. An endoscope visualization device may have lenses and/or fiber optics, for example, for delivering light (or other energy) to illuminate the tissue and capturing images. As shown in Fig. 15B, in some embodiments, visualization device 2086 may include one or more image capturing elements 2094 and one or more illuminating elements 2092. Image capturing element 2094 may include, for example, a CCD or CMOS chip, in some embodiments. Illuminating element 2092 may include, for example, one or more light emitting diodes (LEDs) or fiber optics, in some embodiments.

[0171] In some embodiments, optical cable 2090 may include fiber optics. Some or all of the fiber optics may comprise or may be coupled with illuminating elements 2092. Alternatively or additionally, some or all of the fiber optics may be connected to a camera (not shown). For example, such a camera may be attached to the proximal end of tissue modification device 2080. Optical cable 2090 may alternatively include one or more electrical wires connected to a power source (e.g., to power LED(s)) and/or an image capturing element 2094. Lenses, fiber optics, LED(s), or combinations thereof may be used for illumination with lenses, fiber optics, CCD, CMOS, or combinations thereof used for image capturing, according to various embodiments.

[0172] Referring now to Fig. 16, another embodiment of a tissue modification device 2120 may suitably include an elongate shaft 2132, one or more tissue modifying members 2130, a handle 2124, a visualization device 2122, an optical cable 2128 and a power connector 2126. In this embodiment, visualization device 2122 is located proximal to tissue modifying member(s) 2130 on shaft 2132. In various embodiments, visualization device(s) 2112 may be positioned along shaft 2132 at any desired location.

[0173] Figs. 17A-17E show cross-sectional views of various embodiments of shaft 2132, from the perspective of line A-A in Fig. 16. In the embodiment shown in Fig. 17A, for example, shaft 2132 may include a tissue modifying drive 2134 within a tissue modifying

drive lumen 2140, and a guidewire 2136 within a guidewire lumen 2138. Tissue modifying drive 2134 may be configured to translate or rotate with respect to tissue modifying drive lumen 2140. Examples of tissue modifying drives 2134 include, but are not limited to, a drive shaft, one or more conductive wires, one or more optical fibers, or the like. Various embodiments may also include a motor, which may be located in the handle of the device, near the device distal end, in a separate drive apparatus, or the like.

[0174] In an alternative embodiment, as shown in Fig. 17B, shaft 2132 may include tissue modifying drive 2134 within tissue modifying drive lumen 2140, guidewire 2136 within guidewire lumen 2138, conductive elements 2146 within a visualization lumen 2144, and suction/irrigation lumen 2142. Suction/irrigation lumen 2142 may be used, for example, to deliver gas, fluid or pushable solids (e.g., granular solids) from outside the patient to the distal end of the device or to aspirate gas, fluids, tissue and/or other material from the targeted tissue region to the outside of the patient. Suction/irrigation lumen 2142 may also be used, in some embodiments, to slidably pass instruments, such as a long flexible needle or biopsy forceps. Visualization lumen 2144, in some embodiments, may be configured to receive conductive elements 2146, such as elements to power LEDs at the distal end of the device, and/or to carry the signal from a CCD or CMOS chip located at the distal end of the device that has captured a visual image and converted it into an electronic signal to a display device located outside the patient.

[0175] In yet another alternative embodiment, shown in Fig. 17C, shaft 2132 may include tissue modifying drive 2134 within tissue modifying drive lumen 2140, conductive elements and/or fiber optics 2152 within visualization lumen 2144, and separate suction 2150 and irrigation 2148 lumens. Suction lumen 2150 and irrigation lumen 2148 may be used, in some embodiments, to simultaneously or sequentially deliver and remove gases, fluids and/or pushable solids to and from the distal end of a tissue modification device. Delivery and removal of gases, fluids and/or pushable solids may help clear detached and/or non-detached target tissue and other debris from the treatment site and/or maintain a clear visualization of the target and non-target tissue via the visualization element.

[0176] In another embodiment, illustrated in Fig. 17D, fiber optics 2152 may be disposed within a hollow shaft 2132, in between various lumens 2148, 2150, 2144, 2140. Alternatively, fiber optics 2152 may be replaced with electrical conductors in other embodiments. Fiber optics 2152 may deliver light to illuminate the target tissue and/or

deliver light from the tissue to a viewing device. Visualization lumen 2144, in such an embodiment, may transport light or electrical signals in proximal and/or distal directions.

[0177] In yet another alternative embodiment, as in Fig. 17E, shaft 2132 may include a steering actuator 2154 within a steering lumen 2156. Steering actuator 2154 may be used, for example, to help steer a distal portion of a tissue modification device, as described in further detail above.

[0178] Fig. 18 is an end-on cross-sectional view of tissue modification device 2120 of Fig. 16, shown from the perspective of line B-B. In this embodiment, visualization device 2122 and illuminating elements 2158 are located proximal to tissue modifying member 2130. In the embodiment shown, tissue modifying member 2130 includes a rotating disc mounted on a post in a bearing 2160, with multiple raised cutting edges 2131 on the disc. Two suction/irrigation lumens 2142 allow for introduction and suction of gas, fluid and/or pushable solids from an area of tissue modification.

[0179] Figs. 19A-23B illustrate a number of embodiments of a distal end of a tissue modification device having various different tissue modifying members. In any of these embodiments, the devices may be couplable distally with a guidewire or may extend distally from the tissue modifying portion shown, to extend the device out of the patient distally. Referring to Figs. 19A-19C, in another embodiment, a tissue modification device 2310 may include a tissue modifying member 2312 comprising a movable platform with an abrasive surface and coupled with a drive shaft 2314 extending out of a distal opening 2316. As shown in the various figures, in some embodiments tissue modifying member 2312 may move laterally (Fig. 19A), may translate back and forth (Fig. 19B) and/or may vibrate (Fig. 19C).

[0180] In yet another embodiment, as in Fig. 20, a tissue modification device 2320 may include a tissue modification member 2322 comprising an oval or round platform with an abrasive surface and coupled with a drive shaft 2324 extending out of a distal opening 2326. In such an embodiment, tissue modifying member 2322 may be made to rotate or move in a circular pattern, as well as translate, move laterally, oscillate and/or vibrate according to various embodiments.

[0181] Referring to Fig. 21, in another embodiment a tissue modification device 2330 includes multiple tissue modifying members 2332, each including a movable platform 2333 with an abrasive surface attached to a drive shaft 2334. Tissue modifying members may

move back and forth relative to one another and to the device shaft in any suitable pattern. Moving tissue modifying members 2332 back and forth relative to one another may help them apply tensioning forces to target tissue, thereby enhancing the ability of tissue modifying members 2332 to cut, shear, tear and/or otherwise modify target tissues.

[0182] As shown in Fig. 22, in another alternative embodiment, a tissue modification device 2340 may suitably include tissue modifying members comprising one or more blades, such as a distal blade 2344a and a proximal blade 2344b, each having a cutting edge 2345a, 2345b. In the embodiment shown, proximal blade 2344b is movable and may translated distally toward the opposing distal blade 2344a. In alternative embodiments, distal blade 2344a may be movable or both blades 2344a, 2344b may be movable. Alternative embodiments may include one movable blade, more than two movable blades facing in one direction, more that two movable blades facing in different directions, a movable blade and a backstop against which the blade may be driven, or any other suitable combination of movable and/or immobile blades. Furthermore, any blade of any given embodiment may have any suitable shape, size and overall configuration. In some embodiments, blades may be flat, while in others they may be curved, squared off, ridged, bent, serrated or the like. Blades may be long or short, multiple blades may be aligned closely one after the other, such as in a typical multi-blade razor used for shaving a face, multiple blades may be disposed apart from one another by several millimeters or even centimeters, and/or the like. Blades may have any suitable amount of sharpness or dullness, and in some embodiment a combination of sharper and duller blades may be used. Therefore, although exemplary embodiments of blades are described in detail above and below, any other suitable blades or combinations of blades may be substituted in various embodiments, without departing from the scope of the present invention.

[0183] Blades 2344a, 2344b, or any other blades described in alternative embodiments herein, may be fabricated from metals, polymers, ceramics, any other suitable material or combination of materials. According to various embodiments, suitable metals for blades may include, but are not limited to, stainless steel (303, 304, 316, 316L), nickel-titanium alloy, or cobalt-chromium alloy, for example, Elgiloy® (Elgin Specialty Metals, Elgin, IL, USA), Conichrome® (Carpenter Technology, Reading, PA, USA), or Phynox® (Imphy SA, Paris, France). Polymer materials include nylon, polyester, Dacron®, polyethylene, acetal, Delrin® (DuPont), polycarbonate, nylon, polyetheretherketone (PEEK), and polyetherketoneketone (PEKK). In some embodiments where polymers are used, such polymers may be glass-filled

or carbon-filled to add strength and stiffness. Ceramics may include, but are not limited to, aluminas, zirconias, and carbides. Blades may be manufactured using skills known in the art, for example, metal injection molding (MIM), CNC machining, injection molding, grinding, EDM, sheet metal bending, etching, or the like. Other portions of a tissue modification device, such as a cover over one or more blades or other features, may be made of any suitable material now known or hereafter discovered. A blade cover, for example, may be fabricated in various embodiments of one or more polymeric materials, such as nylon, silicone, polyetheretherketone (PEEK), polyetherketoneketone (PEKK), polytetrafluoroethylene (PTFE), polyurethane (Tecothane,), Pebax (co, USA), polycarbonate, Delrin (co, USA), high-density polyethylene (HDPE), low-density polyethylene (LDPE), HMWPE, UHMWPE, or the like.

[0184] Referring now to Fig. 23A, in one embodiment a tissue modification device 2350 may have a substantially cylindrical, circular, or otherwise curved shaft 2352 as well as one or more substantially cylindrical, circular, or otherwise curved blades 2354. In the embodiment shown, blade 2354 protrudes out of a window 2358 of shaft 2352. When blade 2354 is moved proximally (arrow), its cutting edge 2356 moves toward and perhaps engages with an opposing cutting edge 2356 of shaft 2352.

[0185] In an alternative embodiment, as in Fig. 23B, a tissue modification device 2360 may have a substantially cylindrical, circular, or otherwise curved shaft 2362 as well as one or more substantially cylindrical, circular, or otherwise curved blades 2364. In the embodiment shown, blade 2364 protrudes out of a window 2368 of shaft 2362. Blade 2364 may be rotated (arrows), to cause its cutting edges 2366 cut target tissue. In some embodiments, one or more curved blades 2364 may be translated as well as rotated. In either of the embodiments shown in Figs. 23A and 23B, cut target tissue may optionally be removed through the inside of curved shaft 2352 or curved blade 2364.

[0186] Referring now to Figs. 24A and 24B, in some embodiments, a tissue modification device may include one or more anchoring members 2374 coupled with a distal shaft portion 2370 of the device. In various embodiments, any of a number of suitable anchoring members may be used. Some embodiments of anchoring members have been previously described above, and others will be described further below. In one embodiment, for example, anchoring members 2374 may comprise multiple needles, as shown in Figs. 24A and 24B. Needles 2374 may act not only to anchor distal shaft portion 2370 to tissue, but may also

change one or more characteristics of the tissue. For example, in some embodiments, inserting multiple needles into tissue may stiffen the tissue and thus enhance the ability of one or more tissue modifying members 2372 to cut or otherwise modify the tissue. In one embodiment, anchoring members/needles 2374 may be deployable out of distal shaft portion 2370 (arrow), such that needles 2374 are retracted during delivery of the device into the patient and then deployed into the target tissue when in a desired position. In various embodiments, anchoring members/needles 2374 may extend out of distal shaft portion 2370 in an orientation substantially perpendicular to the longitudinal axis of distal shaft portion 2370 or in any other suitable orientation relative to distal shaft portion 2370 or otherwise non-parallel to the longitudinal axis. During use, the tissue stiffening projections can extend into the target tissue. Needles 2374 will typically have a modulus of elasticity greater than the modulus of elasticity of the target tissue, and thus may stiffen (i.e., increase the effective modulus of elasticity) of the target tissue.

[0187] In the embodiment shown in Figs. 24A and 24B, as well as in any alternative embodiments described herein, one or more members such as tissue anchoring members/needles 2374 may be used to modify tissue in any of a number of suitable ways. For example, in some embodiments, energy may be transmitted to one or more tissue anchoring members/needles 2374 to cool, heat or otherwise transmit energy to the tissue. Such cooling or heating, for example, may further change the stiffness or consistency of the tissue, thus facilitating tissue modification by one or more tissue modifying members. In one embodiment, for example, it may be advantageous to cool or even freeze tissue to increase its stiffness so that it can be more easily cut or abraded. For example, in some embodiments, a cryogenic fluid may be delivered via an irrigation lumen and/or suction/irrigation lumen to directly reduce the temperature of the anchoring members 2374 or to separately cool the target tissue. Any other suitable change may alternatively be made to tissue to enhance a tissue modification procedure according to various embodiments.

[0188] As shown in Fig. 24B, when anchoring members 2374 are in place within target tissue, tissue modifying member 2372 (a blade in the embodiment shown) may be translated out of distal shaft portion to cut or otherwise modify tissue. Tissue modifying member 2372 may advance out of distal shaft portion 2370 in a direction perpendicular or otherwise non-parallel to anchoring members 2374. In some embodiments, anchoring members/needles 2374 may retain target tissue after cutting, so that it may be removed from the patient.

[0189] Referring now to Figs. 25A and 25B, one embodiment of a barrier 602 comprising a woven, braided or non-woven material with a lattice structure 604 is shown. Fig. 25A shows barrier 602 being deployed from delivery device 601, and Fig. 25B shows barrier 602 in its completely deployed (expanded, free) configuration. In various embodiments, barrier 602 may have any of a number of suitable dimensions. For example, in some embodiments, barrier 602 may have a width ranging from about 0.100" to about 3.000", a length ranging from about 0.100" to about 72", and a thickness ranging from about 0.001" to about 0.250". In some embodiments, as described in connection with Figs. 10B and 10D above, barrier 602 may have a narrowed or tapered distal end. Barrier 602 may be manufactured by methods known in the art, such as in a single-layer flat-form or a dual-layer tubular-form that is pressed flat. Material used to fabricate barrier 602, in various embodiments, may be composed of a weave of metallic wire, monofilament or braided. The metallic wire may be made from any suitable material, such as stainless steel (303, 304, 316, 316L), nickel-titanium alloy, cobalt-chromium alloy, Elgiloy® (Elgin Specialty Metals, Elgin, IL, USA), Conichrome® (Carpenter Technology, Reading, PA,USA), Phynox® (Imphy SA, Paris, France) or the like. A woven material may be composed of a weave of polymer strands, monofilament or braided material. Polymer strands in a woven, braided or non-woven material construction may be made from nylon, polyester, Dacron®, polyethylene, Kevlar® (DuPont,), acetal, Delrin® (DuPont,), polycarbonate, nylon, silicone, polyetheretherketone (PEEK), polyetherketoneketone (PEKK), polytetrafluoroethylene (PTFE), polyurethane, UHMWPE, or the like. In some embodiments, barrier 602 may self-expand after being released from a constrained configuration in delivery device 601. In some embodiments, such self-expansion may be achieved by forming barrier 602 from a shape-memory or super-elastic material.

[0190] Referring to Figs. 25C and 25D, in an alternative embodiment, a barrier 612 may include multiple slits 615 extending from opposite edges 613a, 613b toward the longitudinal center of barrier 612 to form multiple tabs 616. Slits 615 may enhance flexibility of barrier 612 by allowing tabs 616 to flex independently. Tabs 616 may then return to their flat-form state individually as delivery device 601 is pulled proximally, as shown in FIG. 25D. Tabs 616 may also conform individually to surrounding tissue, thereby helping protect non-target tissue, in some embodiments. Barrier 612 may be made of any suitable material, such as but not limited to those described above, and slits 615 may be formed by any suitable method, such as die cutting, milling machining, laser cutting, EDM machining, injection molded,

etching, water-jet cutting, and blade cutting. In an alternative embodiment, barrier 612 may be made by assembling multiple tabs 616 to a central member by welding, soldering, brazing, or laser welding, for example.

[0191] Figs. 25E and 25F illustrate another alternative embodiment of a barrier 622 having slits 627 disposed more centrally and not extending to the lateral edges 623a, 623b.

[0192] In another alternative embodiment, shown in Figs. 25G and 25H, a barrier 632 comprises a central support member 639 and multiple lateral ribs 638 that form a skeleton-like framework. In various embodiments, central member 639 and ribs 638 may either comprise the same material or different materials, and any suitable materials may be used, such as but not limited to the materials listed above. In some embodiments, ribs 638 may retain a curvilinear shape after deployment that is heat-set in nickel-titanium or mechanically formed, as shown in Fig. 25G.

[0193] Referring to Figs. 25I and 25J, in another alternative embodiment, a barrier 642 may comprise a flat-form sheet made from polymer, porous polymer, woven or non-woven fabric, metal, porous metal, foam, hydrogel, a double-layer polymer "bag" to create an inflatable bladder, or the like.

[0194] Referring to Figs. 25K and 25L, in another alternative embodiment, a barrier 652 may comprise a central support member 650 and ribs 659 that straighten completely or nearly completely upon deployment. Optionally, barrier 652 may also include a flex-point 651 at which barrier 652 may articulate.

[0195] Figs. 26A and 26B illustrate another alternative embodiment of a barrier device 832, in which device 832 comprises a tubular, woven mesh. Barrier device 832 may assume an elongate, low-profile configuration, as in Fig. 26A, to facilitate its delivery to a treatment area, and may also be compressed from one or both ends to assume a widened/expanded configuration for protecting tissue, as in Fig. 82B. In another embodiment, as in Figs. 27A and 27B, a barrier device may comprise a flat woven mesh.

[0196] Another alternative embodiment of a barrier device 852 is depicted in Figs. 28A and 28B. Here, a first pull wire 854 and a second pull wire 855, extending from opposite ends of a shape changing portion of barrier device 852, may be pulled to cause the shape changing portion to expand or widen (Fig. 28B). In some embodiments, when pull wires 854, 855 are

released, the shape changing portion may resume its original, narrower configuration (Fig. 28A).

[0197] Referring now to Figs. 29A-29B, in another embodiment, a barrier device 862 may be housed in a housing 864 comprising two halves 866, 868, and a lumen for allowing passage of a guidewire 869. When halves 866, 868 are pulled apart, as in Fig. 29B, barrier device 862 is free to expand.

[0198] Referring now to Figs. 30A-30C, in another alternative embodiment, a barrier device 892 may include a piece of hydrogel material, which expands and/or unrolls from a collapsed/rolled configuration (Fig. 30A) to an expanded/unrolled configuration (Fig. 30C) when exposed to one or more fluids, such as saline, water, blood or the like. In one embodiment, hydrogel may be injected directly into an area between target and non-target tissues to form barrier device 892, and device 892 may be left in the patient's body to dissolve after a tissue modification procedure is complete. In other alternative embodiments, barrier device 892 may comprise one or more alternative self-expanding materials or materials that expand upon exposure to fluid.

[0199] In another embodiment, as shown in Figs. 31A-31C, a barrier device 872 may include a woven wire structure including lateral straight wires 874 coupled with crossing wires 877, 878 via multiple loops 876. In one embodiment, lateral wires 874 slide freely through loops 876, to allow barrier device 872 to collapse and expand. Wires 876, 877, 878 may be coupled with end caps 880, 881 at either end of barrier member 872. Some embodiments may also include pull tabs 879, 882 at either end of barrier member 872. As shown in Fig. 31C, when pull tabs 879, 882 are pulled, barrier device 872 may shorten and expand to a wider configuration. As shown in Figs. 31A and 31C, when pull tabs 879, 882 are pulled, an angle between cross wires 877, 878 decreases. In an alternative embodiment, pulling pull tabs 879, 882 may cause barrier device 872 to collapse. In some embodiments, wires 874, 877, 878 themselves may perform the protective function of barrier member 872, while in alternative embodiments a material or membrane may be coupled with wires 874, 877, 878.

[0200] Figs. 32A and 32B illustrate how, in one embodiment, a barrier device 3020 extending through a delivery device 601 may help protect tissue during a tissue modification procedure involving use of a tissue modification device 3024. In various embodiments, tissue modification device 3024 may include, but is not limited to, a rongeur, a curette, a

scalpel, one or more cutting blades, a scissors, a forceps, a probe, a rasp, a file, an abrasive element, one or more small planes, an electrosurgical device, a bipolar electrode, a unipolar electrode, a thermal electrode a rotary powered mechanical shaver, a reciprocating powered mechanical shaver, a powered mechanical burr, a laser, an ultrasound crystal, a cryogenic probe, a pressurized water jet, or any combination of such devices. Tissue modification device 3024 may be advanced and retracted (double-headed arrows) freely on one side of barrier device 3020 and may be used to modify tissue, while barrier device 3020 protects non-target tissue from sustaining unwanted damage. In some embodiments, barrier device 3020 may also be used to help guide tissue modification device 3024 to and/or from a position for performing a tissue modification procedure. Such guidance may be achieved by a shape, surface characteristic and/or one or more guide features of barrier device 3020, according to various embodiments.

[0201] Turning to Figs. 33A and 33B, in another embodiment, a barrier device 3030 may include an open, shape-changing portion 3030, closed, elongate extensions 3034 extending from either end of shape-changing portion 3030, and at least one guide feature 3035 extending through its length. Guide feature 3035 may include, in various embodiments, one or more guidewires (as shown), rails, impressions, lumens, tracks or the like, any of which may facilitate guidance of a tissue modification device 3032 along and/or through barrier device 3030. In various embodiments, guide feature 3035 may comprise a separate device, not attached to barrier member 3030, as in the guidewire of Figs. 33A and 33B. Alternatively, one or more guide features 3035 may be attached to, or integral with, barrier member 3030.

[0202] Fig. 34 shows an embodiment of a barrier device 3050 including a central rail 3052 guide member along which a tissue modification device 3054 may be guided. Fig. 35 shows an alternative embodiment of a barrier device 3060 including a central rail 3062 guide member along which a tissue modification device 3064 may be guided. In some embodiments, barrier devices 3050, 3060 and tissue modification devices 3054, 3064 may be advanced through a delivery device 601, while other embodiments may not employ such a delivery device 601.

[0203] Referring to Fig. 36A, in one embodiment, a barrier device 3070 may include a central channel 3072, accessible by a slit 3076, and multiple flex grooves 3074. Multiple flex grooves 3074 may facilitate collapsing of barrier device 3070. In another embodiment, as in

Fig. 36B, a barrier device 3080 may have a smooth, non-grooved surface and a central channel 3082, accessible by a slit 3086. Slit 3076, 3086 may facilitate coupling and decoupling of a tissue modification device with barrier device 3070, 3080.

[0204] Figs. 37A and 37B show two additional alternative embodiments of barrier devices 3190, 3200. Barrier device 3190 includes a protruding central guide feature 3192, a flat tissue protective portion 3193, and lateral support members 3194. Barrier device 3200 includes a central impression guide feature 3202, a flat tissue protective portion 3203, and lateral support members 3204.

[0205] As described immediately above, in any of a number of different embodiments, a barrier device may include one or more guide features. Such guide features may, in various embodiments, correspond with one or more guide features on a guide device or guide member for guiding the barrier member to a desired location and/or position in a patient. Alternative or additionally, one or more guide features on a barrier device may be used to facilitate guidance of one or more tissue modification devices along, over and/or through the barrier device. Thus, in some embodiments, a barrier member may include multiple guide features for guiding the barrier device and for guiding a tissue modification device. In other embodiments, the same guide feature(s) on a barrier device may be used to guide both the barrier device and a tissue modification device. Any suitable combination of guide feature(s) having any size, shape, pattern or the like may be used according to various emobdiments.

[0206] Fig. 38 illustrates one embodiment of a delivery device 3210 for delivering a barrier device 3220 to a location in a patient. In this embodiment, barrier device 3220 includes a guidewire lumen 3221, through which a guidewire 3222 may extend, and a guide feature 3223, over which one or more tissue modification devices (not shown) may be passed. Optionally, delivery device 3210 may include a visualization lumen 3216, through which a visualization device may be passed, a suction lumen 3214, and an irrigation lumen 3216. In alternative embodiments, delivery device 3210 many have any of a number of suitable different configurations and features. For example, in one embodiment suction lumen 3214 and irrigation lumen 3216 may combined into one lumen, multiple visualization lumens 3216 may be included, and or the like.

[0207] As is mentioned above, in many of the described embodiments, a barrier device may include one or more pieces of material. Such material may include any suitable material or combination, and in some embodiments may comprise a polymer, such as latex, rubber

(viton), nylon, silicone, polyetheretherketone (PEEK), polyetherketoneketone (PEKK), polytetrafluoroethylene (PTFE), polyurethane (Tecothane,), Pebax (co, USA), polycarbonate, Delrin (DuPont, USA), high-density polyethylene (HDPE), low-density polyethylene (LDPE), high-molecular weight polyethylene (HMWPE), ultra-high-molecular weight polyethylene (UHMWPE), paraline coating, or the like. The material may be coated, laminated, impregnated, covered, or over-molded on a barrier device, or alternatively may be attached to a barrier device by adhesives or cements, thermal bonding techniques, with fasteners such as clasps or thread, or by forming pockets in the material which fit over ribs of the barrier.

[0208] In other embodiments, one or more conductive wires may be included in a barrier device, such that the wires may be disposed and selectively activated/exposed along either or both of a target tissue surface or a non-target tissue surface of the barrier device. In one embodiment, for example, wires may be coupled with lateral support members of a barrier device. Conductive wires may be used, for example, to stimulate and thus identify specific tissues, such as nerves, and/or to monitor the position/location of the barrier device by measuring impedance and/or imparting electrical currents to induce stimulation to the target tissue. In one embodiment, an array of wire contact points along a barrier device may be implemented and independently activated to verify that the barrier device is in a desired location/position.

[0209] With reference now to Fig. 39, in some embodiments a tissue modification device 3600 may include an elongate, at least partially flexible body 3602, an abrasive tissue modifying surface 3604, a proximal handle 3606 and a distal handle 3608. As has been mentioned above, in some embodiments abrasive surface 3604 may comprise any of a number of various abrasive members, configurations or the like, such as but not limited to a rasp. Various abrasive surface/rasp embodiments, for example, are described in further detail in PCT Patent Application Pub. No. PCT/US2005/037136, which was previously incorporated by reference. For example, embodiments including abrasive or rasp surfaces are described in Figs. 34, 35, 41, 42, 48, 61, 62, 64, 86-99, 101 and 102, and their accompanying detailed description in PCT Patent Application Pub. No. PCT/US2005/037136.

[0210] In use, the distal end of elongate body 3602 may be advanced through the patient's back, into the epidural space, between target and non-target tissue, and out the patient's back, as in Fig. 39. Distal handle 3608 may then be removably coupled with the distal end of

elongate body 3602 (or near the distal end in alternative embodiments). A user may then grasp proximal handle 3606 and distal handle 3608 and pull on both to apply tensioning force (solid-tipped, upward-pointing arrows) to urge abrasive surface 3604 against the target tissue. The user may also use handles 3606, 3608 to translate elongate body 3602 back and forth (double-headed arrows) to cause abrasive surface 3604 to abrade the target tissue. During a given tissue modification procedure, tensioning force may be applied, using separate handles 3606, 3608, by pulling handles 3606, 3608 in different directions or in the same direction (i.e., parallel to one another). In some procedures, handles 3606, 3608 may be moved about to apply tensioning force from different angles and directions during the procedure. As mentioned above, By "separate handles," it is meant that handles 3606, 3608 are not connected to one another by a common handle or other connecting device or mechanism. Obviously, however, handles 3606, 3608 may be coupled with (in some embodiments removably coupled with) elongate body 3602 (or a shield in other embodiments) at or near its distal and proximal ends or portions.

[0211] Elongate body 3602 may have any suitable dimensions, according to various embodiments. In some embodiments, elongate body 3602 is sufficiently long to extend from outside the patient, through a channel in the spine, such as an intervertebral foramen, and out of the patient through an exit point located apart from the entry point. Elongate body 3602 will typically have a width sufficient to prevent abrasive surface 3604 from cutting completely through bone when tensioning force is applied and body 3602 is translated. For example, in one embodiment, body 3602 may have a width (at least along a portion where abrasive surface 3604 is disposed) of about 3 mm or less, and more preferably about 5 mm or less. Body 3602 may also have a height that facilitates its passage into the patient and between target and non-target tissues. For example, in one embodiment, body 3602 has a height of about 4 mm or less, and more preferably about 2 mm or less.

[0212] In some embodiments, abrasive surface 3604 may be disposed along one side of elongate body 3602 and along a limited length of elongate body 3602, to prevent or minimize unwanted damage to nearby non-target tissues as elongate body 3602 is translated. For example, in some embodiments, abrasive surface 3604 may be disposed along a length of the device measuring no longer than 10 cm, and preferably no more than 6 cm, and even more preferably no more than 3 cm. In alternative embodiments, abrasive surface 3604 may extend along a substantial majority or even the entire length of elongate body 3602 and/or may reside on multiple sides of elongate body 3602. In one embodiment, for example, all of

elongate body 3602 may comprise abrasive surface 3604, and at least a portion of elongate body 3602 may be disposed within a shield or barrier member to protect non-target tissues from damage during a procedure. Some embodiments, however, include at least one non-abrasive side or surface adjacent abrasive surface 3604, to protect non-target tissue from unwanted damage. Such a non-abrasive surface may optionally be made of a lubricious or low-friction material and/or may be coated with a lubricious or low-friction coating, in some embodiments.

[0213] Proximal handle 3606 and distal handle 3608 may have any size, shape or configuration in various embodiments. In fact, in various embodiments, distal handle 3608, proximal handle 3606, or both may be left off altogether. In Fig. 39, proximal handle 3606 is shown as a squeezable handle with a trigger, as has been described previously for use with a bladed, RF or other movable tissue modifying member (or members). Such a squeezable handle 3606 is not required in every embodiment, but may be used in some embodiments, such as when an abrasive/rasp device 3600 may be interchanged with a bladed device, RF device and/or the like during a tissue modification procedure. Thus, in some embodiments, squeezable proximal handle 3606 is removably couplable with elongate body 3602, so that various alternative tissue modifying members may be used with the same proximal handle 3602. In such embodiments, for example, target tissue may be modified using rasp elongate body 3602 and then may be further modified using an RF device, bladed device, powered device or the like. In various embodiments, such devices may be used in any order. Similarly, distal handle 3608 may also be used with more than one device.

[0214] In some embodiments, tissue modification device 3600 may further include one or more electrodes (not shown) coupled with or immediately adjacent abrasive surface 3604 and/or non-abrasive surface(s) of elongate body 3602. Such electrodes may be activated, for example, via a trigger or button on proximal handle 3606 in order to test positioning of abrasive surface 3604 within the patient. For example, once a user believes abrasive surface 3604 to be in position for treating target tissue, an electrode on abrasive surface 3604 may be activated. If abrasive surface 3604 is actually in contact with nerve tissue, which the user does not want to treat or damage, the patient's leg may twitch or jerk, showing the user that abrasive surface 3604 should be repositioned or the procedure aborted. Alternatively or additionally, an evoked EMG response of a patient may be monitored to determine if the activated electrode is touching or near nerve tissue. In another embodiment, electrode may be placed on a non-abrasive surface, so that when activated, it demonstrates that the non-

abrasive surface is facing non-target tissue, as intended. In various embodiments, any combination of electrodes may be used. Further description of such electrodes and their use can be found in PCT Patent Application Pub. No. PCT/US2005/037136.

[0215] Referring now to Figs. 40A-40D, in various embodiments, a rasp or abrasive surface of a tissue modification device may have any of a number of suitable configurations, sizes, numbers of rasp elements and/or the like. A number of such abrasive surfaces, for example, are described in previously incorporated PCT Patent Application Pub. No. PCT/US2005/037136, such as in Figs. 90-96 and the accompanying detailed description. The embodiments shown in Figs. 40A-40D are further examples of rasp/abrasive surface configurations, according to various embodiments.

[0216] In one embodiment, as shown in Fig. 40A, a diagonally patterned rasp member 3624 having multiple notches 3626 may be disposed along one side of an elongate body 3622 of a tissue modification device. Of course, in various embodiments, rasp member 3624 may have any number of bends or may have any other alternative shape or configuration. In alternative embodiments, rasp member 3624 may be made of any of the materials listed in the foregoing description for any alternative embodiments of tissue modifying members. For example, in some embodiments, rasp member 3624 may have hard edge and be comprised of a material like stainless steel or titanium, while in other embodiments rasp member 3624 may be fabricated as an abrasive surface of diamond, tungsten carbide or the like. In yet another embodiment, a braided wire, such as the braided wire used in a Gigli saw, may be adhered to a surface of elongate body 3622 to form rasp member 3624. Obviously, rasp member 3624 may have any of a number of configurations and may be fabricated from any suitable material, and thus, rasp member 3624 is not limited to the examples described here.

[0217] Fig. 40B shows an alternative embodiment, in which a rasp member 3634 and multiple channel openings 3636 are disposed along an elongate body 3632 of a tissue modification device. In such an embodiment, tissue that is abraded off by rasp member 3634 may enter channel openings 3636 into a hollow portion (or multiple hollow portions) of elongate body 3632. In various embodiments, removed tissue may be either stored in such a channel and removed when the tissue modification device is removed from the patient, or may alternatively be directed out of elongate body 3632 using irrigation, suction or a combination thereof.

[0218] In another embodiment, shown in Fig. 40C, a rasp portion 3644, disposed along an elongate body 3642, may include any number of rasp members 3646 and, optionally, any number of channel openings 3648. In some embodiments, rasp members 3646 may have cutting edges that face in the same direction. In such embodiments, rasp members 3646 abrade or cut tissue when elongate body 3642 is translated in one direction and do not abrade or cut tissue when translated in the opposite direction. In various embodiments, rasp members 3646 may also be configured to direct tissue in channel openings 3648.

[0219] Fig. 40D shows another embodiment of a rasp portion 3654 disposed along an elongate body 3652 of a tissue modification device. Rasp portion 3654 again includes multiple rasp members 3656 and multiple channel openings 3658, but in this embodiment, rasp members 3656 have alternating rows of oppositely directed cutting edges. Thus, when elongate body 3652 is translated back and forth, rasp members 3656 abrade or cut tissue as elongate body 3652 travels in both directions.

[0220] With reference now to Fig. 41, in an alternative embodiment, a tissue modification device 3700 may include an elongate, at least partially flexible body 3702, at least part of which is disposed within a shield member 3710 (or "barrier member") having an opening 3712 along its length. Elongate body 3702 may include at least one abrasive surface 3704, which may comprise a rasp or other abrasive surface as discussed above, and which may be exposed through opening 3712 to contact and abrade target tissue. Tissue modification device 3700 may also include a proximal handle 3706 and a distal handle 3708, either or both of which may be removably coupled with elongate body 3702, according to various embodiments. Shield member 3710 may optionally include a proximal anchoring member 3714 and/or a distal anchoring member 3716 for anchoring shield member 3710 outside the patient. In alternative embodiments, proximal handle 3706, distal handle 3708, or both may be coupled with shield member 3710, rather than with body 3702.

[0221] In use, shield member 3710 may be passed into the patient's back, into the epidural space, between target and non-target tissue, and out the patient's back. In various embodiments, elongate body 3702 may be passed into the patient along with shield member 3710 or through shield member 3710 after it is in place. In another embodiment, elongate body 3702 may be passed into patient first, and shield member 3710 may be passed over it into the patient. Abrasive surface 3704 may be positioned so that it is exposed and/or protrudes through opening 3712 on shield member 3710 to contact target tissue. Tensioning

force may be applied to shield member 3710, elongate body 3702, or both, to urge abrasive surface 3704 into the target tissue. For example, in some embodiments, tensioning force may be applied by grasping and pulling on handles 3706, 3708, while in other embodiments, tensioning force may be applied by grasping and pulling on distal and proximal portions of shield member 3710. At some point, either before or after applying tensioning force, anchoring members 3714, 3716 may be coupled with or deployed from shield member 3710. Various alternative embodiments may include only proximal anchoring member 3714 or only distal anchoring member 3716, and the unanchored end of shield member 3714 may be pulled to apply tensioning force. Anchoring members 3714, 3716 may include any suitable device for anchoring or leveraging against the patient's skin, some exemplary embodiments of which are described above in connection with Fig. 6A. In alternative embodiments, anchoring members 3714, 3716 may attach to one or more devices apart from the patient, such as a rail of an operating table or the like. In other alternative embodiments, shield member 3710 may be held relatively stationary by manually holding one or both of its ends. In other embodiments, shield member 3710 may be held relatively stable simply by residing in the patient's own tissue. In further alternative embodiments, both shield member 3710 and body 3702 may be held relatively stable, and one or more actuators on proximal handle 3706 and/or distal handle 3708 may be used to move or otherwise activate abrasive surface 3704 to abrade the target tissue.

[0222] Elongate body 3702 may be translated back and forth through shield member 3710 to cause abrasive surface 3704 to abrade target tissue. Because shield member 3710 generally protects non-target tissue from unwanted damage, abrasive surface 3704 may be disposed along elongate body for any desired length and/or may be disposed about all or substantially all of the circumference of elongate body 3702. In some embodiments, for example, abrasive surface 3704 may extend the entire length of elongate body 3702. In fact, in some embodiments, elongate body 3702 may comprise a rasp, braided wire saw or the like. In some embodiments, shield member 3710 may include one or more protective materials, added layers of material, or the like (not shown) along one or more edges of opening 3712, to prevent damage to such edges of opening 3712 when elongate body 3702 is translated back and forth.

[0223] In various embodiments, shield member 3710, elongate body 3702, or both may include additional features to enhance a tissue modification procedure to treat or alleviate spinal stenosis. For example, in various embodiments, shield member 3710 and/or elongate

body 3702 may include one or more lumens for applying suction and/or irrigation, to help remove tissue debris from the patient. Such debris may be removed through one or more lumens in shield member 3710, one or more lumens in elongate body 3702, or between shield member 3710 and elongate body 3702, in various embodiments. Optionally, one or more electrodes may be positioned on shield member 3710, elongate body 3702, abrasive surface 3704 or some combination thereof, to help allow a user to verify device 3700 is in a desired location in the patient, as described above. In various embodiments, other optional features may also be added.

[0224] Turning now to Figs. 42A and 42B, in another embodiment, a tissue modification device 800 may include an elongate body 802, a widened tissue modifying portion 806 including an abrasive surface 808, tapered portions 810 and a non-abrasive surface 816, a proximal handle 812 and a distal handle 814. (Fig. 42B shows a side view of a portion of device 800.) In one embodiment, elongate body 802 may comprise a metal wire, and tissue modifying portion 806 may comprise a wider section coupled with the wire. Body 802, tissue modifying portion 806 and the like may have any suitable size and configuration, and abrasive surface 808 may have any suitable configuration, examples of which have been described in greater detail above and in PCT Patent Application Pub. No. PCT/US2005/037136, which was previously incorporated by reference. In various embodiments, body 802 may be coupled with tissue modifying portion 806 using any technique, such as welding, attaching with adhesive or the like. In an alternative embodiment, body 802 and tissue modifying portion are formed from one piece of material. Optionally, body 802 and/or tissue modifying portion 806 may include one or more lumens, such as a guidewire lumen, suction lumen, irrigation fluid lumen and/or the like. Device 800 may also include a shield member, one or more electrodes, or any of the additional features described above in conjunction with other embodiments.

[0225] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. Therefore, the foregoing description should not be interpreted to limit the scope of the invention as it is set forth in the claims.

2007226692 12 Dec 2012

CLAIMS:

1. A device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis, the device comprising:

an elongate, at least partially flexible body having a proximal portion and a distal portion;

an abrasive surface disposed along a portion of one side of the elongate body;

a non-abrasive surface located adjacent the abrasive surface so as to face non-target tissue when the abrasive surface is positioned to face target tissue;

a proximal tensioning member coupled with the elongate body at or near the proximal portion for facilitating application of tensioning force to, and translation of, the elongate body; and

at least one coupler at or near the distal portion of the elongate body for coupling a distal tensioning member to the elongate body such that it is not directly connected to the proximal tensioning member, wherein the distal tensioning member facilitates an application of a tensioning force to, and translation of, the elongate body.

2. A device as in claim 1, wherein the elongate body has a cross-sectional shape selected from the group consisting of round, ovoid, ellipsoid, flat, rectangular, square, triangular, symmetric and asymmetric.

3. A device as in claim 1, wherein the elongate body has a width of not more than 5 mm and a height of not more than 2 mm.

4. A device as in claim 1, wherein the at least one abrasive surface comprises a rasp.

5. A device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis, the device comprising:

an elongate, at least partially flexible body having a proximal portion and a distal portion;

at least one abrasive surface disposed along a portion of one side of the elongate body;

at least one non-abrasive surface located adjacent the at least one abrasive surface so as to face non-target tissue when the abrasive surface is positioned to face target tissue;

at least one proximal tensioning member coupled with the elongate body at or near the proximal portion for facilitating application of tensioning force to, and translation of, the elongate body; and

at least one distal tensioning member, coupled with the elongate body by at least one coupler provided at or near the distal portion such that the distal tensioning member is not directly connected to the proximal tensioning member, for facilitating application of tensioning force to, and translation of, the elongate body.

6. A device as in claim 5, wherein the elongate body has a cross-sectional shape selected from the group consisting of round, ovoid, ellipsoid, flat, rectangular, square, triangular, symmetric and asymmetric.

7. A device as in claim 5, wherein the elongate body has a width of not more than 5 mm and a height of not more than 2 mm.

8. A device as in claim 5, wherein the elongate body includes at least one of a guidewire lumen, a rail, a track, and a lengthwise impression along which the device may be passed over a delivery device.

9. A device as in claim 5, wherein the at least one abrasive surface comprises a rasp.

10. A device as in claim 5, wherein at least one of the proximal and distal tensioning members is removably attachable to the elongate body.

11. A device as in claim 5, further comprising at least one lumen in the elongate body for providing at least one of suction and irrigation.

12. A device for modifying tissue in a spine of a patient to treat or alleviate spinal stenosis, the device comprising:

an elongate, at least partially flexible shield member having a proximal portion, a distal portion and at least one opening along its length;

an elongate, at least partially flexible tissue modification member disposed at least partly within the shield member, the tissue modification member having a proximal portion, a distal portion, and at least one abrasive surface;

at least one proximal tensioning member at or near the proximal portion of at least one of the shield member and the tissue modification member for facilitating application of tensioning force in a first direction; and

at least one distal tensioning member coupled to at least one of the shield member and the tissue modification member by at least one coupler provided at or near the distal portion of at least one of the shield member and the tissue modification member such that the distal tensioning member is not directly connected to the proximal tensioning member, for facilitating application of tensioning force in a second direction.

13. A device as in claim 12, wherein the shield member comprises a hollow member, and the opening comprises a window in a sidewall of the hollow member.

14. A device as in claim 13, wherein at least one edge of the window includes a protective surface for protecting the shield member from damage by the abrasive surface.

15. A device as in claim 12, wherein the opening of the shield member extends along one side of the entire length of the shield member.

16. A device as in claim 12, wherein the shield member is removably, slibably couplable with the tissue modification member.

17. A device as in claim 12, wherein the shield member comprises at least one anchor for anchoring the shield member outside the patient.

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18. A device as in claim 17, wherein the shield member comprises:

a proximal anchor; and

a distal anchor.

19. A device as in claim 18, wherein the proximal and distal anchors are removably couplable with the shield member at or near proximal and distal portions thereof, respectively.

20. A device as in claim 12, wherein the shield member includes at least one of a guidewire lumen, a rail, a track, and a lengthwise impression along which the shield member may be passed over a delivery device.

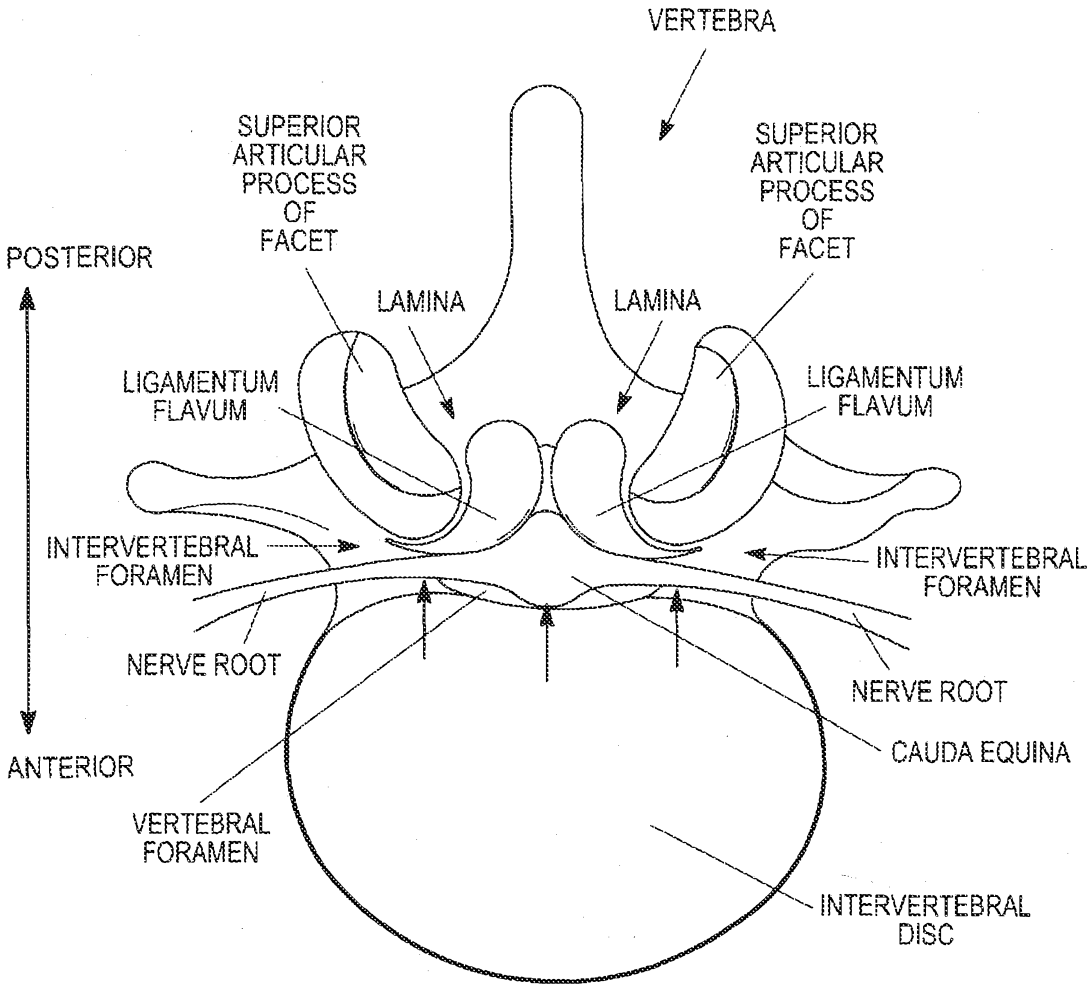
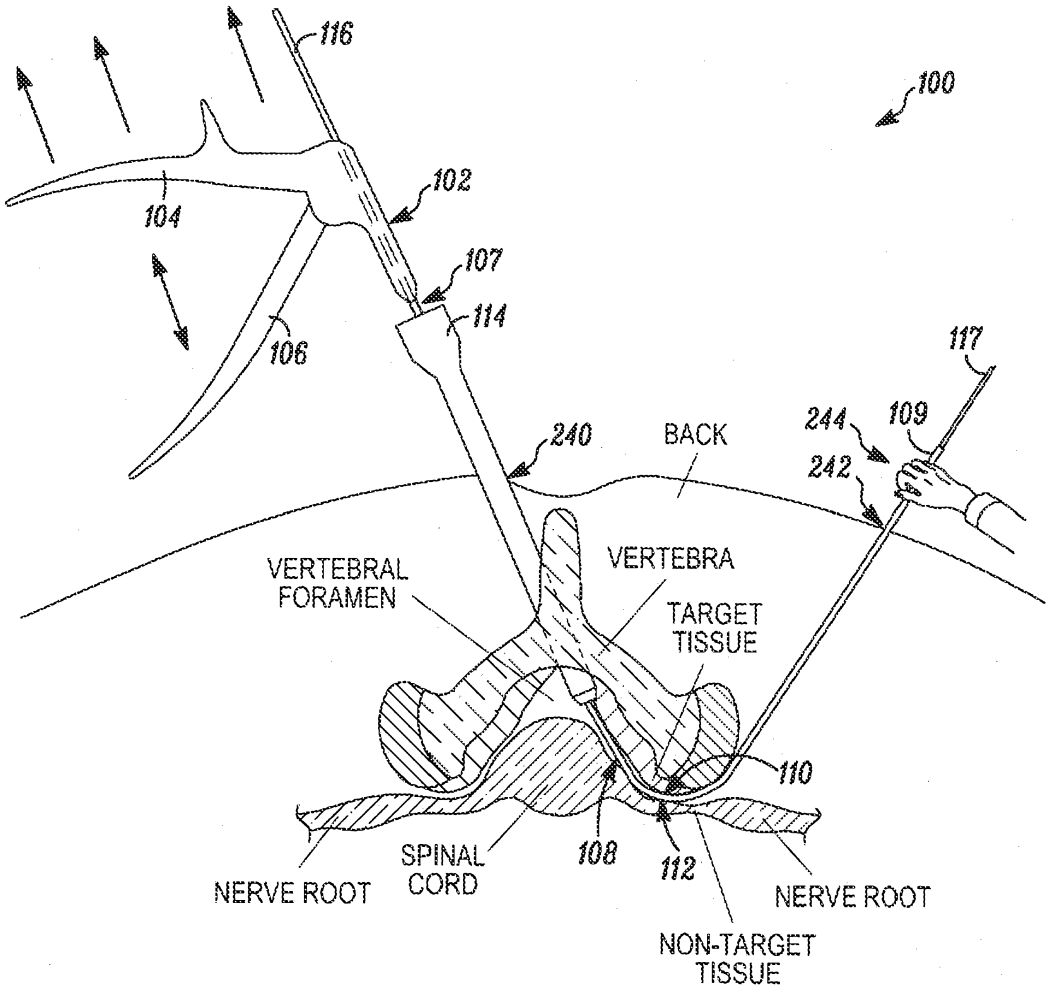

VERTEBRA
SUPERIOR ARTICULAR PROCESS OF FACET
SUPERIOR ARTICULAR PROCESS OF FACET
POSTERIOR
LAMINA
LAMINA
LIGAMENTUM FLAVUM
LIGAMENTUM FLAVUM
INTERVERTEBRAL FORAMEN
INTERVERTEBRAL FORAMEN
NERVE ROOT
NERVE ROOT
CAUDA EQUINA
ANTERIOR
VERTEBRAL FORAMEN
INTERVERTEBRAL DISC

FIG. 1


116
100
102
104
107
114
106
117
240
BACK
244
109
242
VERTEBRAL FORAMEN
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TARGET TISSUE
110
SPINAL CORD
108
112
NERVE ROOT
NERVE ROOT
NON-TARGET TISSUE

FIG. 2

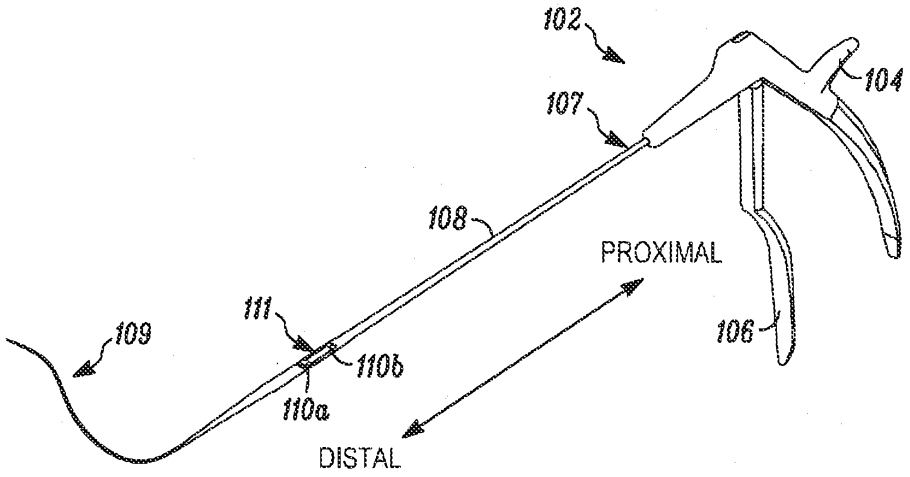

102
104
107
108
PROXIMAL
109
111
110b
110a
106
DISTAL

FIG. 3A

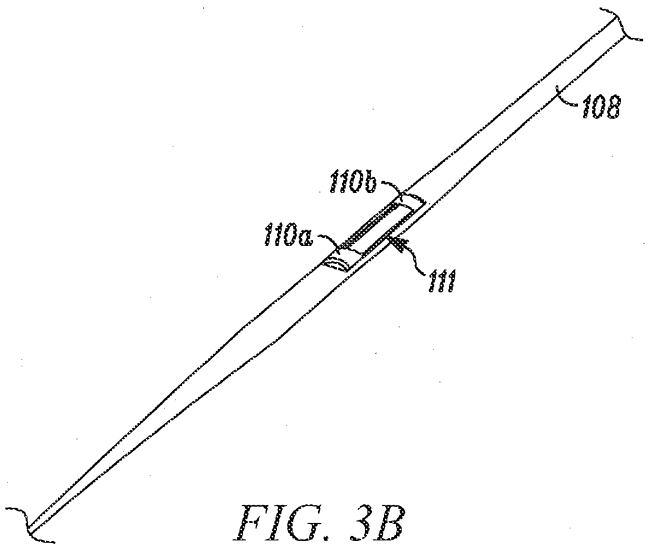

108
110b
110a
111

FIG. 3B

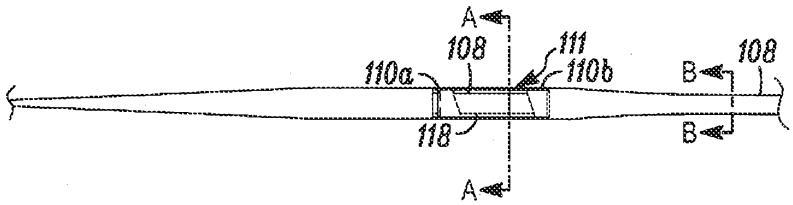


FIG. 3C

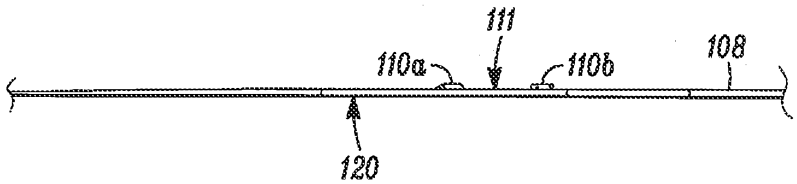
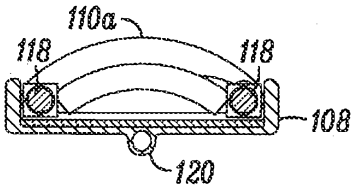
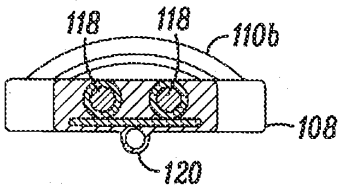


FIG. 3D



SECTION A-A

FIG. 3E



SECTION B-B

FIG. 3F

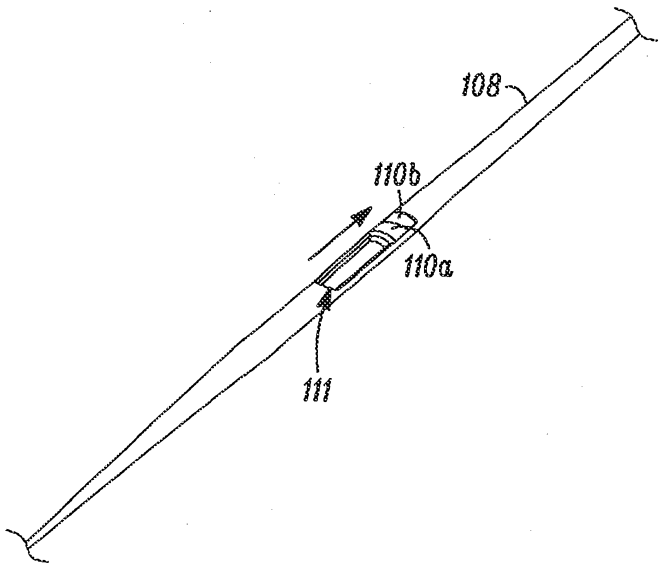


FIG. 3G

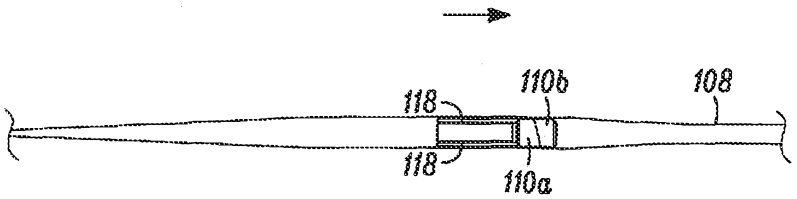


FIG. 3H

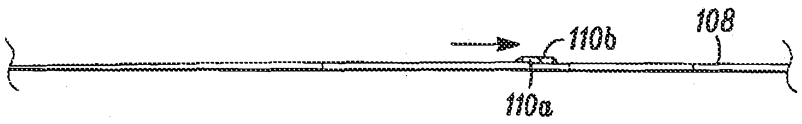


FIG. 3I

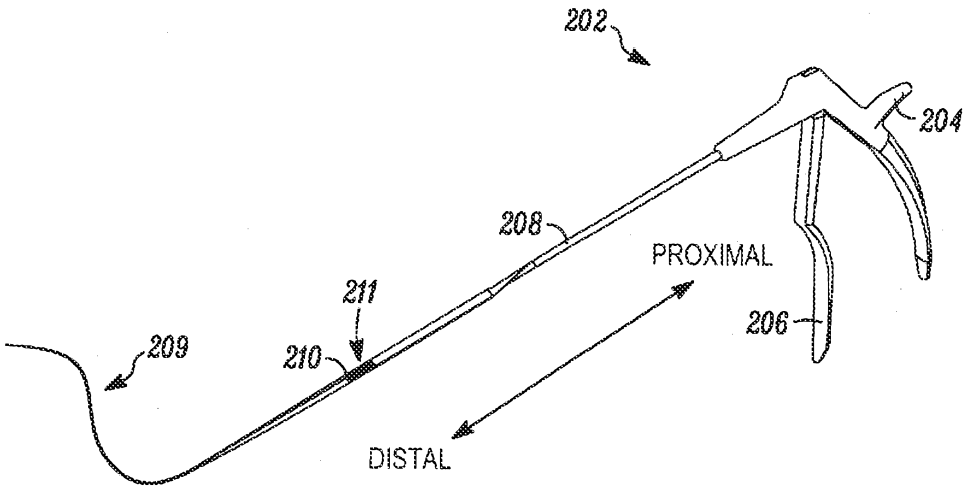


FIG. 4A

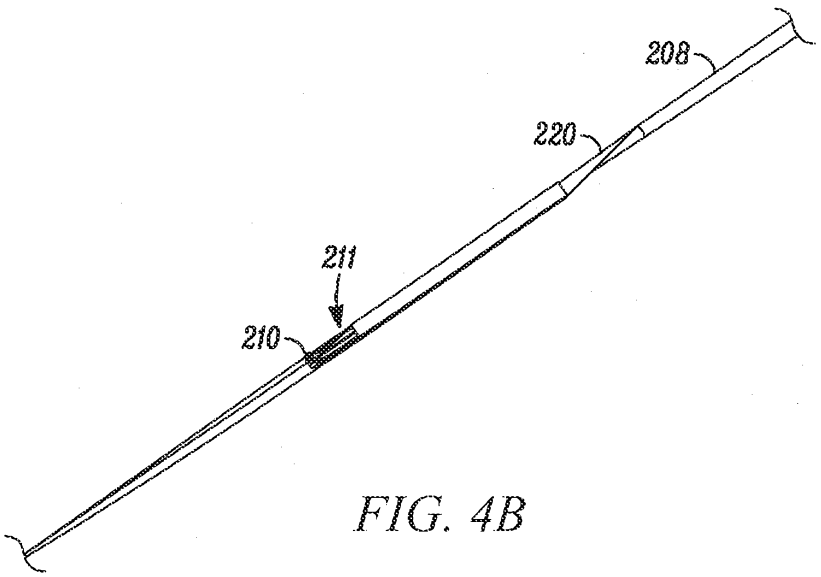


FIG. 4B

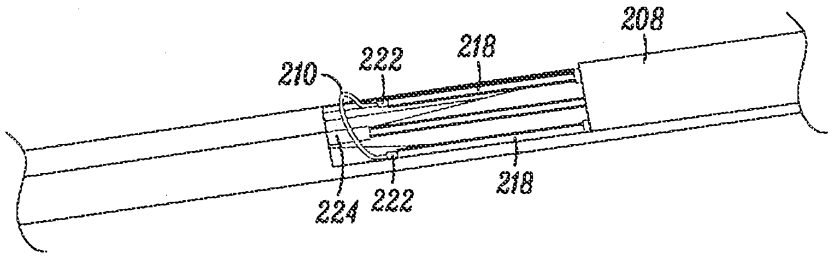

208
218
222
210
218
222
224

FIG. 4C

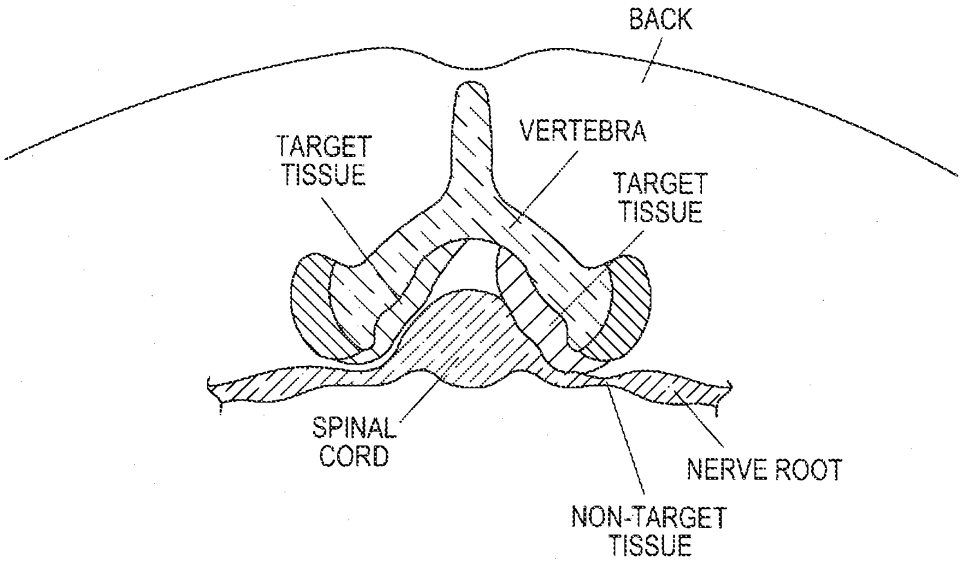

BACK
VERTEBRA
TARGET TISSUE
TARGET TISSUE
SPINAL CORD
NERVE ROOT
NON-TARGET TISSUE

FIG. 5A

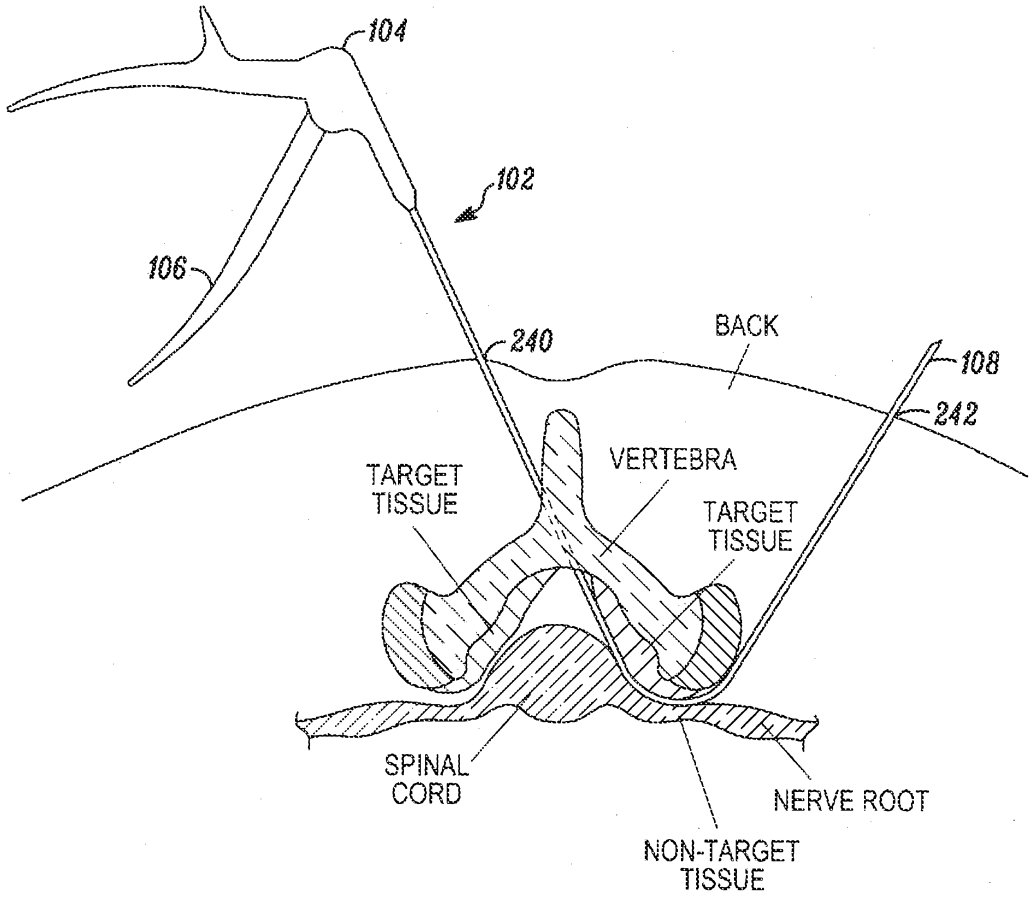

104
102
106
240
BACK
108
242
TARGET TISSUE
VERTEBRA
TARGET TISSUE
SPINAL CORD
NERVE ROOT
NON-TARGET TISSUE

FIG. 5B

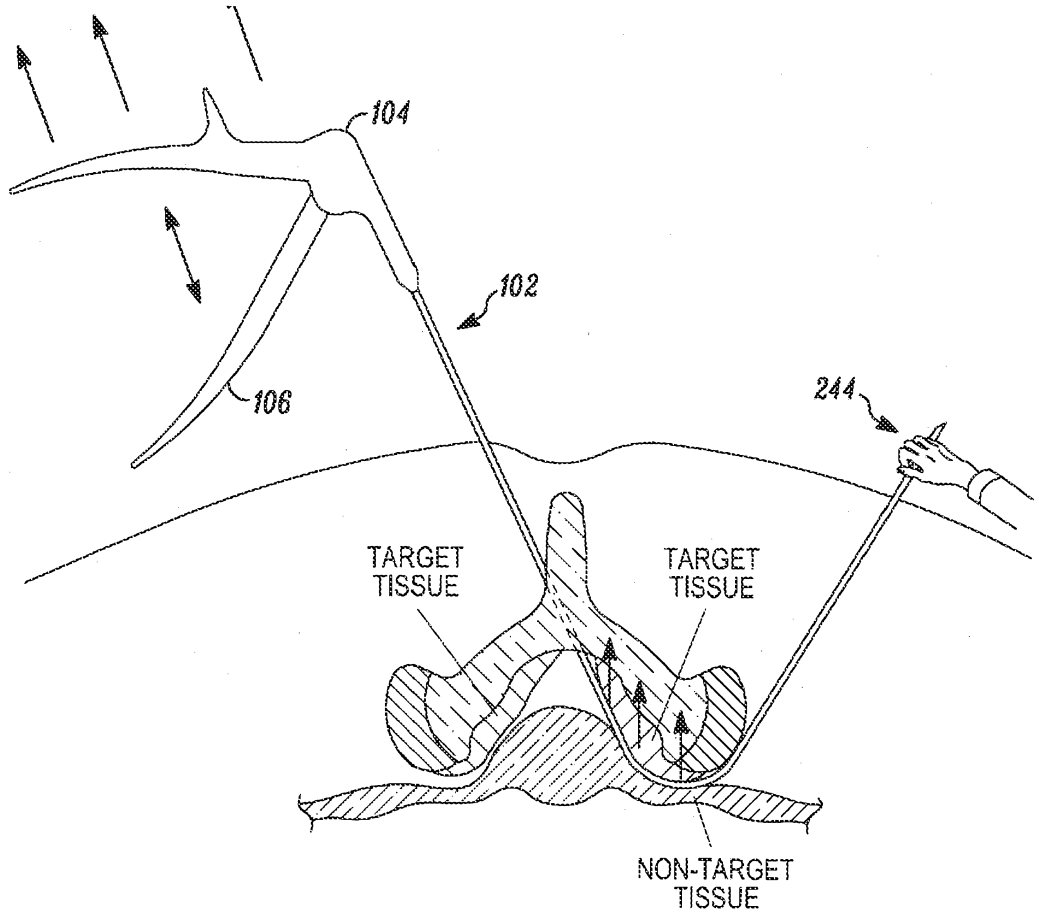

104
102
106
244
TARGET TISSUE
TARGET TISSUE
NON-TARGET TISSUE

FIG. 5C

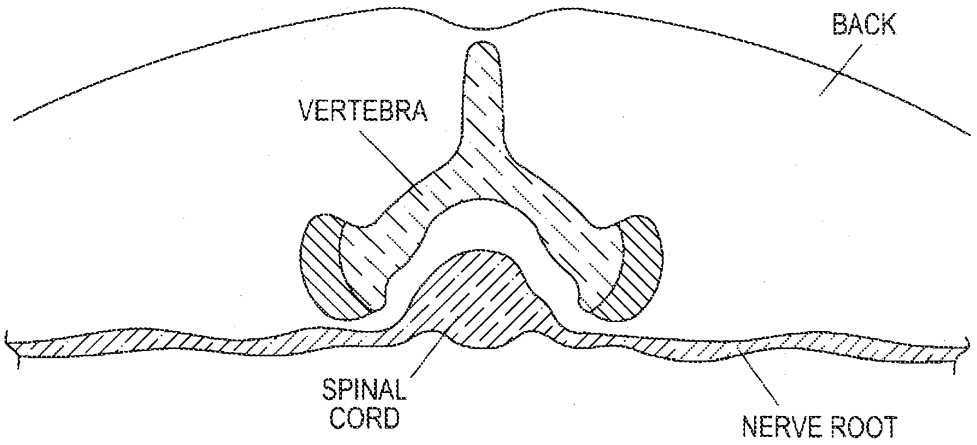

BACK
VERTEBRA
SPINAL CORD
NERVE ROOT

FIG. 5D

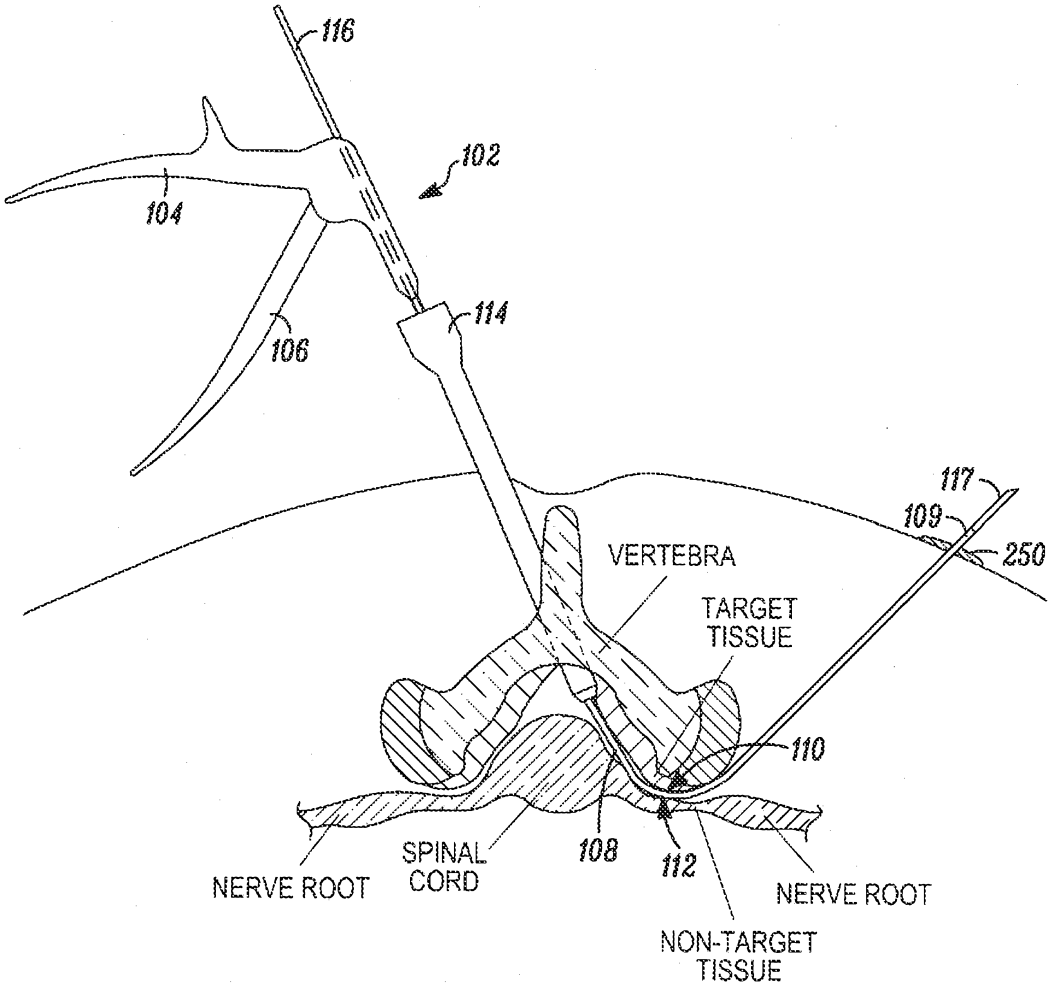

116
102
104
114
106
117
109
250
VERTEBRA
TARGET TISSUE
110
SPINAL CORD
108
112
NERVE ROOT
NERVE ROOT
NON-TARGET TISSUE

FIG. 6A

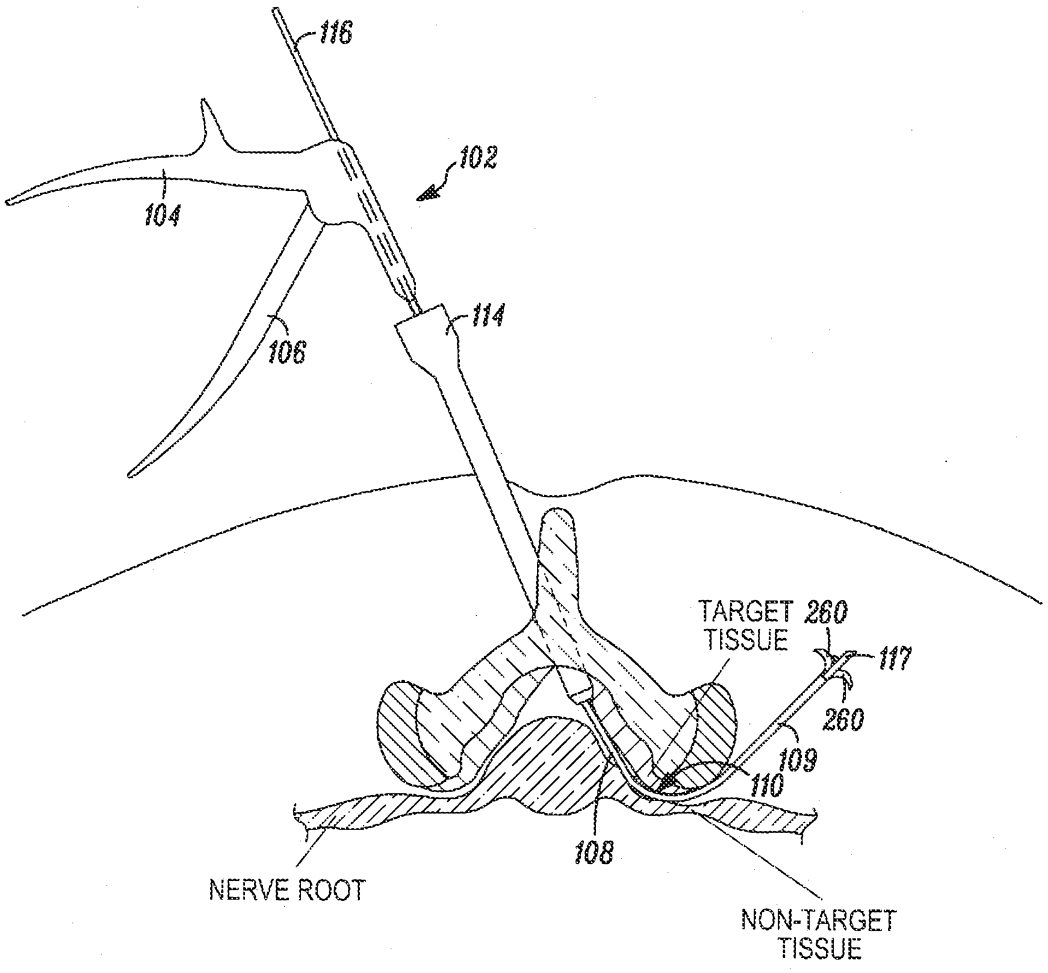

116
102
104
114
106
TARGET TISSUE
260
117
260
109
110
108
NERVE ROOT
NON-TARGET TISSUE

FIG. 6B

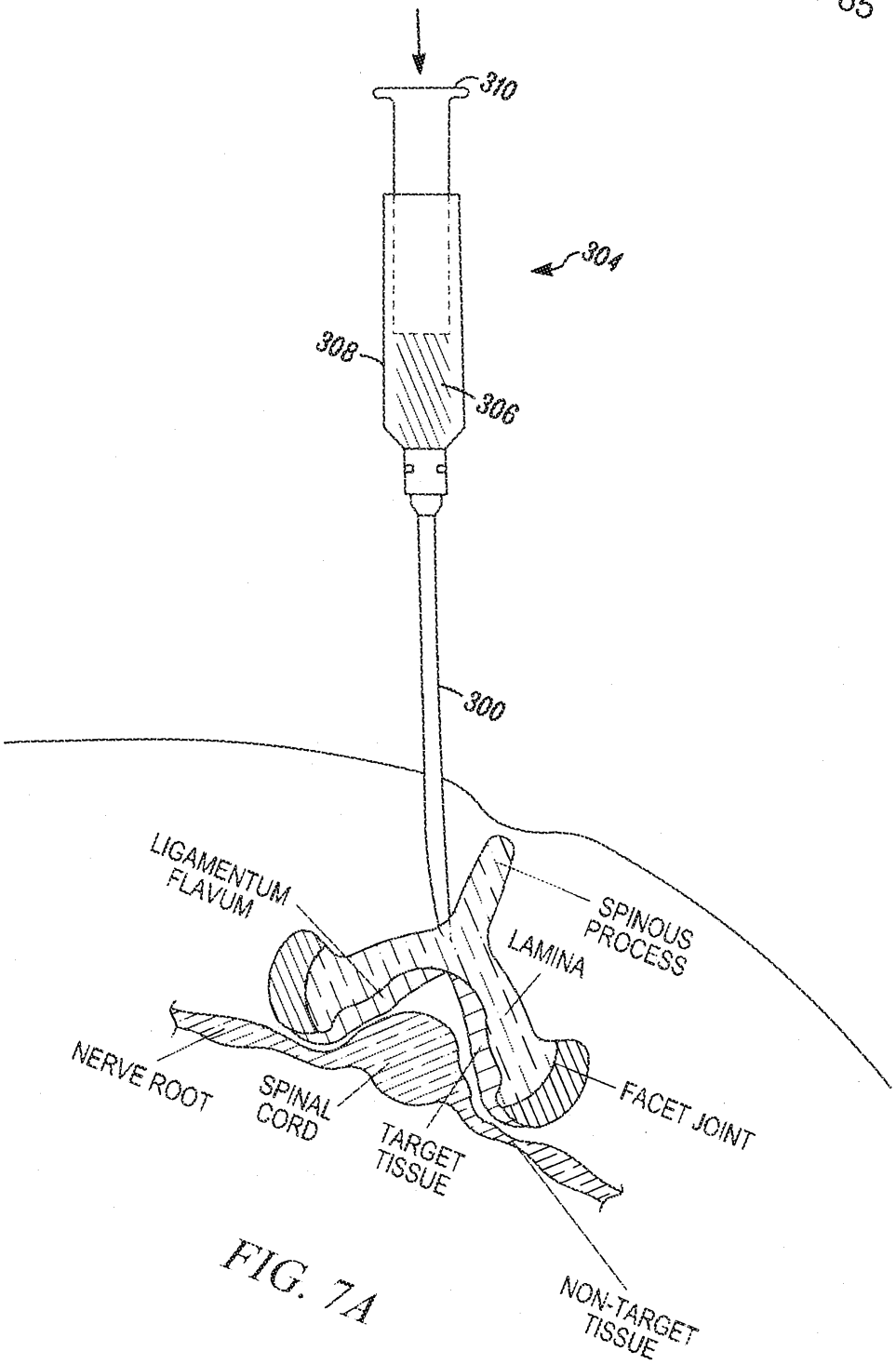

310
304
308
306
300
LIGAMENTUM FLAVUM
SPINOUS PROCESS
LAMINA
NERVE ROOT
SPINAL CORD
TARGET TISSUE
FACET JOINT
NON-TARGET TISSUE

FIG. 7A

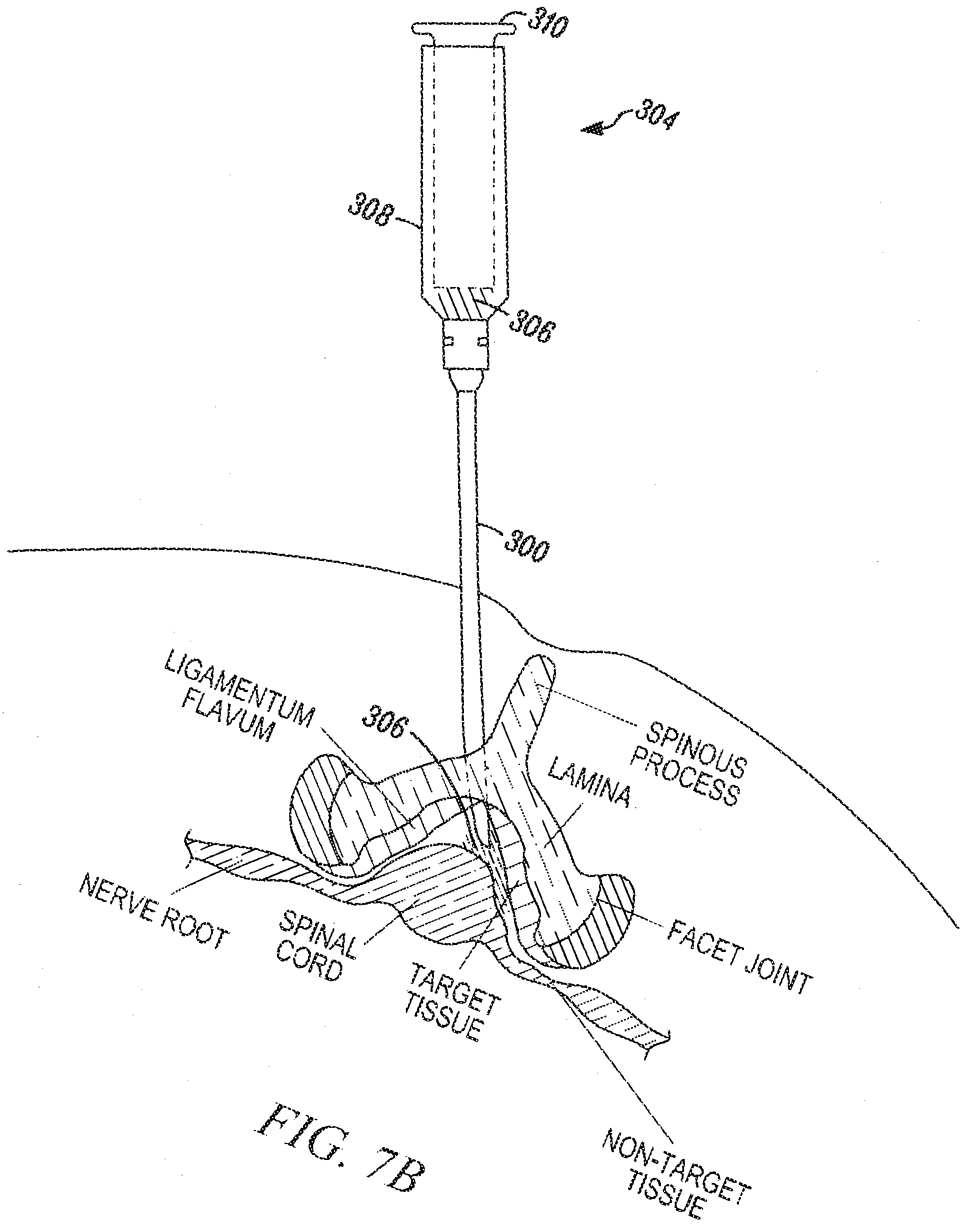

310
304
308
306
300
LIGAMENTUM FLAVUM
306
SPINOUS PROCESS
LAMINA
NERVE ROOT
SPINAL CORD
TARGET TISSUE
FACET JOINT
NON-TARGET TISSUE

FIG. 7B

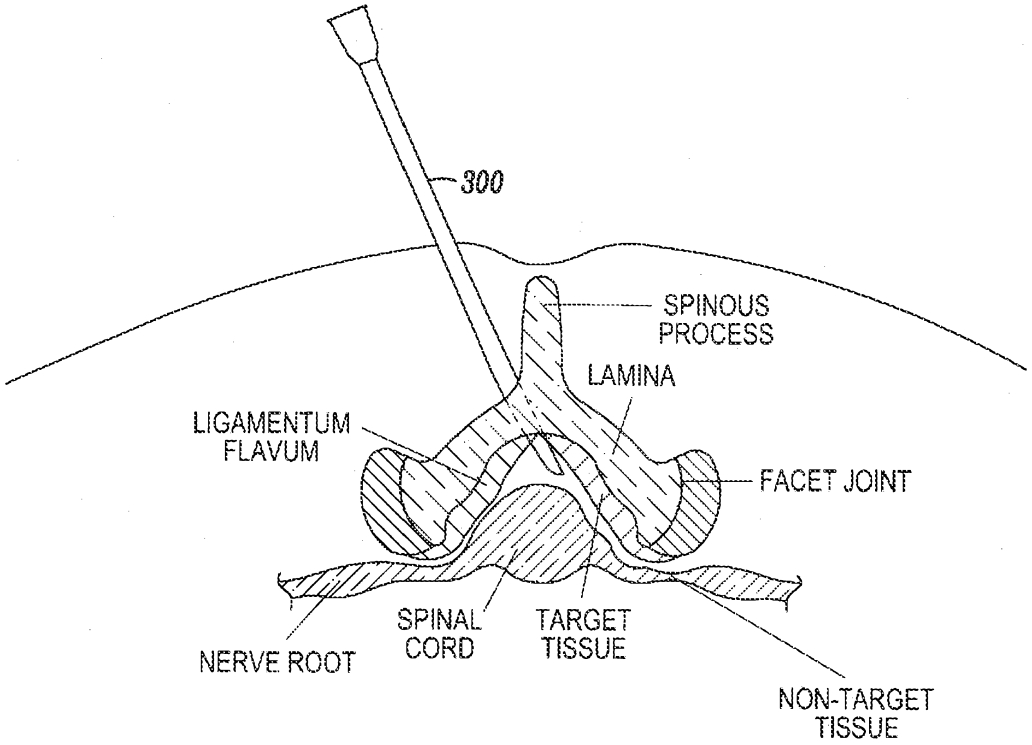

300
SPINOUS PROCESS
LAMINA
LIGAMENTUM FLAVUM
FACET JOINT
SPINAL CORD
TARGET TISSUE
NERVE ROOT
NON-TARGET TISSUE

FIG. 7C

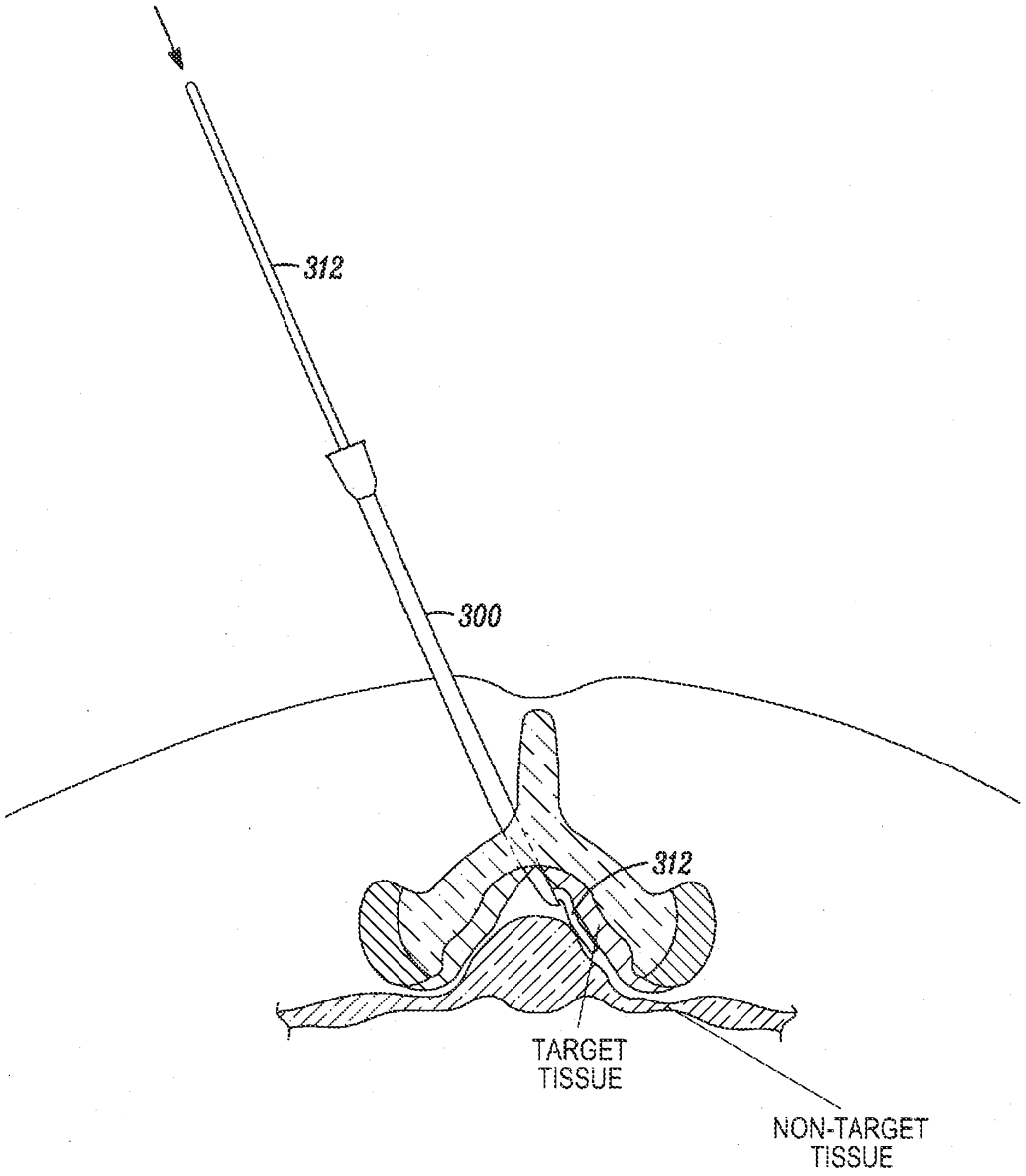


FIG. 7D

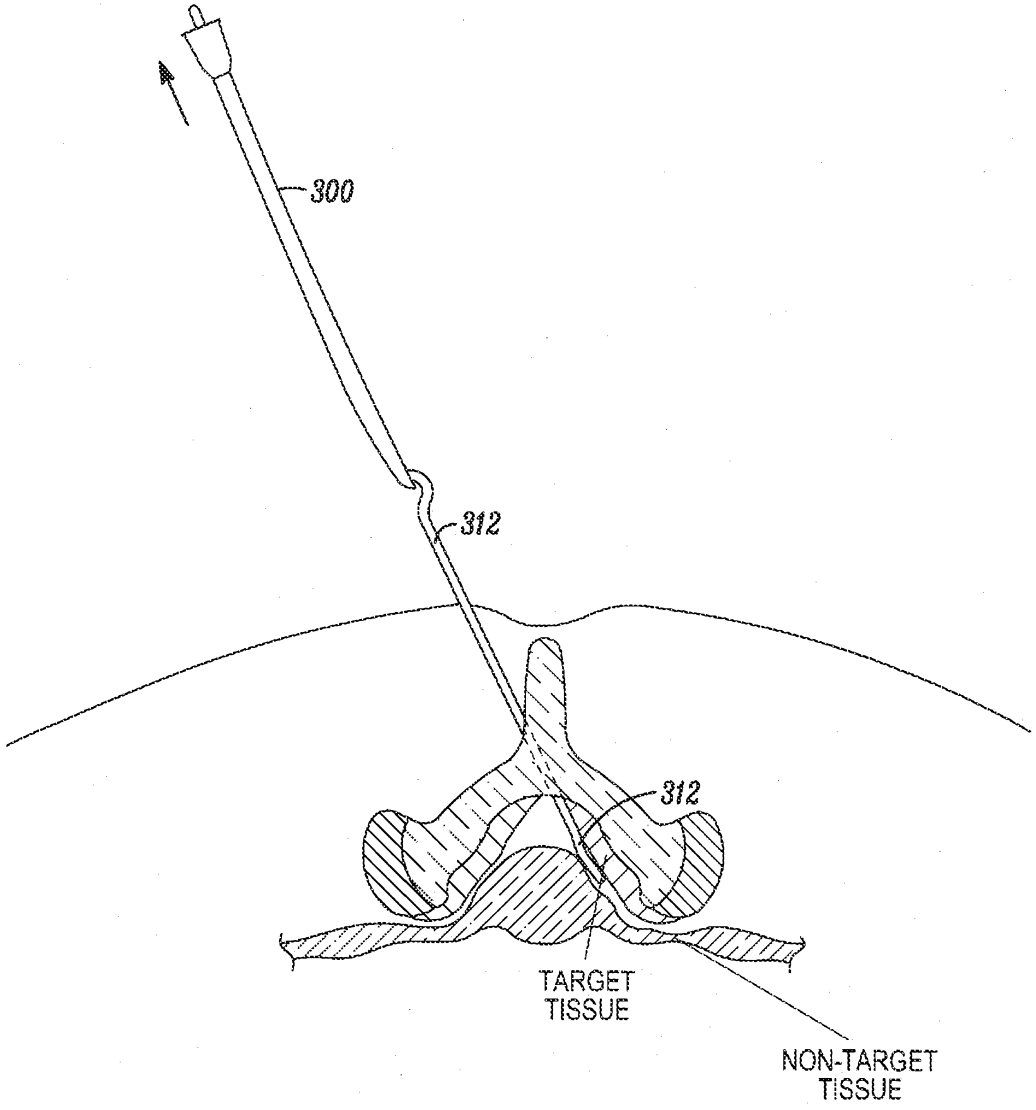


FIG. 7E

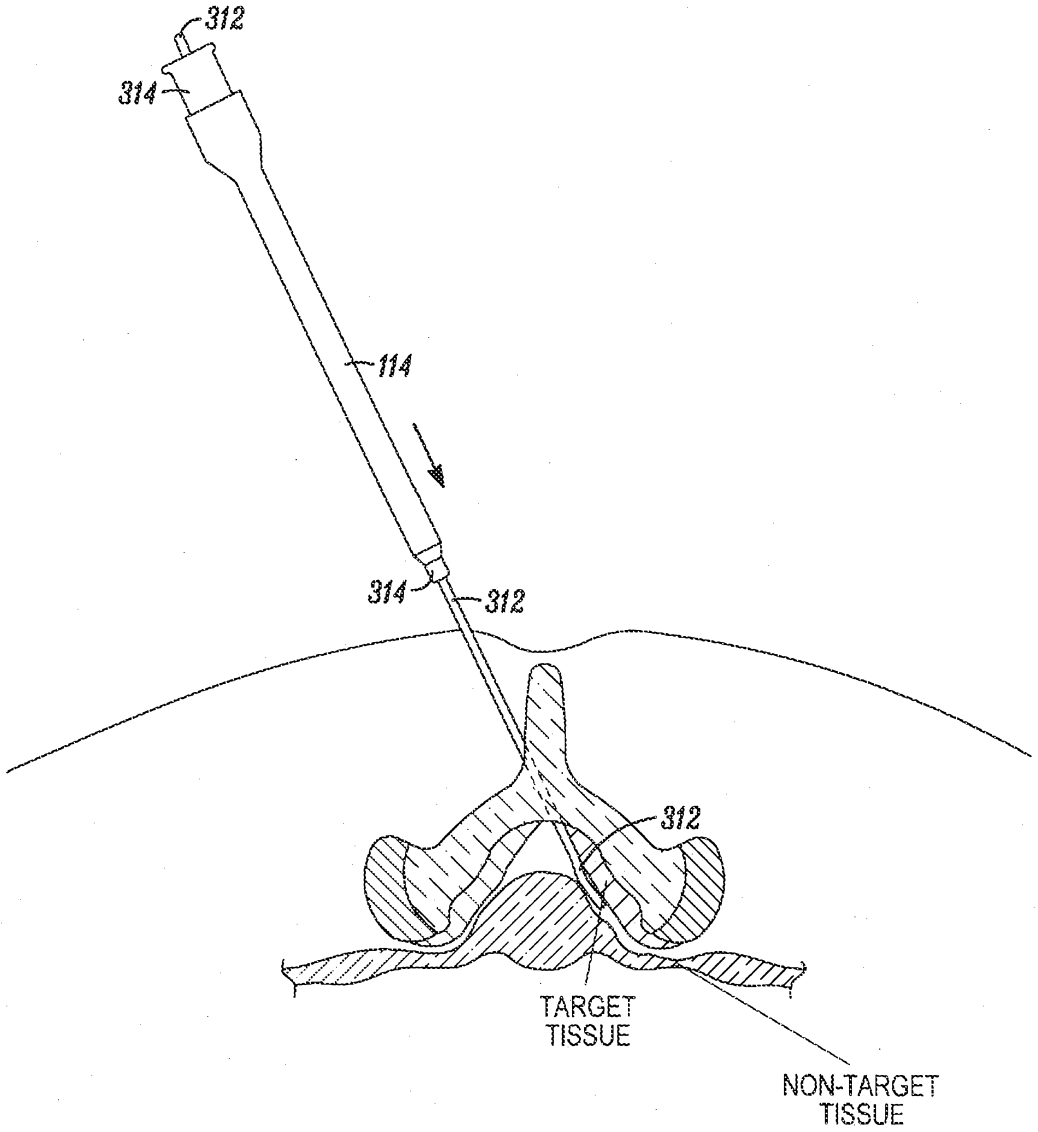


FIG. 7F

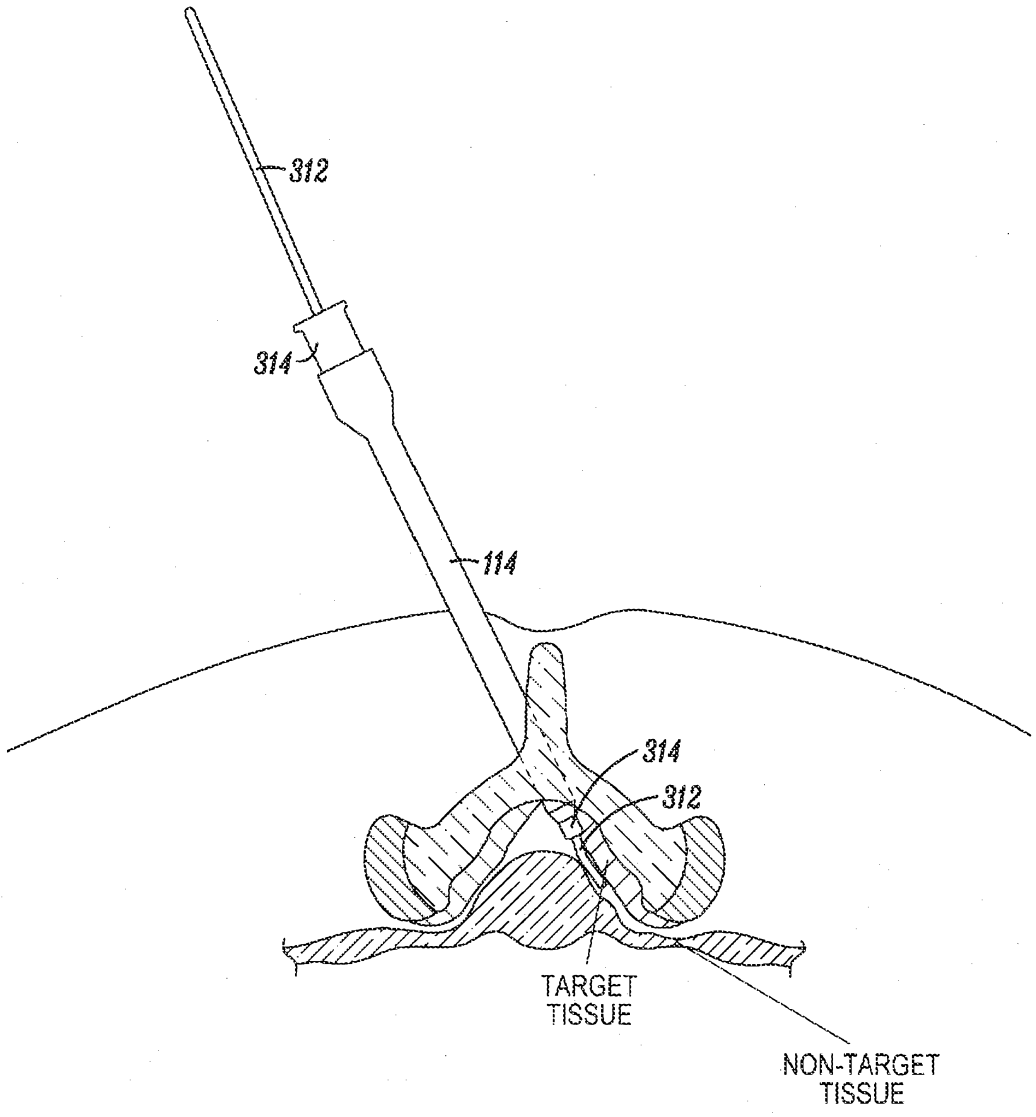


FIG. 7G

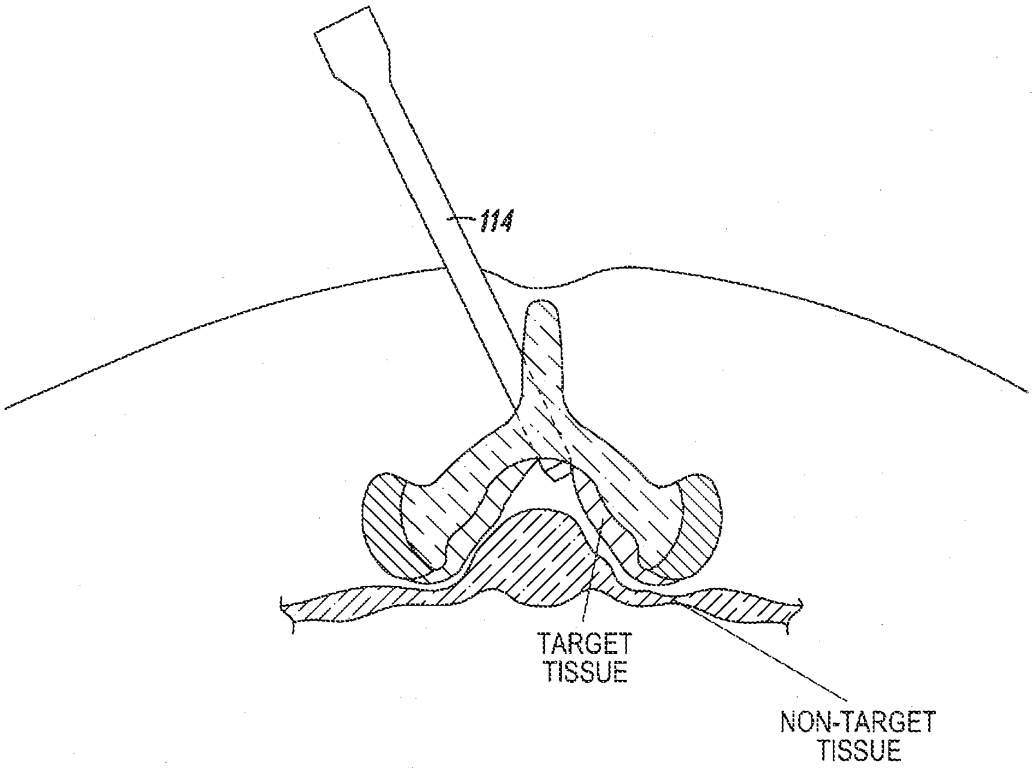


FIG. 7H

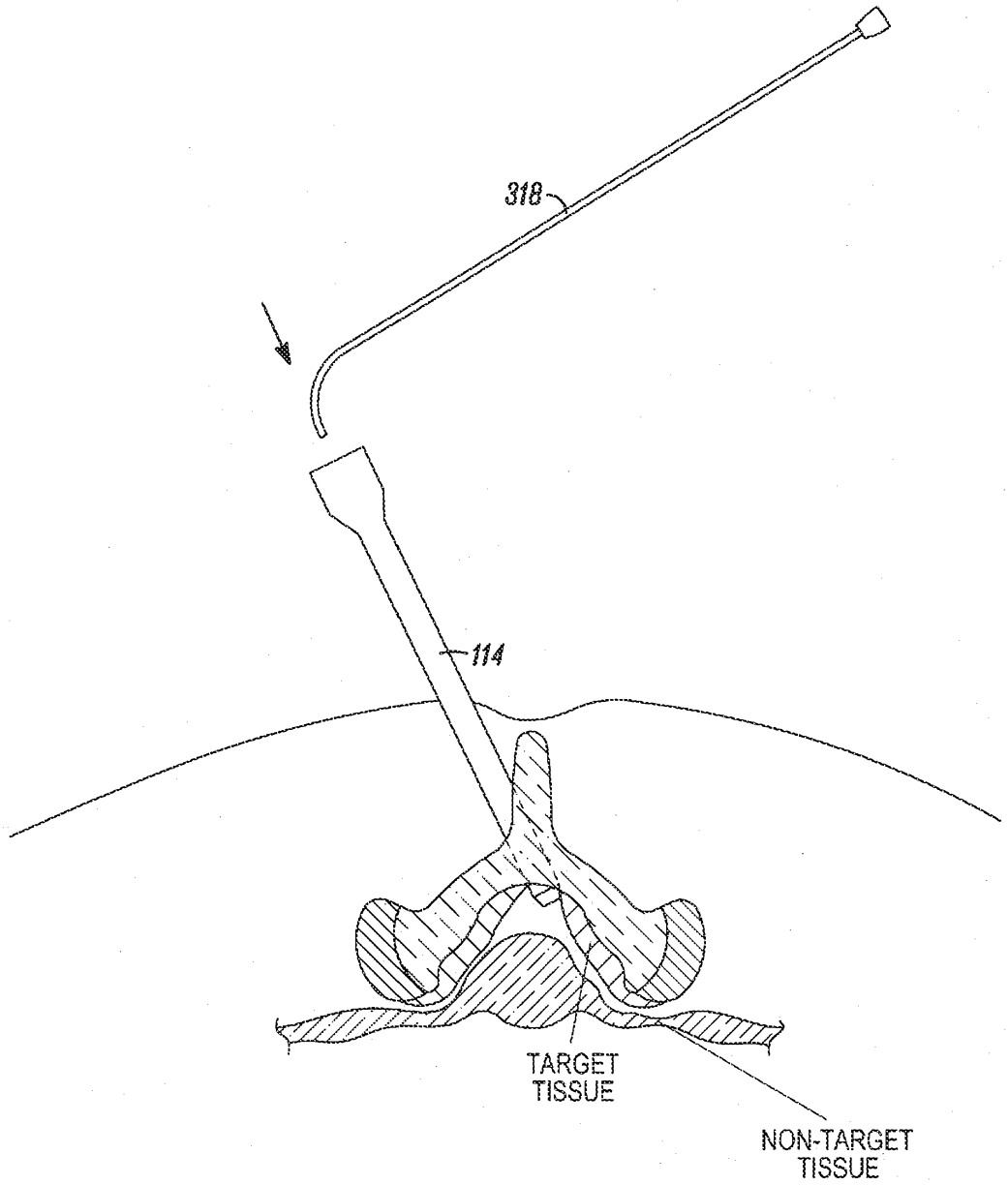


FIG. 7I

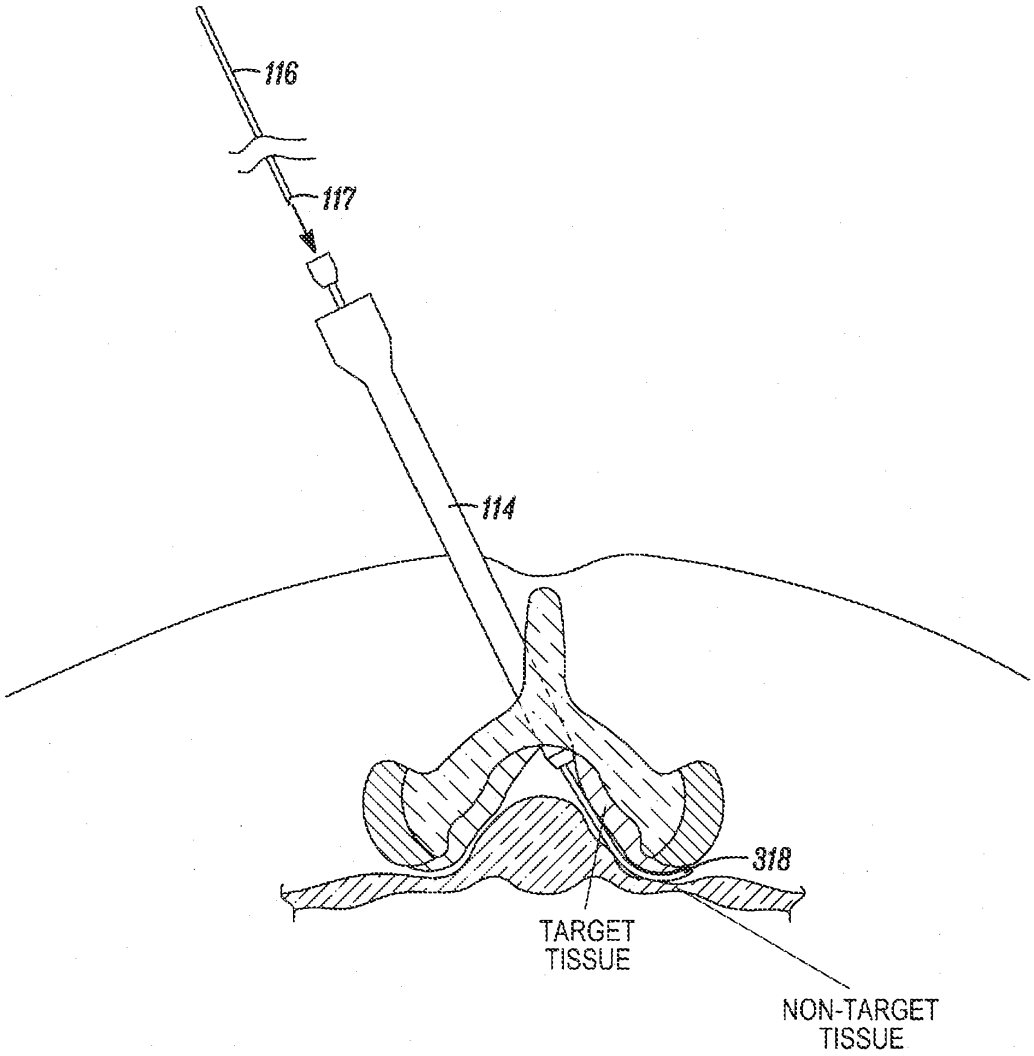


FIG. 7J

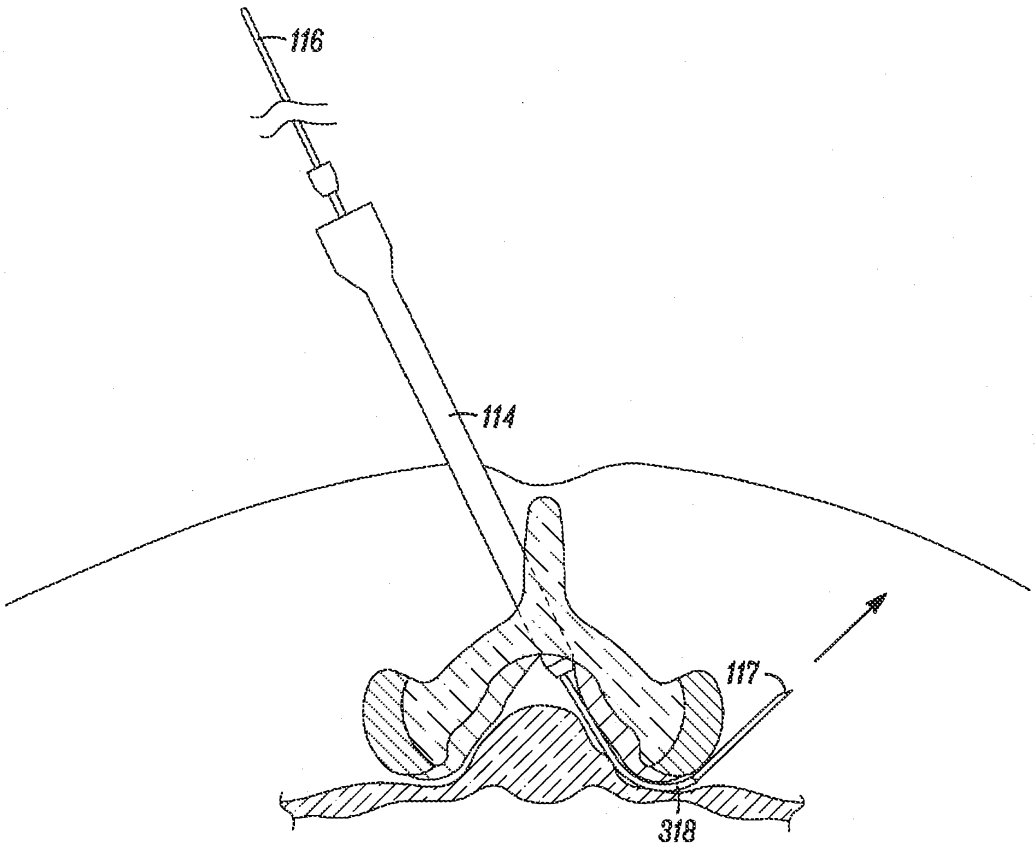


FIG. 7K

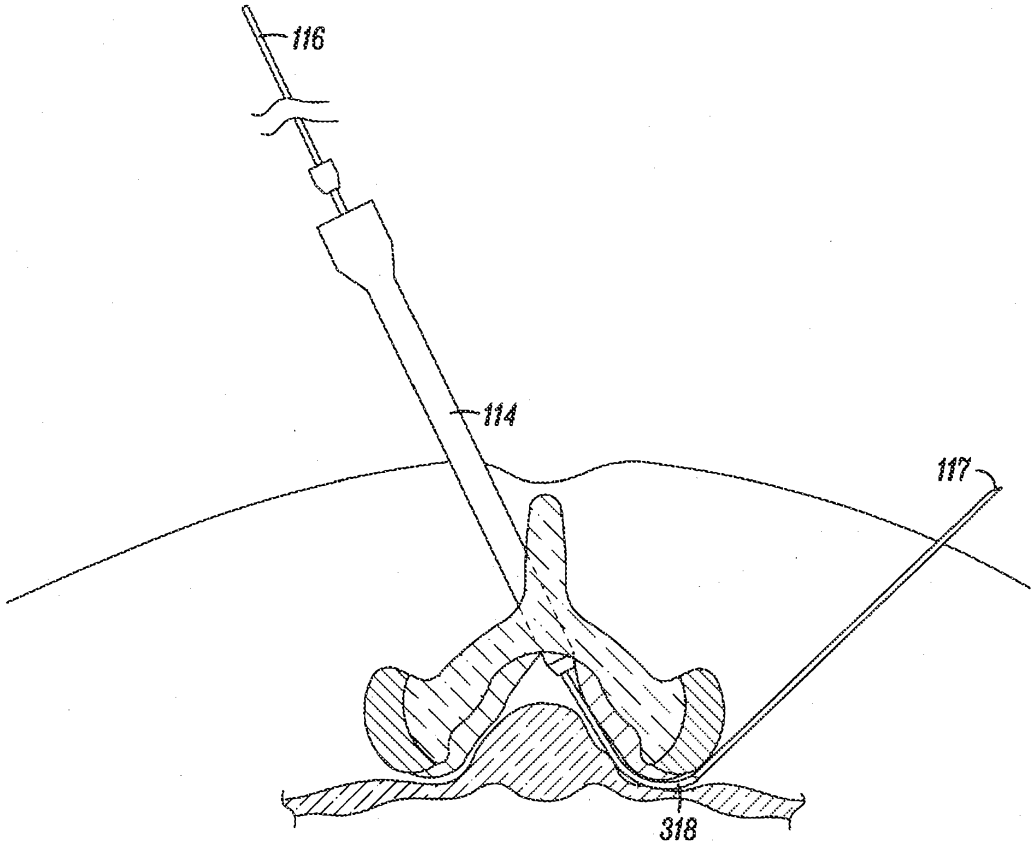


FIG. 7L

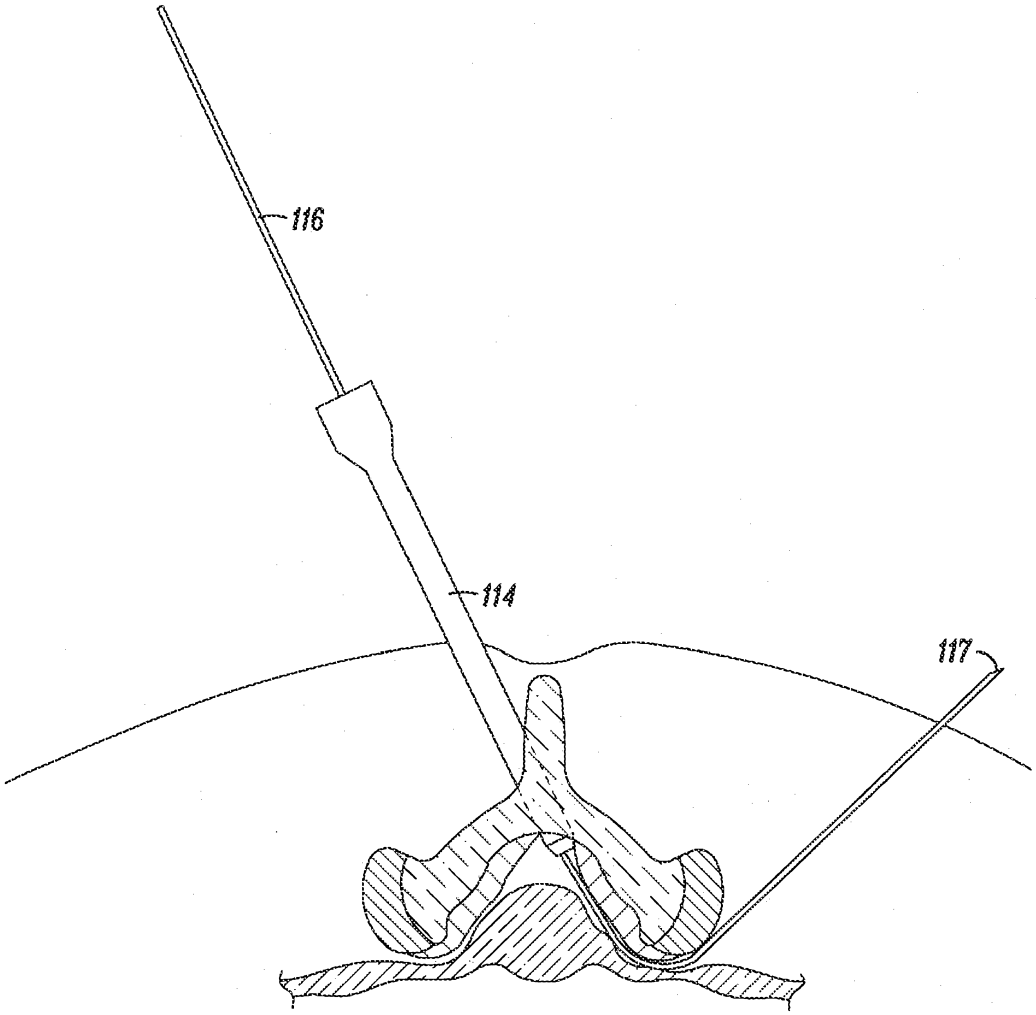


FIG. 7M

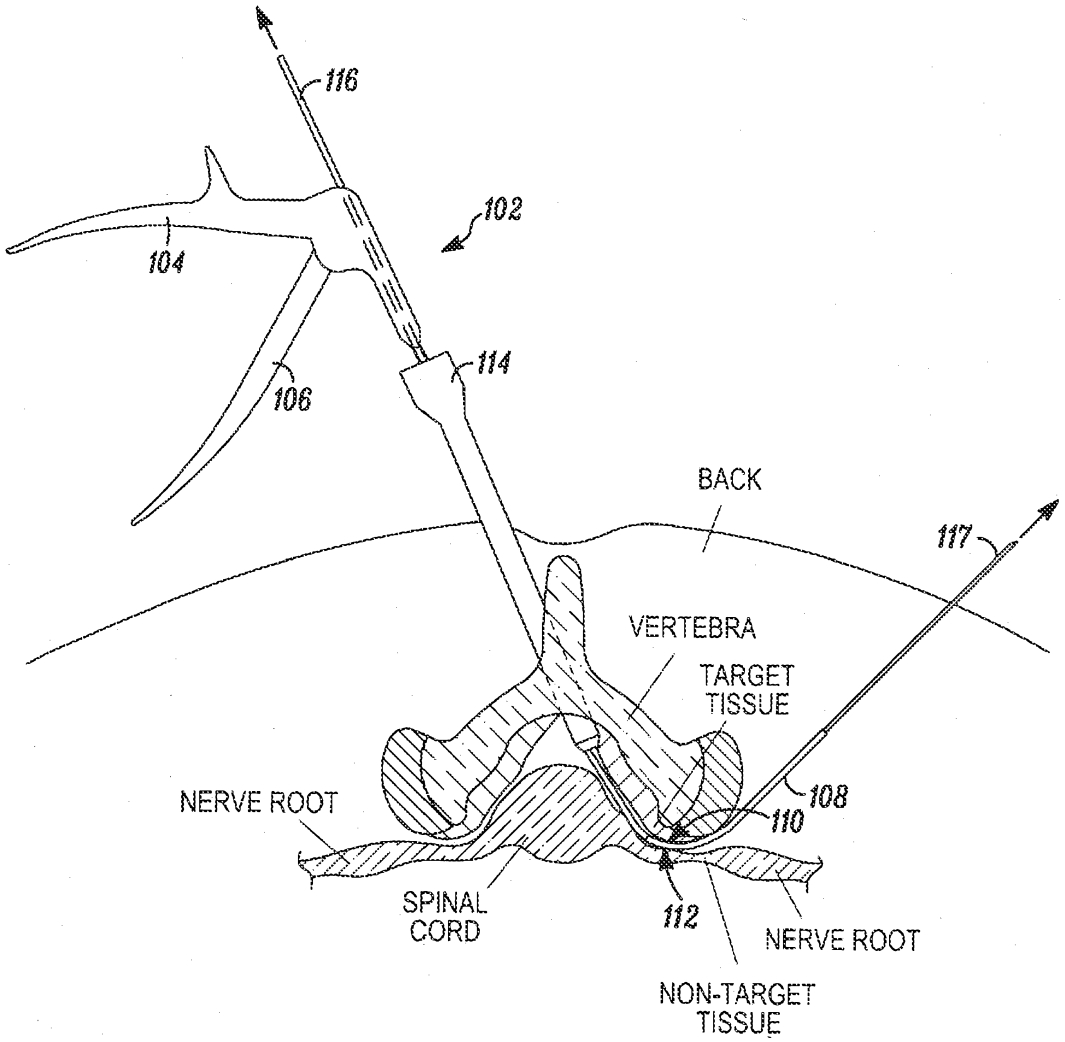

116
102
104
106
114
BACK
117
VERTEBRA
TARGET TISSUE
108
110
NERVE ROOT
SPINAL CORD
112
NERVE ROOT
NON-TARGET TISSUE

FIG. 7N

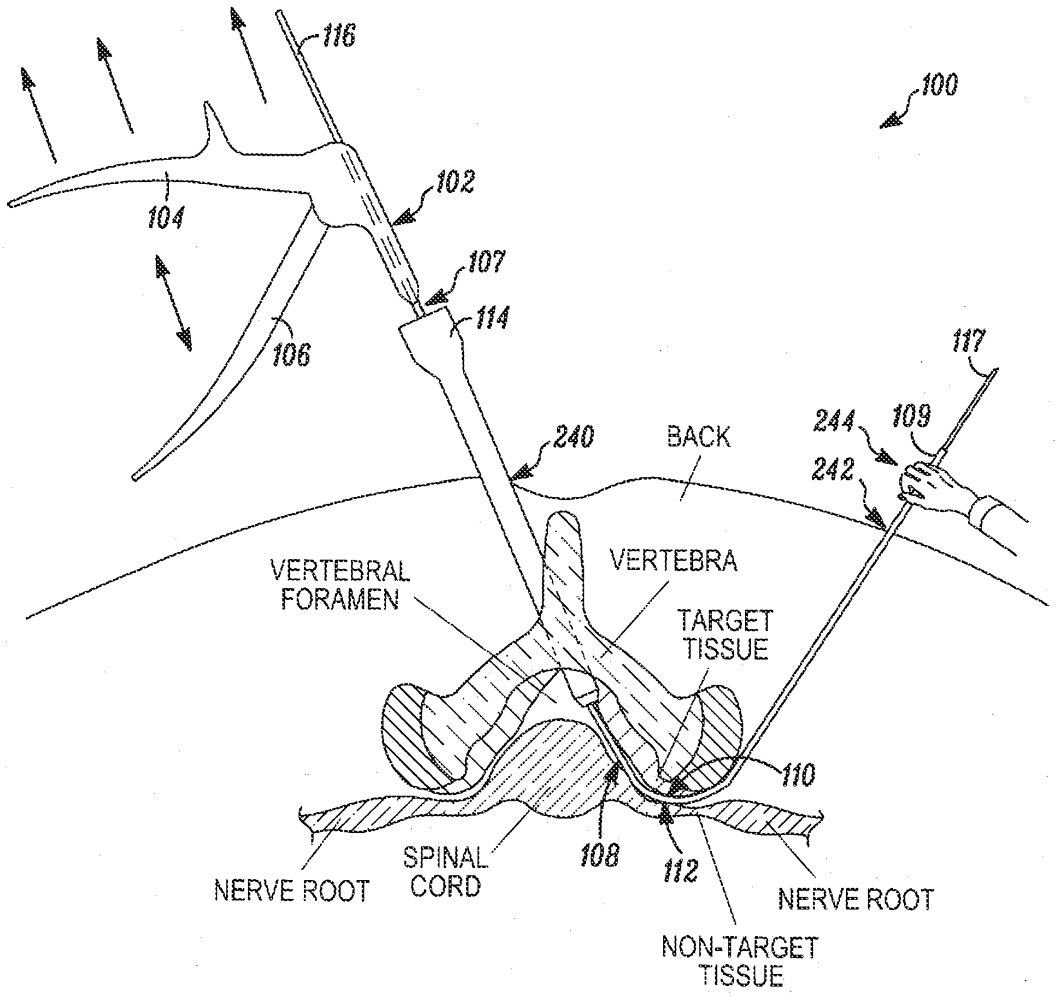

116
100
102
104
107
114
106
117
240
BACK
244
109
242
VERTEBRAL FORAMEN
VERTEBRA
TARGET TISSUE
110
108
112
SPINAL CORD
NERVE ROOT
NERVE ROOT
NON-TARGET TISSUE

FIG. 7O

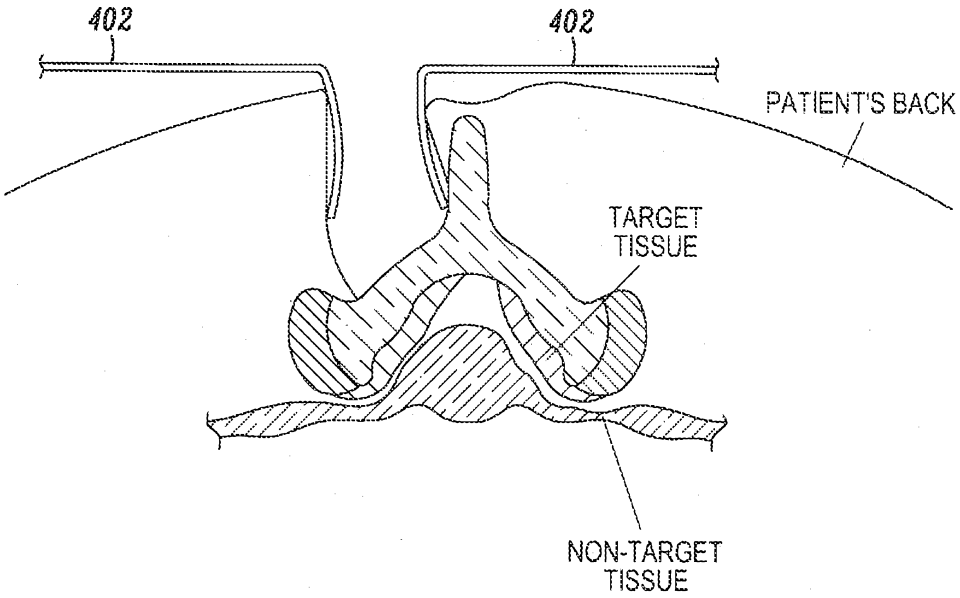

402
402
PATIENT'S BACK
TARGET TISSUE
NON-TARGET TISSUE

FIG. 8A

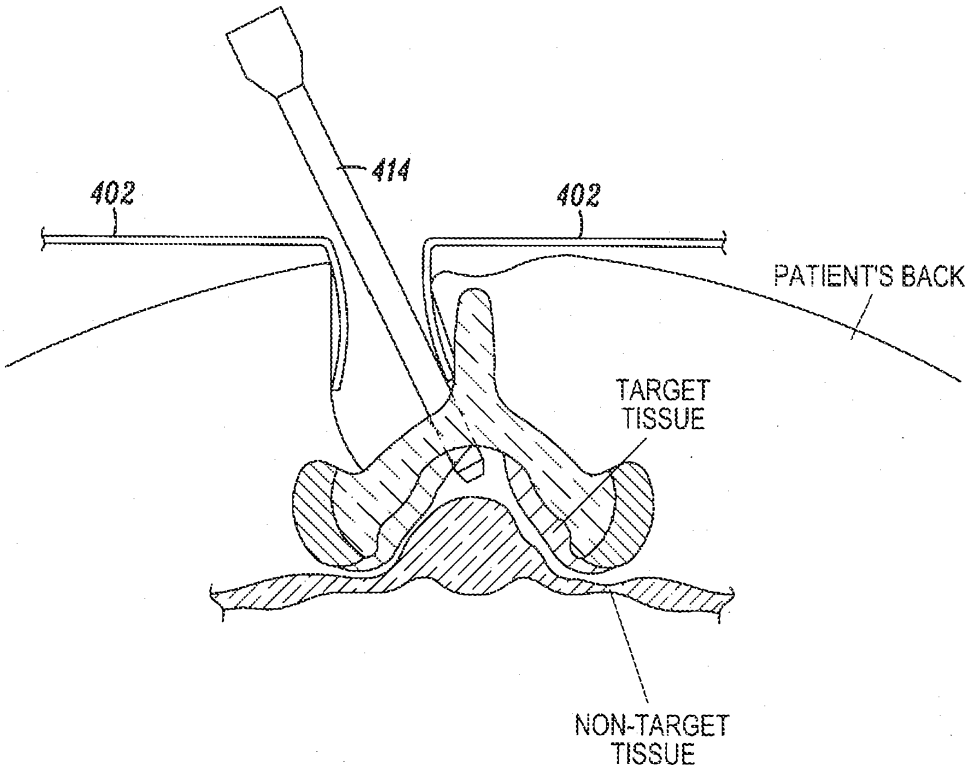

414
402
402
PATIENT'S BACK
TARGET TISSUE
NON-TARGET TISSUE

FIG. 8B

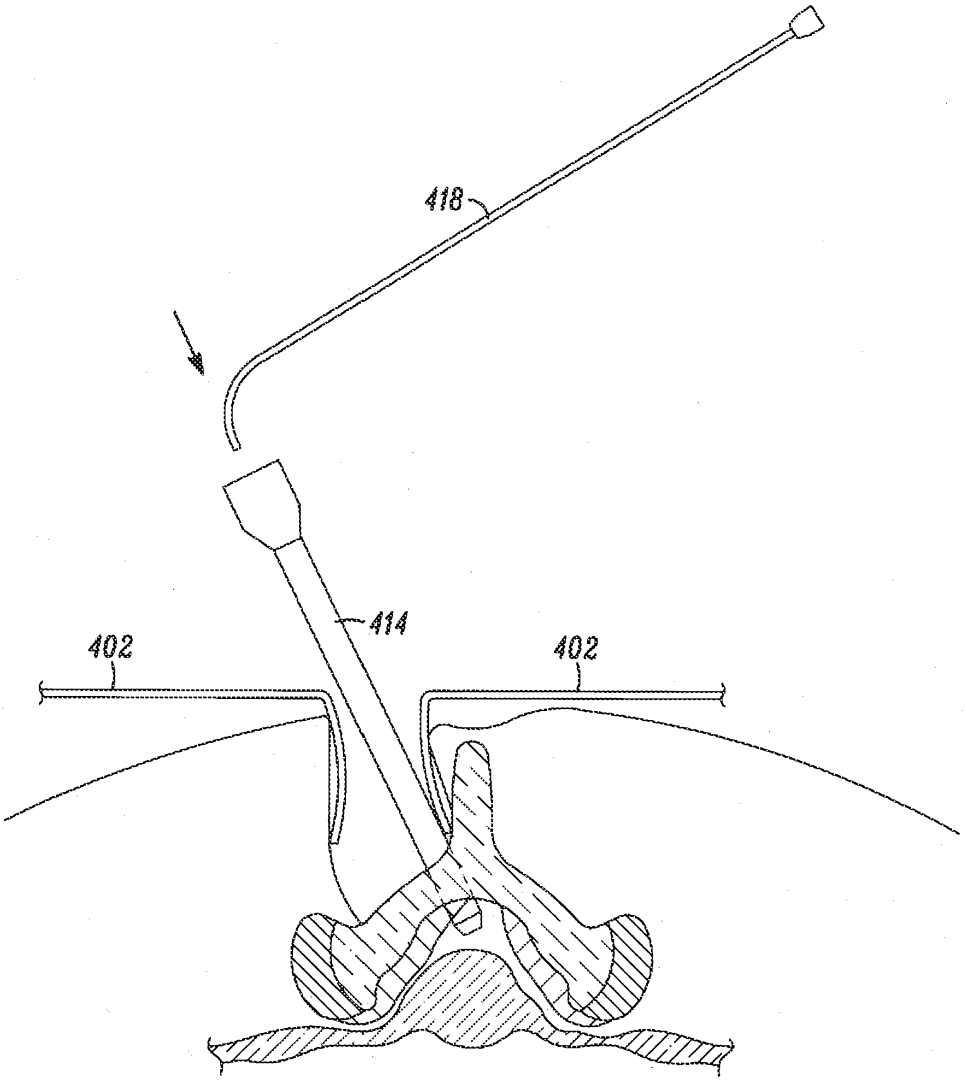


FIG. 8C

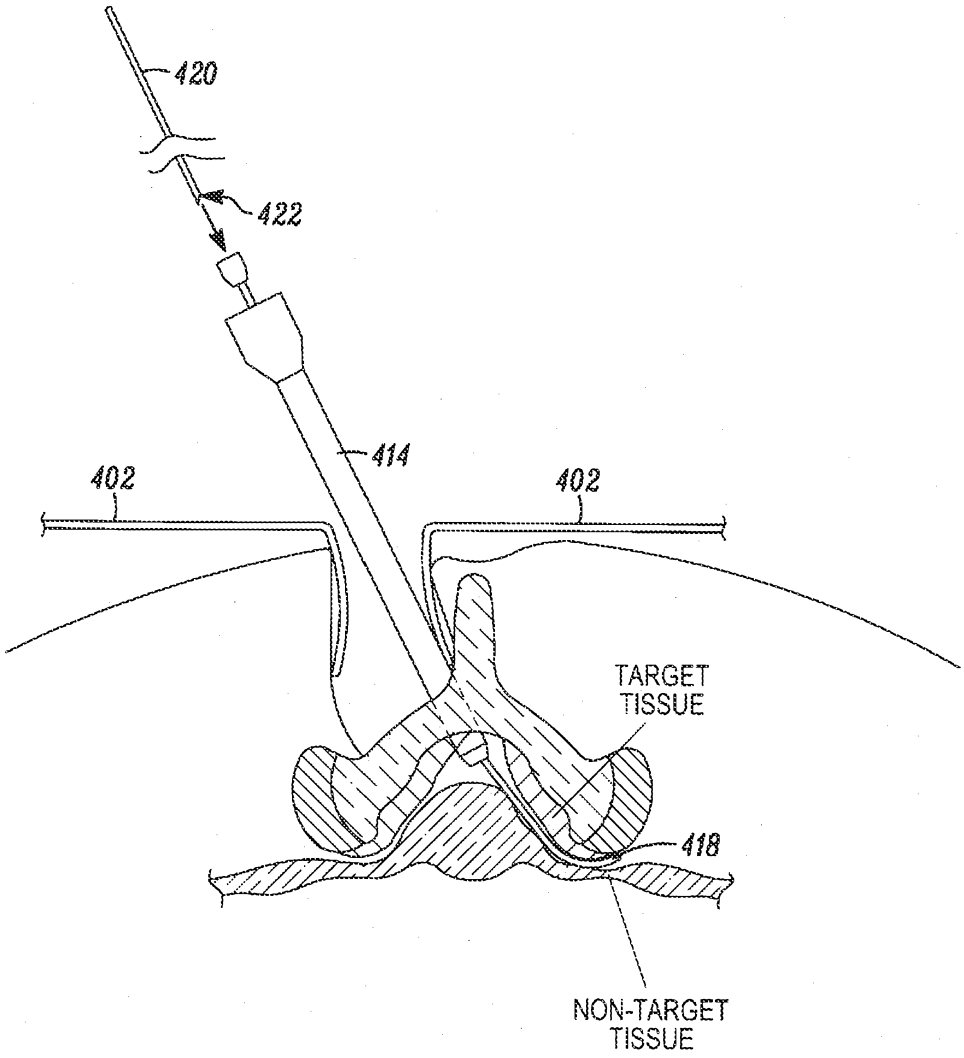


FIG. 8D

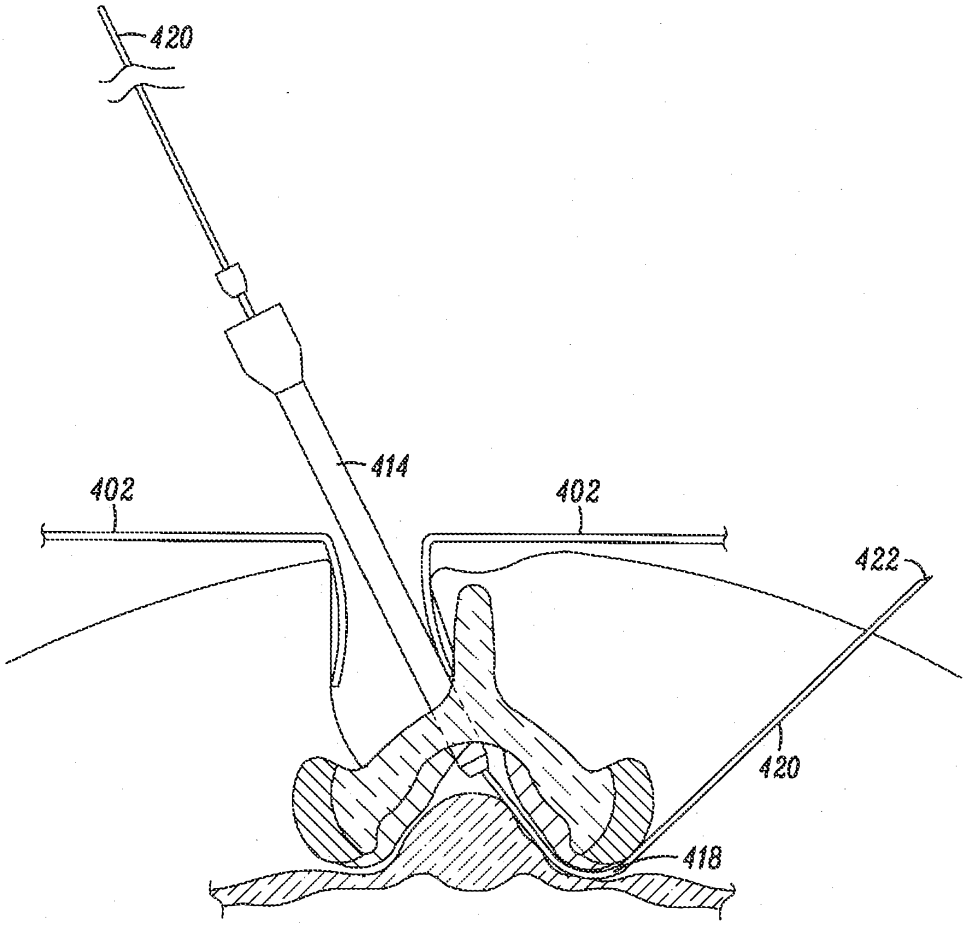


FIG. 8E

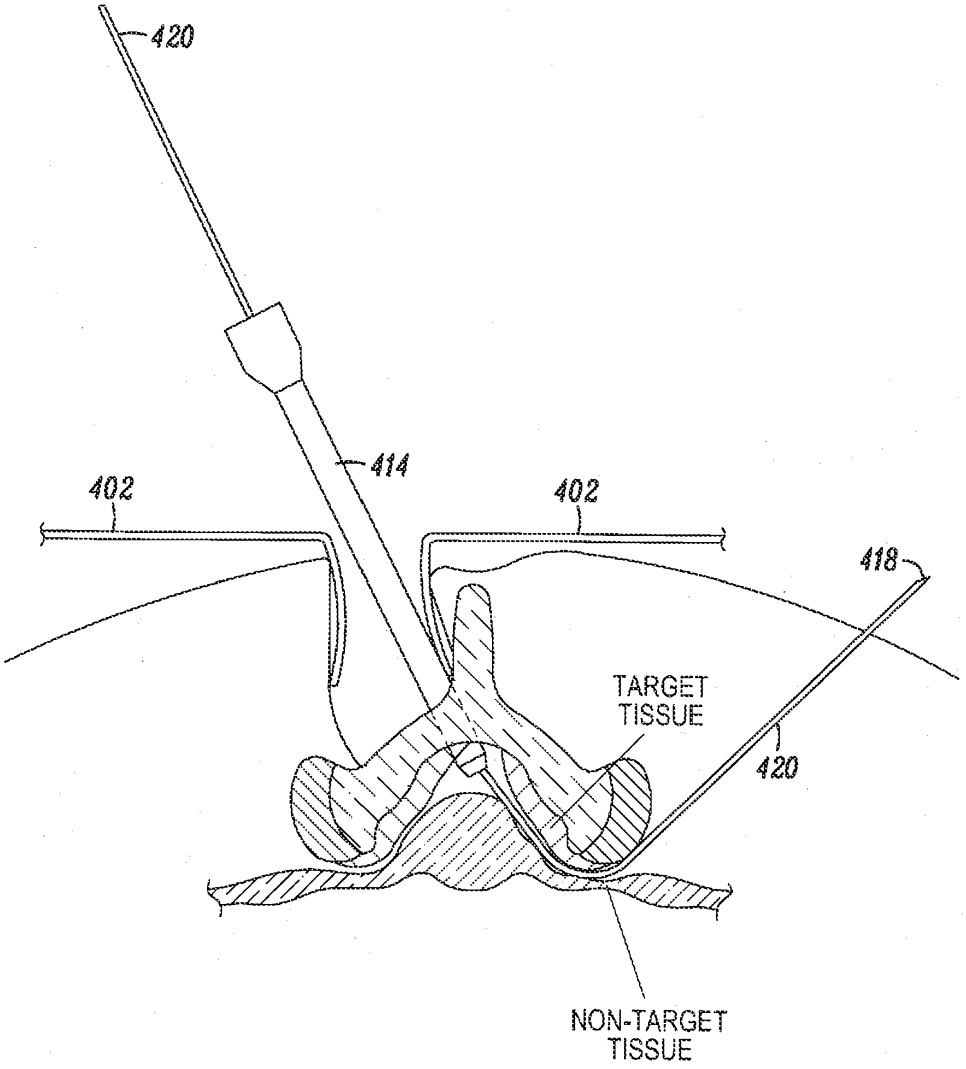


FIG. 8F

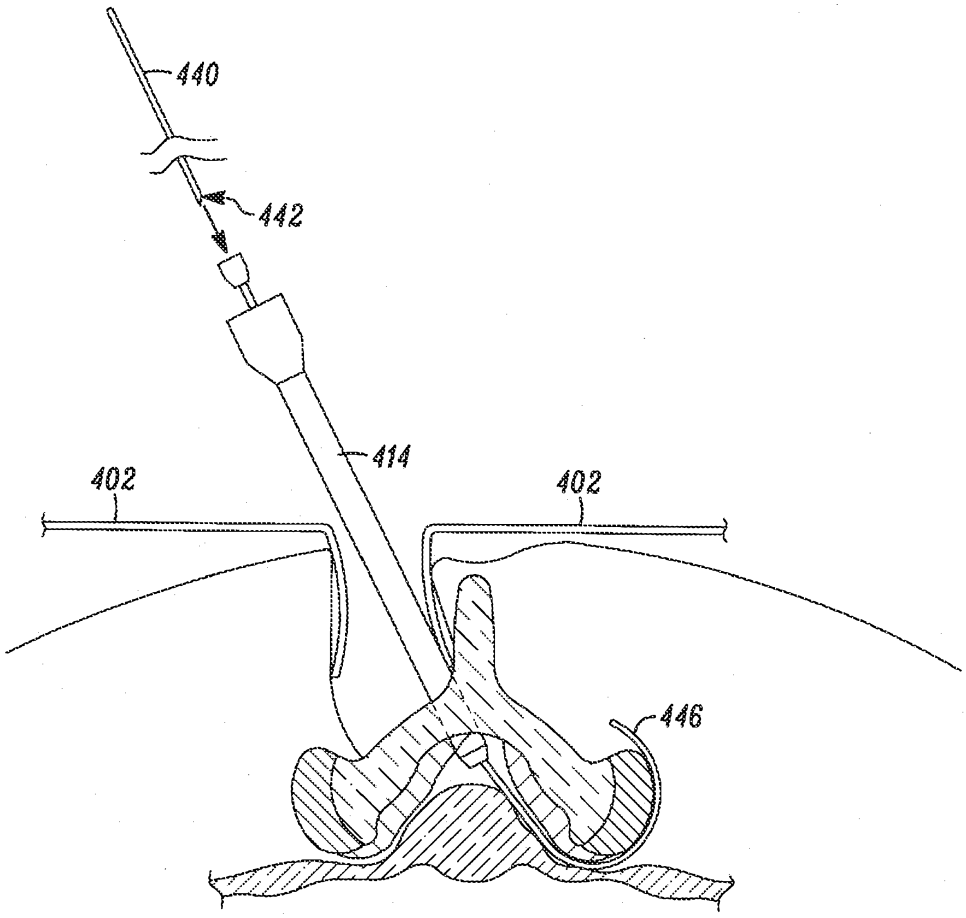


FIG. 9A

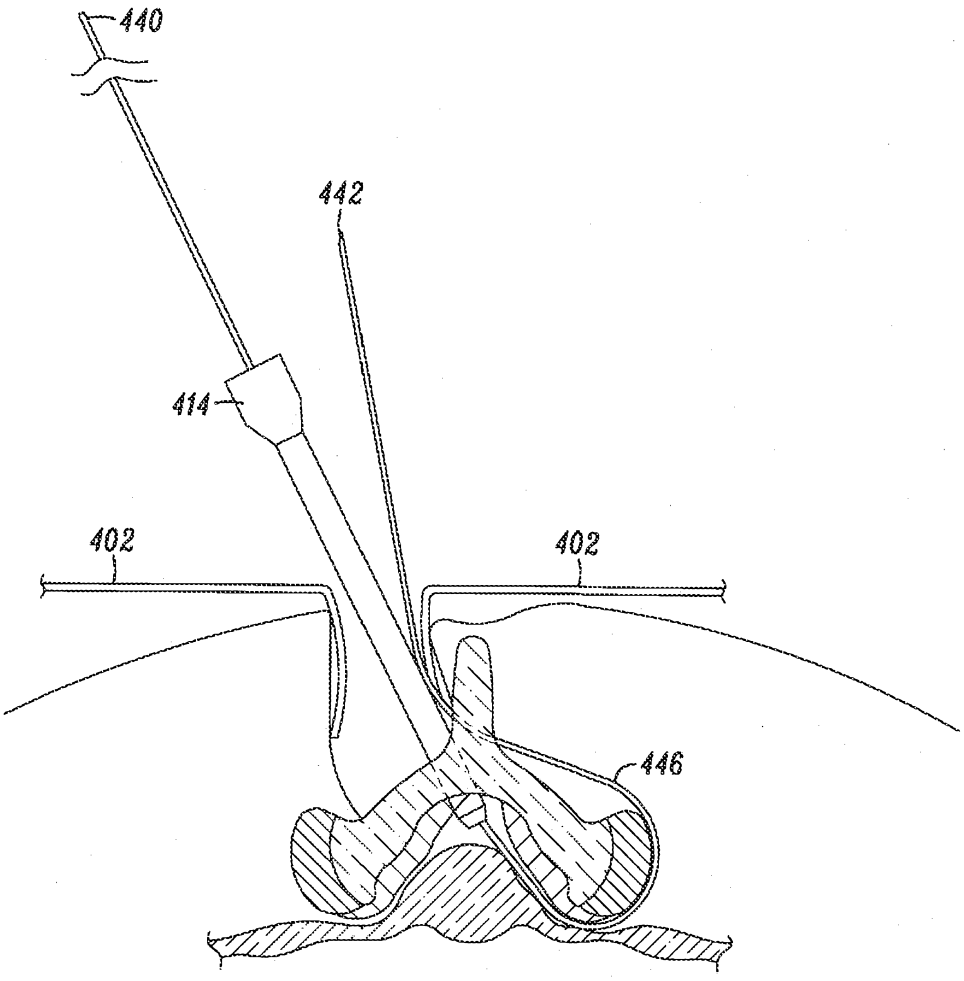


FIG. 9B

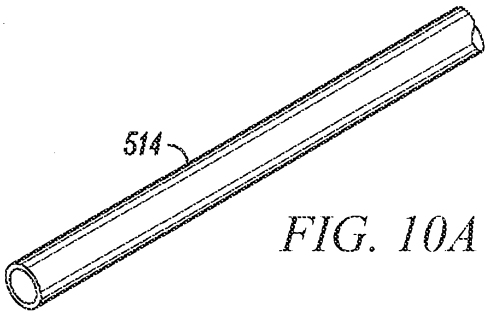


FIG. 10A

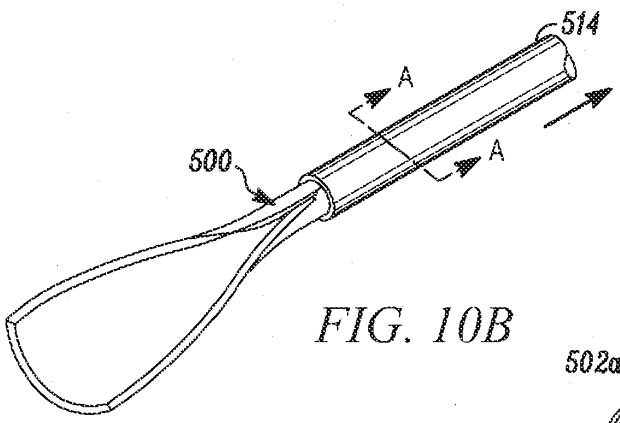
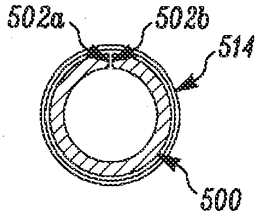


FIG. 10B



SECTION A-A

FIG. 10C

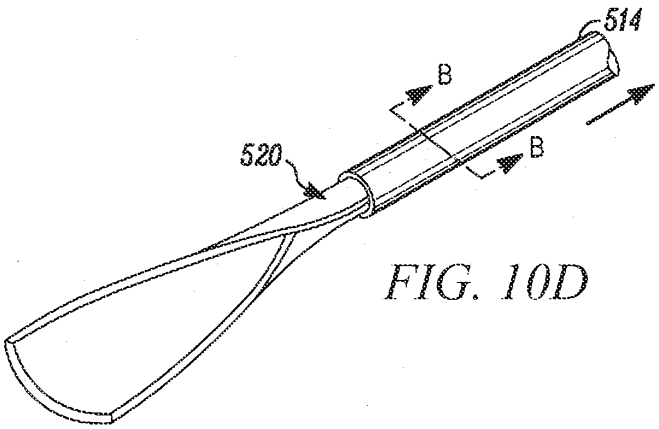
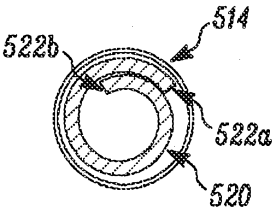


FIG. 10D



SECTION B-B

FIG. 10E

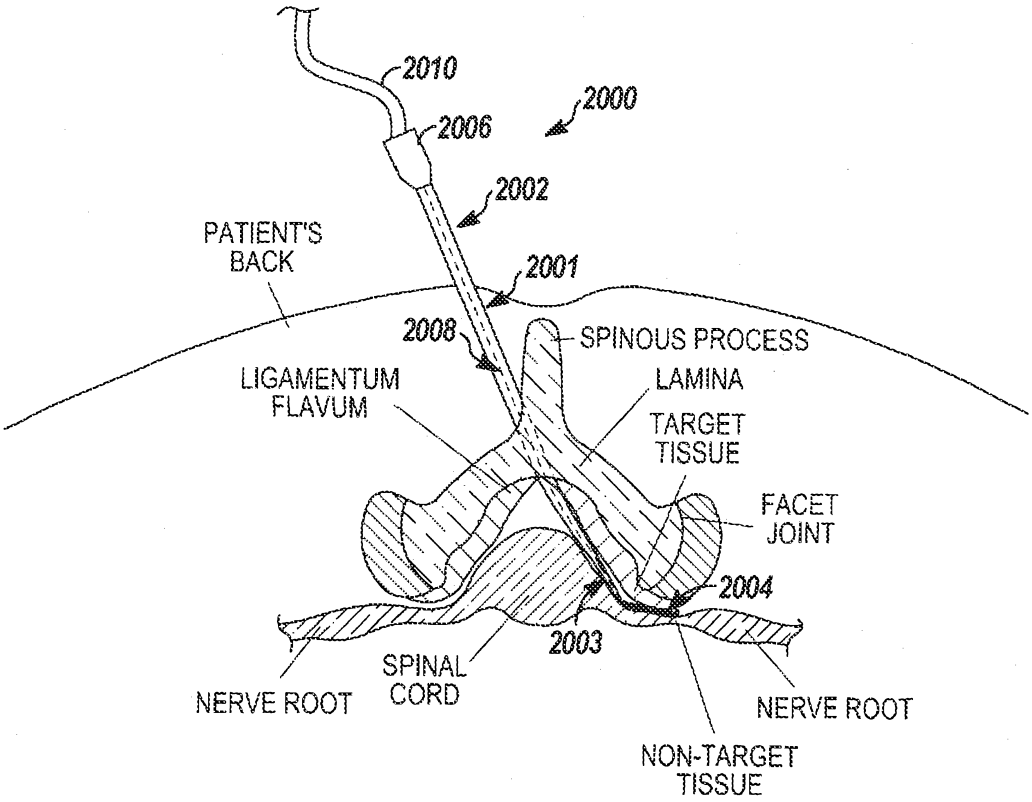

2010
2000
2006
2002
PATIENT'S BACK
2001
2008
SPINOUS PROCESS
LIGAMENTUM FLAVUM
LAMINA
TARGET TISSUE
FACET JOINT
2004
2003
SPINAL CORD
NERVE ROOT
NERVE ROOT
NON-TARGET TISSUE

FIG. 11A

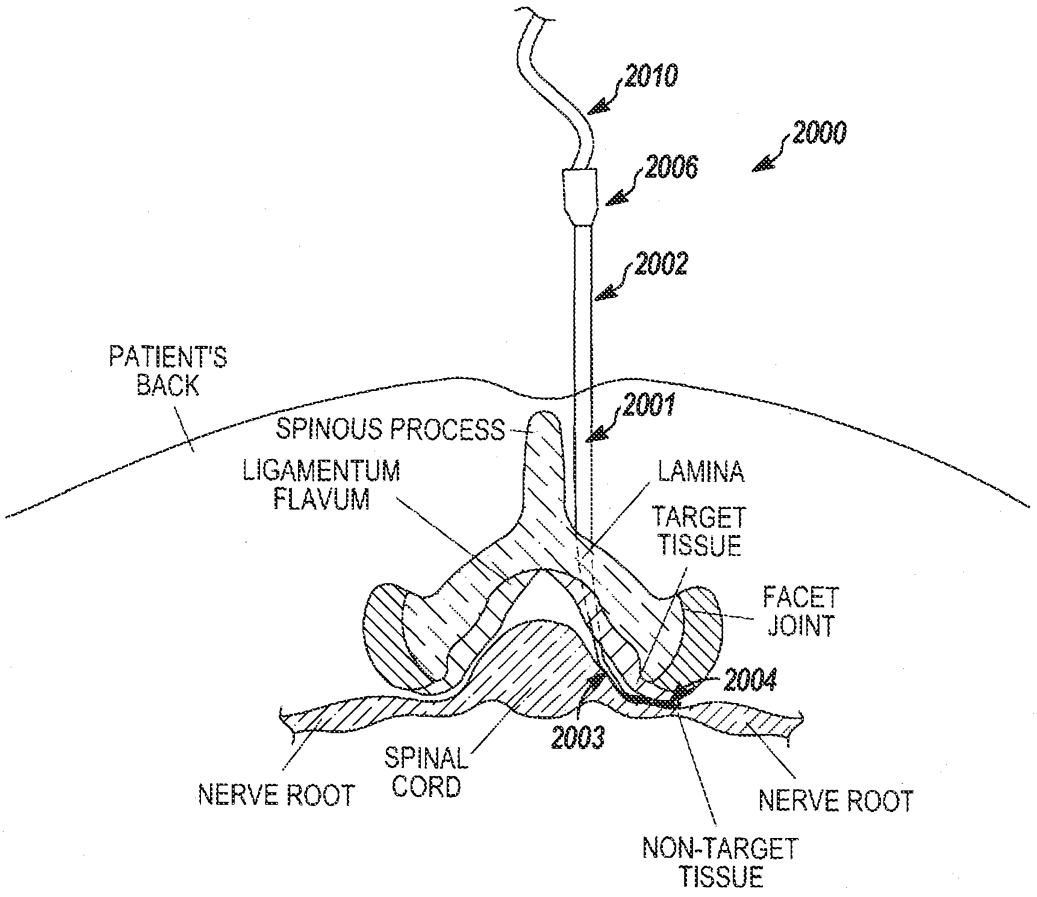

2010
2000
2006
2002
PATIENT'S BACK
2001
SPINOUS PROCESS
LIGAMENTUM FLAVUM
LAMINA
TARGET TISSUE
FACET JOINT
2004
2003
SPINAL CORD
NERVE ROOT
NERVE ROOT
NON-TARGET TISSUE

FIG. 11B

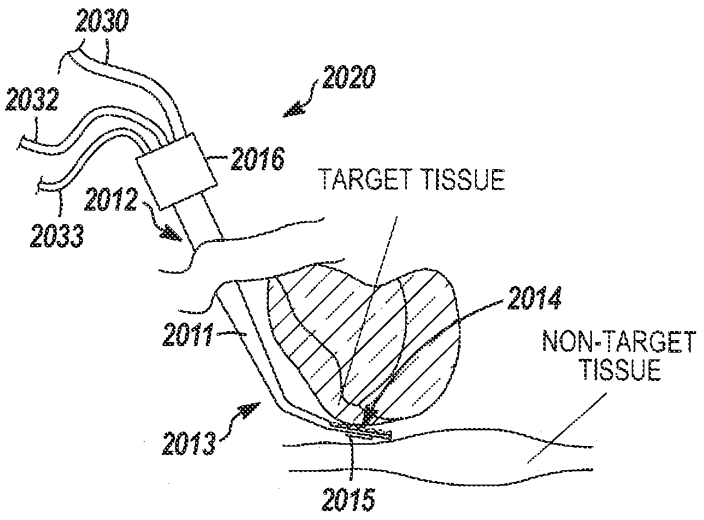


FIG. 12

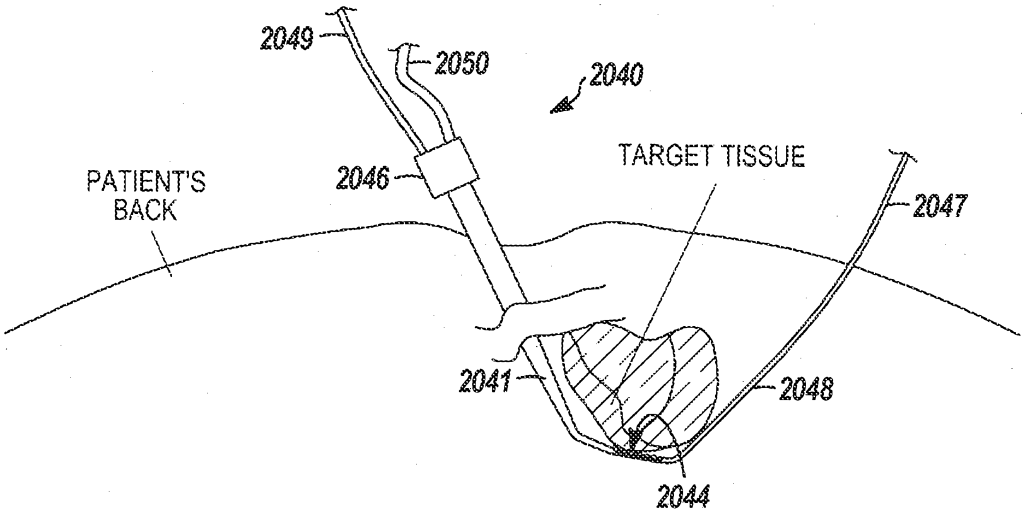


FIG. 13A

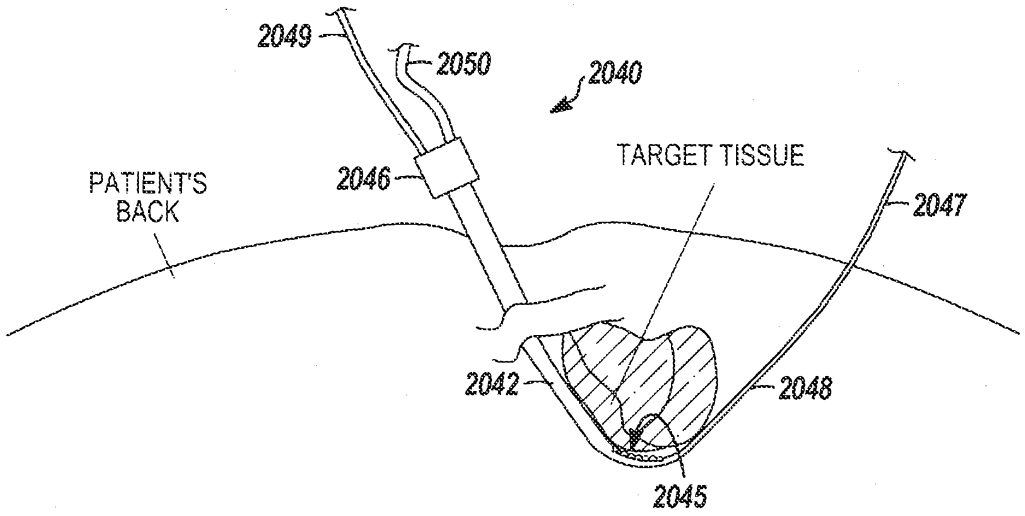


FIG. 13B

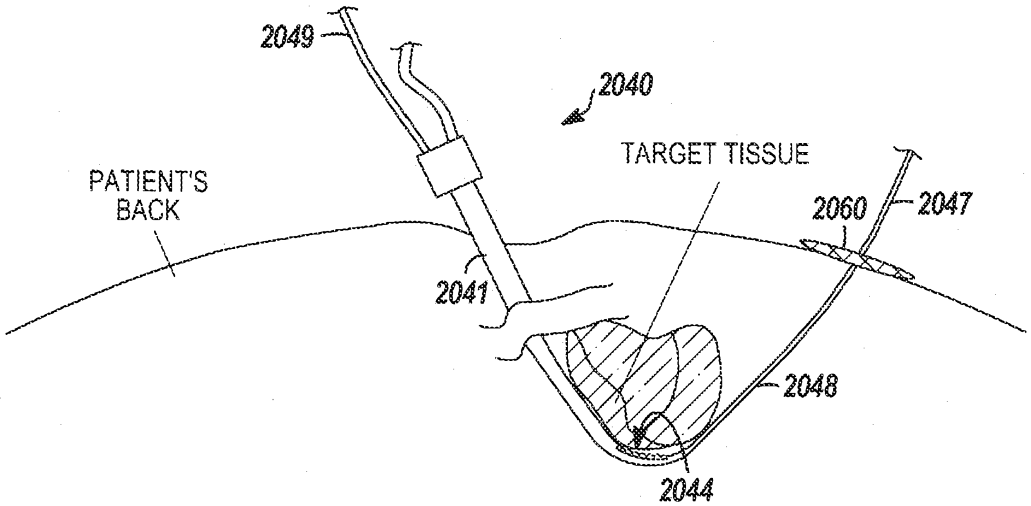


FIG. 13C

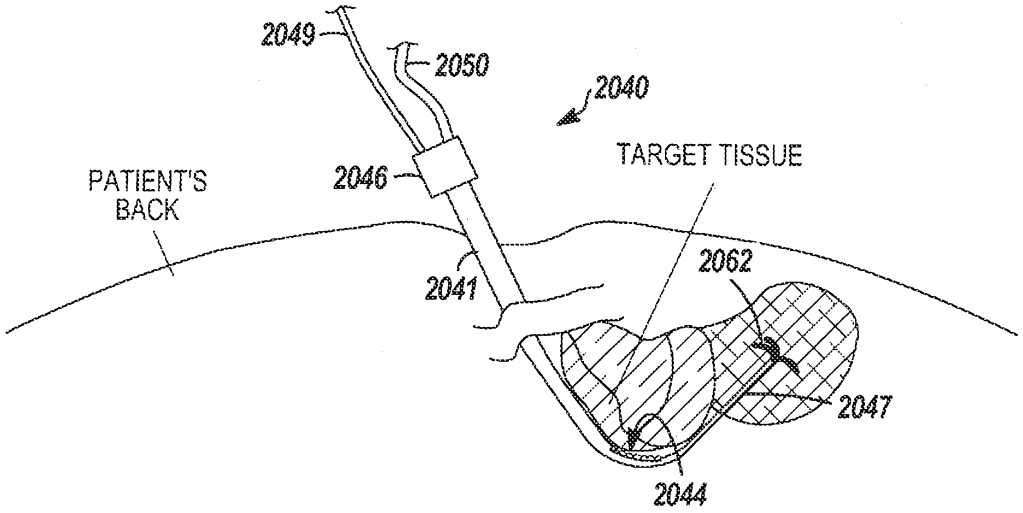


FIG. 13D

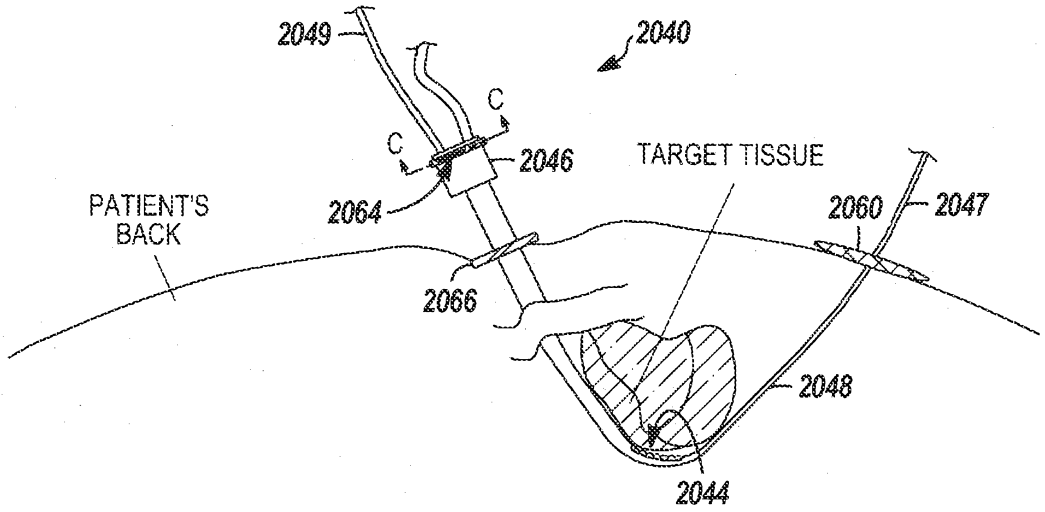


FIG. 13E

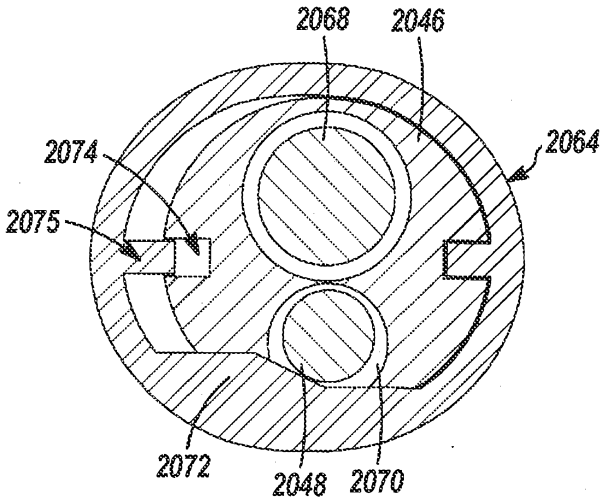


FIG. 13F

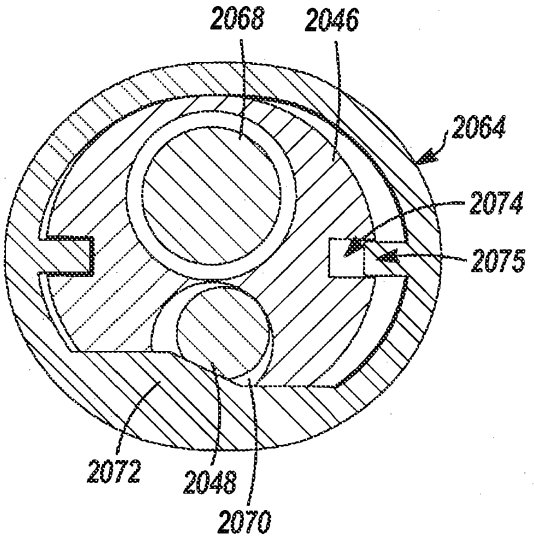


FIG. 13G

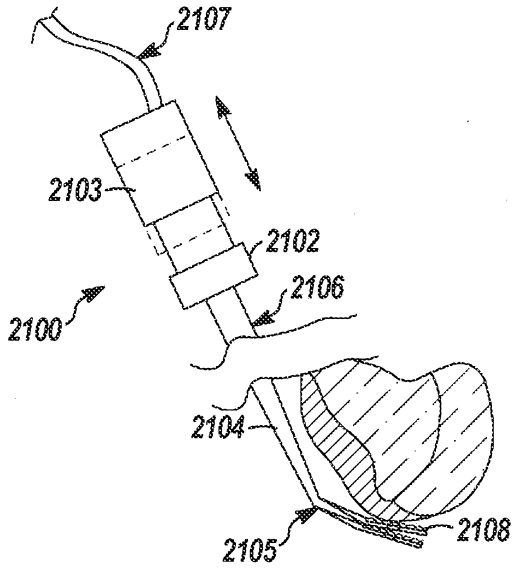


FIG. 14

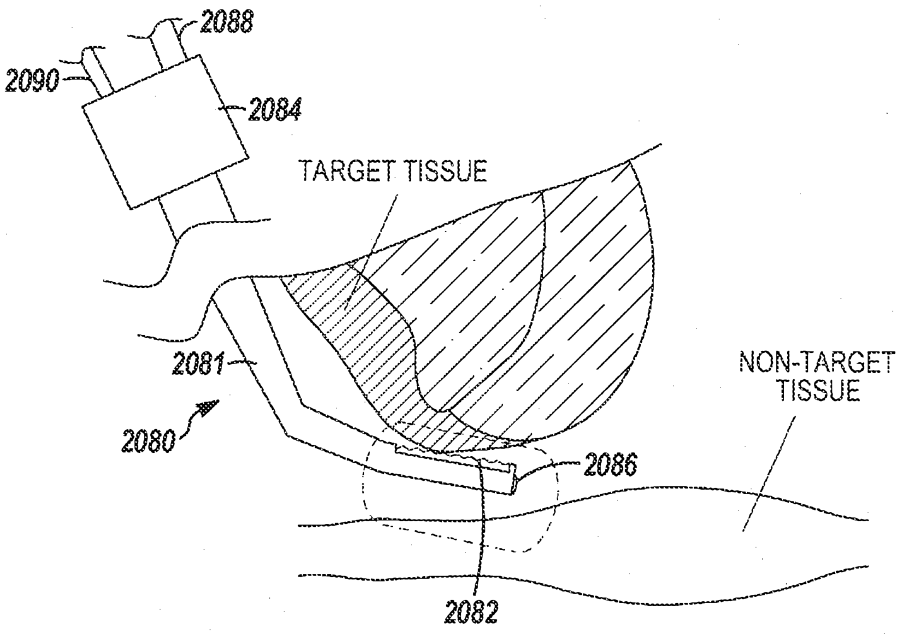


FIG. 15A

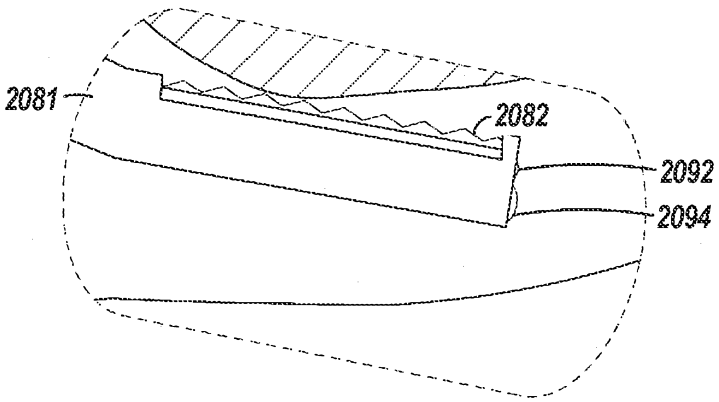


FIG. 15B

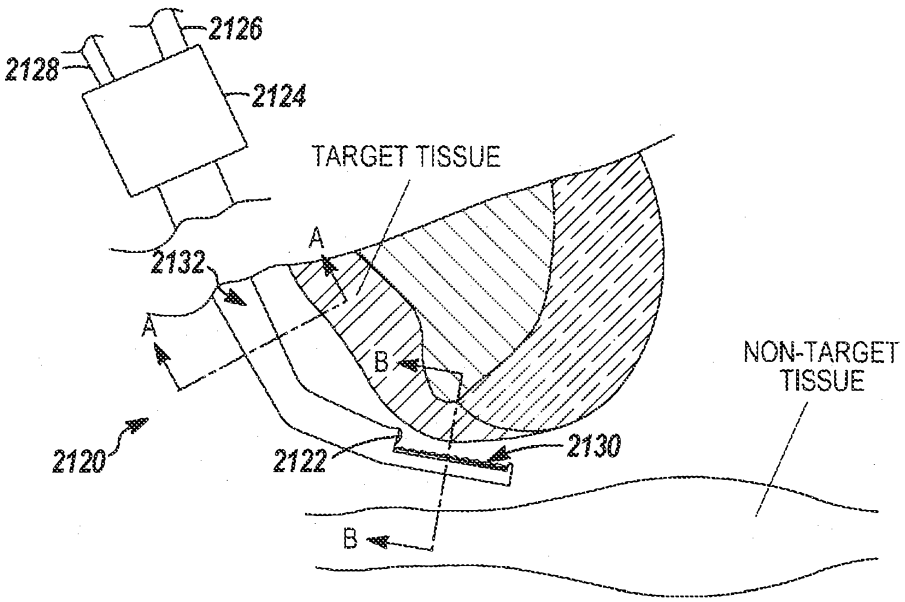


FIG. 16

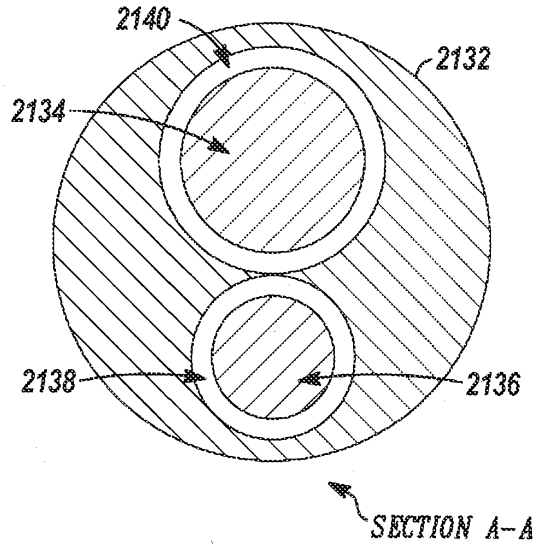


FIG. 17A

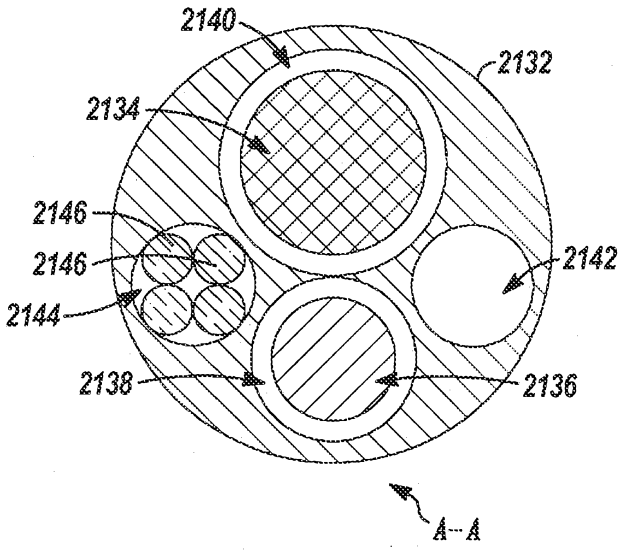


FIG. 17B

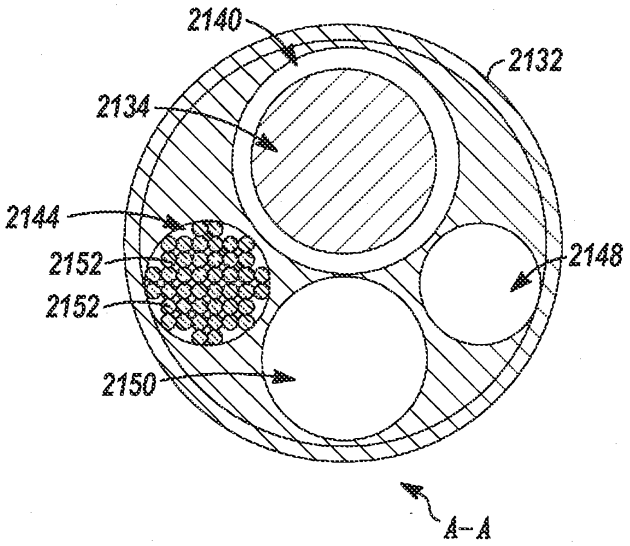


FIG. 17C

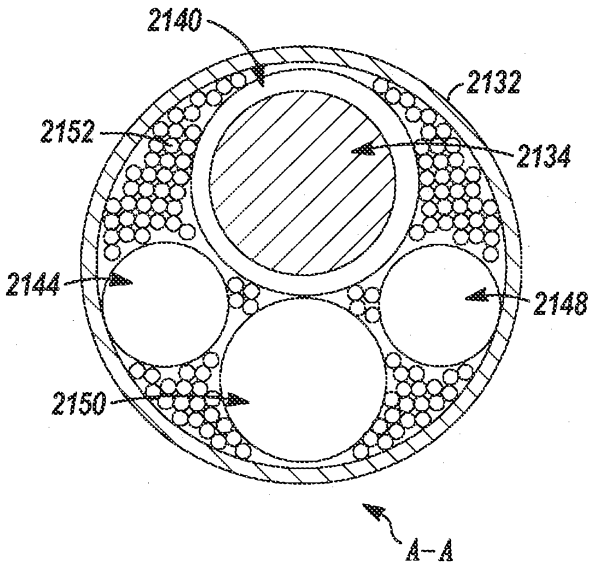


FIG. 17D

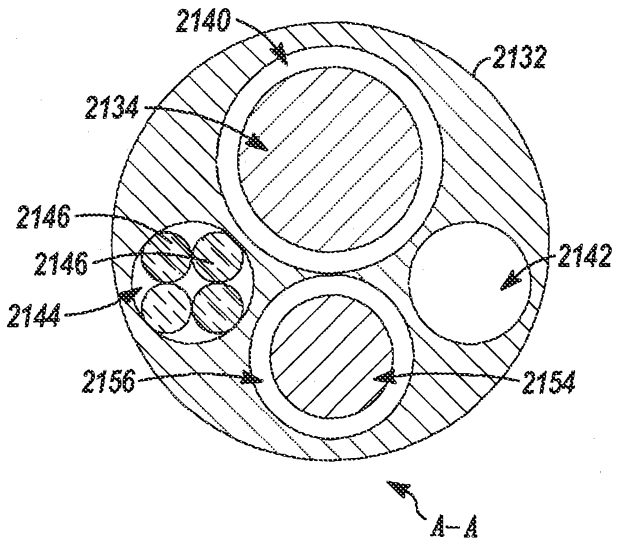
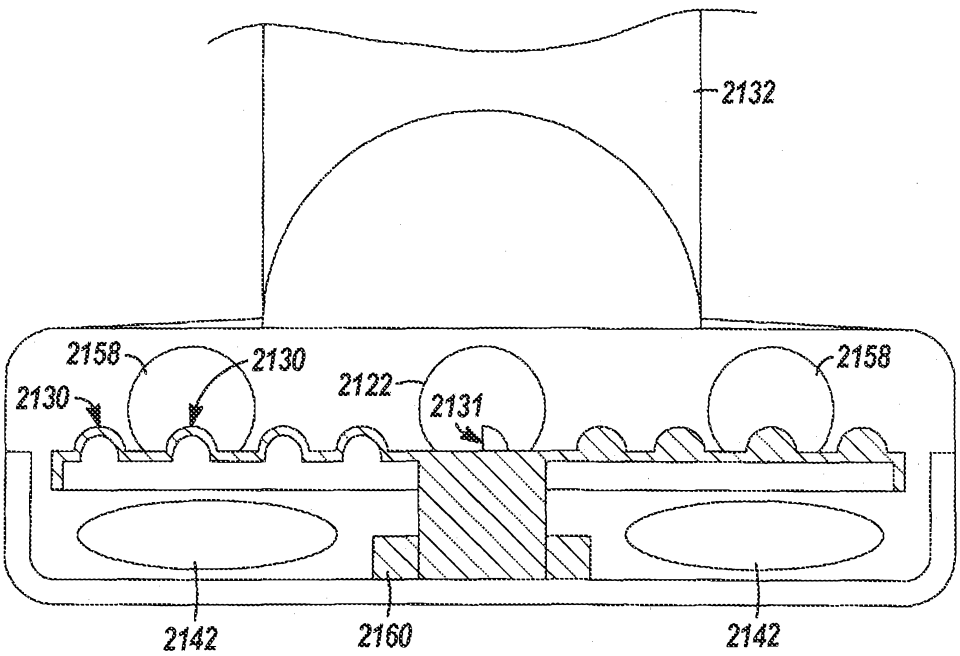


FIG. 17E



SECTION B-B

FIG. 18

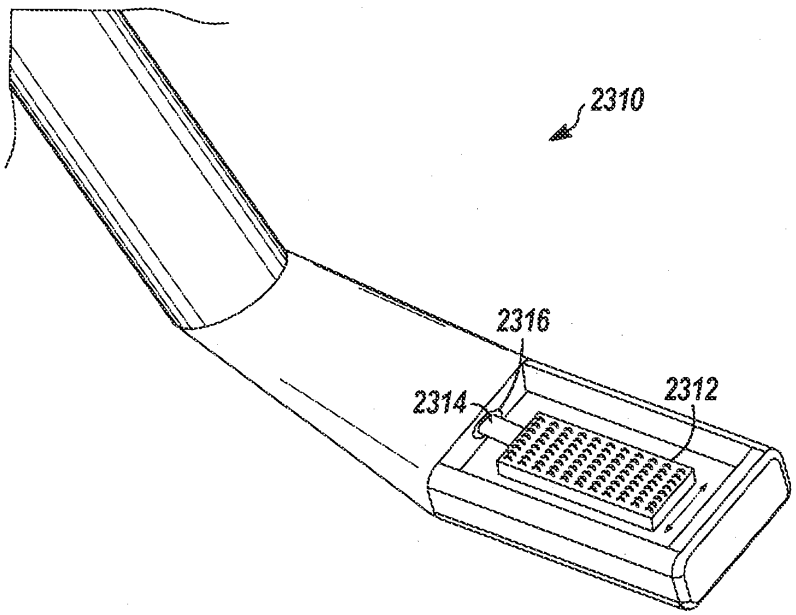


FIG. 19A

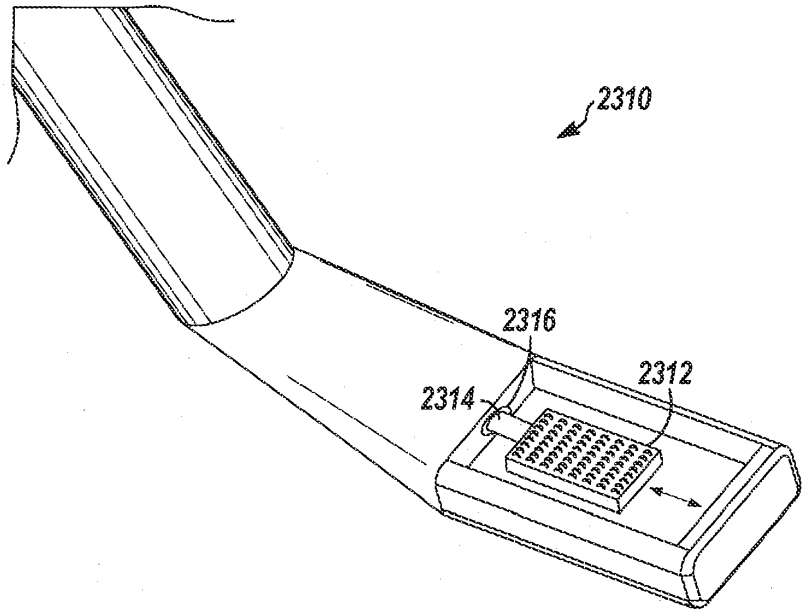


FIG. 19B

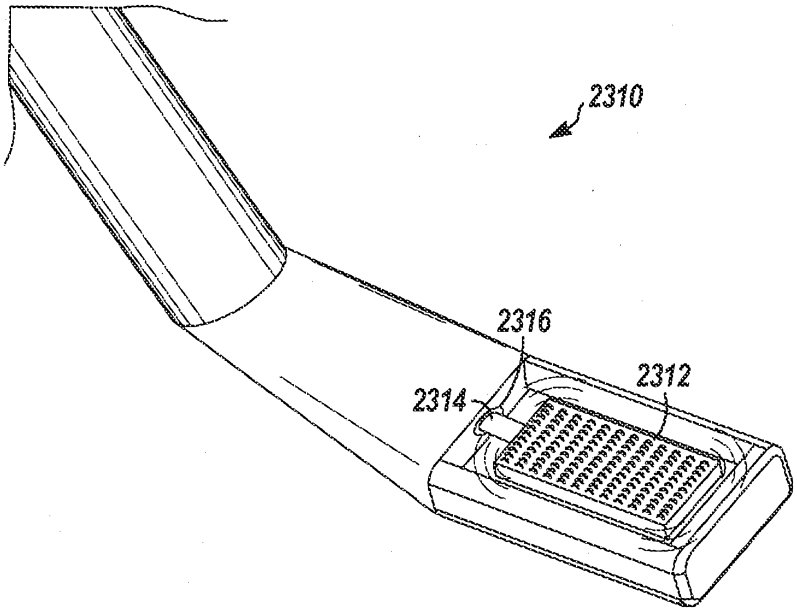


FIG. 19C

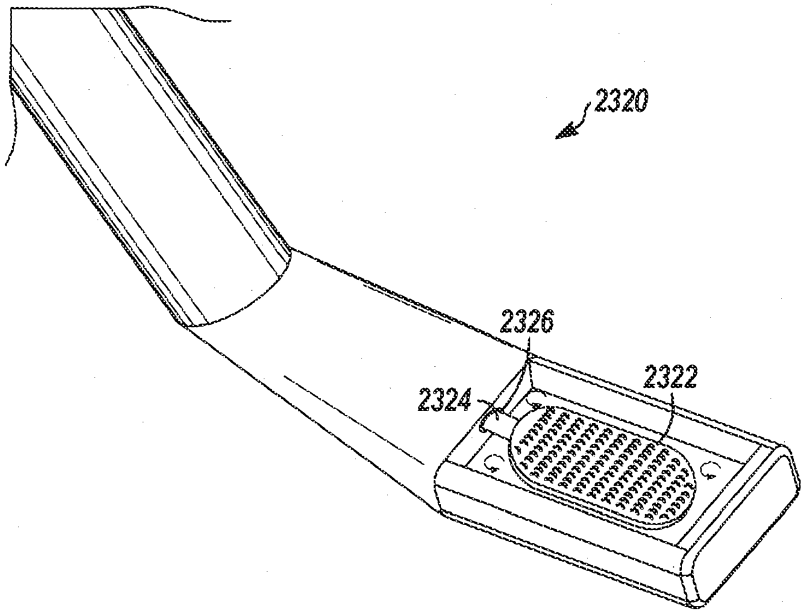


FIG. 20

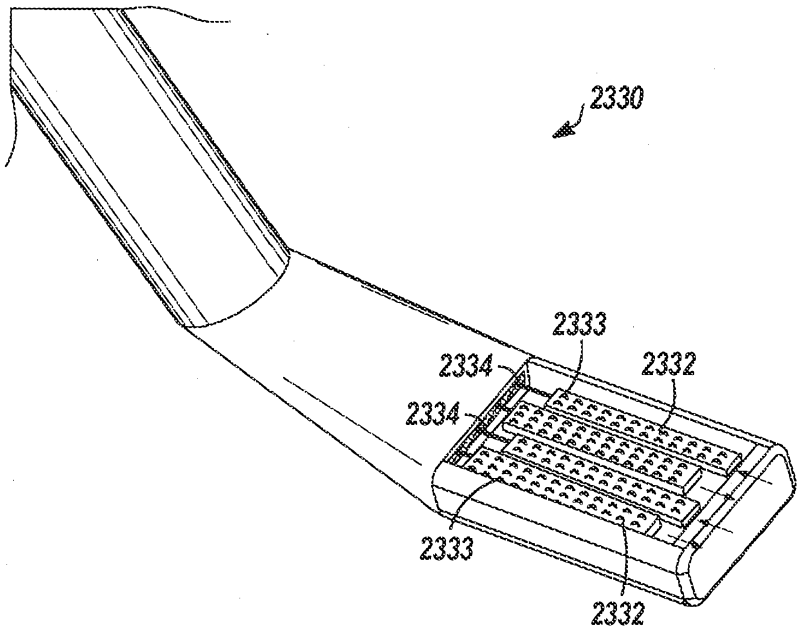

2330
2333
2334
2332
2334
2333
2332

FIG. 21

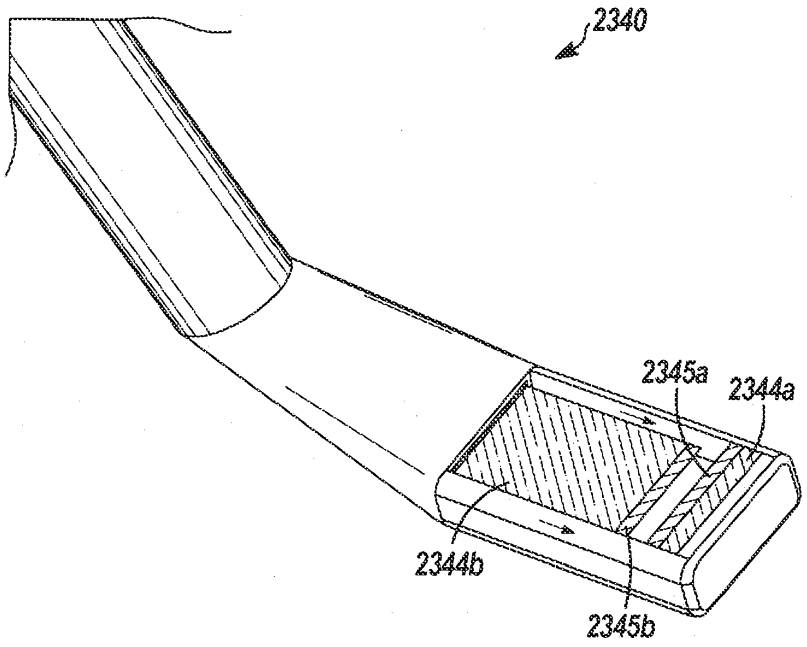

2340
2345a
2344a
2344b
2345b

FIG. 22

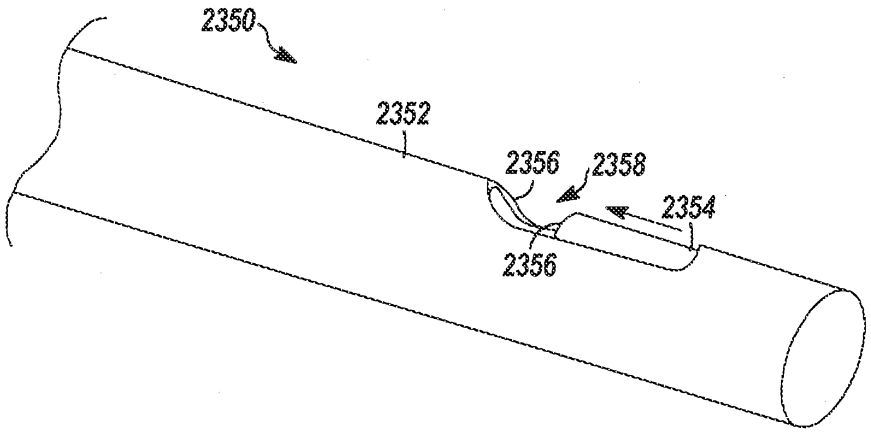


FIG. 23A

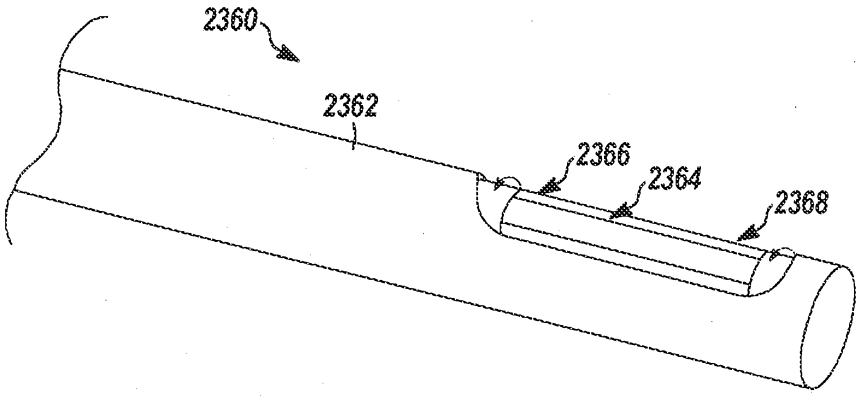


FIG. 23B

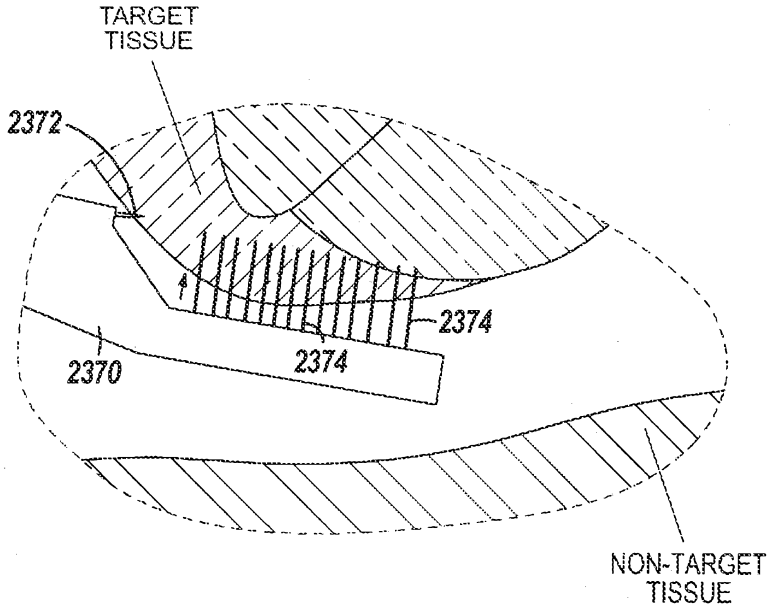


FIG. 24A

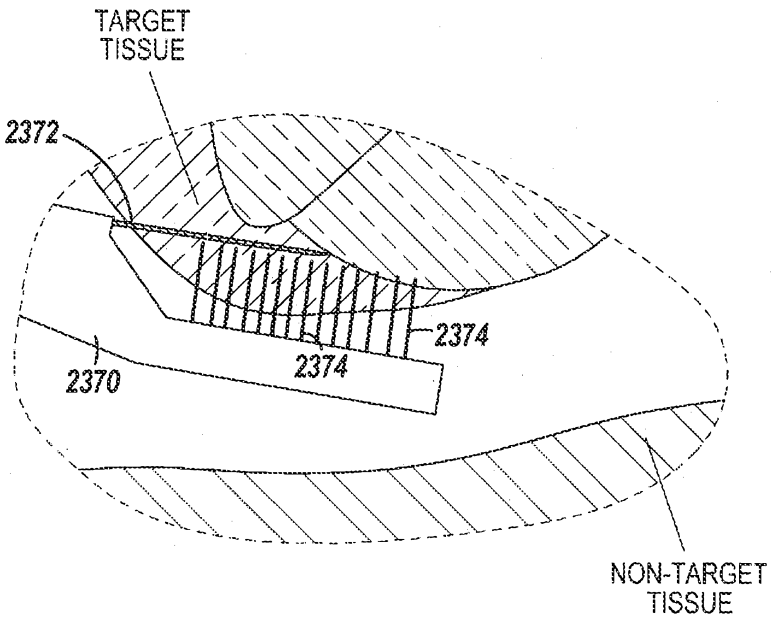


FIG. 24B

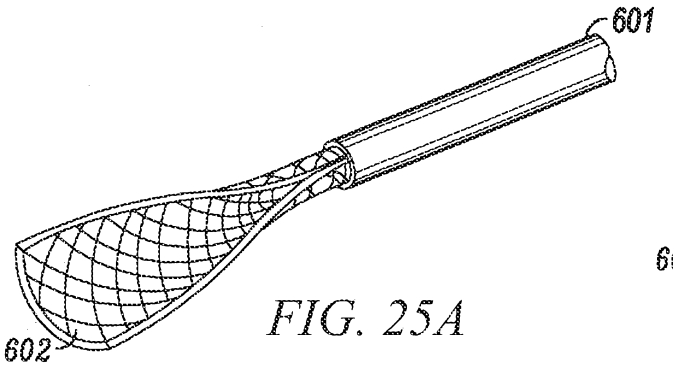


FIG. 25A

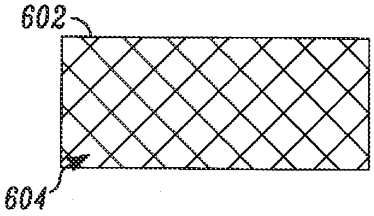


FIG. 25B

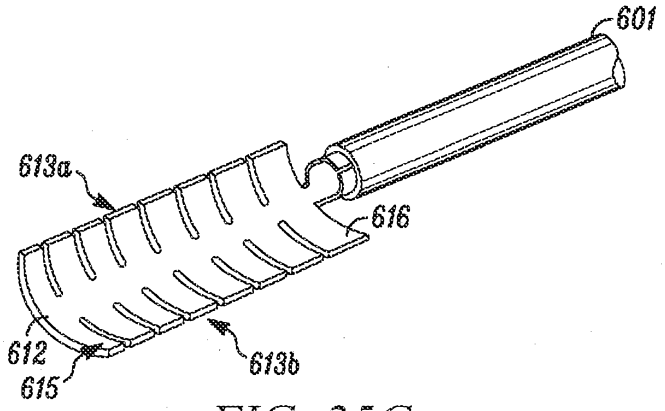


FIG. 25C

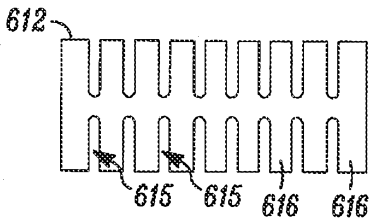


FIG. 25D

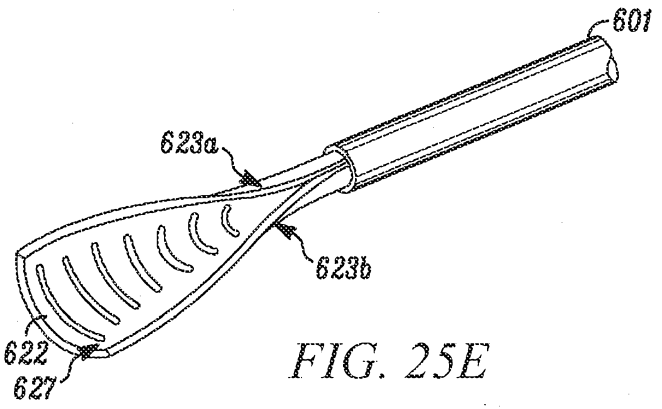


FIG. 25E

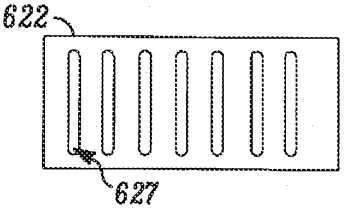


FIG. 25F

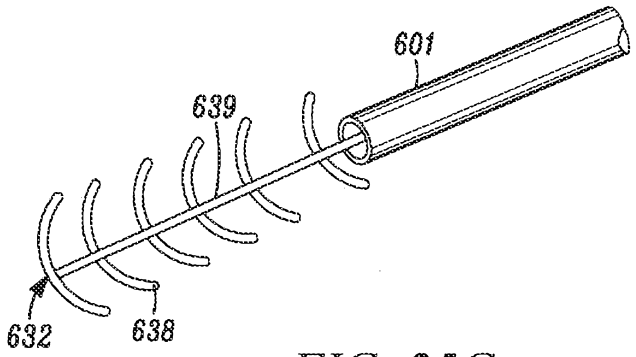


FIG. 25G

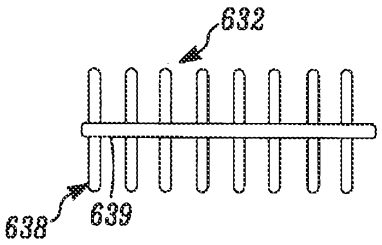


FIG. 25H

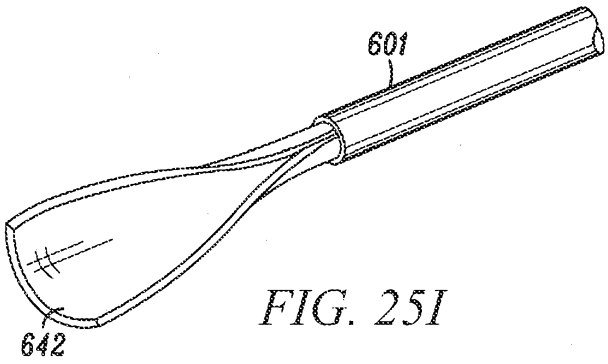


FIG. 25I

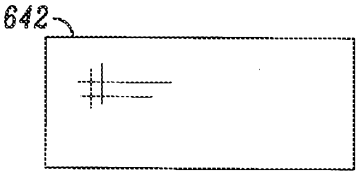


FIG. 25J

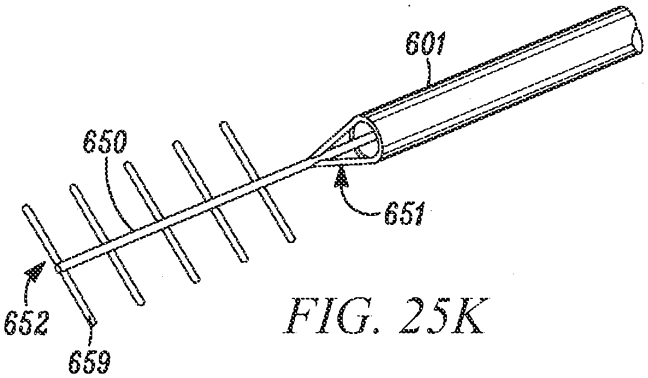


FIG. 25K

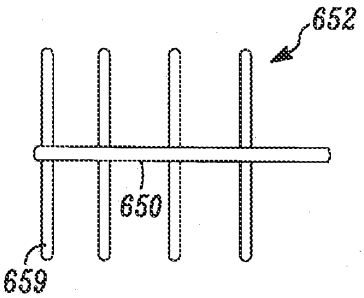


FIG. 25L

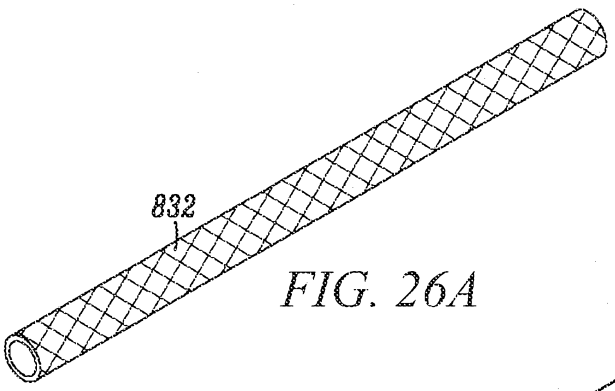


FIG. 26A

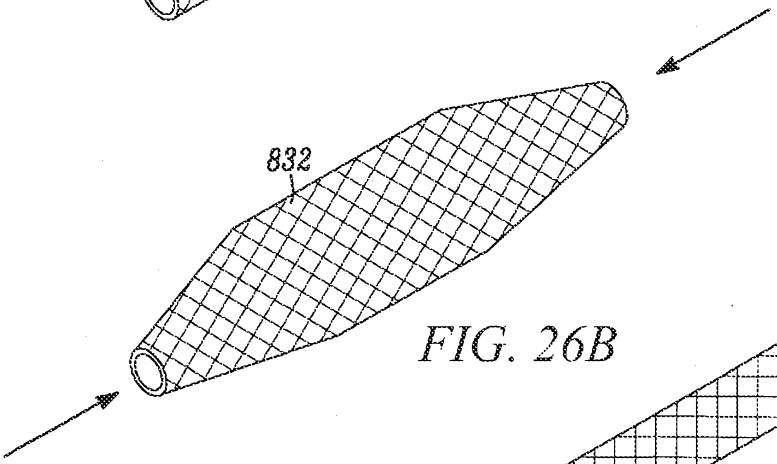


FIG. 26B

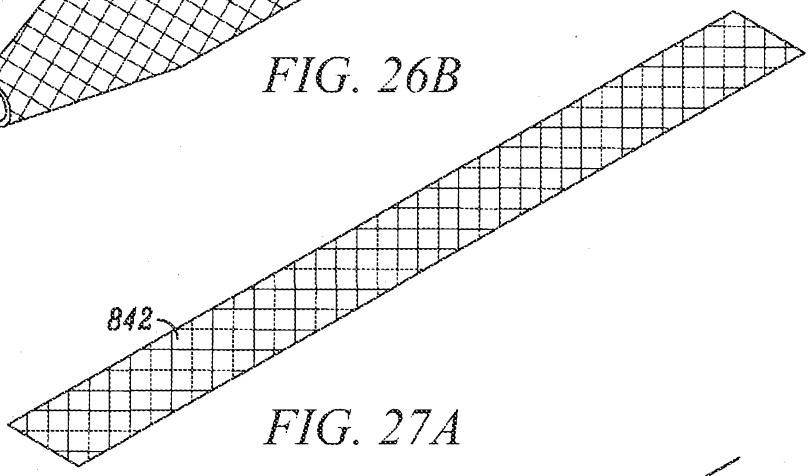


FIG. 27A

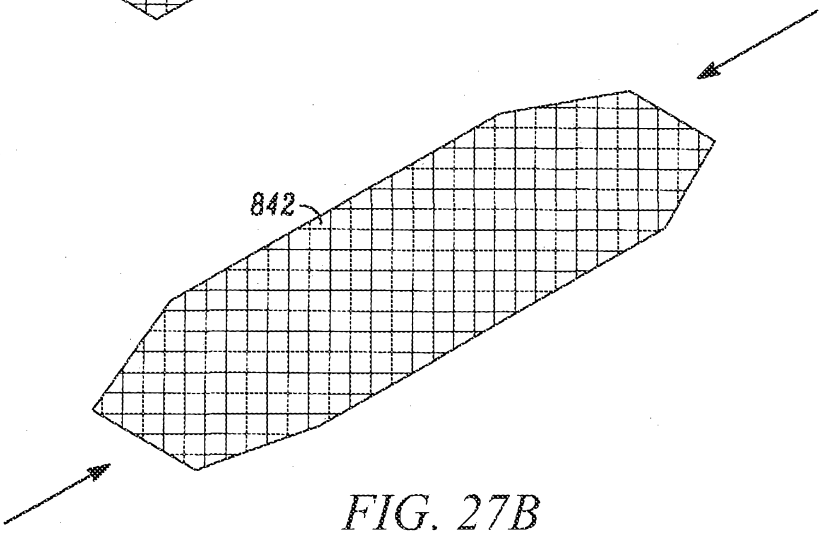


FIG. 27B

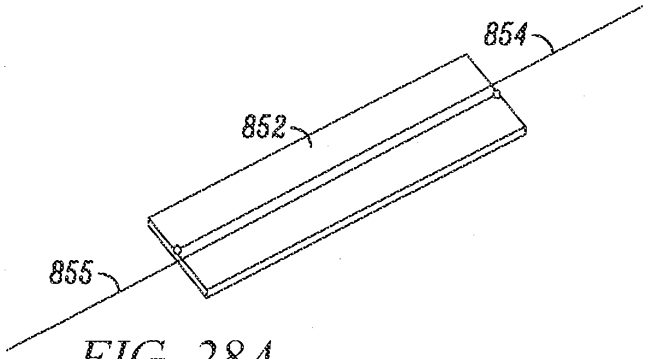


FIG. 28A

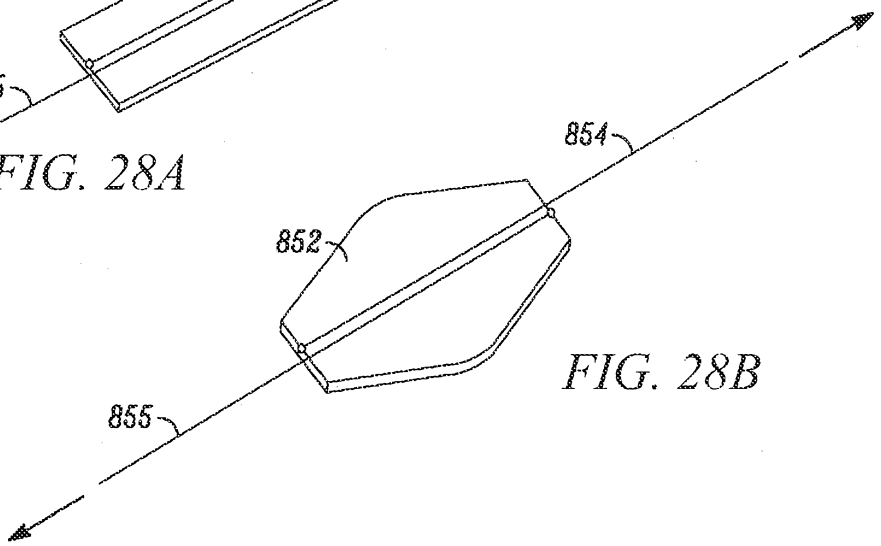


FIG. 28B

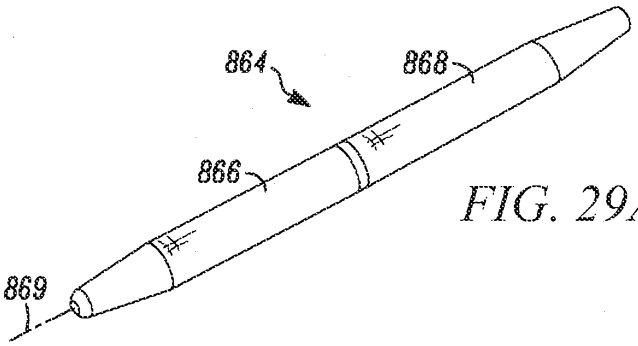


FIG. 29A

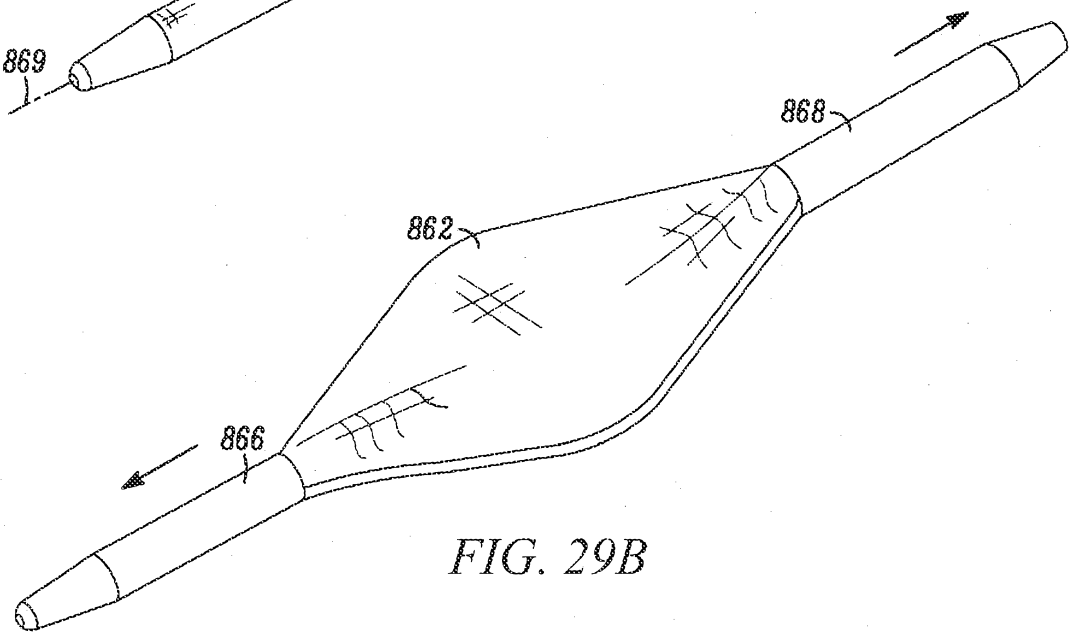


FIG. 29B

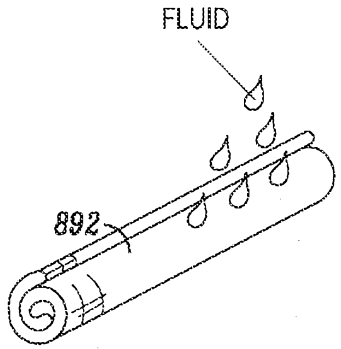


FIG. 30A

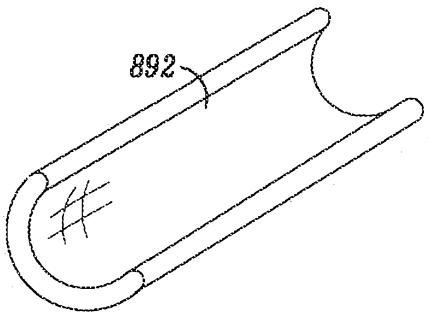


FIG. 30B

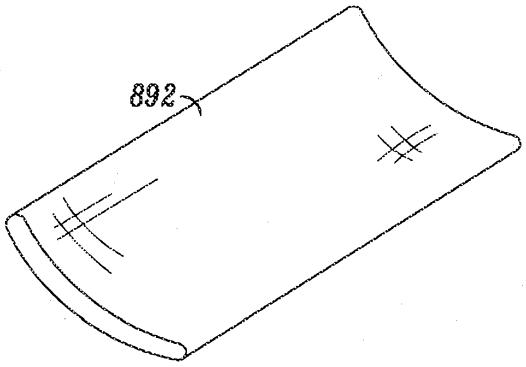


FIG. 30C

FIG. 31B

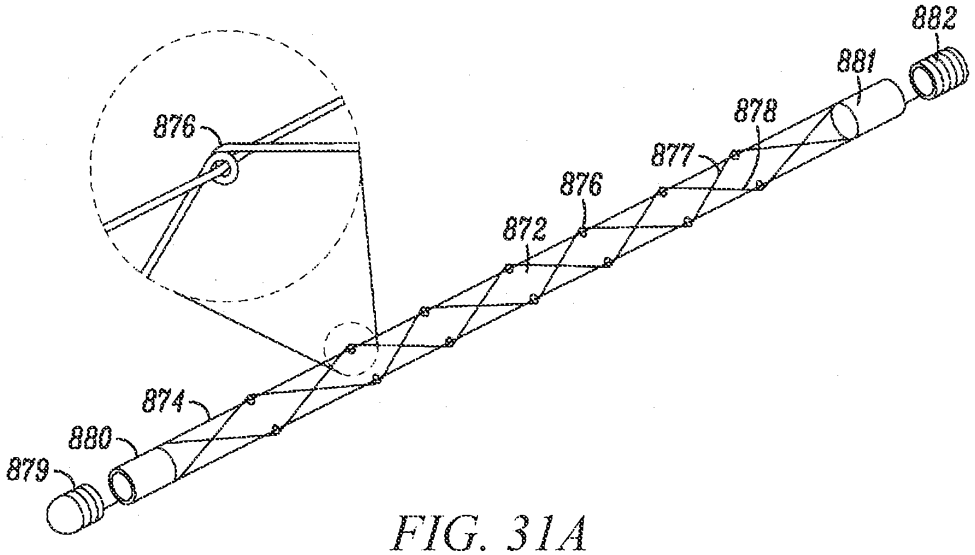


FIG. 31A

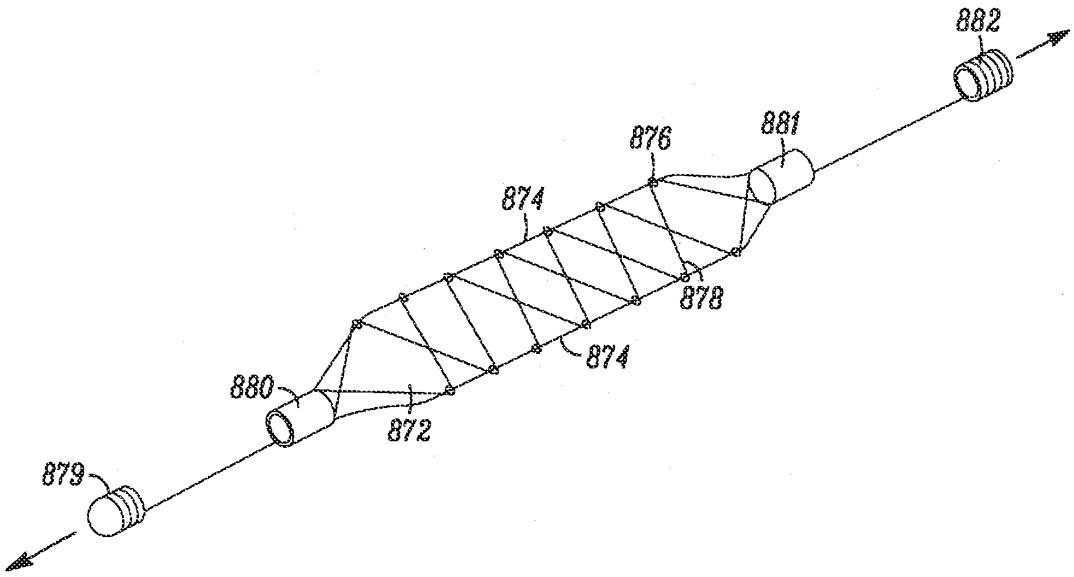


FIG. 31C

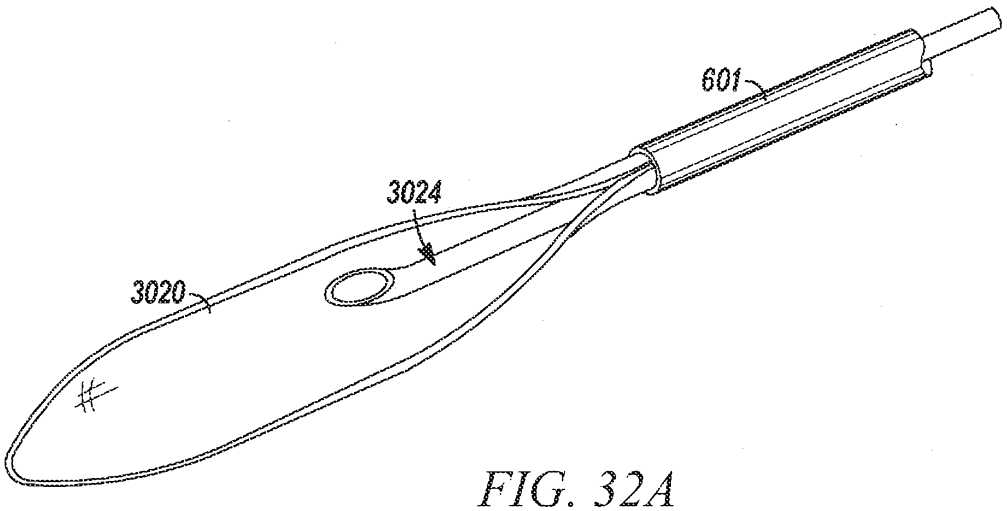


FIG. 32A

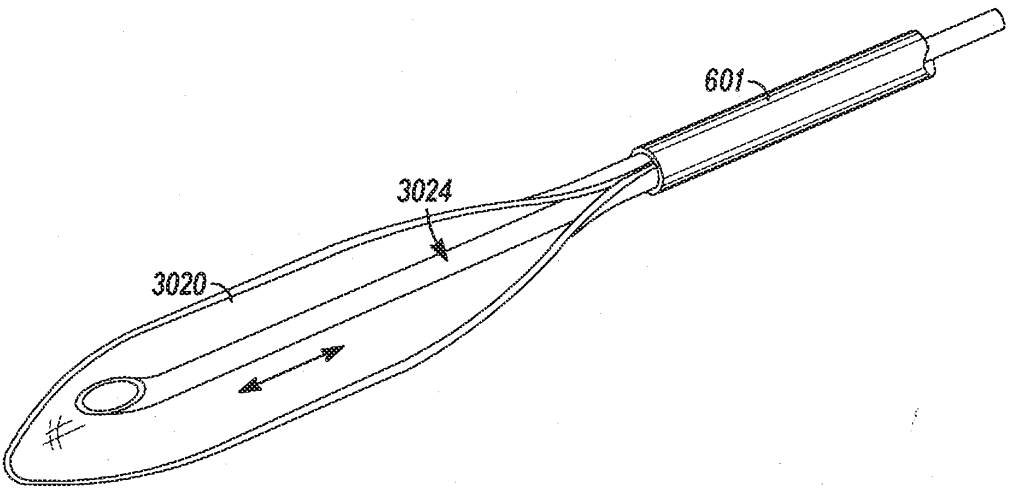


FIG. 32B

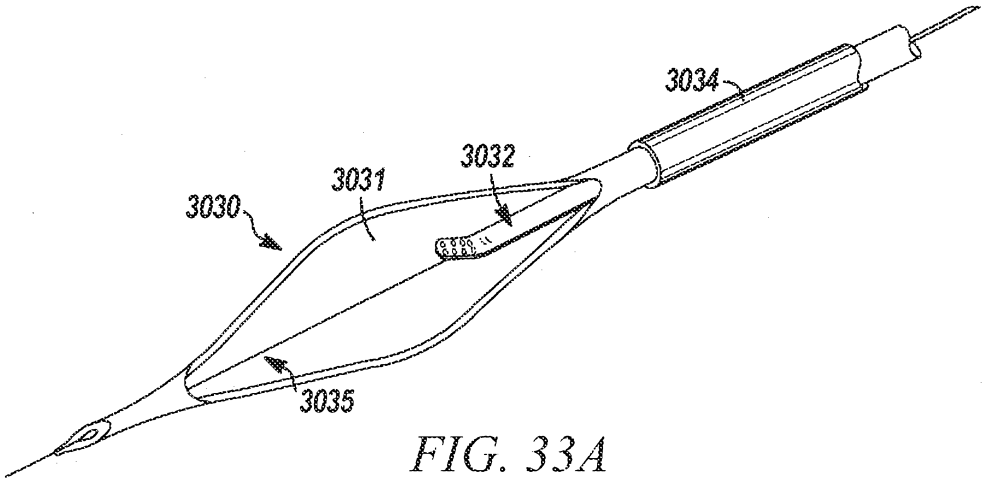


FIG. 33A

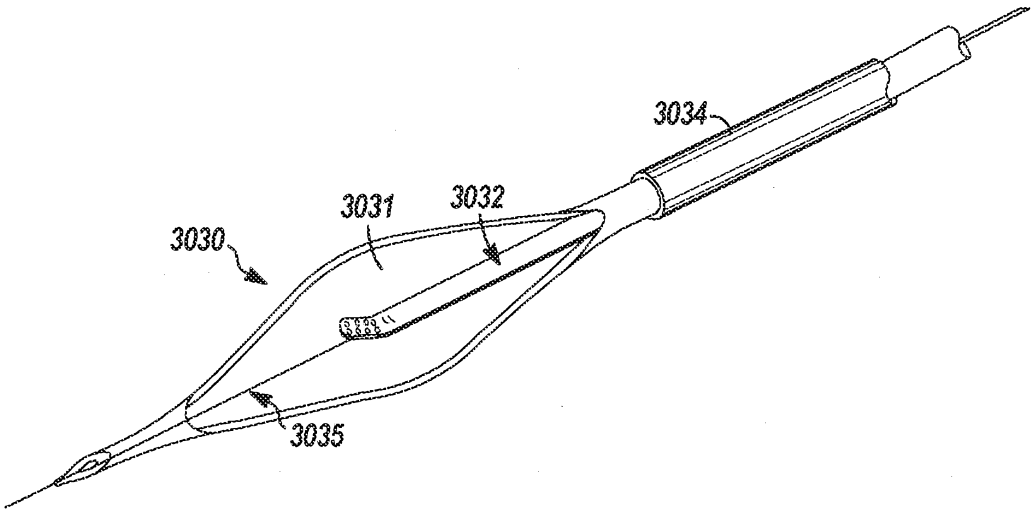


FIG. 33B

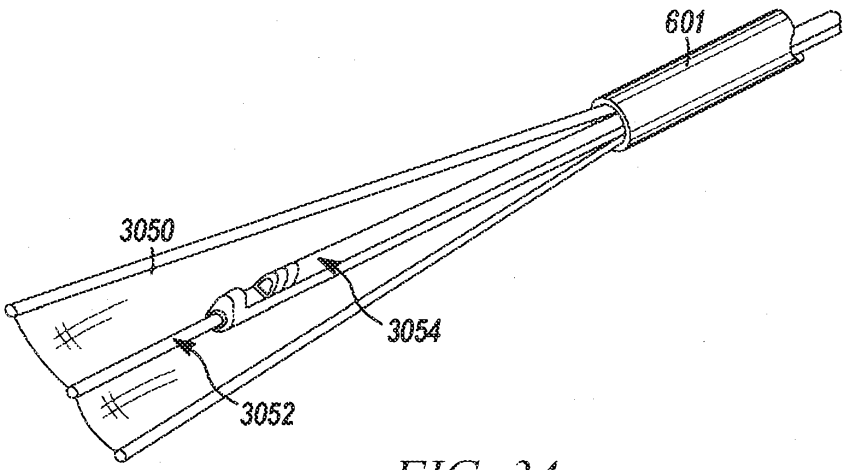


FIG. 34

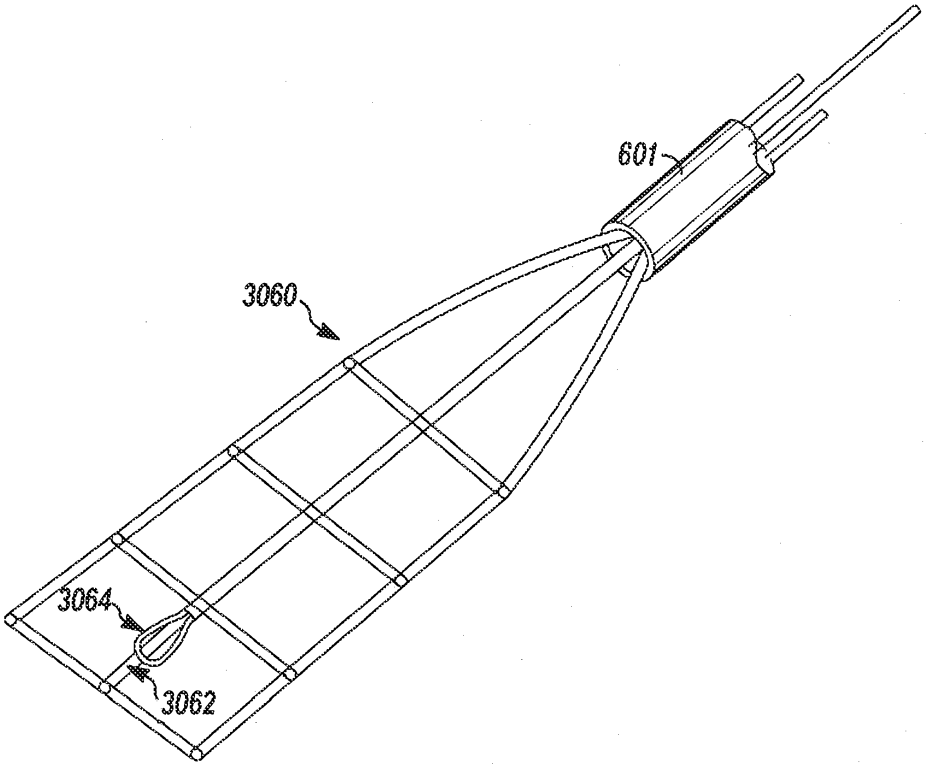


FIG. 35

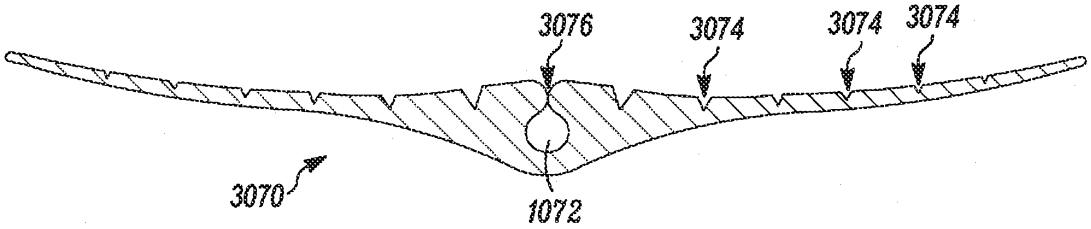


FIG. 36A

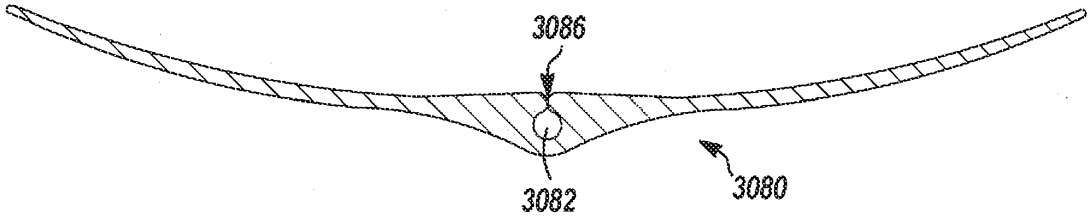


FIG. 36B

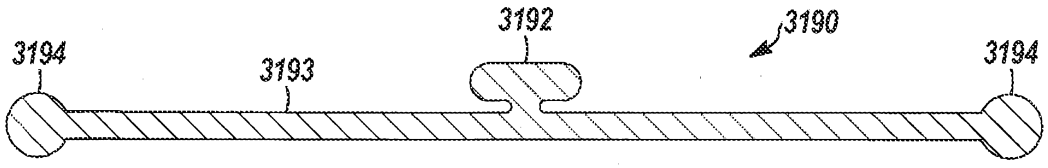


FIG. 37A

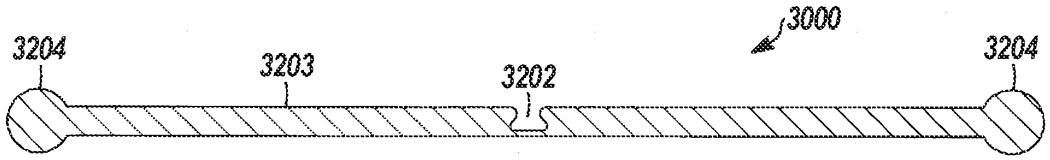


FIG. 37B

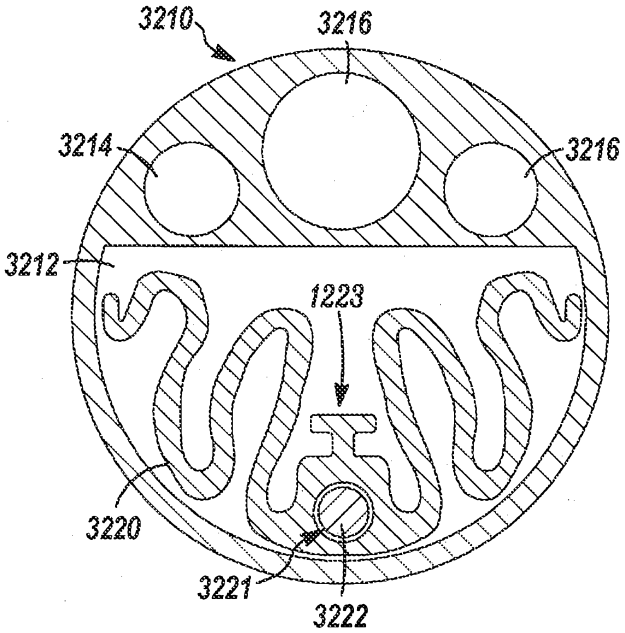


FIG. 38

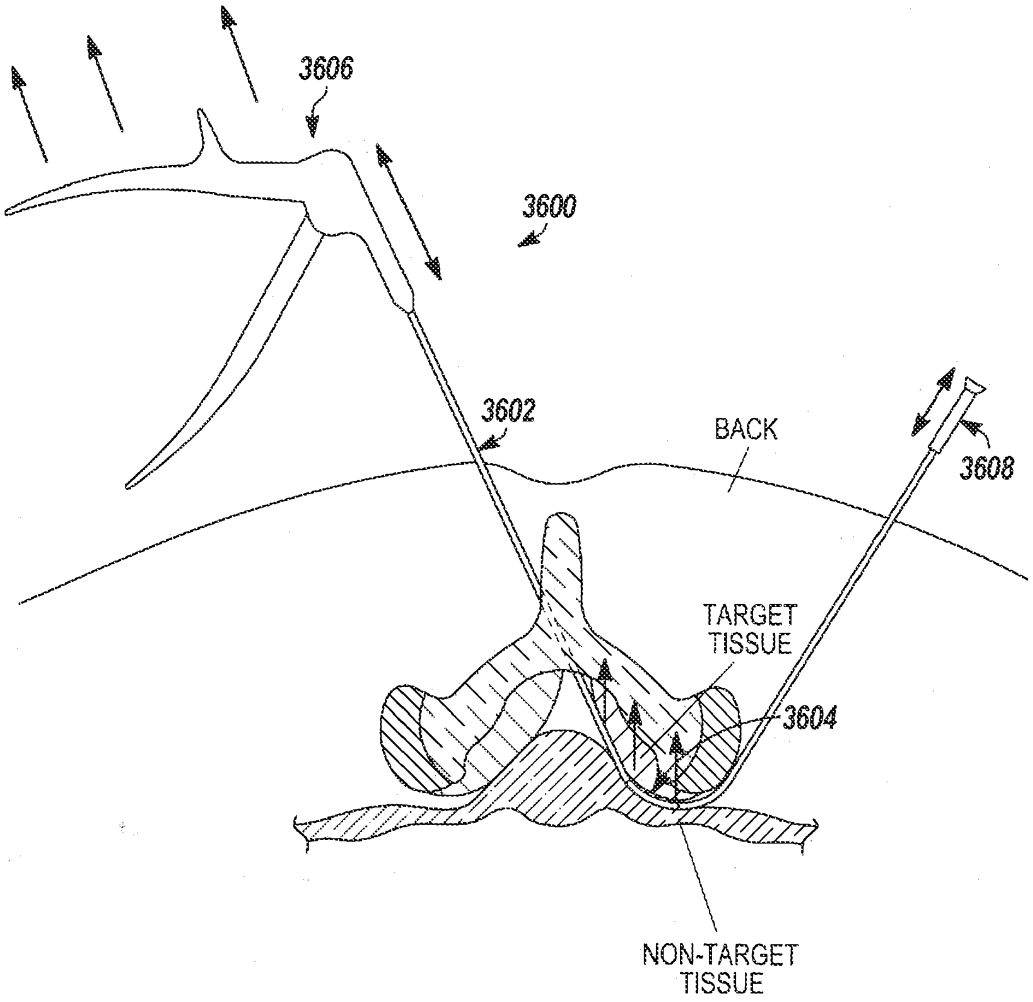

3606
3600
3602
BACK
3608
TARGET
TISSUE
3604
NON-TARGET
TISSUE

FIG. 39

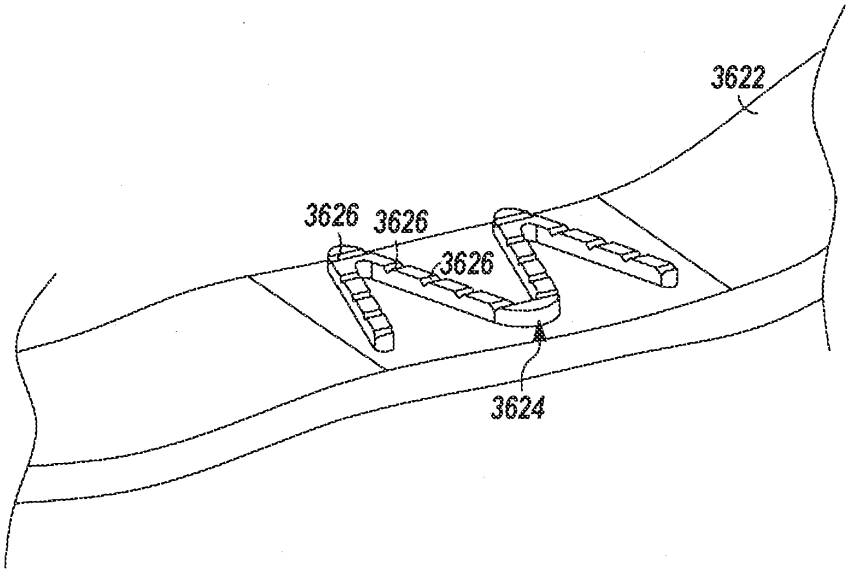


FIG. 40A

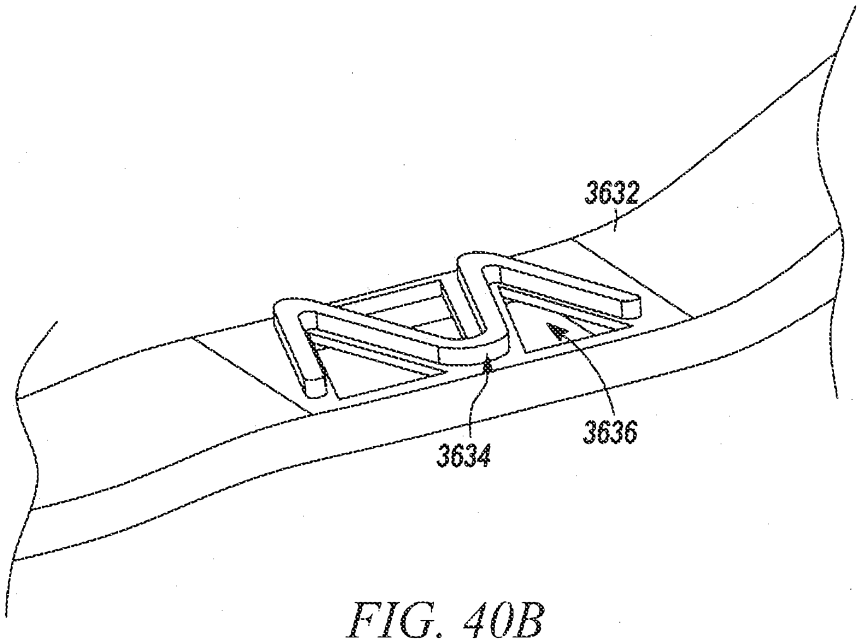


FIG. 40B

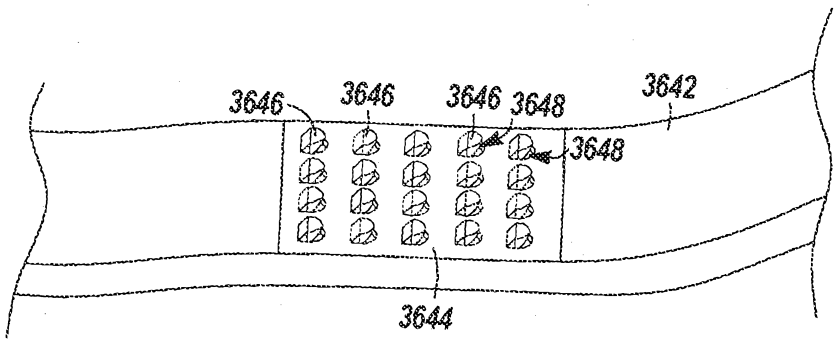


FIG. 40C

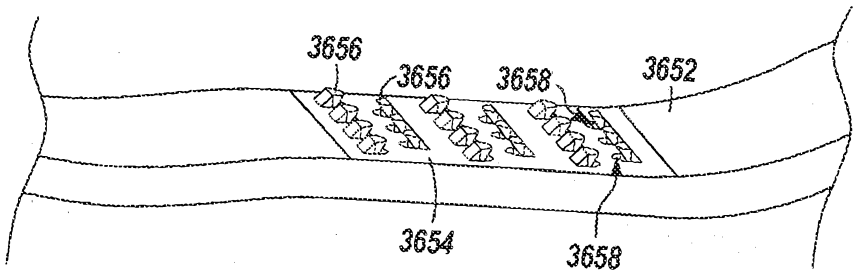


FIG. 40D

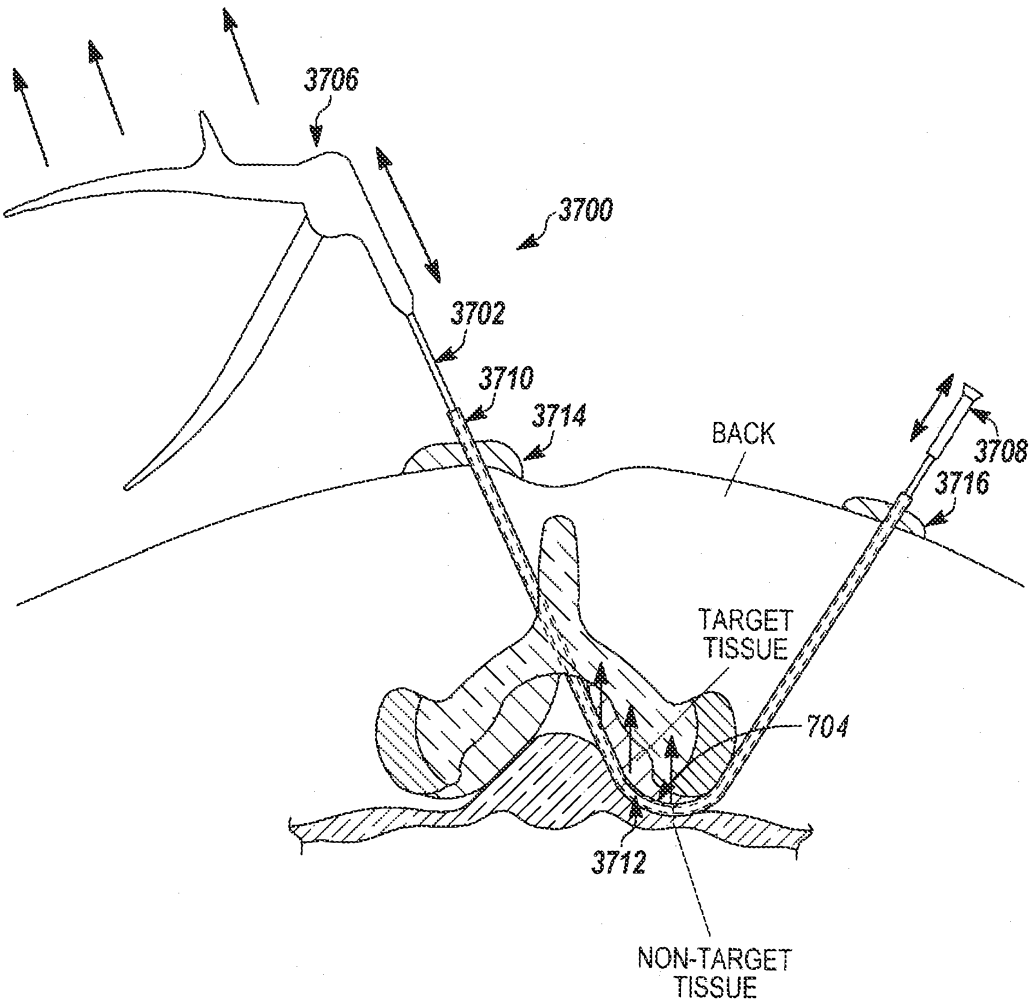

3706
3700
3702
3710
3714
BACK
3708
3716
TARGET
TISSUE
704
3712
NON-TARGET
TISSUE

FIG. 41

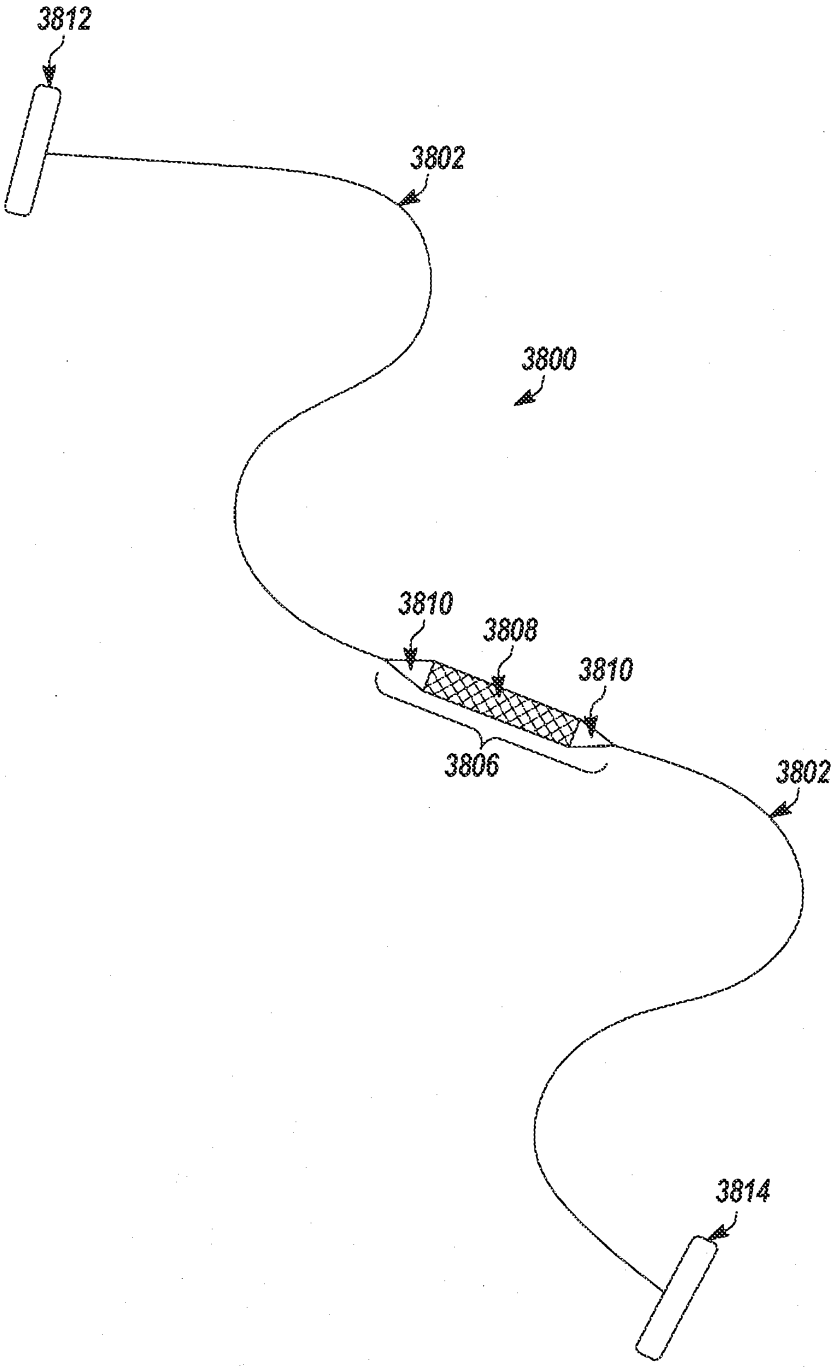


FIG. 42A

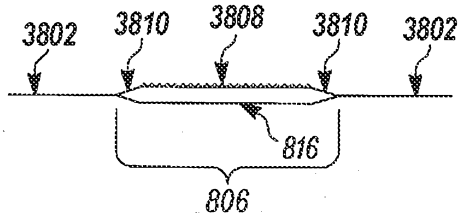


FIG. 42B