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Bleich et al.(54) **METHODS AND APPARATUS FOR TISSUE MODIFICATION****Publication Classification**(51) **Int. Cl.****A61B 17/58** (2006.01)(52) **U.S. Cl.** **606/103**(76) **Inventors:** **Jeffery L. Bleich**, Palo Alto, CA (US);
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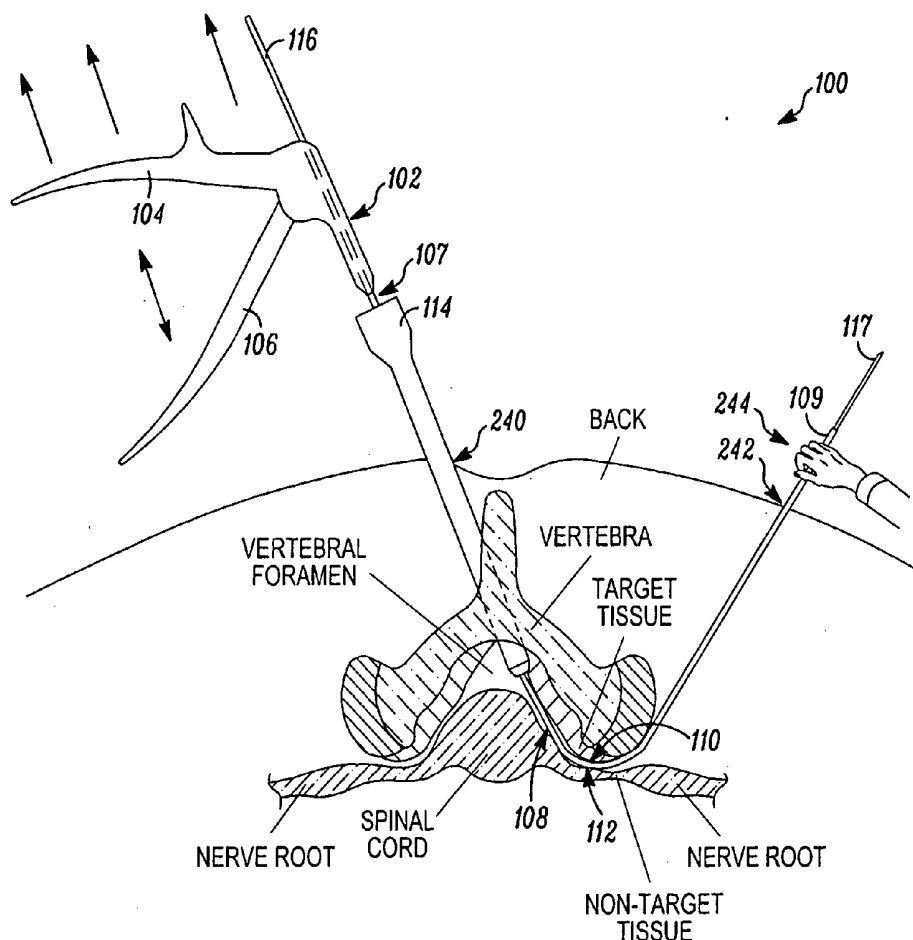
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SAN FRANCISCO, CA 94111-3834 (US)**(57) **ABSTRACT**

A method for modifying tissue in a patient may involve one or more of the following steps: advancing at least a distal portion of at least one elongate, at least partially flexible tissue modification device into a patient and between one or more target tissues and one or more non-target tissues; positioning at least one tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member(s) face the target tissue and do not face the non-target tissue; applying an anchoring force to the tissue modification device at or near the distal portion or a proximal portion of the device; applying a tensioning force to the tissue modification device at or near an opposite end of the device relative to the end to which anchoring force is applied, while maintaining the anchoring force, to urge the tissue modifying member(s) against the target tissue; and modifying the target tissue, using the tissue modifying member(s), while preventing the tissue modifying member(s) from extending significantly beyond the target tissue toward the proximal or distal portion of the tissue modification device during tissue modification.

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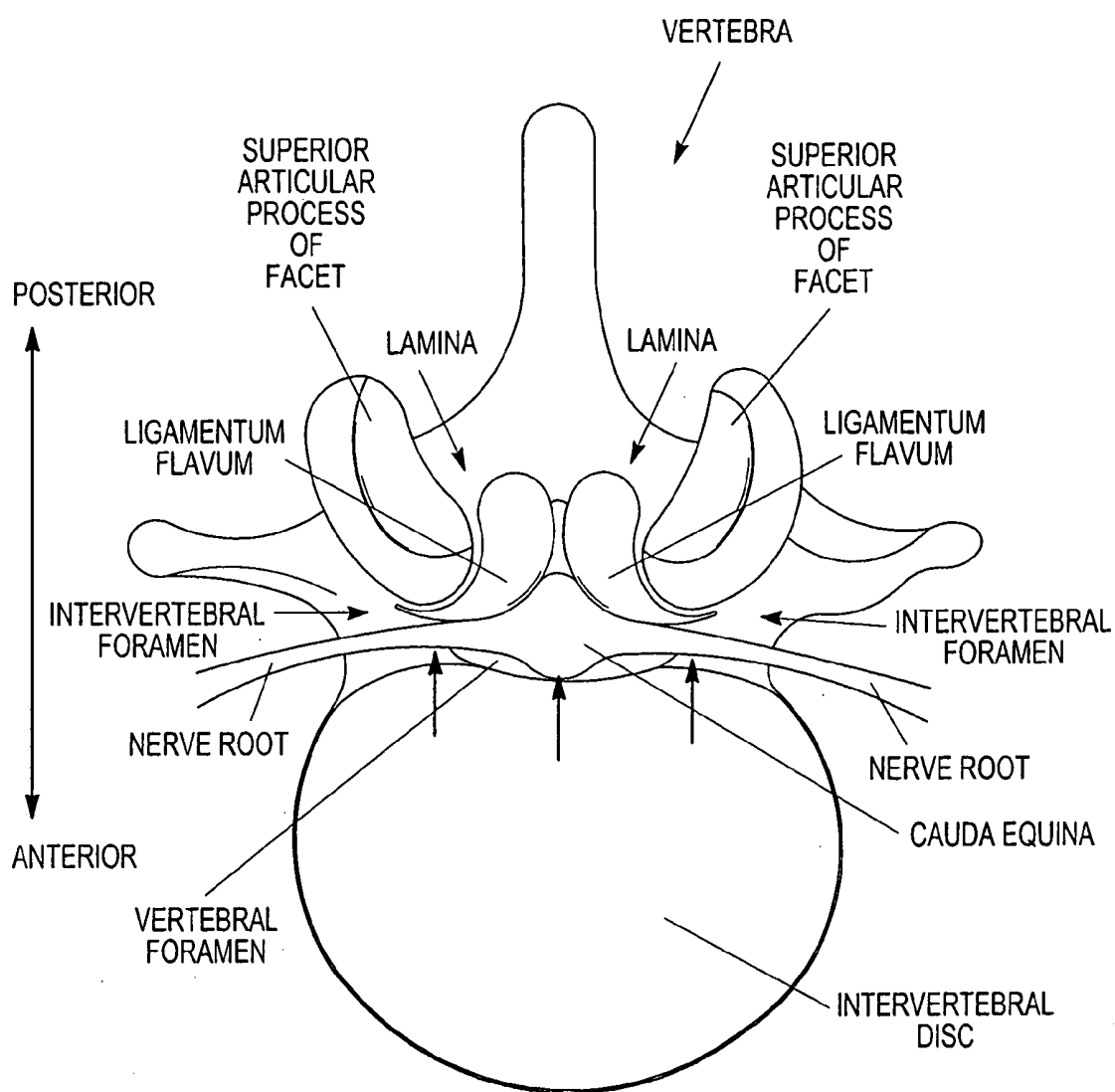


FIG. 1

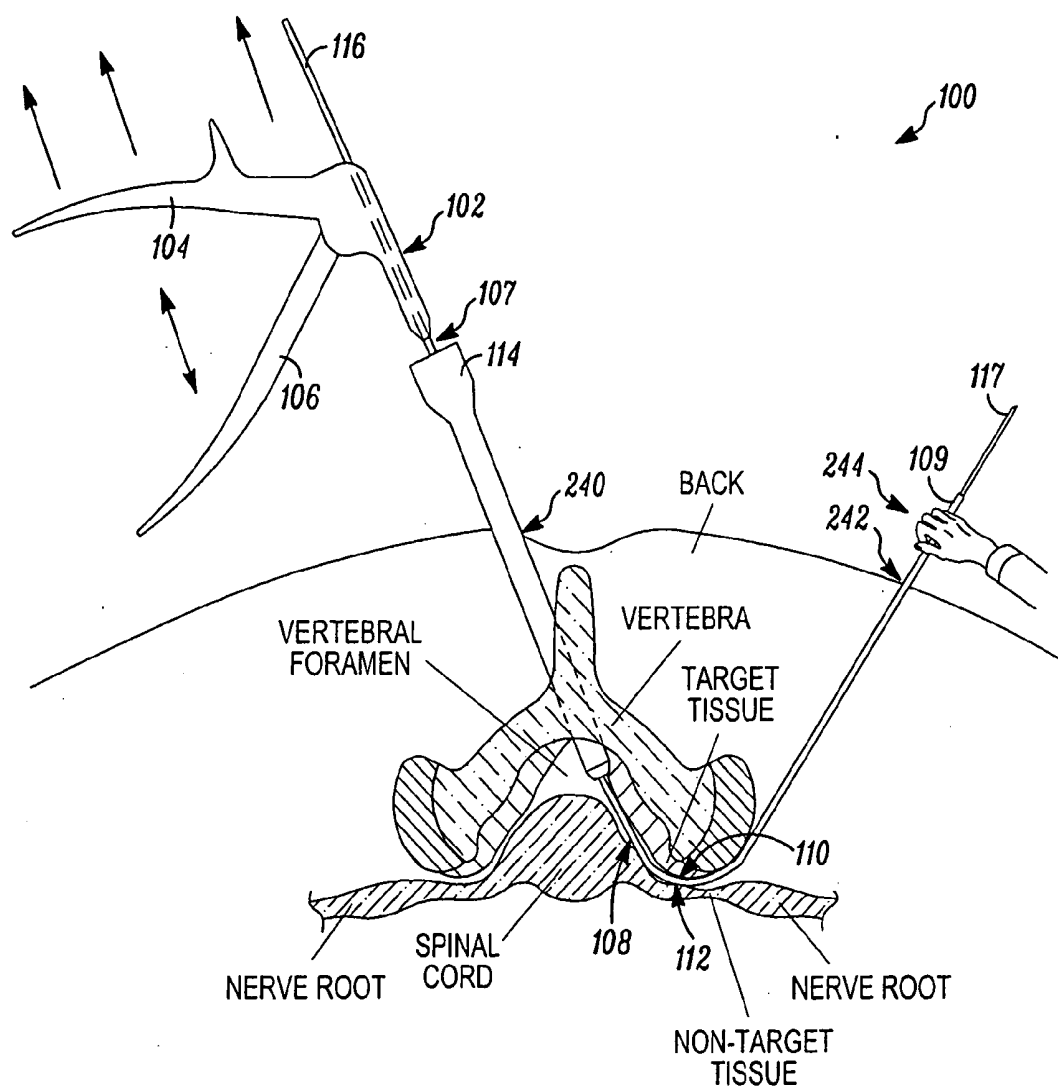


FIG. 2

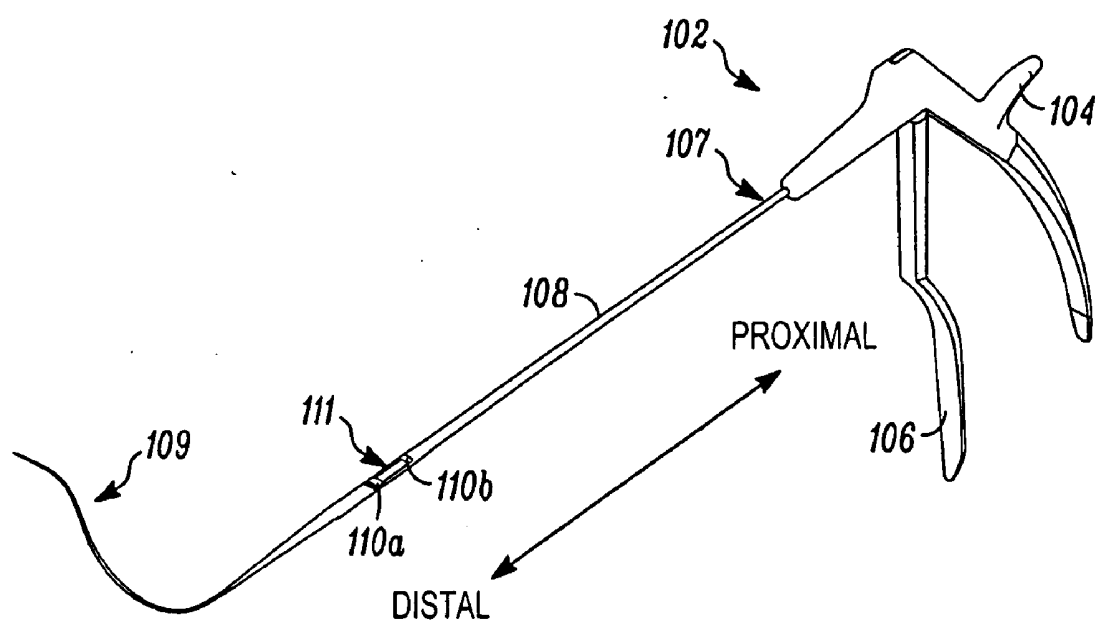


FIG. 3A

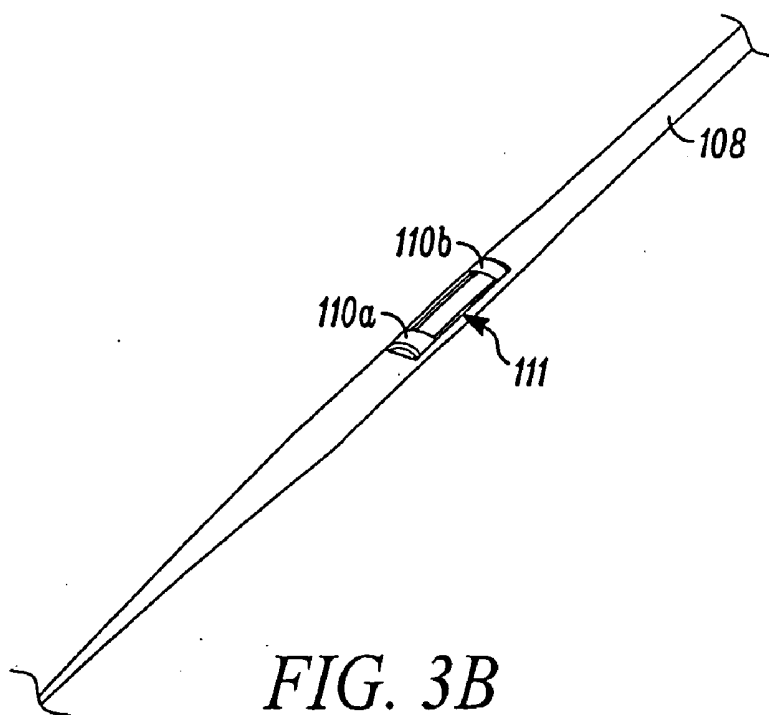


FIG. 3B

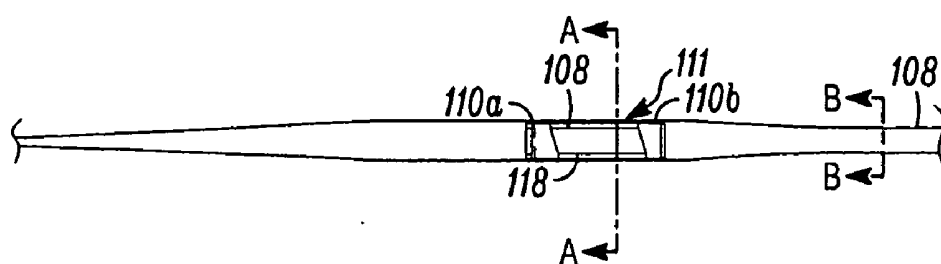


FIG. 3C

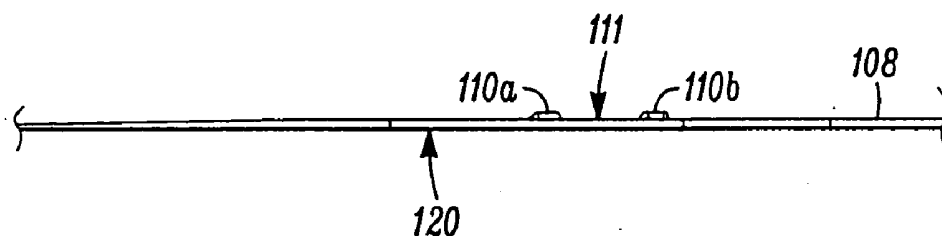
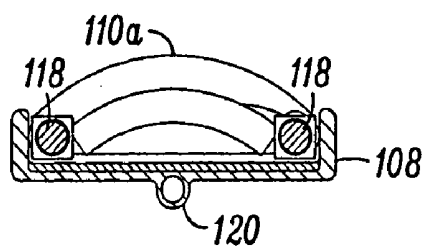
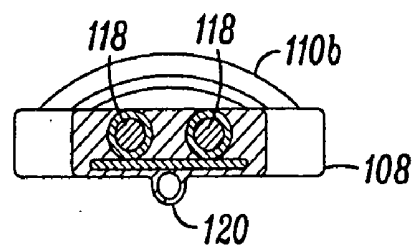


FIG. 3D



SECTION A-A

FIG. 3E



SECTION B-B

FIG. 3F

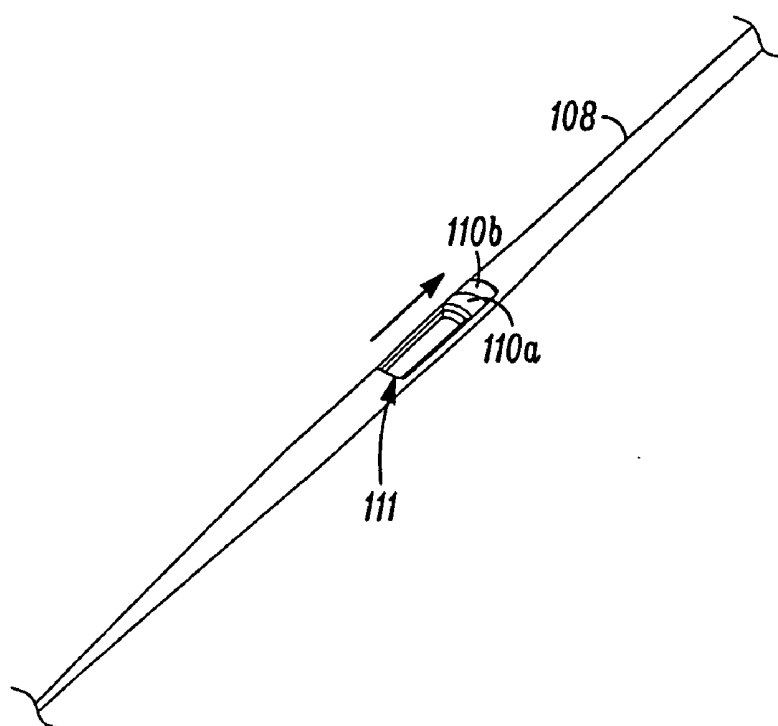


FIG. 3G

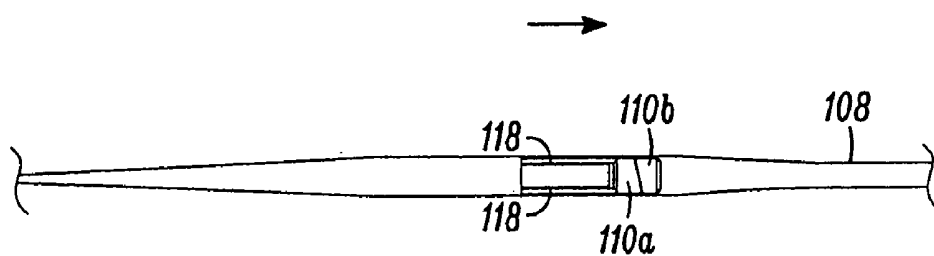


FIG. 3H

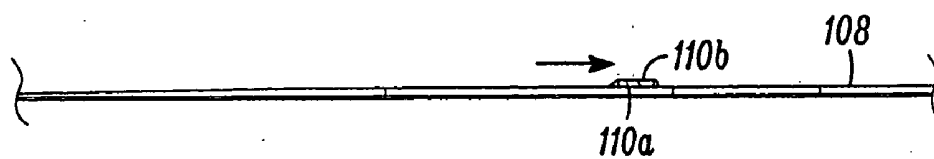


FIG. 3I

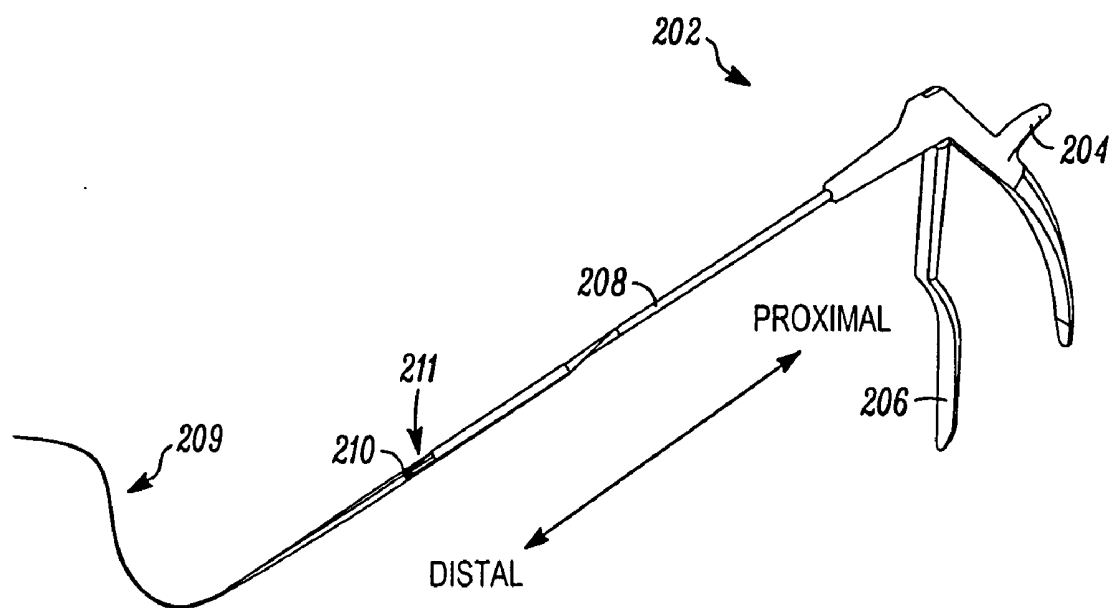


FIG. 4A

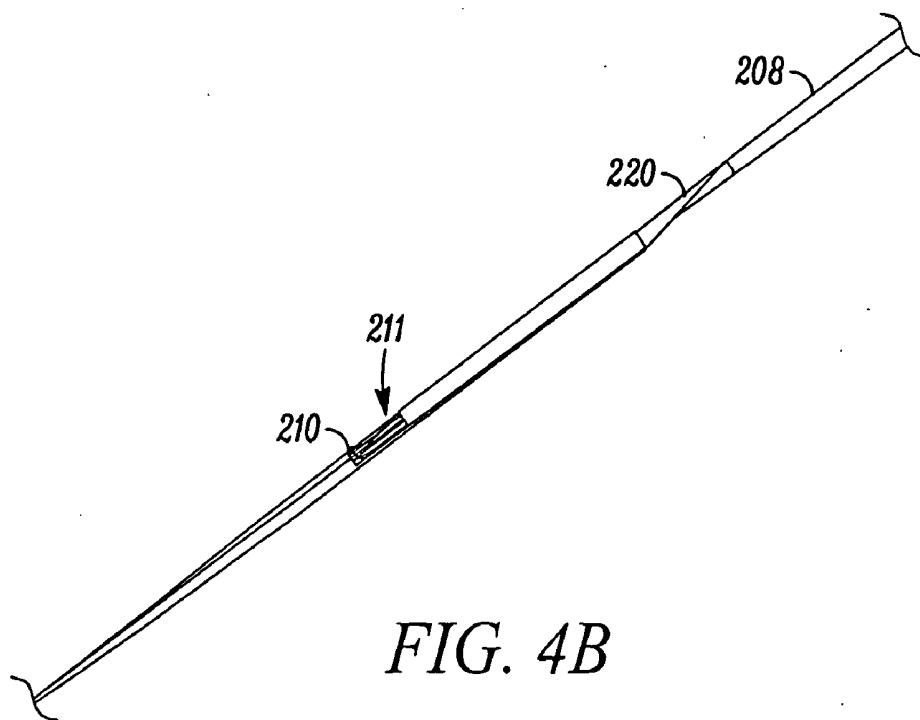


FIG. 4B

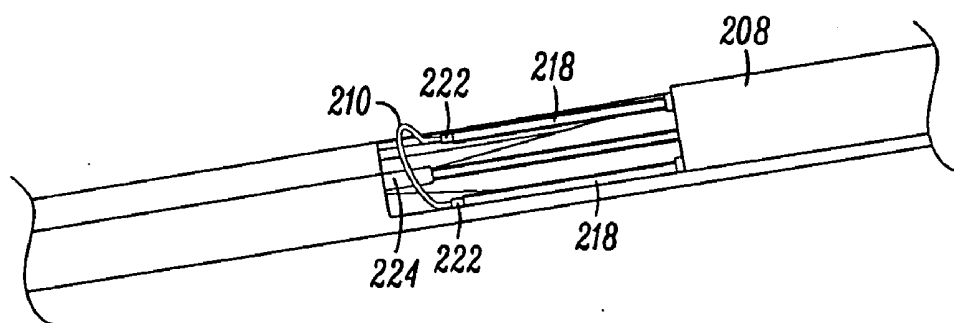


FIG. 4C

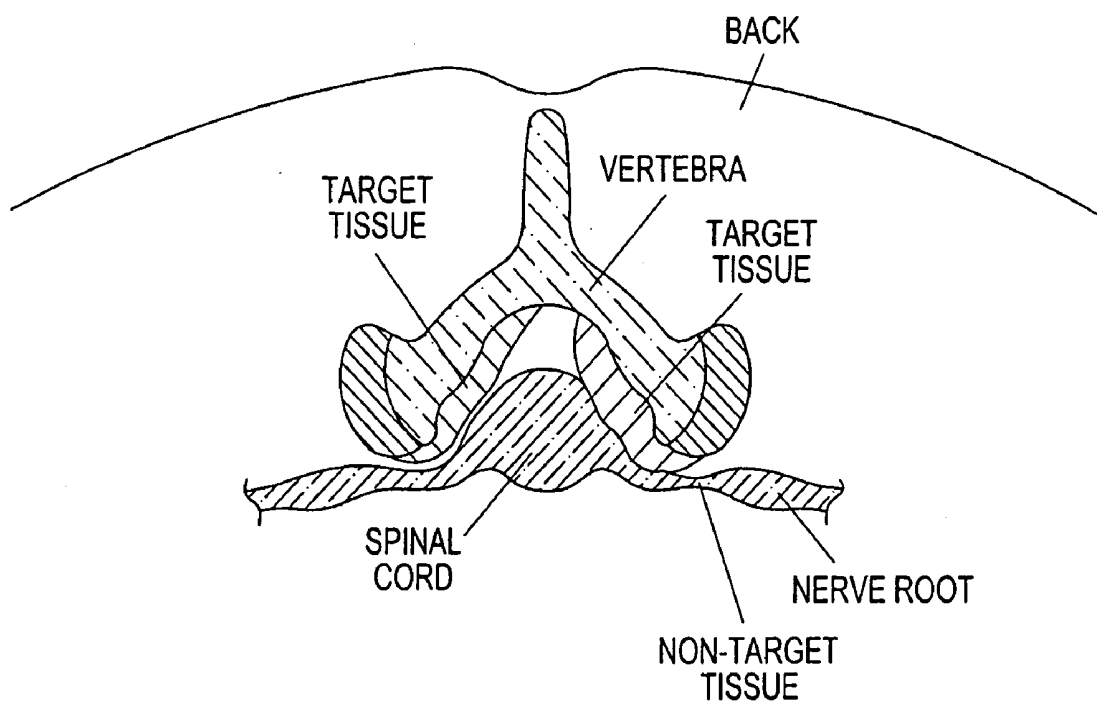


FIG. 5A

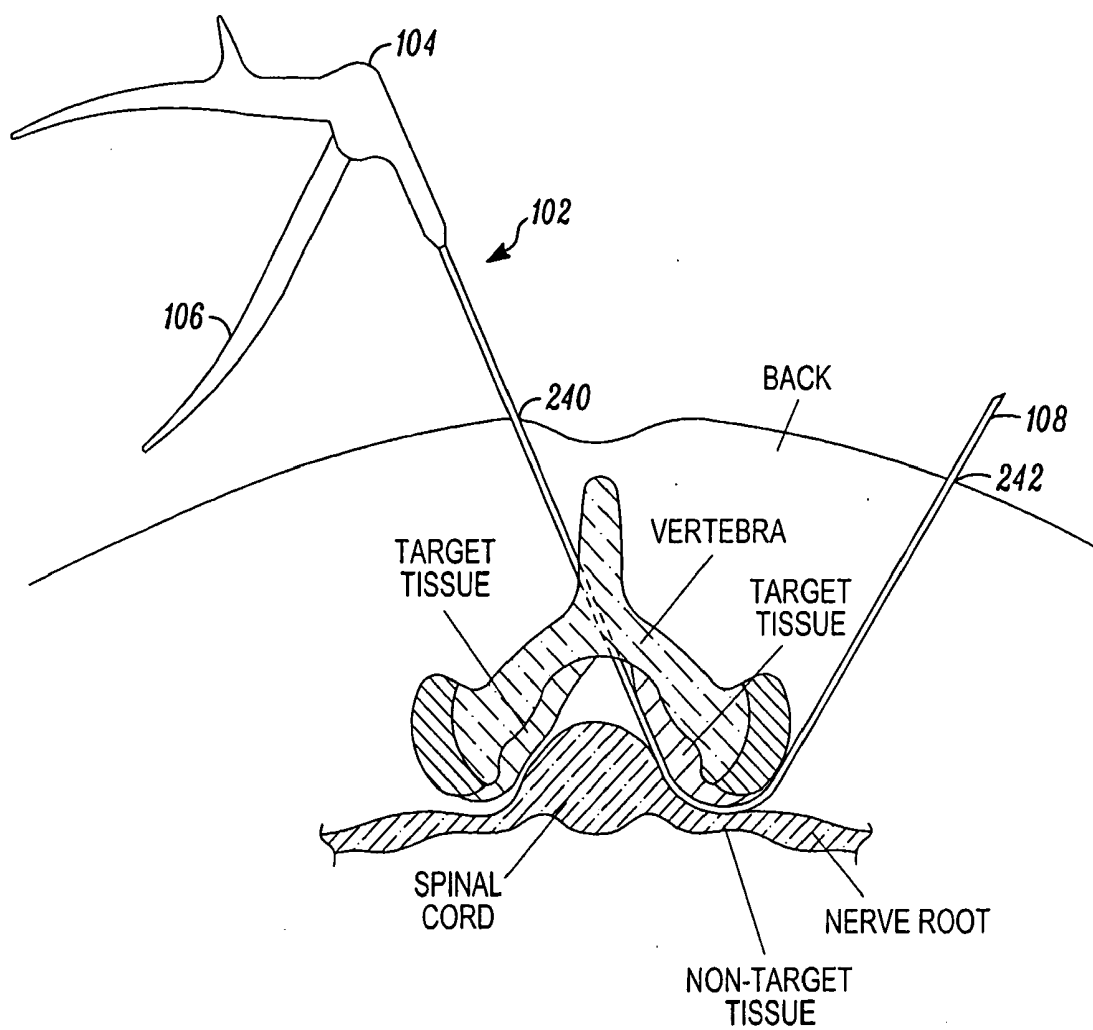


FIG. 5B

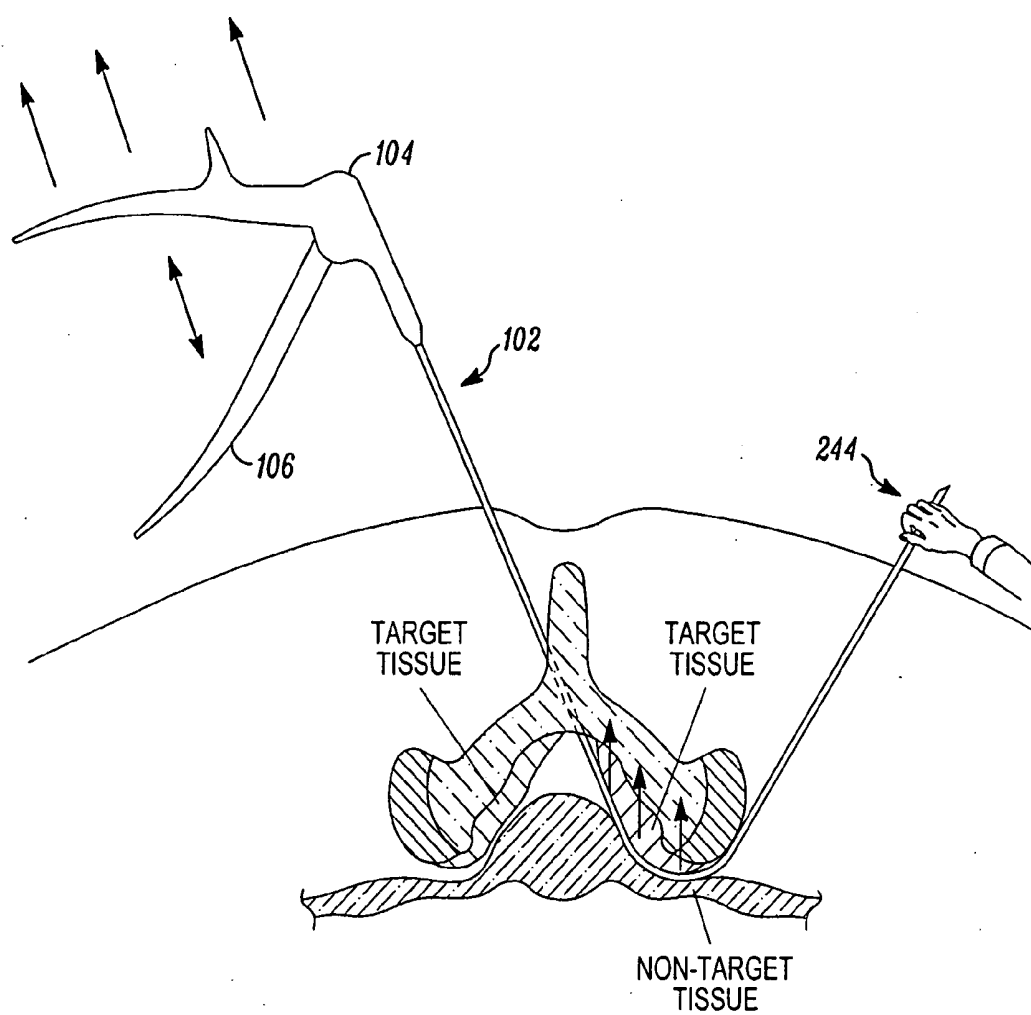


FIG. 5C

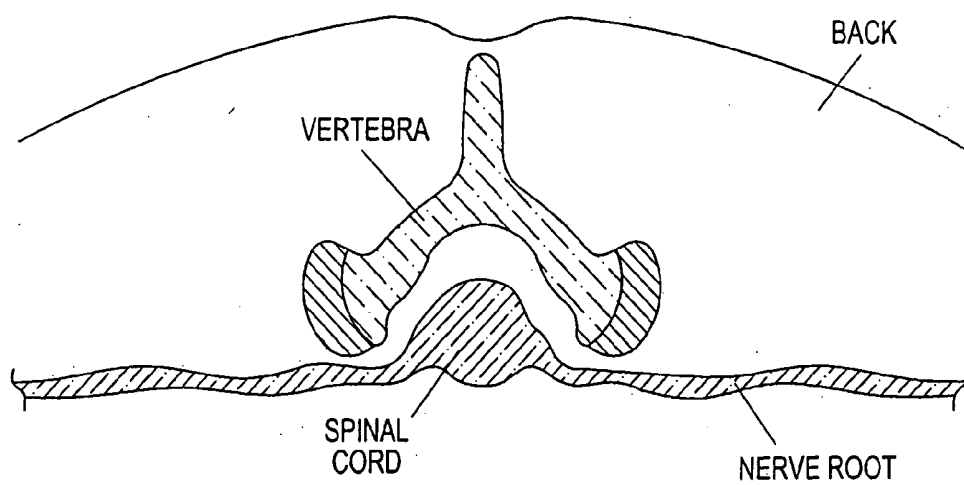


FIG. 5D

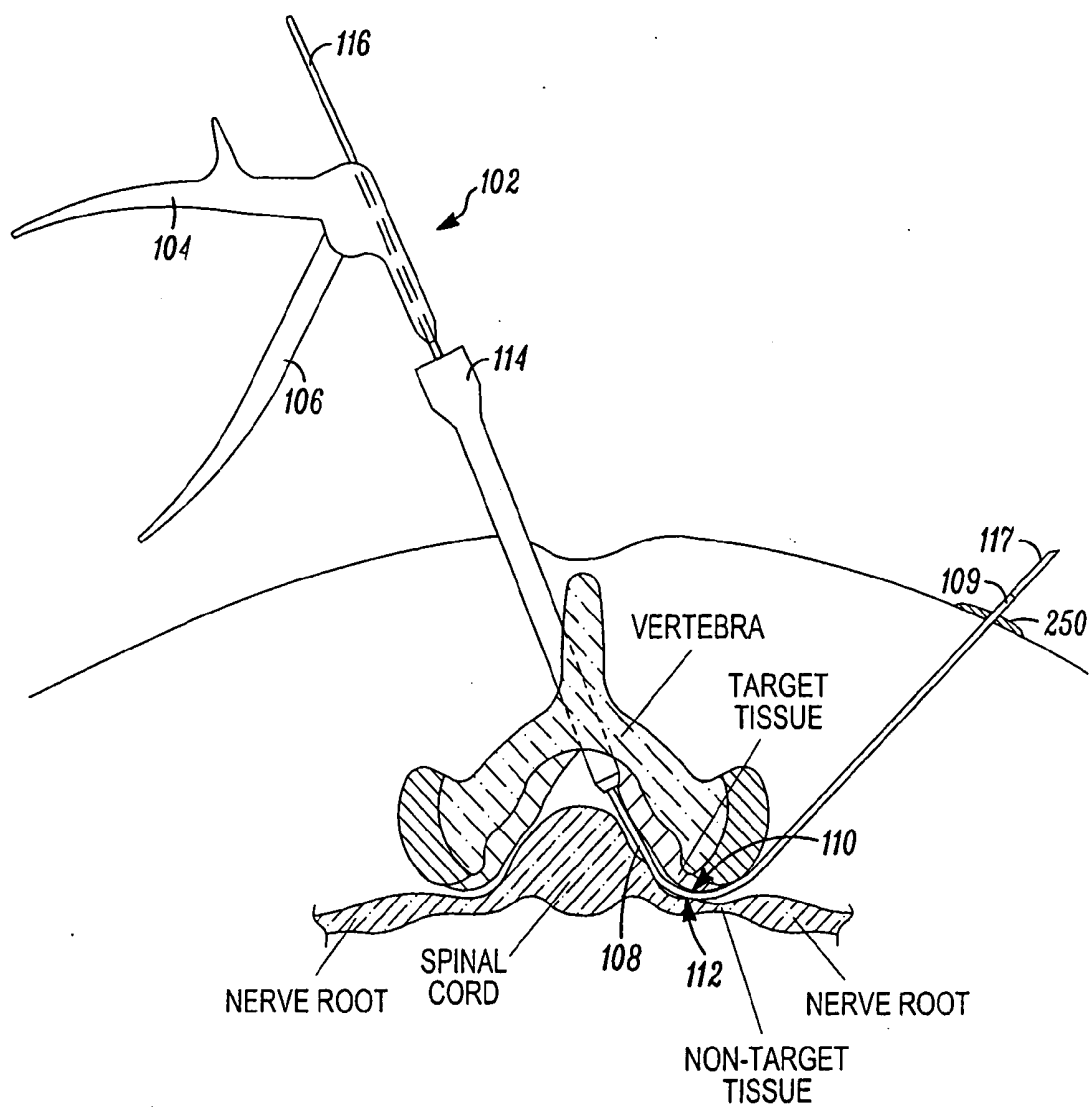


FIG. 6A

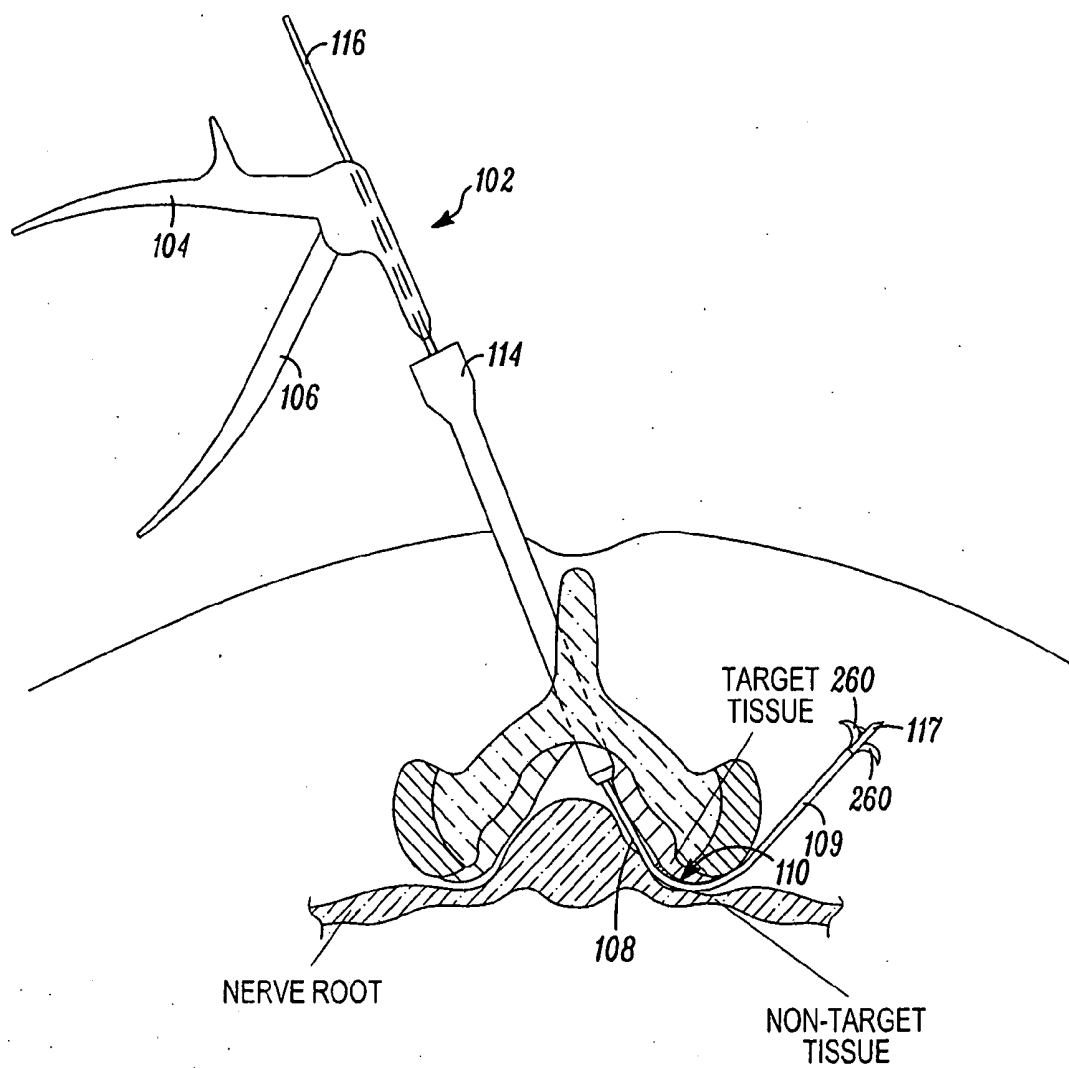


FIG. 6B

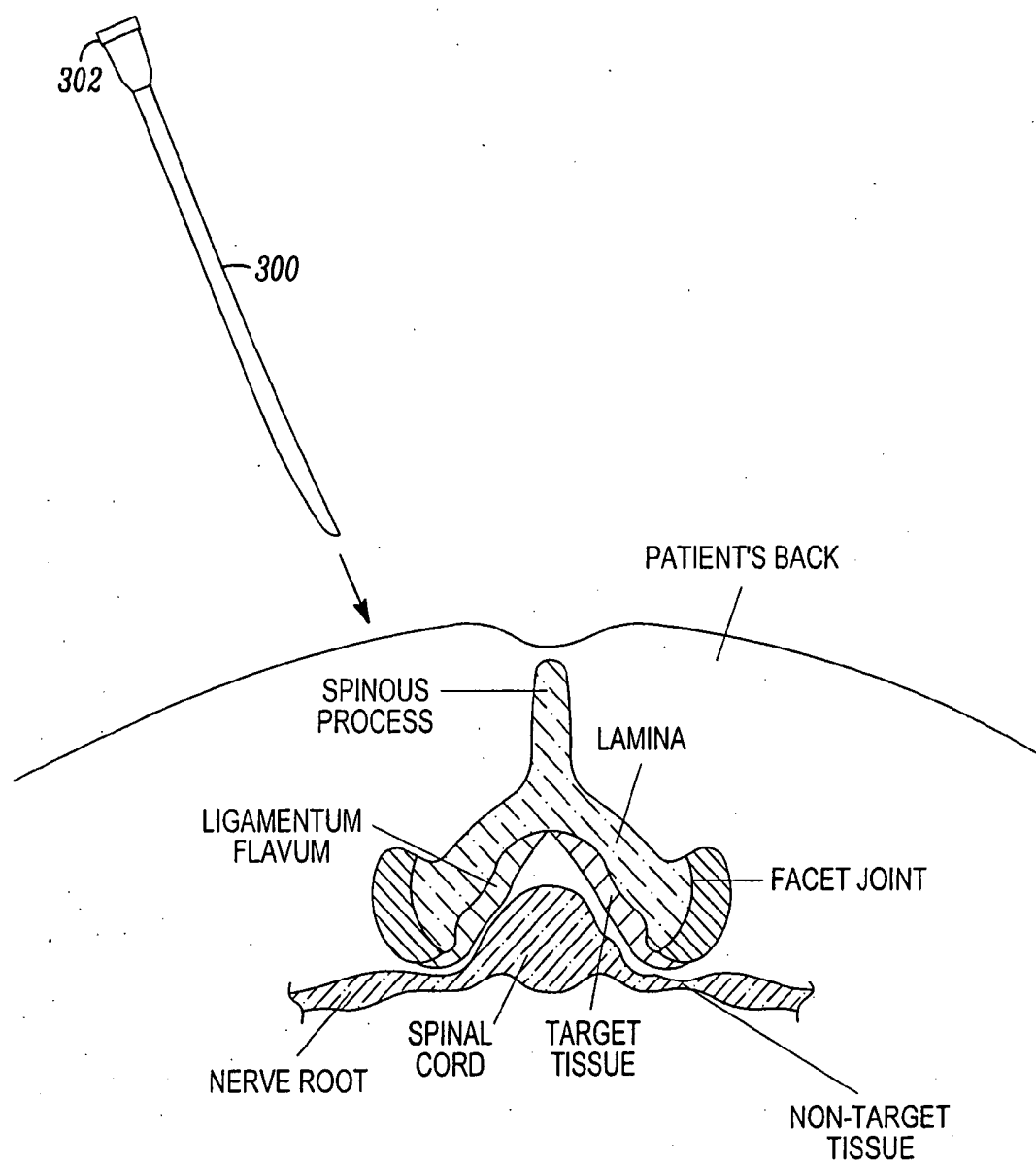


FIG. 7A

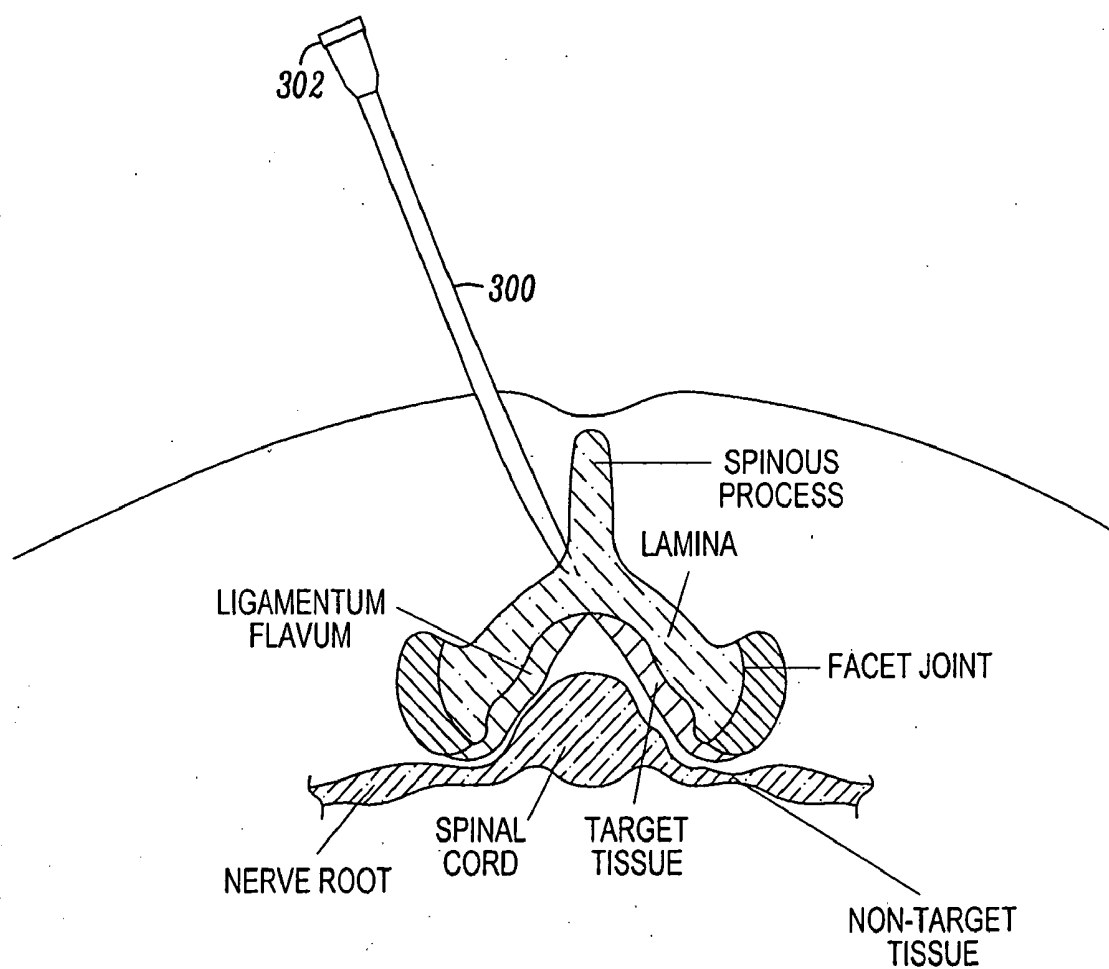


FIG. 7B

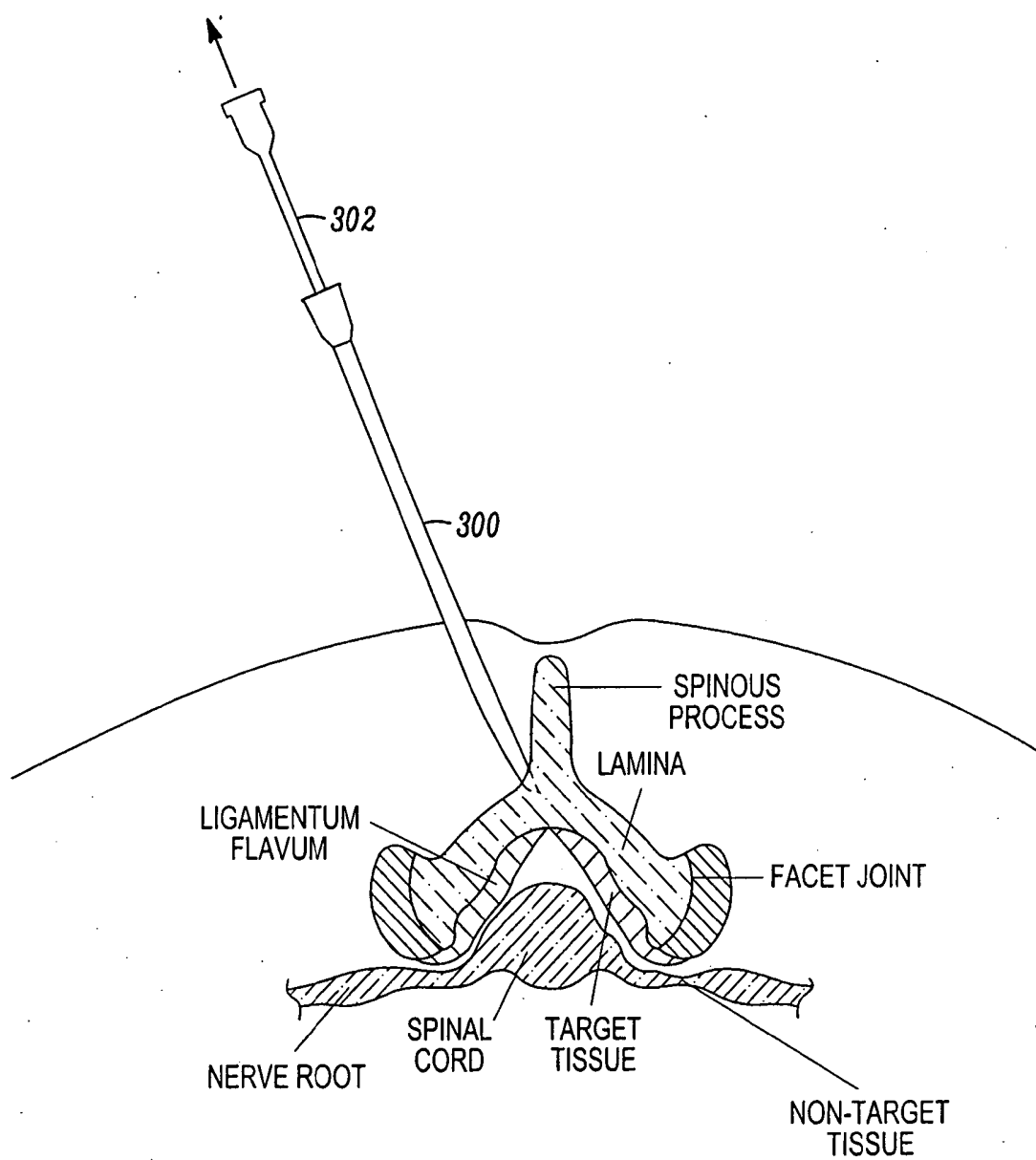


FIG. 7C

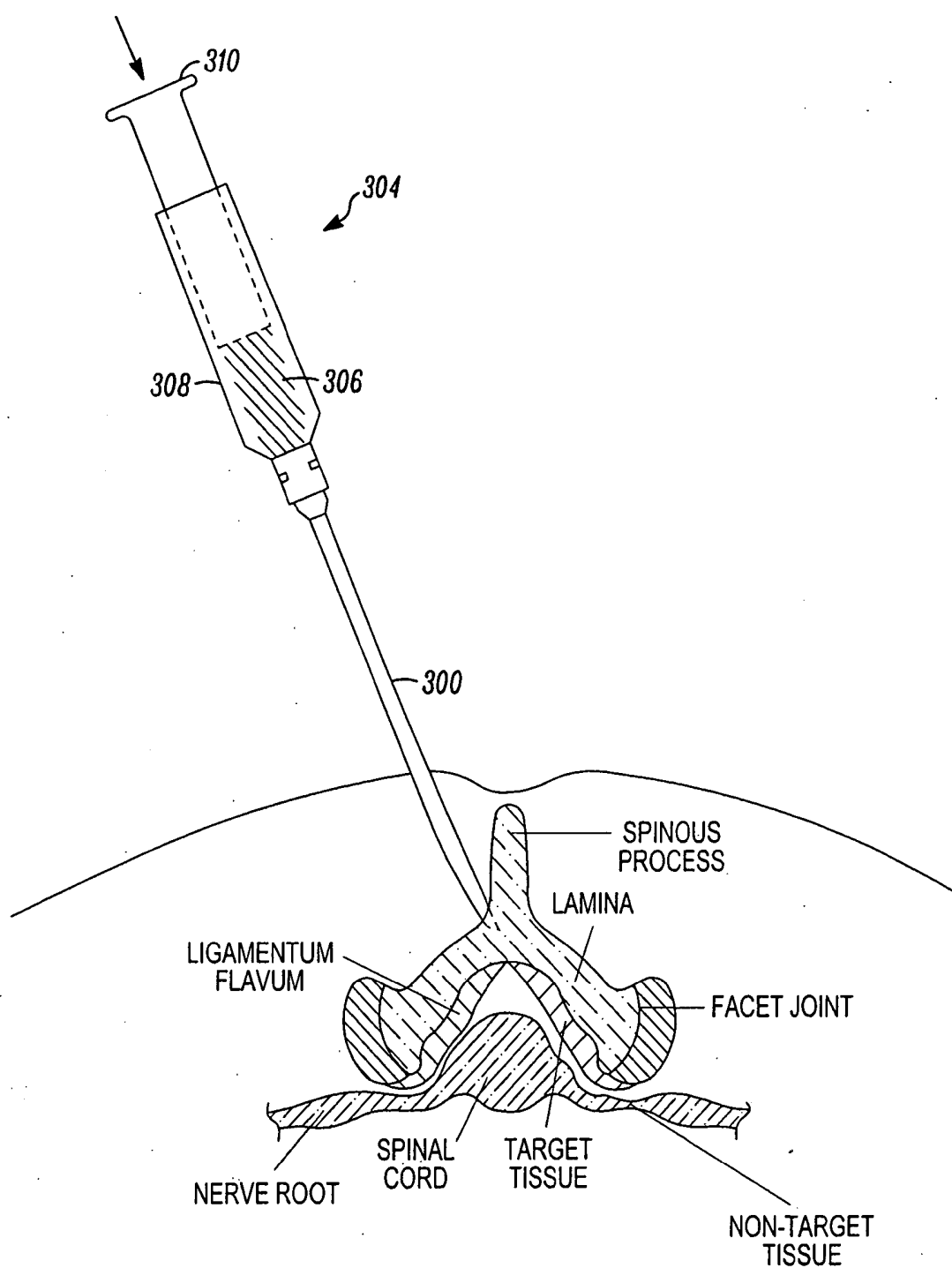


FIG. 7D

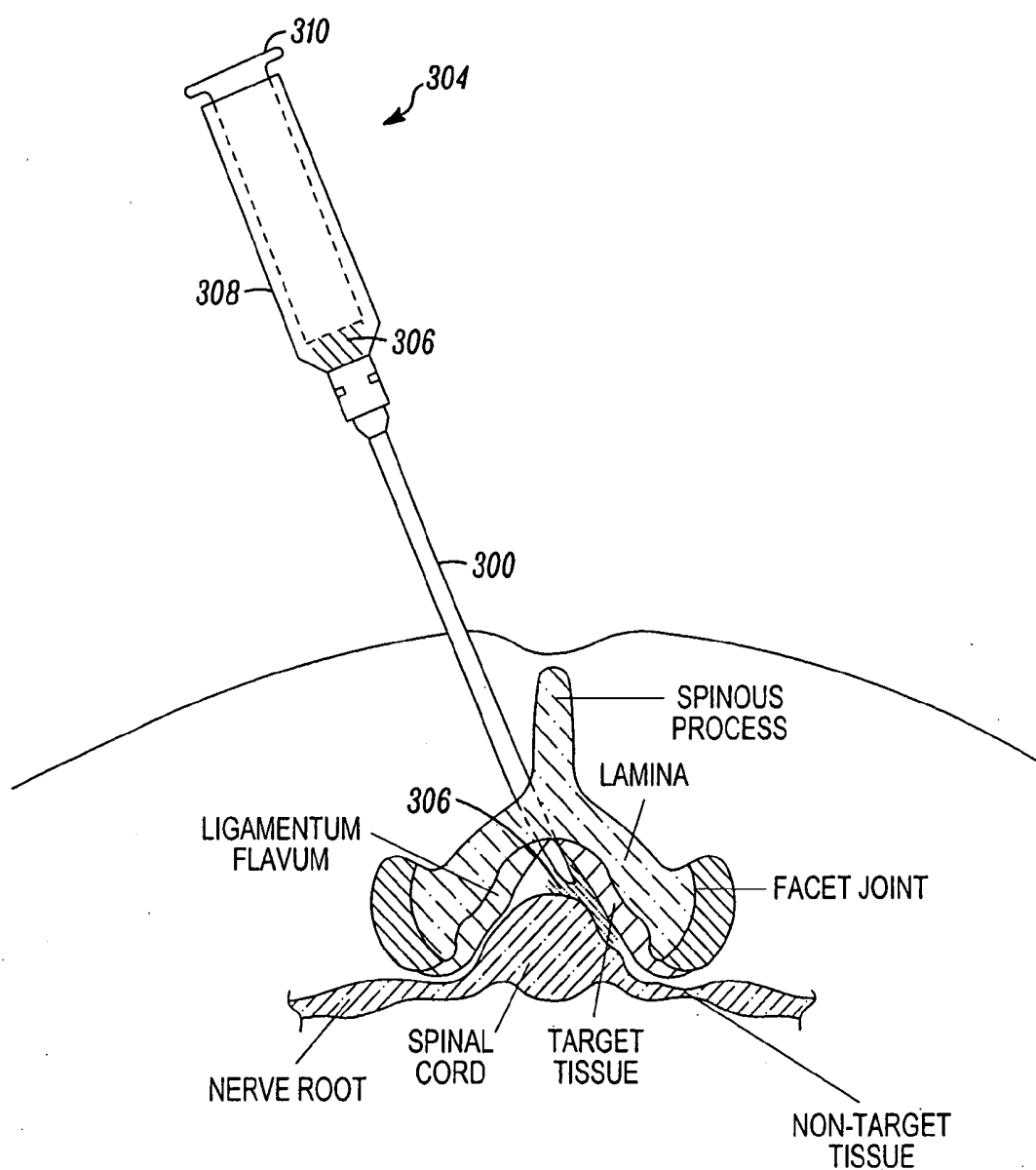


FIG. 7E

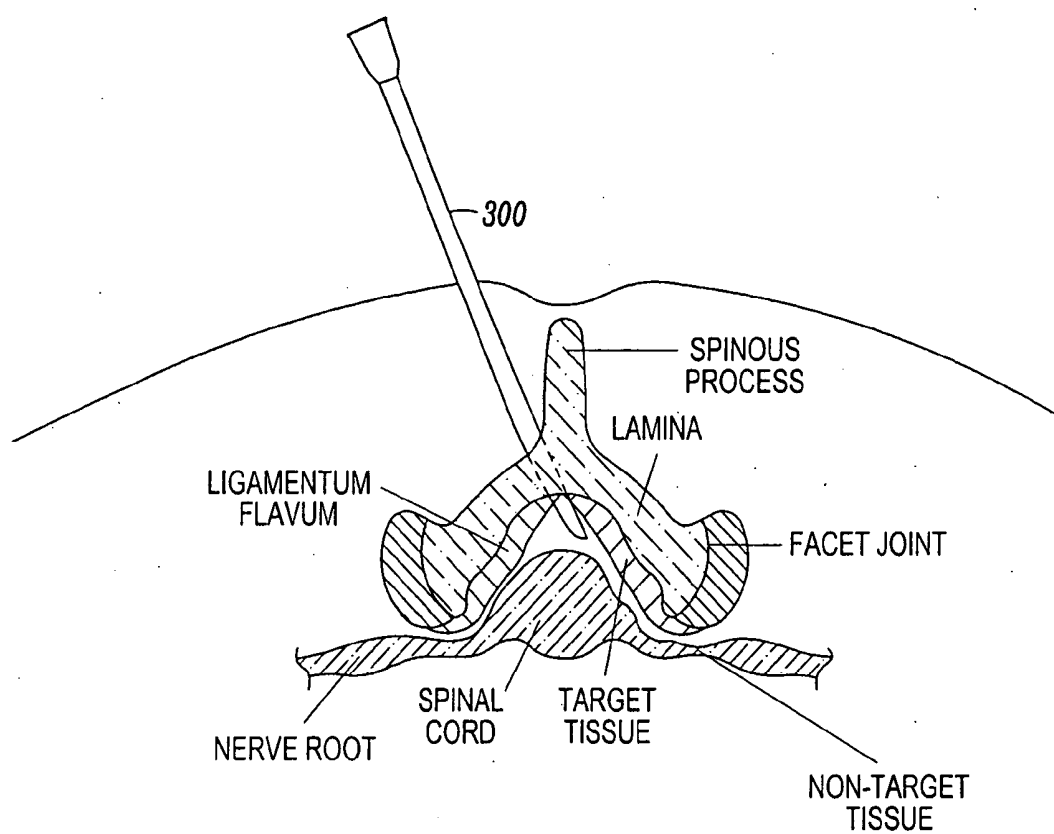


FIG. 7F

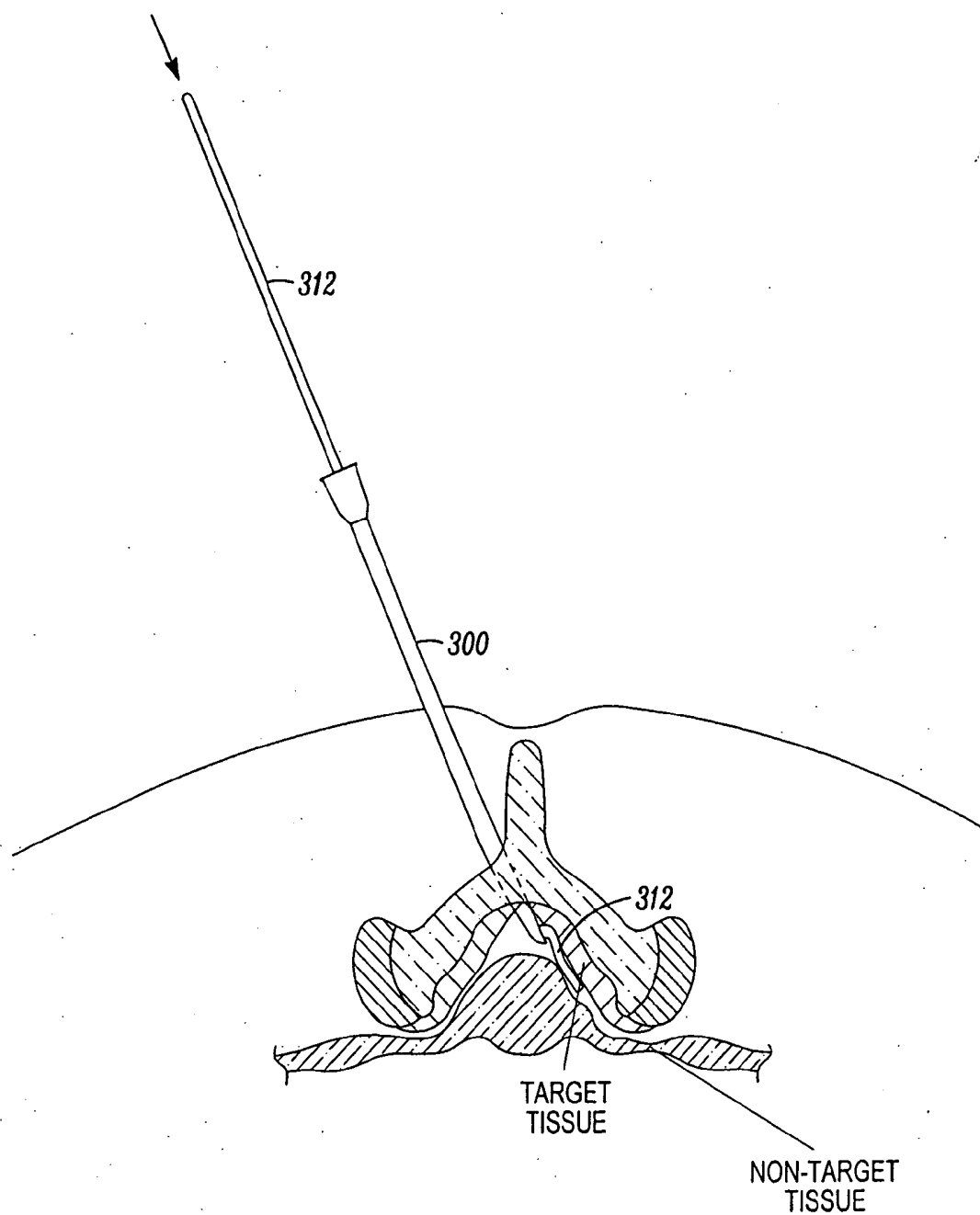


FIG. 7G

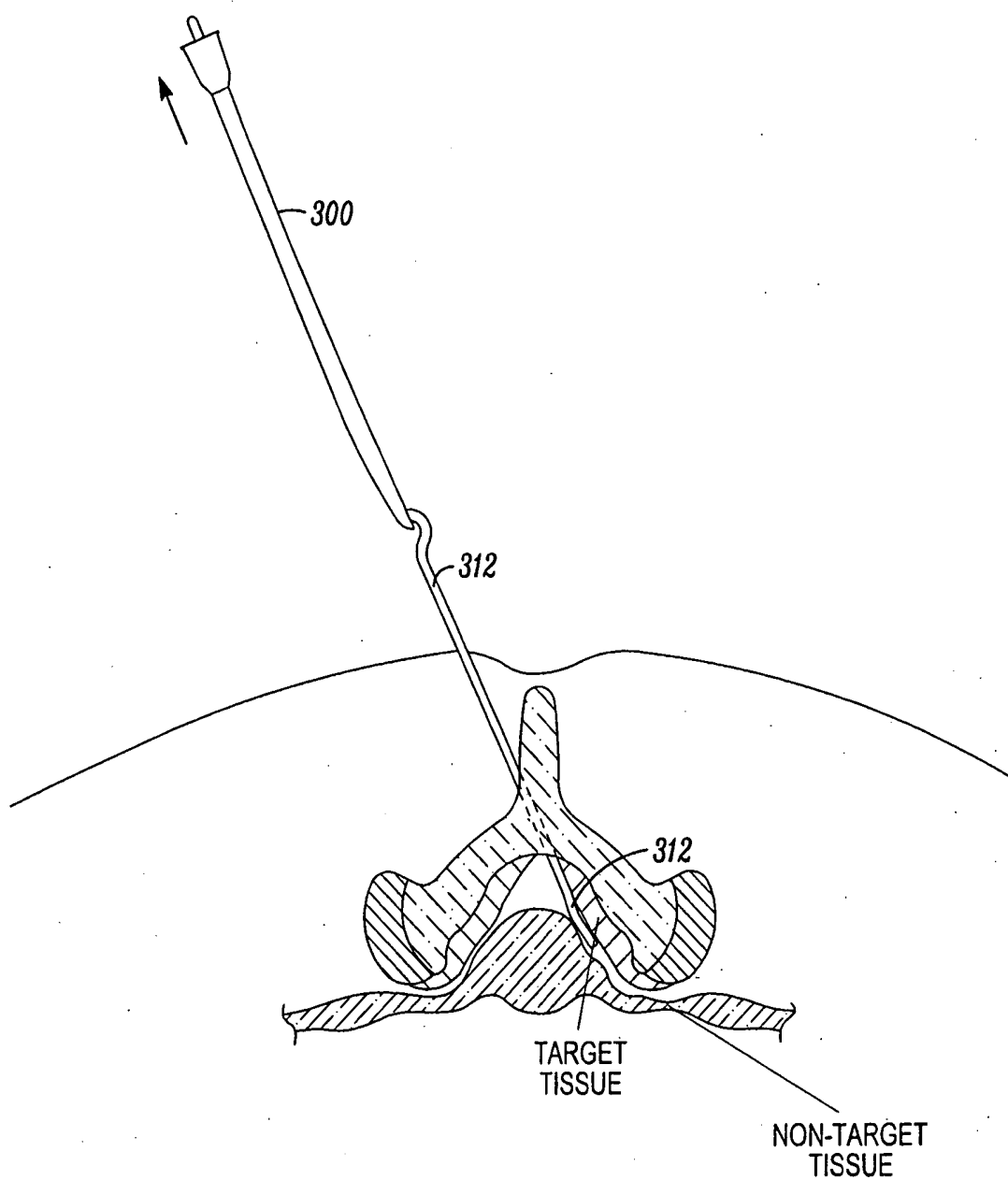


FIG. 7H

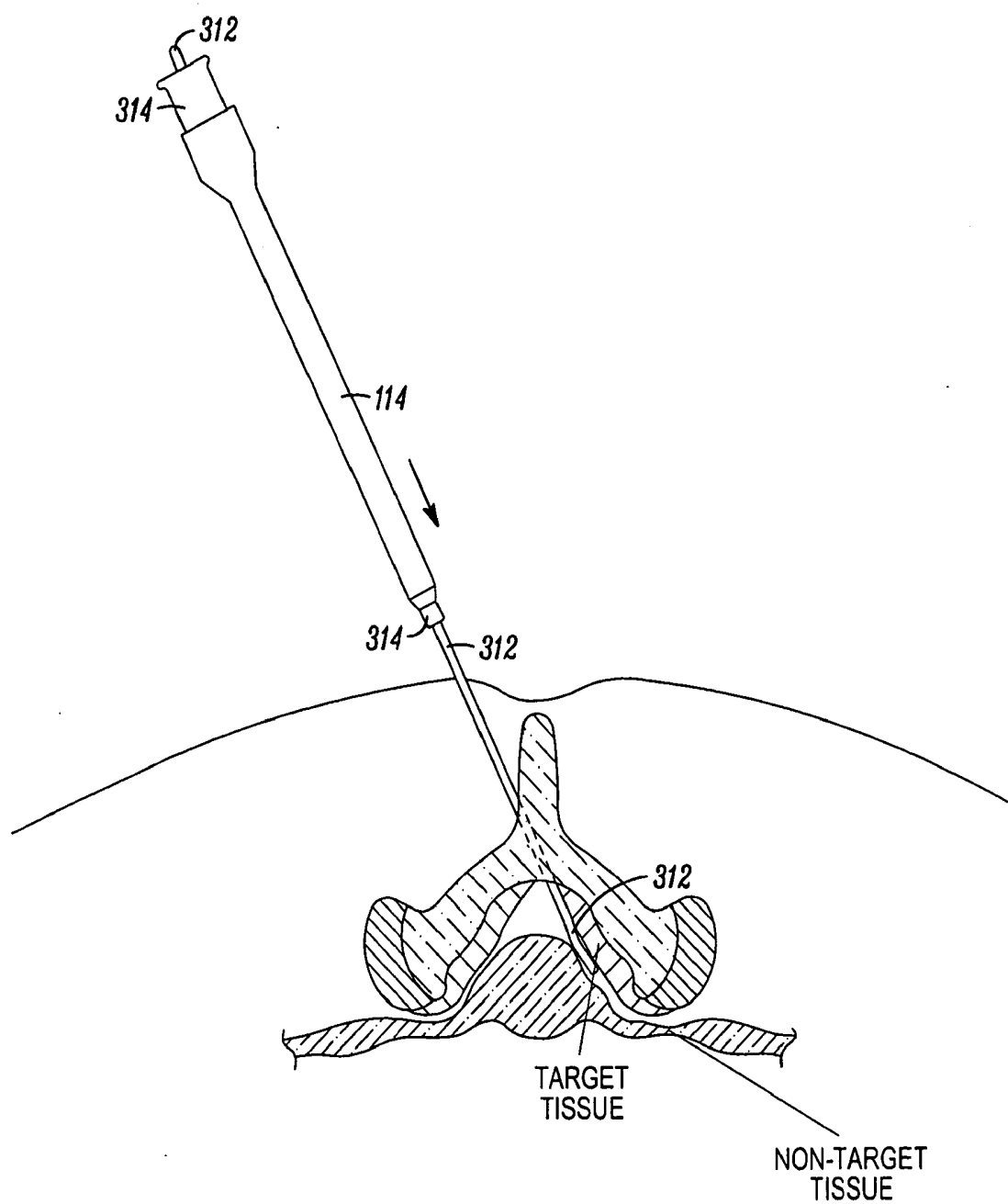


FIG. 7I

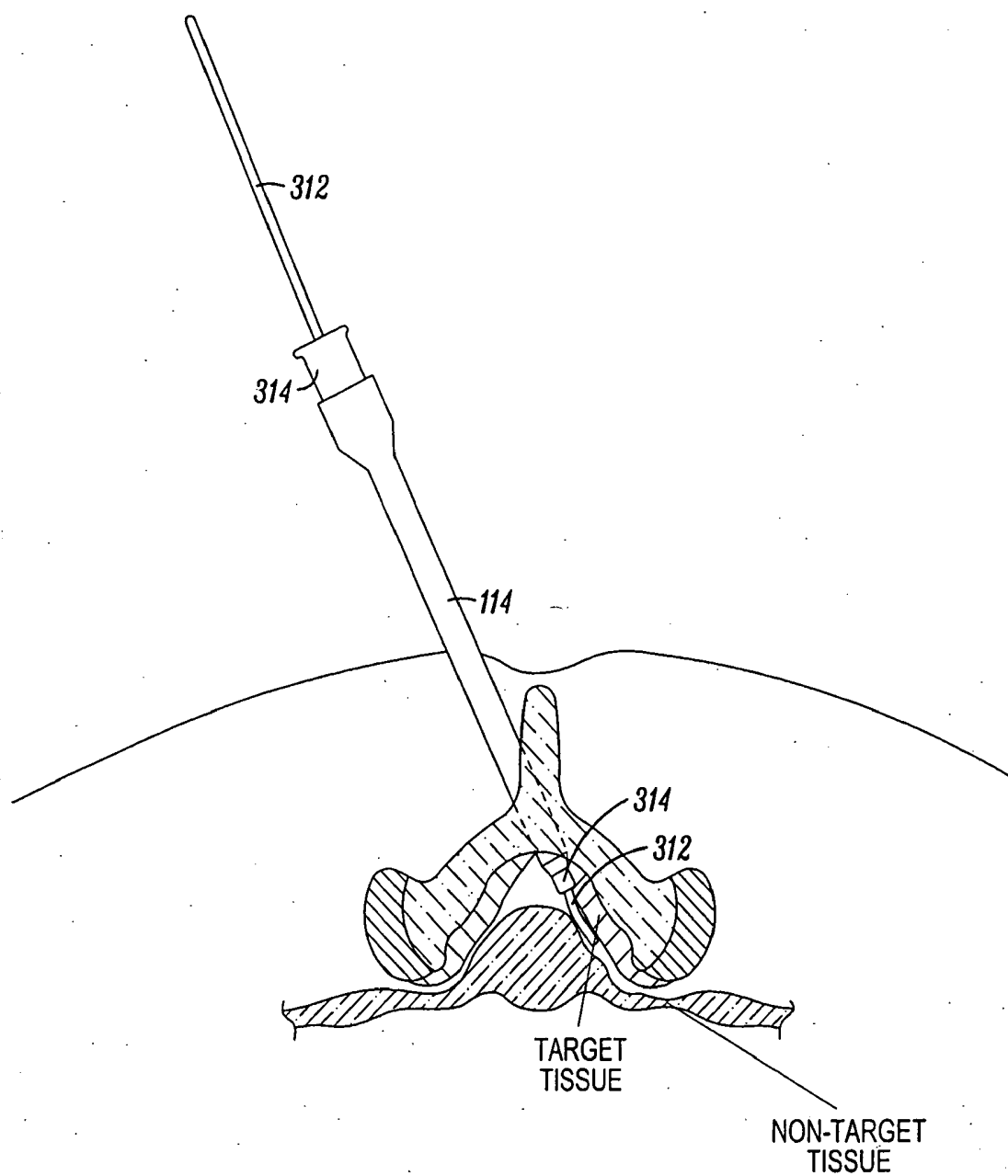


FIG. 7J

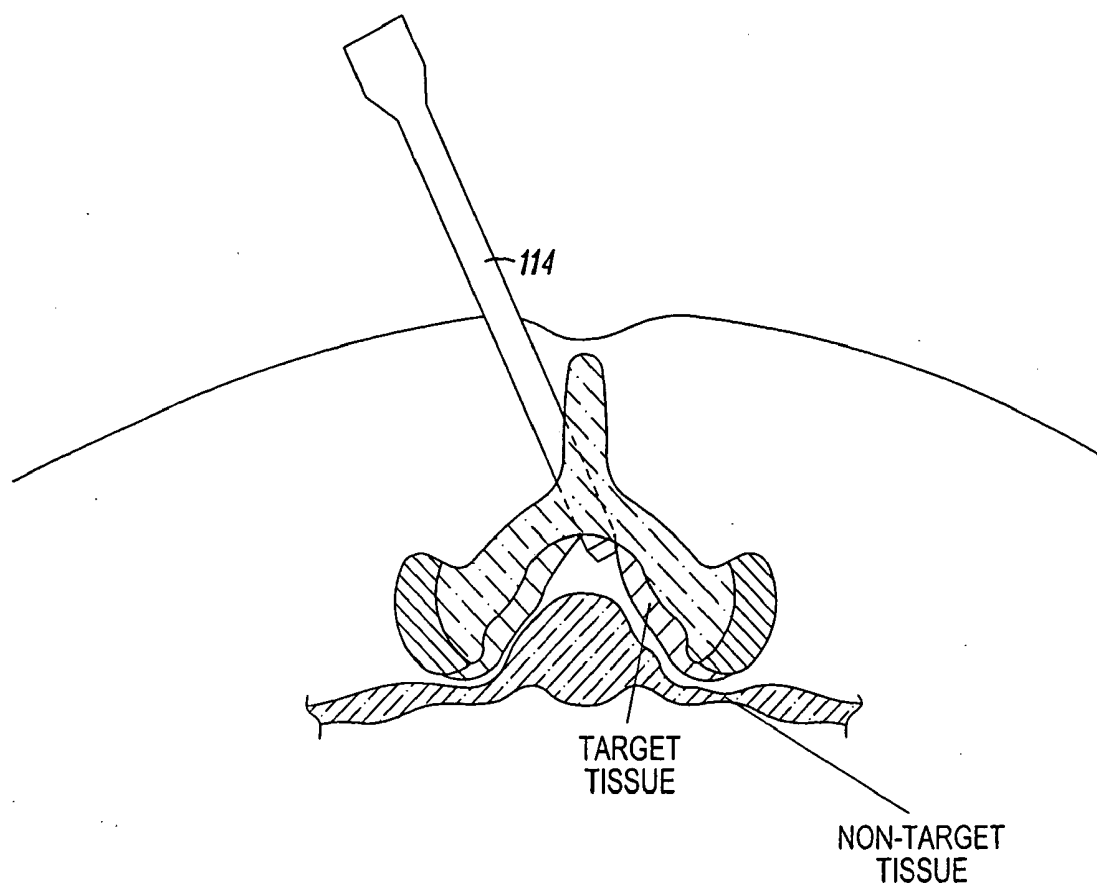


FIG. 7K

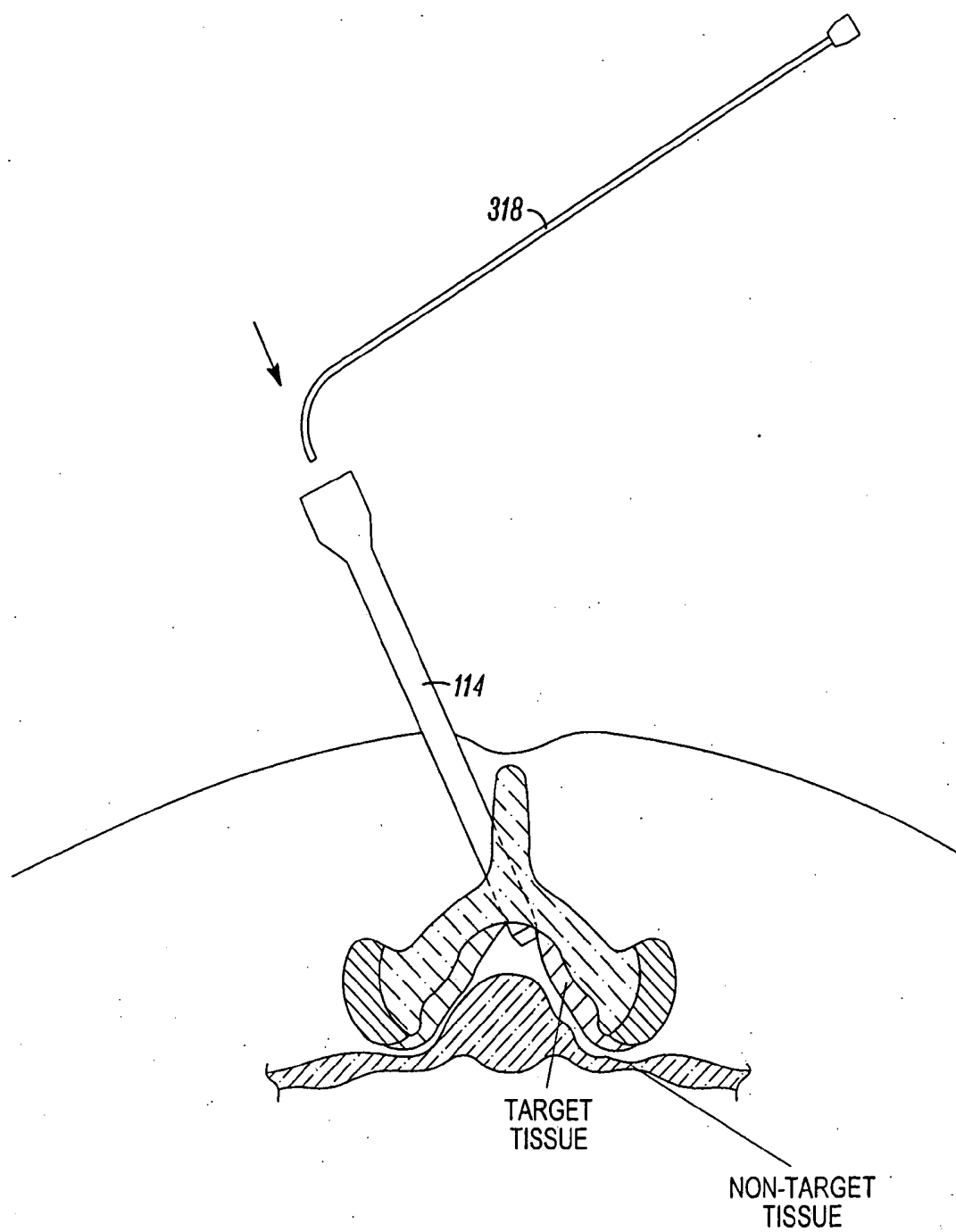


FIG. 7L

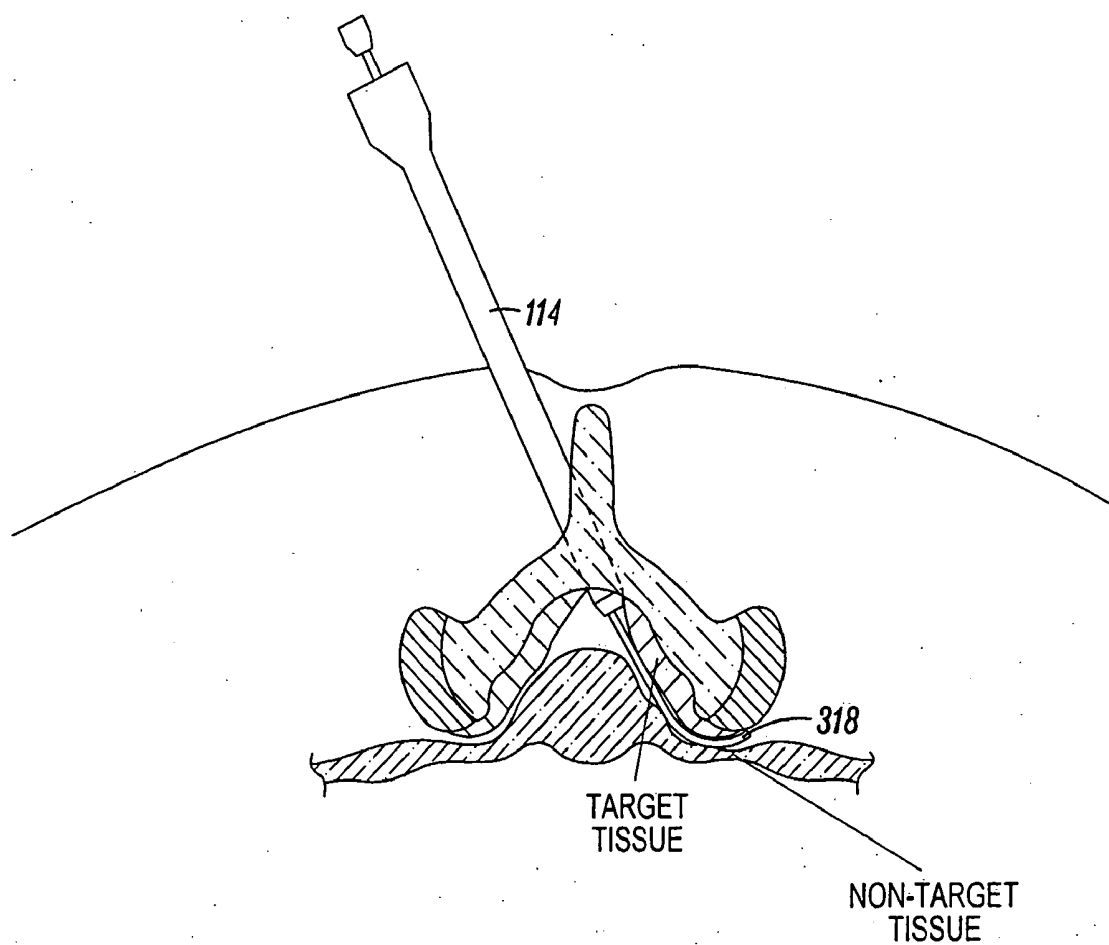


FIG. 7M

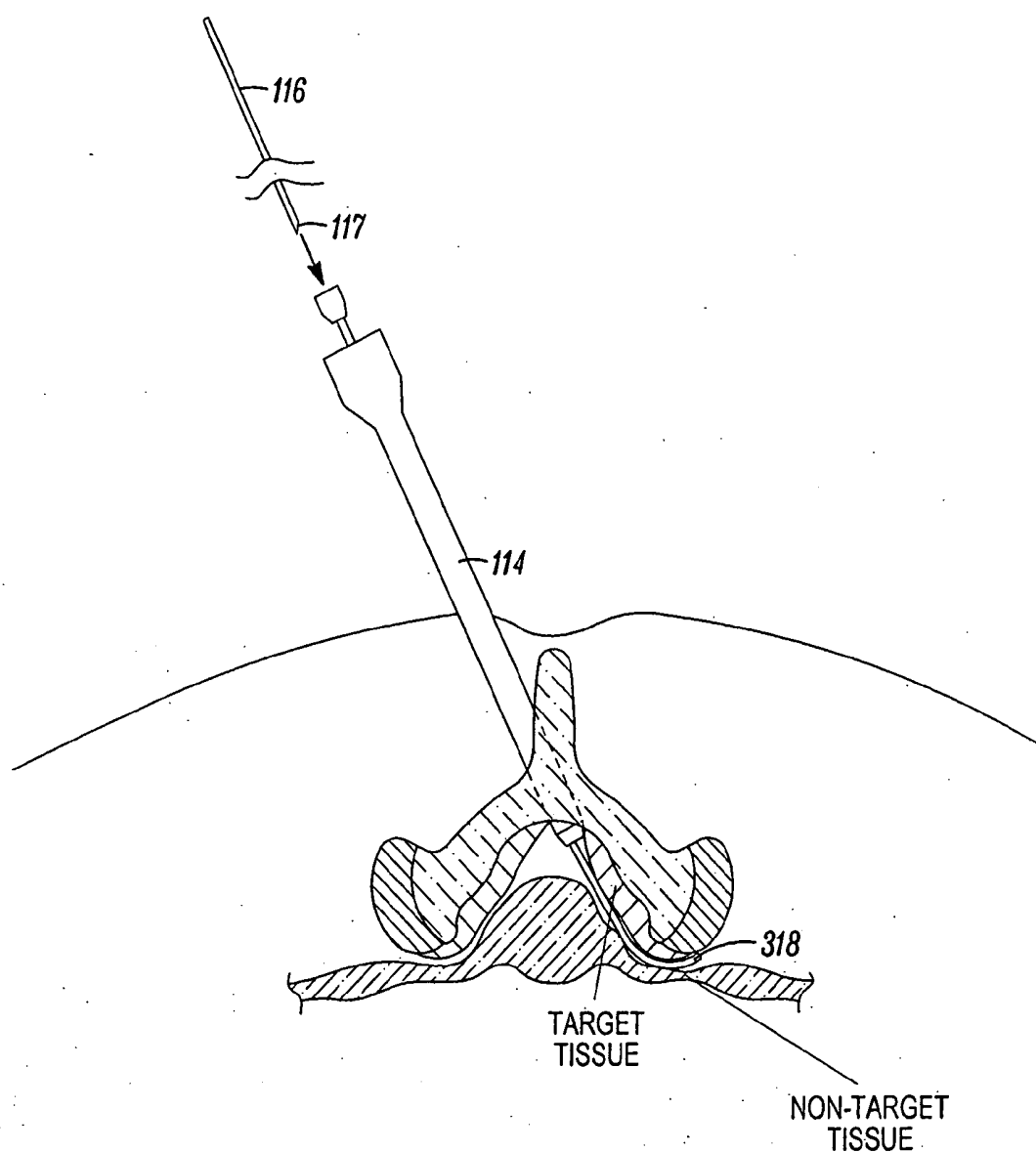


FIG. 7N

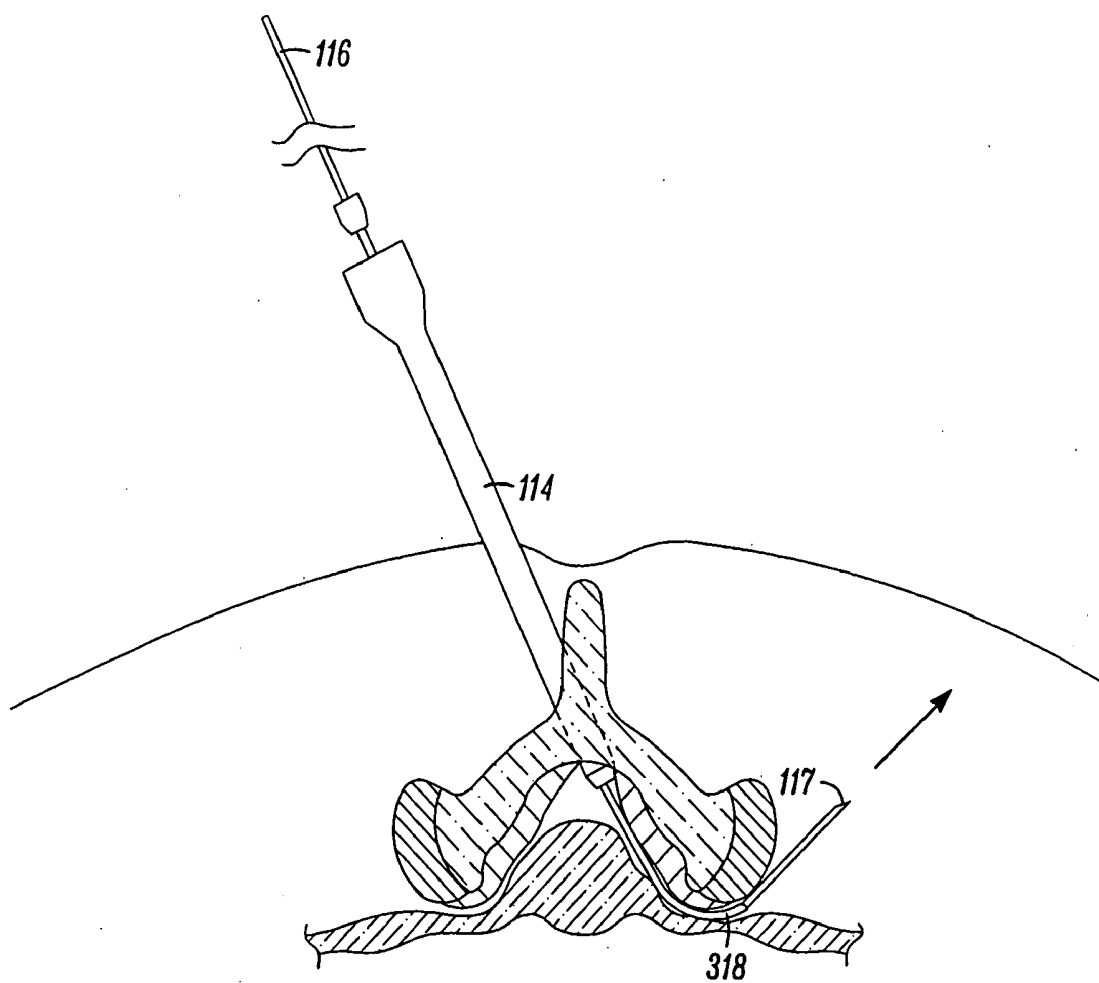


FIG. 70

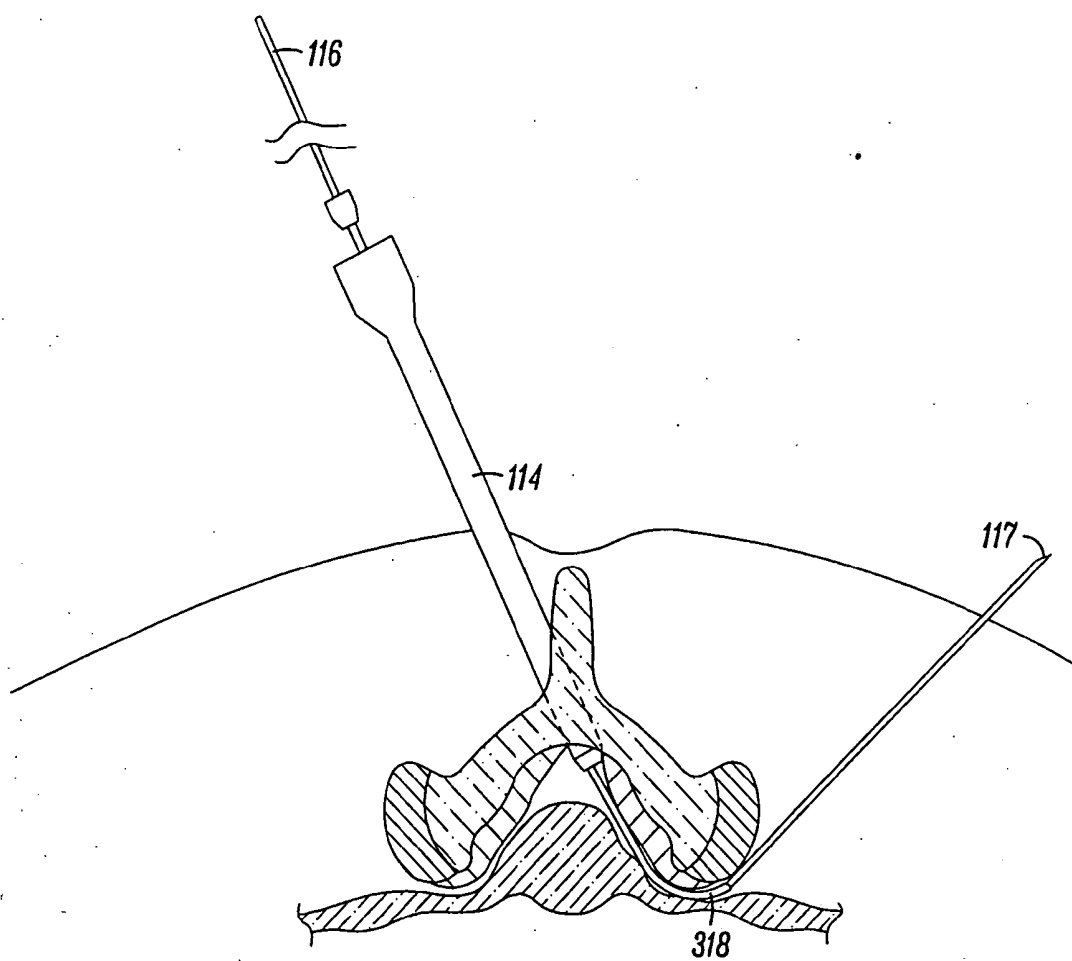


FIG. 7P

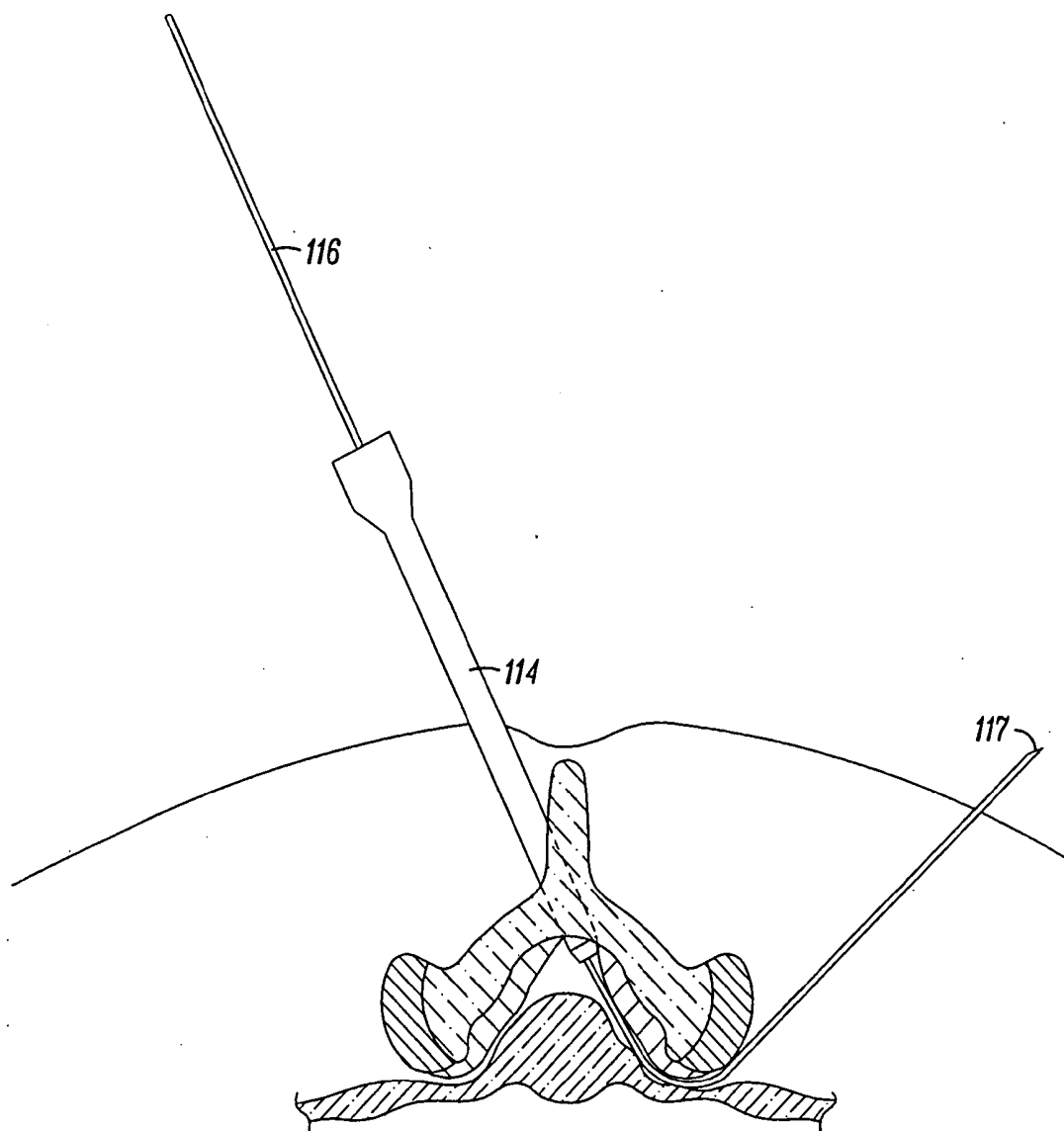


FIG. 7Q

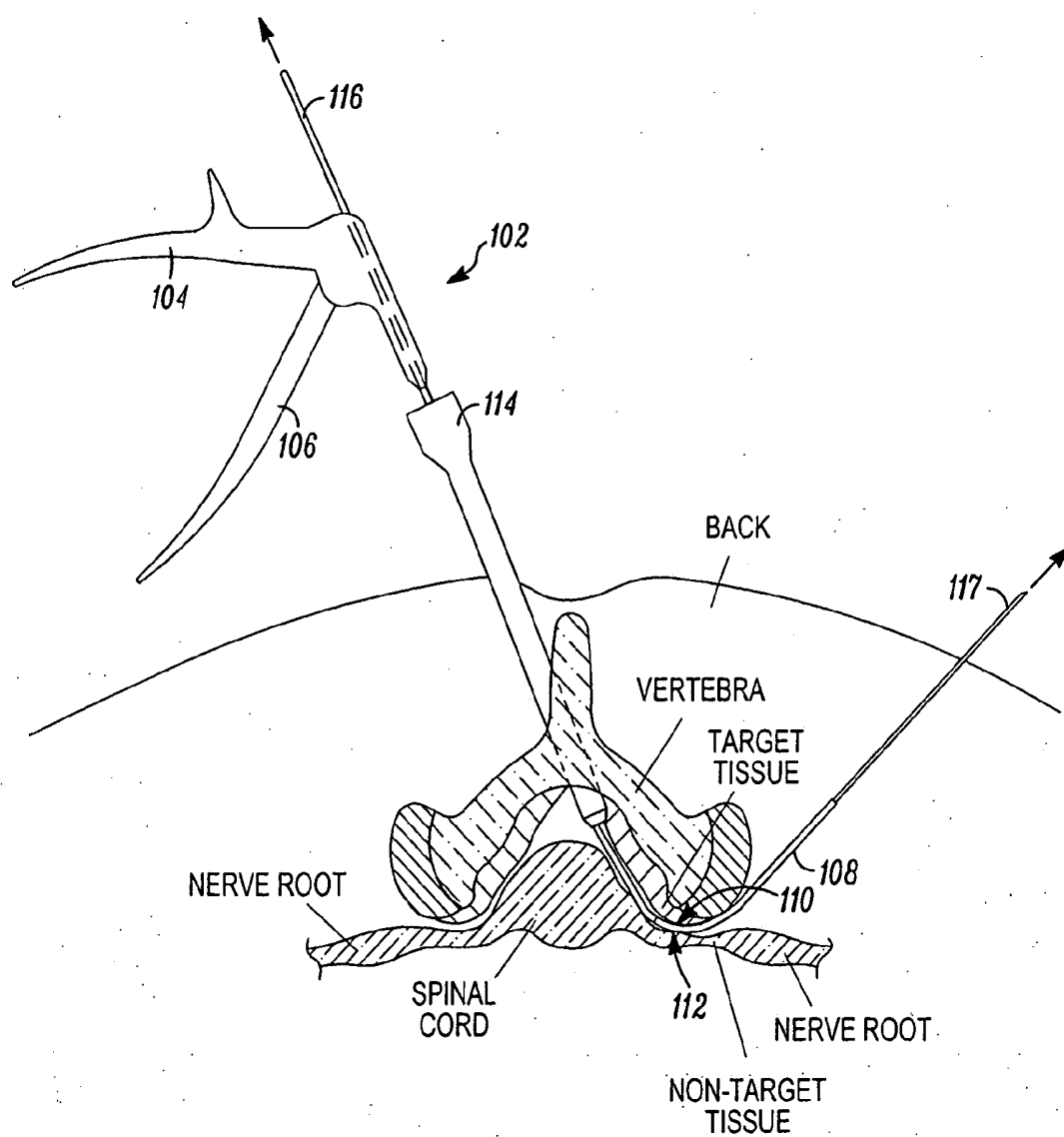


FIG. 7R

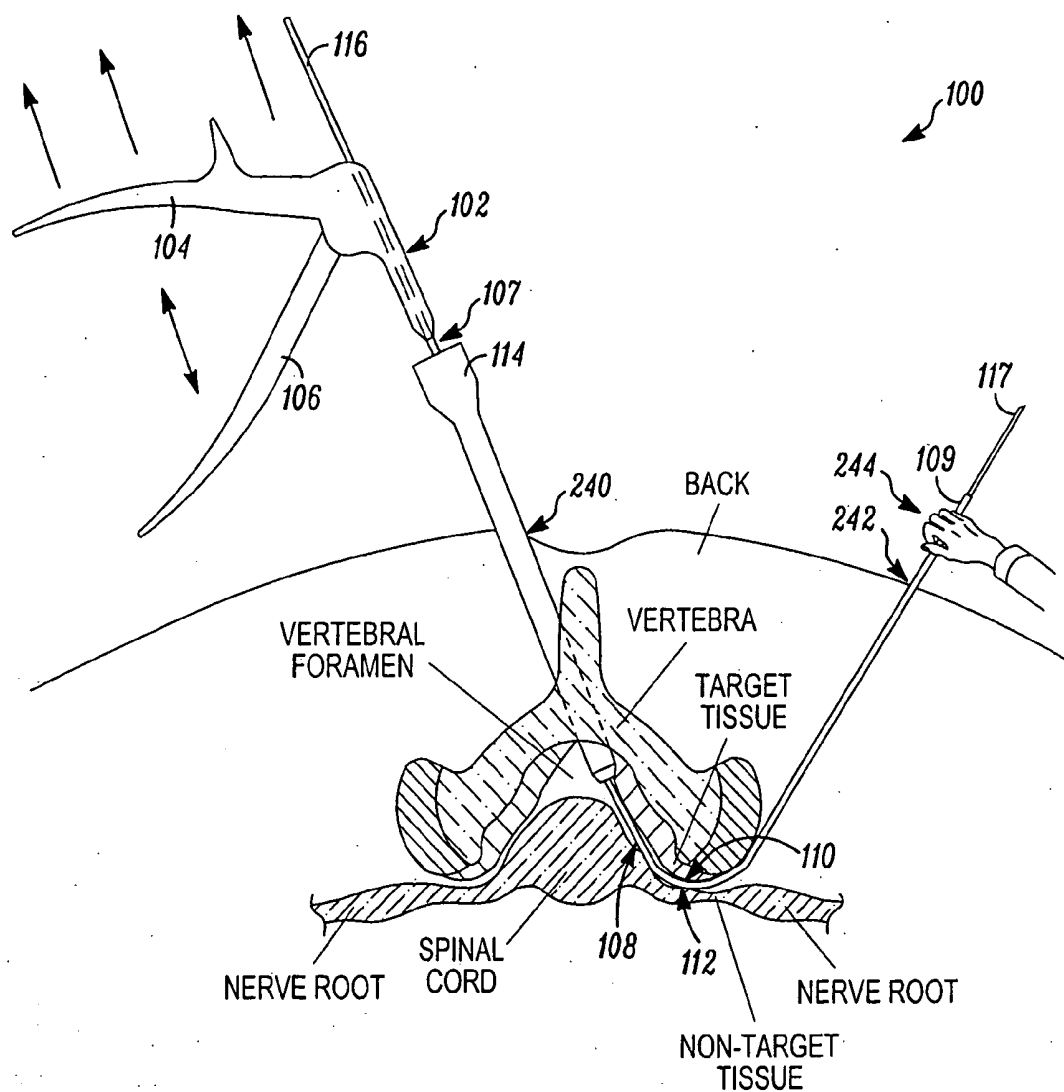


FIG. 7S

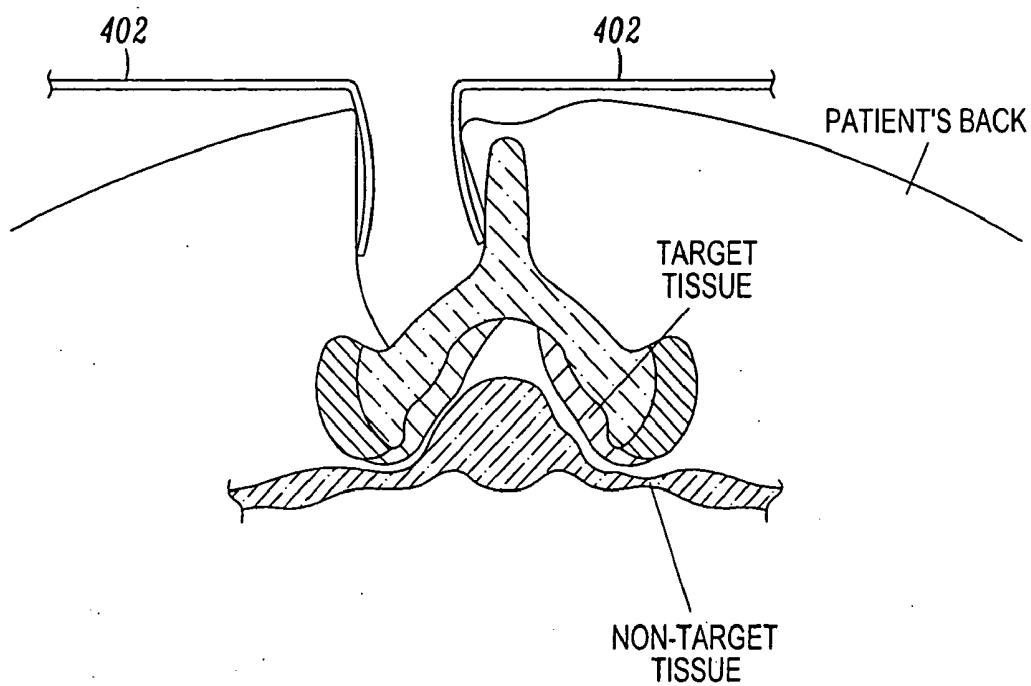


FIG. 8A

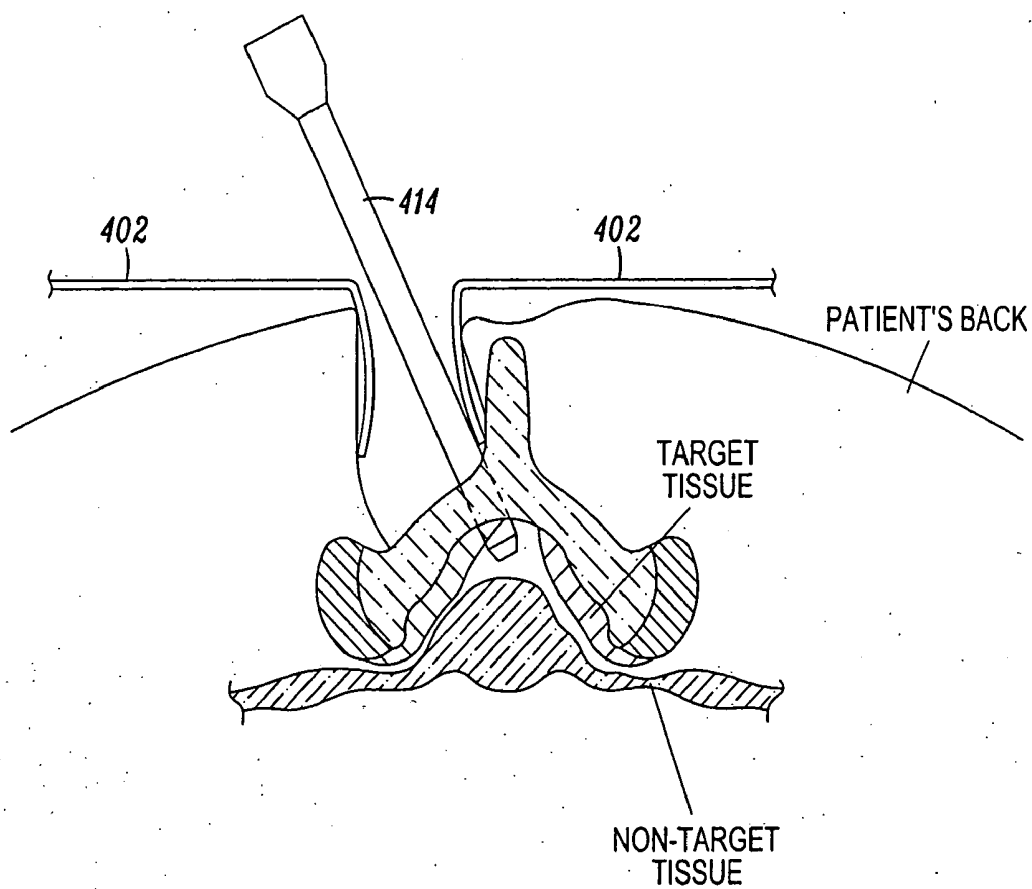


FIG. 8B

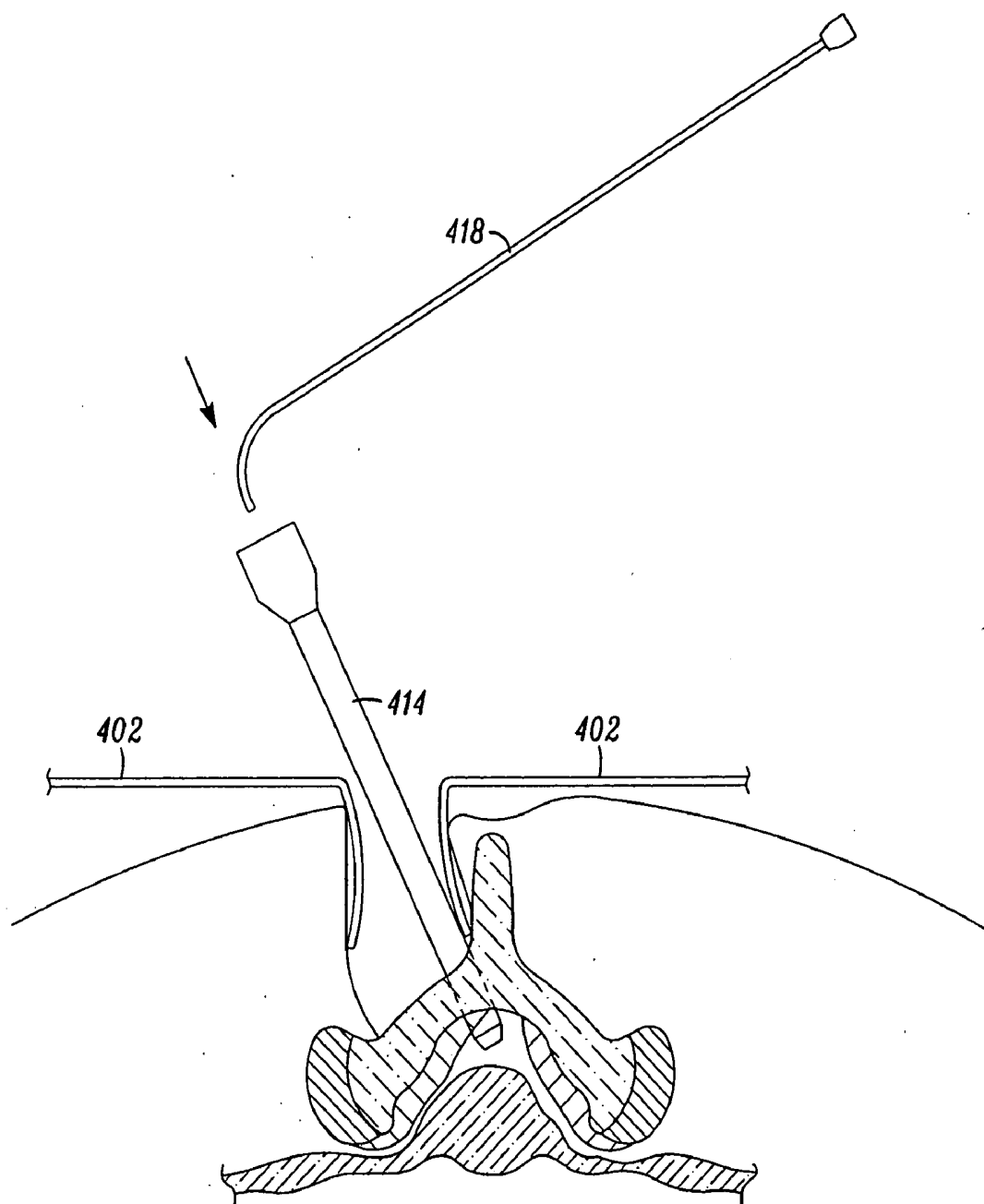


FIG. 8C

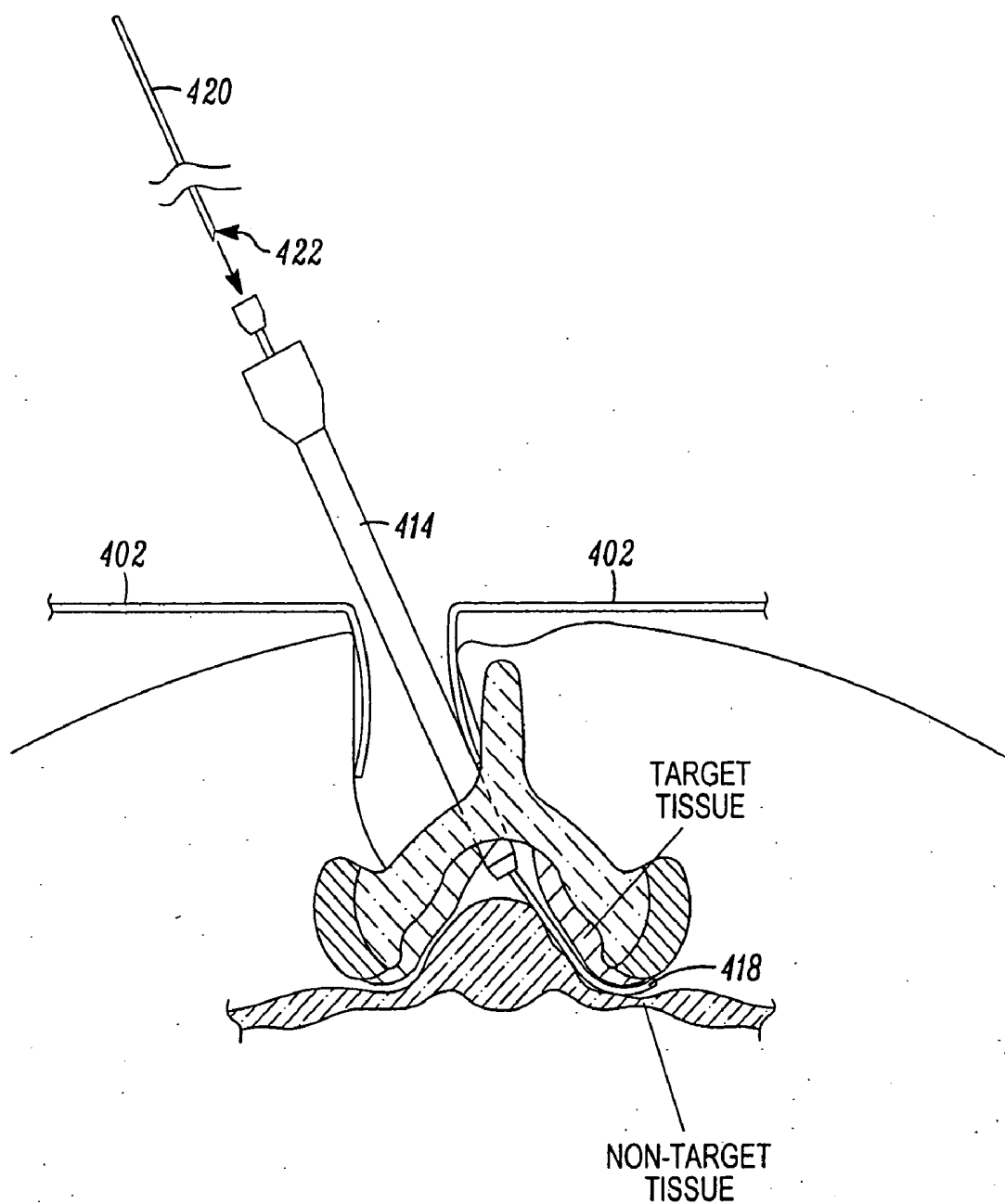


FIG. 8D

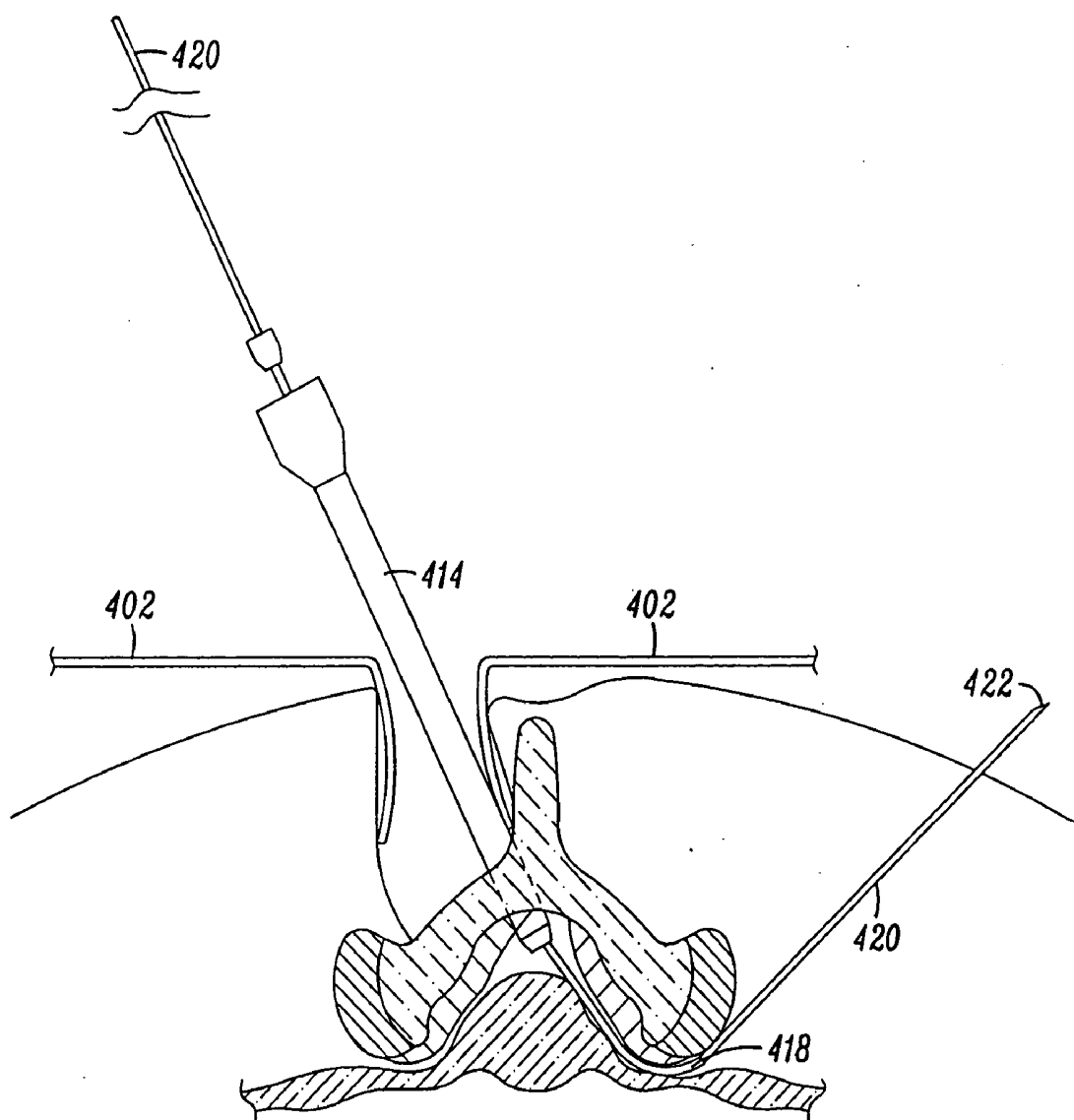


FIG. 8E

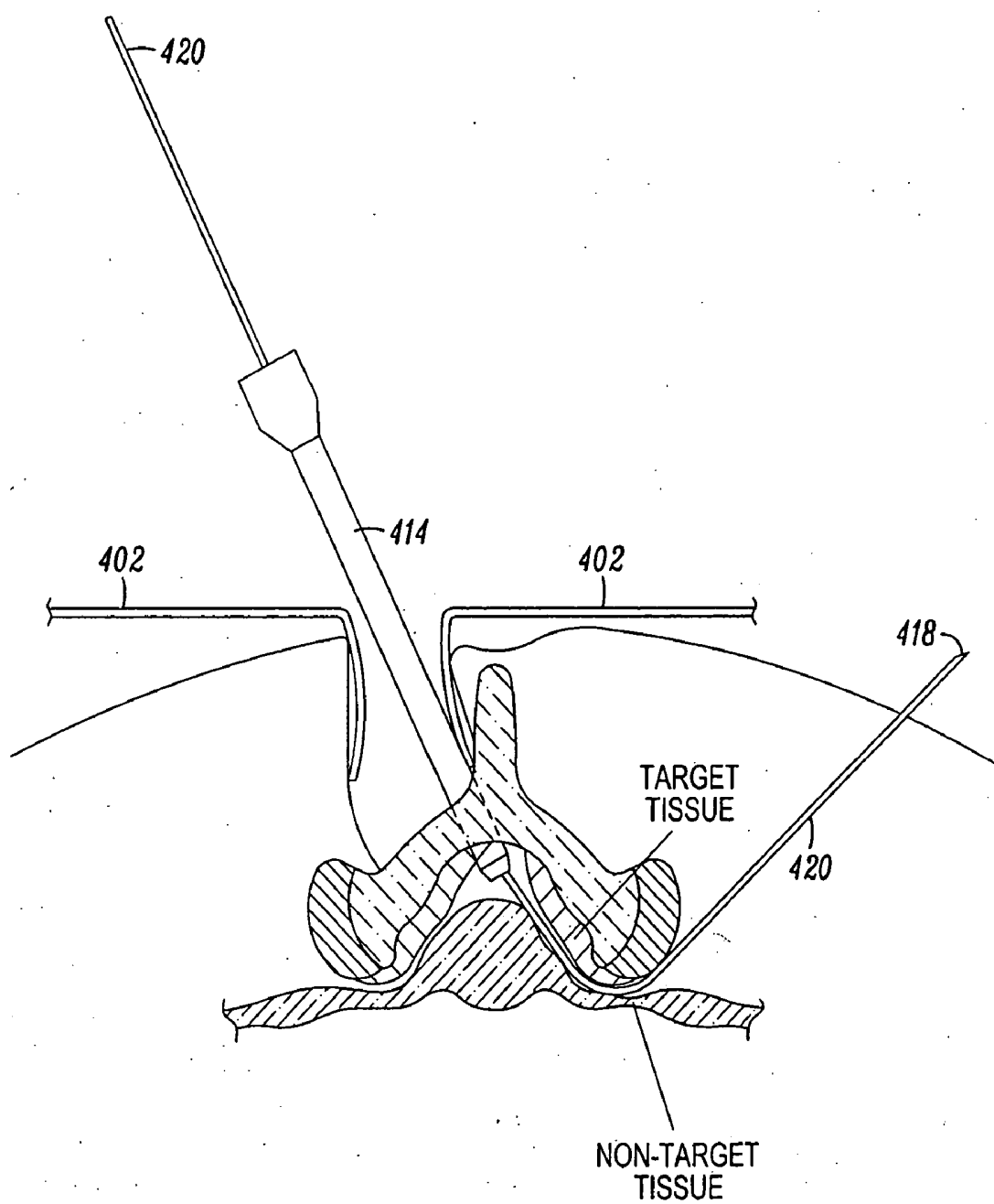


FIG. 8F

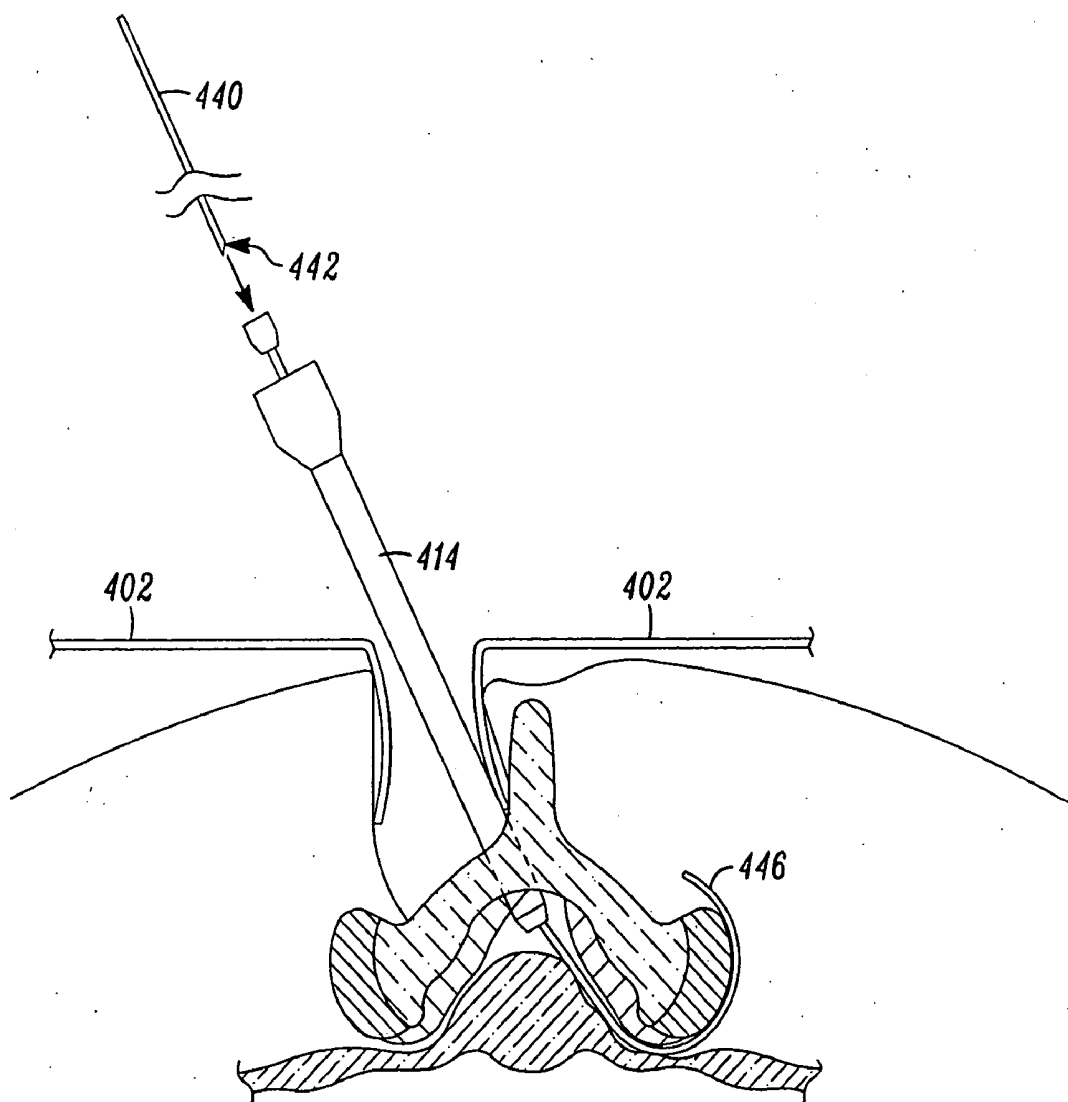


FIG. 9A

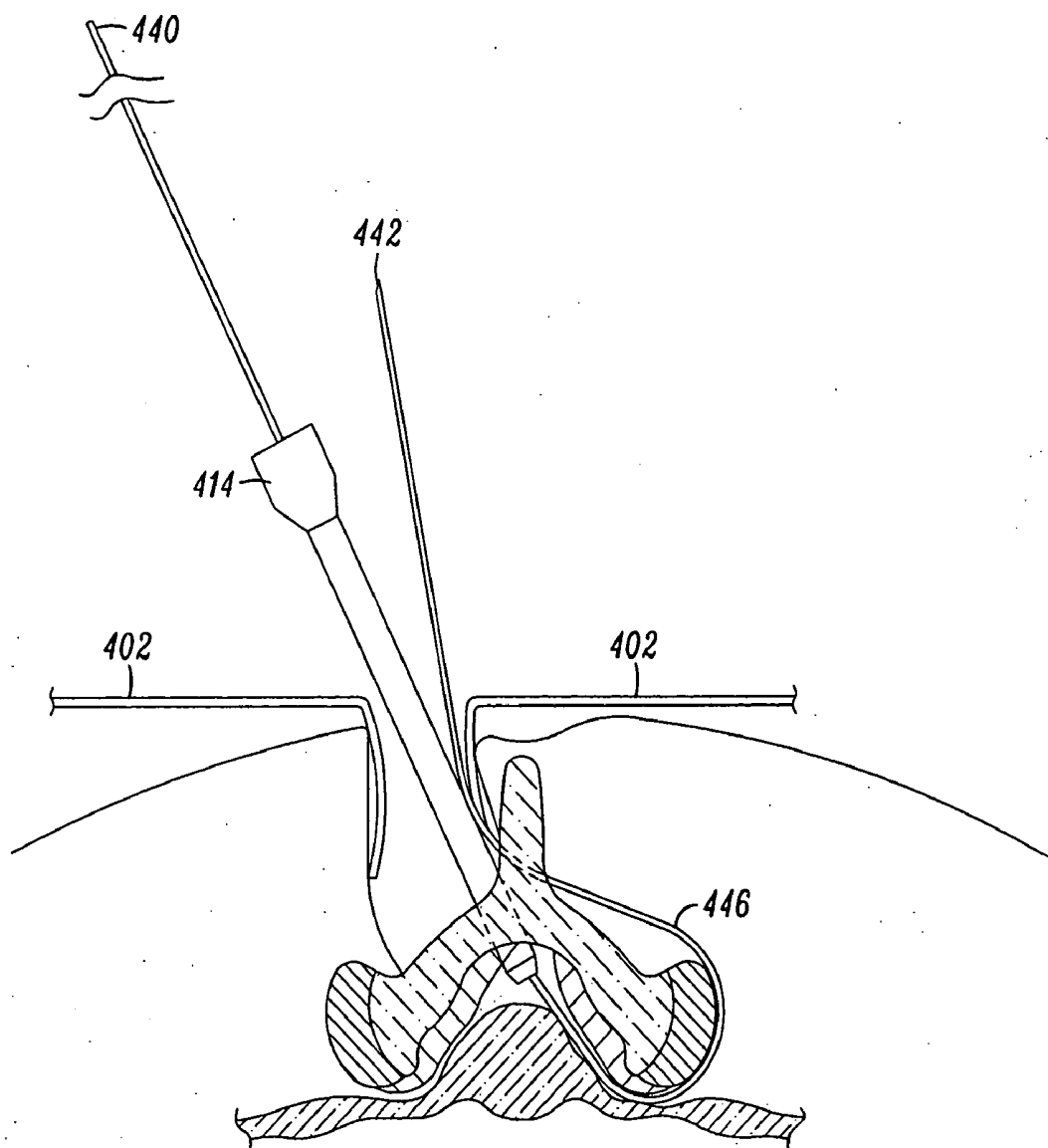


FIG. 9B

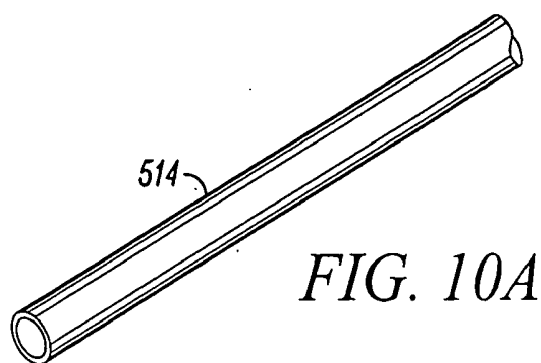


FIG. 10A

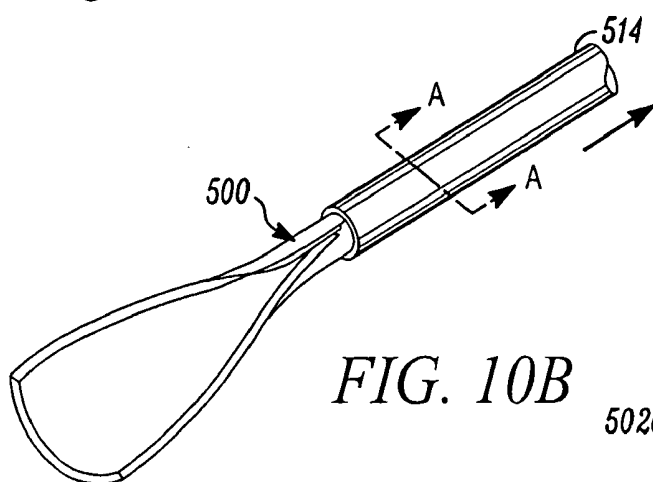
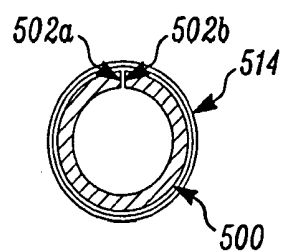


FIG. 10B



SECTION A-A

FIG. 10C

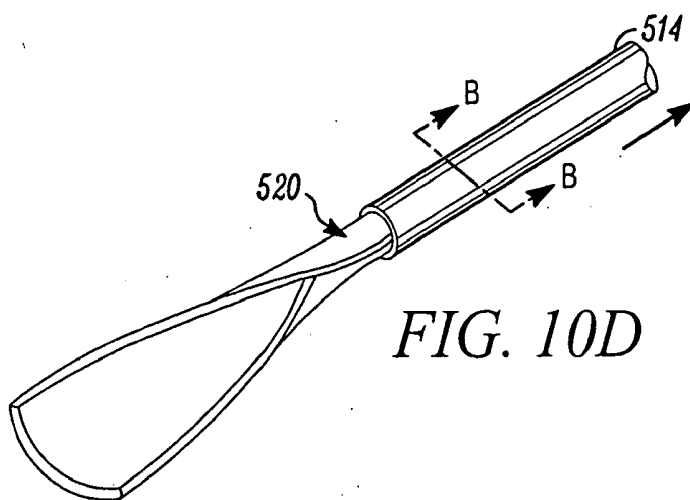
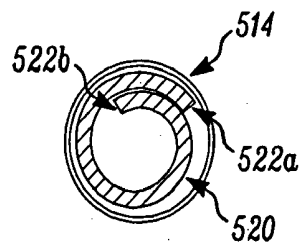


FIG. 10D



SECTION B-B

FIG. 10E

METHODS AND APPARATUS FOR TISSUE MODIFICATION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is related to PCT Patent Application Pub. No. PCT/US2005/037136, the full disclosure of which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to methods and apparatus for modifying tissue in a patient.

[0004] 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.

[0005] 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).

[0006] 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.

[0007] One common cause of spinal stenosis is buckling and thickening of the ligamentum flavum (one of the liga-

ments 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 zygapophyseal 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.

[0008] 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 stenosis include systemic medications and physical therapy. Epidural steroid injections may also be utilized, but they do not provide long 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.

[0009] 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.

[0010] 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.

[0011] 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.

[0012] 2. Description of Background Art

[0013] Flexible wire saws and chain saws, such as thread-wire saws (T-saws) and Gigli saws, have been used since the late 1800s to saw through or file/abrade bone and other tissue in the human body. See, for example, Brunori A et al., "Celebrating the Centennial (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. Pat. No. 8250, issued to P. A. Stohlmann on Nov. 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] A method and apparatus for treating spinal stenosis is described in PCT Patent Application Pub. No. WO 01/08571. A surgical instrument for removing cartilage from a knee cavity is described in U.S. Pat. No. 3,835,859.

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 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 unanchored 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 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, a method for modifying tissue in a patient may involve one or more of the following steps: advancing at least a distal portion of at least one elongate, at least partially flexible tissue modification device into a patient and between one or more target tissues and one or more non-target tissues; positioning at least one tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member(s) face the target tissue and do not face the non-target tissue; applying an anchoring force to the tissue modification device at or near the distal portion or a proximal portion of the device; applying a tensioning force to the tissue modification device at or near an opposite end of the device relative to the end to which anchoring force is

applied, while maintaining the anchoring force, to urge the tissue modifying member(s) against the target tissue; and modifying the target tissue, using the tissue modifying member(s), while preventing the tissue modifying member(s) from extending significantly beyond the target tissue toward the proximal or distal portion of the tissue modification device during tissue modification.

[0020] In another aspect of the invention, a method for modifying tissue in a patient may include one or more of the following steps: advancing at least a distal portion of at least one elongate, at least partially flexible tissue modification device into a patient and between one or more target tissues and one or more non-target tissues; positioning at least one tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member(s) face the target tissue and do not face the non-target tissue; applying a tensioning force to the tissue modification device at or near the distal portion and at or near a proximal portion of the device, to urge the tissue modifying member(s) against the target tissue; and modifying the target tissue, using the tissue modifying member(s), while preventing the tissue modifying member(s) from extending significantly beyond the target tissue toward the proximal or distal portion of the tissue modification device during tissue modification.

[0021] In another aspect of the invention, a method for modifying tissue in a spine of a patient may involve one or more of the following steps: advancing at least a distal portion of at least one elongate, at least partially flexible tissue modification device into an epidural space of the patient and between one or more target tissues and one or more non-target tissues; positioning at least one tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member(s) face the target tissue and do not face the non-target tissue; applying an anchoring force to the tissue modification device at or near the distal portion or a proximal portion of the device; applying a tensioning force to the tissue modification device at or near an opposite end of the device relative to the end to which anchoring force is applied, while maintaining the anchoring force, to urge the tissue modifying member(s) against the target tissue; and applying radiofrequency energy to the target tissue, using the tissue modifying member(s).

[0022] In another aspect of the invention, a method for modifying tissue in a spine of a patient may involve one or more of the following steps: advancing at least a distal portion of at least one elongate, at least partially flexible tissue modification device into an epidural space of the patient and between one or more target tissues and one or more non-target tissues; positioning at least one tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member(s) face the target tissue and do not face the non-target tissue; and translating at least a first blade of the tissue modifying members to move it toward at least a second blade of the tissue modifying members and thus cut the target tissue, while preventing the blades from extending significantly beyond the target tissue toward the proximal or distal portion of the tissue modification device during tissue modification.

[0023] In another aspect of the invention, apparatus for modifying one or more tissues in a patient may include one

or more of the following: an elongate, at least partially flexible body having a proximal portion and a distal portion; at least one tissue modifying member disposed along one side of the body for a limited length approximating a length of a target tissue to be treated; at least one surface located adjacent the at least one tissue modifying member so as to face non-target tissue; at least one actuator coupled with the at least one tissue modifying member and disposed at or near the proximal portion of the body for activating the tissue modifying member(s) to modify target tissue, wherein the at least one actuator is configured to activate the tissue modifying member(s) without significantly translating the elongate body proximally or distally; means at or near the distal portion of the elongate body for facilitating application of anchoring force to the body; and means at or near the proximal portion of the elongate body for facilitating application of tensioning force to the body to urge the at least one tissue modifying member against the target tissue.

[0024] In another aspect of the present invention, an apparatus for modifying one or more tissues in a spine of a patient may include one or more of the following: an elongate, at least partially flexible body having a proximal portion and a distal portion, wherein at least the distal portion is configured to allow it to be advanced into an epidural space of the patient's spine; at least one tissue modifying member located between the proximal and distal portions and disposed along a length of the body approximating a length of a treatment area; at least one protective surface disposed relative to the at least one tissue modifying member such that it faces non-target tissue when the tissue modifying member(s) face target tissue; at least one actuator coupled with the tissue modifying member(s) at or near the proximal portion of the body for activating the tissue modifying member(s) to modify target tissue, wherein the actuator is configured to activate the tissue modifying member(s) without significantly translating the flexible body proximally or distally; and at least one anchoring member at or near the distal portion of the elongate body for facilitating application of an anchoring force to the body.

[0025] In another aspect of the present invention, a system for modifying one or more tissues in a patient may include at least one tissue modification device and an introducer kit for facilitating introduction of the tissue modification device into the patient. The tissue modification device may include one or more of the following: an elongate, at least partially flexible body having a proximal portion and a distal portion; at least one tissue modifying member disposed along one side of the body for a limited length approximating a length of a target tissue to be treated; at least one surface located adjacent the at least one tissue modifying member so as to face non-target tissue; at least one actuator coupled with the at least one tissue modifying member and disposed at or near the proximal portion of the body for activating the tissue modifying member(s) to modify target tissue, wherein the at least one actuator is configured to activate the tissue modifying member(s) without significantly translating the elongate body proximally or distally; means at or near the distal portion of the elongate body for facilitating application of anchoring force to the body; and means at or near the proximal portion of the elongate body for facilitating application of tensioning force to the body to urge the at least one tissue modifying member against the target tissue. The introducer kit may include at least one cannula and/or at least one guidewire passable through the cannula.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] **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;

[0027] **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;

[0028] **FIG. 3A** is a perspective view of a tissue modification device according to one embodiment of the present invention;

[0029] **FIG. 3B** is a perspective view of a portion of the tissue modification device of **FIG. 3A**;

[0030] **FIG. 3C** is a top view of the portion shown in **FIG. 3B**;

[0031] **FIG. 3D** is a side view of the portion shown in **FIGS. 3B and 3C**;

[0032] **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**;

[0033] **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;

[0034] **FIG. 3H** is a top view of the portion shown in **FIG. 3G**;

[0035] **FIG. 3I** is a side view of the portion shown in **FIGS. 3G and 3H**;

[0036] **FIG. 4A** is a perspective view of a tissue modification device according to one embodiment of the present invention;

[0037] **FIG. 4B** is a perspective view of a portion of the tissue modification device of **FIG. 4A**;

[0038] **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;

[0039] **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;

[0040] **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;

[0041] **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;

[0042] **FIGS. 7A-7S** 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;

[0043] **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;

[0044] **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;

[0045] **FIG. 10A** is a perspective view of a distal portion of an introducer sheath according to one embodiment of the present invention;

[0046] **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

[0047] **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.

DETAILED DESCRIPTION OF THE INVENTION

[0048] 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.

[0049] 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.

[0050] 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 lubri-

cious 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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.

[0059] 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.

[0060] 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 rectangular, 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.

[0061] 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.

[0062] 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, Ill., 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, Del.), 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 0.001"-0.050", and more preferably from about 0.010"-0.020".

[0063] 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.

[0064] 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.

[0065] 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 its 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.

[0066] 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, Minn.). 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.

[0067] 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.

[0068] 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.

[0069] 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**.

[0070] 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.

[0071] 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.

[0072] 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.

[0073] 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.

[0074] 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 mem-

ber(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.)

[0075] 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.

[0076] 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.

[0077] 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.

[0078] 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.

[0079] **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.

[0080] Referring now to **FIGS. 7A-7S**, 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.

[0081] Referring to FIG. 7A, in one embodiment a device delivery method first involves advancing an introducer cannula 300 coupled with a stylet 302 into the patient's back. Cannula 300 and stylet 302 are then passed between adjacent vertebrae and into the ligamentum flavum or an adjacent spinal ligament, as shown further in FIG. 7B. As shown in FIG. 7C, when the distal tip of cannula is positioned as desired, stylet 302 is removed. Referring to FIGS. 7D and 7E, a loss of resistance syringe 304 including a plunger 310, barrel 308 and fluid and/or air 306, is coupled with the proximal portion of cannula 300. 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. 7E. Syringe 304 is then removed, as in FIG. 7F, and a guidewire 312 with a non-rigid, atraumatic tip is advanced through cannula 300 into the central spinal canal, as in FIG. 7G. Next, cannula 300 is removed, as in FIG. 7H, leaving behind guidewire 312. As shown in FIGS. 7I and 7J, 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. 7K.

[0082] 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. 7L and 7M. One or more guide members 116, may then be advanced through the guide device 318, as shown in FIGS. 7N-7P. Finally, guide device 318 may be removed, as in FIG. 7Q, 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. 7R. As shown in FIG. 7S, 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. 7R.

[0083] 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.

[0084] 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.

[0085] 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.

[0086] 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.

[0087] 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**.

[0088] 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.

[0089] 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.

[0090] 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.

[0091] 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.

[0092] 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.

[0093] 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.

[0094] **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**.

[0095] 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.

What is claimed is:

1. A method for modifying tissue in a patient, the method comprising:

advancing at least a distal portion of at least one elongate, at least partially flexible tissue modification device into a patient and between one or more target tissues and one or more non-target tissues;

positioning at least one tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member(s) face the target tissue and do not face the non-target tissue;

applying an anchoring force to the tissue modification device at or near the distal portion or a proximal portion of the device;

applying a tensioning force to the tissue modification device at or near an opposite end of the device relative to the end to which anchoring force is applied, while maintaining the anchoring force, to urge the tissue modifying member(s) against the target tissue; and

modifying the target tissue, using the tissue modifying member(s), while preventing the tissue modifying member(s) from extending significantly beyond the target tissue toward the proximal or distal portion of the tissue modification device during tissue modification.

2. A method as in claim 1, wherein advancing the tissue modification device comprises advancing at least the distal portion into an epidural space of the patient's spine and through a spinal channel.

3. A method as in claim 2, wherein the spinal channel comprises an intervertebral foramen.

4. A method as in claim 2, wherein modifying the target tissue comprises modifying at least one of ligament, tendon, tumor, cyst, cartilage, scar, osteophyte, inflammatory and bone tissue.

5. A method as in claim 2, wherein modifying the target tissue reduces impingement of the tissue on at least one of a spinal cord, a branching nerve, dorsal root ganglia, and vascular tissue in the spine.

6. A method as in claim 1, wherein advancing the tissue modification device comprises advancing the distal portion of the device outside the patient through an exit point located apart from a location where the device was advanced into the patient.

7. A method as in claim 6, wherein applying the anchoring force comprises manually grasping the device at or near its distal portion.

8. A method as in claim 6, wherein the anchoring force is applied against the patient's skin at or near the exit point.

9. A method as in claim 6, wherein the anchoring force is applied with a structure outside of and separate from the patient.

10. A method as in claim 1, wherein applying the anchoring force comprises deploying one or more anchoring members located at or near the distal portion of the device within the patient.

11. A method as in claim 10, wherein the anchoring members apply the anchoring force to at least one of ligament, tendon, bone, connective tissue and muscle of the patient.

12. A method as in claim 10, wherein the anchoring members apply the anchoring force at or adjacent the target tissue.

13. A method as in claim 10, wherein the anchoring members apply the anchoring force at a location apart from the target and non-target tissue.

14. A method as in claim 1, wherein advancing the tissue modification device comprises advancing the distal portion of the device outside the patient at or near a location where the device is advanced into the patient.

15. A method as in claim 1, wherein advancing the tissue modification device comprises advancing along or through at least one of a guidewire, a shield, one or more rails, a track, a groove, a flat guide member, a lumen, a slot and a partial lumen.

16. A method as in claim 1, wherein modifying the target tissue comprises at least one of 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 retracting the target tissue.

17. A method as in claim 1, wherein positioning the at least one tissue modifying member prevents damage to the non-target tissue by facing the tissue modifying member(s) away from the non-target tissue.

18. A method as in claim 17, further comprising additionally protecting the non-target tissue by positioning at least one shield device coupled with the tissue modification device between the device and the non-target tissue.

19. A method as in claim 17, wherein positioning the at least one shield device comprises sliding the shield into position along the tissue modification device.

20. A method as in claim 17, wherein the at least one shield device is positioned between the target and non-target tissues before advancing the tissue modification device, and wherein the tissue modification device is advanced by sliding it along the at least one shield device.

21. A method as in claim 1, wherein the method comprises modifying tissue with multiple elongate, flexible devices advanced into the patient in series.

22. A method as in claim 1, wherein the method comprises modifying tissue with multiple elongate, flexible devices positioned in the patient at the same time.

23. A method as in claim 1, wherein preventing the tissue modifying member(s) from extending significantly beyond the target tissue comprises:

holding the tissue modification device as a whole predominantly stable to prevent the device from translating in a direction toward its proximal portion or toward its distal portion; and

activating the at least one tissue modifying member to modify a defined length of tissue.

24. A method as in claim 23, further comprising keeping tissue modification member(s) in close proximity to the target tissue throughout tissue modification.

25. A method as in claim 23, wherein activating the tissue modifying member(s) comprises translating at least one member distally and/or proximally.

26. A method as in claim 24, wherein at least one of a blade and an electrode is translated.

27. A method as in claim 23, wherein activating the tissue modifying member(s) causes them to modify target tissue in an area having a length of no more than 3 cm.

28. A method as in claim 23, wherein activating the tissue modifying member(s) causes them to translate no farther than about 3 cm proximally or distally.

29. A method for modifying tissue in a patient, the method comprising:

advancing at least a distal portion of at least one elongate, at least partially flexible tissue modification device into a patient and between one or more target tissues and one or more non-target tissues;

positioning at least one tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member(s) face the target tissue and do not face the non-target tissue;

applying a tensioning force to the tissue modification device at or near the distal portion and at or near a proximal portion of the device, to urge the tissue modifying member(s) against the target tissue; and

modifying the target tissue, using the tissue modifying member(s), while preventing the tissue modifying member(s) from extending significantly beyond the target tissue toward the proximal or distal portion of the tissue modification device during tissue modification.

30. A method for modifying tissue in a spine of a patient, the method comprising:

advancing at least a distal portion of at least one elongate, at least partially flexible tissue modification device into an epidural space of the patient and between one or more target tissues and one or more non-target tissues;

positioning at least one tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member(s) face the target tissue and do not face the non-target tissue;

applying an anchoring force to the tissue modification device at or near the distal portion or a proximal portion of the device;

applying a tensioning force to the tissue modification device at or near an opposite end of the device relative to the end to which anchoring force is applied, while maintaining the anchoring force, to urge the tissue modifying member(s) against the target tissue; and

applying radiofrequency energy to the target tissue, using the tissue modifying member(s).

31. A method as in claim 30, wherein the spinal channel comprises an intervertebral foramen.

32. A method as in claim 30, wherein modifying the target tissue comprises modifying at least one of ligament, tendon, tumor, cyst, cartilage, osteophyte, scar, inflammatory and bone tissue.

33. A method as in claim 30, wherein modifying the target tissue reduces impingement of the tissue on at least one of a spinal cord, a branching nerve, dorsal root ganglia, and vascular tissue in the spine.

34. A method as in claim 30, wherein advancing the tissue modification device comprises advancing the distal portion of the device outside the patient through an exit point on the patient's skin, wherein the exit point is located apart from the entry point.

35. A method as in claim 34, further comprising:

applying an anchoring force to the tissue modification device at or near the distal portion or a proximal portion of the device; and

applying a tensioning force to the tissue modification device at or near an opposite end of the device relative to the end to which anchoring force is applied, while maintaining the anchoring force, to urge the tissue modifying member(s) against the target tissue.

36. A method as in claim 35, wherein anchoring the tissue modification device comprises manually grasping the device at or near its proximal or distal portion.

37. A method as in claim 35, wherein anchoring the tissue modification device comprises anchoring the device at or near its proximal or distal portion with the patient's skin at or near the exit point.

38. A method as in claim 35, wherein anchoring the tissue modification device comprises deploying one or more anchoring members located at or near the distal portion of the device within the patient.

39. A method as in claim 30, wherein advancing the tissue modification device comprises advancing along or through at least one of a guidewire, a shield, one or more rails, a track, a groove, a flat guide member, a lumen, a slot and a partial lumen.

40. A method as in claim 30, further comprising protecting the non-target tissue by positioning at least one shield device coupled with the tissue removal device between the device and the non-target tissue.

41. A method as in claim 40, wherein positioning the at least one shield device comprises sliding the shield into position along the tissue modification device.

42. A method as in claim 40, wherein the at least one shield device is positioned between the target and non-target tissues before advancing the tissue modification device, and wherein the tissue modification device is advanced by sliding it along the at least one shield device.

43. A method as in claim 40, further comprising activating one or more blades of the tissue modification device or of an additional device positioned in the patient to further modify one or more target tissues.

44. A method as in claim 43, wherein the method comprises modifying tissue with multiple elongate, flexible devices positioned in the patient in series.

45. A method as in claim 43, wherein the method comprises modifying tissue with multiple elongate, flexible devices positioned in the patient at the same time.

46. A method as in claim 30, wherein applying the radiofrequency energy comprises applying at least one of monopolar and bipolar radiofrequency energy.

47. A method as in claim 46, wherein the target tissue is modified in an area having a length of no more than 3 cm.

48. A method for modifying tissue in a spine of a patient, the method comprising:

advancing at least a distal portion of at least one elongate, at least partially flexible tissue modification device into an epidural space of the patient and between one or more target tissues and one or more non-target tissues;

positioning at least one tissue modifying member of the tissue modification device adjacent the target tissue such that the tissue modifying member(s) face the target tissue and do not face the non-target tissue; and

translating at least a first blade of the tissue modifying members to move it toward at least a second blade of the tissue modifying members and thus cut the target tissue, while preventing the blades from extending significantly beyond the target tissue toward the proximal or distal portion of the tissue modification device during tissue modification.

49. Apparatus for modifying one or more tissues in a patient, the apparatus comprising:

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

at least one tissue modifying member disposed along one side of the body for a limited length approximating a length of a target tissue to be treated;

at least one surface located adjacent the at least one tissue modifying member so as to face non-target tissue;

at least one actuator coupled with the at least one tissue modifying member and disposed at or near the proximal portion of the body for activating the tissue modifying member(s) to modify target tissue, wherein the at least one actuator is configured to activate the tissue modifying member(s) without significantly translating the elongate body proximally or distally;

means at or near the distal portion of the elongate body for facilitating application of anchoring force to the body; and

means at or near the proximal portion of the elongate body for facilitating application of tensioning force to the body to urge the at least one tissue modifying member against the target tissue.

50. Apparatus as in claim 49, 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.

51. Apparatus as in claim 49, wherein the elongate body has a width of not more than 5 mm at any point along its length.

52. Apparatus as in claim 49, 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.

53. Apparatus as in claim 49, wherein the tissue modifying member(s) are disposed along a length of the body measuring no longer than 3 cm.

54. Apparatus as in claim 49, wherein the at least one tissue modifying member comprises at least one 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, and a powered mechanical burr, a laser, an ultrasound crystal a cryogenic probe, and a pressurized water jet.

55. Apparatus as in claim 54, wherein the tissue modifying members comprise two opposing blades, at least one of which may be moved to bring the blades together to cut target tissue.

56. Apparatus as in claim 49, wherein at least one tissue modifying member is mobile relative to the elongate body.

57. Apparatus as in claim 49, wherein at least one tissue modifying member is predominantly static relative to the elongate body.

58. Apparatus as in claim 49, wherein the at least one tissue modifying member is deployable out of a window on the elongate body.

59. Apparatus as in claim 49, wherein the at least one actuator is selected from the group consisting of triggers, buttons, pull-wires and switches.

60. Apparatus as in claim 49, wherein the anchoring means are configured to facilitate application of anchoring force inside the patient.

61. Apparatus as in claim 49, wherein the anchoring means are configured to facilitate application of anchoring force outside the patient.

62. Apparatus as in claim 49, wherein the anchoring means are selected from the group consisting of handles, barbs, hooks, screws, toggle bolts, needles, inflatable balloons, meshes, stents, wires, loops, lassos and backstops.

63. Apparatus as in claim 49, wherein the anchoring means are deployable from a first configuration to facilitate delivery of the apparatus to a second configuration to anchor the apparatus.

64. Apparatus as in claim 49, wherein the force application means comprises at least one of a handle, a textured gripping surface, a widened portion of the body, a shaped portion of the body, and a reeling mechanism.

65. Apparatus as in claim 49, further comprising at least one shield member removably couplable with the elongate body to protect the non-target tissue from damage during a tissue modification procedure.

66. Apparatus for modifying one or more tissues in a spine of a patient, the apparatus comprising:

an elongate, at least partially flexible body having a proximal portion and a distal portion, wherein at least the distal portion is configured to allow it to be advanced into an epidural space of the patient's spine;

at least one tissue modifying member located between the proximal and distal portions and disposed along a length of the body approximating a length of a treatment area;

at least one protective surface disposed relative to the at least one tissue modifying member such that it faces non-target tissue when the tissue modifying member(s) face target tissue;

at least one actuator coupled with the tissue modifying member(s) at or near the proximal portion of the body for activating the tissue modifying member(s) to modify target tissue, wherein the actuator is configured to activate the tissue modifying member(s) without significantly translating the flexible body proximally or distally; and

at least one anchoring member at or near the distal portion of the elongate body for facilitating application of an anchoring force to the body.

67. Apparatus as in claim 66, further comprising a handle coupled with the elongate body at or near the proximal portion, where the at least one actuator is coupled with the handle, and wherein the handle is configured to facilitate application of a tensioning force to the elongate body while the anchoring force is applied.

68. Apparatus as in claim 66, 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.

69. Apparatus as in claim 66, wherein the elongate body has a width of not more than 5 mm at any point along its length.

70. Apparatus as in claim 66, 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.

71. Apparatus as in claim 66, wherein the tissue modifying member(s) are disposed along a length of the body measuring no longer than 3 cm.

72. Apparatus as in claim 66, wherein the at least one tissue modifying member comprises at least one 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, and a powered mechanical burr, a laser, an ultrasound crystal a cryogenic probe, and a pressurized water jet.

73. Apparatus as in claim 72, wherein the tissue modifying members comprise two opposing blades, at least one of which may be moved to bring the blades together to cut target tissue.

74. Apparatus as in claim 66, wherein at least one tissue modifying member is mobile relative to the elongate body.

75. Apparatus as in claim 66, wherein at least one tissue modifying member is predominantly static relative to the elongate body.

76. Apparatus as in claim 66, wherein the at least one tissue modifying member is deployable out of a window on the elongate body.

77. Apparatus as in claim 66, wherein the at least one actuator is selected from the group consisting of triggers, buttons, pull-wires, cranks, screws, push rods and switches.

78. Apparatus as in claim 66, wherein the at least one anchoring member comprises a guidewire extending through at least part of the elongate body, beyond the distal portion of the body, and outside the patient.

79. Apparatus as in claim 66, wherein the at least one anchoring member is configured to facilitate application of anchoring force inside the patient.

80. Apparatus as in claim 66, wherein the at least one anchoring member is selected from the group consisting of handles, barbs, hooks, screws, toggle bolts, needles, inflatable balloons, meshes, stents, wires, lassos, backstops and a guidewire extending out of the tissue modification device.

81. Apparatus as in claim 66, wherein the at least one anchoring member is deployable from a first configuration to facilitate delivery of the apparatus to a second configuration to facilitate application of anchoring force.

82. Apparatus as in claim 66, further comprising at least one shield member removably couplable with the elongate body to further protect the non-target tissue from damage during a tissue modification procedure.

83. A system for modifying one or more tissues in a spine of a patient, the system comprising:

tissue modification apparatus, comprising:

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

at least one tissue modifying member disposed along one side of the body for a limited length approximating a length of a target tissue to be treated;

at least one surface located adjacent the at least one tissue modifying member so as to face non-target tissue;

at least one actuator coupled with the at least one tissue modifying member and disposed at or near the proximal portion of the body for activating the tissue modifying member(s) to modify target tissue, wherein the at least one actuator is configured to activate the tissue modifying member(s) without significantly translating the elongate body proximally or distally;

means at or near the distal portion of the elongate body for facilitating application of anchoring force to the body; and

means at or near the proximal portion of the elongate body for facilitating application of tensioning force to the body to urge the at least one tissue modifying member against the target tissue; and

an introducer kit, comprising:

at least one guidewire; and

instructions for use.

84. A system as in claim 83, 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 the at least one guidewire.

85. A system as in claim 83, wherein the at least one tissue modifying member comprises at least one 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, and a powered mechanical burr, a laser, an ultrasound crystal a cryogenic probe, and a pressurized water jet.

86. A system as in claim 83, wherein the at least one tissue modification device comprises multiple tissue modification devices.

87. A system as in claim 83, further comprising at least one shield member removably couplable with the elongate body to protect the non-target tissue from damage during a tissue modification procedure.

88. A system as in claim 83, wherein the introducer kit further comprises:

a dilator; and

an introducer sheath through which the tissue modification device is advanced into the patient.

89. A system as in claim 88, wherein the introducer kit further comprises at least one shaped guide member over which the tissue modification device is advanced into the patient.

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专利名称(译)	用于组织改变的方法和设备		
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摘要(译)

用于改变患者组织的方法可以包括以下步骤中的一个或多个：将至少一个细长的，至少部分柔性的组织改变装置的至少远端部分推进到患者体内以及一个或多个目标组织与一个或多个之间。更多的非靶组织；将组织改变装置的至少一个组织改变构件定位成与靶组织相邻，使得组织改变构件面向靶组织并且不面向非靶组织；在装置的远端部分或近端部分处或附近向组织改变装置施加锚固力；在装置的相对端处或附近施加张力，相对于施加锚固力的端部，同时保持锚固力，以促使组织改变构件抵靠目标组织；使用组织改变构件修改目标组织，同时防止组织改变构件在组织改变期间朝向组织改变装置的近端或远端部分显著延伸超过目标组织。

