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(54) **POWERED TISSUE MODIFICATION DEVICES AND METHODS**

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Publication Classification

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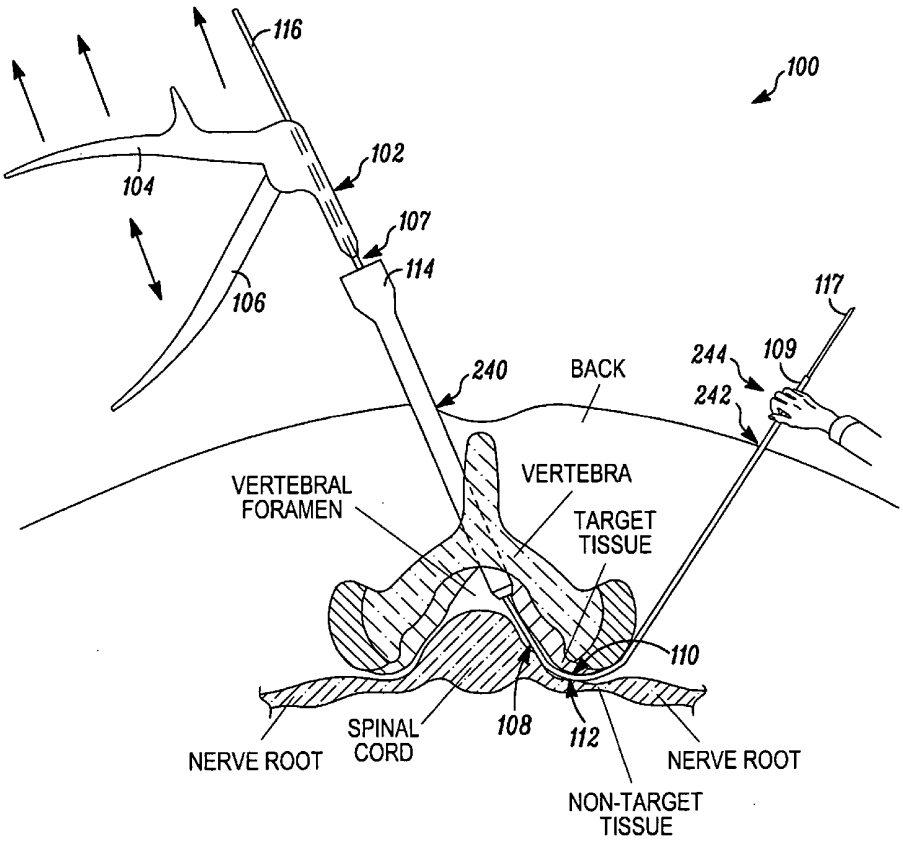
A61B 17/00 (2006.01)

(52) **U.S. Cl.** **606/79**

(57) **ABSTRACT**

A device for modifying tissue in a spine may include: a shaft having a proximal portion and a distal portion, the distal portion having dimensions which allow it to be passed into an epidural space of the spine and between target and non-target tissues; at least one distal force application member extending from the distal portion of the shaft and configured to facilitate application of at least one of anchoring force and tensioning force to the shaft; at least one movable tissue modifying member coupled with the shaft at or near its distal portion; at least one drive member coupled with the at least one tissue modifying member to activate the at least one tissue modifying member; and at least one power transmission member coupled with the at least one drive member to deliver power to the at least one drive member.



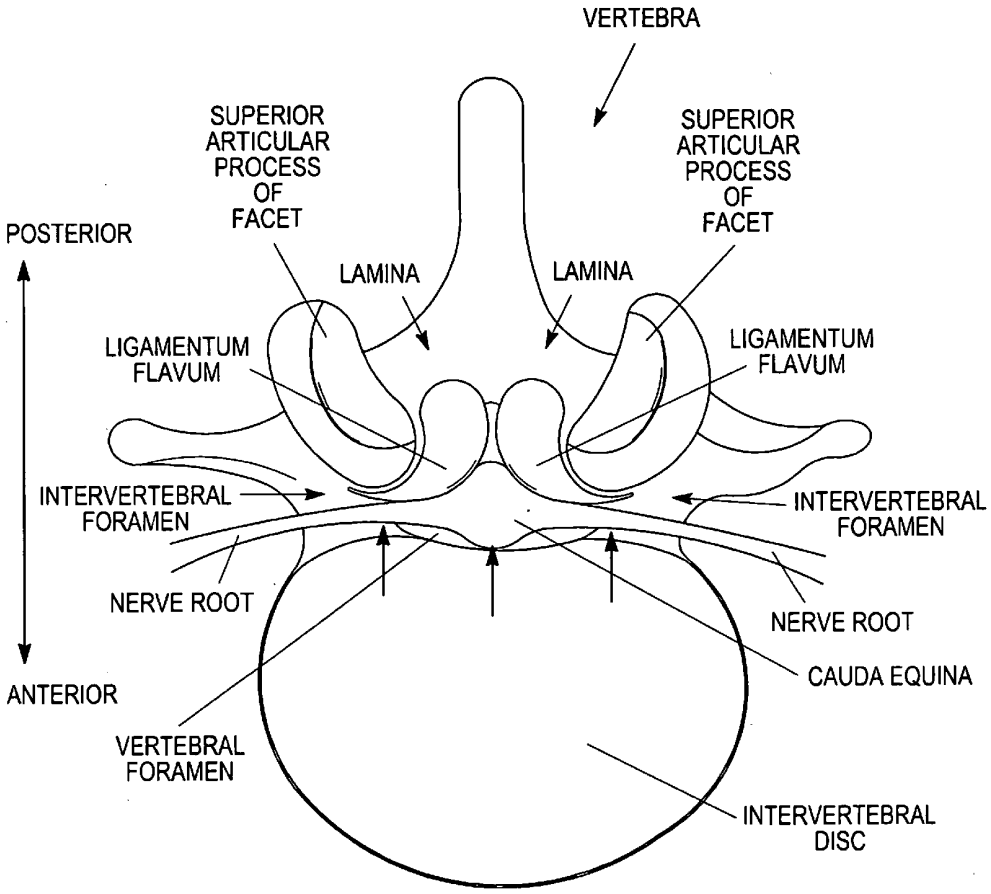

VERTEBRA
SUPERIOR ARTICULAR PROCESS OF FACET
SUPERIOR ARTICULAR PROCESS OF FACET
POSTERIOR
LAMINA
LAMINA
LIGAMENTUM FLAVUM
LIGAMENTUM FLAVUM
INTERVERTEBRAL FORAMEN
INTERVERTEBRAL FORAMEN
NERVE ROOT
NERVE ROOT
CAUDA EQUINA
ANTERIOR
VERTEBRAL FORAMEN
INTERVERTEBRAL DISC

FIG. 1

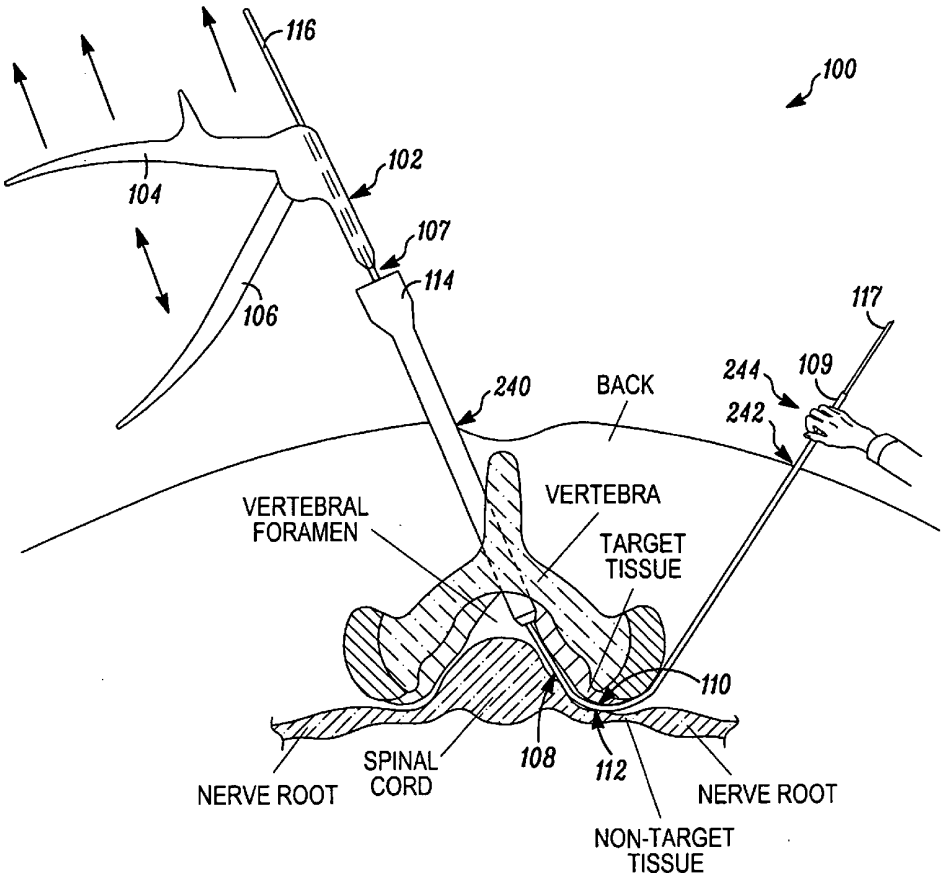
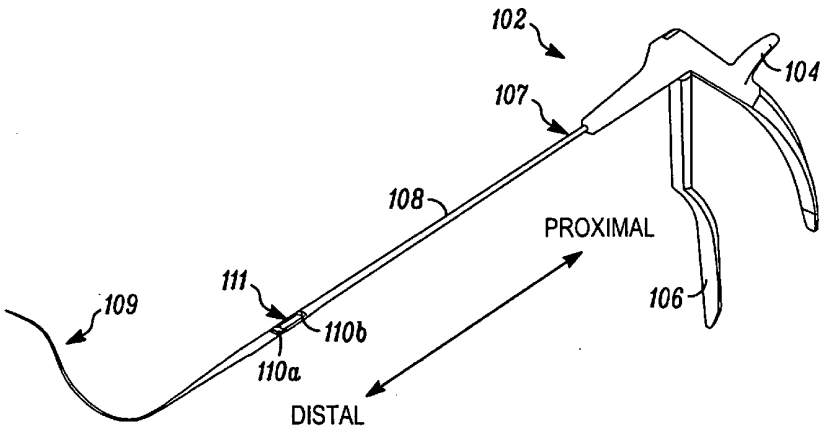

116
100
102
104
107
114
106
117
240
BACK
244
109
242
VERTEBRAL FORAMEN
VERTEBRA
TARGET TISSUE
110
108
112
SPINAL CORD
NERVE ROOT
NERVE ROOT
NON-TARGET TISSUE

FIG. 2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104
107
108
PROXIMAL
109
111
110b
110a
106
DISTAL

FIG. 3A

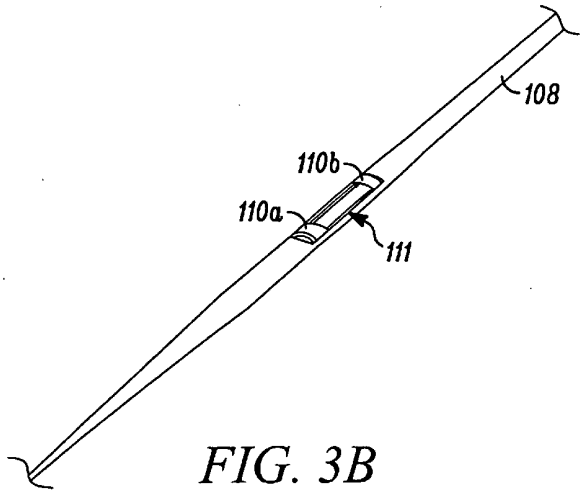

108
110b
110a
111

FIG. 3B

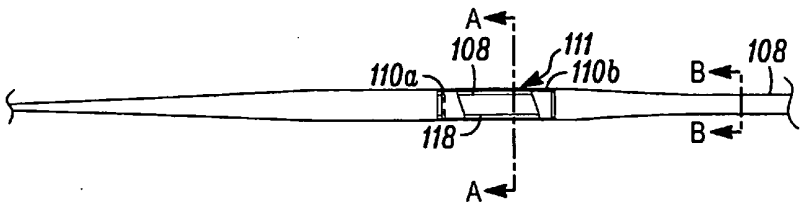


FIG. 3C

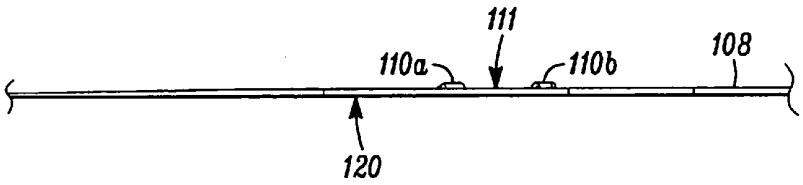
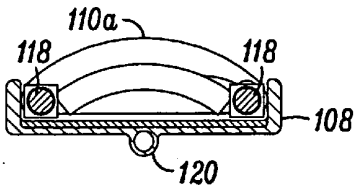
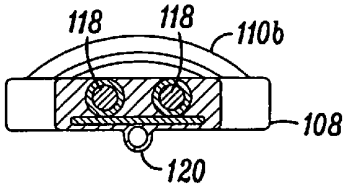


FIG. 3D



SECTION A-A

FIG. 3E



SECTION B-B

FIG. 3F

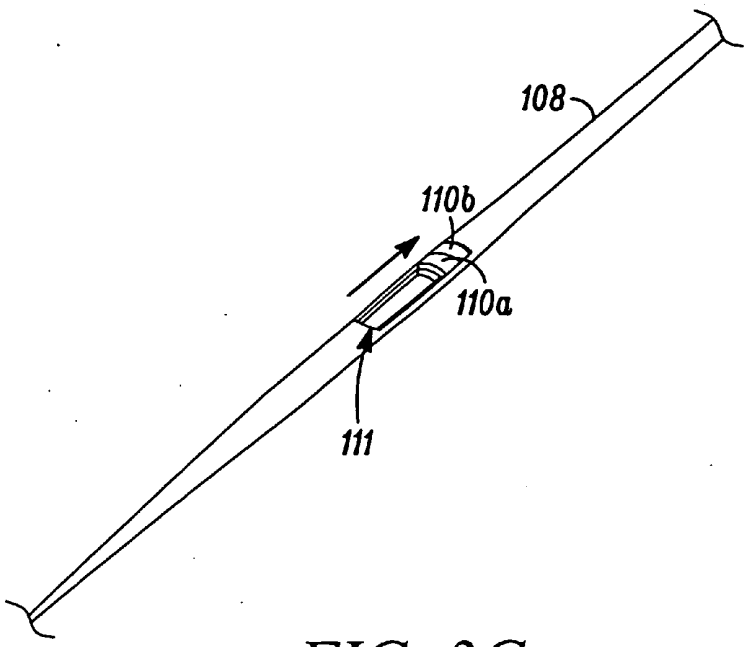


FIG. 3G

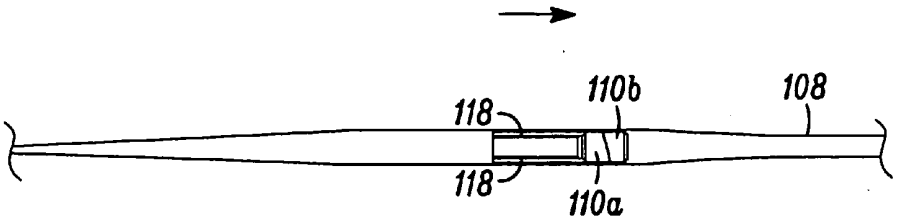


FIG. 3H

FIG. 3I

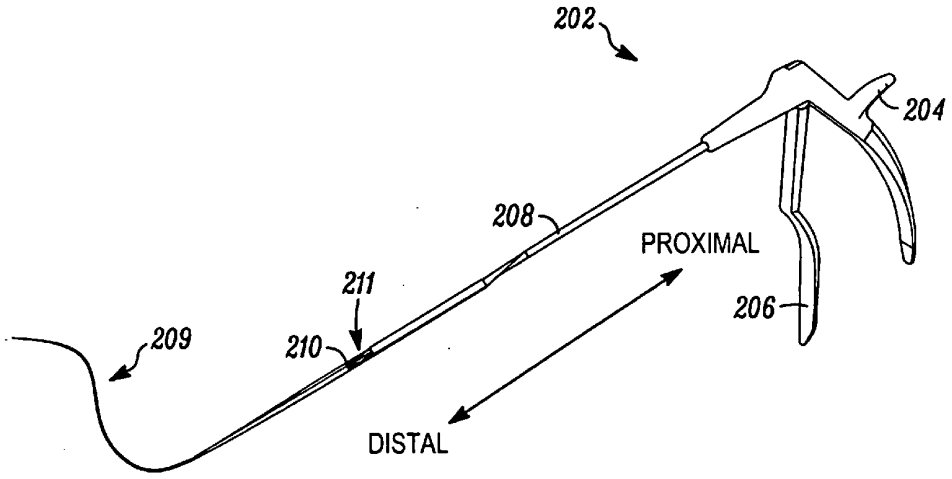


FIG. 4A

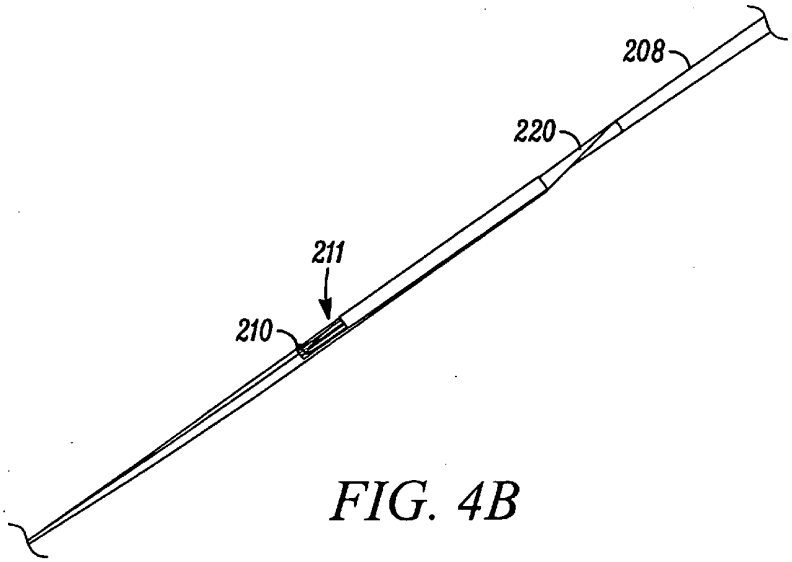


FIG. 4B

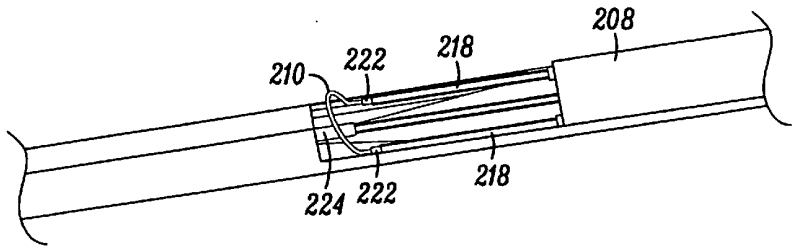

208
218
210
222
224
222
218

FIG. 4C

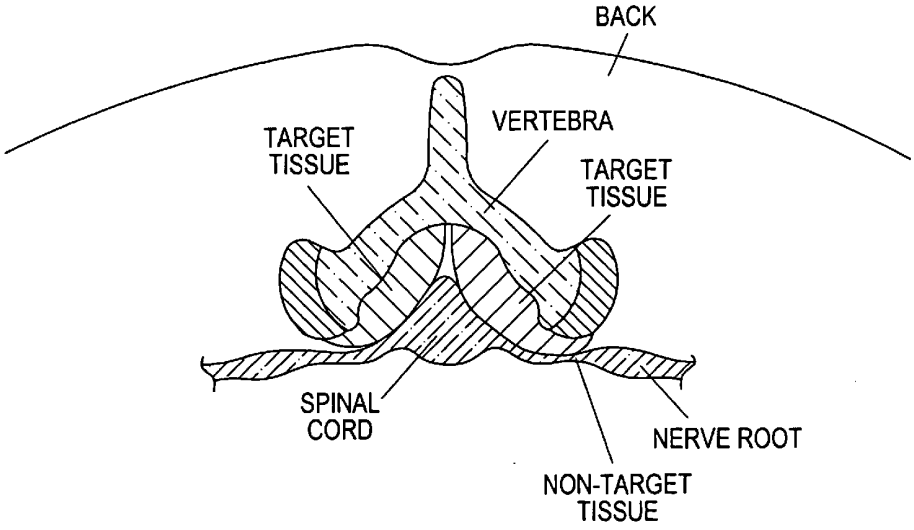

BACK
TARGET TISSUE
VERTEBRA
TARGET TISSUE
SPINAL CORD
NERVE ROOT
NON-TARGET TISSUE

FIG. 5A

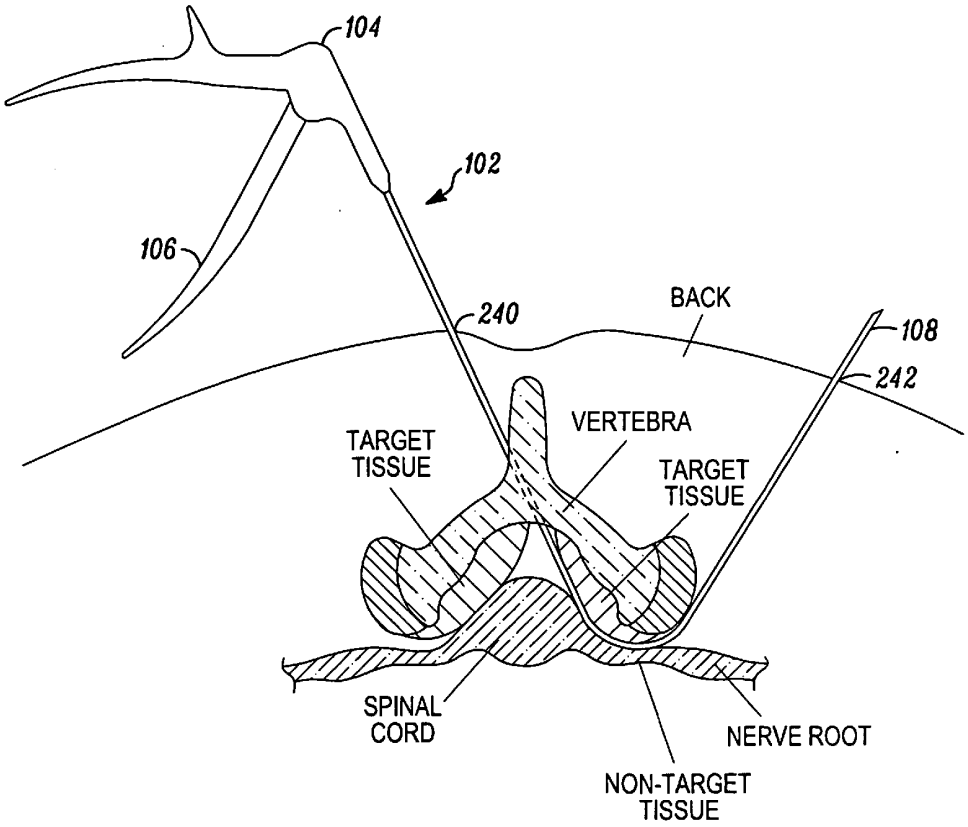

104
102
106
240
BACK
108
242
VERTEBRA
TARGET TISSUE
TARGET TISSUE
SPINAL CORD
NERVE ROOT
NON-TARGET TISSUE

FIG. 5B

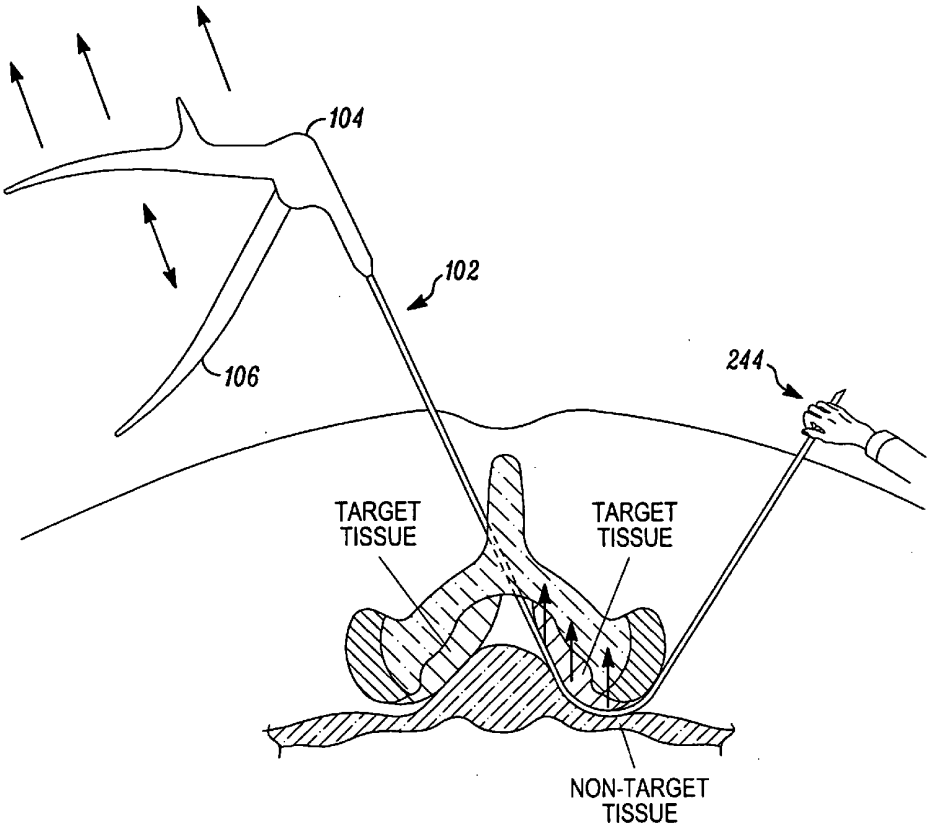

104
102
106
244
TARGET TISSUE
TARGET TISSUE
NON-TARGET TISSUE

FIG. 5C

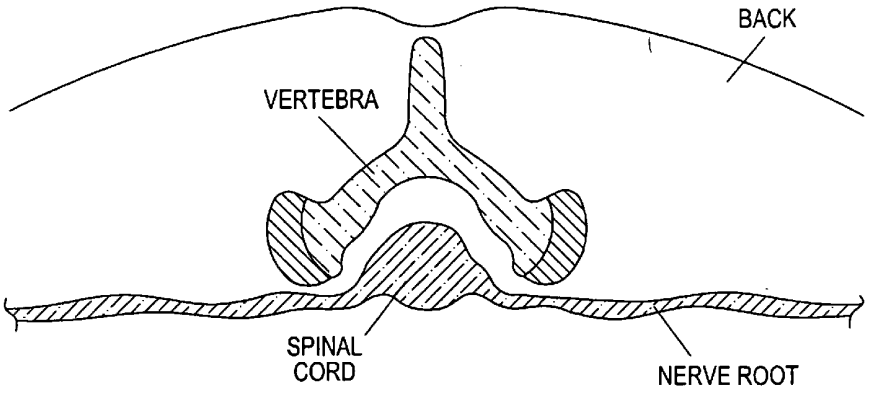
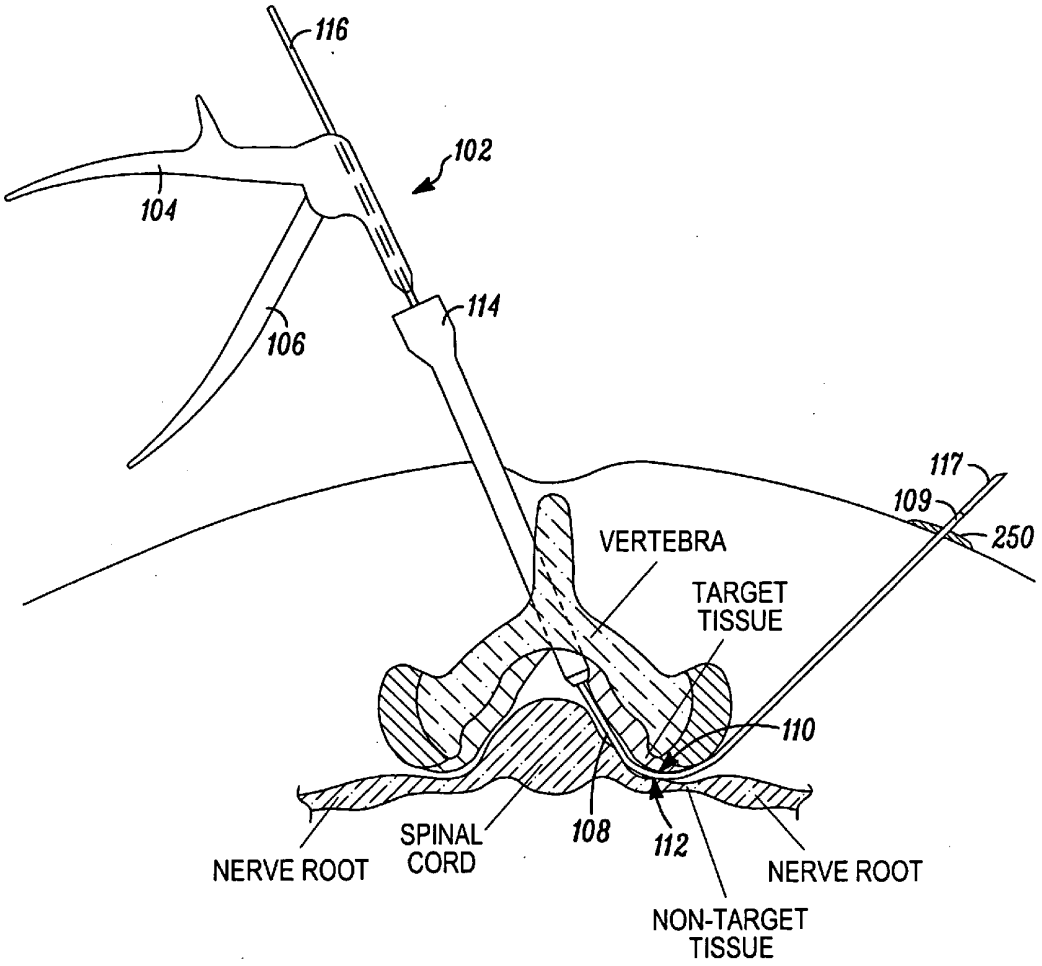

BACK
VERTEBRA
SPINAL CORD
NERVE ROOT

FIG. 5D


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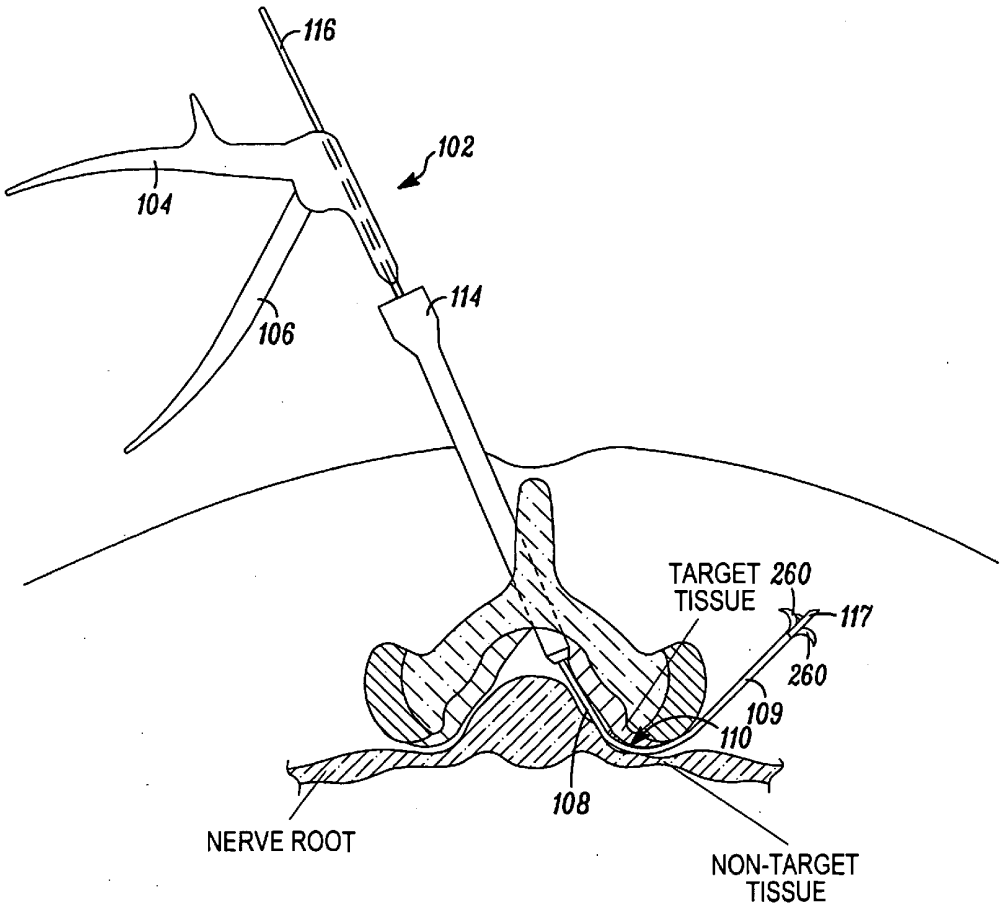
117
109
250
VERTEBRA
TARGET
TISSUE
110
SPINAL
CORD
108
112
NERVE ROOT
NERVE ROOT
NON-TARGET
TISSUE

FIG. 6A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102
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114
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TARGET TISSUE
260
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260
109
110
108
NERVE ROOT
NON-TARGET TISSUE

FIG. 6B

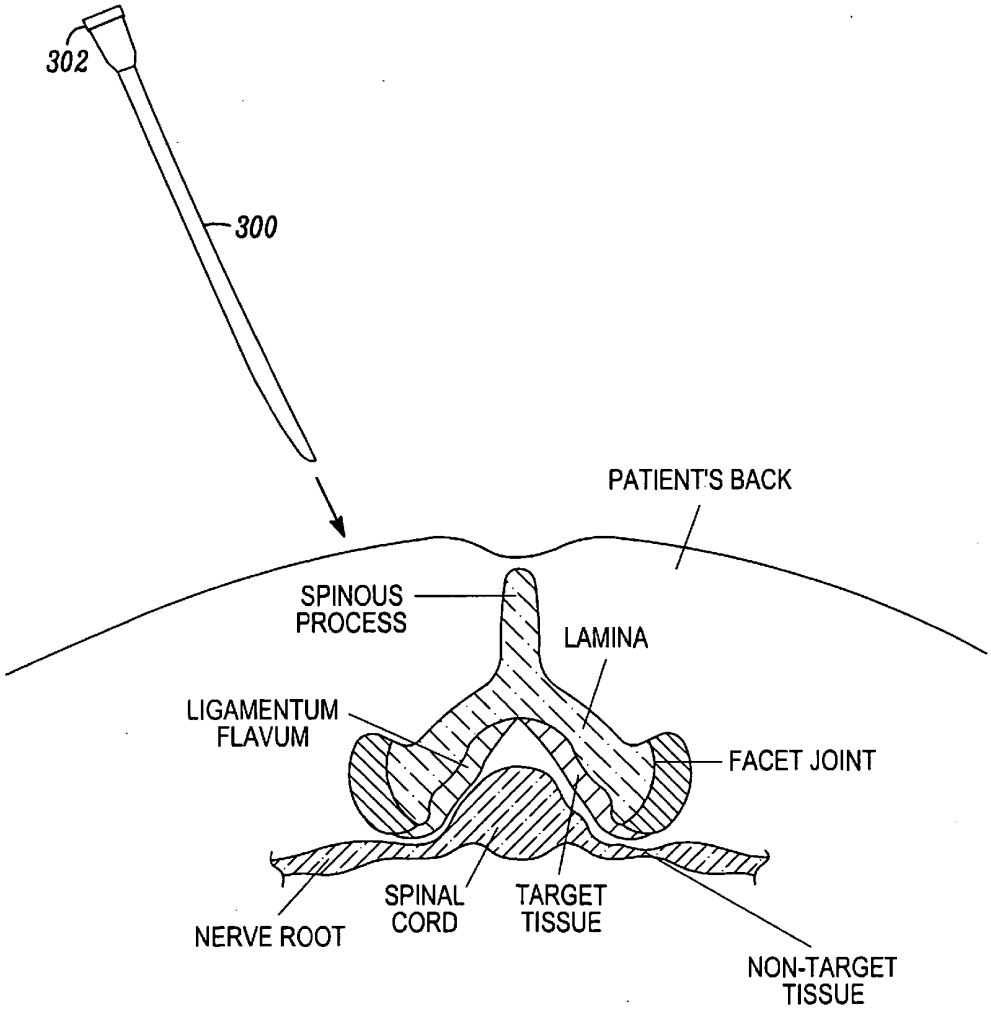

302
300
PATIENT'S BACK
SPINOUS PROCESS
LAMINA
LIGAMENTUM FLAVUM
FACET JOINT
SPINAL CORD
TARGET TISSUE
NERVE ROOT
NON-TARGET TISSUE

FIG. 7A

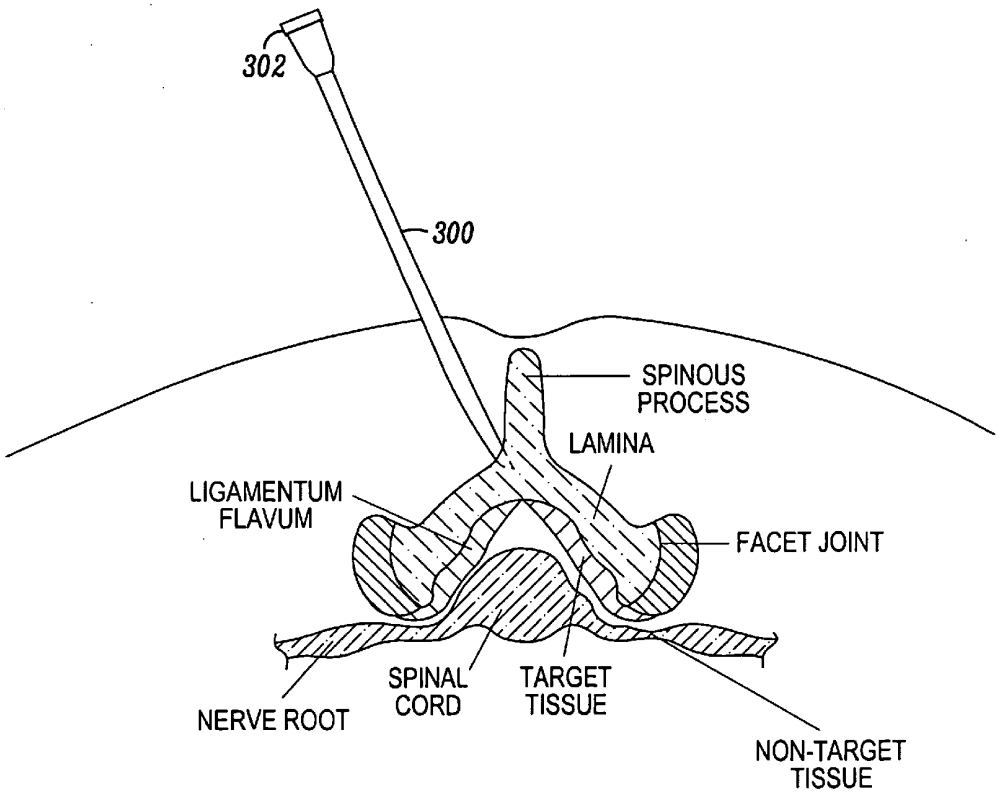

302
300
SPINOUS PROCESS
LAMINA
LIGAMENTUM FLAVUM
FACET JOINT
SPINAL CORD
TARGET TISSUE
NERVE ROOT
NON-TARGET TISSUE

FIG. 7B

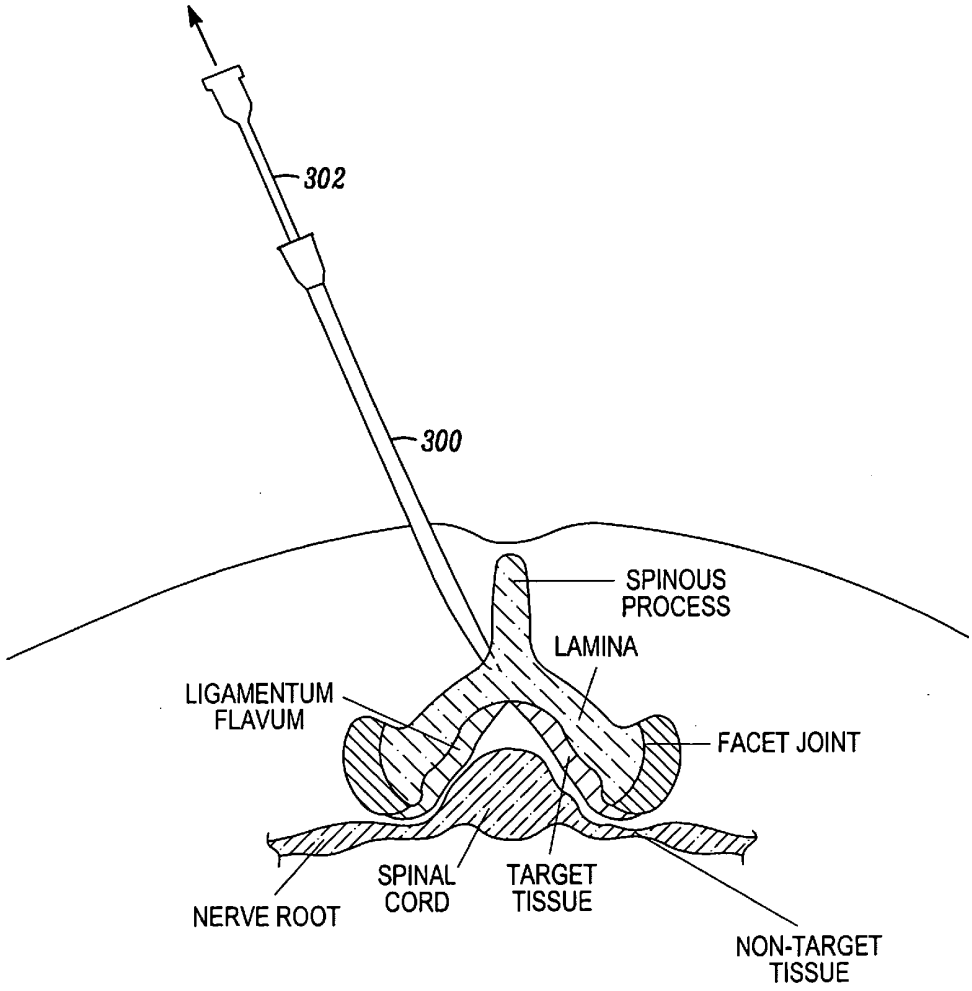
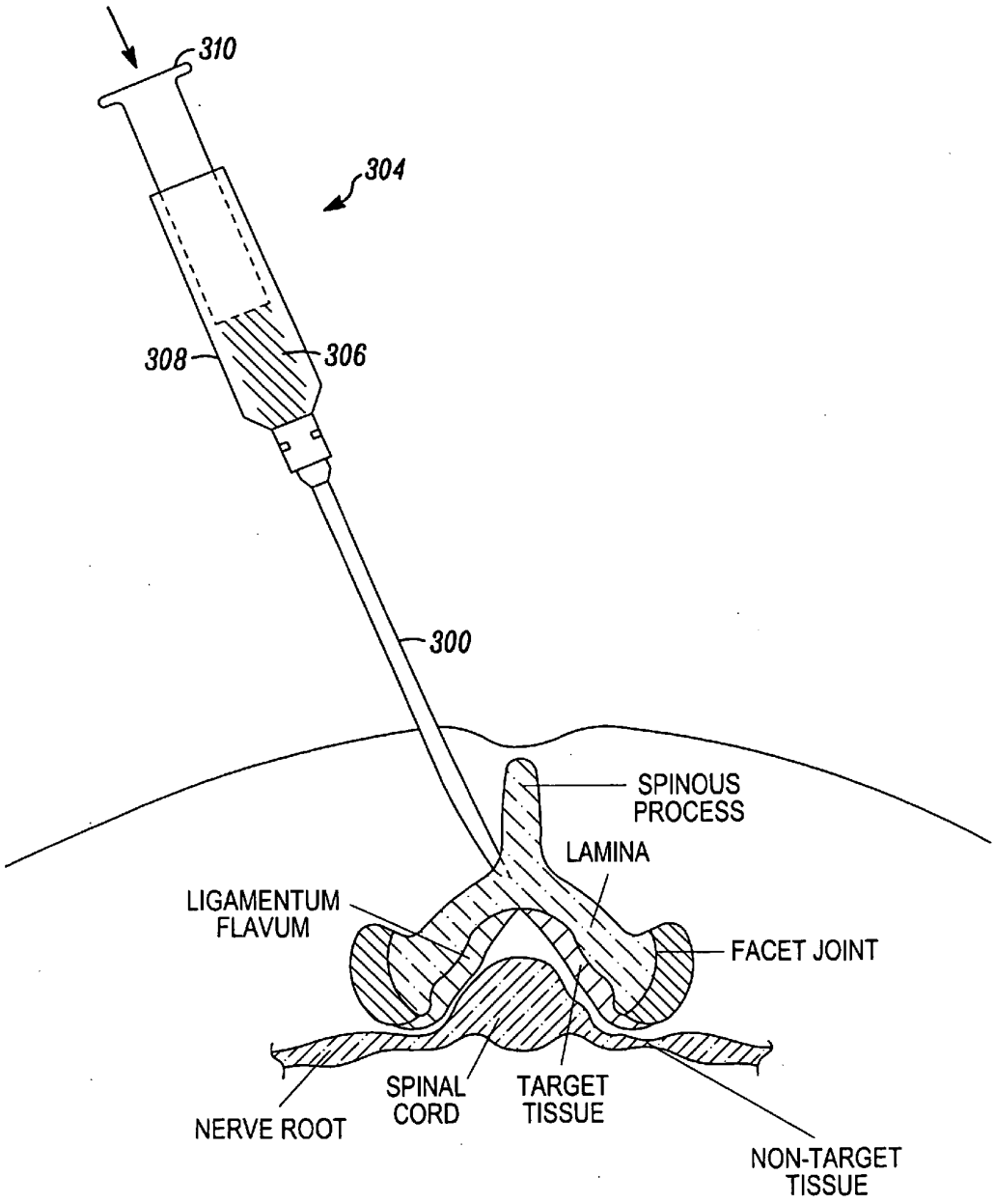

302
300
SPINOUS PROCESS
LAMINA
LIGAMENTUM FLAVUM
FACET JOINT
SPINAL CORD
TARGET TISSUE
NERVE ROOT
NON-TARGET TISSUE

FIG. 7C


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

FIG. 7D

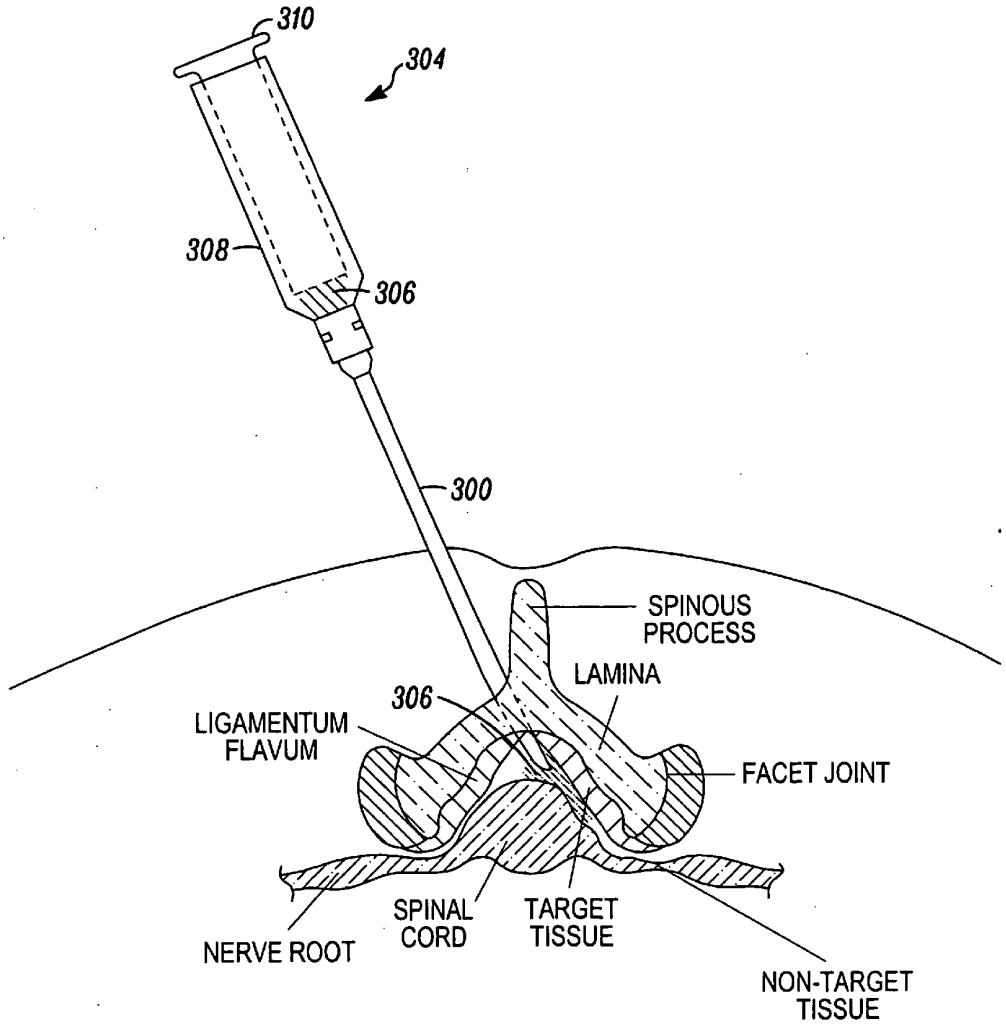

310
304
308
306
300
SPINOUS PROCESS
LAMINA
306
LIGAMENTUM FLAVUM
FACET JOINT
SPINAL CORD
TARGET TISSUE
NERVE ROOT
NON-TARGET TISSUE

FIG. 7E

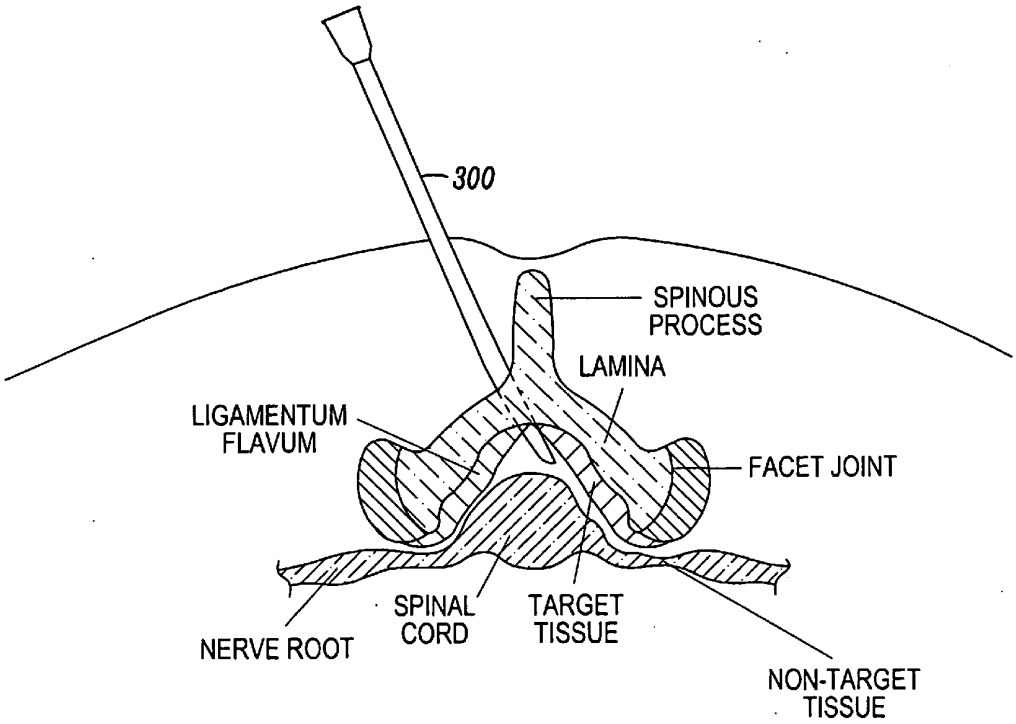

300
SPINOUS PROCESS
LAMINA
LIGAMENTUM FLAVUM
FACET JOINT
SPINAL CORD
TARGET TISSUE
NERVE ROOT
NON-TARGET TISSUE

FIG. 7F

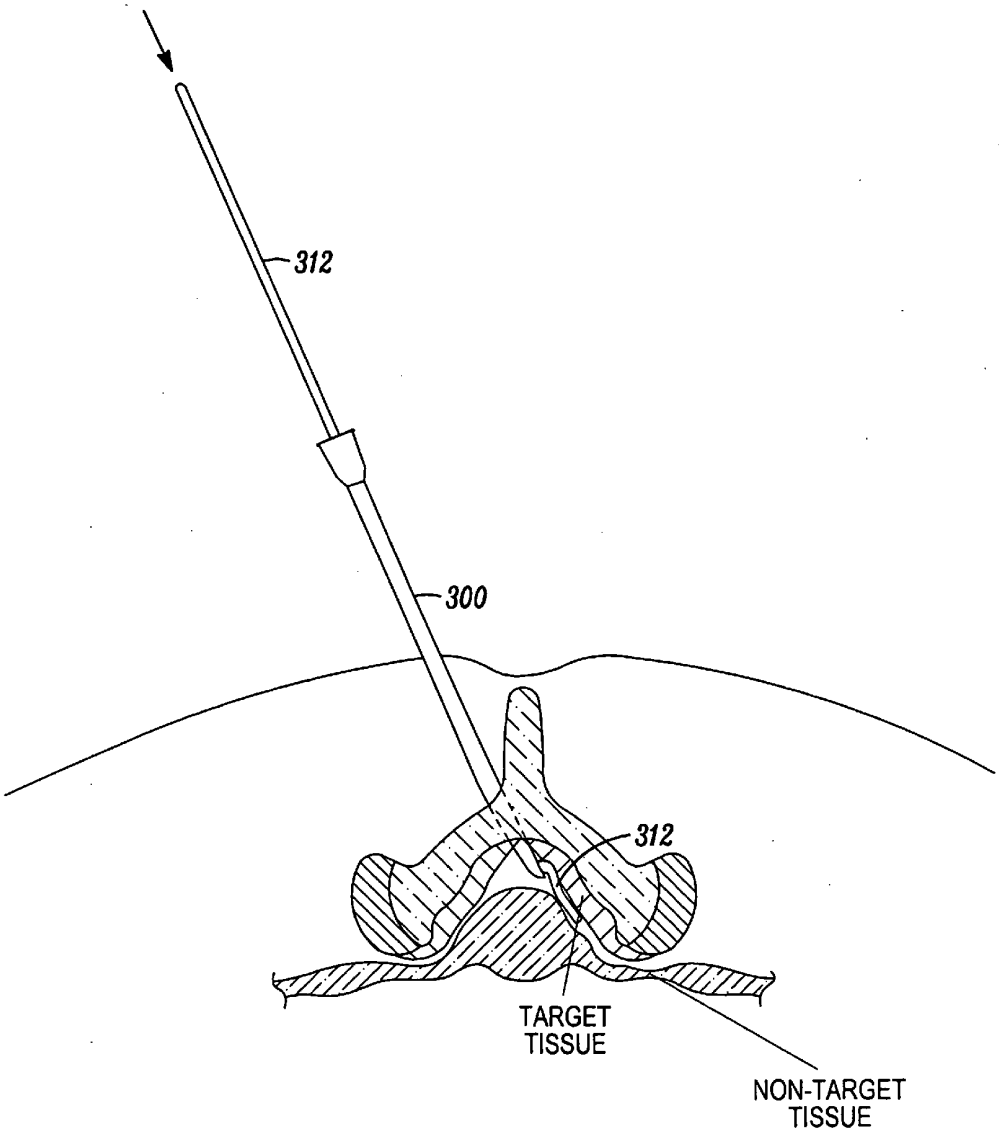


FIG. 7G

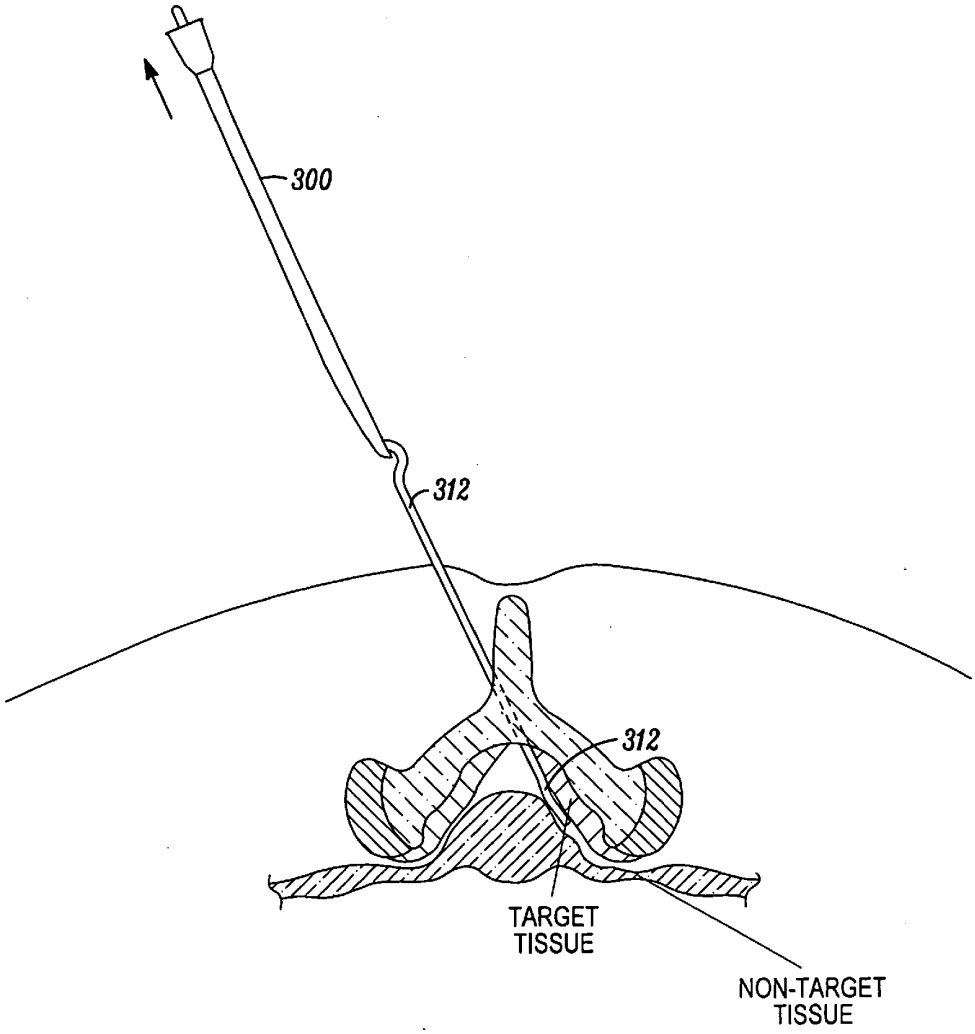


FIG. 7H

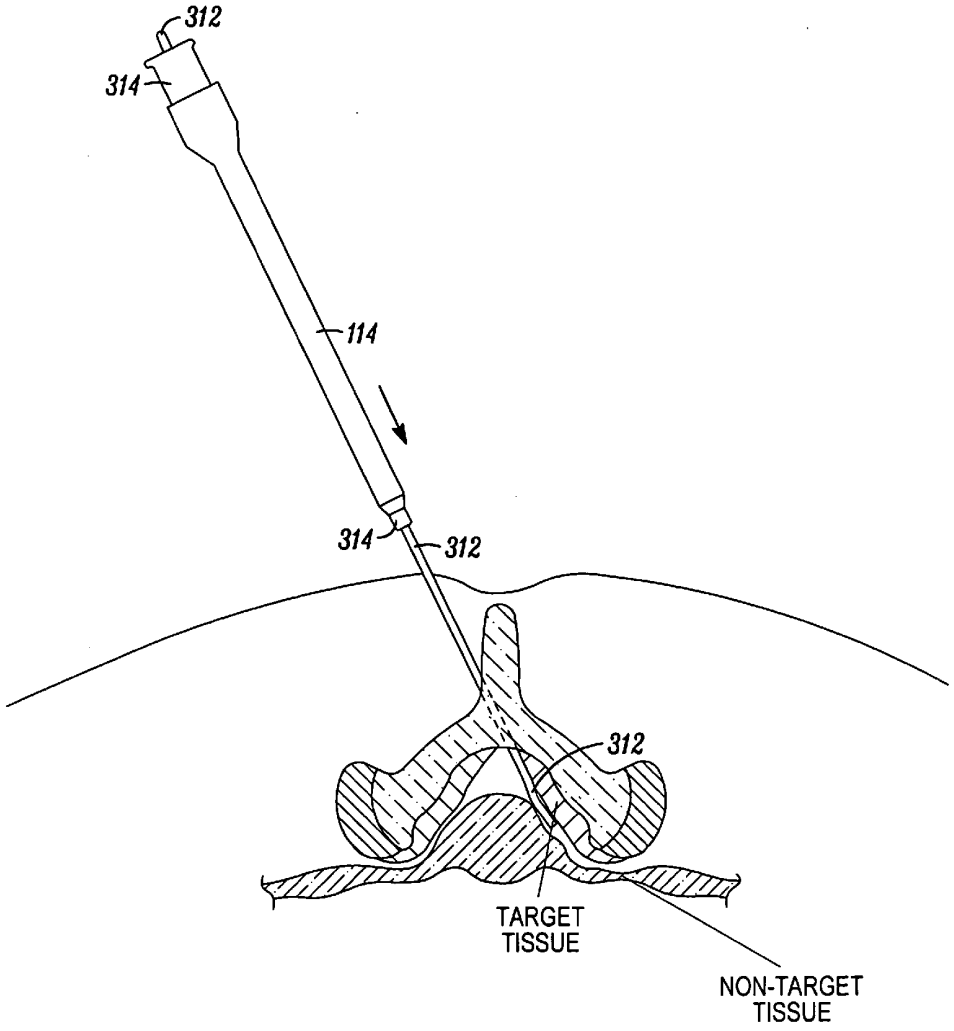


FIG. 7I

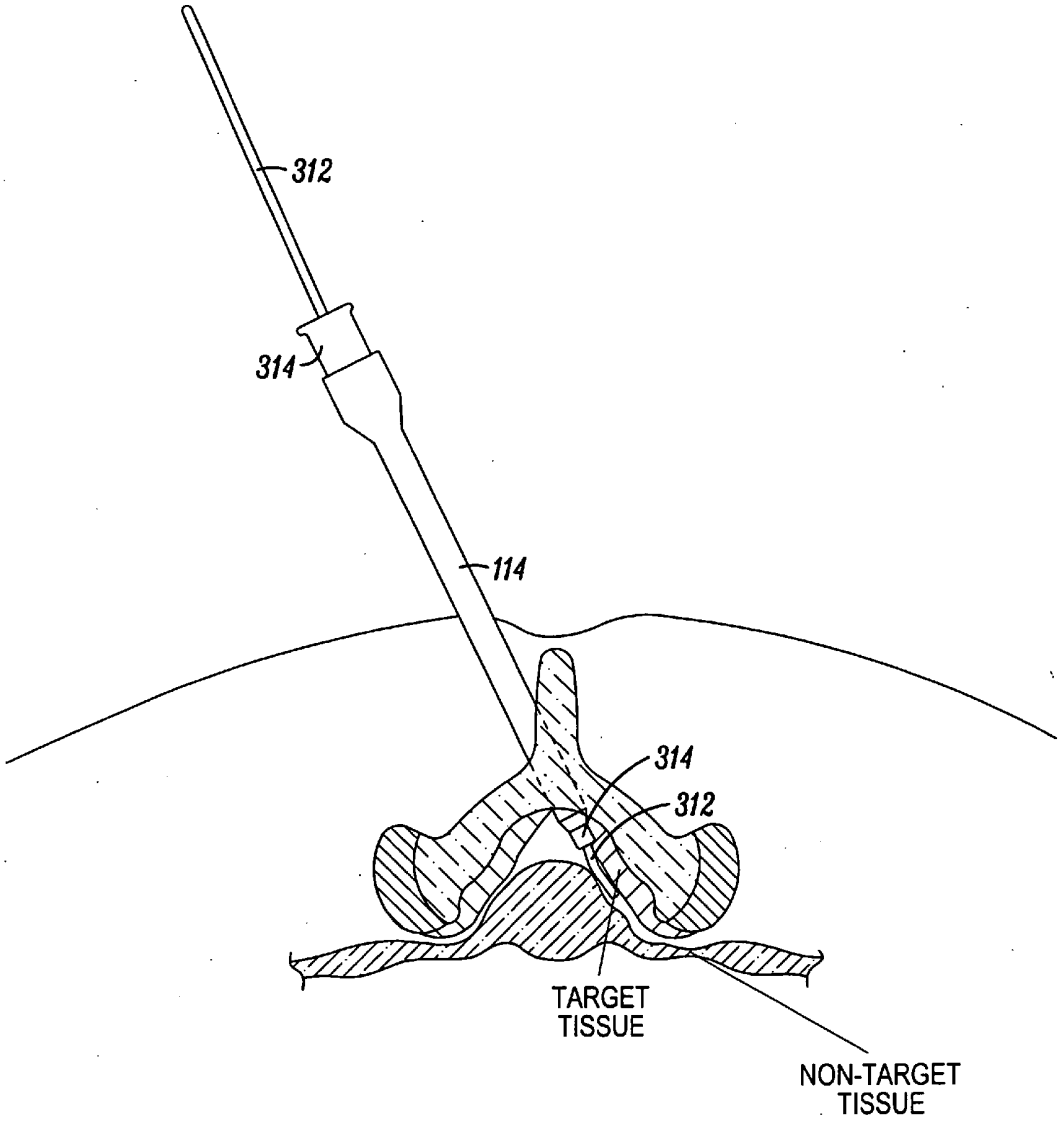


FIG. 7J

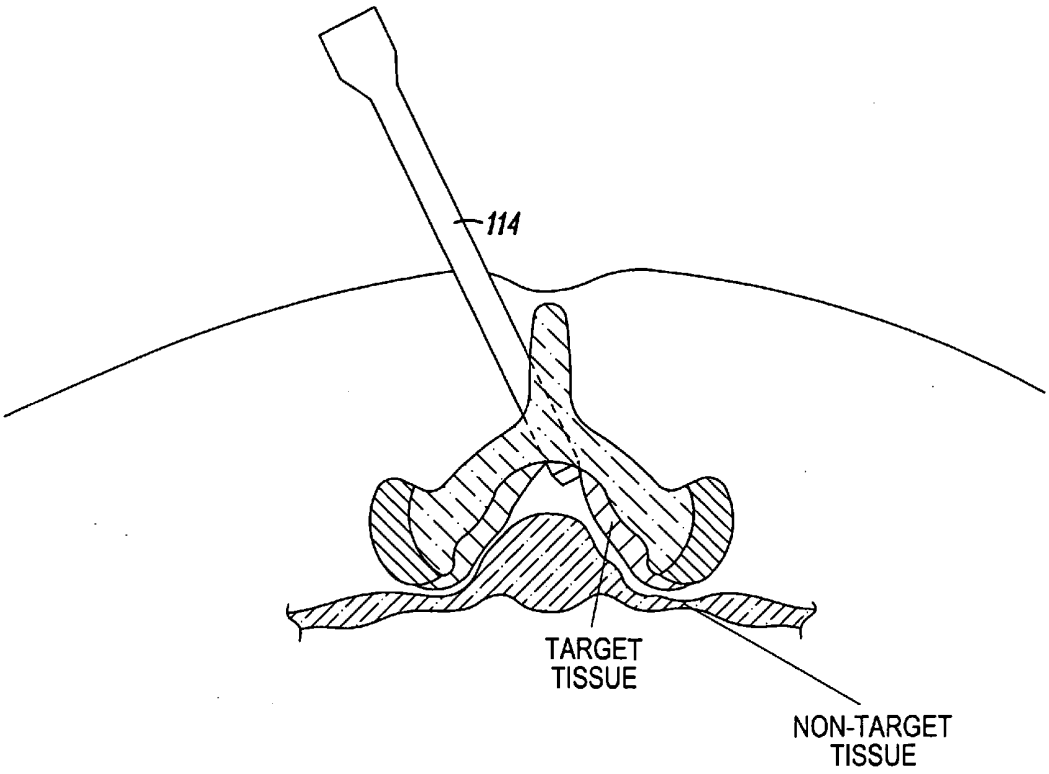


FIG. 7K

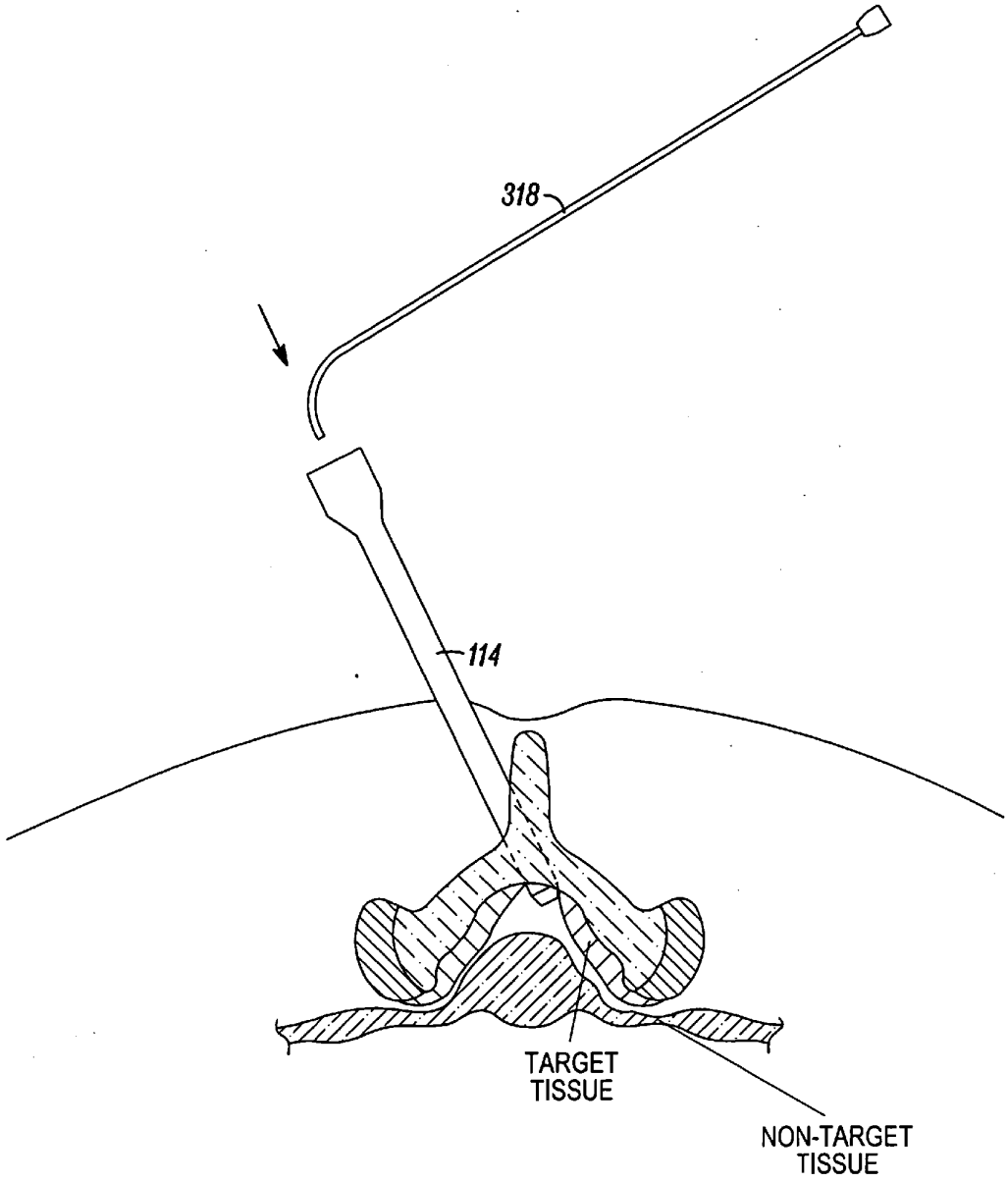


FIG. 7L

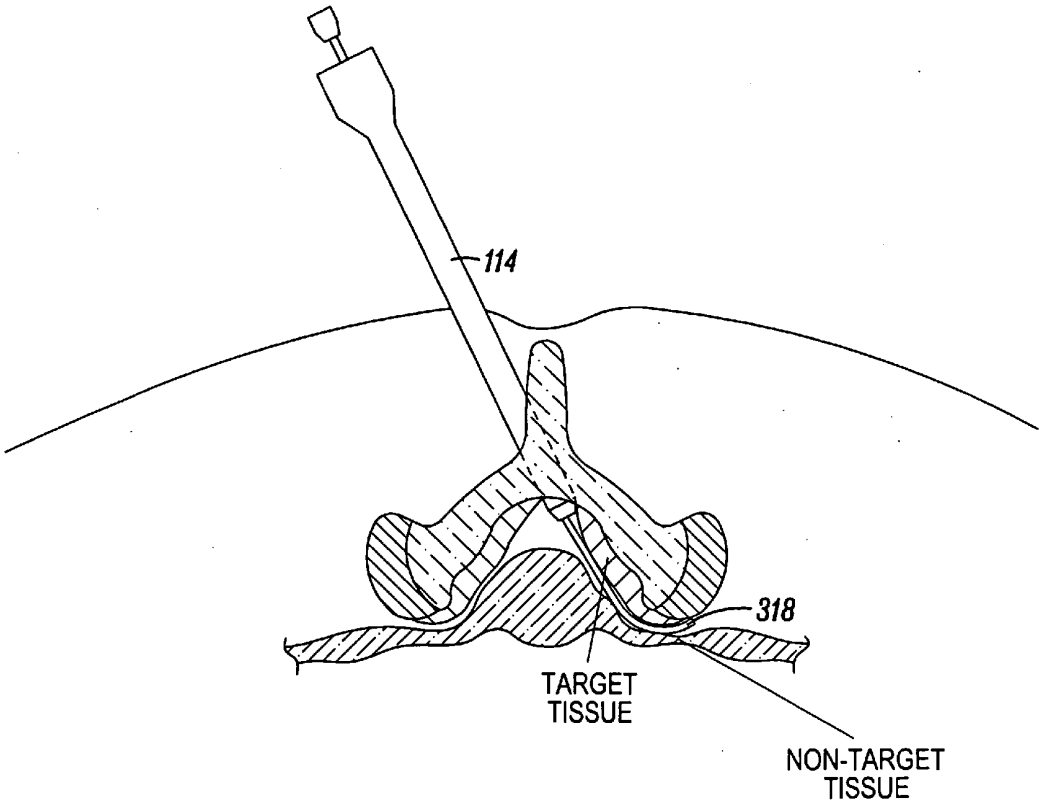


FIG. 7M

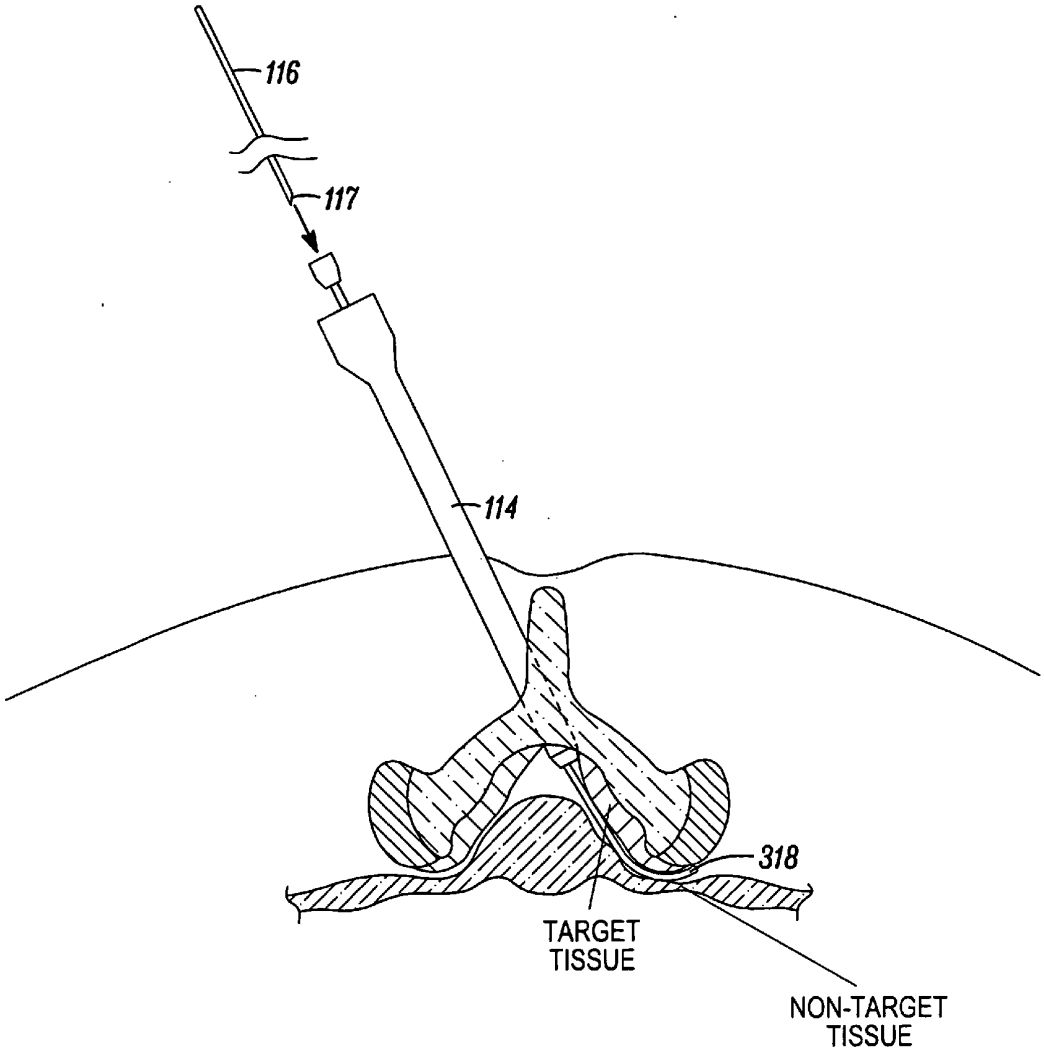


FIG. 7N

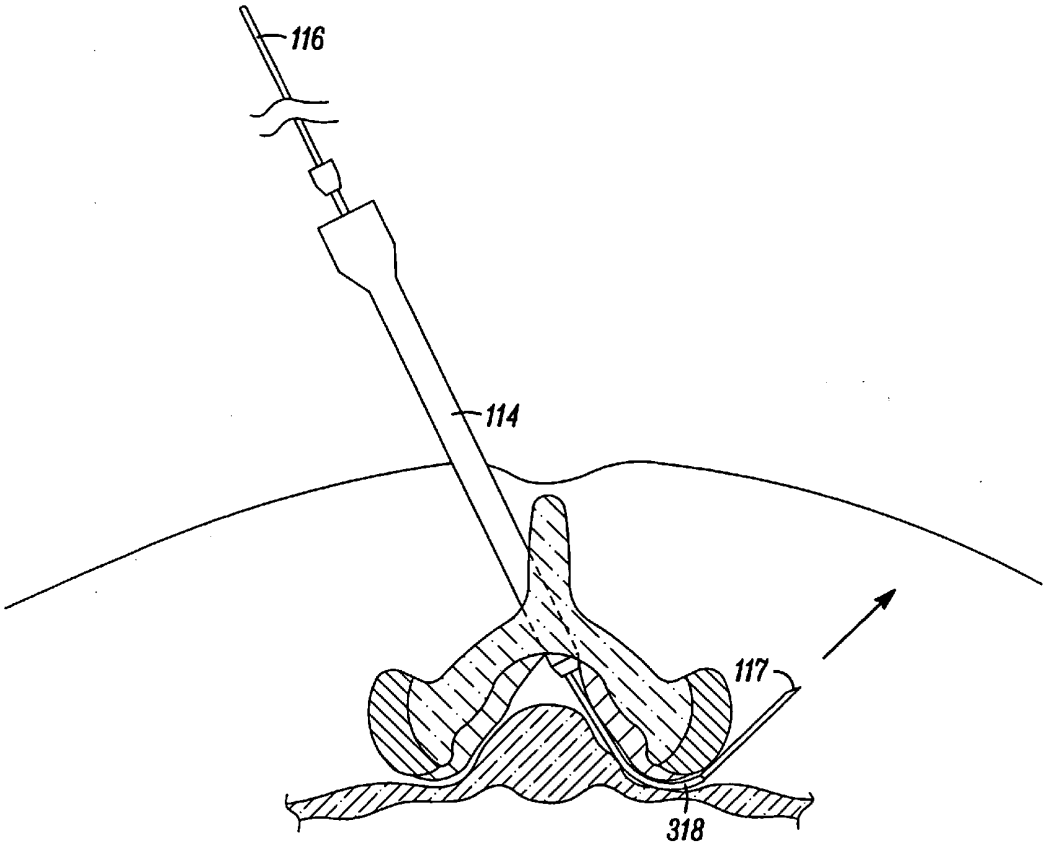


FIG. 7O

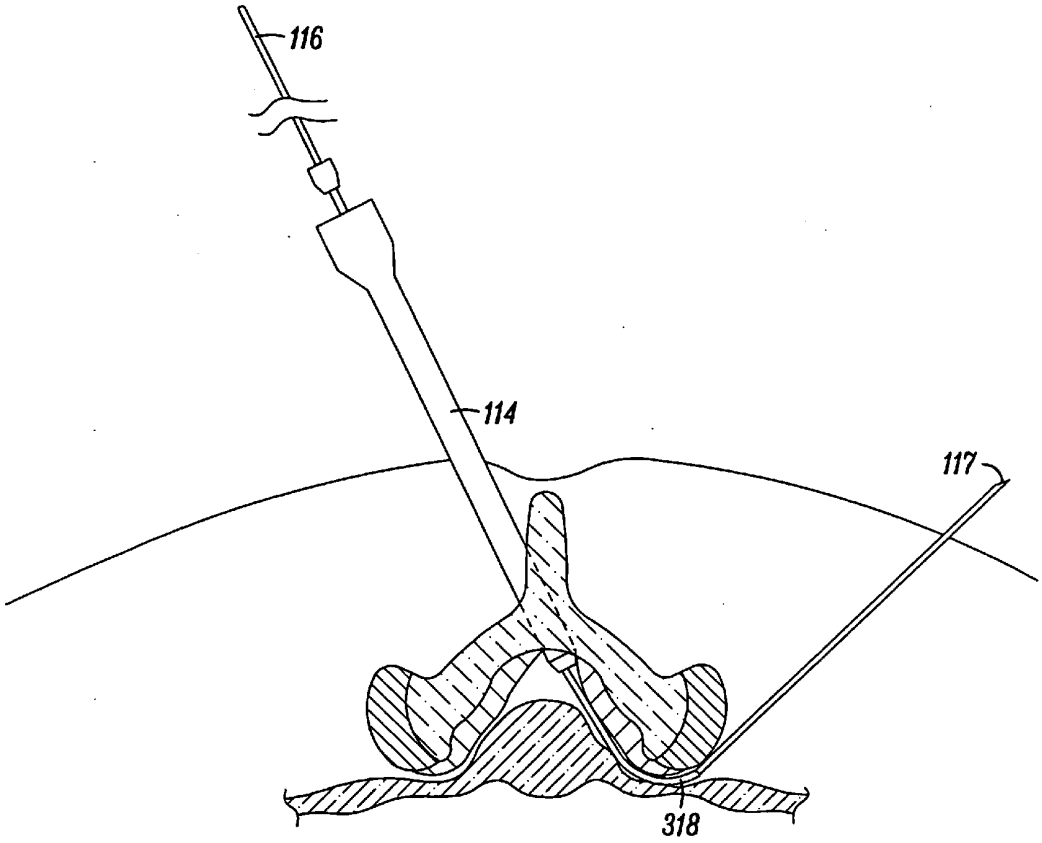


FIG. 7P

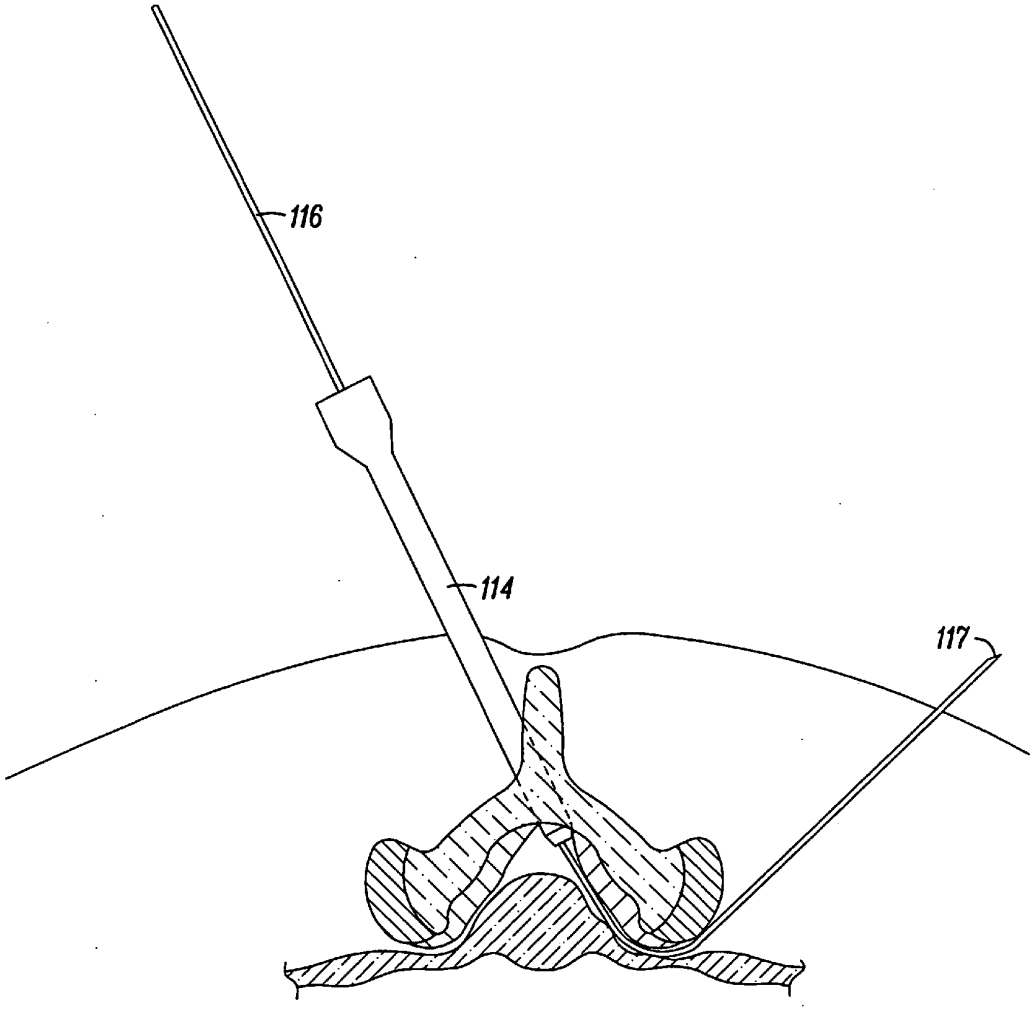


FIG. 7Q

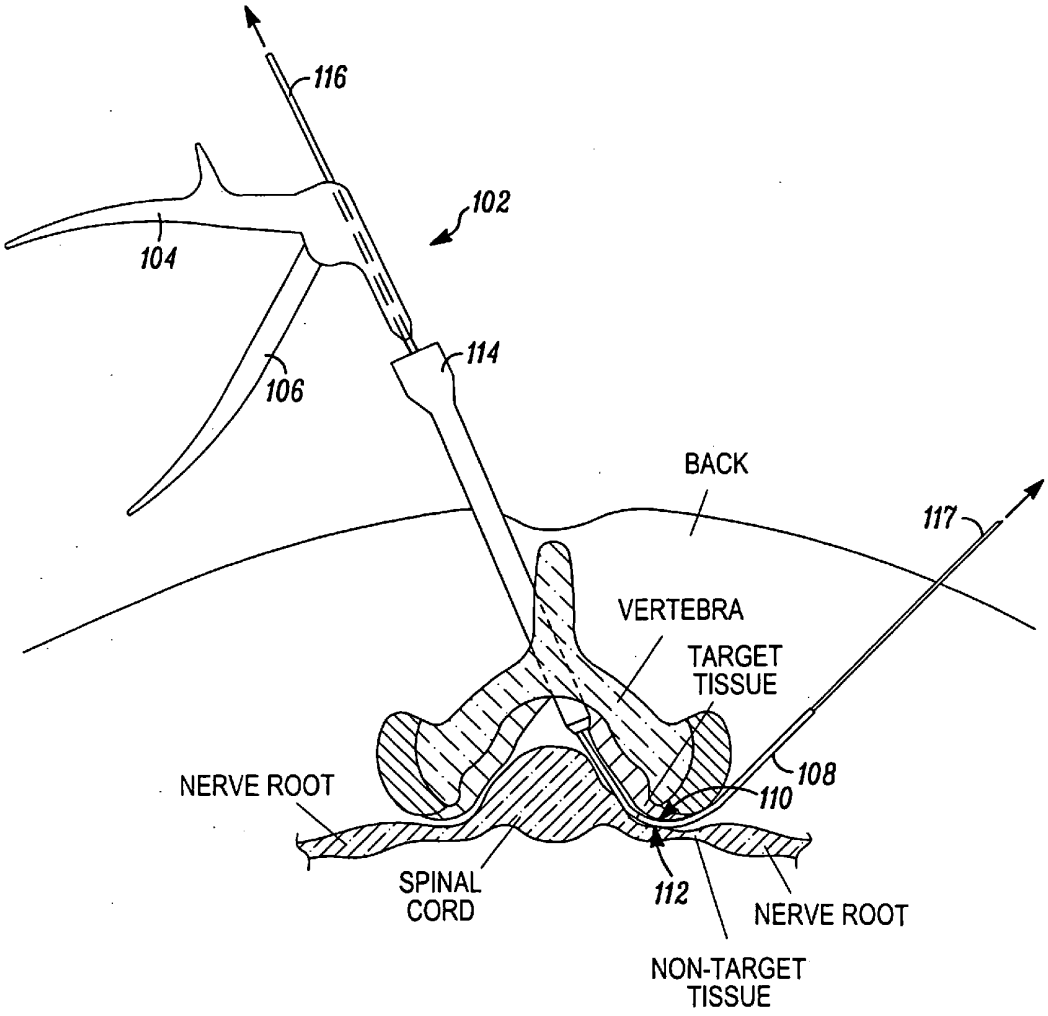
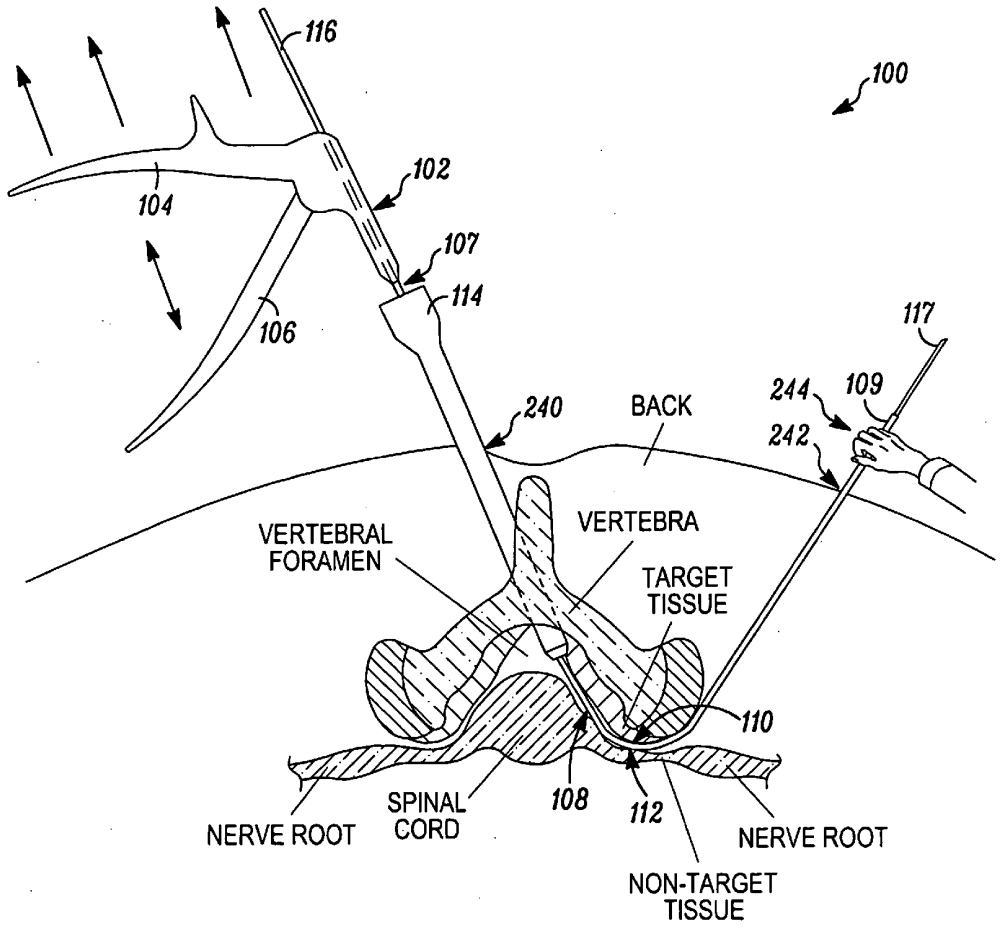

116
102
104
114
106
BACK
117
VERTEBRA
TARGET TISSUE
108
110
NERVE ROOT
SPINAL CORD
112
NERVE ROOT
NON-TARGET TISSUE

FIG. 7R


116
100
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BACK
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242
VERTEBRAL FORAMEN
VERTEBRA
TARGET TISSUE
110
108
112
SPINAL CORD
NERVE ROOT
NERVE ROOT
NON-TARGET TISSUE

FIG. 7S

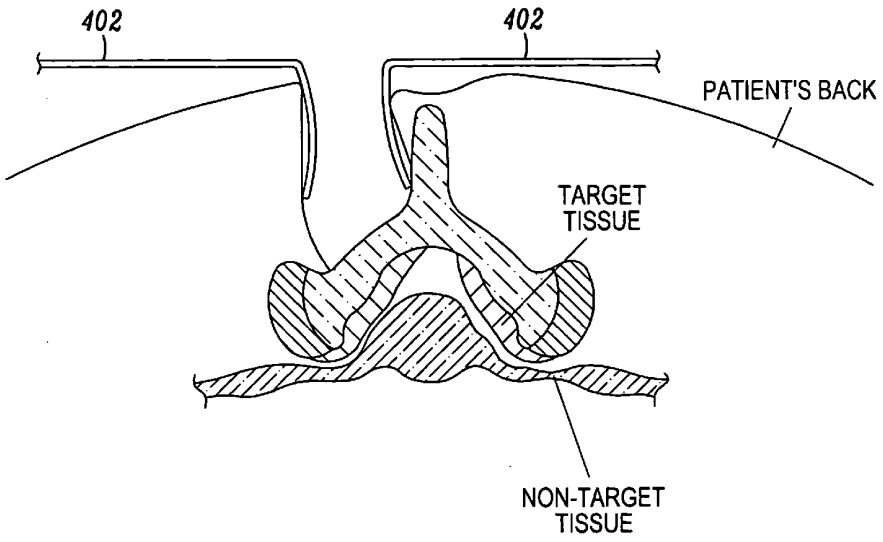

402
402
PATIENT'S BACK
TARGET TISSUE
NON-TARGET TISSUE

FIG. 8A

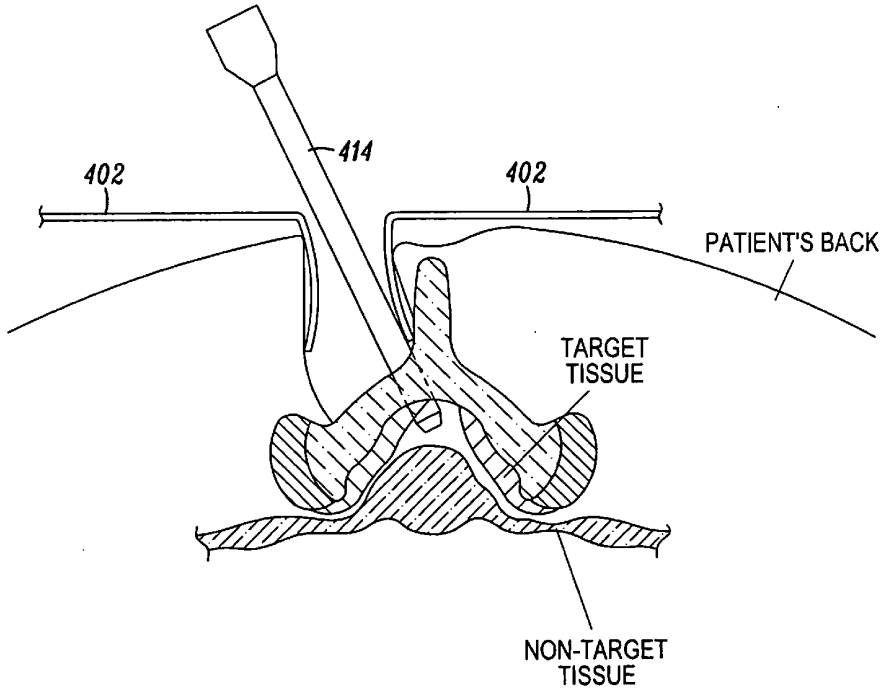

414
402
402
PATIENT'S BACK
TARGET TISSUE
NON-TARGET TISSUE

FIG. 8B

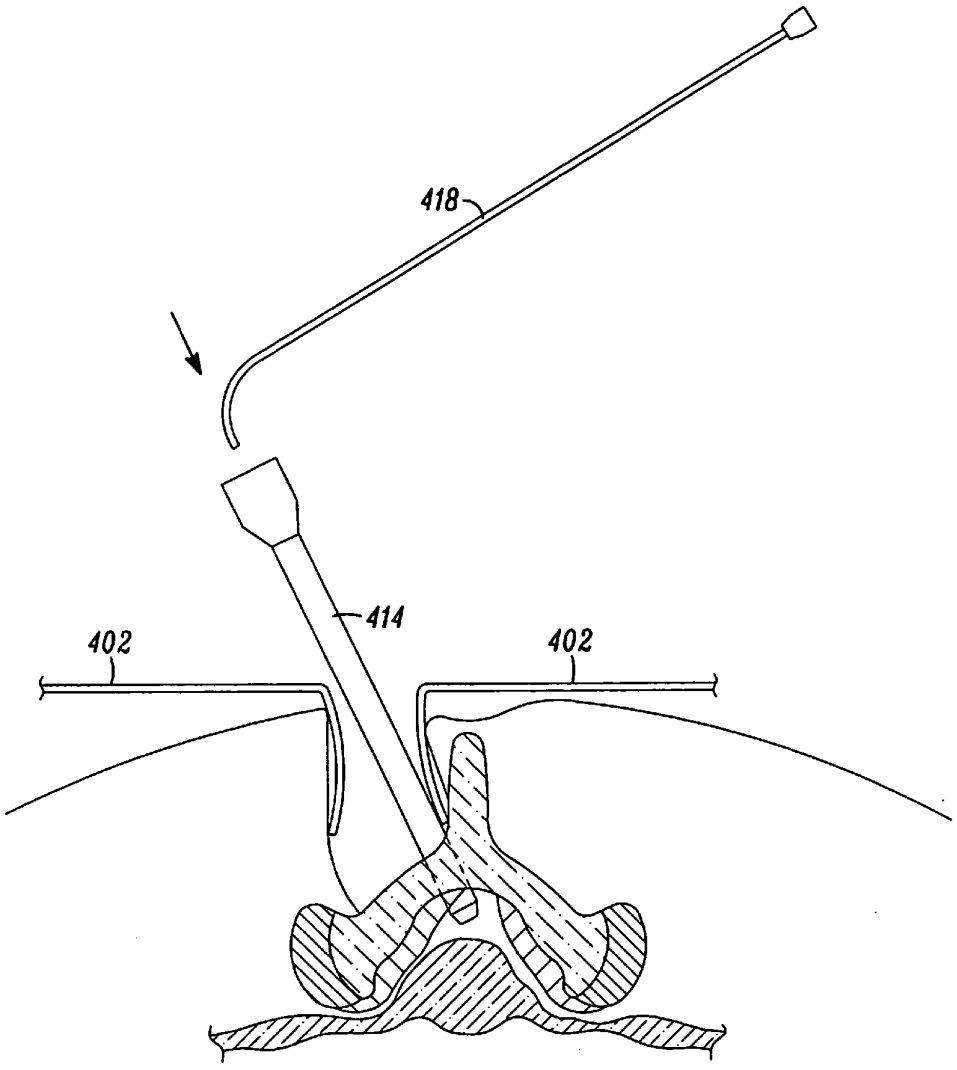


FIG. 8C

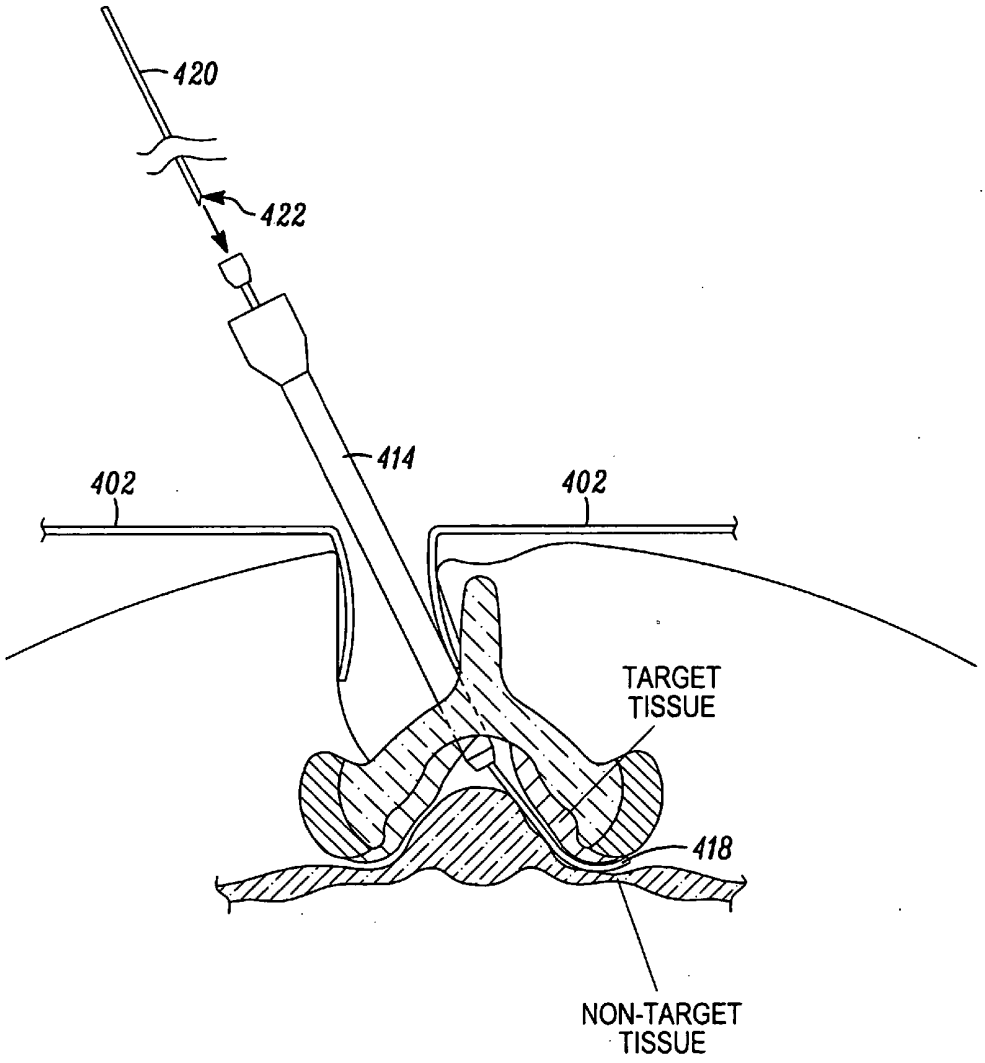


FIG. 8D

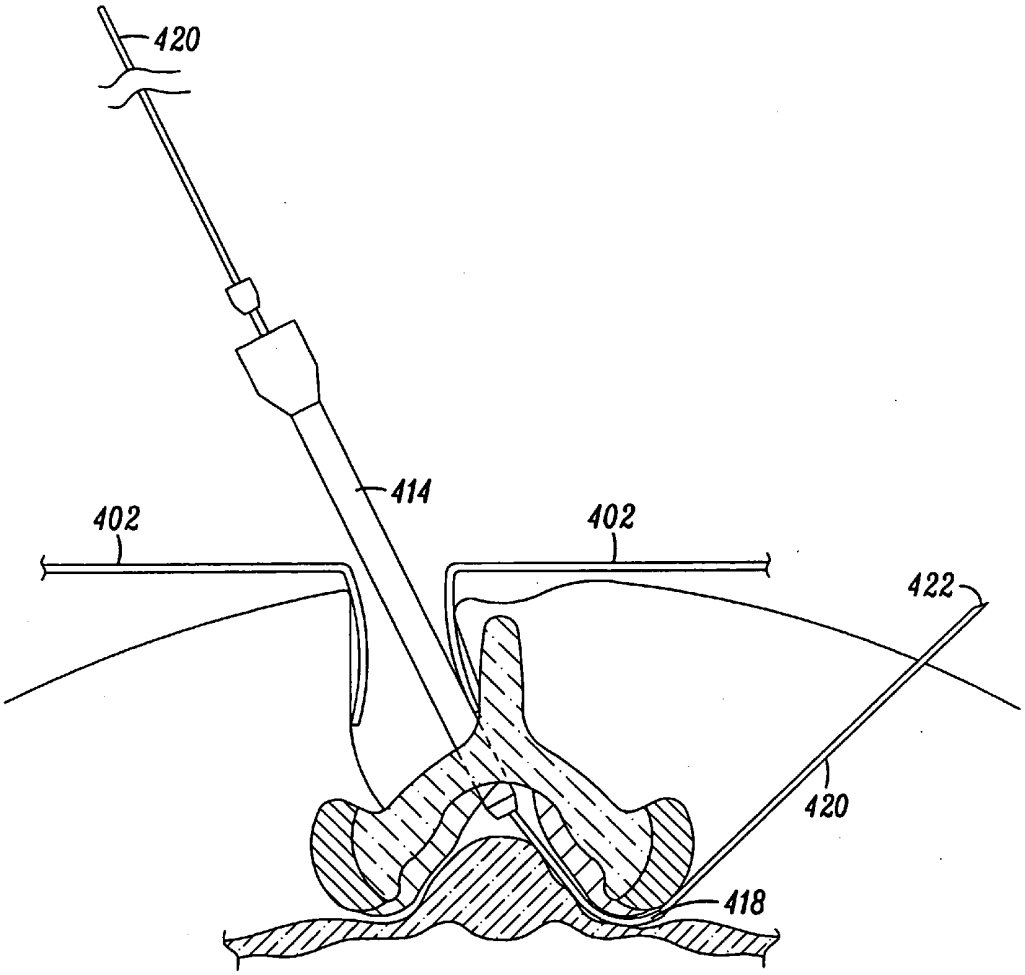


FIG. 8E

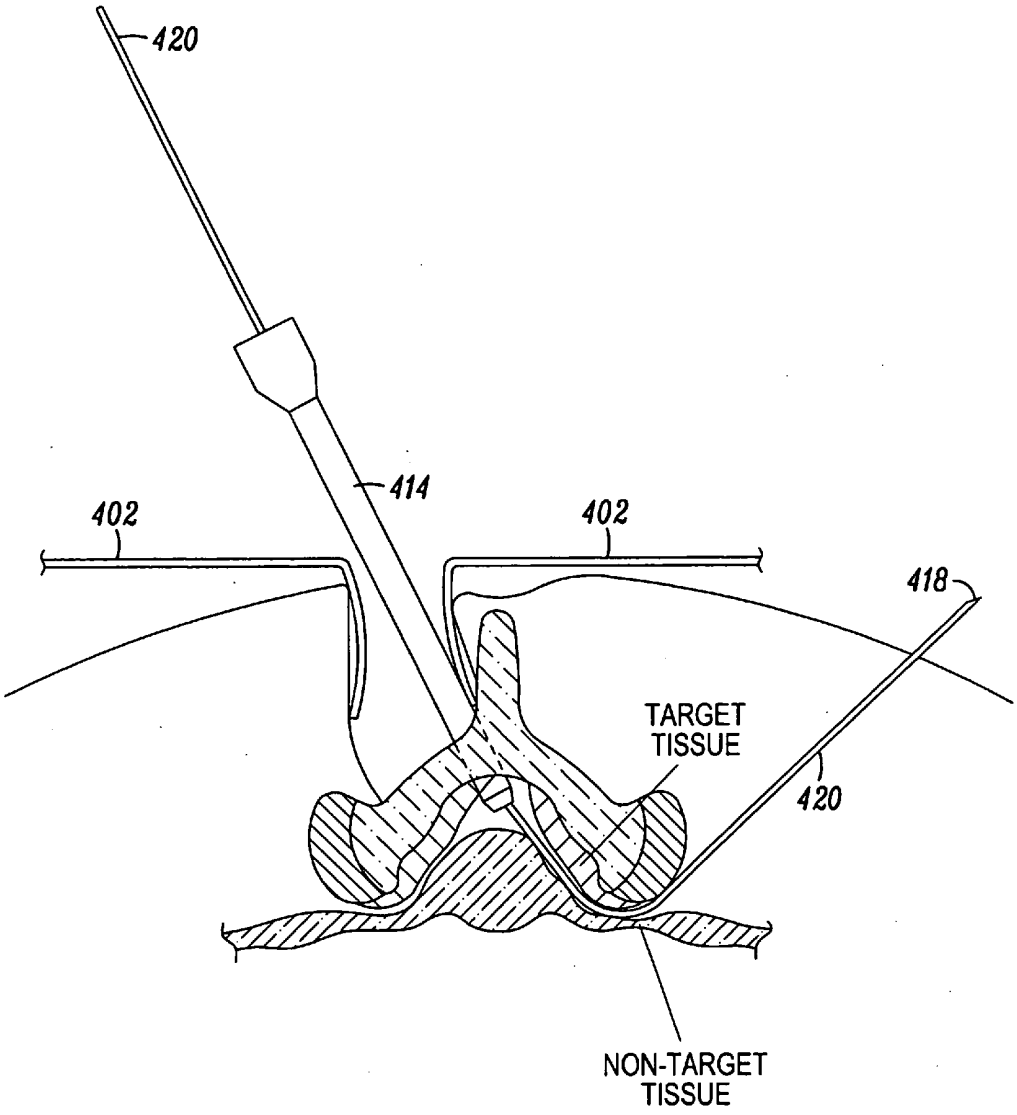


FIG. 8F

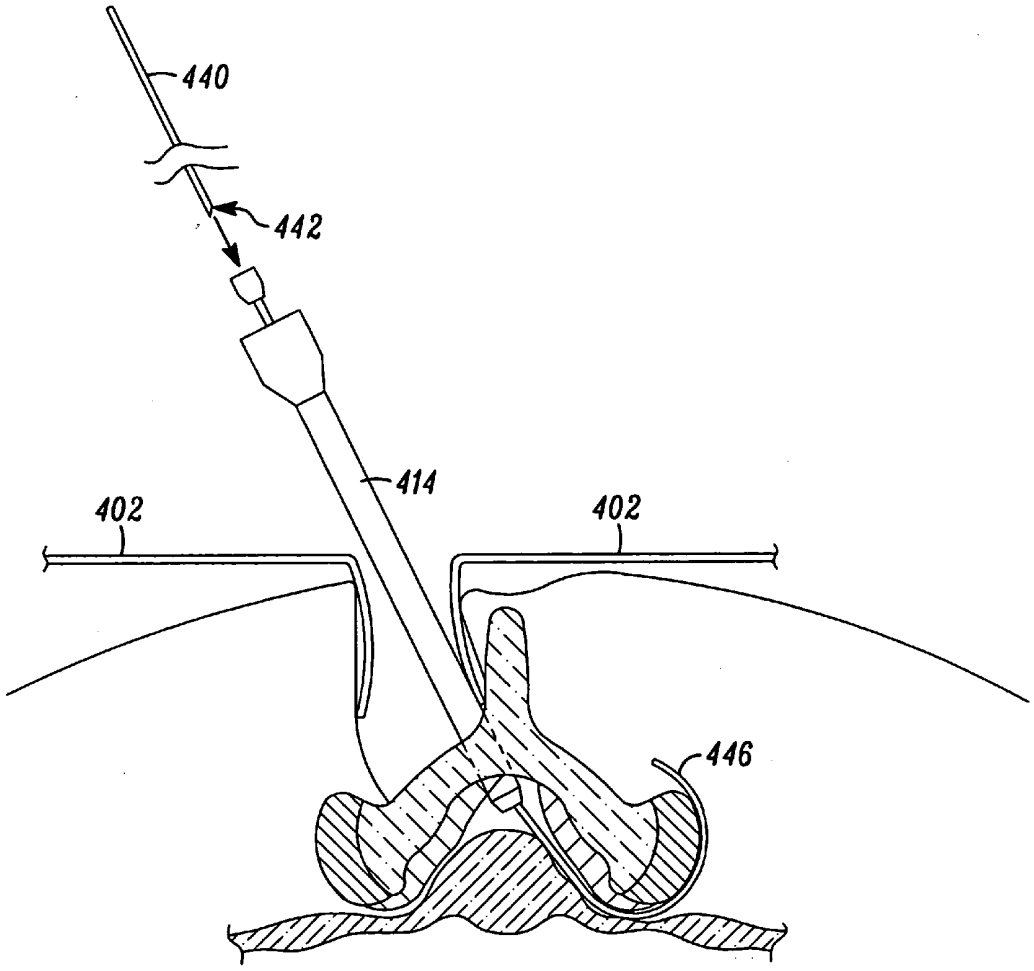


FIG. 9A

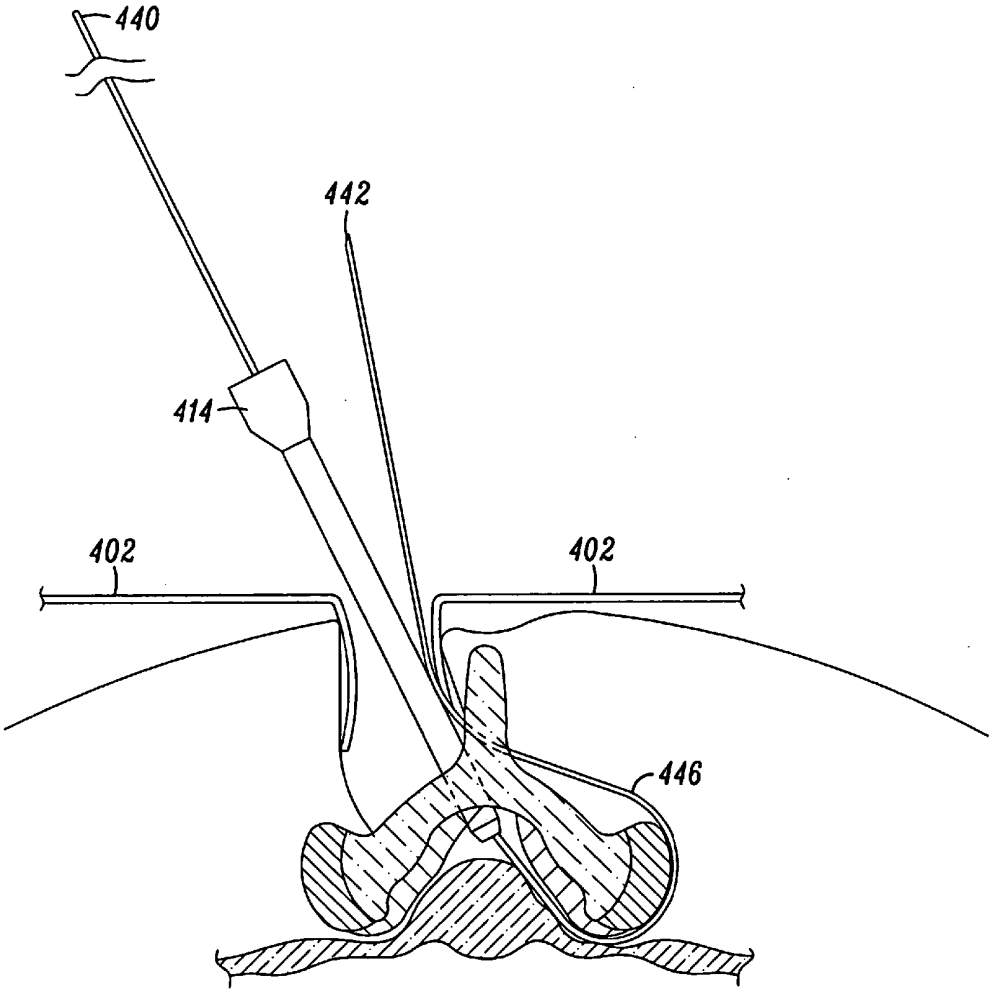


FIG. 9B

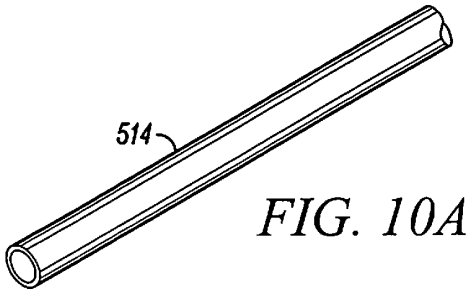


FIG. 10A

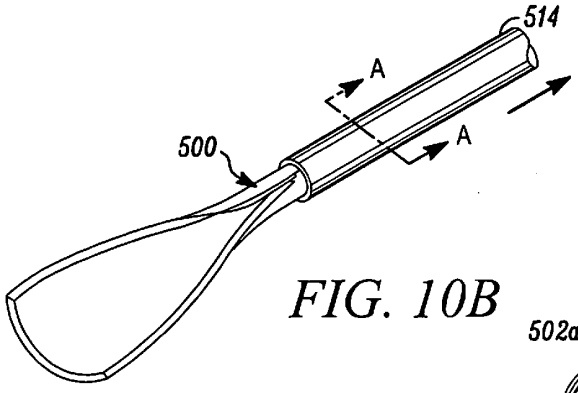
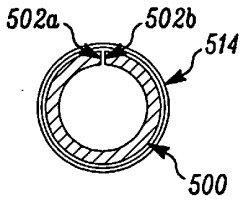


FIG. 10B



SECTION A-A

FIG. 10C

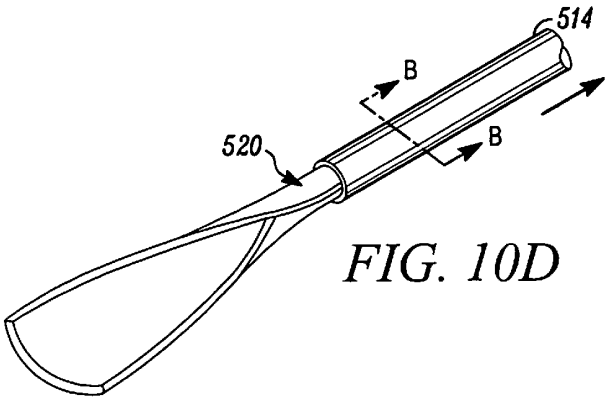
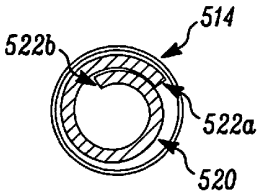


FIG. 10D



SECTION B-B

FIG. 10E

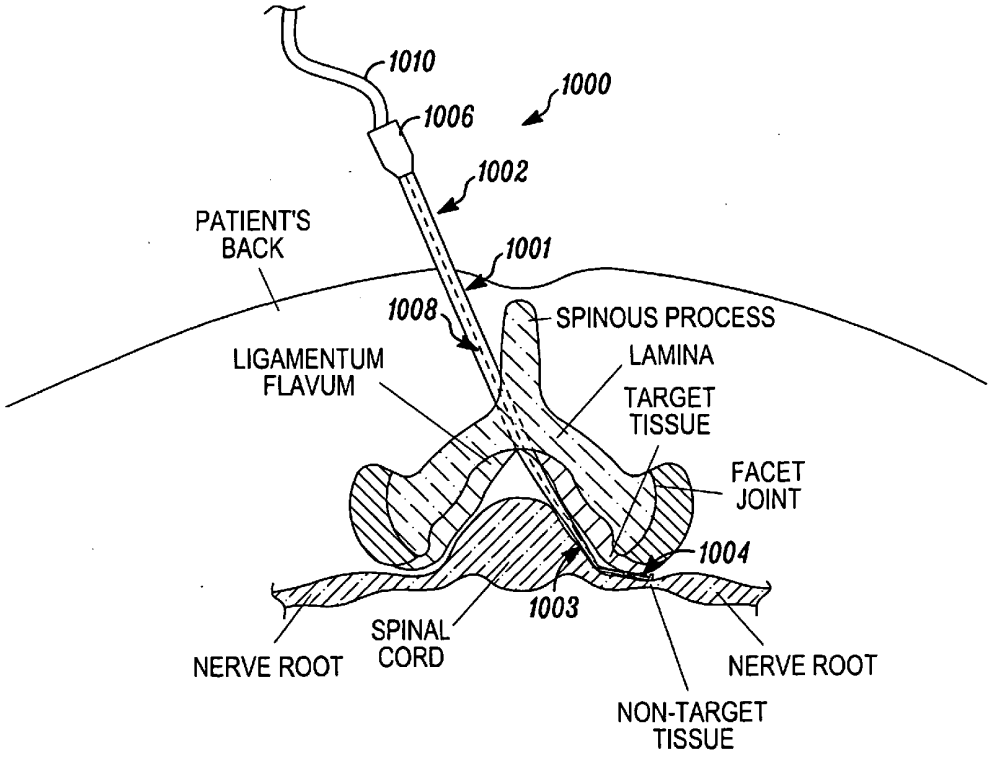

1010
1000
1006
1002
PATIENT'S BACK
1001
1008
SPINOUS PROCESS
LIGAMENTUM FLAVUM
LAMINA
TARGET TISSUE
FACET JOINT
1004
1003
SPINAL CORD
NERVE ROOT
NERVE ROOT
NON-TARGET TISSUE

FIG. 11A

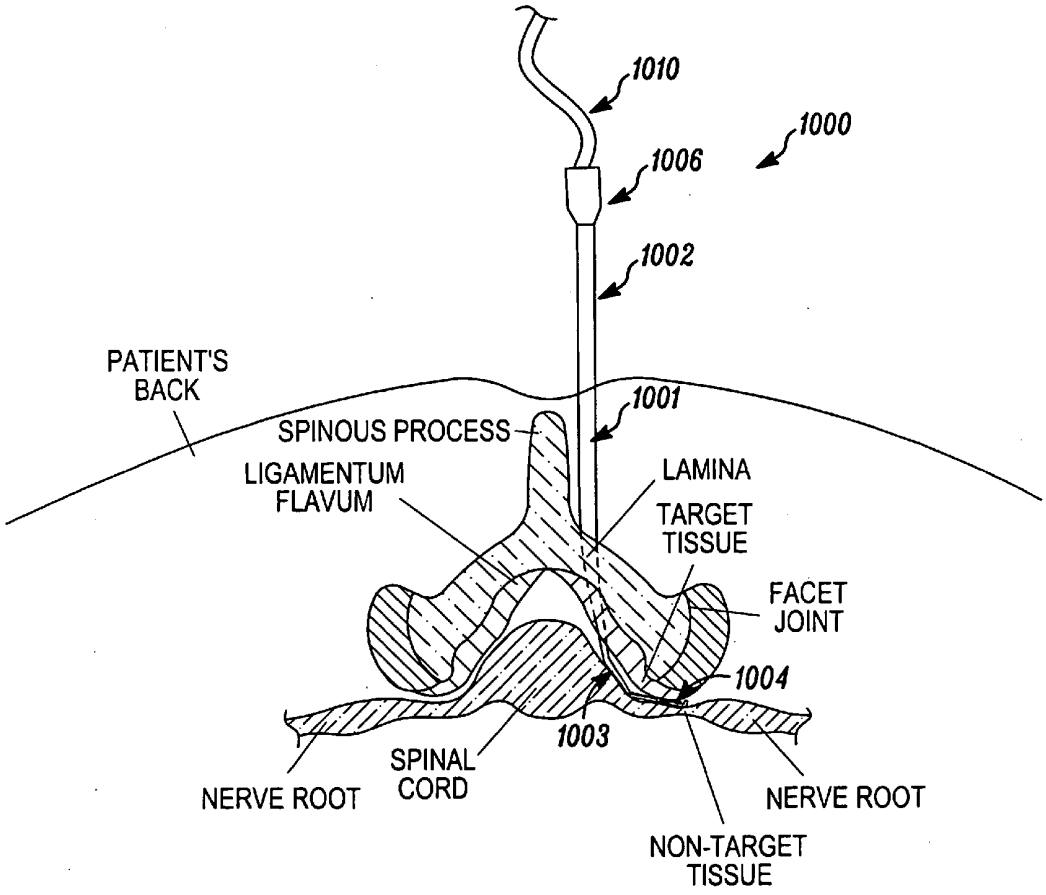

1010
1000
1006
1002
PATIENT'S BACK
1001
SPINOUS PROCESS
LIGAMENTUM FLAVUM
LAMINA
TARGET TISSUE
FACET JOINT
1004
1003
SPINAL CORD
NERVE ROOT
NERVE ROOT
NON-TARGET TISSUE

FIG. 11B

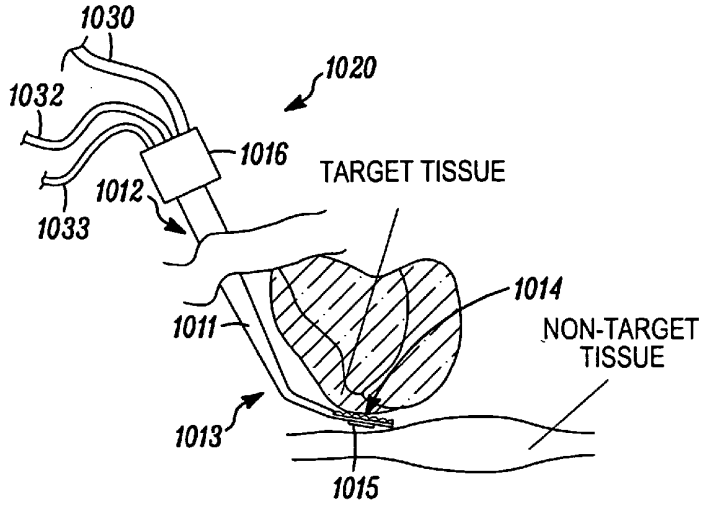


FIG. 12

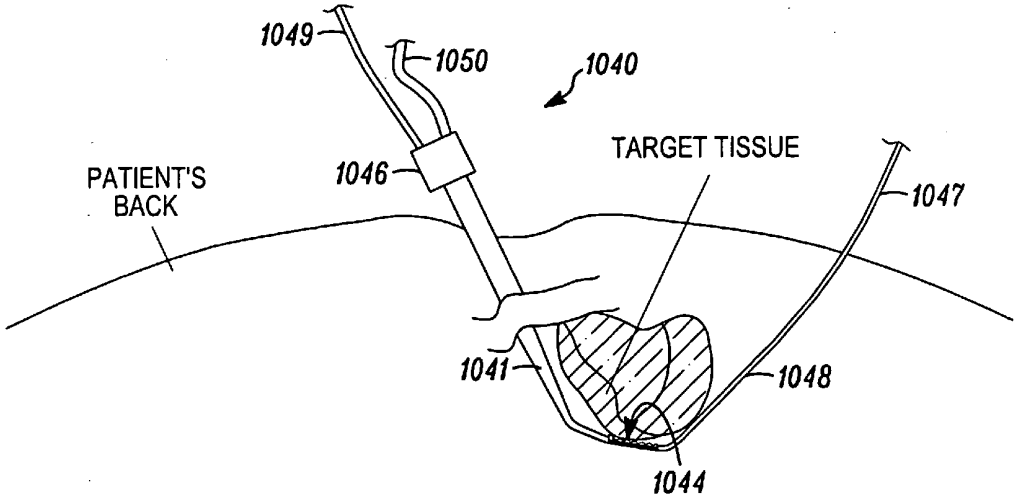


FIG. 13A

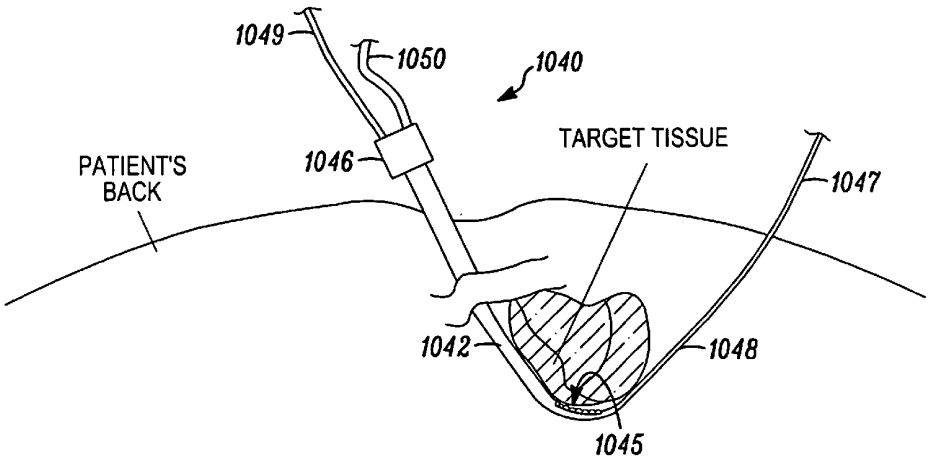


FIG. 13B

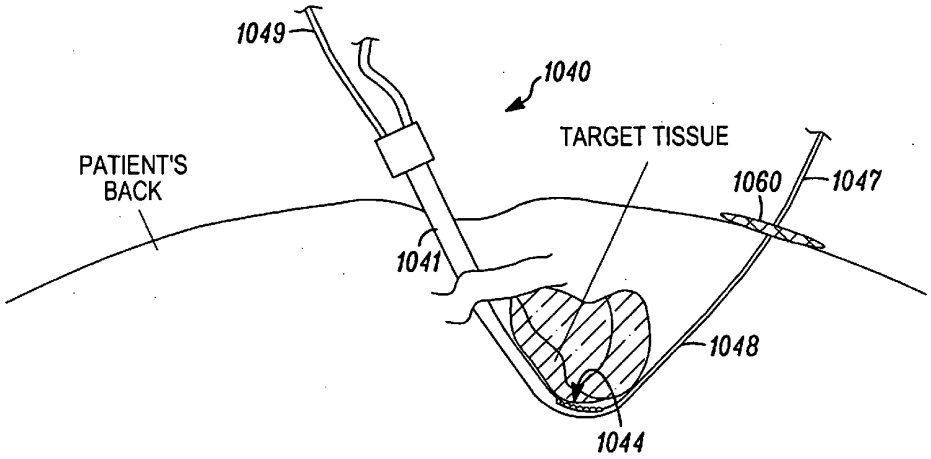


FIG. 13C

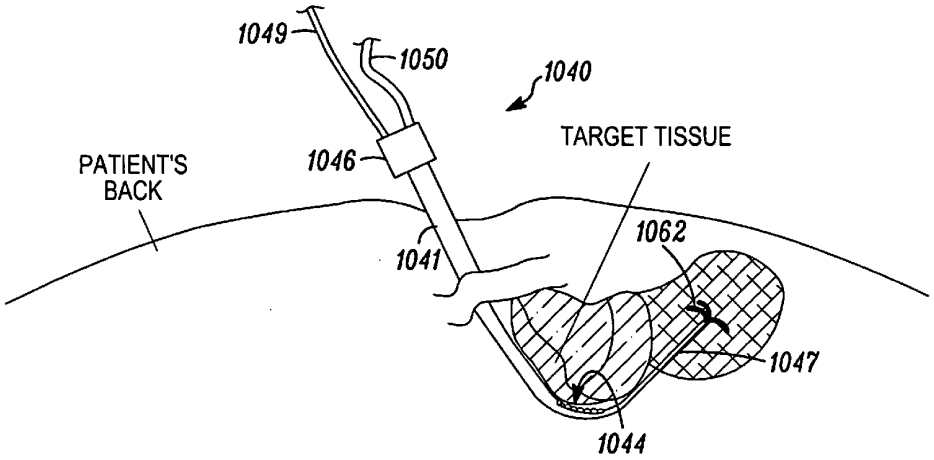


FIG. 13D

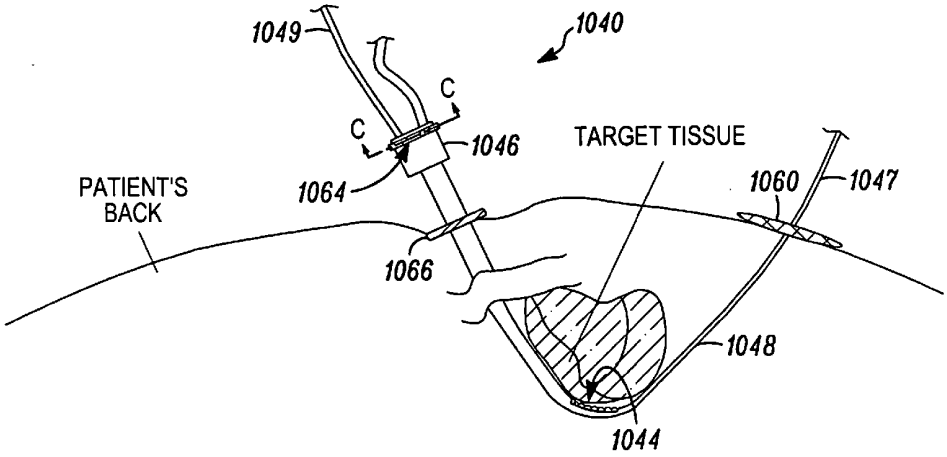


FIG. 13E

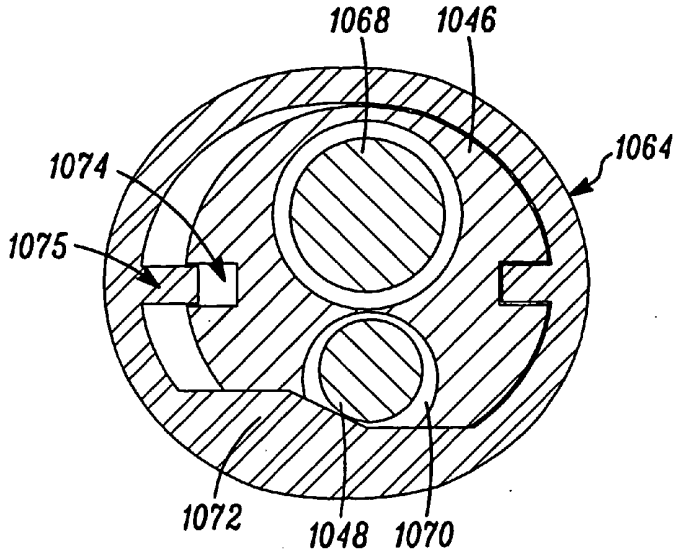


FIG. 13F

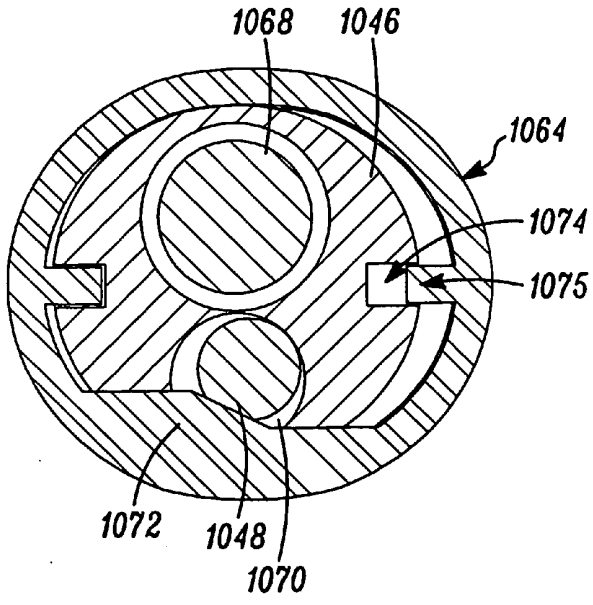


FIG. 13G

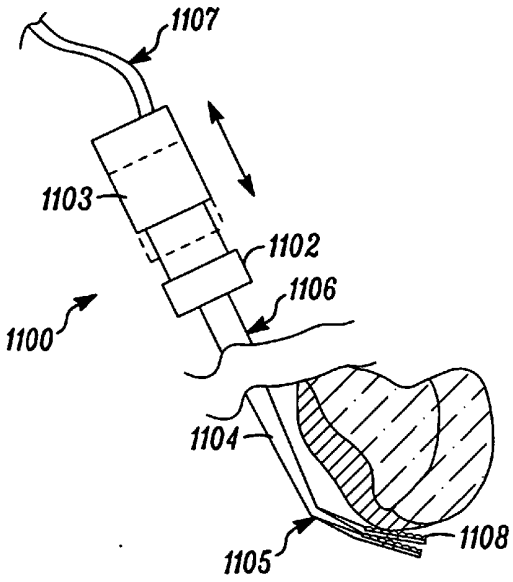


FIG. 14

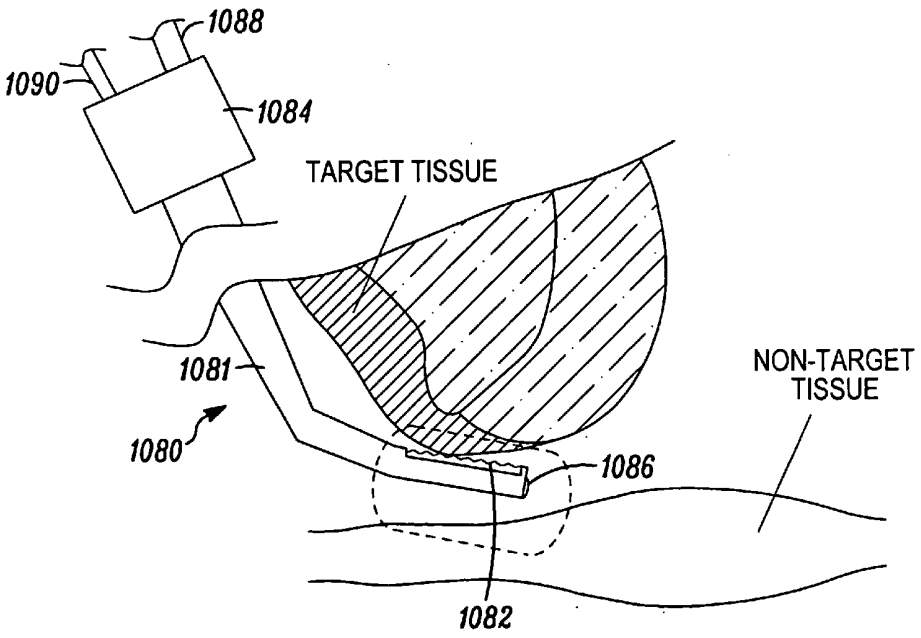


FIG. 15A

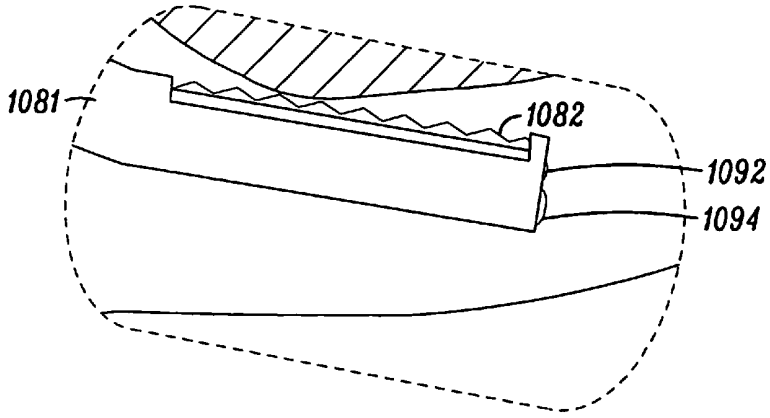


FIG. 15B

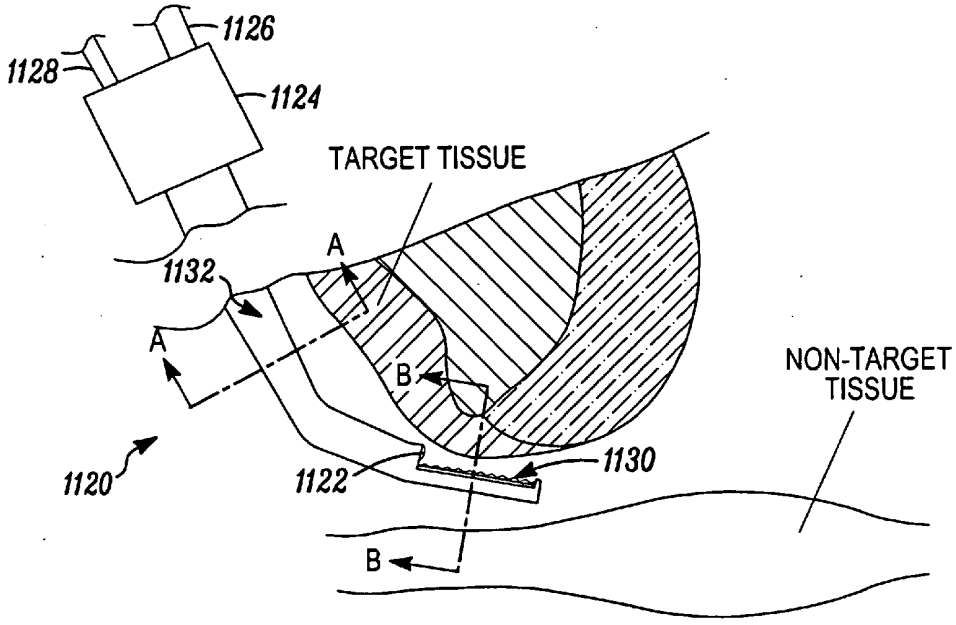


FIG. 16

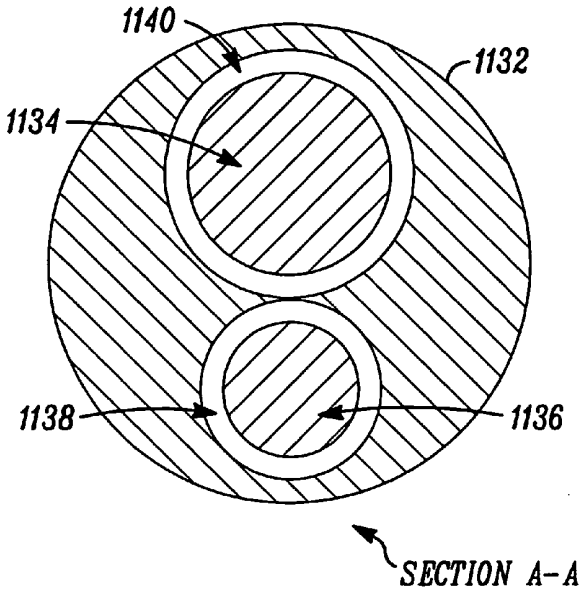


FIG. 17A

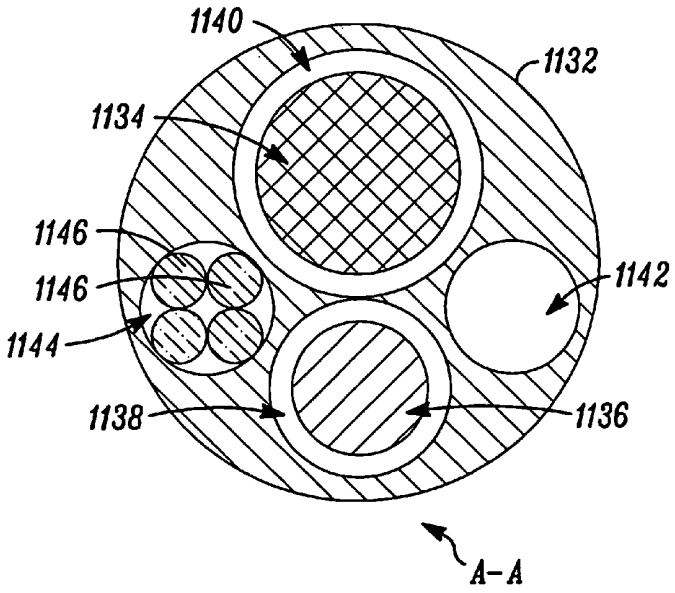


FIG. 17B

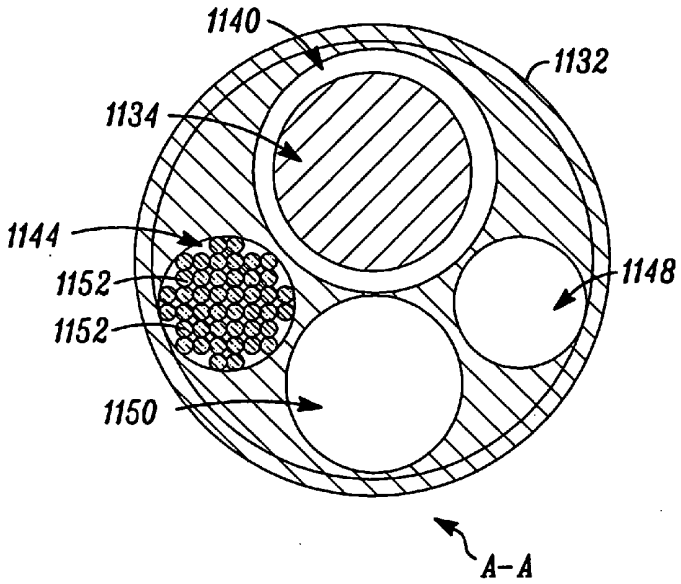


FIG. 17C

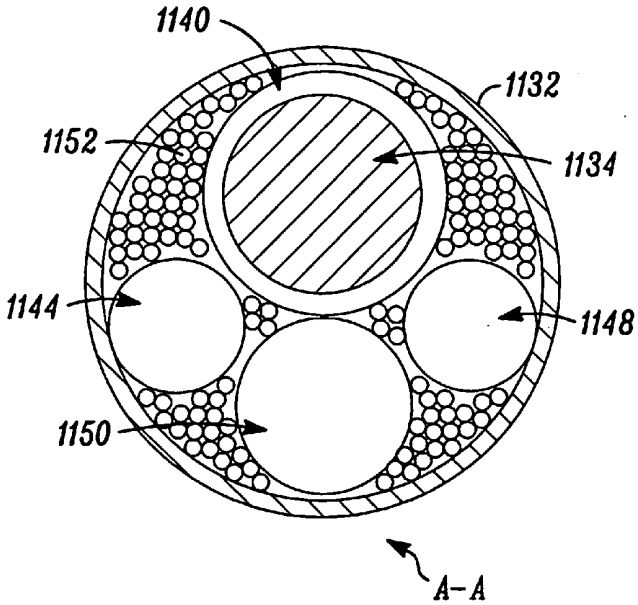


FIG. 17D

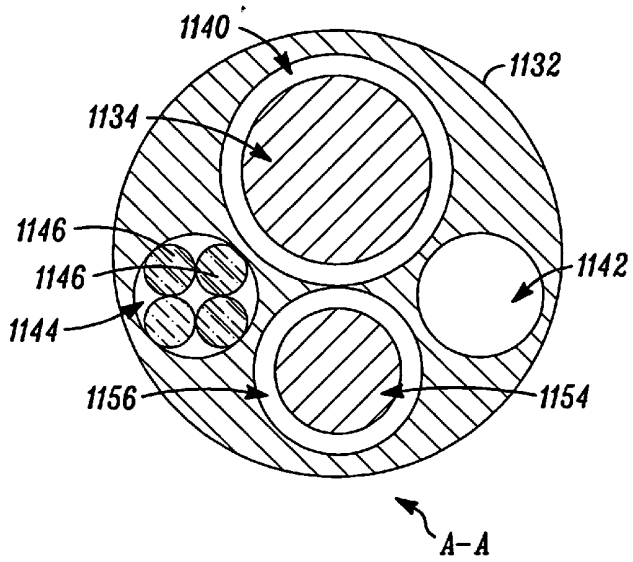
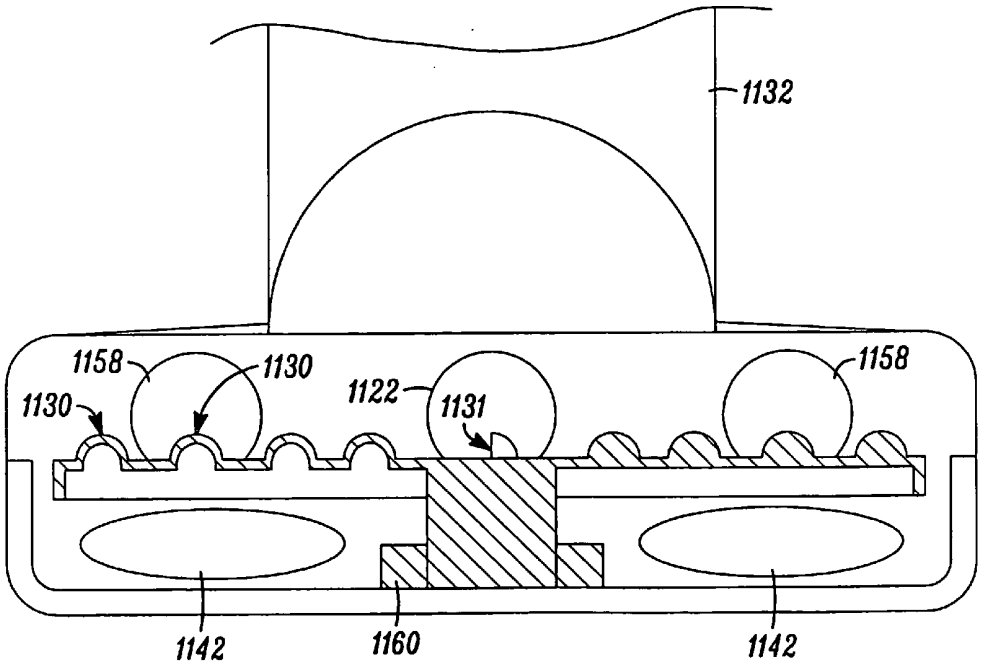


FIG. 17E



SECTION B-B

FIG. 18

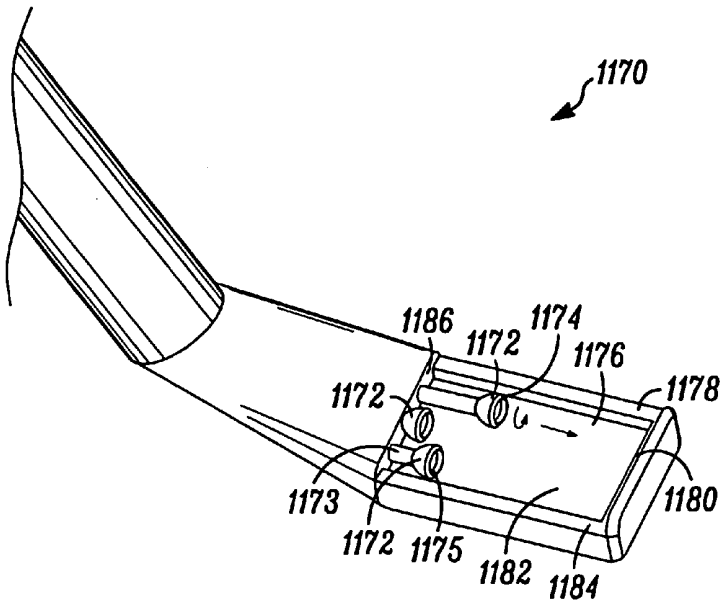


FIG. 19

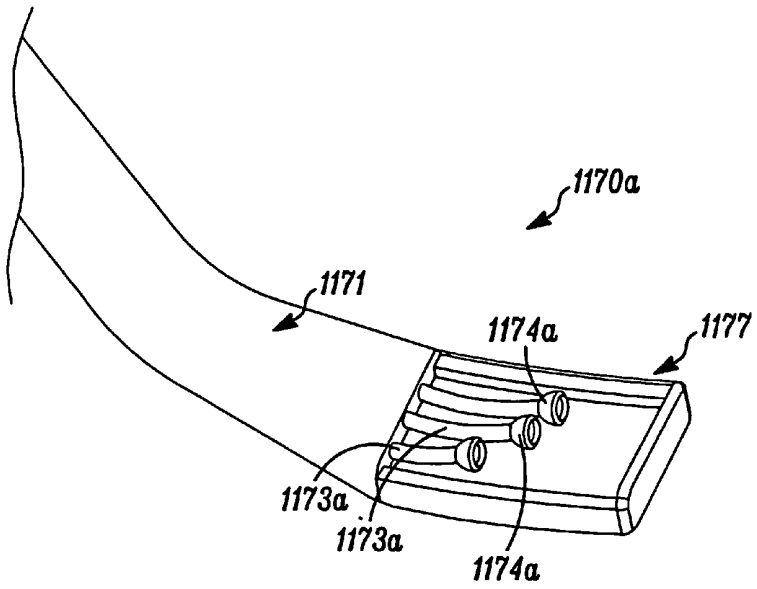


FIG. 19A

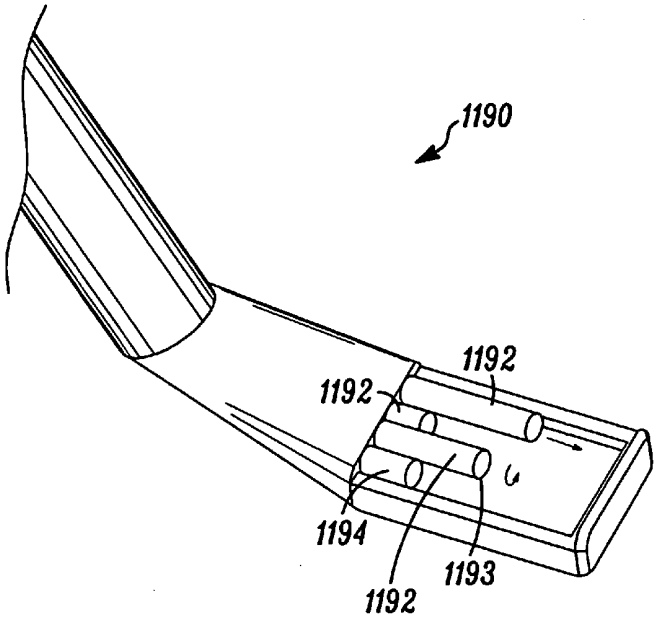

1190
1192
1192
1194
1193
1192

FIG. 20

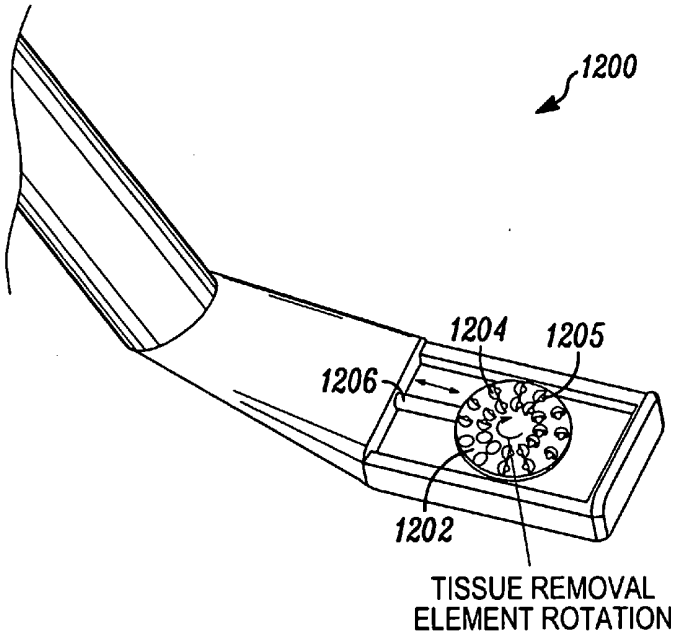

1200
1204
1205
1206
1202
TISSUE REMOVAL
ELEMENT ROTATION

FIG. 21

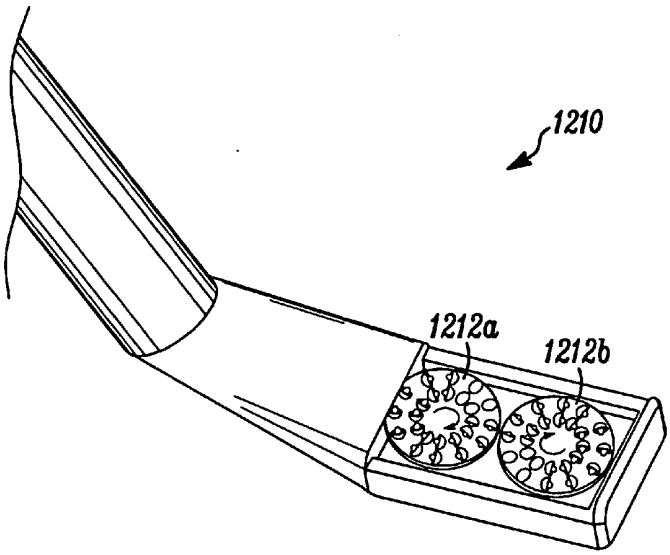


FIG. 22

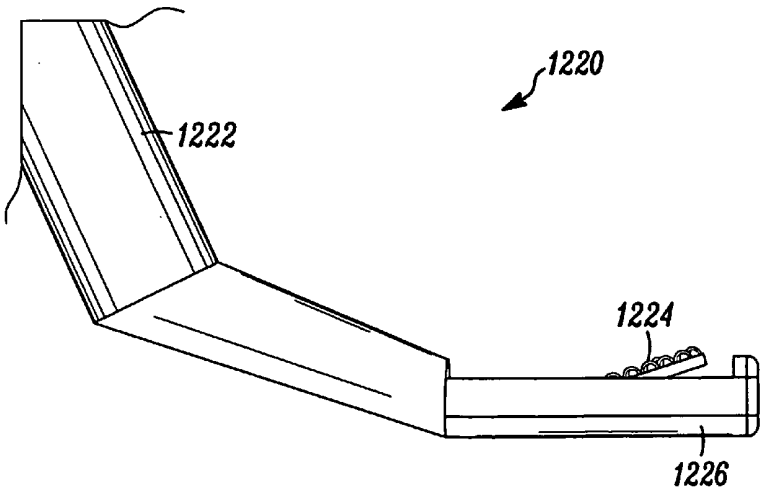


FIG. 23

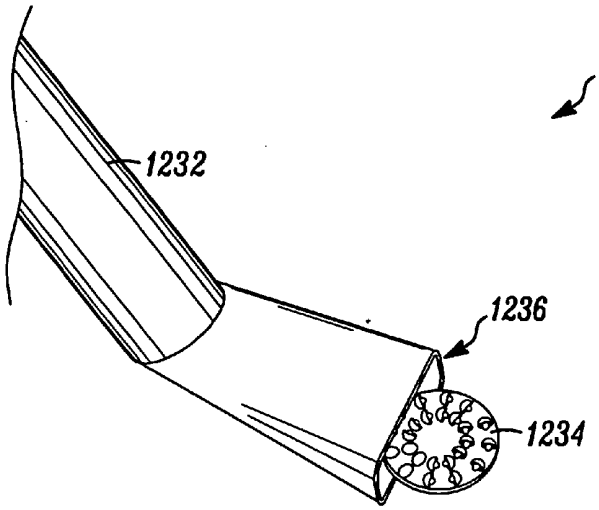

1230
1232
1236
1234

FIG. 24

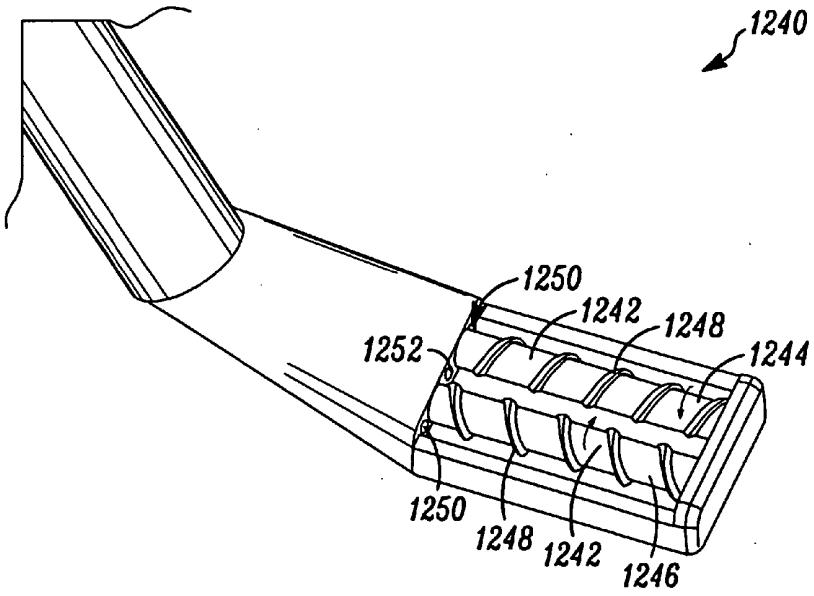

1240
1250
1242
1248
1252
1244
1250
1248
1242
1246

FIG. 25

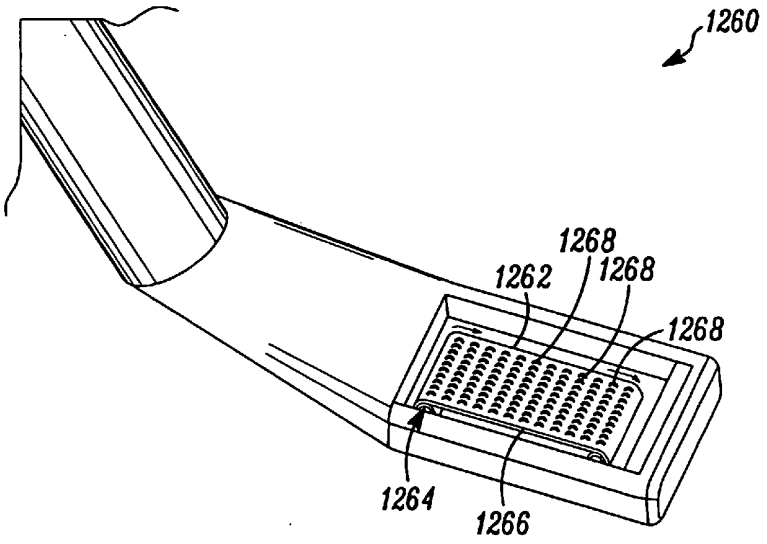


FIG. 26

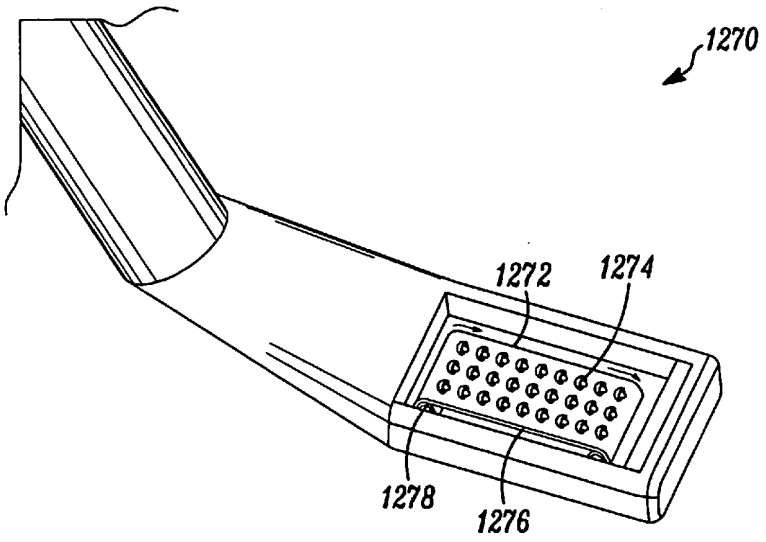


FIG. 27

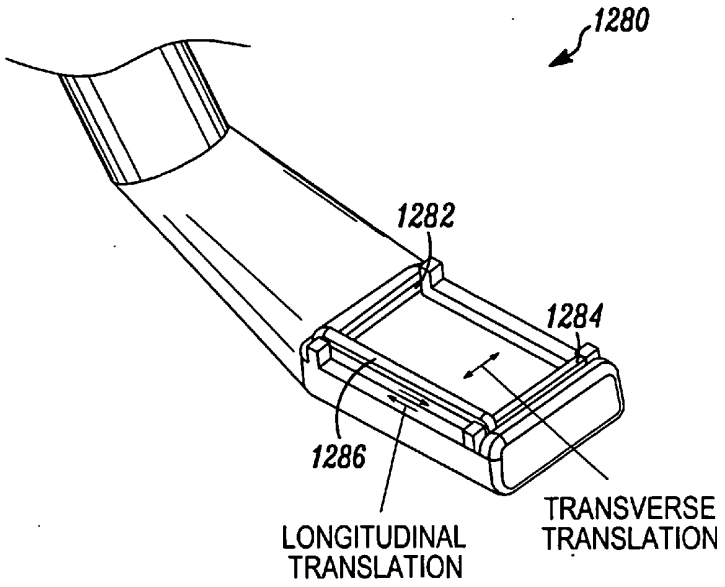

1280
1282
1284
1286
LONGITUDINAL TRANSLATION
TRANSVERSE TRANSLATION

FIG. 28

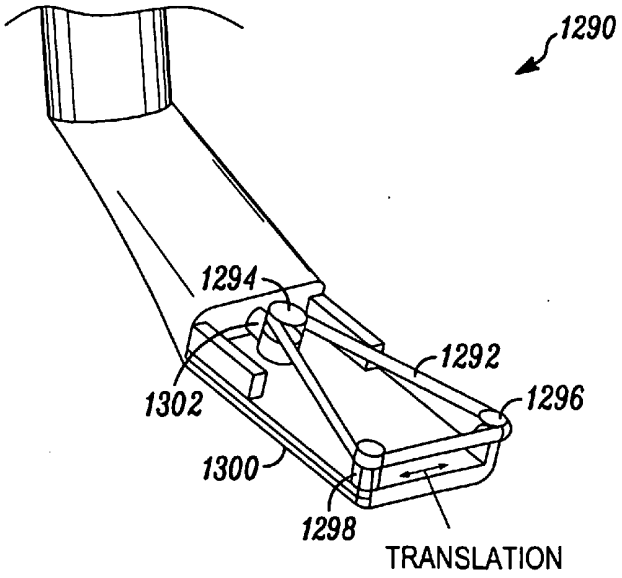

1290
1294
1292
1296
1302
1300
1298
TRANSLATION

FIG. 29

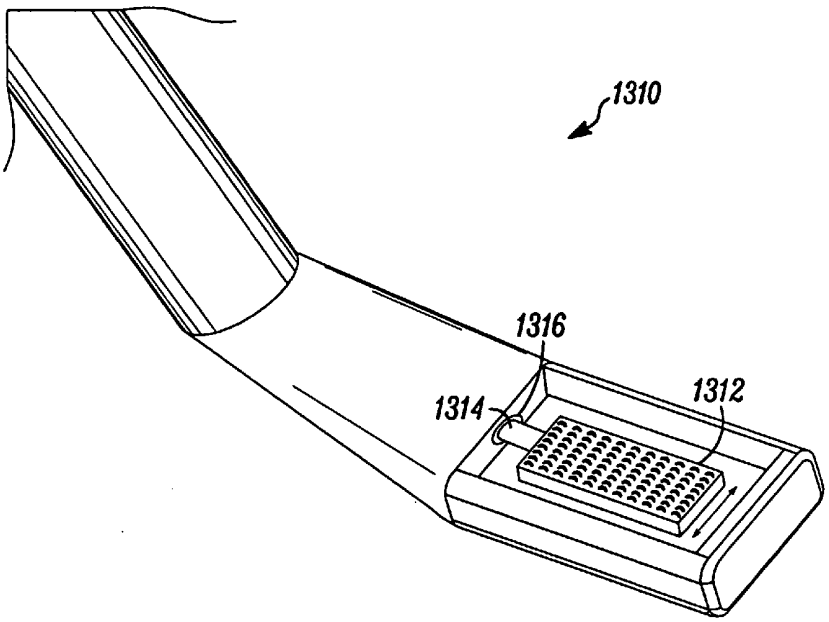


FIG. 30A

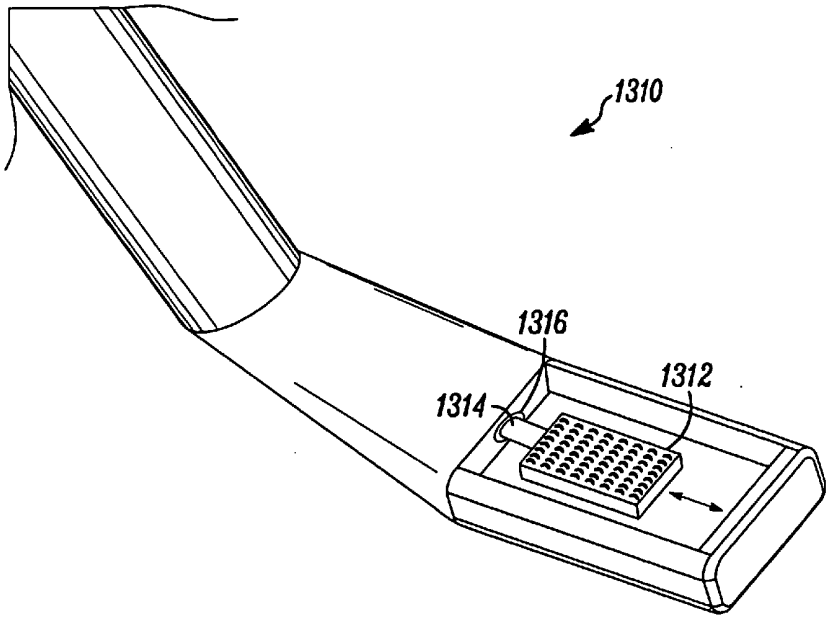


FIG. 30B

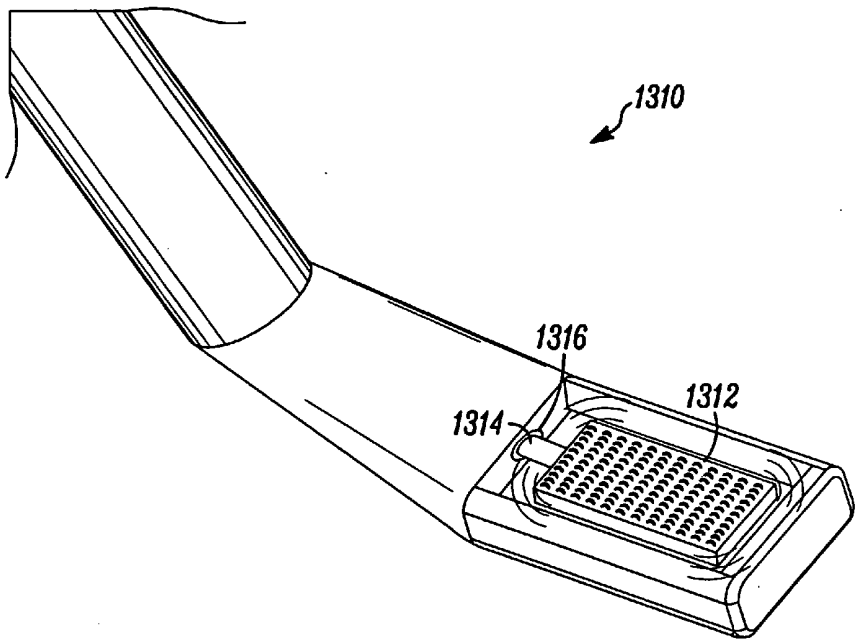


FIG. 30C

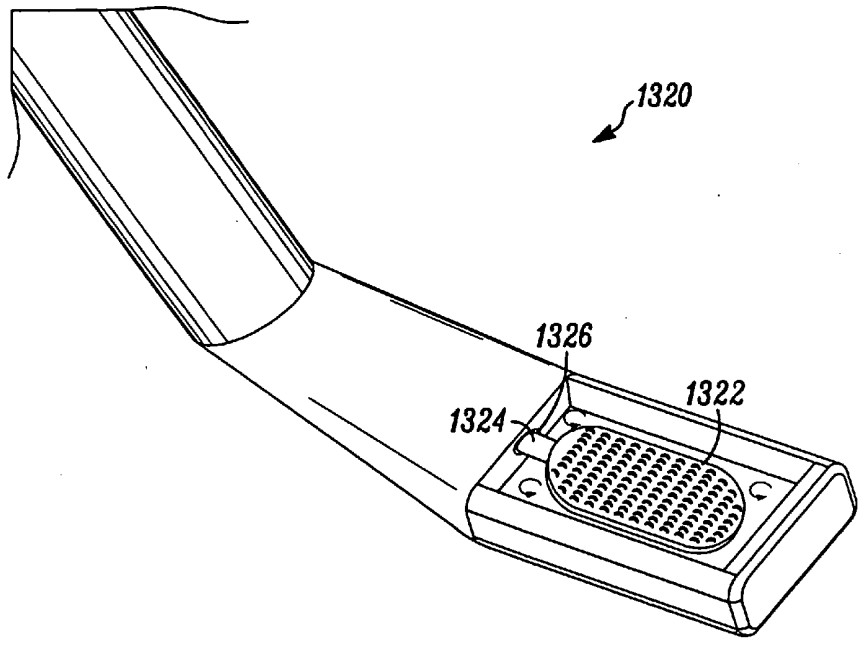


FIG. 31

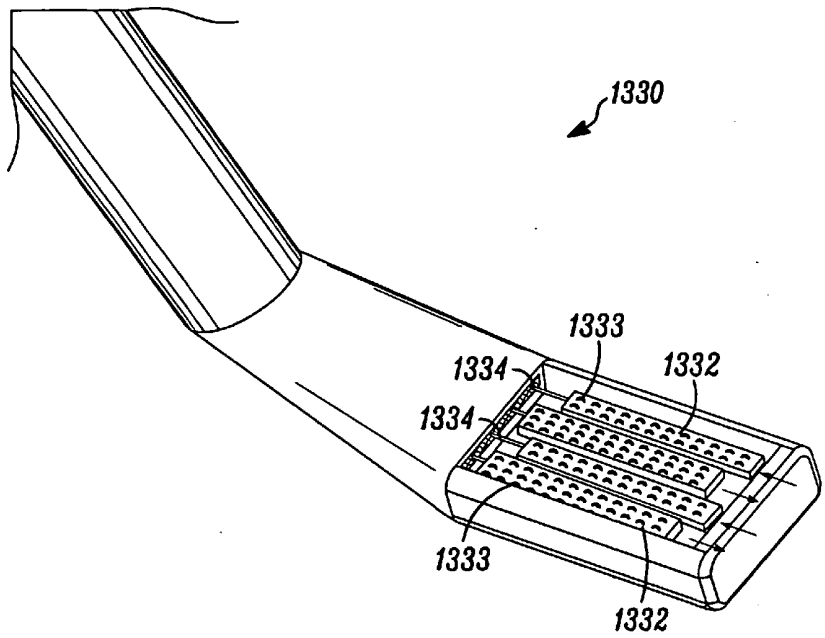

1330
1333
1334
1332
1334
1333
1332

FIG. 32

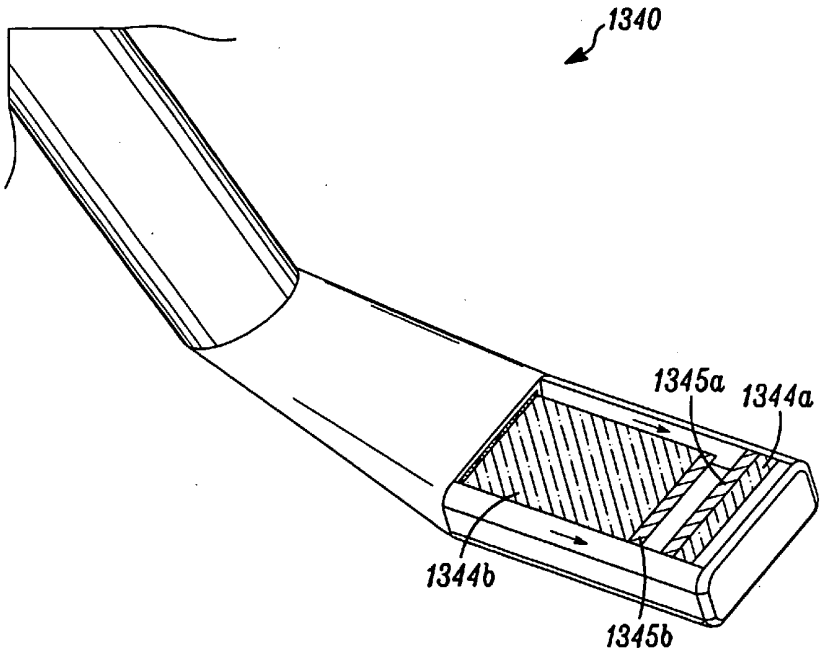

1340
1345a
1344a
1344b
1345b

FIG. 33

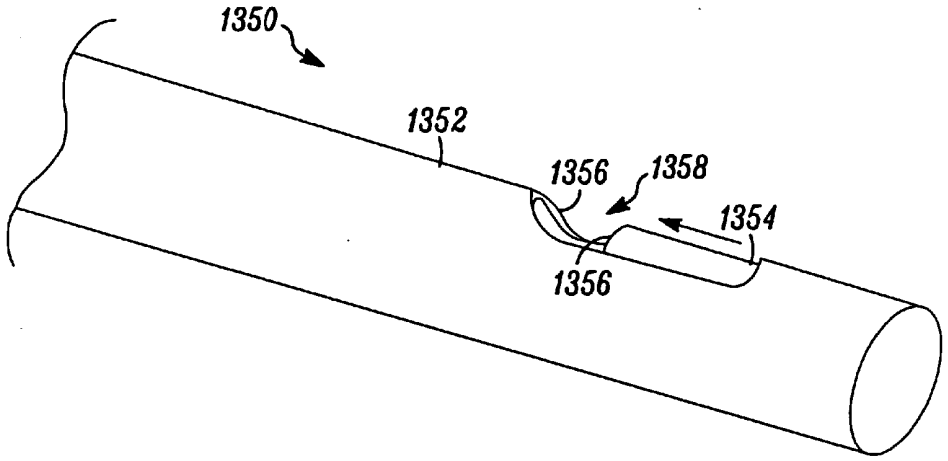


FIG. 34A

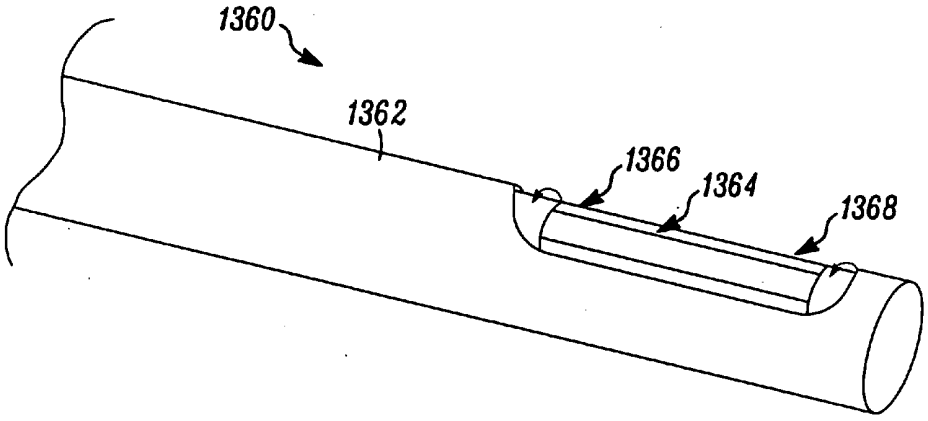


FIG. 34B

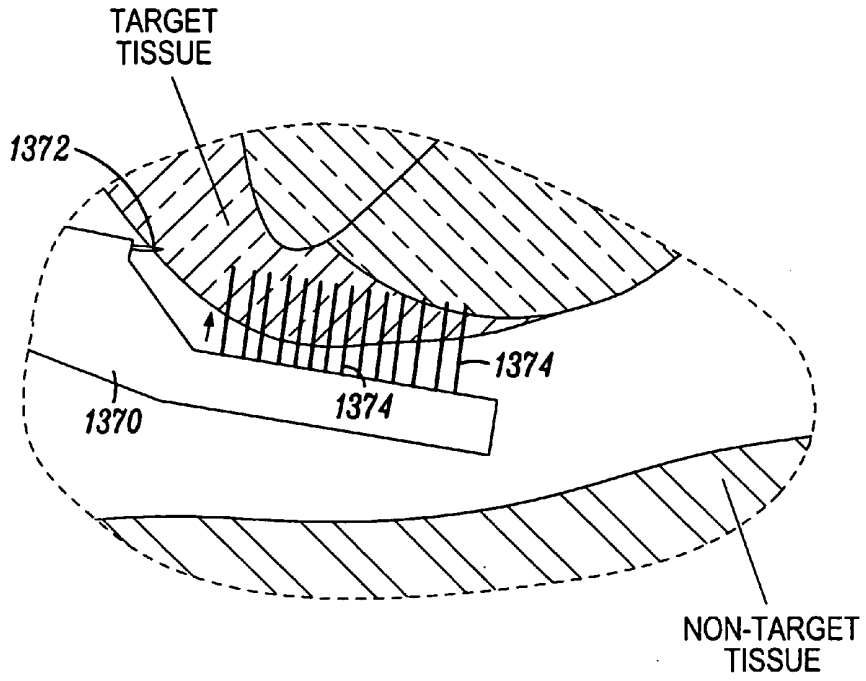


FIG. 35A

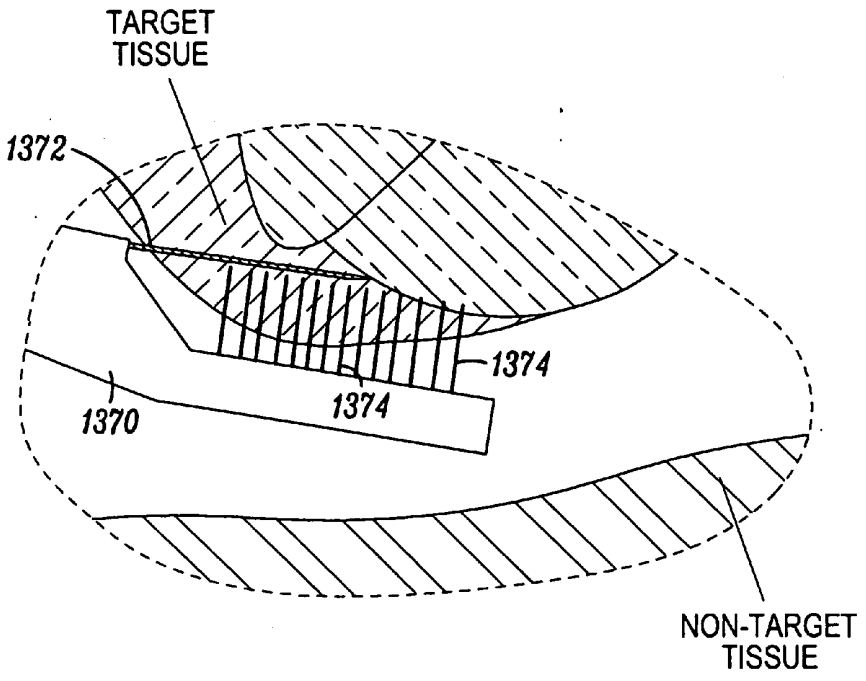


FIG. 35B

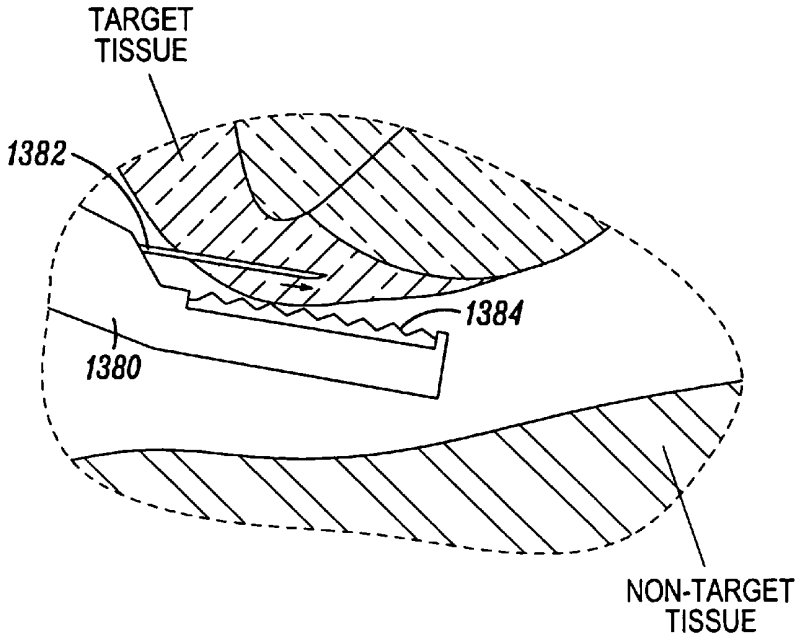


FIG. 36A

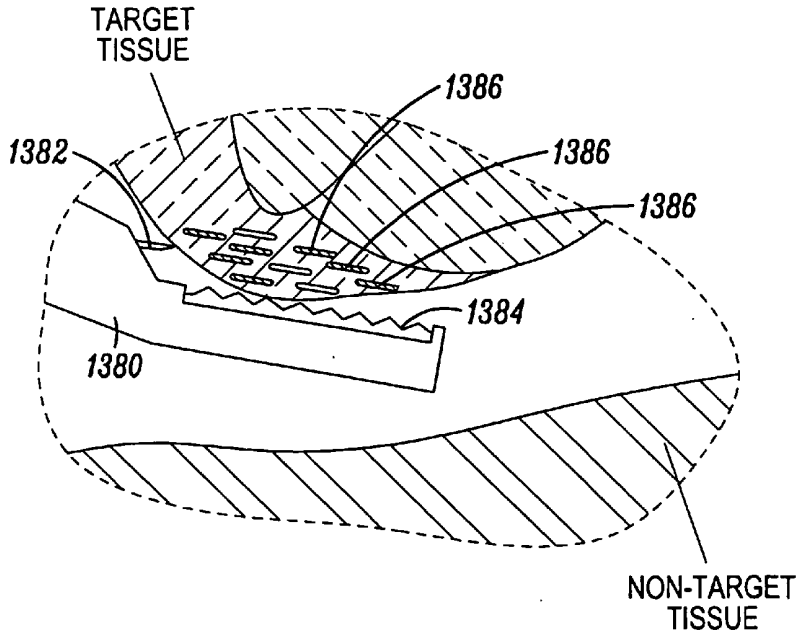


FIG. 36B

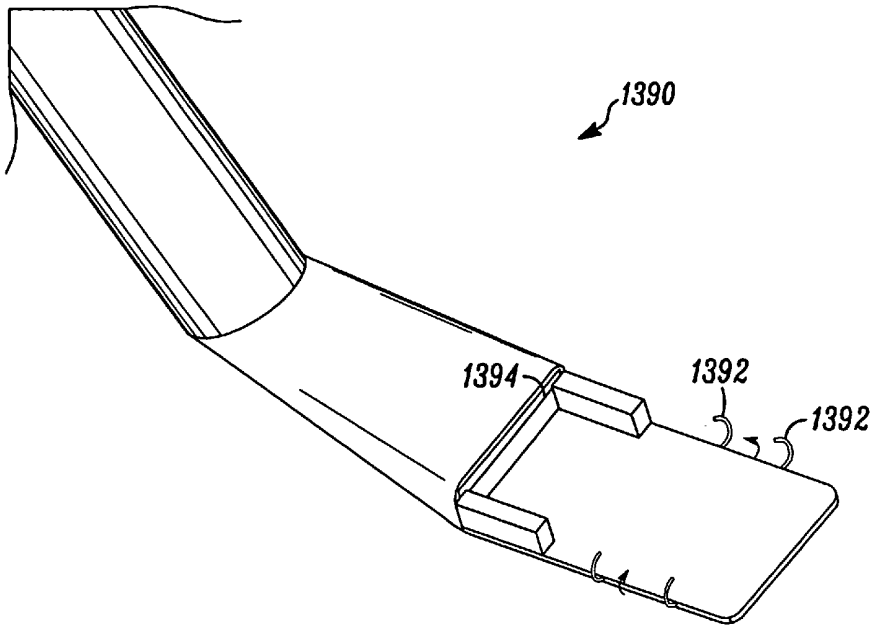


FIG. 37A

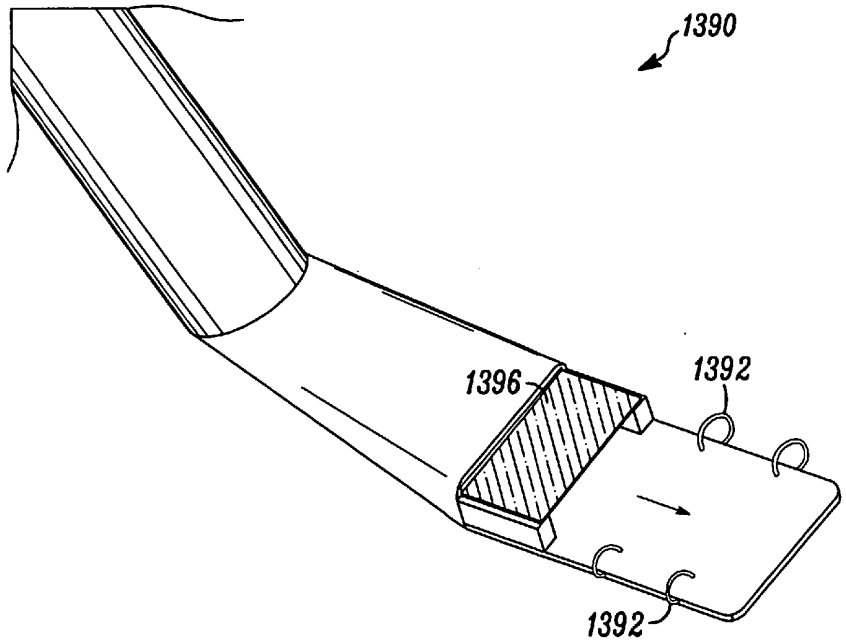


FIG. 37B

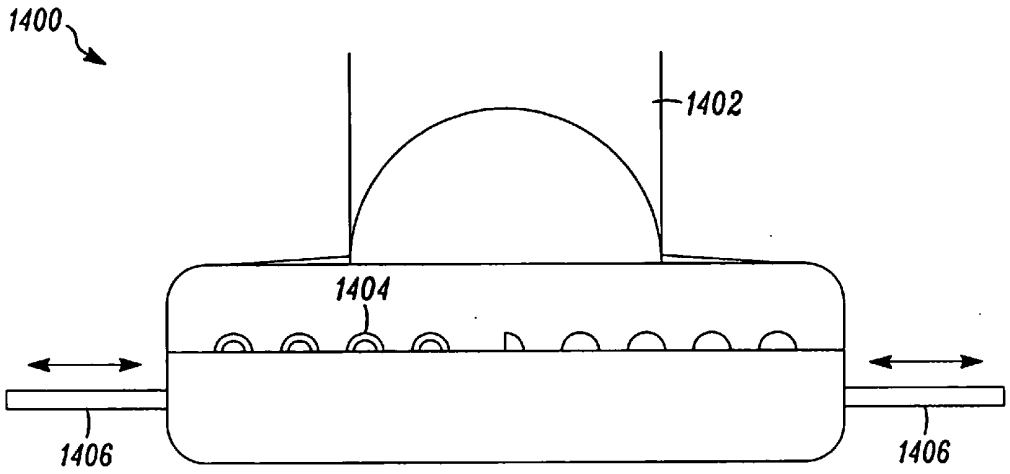


FIG. 38A

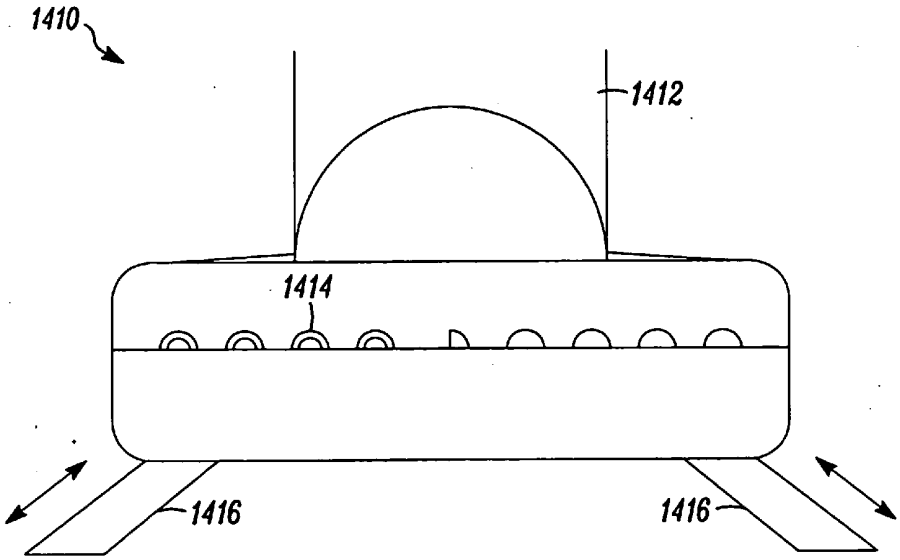


FIG. 38B

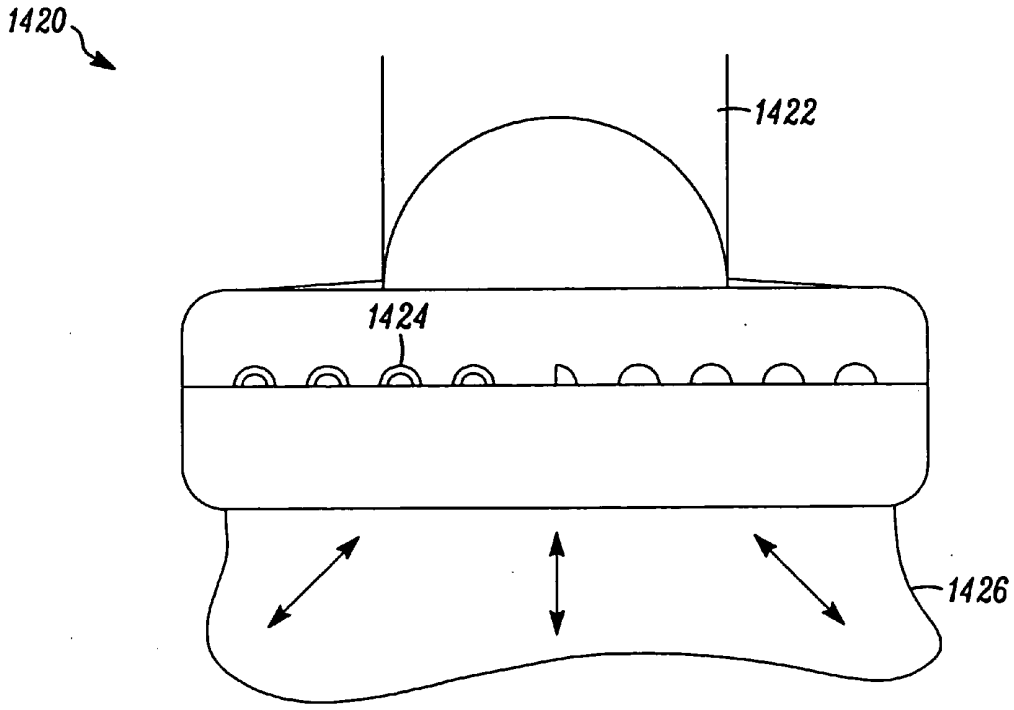


FIG. 38C

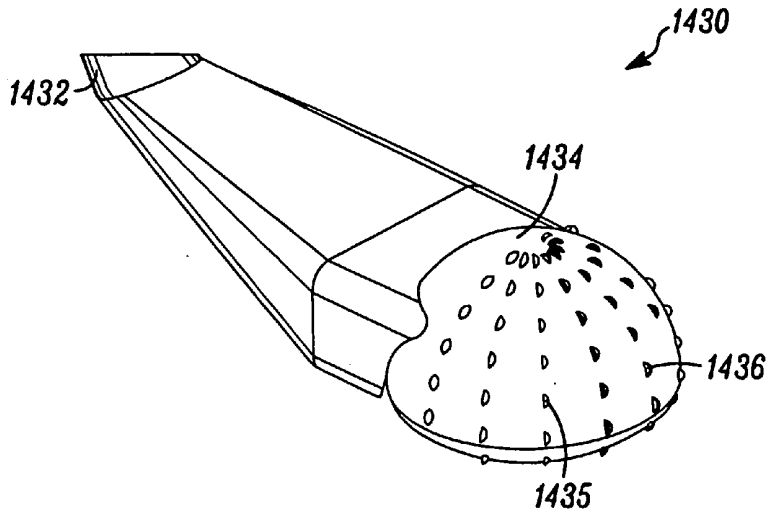


FIG. 39A

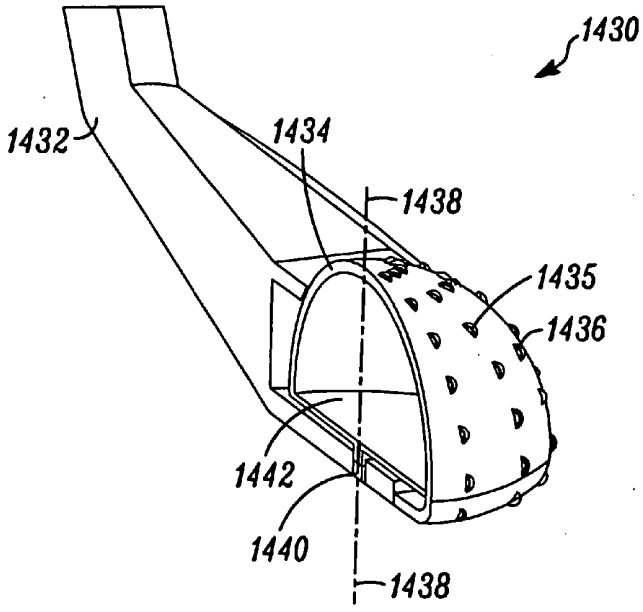


FIG. 39B

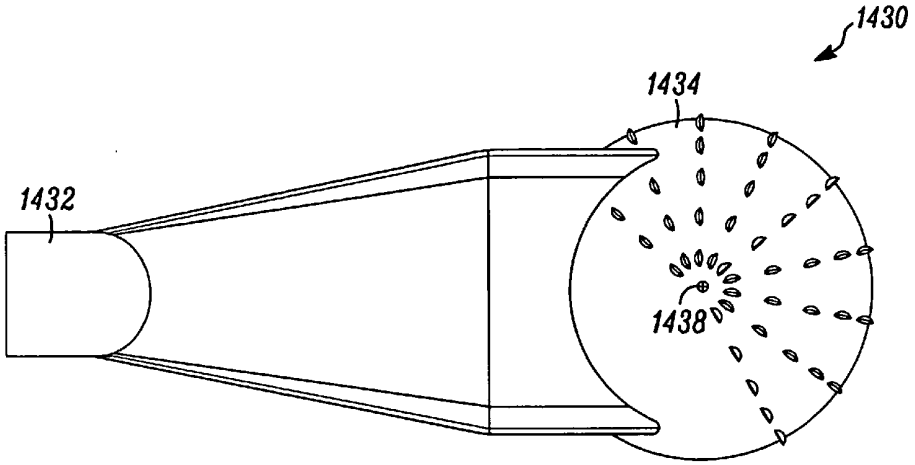


FIG. 39C

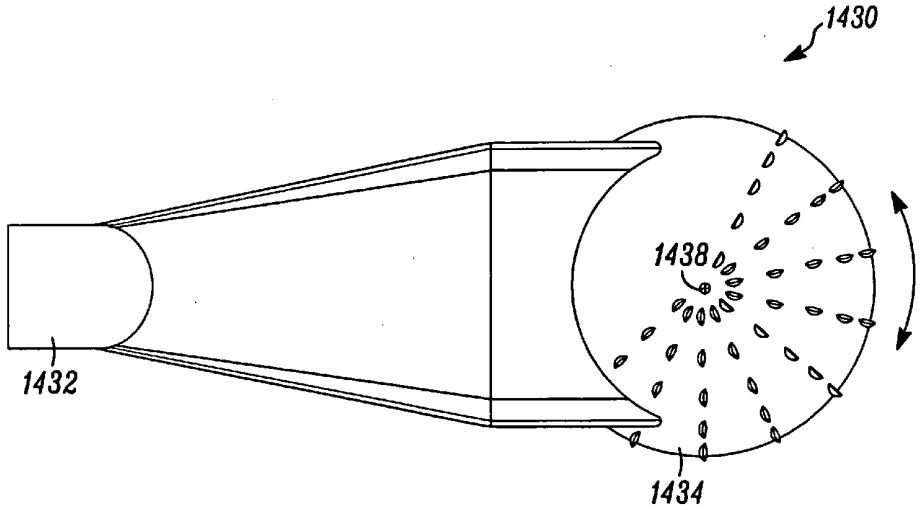


FIG. 39D

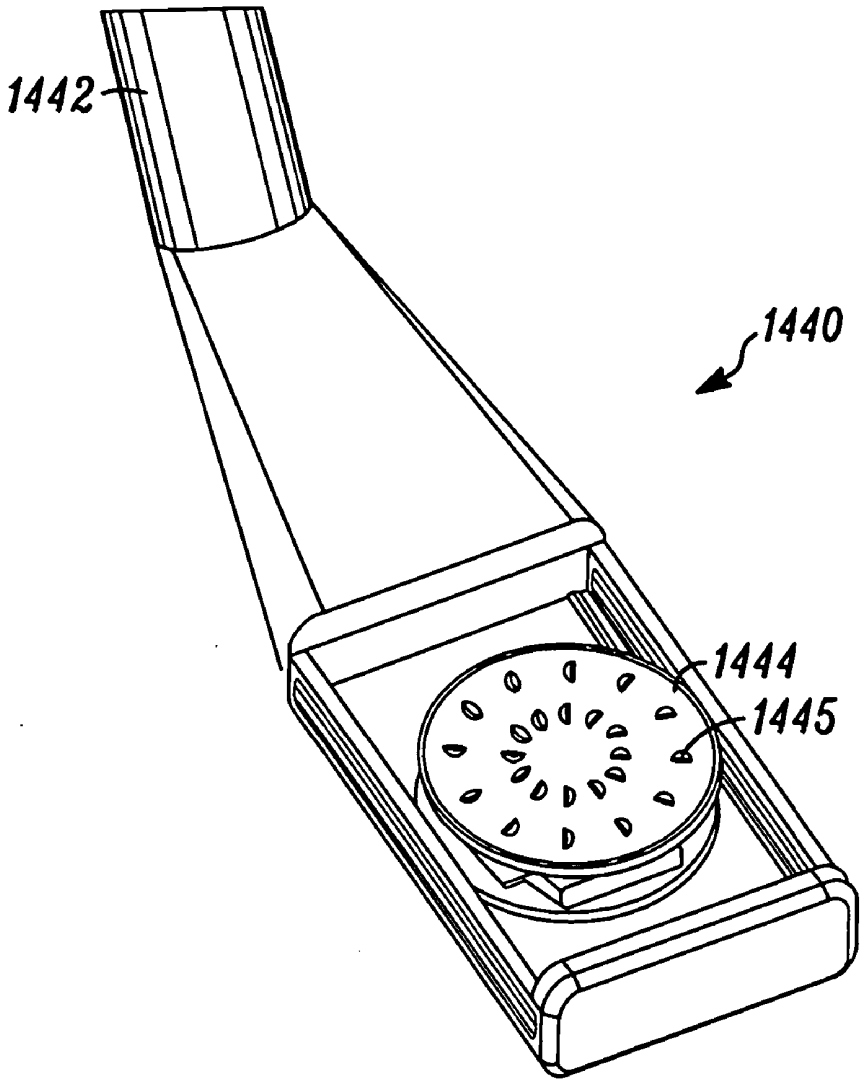


FIG. 40A

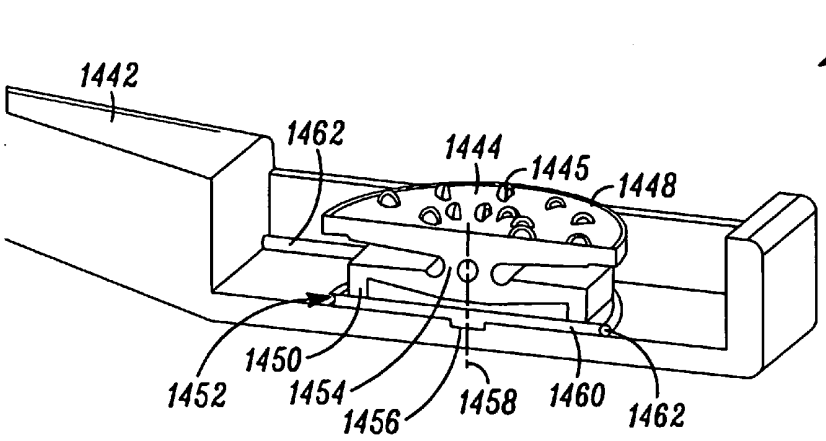


FIG. 40B

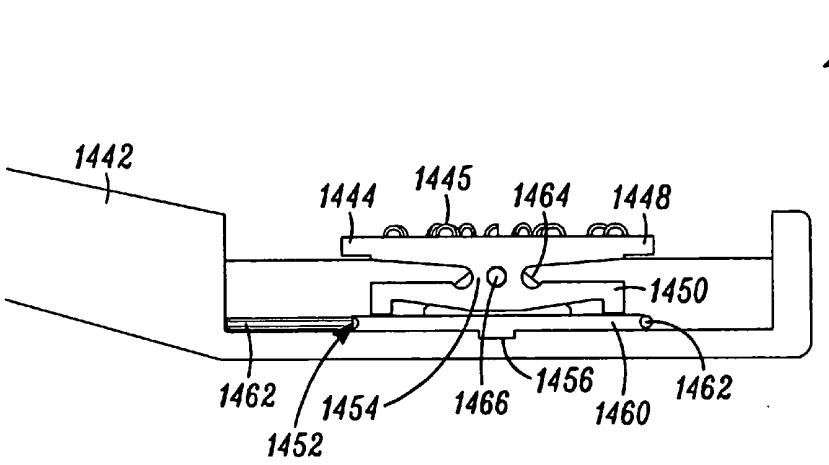


FIG. 40C

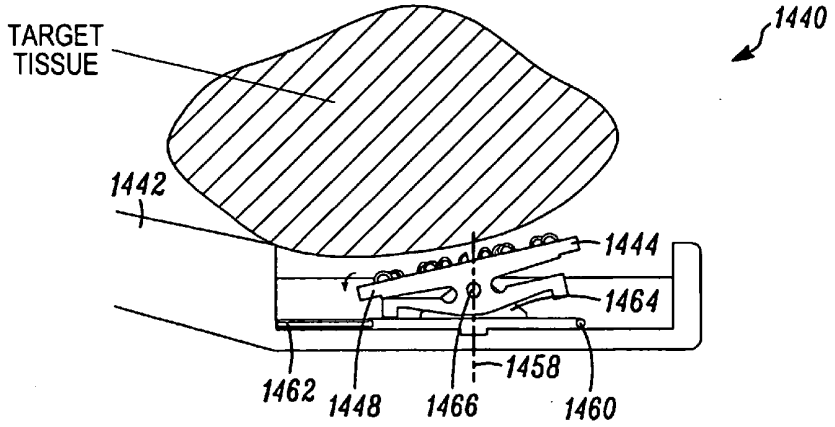


FIG. 40D

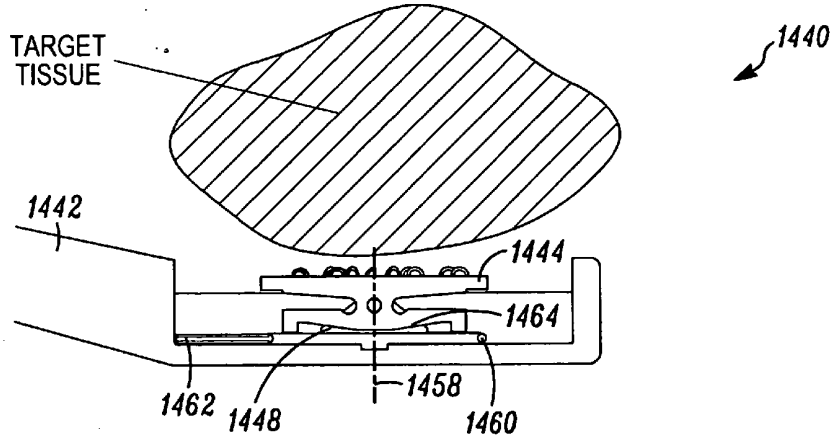


FIG. 40E

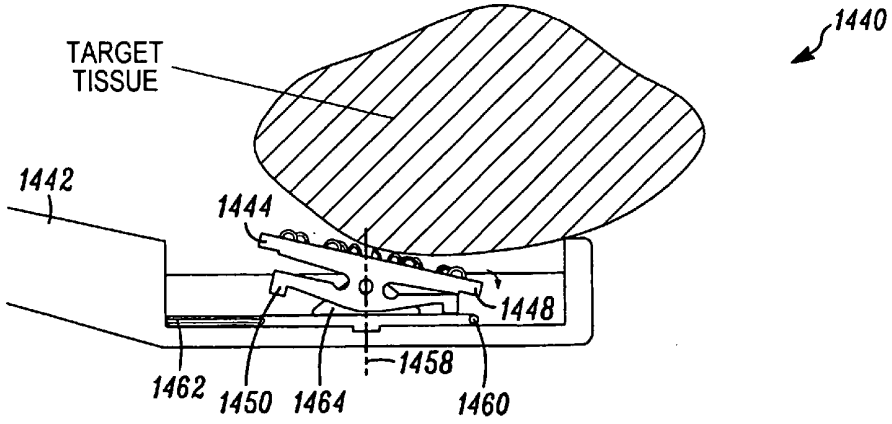


FIG. 40F

POWERED TISSUE MODIFICATION DEVICES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of U.S. patent application Ser. No. 11/375,265, entitled "Methods and Apparatus for Tissue Modification," filed on Mar. 13, 2006 (Attorney Docket No. 78117-200101), the entire disclosure of which is hereby incorporated by reference. PCT Patent Application Pub. No. PCT/US2005/037136, which was incorporated fully by reference in the above-referenced U.S. patent application Ser. No. 11/375,265, is also incorporated fully by reference herein.

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 ligaments attached to and connecting the vertebrae), as shown in FIG. **1**. Buckling or thickening of the ligamentum flavum may impinge on one or more neurovascular structures, dorsal root ganglia, nerve roots and/or the spinal cord itself. Another common cause of neural and neurovascular compression within the spine is disease of one or more of the intervertebral discs (the malleable discs between adjacent vertebrae), which may lead to collapse, bulging or herniation of the disc. In FIG. **1**, an intervertebral disc is shown with three solid-tipped arrows demonstrating how the disc might bulge or herniate into the central spinal canal to impinge upon the spinal cord, cauda equina and/or individual nerve roots. Other causes of neural and neurovascular impingement in the spine include: hypertrophy of one or more facet joints (also known as zygopophaseal joints, facet joints provide articulation between adjacent vertebrae—two vertebral facet superior articular processes are shown in FIG. **1**); formation of osteophytes (bony growths or "bone spurs") on vertebrae; spondylolisthesis (sliding of one vertebra relative to an adjacent vertebra); and (facet joint) synovial cysts. Disc, bone, ligament or other tissue may impinge on the spinal cord, the cauda equina, branching spinal nerves and/or blood vessels in the spine to cause loss of function, ischemia (shortage of blood supply) and even permanent damage of neural or neurovascular tissue. In a patient, this may manifest as pain, impaired sensation and/or loss of strength or mobility.

[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 stensosis include systemic medications and physical therapy. Epidural steroid injections may also be utilized, but they do not provide ling lasting benefits. When these approaches are inadequate, current treatment for spinal stenosis is generally limited to invasive surgical procedures to remove vertebral ligament, cartilage, bone spurs, synovial cysts, cartilage, and bone to provide increased room for neural and neurovascular tissue. The standard surgical procedure for spinal stenosis treatment includes laminectomy (complete removal of the lamina (see FIG. **1**) of one or more vertebrae) or laminotomy (partial removal of the lamina), followed by removal (or "resection") of the ligamentum flavum. In addition, the surgery often includes partial or occasionally complete facetectomy (removal of all or part of one or more facet joints between vertebrae). In cases where a bulging intervertebral disc contributes to neural impingement, disc material may be removed surgically in a discectomy procedure.

[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 targets 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 H is Wire Saw," J Neurosurg 82:1086-1090, 1995. An example of one such saw is described in U.S. Pat. No. 8,250, 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 modifying 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 device for modifying tissue in a spine may include one or more of the following: a shaft having a proximal portion and a distal portion, the distal portion having dimensions which allow it to be passed into an epidural space of the spine and between target and non-target tissues; at least one distal force application member extending from the distal portion of the shaft and configured to facilitate application of at least one of

anchoring force and tensioning force to the shaft; at least one movable tissue modifying member coupled with the shaft at or near its distal portion; at least one drive member coupled with the at least one tissue modifying member to activate the at least one tissue modifying member; and at least one power transmission member coupled with the at least one drive member to deliver power to the at least one drive member.

[0020] In another aspect of the present invention, a device for modifying tissue in a patient may include: an elongate, at least partially flexible body having a proximal portion and a distal portion, the distal portion having dimensions which allow it to be passed between target and non-target tissues in the patient; at least one distal force application member extending from the distal portion of the elongate body and configured to facilitate application of at least one of anchoring force and tensioning force to the elongate body; at least one proximal force application member coupled with the elongate body at or near the proximal portion and configured to facilitate application of tensioning force to the elongate body; at least one movable tissue modifying member coupled with the elongate body; at least one drive member coupled with the at least one tissue modifying member to activate the at least one tissue modifying member; and at least one power transmission member coupled with the at least one drive member to deliver power to the at least one drive member.

[0021] In another aspect of the present invention, a method for modifying tissue in a spine may include one or more of the following steps: passing a distal portion of a tissue modification device into an epidural space of a spine 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 at least one of anchoring force and tensioning force at or near the distal portion and at or near a proximal portion of the tissue modification device to urge the at least one tissue modifying member against the target tissue; and transmitting power to at least one drive member coupled with the at least one tissue modifying member to activate the tissue modifying member(s) and thus modify the target tissue.

[0022] These and other aspects and embodiments are described more fully below in the Detailed Description, with reference to the attached Drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] 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;

[0024] 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;

[0025] FIG. **3**A is a perspective view of a tissue modification device according to one embodiment of the present invention;

[0026] FIG. **3**B is a perspective view of a portion of the tissue modification device of FIG. **3**A;

[0027] FIG. **3**C is a top view of the portion shown in FIG. **3**B;

[0028] FIG. **3**D is a side view of the portion shown in FIGS. **3**B and **3**C;

[0029] FIGS. **3**E and **3**F are cross-sectional views of a portion of the tissue modification device taken through lines A-A and B-B, respectively, shown in FIG. **3**C;

[0030] FIG. **3**G is a perspective view of a portion of the tissue modification device of FIGS. **3**B-**3**F, shown with a blade of the device in a closed position according to one embodiment of the present invention;

[0031] FIG. **3**H is a top view of the portion shown in FIG. **3**G;

[0032] FIG. **3**I is a side view of the portion shown in FIGS. **3**G and **3**H;

[0033] FIG. **4**A is a perspective view of a tissue modification device according to one embodiment of the present invention;

[0034] FIG. **4**B is a perspective view of a portion of the tissue modification device of FIG. **4**A;

[0035] FIG. **4**C is a close-up, perspective view of a portion of the tissue modification device of FIGS. **4**A and **4**B, showing a tissue modifying member according to one embodiment of the present invention;

[0036] FIGS. **5**A-**5**D are cross-sectional views of a spine and demonstrate a methods for using a tissue modification device according to one embodiment of the present invention;

[0037] FIG. **6**A 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;

[0038] FIG. **6**B 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;

[0039] FIGS. **7**A-**7**S 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;

[0040] FIGS. **8**A-**8**F 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;

[0041] FIGS. **9**A-**9**B 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;

[0042] FIG. **10**A is a perspective view of a distal portion of an introducer sheath according to one embodiment of the present invention;

[0043] FIGS. **10**B and **10**C are perspective and cross-sectional views, respectively, of a tissue shield device according to one embodiment of the present invention; and

[0044] FIGS. **10**D and **10**E are perspective and cross-sectional views, respectively, of a tissue shield device according to an alternative embodiment of the present invention.

[0045] FIGS. **11**A and **11**B are cross-sectional views of a spine with a tissue modification device in position for modifying tissue according to various embodiments of the present invention.

[0046] FIG. **12** is a cross-sectional view of a portion of a spine with a tissue modification device in position for modifying tissue according to an alternative embodiment of the present invention.

[0047] FIGS. **13**A-**13**E are cross-sectional views of a portion of a spine with a tissue modification device in position for modifying tissue according to various alternative embodiments of the present invention.

[0048] FIGS. **13**F and **13**G are cross-sectional views of a portion of the tissue modification device of FIG. **13**E, through line C-C on FIG. **13**E, in various configurations according to one embodiment of the present invention.

[0049] FIG. **14** is a cross-sectional view of a portion of a spine with a tissue modification device having a steerable distal portion in position for modifying tissue according to one embodiment of the present invention.

[0050] FIG. **15**A is a cross-sectional view of a portion of a spine with a tissue modification device in position for modifying tissue according to one embodiment of the present invention.

[0051] FIG. **15**B is a close-up of portion D-D of FIG. **15**A.

[0052] FIG. **16** is a cross-sectional view of a portion of a spine with a tissue modification device in position for modifying tissue according to one embodiment of the present invention.

[0053] FIGS. **17**A-**17**E are cross-sectional views taken through line A-A of FIG. **16** according to various alternative embodiments of the present invention.

[0054] FIG. **18** is a cross-sectional view taken through line B-B of FIG. **16** according to one embodiment of the present invention.

[0055] FIGS. **19**-**33** are perspective or side views of a distal portion of a tissue modification device according to various alternative embodiments of the present invention.

[0056] FIGS. **34**A and **34**B are perspective views of a distal portion of a tissue modification device according to alternative embodiments of the present invention.

[0057] FIGS. **35**A and **35**B are side views of a distal portion of a tissue modification device according to one embodiment of the present invention.

[0058] FIGS. **36**A and **36**B are side views of a distal portion of a tissue modification device according to an alternative embodiment of the present invention.

[0059] FIGS. **37**A and **37**B are perspective views of a distal portion of a tissue modification device according to an alternative embodiment of the present invention.

[0060] FIGS. **38**A-**38**C are end-on views of a distal portion of a tissue modification device according to various alternative embodiments of the present invention.

[0061] FIGS. **39**A-**39**D are perspective (FIG. **39**A), cross-sectional (FIG. **39**B) and top (FIGS. **39**C and **39**D) views of a distal portion of a tissue modification device according to one embodiment of the present invention.

[0062] FIGS. **40**A-**40**F are perspective (FIG. **40**A), cross-sectional perspective (FIG. **40**B), and cross-sectional side (FIGS. **40**C-**40**F) views of a distal portion of a tissue modification device according to an alternative embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0063] 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.

[0064] 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.

[0065] Generally, tissue modification device **102** may be advanced to a position in the spine such that tissue modifying member **110** faces target tissue to be modified, such as buckled, thickened or otherwise impinging ligamentum flavum tissue as shown in FIG. **2**. Modification device **102** is configured such that when tissue modifying member **110** faces the target tissue, protective surface(s) **112** face non-target tissue. Protective surface **112** may be simply a length of elongate body **108** or may have one or more protective features, such as a widened diameter, protective or lubricious coating, extendable barrier, drug-eluting coating or ports, or the like. In some instances, protective surface(s) **112** may act as "non-tissue-modifying" surfaces, in that they may not substantially modify the non-target tissue. In alternative embodiments, protective surface(s) **112** may affect non-target tissue by protecting it in some active way, such as by administering one or more protective drugs, applying one or more forms of energy, providing a physical barrier, or the like.

[0066] 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.

[**0067**] 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.

[**0068**] Turning now to FIG. **3**A-**3**I, more detailed figures of one embodiment of tissue modification device **102** are shown. Referring to FIG. **3**A, 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.

[**0069**] 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. **3**C and **3**D, 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.

[**0070**] 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.

[**0071**] 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. **3**A, 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.

[0072] FIGS. **3**B-**3**D 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**.

[0073] Blades **110** include a distal **110***a* and a proximal blade **110***b* 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. **3**C, depicts the angled edges of distal blade **110***a* and proximal blade **110***b*, 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. **3**D, where only blades **110** protrude from the top surface of the elongate body **108**. In one embodiment, also as shown in FIG. **3**D, 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.

[0074] In one embodiment, distal blade **110***a* is coupled with two pull-wires **118**, as seen in FIGS. **3**C, **3**E and **3**F. Pull-wires **118** coupled to and translated by actuator **106** on handle **104** may be used to drive distal blade **110***a* proximally to contact the cutting edge of proximal blade **110***b*, 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 **110***a* and/or proximal blade **110***b* may have an outwardly curvilinear shape along its cutting edge. Alternatively, distal blade **110***a* 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.

[0075] FIGS. **3**E and **3**F show cross-sectional views through elongate body at lines A-A and B-B, respectively, of FIG. **3**C. In some embodiments, all or a portion of elongate body **108**, such as the lower surface shown in FIG. **3**E, 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. **3**E shows distal blade **110** coupled with pull wires **118**. FIG. **3**F shows proximal blade **110***b*, which is not coupled with pull wires **118** but rather fixed to body **108**. In various alternative embodiments, proximal blade **110***b* may be movable distally while distal blade **110***a* is static, both blades may be moved toward one another, or a different number of blades may be used, such as one blade drawn toward a backstop or more than two blades, one or more of which may be mobile. In various alternative embodiments, guide member lumen **120** may be accommodated on a side surface or more centrally within elongate body **108**. In further alternative embodiments, the one or more guide member lumens **120** may comprise one or more various cross sectional shapes, for example substantially round, substantially oval, or substantially rectabular, to accommodate alternative guide members, for example flat or rectangular guidewires, needles or rails. In still other alternative embodiments guide member lumen **120** may be adjustably coupled with the elongate body **108** to enable manipulation of the location of the elongate body **108** and therefore the tissue modifying members **110** relative to the guiding member.

[0076] Referring now to FIGS. **3**G-**3**I, blades **110** are shown in their closed position. In one embodiment, when distal blade **110***a* 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 **110***a* 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.

[0077] 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".

[0078] 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.

[0079] 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.

[0080] In the embodiment shown in FIGS. **3**A-**3**I, 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 **110***a* may be returned to it's starting position by a pulling force generated from the distal end of device **102**, for example by using a distal actuator that is attached to distal wires, or by pulling on the distal guide member which is attached to distal blade **110***a*. In yet another alternative embodiment, proximal blade **110***b* 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 **110***b*. In yet another embodiment, squeezing actuator **106** may cause proximal blade **110***b* to move distally while distal blade **110***a* 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.

[0081] Referring now to FIGS. **4**A-**4**C, 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. **4**B and **4**C, 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. **4**A-**4**C, 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.

[0082] 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.

[0083] Referring to FIG. **4**C, 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. **4**C, 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.

[**0084**] 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**.

[**0085**] 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.

[**0086**] 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.

[**0087**] Referring now to FIGS. **5**A-**5**D, 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. **5**A 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.

[**0088**] In FIG. **5**B, 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.

[**0089**] Referring to FIG. **5**C, once device **102** is positioned in a desired location, anchoring force may be applied at or near the distal portion of elongate body **108**. In one embodiment, applying anchoring force involves a user **244** grasping body **108** at or near its distal portion. In alternative embodiments, as described further below, anchoring force may be applied by deploying one or more anchor members disposed at or near the distal portion of body **108**, or by grasping a guidewire or other guide member extending through at least part of body **108**. Once the anchoring force is applied, proximally-directed tensioning force may be applied to device **102**, such as by pulling proximally on handle **104** (one-directional, diagonal arrows). This tensioning force, when applied to the substantially anchored device **102**, may help urge the tissue modifying member(s) against the target tissue (one-directional, vertical arrows near target tissue), thus enhancing contact with the target tissue and facilitating its modification. With the tissue modifying member(s) contacting the target tissue, actuator **106** may be squeezed or pulled (two-headed arrow) to cause the tissue modifying member(s) to modify tissue. (Alternative actuators may be activated in different ways in alternative embodiments.)

[**0090**] 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.

[**0091**] 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.

[**0092**] Referring to FIG. **5**D, 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. **5**A-**5**C 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. **5**D, 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.

[**0093**] Referring now to FIG. **6**A, 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.

[**0094**] FIG. **6**B 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.

[**0095**] Referring now to FIGS. **7**A-**7**S, 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.

[**0096**] Referring to FIG. **7**A, 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 adja-

cent spinal ligament, as shown further in FIG. **7**B. As shown in FIG. **7**C, when the distal tip of cannula is positioned as desired, stylet **302** is removed. Referring to FIGS. **7**D and **7**E, 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. **7**E. Syringe **304** is then removed, as in FIG. **7**F, and a guidewire **312** with a non-rigid, atraumatic tip is advanced through cannula **300** into the central spinal canal, as in FIG. **7**G. Next, cannula **300** is removed, as in FIG. **7**H, leaving behind guidewire **312**. As shown in FIGS. **7**I and **7**J, 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. **7**K.

[**0097**] 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. **7**L and **7**M. One or more guide members **116**, may then be advanced through the guide device **318**, as shown in FIGS. **7**N-**7**P. Finally, guide device **318** may be removed, as in FIG. **7**Q, 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. **7**R. As shown in FIG. **7**S, 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. **7**R.

[**0098**] 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**.

[**0099**] 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.

[**0100**] 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.

[**0101**] 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.

[0102] Referring now to FIGS. **8**A-**8**E, 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. **8**A, 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. **8**B, an introducer sheath **414** may then be inserted through the incision, between retractors **402**. As in FIG. **8**C, 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. **8**D.

[0103] 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.

[0104] As shown in FIGS. **8**D-**8**E, 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. **8**E). Guide device **418** may then be removed, as in FIG. **8**F, 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.

[0105] Referring now to FIGS. **9**A and **9**B, another alternative open surgical access method is shown. In FIG. **9**A, 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. **9**B, 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.

[0106] 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.

[0107] Referring now to FIGS. **10**A-**10**E, 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. Alternatively, in some embodiments, a protective surface or portion of tissue modification device **102**, **202** may actually modify non-target tissue in a protective manner, such as by delivering a protective drug, coating, fluid, energy or the like to the non-target tissue.

[0108] Optionally, in some embodiments, tissue modification devices or systems may further include one or more tissue barriers (or "shields") for further protecting non-target tissues. Such barriers may be slidably coupled with, fixedly coupled with, or separate from the tissue modification devices with which they are used. In various embodiments, a barrier 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 or otherwise used to modify target tissue. Generally, such a barrier may be interposed between the non-target tissue and one or more tissue modification devices to prevent unwanted damage of the non-target tissue.

[0109] FIG. **10**A shows a distal portion of an introducer device **514** through which a barrier may be introduced. FIGS. **10**B and **10**C show one embodiment of a barrier **500** partially deployed and in cross-section, respectively. Typically, barrier **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. In various embodiments, some of which are described more fully below, barrier **500** 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 delivery device **514** to protect tissue. As shown in FIGS. **10**B and **10**C, barrier **500** may comprise a sheet of material disposed with a first end **502***a* abutting a second end **502***b* within introducer device **514** and unfurling upon delivery. In an alternative embodiment, as shown in FIGS. **10**D and **10**E, opposite ends **522***a* and **522***b* of a barrier **520** may overlap in introducer device **514**. Generally, barrier **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. **7**A-**7**S, **8**A-**8**F and **9**A-**9**B. In some embodiments, barrier **500**, **520** may be

fixedly coupled with or an extension of a tissue modification device. Barrier **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, barrier **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 barrier **500**, **520**.

[**0110**] Referring now to FIGS. **11**A and **11**B, in an alternative embodiment, a powered tissue modification device **1000** suitably includes an elongate shaft **1001** having a proximal portion **1002**, a distal portion **1003** and a longitudinal axis **1008**, one or more tissue modifying members **1004** coupled with shaft **1001** at or near distal portion **1003**, and a handle **1006** coupled with shaft **1001** at or near proximal portion **1002**. Optionally, some embodiments may also include one or more power connectors **1010** for connecting device **1000** with one or more power sources. In some embodiments, shaft **1001** has a size and shape that facilitate passage of at least distal portion **1003** into an epidural space of the spine and between target tissue, such as ligamentum flavum, and non-target tissue, such as neural and/or neurovascular tissue. In some embodiments, shaft **1001** may include one or more bends or curves at or near its distal portion **1003** to further facilitate passage and positioning of device **1000**. In some embodiments, for example, a bend or curve may facilitate passage of at least part of distal portion **1003** at least partway into an intervertebral foramen.

[**0111**] In some embodiments, as shown in FIG. **11**A, distal portion **1003** of device **1000** may be advanced through the skin of the back of a patient, adjacent a spinous process. Distal portion **1003** may then be advanced between the lamina of adjacent vertebral bodies, into the epidural space, and between target and non-target tissues to position tissue modifying member(s) **1004** in a desired location for modifying target tissue. Power may then be provided to activate tissue modifying member(s) **1004** and thus to modify target tissue. A portion of device **1000** adjacent tissue modifying member(s) **1004** may be configured to face non-target tissue while tissue modifying member(s) **1004** face the target tissue, thus preventing unwanted damage or modification of the non-target tissue. In some embodiments, as described more fully above, the portion of device **1000** facing the non-target tissue may be configured to modify the non-target tissue in some way, such as to protect the tissue with a delivered substance, and/or to test the non-target tissue to confirm that it is non-target tissue.

[**0112**] In various embodiments, handle **1006** may have any suitable configuration and features. In some embodiments, handle **1006** includes one or more actuators for activating tissue modifying member(s) **1004**. Power connector **1010** may have any suitable configuration and may deliver any suitable type of energy from an external power source (not shown) to device **1000** in various embodiments, such as but not limited to electric, radiofrequency, ultrasound, laser or conductive energy. In alternative embodiments, device **1000** may be battery operated or use any other suitable source of internal power or energy, and such internal energy source may be housed in handle **1006**, for example. From whatever source, power is typically transmitted to tissue modifying member(s) **1004** to activate them and thus modify tissue.

[**0113**] With reference now to FIG. **11**B, in various embodiments, tissue modification device **1000** may be advanced into a patient using any of a number of suitable techniques and approaches, some of which have been described previously. FIG. **11**A illustrates one approach to advancing distal portion **1003** of device **1000** to a position between target and non-target tissue from a contralateral approach, while FIG. **11**B illustrates an ipsilateral approach. As shown in FIG. **11**B, distal portion **1003** may include two or more bends and/or may be at least partially flexible or steerable to facilitate a desired approach angle, according to various embodiments.

[**0114**] Turning to FIG. **12**, in another embodiment a tissue modification device **1020** includes an elongate shaft **1011** having a proximal portion **1012** and a distal portion **1013**, one or more tissue modification member(s) **1014**, a conductive electrode **1015** coupled with shaft **1011**, a handle **1016**, a power connector **1030**, and multiple additional connection members **1032**, **1033**. Electrode **1015** may be configured to deliver a non-target frequency and non-target amplitude of electrical current to non-target tissue. The non-target frequency and non-target amplitude may stimulate a response from a neural tissue. In one embodiment, a first connection member **1032** may provide power to electrode **1015**, and if non-target-tissue is stimulated by current from the electrode, the observation of this stimulation, as measured by EMG, SSEP or watching for muscular activation, provides evidence that electrode **1015** is adjacent the non-target tissue. A target stimulating electric current may also be delivered through second connection member **1033** to tissue modifying member(s) **1014** (e.g., composed of electrically conductive material) and/or to a target stimulating electrode located adjacent and on the same side of device **1020** as tissue modifying member(s) **1014**. For example, if the target simulating electric current is configured with a frequency and amplitude to stimulate a response from neural tissue, the type (e.g., neural, non-neural) of the tissue immediately adjacent tissue modifying member(s) **1014** may be determined based on the tissue response or lack thereof. In one embodiment, device **1020** may be configured to allow for control of the target stimulating electric current and the non-target stimulating electric current. For example, the target stimulating electric current and the non-target stimulating electric current may be sequentially delivered to distal portion **1013** of device **1020** to determine the location of neural tissue prior to activation of tissue modifying member(s) **1014**, for example, to help ensure that tissue modifying member(s) **1014** do not damage neural tissue.

[**0115**] In various embodiments, tissue modifying member(s) **1014** may include one or more of a rongeur, a curette, a scalpel, one or more cutting blades, a scissors, a forceps, a probe, a rasp, a file, an abrasive element, one or more small planes, an electrosurgical device, a bipolar electrode, a unipolar electrode, a thermal electrode, a rotary powered mechanical shaver, a reciprocating powered mechanical shaver, a powered mechanical burr, a laser, an ultrasound crystal, a cryogenic probe, a pressurized water jet, or some combination thereof. Some embodiments include one tissue modifying member **1014**, while others include multiple

tissue modifying members **1014**. As is described further below, tissue modifying member(s) **1014** may have any of a number of suitable sizes, shapes and configurations and may move or actuate in any suitable way.

[**0116**] Referring now to FIG. **13**A, in an alternative embodiment, a tissue modification device **1040** includes an elongate shaft **1041**, one or more tissue modifying member(s) **1044**, a handle **1046** and a power connector **1050**. Additionally, device **1040** may include a guidewire lumen (not shown) extending through all or part of shaft **1041**, which may allow passage of a guidewire **1048** having proximal **1049** and distal **1047** ends therethrough. In one embodiment, for example, guidewire **1048** may extend from a proximal end of shaft **1041** through a distal end of shaft **1041** and out the patient. In some embodiments, as described previously above, anchoring and/or tensioning force may be applied at or near distal end **1047** and/or proximal end **1049** to help urge tissue modifying member(s) **1044** against target tissue.

[**0117**] In the embodiment shown in FIG. **13**A, tissue modifying member **1044** is shown having relatively flat configuration. In many of the subsequent embodiments described herein, various embodiments of tissue modifying members are also shown as having flat configurations, primarily for ease of description. In alternative embodiments, however, and with reference now to FIG. **13**B, tissue modification device may include a curved and/or flexible tissue modifying member **1045** (or multiple curved and/or flexible members), having a curved/flexible surface for contacting target tissue. Device **1040** may also include a curved and/or flexible shaft **1042**. Such curved and/or flexible tissue modifying members **1045** (or tissue modifying surfaces) and shafts **1042** may facilitate tissue modification in some embodiments, in that tissue modifying members **1045** may more readily conform to target tissue. In alternative embodiments, many if not all of the devices described in the present application may have such curved and/or flexible tissue modifying member(s).

[**0118**] Referring now to FIGS. **13**C-**13**E, several alternative embodiments of anchoring members for use with a tissue modification device are shown. FIG. **13**C, for example, shows tissue modification device **1040** including a wire anchor **1060** coupled with guidewire **1048**. In various embodiments, wire anchor **1060** may be either removably or permanently attached to guidewire **1048** at or near its distal end **1047** to provide anchoring force against the patient's back from outside the patient. Wire anchor **1060** may minimize or prevent guidewire **1048** from moving through the patient's back towards proximal end **1049**. In alternative embodiments, additional anchoring and/or tensioning force may be applied to distal end **1047**, such as by holding and/or pulling distal end **1047** by hand.

[**0119**] In an alternative embodiment, as shown in FIG. **13**D, distal end **1047** of guidewire **1048** may include one or more deployable anchoring members **1062**, which may be deployed within the patient to anchor into tissue of the patient's back, such as muscle, bone, ligament or the like. In one embodiment, for example, guidewire **1048** may have one or more lumens (not shown), and anchoring members **1062** may be translated through the lumen(s) to extend out of distal end **1047**. When a tissue modification procedure is complete, anchoring members **1062** may be retracted within the lumen(s) so that guidewire **1048** may be more easily removed from the patient.

[**0120**] Referring to FIG. **13**E, in another embodiment tissue removal device **1040** may also include one or more proximal shaft anchoring members **1066** and/or one or more proximal guidewire anchoring members **1064**. Shaft anchoring member **1066** may, in alternative embodiments, either be coupled with or removably couplable with shaft **1041** to facilitate application of anchoring force. For example, in one embodiment, shaft anchoring member **1066** may abut the patient's back to resist translation of shaft **1041** into the patient.

[**0121**] Proximal guidewire anchoring member **1064** may be included in handle **1046**, as shown, or in other embodiments may be located proximal or distal to handle **1046**. Guidewire anchoring member **1064** may be used to lock or anchor guidewire **1048** to prevent or minimize its translation into or out of device **1040**. This may help facilitate application of tensioning and/or anchoring force via guidewire **1048**.

[**0122**] FIGS. **13**F and **13**G show cross-sectional views of handle **1046** and proximal guidewire anchoring member **1064** taken through line C-C on FIG. **13**D. In one embodiment, handle **1046** may include proximal guidewire anchoring member **1064**, a tissue modifying drive **1068** in a first lumen, a guidewire **1048** in a guidewire lumen **1070**, multiple guiding slots **1074** with corresponding guiding tabs **1075**, and one or more lobes **1072**. As shown in FIG. **13**F, when guidewire anchoring member **1064** is disengaged, guidewire **1048** may freely translate within guidewire lumen **1070**, because lobe **1072** does not interfere. As shown in FIG. **13**G, when guidewire anchoring member **1064** is engaged, for example by translating and/or rotating guidewire anchoring member **1064** with respect to handle **1046**, guidewire **1048** may friction fit (e.g., clamp, pinch) between lobe **1072** of guidewire anchoring member **1064** and the wall of guide wire lumen **1070**. Guidewire anchoring member **1064** may then be translated and/or rotated back to the original position (FIG. **13**F) to disengage guidewire **1048**.

[**0123**] Referring now to FIG. **14**, in some embodiments a tissue removal device **1100** may include an elongate shaft **1104** having proximal **1106** and distal **1105** portions, one or more tissue modifying members **1108**, a movable handle **1103** coupled with proximal portion **1106**, and a power connector **1107**. In the embodiment shown, distal portion **1105** is at least partially steerable (shown in FIG. **14** as two, overlapping distal portions), and movable handle **1103** may be used (two-headed, straight arrow) to steer distal portion **1105** while holding shaft **1104** relatively stationary. A steerable distal portion **1105** may enhance the ability of tissue modifying members **1108** to contact and apply force against target tissue. In some embodiments, the location of tissue modifying members **1108** may be adjusted, using steerable distal portion **1105**, without significantly moving shaft **1104**. In some embodiments, steerable distal portion **1105** may move in multiple directions, such as laterally and up-and-down, relative to the longitudinal axis of shaft **1104**. Movable handle **1103** may operate with a piston-like motion, in one embodiment, where a distal portion of handle **1102** is attached to the shaft and a proximal portion handle **1103** is

attached to a tensioning member. The tensioning member may translate tension to steerable distal end **1105** when handle **1103** is actuated, which in turn deflects distal end **1105**. In various alternative embodiments, any other handle steering mechanisms and/or other steering mechanisms, many of which are known in the art, may be used.

[**0124**] FIGS. **15**A and **15**B show one embodiment of a tissue modification device **1080**, which includes an elongate shaft **1081**, one or more tissue modifying members **1082**, a handle **1084**, a visualization device **1086**, an optical cable **1090** and a power connector **1088**. Visualization device **1086** may include any suitable device, such as but not limited to an endoscope. An endoscope visualization device may have lenses and/or fiber optics, for example, for delivering light (or other energy) to illuminate the tissue and capturing images. As shown in FIG. **15**B, in some embodiments, visualization device **1086** may include one or more image capturing elements **1094** and one or more illuminating elements **1092**. Image capturing element **1094** may include, for example, a CCD or CMOS chip, in some embodiments. Illuminating element **1092** may include, for example, one or more light emitting diodes (LEDs) or fiber optics, in some embodiments.

[**0125**] In some embodiments, optical cable **1090** may include fiber optics. Some or all of the fiber optics may comprise or may be coupled with illuminating elements **1092**. Alternatively or additionally, some or all of the fiber optics may be connected to a camera (not shown). For example, such a camera may be attached to the proximal end of tissue modification device **1080**. Optical cable **1090** may alternatively include one or more electrical wires connected to a power source (e.g., to power LED(s)) and/or an image capturing element **1094**. Lenses, fiber optics, LED(s), or combinations thereof may be used for illumination with lenses, fiber optics, CCD, CMOS, or combinations thereof used for image capturing, according to various embodiments.

[**0126**] Referring now to FIG. **16**, another embodiment of a tissue modification device **1120** may suitably include an elongate shaft **1132**, one or more tissue modifying members **1130**, a handle **1124**, a visualization device **1122**, an optical cable **1128** and a power connector **1126**. In this embodiment, visualization device **1122** is located proximal to tissue modifying member(s) **1130** on shaft **1132**. In various embodiments, visualization device(s) **1112** may be positioned along shaft **1132** at any desired location.

[**0127**] FIGS. **17**A-**17**E show cross-sectional views of various embodiments of shaft **1132**, from the perspective of line A-A in FIG. **16**. In the embodiment shown in FIG. **17**A, for example, shaft **1132** may include a tissue modifying drive **1134** within a tissue modifying drive lumen **1140**, and a guidewire **1136** within a guidewire lumen **1138**. Tissue modifying drive **1134** may be configured to translate or rotate with respect to tissue modifying drive lumen **1140**. Examples of tissue modifying drives **1134** include, but are not limited to, a drive shaft, one or more conductive wires, one or more optical fibers, or the like. Various embodiments may also include a motor, which may be located in the handle of the device, near the device distal end, in a separate drive apparatus, or the like.

[**0128**] In an alternative embodiment, as shown in FIG. **17**B, shaft **1132** may include tissue modifying drive **1134** within tissue modifying drive lumen **1140**, guidewire **1136** within guidewire lumen **1138**, conductive elements **1146** within a visualization lumen **1144**, and suction/irrigation lumen **1142**. Suction/irrigation lumen **1142** may be used, for example, to deliver gas, fluid or pushable solids (e.g., granular solids) from outside the patient to the distal end of the device or to aspirate gas, fluids, tissue and/or other material from the targeted tissue region to the outside of the patient. Suction/irrigation lumen **1142** may also be used, in some embodiments, to slidably pass instruments, such as a long flexible needle or biopsy forceps. Visualization lumen **1144**, in some embodiments, may be configured to receive conductive elements **1146**, such as elements to power LEDs at the distal end of the device, and/or to carry the signal from a CCD or CMOS chip located at the distal end of the device that has captured a visual image and converted it into an electronic signal to a display device located outside the patient.

[**0129**] In yet another alternative embodiment, shown in FIG. **17**C, shaft **1132** may include tissue modifying drive **1134** within tissue modifying drive lumen **1140**, conductive elements and/or fiber optics **1152** within visualization lumen **1144**, and separate suction **1150** and irrigation **1148** lumens. Suction lumen **1150** and irrigation lumen **1148** may be used, in some embodiments, to simultaneously or sequentially deliver and remove gases, fluids and/or pushable solids to and from the distal end of a tissue modification device. Delivery and removal of gases, fluids and/or pushable solids may help clear detached and/or non-detached target tissue and other debris from the treatment site and/or maintain a clear visualization of the target and non-target tissue via the visualization element.

[**0130**] In another embodiment, illustrated in FIG. **17**D, fiber optics **1152** may be disposed within a hollow shaft **1132**, in between various lumens **1148**, **1150**, **1144**, **1140**. Alternatively, fiber optics **1152** may be replaced with electrical conductors in other embodiments. Fiber optics **1152** may deliver light to illuminate the target tissue and/or deliver light from the tissue to a viewing device. Visualization lumen **1144**, in such an embodiment, may transport light or electrical signals in proximal and/or distal directions.

[**0131**] In yet another alternative embodiment, as in FIG. **17**E, shaft **1132** may include a steering actuator **1154** within a steering lumen **1156**. Steering actuator **1154** may be used, for example, to help steer a distal portion of a tissue modification device, as described in further detail above.

[**0132**] FIG. **18** is an end-on cross-sectional view of tissue modification device **1120** of FIG. **16**, shown from the perspective of line B-B. In this embodiment, visualization device **1122** and illuminating elements **1158** are located proximal to tissue modifying member **1130**. In the embodiment shown, tissue modifying member **1130** includes a rotating disc mounted on a post in a bearing **1160**, with multiple raised cutting edges **1131** on the disc. Two suction/irrigation lumens **1142** allow for introduction and suction of gas, fluid and/or pushable solids from an area of tissue modification.

[**0133**] FIGS. **19**-**40**F illustrate a number of embodiments of a distal end of a tissue modification device having various different tissue modifying members. Referring to FIG. **19**, in one embodiment, a tissue modification device **1170** may include multiple tissue modifying members **1172**, each

including a cup **1174** attached to a drive shaft **1173** and having a cutting edge **1175**. Tissue modifying members are located within an open chamber **1176** formed by multiple walls **1178**, **1180**, **1182**, **1184**, **1186**. Cups **1174** may be rotated and/or translated to cut target tissue disposed in open chamber **1176**, as shown by the curved and straight arrows.

[**0134**] FIG. **19**A illustrates an alternative embodiment in which a tissue modification device **1170***a* may include a shaft **1171**, which is curved and/or flexible along at least part of its length, and a tissue modifying portion **1177**, which is also curved and/or flexible. Tissue modifying portion **1177** may include curved and/or flexible shafts **1173***a*, and cups **1174***a*, similar to those shown in FIG. **19**. As mentioned previously, many of the embodiments described herein may have either flat/straight tissue modifying members/surfaces or curved and/or flexible tissue modifying members/surfaces, according to various embodiments. Therefore, although many of the following embodiments of tissue modifying members are shown and described as having generally flat configurations, in alternative embodiments, many if not all such tissue modifying members may have curved and/or flexible configurations instead.

[**0135**] In an alternative embodiment, shown in FIG. **20**, a tissue modification device **1190** may include multiple tissue modification members **1192**, each comprising a hollow tube **1194** with a cutting edge **1193**. In one embodiment, tubes **1194** may be rotated and translated to cut tissue. Tubes **1194** may also be used for suction and/or irrigation in some embodiments.

[**0136**] FIG. **21** shows another alternative embodiment, in which a tissue modification device **1200** includes a tissue modifying member **1202** comprising a disc and multiple raised cups **1204**, each cup having a cutting edge **1205**, and the disc being mounted on a drive shaft **1206**. In one embodiment, tissue modifying member may oscillate by moving shaft **1206** back and forth and/or may rotate by rotating the disc around an axis.

[**0137**] In another embodiment, as in FIG. **22**, a tissue modification device **1210** may include two rotating tissue modification members **1212***a*, **1212***b*, each comprising a disc with raised cutting members. The discs may rotate in the same directions or opposite directions in various embodiments. Rotating members **1212***a*, **1212***b* in opposite directions may help balance forces between the two members **1212***a*, **1212***b* and target tissue, thereby helping stabilize tissue modification device **1210** and enhance tissue modification procedures.

[**0138**] FIG. **23** illustrates that, in some embodiments, a tissue modifying member **1224** of a tissue modification device **1220** may be angled relative to a longitudinal axis of a distal portion **1126** of a shaft **1222**. Angling tissue modifying member **1224** away from the long axis of distal portion **1126** may allow tissue modifying member **1224** to extend out of a an open chamber or window, for example, to facilitate tissue in various embodiments. Angling tissue modifying member **1224** may also enhance contact of tissue modifying member **1224** with target tissue, thus enhancing tissue modification.

[**0139**] In another alternative embodiment, as in FIG. **24**, a tissue modification device **1230** may include a tissue modification member **1234** that extends out of a distal opening **1236** at the distal end of a shaft **1232**. In some embodiments, tissue modification member **1234** may be moved back and forth to be housed within or to extend out of distal opening **1236**. In other embodiments, tissue modification member **1234** may be fixed in relation to opening **1236**.

[**0140**] FIG. **25** shows another embodiment of a tissue modification device **1240**, which includes tissue modifying members **1242**, each including a rotating shaft **1244**, **1246** and a helical cutting blade **1248**. Device **1240** also may include one or more irrigation ports **1250** and one or more suction ports **1252**. In various embodiments, cutting blades **1248** may be configured to remove both hard and/or soft tissue. Cutting blades **1248** may also be configured to transport separated tissue proximally toward and/or into the shaft of device **1240**, and/or suction port **1252**, so that such tissue may be removed from the patient. Rotating shafts **1244** may be configured to rotate in opposite directions, in some embodiments, thus helping balance forces exerted by tissue modifying members **1242** on target tissues.

[**0141**] In yet another embodiment, shown in FIG. **26**, a tissue modification device **1260** may include a tissue modifying member **1262** comprising a belt **1266**, mounted on rotating rollers **1264** and carrying multiple raised abrasive members **1268**. Rollers **1264** may be activated to rotate, thus causing belt **1266** to move, and thus causing abrasive members **1268** to abrade target tissue.

[**0142**] In a similar alternative embodiment, shown in FIG. **27**, a tissue removal device **1270** may include a tissue modifying member **1272** comprising a belt **1276**, mounted on rotating rollers **1278** and carrying multiple raised cutting members **1274**. Rollers **1278** may be activated to rotate, thus causing belt **1276** to move, and thus causing cutting members **1274** to cut target tissue.

[**0143**] Referring to FIG. **28**, in another alternative embodiment, a tissue removal device **1280** may include a tissue modifying member **1286** comprising one or more wires that move along multiple transverse guide rails **1282**, **1284**. In one embodiment, tissue modifying member **1286** may move laterally along guide rails **1282**, **1284** and may also translate over guide rails **1282**, **1284**. In various embodiments, the tissue modifying member(s) **1286** (i.e., the wire(s)) may translate, rotate, reciprocate and/or oscillate. In some embodiments, the wire(s) may be coated (e.g., on the outer surface) with an abrasive material, and/or have a high friction outer texture. In some embodiments, the wires may be coupled to an energy (e.g., RF current, thermal) generator. In alternative embodiments, wires may be solely at or within the shaft distal portion or may extend from the shaft distal end to a more proximal location along shaft.

[**0144**] FIG. **29** illustrates another embodiment of a tissue modification device **1290**, in which a tissue modifying member **1292** is coupled with rotating drive post **1294** and two free posts **1296**, **1298**. Drive post **1294** is coupled with a drive shaft **1302**, which turns drive post **1294**, thus translating tissue modifying member **1292** to modify tissue. Tissue modifying member **1292** may be elevated above a floor **1300** of the device shaft, so as to more easily contact target tissue. In various embodiments, tissue modifying member **1292** comprises a cutting wire or abrasive wire and may be translated either in one direction or in both direc-

tions. In some embodiments, drive shaft **1302** may be advanced and retracted to further move and/or change the configuration of tissue modifying member **1292**.

[**0145**] Referring now to FIGS. **30**A-**30**C, in another embodiment, a tissue modification device **1310** may include a tissue modifying member **1312** comprising a movable platform with an abrasive surface and coupled with a drive shaft **1314** extending out of a distal opening **1316**. As shown in the various figures, in some embodiments tissue modifying member **1312** may move laterally (FIG. **30**A), may translate back and forth (FIG. **30**B) and/or may vibrate (FIG. **30**C).

[**0146**] In yet another embodiment, as in FIG. **31**, a tissue modification device **1320** may include a tissue modification member **1322** comprising an oval or round platform with an abrasive surface and coupled with a drive shaft **1324** extending out of a distal opening **1326**. In such an embodiment, tissue modifying member **1322** may be made to rotate or move in a circular pattern, as well as translate, move laterally, oscillate and/or vibrate according to various embodiments.

[**0147**] Referring to FIG. **32**, in another embodiment a tissue modification device **1330** includes multiple tissue modifying members **1332**, each including a movable platform **1333** with an abrasive surface attached to a drive shaft **1334**. Tissue modifying members may move back and forth relative to one another and to the device shaft in any suitable pattern. Moving tissue modifying members **1332** back and forth relative to one another may help them apply tensioning forces to target tissue, thereby enhancing the ability of tissue modifying members **1332** to cut, shear, tear and/or otherwise modify target tissues.

[**0148**] As shown in FIG. **33**, in another alternative embodiment, a tissue modification device **1340** may suitably include tissue modifying members comprising one or more blades, such as a distal blade **1344***a* and a proximal blade **1344***b*, each having a cutting edge **1345***a*, **1345***b*. In the embodiment shown, proximal blade **1344***b* is movable and may translated distally toward the opposing distal blade **1344***a*. In alternative embodiments, distal blade **1344***a* may be movable or both blades **1344***a*, **1344***b* may be movable. Alternative embodiments may include one movable blade, more than two movable blades facing in one direction, more that two movable blades facing in different directions, a movable blade and a backstop against which the blade may be driven, or any other suitable combination of movable and/or immobile blades. Furthermore, any blade of any given embodiment may have any suitable shape, size and overall configuration. In some embodiments, blades may be flat, while in others they may be curved, squared off, ridged, bent, serrated or the like. Blades may be long or short, multiple blades may be aligned closely one after the other, such as in a typical multi-blade razor used for shaving a face, multiple blades may be disposed apart from one another by several millimeters or even centimeters, and/or the like. Blades may have any suitable amount of sharpness or dullness, and in some embodiment a combination of sharper and duller blades may be used. Therefore, although exemplary embodiments of blades are described in detail above and below, any other suitable blades or combinations of blades may be substituted in various embodiments, without departing from the scope of the present invention.

[**0149**] Blades **1344***a*, **1344***b*, or any other blades described in alternative embodiments herein, may be fabricated from metals, polymers, ceramics, any other suitable material or combination of materials. According to various embodiments, suitable metals for blades may include, but are not limited to, stainless steel (303, 304, 316, 316L), nickel-titanium alloy, or cobalt-chromium alloy, for example, Elgiloy® (Elgin Specialty Metals, Elgin, Ill., USA), Conichrome® (Carpenter Technology, Reading, Pa., USA), or Phynox® (Imphy SA, Paris, France). Polymer materials include nylon, polyester, Dacron®, polyethylene, acetal, Delrin® (DuPont), polycarbonate, nylon, polyetheretherketone (PEEK), and polyetherketoneketone (PEKK). In some embodiments where polymers are used, such polymers may be glass-filled or carbon-filled to add strength and stiffness. Ceramics may include, but are not limited to, aluminas, zirconias, and carbides. Blades may be manufactured using skills known in the art, for example, metal injection molding (MIM), CNC machining, injection molding, grinding, EDM, sheet metal bending, etching, or the like. Other portions of a tissue modification device, such as a cover over one or more blades or other features, may be made of any suitable material now known or hereafter discovered. A blade cover, for example, may be fabricated in various embodiments of one or more polymeric materials, such as nylon, silicone, polyetheretherketone (PEEK), polyetherketoneketone (PEKK), polytetrafluoroethylene (PTFE), polyurethane (Tecothane,), Pebax (co, USA), polycarbonate, Delrin (co, USA), high-density polyethylene (HDPE), low-density polyethylene (LDPE), HMWPE, UHMWPE, or the like.

[**0150**] Referring now to FIG. **34**A, in one embodiment a tissue modification device **1350** may have a substantially cylindrical, circular, or otherwise curved shaft **1352** as well as one or more substantially cylindrical, circular, or otherwise curved blades **1354**. In the embodiment shown, blade **1354** protrudes out of a window **1358** of shaft **1352**. When blade **1354** is moved proximally (arrow), its cutting edge **1356** moves toward and perhaps engages with an opposing cutting edge **1356** of shaft **1352**.

[**0151**] In an alternative embodiment, as in FIG. **34**B, a tissue modification device **1360** may have a substantially cylindrical, circular, or otherwise curved shaft **1362** as well as one or more substantially cylindrical, circular, or otherwise curved blades **1364**. In the embodiment shown, blade **1364** protrudes out of a window **1368** of shaft **1362**. Blade **1364** may be rotated (arrows), to cause its cutting edges **1366** cut target tissue. In some embodiments, one or more curved blades **1364** may be translated as well as rotated. In either of the embodiments shown in FIGS. **34**A and **34**B, cut target tissue may optionally be removed through the inside of curved shaft **1352** or curved blade **1364**.

[**0152**] Referring now to FIGS. **35**A and **35**B, in some embodiments, a tissue modification device may include one or more anchoring members **1374** coupled with a distal shaft portion **1370** of the device. In various embodiments, any of a number of suitable anchoring members may be used. Some embodiments of anchoring members have been previously described above, and others will be described further below. In one embodiment, for example, anchoring members **1374** may comprise multiple needles, as shown in FIGS. **35**A and **35**B. Needles **1374** may act not only to anchor distal shaft portion **1370** to tissue, but may also change one or more characteristics of the tissue. For example, in some embodi-

ments, inserting multiple needles into tissue may stiffen the tissue and thus enhance the ability of one or more tissue modifying members **1372** to cut or otherwise modify the tissue. In one embodiment, anchoring members/needles **1374** may be deployable out of distal shaft portion **1370** (arrow), such that needles **1374** are retracted during delivery of the device into the patient and then deployed into the target tissue when in a desired position. In various embodiments, anchoring members/needles **1374** may extend out of distal shaft portion **1370** in an orientation substantially perpendicular to the longitudinal axis of distal shaft portion **1370** or in any other suitable orientation relative to distal shaft portion **1370**. or otherwise non-parallel to the longitudinal axis. During use, the tissue stiffening projections can extend into the target tissue. Needles **1374** will typically have a modulus of elasticity greater than the modulus of elasticity of the target tissue, and thus may stiffen (i.e., increase the effective modulus of elasticity) of the target tissue.

[0153] In the embodiment shown in FIGS. **35**A and **35**B, as well as in any alternative embodiments described herein, one or more members such as tissue anchoring members/needles **1374** may be used to modify tissue in any of a number of suitable ways. For example, in some embodiments, energy may be transmitted to one or more tissue anchoring members/needles **1374** to cool, heat or otherwise transmit energy to the tissue. Such cooling or heating, for example, may further change the stiffness or consistency of the tissue, thus facilitating tissue modification by one or more tissue modifying members. In one embodiment, for example, it may be advantageous to cool or even freeze tissue to increase its stiffness so that it can be more easily cut or abraded. For example, in some embodiments, a cryogenic fluid may be delivered via an irrigation lumen and/or suction/irrigation lumen to directly reduce the temperature of the anchoring members **1374** or to separately cool the target tissue. Any other suitable change may alternatively be made to tissue to enhance a tissue modification procedure according to various embodiments.

[0154] As shown in FIG. **35**B, when anchoring members **1374** are in place within target tissue, tissue modifying member **1372** (a blade in the embodiment shown) may be translated out of distal shaft portion to cut or otherwise modify tissue. Tissue modifying member **1372** may advance out of distal shaft portion **1370** in a direction perpendicular or otherwise non-parallel to anchoring members **1374**. In some embodiments, anchoring members/needles **1374** may retain target tissue after cutting, so that it may be removed from the patient.

[0155] FIGS. **36**A and **36**B illustrate an alternative embodiment a tissue stiffening probe **1382** extends out of a distal shaft portion **1380** (FIG. **36**A) and then breaks into multiple tissue stiffening inserts **1386** (FIG. **36**B) to stiffen target tissue before it is modified by a tissue modifying member **1384**. Alternatively, multiple tissue stiffening inserts **1386** may be delivered directly into the tissue. In some embodiments, inserts **1386** may be made from a bioresorbable material, so that if one or more inserts are left in the patient, they will harmlessly resorb in the patient's body.

[0156] In yet another embodiment, shown in FIGS. **37**A and **37**B, a tissue modification device **1390** includes multiple deployable tissue anchoring members **1392** and a tissue modifying blade **1396** that translates through a blade lumen **1394**. Tissue anchoring members **1392** may have a curved or circular configuration upon being deployed from tissue modification device **1390**, and in some embodiments they may serve the dual function of anchoring to tissue and stiffening tissue.

[0157] With reference now to FIG. **38**A, an end-on view of one embodiment of a tissue modification device **1400** shows that anchoring members **1406** may alternatively comprise one or more deployable support members, which may be extended laterally out of a distal shaft portion **1402** to anchor in tissue and support distal shaft portion **1402** and a tissue modifying member **1404**. Any desired number, size, shape and configuration of lateral anchoring members **1406** may be used in various embodiments.

[0158] FIG. **38**B shows an alternative embodiment in which a tissue modification device **1410** includes anchoring members **1416**, which extend laterally and inferiorly from a distal shaft portion **1412** to support distal shaft portion **1412** and tissue modifying member **1414**.

[0159] In yet another embodiment, as shown in FIG. **38**C, an inflatable balloon **1426** may be included on a distal shaft portion **1422** of a tissue modification device **1420** to support distal shaft portion **1422** and tissue modifying member **1424**.

[0160] Referring now to FIGS. **39**A-**39**D, in another alternative embodiment, a tissue modification device **1430** may suitably include a shaft **1432** and a semicircular tissue modifying member **1434**. Tissue modifying member **1434** may include multiple cup-shaped blades **1435**, each having a cutting edge **1436**, and may rotate about a central axle **1440** that defines a central axis of rotation **1438**. In some embodiments, as shown in FIG. **39**B, tissue modifying member **1434** may be hollow and may include a chamber **1442** which may collect cut tissue for removal from the patient. Cups **1435** may be in fluid communication with chamber **1442** such that at least some of the tissue removed by cups **1435** enters chamber **1442**. Suction may be applied to enhance the capture of tissue in chamber **1442** and/or to remove tissue from chamber **1442** proximally through shaft **1432**.

[0161] Each cup **1435** may be spaced apart from adjacent cups **1435** at regular angle intervals, for example, in longitudinal and/or latitudinal direction around tissue modifying member **1434**. Cups **1434** may be disposed on all or part (FIGS. **39**C and **39**D) of the perimeter of tissue modifying member **1434**. Tissue modifying member **1434** may rotate, in various embodiments, either clockwise, counterclockwise or both. In some embodiments, tissue modifying member **1434** may have clockwise and/or counterclockwise rotational limits. For example, such rotational limits may comprise from about −180° to about 180°, or alternatively from about −90° to about 90°, or alternatively from about −45° to about 45°. In some embodiments, tissue modification device **1430** may be counterbalanced (e.g., to minimize vibrations caused by the oscillating or otherwise rotating tissue modifying member **1434** during use). For example, shaft **1432** may comprise an offset-weighted rotating balance shaft.

[0162] Referring now to FIGS. **40**A-**40**F, another alternative embodiment of a tissue modification device **1440** may

include a shaft **1442**, and a tissue modifying member **1444** including multiple cutting members **1445**. (In alternative embodiments, tissue modifying member **1444** may include an abrasive surface in place of cutting members **1445**.) As shown in FIGS. **40**B and **40**C, tissue modifying member **1444** may include a platform **1448**, multiple cutting members **1445**, an axle **1456** defining an axis of rotation **1458**, a bottom plate **1450**, a drive groove **1452**, a cross beam **1454**, and a base plate **1460**. Device **1440** may further include a tissue modifying drive shaft **1462**. Base plate **1460** may be rigidly attached to a mount **1464** (FIG. **40**C). Platform **1448** may be integrated with and/or attached to bottom plate **1450** at cross beam **1454** or, in an alternative embodiment, at a center shaft (not shown). Cross beam **1454** may include a stress relief channel **1466** (FIG. **40**C). Mount **1464** may be rotatably attached to stress relief channel **1466**. For example, mount **1464** may have one or more protruding beams that may extend into stress relief channel **1466**. Mount **1464** may be on one or both sides of the tissue modifying member **1444**. Mount **1464** may be biased with respect to stress relief channel **1466**, for example, to force cross beam **1454** to a configuration (e.g., perpendicular) with respect to base plate **1460** and bottom plate **1450**, as shown in FIGS. **40**B and **40**C.

[**0163**] In various embodiments, platform **1448** may be flexibly and/or rigidly integrated and/or attached to cross beam **1454**. Bottom plate **1450** may be flexibly and/or rigidly integrated and/or attached to cross beam **1454**. Base plate **1460** and/or bottom plate **1450** and/or cross beam **1454** may be attached and/or integrated to drive shaft **1462**. For example, the tissue modifying member **1444** may include a drive groove, and the drive groove may be configured to receive drive shaft **1462**.

[**0164**] FIGS. **40**D-**40**F demonstrate that tissue modifying member **1444** may flex to accommodate and more effectively modify target tissue from a number of orientations. FIG. **40**D illustrates that the target tissue may be proximal to rotational axis **1458**. Top plate **1448** may rotate with respect to bottom plate **1450**. Additionally, all or part of bottom plate **1450** may rotate with respect to base plate **1460**. Top plate **1448** may rotate passively (e.g., forced by pressure against the target tissue) or actively (e.g., driven by a motor or electrical current).

[**0165**] FIG. **40**E illustrates that the target tissue can be substantially aligned with rotational axis **1458**, while FIG. **40**F illustrates that the target tissue can be distal to rotational axis **1458**.

[**0166**] 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. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. For example, in many of the embodiments described above, one or more abrasive tissue modifying members may be substituted for one or more bladed tissue modifying members or vice versa. These an many other modifications may be made to many of the described embodiments. Therefore, the foregoing description is provided primarily for exemplary purposes and 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 device for modifying tissue in a spine, the device comprising:

a shaft having a proximal portion and a distal portion, the distal portion having dimensions which allow it to be passed into an epidural space of the spine and between target and non-target tissues;

at least one distal force application member extending from the distal portion of the shaft and configured to facilitate application of at least one of anchoring force and tensioning force to the shaft;

at least one movable tissue modifying member coupled with the shaft at or near its distal portion;

at least one drive member coupled with the at least one tissue modifying member to activate the at least one tissue modifying member; and

at least one power transmission member coupled with the at least one drive member to deliver power to the at least one drive member.

2. A device as in claim 1, further comprising at least one proximal force application member coupled with the shaft at or near the proximal portion and configured to facilitate application of at least one of anchoring and tensioning force to the shaft.

3. A device as in claim 2, wherein the proximal force application member comprises a handle.

4. A device as in claim 3, further comprising at least one actuator coupled with the handle for activating the at least one drive member to move the at least one tissue modifying member

5. A device as in claim 1, wherein the distal portion of the shaft has a width of not more than 7 mm.

6. A device as in claim 1, wherein the distal portion of the shaft has a height of not more than 2 mm.

7. A device as in claim 1, wherein the shaft includes at least one bend at or near the distal portion.

8. A device as in claim 1, wherein at least part of the distal portion of the shaft is at least one of flexible and steerable.

9. A device as in claim 1, wherein the shaft includes at least one of a guidewire lumen, a rail, a track, and a lengthwise impression along which the shaft may be passed over at least one guide member.

10. A device as in claim 9, wherein the distal force application member comprises at least one guide member having a length sufficient to extend from the proximal portion of the shaft, along at least a portion of the shaft, and beyond the distal portion.

11. A device as in claim 10, further comprising at least one deployable anchoring member coupled at or near a distal portion of the guide member for anchoring the guide member distal portion within a patient.

12. A device as in claim 10, further comprising at least one anchoring member coupled with or removably couplable with a distal portion of the guide member for applying at least one of anchoring and tensioning force to the guide member distal portion outside of a patient.

13. A device as in claim 1, wherein the tissue modifying member(s) are disposed along a length of the distal portion measuring no longer than 3 cm.

14. A device as in claim 1, 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, a powered mechanical burr, a laser, an ultrasound crystal, a cryogenic probe, and a pressurized water jet.

15. A device as in claim 1, wherein the distal force application member comprises at least one deployable anchoring member coupled with the distal portion of the shaft for anchoring the distal portion to tissue.

16. A device as in claim 15, 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, loops, lassos and backstops.

17. A device as in claim 1, wherein the distal force application member includes at least one deployable anchoring member for anchoring the distal portion outside a patient.

18. A device as in claim 1, wherein the distal force application member comprises a distal extension of the shaft.

19. A device as in claim 1, wherein the shaft further comprises at least one window on the distal portion, and wherein the at least one tissue modifying member modifies tissue through the window(s).

20. A device as in claim 19, wherein the at least one tissue modifying member is adjustable to at least partially extend out of the window.

21. A device as in claim 1, further comprising at least one visualization member disposed at or near the distal portion of the shaft for facilitating visualization of a tissue to be modified.

22. A device as in claim 1, further comprising at least one lumen extending through the shaft, the at least one lumen selected from the group consisting of an irrigation fluid lumen, a suction lumen, a combined irrigation/suction lumen, a guidewire lumen, a fiber optic lumen, a lumen for passage of one or more visualization devices, a lumen for passage of the power transmission member(s) and a lumen for passage of one or more steering members.

23. A device as in claim 22, further comprising at least one member extending through at least one of the lumen(s), the at least one member selected from the group consisting of fiber optic cables, electrical conductors, other visualization devices, one or more guidewires, other guide members and one or more steering members.

24. A device as in claim 1, wherein the power transmission member(s) are selected from the group consisting of radiofrequency, ultrasound, laser, microwave, water, thermal and cryogenic power transmission members.

25. A device as in claim 1, wherein the distal portion of the shaft includes at least one tissue protective surface disposed adjacent the tissue modifying member(s) for preventing unwanted damage to nearby tissues during a tissue modification procedure.

26. A device as in claim 1, further comprising at least one barrier device slidably coupled with the shaft for preventing unwanted damage to nearby tissues during a tissue modification procedure.

27. A device as in claim 25 or 26, further comprising at least one stimulation member coupled with the tissue protective surface or the barrier device to stimulate tissue in contact with the tissue protective surface or the barrier device.

28. A device as in claim 1, wherein the shaft includes a hollow chamber at or near its distal end for collecting removed tissue.

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

an elongate, at least partially flexible body having a proximal portion and a distal portion, the distal portion having dimensions which allow it to be passed between target and non-target tissues in the patient;

at least one distal force application member extending from the distal portion of the elongate body and configured to facilitate application of at least one of anchoring force and tensioning force to the elongate body;

at least one proximal force application member coupled with the elongate body at or near the proximal portion and configured to facilitate application of at least one of anchoring and tensioning force to the elongate body;

at least one movable tissue modifying member coupled with the elongate body;

at least one drive member coupled with the at least one tissue modifying member to activate the at least one tissue modifying member; and

at least one power transmission member coupled with the at least one drive member to deliver power to the at least one drive member.

30. A device as in claim 29, wherein the proximal force application member comprises a handle.

31. A device as in claim 30, further comprising at least one actuator coupled with the handle for activating the at least one drive member to activate the at least one tissue modifying member

32. A device as in claim 29, wherein the distal portion of the elongate body has a width of not more than 7 mm.

33. A device as in claim 29, wherein the distal portion of the elongate body has a height of not more than 2 mm.

34. A device as in claim 29, wherein the elongate body includes at least one of a guidewire lumen, a rail, a track, and a lengthwise impression along which the elongate body may be passed over at least one guide member.

35. A device as in claim 34, wherein the distal force application member comprises at least one guide member having a length sufficient to extend from the proximal portion of the elongate body, along at least a portion of the elongate body, and beyond the distal portion.

36. A device as in claim 35, further comprising at least one deployable anchoring member coupled at or near a distal portion of the guide member for anchoring the guide member distal portion within a patient.

37. A device as in claim 35, further comprising at least one anchoring member coupled with or removably couplable with a distal portion of the guide member for applying at

least one of anchoring and tensioning force to the guide member distal portion outside of a patient.

38. A device as in claim 29, wherein the tissue modifying member(s) are disposed along a length of the elongate body measuring no longer than 3 cm.

39. A device as in claim 29, 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, a powered mechanical burr, a laser, an ultrasound crystal, a cryogenic probe, and a pressurized water jet.

40. A device as in claim 29, wherein the distal force application member comprises at least one deployable anchoring member coupled with the distal portion of the elongate body for anchoring the distal portion to tissue.

41. A device as in claim 40, 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, loops, lassos and backstops.

42. A device as in claim 41, wherein the at least one anchoring member is configured to attach to a structure outside the patient's body.

43. A device as in claim 29, wherein the elongate body further comprises at least one window on the distal portion, and wherein the at least one tissue modifying member modifies tissue through the window(s).

44. A device as in claim 43, wherein the at least one tissue modifying member is adjustable to at least partially extend out of the window.

45. A device as in claim 29, further comprising at least one visualization member disposed at or near the distal portion of the elongate body for facilitating visualization of a tissue to be modified.

46. A device as in claim 29, further comprising at least one lumen extending through the elongate body, the at least one lumen selected from the group consisting of an irrigation fluid lumen, a suction lumen, a combined irrigation/suction lumen, a guidewire lumen, a fiber optic lumen, a lumen for passage of one or more visualization devices, a lumen for passage of the power transmission member(s) and a lumen for passage of one or more steering members.

47. A device as in claim 29, further comprising at least one member extending through at least one of the lumen(s), the at least one member selected from the group consisting of fiber optic cables, electrical conductors, other visualization devices, one or more guidewires, other guide members and one or more steering members.

48. A device as in claim 29, wherein the power transmission member(s) are selected from the group consisting of radiofrequency, ultrasound, laser, microwave, water, thermal and cryogenic power transmission members.

49. A device as in claim 29, wherein the distal portion of the elongate body includes at least one tissue protective surface disposed adjacent the tissue modifying member(s) for preventing unwanted damage to nearby tissues during a tissue modification procedure.

50. A device as in claim 29, further comprising at least one barrier device slidably coupled with the elongate body for preventing unwanted damage to nearby tissues during a tissue modification procedure.

51. A device as in claim 29, wherein the elongate body includes a hollow chamber at or near its distal end for collecting removed tissue.

52. A method for modifying tissue in a spine, the method comprising:

passing a distal portion of a tissue modification device into an epidural space of a spine 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 at least one of anchoring force and tensioning force at or near the distal portion and at or near a proximal portion of the tissue modification device to urge the at least one tissue modifying member against the target tissue; and

transmitting power to at least one drive member coupled with the at least one tissue modifying member to activate the tissue modifying member(s) and thus modify the target tissue.

53. A method as in claim 52, wherein passing the distal portion of the tissue modification device includes passing the device into a spinal channel selected from the group consisting of an intervertebral foramen and a central spinal canal.

54. A method as in claim 52, wherein modifying the target tissue comprises modifying at least one of ligament, tendon, tumor, cyst, cartilage, scar, osteophyte, inflammatory and bone tissue.

55. A method as in claim 52, 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.

56. A method as in claim 52, wherein applying the force comprises applying anchoring force to the device at or near the distal portion of the tissue modification device and applying tensioning force at or near the proximal end of the device.

57. A method as in claim 56, wherein applying the anchoring force comprises deploying one or more anchoring members located at or near the distal portion of the device within a patient's body.

58. A method as in claim 57, wherein the anchoring members apply the anchoring force to at least one of ligament, tendon, bone, connective tissue and muscle.

59. A method as in claim 56, wherein applying the anchoring force comprises deploying one or more anchoring members located at or near the distal portion of the device outside a patient's body.

60. A method as in claim 52, further comprising coupling one or more removable force application members to the tissue modification device at or near its distal end, outside a patient's body, to facilitate application of at least one of anchoring and tensioning force.

61. A method as in claim 52, wherein the tissue modification device is passed 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.

62. A method as in claim 61, wherein applying force at or near the distal portion of the device comprises applying at least one of anchoring force and tensioning force to at least one guide member extending from the device.

63. A method as in claim 52, wherein transmitting power to the at least one tissue modifying member causes the member(s) to modify the target tissue by 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.

64. A method as in claim 52, further comprising modifying the target tissue with at least one first tissue modifying member before transmitting power to at least one second tissue modifying member to further modify the target tissue.

65. A method as in claim 64, wherein the first tissue modifying members are configured to modify the consistency of the target tissue, and wherein the second tissue modifying members are configured to remove the target tissue.

66. A method as in claim 64, wherein the first tissue modifying members are selected from the group consisting of needles, anchors, drug delivery devices, fluid delivery devices, heating members, cooling members, electrodes and ultrasound transmission members.

67. A method as in claim 64, wherein modifying the target tissue with the first tissue modifying member(s) comprises deploying one or more anchors or needles into the target tissue.

68. A method as in claim 52, 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.

69. A method as in claim 52, 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.

70. A method as in claim 69, wherein positioning the at least one shield device comprises sliding the shield into position along the tissue modification device.

71. A method as in claim 69, 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.

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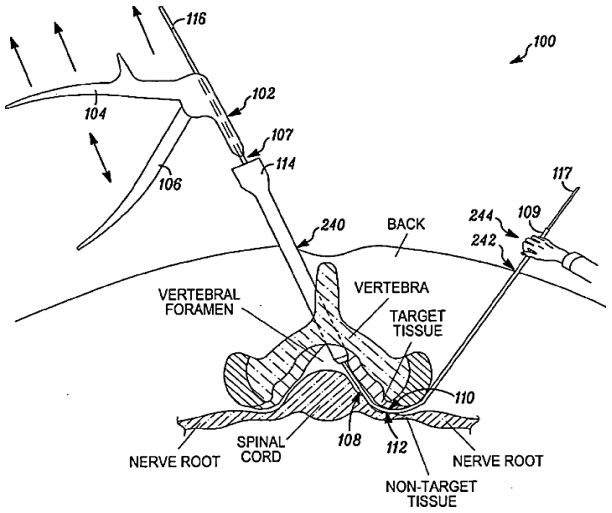
摘要(译)

用于改变脊柱中的组织的装置可包括：具有近端部分和远端部分的轴，远端部分具有允许其进入脊柱的硬膜外腔以及靶组织和非靶组织之间的尺寸;至少一个远端力施加构件从轴的远端部分延伸并且构造成便于向轴施加锚固力和张紧力中的至少一个;至少一个可移动的组织改变构件，在其远端部分处或附近与轴连接;至少一个驱动构件，其与所述至少一个组织改变构件连接，以激活所述至少一个组织改变构件;至少一个动力传输构件与所述至少一个驱动构件连接，以向所述至少一个驱动构件输送动力。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BACK
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109
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VERTEBRAL FORAMEN
VERTEBRA
TARGET TISSUE
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108
112
NERVE ROOT
SPINAL CORD
NERVE ROOT
NON-TARGET TISSUE