



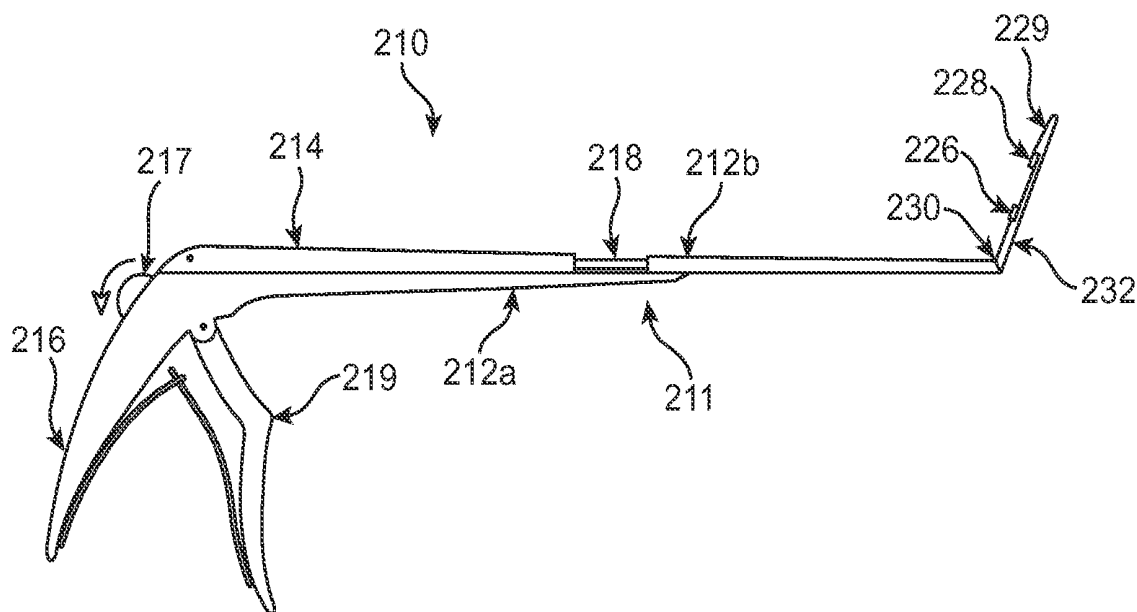
US 20080161809A1

(19) **United States**(12) **Patent Application Publication**
Schmitz et al.(10) **Pub. No.: US 2008/0161809 A1**(43) **Pub. Date: Jul. 3, 2008**(54) **ARTICULATING TISSUE CUTTING DEVICE****Publication Classification**(75) Inventors: **Gregory Schmitz**, Los Gatos, CA (US); **Jeffery L. Bleich**, Palo Alto, CA (US); **Eric C. Miller**, Los Gatos, CA (US)(51) **Int. Cl.**
A61B 17/00 (2006.01)(52) **U.S. Cl.** **606/79**(57) **ABSTRACT**

Correspondence Address:

SHAY GLENN LLP
2755 CAMPUS DRIVE, SUITE 210
SAN MATEO, CA 94403(73) Assignee: **BAXANO, INC.**, Mountain View, CA (US)(21) Appl. No.: **11/538,345**(22) Filed: **Oct. 3, 2006**

A device for cutting ligament and/or bone tissue in a lateral recess and/or an intervertebral foramen of a spine of a patient to treat spinal stenosis may include: an elongate shaft having a rigid proximal portion and a distal portion articulatable relative to the proximal portion; a handle coupled with the proximal portion of the shaft; a tissue cutter disposed on one side of the distal portion of the shaft; a first actuator coupling the handle with the tissue cutter for activating the tissue cutter to cut tissue; and a second actuator coupling the handle with the distal portion for articulating the distal portion relative to the proximal portion. In some embodiments, the distal portion of the shaft may be configured to pass at least partway into an intervertebral foramen of the patient's spine.



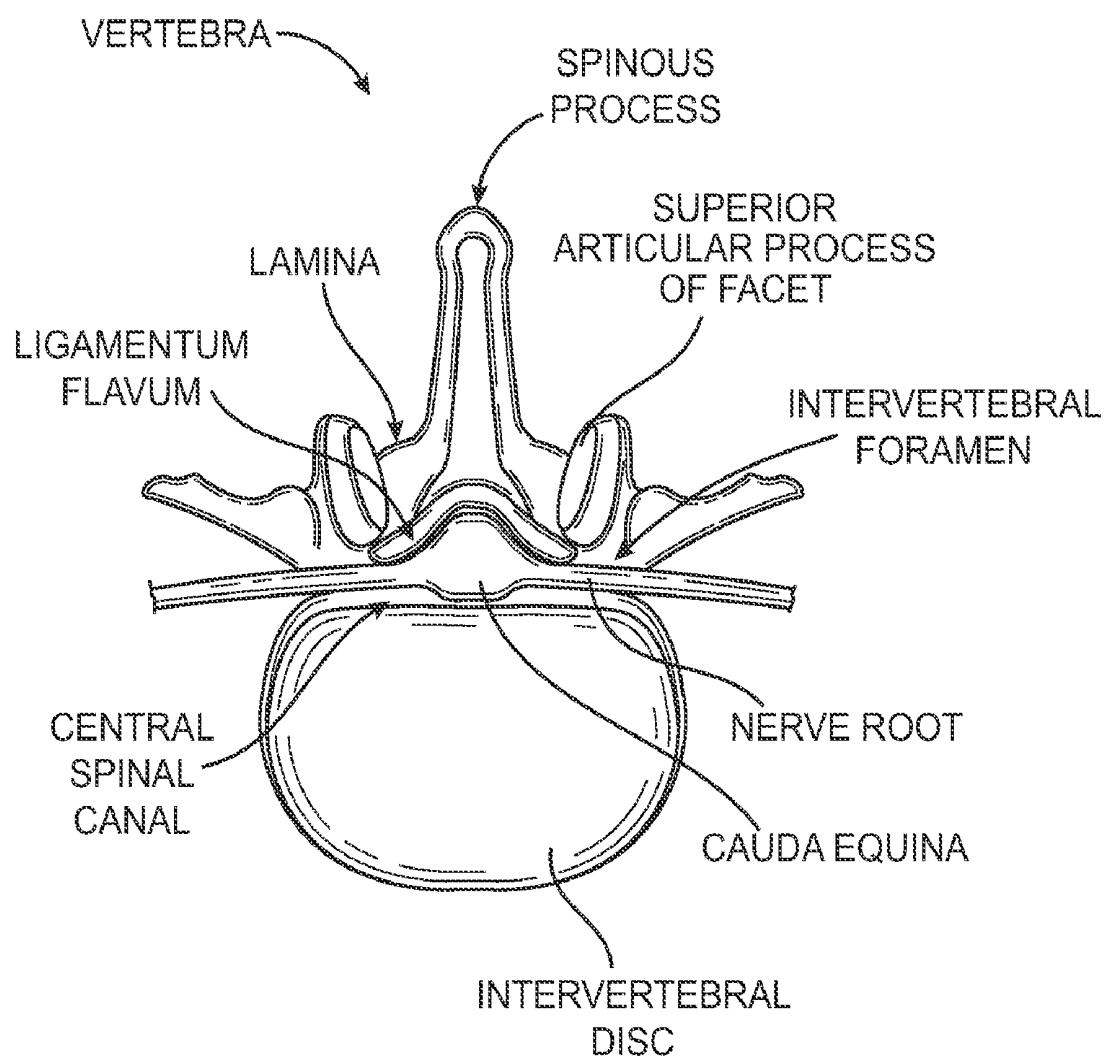


FIG. 1

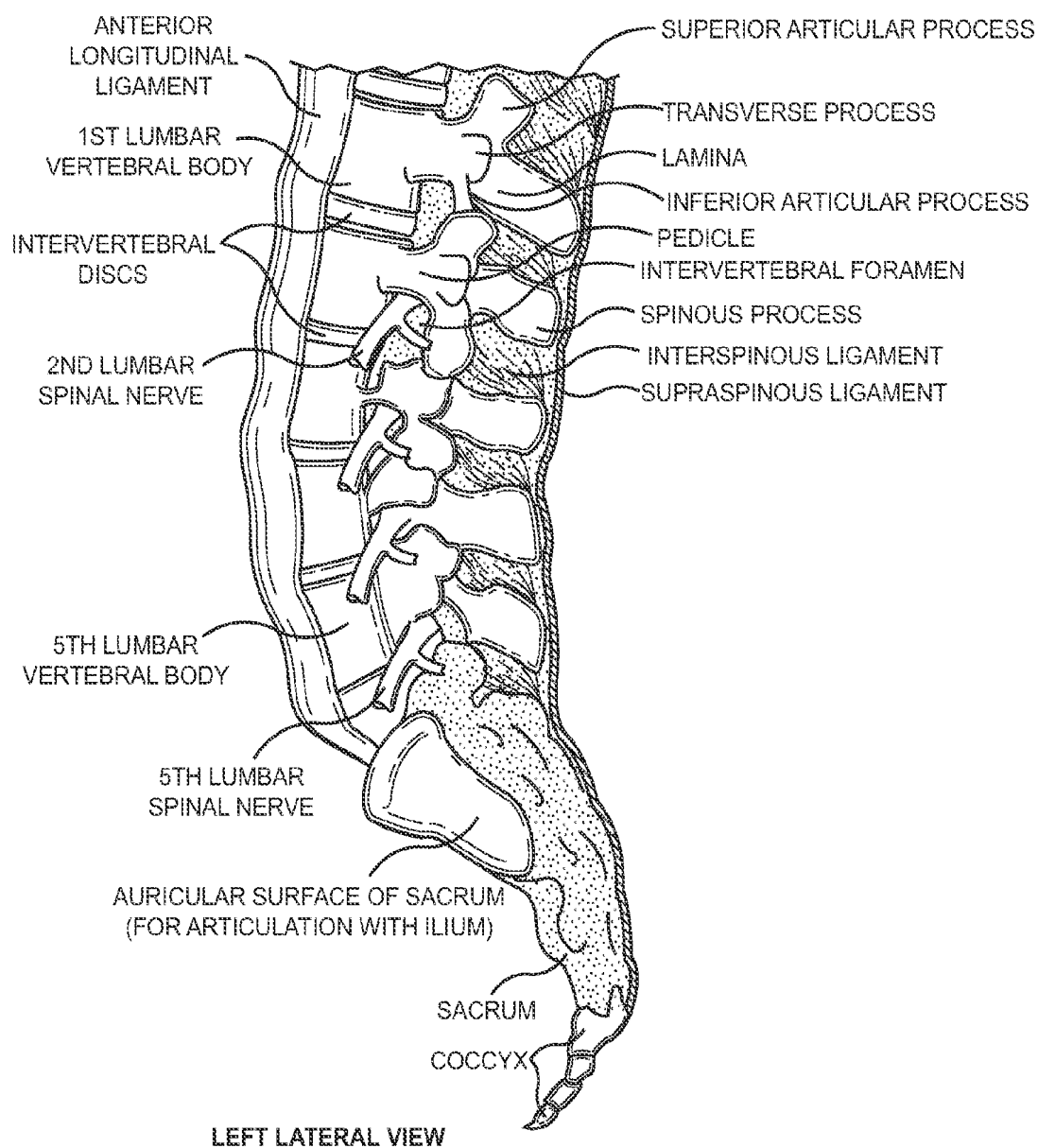


FIG. 2

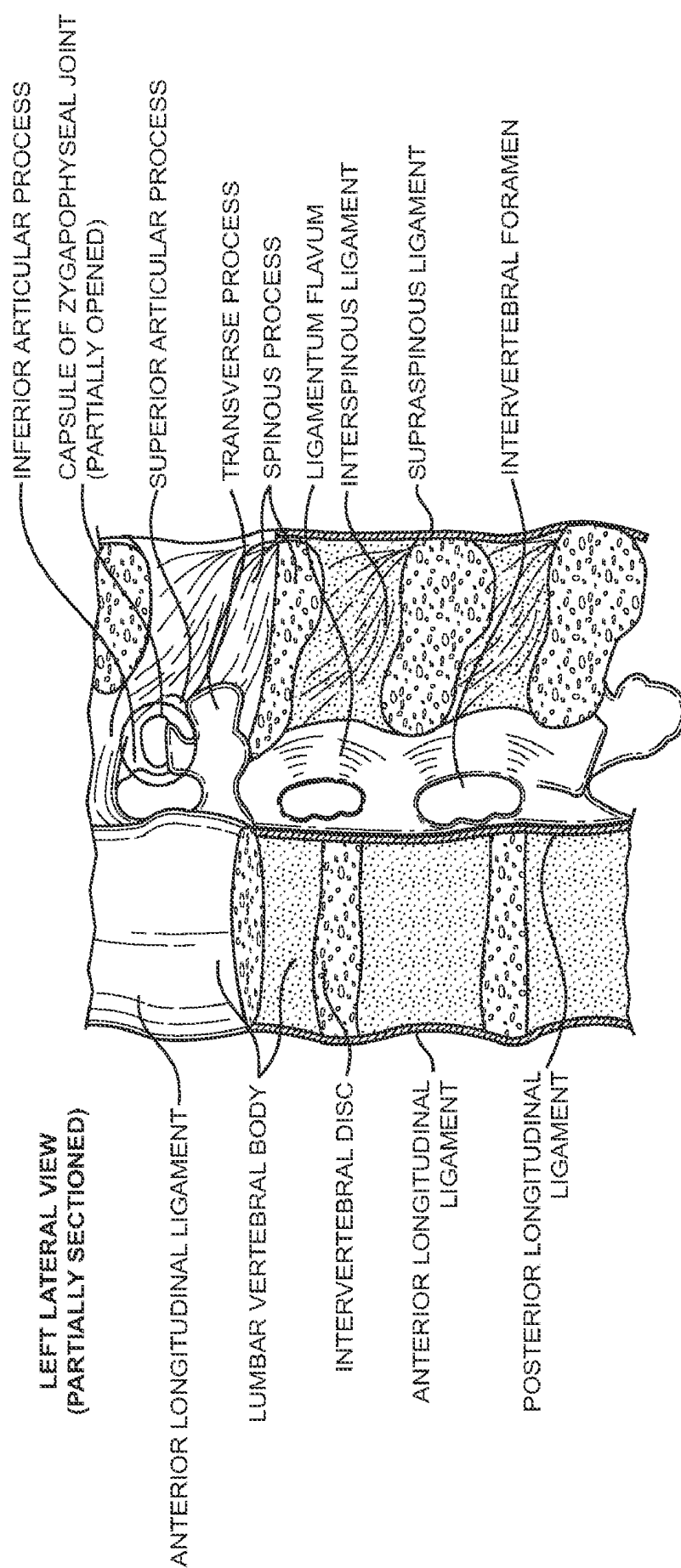


FIG. 3

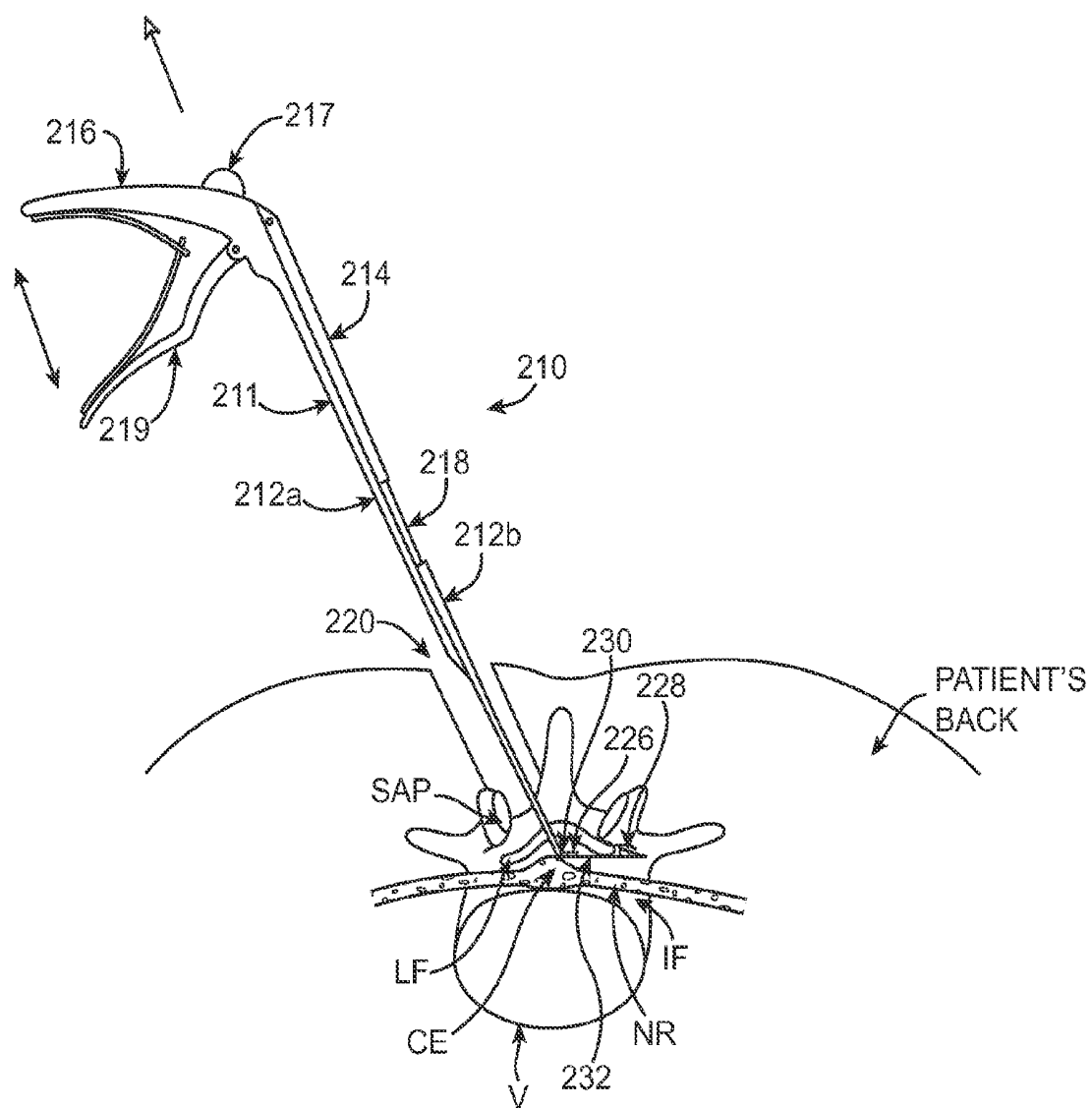
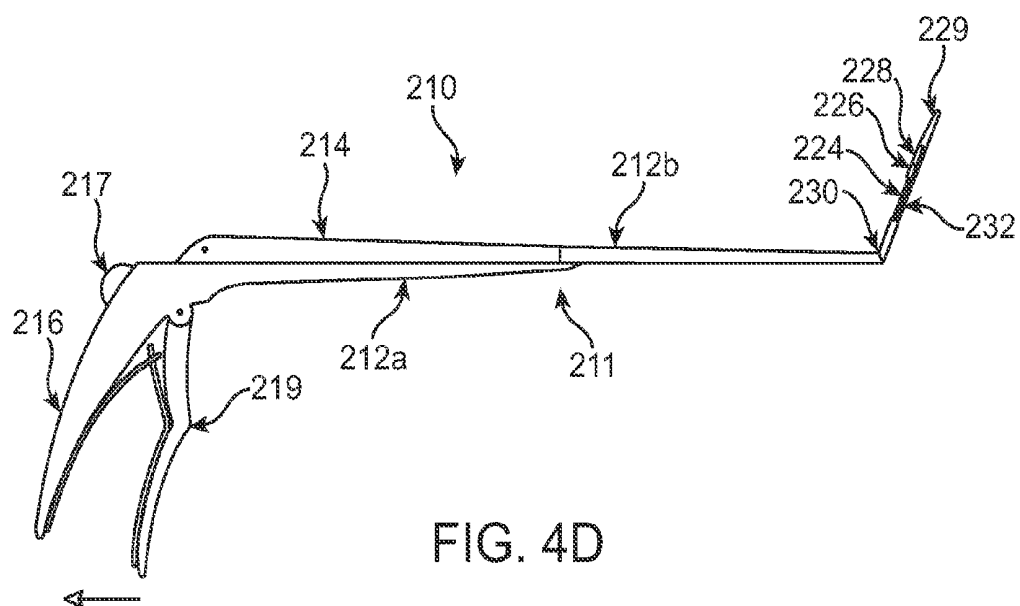
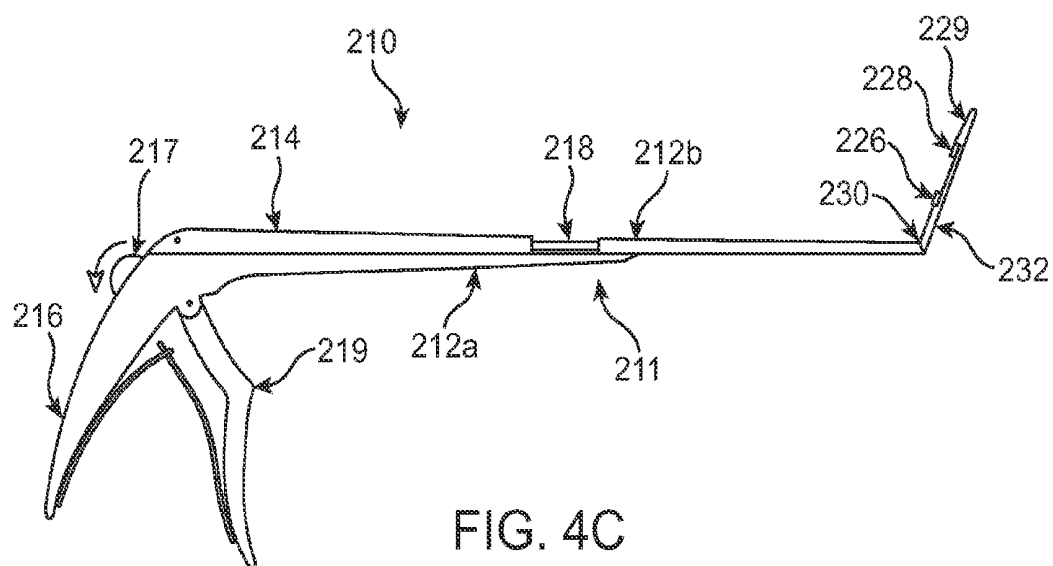
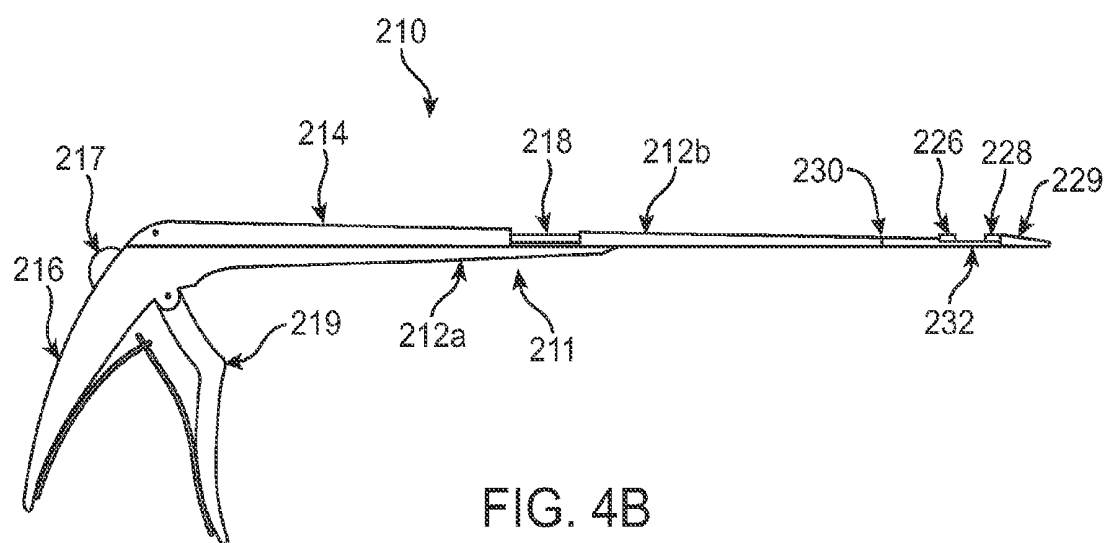


FIG. 4A



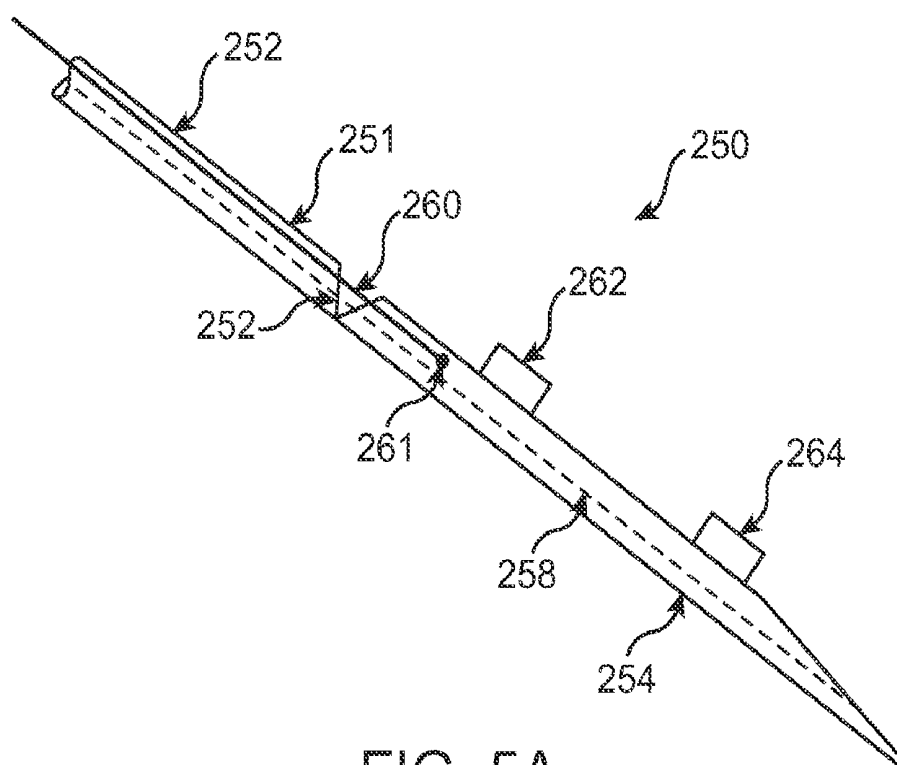


FIG. 5A

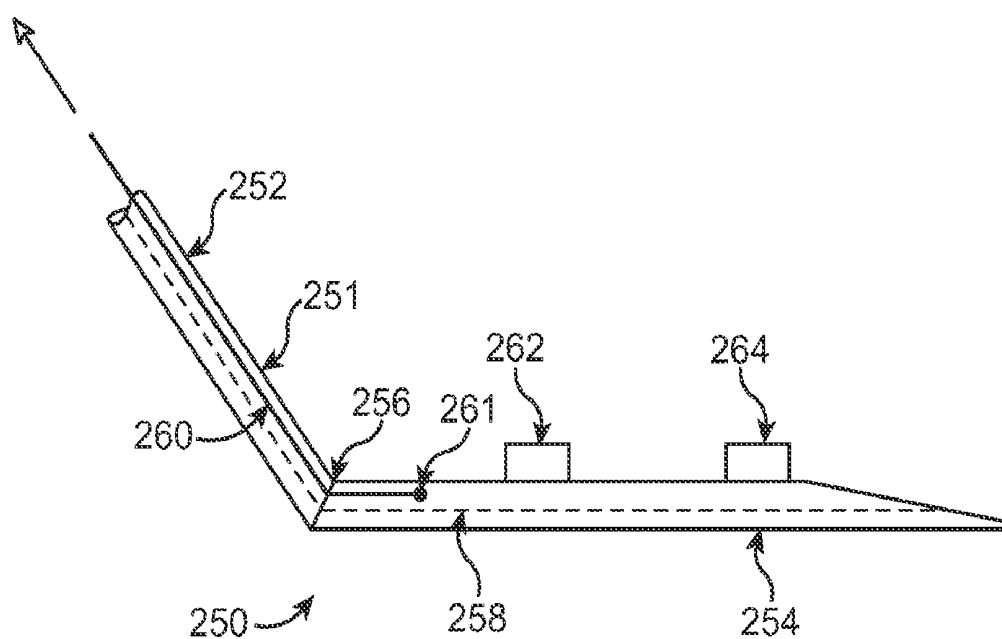


FIG. 5B

FIG. 6B

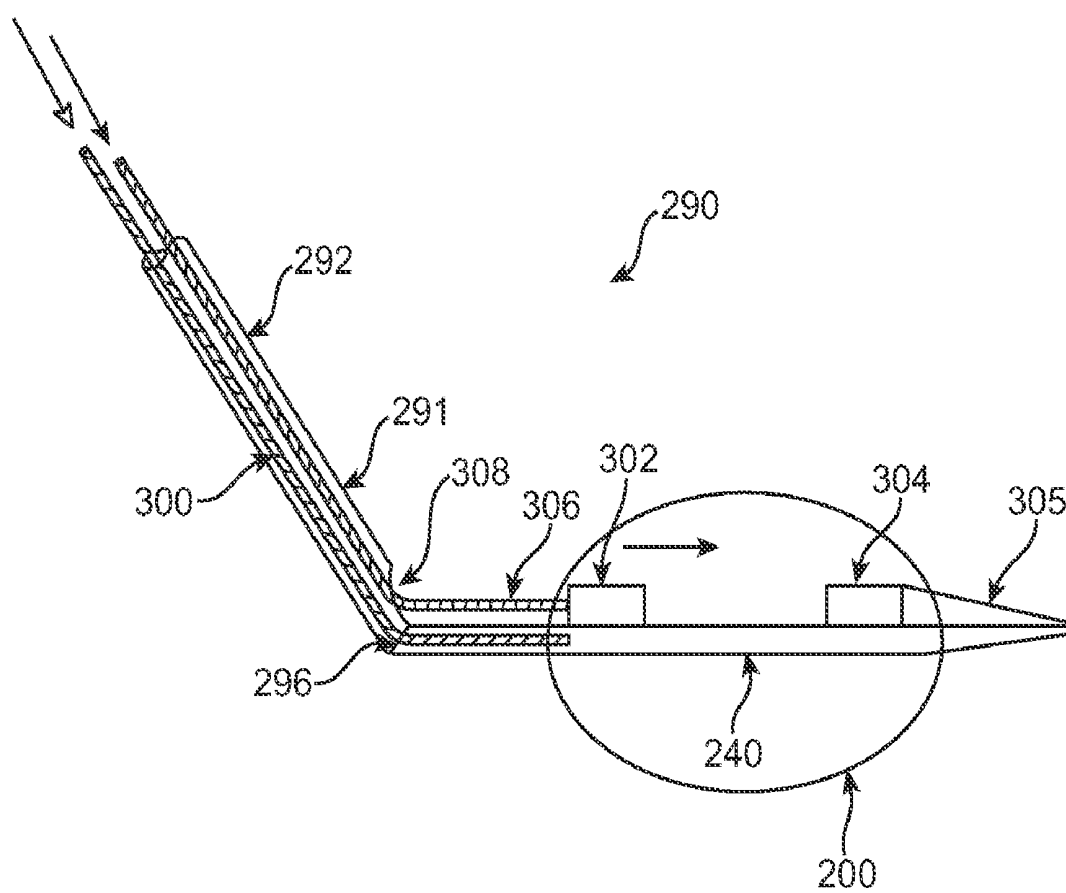


FIG. 7A

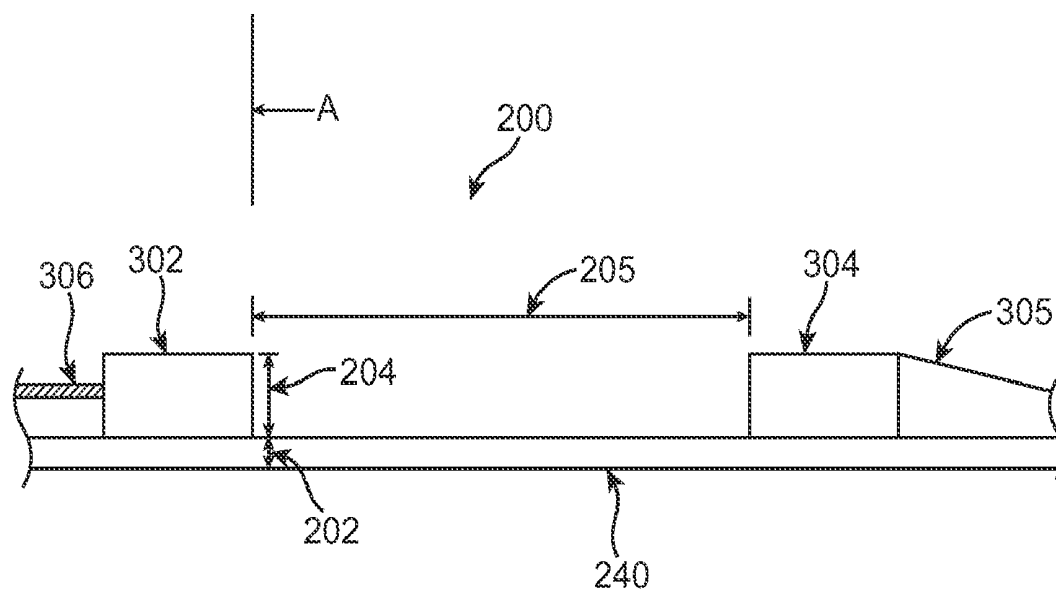


FIG. 7B

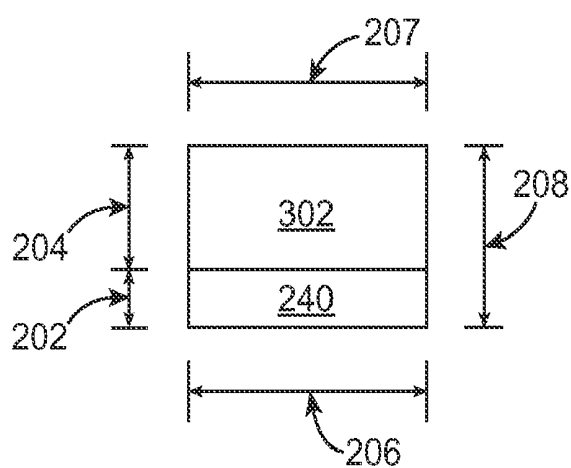


FIG. 7C

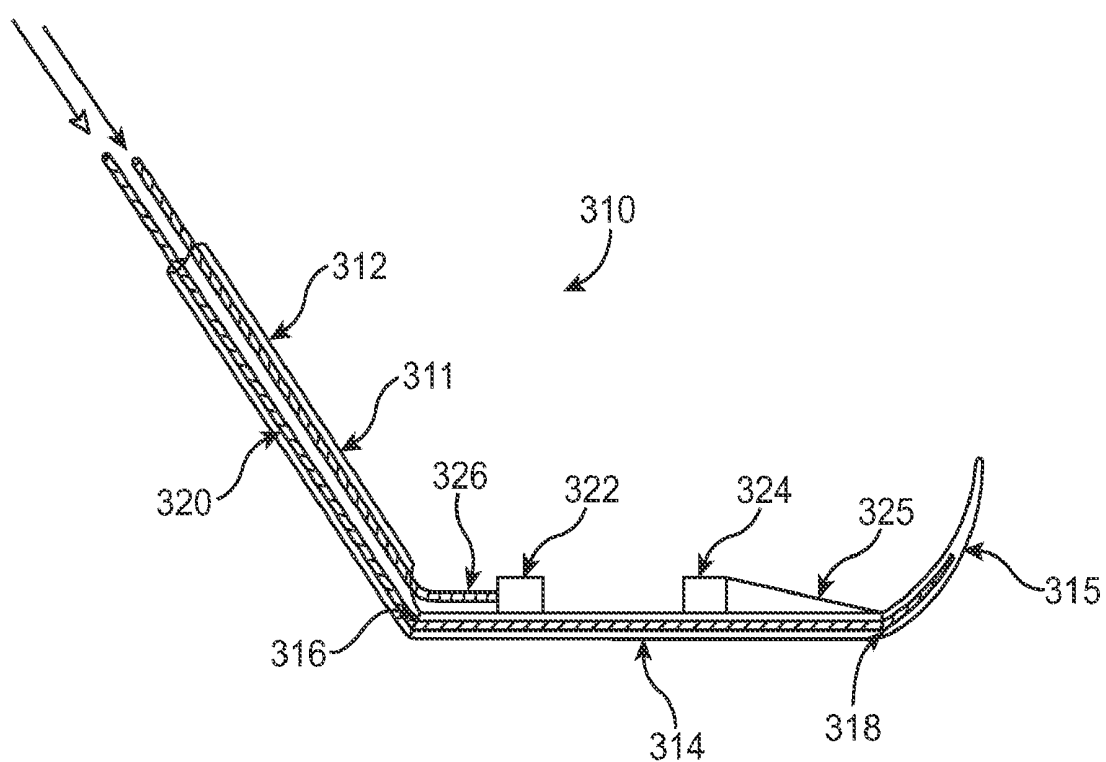


FIG. 8

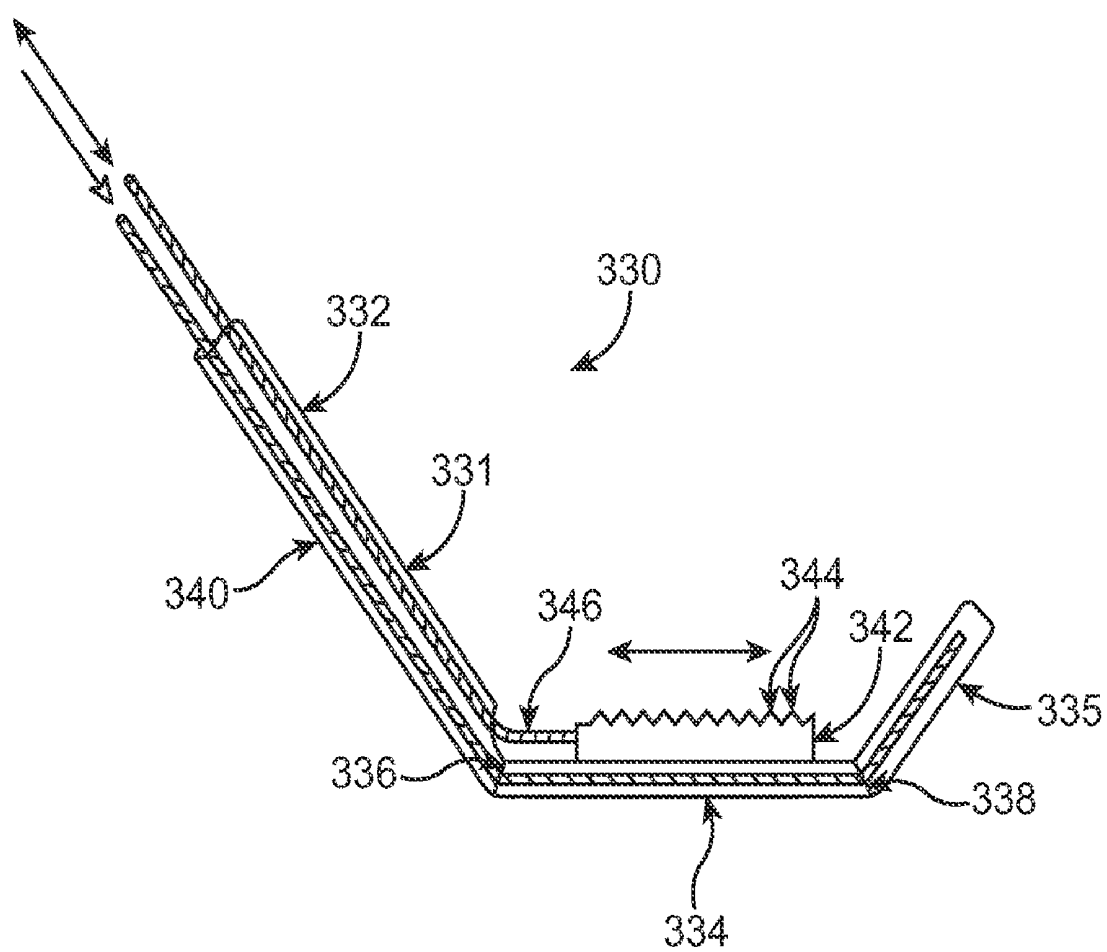
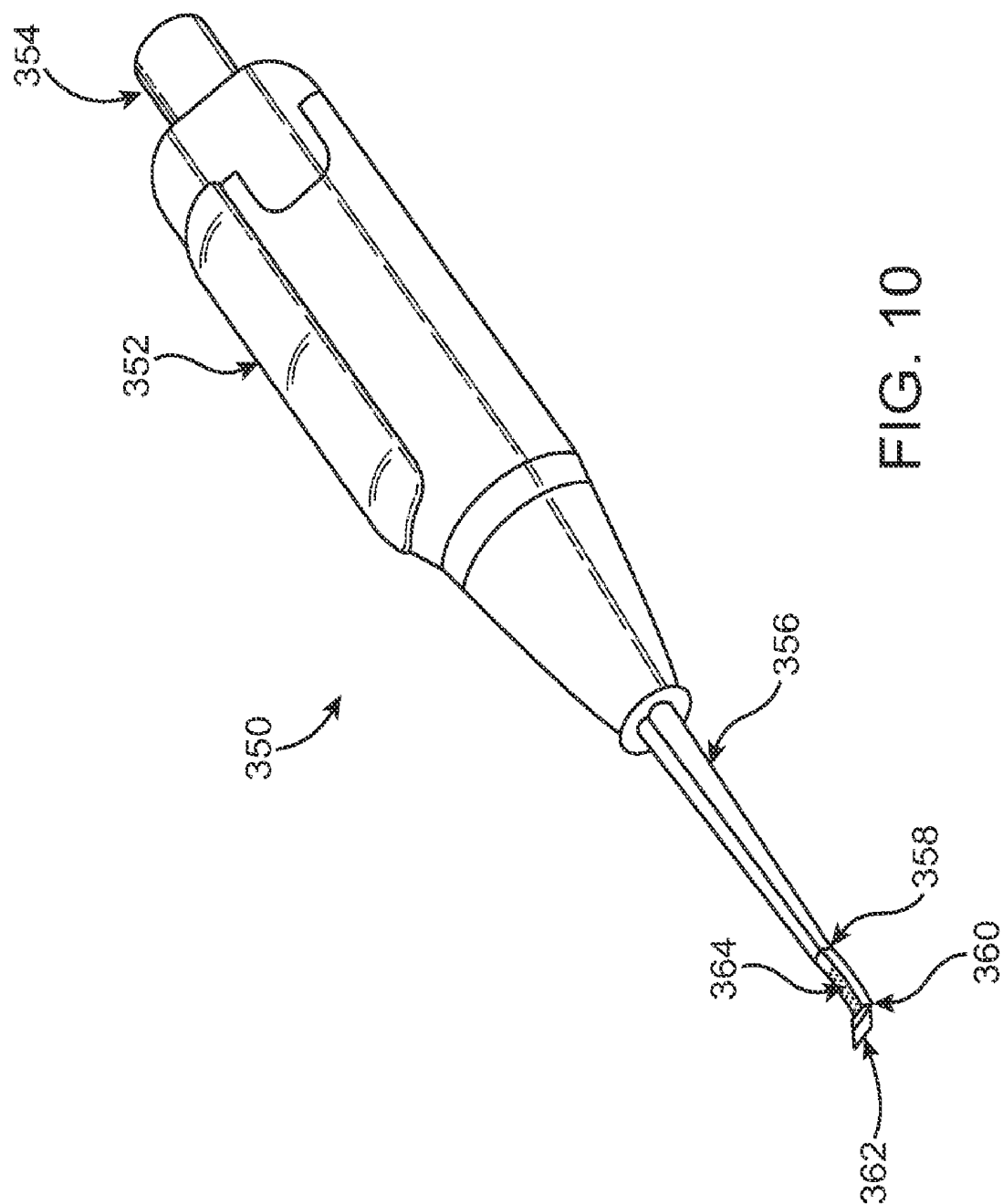


FIG. 9



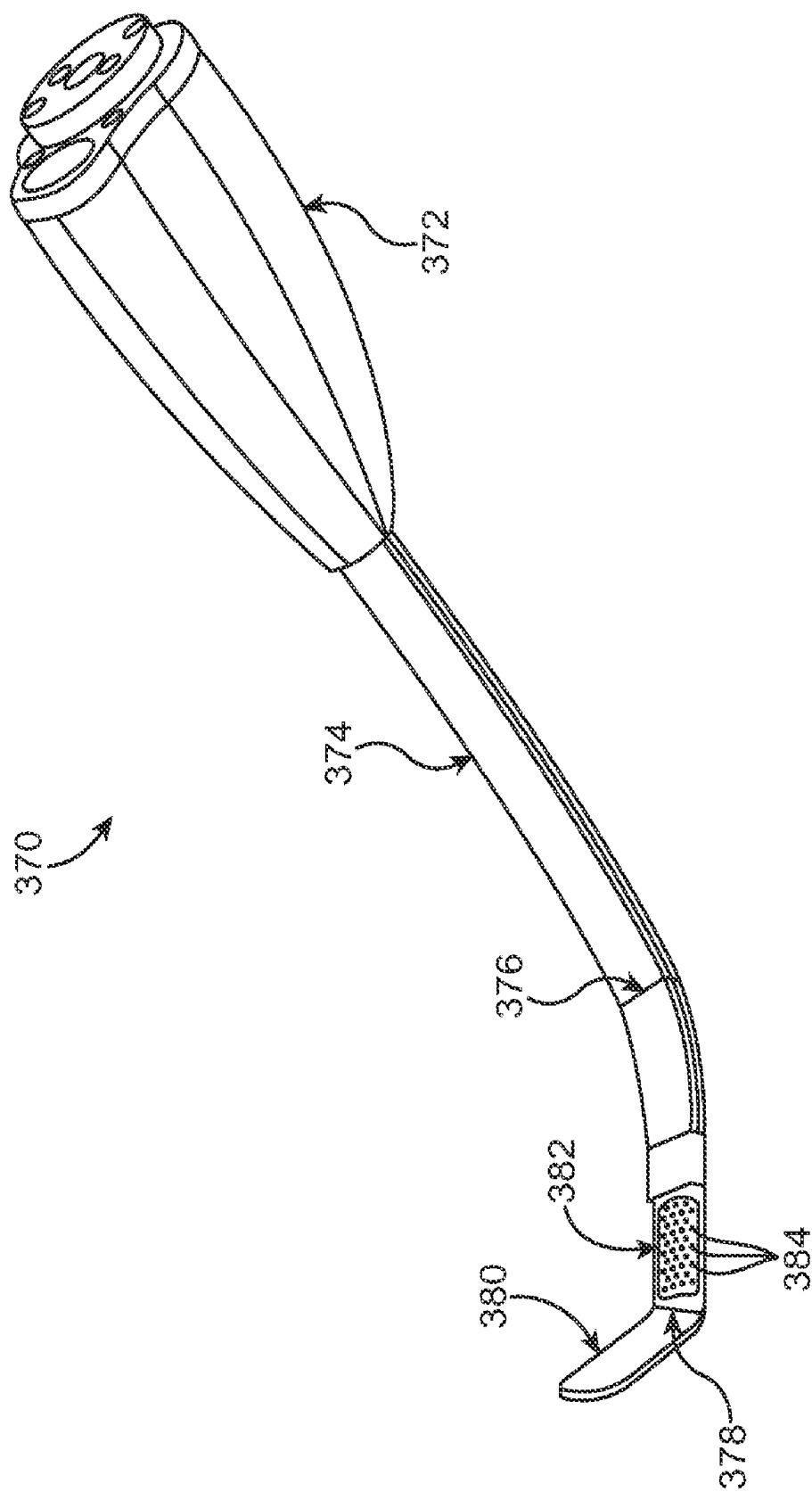


FIG. 11

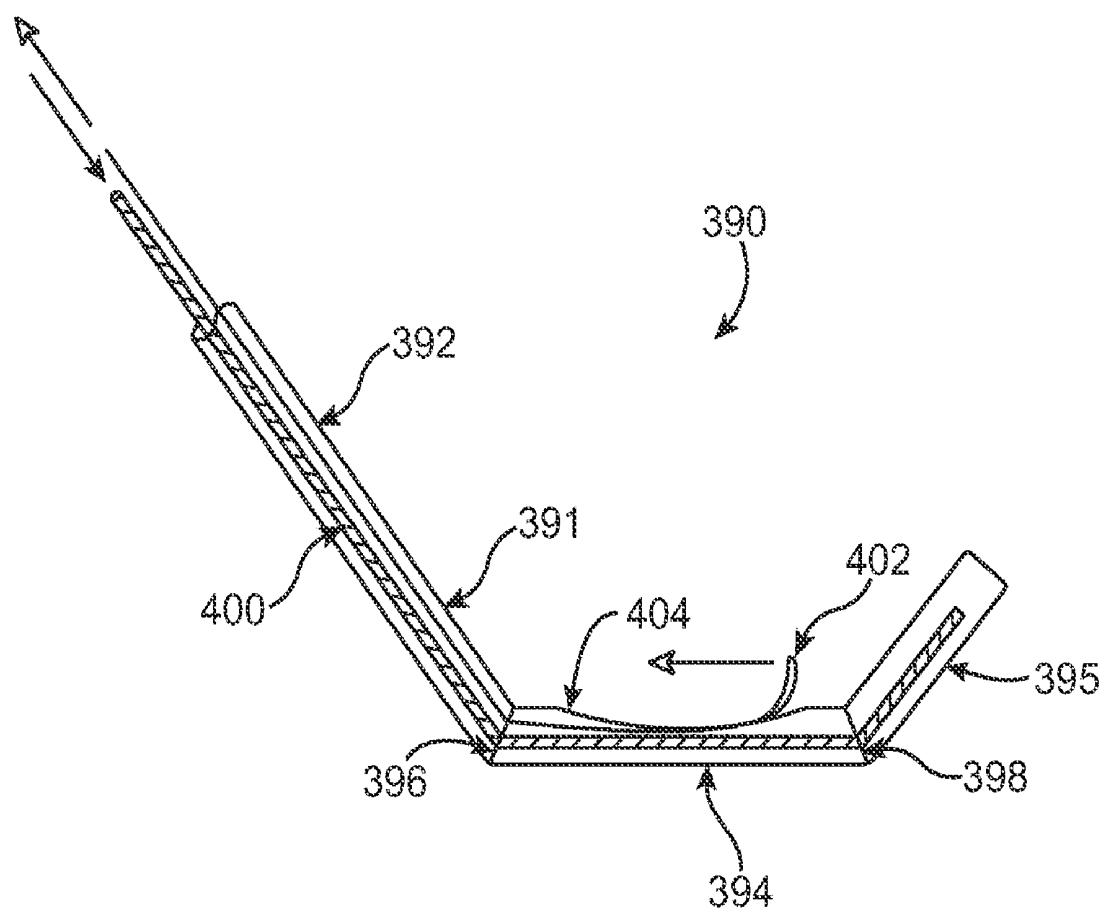


FIG. 12

ARTICULATING TISSUE CUTTING DEVICE

BACKGROUND OF THE INVENTION

[0001] The present invention relates generally to medical/surgical devices and methods. More specifically, the present invention relates to a tissue cutting devices and methods.

[0002] A significant number of surgical procedures involve cutting, shaving, abrading or otherwise contouring or modifying tissue in a patient's body. As the demand for less invasive surgical procedures continually increases, performing various tissue modifications such as cutting, contouring and removing tissue often becomes more challenging. Some of the challenges of minimally invasive procedures include working in a smaller operating field, working with smaller devices, and trying to operate with reduced or even no direct visualization of the structure (or structures) being treated. For example, using arthroscopic surgical techniques for repairing joints such as the knee or the shoulder, it may be quite challenging to cut certain tissues to achieve a desired result, due to the required small size of arthroscopic instruments, the confined surgical space of the joint, lack of direct visualization of the surgical space, and the like. It may be particularly challenging in some surgical procedures, for example, to cut or contour bone or ligamentous tissue with currently available minimally invasive tools and techniques. For example, trying to shave a thin slice of bone off a curved bony surface, using a small-diameter tool in a confined space with little or no ability to see the surface being cut, as may be required in some procedures, may be incredibly challenging or even impossible using currently available devices.

[0003] Examples of less invasive surgical procedures include laparoscopic procedures, arthroscopic procedures, and minimally invasive approaches to spinal surgery, such as a number of less invasive intervertebral disc removal, repair and replacement techniques. One area of spinal surgery in which a number of less invasive techniques have been developed is the treatment of spinal stenosis. Spinal stenosis occurs when one or more tissues in the spine impinges upon neural and/or neurovascular tissue, causing symptoms such as lower limb weakness, numbness and/or pain. This impingement of tissue may occur in one or more of several different areas in the spine, such as in the central spinal canal, or more commonly in the lateral recesses of the spinal canal and/or one or more intervertebral foramina.

[0004] FIGS. 1-3 show various partial views of the lower (lumbar) region of the spine. FIG. 1 shows an approximate top view of a vertebra with the cauda equina (the 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. 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. Intervertebral foramina may also be seen in FIGS. 2 and 3, and nerves extending through the foramina may be seen in FIG. 2.

[0005] 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. (Normal ligamentum flavum is shown in cross section in FIG. 3.) 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 impingement in the spine is hypertrophy of one or more facet joints (or "zygapophyseal joints"), which provide articulation between adjacent vertebrae. (Two vertebral facet superior articular processes are shown in FIG. 1. Each superior articular process articulates with an inferior articular process of an adjacent vertebra to form a zygapophyseal joint. Such a joint is labeled in FIG. 3.) Other causes of spinal stenosis include formation of osteophytes (or "bone spurs") on vertebrae, spondylolisthesis (sliding of one vertebra relative to an adjacent vertebra), facet joint synovial cysts, and collapse, bulging or herniation of an intervertebral disc into the central spinal canal. Disc, bone, ligament or other tissue may impinge on the spinal cord, the cauda equina, branching spinal nerve roots and/or blood vessels in the spine to cause loss of function, ischemia 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.

[0006] In the United States, spinal stenosis occurs with an incidence of between 4% and 6% of adults aged 50 and older and is the most frequent reason cited for back surgery in patients aged 60 and older. Conservative approaches to the treatment of symptoms of spinal stenosis include systemic medications and physical therapy. Epidural steroid injections may also be utilized, but they do not provide long lasting benefits. When these approaches are inadequate, current treatment for spinal stenosis is generally limited to invasive surgical procedures to remove 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 FIGS. 1 and 2) 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). In cases where a bulging intervertebral disc contributes to neural impingement, disc material may be removed surgically in a discectomy procedure.

[0007] 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. Such stress on adjacent vertebrae often leads to further dysfunction of the spine, back pain, lower leg weakness or pain, and/or other symptoms. Furthermore, using current surgical techniques, gaining sufficient access to the spine to perform a laminectomy, facetectomy and spinal fusion requires dissecting through a wide incision on the back and typically causes extensive muscle damage, leading to significant post-operative pain and lengthy rehabilitation. Discectomy procedures require entering through an incision in the patient's abdomen and navigating through the abdominal anatomy to arrive at the spine. Thus, 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. Although a number of less invasive techniques and devices for spinal stenosis surgery have been developed, these techniques still typically require removal of significant amounts of vertebral bone and, thus, typically require spinal fusion.

[0008] Therefore, it would be desirable to have less invasive methods and devices for cutting, shaving, contouring or otherwise modifying target tissue in a spine to help ameliorate or treat spinal stenosis, while preventing unwanted effects on adjacent or nearby non-target tissues. Ideally, such techniques and devices would reduce neural and/or neurovascular 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 tissue cutting devices capable of treating target tissues in parts of the body other than the spine, while preventing damage of non-target tissues. At least some of these objectives will be met by the present invention.

SUMMARY OF THE INVENTION

[0009] In one aspect of the present invention, a device for cutting ligament and/or bone tissue in a lateral recess and/or an intervertebral foramen of a spine of a patient to treat spinal stenosis may include: an elongate shaft having a rigid proximal portion and a distal portion articulatable relative to the proximal portion; a handle coupled with the proximal portion of the shaft; a tissue cutter disposed on one side of the distal portion of the shaft; a first actuator coupling the handle with the tissue cutter for activating the tissue cutter to cut tissue; and a second actuator coupling the handle with the distal portion for articulating the distal portion relative to the proximal portion. In some embodiments, the distal portion of the shaft may be configured to pass at least partway into an intervertebral foramen of the patient's spine.

[0010] By "articulatable," it is meant that the distal portion may be bent, flexed, angled or the like, relative to the proximal portion. In other words, for the purposes of this application, "articulate" encompasses not only to articulate about a joint, but also includes bending, flexing or angling by means of one or more slits, grooves, hinges, joints or other articulating means.

[0011] In various alternative embodiments, the distal portion of the shaft of the device may be rigid, flexible, or part rigid/part flexible. In some embodiments, the distal portion of the shaft may be configured to articulate toward the side on which the tissue cutter is disposed. To make the distal portion of the shaft articulatable relative to the proximal portion, some embodiments may further include an articulation member disposed along the shaft between the proximal and distal portions. As mentioned above, such an articulation member may include, for example, one or more slits, grooves, hinges, joints or the like. In one embodiment, an articulation member may comprise a first material disposed on the side of the shaft on which the tissue cutter is disposed and a second material disposed on an opposite side of the shaft, where the first material is more compressible than the second material.

[0012] In some embodiments, the distal portion of the shaft may be configured to articulate incrementally from a relatively unflexed position to a first flexed position and to at least

a second flexed position. Optionally, the device may further include a locking mechanism for locking the distal portion in an articulated position relative to the proximal portion.

[0013] Any of a number of different tissue cutters may be used in various embodiments. For example, examples of tissue cutters which may be included in the device in some embodiments include but are not limited to blades, abrasive surfaces, files, rasps, saws, planes, electrosurgical devices, bipolar electrodes, monopolar electrodes, thermal electrodes, cold ablation devices, rotary powered mechanical shavers, reciprocating powered mechanical shavers, powered mechanical burrs, lasers, ultrasound devices, cryogenic devices, and water jet devices. In one embodiment, for example, the tissue cutter comprises a translatable blade. In some embodiments, the blade may have a height greater than a height of a portion of the shaft immediately below the blade, and a total height of the blade and the portion of the shaft immediately below the blade may be less than a width of the portion of the shaft immediately below the blade. In some embodiments, the tissue cutter may further include a fixed blade fixedly attached to the shaft, and the translatable blade may move toward the fixed blade to cut tissue. In an alternative embodiment, the tissue cutter may further include a fixed backstop fixedly attached to the shaft, and the translatable blade may move toward the fixed backstop to cut tissue.

[0014] In some embodiments, the second actuator may include a tensioning wire extending from the handle to the distal portion of the shaft and a tensioning member on the handle coupled with the tensioning wire and configured to apply tensioning force to the wire. In an alternative embodiment, the second actuator may include a compression member extending from the handle to the distal portion of the shaft and a force application member on the handle coupled with the compression member and configured to apply compressive force to the compression member. In such embodiments, the compression member may include, for example, one or more wires, substrates and/or fluids.

[0015] Optionally, in some embodiments the shaft may further include a distal tip articulatable relative to the distal portion of the shaft, and the second actuator may extend to the distal tip. The first and second actuators may have any of a number of different configurations in different embodiments, such as but not limited to triggers, squeezable handles, levers, dials, toggle clamps, toggle switches and/or vice grips.

[0016] In another aspect of the present invention, a device for cutting tissue in a human body may include: an elongate shaft having a rigid proximal portion and a distal portion articulatable relative to the proximal portion; a handle coupled with the proximal portion of the shaft; a translatable blade slidably disposed on one side of the distal portion of the shaft; a first actuator coupling the handle with the tissue cutter for activating the tissue cutter to cut tissue; a second actuator coupling the handle with the distal portion for articulating the distal portion relative to the proximal portion; and a locking mechanism configured to lock the distal portion in an articulated configuration relative to the proximal portion. In some embodiments, the translatable blade may have a height greater than a height of a portion of the shaft immediately below the blade, and a total height of the blade and the portion of the shaft immediately below the blade may be less than a width of the portion of the shaft immediately below the blade. In various embodiments, the distal portion of the shaft may be rigid, flexible, or part rigid/part flexible.

[0017] In another aspect of the present invention, a method for cutting ligament and/or bone tissue in a lateral recess and/or an intervertebral foramen of a spine of a patient to treat spinal stenosis may involve: advancing a distal portion of a tissue cutting device into an epidural space of the patient's spine; articulating the distal portion relative to a proximal portion of the device; advancing the distal portion at least partway into an intervertebral foramen of the spine; urging a tissue cutter disposed on one side of the distal portion of the device against at least one of ligament or bone tissue in at least one of the lateral recess or the intervertebral foramen; and activating the tissue cutter to cut at least one of the ligament or bone tissue.

[0018] In some embodiments, the distal portion may be advanced through an access conduit device. In some embodiments, the distal portion may be advanced through the conduit device and between two adjacent vertebrae into the epidural space without removing vertebral bone. Articulating, in one embodiment, may involve applying tensioning force to a tensioning member disposed longitudinally through the device from the proximal portion to the distal portion. Alternatively, articulating may involve applying compressive force to a compressive member disposed longitudinally through the device from the proximal portion to the distal portion. In some embodiments, articulating may involve articulating to a first articulated configuration before advancing the distal portion into the foramen and further articulating to a second articulated configuration after advancing the distal portion at least partway into the foramen. Some embodiments of the method may optionally further include locking the distal portion in an articulated position relative to the proximal portion before urging the tissue cutter against tissue. Such a method may also involve, in some embodiments, unlocking the distal portion, straightening the distal portion relative to the proximal portion, and removing the tissue cutting device from the patient.

[0019] In some embodiments, urging the tissue cutter against tissue may involve applying force to a handle of the tissue cutting device. Activating the tissue cutter, in various embodiments, may involve activating one or more blades, abrasive surfaces, files, rasps, saws, planes, electrosurgical devices, bipolar electrodes, monopolar electrodes, thermal electrodes, cold ablation devices, rotary powered mechanical shavers, reciprocating powered mechanical shavers, powered mechanical burrs, lasers, ultrasound devices, cryogenic devices, and/or water jet devices. For example, in one embodiment, activating the tissue cutter may involve advancing a translatable blade toward one of a stationary blade and a backstop. In an alternative embodiment, activating the tissue cutter may involve retracting a translatable blade toward one of a stationary blade and a backstop. In yet another alternative embodiment, activating the tissue cutter may involve translating two blades toward one another.

[0020] 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

[0021] 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;

[0022] FIG. 2 is a left lateral view of the lumbar portion of a spine with sacrum and coccyx;

[0023] FIG. 3 is a left lateral view of a portion of the lumbar spine, showing only bone and ligament tissue and partially in cross section;

[0024] FIG. 4A is a cross-sectional view of a patient's back and spine with a side view of an articulating rongeur in place for performing a tissue removal procedure, according to one embodiment of the present invention;

[0025] FIGS. 4B-4D are side views of the articulating rongeur of FIG. 4A, demonstrating a method for articulating the rongeur and advancing a cutting blade, according to one embodiment of the present invention;

[0026] FIGS. 5A and 5B are side cross-sectional views of a distal portion of an articulating rongeur, demonstrating articulation, according to one embodiment of the present invention;

[0027] FIGS. 6A and 6B are side cross-sectional views of a distal portion of an articulating rongeur, demonstrating articulation, according to an alternative embodiment of the present invention;

[0028] FIG. 7A is a side cross-sectional view of a distal portion of an articulating rongeur, according to an alternative embodiment of the present invention;

[0029] FIG. 7B is a magnified side cross-sectional view of a portion of FIG. 7B;

[0030] FIG. 7C is an end-on view of the portion of the articulating rongeur of FIG. 7B, from the perspective labeled A in FIG. 7B;

[0031] FIG. 8 is a side cross-sectional view of an articulating rongeur, according to an alternative embodiment of the present invention;

[0032] FIG. 9 is a side cross-sectional view of an articulating tissue cutting device having a reciprocating file tissue cutter, according to one embodiment of the present invention;

[0033] FIG. 10 is a perspective view of an articulating tissue cutting device having a reciprocating file tissue cutter, according to an alternative embodiment of the present invention;

[0034] FIG. 11 is a perspective view of an articulating tissue cutting device having a reciprocating file tissue cutter, according to an alternative embodiment of the present invention; and

[0035] FIG. 12 is a side cross-sectional view of an articulating tissue cutting device having a radiofrequency wire tissue cutter, according to one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0036] Various embodiments of an articulating tissue cutting device for modifying tissue in a patient are provided. Although portions of the following description and accompanying drawing figures generally focus on cutting tissue in a spine, in various embodiments, any of a number of tissues in other anatomical locations in a patient may be modified.

[0037] Referring to FIG. 4A, one embodiment of articulating rongeur 210 may include a shaft having a proximal portion 211, a distal portion 232, and an articulation feature 230 (or "articulation member") between the two. A handle 216 with a squeezable trigger 219 and a dial 217 may be coupled with proximal shaft portion 211. A proximal blade 226 and a distal blade 228 may be disposed along distal shaft portion 232. In some embodiments, both proximal shaft portion 211 and distal shaft portion 232 are predominantly rigid. In alternative embodiments, distal shaft portion 232 may be more flexible than proximal portion 211 or may be largely rigid but may have one or more flexible portions disposed along its

length. Proximal shaft portion **211** may include a proximal stationary portion **212a** coupled with or extending from proximal handle **216**, a distal stationary portion **212b**, and a movable shaft portion **214**. Articulation feature **230** may include any suitable mechanism, such as one or more slits, grooves, hinges, joints and/or combinations of materials, to allow distal portion **232** to articulate relative to proximal portion **211**. As mentioned above, “articulate” includes articulating about a joint, as well as bending, flexing, angling and the like. Distal shaft portion **232** may include a portion that extends underneath and between blades **226**, **228**, which may be referred to as a “substrate,” “platform” or “extension” herein.

[0038] In one embodiment, at least two flexible wires **224** (or “wire bundle”—see FIG. 4D) may slidably extend through a portion of proximal shaft portion **211** and distal shaft portion **232** so that their distal ends attach to proximal blade **226**. Optionally, wires **224** may be bundled together along their entire lengths or along part of their lengths, and such a wire bundle may be partially housed within a wire bundle tube **218**, which may slidably pass through distal stationary shaft portion **212b**. In use, trigger **219** may be squeezed (double-headed, solid-tipped arrow) to advance moveable shaft portion **214**, which advances wire bundle tube **218** and wires **224**, thus advancing proximal blade **226** toward stationary blade **228** to cut tissue.

[0039] In some embodiments, articulating rongeur **210** may be advanced into a patient’s back through an incision **220**, which is shown in FIG. 4A as an open incision but which may be a minimally invasive or less invasive incision in alternative embodiments. Rongeur **210** may be advanced into the patient in a relatively straight configuration and then articulate (or “flexed” or “bent”) at articulation feature **230** to facilitate passing at least part of distal shaft portion **232** into an intervertebral foramen (IF). In some embodiments, an articulating member on handle **216**, such as dial **217**, may be used to apply a force to a flexing member extending from dial **217** to at least articulation feature **230**. The ability of rongeur **210** to articulate about articulation feature **230** may facilitate passage of rongeur **210** between tissues in hard-to-reach or tortuous areas of the body, such as between a nerve root (NR) and facet joint and into an intervertebral foramen (IF). Generally, rongeur **210** may be advanced to a position such that blades **226**, **228** face tissue to be cut in a tissue removal procedure (“target tissue”) and one or more non-cutting surfaces of rongeur **210** face non-target tissue, such as nerve and/or neurovascular tissue. In the embodiment shown in FIG. 4A, blades **226**, **228** are positioned to cut ligamentum flavum (LF) and may also cut hypertrophied bone of the facet joint, such as the superior articular process (SAP). (Other anatomical structures depicted in FIG. 4A include the vertebra (V) and cauda equina (CE)).

[0040] Once rongeur **210** is advanced into the patient to position distal portion **232** at least partway into an intervertebral foramen, articulation feature **230** may be locked into position, either by a locking mechanism in articulation feature **230** itself or alternatively or additionally by a locking mechanism in handle **216**, such as a mechanism coupled with or part of dial **217**. Once articulation feature **230** is locked, handle **16** may be pulled (hollow-tipped arrow) to pull distal shaft portion **232** against target tissue and thus to urge the cutting portion of rongeur **210** (e.g., blades **226**, **228**) against ligamentum flavum (LF), superior articular process (SAP), and/or other target tissue to be cut. Handle **216** may then be

actuated, such as by squeezing in the embodiment shown, which advances moveable shaft **214**, thus advancing wire bundle tube **218**, flexible wires **224** and proximal blade **226**, to cut tissue between proximal blade **226** and distal blade **228**. Handle **216** may be released and squeezed as many times as desired to remove a desired amount of tissue. When a desired amount of tissue has been cut (or at any point during a tissue cutting procedure to monitor progress), rongeur **210** may be removed from the patient’s back.

[0041] As mentioned previously, and as described in greater detail below, in various embodiment articulation feature **230** may take any of a number of different forms and may generally include any suitable feature or features to allow rongeur **210** to flex or be flexed. In various embodiments, articulation feature **230** may include one or more hinges, slits, grooves, joints, materials having varying levels of compressibility or the like.

[0042] Referring now to FIGS. 4B-4D, the articulating and blade advancing functions of articulating rongeur **210** are demonstrated. FIG. 4B shows articulating rongeur **210** in its generally straight configuration. In one embodiment, as shown in FIG. 4C, dial **217** may be turned (hollow-tipped arrow) to articulate distal portion **232**. With distal portion **232** articulated, as shown in FIG. 4D, trigger **219** may be squeezed (hollow-tipped arrow) to advance moveable shaft portion **214**, which in turn advances wires **224** and proximal blade **226** toward distal blade **228** to cut target tissue. In some embodiments, proximal blade **226** may be advanced while rongeur is in its straight or articulated configuration. In some embodiments, rongeur **210** may articulate in increments, such as from a straight configuration to a first flexed configuration to a second flexed configuration and so on. Also in some embodiments, articulation feature **230** may automatically lock into an articulated position. In alternative embodiments, articulation feature **230** may be manually locked, such as by locking dial **217** or the like.

[0043] For further detail regarding a multi-wire tissue cutter device, many of the features of which may be incorporated into articulating rongeur **210**, reference may be made to U.S. patent application Ser. No. 11/____ (Attorney Docket No. 026445-000910US), titled “Multi-Wire Tissue Cutter,” and filed on Aug. 1, 2006, the full disclosure of which is hereby incorporated by reference. In alternative embodiments, different tissue cutting mechanisms may be included in articulating rongeur **210**. For example, in one embodiment, distal blade **228** may be translatable and proximal blade **226** may be stationary. In an alternative embodiment, distal blade **228** and proximal blade **226** may be translated toward one another to cut tissue. A number of such bladed tissue cutting mechanisms are described, for example, in U.S. patent application Ser. No. 11/405,848 (Original Attorney Docket No. 78117-200301), titled “Mechanical Tissue Modification Devices and Methods,” and filed on Apr. 17, 2006, the full disclosure of which is hereby incorporated by reference. In further alternative embodiments, some of which are described in greater detail below, blades **226**, **228** may be replaced altogether by a different tissue cutting mechanism, such as but not limited to one or more abrasive surfaces, files, rasps, saws, planes, electrosurgical devices, bipolar electrodes, monopolar electrodes, thermal electrodes, cold ablation devices, rotary powered mechanical shavers, reciprocating powered mechanical shavers, powered mechanical burrs, lasers, ultrasound devices, cryogenic devices, and/or water jet devices

[0044] Generally, proximal shaft portion **211** and distal shaft portion **232** may be formed of any suitable material, such as but not limited to stainless steel. Wire bundle **224** extends through at least part of wire tube **218**, through distal stationary shaft portion **212b**, and in some embodiments through part of distal shaft portion **232**, and is coupled with proximal blade **226**. Wire tube **218** acts to secure the proximal end of wire bundle **224**, such as by crimping, welding or the like. In alternative embodiments, wire tube **218** may be excluded, and the proximal end of wire bundle **224** may be otherwise coupled with device. For example, in various embodiments, wire bundle **224** may be coupled with moveable shaft portion **214**, may be movably coupled with handle **216**, or the like. In the side view of FIG. 4D, wire bundle **224** appears as a single wire, in this embodiment due to the fact that distal shaft portion **232** flattens wire bundle **224** to a one-wire-thick cross section.

[0045] In various embodiments, proximal shaft portion **211** and distal shaft portion **232** may have any suitable shapes and dimensions and may be made of any suitable materials. For example, in various embodiments, shaft portions **211**, **232** may be made from any of a number of metals, polymers, ceramics, or composites 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). 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.

[0046] Portions of shaft **211**, **232** through which wire bundle **224** travels will generally be predominantly hollow, while other portions may be either hollow or solid. For example, in one embodiment, moveable shaft portion **214** and proximal stationary portion **212a** may be solid, and distal stationary portion **212b** and part of distal portion **232** may be hollow. Although one particular embodiment of a shaft mechanism for moving wire bundle **224** is shown, various embodiments may employ any of a number of alternative mechanisms.

[0047] Wire bundle **224** may include as few as two flexible wires **224** and as many as one hundred or more wires **224**. In some embodiments, for example, between three and 20 wires **224** may be used, and even more preferably, between four and ten wires **224**. Wires **224** may have any of a number of different diameters, so in some embodiments the number of wires **224** used may be determined by the diameter of wire **224** used. In various embodiments, each wire **224** may be a solid wire, a braided wire, a core with an outer covering or the like, and may be made of any suitable material. For example, in various embodiments, wires **224** may be made from any of a number of metals, polymers, ceramics, or composites 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 wires **224** or for portions or

coatings of the wires 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 some embodiments, all wires **224** may be made of the same material, whereas in alternative embodiments, wires **224** may be made of different materials. Individual wires **224** may also have any length, diameter, tensile strength or combination of other characteristics and features, according to various embodiments, some of which are discussed in greater detail below.

[0048] In various embodiments, flexible wires **224** may be bound or otherwise coupled together at one or more coupling points or along the entire length of wire bundle **224**. In one embodiment, for example, wires **224** may be coupled together by a sleeve or coating overlying wire bundle **224**. In another embodiment, wires **224** may only be coupled together at or near their proximal ends, at or near their connection point to tube **218**, moveable shaft portion **214** or the like. In an alternative embodiment, wires **224** may be individually coupled with an actuator, such as handle **216**, and not coupled to one another directly. In any case, wires **224** will typically be able to move at least somewhat, such as laterally, relative to one another.

[0049] In some embodiments, wire bundle **224** may include one or more elongate, flexible members for performing various functions, such as enhancing tissue cutting, visualizing a target area or the like. For example, in various embodiments, wire bundle **224** may include one or more optical fibers, flexible irrigation/suction tubes, flexible high pressure tubes, flexible insulated tubing for carrying high temperature liquids, flexible insulated tubing for carrying low temperature liquids, flexible elements for transmission of thermal energy, flexible insulated wires for the transmission of electrical signals from a sensor, flexible insulated wires for the transmission of electrical signals towards the distal end of the wires, energy transmission wires, or some combination thereof. Examples of visualization devices that may be used include flexible fiber optic scopes, CCD (charge-coupled device) or CMOS (complementary metal-oxide semiconductor) chips at the distal end of flexible probes, LED illumination, fibers or transmission of an external light source for illumination or the like.

[0050] When blades **226**, **228** face target tissue to be modified, such as buckled, thickened or otherwise impinging ligamentum flavum tissue, rongeur **210** is configured such that an atraumatic surface (or multiple atraumatic surfaces) of the distal shaft portion **232** faces non-target tissue. Distal shaft portion **232** may thus act as a tissue protective surface and in various embodiments may have one or more protective features, such as a width greater than the width of blades **226**, **228**, rounded edges, bumpers made of a different material such as a polymer, protective or lubricious coating(s), extendable or expandable barrier member(s), drug-eluting coating or ports, or the like. In some instances, distal shaft portion **232** may include one or more “non-tissue-modifying” surfaces, meaning that such surfaces may not substantially modify the non-target tissue. In alternative embodiments, distal shaft portion **232** may affect non-target tissue by protecting it in some active way, such as by administering one or more pro-

tective drugs, applying one or more forms of energy, providing a physical barrier, or the like.

[0051] Generally, blades **226**, **228** may be disposed on distal shaft portion **232**. Proximal blade **226** may be unattached or moveably/slidably attached to distal shaft portion **232**, so that it is free to translate (or “reciprocate”) along distal shaft portion **232** with the back and forth movement of wire bundle **224**. In one embodiment, for example, proximal blade **226** may be slidably coupled with distal shaft portion **232** via a piece of material wrapped around blade **226** and distal shaft portion **232**. In another embodiment, proximal blade **226** may slide through one or more tracks on distal shaft portion **232**. Distal blade **228** may be fixedly attached to distal shaft portion **232** and thus remain stationary, relative to distal shaft portion **232**, such that proximal blade **226** translates toward stationary distal blade **228** to cut tissue. In alternative embodiments, the distal end of wire bundle **224**, itself, may be used to cut tissue, and rongeur **210** may thus not include proximal blade **226**. For example, each wire **224** may have a sharp, tissue cutting point, or wire bundle **224** as a whole may form a sharp, tissue cutting edge. The distal end of wire bundle **224** may advance toward distal blade **228** to cut target tissue, or in alternative embodiments, wire bundle **224** may advance toward a non-sharp backstop to cut tissue or may simply advance against tissue to ablate it, without pinching the tissue between the wire bundle **224** distal end and any other structure. An example of the latter of these embodiments might be where ultrasound energy is used to reciprocate wire bundle **224**, in which case the reciprocation of wire bundle **224** may be sufficient to cut or ablate tissue, without pinching or snipping between wire bundle and another structure.

[0052] In various embodiments, blades **226**, **228**, or other cutting structures such as the distal ends of wire bundle **224**, a backstop or the like, may be disposed along any suitable length of distal shaft portion **232**. In the embodiment shown in FIG. 5A, for example, blades **226**, **228** are disposed along a length of distal shaft portion **232**. In an alternative embodiment, distal shaft portion **232** may comprise a hollow portion through which wire bundle **224** travels and a window through which wire bundle **224** is exposed. In any case, blades **226**, **228** or other cutting members may be disposed or exposed along a desired length of rongeur **210**, to help limit an area in which the cutting members are active, thus helping to limit the exposure of non-target tissues to such cutting elements. In one embodiment, for example, such as an embodiment of the device to be used in a spinal treatment, blades **226**, **228** may be disposed along a length of distal shaft portion **232** measuring no longer than about 10 cm, and preferably no more than about 6 cm, and even more preferably no more than about 3 cm. In various embodiments, the length along which blades **226**, **228** are disposed may be selected to approximate a length of a specific anatomical treatment area.

[0053] 000531 Blades **226**, **228** 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 blades **226**, **228** or for portions or coatings of blades **226**, **228** 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 **226**, **228** may be manufactured using metal injection molding (MIM), CNC machining, injection molding, grinding and/or the like. Proximal and distal blades **226**, **228** may be attached to wire bundle **224** and distal shaft portion **232**, respectively, via any suitable technique, such as by welding, adhesive or the like.

[0054] In some embodiments, articulating rongeur **210** may include a tissue collection chamber **229** distal to distal blade **228**. For example, distal blade **228** may be hollow and in fluid communication with tissue collection chamber **229**, such that when tissue is cut using blades, **226**, **228**, at least some of the tissue passes under distal blade **228** and into collection chamber **229**. Tissue collection chamber **229** may be made of any suitable material, such as but not limited to any of the materials listed above for making blades **226**, **228**. In one embodiment, for example, chamber **229** may comprise a layer of polymeric material attached between distal blade **228** and distal shaft portion **232**. In another embodiment, collection chamber **229** and distal blade **228** may comprise one continuous piece of material, such as stainless steel. Generally, distal blade **228** and chamber **229** form a hollow, continuous space into which at least a portion of cut tissue may pass after it is cut.

[0055] With reference now to FIGS. 5A and 5B, a portion of an articulating rongeur **250**, according to one embodiment, may include a shaft **251** having a longitudinal axis **258**, a proximal shaft portion **252**, a distal shaft portion **254**, and an articulation feature **256** between the proximal and distal portions **252**, **254**. Rongeur **250** may also include a proximal blade **262** and a distal blade **264** disposed on the distal shaft portion **254**. (In FIGS. 5A and 5B, mechanism for moving one or both of blades **262**, **264** is omitted, to enhance the clarity of the drawing figures.) Rongeur **250** may further include one or more tensioning wires **260**, extending from a handle at the proximal end of rongeur **250** (not shown), through proximal shaft portion **252**, to an attachment point **261** in or on distal shaft portion **254**.

[0056] Tensioning wire **260** generally extends through and is attached to shaft **251** closer to the top/blade side than the bottom/opposite side, relative to longitudinal axis **258**. When tensioning wire **260** is pulled proximally, as depicted by the hollow-tipped arrow in FIG. 5B, shaft **251** articulates, bends or flexes toward the blade side of shaft **251** by articulating at articulation feature **256**. In various embodiments, articulation feature **256** may include any suitable number of slits, grooves, hinges, joints or the like. In one embodiment, for example, articulation feature **256** may include two materials on opposite sides of shaft **251**, with a more easily compressible material located on the top side (or blade side) of articulation feature **256** and a less easily compressible material located on the opposite/bottom side.

[0057] In some embodiments, tensioning wire **260** may extend only to a distal side of articulation feature **256** and attach there, rather than extending into distal shaft portion **254**. Alternatively, tensioning wire **260** may extend farther distally on distal portion **254**, to attach at a point at or near distal blade **264** or even at or near the extreme distal end of shaft **251**. In such cases, a sufficient amount of tensioning force applied to tensioning wire **260** may cause distal portion

254 to curl or bend in the direction of the blade side of shaft **251**. If distal portion **254** is made of a relatively rigid material, such bending may be minimal, while if distal portion **254** is made of a more flexible material, such bending may be more significant. In some cases, such bending may facilitate passage of distal portion **254** around a curved surface, through an anatomical curved passage between tissues, or the like. For example, in some embodiments, distal shaft portion **254** may be made of a relatively flexible material, which may facilitate its passage into a small space, between tissues or the like. Applying tensioning force via tensioning wire **260** may, in such an embodiment, not only articulate shaft **251** at articulation feature **256**, but may also stiffen or rigidify distal portion **254**, so that device **250** may be pulled back to urge the stiffened/rigidified distal portion **254** against target tissue.

[0058] Tensioning wire **260** generally comprises a high-strength wire, cable, cord or the like and may be made of any suitable material. In one embodiment, for example, tensioning wire **260** may be made of carbon fiber. Other suitable metals from which tensioning wires **260** may be constructed 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). 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.

[0059] In various embodiments, any number of tensioning wires **260** may be used, such as between one and **100** wires **260**. In cases where multiple wires **260** are used, it may be possible in some embodiments to further steer distal shaft portion **254** by individually manipulating one or more wires **260** relative to other wires. In one embodiment, tensioning wires **260** may extend through a lumen of shaft **251** and may be attached at attachment point **261** via any suitable means, such as adhesive, welding, crimping, pressure fitting or the like. In some embodiments, tensioning wire **260** may be sufficiently strong that an amount of tensioning force may be applied that can bend distal portion **254** and/or render distal portion **254** more stiff or rigid.

[0060] In an alternative embodiment, and with reference now to FIGS. **6A** and **6B**, a portion of an articulating rongeur **270** may include a shaft **271** having a longitudinal axis **278**, a proximal shaft portion **272**, a distal shaft portion **274**, and an articulation feature **275** including multiple flex slits **276**. Rongeur **270** may also include a proximal blade **282** and a distal blade **284** disposed on the distal shaft portion **274**. (Again, in FIGS. **6A** and **6B**, mechanism for moving one or both of blades **282**, **284** is omitted, to enhance the clarity of the drawing figures.) Rongeur **270** may further include one or more compression members **280**, extending from a handle at the proximal end of rongeur **270** (not shown), through proximal shaft portion **272**, to at least articulation feature **275**, and in some embodiments (as in FIGS. **6A** and **6B**) to an attachment point **281** in distal shaft portion **274**.

[0061] As described above, in various embodiments, articulation feature **275** may include any suitable number of flex slits **276**, grooves, hinges, joints, differing materials or the like. Compression member **280** extends through shaft **271**

closer to the bottom/opposite side than the top/blade side, relative to longitudinal axis **278**. When compressive (or “pushing”) force is applied to compression member **280**, as depicted by the hollow-tipped arrow in FIG. **6B**, shaft **271** bends or flexes toward the blade side of shaft **271** by bending/flexing at articulation feature **275**.

[0062] In some embodiments, compression member **280** may extend only to a distal side of articulation feature **275** and attach there, rather than extending into distal shaft portion **274**. Alternatively, compression member **280** may extend farther distally on distal portion **274**, to attach at a point at or near distal blade **284** or even at or near the extreme distal end of shaft **271**. In such cases, a sufficient amount of compressive force applied to compression member **280** may cause distal portion **274** to curl or bend in the direction of the blade side of shaft **271**. If distal portion **274** is made of a relatively rigid material, such bending may be minimal, while if distal portion **274** is made of a more flexible material, such bending may be more significant. In some cases, such bending may facilitate passage of distal portion **274** around a curved surface, through an anatomical curved passage between tissues, or the like. For example, in some embodiments, distal shaft portion **274** may be made of a relatively flexible material, which may facilitate its passage into a small space, between tissues or the like. Applying tensioning force via compression member **280** may, in such an embodiment, not only articulate shaft **271** at articulation feature **275**, but may also stiffen or rigidify distal portion **274**, so that device **270** may be pulled back to urge the stiffened/rigidified distal portion **274** against target tissue.

[0063] Compression member **280** may generally comprise any of a number of force transmitting members, such as one or more high-strength wires, a material substrate, a column of fluid or the like. A wire, substrate or other solid compression member **280** may be made of any suitable material, such as but not limited to carbon fiber, 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). 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.

[0064] In various embodiments, any number of compression members **280** may be used, such as between one and **100** compression wires or the like. In cases where multiple compression members **280** are used, it may be possible in some embodiments to further steer distal shaft portion **274** by individually manipulating one or more compression members **280** relative to others. In one embodiment, compression member **280** may extend through a lumen of shaft **271** and may be attached at attachment point **281** via any suitable means, such as adhesive, welding, crimping, pressure fitting or the like. In one embodiment, for example, compression member **280** may abut a structure such as a backstop, screw drive or the like. In some embodiments, compression member **280** may be sufficiently strong that an amount of tensioning force may be applied that can bend distal portion **274** and/or render distal portion **274** more stiff or rigid.

[0065] In one alternative embodiment (not shown), a rongeur may include both one or more tensioning members 260 and one or more compression members 280. In such an embodiment, both tensioning and compression force may be applied to the rongeur to flex its shaft at one or more locations along its length.

[0066] Referring now to FIG. 7A, another embodiment of an articulating rongeur 290 is shown in cross-section. Articulating rongeur 290 (of which only a portion is shown) may include a shaft 291 having a proximal shaft portion 292, a distal shaft platform 240 (or “substrate” or “extension”), and an articulation feature 296. Rongeur 290 may also include a proximal blade 302, slidably disposed on platform 240 and coupled with a blade actuating wire 306 that extends through proximal shaft portion 292 and out an aperture 308 therein. A distal blade 304 may be fixedly attached to platform 240, and a tissue capture member 305 may be disposed between distal blade 304 and platform 240 to capture cut tissue that passes under blade 304. Rongeur 290 may further include one or more compression members 300, as described above in reference to FIGS. 6A and 6B. Compressive force may be applied to compression member 300 (hollow-tipped arrow) to articulate rongeur 290 about articulation feature 296, and blade articulating wire 306 may be advanced to advance proximal blade 302 (solid-tipped arrows) to cut tissue.

[0067] In various embodiments, platform 240 may comprise an extension of a lower surface of proximal shaft portion 292. Alternatively or additionally, platform 240 may comprise one or more separate pieces of material coupled with proximal shaft portion 292, such as by welding or attaching with adhesive. Platform 240 may comprise the same or different material(s) as proximal shaft portion 292, according to various embodiments, and may have any of a number of configurations. For example, platform 240 may comprise a flat, thin, flexible strip of material (such as stainless steel). In an alternative embodiment, platform 240 may have edges that are rounded up to form a track through which proximal blade 302 may travel. In some embodiments, platform 240 may be flexible, allowing it to bend, while in other embodiments, platform 240 may be predominantly rigid, so that it does not bend or bends only slightly when compressive force is applied to compressive member 300. In various embodiments, platform 240 may be made more rigid by making platform 240 more thick and/or by using more rigid material to construct platform 240. In some embodiments, platform 240 may be made of a shape memory material and given a curved shape, while in other embodiments platform 240 may be rigid and curved or rigid and straight. Differently shaped platforms 240 and/or platforms 240 having different amounts of flexibility may facilitate use of different embodiments of rongeur 290 in different locations of the body. A more rigid platform 240, for example, may facilitate cutting of a hard material such as bone with blades 302, 304.

[0068] Some embodiments of rongeur 290 may further include one or more electrodes coupled with platform 240, for transmitting energy to tissues and thereby confirm placement of rongeur 290 between target and non-target tissues. For example, one or more electrodes may be placed on a lower surface of platform 240, and the electrode(s) may be stimulated to help confirm the location of neural tissue relative to blades 302, 304. In such embodiments, nerve stimulation may be observed as visible and/or tactile muscle twitch and/or by electromyography (EMG) monitoring or other nerve activity monitoring. In various alternative embodiments, additional or

alternative devices for helping position, use or assess the effect of rongeur 210 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 rongeur 210.

[0069] Referring now to FIGS. 7B and 7C, a side view (FIG. 7B) and an end-on view (FIG. 7C) of a portion 200 of rongeur 290 (circled in FIG. 7A) are shown. (FIG. 7C is a view from the perspective labeled A in FIG. 7B.) It has been found that in some embodiments, various components and portions of tissue cutting rongeur 290 may preferably have a combination of dimensions that facilitate passage into a small space and effective tissue cutting. In various embodiments, the dimensions described below may be applied to any tissue cutting device, especially devices designed to cut tissue located in small anatomical passageways or spaces, such as in and around an intervertebral foramen of a spine. For example, a number of alternative tissue cutting devices are described in U.S. patent application Ser. No. 11/405,848, entitled “Mechanical Tissue Modification Devices and Methods” (Original Attorney Docket No. 78117-200301), and filed Apr. 17, 2006, the full disclosure of which is hereby incorporated by reference. In that disclosure, for example, one of the embodiments a tissue cutting device includes a translatable blade that is retracted via two pull wires. It is contemplated that the dimensional characteristics described below may be applied to such a device, as well as to other tissue cutting devices in other alternative embodiments.

[0070] Referring again to FIGS. 7B and 7C, in one embodiment, platform 240 (or “substrate”) may have a substrate height 202 (or “thickness”), blades 302, 304 may have a blade height 204, edges of blades 302, 304 may be separated by a blade opening distance 205, blades 302, 304 may have a blade width 207, platform 240 may have a substrate width 206, and each blade 26, 28 together with platform 240 may have a total device height 208. (Substrate height 202 or substrate width 206 may also be referred to as the height or width of “a portion of the shaft immediately below the blade(s).”) Each of these various dimensions may be adjusted according to various embodiments and for various applications to different parts of patient anatomy. Some embodiments, for example, may be configured for use in and near an intervertebral foramen of a spine. In an alternative embodiment, dimensions of rongeur 290 may be selected for use in a shoulder surgery procedure, a knee surgery procedure, a hand surgery procedure or the like.

[0071] In some embodiments, the portion 200 of rongeur 290 may have an overall size and dimensions such that it may be passed into an epidural space of a spine and at least partially into an intervertebral space of the spine, so that it may be used to cut ligament and/or bone in the spine to treat neural and/or neurovascular impingement. In some embodiments, for example, substrate height 202 may be less than blade height 204. In other words, the ratio of substrate height 202 to blade height may be approximately less than one, and in some embodiments approximately less than or equal to $\frac{3}{4}$. In these or other embodiments, total height 208 (of blade 302 and platform 240) may be less than substrate width 206 and/or blade width 207. (In some embodiments, substrate width 206

may be approximately equal to blade width **207**, as shown, while in alternative embodiments, substrate width **206** may be greater than blade width **207**.) In other words, the ratio of total height **208** to width **207** may be approximately less than one, and in some embodiments approximately less than or equal to $\frac{3}{4}$. In some embodiments, rongeur **290** may have a combination of a ratio of substrate height **202** to blade height approximately less than one and a ratio of total height **208** to width **206** approximately less than one. Such a configuration is contrary to that of traditional rongeurs, which include cutting blades thinner than their underlying supporting structure and which have a total height greater than the width of the device. In one embodiment, for example, blade opening distance **205** may be between about 0.1 inches and about 0.5 inches, substrate height **202** may be between about 0.010 inches and about 0.050 inches, blade height **204** may be between about 0.010 inches and about 0.075 inches, and blade width **207** may be between about 0.2320 and about 0.400 inches. More preferably, in one embodiment, blade opening distance **205** may be between about 0.3 inches and about 0.35 inches, substrate height **202** may be between about 0.025 inches and about 0.035 inches, blade height **204** may be between about 0.040 inches and about 0.060 inches, and blade width **207** may be between about 0.165 and about 0.250 inches. In alternative embodiments, such as for use in other parts of the body, rongeur **290** may have any of a number of different combinations of dimensions.

[0072] To optimize rongeur **290** for any of a number of possible uses, the dimensions described above may be combined with any of a number of materials for the various components of rongeur **290**. Examples of such materials for blades **302**, **304**, platform **240** and the like have been listed previously. In some embodiments, for example, platform **240** may be made of a material and may have a height or thickness **202** such that it is predominantly stiff or rigid, even when placed under tension against a rounded surface. In another embodiment, platform **240** may be more flexible, to allow for greater bending around a surface. Using various combinations of dimensions and materials, rongeur **290** may be configured to cut any of a number of tissues in any of a number of locations in the body.

[0073] Referring now to FIG. 8, another embodiment of an articulating rongeur **310** is shown in cross-section. Articulating rongeur **310** (of which only a portion is shown) may include a shaft **311** having a proximal shaft portion **312**, a distal shaft platform **314** (or “substrate” or “extension”), and an articulation feature **316**. Shaft **311** may also include an additional articulation feature **318** and a distal tip **315**. Rongeur **310** may also include a proximal blade **322**, slidably disposed on platform **314** and coupled with a blade actuating wire **326** that extends through proximal shaft portion **312** and out an aperture therein. A distal blade **324** may be fixedly attached to platform **314**, and a tissue capture member **325** may be disposed between distal blade **324** and platform **314** to capture cut tissue that passes under blade **324**. Rongeur **310** may further include one or more compression members **320**, as described above in reference to FIGS. 6A and 6B. Compressive force may be applied to compression member **320** (hollow-tipped arrow) to articulate rongeur **310** about articulation feature **316**, and blade articulating wire **326** may be advanced to advance proximal blade **322** (solid-tipped arrows) to cut tissue.

[0074] In the embodiment of FIG. 8, compression member **320** extends through proximal shaft portion **312**, through

distal platform **314**, and into distal tip **315**. When compressive force is applied to compression member **320**, the force is transmitted all the way to distal tip **315**, so that rongeur articulates both at articulation feature **316** and at additional articulation feature **318**. In some embodiments, it may be possible to articulate rongeur incrementally, such as by articulating in a first increment at articulation feature **316** and in a second increment at additional articulation feature **318**. It may also be possible, in some embodiments, to apply sufficient compressive force to compression member **320** to bend or curl distal tip **315**, as shown in FIG. 8. Such bending may facilitate curving rongeur **310** around a curve tissue surface, for example. As described above, in some embodiments, compressive force may also act to bend distal platform **314**.

[0075] Referring now to FIG. 9, in one embodiment, an articulating tissue cutting device **330** may suitably include a shaft **331** having a proximal portion **332**, a distal portion **334** including a distal tip **335**, a first articulation feature **336** and a second articulation feature **338**. Device **330** may further include a powered reciprocating file **342** having multiple tissue cutting elements **344** and coupled with a drive mechanism **346**. A compressive member **340** may be disposed through and attached to shaft **331** for applying compressive force (hollow-tipped arrow) to articulate shaft **331** at articulation features **336**, **338**.

[0076] Shaft **331** and compressive member **340** may have any of the features described above in relation to alternative embodiments. Powered reciprocating file **342** may comprise any suitable reciprocating file device, such as those known in the art and any reciprocating files invented in the future. Generally, file **342** may be reciprocated back and forth (solid, double-headed arrows) by drive mechanism **346** while device **330** is pulled back to urge cutting elements **344** against target tissue, so that cutting elements **344** cut tissue. In some embodiments, cutting elements **344** may open into a collection chamber or area in distal portion **334**, where cut tissue may be collected and/or transported proximally through shaft **331** and out of device **330**.

[0077] In various embodiments, file **342** and drive mechanism **346** may take any of a number of different forms. Various powered reciprocating file devices are described, for example, in U.S. patent application Ser. No. 11/406,486 (Original Attorney Docket No. 78117-200501), titled “Powered Tissue Modification Devices and Methods,” and filed Apr. 17, 2006, the full disclosure of which is hereby incorporated by reference. In one embodiment, reciprocating file **342** may comprise a file such as that invented by Richard J. Harp, founder of SurgiFile, Inc. (The SurgiFile device is described, for example, in U.S. patent application Ser. No. 11/259,625 (Pub. No. 2006/0161189), the full disclosure of which is hereby incorporated by reference). By including one or more articulation features **336**, **338** in shaft **331**, reciprocating surgical file device **330** may have enhanced ability to reach one or more difficult to reach anatomical areas and/or to gain leverage against one or more structures to facilitate urging file **342** against target tissue.

[0078] With reference now to FIG. 10, in one embodiment, an articulating reciprocating file tissue cutting device **350** may include a handle **352** with a power source connector **354**, a shaft **356** having a first articulation feature **358**, a second articulation feature **360** and a distal tip, and a reciprocating file **364**. The various portions of shaft **356** may have any of the features described above in relation to various alternative embodiments. An alternative embodiment of device **350** may

include only one articulation feature **358**, **360**, rather than two. Otherwise, device **350** may include any of the features described in U.S. patent application Ser. No. 11/259,625, which was previously incorporated by reference.

[0079] FIG. 11 shows a distal portion of another alternative embodiment of an articulating reciprocating file tissue cutting device **370**. In one embodiment, device **370** may include a handle connector **372**, a shaft **374** including a first articulation feature **376**, a second articulation feature **378** and a distal tip **380**, and a reciprocating file **382** having multiple tissue cutting elements **384**. As with the previous embodiment, shaft **374** may have any of the various features described above in relation to other embodiments, and device **370** may have any of the features described in U.S. patent application Ser. No. 11/259,625, which was previously incorporated by reference.

[0080] Referring now to FIG. 12, in another embodiment, an articulating tissue cutting device **390** may include a shaft **391** having a proximal portion **392**, a distal portion **394**, a distal tip **395**, a first articulation feature **396** and a second articulation feature **398**. A compression member **400** may be disposed through shaft **391** to articulate shaft **391** at articulation features **396**, **398**. An electrosurgical tissue cutting member **402** may extend through shaft **391** and protrude through (or be exposed through) a window **404** on distal portion **394**. Tissue cutting member **402**, for example, may comprise a radiofrequency (RF) device, such as a monopolar or bipolar electrosurgical device. In one embodiment, tissue cutting member **402** may be configured as a wire loop. Tissue cutting member **402** may be advanced out of window **404**, activated with RF energy, and then retracted (hollow-tipped arrow) to cut tissue, such as ligamentum flavum tissue in the spine or other soft tissue. Further details of such RF tissue cutting devices are provided in U.S. patent application Ser. No. 11/405,848, which was previously incorporated by reference. In one embodiment, tissue cut by tissue cutting member **402** may fall into a tissue collection chamber or hollow area in shaft distal portion **394**.

[0081] In other alternative embodiments of an articulating tissue cutting device, any of a number of other tissue cutting mechanisms may be used. Exemplary embodiments described above include bladed cutters, reciprocating files, and RF wire cutters, but any other suitable tissue cutting member (or members) may be included in alternative embodiments. For example, tissue cutting members may include but are not limited to blades, abrasive surfaces, files, rasps, saws, planes, electrosurgical devices, bipolar electrodes, monopolar electrodes, thermal electrodes, cold ablation devices, rotary powered mechanical shavers, reciprocating powered mechanical shavers, powered mechanical burrs, lasers, ultrasound devices, cryogenic devices, and/or water jet devices.

[0082] 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. These and 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.

We claim:

1. A device for cutting ligament and/or bone tissue in a lateral recess and/or an intervertebral foramen of a spine of a patient to treat spinal stenosis, the device comprising:

- an elongate shaft having a rigid proximal portion and a distal portion articulatable relative to the proximal portion;
- a handle coupled with the proximal portion of the shaft;
- a tissue cutter disposed on one side of the distal portion of the shaft;
- a first actuator coupling the handle with the tissue cutter for activating the tissue cutter to cut tissue; and
- a second actuator coupling the handle with the distal portion for articulating the distal portion relative to the proximal portion.

2. A device as in claim 1, wherein the distal portion of the shaft is configured to pass at least partway into an intervertebral foramen of the patient's spine.

3. A device as in claim 1, wherein the distal portion of the shaft is rigid.

4. A device as in claim 1, wherein the distal portion of the shaft is configured to articulate toward the side on which the tissue cutter is disposed.

5. A device as in claim 1, further comprising an articulation member disposed along the shaft between the proximal and distal portions.

6. A device as in claim 5, wherein the articulation member is selected from the group consisting of slits, grooves, hinges and joints.

7. A device as in claim 5, wherein the articulation member comprises:

- a first material disposed on the side of the shaft on which the tissue cutter is disposed; and
- a second material disposed on an opposite side of the shaft, wherein the first material is more compressible than the second material.

8. A device as in claim 1, wherein the distal portion of the shaft is configured to articulate incrementally from a relatively unflexed position to a first flexed position and to at least a second flexed position.

9. A device as in claim 1, further comprising a locking mechanism coupled with the at least part of the device for locking the distal portion in an articulated position relative to the proximal portion.

10. A device as in claim 1, wherein the tissue cutter is selected from the group consisting of blades, abrasive surfaces, files, rasps, saws, planes, electrosurgical devices, bipolar electrodes, monopolar electrodes, thermal electrodes, cold ablation devices, rotary powered mechanical shavers, reciprocating powered mechanical shavers, powered mechanical burrs, lasers, ultrasound devices, cryogenic devices, and water jet devices.

11. A device as in claim 10, wherein the tissue cutter comprises a translatable blade, wherein the blade has a height greater than a height of a portion of the shaft immediately below the blade, and wherein a total height of the blade and the portion of the shaft immediately below the blade is less than a width of the portion of the shaft immediately below the blade.

12. A device as in claim 11, wherein the tissue cutter further comprises a fixed blade fixedly attached to the shaft, wherein the translatable blade moves toward the fixed blade to cut tissue.

13. A device as in claim 11, wherein the tissue cutter further comprises a fixed backstop fixedly attached to the shaft, wherein the translatable blade moves toward the fixed backstop to cut tissue.

14. A device as in claim 1, wherein the second actuator comprises:

- a tensioning wire extending from the handle to the distal portion of the shaft; and
- a tensioning member on the handle coupled with the tensioning wire and configured to apply tensioning force to the wire.

15. A device as in claim 1, wherein the second actuator comprises:

- a compression member extending from the handle to the distal portion of the shaft; and
- a force application member on the handle coupled with the compression member and configured to apply compressive force to the compression member.

16. A device as in claim 15, wherein the compression member is selected from the group consisting of wires, substrates and fluids.

17. A device as in claim 1, wherein the shaft further includes a distal tip articulatable relative to the distal portion of the shaft, wherein the second actuator extends to the distal tip.

18. A device as in claim 1, wherein the first and second actuators are selected from the group consisting of triggers, squeezable handles, levers, dials, toggle clamps, toggle switches and vice grips.

19. A device for cutting tissue in a human body, the device comprising:

- an elongate shaft having a rigid proximal portion and a distal portion articulatable relative to the proximal portion;
- a handle coupled with the proximal portion of the shaft;
- a translatable blade slidably disposed on one side of the distal portion of the shaft;
- a first actuator coupling the handle with the tissue cutter for activating the tissue cutter to cut tissue;
- a second actuator coupling the handle with the distal portion for articulating the distal portion relative to the proximal portion; and
- a locking mechanism configured to lock the distal portion in an articulated configuration relative to the proximal portion.

20. A device as in claim 19, wherein the translatable blade has a height greater than a height of a portion of the shaft immediately below the blade, and wherein a total height of the blade and the portion of the shaft immediately below the blade is less than a width of the portion of the shaft immediately below the blade.

21. A device as in claim 19, wherein the distal portion of the shaft is rigid.

22. A method for cutting ligament and/or bone tissue in a lateral recess and/or an intervertebral foramen of a spine of a patient to treat spinal stenosis, the method comprising:

- advancing a distal portion of a tissue cutting device into an epidural space of the patient's spine;

articulating the distal portion relative to a proximal portion of the device;

advancing the distal portion at least partway into an intervertebral foramen of the spine;

urging a tissue cutter disposed on one side of the distal portion of the device against at least one of ligament or bone tissue in at least one of the lateral recess or the intervertebral foramen; and

activating the tissue cutter to cut at least one of the ligament or bone tissue.

23. A method as in claim 22, wherein advancing the distal portion comprises advancing through an access conduit device.

24. A method as in claim 23, wherein the distal portion is advanced through the conduit device and between two adjacent vertebrae into the epidural space without removing vertebral bone.

25. A method as in claim 22, wherein articulating comprises applying tensioning force to a tensioning member disposed longitudinally through the device from the proximal portion to the distal portion.

26. A method as in claim 22, wherein articulating comprises applying compressive force to a compressive member disposed longitudinally through the device from the proximal portion to the distal portion.

27. A method as in claim 22, wherein articulating comprises:

- articulating to a first articulated configuration before advancing the distal portion into the foramen; and
- further articulating to a second articulated configuration after advancing the distal portion at least partway into the foramen.

28. A method as in claim 22, further comprising locking the distal portion in an articulated position relative to the proximal portion before urging the tissue cutter against tissue.

29. A method as in claim 28, further comprising:

- unlocking the distal portion;
- straightening the distal portion relative to the proximal portion; and
- removing the tissue cutting device from the patient.

30. A method as in claim 22, wherein urging the tissue cutter against tissue comprises applying force to a handle of the tissue cutting device.

31. A method as in claim 22, wherein activating the tissue cutter comprises activating a device selected from the group consisting of blades, abrasive surfaces, files, rasps, saws, planes, electrosurgical devices, bipolar electrodes, monopolar electrodes, thermal electrodes, cold ablation devices, rotary powered mechanical shavers, reciprocating powered mechanical shavers, powered mechanical burrs, lasers, ultrasound devices, cryogenic devices, and water jet devices.

32. A method as in claim 31, wherein activating the tissue cutter comprises advancing a translatable blade toward one of a stationary blade and a backstop.

33. A method as in claim 31, wherein activating the tissue cutter comprises retracting a translatable blade toward one of a stationary blade and a backstop.

34. A method as in claim 31, wherein activating the tissue cutter comprises translating two blades toward one another.

* * * * *

专利名称(译)	铰接式组织切割装置		
公开(公告)号	US20080161809A1	公开(公告)日	2008-07-03
申请号	US11/538345	申请日	2006-10-03
[标]申请(专利权)人(译)	巴克萨诺公司		
申请(专利权)人(译)	BAXANO INC.		
当前申请(专利权)人(译)	BAXANO INC.		
[标]发明人	SCHMITZ GREGORY BLEICH JEFFERY L MILLER ERIC C		
发明人	SCHMITZ, GREGORY BLEICH, JEFFERY L. MILLER, ERIC C.		
IPC分类号	A61B17/00		
CPC分类号	A61B17/1604 A61B17/1611 A61B2017/003 A61B17/1671 A61B18/14 A61B17/1659		
外部链接	Espacenet USPTO		

摘要(译)

用于切割患者脊柱的侧向凹陷和/或椎间孔中的韧带和/或骨组织以治疗椎管狭窄的装置可包括：细长轴，其具有刚性近侧部分和相对于近侧可铰接的远侧部分一部分；手柄与轴的近端部分连接；组织切割器，设置在轴的远端部分的一侧；第一致动器，将手柄与组织切割器连接，用于激活组织切割器以切割组织；第二致动器将手柄与远端部分连接，以使远端部分相对于近端部分铰接。在一些实施例中，轴的远侧部分可构造至少部分地进入患者脊柱的椎间孔。

