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(54) **TISSUE ACCESS GUIDEWIRE SYSTEM AND METHOD**

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(52) **U.S. Cl.** **600/210**

(57) **ABSTRACT**

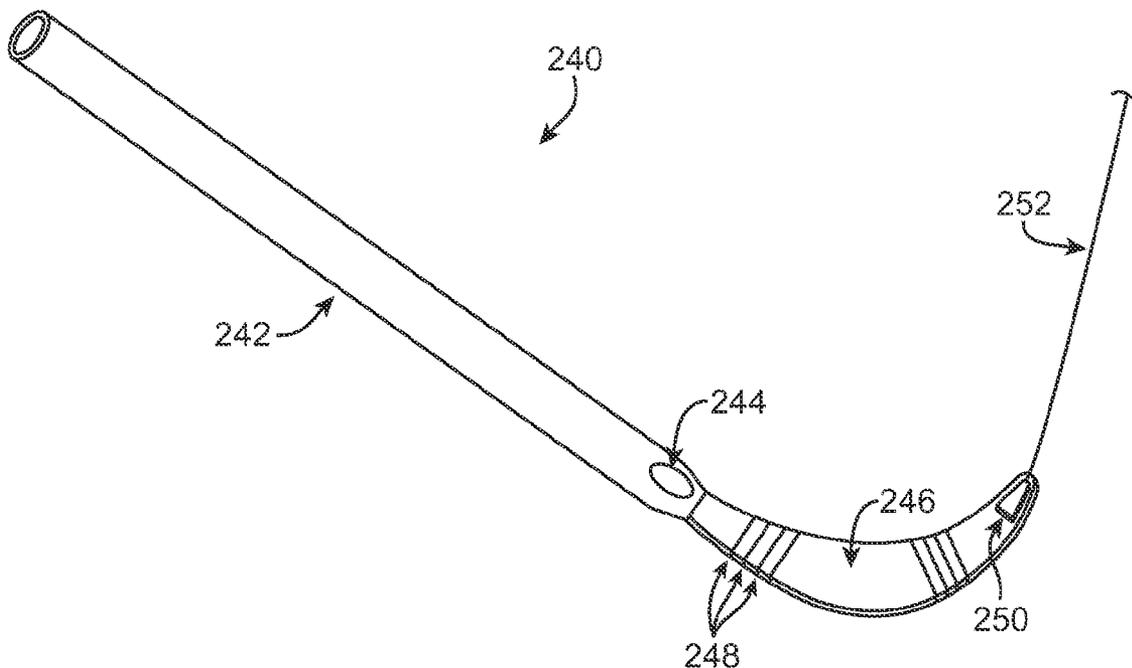
A method and system for guiding at least a portion of a surgical device to a desired position between two tissues in a patient's body involves coupling a guidewire to the device and pulling the distal end of the guidewire to guide at least a portion of the surgical device to a desired position between the two tissues. The surgical device generally includes one or more guidewire coupling members and may comprise a tissue access device. A system may include a guidewire and a surgical device. In some embodiments, a guidewire, a tissue access device, and one or more additional devices to use with the access device may be provided. Methods, devices and systems may be used in open, less-invasive or percutaneous surgical procedures, in various embodiments.

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(21) Appl. No.: **11/468,252**



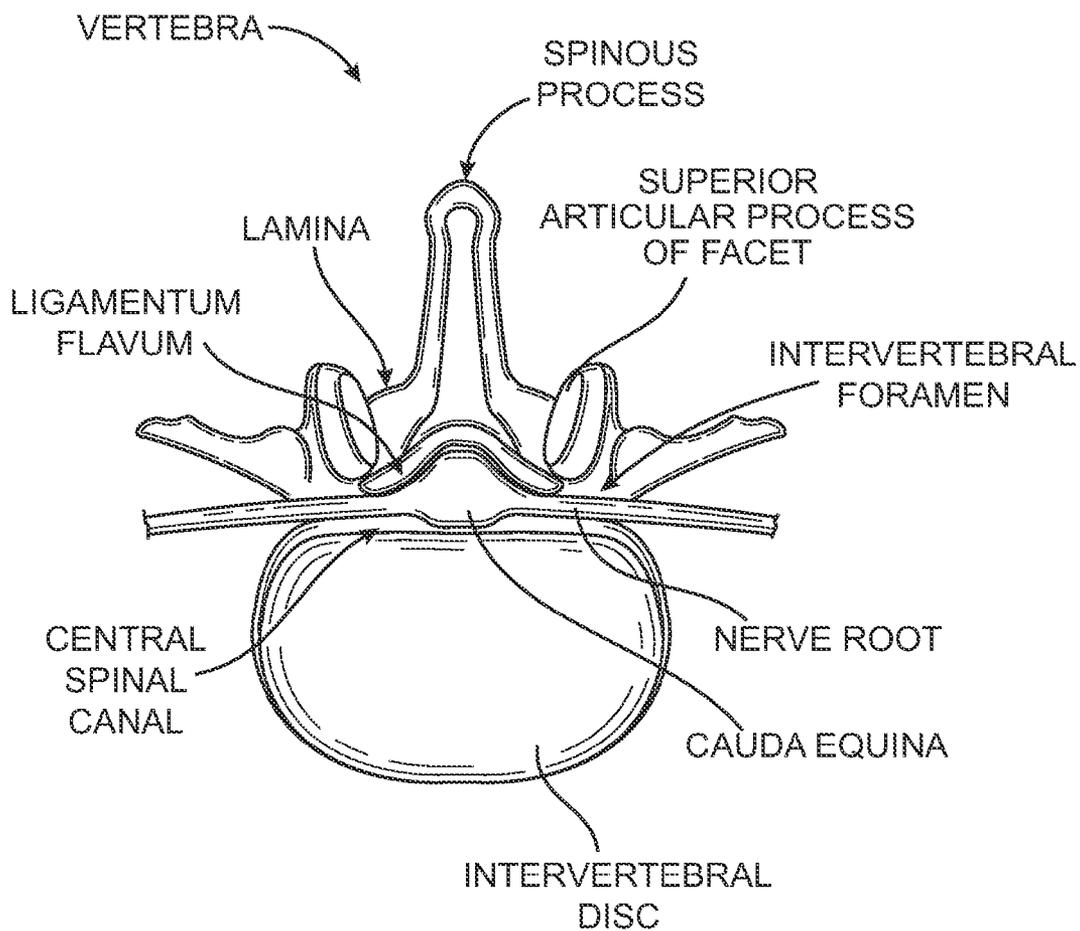


FIG. 1

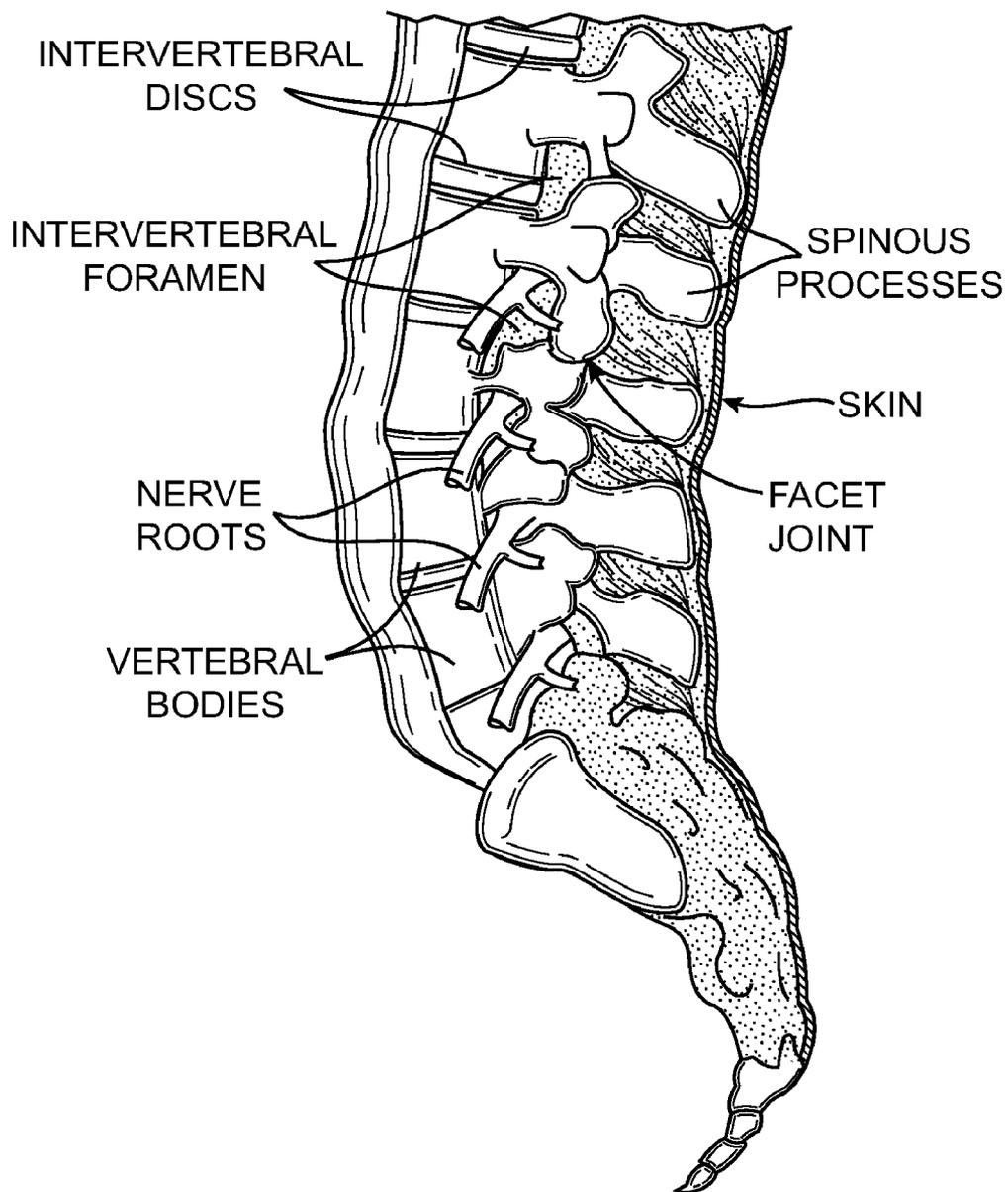


FIG. 2

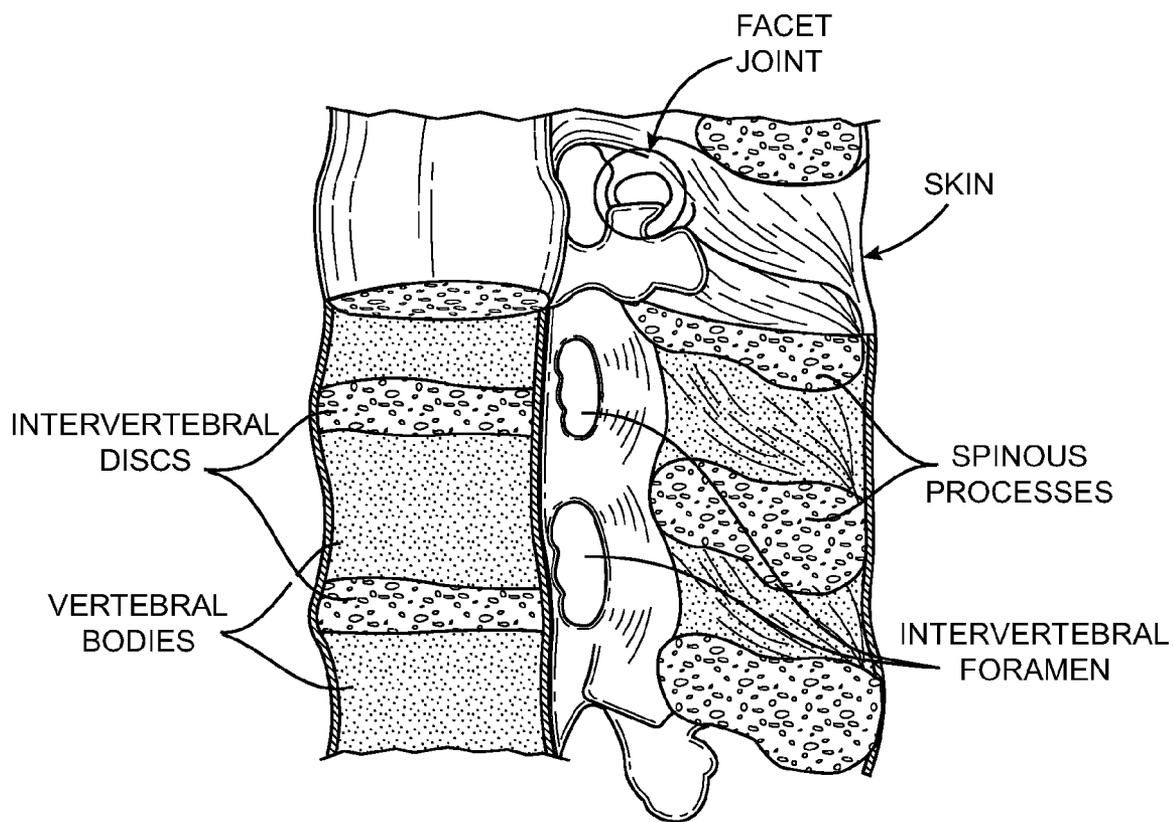


FIG. 3

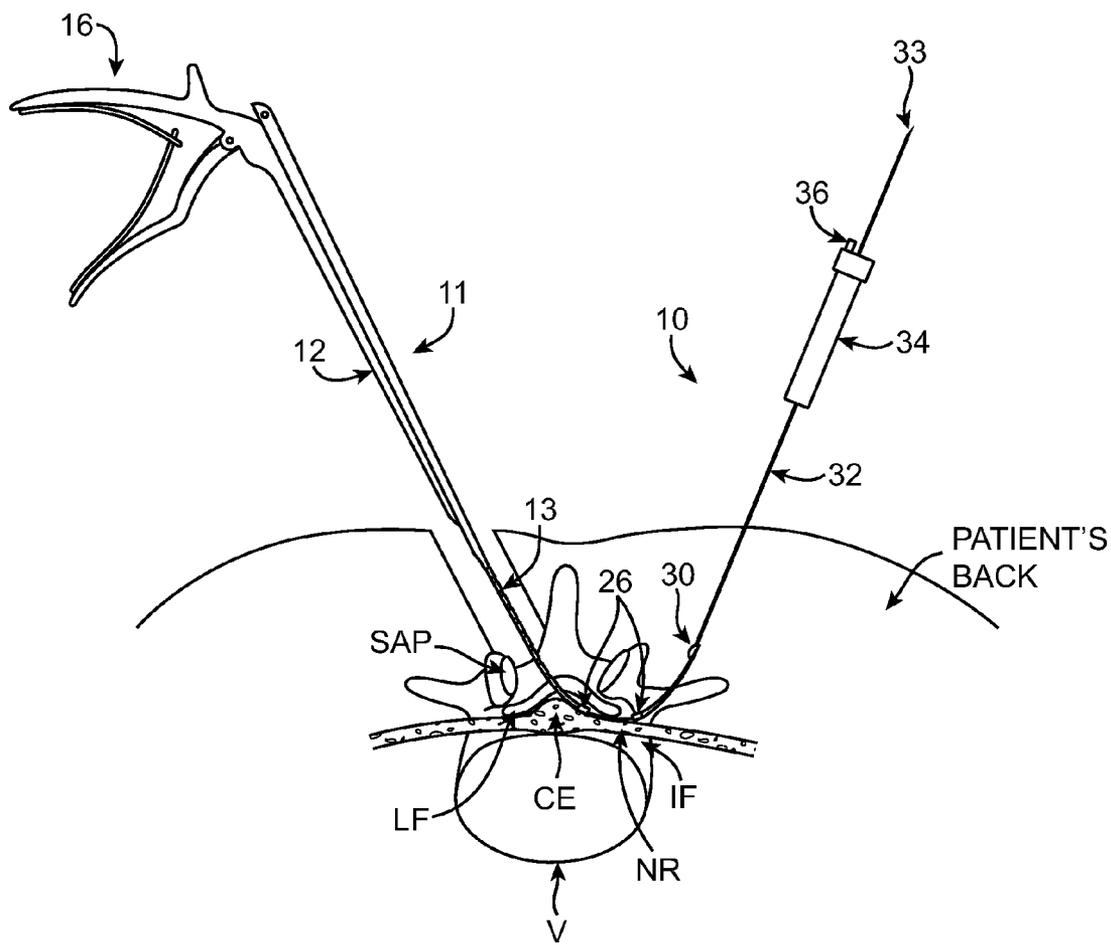


FIG. 4

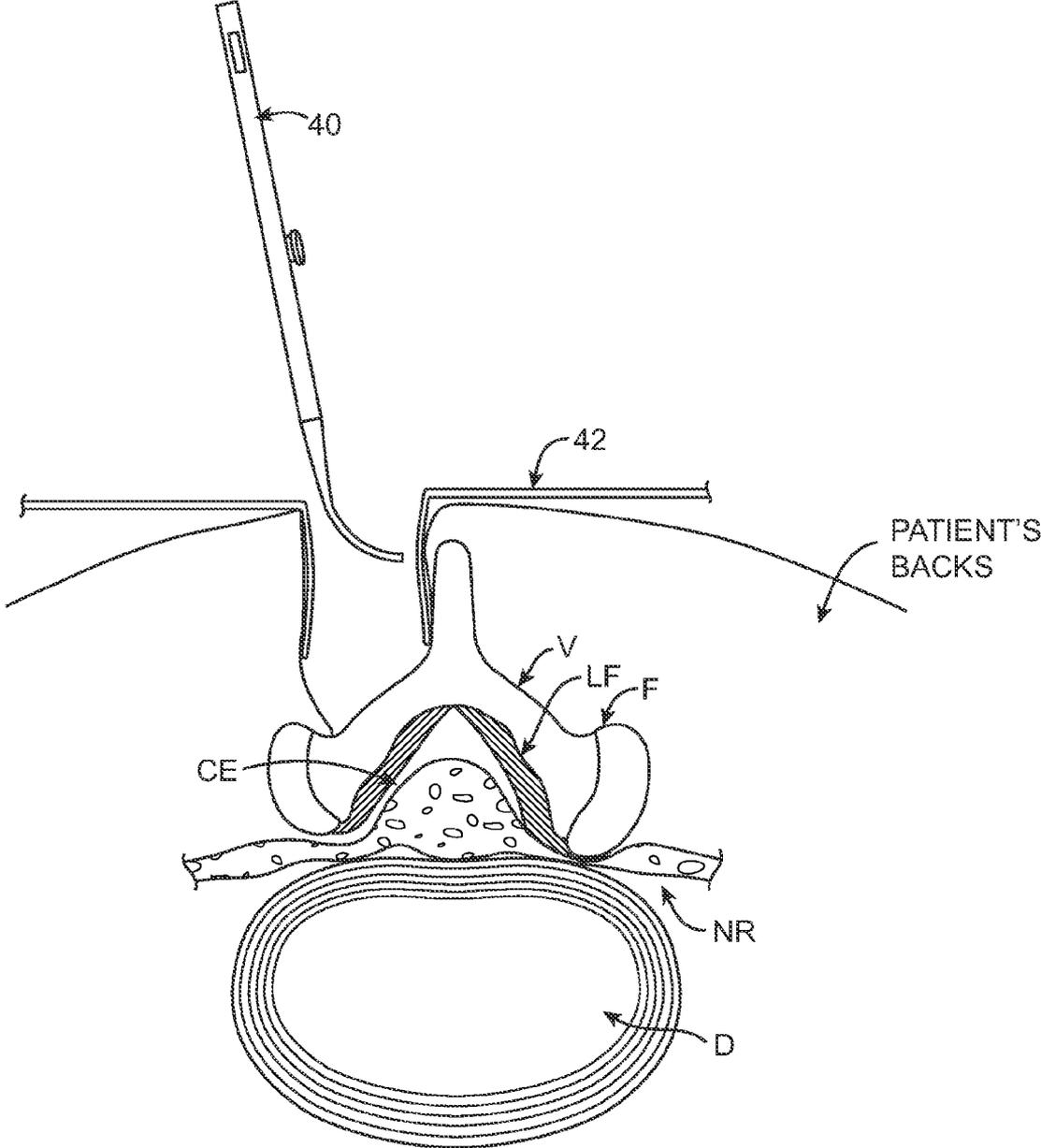


FIG. 5A

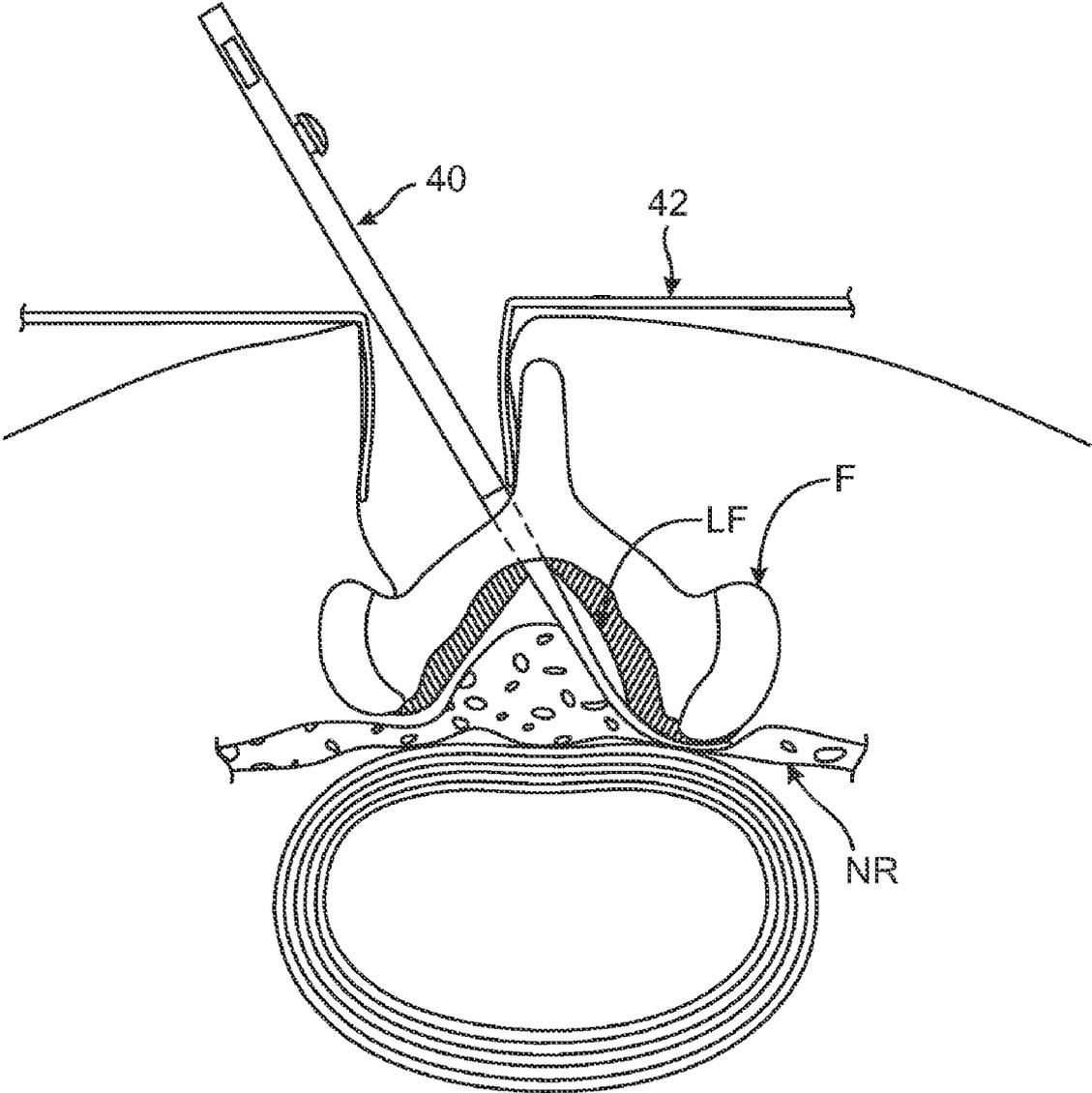


FIG. 5B

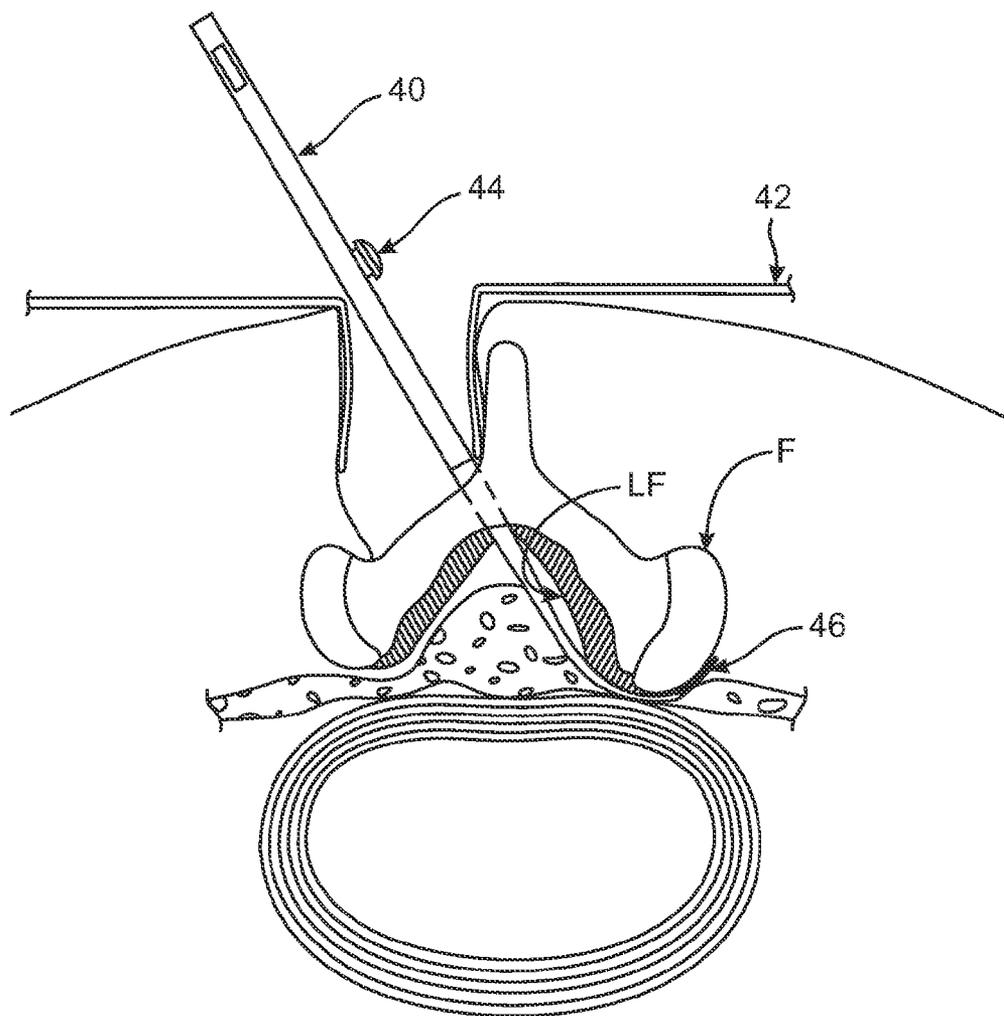


FIG. 5C

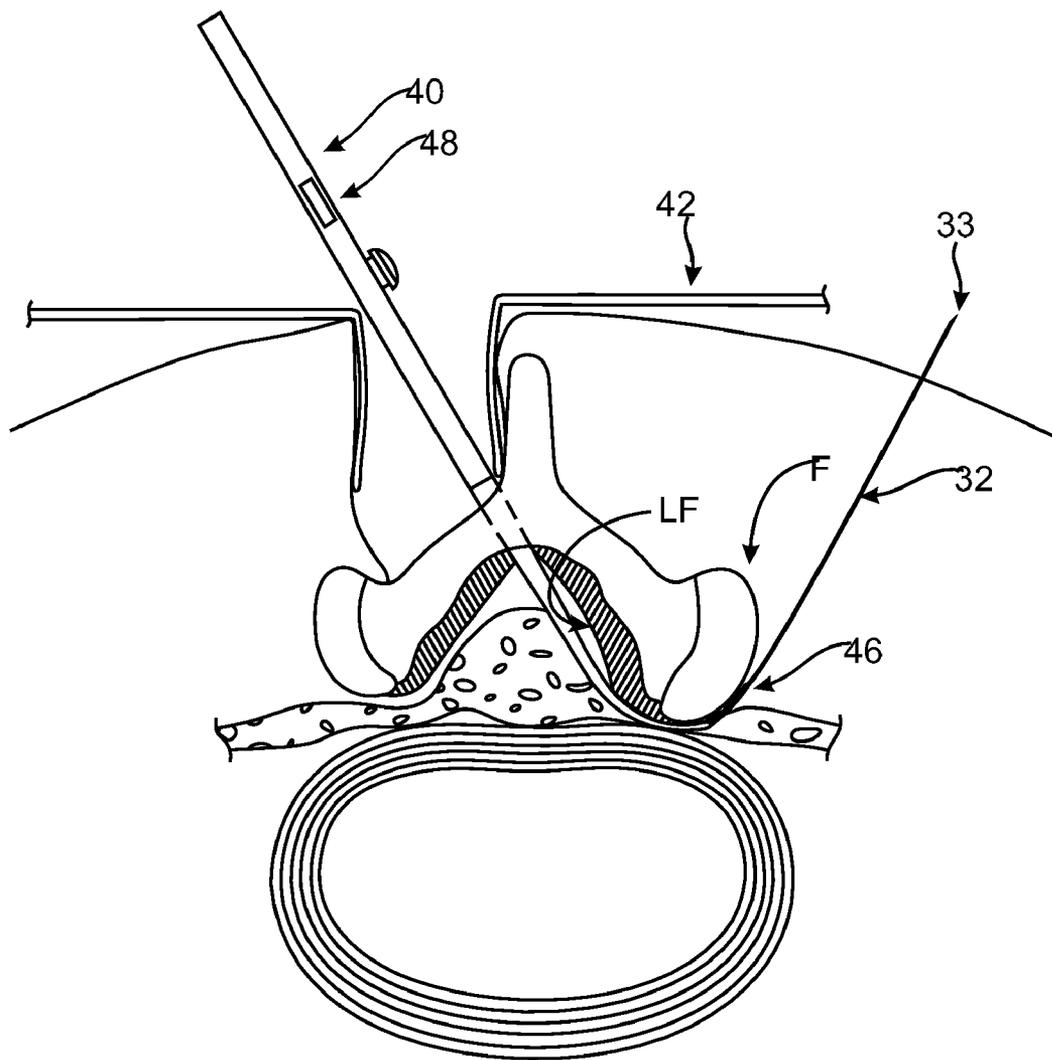


FIG. 5D

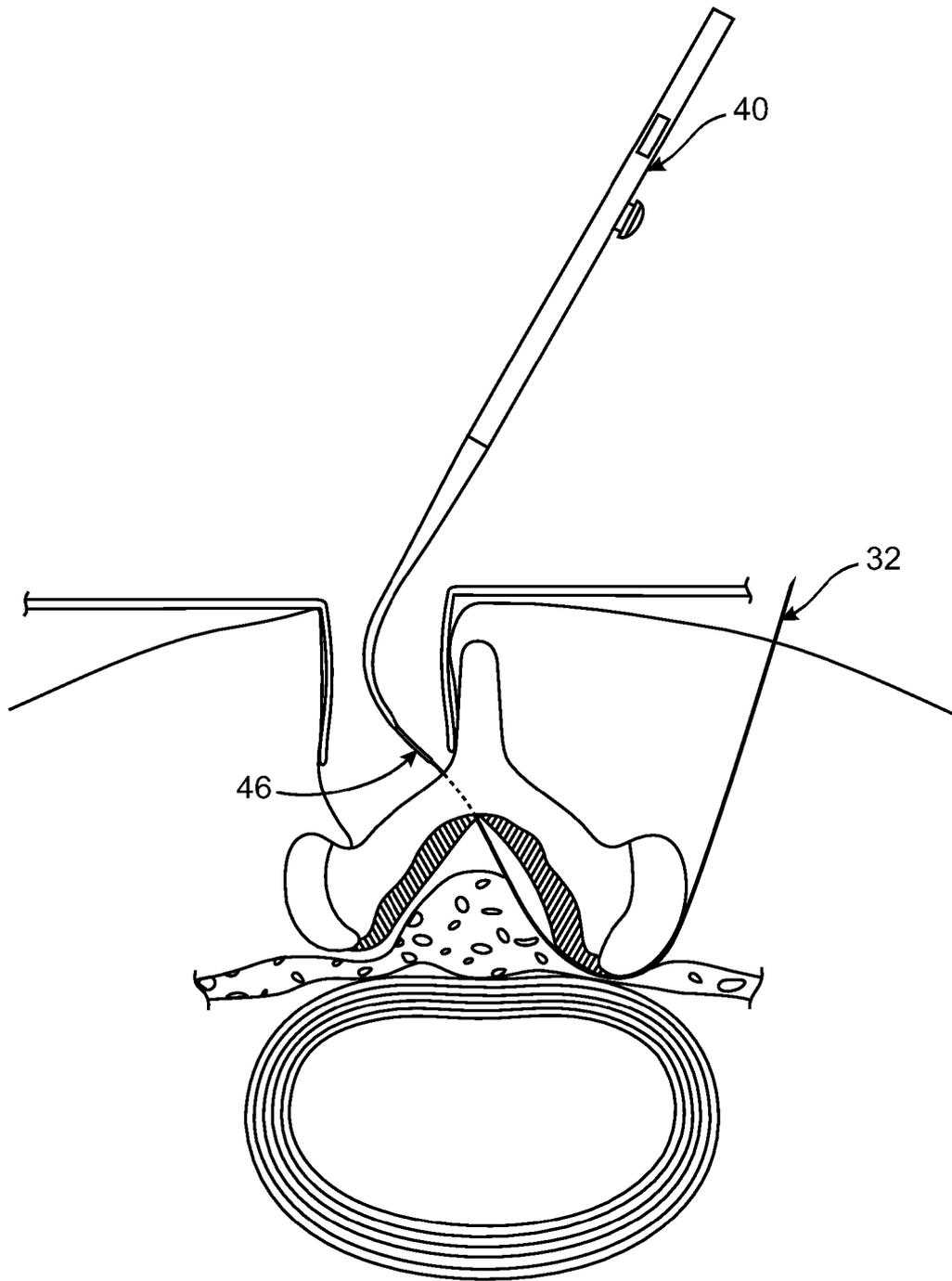


FIG. 5E

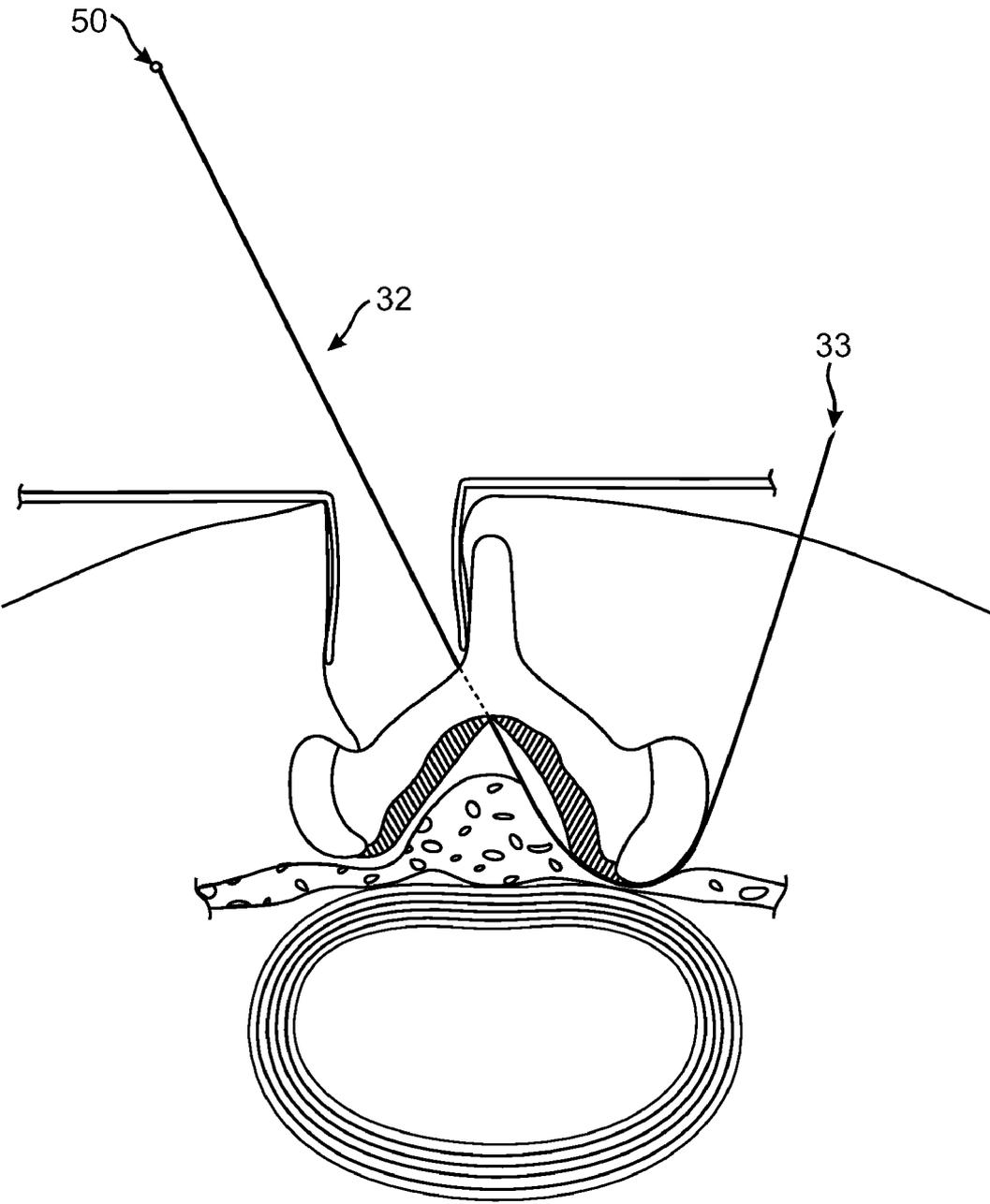


FIG. 5F

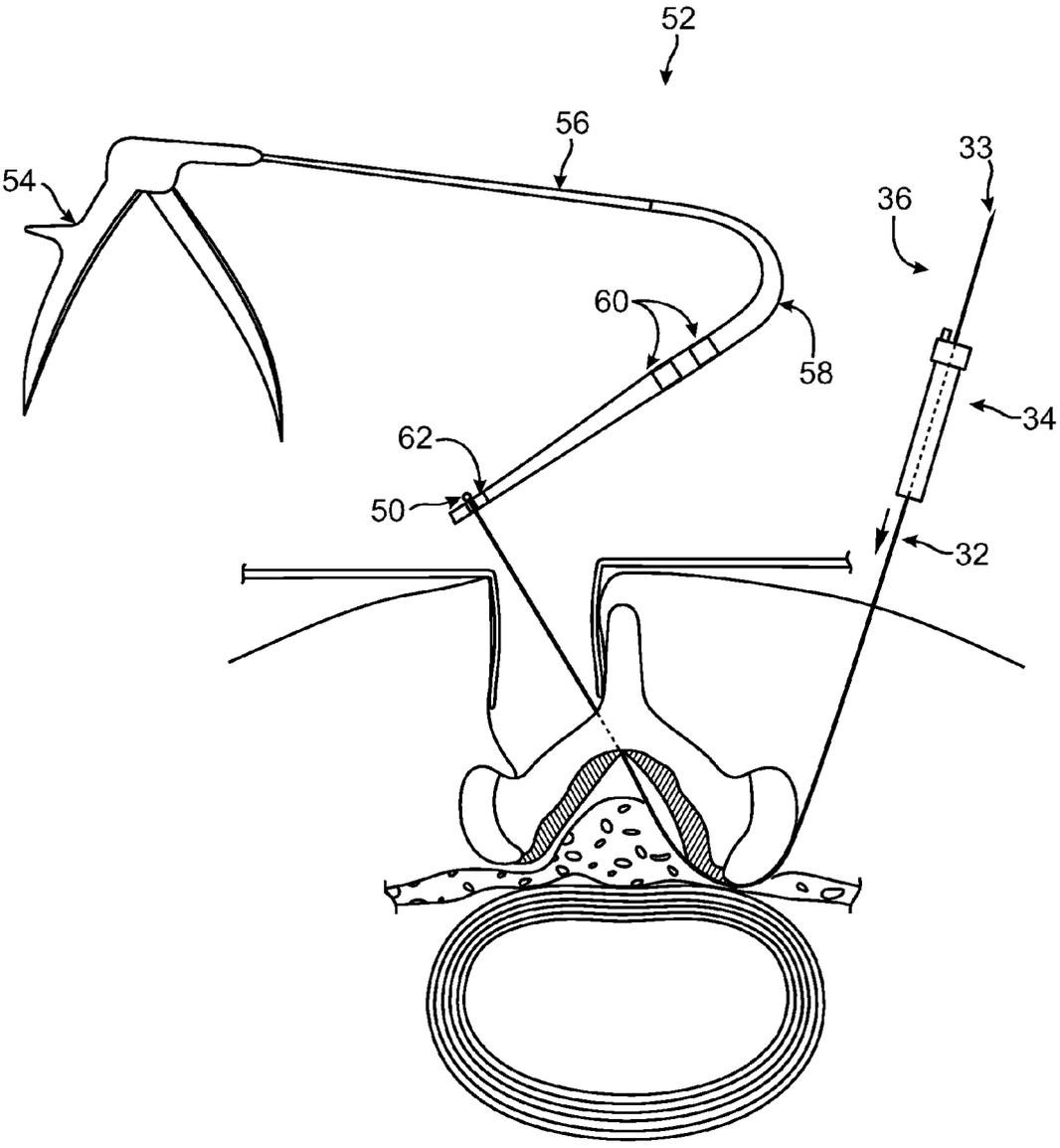


FIG. 5G

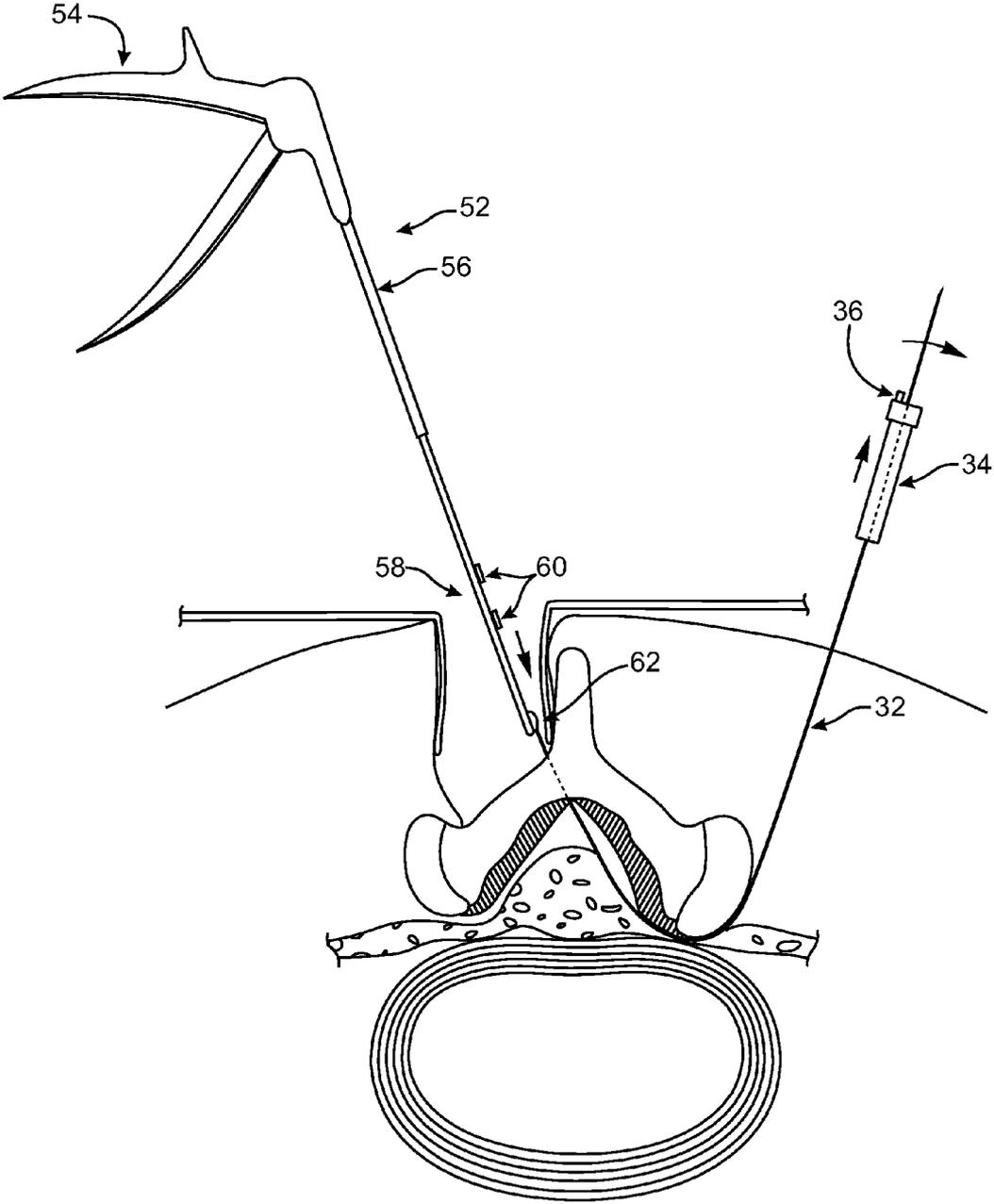


FIG. 5H

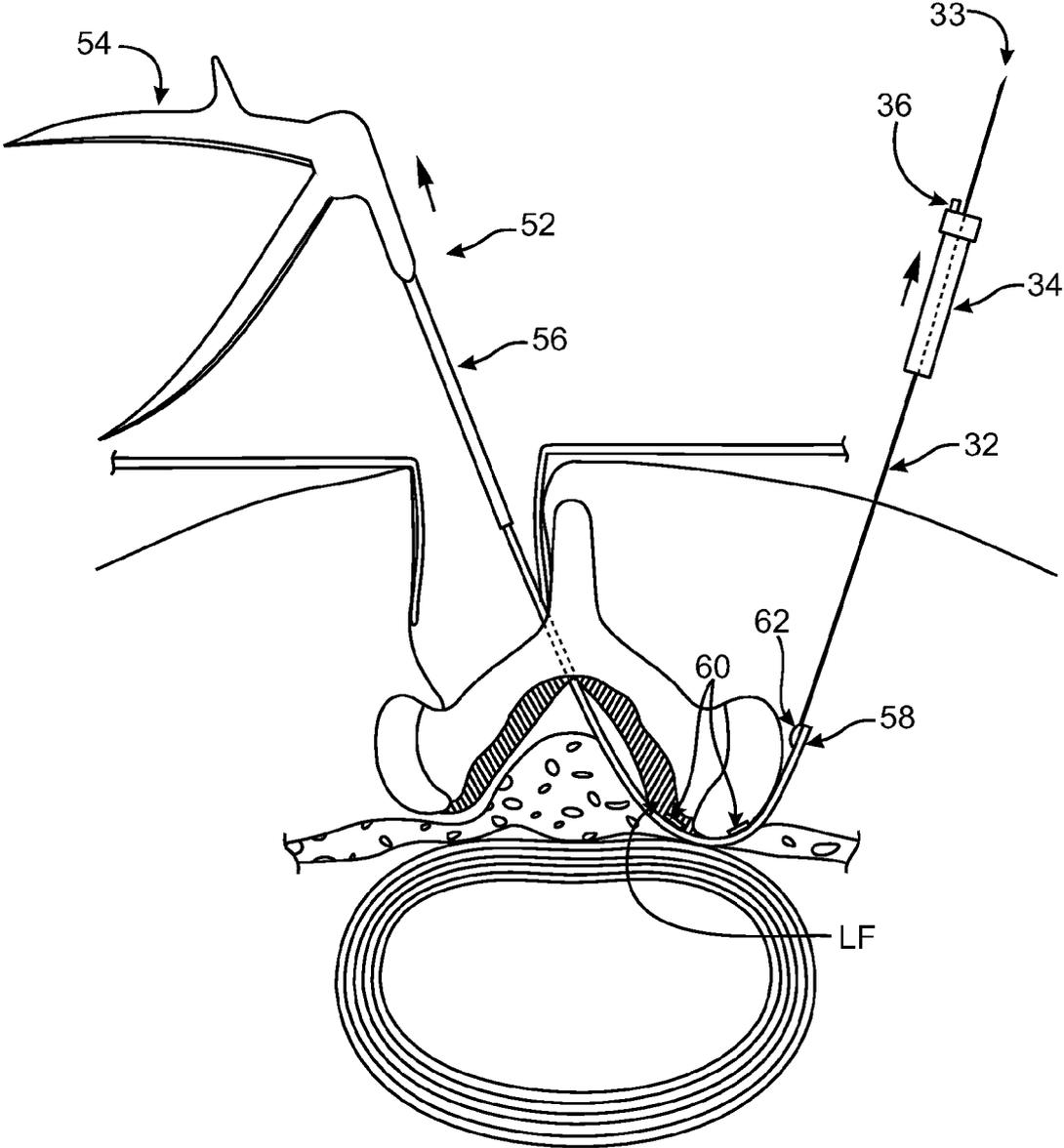


FIG. 5I

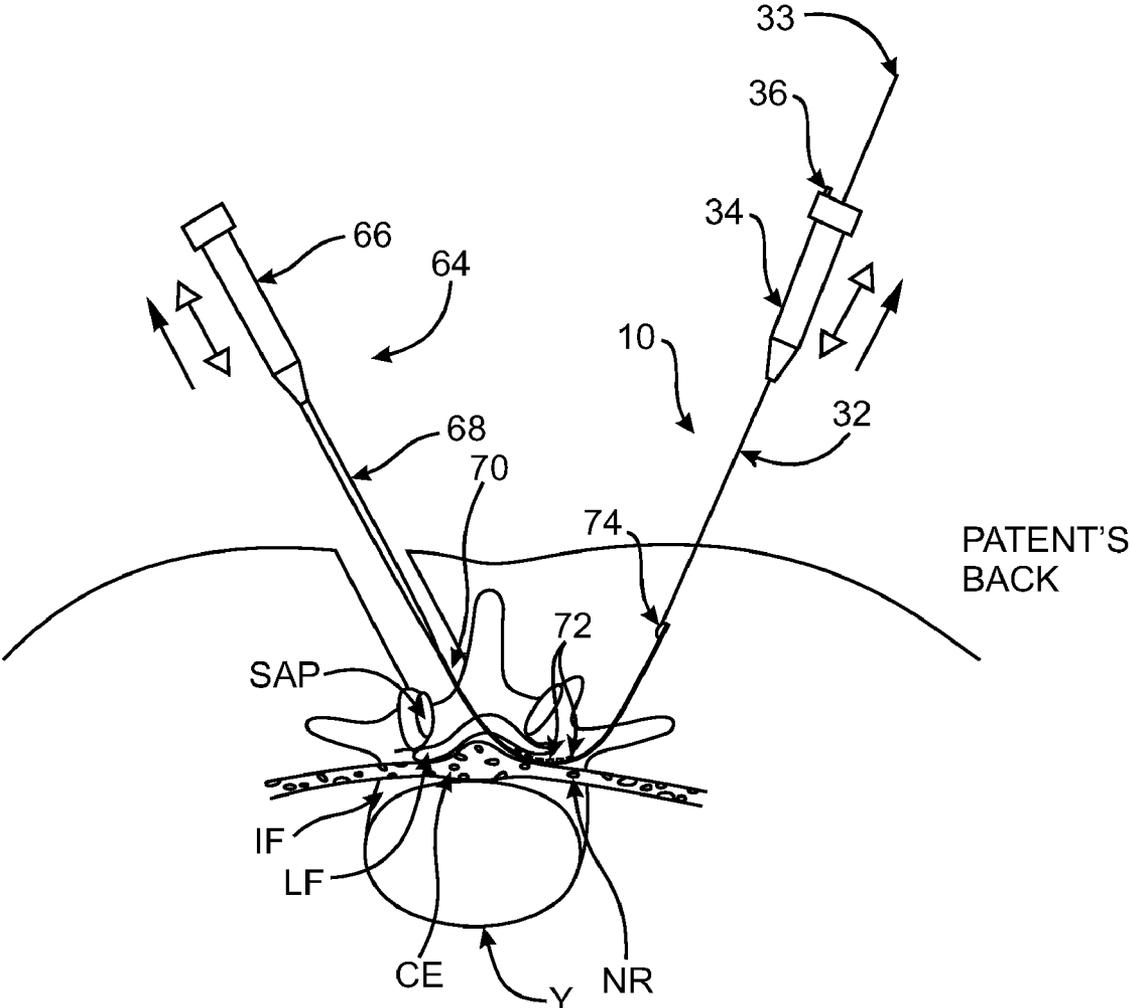


FIG. 6

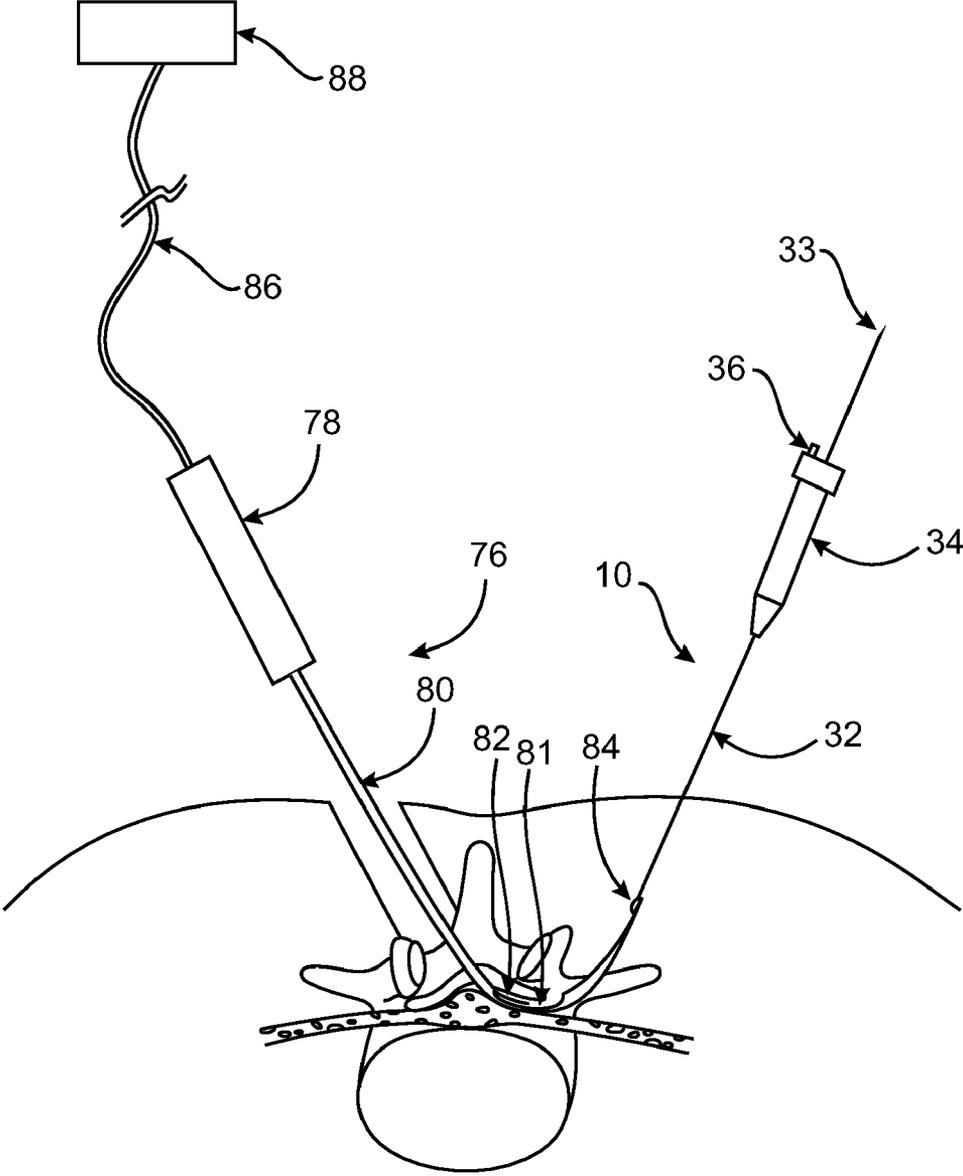


FIG. 7

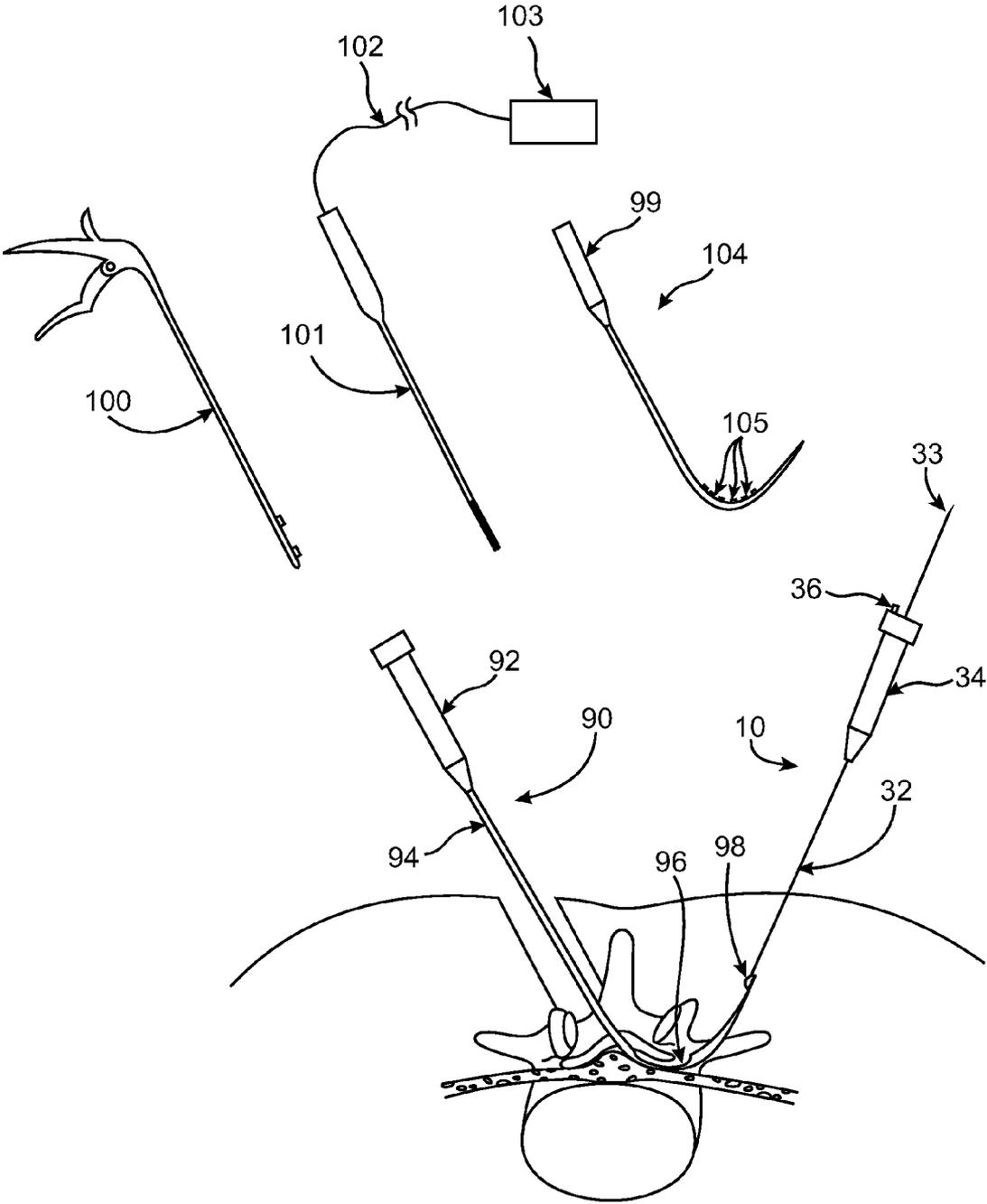


FIG. 8A

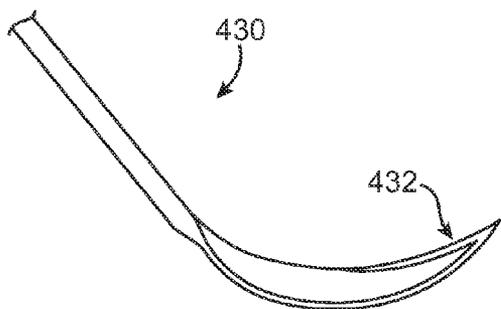


FIG. 8B

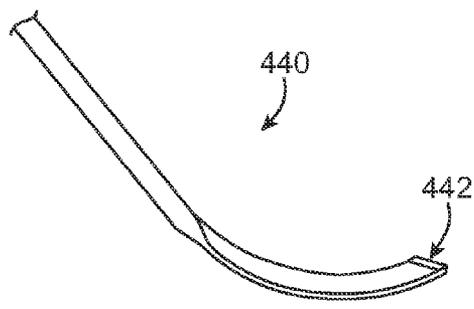


FIG. 8C

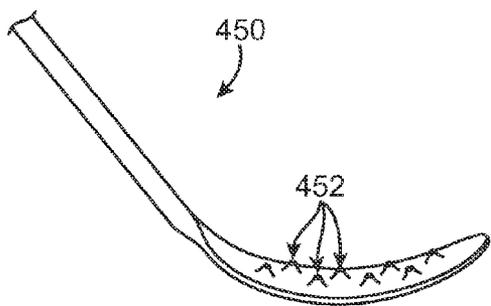


FIG. 8D

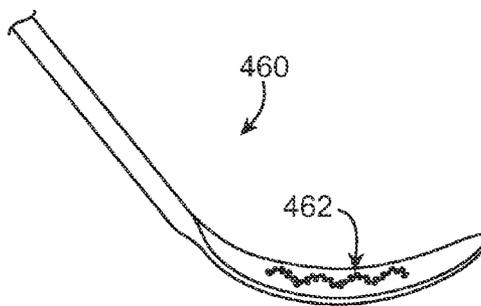


FIG. 8E

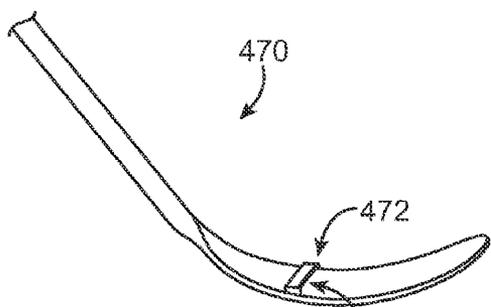


FIG. 8F

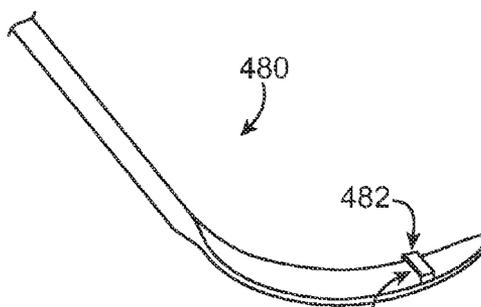


FIG. 8G

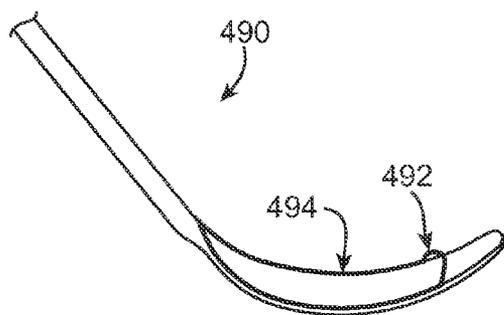


FIG. 8H

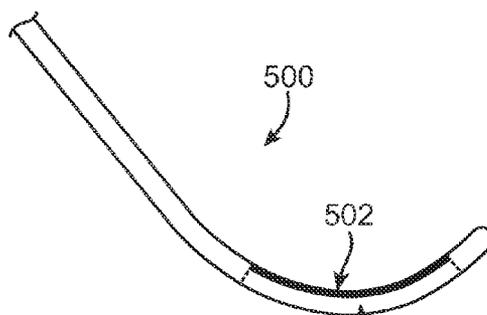


FIG. 8I

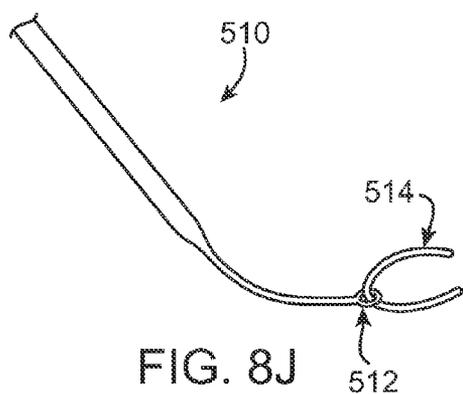


FIG. 8J

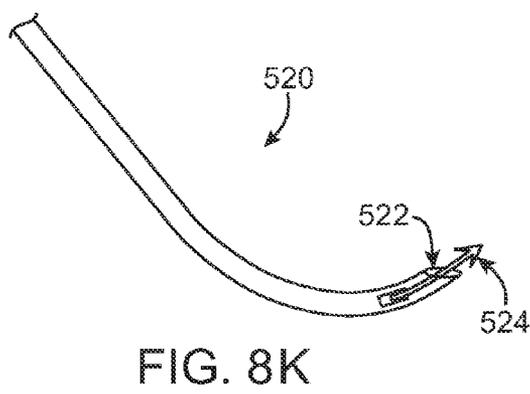


FIG. 8K

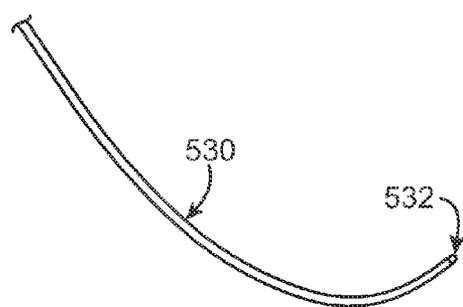


FIG. 8L

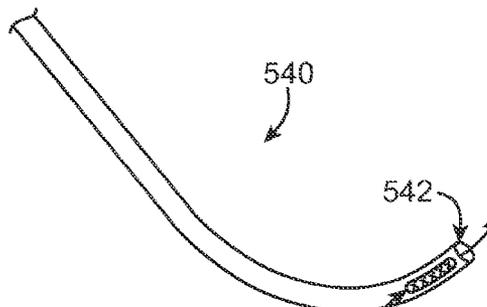


FIG. 8M

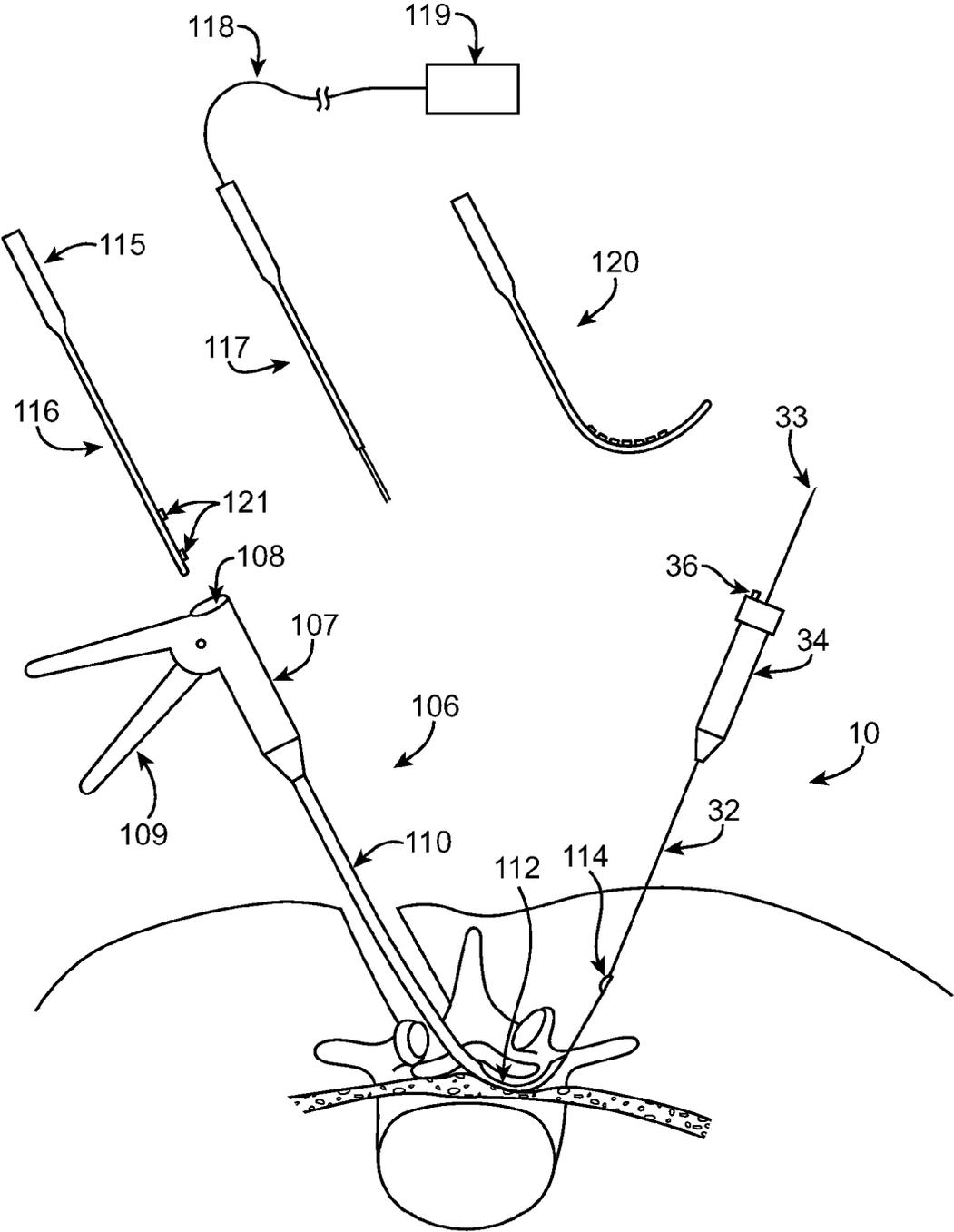


FIG. 9

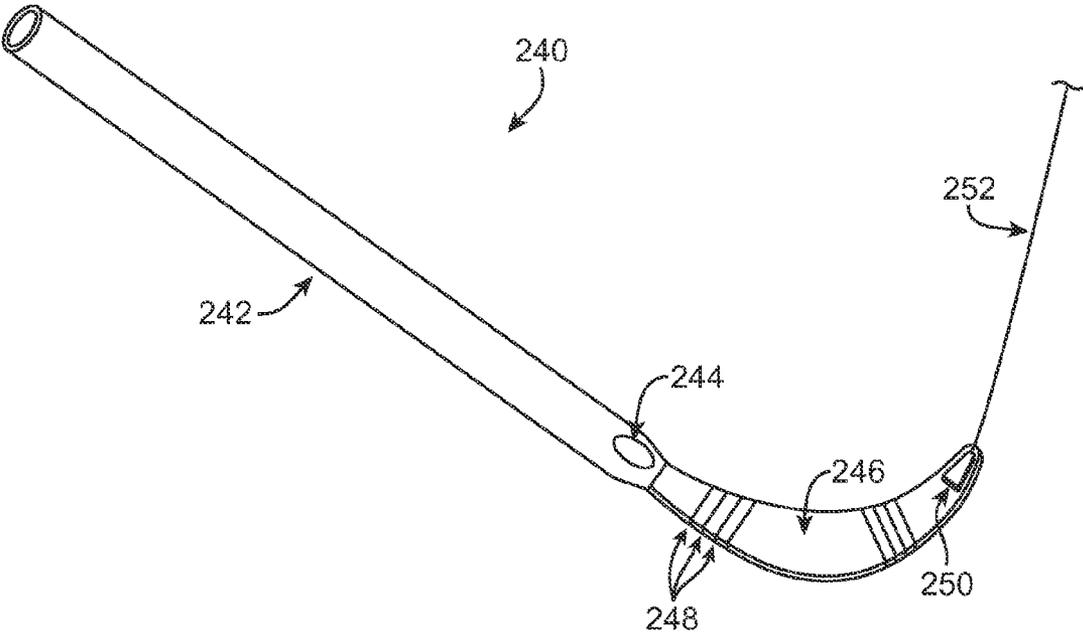


FIG. 10

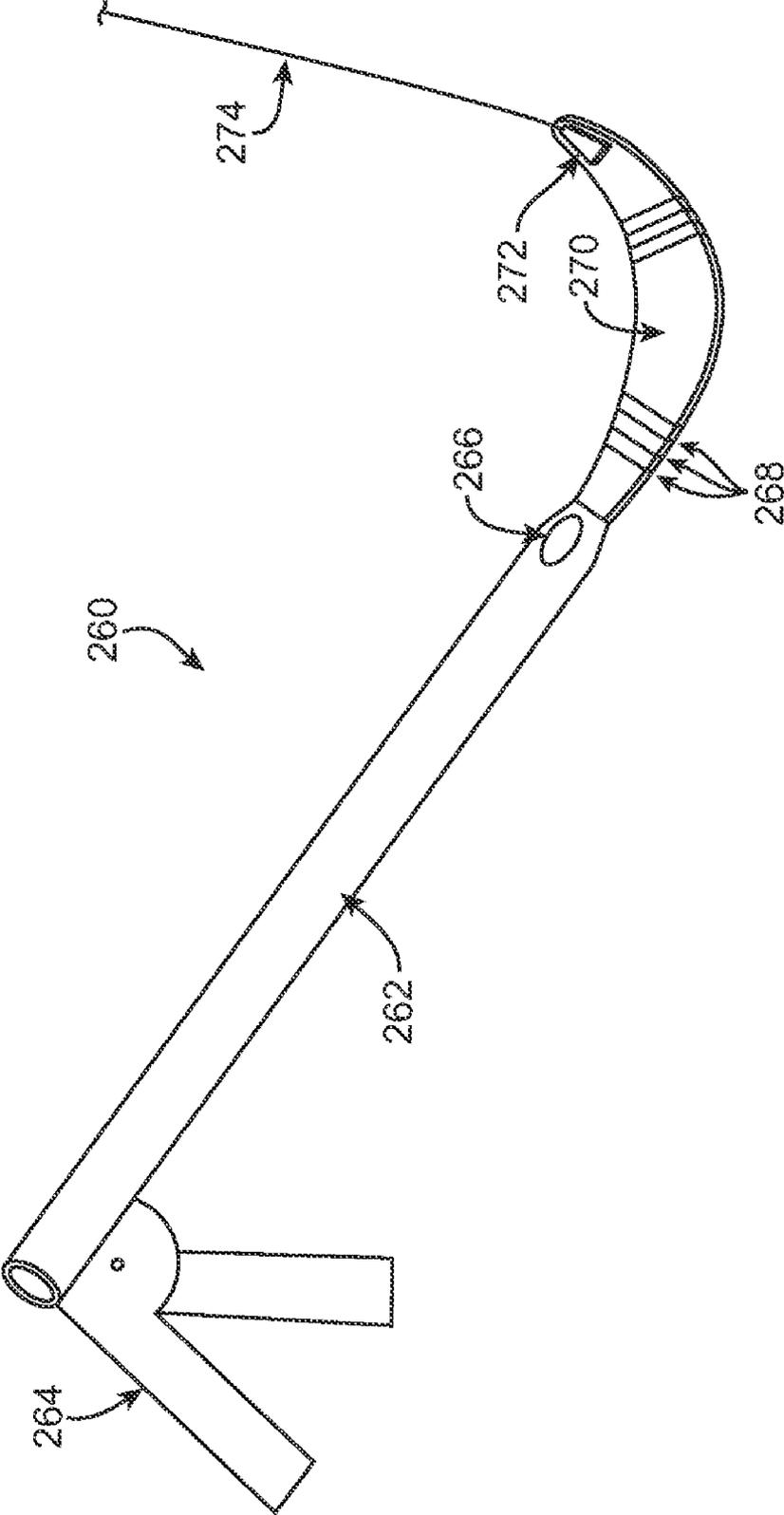


FIG. 11

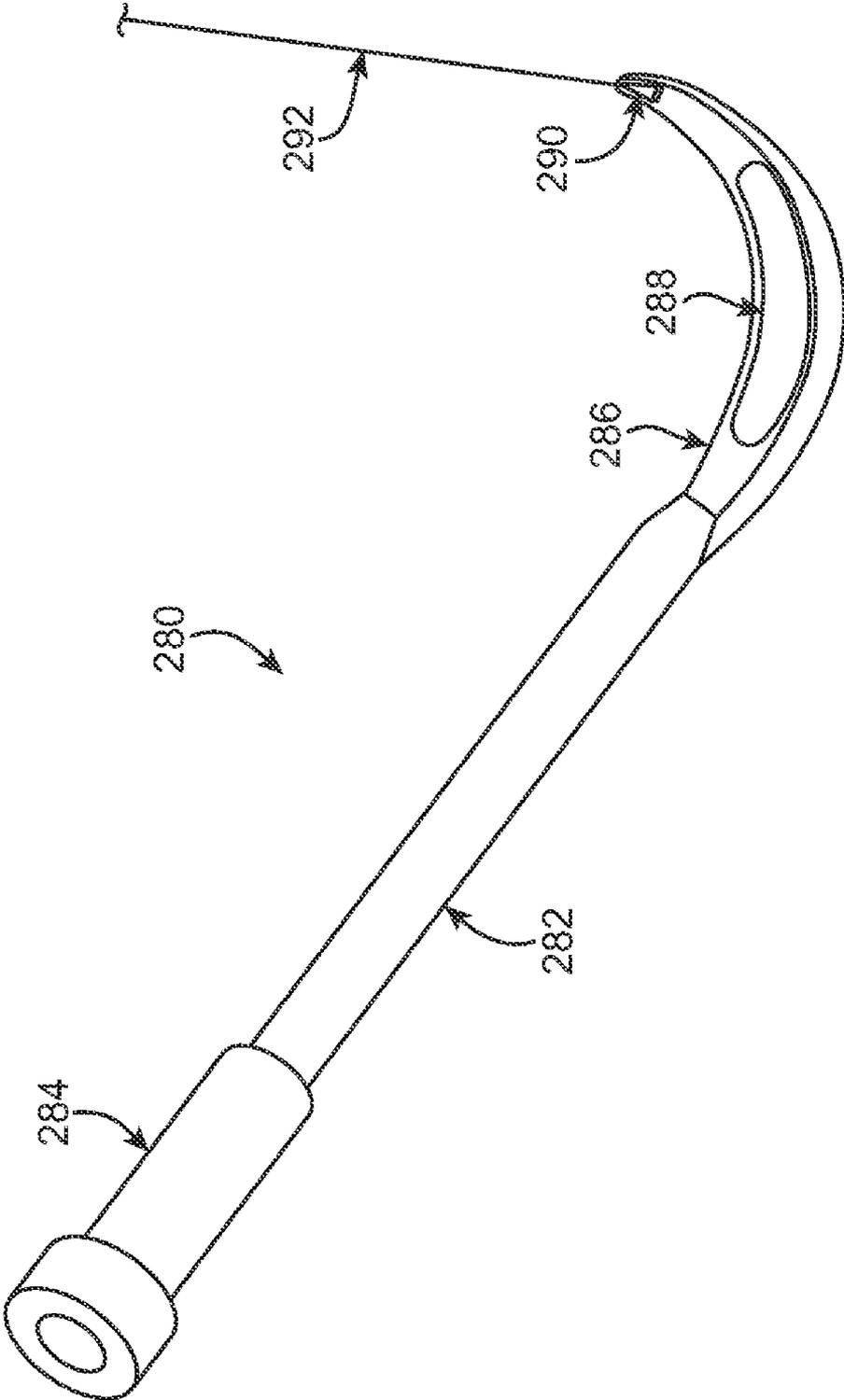
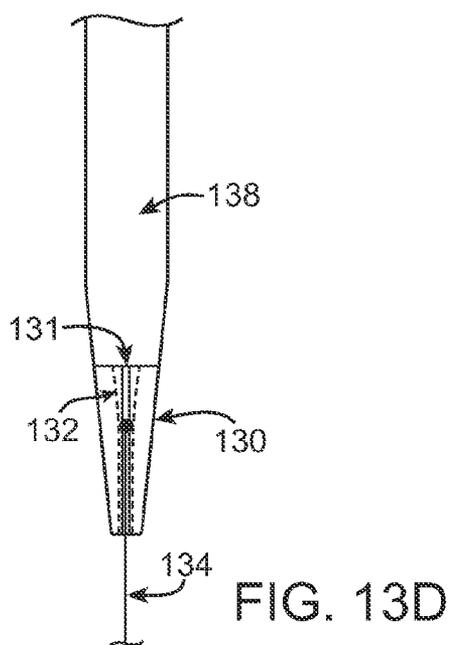
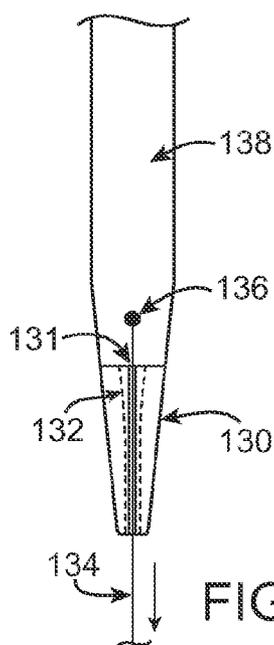
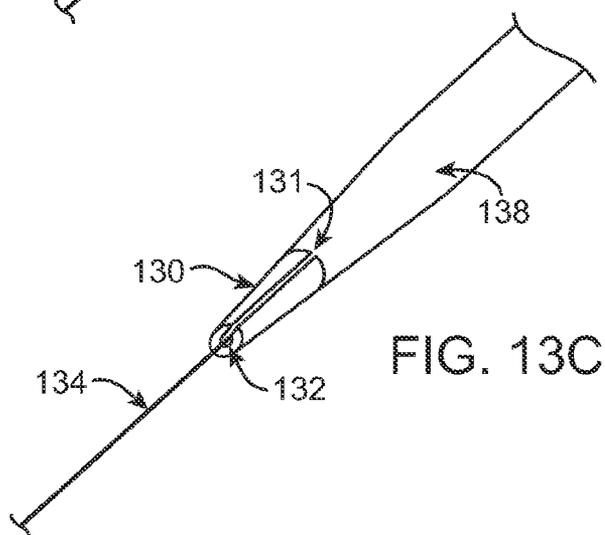
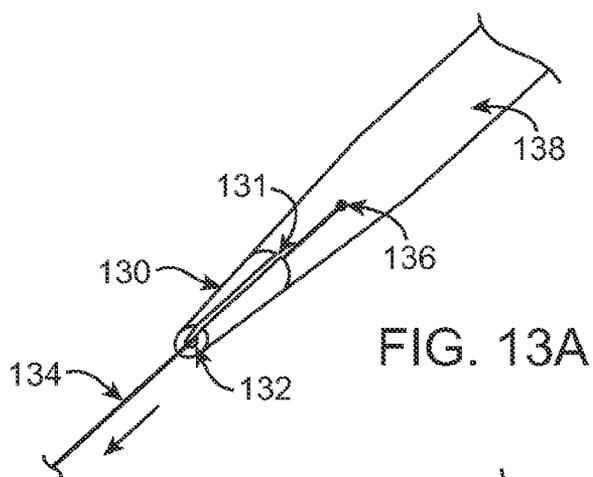


FIG. 12



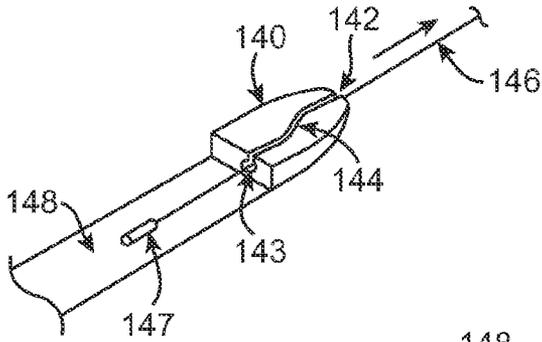


FIG. 14A

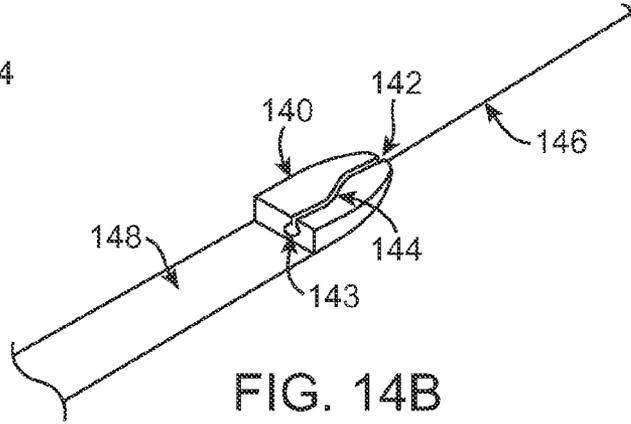


FIG. 14B

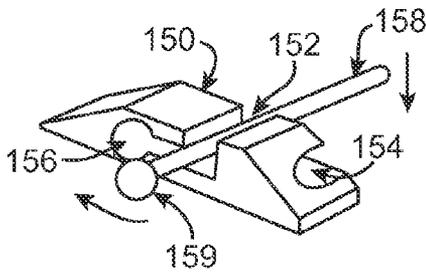


FIG. 15A

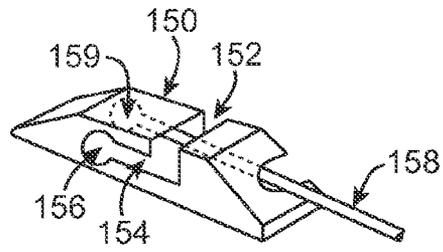


FIG. 15C

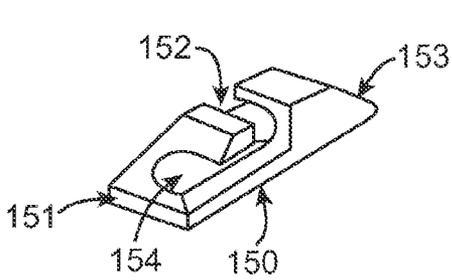


FIG. 15E

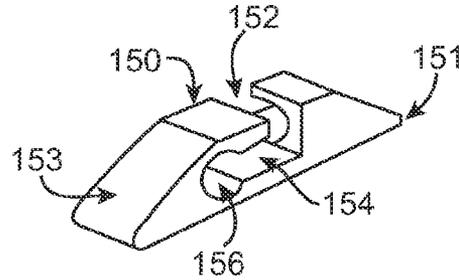


FIG. 15F

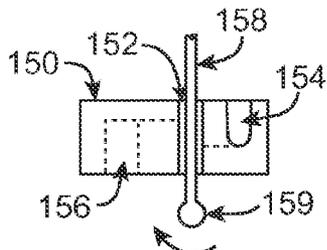


FIG. 15B

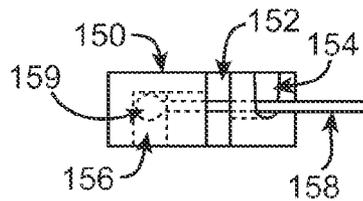


FIG. 15D

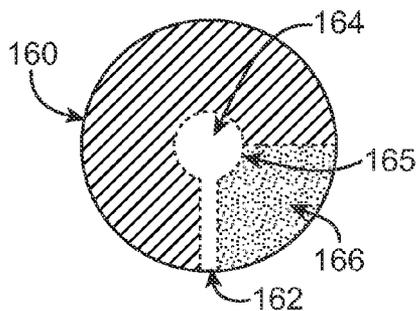


FIG. 16B

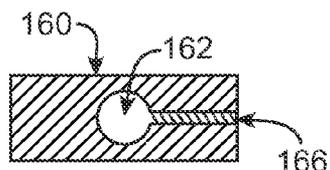


FIG. 16C

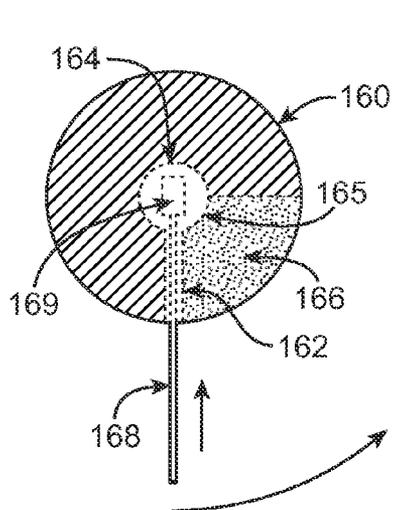


FIG. 16D

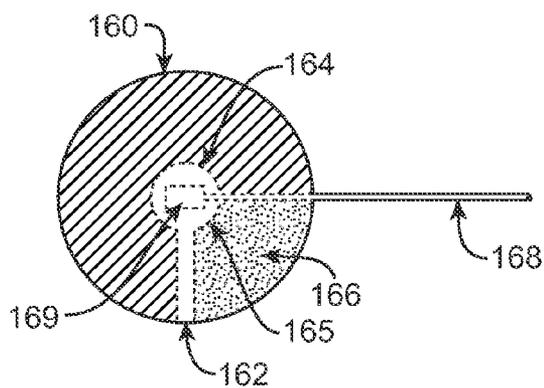


FIG. 16E

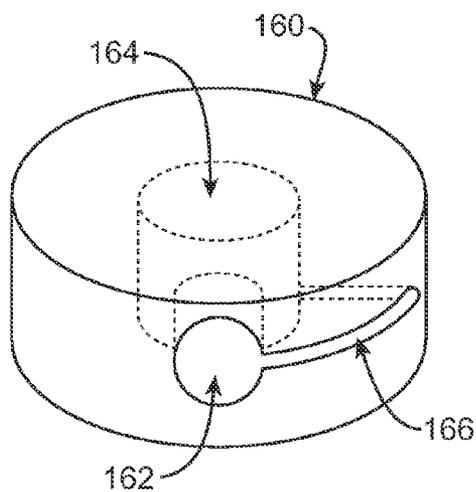


FIG. 16A

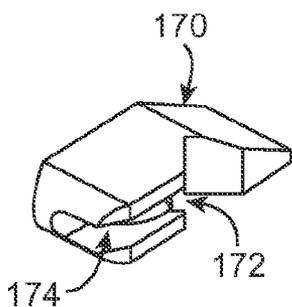


FIG. 17A

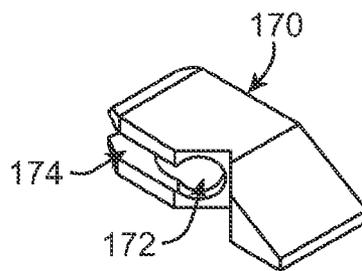


FIG. 17B

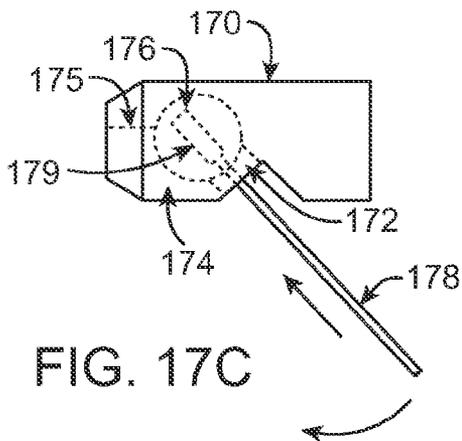


FIG. 17C

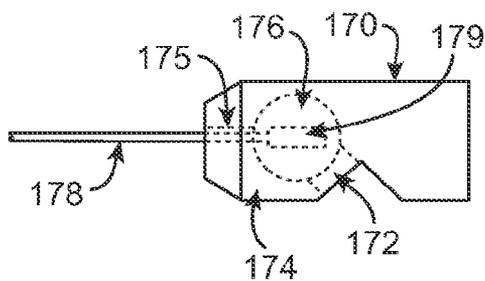


FIG. 17D

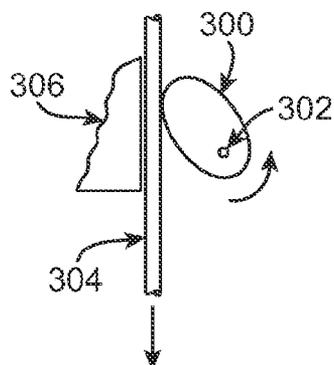


FIG. 18A

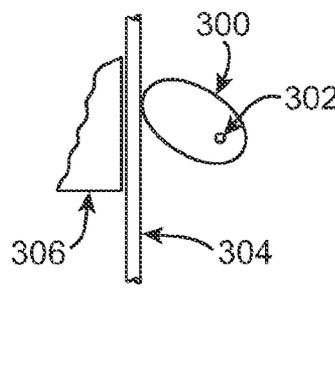


FIG. 18B

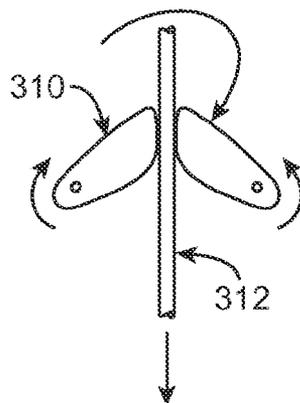


FIG. 19

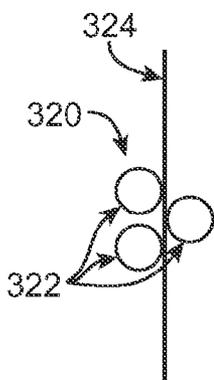


FIG. 20A

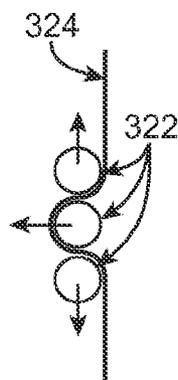


FIG. 20B

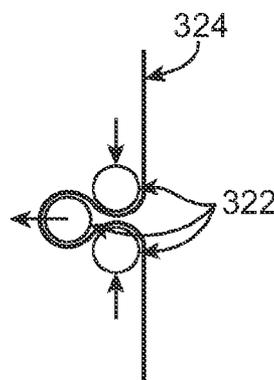


FIG. 20C

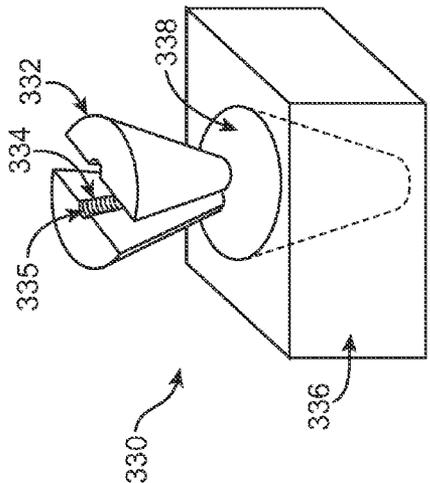


FIG. 21A

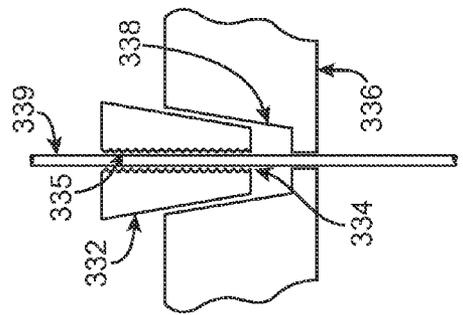


FIG. 21B

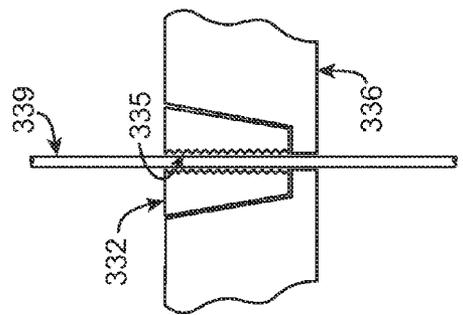


FIG. 21C

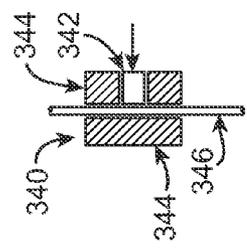


FIG. 22

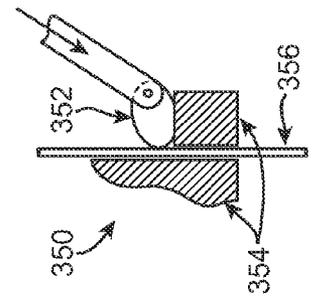


FIG. 23

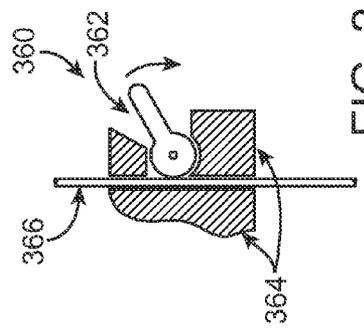
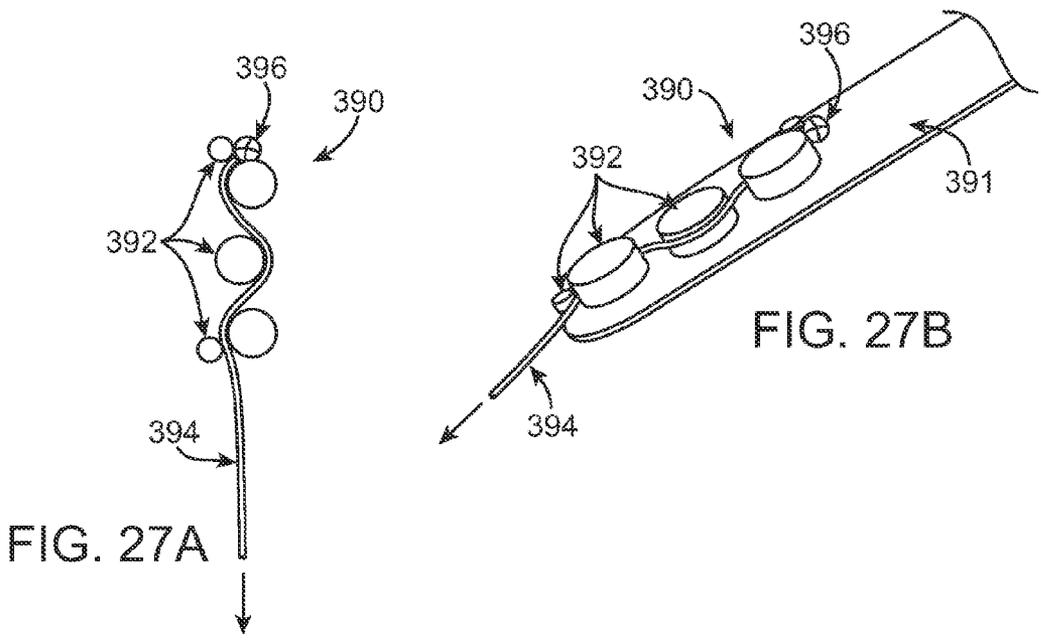
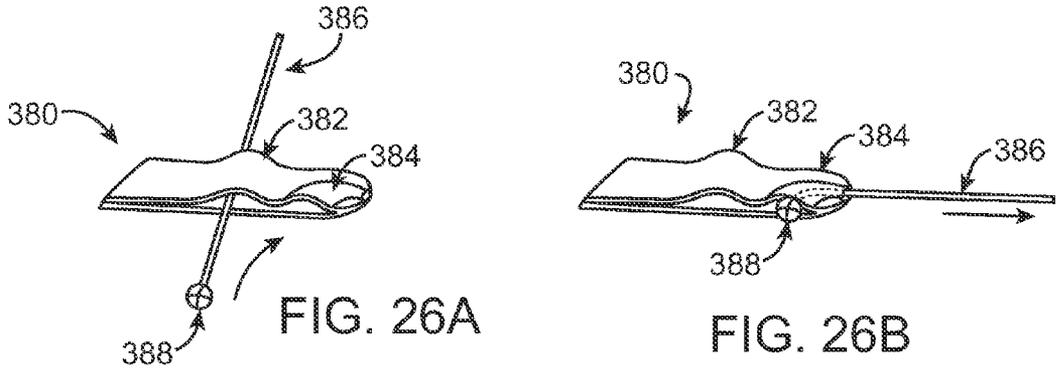
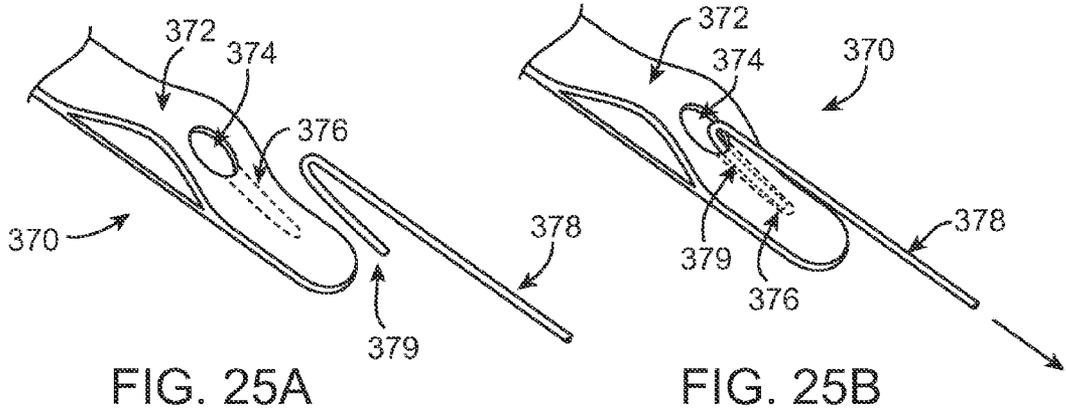


FIG. 24



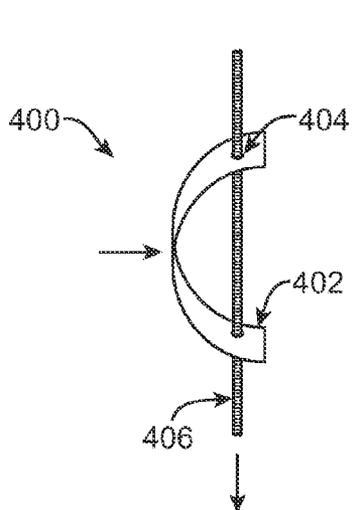


FIG. 28A

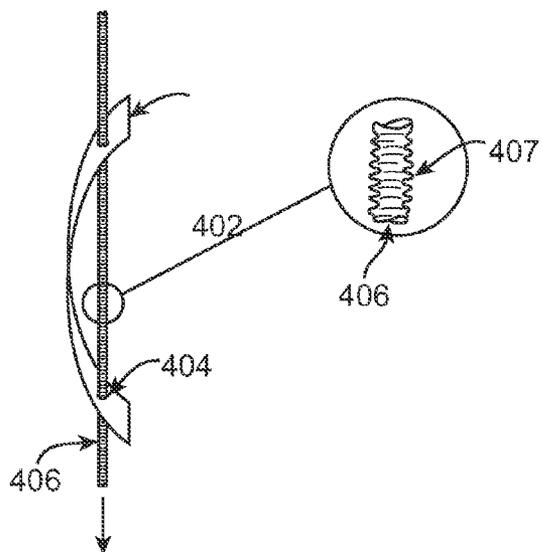


FIG. 28B

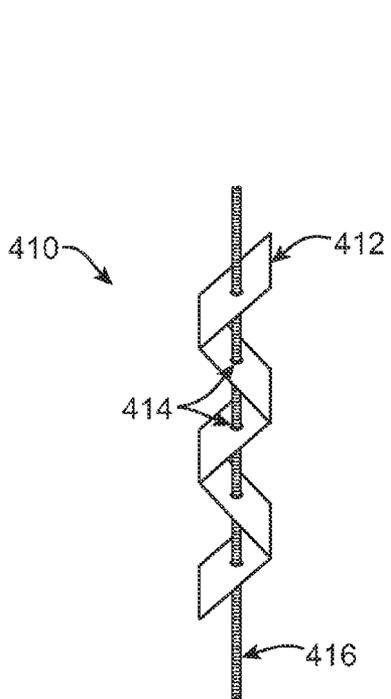


FIG. 29

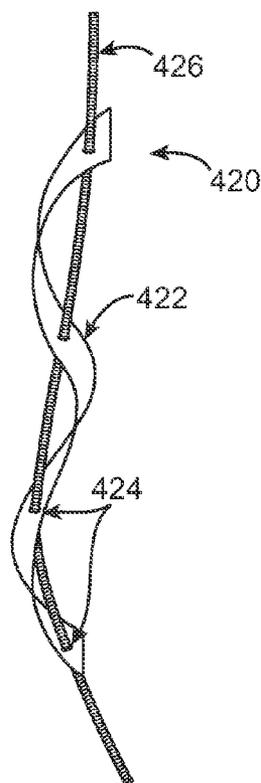


FIG. 30

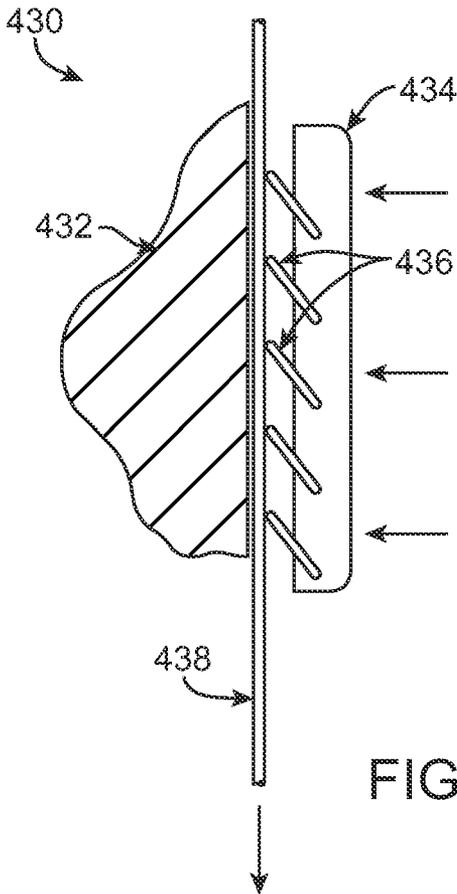


FIG. 31

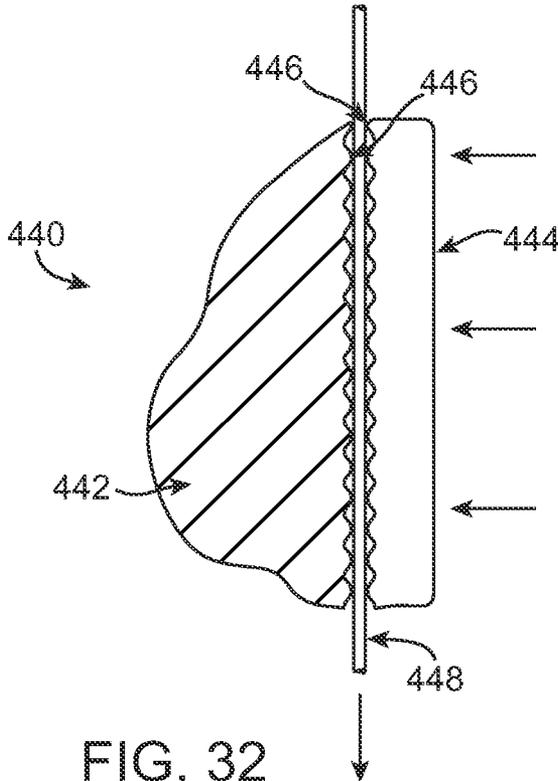
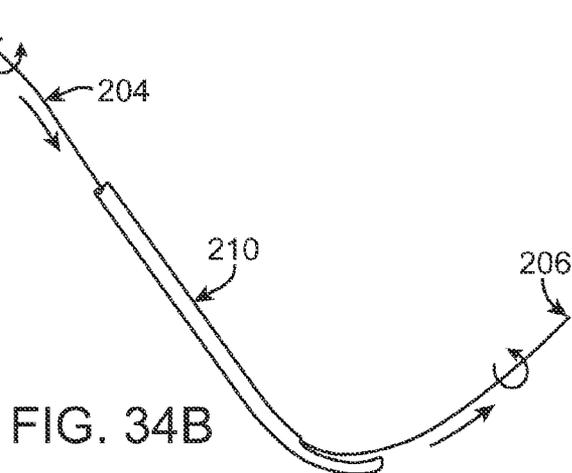
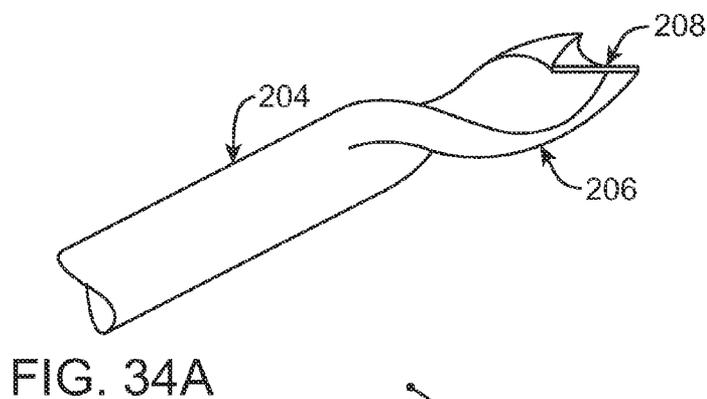
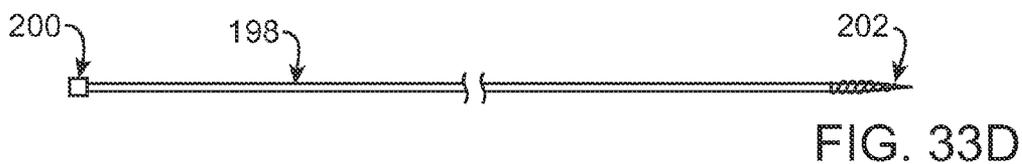
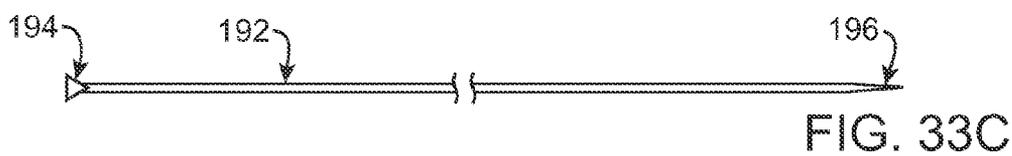
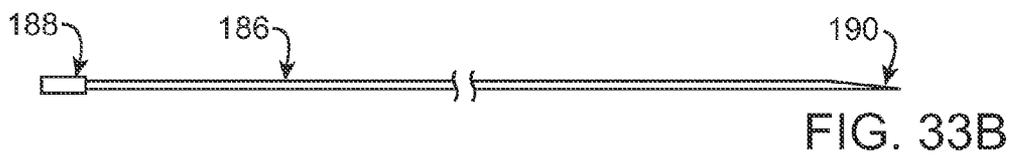
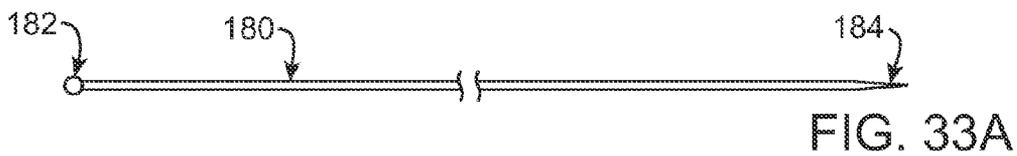


FIG. 32



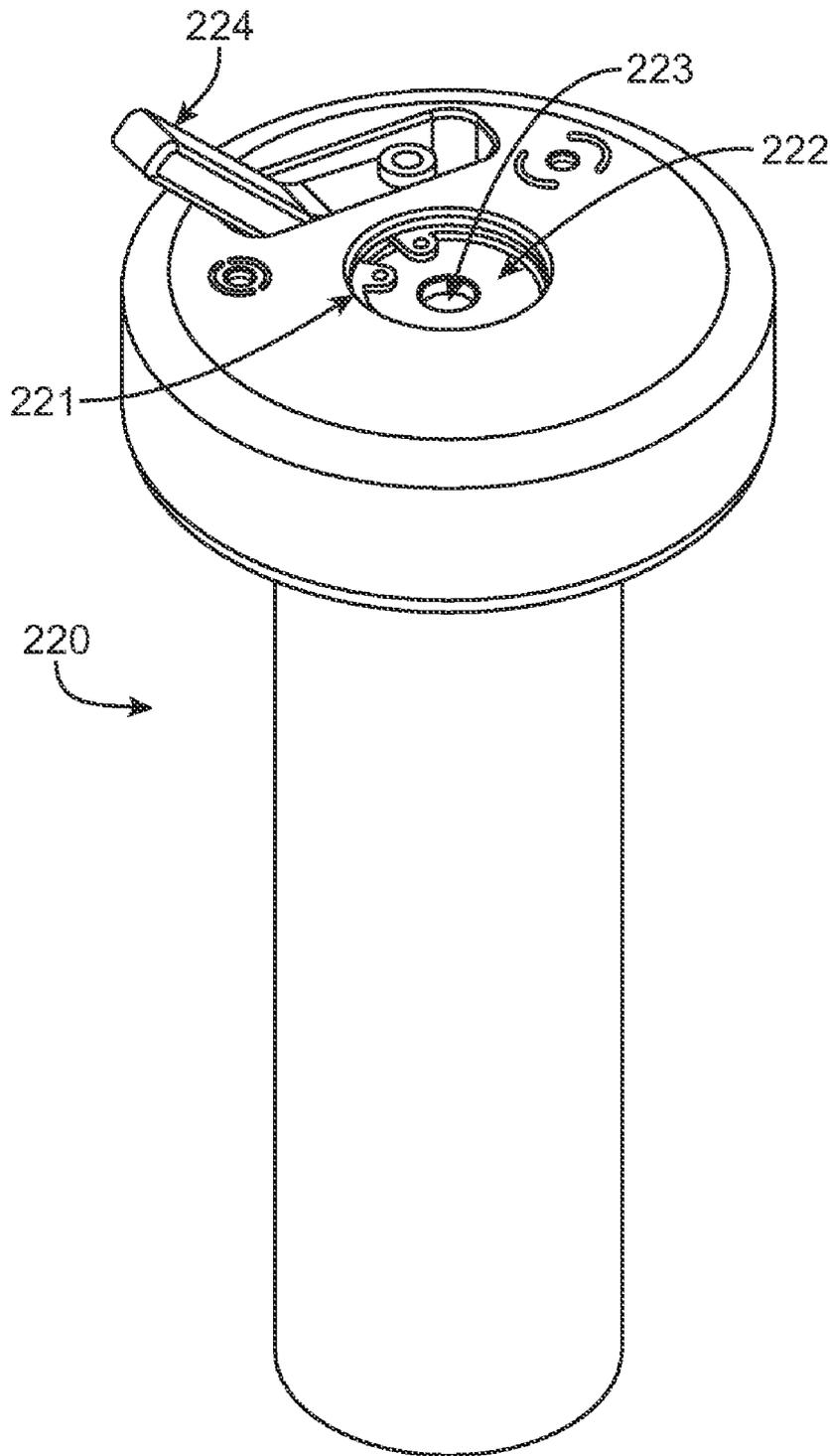


FIG. 35A

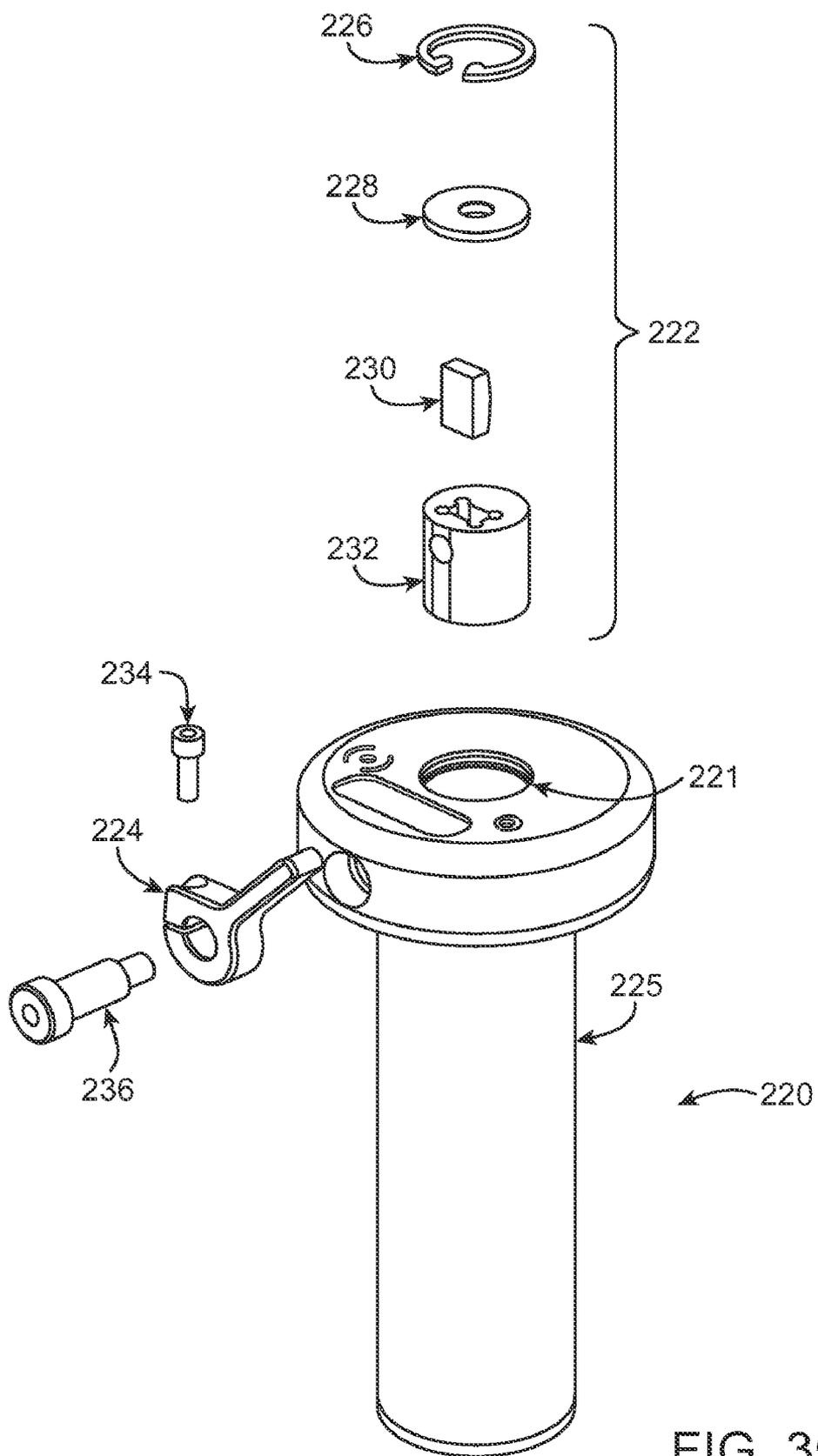


FIG. 35B

TISSUE ACCESS GUIDEWIRE SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is related to U.S. Patent Application Serial No. _____, entitled "Tissue Access Guidewire System and Method" (Attorney Docket No. 026445-001000US), filed concurrently herewith, the disclosure of which is incorporated fully by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates generally to medical/surgical devices and methods. More specifically, the present invention relates to a guidewire system and method for advancing one or more surgical devices between tissues in a patient.

[0003] In recent years, less invasive (or "minimally invasive") surgical techniques have become increasingly more popular, as physicians, patients and medical device innovators have sought to achieve similar or improved outcomes, relative to conventional surgery, while reducing the trauma, recovery time and side effects typically associated with conventional surgery. Developing less invasive surgical methods and devices, however, can pose many challenges. For example, some challenges of less invasive techniques 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. These challenges are compounded by the fact that target tissues to be modified often reside very close to one or more vital, non-target tissues, which the surgeon hopes not to damage. One of the initial obstacles in any given minimally invasive procedure, therefore, is positioning a minimally invasive surgical device in a desired location within the patient to perform the procedure on one or more target tissues, while avoiding damage to nearby non-target tissues.

[0004] 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 neural and/or neurovascular tissue in the spine becomes impinged by one or more structures pressing against them, 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, or more commonly in the lateral recesses of the spinal canal and/or one or more intervertebral foramina.

[0005] 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.

[0006] 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 "zygopophaseal 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 zygapophaseal 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.

[0007] 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.

[0008] 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 adja-

cent 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.

[0009] Therefore, it would be desirable to have less invasive surgical methods and systems for treating spinal stenosis. For example, it would be desirable to have devices or systems for positioning a less invasive device in a patient for performing a less invasive procedure. Ideally, such systems and devices would be less invasive than currently available techniques and thus prevent damage to non-target vertebral bone and neural and neurovascular structures. Also ideally, such systems and devices would also be usable (or adaptable for use) in positioning a surgical device in parts of the body other than the spine, such as in joints for performing various arthroscopic surgical procedures, between a cancerous tumor and adjacent tissues for performing a tumor resection, and the like. At least some of these objectives will be met by the present invention.

SUMMARY OF THE INVENTION

[0010] In one aspect of the present invention, a method for guiding at least a portion of a surgical device to a desired position between two tissues in a patient's body may involve: advancing a distal end of a guidewire into the patient's body, between two tissues, and out of the body, while maintaining a proximal end of the guidewire outside the body; coupling the proximal end of the guidewire with at least one coupling member on or near a distal end of a surgical device; and pulling the distal end of the guidewire to guide at least a portion of the surgical device to a desired position between the two tissues. In some embodiments, the distal end of the guidewire may be advanced through a guidewire introducer device having at least one lumen. Alternatively, the distal end of the guidewire may be advanced through a guidewire lumen of the surgical device. In some embodiments, the distal end of the guidewire may be sharpened, to facilitate its passage through tissue. For example, in various embodiments, the distal end may be passed through tissue of the patient's body by pushing and turning a guidewire having a drill-shaped or corkscrew-shaped tip. In some embodiments, the guidewire is advanced into an epidural space and through an intervertebral foramen of the patient's spine.

[0011] In one embodiment, the guidewire and coupling member may be coupled by fitting a shaped proximal end of the guidewire into the at least one coupling member at or near the distal end of the surgical device. Optionally, cou-

pling may further involve rotating at least one of the guidewire and the surgical device to lock the shaped proximal end into the coupling member(s). In some embodiments the guidewire and surgical device may be removably coupled, while in alternative embodiments, they may be permanently coupled.

[0012] In some embodiments, the method may further include performing a surgical procedure on at least one of the two tissues, using the surgical device, removing the surgical device from the body. Such a method may optionally further involve detaching the guidewire from the surgical device, coupling the proximal end of the guidewire with a coupling member on or near a distal end of a second surgical device, pulling the distal end of the guidewire to guide at least a portion of the second surgical device to a desired position between the two tissues, and performing a surgical procedure on at least one of the two tissues, using the second surgical device. These steps may be repeated, in various embodiments, with as many surgical devices as desired. In some embodiments, the surgical procedure may be performed with the guidewire attached to the surgical device. The method may further include pulling the distal end of the guidewire and a proximal end of the surgical device, to urge an active portion of the surgical device against a target tissue. Typically, the surgical procedure may be performed on one or more target tissues while one or more non-target tissues are protected from harm by at least one atraumatic portion of the surgical device.

[0013] In another aspect of the present invention, a method for performing a procedure on a target tissue in a patient's body may involve: coupling a proximal end of a guidewire with at least one coupling member on or near a distal end of a surgical device; pulling a distal end of the guidewire to guide at least a portion of the surgical device to a desired position between the two tissues, such that an active portion of the surgical device faces target tissue and an atraumatic portion of the surgical device faces non-target tissue; and performing a procedure on the target tissue, using the surgical device. In some embodiments, the surgical device may comprise a tissue modification device, and performing the procedure may comprise modifying the target tissue with the tissue modification device coupled with the guidewire. Alternatively, the surgical device may comprise a tissue access device, and the method may further involve, before the performing step, advancing a tissue modification device through the tissue access device. Some embodiments of the method may further involve pulling on the distal end of the guidewire and a proximal end of the surgical device to urge the active portion of the surgical device against the target tissue.

[0014] In another aspect of the present invention, a system for guiding a surgical device to a desired position between two different tissues in a human body, the two tissues having a natural tissue interface therebetween, may include a guidewire having a first end and a second end with an axis therebetween and a first coupling member and a surgical device having a proximal end and a distal end with a second coupling member disposed at or near the distal end, the first and second coupling members being separable. In one embodiment, one of the coupling members may comprise a receiving coupling member configured for receiving the other coupling member so as to allow the surgical device to be pulled distally along the natural tissue interface by axial tension of the guidewire. In one embodiment, the other

coupling member may comprise a small profile portion extending from a shaped element, the shaped element having a profile larger than the small profile portion, the receiving coupling member comprising a channel for receiving the shaped element and a slot for receiving the small profile portion so that the shaped element is captured by the receiving coupling member when the shaped portion is inserted into the channel and the guidewire pulls the surgical device distally along the natural tissue interface. Optionally, the other coupling member may be disposed on the guidewire, and the small profile portion may comprise a portion of the shaft of the guidewire, wherein the channel is angularly offset from the axis of the guidewire when the guidewire pulls the surgical device distally so that the coupling members are releasably affixed together by inserting the shaped element along the channel and rotating the guidewire about a rotation axis extending laterally from the axis of the guidewire.

[0015] In some embodiments, the distal end of the surgical device may be configured to effect blunt dissection of the natural tissue interface between the first and second tissues. Also in some embodiments, the first coupling member may comprise a shaped element at the first end for coupling with the at least one guidewire coupling member; and the second end may comprise a sharpened distal tip to facilitate passage through of the guidewire through tissue. For example, the shaped element may have a shape such as but not limited to that of a ball, a cylinder, a teardrop, a cube, a pyramid, a diamond or a hook. The sharpened distal tip, in various embodiments, may have a shape such as but not limited to that of pointed, beveled, double-beveled, drill-tip shaped or corkscrew. In some embodiments, the receiving coupling member may comprise at least one movable part configured to move from an open position to a closed position to hold the guidewire. In some embodiments, the surgical device may comprise a tissue access device, and the system may optionally further include at least one additional surgical device configured to pass at least partway through the tissue access device to help perform a procedure on target tissue. Optionally, the system may also include a guidewire handle for coupling with the guidewire outside the body to facilitate pulling the guidewire.

[0016] In another aspect of the present invention, a tissue access device for providing access to target tissue in a patient's body while protecting non-target tissue may include: a shaft having a proximal portion, a distal portion, and at least one lumen passing longitudinally through at least the proximal portion to allow passage of at least one additional device therethrough; at least one side-facing aperture in at least one of the proximal and distal shaft portions, through which the at least one additional device may be exposed to the target tissue; and a guidewire coupling member on the distal portion of the shaft for coupling with a guidewire to allow the tissue access device to be pulled behind the guidewire to position its distal portion between the target and non-target tissues with the aperture facing the target tissue.

[0017] In various embodiments, part of the shaft may be rigid and part of the shaft may be flexible, or the entire shaft may be either rigid or flexible. For example, in some embodiments the proximal portion may be rigid and the distal portion may be at least partially flexible. Optionally, a flexible distal portion may be steerable from a relatively straight configuration to a curved configuration, and the

device may further include at least one steering actuator extending from the proximal portion to the distal portion. In some embodiments, the lumen may pass through both the proximal and distal portions, and the aperture may be located in the distal portion. Alternatively, the lumen may pass through only the proximal portion, and the aperture may be positioned in a distal region of the proximal portion, such that when part of the additional device passes through the aperture, it is located above the distal portion of the shaft.

[0018] Optionally, the device may further include at least one electrode coupled with at least one surface of the distal portion of the shaft and configured to stimulate nerve tissue. In some embodiments, the guidewire coupling member may be configured to removably couple with a shaped member at one end of a guidewire. Optionally, the device may further include a handle coupled with a proximal end of the proximal portion.

[0019] In another aspect of the present invention, a system for providing access to target tissue in a patient's body while protecting non-target tissue may include a tissue access device and a guidewire configured to couple with a guidewire coupling member on the access device. The access device may include: a shaft having a proximal portion, a distal portion, and at least one lumen passing longitudinally through at least the proximal portion to allow passage of at least one additional device therethrough; at least one side-facing aperture in at least one of the proximal and distal shaft portions, through which the at least one additional device may be exposed to the target tissue; and a guidewire coupling member on the distal portion of the shaft for coupling with a guidewire to allow the tissue access device to be pulled behind the guidewire to position its distal portion between the target and non-target tissues with the aperture facing the target tissue.

[0020] In some embodiments, the guidewire may have a sharp distal tip and a shaped member on a proximal tip for coupling with the guidewire coupling member. Optionally, the system may further include at least one additional device configured to pass through the tissue access device to expose at least an active portion of the additional device through the side-facing aperture. Examples of such an additional device include, but are not limited to, tissue cutting devices, tissue ablation devices, tissue abrasion devices, other tissue removal devices, other tissue modification devices, tissue storage devices, tissue transport devices, drug delivery devices, implant delivery devices, material delivery devices, visualization devices and diagnostic devices.

[0021] Some embodiments of the system may further include one or more anchoring devices for coupling the shaft of the tissue access device with a structure inside and/or outside the patient to stabilize the tissue access device. In some embodiments, the tissue access device may further include a handle coupled with a proximal end of the proximal shaft portion. The system may also optionally include a guidewire handle for coupling with the guidewire outside the patient to facilitate pulling on the guidewire to apply tensioning force.

[0022] In another aspect of the present invention, a method for providing access to target tissue in a patient's body while protecting non-target tissue may involve: passing a guidewire between the target and non-target tissues; coupling the guidewire with a guidewire coupling member on a distal portion of a tissue access device; and pulling the guidewire through the patient's body to pull the distal

portion of the tissue access device between the target and non-target tissues such that a side-facing aperture of the tissue access device faces the target tissue. When the distal portion of the access device is positioned between the target and non-target tissues, a proximal portion of the device may extend outside the patient, such that at least one tissue modification device may be passed through at least the proximal portion to expose one or more tissue modifying members through the side-facing aperture.

[0023] Optionally, the method may further include identifying at least the non-target tissue before passing the guidewire. Also optionally, the method may further involve: advancing a first tissue modification device through the tissue access device to expose at least one tissue modification member of the device through the side-facing aperture of the access device; pulling the guidewire and at least one of the tissue access device and the tissue modification device to urge the at least one tissue modification member against the target tissue; and activating the tissue modification member(s) to modify the target tissue while protecting the non-target tissue with the distal portion of the access device. In some embodiments, the method may further involve: removing the first tissue modification device from the patient's body, through the access device; advancing a second tissue modification device through the tissue access device to expose at least one tissue modification member of the device through the side-facing aperture of the second access device; pulling the guidewire and at least one of the tissue access device and the second tissue modification device to urge the at least one tissue modification member against the target tissue; and activating the tissue modification member(s) to modify the target tissue. In some embodiments, activating the tissue modification member(s) may involve actuating at least one actuation member on a handle of the tissue access device. In some embodiments, the method may further involve coupling the tissue access device with a structure inside and/or outside the patient, using at least one anchoring device, to stabilize the access device. The method may further involve activating at least one electrode on the distal portion of the tissue access device to confirm placement of the distal portion between the target and non-target tissues.

[0024] 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

[0025] 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;

[0026] FIG. 2 is a left lateral view of the lumbar portion of a spine with sacrum and coccyx;

[0027] 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;

[0028] FIG. 4 is a cross-sectional view of a patient's back and spine with a side view of a guidewire and tissue modification system in place for performing a tissue removal procedure, according to one embodiment of the present invention;

[0029] FIG. 6, is a cross-sectional view of a patient's back and spine and a side view of a rasp device and guidewire system, according to one embodiment of the present invention;

[0030] FIG. 7, is a cross-sectional view of a patient's back and spine and a side view of an ultrasound device and guidewire system, according to one embodiment of the present invention;

[0031] FIG. 8A, is a cross-sectional view of a patient's back and spine and a side view of a tissue access device with swappable tissue modification devices and a guidewire system, according to one embodiment of the present invention;

[0032] FIGS. 8B-8M are side/perspective views of distal portions of a number of different devices which may be placed through/used with a tissue access device such as that shown in FIG. 8A, according to various embodiments of the present invention;

[0033] FIG. 9, is a cross-sectional view of a patient's back and spine and a side view of a tissue access device with swappable tissue modification devices and a guidewire system, according to an alternative embodiment of the present invention;

[0034] FIG. 10 is a perspective view of a tissue access device coupled with a guidewire, according to one embodiment of the present invention;

[0035] FIG. 11 is a perspective view of a tissue access device coupled with a guidewire, according to an alternative embodiment of the present invention;

[0036] FIG. 12 is a perspective view of a tissue access device coupled with a guidewire, according to an alternative embodiment of the present invention;

[0037] FIGS. 13A and 13C are perspective views, and FIGS. 13B and 13D are top views, of a distal end of a tissue modification device with guidewire coupling member and a shaped guidewire, according to one embodiment of the invention;

[0038] FIGS. 14A and 14B are perspective views of a distal end of a tissue modification device with guidewire coupling member and a shaped guidewire, according to an alternative embodiment of the invention;

[0039] FIGS. 15A and 15C are perspective views of a guidewire coupling member and a shaped guidewire, demonstrating a method for coupling the two, according to one embodiment of the present invention;

[0040] FIGS. 15B and 15D are top views of the guidewire coupling member and shaped guidewire of FIGS. 15A and 15C;

[0041] FIGS. 15E and 15F are different perspective views of the guidewire coupling member of FIGS. 15A and 15C, without the shaped guidewire;

[0042] FIGS. 16A-16C are perspective, top and side views, respectively, of a guidewire coupling member, according to an alternative embodiment of the present invention;

[0043] FIGS. 16D and 16C are top views of the guidewire coupling member of FIGS. 16A-16C and a shaped guidewire, demonstrating a method for coupling the coupling member with a shaped guidewire, according to one embodiment of the present invention;

[0044] FIGS. 17A and 17B are perspective views of a guidewire coupling member, according to an alternative embodiment of the present invention;

[0045] FIGS. 17C and 17D are top views of the guidewire coupling member of FIGS. 17A and 17B and a shaped guidewire, demonstrating a method for coupling the coupling member with the guidewire, according to one embodiment of the present invention;

[0046] FIGS. 18A and 18B are top views of a single-cam guidewire coupling member, according to an alternative embodiment of the present invention;

[0047] FIG. 19 is a top view of a double-cam guidewire coupling member, according to an alternative embodiment of the present invention;

[0048] FIGS. 20A-20C are top views of a movable-piece guidewire coupling member, according to an alternative embodiment of the present invention;

[0049] FIG. 21A is a perspective view, and FIGS. 21B and 21C are side cross-sectional views, of a split-cone guidewire coupling member, according to an alternative embodiment of the present invention;

[0050] FIG. 22 is a top view of a flat anvil guidewire coupling member, according to an alternative embodiment of the present invention;

[0051] FIG. 23 is a top view of a corner pinch guidewire coupling member, according to an alternative embodiment of the present invention;

[0052] FIG. 24 is a top view of an eccentric cam guidewire coupling member, according to an alternative embodiment of the present invention;

[0053] FIGS. 25A and 25B are perspective views of a hooked guidewire and receiving guidewire coupling member, according to an alternative embodiment of the present invention;

[0054] FIGS. 26A and 26B are perspective views of a ball-and-socket guidewire and guidewire coupling member, according to an alternative embodiment of the present invention;

[0055] FIGS. 27A and 27B are top and perspective views, respectively, of a spool trap guidewire coupling member, according to an alternative embodiment of the present invention;

[0056] FIGS. 28A and 28B are side views of a semicircular ribbon guidewire coupling member with textured guidewire, according to an alternative embodiment of the present invention;

[0057] FIG. 29 is a side view of a folded ribbon guidewire coupling member with textured guidewire, according to an alternative embodiment of the present invention;

[0058] FIG. 30 is a side view of a ribbon guidewire coupling member, according to an alternative embodiment of the present invention;

[0059] FIG. 31 is a side view of a multi-point guidewire coupling member, according to one embodiment of the present invention;

[0060] FIG. 32 is a side view of a rough-surface guidewire coupling member, according to one embodiment of the present invention;

[0061] FIGS. 33A-33D are side views of proximal and distal ends of various guidewires, according to various embodiments of the present invention;

[0062] FIG. 34A is a perspective view of a drill-shaped distal end of a guidewire, according to one embodiment of the present invention;

[0063] FIG. 34B is a side view of a guidewire as in FIG. 34A, being passed through a probe device; and

[0064] FIG. 35A and 35B are perspective and exploded views of a handle for grasping a guidewire, according to one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0065] Various embodiments of a guidewire system and method for positioning one or more surgical devices in a patient are provided. Although the following description and accompanying drawing figures generally focus on positioning various surgical devices in a spine, in alternative embodiments, guidewire systems and methods of the present invention may be used to position any of a number of devices in other anatomical locations in a patient's body.

[0066] Referring to FIG. 4, one embodiment of a guidewire system 10 is shown coupled with a tissue cutting device 11 in position within a patient's spine. Further description of various embodiments of cutting device 11 may be found in U.S. patent application Ser. No. 11/461,740, entitled "Multi-Wire Tissue Cutter" (Attorney-Docket No. 026445-000900US), and filed Aug. 1, 2006, the full disclosure of which is hereby incorporated by reference. A number of alternative embodiments of cutting devices, many of which may be used (or adapted for use) with guidewire system 10, are further described in U.S. patent application Ser. No. 11/375,265, entitled "Methods and Apparatus for Tissue Modification" (Original Attorney-Docket No. 78117-200101), and filed Mar. 13, 2006; Ser. No. 11/405,848, entitled "Mechanical Tissue Modification Devices and Methods" (Original Attorney-Docket No. 78117-200301), and filed Apr. 17, 2006; Ser. No. 11/406,486, entitled "Powered Tissue Modification Devices and Methods" (Original Attorney-Docket No. 78117-200501 US), and filed Apr. 17, 2006; and Ser. No. 11/429,377, entitled "Flexible Tissue Rasp" (Original Attorney-Docket No. 78117-200201), and filed May 4, 2006. The full disclosures of all of the foregoing references are hereby incorporated by reference.

[0067] As described in further detail in U.S. patent application Ser. No. 11/461,740, tissue cutting device 11 may include a shaft 12, a proximal handle 16, a flexible distal portion 13, two or more cutting blades 26 and a guidewire coupling member 30. Guidewire system 10 may include a guidewire 32 having a sharpened tip 33 (often referred to herein as the "sharpened distal tip") for facilitating advancement of guidewire 32 through tissue. Optionally, guidewire 32 may also include a shaped member (not visible in FIG. 4) at the end opposite sharpened tip 33 (often referred to herein as the guidewire "proximal end") for coupling with coupling member 30. Guidewire system 10 may also include a guidewire handle 34 (or "distal handle") for coupling with guidewire 32, which in some cases may include a tightening member 36 for securing a portion of guidewire 32 within guidewire handle 34.

[0068] In some embodiments, cutting device 11 may be advanced into a patient's back through an incision 20, which is shown in FIG. 4 as an open incision but which may be a minimally invasive or less invasive incision in alternative embodiments. In some embodiments, device 11 may be advanced by coupling guidewire connector 30 with guidewire 32 that has been advanced between target and non-target tissues, and then pulling guidewire 32 to pull device 11 between the tissues. Various embodiments of such a method for delivering a device are described in further detail below. Generally, guidewire system 10 may be used to

pull flexible distal portion **13** into place between tissues in hard-to-reach or tortuous areas of the body, such as between a nerve root (NR) and facet joint and through an intervertebral foramen (IF). Generally, flexible portion **13** may be advanced to a position such that blades **26** face tissue to be cut in a tissue removal procedure (“target tissue”) and a non-cutting surface (or surfaces) of flexible portion **13** faces non-target tissue, such as nerve and/or neurovascular tissue. In the embodiment shown in FIG. **4**, blades **26** 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. **4** include the vertebra (V) and cauda equina (CE)). In various alternative embodiments, flexible portion **13** may be replaced with a curved, rigid portion, a steerable portion, a straight portion with a distal extension or the like. The configuration, dimensions, flexibility, steerability, materials and the like of flexible portion **13** may be adjusted, in alternative embodiments, depending on a type of tissue or anatomical structure to be accessed or modified.

[0069] Before or after blades **26** are located in a desired position, guidewire **32** may be removably coupled with guidewire handle **34**, such as by passing guidewire **32** through a central bore in handle **34** and moving tightening member **36** to secure a portion of guidewire **32** within handle **34**. A physician (or two physicians or one physician and an assistant) may then pull on proximal handle **16** and distal handle **34** to apply tensioning force to guidewire **32** and cutting device **11** and to urge the cutting portion of device **11** against ligamentum flavum (LF), superior articular process (SAP), or other tissue to be cut. Proximal handle **16** may then be actuated, such as by squeezing in the embodiment shown, to cause one or both blades **26** to move toward one another to cut tissue. Proximal handle **16** 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, guidewire **32** may be released from distal handle **34**, and cutter device **11** and guidewire **32** may be removed from the patient’s back.

[0070] With reference now to FIGS. **5A-51**, one embodiment of a method for advancing a tissue modifying device into a patient’s body using a guidewire delivery system is shown. Although this method is shown in reference to placement of a device in a spine, in various alternative embodiments, such a method may be used to place similar or alternative tissue modification devices in other locations in a human body, such as between tissues in a joint space, in the abdominal cavity, or in the carpal tunnel of the wrist, between bone and soft tissue in other parts of the body, and the like.

[0071] Referring to FIG. **5A**, in one embodiment of a method for advancing a tissue modifying device, a probe **40** may be inserted into a patient’s back using an open technique facilitated by retractors **42**. Target tissues of a procedure, in this embodiment, may include ligamentum flavum (LF) and/or facet joint (F) tissue of a vertebra (V), which may impinge on non-target tissues, such as nerve root (NR) and/or cauda equina (CE), of the lumbar spine. Also depicted in FIG. **5A** is an intervertebral disc (D). In FIG. **5B**, a curved distal portion of probe **40** has been advanced to a position between target ligamentum flavum (LF) and non-target nerve root (NR) tissues. As depicted in FIG. **5C**, in some embodiments, a curved guide member **46** may next be advanced out of an aperture on the curved distal portion of

probe **40**. In one embodiment, for example, guide member **46** may be housed within probe and advanced out of the distal aperture by advancing a slide member **44** on the shaft of probe **40**. Next, as shown in FIG. **5D**, guidewire **32** may be advanced through guide member **46** and out of the patient’s back, using sharpened tip **33** to facilitate passage through the patient’s back tissue. Probe **40** may then be removed, as shown in FIG. **5E**, leaving guidewire **32** in place between the target and non-target tissues, as shown in FIG. **5F**. Also shown in FIG. **5F** is a shaped member **50** (in this embodiment, a ball) on the proximal end of guidewire **32**.

[0072] Further description of methods, devices and systems for advancing a guidewire between tissues using a probe are provided in U.S. patent application Ser. No. 11/429,377, entitled “Spinal Access and Neural Localization” (Attorney-Docket No. 026445-000724US) and filed on Jul. 13, 2006, the full disclosure of which is hereby incorporated by reference. As described in that reference, in some embodiments, the curved distal portion of probe **40**, curved guide member **46**, or both may include one, two or more electrodes to help locate nerve tissue before placing guidewire **32**. Such neural localization helps ensure that guidewire **32** is positioned between target and non-target tissue, which in turn helps ensure that a tissue modification device (or devices) placed using guidewire **32** are oriented so that a tissue modifying portion (or portions) of the device face and act on target tissue and not on non-target tissue such as neural tissue.

[0073] Referring now to FIG. **5G**, once guidewire **32** is positioned between tissues, its proximal end with shaped member **50** may be coupled with a coupling member **62** on a distal end of a tissue modification device **52**. Tissue modification device **52**, in one embodiment, may include a proximal handle **54**, a rigid proximal shaft portion **56**, a flexible distal shaft portion **58**, tissue cutting blades **60**, and coupling member **62**. Coupling member **62**, various embodiments of which are described in greater detail below, may be either attached to or formed in distal shaft portion **58**. In some embodiments, such as the one depicted in FIG. **5G**, to attach guidewire **32** to coupling member **62**, guidewire **32** may be laid into a channel on coupling member **62**, and guidewire **32** and/or distal portion **58** may be rotated, relative to one another, to lock shaped member **50** into coupling member. Various alternative embodiments for coupling guidewires **32** with coupling members **62** are described in greater detail below. Before, after or during coupling of guidewire **32** and tissue modification device **52**, guidewire **32** may also be coupled with distal guidewire handle **34**, such as by advancing distal handle **34** over guidewire **32** (solid-tipped arrow).

[0074] As depicted in FIG. **5H**, tightening member **36** may next be moved (curved, solid-tipped arrow) to tighten distal handle **34** around guidewire **32**. Distal handle **34** may then be pulled (straight, solid-tipped arrow) to pull guidewire **32** and thus advance distal shaft portion **58** of tissue modification device **52** into place between target and non-target tissues in the spine, as shown in FIG. **5I**. Once device **52** is positioned as desired, as depicted in FIG. **5I**, proximal handle **54** and distal handle **34** may be pulled (straight, solid-tipped arrows), to apply tensioning force to guidewire **32** and device **52** and thus urge flexible portion **58** and blades **60** against target tissue, such as ligamentum flavum (LF) and/or facet joint (F) tissue. Handle **54** may then be

actuated (curved, double-tipped arrow) to cause blades 60 to cut target tissue. When a desired amount of tissue is cut, guidewire 32 may be released from distal handle 34, and tissue modification device 52 and guidewire 32 may be removed from the patient's back. This method for advancing tissue modification device 52 using guidewire 32 is but one exemplary embodiment.

[0075] Various aspects of the method embodiment just described, such as the number or order of steps, may be changed without departing from the scope of the invention. Furthermore, a number of alternative embodiments of various devices and device elements are described below, which may be used in various embodiments of such a method. For example, in one alternative embodiment (not shown), probe 40 and tissue modification device 52 may be combined into one device. Such a device may include a guidewire lumen through which guidewire 32 may be passed. The combined device may be partially inserted into a patient, and guidewire 32 advanced between target and non-target tissues through the guidewire lumen. Shaped member 50 of guidewire 32 may then catch on one or more coupling members 62 of the combined device, to allow the device to be pulled into position between the target and non-target tissues. Guidewire 32 may then further be used to help apply tensioning force to the device to urge an active portion against target tissues. In another alternative embodiment, access to the intervertebral foramen may be achieved using a lateral approach, rather than a medial approach. These are but two examples of many alternative embodiments, and a number of other alternatives are contemplated.

[0076] With reference now to FIG. 6, guidewire system 10 is shown with an alternative embodiment of a tissue modification device 64, which may include a proximal handle 66, a rigid proximal shaft portion 68, and a distal flexible shaft portion 70. Multiple abrasive members 72 and a guidewire coupling member 74 may be coupled with one side of flexible shaft portion 70. In this embodiment, guidewire 32 may be coupled with coupling member 74 and used to pull distal shaft portion 70 of modification device 64 into place between target and non-target tissues. Proximal handle 66 and distal handle 34 may then be pulled/tensioned (solid-tipped arrows) to urge abrasive members 72 against the target tissue, and handles 66, 34 may further be used to reciprocate device 64 and guidewire 32 back and forth (hollow/double-tipped arrows) to modify the target tissue. Reciprocation and tensioning may be continued until a desired amount of tissue is removed, at which point guidewire 32 may be released from distal handle 34, and device 64 and guidewire 32 may be removed from the patient's back. In various embodiments, tissue modification device 64 may include any of a number of abrasive members 72, abrasive materials, or the like, which may be arrayed along distal shaft portion 70 for any desired length and in any desired configuration. Further examples of abrasive members 70, materials, surfaces and the like are described in U.S. patent application Ser. No. 11/429,377, which was previously incorporated by reference. In various alternative embodiments, shaft portions 68, 70 may both be rigid or may both be flexible and may have different cross-sectional shapes or the same shape.

[0077] Referring to FIG. 7, in another alternative embodiment, an ultrasound tissue modification device 76 may be advanced into position in a patient's back using guidewire system 10. In one embodiment, for example, ultrasound

device 76 may include a proximal handle 78, a hollow shaft 80 having a distal window 81, multiple ultrasound wires 82 extending through shaft 80 and into window 81, a guidewire connector 84 coupled with a tapered distal end of shaft 80, an ultrasound generator 88, and a wire 86 coupling handle 78 with generator 88. Handle 78 may include, for example, an ultrasound transducer, horn and/or other ultrasound transmission components. Shaft 80 may be completely rigid, completely flexible, or part rigid/part flexible, according to various embodiments. Ultrasound energy provided by generator 88 may be converted in handle 78 to reciprocating motion of wires 82, and reciprocating wires 82 may be used to cut, chisel or otherwise modify soft and/or hard tissues. Further description of such an embodiment is provided in U.S. patent application Ser. No. 11/461,740, which was previously incorporated by reference. Guidewire connector 84 may comprise one of a number of different connectors, various embodiments of which are described in further detail below.

[0078] In another embodiment, and with reference now to FIG. 8A, guidewire system 10 may be used to pull/advance a tissue access device 90 into place between target and non-target tissues. Tissue access device 90, for example, may include a proximal handle 92, a hollow shaft 94 having a distal curved portion with a distal window 96, and a guidewire connector 98 coupled with a tapered distal end of shaft 94. As with previously described embodiments, shaft 94 may be flexible along its entire length, rigid along its entire length, or rigid in part and flexible in part, and may be made of any suitable material or combination of materials. In some embodiments, shaft 94 may also be steerable, such as with one or more pull wires or other steering mechanisms, for example to steer or curve a distal portion of shaft 94.

[0079] Once access device 90 is in a desired position, with window 96 facing target tissue (such as ligamentum flavum and/or facet joint bone in the spine) and an atraumatic surface of shaft 94 facing non-target tissue, any of a number of compatible tissue modification devices 100, 101, 104 or other devices may be advanced through access device 90 to perform a tissue modification procedure or other functions. Such devices may swappable in and out of access device 90 and may be in the form of cartridges, so that various cartridges may be inserted and removed as desired, over the course of a procedure. Examples of several tissue modification devices are shown in FIG. 8A, including a rongeur device 100, an ultrasound device 101 (including wire 102 and ultrasound generator 103), and an abrasive, reciprocating device 104. Further examples of tissue modification and other devices are described below with reference to FIGS. 8B-8M.

[0080] In one embodiment, for example, at least a distal portion of each tissue modification device 100, 101, 104 may be flexible, and a proximal portion of each modification device 100, 101, 104 may have a locking feature for locking into proximal handle 92 of access device 90. Thus, a given modification device, such as abrasive device 104, may be advanced into handle 92 and shaft 94, so that abrasive members 105 of device 104 are exposed through window 96 and locking feature 99 of device couples and locks within handle 92. A user may then grasp handles 34 and 92, pull up to urge abrasive members 105 against target tissue, and reciprocate access device 90 and guidewire system 10 back and forth to remove target tissue. The user may then choose

to remove abrasive device **104** and insert one of the other devices **100**, **101** to further modify target tissues.

[0081] In various embodiments, any of a number of tissue modification devices and/or other devices may be provided (for example as cartridges) for used with access device **90**. In some embodiments, one or more of such devices may be provided with access device **90** and guidewire device **10** as a system or kit. Any given tissue modification device may act on tissue in a number of different ways, such as by 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 target tissue. Non-tissue-modifying devices or cartridges may additionally or alternatively be provided, such as but not limited to devices for: capturing, storing and/or removing tissue; delivering a material such as bone wax or a pharmacologic agent such as thrombin, NSAID, local anesthetic or opioid; delivering an implant; placing a rivet, staple or similar device for retracting tissue; delivering a tissue dressing; cooling or freezing tissue for analgesia or to change the tissue's modulus of elasticity to facilitate tissue modification; visualizing tissue; and/or diagnosing, such as by using ultrasound, MRI, reflectance spectroscopy or the like. In given method, system or kit, any combination of tissue modification and/or non-tissue-modifying devices may be used with access device **90**.

[0082] With reference now to FIGS. **8B-8M**, distal portions of a number of exemplary embodiments of devices (which may be in cartridge form in some embodiments) for use with access device **90** are shown. FIG. **8B** shows a device **430** including a sharpened, pointed, double-beveled distal tip **432**. Tip **432** may be advanced across window **96** of access device **90** to cut tissue. FIG. **8C** shows a device **440** including a diagonal-edge distal cutting tip **442**, which may be used in a similar manner to cut tissue. FIG. **8D** shows a device **450** including multiple volcano-shaped abrasive members **452**. In alternative embodiments of abrasive devices, any suitable abrasive members or surfaces may be used. FIG. **8E**, for example, shows a device **460** including a portion of a Gigli saw **462** attached to the device's upper surface, such as by welding. Any of a number of blades may alternatively be attached to a device, such as in the device **470** shown in FIG. **8F**. Here, device **470** includes a proximally placed blade **472** having a cutting edge **474**, which may be advanced across window **96** to cut tissue. FIG. **8G** shows an alternative embodiment in which a device **480** includes a distally placed blade **482** with a cutting edge **484** that may be drawn back/retracted across window **96** to cut tissue. In another tissue-modifying embodiment, FIG. **8H** shows a device **490** including a radiofrequency (RF) loop electrode **492** for cutting tissue and extending proximally via two insulated wires **494**.

[0083] With reference to FIG. **8I**, in an alternative embodiment, a device **500** may include a side-facing aperture **502** and a chamber **504**. Device **500** may be advanced into access device **90** to align aperture **502** with window **96** and may then be used to collect tissue in chamber **504**. Device **500** may then be removed through access device **90** to remove the tissue from the patient. This may be repeated as many times as desired, to remove cut tissue from the patient. FIG. **8J** shows a device **510** having a clamp **512** for delivering an implant **514**. Implant **514**, for example, may be a posterior decompression implant such as the X STOP® Interspinous

Process Decompression (IPD®), offered by St. Francis Medical Technologies, Inc.® (Alameda, Calif.), a foraminal implant such as that described in PCT Patent Application Pub. No. WO 2006/042206A2, or any other suitable implant for the spine or other area of the body. FIG. **8K** shows an embodiment of a device **520** used for delivering a rivet (or "tissue anchor") **524** through a distal aperture **522**. In one embodiment, for example, tissue anchor **524** may be anchored to bone and used to retract ligamentum flavum tissue to increase the area of a space in the spine. Such a device is described in more detail, for example in U.S. patent application Ser. No. 11/250,332, entitled "Devices and Methods for Selective Surgical Removal of Tissue," (Original Attorney Docket No. BXNONP00100), and filed Oct. 15, 2004, the full disclosure of which is hereby incorporated by reference.

[0084] In another embodiment, and with reference to FIG. **8L**, a visualization device **530** having a visualization element **532** may be used with access device **90**. Such a device may include, for example, an endoscope, fiber optics, a camera coupled with a catheter or the like. In other embodiments, ultrasound, MRI, spectroscopy or other diagnostic or visualization devices may be used. FIG. **8M** shows an alternative embodiment of a device **540**, which includes a distal aperture **542** through which a tissue dressing **544** may be delivered. Tissue dressing **544**, for example, may include one or more fabrics, gel foam or the like. In some embodiments, one or more pharmacologic agents may be delivered through device **540**. Alternatively or additionally, irrigation and/or suction may be provided through device **540**. As should be apparent from the foregoing description, any suitable device, cartridge or combination of devices/cartridges may be used with access device **90** in various embodiments.

[0085] Referring now to FIG. **9**, another embodiment of a tissue access device **106**, which may be advanced to a position in a patient's back using guidewire system **10**, is shown. Tissue access device **106** may include, for example, a proximal handle **107** having a hollow bore **108** and an actuator **109**, a hollow shaft **110** extending from proximal handle **107** and having a distal curved portion and a distal window **112**, and a guidewire coupling member **114** coupled with a tapered distal end of shaft **110**. As with the previously described embodiment, a number of different tissue modification devices **116**, **117**, **120** may be inserted and removed from access device **106** to perform a tissue modification procedure, such as a rongeur **116**, an ultrasound device **117** (including a wire **118** and generator **119**), and an abrasive device **120**. In the embodiment of FIG. **9**, however, handle **107** includes the additional feature of actuator **109**, which may be used to activate one or more tissue modifying members of various tissue modification devices. For example, rongeur **116** may be advanced into hollow bore **108** and shaft **110**, to position blades **121** of rongeur **116** so as to be exposed through window **112**, and to lock a locking member **115** of rongeur **116** within handle **107**. Actuator **109** may then be moved back and forth (by squeezing and releasing, in the embodiment shown) to move one or both blades **121** back and forth to cut target tissue. Optionally, rongeur **116** may then be removed from access device **106** and a different modification device **117**, **120** inserted to further modify target tissue. Actuator **109** may be used with some modification devices and not others. Again, in some

embodiments, access device **106**, guidewire system **10** and one or more modification devices **116**, **117**, **120** may be provided as a system or kit.

[0086] With reference now to FIG. **10**, a perspective view of one embodiment of a tissue access device **240** is shown. Device **240** may include an elongate, hollow shaft **242** having a distal aperture **244**, a distal extension **246** (or “platform” or “tissue shield”) extending beyond shaft **242**, and a guidewire coupling member **250** attached to distal extension **246** for coupling with a guidewire **252**. Both shaft **242** and distal extension **246** may be either rigid or flexible, in various embodiments. In the embodiment shown, distal extension **246** includes multiple flexibility slits **248** to enhance flexibility of that portion of device **240**. Shaft **242**, distal extension **246** and guidewire coupling member **250** may be made of any suitable material (or materials), and may be made from one piece of material as a single extrusion or from separate pieces attached together, in alternative embodiments. Suitable materials include, for example, metals, polymers, ceramics, or composites thereof. Suitable metals 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). Ceramics may include, but are not limited to, aluminas, zirconias, and carbides.

[0087] In addition to various materials, tissue access device **240** may have any desired combination of dimensions and shapes. In some embodiments, for example, shaft **242** and distal extension **246** have different cross-sectional shapes, while in other embodiments, they may have the same cross-sectional shape. Some embodiments may include additional features, such as a mechanism for changing distal extension **246** from a straight configuration to a curved configuration (such as with one or more pull wires).

[0088] Any of a number of different surgical/tissue modification devices, such as but not limited to those described in reference to FIGS. **8** and **9**, may be used in conjunction with tissue access device **240**. Such a tissue modification device may be used, for example, by passing the device through shaft **242**, such that a portion of the device extends out of aperture **244** to perform a procedure, while distal extension **246** protects non-target tissue from harm. In various embodiments, multiple surgical devices may be passed through and used with tissue access device **240**, either serially or simultaneously, depending on the configuration of access device **240** and the constraints of the operating field and anatomy.

[0089] Referring to FIG. **11**, in another embodiment, a tissue access device **260** includes an elongate, hollow shaft **262**, a handle **264**, a distal aperture **266**, and a distal extension **270** having flexibility slits **268** and coupled with a guidewire coupling member **272**, which may be coupled with a guidewire **274**. This embodiment of tissue access device **260** is similar to the one described immediately above but includes the additional feature of handle **264**, which in some embodiments may be used to actuate one or more surgical/tissue modification devices passed through access device **260**.

[0090] FIG. **12** depicts another alternative embodiment of a tissue access device **280**, including a proximal shaft portion **282**, a distal shaft portion **286**, and a handle **284**. Distal shaft portion **286** includes a window **288**, through which a portion of a surgical/tissue modification device may be exposed to perform a procedure, and a guidewire coupling member **290**, which may be coupled with a guidewire **292**. As with the previously described embodiments, any of a number of surgical devices may be passed through and used with tissue access device **280**, according to various embodiments. Tissue modifying portions of such devices may be exposed through or may even extend out of window **288** to perform any of a number of procedures, while distal shaft portion **286** otherwise protects non-target tissue from damage. In various embodiments, shaft portions **282**, **286** may both be flexible, both be rigid, or one may be flexible and the other rigid. In one embodiment, for example, shaft **282**, **286** may comprise a flexible catheter, while in an alternative embodiment, shaft **282**, **286** may comprise a rigid, probe-like structure.

[0091] Any of the embodiments described in FIGS. **10-12** may further optionally include one or more external support devices, which removably attach to shaft **242**, **262**, **282** and one or more stabilizing structures outside the patient, such as a retractor, bed rail, or the like. Such support devices, such as detachable support arms, may be provided with a tissue access device **240**, **260**, **280** as part of a system or kit and may be used to help support/stabilize the access device during use.

[0092] With reference now to FIGS. **13A-13D**, one embodiment of a surgical device distal portion **138** with a guidewire coupling member **130** is shown in conjunction with a shaped guidewire **134**. Guidewire coupling member **130** may generally include a slit **131** and a bore **132**. Guidewire **134** may include a shaped member **136** at one end, which is shown as a ball-shaped member **136** but may have any of a number of suitable shapes in alternative embodiments. Generally, guidewire **134** and shaped member **136** may be made of any suitable material, such as but not limited to any of a number of metals, polymers, ceramics, or composites thereof. Suitable materials, 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). Ceramics may include but are not limited to aluminas, zirconias, and carbides. Shaped member **136** may be formed by attaching a separate member to one end of guidewire **134**, such as by welding, or may be formed out of the guidewire material itself.

[0093] In the embodiment shown, guidewire **134** may be coupled with coupling member **130** by first placing guidewire **134** through slit **131** into bore **132**, as shown in perspective view FIG. **13A** and top view FIG. **13C**. Guidewire **134** may then be pulled through bore **132** (solid-tipped arrows in FIGS. **13A** and **13C**), to pull shaped member **136** into bore **132**, as shown in perspective view FIG. **13B** and top view FIG. **13D**. As visible in FIGS. **13B** and **13D**, bore **132** may be tapered, so that shaped member

136 may enter bore **132** but may only travel partway through before reaching a diameter of bore **132** through which it cannot pass. In an alternative embodiment, bore **132** may include a hard stop rather than a taper. In any case, shaped member **136** may be pulled into bore **132** to cause it to lodge there, and additional pulling or tensioning force may be applied to guidewire **134** without risk of pulling shaped member **136** farther through bore **132**. Guidewire **134** may thus be used to pull surgical device **138** through tissue and into a desired position for performing a procedure, and may further be used to apply tensioning/pulling force to surgical device **138** to help urge a tissue modifying portion of device **138** against target tissues.

[0094] As with many of the embodiments described previously and hereafter, guidewire coupling member **130** may be either attached to or formed as an integral part of surgical device distal portion **138**, according to various embodiments. Coupling member **130** may be made of any suitable material, as has been mentioned previously, and may have any desired dimensions and any of a number of different configurations, some of which are described in further detail below. In various embodiments, coupling member **130** may be attached to an extreme distal end of surgical device **138** or may be positioned at or near the extreme distal end. Although coupling member **130** is typically attached to or extending from a top or upper surface of surgical device **138**, in some embodiments it may alternatively be positioned on a bottom/lower surface or other surface.

[0095] In another embodiment, and with reference now to FIGS. **14A** and **14B**, a guidewire coupling member **140** including a slit **142** with one or more curves **144** and a bore **143** may be attached to a surgical device distal portion **148**. A guidewire **146** having a cylindrical shaped member **147** at one end may be placed through slit **142** into bore **143** and pulled distally (solid-tipped arrow), as shown in FIG. **14A**. When shaped member **147** is pulled into bore **143**, it is stopped by, and cannot pass through, curves **144**, thus allowing guidewire **146** to be used to pull device **148** into place between target and non-target tissues and apply tensioning force.

[0096] Referring to FIGS. **15A-15F**, an alternative embodiment of a guidewire coupling member **150** is shown with a shaped guidewire **158**. Guidewire coupling member **150** may include a transverse slit **152**, an axial channel **154** and a transverse bore **156**. FIG. **15E** shows a front perspective view of coupling member **150**, where member **150** would be mounted on a surgical device such that a front side **151** would face distally and a back side **153** would face proximally. FIG. **15F** shows a rear perspective view of coupling member **150** with back side **153** and front side **151**.

[0097] FIG. **15A** is a rear/left perspective view, and FIG. **15B** is a top view, both showing guidewire **158** with a ball-shaped member **159** being placed through transverse slit **152** into channel **154**. Channel **154** is generally an open portion within coupling member **150**, having a diameter similar to or the same as that of slit **152**, to allow guidewire **158** to be rotated through coupling member **150**, as depicted by the solid-tipped, curved arrow in FIGS. **15A** and **15B**. Bore **156** is sized to allow ball-shaped member **159** to travel into it to rest within coupling member **150**, as shown in FIGS. **15C** and **15D**. Ball-shaped member **159** is sized such that, when shaped guidewire **158** is rotated into position within coupling member **150**, it cannot travel through channel **154**, and is thus trapped within bore **156**. Guidewire **158**

may thus be pulled, to pull a device into position and/or to apply tension to the device, without guidewire **158** pulling out of coupling member **150**. Guidewire **158** may be disengaged from coupling member **150** by rotating guidewire **158**, coupling member **150** or both, to release shaped member **159** from bore **156**. In one embodiment, coupling member **150** may be attached to a top surface of a distal portion of a surgical device, such as by welding, adhesive or other attachment means.

[0098] An alternative embodiment of a guidewire coupling member **160** is depicted in FIGS. **16A-16E**. In this embodiment, guidewire coupling member **160** includes a channel **162**, a central bore **164** and a side channel, as shown in perspective view FIG. **16A**, top view FIG. **16B** and side view FIG. **16C**. Channel **162** is generally shaped and sized to allow a shaped member **169** of a guidewire **168** to pass longitudinally therethrough. Central bore **164** is shaped and sized to allow shaped member **169** to rotate within bore **164**. Side channel **166** is shaped and sized to allow guidewire **168** to pass therethrough when guidewire **168** is rotated about an axis through shaped member **169**. An angle **165** formed by channel **162** and an opposite end of side channel **166** may be any desired angle, in various embodiments. For example, the angle in the embodiment shown (best seen in FIGS. **16B**, **16D** and **16E**) is approximately 90 degrees. In alternative embodiments, the angle could instead be less than 90 degrees or greater than 90 degrees. In one embodiment, for example, an angle of about 135 degrees may be used, while in another embodiment, an angle of about 180 degrees may be used.

[0099] As depicted in FIG. **16D**, shaped member **169** of guidewire **168** may be passed through channel **162** and into central bore **164** (hollow-tipped arrow). Guidewire **168** may then be rotated about an axis approximately through shaped member **169** (solid-tipped, curved arrow). When rotated, guidewire **168** passes through side channel **166** to its end, as shown in FIG. **16E**. Guidewire **168** may then be pulled, to pull a device attached to coupling member **160** to a desired position in a patient's body, such as between target and non-target tissues. Rotated shaped member **169** is trapped within central bore **164**, due to its shape and size, and cannot pass into either side channel **166** or channel **162**. To remove guidewire **168** from coupling member **160**, guidewire **168** may be rotated back to the position shown in FIG. **16D** and withdrawn from coupling member **160** through channel **162**.

[0100] Referring now to FIGS. **17A-17D**, another alternative embodiment of a guidewire coupling member **170** is shown. FIGS. **17A** and **17B** are front perspective and rear perspective views, respectively, in which a channel **172** and a side channel **174** of coupling member **170** may be seen. FIGS. **17C** and **17D** are top views, showing coupling member **170** with an inserted guidewire **178**. As seen in FIG. **17C**, guidewire **178** with a shaped distal member **179** may be advanced through channel **172** (hollow-tipped arrow), to position shaped member **179** in a central bore **176** of coupling member **170**. Guidewire **178** may then be rotated through side channel **174** about an axis approximately about shaped member **179** (solid-tipped, curved arrow). As shown in FIG. **17D**, guidewire **178** may be rotated until it hits an end **175** of side channel **174**. Guidewire **178** may then be pulled to pull a device attached to coupling member **170**, as shaped member **179** will be trapped within central bore **176**, due to its shape and size. When desired, guidewire **178** may be removed from coupling member **170** by rotating

guidewire 178 back to the position shown in FIG. 17C and withdrawing it through channel 172. Channel 172 may be located at any desired angle, relative to end 175 of side channel 174. In the embodiment shown, for example, the angle is approximately 135 degrees. As in the embodiment described immediately above, channel 172 is generally shaped and sized to allow shaped member 179 to pass longitudinally therethrough, central bore 176 is shaped and sized to allow shaped member 179 to rotate within bore 176, and side channel 174 is shaped and sized to allow guidewire 178 to pass therethrough when guidewire 178 is rotated.

[0101] Turning to FIGS. 18A and 18B, in another alternative embodiment, a guidewire coupling member may include a cam 300 and a stationary portion 306 (only a part of which is shown). Cam may 300 rotate about an axis 302 from an open position (FIG. 18A), which allows a guidewire 304 to pass through, to a closed position (FIG. 18B), which traps guidewire 304 against stationary portion 306. In one embodiment, cam 300 may automatically move from open to closed positions as guidewire 304 is advanced (hollow-tipped arrow in FIG. 18A) and may move from closed to open positions as guidewire 304 is retracted. Some embodiments of a coupling member, such as that shown in FIGS. 18A and 18B, may be used with a guidewire 304 that does not have a shaped member on its proximal end. Alternatively, such a coupling member may also be used with a shaped guidewire.

[0102] FIG. 19 shows an alternative embodiment of a guidewire coupling member, which includes two opposing cams 310 that rotate toward one another (curved arrows) to grip and hold a guidewire 312. As with the previous embodiment, this coupling member may be used, in various embodiments, either with a guidewire having a shaped proximal end or an unshaped guidewire 312.

[0103] Referring now to FIGS. 20A-20C, in another embodiment, a guidewire coupling member 320 (shown in top view) may include three movable rollers 322. In an open position, as in FIG. 20A, rollers 322 may be arrayed to allow a guidewire 324 to pass through them. Rollers 322 may be moved, relative to one another (solid-tipped arrows), to partially constrain guidewire 324 (FIG. 20B) or to completely constrain guidewire 324 (FIG. 20C). Rollers 322 may be moved back to the open position (FIG. 20A) to release guidewire 324.

[0104] In an alternative embodiment, and referring now to FIGS. 21A-21C, a guidewire coupling member 330 may include a multi-piece cone 332 having a core 334 with a textured inner surface 335, and a stationary portion 336 having a receptacle 338 for receiving cone 332. In an open position, as in FIG. 21B, the two halves of cone 332 are separated and not wedged into receptacle 338, so that a guidewire 339 may be passed through core 334. Cone 332 may be moved to a closed position, as in FIG. 21C, to grip guidewire 339 with textured surface 335 and prevent guidewire 339 from moving further through core 334. In one embodiment, for example, as guidewire 339 moves through core 334, it may generate friction with textured surface 335 and thus pull cone 332 into receptacle. As with several previous embodiments, guidewire 339 may either include a proximal shaped member or may not include such a member, in various embodiments.

[0105] With reference now to FIG. 22, in another embodiment, a guidewire coupling member 340 may include a flat anvil 342 and one or more stationary portions 344. Anvil

may be moved (hollow-tipped arrow) to pinch a guidewire 344 between itself and stationary portion 344.

[0106] In an alternative embodiment, shown in FIG. 23, a guidewire coupling member 350 may include a corner-pinch mechanism 352 and one or more stationary portions 354. Mechanism 352 may be advanced (hollow-tipped arrow) to pinch guidewire 356 against stationary member 354 and thus prevent it from moving further through coupling device 350.

[0107] Referring to FIG. 24, another embodiment of a guidewire coupling member 360 is shown, which includes an eccentric cam 362 that rotates (hollow-tipped arrow) to pinch a guidewire 366 between itself and a stationary portion 364.

[0108] In another embodiment, with reference to FIGS. 27A and 27B, a guidewire coupling member 390 may include multiple spools 392, through which a guidewire 394 may pass, until a shaped member 396 on one end of guidewire 394 gets caught. FIG. 27B shows coupling member 390 attached with an upper surface of a surgical device distal end 391.

[0109] In yet another embodiment, and with reference now to FIGS. 28A and 28B, a guidewire coupling member 400 may include a semi-circular ribbon 402 having two apertures 404. With this embodiment of coupling member 400 (as well as other embodiment described herein), a textured guidewire 406 may be used. As textured guidewire 406 passes through apertures 404, friction caused by the textured surface 407 causes ribbon 402 to flatten (FIG. 28B), thus trapping guidewire 406 in apertures 404. Ribbon 402 may be made of metal or any other suitable material, examples of which have been listed previously.

[0110] Referring to FIG. 29, another alternative embodiment is shown, in which a guidewire coupling member 410 includes a folded ribbon 412 having multiple apertures 414. Ribbon 412 may flatten as a textured guidewire 416 passes through it, thus causing apertures to trap guidewire 416.

[0111] Another embodiment of a guidewire coupling member 420 is shown in FIG. 30. In this embodiment, coupling member 420 includes a curved ribbon 422 with multiple apertures 424. Ribbon 422 may flatten to constrain a guidewire 426 in apertures 424, as with the previously described embodiments. Some embodiments of such ribbon-shaped coupling members 400, 410, 420 may function with a non-textured guidewire as well as, or in place of, a textured guidewire.

[0112] Referring to FIG. 31, in another embodiment, a guidewire coupling member 430 for removably coupling with a guidewire 438 may include a stationary portion 432 and a movable portion 434. Movable portion 434 may include multiple contact members 436 or locking edges, configured to hold guidewire 438 when movable portion 434 is pushed against it (hollow-tipped arrows). Movable portion 434 may be moved using any suitable technique or means in various embodiments. Contact members 436 generally press guidewire 438 against stationary portion 432 such that it will not move through coupling member 430 when pulled (solid-tipped arrow), thus allowing a device coupled with coupling member 430 to be pulled using guidewire 438.

[0113] In another embodiment, and with reference now to FIG. 32, a guidewire coupling member 440 may include a stationary portion 442 and a movable portion 444, each of which has a roughened surface 446 facing one another. Movable portion 444 may be moved toward stationary portion 442 (hollow-tipped arrows) to trap guidewire 446 in

between, thus preventing guidewire 446 from moving through coupling member 440 and thus allowing a device coupled with coupling member 440 to be pulled via guidewire 448.

[0114] Turning to FIGS. 33A-33D, several alternative embodiments of a guidewire for use with various embodiments of a guidewire coupling member and guidewire system are shown. In some embodiments of a guidewire system, any of a number of currently available guidewires may be used. In other embodiments, a textured guidewire without a shaped member on either end may be used. Each of the embodiments shown in FIGS. 33A-33D, by contrast, has some kind of shaped member on a proximal end of the guidewire for coupling with a guidewire coupling member and some kind of sharpened or otherwise shaped distal tip for facilitating passage of the guidewire through tissue.

[0115] In various embodiments, guidewires may comprise 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 one embodiment, a guidewire may be made of Nitinol. In various alternative embodiments, guidewires 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 guidewires or for portions or coatings of guidewires 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.

[0116] In the embodiment shown in FIG. 33A, a guidewire 180 includes a ball-like shaped member 182 attached to its proximal end and a pointed distal tip 184. As with all the following exemplary embodiments, shaped member 182 may be either a separate piece attached to guidewire 180 by welding or other means or may be a proximal end of guidewire 180, formed into shaped member 182. FIG. 33B shows a guidewire 186 with a cylindrical shaped member 188 and a beveled distal tip 190. FIG. 33C shows a guidewire 192 with a pyramidal shaped member 194 and a double-beveled distal tip 196. FIG. 33D shows a guidewire 198 with a cubic shaped member 200 and a threaded distal tip 202. In alternative embodiments, any of the shaped members 182, 188, 194, 200 may be combined with any of the distal tips 184, 190, 196, 202. In yet other alternative embodiments, the shaped members and/or distal tips may have other shapes and/or sizes. Thus, the embodiments shown in FIGS. 33A-33D are provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is described by the claims.

[0117] Referring now to FIGS. 34A and 34B, another embodiment of a guidewire 204 may include a drill-shaped distal tip 206 with a cutting edge 208. Such a drill-shaped tip 206 may facilitate passage of guidewire 204 through tissue, as shown in FIG. 34B. Guidewire 204 may be advanced through a probe 210 and through tissue (not shown) by

simultaneously pushing (solid-tipped, straight arrows) and twisting (hollow-tipped, curved arrows) guidewire 204 from its proximal end. Drill-shaped tip 206 may facilitate passage of guidewire 204 through tissue by acting as a drill.

[0118] With reference to FIG. 35A, in some embodiments, a guidewire system may include a guidewire handle 220 for grasping a guidewire outside the patient. Such a guidewire handle 220 may include, for example, a guidewire clamping mechanism 222 housed in a central, longitudinal bore 221 of handle 220 and including a central guidewire aperture 223. Handle 220 may also include a lock lever 224 for tightening clamping mechanism 222 around a guidewire. At some points in the present application, handles similar to handle 220 are referred to as “distal handles,” and handles coupled with various tissue modification devices are referred to as “proximal handles.” These terms, “distal” and “proximal,” are generally used to distinguish the two types of handles and to denote that one is more proximal than the other, during use, to a first incision or entry point into a patient, through which a guidewire system is placed and then used to pull a tissue modification device into position in the patient. “Distal” and “proximal,” however, are used merely for clarification and do not refer to the relation of any device to specific anatomical structures, the position of a physician/user of the described devices/systems, or the like. Thus, in various embodiments, either type of handle may be “distal” or “proximal” relative to various structures, users or the like. For the purposes of FIGS. 35A and 35B, the embodiment is described as guidewire handle 220, denoting its function of holding a guidewire.

[0119] FIG. 35B provides an exploded view guidewire handle 220. A handle body 225 may be made of any suitable material and have any desired shape and size. In various alternative embodiments, for example, handle body 220 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). Ceramics may include but are not limited to aluminas, zirconias, and carbides.

[0120] Clamping mechanism 222 may include, for example, a snap ring 226, a keeper washer 228, a flat anvil 230, and a cage barrel 232, all of which fit within central bore 221 of handle body 225. Lock lever 224 may be coupled with a pinch screw 234 and a shoulder screw 236. When lock lever 224 is turned in one direction, it pushes shoulder screw 236 against clamping mechanism 222 to cause mechanism 222 to clamp down on a guidewire. Lock lever 224 may be turned in an opposite direction to loosen clamping mechanism 222, thus allowing a guidewire to be introduced into or release from central guidewire aperture 223.

[0121] 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 per-

formed 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. 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 tissue access device for providing access to target tissue in a patient's body while protecting non-target tissue, the device comprising:

a shaft having a proximal portion, a distal portion, and at least one lumen passing longitudinally through at least the proximal portion to allow passage of at least one additional device therethrough;

at least one side-facing aperture in at least one of the proximal and distal shaft portions, through which the at least one additional device may be exposed to the target tissue; and

a guidewire coupling member on the distal portion of the shaft for coupling with a guidewire to allow the tissue access device to be pulled behind the guidewire to position its distal portion between the target and non-target tissues with the aperture facing the target tissue.

2. A device as in claim 1, wherein part of the shaft is rigid and part of the shaft is flexible.

3. A device as in claim 2, wherein the distal portion is at least partially flexible.

4. A device as in claim 3, wherein the flexible distal portion is steerable from a relatively straight configuration to a curved configuration, the device further comprising at least one steering actuator extending from the proximal portion to the distal portion.

5. A device as in claim 1, wherein the lumen passes through both the proximal and distal portions, and wherein the aperture is in the distal portion.

6. A device as in claim 1, wherein the lumen passes through only the proximal portion, and wherein the aperture is positioned in a distal region of the proximal portion, such that when part of the additional device passes through the aperture, it is located above the distal portion of the shaft.

7. A device as in claim 1, further comprising at least one electrode coupled with at least one surface of the distal portion of the shaft and configured to stimulate nerve tissue.

8. A device as in claim 1, wherein the guidewire coupling member is configured to removably couple with a shaped member at one end of a guidewire.

9. A device as in claim 1, further comprising a handle coupled with a proximal end of the proximal portion.

10. A system for providing access to target tissue in a patient's body while protecting non-target tissue, the system comprising:

a tissue access device comprising:

a shaft having a proximal portion, a distal portion, and at least one lumen passing longitudinally through at least the proximal portion to allow passage of at least one additional device therethrough;

at least one side-facing aperture in at least one of the proximal and distal shaft portions, through which the at least one additional device may be exposed to the target tissue; and

a guidewire coupling member on the distal portion of the shaft for coupling with a guidewire to allow the

tissue access device to be pulled behind the guidewire to position its distal portion between the target and non-target tissues with the aperture facing the target tissue; and

a guidewire configured to couple with the guidewire coupling member.

11. A system as in claim 10, wherein the guidewire comprises a sharp distal tip and a shaped member on a proximal tip for coupling with the guidewire coupling member.

12. A system as in claim 10, further comprising at least one additional device configured to pass through the tissue access device to expose at least an active portion of the additional device through the side-facing aperture.

13. A system as in claim 12, wherein the at least one additional device is selected from the group consisting of tissue cutting devices, tissue ablation devices, tissue abrasion devices, other tissue removal devices, other tissue modification devices, tissue storage devices, tissue transport devices, drug delivery devices, implant delivery devices, material delivery devices, visualization devices and diagnostic devices.

14. A system as in claim 10, further comprising an anchoring device for coupling the shaft of the tissue access device with a structure outside the patient to stabilize the tissue access device.

15. A system as in claim 10, further comprising an anchoring device for coupling the shaft of the tissue access device with a structure inside the patient to stabilize the tissue access device.

16. A system as in claim 10, wherein the tissue access device further comprises a handle coupled with a proximal end of the proximal shaft portion.

17. A system as in claim 10, further comprising a guidewire handle for coupling with the guidewire outside the patient to facilitate pulling on the guidewire to apply tensioning force.

18. A method for providing access to target tissue in a patient's body while protecting non-target tissue, the method comprising:

passing a guidewire between the target and non-target tissues;

coupling the guidewire with a guidewire coupling member on a distal portion of a tissue access device; and

pulling the guidewire through the patient's body to pull the distal portion of the tissue access device between the target and non-target tissues such that a side-facing aperture of the tissue access device faces the target tissue,

wherein, when the distal portion of the access device is positioned between the target and non-target tissues, a proximal portion of the device extends outside the patient, such that at least one tissue modification device may be passed through at least the proximal portion to expose one or more tissue modifying members through the side-facing aperture.

19. A method as in claim 18, further comprising identifying at least the non-target tissue before passing the guidewire.

20. A method as in claim 18, further comprising: advancing a first tissue modification device through the tissue access device to expose at least one tissue modification member of the device through the side-facing aperture of the access device;

pulling the guidewire and at least one of the tissue access device and the tissue modification device to urge the at least one tissue modification member against the target tissue; and

activating the tissue modification member(s) to modify the target tissue while protecting the non-target tissue with the distal portion of the access device.

21. A method as in claim **20**, further comprising:

removing the first tissue modification device from the patient's body, through the access device;

advancing a second tissue modification device through the tissue access device to expose at least one tissue modification member of the device through the side-facing aperture of the second access device;

pulling the guidewire and at least one of the tissue access device and the second tissue modification device to urge the at least one tissue modification member against the target tissue; and

activating the tissue modification member(s) to modify the target tissue.

22. A method as in claim **20**, wherein activating the tissue modification member(s) comprises actuating at least one actuation member on a handle of the tissue access device.

23. A method as in claim **18**, further comprising coupling the tissue access device with a structure outside the patient, using at least one anchoring device, to stabilize the access device.

24. A method as in claim **18**, further comprising coupling the tissue access device with a structure inside the patient, using at least one anchoring device, to stabilize the access device.

25. A method as in claim **18**, further comprising activating at least one electrode on the distal portion of the tissue access device to confirm placement of the distal portion between the target and non-target tissues.

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