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(54) **SURGICAL ACCESS SYSTEM AND RELATED METHODS**

(75) Inventors: **Patrick Miles**, San Diego, CA (US); **Scot Martinelli**, Mountain Top, PA (US); **Eric Finley**, Poway, CA (US)

(73) Assignee: **NuVasive, Inc.**, San Diego, CA (US)

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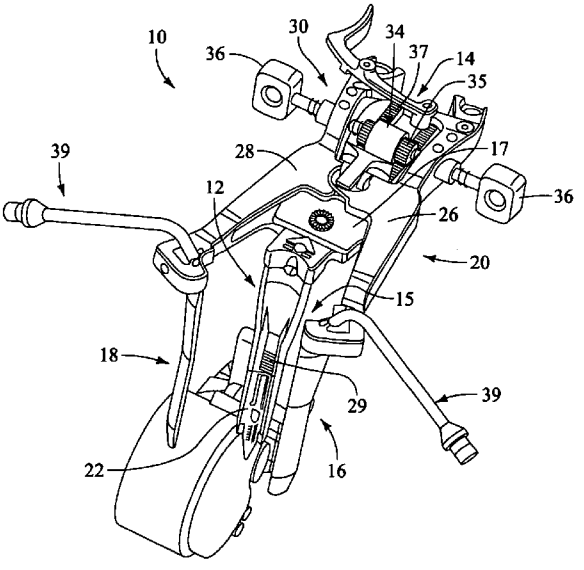
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Primary Examiner — Mark W Bockelman
(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

(57) **ABSTRACT**

A surgical access system including a tissue distraction assembly and a tissue refraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor to a surgical target site.

29 Claims, 22 Drawing Sheets



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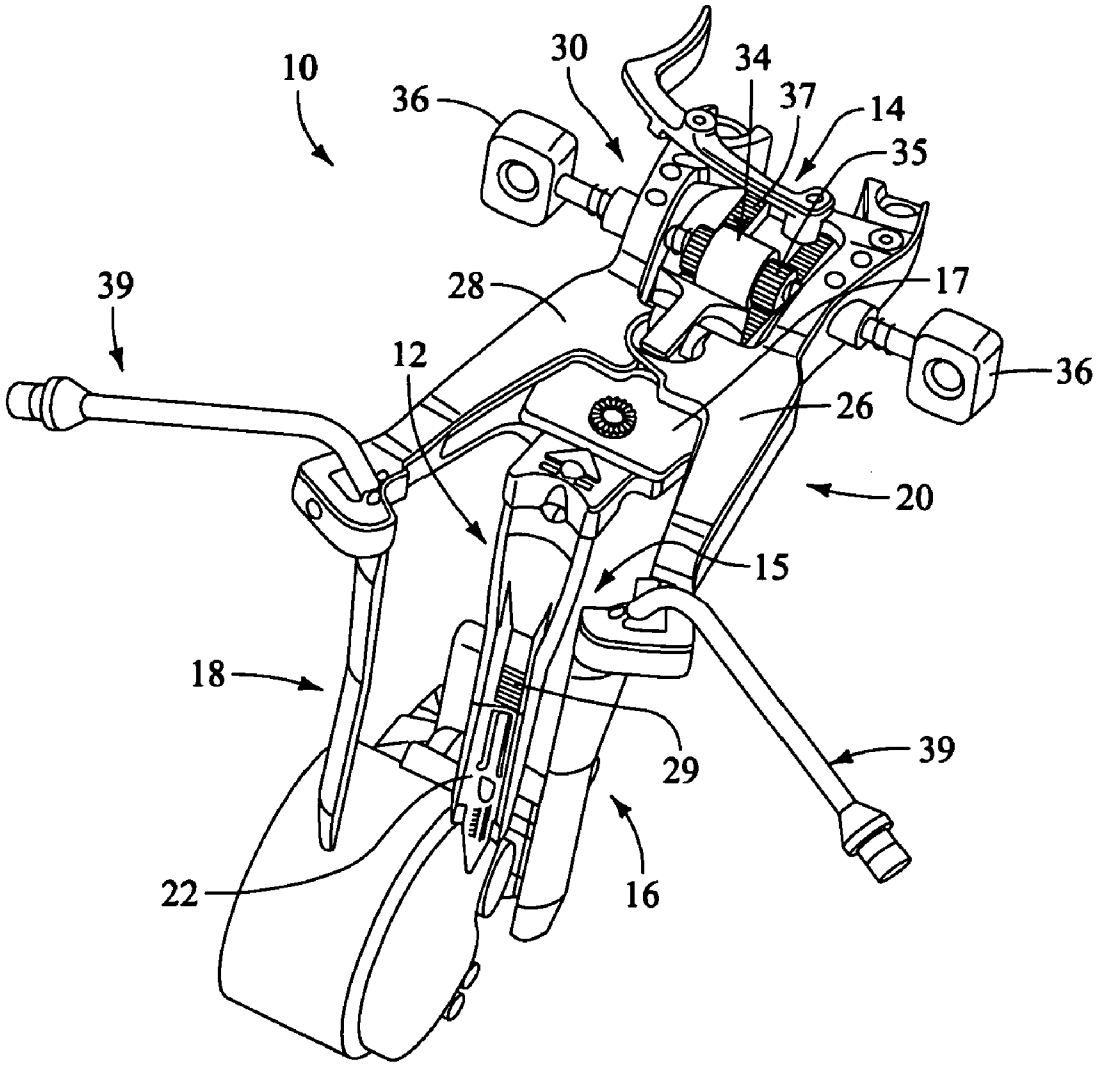


FIG. 1

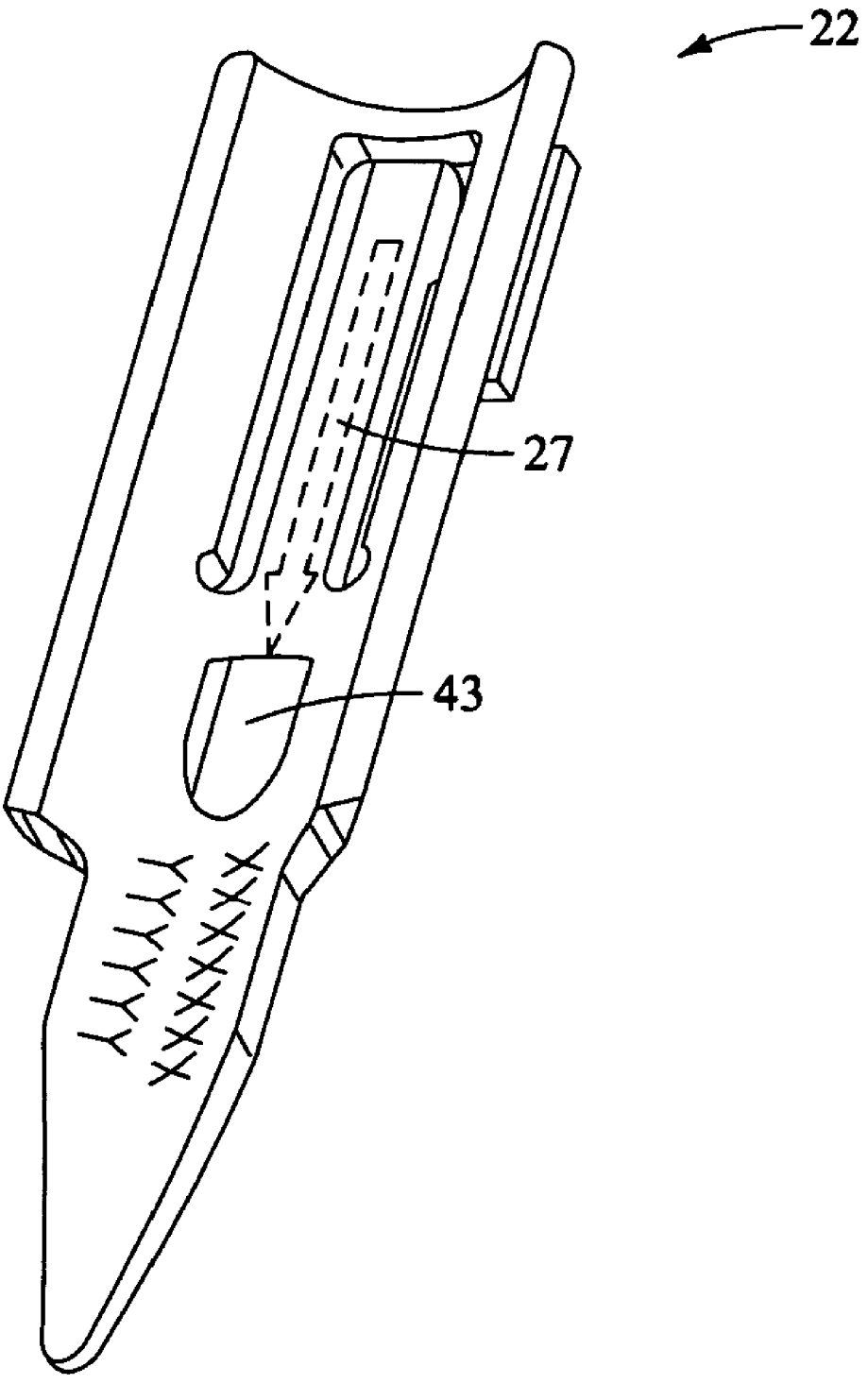


FIG. 2

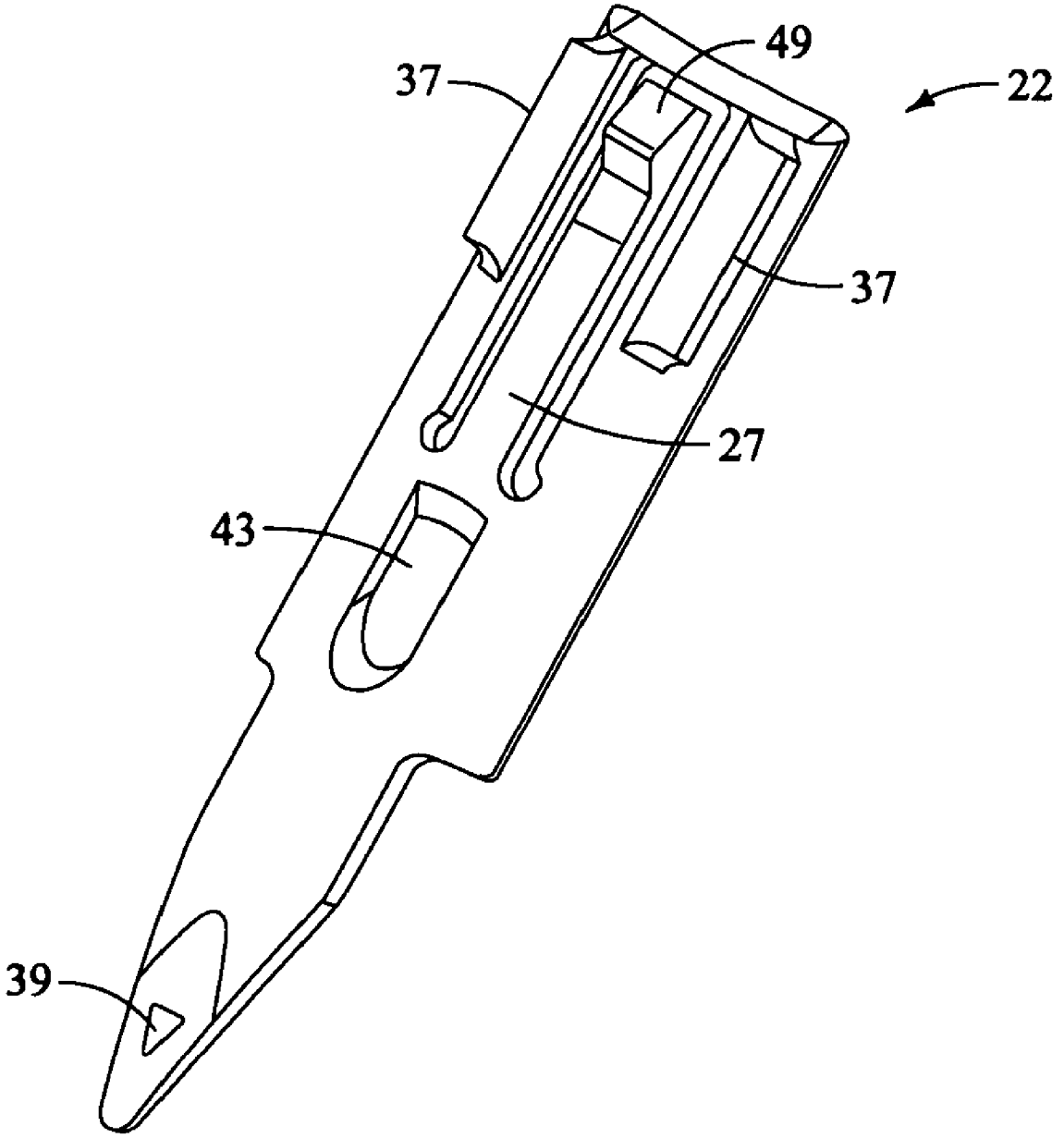


FIG. 3

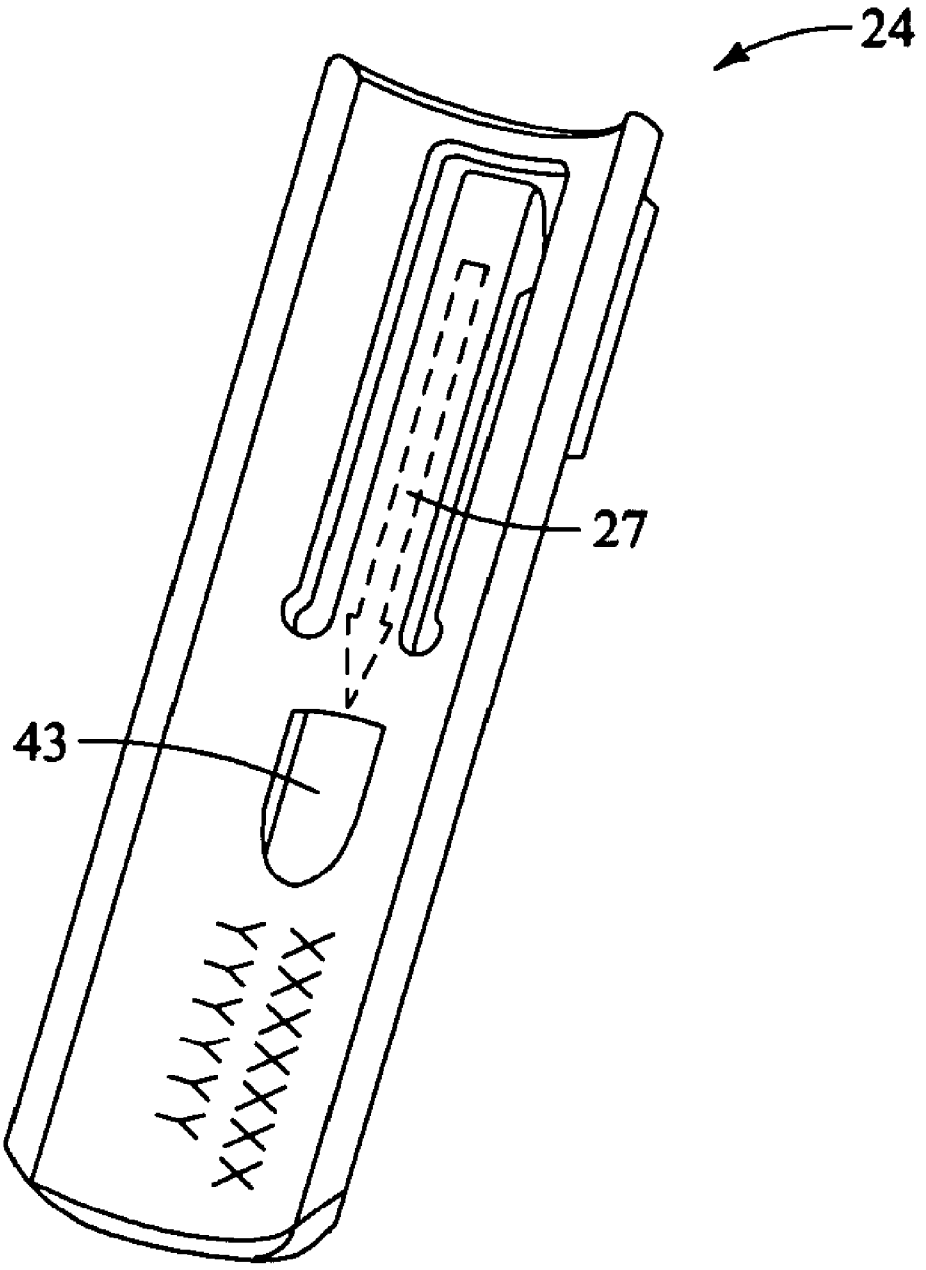


FIG. 4

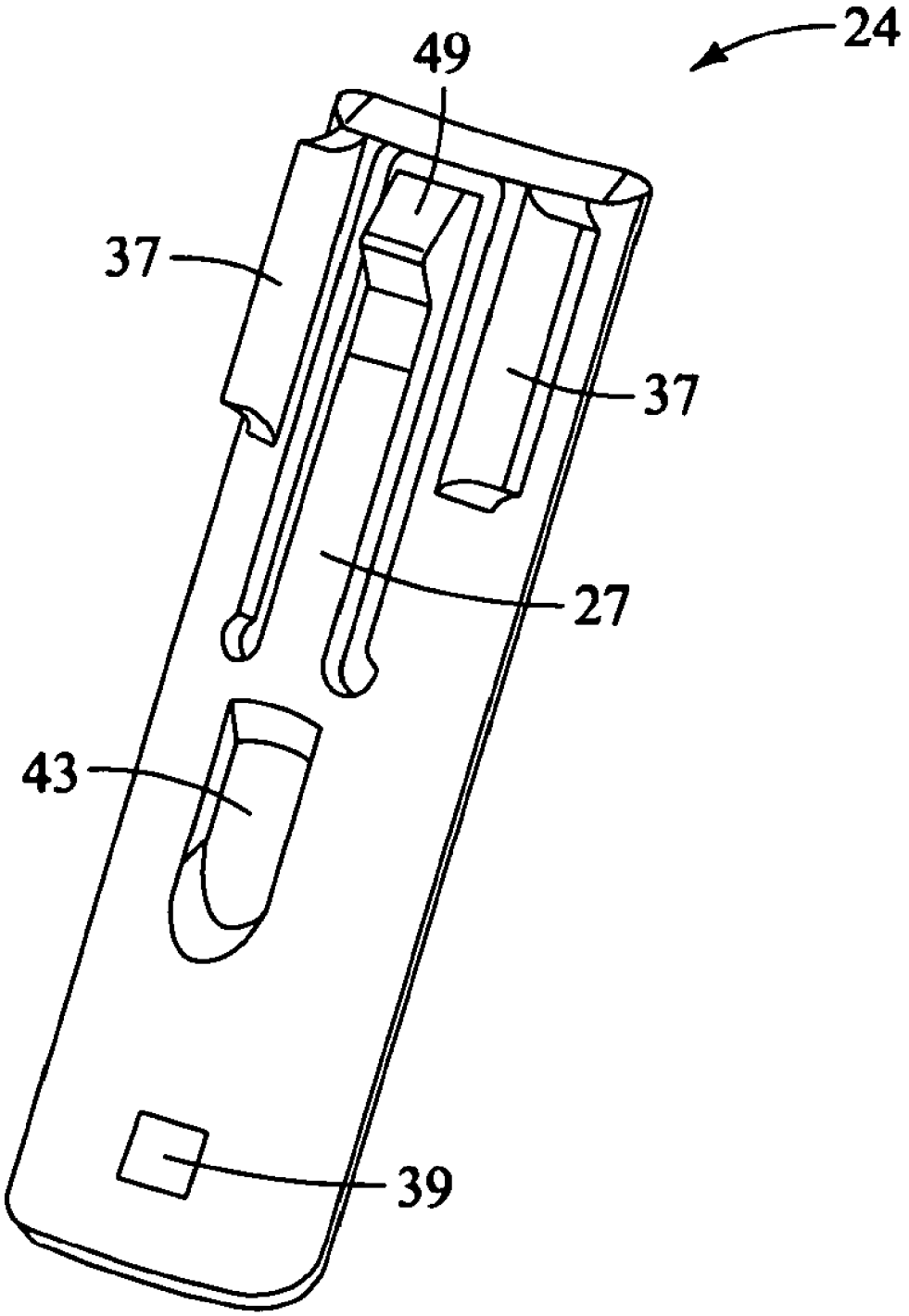


FIG. 5

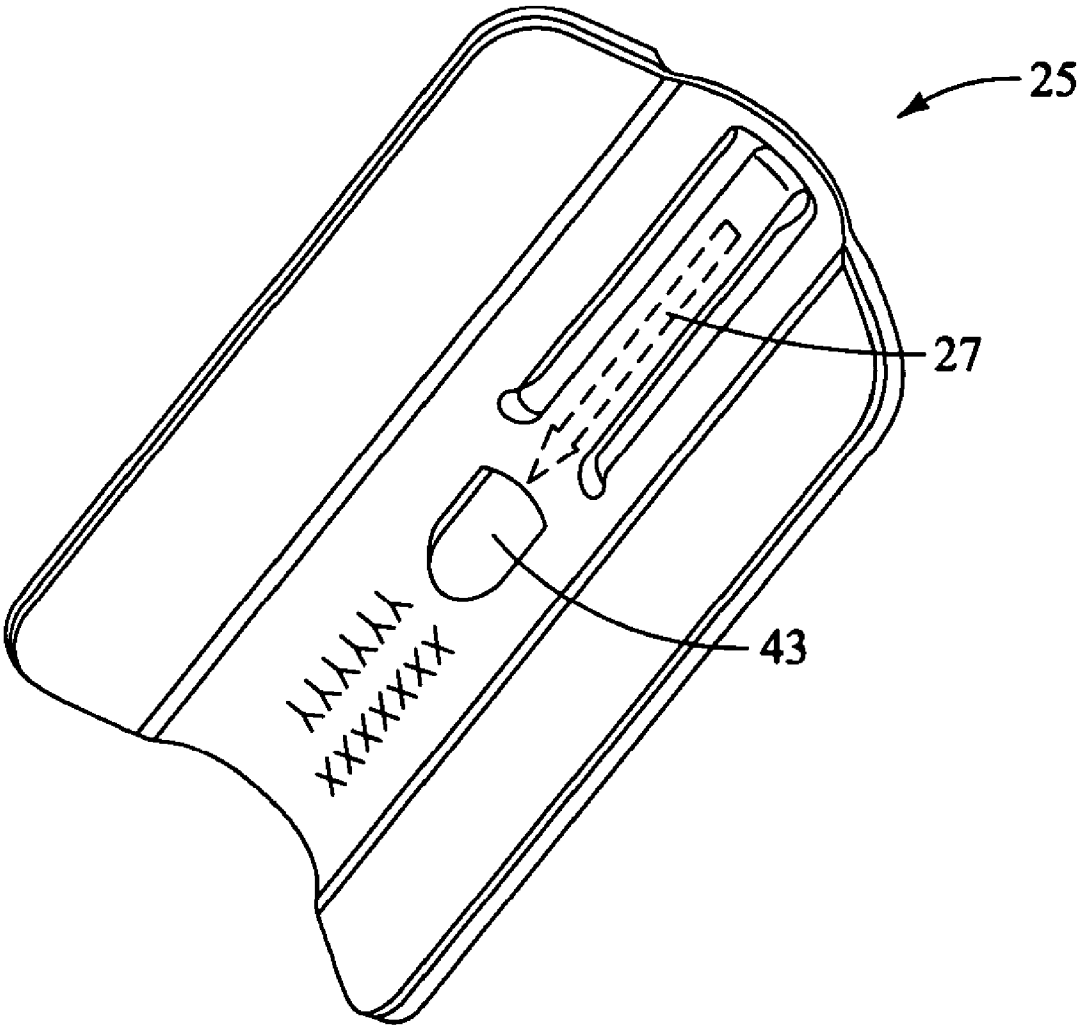


FIG. 6

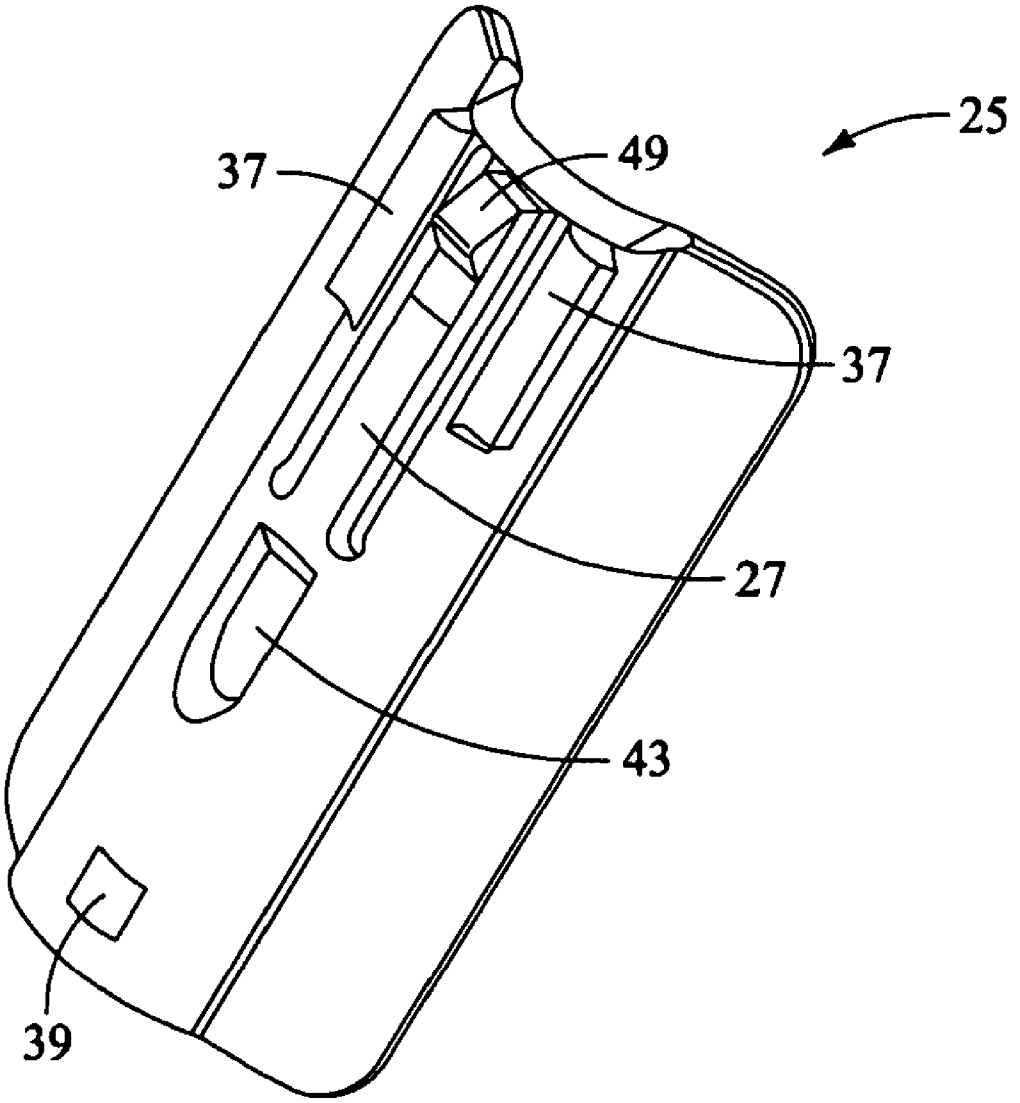


FIG. 7

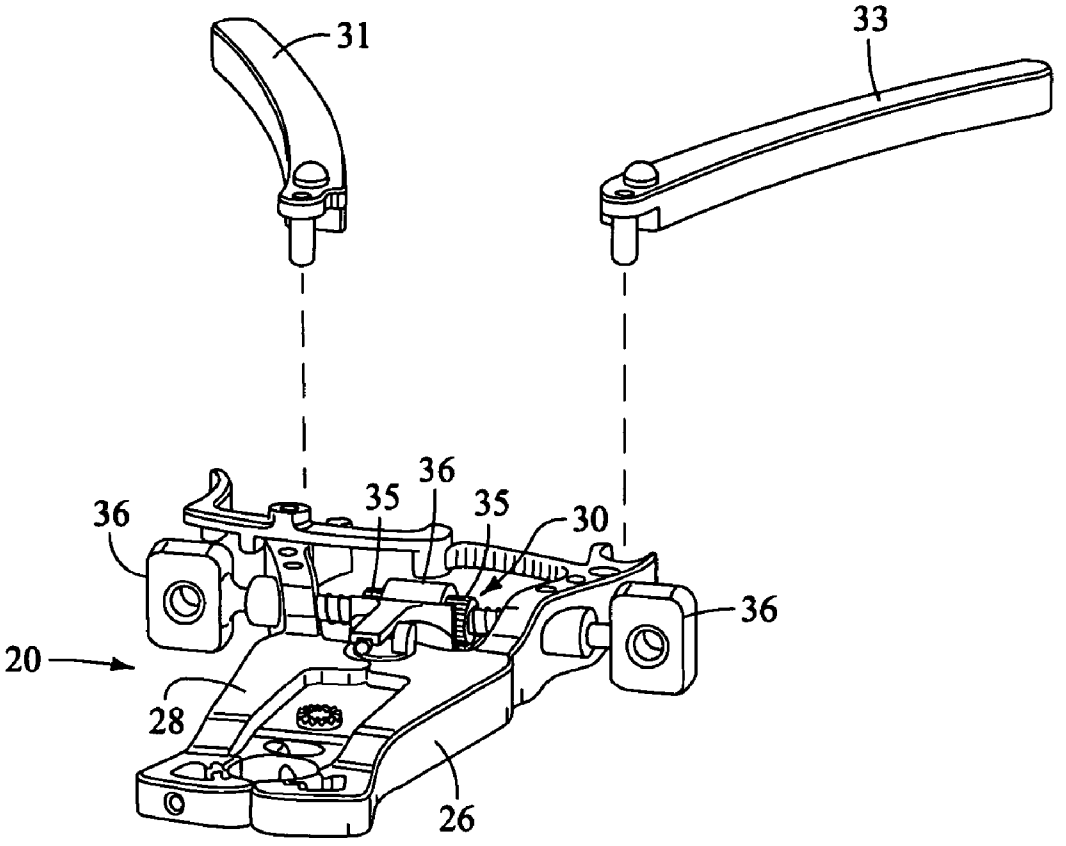


FIG. 8

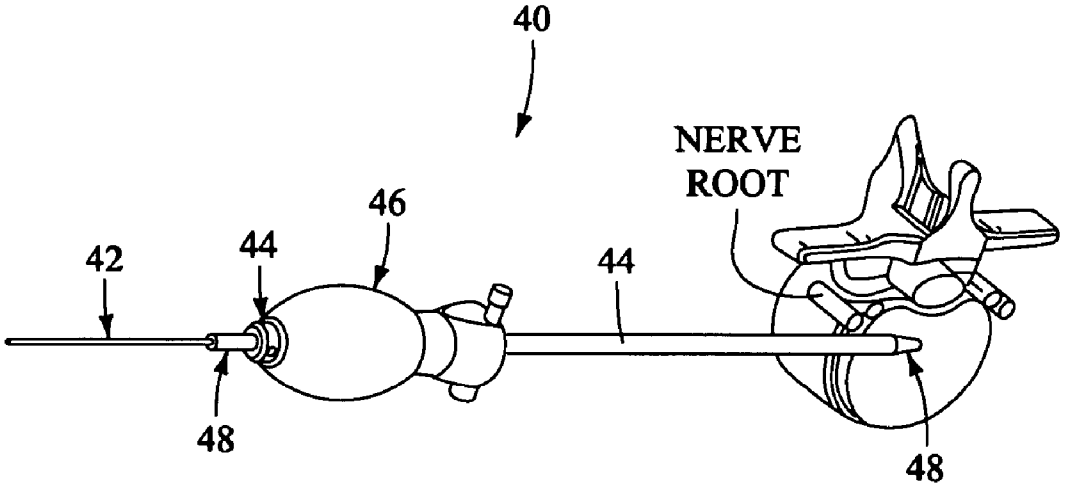


FIG. 9

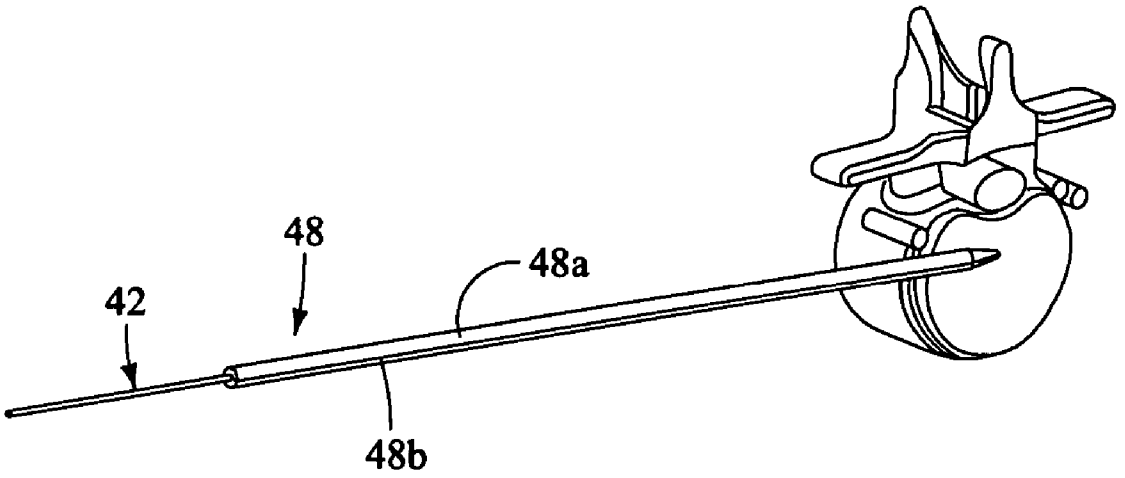


FIG. 10

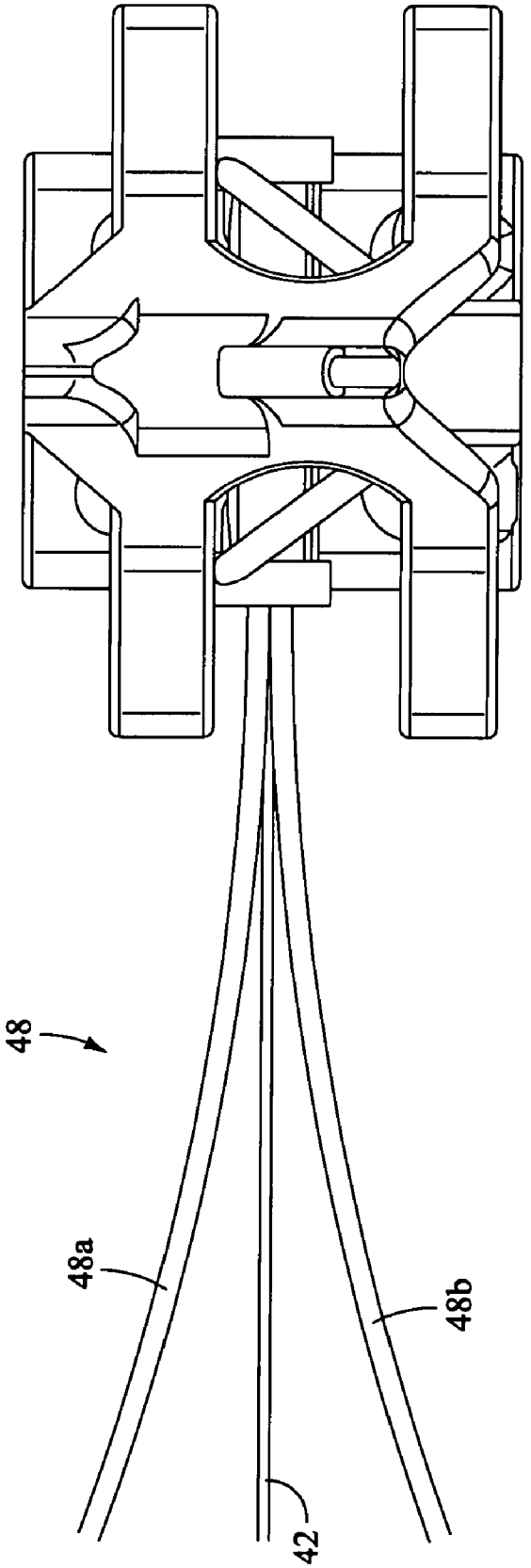


FIG. 11

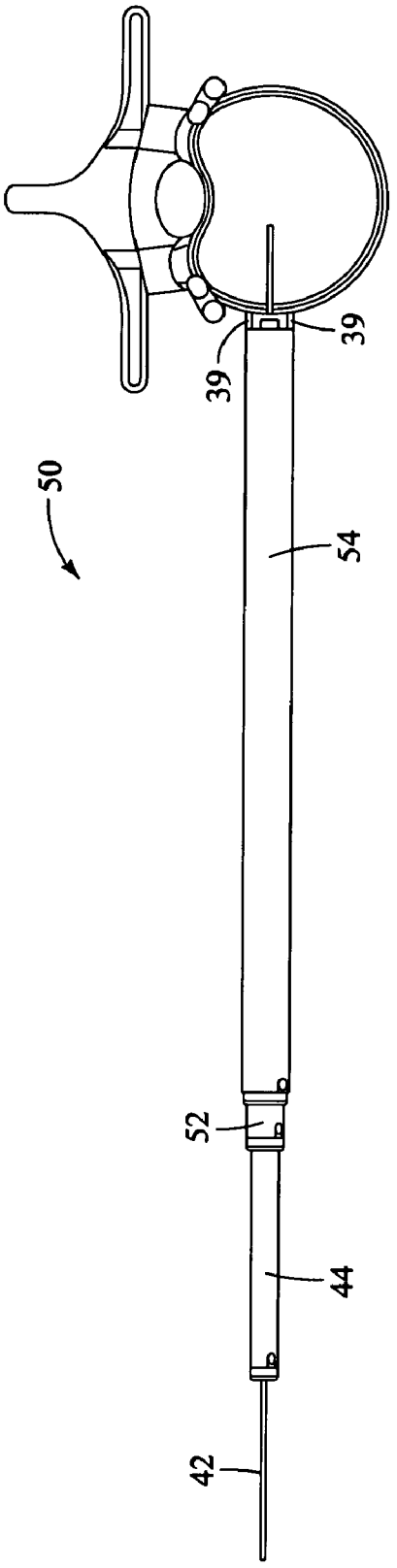


FIG. 12

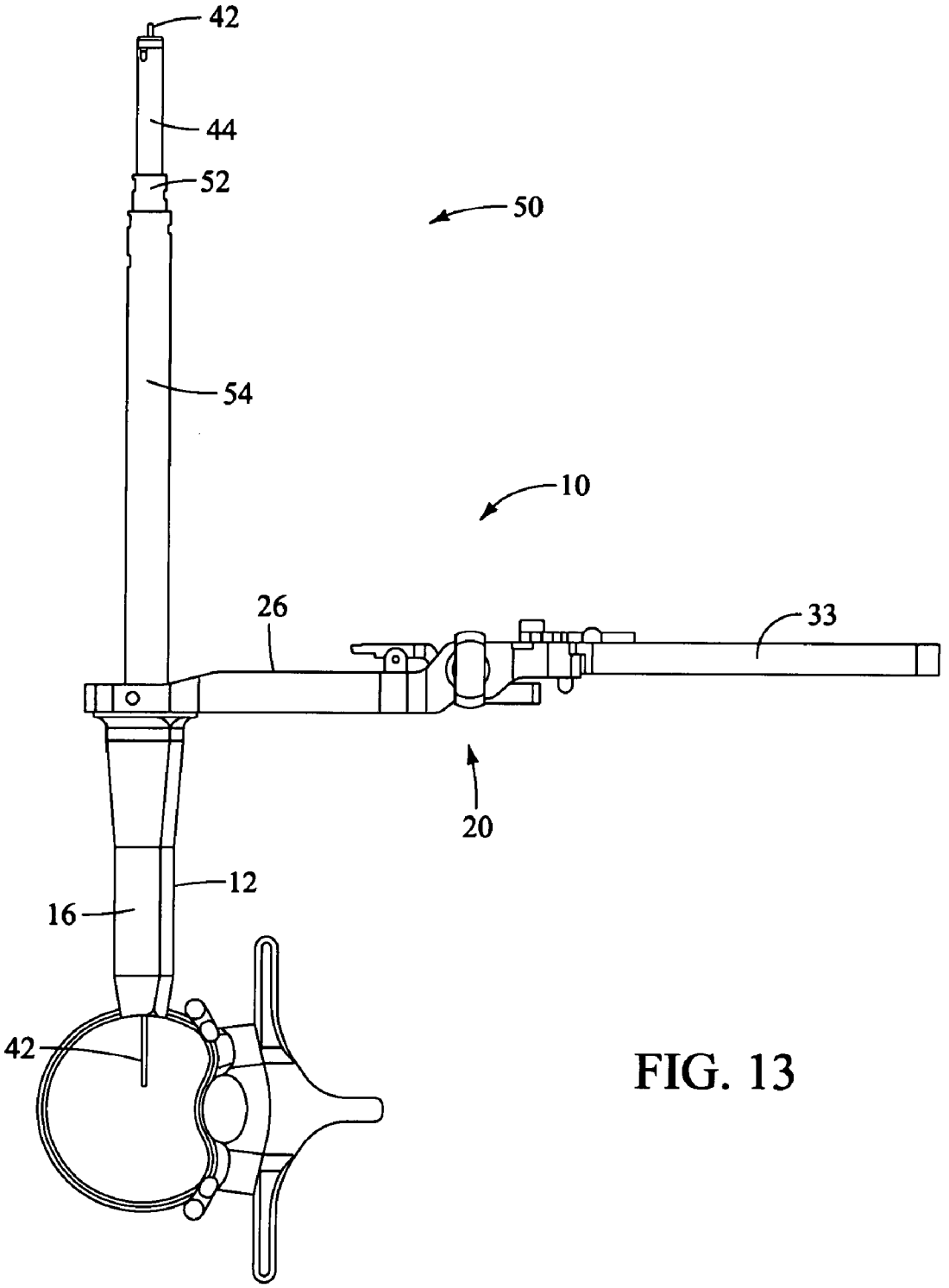


FIG. 13

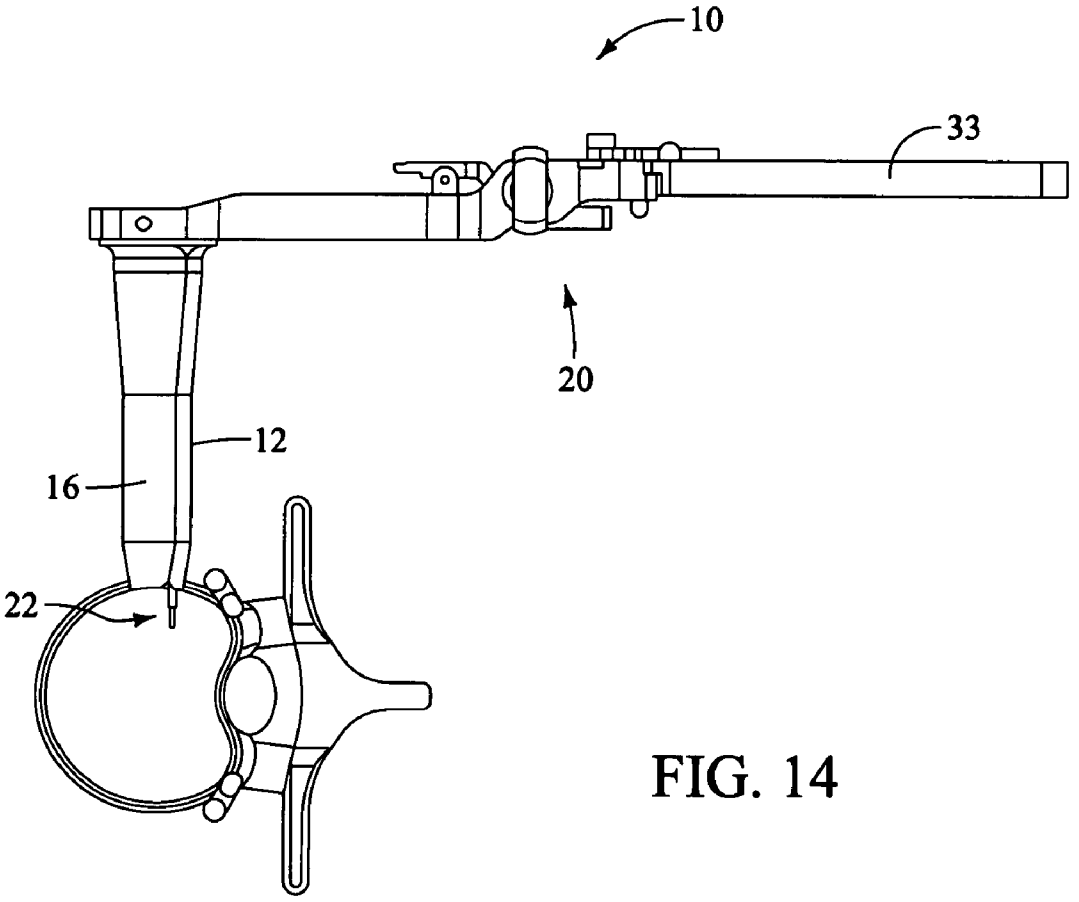


FIG. 14

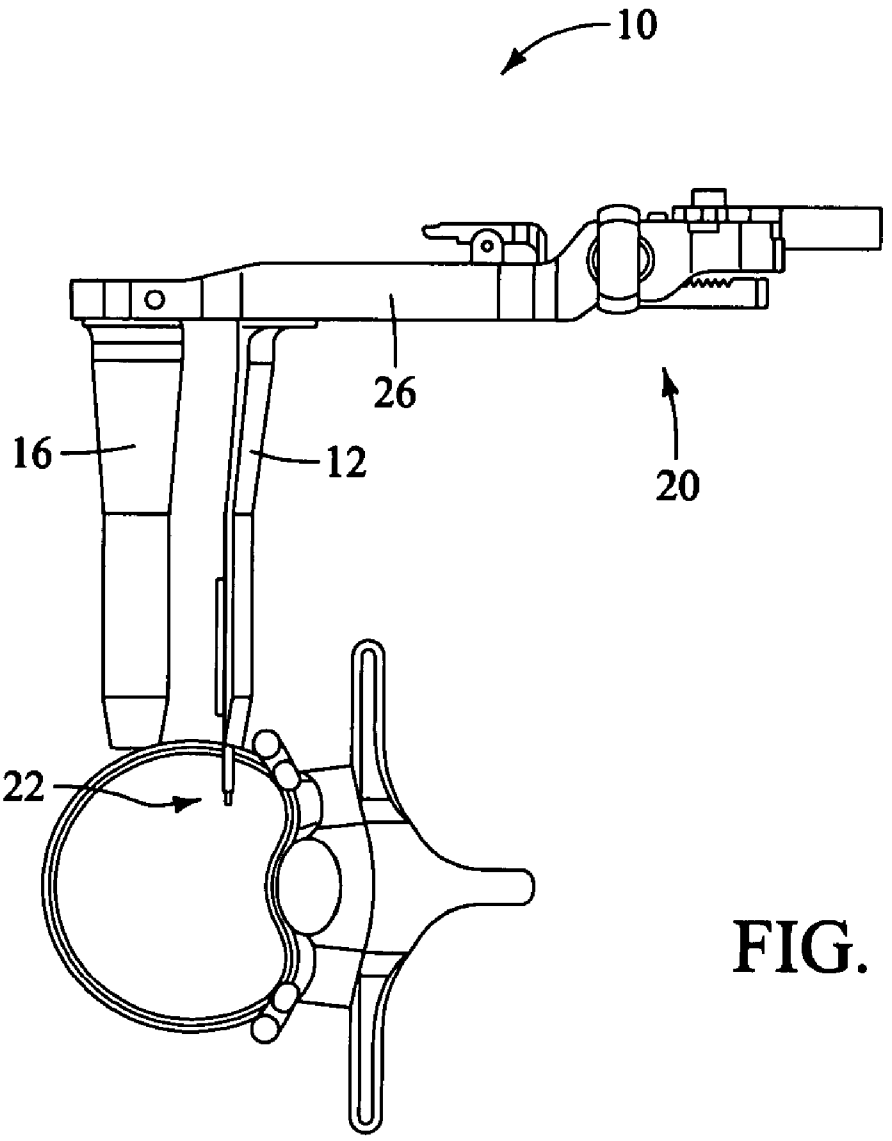


FIG. 15

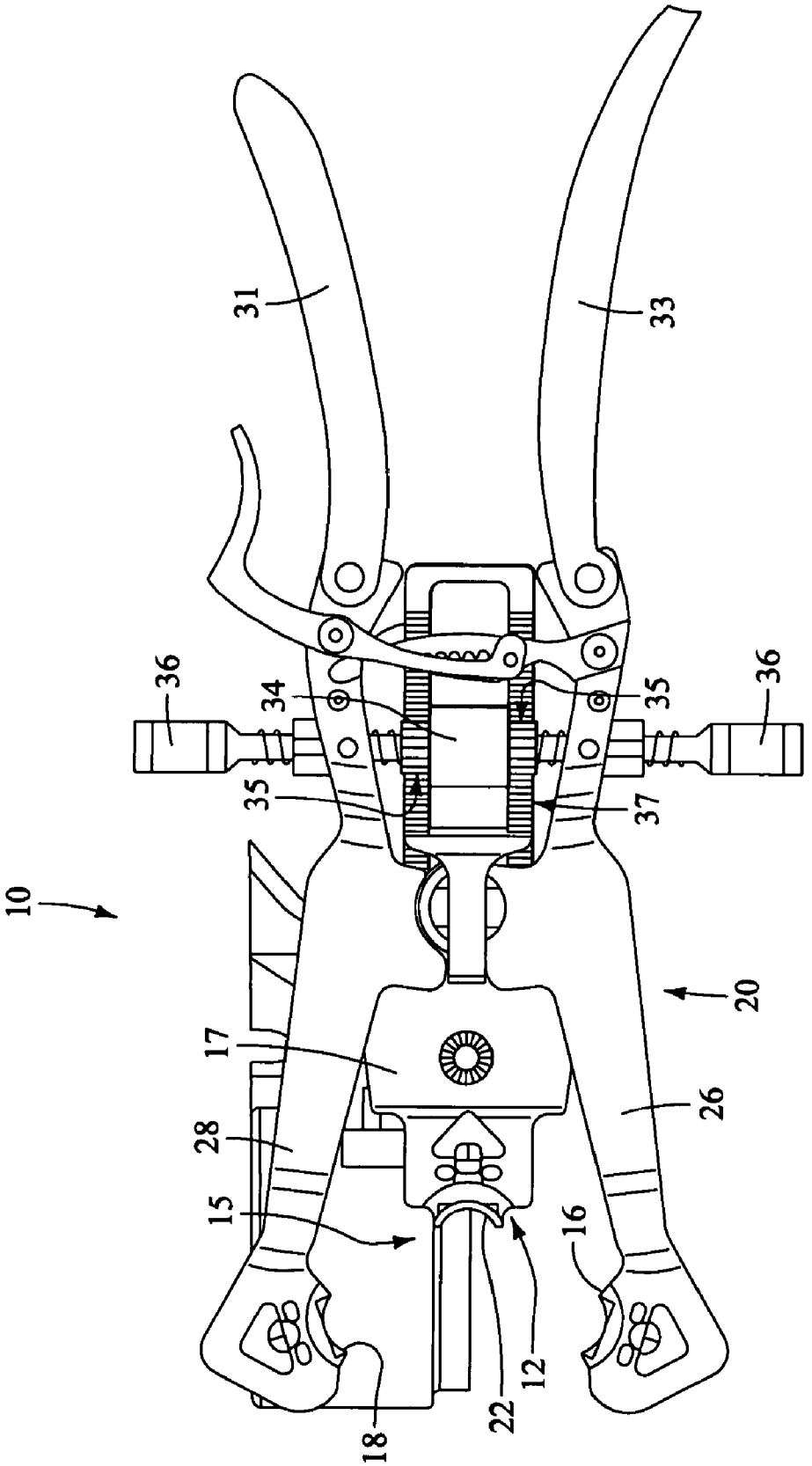


FIG. 16

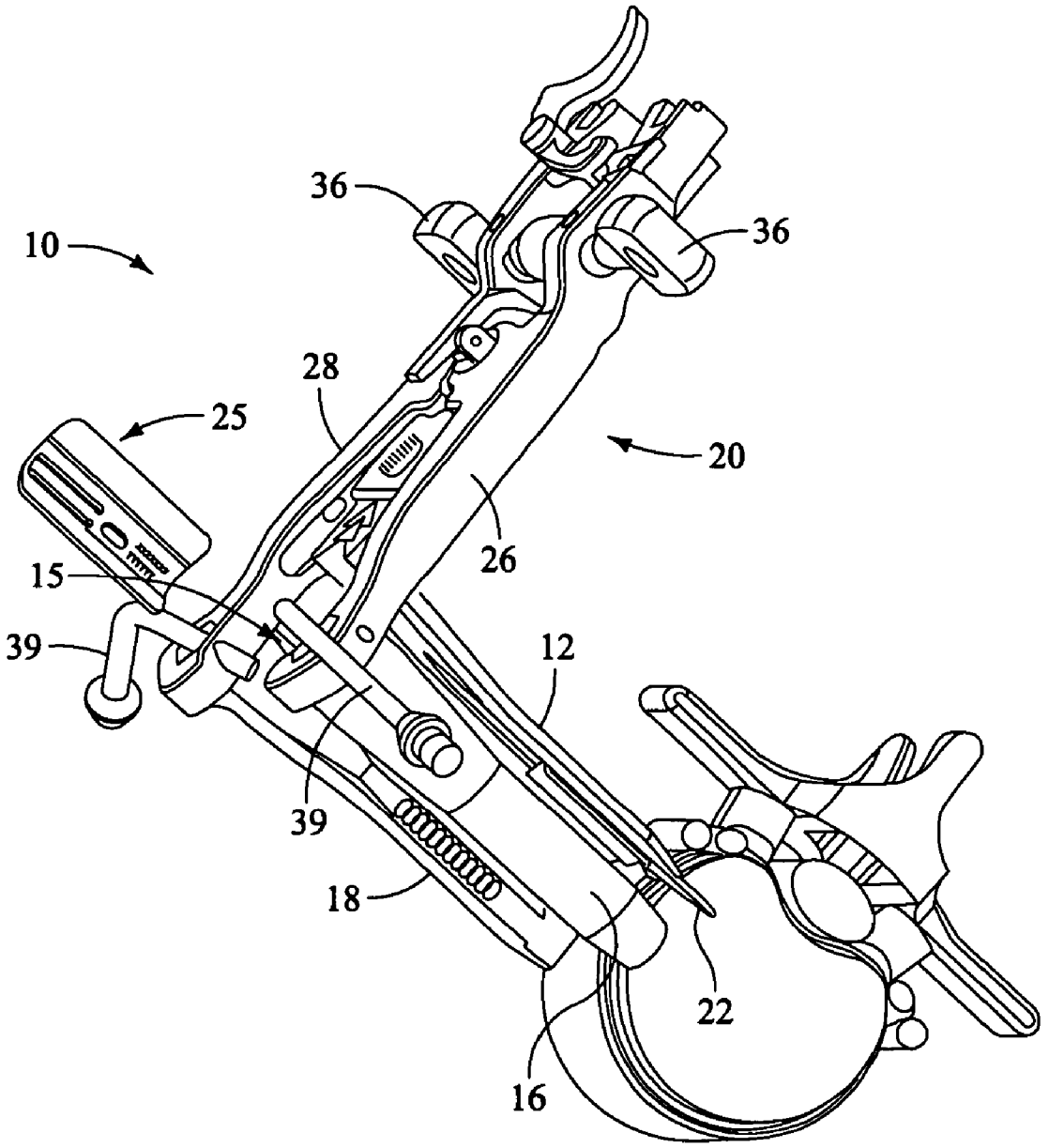


FIG. 17

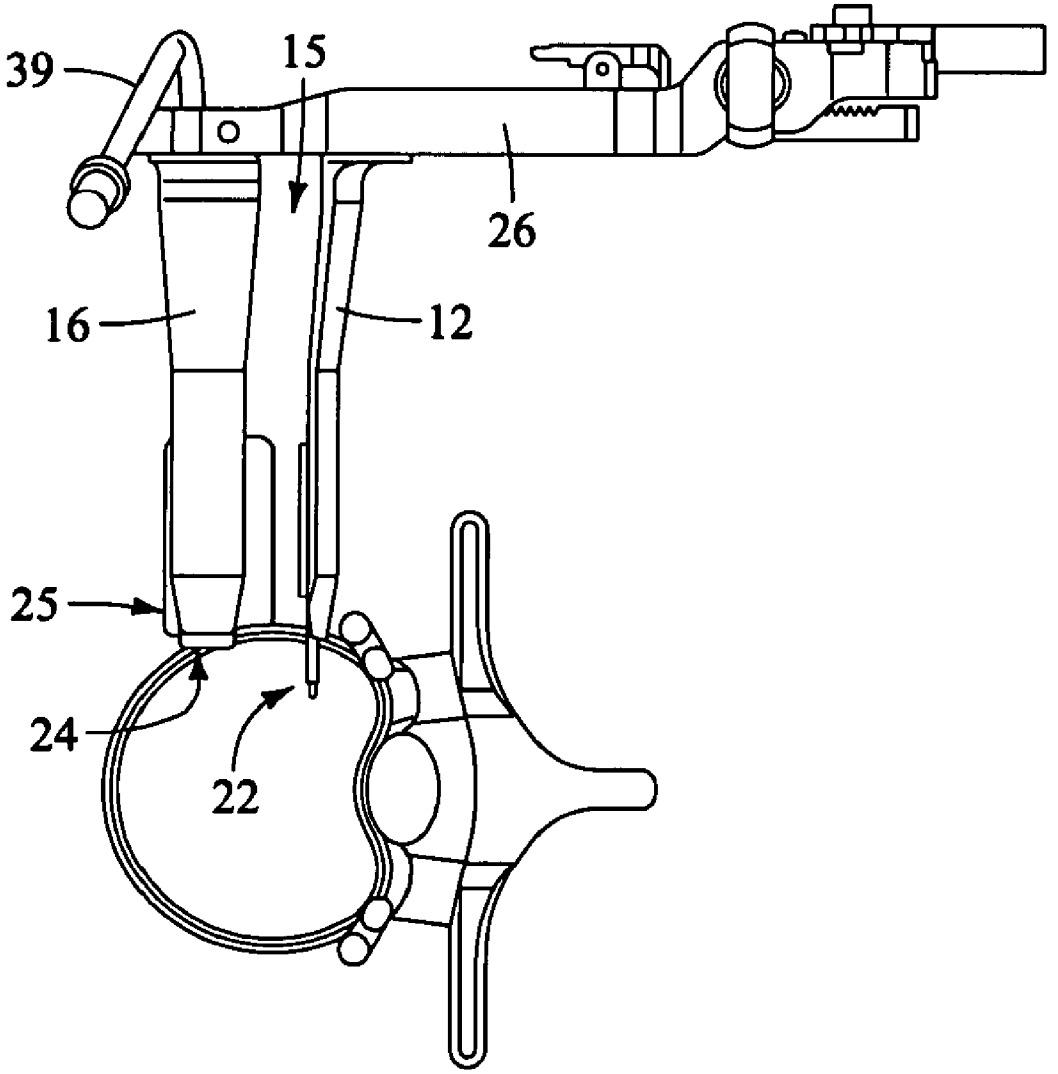


FIG. 18

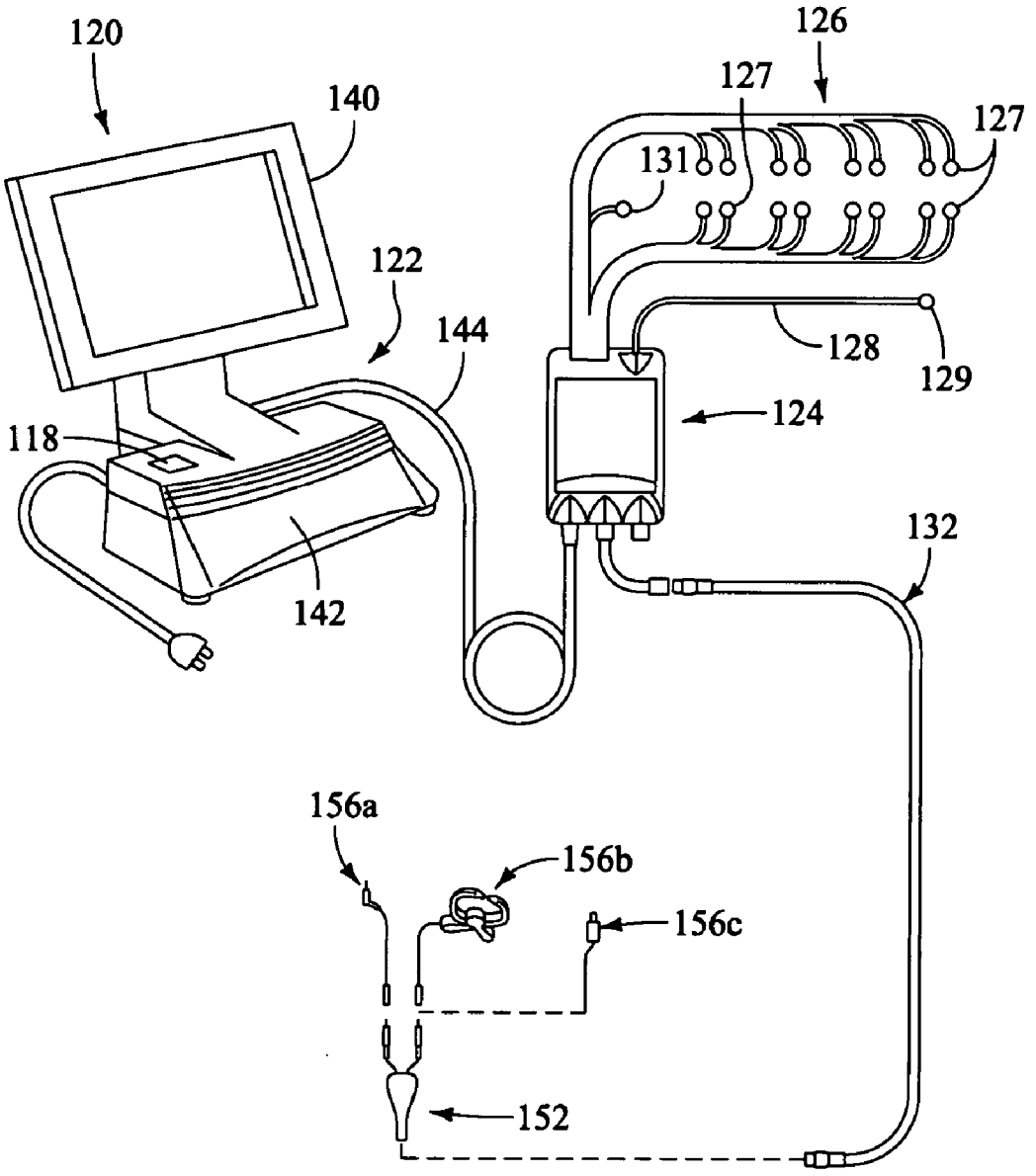

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156b
156c
152

FIG. 19

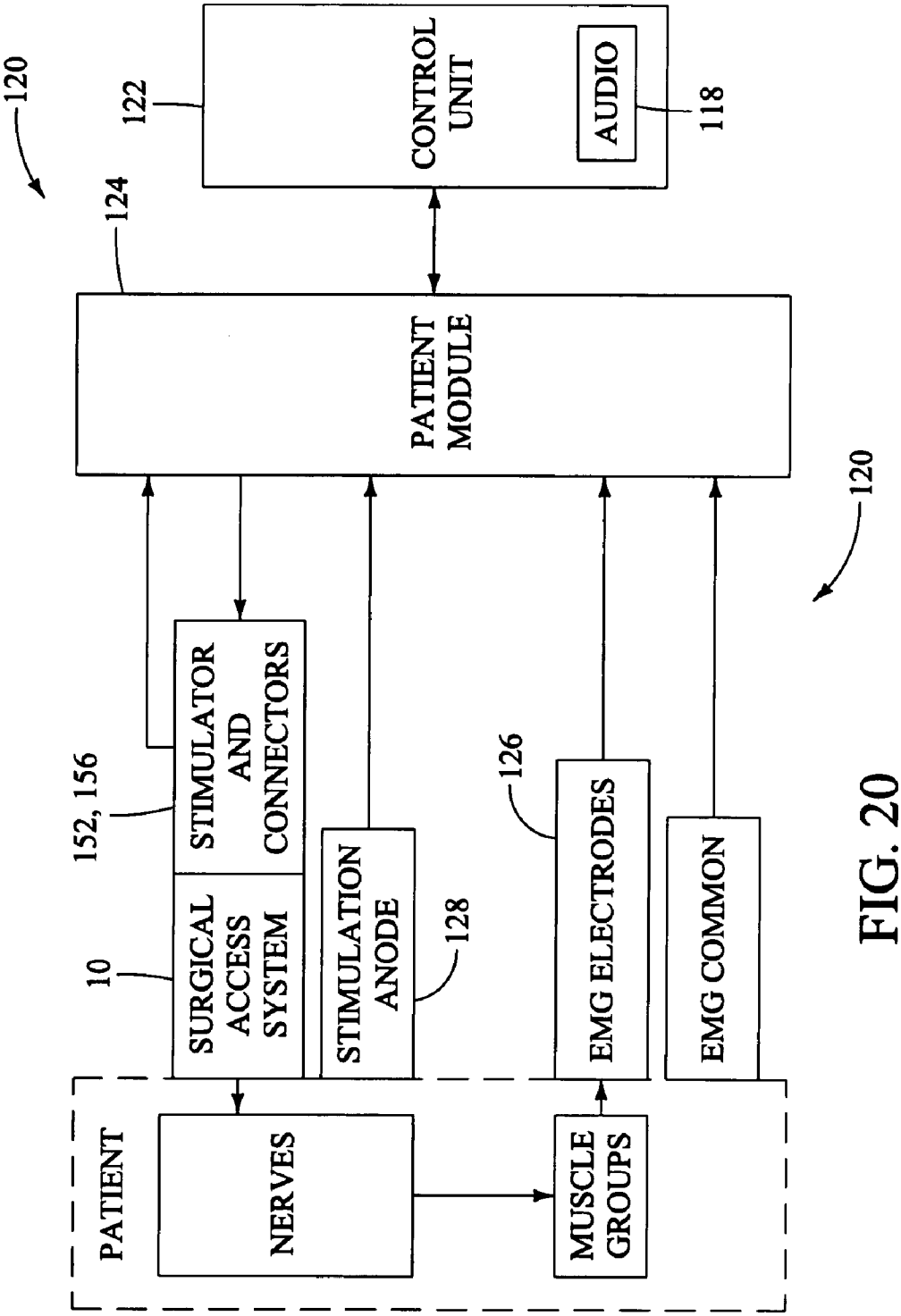

120
122
CONTROL UNIT
AUDIO
118
124
PATIENT MODULE
120
152, 156
STIMULATOR AND CONNECTORS
126
10
SURGICAL ACCESS SYSTEM
STIMULATION ANODE
128
EMG ELECTRODES
EMG COMMON
PATIENT
NERVES
MUSCLE GROUPS

FIG. 20

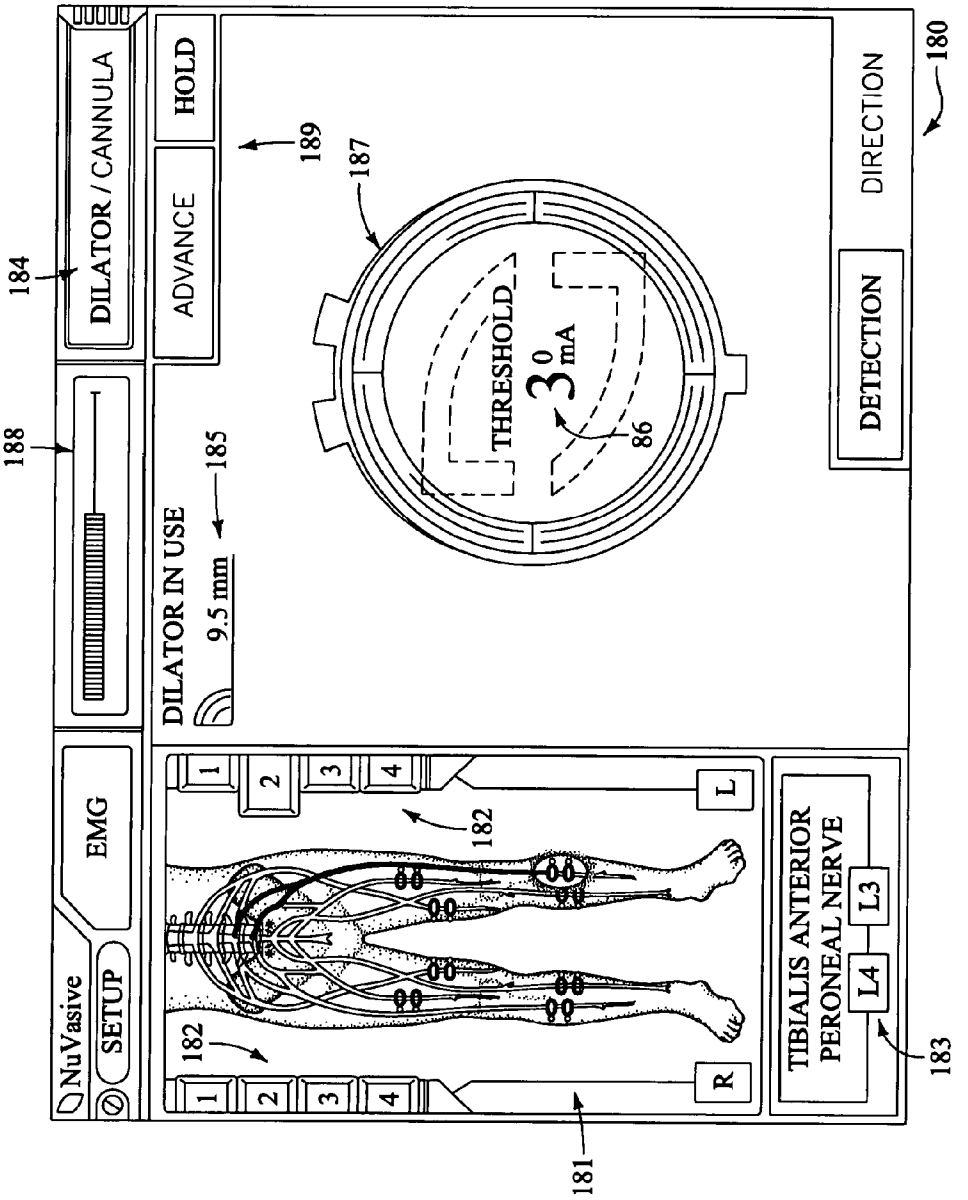

NuVasive
SETUP
EMG
DILATOR / CANNULA
ADVANCE
HOLD
DILATOR IN USE
9.5 mm
THRESHOLD
30 mA
86
DETECTION
DIRECTION
TIBIALIS ANTERIOR
PERONEAL NERVE
L3
L4
R
L
1
2
3
4
180
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FIG. 21

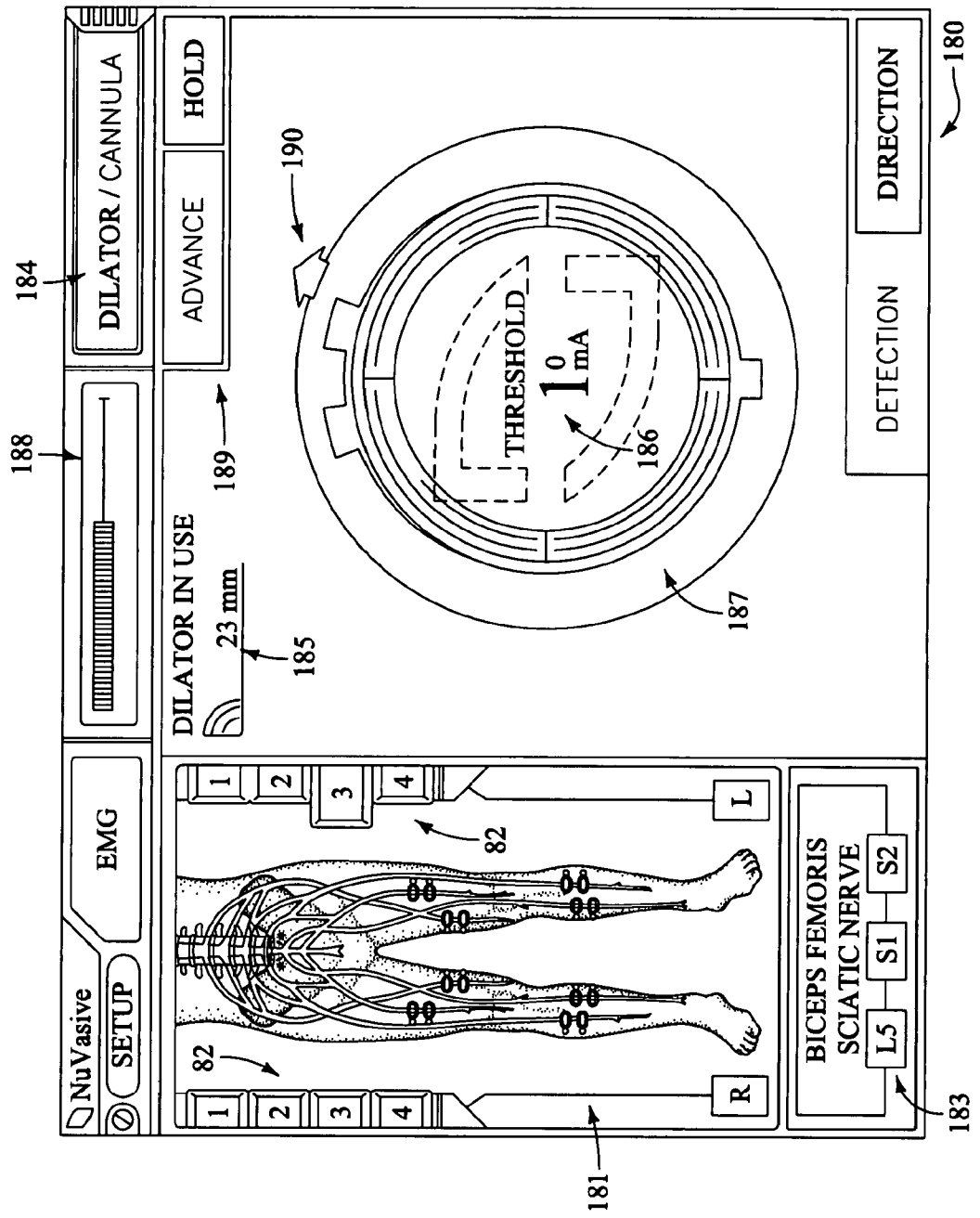

NuVasive
SETUP
EMG
DILATOR / CANNULA
ADVANCE
HOLD
DILATOR IN USE
23 mm
THRESHOLD
10 mA
1
DETECTION
DIRECTION
BICEPS FEMORIS
SCIATIC NERVE
L5
S1
S2
R
L
1
2
3
4
82
184
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FIG. 22

SURGICAL ACCESS SYSTEM AND RELATED METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a division of U.S. patent application Ser. No. 11/789,284, filed on Apr. 23, 2007 (now U.S. Pat. No. 8,016,767), which is a division of U.S. patent application Ser. No. 11/137,169 (now U.S. Pat. No. 7,207,949), filed on May 25, 2005, which is a continuation of PCT Application Serial No. PCT/US04/31768, filed Sep. 27, 2004, which claims the benefit of priority from U.S. Provisional Patent Application Ser. No. 60/506,136, filed Sep. 25, 2003, the entire contents of which are hereby expressly incorporated by reference into this disclosure as if set forth fully herein. The present application also incorporates by reference the following commonly owned patent applications in their entireties: PCT App. Ser. No. PCT/US02/22247, entitled "System and Methods for Determining Nerve Proximity, Direction, and Pathology During Surgery," filed on Jul. 11, 2002; PCT App. Ser. No. PCT/US02/30617, entitled "System and Methods for Performing Surgical Procedures and Assessments," filed on Sep. 25, 2002; PCT App. Ser. No. PCT/US02/35047, entitled "System and Methods for Performing Percutaneous Pedicle Integrity Assessments," filed on Oct. 30, 2002; and PCT App. Ser. No. PCT/US03/02056, entitled "System and Methods for Determining Nerve Direction to a Surgical Instrument," filed Jan. 15, 2003 (collectively "NeuroVision PCT Applications").

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to systems and methods for performing surgical procedures and, more particularly, for accessing a surgical target site in order to perform surgical procedures.

II. Discussion of the Prior Art

A noteworthy trend in the medical community is the move away from performing surgery via traditional "open" techniques in favor of minimally invasive or minimal access techniques. Open surgical techniques are generally undesirable in that they typically require large incisions and high amounts of tissue displacement to gain access to the surgical target site, which produces concomitantly high amounts of pain, lengthened hospitalization (increasing health care costs), and high morbidity in the patient population. Less-invasive surgical techniques (including so-called "minimal access" and "minimally invasive" techniques) are gaining favor due to the fact that they involve accessing the surgical target site via incisions of substantially smaller size with greatly reduced tissue displacement requirements. This, in turn, reduces the pain, morbidity and cost associated with such procedures. The access systems developed to date, however, fail in various respects to meet all the needs of the surgeon population.

One drawback associated with prior art surgical access systems relates to the ease with which the operative corridor can be created, as well as maintained over time, depending upon the particular surgical target site. For example, when accessing surgical target sites located beneath or behind musculature or other relatively strong tissue (such as, by way of example only, the psoas muscle adjacent to the spine), it has been found that advancing an operative corridor-establishing instrument directly through such tissues can be challenging and/or lead to unwanted or undesirable effects (such as stressing or tearing the tissues). While certain efforts have been undertaken to reduce the trauma to tissue while creating an operative corridor, such as (by way of example only) the sequential dilation system of U.S. Pat. No. 5,792,044 to Foley et al., these attempts are nonetheless limited in their applicability based on the relatively narrow operative corridor. More specifically, based on the generally cylindrical nature of the so-called "working cannula," the degree to which instruments can be manipulated and/or angled within the cannula can be generally limited or restrictive, particularly if the surgical target site is a relatively deep within the patient.

Efforts have been undertaken to overcome this drawback, such as shown in U.S. Pat. No. 6,524,320 to DiPoto, wherein an expandable portion is provided at the distal end of a cannula for creating a region of increased cross-sectional area adjacent to the surgical target site. While this system may provide for improved instrument manipulation relative to sequential dilation access systems (at least at deep sites within the patient), it is nonetheless flawed in that the deployment of the expandable portion may inadvertently compress or impinge upon sensitive tissues adjacent to the surgical target site. For example, in anatomical regions having neural and/or vasculature structures, such a blind expansion may cause the expandable portion to impinge upon these sensitive tissues and cause neural and/or vasculature compromise, damage and/or pain for the patient.

This highlights yet another drawback with the prior art surgical access systems, namely, the challenges in establishing an operative corridor through or near tissue having major neural structures which, if contacted or impinged, may result in neural impairment for the patient. Due to the threat of contacting such neural structures, efforts thus far have largely restricted to establishing operative corridors through tissue having little or substantially reduced neural structures, which effectively limits the number of ways a given surgical target site can be accessed. This can be seen, by way of example only, in the spinal arts, where the exiting nerve roots and neural plexus structures in the psoas muscle have rendered a lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine virtually impossible. Instead, spine surgeons are largely restricted to accessing the spine from the posterior (to perform, among other procedures, posterior lumbar interbody fusion (PLIF)) or from the anterior (to perform, among other procedures, anterior lumbar interbody fusion (ALIF)).

Posterior-access procedures involve traversing a shorter distance within the patient to establish the operative corridor, albeit at the price of oftentimes having to reduce or cut away part of the posterior bony structures (i.e. lamina, facets, spinous process) in order to reach the target site (which typically comprises the disc space). Anterior-access procedures are relatively simple for surgeons in that they do not involve reducing or cutting away bony structures to reach the surgical target site. However, they are nonetheless disadvantageous in that they require traversing through a much greater distance within the patient to establish the operative corridor, oftentimes requiring an additional surgeon to assist with moving the various internal organs out of the way to create the operative corridor.

The present invention is directed at eliminating, or at least minimizing the effects of, the above-identified drawbacks in the prior art.

SUMMARY OF THE INVENTION

The present invention accomplishes this goal by providing a novel access system and related methods which involve detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the

establishment of an operative corridor through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient. It is expressly noted that, although described herein largely in terms of use in spinal surgery, the access system of the present invention is suitable for use in any number of additional surgical procedures wherein tissue having significant neural structures must be passed through (or near) in order to establish an operative corridor.

According to one broad aspect of the present invention, the access system comprises a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures. The tissue distraction assembly (in conjunction with one or more elements of the tissue retraction assembly) is capable of, as an initial step, distracting a region of tissue between the skin of the patient and the surgical target site. The tissue retraction assembly is capable of, as a secondary step, being introduced into this distracted region to thereby define and establish the operative corridor. Once established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure. The electrode(s) are capable of, during both tissue distraction and retraction, detecting the existence of (and optionally the distance and/or direction to) neural structures such that the operative corridor may be established through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient. In this fashion, the access system of the present invention may be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

The tissue distraction assembly may include any number of components capable of performing the necessary distraction. By way of example only, the tissue distraction assembly may include a K-wire, an initial dilator of split construction, and one or more dilators of traditional (that is, non-split) construction for performing the necessary tissue distraction to receive the remainder of the tissue retractor assembly thereafter. One or more electrodes may be provided on one or more of the K-wire and dilator(s) to detect the presence of (and optionally the distance and/or direction to) neural structures during tissue distraction.

The tissue retraction assembly may include any number of components capable of performing the necessary retraction. By way of example only, the tissue retraction assembly may include one or more retractor blades extending from a handle assembly. The handle assembly may be manipulated to open the retractor assembly; that is, allowing the retractor blades to separate from one another (simultaneously or sequentially) to create an operative corridor to the surgical target site. In a preferred embodiment, this is accomplished by maintaining a posterior retractor blade in a fixed position relative to the surgical target site (so as to avoid having it impinge upon any exiting nerve roots near the posterior elements of the spine) while the additional retractor blades (i.e. cephalad-most and caudal-most blades) are moved or otherwise translated away from the posterior retractor blade (and each other) so as to create the operative corridor in a fashion that doesn't infringe upon the region of the exiting nerve roots.

The retractor blades may be optionally dimensioned to receive and direct a rigid shim element to augment the structural stability of the retractor blades and thereby ensure the operative corridor, once established, will not decrease or become more restricted, such as may result if distal ends of the retractor blades were permitted to "slide" or otherwise move in response to the force exerted by the displaced tissue. In a preferred embodiment, only the posterior retractor blade is equipped with such a rigid shim element. In an optional aspect, this shim element may be advanced into the disc space after the posterior retractor blade is positioned, but before the retractor is opened into the fully retracted position. The rigid shim element is preferably oriented within the disc space such that is distracts the adjacent vertebral bodies, which serves to restore disc height. It also preferably advances a sufficient distance within the disc space (preferably past the midline), which serves the dual purpose of preventing post-operative scoliosis and forming a protective barrier (preventing the migration of tissue (such as nerve roots) into the operative field and the inadvertent advancement of instruments outside the operative field).

The retractor blades may optionally be equipped with a mechanism for transporting or emitting light at or near the surgical target site to aid the surgeon's ability to visualize the surgical target site, instruments and/or implants during the given surgical procedure. According to one embodiment, this mechanism may comprise, but need not be limited to, coupling one or more light sources to the retractor blades such that the terminal ends are capable of emitting light at or near the surgical target site. According to another embodiment, this mechanism may comprise, but need not be limited to, constructing the retractor blades of suitable material (such as clear polycarbonate) and configuration such that light may be transmitted generally distally through the walls of the retractor blade light to shine light at or near the surgical target site. This may be performed by providing the retractor blades having light-transmission characteristics (such as with clear polycarbonate construction) and transmitting the light almost entirely within the walls of the retractor blade (such as by frosting or otherwise rendering opaque portions of the exterior and/or interior) until it exits a portion along the interior (or medially-facing) surface of the retractor blade to shine at or near the surgical target site. The exit portion may be optimally configured such that the light is directed towards the approximate center of the surgical target site and may be provided along the entire inner periphery of the retractor blade or one or more portions therealong.

BRIEF DESCRIPTION OF THE DRAWINGS

Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

FIG. **1** is a perspective view of a tissue retraction assembly (in use) forming part of a surgical access system according to the present invention;

FIGS. **2-3** are perspective views illustrating the front and back of a shim element for use with a posterior retractor blade of the retractor according to the retractor of the present invention;

FIGS. **4-5** are perspective views illustrating the front and back of a narrow retractor extender for use with one of a cephalad and caudal retractor blade according to the retractor of the present invention;

FIGS. **6-7** are perspective views illustrating the front and back of a wide retractor extender for use with one of a cephalad and caudal retractor blade according to the retractor of the present invention;

FIG. **8** is a perspective, partially exploded view of the refractor assembly of the present invention, without the retractor blades;

FIG. **9** is a perspective view illustrating the components and use of an initial distraction assembly (i.e. K-wire, an initial dilating cannula with handle, and a split-dilator housed within the initial dilating cannula) forming part of the surgical access system according to the present invention, for use in distracting to a surgical target site (i.e. annulus);

FIG. **10** is a perspective view illustrating the K-wire and split-dilator of the initial distraction assembly with the initial dilating cannula and handle removed;

FIG. **11** is a posterior view of the vertebral target site illustrating the split-dilator of the present invention in use distracting in a generally cephalad-caudal fashion according to one aspect of the present invention;

FIG. **12** is a side view illustrating the use of a secondary distraction assembly (comprising a plurality of dilating cannulae over the K-wire) to further distract tissue between the skin of the patient and the surgical target site according to the present invention;

FIG. **13** is a side view of a retractor assembly according to the present invention, comprising a handle assembly having three (3) retractor blades extending there from (posterior, cephalad-most, and caudal-most) disposed over the secondary distraction assembly of FIG. **12** (shown in a first, closed position);

FIG. **14** is a side view of a retractor assembly according to the present invention, comprising a handle assembly having three (3) retractor blades extending there from (posterior, cephalad-most, and caudal-most) with the secondary distraction assembly of FIG. **12** removed and shim element introduced;

FIGS. **15-16** are perspective and top views, respectively, of the retractor assembly in a second, opened (i.e. retracted) position to thereby create an operative corridor to a surgical target site according to the present invention;

FIGS. **17-18** are perspective and side views, respectively, of the retractor assembly in the second, opened (i.e. retracted) position (with the secondary distraction assembly removed) and with the retractor extenders of FIGS. **4-5** and **6-7** coupled to the retractor according to the present invention.

FIG. **19** is a perspective view of an exemplary nerve monitoring system capable of performing nerve monitoring before, during and after the creating of an operative corridor to a surgical target site using the surgical access system in accordance with the present invention;

FIG. **20** is a block diagram of the nerve monitoring system shown in FIG. **19**; and

FIGS. **21-22** are screen displays illustrating exemplary features and information communicated to a user during the use of the nerve monitoring system of FIG. **19**.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. It is furthermore to be readily understood that, although discussed below primarily within the context of spinal surgery, the surgical access system of the present invention may be employed in any number of anatomical settings to provide access to any number of different surgical target sites throughout the body. The surgical access system disclosed herein boasts a variety of inventive features and components that warrant patent protection, both individually and in combination.

The present invention involves accessing a surgical target site in a fashion less invasive than traditional "open" surgeries and doing so in a manner that provides access in spite of the neural structures required to be passed through (or near) in order to establish an operative corridor to the surgical target site. Generally speaking, the surgical access system of the present invention accomplishes this by providing a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures.

These electrodes are preferably provided for use with a nerve surveillance system such as, by way of example, the type shown and described in the co-pending and commonly assigned NeuroVision PCT Applications referenced above, the entire contents of which are expressly incorporated by reference as if set forth herein in their entirety. Generally speaking, this nerve surveillance system is capable of detecting the existence of (and optionally the distance and/or direction to) neural structures during the distraction and retraction of tissue by detecting the presence of nerves by applying a stimulation signal to such instruments and monitoring the evoked EMG signals from the myotomes associated with the nerves being passed by the distraction and retraction systems of the present invention. In so doing, the system as a whole (including the surgical access system of the present invention) may be used to form an operative corridor through (or near) any of a variety of tissues having such neural structures, particularly those which, if contacted or impinged, may otherwise result in neural impairment for the patient. In this fashion, the access system of the present invention may be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

The tissue distraction assembly of the present invention (comprising a K-wire, an initial dilator, and a split-dilator disposed within the initial dilator) is employed to distract the tissues extending between the skin of the patient and a given surgical target site (preferably along the posterior region of the target intervertebral disc). A secondary distraction assembly (i.e. a plurality of sequentially dilating cannulae) may optionally be employed after the initial distraction assembly to further distract the tissue. Once distracted, the resulting void or distracted region within the patient is of sufficient size to accommodate a tissue retraction assembly of the present invention. More specifically, the tissue retraction assembly (comprising a plurality of retractor blades extending from a handle assembly) may be advanced relative to the secondary distraction assembly such that the retractor blades, in a first, closed position, are advanced over the exterior of the secondary distraction assembly. At that point, the handle assembly may be operated to move the retractor blades into a second, open or "retracted" position to create an operative corridor to the surgical target site.

According to one aspect of the invention, following (or before) this retraction, a posterior shim element (which is preferably slideably engaged with the posterior retractor

blade) may be advanced such that a distal shim extension in positioned within the posterior region of the disc space. If done before retraction, this helps ensure that the posterior retractor blade will not move posteriorly during the retraction process, even though the other retractor blades (i.e. cephalad-most and caudal-most) are able to move and thereby create an operative corridor. Fixing the posterior retractor blade in this fashion serves several important functions. First, the distal end of the shim element serves to distract the adjacent vertebral bodies, thereby restoring disc height. It also rigidly couples the posterior retractor blade in fixed relation relative to the vertebral bodies. The posterior shim element also helps ensure that surgical instruments employed within the operative corridor are incapable of being advanced outside the operative corridor, preventing inadvertent contact with the exiting nerve roots during the surgery. Once in the appropriate retracted state, the cephalad-most and caudal-most retractor blades may be locked in position and, thereafter, retractor extenders advanced therealong to prevent the ingress or egress of instruments or biological structures (i.e. nerves, vasculature, etc. . . .) into or out of the operative corridor. Once the operative corridor is established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure.

FIG. **1** illustrates a tissue retraction assembly **10** forming part of a surgical access system according to the present invention. The retraction assembly **10** includes a plurality of retractor blades extending from a handle assembly **20**. By way of example only, the handle assembly **20** is provided with a first retractor blade **12**, a second retractor blade **16**, and a third retractor blade **18**. The retractor assembly **10** is shown in a fully retracted or "open" configuration, with the retractor blades **12**, **16**, **18** positioned a distance from one another so as to form an operative corridor **15** there between and extending to a surgical target site (e.g. an annulus of an intervertebral disc). Although shown and described below with regard to the three-bladed configuration, it is to be readily appreciated that the number of retractor blades may be increased or decreased without departing from the scope of the present invention. Moreover, although described and shown herein with reference to a generally lateral approach to a spinal surgical target site (with the first blade **12** being the "posterior" blade, the second blade **16** being the "cephalad-most" blade, and the third blade **18** being the "caudal-most" blade), it will be appreciated that the refractor assembly **10** of the present invention may find use in any number of different surgical approaches, including generally posterior, generally postero-lateral, generally anterior and generally antero-lateral.

The retractor blades **12**, **16**, **18** may be equipped with various additional features or components. By way of example only, posterior retractor blade **12** may be equipped with a shim element **22** (shown more clearly in FIGS. **2-3**). Shim element **22** serves to distract the adjacent vertebral bodies (thereby restoring disc height), helps secure the retractor assembly **10** relative to the surgical target site, and forms a protective barrier to prevent the ingress or egress of instruments or biological structures (i.e. nerves, vasculature, etc. . . .) into or out of the operative corridor. Each of the remaining retractor blades (cephalad-most blade **16** and caudal-most blade **18**) may be equipped with a refractor extender, such as the narrow refractor extender **24** shown in FIGS. **4-5** or the wide retractor extender **25** shown in FIGS. **6-7**. The retractor extenders **24**/**25** extend from the cephalad-most and caudal-most retractor blades **16**, **18** to form a protective barrier to prevent the ingress or egress of instruments or biological structures (i.e. nerves, vasculature, etc. . . .) into or out of the operative corridor **15**.

According to the present invention, any or all of the retractor blades **12**, **16**, **18**, the shim element **22** and/or the retractor extenders **24**/**25** may be provided with one or more electrodes **39** (preferably at their distal regions) equipped for use with a nerve surveillance system, such as, by way of example, the type shown and described in the NeuroVision PCT Applications. Each of the shim element **22** and/or the retractor extenders **24**/**25** may also be equipped with a mechanism to selectively and releasably engage with the respective retractor blades **12**, **16**, **18**. By way of example only, this may be accomplished by configuring the shim element **22** and/or the retractor extenders **24**/**25** with a tab element **27** capable of engaging with corresponding ratchet-like grooves (shown at **29** in FIG. **1**) along the inner-facing surfaces of the retractor blades **12**, **16**, **18**. Each of the shim element **22** and/or the retractor extenders **24**/**25** is provided with a pair of engagement elements **37** having, by way of example only, a generally dove-tailed cross-sectional shape. The engagement elements **37** are dimensioned to engage with receiving portions on the respective retractor blades **12**, **16**, **18**. In a preferred embodiment, each of the shim element **22** and/or the retractor extenders **24**/**25** are provided with an elongate slot **43** for engagement with an insertion tool (not shown). Each tab member **27** is also equipped with an enlarged tooth element **49** which engages within corresponding grooves **29** provided along the inner surface of the retractor blades **12**, **16**, **18**.

The handle assembly **20** may be coupled to any number of mechanisms for rigidly registering the handle assembly **20** in fixed relation to the operative site, such as through the use of an articulating arm mounted to the operating table. The handle assembly **20** includes first and second arm members **26**, **28** hingedly coupled via coupling mechanism shown generally at **30**. The cephalad-most retractor blade **16** is rigidly coupled (generally perpendicularly) to the end of the first arm member **26**. The caudal-most retractor blade **18** is rigidly coupled (generally perpendicularly) to the end of the second arm member **28**. The posterior retractor blade **12** is rigidly coupled (generally perpendicularly to) a translating member **17**, which is coupled to the handle assembly **20** via a linkage assembly shown generally at **14**. The linkage assembly **14** includes a roller member **34** having a pair of manual knob members **36** which, when rotated via manual actuation by a user, causes teeth **35** on the roller member **34** to engage within ratchet-like grooves **37** in the translating member **17**. Thus, manual operation of the knobs **36** causes the translating member **17** to move relative to the first and second arm members **26**, **28**.

Through the use of handle extenders **31**, **33** (FIG. **8**), the arms **26**, **28** may be simultaneously opened such that the cephalad-most and caudal-most retractor blades **16**, **18** move away from one another. In this fashion, the dimension and/or shape of the operative corridor **15** may be tailored depending upon the degree to which the translating member **17** is manipulated relative to the arms **26**, **28**. That is, the operative corridor **15** may be tailored to provide any number of suitable cross-sectional shapes, including but not limited to a generally circular cross-section, a generally ellipsoidal cross-section, and/or an oval cross-section. Optional light emitting devices **39** may be coupled to one or more of the retractor blades **12**, **16**, **18** to direct light down the operative corridor **15**.

FIG. **9** illustrates an initial distraction assembly **40** forming part of the surgical access system according to the present invention. The initial distraction assembly **40** includes a

K-wire **42**, an initial dilating cannula **44** with handle **46**, and a split-dilator **48** housed within the initial dilating cannula **44**. In use, the K-wire **42** and split-dilator **48** are disposed within the initial dilating cannula **44** and the entire assembly **40** advanced through the tissue towards the surgical target site (i.e. annulus). Again, this is preferably accomplished while employing the nerve detection and/or direction features described above. After the initial dilating assembly **40** is advanced such that the distal ends of the split-dilator **48** and initial dilator **44** are positioned within the disc space (FIG. **9**), the initial dilator **44** and handle **46** are removed (FIG. **10**) to thereby leave the split-dilator **48** and K-wire **42** in place. As shown in FIG. **11**, the split-dilator **48** is thereafter split such that the respective halves **48***a*, **48***b* are separated from one another to distract tissue in a generally cephalad-caudal fashion relative to the target site. The split dilator **48** may thereafter be relaxed (allowing the dilator halves **48***a*, **48***b* to come together) and rotated such that the dilator halves **48***a*, **48***b* are disposed in the anterior-posterior plane. Once rotated in this manner, the dilator halves **48***a*, **48***b* are again separated to distract tissue in a generally anterior-posterior fashion. Each dilator halve **48***a*, **48***b* may be, according to the present invention, provided with one or more electrodes (preferably at their distal regions) equipped for use with a nerve surveillance system, such as, by way of example, the type shown and described in the NeuroVision PCT Applications.

Following this initial distraction, a secondary distraction may be optionally undertaken, such as via a sequential dilation system **50** as shown in FIG. **12**. According to the present invention, the sequential dilation system **50** may include the K-wire **42**, the initial dilator **44**, and one or more supplemental dilators **52**, **54** for the purpose of further dilating the tissue down to the surgical target site. Once again, each component of the secondary distraction assembly **50** (namely, the K-wire **42**, the initial dilator **44**, and the supplemental dilators **52**, **54** may be, according to the present invention, provided with one or more electrodes (preferably at their distal regions) equipped for use with a nerve surveillance system, such as, by way of example, the type shown and described in the NeuroVision PCT Applications.

As shown in FIG. **13**, the retraction assembly **10** of the present invention is thereafter advanced along the exterior of the sequential dilation system **50**. This is accomplished by maintaining the retractor blades **12**, **16**, **18** in a first, closed position (with the retractor blades **12-16** in generally abutting relation to one another). Once advanced to the surgical target site, the sequential dilation assembly **50** may be removed and the shim element **22** engaged with the posterior refractor blade **12** such that the distal end thereof extends into the disc space as shown in FIG. **14**. At this point, the handle assembly **20** may be operated to move the retractor blades **16**, **18** into a second, open or "retracted" position as shown generally in FIGS. **15-16**. As one can see, the posterior retractor blade **12** is allowed to stay in the same general position during this process, such that the cephalad-most and caudal-most refractor blades **14**, **16** move away from the posterior retractor blade **12**. At this point, the narrow and wide retractor extenders **24**, **25** may be engaged with the caudal-most retractor blade **18** and cephalad-most retractor blade **16**, respectively, as shown in FIGS. **17-18**.

As mentioned above, any number of distraction components and/or retraction components (including but not limited to those described herein) may be equipped to detect the presence of (and optionally the distance and/or direction to) neural structures during the steps tissue distraction and/or retraction. This is accomplished by employing the following steps: (1) one or more stimulation electrodes are provided on the various distraction and/or retraction components; (2) a stimulation source (e.g. voltage or current) is coupled to the stimulation electrodes; (3) a stimulation signal is emitted from the stimulation electrodes as the various components are advanced towards or maintained at or near the surgical target site; and (4) the patient is monitored to determine if the stimulation signal causes muscles associated with nerves or neural structures within the tissue to innervate. If the nerves innervate, this may indicate that neural structures may be in close proximity to the distraction and/or retraction components.

Neural monitoring may be accomplished via any number of suitable fashions, including but not limited to observing visual twitches in muscle groups associated with the neural structures likely to found in the tissue, as well as any number of monitoring systems, including but not limited to any commercially available "traditional" electromyography (EMG) system (that is, typically operated by a neurophysiologist). Such monitoring may also be carried out via the surgeon-driven EMG monitoring system shown and described in the following commonly owned and co-pending NeuroVision PCT Applications referenced above. In any case (visual monitoring, traditional EMG and/or surgeon-driven EMG monitoring), the access system of the present invention may advantageously be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

FIGS. **19-20** illustrate, by way of example only, a monitoring system **120** of the type disclosed in the NeuroVision PCT Applications suitable for use with the surgical access system **10** of the present invention. The monitoring system **120** includes a control unit **122**, a patient module **124**, and an EMG harness **126** and return electrode **128** coupled to the patient module **124**, and a cable **132** for establishing electrical communication between the patient module **124** and the surgical access system of the present invention (retractor assembly **10** of FIG. **1** and distraction assemblies **40**, **50** of FIGS. **9-12**). More specifically, this electrical communication can be achieved by providing, by way of example only, a hand-held stimulation controller **152** capable of selectively providing a stimulation signal (due to the operation of manually operated buttons on the hand-held stimulation controller **152**) to one or more connectors **156***a*, **156***b*, **156***c*. The connectors **156***a*, **156***b*, **156***c* are suitable to establish electrical communication between the hand-held stimulation controller **152** and (by way of example only) the stimulation electrodes on the K-wire **42**, the dilators **44**, **48**, **52**, **54**, the refractor blades **12**, **16**, **18** and/or the shim members **22**, **24**, **25** (collectively "surgical access instruments").

In order to use the monitoring system **120**, then, these surgical access instruments must be connected to the connectors **156***a*, **156***b* and/or **156***c*, at which point the user may selectively initiate a stimulation signal (preferably, a current signal) from the control unit **122** to a particular surgical access instruments. Stimulating the electrode(s) on these surgical access instruments before, during and/or after establishing operative corridor will cause nerves that come into close or relative proximity to the surgical access instruments to depolarize, producing a response in a myotome associated with the innervated nerve.

The control unit **122** includes a touch screen display **140** and a base **142**, which collectively contain the essential processing capabilities (software and/or hardware) for controlling the monitoring system **120**. The control unit **122** may include an audio unit **118** that emits sounds according to a location of a surgical element with respect to a nerve. The

patient module **124** is connected to the control unit **122** via a data cable **144**, which establishes the electrical connections and communications (digital and/or analog) between the control unit **122** and patient module **124**. The main functions of the control unit **122** include receiving user commands via the touch screen display **140**, activating stimulation electrodes on the surgical access instruments, processing signal data according to defined algorithms, displaying received parameters and processed data, and monitoring system status and report fault conditions. The touch screen display **140** is preferably equipped with a graphical user interface (GUI) capable of communicating information to the user and receiving instructions from the user. The display **140** and/or base **142** may contain patient module interface circuitry (hardware and/or software) that commands the stimulation sources, receives digitized signals and other information from the patient module **124**, processes the EMG responses to extract characteristic information for each muscle group, and displays the processed data to the operator via the display **140**.

In one embodiment, the monitoring system **120** is capable of determining nerve direction relative to one or more of the K-wire **42**, the dilators **44**, **48**, **52**, **54**, the retractor blades **12**, **16**, **18** and/or the shim elements **22**, **24**, **25** before, during and/or following the creation of an operative corridor to a surgical target site. Monitoring system **120** accomplishes this by having the control unit **122** and patient module **124** cooperate to send electrical stimulation signals to one or more of the stimulation electrodes provided on these instruments. Depending upon the location of the surgical access system **10** within a patient (and more particularly, to any neural structures), the stimulation signals may cause nerves adjacent to or in the general proximity of the surgical access system **10** to depolarize. This causes muscle groups to innervate and generate EMG responses, which can be sensed via the EMG harness **126**. The nerve direction feature of the system **120** is based on assessing the evoked response of the various muscle myotomes monitored by the system **120** via the EMG harness **126**.

By monitoring the myotomes associated with the nerves (via the EMG harness **126** and recording electrode **127**) and assessing the resulting EMG responses (via the control unit **122**), the surgical access system **10** is capable of detecting the presence of (and optionally the distant and/or direction to) such nerves. This provides the ability to actively negotiate around or past such nerves to safely and reproducibly form the operative corridor to a particular surgical target site, as well as monitor to ensure that no neural structures migrate into contact with the surgical access system **10** after the operative corridor has been established. In spinal surgery, for example, this is particularly advantageous in that the surgical access system **10** may be particularly suited for establishing an operative corridor to an intervertebral target site in a postero-lateral, trans-psoas fashion so as to avoid the bony posterior elements of the spinal column.

FIGS. **21-22** are exemplary screen displays (to be shown on the display **140**) illustrating one embodiment of the nerve direction feature of the monitoring system shown and described with reference to FIGS. **19-20**. These screen displays are intended to communicate a variety of information to the surgeon in an easy-to-interpret fashion. This information may include, but is not necessarily limited to, a display of the function **180** (in this case "DIRECTION"), a graphical representation of a patient **181**, the myotome levels being monitored **182**, the nerve or group associated with a displayed myotome **183**, the name of the instrument being used **184** (in this case, a dilator **46**, **48**), the size of the instrument being used **185**, the stimulation threshold current **186**, a graphical representation of the instrument being used **187** (in this case, a cross-sectional view of a dilator **44**, **48**) to provide a reference point from which to illustrate relative direction of the instrument to the nerve, the stimulation current being applied to the stimulation electrodes **188**, instructions for the user **189** (in this case, "ADVANCE" and/or "HOLD"), and (in FIG. **22**) an arrow **190** indicating the direction from the instrument to a nerve. This information may be communicated in any number of suitable fashions, including but not limited to the use of visual indicia (such as alpha-numeric characters, light-emitting elements, and/or graphics) and audio communications (such as a speaker element). Although shown with specific reference to a dilating cannula (such as at **184**), it is to be readily appreciated that the present invention is deemed to include providing similar information on the display **140** during the use of any or all of the various instruments forming the surgical access system **10** of the present invention, including the initial distraction assembly **40** (i.e. the K-wire **42** and dilators **44**, **48**) and/or the retractor blades **12**, **16**, **18** and/or the shim elements **22**, **24**, **25**.

As evident from the above discussion and drawings, the present invention accomplishes the goal of gaining access a surgical target site in a fashion less invasive than traditional "open" surgeries and, moreover, does so in a manner that provides the ability to access such a surgical target site regardless of the neural structures required to be passed through (or near) in order to establish an operative corridor to the surgical target site. The present invention furthermore provides the ability to perform neural monitoring in the tissue or regions adjacent the surgical target site during any procedures performed after the operative corridor has been established. The surgical access system of the present invention can be used in any of a wide variety of surgical or medical applications, above and beyond the spinal applications discussed herein. Such spinal applications may include any procedure wherein instruments, devices, implants and/or compounds are to be introduced into or adjacent the surgical target site, including but not limited to discectomy, fusion (including PLIF, ALIF, TLIF and any fusion effectuated via a lateral or far-lateral approach and involving, by way of example, the introduction of bone products (such as allograft or autograft) and/or devices having ceramic, metal and/or plastic construction (such as mesh) and/or compounds such as bone morphogenic protein), total disc replacement, etc. . . .).

Moreover, the surgical access system of the present invention opens the possibility of accessing an increased number of surgical target sites in a "less invasive" fashion by eliminating or greatly reducing the threat of contacting nerves or neural structures while establishing an operative corridor through or near tissues containing such nerves or neural structures. In so doing, the surgical access system of the present invention represents a significant advancement capable of improving patient care (via reduced pain due to "less-invasive" access and reduced or eliminated risk of neural contact before, during, and after the establishment of the operative corridor) and lowering health care costs (via reduced hospitalization based on "less-invasive" access and increased number of suitable surgical target sites based on neural monitoring). Collectively, these translate into major improvements to the overall standard of care available to the patient population, both domestically and overseas.

What is claimed is:

1. A system for forming an operating corridor to a lumbar spine, comprising:

an elongate member deliverable to a spinal disc along a lateral, trans-psoas path to the lumbar spine such that a distal tip region of the elongate member penetrates into

an annulus of the spinal disc, the distal tip region of the elongate member including a stimulation electrode to deliver electrical stimulation for nerve monitoring when the stimulation electrode is positioned along the lateral, trans-psoas path to the lumbar spine;

a dilator system to create a distraction corridor along the lateral, trans-psoas path to the lumbar spine, the dilator system comprising at least one dilator cannula that slidably engages an exterior of the elongate member, the at least one dilator being deliverable to the spinal disc along the lateral, trans-psoas path to the lumbar spine;

a three-bladed retractor assembly slidable over the dilator system toward the spinal disc along the lateral, trans-psoas path, the three-bladed retractor assembly including:

a blade holder assembly and first, second, and third retractor blades that extend generally perpendicularly relative to arm members of the blade holder assembly,

wherein the three-bladed retractor assembly is adjustable from a first position in which the first, second, and third retractor blades are adjacent to one another and slidable over the dilator system to a second position in which the second and third retractor blades are moved away from the first retractor blade to enlarge the distraction corridor and thereby form an operative corridor along the lateral, trans-psoas path to the lumbar spine,

wherein the first retractor blade is linearly movable relative to the second and third retractor blades in response to rotation of a knob element on the blade holder assembly, and

wherein the second and third retractor blades are movable relative to the first blade in response to pivoting movement of two of the arm members of the blade holder assembly; and

wherein when the three-bladed retractor assembly is adjusted to the second position to form the operative corridor along the lateral, trans-psoas path to the lumbar spine, the first retractor blade is a posterior-most retractor blade of the first, second, and third retractor blades and the operative corridor is dimensioned so as to pass an implant through the operative corridor and into the lumbar spine.

2. The system of claim **1**, wherein when the three-bladed retractor assembly is adjusted to the second position to form the operative corridor, the first retractor blade is the posterior-most retractor blade, the second blade is a cephalad-most retractor blade, and the third blade is a caudal-most retractor blade.

3. The system of claim **2**, wherein when the three-bladed retractor assembly is adjusted to the second position to form the operative corridor, the cephalad-most retractor blade and the caudal-most retractor blade are moved away from one another to define a cross-sectional shape of the operative corridor that is one of generally ellipsoidal and oval.

4. The system of claim **2**, wherein the three-bladed retractor assembly includes a plurality of light emitting devices to direct light through the operative corridor toward the spinal disc, the plurality of light emitting devices including a first light emitting device that coupled to the cephalad-most retractor blade and a second light emitting device coupled to the caudal-most retractor blade.

5. The system of claim **1**, wherein the two arm members of the blade holder assembly comprise a first pivotable arm member coupled to the second refractor blade and a second pivotable arm member coupled to the third retractor blade.

6. The system of claim **5**, wherein the blade holder assembly further comprises a translating arm member coupled to the first retractor blade.

7. The system of claim **6**, wherein the rotation of the knob element of the blade holder assembly causes the translating arm member to linearly adjust a position of the first retractor blade relative to the second and third retractor blades, and wherein at least a portion of each of the first and second pivotable arm members is arranged between the rotatable knob element and the first, second, and third retractor blades.

8. The system of clam **1**, wherein the three-bladed retractor assembly includes a shim element removably engageable with the first refractor blade so that a distal portion of the shim element extends from a distal end of the first retractor blade.

9. The system of claim **8**, wherein when the three-bladed retractor assembly is advanced toward the spinal disc along the lateral, trans-psoas path, the distal portion of the shim element is positioned in the spinal disc to secure the first retractor blade in fixed relation relative the lumbar spine.

10. The system of clam **9**, wherein the shim element is removably engageable with grooves along an inner-facing of the first retractor blade.

11. The system of clam **10**, wherein the three-bladed retractor assembly includes a first retractor extension member that is removably engageable with the second retractor blade and a second refractor extension member that is removably engageable with the third retractor blade.

12. The system of clam **11**, wherein the first retractor extension member is removably engageable with grooves along an inner-facing of the second retractor blade, and the second retractor extension member is removably engageable with grooves along an inner-facing of the third retractor blade.

13. The system of claim **1**, wherein the blade holder assembly further comprises handle extenders coupled to the two arm members, the second and third refractor blades simultaneously moving in response to movement of the handle extenders.

14. The system of claim **1**, wherein the elongated member is advanced together with the at least one dilator cannula along the lateral, trans-psoas path to the lumbar spine.

15. The system of claim **1**, wherein when the three-bladed retractor assembly is adjusted to create the operative corridor, the first, second, and third retractor blades are spaced apart and maintained generally parallel to one another.

16. The system of claim **1**, wherein when the three-bladed retractor assembly is in the first position, the first, second, and third retractor blades are in generally abutting relation with one another.

17. The system of claim **1**, wherein the dilator system comprises a plurality of supplemental dilators for sequential insertion along the lateral, trans-psoas path to the lumbar spine.

18. The system of claim **1**, wherein the elongate member comprises a K-wire.

19. The system of claim **1**, further comprising a monitoring system that delivers an electrical stimulation sign to the stimulation electrode of the elongate member, monitors electromyographic activity detected by a set of sensor electrodes in leg muscle myotomes associated with nerves in the vicinity of the spinal disc, and displays to a user: a numeric stimulation threshold required to obtain the electromyographic activity in said leg muscle myotomes, a graphical representation of a patient, and myotomes levels being monitored.

20. The system of claim **18**, wherein the monitoring system comprises a control unit having a video display device, a patient module connected to the control unit via a data cable,

an EMG sensor harness having the set of sensor electrodes connected to the patient module.

21. A system for forming an operating corridor to a lumbar spine, comprising:

a dilator system to create a distraction corridor along a lateral, trans-psoas path to the lumbar spine, wherein said dilator system comprises at least two dilators of sequentially larger widths deliverable to a spinal disc along the lateral, trans-psoas path to the lumbar spine, a second dilator of said at least two dilators being slidably engageable with an exterior of a first of said at least two dilators, at least one of the first and second dilators including a stimulation electrode to deliver electrical stimulation for nerve monitoring when the stimulation electrode is positioned along the lateral, trans-psoas path to the lumbar spine;

a three-bladed retractor assembly slidable over the dilator system toward the spinal disc along the lateral, trans-psoas path, the three-bladed retractor assembly including:

a blade holder assembly and first, second, and third retractor blades that extend generally perpendicularly relative to arm members of the blade holder assembly,

wherein the three-bladed retractor assembly is adjustable from a first position in which the first, second, and third retractor blades are adjacent to one another and slidable over the dilator system to a second position in which the second and third retractor blades are moved away from the first retractor blade to enlarge the distraction corridor and thereby form an operative corridor along the lateral, trans-psoas path to the lumbar spine,

wherein the first retractor blade is linearly movable relative to the second and third retractor blades in response to rotation of a knob element on the blade holder assembly,

wherein the second refractor blade is movable relative to the first blade in response to pivoting movement of a first pivotable arm member of said arm members which is coupled to the second retractor blade, and wherein the third retractor blade is movable relative to the first blade in response to pivoting movement of a second pivotable arm member of said arm members which is coupled to the third refractor blade; and

wherein when the three-bladed retractor assembly is adjusted to the second position to form the operative corridor along the lateral, trans-psoas path to the lumbar spine, the first retractor blade is a posterior-most retractor blade of the first, second, and third retractor blades and the operative corridor is dimensioned so as to pass an implant through the operative corridor and into the lumbar spine.

22. The system of claim **21**, wherein when the three-bladed retractor assembly is adjusted to the second position to form the operative corridor, the first retractor blade is the posterior-most retractor blade, the second blade is a cephalad-most retractor blade, and the third blade is a caudal-most refractor blade.

23. The system of claim **22**, wherein the three-bladed retractor assembly includes a plurality of light emitting devices to direct light through the operative corridor toward the spinal disc, the plurality of light emitting devices including a first light emitting device that coupled to the cephalad-most retractor blade and a second light emitting device coupled to the caudal-most retractor blade.

24. The system of claim **21**, wherein said arm members of the blade holder assembly further comprise a translating arm member coupled to the first retractor blade, wherein the rotation of the knob element of the blade holder assembly causes the translating arm member to linearly adjust a position of the first retractor blade relative to the second and third retractor blades.

25. The system of clam **21**, wherein the three-bladed retractor assembly includes an intradiscal shim element having a proximal portion removably engageable with the first retractor blade so that a distal portion of the shim element extends from a distal end of the first retractor blade and is configured to penetrate into the spinal disc, wherein the proximal portion of the shim element is slidably engageable with grooves defined along the first retractor blade.

26. The system of claim **21**, wherein the second and third retractor blades are configured to simultaneously move in response to movement of the first and second pivotable arm members.

27. The system of claim **21**, further comprising an elongate member deliverable to a spinal disc along a lateral, trans-psoas path to the lumbar spine such that a distal tip region of the elongate member is configured to penetrate into an annulus of the spinal disc, said first dilator being configured to slidably engage an exterior of the elongate member.

28. The system of claim **21**, wherein when the three-bladed retractor assembly is in the first position, the first, second, and third retractor blades are in generally abutting relation with one another.

29. The system of claim **21**, further comprising a monitoring system that delivers an electrical stimulation sign to the stimulation electrode, monitors electromyographic activity detected by a set of sensor electrodes in leg muscle myotomes associated with nerves in the vicinity of the spinal disc, and displays to a user a numeric stimulation threshold required to obtain the electromyographic activity in said leg muscle myotomes, wherein the monitoring system comprises a control unit having a video display device, a patient module connected to the control unit via a data cable, an EMG sensor harness having the set of sensor electrodes connected to the patient module.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,355,780 B2
APPLICATION NO. : 12/623016
DATED : January 15, 2013
INVENTOR(S) : Patrick Miles

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims:

In Column 14 Line 11, In Claim 8, delete “clam” and insert --claim--, therefor.

In Column 14 Line 20, In Claim 10, delete “clam” and insert --claim--, therefor.

In Column 14 Line 23, In Claim 11, delete “clam” and insert --claim--, therefor.

In Column 14 Line 28, In Claim 12, delete “clam” and insert --claim--, therefor.

In Column 16 Line 19, In Claim 25, delete “clam” and insert --claim--, therefor.

Signed and Sealed this
Thirtieth Day of April, 2013

Teresa Stanek Rea
Acting Director of the United States Patent and Trademark Office