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(54) SPINAL SURGERY METHODS USING A ROBOTIC INSTRUMENT SYSTEM

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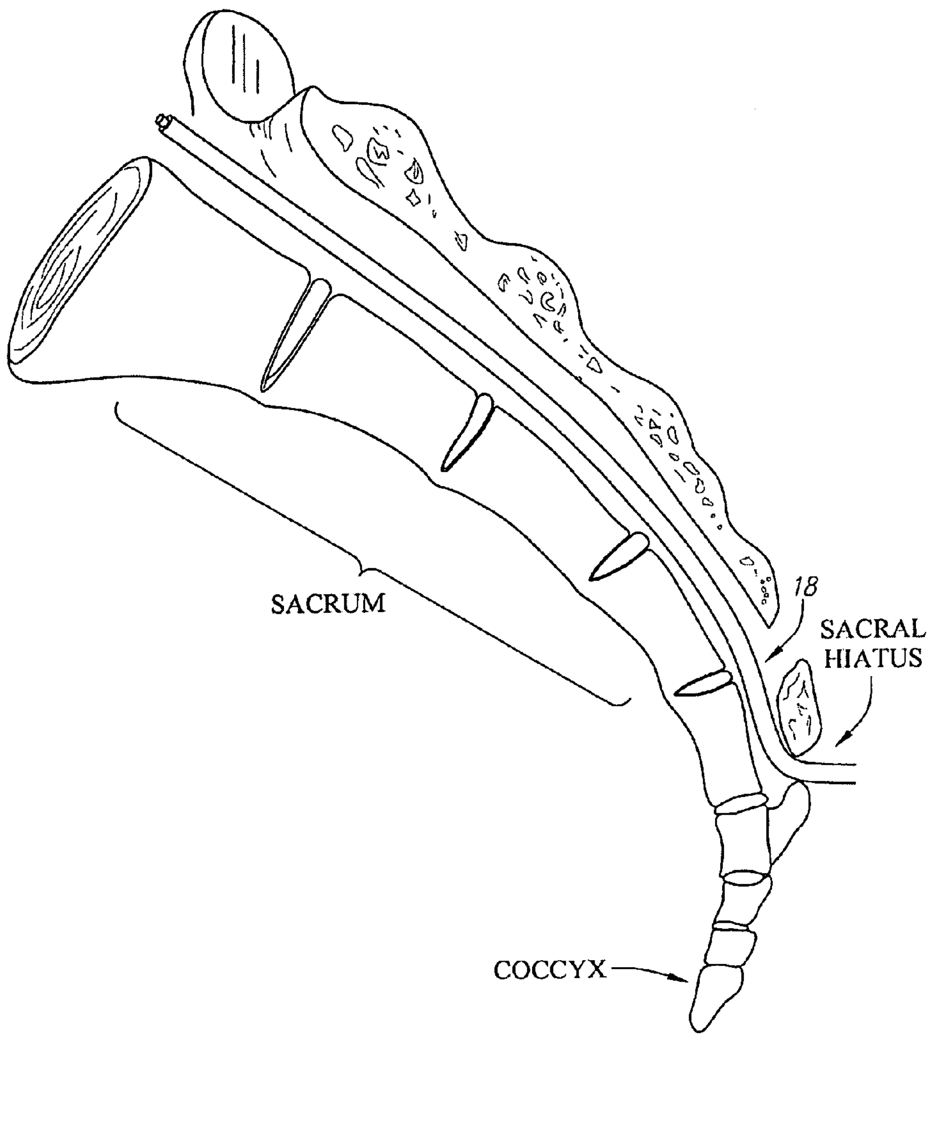
(57) ABSTRACT

Methods of performing various minimally invasive spinal surgical applications with a flexible, robotically controlled catheter instrument are disclosed. In one embodiment, a surgical method comprises inserting a robotically controlled, flexible catheter instrument through the sacral hiatus and into the epidural space of the spine, and advancing the catheter instrument toward the lumbar spine, to an area of the spine to be treated. The catheter instrument is then used to perform a therapeutic procedure on the spine, such as (without limitation), the delivery of a spinal stabilization device, or performing a lumbar discectomy, laminectomy, forminotomy, kyphoplasty, or spineoplasty.



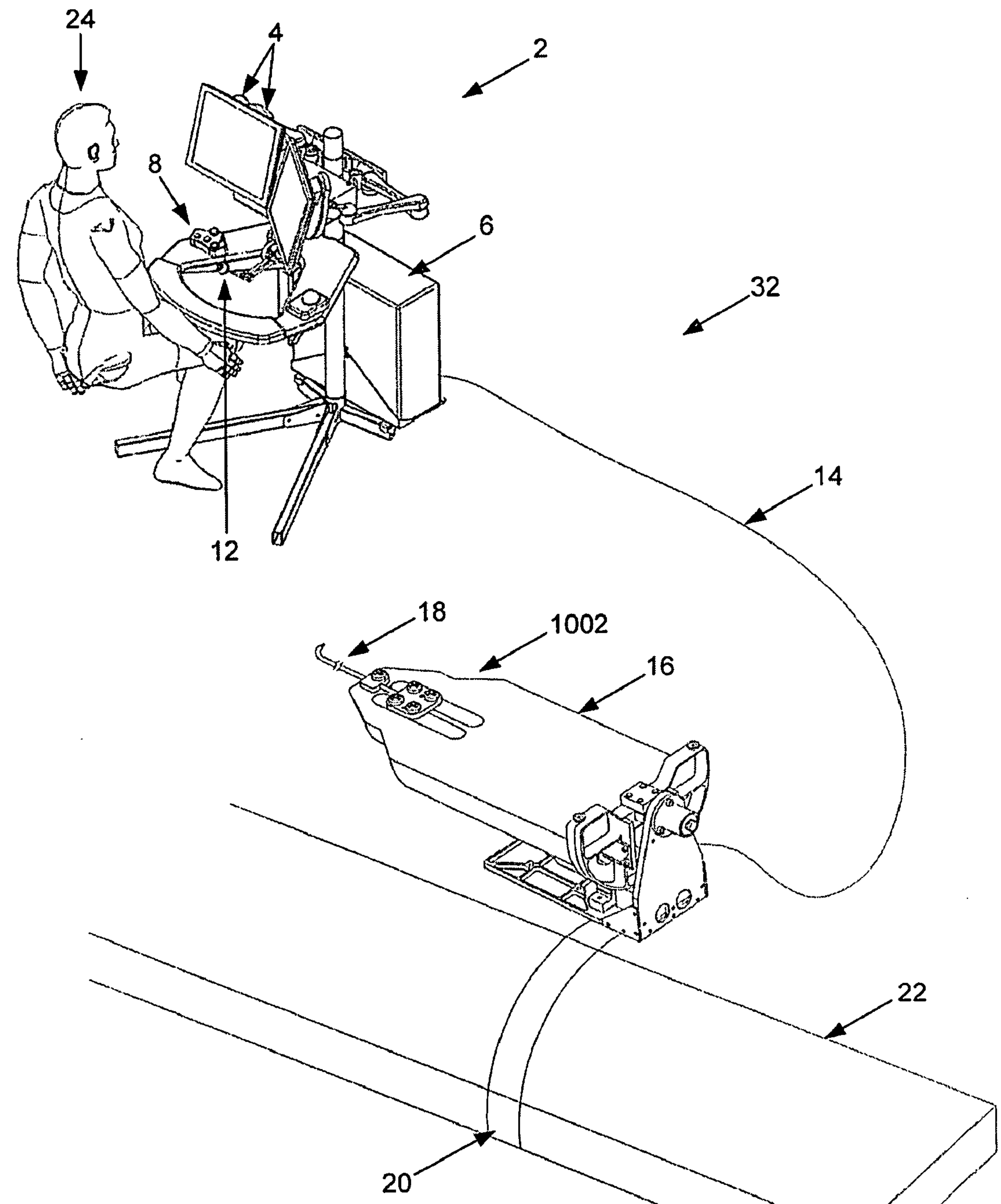


FIG. 1A

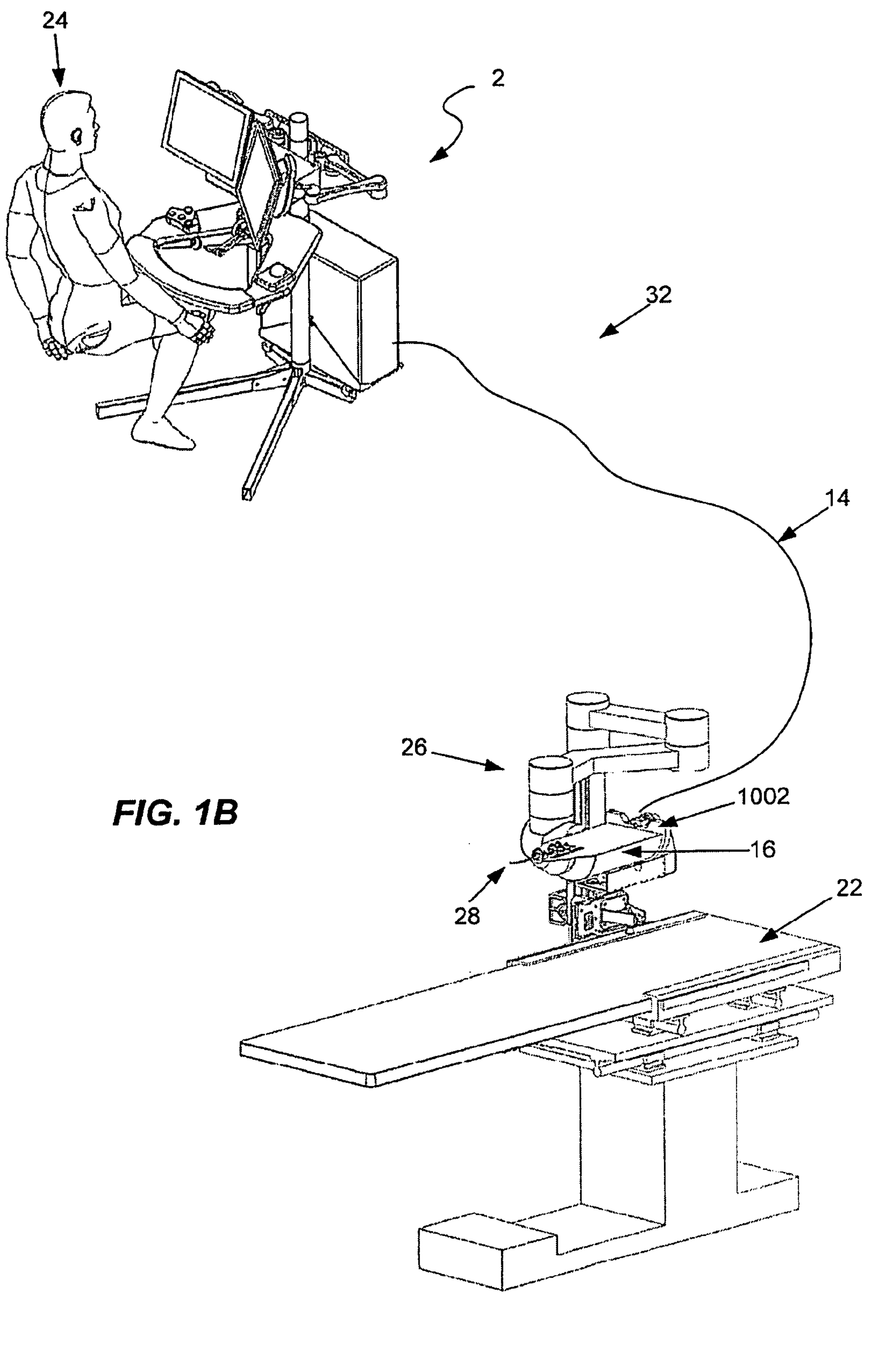


FIG. 1B

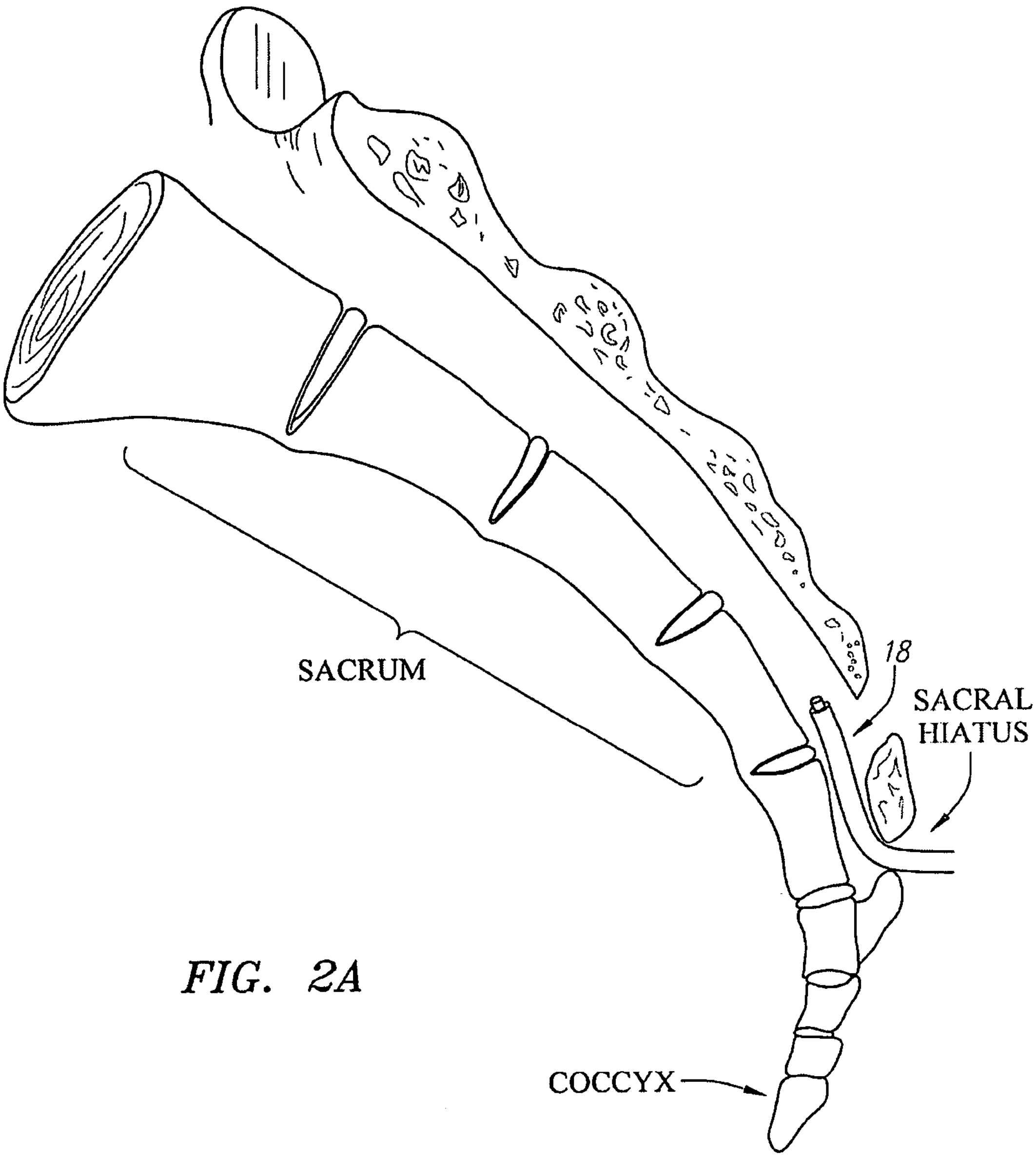


FIG. 2A

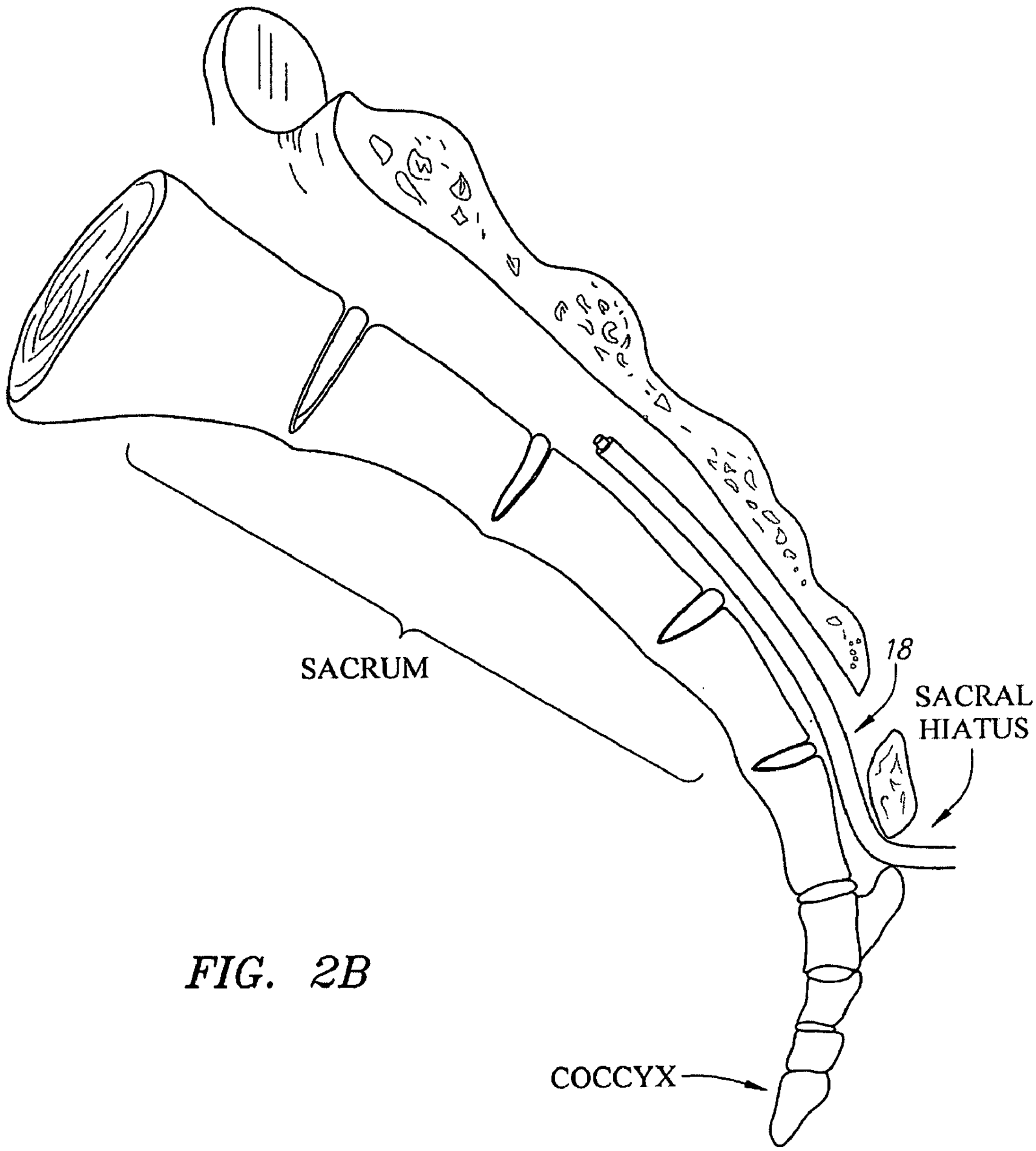


FIG. 2B

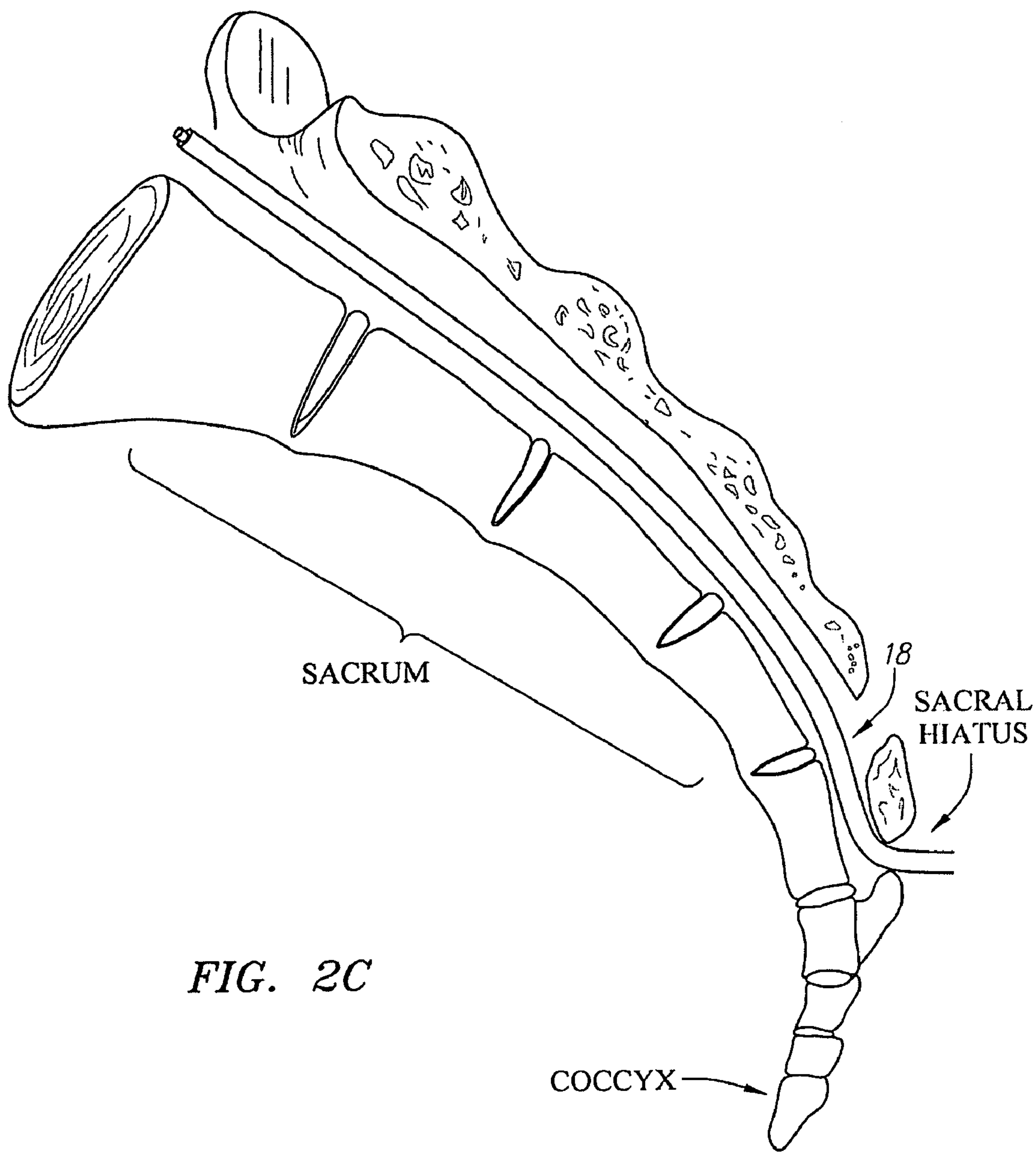


FIG. 2C

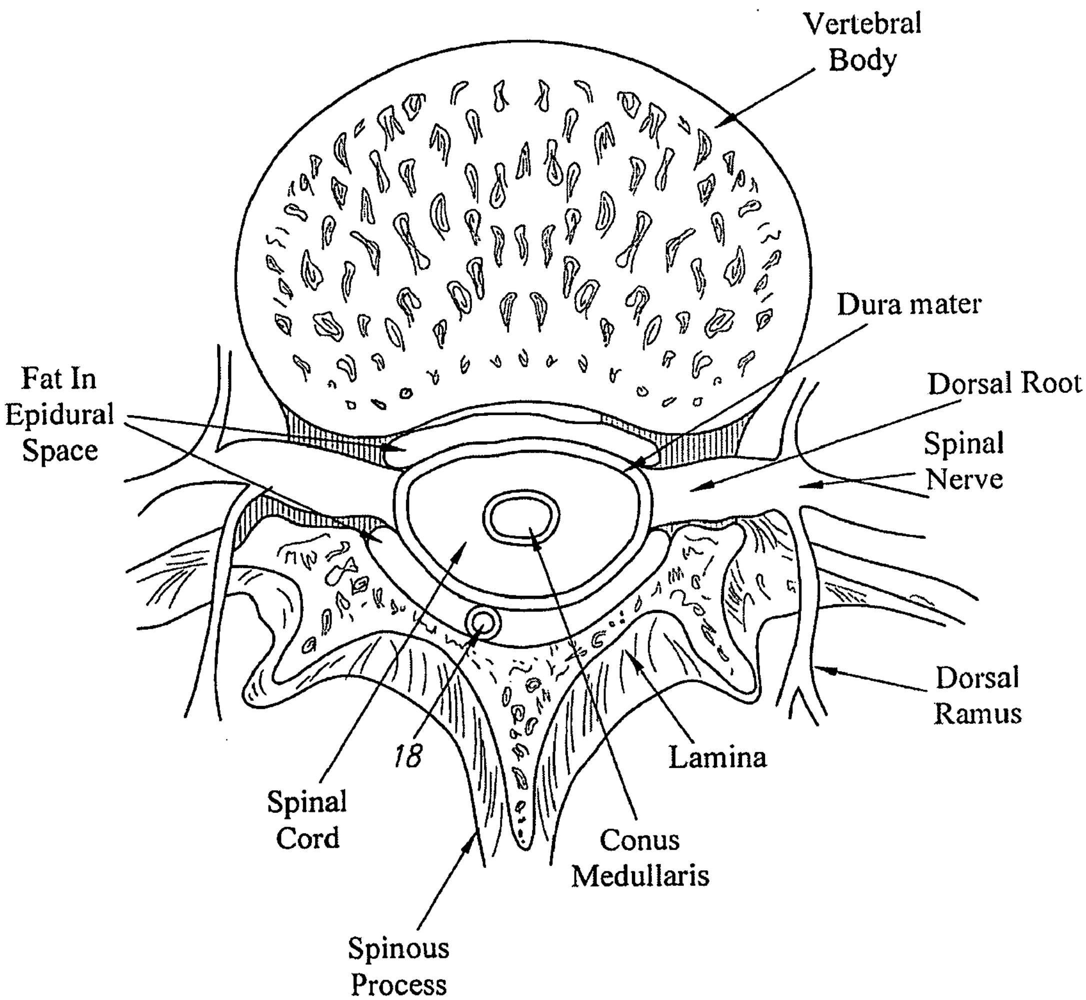

Vertebral Body
Dura mater
Dorsal Root
Spinal Nerve
Fat In Epidural Space
Dorsal Ramus
Lamina
18
Spinal Cord
Conus Medullaris
Spinous Process

FIG. 2D

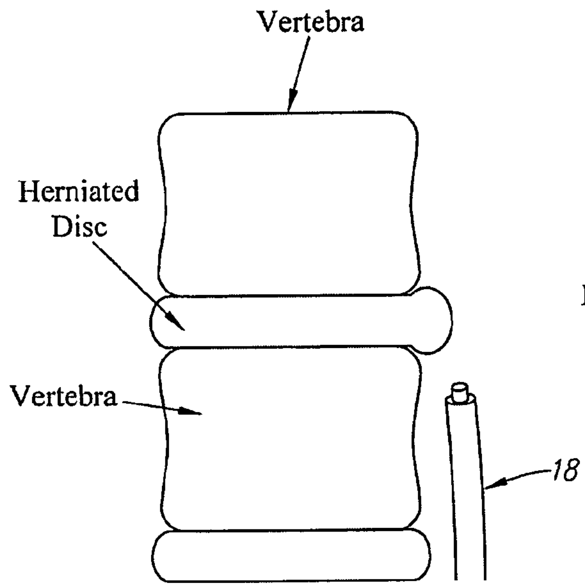


FIG. 3A

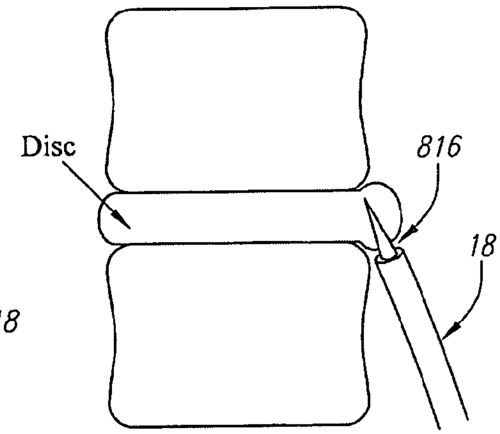


FIG. 3B

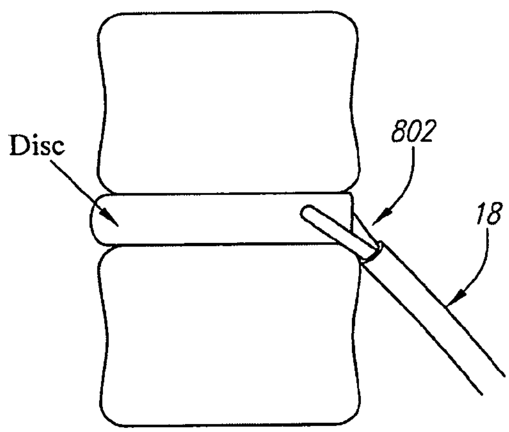


FIG. 3C

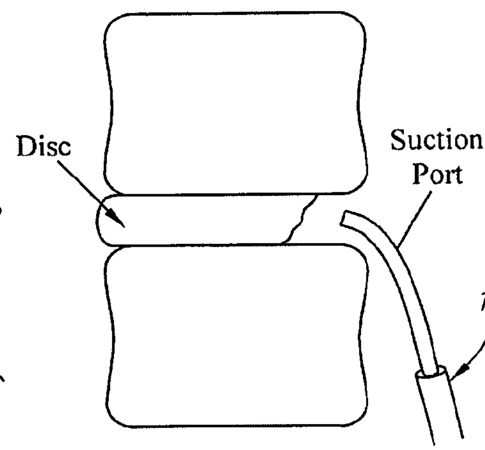


FIG. 3D

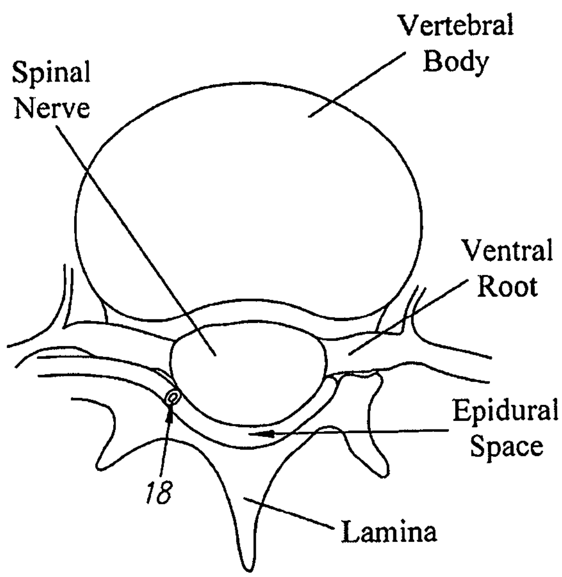


FIG. 4A

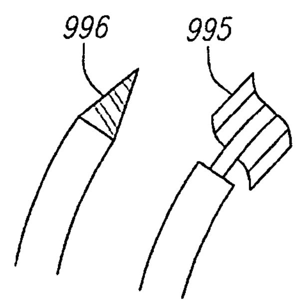


FIG. 4B

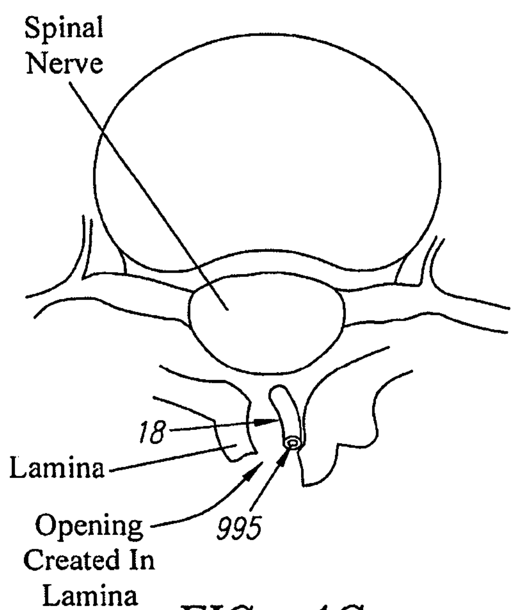


FIG. 4C

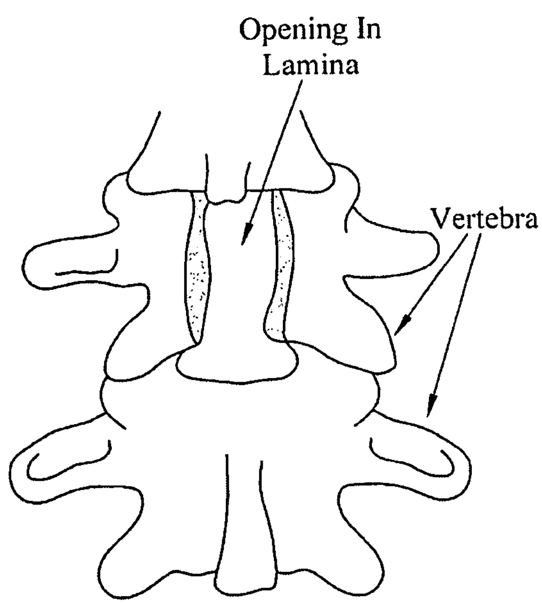


FIG. 4D

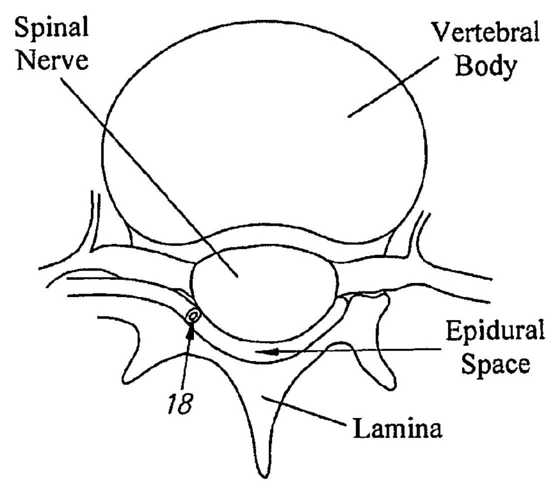


FIG. 5A

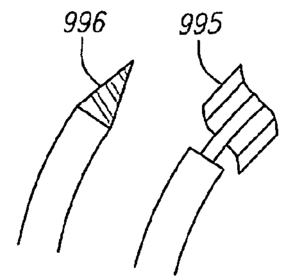


FIG. 5B

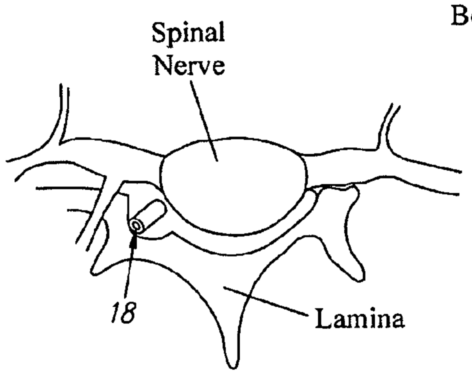


FIG. 5C

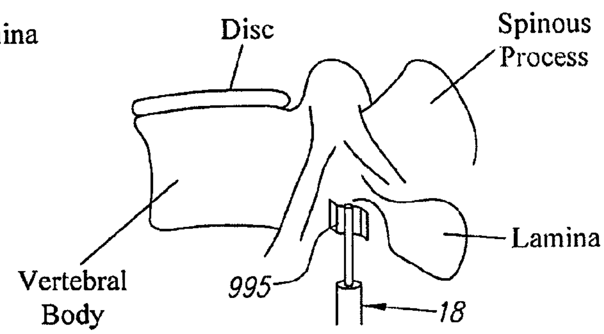


FIG. 5D

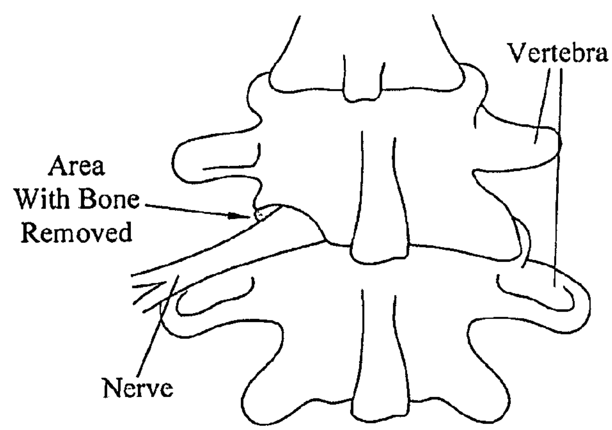


FIG. 5E

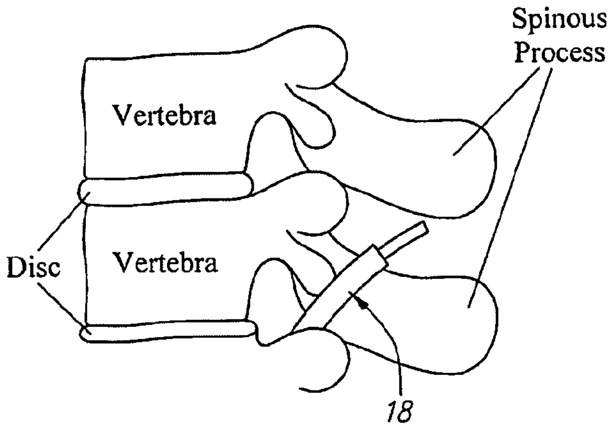


FIG. 6A

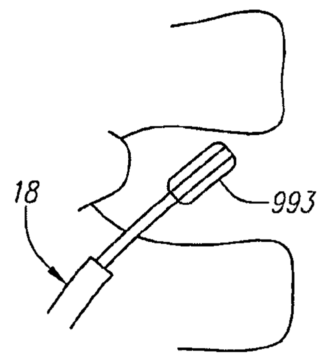


FIG. 6B

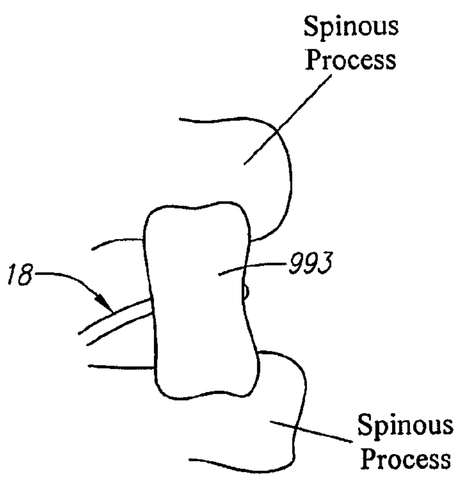


FIG. 6C

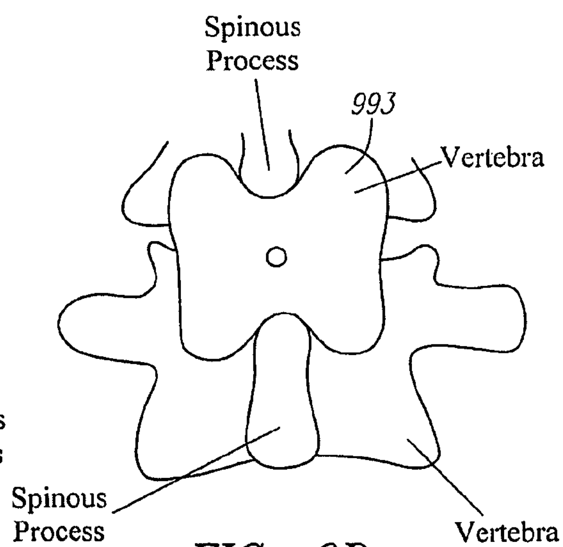


FIG. 6D

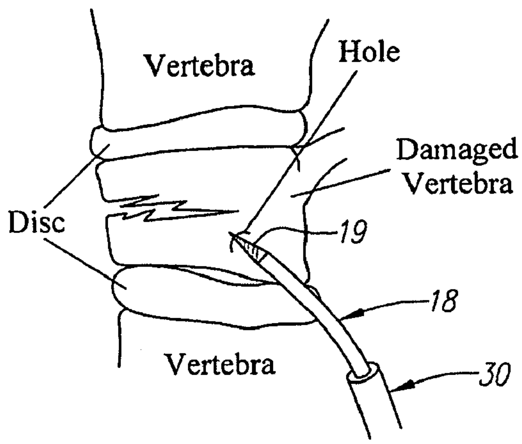


FIG. 7A

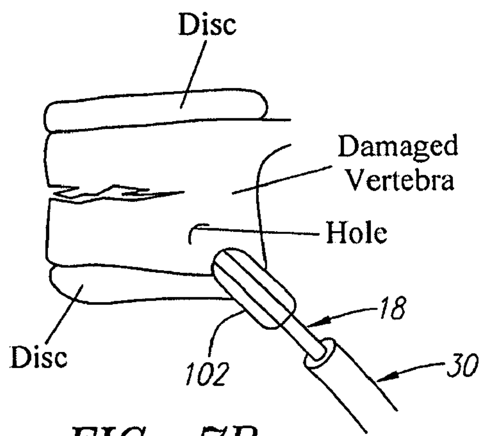


FIG. 7B

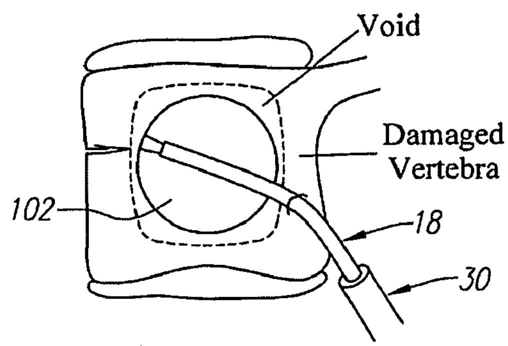


FIG. 7C

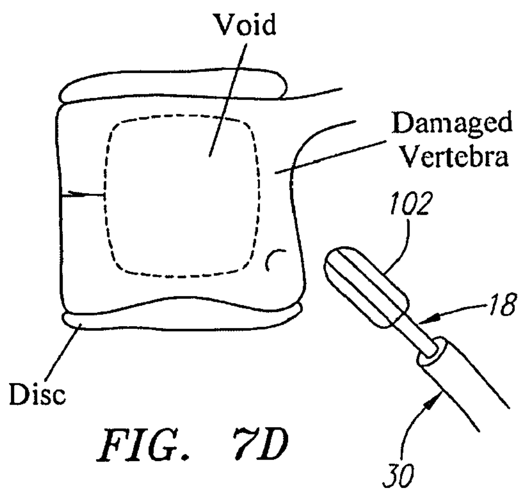


FIG. 7D

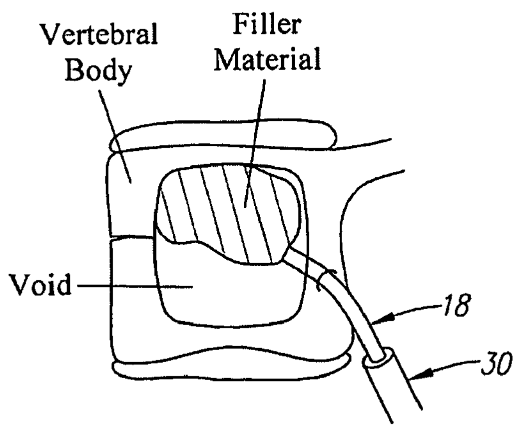


FIG. 7E

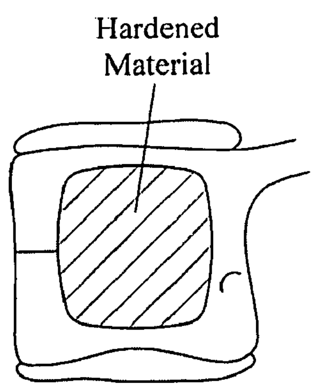


FIG. 7F

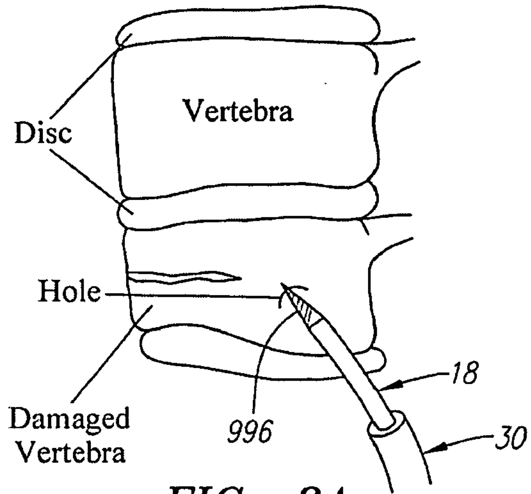


FIG. 8A

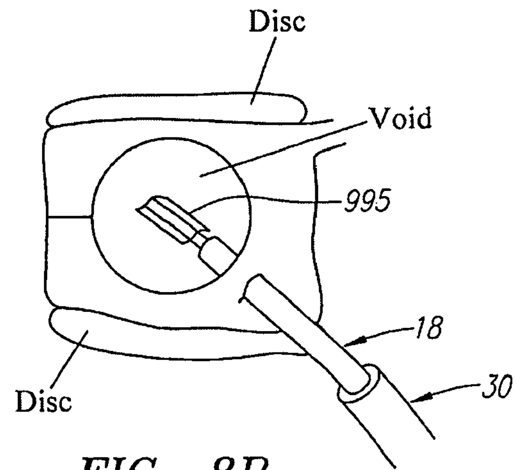


FIG. 8B

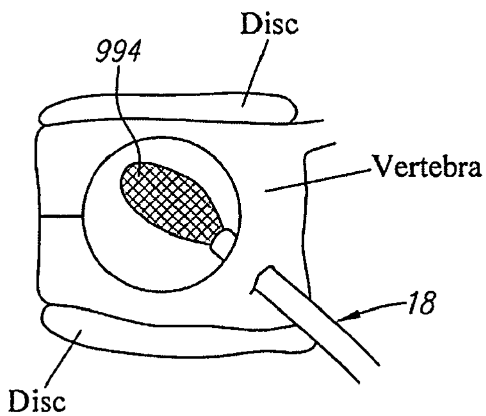


FIG. 8C

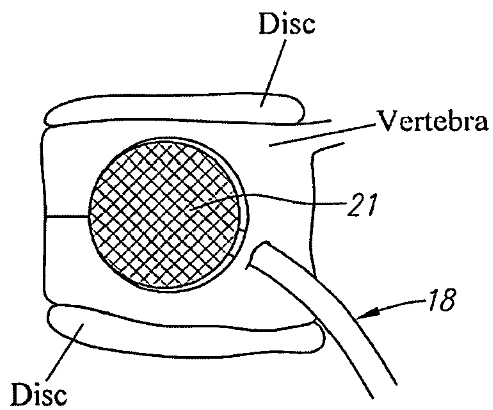


FIG. 8D

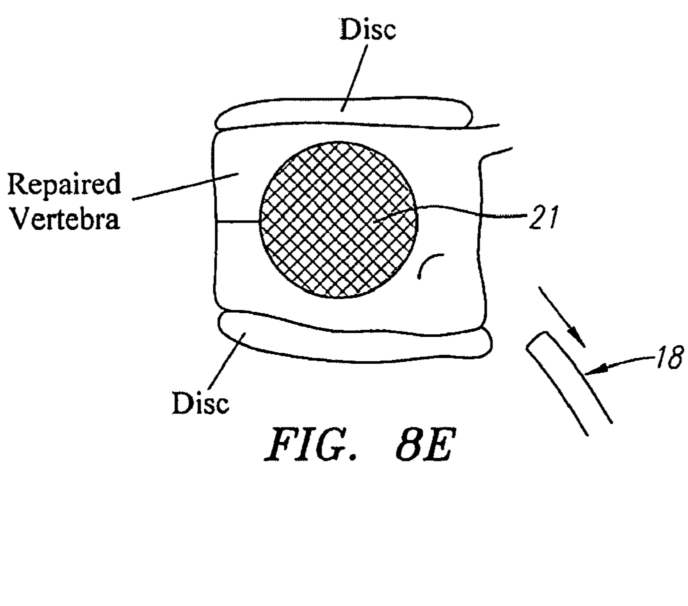


FIG. 8E

SPINAL SURGERY METHODS USING A ROBOTIC INSTRUMENT SYSTEM

RELATED APPLICATION DATA

[0001] The present application claims the benefit under 35 U.S.C. § 119 to U.S. Provisional Patent Application Ser. Nos. 60/899,048, filed on Feb. 2, 2007, and 60/900,584, filed on Feb. 8, 2007. The foregoing applications are hereby incorporated by reference into the present application in its entirety.

FIELD OF INVENTION

[0002] The invention relates generally to robotically controlled systems, such as telerobotic surgical systems, and more particularly to a using a robotic instrument system for performing spinal surgery procedures.

BACKGROUND

[0003] Robotic interventional systems and devices are well suited for use in performing minimally invasive medical procedures, as opposed to conventional techniques wherein the patient's body cavity is open to permit the surgeon's hands access to internal organs. For example, there is a need for a highly controllable yet minimally sized system to facilitate imaging, diagnosis, and treatment of tissues which may lie deep within a patient, and which may be accessed transcutaneously (through a surgical port) or via naturally-occurring pathways such as blood vessels, other lumens, via surgically-created wounds of minimized size, or combinations thereof.

SUMMARY OF THE INVENTION

[0004] The present invention is directed to methods of performing various surgical procedures using such robotic instrument systems. The methods include various, minimally invasive spinal surgical applications with a flexible, robotically controlled catheter instrument. In one embodiment, the method comprises inserting a robotically controlled, flexible catheter instrument through the sacral hiatus and into the epidural space of the spine. A distal end portion of the catheter instrument is advanced toward the lumbar spine to an area of the spine to be treated. Then, the catheter instrument is used to perform a therapeutic procedure on the spine. Examples of spinal procedures that can be performed using the present invention include a lumbar discectomy, a laminectomy, a forminotomy, the delivery of a spinal stabilization device, a kyphoplasty, a spineoplasty, or other spinal surgery.

[0005] The catheter instrument may be equipped with a tool, illumination fiber, image capture device, laser, irrigation port, suction port, needle, working cannula, grasper, shaving port, blade, drill or other end-effector useful for the particular spinal procedure being performed. In addition, two or more such catheter instruments may be utilized in the methods of the present invention. As used herein, the term "disposed on" or "carried by" relative to a structure shall include without limitation, attached to, coupled to, inserted through, integral with, the structure, and shall not be limited to any particular mounting method or location relative to the structure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] The drawings illustrate the design and utility of illustrated embodiments of the invention, in which similar elements are referred to by common reference numerals.

[0007] FIG. **1**A illustrates one embodiment of a robotic catheter system;

[0008] FIG. **1**B illustrates another embodiment of a robotic catheter system;

[0009] FIGS. **2**A-**2**D illustrate one embodiment of a method wherein a flexible, robotically steerable catheter instrument is driven through the sacral hiatus and into the epidural space;

[0010] FIGS. **3**A-**3**D illustrate one embodiment of a method for a lumbar discectomy procedure using a flexible, robotically steerable catheter instrument;

[0011] FIGS. **4**A-**4**D illustrate one embodiment of a method for a lumbar laminectomy procedure using a flexible, robotically steerable catheter instrument;

[0012] FIGS. **5**A-**5**E illustrate one embodiment of a method for a foraminotomy procedure using a flexible, robotically steerable catheter instrument;

[0013] FIGS. **6**A-**6**D illustrate one embodiment of a method for delivering a spinal stabilization device using a flexible, robotically steerable catheter instrument;

[0014] FIGS. **7**A-**7**F illustrate one embodiment of a method for a kyphoplasty procedure using a flexible, robotically steerable catheter instrument; and

[0015] FIGS. **8**A-**8**E illustrate one embodiment of a method for a spineoplasty procedure using a flexible, robotically steerable catheter instrument.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0016] The present invention is directed to robotic catheter systems and methods of performing various back and spinal surgical procedures using such robotic catheter systems. Injury, aging, improper body mechanics, and normal wear and tear can all cause injury to the spine. And damage to any part of the back, especially to the nerves, can cause pain and other symptoms. Although most back problems are successfully handled with non-surgical treatments, such as anti-inflammatory medication, ice, heat, gentle massage or physical therapy, a percentage of back problems require surgery for relief. For example, some of the spine conditions that may be treated with spinal surgery include spondylolisthesis, stenosis, degenerative disc disease, herniated disc, sciatica, spine fractures, spine tumors, scoliosis, and osteoporosis. In general, spine surgery may be used to help decompress a nerve root or the spinal cord, stabilize an unstable or painful segment with fusion surgery, or reduce a deformity.

[0017] FIGS. **1**A and **1**B illustrate example of embodiments of robotic catheter systems (**32**) suitable for use in performing the surgical procedures described herein. Referring first to FIG. **1**A, one embodiment of a robotic catheter system (**32**), includes an operator control station (**2**) located remotely from an operating table (**22**), and a robotic catheter assembly (**1002**) (also referred to as a catheter instrument). The robotic catheter assembly (**1002**) is coupled to the operating table (**22**) by an instrument driver mounting brace (**20**). The robotic catheter assembly (**1002**) comprises a robotic instrument driver (**16**) and an instrument (**18**), such as a guide instrument (**18**) (also referred to herein as an instrument guide catheter, guide catheter, robotic guide instrument, robotic guide catheter, catheter instrument or the like). A communication link (**14**) transfers signals between the operator control station (**2**) and instrument driver (**16**). The instrument driver mounting brace (**20**) of the depicted embodiment is a relatively simple, arcuate-shaped structural member configured to position the instrument driver (**16**) above a patient (not shown) lying on the table (**22**).

[0018] In FIG. **1**B, another embodiment of a robotic catheter system (**32**) is depicted, wherein the arcuate-shaped member (**20**) is replaced by a movable support assembly (**26**). The support assembly (**26**) is configured to movably support the instrument driver (**16**) above the operating table (**22**) in order to position the instrument driver (**16**) for convenient access into desired locations relative to a patient (not shown). The support assembly (**26**) in FIG. **1**B is also configured to lock the instrument driver (**16**) into position once it is positioned.

[0019] The instrument (**18**) is typically an elongate, flexible device configured to be inserted into a patient's body. As non-limiting examples, an instrument (**18**) may comprise an intravascular catheter, an endoscopic surgical instrument or other medical instrument. The instrument (**18**) may also comprise an instrument assembly (**28**) (also referred to herein as a catheter assembly (**28**)) comprising a robotic guide instrument (**18**), or a coaxially coupled and independently controllable robotic sheath instrument (**30**) (also referred to as a sheath catheter (**30**)) and a robotic guide instrument (**18**), as described in the U.S. Patent Applications incorporated by reference below. The instrument (**18**) or instrument assembly (**28**) is configured to be operable via the instrument driver (**16**) such that the instrument driver (**16**) can operate to steer the instrument (**18**) or instrument assembly (**28**) and also to operate tools and devices which may be provided on the instrument assembly (**18**) or instrument assembly (**28**) (e.g. an imaging device or cutting tool disposed on the distal end of the instrument (**18**) or instrument assembly (**28**)). The guide instrument (**18**) may be movably positioned within the working lumen of the sheath instrument (**30**) to enable relative insertion of the two instruments (**30**, **18**), relative rotation, or "roll" of the two instruments (**30**, **18**), and relative steering or bending of the two instruments (**30**,**18**) relative to each other, particularly when a distal portion of the guide instrument (**18**) is inserted beyond the distal tip of the sheath instrument (**30**).

[0020] The procedures described herein may be performed with robotically steerable instruments, such as those described in the below-referenced patent application, U.S. patent application Ser. No. 11/481,433.

[0021] Exemplary embodiments of an operator control station (**2**), an instrument driver (**16**), an instrument (**18**) and instrument assembly (**28**), a robotic sheath instrument (**30**), a robotic guide instrument (**18**), and various instruments (**50**), are described in detail in the following U.S. Patent Applications, and are incorporated herein by reference in their entirety:

[0022] U.S. patent application Ser. Nos. 10/923,660, filed Aug. 20, 2004; 10/949,032, filed Sep. 24, 2005; 11/073,363, filed Mar. 4, 2005; 11/173,812, filed Jul. 1, 2005; 11/176,954, filed Jul. 6, 2005; 11/179,007, filed Jul. 6, 2005; 11/202,925, filed Aug. 12, 2005; 11/331,576, filed Jan. 13, 2006; U.S. Provisional Patent Application Nos. 60/785,001, filed Mar. 22, 2006; 60/788,176, filed Mar. 31, 2006; U.S. patent application Ser. Nos. 11/418,398, filed May 3, 2006; 11/481,433, filed Jul. 3, 2006; 11/637,951, filed Dec. 11, 2006; 11/640,099, filed Dec. 14, 2006; and U.S. Provisional Patent Applications Nos. 60/833,624, filed Jul. 26, 2006, and 60/835,592, filed Aug. 3, 2006.

[0023] For clarity, the sheath and guide catheter instruments described in the exemplary embodiments below may be described as having a single lumen/tool/end-effector, etc. However, it is contemplated that alternative embodiment of catheter instruments may have a plurality of lumens/tools/end-effectors/ports, etc. Furthermore, it is contemplated that in some embodiments, multiple catheter instruments may be delivered to a surgical site via a single multi-lumen sheath, each of which is robotically driven and controlled by via an instrument driver. Some of the catheter instruments described herein, are noted as flexible. It is contemplated that different embodiments of flexible catheters may be designed to have varying degrees of flexibility and control. For example, one catheter embodiment may have controlled flexibility throughout its entire length whereas another embodiment may have little or no flexibility in a first portion and controlled flexibility in a second portion. Similarly, different embodiments of these catheters may be implemented with varying degrees of freedom.

[0024] Turning now to FIGS. **2**A-**2**E illustrate a number of embodiments of methods for various minimally invasive spinal surgeries that may be performed with a robotic catheter system (**32**) such as that described above and in aforementioned U.S. patent application Ser. No. 11/481,433. Furthermore, a robotic catheter system (**32**) may be used to control one or more catheter assemblies (**28**) into the spine. In some embodiments, a guide catheter (**18**) may be introduced into the spine without a sheath catheter (**30**), or vice versa. In other embodiments, a guide catheter (**18**) and sheath catheter (**30**) are both introduced into the spine. In alternative embodiments, the guide and/or sheath may be used to deliver other catheter devices or tools or end-effectors into the spine to perform spinal surgeries. This and the surgical procedures disclosed below may be performed with the aid of various medical imaging modalities such as X-ray, fluoroscopy, MR, CT, ultrasound, etc.

[0025] FIG. **2**A illustrates one embodiment of a method wherein a flexible, robotically steerable catheter (**18**) being driven through the sacral hiatus and into the epidural space. FIGS. **2**B-**2**C illustrate the catheter (**18**) traveling up towards the lumbar spine via the epidural space. FIG. **2**D is a cross-sectional view of the catheter (**18**) in the epidural space between the spinal cord and the lamina of the vertebral body.

[0026] One common condition is a spinal disc herniation or more commonly known as a slipped disc. Many types of problems can reduce the amount of space in the spine, resulting in pinched nerves. As people age, the spinal discs may dry out and shrink, thus reducing their effectiveness as shock absorbers. These discs also act to prevent the vertebrae from rubbing against each other. Throughout the length of the spine is a central tube, surrounded by bone and discs, called the spinal canal. Inside the spinal canal are the spinal cord, the cauda equine, and spinal nerves. A pair of spinal nerves brand out at each vertebral level. The intervertebral discs lie in front of the spinal nerves and are situated between the vertebrae. Disc herniation can occur in any disc in the spine, but the two most common forms are the cervical disc herniation and the lumbar disc herniation, the latter being more common, causing lumbago and often leg pain as well. Cervical disc herniations occur in the neck, most often between the sixth and seventh cervical vertebral bodies. Thoracic discs are very stable and herniations in this region are quite rare. Lumbar disc herniations occur in the lower back, most often between the fourth and fifth lumbar vertebral bodies or between the fifth and the sacrum. The lowermost discs (L4/5 and L5/S1) are most prone to wear and tear and potential rupture. Discs may also bulge or rupture, causing nearby nerves to become irritated. Once an annular tear occurs, it may heal or it may allow nucleus to come out of the center of the disc into the spinal canal. This may be referred to by a variety of terms including disc prolapse, ruptured disc, slipped disc, extruded disc, etc. To relieve pressure on the spinal cord or nerves, portions of bone and/or discs may need to be removed. Lumbar discectomy is a surgical procedure to remove part of a problem intervertebral disc in the lower back, for example, removal of herniated disc material, usually in the lumbar region of the spine. This procedure is commonly used when a herniated or ruptured disc in the lower back is putting pressure on a nerve root.

[0027] The main goal of discectomy surgery is to relieve pressure on the spinal cord or spinal nerve by widening the spinal canal or removing the part of the disc that is putting pressure on a spinal nerve root. Taking out the injured portion of the disc also reduces chances that the disc will be herniated again. The two main parts of a disc are the annulus fibrosis and the nucleus pulposus. The lamina bone forms the protective covering over the back of the spinal cord. A traditional procedure may consist of a laminotomy and discectomy, but a minimally invasive method called microdiscectomy or microendoscopic discectomy is often now performed instead. Whereas a traditional laminotomy involves taking off part of the lamina bone to provide greater room for the surgeon to take out part of the disc during the discectomy, a surgeon performs a lumbar microdiscectomy procedure through a very small incision in the posterior region of the patient's low back directly over the problem disc.

[0028] Typically, a small window is made on one side of a spinous process through the removal of some bone and ligament to allow visualization of the disc bulge and involved root. In some procedures, the skin and soft tissues may be separated to expose the bones along the back of the spine and a retractor used to spread apart the lamina bones above and below the disc. Through gentle dissection, the interface between the root and the disc bulge is identified and the offending fragment can be removed. The method of one embodiment involves deploying thin wires or dilators through the incision to the region of interest. This way, a flexible catheter or endoscope may be driven to the area. In order to access the nerve, the lamina may be removed with a small, high-speed drill or small bone-biting tool (Kerrison rongeur) mounted at the distal tip of a flexible catheter. The surgeon may also make a tiny slit in the ligamentum flavum, exposing the spinal nerves. All the nerves, except the exciting nerve, are grouped together in the thecal sac where they float loosely in spinal fluid. A special hook or retractor may be placed under the spinal nerve root to lift it so that the surgeon can see the injured disc or source of pressure (i.e., disc fragment, osteophyte or bone spur, protruding/degenerating disc, facet arthritis, cysts, tumors). The outer annulus fibrosis of the disc is sliced open and material from inside nucleus pulposus of the disc is scooped out. Various tools may be used with the catheter to remove the ruptured disc and other loose fragments of disc in the surrounding area. Because only the injured portion is removed, the disc is left intact and functioning. The surgeon may also check the spinal nerves where they travel from the spinal canal through the neural foramina. The surgeon inspects the area about the nerve root to ensure that the nerve root is free to move, otherwise the neural foramen may also be cleaned. In some instances, a spinal fusion with instrumentation may be performed to help stabilize the spine. A spinal fusion involves grafting a small piece of bone onto the spine and using spinal hardware, such as screws and rods, to support the spine and provide stability. The wound may be irrigated with antibiotics and the catheter withdrawn. The muscles and soft tissues are put back in place and the skin is stitched together. The incision may be closed using either absorbable sutures or skin sutures or Steri-Strips.

[0029] Because of the proximity of the spinal cord and associated nerves during these types of surgical procedures, precise control and maneuverability of any surgical tools or catheter being used is desirable to avoid unintentional injury. The methods for a lumbar discectomy or microdiscectomy surgical procedure such as that described above may be performed with one or more flexible, robotically steerable catheter instruments and robotic catheter system such as those described in detail in U.S. patent application Ser. No. 11/176,598, incorporated by reference herein in its entirety. In some embodiments, the catheters may also be equipped with a tool, illumination fiber, image capture device, laser, irrigation port, suction port, needle, working cannula, grasper, shaving port, blade, drill, or other end-effector, etc, but are not limited as such. It is contemplated that other types of instruments may be attached and/or used at the distal portion of other embodiments of the catheter. Similarly, one or more instruments may be deployed through the one or more lumens that may exist within these catheters.

[0030] FIGS. **3**A-**3**D illustrate one embodiment of a method for a lumbar discectomy procedure using a flexible, robotically steerable catheter (**18**). FIG. **3**A illustrates a flexible, robotically steerable catheter (**18**) being driven to a herniated disc in the lumbar spine. Access was taken through the sacral hiatus and along through the epidural space. FIG. **3**B illustrates a needle (**816**) being used to puncture the herniated disc to allow drainage. FIG. **3**C illustrates removal of parts of the herniated disc. This may be done via a variety of tools, in this case a grasper (**802**) is being used. FIG. **3**D illustrates a catheter (**18**) with a working lumen through which a variety of treatments can be applied: suction, drainage, lavage, and/or delivery of medication.

[0031] Laminectomy is a surgical procedure for treating spinal stenosis or neural impingement by relieving pressure on the spinal cord. Laminectomy involves the removal of the lamina area of the vertebral body to alleviate spinal stenosis, i.e. numbness in the legs. Conditions such as spinal stenosis or spondylolisthesis may be remedied with a lumbar laminectomy. The lamina of the vertebra is removed or trimmed to widen the spinal canal and create more space for the spinal nerves. A laminectomy is often performed to permit removal of, or reshaping of, a spinal disc as part of a lumbar discectomy as described above. Note that laminotomy and laminectomy are both surgical procedures involving the lamina, the thin bony layer covering the spinal canal. During back surgery, this lamina may obstruct the viewing of an intervertebral disc. In contrast to a laminotomy procedure, which involves the partial removal of the lamina, a laminectomy procedure involves the complete removal of the lamina.

[0032] During a laminectomy, a patient is lying prone on the operating table. The skin and muscle are cut to obtain access to the vertebrae. A flexible catheter may be inserted into the opening to remove the lamina. By using a catheter to perform the procedure, the size of the incision necessary and the resulting trauma to the patient may be reduced. Depending on the particular situation, the surgeon may continue to drive the robotically controlled catheter about the vertebrae to trim protruding bits of a herniated disc as discussed above. Once the surgery is completed, the muscle and skin are sutured close.

[0033] FIGS. **4**A-**4**D illustrate one embodiment of a method for a lumbar laminectomy procedure using a flexible, robotically steerable catheter (**18**). As discussed above, different embodiments of a catheter may be equipped with various types of tools at the distal end and a varying number of through lumens may be provided. FIG. **4**A illustrates a flexible, robotically steerable catheter (**18**) being driven through the epidural space to the area of treatment for spinal stenosis. FIG. **4**B illustrates a drill bit tip (**996**) and a router bit tip (**995**) which can be advanced via a catheter (**18**) to the area of treatment and used to remove the lamina. FIG. **4**C illustrates removal of part of the lamina using the router bit tip (**995**) to relieve pressure on the spinal cord. FIG. **4**D illustrates a posterior view of the spine with the removed section of lamina.

[0034] Foraminotomy is a surgical operation for relieving pressure on nerves that are being compressed by the intervertebral foramina. Foraminotomy involves the removal of bone material along the spine to take pressure off the spinal nerve, thereby alleviating a spinal stenosis. The intervertebral foramina are passages through the bones of the vertebrae that pass nerve bundles to the body from the spinal cord. During a foraminotomy, the passageway may be enlarged to ease the pressure on a nerve. In some instances, a foraminotomy may be combined with other procedures such as a laminotomy or laminectomy. One type of foraminotomy is a keyhole foraminotomy. This is a minimally invasive procedure in which an incision is made in the back of the neck or another posterior position of the patient's back. The muscle is peeled away to reveal the bone underneath and a small hole is cut into the vertebra. A flexible catheter may be inserted through this opening to visualize the foramen and to remove the impinging bone or disk material. Special cutting instruments and/or a drill may be used to remove bone spurs, thickened ligaments, and debris. The process of nerve root decompression comprises removing these tissues from the neuroforamen to increase the space for the nerve root. In some instances, cortisone may also be applied over the nerve root via a port on the flexible catheter. Once pressure on the nerve is released, the catheter instrument may be withdrawn and the muscles move back into place. The incision may be closed using absorbable sutures, Steri-Strips, non-absorbable sutures, surgical staples, etc. Foraminotomy procedures may be used to treat conditions including: foraminal stenosis, herniated disc, bulging disc, pinched nerve or nerve root compression, scar tissue formation, bone spurs, arthritis of the spine, and sciatica.

[0035] FIGS. **5**A-**5**E illustrate one embodiment of a method for a foraminotomy procedure using a flexible, robotically steerable catheter (**18**). As discussed above, different embodiments of a catheter may be equipped with various types of tools at the distal end and a varying number of through lumens may be provided. FIG. **5**A illustrates a flexible, robotically steerable catheter (**18**) being driven through the epidural space to the area of treatment to remove pressure off the spinal nerve. FIG. **5**B illustrates a drill bit tip (**996**) and a router bit tip (**995**) which can be driven via a catheter (**18**) to the area of treatment. FIG. **5**C is a cross-sectional view of the removal of bone material to alleviate pressure on the spinal nerve. FIG. **5**D is a side view of the router bit tip catheter tool (**995**) being used to remove bone material. FIG. **5**E is a posterior view of the spine showing the removed section of bone material to allow room for the spinal nerve.

[0036] A common technique for correcting spinal problems is spinal fusion, which essentially welds or couples together specific bony segments of the spine to enhance bone growth into a solid and stable construct. The spinal fusion may be facilitated by the delivery of a spinal stabilization device. Spinous processes are located in the very back of the spinal column near the skin surface. A wide variety of spinal stabilization devices have been developed to facilitate spinal fusion. For example, these devices may include special plates, rods (i.e., Harrington or Knodt rods), hooks, screws, spacers, crosslinking devices, and many others. There are also several types of interspinous devices on the market including the X-STOP Interspinous Process Decompression device made by St. Francis Medical Technologies of Concord, Calif., the Wallis Mechanical Normalization device of Abbott Spine of Austin, Tex., the DIAM Spinal Stabilization System available from Medtronic Sofamor Danek of Memphis, Tenn., and the Coflex Interspinous Implant available from Paradigm Spine of New York, N.Y., all of which may be surgically implanted into a patient with the use of a flexible, robotically controlled catheter instrument and system.

[0037] With a minimally invasive surgical procedure, one or more interspinous process spacers may be implanted to open the foramen, thus relieving the nerve endings and unloading the intervertebral discs. A surgeon may utilize a catheter device to access the surgical space on the spine and to deliver one or more stabilization devices. In some situations, a plurality of catheter devices may be utilized to perform the device implant or installation.

[0038] One situation wherein a method for spinal fusion may be used is a discectomy procedure that actually removes an intervertebral disc because the herniated disc is so badly damaged. After the disc is removed, a spinal instrumentation and fusion procedure may be performed to restore the lost disc height as a result of the removed disk and to join the adjacent vertebrae together to stabilize those segments of the spine. A low profile segmental spinal instrumentation system such as the X10 Crosslink Plate Spinal System also available from Medtronic Sofamor Danek of Memphis, Tenn. may be deployed with a flexible catheter in one embodiment. Crosslinking devices are transverse implants that connect an implanted rod on one side of the spine to an implanted rod on the other side. In some instances, a drill or scraper at the distal tip of the catheter may remove an amount of bone from the spinal segment so that the crosslinking devices or bone graft may be implanted.

[0039] Another method for spinal stabilization is a DIAM Spinal Stabilization System available from Medtronic Sofamor Danek. The DIAM system is an alternative to spinal fusion. Through a small incision, a flexible catheter may be used to insert an H-shaped silicone DIAM implant between two spinous processes to treat spinal stenosis. The outer mesh band and tether of the DIAM implant are fabricated from polyester and the crimp is made of titanium. Because the implant device is available in a variety of sizes to accommodate individual patient anatomy, different embodiments of a flexible catheter may be adapted to handle different devices. For example, one implementation of a catheter may be designed to handle multiple models of an implant device.

[0040] FIGS. **6**A-**6**D illustrate one embodiment of a method for delivering a spinal stabilization (**993**) device using a flexible, robotically steerable catheter (**18**). As discussed above, different embodiments of a catheter may be equipped with various types of tools at the distal end and a varying number of through lumens may be provided. FIG. **6**A illustrates a flexible, robotically steerable guide catheter (**18**) entering the interstitial space between two spinous processes. FIG. **6**B illustrates the catheter (**18**) with an inflatable/fillable pre-formed spinal stabilization device (**993**) being inserted into the interstitial space between the two spinous processes. FIG. **6**C illustrates the inflated/filled device (**993**) being deployed and taking shape between the two spinal processes. FIG. **6**D illustrates a posterior view of the spinal stabilization device (**993**) fully inflated/filled and in place between the two spinous processes.

[0041] One minimally invasive surgical technique for stabilizing fractured vertebra is a vertebroplasty procedure wherein bone cement is percutaneously injected into a fractured vertebra. However, a kyphoplasty procedure developed primarily by Kyphon Inc. of Sunnyvale, Calif. has improved upon that. Kyphoplasty is a treatment of osteoporotic vertebral compression fractures (VCF) using balloon catheters. Kyphoplasty is a minimally invasive spinal surgery procedure where the original height and angle of kyphosis of a fractured vertebra may be restored, followed by its stabilization using injected bone filler material.

[0042] Kyphoplasty is generally used to treat painful progressive vertebral body collapse/fractures (VCFs), which may be caused by osteoporosis or the spread of tumor to the vertebrae body. Some vertebral compression fractures (VCFs) are clinically unstable. Some VCFs may involve significant loss of function due to bone pressing on the spinal cord or spinal nerves. Kyphoplasty is designed to stop the pain caused by the bone fracture, to stabilize the bone, and to restore some or all of the lost vertebral body height due to the compression fracture. In a number of applications, the height and angle restoration is accomplished through hydraulic or mechanical intravertebral expansion.

[0043] During a kyphoplasty procedure, one or more small incisions are made on the patient's back. One or more catheters with a through lumen is inserted into the vertebral body and a balloon is deployed at the distal tip. The balloon is inflated via a port on the catheter, thus pushing the bone back towards its normal height and shape. Once a cavity is created, the inflatable balloon bone tamp may be removed. Bone cement is then delivered through a catheter instrument to fill the cavity. For one embodiment, the bone cement is comprised of a vinyl polymer such as polymethyl methacrylate (PMMA). The catheters and surgical instruments are removed from the patient and the incisions closed.

[0044] One of the perceived benefits of kyphoplasty over vertebroplasty is that kyphoplasty uses a balloon to create a void in the cancellous part of the collapsed vertebral body that can then be filled with a more viscous bone cement. The viscous properties of this bone cement decrease the likelihood that the cement will leak out of the vertebral body and affect other parts of the vertebra, especially the spinal cavity which contains the sensitive spinal nerves. Inflating the balloon within the bone can also help reduce the deformity created by the collapsed bone, as the balloon helps restore some or most of the vertebral height and shape. By restoring some percentage of the vertebral body's pre-fracture height, it may be possible to alleviate some of the pain caused by compression of the thoracic cavity.

[0045] FIGS. **7**A-**7**F illustrate one embodiment of a method for a kyphoplasty procedure using a flexible, robotically steerable catheter (**18**). In this example, the procedure is performed with a sheath catheter (**30**) and a guide catheter (**18**) instrument set. As discussed above, different embodiments of a catheter may be equipped with various types of tools at the distal end and a varying number of through lumens may be provided. FIG. **7**A illustrates a small hole being drilled into the affected vertebra with an end-effector (**19**) mounted to the distal tip of a flexible, robotically steerable catheter (**18**). FIG. **7**B illustrates insertion of a balloon (**102**) through a flexible, robotically steerable catheter (**18**) into the hole. FIG. **7**C illustrates inflation of the balloon (**102**) to create a void and to return the affected vertebra to its proper position/height. FIG. **7**D illustrates the deflated balloon catheter (**102**) being removed and leaving behind a cavity/void to be filled within the affected vertebra. FIG. **7**E illustrates the void being filled with a material such as bone cement via the working lumen of a catheter (**18**). FIG. **7**F illustrates the finished view of the hardened material in the void to restore the affected vertebra to its original position.

[0046] As disclosed above, minimally invasive procedures such as vertebroplasty or kyphoplasty have been performed to remedy VCFs. These procedures use an injection of bone cement to support the vertebra. While these procedures have been effective for many patients, some procedures have also resulted in unintended events including cement leakage, toxicity reactions, and an increased potential for fracture of an adjacent vertebral body.

[0047] An alternative minimally invasive spinal repair technique is a spineoplasty developed by Spineology of St. Paul, Minn. Spineoplasty is a minimally invasive procedure that uses the OptiMesh Deployable Grafting System and biologically-friendly bone graft. Spineoplasty is similar to Kyphoplasty, but this time the void/cavity is dug out and a mesh bag (such as an Optimesh device, described below) is inserted. The bag is filled with bone graft material and left in the cavity to harden.

[0048] The OptiMesh, also available from Spineology, is a three-dimensional deployable mesh pouch for implantation into skeletal defects. Once implanted into place, the empty pouch is filled to the desired size. By using bone graft instead of bone cement, the center of the vertebra is allowed to heal. In Spineoplasty, the OptiMesh implant contains the graft, enabling the graft to potentially reduce deformity and support the vertebra. The contained bone graft, in addition to having the potential to incorporate, provides support to the vertebral body that can significantly reduce pain and increase mobility while healing occurs. With a spineoplasty, the size and shape of the damaged vertebra may be restored.

[0049] FIGS. **8**A-**8**E illustrate one embodiment of a method for a spineoplasty procedure using a flexible, robotically steerable catheter (**18**). As discussed above, different embodiments of a catheter may be equipped with various types of tools at the distal end and a varying number of through lumens may be provided. The patient is sedated and lies prone on the surgical bed. A very small incision is made along the spine. A catheter (**18**) is inserted through the incision to create a cavity in the vertebra. FIG. **8**A illustrates a small hole being drilled into the affected vertebra with a drill bit (**996**) mounted on the distal tip of a flexible, robotically steerable catheter (**18**). FIG. **8**B illustrates a cavity being created using router bit tip (**995**) on the end of the flexible catheter (**18**) through the hole. In alternative embodiments, a cavity may be created with an expanding shape tool or a bone scraper. FIG. **8**C illustrates the delivery of the OptiMesh pouch device (**994**) into the cavity via the robotically controlled catheter (**18**) inserted through the hole. The empty OptiMesh pouch device (**994**) is implanted into position. FIG. **8**D illustrates the OptiMesh device (**994**) being filled with bone graft material (**21**) via the working lumen of the catheter (**18**). The mesh pouch (**994**) is inflated with bone graft to support the damaged vertebra and then released. FIG. **8**E illustrates the cavity filled by the OptiMesh pouch being allowed to harden and also shows the removal of the catheter (**18**).

[0050] While multiple embodiments and variations of the many aspects of the invention have been disclosed and described herein, such disclosure is provided for purposes of illustration only. Many combinations and permutations of the disclosed system are useful in minimally invasive surgery, and the system is configured to be flexible. While multiple embodiments and variations of the many aspects of the invention have been disclosed and described herein, such disclosure is provided for purposes of illustration only. Many combinations and permutations of the disclosed system are useful in minimally invasive surgery, and the system is configured to be flexible. Many combinations and permutations of the disclosed system are useful in minimally invasive surgery, and the system is configured to be flexible, and it should be understood that the invention generally, as well as the specific embodiments described herein, are not limited to the particular forms or methods disclosed, but also cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

What is claimed is:

1. A method for performing a medical procedure on a patient's spine, comprising:

inserting a robotically controlled, flexible catheter instrument through the sacral hiatus and into the epidural space of the spine;

robotically maneuvering a distal end portion of the catheter instrument toward the lumbar spine; and

performing a therapeutic procedure on the spine using said catheter instrument.

2. The method of claim **1**, wherein the therapeutic procedure is a lumbar discectomy.

3. The method of claim **1**, wherein performing the therapeutic procedure comprises:

puncturing a herniated disc using a needle coupled to the catheter instrument;

removing a part of the herniated disc using an end effector coupled to the catheter instrument; and

draining an area of the herniated disc using a suction port disposed on the catheter instrument.

4. The method of claim **1**, wherein the therapeutic procedure comprises a laminectomy.

5. The method of claim **1**, wherein performing the therapeutic procedure comprises removing a portion of the lamina of the spine using an end effector coupled to the catheter instrument to relieve pressure on the spinal cord of the spine.

6. The method of claim **5**, wherein said end effector comprises a drill bit or a router bit.

7. The method of claim **1**, wherein the therapeutic procedure comprises a forminotomy.

8. The method of claim **1**, wherein performing the therapeutic procedure comprises removing material from the bones of the vertebrae that pass nerve bundles to the body from the spinal cord of the spine using an end effector coupled to the catheter instrument.

9. The method of claim **8**, wherein the end effector comprises a drill bit or a router bit.

10. The method of claim **1**, wherein the therapeutic procedure comprises the delivery of a spinal stabilization device.

11. The method of claim **1**, wherein performing the therapeutic procedure comprises:

robotically maneuvering the distal end portion of the catheter instrument to an interstitial space between two spinous processes of the spine;

inserting a deflated spinal stabilization device carried by the catheter instrument into the interstitial space; and

inflating the spinal stabilization device.

12. The method of claim **1**, wherein performing the therapeutic procedure comprises:

robotically maneuvering the distal end portion of the catheter instrument to an interstitial space between two spinous processes of the spine;

removing at least a part of an intervertebral disc using an end effector coupled to the catheter instrument;

inserting a deflated spinal stabilization device carried by the catheter instrument into the interstitial space; and

inflating the spinal stabilization device.

13. The method of claim **1**, wherein the therapeutic procedure is a kyphoplasty procedure.

14. The method of claim **1**, wherein performing the therapeutic procedure comprises:

drilling a hole into a damaged vertebra of the spine using an end effector coupled to the catheter instrument;

inserting a balloon carried by the catheter instrument through the hole and into an interior cavity of the vertebra;

inflating the balloon to displace damaged vertebral tissue located in the interior of the vertebra to thereby enlarge the cavity;

deflating and removing the balloon from the cavity; and

introducing a filling material into the cavity through the hole using the catheter instrument.

15. The method of claim **1**, wherein the therapeutic procedure is a spineoplasty.

16. The method of claim **1**, wherein performing a therapeutic procedure comprises:

drilling a hole into a damaged vertebra of the spine using a first end effector coupled to the catheter instrument;

creating a cavity in the damaged vertebra using a second end effector coupled to the catheter instrument;

inserting a porous retainer into the cavity using the catheter instrument; and

introducing bone graft material into the retainer via a working lumen of the catheter instrument.

17. A method for performing a medical procedure on a patient's spine, comprising:

inserting two or more robotically controlled, flexible catheter instruments through the sacral hiatus and into the epidural space of the spine;

robotically maneuvering the two or more catheter instruments toward the lumbar spine; and

performing a therapeutic procedure on the spine using the two or more catheter instruments.

18. The method of claim **17**, wherein respective one or more end effectors are coupled to respective distal end portions of each of the two or more catheter instruments.

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