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- (71) **Applicant:** AUCTUS SURGICAL, LLC [US/US]; 318 Main Street, Suite 3H, San Francisco, CA 94105 (US).
- (72) **Inventors:** BARRETT, John; c/o Auctus Surgical, LLC, 318 Main Street, Suite 3H, San Francisco, CA 94105 (US). KADABA, Murali; c/o Auctus Surgical, LLC, 318 Main Street, Suite 3h, San Francisco, CA 94105 (US). ASHLEY, John; C/o Auctus Surgical, LLC, 318 Main Street, Suite 3H, San Francisco, CA 94105 (US).
- (74) **Agent:** KOHLER, Thomas, D.; Downs Rachlin Martin PLLC, 199 Main Street, P.O. Box 190, Burlington, VT 05402-0190 (US).
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(54) **Title:** SPINAL CURVATURE MODULATION SYSTEMS

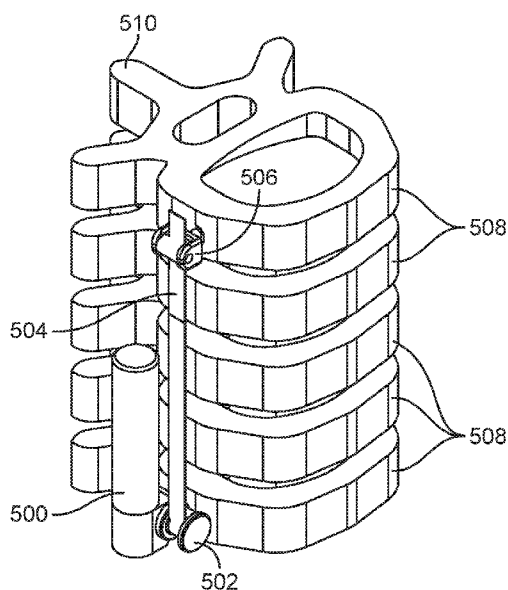


FIG. 17

(57) **Abstract:** Spinal curvature modulation systems, methods and related devices and instrumentation are disclosed, which include a flexible tether, a tether tensioning unit and bone anchors for the flexible tether that allow the tether to be secured across multiple vertebrae in a region of treatment. When the flexible tether is attached to multiple vertebrae, it can be used to correct spinal deformities. Tension in the flexible tether is adjustable transcatheterly without invasive surgical procedures by use of remotely driven actuators, such as a magnet-driven motor, or by a small tool insertable through a small incision. Disclosed systems and methods thus allow for multiple adjustments of tether tension, and spinal curvature, over time without repeated, highly invasive, spinal surgeries.

## SPINAL CURVATURE MODULATION SYSTEMS

## FIELD OF THE INVENTION

**[0001]** The present disclosure relates generally to orthopedic devices and methods for correcting or modulating spinal deformities utilizing non-fusion surgical treatments. More specifically, the disclosure relates to a non-fusion scoliosis construct which incorporates a flexible tether whose tension can be adjusted by a remotely controlled internal engine or by other mechanical means in a non-invasive manner. This facilitates the maintenance of corrective forces on the curvature of the spine without significant invasive surgical intervention.

## BACKGROUND

**[0002]** Scoliosis is generally a term used to describe an abnormal curvature of the spine, usually in the thoracic or thoracolumbar region. Scoliosis is commonly broken up into different treatment groups, Adolescent Idiopathic Scoliosis, Early Onset Scoliosis and Adult (degenerative) Scoliosis.

**[0003]** Adolescent Idiopathic Scoliosis (AIS) typically affects children between ages 10 and 16, and becomes most severe during growth spurts that occur as the body is developing. One to two percent of children between ages 10 and 16 have some amount of scoliosis. Of every 1000 children, two to five develop curves that are serious enough to require treatment. The degree of scoliosis is typically described by the Cobb angle, which is determined, usually from x-ray images, by taking the most tilted vertebrae above and below the apex of the curved portion and measuring the angle between intersecting lines drawn perpendicular to the top of the top vertebra and the bottom of the bottom vertebra. The term "idiopathic" means that the exact cause of this curvature is unknown. Some have speculated that scoliosis occurs when, during rapid growth phases, the ligamentum flavum of the spine is too tight and hinders symmetric growth of the spine. For example, as the anterior portion of the spine elongates faster than the posterior portion, the thoracic spine begins to straighten, until it curves laterally, often with an accompanying rotation. In more severe cases, this rotation actually creates a noticeable deformity, wherein one shoulder is lower than the other.

**[0004]** Typically, patients with a Cobb angle of 20° or less are not treated, but are continually followed up, often with subsequent x-rays. Patients with a Cobb angle of 40° or greater are usually recommended for fusion surgery. It should be noted that many patients do not receive this spinal assessment, for numerous reasons. Many school districts do not perform this assessment, and many children do not regularly visit a physician, so often, the curve progresses rapidly and severely. In

AIS, the ratio of females to males for curves under  $10^\circ$  is about one to one, however, at angles above  $30^\circ$ , females outnumber males by as much as eight to one. Fusion surgery can be performed on the AIS patients or on adult scoliosis patients. In a typical posterior fusion surgery, an incision is made down the length of the back and Titanium or stainless steel straightening rods are placed along the curved portion. These rods are typically secured to the vertebral bodies with pedicle screws, in a manner that allows the spine to be straightened. Usually, at the section desired for fusion, the intervertebral disks are removed and bone graft material is placed to create the fusion. Alternatively, the fusion surgery may be performed anteriorly. A lateral and anterior incision is made for access. Usually, one of the lungs is deflated in order to allow access to the spine from this anterior approach.

**[0005]** In a less-invasive version of the anterior procedure, instead of the single long incision, approximately five incisions, each about three to four cm long are made in several of the intercostal spaces (between the ribs) on one side of the patient. In one version of this minimally-invasive surgery, rods and bone screws are placed and are secured to the vertebrae on the anterior convex portion of the curve. Once the patient reaches spinal maturity, it is difficult to remove the rods and associated hardware in a subsequent surgery, because the fusion of the vertebrae usually incorporates the rods themselves. Standard practice is to leave this implant in for life. With either of these two surgical methods, after fusion, the patient's spine is now relatively straight, but depending on how many vertebrae were fused, there are often limitations in the degree of flexibility, both in bending and twisting. As these fused patients mature, the fused section can impart large stresses on the adjacent non-fused vertebrae, and often, other problems including pain can occur in these areas, sometimes necessitating further surgery. This tends to be in the lumbar portion of the spine that is prone to problems in aging patients. Many physicians are now interested in non-fusion surgery for scoliosis, which may eliminate some of the drawbacks of fusion.

**[0006]** One group of patients in which the spine is especially dynamic is the subset known as Early Onset Scoliosis (EOS), which typically occurs in children before the age of five, and more often in boys than in girls. This is a more rare condition occurring in only about one or two out of 10,000 children, but can be severe, sometimes affecting the normal development of organs. Because of the fact that the spines of these children will still grow a large amount after treatment, non-fusion distraction devices known as growing rods have been developed. These devices are typically adjusted approximately every six months, to match the child's growth, until the child is at least eight years old, sometimes until they are 15 years old. Each adjustment requires a surgical incision to

access the adjustable portion of the device. Because the patients may receive the device at an age as early as six months old, this treatment requires a large number of surgeries. Because of the multiple surgeries, these patients have a high preponderance of infection.

**[0007]** In AIS patients, the treatment methodology for those with a Cobb angle between 20° and 40° is controversial. Many physicians prescribe a brace (for example, the Boston Brace), that the patient must wear on their body and under their clothes 18 to 23 hours a day until they become skeletally mature, for example to age 16. Because these patients are all passing through their socially demanding adolescent years, it is quite a serious prospect to be forced with the choice of either wearing a somewhat bulky brace that covers most of the upper body, having fusion surgery that may leave large scars and also limit motion, or doing nothing and running the risk of becoming disfigured and possibly disabled. The patient compliance with brace wearing has been so problematic that there have been special braces constructed which sense the body of the patient, and keep track of the amount of time per day that the brace is worn. Coupled with the inconsistent patient compliance with brace usage, is a feeling by many physicians that braces, even if used properly, are not at all effective in treating scoliosis. These physicians may agree that bracing can possibly slow down or even temporarily stop curve (Cobb angle) progression, but they have noted that as soon as the treatment period ends and the brace is no longer worn, often the scoliosis rapidly progresses, to a Cobb angle even more severe than it was at the beginning of treatment up until skeletal maturity.

**[0008]** In the treatment of patients with AIS, surgeons are leaning more towards non-fusion approaches using rigid growing rods. The growth of the rod is configured to be consistent with the normal growth pattern of the adolescent patient and the length of the rod is modulated by a magnetic system via an external magnetic driver in a non-invasive manner. Some surgeons are now beginning to use flexible tethers instead of rigid rods. In this method, a tether is applied on the convex side of the scoliosis curve using pedicle screws applied posteriorly or laterally onto each vertebra. The tether is appropriately tensioned to correct the curvature intraoperatively. As the patient grows, the tension in the tether is adjusted periodically (usually every 6 months) via a surgical approach. This procedure requires periodic re-operation subjecting the patient to an extended recovery period. Therefore, there is a need for spinal construct utilizing flexible tethers with an ability to modulate the tension of the tether from outside the body in a non-invasive manner.

## SUMMARY OF THE DISCLOSURE

**[0009]** In one implementation, the present disclosure is directed to a spinal curve modulation system for treating spinal curvature along a treatment region of the spine. The system includes a flexible tether of sufficient length to extend across the treatment region of the spine including across at least three adjacent vertebral bodies in a cranial-caudal direction; at least one first bone anchor configured to be fixed to a first vertebra and to an end of the flexible tether; a tether tensioning unit comprising a tether interface and a drive mechanism operatively linked to the tether interface to adjust tension in the flexible tether; and at least one second bone anchor configured to fix the tether tensioning unit to a vertebra across the treatment region from at the at least one first bone anchor; wherein the tether tensioning unit is actuatable to adjust tension in the flexible tether without surgically exposing the flexible tether or the at least one first bone anchor.

**[0010]** In another implementation, the present disclosure is directed to a spinal curve modulation system for treating spinal curvature along a treatment region of the spine. The system includes a flexible tether of sufficient length to extend across the treatment region of the spine including across at least three adjacent vertebral bodies in a cranial-caudal direction; at least one first bone anchor including a tether attachment means; a transcutaneously actuatable drive mechanism; a tether receiving spool operatively linked to the drive mechanism for rotation of the tether receiving spool to adjust tension in the flexible tether; at least one second bone anchor configured to anchor the rotary drive mechanism and tether receiving spool to a vertebra across the treatment region from at least one the first bone anchor; and a transcutaneous actuator configured to actuate the drive mechanism transcutaneously.

**[0011]** In still another implementation, the present disclosure is directed to a method of treating an abnormal spinal curvature along a treatment region of the spine. The method includes providing surgical access to the treatment region of the spine, the treatment region extending along the spine in a generally cranial-caudal direction and spanning at least three adjacent vertebrae; fixing an anchor element on a selected vertebra at a first end of the treatment region; fixing a tether tension adjustment mechanism on a selected vertebra at a second end of the treatment region; extending a flexible tether between the tension adjustment mechanism and the anchor element, wherein the flexible tether is fixed to the anchor element and engages the tension adjustment mechanism for adjustment of tension in the flexible tether; manipulating the tension adjustment mechanism to initially tension the flexible tether so as to reposition vertebrae across the treatment region; closing

the surgical access to the treatment region of the spine; and post-operatively, subsequent to closing the surgical access and without reopening or creating new surgical access to the flexible tether or anchor elements, manipulating the tension adjustment mechanism in vivo to periodically adjust tension in the flexible tether.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0012]** For the purpose of illustrating the invention, the drawings show aspects of one or more embodiments of the invention. However, it should be understood that the present invention is not limited to the precise arrangements and instrumentalities shown in the drawings, wherein:

FIGS. 1A-D are illustrations of a spine from a posterior view with a tether attached laterally.

FIGS. 2A-D are illustrations of a spine from a posterior view with a tether attached posteriorly.

FIG. 3 is an illustration of a vertebra from a posterior view with a tether screw attached laterally.

FIG. 4 is an illustration of an exemplary embodiment of a spinal curvature modulation system.

FIG. 5 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 6 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 7 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 8 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 9 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 10 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 11 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 12 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 13 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 14 is an illustration of an alternate embodiment of a spinal curvature modulation system.

FIG. 15 is an illustration of a magnetic drive mechanism for adjusting a spinal curvature modulation system.

FIG. 16 is a flow chart illustration of a treatment method for spinal curvature modulation.

FIG. 17 is a perspective view of a further alternative embodiment of a spinal curvature modulation system according to the present disclosure.

FIG. 17A is a perspective view of tether tensioning unit and bone anchor utilized to fix the tether tensioning unit to a vertebrae according to embodiments described herein.

FIGS. 18, 19, 20, 21, 22, and 23A are perspective views of embodiments of spinal curvature modulation systems showing alternative positioning in accordance with the present disclosure.

FIG. 23B is a cephalad view of an alternative embodiment of the spinal curvature modulation system shown in FIG. 23A.

FIG. 23C illustrates posterior positioning of a spinal curvature modulation system according to embodiments described herein.

FIG. 24A is a perspective view of an anchor screw for a spinal curvature modulation system.

FIG. 24B is a front view of the anchor screw shown in FIG. 24A.

FIG. 24C is a detailed view of the anchor screw shown in FIG. 24B.

FIG. 25A is a perspective view of an alternate anchor screw for a spinal curvature modulation system.

FIG. 25B is a front view of the anchor screw shown in FIG. 25A.

FIG. 25C is a sectional view of the anchor screw shown in FIG. 25B through line A-A.

FIG. 25D is a detailed view of the anchor screw shown in FIG. 25C in an unlocked position.

FIG. 25E is a detailed view of the anchor screw shown in FIG. 25C in a locked position.

FIG. 26 is a perspective view of a slip screw for a spinal curvature modulation system.

FIG. 27 is a perspective view of a slip staple for a spinal curvature modulation system.

FIG. 28 is a perspective view of an alternate slip screw for a spinal curvature modulation system.

FIG. 29A is an illustration of a spine from a posterior view with an alternate embodiment of the spinal curvature modulation system attached laterally.

FIG. 29B is an illustration of a spine from a lateral view of the embodiment of the spinal curvature modulation system shown in FIG. 29A.

FIG. 30 is a perspective view of an alternate tension adjustment mechanism for the spinal curvature modulation system.

FIG. 31A is a perspective view of an alternate embodiment of a tension adjustment mechanism for the spinal curvature modulation system.

FIG. 31B is a perspective view of the tension adjustment mechanism of FIG. 31A with a housing removed.

FIG. 32A is a perspective view of a globoid worm and spur gear mechanism.

FIG. 32B is a side view of the globoid worm and spur gear mechanism shown in FIG. 32A.

#### DETAILED DESCRIPTION

**[0013]** Embodiments described herein are directed to spinal curvature modulation systems, methods and related devices and instrumentation. In general and as described in greater detail below, embodiments of described systems include a flexible tether, a tether tensioning unit and bone anchors for the flexible tether that allow the tether to be secured across multiple vertebrae in a region of treatment. Tension in the flexible tether is adjustable transcutaneously with remote devices or with an elongate tool requiring only a small access incision, typically about 2 cm or less. Embodiments described thus allow for multiple adjustments of tether tension, and spinal curvature, over time without repeated, highly invasive, spinal surgeries.

**[0014]** FIG. 1A shows a spine with a given angular deformity with angle  $\alpha$ . With a lateral approach, screws can be placed into the vertebrae on the convex side of the curve, above and below the apex. Threaded through the screws is a flexible tether. This tether is fixed at the topmost and bottommost instrumented vertebrae across a region of treatment, but if there are any intermediate instrumented vertebrae, the tether is allowed to slide in eyes formed at the screw heads. How many vertebrae are instrumented is determined clinically but must be greater than or equal to 2. FIG. 1B shows a tensile force applied to the tether at location (A) and location (C) to correct the deformity. It is not necessary for the tensile force to be applied at both locations. Tensile force at location (A) and/or location (C) will correct the deformity. FIG. 1C shows an equal and opposite tensile force applied to the tether at location (B) to correct the deformity. FIG. 1D shows the same spine after tension force is applied at location (A), (B) and/or (C). The angular deformity has been corrected.

**[0015]** FIG. 2A shows a spine with a given angular deformity with angle  $\alpha$ . With a posterior approach, pedicle screws can be placed into the vertebrae on the convex side of the curve, above and below the apex. Threaded through the pedicle screws is a flexible tether. This tether is fixed at the topmost and bottommost instrumented vertebrae, but if there are any intermediate instrumented vertebrae, the tether is again allowed to slide in the screw heads. How many vertebrae are instrumented is determined clinically but must be greater than or equal to 2. FIG. 2B shows a tensile force applied to the tether at location (A) and location (C) to correct the deformity. It is not



necessary for the tensile force to be applied at both locations. Tensile force at location (A) and/or location (C) will correct the deformity. FIG. 2C shows an equal and opposite tensile force applied to the tether at location (B) to correct the deformity. FIG. 2D shows the same spine after tension force is applied at location (A), (B) and/or (C). The angular deformity has been corrected.

**[0016]** FIG. 3 shows a screw 90 implanted into a vertebra (V). This screw is designed such that the tether may be threaded through eye 92 in the screw head such that the tether is constrained, but may still slide. Screw 90 also may be used to fix the free end of the tether to a vertebra by passing the tether through the eye and fastening it back to itself such as with a crimpable ferrule or other cable fixation device. A socket for a driving tool may also be provided on the outer end of the screw head.

**[0017]** FIG. 4 schematically illustrates an embodiment of a spinal curvature modulation system. The system includes a tether tensioning unit 99, which in this example comprises a transcutaneously actuatable drive mechanism including an internal actuator 100 acting through gearbox 101 to drive worm gear 102 and tether interface 103. The worm gear in turn drives tether interface 103 to tension or de-tension flexible tether 104. In one example, internal actuator 100 may comprise a magnetic motor with a remotely controllable rotatable magnet, which can be driven by an external driver mechanism (see, e.g. FIG. 15). The external driver mechanism may comprise another rotatable magnet and a mechanism for controlling the rotation of that magnet, for example an electric motor and control system. An exemplary gear set for gearbox 101 is shown in FIGS. 32A and 32B. In one example, rotation of worm gear 102 rotates a tether interface 103 through engagement with meshing spur gear teeth. In one alternative the teeth of the spur gear may directly engage the flexible tether to form tether interface 103 such that when the spur gear rotates it provides a force on the tether 104 to either increase or decrease the tension in the tether 104. In an alternative embodiment, a separate tether engaging member is combined with the spur gear, for example integrally side by side or disposed on a common shaft, to form tether interface 103. In such an alternative embodiment, the tether engaging member may be formed as a wheel, disk or other rotatable member with a periphery configured to mesh with the material of the flexible tether, such as teeth, spikes, abrasive or other high friction surface. In one example, tether 104 may be formed as a cable, band or ribbon made from a braided polymer or metal, for example ultra-high molecular weight polyethylene (UHMWPE), polyethylene terephthalate (PET), thermoplastic polycarbonate polyurethane (PCU, e.g., Bionate®) or a multilayered polymeric strand comprising low molecular and high molecular

weight polyethylene. Metals employed may comprise stainless steel, titanium and alloys thereof in solid or braided configurations. The tether 104 may be designed with a tensile strength higher than 300N. When the tether 104 is attached to multiple vertebrae it can be used to correct spinal deformities as described herein. Flexibility of tether 104 should be at least sufficient to conform to the existing curvature of the area of the spine to be treated without experiencing plastic deformation, in other words, sufficient to maintain resiliency in all modes of operation.

**[0018]** It is to be understood that the embodiments disclosed herein are disclosed as exemplary embodiments to illustrate, when considered as a disclosure as a whole, the various features, components and steps of embodiments of the present invention. Each combination of components as would be understood by persons of ordinary skill in the art based on the teachings herein is not explicitly shown because all possible combinations will be appreciated and understood from the embodiments illustrated. For example, it will be understood that unless otherwise described any disclosed internal actuator, gearbox and drive gear disclosed may be used in any combination to make up a tether tensioning unit in accordance with the teachings of the present disclosure. Similarly, any compatible combination of disclosed tether interface and flexible tether may be used together with any disclosed tether tensioning unit. Thus, it will be understood, for example, that tether tensioning unit 99, while illustrated above as employing a magnetically actuated internal actuator 100, may also employ any other internal actuator within the scope of the present disclosure.

**[0019]** FIG. 5 schematically illustrates another embodiment of a spinal curvature modulation system utilizing a flexible band tether in which tension is controlled by tether tensioning unit 109. In this exemplary embodiment, the system includes a rotatable magnet 110 as an internal actuator, which can be driven by an external driver mechanism (see, e.g., FIG. 15). The rotation of the magnet 110 drives a gearbox 111 which in turn drives a worm gear 112; the worm gear acting as the tether interface. The teeth of the worm gear 112 mesh with diagonal cuts in a band tether 113. Rotation of the worm gear 112 provides a force on the band tether 113 to either increase or decrease the tension in the band tether 113. When the band tether 113 is attached to multiple vertebrae, it can be used to correct spinal deformities.

**[0020]** FIG. 6 schematically illustrates a further embodiment of a spinal curvature modulation system in which flexible tether tension is controlled by tether tensioning unit 119. The system includes an electric motor 120 as internal actuator which can be driven by an externally induced current or via subcutaneous power leads (see, e.g., FIG. 10). A suitable electric motor for this

purpose may be one that provides power in the range of about 1.0-1.2 W. Alternatively, electric motor 120 may be replaced with a magnetic drive or other internal actuator as described herein. The rotation of the motor 120 drives a gearbox 121 which in turn drives a worm gear 122. Rotation of the worm gear 122 rotates the tether interface, in this example a spur gear 123 attached to or integral with spool 124 such that they rotate together. When the spool 124 rotates it provides a force on the tether 125 to either increase or decrease the tension in the tether 125. When the tether 125 is attached to multiple vertebrae, it can be used to correct spinal deformities.

**[0021]** FIG. 7 schematically illustrates another embodiment of a spinal curvature modulation system in which flexible tether tension is controlled by tether tensioning unit 129. The system includes internal actuator 130 as described in other embodiments which can be driven by, for example, an external driver mechanism (see, e.g. FIG. 15) or induction or directly delivered current (see, e.g., FIG. 10). Alternatively, a manual drive may be used. The rotation of the internal actuator 130 drives a gearbox 131 which in turn drives a bevel gear 132. Rotation of the bevel gear 132 rotates the tether interface comprising, in this example, a second bevel gear 133 and spur gear 134, which may be attached or integrally formed. Bevel gear 133 is perpendicular from the first bevel gear 132 and spur gear 134 is attached to the second bevel gear 133 such that they rotate together. The teeth of the spur gear 134 mesh with two flexible tethers 135 which continue in opposite directions. When the spur gear 134 rotates it provides equal and opposite forces on the two tethers 135 to either increase or decrease the tension in the tethers 135. When the tethers 135 are attached to multiple vertebrae, it can be used to correct spinal deformities.

**[0022]** FIG. 8 schematically illustrates a detail of an alternative embodiment of a spinal curvature modulation system. In this example, the system includes a rotatable magnet 140 as internal actuator, which can be driven by an external driver mechanism (see, e.g. FIG. 15). The magnet 140 is attached to a housing 141 such that they rotate together. The housing is attached to two tethers 142 such that when the housing 141 rotates, it provides equal and opposite forces on the two tethers 142 to either increase or decrease the tension in the tethers 142. When the tethers 142 are attached to multiple vertebrae, it can be used to correct spinal deformities.

**[0023]** FIG. 9 schematically illustrates another exemplary embodiment of a spinal curvature modulation system in which flexible tension is controlled by tether tensioning unit 149. The system includes a rotatable magnet 150 as internal actuator, which can be driven by an external driver mechanism (see, e.g., FIG. 15). Once again, as elsewhere described herein, other disclosed internal

actuators may be substituted for the magnetic drive. The rotation of the magnet 150 drives a gearbox 151 which in turn drives tether interface 152, in this case formed as a threaded cylinder or other axially rotatable member. As tether interface 152 rotates, the threads of the threaded portion (referenced by a plane coincident with the axis of rotation) translate up or down. The threads of tether interface 152 thus mesh with a flexible tether 153 such that rotation provides a force on the tether 153 to either increase or decrease the tension in the tether 153. When the tether 153 is attached to multiple vertebrae, it can be used to correct spinal deformities.

**[0024]** FIG. 10 schematically illustrates an embodiment of a tether tensioning unit for a spinal curvature modulation system in which an electronic drive mechanism is provided. A wire coil 160 draws power from an externally positioned inductive wireless power transfer device 164 to feed an electric motor 161 to drive a gearbox 162, which in turn can be used in conjunction with mechanisms in the other embodiments described herein to apply a force on a tether to either increase or decrease the tension in the tether. Alternatively, or additionally, subcutaneous leads 163 may be provided, which can be easily accessed and direct power applied thereby. Examples of inductive wireless power transfer systems suitable for use in embodiments of the present invention are disclosed, for example, in U.S. Patent No. 6,092,531 and U.S. Patent Publication No. 2010/0201315, which are incorporated by reference herein in their entirety.

**[0025]** FIG. 11 schematically illustrates a detail of another embodiment of a spinal curvature modulation system utilizing a manual, hand-driven drive mechanism. In this example, the internal actuator comprises housing 170, which holds a drive nut 171. Drive nut 171 can be accessed through a small incision and can be rotated with an elongate manual tool 172 configured to engage the internal actuator. The drive nut 171 can be used in conjunction with other internal actuators described herein to provide redundant drive mechanisms for applying a force on a tether to either increase or decrease the tension in the tether. As used herein, a small incision, to permit access of an elongate tool to actuate a manual drive internal actuator, is an incision generally between about 1-3 cm in length and more typically about 2 cm in length.

**[0026]** FIG. 12 schematically illustrates a further alternative embodiment of a spinal curvature modulation system where a tether tension sensor 180 is integrated into the tether tensioning unit 181 to measure the tension applied to the tether 182. Sensor 180 may comprise a compatible tension sensing device, such as single roller or multi-roller sensors or direct strain gauge sensors, as may be selected by persons of ordinary skill in the art based on the teachings herein. Sensor 180 may be

configured to directly sense tension in the flexible tether or it may be positioned to sense torque or force within tether tensioning unit as an indicator of tension in the flexible tether. Tether tensioning unit 181 may comprise any of the magnetic, electronic or manual drive mechanisms as disclosed herein, or other suitable mechanism as may be derived by a person of ordinary skill based on the teachings of the present disclosure.

**[0027]** FIG. 13 schematically illustrates another alternative embodiment of a spinal curvature modulation system in which flexible tether tension is controlled by tether tensioning unit 189. The system includes a rotatable magnet 190 as an internal actuator, which can be driven by an external driver mechanism (see, e.g., FIG. 15). The rotation of the magnet 190 drives a gearbox 191 which in turn drives the tether interface, in this example, formed as worm gear 192. The teeth of the worm gear 192 mesh with tooth-shaped cuts in a band tether 193. Rotation of the worm gear 192 provides a force on the band tether 193 to either increase or decrease the tension in the band tether 193. When the band tether 193 is attached to multiple vertebrae, it can be used to correct spinal deformities.

**[0028]** FIG. 14 schematically illustrates an alternative embodiment of a spinal curvature modulation system in which flexible tether tension is controlled by tether tensioning unit 199. In this example, tether tensioning unit 199 includes a rotatable magnet drive 200 as elsewhere described, but may alternatively employ other internal actuators as also described. The rotation of the magnet 200 drives a gearbox 201 which in turn drives a bevel gear 202. Bevel gear 202 engages the tether interface comprising, in this example, a second bevel gear 203 and spur gear 204. Thus, rotation of the bevel gear 202 rotates second bevel gear 203 which is perpendicular from the first bevel gear 202. Spur gear 204 is attached to the second bevel gear 203 such that they rotate together. The teeth of the spur gear 204 mesh with diagonal cuts in a band tether 205. Rotation of the spur gear 204 provides a force on the band tether 205 to either increase or decrease the tension in the band tether 205. When the band tether 205 is attached to multiple vertebrae, it can be used to correct spinal deformities.

**[0029]** The use of a gear box 201 between the magnet 200 and the bevel gear 202 is highly advantageous for transferring the lower force of the rotating magnet to a much higher force required for tensioning the band tether 205 to correct deformities of the spine. In one particular embodiment the gear box 201, bevel gears 202 and 203, and spur gear 204 transfer 1000 rotations of the magnet 200 into 1 mm of translation of the tether band 205. In addition to transferring sufficient

force for correcting deformities of the spine, the gear box 201 and related bevel gears 202 and 203 and spur gears 204 are also beneficial in resisting the forces the corrected spine will place on the system as it tries to resist the correction. The gear box 201, bevel gears 202 and 203 and spur gears 204 act as a lock preventing the tension in the tether band 205 from reversing rotation of the spinal curvature modulation system. A gearbox that reduces the rotations of the rotating magnet at a ratio of approximately 1000 to 1 is beneficial at resisting the forces from the spine. Depending on parameters such as the type and size of the internal actuator, gear reduction ratios in the range of about 300:1 to about 5000:1 may be utilized in the gearbox.

**[0030]** FIG. 15 schematically illustrates one exemplary embodiment of an external magnetic drive mechanism 300 as may be utilized with magnetically driven embodiments described herein. In this embodiment, housing 302 contains drive magnet 304 and motor 306 connected to drive magnet 304 via drive shaft 308. Controller 310 controls the operation of motor 306. Controller 310 may include a programmable processor or other control system to permit precise, preprogrammed control, as well as intra-procedural adjustments by the surgeon. Controller 310 may also include a sensor or other wireless communication device, for example, to receive tether tension information from a tension sensor such as sensor 180, shown in FIG. 12. Further details of suitable magnetic drive mechanisms are disclosed, for example, in U.S. Patent Nos. 8,915,915 and 8,439,915, both of which are incorporated herein in their entirety.

**[0031]** FIG. 16 is a flow chart illustrating one exemplary embodiment of a treatment method 400 according to the present disclosure. As shown in FIG. 16, after an initial patient assessment 402, a determination is made as to the region to be treated including the vertebrae to be treated and the number and location of pedicle screws to be placed 404. A surgical access is created to the treatment region and bone anchors, typically, pedicle screws or other suitable bone anchors, are then placed 406 as determined in the prior step in accordance with standard surgical procedures. Exemplary bone anchors are illustrated in FIGS. 3, 24A and 25A. After placement of the bone anchor is confirmed, one or more tethers are installed 408 corresponding to the treatment modality determined in the initial assessment. Installation of the tether typically comprises attachment of a tether-free end to a bone anchor at one end of the treatment region and attachment of the tether tensioning unit to a bone anchor at an opposite end of the treatment region. When dual acting or opposed tethers are employed, for example as shown in FIGS. 6-8, then the tether tensioning unit may be secured to a bone anchor in a mid-range of the treatment region and tethers secured to bone

anchors at opposite ends of the treatment region. After installation of the tether(s), the tethers are initially tensioned 410. Initial tensioning may be accomplished before closure in order to confirm proper function. At periodic intervals after healing from the initial surgery to install the system, the patient is reassessed in follow-up assessments 412. An amount of additional movement is determined and corresponding additional or retensioning calculated based on the determined movement. Re-tensioning is remotely or manually effected 414 without creating a new surgical access to the tether or bone anchors using a drive mechanism appropriate for the installed system based on the follow-up assessment. Follow-up assessment and re-tensioning may be repeated as necessary until follow-up assessment indicates treatment is complete. Thereafter, the installed distraction system may be surgically removed 416.

**[0032]** FIG. 17 shows another exemplary spinal curvature modulation system attached laterally to a spine. The system comprises tether tensioning unit 500, flexible tether 504, a tether interface 502, in this case formed as a spool, and a tether bone anchor 506 attached to at least two vertebral bodies 508. One tether bone anchor 506 is attached to a vertebral body 508 at one end of the flexible tether 504 and tether tensioning unit 500 is attached to a vertebral body 508 at the other end of the flexible tether 504 with a second bone anchor as shown in FIG. 17A. The flexible tether 504 is wrapped around the tether spool 502 at one end and is fixed at the tether anchor 506 at the other end. The tension in the flexible tether 504 is increased or decreased by tether tensioning unit 500 by rotation of the tether spool 502 as was described above. Tether tensioning unit 500 can be positioned in any of a number of locations and still perform its function. Tether tensioning unit 500 can be comprised of any of the various elements described in the embodiments shown in FIGS. 4-14.

**[0033]** In FIG. 17, tether tensioning unit 500 is positioned posterior and superior in relationship to tether interface 502 as indicated by the spinous process 510 which is on the posterior of the spine. In FIG. 18 tether tensioning unit 500 is positioned posterior and inferior to tether interface 502 and flexible tether 504. In FIG. 19 tether tensioning unit 500 is positioned anterior and superior to tether interface 502. In FIG. 20 tether tensioning unit 500 is positioned anterior and inferior to tether interface 502 and flexible tether 504. In FIG. 21 tether tensioning unit 500 is positioned posterior and lateral to tether interface 502 and flexible tether 504. In FIG. 22 tether tensioning unit 500 is positioned anterior and lateral to tether interface 502 and flexible tether 504. In FIG. 23A tether tensioning unit 500 is positioned posterior and medial to tether interface 502 and flexible tether 504.

The medial location can be better seen in FIG. 23B which shows a cutaway view of the vertebral body 508 revealing tether tensioning unit 500 inside the vertebral body 508. The tether tensioning unit may be attached to the vertebral body by a screw or staple extending from the mechanism as shown, for example in FIG. 17A. With the medial location, tether tensioning unit itself can have an external threaded profile 501 or extending staple arms for direct attachment to the vertebral body. Tether tensioning unit 500 can also be positioned anterior and medial to the flexible tether 504 (not shown). There are many reasons a surgeon may select different adjustment mechanism locations including but not limited to a) preservation of the normal motion of the adjacent spine segments above or below the spinal curvature modulation system, b) avoid impingement of any sensitive nearby anatomic member, or c) the desire to have a low profile implant that does not create any visible change to the patient's outside appearance. Although FIGS. 17-23C show tether tensioning unit 500 located at a caudal end of the treatment region or spine segment being treated, tether tensioning unit 500 can alternately be located at the cephalad end or in the middle of the treatment region as previously described and still be positioned in the various locations described relative to the flexible tether 504. With positioning in or proximate the middle of the treatment region, dual tether devices such as shown in FIGS. 6-8 may be employed.

**[0034]** FIGS. 18-23B also show the spinal curvature modulation system attached laterally to the vertebral bodies 508. As previously described, the spinal curvature modulation system can also be attached from the posterior side or posterior-lateral side to the vertebral bodies 508 as shown in FIG. 23C. All of the various locations of tether tensioning unit 500 relative to the spine segment and all of the various positions relative to the flexible tether 504 described above with lateral attachment are also possible with the posterior or posterior-lateral attachment location.

**[0035]** FIGS. 24A, B and C show one possible anchor screw 600 for fixing one end of a flexible tether (not shown) to the vertebral body (not shown). The anchor screw 600 is comprised at one end of a threaded body 602 for attachment to the vertebral body and at the other end a head 604 for securing the tether. The head 604 contains a set screw 610 and a clamping plate 608. The head 604 and clamping plate 608 define an opening 606 through which a flexible tether can be inserted. Once the tether has been positioned through the opening 606, the set screw 610 can be advanced against the clamping plate 608 until the clamping plate 608 compresses the tether against the base of the head 604 securing the tether and preventing any relative motion of the tether relative to the anchor screw 600. The head 604 can have an outer profile that is designed to be captured by a screw



driving device for the purpose of advancing the anchor screw 600 into the vertebral body. Head 604, as shown in FIGS. 24A, B and C, has substantially square outer profile, but any type of profile that is commonly used for capture by a driving mechanism is possible, including but not limited to hexagonal, octagonal, and star-shaped.

**[0036]** FIGS. 25A-E show an alternative embodiment of an anchor screw 700 for fixing one end of a flexible tether, illustrated here as tether 720, to the vertebral body (not shown). The anchor screw 700 is comprised at one end of a threaded body 702 for attachment to the vertebral body and at the other end a head 704 for securing the tether. The head 704 contains a cam 706 and a cam pin 708. The head 704 and the cam 706 define an opening 710 through which a flexible tether can be inserted. As shown in FIG. 25E once the tether 720 is positioned through the opening 710, the cam 706 can rotate around the cam pin 708 to compress the tether 720 against the base 712 of the head 704 securing the tether 720 and preventing any relative motion of the tether 720 relative to the anchor screw 700. In general, tension applied to the tether in a direction away from the cam will cause the cam to further tighten on the tether, however, cam 706 may also include a biasing member (not shown) such as a torsional spring that biases the cam 706 against the base 712. The biased cam 706 will eliminate the opening 710 but would not be biased with a force sufficient to prevent the tether 720 from being advanced past the biased cam 706 in one direction. In this manner the anchor screw 700 will allow the tether 720 to be advance in one direction but will prevent the tether 720 from movement in the other.

**[0037]** FIG. 26 shows an embodiment of a bone anchor formed as a slip screw 800. The slip screw 800 is comprised of a threaded body 802 at one end and a head 804 at the other end. The head 804 has an opening 806 configured to allow through clearance of the tether (not shown). The slip screw 800 is used to guide the tether relative to the vertebral bodies between the two end attachment points of the tether.

**[0038]** FIG. 27 shows an alternative form of bone anchor as a slip staple 820. The slip staple 820 is comprised of one or more staple arms 822a-b at one end and a head 824 at the other end. The head 824 has an opening 826 configured to allow through clearance of the tether (not shown). The slip staple 820 is also used to guide the tether relative to the vertebral bodies between the two tether end attachment points. It is the surgeon's preference according to the patient's anatomic size and bone quality to use screws or staples for attachment of the spinal curvature modulation system to the patient's vertebral bodies. The staple attachment method can also be used

to attach tether tensioning unit at one end of the tether and the anchor mechanism at the other. It is also the surgeon's preference to use slip screws 800 or slip staples 820 at the vertebral bodies located between the tether's two end attachment points, or to use anchor screws 700 at the vertebral bodies located between the tether's two end attachment points as well as at one anchor point. When slip screws 800 or slip staples 820 are used at the intermediate locations, the tension in the tether will be substantially constant between the two end attachment points. When anchor screws 700 are used at the intermediate attachment locations, the tension in the tether will vary between each of the separate anchor segments.

**[0039]** FIG. 28 shows an alternate embodiment of the slip screw 840. The slip screw 840 is comprised of a threaded body 842 at one end and a head 844 at the other end. The head 844 has an opening 846 configured to allow through clearance of the tether (not shown). The head 844 also has a slot 848 configured for positioning the opening 846 at varying distances relative to the threaded body 842. The varying distance of the opening 846 for guiding the tether can be beneficial for preserving spinal kyphosis as is illustrated in FIGS. 29A-B. The spinal curvature modulation system is designed to reduce the Cobb angle of the spine as described herein.

**[0040]** In FIG. 29A the system is attached to vertebral bodies 508 with tether tensioning unit 500 attached at one end, the anchor screw 800 attached at the other end and slip screws 840a-c attached at intermediate levels. FIG. 29B shows the lateral view where the attachment points of the spinal curvature modulation system relative to the vertebral bodies 508 are shown to lie approximately on the midline (dashed line) of each vertebral body 508. The flexible tether 504 passes through the openings 846 of the slip screw 840, but the flexible tether 504 is not on the vertebral body 508 midline as the openings 846 are not lined up with the threaded bodies 842. This allows the flexible tether 504 to induce and/or preserve the kyphotic curvature of the spine in the sagittal plane which is a normal healthy curve while at the same time reducing the scoliotic curve in the coronal plane which is abnormal. The slip screws 840 located more in the middle of the spinal curvature modulation system can have openings 846 that are more offset from the midline than slip screws 840 located closer to the end attachment points. The openings 846 can be adjustably offset as illustrated in FIG. 28, or the openings 846 can be offset various non-adjustable fixed distances from the threaded body 842. The openings 846 can also be offset from one or more staple arms 822a-b rather than from a threaded body 842.

**[0041]** Also shown in FIGS. 29A and B is an optional tether stop 850. One or more tether stops 850 may be placed on the tether at selected locations to limit movement of one spine segment as relative to other segments across the treatment region. Tether stop 850 may be formed, for example, as a crimpable bead or ferrule and applied to the tether by the surgeon as needed at the time of installation of the tether and tensioning unit.

**[0042]** As previously described, the two end points, tether tensioning unit 500 and anchor device can be attached to the vertebral bodies by a threaded rod, a staple arm or any other common attachment mechanism including but not limited to bands, expandable rods, and the like. The connection between the anchor device and tether tensioning unit or the anchor device can be rigid as depicted in FIGS. 25-28 or the connections can allow some articulation or relative range of motion such as through a ball and socket type of connection.

**[0043]** FIG. 30 shows another alternative tether tensioning unit 540, which is comprised of a tether interface spool 542 and a manual internal actuator 544. When the manual internal actuator 544 is rotated by an outside force (see, e.g., FIG. 11), it rotates the tether interface spool 542 through internal gears (e.g., FIGS. 4-11). The tool interface of manual internal actuator 544 is shown as an external hexagonal shape, but any commonly used driver shape can be used, including but not limited to an internal slot, a square shape or star shape, both of which could be either internal or external or the like.

**[0044]** FIGS. 31A-B show another embodiment of a tether tensioning unit 580 that is comprised of a manual internal actuator 584, a tether interface spool 582, a tension relief device 588, and a housing 586. When the manual internal actuator 584 is rotated by an outside force, it rotates the tether spool 582 either directly or through internal gears. In FIG. 31B the housing 586 has been removed to show an internal ratchet 592 and pawl 590 that allows the tether spool 582 to rotate in one forward direction to increase tension but prevents the tether spool 582 from rotating in the reverse direction to relieve tension. The tension relief device 588 can be actuated to raise the pawl 590 away from the ratchet 592 to allow the tether spool 582 to rotate in the reverse direction and release tension in the tether. This ratchet and tension release mechanism is not limited to the manually driven mechanism shown, but can also be included in the previously described magnet driven tension adjusting mechanisms. Likewise the actuation of the pawl 590 to allow reverse rotation of the tether spool 582 is not limited to manual actuation but also can be achieved through a

second magnetic driven mechanism, or through an electrically driven mechanism such as but not limited to a solenoid.

**[0045]** The reduction of tether tension can be achieved by many other mechanisms in addition to this ratchet and pawl system. The tether tension can be reduced automatically when a sufficient tension is reached through a slip clutch type of mechanism. A slip clutch can be designed to release tether tension to prevent tension from becoming so great that it causes damage to spinal elements such as ligaments or intervertebral discs. Sensors as previously described can also be positioned at either end of the tether or anywhere along the length of the tether to measure the tether tension and prevent excessive tether tension by either sending a signal to automatically open a pawl and ratchet type tension release mechanism as previously described, or send a signal to an external control to inform the surgeon and/or the patient that excessive tension exists which should be reduced through the tension adjustment mechanism. The external controller can be paired wirelessly to other devices such as computers or smart phones so that a surgeon located remotely can be quickly notified. An internal sensor can be powered by an implanted battery or by power delivered through induction from an induction source located externally. The sensor can measure the tension in the tether directly, or it can measure the deflection the tether tension creates in the tether spool or anchor screw head or it could be located to measure the bending moment of the anchor screw's threaded body or staple arm. The sensor can also measure a different parameter not directly related to tether tension such as the number of rotations of the magnet. In one particular embodiment two Hall-effect sensors can be located in the external driver on either side of the driving magnet. These sensors can detect the rotation of the implant magnet by subtracting out the signal from the driving magnet. In this manner the external controller can collect data that the internal magnet is rotating as desired. The use of one or more Hall-effect sensors to measure the rotation of the implanted magnet can result in a noisy signal as the sensor's measurement of the more proximal control magnet will produce a much higher signal than the weaker signal from the distal implanted magnet. In addition to the use of two Hall-effect sensors to measure magnet rotation, the controller can also contain a current sensor to measure the amount of current that is being drawn by the motor rotating the control magnet. When the control magnet is initially rotated by the control motor but not magnetically coupled to the implanted magnet, a specific amount of current is drawn by the motor. When the control magnet couples with the implanted magnet, the load on the motor rotating the control magnet increases in order to rotate both the control magnet and the coupled magnet. The measurement of the current drawn by the control motor with a current sensor can be used to determine if the control

magnet and the implanted magnet are coupled. On occasion there could be occurrences of magnet stalling due to an excessive load on the implanted magnet. Use of a current sensor will still show an increase in current drawn when the control magnet and implant magnet are coupled but stalled. The combination of a current sensor and one or more Hall-effect sensors can help to provide information of internal magnet rotation (and therefore tether tension adjustment) regardless of the different conditions such as magnet coupling or magnet stalling.

**[0046]** FIGS. 32A-B show a gear system 900 comprised of a globoid-shaped worm gear 902 and mating spur gear 904. The contour 906 of the worm gear 902 is higher on the ends and lower in the middle. This globoid shape allows a great force to be transferred from the worm gear to the spur gear for any given nominal diameter of worm and spur gears. The gear system 900 can be used in any of the previously described tension adjusting mechanisms to transfer the magnetic (or manual) driving force to the tether. This transfer of greater force is of particular importance in an implanted tension adjusting mechanism as it is important to keep the implant as small as possible while still delivering sufficient force to tension the tether to ensure proper adjustment of the curved spine.

**[0047]** The foregoing has been a detailed description of illustrative embodiments of the invention. It is noted that in the present specification and claims appended hereto, conjunctive language such as is used in the phrases “at least one of X, Y and Z” and “one or more of X, Y, and Z,” unless specifically stated or indicated otherwise, shall be taken to mean that each item in the conjunctive list can be present in any number exclusive of every other item in the list or in any number in combination with any or all other item(s) in the conjunctive list, each of which may also be present in any number. Applying this general rule, the conjunctive phrases in the foregoing examples in which the conjunctive list consists of X, Y, and Z shall each encompass: one or more of X; one or more of Y; one or more of Z; one or more of X and one or more of Y; one or more of X and one or more of Z; one or more of Y and one or more of Z; and one or more of X, one or more of Y and one or more of Z.

**[0048]** Various modifications and additions can be made without departing from the spirit and scope of this invention. Features of each of the various embodiments described above may be combined with features of other described embodiments as appropriate in order to provide a multiplicity of feature combinations in associated new embodiments. Furthermore, while the foregoing describes a number of separate embodiments, what has been described herein is merely illustrative of the application of the principles of the present invention. Additionally, although

particular methods herein may be illustrated and/or described as being performed in a specific order, the ordering is highly variable within ordinary skill to achieve aspects of the present disclosure. Accordingly, this description is meant to be taken only by way of example, and not to otherwise limit the scope of this invention.

**[0049]** Exemplary embodiments have been disclosed above and illustrated in the accompanying drawings. It will be understood by those skilled in the art that various changes, omissions and additions may be made to that which is specifically disclosed herein without departing from the spirit and scope of the present invention.

What is claimed is:

1. A spinal curve modulation system for treating spinal curvature along a treatment region of the spine, comprising:
  - a flexible tether of sufficient length to extend across the treatment region of the spine including across at least three adjacent vertebral bodies in a cranial-caudal direction; at least one first bone anchor configured to be fixed to a first vertebra and to an end of the flexible tether;
  - a tether tensioning unit comprising a tether interface and a drive mechanism operatively linked to the tether interface to adjust tension in the flexible tether; and
  - at least one second bone anchor configured to fix the tether tensioning unit to a vertebra across the treatment region from at said at least one first bone anchor;wherein said tether tensioning unit is actuatable to adjust tension in the flexible tether without surgically exposing the flexible tether or said at least one first bone anchor.
2. The spinal curve modulation system of claim 1, further comprising at least one tether guide having a bone anchor and a guide portion configured to slidably receive the flexible tether.
3. The spinal curve modulation system of claim 2, wherein the guide portion comprises a head defining an opening through which the flexible tether may slide along a longitudinal direction.
4. The spinal curve modulation system of claims 1-3, wherein the flexible tether has sufficient flexibility to conform to a curvature of the spine to be treated without plastic deformation of said flexible tether.
5. The spinal curve modulation system of claims 1-4, wherein said flexible tether comprises a flat band or ribbon formed of polymer or metal.
6. The spinal curve modulation system of claims 1-5, wherein said flexible tether comprises a flat band or ribbon formed of polymer or metal and having slots configured for engaging drive teeth.
7. The spinal curve modulation system of claims 1-4, wherein said flexible tether comprises a braided polymer or metal cable.
8. The spinal curve modulation system of claims 1-4, wherein said flexible tether comprises a toothed strip.

9. The spinal curve modulation system of claims 1-8, wherein said flexible tether is made of one or a composite of stainless steel, titanium, ultra-high molecular weight polyethylene, polyethylene terephthalate, thermoplastic polycarbonate polyurethane, or multilayered polymeric strands comprising low molecular and high molecular weight polyethylene.
10. The spinal curve modulation system of claims 1-6, wherein said tether interface comprises a spool onto which the flexible tether may be wound and unwound.
11. The spinal curve modulation system of claims 1-4 and 6, wherein said tether interface comprises a worm gear.
12. The spinal curve modulation system of claims 1-9, wherein said tether interface comprises a rotatable member engageable with the drive mechanism, the rotatable member having a periphery configured to grip the flexible tether.
13. The spinal curve modulation system of claim 12, wherein the periphery of the rotatable member comprises a friction engagement surface.
14. The spinal curve modulation system of claim 12, wherein the periphery of the rotatable member comprises a toothed surface.
15. The spinal curve modulation system of claims 1-14, wherein said system further comprises at least two first anchor members and the flexible tether has two free ends and engages the tether interface between the two free ends such that rotation of the tether interface retracts or extends the flexible tether ends in opposite directions.
16. The spinal curve modulation system of claim 15, wherein flexible tether comprises two separate tether members, each engaging the tether interface at one end.
17. The spinal curve modulation system of claims 1-16, wherein said drive mechanism comprises a rotational magnetic motor and said system further comprises an external magnet actuator.
18. The spinal curve modulation system of claims 1-17, wherein said drive mechanism comprises a manually actuatable gearbox driving the tether interface.
19. The spinal curve modulation system of claim 18, wherein said gear box is manually actuatable and includes a tool interface positioned on the tether tensioning unit to be accessible through a small, minimally invasive incision, and said system further comprises a



- tool adapted to mate with said tool interface and insertable through a small, minimally invasive incision.
20. The spinal curve modulation system of claim 18, wherein said gearbox provides a gear reduction of between about 300:1 to about 5000:1.
  21. The spinal curve modulation system of claims 1-20, wherein said drive mechanism comprises an electric motor engaging the tether interface through said gearbox.
  22. The spinal curve modulation system of claim 21, further comprising a subcutaneous induction coil for providing current to the electric motor and an external induction coil actuator.
  23. The spinal curve modulation system of claim 21, further comprising implantable subcutaneous electrical leads for providing current to the electric motor, said leads selectively connectable to an external power source.
  24. The spinal curve modulation system of claim 21, wherein said drive mechanism further includes a battery and remotely actuatable switch to activate the motor, and said system further comprises a remote, wireless controller configured to actuate said switch and control operation of the motor thereby.
  25. The spinal curve modulation system of claims 1-24, wherein said first bone anchor comprises a screw, suture or staple body with a proximal tether capture means.
  26. The spinal curve modulation system of claim 25, wherein said proximal tether capture means comprises a cam configured to capture the flexible tether in response to tension applied to the flexible tether.
  27. The spinal curve modulation system of claim 25, wherein said proximal tether capture means comprises a screw-driven clamp.
  28. The spinal curve modulation system of claim 25, wherein said proximal tether capture means comprises an eye formed on the screw, suture or staple body.
  29. The spinal curve modulation system of claims 1-28, further comprising a flexible tether tension sensor configured to provide an output indicative of flexible tether tension.
  30. The spinal curve modulation system of claim 29, further comprising a controller communicating with the drive mechanism and tension sensor, the controller including a

- tension limiter and configured to limit tension in said flexible tether to a predetermined value.
31. A spinal curve modulation system for treating spinal curvature along a treatment region of the spine, comprising:
- a flexible tether of sufficient length to extend across the treatment region of the spine including across at least three adjacent vertebral bodies in a cranial-caudal direction;
  - at least one first bone anchor including a tether attachment means;
  - a transcutaneously actuatable drive mechanism;
  - a tether receiving spool operatively linked to the drive mechanism for rotation of the tether receiving spool to adjust tension in the flexible tether;
  - at least one second bone anchor configured to anchor the rotary drive mechanism and tether receiving spool to a vertebra across the treatment region from at least one said first bone anchor; and
  - a transcutaneous actuator configured to actuate said drive mechanism transcutaneously.
32. The spinal curve modulation system of claim 31, wherein said first bone anchor comprises a screw, suture or staple body with a proximal clamp configured to receive and capture the flexible tether.
33. The spinal curve modulation system of claim 32, wherein the proximal clamp of said first bone anchor comprises a cam configured to tighten on the tether in response to tension applied to the tether.
34. The spinal curve modulation system of claims 31-33, wherein said transcutaneously actuatable drive mechanism comprises an internal actuator configured to receive actuation input from the transcutaneous actuator and to drive a gear reduction box in response to said input, wherein the gear reduction box has an output linked to the tether receiving spool.
35. The spinal curve modulation system of claim 34, wherein said transcutaneous actuator comprises an elongate tool insertable through a small incision to manually rotate the internal actuator without surgically exposing the flexible tether, or the at least one first bone anchor.
36. The spinal curve modulation system of claim 34 or 35, wherein said internal actuator comprises a wirelessly, remotely actuatable motor and said transcutaneous actuator comprises a remote actuator configured to remotely and wirelessly actuate said motor.

37. The spinal curve modulation system of claim 36, wherein said remotely actuatable motor comprises a magnetic motor and said remote actuator comprises a rotating magnet actuator.
38. The spinal curve modulation system of claim 36, wherein said remotely actuatable motor comprises an electric motor.
39. A method of treating an abnormal spinal curvature along a treatment region of the spine, comprising:
- providing surgical access to the treatment region of the spine, the treatment region extending along the spine in a generally cranial-caudal direction and spanning at least three adjacent vertebrae;
  - fixing an anchor element on a selected vertebra at a first end of the treatment region;
  - fixing a tether tension adjustment mechanism on a selected vertebra at a second end of the treatment region;
  - extending a flexible tether between said tension adjustment mechanism and the anchor element, wherein the flexible tether is fixed to the anchor element and engages said tension adjustment mechanism for adjustment of tension in the flexible tether;
  - manipulating said tension adjustment mechanism to initially tension the flexible tether so as to reposition vertebrae across the treatment region;
  - closing the surgical access to the treatment region of the spine; and
  - post-operatively, subsequent to closing the surgical access and without reopening or creating new surgical access to the flexible tether or anchor elements, manipulating said tension adjustment mechanism in vivo to periodically adjust tension in the flexible tether.
40. The method of claim 39, wherein said post-operatively manipulating said tension adjustment mechanism comprises remotely controlling a magnetically driven motor in said tension adjustment mechanism.
41. The method of claim 39, further comprising:
- fixing at least one tether guide to at least one vertebra between said selected vertebrae, the tether guide including defining an opening configured to permit sliding of the flexible tether therethrough; and
  - placing the flexible tether through the tether guide opening before fixing the flexible tether to the anchor element.

42. The method of claim 41, further comprising:  
fixing plural tether guides, one each to plural vertebrae between said selected vertebrae  
and placing the flexible tether through each tether guide opening; and  
controlling kyphotic curvature of the spine in a sagittal plane while reducing scoliotic  
curvature of the spine in a coronal plane by manipulating the retractor to tension the  
flexible tether through said tether guides.
43. The method of claim 39, wherein said post-operatively manipulating said tension adjustment  
mechanism comprises making a small incision and inserting an elongate tool through the  
small incision to engage and rotate said tension adjustment mechanism.
44. The method of claim 39, wherein said tension adjustment mechanism includes a wirelessly  
controllable motor and said post-operatively manipulating said tension adjustment  
mechanism comprises manipulating the wirelessly controllable motor with a remote, wireless  
controller external to the body.
45. The method of claim 44, wherein said wirelessly controllable motor comprises a magnetic  
motor and said manipulating the wirelessly controllable motor comprises rotating at least one  
magnet in said remote, wireless controller.
46. The method of claim 44, wherein said wirelessly controllable motor comprises an electric  
motor and said manipulating the wirelessly controllable motor comprises inducing a current  
in a subcutaneously implanted coil communicating with the electric motor to provide current  
thereto.

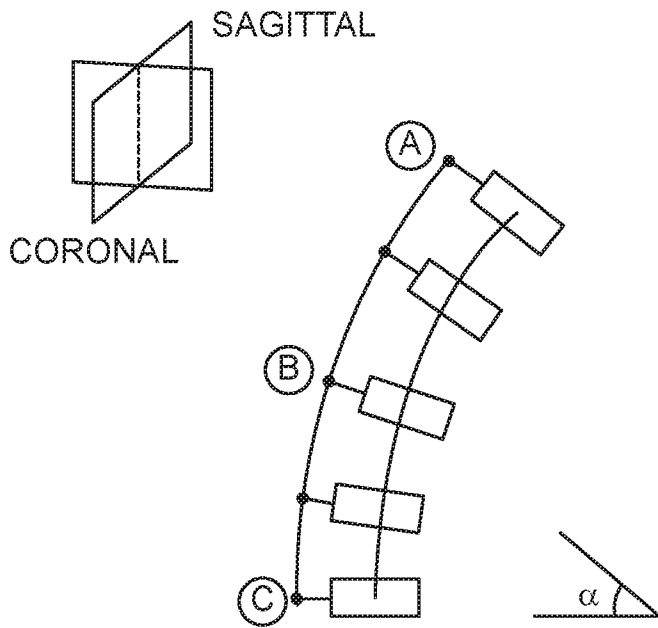
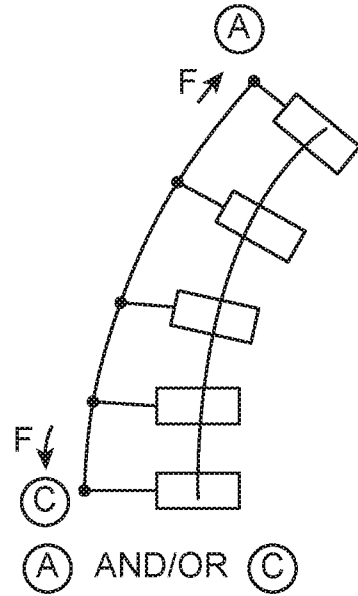


FIG. 1A



(A) AND/OR (C)

FIG. 1B

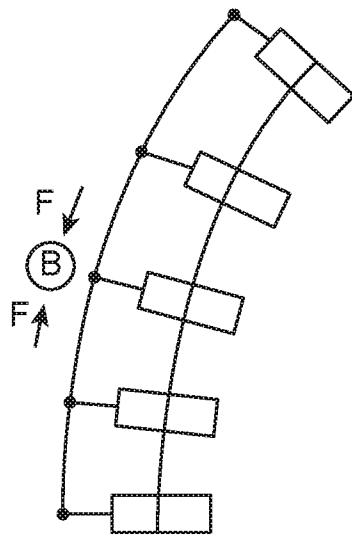


FIG. 1C

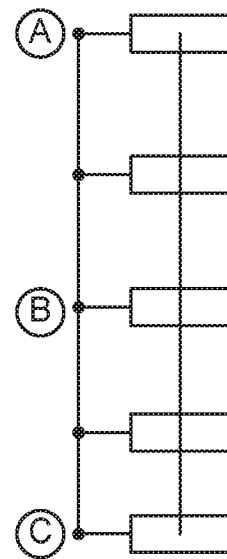


FIG. 1D

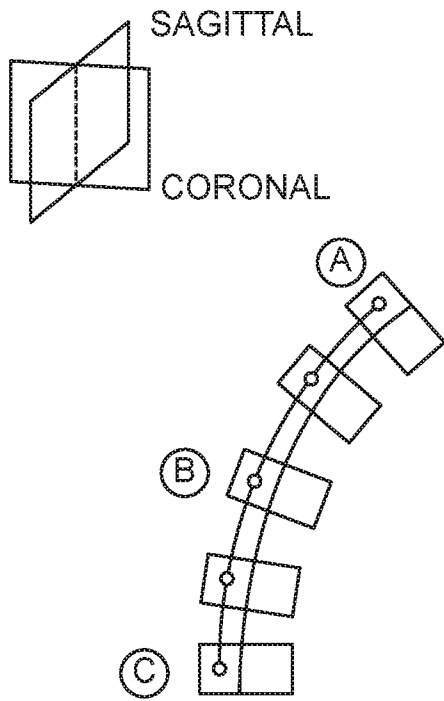


FIG. 2A

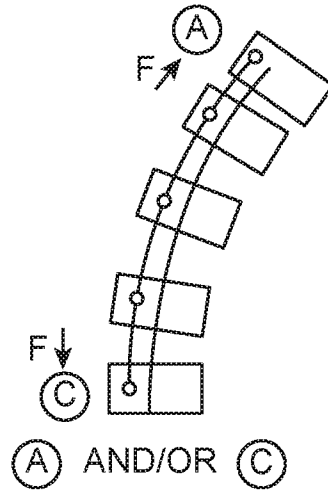
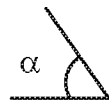


FIG. 2B

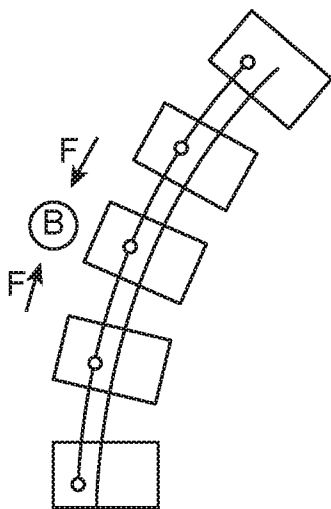


FIG. 2C

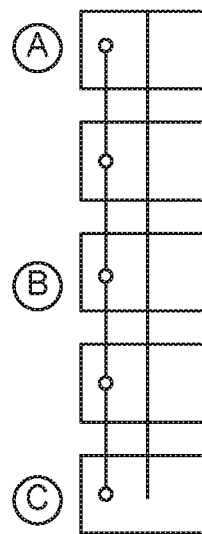


FIG. 2D

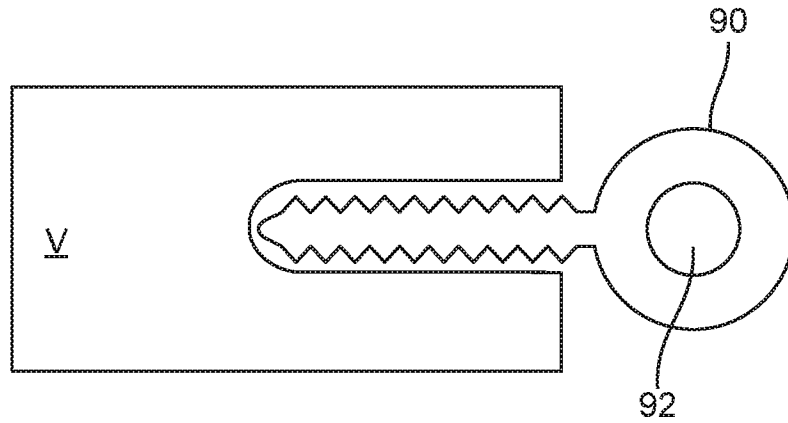


FIG. 3

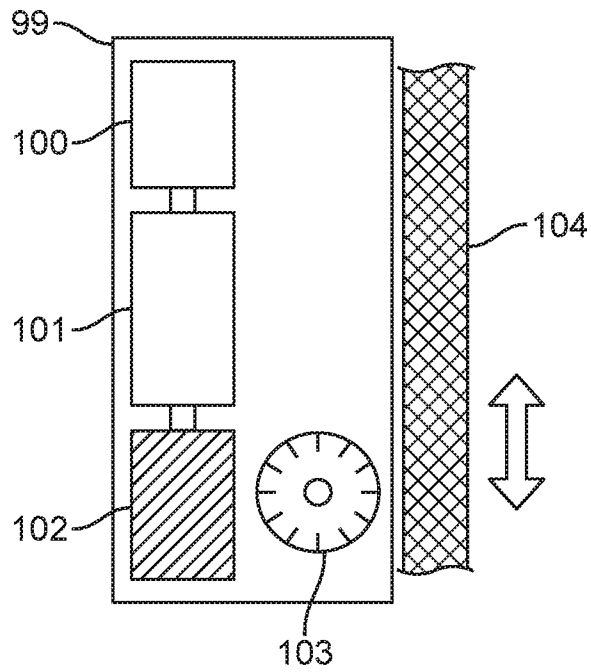


FIG. 4

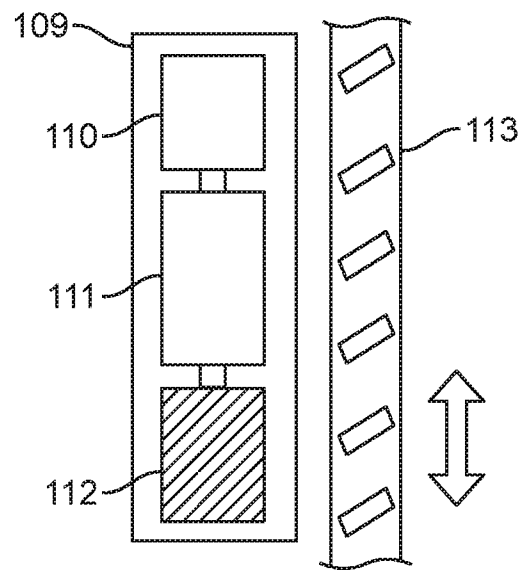


FIG. 5

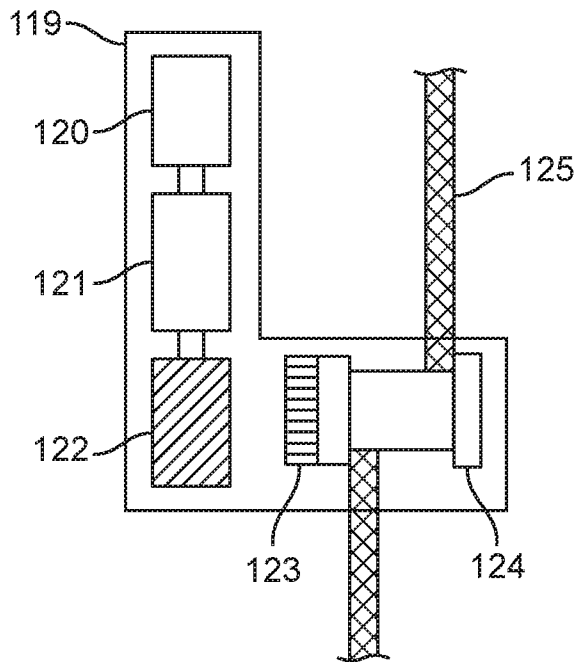


FIG. 6

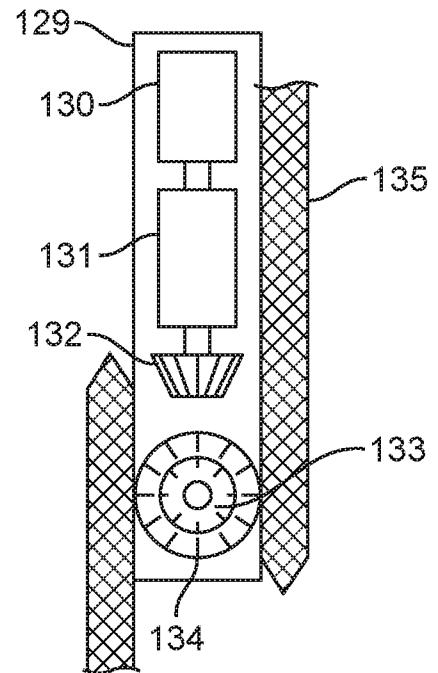


FIG. 7

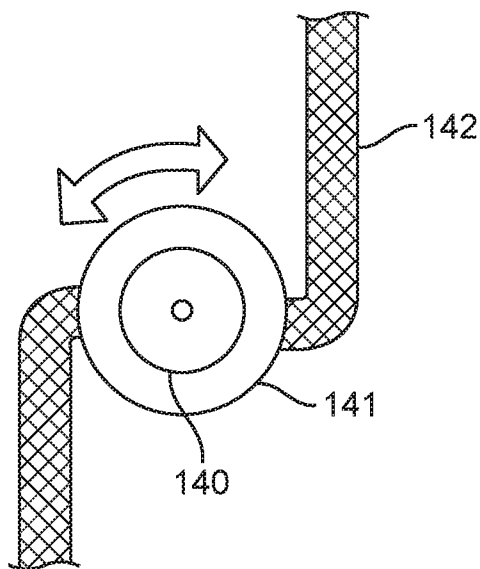


FIG. 8

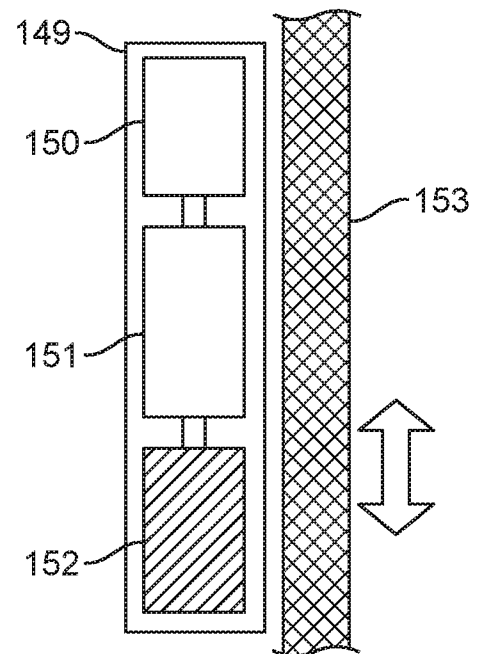


FIG. 9



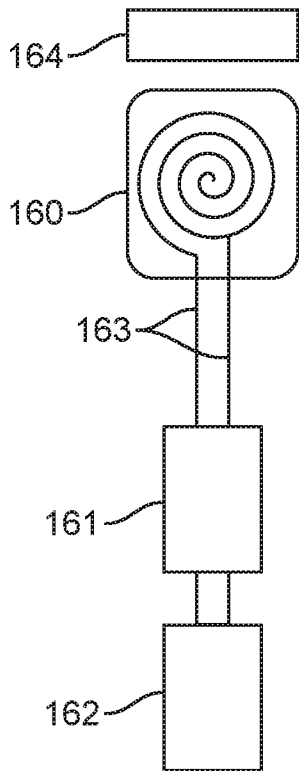


FIG. 10

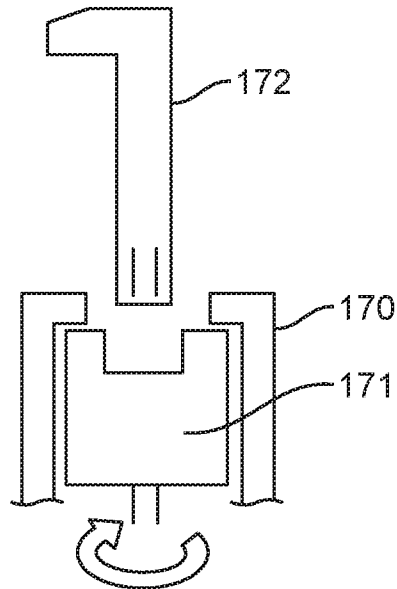


FIG. 11

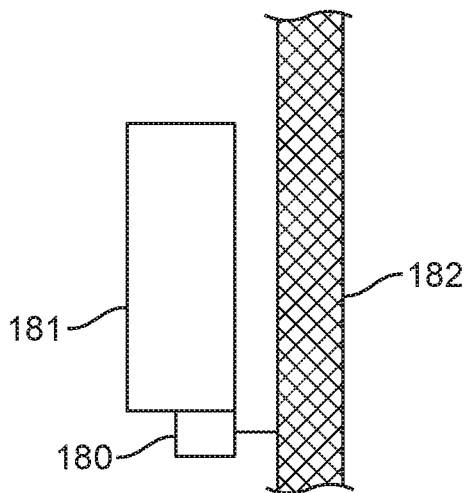


FIG. 12

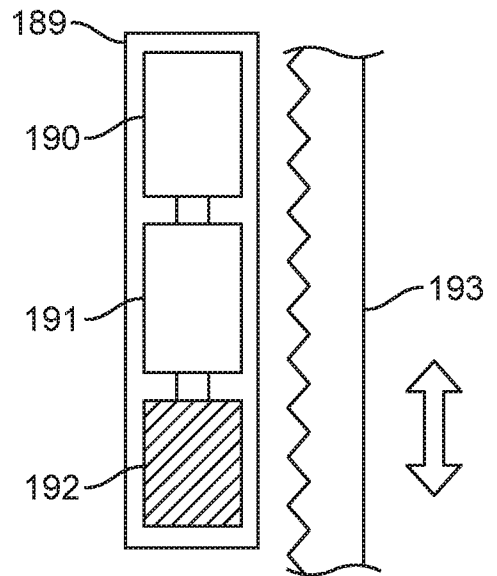


FIG. 13

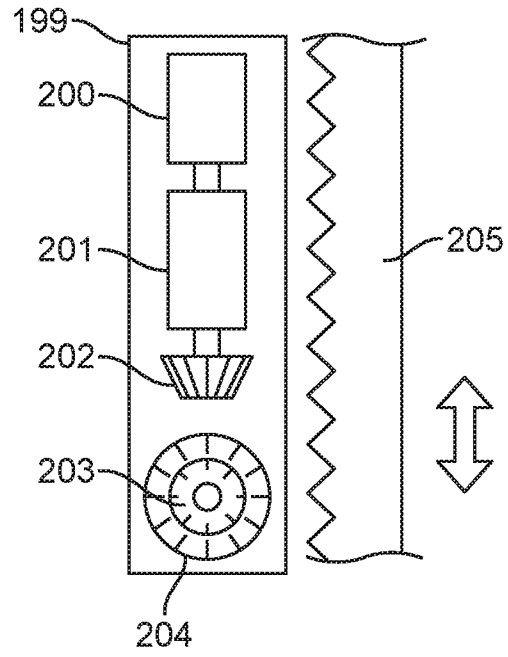


FIG. 14

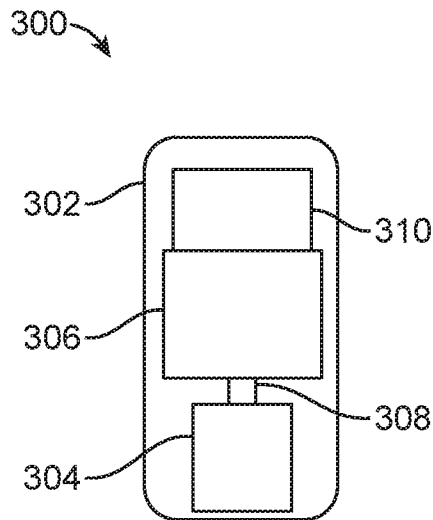


FIG. 15

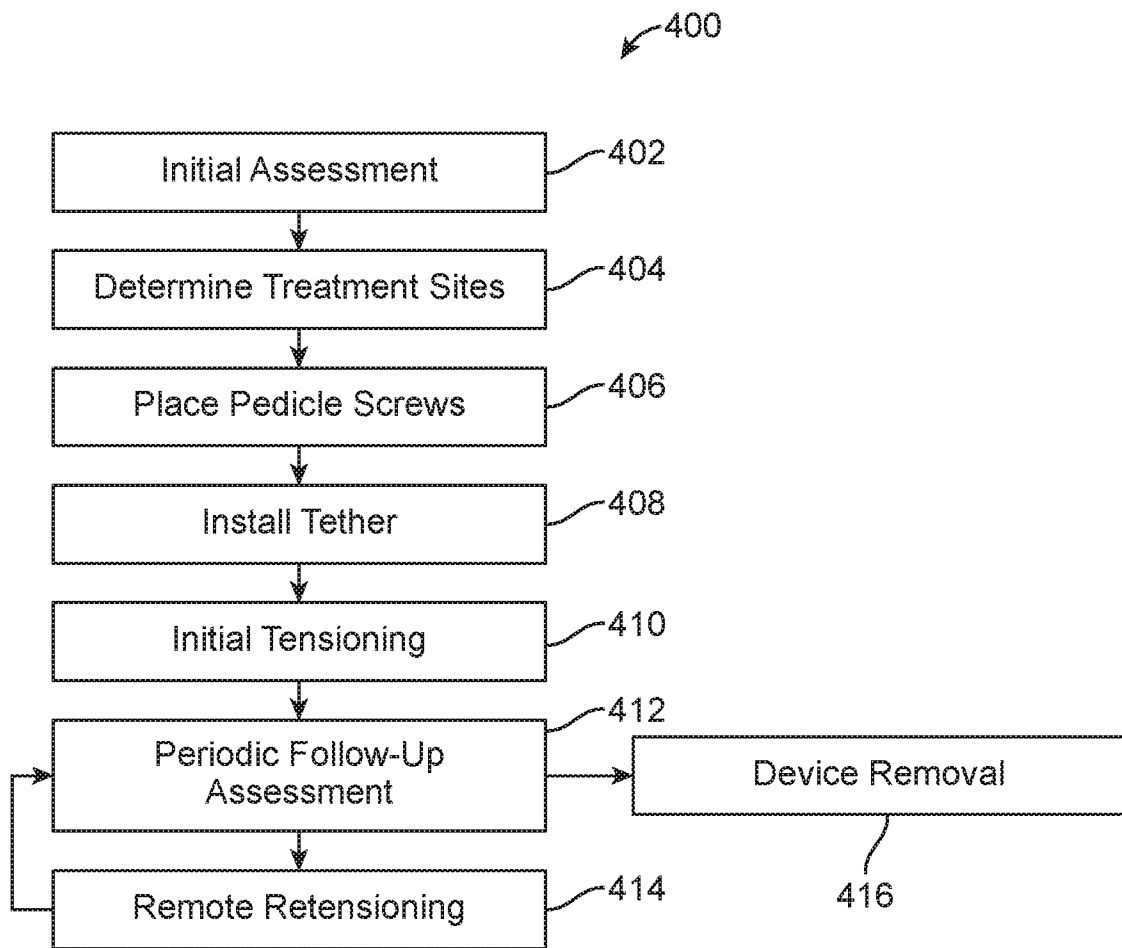


FIG. 16

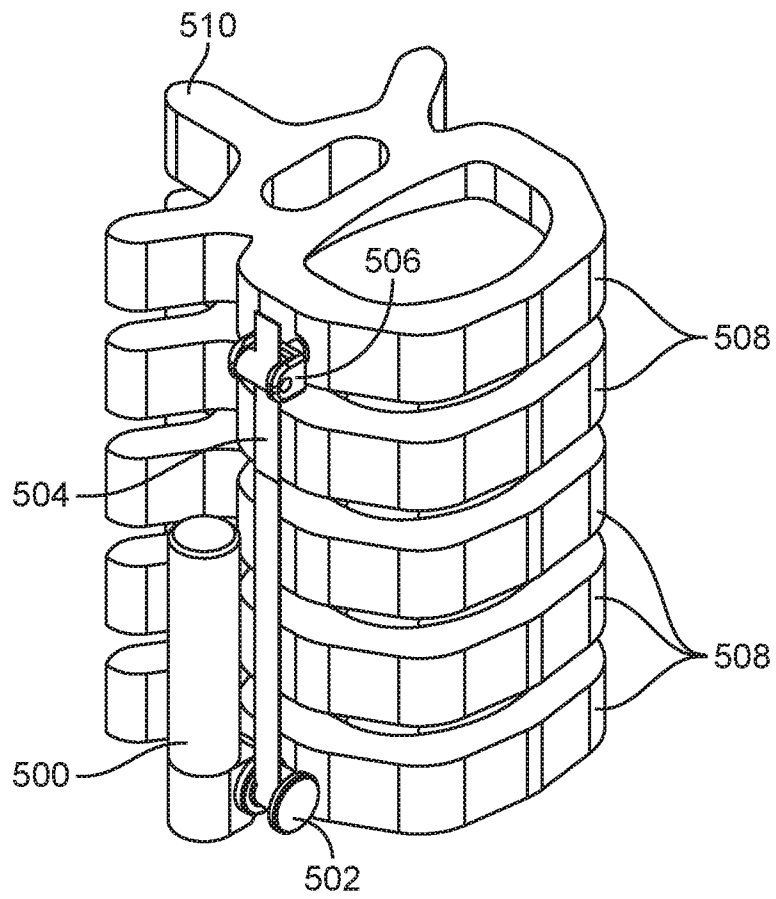


FIG. 17

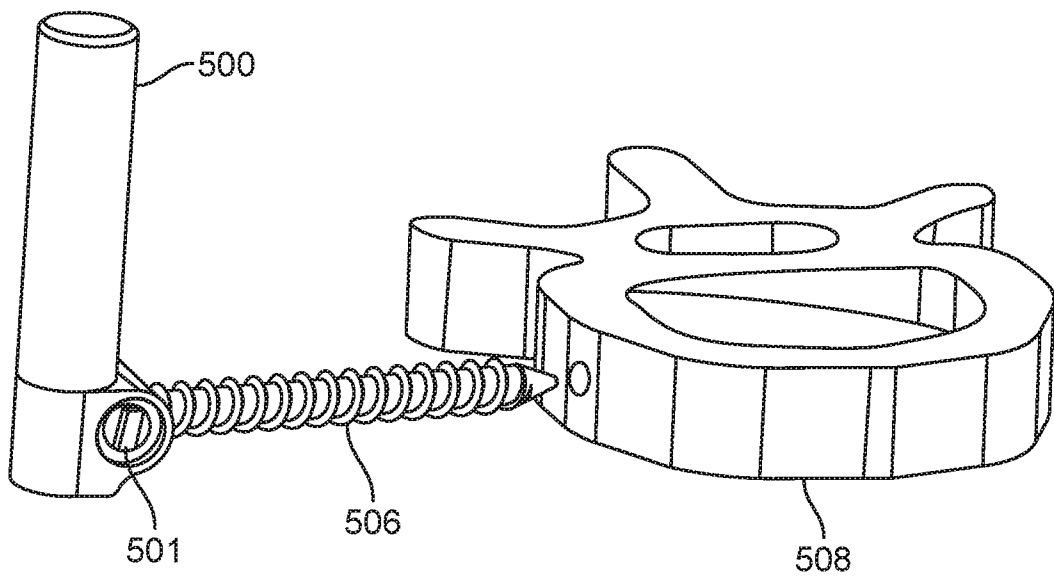


FIG. 17A

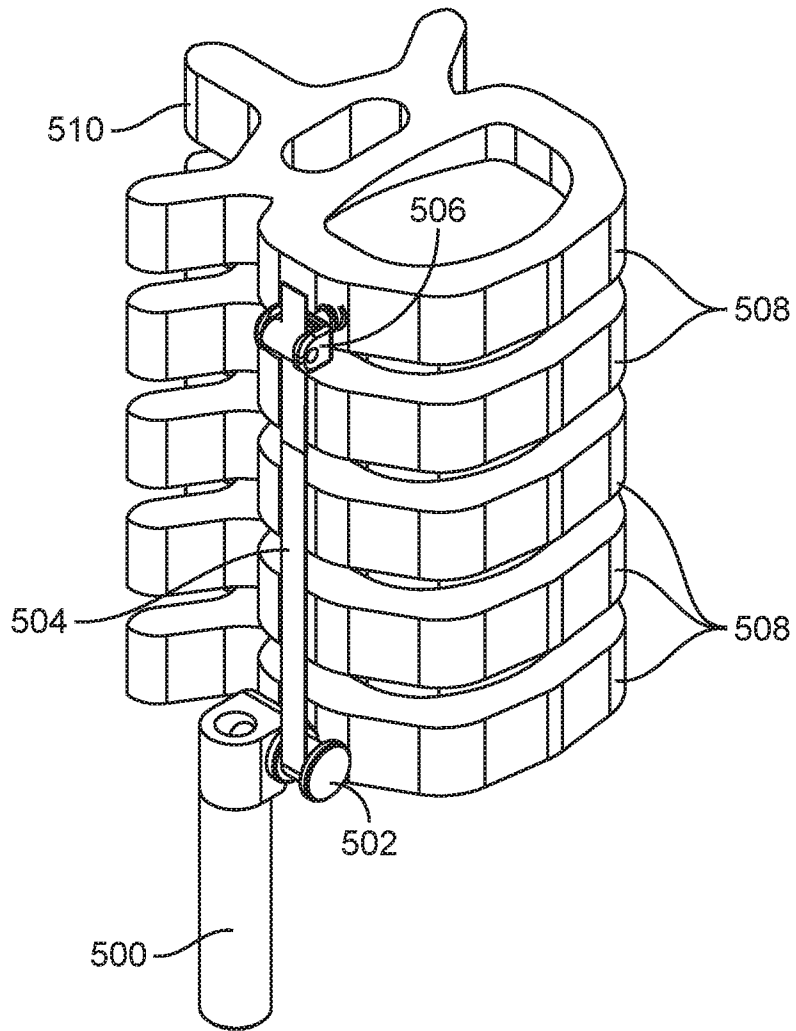


FIG. 18

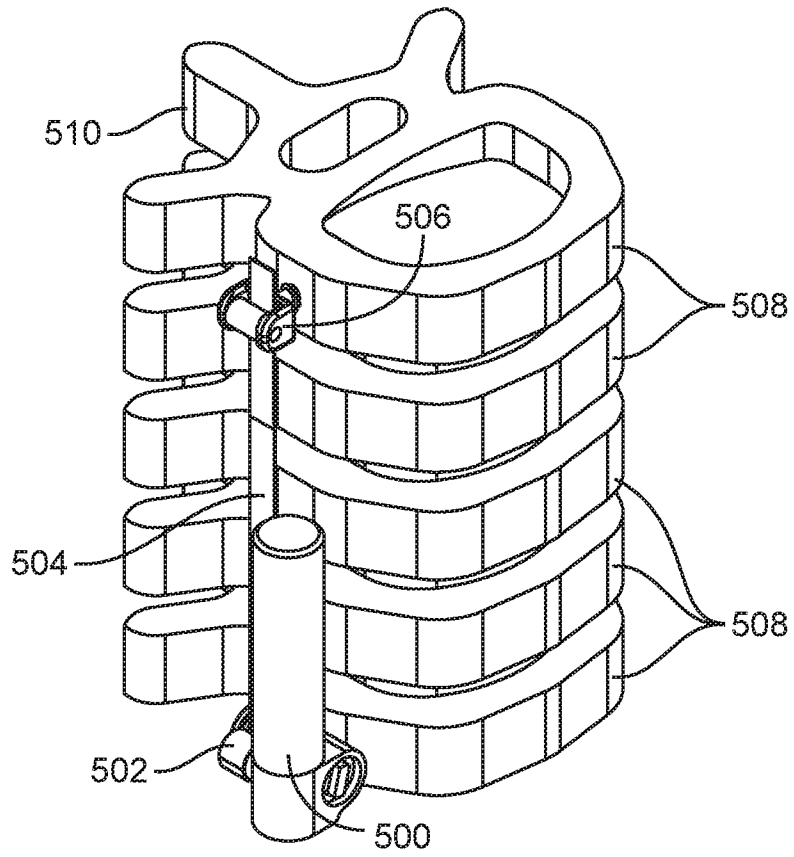


FIG. 19

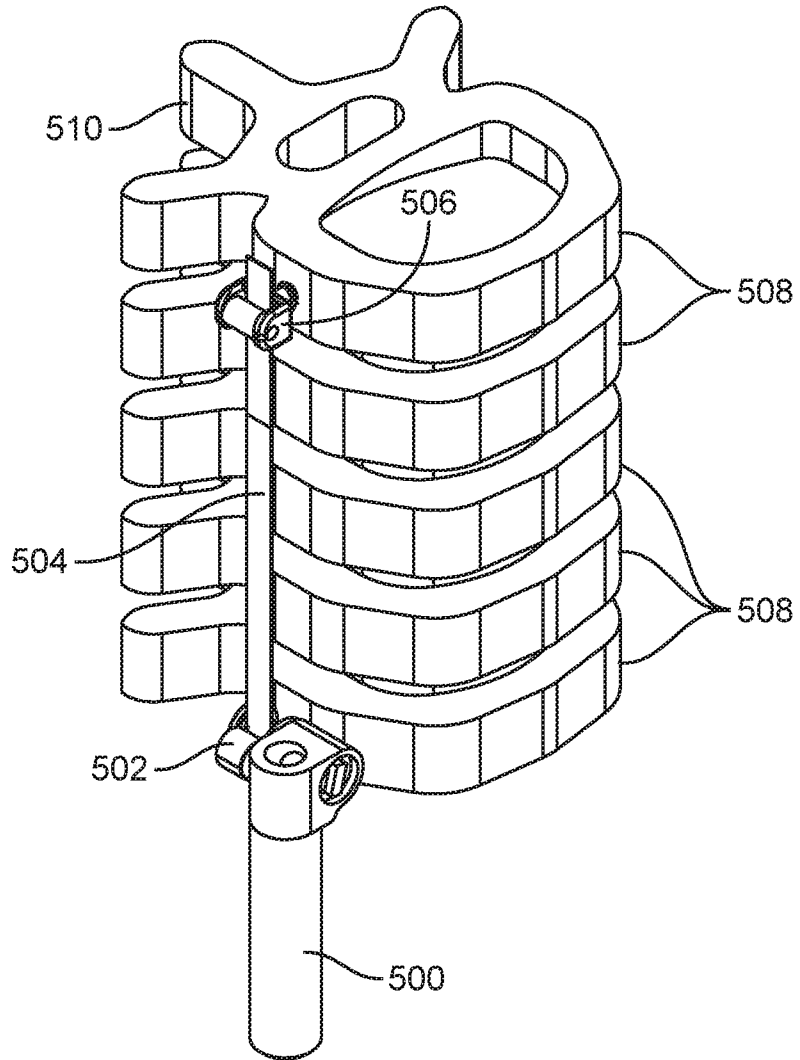


FIG. 20



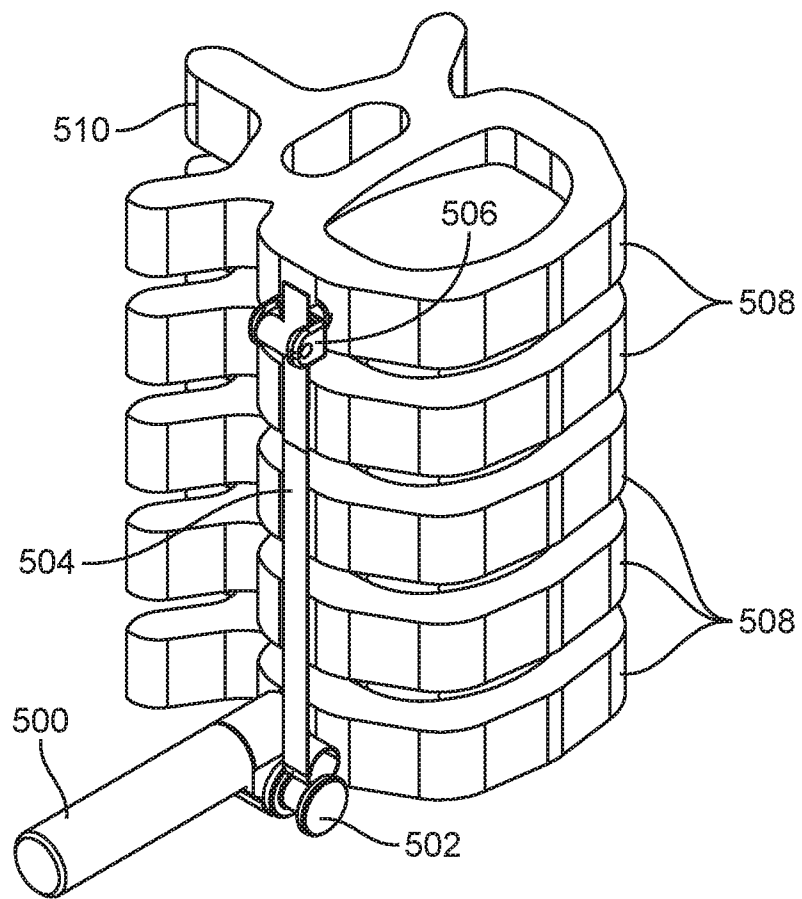


FIG. 21

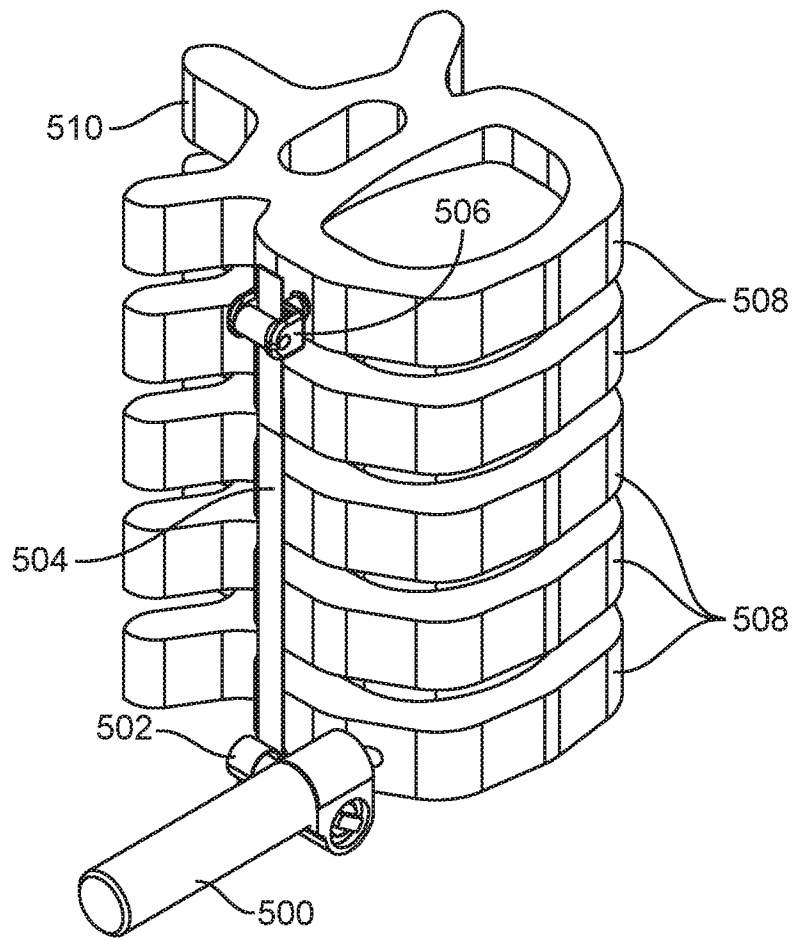


FIG. 22

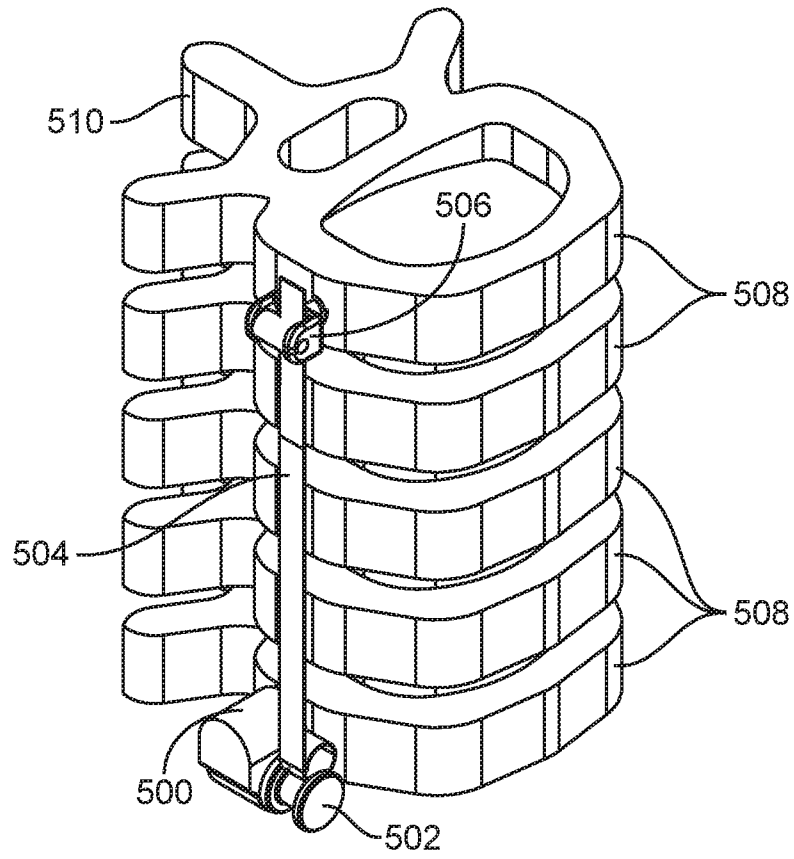


FIG. 23A

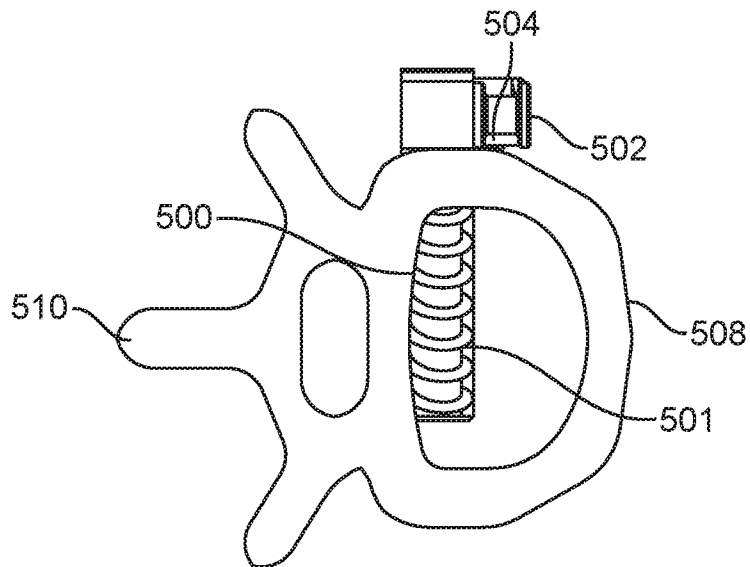


FIG. 23B

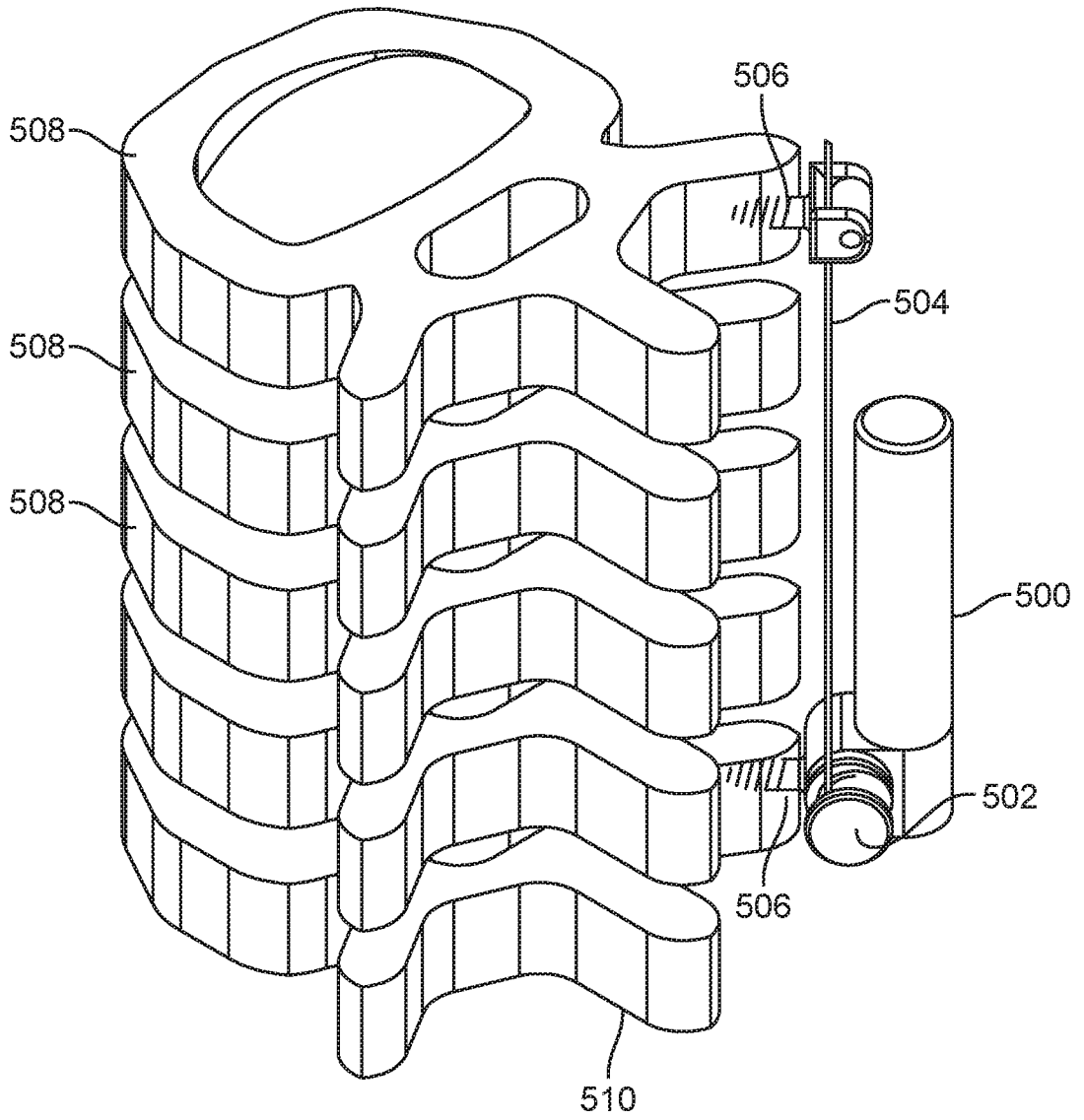


FIG. 23C

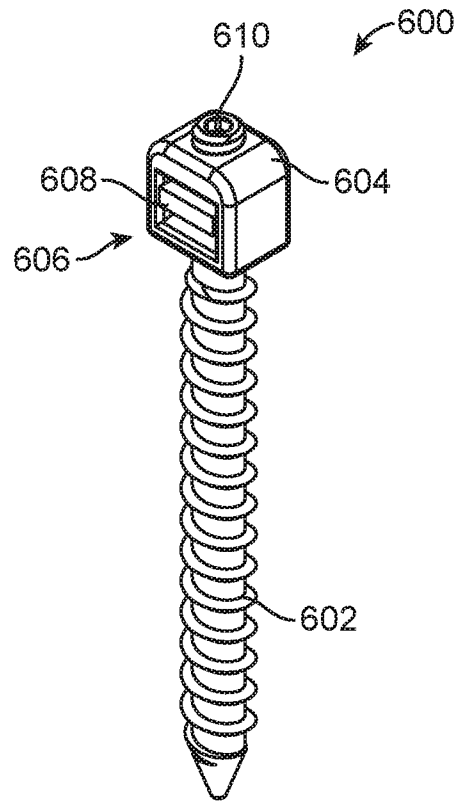


FIG. 24A

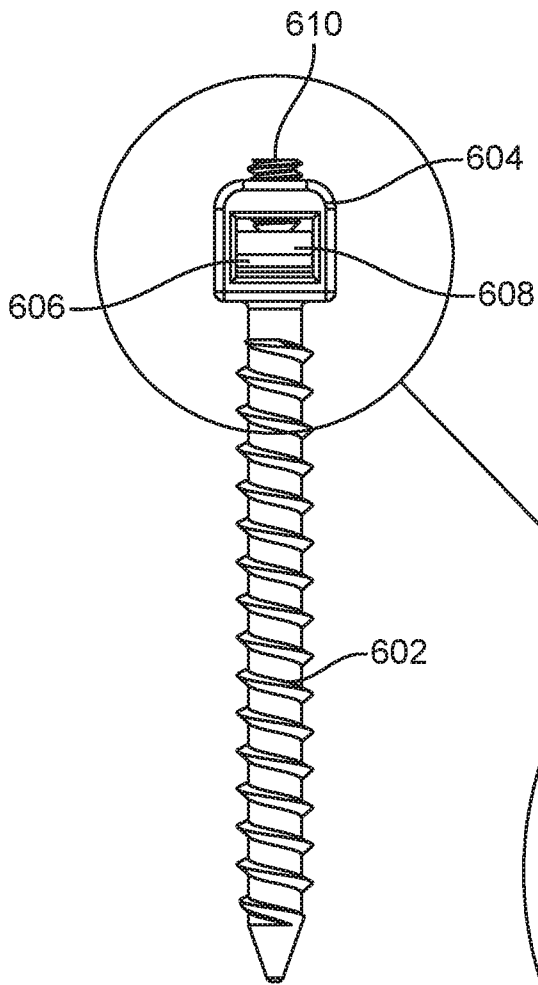


FIG. 24B

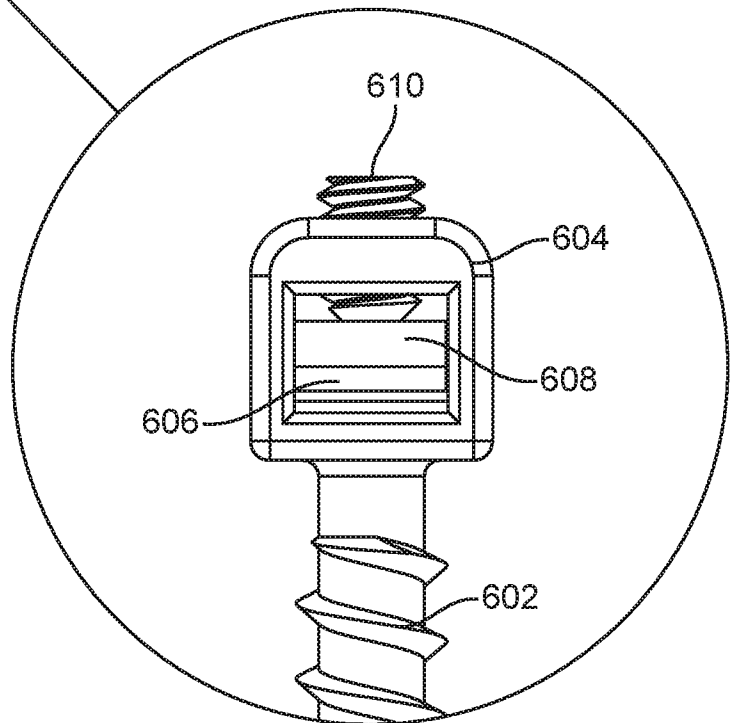


FIG. 24C

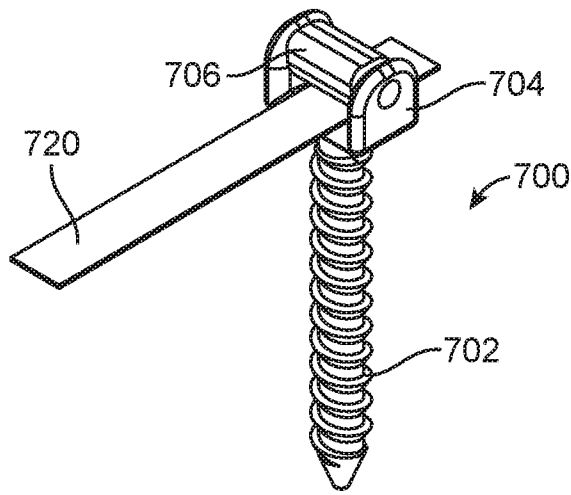


FIG. 25A

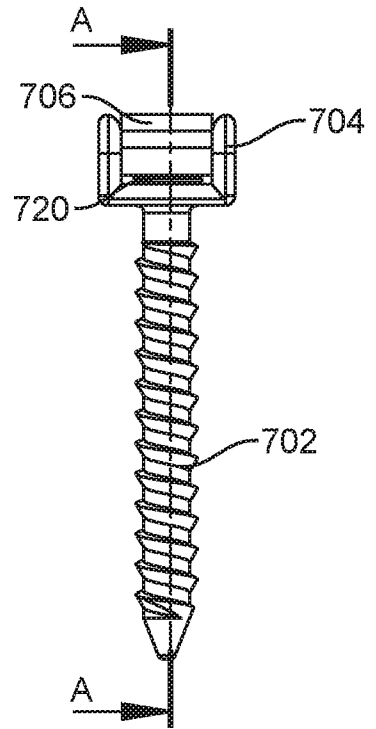


FIG. 25B

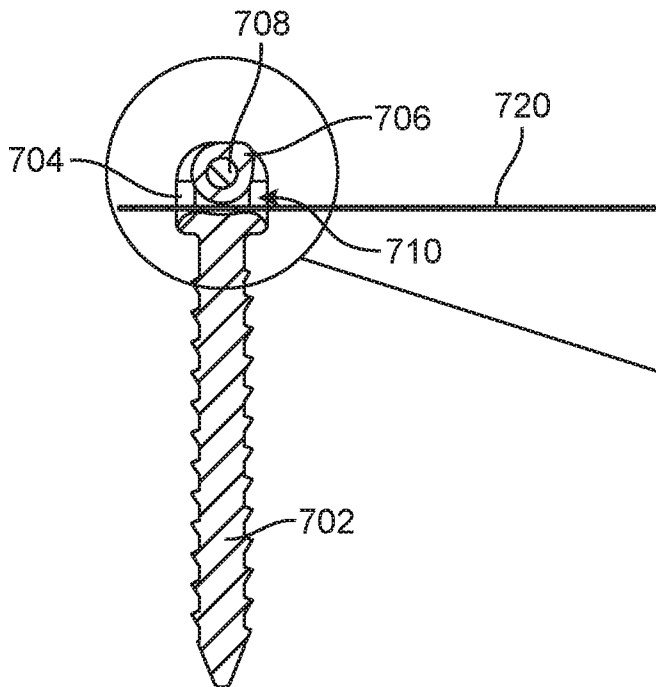


FIG. 25C

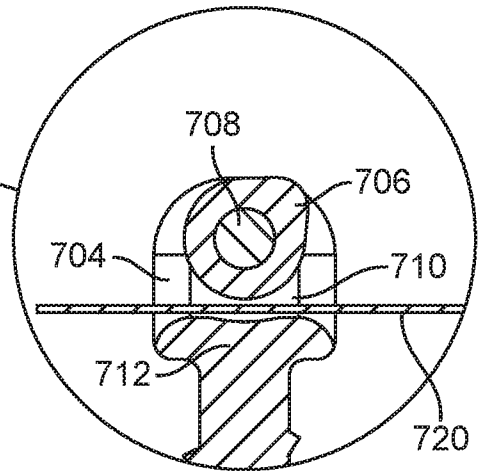


FIG. 25D

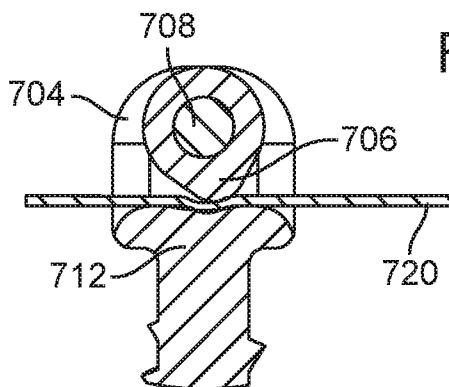


FIG. 25E

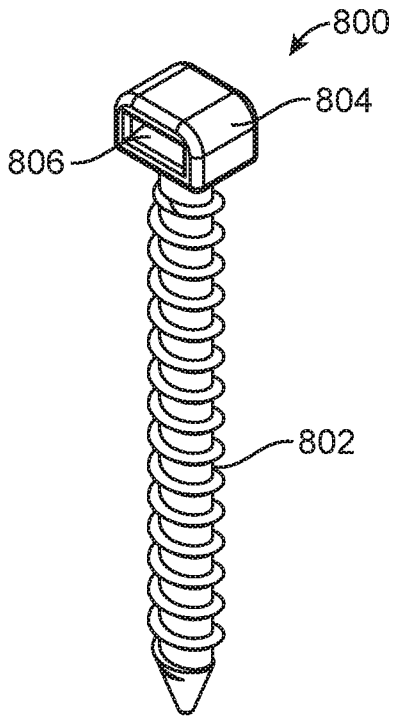


FIG. 26

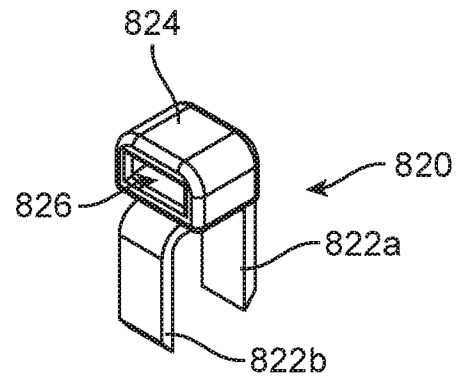


FIG. 27

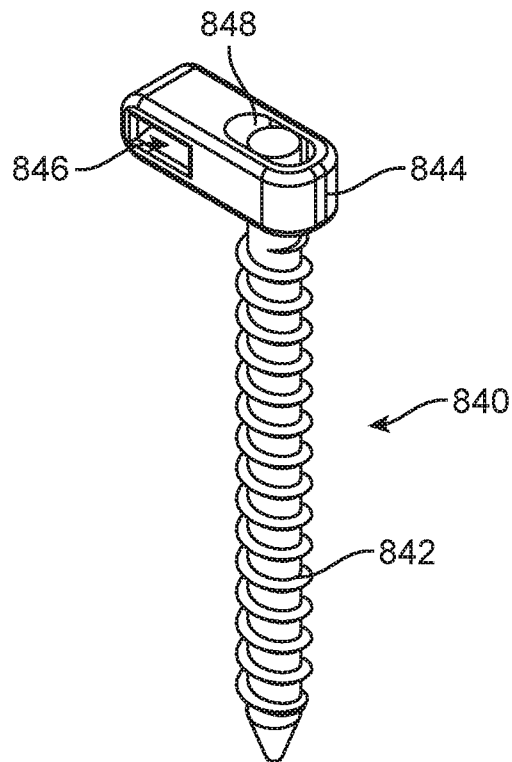


FIG. 28

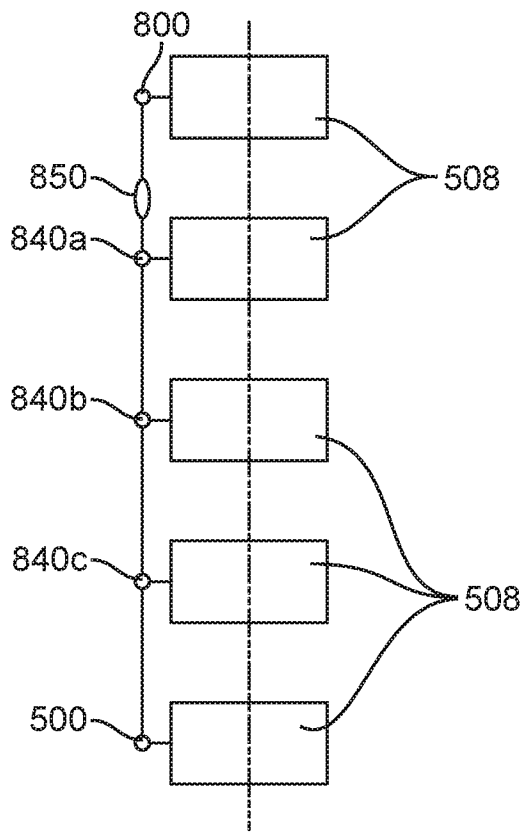


FIG. 29A

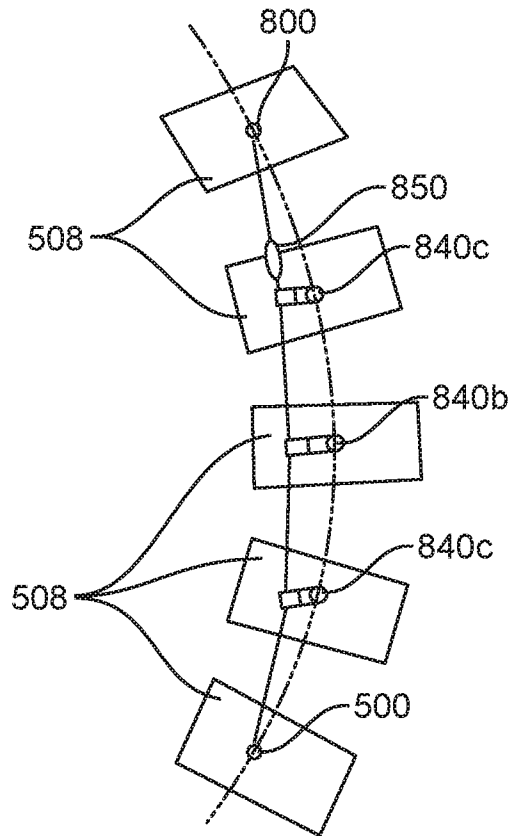


FIG. 29B



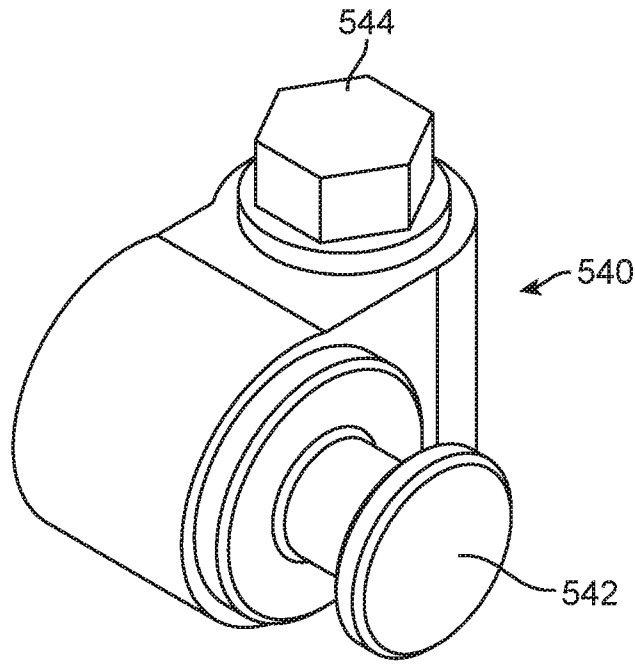


FIG. 30

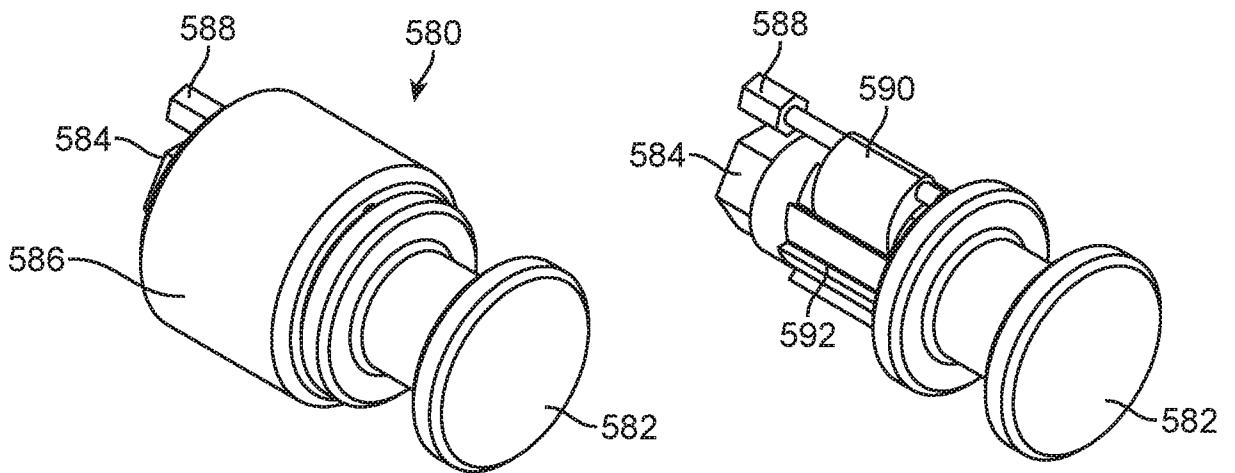


FIG. 31A

FIG. 31B

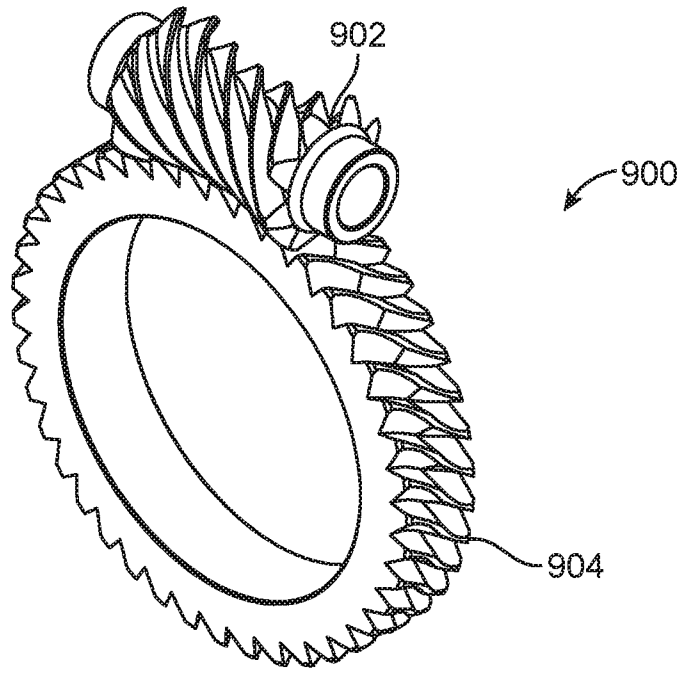


FIG. 32A

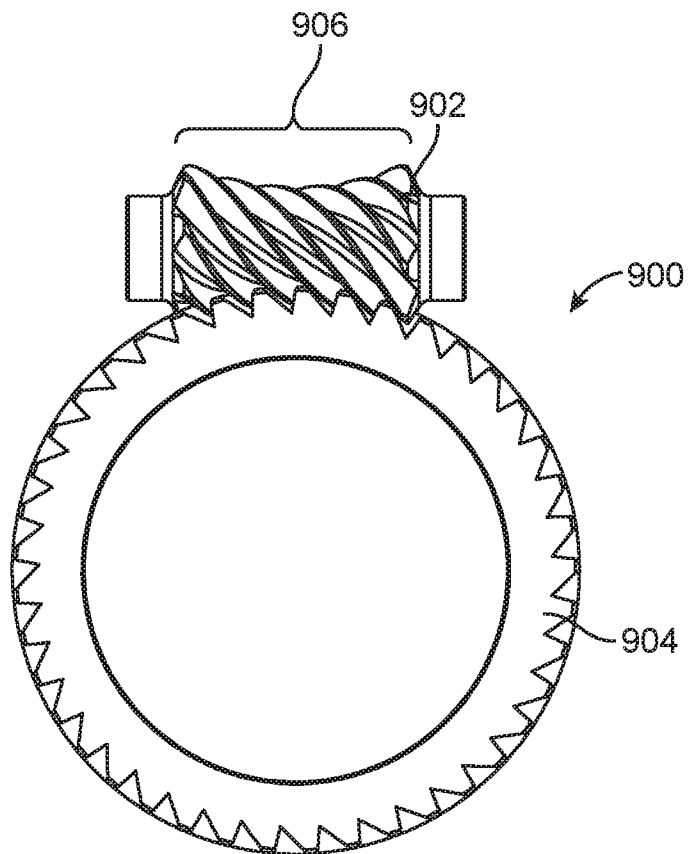


FIG. 32B

INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2017/033592

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61B17/70  
ADD.  
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED  
Minimum documentation searched (classification system followed by classification symbols)  
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/033436 A1 (SONG JOHN K [US] ET AL) 7 February 2008 (2008-02-07)	1-4,7, 10-14, 18,19,25
A	paragraph [0055] - paragraph [0056]; figures 1,2 paragraph [0058]; figure 4 paragraph [0059]; figure 5 paragraph [0060]; figures 8A, 8B paragraph [0061]; figures 9A, 9B paragraph [0062]; figures 10A, 10B paragraph [0063]; figures 11A, 11B paragraph [0064] - paragraph [0065]; figures 12-14 paragraph [0067]; figure 15 ----- -/--	5,6,8, 15,17, 20-24, 26-38

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search  18 July 2017	Date of mailing of the international search report  28/07/2017
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Filali, Salima
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## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2017/033592

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/112207 A1 (WALKER BLAIR [US] ET AL) 30 April 2009 (2009-04-30) paragraph [0152] - paragraph [0154]; figure 36 paragraph [0155] - paragraph [0157]; figures 40, 41 paragraph [0158]; figure 43 paragraph [0160]; figure 44 -----	1-38
A	US 2010/318129 A1 (SEME STEVEN J [US] ET AL) 16 December 2010 (2010-12-16) paragraph [0042]; figure 4 paragraph [0041] - paragraph [0042]; figure 1 -----	1-38
A	US 2014/094851 A1 (GORDON JEFFREY DAVID [US]) 3 April 2014 (2014-04-03) paragraph [0030] - paragraph [0032]; figures 1, 2 paragraph [0033] - paragraph [0034]; figures 3, 4 paragraph [0008] paragraph [0044] paragraph [0037]; figure 8 -----	1-38

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2017/033592

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: **39-46**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**see FURTHER INFORMATION sheet PCT/ISA/210**
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.1

Claims Nos.: 39-46

Claims 39-46 relate to a "method of treating " and "providing surgical access to the treatment region of the spine". The method is thus clearly of surgical nature. No international search and no preliminary examination are required for such methods (Art. 17(2)(a)i, Rule 39.1(iv); Art. 34(4)(a)I, Rule 67.1(iv) PCT).

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/033592

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008033436	A1	07-02-2008	NONE
-----			
US 2009112207	A1	30-04-2009	CA 2703562 A1 07-05-2009
		CN 101917918 A	15-12-2010
		CN 102920500 A	13-02-2013
		EP 2209431 A1	28-07-2010
		JP 5860496 B2	16-02-2016
		JP 2011502003 A	20-01-2011
		JP 2014204988 A	30-10-2014
		JP 2016013464 A	28-01-2016
		US 2009112207 A1	30-04-2009
		US 2009112262 A1	30-04-2009
		US 2009112263 A1	30-04-2009
		US 2012157996 A1	21-06-2012
		US 2013296859 A1	07-11-2013
		US 2015173820 A1	25-06-2015
		US 2016030089 A1	04-02-2016
		WO 2009058546 A1	07-05-2009
-----			
US 2010318129	A1	16-12-2010	EP 2442737 A1 25-04-2012
			US 2010318129 A1 16-12-2010
			WO 2010147744 A1 23-12-2010
-----			
US 2014094851	A1	03-04-2014	EP 2900180 A1 05-08-2015
			JP 2015531279 A 02-11-2015
			US 2014094851 A1 03-04-2014
			US 2016051286 A1 25-02-2016
			WO 2014052944 A1 03-04-2014
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