



(51) International Patent Classification:
A61B 17/58 (2006.01)

(21) International Application Number:

PCT/US2010/034197

(22) International Filing Date:

10 May 2010 (10.05.2010)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

12/465,098 13 May 2009 (13.05.2009) US

(71) Applicant (for all designated States except US): **DEPUY SPINE, INC.** [US/US]; 325 Paramount Drive, Raynham, MA 02767-0350 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **STAD, Shawn, D.** [US/US]; c/o Depuy Spine, Inc., 325 Paramount Drive, Raynham, MA 02767 (US). **MURPHY, Raymond** [US/US]; c/o Depuy Spine, Inc., 325 Paramount Drive, Raynham, MA 02767 (US).

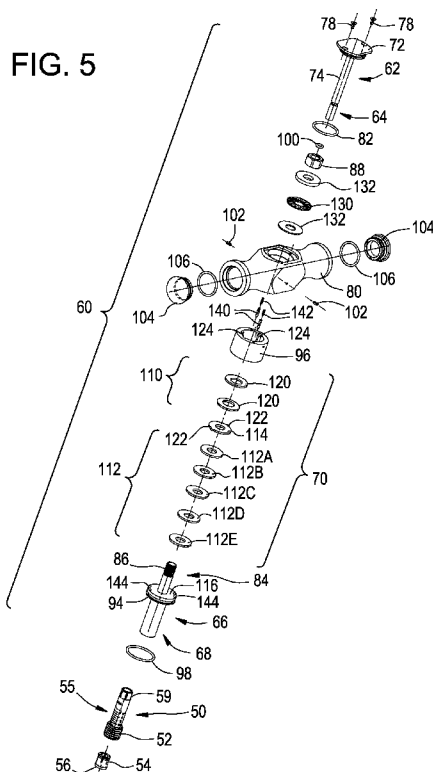
(74) Agents: **JOHNSON, Philip, S.** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK,

[Continued on next page]

(54) Title: TORQUE LIMITED INSTRUMENT FOR MANIPULATING A SPINAL ROD RELATIVE TO A BONE ANCHOR



(57) Abstract: An instrument for adjusting a spinal rod relative to a bone anchor includes a handle connecting a set screw driver with a reduction collar. The handle includes an inner shaft engageable with the set screw driver, an outer shaft engageable with the reduction collar, and a clutch connecting the inner shaft to the outer shaft and permitting selective rotation of the inner shaft relative to the outer shaft, and thus, selective rotation of the set screw driver relative to the reduction collar. The handle clutch may include a spring and a plurality of disc clutch members positioned about the outer shaft. The spring biases the disc clutch members into contact with one another and at least one disc clutch member may rotate relative to an adjacent disc clutch member upon application of a torque to the reduction collar and the outer shaft greater than a preselected torque value.



SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Declarations under Rule 4.17:

- *as to the identity of the inventor (Rule 4.17(i))*
- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

- *with international search report (Art. 21(3))*

TORQUE LIMITED INSTRUMENT FOR MANIPULATING A SPINAL ROD RELATIVE TO A BONE ANCHOR

Background

[01] Spinal fixation devices are used in orthopedic surgery to align and/or fix a desired relationship between adjacent vertebral bodies. Such devices typically include a spinal connector, such as a spinal rod, that is coupled to adjacent vertebrae by attaching the element to various anchoring devices, such as hooks, bolts, wires, or screws. The spinal rods can have a predetermined contour that has been designed according to the properties of the target implantation site, and once installed, the spinal rod and the anchors holds the vertebrae in a desired spatial relationship, either until desired healing or spinal fusion has taken place, or for some longer period of time.

[02] Spinal connectors, such as spinal rods, can be anchored to specific portions of the vertebra. Since each vertebra varies in shape and size, a variety of anchoring devices have been developed to facilitate engagement of a particular portion of the bone. Pedicle screw assemblies, for example, have a shape and size that is configured to engage pedicle bone. Such screws typically include a threaded shank that is adapted to be threaded into a vertebra, and a head portion having a rod-receiving element, usually in the form of a U-shaped slot formed in the head. A set-screw, plug, or similar type of fastening mechanism, is used to lock the spinal rod into the rod-receiving head of the pedicle screw. In use, the shank portion of each screw is threaded into a vertebra, and once properly positioned, a spinal rod is seated through the rod-receiving member of each screw and the rod is locked in place by tightening a set screw or other fastener mechanism to securely interconnect each screw and the spinal rod.

[03] While current spinal fixation systems have proven effective, one challenge associated with such systems is mounting the spinal rods into the rod-receiving member of various fixation devices. In particular, it can be difficult to align and seat the rod into the rod receiving portion of adjacent anchors due to the positioning of the

vertebra into which the anchors are mounted. Thus, the use of a spinal rod reduction device, also sometimes referred to as a spinal rod approximator, is often required in order to grasp the head of the anchor and reduce the rod into the rod-receiving head of the bone anchor.

[04] While several rod reduction devices are known in the art, some tend to be bulky and cumbersome to use and, thus, are unsuitable for use all procedures, particularly in minimally invasive surgical procedures in which the skin incisions and tissue pathways to the spine are relatively small and restricted. Accordingly, there is a need for improved rod reduction devices and methods for seating a spinal rod in a rod-receiving member of one or more spinal anchors.

Summary

[05] Disclosed herein are instruments for adjusting the position of a spinal rod relative to a bone anchor that are particularly suited for use in minimally invasive spinal procedures in which the spinal rod is delivered to the bone anchors through screw extensions connected to one or more of the bone anchors. In such procedures, the bone anchors and the screw extensions may be delivered through separate minimally invasive incisions, such as stab incisions. The screw extensions operate as independent pathways to the bone anchor through which instruments and implants, such as the spinal rod and the set screw for each bone anchor, may be delivered to the bone anchor implanted in the vertebra of the patient's spine. The rod adjustment instruments disclosed herein are designed to work within the screw extensions without the need to expand or enlarge the skin incisions or tissue pathways from the skin incisions to the bone anchors implanted in the vertebra of the patient's spine.

[06] Accordingly, an instrument for adjusting the position of a spinal rod relative to a bone anchor may include a generally tubular screw extension connectable to the bone anchor, a reduction cap removably connectable to the screw extension, a set screw driver, an externally threaded collar positioned about and rotatable relative to the drive shaft of the set screw driver and engagable with an internal thread provided on the bore of the reduction cap, and a handle connectable to the set screw driver and the collar. The handle may include an inner shaft having a distal end configured to engage the proximal end of the driver shaft of the set screw driver, an outer shaft

having a distal end configured to engage the threaded collar, and a clutch connecting the inner shaft to the outer shaft and permitting selective rotation of the inner shaft relative to the outer shaft, and thus, selective rotation of the set screw driver relative to the collar. The clutch may include a spring and a plurality of disc clutch members positioned about the outer shaft. The spring biases the disc clutch members into contact with one another and into contact with the outer shaft. At least one disc clutch member may rotate relative to an adjacent disc clutch member upon application of a torque to the outer shaft greater than a preselected torque value.

Brief Description of the Figures

[07] These and other features and advantages of the instruments and methods disclosed herein will be more fully understood by reference to the following detailed description in conjunction with the attached drawings in which like reference numerals refer to like elements through the different views. The drawings illustrate principles of the instruments and methods disclosed herein and, although not to scale, show relative dimensions.

[08] FIGURE 1 is a perspective view of an exemplary spinal fixation system including a plurality of bone anchors, each connected to a vertebra, a plurality of screw extensions, each connected one of the bone anchors, a spinal rod connecting the bone anchor together, and plurality of instruments for adjusting the spinal rod relative to the bone anchors;

[09] FIGURE 2 is a perspective view of the spinal fixation system of FIGURE 1, illustrating the positioning of a set screw driver and a threaded collar within a reduction cap and the screw extension to which the reduction cap is connected;

[10] FIGURE 3 is a side view of one of the instruments for adjusting the spinal rod relative to the bone anchors, illustrating the handle connected to set screw driver and the threaded collar;

[11] FIGURE 4 is a side view in cross section of the instrument of FIGURE 3 taken along line A-A in FIGURE 3;

[12] FIGURE 5 is an exploded view of the instrument of FIGURE 3 with the set screw driver removed; and

[13] FIGURE 6 is a side view of the outer shaft of the clutch of the instrument of FIGURE 3.

Detail Description of Exemplary Embodiments

[14] Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the instruments and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the instruments and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

[15] The articles "a" and "an" are used herein to refer to one or to more than one (i.e. to at least one) of the grammatical object of the article. By way of example, "an element" means one element or more than one element.

[16] The terms "comprise," "include," and "have," and the derivatives thereof, are used herein interchangeably as comprehensive, open-ended terms. For example, use of "comprising," "including," or "having" means that whatever element is comprised, had, or included, is not the only element encompassed by the subject of the clause that contains the verb.

[17] FIGURES 1-5 illustrate an exemplary embodiment of a spinal fixation system including a plurality of bone anchors 12, each of which is implanted in a vertebra VB of a patient's spine, a spinal rod 10 connecting the bone anchors, and a plurality of screw extensions 14, each connected to one of the bone anchors. The exemplary spinal fixation system is a minimally invasive spinal system that allows a spinal surgeon to align and/or fix a number of vertebrae of a patient's spine to treat a wide range of spinal pathologies, including the treatment of degenerative disc disease and the correction of spinal deformities. In the exemplary system, the implanted bone

anchors 12 are polyaxial pedicle screws, such as the VIPER polyaxial pedicle screws available from DePuy Spine, Inc., of Raynham, MA. The exemplary polyaxial pedicle screws 12 include a U-shaped channel for receiving the spinal rod 10 therein and a set screw 18. The U-shaped channel is defined by two spaced apart arms and the set screw 18 is engageable with an internal thread provided on the arms to secure the spinal rod 10 within the U-shaped channel and to the polyaxial bone screw 12. Suitable polyaxial pedicle screws are described in U.S. Patent No. 7,179,261, which is incorporated herein by reference. Other types of bone anchors also may be used including monoaxial screws, uniplanar screws, and hooks. In addition to the set screw 18, other types of closure mechanisms, including a twist-in cap, the Monarch Typhoon Cap closure available from DePuy Spine, Inc, of Raynham, MA or a two piece set screw, such as the Expedium Dual Innie closure available from DePuy Spine, Inc, of Raynham, MA.

[18] The exemplary screw extensions 14 are generally tubular in shape and have a central lumen extending from the proximal end 20 of the screw extension 14 to the distal end 22 of the screw extension 14. The central lumen of each screw extension 14 is sized to receive instruments and implants therethrough. The screw extensions 14 may include a pair of opposed longitudinal slots 24 that open to the central lumen of the screw extension 14. The slots 24 open at the distal end 22 of the screw extension 14 and extend axially from the distal end 22 of the screw extension. The screw extensions provide a number of functions including facilitating the delivery of the spinal rod 10 to the bone anchors 12 in a minimally invasive manner. In one exemplary minimally invasive surgical technique, each bone anchors 12 and each screw extension 14 may be delivered percutaneously to a vertebra of the spine through a separate and independent minimally invasive incision, such as a stab incision. The spinal rod 10 may be introduced to the bone anchors 12 through one of the screw extensions 14, or through one of the minimally invasive incisions, and guided into position beneath the skin and fascia. Exemplary screw extensions are described in U.S. Patent No. 7,179,261 and U.S. Patent Application Publication No. 2008/0077134 and U.S. Patent Application No. 12/244,268, each of which is incorporated herein by reference. Exemplary minimally invasive surgical techniques are described in U.S. Patent No. 7,527,638, U.S. Patent Application Publication No.

2005/0131422, and U.S. Patent Application Publication No. 2009/0082811, each of which is incorporated herein by reference.

[19] The exemplary spinal system includes an instrument for adjusting the position of the spinal rod 10 relative to one or more of the bone anchors 12. The instrument may include a reduction cap 30 removably connectable to the proximal end 20 of one of the screw extensions 14, a set screw driver 40, an externally threaded collar 50 positioned about and rotatable relative to the drive shaft 42 of the set screw driver 40 and a handle 60 connectable to the set screw driver 40 and the collar 50.

[20] The reduction cap 30 has an internal bore extending therethrough that includes an internal thread 32 for engaging an external thread 52 provided on the collar 50. The reduction cap 30 may include a mating element 32 disposed on the distal end of the reduction cap 30 and adapted to removably mate the reduction cap to one or more of the screw extensions 14. The mating element 32 may include a pawl disposed within the bore of the cap 30 that can engage a groove or slot 28 provided on the proximal end 20 of the screw extension 14. Alternatively, the mating element 32 may be one or more threads for engaging a corresponding thread on the proximal end 20 of the screw extension 14, a ball and plunger configuration, or other suitable mechanisms for removably connecting the reduction cap 30 to the screw extension in a manner that permits axial adjustment of the spinal rod with the set screw driver 40. Exemplary reduction caps are disclosed in U.S. Patent Application Publication No. 2008/0243190, which is incorporated herein by reference.

[21] In alternative embodiments, the central lumen of screw extension 14 may include an internal thread to facilitate reduction of the spinal rod 10 relative to the bone anchor 12. In such embodiments, the internal thread may be provided at the proximal end 20 of the screw extension 14, for example, and may be engaged by the externally threaded collar 50, thereby eliminating the need for the reduction cap 30.

[22] The exemplary set screw driver 40 includes a drive shaft 42 extending from a proximal end 44 to a distal end 46. The proximal end 44 of the set screw driver 40 includes a drive feature that facilitates rotation of the set screw driver 40 by the handle 60. In the exemplary embodiment, the drive feature is hexagonal shaped, in cross section, post 48 that is sized and shaped to fit within a complementary shaped

recess 76 within the inner shaft 62 of the handle 60. The distal end 46 of the set screw driver is sized and shaped to fit within the mating feature of the set screw 18. In the exemplary embodiment, the distal end 46 is configured to retain the set screw 18 until released by axially advancing the distal end 46 relative to the set screw 18. An axial stop 49, in the form of a shoulder or a rib, is provided on the drive shaft 42 of the set screw driver 40.

[23] The threaded collar 50 is generally tubular in shape and includes a central lumen. The threaded collar 50 may be positioned about the drive shaft 42 of the set screw driver 40 and may rotate relative to the drive shaft 42 of the set screw driver 40. To facilitate rotation of the collar 50 relative to the drive shaft 42, the collar 50 may include a bushing 54 positioned within the central lumen of the threaded collar 50. The distal end 56 of bushing 54 engages the axial stop 49 of the set screw driver 40. The proximal end 58 of the threaded collar 50 includes a drive feature that facilitates rotation of the collar 50 by the handle 60. In the exemplary embodiment, the drive feature is a hexagonal shaped, in cross section, section 59 that is sized and shaped to fit within a complementary shaped recess 92 within the outer shaft 66 of the handle 60. The outer surface of the threaded collar 50 may include indicia 55 to indicate the position of the threaded collar 50, as well as the set screw 18, relative to the screw extension 14 and the screw 12. The indicia 55 may be a series of depth markers indicating the depth of collar 50 relative to the screw extension 14.

[24] The handle 60 may include an inner shaft 62 having a distal end 64 configured to engage the proximal end 44 of the driver shaft 42 of the set screw driver 40, an outer shaft 66 having a distal end 68 configured to engage the threaded collar 50, and a clutch 70 connecting the inner shaft 62 to the outer shaft 66 and permitting selective rotation of the inner shaft 62 relative to the outer shaft 66, and thus, selective rotation of the set screw driver 40 relative to the collar 50.

[25] The inner shaft 62, in the exemplary embodiment, includes a proximal flange 72 and a cylindrical body 74 that terminates with a recess 76 configured to engage the post 48 of the set screw driver 40 and transmit rotational motion thereto. The proximal flange 72 may be secured to the top of handle body 80 by fasteners 78 and an O-ring 82 may be positioned between the flange 72 and the handle body 80.

[26] The outer shaft 66, in the exemplary embodiment, may be generally tubular in shape having a central lumen sized and shaped to receive the inner shaft 62 therein. The proximal end 84 of the outer shaft 66 includes an external thread 86 for engagement with a torque adjustment mechanism, a nut 88 in the exemplary embodiment, as described in more detail below. The distal end 68 of the outer shaft 66 includes a recess 92 configured to engage the hexagonal section 59 of the collar 50 and transmit rotational motion thereto. The outer shaft 66 may include a flange 94 that engages a clutch housing 96 secured to the bottom of the handle body 80. An O-ring 98 may be positioned between the flange 94 and the clutch housing 96 and an O-ring 100 may be positioned between the inner shaft 62 and the outer shaft 66.

[27] The handle clutch 70 is positioned within the cylindrically shaped clutch housing 96, which is secured within the handle body 80. Dowel pins 102 extend through the handle body 80 into the clutch housing 96 to prevent rotation of the clutch housing relative to the handle body 80. Two handle caps 104 and complementary O-rings 106 connect to the handle body 80 to seal the handle body 80.

[28] O-rings 82, 98, 100, and 106 seal the handle body 80 to prevent fluids from entering the handle body 80 during sterilization procedures.

[29] The handle clutch 70 may include a spring 110 and a plurality of disc clutch members 112 positioned about the outer shaft 66. The spring 110 biases the disc clutch members 112 into contact with one another and into contact with the outer shaft 66, in particular into contact with the flange 94. During use of the instrument, at least one disc clutch member 112A may rotate relative to an adjacent disc clutch member 112B upon application of a torque to the collar 50 and outer shaft 66 greater than a preselected torque value, thereby allowing the inner shaft 62 and the set screw driver 40 to rotate relative to the outer shaft 66 and the collar 50.

[30] In the exemplary embodiment, the clutch 70 includes five adjacent disc clutch members 112A-112E. In alternative embodiments, any number of adjacent disc clutch members may be employed. For example, in one alternative embodiment, two disc clutch members may be employed. Moreover, in certain alternative embodiments, the proximal facing surface 116 of the axial stop 94 of the outer shaft 66 may have a disc clutch member connected thereto or may otherwise function as a

disc clutch member by, for example, coating the proximal facing surface 116 with an appropriate wear resistant material, such as a ceramic or polymer coating. In such embodiments, the proximal facing surface 116 may engage a single disc clutch member 112E interposed between the anti-rotation washer 114 and the proximal facing surface 116, without any further disc clutch members being provided. Likewise, the distal facing surface of the anti-rotation washer 114, if included, may have a disc clutch member connected thereto or may otherwise function as a disc clutch member by, for example, coating the distal facing surface with an appropriate wear resistant material, such as a ceramic or polymer coating. In such embodiments, the distal facing surface of the anti-rotation washer 114 may engage a single disc clutch member 112 interposed between the anti-rotation washer 114 and the proximal facing surface 116, without any further disc clutch members being provided or may directly engage the proximal facing surface 116 with the proximal facing surface 116 operating as a disc clutch member.

[31] The disc clutch members 112A-E may be constructed from a material selected to reduce wear on the clutch members. For example, the disc clutch members 112A-E may be constructed from metal, such as steel, from a ceramic material, from a polymer material, or from a composite material such as fiberglass. In certain embodiments, the disc clutch members may be constructed from the same material. In other embodiments, one or more of the clutch members may be selected from different materials. For example, disc clutch members 112A, 112C, and 112E may be constructed from a first material, such as fiberglass, and disc clutch members 112B and 112D may be constructed from a second material, distinct from the first material, such as steel.

[32] In the exemplary embodiment, the spring 110 includes a pair of Belleville springs 120 positioned about the outer shaft 66. Any number of Belleville springs, including a single Belleville spring, may be employed to provide a compressive force on the disc clutch members 112A-E. In the exemplary embodiment, the Belleville springs 120 bias the disc clutch members 112A-E into contact with the proximal facing surface 116 of the axial stop 94 of the outer tube 66 to thereby provide an axially compressive force on the disc clutch members. One or more springs other

than Belleville springs may be employed to provide the compressive force on the clutch members.

[33] The clutch 70 may include an anti-rotation washer 114 positioned between spring 110 and the disc clutch members to prevent wearing of the spring 110 by engagement with a rotating clutch member. In the exemplary embodiment, the anti-rotation washer 114 is positioned between the distal Belleville washer 120 and the proximal disc clutch member 112A. The anti-rotation washer 114 may include one or more projections 122 that are sized and shaped to fit within complementary axial slots 124 provided in the clutch housing 96.

[34] The exemplary instrument may include an adjustment member for adjusting the reselected torque value above which one or more of the clutch members may rotate. In the exemplary embodiment, the adjustment member is nut 88 that engages the external thread 86 on the proximal end 84 of the outer shaft 66. Advancing the nut 88 toward the clutch members 112 and the spring 110 increases the axial compressive force on the clutch members 112, thereby increasing the torque above which one or more of the clutch members may rotate. Conversely, moving the nut 88 away from the clutch members 112 and the spring 110 decreases the axial compressive force on the clutch members 112, thereby decreasing the torque above which one or more of the clutch members may rotate. A thrust bearing 130 and a pair of bearing races 132, provided on either side of the thrust bearing 130, may be positioned between the nut 88 and the spring 110. The thrust bearing 130 and bearing races 132 inhibit rotation of the nut 88 during operation of the clutch 70.

[35] The exemplary instrument may include a mechanism to inhibit rotation of the outer shaft 66 in one direction. In the exemplary embodiment, the mechanism includes a pair of pins 140 positioned within the wall of the clutch housing 96 that extend from the distal end of the clutch housing 96 to engage the proximal facing surface 116 of the flange 94 of the outer shaft 66. Springs 142 bias the pins 140 into contact with the proximal facing surface 116 of the flange 94 of the outer shaft 66. The proximal facing surface 116 of the flange 94 includes a pair of opposed ramped indents 144, each having an angled surface 146, oriented at an angle to the proximal facing surface 116, and a stop surface 148, oriented approximately perpendicular to the proximal facing surface, as best illustrated in FIGURE 6. During rotation of outer

shaft 66 in a first direction, indicated by Arrow X, the pin 140 may move through the indent 144 via the angled surface 146. Rotation of the outer shaft 66 in the opposite direction, indicated by the Arrow Y, causes the pin 140 to contact the stop surface 148, which prevents further motion of the pin 140, and the outer shaft 66, relative to the handle housing 80. In this manner, the clutch 70 may function in one rotational direction (Arrow X) but not the other rotational direction (Arrow Y).

[36] One exemplary method of using the exemplary instrument may include connecting one of the screw extensions 14 to a bone anchor 12 and implanting the bone anchor 12 into a vertebra VB, as illustrated in FIGURE 1. As discussed above, the bone anchors 12, the screw extensions 14, and the spinal rod 10 using minimally invasive surgical technique, including, for example, delivering the screw extensions 14 and the bone anchors 12 through separate minimally invasive incisions. Any number of bone anchors 12 and corresponding screw extensions 14 may be employed depending on the procedure being performed. A spinal rod 10 may be delivered into proximity to the bone anchors 12 by, for example, positioning the spinal rod 10 through the longitudinal slots 24 of the screw extensions 14.

[37] A reduction cap 30 may be connected to one or more of the screw extensions 14. As illustrated in FIGURES 1 and 2, a set screw driver 40 may be positioned through the reduction cap 30 and the screw extension 14 with a set screw 18 engaged to a distal end 46 of the set screw driver 40. An externally threaded collar 50 may be positioned about the set screw driver 40. The collar 50 is rotatable relative to the driver 40 and advanced to engaging an axial stop 49 on the driver 40.

[38] The handle 60, including the clutch 70, may be positioned about the distal ends of the collar 50 and the set screw driver 40. The distal end 64 of the inner shaft 74 engages the post 48 at the proximal end 44 of the set screw driver 40 and the distal end 68 of the outer shaft 66 engages the post 59 at the proximal end of the collar 50. The handle 60 connected to the set screw driver 40 and the collar 50 may be rotated in a first direction, e.g., a clockwise direction, to engage the external thread 52 of the collar 50 with the internal thread 32 of the reduction cap 30. The handle 60 may continue to be rotated in the first direction to axially advance the set screw driver 40 and the collar 50 distally within the screw extension 14 and to advance the set screw

18 into contact with the spinal rod 10. The axial advancement of the set screw 18 against the spinal rod 10 axially positions the spinal rod 10 within the bone anchor 12.

[39] By continuing to rotate the handle 60 in the first direction, the set screw 18 may be advanced into engagement with an internal thread of the bone anchor 12. Engagement of the set screw 18 with the internal thread on the bone anchor 12 may increase the torque on the collar 50, which is threadedly engaged to the reduction cap 30, thereby increasing the torque on the outer shaft 66 of the clutch 70. If the increase torque exceeds the preselected torque value, at least one disc clutch member 112 of the clutch 70 will rotate relative to an adjacent disc clutch member 112 of the clutch 70, thereby allowing the set screw driver 40 to rotate independently of the collar 50 and thereby advance the set screw 18 into engagement with bone anchor 12 and capture the spinal rod 10 within the bone anchor 12. As the torque on the collar 50 and the outer shaft 66 decreases below the preselected torque value, the clutch members 112 will rotate together, allowing the collar 50 and set screw driver 40 to rotate together. During advancement of the set screw 18 into its final position capturing the spinal rod 12, the torque on the collar 50 and outer shaft 66 may cycle above and below the preselected torque value and, correspondingly, the clutch 70 will permit rotation of the collar 50 relative to the set screw driver 40 to reduce the torque and prohibit such rotation when the torque is below the preselected torque value.

[40] Once the set screw 18 is properly positioned, the set screw driver 40 and collar 50 may be removed from the screw extension 14 and the screw extension 14 may be disconnected from the bone anchor 12.

[41] While the exemplary method has been described in connection with minimally invasive surgical procedures in which the screw extensions 14 and the bone anchors 12 are delivered through minimally invasive incisions, such as separate stab incisions, the instruments disclosed herein may be used in non-minimally invasive procedures, e.g., open procedures, in which the screw extensions 14 and the bone anchors 12 are delivered through one or more large incisions. In such open procedures, the screw extensions 14 may be connected to the bone anchors 12 after implantation of the bone anchors 12 and/or delivery of the spinal rod 10 to the bone anchors 12. In such exemplary embodiments, the screw extensions 14 need not include extended longitudinal slots 24. Instead, the slots 24 may extend a minimal distance from the

distal end 22 of the screw extension 14 sufficient to permit rod reduction. Exemplary screw extensions for such open procedures are described in U.S. Patent Application Publication No. 2006/0200132 and U.S. Patent Application Publication No. 2007/016209, each of which is incorporated herein by reference.

[42] While the instruments and methods of the present invention have been particularly shown and described with reference to the exemplary embodiments thereof, those of ordinary skill in the art will understand that various changes may be made in the form and details herein without departing from the spirit and scope of the present invention. Those of ordinary skill in the art will recognize or be able to ascertain many equivalents to the exemplary embodiments described specifically herein by using no more than routine experimentation. Such equivalents are intended to be encompassed by the scope of the present invention and the appended claims.

1. A spinal fixation system comprising:
 - a spinal rod,
 - a plurality of bone anchors, one or more of the bone anchors having a U-shaped channel for receiving the spinal rod therein and a set screw, the U-shaped channel defined by two spaced-apart arms, the set screw having an external thread engagable with an internal thread provided on the arms to secure the spinal rod in the U-shaped channel,
 - a plurality of generally tubular screw extensions, each screw extension connectable to one of the bone anchors and having a central lumen extending from a proximal end to a distal end of the screw extension, the central lumen sized to receive instruments and implants therethrough,
 - a reduction cap having a bore extending therethrough, an internally threaded driving element, and a mating element disposed on a distal end thereof and adapted to removably mate the cap to one of the screw extensions,
 - a set screw driver comprising a drive shaft having a proximal end and terminating at a distal end sized and shaped to fit within a mating feature on the set screw of a bone anchor,
 - an externally threaded collar positioned about the drive shaft and rotatable relative to the drive shaft, the collar engaging an axial stop on the drive shaft, the collar engagable with the internally threaded drive element of the reduction cap, and
 - a handle comprising an inner shaft having a distal end configured to engage the proximal end of the driver shaft of the set screw driver, an outer shaft having a distal end configured to engage the threaded collar, and a clutch connecting the inner shaft to the outer shaft and permitting selective rotation of the inner shaft relative to the outer shaft, the clutch comprising a spring and a plurality of disc clutch members positioned about the outer shaft, the spring biasing the disc clutch members into contact with one another and into contact with the outer shaft, at least one disc clutch member rotating relative to an adjacent disc clutch member upon application of a torque to the outer shaft greater than a preselected torque value.
2. The system of claim 1, wherein the spring comprises one or more Belleville springs positioned about the outer shaft.

3. The system of claim 1, wherein the outer shaft of the handle includes an axial stop, at least one of the disc clutch members being biased into engagement with the axial stop by the spring.
4. The system of claim 3, wherein one of the disc clutch members is coupled to the axial stop.
5. The system of claim 1, wherein the handle includes an adjustment member for adjusting the preselected torque value.
6. The system of claim 5, wherein the adjustment member is a nut engaged with an external thread on the outer shaft of the handle, the nut applying an axial force on the clutch, wherein adjustment of the axial position of the nut on the outer shaft adjusts the axial force on the clutch.
7. The system of claim 1, wherein each screw extension has a pair of opposed longitudinal slots opening to the lumen of the screw extension, the slots opening at the distal end of the screw extension and extending axially from the distal end of the screw extension.
8. An instrument for adjusting the position of a spinal rod relative to a bone anchor, the instrument comprising:
 - a generally tubular screw extension connectable to the bone anchor and having a central lumen extending from a proximal end to a distal end of the screw extension,
 - a reduction cap having a bore extending therethrough, the bore including an internal thread, the reduction cap removably connectable to the screw extension,
 - a set screw driver comprising a drive shaft having a proximal end and terminating at a distal end sized and shaped to fit within a mating feature on a set screw for the bone anchor,
 - an externally threaded collar positioned about the drive shaft and rotatable relative to the drive shaft, the collar engaging an axial stop on the drive shaft, the collar engagable with the internal thread of the reduction cap, and

a handle comprising an inner shaft having a distal end configured to engage the proximal end of the driver shaft of the set screw driver, an outer shaft having a distal end configured to engage the threaded collar, and a clutch connecting the inner shaft to the outer shaft and permitting selective rotation of the inner shaft relative to the outer shaft, the clutch comprising a spring and a plurality of disc clutch members positioned about the outer shaft, the spring biasing the disc clutch members into contact with one another and into contact with the outer shaft, at least one disc clutch member rotating relative to an adjacent disc clutch member upon application of a torque to the outer shaft greater than a preselected torque value.

9. The instrument of claim 8, wherein the spring comprises one or more Belleville springs positioned about the outer shaft.

10. The instrument of claim 8, wherein the outer shaft of the handle includes an axial stop, the disc clutch members being biased into engagement with the axial stop by the spring.

11. The instrument of claim 10, wherein one of the disc clutch members is coupled to the axial stop.

12. The instrument of claim 8, wherein the handle includes an adjustment member for adjusting the preselected torque value.

13. The instrument of claim 12, wherein the adjustment member is a nut engaged with an external thread on the outer shaft of the handle, the nut applying an axial force on the clutch, wherein adjustment of the axial position of the nut on the outer shaft adjusts the axial force on the clutch.

14. The instrument of claim 8, wherein the screw extension has a pair of opposed longitudinal slots opening to the lumen of the screw extension, the slots opening at the distal end of the screw extension and extending axially from the distal end of the screw extension.

15. A method of positioning a spinal rod relative to a bone anchor, the method comprising:

connecting a generally tubular screw extension to the bone anchor, the screw extension having a central lumen extending from a proximal end to a distal end of the screw extension and a pair of opposed longitudinal slots opening to the central lumen, implanting the bone anchor into a vertebra,

delivering a spinal rod into proximity to the bone anchor, the spinal rod being positioned through the longitudinal slots during delivery,

connecting a reduction cap to the screw extension, the reduction cap having a bore extending therethrough, the bore including an internal thread,

positioning a set screw driver through the reduction cap and the screw extension with a set screw engaged to a distal end of the set screw driver, the set screw driver having an externally threaded collar positioned about the set screw driver, the collar being rotatable relative to the driver and engaging an axial stop on the driver,

rotating a handle connected to the set screw driver and the collar to engage the external thread of the collar with the internal thread of the reduction cap, the handle comprising an inner shaft having a distal end configured to engage a proximal end of the set screw driver, an outer shaft having a distal end configured to engage the collar, and a clutch connecting the inner shaft to the outer shaft and permitting selective rotation of the inner shaft relative to the outer shaft, the clutch comprising a spring and a plurality of disc clutch members positioned about the outer shaft, the spring biasing the disc clutch members into contact with one another and into contact with the outer shaft,

continuing to rotate the handle to axially advance the set screw driver and the collar distally within the screw extension and to advance the set screw into contact with the spinal rod, axial advancement of the set screw against the spinal rod axially positioning the spinal rod within the bone anchor,

continuing to rotate the handle to advance the set screw into engagement with an internal thread of the bone anchor, at least one disc clutch member of the handle rotating relative to an adjacent disc clutch member of the handle upon application of a torque to collar and the outer shaft of the handle greater than a preselected torque value thereby allowing the set screw driver to rotate independently of the collar and

thereby advance the set screw into engagement with bone anchor and capture the spinal rod within the bone anchor,

removing the set screw driver from the screw extension, and
disconnecting the screw extension from the bone anchor.

16. An instrument for adjusting the position of a spinal rod relative to a bone anchor, the instrument comprising:

a generally tubular screw extension connectable to the bone anchor and having a central lumen extending from a proximal end to a distal end of the screw extension, the central lumen including an internal thread at the proximal end thereof,

a set screw driver having a proximal end and terminating at a distal end sized and shaped to fit within a mating feature on a set screw for the bone anchor,

an externally threaded collar positioned about the set screw driver and rotatable relative to the set screw driver, the collar engaging an axial stop on the set screw driver, the collar engagable with the internal thread of the screw extension, and

a handle comprising an inner shaft having a distal end configured to engage the proximal end of the set screw driver, an outer shaft having a distal end configured to engage the threaded collar, and a clutch connecting the inner shaft to the outer shaft and permitting selective rotation of the inner shaft relative to the outer shaft, the clutch comprising a spring and a plurality of disc clutch members positioned about the outer shaft, the spring biasing the disc clutch members into contact with one another and into contact with the outer shaft, at least one disc clutch member rotating relative to an adjacent disc clutch member upon application of a torque to the outer shaft greater than a preselected torque value.

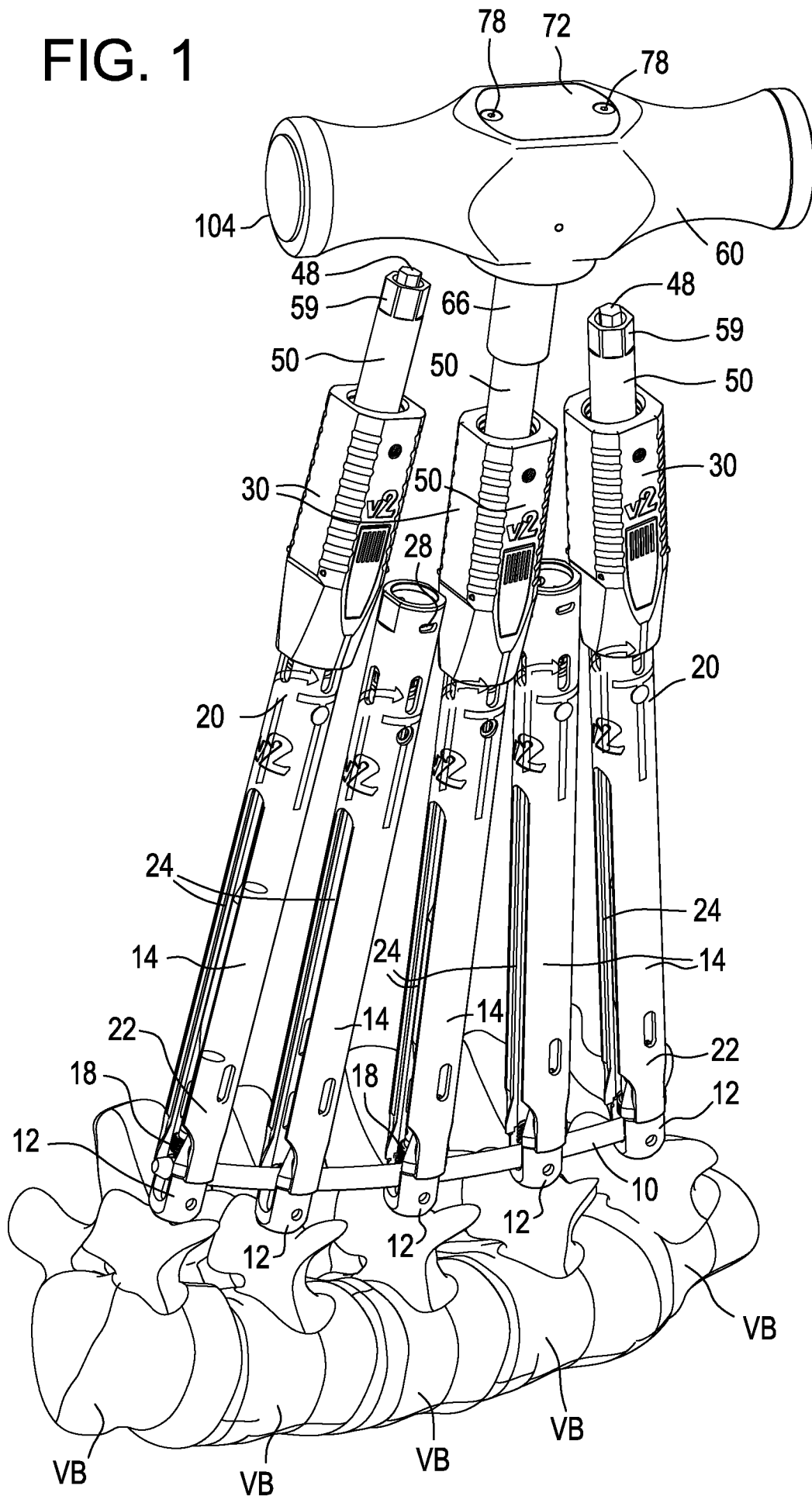
17. The instrument of claim 16, wherein the spring comprises one or more Belleville springs positioned about the outer shaft.

18. The instrument of claim 16, wherein the outer shaft of the handle includes an axial stop, the disc clutch members being biased into engagement with the axial stop by the spring.

19. The instrument of claim 18, wherein one of the disc clutch members is coupled to the axial stop.
20. The instrument of claim 16, wherein the handle includes an adjustment member for adjusting the preselected torque value.
21. The instrument of claim 20, wherein the adjustment member is a nut engaged with an external thread on the outer shaft of the handle, the nut applying an axial force on the clutch, wherein adjustment of the axial position of the nut on the outer shaft adjusts the axial force on the clutch.
22. The instrument of claim 16, wherein the screw extension has a pair of opposed longitudinal slots opening to the lumen of the screw extension, the slots opening at the distal end of the screw extension and extending axially from the distal end of the screw extension.

1/5

FIG. 1



2/5

FIG. 2

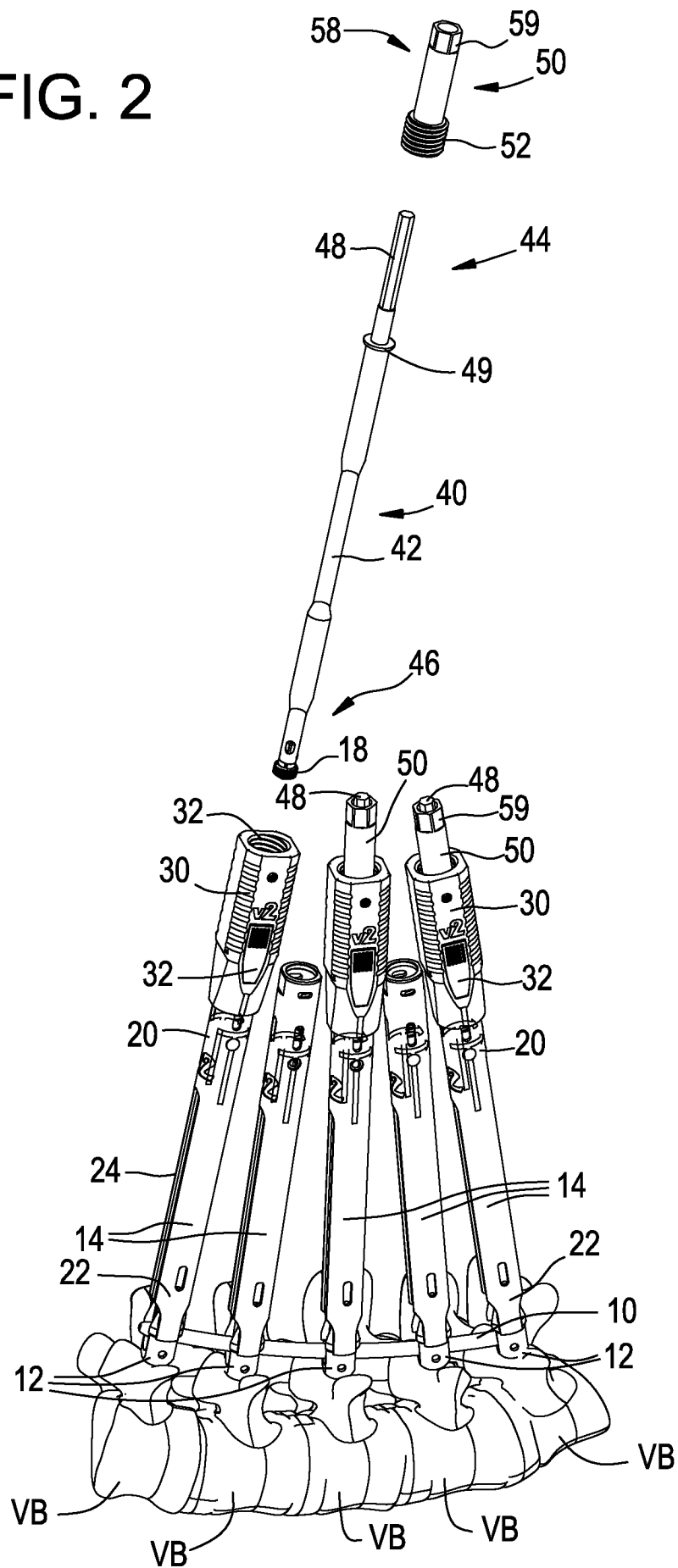


FIG. 3

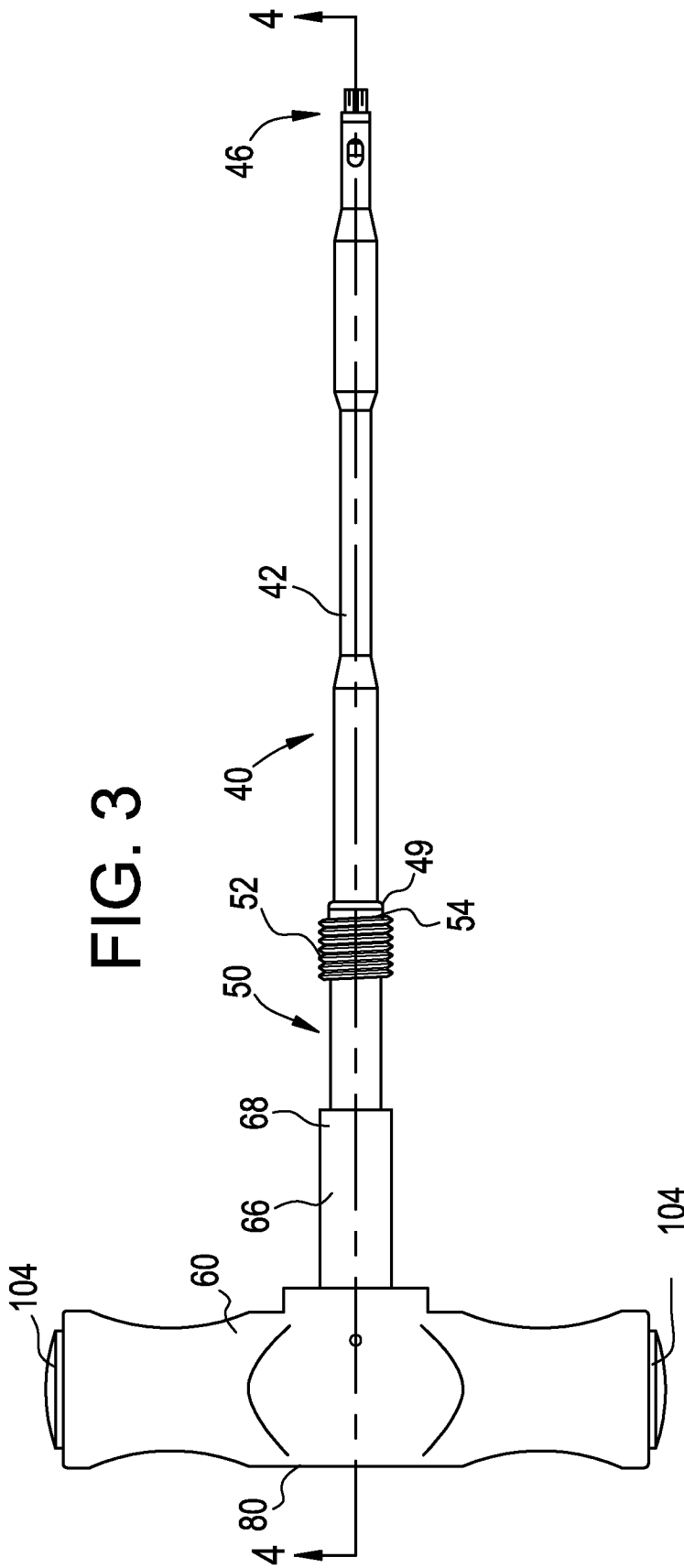
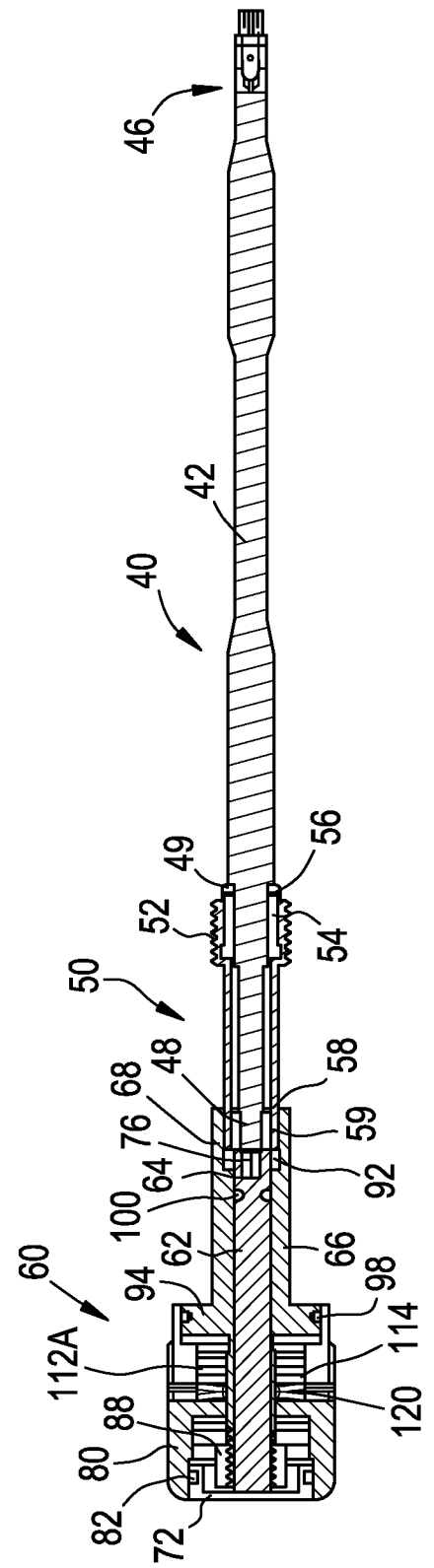


FIG. 4



4/5

FIG. 5

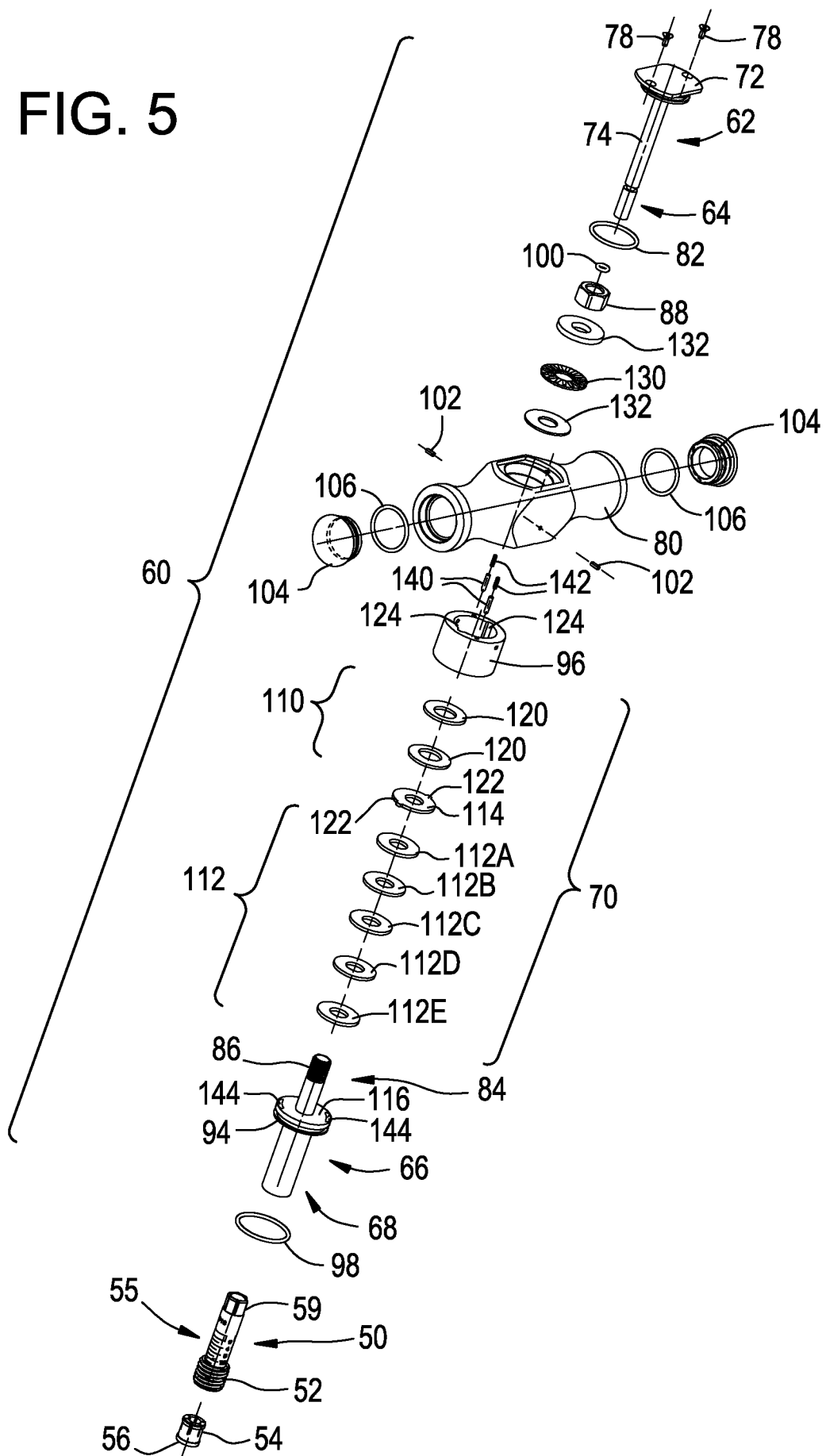
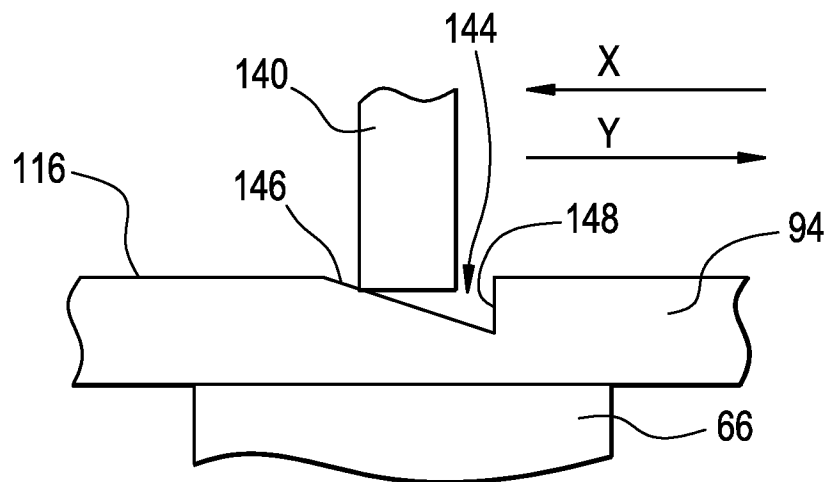


FIG. 6



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/034197

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61B 17/58 (2010.01) USPC - 606/279 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) IPC(8) - A61B 17/00, 17/58, 17/88 (2010.01) USPC - 606/200-299 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) MicroPatent		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0243190 A1 (DZIEDZIC et al) 02 October 2008 (02.10.2008) entire document	8, 10-13, 15, 16, 18-21
-		
Y		1-7, 9, 14, 17, 22
Y	US 7,527,638 B2 (ANDERSON et al) 05 May 2009 (05.05.2009) entire document	1-7, 14, 22
Y	US 3,677,378 A (TROEGER) 18 July 1972 (18.07.1972) entire document	2, 9, 17
A	US 2008/0077134 A1 (DZIEDZIC et al) 27 March 2008 (27.03.2008) entire document	1-22
A	US 2006/0200132 A1 (CHAO et al) 07 September 2006 (07.09.2006) entire document	1-22
☐ Further documents are listed in the continuation of Box C. ☐		
* 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 24 June 2010		Date of mailing of the international search report 08 JUL 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774