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Wall et al.

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(54) **SPINAL IMPLANT SYSTEM AND METHOD**

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(51) **Int. Cl.**

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A61B 17/86	(2006.01)
A61B 17/88	(2006.01)
A61B 90/00	(2016.01)
A61B 34/20	(2016.01)

(52) **U.S. Cl.**

CPC ***A61B 17/7082*** (2013.01); ***A61B 17/86*** (2013.01); ***A61B 17/8886*** (2013.01); *A61B 17/7035* (2013.01); *A61B 34/20* (2016.02); *A61B 90/39* (2016.02)

(58) **Field of Classification Search**

CPC A61B 17/7074–7082

See application file for complete search history.

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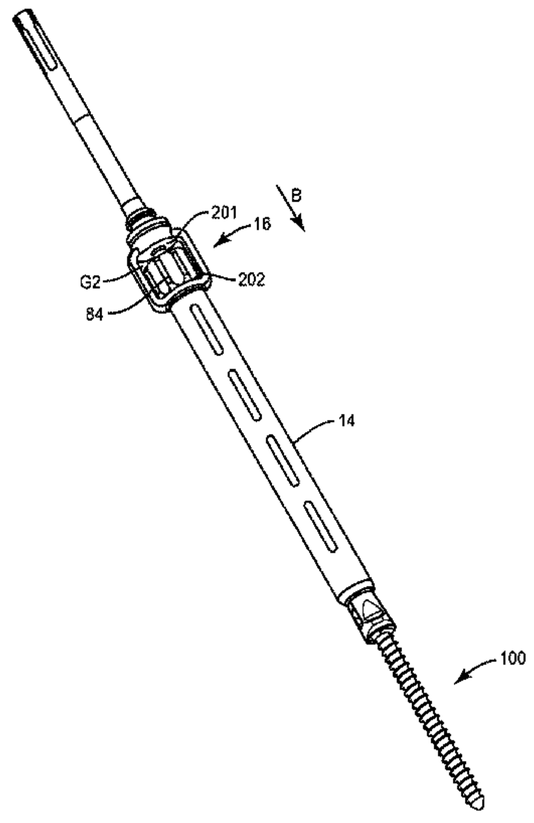
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Primary Examiner — Eduardo C Robert
Assistant Examiner — Michelle C Eckman

(57) **ABSTRACT**

A surgical instrument comprises an outer sleeve including an inner surface that defines a cavity. An inner shaft is fixed with the outer sleeve and extending within the cavity. The inner shaft includes a drive engageable with a first mating surface of a bone fastener. An inner sleeve is disposed between the inner shaft and the outer sleeve. The inner sleeve is rotatable relative to the outer sleeve and includes an element connectable with a second mating surface of the bone fastener. Systems, spinal implants and methods are disclosed.

19 Claims, 18 Drawing Sheets



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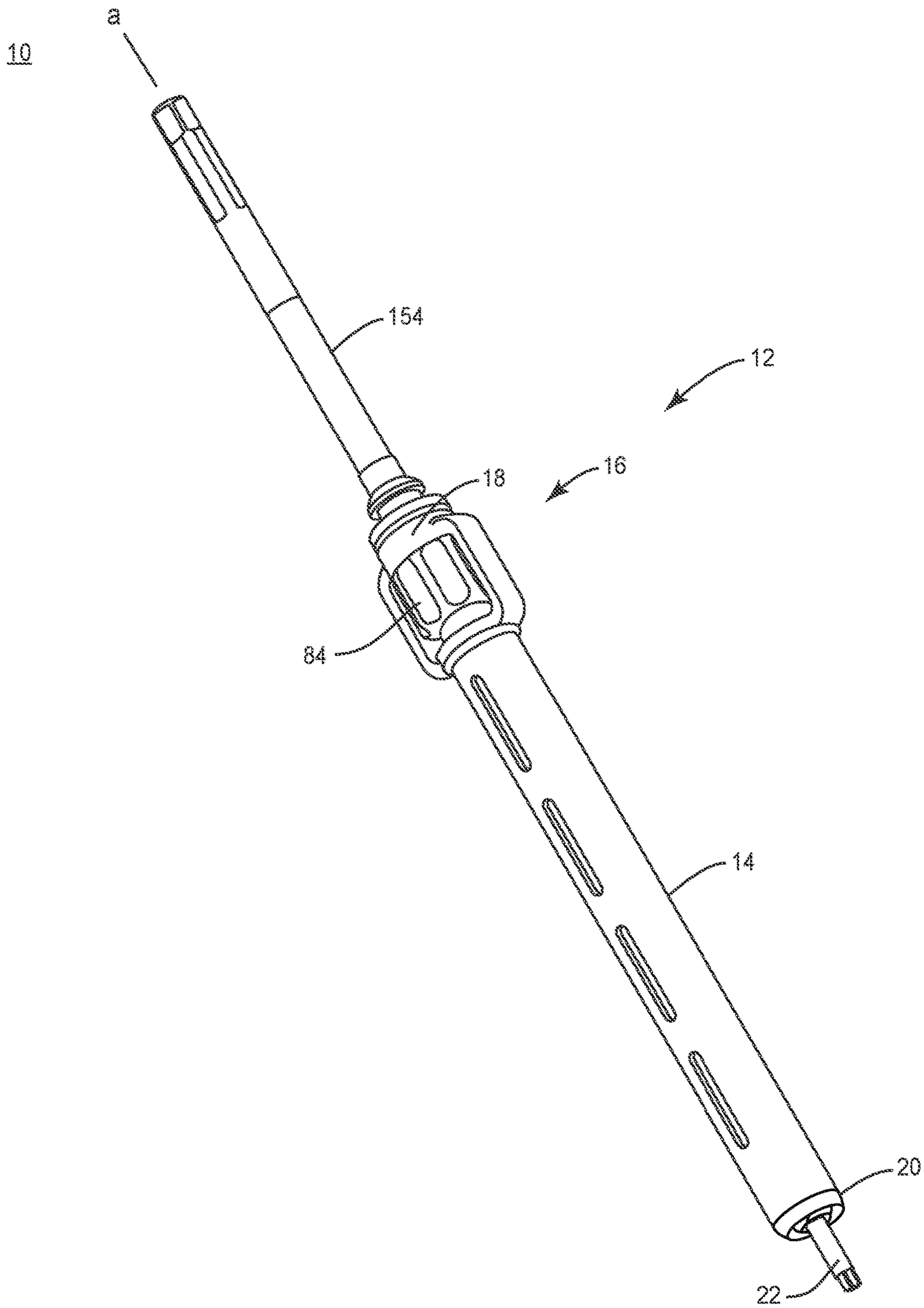


FIG. 1

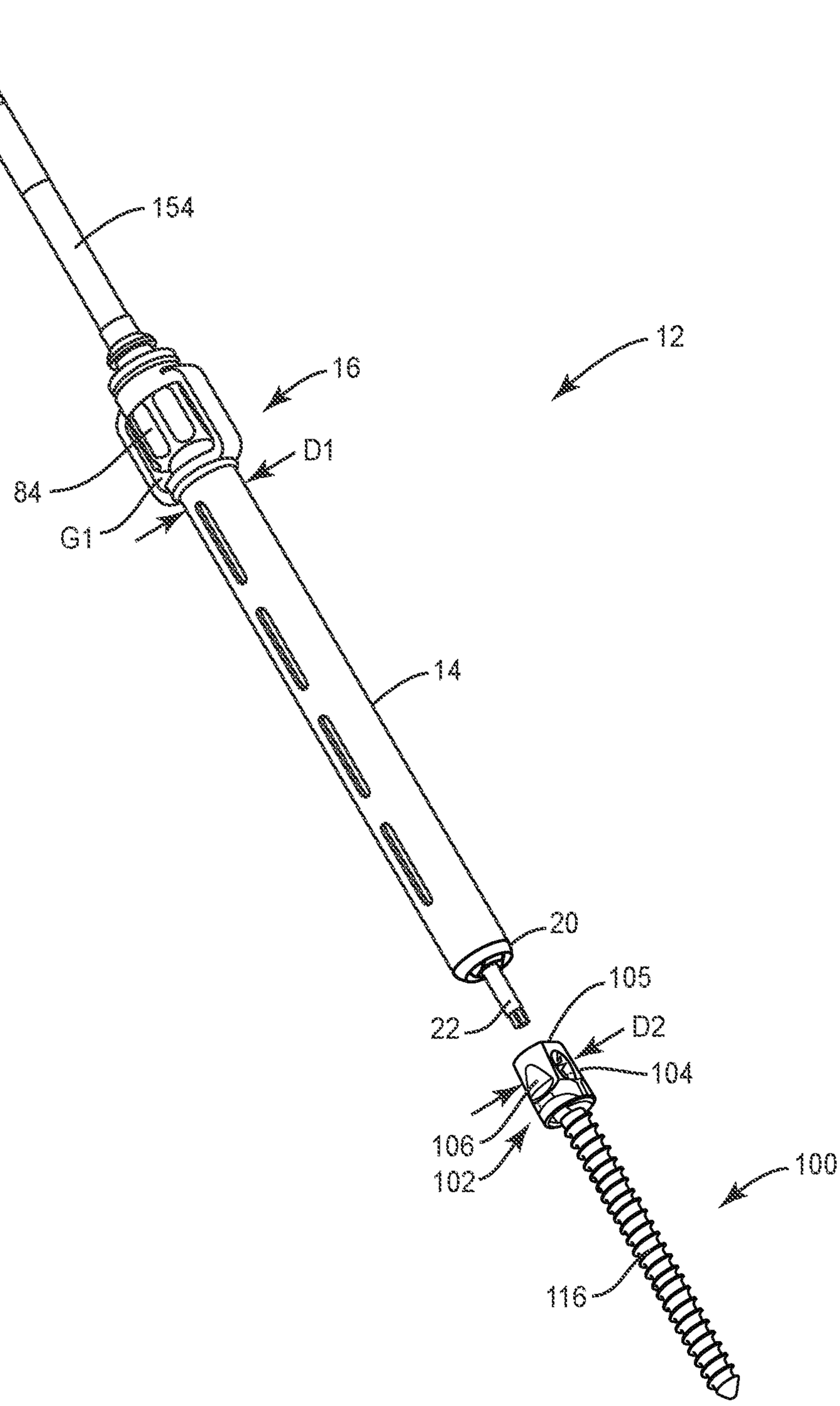


FIG. 2

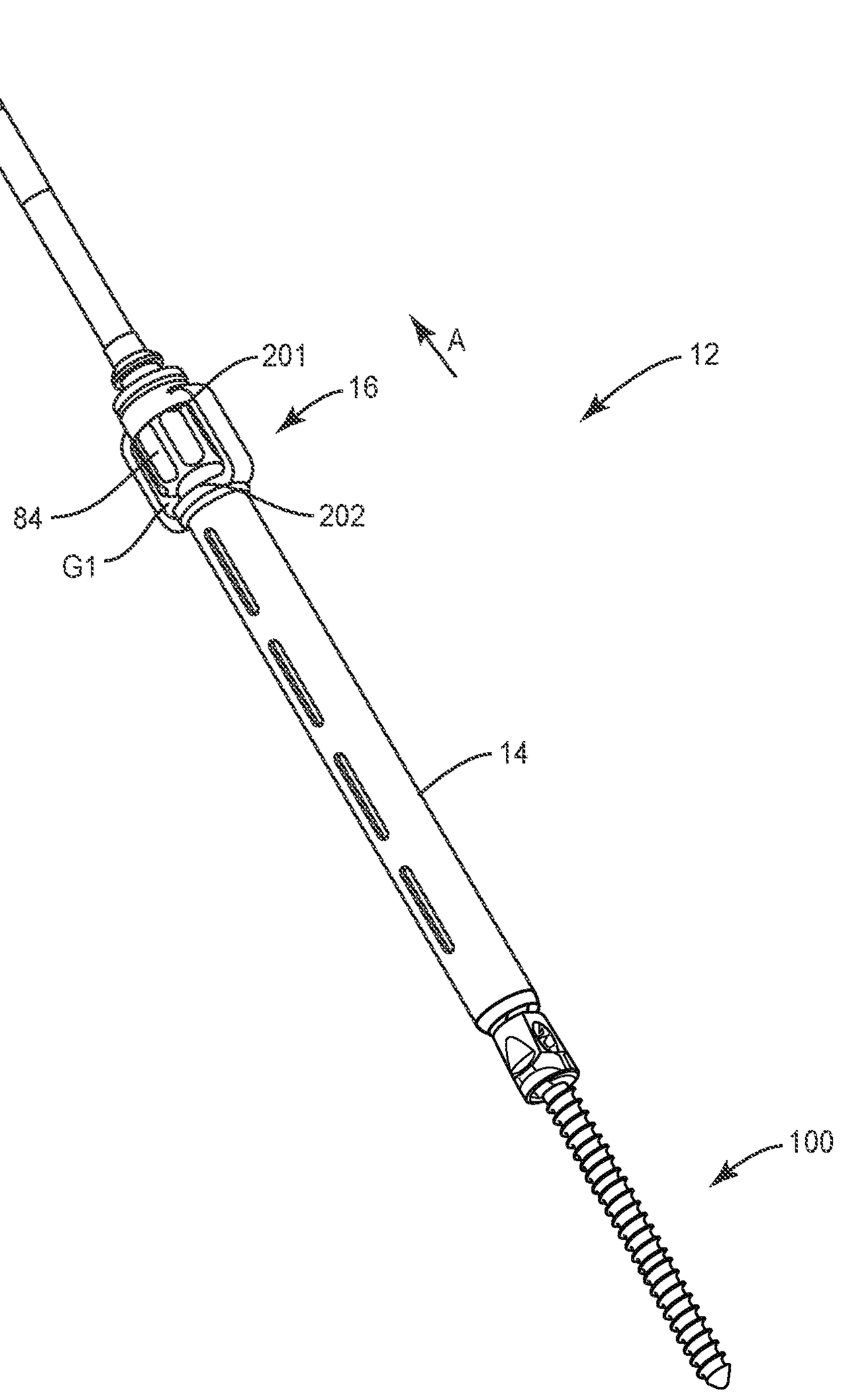


FIG. 3

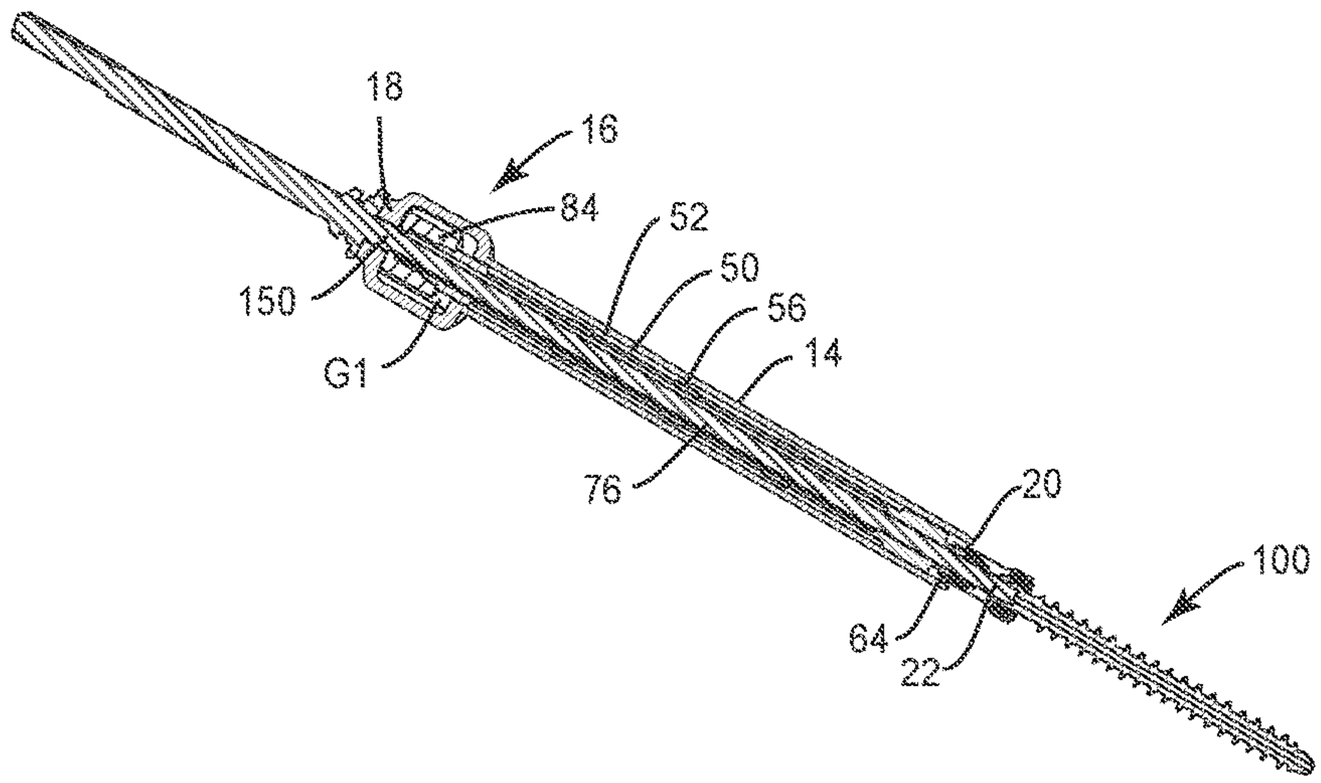

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FIG. 4

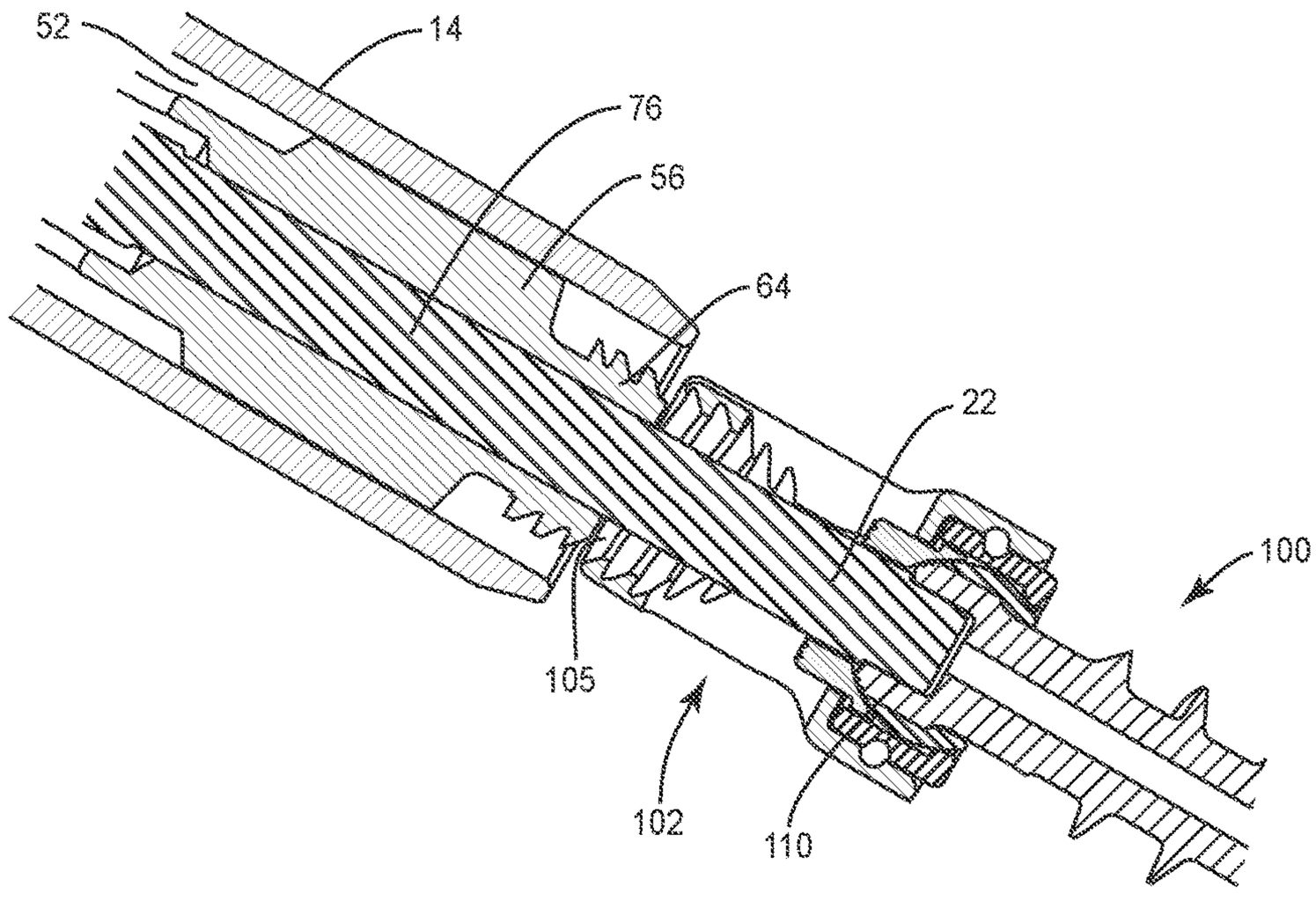

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FIG. 5

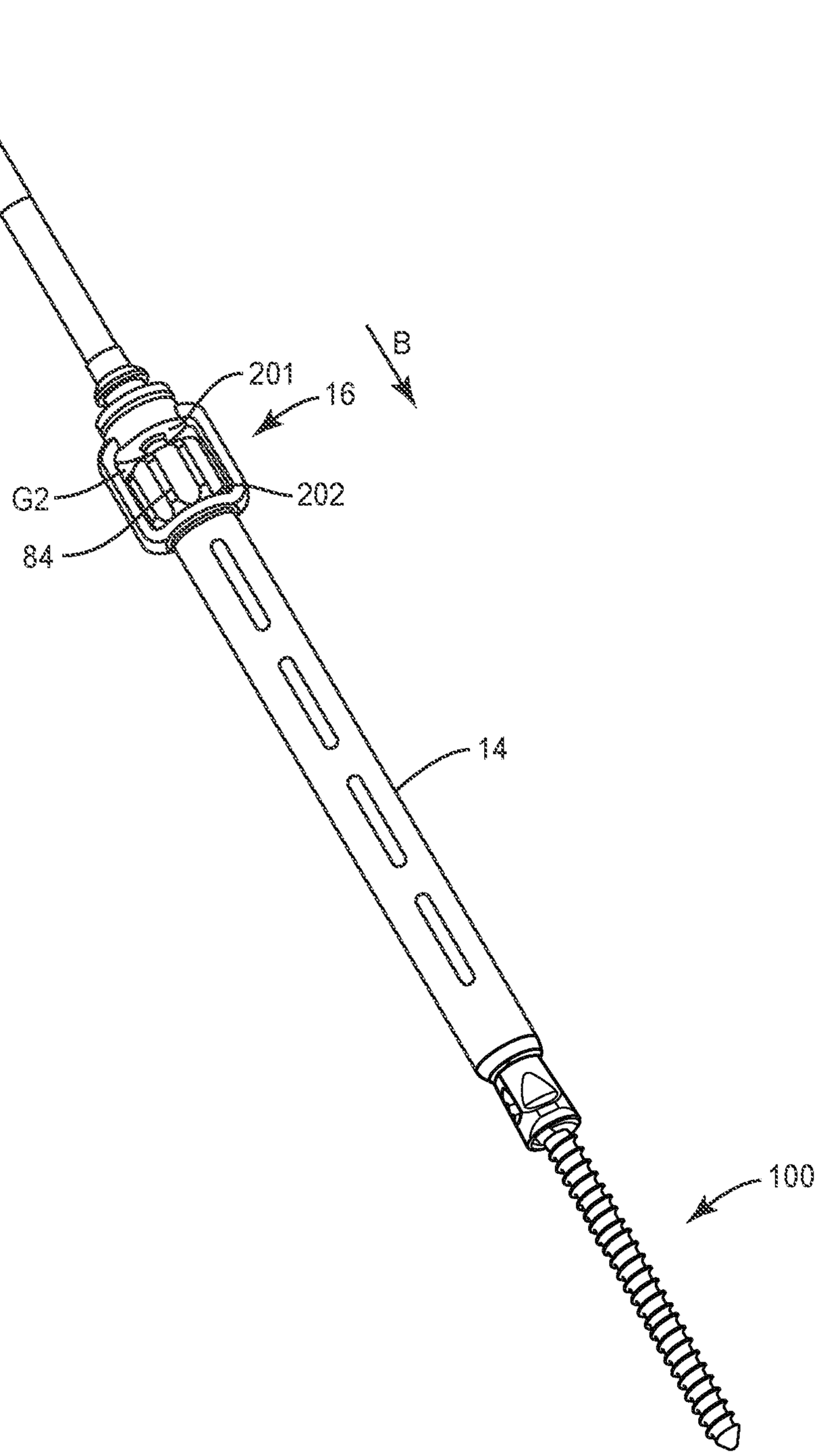


FIG. 6

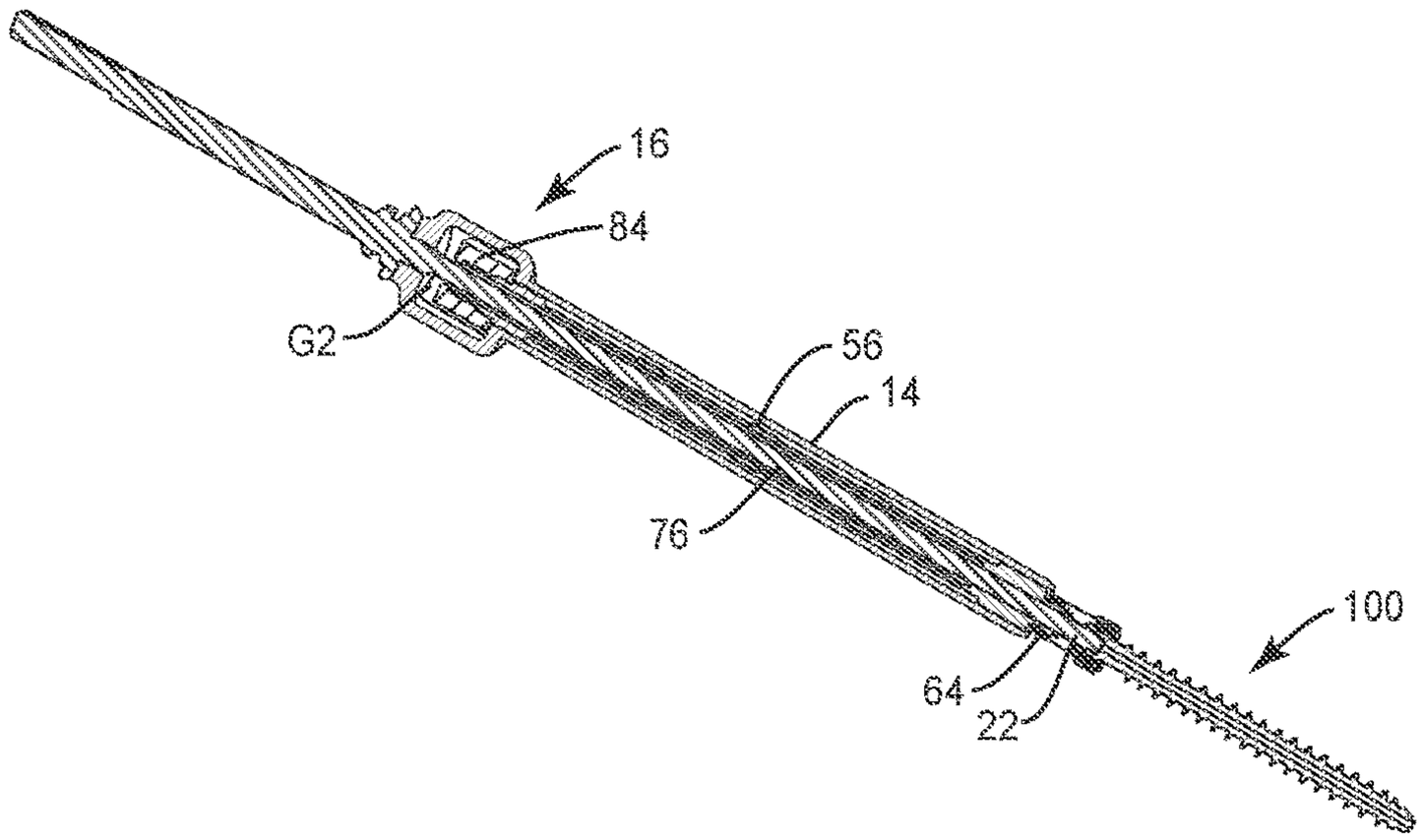


FIG. 7

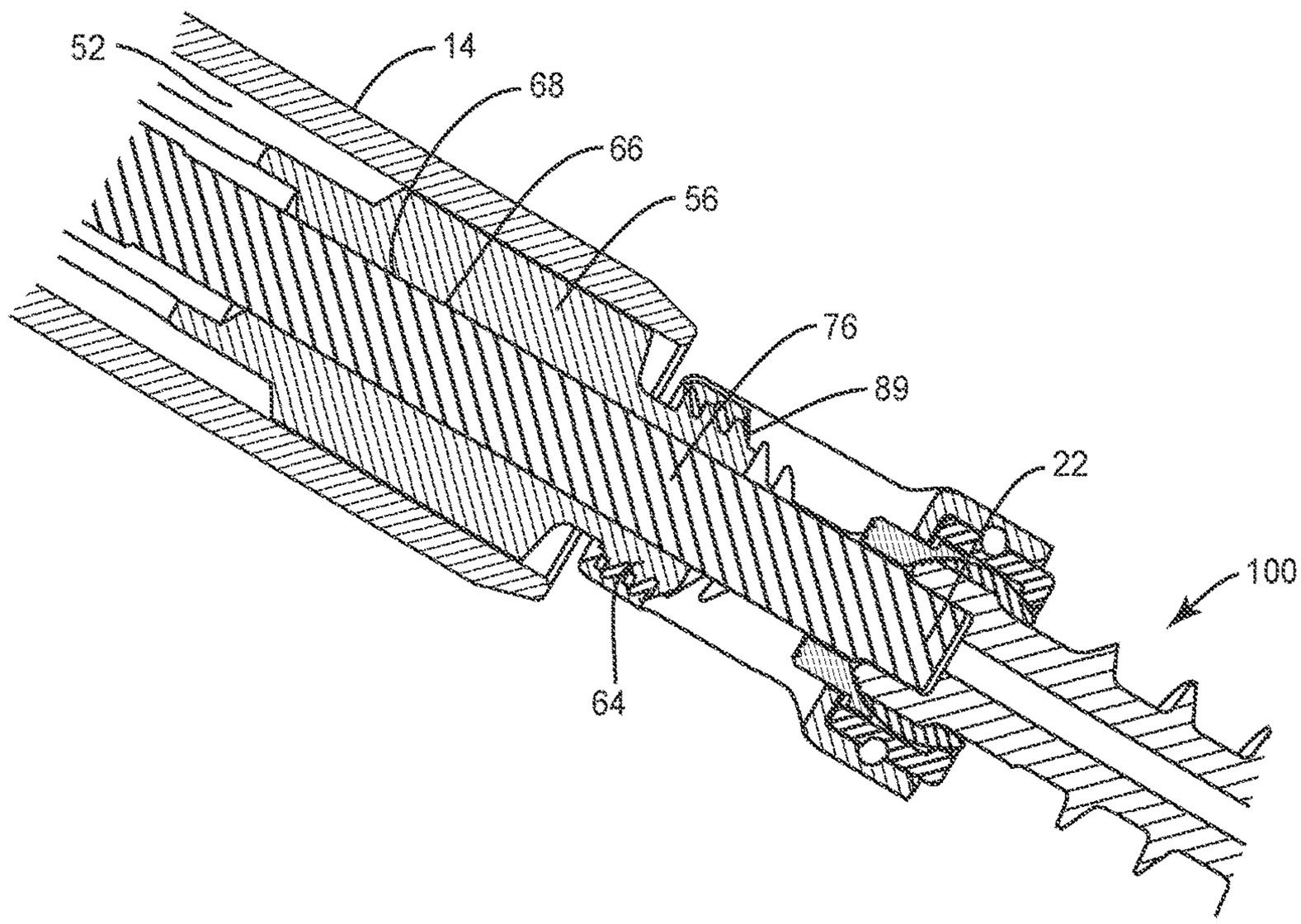


FIG. 8

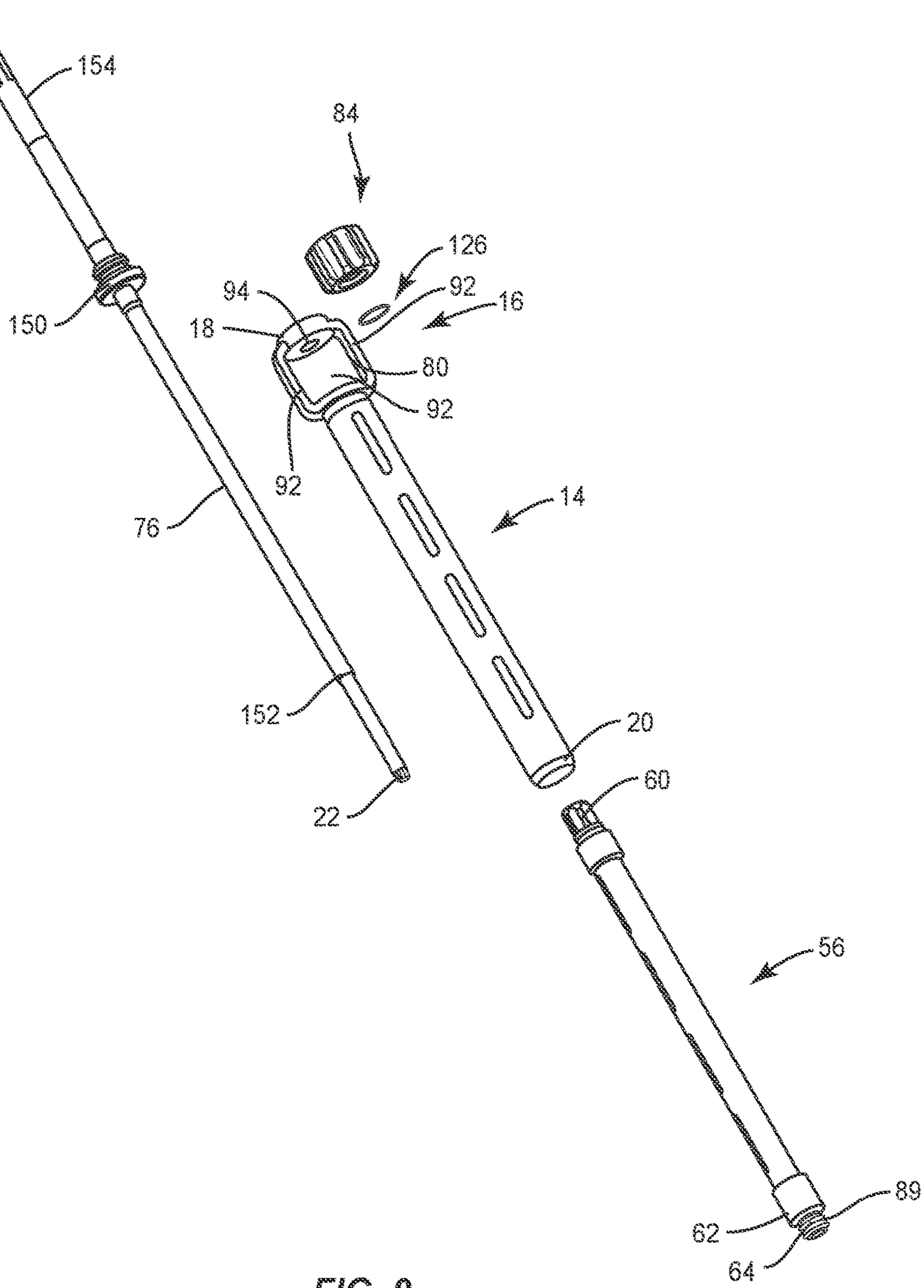


FIG. 9

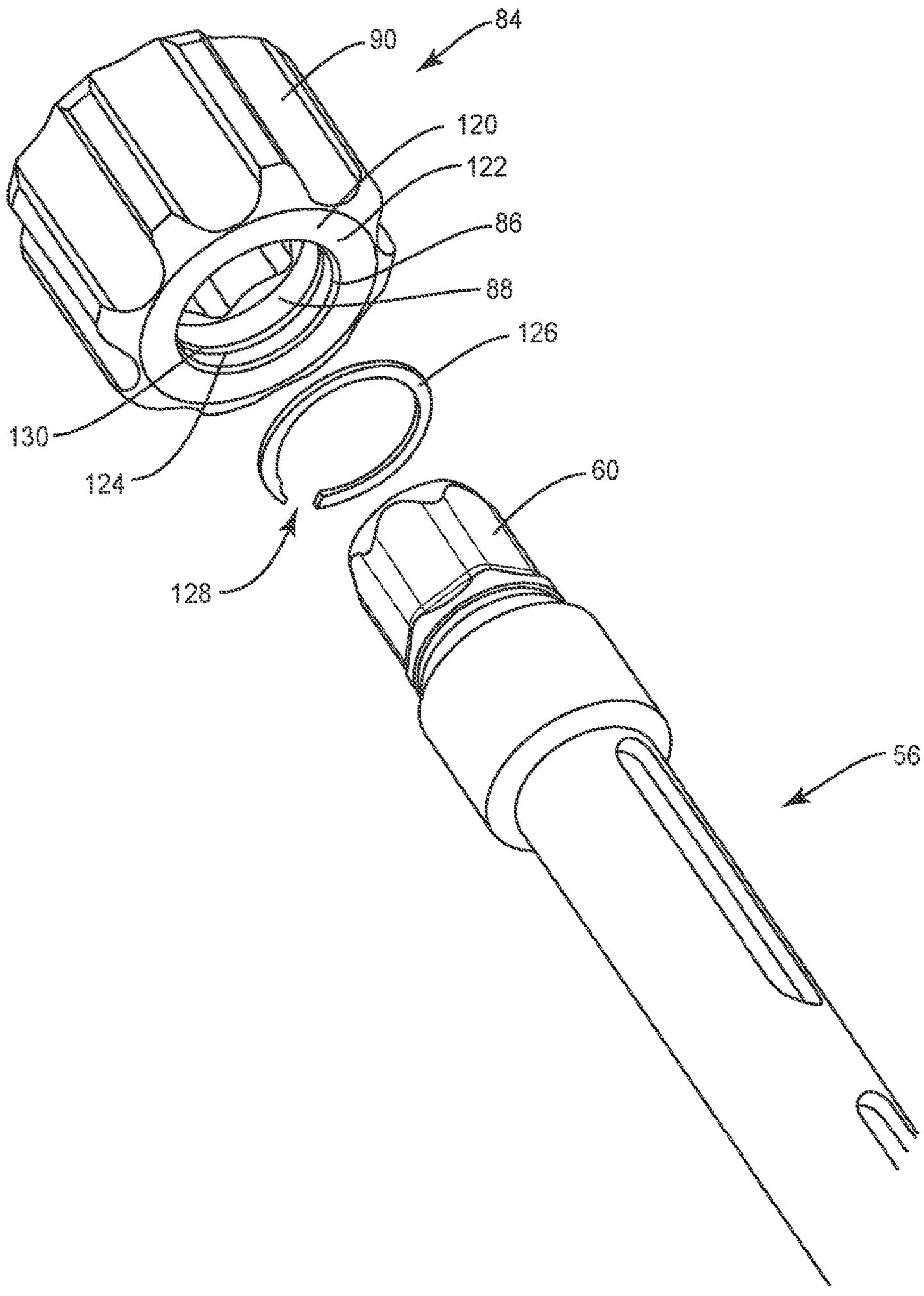


FIG. 10

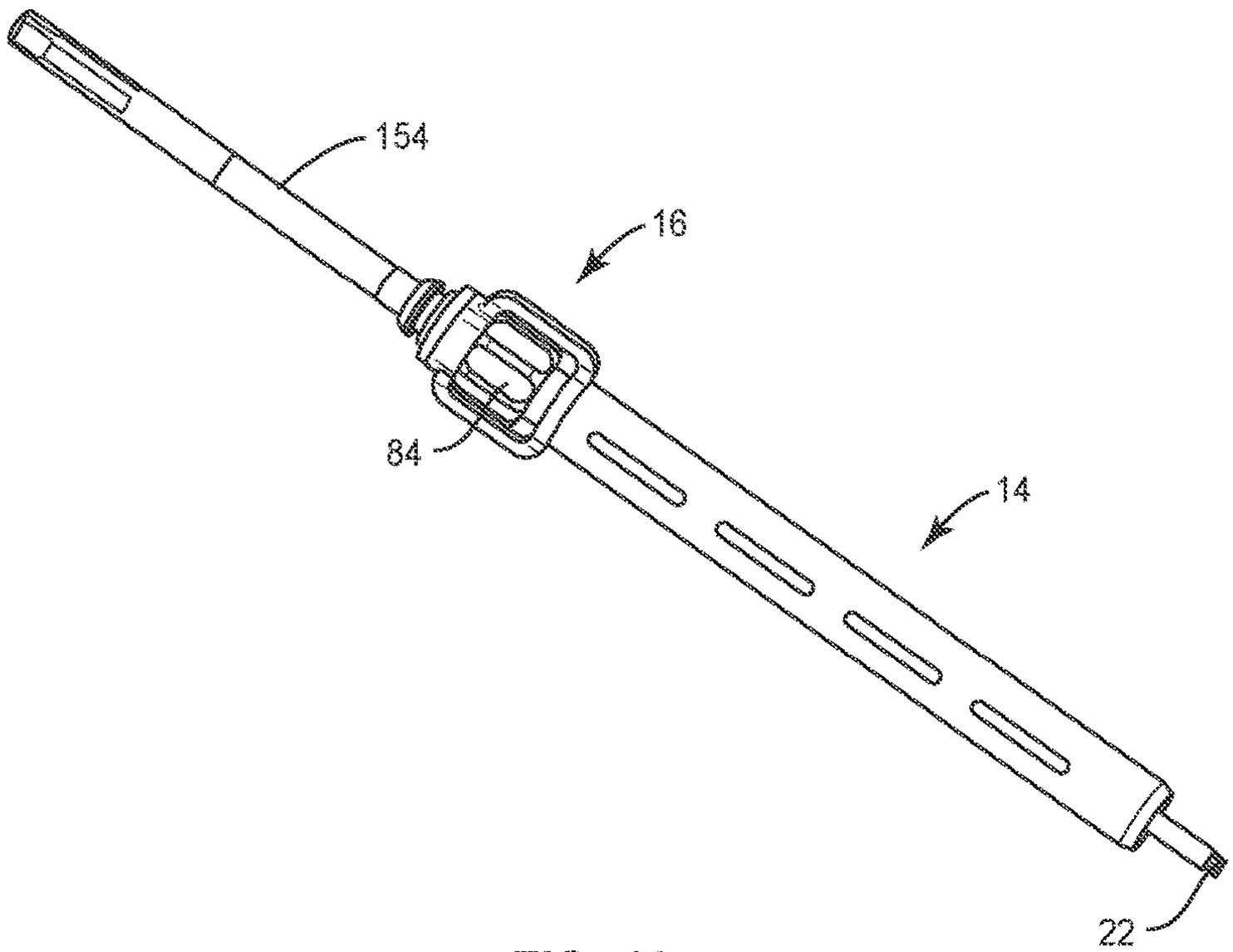


FIG. 11

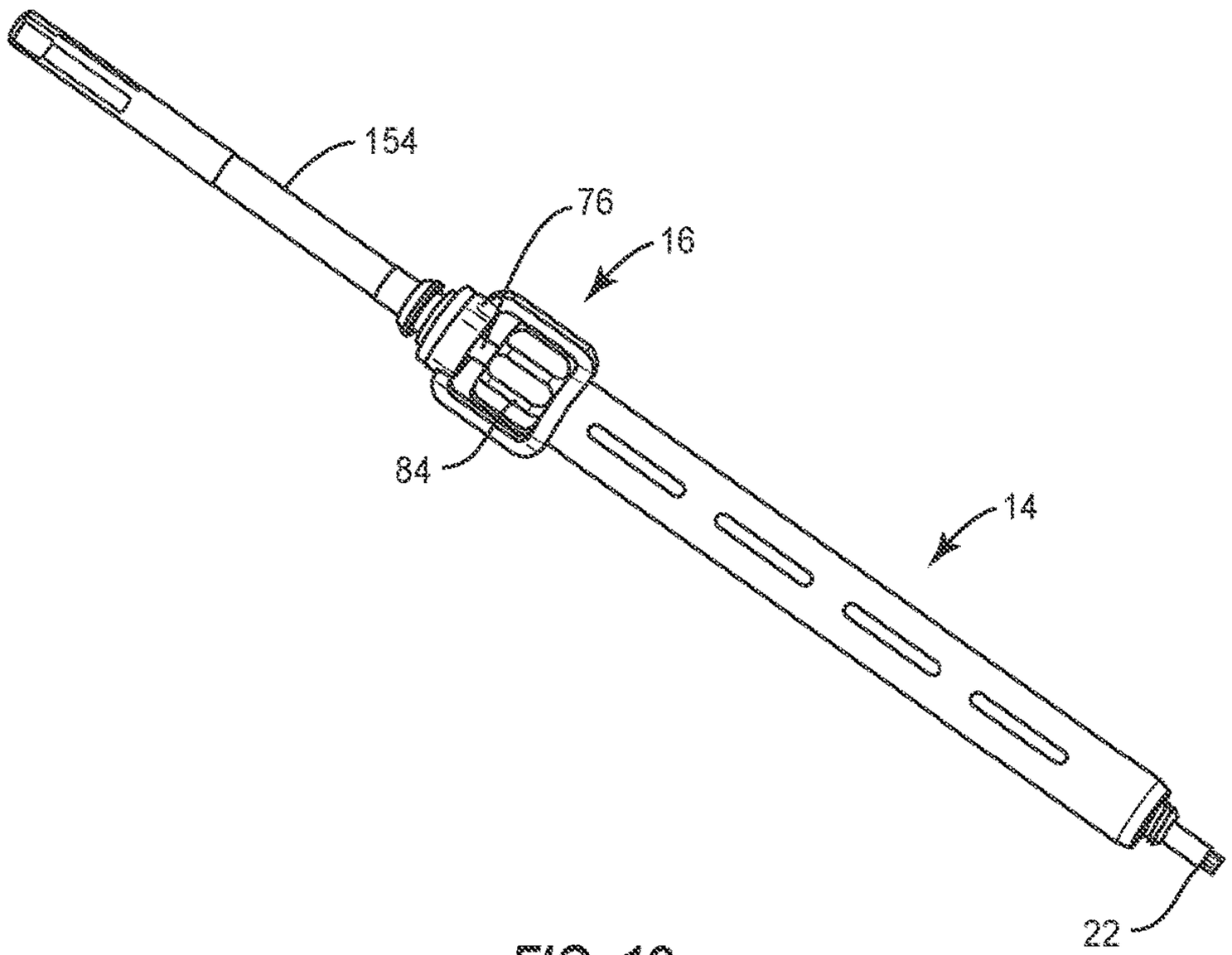


FIG. 12

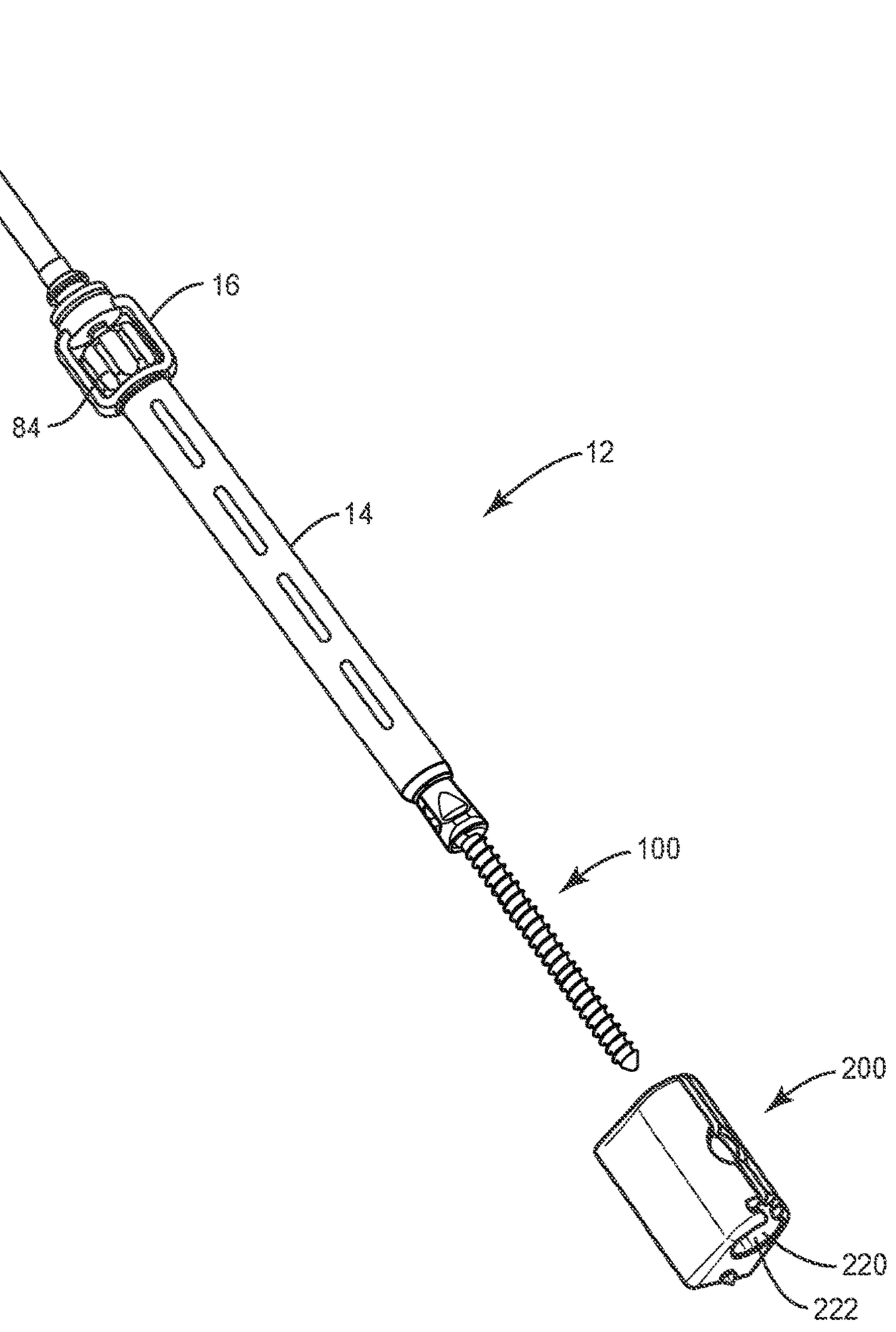


FIG. 13

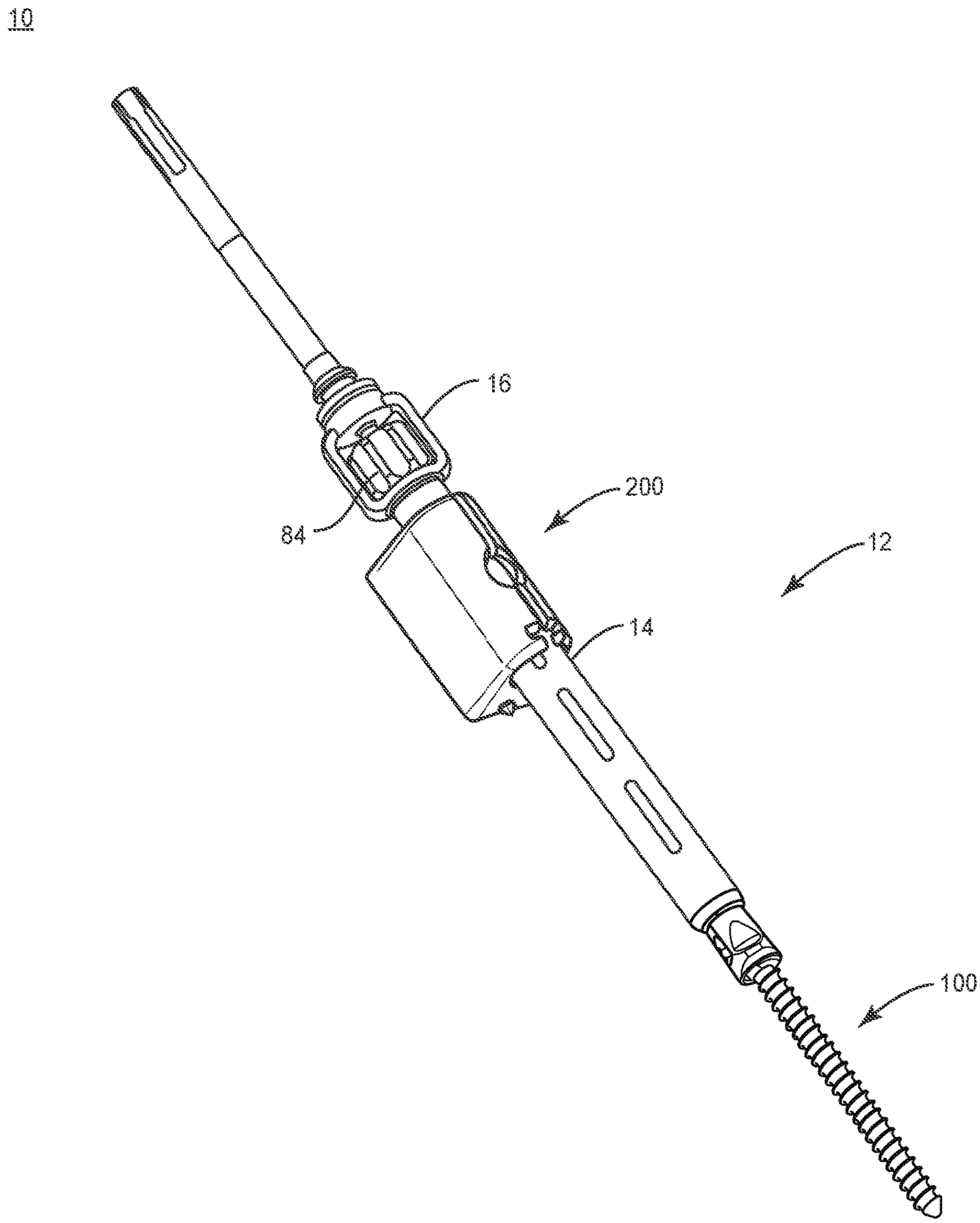


FIG. 14

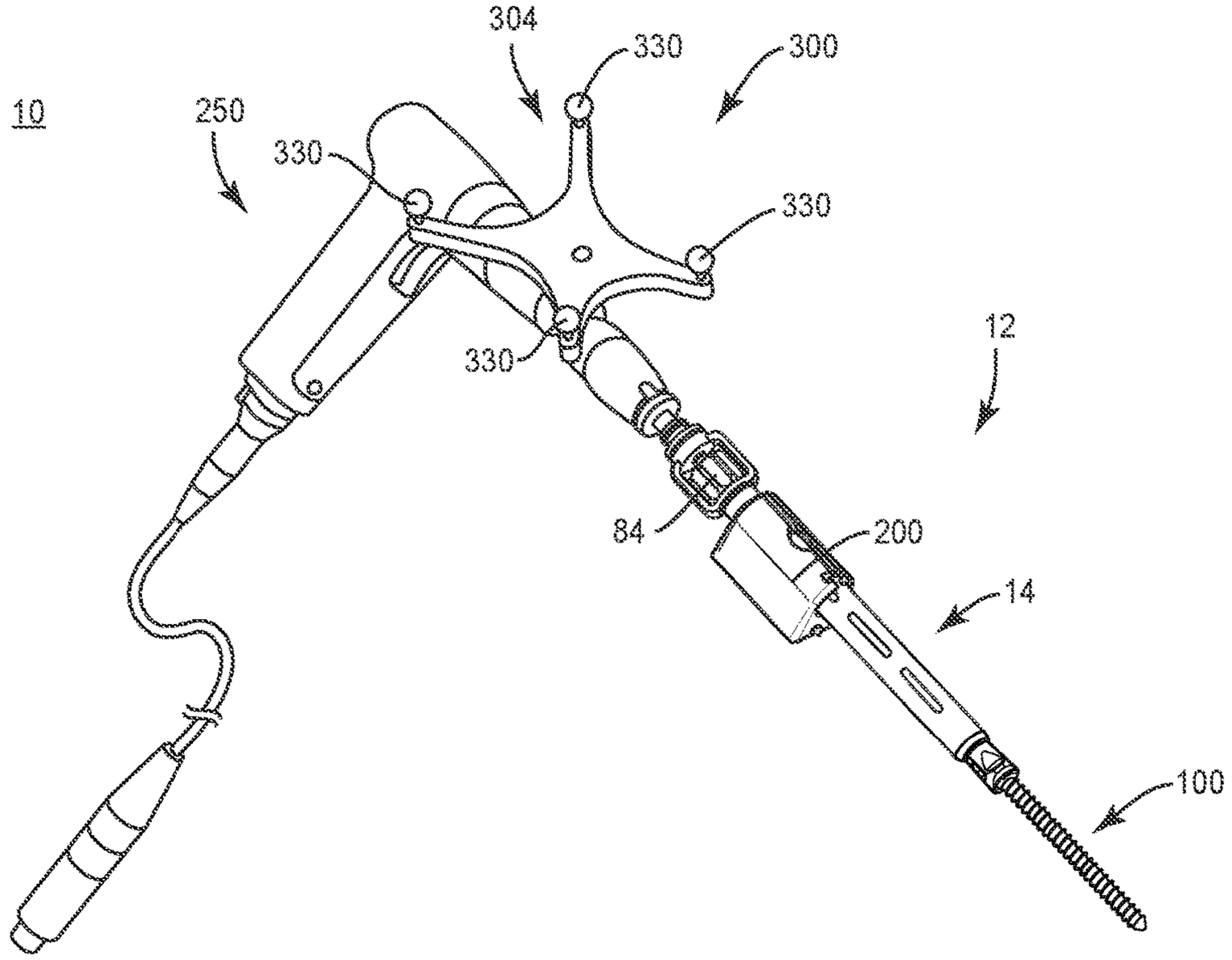


FIG. 15

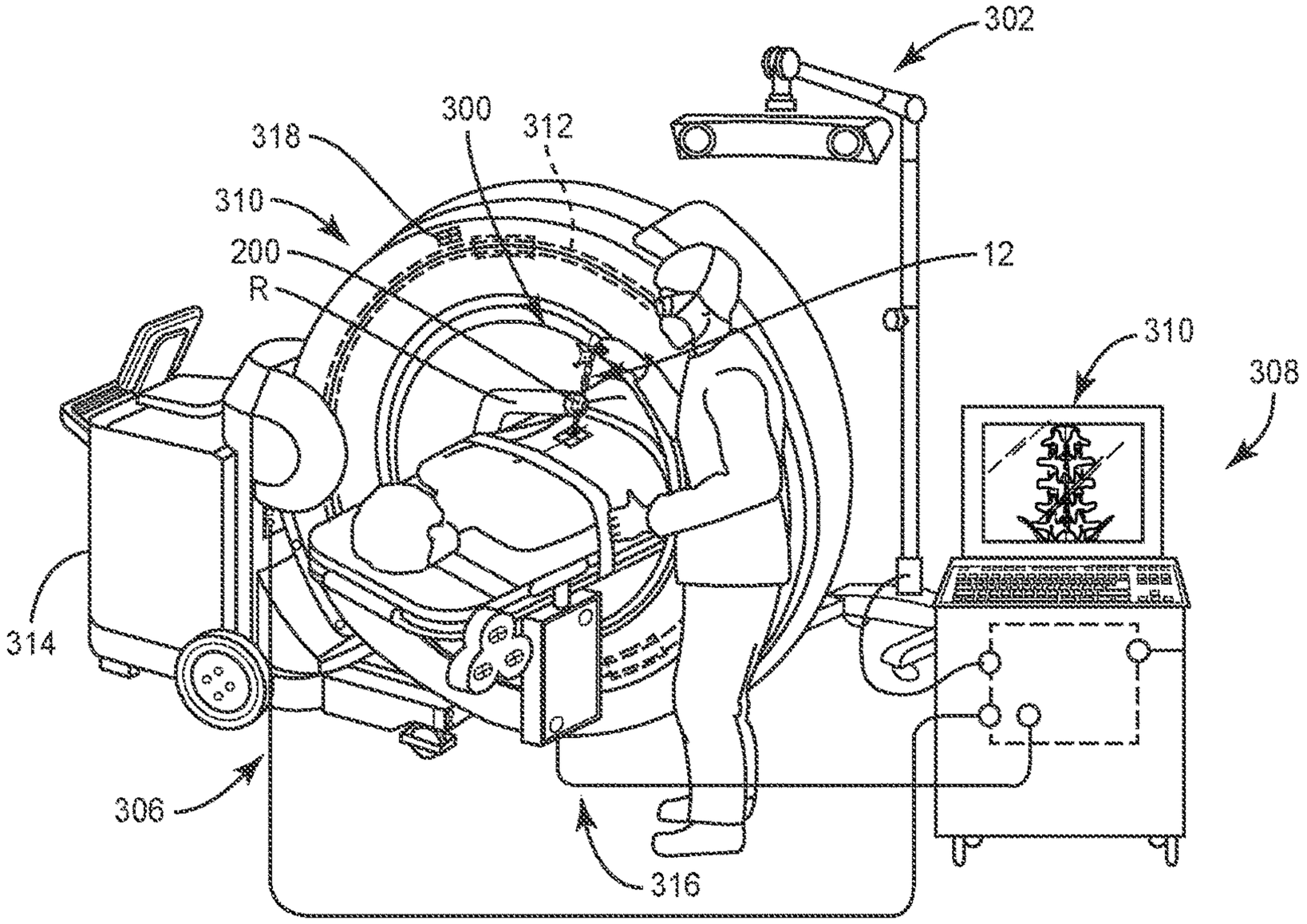


FIG. 16

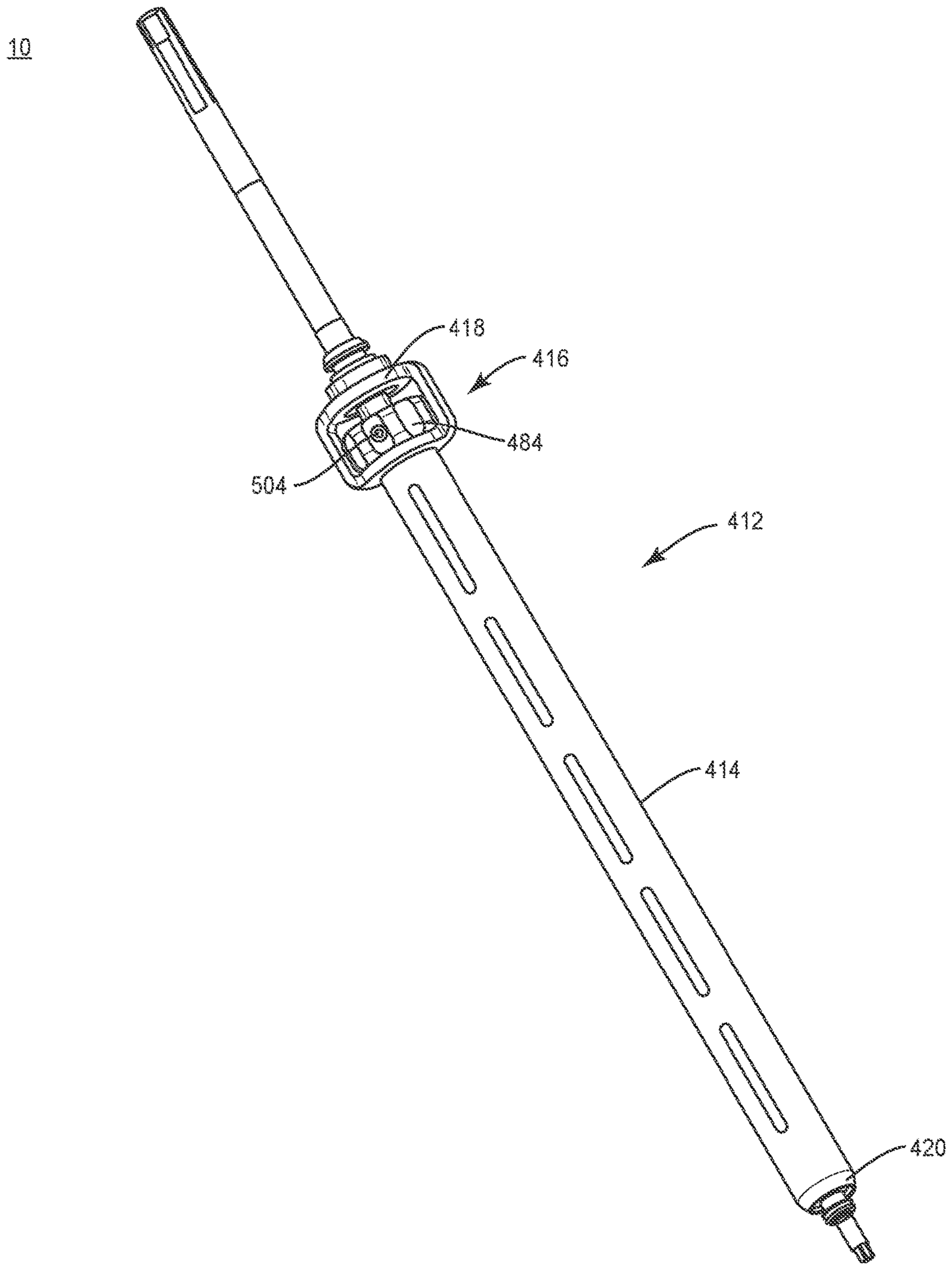


FIG. 17

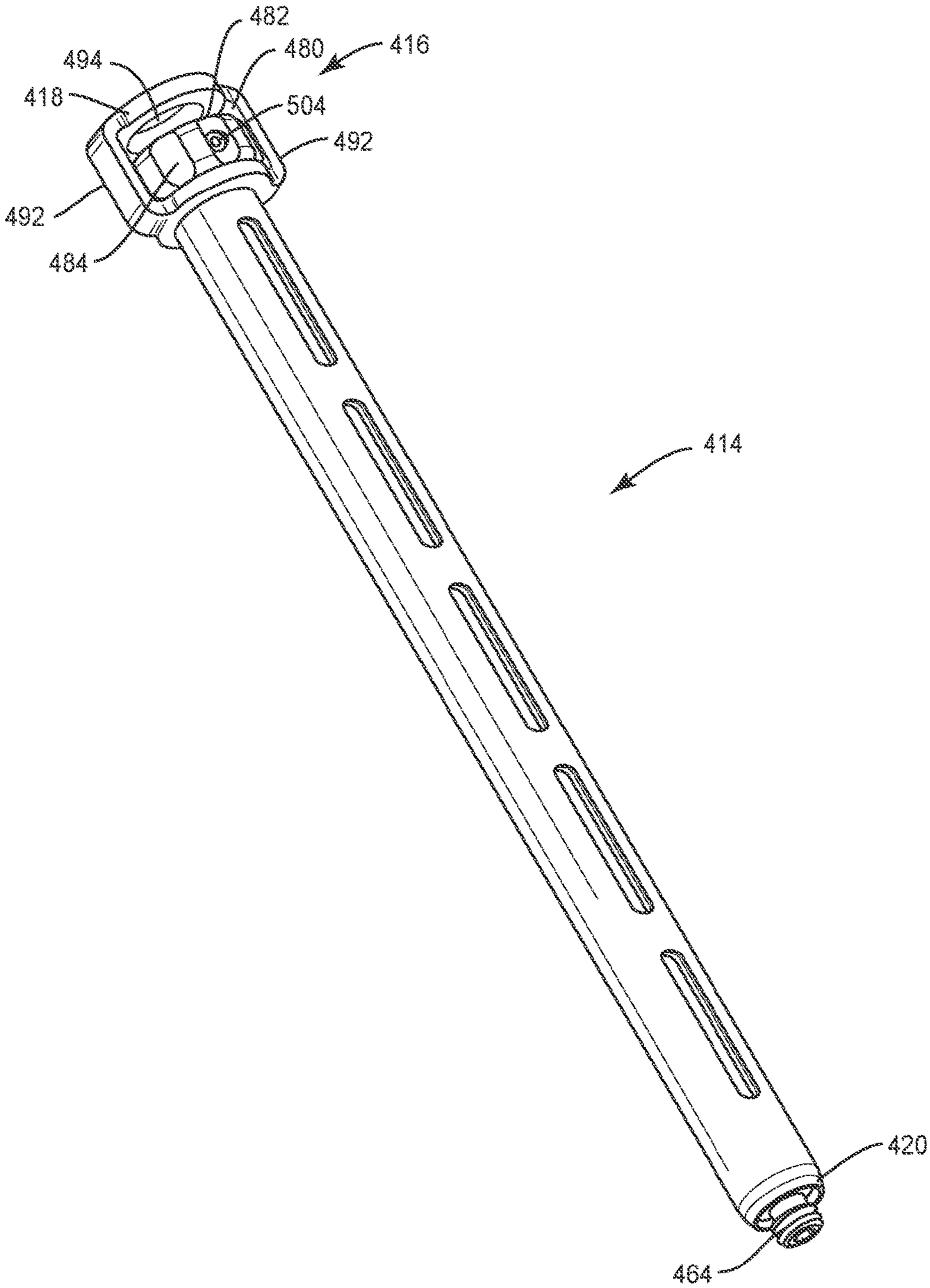


FIG. 18

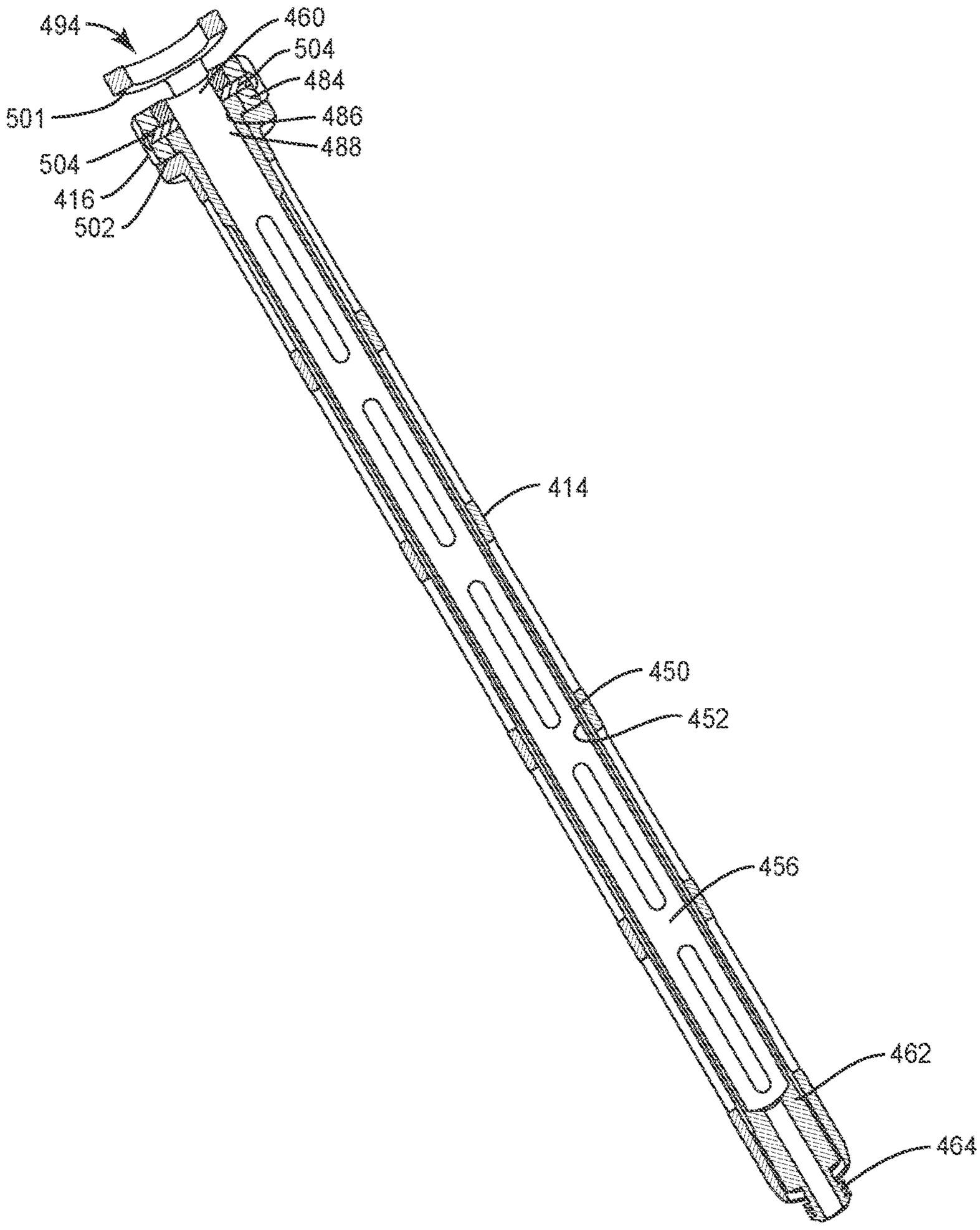


FIG. 19

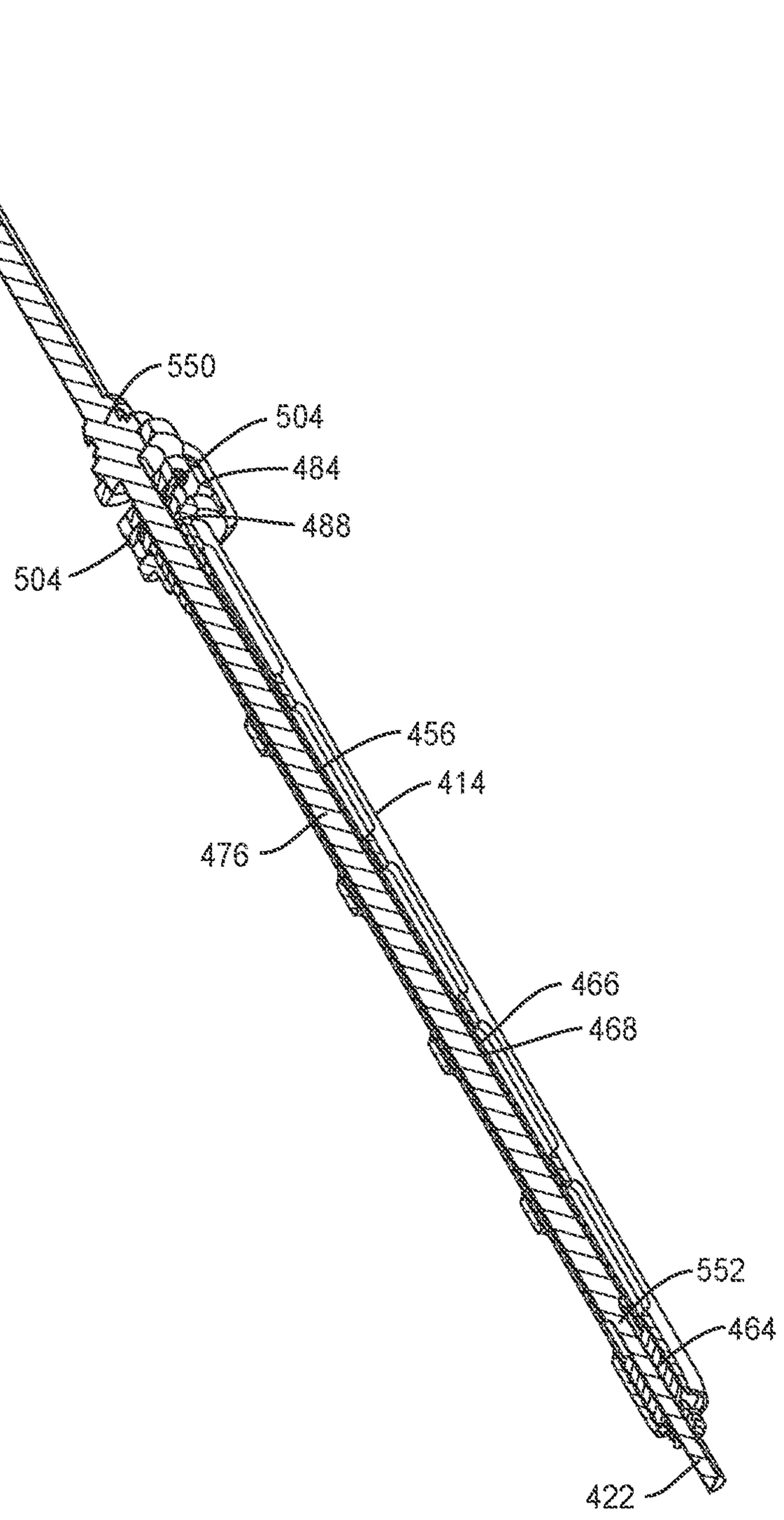


FIG. 20

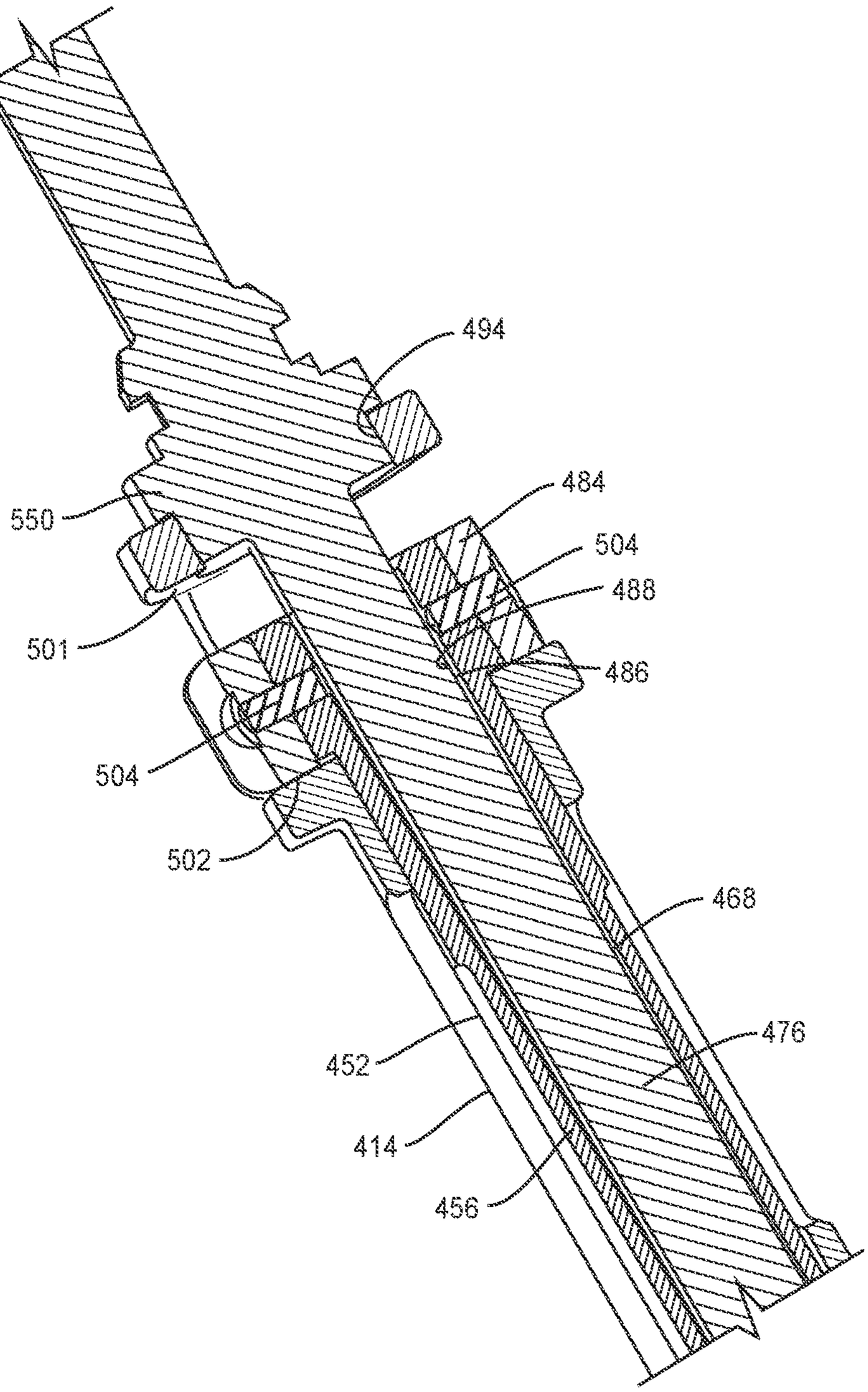


FIG. 21

SPINAL IMPLANT SYSTEM AND METHOD

TECHNICAL FIELD

The present disclosure generally relates to medical devices for the treatment of musculoskeletal disorders, and more particularly to a spinal implant system and a method for treating a spine.

BACKGROUND

Spinal pathologies and disorders such as scoliosis and other curvature abnormalities, kyphosis, degenerative disc disease, disc herniation, osteoporosis, spondylolisthesis, stenosis, tumor and fracture may result from factors including trauma, disease and degenerative conditions caused by injury and aging. Spinal disorders typically result in symptoms including deformity, pain, nerve damage, and partial or complete loss of mobility.

Non-surgical treatments, such as medication, rehabilitation and exercise can be effective, however, may fail to relieve the symptoms associated with these disorders. Surgical treatment of these spinal disorders includes correction, fusion, fixation, discectomy, laminectomy and implantable prosthetics. As part of these surgical treatments, spinal constructs such as vertebral rods are often used to provide stability to a treated region. Rods redirect stresses away from a damaged or defective region while healing takes place to restore proper alignment and generally support vertebral members. During surgical treatment, one or more rods and bone fasteners can be delivered to a surgical site. The rods may be attached via the fasteners to the exterior of two or more vertebral members. Surgical treatment may employ surgical instruments and implants that are manipulated for engagement with vertebrae to position and align one or more vertebrae. This disclosure describes an improvement over these prior technologies.

SUMMARY

In one embodiment, a surgical instrument is provided. The surgical instrument comprises an outer sleeve including an inner surface that defines a cavity. An inner shaft is fixed with the outer sleeve and extending within the cavity. The inner shaft includes a drive engageable with a first mating surface of a bone fastener. An inner sleeve is disposed between the inner shaft and the outer sleeve. The inner sleeve is rotatable relative to the outer sleeve and includes an element connectable with a second mating surface of the bone fastener. In some embodiments, systems, spinal implants and methods are disclosed.

In one embodiment, the surgical instrument includes an outer sleeve having an inner surface that defines an axial cavity. An inner shaft is fixed with the outer sleeve and extending within the cavity. The inner shaft includes a drive engageable with a drive socket of a bone fastener shaft. An inner sleeve is disposed between the inner shaft and the outer sleeve in a relative co-axial orientation. The inner sleeve is rotatable relative to the outer sleeve and includes an element connectable with an inner threaded surface of a bone fastener receiver. A rotatable actuator is connected with the inner sleeve and includes visual indicia of a non-locking configuration and a locking configuration with the inner threaded surface.

In one embodiment, a spinal implant system is provided. The spinal implant system comprises a surgical instrument including an outer sleeve and an inner shaft fixed with the outer sleeve and including a drive engageable with a bone fastener shaft, and an inner sleeve that is rotatable relative to the outer sleeve and including an element connectable with a threaded surface of a bone fastener receiver. A guide member includes an inner surface that defines a cavity configured for disposal of the outer sleeve and an image guide being oriented relative to a sensor to communicate a signal representative of a position of the guide member.

BRIEF DESCRIPTION OF THE DRAWINGS

The present disclosure will become more readily apparent from the specific description accompanied by the following drawings, in which:

FIG. **1** is a perspective view of components of one embodiment of a surgical system in accordance with the principles of the present disclosure;

FIG. **2** is a perspective view of components of one embodiment of a surgical system in accordance with the principles of the present disclosure;

FIG. **3** is a perspective view of the components of the surgical system shown in FIG. **2**;

FIG. **4** is a cross section view of the components shown in FIG. **3**;

FIG. **5** is a break away view of the components shown in FIG. **4**;

FIG. **6** is a perspective view of the components of the surgical system shown in FIG. **2**;

FIG. **7** is a cross section view of the components shown in FIG. **6**;

FIG. **8** is a break away view of the components shown in FIG. **7**;

FIG. **9** is a perspective view of components of one embodiment of a surgical system in accordance with the principles of the present disclosure with parts separated;

FIG. **10** is a break away perspective view of components of one embodiment of a surgical system in accordance with the principles of the present disclosure;

FIG. **11** is a perspective view of components of one embodiment of a surgical system in accordance with the principles of the present disclosure;

FIG. **12** is a perspective view of the components shown in FIG. **12**;

FIG. **13** is a perspective view of components of one embodiment of a surgical system in accordance with the principles of the present disclosure;

FIG. **14** is a perspective view of the components shown in FIG. **13**;

FIG. **15** is a perspective view of components one embodiment of a surgical system in accordance with the principles of the present disclosure;

FIG. **16** is a perspective view of components of one embodiment of a surgical system in accordance with the principles of the present disclosure;

FIG. **17** is a perspective view of components one embodiment of a surgical system in accordance with the principles of the present disclosure;

FIG. **18** is a perspective view of components of the system shown in FIG. **17**;

FIG. **19** is a cross section view of the components shown in FIG. **18**;

FIG. **20** is a cross section view of the components shown in FIG. **17**; and

FIG. **21** is a break away view of the components shown in FIG. **20**.

DETAILED DESCRIPTION

The exemplary embodiments of the surgical system and related methods of use disclosed are discussed in terms of

medical devices for the treatment of musculoskeletal disorders and more particularly, in terms of a spinal implant system and a method for treating a spine. In some embodiments, the systems and methods of the present disclosure comprise medical devices including surgical instruments and implants that are employed with a surgical treatment, as described herein, for example, with a cervical, thoracic, lumbar and/or sacral region of a spine.

In some embodiments, the present surgical system comprises a surgical instrument that comprises a screw driver with a disengagement feature. In some embodiments, the driver is configured for use with a spinal implant, such as, for example, a bone fastener. The bone fastener may include open tulip head receivers and/or closed tulip head receivers. In some embodiments, the driver includes an outer sleeve and inner shaft that are configured as drive and guidance components. In some embodiments, the driver includes an inner sleeve configured with a screw to retain the bone fastener with the driver. In some embodiments, the inner shaft, inner sleeve and outer sleeve are co-axial to facilitate axial translation of the inner sleeve.

In some embodiments, the driver includes a knob that serves as a visual indicator of whether or not the driver is fully disengaged from an implant. In some embodiments, the screw driver is employed with robotic guidance and provides indicia of the driver being fully unthreaded from an implant. In some embodiments, the screw driver provides visual indicia that the screw driver is unthreaded from the implant in a minimally invasive surgical procedure. For example, the screw driver provides visual indicia whether the screw driver is or is not engaged.

In some embodiments, the present surgical system includes a screw driver including an outer shaft or sleeve having an outside diameter that is slightly larger than a screw spin diameter of a bone screw. This configuration allows the bone screw and the screw driver to pass through the end effector. In some embodiments, the screw driver includes a thumb wheel that is connected to a retention screw that threads into the bone screw.

In some embodiments, the driver includes an inner shaft having a Torx tip configured for engagement with the bone fastener. In some embodiments, upon engagement of the Torx tip with the bone fastener, an actuator, such as, for example, a thumb wheel is actuated to cause an inner sleeve and screw to tighten and pull the bone fastener into engagement with the driver. In some embodiments, the inner sleeve translates axially relative to the outer sleeve and the inner shaft. The outer sleeve is fixed to the inner shaft, such as, for example by welding.

In some embodiments, the present surgical system includes a screw driver that is employed with a method of use, which includes the step of retracting the inner sleeve. In some embodiments, the method of use includes the step of connecting the bone fastener with the Torx tip. In some embodiments, the method of use includes the step of actuating the knob to rotate the inner sleeve and the screw into engagement with the bone fastener.

In some embodiments, a co-axial orientation of the inner shaft, inner sleeve and outer sleeve allows the inner sleeve to relatively translate. In some embodiments, translation of the inner sleeve prevents disengagement of the bone fastener from the driver when being used with a robotic end effector. In some embodiments, this configuration facilitates use with bone fasteners having a closed tulip head configuration.

In some embodiments, the present surgical system includes a screw driver that is employed with a method of use, which includes the step of translating the inner sleeve into engagement with the bone fastener. In some embodiments, the method of use includes translating the inner sleeve in an opposite direction to disengage from the bone fastener. In some embodiments, the thumb wheel is configured to provide a visual indicator of whether the inner sleeve is engaged or disengaged with the bone fastener. In some embodiments, the visual indicator facilitates removal of the driver in minimally invasive surgical procedures.

In some embodiments, the present surgical system includes a screw driver that is employed with a method of assembling components of the present system, which includes the step of disposing a snap ring with a groove disposed with an inner surface of the thumb wheel. In some embodiments, the method includes the step of inserting the thumb wheel with the outer sleeve. In some embodiments, the method includes the step of inserting the inner shaft through the outer sleeve and thumb wheel, which retains the thumb wheel loosely. In some embodiments, the method includes the step of fixing and/or welding the inner shaft with the outer sleeve. In some embodiments, the method includes the step of inserting the inner sleeve into the outer sleeve and snap fitting the inner sleeve with the thumb wheel via the snap ring to retain the inner sleeve with the thumb wheel. In some embodiments, the inner sleeve and the thumb wheel include mating hexagonal features to form a keyed connection. In some embodiments, the inner shaft is fixed with and/or welded on to the outer sleeve to retain all internal components. In some embodiments, cleaning slots are providing for proper flushing/cleaning.

In some embodiments, the present surgical system includes a screw driver that is employed with a method of assembling components of the present system, which includes the step of initially inserting the thumb wheel with the outer sleeve. In some embodiments, the method includes the step of inserting the inner sleeve into the outer sleeve. In some embodiments, an opening disposed with the outer sleeve is sized to receive the inner sleeve to facilitate translation of the inner sleeve relative to the outer sleeve. In some embodiments, the method includes the step of engaging pins with the thumb wheel and the inner sleeve. In some embodiments, the method includes the step of laser welding the pins with the thumb wheel and the inner sleeve to relatively fix the thumb wheel and the inner sleeve. In some embodiments, the method includes the step of inserting the inner shaft through the outer sleeve and thumb wheel. In some embodiments, the method includes the step of fixing and/or welding the inner shaft with the outer sleeve.

In some embodiments, the present surgical system comprises a surgical instrument that comprises a screw driver that can be employed with bone fasteners and one or more implant supports for treating a spine. In some embodiments, the present surgical system includes a surgical instrument that can easily connect and disconnect from a bone fastener. In some embodiments, the present surgical system includes a surgical instrument that can be employed with an end effector of a robotic arm to facilitate implant with the robotic arm. In some embodiments, the surgical instrument is guided through the end effector for a guide-wireless screw insertion. In some embodiments, the surgical instrument comprises a robot screw driver employed with robotic and/or navigation guidance, which may include an image guide.

In some embodiments, the present surgical system includes a screw driver having an outer shaft and a drive tip that engages a bone fastener. In some embodiments, the outer shaft and the drive tip are of one piece construction. In some embodiments, the one piece construction allows tol-

erances to be controlled tightly for improved accuracy of trajectory during implant insertion. In some embodiments, the drive tip includes a Torx configuration. In some embodiments, the present surgical system includes a screw driver having an internal retention mechanism. In some embodiments, the retention mechanism is fixed with a receiver of a bone fastener to resist and/or prevent disengagement of the retention mechanism from the receiver, for example, due to connection or friction with the end effector or tissue.

In some embodiments, the present surgical system includes a screw driver for use with robotic surgery. In some embodiments, the screw driver can be employed with fixed-axis screws (FAS), uni-axial screws (UAS), sagittal adjusting screws (SAS), transverse sagittal adjusting screws (TSAS) and multi-axial screws (MAS) screws, and allows the screws to be driven through a robotic end effector. In some embodiments, the screw driver includes a one piece outer sleeve having a tip. In some embodiments, the screw driver includes an internal retaining device that prevents accidental disengagement and/or unthreading.

In some embodiments, the present surgical system includes a screw driver including an outer shaft or sleeve having an outside diameter that is slightly larger than a screw spin diameter of a bone screw. This configuration allows the bone screw and the screw driver to pass through the end effector. In some embodiments, the screw driver includes a thumb wheel that is connected to a retention screw that threads into the bone screw. In some embodiments, the present surgical system includes tab extenders connected to the screw driver and prevented from extending outside the outside diameter of the screw driver by engaging undercuts of the screw driver. This configuration prevents an interference or hang-up if the bone screw needs to be removed through the end effector.

In some embodiments, the present surgical system includes a screw driver that includes a quick connect shaft, an inner shaft, a thumb wheel, an outer driver shaft and a retention screw. In some embodiments, the retention screw is axially translatable between a first position, for example, a non-locking position prior to tightening, and a second position, for example, a locking position after tightening. In some embodiments, this configuration allows the drive tip to engage the bone screw prior to rotating the thumb wheel for tightening the screw driver to the bone screw.

In some embodiments, the surgical system of the present disclosure may be employed to treat spinal disorders such as, for example, degenerative disc disease, disc herniation, osteoporosis, spondylolisthesis, stenosis, scoliosis and other curvature abnormalities, kyphosis, tumor and fractures. In some embodiments, the surgical system of the present disclosure may be employed with other osteal and bone related applications, including those associated with diagnostics and therapeutics. In some embodiments, the disclosed surgical system may be alternatively employed in a surgical treatment with a patient in a prone or supine position, and/or employ various surgical approaches to the spine, including anterior, posterior, posterior mid-line, direct lateral, postero-lateral, and/or antero-lateral approaches, and in other body regions. The surgical system of the present disclosure may also be alternatively employed with procedures for treating the lumbar, cervical, thoracic, sacral and pelvic regions of a spinal column. The surgical system of the present disclosure may also be used on animals, bone models and other non-living substrates, such as, for example, in training, testing and demonstration.

The surgical system of the present disclosure may be understood more readily by reference to the following detailed description of the embodiments taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this application is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting. In some embodiments, as used in the specification and including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment. It is also understood that all spatial references, such as, for example, horizontal, vertical, top, upper, lower, bottom, left and right, are for illustrative purposes only and can be varied within the scope of the disclosure. For example, the references "upper" and "lower" are relative and used only in the context to the other, and are not necessarily "superior" and "inferior".

As used in the specification and including the appended claims, "treating" or "treatment" of a disease or condition refers to performing a procedure that may include administering one or more drugs to a patient (human, normal or otherwise or other mammal), employing implantable devices, and/or employing instruments that treat the disease, such as, for example, microdiscectomy instruments used to remove portions bulging or herniated discs and/or bone spurs, in an effort to alleviate signs or symptoms of the disease or condition. Alleviation can occur prior to signs or symptoms of the disease or condition appearing, as well as after their appearance. Thus, treating or treatment includes preventing or prevention of disease or undesirable condition (e.g., preventing the disease from occurring in a patient, who may be predisposed to the disease but has not yet been diagnosed as having it). In addition, treating or treatment does not require complete alleviation of signs or symptoms, does not require a cure, and specifically includes procedures that have only a marginal effect on the patient. Treatment can include inhibiting the disease, e.g., arresting its development, or relieving the disease, e.g., causing regression of the disease. For example, treatment can include reducing acute or chronic inflammation; alleviating pain and mitigating and inducing re-growth of new ligament, bone and other tissues; as an adjunct in surgery; and/or any repair procedure. In some embodiments, as used in the specification and including the appended claims, the term "tissue" includes soft tissue, ligaments, tendons, cartilage and/or bone unless specifically referred to otherwise.

The following discussion includes a description of a surgical system including a surgical instrument, related components and methods of employing the surgical system in accordance with the principles of the present disclosure. Alternate embodiments are also disclosed. Reference is made in detail to the exemplary embodiments of the present disclosure, which are illustrated in the accompanying figures. Turning to FIGS. **1-16**, there are illustrated components of a surgical system, such as, for example, a spinal implant system **10**.

The components of spinal implant system **10** can be fabricated from biologically acceptable materials suitable for medical applications, including metals, synthetic polymers, ceramics and bone material and/or their composites. For example, the components of spinal implant system **10**, individually or collectively, can be fabricated from materials such as stainless steel alloys, aluminum, commercially pure titanium, titanium alloys, Grade 5 titanium, super-elastic titanium alloys, cobalt-chrome alloys, superelastic metallic alloys (e.g., Nitinol, super elasto-plastic metals, such as GUM METAL®), ceramics and composites thereof such as calcium phosphate (e.g., SKELITE™), thermoplastics such as polyaryletherketone (PAEK) including polyetheretherketone (PEEK), polyetherketoneketone (PEKK) and polyetherketone (PEK), carbon-PEEK composites, PEEK-$BaSO_4$ polymeric rubbers, polyethylene terephthalate (PET), fabric, silicone, polyurethane, silicone-polyurethane copolymers, polymeric rubbers, polyolefin rubbers, hydrogels, semi-rigid and rigid materials, elastomers, rubbers, thermoplastic elastomers, thermoset elastomers, elastomeric composites, rigid polymers including polyphenylene, polyimide, polyimide, polyetherimide, polyethylene, epoxy, bone material including autograft, allograft, xenograft or transgenic cortical and/or corticocancellous bone, and tissue growth or differentiation factors, partially resorbable materials, such as, for example, composites of metals and calcium-based ceramics, composites of PEEK and calcium based ceramics, composites of PEEK with resorbable polymers, totally resorbable materials, such as, for example, calcium based ceramics such as calcium phosphate, tricalcium phosphate (TCP), hydroxyapatite (HA)-TCP, calcium sulfate, or other resorbable polymers such as polyaetide, polyglycolide, polytyrosine carbonate, polycaroplaetohe and their combinations.

Various components of spinal implant system **10** may have material composites, including the above materials, to achieve various desired characteristics such as strength, rigidity, elasticity, compliance, biomechanical performance, durability and radiolucency or imaging preference. The components of spinal implant system **10**, individually or collectively, may also be fabricated from a heterogeneous material such as a combination of two or more of the above-described materials. The components of spinal implant system **10** may be monolithically formed, integrally connected or include fastening elements and/or instruments, as described herein.

Spinal implant system **10** is employed, for example, with a fully open surgical procedure, a minimally invasive procedure including percutaneous techniques, and mini-open surgical techniques to deliver and introduce instrumentation and/or a spinal implant, such as, for example, a bone fastener, at a surgical site of a patient, which includes, for example, a spine. In some embodiments, the spinal implant can include one or more components of one or more spinal constructs, such as, for example, interbody devices, interbody cages, bone fasteners, spinal rods, tethers, connectors, plates and/or bone graft, and can be employed with various surgical procedures including surgical treatment of a cervical, thoracic, lumbar and/or sacral region of a spine.

Spinal implant system **10** includes a surgical instrument, such as, for example, a driver **12**. Driver **12** can be employed with an end effector **200** (FIG. **10**) of a robotic arm R (FIG. **16**) to facilitate implant with robotic arm R. Driver **12** is guided through end effector **200** for guide-wireless insertion of a spinal implant, such as, for example, a bone fastener **100**, as described herein.

Driver **12** includes a member, such as, for example, an outer tubular sleeve **14**. Outer sleeve **14** extends between a proximal end **18** and a distal end **20**. Outer sleeve **14** defines a longitudinal axis a. In some embodiments, outer sleeve **14** may have various configurations including, for example, round, oval, polygonal, irregular, consistent, variable, uniform and non-uniform. Outer sleeve **14** includes a diameter D**1**. In some embodiments, diameter D**1** is slightly larger than a screw spin diameter D**2** of bone fastener **100**. This configuration allows bone fastener **100** and driver **12** to pass through end effector **200** of the robotic arm, as described herein.

Outer sleeve **14** includes a surface **50** that defines an axial cavity **52**. Cavity **52** is configured for disposal of an inner sleeve **56** and an inner shaft **76**, as described herein. Outer sleeve **14** includes a collar body **16** having a surface **80**. Surface **80** defines a cavity **82**. Body **16** includes bifurcated arms **92** disposed about cavity **82** to facilitate disposal and access to an actuator, such as, for example, a thumb wheel **84** therein. Body **16** includes opening **94** disposed at end **18**. Opening **94** is in communication with cavity **82** and in alignment with cavity **52** to facilitate insertion of inner shaft **76** into end **18**, through wheel **84** and into cavity **52** for assembly, as described herein. Wheel **84** is configured to actuate rotation of inner sleeve **56** and an engagement element, such as, for example, a screw **64**, as described herein. Wheel **84** includes a surface **86** that defines a cavity **88**. Cavity **88** is configured for disposal of a correspondingly shaped portion of inner sleeve **56**, as shown in FIGS. **9** and **10**.

Wheel **84** includes a wall **120** having a surface **122**. Surface **122** defines a groove **124** configured for disposal of a band, such as, for example, a circumferential ring **126**, as shown in FIG. **10**. Ring **126** includes a circumference that extends between ends defining an opening, such as, for example, a gap **128**, which facilitates expansion and contraction of ring **126**. Groove **124** includes a portion, such as, for example, a circumferential channel **130**. In some embodiments, inner sleeve **56** is manually engageable with wheel **84** in a snap-fit assembly such that ring **126** translates into channel **130** to capture inner sleeve **56**. Ring **126** is expandable and resilient between a contracted and/or capture orientation and an expanded orientation, as described herein.

Inner sleeve **56** extends between an end **60** and an end **62**. End **60** is engageable with wheel **84**. Wheel **84** actuates rotation of inner sleeve **56** and screw **64**, as described herein. Surface **86** engages end **60** in an interference fit to facilitate simultaneous rotation of wheel **84**, inner sleeve **56** and screw **64**. In some embodiments, surface **86** defines a hexagonal cross section of cavity **88** for a mating engagement with correspondingly shaped end **60** of inner sleeve **56**. In some embodiments, cavity **88** includes various configurations, such as, for example, hexalobe, cruciform, phillips, square, polygonal, star cross sectional configuration for a mating engagement with correspondingly shaped portion of inner sleeve **56**. In some embodiments, wheel **84** includes a surface **90** configured to facilitate gripping of wheel **84**, such as, for example a knurled surface.

Assembly of inner sleeve **56** with wheel **84** includes aligning end **60** with cavity **88**. End **60** translates through and relative to ring **126** to move ring **126** into an expanded orientation, as described herein. Ring **126** is resiliently biased to the capture orientation such that inner sleeve **56** is attached with wheel **84**, as described herein. Disengagement of inner sleeve **56** from wheel **84** is resisted and/or pre-

vented. Ring **126** is configured to resist and/or prevent axial translation of inner sleeve **56** relative to wheel **84**

Inner sleeve **56** includes an inner surface **66**. Surface **66** defines an axial channel **68** configured for moveable disposal of inner shaft **76**, as described herein. Channel **68** extends co-axial with cavity **52**. In some embodiments, channel **68** is disposed at alternate orientations relative to axis a, such as, for example, at transverse, perpendicular and/or other angular orientations such as acute or obtuse, and/or may be offset or staggered. End **62** of inner sleeve **56** includes screw **64**. Screw **64** includes an outer surface having a thread form **89**. Thread form **89** is configured for engagement with a mating surface, such as, for example, thread forms of arms **104**, **106** of bone fastener **100** to pull and or draw bone fastener **100** into engagement with driver **12**, as described herein.

Wheel **84** is translatable within cavity **82** causing simultaneous axial movement of inner sleeve **56** and screw **64** relative to outer sleeve **14**. Body **16** includes ends **201**, **202** that define a range of axial translation of wheel **84** relative to outer sleeve **14**. Wheel **84** is moveable relative to outer sleeve **14** between a proximal position and a distal position. In the proximal position, wheel **84** provides visual indicia of a non-locking configuration of screw **64** relative to bone fastener **100**, as shown in FIGS. **3-5**. In the distal position, wheel **84** provides visual indicia of a locking configuration of screw **64** relative to bone fastener **100**, as shown in FIGS. **6-8**.

Wheel **84** provides visual indicia displaying the locking and/or non-locking configuration of screw **64** by a position of wheel **84** relative to outer sleeve **14**. For example, wheel **84** is disposed or translates, in a direction shown by arrow A in FIG. **3**, such that a gap G**1** is viewable. Gap G**1** is disposed between wheel **84** and end **202**. Gap G**1** is viewable to indicate that screw **64** is disposed in the non-locking configuration relative to bone fastener **100**. Wheel **84** is translatable, in a direction shown by arrow B in FIG. **6**, closing gap G**1** such that a gap G**2** is viewable. Gap G**2** is disposed between wheel **84** and end **201**. Gap G**2** is viewable to indicate that screw **64** is disposed in the locking configuration relative to bone fastener **100**. In some embodiments, translation of wheel **84** and the visual indicia indicating the disengaged, non-locking configuration of screw **64** relative to bone fastener **100** facilitates removal of driver **12** in minimally invasive surgical procedures.

In some embodiments, the indicia of a non-locking and/or a locking configuration may include alternative visual indicia, tactile indicia, audible indicia, one or more components having markers for identification under x-ray, fluoroscopy, CT or other imaging techniques, at least one light emitting diode, a wireless component, a wired component, a near field communication component and/or one or more components that generate acoustic signals, magnetic signals, electromagnetic signals and/or radiologic signals. In some embodiments, the indicia includes a notch, slot, bead, detent, bump, print, label, score, color coding and/or cavity disposed on wheel **84**. In some embodiments, the indicia may be attachable with or adhered to wheel **84**.

Inner shaft **76** extends between an end **150** and an end **152**. Inner shaft **76** is disposable with channel **68**, as described herein. End **150** is fixed with outer sleeve **14** such that rotation of inner shaft **76** causes simultaneous rotation of outer sleeve **14**. In some embodiments, inner shaft **76** is welded with outer sleeve **14**. Inner shaft **76** is rotatable independently of inner sleeve **56** such that rotation of inner shaft **76** to engage bone fastener **100** is separate and apart from rotation of inner sleeve **56** and screw **64**. In some embodiments, inner shaft **76** includes a portion **154** configured to facilitate connection of driver **12** with a surgical instrument, such as, for example, an actuator/drill **250**, as shown in FIG. **15**. In some embodiments, inner shaft **76** includes quick connect surfaces or keyed geometry, such as, for example, triangle, hex, square or hexalobe to facilitate connection with actuator **250**.

End **152** of inner shaft **76** includes a distal tip, such as, for example, drive **22**, as shown in FIG. **1**. Drive **22** is integrally connected or monolithically formed with inner shaft **76**. This configuration facilitates control of tolerances to optimize accuracy of the connection of inner shaft **76** with bone fastener **100**. Drive **22** is engageable with a spinal implant, such as, for example, bone fastener **100**. For example, drive **22** fits with and is engageable with a mating surface, such as, for example, a socket **110** of bone fastener **100**. Rotation of inner shaft **76** simultaneously rotates drive **22** to drive, torque, insert or otherwise connect bone fastener **100** with tissue, as described herein. In some embodiments, drive **22** includes a hexalobe geometry for a mating engagement with a correspondingly shaped socket **110**. In some embodiments, drive **22** can alternatively include a cruciform, phillips, square, hexagonal, polygonal, star cross sectional configuration for disposal of a correspondingly shaped socket **110**.

Wheel **84** is inserted laterally into cavity **82**. Inner shaft **76** is inserted from end **18**, through opening **94**, through cavity **88** to provisionally connect wheel **84** with outer sleeve **14**. Inner shaft **76** is welded to outer sleeve **14**. Inner sleeve **56** is inserted from end **20** of outer sleeve **14** into engagement with wheel **84**, as described herein. Inner shaft **76** is disposed with cavity **68** of inner sleeve **56**. Inner sleeve **56** is rotatable relative to outer sleeve **14** and inner shaft **76**. Inner shaft **76** and outer sleeve **14** simultaneously rotate relative to inner sleeve **56**.

Bone fastener **100** includes receiver **102**. Receiver **102** extends along axis a when connected with outer sleeve **14**. Receiver **102** includes a pair of spaced apart arms **104**, **106** that define an implant cavity configured for disposal of a component of a spinal construct, such as, for example, a spinal rod (not shown). Arms **104**, **106** are connected at proximal ends of receiver **102** to define a closed tulip bone screw including a closed spinal rod slot, as shown in FIG. **2**. Receiver **102** defines an opening **105** between arms **104**, **106**. In some embodiments, receiver **102** comprises an open tulip bone screw head.

Receiver **102** includes socket **110** configured for engagement with drive **22**, as described herein. Receiver **102** includes an inner surface having a thread form located adjacent arm **104** and a thread form located adjacent arm **106**. The thread forms of arms **104**, **106** are configured for engagement with thread form **89** to retain bone fastener **100** with driver **12**, as described herein. Bone fastener **100** includes a threaded shaft **116**. Shaft **116** is configured to penetrate tissue, such as, for example, bone.

In use, drive **22** is aligned with closed receiver **102** and passed through opening **105** for disposal with socket **110**, as shown in FIG. **2**. Bone fastener **100** is connected with driver **12**. Drive **22** is engaged with socket **110** and screw **64** is disposed with inner sleeve **56** and assembled with outer sleeve **14** for axial translation relative to outer sleeve **14** and along inner shaft **76** between a non-locking configuration, as shown in FIGS. **3-5**, and a locking configuration, as shown in FIGS. **6-8**, with a spinal implant, such as, for example, bone fastener **100**.

Wheel **84** is disposed in the proximal position and provides visual indicia, including gap G**1**, of the non-locking configuration of screw **64** relative to bone fastener **100**, as

shown in FIG. **4**. Drive **22** is engaged with socket **110** such that bone fastener **100** is connected with outer sleeve **14**, and thread form **89** is aligned with the thread forms of arms **104**, **106** for engagement therebetween to retain bone fastener **100** with driver **12**, as shown in FIG. **5**. Wheel **84** is manipulated for rotation such that inner sleeve **56** rotates screw **64** relative to and independent of outer sleeve **14**. Screw **64** is aligned with closed receiver **102** and passed through opening **105**. Thread form **89** engages the thread forms of arms **104**, **106** and inner sleeve **56** axially translates screw **64** into receiver **102**. The threaded engagement of screw **64** and receiver **102** pulls and/or draws bone fastener **100** into the locking configuration with driver **12** for releasable fixation therebetween, as shown in FIG. **8**. Wheel **84** is disposed in the distal position and provides visual indicia, including gap G**2**, of the locking configuration of screw **64** relative to bone fastener **100**, as shown in FIGS. **6** and **7**.

Inner shaft **76** with drive **22** is connected with outer sleeve **14**, as described herein, and inner shaft **76** and outer sleeve **14** are rotated to drive, torque, insert or otherwise connect bone fastener **100** with adjacent tissue. Screw **64** remains releasably fixed with receiver **102**, independent of inner shaft **76** and outer sleeve **14** rotation and/or engagement or friction with components of spinal implant system **10** as described herein, to resist and/or prevent disengagement or unthreading of screw **64** from receiver **102**. In some embodiments, wheel **84** is manipulated for rotation such that inner sleeve **56** and screw **64** rotates relative to outer sleeve **14**, and thread form **89** disengages the thread forms of arms **104**, **106**. Screw **64** axially translates from receiver **102** to unthread driver **12** from receiver **102** such that wheel **84** is disposed in the proximal position and provides visual indicia, including gap G**1**, of the non-locking configuration of screw **64** relative to bone fastener **100**, as shown in FIGS. **3** and **4**.

In some embodiments, driver **12** includes a navigation component **300**, as shown in FIGS. **15** and **16**. Driver **12** is configured for disposal adjacent a surgical site such that navigation component **300** is oriented relative to a sensor array **302** to facilitate communication between navigation component **300** and sensor array **302** during a surgical procedure, as described herein. Navigation component **300** is configured to generate a signal representative of a position of bone fastener **100** relative to driver **12** and/or tissue. In some embodiments, the image guide may include human readable visual indicia, human readable tactile indicia, human readable audible indicia, one or more components having markers for identification under x-ray, fluoroscopy, CT or other imaging techniques, at least one light emitting diode, a wireless component, a wired component, a near field communication component and/or one or more components that generate acoustic signals, magnetic signals, electromagnetic signals and/or radiologic signals. In some embodiments, navigation component **300** is connected with portion **154** or outer sleeve **14** via an integral connection, friction fit, pressure fit, interlocking engagement, mating engagement, dovetail connection, clips, barbs, tongue in groove, threaded, magnetic, key/keyslot and/or drill chuck.

Navigation component **300** includes an emitter array **304**. Emitter array **304** is configured for generating a signal to sensor array **302** of a surgical navigation system **306**, as shown in FIG. **16** and described herein. In some embodiments, the signal generated by emitter array **304** represents a position of bone fastener **100** relative to driver **12** and relative to tissue, such as, for example, bone. In some embodiments, the signal generated by emitter array **304** represents a three dimensional position of bone fastener **100** relative to tissue.

In some embodiments, sensor array **302** receives signals from emitter array **304** to provide a three-dimensional spatial position and/or a trajectory of bone fastener **100** relative to driver **12** and/or tissue. Emitter array **304** communicates with a processor of computer **308** of navigation system **306** to generate data for display of an image on monitor **310**, as described herein. In some embodiments, sensor array **302** receives signals from emitter array **304** to provide a visual representation of a position of bone fastener **100** relative to driver **12** and/or tissue. See, for example, similar surgical navigation components and their use as described in U.S. Pat. Nos. 6,021,343, 6,725,080, 6,796,988, the entire contents of each of these references being incorporated by reference herein.

Surgical navigation system **306** is configured for acquiring and displaying medical imaging, such as, for example, x-ray images appropriate for a given surgical procedure. In some embodiments, pre-acquired images of a patient are collected. In some embodiments, surgical navigation system **306** can include an O-arm® imaging device **310** sold by Medtronic Navigation, Inc. having a place of business in Louisville, Colo., USA. Imaging device **310** may have a generally annular gantry housing that encloses an image capturing portion **312**.

In some embodiments, navigation system **306** comprises an image capturing portion **314** that may include an x-ray source or emission portion and an x-ray receiving or image receiving portion located generally or as practically possible 180 degrees from each other and mounted on a rotor (not shown) relative to a track of image capturing portion **314**. Image capturing portion **314** can be operable to rotate 360 degrees during image acquisition. Image capturing portion **314** may rotate around a central point or axis, allowing image data of the patient to be acquired from multiple directions or in multiple planes. Surgical navigation system **306** can include those disclosed in U.S. Pat. Nos. 8,842,893, 7,188,998; 7,108,421; 7,106,825; 7,001,045; and 6,940,941; the entire contents of each of these references being incorporated by reference herein.

In some embodiments, surgical navigation system **306** can include C-arm fluoroscopic imaging systems, which can generate three-dimensional views of a patient. The position of image capturing portion **314** can be precisely known relative to any other portion of an imaging device of navigation system **306**. In some embodiments, a precise knowledge of the position of image capturing portion **314** can be used in conjunction with a tracking system **316** to determine the position of image capturing portion **314** and the image data relative to the patient.

Tracking system **316** can include various portions that are associated or included with surgical navigation system **306**. In some embodiments, tracking system **316** can also include a plurality of types of tracking systems, such as, for example, an optical tracking system that includes an optical localizer, such as, for example, sensor array **302** and/or an EM tracking system that can include an EM localizer. Various tracking devices can be tracked with tracking system **316** and the information can be used by surgical navigation system **306** to allow for a display of a position of an item, such as, for example, a patient tracking device, an imaging device tracking device **318**, and an instrument tracking device, such as, for example, emitter array **304**, to allow selected portions to be tracked relative to one another with the appropriate tracking system.

In some embodiments, the EM tracking system can include the STEALTHSTATION® AXIEM™ Navigation System, sold by Medtronic Navigation, Inc. having a place of business in Louisville, Colo. Exemplary tracking systems are also disclosed in U.S. Pat. Nos. 8,057,407, 5,913,820, 5,592,939, the entire contents of each of these references being incorporated by reference herein.

Fluoroscopic images taken are transmitted a computer **314** where they may be forwarded to computer **308**. Image transfer may be performed over a standard video connection or a digital link including wired and wireless. Computer **308** provides the ability to display, via monitor **310**, as well as save, digitally manipulate, or print a hard copy of the received images. In some embodiments, images may also be displayed to the surgeon through a heads-up display.

In some embodiments, surgical navigation system **306** provides for real-time tracking of the position of bone fastener **100** relative to driver **12** and/or tissue can be tracked. Sensor array **302** is located in such a manner to provide a clear line of sight with emitter array **304**, as described herein. In some embodiments, fiducial markers **330** of emitter array **304** communicate with sensor array **302** via infrared technology. Sensor array **302** is coupled to computer **308**, which may be programmed with software modules that analyze signals transmitted by sensor array **302** to determine the position of each object in a detector space.

Driver **12** is configured for use with a guide member, such as, for example, an end effector **200** of a robotic arm R. End effector **200** includes a surface **220** that defines a cavity, such as, for example, a channel **222**. Channel **222** is configured for passage of bone fastener **100** and disposal of driver **12**. Robotic arm R includes position sensors (not shown), similar to those referenced herein, which measure, sample, capture and/or identify positional data points of end effector **200** in three dimensional space for a guide-wireless insertion of bone fasteners **100** with selected vertebral levels. In some embodiments, the position sensors of robotic arm R are employed in connection with surgical navigation system **306** to measure, sample, capture and/or identify positional data points of end effector **200** in connection with surgical treatment, as described herein. The position sensors are mounted with robotic arm R and calibrated to measure positional data points of end effector **200** in three dimensional space, which are communicated to computer **308**.

In assembly, operation and use, spinal implant system **10**, similar to the systems and methods described herein, is employed with a surgical procedure, such as, for example, a treatment of an applicable condition or injury of an affected section of a spinal column and adjacent areas within a body. In some embodiments, one or all of the components of spinal implant system **10** can be delivered or utilized as a pre-assembled device or can be assembled in situ. Spinal implant system **10** may be completely or partially revised, removed or replaced.

In use, to treat vertebrae (not shown), a medical practitioner obtains access to a surgical site in any appropriate manner, such as through incision and retraction of tissues. In some embodiments, spinal implant system **10** can be used in any existing surgical method or technique including open surgery, mini-open surgery, minimally invasive surgery and percutaneous surgical implantation, whereby the vertebrae is accessed through a mini-incision, or sleeve that provides a protected passageway to the area. Once access to the surgical site is obtained, the particular surgical procedure can be performed for treating the spine disorder.

An incision is made in the body of a patient and a cutting instrument (not shown) creates a surgical pathway for implantation of components of spinal implant system **10**. A preparation instrument (not shown) can be employed to prepare tissue surfaces of the vertebrae as well as for aspiration and irrigation of a surgical region.

Pilot holes (not shown) are made in selected levels of vertebrae for receiving bone fasteners **100**. Drive **22** is aligned with closed receiver **102** and passed through opening **105** for disposal with socket **110**, as shown in FIG. **2**. Bone fastener **100** is connected with driver **12**. Drive **22** is engaged with socket **110** and screw **64** is disposed with inner sleeve **56** for axial translation relative to outer sleeve **14** between a non-locking configuration, as shown in FIGS. **3-5**, and a locking configuration, as shown in FIGS. **6-8**, with bone fastener **100**.

Wheel **84** is disposed in the proximal position and provides visual indicia, including gap G**1**, of the non-locking configuration of screw **64** relative to bone fastener **100**, as shown in FIG. **4**. Thread form **89** is aligned with the thread forms of arms **104**, **106** for engagement therebetween to retain bone fastener **100** with driver **12**, as shown in FIG. **5**. Wheel **84** is manipulated for rotation such that inner sleeve **56** rotates screw **64** relative to and independent of outer sleeve **14**. Screw **64** is aligned with closed receiver **102** and passed through opening **105**. Thread form **89** engages the thread forms of arms **104**, **106** and inner sleeve **56** axially translates screw **64** into receiver **102**. The threaded engagement of screw **64** and receiver **102** pulls and/or draws bone fastener **100** into the locking configuration with driver **12** for releasable fixation therebetween, as shown in FIG. **8**. Wheel **84** is disposed in the distal position and provides visual indicia, including gap G**2**, of the locking configuration of screw **64** relative to bone fastener **100**, as shown in FIGS. **6** and **7**.

Driver **12**, connected with bone fastener **100**, is oriented for disposal with end effector **200** of robotic arm R, as described herein. The assembly of driver **12**/bone fastener **100** is disposed with channel **220** for implantation of one or more bone fasteners **100** with vertebrae employing robotic arm R and/or surgical navigation system **306**, as described herein. Actuator **250** is connected with inner shaft **76** and drive **22** engages bone fastener **100**, as described herein, and inner shaft **76** and outer sleeve **14** are rotated to drive, torque, insert or otherwise connect bone fastener **100** with adjacent tissue. Screw **64** remains releasably fixed with receiver **102**, independent of inner shaft **76** and outer sleeve **14** rotation and/or engagement or friction with end effector **200** to resist and/or prevent disengagement or unthreading of screw **64** from receiver **102**. In some embodiments, driver **12** is manipulated to deliver one or more bone fasteners **100** to a surgical site including vertebrae.

Sensor array **302** receives signals from navigation component **300** to provide a three-dimensional spatial position and/or a trajectory of the assembly of driver **12**/bone fastener **100**, which may be disposed with end effector **200**, relative to vertebrae and/or components of spinal implant system **10** for display on monitor **310**. Wheel **84** is manipulated for rotation such that inner sleeve **56** and screw **64** rotates relative to outer sleeve **14**, and thread form **89** disengages the thread forms of arms **104**, **106**. Screw **64** axially translates through opening **105** from receiver **102** to unthread driver **12** from receiver **102** such that wheel **84** is disposed in the proximal position and provides visual indicia, including gap G**1**, of the non-locking configuration of screw **64** relative to bone fastener **100**, as shown in FIGS. **3** and **4**.

Upon completion of a procedure, as described herein, the surgical instruments, assemblies and non-implanted compo-

nents of spinal implant system **10** are removed and the incision(s) are closed. One or more of the components of spinal implant system **10** can be made of radiolucent materials such as polymers. Radiomarkers may be included for identification under x-ray, fluoroscopy, CT or other imaging techniques. In some embodiments, spinal implant system **10** may include one or a plurality of spinal rods, plates, connectors and/or bone fasteners for use with a single vertebral level or a plurality of vertebral levels.

In some embodiments, one or more bone fasteners, as described herein, may be engaged with tissue in various orientations, such as, for example, series, parallel, offset, staggered and/or alternate vertebral levels. In some embodiments, the bone fasteners may comprise multi-axial screws, sagittal adjusting screws, pedicle screws, mono-axial screws, uni-planar screws, facet screws, fixed screws, tissue penetrating screws, conventional screws, expanding screws, wedges, anchors, buttons, clips, snaps, friction fittings, compressive fittings, expanding rivets, staples, nails, adhesives, posts, fixation plates and/or posts.

In one embodiment, spinal implant system **10** includes an agent, which may be disposed, packed, coated or layered within, on or about the components and/or surfaces of spinal implant system **10**. In some embodiments, the agent may include bone growth promoting material, such as, for example, bone graft to enhance fixation of the components and/or surfaces of spinal implant system **10** with vertebrae. In some embodiments, the agent may include one or a plurality of therapeutic agents and/or pharmacological agents for release, including sustained release, to treat, for example, pain, inflammation and degeneration.

In one embodiment, as shown in FIGS. **17-21**, spinal implant system **10**, similar to the systems and methods described herein, includes a driver **412**, similar to driver **12** described herein. Driver **412** can be employed with end effector **200** of robotic arm R to facilitate implant with robotic arm R, as described herein. Driver **412** is guided through end effector **200** for guide-wireless insertion of a spinal implant, such as, for example, bone fastener **100**, as described herein.

Driver **412** includes an outer tubular sleeve **414**, similar to outer sleeve **14** described herein. Outer sleeve **414** extends between a proximal end **418** and a distal end **420**. Outer sleeve **414** includes a surface **450** that defines an axial cavity **452**. Cavity **452** is configured for disposal of an inner sleeve **456**, similar to sleeve **56** described herein, and an inner shaft **476**, similar to inner shaft **76** described herein. Outer sleeve **414** includes a collar body **416**, similar to body **16** described herein, having a surface **480**. Surface **480** defines a cavity **482**. Body **416** includes bifurcated arms **492** disposed about cavity **482** to facilitate disposal and access to a thumb wheel **484** therein, similar to thumb wheel **84** described herein. Body **416** includes opening **494** disposed at end **418**. Opening **494** includes a diameter configured to receive inner sleeve **456** to facilitate translation of inner sleeve **456** relative to outer sleeve **14** during assembly, as described herein. Opening **494** is in communication with cavity **482** and in alignment with cavity **452** to facilitate insertion of inner sleeve **465** and inner shaft **476** into end **418**, through wheel **484** and into cavity **452** for assembly, as described herein. Wheel **484** is configured to actuate rotation of inner sleeve **456** and a screw **464**, similar to that described herein. Wheel **484** includes a surface **486** that defines a cavity **488**. Cavity **488** is configured for disposal of a correspondingly shaped portion of inner sleeve **456**, as shown in FIG. **21**.

Inner sleeve **456** extends between an end **460** and an end **462**. End **460** is engageable with wheel **484**. Wheel **484** actuates rotation of inner sleeve **456** and screw **464**, similar to that described herein. Inner sleeve **456** is fixed with wheel **484** by pins **504**, as shown in FIGS. **19-21**. Pins **504** are configured to fix wheel **484** relative to inner sleeve **456** to resist and/or prevent rotation of wheel **484** relative to inner sleeve **456** to facilitate simultaneous rotation of wheel **484**, inner sleeve **456** and screw **464**.

Inner sleeve **456** includes an inner surface **466**. Surface **466** defines an axial channel **468** configured for moveable disposal of inner shaft **476**, as described herein. End **462** of inner sleeve **456** includes screw **464** configured to pull and or draw bone fastener **100** into engagement with driver **412**, similar to screw **64** described herein.

Wheel **484** is translatable within cavity **482** causing simultaneous axial movement of inner sleeve **456** and screw **464** relative to outer sleeve **414**. Body **416** includes ends **501**, **502** that define a range of axial translation of wheel **484** relative to outer sleeve **414**. Wheel **484** is moveable relative to outer sleeve **414** between a proximal position and a distal position, as described herein. In the proximal position, wheel **484** provides visual indicia of a non-locking configuration of screw **464** relative to bone fastener **100**, as described herein. In the distal position, wheel **484** provides visual indicia of a locking configuration of screw **464** relative to bone fastener **100**, as described herein.

Inner shaft **476** extends between an end **550** and an end **552**. Inner shaft **476** is disposable with channel **468**. End **550** is fixed with outer sleeve **414** such that rotation of inner shaft **476** causes simultaneous rotation of outer sleeve **414**. Inner shaft **476** is welded with outer sleeve **414**. Inner shaft **476** is rotatable independently of inner sleeve **456** such that rotation of inner shaft **476** to engage bone fastener **100** is separate and apart from rotation of inner sleeve **456** and screw **464**. End **552** of inner shaft **476** includes a drive **422**, similar to drive **22** described herein.

For assembly of driver **412**, wheel **484** is inserted laterally into cavity **482**. Inner sleeve **456** is inserted from end **418** of outer sleeve **414**, through opening **494** and through cavity **452**, as shown in FIG. **18**. Pins **504** are fixed with wheel **484** and inner sleeve **456**, such as, for example, by laser welding, as shown in FIG. **19**. After connection of inner sleeve **456** with outer sleeve **414**, inner shaft **476** is inserted from end **418**, through opening **494** and, through cavity **488** to provisionally connect wheel **484** with outer sleeve **414**, as shown in FIGS. **20** and **21**. Inner shaft **476** is welded to outer sleeve **414**. Inner shaft **476** is disposed with cavity **468** of inner sleeve **456**. Inner sleeve **456** is rotatable relative to outer sleeve **414** and inner shaft **476**. Inner shaft **476** and outer sleeve **414** simultaneously rotate relative to inner sleeve **456**, as described herein.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplification of the various embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is:

1. A surgical instrument comprising:

an outer sleeve including an inner surface that defines a cavity;

an inner shaft permanently fixed with the outer sleeve and extending within the cavity, the inner shaft including a tip engageable with a first mating surface of a bone fastener; and

an inner sleeve defining a passageway, the inner shaft being disposed in the passageway, the inner sleeve being rotatable relative to the outer sleeve and includ-

ing an outer surface connectable with a second mating surface of the bone fastener.

2. A surgical instrument as recited in claim **1**, wherein the inner sleeve is disposed between the inner shaft and the outer sleeve within the cavity in a relative coaxial orientation.

3. A surgical instrument as recited in claim **1**, wherein the tip is a distal tip of the inner shaft and the first mating surface includes a drive socket of a bone fastener shaft.

4. A surgical instrument as recited in claim **1**, further comprising a rotatable actuator connected with the inner sleeve.

5. A surgical instrument as recited in claim **4**, wherein the rotatable actuator includes a knurled wheel including an inner surface engageable with the inner sleeve for rotation therewith.

6. A surgical instrument as recited in claim **1**, wherein the outer surface is threaded and connectable with the second mating surface.

7. A surgical instrument as recited in claim **1**, wherein the inner sleeve is axially translatable relative to the outer sleeve.

8. A surgical instrument as recited in claim **1**, wherein the inner sleeve is axially translatable relative to the outer sleeve between a non-locking configuration and a locking configuration with the second mating surface.

9. A surgical instrument as recited in claim **1**, further comprising an actuator connected with the inner sleeve and including visual indicia of engagement of the outer surface with the second mating surface.

10. A surgical instrument as recited in claim **9**, wherein the actuator is axially translatable relative to the outer sleeve to provide visual indicia of a non-locking configuration and a locking configuration.

11. A surgical instrument as recited in claim **9**, wherein the visual indicia includes the actuator disposed in a proximal position relative to the outer sleeve to provide visual indicia of a non-locking configuration and in a distal position relative to the outer sleeve to provide visual indicia of a locking configuration.

12. A surgical instrument as recited in claim **1**, further comprising an actuator fixed with the inner sleeve in rotation and axial translation.

13. A surgical instrument as recited in claim **12**, wherein the inner sleeve and the actuator are connected via at least one pin.

14. A surgical instrument as recited in claim **12**, wherein the inner sleeve and the actuator are engageable in a snap-fit assembly.

15. A surgical instrument as recited in claim **12**, wherein the inner surface of the actuator includes a wall defining a groove, and further comprising a band that is expandable within the groove, the inner sleeve being manually engageable with the band to connect the inner sleeve and the actuator.

16. A surgical instrument as recited in claim **12**, wherein the inner surface of the actuator includes a wall defining a groove, and further comprising a circumferential ring that defines a gap and is expandable within the groove between a capture orientation and an expanded orientation.

17. A surgical instrument as recited in claim **1**, wherein the passageway is coaxial with the cavity.

18. A surgical instrument comprising:

an outer sleeve including an inner surface that defines a cavity;

an inner shaft fixed with the outer sleeve and extending within the cavity, the inner shaft including a tip engageable with a first mating surface of a bone fastener;

an inner sleeve disposed between the inner shaft and the outer sleeve, the inner sleeve being rotatable relative to the outer sleeve and including an outer surface connectable with a second mating surface of the bone fastener; and

an actuator connected with the inner sleeve and including visual indicia of engagement of the outer surface with the second mating surface,

wherein the actuator is axially translatable relative to the outer sleeve to provide visual indicia of a non-locking configuration and a locking configuration.

19. A surgical instrument comprising:

an outer sleeve including an inner surface that defines a cavity;

an inner shaft fixed with the outer sleeve and extending within the cavity, the inner shaft including a tip engageable with a first mating surface of a bone fastener;

an inner sleeve disposed between the inner shaft and the outer sleeve, the inner sleeve being rotatable relative to the outer sleeve and including an outer surface connectable with a second mating surface of the bone fastener; and

an actuator fixed with the inner sleeve in rotation and axial translation.

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