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- (73) Patenthaver: **NuVasive Specialized Orthopedics, Inc., 7475 Lusk Blvd, San Diego, CA 92121, USA**
- (72) Opfinder: **POOL, Scott, 25291 Bentley, Laguna Hills, California 92656, USA**
WALKER, Blair, 24742 San Doval Lane, Mission Viejo, California 92691, USA
- (74) Fuldmægtig i Danmark: **Holme Patent A/S, Valbygårdsvej 33, 2500 Valby, Danmark**
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DESCRIPTION

Field of the Invention

[0001] The field of the invention generally relates to medical devices for treating conditions involving the skeletal system and in particular bone growth applications.

Background of the Invention

[0002] Distraction osteogenesis, also known as distraction callotasis and osteodistraction has been used successfully to lengthen long bones of the body. Typically, the bone, if not already fractured, is purposely fractured by means of a corticotomy, and the two segments of bone are gradually distracted apart, which allows new bone to form in the gap. If the distraction rate is too high, there is a risk of nonunion, if the rate is too low, there is a risk that the two segments will completely fuse to each other before the distraction period is complete. When the desired length of the bone is achieved using this process, the bone is allowed to consolidate. Distraction osteogenesis applications are mainly focused on the growth of the femur or tibia, but may also include the humerus, the jaw bone (micrognathia), or other bones. The reasons for lengthening or growing bones are multifold, the applications including, but not limited to: post osteosarcoma bone cancer; cosmetic lengthening (both legs-femur and/or tibia) in short stature or dwarfism/achondroplasia; lengthening of one limb to match the other (congenital, post-trauma, post-skeletal disorder, prosthetic knee joint), non-unions.

[0003] Distraction osteogenesis using external fixators has been done for many years, but the external fixator can be unwieldy for the patient. It can also be painful, and the patient is subject to the risk of pin track infections, joint stiffness, loss of appetite, depression, cartilage damage and other side effects. Having the external fixator in place also delays the beginning of rehabilitation.

[0004] In response to the shortcomings of external fixator distraction, intramedullary distraction nails have been surgically implanted which are contained entirely within the bone. Some are automatically lengthened via repeated rotation of the patient's limb. This can sometimes be painful to the patient, and can often proceed in an uncontrolled fashion. This therefore makes it difficult to follow the strict daily or weekly lengthening regime that avoids nonunion (if too fast) or early consolidation (if too slow). Lower limb distraction rates are on the order of one millimeter per day. Other intramedullary nails have been developed which have an implanted motor and are remotely controlled. The motorized intramedullary nails have an antenna which needs to be implanted subcutaneously, thus complicating the surgical procedure, and making it more invasive. These devices are therefore designed to be lengthened in a controlled manner, but due to their complexity, may not be manufacturable as an affordable product. Others have proposed intramedullary distractors containing and implanted magnet, which allows the

distraction to be driven electromagnetically by an external stator (i.e., a large electromagnet). Because of the complexity and size of the external stator, this technology has not been reduced to a simple and cost-effective device that can be taken home, to allow patients to do daily lengthenings.

[0005] US 2009/0112207 A1 discloses a lengthening device according to the preamble of claim 1.

Summary of the Invention

[0006] The invention, which is defined by the appended claims, provides a lengthening device configured for placement inside or across bone having first and second separate sections. The device includes a housing configured for attachment to one of the first and second separate bone sections and a distraction shaft having an internal cavity along a length thereof and configured for attachment to the other of the first and second separate bone sections. The device includes a permanent magnet configured for rotation relative to the housing and having at least two poles, the permanent magnet operatively coupled to a lead screw, the lead screw interfacing with a threaded portion of the internal cavity of the distraction shaft. A thrust bearing is disposed in the housing and interposed between the lead screw and the permanent magnet, the thrust bearing sandwiched between first and second abutments in the housing.

Brief Description of the Drawings

[0007]

FIG. 1 illustrates side view of an intramedullary lengthening device in place within a bone according to one embodiment.

FIG. 2 illustrates a side view of the intramedullary lengthening device of FIG. 1.

FIG. 3A illustrates a cross-sectional view of the intramedullary lengthening device of FIGS. 1 and 2 taken along the line 3A-3A of FIG. 2.

FIG. 3B illustrates a detailed view of the intramedullary lengthening device of FIG. 3A from the area of circle 3B.

FIG. 3C illustrates a cross-sectional view of the intramedullary lengthening device of FIGS. 1 and 2 taken along the line 3C in FIG. 2.

FIG. 4A illustrates a view of several of the internal components of the intramedullary lengthening device of the prior FIGS.

FIG. 4B illustrates a lip seal configured for use in the intramedullary lengthening device of the prior FIGS.

FIG. 5 illustrates a detailed view of several internal components of the drive mechanism of the intramedullary lengthening device of the prior figures.

FIG. 6 illustrates a perspective view of an external adjustment device.

FIG. 7 illustrates an exploded view of the magnetic handpiece of the external adjustment device of FIG. 6.

FIG. 8 illustrates a cross-sectional representation of a prior art electromagnetic external device being positioned around a patient's lower thigh.

FIG. 9 illustrates a cross-sectional representation of the external adjustment device handpiece of FIGS. 6 and 7 being positioned on a patient's lower thigh.

FIG. 10 illustrates a sterilizable kit for use with a modular intramedullary lengthening device.

FIG. 11 illustrates a modular intramedullary lengthening device according to one embodiment.

FIG. 12 illustrates one end of the actuator of the intramedullary lengthening device of FIG. 11.

FIG. 13 illustrates an extension rod of the modular intramedullary lengthening device.

FIG. 14 illustrates a second view of the extension rod of FIG. 13.

FIG. 15 illustrates a proximal drill guide for insertion and attachment of the modular intramedullary lengthening device.

FIG. 16 illustrates a removal tool for removal of the modular intramedullary lengthening device.

FIG. 17 illustrates a torque limiting driver for attaching the extension rod to the actuator of the modular intramedullary device.

FIG. 18 illustrates a section of the actuator of the modular intramedullary lengthening device.

FIG. 19 illustrates a gap (G) between a magnetic handpiece and an intramedullary lengthening device.

FIG. 20 illustrates a locking screw driver for use with the intrameduallary lengthening device.

FIG. 21A illustrates a locking screw for use with the intramedullary lengthening device.

FIG. 21B illustrates the locking screw of FIG. 21A taken along line 21B-21B of FIG. 21A.

Detailed Description of the Illustrated Embodiments

[0008] FIG. 1 illustrates the side view of an intramedullary lengthening device 110 which has

been placed through a hole or bore 108 contained within a bone 100. The hole or bore 108 may be made by drilling, reaming and the like and may extend through both cortical bone (at the end) and through cancellous (spongy) bone. The intramedullary lengthening device 110 illustrated in FIG. 1 includes a housing 112 and a distraction shaft 114. In order to grow or lengthen the bone 100, the bone 100 either has a pre-existing separation 106 or is purposely cut or broken to create this separation 106, dividing the bone into a first section 102 and a second section 104. The cut may be done prior to inserting and securing the intramedullary lengthening device 110, or may be done after the device 110 is inserted, for example by use of a flexible Gigli saw. The distraction shaft 114 of the intramedullary lengthening device 110 is attached to the first section 102 using one or more attachment screws 118. Fasteners other than screws 118 known to those skilled in the art may also be used to secure the distraction shaft 114 to the first section 102 of the bone 100. The housing 112 of the intramedullary lengthening device 110 is secured to the second section 104 of bone 100 using one or more attachment screws 116. Again, fasteners other than screws 116 may be used to secure the housing 112 to the second section 104 of bone 100.

[0009] Over the treatment period, the bone 100 is continually distracted, creating a new separation 106, into which osteogenesis can occur. Continually distracted is meant to indicate that distraction occurs on a regular basis which may be on the order of every day or every few days. An exemplary distraction rate is one millimeter per day although other distraction rates may be employed. That is to say, a typical distraction regimen may include a daily increase in the length of the intramedullary lengthening device 110 by about one millimeter. This may be done, for example, by four lengthening periods per day, each having 0.25 mm of lengthening. The intramedullary lengthening device 110, as will be shown in the following FIGS., has a magnetic drive system, which allows the distraction shaft 114 to be telescopically extended from the housing 112, thus forcing the first section 102 and the second section 104 of the bone 100 apart from one another. As the distraction is performed, a portion of the housing 112 is able to slide within the hole or bore 108 of the first section 102 of bone 100 within a displacement section 120. The orientation of the intramedullary lengthening device 110 within the bone may be opposite of that shown in FIG. 1. For example, the distraction shaft 114 may be coupled to the second section 104 of the bone 100 and the housing 112 may be coupled to the first section 102 of the bone 100. For example, the intramedullary lengthening device 110 may be placed retrograde, from a hole or bore starting at the distal end of the bone 100.

[0010] Turning to FIGS. 2 through 5, the intramedullary lengthening device 110 has one or more distraction shaft screw holes 122 in the distraction shaft 114 through which the screws 118 (FIG. 1) may be placed. Likewise, the housing 112 is attached to an end cap 130 which has one or more housing screw holes 124 through which the screws 116 (FIG. 1) may be placed. The housing 112 of the intramedullary lengthening device 110 includes a magnet housing 128 and a splined housing 126. These housings 126, 128 may be attached to each other by means of welding, adhesive bonding or other joining techniques. The magnet housing 128 is sealably closed at one end (the end opposite the interface with the splined housing 126) by the attachment of the end cap 130. The end cap 130 may be attached to the magnet housing 128 by means of welding, adhesive bonding or other joining techniques. In use, the

distraction shaft 114 is driven from the housing 112 by means of a lead screw 136 which turns inside a nut 140 that is secured to an inner surface adjacent to a cavity 137 of the distraction shaft 114. The lead screw 136 is mechanically coupled, in an indirect manner, to cylindrical permanent magnet 134 contained within the magnet housing 128. As explained in more detail below, rotation of the cylindrical permanent magnet 134, which is magnetically driven by an external adjustment device 180 (FIG. 6), effectuates rotation of the lead screw 136.

[0011] Cylindrical magnet 134 is fixedly contained within a magnet casing 158 using, for example, an adhesive such as an epoxy. The magnet casing 158 rotates relative to the magnet housing 128. The cylindrical magnet 134 may be a rare earth magnet such as Nd-Fe-B and may be coated with Parylene or other protective coatings in addition to being protected within the magnet casing 158, for example hermetically potted with epoxy. The magnet casing 158 contains an axle 160 on one end which attaches to the interior of a radial bearing 132. The outer diameter of the radial bearing 132 is secured to the interior of the end cap 130. This arrangement allows the cylindrical magnet 134 to rotate with minimal torsional resistance. At its other, opposing end, the magnet housing 158 includes an axle 161, which is attached to a first planetary gear set 154. The axle 161 includes the sun gear of the first planetary gear set 154, the sun gear turning the planetary gears of the first planetary gear set 154. The first planetary gear set 154 serves to reduce the rotational speed and increase the resultant torque delivery from the cylindrical magnet 134 to the lead screw 136. A second planetary gear set 156 is also shown between the first planetary gear set 154 and the lead screw 136, for further speed reduction and torque augmentation. The number of planetary gear sets and/or the number of teeth in the gears may be adjusted, in order to achieve the desired speed and torque delivery. For example, a lead screw with eighty (80) threads per inch attached to two planetary gear sets of 4:1 gear ratio each inside a 9 mm device with magnet location in the distal femur can achieve at least 100 lb. of distraction force at a greater than average distance or gap from the external device (FIG. 9 or FIG. 19). The planetary gear sets 154, 156 output to a planetary gear output shaft 144. The planetary gear output shaft 144 extends through a thrust bearing 138 and is secured (by welding and the like) to a lead screw coupling cap 146. The lead screw 136 is secured to the lead screw coupling cap 146 by a locking pin 142, which extends through a hole in the lead screw 136 and holes in the lead screw coupling cap 146. A locking pin retainer 148 is a cylinder that surrounds the locking pin 142, holding this assembly together. Attaching the lead screw 136 to the rest of the magnet/gear assembly in this manner, assures that the design is not over-constrained, and thus that the lead screw 136 does not gall with the nut 140. In addition, a biocompatible grease, for example KRYTOX, may be used on the moving parts (lead screw, nut, bearings, housing, and distraction shaft) in order to minimize frictional losses. The lead screw 136 is able to freely rotate within a cavity 137 of the distraction shaft 114, and only need engage with the short length of the nut 140, this feature also minimizing frictional losses.

[0012] The thrust bearing 138 serves to protect the magnet/gear assembly of the drive from any significant compressive or tensile stresses. The thrust bearing 138 consists of two separate races with ball bearings between the two races. When there is a compressive force on the device, for example, when distracting a bone 100, and thus resisting the tensile strength

of the soft tissues, the thrust bearing 138 abuts against a magnet housing abutment or lip 150 located in the magnet housing 128. Additionally, though the device is not typically intended for pulling bones together, there may be some applications where this is desired. For example, in certain compressive nail applications it is the goal to hold two fractured sections of a bone together. Because the bone 100 may have fractured in a non-uniform or shattered pattern, it may be difficult to determine the desired length of the nail until after it is implanted and fully attached. In these situations, it can be easy to misjudge the length, and so a gap may exist between the bones. By placing a slightly extended intramedullary device 110 and securing it, the device 110 may be retracted magnetically, after it has been secured within the bone fragments, so that it applies the desired compression between the two fragments. In these compressive nail applications, there would be tensile force on the device 110 and the thrust bearing 138 would abut against a splined housing abutment or lip 152. In both situations, the thrust bearing 138 and a rigid portion of one of the housing sections take the large stresses, not the magnet/gear assembly of the drive system. In particular, the thrust bearing 138 is sandwiched between the abutment or lip 150 and the abutment or lip 152.

[0013] Turning specifically to FIGS. 4A and 5, the housing components have been removed to reveal various internal features, including a collar that allows sliding of the distraction shaft 114 within the housing 112, and which also keeps the distraction shaft 114 from being able to rotate within the housing 112. This allows full stability of the bone 100. Distraction shaft 114 contains several axial grooves 166. The grooves 166 have semi-circular indentation cross-sections which allow several balls 164 to roll within them. The balls 164 are trapped within a linear ball cage 162. The splined housing 126 which fits over the balls 164 and linear ball cage 162 has axial grooves 163 (FIG. 3C) along its inner diameter surface that are similar to the axial grooves 166 of the distraction shaft 114. In this regard, the balls 164 and the ball cage 162 are interposed between the distraction shaft 114 and the splined housing 126. Therefore, the balls 164 are held in place by the linear ball cage 162, and mechanically lock the respective grooves to each other, thus impeding rotation of the distraction shaft 114 within the housing 112. However, the balls 164 are able to roll within the linear ball cage 162, thus allowing axial displacement of the distraction shaft 114 in relation to the splined housing 126 of the housing 112 with very low friction. A lip seal flange 168 contains a custom cross-section lip seal 169 (shown in FIG. 4B) which allows a sliding seal between the distraction shaft 114 and the splined housing 126, thus protecting the inner contents of the entire assembly from the body environment. The lip seal 169 includes a base portion 173, which seals against the inner diameter of the lip seal flange 168 (and thus the splined housing 126 which is attached to the lip seal flange 168). The lip seal 169 also includes protrusions 171 which slidingly seal against the axial grooves 166 of the distraction shaft 114. Inner surface 175 of the lip seal 169 slidingly seals against the overall outer diameter of the distraction shaft 114. It should also be noted that the lip seal 169 may be made from silicone, EPDM or other rubber materials, and may be coated with silicone oil, to aid in lubricity. Also, the balls, grooves and ball cage may be coated with silicone oil or a liquid perfluorinated polyether such as KRYTOX to aid in lubricity. FIG. 5 shows a portion of the magnet casing 158 removed so that the South pole 170 and North pole 172 of the cylindrical magnet 134 may be illustrated.

[0014] FIG. 6 illustrates an external adjustment device 180 which is used to non-invasively distract the intramedullary lengthening device 110 by means of a magnetic coupling which transmits torque. The external adjustment device 180 comprises a magnetic handpiece 178, a control box 176 and a power supply 174. The control box 176 includes a control panel 182 having one or more controls (buttons, switches or tactile, motion, audio or light sensors) and a display 184. The display 184 may be visual, auditory, tactile, the like or some combination of the aforementioned features. The external adjustment device 180 may contain software which allows programming by the physician. For example, the physician may desire that the patient take home the external adjustment device 180 in order that the patient or member of the patient's family or friends make daily distractions of the intramedullary lengthening device 110 implanted in the patient. However, the physician is able to keep the person operating the external adjustment device 180 from over distracting the patient by programming this into the control box 176. For example, the physician may pre-program the control 176 box so that only one (1) mm of distraction is allowed per day. The physician may additionally pre-program the control box 176 so that no more than 0.5 mm may be distracted during any two hour period, or that no more than 0.25 mm may be retracted during a five minute period. Settings such as these may serve to assure that the patient not be capable of causing severe damage to the bone or tissue, nor disrupt the lengthening process.

[0015] Preferably, such instructions or limits may be pre-programmed by the physician or even the manufacturer in a secure fashion such that user cannot alter the pre-programmed setting(s). For example, a security code may be used to pre-program and change the daily distraction limit (or other parameters). In this example, the person operating the external adjustment device 180 will not be able to distract more than one (1) mm in a day (or more than two mm in a day), and will not have the security code to be able to change this function of the external adjustment device 180. This serves as a useful lockout feature to prevent accidental over-extension of the intramedullary lengthening device 110. The safety feature may monitor, for example, rotational movement of magnets 186 of the external adjustment device 180, described in more detail below, or the safety feature may monitor rotation of the cylindrical magnet 134 in the intramedullary lengthening device 110, via non-invasive sensing means.

[0016] FIG. 7 shows the detail of the magnetic handpiece 178 of the external adjustment device 180, in order to elucidate the manner that the magnets 186 of the external device serve to cause the cylindrical magnet 134 of the intramedullary lengthening device 110 to turn. As seen in FIG. 7, there are two (2) magnets 186 that have a cylindrical shape. The magnets 186 are made from rare earth magnets. The magnets 186 may have the same radial two pole configuration as the cylindrical magnet 134 seen in FIG. 5. The magnets 186 are bonded or otherwise secured within magnetic cups 187. The magnetic cups 187 include a shaft 198 which is attached to a first magnet gear 212 and a second magnet gear 214, respectively. The orientation of the poles of each the two magnets 186 are maintained in relation to each other by means of the gearing system (by use of center gear 210, which meshes with both first magnet gear 212 and second magnet gear 214). For example, it may be desired that the south pole of one of the magnets 186 is facing up whenever the south pole of the other magnet 186 is facing down. This arrangement, for example, maximizes the torque that can be placed on

the cylindrical magnet 134 of the intramedullary lengthening device 110.

[0017] The components of the magnetic handpiece 178 are held together between a magnet plate 190 and a front plate 192. Most of the components are protected by a cover 216. The magnets 186 rotate within a static magnet cover 188, so that the magnetic handpiece 178 may be rested directly on the patient, while not imparting any motion to the external surfaces of the patient. Prior to distracting the intramedullary lengthening device 110, the operator places the magnetic handpiece 178 over the patient near the location of the cylindrical magnet 134 as seen in FIG. 9. A magnet standoff 194 that is interposed between the two magnets 186 contains a viewing window 196, to aid in the placement. For instance, a mark made on the patient's skin at the appropriate location with an indelible marker may be viewed through the viewing window 196. To perform a distraction, the operator holds the magnetic handpiece 178 by its handles 200 and depresses a distract switch 228, causing motor 202 to drive in a first direction. The motor 202 has a gear box 206 which causes the rotational speed of an output gear 204 to be different from the rotational speed of the motor 202 (for example, a slower speed). The output gear 204 then turns a reduction gear 208 which meshes with center gear 210, causing it to turn at a different rotational speed than the reduction gear 208. The center gear 210 meshes with both the first magnet gear 212 and the second magnet gear 214 turning them at a rate which is identical to each other. Depending on the portion of the body where the magnets 186 of the external adjustment device 180 are located, it is desired that this rate be controlled, to minimize the resulting induced current density imparted by magnet 186 and cylindrical magnet 134 through the tissues and fluids of the body. For example a magnet rotational speed of 60 RPM or less is contemplated although other speeds may be used such as 35 RPM or less. At any time, the distraction may be lessened by depressing the retract switch 230. For example, if the patient feels significant pain, or numbness in the area being lengthened.

[0018] A cross section of a patient's lower thigh 218 with the intramedullary lengthening device 110 implanted within the femur 220 is shown in FIGS. 8 and 9. In FIG. 9, the magnetic handpiece 178 of the external adjustment device 180 is shown in position to adjust the cylindrical magnet 134 of the intramedullary lengthening device 110. In FIG. 8, however, a scale depiction of a prior art magnetic stator "donut" 222 demonstrates the comparative efficiency of the two designs (FIG. 8 illustrates an intramedullary lengthening device 110 of the type described herein placed in a "prior art" magnetic stator "donut" 222). The prior art magnetic stator "donut" 222 is large, expensive, and difficult to transport to a patient's home for daily adjustments. In addition, the use of a circular cross-section as a one-size-fits-all device is not very efficient because of several reasons: the cross section of most limbs is not circular, the bone is usually not centered within the limb and patients' limbs come in many different sizes. In FIG. 8, the thigh has been placed through the circular hole in the magnetic stator "donut" and the posterior portion 232 of the thigh rests at the lower portion 226 of the magnetic stator "donut" 222. The strength of a magnetic field decreases in accordance with a power (such as the inverse square) of the distance, depending on the complexity of the specific field geometry. Therefore, in any magnetic design, making the distance between the driving magnetic field and the driven magnet as small as possible is desirable. The size of the patient's lower thigh 218

and the decision to how it is placed within the magnetic stator "donut" 222 in FIG. 8 create a geometry so that the distance L_1 between the cylindrical magnet 134 and the upper portion 224 of the magnetic stator "donut" 222 is about the same as the distance L_2 between the cylindrical magnet 134 and the lower portion 226 of the magnetic stator "donut" 222. However, if the anterior portion 234 of the thigh were instead placed against the upper portion 224 of the magnetic stator "donut" 222, the length L_1 would become less while the length L_2 would become greater. Because each patient has a different sized limb, and because small limbs like the upper arm as well as large limbs such as the upper leg are desired for treatment, the magnetic stator "donut" 222 of FIG. 8 is almost impossible to optimize. Therefore, an extra large magnetic field needs to be generated as the standard magnetic field of the device, thus requiring more expense (for the hardware to power this larger field). This in turn means that each patient will be exposed to a larger magnetic field and larger tissue and fluid current density than is really required. It may be desired to maintain patient exposure to magnetic fields of 2.0 Tesla or less during operation of the device. It may also be desired to maintain patient exposure of the patient's tissues and fluids to current densities of no more than 0.04 Amperes/meters² (rms). In addition, because the intramedullary lengthening device 110 is secured to the bone 100, unnecessarily large magnetic fields may cause unwanted motion of the bone 100, for example in any of the radial directions of the cylindrical magnet 134. If the magnetic field is too high, the patient's leg may be moved out of ideal position, and may even cause the patient some annoyance, including pain.

[0019] The configuration of the magnetic handpiece 178 of the external adjustment device 180 as shown in FIG. 9 optimizes the ability of the magnets 186 to deliver torque to the cylindrical magnet 134 of the intramedullary lengthening device 110, without exposing the patient to large magnetic fields. This also allows the cylindrical magnet 134 of the intramedullary lengthening device 110 to be designed as small as possible, lowering the implant profile so that it may fit into the humerus, or the tibia and femurs of small stature patients, such as those who might desire cosmetic limb lengthening. As mentioned, a 9 mm diameter intramedullary lengthening device can deliver 100 lb. distraction force, and even 8 mm and 7 mm devices are contemplated. The alternating orientation of the two magnets 186 (i.e., north pole of one magnet 186 corresponding with south pole of the other magnet 186) creates an additive effect of torque delivery to cylindrical magnet 134, and thus maximizes distraction force for any specific cylindrical magnet 134 size. Also, the separation (S) between the centers of the two magnets 186 (for example 70 mm), and the resulting concave contour 238 (FIGS. 6 and 7), match with the curvature of the outer surfaces of the majority of limbs, thus making the distances L_3 and L_4 between each of the magnets 186 and the cylindrical magnet 134 as small as possible. This is especially aided by the concave contour 238 of the magnetic handpiece 178. Also, skin and fat may be compressed by the magnet covers 188 causing an indentation 236 on one or both sides which allows the distances L_3 and L_4 between each of the magnets 186 and the cylindrical magnet 134 to be yet smaller.

[0020] FIG. 10 illustrates a sterilizable kit 400 containing a plurality of extension rods 406 which are configured to be attached to an actuator 412 (FIG. 11) in order to construct a

modular intramedullary lengthening device 410 (FIG. 11). In a one example, the actuator 412 is supplied sterile, and the extension rods 406 and the remainder of the contents of the sterilizable kit 400 are sterilizable by autoclave (e.g., steam), Ethylene Oxide or other methods known to those skilled in the art. The sterilizable kit 400 contents includes one or more of the extension rods 406 and accessories 408 for use in the insertion, attachment, adjustment and removal of the modular intramedullary lengthening device 410. The contents are located within a first sterilizable tray 402 and a second sterilizable tray 404. Second sterilizable tray 404 and first sterilizable tray 402 have a plurality of holes 405 to allow gas to enter. Other items in the kit 400 will be described in several of the following figures.

[0021] Turning to FIG. 11 the assembly of the modular intramedullary lengthening device 410 is shown. The actuator 412 is designed to be placed in the bone of the patient in the opposite orientation than that of the intramedullary lengthening device 110 of FIG. 1. Therefore, the distraction shaft 413 is orientated towards the distal end of the bone (distal is the down direction of FIG. 11). Distal screw holes 415 in the distraction shaft 413 allow the placement of distal locking screws 420. The distal locking screws 420 (FIGS. 21A and 21B) have proximal threads 417 for engaging the bone, while the remainder of the shaft 419 of the distal locking screws 420 is of a constant diameter for maximum strength and stability. At the proximal end 421 of the actuator 412 there is a hexagonally-shaped male hub 414 containing a transverse set screw 416, within a threaded hole 429 of the hexagonal male hub 414 (FIG. 12). The extension rod 406 (FIGS. 13 and 14) has a corresponding hexagonal hole 428 or female end into which the hexagonal male hub 414 of the actuator 412 is placed. The transverse set screw 416 is nested within the threaded hole 429 of the hexagonal male hub 414 so that it does not interfere with the hexagonal hole 428 of the extension rod 406, when they are placed together. There are two set screw holes 422 in the wall of the extension rod 406 which are in line with each other. The actuator 412 and extension rod 406 are placed together so that the set screw holes 422 extend coaxially with the set screw 416. This allows a male hex 490 of a set screw tightening driver, such as the torque limiting driver 488 of FIGS. 10 and 17, to be inserted into a hex hole of the set screw 416. When the torque limiting driver 488 is tightened and ratchets at its set control torque, the other end of the set screw 416, which is either threaded or a non threaded peg, inserts into the opposite set screw hole 422, thus tightly securing the actuator 412 to the extension rod 406. The set screw holes 422 are sized to allow the male hex 490 to smoothly clear, but the non-threaded peg of the set screw 416 clear very slightly, making a static connection that cannot be easily loosened during implantation. If desired, bone cement may be placed in annulus of set screw hole 422, to even further bond set screw 416. Also, a second screw may be screwed in behind the head of the set screw into the female thread that the set screw 416 was originally nested in. The head of this second screw will add additional resistance to shear failure of the set screw 416. In addition, the second screw can be tightened so that it jams into the set screw 416, thus making back-out of the set screw 416 unlikely. Any non-circular cross-section may be used in place of the hex cross-section, for example a square or oval cross-section.

[0022] Proximal locking screws 418 insert through locking screw holes 430 in the extension rod 406. The extension rod 406 may be straight, or may have a specific curve 432, for example,

for matching the proximal end of the femur or tibia. It can be appreciated that the modular arrangement allows the actuator 412 to be attached to one of numerous different models of extension rods 406, having different lengths, curves (including straight), diameters, hole diameters, and angulations. The first sterilization tray 402 may include many of these different extension rods 406, which may be selected as appropriate, and attached to the actuator 412. Because the actuator 412 is supplied sterile, this arrangement is also desirable, as only a single model need be supplied. However, if desired, several models of actuator may exist, for example, different diameters (10.5 mm, 12.0 mm, 9 mm, 7.5 mm) or with different distal screw hole diameters, configurations or angulations. The preferred configuration for a multitude of patients and different bone types and sizes can be available, with a minimum number of sterile actuator models.

[0023] Turning to FIG. 15, a proximal drill guide 434 is illustrated and is configured for attaching to the modular intramedullary lengthening device 410 to ease its insertion into the intramedullary canal, the drilling of holes in the bone and the attachment of the proximal locking screws 418 to the bone. The proximal drill guide 434 comprises an extension arm 436 attached to a connection tube 446 through which a locking rod 448 is inserted. The locking rod 448 has a locking knob 450 at the proximal end and a male thread 452 at the distal end. In order to temporarily attach the proximal drill guide 434 to the modular intramedullary lengthening device 410, a locking tab 454 of the proximal drill guide 434 is inserted into a locking groove 424 of the extension rod 406 and the locking knob 450 is turned, threading the male thread 452 of the locking rod 448 into a female thread 426 of the extension rod 406. Prior to the procedure a drill guide extension 438 is attached via a knob 440 to the extension arm 436. After reaming the medullary canal of the bone to a diameter slightly larger than the outer diameter of the modular intramedullary lengthening device 410 (for example 11 mm), distal end of the modular intramedullary lengthening device 410 is inserted into the medullary canal and the flat proximal surface of the locking knob 450 is hammered with a mallet, allowing the modular intramedullary lengthening device 410 to be inserted to the correct depth. Dimension X is sufficient to clear large thighs or hips (in the worst case femoral application). For example, 8 to 10 cm is appropriate. Once the modular intramedullary lengthening device 410 is in place in the medullary canal, the proximal drill guide 434 is left attached and a guide sleeve 442 is placed through one of the holes 456, 458, 460, 462 and slid so that the distal end 443 reaches the skin of the patient. The drill guide extension 438, extension arm 436 and holes 456, 458, 460, 462 are dimensioned and oriented so that the guide sleeve 442 is oriented at the exact angle to allow drilling and placement of screws through the locking screws holes 430 of the extension rod 406 and through the bone. The skin of the patient is cut and a drill bushing 444 is placed through the incision, with the tapered tip 445 passing through tissue and reaching the bone to be drilled. For example, drills and locking screws may be inserted down the drill bushing 444, or alternatively, drills may be inserted down the drill bushing 444 and then, after the drilling is complete, the drill bushing 444 is removed and proximal locking screw 418 is inserted down the guide sleeve 442. Alternative guide sleeves 464 and drill bushings 466 can be placed through holes 460 and 462, as seen in FIG. 10.

[0024] Turning to FIG. 16, a removal tool 468 is illustrated. The removal tool 468 is used after

the distraction period and consolidation period are complete. To remove the modular intramedullary lengthening device 410 from the medullary canal, the skin is incised and bone exposed at the locations of the proximal and distal locking screws 418, 420 and at the proximal end of the modular intramedullary lengthening device 410. A removal rod 470 is connected to the female thread 426 of the extension rod 406 of the modular intramedullary lengthening device 410 by inserting the engagement tip 476 and screwing the male thread 474 into the female thread 426, holding onto the locking knob 472. The locking knob 472 contains a female thread 478 which allows the attachment of a male thread 486 of a removal extension 480, which has an impact knob 482 and removal hammer 484. The male thread 486 is coupled to the removal extension 480 by a pivot 477 of a pivoting base 479. The male thread 486 is secured to the female thread 478 by grasping and turning the impact knob 482. Prior to removing the modular intramedullary lengthening device 410, the proximal and distal locking screws 418, 420 are removed. They may be removed with the use of the locking screw driver 498 (FIGS. 10 and 20), which has a male hex tip 497 to engage the proximal ends of the locking screws 418, 420. A screw capture rod 500 (FIGS. 10 and 20) inserts down the center of the locking screw driver 498 and has a male threaded tip 501. At a deeper portion past the female hex 513 in the locking screws 418, 420 (FIGS. 21A and 21B) is a female thread 511. The male threaded tip 501 of the screw capture rod 500 threads into the female thread 511 of the locking screws 418, 420, and tightened by using the tightening handle 503 of the screw capture rod 500 which sits at the handle end 509 of the locking screw driver 498 so that once the locking screws 418, 420 are removed from the bone, they are still secured to the locking screw driver 498, and will not become prematurely displaced. For example, the locking screws 418, 420 will not be lost or dropped into the patient. The modular intramedullary lengthening device 410 may now be removed from the medullary canal by grasping the removal hammer 484, and moving it quickly in the direction (D) so that hammer impact surface 485 strikes knob impact surface 483. This is done until the modular intramedullary lengthening device 410 is completely removed. It should be noted that locking knob 450 of the proximal drill guide 434 of FIG. 15 also has a female thread (not pictured) so that during the insertion of the modular intramedullary lengthening device 410, if it is desired to remove the device for any reason, the male thread 486 of the removal tool 468 may be attached to the female thread of the locking knob 450, and the removal hammer 484 can be used against the impact knob 482 to remove the modular intramedullary lengthening device 410.

[0025] The torque limiting driver 488 of FIG. 17 comprises a handle 496 and a shaft 492 having a torque-specific ratchet 494 connecting them. The male hex tip 490, fits into the hex hole of the set screw 416, or even into the female hex 513 of the locking screws 418, 420. An exemplary ratcheting torque for the set screw 416 is 9 inch-pounds (1.0 Newton-meter), and an exemplary hex size is 1/16" (1.59 mm).

[0026] FIG. 18 illustrates the actuator 412 of FIG. 11 in a sectional view. The distal screw holes 415 are visible in the distraction shaft 413. The distraction shaft 413 is shown in a fully extended position in relation to the housing 312. The cavity 337 has opened to its maximum length. In this embodiment, the distraction shaft 413 has a purely cylindrical surface, and is dynamically sealed to the housing 312 by two o-ring seals 502. The o-ring seals 502 may be

made of silicone, EPDM, or other rubber materials, and may be coated with silicone oil, to aid in lubricity. There are four axially extending grooves 326 on the inner wall of the housing 312. Tabs 504 on the end of the distraction shaft 413 fit into these grooves 326 to keep the distraction shaft 413 from being able to rotate with respect to the housing 312. The housing 312 is welded to a magnet housing 328 and the magnet housing 328 is welded to hexagonal male hub 414. The set screw 416 on the hexagonal male hub 414 is used to attach the actuator 412 to the extension rod 406. The cylindrical permanent magnet 334 is cased with epoxy inside magnet casing 358 having an end pin 360. The end pin 360 inserts through radial bearing 332, allowing it to rotate with low friction. As the magnet 334 is rotated by the external magnets, first planetary gear set 354, second planetary gear set 356 and third planetary gear set 357 allow a total reduction of 64:1 ($4 \times 4 \times 4$). Each gear set allows a 4:1 reduction. Planetary gear output shaft 344 is attached to lead screw 336 by locking pin 342, and locking pin 342 is held in place by cylindrical locking pin retainer 348. Thrust bearing 338 abuts housing abutment or lip 352 and magnet housing abutment or lip 350 (thrust bearing 338 is sandwiched between housing abutment or lip 352 and magnet housing abutment or lip 350). Therefore, thrust bearing 338 abuts housing abutment or lip 352 in tension and magnet housing abutment or lip 350 in compression. It should be noted that the sandwich arrangement allows for some slop or play between the thrust bearing 338 and the housing abutment or lip 352 and the magnet housing abutment or lip 350. Lead screw 336 engages with nut 340, which is secured within distraction shaft 413. With the 64:1 gear reduction of this embodiment, distraction forces of greater than 1334 Newtons (300 pounds) have been consistently achieved with a gap (G in FIG. 19) of 5.08 cm (2 inches) between the magnetic hand piece 178 and the intramedullary lengthening device 110. This is sufficient for distracting a large range of typical patients.

[0027] It should be noted that although the intramedullary lengthening devices presented are shown to be used in a preferred orientation (distal vs. proximal), any of these devices may be used with the distraction shaft pointing distally or proximally. In addition, the invention may also be applied to distractable bone plates that are not located within the intramedullary canal, but are external to the bone.

[0028] An alternative lengthening scheme than those presented above may be also used. For example, one alternative includes the purposeful over-lengthening (to further stimulate growth) followed by some retraction (to minimize pain). For instance, each of four daily 0.25 mm lengthening periods may consist of 0.35 mm of lengthening, followed by 0.10 mm of retraction.

[0029] The materials of the accessories 408 are medical grade stainless steel, though other materials of varying densities may be used depending on the desired weight and the required size. The majority of the components of the intramedullary lengthening devices are preferably Titanium or Titanium alloys although some of the internal components may be made from stainless steel.

[0030] While embodiments of the present invention have been shown and described, various modifications may be made without departing from the scope of the present invention. As one

example, the devices described herein may be used to lengthen or reform a number of other bones such as the mandible or the cranium. The invention, therefore, should not be limited, except to the following claims.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

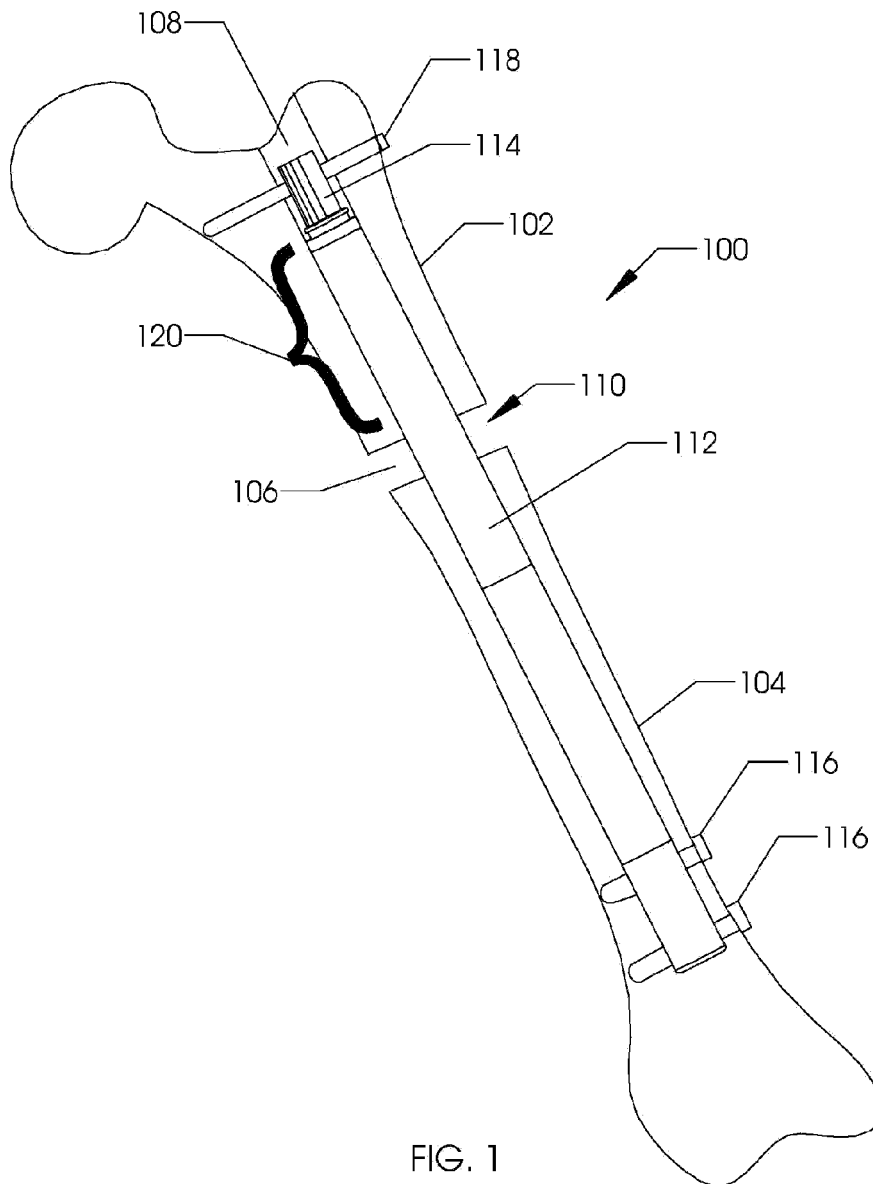
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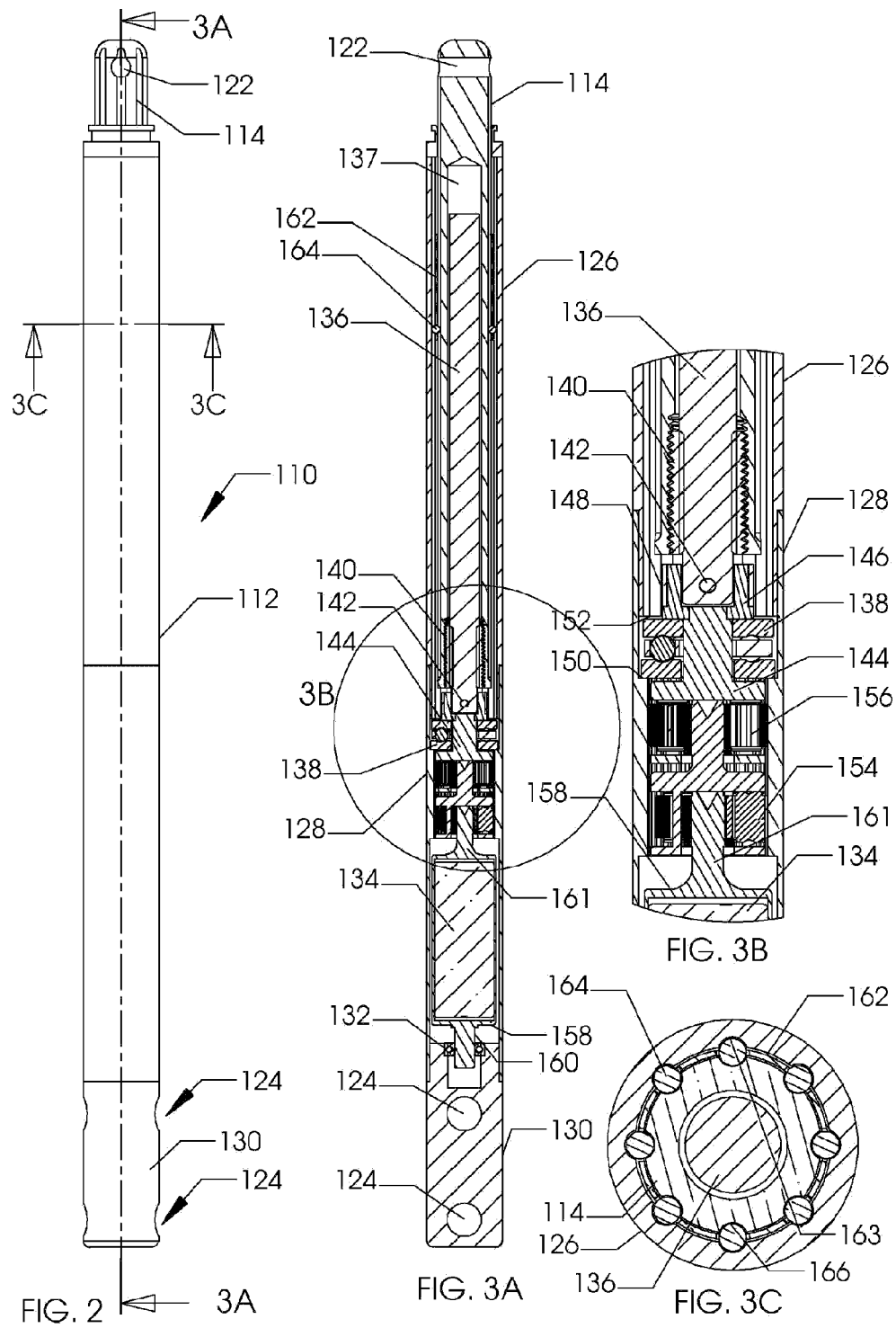
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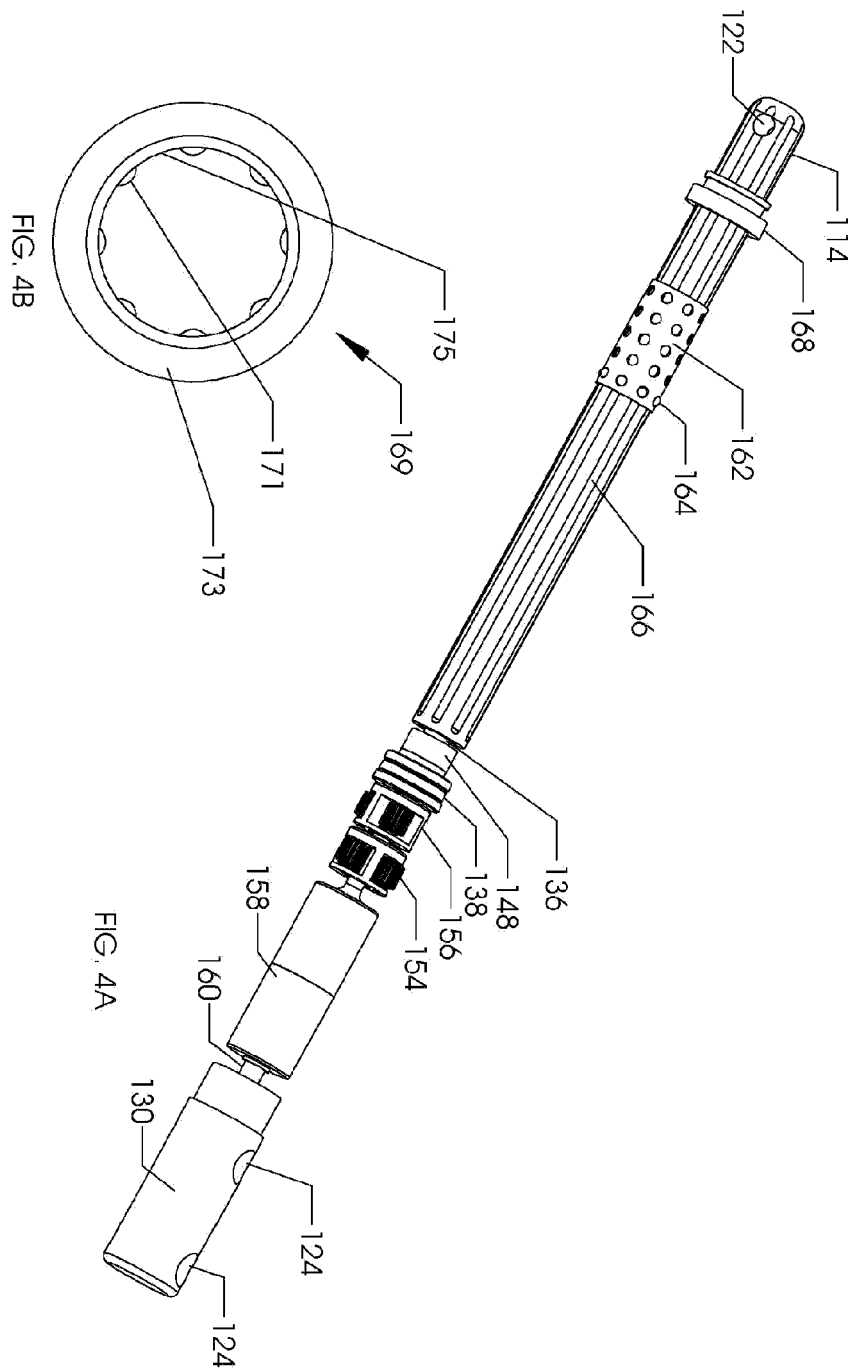
1. Forlængelsesindretning (110) konfigureret til placering inden i eller på tværs af knogle, som har første (102) og anden (104) separate sektioner, omfattende:
et hus (112), som er konfigureret til fastgørelse til en af den første (102) og anden (104) separate knoglesektioner;
en strækningsaksel (114), som har et indvendigt hulrum langs en længde deraf og er konfigureret til fastgørelse til den anden af den første (102) og anden (104) separate knoglesektion;
en permanent magnet (134), som er konfigureret til rotation i forhold til huset (112), og som har mindst to poler, den permanente magnet (134) er operativt koblet til en ledeskruer (136), ledeskruen (136) er i kontakt med en gevindskåret del af strækningsakslens (114) indre hulrum; **kendetegnet ved at**
en indvendig væg i huset (112) indbefatter et første fæste (150) og et anden fæste (152); og ved at forlængelsesindretningen yderligere omfatter et aksialleje (138), som er anbragt i huset (112) og er indskudt mellem ledeskruen (136) og den permanente magnet (134), aksiallejet (138) er klemmt inde mellem det første fæste (150) og det anden fæste (152).
2. Forlængelsesindretning (110) ifølge krav 1, hvori rotation af den permanente magnet (134) i en første retning gennem flere rotationer bevirker, at ledeskruen (136) anbringes i kompression og bevirker at aksiallejet (138) har tendens til at bevæge sig eller faktisk bevæger sig i en første aksial retning og kommer i kontakt med det første fæste (150), og hvori rotationen af den permanente magnet (134) i en anden retning gennem flere rotationer bevirker, at ledeskruen (136) anbringes trækpåvirket, og bevirker at aksiallejet (138) har tendens til at bevæge sig eller faktisk bevæger sig i en anden aksial retning, modsat den første aksiale retning, og kommer i kontakt med det anden fæste (152).
3. Forlængelsesindretning (110) ifølge krav 1, yderligere omfattende flere mellemliggende tandhjul, som er anbragt mellem den permanente magnet og ledeskruen.
4. Forlængelsesindretning ifølge krav 3, yderligere omfattende en ledeskruerkoblingsanordning (146), som er fastgjort til en udgangsaksel (144) på mindst ét af de flere tandhjul (154), hvori ledeskruen (136) er fastgjort til ledeskruerkoblingsanordningen (146).

5. Forlængelsesindretning ifølge krav 4, hvori ledeskruen (136) er fastgjort til ledeskruekoblingsanordningen (146) via en låsestift (142).
6. Forlængelsesindretning (110) ifølge krav 1, hvori strækningsakslen (114) omfatter første flere langsgående riller (166) placeret på en ydre overflade deraf, og en indre overflade af huset omfatter anden flere langsgående riller (166), og hvori en kugleholder (162) indeholdende en flere kugler (164), som er konfigurerede til at rulle inden i de første og anden langsgående riller (166), er placeret mellem strækningsakslen (114) og huset (112).
7. Forlængelsesindretning (110) ifølge krav 1, yderligere omfattende en ekstern justeringsindretning (180), som omfatter mindst en roterbar permanent magnet (186).
8. Forlængelsesindretning (110) ifølge krav 7, hvori den eksterne justeringsindretning (180) omfatter to roterbare permanente magneter (186).
9. Forlængelsesindretning (110) ifølge krav 7 og 8, hvori betjeningen af den eksterne justeringsindretning (180) ved et mellemrum på 5,08 cm fra huset (112) genererer en strækningskraft på mere end 1334 Newton.

DRAWINGS







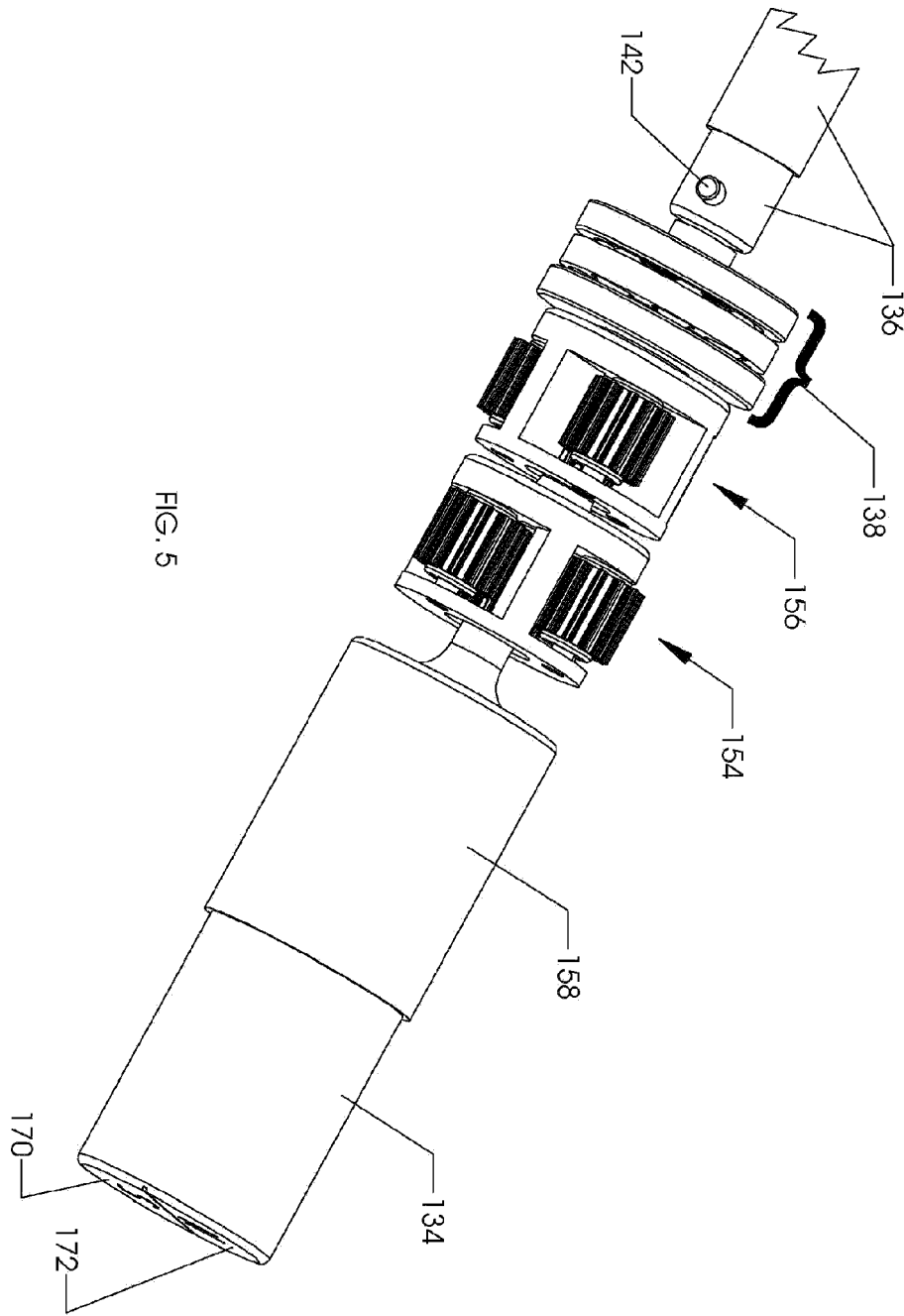
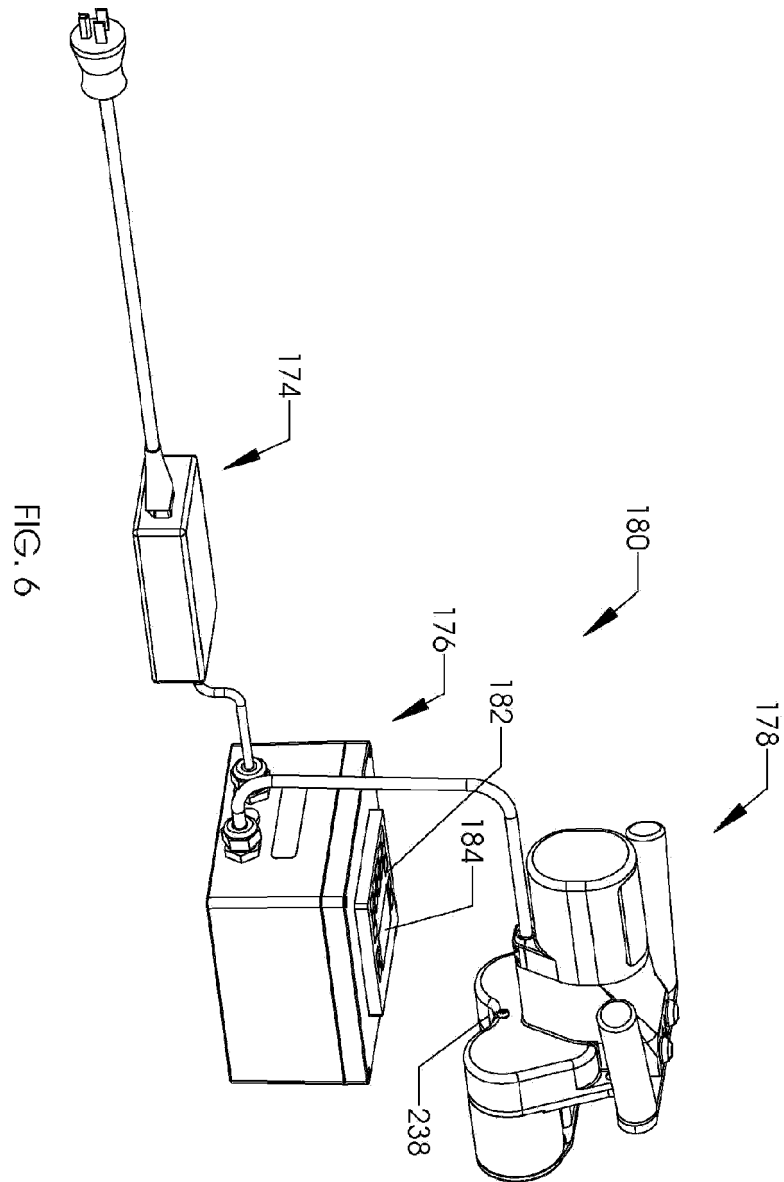
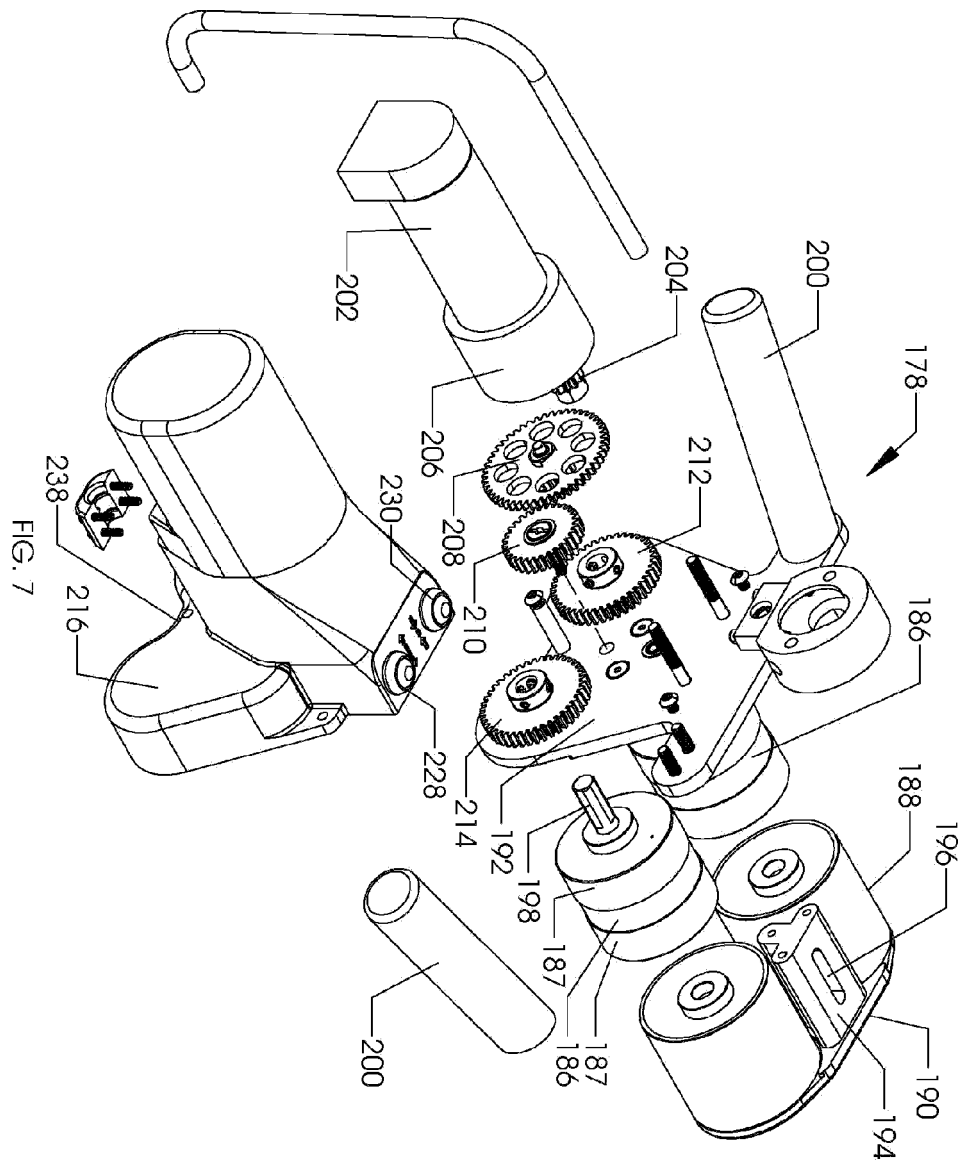
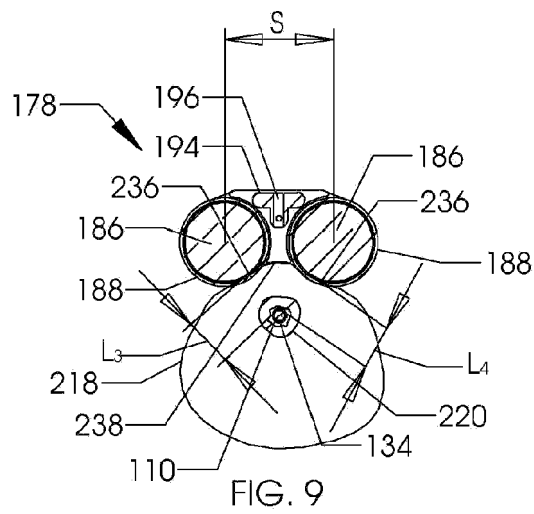
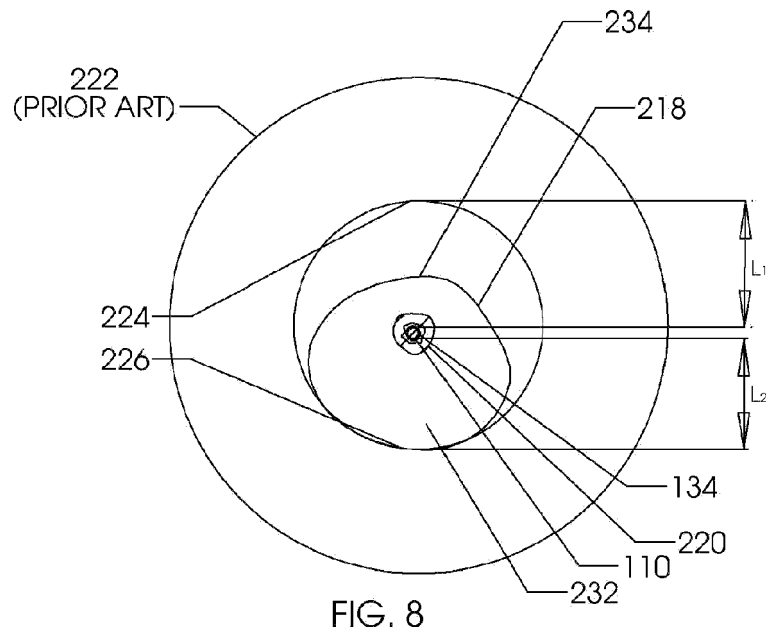
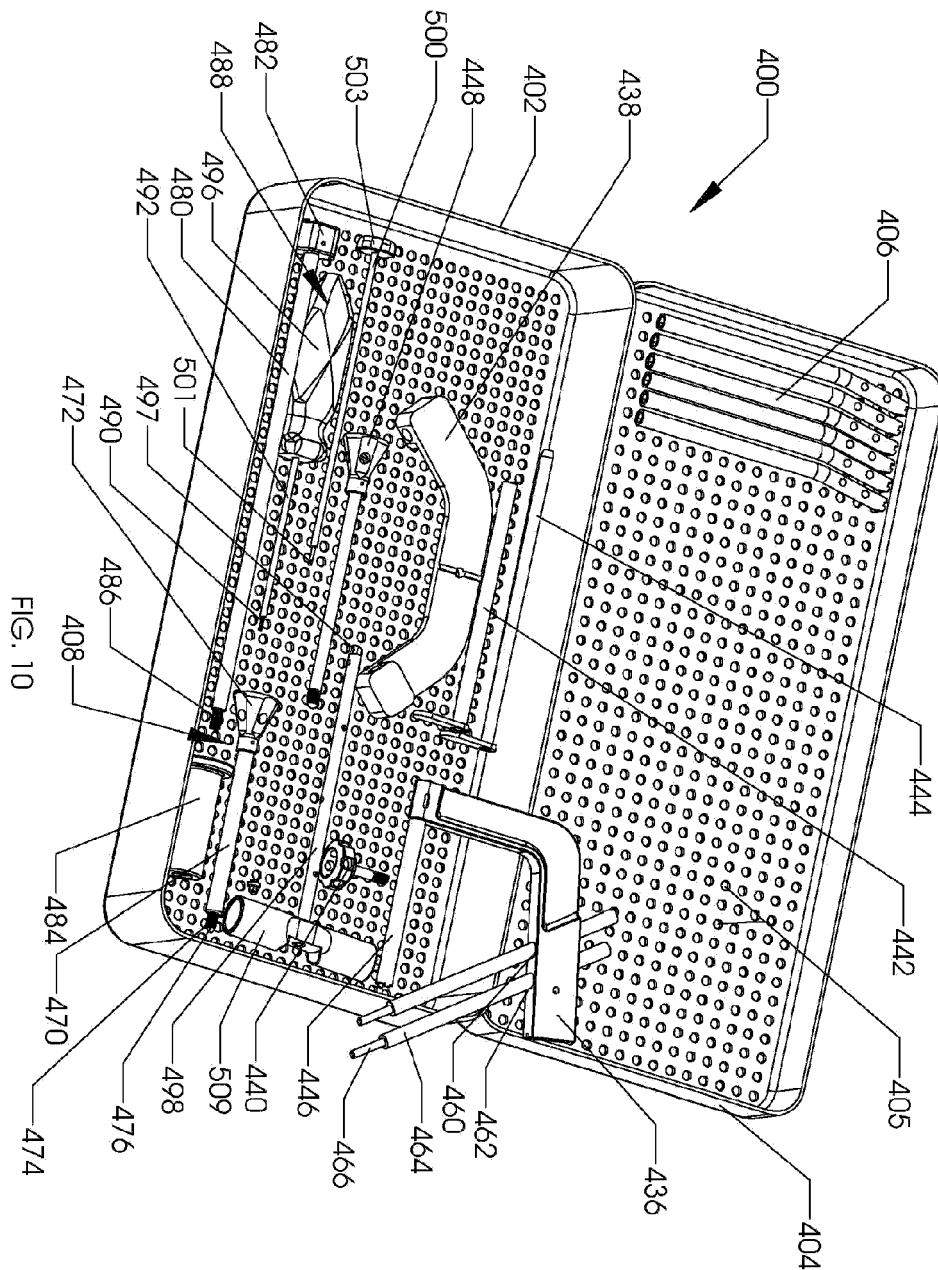


FIG. 5









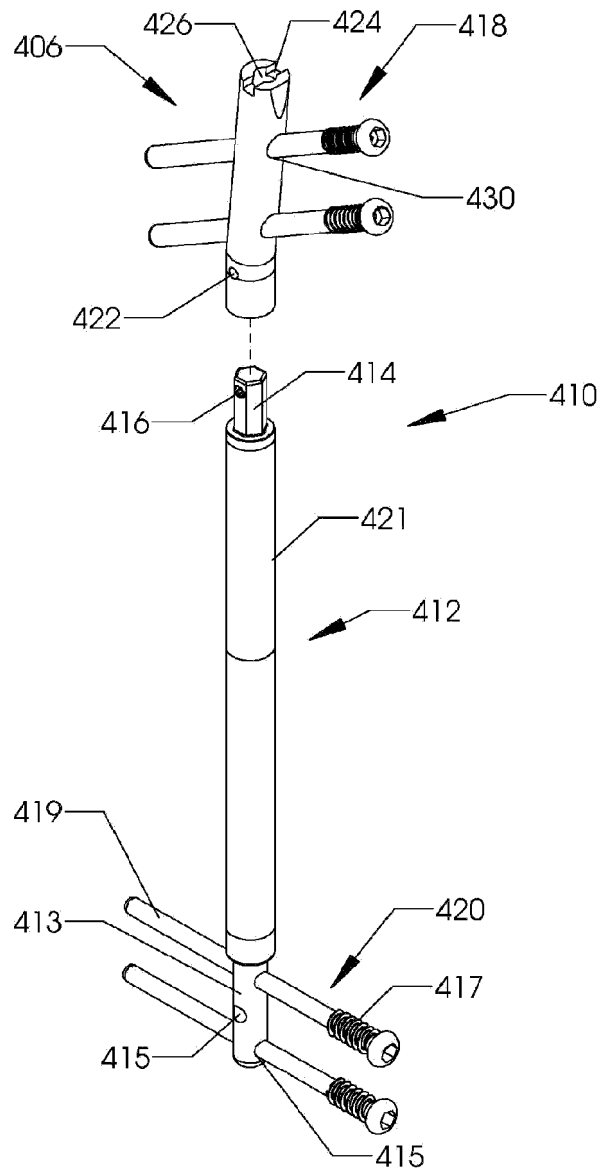
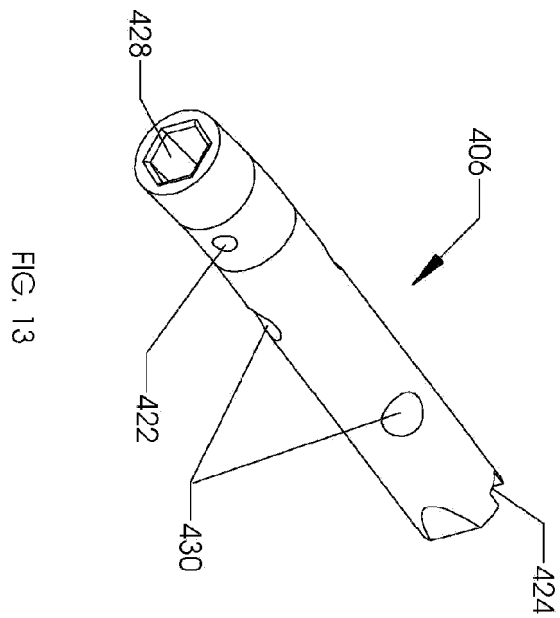
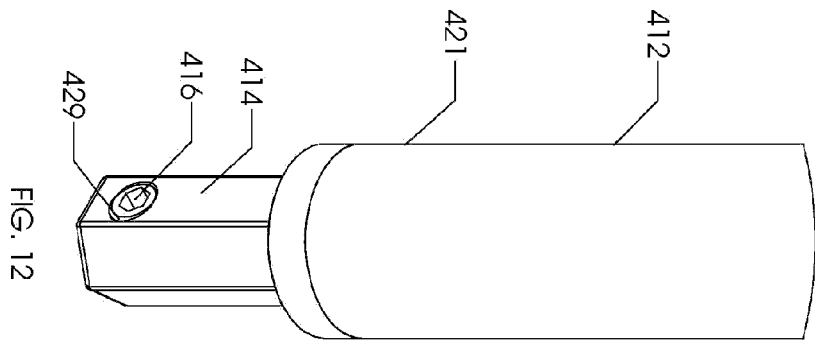
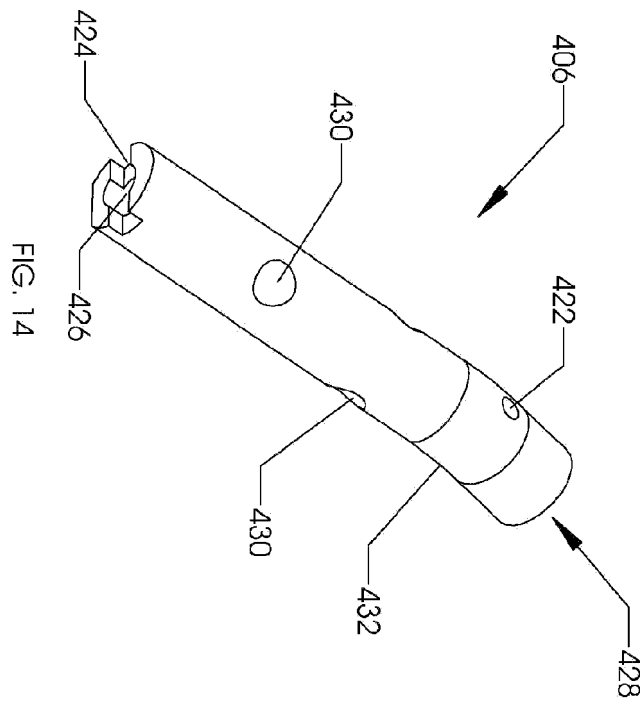
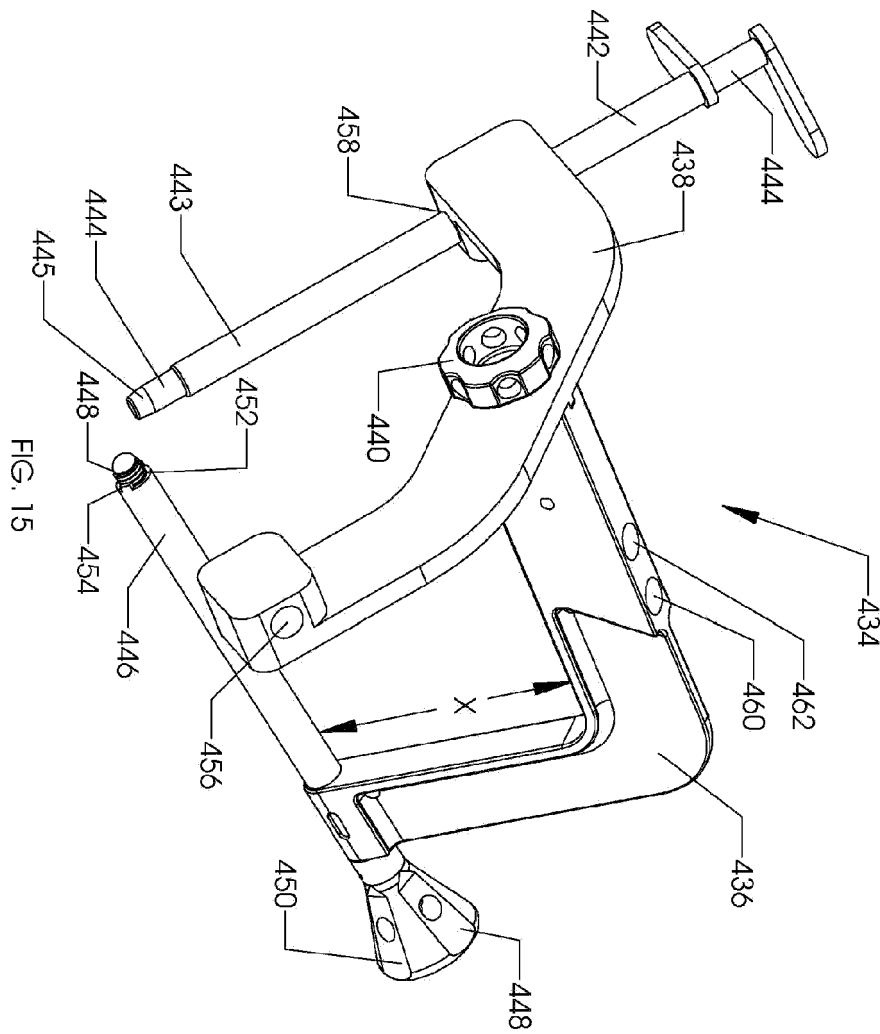


FIG. 11







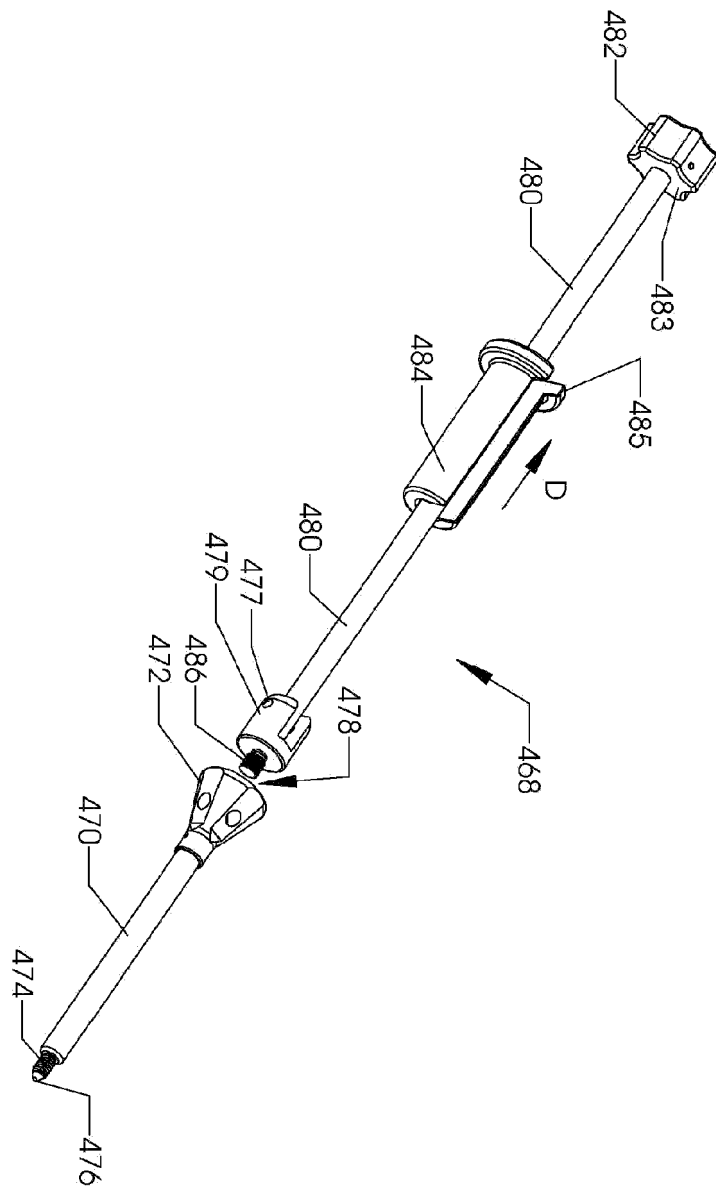


FIG. 16

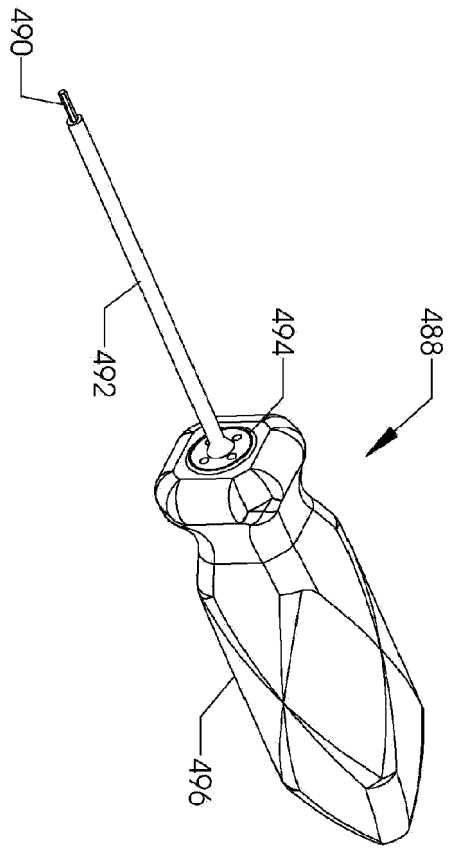


FIG. 17

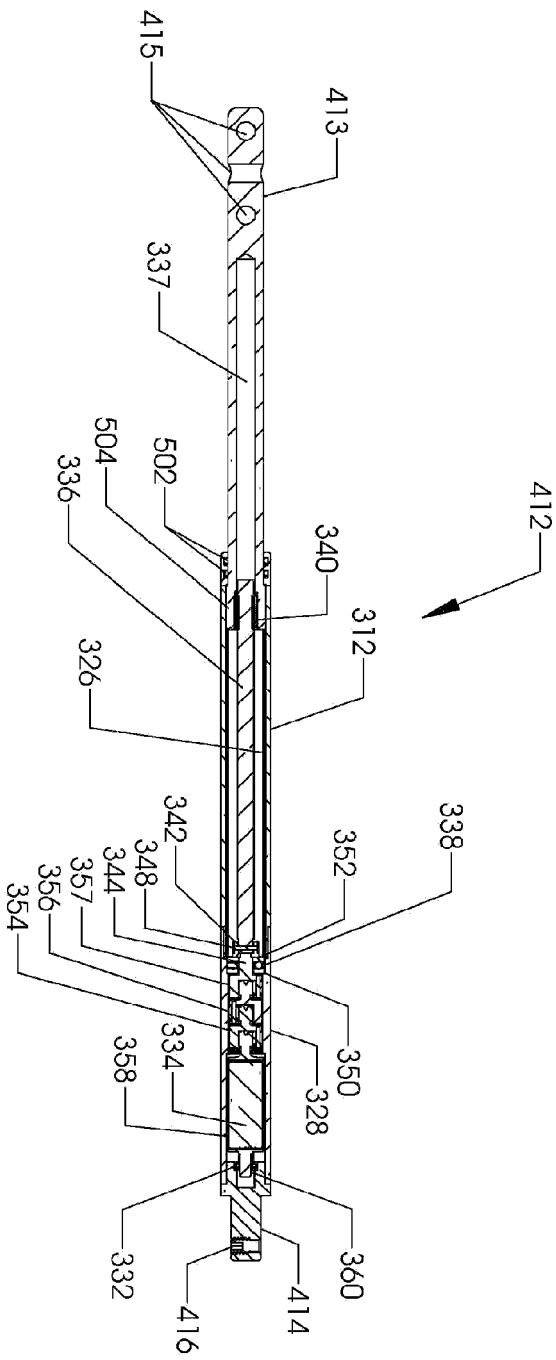


FIG. 18

