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(54) **INTRAMEDULLARY IMPLANTS FOR REPLACING LOST BONE**

(71) Applicant: **NuVasive Specialized Orthopedics, Inc.**, San Diego, CA (US)

(72) Inventors: **Scott Pool**, Laguna Hills, CA (US); **Blair Walker**, Mission Viejo, CA (US)

(73) Assignee: **NuVasive Specialized Orthopedics, Inc.**, San Diego, CA (US)

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(58) **Field of Classification Search**
CPC ... A61B 17/7216; A61B 17/84; A61B 17/846; A61B 17/86; A61B 17/8872
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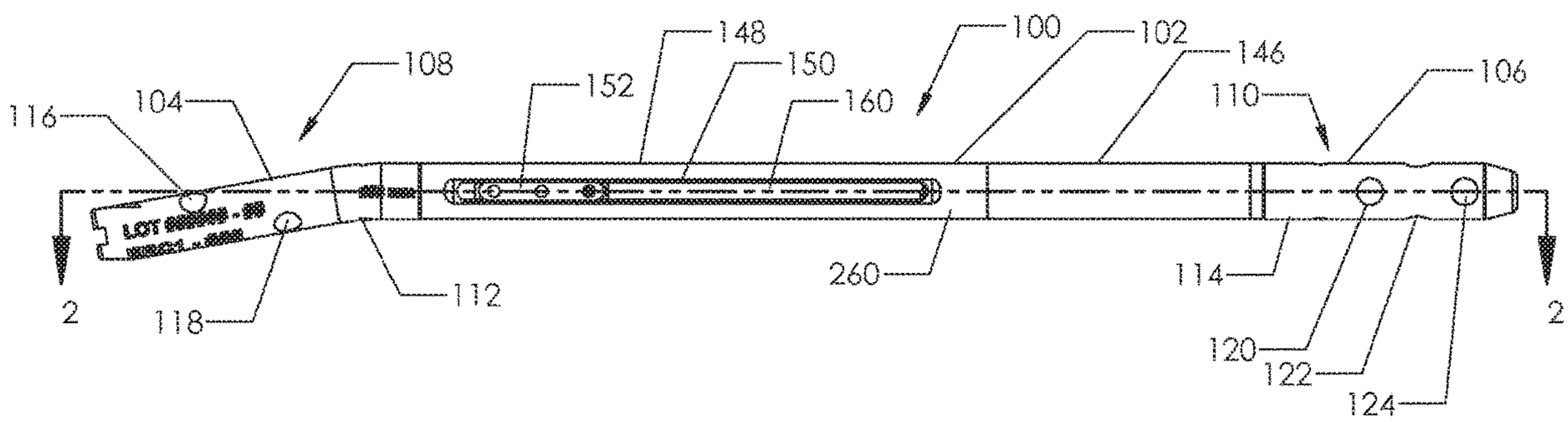
(57) **ABSTRACT**

A bone transport system includes a nail having a proximal end and a distal end, the proximal end configured for securing to a first portion of bone, the distal end configured for securing to a second portion of bone. The system includes a housing having a wall with a longitudinal opening extending a length along a portion thereof. The system further includes a transport sled having a length that is shorter than the length of the longitudinal opening, the transport sled configured for securing to a third portion of bone, the transport sled further configured to be moveable along the longitudinal opening. The system further includes a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein actuation of the magnetic assembly moves the transport sled along the longitudinal opening. The system further includes a ribbon extending on opposing sides of the transport sled and substantially covering the longitudinal opening.

20 Claims, 16 Drawing Sheets



Related U.S. Application Data

application for the reissue of Pat. No. 9,770,274, which is a continuation of application No. 14/451,190, filed on Aug. 4, 2014, now Pat. No. 9,421,046, which is a continuation of application No. 13/655,246, filed on Oct. 18, 2012, now Pat. No. 9,044,281.

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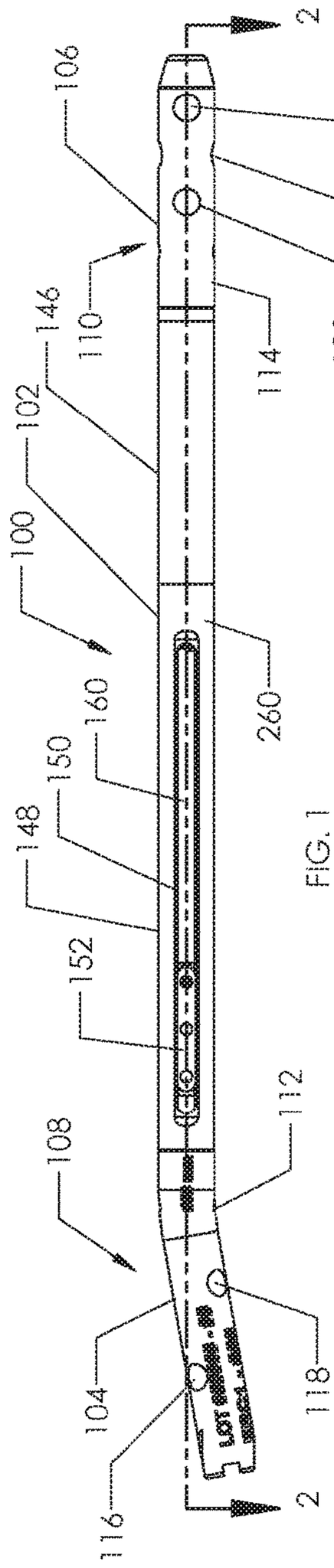


FIG. 1

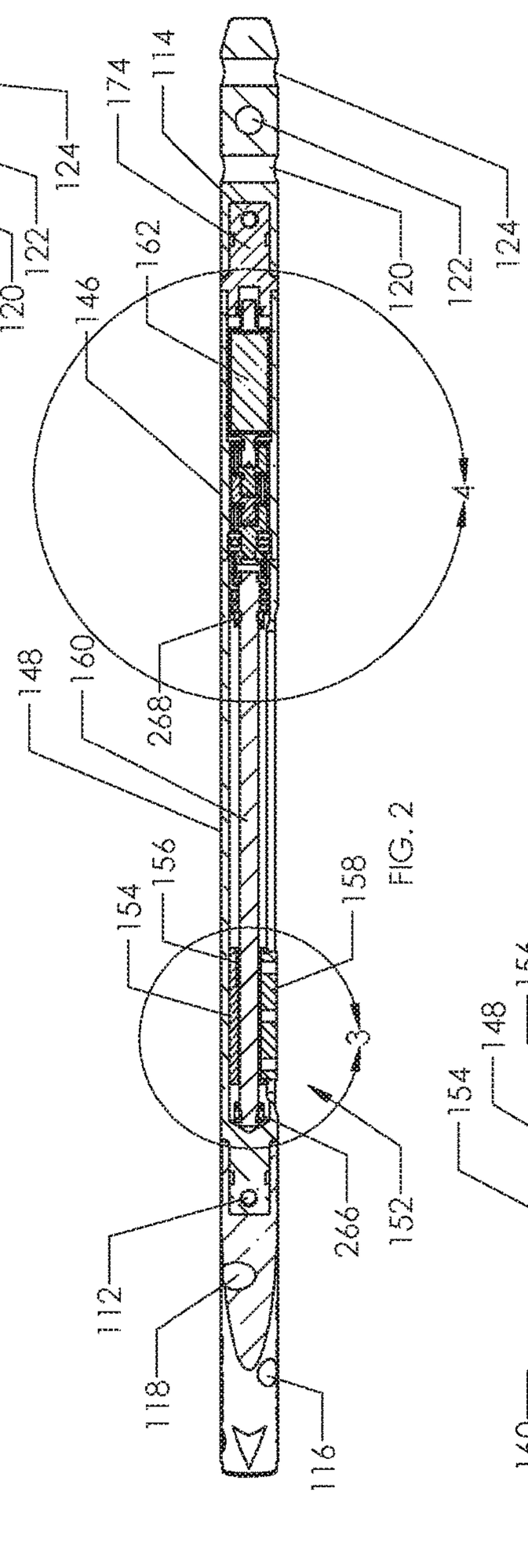
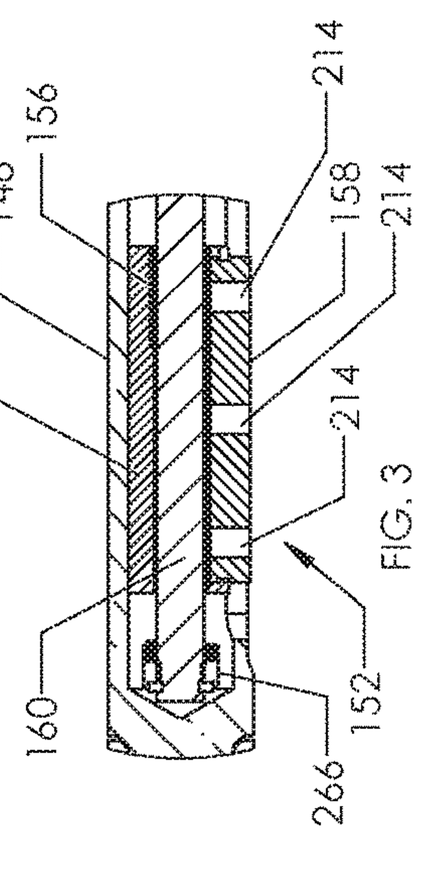


FIG. 2



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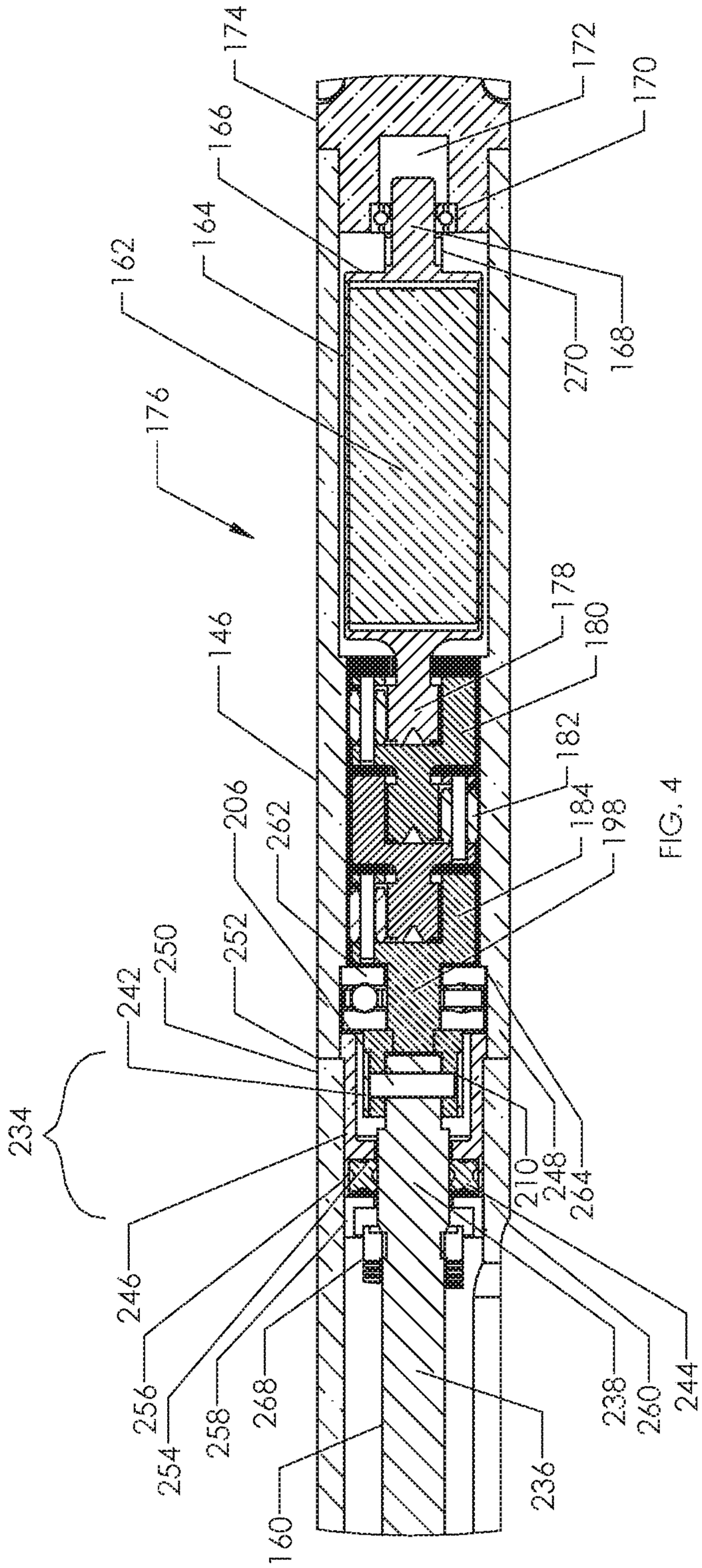
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FIG. 4

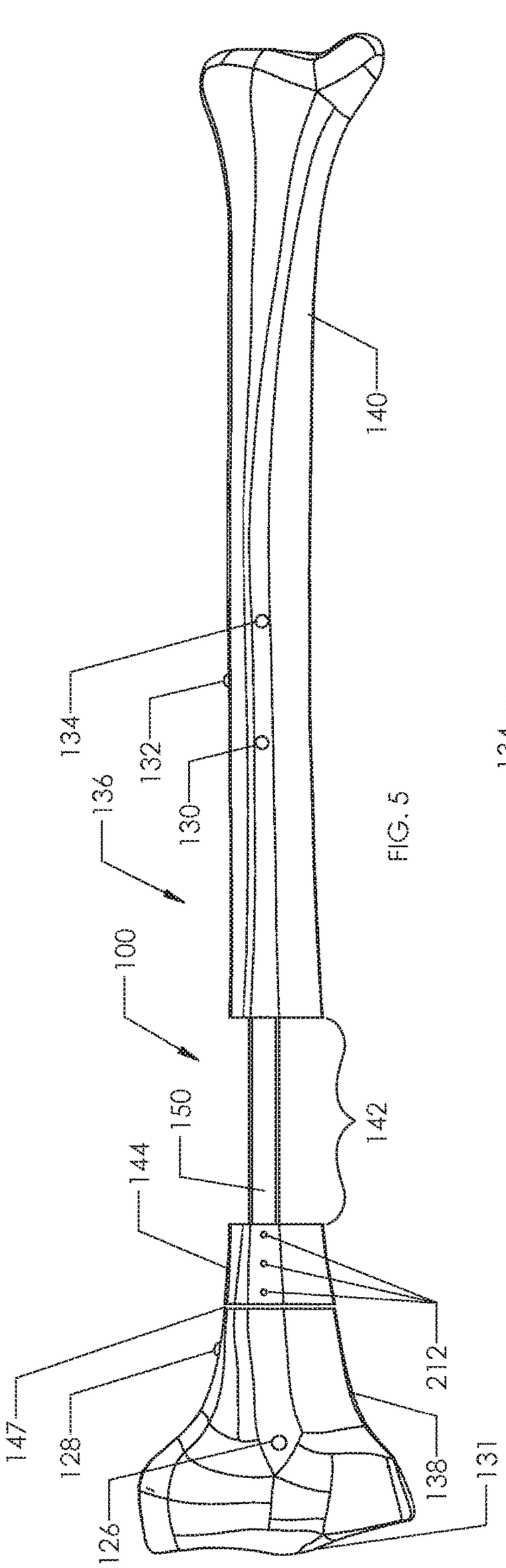
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FIG. 5

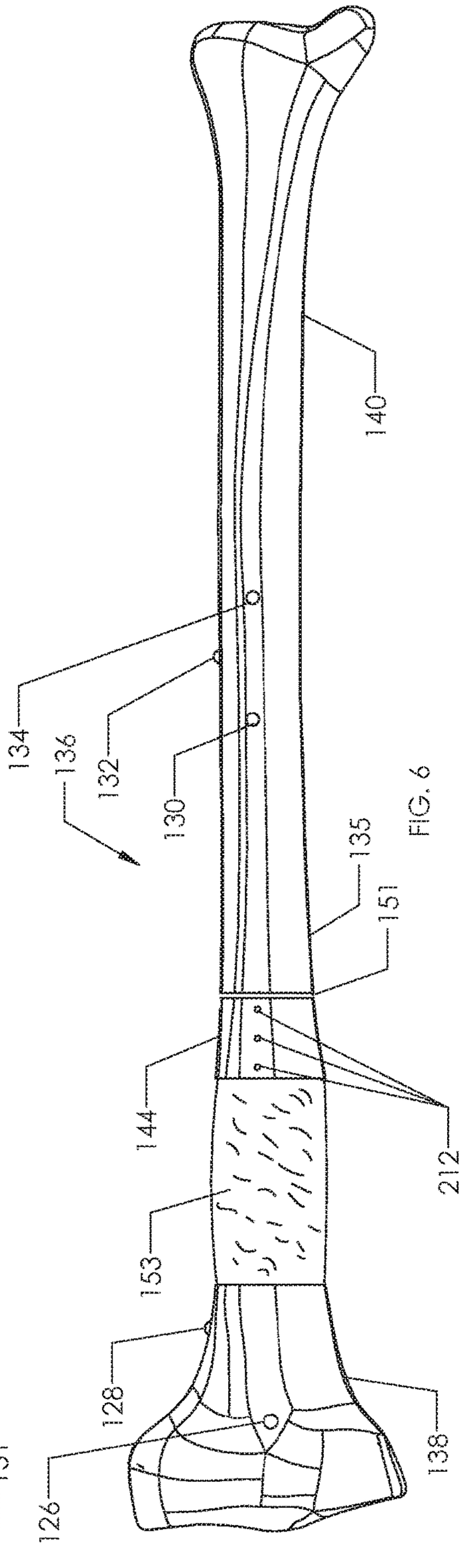
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FIG. 6

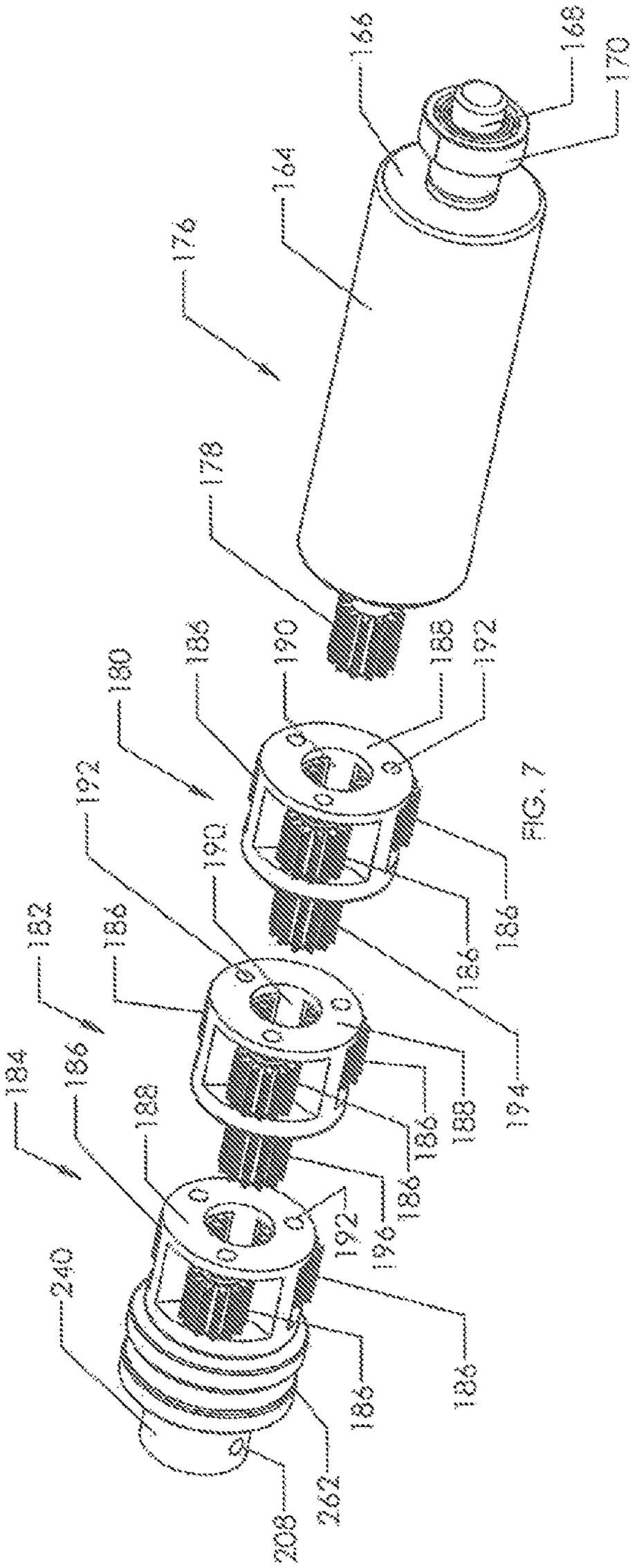
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FIG. 7

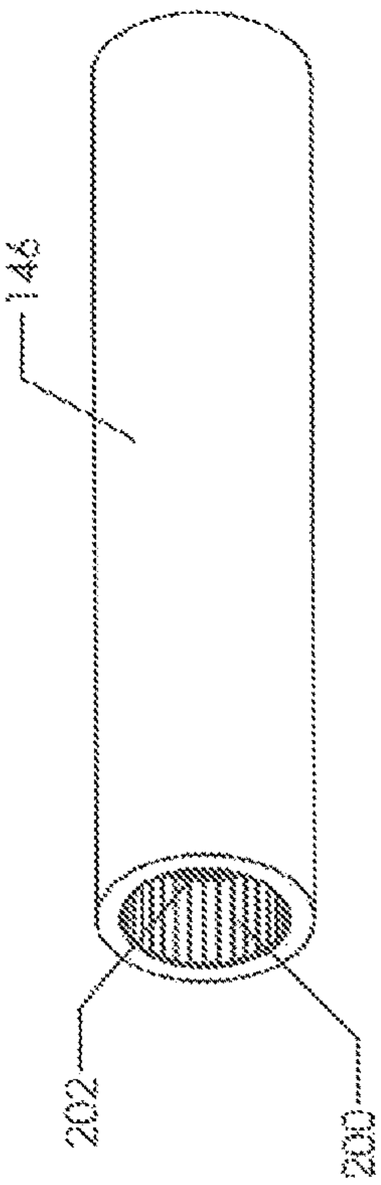
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FIG. 8

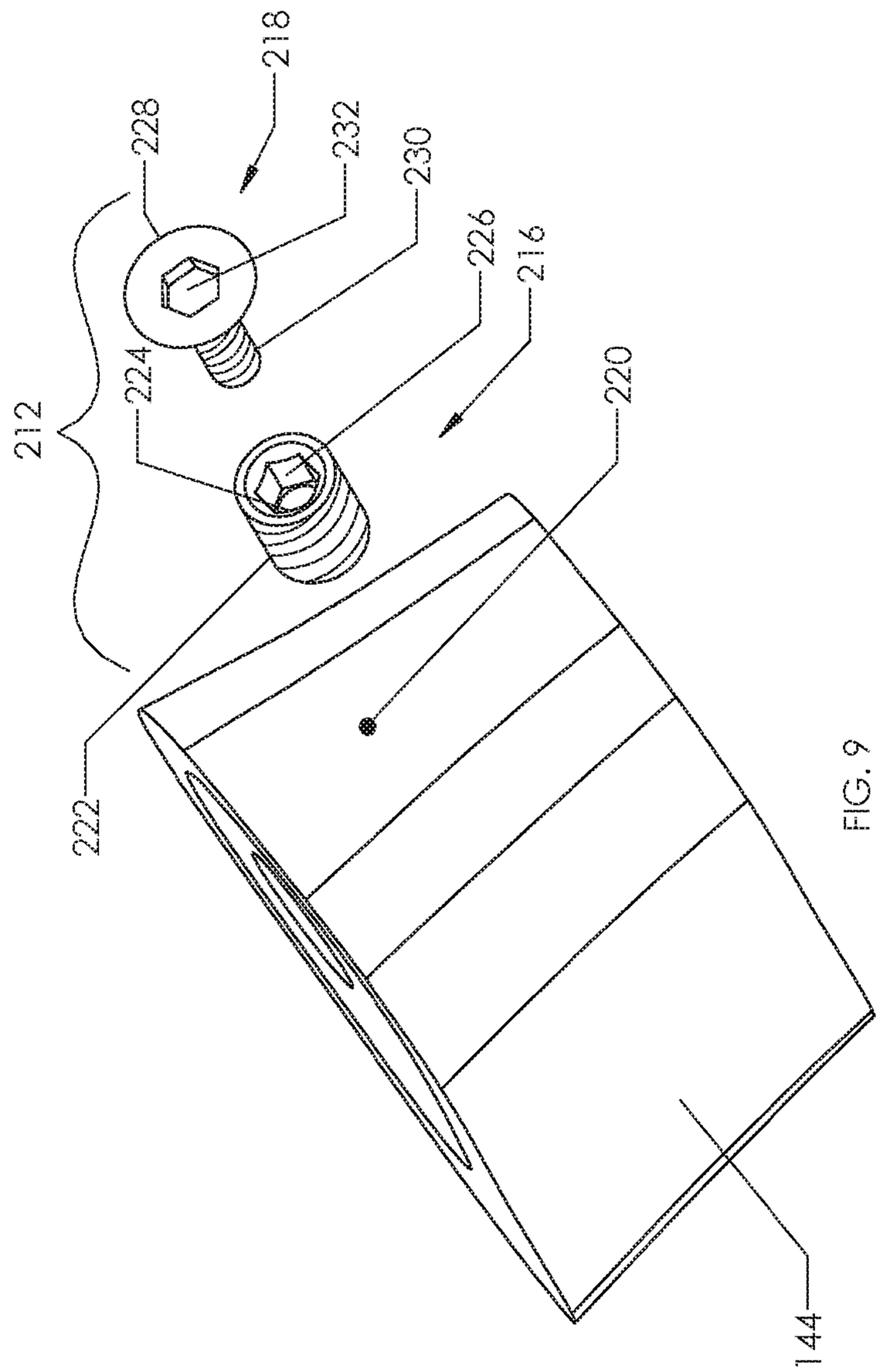


FIG. 9

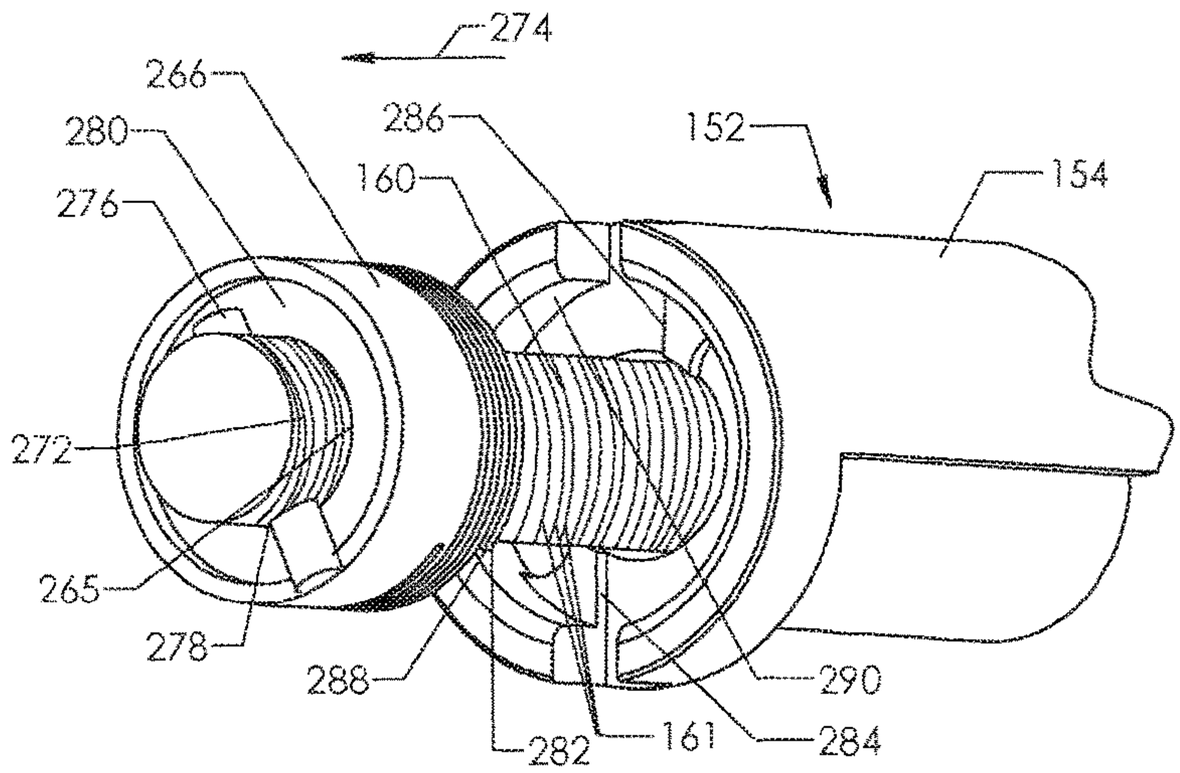


FIG. 10

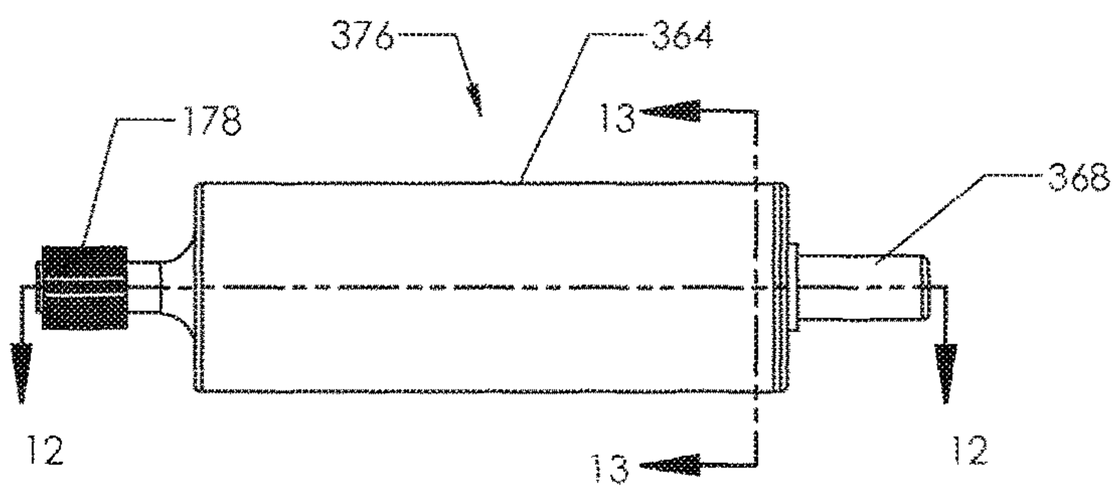


FIG. 11

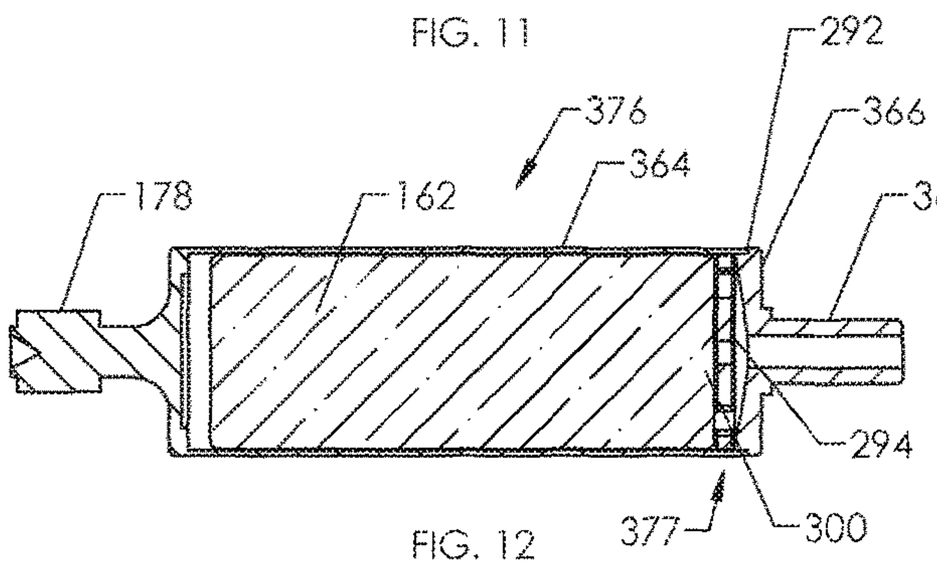


FIG. 12

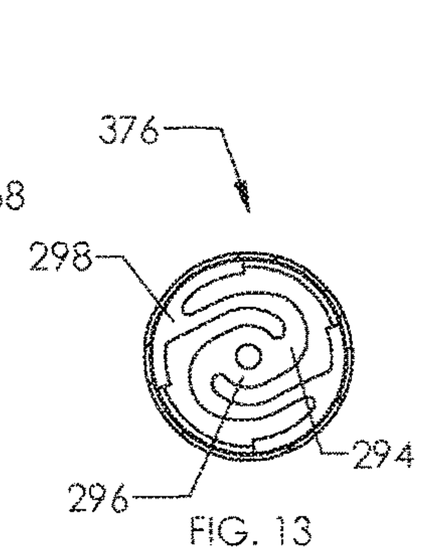


FIG. 13

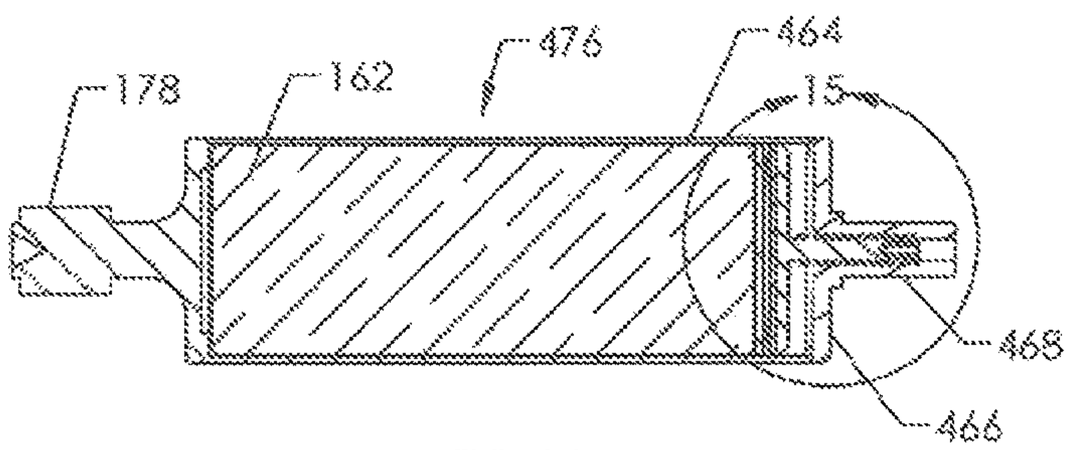


FIG. 14

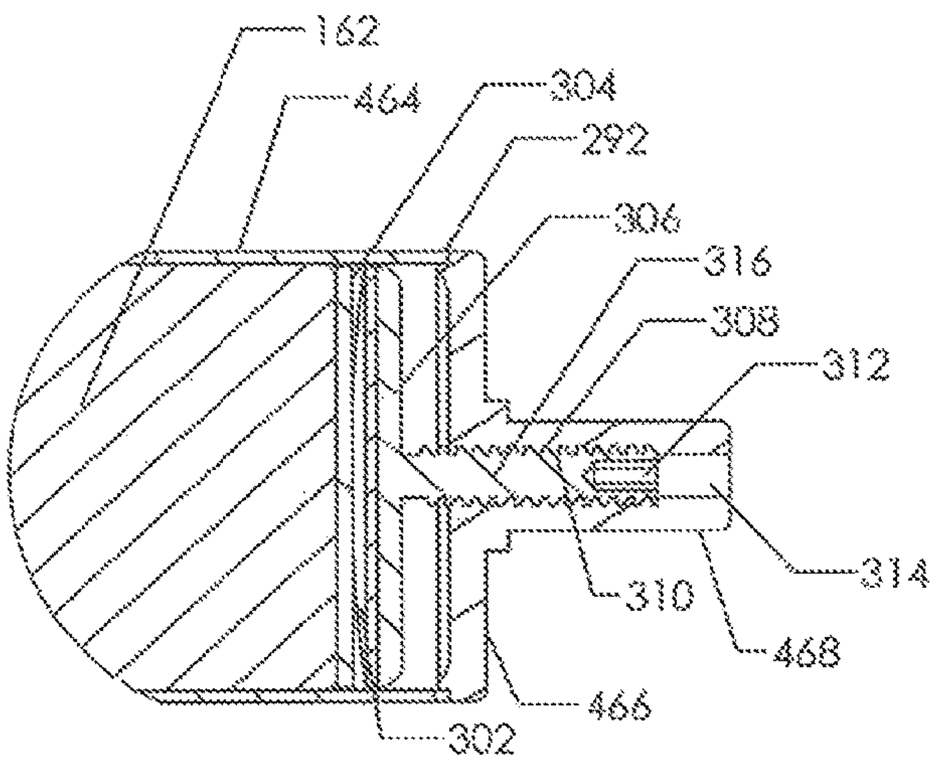


FIG. 15

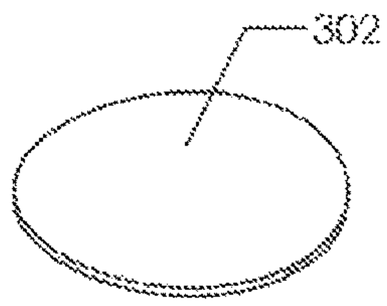


FIG. 16

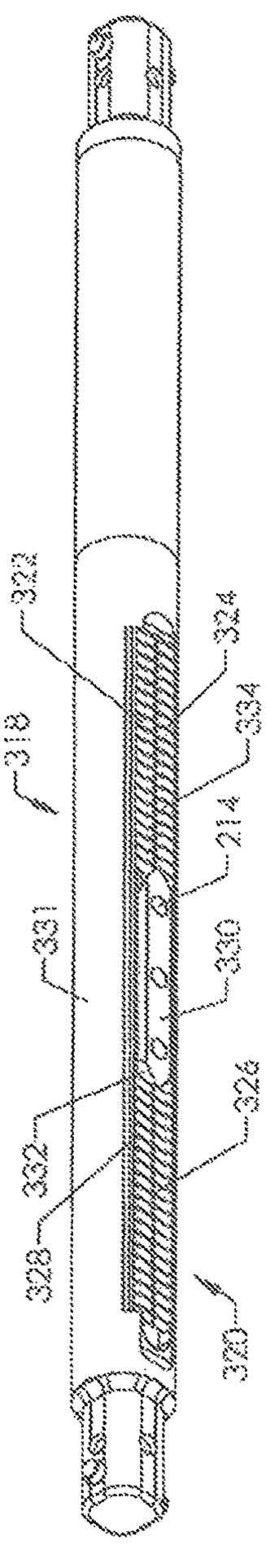


FIG. 17

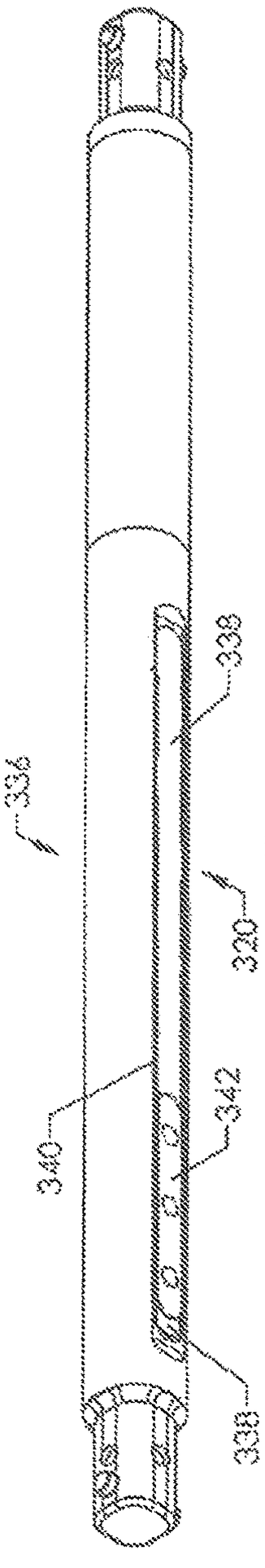
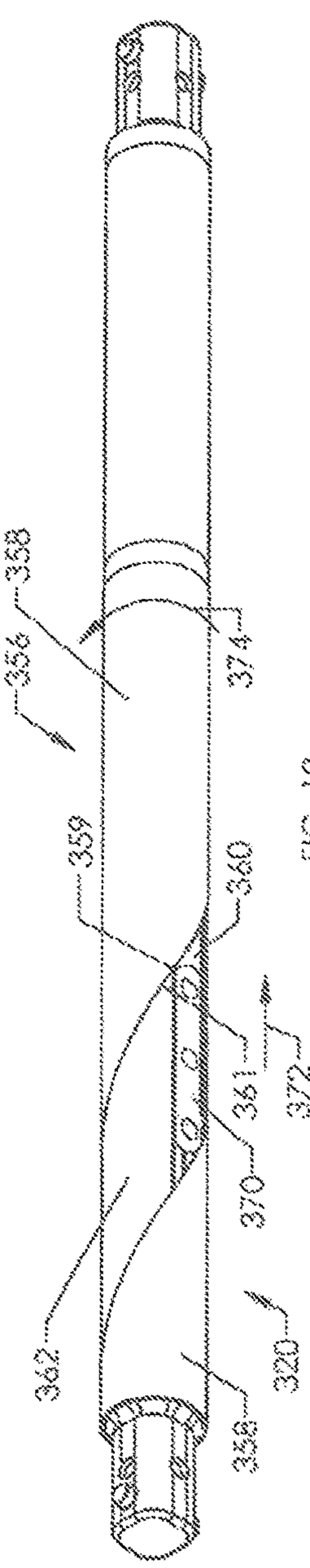


FIG. 18



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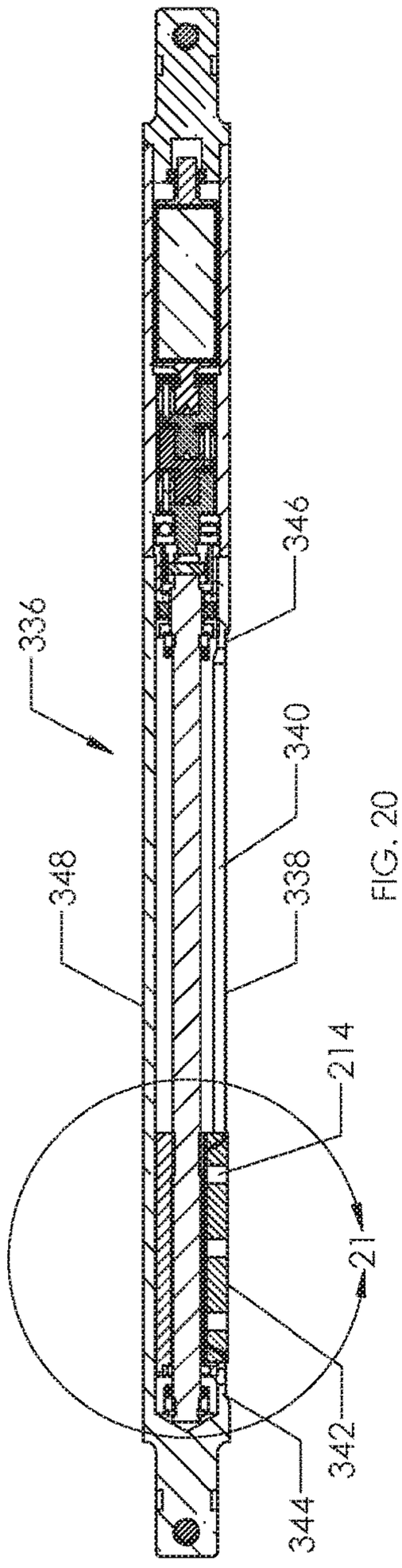
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FIG. 20

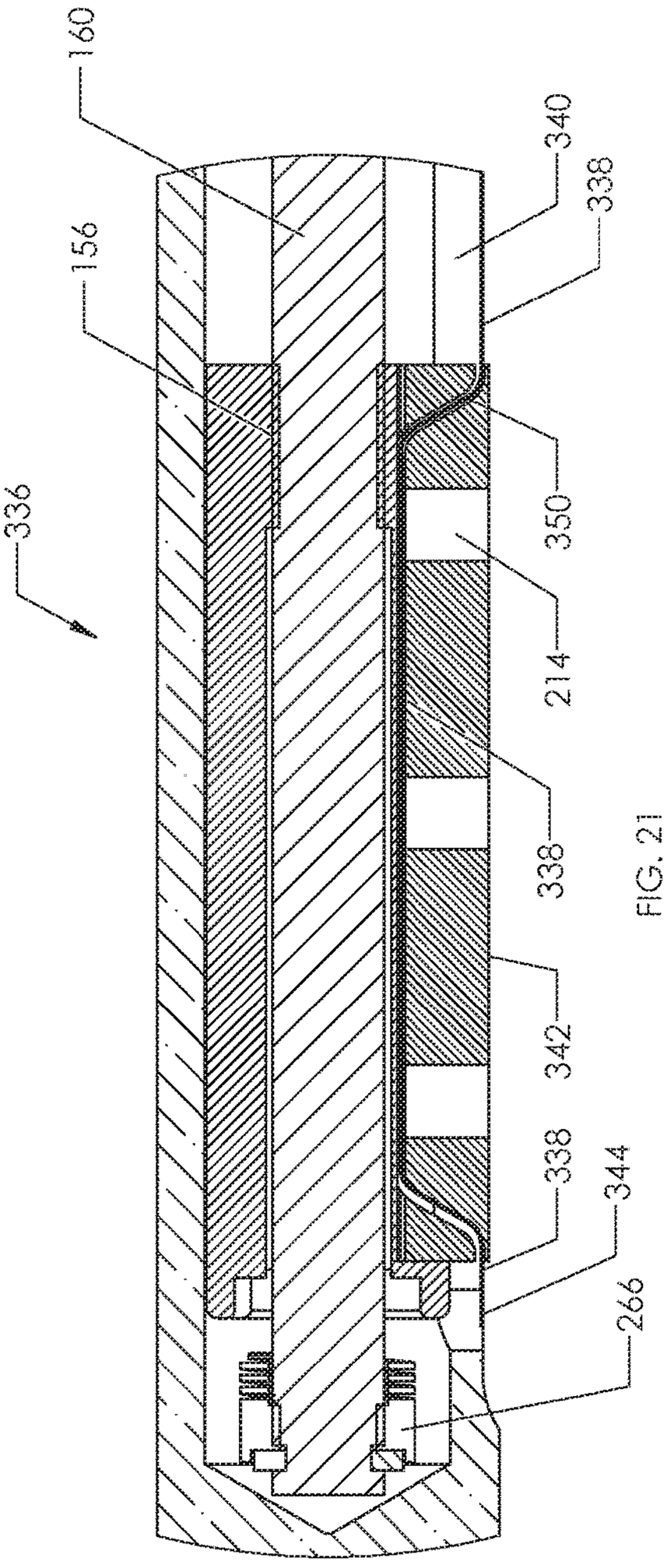
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FIG. 21

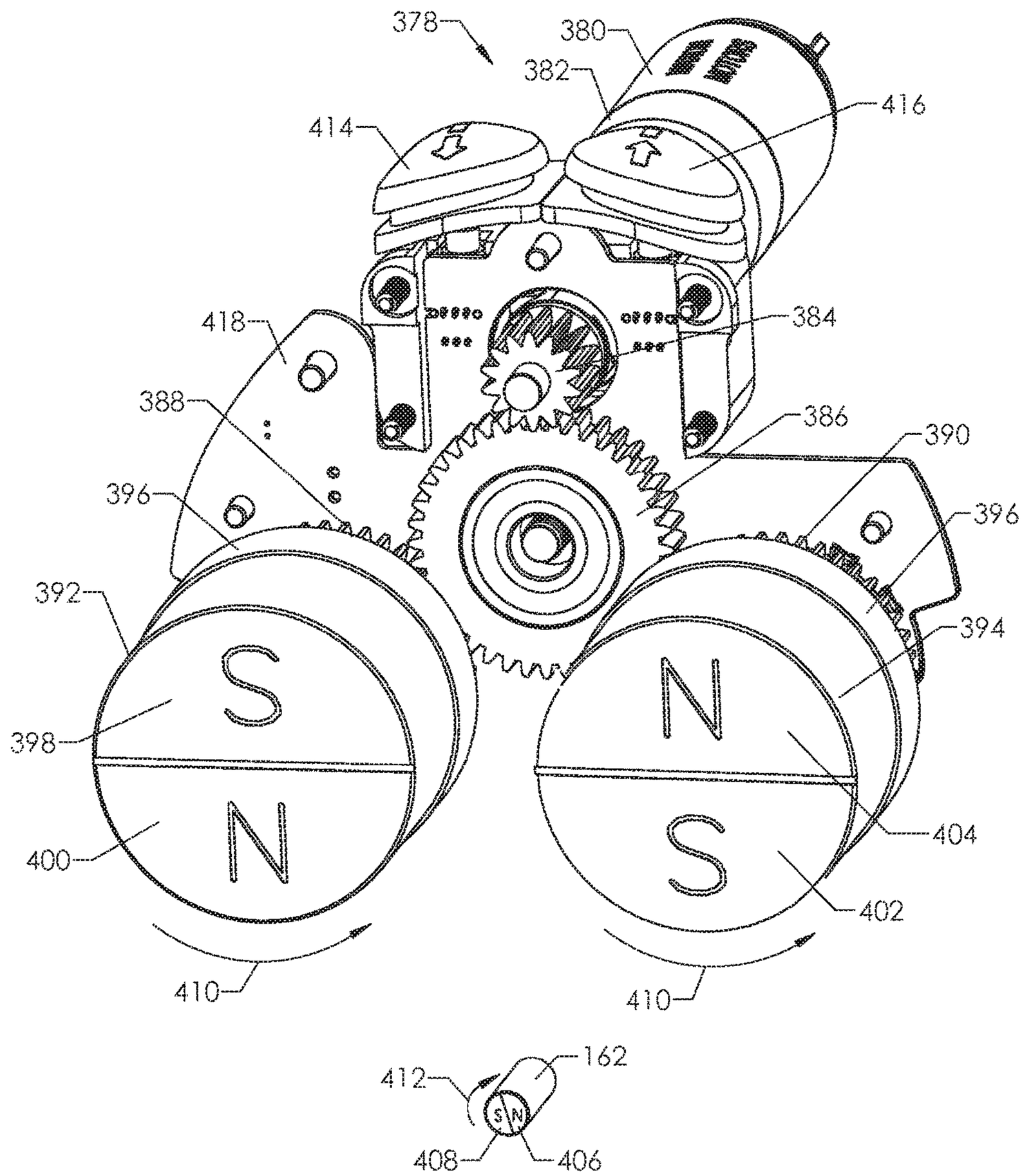
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FIG. 22

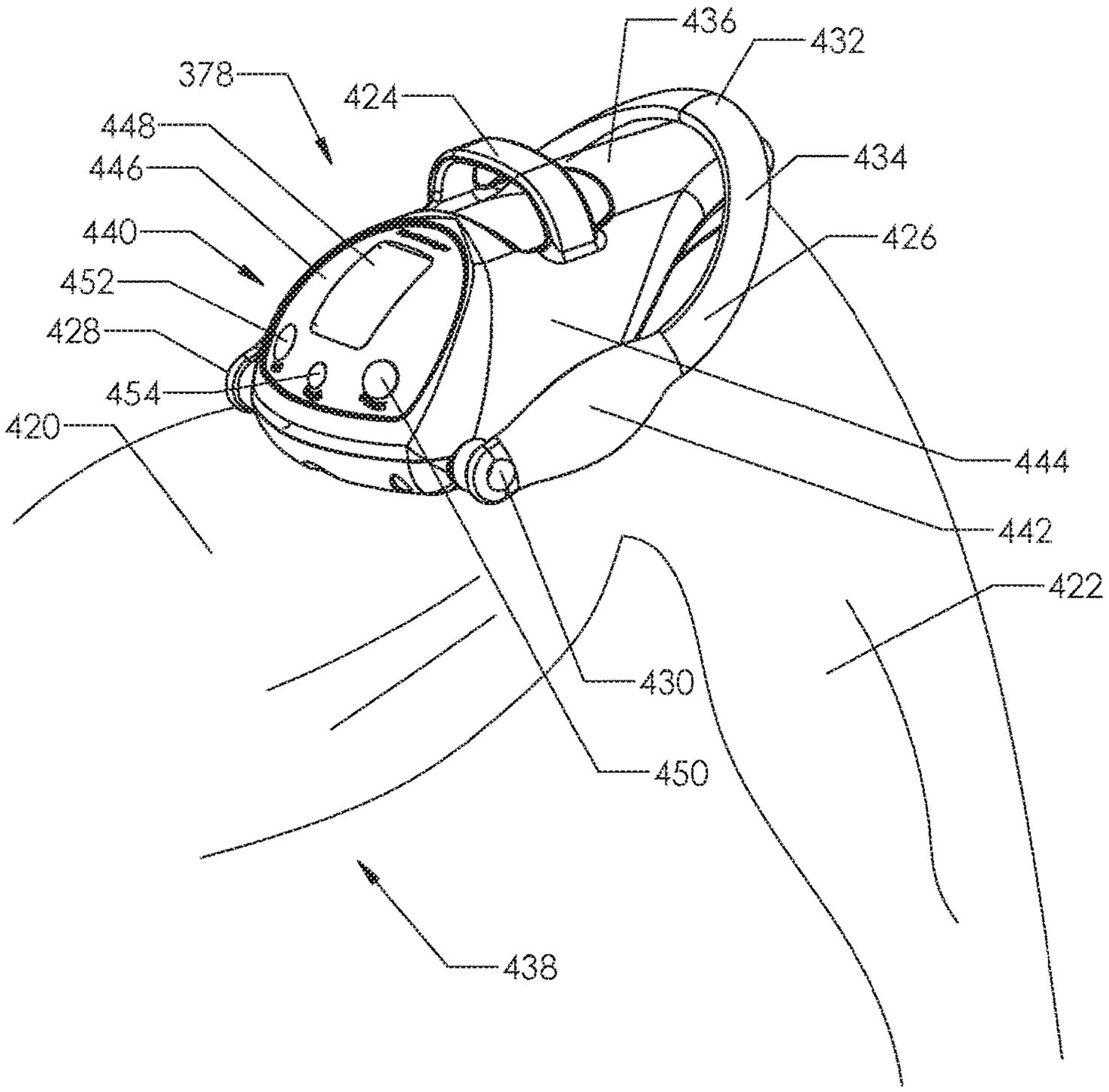
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FIG. 23

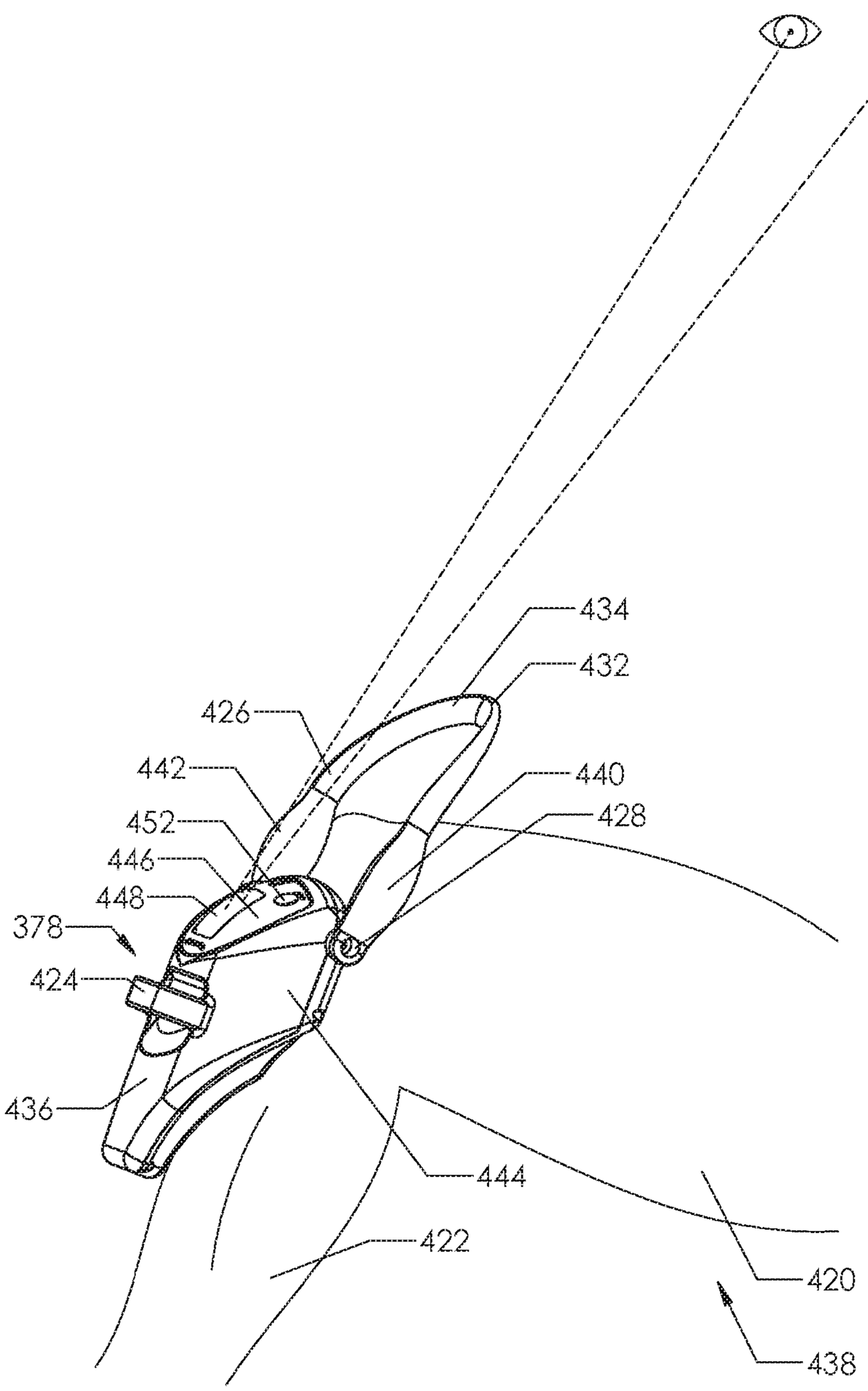

FIG. 24

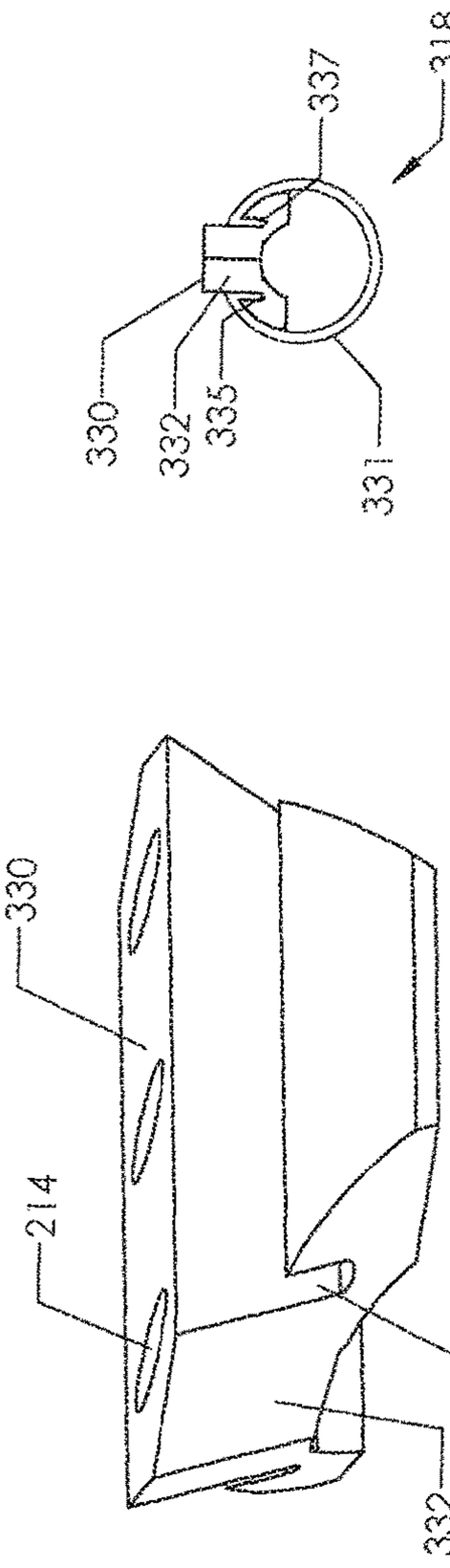

FIG. 25A

FIG. 25B

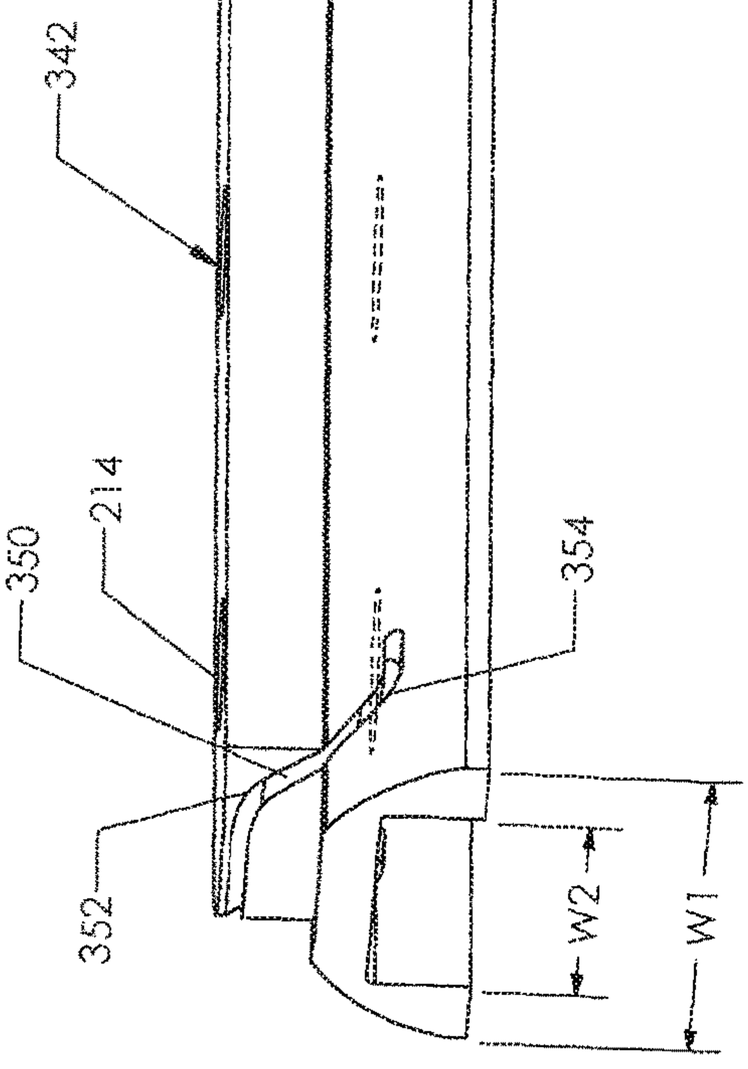

FIG. 26

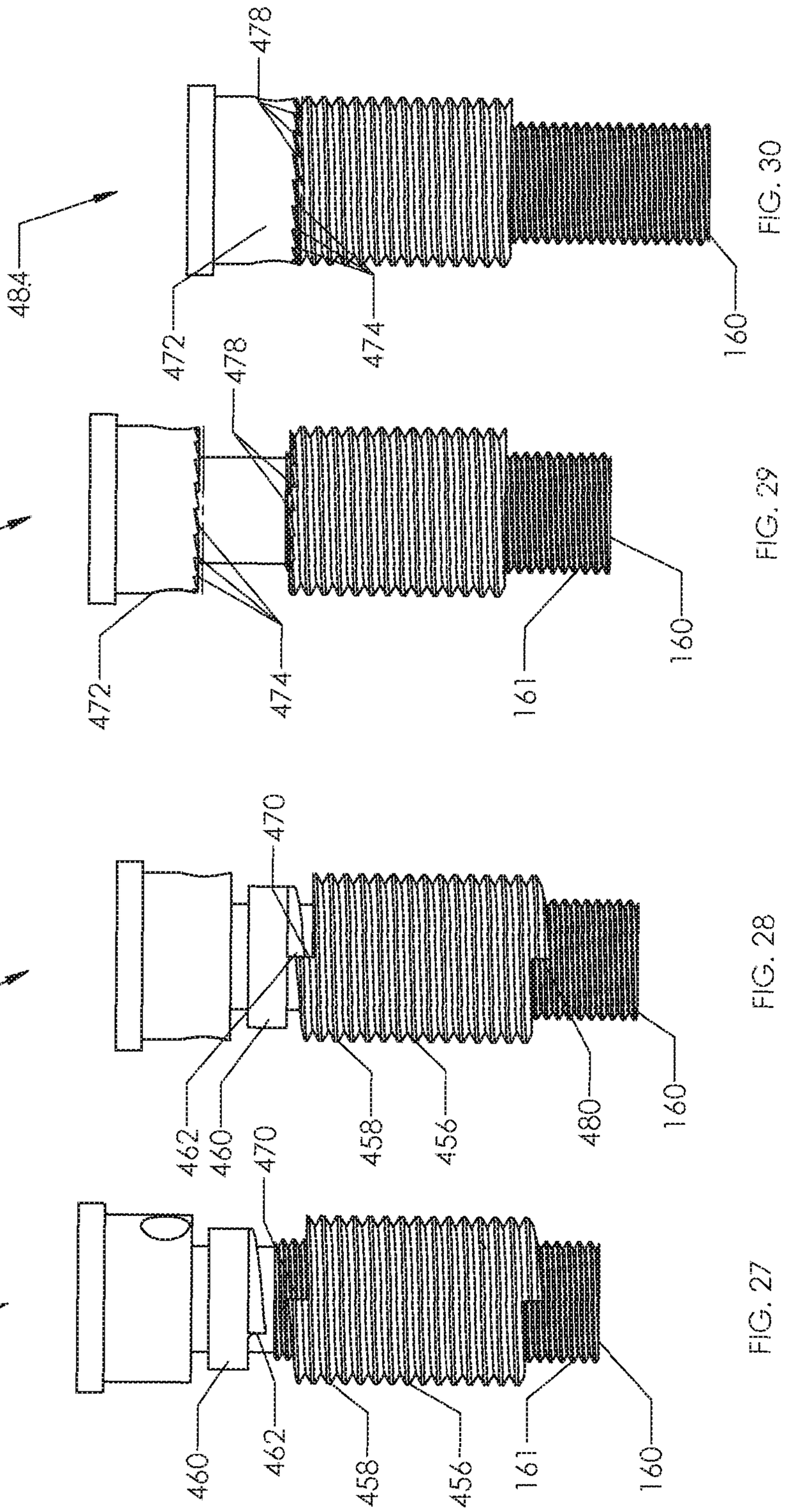

FIG. 30

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FIG. 27

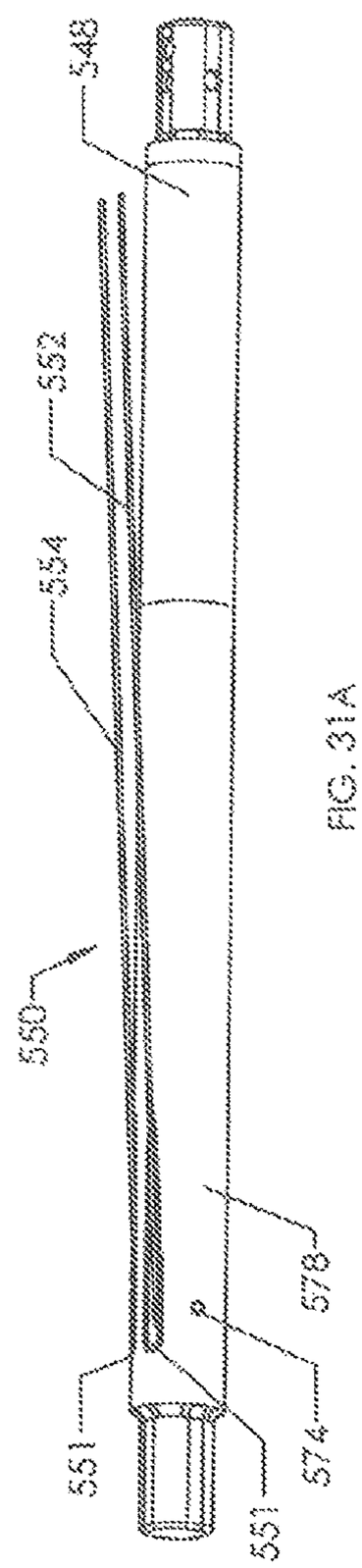

FIG. 31A

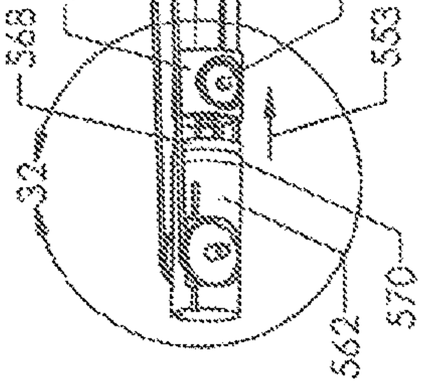

FIG. 31B

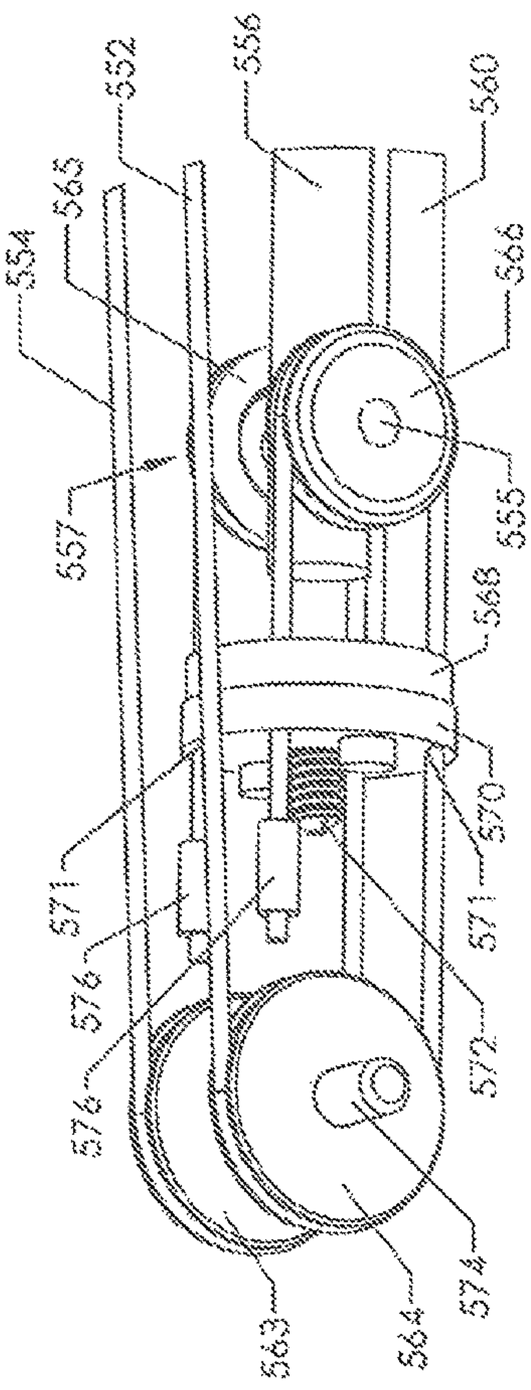

FIG. 32

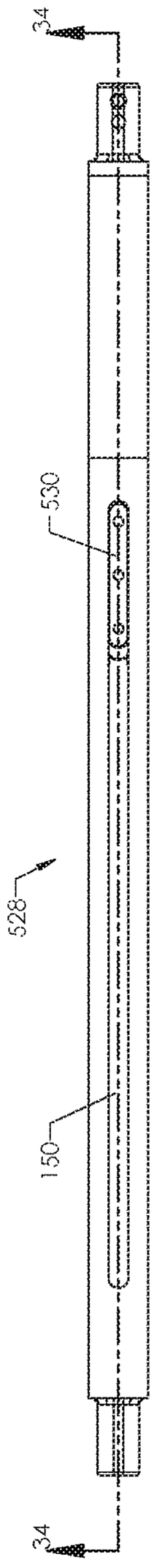

FIG. 33

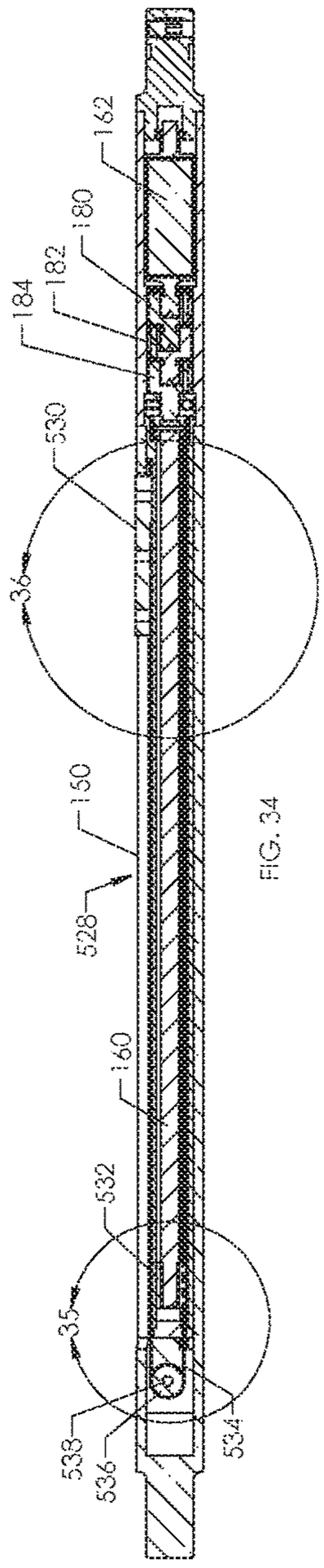

FIG. 34

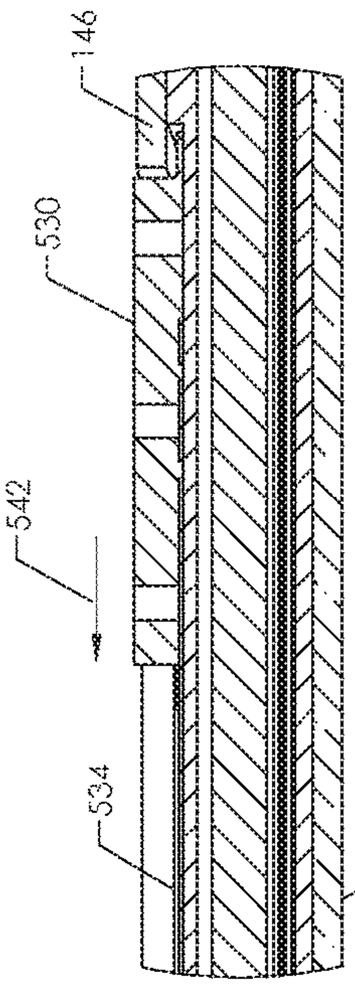

FIG. 36

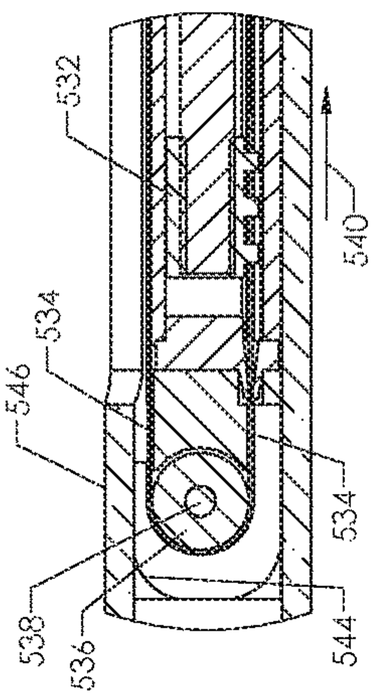

FIG. 35

INTRAMEDULLARY IMPLANTS FOR REPLACING LOST BONE

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

[INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS] *CROSS-REFERENCE TO RELATED APPLICATIONS*

Notice: More than one reissue application has been filed for the reissue of U.S. Pat. No. 9,770,274. The applications for reissue of U.S. Pat. No. 9,770,274 include application Ser. No. 16/577,436, filed on Sep. 20, 2019, and present application Ser. No. 17/714,600, filed on Apr. 6, 2022.

This application is *an application for reissue of U.S. Pat. No. 9,770,274, and is also a divisional of U.S. application Ser. No. 16/577,436, filed Sep. 20, 2019, which is an application for reissue of U.S. Pat. No. 9,770,274. U.S. Pat. No. 9,770,274 issued on Sep. 26, 2017 on U.S. application Ser. No. 15/212,090, filed Jul. 15, 2016, which is* a continuation of U.S. [patent] application Ser. No. 14/451,190, filed Aug. 4, 2014, *now U.S. Pat. No. 9,421,046, issued Aug. 23, 2016,* which is a continuation of U.S. [patent] application Ser. No. 13/655,246, filed Oct. 18, 2012, now U.S. Pat. No. 9,044,281, *issued Jun. 2, 2015.* [Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.]

BACKGROUND OF THE INVENTION

Field of the Invention

The field of the invention generally relates to medical devices for treating disorders of the skeletal system.

Description of the Related Art

Distraction osteogenesis is a technique which has been used to grow new bone in patients with a variety of defects. For example, limb lengthening is a technique in which the length of a bone (for example a femur or tibia) may be increased. By creating a corticotomy, or osteotomy, in the bone, which is a cut through the bone, the two resulting sections of bone may be moved apart at a particular rate, such as one (1.0) mm per day, allowing new bone to regenerate between the two sections as they move apart. This technique of limb lengthening is used in cases where one limb is longer than the other, such as in a patient whose prior bone break did not heal correctly, or in a patient whose growth plate was diseased or damaged prior to maturity. In some patients, stature lengthening is desired, and is achieved by lengthening both femurs and/or both tibia to increase the patient's height.

Bone transport is a similar procedure, in that it makes use of osteogenesis, but instead of increasing the distance between the ends of a bone, bone transport fills in missing bone in between. There are several reasons why significant amounts of bone may be missing. For example, a prior non-union of bone, such as that from a fracture, may have become infected, and the infected section may need to be removed. Segmental defects may be present, the defects often occurring from severe trauma when large portions of bone are severely damaged. Other types of bone infections

or osteosarcoma may be other reasons for a large piece of bone that must be removed or is missing.

Limb lengthening is often performed using external fixation, wherein an external distraction frame is attached to the two sections of bone by pins which pass through the skin. The pins can be sites for infection and are often painful for the patient, as the pin placement site remains a somewhat open wound "pin tract" throughout the treatment process. The external fixation frames are also bulky, making it difficult for patient to comfortably sit, sleep and move. Intramedullary lengthening devices also exist, such as those described in U.S. Patent Application Publication No. 2011/0060336, which is incorporated by reference herein. Bone transport is typically performed by either external fixation, or by bone grafting.

In external fixation bone transport, a bone segment is cut from one of the two remaining sections of bone and is moved by the external fixation, usually at a rate close to one (1.0) mm per day, until the resulting regenerate bone fills the defect. The wounds created from the pin tracts are an even worse problem than in external fixation limb lengthening, as the pins begin to open the wounds larger as the pins are moved with respect to the skin. In bone grafting, autograft (from the patient) or allograft (from another person) is typically used to create a lattice for new bone growth. Bone grafting can be a more complicated and expensive surgery than the placement of external fixation pins.

SUMMARY OF THE INVENTION

In one embodiment of the invention, a bone transport system includes a nail having a proximal end and a distal end, the proximal end configured for securing to a first portion of bone, the distal end configured for securing to a second portion of bone. The system includes a housing having a wall with a longitudinal opening extending a length along a portion thereof. The system further includes a transport sled having a length that is shorter than the length of the longitudinal opening, the transport sled configured for securing to a third portion of bone, the transport sled further configured to be moveable along the longitudinal opening. The system further includes a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein actuation of the magnetic assembly moves the transport sled along the longitudinal opening. The system further includes a ribbon extending on opposing sides of the transport sled and substantially covering the longitudinal opening.

In another embodiment of the invention, a bone transport system includes a nail having a proximal end and a distal end, the proximal end configured for securing to a first portion of bone, the distal end configured for securing to a second portion of bone. The system further includes a housing section having a wall with a longitudinal opening extending along a portion thereof and having a length. The system further includes a transport sled having a length that is shorter than the length of the longitudinal opening, the transport sled configured for securing to a third portion of bone, the transport sled further configured to move along the longitudinal opening. The system further includes a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein actuation of the magnetic assembly moves the transport sled along the longitudinal opening. The system further includes a dynamic cover which is configured to cover substantially all of the portion of the longitudinal

opening that is not occupied by the transport sled independent of the position of the transport sled along the length of the longitudinal opening.

In another embodiment of the invention, a method for performing a bone transport procedure includes placing a bone transport system within an intramedullary canal of a bone, the bone transport system comprising a nail having a proximal end and a distal end, a housing section having a wall with a longitudinal opening extending along a portion thereof, a transport sled disposed in the longitudinal opening and configured to move along the longitudinal opening in response to actuation of a magnetic assembly disposed within the nail, and a dynamic cover configured to cover substantially all of the longitudinal opening not occupied by the transport sled. The method further includes securing the proximal end of the nail to a first portion of bone, securing the distal end of the nail to a second portion of bone, and securing a third portion of bone to the transport sled. The method further includes applying a moving magnetic field to the magnetic assembly to actuate the magnetic assembly and cause the transport sled to move along the longitudinal opening, wherein the dynamic cover substantially covers all of the longitudinal opening regardless of the location of the transport sled within the longitudinal opening.

In another embodiment of the invention, a bone transport system includes a nail having a proximal end and a distal end, the proximal end configured for securing to a first portion of bone, the distal end configured for securing to a second portion of bone. The system further includes a housing section having a wall with a longitudinal opening extending along a portion thereof and having a length. The system further includes a transport sled having a length that is shorter than the length of the longitudinal opening, the transport sled configured for securing to a third portion of bone, the transport sled disposed within the longitudinal opening and further configured to move along the longitudinal opening. The system further includes a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein actuation of the magnetic assembly turns a lead screw, which in turn moves the transport sled along the longitudinal opening, and wherein the lead screw includes a threaded surface having a coating thereon, the coating selected from either molybdenum disulfide or amorphous diamond-like carbon.

In another embodiment of the invention, and implantable dynamic apparatus includes a nail having a first portion and a second portion, the first portion of the nail configured for securing to a first portion of bone, the second portion of the nail configured for securing to a second portion of bone, the second portion of the nail configured to be longitudinally moveable with respect to the first portion of the nail, wherein the second portion of the nail includes an internally threaded feature. The apparatus further includes a magnetic assembly configured to be non-invasively actuated by a moving magnetic field. The apparatus further includes a lead screw having an externally threaded portion, the lead screw coupled to the magnetic assembly, wherein the externally threaded portion of the lead screw engages the internally threaded feature of the second portion of the nail, wherein actuation of the magnetic assembly turns the lead screw, which in turn changes the longitudinal displacement between the first portion of the nail and the second portion of the nail. The apparatus further includes a first abutment surface coupled to the lead screw, a second abutment surface coupled to the second portion of the nail, and wherein the turning of the lead screw in a first direction causes the first abutment to contact the second abutment, stopping the motion of the lead screw with respect to the second portion of the nail, and wherein subsequent turning of the nail in a second direction is not impeded by any jamming between the internally threaded feature and the externally threaded portion.

In another embodiment of the invention, a bone transport system includes a nail having a proximal end and a distal end, the proximal end configured for securing to a first portion of bone, the distal end configured for securing to a second portion of bone. The system further includes a housing section having a wall with a longitudinal opening extending along a portion thereof. The system further includes a transport sled configured for securing to a third portion of bone, the transport sled disposed within the longitudinal opening and further configured to be moveable along the longitudinal opening, the transport sled having a first stopping surface. The system further includes a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein actuation of the magnetic assembly rotates a lead screw operatively coupled thereto and moves the transport sled along the longitudinal opening. The system further includes a stop secured to the lead screw and having a second contact surface, and wherein when the first contact surface contacts the second contact surface in response to rotation of the lead screw, the stop is configured to radially expand and prevent additional rotation of the lead screw.

In another embodiment of the invention, a non-invasively adjustable implant includes a nail having a first portion and a second portion, the first portion of the nail configured for securing to a first portion of bone, the second portion of the nail configured for securing to a second portion of bone, the second portion of the nail configured to be longitudinally moveable with respect to the first portion of the nail. The implant further includes a magnetic assembly configured to be non-invasively actuated. The system further includes a cylindrical permanent magnet having at least two radially-directed poles, the cylindrical permanent magnet configured to be turned by a moving magnetic field, the cylindrical permanent magnet held by a magnet holder, the magnet holder rotationally coupled to the magnetic assembly, wherein actuation of the magnetic assembly changes the longitudinal displacement between the first portion of the nail and the second portion of the nail. The implant further includes a friction applicator which couples the magnet holder to the cylindrical permanent magnet, wherein the friction applicator is configured to apply a static frictional torque to the magnet so that when a moving magnetic field couples to the cylindrical permanent magnet at a torque below the static frictional torque, the cylindrical permanent magnet and the magnet hold turn in unison, and when a moving magnetic field couples to the cylindrical permanent magnet at a torque above the static frictional torque, the cylindrical permanent magnet turns while the magnet holder remains rotationally stationary.

In another embodiment of the invention, a bone transport system includes a nail having a proximal end and a distal end, the proximal end configured for securing to a first portion of bone, the distal end configured for securing to a second portion of bone. The system further includes a housing section having a wall with a longitudinal opening extending along a portion thereof. The system further includes a transport sled configured for securing to a third portion of bone, the transport sled disposed within the longitudinal opening and further configured to be moveable along the longitudinal opening. The system further includes

a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein actuation of the magnetic assembly moves the transport sled along the longitudinal opening, the magnetic assembly having a magnetic housing containing a permanent magnet therein and a biasing member interposed between the magnetic housing and the permanent magnet, wherein the magnetic housing and the permanent magnet are rotationally locked by the biasing member up to a threshold torque value.

In another embodiment of the invention, a bone transport system includes a nail having a proximal end and a distal end, the proximal end configured for securing to a first portion of bone, the distal end configured for securing to a second portion of bone. The system further includes a housing having a wall with a longitudinal opening extending along a portion thereof. The system further includes a transport sled disposed within the longitudinal opening and further configured to be moveable along the longitudinal opening. The system further includes a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein actuation of the magnetic assembly rotates a lead screw operatively coupled to a nut moveable along a length of the lead screw in response to rotation thereof. The system further includes a ribbon secured to the nut at one end and secured to the transport sled at an opposing end, the ribbon passing over at least one pulley, wherein movement of the nut in a first direction translates into movement of the transport sled in a second, opposing direction.

In another embodiment of the invention, a method for performing a bone transport procedure includes preparing the medullary canal of a bone for placement of a nail configured to change its configuration at least partially from a moving magnetic field supplied by an external adjustment device, the change in configuration including the longitudinal movement of a transport sled. The method further includes placing a nail within the medullary canal of the bone, securing a first end of the nail to a first portion of the bone, and securing a second end of the nail to a second portion of the bone. The method further includes storing information in the external adjustment device, the information including the orientation of the nail within the bone and the direction of planned movement of the transport sled.

In another embodiment of the invention, a bone transport system includes a nail having a first end and a second end, the first end configured for securing to a first portion of bone, the second end configured for securing to a second portion of bone. The system further includes a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein actuation of the magnetic assembly rotates a lead screw operatively coupled to a nut moveable along a length of the lead screw in response to rotation thereof, the nut containing at least one pulley affixed thereto. The system further includes at least one pulley disposed within the nail at the first end. The system further includes at least one tension line fixed relative to the first end and passing over both the at least one pulley of the nut and the at least one pulley disposed within the nail at the first end, and wherein the tension line is configured to be secured to a third portion of bone.

In another embodiment of the invention, a bone transport system includes a nail having a proximal end and a distal end, the proximal end configured for securing to a first portion of bone, the distal end configured for securing to a second portion of bone. The system further includes a housing section having a wall with a longitudinal opening extending along a portion thereof. The system further includes a transport sled configured for securing to a third portion of bone, the transport sled disposed within the longitudinal opening and further configured to be moveable along the longitudinal opening. The system further includes a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein actuation of the magnetic assembly moves the transport sled along the longitudinal opening, and wherein the nail has an ultimate failure torque greater than 19 Newton-meters.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates an intramedullary bone transport device for replacing lost bone according to one embodiment.

FIG. **2** illustrates a longitudinal section of the intramedullary bone transport device of FIG. **1**.

FIG. **3** illustrates detail **3** of FIG. **2**.

FIG. **4** illustrates detail **4** of FIG. **2**.

FIG. **5** illustrates the intramedullary bone transport device secured within the medullary canal of a tibia, prior to transporting a bone segment.

FIG. **6** illustrates the intramedullary bone transport device secured within the medullary canal of a tibia, after transporting a bone segment.

FIG. **7** illustrates an exploded view of the internal components located within an enclosed housing portion of an actuator of the intramedullary bone transport device.

FIG. **8** illustrates an enclosed housing portion of the actuator of the intramedullary bone transport device.

FIG. **9** illustrates a screw assembly for securing a transport sled to a bone segment.

FIG. **10** illustrates detail view of an end stop for avoiding jamming of a transport sled.

FIG. **11** illustrates a spring friction slip clutch incorporated into a magnetic assembly.

FIG. **12** illustrates a longitudinal section of FIG. **11**, taken along lines **12-12**.

FIG. **13** illustrated a cross-section of FIG. **11**, taken along lines **13-13**.

FIG. **14** illustrates an adjustable friction slip clutch incorporated into a magnetic assembly.

FIG. **15** illustrates detail **15** of FIG. **14**.

FIG. **16** illustrates a wave disc used as a spring component in the slip clutch of FIGS. **14** and **15**.

FIG. **17** illustrates the actuator of an intramedullary bone transport device having a dynamic cover according to a first embodiment.

FIG. **18** illustrates the actuator of an intramedullary bone transport device having a dynamic cover according to a second embodiment.

FIG. **19** illustrates the actuator of an intramedullary bone transport device having a dynamic cover according to a third embodiment.

FIG. **20** is a longitudinal section of the actuator of FIG. **18**.

FIG. **21** illustrates detail **21** of the actuator of FIG. **20**.

FIG. **22** illustrates internal components of an external adjustment device for non-invasively adjusting an intramedullary bone transport device according to one embodiment.

FIG. **23** illustrates an external adjustment device in a configuration for adjusting an intramedullary bone transport device implanted within the femur.

FIG. **24** illustrates an external adjustment device in a configuration for adjusting an intramedullary bone transport device implanted within the tibia.

FIG. **25**A illustrates the transport sled of the intramedullary bone transport device of FIG. **17**.

FIG. **25**B illustrates a cross-section of the transport sled in the open housing of the intramedullary bone transport device of FIG. **17**.

FIG. **26** illustrates the transport sled of the intramedullary bone transport device of FIG. **18**.

FIG. **27** illustrates an alternative embodiment of an end stop prior to reaching the end of travel.

FIG. **28** illustrates the end stop of FIG. **27** at the end of travel in one direction.

FIG. **29** illustrates an additional embodiment of an end stop prior to reaching the end of travel.

FIG. **30** illustrates the end stop of FIG. **29** at the end of travel in one direction.

FIG. **31**A illustrates an intramedullary bone transport device having a reverse block and tackle arrangement.

FIG. **31**B illustrates the intramedullary bone transport device of FIG. **31**A with a portion of the housing removed.

FIG. **32** illustrates detail **32** of FIG. **31**B with portions removed for clarity.

FIG. **33** illustrates an intramedullary bone transport device having an alternative drive system.

FIG. **34** illustrates a longitudinal section of the intramedullary bone transport device of FIG. **33** taken along lines **34-34**.

FIG. **35** illustrates detail **35** of FIG. **34**.

FIG. **36** illustrates detail **36** of FIG. **34**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** illustrates an intramedullary bone transport device **100** in a "nail" configuration, having an actuator **102**, a first extension rod **104** coupled to the actuator **102** at a first end **108** of the intramedullary bone transport device **100**, and a second extension rod **106** coupled to the actuator **102** *at* a second end **110** of the intramedullary bone transport device **100**. First extension rod **104** and second extension rod **106** are secured to actuator **102** by set screws **112**, **114**. A variety of different extension rods are available, each having a particular angulation and length. In FIG. **1**, first extension rod **104** is angled for use in the proximal tibia while second extension rod **106** is straight for use in the distal tibia. Multiple configurations are contemplated for tibial use, as well as antegrade use in the femur and retrograde use in the femur. Holes **116**, **118**, **120**, **122**, **124** are configured with specific diameters and orientations, in order to accommodate bone screws **126**, **128**, **130**, **132**, **134** for securing intramedullary bone transport device **100** to the bone as seen in FIGS. **5** and **6**. FIGS. **5** and **6** show the intramedullary bone transport device **100** secured in the medullary canal of a tibia **136**. The tibia **136** is shown having a proximal portion **138** and a distal portion **140**. Additionally, there is a missing section **142** of tibia **136**. The bone that was originally in this missing section **142** may be missing because of several reasons. It may have been destroyed because of severe trauma to this area of the tibia. It may also have been removed as part of a treatment of osteosarcoma in this area. The intramedullary bone transport device **100** facilitates the replacement of this bone by facilitating the controlled movement of a bone segment **144**, which can be cut from one of the two portions **138**, **140** of the tibia **136**. In the case illustrated in FIGS. **5** and **6**, the bone segment **144** is cut from the proximal portion **138** of the tibia **136**.

Returning to FIG. **1**, the actuator **102** includes an enclosed housing **146** and an open housing **148**. The open housing **148** contains a longitudinal slit **150** on one side along which a transport sled **152** is configured for axial movement. Longitudinal slit has a length of 140 mm, but can be a range of lengths, depending on the desired amount of bone transport. Referring more specifically to FIGS. **2**, **3** and **4**, the transport sled **152** includes a moveable transport tube **154** having an internal nut **156**. A support stage **158** is attached to the transport tube **154**, the support stage **158** being configured for axial movement within the longitudinal slit **150** of the open housing **148**. The internal nut **156** is threaded and coupled to a correspondingly threaded lead screw **160**, so that rotation of the lead screw **160** in a first rotational direction causes the transport tube **154** and support stage **158** (i.e., transport sled **152**) to move along the longitudinal slit **150** in a first axial direction and rotation of the lead screw **160** in a second, opposite rotational direction causes the transport sled **152** to move along the longitudinal slit **150** in a second axial direction, opposite of the first axial direction. Internal nut **156** may have female threads cut directly into the transport tube **154**. Alternatively, internal nut **156** may have external male threads and the transport tube **154** may have internal female threads, so that the internal female threads of the transport tube **154** and the external male threads of the internal nut **156** create a helical engagement surface. The two parts may be held together at this surface with adhesive, epoxy, etc. A representative thread design is **80** turns per inch.

Intramedullary bone transport device **100** is configured to allow controlled, precise translation of the transport sled **152** along the length of the longitudinal slit **150** by non-invasive remote control, and thus controlled, precise translation of the bone segment **144** that is secured to the transport sled **152**. Within the enclosed housing **146** of the actuator **102** is located a rotatable magnetic assembly **176**. Further detail can be seen in FIGS. **7** and **8**. The magnetic assembly **176** includes a cylindrical, radially-poled permanent magnet **162** (FIG. **22**) contained within a magnet housing **164** having an end cap **166**. The permanent magnet **162** may include rare earth magnet materials, such as Neodymium-Iron-Boron. The permanent magnet **162** has a protective Phenolic coating and may be held statically within the magnet housing **164** and end cap **166** by epoxy or other adhesive. The magnet housing **164**, end cap **166** and epoxy form a seal to further protect the permanent magnet **162**. Magnet housing **164** may also be welded to end cap **166** to create a hermetic seal. End cap **166** includes cylindrical extension or axle **168** which fits within the inner diameter of a radial bearing **170**, allowing for low friction rotation. Outer diameter of radial bearing **170** fits within cavity **172** of an actuator end cap **174** as seen, for example, in FIG. **4**. Actuator end cap **174** may be welded to enclosed housing **146** of actuator **102**. Referring to FIG. **7**, the magnetic assembly **176** terminates at an opposing end in a first sun gear **178** which is integral to magnet housing **164**. First sun gear **178** may also be made as a separate component and secured to magnet housing **164**, for example by welding. First sun gear **178** turns with rotation of magnetic assembly **176** (in a 1:1 fashion) upon application of a moving magnetic field applied to the patient from an external location. The first sun gear **178** is configured to insert within opening **190** of a first gear stage **180** having three planetary gears **186** which are rotatably held in a frame **188** by axles **192**. Second sun gear **194**, which is the output of the first gear stage **180**, turns with frame. The identical components exist in second gear stage **182**, which outputs to a third sun gear **196**, and third gear stage **184**, which outputs to an output shaft **198** as best seen in FIG. **4**. Along the length that the gear stages **180**, **182**, **184** extend,

the inner wall **200** of enclosed housing **146** (as seen in FIG. **8**) has internal teeth **202** along which the externally extending teeth **204** of the planetary gears **186** engage, as they turn. Each gear stage illustrated has a 4:1 gear ratio, so the output shaft **198** turns once for every **64** turns of the magnetic assembly **176**. The output shaft **198** is coupled to lead screw **160** by a pin **206** (FIG. **4**) which passes through holes **208** in a lead screw coupling cup **240** (FIG. **7**) which is welded to output shaft **198** and a hole **210** in the lead screw **160** (FIG. **4**). Pin **206** is held in place by retaining cylinder **242**. A pin **206** diameter of 0.055 inches on a pin **206** made from 400 series stainless steel allows for a tensile break force of over 600 pounds between the lead screw **160** and the lead screw coupling cup **240**. The torque applied on the magnetic assembly **176** by the action of the rotating magnetic field on the cylindrical permanent magnet **162**, is therefore augmented on the order of 64 times in terms of the turning torque of the lead screw **160**. This allows the transport sled **152** to be able to move with high precision. Returning to FIGS. **5** and **6**, bone segment **144** is attached to transport sled **152** by three screw assemblies **212**, which engage with internally threaded holes **214** of the support stage **158** of the transport sled **152**. Because of the 64:1 gear ratio, the intramedullary bone transport device is able to axially displace the bone segment **144** against severe resisting forces, for example those created by soft tissue. A thrust bearing **262** (FIG. **4**) is sandwiched between the lead screw **160** and the gear stages **180**, **182**, **184** in order to protect the gear stages **180**, **182**, **184** and the magnetic assembly **176** from high compressive forces. The thrust bearing **262** butts up against a flange **264** inside the enclosed housing **146**. A shim spacer **270** can be added to assembly in order to maintain a desired amount of axial play. Shim spacer **270** can be a tube, chosen from a variety of lengths to optimize this axial spacing of the components.

FIG. **9** illustrates a bone segment **144** and a screw assembly **212** for securing the bone segment **144** to the support stage **158** of the transport sled **152**. For clarity purposes, the remainder of the tibia is not shown, nor is the transport sled, which would be located inside the reamed medullary canal of the bone segment **144**. A drill site **220** is chosen for drilling through the bone segment **144**. This drill site **220** corresponds to one of the threaded holes **214** of the support stage **158** of the transport sled **152**, and is located using fluoroscopy or surgical navigation during the surgical procedure. The holes **214** themselves may be made with radiopaque markings to further locate them. The cortex of a single wall of the bone segment **144** is drilled at the drill location **220** to make a pilot hole. A conventional tap (not shown) may then be used to cut internal threads in the bone at the drill location. Cannulated screw **216** is then secured into the tapped hole with external threads **222** engaging with tapped threads. Alternatively, if the cannulated screw **216** is self-tapping, then the initial hole need only be piloted. Cannulated screw is tightened into place with a hex driver, which engages with female hex **226**. Torx® shapes may be used instead of hex shapes. Inner screw **218**, having a head **228** and a threaded shaft **230** is then placed through a non-threaded through hole **224** in the cannulated screw **216** and threaded shaft **230** is engaged with and tightened into threaded hole **214** of the support stage **158** of the transport sled **152**. Hex driver is placed into female hex **232** to tighten inner screw **218**. As illustrated in FIGS. **5** and **6**, there may be three of these connections made, to connect three screw assemblies **212** with the three threaded screw holes **214** of the support stage **158** of the transport sled **152**, though at times it might be desired to make fewer than three connections or even more than three connections.

Referring back to FIG. **4**, the gear stages **180**, **182**, **184** and the magnetic assembly **176** are protected from any biological material that may enter longitudinal slit **150**, by a dynamic seal assembly **234**. The lead screw **160** includes a long threaded portion **236** and a smooth diameter (non-threaded) portion **238**. An O-ring **244** having an "X" cross-section seals over the outer diameter of the smooth diameter portion **238** and maintains the seal during rotation. A retaining structure **246** is welded with termination **248** of enclosed housing **146** and termination **250** of open housing at weld point **252**. A face **254** of retaining structure **246** serves as an axial abutment of O-ring **244** while longitudinal extension **256** of retaining structure **246** retains O-ring **244** at its outer diameter. The retaining structure **246** also further retains thrust bearing **262**. A seal gland **258** presses or snaps in place within the inner diameter of enclosed portion **260** of open housing, to further retain O-ring **244**. The O-ring **244** material may be EPDM or other similarly performing material.

The majority of components in the intramedullary bone transport device can be made of titanium, or titanium alloys, or other metals such as stainless steel or cobalt chromium. Bearings **170**, **262** and pin **206** can be made of 400 series stainless steel. A 10.7 mm diameter actuator having a longitudinal slit **150** length of approximately 134 mm has a total transport length of 110 mm. A 10.7 mm diameter actuator having a longitudinal slit **150** length of approximately 89 mm allows for a total transport length of 65 mm. A torsional finite element analysis was performed on a Titanium-6-4 alloy actuator having these dimensions. The yield torque was 25 Newton-meters. This compares favorably to commonly used trauma nails, some of which experience failure (ultimate torque) at 19 Newton-meters. Yield torque is defined as the torque at which the nail begins to deform plastically, and thus the ultimate torque of the 10.7 mm diameter actuator is above the 25 Newton-meter yield torque.

In FIGS. **2** through **4**, the transport sled **152** abuts end stops **266**, **268** at each respective end of its travel over the lead screw **160**. FIG. **10** illustrates an end stop **266** having a threaded inner diameter **265** configured for engaging the external threads **161** of lead screw **160**. Pin **276** is fit through hole **278** on end **272** of lead screw **160**, and is sized so that pin **276** fits within the inner diameter of counterbore **280** on end stop **266**, thus limiting the axial travel of the end stop **266** in first axial direction **274**. An analogous assembly may be used, using instead a c-clip which clips over a circumferential groove around the end **272** of the lead screw **160**, thus replacing the hole **278** and the pin **276**. Still referring to FIG. **10**, a spring portion **282** is laser cut at one end of end stop **266**. End of transport tube **154** includes ledges **284**, **286** which are configured so that when transport tube **154** approaches end stop **266**, the end **288** of spring portion **282** abuts one of the ledges **284**, **286**. Because the end stop **266** is held statically be combination of counterbore **280**, threads **161**, **265**, and pin **276**, the end **288** places a tangential force on ledge **284** or **286** of transport tube **154**. This causes spring portion **282** to increase in diameter until it is restrained by inner wall **290** of transport tube **154**. The transport sled **152** is thus stopped axially, and even if a large torque is placed on permanent magnet **162** by an external rotating magnetic field. Thus, even a large force that pushes transport sled **152** will not cause the transport tube **154** to jam with lead screw **160**, because the binding is between spring portion **282** of end stop **266** and inner wall **290** of transport tube **154**, and

not between internal nut **156** and lead screw **160**. When subsequently a torque is placed in an opposite direction on permanent magnet **162** by a rotating magnetic field to move the transport sled **152** in a direction opposite the first axial direction **274** the tangential force between the end **288** and one of ledge **286** or **286** decreases, the spring portion **282** decreases in diameter and the transport tube **154** is free to move away from the end **288** of spring portion **282**. End stop **268**, seen at other end of lead screw **260** in FIG. **4**, does not need a pin **276** or c-clip to hold it axially, but instead abuts the increase in diameter between the smaller diameter threaded portion **236** of the lead screw **[260]** *160* and the smooth diameter portion **238** of the lead screw **[260]** *160*. The spring portion **282** of end stop **266**, **268** may alternatively be made from a split lock washer, for simplicity and cost purposes. FIGS. **11-13** illustrate an alternative magnetic assembly **376** having a spring friction slip clutch **377**. The slip clutch **377** serves to limit the maximum amount of force applied on the body tissue, in this case the bone segment **144** and its neighboring soft tissue. It should be noted that the assembly described may be used on other devices that are not bone transport devices, for example, limb lengthening devices, spine distraction devices, jaw distraction devices and cranial distraction devices in which too large of a torque applied to the permanent magnet **162** results in too large of a distraction force, and thus possible damage to tissue or pain. In the alternative magnetic assembly **376**, the permanent magnet **162** is held inside a magnetic housing **364** and an end cap **366** having a cylindrical extension or axle **368**. In this case, however, the permanent magnet **162** is not bonded in place, but is held in place with respect to the magnetic housing **364** and end cap **366** by the use of friction. The magnetic housing **364** and end cap **366** are welded together along a circumferential weld **292**. A spring **294** is laser cut or etched from a material such as superelastic Nitinol®, and may be heat formed so that center portion **296** is axially displaced from outer portion **298**, giving it spring capabilities in the axial direction. FIG. **12** shows the spring **294** trapped between the permanent magnet **162** and the end cap **366**, so that the center portion **296** of spring **294** is axially compressed and therefore places a normal force on the end **300** of the permanent magnet **162**. By controlling the material, the thickness and the dimensions of the spring **294**, a controlled spring constant is achieved, thus applying a consistent normal force, and proportional frictional torque that must be overcome in order to allow permanent magnet **162** to rotate freely within magnet housing **364** and end cap **366**. For example, in a scoliosis distraction device, it is desired that at a torque up to two inch-pounds (0.23 Newton-meter), the permanent magnet **162** and the magnet housing/end cap **364/366** remain static to each other, thus allowing the magnetic assembly **376** to turn the lead screw **160**. In this application, the gear stages **180**, **182**, **184** may be omitted. This represents a distraction force of approximately 125 pounds (556 Newton), at which damage may occur to vertebrae at their attachment point to the implant. Above two inch-pounds, it may be desired that the spring **294** allow the permanent magnet **162** to turn freely with respect to the magnet housing/end cap **364/366**, thus stopping the turning of the lead screw. Alternatively, in a bone transport or limb lengthening device having gear stages **180**, **182**, **184**, and a total gear ratio of 64:1, it may be desired that this slippage occur at 0.046 inch-pounds (0.005 Newton-meter). This limit would potentially be desired in order to protect the device itself or to protect the bone or soft tissue, for example in a patient with an intramedullary tibial implant, in which the external moving magnetic field is placed extremely close to the permanent magnet **162**, and thus able to apply a significantly large torque to it.

FIGS. **14-16** illustrate an alternative magnetic assembly **476** which can be adjusted upon assembly in order to set a specific amount of slip torque between the permanent magnet **162** and the magnet housing **464** and end cap **466**. A wave disc **302** (similar to a wave washer, but without a center hole) is held between a flat washer **304** and an adjustable compression stage **306**. The flat washer **304** serves to protect the permanent magnet **162** and also provide a consistent material surface for friction purposes. The wave disc **302** may be made from stainless steel, and the flat washer **304** may be made from a titanium alloy. Adjustable compression stage **306** has a shaft **316** with a male thread **308** which is engaged within female threads **310** of a cylindrical extension **468**. A hex tool may be placed within access hole **314** of the cylindrical extension **468** and into female hex **312** of the shaft **316** of the adjustable compression stage **306**. Turning in one direction increases compression on the wave disc **302** and thus increases the normal force and frictional slip torque. Turning in the opposite direction decreases these values. Upon assembly, adhesive may be placed on the threads **308**, **310** to permanently bond the adjustable compression stage **306** to the cylindrical extension **468** and maintain the desired amount of frictional slip torque.

The intramedullary bone transport device **100** having a longitudinal slit **150** as shown in FIGS. **1-4** is configured to be implanted within a reamed medullary canal. For example a 10.7 mm diameter device may necessitate reaming to a diameter of 11.0 mm to 13.0 mm. At the beginning of implantation, a certain portion of the longitudinal slit **150** is located where there is no bone (FIG. **5**). Because the longitudinal slit **150** is thus exposed to both the internal environment of the medullary canal and the soft tissue (muscle, etc.) of the limb being treated, there is a potential for biological tissue growth on the moveable portions of the mechanism, such as the lead screw **160**. One way to protect the threads of the lead screw **160**, is by adding a special coating to the surface of the lead screw **160**. Coatings may be applied a variety of ways, for example through deposition, and preferably are biocompatible, hard, thin and resistant to adherence of body tissues or fluids. Exemplary coatings include MoST® (based on molybdenum disulfide) or ADLC (Amorphous Diamond-like Carbon).

Though the coating of the lead screw **160** may prevent biological adherence, it may also be desired to prevent any ingrowth or protuberance of bone material into the longitudinal slit **150**. One reason that this protuberance may interfere with the treatment of the patient is that it may push against some of the dynamic structures of the bone transport device **100**, limiting their functionality. Another reason is that ingrowth of bone into the longitudinal slit **150** may make removal of the bone transport device **100** more difficult, more or less "locking" it in place. Several embodiments of bone transport device **100** having dynamic covers **320** are presented in FIGS. **17** through **19**, each dynamic cover **320** with the capability of protecting the longitudinal slit **150** from the ingrowth of bone, while still allowing for the functionality of the transport sled **152** mechanism of the bone transport device **100**. FIG. **17** illustrates a bone transport device **318** having a dynamic cover **320** including two opposing combs **322**, **324**, each of whose teeth extend towards the center line **326** of the longitudinal slit **328**. The dynamic cover **320** substantially covers the portion of the longitudinal slit **328** not occupied by the transport sled **152**. Comb material may be chosen from superelastic Nitinol,

MP35N, Elgiloy® which are biocompatible and have a good combination of strength and repetitive bending characteristics. Individual comb teeth **334** may be 0.105" in length, 0.050" in width and 0.003" in thickness. Transport sled **330** has a specially angled prow **332** on each end, the prows causing the teeth **334** of the combs **322**, **324** on each side to be pushed against the side of the slit **328** with relatively low force as the transport sled **330** passes by that particular area. The prow **322** is symmetric along the centerline **326**. After the transport sled **330** passes by, the teeth **334** return to their original position covering their half of the slit **328**. The angulation of the prow **332**, allows the transport sled **330** to slide past the flexing teeth **334** with minimal interference or frictional force. An exemplary included angle of the top of the prow **332** (in relation to the centerline **326**) is 60°. A more detailed view of the transport sled **330** is seen in FIGS. **25**A and **25**B. Grooves **335** on each side of transport sled **330** allow transport sled **330** to ride along rails **337** at edges of slit **328** along the open housing **331** of bone transport device **318**.

FIG. **18** illustrates a bone transport device **336** having a dynamic cover **320** having a static ribbon **338** which covers the slit **340**. Transport sled **342** is configured to slide over the static ribbon **338**. The bone transport device **336** having a static ribbon **338** is shown in more detail in FIGS. **20** and **21**. Static ribbon **338** is secured to the open housing **348** at first end **344** and second end **346**, both ends adjacent to slit **340**. Static ribbon **338** is made of 0.002" thick Nitinol and has a width of 0.140". A detailed view of the transport sled **342** is shown in FIG. **26**. The transport sled **342** has a total width (W**1**) of 0.288". A channel **350** is wirecut in each end of transport sled **342**, the channel **350** allows the static ribbon **338** to pass from the outside to the inside of transport sled **342** (and vice versa). During operation, the static ribbon **338** stays in place, while the transport sled **342** slides over it. The channel **350** width (W**2**) is 0.191", and channel thickness is 0.012" giving enough space for the 0.002" thick static ribbon **338** to slide freely with respect to the transport sled **342**. A first radius **352** and a second radius **354** further aid in smooth sliding of the transport sled **342** over the static ribbon **338**. The centerline of channel **350** through each radius **352**, **354** follows a 0.036" radius. As with many components of the bone transport device **336**, the transport sled **342** may be made from Titanium alloy, for example titanium-6A1-4V. Alternatively, the components may be made of cobalt chromium or stainless steel. By controlling the tension at which the static ribbon **338** is held, the dynamic frictional force as the transport sled **342** slides over the static ribbon **338** can be varied, but is typically on the order of about one pound. An alternative to bone transport device **336** is envisioned, wherein the static ribbon **338** is replaced by a ribbon which is fixedly secured to the transport sled **342**, and which slides in a similar manner to a conveyor belt.

FIG. **19** illustrates a bone transport device **356** with a dynamic cover **320** having a freely rotatable spiral-cut tube **358** configured to cover the slit **360**. Spiral-cut tube **358** has a single spiral gap or cut **362** in its wall, helically oriented along its length. The width of the spiral gap **362** in the axial direction is about the same as the length of the transport sled **370**. As the transport sled **370** moves in an axial direction **372**, the spiral cut tube **358** is forced to turn in a rotational direction **374**, as the leading end **359** transport sled **370** contacts the edge **361** of the spiral cut tube **358** along the spiral gap **362**. In this manner, the spiral-cut tube **358** always covers the portion of the slit **360** that is not already covered by the transport sled **370**. Spiral-cut tube **358** may be formed from a number of different materials, such as PEEK (polyether ether ketone) or titanium, stainless steel or cobalt chromium.

An alternative to the mechanical dynamic covers **320** of FIGS. **17-19**, a self-healing hydrogel may be coated or sprayed over the longitudinal slit **150**. Hydrogels of this type have been described in "Rapid self-healing hydrogels" by Phadke et. al., Proceedings of the National Academy of Sciences, Volume 109, No. 12, pages 4383-4388, which is incorporated by reference herein. A self-healing hydrogel acts like molecular Velcro®, and can cover the area of the longitudinal slit **150**. As the transport sled **152** moves longitudinally, the hydrogel is slit open in the direction of longitudinal movement of the transport sled **152**, while the transport sled **152** moves away from an already slit portion of the hydrogel. By controlling the pH and side chain molecule lengths in the manufacture of the hydrogel, a hydrogel can be made that both allows the slitting by the transport sled **152** and allows the rebinding of the prior slit.

FIGS. **22-24** illustrate an external adjustment device **378** configured for applying a moving magnetic field to allow for non-invasive adjustment of the bone transport device **100**, **318**, **336**, **356** by turning a permanent magnet **162** within the bone transport device **100**, **318**, **336**, **356**, as described. FIG. **22** illustrates the internal components of the external adjustment device **378**, and for clear reference, shows the permanent magnet **162** of the bone transport device **100**, **318**, **336**, **356**, without the rest of the assembly. The internal working components of the external adjustment device **378** may, in certain embodiments, be similar to that described in U.S. Patent Application Publication No. 2012/0004494, which is incorporated by reference herein. A motor **380** with a gear box **382** outputs to a motor gear **384**. Motor gear **384** engages and turns central (idler) gear **386**, which has the appropriate number of teeth to turn first and second magnet gears **388**, **390** at identical rotational speeds. First and second magnets **392**, **394** turn in unison with first and second magnet gears **388**, **390**, respectively. Each magnet **392**, **394** is held within a respective magnet cup **396** (shown partially). An exemplary rotational speed is 60 RPM or less. This speed range may be desired in order to limit the amount of current density induced in the body tissue and fluids, to meet international guidelines or standards. As seen in FIG. **22**, the south pole **398** of the first magnet **392** is oriented the same as the north pole **404** of the second magnet **394**, and likewise, the first magnet **392** has its north pole **400** oriented the same as the south pole **402** of the second magnet **394**. As these two magnets **392**, **394** turn synchronously together, they apply a complementary and additive moving magnetic field to the radially-poled, permanent magnet **162**, having a north pole **406** and a south pole **408**. Magnets having multiple north poles (for example, two) and multiple south poles (for example, two) are also contemplated in each of the devices. As the two magnets **392**, **394** turn in a first rotational direction **410** (e.g., counter-clockwise), the magnetic coupling causes the permanent magnet **162** to turn in a second, opposite rotational direction **412** (e.g., clockwise). The rotational direction of the motor **380** and corresponding rotational direction of the magnets **392**, **394** is controlled by buttons **414**, **416**. One or more circuit boards **418** contain control circuitry for both sensing rotation of the magnets **392**, **394** and controlling the rotation of the magnets **392**, **394**.

FIGS. **23** and **24** show the external adjustment device **378** for use with a bone transport device **100**, **318**, **336**, **356** placed in the femur (FIG. **23**) or the tibia (FIG. **24**). The external adjustment device **378** has a first handle **424** for

carrying or for steadying the external adjustment device **378**, for example, steadying it against an upper leg **420**, as in FIG. **23**. An adjustable handle **426** is rotationally attached to the external adjustment device **378** at pivot points **428**, **430**. Pivot points **428**, **430** have easily lockable/unlockable mechanisms, such as a spring loaded brake, ratchet or tightening screw, so that a desired angulation of the adjustable handle **426** in relation to housing **436** can be adjusted and locked in orientation. Adjustable handle **426** is shown in two different positions in FIGS. **23** and **24**. In FIG. **23**, adjustable handle **426** is set so that apex **432** of loop **434** rests against housing **436**. In this position, patient **438** is able to hold onto one or both of grips **440**, **442** while the adjustment procedure (for example transporting bone between 0.10 mm and 1.50 mm) is taking place. It is contemplated that the procedure could also be a lengthening procedure for an intramedullary bone lengthening device or a lengthening procedure for a lengthening plate which is attached external to the bone. Turning to FIG. **24**, when the bone transport device **100**, **318**, **336**, **356** is implanted in a tibia, the adjustable handle **426** may be changed to a position in which the patient **438** can grip onto the apex **432** so that the magnet area **444** of the external adjustment device **378** is held over the portion the bone transport device **100**, **318**, **336**, **356** containing the permanent magnet **162**. In both cases, patient is able to clearly view control panel **446** including a display **448**. In a different configuration from the two directional buttons **414**, **416** in FIG. **22**, control panel **446** includes a start button **450**, a stop button **452** and a mode button **454**. Control circuitry contained on circuit boards **418** may be used by the surgeon to store important information related to the specific aspects of each particular patient. For example, in some patients an implant may be placed antegrade into the tibia. In other patients the implant may be placed either antegrade or retrograde into the femur. In each of these three cases, it may be desired to transport the bone either from distal to proximal or from proximal to distal. There are thus six (6) different scenarios. By having the ability to store information of this sort that is specific to each particular patient within the external adjustment device **378**, the external adjustment device **378** can be configured to direct the magnets **392**, **394** to turn in the correct direction automatically, while the patient need only place the external adjustment device **378** at the desired position, and push the start button **450**. The information of the maximum allowable bone transport length per day and maximum allowable bone transport length per session can also be input and stored by the surgeon for safety purposes. These may also be added via an SD card or USB device, or by wireless input. An additional feature is a camera at the portion of the external adjustment device **378** that is placed over the skin. For example, the camera may be located between first magnet **392** and second magnet **394**. The skin directly over the implanted permanent magnet **162** may be marked with indelible ink. A live image from the camera is then displayed on the display **448** of the control panel **446**, allowing the user to place the first and second magnets **392**, **394** directly over the area marked on the skin. Crosshairs can be overlayed on the display **448** over the live image, allowing the user to align the mark on the skin between the crosshairs, and thus optimally place the external adjustment device **378**.

FIGS. **27** and **28** illustrate an alternative embodiment to the anti-jamming end stop described in FIGS. **2-4** and in FIG. **10**. Transport sled **152** has been removed so that the rest of the anti-jamming assembly **482** can clearly be seen. Internal nut **456** is similar to internal nut **156** of FIGS. **2-4**, **10** in that it can be made, simply as an internal thread of the transport tube **154**, or alternatively, it can be a separate component. For example, the outer surface of the internal nut **456** may be made with an external thread **458** and the inner surface of the transport tube **154** may be made with a mating internal thread. These two surfaces may be bonded to each other, with adhesives, epoxies, etc., so that the internal thread of the internal nut **456** mates with the external threads **161** of the lead screw **160**. In FIG. **27**, a single pawl ring **460**, having a single pawl **462** is secured to the lead screw **160** by welding, adhesive, epoxy or other methods. The single pawl **462** thus turns in unison with the lead screw **160**. The end of the internal nut **456** has a ledge **470** at its end. This ledge **470** is configured to abut the single pawl **462** when the lead screw **160** reaches the end of its desired travel in relation to the internal nut **456**. In FIG. **27**, there are several turns remaining in the travel of the lead screw **160**. In FIG. **28**, the lead screw has reached the end of its desired travel and the single pawl **462** now abuts the ledge **470**, thus not allowing any more rotation in this direction for the lead screw **160**. The opposing forces between the single pawl **462** and the ledge **470** assure that the internal threads of the internal nut **456** will not jam with the external threads **161** of the lead screw **160**. Another single pawl **480** at the opposite end of the internal nut **456** may be used to engage with another ledge (not shown) at the opposite end of the lead screw **160**, thus eliminating jamming at the opposite end of travel of the internal nut **456** and lead screw **160**.

FIGS. **29** and **30** show an alternative anti jamming assembly **484** to the embodiment of FIGS. **27** and **28**. In FIG. **29**, the end piece **472** of the lead screw **160** has multiple pawls **474**, which engage multiple ledges or teeth **478** when lead screw **160** reaches the end of its travel. The stress between the pawl and ledge is now distributed amongst multiple pawls **474** and ledges or teeth **478**, thus also allowing a smaller axial dimension of the pawls **474** and ledges **478**.

Returning to FIGS. **5** and **6**, a bone transport procedure is described. After patient is prepped for surgery, a drill entry point **131** is chosen to ream a hole in the medullary canal of the tibia **136**. Intramedullary bone transport device **100** is inserted into reamed medullary canal and secured with bone screws **126**, **128**, **130**, **132**, **134**. Prior to creating an osteotomy **147**, bone segment **144** for transport is chosen and secured to transport sled **152** with screw assemblies **[112]** *212* as described herein. Osteotomy **147** is then made, freeing bone segment **144** from proximal portion of tibia **138**. Osteotomy **147** may be made with osteotomes or a Gigli saw. As an alternative, the osteotomy **147** may be made prior to securing the bone segment **144** to the transport sled **152**. Prior to recovering the patient, a test transport procedure may be performed in the operating theater, for example using an external adjustment device **378** covered with a sterile drape. This test transport procedure may be done either to confirm that the intramedullary bone transport device **100** has not been damaged by the insertion procedure or to set the osteotomy **147** at a desired initial gap distance, for example zero (0) to five (5.0) mm. The patient is then recovered, and within the first week after surgery, non-invasive bone transport procedures are initiated by the physician, patient or family or friend of patient, typically consisting of transporting about 1 mm per day. For example 1 mm, once per day, or 0.5 mm, twice per day, 0.33 mm, three times per day, etc. using the external adjustment device **378** as in FIGS. **23** and **24**. As the bone segment **144** transports, new bone **153** begins to form where the missing portion **142** had previously been. Towards the end of the patient's transport period of treatment, the bone segment **144** nears the proximal end **135** of the distal portion **140** of

the tibia **136**. (All procedures described may be done on a variety of different bones.) A final gap **151** may be decided upon by the physician, and when this final gap **151** is reached (for example, 5 mm), the surgeon may desire to do a grating procedure to facilitate the continuity of bone between the bone segment **144** and the distal portion **140** of the tibia **136**. The new bone **153** is typically allowed approximately one month per 10 mm of transported length to consolidate, but this time period can vary greatly depending upon the biological characteristic (e.g. diabetes) and habits (e.g. smoking) of the patient.

FIG. **31**A illustrates an intramedullary bone transport device **550** having a reverse block and tackle arrangement according to another embodiment. A first housing portion **578** and a second housing portion **548** enclose the internal reverse block and tackle components, shown in FIGS. **31**B and **32**. First housing portion **578** contains two slits **551** through which first tension line **552** and second tension line **554** exit. After implantation, bone segment **144** is secured to tension lines **552**, **554** using bone screws having a clamp feature at their tips that enters the intramedullary canal and grips each of the tension lines **552**, **554**. The lead screw **556** is turned by permanent magnet **162** and gear stages **180**, **182**, **184** as in other embodiments. The nut **558** moves along lead screw **556** in first direction **553** as lead screw **556** is turned. The tension lines **552**, **554** wrap around nut pulleys **566**, **565** respectively (shown without nut **558** in FIG. **32**). The nut pulleys **566**, **565** are held rotatably to the nut **558** by pins **555**, **557**. The exit pulleys **563**, **564** are held rotatably to the wire seal block **562** and first housing portion **578** with axle pin **574**, which may be welded to the first housing portion **578** at each end. The tension lines **552**, **554** wrap around exit pulleys **564**, **563** respectively. At the end of tension lines **552**, **554** are crimped lugs **576**, which are secured axially within cavities in the wire seal block **562**. A seal **570** is sandwiched between the wire seal block **562** and a seal support plate **568** by screw **572**. The four (4) inner diameters **571** passing through the seal **570** are sized to be slightly smaller than the outer diameter of the tension lines **552**, **554**, so that any body fluids entering through slits **551** cannot enter further into the section of first housing portion **578** and second housing portion **548** containing lead screw **556**, nut **558**, permanent magnet **162** and gear stages **180**, **182**, **184**. The seal **570** is made from an elastomer such as EPDM, so that tension lines **552**, **554** may move through inner diameters **571** while still maintaining a sealed condition. In FIG. **32**, the nut **558** and the wire seal block **562** are not shown so that more detail of the pathway of the tension lines **552**, **554** may be seen. A guide rod **560** is secured to the assembly of the wire seal block **562**, seal **570**, and seal support plate **568**. The nut **558** has an off center guide hole sized for sliding over the guide rod **560**. As the nut **558** moves in first direction **553** over turning lead screw **556**, nut pulleys **566**, **565** move along with nut **558**, causing each tension line **552**, **554** to be pulled around exit pulleys **564**, **563**, thus allowing tension lines **552**, **554** to pull bone segment **144** in second direction **559**. Because of the reverse block and tackle arrangement, the tension lines **552**, **554** move at a axial rate that is twice as fast as the rate of axial movement rate of the nut **558**. Thus, for a nut **558** that travels only 55 mm total travel over lead screw **556**, the tension lines **552**, **554** are each pulled for 110 mm total travel, allowing for a compact device which still produces a large amount of bone transport length capability.

FIGS. **33** through **36** illustrate an intramedullary bone transport device **528** according to another embodiment having a ribbon-driven transport sled **530**. Lead screw **160** is driven by permanent magnet **162**, with gear stages **180**,**182**, **184** as in FIGS. **1-4**, however, the connection between lead screw **160** and transport sled **530** is no longer direct. Nut **532** having internal threading is coupled to lead screw **160** and moves longitudinally as lead screw **160** turns. Ribbon **534** is secured to nut **532**, for example by welding or crimping, at one end and to transport sled **530** at the other end. Pulley **536** is rotatably coupled to enclosed housing **546** via axle **538**. Ribbon **534** extends around pulley **536** so that movement of nut **532** in first direction **540** pulls ribbon **534** around pulley **536**, causing transport sled to move in second direction **542**. The multiple types of dynamic covers **320** described in prior embodiments, would also be usable in this embodiment. The ribbon in FIGS. **33-36** is a single material ribbon made from Nitinol or stainless steel, for example 0.006" thick Nitinol ribbon. As yet a further embodiment, ribbon **534** may be constructed of a laminate of several ribbon layers bonded together, for example four layers of 0.002" thick Nitinol or three layers of 0.003" thick Nitinol. The layers are bonded together with a flexible adhesive, such as a urethane adhesive, which allows the layers to slide slightly in longitudinal relation to each other, as they move around the pulley **536**. Each of the layers may be a single ribbon structure as described, or may also be a multifilar, woven ribbon. The laminate construction allows for a nut **532** that not only can pull transport sled **530**, but also push transport sled **530**, due to the increased column stiffness during compression. When this push/pull embodiments is in push mode, radii **544** (as seen in FIG. **35**) in the inner walls of enclosed housing **546** serve as a path for the ribbon **534** when the ribbon **534** is in compression (pushing). Ribbon **534** can refer to any analogous tensile member, for example one or more wires or cables configured to extend around pulley **536**.

Other alternatives exist for constructing any of the embodiments presented herein. As one example, instead of solid rare earth magnet material, the magnets presented may be made as composite rare earth magnets, such as those described in U.S. Patent Application Publication Nos. 2011/0057756, 2012/0019341, and 2012/0019342, which are incorporated by reference herein.

A maintenance feature, such as a magnetic plate, may be incorporated on any of the embodiments of the implant devices presented herein, such as those described in U.S. Patent Application Publication No. 2012/0035661.

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. The invention, therefore, should not be limited, except to the following claims, and their equivalents.

What is claimed is:

[1. An implantable dynamic apparatus comprising:

a nail having a first portion and a second portion, the first portion of the nail configured for securing to a first portion of bone, the second portion of the nail configured for securing to a second portion of bone;

the second portion of the nail configured to be longitudinally moveable with respect to the first portion of the nail, wherein the second portion of the nail includes an internally threaded feature;

a magnetic assembly configured to be non-invasively actuated by a moving magnetic field;

a lead screw having an externally threaded portion, the lead screw coupled to the magnetic assembly, wherein the externally threaded portion of the lead screw engages the internally threaded feature of the second portion of the nail;

wherein actuation of the magnetic assembly turns the lead screw, which in turn changes the longitudinal displacement between the first portion of the nail and the second portion of the nail;

a first abutment surface coupled to the lead screw;

a second abutment surface coupled to the second portion of the nail; and

wherein the turning of the lead screw in a first direction causes the first abutment surface to contact the second abutment surface, stopping the motion of the lead screw with respect to the second portion of the nail, and wherein subsequent turning of the nail in a second direction is not impeded by any jamming between the internally threaded feature and the externally threaded portion.]

2. A method for performing a bone transport procedure, the method comprising:

preparing the medullary canal of a bone for placement of an implantable dynamic apparatus configured to change its configuration at least partially from a moving magnetic field supplied by an external adjustment device, the change in configuration comprising the longitudinal movement of a transport sled;

placing the implantable dynamic apparatus within the medullary canal of the bone;

securing a first end of a nail to a first portion of the bone;

securing a second end of a nail to a second portion of the bone; and

storing information in the external adjustment device, the information comprising an orientation of the nail within the bone and a direction of planned movement of the transport sled.

3. The method of claim 2, wherein the implantable dynamic apparatus further comprises:

a housing having a wall with a longitudinal opening extending a length along a portion thereof;

the transport sled disposed in the longitudinal opening and configured to move along the longitudinal opening;

a magnetic assembly disposed within the nail and configured to be non-invasively actuated by the moving magnetic field;

a lead screw coupled to the magnetic assembly;

a first abutment coupled to the lead screw; and

a second abutment coupled to the second end of the nail, and wherein the method further comprises:

securing a third portion of the bone to the transport sled; and

applying the moving magnetic field to the magnetic assembly, thereby actuating the magnetic assembly and causing the lead screw to rotate and the transport sled to move along the longitudinal opening,

wherein a rotation of the lead screw in a first direction causes the first abutment to contact the second abutment and stops the motion of the lead screw with respect to the nail.

4. The method of claim 3, wherein an externally threaded portion of the lead screw and an internally threaded feature of the nail are configured to allow turning of the nail in a second direction, opposite the first direction subsequent to the applying step.

5. The method of claim 3, further comprising:

by applying the moving magnetic field to the magnetic assembly, causing an externally threaded portion of the lead screw to engage with an internally threaded feature of the nail.

6. The method of claim 3, wherein the transport sled has a length that is shorter than the length of the longitudinal opening.

7. The method of claim 3, wherein the lead screw comprises an externally threaded surface having a coating thereon.

8. The method of claim 3, wherein the applying of the moving magnetic field further comprises using the external adjustment device to rotate at least one rotatable magnet.

9. A method for performing a bone transport procedure, the method comprising:

placing an implantable dynamic apparatus within a medullary canal of a bone, the implantable dynamic apparatus comprising:

a nail having a proximal end and a distal end;

a housing having a wall with a longitudinal opening extending a length along a portion thereof;

a transport sled disposed in the longitudinal opening and configured to move along the longitudinal opening, the transport sled including a first contact surface;

a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field;

a lead screw coupled to the magnetic assembly;

securing the proximal end of the nail to a first portion of the bone;

securing the distal end of the nail to a second portion of the bone;

securing a third portion of the bone to the transport sled;

applying the moving magnetic field to the magnetic assembly to actuate the magnetic assembly and cause the lead screw to rotate and the transport sled to move along the longitudinal opening; and

securing a stop having a second contact surface to the lead screw, wherein in response to the rotation of the lead screw, the stop radially expands and prevents additional rotation of the lead screw.

10. The method of claim 9, wherein the magnetic assembly comprises a cylindrical permanent magnet configured to be turned by the moving magnetic field.

11. The method of claim 10, wherein the cylindrical permanent magnet is held by a magnet holder rotationally coupled to the magnetic assembly.

12. The method of claim 9, wherein the applying comprises applying the moving magnetic field by using an external adjustment device to rotate at least one rotatable magnet.

13. The method of claim 12, further comprising: storing information in the external adjustment device, the information comprising an orientation of the nail within the bone and a direction of planned movement of the transport sled.

14. A method for performing a bone transport procedure, the method comprising:

placing an implantable dynamic apparatus within a medullary canal of a bone, the implantable dynamic apparatus comprising:

a nail having a proximal end and a distal end,

a housing having a wall with a longitudinal opening extending a length along a portion thereof,

a transport sled disposed in the longitudinal opening and configured to move along the longitudinal opening,

a magnetic assembly disposed within the nail and configured to be non-invasively actuated by a moving magnetic field, wherein the magnetic assembly comprises a cylindrical permanent magnet config-

ured to be turned by the moving magnetic field and to be held by a magnet holder rotationally coupled to the magnetic assembly, and

a lead screw coupled to the magnetic assembly;

securing the proximal end of the nail to a first portion of the bone;

securing the distal end of the nail to a second portion of the bone;

securing a third portion of the bone to the transport sled; and

applying the moving magnetic field to the magnetic assembly, thereby actuating the magnetic assembly,

wherein the actuating causes the lead screw to rotate and the transport sled to move along the longitudinal opening.

15. The method of claim 14, further comprising coupling the magnet holder to the cylindrical permanent magnet.

16. The method of claim 15, wherein the coupling further comprises:

applying a static frictional torque to the cylindrical permanent magnet,

wherein:

when the moving magnetic field couples to the cylindrical permanent magnet at a torque below the static frictional torque, the cylindrical permanent magnet and the magnet holder turn in unison, and

when the moving magnetic field couples to the cylindrical permanent magnet at a torque above the static frictional torque, the cylindrical permanent magnet turns while the magnet holder remains rotationally stationary.

17. The method of claim 16, further comprising adjusting the static friction torque over a range of static frictional torques.

18. The method of claim 14, wherein the magnetic assembly comprises a magnetic housing containing the cylindrical permanent magnet therein and a biasing member interposed between the magnetic housing and the cylindrical permanent magnet, wherein the magnetic housing and the cylindrical permanent magnet are rotationally locked by the biasing member up to a threshold torque value.

19. The method of claim 14, further comprising:

coupling the lead screw to a nut moveable along a length of the lead screw in response to rotation thereof; and

securing a ribbon to the nut at one end and to the transport sled at an opposing end and passing the ribbon over at least one pulley, wherein movement of the nut in a first direction translates into movement of the transport sled in a second, opposing direction.

20. The method of claim 14, further comprising:

coupling the lead screw to a nut moveable along a length of the lead screw in response to rotation thereof, the nut containing at least one nut pulley affixed thereto;

disposing at least one exit pulley within the implantable dynamic apparatus at the proximal end;

fixing at least one tension line relative to the proximal end and passing the at least one tension line over both the at least one nut pulley and the at least one exit pulley; and

securing the at least one tension line to the third portion of bone.

21. The method of claim 14, wherein the applying comprises applying the moving magnetic field by using an external adjustment device comprising at least one rotatable magnet, and the method further comprises storing information in the external adjustment device, the information comprising an orientation of the nail within the bone and a direction of planned movement of the transport sled.

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