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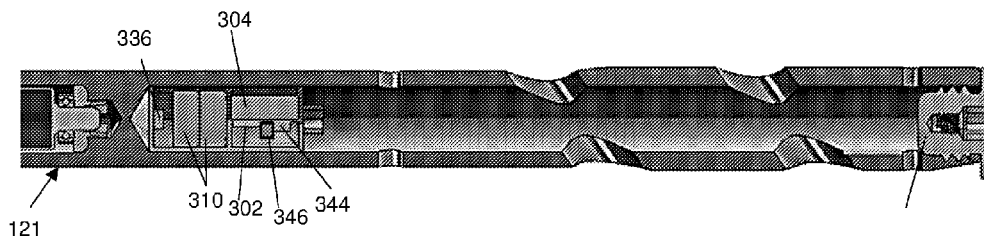


FIG. 8

120

(57) Abstract: Aspects of the disclosure relate to an adjustable implant configured to be implanted into a patient that includes an adjustable portion moveable relative to a housing. The adjustable implant may include various smart components for enhancing operation of the implant. Smart components may include a controller for managing operations and a transducer for communicating ultrasound data with an external interface device. Additional smart components may include a load cell within the housing for measuring an imparted load; a sensor for measuring angular position of the adjustable portion; a dual sensor arrangement for measuring imparted forces; a reed switch; a half piezo transducer; and an energy harvester.



## ADJUSTABLE IMPLANT, SYSTEM AND METHODS

### CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of US Provisional Application No. 63/152,562, filed February 23, 2021.

### TECHNICAL FIELD

[0002] The subject matter described herein relates to an adjustable implant, an adjustable implant system and associated methods.

### BACKGROUND

[0003] 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.

[0004] 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.

### SUMMARY

[0005] A first aspect of the disclosure relates to an adjustable implant configured to be implanted into a patient. The adjustable implant may include: an adjustable portion moveable relative to the housing;

and a load cell within the housing for measuring a load imparted on the implant during movement of the adjustable portion relative to the housing or during movement of a bone relative to the housing.

[0006] A second aspect of the disclosure relates to a method. The method includes: adjusting an adjustable implant having: a housing; an adjustable portion moveable relative to the housing; and a load cell within the housing for measuring a load; and measuring, with the load cell, the load imparted on the implant during movement of the adjustable portion relative to the housing or during movement of a bone relative to the housing.

[0007] A third aspect of the disclosure relates to an adjustable implant. The adjustable implant includes: a housing; an adjustable portion movable relative to the housing; an actuator positioned within the housing and configured to cause movement of the adjustable portion relative to the housing; and a sensor positioned adjacent to the actuator and configured to monitor an angular position of the actuator.

[0008] A fourth aspect of the disclosure relates to a method. The method includes: adjusting an adjustable implant, the adjustable implant including: a housing; an adjustable portion moveable relative to the housing; an actuator positioned within the housing and configured to cause movement of the adjustable portion relative to the housing; and a sensor positioned adjacent to the actuator and configured to monitor an angular position of the actuator; sensing, via the sensor, an angular position of the actuator; and calculating a distraction length or a compression length of the adjustable implant based upon the number of rotations of the actuator.

[0009] A fifth aspect of the disclosure relates to an adjustable implant. The adjustable implant includes: a housing; an adjustable portion moveable relative to the housing; a first actuator configured to cause movement of the adjustable portion relative to the housing, the first actuator being actuated by an external adjustment device having a second actuator therein; a first sensor configured to measure a position of the first actuator; and a second sensor configured to measure a position of the second actuator within the external adjustment device.

[0010] A sixth aspect of the disclosure relates to a method. The method includes: adjusting an adjustable implant, the adjustable implant having a housing and an adjustable portion moveable relative to the housing; measuring a position of a first actuator of the adjustable implant, the first actuator being configured to cause movement of the adjustable portion relative to the housing; measuring a position of a second actuator of an external adjustment device, the external adjustment device configured to actuate the first actuator of the adjustable implant; and determining at least one

of a distraction force, a distraction torque, a compression force, and a compression length based on the position of the first actuator and the position of the second actuator at a given time.

[0011] A seventh aspect of the disclosure relates to an adjustable implant. The adjustable implant includes: a housing; an adjustable portion moveable relative to the housing; a first actuator configured to cause movement of the adjustable portion relative to the housing, the first actuator being actuated by an external adjustment device having a second actuator therein; a first sensor located at a first position in the housing configured to measure a first magnetic field of the first actuator relative to the second actuator; a second sensor located at a second position in the housing configured to measure a second magnetic field of the first actuator relative to the second actuator; and a controller that determines at least one force by analyzing the first magnetic field and the second magnetic field.

[0012] An eighth aspect of the disclosure relates to a method. The method includes: adjusting an adjustable implant, the adjustable implant having a housing and an adjustable portion, the adjustable implant having a first actuator configured to cause movement of the adjustable portion relative to the housing in response to movement of a second actuator of an external adjustment device; using a first sensor positioned at a first location in the housing to measure a first magnetic field of the first actuator of the adjustable implant relative to the second actuator; using a second sensor positioned at a second location in the housing to measure a second magnetic field of the first actuator of the adjustable implant relative to the second actuator; and determining at least one force by analyzing the first magnetic field and the second magnetic field.

[0013] A ninth aspect of the disclosure relates to a signal transmission device. The signal transmission device includes: a housing; a half-cylinder piezoelectric transducer positioned within the housing and having an inner diameter and an outer diameter; a metal backing positioned adjacent the inner diameter; and a semiconductor package positioned within the housing and substantially surrounding the half-cylinder piezoelectric transducer and the metal backing.

[0014] A tenth aspect of the disclosure relates to an adjustable implant. The adjustable implant included: an implant housing; and a signal transmission device positioned within the implant housing, the signal transmission device including: a half-cylinder piezoelectric transducer having an inner diameter and an outer diameter; a metal backing positioned adjacent the inner diameter; and a semiconductor package positioned within the housing and substantially surrounding the half-cylinder piezoelectric transducer and the metal backing.

[0015] An eleventh aspect of the disclosure relates to an adjustable implant. The adjustable implant includes: a housing; an adjustable portion moveable relative to the housing upon application of a force

supplied by an external adjustment device; a sensor disposed within the housing and configured to measure an angular position of an actuator positioned within the housing; a controller communicatively coupled to the sensor and configured to determine at least one of a distraction force and distraction length based on the angular position of the actuator; and a switch configured to activate at least one of the controller and sensor.

[0016] A twelfth aspect of the disclosure relates to a method. The method includes: providing an adjustable implant including: a housing and an adjustable portion moveable relative to the housing upon actuation of an actuator within the housing upon application of a force supplied by an external adjustment device; a sensor configured to sense an angular position of the actuator; and communicatively coupled to the sensor and configured to determine at least one of a distraction force and distraction length based on the angular position of the actuator; and activating at least one of the controller and the sensor when the external adjustment device is within a threshold proximity to the adjustable implant.

[0017] A thirteenth aspect of the disclosure relates to an implant configured to be implanted within a patient. The implant includes: a controller; an energy harvesting component configured to harvest energy imparted on the implant during movement of the patient having the implant therein; and an energy storage device configured to store the energy harvested by the energy harvesting component, wherein the energy harvested by the energy harvesting component provides power for the controller.

[0018] A fourteenth aspect of the disclosure relates to a method. The method includes: implanting an implant within a patient; harvesting energy from stresses imparted on the implant during movement by the patient having the implant implanted therein; and using the harvested energy to power at least one of a controller and a transducer of the implant.

## **BRIEF DESCRIPTION OF DRAWINGS**

[0019] The accompanying drawings, which are incorporated in and constitute a part of this specification, show certain aspects of the subject matter disclosed herein and, together with the description, help explain some of the principles associated with the disclosed implementations. In the drawings,

[0020] FIG. 1 shows a side view of an adjustable implant according to embodiments of the disclosure;

[0021] FIG. 2 shows a cross-sectional view of an adjustable implant according to FIG. 1;

[0022] FIG. 3 shows an enlarged cross-sectional view of the actuating components of the adjustable implant at region A;

[0023] FIG. 4 shows an enlarged cross-sectional view of the adjustable implant at region B;

[0024] FIG. 5 shows a perspective view of the load cell of the adjustable implant according to embodiments of the disclosure;

[0025] FIG. 6 shows a perspective view of the magnet of the actuator of the implant;

[0026] FIG. 7 shows a schematic of the sensor, controller, transducer, and power supply components according to embodiments of the disclosure;

[0027] FIG. 8 shows an enlarged cross-sectional view of an alternative embodiment of the adjustable implant at region B without the load cell;

[0028] FIG. 9 shows a schematic of the first sensor, second sensor, controller, transducer, and power supply components according to embodiments of the disclosure;

[0029] FIG. 10 shows a phase shift diagram of the relationship of the magnet of the implant and the magnet of the external adjustment device;

[0030] FIG. 11 shows a schematic of a system used to determine the distraction force/torque by the adjustable implant of FIG. 8 according to one embodiment;

[0031] FIG. 12 shows schematics of various techniques for using dual sensors to analyze magnetic fields;

[0032] FIG. 13 shows a perspective view of a signal transmission device according to embodiments of the disclosure;

[0033] FIG. 14 shows a cross-sectional view of the signal transmission device within the housing of the implant according to embodiments of the disclosure;

[0034] FIG. 15 shows a schematic of an energy harvesting system according to embodiments of the disclosure;

[0035] FIG. 16 shows an illustrative external interface device;

[0036] FIG. 17 shows a front view of an external adjustment device according to embodiments of the disclosure;

[0037] FIG. 18 shows a cross-sectional side view the external adjustment device according to embodiments of the disclosure;

[0038] FIG. 19 shows a cross-sectional view of a magnet drive system including a motor having an internal motor speed sensor; and

[0039] FIG. 20 depicts an illustrative computing system according to embodiments of the disclosure.

[0040] It is noted that the drawings of the subject matter are not necessarily to scale. The drawings are intended to depict only typical aspects of the subject matter, and therefore, should not be

considered as limiting the scope of the disclosed subject matter. In the drawings, like numbering represents like elements between the drawings.

## **DETAILED DESCRIPTION**

[0041] The present disclosure describes various embodiments of an adjustable implant, an adjustable implant system and associated methods. The embodiments described herein can be used as an extramedullary limb lengthening device/system, intramedullary limb lengthening device/system, an adjustable spinal device/system. It is also contemplated that the embodiments described herein can be used in spinal fixation devices/systems, such as for example, in the treatment of scoliosis. More specifically, the present disclosure is directed to an adjustable implant having smart electronics that allows the adjustable implant to work more efficiently and intelligibly.

[0042] In certain embodiments, a system is provided for adjusting the position of two bone portions relative to each other that includes: (1) an adjustable implant 100 having various smart components (FIGS. 1-4) fixed within a patient, (2) an external adjustment device 400 (also referred to as an external remote control “ERC”) positioned external to the patient (FIGS. 17-19), and (3) an external interface device 305, e.g., a computer, a tablet, a smartphone, one or more Apps, etc., (FIG. 16) for interfacing with smart components in the adjustable implant 100. In alternative embodiments, some or all of the functions provided by external interface device 305 are integrated into external adjustment device 400.

### **I. General Implant Discussion**

[0043] FIG. 1 shows a perspective view of the adjustable implant (i.e., distraction/compression device) 100. As shown, the adjustable implant 100 includes a housing 102 and an adjustable portion 104 moveable relative to the housing 102. The adjustable portion 104 may include a distraction rod configured to telescopically move relative to the housing 102. The housing 102 includes at least one fixation aperture 106 configured to receive a bone anchor therein for coupling the housing 102 to a first bone portion. The adjustable portion 104 includes at least one fixation aperture 108 configured to receive a bone anchor therein for coupling the adjustable portion 104 to a second bone portion. Thus, the second bone portion may also move relative to the first bone portion during movement of the adjustable portion 104 relative to the housing 102.

[0044] In order to grow or lengthen bone, the bone either has a pre-existing separation or is purposely cut or broken (e.g., via an osteotomy) to create this separation, dividing the bone into a first section

and a second section. The cut may be done prior to implanting and securing the implant 100 or may be done after the implant 100 is implanted, for example by use of a flexible Gigli saw. As will be described herein, the adjustable portion 104 is configured to contract and/or retract relative to the housing 102. The implant 100 is configured to allow controlled, precise translation of the adjustable portion 104 relative to the housing 102 by non-invasive remote control, and thus controlled, precise translation of the bone segment that is secured to the adjustable portion 104 relative to the bone segment coupled to the housing 102.

[0045] Over the treatment period, the bone is regularly distracted, creating a new separation, into which osteogenesis can occur. Regularly distracted is meant to indicate that distraction occurs on a regular or periodic basis which may be on the order of every day or every few days. An exemplary distraction rate is one millimeter per day, although, other distraction rates may be employed. That is to say, a typical distraction regimen may include a daily increase in the length of the implant 100 by about one millimeter. This may be done, for example, by four lengthening periods per day, each having 0.25 mm of lengthening. The implant 100, as disclosed in more detail below, has a magnetic drive system, which allows the adjustable portion 104 to be telescopically extended from the housing 102, thus forcing the first section and the second section of the bone apart from one another. The implant 100 can also be regular compressed for controlled fusion of bone.

[0046] FIG. 2 depicts a cross-sectional view of the implant 100 shown in Figure 1, which shows at one end, the housing 102 has an opening 118 for receiving the adjustable portion 104. FIG. 2 also highlights two sections A and B, which are depicted in greater detail in FIGS. 3 and 4 respectively. FIG. 3 generally depicts an enlarged cross-sectional view of the actuating components of the implant 100 and FIG. 4 depicts an enlarged cross-sectional view of various “smart components” of the implant 100.

[0047] As shown in FIG. 3, one or more o-rings 119 can be positioned about the adjustable portion 104 between the adjustable portion 104 and the housing 102. In some embodiments, a portion of the outer surface of the adjustable portion 104 and/or a portion of an internal surface of the housing 102 can be recessed to accommodate the o-ring(s) 119. The o-ring(s) 119 can help facilitate proper sealing between the housing 102 and the adjustable portion 104 so that bodily fluid does not enter the housing 102 when the implant 100 is implanted. The housing 102 is sealably closed at the other end by the attachment of an end cap 120. The end cap 120 may be attached to the housing 102 by means of welding, adhesive bonding, or other joining techniques. Further, an o-ring (not shown) may be provided between the end cap 120 and the housing 102 to help provide a seal. In use, the adjustable



portion 104 is driven from the housing 102 by means of an actuator 121. The actuator may include a lead screw 122 and a cylindrical permanent magnet 123. The lead screw 122 turns inside a nut 126 that is secured to an inner surface adjacent to a cavity of the adjustable portion 104 in which the lead screw 122 is disposed. The nut 126 is positioned between the lead screw 122 and the adjustable portion 104. The lead screw 122 is mechanically coupled, in an indirect manner, to the cylindrical permanent magnet 123 contained within a magnet housing 124. As explained in more detail herein, rotation of the cylindrical permanent magnet 123, which is magnetically driven by an external adjustment device 400 (FIGS. 17-19), effectuates rotation of the lead screw 122. Rotation of the lead screw 122 then translates into axial movement of the adjustable portion 104 relative to the housing 102.

[0048] The cylindrical permanent magnet 123 is fixedly contained within a magnet casing 126 using, for example, an adhesive such as an epoxy. The magnet casing 126 rotates relative to the magnet housing 124. The cylindrical magnet 123 may be a rare earth magnet such as Nd—Fe—B and may be coated with Parylene or other protective coatings in addition to being protected within the magnet casing 126, for example hermetically potted with epoxy. The magnet casing 126 contains an axle 132 on one end which attaches to the interior of a radial bearing 134. This arrangement allows the cylindrical magnet 134 to rotate with minimal torsional resistance. A maintenance member 136 may be positioned in proximity to and/or adjacent to the cylindrical permanent magnet 123. The maintenance member 136 keeps the implant 100 from being accidentally adjusted by movements of the patient. The maintenance member 136 is positioned proximate and axially spaced from the magnet 123. The maintenance member 136 is made from a magnetically permeable material, such as 400 series stainless steel. The maintenance member 136 can, for example, be generally cylindrical in shape having two spaced apart tabs separated by gaps. When the implant 100 is not being adjusted (e.g., using an external adjustment device), the magnetic poles of the radially-poled cylindrical magnet are magnetically attracted to the tabs. However, when the magnet 123 is forced to rotate due to the effect of a sufficiently large rotating magnetic field, the magnet 123 overcomes the smaller attractions of the tabs. The maintenance member 136 also includes flanged extension and/or flanged extension fingers for engaging with the end cap 120 and/or housing 102. Additional details of the maintenance member can be found in U.S. Pat. Pub. 20190015138, filed July 26, 2018, which is incorporated herein by reference as if set forth in its entirety. Other maintenance members such as those disclosed in U.S. 8,734,488 filed August 4, 2011 and U.S. App. No. 13/525,058 filed June 15, 2012 can also be used, each of which are incorporated herein by reference as if set forth in its entirety.

[0049] At its other, opposing end, the magnet housing 126 includes an axle 142, which is attached to a first planetary gear set 144. The axle 142 includes the sun gear of the first planetary gear set 144, the sun gear turning the planetary gears of the first planetary gear set 144. The first planetary gear set 144 serves to reduce the rotational speed and increase the resultant torque delivery from the cylindrical magnet 123 to the lead screw 122. A second planetary gear set 146 and a third planetary gear set 148 are also shown between the first planetary gear set 144 and the lead screw 136, for further speed reduction and torque augmentation. The number of planetary gear sets and/or the number of teeth in the gears may be adjusted, in order to achieve the desired speed and torque delivery.

[0050] The planetary gear sets 144, 146, 148 output to a planetary gear output shaft 152. The planetary gear output shaft 152 extends through a thrust bearing 154 and is secured (by welding and the like) to a lead screw coupling cap 156. The lead screw 122 is secured to the lead screw coupling cap 156 by a locking pin 158, which extends through a hole in the lead screw 122 and holes in the lead screw coupling cap 156. A locking pin retainer 162 is a cylinder that surrounds the locking pin 158, holding this assembly together. Attaching the lead screw 122 to the rest of the magnet/gear assembly in this manner, assures that the design is not over-constrained, and thus that the lead screw 122 does not gall with the nut 126. In addition, a biocompatible grease and/or fluorinated oil, such as, for example Krytox ® (Krytox is a registered trademark of E. I. DU PONT DE NEMOURS AND COMPANY), may be used on the moving parts (lead screw, nut, bearings, housing, and distraction shaft) in order to minimize frictional losses. The lead screw 122 is able to freely rotate within a cavity of the distraction shaft 104, and only need engage with the short length of the nut 126, this feature also minimizing frictional losses.

## **II. Smart Components**

[0051] In certain embodiments, one or more smart components are described that enhance the operation of the implant 100. As shown in FIG. 4, the various smart components can be positioned within a chamber in the housing 102 that is separate from the actuating components (i.e., the actuator 121).

[0052] At the core of these enhancements is a controller 302 that provides, e.g., data processing and storage operations, and may be any type of controller known and used in the art including: high performance microcontrollers (MCUs), Programmable System on Chip (PSoC), Application Specific Integrated Circuit (ASIC) or any other type of controller or microcomputer. The controller 302 may be disposed on a printed circuit board which may also contain other electronic circuitry and connect

other electrical components including: Analog to Digital Converter (ADC), Digital to Analog Converter (DAC), op-amps, memory, or any other electrical component. The controller 302 may further include a frequency synthesizer (i.e., creates carrier waves for the transceiver), power amplifiers, noise filters (i.e., conditions carrier wave), power and read strain gauges (i.e., force sensor controls), and may be configured to adjust carrier waves, power, etc., such as by computer executable instructions that interface with a user via a graphical user interface, as discussed below.

[0053] In addition, in certain embodiments, a transducer 304 coupled to the controller 302 provides a communication platform to exchange data with an external interface device 305 (FIG. 16) using, e.g., ultrasonic or ultrasound communications. In certain embodiments, the communication platform may include any device that induces sound waves or a mechanical vibration, and converts soundwaves to electronic signals, including for example: a piezoelectric transducer, a single crystal ultrasonic transducer, a lead zirconate titanate (PZT) ultrasonic transducer, piezoelectric polyvinylidene fluoride (PVDF) ultrasonic transducer, capacitive micromachined ultrasonic transducers (CMUT), piezoelectric micromachined ultrasonic transducers (PMUT), or any ultrasonic transducer known and used in the art. In some embodiments, the ultrasonic transducer may include one or more of: a thin film ultrasonic transducer, a flat ultrasonic transducer, a tubular ultrasonic transducer, a half-tubular ultrasonic transducer, etc. A benefit, for example, of a thin film ultrasonic transducer is the reduced thickness of the ultrasonic transducer. A benefit, for example, of a flat ultrasonic transducer is improved transmission and reception characteristics. A benefit, for example, of a tubular ultrasonic transducer is multi-directional (360° radial directional) transmission and reception. The type of ultrasonic transducer may be chosen to complement the application of the adjustable implant 100. In another embodiment, the transducer 304 can include a radiofrequency transducer. The transducer 304 is configured to receive instructions and data from the controller and configured to send such instructions and data to an external adjustment device 400 (FIGS. 17-19) and/or an external interface device 305, via, for example, ultrasound or radiofrequency waves. The transducer 304 is also configured to receive data and/or treatment instructions from the external interface device 305 or external adjustment device 400. It is understood that while various embodiments described herein utilize an ultrasonic device for a communication platform, any wireless device or technology could likewise be utilized, e.g., radio, Bluetooth, etc.

[0054] In order to power the smart components of the implant 100, one or more power supply components 310 may be used. The power supply components 310 include at least one battery energy storage device. For example, at least one lithium-ion battery or silver oxide battery could be used.

However, any other now known or later developed medical grade energy storage device could be used without departing from aspects of the disclosure.

[0055] Further details of various smart components are provided below. It is understood that an implant may include one or more of the following components.

#### **A. Load Cell**

[0056] Referring to FIGS. 4 and 5, the load cell 306 is positioned within the housing 102 and is configured to measure a linear load, i.e., force, imparted on the adjustable implant 100. Illustrative types of loads that can be measured include “bone loading” and “elongation distraction.” Bone loading measures the amount of stress on the bone resulting from weight bearing activities, e.g., standing, walking, lifting, etc. Elongation distraction (or contraction) refers to the amount of stress imparted on the bone when the implant 100 is being adjusted, i.e., during movement of the adjustable portion 104 relative to the housing 102.

[0057] As shown in FIG. 4, both the housing 102 and load cell 306 include one or more apertures 106, 334, respectively, for receiving bone anchors therein (not shown). The apertures 334 of the load cell 306 have a smaller diameter than the apertures 106 within the housing 102 to allow the bone anchors to primarily anchor to the load cell 306, as opposed to the housing 102. This arrangement accordingly allows the load cell 306 to slide within the housing when a linear force is applied. The load may for example result from an adjustment of the implant (i.e., the adjustable portion 104 relative to the housing 102) or from a bone loading activity in which a force is applied to the load cell via bone anchors (e.g., bone relative to the housing 102). The linear motion of the load cell 306 then allows the load imparted on the bone or adjustable implant 100 to be detected by the load cell 306. In the example shown, the two apertures are shown angled within the implant 100. However, it is understood that other arrangements could be utilized, e.g., one, three or four perpendicular apertures, etc.

[0058] The load cell 306 includes at least one sensor, such as for example, a strain gauge. As shown in FIG. 5, the load cell 306 includes a substantially tubular body 308 having a first portion 312 with an outer diameter that is smaller than an outer diameter of the remaining portion 314 of the tubular body 308. In certain embodiments, the load cell comprises a force transducer that converts a force into an electrical signal. As the force applied to the load cell increases, the electrical signal changes proportionally, e.g., based on a change in electrical resistance. As shown, the first portion 312 of the load cell 306 includes a strain gauge having a first sensing element 316 and a second sensing element 318 that, e.g., are configured in a Wheatstone bridge arrangement to generate a voltage output that

measures a displacement, e.g., in the range of 0-10 mm. Accordingly, as linear stress is imparted to the bone and/or implant 100, the load cell 306 can generate a voltage that is converted into a load value by the controller 302.

[0059] In some embodiments, the load cell 306 is coupled within the housing 102 via pin 320 (FIG. 4) extending through a pin hole 322 (FIG. 5) within the load cell 306 at a first end. However, other means for coupling the load cell 306 to the housing 102 can also be used without departing from aspects of the disclosure, such as for example a retainer member such as the one disclosed in US 63/053,036 filed on July 17, 2020, which is incorporated by reference as if set forth in its entirety.

[0060] Opposite the first end, the load cell 306 can be coupled to the controller 302 via wiring 324. In some embodiment, a protective housing (e.g., composed of a polymer such as polyether ether ketone (PEEK)) 326 can be positioned adjacent the load cell 306 within the housing 102. The protective housing 326 substantially surrounds the wiring 324 from the load cell 306 to the controller 302 within the housing 326 and protects the wiring 324 within housing 102.

[0061] As shown in FIG. 7, the controller 302 is configured to receive electrical signals from the load cell 306 via the wiring 324 and calculate load characteristics, e.g., a distraction force and/or distraction length. In addition, the arrangement can be configured to determine a compression force, and/or compression length based on the load measured by the load cell 306 when the implant 100 is used as a compression device. The controller 302 is configured to digitize the data obtained by the load cell 306, process the data and modulate the data into an ultrasound signal to be communicated by the transducer 304 to an external interface device 305 via a transceiver 307. The external interface device 305 and the transceiver 307 are each positioned external to the patient.

[0062] An illustrative method involving a load cell 306 includes implanting the implant 100 within a patient, such as for example within an intramedullary canal of a bone. An osteotomy is performed to create a first bone portion and a second bone portion. The housing 102 is coupled to the first bone portion and the adjustable portion 104 is coupled to the second bone portion. The method also includes adjusting the implant 100 having the housing 102, an adjustable portion/rod 104 moveable relative to the housing and a load cell 306 within the housing 102 for measuring a load imparted on the implant 100 during movement of the adjustable portion 104 relative to the housing 102. The method also includes measuring the load imparted on the implant 100 during movement of the adjustable portion 104 relative to the housing 102. More specifically, the measuring of the load includes using the load cell 306 to measure the load imparted on the bone anchors (not shown) positioned within the apertures 106 of the housing 102 and the apertures 334 of the load cell. The method can also include sending

the measured load to an external interface device 305 via the transducer 304 and a transceiver 307. A medical professional can then view the measured load data from the external interface device 305 and use the measure load to determine additional data, such as for example, a distraction force, distraction torque and a distraction length or a compression force, compression torque and a compression length. The medical professional can then determine treatment instructions based on such data. The implant 100 and/or external adjustment device 400 can receive the treatment instructions and adjust the implant 100 based on the treatment instructions.

### **B. Actuator Position Sensing**

[0063] Position sensing may be provided to determine a position of the actuator 121, e.g., how far it has been distracted or compressed, by measuring and tracking angular (i.e., rotational) movements of the actuator 121. To achieve this, a sensor 336 such as that shown in FIG. 4 can be utilized to monitor an angular position of the actuator 121 of the adjustable implant 100. More specifically, the sensor 336 is configured to monitor an angular position of the magnet 123 of the actuator 121 (FIG. 3), for example, by measuring at least one of a magnetic field strength, polarity, and dynamic direction. For example, as shown in FIG. 6 the sensor 336 monitors a position of the dipole moment or vector  $V_{\text{Pole}}$  representing the direction of the magnetic field of the magnet 123 of the actuator 121 as it rotates about the axis extending longitudinally through the magnet,  $V_{\text{axis}}$  representing possible angles of  $0^\circ$  -  $360^\circ$ .

[0064] In one embodiment, the sensor 336 can include a hall effect sensor, and more specifically, a unidirectional hall effect sensor, e.g., implemented on a printed circuit board. The sensor 336 can also include a rotary hall effect sensor, which can include, for example, a 4-hall element arrangement. The sensor 336 is positioned adjacent to and/or in proximity to the actuator 121. More specifically, the sensor 336 is positioned such that the sensor 336 can monitor the magnetic field emanating from the magnet 123 of the actuator 121 and collect angular position data. For example, in one embodiment, at each full rotation, sensor 336 can output a predefined signal. In other embodiments, sensor 336 can output a predefined signal at partial rotations, e.g., each quarter rotation as determined by a 4-hall element arrangement.

[0065] As shown in the illustrative system diagram of FIG. 7, the sensor 336 is communicatively coupled to the controller 302 (e.g., via wiring) and the controller 302 is configured to receive the angular position data of the actuator 121 from the sensor 336. In one embodiment, the controller 302 is configured to calculate and/or determine a distraction length or compression length of the adjustable

implant 100 based on the number of rotations (or partial rotations) of the actuator 121. More specifically, the number of rotations of the actuator 121 can be correlated (e.g., with a look-up table) to a number of rotations of the lead screw 122 (FIG. 3) which is then used to determine the overall distraction length or compression length of the implant 100. In alternative embodiments, the collected rotation data can simply be digitized packaged for transmission to an external interface device 305, which can calculate a distraction or compression length.

[0066] In certain embodiment, the controller 302 is communicatively coupled to the transducer 304 (e.g., via wiring) and is configured to send data such as the number of rotations to external interface device 305 to be viewed by a medical professional and/or the patient. More specifically, a transceiver 307 positioned external the patient can be used to demodulate the signal transmitted by the transducer 304 into meaningful data digestible and interpretable by the external interface device 305. Once the signal is demodulated, the external transceiver 307 can send the demodulated data to the external interface device 305.

[0067] An illustrative method involving actuator position sensing includes implanting the implant 100 within a patient, such as for example within an intramedullary canal of a bone. An osteotomy is performed to create a first bone portion and a second bone portion. The housing 102 is coupled to the first bone portion and the adjustable portion 104 is coupled to the second bone portion. The method also includes adjusting the implant 100 having the housing 102, the adjustable portion/rod 104 moveable relative to the housing 102, an actuator 121 positioned within the housing 102 and configured to cause movement of the adjustable portion 104 relative to the housing 102; and a sensor 336 positioned adjacent to the actuator 121 and configured to monitor an angular position of the actuator 121 of the implant 100. The method also includes sensing, via the sensor 336, an angular position of the actuator 121, or more specifically, the magnet 123 of the actuator 121. The angular position of the magnet 123 can be used to determine a number of rotations of the magnet 123. The method also includes calculating a distraction length or compression length of the implant 100 based upon a number of rotations of the magnet 123/actuator 121. More specifically, the controller 302 positioned within the housing 102 and communicatively coupled to the sensor 336 is configured to determine the distraction length or the compression length of the implant 100. At least one of the distraction length, compression length or the number of rotations of the actuator 121 can be sent to an external interface device 305 via the transducer 304 which is also positioned within the housing 102 and the transceiver 307 positioned external to the patient. A medical professional can then view the determined distraction length and/or number of rotations of the actuator 121 via the external interface

device 305. The medical professional can then determine treatment instructions based on such data. The implant 100 and/or external adjustment device 400 can receive the treatment instructions and adjust the implant 100 based on the treatment instructions.

### **C. Dual Magnet Load Sensors**

#### **1. Implant and External Magnet Sensing**

[0068] In a further embodiment, in place of or in addition to using a load cell 306 to measure a compression/distraction force, a dual sensor arrangement as described in FIGS. 8-12 may be implemented to measure force loads associated with the adjustable implant 100. In the illustrative embodiment of FIG. 8, a first sensor 336 is included that is configured to measure a position and/or magnetic field information of the actuator 121 of the adjustable implant 100 (e.g., as described herein with reference to the actuator position sensing system) and a second sensor 346 is included in the implant 100 that is configured to measure a position and/or magnetic field information of the external actuator magnet 440 of the external adjustment device 400 (FIGS. 17-19). The moments of the two associated magnets are then evaluated with an algorithm to determine, e.g., a torque and/or compression/distraction force.

[0069] The first sensor 336 and second sensor 346 each include, for example, a printed circuit board having at least one sensor such as, for example, a hall effect sensor, configured to measure at least one of a magnetic field strength, polarity, and dynamic direction. In one example, the first sensor 336 includes a unidirectional hall effect sensor to read the position of the internal actuator magnet 123 and the second sensor 346 includes an omnidirectional hall effect sensor to read the position of the magnet of the external actuator 440 of the external adjustment device 400.

[0070] The first sensor 336 can be positioned adjacent to and/or in proximity to the actuator 121 and may comprise a multiple hall effect sensor configured to make differential strength measurements. In one embodiment, the first sensor 336 can include a rotary hall effect sensor (e.g., a four-hall effect sensor) and the second sensor 346 configure to measure magnetic strength in three axis. The second sensor 346 can be positioned at a location where the external magnet and internal magnet are least coupled, e.g., on an opposite side of the controller 302 from the first sensor 336 such that the controller 302 is positioned between the first 336 and second sensors 346. The controller 302 is configured to determine a position of the first actuator 336 and the second actuator 440 relative to each other at a given time based on data from obtained by the first and second sensors 336, 346. More particularly, the controller 302 is configured to monitor a position of the rotating magnet 123 (FIG. 3) of the



actuator 121 and a position of the at least one rotating permanent magnet of the external actuator 440 in the external adjustment device 400.

[0071] FIG. 10 shows a phase shift diagram with line A representing the phase shift of the magnet of external actuator 440 of the external adjustment device 400 and line B representing the phase shift of the magnet 123 of the implant 100. As shown, the magnet 123 may lag behind the actuator 440 due at least in part to the torque put on the magnet 123 from the gear assembly (planetary gears 144, 146, 148) and the lead screw 122 interacting with the adjustable portion 104 such that a phase angle can be determined. By analyzing the lag/phase angle, coupling states, stalling states, force measurements, non-union states, consolidation states, etc., can be determined. For example, if line B lags too far behind line A, a stalling condition may have occurred.

[0072] FIG. 11 shows an illustrative schematic of how the distraction force or distraction torque, or the compression force or compression torque can be calculated. In one embodiment, the sensor 336 monitors the rotating magnetic field from the implant actuator 121 and provides an angular position of the magnet 123. The sensor 346 monitors the rotating magnetic field of the actuator 440 of the external adjustment device 400 and, e.g., provides the x, y, and z components, yaw, pitch and roll of the magnetic field. An algorithm 337 can be used to process the angular position of the rotating magnet 440 of the external adjustment device 400 and/or a distance of the rotating magnet 440 from the sensor 346 and determines one or more forces (e.g., a distraction force and distraction torque, and/or compression force and compression torque) based on the angular position of the implant magnet 123 and the angular position of the rotating magnet 440. In some embodiments, the algorithm 337 calculates one or more forces by applying one or more functions or lookup tables to readings from the sensors 336, 346. In some examples, readings from the sensors 336, 346 are provided as input to a machine learning algorithm trained on angular position and/or magnetic field data to output force information.

[0073] FIG. 9 depicts an associated system diagram in which the controller 302 captures and processes data from sensors 336, 346. Once processed, the transducer 304 is configured to send data associated with the first sensor 336 and the second sensor 346 to an external interface device 305 to be viewed by a medical professional and/or a patient. More specifically, an external transceiver 307 positioned external the patient can be used to demodulate the signal transmitted by the transducer 304 into meaningful data digestible and interpretable by the external interface device 305. Once the signal is demodulated, the transceiver 307 can send the demodulated data to the external interface device 305. Depending on the implementation, either controller 302 or an external system can implement

algorithms to compute the force information from measurements captured by sensors 336, 346. In some examples, an algorithm calculates the distraction/compression force/torque by applying one or more functions or lookup tables to the measurements captured by the sensor 336, 346. In some embodiments, the measurements are provided as input to a machine learning algorithm trained on distraction force/torque data and the distraction force/torque is provided as output.

[0074] The top half of FIG. 12 describes the relationship between the implant magnet 123 and the external (ERC) magnet. As shown on the left, the external magnet and implant magnet are coupled. In the middle, when the ERC magnet tilts, the implant magnet follows immediately indicating the two are in phase with no torque. On the right, the implant magnet tilt lags behind the ERC magnet, indicating a counter torque.

[0075] An illustrative method involving a dual sensor arrangement includes implanting the implant 100 within a patient, such as for example within an intramedullary canal of a bone. An osteotomy is performed to create a first bone portion and a second bone portion. The housing 102 is coupled to the first bone portion and the adjustable portion 104 is coupled to the second bone portion. The implant 100 having the housing 102 and the adjustable portion 104 moveable relative to the housing 102 is adjusted. A position of the actuator 121 configured to cause movement of the adjustable portion 104 relative to the housing 102 is measured via the sensor 336. A position of the actuator 414, 416 of an external adjustment device 400 configured to actuate the actuator 121 of the implant 100 is measured via the sensor 346. At least one of a distraction force a distraction torque, a compression force, and compression torque is determined based on a position of the actuator 121 and a position of the actuator 414, 416. As discussed herein, the sensor 336 includes a unidirectional hall effect sensor and the sensor 346 includes an omnidirectional hall effect sensor. The controller 302 is positioned between the sensors 336, 346 and determines at least one of a distraction force, a distraction torque, compression force, and compression torque. at least one of the distraction force, distraction torque, compression force, and compression torque is sent via the transducer 304 to an external interface device 305 and via the transceiver 307 (FIGS. 7 and 9). A medical professional can then view the determined distraction force, distraction torque, compression force, and/or compression torque via the external interface device. The medical professional can then determine treatment instructions based on such data. The implant 100 and/or external adjustment device 400 can receive the treatment instructions and adjust the implant 100 based on the treatment instructions.

## 2. Dual Implant-Magnet Sensing

[0076] In an alternative embodiment for measuring loads within the implant 100, dual multi-dimensional sensors 341, 343 are utilized to obtain two separate magnetic field readings associated with the implant's magnet 123 relative to the external magnet 440 of the external adjustment device 400, as shown in the bottom half of FIG. 12. Unlike the prior arrangement, this arrangement determines one or more associated forces independently of the position of the external adjustment device 400. Instead, the two sensors 341, 343 are strategically located at different positions in the housing to read the magnetic field (i.e., field vectors) of the implant magnet 123 relative to the external magnet 440 of the external adjustment device 400, e.g., as the external magnet interacts with the implant magnet 123. The sensed magnetic field results can then be evaluated by the controller 102 to determine load values (i.e., forces). Multi-dimensional sensors 341, 343 may for example include three-dimensional or multi-axis hall effect sensors configured to read field vectors in multiple dimensions.

[0077] This approach is further described with reference to the bottom half of FIG. 12. When the moment of the implant magnet 123 follows that of the external magnet, the magnetic field vectors or lines are the same. However, when the moment of the implant magnet 123 lags the moment of the external magnet 440, the vectors 345 near the implant magnet will lag behind the vectors 347 farther from the implant magnet 123. That is, magnetic field lines are parallel to the axes of the implant when the two moments are pointing in the same direction. However, when the moment of the implant magnet lags, the field lines would look helical or skewed as shown. The rotation of the moment may be described with the formula:

Theta = tangent (magnitude of x/ magnitude of y).

[0078] In certain embodiments, the moment 347 of the sensor 343 further away from the implant magnet 123 is used as the reference, and when the sensor 341 closer to the implant magnet observes a lag, the angle is subtracted from the reference. The lag is, e.g., caused by a counter-torque, which is directly proportional to the counter-force, which is the resisting force against the soft tissues when the implant 100 is distracted.

[0079] To correlate the angular lag to a linear force, the linear force can be calibrated by a test instrument, e.g., an ERC fixture, which is instrumented with a force gauge that can constrain the two ends of the implant 100. When the implant 100 is extended by the ERC, the linear force is recorded. The same approach can monitor stalling and coupling/decoupling between two magnets and can locate the moving external magnet in space.

#### **D. Half-Cylinder Piezo Signal Transmission**

[0080] Turning to FIGS. 13-14, in yet another embodiment, the described transducer 304 may include a signal transmission device 500 that includes a half-cylinder piezoelectric transducer 502 for communicating data. Like transducer 304 of FIGS. 4 and 7, the signal transmission device 500 is configured to transmit data associated with the adjustable implant 100 to an external adjustment device 400 or an external interface device 305, e.g., to be viewed by a medical professional and/or a patient. For example, a transceiver 307 (FIG. 7) positioned external the patient can be used to demodulate the signal transmitted by the signal transmission device 500 into meaningful data digestible and interpretable, e.g., by the external interface device 305. Once the signal is demodulated, the transceiver 307 can send the demodulated data to the external interface device 305.

[0081] The signal transmission device 500 is configured to transmit a directional signal relative to the patient having the adjustable implant 100 implanted therein. As shown in FIGS. 13 and 14, the signal transmission device 500 may include a half-cylinder piezoelectric transducer 502 positioned within a package 504 that is positioned within the housing 102. Housing 102 may comprise any metallic housing. In one embodiment, the housing 102 can include a titanium housing. In another embodiment, the housing 102 can include non-ferrous, biocompatible metal such as, for example, a Biodur ® (Biodur is a registered trademark of CRS HOLDINGS, INC.) housing. As shown, the half-cylinder piezoelectric transducer 502 includes an inner diameter 506 (FIG. 14) and an outer diameter 508 (FIG. 14). A metal backing 510 is positioned adjacent the inner diameter 506. The metal backing 510 can include, for example, a stainless steel. The metal backing 510 may be a half-cylinder metal backing. Disposed between the half piezoelectric transducer 502 and the metal backing 510 is a filler 511 (FIG. 14), which can include any viscous material that closely matches the acoustic impedance of the piezoelectric transducer and housing including, e.g., water, mineral oil, acoustic gel, etc. In an illustrative embodiment, the filler 511 can include, e.g., at least one of: a bio-compatible epoxy, fluorinated oil such as Krytox ® (Krytox is a registered trademark of E. I. DU PONT DE NEMOURS AND COMPANY), and silicon oil. The package 512 is positioned within the housing 102 and substantially surrounding the half-cylinder piezoelectric transducer 502 and the metal backing 510. As shown, the package 504 is positioned adjacent the outer diameter of 508 of the half-cylinder piezoelectric transducer 502. Disposed between the half piezoelectric transducer 502 and the semiconductor package 504 is a filler 513. The package 504 can also house the power supply components 310. The filler 513 can include at least one of: a super epoxy, fluorinated oil such as

Krytox ® (Krytox is a registered trademark of E. I. DU PONT DE NEMOURS AND COMPANY), and silicon oil. The half-cylinder piezoelectric transducer 502 can be a 1 KHz – 10 MHz piezoelectric transducer, e.g., 250KHz. A filler 514 may be positioned within the housing 504 and substantially surround the package 504, the half-cylinder piezoelectric transducer 502 and the metal backing 510. In one embodiment the filler 514 include at least one of: super epoxy, fluorinated oil such as Krytox ® (Krytox is a registered trademark of E. I. DU PONT DE NEMOURS AND COMPANY), and silicon oil.

[0082] As shown by arrows 505 in FIG. 14, this configuration of the signal transmission device 500 ensures strong signal in a desired direction relative to the patient (e.g., laterally from patient) so that it can be picked up by the external interface device 305 and/or transceiver 307. In this half cylinder arrangement, metal backing 510 acts as reflector such that signals 505 are concentrated, e.g., within a 180 degree radius. Accordingly, strong signal strength can be achieved with less power relative to a full 360 degree arrangement. Note that while signal transmission device 500 includes a half-cylinder (i.e., 180 degree) piezoelectric transducer 502, other partial-cylinder transducers could likewise be utilized, e.g., a three-quarter cylinder transducer, a one quarter cylinder transducer, etc.

[0083] In still further embodiments, the piezoelectric transducer can have any cross-sectional shape that conforms to the implant housing, e.g., oval, rectangular, polygonal, etc. In such cases, the transducer can likewise be configured to directionally focus signals in a manner similar to the half piezo arrangement. For instance, a one third oval, half oval, etc., cross-section could be implemented to focus signals in a desired direction (i.e., less than 360 degrees). In still further cases, a phase array transducer arrangement could be implemented to channel signals in a desired direction.

[0084] Also positioned within the signal transmission device 500 is a printed circuit board 516. The printed circuit board 516 can include the controller 302 (FIGS. 4-9) thereon. Further, the printed circuit board 516 can include the switch 344 (FIGS. 4 and 8) and the sensor 346 (FIGS. 8-9) when used.

[0085] In an illustrative embodiment, external transceiver 307 of external interface device 305 may be placed laterally on a body part such as a leg. In this case, the external interface device 305 is an independent standalone device separate from an external adjustment device 400 that may be used at the same time. The transceiver can be configured to take up the different space than the external adjustment device 400, which, e.g., will be sitting anterior to the leg.

### **E. Energy Harvesting System**

[0086] As shown in FIG. 15, in another embodiment, the implant 100 can include an energy harvesting system that captures energy, e.g., mechanical energy, heat energy, etc., associated with the implant 100 and converts the energy to electrical energy. The system may include an energy harvesting component 602, a power management unit 600, energy storage components 310 and sensors 606. The energy storage components 310 may for example include a battery that supplies electricity to loads 604, such as the various smart components. Sensors 606 may be used to facilitate management of the system, e.g., determine amounts of energy being harvested, used, etc.

[0087] In one embodiment, a transducer 304 (FIG. 4) and/or half-cylinder piezoelectric transducer 502 (FIGS. 13 and 14) can be configured to harvest energy imparted on the implant 100 during movement of the patient having the implant 100 implanted therein. That is, the transducer 304, 502 itself acts as the energy harvesting component 602. In this embodiment, the power storage components 310 are configured to store energy harvested from the transducer 304. However, it is to be understood that an energy harvesting component 602 separate from the transducer 304 can be provided without departing from aspects of the disclosure such as, for example, a magnet and coil, an electromagnet, and a RF harvester. With further reference to FIG. 4, the energy harvested by the transducer 304 can be configured to provide power for at least one of the controller 302, the transducer 304, the load cell 306, one or more sensors 336, 346 and/or any other smart components of the implant 100. Wiring may couple the transducer 304 and the energy storage components 310 such that the energy harvested by the transducer 304 can be transferred to the energy storage components 310 and back to the transducer 304 to power the transducer 304 when needed. The wiring can include a printed circuit board having a power management unit 600 thereon configured to adjust a voltage of the energy harvested by the energy harvesting component. As shown in FIG. 15, the power management unit 600 collects the voltage signal from the energy harvesting component 602 (e.g., transducer 304, 502) and adjusts or modifies the voltage harvested to a level that can be stored within the energy storage components 310.

[0088] The energy harvesting component 602 is placed to capture the surrounding energy, e.g., vibration, electromagnetic, magnetic, heat, etc., and convert it into an electrical energy. Voltage is induced, e.g., when the transducer 304 is going through a strain. Often the voltage is in the format of AC swinging between negative and positive potentials. In one embodiment, a rectifier is used to collect just the positive voltage, otherwise the positive and negative cancels out. To store the power efficiently into an energy format, the raw power is often regulated with a current flow manager. Switches are placed to traffic the inflow and outflow of electrical power to loads 604, such as one of

the smart components. In the case where transducer 304 acts as the energy harvester, the same or another piezoelectric transducer may be used for communication, e.g., to induce ultrasound signals.

[0089] There is also wiring coupling the energy storage components 310 to the controller 302, sensors 336, 346 and load cell 306 such that the energy storage components 310 can supply the harvested energy to those components as well. As noted, the transducer 304 can be a piezoelectric transducer. In this embodiment, the transducer 304 is coupled to an internal surface of the housing 102. More specifically, the transducer 304 is coupled to an internal surface of the housing 102 at a location of the implant 100 that receives tension or compressive stresses due to movement of the patient. The transducer 304 harvests energy from stress generated by the implant 100 due to the bending force imparted on the implant 100 during movement of the patient. Therefore, in this embodiment, the implant 100 smart components are powered by the energy harvested directly from movement of the patient. In certain embodiments, the transducer 304, 502 can act as both a communication device and an energy harvesting device. In other embodiments, implant 100 includes a first transducer for communication and a second transducer for energy harvesting.

[0090] An illustrative method using energy harvesting includes implanting the implant 100 within a patient, such as for example within an intramedullary canal of a bone. An osteotomy is performed to create a first bone portion and a second bone portion. The housing 102 is coupled to the first bone portion and the adjustable portion 104 is coupled to the second bone portion. The method further includes harvesting energy from stresses imparted on the implant 100 during movement by the patient having the implant 100 implanted therein and using the harvested energy to power at least one of the smart components. As discussed herein, the energy harvesting system can include the transducer 304 configured to send data to an external interface device 305 (FIGS. 7 and 9) via transceiver 307 (FIGS. 7 and 9) positioned external to the patient. The data can include at least one of: a distraction force, a distraction length, a compression force, a compression torque, a compression length, a compressive stress, a tension stress, a biological condition, and a position of the implant 100. A medical professional can then view the data and determine treatment instructions (e.g., a distraction length, a distraction time, a distraction force, compression length, compression time, compression force) and send such instructions to the implant 100 and/or external adjustment device 400 via the external interface device 305. The implant 100 is adjusted such that adjustable portion 104 moves relative to the housing 102. Thus, the second bone portion moves relative to the first bone portion.

## F. Reed Switch

[0091] In various embodiments, the implant 100 can include a switch 344 such as that shown in FIG. 4 for preserving power when one or more of the smart components are not in use. In one example, the switch 344 can include an electrical switch such as a reed switch that is operated by an applied magnetic field (such as from an external adjustment device 400 having at least one magnet 440 therein). In this example, the reed switch can be a normally-open reed switch that is configured to close or complete the circuit upon application of a magnetic field. The switch 344 can for example be configured to activate any component, e.g., the controller 302, transducer 304, load cell 306, sensors, etc., when the external adjustment device 400 (FIGS. 17-19) is in proximity to the adjustable implant 100. The switch 344 can be configured to activate (i.e., turn on) when a threshold distance between the adjustable implant 100 and the external adjustment device 400 is reached (e.g., 2-4 inches). The switch 344 can be configured to deactivate components when the external adjustment device 400 is farther than or outside of the threshold distance relative to the adjustable implant 100 such that an activatable component is in a resting or off state when the external adjustment device 400 is farther than the threshold distance relative to the adjustable implant 100. The switch 344 is operatively coupled to the activatable components via wiring (not shown). The switch 344 can be utilized in conjunction with a power management system for some or all the components in the implant 100 that require power supply components 310. In certain embodiments, the reed switch 344 can be configured to activate the controller 302, and the controller 302 can in turn manage power for other smart components (e.g., turn them on and off as needed).

[0092] An illustrative method involving a reed switch includes providing the implant 100 including the housing 102 and the adjustable portion 104 moveable relative to the housing 102 upon application of a force supplied by an external adjustment device 400, a sensor 336 configured to sense monitor a position of the actuator 121 of the adjustable implant 100, and a controller 302 disposed within the housing 102 and communicatively coupled to the sensor 336. The method also includes implanting the implant 100 within a patient, such as for example within an intramedullary canal of a bone. An osteotomy is performed to create a first bone portion and a second bone portion. The housing 102 is coupled to the first bone portion and the adjustable portion 104 is coupled to the second bone portion. The method also includes activating at least one of the controller 302, transducer 304 and/or sensors when the external adjustment device 400 is within a threshold proximity to the implant 100. The method also includes deactivating the at least one of the controller 302, transducer 304, and/or sensors when the external adjustment device 400 is outside of a threshold proximity to the implant 100. In one



embodiment, once activated via the reed switch when the external adjustment device 400 is within the threshold proximity, the sensor 336 senses the angular position of the actuator 121. The controller 302 is configured to receive the angular position data from the sensor 336 and digitize the data when the external adjustment device 400 is within the threshold proximity. The controller 302 is also configured to send the digitized data to the transducer 304 when the external adjustment device 400 is in proximity to the implant 100. In one embodiment, the transducer 304 is configured to communicate with the external interface device 305 via radiofrequency waves. In another embodiment, the transducer 304 is configured to communicate with the external interface device via ultrasound waves. The transducer 304 communicates the at least one of the distraction force, distraction torque, distraction length, compression force, compression torque, and compression length when the external adjustment device 400 is within a threshold distance relative to the adjustable implant.

### **G. External Interface Device**

[0093] FIG. 16 depicts an illustrative external interface device 305 configured to interact with implant device 100 implanted in body 101. The external interface device 305 may comprise a handheld device that can be placed on or near the skin of a patient to allow a user to interact with (e.g., communicate, control, etc.) the controller in implant 100, e.g., via a transducer 304, 502. In certain embodiments, device 305 may include an external transceiver 307 configured to communicate (i.e., receive data and transmit data) with the implant 100. In certain embodiments, the transceiver 307 includes a transducer 309 capable of receiving or sending ultrasonic signals to and from a transducer 304, 502 in the implant 100. Device 305 may also include, e.g., a controller/GUI 311 that allows the operator to control and interact with the device 305, one or more power supply components 313, a processor 315, and a communication system 317. The external transceiver 307 may be configured to communicate, for example, via ultrasound, radiofrequency, or other types of signals. In the case where ultrasound is used, the transducer 309 can include any of the types of transducers discussed relative to the transducer 304, 502. The controller 311 is configured to manage the external interface device 305 and can include any of the types of controllers discussed relative to the controller 302 (FIG. 4). The power supply components 313 are configured to supply power for the external interface device 305 and can include any of the power supply components discussed relative to the power supply components 310 (FIG. 4). Device 305 may be configured to interface with a smart device 301 (e.g., a smart phone, tablet, laptop, etc.) that allows a user to view and manage information transmitted from the implant via device 305, including data generated by smart components. Smart device 301 may also be configured to

send data and commands to the implant 100 via device 305. The smart device 301 may be implemented with a downloadable App. The smart device 301 allows for the patient or medical professional to easily interact with the implant 100 and external interface device 305. In some embodiments, the features of smart device 301 and external interface device 305 are integrated into a single device.

### **III. General External Adjustment Device Discussion**

[0094] Actuation of the actuator 121 can be caused and controlled by an external adjustment device such as those described in U.S. Pat. No. 8,382,756 filed on November 20, 2009, U.S. 9,248,043 filed June 29, 2011, U.S. Pat. No. 9,078,711 filed on June 6, 2012, U.S. Pat. No. 9,044,281 filed on October 18, 2012, U.S. App. No. 13/172,598 filed on June 29, 2011, US. App. No. 14/698,665 filed on April 28, 2015, U.S. App. No. 14/932,904 filed on November 4, 2015, U.S. 16/004,099 filed on December 12, 2016, and App. No. PCT/US2020/017338 filed on February 7, 2020, all of which are incorporated herein by reference as if set forth in their entirety. external interface device 305

[0095] The external adjustment device 400, may include a housing 401 having a handle 402 and a display 403. The handle 402 is shown extending upwardly from the housing 401. In some embodiments, the display 403 may be integrated with the housing 401 of the external adjustment device 400. In the illustrated embodiment, the external adjustment device 400 is configured to receive a removable controller 410 having a display 403, with the display 403 being an integral part of the removable controller 410.

[0096] According to an exemplary embodiment, the controller 410 may be a handheld electronic device. The handheld electronic device may be, for example, a smartphone, a tablet, and any other known handheld electronic device. The handheld electronic device may contain and may be operatively connected to a display and/or one or more wireless communication protocols (e.g., Wi-Fi or Bluetooth®). The display of the handheld electronic device may be disposed adjacent to a top surface of the external adjustment device 400, such that the display 403 can communicate information to and receive instructions from a user during use.

[0097] For example, in some embodiments the display 403 may present to a user a graphical user interface (GUI). The display 403 may include one or more of a touchscreen or touchscreen technology, including, for example, capacitive touchscreen technology. The GUI may communicate adjustment instructions to a user which may correspond to a treatment regimen to guide the user in adjusting the adjustable implant in accordance with the treatment regimen. Additionally, the GUI may include one

or more touchscreen digital buttons configured to activate and control the external adjustment device 400.

[0098] FIG. 17 shows a front view of the external adjustment device 400, the external adjustment device 400 including a power supply input 422 and a data connection port 412. Additionally, a bottom surface of the housing 401 is shown including a curvature configured to form to a patient's body and minimize a distance (GAP) between the magnet 440 and a magnet 118 (FIG. 3) of the adjustable implant 100 (FIG. 14). The power supply input 422 may be configured to removably receive an AC power supply. The data connection port 412 may be configured to removably receive a data communication cable. The data communication cable may be configured to connect the external adjustment device 400 to a tertiary device to one or more of update the controller 410 software and download data from the controller 410.

[0099] FIG. 18 shows a cross-sectional side view of the external adjustment device 400 in accordance with the first embodiment. The external adjustment device 400 shown including the housing 401, the controller 410, an internal power storage device 420, a motor 430, and at least one magnet 440.

[0100] The internal power storage device 420 and wireless communication capabilities of the controller 440, may provide for wireless operation of the external adjustment device 400. The internal power storage device 420 may negate the need for a power chord during operation. The controller 410 may provide a low voltage control system negating the need for a bulky external control module. And wireless communication capabilities, for example one or more of RF, Wi-Fi Bluetooth® may enable the external adjustment device 400 and the controller 410 for remote operation. The remote operation may be achieved by one or more of a tertiary device in the same room, and across the internet by a tertiary device on the other side of the globe.

[0101] In some embodiments, the controller 410 may be a control board disposed within the housing 401 of the external adjustment device 400. The display 403 may include any type of display 403, including for example: LED, LCD, OLED, and any other known display and touchscreen technology. The control interface board 411 may contain or be in communication with one or more communication circuit, for example, one or more of Wi-Fi, cellular networks, or Bluetooth®, enabling communication between the external adjustment device 400 and one or more tertiary devices.

[0102] In FIG. 18, the controller 410 is shown operably connected to a controller interface board 411 by at least one interconnect. In some embodiments, this connection may be established via a physical connection as illustrated, and in some embodiments, a wireless connection, for example, Bluetooth®.

The control interface board 411 may be further connected to one or more of a power interface board 421, the power storage device 420, and the actuator 430.

[0103] The controller 410 may be remotely accessible and remotely controllable by a tertiary device allowing for remote operation of the external adjustment device 400 by a user from outside of a sterile field.

[0104] The external adjustment device 400 is also shown including an internal power storage device 420. The power storage device 420 may include a battery, a capacitor, and any other power storage device known and used in the art. The power storage device may be rechargeable and the external adjustment device 400 may include a recharging circuit configured to recharge the power storage device 420 using an external power source. The external power source, for example a power supply, may be operably connected to the recharging circuit of the power storage device via the power supply input. The power storage device 420, and/or at least a portion of the recharging circuit, may be disposed adjacent to a surface of the external adjustment device 400, enabling connection of a power supply charge cable to the external adjustment device 400. In some embodiments, the recharging circuit may enable wireless charging of the internal power storage device 420, using induction to wirelessly transfer power. In some embodiments, the recharging circuit may be part of and connected to one or more of the power distribution board 421 and the power storage device 400.

[0105] In the illustrated embodiment, the power storage device 420 is a battery. The battery 420 is mounted to a chassis of the external adjustment device 400, adjacent to a surface of the external adjustment device 400 enabling connection of a power supply to the external adjustment device 400 at a power supply input 422. The battery 420 includes a power interface board 421, configured to interface with and communicate power to the motor 430. The power interface board 421 may be operably coupled to one or more of the motor 430 and the control interface board 411. The power interface board 421 may also communicate electrical energy from one or more of a power supply input 422 and the power storage device 420, to the controller 410.

[0106] The actuator of the external adjustment device 400 includes an electronic motor 430. The driver of the external adjustment device 400 includes a magnet 440 rotatably coupled to the electronic motor 430. The motor 430 may be operably connected to one or more of the controller 410, the control interface board 411, the power interface board 421 and the internal power storage device 420. In the illustrated embodiment the electronic motor 430 is operably connected to the internal power storage device 420 by the power interface board 421. The power interface board 421 may include power distribution circuits to communicate electrical energy to the electronic motor 430 from one or more

of the power supply input 422 and the internal power storage device 420. The power interface board 421 may also be operably connected to the control interface board 411, to relay control information from the controller 410 to the motor 430. In some embodiments, the controller 410 may be in direct communication with the motor 430, and in some embodiments the controller 410 may be connected to the electronic motor via a wireless connection, for example a Bluetooth® connection.

[0107] The motor 430 may include any type of motor capable of rotating the magnet 440. The motor 430 is an electric motor and may include a rotational speed sensor 432. The rotational speed sensor 432 connected to and in communication with one or more of the control interface board 411 and the controller 410. In some embodiments, the internal speed sensor 432 may include for example one or more of an encoder and a digital output of an electronic motor. In some embodiments, the motor 430 is configured to communicate rotational speed data to the controller 410 wirelessly.

[0108] FIG. 19 shows an enhanced cross-sectional view of the motor 430 and the magnet 440 of the external adjustment device 400 in accordance with a first embodiment. The magnet 440 is shown rotatably coupled to the motor 430 by one or more couplings 431. In the illustrated embodiment, the magnet 440 includes an internal cavity 441 having an internal surface 442 and having a tapered profile. A magnet drive shaft 433 is shown including a magnet contact surface 434 having a tapered profile. The tapered profile of the magnet drive shaft 433 is configured to communicate with the tapered profile of the internal surface 442 of the magnet 440. This enables the magnet 440 to be secured to the magnet drive shaft 433 by a friction fit, the magnet 440 configured to be held onto the magnet drive shaft 433 by a cap 435 and the communicating tapered profiles. In some embodiments, the magnet 440 may be attached to the magnet drive shaft 433 using an adhesive material.

[0109] The magnet 440 may comprise any magnetic element including a radially polarized cylindrical magnet, a permanent magnet, an electromagnet, and any other magnetic element known and used in the art. The magnet 440 is configured to magnetically couple with a permanent magnet 118 of an adjustable implant 100 and to rotate the permanent magnet 118 and adjust the adjustable implant 100. Upon a rotation of the magnet 440, a rotating magnetic field will be generated, placing a force on the magnetically coupled permanent magnet 118 of the adjustable implant 100, thereby inducing a rotation of the permanent magnet 118 and subsequent adjustment of the adjustable implant 100.

[0110] In some embodiments, the external adjustment device 400 includes one or more sensors configured to monitor a rotational speed of the magnet 440. In some embodiments, the sensors include magnetic sensors, for example Hall-Effect sensors disposed on one or more of the housing 401, a plate, and a chassis, and may be placed adjacent to the magnet 440. In some embodiments, the sensors

include photo-sensors. The magnet may include one or more circular optical encoder strips to work in conjunction with the photo-sensors. U.S. patent application Ser. No. 14/932,904 describes various systems and methods for non-invasively detecting the force generated by a non-invasively adjustable implant, the entire contents of which are hereby incorporated by reference.

[0111] In the illustrated embodiment the external adjustment device 400 includes a motor 430 having one or more rotational speed sensor 432 configured to detect a change in a motor angular velocity (V), and thereby as described below non-invasively detect a rotation of the permanent magnet 118 of the adjustable implant 100. The motor 430 has torque characteristics that allows for little variation in motor angular velocity (V) during a motor rotation and corresponding magnet 440 rotation, when there is no implant or ferrous material located near the ERC magnet or magnetically coupled to the magnet 440.

[0112] When an adjustable implant 100 having a magnet 118 is in close proximity to the rotating magnet 440, and for example magnetically coupled to the magnet 440, the magnetic poles of both magnets cause a changing load on the motor 430 twice per revolution. This causes the magnet 440 to increase or decrease in angular velocity, with the variations detectable by the rotational speed sensor 432.

[0113] One or more example computing environments 100 can be used to implement techniques described herein. The computing environment 100 is a set of one or more virtual or physical computers configured to cause output based on data. In many examples, the computing environment 100 is a workstation, desktop computer, laptop computer, server, mobile computer, smartphone, tablet, embedded computer, other computers, or combinations thereof. In other examples, the computing environment is a virtual machine, group of computers, other computing environments, or combinations thereof.

[0114] In the illustrated example, the computing environment 1000 includes one or more processors 1010, memory 1020, and an interface 1030 coupled to a network 1002. The network 1002 is a group of communicatively coupled computing environments and associated hardware, such as a local area network, the Internet, other networks, or combinations thereof.

[0115] The one or more processors 1010 are one or more physical or virtual components configured to obtain and execute instructions. In many examples, the one or more processors 1010 are central processing units, but can take other forms such as microcontrollers, microprocessors, graphics processing units, tensor processing units, other processors, or combinations thereof.

[0116] The memory 1020 is one or more physical or virtual components configured to store information, such as data or instructions. In some examples, the memory 1020 includes the computing environment's main memory (e.g., random access memory) or long-term storage memory (e.g., a solid state drive). The memory can be transitory or non-transitory computer-readable or processor-readable storage media.

[0117] The interface 1030 is a set of one or more components by which the computing environment 1000 can provide output or receive input. For example, the interface 1030 can include one or more user input components, such as one or more sensors, buttons, pointers, keyboards, mice, gesture controls, touch controls (e.g., touch-sensitive strips or touch screens), eye trackers, voice recognition controls (e.g., microphones coupled to appropriate natural language processing components), other user input components, or combinations thereof. The interface 1030 can include one or more user output components, such as one or more lights, displays, speakers, haptic feedback components, other user output components, or combinations thereof. The interface 1030 can further include one or more components configured to provide output to or receive input from other devices, such as one or more ports (e.g., USB ports, THUNDERBOLT ports, serial ports, parallel ports, Ethernet ports) or wireless communication components (e.g., components configured to communicate according to one or more radiofrequency protocols, such as WI-FI, BLUETOOTH, ZIGBEE, or other protocols).

[0118] The computing environment 1000 can include one or more additional components or connections among components (e.g., busses).

[0119] The computing environment 1000 can be configured to implement one or more aspects described herein. Algorithms, steps, or procedures for so configuring the computing environment and performing functions described herein can be understood from the description herein in view of knowledge in the art of how to implement computer functions.

[0120] The computing environment 1000 can be configured to implement one or more aspects described herein. Algorithms, steps, or procedures for so configuring the computing environment and performing functions described herein can be understood from the description herein in view of knowledge in the art of how to implement computer functions.

[0121] Example techniques for implementing such computer functions include frameworks and technologies offering a full stack of plug-and-play capabilities for implementing desktop and browser-based applications (e.g., the applications implementing aspects described herein). The frameworks can provide a desktop web application featuring or using an HTTP server such as NODEJS or KATANA and an embeddable web browser control such as the CHROMIUM EMBEDDED

FRAMEWORK or the JAVA/.NET CORE web view. The client-side frameworks can extend that concept by adding plug-and-play capabilities to desktop and the web shells for providing apps capable of running both on the desktop and as a web application. One or more components can be implemented using a set of OWIN (Open Web Interface for .NET) components built by MICROSOFT targeting the traditional .NET runtime. KATANA, and by definition OWIN, allow for chaining together middleware (OWIN-compliant modules) into a pipeline thus offering a modular approach to building web server middleware. For instance, the client-side frameworks can use a Katana pipeline featuring modules such as SIGNALR, security, an HTTP server itself. The plug-and-play capabilities can provide a framework allowing runtime assembly of apps from available plugins. An app built atop of a plug-and-play framework can have dozens of plugins, with some offering infrastructure-level functionality and other offering domain-specific functionality. The CHROMIUM EMBEDDED FRAMEWORK is an open source framework for embedding the CHROMIUM browser engine with bindings for different languages, such as C# or JAVA. OWIN is a standard for an interface between .NET web applications and web servers aiming at decoupling the relationship between ASP.NET applications and IIS by defining a standard interface.

[0122] Further example techniques for implementing such computer functions or algorithms include frameworks and technologies provided by or in conjunction with programming languages and associated libraries. For example, languages such as C, C++, C#, PYTHON, JAVA, JAVASCRIPT, RUST, assembly, HASKELL, other languages, or combinations thereof can be used. Such languages can include or be associated with one or more standard libraries or community provided libraries. Such libraries in the hands of someone skilled in the art can facilitate the creation of software based on descriptions herein, including the receiving, processing, providing, and presenting of data. Example libraries for PYTHON and C++ include OPENCV (e.g., which can be used to implement computer vision and image processing techniques), TENSORFLOW (e.g., which can be used to implement machine learning and artificial intelligence techniques), and GTK (e.g., which can be used to implement user interface elements). Further examples include NUMPY for PYTHON (e.g., which can be used to implement data processing techniques). In addition, other software can provide application programming interfaces that can be interacted with to implement one or more aspects described herein. For example, an operating system for the computing environment (e.g., WINDOWS by MICROSOFT CORP., MACOS by APPLE INC., or a LINUX-based operating system such as UBUNTU by CANONICAL LTD.) or another component herein (e.g., an operating system of a robot, such as IIQKA.OS or SUNRISE.OS by KUKA ROBOTICS CORPORATION where the robot is a



model of KUKA ROBOTICS CORPORATION) can provide application programming interfaces or libraries to usable to implement aspects described herein. As a further example, a provider of a navigation system, laser console, wireless card, display, motor, sensors, or another component may not only provide hardware components (e.g., sensor, a camera, wireless card, motor, or laser generator), but also software components (e.g., libraries, drivers, or applications) usable to implement features with respect to the components.

[0123] In the descriptions above and in the claims, phrases such as “at least one of” or “one or more of” may occur followed by a conjunctive list of elements or features. The term “and/or” may also occur in a list of two or more elements or features. Unless otherwise implicitly or explicitly contradicted by the context in which it is used, such a phrase is intended to mean any of the listed elements or features individually or any of the recited elements or features in combination with any of the other recited elements or features. For example, the phrases “at least one of A and B;” “one or more of A and B;” and “A and/or B” are each intended to mean “A alone, B alone, or A and B together.” A similar interpretation is also intended for lists including three or more items. For example, the phrases “at least one of A, B, and C;” “one or more of A, B, and C;” and “A, B, and/or C” are each intended to mean “A alone, B alone, C alone, A and B together, A and C together, B and C together, or A and B and C together.” Use of the term “based on,” above and in the claims is intended to mean, “based at least in part on,” such that an unrecited feature or element is also permissible.

[0124] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the disclosure. As used herein, the terms “first,” “second,” and the like, do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “a” and “an” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced items. It will be further understood that the terms “comprises” and/or comprising,” when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups. As used herein, “substantially” refers to largely, for the most part, entirely specified or any slight deviation which provides the same technical benefits of the disclosure.

[0125] The implementations set forth in the foregoing description do not represent all implementations consistent with the subject matter described herein. Instead, they are merely some examples consistent with aspects related to the described subject matter. Although a few variations have been described in detail herein, other modifications or additions are possible. In particular,

further features and/or variations can be provided in addition to those set forth herein. For example, the implementations described above can be directed to various combinations and sub-combinations of the disclosed features and/or combinations and sub-combinations of one or more features further to those disclosed herein. In addition, the logic flows depicted in the accompanying figures and/or described herein do not necessarily require the particular order shown, or sequential order, to achieve desirable results. The scope of the following claims may include other implementations or embodiments.

## CLAIMS

What is claimed is:

1. An adjustable implant configured to be implanted into a patient, the adjustable implant comprising:
  - a housing;
  - an adjustable portion moveable relative to the housing; and
  - a load cell within the housing for measuring a load imparted on the implant during movement of the adjustable portion relative to the housing or during movement of a bone relative to the housing.
2. The adjustable implant of claim 1, wherein the load cell includes at least one sensor.
3. The adjustable implant of claim 1, wherein the load cell is coupled with the housing.
4. The adjustable implant of claim 3, wherein the load cell is coupled with the housing via a pin.
5. The adjustable implant of claim 1, further comprising:
  - a controller within the housing and configured to determine at least one of a distraction force and a compression force based on the load measured by the load cell.
6. The adjustable implant of claim 5, further comprising:
  - wiring coupling the load cell and the controller.
7. The adjustable implant of claim 6, further comprising:
  - a polymer housing surrounding the wiring within the housing.
8. The adjustable implant of claim 5, further comprising:
  - a transducer configured to send the at least one of the distraction force and the compression force to an external interface device.
9. The adjustable implant of claim 1, further comprising:
  - apertures within the housing for receiving bone anchors therein.

10. The adjustable implant of claim 9, wherein the load cell includes apertures therein corresponding to the apertures within the housing for receiving the bone anchors therein to couple the load cell to the bone.
11. The adjustable implant of claim 10, wherein the apertures of the load cell have a smaller diameter than a diameter of the apertures within the housing.
12. The adjustable implant of claim 1, wherein the load cell includes a first strain gauge and a second strain gauge.
13. The adjustable implant of claim 5, further comprising a reed switch configured to power on the controller in response to an external device being within a threshold distance of the adjustable implant and power off the controller in response to the external device being outside the threshold distance of the adjustable implant.
14. The adjustable implant of claim 1, further comprising:  
an actuator configured to cause movement of the adjustable portion relative to the housing;  
and  
a sensor configured to determine an amount of rotation of actuator.
15. The adjustable implant of claim 14, further comprising:  
a controller configured to digitize data acquired by the load cell and modulate the data into an ultrasound signal; and  
a transducer configured to send the ultrasound signal comprising the digitized data to an external interface device.
16. The adjustable implant of claim 15, wherein the data includes at least one of: the load imparted on the implant, a distraction length of the implant, a compression length of the implant, a distraction force of the implant, and a compression force of the implant.

17. A method comprising:
- adjusting an adjustable implant having:
    - a housing;
    - an adjustable portion moveable relative to the housing; and
    - a load cell within the housing for measuring a load; and
  - measuring, with the load cell, the load imparted on the implant during movement of the adjustable portion relative to the housing or during movement of a bone relative to the housing.
18. The method of claim 17, wherein housing includes apertures therein for receiving bone anchors.
19. The method of claim 18, wherein the load cell includes apertures therein corresponding to the apertures within the housing for receiving the bone anchors therein to couple the load cell to the bone.
20. The method of claim 19, wherein the apertures of the load cell have a smaller diameter than the diameter of the apertures within the housing.
21. The method of claim 20, wherein the measuring of the load includes using the load cell to measure the load imparted on the bone anchors.
22. The method of claim 17, further comprising:
- sending the measured load to an external interface device.
23. The method of claim 17, further comprising:
- receiving treatment instructions from the external interface device.
24. The method of claim 23, further comprising:
- adjusting the implant based on the treatment instructions.
25. The method of claim 17, further comprising:
- determining at least one of a distraction force, a compression force, a distraction length and a compression length based on the measured load.

26. An adjustable implant comprising:
- a housing;
  - an adjustable portion movable relative to the housing;
  - an actuator positioned within the housing and configured to cause movement of the adjustable portion relative to the housing; and
  - a sensor positioned adjacent to the actuator and configured to monitor an angular position of the actuator.
27. The adjustable implant of claim 26, further comprising:
- a controller communicatively coupled to the sensor and configured to receive angular position data from the sensor.
28. The adjustable implant of claim 27, wherein the controller is configured to determine a number of rotations of the actuator in response to processing the angular position data.
29. The adjustable implant of claim 28, wherein the controller is configured to calculate a distraction length or a compression length of the adjustable implant based on the number of rotations of the actuator.
30. The adjustable implant of claim 29, further comprising:
- a transducer configured to send data including at least one of the number of rotations, distraction length and compression length to an external interface device.
31. The adjustable implant of claim 26, wherein the sensor includes a hall effect sensor that detects a magnetic field of an actuator magnet.
32. The adjustable implant of claim 31, wherein the hall effect sensor includes one of a unidirectional hall effect sensor, a rotary hall effect sensor and a rotary hall effect sensor having a 4-hall element arrangement.

33. The adjustable implant of claim 27, further comprising a reed switch configured to power on the controller in response to an external device being within a threshold distance of the adjustable implant and power off the controller in response to the external device being outside the threshold distance of the adjustable implant.

34. The adjustable implant of claim 26, further comprising a load cell having a strain gauge for measuring a linear force imparted on the housing.

35. A method comprising:

adjusting an adjustable implant, the adjustable implant including:

a housing;

an adjustable portion moveable relative to the housing;

an actuator positioned within the housing and configured to cause movement of the adjustable portion relative to the housing; and

a sensor positioned adjacent to the actuator and configured to monitor an angular position of the actuator;

determining a number of rotations of the actuator based on monitoring of the angular position; and

calculating a distraction length or a compression length of the adjustable implant based upon the number of rotations of the actuator.

36. The method of claim 35, wherein the adjustable implant further includes a controller positioned within the housing and communicatively coupled to the sensor.

37. The method of claim 35, wherein the sensor includes a hall effect sensor.

38. The method of claim 35, further comprising:

sending data that includes at least one of the number of rotations, the distraction length or the compression length to an external interface device.

39. The method of claim 38, wherein the adjustable implant further includes a transducer positioned within the housing for sending data.

40. The method of claim 38, further comprising receiving treatment instructions from the external interface device to adjust the adjustable portion.

41. The method of claim 40, wherein the treatment instructions are based on the calculated distraction length or compression length.

42. The method of claim 36, wherein the controller and sensor are activated and deactivated by a reed switch in response to a proximity of an external device.

43. An adjustable implant comprising:

a housing;

an adjustable portion moveable relative to the housing;

a first actuator configured to cause movement of the adjustable portion relative to the housing, the first actuator being actuated by an external adjustment device having a second actuator therein;

a first sensor configured to measure a position of the first actuator; and

a second sensor configured to measure a position of the second actuator within the external adjustment device.

44. The adjustable implant of claim 43, wherein the first sensor is a hall effect sensor.

45. The adjustable implant of claim 44, wherein the hall effect sensor is a unidirectional hall effect sensor.

46. The adjustable implant of claim 43, wherein the second sensor is a hall effect sensor.

47. The adjustable implant of claim 46, wherein the hall effect sensor is an omnidirectional hall effect sensor.



48. The adjustable implant of claim 43, further comprising:

a controller disposed between the first sensor and the second sensor, the controller configured to determine a position of the first and second actuator relative to each other at a given time.

49. The adjustable implant of claim 48, wherein the first actuator includes a rotating permanent magnet and the second actuator includes at least one rotating permanent magnet.

50. The adjustable implant of claim 49, wherein the controller is configured to monitor a position of the rotating permanent magnet of the first actuator and a position of the at least one rotating permanent magnet of the second actuator.

51. The adjustable implant of claim 50, wherein the controller is configured to determine at least one of a distraction force, a distraction torque, a compression force, and compression torque of the adjustable implant based on the position of the rotating permanent magnet of the first actuator and the at least one rotating permanent magnet of the second actuator.

52. The adjustable implant of claim 43, further comprising:

a transducer configured to send data associated with the first sensor and the second sensor to an external interface device.

53. A method comprising:

adjusting an adjustable implant, the adjustable implant having a housing and an adjustable portion moveable relative to the housing;

measuring a position of a first actuator of the adjustable implant, the first actuator being configured to cause movement of the adjustable portion relative to the housing;

measuring a position of a second actuator of an external adjustment device, the external adjustment device configured to actuate the first actuator of the adjustable implant; and

determining at least one of a distraction force, a distraction torque, a compression force, and a compression length based on the position of the first actuator and the position of the second actuator at a given time.

54. The method of claim 53, wherein the adjustable implant includes a first sensor and a second sensor.

55. The method of claim 54, wherein the measuring of the position of the first actuator includes measuring the position of the first actuator via the first sensor, and wherein the measuring of the position of the second actuator includes measuring the position of the second actuator via the second sensor.

56. The method of claim 55, wherein the first sensor includes a first hall effect sensor and the second sensor includes a second hall effect sensor.

57. The method of claim 56, wherein the first hall effect sensor includes a unidirectional hall effect sensor and the second hall effect sensor includes an omnidirectional hall effect sensor.

58. The method of claim 53, wherein the adjustable implant further includes a controller positioned between the first and second sensors.

59. The method of claim 58, further comprising using the controller for determining the at least one of the distraction force, the distraction torque, the compression force, and the compression torque.

60. The method of claim 53, further comprising:

sending the at least one of the distraction force, the distraction torque, the compression force, and the compression torque via a transducer to an external interface device.

61. The method of claim 60, further comprising:

determining treatment instructions based on the at least one the distraction force, the distraction torque, the compression force, and the compression torque.

62. The method of claim 61, further comprising:

adjusting the adjustable implant based on the treatment instructions.

63. An adjustable implant comprising:

a housing;

an adjustable portion moveable relative to the housing;

a first actuator configured to cause movement of the adjustable portion relative to the housing, the first actuator being actuated by an external adjustment device having a second actuator therein;

a first sensor located at a first position in the housing configured to measure a first magnetic field of the first actuator relative to the second actuator;

a second sensor located at a second position in the housing configured to measure a second magnetic field of the first actuator relative to the second actuator; and

a controller that determines at least one force by analyzing the first magnetic field and the second magnetic field.

64. The adjustable implant of claim 63, wherein the first actuator includes a first rotating permanent magnet and the second actuator includes a second rotating permanent magnet.

65. The adjustable implant of claim 64, wherein the controller is configured to monitor a position of the first rotating permanent magnet relative to the second permanent magnet r.

66. The adjustable implant of claim 64, wherein the controller is configured to determine at least one of a distraction force, a distraction torque, a compression force, and compression torque of the adjustable implant.

67. The adjustable implant of claim 63, wherein the first sensor and the second sensor comprise multi-dimensional hall effect sensors.

68. The adjustable implant of claim 63, further comprising:

a transducer configured to send data associated with the first sensor and the second sensor to an external interface device.

69. The adjustable implant of claim 63, further comprising:

a reed switch configured to active and deactivate at least one of the controller or first and second sensors in response to a proximity of an external device to the housing.

70. A method comprising:

adjusting an adjustable implant, the adjustable implant having a housing and an adjustable portion, the adjustable implant having a first actuator configured to cause movement of the adjustable portion relative to the housing in response to movement of a second actuator of an external adjustment device;

using a first sensor positioned at a first location in the housing to measure a first magnetic field of the first actuator of the adjustable implant relative to the second actuator;

using a second sensor positioned at a second location in the housing to measure a second magnetic field of the first actuator of the adjustable implant relative to the second actuator; and

determining at least one force by analyzing the first magnetic field and the second magnetic field.

71. The method of claim 70, wherein the first actuator includes a first rotating permanent magnet and the second actuator includes a second rotating permanent magnet.

72. The method of claim 71, wherein the first actuator includes a first rotating permanent magnet and the second actuator includes a second rotating permanent magnet.

73. The method of claim 70, wherein a controller implement in the adjustable implant is configured to determine at least one of a distraction force, a distraction torque, a compression force, and compression torque of the adjustable implant.

74. The method of claim 70, wherein the first sensor and the second sensor comprise multi-dimensional hall effect sensors.

75. The method of claim 70, further comprising:

send data associated with the first sensor and the second sensor to an external interface device via a transducer.

76. The method of claim 70, further comprising:  
using a reed switch to active and deactivate at least one of the controller or first and second sensors in response to a proximity of an external device to the housing.
77. The method of claim 73, further comprising:  
determining treatment instructions for the adjustable implant based on the at least one the distraction force, the distraction torque, the compression force, and the compression torque.
78. The method of claim 77, further comprising:  
adjusting the adjustable implant based on the treatment instructions.
79. A signal transmission device comprising:  
a housing;  
a half-cylinder piezoelectric transducer positioned within the housing and having an inner diameter and an outer diameter;  
a metal backing positioned adjacent the inner diameter; and  
a package positioned within the housing and substantially surrounding the half-cylinder piezoelectric transducer and the metal backing,  
wherein the half-cylinder piezoelectric transducer is configured to directionally transmit data to a receiver via an ultrasound signal.
80. The signal transmission device of claim 79, wherein the piezoelectric transducer is a 1 KHz – 1 MHz piezoelectric transducer.
81. The signal transmission device of claim 79, wherein the housing includes a titanium housing.
82. The signal transmission device of claim 79, wherein the housing includes a non-ferrous, biocompatible metal.
83. The signal transmission device of claim 79, wherein the package includes a titanium package.

84. The signal transmission device of claim 79, wherein the package includes a non-ferrous, biocompatible metal.
85. The signal transmission device of claim 79, wherein the metal backing includes stainless steel.
86. The signal transmission device of claim 79, wherein the metal backing is a half-cylinder metal backing.
87. The signal transmission device of claim 79, further comprising:  
a filler positioned within the housing.
88. The signal transmission device of claim 87, wherein the filler includes fluorinated oil.
89. The signal transmission device of claim 87, wherein the filler includes silicone oil.
90. The signal transmission device of claim 87, wherein the filler includes a super epoxy.
91. An implant comprising:  
an implant housing; and  
a signal transmission device positioned within the implant housing, the signal transmission device including:  
a partial-cylinder piezoelectric transducer having an inner diameter and an outer diameter;  
a metal backing positioned adjacent the inner diameter; and  
a semiconductor package positioned within the housing and substantially surrounding the partial-cylinder piezoelectric transducer and the metal backing,  
wherein the partial-cylinder piezoelectric transducer is configured to directionally transmit data to a receiver via an ultrasound signal.
92. The implant of claim 91, wherein the piezoelectric transducer is a 100 KHz – 1 MHz piezoelectric transducer.

93. The implant of claim 91, wherein the implant housing includes a titanium housing.
94. The implant of claim 91, wherein the implant housing includes a non-ferrous, biocompatible metal.
95. The implant of claim 91, wherein the package includes a titanium package.
96. The implant of claim 91, wherein the package includes a non-ferrous biocompatible metal.
97. The implant of claim 91, wherein the metal backing includes stainless steel.
98. The implant of claim 91, wherein the metal backing is a partial-cylinder metal backing.
99. The implant of claim 91, further comprising:  
a filler positioned within the implant housing.
100. The implant of claim 99, wherein the filler includes at least one of fluorinated oil, silicone oil, and a super epoxy.
101. The implant of claim 91, wherein the signal transmission device is configured to transmit data associated with the implant to an external interface device.
102. The implant of claim 101, wherein the signal transmission device is configured to direction a signal laterally relative to a patient that the implant is implanted therein.
103. An implant configured to be implanted within a patient, the implant comprising:  
a controller;  
an energy harvesting component configured to harvest energy imparted from the implant during movement of the patient having the implant therein; and  
an energy storage device configured to store the energy harvested by the energy harvesting component,

wherein the energy harvested by the energy harvesting component provides power for the controller.

104. The implant of claim 103, further comprising:

wiring coupling the energy harvesting component and the energy storage component.

105. The implant of claim 104, wherein the wiring includes a printed circuit board disposed between the energy harvesting component and the energy storage component.

106. The implant of claim 103, wherein the printed circuit board includes a power management unit configured to adjust a voltage of the energy harvested by the energy harvesting component.

107. The implant of claim 104, further comprising:

wiring coupling the energy storage component to the controller.

108. The implant of claim 103, wherein the energy harvesting component includes a piezoelectric transducer.

109. The implant of claim 108, wherein the piezoelectric transducer is coupled to an internal surface of a housing of the implant.

110. The implant of claim 109, wherein the piezoelectric transducer is coupled to an internal surface of the housing at a location of the implant that receives tension or compressive stresses due to movement of the patient.

111. The implant of claim 110, wherein the piezoelectric transducer is a transceiver, and the transceiver is configured to communicate to an external interface device via radiofrequency waves.

112. The implant of claim 110, wherein the piezoelectric transducer is a transceiver, and the transceiver is configured to communicate to an external interface device via ultrasound waves.



113. The implant of claim 110, wherein the energy harvested by the energy harvesting component provides power for the piezoelectric transducer.

114. The implant of claim 109, further comprising:

a housing; and

an adjustable portion configured for telescopic movement relative to the housing.

115. The implant of claim 114, wherein the energy storage component is coupled to an internal surface of the adjustable portion at an end of the adjustable portion disposed within the housing.

116. A method comprising:

implanting an implant within a patient;

harvesting energy from stresses imparted on the implant during movement by the patient having the implant implanted therein; and

using the harvested energy to power at least one of a controller and a transducer of the implant.

117. The method of claim 116, further comprising:

sending, via the transducer, data to an external interface device positioned external to the patient.

118. The method of claim 117, wherein the data includes at least one: a distraction force, a distraction torque, a distraction length, a compression force, a compression torque, a compression length, a compressive stress, a tension stress, a biological condition, and a position of the implant.

119. The method of claim 117, further comprising:

receiving, via the controller, treatment instructions from external interface device.

120. The method of claim 119, wherein the treatment instructions include at least one of: a distraction length, a distraction force, distraction torque, a distraction time, a compression length, a compression force, a compression torque, and a compression time.

121. The method of claim 116, wherein the implanting of the implant includes implanting the implant within an intramedullary canal of a bone within the patient.

122. The method of claim 116, wherein the implanting of the implanting includes coupling the implant to a first bone portion and a second bone portion within the patient.

123. The method of claim 122, further comprising:

adjusting the implant such that the second bone portion moves relative to the first bone portion.

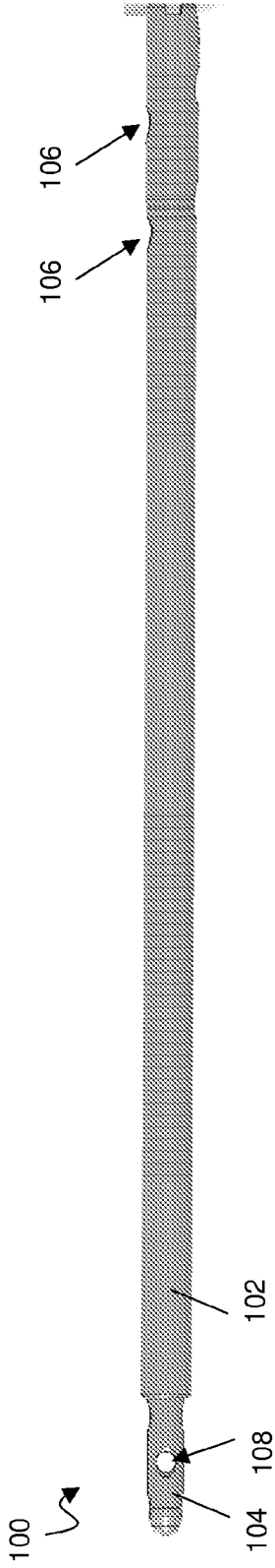


FIG. 1

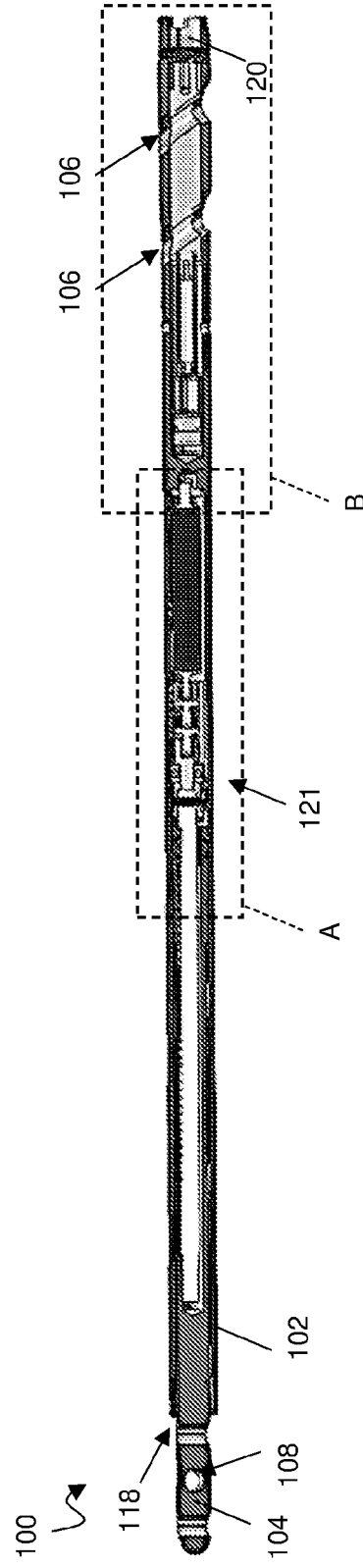


FIG. 2

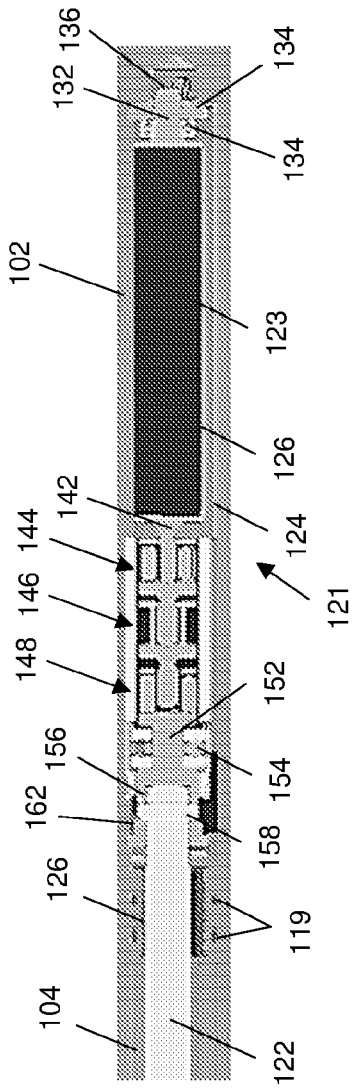


FIG. 3

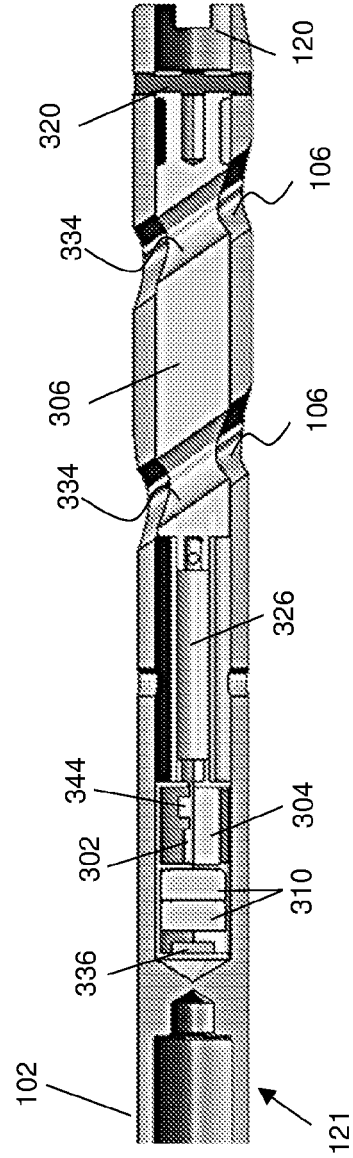


FIG. 4

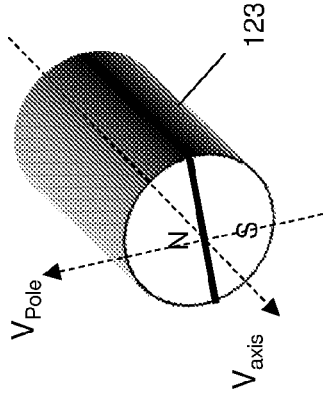


FIG. 6

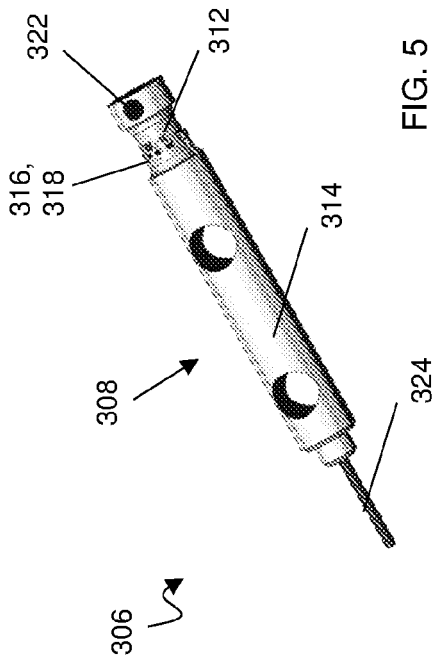


FIG. 5

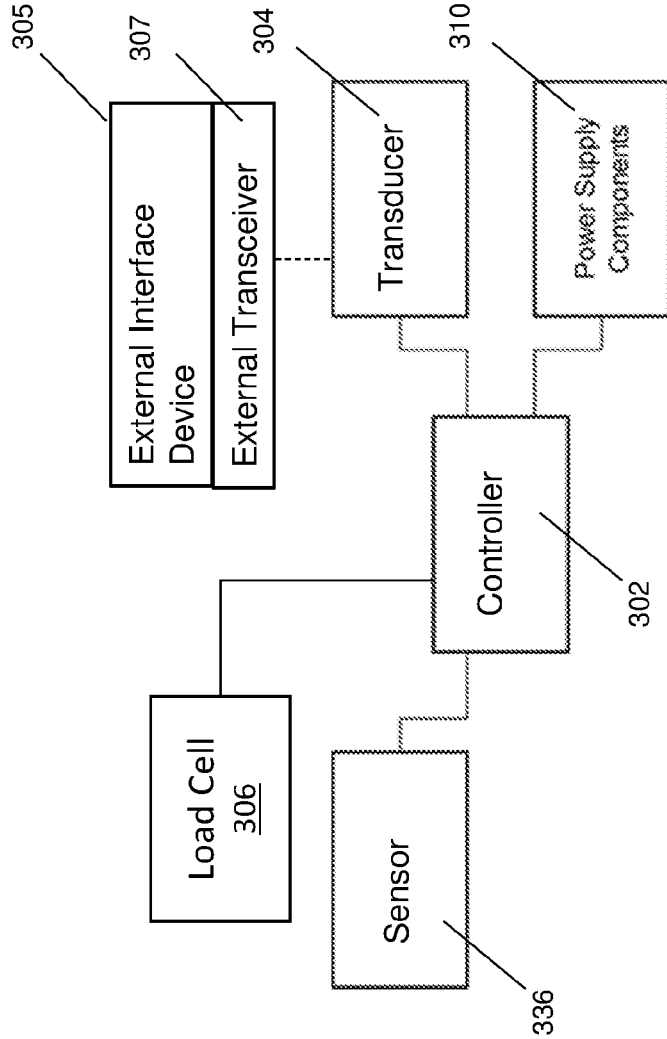


FIG. 7

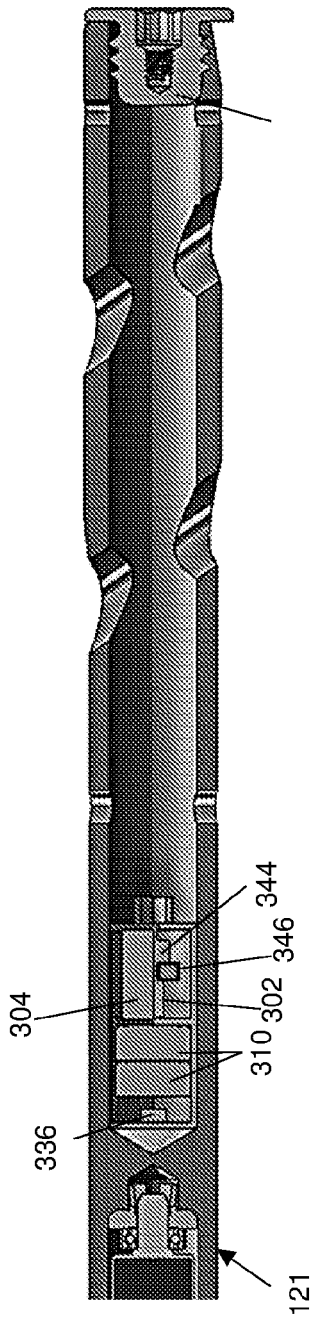


FIG. 8

120

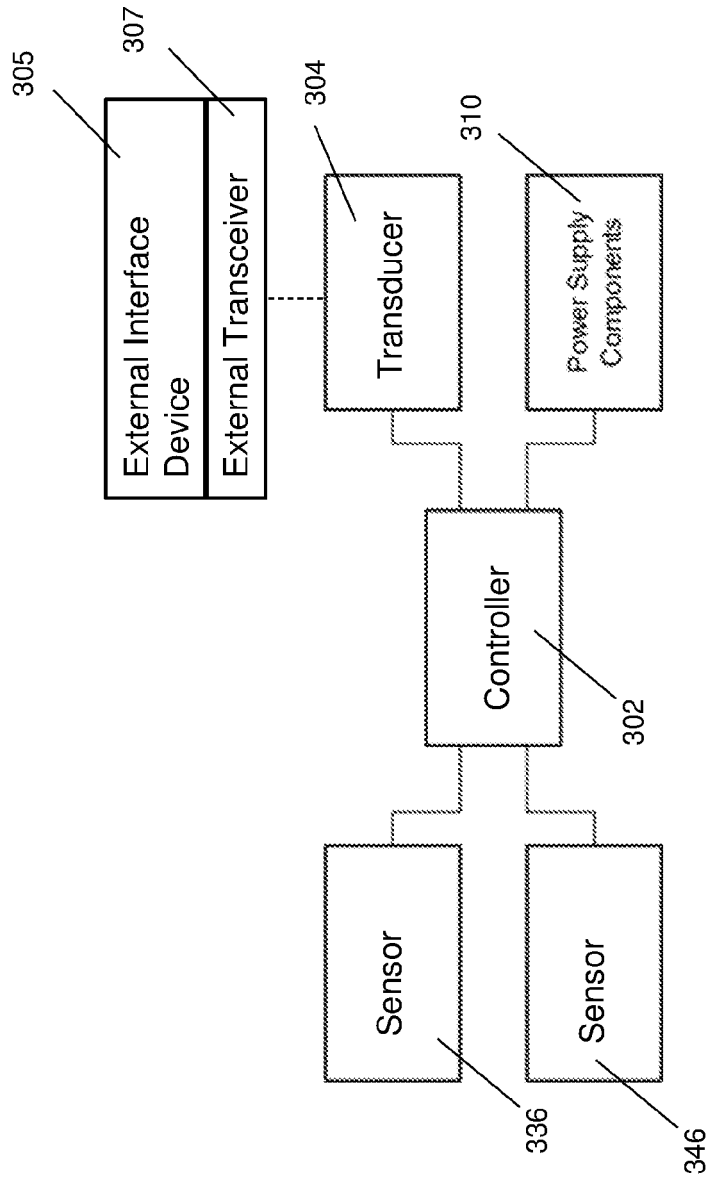


FIG. 9

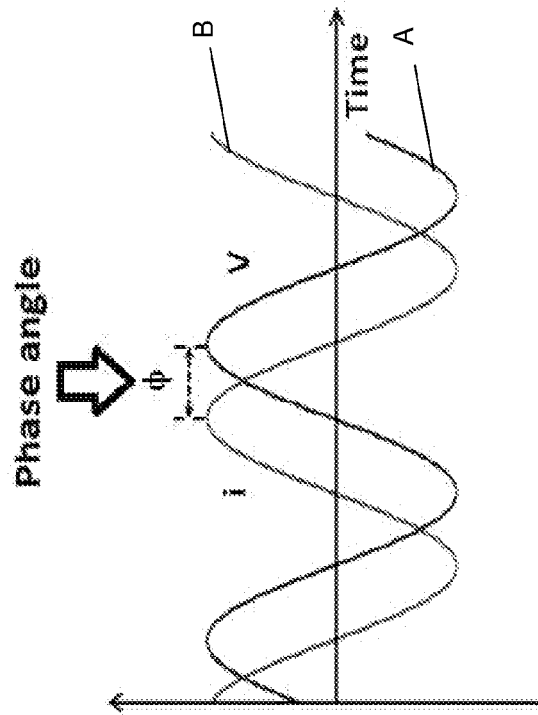


FIG. 10

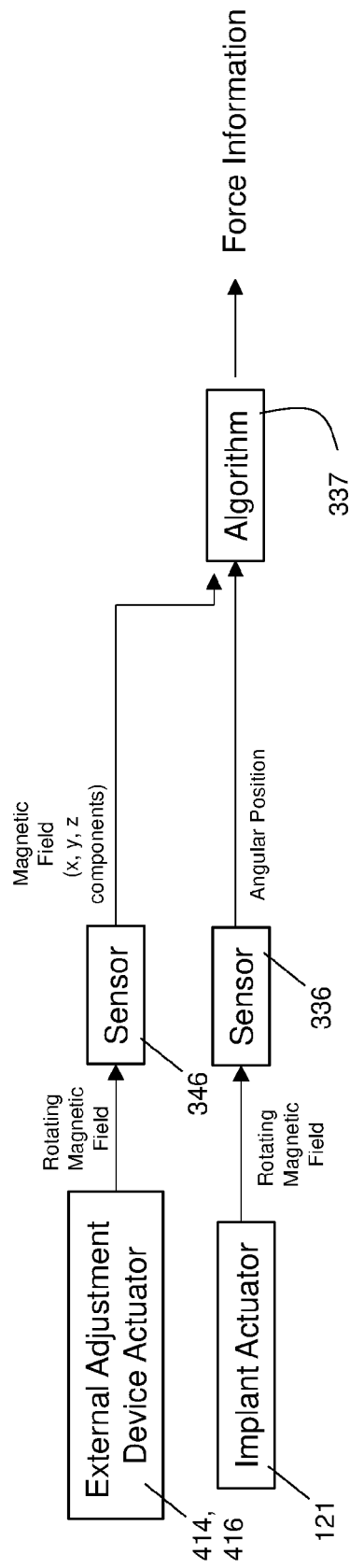
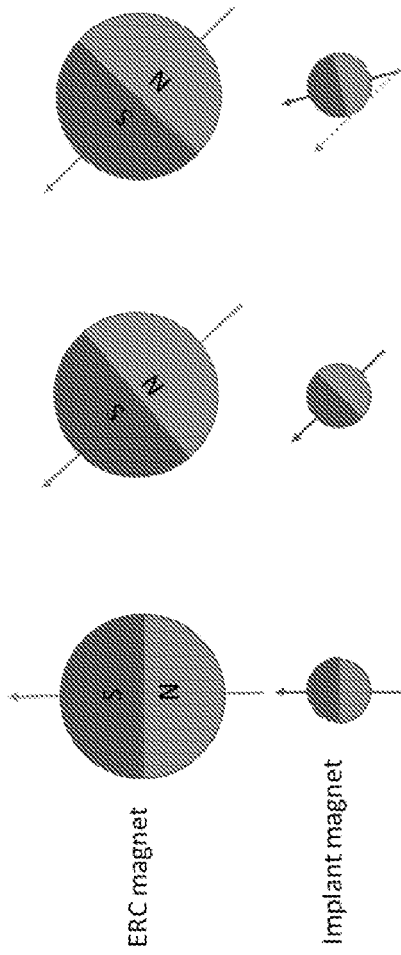


FIG. 11

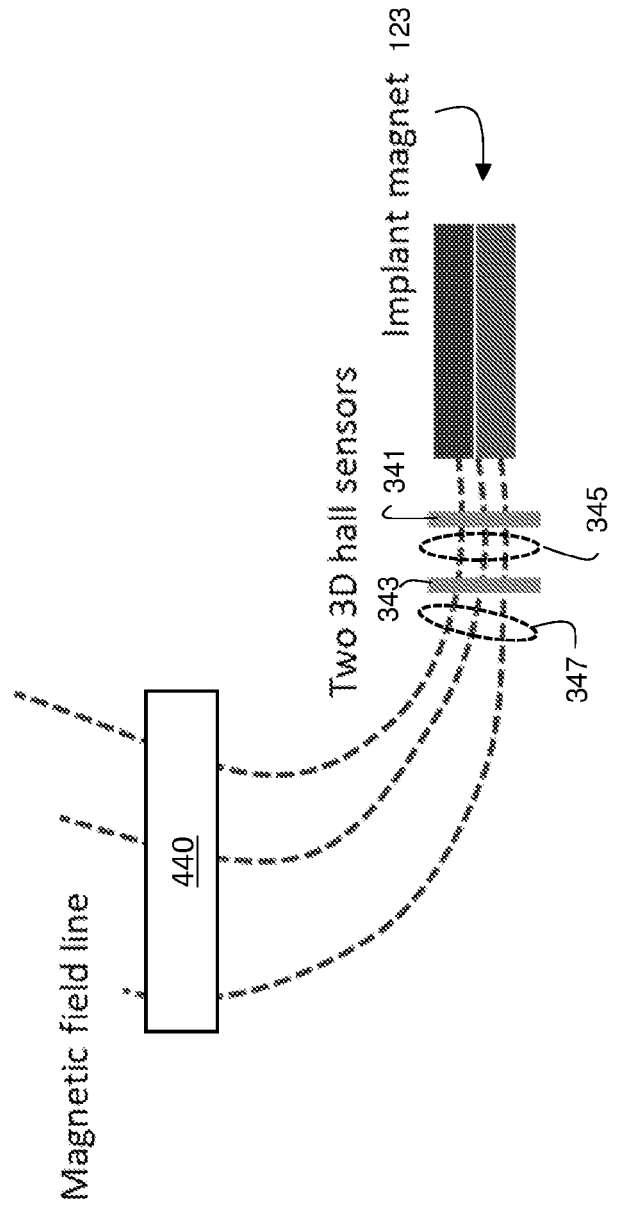


Phase difference correlates to loading force



Implant magnet couples with the ERC  
Two are in-phase. when there is no torque  
Implant angle lags when there is a torque

FIG. 12



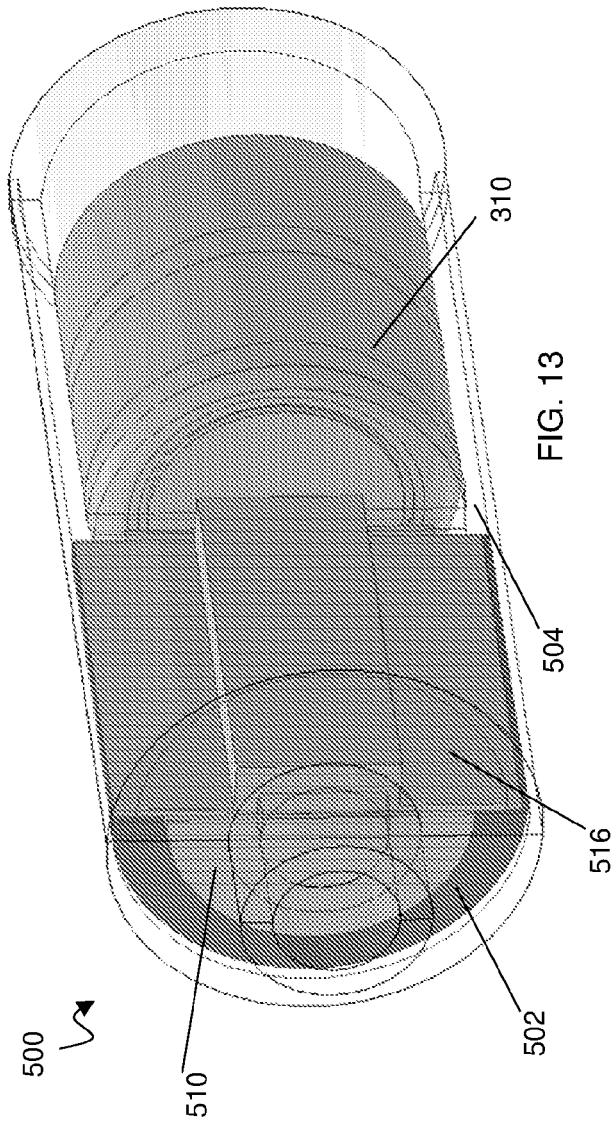


FIG. 13

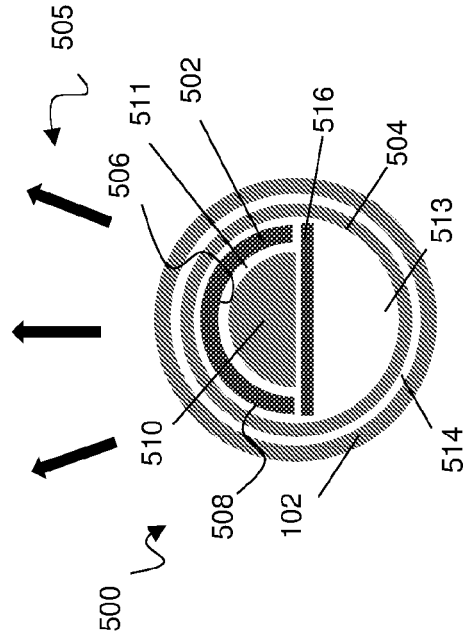


FIG. 14

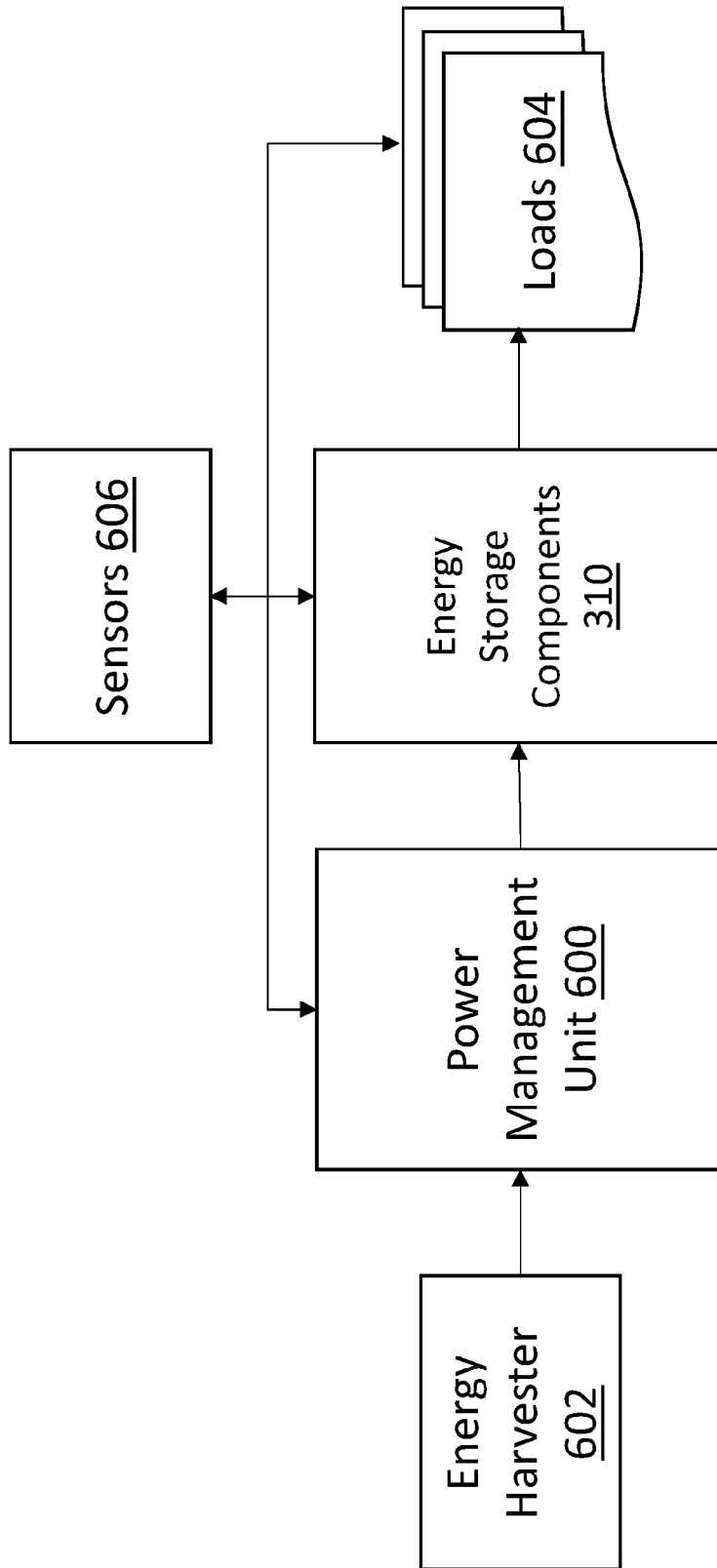


FIG. 15

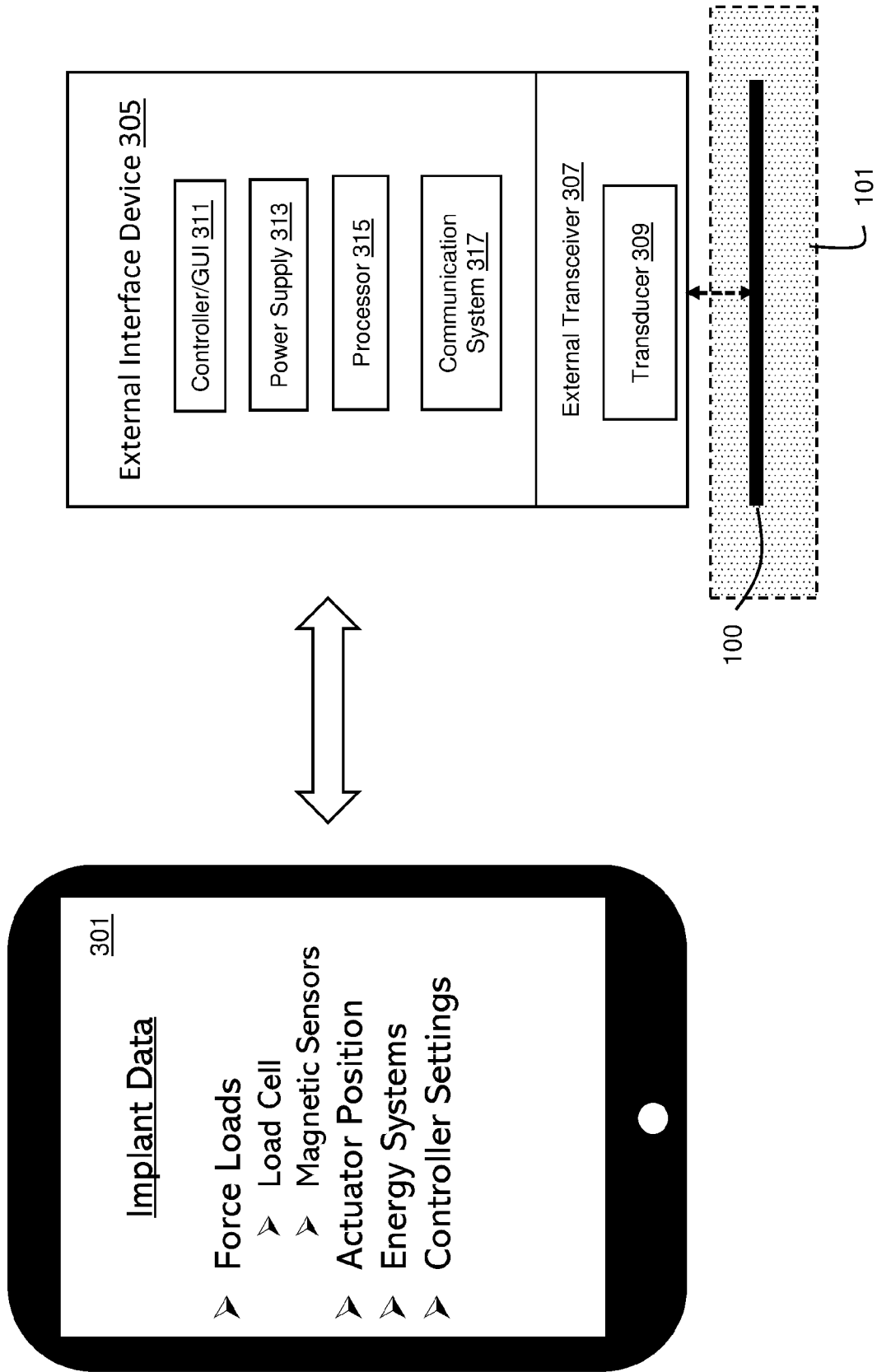


FIG. 16

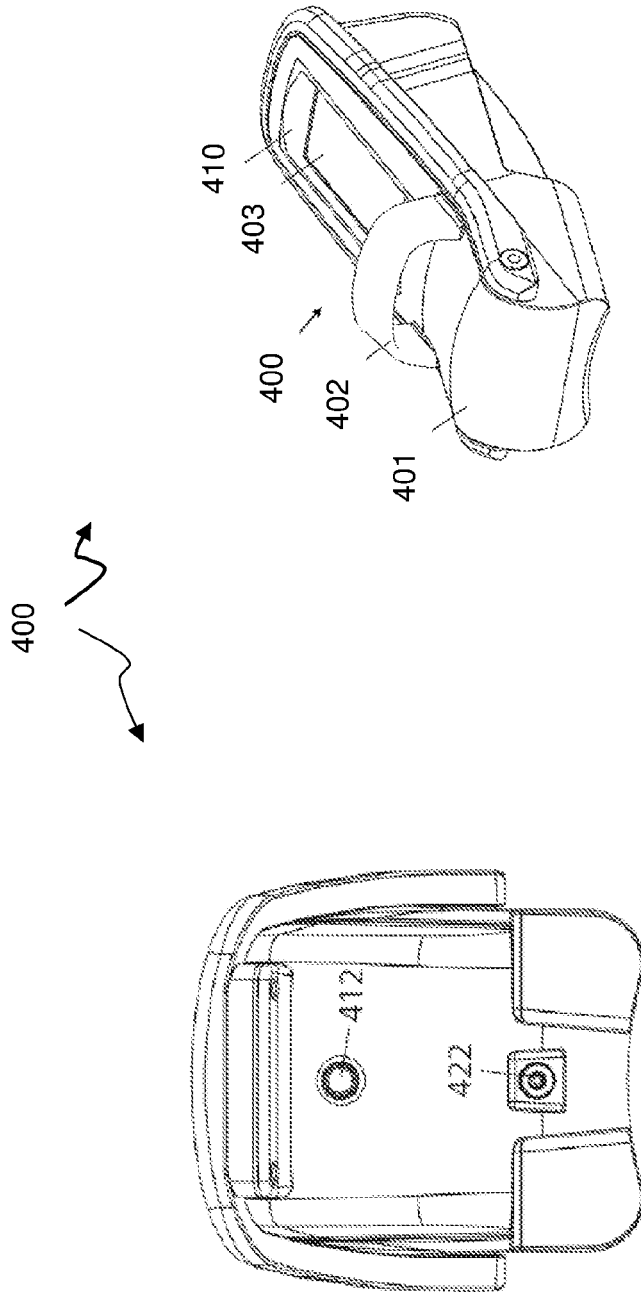


FIG. 17

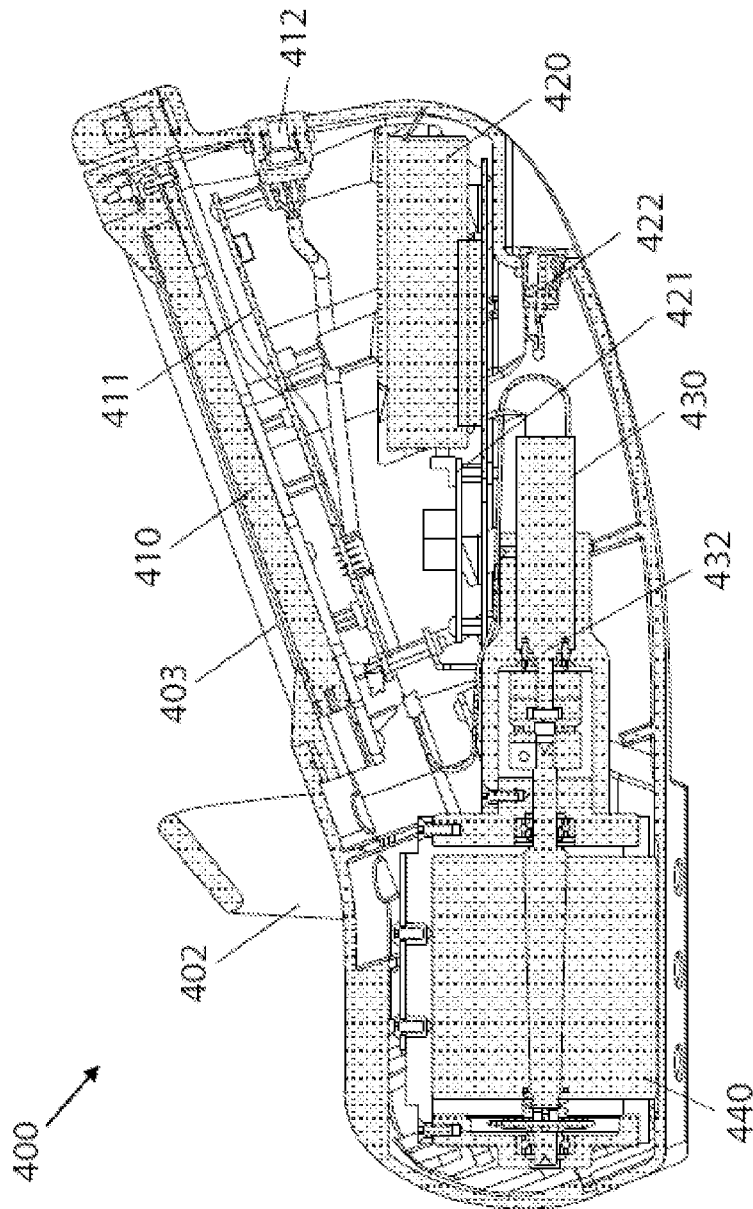


FIG. 18

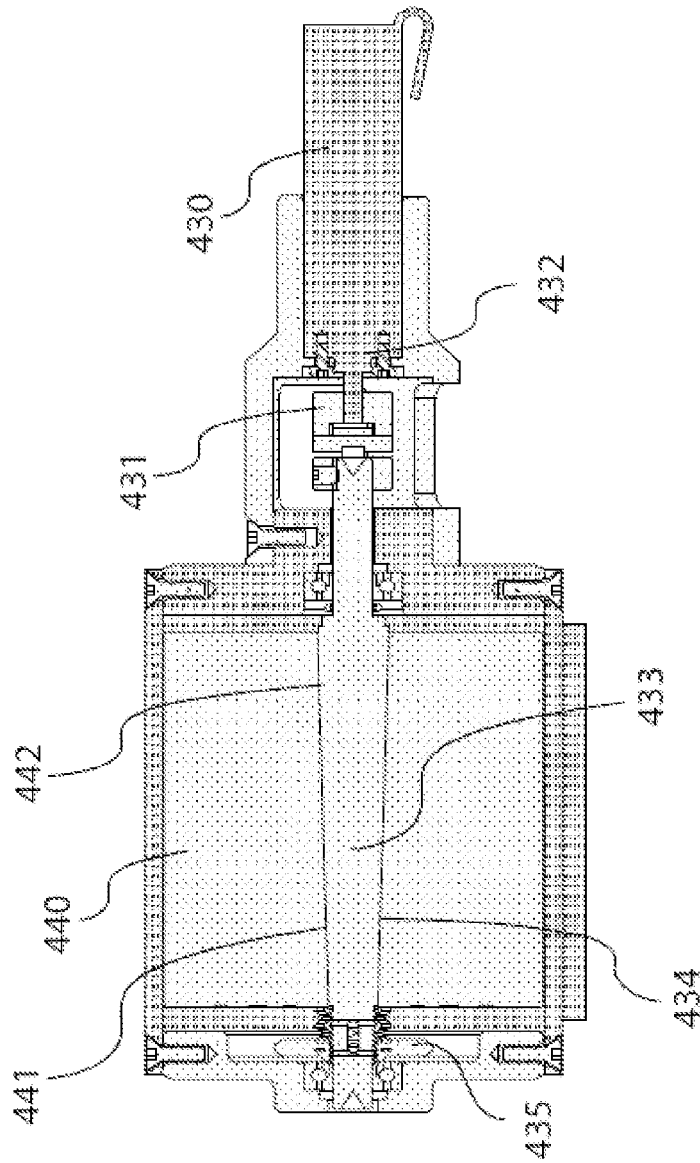


FIG. 19

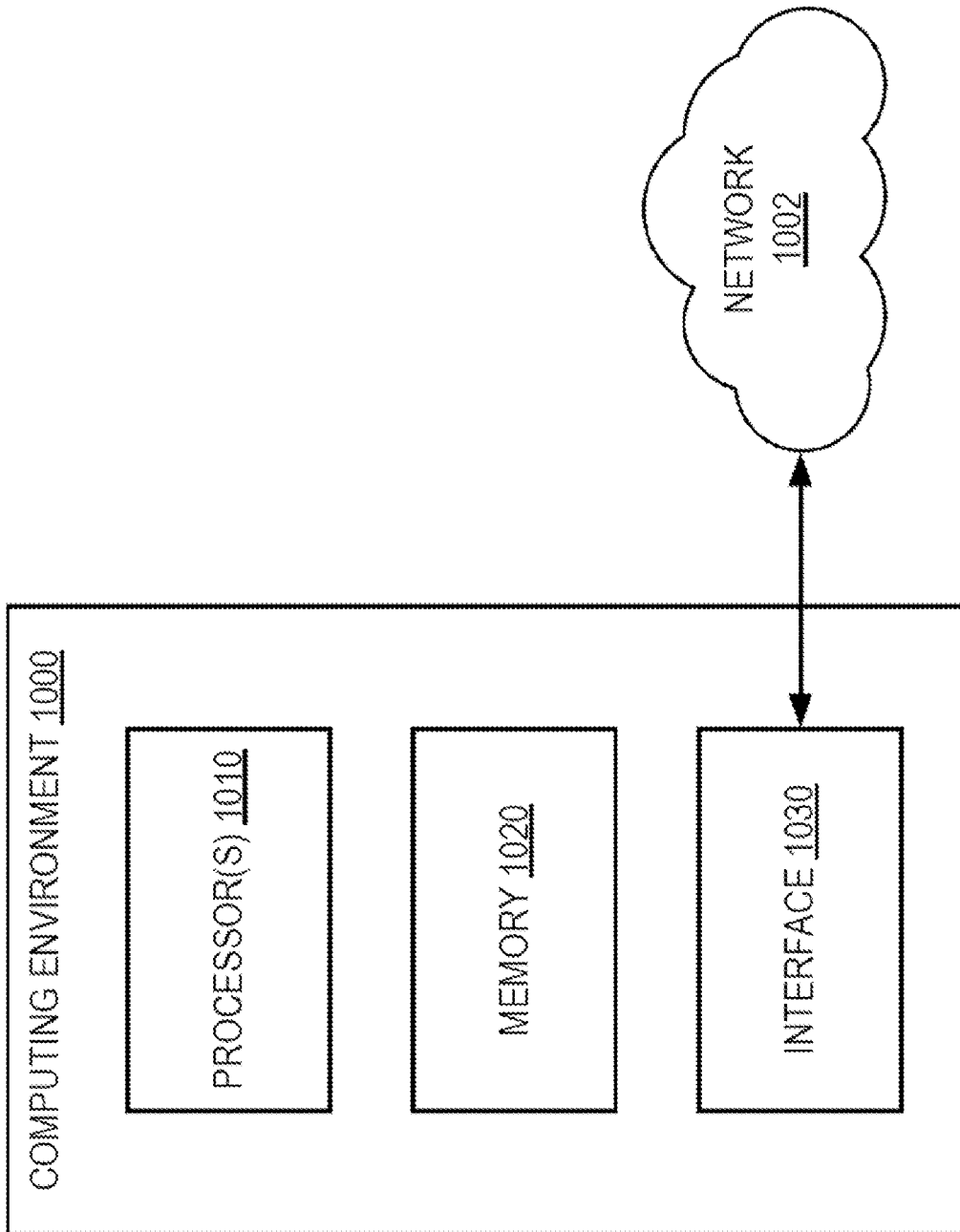


FIG. 20