(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
05 November 2020 (05.11.2020)

WIPO | PCT

(10) International Publication Number
WO 2020/223207 A2

(51) International Patent Classification:
A61B 17/72 (2006.01) *A61B 17/60* (2006.01)
A61B 17/80 (2006.01) *A61F 2/32* (2006.01)
A61B 5/00 (2006.01) *A61F 2/38* (2006.01)
A61B 17/58 (2006.01)

(21) International Application Number:
PCT/US2020/030221

(22) International Filing Date:
28 April 2020 (28.04.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/842,190 02 May 2019 (02.05.2019) US

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(54) Title: TECHNIQUES AND MEDICAL IMPLANT DEVICES FOR PASSIVE MEASUREMENT OF HEALING INFORMATION FOR ANATOMICAL STRUCTURES

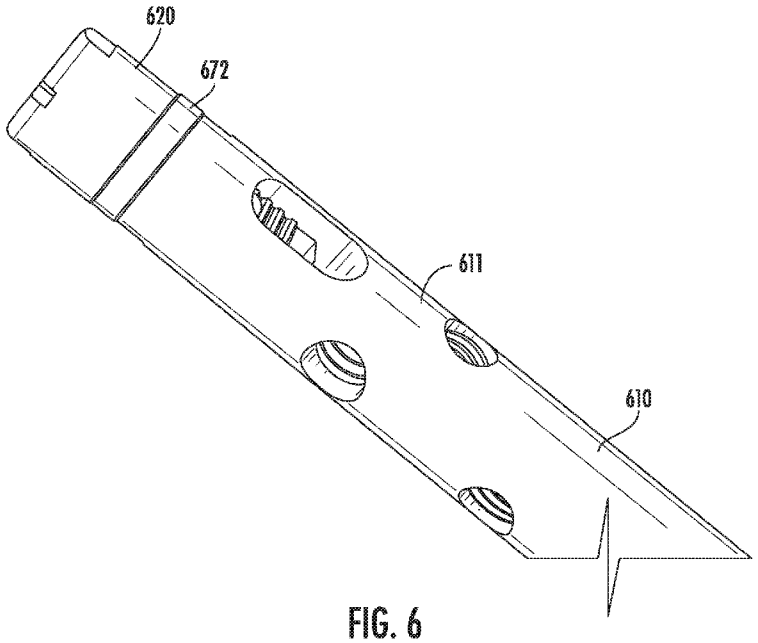

FIG. 6

(57) Abstract: A medical implant system, for instance, an orthopedic device, including an improved passive sensing system is disclosed. In one embodiment, a medical implant system may include a bone fixation device, a sensor coupled to the bone fixation device to passively measure a force imparted on the bone fixation device by a bone structure, the sensor comprising a resonator circuit having a pair of opposing coils separated by a distance and an insulating layer arranged between the opposing coils, the distance to change responsive to the force, the resonator circuit to generate a resonance frequency responsive to exposure to a radiofrequency (RF) field, the resonance frequency to modulate based on the distance. A change in resonant frequency from the sensor (LC sensor coils) that occurs from a biomechanical load can be detected wirelessly to determine the progression of healing of a bone structure. Other embodiments

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[Continued on next page]

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

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

are described.

TECHNIQUES AND MEDICAL IMPLANT DEVICES FOR PASSIVE MEASUREMENT OF HEALING INFORMATION FOR ANATOMICAL STRUCTURES

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This is a non-provisional, and claims the benefit of the filing date, of pending U.S. provisional patent application number 62/842,190, filed May 2, 2019, entitled "Orthopedic Bone Fixation Device with a Passive Inductor-Capacitor (LC) Resonant Sensor," which application is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0002] The present disclosure generally relates to medical implant devices, and, more particularly, to devices associated with a sensing system operative to passively measure forces imparted on the medical implant device by an anatomical structure.

BACKGROUND

[0003] Determining the progress of healing is an important part of the recovery process for patients that have undergone a serious medical condition, such as a surgical procedure, a broken bone, and/or the like. Conventional processes for examining the healing status of a patient have generally involve direct investigation by a physician or other healthcare professional.

[0004] For example, monitoring the progress of fracture healing in a patient is usually assessed using a combination of patient testimony, clinical examination, and periodical X-rays. However, subjecting a patient to repeated X-rays can be a health concern. In addition, X-rays may not be reliable because interpretation is highly dependent on experience, leading to relatively poor inter-observer and intra-observer reliability, and partly because of the lack of an accepted definition of radiographic union. Moreover, the information gathered during an X-Ray examination is not strictly related to the mechanical properties of the healing fracture site. Patient testimony and clinical examination are inefficient, prone to error, and require clinical visits. In addition, these techniques are not able to directly examine the healing region, leading to inaccurate assessments.

[0005] Major orthopedic procedures typically require a bone fixation device (i.e., a medical implant). For example, for a fracture, an intramedullary (IM) nail, bone plate, and/or the like may be used to support the patient's weight with an appropriate amount of stability to

allow the surrounding fractured bone region to heal. Knee and hip replacement procedures may involve a total knee replacement (TKR) or total hip replacement (THR) device to supplant patient anatomy to restore mobility and/or relieve joint pain. After an orthopedic procedure, the bone typically recovers its functionality over time and eventually absorbs most of the load in the bone/implant system. Knowledge of these properties is important to the patient and healthcare provider in terms of rehabilitation, potential secondary treatment, and determining the optimal time to return to normal activities.

[0006] Bone healing can be monitored in real-time using an array of implantable strain gauges attached to the orthopedic implant device, with the strain on the bone fixation device continuously decreasing during a normal healing progress. As such, measuring the strain on the orthopedic implant device provides an objective clinical measure for a patient return to normal weight bearing and monitoring activity that could potentially place the bone fixation device or surgery at risk for biomechanical failure. For example, it has been determined that the risk of failure is 15 times higher in patients that did not follow recommended postoperative restrictions and/or when experimentally measured deformation was above the fatigue limit for the orthopedic implant device.

[0007] Existing attempts to use strain gauges in orthopedic implant devices have required extensive changes to the design of the bone fixation device to accommodate the sensors and electronics that enable power and telemetry. For example, sensors generally need to be positioned within a machined recess in an outer surface of the bone fixation device to prevent the sensors from being subjected to excessive mechanical damage associated with abrasion forces, packaged in a biocompatible material, such as epoxy resin or silicone rubber due to their potential toxic effects to mammalian cells, hermetically sealed within a welded cavity to prevent them from being damaged by excessive moisture, and/or positioned close to the fracture site (or sufficiently far away from the neutral axis) in order to maximize their sensitivity to changes in load strain during fracture healing.

[0008] In addition, the sensor and telemetry system have to be miniaturized to fit within the footprint of standard orthopedic implant devices, without modifications that could jeopardize the performance or reduce the effectiveness of the orthopedic implant device at its primary job, supporting the bone structure during healing. Conventional systems have attempted to provide long-term power systems, for example, in the form of enhanced and safer battery technology, unobtrusive electromagnetic induction via a miniaturized wearable reader device, or alternative approaches such as an implantable battery or energy harvesting

from either applied biomechanical forces, ambient RF signals/backscatter, solar, body temperature or vibration/kinetic movement. However, the additional cost of these modifications has in conventional devices has not been low enough to make these devices commercially competitive and, therefore, a valuable tool of healthcare providers.

[0009] For these reasons among others, a need remains for further improvements in this technological field. The present disclosure addresses this need.

SUMMARY

[0010] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended as an aid in determining the scope of the claimed subject matter.

[0011] In accordance with various aspects of the described embodiments is an intramedullary nail system that may include an intramedullary nail and at least one sensor coupled to the intramedullary nail to passively measure at least one force imparted on the intramedullary nail by a bone structure, the at least one sensor comprising at least one resonator circuit having a pair of opposing coils separated by a distance and an insulating layer arranged between the opposing coils, the distance to change responsive to the at least one force, the at least one resonator circuit operative to generate a resonance frequency responsive to exposure to a radiofrequency (RF) field, the resonance frequency to modulate based on the distance.

[0012] In some embodiments of the intramedullary nail system, the insulating layer may be formed of one of a dielectric material or an air gap. In some embodiments of the intramedullary nail system, the at least one force may include an axial force on the intramedullary nail by the bone structure. In various embodiments of the intramedullary nail system, the system may include a bone screw having a head and configured to fasten the intramedullary nail to the bone structure, the at least one sensor having a halo form factor and arranged between the head and an external surface of the bone structure.

[0013] In various embodiments of the intramedullary nail system, the system may include a removable nail cap configured to be affixed to an end of a body of the intramedullary nail, the at least one sensor having a halo form factor and between the cap and the body of the intramedullary nail. In some embodiments of the intramedullary nail system, the system may include a recess formed in a portion of the intramedullary nail, the at least one sensor

arranged within at least a portion of the recess. In various embodiments of the intramedullary nail system, the recess may include a collar arranged around a portion of an outer surface of the intramedullary nail, the at least one sensor having a halo form factor and arranged around the collar. In some embodiments of the intramedullary nail system, the recess may include a pocket arranged in a portion of an outer surface of the intramedullary nail, the at least one sensor arranged within the pocket.

[0014] In various embodiments of the intramedullary nail system, the system may include a cavity formed in a portion of the intramedullary nail, the at least one sensor arranged within at least a portion of the cavity, the cavity comprising one of a cannulation or an aperture. In some embodiments of the intramedullary nail system, the system may include a monitor operative to transmit the RF field to the at least one sensor. In some embodiments of the intramedullary nail system, the monitor may be operative to receive the resonance frequency from the at least one sensor.

[0015] In accordance with various aspects of the described embodiments, a medical implant system may include a bone fixation device and at least one sensor coupled to the bone fixation device to passively measure at least one force imparted on the bone fixation device by a bone structure, the at least one sensor may include at least one resonator circuit having a pair of opposing coils separated by a distance and an insulating layer arranged between the opposing coils, the distance to change responsive to the at least one force, the at least one resonator circuit operative to generate a resonance frequency responsive to exposure to a radiofrequency (RF) field, the resonance frequency to modulate based on the distance.

[0016] In some embodiments of the medical implant system, the bone fixation device may include a hip replacement device. In various embodiments of the medical implant system, the hip replacement device may include a femoral head and a taper, the at least one sensor arranged between the femoral head and the taper. In various embodiments of the medical implant system, the bone fixation device may include an acetabular cap configured to engage the femoral head, the at least one sensor arranged between the acetabular cap and the femoral head. In various embodiments of the medical implant system, the bone fixation device may include a knee implant device having a tibial tray and an insert block coupled to the tibial tray, the at least one sensor arranged between the insert block and the tibial tray.

[0017] In various embodiments of the medical implant system, the knee implant device may include a femoral component, the at least one sensor arranged within the femoral component to engage at least a portion of a femur. In some embodiments of the medical

implant system, the system may include a monitor operative to transmit the RF field to the at least one sensor, and receive the resonance frequency from the at least one sensor.

[0018] In accordance with various aspects of the described embodiments method of monitoring a healing status of a bone structure. The method may include providing at least one sensor coupled to a bone fixation device to passively measure at least one force imparted on the bone fixation device by the bone structure, the at least one sensor comprising at least one resonator circuit having a pair of opposing coils separated by a distance and an insulating layer arranged between the opposing coils, the distance to change responsive to the at least one force, the at least one resonator circuit operative to generate a resonance frequency responsive to exposure to a radiofrequency (RF) field, the resonance frequency to modulate based on the distance, transmitting the RF field to the at least one sensor, receiving the resonance frequency from the at least one sensor, and generating healing information indicating a healing status of the bone structure based on the resonance frequency.

[0019] In some embodiments of the method, the bone fixation device may include one of an intramedullary nail, a hip replacement device, a knee replacement device, or a bone fixation device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] **FIG. 1** depicts an example of a first operating environment that may be representative of some embodiments of the present disclosure;

[0021] **FIGS. 2A-2C** depict examples of a resonant circuit representative of some embodiments of the present disclosure;

[0022] **FIGS. 3A-3C** depict examples of a resonant circuit representative of some embodiments of the present disclosure;

[0023] **FIG. 4** depicts an example of a second operating environment that may be representative of some embodiments of the present disclosure;

[0024] **FIGS. 5A-5C** depict an example of a medical implant device having a passive sensor device associated with a fastener element that may be representative of some embodiments of the present disclosure;

[0025] **FIG. 6** depicts an example of a medical implant device having a passive sensor device associated with a cap element that may be representative of some embodiments of the present disclosure;

[0026] **FIG. 7** depicts an example of a medical implant device having a passive sensor device associated with a collar recess that may be representative of some embodiments of the present disclosure;

[0027] **FIG. 8** depicts an example of a medical implant device having a passive sensor device associated with a recessed cavity that may be representative of some embodiments of the present disclosure;

[0028] **FIG. 9** depicts an example of a medical implant device having a passive sensor device associated with a cavity that may be representative of some embodiments of the present disclosure;

[0029] **FIG. 10** depicts an example of a medical implant device having a passive sensor device associated with a cannulation that may be representative of some embodiments of the present disclosure;

[0030] **FIG. 11** depicts an example of a hip replacement medical implant device having a passive sensor device that may be representative of some embodiments of the present disclosure;

[0031] **FIGS. 12A-12C** depict an example of a knee replacement medical implant device having a passive sensor device that may be representative of some embodiments of the present disclosure;

[0032] **FIG. 13** depicts an example of an external fixator device having a passive sensor device that may be representative of some embodiments of the present disclosure;

[0033] **FIG. 14** depicts an example of an external fixator device having a passive sensor device that may be representative of some embodiments of the present disclosure; and

[0034] **FIG. 15** illustrates a graph of displacement-frequency transduction in accordance with the present disclosure.

[0035] The drawings are not necessarily to scale. The drawings are merely representations, not intended to portray specific parameters of the disclosure. The drawings are intended to depict example embodiments of the disclosure, and therefore should not be considered as limiting in scope. In the drawings, like numbering represents like elements.

[0036] Furthermore, certain elements in some of the figures may be omitted, or illustrated not-to-scale, for illustrative clarity. The cross-sectional views may be in the form of "slices", or "near-sighted" cross-sectional views, omitting certain background lines otherwise visible in a "true" cross-sectional view, for illustrative clarity. Furthermore, for clarity, some reference numbers may be omitted in certain drawings.

DETAILED DESCRIPTION

[0037] For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the embodiments illustrated in the figures and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the disclosure is thereby intended. Any alterations and further modifications in the described embodiments, and any further applications of the principles of the present disclosure as described herein are contemplated as would normally occur to one skilled in the art to which the disclosure relates.

[0038] Various features, aspects, or the like of a healing status analysis system and method will now be described more fully hereinafter with reference to the accompanying drawings, in which one or more aspects of the healing status analysis system and/or method will be shown and described. It should be appreciated that the various features, aspects, or the like may be used independently of, or in combination, with each other. It will be appreciated that the healing status analysis system and method as disclosed herein may be embodied in many different forms and should not be construed as being limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will convey certain illustrations of aspects of the healing status analysis system and method to those skilled in the art

[0039] The present disclosure relates generally to a healing status analysis system configured to generate healing status information for an anatomical structure based on sensor information measured from the anatomical structure. In some embodiments, internal or external medical implant devices may include an improved passive sensing system, such as a resonant circuit or passive inductor-capacitor (LC) sensor. The passive sensing system may be configured to measure one or more forces imparted on the anatomical structure to provide sensor information to the healing status information system. The sensor information may be used to determine a healing status of the anatomical structure, for example, whether more or less force is being imparted on the passive sensing system as the anatomical structure progresses through a healing process.

[0040] In some embodiments, the medical implant devices may include an orthopedic device. Non-limiting examples of orthopedic devices may include bone fixation devices, bone fasteners (i.e., screws or nails), cortical bone screws, cancellous bone screws, intramedullary (IM) nails, total hip replacement (THR) systems, total knee replacement (TKR) systems, external fixators, Taylor spatial frames, bone plates, components thereof,

combinations thereof, components thereof, any orthopedic device now known or hereafter developed, and/or the like.

[0041] In various embodiments, the passive sensor system may include a sensor formed using a resonant circuit. In exemplary embodiments, the resonant circuit may include an inductor-capacitor (LC) circuit. The resonant circuit may operate via a passive load sensing system that functions by detuning a dielectric resonator (LC resonator). In some embodiments, one or more LC sensors may be strategically located within a bone fixation device, which each LC sensor including a coil that is used as an antenna for an inductive link to a reader or monitoring device, a resistor (or resistance of the wires) and a capacitor (the sensor). The LC circuit can act as an electrical resonator, an electrical analogue of a tuning fork, storing energy oscillating at the circuit's resonant frequency. The LC circuit may be inductively coupled to an external reader or monitoring device. In general, measurements may be performed by utilizing the properties of the inductive link; therefore, passive sensor systems according to various embodiments as a whole may consume very little amount of energy

[0042] As will be described in greater detail below, in one example embodiment, an orthopedic bone fixation device may include at least one passive LC sensor or tag. The sensor tag may be constructed from a pair of two anti-aligned Archimedean coils separated by an insulating layer of known dielectric properties. In some embodiments, the coils may be anti-aligned (i.e., coiled in opposite directions). In various embodiments, the two coils may be Archimedean coils.

[0043] The two coils in each sensor tag may be inductively and capacitively coupled due to their close proximity. Thus arranged, a resonant LC circuit or tank may be formed. In use, the capacitor changes in response to the parameter of interest, resulting in a shift in its resonant frequency. In the case of an IM nail, for example, the LC sensor circuit can be located between the head of the screw and the surface of the bone at fixed positions along the length of the IM nail or sandwiched between a removable nail cap and the proximal end of the nail providing information on the stability of the implant and the progression of bone healing.

[0044] The dielectric properties and coil geometry of the LC circuit can be tailored to measure either an axial compression force, pressure, displacement or bending or shearing force depending on its proximity with respect to the orthopedic implant and/or patient anatomy. An externally positioned readout coil may be magnetically coupled to the internal

LC sensor to wirelessly interrogate the LC sensor during rehabilitation, and the resonant frequency of the LC sensor may be detected through monitoring the impedance or input return loss of the readout coil. To remotely detect the sensor's response during fracture healing, a reader device, monitoring device, or other network analyzer may generate a frequency-varying electromagnetic field through the antenna to the sensor's inductor and then monitor the change in the antenna's impedance. Moreover, resonant signatures from multiple implantable LC sensors can be interpolated independently using a dip-grid meter.

[0045] In one embodiment, prior to data collection from the implant, the background impedance (measurement with no sensor present) may be initially collected so that all subsequent measurements during bone healing can be subtracted from the background coil impedance to obtain a pure sensor responses from the orthopedic device (e.g., the IM nail, the bone screw(s)).

[0046] In some embodiments in which an LC sensor is designed to be used as a force/load transducer, bone healing can be interpreted through the shift in resonant frequency. For example, when an axial compression force is exerted through the parallel plate capacitor sandwiched between the proximal end of the IM nail and the nail cap, the distance between the capacitor plates decreases, thus shifting the observed resonant peak. As the bone heals, the load exerted through the proximal end of the nail reduces, the distance between the capacitor plates increases, thus shifting the resonant peak in the opposite direction.

[0047] In some embodiments, an orthopedic bone fixation device may be equipped with at least one passive inductor-capacitor (LC) sensor tag that constructed from a pair of two anti-aligned Archimedean coils separated by an insulating layer of known dielectric properties. The two coils in each sensor tag may be inductively and capacitively coupled due to their close proximity forming a resonant LC tank or sensor. The capacitor changes in response to the parameter of interest, resulting in a shift in its resonant frequency. In the case of an IM nail, the LC sensor circuit can be located between the head of the screw and the surface of the bone at fixed positions along the length of the IM nail or sandwiched between a removable nail cap and the proximal end of the nail providing information on the stability of the implant and the progression of bone healing.

[0048] The dielectric properties and coil geometry of the LC circuit can be tailored to measure either an axial compression force, pressure, displacement or bending or shearing force depending on its proximity with respect to the orthopedic implant and patient anatomy. An externally positioned readout coil may be removably magnetically coupled to the internal

LC sensor(s) to wirelessly interrogate the LC sensor(s) during rehabilitation, and the resonant frequency of the sensor is detected through monitoring the impedance or input return loss of the readout coil. To remotely detect the sensor's response during fracture healing, a network analyzer or other monitoring device may generate a frequency-varying electromagnetic field (an RF field) through the antenna to the sensor's inductor and then monitors the change in the antenna's impedance. Moreover, resonant signatures from multiple implantable LC sensors can be interpolated independently, for example, using a dip-grid meter.

[0049] Prior to data collection from the implant, the background impedance (for instance, measurement with no sensor present) may be collected so that all subsequent measurements during bone healing can be subtracted from the background coil impedance to obtain the isolated or pure sensor responses from either orthopedic device, such as an IM nail or bone screw(s).

[0050] If the LC sensor is designed to be used as a force/load transducer, bone healing can be interpreted through the shift in resonant frequency. For example, when an axial compression force is exerted through the parallel plate capacitor sandwiched between the proximal end of the nail and the nail cap, the distance between the capacitor plates decreases, thereby shifting the observed resonant peak. As the bone heals, the load exerted through the proximal end of the nail reduces, the distance between the capacitor plates increases, thereby shifting the resonant peak in the opposite direction.

[0051] LC sensors do not require an additional power source from either a wireless inductive charging circuit or a battery cell for their operation compared to other sensors, such as strain gauges, accelerometers, and/or the like. Piezoelectric energy harvesting devices have been proposed as an alternative method to continuously power sensors for orthopedic implants. However, in conventional systems, the strain energy required to activate the wireless transmission is typically too large for self-powered sensing of microstrain variations. For example, standard sensors may require 100 times more power than what would be available under normal physiological conditions (e.g., $<1\mu W$). In addition to ultralow power levels, the occurrence of loading cycles is sporadic during rehabilitation, necessitating integration of self-powered computation and sensing with non-volatile storage.

[0052] The "battery-free" approach offered by LC sensors according to some embodiments may ensures that the implant can be monitored indefinitely after the fracture has healed, if required. The simplified structure of an LC sensor circuit, for instance, requiring no on-board signal conditioning electronics, no electrical connections, allows

sensor systems according to various embodiments to be manufactured efficiently and at low cost (for instance, at batch scale).

[0053] Integration of LC sensors into medical implant devices according to some embodiments, such as the disclosed orthopedic implants, may involve little to no modification of the implant itself. The design of the LC sensor can be tailored to fit a specific design feature on the device, including, without limitation, underneath the head of a bone screw, embedded/injection molded within a poly insert of a total knee replacement implant, underneath a femoral head of a modular total hip replacement, between the U-Joint of a strut and a shoulder joint on an external fixator, a machined recess underneath a bone plate or within one of the spare screw-holes, and/or the like.

[0054] In various embodiments, enhancement of the coupling (read range) between the external reader coil and the LC sensor may be achieved by improving the sensitivity and quality (Q) factor of the sensor as well as the signal extraction method, and in particular, adopting a resonant repeater between the external readout coil and the inductor. The reading distance can also be increased by increasing the coupling coefficient between the reader and sensor coils. Furthermore, an increase in the coupling coefficient may be possible by increasing the mutual inductance between the coils, which can be made, for instance, by increasing the diameter of the coils and/or increasing the number of turns in the coils.

[0055] An LC sensor is a self-contained unit that does not require any physical connections between the sensing components and the processing apparatus, which makes them attractive sensing elements for orthopedic implants that are subject to multi-axial forces. In addition, wireless LC sensors have the capacity to operate in a passive mode obviating the need for a battery, which has a limited lifespan. Instead, as described in more detail below, passive LC sensors may receive power remotely via magnetic or electromagnetic forces from an external reader/antenna or other monitoring device. Although each individual LC sensor is a single channel system, multiple LC sensors located on the implant can be interrogated independently, for example, using a dip grid meter or similar monitoring device.

[0056] Embodiments of medical implant devices, such as bone fixation devices, of the present disclosure provide numerous technological advantages over existing systems. In one non-limiting example technological advantage, a bone fixation device configured according to some embodiments may be relatively simple to fabricate and/or require minimal to no modifications to an existing device (for instance, an existing orthopedic device or implant) to reduce cost and/or ease of use. In another non-limiting example technological advantage, a

bone fixation device according to some embodiments may avoid design complexity and impact on the primary functions of the bone fixation device being measured (e.g., stabilization of bone fracture in the case of an IM nail). In an additional non-limiting example technological advantage, bone fixation devices according to some embodiments may be mechanically robust (e.g., able to withstand millions of cycles of biomechanical loading without failure and function in a physiological environment) and electrically robust (e.g., free from complex electronics, contain no on-board signal conditioning electronics, possess no electrical connections to minimize potential of early failures, etc.). In a further non-limiting example technological advantage, bone fixation devices according to some embodiments may be capable of being powered and/or communicating wirelessly, either continuously or intermittently, using, for example, battery-less telemetry. In another non-limiting technological advantage, sensor devices (for instance, LC sensors or resonant sensors) configured according to some embodiments may be releasably affixed or mounted to a medical implant device. In this manner, sensor devices according to some embodiments may be used as an optional addition to a medical implant device (compared with conventional devices that are required to be permanently or semi-permanently affixed to a medical implant device, for example, to accommodate power and/or telemetry systems).

[0057] Healing status analysis processes according to some embodiments may provide multiple technological advantages and technical features over conventional systems, including improvements to computing technology. One non-limiting example of a technological advantage may include efficient and accurate determination of a healing status of a patient using sensor information captured via an LC sensor within an IM nail, THR, TKR, external fixators, Taylor spatial frames, and/or bone plates that is not available using existing technology. A problem in computing technology for existing systems involves the ability to present healing information on a computing display using low-power medical implant devices that do not require secondary power sources (e.g., batteries, induction power, etc.). Some embodiments may provide an improvement in computing technology by facilitating presentation of a healing status on a remote computing device using completely self-powered, energy harvesting medical implant devices through the novel combined use of patient information and sensor information. Other technological advantages are provided by various embodiments and are described in the present disclosure

[0058] **FIG. 1** illustrates an example of an operating environment 100 that may be representative of some embodiments. As shown in FIG. 1, operating environment 100 may

include a healing status analysis system 105. In various embodiments, healing status analysis 105 may include a computing device 110 communicatively coupled to network 190 via a transceiver 180. Computing device 110 may be or may include one or more logic devices, including, without limitation, a server computer, a client computing device, a personal computer (PC), a workstation, a laptop, a notebook computer, a smart phone, a tablet computing device, and/or the like. Embodiments are not limited in this context.

[0059] In some embodiments, healing status analysis system 105 may include a medical implant device 160 configured to be implanted in or on a portion 152 of a patient 150. A non-limiting example of a portion of the human body 152 may include a bone structure, such as a femur, a knee joint, a hip joint, a shoulder joint, a tibia, an external portion of an appendage (for instance, for an external fixator), such as an arm or leg, and/or the like. In some embodiments, medical implant device 160 may include bone fixation devices, bone fasteners (i.e., screws or nails), cortical bone screws, cancellous bone screws, intramedullary (IM) nails, total hip replacement (THR) systems, total knee replacement (TKR) systems, external fixators, Taylor spatial frames, bone plates. Although IM nails, THRs, and TKRs are used in examples in the present disclosure, embodiments are not so limited, as any orthopedic device now known or hereafter developed, components thereof, combinations thereof, components thereof, and/or the like capable of being used according to some embodiments are contemplated herein.

[0060] Medical implant device 160 may be associated with at least a portion of a sensor system 170 having one or more sensors 172a-n. In some embodiments, sensors 172a-n may be or may include a resonant circuit or LC circuit. In some embodiments, resonant circuits 172a-n may be formed the same or substantially similar to the LC circuits described in Drazan et al., "Archimedean Spiral Pairs with no Electrical Connections as a Passive Wireless Implantable Sensor," Journal of Biomedical Research, Vol. 1(1) (2014) and/or U.S. Patent No. 9,662,066.

[0061] **FIGS. 2A-2C** depict examples of a resonant circuit representative of some embodiments of the present disclosure. Referring to FIG. 2A, therein is depicted resonant circuit 172A formed of two coils 210, 211 separated by a distance 216. In some embodiments, an insulating layer 215 may be arranged between coils 210, 211. In some embodiments, insulating layer 215 may be or may include an air gap. In various embodiments, insulting layer 215 may include or may be a dielectric layer, such as silicone or other non-conductive material. In various embodiments, insulating layer 215 may be either a

stiff insulating material such as polymethylmethacrylate (PMMA), epoxy and aromatic polyimides or a flexible insulating material such as polydimethylsiloxane (PDMS), hydrogel and Parylene C. The material of insulating layer 215 may be based on various factors, including, without limitation, force (strain, pressure, etc.) sensitivity, range requirements, and/or the like (for instance, softer materials are more sensitive but have a lower operational range and harder material are less sensitive but have a wider operating range). In addition, the change in spacing of coils 210, 211 in response to a force may be associated (for instance, may be proportional) with the mechanical properties of insulting material 215.

[0062] Windings of the coils 210, 211 may be insulated from the opposing coil to prevent an electrical short from occurring and may be insulated from the metal body of the implant, for example, to reduce or eliminate interference and other signal noise (for example, which may affect the read distance). Signals from coils 210, 211 formed according to some embodiments may be read from a relatively close distance (for example, from about 5 cm to about 20 cm or more). In various embodiments, interference or other signal distortion may be compensated by amplifying the driving RF signal, increasing the number of coils in the reader/resonator (for instance, of monitor 174), placing the sensor 172 such that it is externally accessible to signals (see, for example, FIGS. 5A, 6, 7, and 9) or in a pocket with a relative distance (for example, greater than about 1 mm) distance between sensor 172 and the wall(s) of the pocket (see, for example, FIG. 8), and/or having the antenna of sensor 172 surrounding a portion of the fixation device containing sensor 172. In some embodiments, insulating layer 215 may include a dielectric layer to reduce or event eliminate "proximity to metal" signal artifacts.

[0063] Referring to FIG. 2B, in some embodiments, a resonant circuit 172b may be formed as a "halo" or "ring" circuit, for example, having an opening 217 arranged in coils 210, 211. In general, a halo-shaped resonant circuit 172b design may allow, among other things, resonant circuit 172b to be located over an existing design feature on a bone fixation device, such as the shaft of a bone screw, a proximal end of an IM nail between a removable nail cap and the IM nail body, and/or the like. In another example, a halo-shaped resonant sensor 172b may ensure that the cannulation of an IM nail is maintained, which may be critical to allow instrumentation to be used during surgery, for instance, to reduce the fracture and distal lock the screw holes. In another example, a halo-shaped resonant sensor 172b may allow resonant sensor 172b to be positioned between the head of a bone screw and the surface of the bone (see, for example, FIG. 5B).

[0064] There may be no direct electrical connections between coils 210, 211, which may be inductively and/or capacitively coupled due to their close proximity. As shown in the block diagram of FIG. 2C, the configuration of coils 210, 211 may form a resonant circuit 172C having a capacitor 226 and an inductor 228. For example, when two flat Archimedean spiral coils (e.g., coils 210, 211) are placed in parallel with a thin dielectric layer between, the coils act as both the inductor and the capacitor plates.

[0065] Distance or spacing 216 between coils 210, 211 or thickness of (dielectric) insulating layer 215 can be varied. A change in distance 216 between coils 210, 211 may modulate electrical characteristics of the resonant sensor 172. For example, exposure of resonant sensor 172 to an external radiofrequency (RF) field may cause sensor 172 to resonate to generate a resonant frequency. The resonant frequency can be monitored wirelessly using a return loss parameter as measured by a monitoring device 174. Changes in the resonant frequency may be caused solely by changes in distance between the coils 210, 211. Referring to FIG. 1, a monitor 174 device may impart an RF field (for instance, an electromagnetic field) (*A*) on sensors 172a-n. As a result, sensors 172a-n may resonate at a resonance frequency (*B*), which may be detected by monitor 174 and provided to computing device as sensor information 142 (*C*). In some embodiments, the interrogation frequency (i.e., RF field (*A*)) of monitor 174 may be about ten-fold greater than load frequency. For example, for walking load frequency of about 1 Hz, the interrogation frequency may be about 10 Hz. Monitoring or interrogation of sensors 172a-n may be continuously or at intervals, for example, determined by a healthcare provider. For instance, follow-up appointments for patients with IM nails may be at 2 weeks, 6, weeks, and 12 weeks following the implantation procedure; for a Taylor spatial frame, follow-up monitoring may be on a weekly basis during an adjustment phase of about 90 days; other types of medical implant devices (e.g., THR, TKR), may follow their typical follow-up schedule. Although monitor 174 and computing device 110 are depicted as separate devices in FIG. 1, embodiments are not so limited as monitor 174 may be an embedded device of computing device 110 (or vice versa).

[0066] For example, to remotely detect sensor 172a-n response during fracture (or other) healing, monitor 174 may generate a frequency-varying electromagnetic field through an antenna to the sensor's 172a-n inductor and then monitors the change in the antenna's impedance. In some embodiments, RF communication may be achieved via an external antenna, which facilitates wireless monitoring (see, for example, FIG. 4). A sensor coil of sensor 172a-n is the internal antenna. Accordingly, no other telemetry requirements required

to be installed in medical implant device 160. Monitor 174 may include an antenna and signal conditioner. An inductor coil (L1) has a resonance frequency that can be picked up by a coupled external antenna of monitor. Resonant frequency of sensor 172a-n can be detected wirelessly by monitoring the spectrum of the return loss parameter via monitor 174. Multiple sensors 172-an can be read simultaneously using a grid-dip oscillator monitor 174. The grip-dip meter measures the amount of absorption of a high frequency inductively coupled magnetic field by nearby objects such as the internal RC circuits.

[0067] The effective range/sensitivity of sensors 172-an may be influenced by dielectric layer thickness/modulus and coil geometry (e.g., inner diameter, outer diameter, thickness, number of turns of conductor wire, and/or the like). In some embodiments, a read range of monitor 174 may be about 5 cm, about 6 cm, about 7 cm, about 8 cm, about 9 cm, about 10 cm, about 15 cm, about 20 cm, and any value or range between any two of these values (including endpoints). Read ranges of wireless passive LC circuits, such as sensors 172-an, can be extended for larger patients using magnetic ferrite cores located at the rear of the external coil pairs to make the reader more directional along the axis of the ferrite. The read range can also be optimized by considering the reader's power, the power consumption of the LC circuit, the LC Tag quality factor (Q), the LC Tag's tuning frequency, the reader's antenna aperture, and the LC Tag's antenna aperture. Secondary considerations may also include the LC Tag's modulation depth, the reader's signal-to-noise ratio, the LC Tag's power-conversion efficiency, the reader's antenna tuning and carrier accuracy, the reader's filter quality, how well the reader's driver matches the antenna, the microcontroller's speed and code efficiency, and the LC Tag's data rate. Embodiments are not limited in this context.

[0068] Sensors 172a-n, such as LC sensors, can function as either a displacement or force transducer by using either an air gap or solid dielectric material respectively of known stiffness between the two parallel coils. Sensors 172a-n may be fabricated using various techniques and materials known to those in the art, including, without limitation, printed circuit board (PCB) or microfabrication techniques including electroplating and photolithographic mask design.

[0069] **FIGS. 3A-3C** depict examples of a resonant circuit representative of some embodiments of the present disclosure. Referring to FIG. 3A, therein is depicted a top-down view of resonant circuit 172a associated with a capping layer 306, for example, to hermetically seal coils 210, 211 and insulating layer 215. In some embodiments, each individual coil 210, 211 may be hermetically sealed to prevent unwanted changes to the

properties of the dielectric material, for example, from exposure to body fluids. For instance, the surrounding media in the bone canal can detune the resonant frequency of the LC sensor resulting in a bias. In some embodiments, the hermetic capping layer 306 may be located at the top surfaces of coils 210, 211 and can be added to help isolate resonant circuit 172 and/or portions thereof from the surrounding biological media. Non-limiting examples of materials used to form capping layer 306 may include glass or parlyene C, poly (acrylic acid), and/or diethanolamine. For example, a 1 mm glass or parlyene C capping/coating layer 306 may be applied on the outer surfaces of a packaged resonant sensor 172, which may be sufficient to reduce the effects of biological media on sensor signal to acceptable levels (e.g., <1% to minimize the risk of parasitic capacitance). FIG. 3B depicts a top-down view of resonant circuit 172b having a halo form factor.

[0070] FIG. 3C depicts a perspective view of resonant circuit 172c. The geometry of the round coils is defined by the inner diameter (Di), the outer diameter (Do), number of turns (N) and the coil separation (l), and each coil's cross sectional geometry. In some embodiments, dimensions of the sensor may include an about 10 to about 15 mm outer diameter, an about 4 to about 5 mm internal diameter, a dielectric spacing of about 2 to about 5 mm, a number of turns of coil of about 20 to about 40, a coil wire diameter of about 0.1 to about 0.2 mm, a gap between windings of about 0.01 to about 0.02 mm, an insulator dielectric constant between about 1 (air) to about 5 (silicone rubber).

[0071] Referring again to FIG. 1, healing status analysis logic 130, for instance, via a healing status application 148 operating on computing device 110, may operate to determine healing information 144 based on sensor information 142. In general, healing information 144 may include a healing status of patient 150. For example, a healing status analysis process may determine the healing stage of a fractured bone of patient 150, the healing progress or stage of a replaced joint, the condition of a TKR, THR, and/or the like. In some embodiments, a healing status may include information indicating that there is abnormal, aberrant, unexpected, or otherwise an issue with the healing progress. For example, healing status application 148, for example, via healing status analysis logic 130, may determine or be instructed of a healing timeline (e.g., the patient should be at stage X by week Y) or other expectation of healing progress. Healing status application 148 may determine that the patient is experiencing abnormal healing, for example, because they are not at a particular stage at an expected time, because of another detected abnormality (e.g., elevated temperature, abnormal gait, and/or the like), and/or because of an unexpected change in

resonance frequency of sensors 172a-n.. For example, healing status application 148 may determine a loosening of a hip/THR or knee/TKR, for example, via monitoring sensor 172 signals for sharp changes (for instance, greater than a threshold, such as greater than about 5%) in the resonant frequency, which may indicate an unexpected change in the condition of the hip/THR or knee/TKR associated with sensor 172.

[0072] In some embodiments, healing status application 148 may generate an abnormal healing status message, alert, or other signal indicating an abnormal healing condition. In various embodiments, healing status application 148 may determine a treatment recommendation based on sensor information 142, healing information 144, and/or the like for the abnormal healing status. For example, healing status application 148 may access a database of health information to determine a treatment recommendation based on available information. For instance, other sensors or measurements may detect a high temperature for patient, which may indicate an infection; healing status application 148 may generate a treatment recommendation for patient 150 to be checked for an infection.

[0073] Computing device 110 may be configured to manage, among other things, operational aspects of a healing status analysis process according to some embodiments. Although only one computing device 110 is depicted in FIG. 1, embodiments are not so limited. In various embodiments, the functions, operations, configurations, data storage functions, applications, logic, and/or the like described with respect to computing device 110 may be performed by and/or stored in one or more other computing devices (not shown), for example, coupled to computing device 110 via network 170. A single computing device 110 is depicted for illustrative purposes only to simplify FIGS. 1 and 2. Embodiments are not limited in this context.

[0074] Computing device 110 may include a processor circuitry 120 that may include and/or may access various logics for performing processes according to some embodiments. For instance, processor circuitry 120 may include and/or may access a healing status analysis logic 130 and/or a sensor information logic 132. Processing circuitry 120, healing status analysis logic 130, and/or sensor information logic 132, and/or portions thereof may be implemented in hardware, software, or a combination thereof. As used in this application, the terms "logic," "component," "layer," "system," "circuitry," "decoder," "encoder," "control loop," and/or "module" are intended to refer to a computer-related entity, either hardware, a combination of hardware and software, software, or software in execution, examples of which are provided by the exemplary computing architecture 2300. For example, a logic,

circuitry, or a module may be and/or may include, but are not limited to, a process running on a processor, a processor, a hard disk drive, multiple storage drives (of optical and/or magnetic storage medium), an object, an executable, a thread of execution, a program, a computer, hardware circuitry, integrated circuits, application specific integrated circuits (ASIC), programmable logic devices (PLD), digital signal processors (DSP), field programmable gate array (FPGA), a system-on-a-chip (SoC), memory units, logic gates, registers, semiconductor device, chips, microchips, chip sets, software components, programs, applications, firmware, software modules, computer code, a control loop, a computational model or application, an AI model or application, an ML model or application, a proportional-integral-derivative (PID) controller, FG circuitry, variations thereof, combinations of any of the foregoing, and/or the like.

[0075] Although healing status analysis logic 132 is depicted in FIG. 1 as being within processor circuitry 120, embodiments are not so limited. For example, healing status analysis logic 130, sensor information logic 132, and/or any component thereof may be located within an accelerator, a processor core, an interface, an individual processor die, implemented entirely as a software application (for instance, a healing status application 148) and/or the like.

[0076] Memory unit 130 may include various types of computer-readable storage media and/or systems in the form of one or more higher speed memory units, such as read-only memory (ROM), random-access memory (RAM), dynamic RAM (DRAM), Double-Data-Rate DRAM (DDRAM), synchronous DRAM (SDRAM), static RAM (SRAM), programmable ROM (PROM), erasable programmable ROM (EPROM), electrically erasable programmable ROM (EEPROM), flash memory, polymer memory such as ferroelectric polymer memory, ovonic memory, phase change or ferroelectric memory, silicon-oxide-nitride-oxide-silicon (SONOS) memory, magnetic or optical cards, an array of devices such as Redundant Array of Independent Disks (RAID) drives, solid state memory devices (e.g., USB memory, solid state drives (SSD) and any other type of storage media suitable for storing information. In addition, memory unit 130 may include various types of computer-readable storage media in the form of one or more lower speed memory units, including an internal (or external) hard disk drive (HDD), a magnetic floppy disk drive (FDD), and an optical disk drive to read from or write to a removable optical disk (e.g., a CD-ROM or DVD), a solid state drive (SSD), and/or the like.

[0077] Memory unit 130 may store various types of information and/or applications for a healing status analysis process according to some embodiments. For example, memory unit 130 may store sensor information 142, healing information 144, and/or a healing status application 148. In some embodiments, some or all of sensor information 142, healing information 144, and/or a healing status application 148 may be stored in one or more data stores 192a-n accessible to computing device 110 via network 190.

[0078] In some embodiments, healing status analysis logic 130, for example, via sensor information logic 132, and/or healing status application 148, may operate to analyze sensor information 142 to generate healing information 144. In various embodiments, healing information 144 may include a healing status of a portion of a human body, such as a stage of fracture healing (see, for example, FIG. 4).

[0079] In various embodiments, sensor information 142 may include data, signals, and/or other information associated with sensor 172 and/or operation thereof received, for example, via monitor 174. For example, sensor information 142 may include a resonance frequency of sensors 172a-n. In another example, sensor information 142 may include displacement-frequency transduction information for sensors 172a-n, such as a displacement-frequency transduction curve. For example, **FIG. 15** depicts a graph of displacement-frequency transduction curve that may be adaptable, extrapolated, or otherwise configured for use for sensor configurations according to some embodiments.

[0080] In some embodiments, healing status analysis logic 130, for example, via sensor information logic 132, and/or healing status application 148, may be configured to translate sensor information into healing information 144. For example, a resonance frequency generated by sensor 162 (and/or information associated therewith) may be provided to healing status analysis logic 130 which may convert this information into healing information 144 (for instance, an estimate of a healing stage of bone structure 152). In some embodiments, healing status analysis logic 130 may use or include models, such as machine learning (ML), neural network (NN), or other artificial intelligence (AI) models to model patient information 144 in combination with sensor information 142 to determine healing information 146.

[0081] In some embodiments, healing status application 148 may be or may include an application being executed on computing device 110 (including a mobile application or "app" executing on a mobile device form factor). Healing status application 148 may include or may be an application interface for healing status analysis logic 130 and/or components

thereof. Healing status application 148 may receive sensor information 142 and may determine healing information 144. In some embodiments, healing status application 148 may present healing information 144 on display device 182. In some embodiments, healing information 144 may include a diagnosis, estimate, prediction, or other information associated with the healing status of bone structure 152.

[0082] **FIG. 4** depicts an example of a second operating environment that may be representative of some embodiments of the present disclosure. As shown in FIG. 4, operating environment 400 may include an architecture for a single-channel LC resonator circuit. An LC sensor 172 may be contacted by a signal 420, such as an RF signal, magnetic field, electromagnetic field, and/or the like. A change in resonant frequency of sensor 172 may be remotely captured from an external antenna 174 through monitoring an impedance change of sensor 172. The architecture may include an external excitation "readout" coil 416, RF amplifier 414, RF generate 412, and/or a computing device 410. The generated data, for instance, received by computing device 410 may be or may be used to generate displacement–frequency transduction curves during, for example, during fracture healing.

[0083] In some embodiments, sensor 172 may be an LC resonator, which can function as a force/load transducer by using either a solid dielectric material of known stiffness or an air gap between two parallel Archimedean coils. For example, sensor 172 may be or may include a single channel LC sensor formed essentially as a parallel plate capacitor comprised of copper wire formed into two Archimedean spirals on either side of a solid compressible dielectric disk. The wire may be formed of various conductive materials, including, without limitation, copper, gold, silver, and/or the like. The capacitor of sensor operates to sense changes in either load (axial, bend, shear) or displacement through a change in capacitance. An inductor of sensor 172 may be or may include a coil, which stores electrical energy in its magnetic field. For example, an inductor may be wired in series with a capacitor (see, for example, FIG. 2), such that it resonates at a characteristic frequency when exposed to an RF signal, such as an oscillating electromagnetic waves. The inductor may be operative to couple to an external antenna, receiving power and transmitting information about changes in resonant frequency. In this manner, the LC sensor requires no on-board signal conditioning electronics in order to measure a force and provide sensor information indicating the force.

[0084] Resonant sensors according to some embodiments may have various load sensitivity configurations. For example, resonant sensors may be configured to detect (or be sensitive to) axial, bending, and shear forces. In use, a resonant sensor may be exposed to

both sustained static and dynamical loading during fracture healing. Accordingly, resonant sensors according to some embodiments may be configured to minimize or even eliminate creep and/or hysteresis. For example, a highly hydrophobic biocompatible polymer such as PMMA with high stiffness may be used to minimize or even eliminate hysteresis.

[0085] Combinations of shear, bending and/or axial loading on a resonant circuit may potentially confounds the sensitivity of the system. Accordingly, in some embodiments, resonant circuits may be integrated into an orthopedic device, such as an IM nail system in a manner that promotes exposure of the resonant circuit to axial loading without shear and bending forces, bending loading without axial compression and shear forces, or shear without axial compression and bending forces, depending on the force of interest. For example, an axial and bending force, which is typically applied through the proximal end of the IM nail could be converted to a purely transverse load using a mechanical deflector, force concentrator, or other structural element located in close proximity to the LC sensor.

[0086] **FIGS. 5A-5C** depict an example of a medical implant device having a passive sensor device associated with a fastener element that may be representative of some embodiments of the present disclosure. As shown in FIG. 5A, a medical implant device may include an IM nail 510 or similar bone fixation device. IM nail 510 may include one or more bone screws 520 having a shaft 522 protruding through an opening in IM nail 510 and a head 521. A sensor 572 that includes a resonant circuit according to some embodiments may have a halo form factor and may be arranged between head 521 and body of IM nail 510.

[0087] Referring to FIG. 5B, in some embodiments, bone screw 520 may be a cortical bone screw having sensor 572 arranged directly underneath head 521. In some embodiments, after a hole has been drilled into the bone to receive the locking cortical screw 520, a further drilling step may be performed to counter-sink at least a portion of sensor 572 to reduce or even eliminate a portion of sensor 572 and/or head 521 protruding above an external surface of the bone.

[0088] Referring to FIG. 5C, therein is depicted loads imparted on bone screw 520. For example, when a compression load is exerted through IM nail 510 arranged in bone 540, screw 520 may be subjected to a 3-point bend force due to bi-cortical fixation with the near and far cortical bone, for instance through support forces 531 and 532 in response to load force 530. The 3-point bend force may result in a deformation of the dielectric between the two coils of sensor 572 resulting in a change in coil spacing. This in turn modulates

capacitance and frequency. Alternatively, the sensor can measure shear forces if configured so that application of shear changes the overlapping area of the capacitor.

[0089] In some embodiments, sensors 572, such as LC circuits, can be positioned underneath heads 521 of multiple locking screws 520 positioned at the distal and proximal end of an implant, such as IM nail 510. In some embodiments, each sensor may be analyzed individually, for example, using a dip grid detector, which can discriminate multiple resonant frequencies simultaneously from nearby LC circuits.

[0090] **FIG. 6** depicts an example of a medical implant device having a passive sensor device associated with a cap element that may be representative of some embodiments of the present disclosure. As shown in FIG. 6, an IM nail 610 may include a removable cap 620 at one end of IM nail 610. A sensor 672 may be arranged between cap 620 and body 611 of IM nail.

[0091] In some embodiments, when the proximal end of IM nail 610 is subjected to an axial compression force, the load is transferred through the nail cap and onto sensor 672, for example, in the form of a parallel plate capacitor, which is sandwiched between the proximal end of IM nail 610 nail and removable cap 620. Application of an axial load through body 611 may result in compression of the dielectric material of sensor 672, which in turn, will decrease the LC coil spacing. As a result, the capacitance increases and the resonant frequency decreases. As the bone heals, the load exerted through the proximal end of IM nail 610 reduces, the distance between the capacitor plates increases; therefore, the capacitance decreases and the resonant frequency increases.

[0092] **FIG. 7** depicts an example of a medical implant device having a passive sensor device associated with a collar recess that may be representative of some embodiments of the present disclosure. An IM nail 710 may include a machined collar 711 configured to have a halo sensor 772 arranged therein. Machined collar 711 may be a circumferentially machined recess within an external wall of IM nail 710. In some embodiments, sensor 772 may be attached to the base of collar or pocket 711 with an adhesive, such as epoxy resin. In some embodiments, the length and width of machined pocket 711 may be greater than the dimensions of sensor 772 to improve magnetic coupling with an external reader and/or to reduce noise artifacts from "proximity to metal" of IM nail 710.

[0093] **FIG. 8** depicts an example of a medical implant device having a passive sensor device associated with a recessed cavity that may be representative of some embodiments of the present disclosure. As shown in FIG. 8, an IM nail 810 may have an external recess or

cavity 811 configured to have a sensor 872 arranged therein. Recess 811 may be a longitudinal machined recess within an external wall of IM nail 810 and attached to the base of the pocket with an adhesive, such as epoxy resin. The length and/or width of machined recess 811 may be greater the dimensions of sensor 872 to improve magnetic coupling with the external reader and/or to reduce noise artifacts from "proximity to metal" of IM nail 810.

[0094] **FIG. 9** depicts an example of a medical implant device having a passive sensor device associated with a cavity that may be representative of some embodiments of the present disclosure. As shown in FIG. 9, an IM nail 910 may include one or more cavities 911 arranged therein. In some embodiments, cavities 911 may include holes, apertures, slots, and/or the like. In various embodiments, cavities 911 may include holes originally configured for bone screws or other fixation devices. A sensor 972 may be arranged within cavity 911. In some embodiments, sensor 972 may have a halo form factor. In various embodiments, sensor 972 may be press-fitted, for example, within a redundant screw-hole or slot, and affixed with an adhesive, such as epoxy resin.

[0095] **FIG. 10** depicts an example of a medical implant device having a passive sensor device associated with a cannulation that may be representative of some embodiments of the present disclosure. In some embodiments, an IM nail 1010 may have a cannulation 1011 in a body portion thereof. A sensor 1072 may be arranged within cannulation 1011. In various embodiments, sensor 1072 may be press-fitted into cannulation and affixed with an adhesive, such as epoxy resin.

[0096] **FIG. 11** depicts an example of a hip replacement medical implant device having a passive sensor device that may be representative of some embodiments of the present disclosure. As shown in FIG. 11, a THR 1110 may include a femoral head 1111 configured to engage a taper 1112, and a femoral stem 1113. In some embodiments, a sensor 1172a may be arranged between taper 1112 and femoral head 1111, for example, to measure forces exerted through the metal taper lock. In various embodiments, an acetabular cup 1114 (shown in cross-section in FIG. 11) may be arranged to engage femoral head 1111. In some embodiments, a sensor 1172b may be arranged within acetabular cup 1114.

[0097] In axial loading, the dielectric material between the coils compresses causing a decrease in plate spacing, which in turn increases capacitance and decreases the resonant frequency. Sensors 1172a and/or 1172b could also be used to indicate loosening and/or trunnion corrosion to predict early implant failure of THR 1110, for example, for a sensor 1172a, 1172b configured to measure displacement. For example, in some embodiments, a

sensor configured to measure displacement may have an air gap between the two plates. In various embodiments, LC sensors comprised of a movable inductor and a fixed inductor-capacitor resonant circuit may also cause the sensor resonant frequency to be displacement dependent.

[0098] **FIGS. 12A-12C** depict an example of a knee replacement medical implant device having a passive sensor device that may be representative of some embodiments of the present disclosure. Referring to FIG. 12A, therein is depicted a TKR 1210 having a tibial tray 1201 and a block insert 1220 (for example, a polyethylene block insert). In some embodiments, one or more sensors 1272 may be located under block insert 1220. In various embodiments, sensors 1272 may include a pair of sensors.

[0099] Sensors 1272 may be placed in either or both the medial or lateral condyles to observe joint balance and discriminate between medial and lateral compartmental loading. Sensors 1272 may also be configured to determine the degree of medial–lateral symmetry in lift-off. In various embodiments, sensors 1272 could be injection molded into block insert 1220, thereby simplifying and reducing the cost associated with integration within TKR 1210, which is a substantial improvement over conventional systems that require power supplies (e.g., batteries), telemetry systems, and other electronics to be stored within components of a TKR (such as a cone or stem).

[0100] Referring to FIG. 12C, therein is depicted a TKR 1210 having a femoral component 1230. In some embodiments, at least one sensor 1272 may be arranged within femoral component 1230, for example, configured to engage a portion of a femur arranged within femoral component 1230.

[0101] **FIG. 13** depicts an example of an external fixator device having a passive sensor device that may be representative of some embodiments of the present disclosure. In some embodiments, an external fixator device 1310 may include a Taylor spatial frame or similar structure. As shown in detailed section 1305, sensors 1372 may be arranged in contact with portions of external fixator device 1310. For example, sensors 1372 may be arranged in contact with struts 1311 of external fixator device 1310.

[0102] Sensors 1372 could be used to measure frame loading from each of struts 1311 of a Taylor Spatial Frame, for example, to determine the optimum time for frame removal. In various embodiments, sensors 1372 may be or may include an LC circuit, having a halo form factor, configured as a bushing located between the U-Joint of strut 1372 and the shoulder joint on external fixator device 1310.

[0103] **FIG. 14** depicts an example of an external fixator device having a passive sensor device that may be representative of some embodiments of the present disclosure. As shown in FIG. 14, an external fixator device 1410 may be or may include a bone plate having one or more sensors 1472 within a spare screw hole 1411 or other opening. In various embodiments, sensor 1472 may be configured to measure plate loading. In some embodiments, sensor 1472 may be configured as a bushing, washer, or other similar structure that may be arranged under a head of screw 1420.

[0104] Sensor devices (for instance, LC sensors or resonant sensors) configured according to some embodiments may be releasably affixed or mounted to a medical implant device, for example, due to their flexibility and/or small form factor. In this manner, sensor devices according to some embodiments may be used as an optional addition to a medical implant device (compared with conventional devices that are required to be permanently or semi-permanently affixed to a medical implant device, for example, to accommodate power and/or telemetry systems). In addition, sensor devices according to some embodiments may be incorporated into existing medical implant devices with little or no modifications to the medical implant device. For instance, sensor devices may be arranged in existing locations or elements of medical implant devices determined to receive a force imparted on the medical implant device. For example, in reference to the medical implant devices depicted in FIGS. 5A and 9-14, the sensors depicted therein may be releasably installed in or on existing elements of the medical implant devices (for instance, without modification to the existing elements and/or medical implant devices).

[0105] In some embodiments, medical implant devices configured according to some embodiments may be associated with a force concentrator. In general, a force concentrator is configured to attach to a loadbearing medical device and to produce a transverse force related to an eccentric axial force applied to the loadbearing medical device. Accordingly, sensors and/or components thereof (for instance, a resonant circuit) may be arranged to receive a force via, at least in part, a force concentrator. Non-limiting examples of force concentrators may be found in Patent Cooperation Treaty (PCT) International Patent Application Publication No. 20/2019/210047 of PCT International Application No. PCT/US2019/029094.

[0106] In accordance with various aspects of the present disclosure, a number of advantages over conventional sensing systems can be achieved. Some of these advantages will now be described.

[0107] LC sensors (or resonant circuits) according to some embodiments may not require an additional power source from either a wireless inductive charging circuit or a battery cell for their operation. LC sensors according to some embodiments may require ultralow power levels. This is in contrast to currently known sensors such as strain gauges and accelerometers. Piezoelectric energy harvesting sensors, which have also been proposed, require strain energy to activate the wireless transmission. The strain energy is typically too large for self-powered sensing of microstrain variations. Piezoelectric energy harvesting sensors typically require 100 times more power than what would be available under normal physiological conditions (<1μW). In addition, the occurrence of loading cycles is sporadic during rehabilitation necessitating integration of self-powered computation and sensing with non-volatile storage.

[0108] The "battery-free" approach offered by the LC sensor according to some embodiments may also ensure that the implant can be monitored indefinitely after the fracture has healed, if required.

[0109] The simplified structure of an LC sensor circuit according to some embodiments may (e.g., no on-board signal conditioning electronics, no electrical connections, etc.) make LC sensors according to some embodiments may attractive for manufacturing at batch scale due to their low cost.

[0110] A medical implant device, such as an IM nail, THR device, TKR, device, and/or the like, may include multiple sensing systems, of which an LC sensor according to some embodiments may be included as a separate system. For example, an orthopedic device may include an LC sensor along with a conventional strain gauge system, which includes the strain sensor, power source(s), and telemetry. Unlike conventional systems, an LC sensor system according to some embodiments may not necessarily be permanently installed in a medical implant device; rather, an LC sensor system may be removably installed. Accordingly, an LC sensor according to some embodiments may be considered by medical professionals as a separate or modular component of an implant instrument set, providing the medical professional with the option to purchase it separately from the implant because, for example, certain embodiments may be installed in existing implants even though they were not specifically designed for this purpose.

[0111] Integration of LC sensors according to some embodiments into orthopedic implants involves little to no modification of the implant itself, for example, due to the

flexibility and/or small form factor of LC sensors, the need for substantive changes to an implant to allow for installation of an LC sensor may be reduced or even eliminated.

[0112] The design of LC sensors according to some embodiments may be tailored to fit a specific design feature on the device. For example, an LC sensor according to some embodiments may be positioned (a) underneath the head of a bone screw, (b) embedded/injection molded within a poly insert of a total knee replacement implant, (c) underneath the femoral head of a modular total hip replacement, (d) between the U-Joint of the strut and the shoulder joint on an external fixator, and (e) a machined recess underneath a bone plate or within one of the spare screw-holes.

[0113] Enhancing the coupling (read range) between the external reader coil and the LC sensor can be achieved by improving the sensitivity and Q factor of the sensor as well as the signal extraction method, and in particular, adopting a resonant repeater between the external readout coil and the inductor. The reading distance can also be increased by increasing the coupling coefficient between the reader and sensor coils. Increase in the coupling coefficient is possible by increasing the mutual inductance between the coils, which can be made, e.g. by increasing the diameter of the coils or increasing the number of turns in the coils.

[0114] LC sensors according to some embodiments may be a self-contained unit that does not require any physical connections between the sensing components and the processing apparatus, which makes them attractive propositions for orthopaedic implants that are subject to multi-axial forces. There are also no on-board electronics.

[0115] Wireless LC sensors according to some embodiments may have the capacity to operate in a passive mode obviating the need for a battery, which has a limited lifespan. Instead, the passive device can receive power remotely via magnetically or electromagnetic forces from an external reader/antenna.

[0116] Although an LC sensor is a single channel system, multiple LC sensors according to some embodiments may be incorporated into an implant, the LC sensors can be interrogated independently via, for example, a dip grid meter.

[0117] In accordance with the principles disclosed herein, in one embodiment, the LC resonator circuit can be arranged as a parallel plate capacitor including a coil for using an antenna for an inductive link, a resistor and a capacitor (e.g., the sensor).

[0118] In one embodiment, a wireless LC resonator is arranged and configured to operate in a passive mode obviating the need for a battery.

[0119] In one embodiment, a bone fixation device includes at least one LC resonant sensor for tracking the progression of fracture healing, measuring implant loading and implant micro-motion.

[0120] In one embodiment, the LC sensor is arranged and configured in the form of a halo, a disc, a donut, etc. to enable the LC sensor to conform to a specific design feature on an orthopedic implant such as, for example, a cannulation formed in the implant, a threaded screw, a cap, a lug, a thread rod, a threaded hole, a taper lock, etc.

[0121] In one embodiment, the LC sensor includes a "capping layer" located on an outer surface of the LC sensor to reduce the effects of biological media on sensor signal to acceptable levels minimizing the risk of parasitic capacitance.

[0122] In one embodiment, the LC sensor includes a pair of individual conductor coils hermetically sealed with a soft encapsulant to prevent unwanted changes to the properties of the dielectric material from body fluids.

[0123] In one embodiment, the LC sensor includes a dielectric layer positioned between the conductor coils and the metal body of an implant to help minimize "proximity to metal" artefact.

[0124] In one embodiment, a bone fixation device can be in the form of an IM nail. The IM nail including at least one LC sensor positioned between a removable nail cap and a proximal end of the nail.

[0125] In one embodiment, a bone fixation device includes at least one LC sensor designed as a bushing located underneath the head of a bone screw(s).

[0126] In one embodiment, a bone fixation device includes multiple LC sensors connected to a common inductor enabling them to be monitored simultaneously using a dip-grid detector, which will significantly shorten monitoring time.

[0127] In one embodiment, an LC resonator(s) is inductively coupled to a base station or an external reader device allowing a measurement to be performed by utilizing the properties of this link.

[0128] In one embodiment, a readout system may be provided. The readout system includes a reader coil inductively coupled to at least one LC resonant sensor, a measurement unit, and a PC post processing unit, which enables wireless interrogation.

[0129] In one embodiment, a measurement unit may be provided. The measurement unit generates an output voltage representing the sensor resonance, which converts the output voltage to numerical form, and saves the converted digital data.

[0130] In one embodiment, a PC post-processing unit may be provided. The PC post-processing unit may process the digital data from the implantable LC resonant sensors and calculate their resonance frequency, which correlates with a change in coil spacing, and capacitance.

[0131] In one embodiment, an LC sensor resonant frequency may be provided. The LC sensor resonant frequency can be detected by measuring the phase shift of the reader coil using either a network analyzer or impedance analyzer.

[0132] In one embodiment, an external fixation system such as, for example, the Taylor Spatial Frame can include at least one LC resonant frequency sensor designed as a bushing, which can be located between the U-joint of the strut and the shoulder joint on the frame.

[0133] In one embodiment, a molded polyethylene insert of a Total Knee Replacement (TKR) can be designed and configured to receive at least one LC resonator that could be placed in either or both the medial or lateral condyles to observe joint balance and discriminate between medial and lateral compartmental loading.

[0134] In one embodiment, a modular Total Hip Replacement (THR) can be designed and configured to receive an LC sensor located underneath the femoral head to measure forces exerted through the metal taper lock and used to indicate loosening and/or trunnion corrosion to predict early implant failure of the implant.

[0135] In one embodiment, a bone plate can be designed and configured to receive an LC resonator to measure plate loading during bone healing, which could be configured as a bushing located underneath the screw head or located within one of the spare screw-holes.

[0136] While the present disclosure has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the certain embodiments have been shown and described and that all changes, alternatives, modifications and equivalents that come within the spirit of the disclosure are desired to be protected.

[0137] It should be understood that while the use of words such as preferable, preferably, preferred or more preferred utilized in the description above indicate that the feature so described may be more desirable, it nonetheless may not be necessary and embodiments lacking the same may be contemplated as within the scope of the present disclosure, the scope being defined by the claims that follow. In reading the claims, it is intended that when words such as "a," "an," "at least one," or "at least one portion" are used there is no intention to limit the claim to only one item unless specifically stated to the contrary in the claim.

When the language “at least a portion” and/or “a portion” is used the item can include a portion and/or the entire item unless specifically stated to the contrary.

CLAIMS

What is claimed is:

1. A intramedullary nail system, comprising:

an intramedullary nail; and

at least one sensor coupled to the intramedullary nail to passively measure at least one force imparted on the intramedullary nail by a bone structure, the at least one sensor comprising at least one resonator circuit having a pair of opposing coils separated by a distance and an insulating layer arranged between the opposing coils, the distance to change responsive to the at least one force, the at least one resonator circuit operative to generate a resonance frequency responsive to exposure to a radiofrequency (RF) field, the resonance frequency to modulate based on the distance.

2. The intramedullary nail system of claim 1, the insulating layer formed of one of a dielectric material or an air gap.

3. The intramedullary nail system of claim 1, the at least one force comprising an axial force on the intramedullary nail by the bone structure.

4. The intramedullary nail system of claim 1, further comprising a bone screw having a head and configured to fasten the intramedullary nail to the bone structure, the at least one sensor having a halo form factor and arranged between the head and an external surface of the bone structure.

5. The intramedullary nail system of claim 1, further comprising a removable nail cap configured to be affixed to an end of a body of the intramedullary nail, the at least one sensor having a halo form factor and between the cap and the body of the intramedullary nail.

6. The intramedullary nail system of claim 1, further comprising a recess formed in a portion of the intramedullary nail, the at least one sensor arranged within at least a portion of the recess.

7. The intramedullary nail system of claim 6, the recess comprising a collar arranged around a portion of an outer surface of the intramedullary nail, the at least one sensor having a halo form factor and arranged around the collar.

8. The intramedullary nail system of claim 6, the recess comprising a pocket arranged in a portion of an outer surface of the intramedullary nail, the at least one sensor arranged within the pocket.

9. The intramedullary nail system of claim 1, further comprising a cavity formed in a portion of the intramedullary nail, the at least one sensor arranged within at least a portion of the cavity, the cavity comprising one of a cannulation or an aperture.

10. The intramedullary nail system of claim 1, further comprising a monitor operative to transmit the RF field to the at least one sensor.

11. The intramedullary nail system of claim 10, the monitor operative to receive the resonance frequency from the at least one sensor.

12. A medical implant system, comprising:

a bone fixation device; and

at least one sensor coupled to the bone fixation device to passively measure at least one force imparted on the bone fixation device by a bone structure, the at least one sensor comprising at least one resonator circuit having a pair of opposing coils separated by a distance and an insulating layer arranged between the opposing coils, the distance to change responsive to the at least one force, the at least one resonator circuit operative to generate a resonance frequency responsive to exposure to a radiofrequency (RF) field, the resonance frequency to modulate based on the distance.

13. The medical implant system of claim 12, the bone fixation device comprising a hip replacement device.

14. The medical implant system of claim 13, the hip replacement device comprising a femoral head and a taper, the at least one sensor arranged between the femoral head and the taper.

15. The medical implant system of claim 14, the bone fixation device comprising an acetabular cap configured to engage the femoral head, the at least one sensor arranged between the acetabular cap and the femoral head.

16. The medical implant system of claim 12, the bone fixation device comprising a knee implant device having a tibial tray and an insert block coupled to the tibial tray, the at least one sensor arranged between the insert block and the tibial tray.

17. The medical implant system of claim 16, the knee implant device comprising a femoral component, the at least one sensor arranged within the femoral component to engage at least a portion of a femur.

18. The medical implant system of claim 1, further comprising a monitor operative to:
transmit the RF field to the at least one sensor, and
receive the resonance frequency from the at least one sensor.

19. A method of monitoring a healing status of a bone structure, comprising:
providing at least one sensor coupled to a bone fixation device to passively measure at least one force imparted on the bone fixation device by the bone structure, the at least one sensor comprising at least one resonator circuit having a pair of opposing coils separated by a distance and an insulating layer arranged between the opposing coils, the distance to change responsive to the at least one force, the at least one resonator circuit operative to generate a resonance frequency responsive to exposure to a radiofrequency (RF) field, the resonance frequency to modulate based on the distance;
transmitting the RF field to the at least one sensor;
receiving the resonance frequency from the at least one sensor; and
generating healing information indicating a healing status of the bone structure based on the resonance frequency.

20. The method of claim 19, the bone fixation device comprising one of an intramedullary nail, a hip replacement device, a knee replacement device, or a bone fixation device.

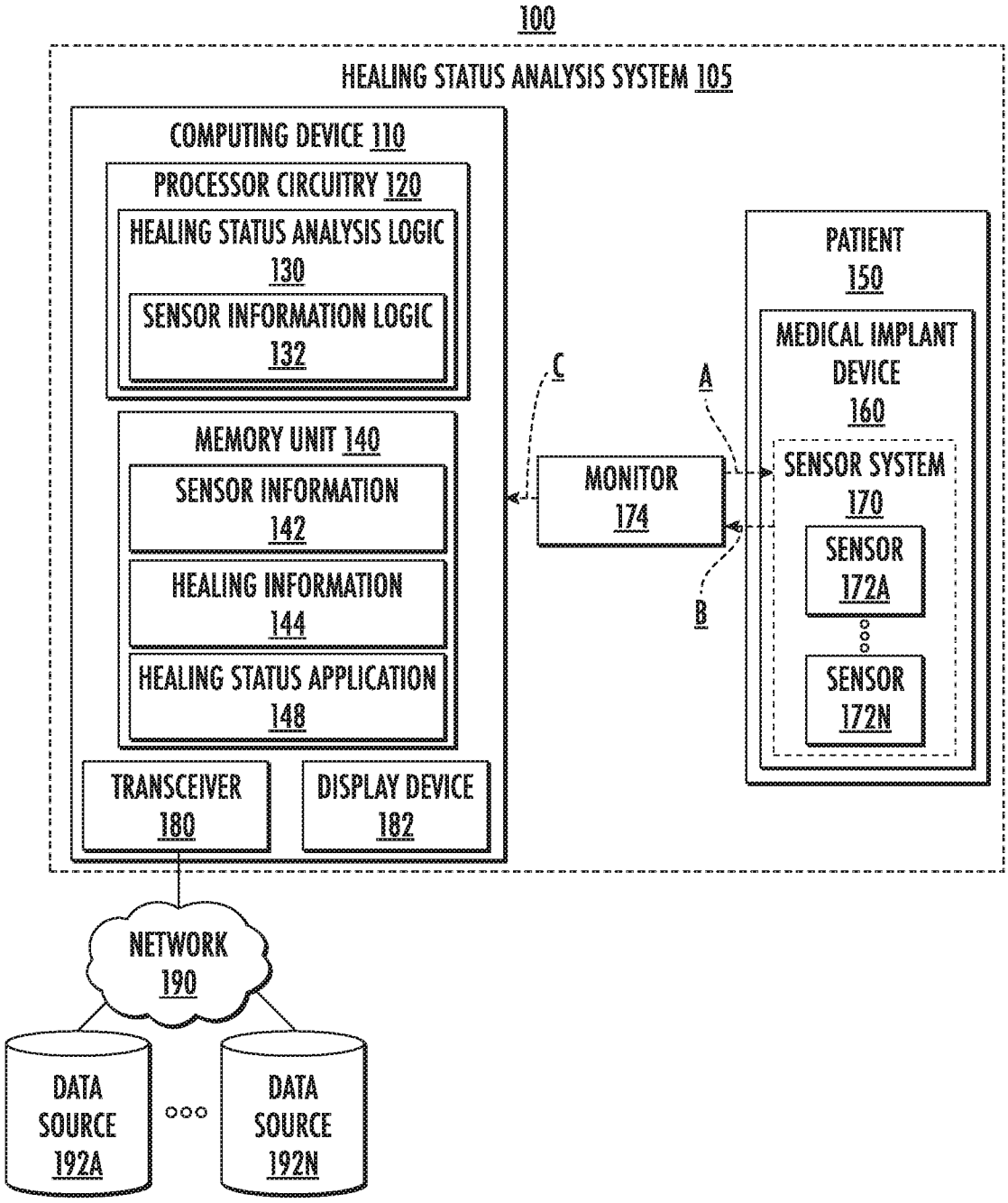
100
HEALING STATUS ANALYSIS SYSTEM 105
COMPUTING DEVICE 110
PROCESSOR CIRCUITRY 120
HEALING STATUS ANALYSIS LOGIC 130
SENSOR INFORMATION LOGIC 132
MEMORY UNIT 140
SENSOR INFORMATION 142
HEALING INFORMATION 144
HEALING STATUS APPLICATION 148
TRANSCEIVER 180
DISPLAY DEVICE 182
PATIENT 150
MEDICAL IMPLANT DEVICE 160
SENSOR SYSTEM 170
SENSOR 172A
SENSOR 172N
MONITOR 174
A
B
C
NETWORK 190
DATA SOURCE 192A
DATA SOURCE 192N

FIG. 1

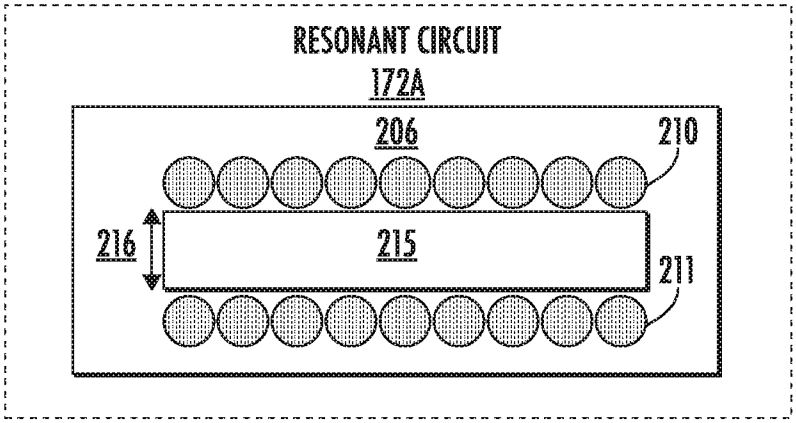

FIG. 2A

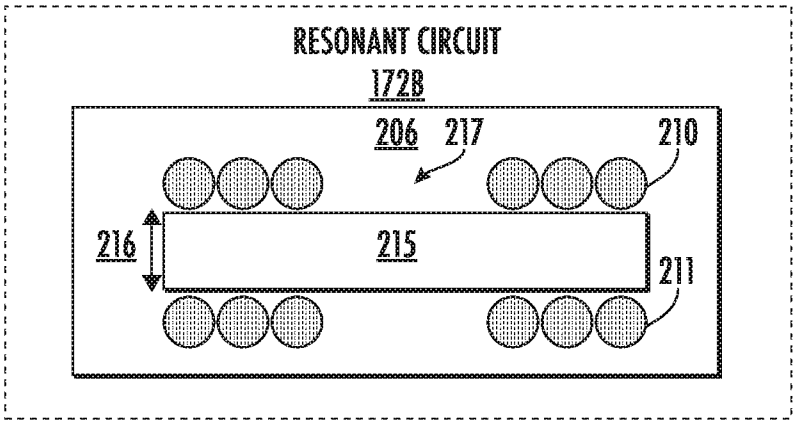

FIG. 2B

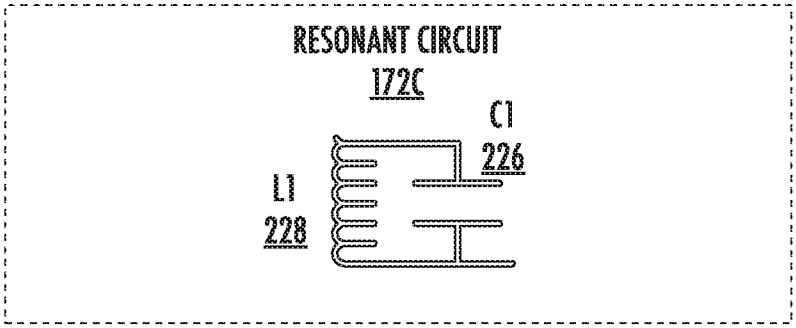

FIG. 2C

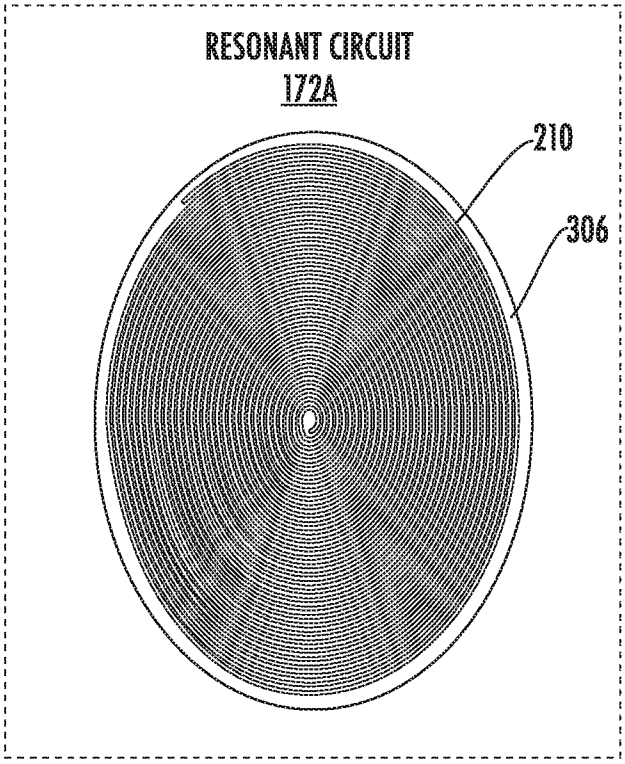
RESONANT CIRCUIT
172A
210
306

FIG. 3A

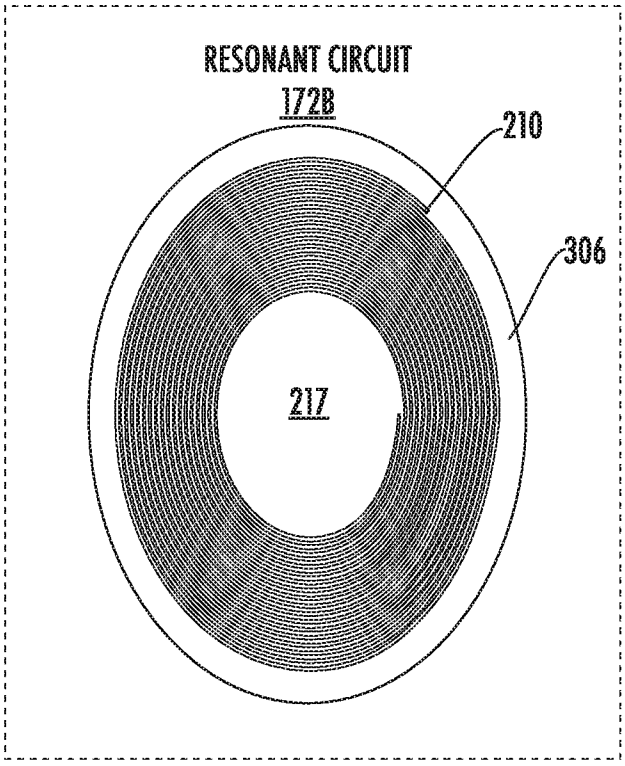
RESONANT CIRCUIT
172B
210
306
217

FIG. 3B

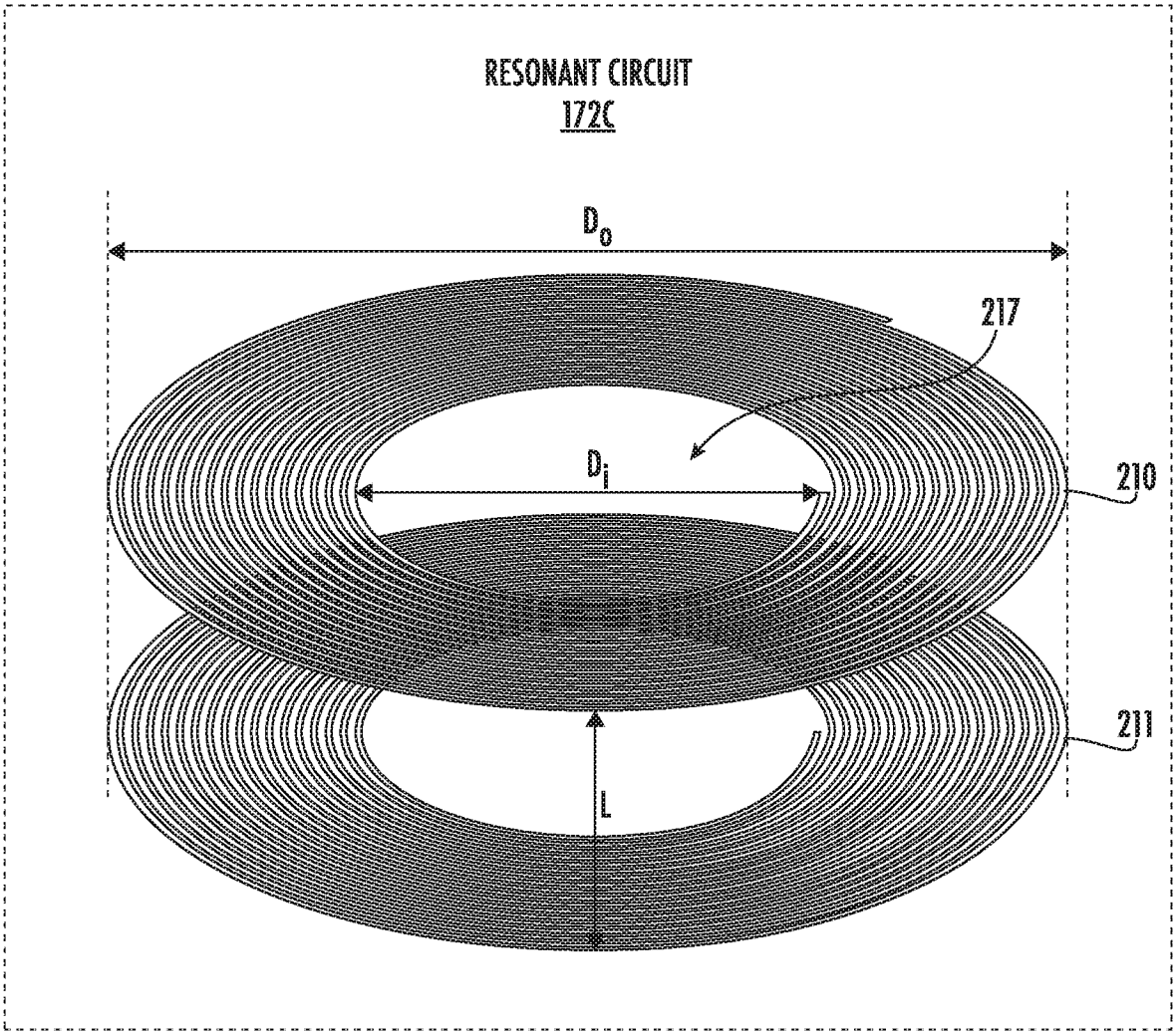

FIG. 3C

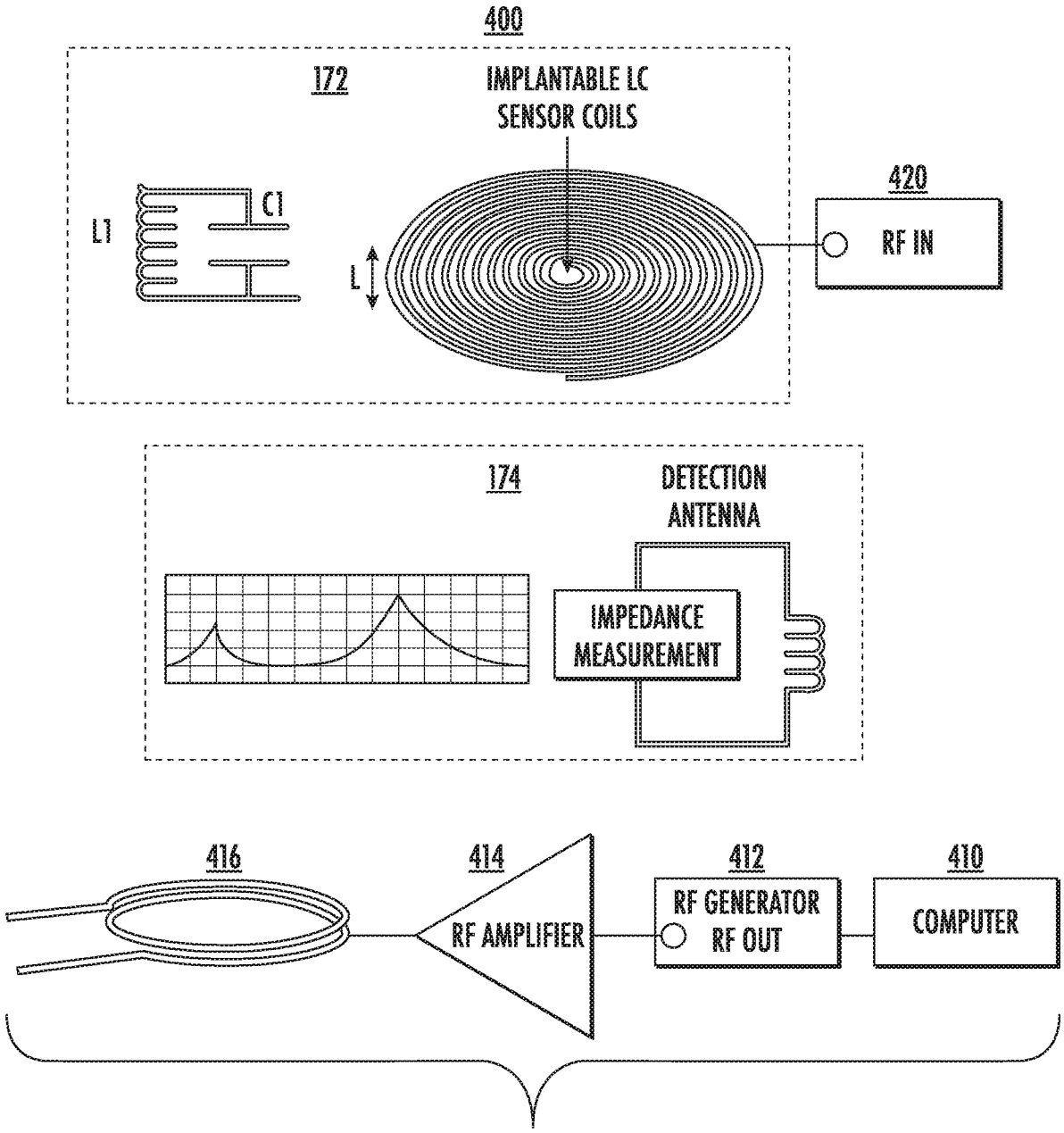
400
172
IMPLANTABLE LC
SENSOR COILS
L1
C1
L
420
RF IN
174
DETECTION
ANTENNA
IMPEDANCE
MEASUREMENT
416
414
RF AMPLIFIER
412
RF GENERATOR
RF OUT
410
COMPUTER

FIG. 4

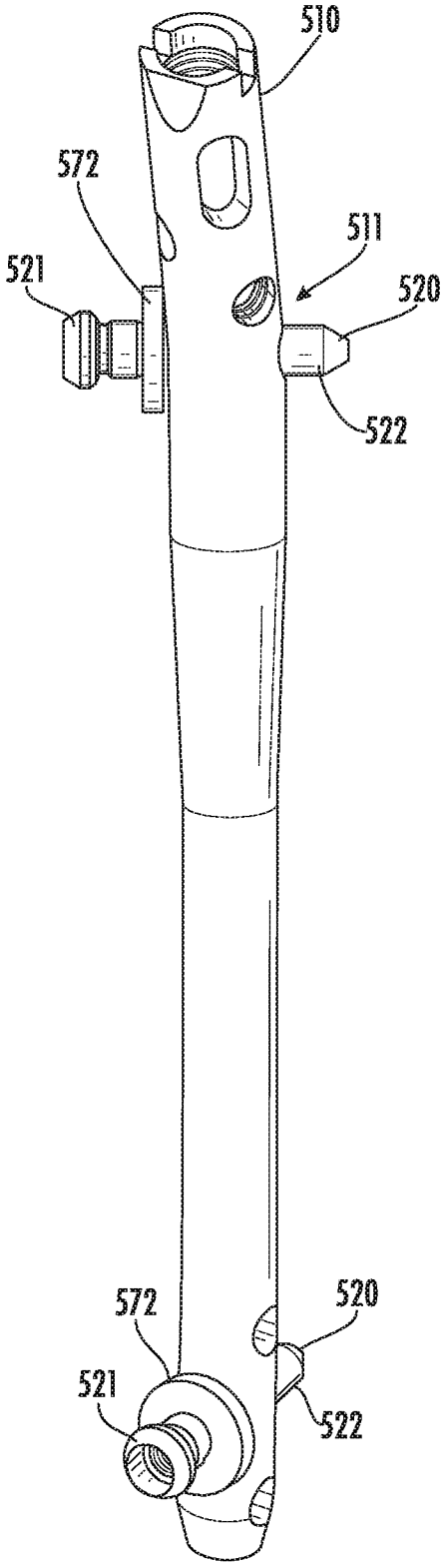

FIG. 5A

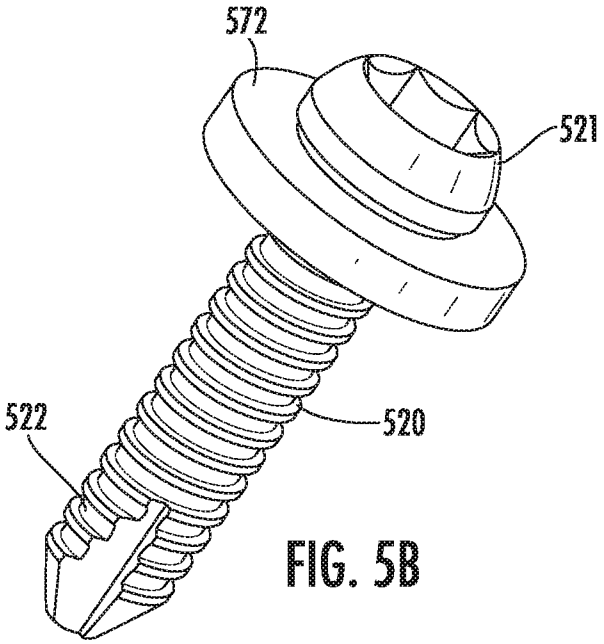

FIG. 5B

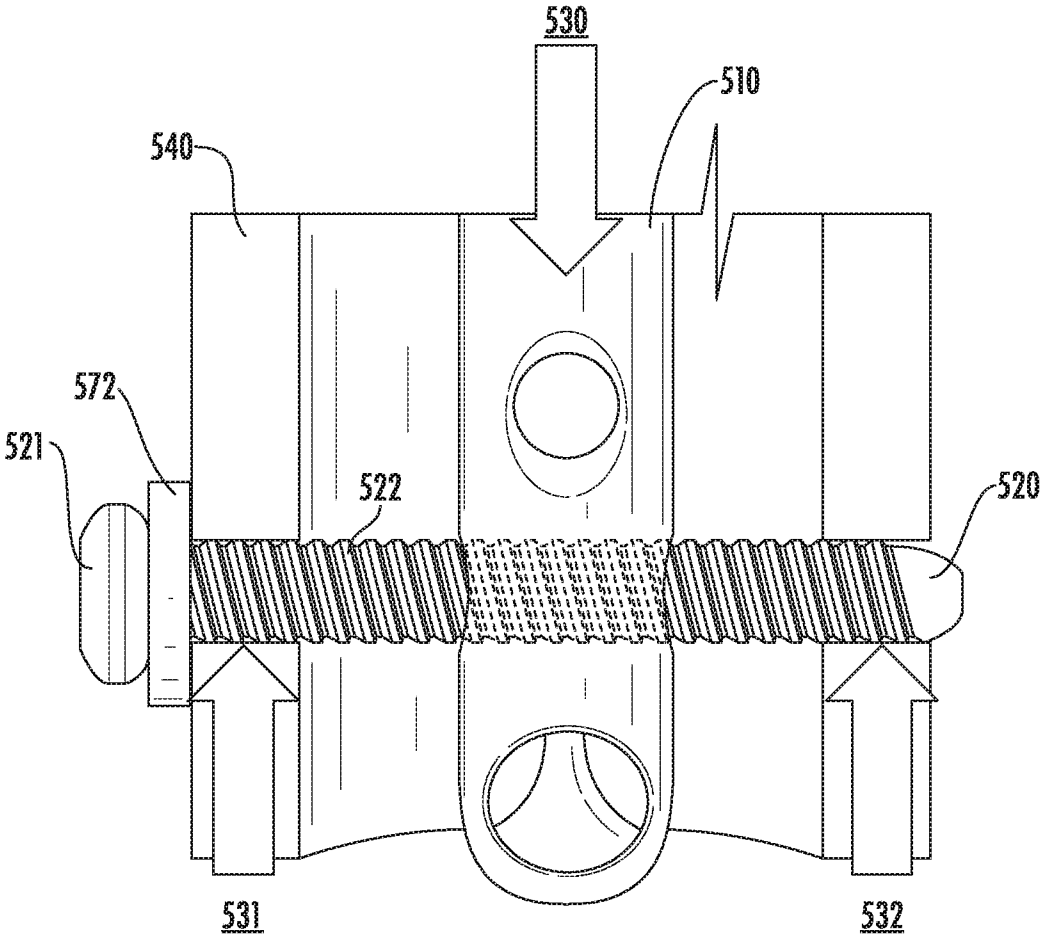

FIG. 5C

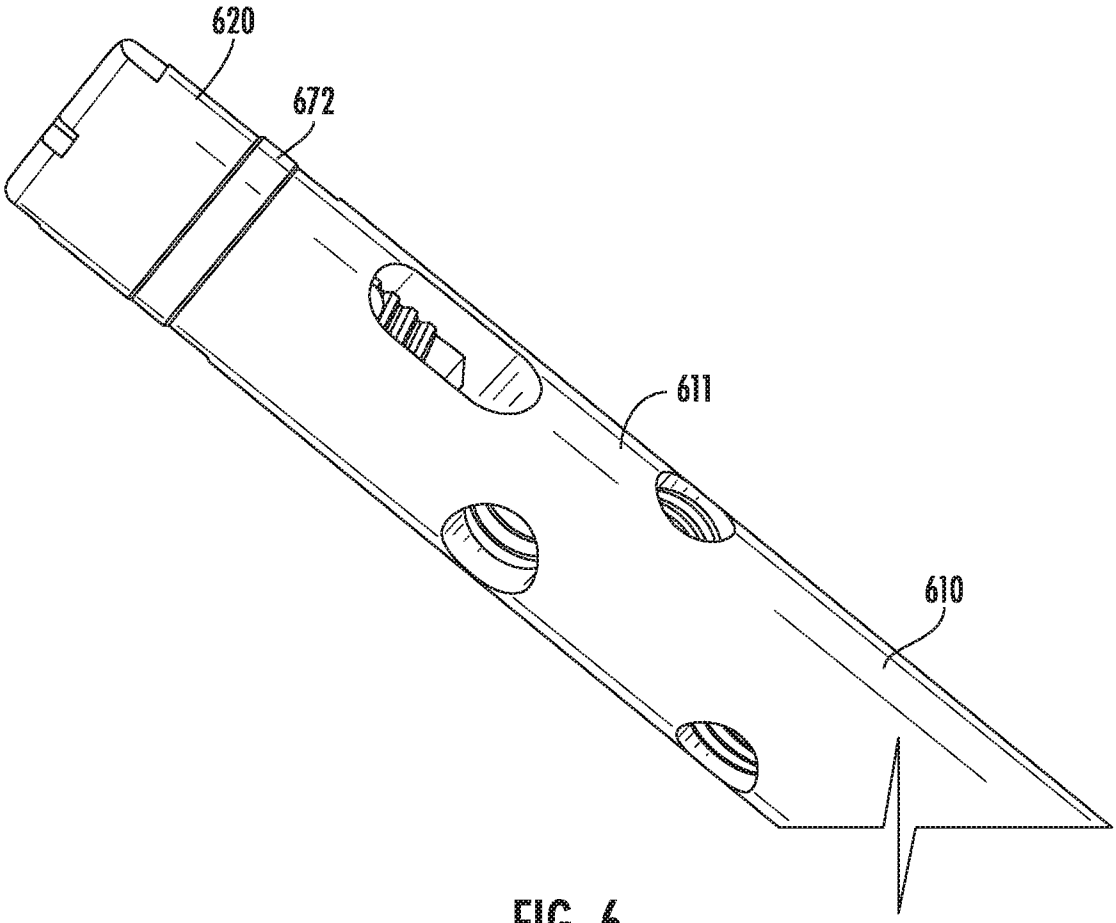

FIG. 6

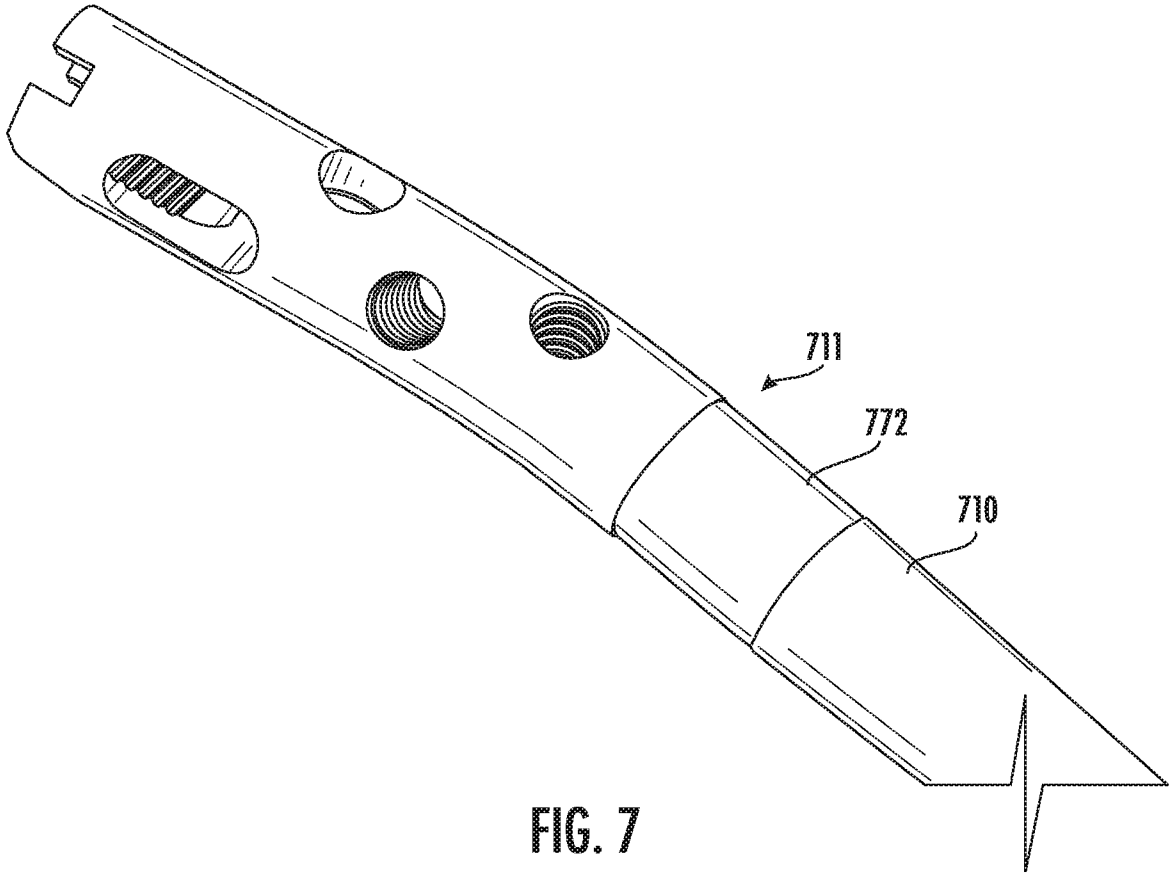

FIG. 7

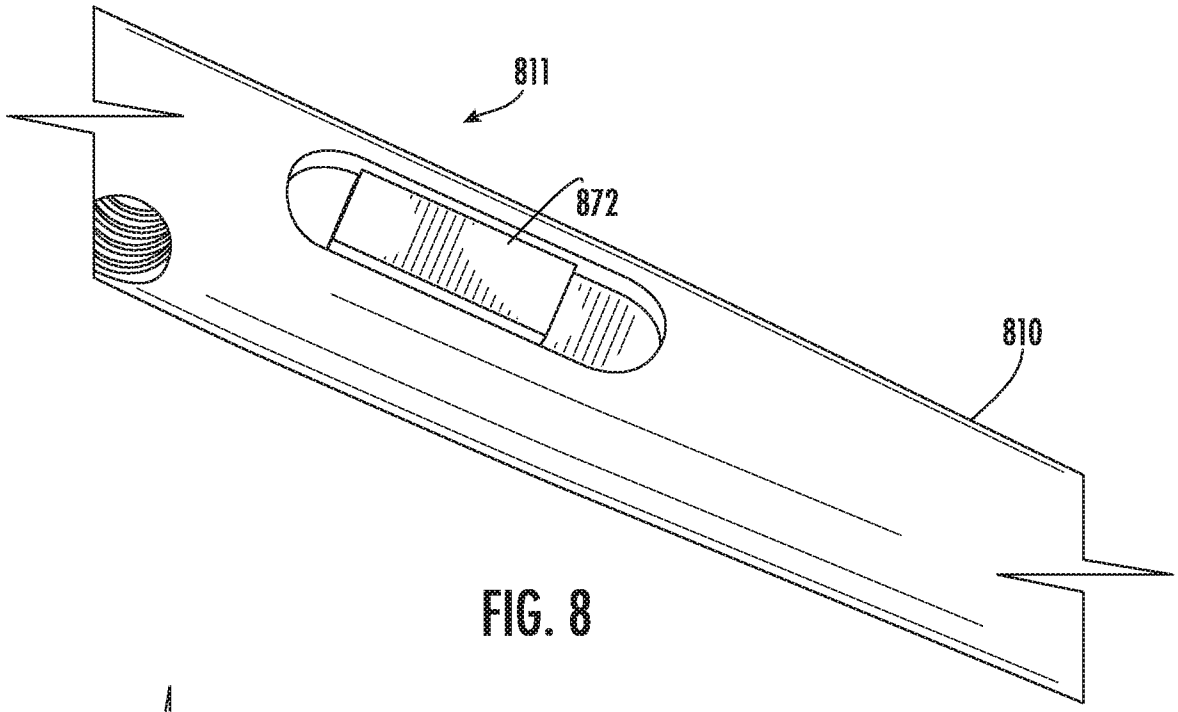

FIG. 8

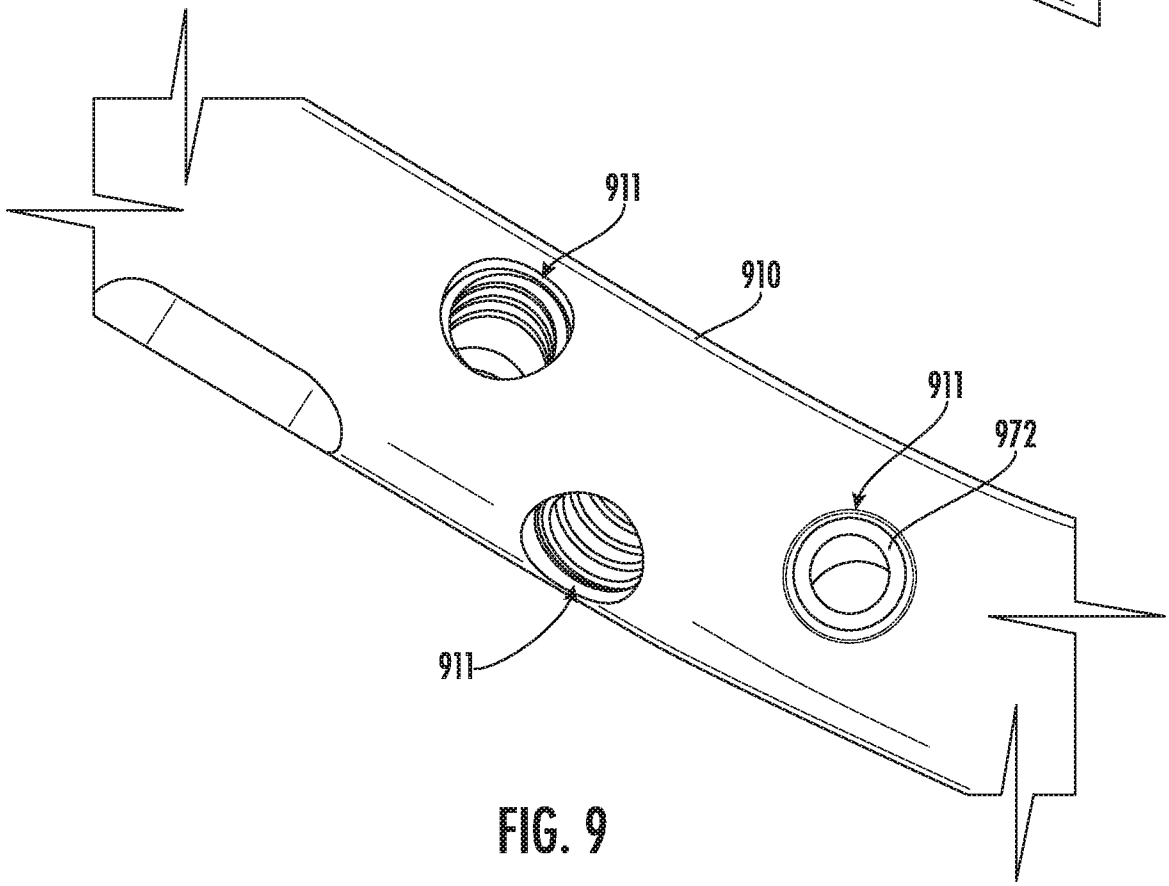

FIG. 9

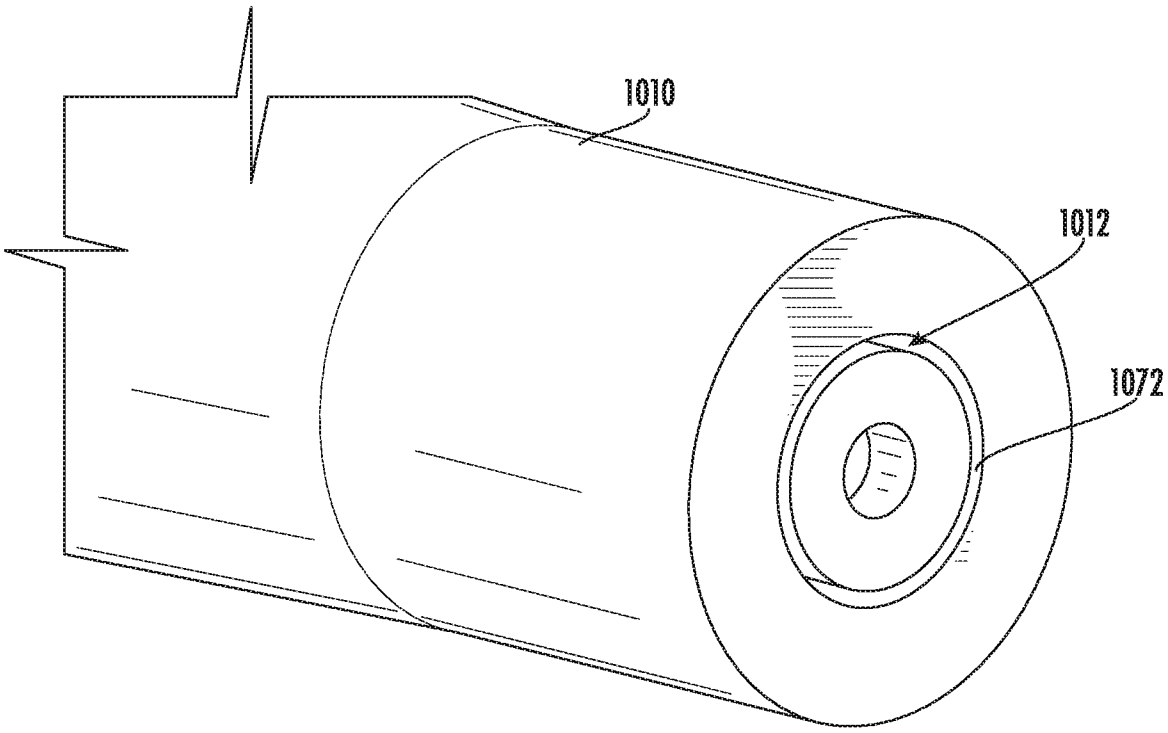

FIG. 10

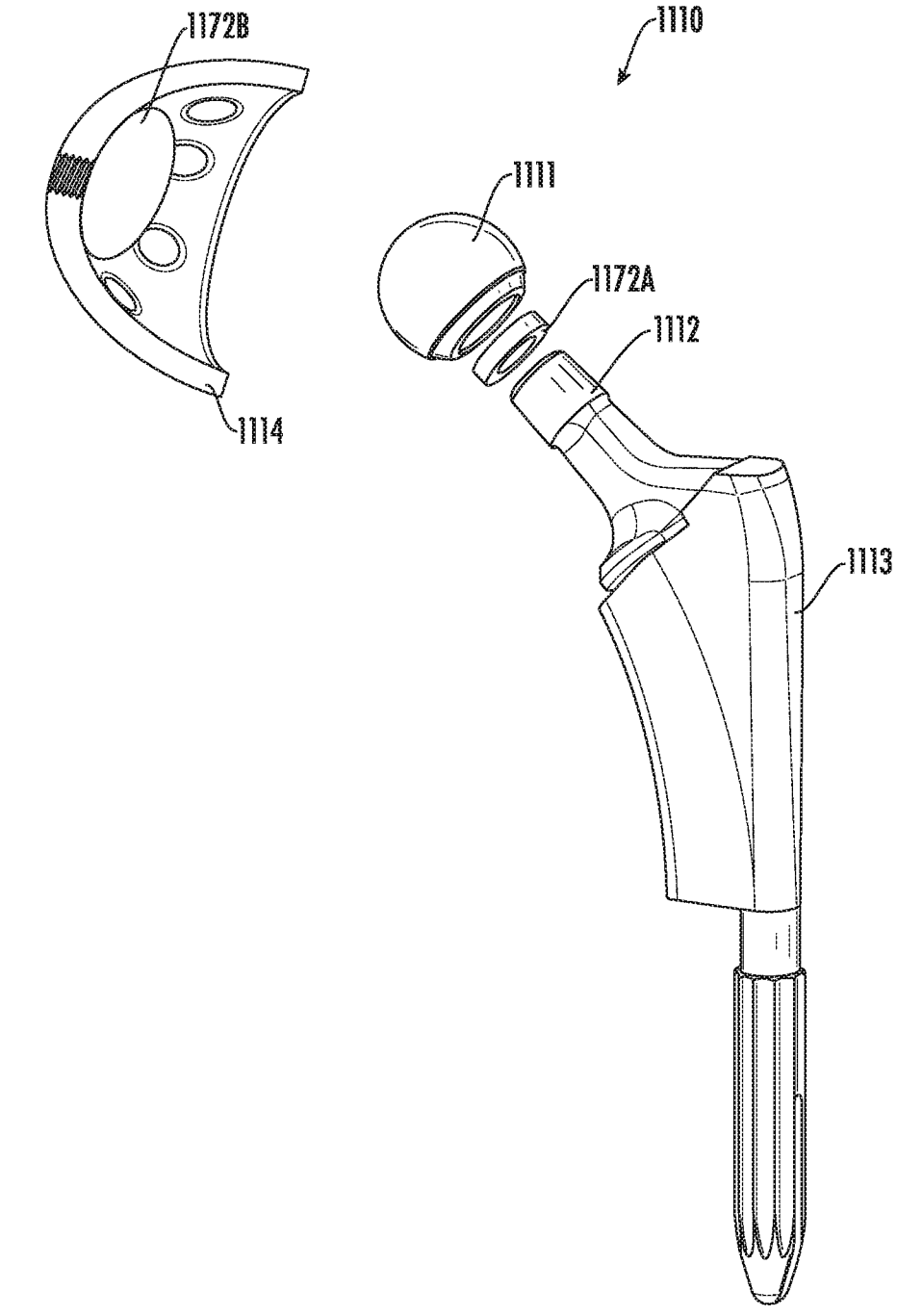

FIG. 11

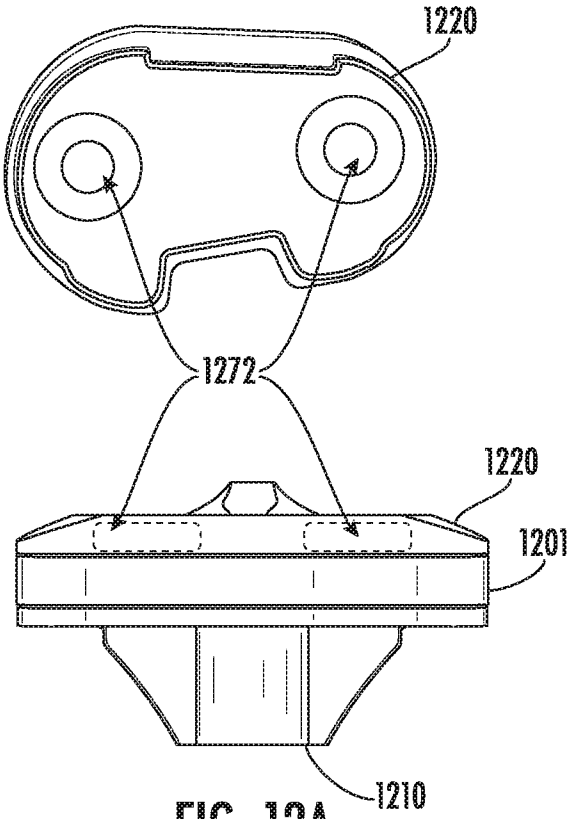

FIG. 12A

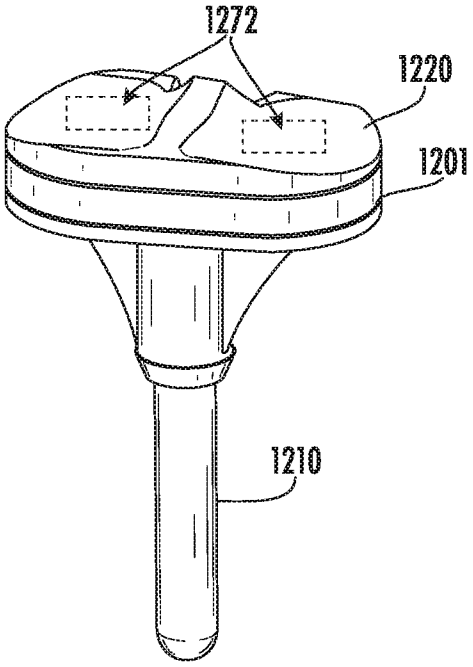

FIG. 12B

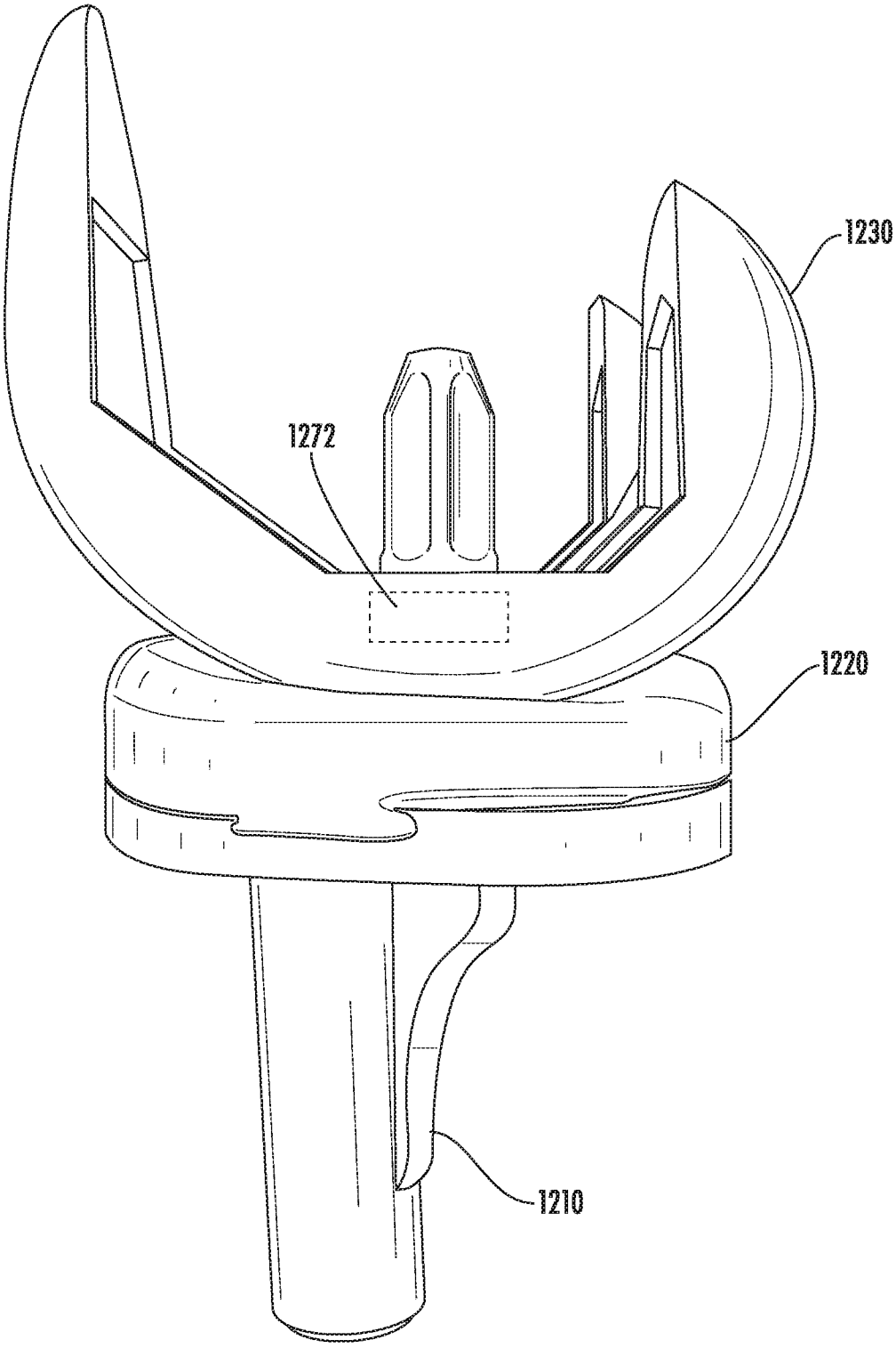

FIG. 12C

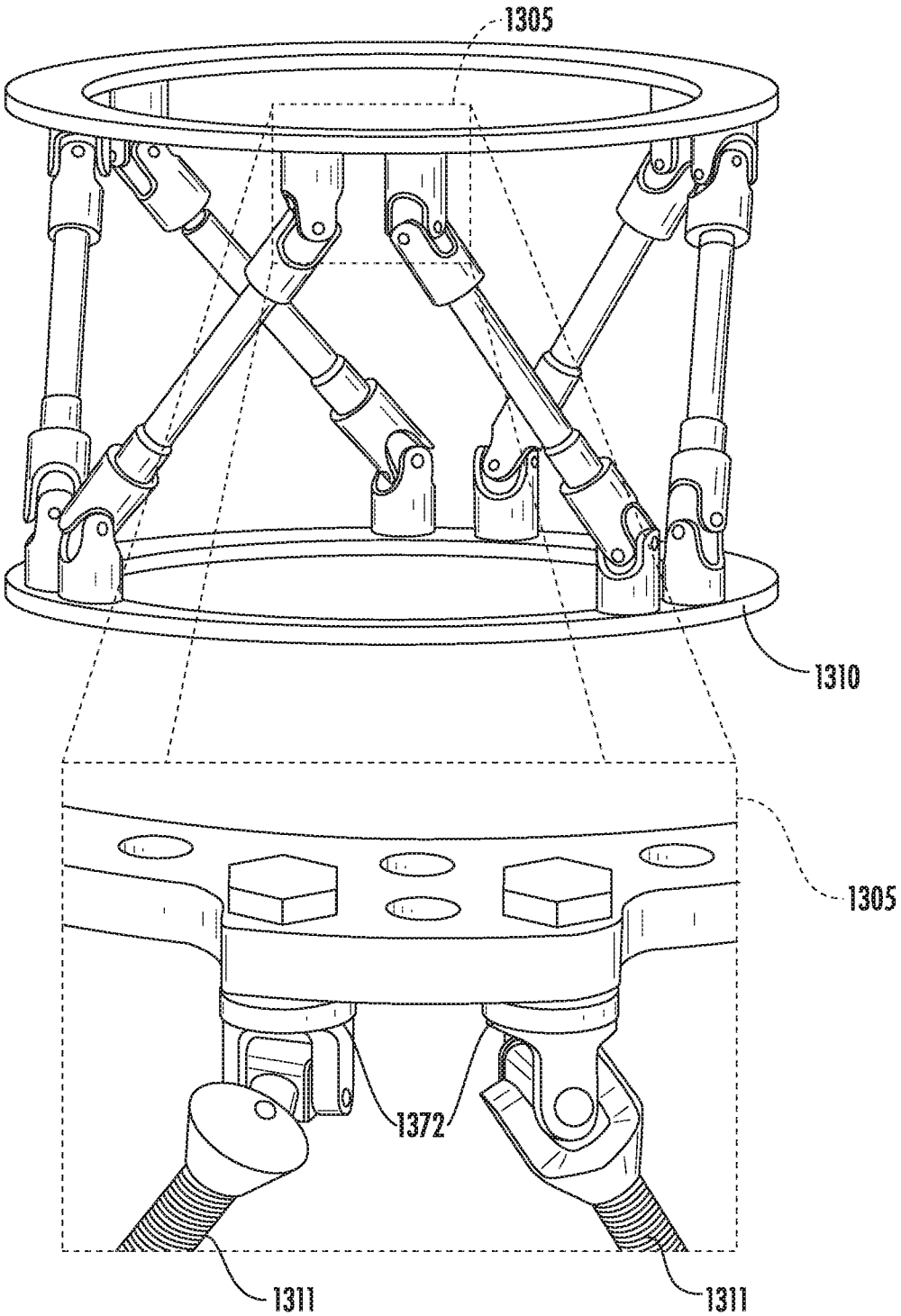

FIG. 13

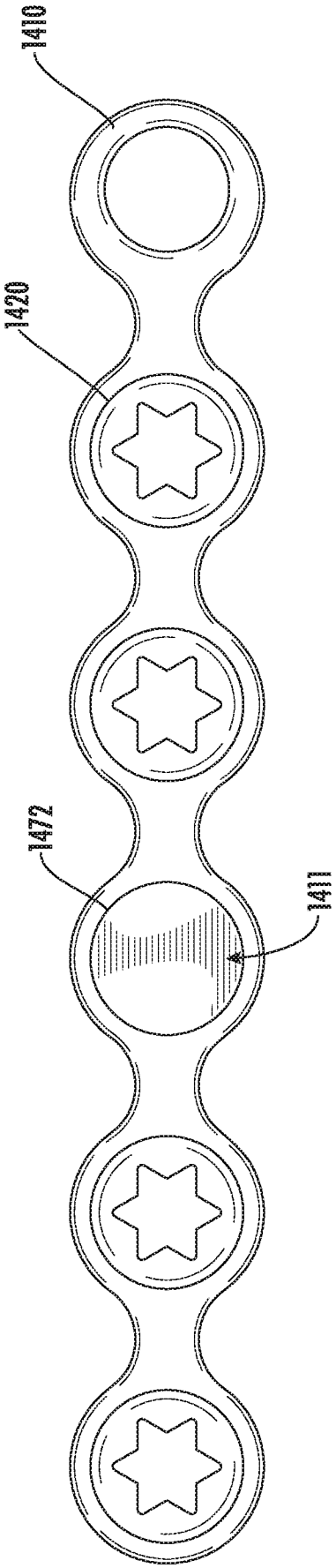

FIG. 14

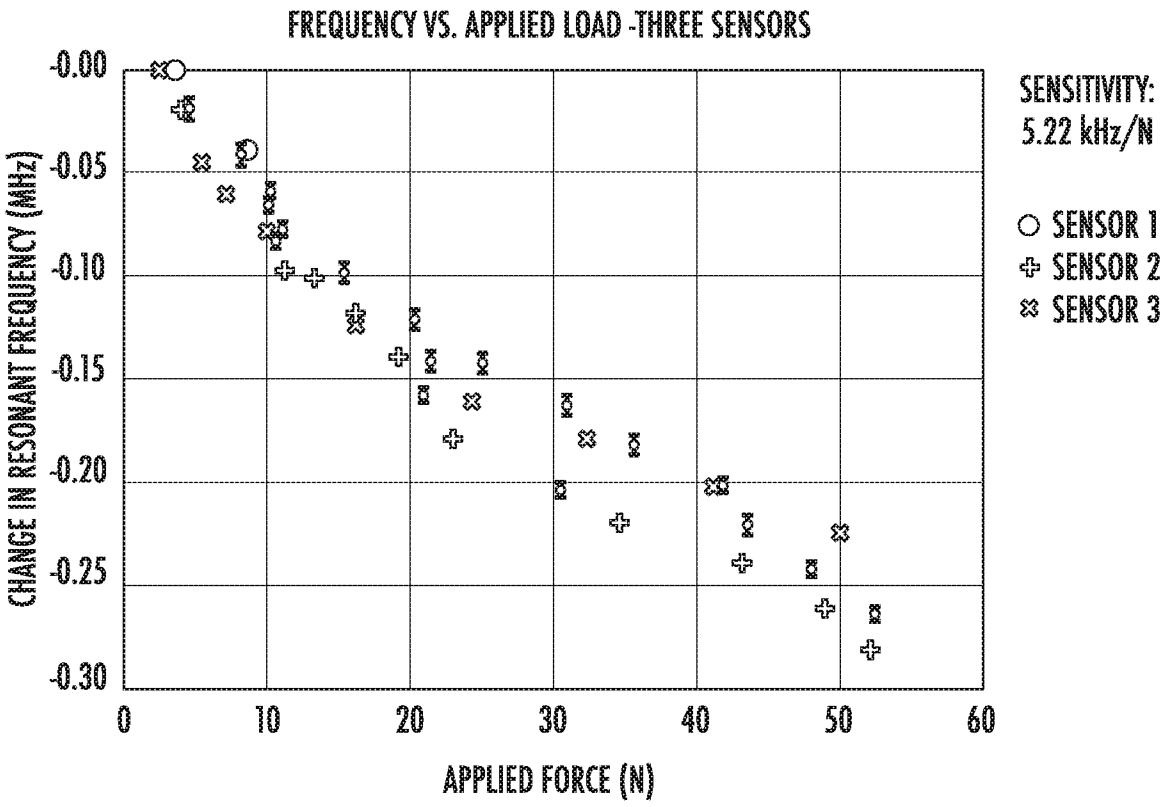
FREQUENCY VS. APPLIED LOAD -THREE SENSORS
CHANGE IN RESONANT FREQUENCY (MHz)
-0.00
-0.05
-0.10
-0.15
-0.20
-0.25
-0.30
0
10
20
30
40
50
60
APPLIED FORCE (N)
SENSITIVITY:
5.22 kHz/N
SENSOR 1
SENSOR 2
SENSOR 3

FIG. 15