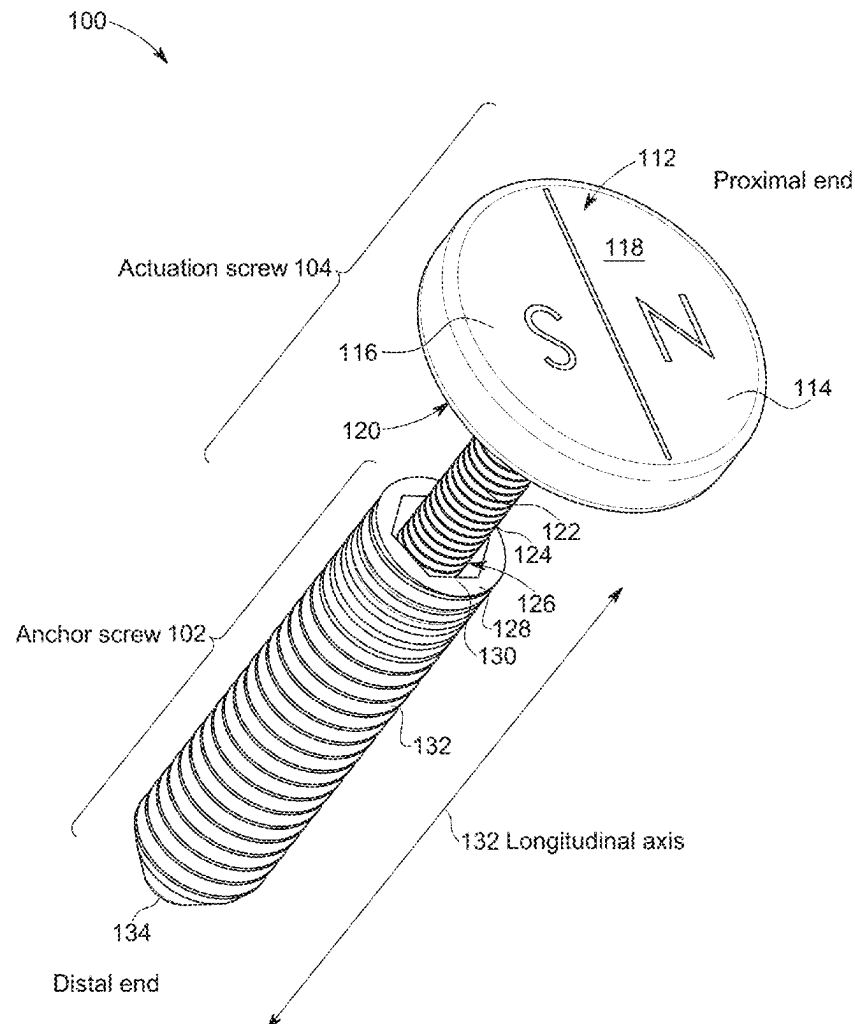




US 20250261969A1

(19) **United States**(12) **Patent Application Publication**
Cheng et al.(10) **Pub. No.: US 2025/0261969 A1**(43) **Pub. Date: Aug. 21, 2025**(54) **MAGNETICALLY ACTUATED SYSTEMS
AND DEVICES FOR PERFORMING
DISTRACTION HISTOGENESIS SURGICAL
PROCEDURES****Publication Classification**(51) **Int. Cl.***A61B 17/66* (2006.01)*A61B 17/00* (2006.01)(52) **U.S. Cl.**CPC *A61B 17/66* (2013.01); *A61B 2017/00477*
(2013.01); *A61B 2017/00876* (2013.01)(71) Applicant: **BioDynamik, Inc.**, Lake Forest, CA
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(US); **Emmon Johnny Chen**, Lake
Forest, CA (US)(73) Assignee: **BioDynamik, Inc.**, Lake Forest, CA
(US)(21) Appl. No.: **19/054,227**(22) Filed: **Feb. 14, 2025****Related U.S. Application Data**(60) Provisional application No. 63/554,970, filed on Feb.
17, 2024.(57) **ABSTRACT**

Systems, methods, and devices for performing a distraction histogenesis surgical procedure. A system includes an anchor screw comprising a hollow interior defined by a sidewall, wherein the anchor screw comprises internal actuation threading attached to an interior surface of the sidewall and further comprises external anchor threading attached to an exterior surface of the sidewall. The system includes an actuation screw comprising a screw shaft that comprises external actuation threading. The system includes a magnet coupled to the actuation screw. The system is such that the external actuation threading of the screw shaft corresponds with the internal actuation threading of the anchor screw. The system is such that rotation of the magnet causes synchronous rotation of the actuation screw.



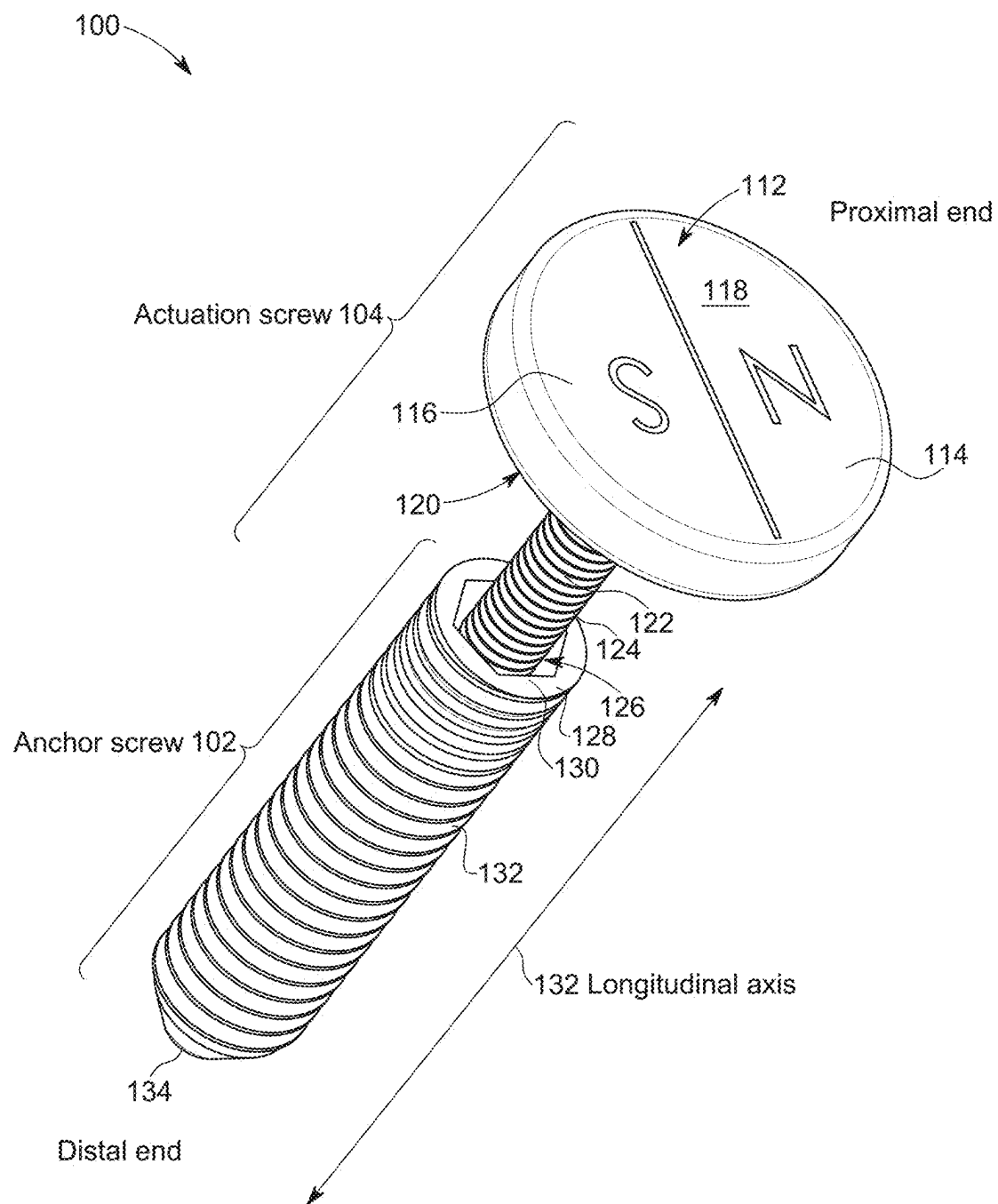


FIG. 1

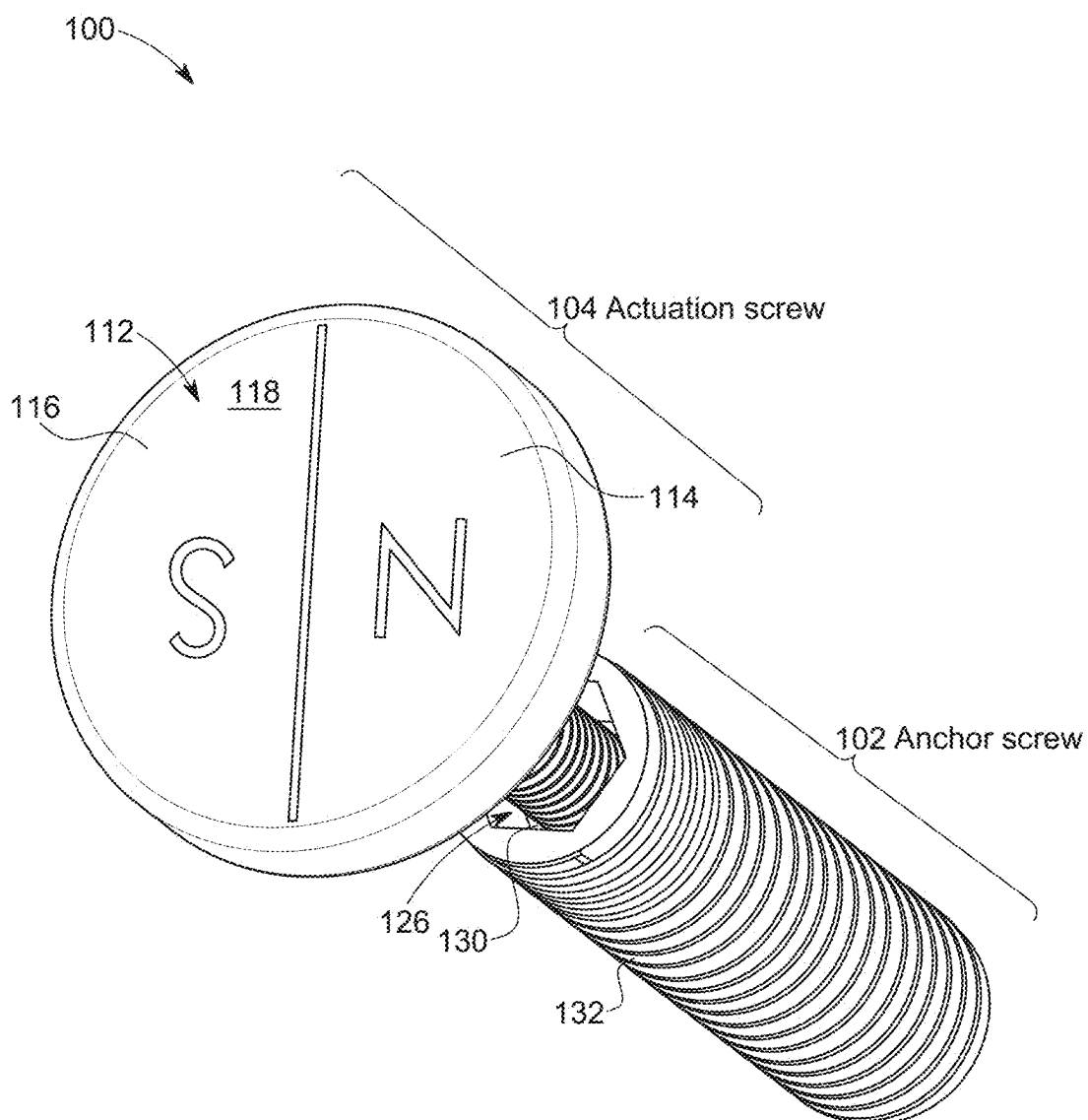


FIG. 2

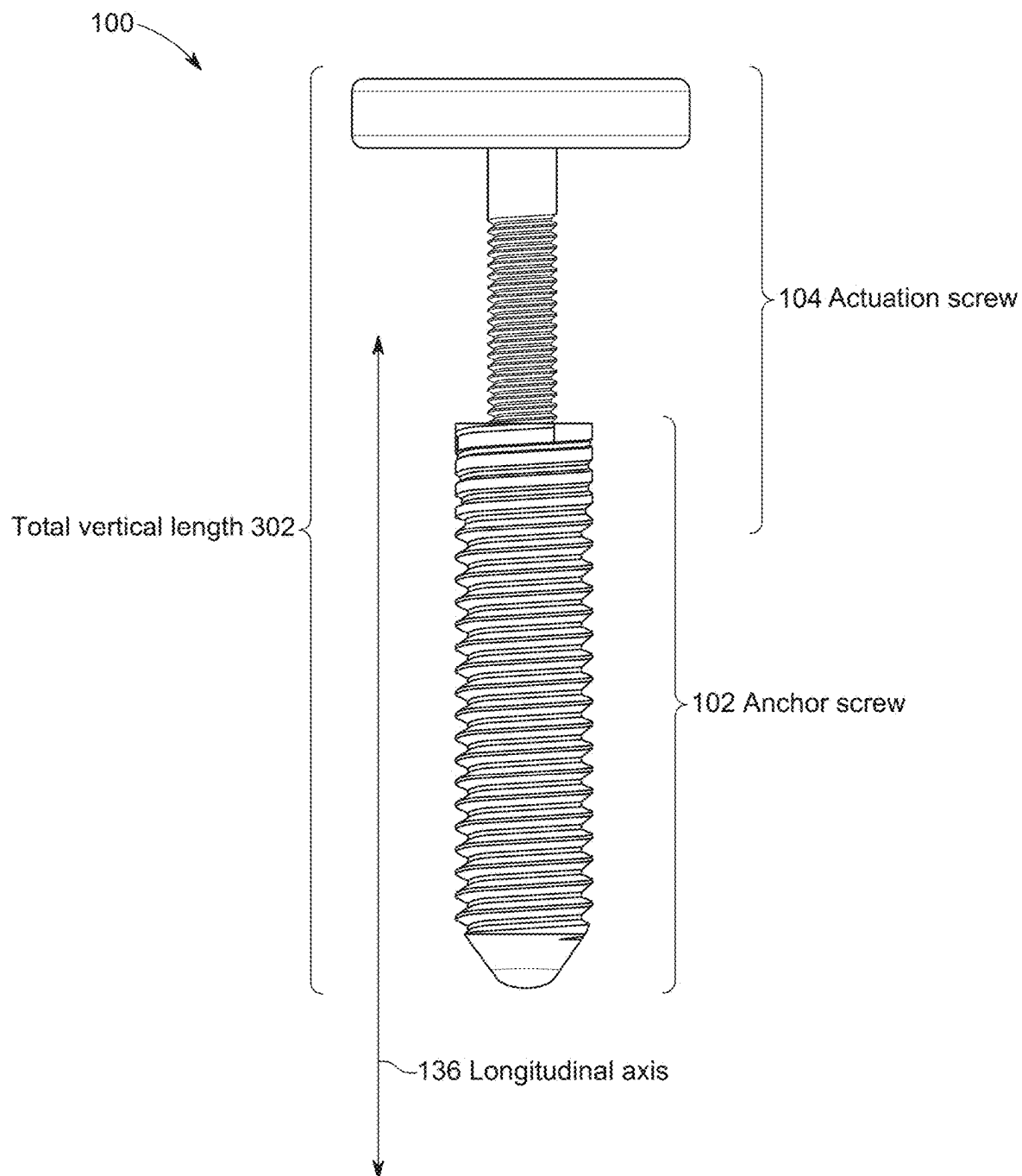


FIG. 3

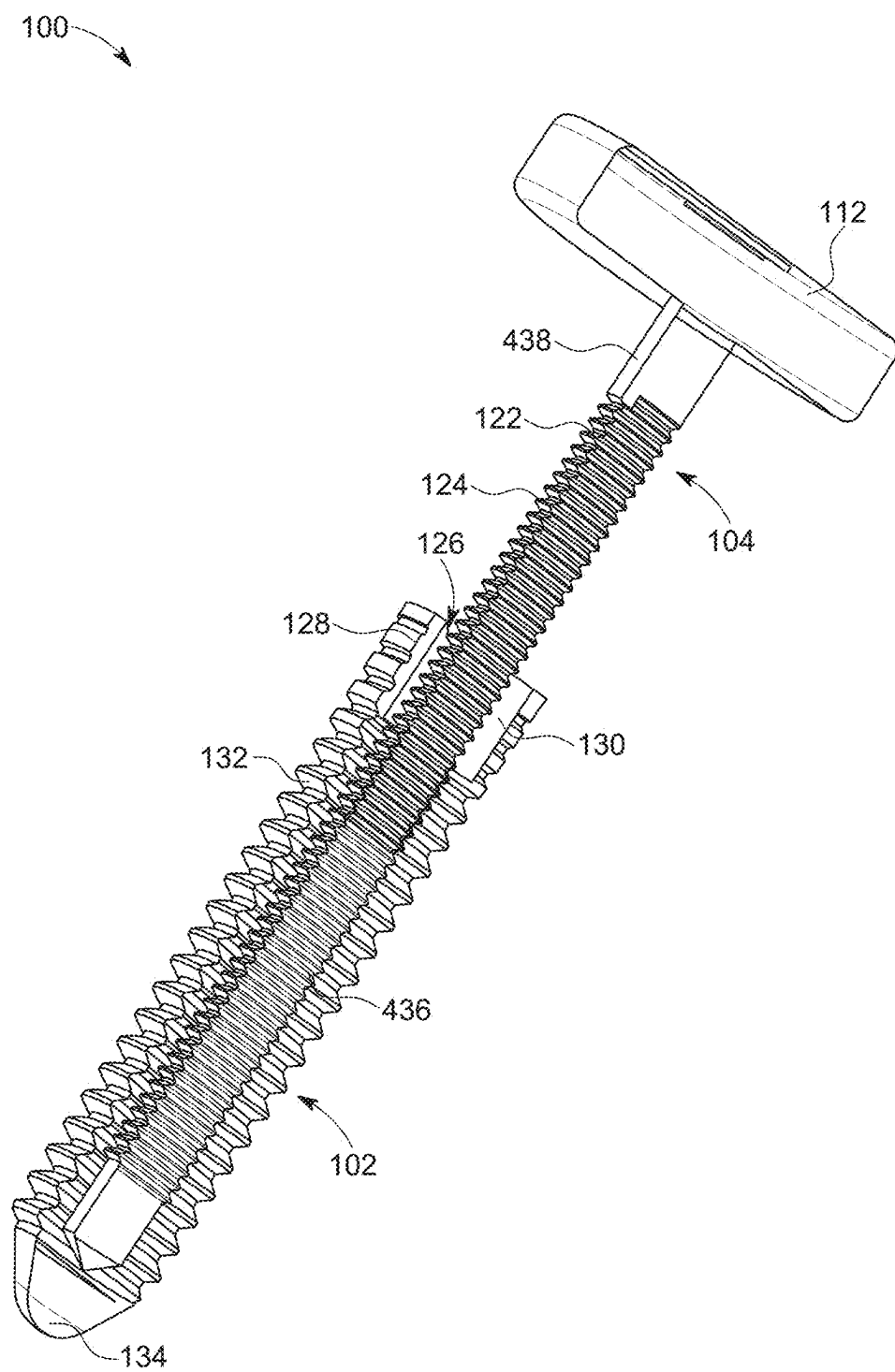


FIG. 4

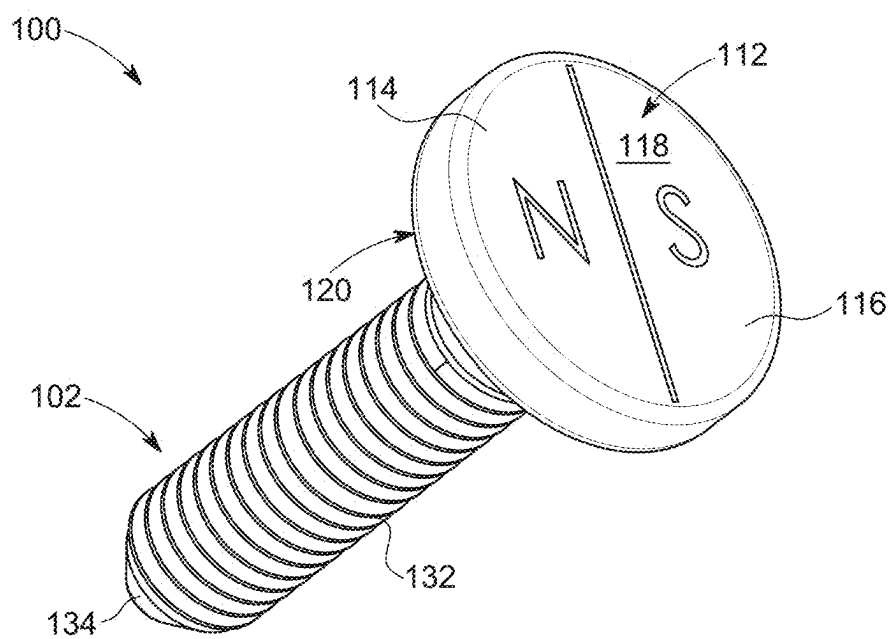


FIG. 5

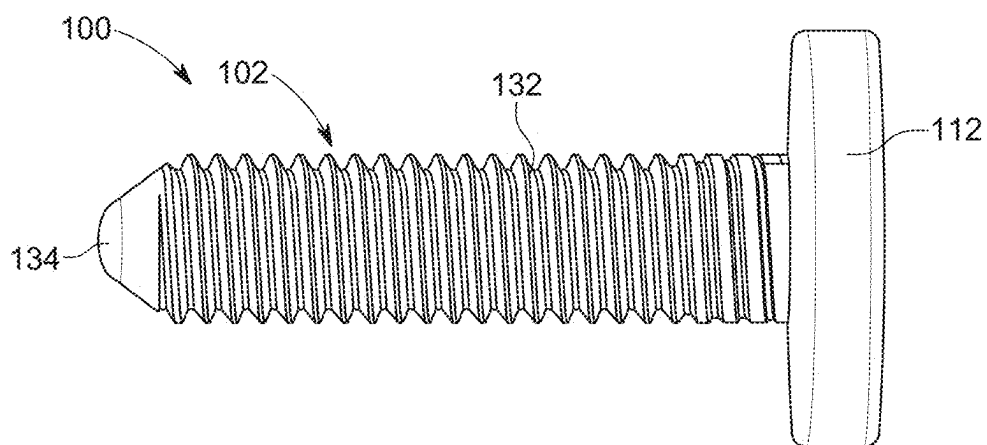


FIG. 6

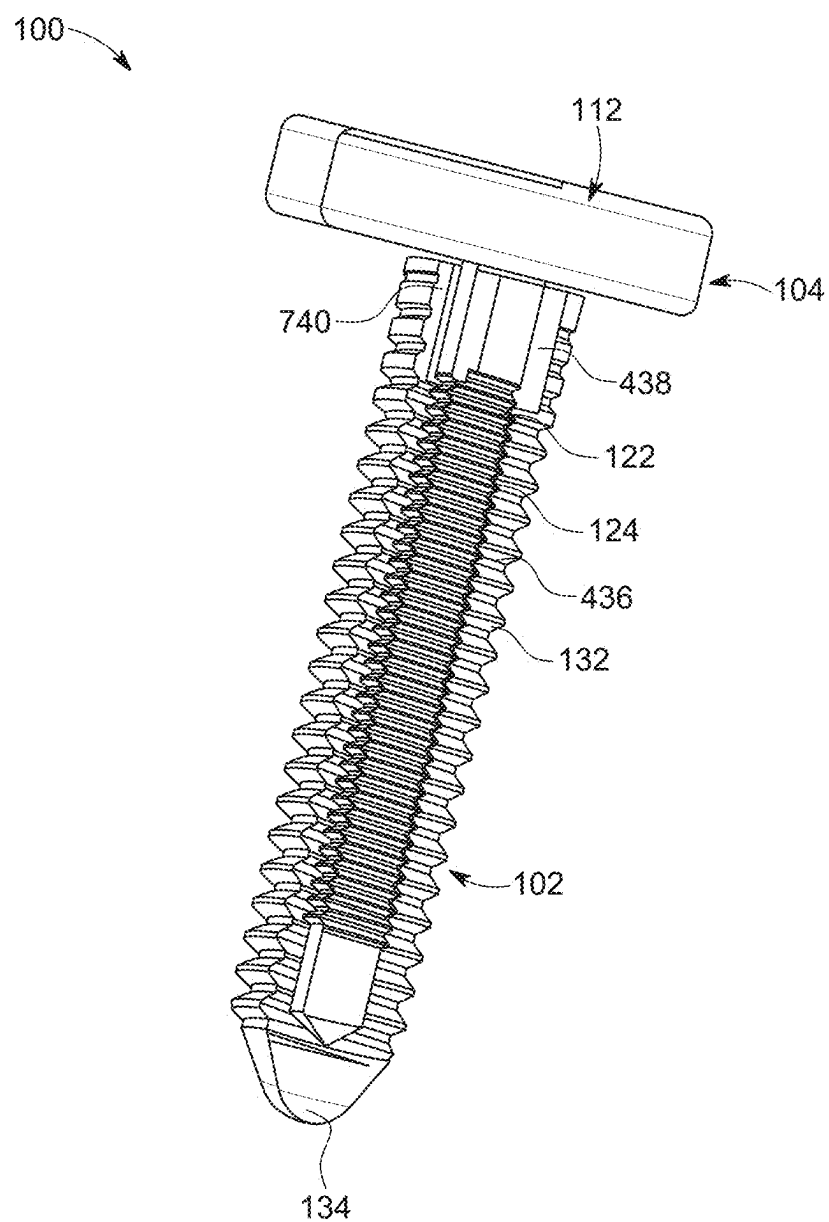


FIG. 7

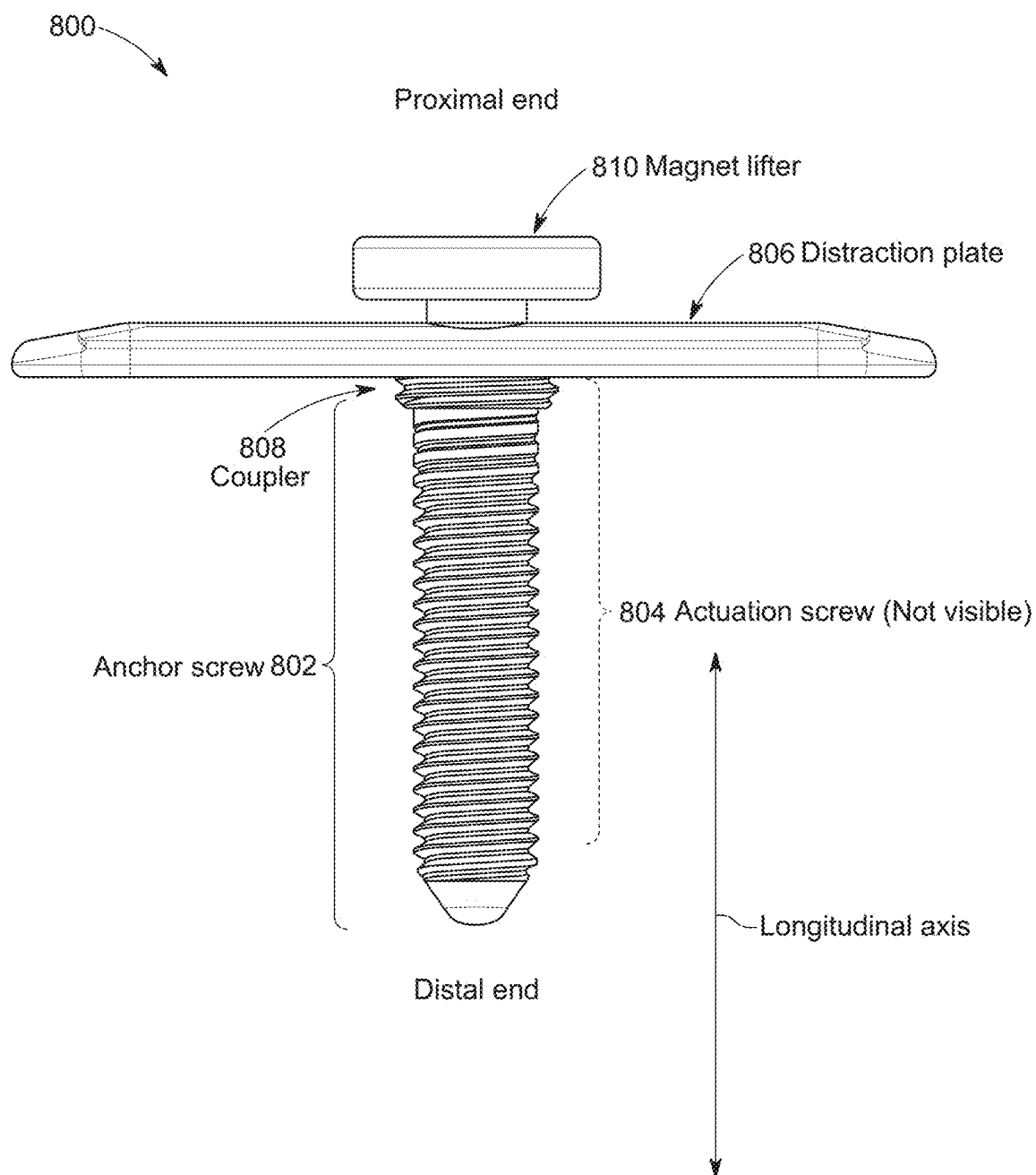


FIG. 8

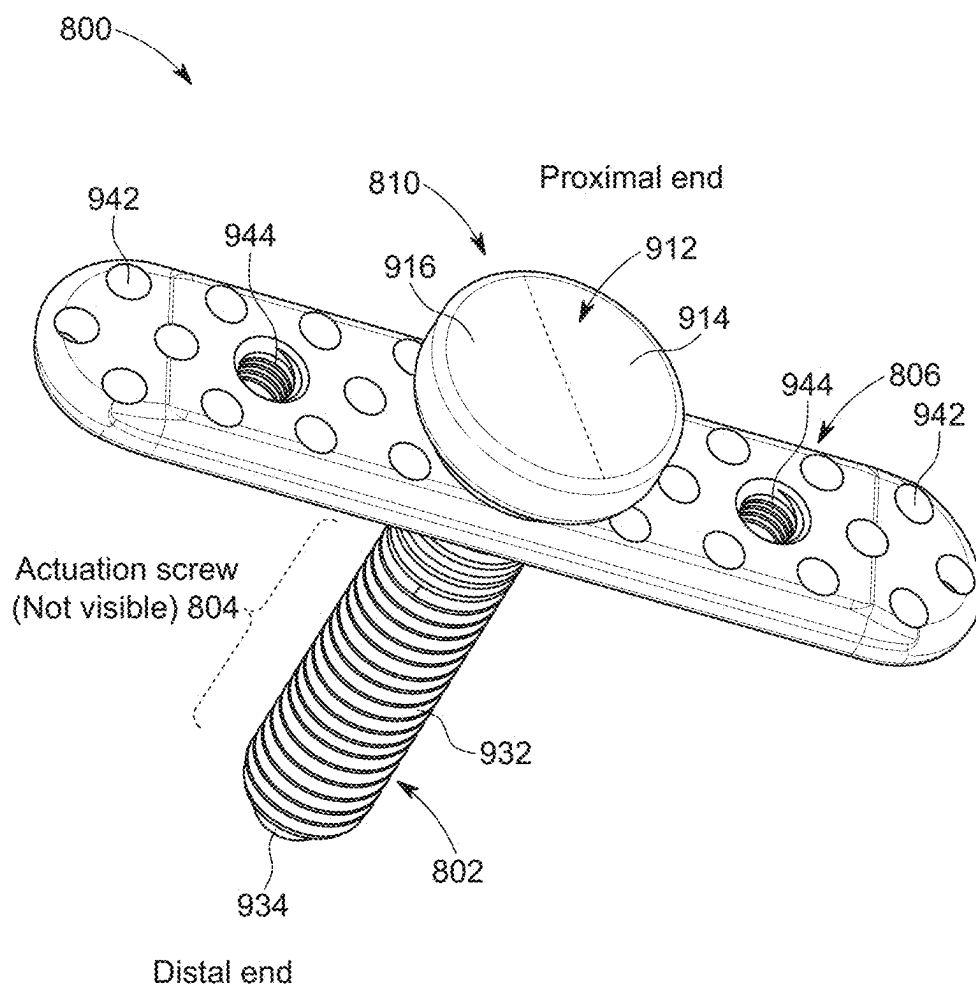


FIG. 9

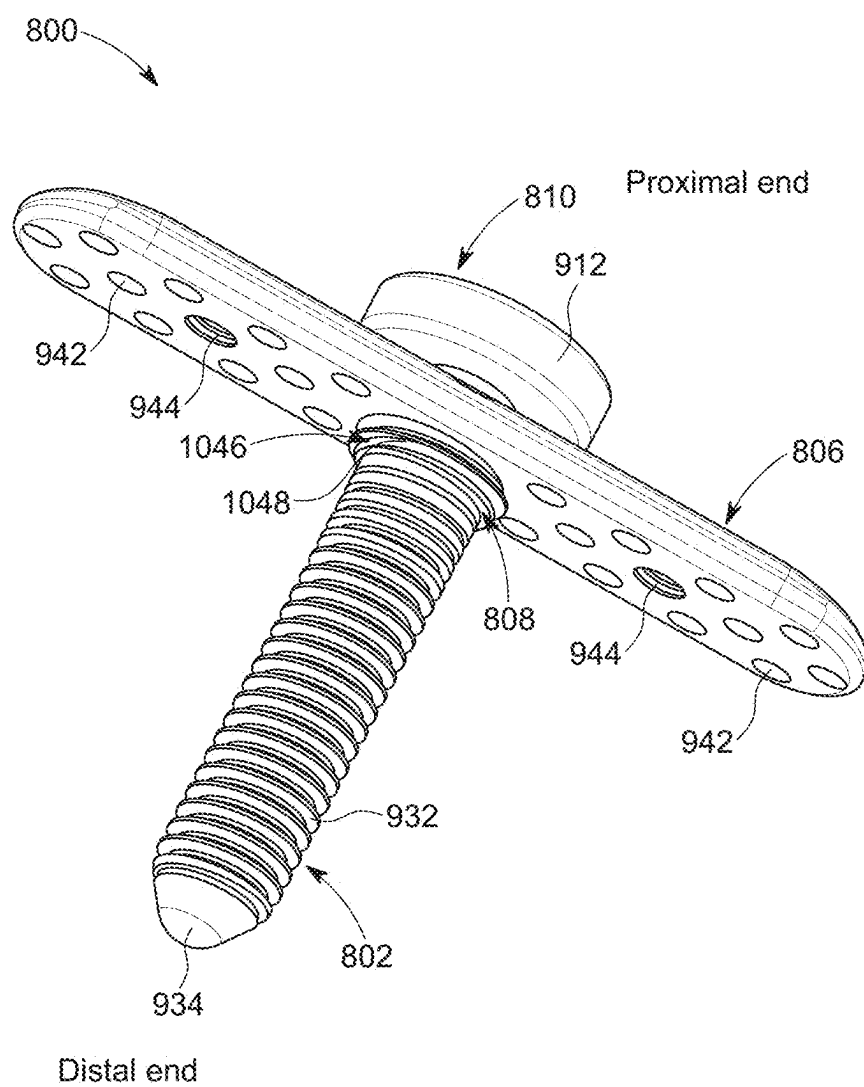


FIG. 10

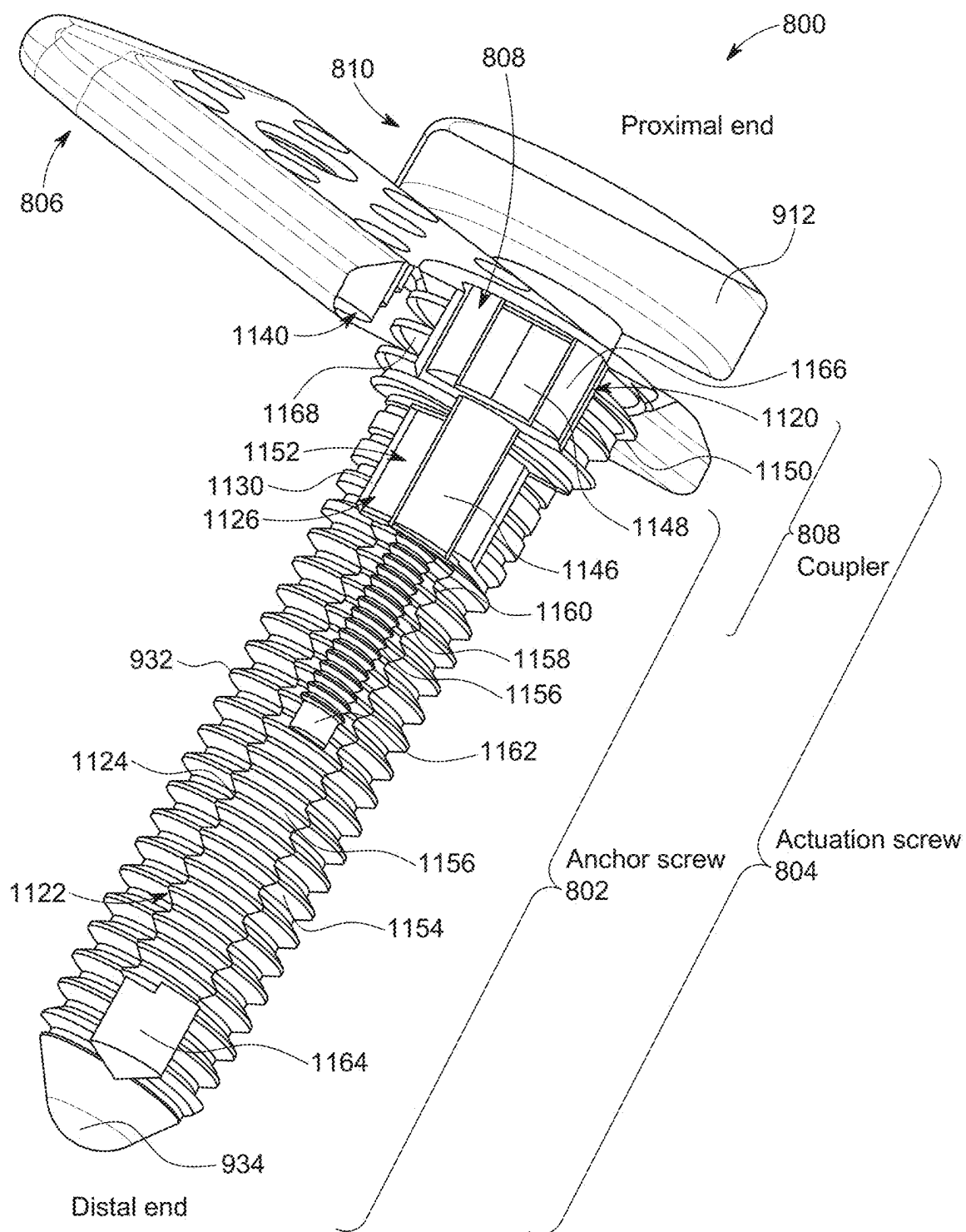


FIG. 11

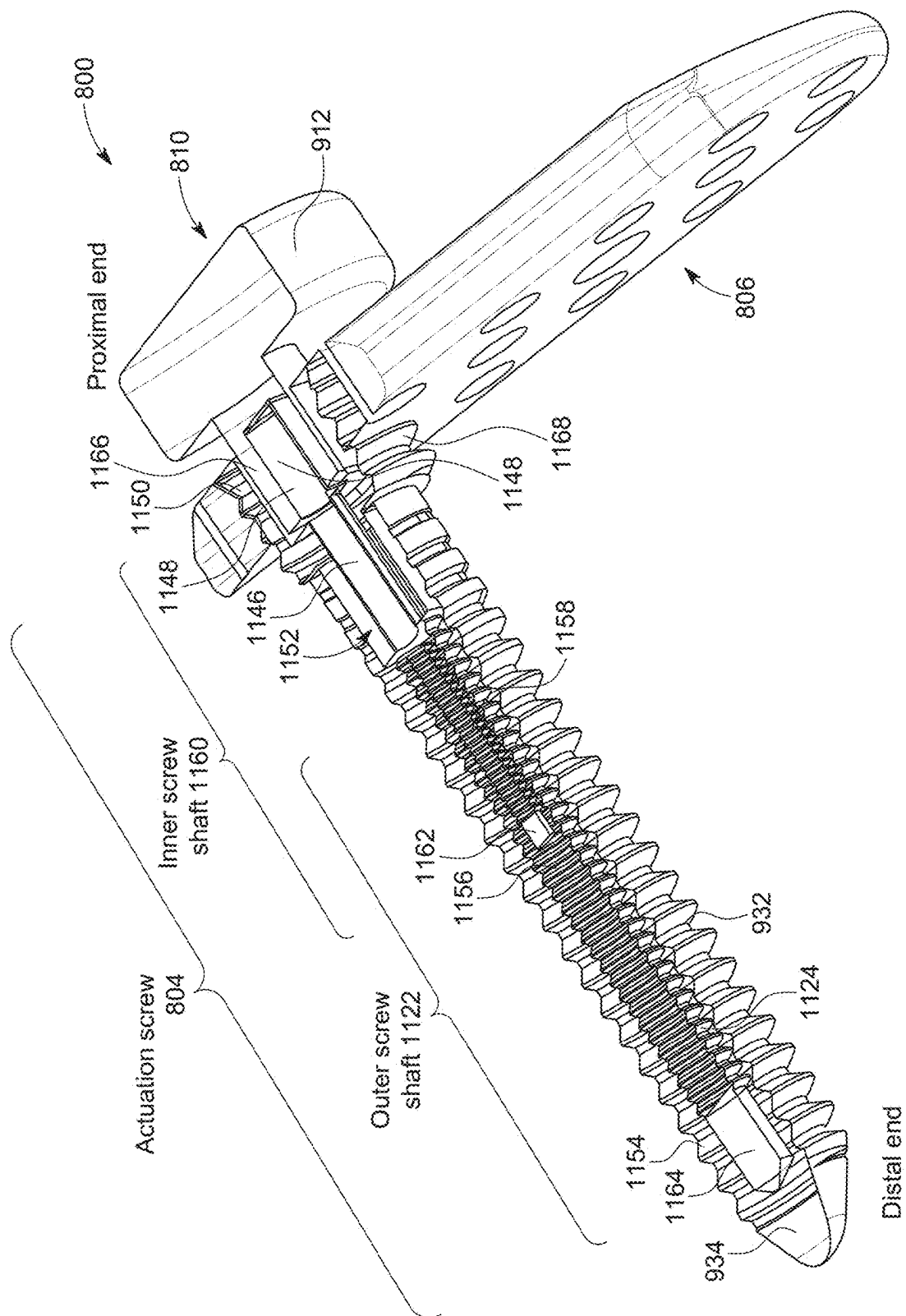


FIG. 12

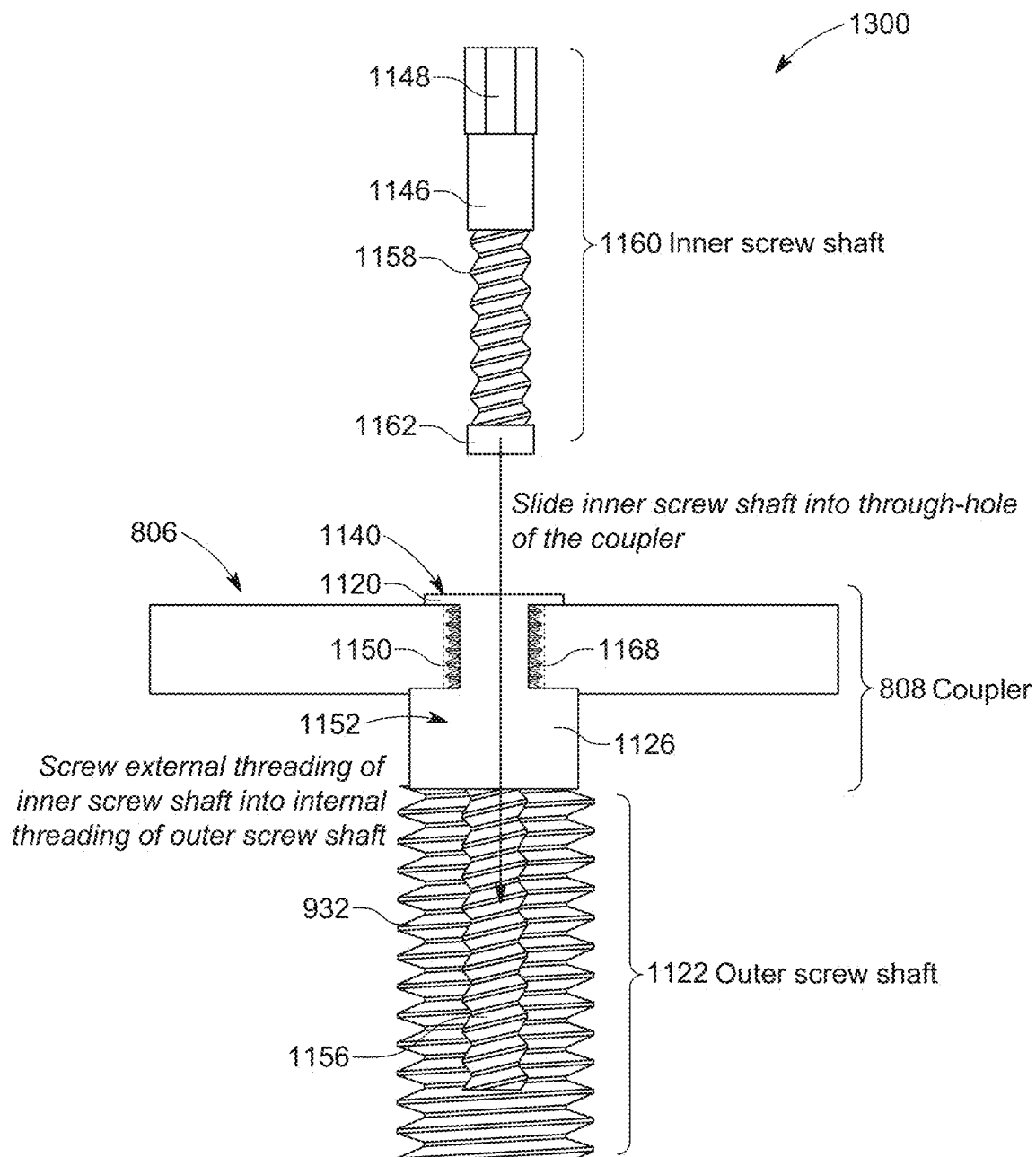


FIG. 13

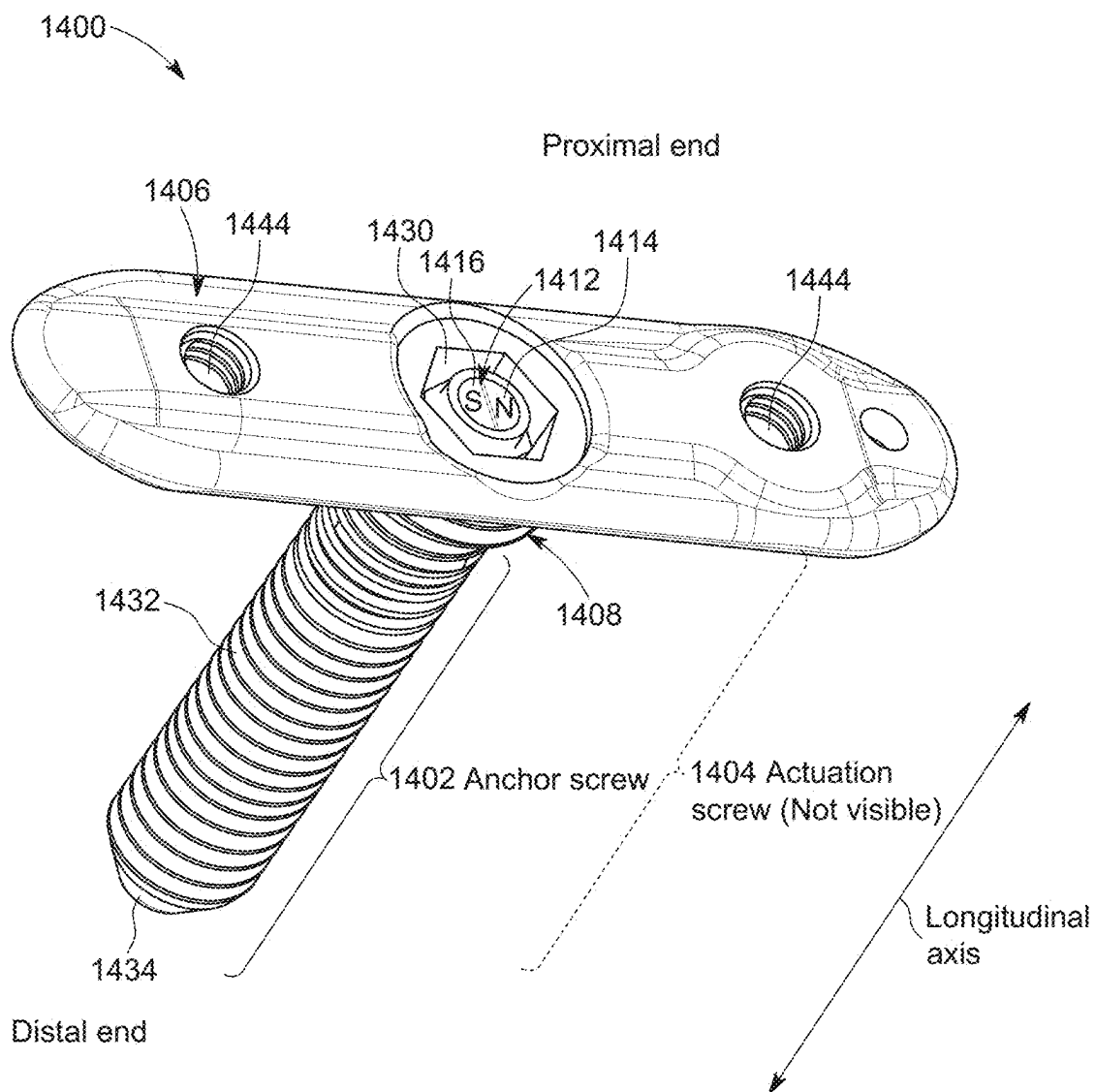


FIG. 14

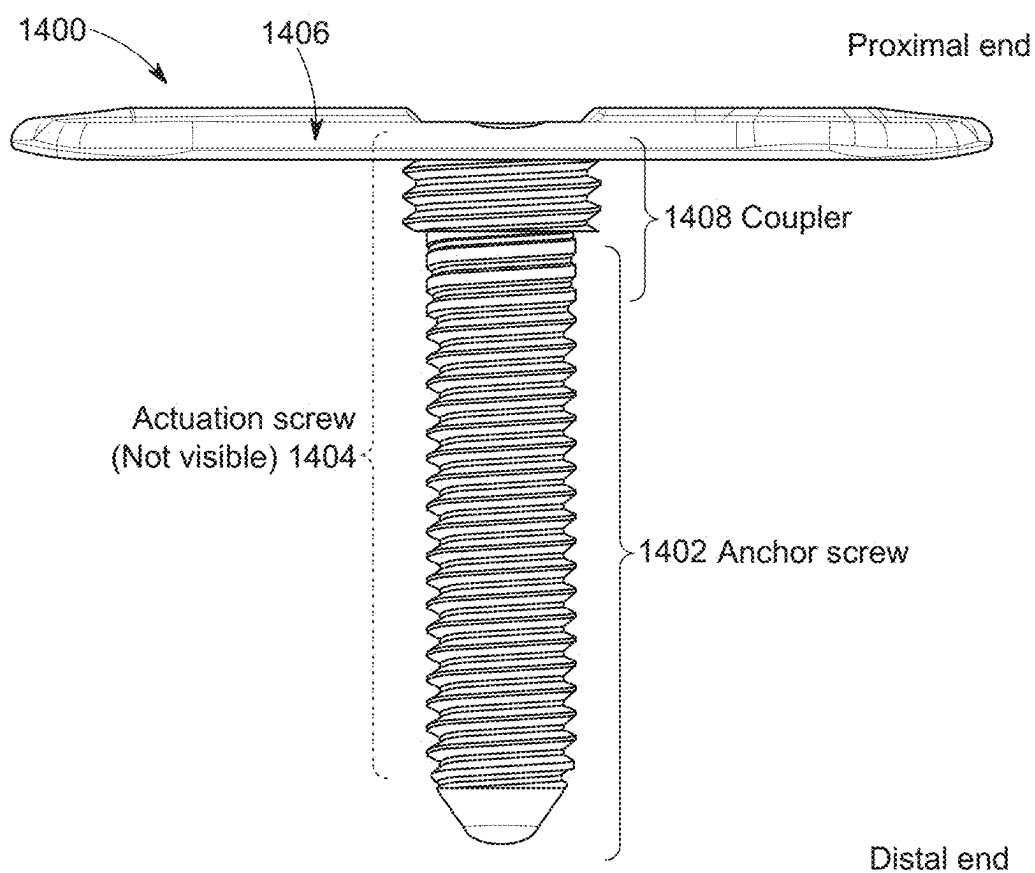


FIG. 15

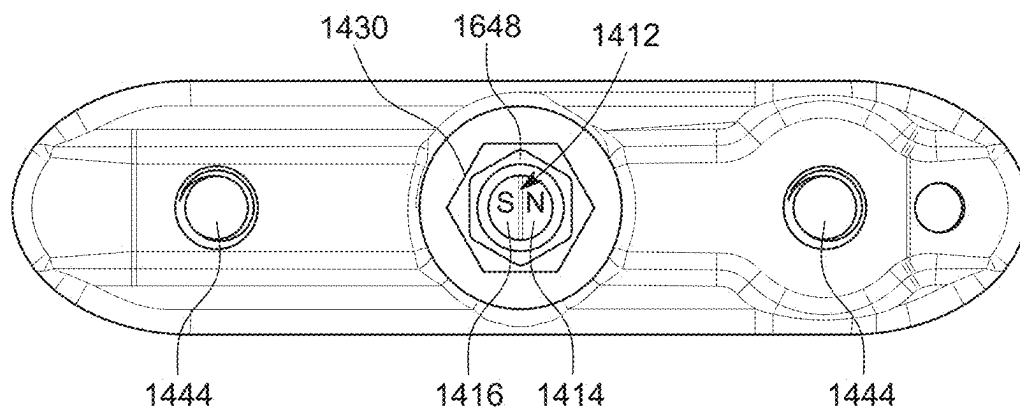


FIG. 16

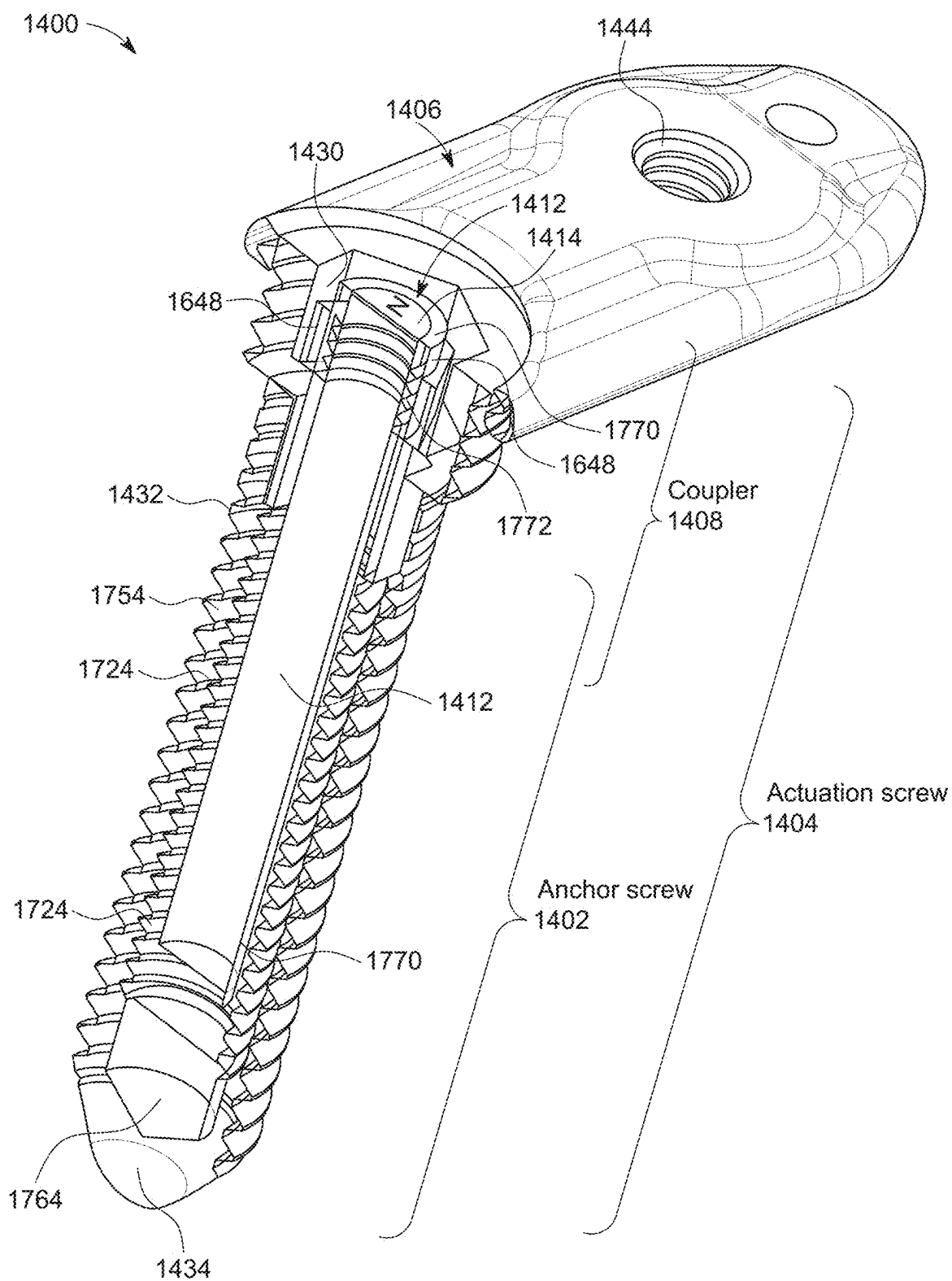


FIG. 17

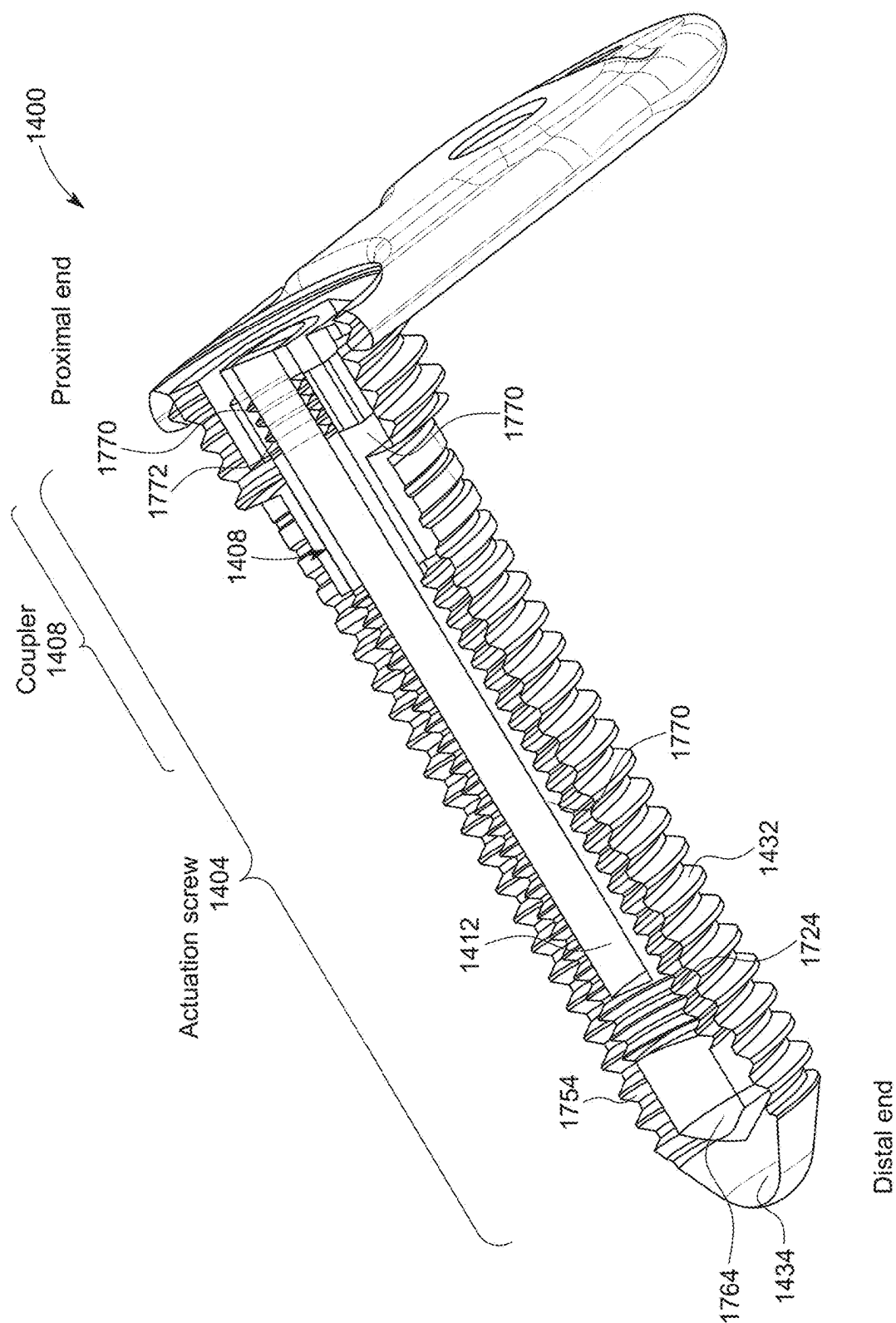


FIG. 18

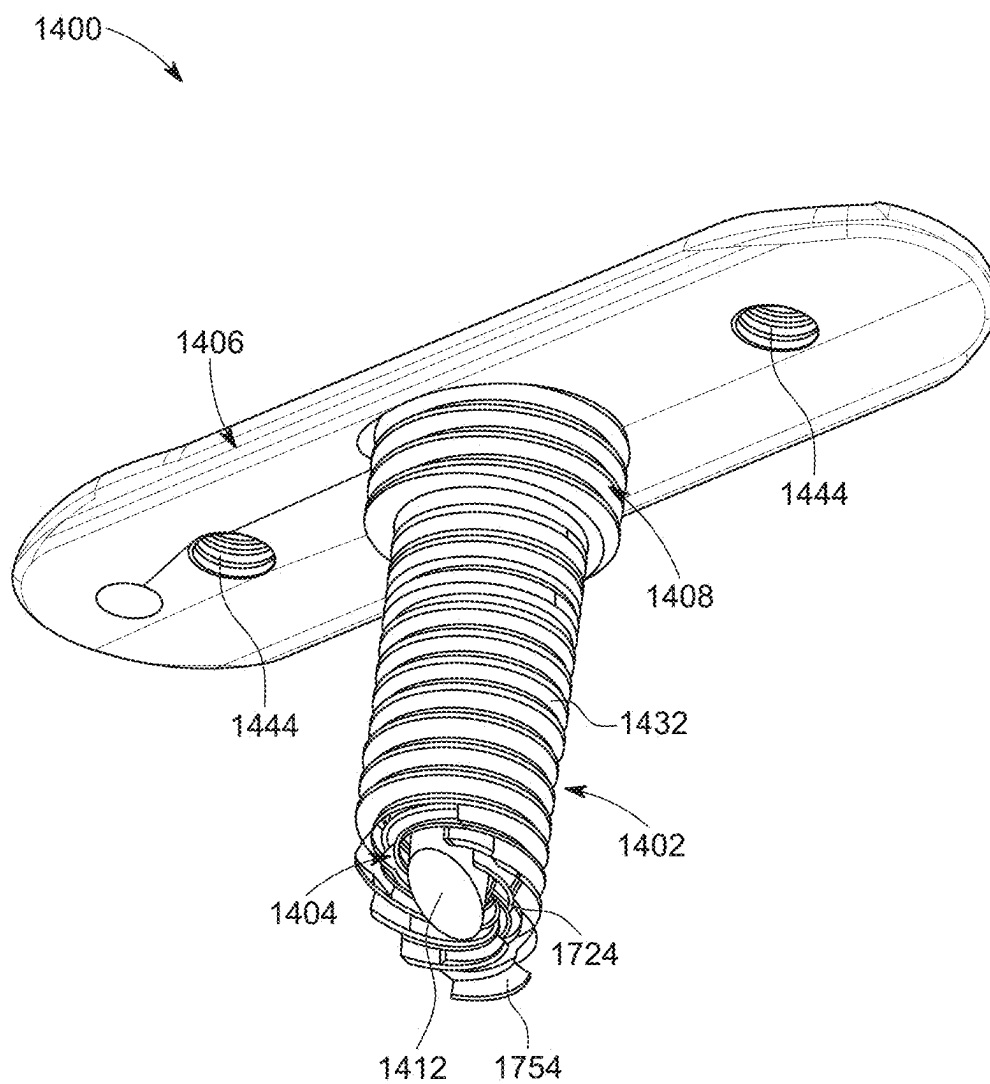


FIG. 19

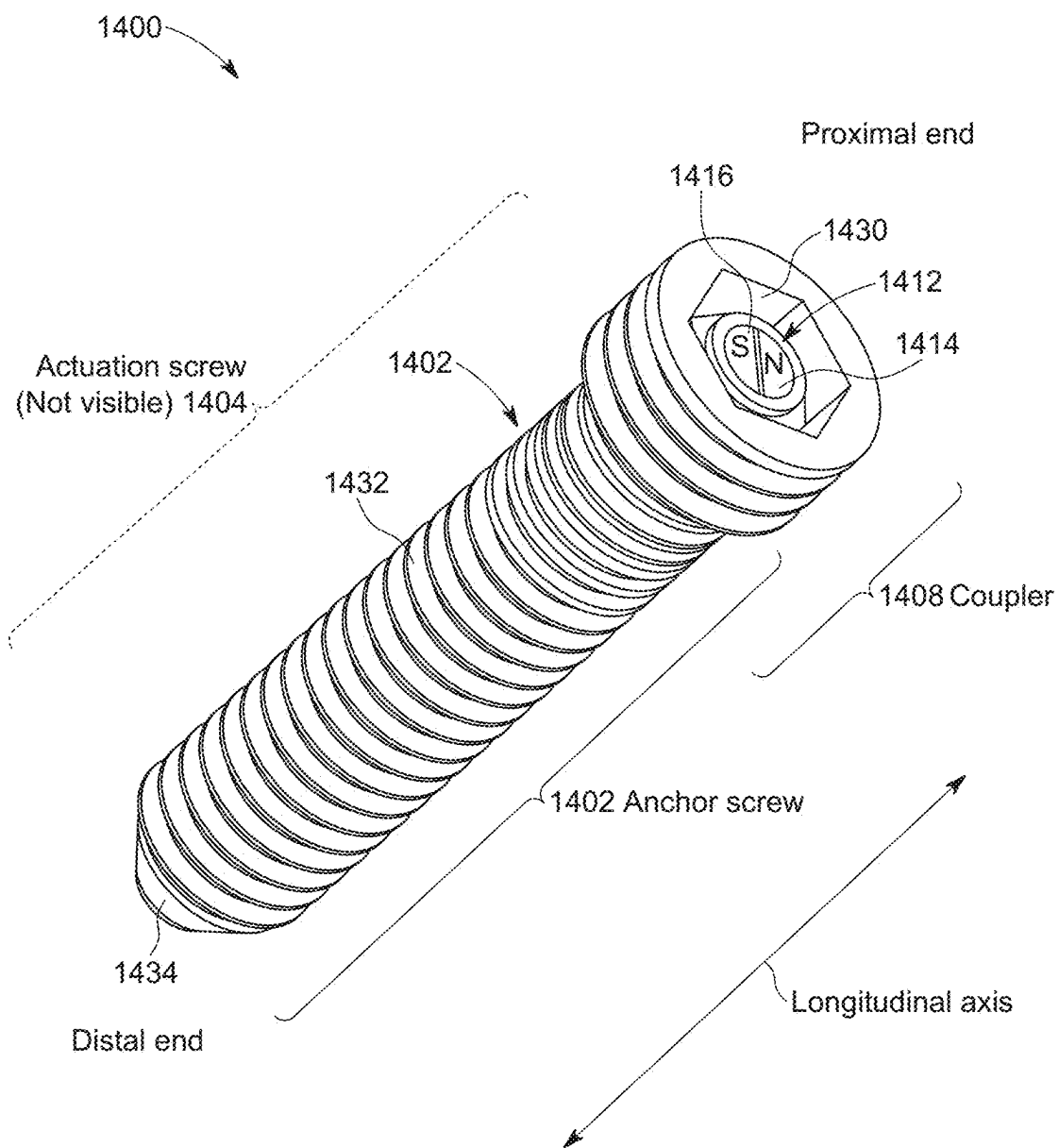


FIG. 20

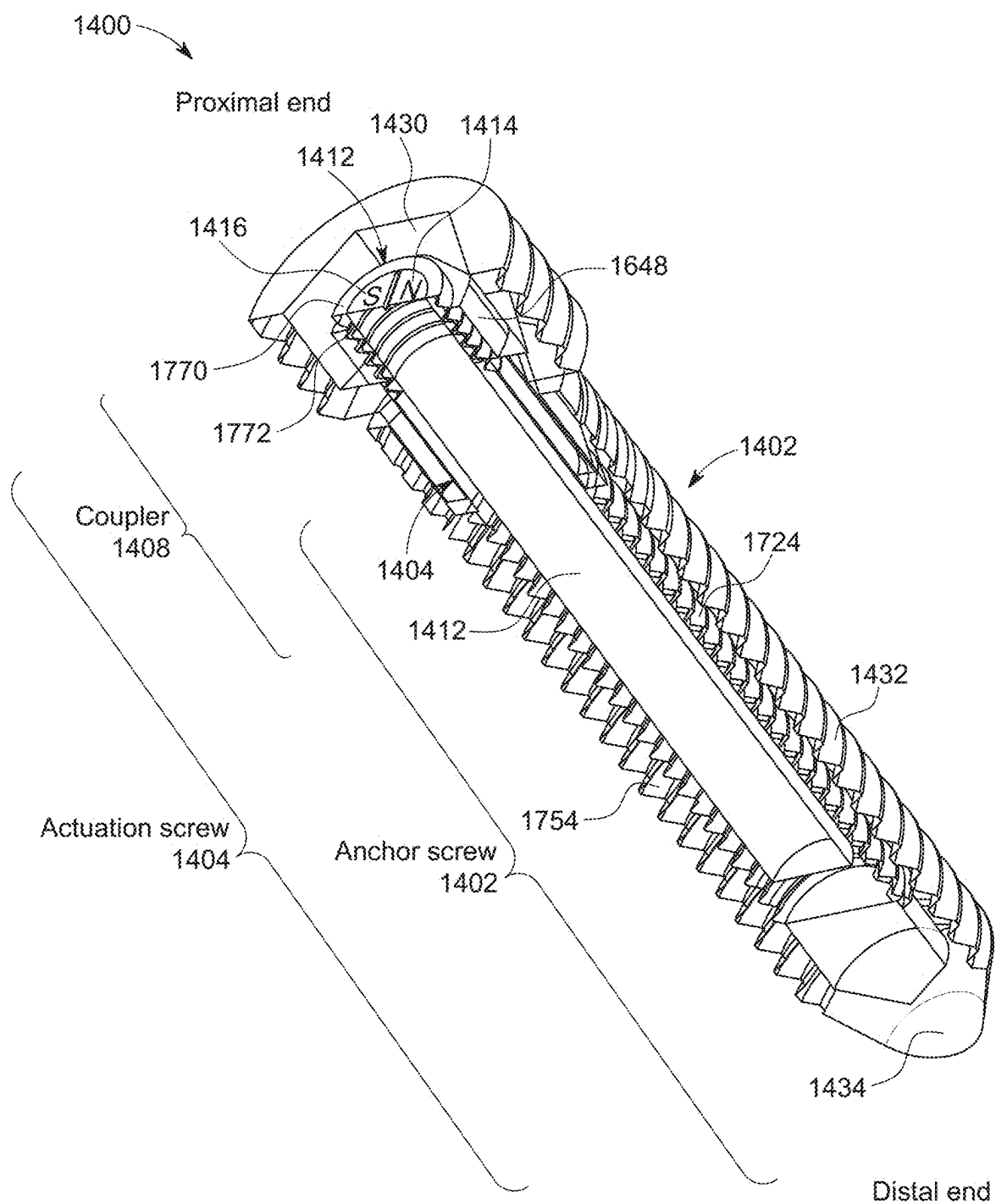


FIG. 21

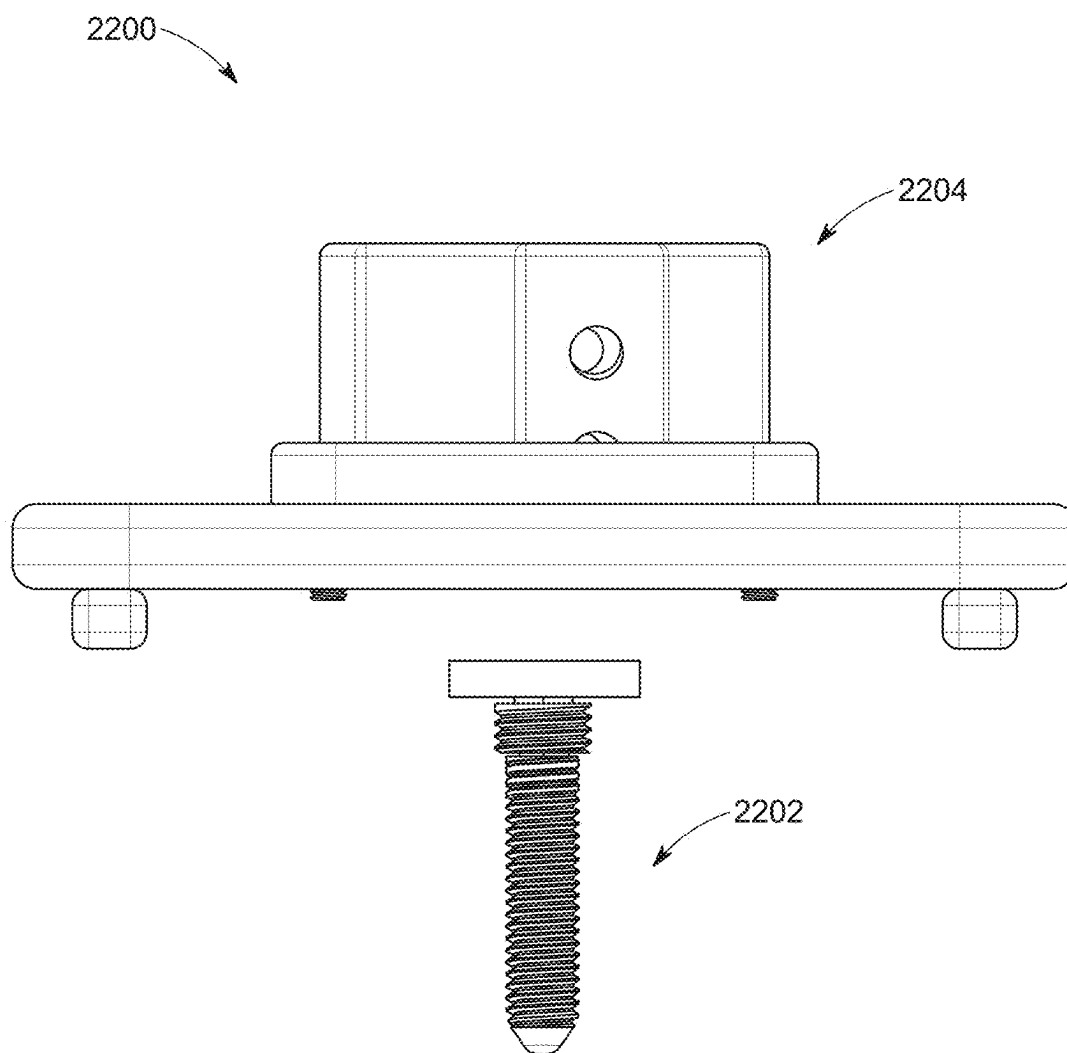


FIG. 22

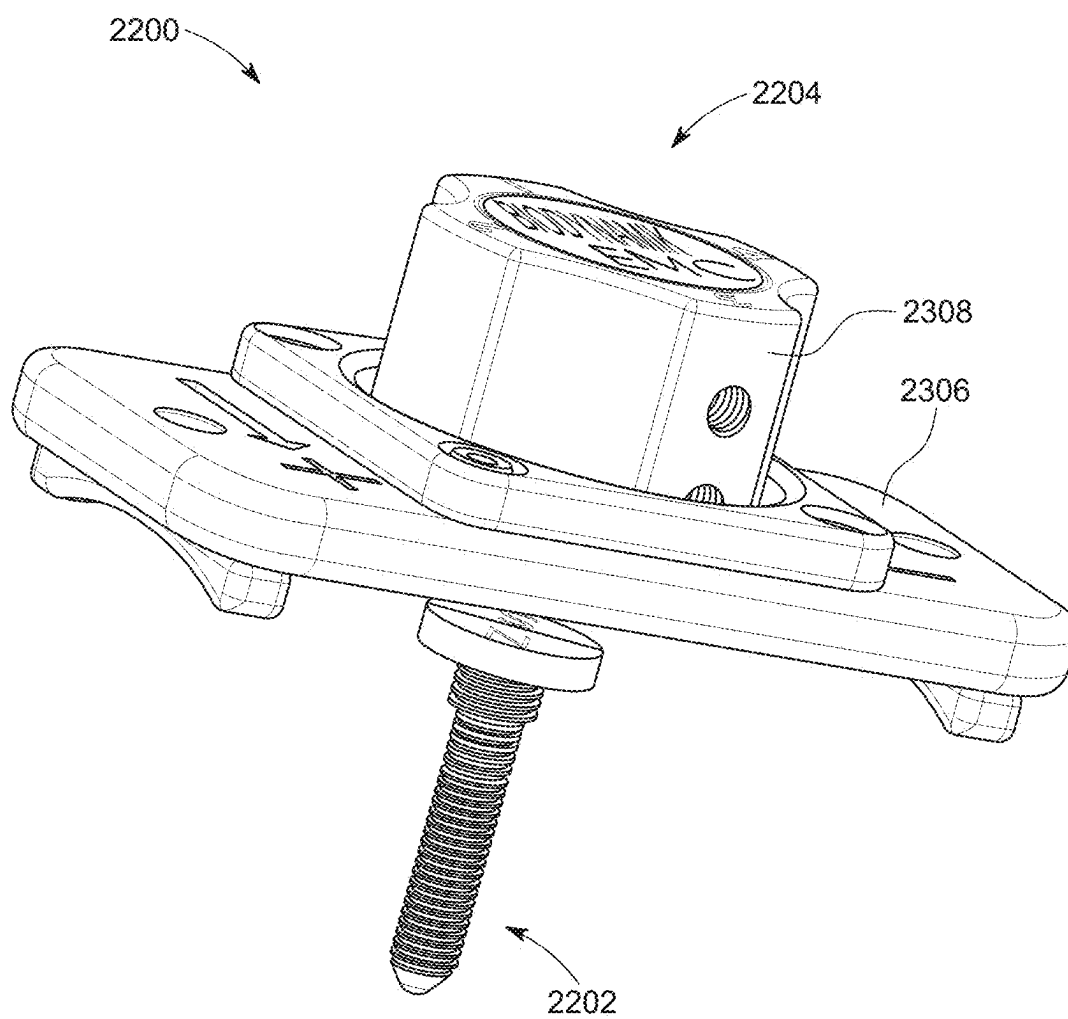


FIG. 23

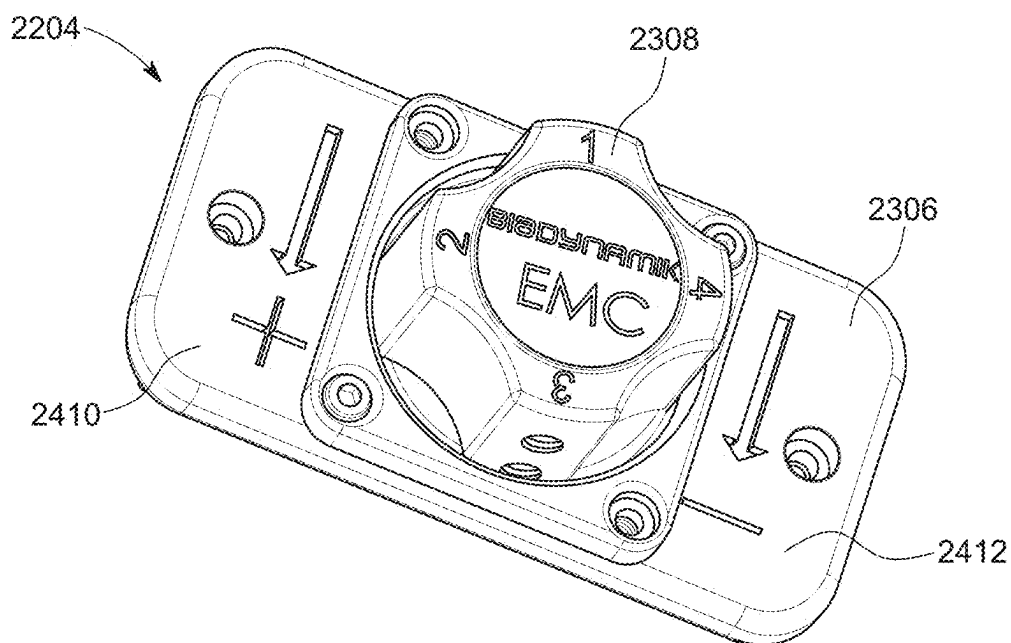


FIG. 24

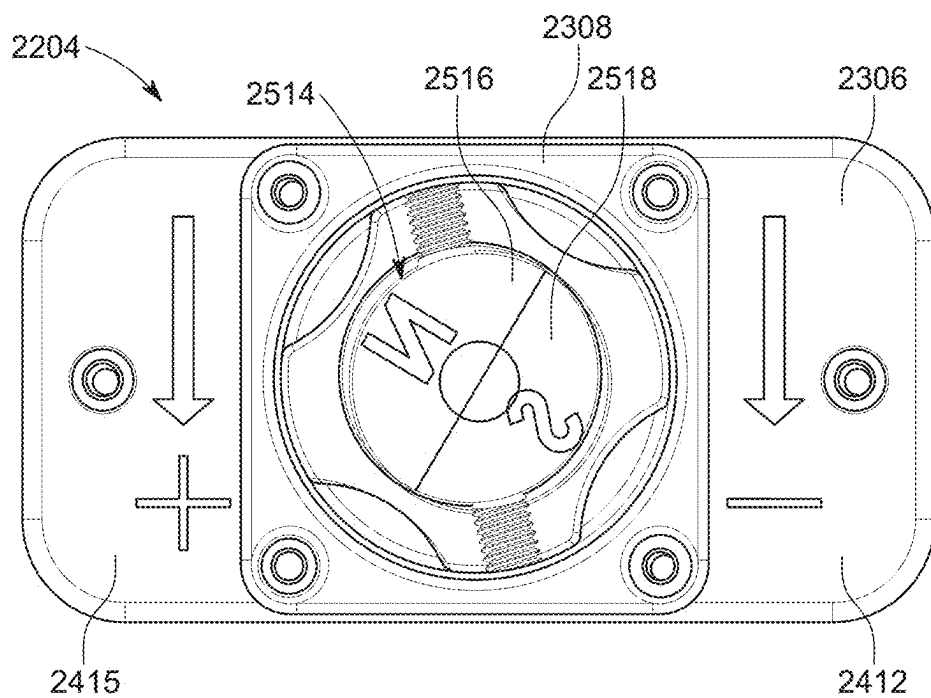


FIG. 25

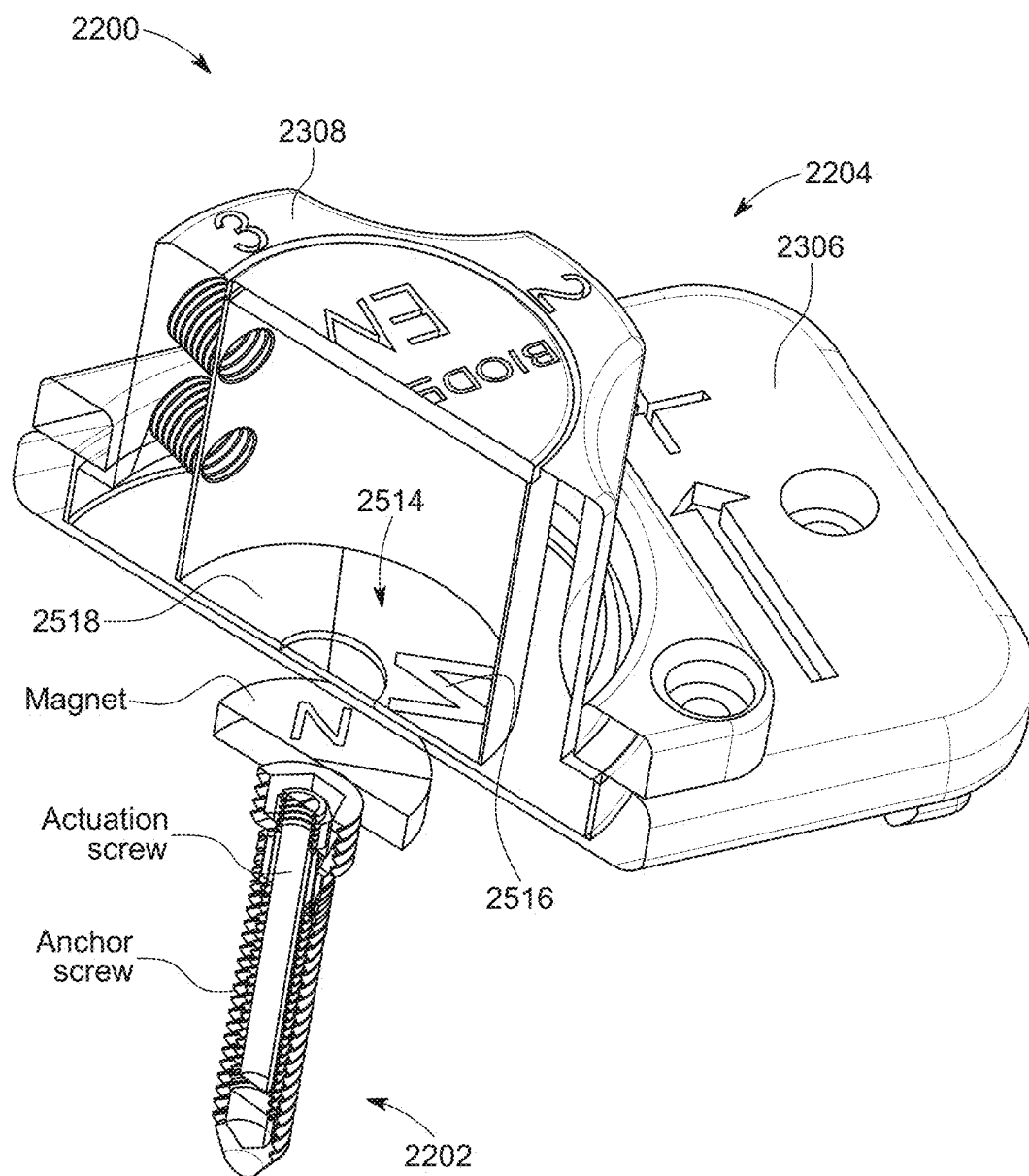


FIG. 26

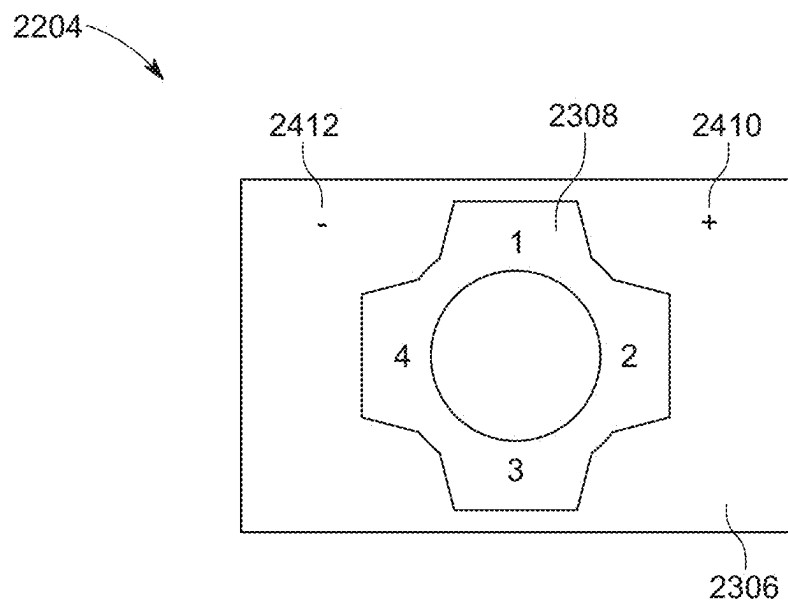


FIG. 27A

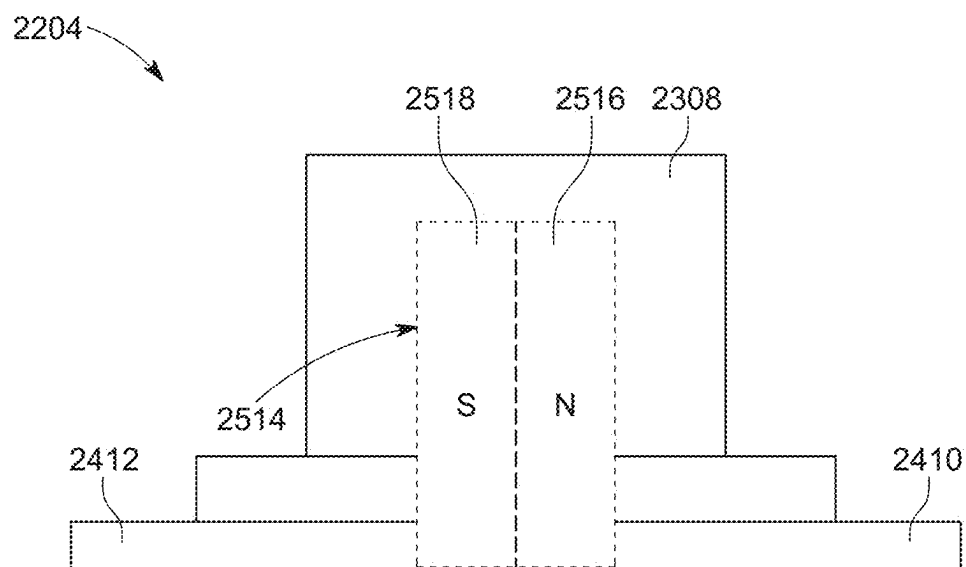


FIG. 27B

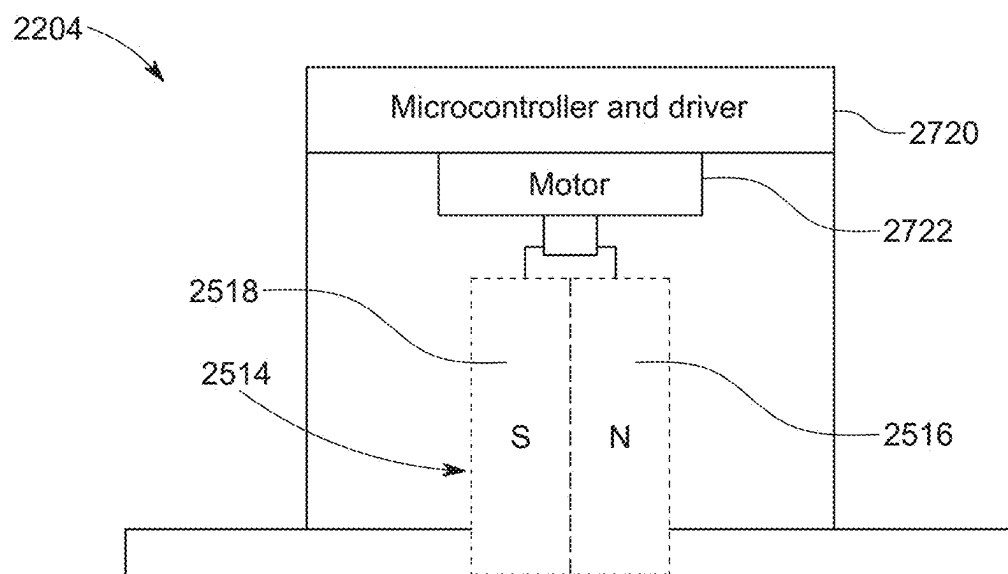


FIG. 27C

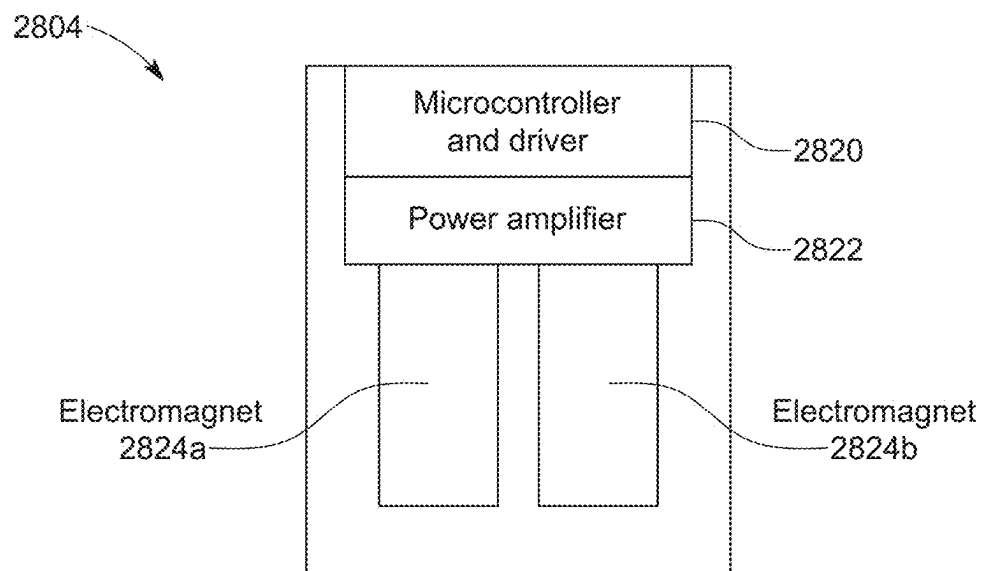


FIG. 28

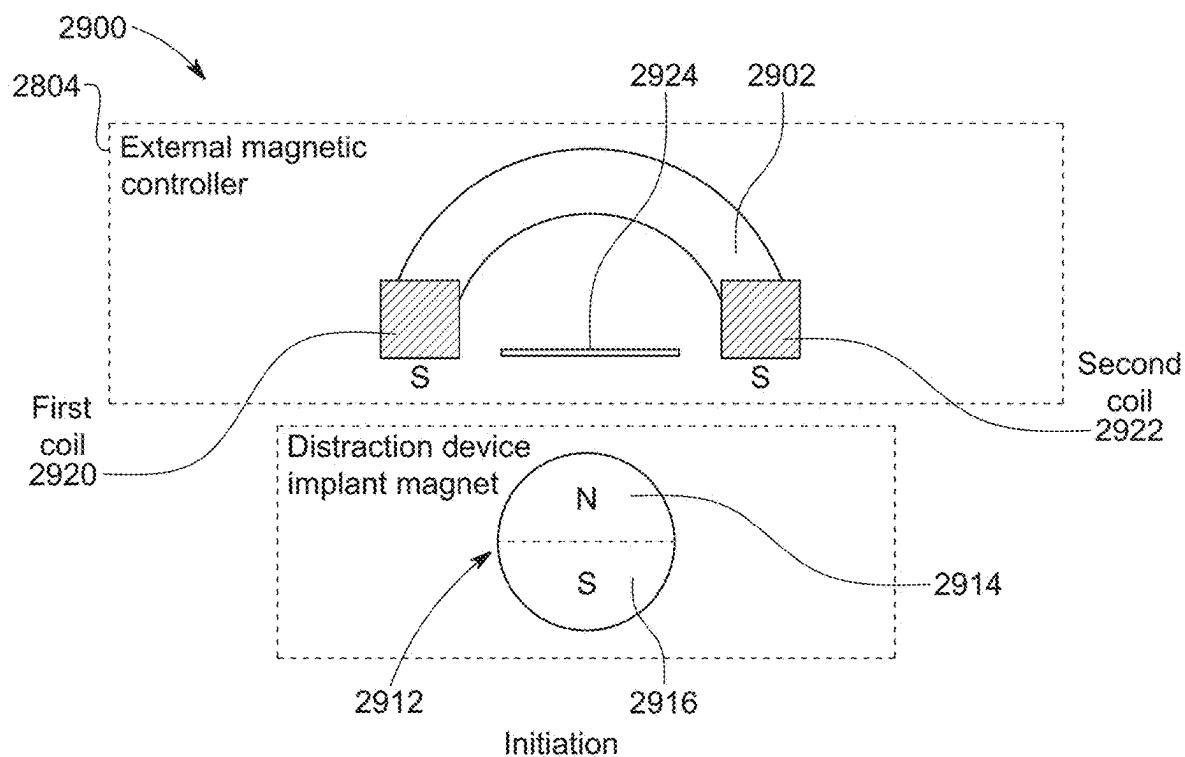


FIG. 29A

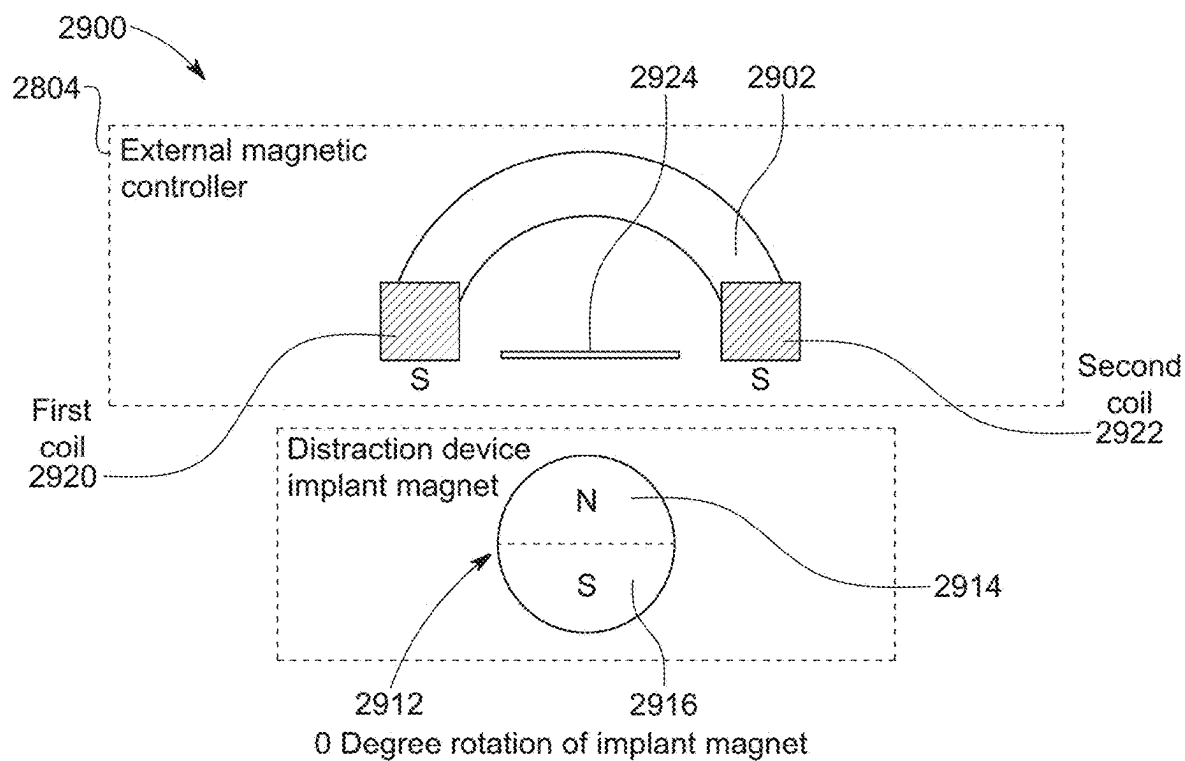


FIG. 29B

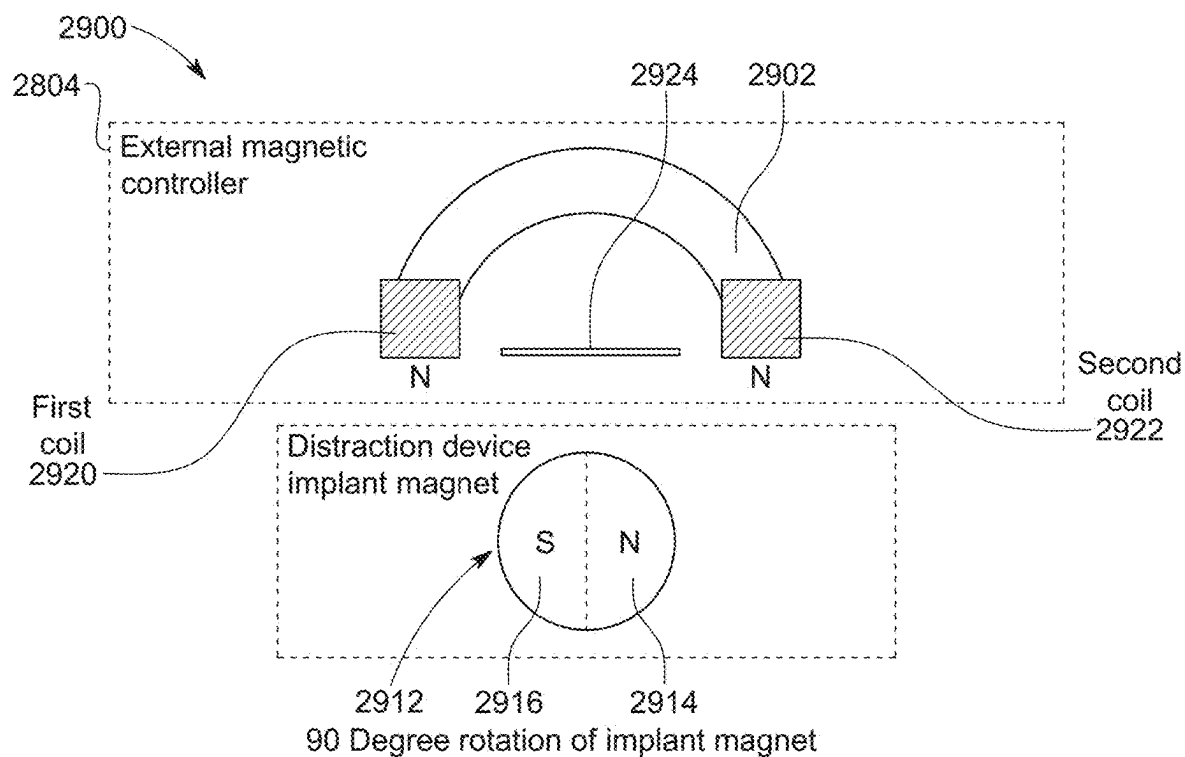


FIG. 29C

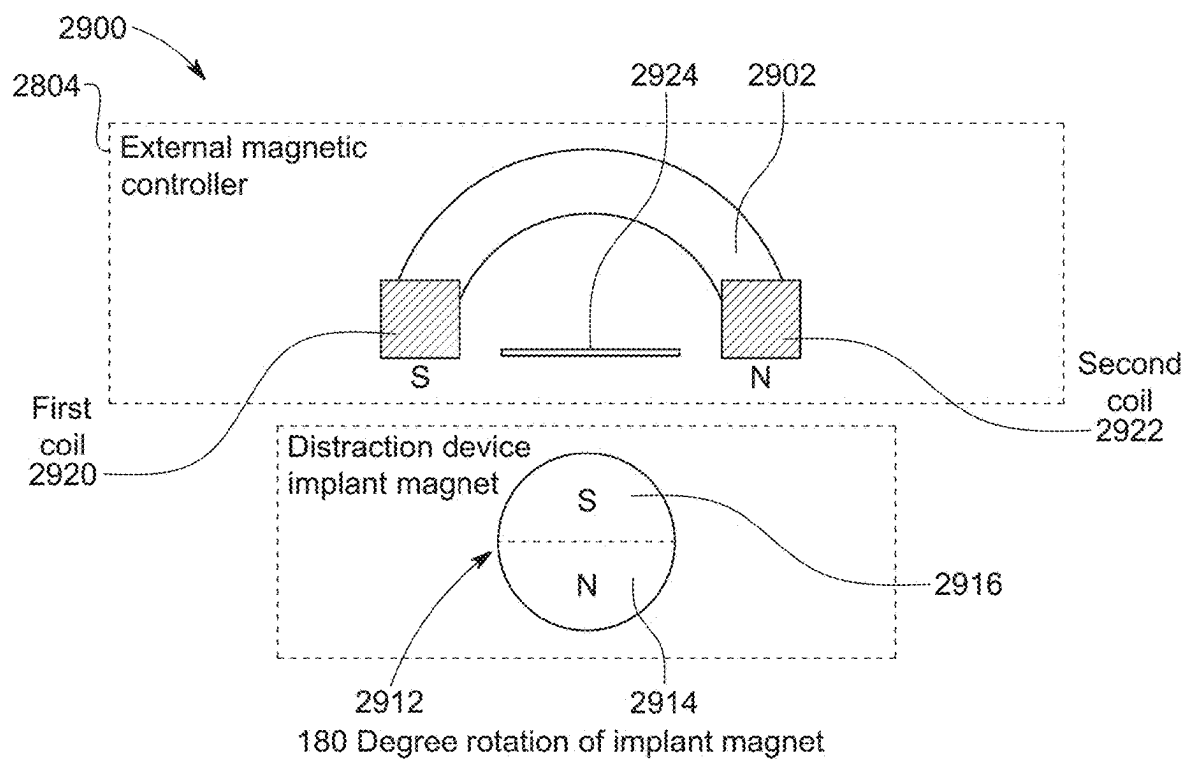


FIG. 29D

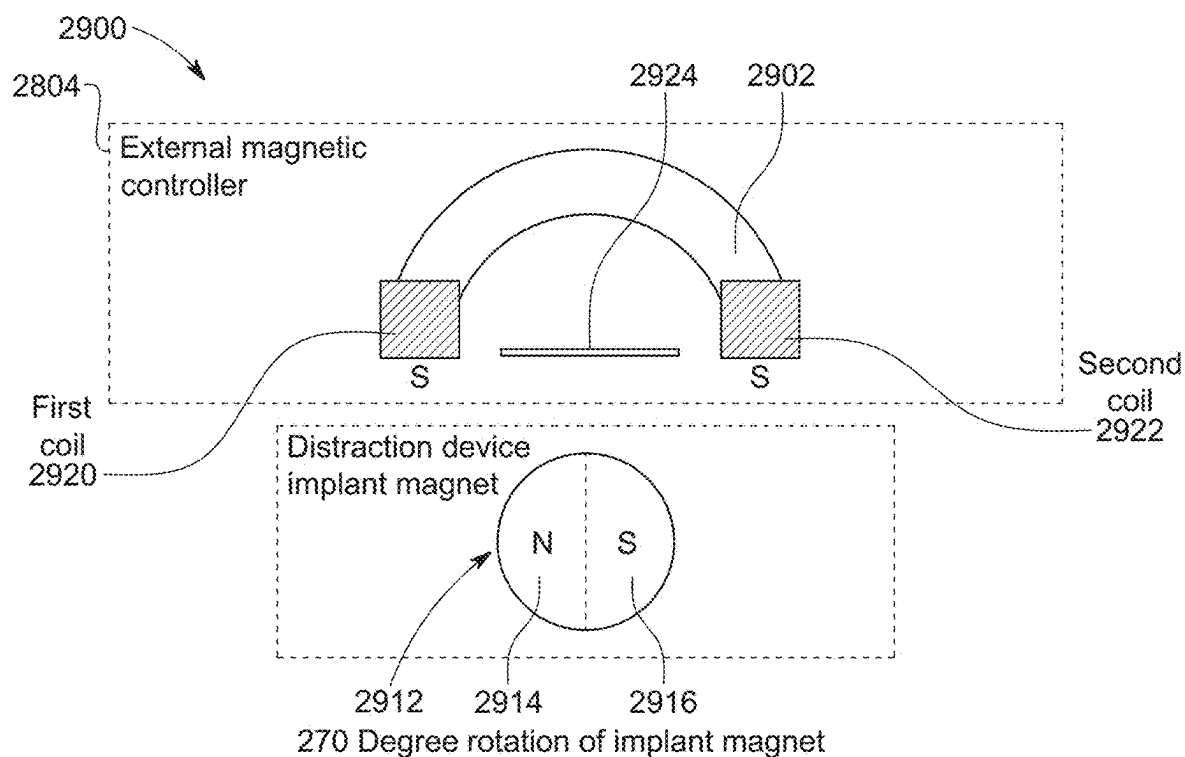


FIG. 29E

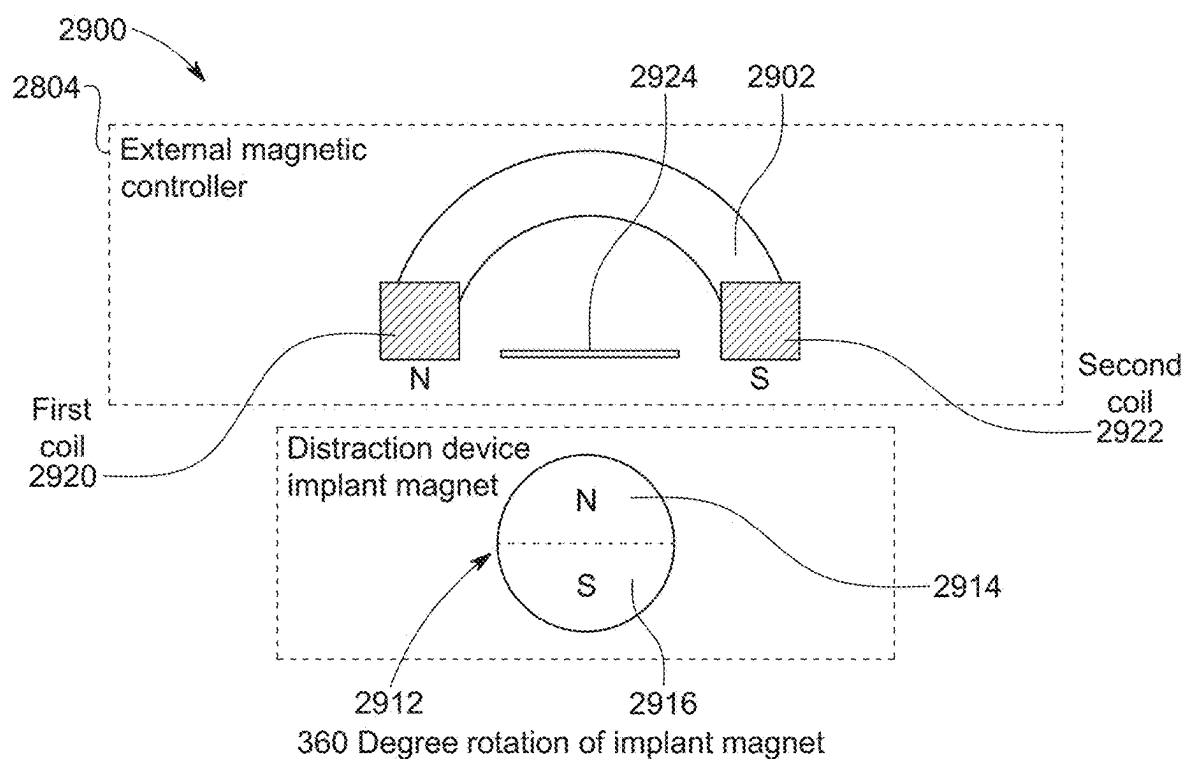


FIG. 29F

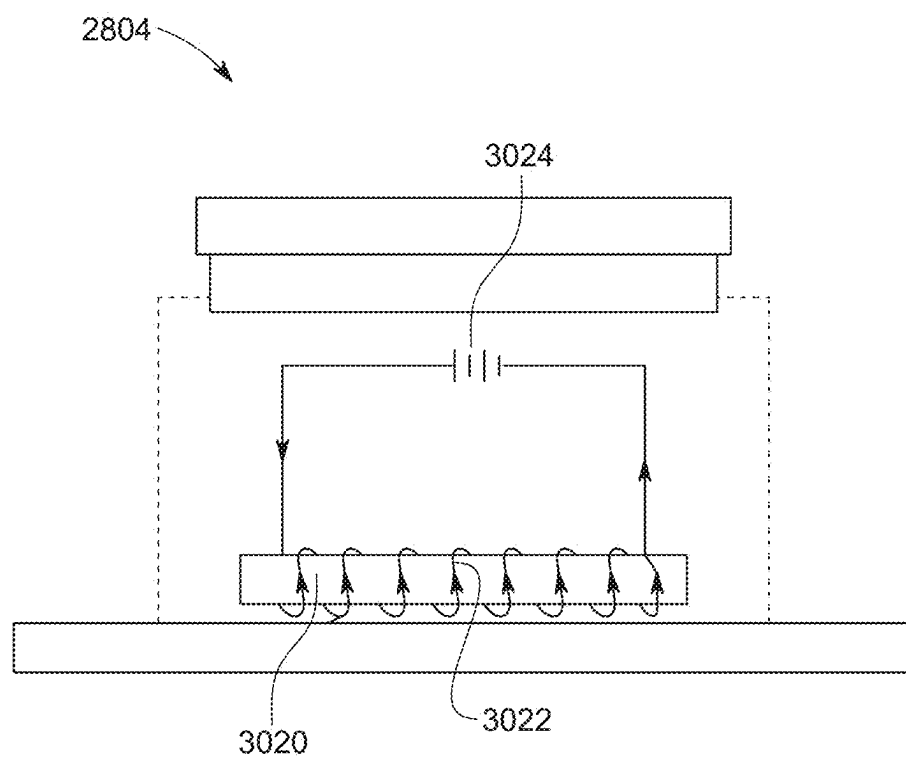


FIG. 30

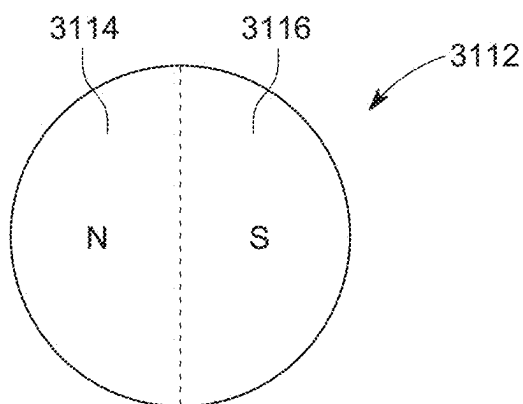


FIG. 31A

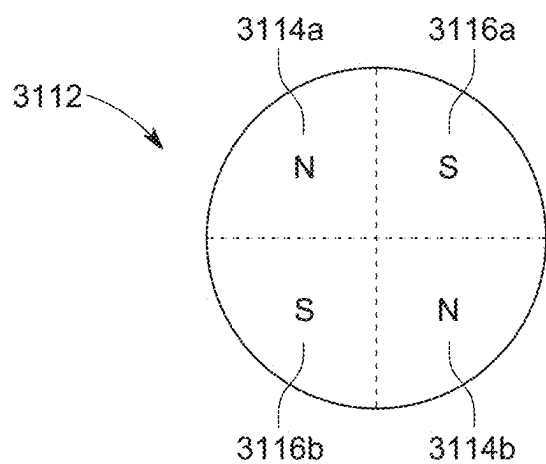


FIG. 31B

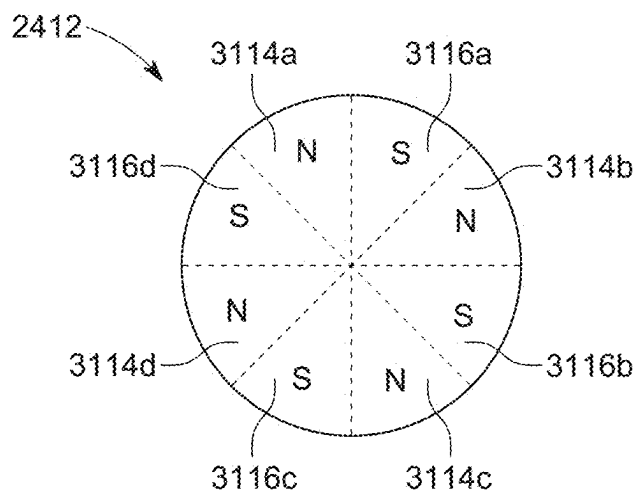


FIG. 31C

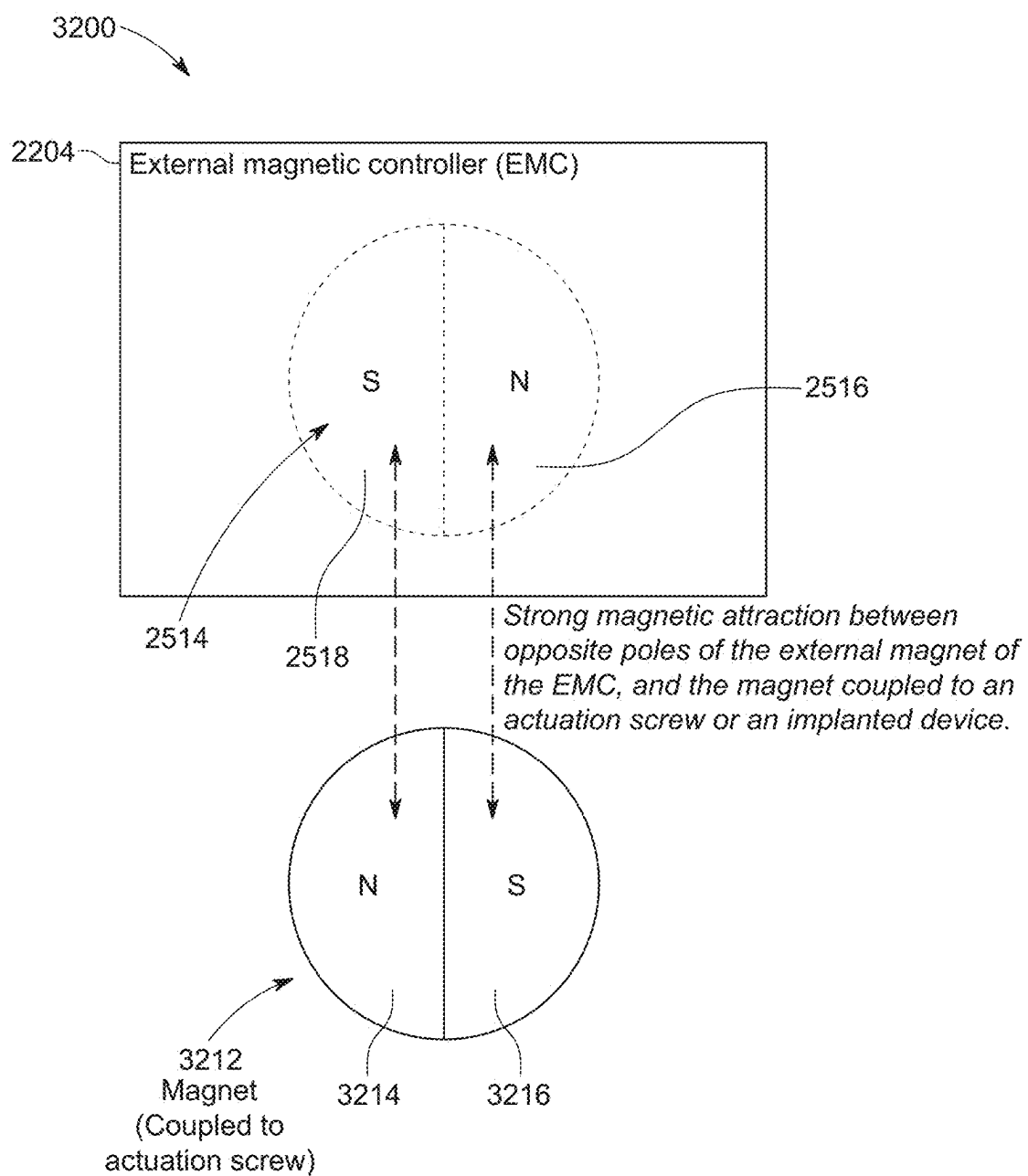


FIG. 32A

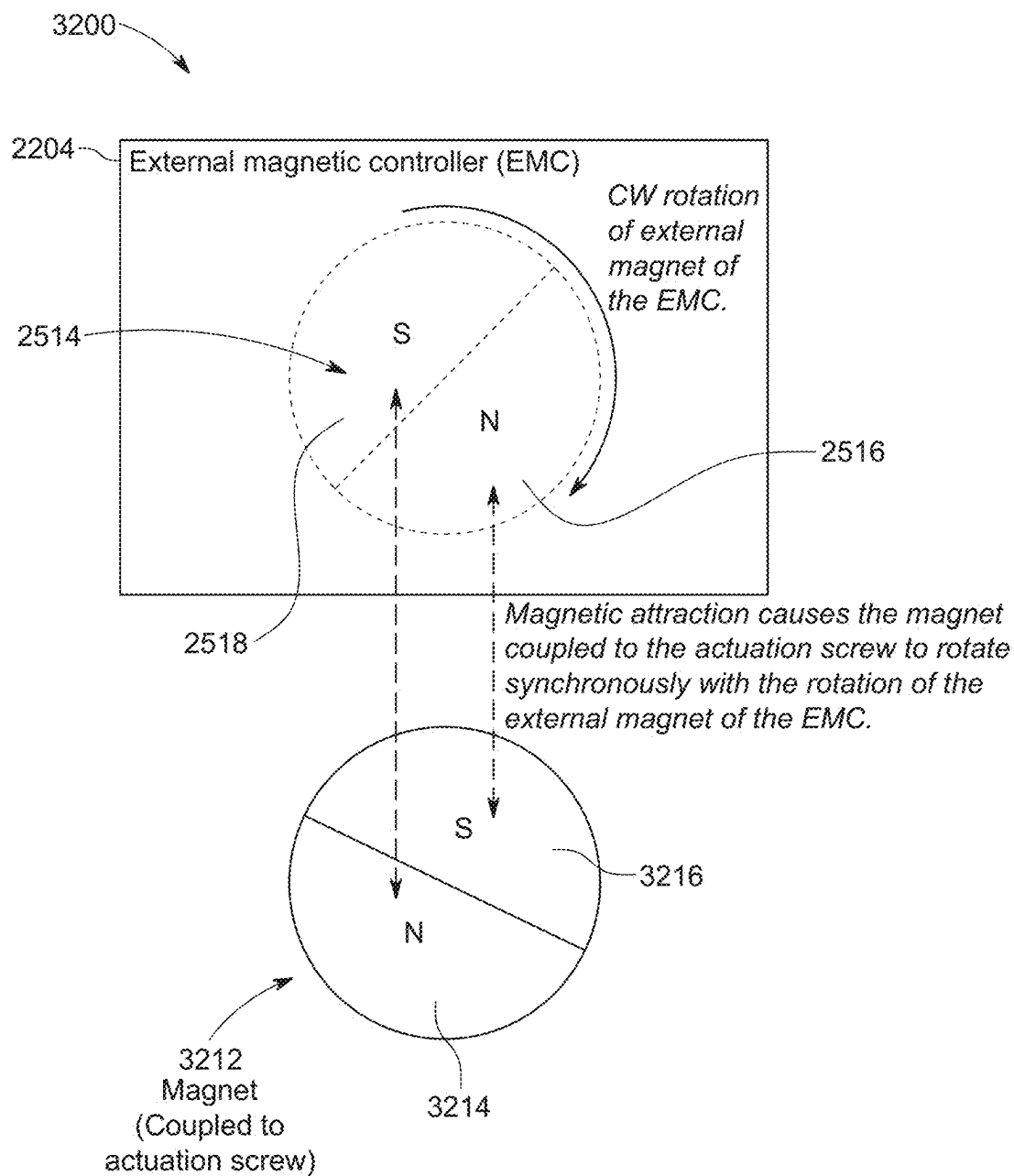


FIG. 32B

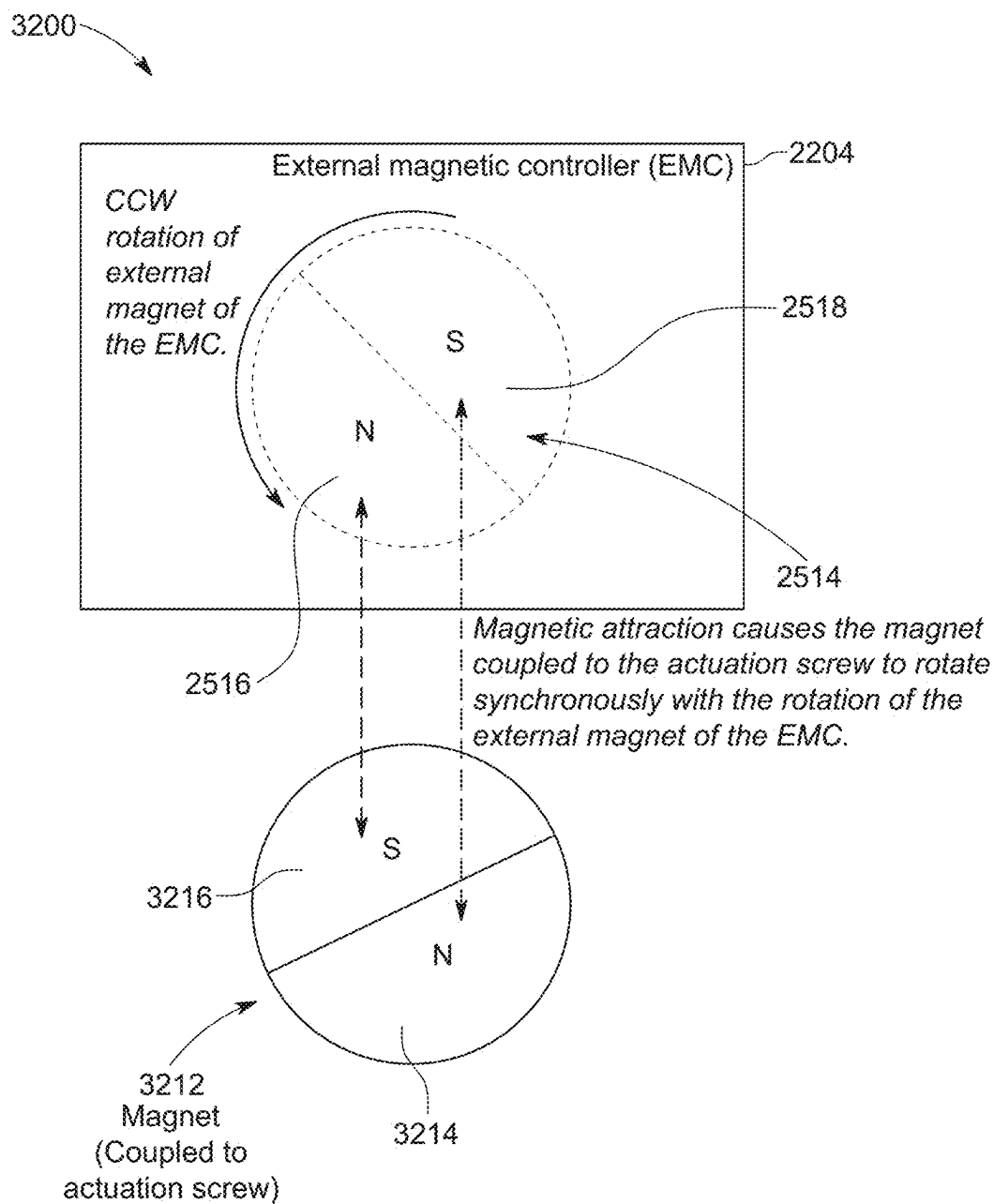


FIG. 32C

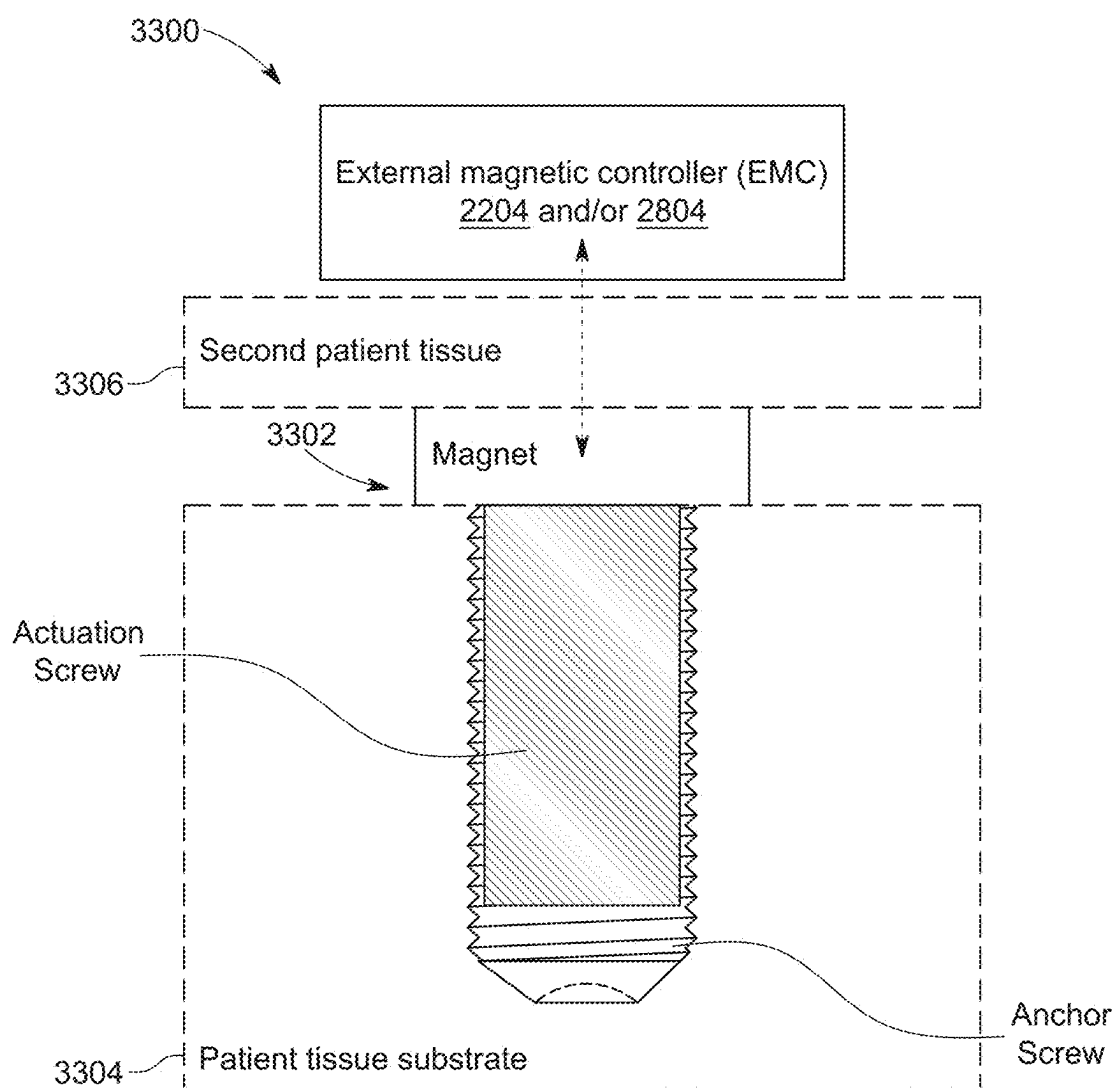


FIG. 33

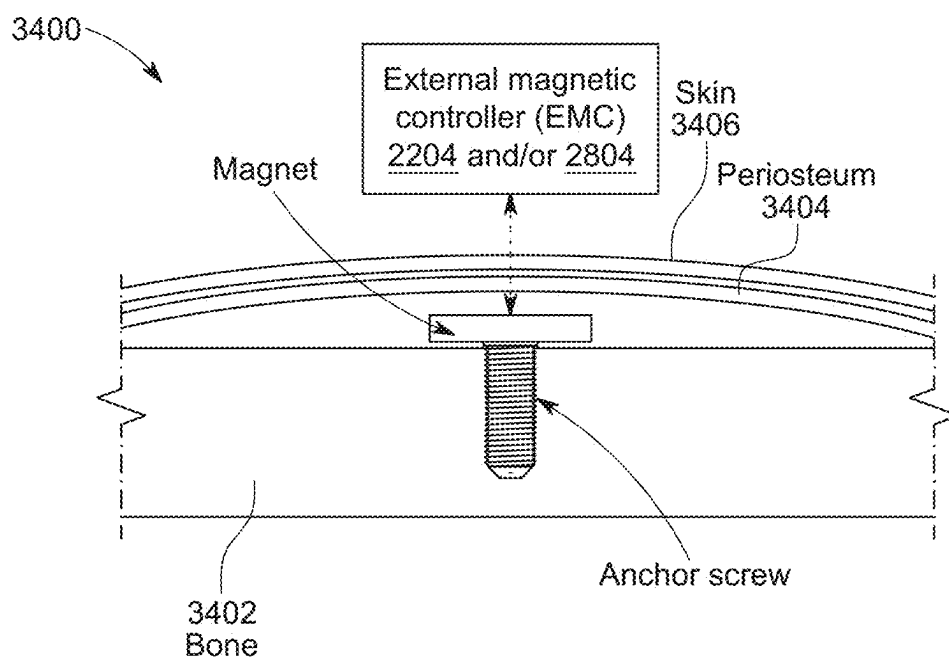


FIG. 34A

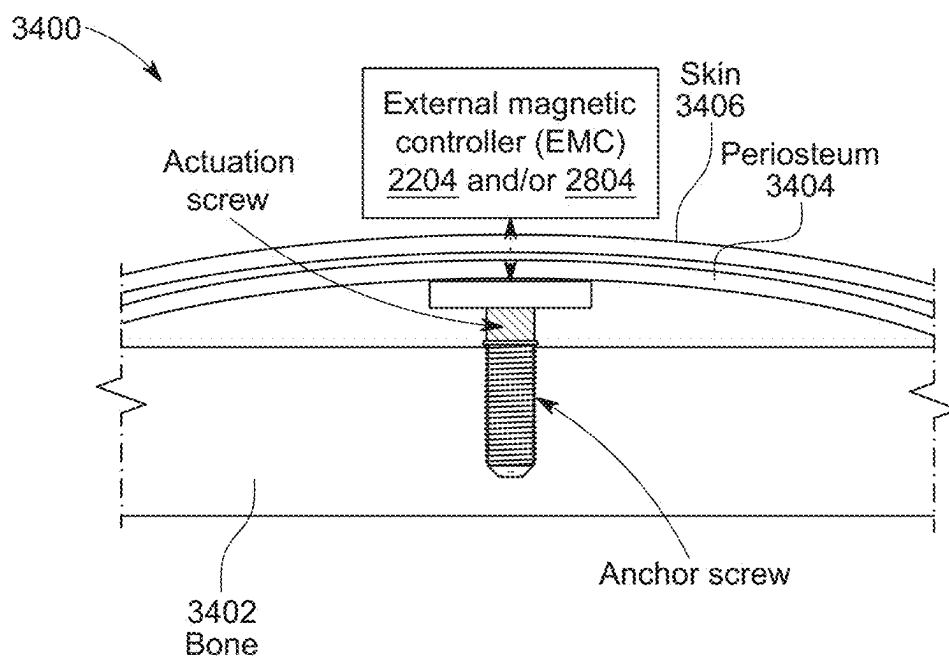


FIG. 34B

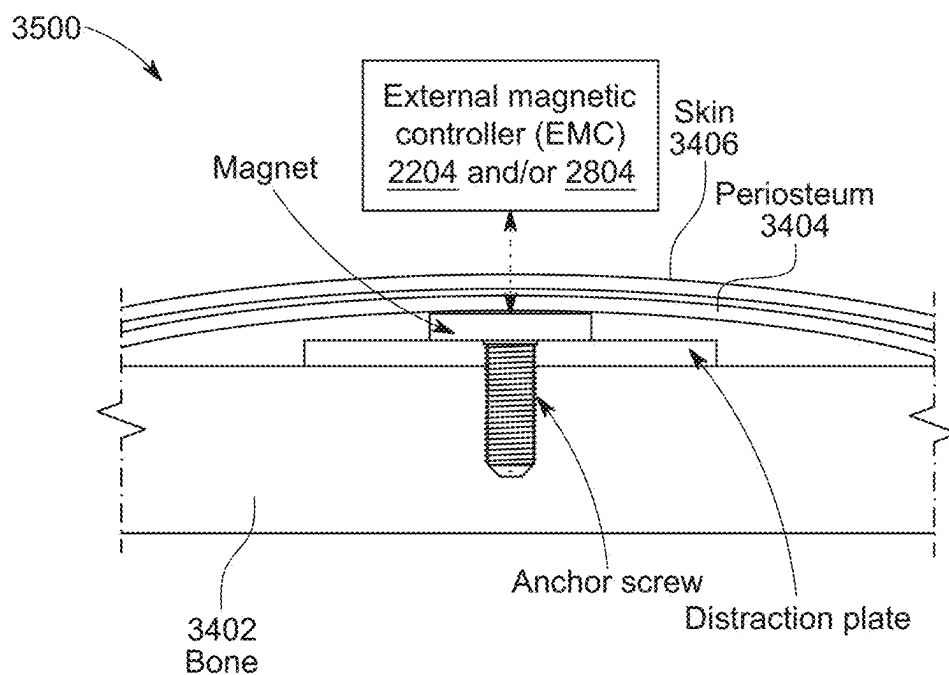


FIG. 35A

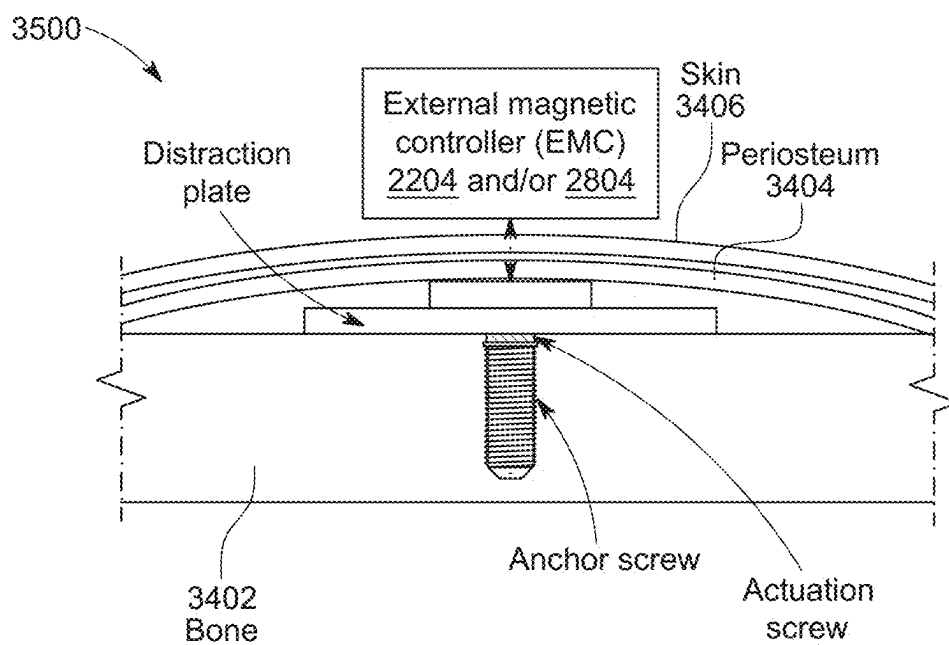


FIG. 35B

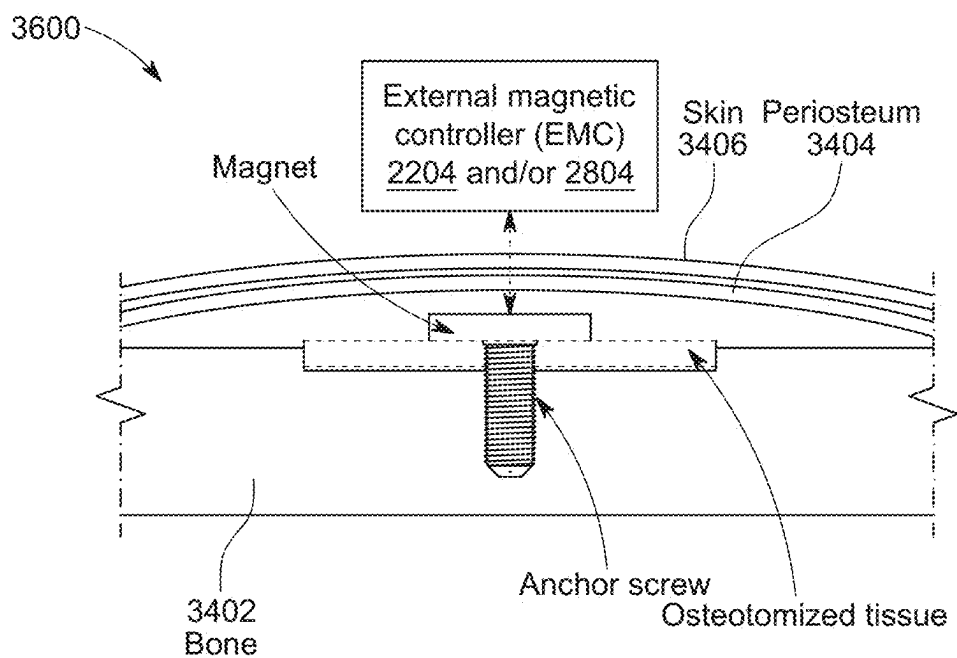


FIG. 36A

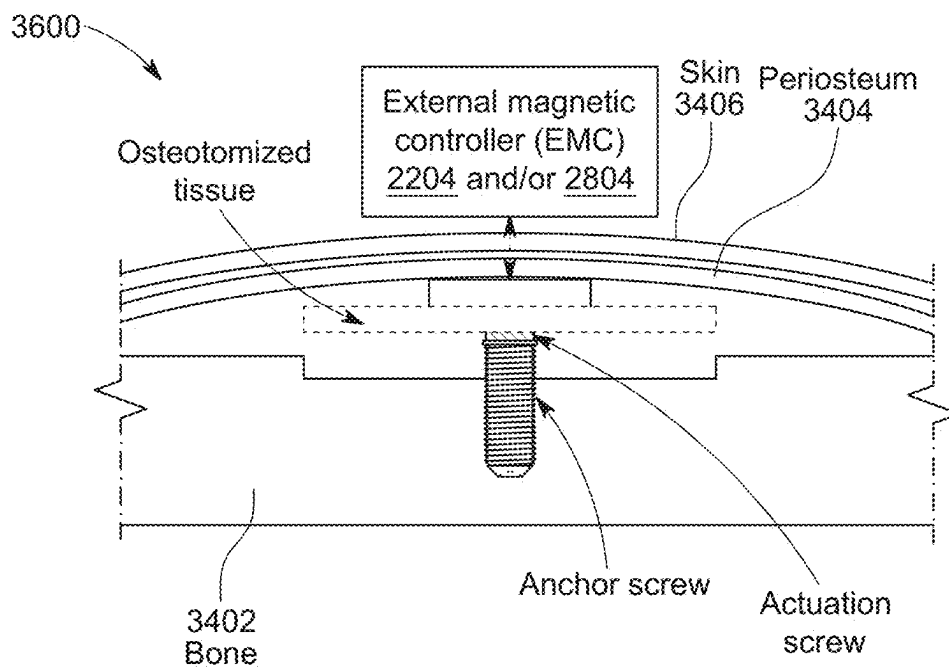


FIG. 36B

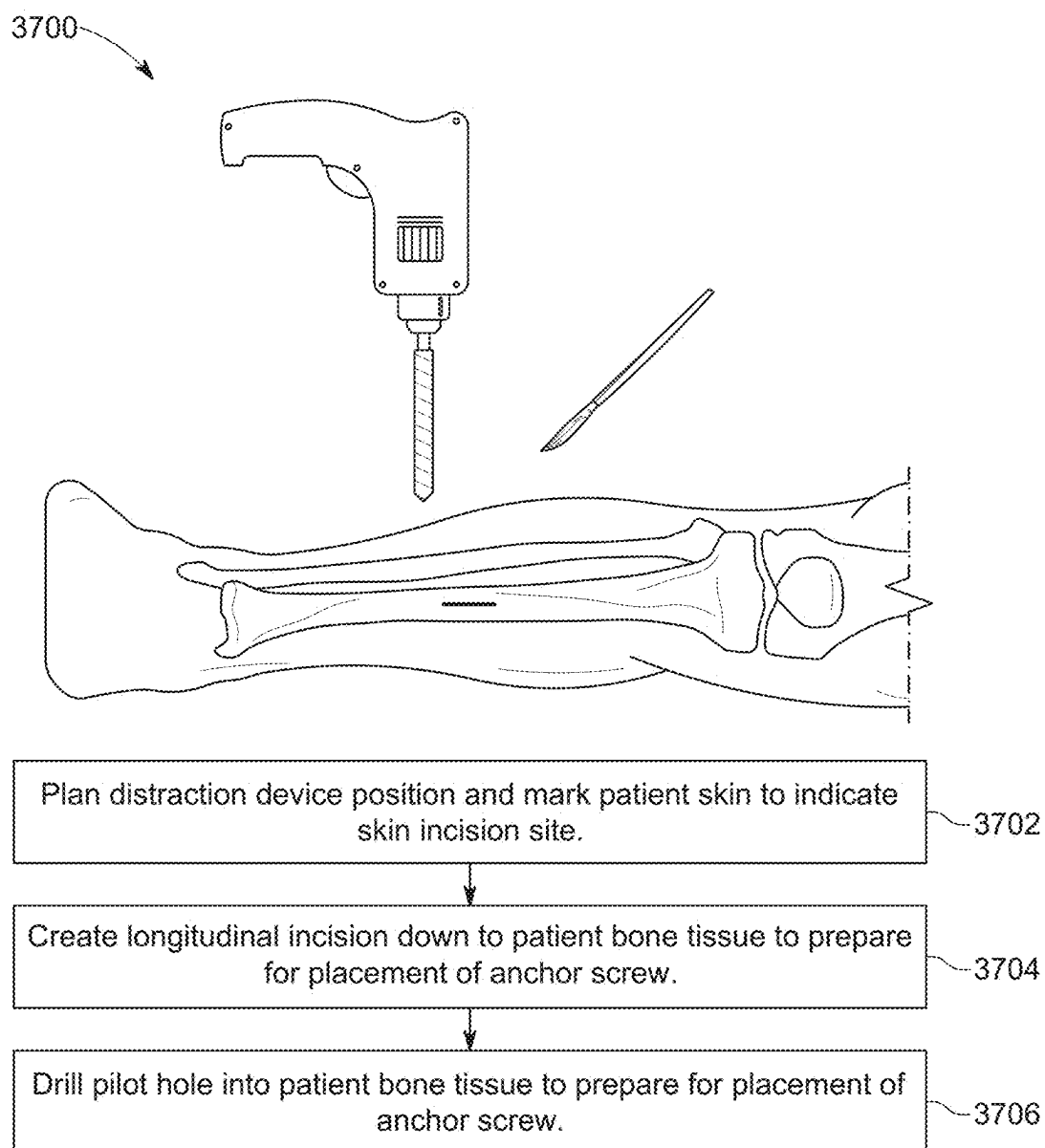


FIG. 37A

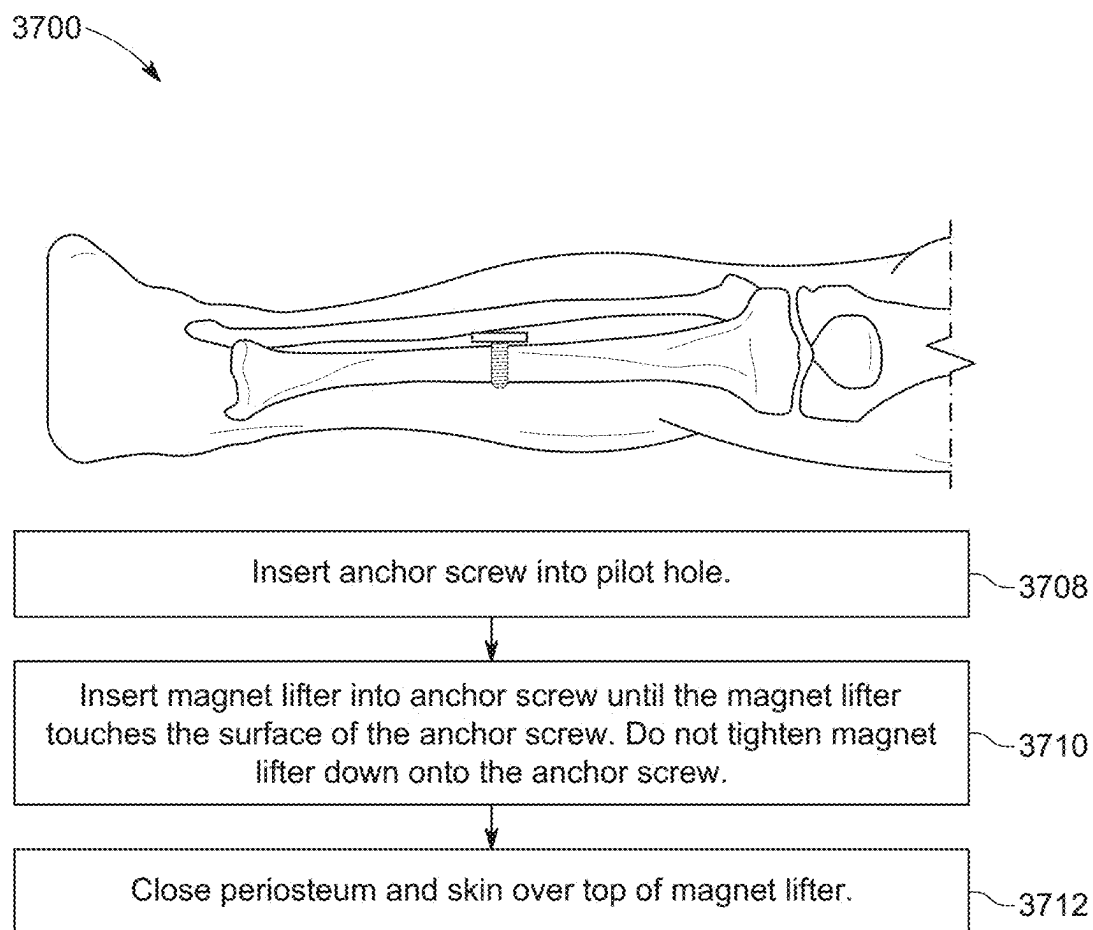


FIG. 37B

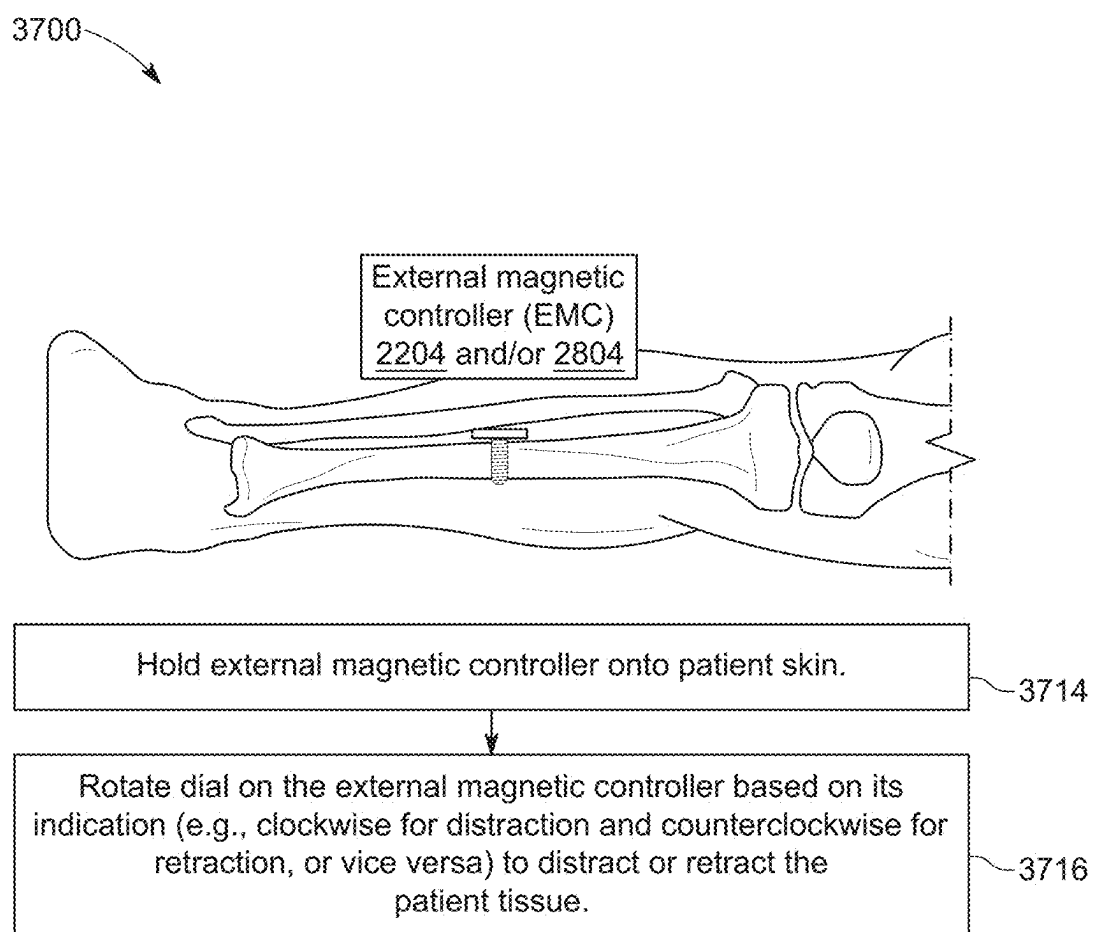


FIG. 37C

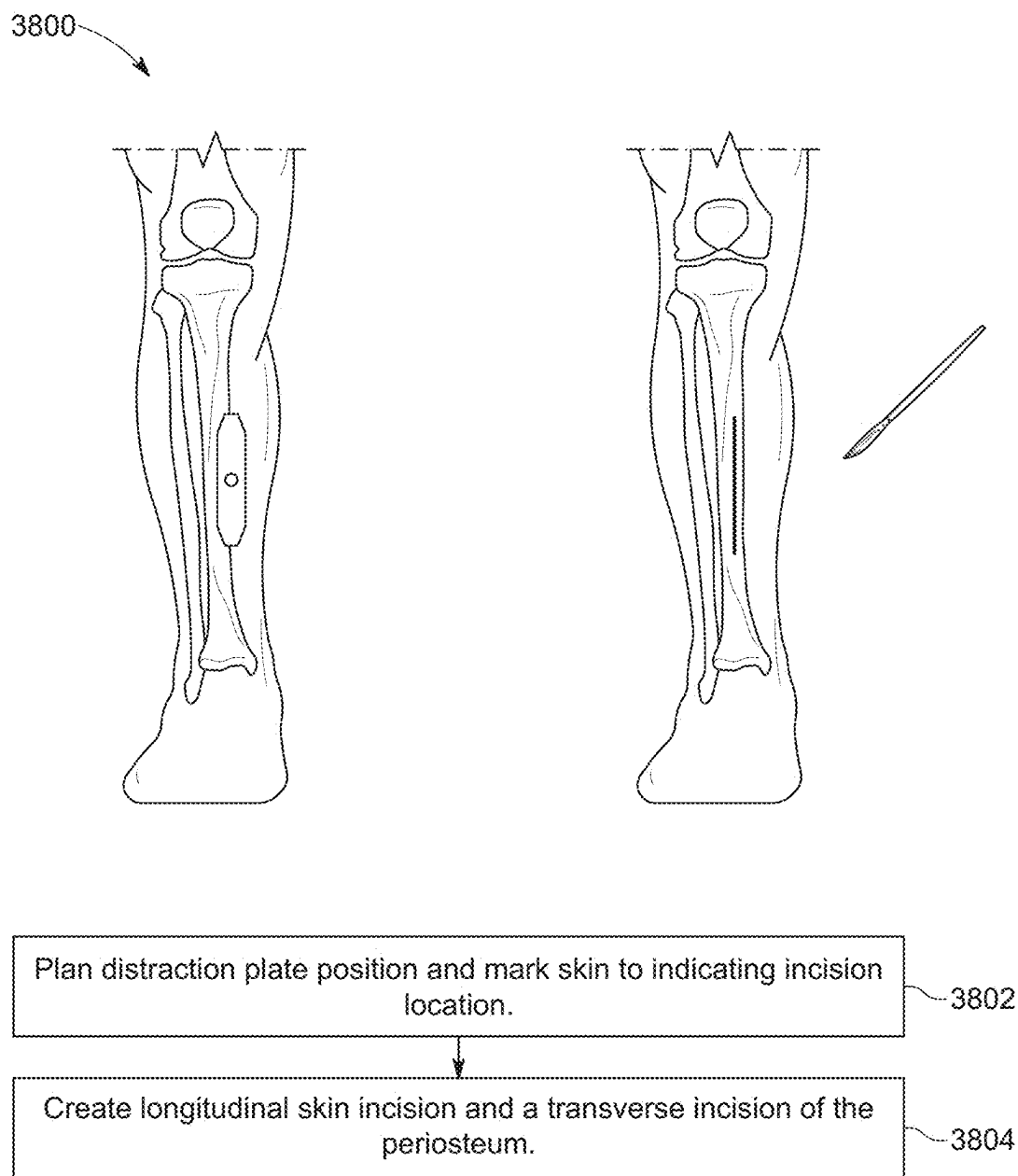
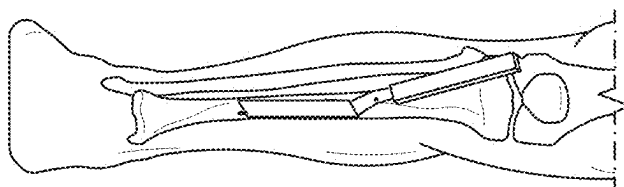


FIG. 38A

3800



Insert periosteal elevator to prepare subperiosteal tunnel on both sides of the incision.

3806

Wherein on a distal end of the patient's bone, the periosteal elevator is inserted for a whole length of the distraction plate.

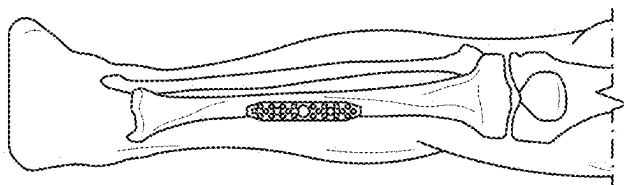
3808

Wherein on a proximal end of the patient's bone, the periosteal elevator is inserted for a half length of the distraction plate.

3810

FIG. 38B

3800



Insert entire distraction plate under periosteum on the distal side.

3812

Pull distraction plate back under periosteum on the proximal side.

3814

Align the central threaded hole of the distraction plate with the incision through the periosteum.

3816

FIG. 38C

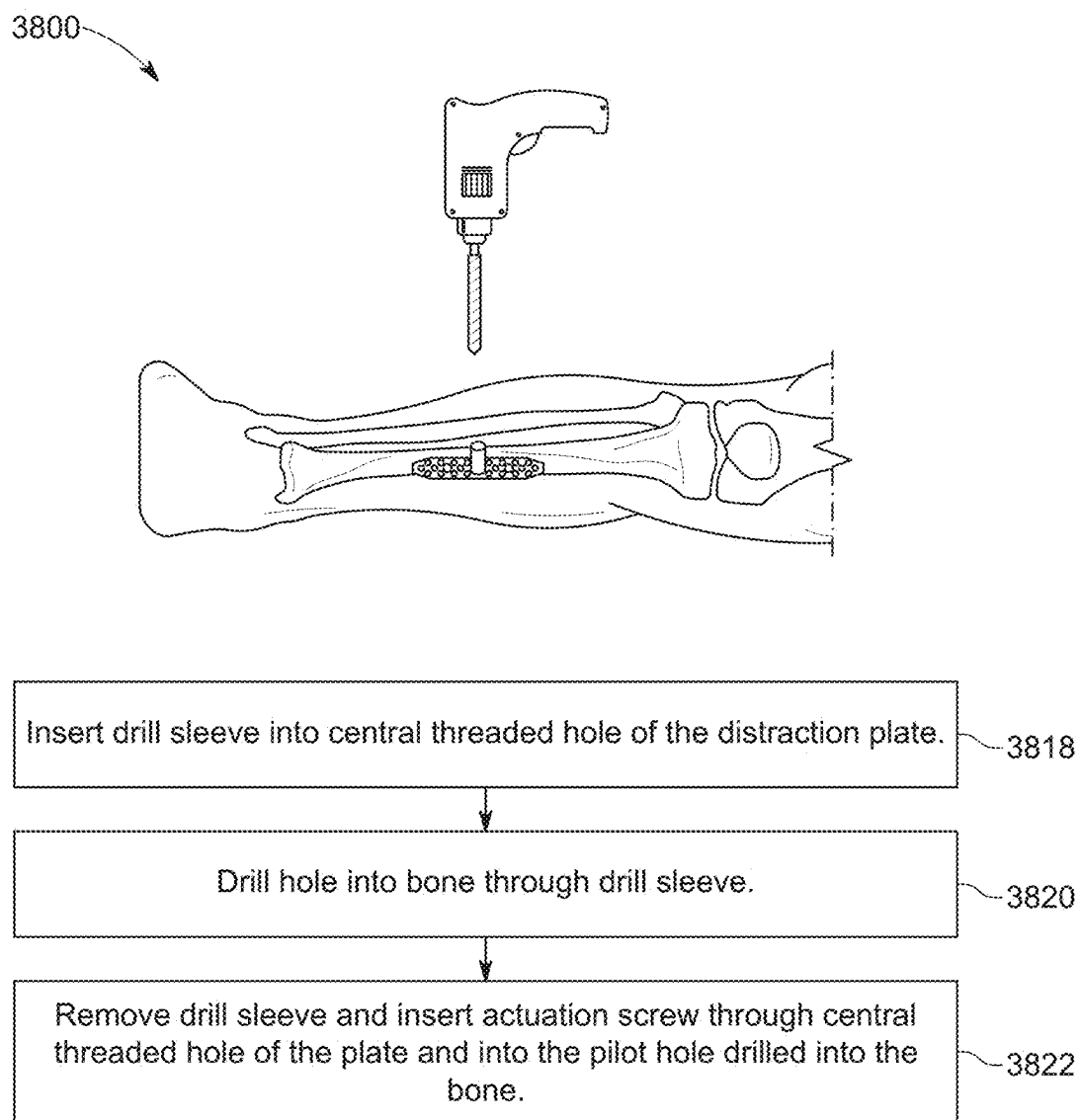


FIG. 38D

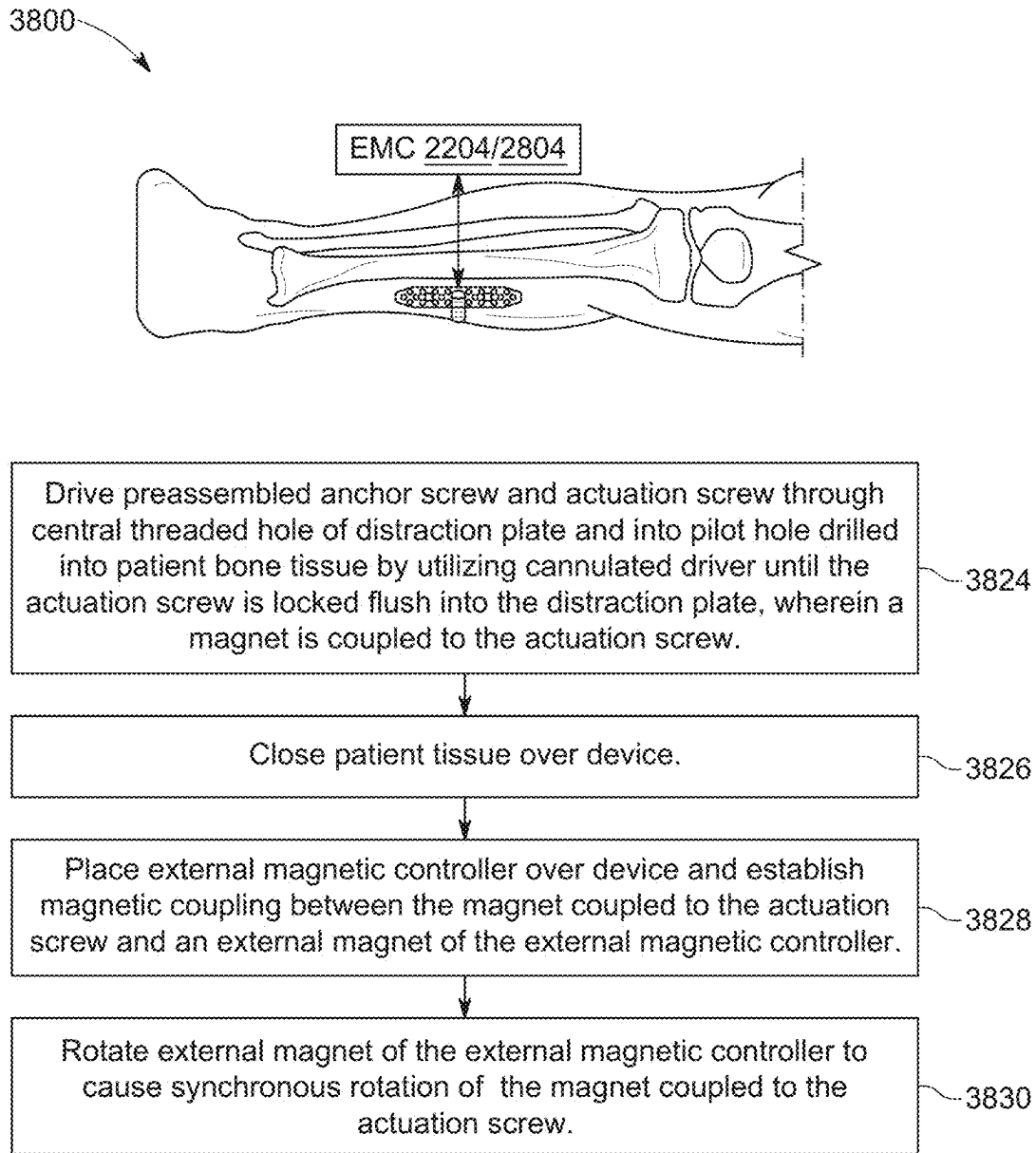


FIG. 38E

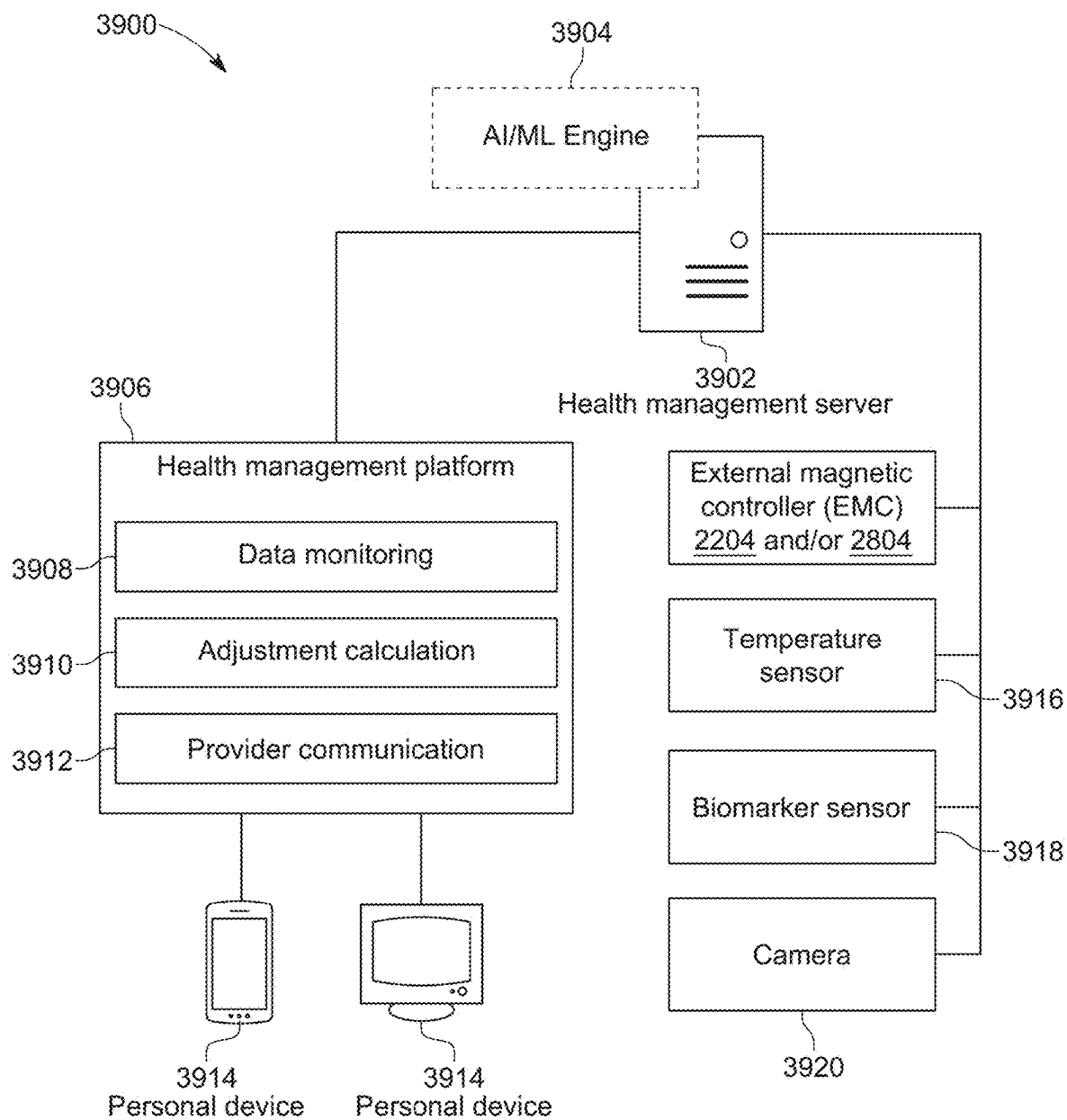


FIG. 39

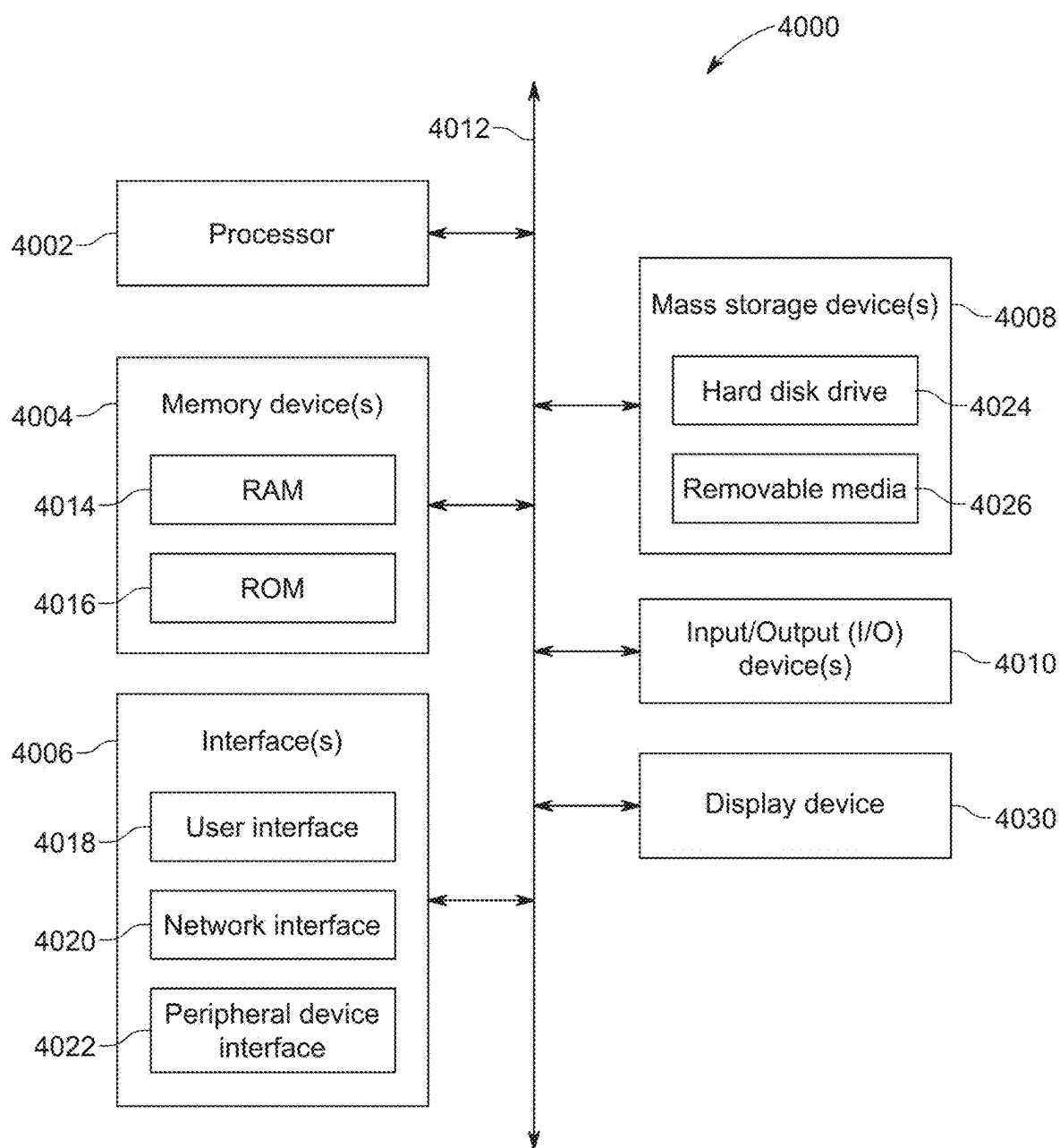


FIG. 40

MAGNETICALLY ACTUATED SYSTEMS AND DEVICES FOR PERFORMING DISTRACTION HISTOGENESIS SURGICAL PROCEDURES

TECHNICAL FIELD

[0001] The disclosure relates generally to systems, methods, and devices for surgical procedures, and relates specifically to systems, methods, and devices for distraction histogenesis procedures such as periosteal distraction.

BACKGROUND

[0002] In some cases, a patient benefits from perfusion improvement and tissue regeneration to aid in recovery from vascular damage, tissue trauma, bone defects, nerve damage, and other wounds. Tissue regeneration can be a major challenge for patient care and can be particularly difficult for patients experiencing chronic wounds, ischemic diseases, diabetic foot ulcers, bone defects, and other health challenges.

[0003] Tissue regeneration is particularly difficult to trigger when treating diabetic patients, and especially when treating diabetic foot ulcers. Currently, there are few known successful treatments for recalcitrant diabetic foot ulcers. Ongoing research suggests there may be some success in topical therapies and oxygen treatments, but these treatments show limited success.

[0004] Additionally, it can be difficult to successfully trigger bone regeneration in response to a bone defect, fracture, or other trauma. Commonly used therapies for bone regeneration include bone graft substitutes, guided bone regeneration (GBR), distraction osteogenesis (DO), and periosteal distraction osteogenesis (PDO). PDO is a combination of tissue expansion and GBR and is implemented to create an artificial space between the bone surface and periosteum layer by expanding the periosteum, muscle, and skin at the same time.

[0005] Traditional devices for performing distraction histogenesis, and specifically for performing periosteal distraction osteogenesis, include numerous external components that may be bothersome and painful for the patient, can be difficult and time consuming to install, require numerous component implanted into patient bone tissue, and can be difficult to adjust as time goes on. What is needed are systems, methods, and devices for performing distraction histogenesis that improve patient outcomes, reduce surgery complexity, reduce the number of percutaneous sites, and reduce the quantity of cumbersome and painful external components.

[0006] In view of the foregoing, disclosed herein are systems, methods, and devices for improved surgical procedures, and specifically for improved distraction histogenesis procedures such as periosteal distraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Non-limiting and non-exhaustive implementations of the present disclosure are described with reference to the following figures, wherein like reference numerals refer to like parts throughout the various views unless otherwise specified. Advantages of the present disclosure will become better understood with regard to the following description and accompanying drawings where:

[0008] FIG. 1 is a perspective view of a system for performing a distraction histogenesis surgical procedure, and specifically illustrates wherein an actuation screw is partially screwed into an anchor screw such that the device is partially distracted;

[0009] FIG. 2 is a perspective view of a system for performing a distraction histogenesis surgical procedure, and specifically illustrates wherein an actuation screw is partially screwed into an anchor screw such that the device is partially distracted;

[0010] FIG. 3 is a straight-on side view of a system for performing a distraction histogenesis surgical procedure, and specifically illustrates wherein an actuation screw is partially screwed into an anchor screw such that the device is partially distracted;

[0011] FIG. 4 is a perspective cross-sectional view of a system for performing a distraction histogenesis surgical procedure, and specifically illustrates wherein an actuation screw is partially screwed into an anchor screw such that the device is partially distracted;

[0012] FIG. 5 is a perspective view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0013] FIG. 6 is a straight-on side view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0014] FIG. 7 is a perspective cross-sectional view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0015] FIG. 8 is a straight-on side view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0016] FIG. 9 is an overhead perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0017] FIG. 10 is an underside perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0018] FIG. 11 is a cross-sectional perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0019] FIG. 12 is a cross-sectional perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a distraction plate, and wherein an actuation screw is fully screwed into an

anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0020] FIG. 13 is a schematic illustration of a cross-sectional straight-on side view of an anti-rotational assembly;

[0021] FIG. 14 is a perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a magnetic core and a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0022] FIG. 15 is a straight-on side view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a magnetic core and a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0023] FIG. 16 is an aerial top-down view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a magnetic core and a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0024] FIG. 17 is a cross-sectional perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a magnetic core and a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0025] FIG. 18 is a cross-sectional perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a magnetic core and a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0026] FIG. 19 is a cross-sectional perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a magnetic core and a distraction plate, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0027] FIG. 20 is a perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a magnetic core, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0028] FIG. 21 is a perspective cross-sectional view of a system for performing a distraction histogenesis surgical procedure, wherein the device includes a magnetic core, and wherein an actuation screw is fully screwed into an anchor screw such that the device is fully retracted and has its minimum total vertical length;

[0029] FIG. 22 is a straight-on side view of a system for performing a distraction histogenesis surgical procedure, wherein the system includes an external magnetic controller (EMC) that forms a magnetic coupling with a magnet of a distraction device;

[0030] FIG. 23 is a perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the system includes an EMC that forms a magnetic coupling with a magnet of a distraction device;

[0031] FIG. 24 is an overhead perspective view of an EMC configured to form a magnetic coupling with a magnet of a distraction device;

[0032] FIG. 25 is a cross-sectional aerial top-down view of an EMC configured to form a magnetic coupling with a magnet of a distraction device;

[0033] FIG. 26 is a cross-sectional perspective view of a system for performing a distraction histogenesis surgical procedure, wherein the system includes an EMC that forms a magnetic coupling with a magnet of a distraction device;

[0034] FIG. 27A is a schematic illustration of an aerial top-down view of an EMC;

[0035] FIG. 27B is a schematic illustration of a cross-sectional straight-on side view of an EMC including an external magnet;

[0036] FIG. 27C is a schematic illustration of a cross-sectional straight-on side view of an EMC including an external magnet and a motor;

[0037] FIG. 28 is a schematic illustration of a cross-sectional straight-on side view of an EMC including electromagnets;

[0038] FIGS. 29A-29F are schematic illustrations of a system for driving an implant magnet of a distraction device with an EMC comprising electromagnets and a Hall effect sensor or Hall effect array;

[0039] FIG. 30 is a schematic illustration of a straight-on cross-sectional side view of an EMC including an electromagnet;

[0040] FIG. 31A is a schematic illustration of a cross-sectional aerial top-down view of a magnet of a distraction device or an external magnet of an EMC that includes two poles;

[0041] FIG. 31B is a schematic illustration of a cross-sectional aerial top-down view of a magnet of a distraction device or an external magnet of an EMC that includes four poles;

[0042] FIG. 31C is a schematic illustration of a cross-sectional aerial top-down view of a magnet of a distraction device or an external magnet of an EMC that includes eight poles;

[0043] FIG. 32A is a schematic illustration illustrating magnetic attraction between a magnet of a distraction device and an external magnet of an EMC;

[0044] FIG. 32B is a schematic illustration illustrating magnetic attraction between a magnet of a distraction device and an external magnet of an EMC, and further illustrates synchronous rotation of the magnet of the distraction device in response to clockwise rotation of the external magnet of an EMC;

[0045] FIG. 32C is a schematic illustration illustrating magnetic attraction between a magnet of a distraction device and an external magnet of an EMC, and further illustrates synchronous rotation of the magnet of the distraction device in response to counterclockwise rotation of the external magnet of an EMC;

[0046] FIG. 33 is a schematic illustration of a system for performing a distraction histogenesis surgical procedure on patient tissue;

[0047] FIGS. 34A and 34B are schematic illustrations of a system and process for performing a distraction histogenesis surgical procedure with an EMC;

[0048] FIGS. 35A and 35B are schematic illustrations of a system and process for performing a distraction histogenesis surgical procedure with an EMC;

[0049] FIGS. 36A and 36B are schematic illustrations of a system and process for performing a distraction histogenesis and osteotomy surgical procedure with an EMC;

[0050] FIGS. 37A-37C are schematic flow chart diagrams of a method for performing a distraction histogenesis surgical procedure;

[0051] FIGS. 38A-38E are schematic flow chart diagrams of a method for performing a distraction histogenesis surgical procedure;

[0052] FIG. 39 is a schematic block diagram of a system for monitoring health data and remotely actuating adjustment of a distraction device; and

[0053] FIG. 40 is a schematic block diagram of an example computing device.

DETAILED DESCRIPTION

[0054] Described herein are systems, methods, and devices for promoting revisualization, improving perfusion and triggering tissue regeneration. The disclosures herein may be implemented to trigger regeneration of bone tissue, vascular tissue, microvascular tissue, skin tissue, nerve tissue, and other tissue types. The systems, methods, and devices described herein may be utilized to perform distraction histogenesis surgical procedures on various tissue types and may specifically be utilized to perform periosteal distraction osteogenesis to trigger regeneration of vascular and soft tissues.

[0055] What is needed are improved systems, methods, and devices for periosteal distraction that reduce the risks of infections, reduce the risks of device complications, reduce surgery complexity, reduce the quantity of percutaneous sites prone to infection, reduce the number of external components that may be cumbersome and painful for the patient, and reduce the complexity of tasks performed after surgery. Additionally, what is needed are systems, methods, and devices for triggering regeneration of non-bone tissue types through distraction histogenesis, including, for example, promoting revascularization for the healing of diabetic foot ulcers and other ischemic limb diseases.

[0056] In view of the foregoing, described herein systems, methods, and devices for initiating tissue growth through distraction histogenesis. The distraction histogenesis techniques described herein may be utilized to treat tissue defects by raising systemic growth factor levels. One or more of the devices described herein can be coupled to many different tissues in the body, because the devices are internal and implantable.

[0057] In the following description of the disclosure, reference is made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration specific implementations in which the disclosure may be practiced. It is understood that other implementations may be utilized, and structural changes may be made without departing from the scope of the disclosure.

[0058] Before the structures, systems, methods, and compositions described herein are disclosed, it is to be understood that this disclosure is not limited to the particular structures, configurations, process steps, and materials disclosed herein as such structures, configurations, process steps, and materials may vary somewhat. It is also to be understood that the terminology employed herein is used for the purpose of describing particular embodiments only and

is not intended to be limiting since the scope of the disclosure will be limited only by the appended claims and equivalents thereof.

[0059] In describing and claiming the subject matter of the disclosure, the following terminology will be used in accordance with the definitions set out below.

[0060] As used herein, the terms “comprising,” “including,” “containing,” “characterized by,” and grammatical equivalents thereof are inclusive or open-ended terms that do not exclude additional, unrecited elements or method steps.

[0061] As used herein, the phrase “consisting of” and grammatical equivalents thereof exclude any element, step, or ingredient not specified in the claim.

[0062] As used herein, the phrase “consisting essentially of” and grammatical equivalents thereof limit the scope of a claim to the specified ingredients, materials, or steps and those that do not materially affect the basic and novel characteristic or characteristics of the claimed disclosure.

[0063] Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art to which this disclosure pertains and belongs.

[0064] Reference will now be made in detail to the exemplary embodiments, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers are used throughout the drawings to refer to the same or like parts. It is further noted that elements disclosed with respect to particular embodiments are not restricted to only those embodiments in which they are described. For example, an element described in reference to one embodiment or figure, may be alternatively included in another embodiment or figure regardless of whether or not those elements are shown or described in another embodiment or figure. In other words, elements in the figures may be interchangeable between various embodiments disclosed herein, whether shown or not.

[0065] Referring now to the figures, FIG. 1 is a perspective view of a system 100 for performing a distraction histogenesis surgical procedure. The system 100 may be utilized to perform various distraction procedures, including those performed on soft tissues. The system 100 may specifically be utilized to perform a periosteal distraction surgical procedure to lift a periosteum tissue away from adjacent bone tissue and thereby trigger tissue generation.

[0066] The system 100 is configured to be implanted into a patient during a surgical procedure. After implantation, the system 100 may be distracted or retracted according to the patient's needs. In an example use-case, the system 100 is implanted in between bone tissue and a periosteum layer of a patient. The surgical site may be fully closed over the system 100 to prevent infection, and this may include suturing shut one or more of the periosteum or skin layers over the system 100. The system 100 may then be magnetically actuated without physically touching the device. The magnetic coupling may be performed with an external magnetic controller (EMC) as described herein, or another similar device. A user may thereby utilize an external magnet or electromagnet to distract or retract the system 100 in a controlled manner while the system 100 is installed in the patient.

[0067] The system 100 includes two primary components, including an anchor screw 102 and an actuation screw 104. The system 100 includes a longitudinal axis, and the actua-

tion screw **104** is configured to move up and down along the longitudinal axis and relative to the anchor screw **102**. When the actuation screw **104** is distracted from the anchor screw **102** as shown in FIG. 1, the system **100** has a longer total length. When the actuation screw **104** is fully retracted into the anchor screw **102**, the system **100** has its minimum total length.

[0068] As shown in FIG. 1, at least a portion of the actuation screw **104** is configured to be disposed within and encased by the anchor screw **102**. The anchor screw **102** is configured to be screwed into a first tissue of a patient and may specifically be configured to be screwed into bone tissue. The actuation screw **104** is configured to move up and down relative to a longitudinal axis of the anchor screw **102** to adjust an overall length of the system **100**. The vertical position of the actuation screw **104** relative to the anchor screw **102** may be adjusted over time to cause distraction or retraction of a second tissue of the patient.

[0069] The actuation screw **104** includes a screw shaft **122** and a plate magnet **112** attached to the screw shaft **122**. The plate magnet **112** includes at least a first pole **114** and a second pole **116**, and the plate magnet **112** may include additional poles depending on the implementation. The plate magnet **112** may have, for example, four poles, six poles, eight poles, and so forth, without departing from the scope of the disclosure. In some cases, it may be desirable to design the plate magnet **112** with a higher quantity of poles to enable more granularity in unscrewing and screwing the actuation screw **104**.

[0070] The first pole **114** and the second pole **116** comprise opposite magnetic polarity relative to one another. The plate magnet **112** includes a magnet top surface **118** and a magnet bottom surface **120** (not visible in the view illustrated in FIG. 1) that is opposite to the magnet top surface **118**. As shown in FIG. 1, the first pole **114** and the second pole **116** are located adjacent to one another such that each of the first pole **114** and the second pole **116** is located at least on the magnet top surface **118** of the plate magnet **112**. The screw shaft **122** is attached to the magnet bottom surface **120** of the plate magnet **112**. The screw shaft **122** comprises external threading **124** that is configured to engage with internal threading disposed within a hollow interior of the anchor screw **102**.

[0071] The anchor screw **102** comprises the longitudinal axis running along a length of the anchor screw **102**. The actuation screw **104** is configured to engage with the anchor screw to adjust a vertical position of the plate magnet **112** along the longitudinal axis of the anchor screw **102**. The anchor screw **102** includes a hollow interior **126** defined by a sidewall **128**. The anchor screw **102** includes internal threading (not visible in FIG. 1) on an interior surface of the sidewall **128**. The internal threading of the anchor screw **102** corresponds with the external threading **124** of the screw shaft **122** of the actuation screw **104**. The anchor screw **102** includes external threading **132** on an exterior surface of the sidewall **128**. The external threading **132** is configured to engage with a first tissue of a patient to anchor the anchor screw **102** to the first tissue. The anchor screw **102** include a tip **134** disposed at a proximal (i.e., the end proximal to an interior of a patient when the anchor screw **102** is installed into the first tissue of the patient).

[0072] The anchor screw **102** includes a socket interface **130** disposed at a proximal end of the anchor screw **102**, and the socket interface **130** provides a means to directly rotate

the anchor screw **102**. The socket interface **130** may include a recess comprising a polygonal cross-sectional geometry such as a quadrilateral, pentagonal, hexagonal, and so forth, cross-sectional geometry. The polygonal cross-sectional geometry of the socket interface **130** enables a machine or human user to get sufficient torque when directly screwing the anchor screw **102**.

[0073] FIG. 2 is a perspective view of the system **100** for performing a distraction histogenesis surgical procedure. The plate magnet **112** of the actuation screw **104** may comprise a strong magnet that extends the entire thickness of the magnet plate. The strength of the plate magnet **112** may be sufficient to ensure the plate magnet **112** maintains stable magnetic coupling with an external magnet that is located external to the patient tissue, even when the magnet is installed within the patient's body. In an implementation, the plate magnet **112** is installed underneath several layers of patient tissue, including, for example, periosteum, fat, tendons, ligaments, and skin. The plate magnet **112** may be sufficiently strong to maintain a magnetic coupling with a separate external magnet that is located entirely external to the patient's body.

[0074] FIG. 3 is a straight-on side view of the system **100** for performing a distraction histogenesis surgical procedure. Like FIGS. 1 and 2, FIG. 3 also illustrates wherein the actuation screw **104** is partially distracted or screwed out of the anchor screw **102**. The position of the actuation screw **104** along the longitudinal axis of the anchor screw **102** adjusts the total vertical length **302** of the system **100**.

[0075] In practice, the anchor screw **102** may be fully screwed into a first tissue of a patient, such as a bone tissue, such that only the distal end of the anchor screw is visible or located outside the first tissue. The actuation screw **104** may then be fully screwed into the anchor screw **102** to achieve a minimum total vertical length **302** for the system **100**. The actuation screw **104** may be gradually unscrewed from the anchor screw **102** to increase the total vertical length **302** of the device, and thereby cause distraction of a second tissue that is disposed above the actuation screw **104**. The actuation screw **104** may be screwed further into the anchor screw **102** at any time to cause retraction of the second tissue.

[0076] FIG. 4 is a perspective cross-sectional view of the system **100** for performing a distraction histogenesis surgical procedure, wherein the actuation screw **104** is partially distracted from the anchor screw **102**. The cross-sectional view in FIG. 4 enables viewing of internal threading **436** disposed along an interior side of the sidewall **128** of the anchor screw **102**.

[0077] The actuation screw **104** is coupled to the anchor screw **102** by interfacing the external threading **124** of the actuation screw **104** with the internal threading **436** of the anchor screw **102**. Because the actuation screw **104** is screwed into the anchor screw **102**, the actuation screw **104** is prevented from sliding out of the anchor screw **102** when the plate magnet **112** of the actuation screw **104** coupled to another external magnetic component.

[0078] As shown in FIG. 4, the screw shaft **122** of the actuation screw **104** may include a smooth portion **438** disposed in between the plate magnet **112** and the portion comprising external threading **124**. The actuation screw **104** may include a singular indivisible piece including each of the portion comprising external threading **124**, the smooth portion **438**, and the plate magnet **112**.

[0079] FIG. 5 is a perspective view of the system 100 for performing a distraction histogenesis surgical procedure, wherein the actuation screw 104 is fully screwed into the anchor screw 102 such that the system 100 is fully retracted and has its minimum total vertical length.

[0080] FIG. 6 is a straight-on side view of the system 100 for performing a distraction histogenesis surgical procedure, wherein the actuation screw 104 is fully screwed into the anchor screw 102 such that the system 100 is fully retracted and has its minimum total vertical length.

[0081] As shown in FIGS. 5 and 6, the screw shaft (see 122) of the actuation screw 104 is not visible when the actuation screw 104 is fully retracted into the anchor screw 102. The system 100 may include the configuration illustrated in FIGS. 5 and 6 when the system 100 is first installed into patient tissue. Depending upon the implementation and the specific health considerations of the patient, a surgeon may fully close one or more layers of patient tissue over the plate magnet 112 of the actuation screw 104. This may reduce the likelihood of infection and improve patient outcomes.

[0082] FIG. 7 is a perspective cross-sectional view of the system 100 for performing a distraction histogenesis surgical procedure, wherein the actuation screw 104 is fully screwed into the anchor screw 102 such that the system 100 is fully retracted and has its minimum total vertical length.

[0083] As shown in FIG. 7, the length of the screw shaft 122 of the actuation screw 104 may be screwed into the anchor screw 102 for most of a length of the anchor screw 102. The actuation screw 104 may be securely distracted out of the anchor screw 102 as long as the actuation screw 104 is still coupled to the anchor screw 102 through the corresponding threading. The actuation screw 104 may further be fully removed from the anchor screw 102 by unscrewing the screw shaft 122 from the anchor screw 102.

[0084] The cross-sectional view of FIG. 7 enables partial viewing of a socket head 740 of the anchor screw 102. The socket head 740 includes a polygonal cross-sectional geometry to enable a machine or human user to achieve sufficient torque to screw the anchor screw 102 into an anchoring substrate, such as bone tissue. The socket head 740 may include a quadrilateral, pentagonal, hexagonal, and so forth, polygonal cross-sectional geometry. The socket head 740 may be utilized with a corresponding driver that comprises the same polygonal cross-sectional geometry. The socket head 740 may be utilized to screw the anchor screw 102 into a substrate, or two unscrew the anchor screw 102 from the substrate, when the actuation screw 104 is not disposed within the anchor screw 102.

[0085] In an exemplary use-case, the system 100 is installed in a bone tissue of a patient to perform a periosteal distraction surgical procedure. A surgeon may first drill a pilot hole into the bone tissue, wherein the pilot is sized based on the outer diameter of the anchor screw 102. The surgeon may then screw the anchor screw 102 into the pilot hole by utilizing a driver that corresponds with the socket head 740 of the anchor screw 102. After the anchor screw 102 is installed in the bone tissue, the surgeon may then screw the actuation screw 102 into the anchor screw 104.

[0086] FIG. 8 is a straight-on side view of a system 800 for performing a distraction histogenesis surgical procedure. The system 800 is like the system 100 first described in connection with FIG. 1, but for the system 800 additionally including a distraction plate 806. The distraction plate 806

may aid in a distraction histogenesis procedure to lift a second tissue away from a first tissue and/or to stretch the second tissue.

[0087] Like the system 100 first described in connection with FIG. 1, the system 800 is also configured to magnetically coupled to an external magnet or electromagnet. The system 800 may be installed within a patient, and then distracted (i.e., expanded) or retracted (i.e., contracted) by establishing a magnetic coupling between the system 800 and an external magnetic controller. Thus, the system 800 may be installed within the patient and the patient's skin barrier may be fully closed over the system 800. The system 800 may still be distracted and retracted by establishing a magnetic coupling between the system 800 and the external magnetic controller that is located external to the patient's skin barrier.

[0088] The system 800 includes the anchor screw 802 that is configured to be anchored into a first tissue of a patient. The system 800 includes the actuation screw 804 that is disposed within a hollow interior formed by a sidewall of the anchor screw 802. The anchor screw 802 is similar to the anchor screw 102 first described in connection with FIG. 1 and may include all of the components associated with the anchor screw 102. The actuation screw 804 is similar to the actuation screw 104 first described in connection with FIG. 1 and may include all of the component associated with the actuation screw 104.

[0089] The system 800 may include a combined actuation screw 804 and magnet lifter 810 such that the magnet lifter 810 cannot be readily separated from the actuation screw 804. In this case, the actuation screw 804 is similar to the actuation screw 104 first described in connection with FIG. 1, wherein the actuation screw 804 is a single component including each of a screw shaft and a plate magnet.

[0090] The system 800 may include a separate actuation screw 804 and magnet lifter 810 such that the actuation screw 804 and the magnet lifter 810 constitute separate components that may interface with one another. In this case, the actuation screw 804 may include a screw shaft and a first rotational driver interface, and the magnet lifter 810 may include a plate magnet and a corresponding second rotational driver interface. In an example implementation, the actuation screw 804 may include a driver head, and the magnet lifter 810 may include a corresponding socket interface, such that the socket interface of the magnet lifter 810 may be utilized to drive rotation of the actuation screw 804.

[0091] The system 800 further includes a distraction plate 806 coupled to the actuation screw 804. The system 800 includes a coupler 808 that couples the distraction plate 806 to the actuation screw 804 in a manner that prevents the distraction plate 806 from synchronously rotating with the actuation screw 804, while ensuring the distraction plate 806 is still axially coupled to the actuation screw 804 (i.e., the distraction plate 806 and the actuation screw 804 each distract away from the anchor screw 802 and retract toward the anchor screw 802 when the actuation crew 804 is rotated).

[0092] FIG. 9 is an overhead perspective view of the system 800 for performing a distraction histogenesis surgical procedure. The overhead perspective view shown in FIG. 9 enables further viewing of the distraction plate 806.

[0093] The distraction plate 806 may include a central threaded hole, which is not visible in FIG. 9 because the coupler 808 and anchor screw 802 are disposed within the

central threaded hole. The central threaded hole may include internal threading that interfaces with one or more of the coupler **808** or the anchor screw **802**. The distraction plate **806** may additionally include one or more peripheral threaded holes **944** comprising internal threading. The peripheral threaded holes **944** may be utilized to anchor the distraction plate **806** to a patient tissue. In an exemplary use-case, the peripheral threaded holes **944** are utilized to anchor the distraction plate **806** to osteotomized bone tissue, such that distraction of the anchor plate **806** causes likewise distraction of the osteotomized bone tissue.

[0094] The distraction plate **806** may additionally include one or more non-threaded holes **942**. The non-threaded holes **942** may reduce the overall mass of the distraction plate **806** and may additionally permit patient fluids and tissues to permeate through the distraction plate **806**.

[0095] The magnet lifter **810** includes a plate magnet **912** that includes at least a first pole **914** and a second pole **916**. The first pole **914** and the second pole **916** comprise opposite polarity relative to one another. The plate magnet **912** may include additional poles, including, for example, four poles, six poles, eight poles, and so forth, without departing from the scope of the disclosure. In some cases, it may be desirable to design the plate magnet **912** with numerous poles to enable finer granularity when unscrewing and screwing the actuation screw.

[0096] As discussed herein, the magnet lifter **810** may comprise a separate component from the actuation screw **804**, or the magnet lifter **810** and actuation screw **804** may comprise a single indivisible component. If the magnet lifter **810** and the actuation screw **804** comprise a single indivisible component, then the plate magnet **912** may be attached directly to a screw shaft of the actuation screw.

[0097] Like the anchor screw **102** first described in connection with FIG. 1, the anchor screw **802** includes external threading **932** that is configured to interface with a substrate, which may include a substrate tissue of a patient. In an exemplary use-case, the external threading **932** is utilized to install the anchor screw **802** into bone tissue of the patient. The anchor screw **804** additionally includes an anchor tip **934** disposed at a distal end of the anchor screw **804**. The size and geometry of the anchor tip **934** may be optimized for the intended use-case and may specifically depend upon the identity of the substrate tissue.

[0098] FIG. 10 is an underside perspective view of the system **800** for performing a distraction histogenesis surgical procedure. The underside view in FIG. 10 enables viewing of portions of the coupler **808**.

[0099] FIG. 11 is a cross-sectional perspective view of the system **800** for performing a distraction histogenesis surgical procedure. The cross-sectional view of FIG. 11 enables viewing of the actuation screw **804** for the first time, and further enables viewing of various components of the coupler **808**, the magnet lifter **810**, and the anchor screw **802**.

[0100] The cross-sectional view of FIG. 11 enables viewing of the full length of each of the anchor screw **802**, the actuation screw **804**, and the coupler **808**. As shown in FIG. 11, the anchor tip **934** of the anchor screw **802** serves as the distal-most point of the system **800**. The actuation screw **804** is disposed within the anchor screw **802** and is further disposed through the coupler **808**. The coupler **808** extends through the distraction plate **806** and partially down into the anchor screw **802** when the device is in a fully retracted position as shown in FIG. 11.

[0101] The cross-sectional view of FIG. 11 further enables viewing of various components of the actuation screw **804**. The actuation screw **804** may include each of an outer screw shaft **1122** and an inner screw shaft **1160**, wherein the inner screw shaft **1160** is configured to be disposed at least partially within the outer screw shaft **1122**.

[0102] The system **800** includes the coupler **808** that is configured to axially couple the distraction plate **806** to the actuation screw **804** while ensuring the distraction plate **806** is not also rotationally coupled to the actuation screw **804**. The coupler **808** includes an anchoring interface **1120** and a rotational interface **1126**. The rotational interface **1126** is attached to the anchoring interface **1120**, and the rotational interface **1126** is located distal relative to the anchoring interface **1120**. The anchoring interface **1120** of the coupler **808** includes external threading **1168** that corresponds with internal threading **1150** of a central threaded hole **1140** of the distraction plate **806**. The external threading **1168** of the anchoring interface **1120** thus enables the coupler **808** to be screwed into and secured to the central threaded hole **1140** of the distraction plate **806**.

[0103] When the actuation screw **804** is installed within the coupler **808** and the anchor screw **802**, a driver head **1148** of the actuation screw **804** may be approximately disposed within a hollow interior space defined by the anchoring interface **1120** of the coupler **808**.

[0104] The rotational interface **1126** may include a polygonal cross-sectional geometry that matches the polygonal cross-sectional geometry of the socket interface **1130** of the anchor screw **802**. In the example illustrated in FIG. 11, the rotational interface **1126** includes a hexagonal cross-sectional geometry, and may thus be referred to as a hex driver. The exemplary socket interface **1130** illustrated in FIG. 11 corresponds with the rotational interface **1126** and thus includes a hex socket. It should be appreciated that the rotational interface **1126** and the socket interface **1130** may include various numbers of sides as deemed appropriate, including, for example, a quadrilateral, pentagonal, hexagonal, octagonal, and so forth, polygonal cross-sectional geometry.

[0105] The coupler **808** comprises a hollow interior and a through hole, such that the coupler **808** is configured to receive the actuation screw **804**. In the orientation illustrated in FIG. 11, the actuation screw **804** extends up through the coupler **808** and then interfaces with the magnet lifter **810**. The coupler **808** comprises a smooth hollow interior that enables the actuation screw **804** to freely rotate within the coupler **808**. The magnet lifter **810** may drive rotation of the actuation screw **804** by interfacing the driver head **1148** of the actuation screw **804**. When this occurs, the actuation screw **804** may rotate freely within the coupler **808** while screwing into or out of the anchor screw **802**. Thus, the coupler **808** enables the actuation screw **804** to rotate out of and into the anchor screw **802** without causing synchronous rotation of the distraction plate **806**.

[0106] The coupler **808** enables the distraction plate **806** to be axially coupled to the actuation screw **804** such that distraction plate **806** moves vertically along the longitudinal axis of the system **800** while remaining rotationally stationary when the actuation screw **804** is screwed into and out of the anchor screw **802**.

[0107] The outer screw shaft **1122** of the actuation screw **804** interfaces directly with the anchor screw **802**. The outer screw shaft **1122** includes a sidewall that defines a hollow

interior, wherein external threading 1124 is attached to an exterior surface of the outer screw shaft 1122 sidewall, and wherein internal threading 1156 is attached to an interior surface of the outer screw shaft 1122 sidewall. The proximal end of the outer screw shaft 1122 is located at a distal end of the coupler 808. The distal end of the outer screw shaft 1122 is formed by an outer actuation point 1164, which is disposed within the hollow interior of the anchor screw 802 and may nearly reach the distal-most end of the anchor screw 802. The entirety of the outer screw shaft 1122 is located distal relative to the coupler 808 and the distraction plate 806.

[0108] The external threading 1124 of the outer screw shaft 1122 is configured to interface with internal threading 1154 attached to an interior surface of a sidewall of the anchor screw 802. Thus, the outer screw shaft 1122 is configured to mate the actuation screw 804 to the anchor screw 802. The inner screw shaft 1160 does not mate directly with the anchor screw 802 and contributes to axially coupling the actuation screw 804 to the distraction plate 806 without also rotationally coupling the actuation screw 804 to the distraction plate 806.

[0109] The inner screw shaft 1160 is configured to be disposed within at least a portion of the outer screw shaft 1122. The proximal end of the inner screw shaft 1160 comprises a screw head 1148 that may be located within a portion of the coupler 808 and/or the distraction plate 806. The distal end of the inner screw shaft 1160 comprises an inner actuation point 1162 that is disposed within the hollow interior formed by the outer screw shaft 1122. The inner screw shaft 1160 is configured to be disposed through the hollow interior 1152 through-hole of the coupler 808, and thus, in combination with the coupler 808, the inner screw shaft 1160 enables the actuation screw 804 to be axially coupled to the distraction plate 806 without also being rotationally coupled to the distraction plate 806.

[0110] The inner screw shaft 1160 includes a threaded portion that includes the external threading 1158. The inner screw shaft 1160 may additionally include a smooth portion 1146. The smooth portion 1146 is configured to be disposed within the hollow interior 1152 defined by the rotational interface 1126 of the coupler 808. The smooth portion 1146 of the inner screw shaft 1160 may rotate freely within the rotational interface 1126 of the coupler 808.

[0111] The screw head 1148 of the inner screw shaft 1160 of the actuation screw 804 is configured to interface with an actuation screw coupling head 1166 of the magnet lifter 810. The actuation screw coupling head 1166 may be disposed within the hollow interior space located in between an inner surface of the anchoring interface 1120 of the coupler 808, and the outer surface of the screw head 1148 of the actuation screw 804. When the screw coupling head 1166 is located within that hollow interior space, the screw coupling head 1166 may form an interference fit with the screw head 1148 and then drive rotation of the inner screw shaft 1160 of the actuation screw 804. This may likewise drive rotation of the actuation screw 804 without driving synchronous rotation of the coupler 808 or the distraction plate 806.

[0112] The rotational interface 1126 of the coupler 808 includes a polygonal cross-sectional exterior geometry that enables the rotational interface 1126 to form a torque coupling with the corresponding polygonal cross-sectional interior geometry of a socket interface 1130 of the anchor

screw 802. This enables a user to simultaneously implant the actuation screw 804 and the anchor screw 802 into a patient as a single unit.

[0113] Further as shown in the cross-sectional view, the central threaded hole 1140 of the distraction plate 806 includes internal threading 1150 that corresponds with external threading 1168 of the anchoring interface 1120 of the coupler 808. This enables the coupler 808 to be securely screwed into the distraction plate 806. Further as shown in the cross-sectional view, the anchor screw 802 includes internal threading 1154 that corresponds with the external threading 1124 of the outer screw shaft 1122 of the actuation screw 804.

[0114] FIG. 12 is a perspective cross-sectional view of the system 800 for performing a distraction histogenesis procedure, wherein the actuation screw 804 is fully retracted into the anchor screw 802. The cross-sectional view illustrated in FIG. 12 shows that the screw head 1148 of the actuation screw 804 may have an external cross-sectional polygonal geometry that corresponds with an internal cross-sectional polygonal geometry of the screw coupling head 1166 of the magnet lifter 810. This ensures the magnet lifter 810 may have sufficient torque to rotate the actuator screw 804.

[0115] The brackets in FIG. 12 further illustrate how the combination of the outer screw shaft 1122 and the inner screw shaft 1160 make up the actuation screw 804. As shown, the inner screw shaft 1160 is partially disposed within the outer screw shaft 1122, and additionally passes through the coupler 808 and terminates within the central threaded hole 1140 of the distraction plate 806.

[0116] FIG. 13 is a schematic illustration of an exploded straight-on side view of an anti-rotation assembly 1300, which is a component of the system 800 described herein. The anti-rotation assembly 1300 includes components of the actuation screw 804 (including the inner screw shaft 1160 and the outer screw shaft 1122), the coupler 808, and the distraction plate 806. The anti-rotation assembly 1300 enables the distraction plate 806 to be axially coupled to the actuation screw 804 without also being rotationally coupled to the actuation screw 804.

[0117] The anti-rotation assembly 1300 includes the actuation screw 804, which includes the inner screw shaft 1160 and the outer screw shaft 1122. The outer screw shaft 1122 comprise a diameter that is greater than a diameter of an entrance through-hole to the rotational interface 1126 of the coupler 808, and this prevents the outer screw shaft 1122 from sliding up into the coupler 808 or the distraction plate 806. The inner screw shaft 1160 comprises a diameter that is smaller than the diameter of the central threaded hole 1140 of the distraction plate 806. The diameter of the inner screw shaft 1160 is also smaller than the diameter of a hollow interior 1152 defining a through-hole extending through the entirety of the coupler 808, including the anchoring interface 1120 and the rotational interface 1126.

[0118] During assembly or installation, the inner screw shaft 1160 is slid through the through-hole defined by the sidewall of the coupler 808. The inner screw shaft 1160 is then securely coupled to the outer screw shaft 1122 by screwing the external threading 1158 of the inner screw shaft 1160 into the internal threading 1156 disposed within the hollow interior of the outer screw shaft 1122. The inner screw shaft 1160 will be fully installed within the outer screw shaft 1122 when the screw head 1148 is located approximately within the central threaded hole 1140 of the

distraction plate **806** and/or when the smooth portion **1146** of the inner screw shaft **1160** is aligned with the rotational interface **1126** of the coupler **808**. The outer screw shaft **1122** may include stopper that prevents the inner screw shaft **1160** from being screwed in any deeper than desired. The smooth portion **1146** of the inner screw shaft **1160** may include a diameter that is smaller than a diameter of the rotational interface **1126** of the coupler **808**.

[0119] The external threading **1158** of the inner screw shaft **1160** may be tightly engaged with the internal threading **1156** of the outer screw shaft **1122** to prevent these two components of the actuation screw (see **804**) from becoming separated. In some cases, the inner screw shaft **1160** may be glued into the outer screw shaft **1122** to ensure a tight and semi-permanent installation. This may help ensure that a loosening rotation of the actuation screw (see **804**) to remove the actuation screw from the anchor screw (see **802**) does not also loosen the inner screw shaft **1160** from the outer screw shaft **1122**.

[0120] The anchoring interface **1120** of the coupler **808** includes the external threading **1168** that is configured to interface with corresponding internal threading **1150** of the central threaded hole **1140** of the distraction plate **806**. This ensures the coupler **808** is releasably locked into the distraction plate **806**. When the coupler **808** is further coupled to the actuation screw **804**, this further ensures that the distraction plate **806** moves up and down along the longitudinal axis of the system **800** synchronously with the actuation screw **804**.

[0121] The coupler **808** enables the distraction plate **806** to move vertically along the longitudinal axis of the system **800** while remaining rotationally stationary when the actuation screw **804** is screwed into and out of the anchor screw **802**. In practice, if the system **800** is installed in between bone tissue and periosteum tissue to perform periosteal distraction, this ensures the distraction plate **806** remains in place underneath the periosteum tissue, and only moves outward and inward to lift and lower the patient periosteum, without rotating underneath patient periosteum.

[0122] FIGS. 14-21 illustrate various views of a system **1400** for performing a distraction histogenesis surgical procedure. FIGS. 14-19 illustrate wherein the system **1400** includes a distraction plate, and FIGS. 20-21 illustrate wherein the system **1400** does not include the distraction plate. The system **1400** may be utilized with or without the distraction plate based on patient needs. In some cases, the system **1400** may be installed without the distraction plate, and then the distraction plate may be added later based on patient needs, and vice versa.

[0123] The system **1400** is configured to be magnetically coupled to an external magnet or electromagnet. Like the devices **100**, **800** first described in connection with FIGS. 1 and 8, respectively, the system **1400** may be installed within a patient, and then distracted (i.e., expanded) or retracted (i.e., contracted) by establishing a magnetic coupling between the system **1400** and an external magnetic controller (EMC). Thus, the system **1400** may be installed within the patient and the patient's skin barrier may be fully closed over the system **1400**. The system **1400** may still be distracted and retracted by establishing a magnetic coupling between the system **1400** and the external magnetic controller that is located external to the patient's skin barrier.

[0124] The system **1400** may be utilized in connection with a distraction plate (see, e.g., the distraction plate **806**

first described in connection with FIG. 8) or may be utilized without the distraction plate. The decision on whether to include a distraction plate will be made by a healthcare provider depending upon the patient needs.

[0125] FIG. 14 is a perspective view of the system **1400** with the distraction plate **1406**. The system **1400** includes an actuation screw **1404** fully retracted into an anchor screw **1402**. Like the system **800** first described in connection with FIG. 8, the distraction plate **1406** is axially coupled to the actuation screw **1404** without also being rotationally coupled to the actuation screw **1404**.

[0126] The system **1400** includes the anchor screw **1402** and the actuation screw **1404** configured to be disposed within the anchor screw **1402**. The actuation screw **1404** comprises a magnetic core **1412** that comprising at least two poles, including at least a first pole **1414** and a second pole **1416**. The magnetic core **1412** may comprise an elongated geometry such that each of the first pole **1414** and the second pole **1416** runs along a length of the magnetic core **1412**. The magnetic core **1412** may comprise a length that is substantially equivalent to a length of the actuation screw **1404**. The magnetic core **1412** may include more than two poles, and in some cases, this may be desirable to enable a machine or user to rotate the actuation screw **1404** (and thereby distract or retract the actuation screw **1404** from the anchor screw **1402**) with increased granularity. The magnetic core **1412** may include two, four, six, eight, ten, or more poles in various implementations. Each of the various poles of the magnetic core **1412** may run the length of the magnetic core.

[0127] The actuation screw **1404** may include the magnetic core **1412** fully integrated into the actuation screw **1404** to form a singular indivisible element. In alternative implementations, the actuation screw **1404** may include a sidewall that defines a hollow interior, and the magnetic core **1412** may be disposed within the hollow interior. In such an implementation, the magnetic core **1412** may form an interference fit with the sidewall of the actuation screw **1404** and/or the magnetic core **1412** may include external threading that is configured to interface with internal threading of the anchor screw **1402**.

[0128] The anchor screw **1402** comprises a sidewall that defines a hollow interior. The anchor screw **1402** includes external threading **1432** attached to an exterior surface of the sidewall, and the external threading **1432** is configured to interface with a patient tissue substrate. The anchor screw **1402** may additionally include internal threading (see **1754** at FIG. 17) attached to an interior surface of the sidewall. The internal threading **1754** of the anchor screw **1402** is configured to interface with corresponding external threading (see **1724** at FIG. 17) of the actuation screw **1404**.

[0129] The system **1400** includes the distraction plate **1406** that may be utilized to provide a larger surface for distracting a patient tissue. The distraction plate **1406** includes a central threaded hole configured to receive a coupler **1408**. Like the coupler **808** described in connection with the system **800** first illustrated in FIG. 8, the coupler **1408** is configured to axially couple the distraction plate **1406** to the actuation screw **1404**.

[0130] The coupler **1408** may include a socket interface **1430** comprising a polygonal cross-sectional geometry. The socket interface **1430** provides a means to remove the coupler **1408**, actuation screw **1404**, and anchor screw **1402** from a patient tissue substrate.

[0131] FIG. 15 is a straight-on side view of the system 1400 for performing a distraction histogenesis surgical procedure. FIG. 15 includes brackets illustrating the approximate lengths of the anchor screw 1402, actuation screw 1404, and coupler 1408. The actuation screw 1404 is disposed within the anchor screw 1402 and is thus not visible in a straight-on side view. The actuation screw 1404 may descend approximately to an end of the anchor screw 1402. The actuation screw 1404 may also be disposed through the coupler 1408 and the distraction plate 1406 and then terminate at approximately an upper surface of the distraction plate 1406.

[0132] FIG. 16 is a straight-on aerial top-down view of the system 1400 for performing a distraction histogenesis surgical procedure.

[0133] The socket interface 1430 of the coupler 1408 may include a polygonal cross-sectional geometry like the hexagonal geometry shown in FIG. 16. The socket interface 1430 is configured to interface with a corresponding driver having a polygonal cross-sectional geometry. The socket interface 1430 enables a user to unscrew the anchor screw 1402 from a patient tissue substrate.

[0134] The actuation screw 1404 may include a screw head 1648 that includes a polygonal cross-sectional geometry, such as a quadrilateral, pentagonal, hexagonal, and so forth, polygonal cross-sectional geometry. In the example illustrated herein, the screw head 1648 of the actuation screw 1404 includes a hexagonal driver head geometry. The socket interface 1430 may be sized such that the screw head 1648 may rotate within the socket interface 1430.

[0135] FIG. 17 is a cross-sectional perspective view of the system 1400 for performing a distraction histogenesis surgical procedure, wherein the actuation screw 1404 is fully retracted into the anchor screw 1402. The cross-sectional view of FIG. 17 enables viewing of the actuation screw 1404 that is fully screwed into the anchor screw 1402.

[0136] The actuation screw 1404 may include the screw head 1648 comprising a polygonal cross-sectional geometry. The screw head 1648 includes the polygonal cross-sectional geometry to enable a user or automated fixator adjuster to achieve sufficient torque when manually adjusting a position of the actuation screw 1404. Additionally, the polygonal cross-sectional geometry of the screw head 1648 enables a user to screw the entire system 1400 into a patient tissue substrate during an implantation surgery. Likewise, the polygonal cross-sectional geometry of the screw head 1648 aids in unscrewing the actuation screw 1404 during a removal surgery.

[0137] Like the actuation screw 104 first described in connection with FIG. 1, the actuation screw 1404 also includes external threading 1724 along a longitudinal shaft of an exterior of the actuation screw 1404. In some cases, the external threading 1724 may be attached directly to the magnetic core 1412. In other implementations, the external threading 1724 may be attached to a sidewall of the actuation screw 1404, and the magnetic core 1412 may be disposed within a hollow interior space defined by the sidewall of the actuation screw 1404. The external threading 1724 is configured to interface with corresponding internal threading 1754 of the anchor screw 1402. The actuation screw 1404 may include an actuation point 1764 disposed at a distal end of the actuation screw 1404. The actuation screw 1404 may be sized such that the actuation point 1764 is located near the anchor tip 1434 of the anchor screw 1402.

[0138] The actuation screw 1404 may be screwed into and out of the anchor screw 1402 by manually rotating the actuation screw 1404 with the screw head 1648. The actuation screw 1404 may additionally be screwed into and out of the anchor screw 1402 by rotating the magnetic core 1412. The magnetic core 1412 may be magnetically coupled to a corresponding magnet or electromagnet of an EMC. When the corresponding magnet of the EMC is rotated, the magnetic core 1412 of the actuation screw 1404 will also rotate. Thus, the EMC may be utilized to distract and retract the actuation screw 1404 without physically touching the actuation screw 1404. This enables a healthcare provider to implant the system 1400 and then close the patient's skin to reduce the likelihood of infection.

[0139] The magnetic core 1412 may include an elongated cylindrical geometry as shown in FIG. 17. The actuation screw 1404 may include an inner sheath 1770 configured to receive the magnetic core 1412. The inner sheath 1770 may be disposed within an outer sheath of the actuation screw 1404, wherein the outer sheath includes the external threading 1724 configured to engage with the internal threading 1754 of the anchor screw 1402. The inner sheath 1770 may include external threading 1772 that is configured to engage with corresponding internal threading of the screw head 1648 of the actuation screw 1404. The inner sheath 1770 may form a tight interference fit with the magnetic core 1412. In some cases, the magnetic core 1412 may be glued into or otherwise adhered to the inner sheath 1770.

[0140] The system 1400 may be implemented without the inner sheath 1770. In such an implementation, the magnetic core 1412 may be directly coupled to the actuation screw 1404 and then disposed within a hollow interior defined by the actuation screw 1404.

[0141] The magnetic core 1412 is coupled to the actuation screw 1404 such that rotation of the magnetic core 1412 causes corresponding rotation of the actuation screw 1404. When the magnetic core 1412 is magnetically coupled to a magnet or electromagnet of an EMC, the magnetic core 1412 may be rotated without directly contacting any component of the system 1400. The remote rotation of the magnetic core 1412 causes corresponding rotation of the actuation screw 1404 and may thereby cause the actuation screw 1404 to screw out of and into the anchor screw 1402. As described herein, the coupler 1408 serves as an anti-rotation assembly that enables the distraction plate 1406 to remain rotationally stationary when the actuation screw 1404 is screwed out of and into the anchor screw 1402.

[0142] FIG. 18 is a cross-sectional perspective view of the system 1400 for performing a distraction histogenesis surgical procedure. The cross-sectional view of FIG. 18 enables further viewing of the inner sheath 1770 that may be disposed around the magnetic core 1412. The magnetic core 1412 may be arranged such that each pole of the magnetic core 1412 runs an entire longitudinal length of the magnetic core 1412.

[0143] FIG. 19 is a cross-sectional perspective view of the system 1400 for performing a distraction histogenesis surgical procedure. The cross-sectional in FIG. 19 is cut through a portion of the magnetic core 1412, actuation screw 1404, and anchor screw 1402. FIG. 19 illustrates wherein the system 1400 does not include an inner sheath (see 1770 at FIG. 17) disposed around the magnetic core 1412. Instead, the magnetic core 1412 is disposed directly within a hollow interior defined by a sidewall of the actuation screw 1404.

[0144] FIGS. 20 and 21 illustrate views of the system 1400 without the distraction plate (see 1406 first illustrated in FIG. 14). FIG. 20 is a perspective view of the system 1400 and FIG. 21 is a cross-sectional perspective view of the system 1400. The system 1400 may be utilized with or without the distraction plate (see 1406) according to patient needs. In some cases, the system 1400 may be installed without the distraction plate, and then the distraction plate may be later added based on patient progression. In other cases, the system 1400 may be installed with the distraction plate, and then the distraction plate may be later removed based on patient progression.

[0145] The cross-sectional view of FIG. 21 illustrates wherein the inner sheath 1770 is disposed around the magnetic core 1412 only at a proximal end of the magnetic core 1412. The inner sheath 1770 may be glued to the magnetic core 1412 or otherwise adhered to the magnetic core 1412. The external threading 1772 of the inner sheath 1770 may then be utilized to couple the magnetic core to the screw head 1648 of the actuation screw 1404.

[0146] FIG. 22 is a straight-on side view of a system 2200 for performing a distraction histogenesis surgical procedure, and then actuating distraction and retraction of a device through a magnetic coupling. The system 2200 includes a distraction device 2202 for performing a distraction histogenesis surgical procedure. The system 2200 additionally includes an external magnetic controller (EMC) 2204 that forms a magnetic coupling with a magnet of the distraction device 2202.

[0147] In the example illustrated in FIG. 22, the distraction device 2202 is like the system 100 first described in connection with FIG. 1. However, the distraction device 2202 of the system 1400 may include a distraction plate and include components similar to the system 800 first described in connection with FIG. 8. Likewise, the system 1400 may include a distraction device 2202 including a magnetic core and include components similar to the system 1400 first described in connection with FIG. 14. The EMC 2204 may be utilized in connection with any of the magnetic devices described herein, including at least the devices 100, 800, 1400 first described in connection with FIGS. 1, 8, and 14, respectively.

[0148] FIG. 23 is a perspective view of the system 2200 for performing a distraction histogenesis surgical procedure, and then actuating distraction and retraction of a device through a magnetic coupling. The EMC 2204 may include a bottom plate 2306 configured to rest against a patient. The EMC 2204 may additionally include a dial 2308 to enable a machine or human user to rotate an external magnet of the EMC 2204.

[0149] FIG. 24 is an overhead perspective view of the EMC 2204 for actuating distraction and retraction of a device through a magnetic coupling. The EMC 2204 may additionally include external markers, including a positive rotational marker 2410 indicating the direction to rotate the dial 2308 to distract an actuation screw, i.e., the direction to turn the dial 2308 to unscrew the actuation screw from the corresponding anchor screw. The EMC 2204 may additionally include a negative rotational marker 2412 indicating the direction to rotate the dial 2308 to retract the actuation screw, i.e., the direction to turn the dial 2308 to screw the actuation screw further into the corresponding anchor screw.

[0150] FIG. 25 is a cross-sectional aerial top-down view of the EMC 2204 for actuating distraction and retraction of

a device through a magnetic coupling. The EMC 2204 includes an external magnet 2514 that comprises at least two poles having opposite polarity. As described herein, the external magnet 2514 is described as being “external” because it may be located external to patient tissue and still form a magnetic coupling with a magnetic device implanted inside the patient.

[0151] The external magnet 2514 includes at least a first pole 2516 and a second pole 2518 that are located adjacent to one another. The external magnet 2514 may include additional poles, including for example, four poles, six poles, eight poles, and so forth. In some cases, it may be desirable to include a higher quantity of poles to provide increased granularity when rotating the external magnet 2514.

[0152] The quantity of poles of the EMC 2204 may match the quantity of poles in a corresponding magnet of a device for performing a distraction histogenesis surgical procedure (see, e.g., the plate magnet 112 first described in connection with FIG. 1; the plate magnet 912 first described in connection with FIG. 9; or the magnetic core 1412 first described in connection with FIG. 14). The poles of the magnet of the device (see, e.g., 100, 800, or 1400) may alternate in polarity like pie slices around the magnet. Likewise, the poles of the external magnet 2514 of the EMC 2204 may alternate in polarity like pie slices around the external magnet 2514.

[0153] FIG. 26 is a cross-sectional perspective view of the system 2200 for performing a distraction histogenesis surgical procedure, and then actuating distraction and retraction of a device through a magnetic coupling. As shown in FIG. 26, a magnetic coupling is formed between the external magnet 2514 of the EMC 2204 and a corresponding magnet of the distraction device 2202.

[0154] In the example implementation illustrated in FIG. 26, the magnet of the distraction device 2202 includes two poles, including a North pole and a South pole. Likewise, the external magnet 2514 of the EMC 2204 includes two poles, including a North pole and a South pole. The opposite polarities attract between the magnet of the distraction device 2202 and the external magnet 2514 of the EMC 2204. This forms a magnetic coupling between the distraction device 2202 and the EMC 2204 that may be established even through numerous layers of intervening materials. The magnetic coupling may be sufficiently strong to be maintained through material layers such as periosteum, fat, fascia, skin, fabric, medical bandaging, and so forth.

[0155] FIGS. 27A-27C are schematic illustrations of an EMC 2204 including an external magnet 2514. The EMC 2204 may be manually actuated by a user or automatically actuated by an electronic controller in communication with a motor.

[0156] FIG. 27A is a schematic illustration of an aerial top-down view of the EMC 2204. The EMC 2204 is configured to be magnetically coupled to the systems described herein, including any of the devices 100, 800, 1400 first described in connection with FIGS. 1, 8, and 14, respectively.

[0157] The EMC 2204 includes a housing that comprises the dial 2308 that may be rotated clockwise and counter-clockwise. In the example illustrated in FIG. 27, the dial 2308 may be rotated clockwise to rotate in a positive 2410 direction, which would further distract an actuation screw, and thus unscrew the actuation screw from a corresponding anchor screw to lift the actuation screw away from the

anchor screw. The dial **2308** may be rotated counterclockwise in a negative **2412** direction, which would retract the actuation screw, and thus further screw the actuation screw into the corresponding anchor screw.

[0158] FIG. 27B is a schematic illustration of a straight-on cross-sectional view of the EMC **2204**. The EMC **2204** includes the external magnet **2514** that includes a first polarity **2518** and a second polarity **2518**. Like the magnet of an actuation screw, the external magnet **2514** is arranged such that each of the first polarity **2516** and the second polarity **2518** are located at the ends of the external magnet **2514**. The external magnet **2514** may include a cylindrical geometry as shown in FIG. 27B, and in this implementation, the first polarity **2516** and the second polarity **2518** run the entire length of cylindrical geometry.

[0159] FIG. 27C is a schematic illustration of a straight-on cross-sectional view of the EMC **2204**, wherein the EMC further includes a microcontroller and driver **2720** that is in electronic communication with a motor **2722**. The motor **2722** is mechanically coupled to the external magnet **2514** such that rotation of the motor **2722** may cause rotation of the external magnet **2514**.

[0160] FIG. 28 is a schematic illustration of a straight-on cross-sectional view of an EMC **2804** that includes one or more electromagnets **2824a**, **2824b**. The EMC **2804** may include a microcontroller and driver **2820** in electronic communication with the electromagnets **2824a**, **2824b**. The EMC **2804** may additionally include a power amplifier **2822** in electronic communication with the electromagnets **2824a**, **2824b** and the microcontroller and driver **2820**, wherein the power amplifier **2822** powers a coil of the electromagnets **2824a**, **2824b**.

[0161] FIGS. 29A-29F are schematic illustrations of a system **2900** for driving an implant magnet **2912** of a distraction device with an EMC **2804** that includes electromagnets. FIGS. 29A-29F include a schematic illustration of a cross-sectional straight-on side view of the EMC **2804**, and additionally include an aerial top-down view of the implant magnet **2912** of the distraction device to provide context to the current rotational position of the implant magnet **2912**.

[0162] The system **2900** includes the implant magnet **2912**, which is a component of a distraction device and is implanted in a patient. The implant magnet **2912** may include the plate magnet **112** of the distraction device first illustrated in connection with FIG. 1. The implant magnet **2912** may include the plate magnet **912** of the distraction device first illustrated in connection with FIG. 8. The implant magnet **2912** may include the magnetic core **1412** of the distraction device first illustrated in connection with FIG. 14. The implant magnet **2912** includes at least a first pole **2914** and a second pole **2916**. The implant magnet **2912** may include more than two poles, and may specifically include four, six, eight, or more poles.

[0163] The system **2900** is arranged such that the EMC **2804** includes a two-pole electromagnet **2902** comprising a first coil **2920** and a second coil **2922**. The EMC **2804** includes a Hall effect sensor or Hall effect array **2924** configured to track a current orientation of the implant magnet **2912** of the distraction device. The system **2900** may be implemented with a two pole electromagnet **2902** that is connected as shown in FIGS. 29A-29F. The system **2900** may alternatively be implemented with a two pole electromagnet **2902** that comprises two separate (non-connected) electromagnets.

[0164] The schematic illustrations of FIGS. 29A-29F describe a principle of traveling waves that enable granular rotation of the implant magnet **2912** by engaging the two-pole electromagnet **2902** of the EMC **2804**. The two-pole electromagnet **2902** may be arranged as an array around the implant magnet **2912** when the EMC **2804** is placed on the patient's skin to form a magnetic coupling with the implant magnet **2912**.

[0165] FIG. 29A illustrates an initiation orientation for the system **2900**. The two-pole electromagnet **2902** includes the first coil **2920** and the second coil **2922**. The EMC **2804** further includes the Hall effect sensor or Hall effect array **2924** to track the current rotational orientation of the implant magnet **2912**. The first coil **2920** and the second coil **2922** are located at approximately the junction between the first pole **2914** and the second pole **2916** of the implant magnet **2912**.

[0166] FIG. 29B illustrates a zero degree rotation orientation for the system **2900**, wherein all components of the system are in the same configuration as described in connection with the initiation orientation of FIG. 29A.

[0167] FIG. 29C illustrates a 90 degree rotation orientation for the system **2900**. The implant magnet **2912** has rotated 90 degrees relative to the initiation orientation illustrated in FIG. 29A. The second coil **2922** is engaged.

[0168] FIG. 29D illustrates a 180 degree rotation orientation for the system **2900**. The implant magnet **2912** has rotated 180 degrees relative to the initiation orientation illustrated in FIG. 29A. The second coil **2922** is engaged.

[0169] FIG. 29E illustrates a 270 degree rotation orientation for the system **2900**. The implant magnet **2912** has rotated 270 degrees relative to the initiation orientation illustrated in FIG. 29A. The second coil **2922** is engaged.

[0170] FIG. 29F illustrates a 360 degree rotation orientation for the system **2900**. The implant magnet **2912** has the same rotational position as the initiation orientation illustrated in FIG. 29A. The first coil **2920** and the second coil **2922** are engaged.

[0171] FIG. 30 is a schematic illustration of a straight-on cross-sectional view of an EMC **2804** comprising an electromagnet. The EMC **2804** may be utilized in connection with any of the devices described herein, including any of the devices **100**, **800**, or **1400** first described in connection with any of FIG. 1, 8, or 14, respectively. The EMC **2804** may be used in connection with any of the methods, systems, or described herein. The electromagnet-based EMC **2804** illustrated in FIG. 30 is interchangeable with the magnet-based EMC **2204** first illustrated in FIG. 22, as long as the electromagnet-based EMC **2804** is suitable for use based on a particular patient's health history.

[0172] The EMC **2804** may include housing components similar or identical to the housing components associated with the magnet-based EMC **2204** first illustrated in connection with FIG. 22. The electromagnet-based EMC **2804** includes an electromagnet comprising a rod **3020**, a coil **3022** wrapped around the rod **3020**, and a battery **3024**. The coil **3022** may be driven by a power amplifier and controller by a microcontroller.

[0173] FIGS. 31A-31C are schematic cross-sectional aerial top-down views of exemplary magnets that may be utilized in connection with any of the devices described herein, including, for example, the devices **100**, **800**, or **1400** first described in connection with FIG. 1, 8, or 14, respec-

tively. FIGS. 31A-31C each illustrate an aerial top-down view of a top of a magnet 3112 or cross-sectional slice of the magnet 3112.

[0174] FIG. 31A illustrate an example wherein the magnet 3112 includes two poles, including a first pole 3114 including a first polarity and a second pole 3116 including a second polarity. The first polarity is opposite to the second polarity. The poles 3114, 3116 are adjacent to one another in the cross-sectional slice such that each of the poles 3114, 3116 comprises a half-circle cross-sectional geometry.

[0175] FIG. 31B illustrates an example wherein the magnet 3112 includes four poles, including two of a first pole 3114a, 3114b each having a first polarity. The magnet 3112 further includes two of a second pole 3116a, 3116b each having a second polarity that is opposite to the first polarity. The poles are arranged in an alternating fashion such that any of the first pole 3114a, 3114b is adjacent to two of the second pole 3116a, 3116b. The poles are further arranged such that each of the poles 3114a, 3114b, 3116a, 3116b comprises a circular sector (pie slice) cross-sectional geometry.

[0176] FIG. 31C illustrates an example wherein the magnet 3112 includes eight poles, including four of a first pole 3114a, 3114b, 3114c, 3114d each having a first polarity. The magnet 3112 further includes four of a second pole 3116a, 3116b, 3116c, 3116d each having a second polarity that is opposite to the first polarity. The poles are arranged in an alternating fashion such that any of the first pole 3114a, 3114b, 3114c, 3114d is adjacent to two of the second pole. Likewise, any of the second pole 3116a, 3116b, 3116c, 3116d is adjacent to two of the first pole. The poles are further arranged such that each of the poles 3114a-3114d, 3116a-3116d comprises a circular sector (pie slice) cross-sectional geometry.

[0177] The devices 100, 800, 1400 described herein may be implemented with a magnet that comprises a plurality of a first pole having a first polarity, and a plurality of second pole having a second polarity that is opposite to the first polarity. Additionally, any of the external magnetic controllers 1404 described herein may include an external magnet that comprises a plurality of a first pole having a first polarity, and a plurality of second pole having a second polarity that is opposite to the first polarity. The systems described herein may be implemented such that the magnet of the distraction device includes the same quantity of poles as the external magnet of the external magnetic controller. In some cases, it may be desirable to include a greater quantity of poles to enable increased granularity when rotating the external magnet of the EMC, which causes synchronous rotation of the magnet of the distraction device, and which further causes synchronous rotation of the actuation screw of the distraction device.

[0178] FIGS. 32A-32C are schematic illustrations depicting the magnetic coupling between a magnet 3212 of an actuation screw (see, e.g., 104, 804, 1404), and an external magnet 2514 of an EMC 2204. As shown in FIG. 32A, a first polarity 3214 of the magnet 3212 of the actuation screw establishes a magnetic attraction with the second polarity 2518 of the external magnet 2514. In the example illustrated in FIGS. 32A-32C, the first polarity 3214 of the magnet 3212 is a North polarity, and the second polarity 2518 of the external magnet 2514 is a South polarity. Similarly, the second polarity 3216 of the magnet 3212 establishes a magnetic attraction with the first polarity 2516 of the external magnet 2514.

In the example illustrated in FIGS. 32A-32C, the second polarity 3216 of the magnet 3212 is a South polarity, and the first polarity 2516 of the external magnet 2514 is a North polarity. It should be appreciated that the polarities may be altered, and the polarities illustrated in FIGS. 32A-32B are exemplary only.

[0179] As shown in FIG. 32B, rotation of the external magnet 2514 of the EMC 2204 in a clockwise direction causes synchronous rotation of the magnet 3212 of the actuation screw due to the magnetic attraction of the corresponding magnetic poles. A patient or healthcare provider may thus place the EMC 2204 externally on the patient, establish the magnetic attraction between the EMC 2204 and the magnet 3212, and then distract or retract the actuation screw by rotating the external magnet 2514 of the EMC 2204.

[0180] As shown in FIG. 32C, rotation of the external magnet 2514 of the EMC 2204 in a counterclockwise direction causes synchronous rotation of the magnet 3212 of the actuation screw due to the magnetic attraction of the corresponding magnetic poles. A patient or healthcare provider may thus place the EMC 2204 externally on the patient, establish the magnetic attraction between the EMC 2204 and the magnet 3212, and then distract or retract the actuation screw by rotating the external magnet 2514 of the EMC 2204.

[0181] FIG. 33 is a schematic illustration of a distraction configuration 3300 for distracting or retracting a patient tissue after installation of a device 3302 for performing a distraction histogenesis surgical procedure. The device 3302 may include any of the suitable devices described herein, including, for example, any of the devices 100, 800, 1400 first described in any of FIG. 1, 8, or 14, respectively.

[0182] The distraction configuration 3300 includes an anchor screw anchored into a patient tissue substrate 3304. In the case of a periosteal distraction procedure, the patient tissue substrate 3304 may include bone tissue. However, the distraction configuration 3302 may be implemented on other patient tissue types. The distraction configuration 3300 includes a magnet of an actuation screw disposed in between the patient tissue substrate 3304 and a second patient tissue 3306. In the case of the periosteal distraction procedure, the patient tissue substrate 3304 may include the bone tissue, and the second patient tissue 3306 may include a periosteum layer. The distraction configuration 3300 includes the EMC 2204, 2804 located external to at least the second patient tissue 3306. In the case of a periosteal distraction procedure, the EMC 2204, 2804 may be located externally to the periosteum layer and may additionally be located externally to other layers such as connective tissue, fat, muscle, skin, and so forth.

[0183] The systems, methods, and devices described herein enable a healthcare provider to install a device for performing a distraction histogenesis procedure, and then fully close up the patient's skin barrier after installation. A user may then distract or retract the system by forming a magnetic attraction between the magnet coupled to an actuation screw, and the external magnet of the EMC 2204, 2804. This magnetic attraction enables the user to distract or retract the actuation screw over time without reopening the patient's skin barrier. This reduces the likelihood of infection and significantly improve patient outcomes.

[0184] FIGS. 34A and 34B are schematic illustrations of a distraction configuration 3400 for performing a periosteal

distraction surgical procedure on patient tissue. FIG. 34A illustrates wherein a device is fully retracted. FIG. 34B illustrates wherein the device is partially distracted. FIGS. 34A-34B specifically illustrate wherein the distraction device does not include a distraction plate.

[0185] The systems, methods, and devices described herein may be utilized to perform various distraction histogenesis procedures on various tissue types, including a variety of soft tissues. The systems, methods, and devices described herein may specifically be utilized to perform a periosteal distraction surgical procedure as depicted in FIGS. 34A-34B. The distraction configuration 3400 for a periosteal distraction procedure includes anchoring the anchor screw into a bone 3402 of a patient, and then fully screwing the actuation screw into the anchor screw. A periosteum 3404 may be pulled over a magnet coupled to the actuation screw, and the skin 3406 of the patient may be fully sutured shut to reduce the likelihood of infection. After the distraction device is installed, a user may place the EMC 2204, 2804 on the patient's skin over the actuation screw. When the EMC 2204, 2804 forms a magnetic attraction with the magnet coupled to the actuation screw, the user may rotate the dial of the EMC 2204, 2804 to synchronously rotate the actuation screw within the anchor screw. The user may thereby distract or retract the actuation screw within the anchor screw. As shown in FIG. 34B, when the actuation screw is partially distracted from the anchor screw, the periosteum 3404 and skin 3406 layers of the patient will be lifted away from the bone 3402 of the patient. This may trigger regeneration of bone tissue.

[0186] The distraction configuration 3400 may be performed utilizing any of the devices described herein. The distraction configuration 3400 may be performed utilizing the system 100 first described in connection with FIG. 1, wherein an anchor screw 102 is configured to receive an actuation screw 104 that includes a plate magnet 112 attached to the actuation screw 104. The plate magnet 112 may serve to stretch a second tissue layer up and away from the patient tissue substrate.

[0187] The distraction configuration 3400 may be performed utilizing the system 1400 first described in connection with FIG. 14, and specifically the implementation without the distraction plate as illustrated in FIGS. 20-21, wherein an anchor screw 1402 is configured to receive an actuation screw 1404 that is coupled to a magnetic core 1412. The magnetic core 1412 may serve to stretch a second tissue layer up and away from the patient tissue substrate.

[0188] FIGS. 35A and 35B are schematic illustrations of a distraction configuration 3500 for performing a periosteal distraction surgical procedure on patient tissue. FIG. 35A illustrates wherein a device is fully retracted. FIG. 35B illustrates wherein the device is partially distracted. FIGS. 35A-35B specifically illustrate wherein the distraction device includes a distraction plate.

[0189] The systems, methods, and devices described herein may be utilized to perform various distraction histogenesis procedures on various tissue types, including a variety of soft tissues. The systems, methods, and devices described herein may specifically be utilized to perform a periosteal distraction surgical procedure as depicted in FIGS. 35A-35B. The distraction configuration 3500 for a periosteal distraction procedure includes anchoring the anchor screw into a bone 3402 of a patient, and then fully screwing the actuation screw into the anchor screw. A

periosteum 3404 may be pulled over a magnet coupled to the actuation screw, and the skin 3406 of the patient may be fully sutured shut to reduce the likelihood of infection. After the distraction device is installed, a user may place the EMC 2204, 2804 on the patient's skin over the actuation screw. When the EMC 2204, 2804 forms a magnetic attraction with the magnet coupled to the actuation screw, the user may rotate the dial of the EMC 2204, 2804 to synchronously rotate the actuation screw within the anchor screw. The user may thereby distract or retract the actuation screw within the anchor screw. As shown in FIG. 35B, when the actuation screw is partially distracted from the anchor screw, the periosteum 3404 and skin 3406 layers of the patient will be lifted away from the bone 3402 of the patient. This may trigger regeneration of bone tissue.

[0190] The distraction configuration 3500 may be performed utilizing the system 800 first described in connection with FIG. 8, wherein an anchor screw 802 is configured to receive an actuation screw 804 that is coupled to a plate magnet 812 and coupled to a distraction plate 806. The plate magnet 812 and the distraction plate 806 may each serve to stretch a second tissue layer up and away from the patient tissue substrate. In some cases, the distraction plate may be secured to an osteotomized tissue such that the osteotomized tissue is also distracted away from the bone 3402 when the distraction plate is distracted away from the bone 3402.

[0191] The distraction configuration 3500 may be performed utilizing the system 1400 first described in connection with FIG. 14, wherein an anchor screw 1402 is configured to receive an actuation screw 1404 that is coupled to a magnetic core 1412 and may optionally additionally be coupled to a distraction plate (not shown in FIGS. 14-15). The magnet 1412 and the distraction plate (if utilized) may each serve to stretch a second tissue layer up and away from the patient tissue substrate. In some cases, the distraction plate may be secured to an osteotomized tissue such that the osteotomized tissue is also distracted away from the bone 3402 when the distraction plate is distracted away from the bone 3402.

[0192] FIGS. 36A and 36B are schematic illustrations of a distraction configuration 3600 for performing an osteotomy distraction surgical procedure on patient tissue. FIG. 36A illustrates wherein a device is fully retracted. FIG. 36B illustrates wherein the device is partially distracted. The distraction configuration 3600 may be performed with or without a distraction plate. If the distraction plate is utilized, then the osteotomized tissue may be secured to the distraction plate. If the distraction plate is not utilized, then the osteotomized tissue may be secured to another component of the distraction device, such as the actuation screw or the coupler.

[0193] The systems, methods, and devices described herein may be utilized to perform various distraction histogenesis procedures on various tissue types, including a variety of soft tissues. The systems, methods, and devices described herein may specifically be utilized to perform an osteotomy distraction surgical procedure as depicted in FIGS. 36A-36B. The distraction configuration 3600 for an osteotomy distraction procedure includes anchoring the anchor screw into a bicortical bone 3402 of a patient, cutting out a portion of the nearside/proximal bone (i.e., the osteotomized tissue), anchoring a portion of the device to the osteotomized tissue, and fully screwing the actuation screw into the anchor screw. A periosteum 3404 may be pulled

over a magnet coupled to the actuation screw, and the skin **3406** of the patient may be fully sutured shut to reduce the likelihood of infection. In another embodiment, the periosteum **3404** may be placed underneath the magnet coupled to the actuation screw. After the device is installed, a user may place the EMC **2204**, **2804** on the patient's skin over the actuation screw. When the EMC **2204**, **2804** forms a magnetic attraction with the magnet coupled to the actuation screw, the user may rotate the dial of the EMC **2204**, **2804** to synchronously rotate the actuation screw within the anchor screw. The user may thereby distract or retract the actuation screw within the anchor screw. As shown in FIG. **36B**, when the actuation screw is partially distracted from the anchor screw, the periosteum **3404** and skin **3406** layers of the patient will be lifted away from the bone **3406** of the patient, and the osteotomized tissue will likewise lift away from the anchoring bone tissue. This may trigger regeneration of bone, vascular or other soft tissue.

[**0194**] The distraction configuration **3600** may be performed utilizing the system **100** first described in connection with FIG. **1**, wherein an anchor screw **102** is configured to receive an actuation screw **104** that includes a plate magnet **112** attached to the actuation screw **104**. The plate magnet **112** may serve to stretch a second tissue layer up and away from the patient tissue substrate. The osteotomized bone tissue may be anchored to one or more of the plate magnet **112** or the actuation screw **104**.

[**0195**] The distraction configuration **3600** may be performed utilizing the system **800** first described in connection with FIG. **8**, wherein an anchor screw **802** is configured to receive an actuation screw **804** that is coupled to a plate magnet **812** and may optionally additionally be coupled to a distraction plate **806**. The plate magnet **812** and the distraction plate **806** (if utilized) may each serve to stretch a second tissue layer up and away from the patient tissue substrate. The osteotomized tissue may be anchored to the distraction plate **806**.

[**0196**] The distraction configuration **3600** may be performed utilizing the system **1400** first described in connection with FIG. **14**, wherein an anchor screw **1402** is configured to receive an actuation screw **1404** that is coupled to a magnetic core **1412** and may optionally additionally be coupled to a distraction plate (not shown in FIGS. **14-15**). The magnetic core **1412** and the distraction plate (if utilized) may each serve to stretch a second tissue layer up and away from the patient tissue substrate. The osteotomized tissue may be anchored to the distraction plate if utilized. The osteotomized tissue may be anchored to one or more of the coupler or the actuation screw if the distraction plate is not utilized.

[**0197**] FIGS. **37A-37C** are schematic flow chart diagrams of a method **3700** for performing a distraction histogenesis surgical procedure. The method **3700** described in FIGS. **37A-37C** refers to steps for performing a periosteal distraction procedure to distract a periosteum layer away from a bone tissue layer. However, the method **3700** may be easily modified to perform similar steps on other tissue types.

[**0198**] The method **3700** includes planning at **3702** a distraction device position and marking patient skin to indicating skin incision site. The method **3700** includes creating at **3704** a longitudinal incision down to patient bone tissue to prepare for placement of anchor screw. The method **3700** includes drilling at **3706** a pilot hole into patient bone tissue to prepare for placement of anchor screw. The method

3700 includes inserting at **3708** the anchor screw into the pilot hole. The method **3700** includes inserting at **3710** an actuation screw (i.e., magnetic lifter) into the anchor screw until the actuation screw touches the surface of the anchor screw, and without tightening the actuation screw down onto the anchor screw. The method **3700** includes closing at **3712** the periosteum and skin over the top of the actuation screw. The method **3700** includes holding at **3714** the external magnetic controller on to the patient skin. The method **3700** includes rotating at **3718** the dial on the external magnetic controller based on its indication to distract or retract the patient tissue.

[**0199**] FIGS. **38A-38E** are schematic block diagrams of a method **3800** for performing a distraction histogenesis surgical procedure utilizing the systems and devices described herein. In FIGS. **38A-38E**, the method **3800** is being performed on a tibia bone of a patient as an exemplary use-case. It should be appreciated that the systems, methods, and devices described herein may be utilized on alternative bones and tissues as deemed appropriate. The systems described herein may be utilized to perform a periosteal distraction procedure as described in connection with FIGS. **38A-38E**. The systems described herein may additionally be utilized to perform distraction histogenesis procedures on other tissue types.

[**0200**] The method **3800** may begin with planning a distraction plate position at **3802** and marking the patient's skin to indicate an incision location. This step is only necessary if the healthcare provider determines that a distraction plate would improve patient outcomes based on the patient's unique health circumstances. In some cases, the healthcare provider may determine that a distraction plate is not necessary, and that the patient may benefit from only the use of an anchor screw and actuation screw for distracting and retracting the patient's tissue.

[**0201**] The method **3800** includes creating at **3804** a longitudinal or transverse skin incision and a transverse incision of the patient's periosteum layer. The method **3800** includes inserting at **3806** a periosteal elevator to prepare subperiosteal tunnel on both sides of the incision. The method **3800** is such that on a distal end of the patient's bone, the periosteal elevator is inserted for a whole length of the distraction plate. The method **3800** is such that on a proximal end of the patient's bone, the periosteal elevator is inserted for a half-length of the distraction plate. The method **3800** includes inserting at **3812** the entire distraction plate under the periosteum on the distal side. The method **3800** includes pulling at **3814** the distraction plate back under the periosteum on the proximal side. The method **3800** include aligning at **3816** the central threaded hole of the distraction plate with the incision through the periosteum. The method **3800** includes inserting at **3818** a drill sleeve into the central threaded hole of the distraction plate. The method **3800** includes drilling at **3820** a hole into the patient's bone, wherein a drill bit is disposed through the drill sleeve. The method **3800** includes removing at **3822** the drill sleeve and inserting the anchor screw through the central threaded hole of the distraction plate and into the pilot hole drilled into the patient's bone. The method **3800** includes driving at **3824** a preassembled anchor screw and actuation screw through central threaded hole of distraction plate and into pilot hole drilled into patient bone tissue by utilizing cannulated driver until the actuation screw is located flush into the distraction plate, and wherein a magnet is coupled to the actuation

screw. The method **3800** includes closing at **3826** patient tissue over the device to reduce a likelihood of infection. The method **3800** includes placing at **3828** an external magnetic controller over the device and establishing a magnetic coupling between the magnet coupled to the actuation screw (installed within the patient) and an external magnet of the external magnetic controller. The method **3800** includes rotating at **3830** the external magnet of the external magnetic controller to cause synchronous rotation of the magnet coupled to the actuation screw.

[0202] FIG. **39** is a schematic block diagram of a system **3900** for remotely monitoring and controlling a distraction device. The system **3900** may be utilized in connection with any of the systems, methods, or devices described herein. The system **3900** may specifically be utilized in connection with any of the distraction devices described herein.

[0203] The system **3900** includes a health management server **3902** that processes operations for a health management platform **3906**. The health management server **3902** renders a graphical user interface (GUI) that is made accessible by way of the health management platform **3906**. The health management platform **3906** is made accessible to one or more personal devices **3914** by way of a computer-executed application, web browser, or other means. The health management platform **3906** may be accessed with a personal device **3914** that is in communication with a network, such as wide area network, local area network, the Internet, and so forth.

[0204] The health management server **3902** may optionally include an artificial intelligence and/or machine learning (AI/ML) engine **3904**. The AI/ML engine **3904** is trained upon a set of training data. The AI/ML engine **3904** may be trained to assess data output by any of the EMC **2204**, **2804**, a temperature sensor **3916**, a biomarker sensor **3918**, and/or a camera **3920** to monitor the status of a distraction device and determine whether there is a likely issue with the patient. The AI/ML engine **3904** may further be trained on data from numerous orthopedic procedures, including osteotomy and distraction histogenesis procedures, to generate a proposed treatment protocol for adjusting a fixator with an automated fixator adjuster that may be integrated into the EMC **2204**, **2804**.

[0205] The health management platform **3906** may include modules for providing information regarding data monitoring **3908**, adjustment calculation **3910**, provider communication **3912**, and so forth. The health management platform **3906** may be rendered on an application that is run on a personal device **3914**, such as a mobile phone, a tablet, or other personal computer. The health management platform **3906** may be rendered on a web browser that is accessible by way of a personal device **3914** connected to the Internet or LoRaWAN.

[0206] Patients, healthcare providers, administrators, and other users may access the health management platform **3906** with a personal device **3914** to view up-to-date data provided by any of the temperature sensor **3916**, biomarker sensor **3918**, or camera **3920**. Additionally, the health management platform **3906** provides current and past information regarding adjustment calculations **3910** for a fixator that is currently or was previously fixated to a patient. The adjustment calculations **3910** may be utilized to change or maintain protocols to be implemented by an automated fixator adjuster integrated into the EMC **2204**, **2804**. The health management platform **3912** provides a means for

secure bidirectional communication with patients and healthcare providers by way of the provider communication **3912** module. The health management platform **3912** additionally provides a means for secure bidirectional communication with devices such as the EMC **2204**, **2804**, temperature sensor **3916**, biomarker sensor **3918**, and the camera **3920**.

[0207] The EMC **2204**, **2804** may be automated to engage the magnetic and cause distraction or retraction without manual user intervention. The EMC **2204**, **2804** may include one or more processors configured to execute instructions stored in non-transitory computer readable storage medium. The processors of the EMC **2204**, **2804** may receive instructions from any of the health management server **3902**, a locally stored memory device with the EMC **2204**, **2804**, or from another source such as the personal device **3914**. The EMC **2204**, **2804** may automatically lift or lower the compliant elongated member of a distraction device to make real-time adjustments in accordance with a healthcare provider's protocol. A healthcare provider may amend the adjustment protocol by communicating with the health management server **3902** by way of the health management platform **3906**.

[0208] The EMC **2204**, **2804** may include one or more Bluetooth® low energy chips and/or near-field communication chips that enable the EMC **2204**, **2804** may wirelessly communicate with personal devices **3914** by way of Bluetooth® or near-field communication. The EMC **2204**, **2804** may further be equipped with Wi-Fi® or LoRaWAN capability that enables the EMC **2204**, **2804** to wirelessly communicate with the health management server **3902** directly.

[0209] The EMC **2204**, **2804** may be automated to rotate the magnet and cause distraction or retraction of implant without manual user intervention. The EMC **2204**, **2804** may include one or more processors configured to execute instructions stored in non-transitory computer readable storage medium. The processors of the EMC **2204**, **2804** may receive instructions from any of the health management server **3902**, a locally stored memory device with the external magnetic controller **1700**, or from another source such as the personal device **3914**. The EMC **2204**, **2804** may automatically lift or lower the compliant elongated member of a distraction device to make real-time adjustments in accordance with a healthcare provider's protocol. A healthcare provider may amend the adjustment protocol by communicating with the health management server **3902** by way of the health management platform **3906**, or through the personal device **3914**.

[0210] The temperature sensor **3916** may be temporarily installed within a patient to monitor the real-time internal temperature of the patient. Data output by the temperature sensor **3916** may be assessed to determine if patient tissue is inflamed or if the patient may have an infection at the surgical site.

[0211] The biomarker sensor **3918** may be temporarily installed within a patient to monitor the real-time presence of certain biomarkers. The biomarker sensor **3918** may specifically be tuned to monitor the presence of biomarkers that may signal the patient currently has an infection at the surgical site. The data output by the biomarker sensor **3918** may be utilized to determine if the patient likely has an infection at the surgical site and requires additional care.

[0212] The camera **3920** may include a standalone camera or one or more image sensors, light sources, photocells,

other sensors, and other features associated with another computing device such as a mobile phone. In some cases, a personal device **3914** comprising a camera communicates with the health management server **3902** by way of a computer-executed application. The health management server **3902** executes the application and may communicate directly with the camera **3920** to receive images and other data captured by the camera **3920**. In some cases, the camera **3920** may be integrated with any of the systems described herein and may capture up-to-date pictures of a fixator installed on a patient.

[0213] The EMC **2204**, **2804** comprises one or more processors configured to execute instructions stored in non-transitory computer readable storage medium. The processors of the EMC **2204**, **2804** may receive instructions from any of the health management server **3902**, a locally stored memory device with the EMC **2204**, **2804**, or from another source such as the personal device **3914**. A healthcare provider may amend the adjustment protocol by communicating with the health management server **3902** by way of the health management platform **3906**.

[0214] The EMC **2204**, **2804** may include one or more Bluetooth® low energy chips and/or near-field communication chips that enable the EMC **2204**, **2804** to wirelessly communicate with personal devices **3914** by way of Bluetooth® or near-field communication. The EMC **2204**, **2804** may further be equipped with Wi-Fi® or LoRaWAN capability that enables the EMC **2204**, **2804** to wirelessly communicate with the health management server **3902** directly.

[0215] The temperature sensor **3916**, biomarker sensor **3916**, and camera **3920** may include separate components that individually communicate with the health management server **3902** over a network connection. In other implementations, one or more of the temperature sensor **3916**, the biomarker sensor **3918**, or the camera **3920** may be integrated into the EMC **2204**, **2804**.

[0216] The personal device **3914** is any personal computing device that can communicate with the health management server **3902**. The personal device **3914** may include a smart phone, a tablet, a laptop, a personal computer, virtual or augmented reality device, and so forth. The personal devices **3914** may communicate with the health management server **3902** by way of a local area network (LAN) connection, a wide area network (WAN) connection, or another network connection.

[0217] The personal device **3914** may include an application installed thereon for enabling streamlined communication with the health management server **3902**. The application is configured for multiple platforms, including, for example, smart phone platforms, tablet platforms, Android® operating systems, Linux® operating systems, Windows® operating systems, iOS® operating systems, Macintosh® operating systems, and so forth. The application is configured to provide secure bidirectional communication with one or more of the health management server **3902**, the EMC **2204**, **2804**, the temperature sensor **3916**, the biomarker sensor **3918**, or the camera **3920**. The application may wirelessly receive sensor information, system status information, and may further send commanding signals to sensors and system components. The application is configured to display system information through one or more means, including, for example, graphic displays, audible

sounds, videos, and so forth. The application is configured to receive user input and is capable of communicating with multiple systems.

[0218] Referring now to FIG. 40, a block diagram of an example computing device **4000** is illustrated. Computing device **4000** may be used to perform various procedures, such as those discussed herein. Computing device **4000** can perform various monitoring functions as discussed herein, and can execute one or more application programs, such as the application programs or functionality described herein. Computing device **4000** can be any of a wide variety of computing devices, such as a desktop computer, in-dash computer, vehicle control system, a notebook computer, a server computer, a handheld computer, tablet computer and the like.

[0219] Computing device **4000** includes one or more processor(s) **4012**, one or more memory device(s) **4004**, one or more interface(s) **4006**, one or more mass storage device(s) **4008**, one or more Input/output (I/O) device(s) **4010**, and a display device **4030** all of which are coupled to a bus **4012**. Processor(s) **4012** include one or more processors or controllers that execute instructions stored in memory device(s) **4004** and/or mass storage device(s) **4008**. Processor(s) **4012** may also include diverse types of computer-readable media, such as cache memory.

[0220] Memory device(s) **4004** include various computer-readable media, such as volatile memory (e.g., random access memory (RAM) **4014**) and/or nonvolatile memory (e.g., read-only memory (ROM) **4016**). Memory device(s) **4004** may also include rewritable ROM, such as Flash memory.

[0221] Mass storage device(s) **4008** include various computer readable media, such as magnetic tapes, magnetic disks, optical disks, solid-state memory (e.g., Flash memory), and so forth. As shown in FIG. 40, a particular mass storage device **4008** is a hard disk drive **4024**. Various drives may also be included in mass storage device(s) **4008** to enable reading from and/or writing to the various computer readable media. Mass storage device(s) **4008** include removable media **4026** and/or non-removable media.

[0222] I/O device(s) **4010** include various devices that allow data and/or other information to be input to or retrieved from computing device **4000**. Example I/O device(s) **4010** include cursor control devices, keyboards, keypads, microphones, monitors, touchscreen devices, or other display devices, speakers, printers, network interface cards, modems, and the like.

[0223] Display device **4030** includes any type of device capable of displaying information to one or more users of computing device **4000**. Examples of display device **4030** include a monitor, display terminal, video projection device, and the like.

[0224] Interface(s) **4006** include various interfaces that allow computing device **4000** to interact with other systems, devices, or computing environments. Example interface(s) **4006** may include any number of different network interfaces **4020**, such as interfaces to local area networks (LANs), wide area networks (WANs), wireless networks, and the Internet. Other interface(s) include user interface **4018** and peripheral device interface **4022**. The interface(s) **4006** may also include one or more user interface elements **4018**. The interface(s) **4006** may also include one or more peripheral interfaces such as interfaces for printers, pointing devices (mice, track pad, or any suitable user interface now

known to those of ordinary skill in the field, or later discovered), keyboards, and the like.

[0225] Bus 4012 allows processor(s) 4012, memory device(s) 4004, interface(s) 4006, mass storage device(s) 4008, and I/O device(s) 4010 to communicate with one another, as well as other devices or components coupled to bus 4012. Bus 4012 represents one or more of several types of bus structures, such as a system bus, PCI bus, IEEE bus, USB bus, and so forth.

[0226] For purposes of illustration, programs and other executable program components are shown herein as discrete blocks, although it is understood that such programs and components may reside at various times in different storage components of computing device 4000 and are executed by processor(s) 4012. Alternatively, the systems and procedures described herein can be implemented in hardware, or a combination of hardware, software, and/or firmware. For example, one or more application specific integrated circuits (ASICs) can be programmed to conduct one or more of the systems and procedures described herein. As used herein, the terms “module” or “component” are intended to convey the implementation apparatus for accomplishing a process, such as by hardware, or a combination of hardware, software, and/or firmware, for the purposes of performing all or parts of operations disclosed herein. The terms “module” or “component” are intended to convey independent in how the modules, components, or their functionality or hardware may be implemented in different embodiments.

Examples

[0227] The following examples pertain to further embodiments.

[0228] Example 1 is a system for performing a distraction histogenesis surgical procedure. The system includes an anchor screw comprising a hollow interior defined by a sidewall. The system includes an actuation screw comprising: a magnet comprising a first pole and a second pole; and a screw shaft attached to the magnet. The system is such that the screw shaft is configured to be disposed within the hollow interior defined by the sidewall of the anchor screw.

[0229] Example 2 is a system as in Example 1, wherein the anchor screw comprises: external threading on an external surface of the sidewall; and internal threading on an internal surface of the sidewall.

[0230] Example 3 is a system as in any of Examples 1-2, wherein the screw shaft of the actuation screw comprises magnet external threading, and wherein the magnet external threading corresponds with the internal threading of the anchor screw.

[0231] Example 4 is a system as in any of Examples 1-3, wherein the magnet external threading engages with the internal threading of the anchor screw such that the actuation screw moves up or down along a longitudinal axis of the anchor screw in response to rotation of the magnet.

[0232] Example 5 is a system as in any of Examples 1-4, wherein the magnet comprises a bottom surface attached to the screw shaft; wherein the magnet comprises a top surface located opposite to the bottom surface; and wherein the first pole is located adjacent to the second pole such that each of the first pole and the second pole is disposed at the top surface of the magnet.

[0233] Example 6 is a system as in any of Examples 1-5, further comprising an external magnetic controller compris-

ing an external magnet configured to magnetically engage with the magnet of the actuation screw, wherein the external magnet comprises: a first external pole configured to magnetically attract to the first pole of the magnet; and a second external pole configured to magnetically attract to the second pole of the actuation screw.

[0234] Example 7 is a system as in any of Examples 1-6, wherein the external magnet comprises a bottom surface configured to be disposed adjacent to an external tissue of a patient; wherein the first external pole is located adjacent to the second external pole such that each of the first external pole and the second external pole is disposed at the bottom surface of the external magnet.

[0235] Example 8 is a system as in any of Examples 1-7, wherein the first pole of the actuation screw is located adjacent to the second pole of the actuation screw such that each of the first pole and the second pole is disposed at a top surface of the magnet; wherein the top surface of the magnet is configured to magnetically engage with the bottom surface of the external magnet in response to magnetic attraction between the first external pole and the first pole, and further in response to magnetic attraction between the second external pole and the second pole.

[0236] Example 9 is a system as in any of Examples 1-8, wherein rotation of the external magnet causes rotation of the actuation screw in response to magnetic attraction between: the first external pole of the external magnet and the first pole of the actuation screw; and the second external pole of the external magnet and the second pole of the actuation screw.

[0237] Example 10 is a system as in any of Examples 1-9, wherein the first pole of the actuation screw and the first external pole of the external magnetic controller comprise opposite polarity; and wherein the second pole of the actuation screw and the second external pole of the external magnetic controller comprise opposite polarity.

[0238] Example 11 is a system as in any of Examples 1-10, wherein rotation of the external magnet of the external magnetic controller causes rotation of the magnet of the actuation screw, in response to establishing an attraction between the external magnet and the magnet.

[0239] Example 12 is a system as in any of Examples 1-11, wherein the anchor screw is configured to be screwed into a tissue of a patient and remain stationary within the tissue of the patient; and wherein the screw shaft is configured to rotate within the hollow interior of the anchor screw to cause the actuation screw to move up or down along a longitudinal axis of the anchor screw and relative to a position of the anchor screw.

[0240] Example 13 is a system as in any of Examples 1-12, wherein the anchor screw is configured to be screwed into a bone tissue of a patient and remain stationary within the bone tissue of the patient; wherein the magnet of the actuation screw is configured to be disposed adjacent and underneath a periosteum of the patient; and wherein the screw shaft is configured to rotate within the hollow interior of the anchor screw to cause the actuation screw to move up or down along a longitudinal axis of the anchor screw and relative to a position of the anchor screw, to cause distraction or retraction of the periosteum of the patient.

[0241] Example 14 is a system as in any of Examples 1-13, wherein the anchor screw is configured to be screwed into a first tissue of a patient; and wherein a position of the actuation screw relative to a longitudinal axis of the anchor

screw is adjusted and maintained by rotating the screw shaft within the hollow interior of the anchor screw.

[0242] Example 15 is a system as in any of Examples 1-14, wherein the position of the actuation screw is optimized and adjusted to cause distraction or retraction of a second tissue of the patient.

[0243] Example 16 is a system as in any of Examples 1-15, further comprising an external magnetic controller configured to cause rotation of the actuation screw, wherein the external magnetic controller comprises: an external magnet configured to magnetically engage with the magnet of the actuation screw; a motor driver; a power source comprising a battery or external power source; a processor; and a motor in mechanical communication with the external magnet and configured to rotate the external magnet; wherein the processor is in electronic communication with the motor and causes the motor to rotate the external magnet according to a schedule via the motor driver.

[0244] Example 17 is a system as in any of Examples 1-16, wherein the external magnetic controller further comprises an antenna for receiving instructions over a network, and wherein the instructions comprise the schedule.

[0245] Example 18 is a system as in any of Examples 1-17, wherein the external magnetic controller further comprises one or more of a temperature sensor, a biomarker sensor, or a camera.

[0246] Example 19 is a system for performing a distraction histogenesis surgical procedure. The system includes an external magnetic controller comprising an external magnet. The system includes an anchor screw comprising a hollow interior defined by a sidewall. The system includes an actuation screw comprising: a magnet comprising a first pole and a second pole; and a screw shaft attached to the magnet. The system is such that the screw shaft is configured to be disposed within the hollow interior defined by the sidewall of the anchor screw. The system is such that the external magnet is configured to magnetically engage with the magnet of the magnetic lifter such that rotation of the external magnet causes rotation of the actuation screw.

[0247] Example 20 is a method for performing a distraction histogenesis surgical procedure. The method includes installing an anchor screw in a first tissue of a patient, wherein the anchor screw comprises a hollow interior defined by a sidewall. The method includes installing an actuation screw within the hollow interior of the anchor screw, wherein the actuation screw comprises: a magnet comprising a first pole and a second pole; and a screw shaft attached to the magnet. The method includes causing an external magnet to magnetically engage with the magnet of the actuation screw. The method includes rotating the external magnet to cause rotation of the magnet, and thereby adjust a position of the actuation screw along a longitudinal axis of the anchor screw.

[0248] Example 21 is a system. The system includes an anchor screw comprising a hollow interior defined by a sidewall, wherein the anchor screw comprises internal actuation threading attached to an interior surface of the sidewall and further comprises external anchor threading attached to an exterior surface of the sidewall. The system includes an actuation screw comprising a screw shaft that comprises external actuation threading. The system includes a magnet coupled to the actuation screw. The system is such that the external actuation threading of the screw shaft corresponds with the internal actuation threading of the

anchor screw. The system is such that rotation of the magnet causes synchronous rotation of the actuation screw.

[0249] Example 22 is a system as in Example 21, wherein the rotation of the magnet causes the synchronous rotation of the actuation screw and thereby causes the actuation screw to screw into or out of the hollow interior defined by the sidewall of the anchor screw.

[0250] Example 23 is a system as in any of Examples 21-22, further comprising a distraction plate coupled to the actuation screw, wherein the distraction plate is axially coupled to the actuation screw such that: the distraction plate lifts away from the anchor screw in response to the synchronous rotation of the actuation screw causing the actuation screw to screw out of the hollow interior of the anchor screw; the distraction plate lowers toward the anchor screw in response to the synchronous rotation of the actuation screw causing the actuation screw to screw into the hollow interior of the anchor screw.

[0251] Example 24 is a system as in any of Examples 21-23, further comprising a coupler that couples the distraction plate to the actuation screw, wherein the coupler permits the actuation screw to rotate independently of the distraction plate such that the distraction plate remains rotationally stationary in response to the synchronous rotation of the actuation screw causing the actuation screw to screw into or out of the hollow interior of the anchor screw.

[0252] Example 25 is a system as in any of Examples 21-24, further comprising: a distraction plate comprising a threaded hole that comprises internal threading; and a coupler comprising a coupler sidewall defining a hollow interior, wherein the coupler comprises external threading attached to an exterior surface of the coupler sidewall; wherein the internal threading of the threaded hole of the distraction plate corresponds with the external threading of the coupler.

[0253] Example 26 is a system as in any of Examples 21-25, wherein the coupler further comprises a smooth surface on the interior surface of the coupler sidewall.

[0254] Example 27 is a system as in any of Examples 21-26, wherein the screw shaft of the actuation screw further comprises a smooth portion that does not comprise the external actuation threading; and wherein the coupler is configured to couple the actuation screw to the distraction plate such that: the coupler is screwed into the threaded hole of the distraction plate by interfacing the external threading of the coupler with the internal threading of the threaded hole; and the actuation screw is disposed within the hollow interior of the coupler such that the smooth portion of the screw shaft of the actuation screw rotates freely within the hollow interior of the coupler.

[0255] Example 28 is a system as in any of Examples 21-27, wherein the coupler is configured to couple the actuation screw to the distraction plate such that: the distraction plate is axially coupled to the actuation screw such that the distraction plate lifts away from the anchor screw in response to the synchronous rotation of the actuation screw causing the actuation screw to screw out of the hollow interior of the anchor screw; the distraction plate is axially coupled to the actuation screw such that the distraction plate lowers toward the anchor screw in response to the synchronous rotation of the actuation screw causing the actuation screw to screw into the hollow interior of the anchor screw; and the distraction plate is not rotationally coupled to the actuation screw such that the distraction plate remains

rotationally stationary in response to the synchronous rotation of the actuation screw causing the actuation screw to screw out of or into the hollow interior of the anchor screw.

[0256] Example 29 is a system as in any of Examples 21-28, wherein the magnet comprises: a circular cross-sectional geometry; a first pole comprising a first polarity; and a second pole comprising a second polarity; wherein the first polarity is opposite to the second polarity; and wherein the circular cross-sectional geometry comprises each of the first pole and the second pole such that each of the first pole and the second pole comprises a half-circle cross-sectional geometry.

[0257] Example 30 is a system as in any of Examples 21-29, wherein the magnet comprises: a circular cross-sectional geometry; a plurality of a first pole comprising a first polarity; and a plurality of a second pole comprising a second polarity; wherein the first polarity is opposite to the second polarity; wherein the circular cross-sectional geometry comprises the plurality of the first pole and the plurality of the second pole arranged in an alternating orientation such that each of the plurality of the first pole is adjacent to two of the plurality of second pole, and further such that each of the plurality of the second pole is adjacent to two of the plurality of the first pole; and wherein each of the plurality of the first pole and each of the plurality of the second pole comprises a circular sector cross-sectional geometry.

[0258] Example 31 is a system as in any of Examples 21-30, wherein the magnet comprises a plate magnet comprises a top surface and a bottom surface, wherein the bottom surface is coupled to the actuation screw, and wherein each of a first polarity and a second polarity of the magnet is present on the top surface.

[0259] Example 32 is a system as in any of Examples 21-31, wherein the magnet comprises an elongated magnetic core disposed within a hollow interior defined by the actuation screw.

[0260] Example 33 is a system as in any of Examples 21-32, wherein the magnet is a component of the actuation screw, and wherein the magnet comprises an elongated magnetic core forming a component of the actuation screw.

[0261] Example 34 is a system as in any of Examples 21-33, further comprising an external magnetic controller comprising an external magnet configured to magnetically engage with the magnet, wherein rotation of the external magnet comprises synchronous rotation of the magnet, and thereby further causes the synchronous rotation of the actuation screw.

[0262] Example 35 is a system as in any of Examples 21-34, wherein the external magnet comprises a bottom surface configured to be disposed adjacent to an external tissue of a patient; wherein a first external pole of the external magnet is located adjacent to a second external pole of the external magnet such that each of the first external pole and the second external pole is disposed at the bottom surface of the external magnet.

[0263] Example 36 is a system as in any of Examples 21-35, wherein a first pole of the magnet is located adjacent to a second pole of the magnet such that each of the first pole and the second pole is disposed at a top surface of the magnet; and wherein the top surface of the magnet is configured to magnetically engage with the bottom surface of the external magnet in response to establishing a magnetic attraction between the magnet and the external magnet.

[0264] Example 37 is a system as in any of Examples 21-36, wherein the anchor screw is configured to be screwed into a tissue of a patient and remain stationary within the tissue of the patient; and wherein the screw shaft of the actuation screw is configured to rotate within the hollow interior of the anchor screw to cause the actuation screw to move up or down along a longitudinal axis of the anchor screw and relative to a position of the anchor screw.

[0265] Example 38 is a system as in any of Examples 21-37, wherein the anchor screw is configured to be screwed into a bone tissue of a patient and remain stationary within the bone tissue of the patient; wherein the magnet is configured to be disposed underneath a periosteum of the patient; wherein the rotation of the magnet causes the synchronous rotation of the actuation screw such that rotation of the magnet in a first direction causes the actuation screw to distract out of the anchor screw and thereby cause distraction of the periosteum of the patient; and wherein the rotation of the magnet causes the synchronous rotation of the actuation screw such that rotation of the magnet in a second direction causes the actuation screw to retract into the anchor screw and thereby cause retraction of the periosteum of the patient.

[0266] Example 39 is a system as in any of Examples 21-38, wherein the anchor screw is configured to be screwed into a tissue substrate of a patient; and wherein a position of the actuation screw relative to a longitudinal axis of the anchor screw is adjusted and maintained by rotating the screw shaft within the hollow interior of the anchor screw.

[0267] Example 40 is a system as in any of Examples 21-39, further comprising an external magnetic controller configured to form a magnetic coupling with the magnet, wherein the external magnetic controller comprises: an external magnet configured to form the magnetic coupling with the magnet; a processor; and a motor in mechanical communication with the external magnet, wherein the motor causes rotation of the external magnet, which thereby causes synchronous rotation of the magnet in response to establishing the magnetic coupling, and which further thereby causes the synchronous rotation of the actuation screw; wherein the processor is in electronic communication with the motor and causes the motor to rotate the external magnet according to a schedule.

[0268] Example 41 is a system as in any of Examples 21-40, further comprising an external magnetic controller configured to form a magnetic coupling with magnet, wherein the magnet is an implant magnet installed within a patient, and wherein the external magnetic controller comprises: one or more electromagnets with coils configured an electromagnet configured to form the magnetic coupling with the implant magnet; one or more power amplifiers or coil drivers; one or more Hall effect sensors or Hall effect array configured to read a magnetic position of the implant magnet; and a processor; wherein the processor causes actuation of the one or more electromagnets to form the magnetic coupling with the implant magnet and cause synchronized rotation of the implant magnet via the power drivers with feedback from the one or more Hall effect sensors or Hall effect array.

[0269] Example 42 is a system as in any of Examples 21-41, wherein the external magnetic controller further comprises an antenna for receiving instructions over a network, and wherein the instructions comprise the schedule.

[0270] Example 43 is a system as in any of Examples 21-42, wherein the external magnetic controller further comprises one or more of a temperature sensor, a biomarker sensor, or a camera.

[0271] Example 44 is a system for performing a distraction histogenesis surgical procedure, the system comprising: an external magnetic controller comprising an external magnet; and a device configured to be implanted within a patient. The device includes an anchor screw comprising a hollow interior defined by a sidewall, wherein the anchor screw comprises internal actuation threading attached to an interior surface of the sidewall and further comprises external anchor threading attached to an exterior surface of the sidewall. The device includes an actuation screw comprising a screw shaft that comprises external actuation threading. The device includes a magnet coupled to the actuation screw. The device is such that the external actuation threading of the screw shaft corresponds with the internal actuation threading of the anchor screw. The system is such that rotation of the external magnet causes synchronous rotation of the magnet in response to forming a magnetic coupling between the external magnet and the magnet. The device is such that the synchronous rotation of the magnet causes synchronous rotation of the actuation screw.

[0272] The foregoing description has been presented for purposes of illustration. It is not exhaustive and does not limit the invention to the precise forms or embodiments disclosed. Modifications and adaptations will be apparent to those skilled in the art from consideration of the specification and practice of the disclosed embodiments. For example, components described herein may be removed and other components added without departing from the scope or spirit of the embodiments disclosed herein or the appended claims.

[0273] Other embodiments will be apparent to those skilled in the art from consideration of the specification and practice of the disclosure disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A system for performing a distraction histogenesis surgical procedure, the system comprising:

an anchor screw comprising a hollow interior defined by a sidewall, wherein the anchor screw comprises internal actuation threading attached to an interior surface of the sidewall and further comprises external anchor threading attached to an exterior surface of the sidewall;

an actuation screw comprising a screw shaft that comprises external actuation threading; and

a magnet coupled to the actuation screw;

wherein the external actuation threading of the screw shaft corresponds with the internal actuation threading of the anchor screw; and

wherein rotation of the magnet causes synchronous rotation of the actuation screw.

2. The system of claim 1, wherein the rotation of the magnet causes the synchronous rotation of the actuation screw and thereby causes the actuation screw to screw into or out of the hollow interior defined by the sidewall of the anchor screw.

3. The system of claim 2, further comprising a distraction plate coupled to the actuation screw, wherein the distraction plate is axially coupled to the actuation screw such that:

the distraction plate lifts away from the anchor screw in response to the synchronous rotation of the actuation screw causing the actuation screw to screw out of the hollow interior of the anchor screw;

the distraction plate lowers toward the anchor screw in response to the synchronous rotation of the actuation screw causing the actuation screw to screw into the hollow interior of the anchor screw.

4. The system of claim 3, further comprising a coupler that couples the distraction plate to the actuation screw, wherein the coupler permits the actuation screw to rotate independently of the distraction plate such that the distraction plate remains rotationally stationary in response to the synchronous rotation of the actuation screw causing the actuation screw to screw into or out of the hollow interior of the anchor screw.

5. The system of claim 1, further comprising:

a distraction plate comprising a threaded hole that comprises internal threading; and

a coupler comprising a coupler sidewall defining a hollow interior, wherein the coupler comprises external threading attached to an exterior surface of the coupler sidewall;

wherein the internal threading of the threaded hole of the distraction plate corresponds with the external threading of the coupler.

6. The system of claim 5, wherein the coupler further comprises a smooth surface on the interior surface of the coupler sidewall.

7. The system of claim 6, wherein the screw shaft of the actuation screw further comprises a smooth portion that does not comprise the external actuation threading; and

wherein the coupler is configured to couple the actuation screw to the distraction plate such that:

the coupler is screwed into the threaded hole of the distraction plate by interfacing the external threading of the coupler with the internal threading of the threaded hole of the distraction plate; and

the actuation screw is disposed within the hollow interior of the coupler such that the smooth portion of the screw shaft of the actuation screw rotates freely within the hollow interior of the coupler.

8. The system of claim 7, wherein the coupler is configured to couple the actuation screw to the distraction plate such that:

the distraction plate is axially coupled to the actuation screw such that the distraction plate lifts away from the anchor screw in response to the synchronous rotation of the actuation screw causing the actuation screw to screw out of the hollow interior of the anchor screw;

the distraction plate is axially coupled to the actuation screw such that the distraction plate lowers toward the anchor screw in response to the synchronous rotation of the actuation screw causing the actuation screw to screw into the hollow interior of the anchor screw; and

the distraction plate is not rotationally coupled to the actuation screw such that the distraction plate remains rotationally stationary in response to the synchronous rotation of the actuation screw causing the actuation screw to screw out of or into the hollow interior of the anchor screw.

9. The system of claim 1, wherein the magnet comprises: a circular cross-sectional geometry; a first pole comprising a first polarity; and a second pole comprising a second polarity; wherein the first polarity is opposite to the second polarity; and wherein the circular cross-sectional geometry comprises each of the first pole and the second pole such that each of the first pole and the second pole comprises a half-circle cross-sectional geometry.
10. The system of claim 1, wherein the magnet comprises: a circular cross-sectional geometry; a plurality of a first pole comprising a first polarity; and a plurality of a second pole comprising a second polarity; wherein the first polarity is opposite to the second polarity; wherein the circular cross-sectional geometry comprises the plurality of the first pole and the plurality of the second pole arranged in an alternating orientation such that each of the plurality of the first pole is adjacent to two of the plurality of second pole, and further such that each of the plurality of the second pole is adjacent to two of the plurality of the first pole; and wherein each of the plurality of the first pole and each of the plurality of the second pole comprises a circular sector cross-sectional geometry.
11. The system of claim 1, wherein the magnet comprises a plate magnet comprises a top surface and a bottom surface, wherein the bottom surface is coupled to the actuation screw, and wherein each of a first polarity and a second polarity of the magnet is present on the top surface.
12. The system of claim 1, wherein the magnet comprises an elongated magnetic core disposed within a hollow interior defined by the actuation screw.
13. The system of claim 1, wherein the magnet is a component of the actuation screw, and wherein the magnet comprises an elongated magnetic core forming a component of the actuation screw.
14. The system of claim 1, further comprising an external magnetic controller comprising an external magnet configured to magnetically engage with the magnet, wherein rotation of the external magnet comprises synchronous rotation of the magnet, and thereby further causes the synchronous rotation of the actuation screw.
15. The system of claim 14, wherein the external magnet comprises a bottom surface configured to be disposed adjacent to an external tissue of a patient; wherein a first external pole of the external magnet is located adjacent to a second external pole of the external magnet such that each of the first external pole and the second external pole is disposed at the bottom surface of the external magnet.
16. The system of claim 15, wherein a first pole of the magnet is located adjacent to a second pole of the magnet such that each of the first pole and the second pole is disposed at a top surface of the magnet; and wherein the top surface of the magnet is configured to magnetically engage with the bottom surface of the external magnet in response to establishing a magnetic attraction between the magnet and the external magnet.
17. The system of claim 1, wherein the anchor screw is configured to be screwed into a tissue of a patient and remain stationary within the tissue of the patient; and

wherein the screw shaft of the actuation screw is configured to rotate within the hollow interior of the anchor screw to cause the actuation screw to move up or down along a longitudinal axis of the anchor screw and relative to a position of the anchor screw.

18. The system of claim 1, wherein the anchor screw is configured to be screwed into a bone tissue of a patient and remain stationary within the bone tissue of the patient;

wherein the magnet is configured to be disposed underneath a periosteum of the patient;

wherein the rotation of the magnet causes the synchronous rotation of the actuation screw such that rotation of the magnet in a first direction causes the actuation screw to distract out of the anchor screw and thereby cause distraction of the periosteum of the patient; and wherein the rotation of the magnet causes the synchronous rotation of the actuation screw such that rotation of the magnet in a second direction causes the actuation screw to retract into the anchor screw and thereby cause retraction of the periosteum of the patient.

19. The system of claim 1, wherein the anchor screw is configured to be screwed into a tissue substrate of a patient; and

wherein a position of the actuation screw relative to a longitudinal axis of the anchor screw is adjusted and maintained by rotating the screw shaft within the hollow interior of the anchor screw.

20. The system of claim 1, further comprising an external magnetic controller configured to form a magnetic coupling with the magnet, wherein the external magnetic controller comprises:

an external magnet configured to form the magnetic coupling with the magnet;

a processor; and

a motor driver in mechanical communication with the external magnet, wherein the motor causes rotation of the external magnet, which thereby causes synchronous rotation of the magnet in response to establishing the magnetic coupling, and which further thereby causes the synchronous rotation of the actuation screw;

wherein the processor is in electronic communication with the motor and causes the motor to rotate the external magnet according to a schedule and via the motor driver.

21. The system of claim 1, further comprising an external magnetic controller configured to form a magnetic coupling with the magnet, wherein the external magnetic controller comprises:

one or more electromagnets configured to form the magnetic coupling with the magnet;

a Hall effect sensor configured to read a magnetic position of the magnet;

one or more power drivers; and

a processor;

wherein the processor controls synchronized actuation of the one or more electromagnets to form the magnetic coupling with the magnet and cause synchronized rotation of the magnet via the one or more power drivers with feedback from the Hall effect sensor.

22. The system of claim 20, wherein the external magnetic controller further comprises an antenna for receiving instructions over a network, and wherein the instructions comprise the schedule.

23. The system of claim **20**, wherein the external magnetic controller further comprises one or more of a temperature sensor, a biomarker sensor, or a camera.

24. A system for performing a distraction histogenesis surgical procedure, the system comprising:

- an external magnetic controller comprising an external magnet; and

- a device configured to be implanted within a patient, wherein the device comprises:

- an anchor screw comprising a hollow interior defined by a sidewall, wherein the anchor screw comprises internal actuation threading attached to an interior surface of the sidewall and further comprises external anchor threading attached to an exterior surface of the sidewall;

- an actuation screw comprising a screw shaft that comprises external actuation threading; and

- a magnet coupled to the actuation screw;

- wherein the external actuation threading of the screw shaft corresponds with the internal actuation threading of the anchor screw;

- wherein rotation of the external magnet causes synchronous rotation of the magnet in response to forming a magnetic coupling between the external magnet and the magnet; and

- wherein rotation of the magnet causes synchronous rotation of the actuation screw.

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