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(54) **SYSTEMS, METHODS, AND DEVICES FOR DISTRACTION HISTOGENESIS**

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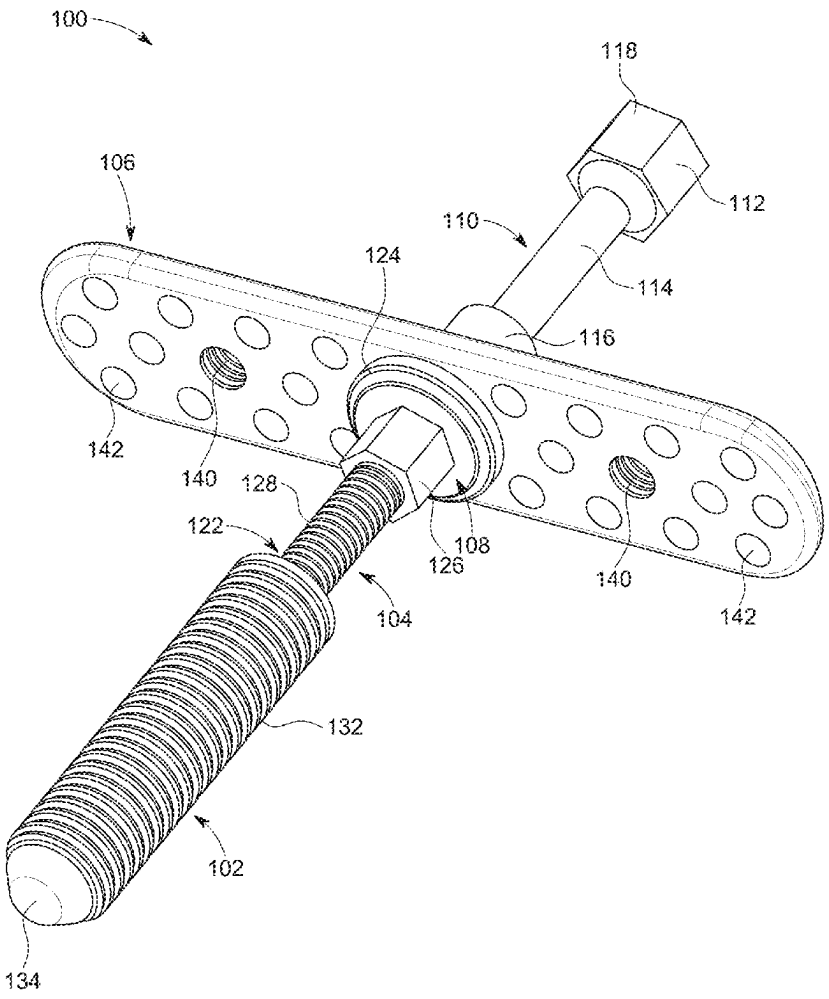
(52) **U.S. Cl.**

CPC ***A61B 17/8019*** (2013.01); *A61B 2017/00221* (2013.01); *A61B 2017/00398* (2013.01)

(57) **ABSTRACT**

Systems, methods, and devices for distraction histogenesis and angiogenesis. 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 external actuation threading attached to an exterior surface of the actuation screw. The system includes a distraction plate coupled to the actuation screw. The system is such that the external actuation threading corresponds with the internal actuation threading such that the actuation screw is configured to be screwed into the hollow interior of the anchor screw. The system is such that the distraction plate is rotationally independent of the actuation screw. The system includes an actuation screw adjustor which can be either manual or automatic.



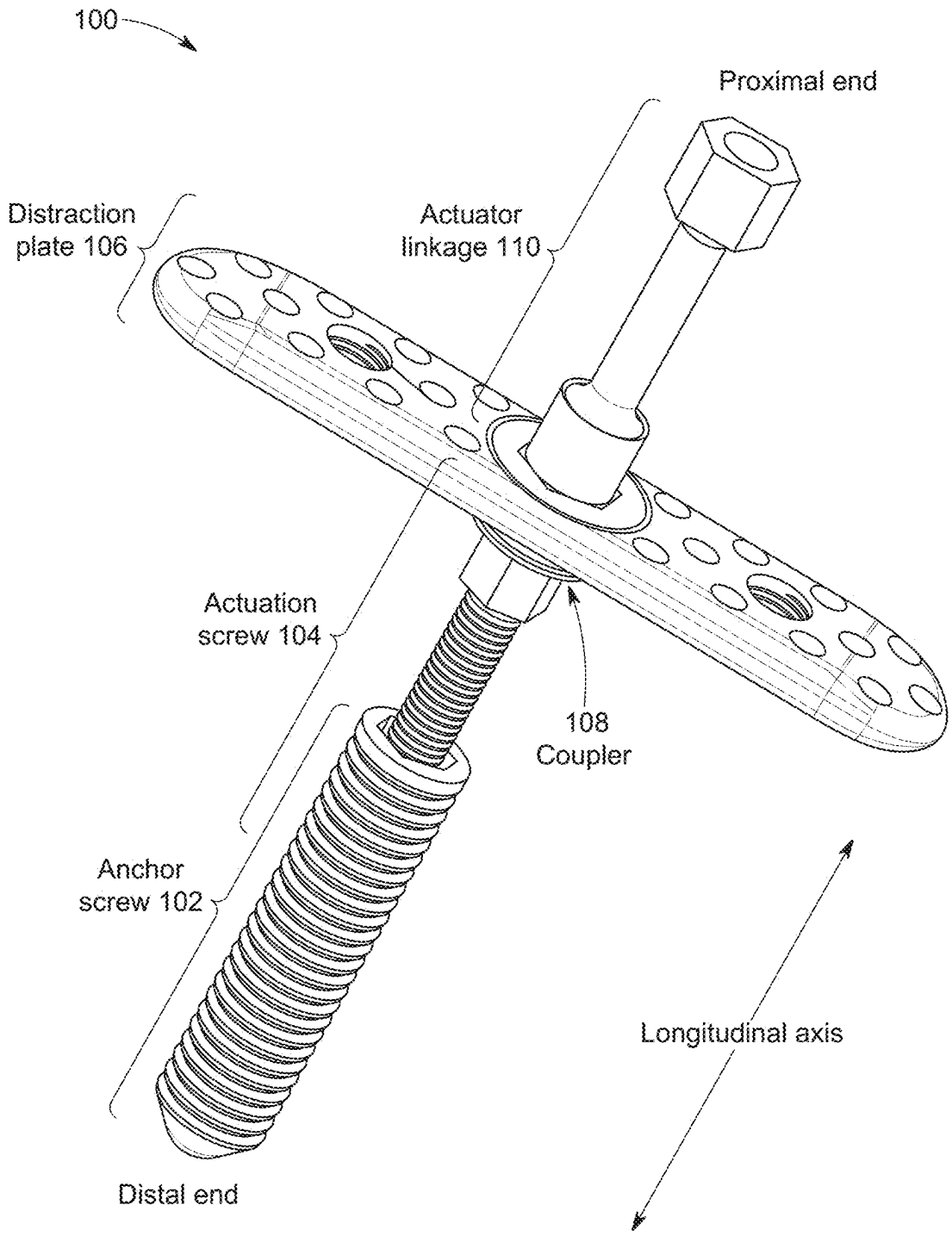

100
Proximal end
Distraction plate 106
Actuator linkage 110
Actuation screw 104
108 Coupler
Anchor screw 102
Longitudinal axis
Distal end

FIG. 1A

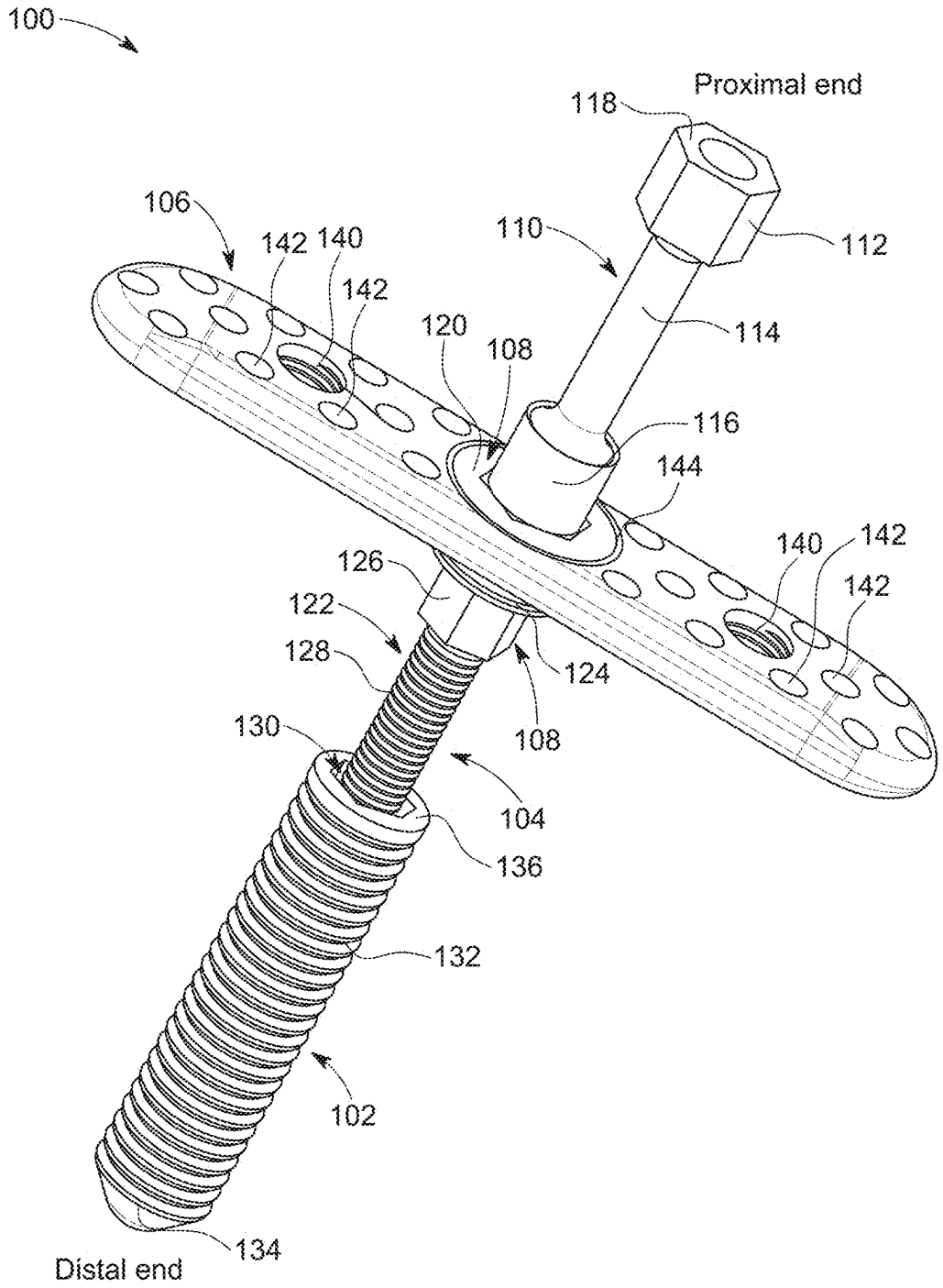

100
Proximal end
118
106
142
140
142
110
112
120
108
114
116
144
140
142
142
126
122
128
124
130
108
104
136
132
102
134
Distal end

FIG. 1B

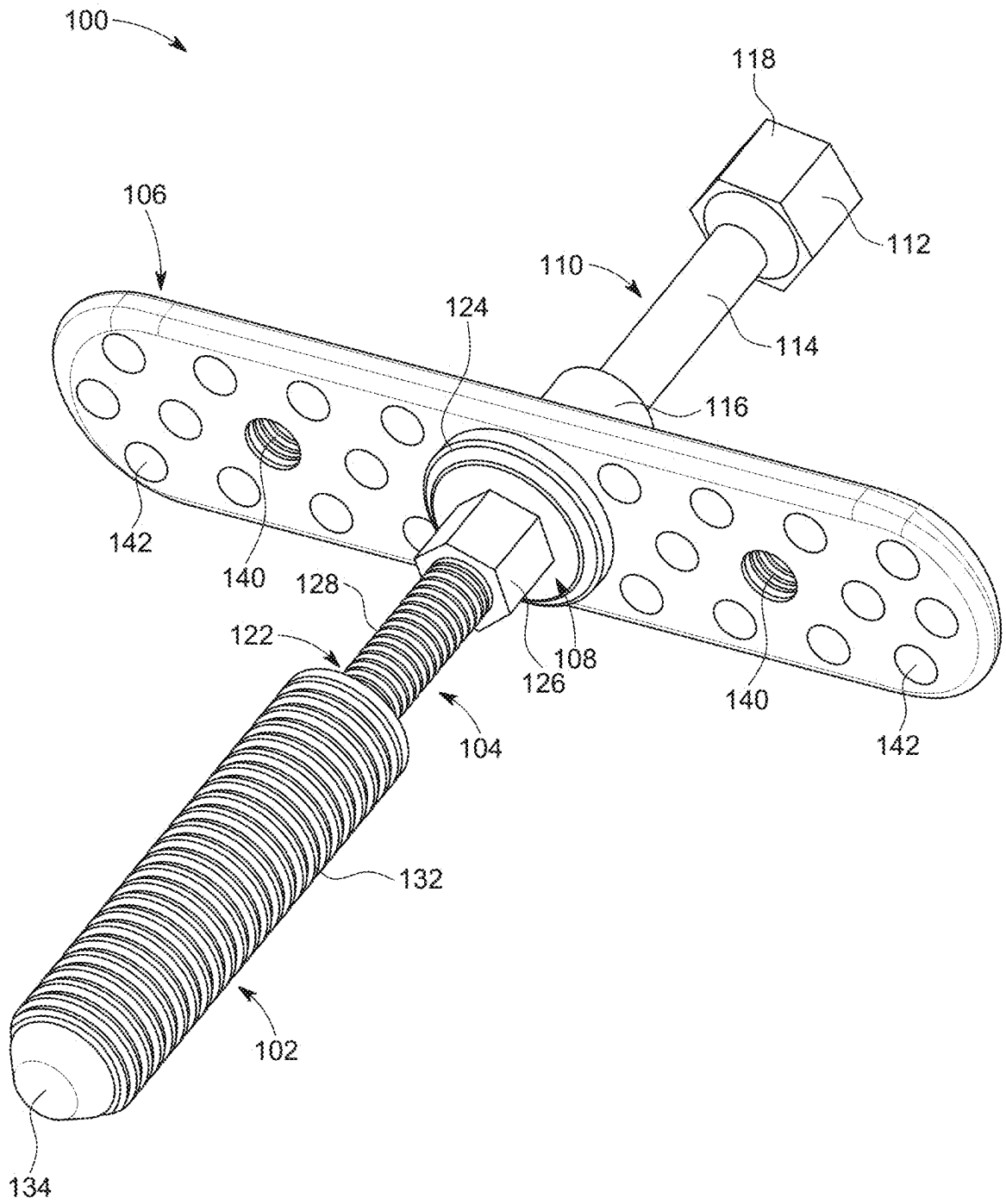

100
118
106
112
110
124
114
116
142
140
128
122
108
126
140
142
104
132
102
134

FIG. 2

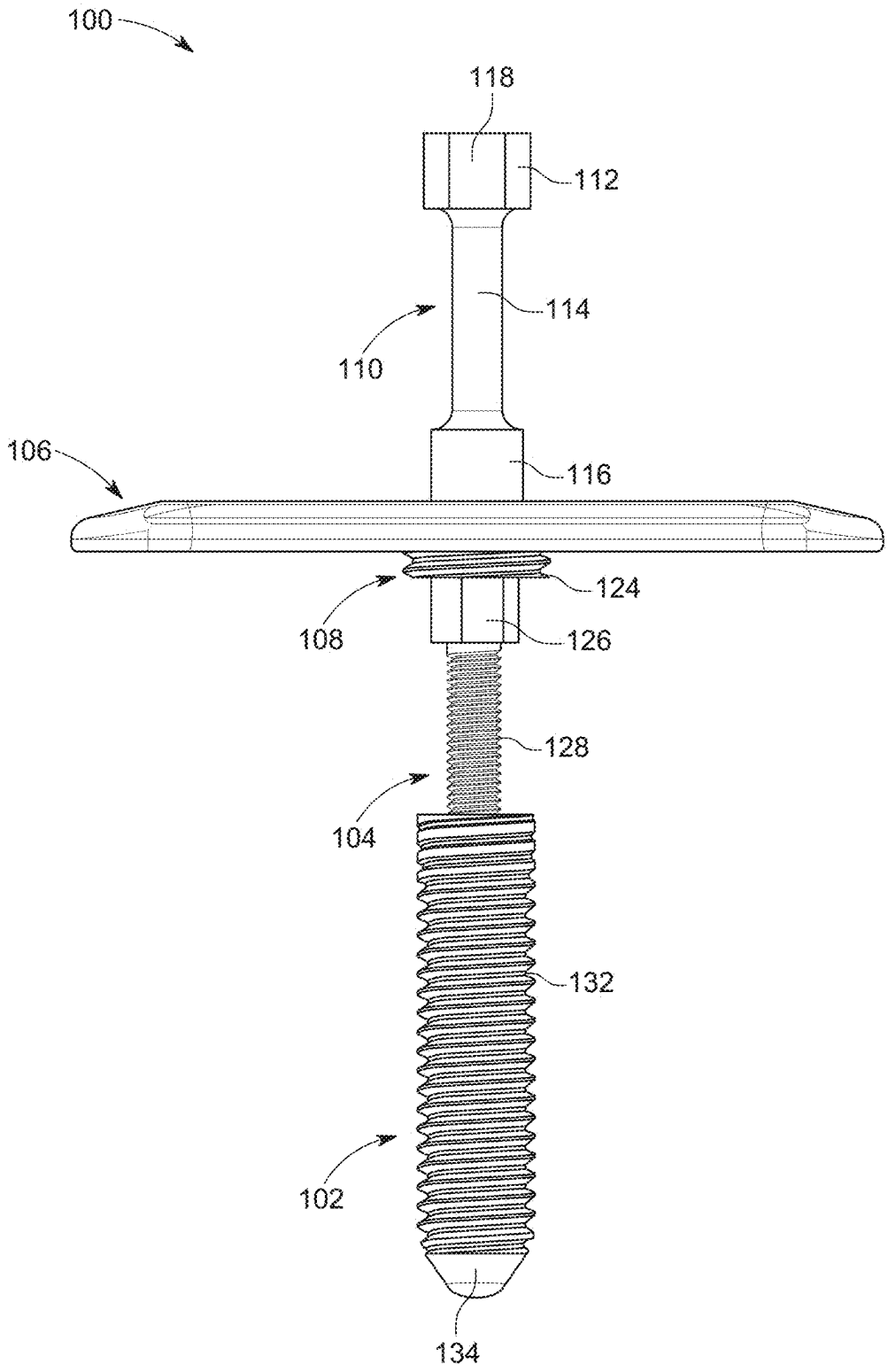


FIG. 3

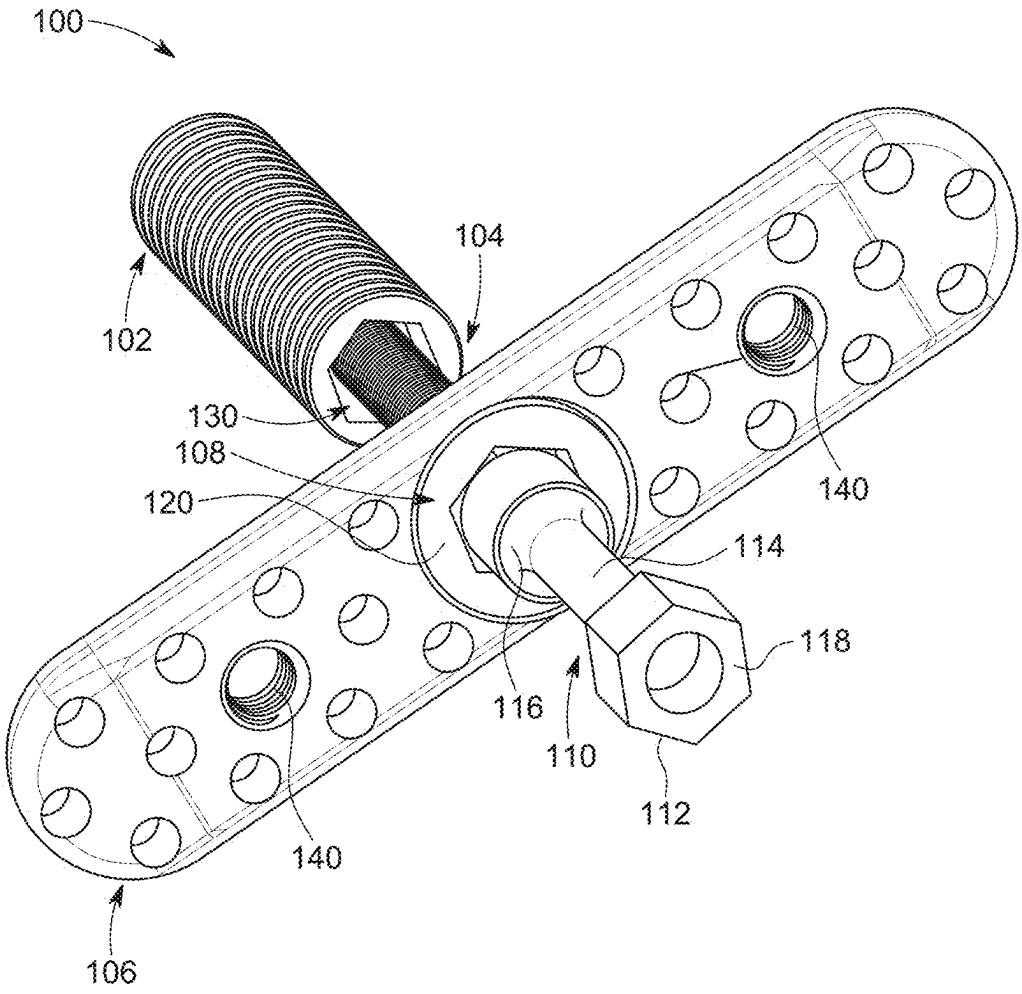


FIG. 4

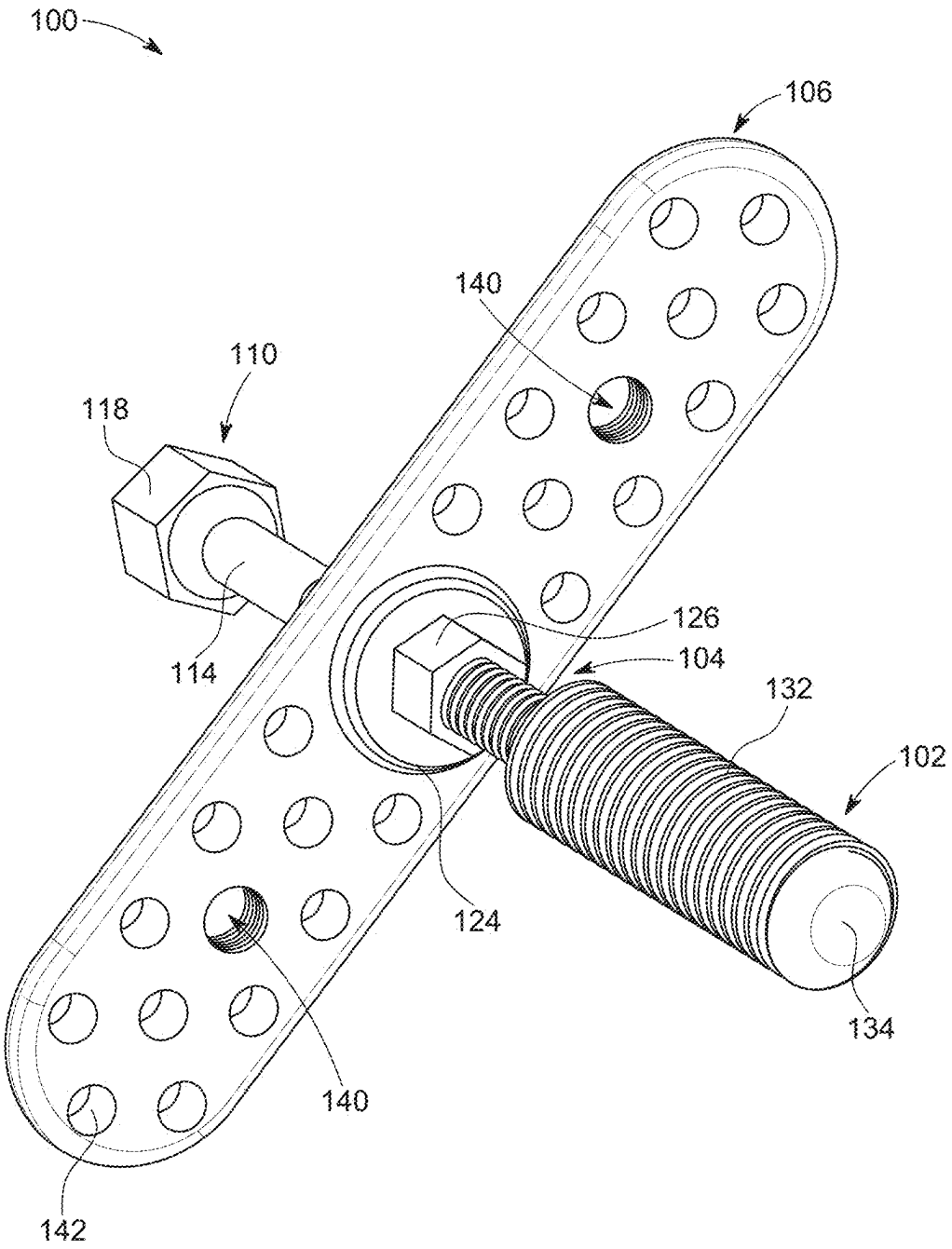


FIG. 5

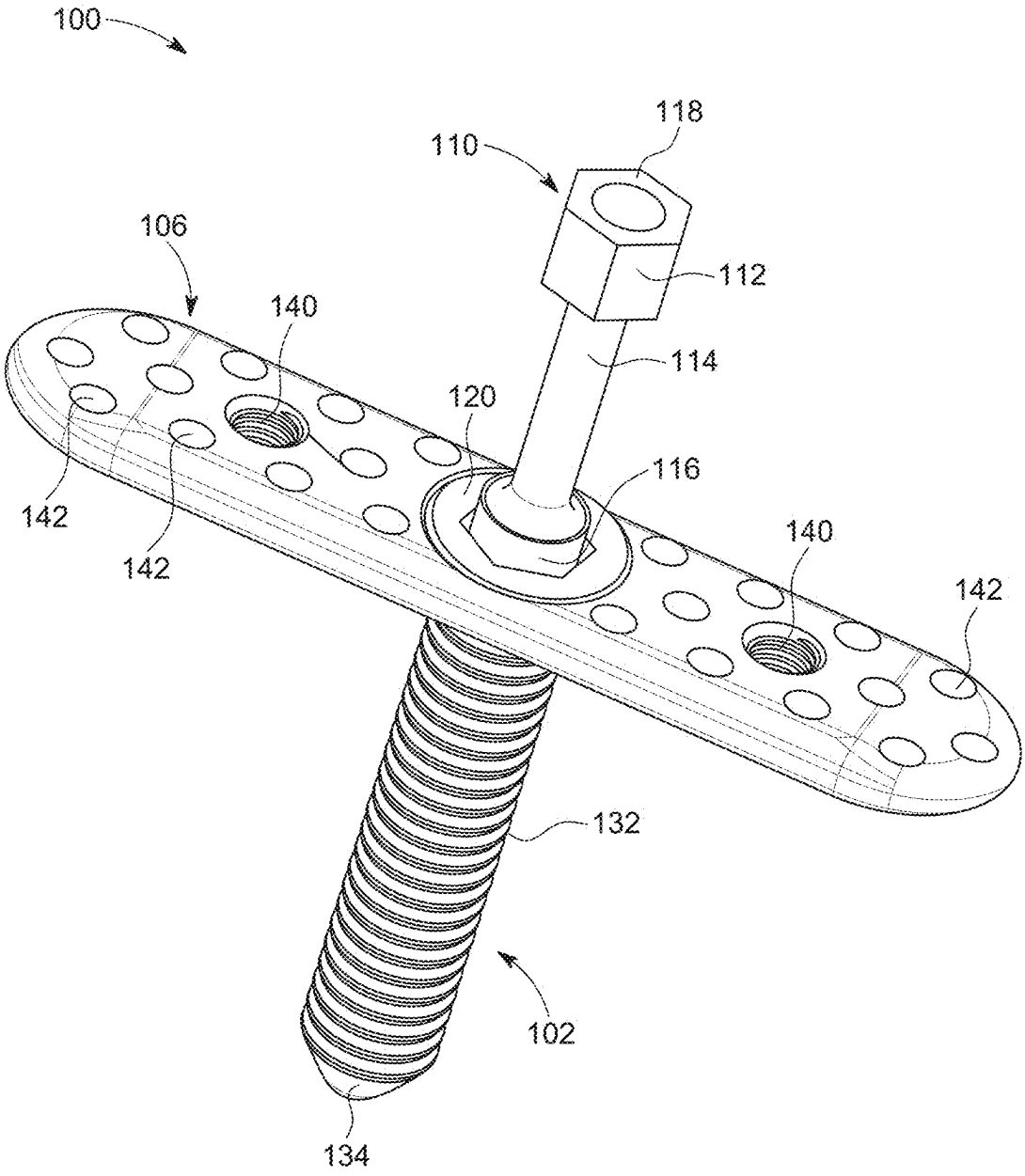


FIG. 6

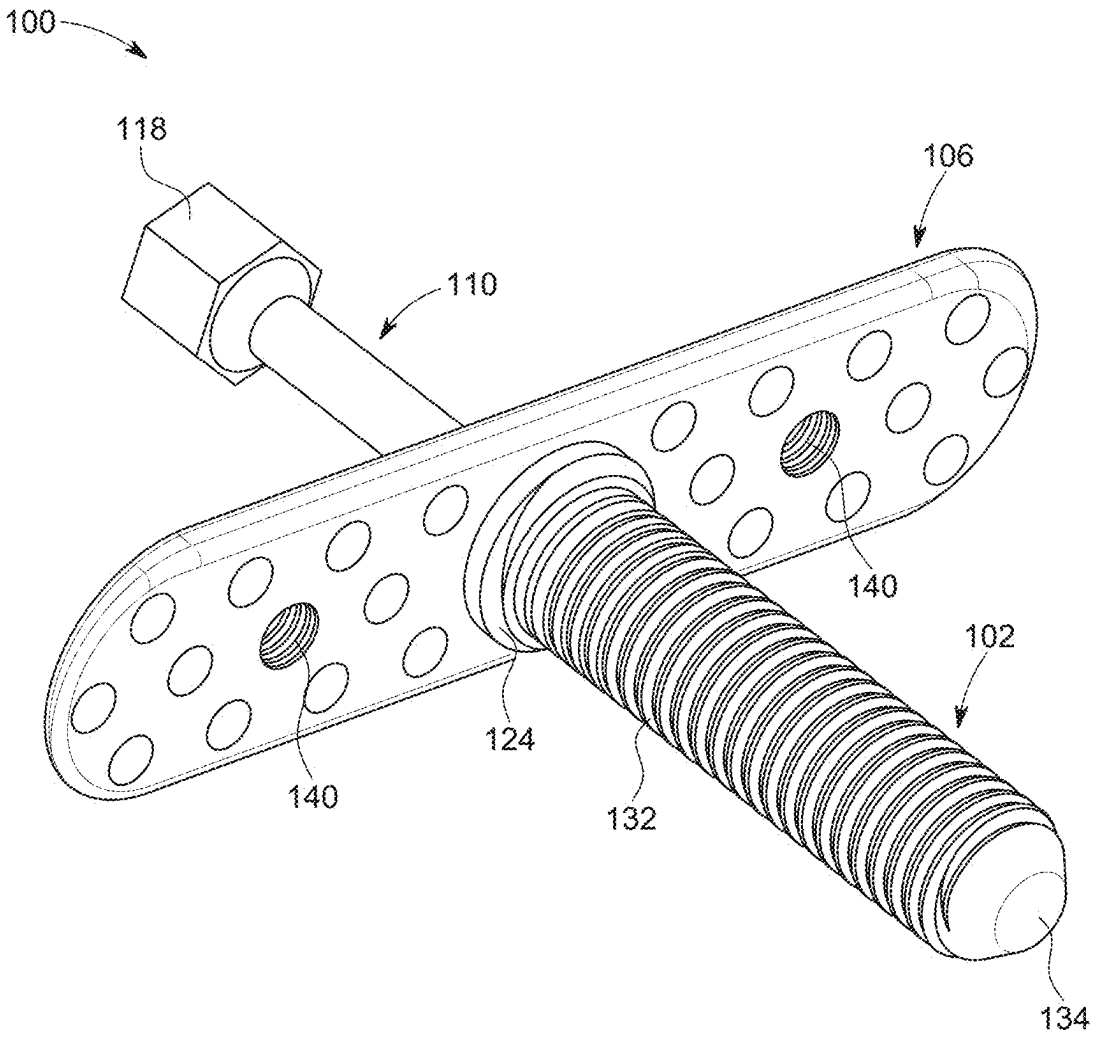


FIG. 7

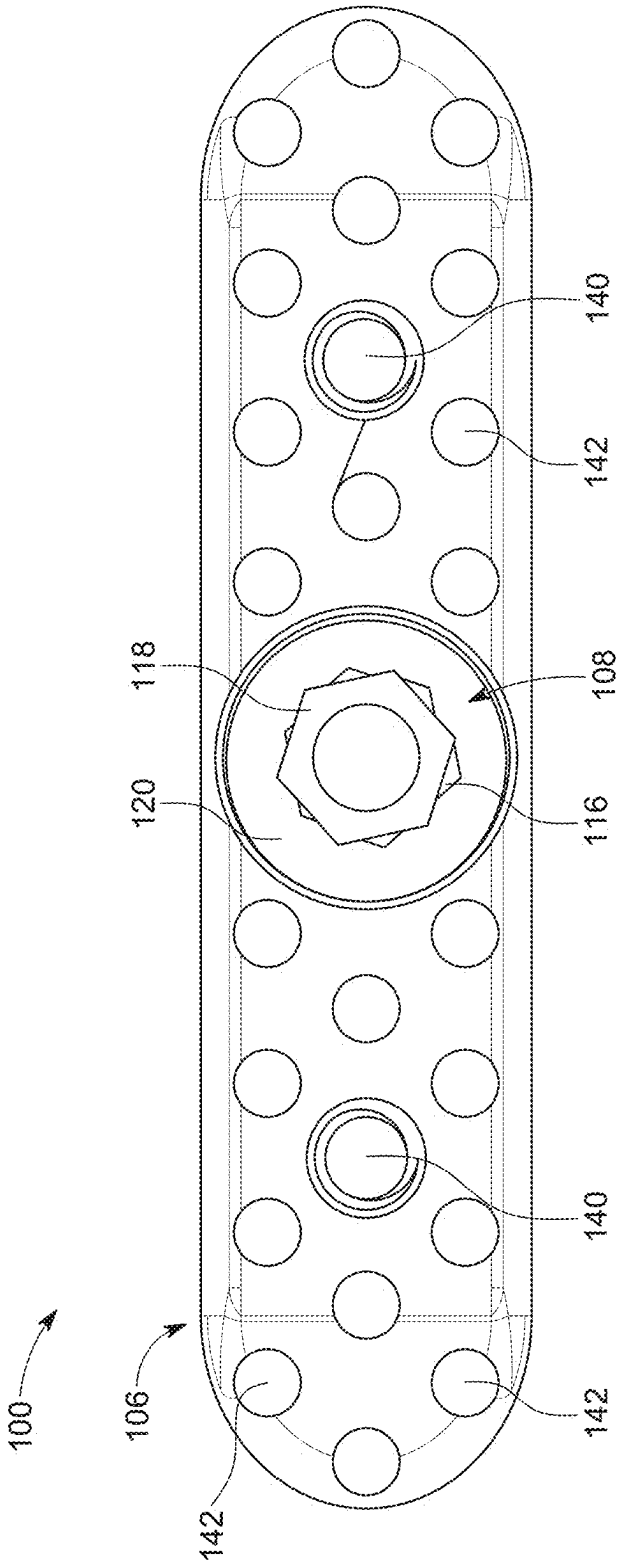


FIG. 8

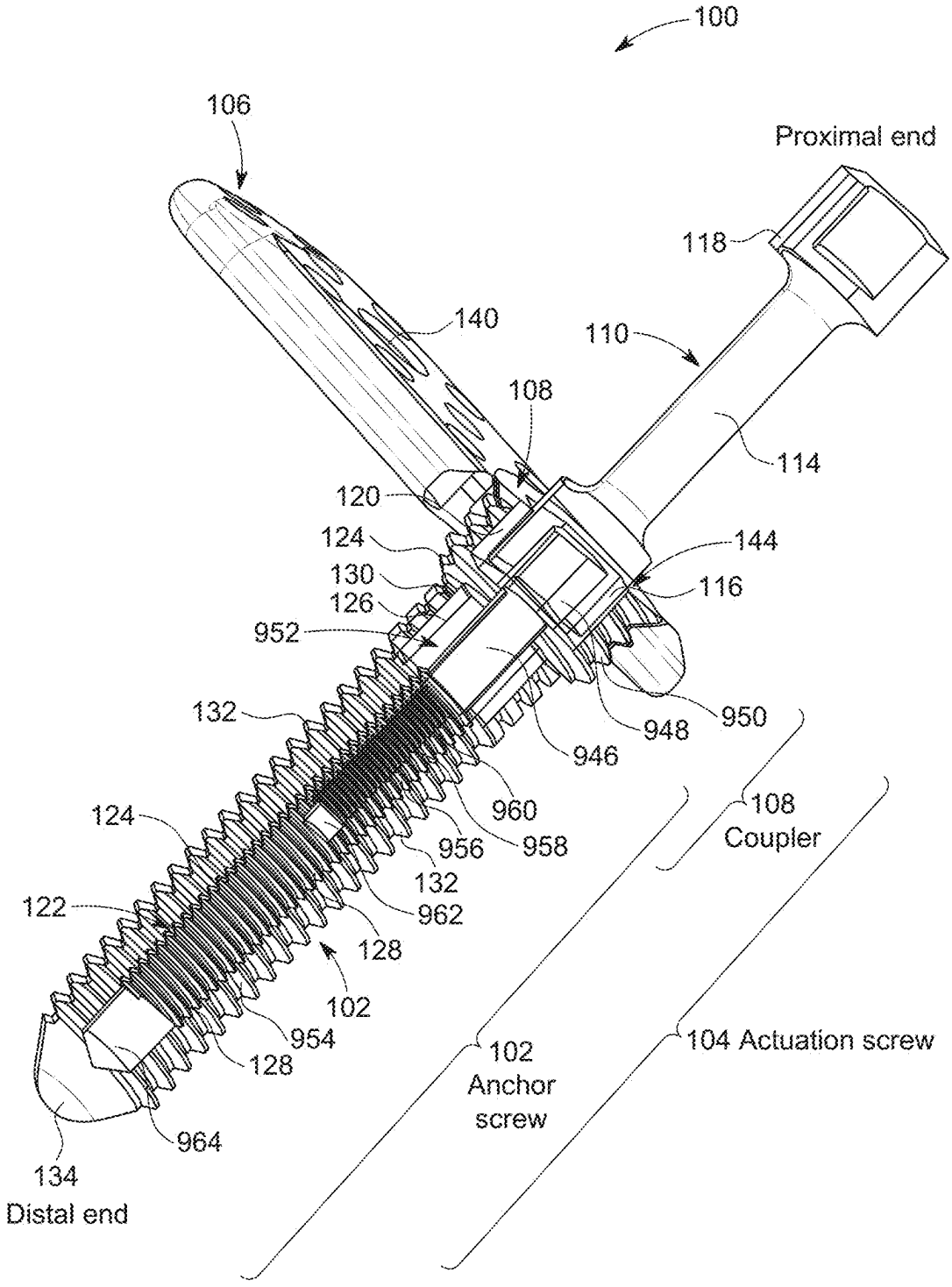

100
106
Proximal end
118
140
110
108
114
120
124
144
130
116
126
952
132
948
950
946
960
124
108
Coupler
956
958
132
122
962
128
102
954
128
102
Anchor
screw
104 Actuation screw
964
134
Distal end

FIG. 9

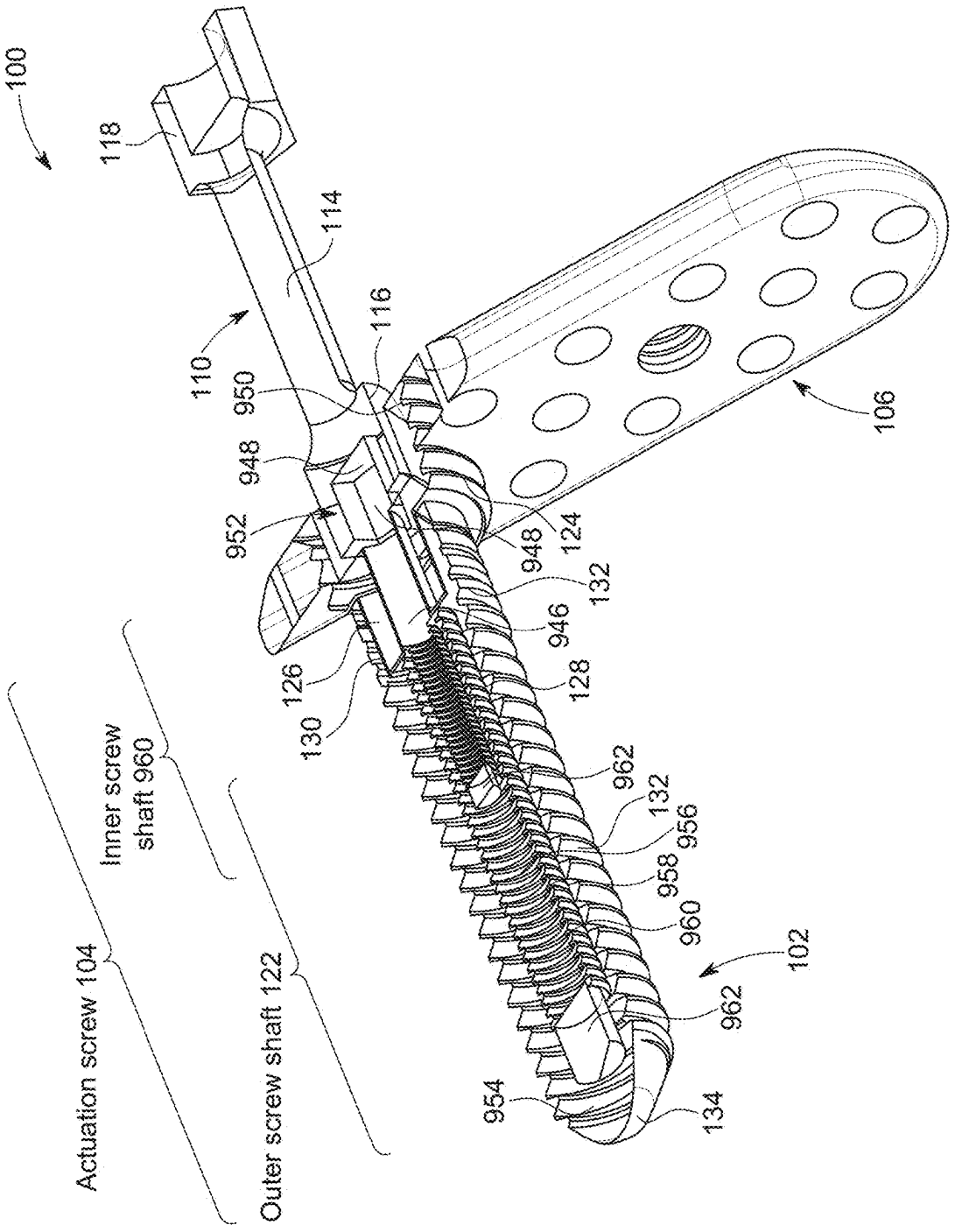

100
118
114
116
110
950
948
952
948
124
132
946
128
126
130
962
132
956
958
960
102
962
954
134
106
Actuation screw 104
Inner screw shaft 960
Outer screw shaft 122

FIG. 10

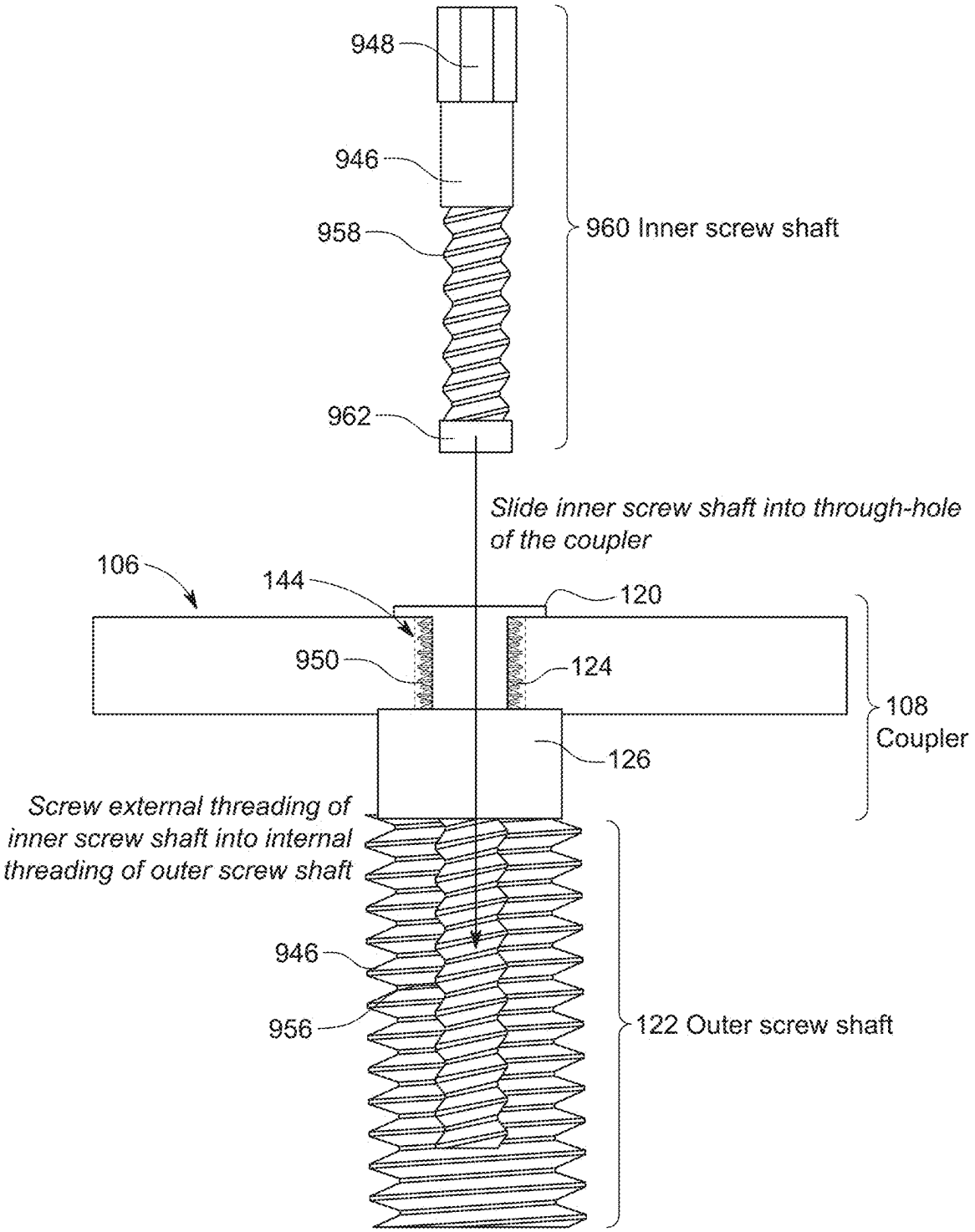

948
946
958
960 Inner screw shaft
962
Slide inner screw shaft into through-hole of the coupler
106
144
120
950
124
108 Coupler
126
Screw external threading of inner screw shaft into internal threading of outer screw shaft
946
956
122 Outer screw shaft

FIG. 11A

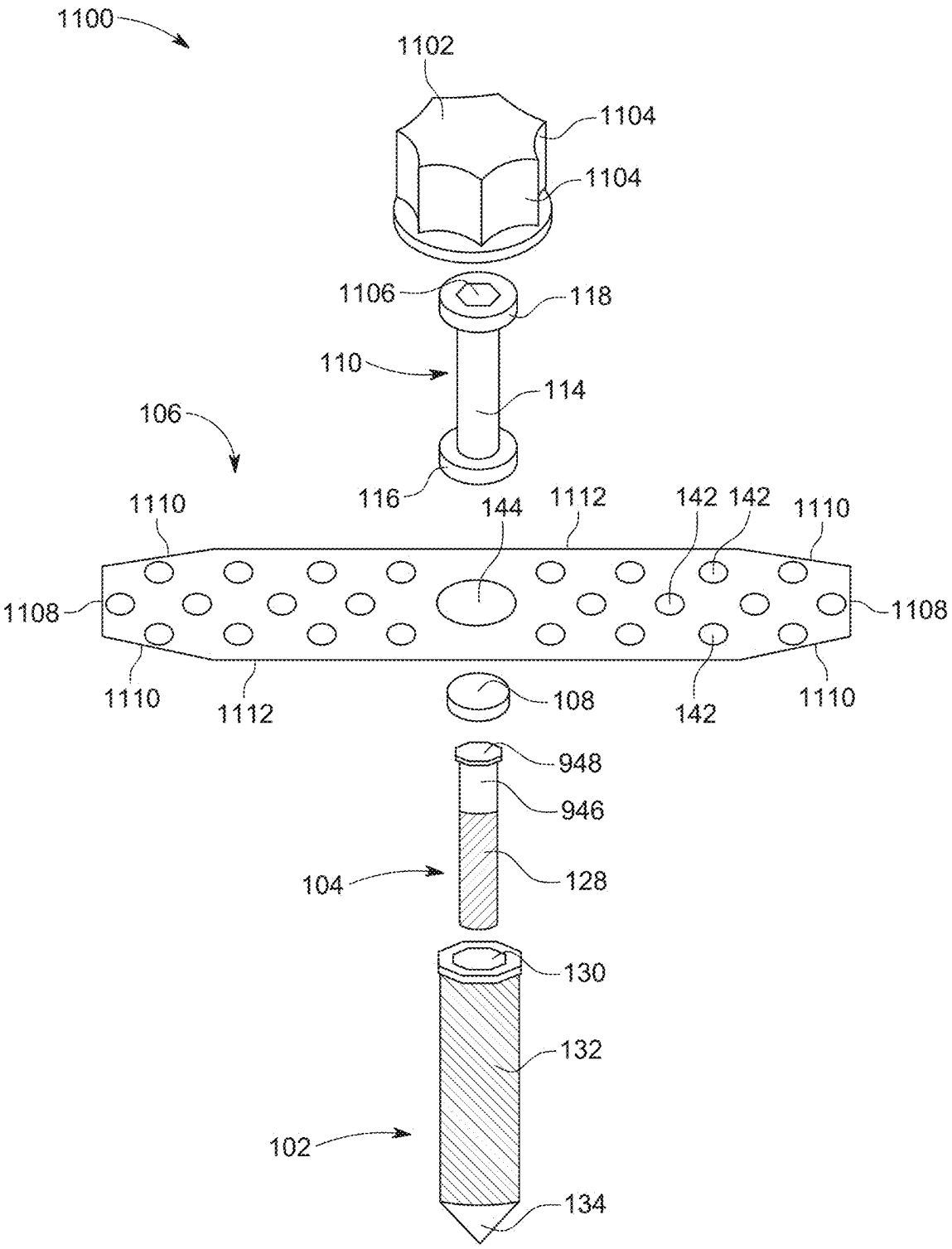

1100
1102
1104
1104
1106
118
110
114
106
116
1110
144
1112
142
142
1110
1108
1108
1110
1112
108
142
1110
948
946
104
128
130
132
102
134

FIG. 11B

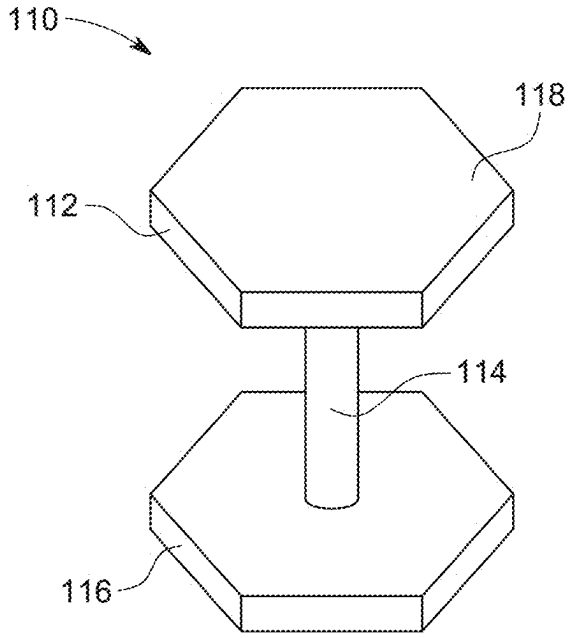


FIG. 12

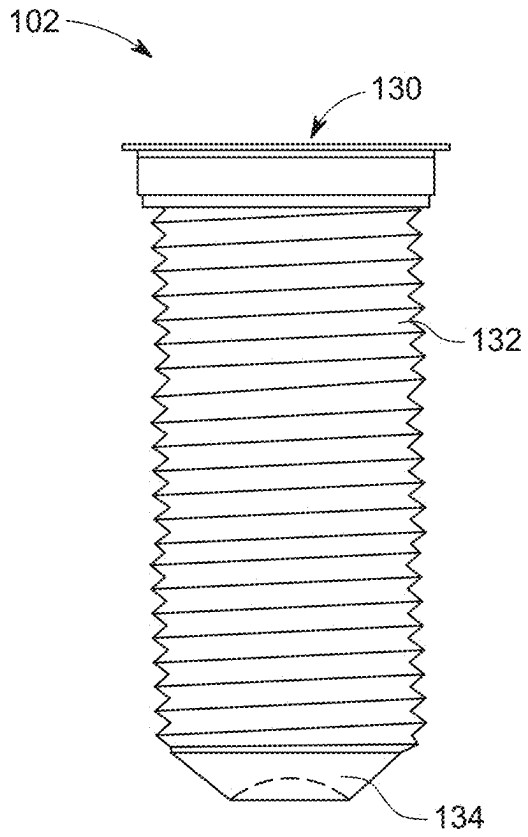


FIG. 13

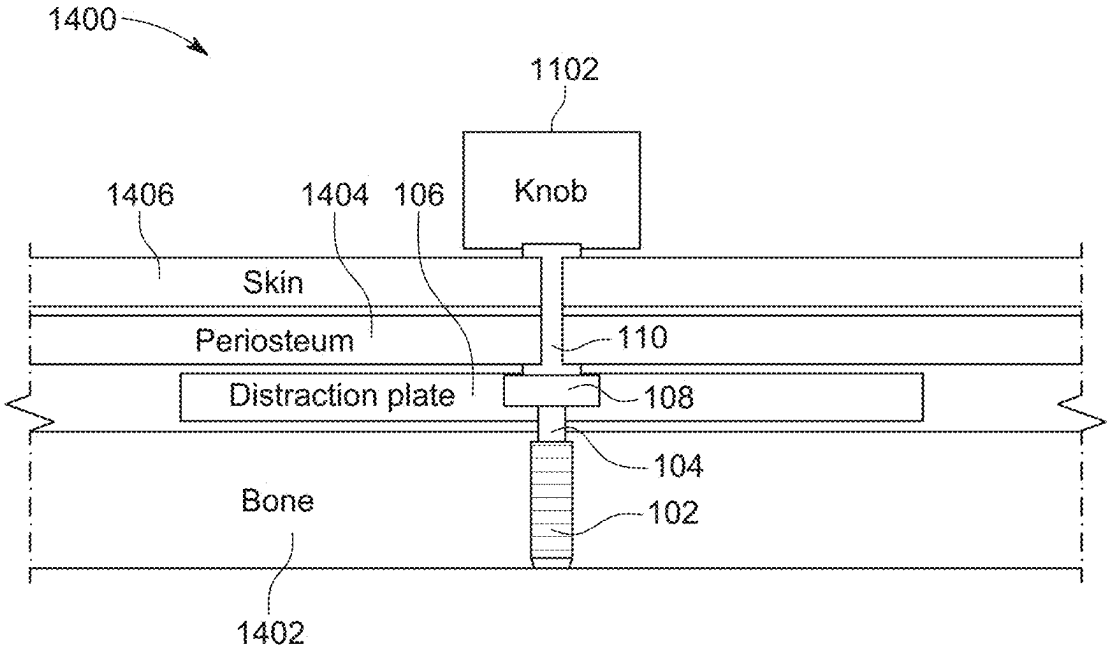

1400
1102
Knob
1406
1404
106
Skin
Periosteum
110
Distraction plate
108
104
Bone
102
1402

FIG. 14

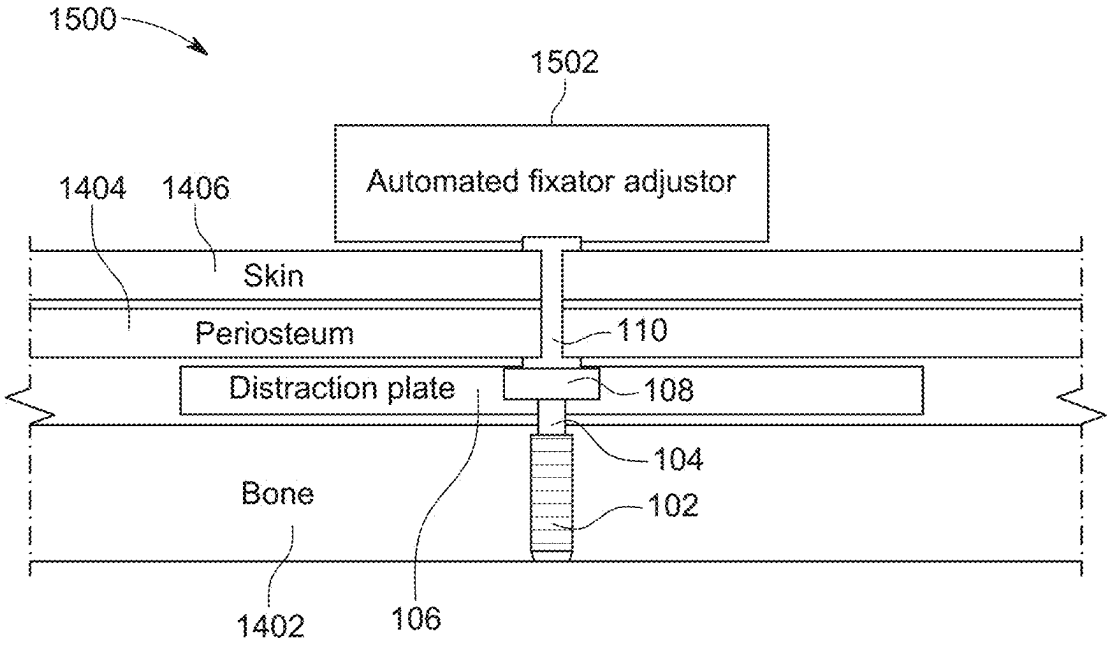

1500
1502
Automated fixator adjustor
1404
1406
Skin
Periosteum
110
Distraction plate
108
104
Bone
102
1402
106

FIG. 15

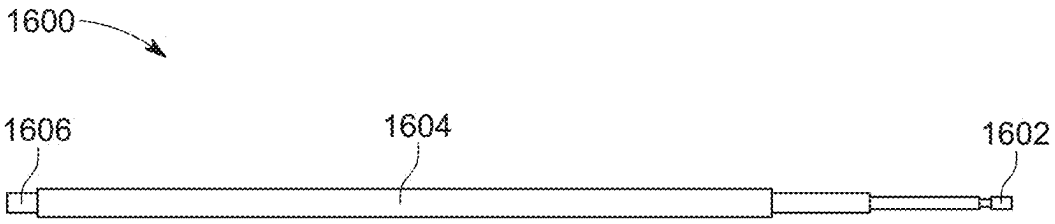


FIG. 16

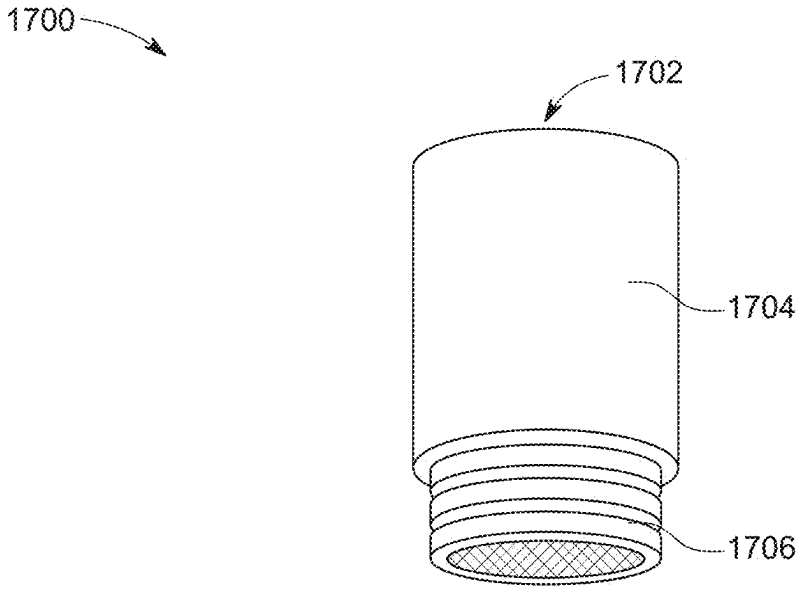


FIG. 17

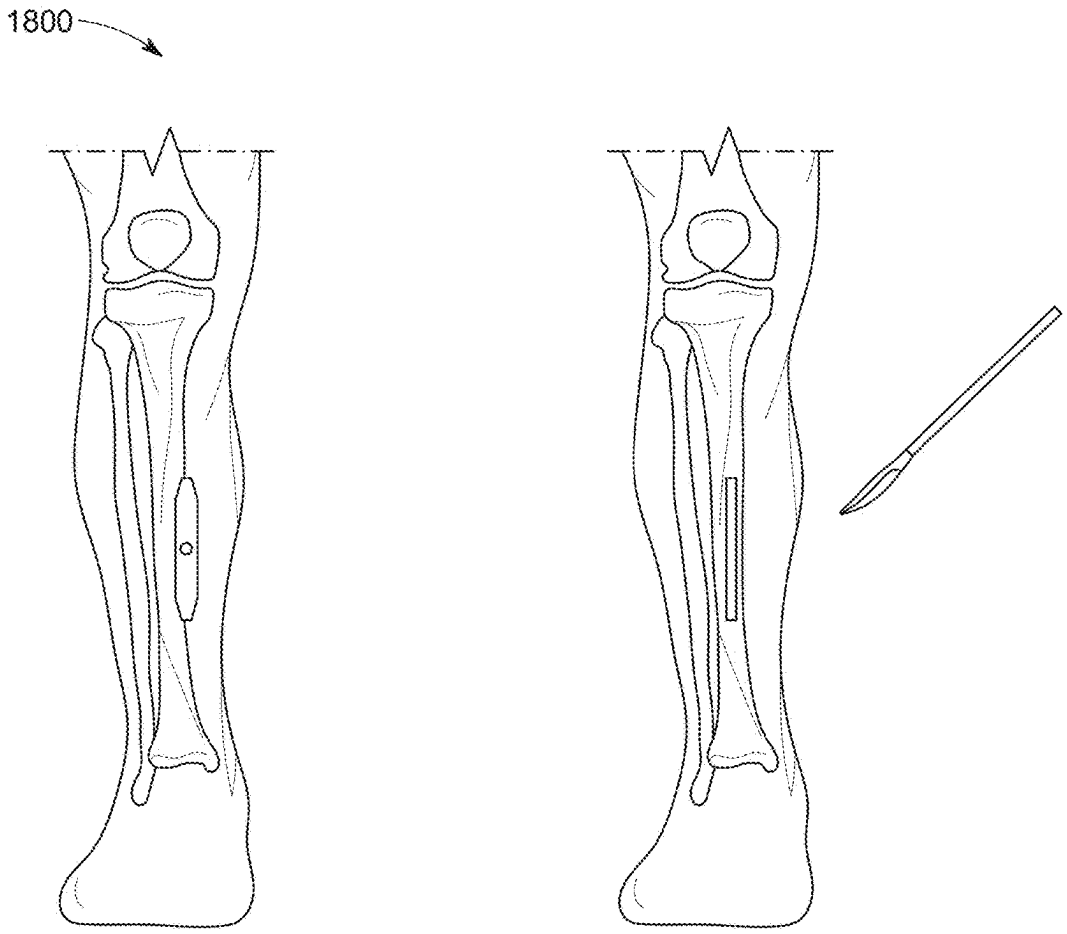
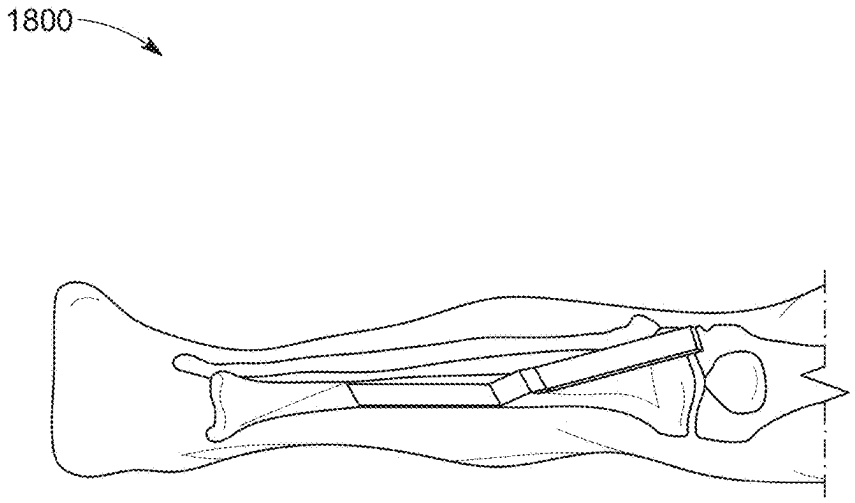

1800
Plan distraction plate position and mark skin to indicating incision location.
1802
Create longitudinal skin incision and a transverse incision of the periosteum.
1804

FIG. 18A


1800

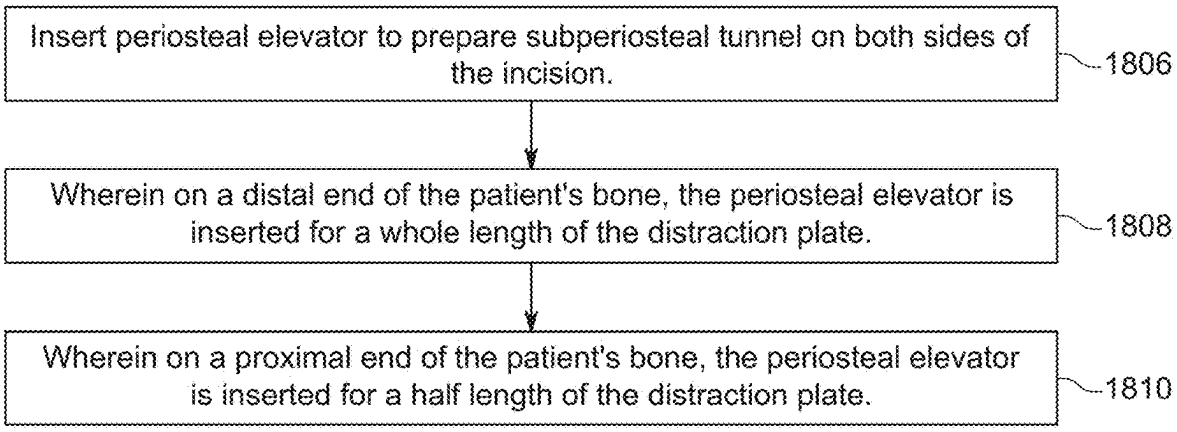
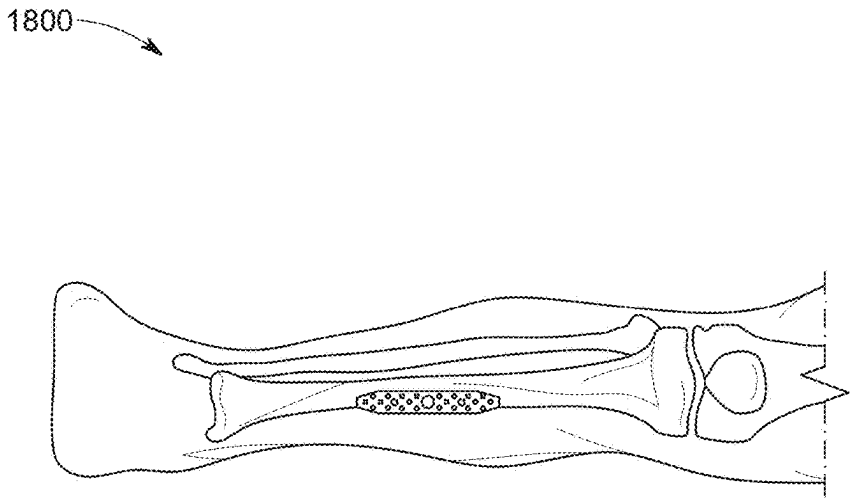

Insert periosteal elevator to prepare subperiosteal tunnel on both sides of the incision.
1806
Wherein on a distal end of the patient's bone, the periosteal elevator is inserted for a whole length of the distraction plate.
1808
Wherein on a proximal end of the patient's bone, the periosteal elevator is inserted for a half length of the distraction plate.
1810

FIG. 18B


1800

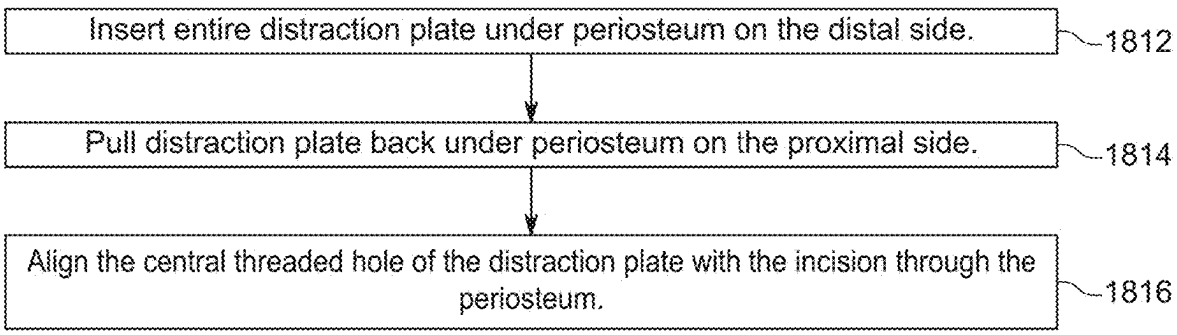
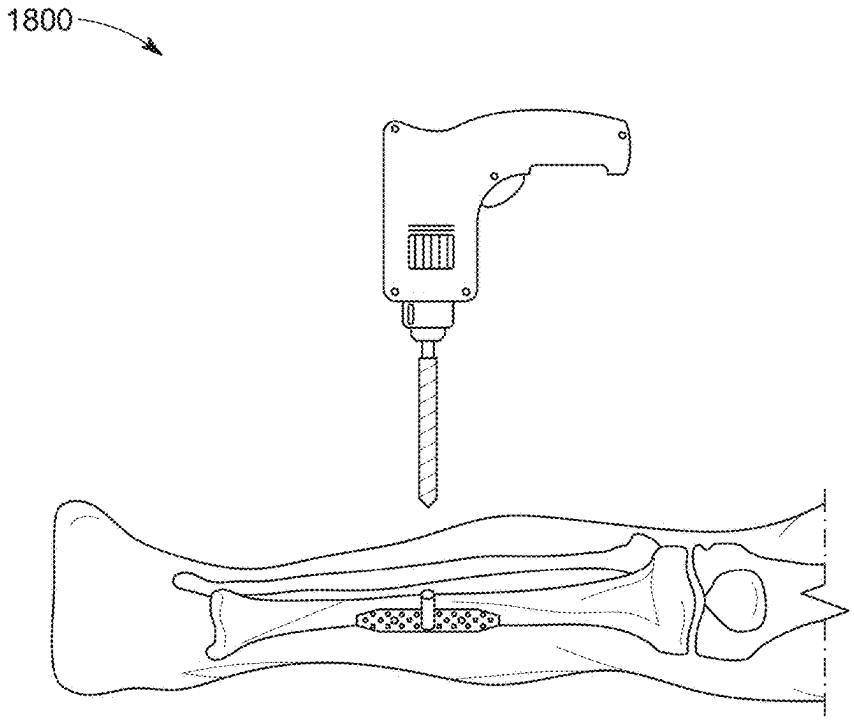

Insert entire distraction plate under periosteum on the distal side.
1812
Pull distraction plate back under periosteum on the proximal side.
1814
Align the central threaded hole of the distraction plate with the incision through the periosteum.
1816

FIG. 18C


1800

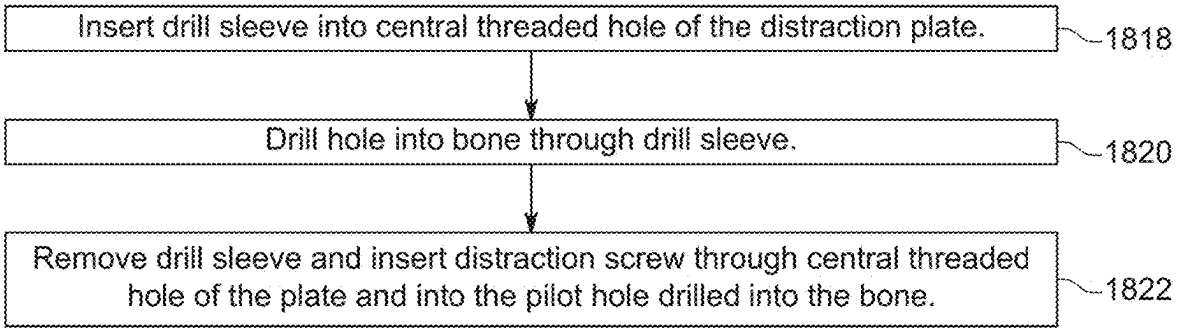
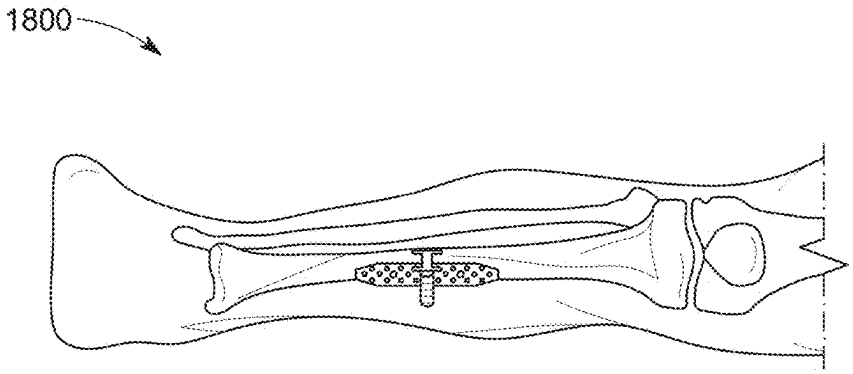

Insert drill sleeve into central threaded hole of the distraction plate.
1818
Drill hole into bone through drill sleeve.
1820
Remove drill sleeve and insert distraction screw through central threaded hole of the plate and into the pilot hole drilled into the bone.
1822

FIG. 18D


1800

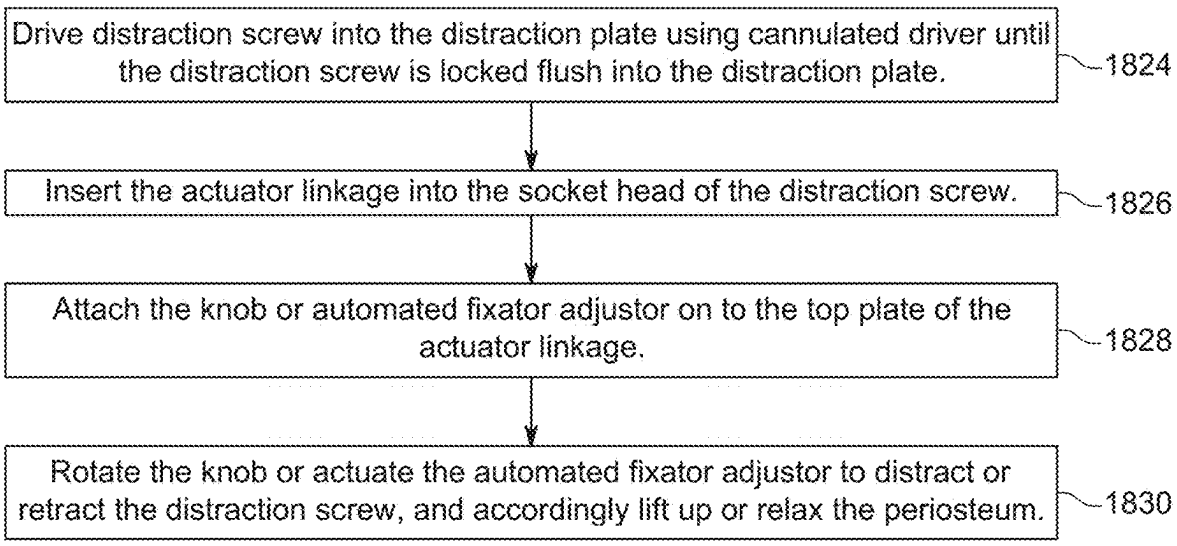

Drive distraction screw into the distraction plate using cannulated driver until the distraction screw is locked flush into the distraction plate.
1824
Insert the actuator linkage into the socket head of the distraction screw.
1826
Attach the knob or automated fixator adjustor on to the top plate of the actuator linkage.
1828
Rotate the knob or actuate the automated fixator adjustor to distract or retract the distraction screw, and accordingly lift up or relax the periosteum.
1830

FIG. 18E

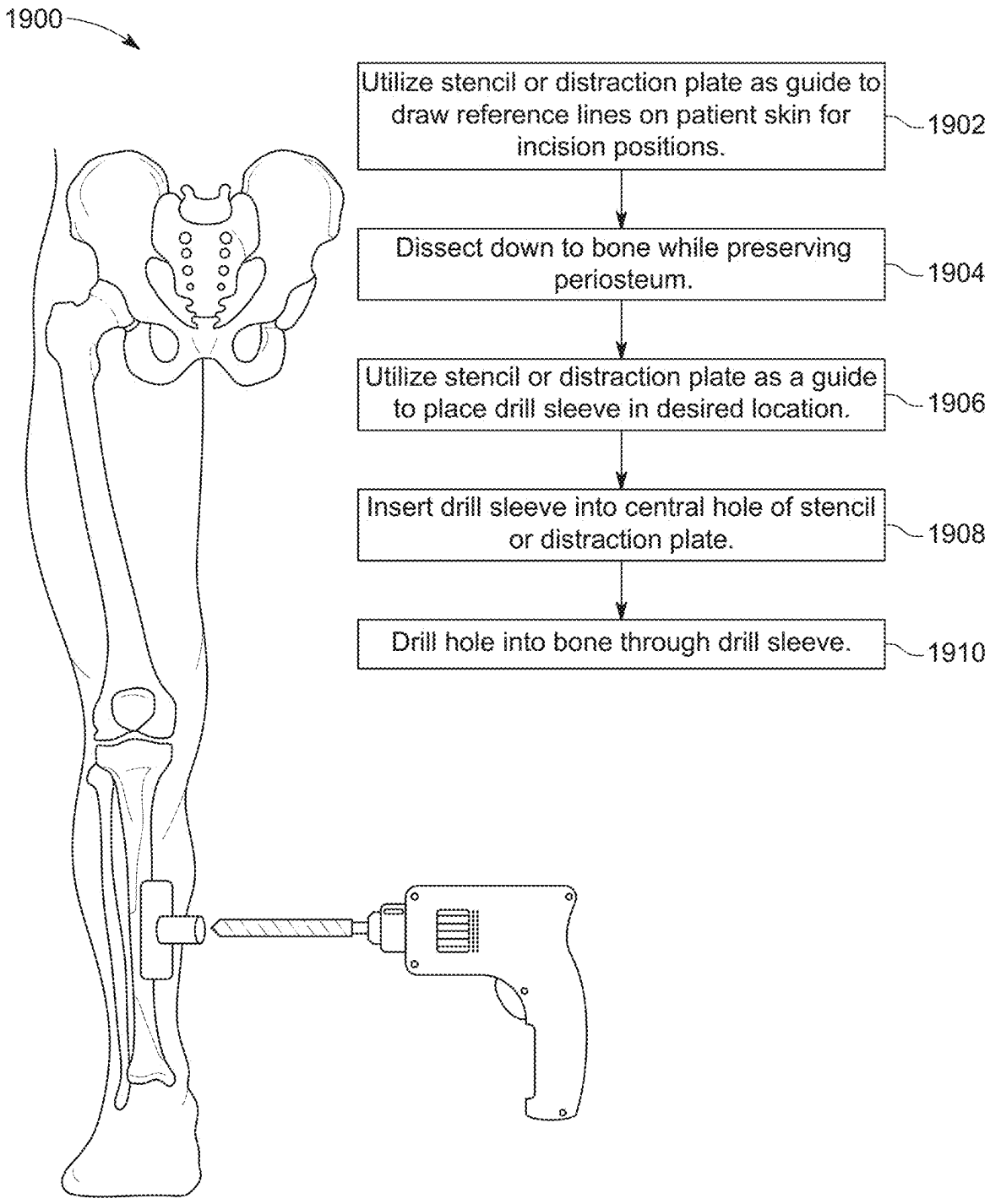

1900
Utilize stencil or distraction plate as guide to draw reference lines on patient skin for incision positions.
1902
Dissect down to bone while preserving periosteum.
1904
Utilize stencil or distraction plate as a guide to place drill sleeve in desired location.
1906
Insert drill sleeve into central hole of stencil or distraction plate.
1908
Drill hole into bone through drill sleeve.
1910

FIG. 19A

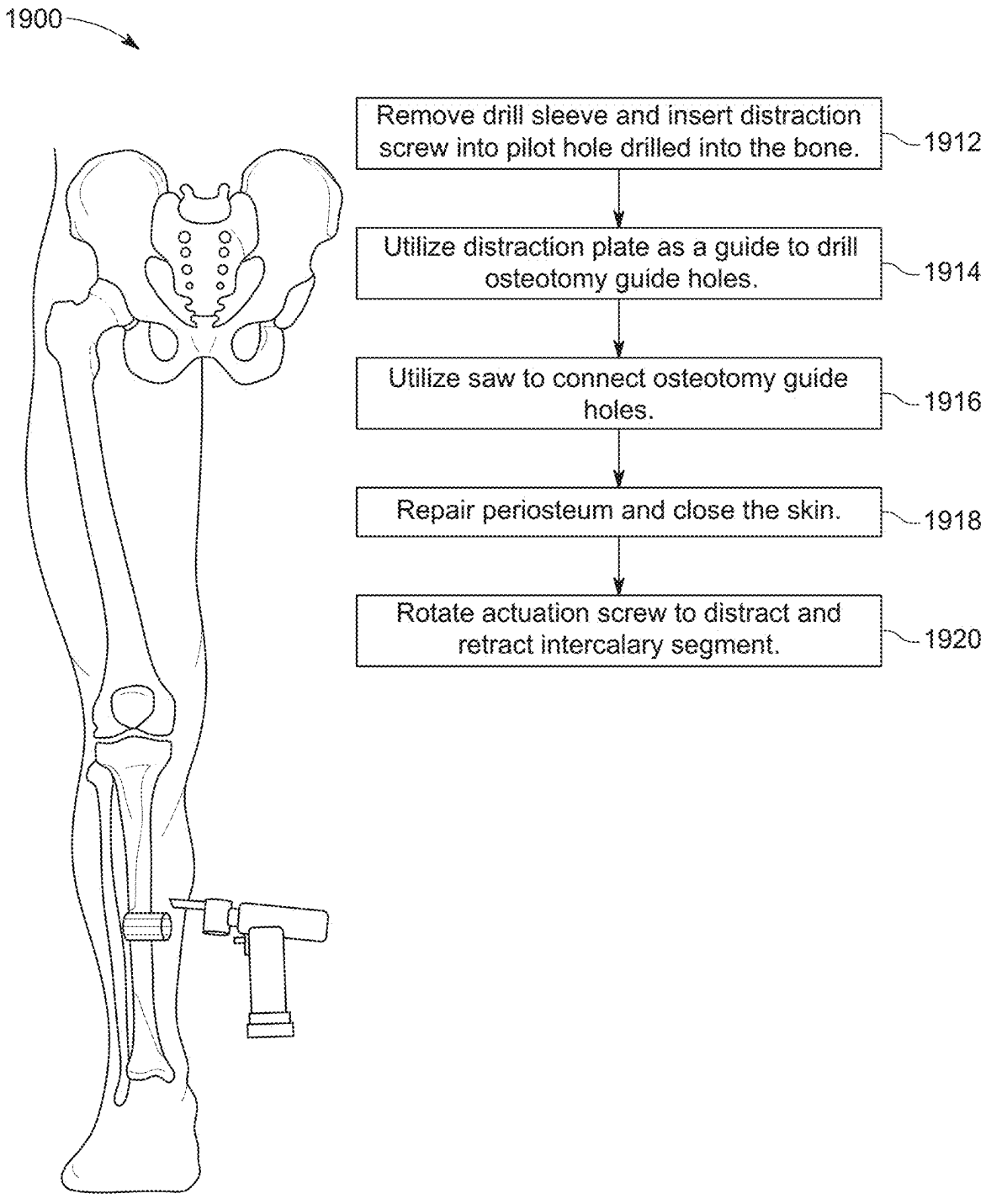

1900
Remove drill sleeve and insert distraction screw into pilot hole drilled into the bone.
1912
Utilize distraction plate as a guide to drill osteotomy guide holes.
1914
Utilize saw to connect osteotomy guide holes.
1916
Repair periosteum and close the skin.
1918
Rotate actuation screw to distract and retract intercalary segment.
1920

FIG. 19B

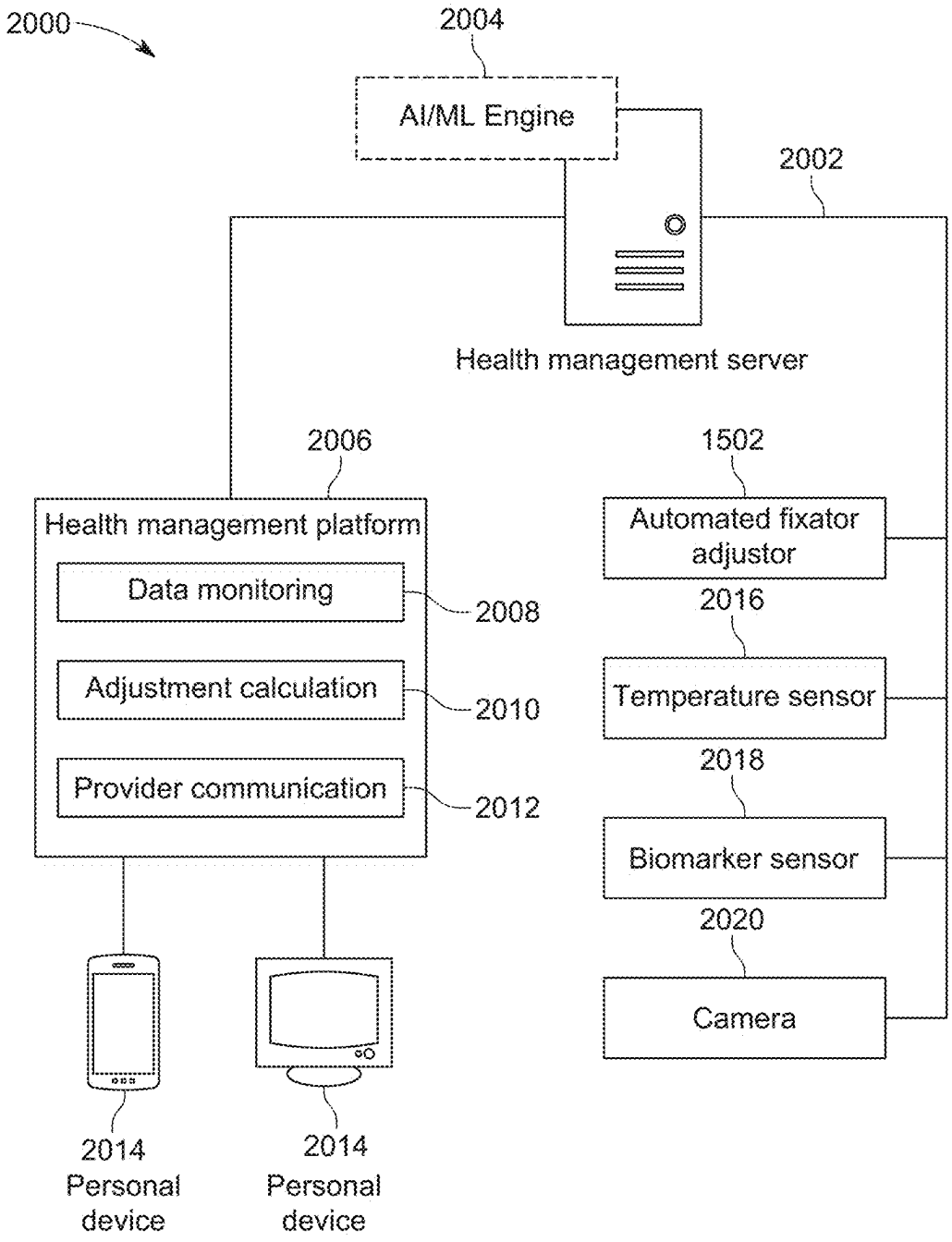

2000
2004
AI/ML Engine
2002
Health management server
2006
Health management platform
Data monitoring
2008
Adjustment calculation
2010
Provider communication
2012
1502
Automated fixator adjustor
2016
Temperature sensor
2018
Biomarker sensor
2020
Camera
2014
Personal device
2014
Personal device

FIG. 20

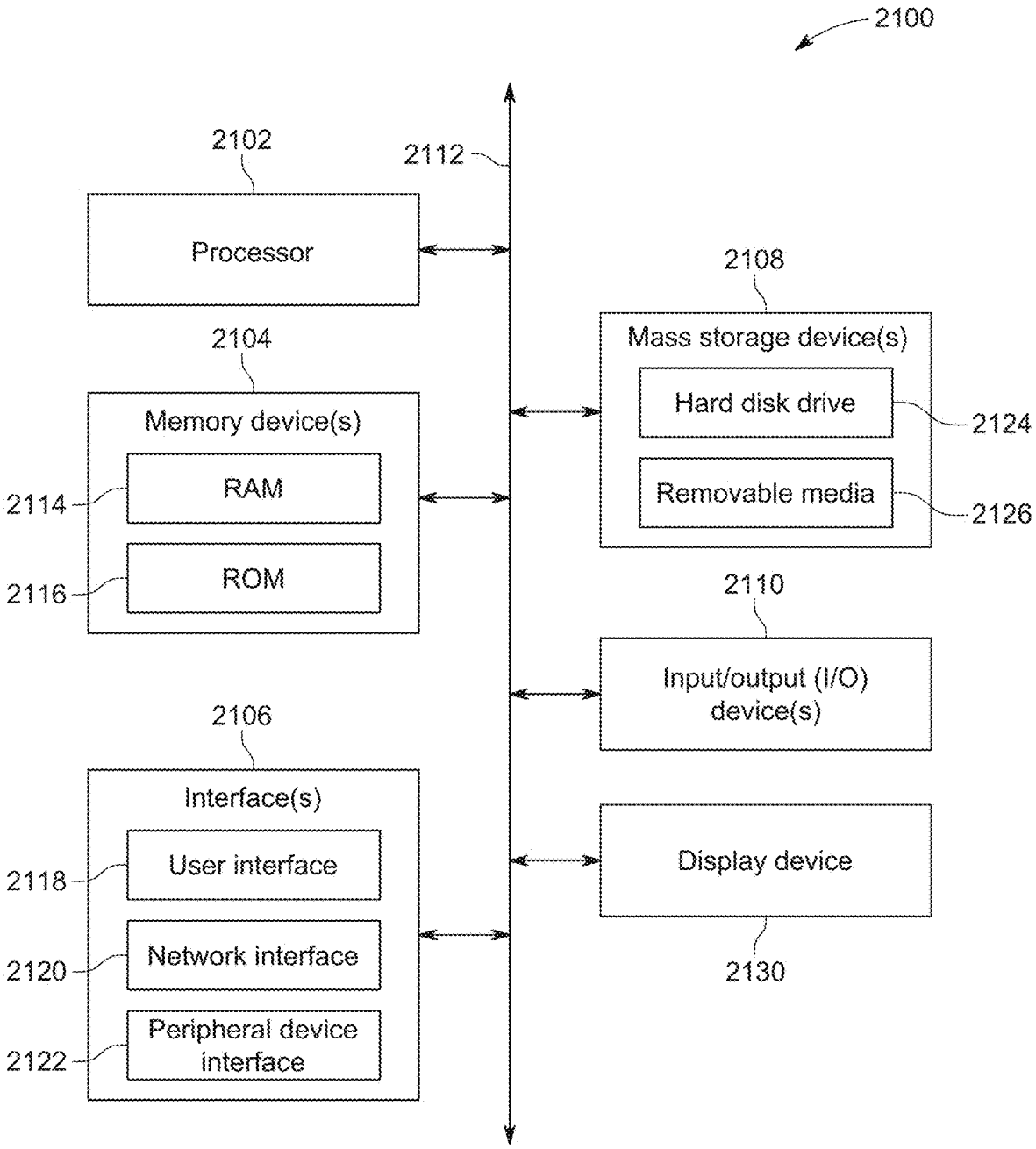

2100
2102
2112
Processor
2108
Mass storage device(s)
2104
Hard disk drive
2124
Memory device(s)
2114
RAM
Removable media
2126
2116
ROM
2110
Input/output (I/O) device(s)
2106
Interface(s)
2118
User interface
Display device
2120
Network interface
2130
2122
Peripheral device interface

FIG. 21

SYSTEMS, METHODS, AND DEVICES FOR DISTRACTION HISTOGENESIS

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 procedure and angiogenesis procedures.

BACKGROUND

[0002] In some cases, a patient benefits from improved blood flow and tissue regeneration to aid in recovery from vascular occlusion or 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 ischemic diseases, chronic wounds, 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 angiogenesis, and specifically for performing periosteal distraction, 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, and reduce the complexity of tasks that need to be performed after surgery.

[0006] In view of the foregoing, disclosed herein are systems, methods, compositions, 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**A is an overhead perspective view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is at least partially distracted from an anchor screw;

[0009] FIG. **1**B is an overhead perspective view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is at least partially distracted from an anchor screw;

[0010] FIG. **2** is an underside perspective view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is at least partially distracted from an anchor screw;

[0011] FIG. **3** is a straight-on wide view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is at least partially distracted from an anchor screw;

[0012] FIG. **4** is an overhead perspective view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is at least partially distracted from an anchor screw;

[0013] FIG. **5** is an underside perspective view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is at least partially distracted from an anchor screw;

[0014] FIG. **6** is an overhead perspective view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is fully retracted into an anchor screw;

[0015] FIG. **7** is an underside perspective view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is fully retracted into an anchor screw;

[0016] FIG. **8** is an aerial top-down view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is fully retracted into an anchor screw;

[0017] FIG. **9** is a perspective cross-sectional view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is fully retracted into an anchor screw;

[0018] FIG. **10** is a perspective cross-sectional view of a system for performing a distraction histogenesis surgical procedure, wherein an actuation screw is fully retracted into an anchor screw;

[0019] FIG. **11**A is a schematic illustration of an exploded perspective view of an anti-rotational assembly, which is a component of a system for performing a distraction histogenesis surgical procedure;

[0020] FIG. **11**B is a schematic illustration of an exploded perspective view of a system for performing a distraction histogenesis surgical procedure;

[0021] FIG. **12** is a schematic illustration of a side view of an actuator linkage;

[0022] FIG. **13** is a schematic illustration of a straight-on side view of an anchor screw;

[0023] FIG. **14** is a schematic illustration of a system for performing a distraction histogenesis surgical procedure with manual manipulation of an actuation screw;

[0024] FIG. **15** is a schematic illustration of a system for performing a distraction histogenesis surgical procedure with automated manipulation of an actuation screw;

[0025] FIG. **16** is a schematic illustration of a side view of a cannulated driver;

[0026] FIG. **17** is a schematic illustration of a perspective view of a drill sleeve;

[0027] FIGS. **18**A-**18**E are schematic block diagrams of a method for performing a distraction histogenesis surgical procedure;

[0028] FIGS. **19**A-**19**B are schematic block diagrams of a method for performing a distraction histogenesis surgical procedure;

[0029] FIG. **20** is a schematic block diagram of a system for monitoring health data and remotely actuating adjustment of a distraction device; and

[0030] FIG. **21** is a schematic block diagram of an example computing device.

DETAILED DESCRIPTION

[0031] Described herein are systems, methods, and devices for triggering tissue regeneration and improving perfusion of patient fluids and releasing growth factors. 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 and angiogenesis surgical procedures on various tissue types. The systems, methods, and devices described herein may specifically be utilized to perform periosteal distraction and osteotomy procedures to trigger regeneration of soft tissue.

[0032] A system described herein is designed for performing a distraction histogenesis procedure on a patient. The system includes a distraction plate configured to be disposed in between a periosteum and an outer surface of a bone. The system includes an anchor screw configured to be attached to the distraction plate and an actuator linkage configured to be attached to the anchor screw. The system includes an adjustor configured to be attached to the actuator linkage, wherein the adjustor rotates the actuator linkage to distract or retract the distractor plate. The position of the distractor plate may be adjusted manually by a user or may be adjusted automatically by a device comprising a motor or gearmotor that is mechanically coupled to the actuator linkage.

[0033] Periosteal distraction is a surgical technique that is traditionally used to treat bone defects by stimulating bone growth. Periosteal distraction is designed to gradually separate the periosteum from underlying bone tissue, which creates an artificial space between the bone surface and periosteum. In response, the body generates new bone tissue with no need for corticotomy. Periosteal distraction is minimally invasive when compared to traditional bone grafting techniques, and the procedure encourages the body to generate its own bone, which typically integrates more successfully than synthetic materials.

[0034] 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 and angiogenesis, including, for example, promoting revascularization for the healing of diabetic foot ulcers.

[0035] 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.

[0036] 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.

[0037] 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.

[0038] In describing and claiming the subject matter of the disclosure, the following terminology will be used in accordance with the definitions set out below.

[0039] 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.

[0040] As used herein, the phrase "consisting of" and grammatical equivalents thereof exclude any element, step, or ingredient not specified in the claim.

[0041] 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.

[0042] 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.

[0043] 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.

[0044] Referring now to the figures, FIGS. **1**A and **1**B are perspective views of a system **100** for performing a distraction histogenesis surgical procedure. The system **100** may specifically be utilized to perform a periosteal distraction surgical procedure to lift periosteum away from bone tissue and thereby trigger regeneration of bone or other soft tissues. The system **100** represents an improvement over traditional

periosteal distraction systems known in the art because it reduces the quantity of screws drilled into patient bone tissue, reduces the total time required to perform the procedure, reduces the external machinery required to be managed by the patient, reduce the pain and the risk of infection related to the distraction operation, and improves the ease of distracting and retracting the distraction plate. The system **100** includes a small number of separate components and thus reduces the number of items that must be prepared and sterilized prior to the procedure.

[0045] The device **100** is configured to be implanted into a patient during a surgical procedure. After implantation, the device **100** may be distracted or retracted according to the patient's needs. In an example use-case, the device **100** is implanted in between bone tissue and a periosteum layer of a patient. The device **100** may then be coupled to an automated adjuster or manual adjuster to distract and retract the device while the device is installed within the patient.

[0046] The device **100** includes several primary components, including at least an anchor screw **102** and an actuation screw **104**. The device **100** further includes a distraction plate **106** that is axially coupled to the actuation screw **104**. The device **100** includes a coupler **108** that axially couples the distraction plate **106** to the actuation screw **104** while ensuring the distraction plate **106** and the actuation screw **104** are not also rotationally coupled. Thus, the coupler **108** ensures the actuation screw **104** may rotate without causing synchronous rotation of the distraction plate **106**.

[0047] As shown in FIG. **1**A, 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 tissue substrate 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 device **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.

[0048] The device **100** includes a longitudinal axis, and the actuation 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 rotated in a first direction, the actuation screw **104** may be unscrewed from the anchor screw **102** and thus distracted away from the anchor screw **102**. When the actuation screw **104** is rotated in a second direction, the actuation screw **104** may be screwed into the anchor screw **102** and thus retracted into the anchor screw **102**. The coupler **108** ensures that the distraction plate **106** is axially coupled to the actuation screw **104** such that the distraction plate **106** also distracts away from the anchor screw **102** or retracts in toward the anchor screw **102** synchronously with the actuation screw **104**. The coupler **108** further ensures that the distraction plate **106** is not rotationally coupled to the actuation screw **104**, such that the distraction plate **106** may remain rotationally stationary while the actuation screw **104** is screwed into or out of the anchor screw **102**. When the actuation screw **104** is distracted from the anchor screw **102** as shown in FIG. **1**, the device **100** has a longer total length. When the actuation screw **104** is fully retracted into the anchor screw **102**, the device **100** has its minimum total length.

[0049] The distraction plate **106** is optional depending upon the condition of the patient and the intended surgical procedure. In some cases, the distraction plate **106** is useful to gently lift or stretch a certain type of patient tissue. In other cases, the distraction plate **106** is unnecessary or may hinder the distraction of a certain type of patient tissue.

[0050] In a first exemplary use-case, the system **100** is utilized to perform a periosteal distraction procedure. In this first exemplary use-case, the anchor screw **102** is anchored into bone tissue and the distraction plate **106** is coupled to the actuation screw **104**, such that distraction of the actuation screw **104** causes the distraction plate **106** to lift away from the anchor screw **102** and stretch a periosteum tissue disposed over the bone tissue.

[0051] In a second exemplary use-case, the system **100** is utilized to perform a distraction histogenesis procedure on osteotomized bone tissue. In this second exemplary use-case, the anchor screw **102** is anchored into stationary bone tissue, and a head of the actuation screw **104** is coupled to osteotomized bone tissue, such that distraction of the actuation screw **104** causes the osteotomized bone tissue to lift away from stationary bone tissue. In this second exemplary use-case, the system **100** may be utilized without the distraction plate **106**.

[0052] In a third exemplary use-case, the system **100** is utilized to perform both periosteal distraction and distraction histogenesis procedure simultaneously on osteotomized bone tissue. In this third exemplary use-case, the anchor screw **102** is anchored into stationary bone tissue, and the distraction plate **106** is coupled to both the actuation screw **104** and the osteotomized bone tissue, such that distraction of the actuation screw **104** causes the distraction plate **106** to lift away from the anchor screw **102**, which would cause the osteotomized bone tissue to lift away from stationary bone tissue and stretch a periosteum tissue disposed over both the bone tissue and over the distraction plate at the same time. In this third exemplary use-case, the system **100** may be utilized with the distraction plate **106**.

[0053] Referring now to FIG. **1**B, the anchor screw **102** of the system includes external threading **132** configured to be screwed into and securely anchored to tissue substrate of a patient. In some cases, the external threading **132** of the anchor screw **102** is optimized for screwing the anchor screw **102** into bone tissue of the patient. The anchor screw **102** additionally includes an anchor tip **134** to aid during the implantation procedure. 1 The specifications of the external threading **132** may be optimized and adjusted depending on the type of tissue the anchor screw **102** will be screwed into.

[0054] The anchor screw **102** include a sidewall **136** that defines a hollow interior. The anchor screw **102** includes a socket interface **130** disposed at a proximal end of the anchor screw **102**. The socket interface **130** provides a means to directly rotate the anchor screw **102**. Thus, the anchor screw **102** could be independently installed into a tissue substrate without utilizing other components of the system **100**, by driving the anchor screw **102** into the tissue substrate by engaging a driver with the socket interface **130**. Conversely, the anchor screw **102** could be extracted from the tissue substrate by disposing a driver within the socket interface **130** and then unscrewing the anchor screw **102** from the tissue substrate.

[0055] The anchor screw **102** includes the external threading **132** attached to an exterior surface of the sidewall **136**, and additionally includes internal threading (not visible in FIG. **1**B) attached to an interior surface of the sidewall **136**. The internal threading corresponds with external threading

128 of an outer screw shaft 122 of the actuation screw 104 such that the actuation screw 104 may be securely and releasably screwed into the hollow interior of the anchor screw 102. Thus, the actuation screw 104 may be screwed into the hollow interior of the anchor screw 102, and the actuation screw 104 may likewise be screwed out of the hollow interior of the anchor screw 102.

[0056] When the system 100 is implanted into a patient, a surgeon may first place the distraction plate 106 in the planned location such that the distraction plate rests on a first patient tissue. In some cases, the distraction plate 106 may be disposed in between the first patient tissue and a second patient tissue that is located external relative to the first patient tissue. When the distraction plate 106 is disposed in the desired location, the surgeon may utilize one or more of the holes disposed through the distraction plate 106 as a guide to drill a pilot hole into the first patient tissue and/or anchor the distraction plate 106 to the first patient tissue. After the surgeon has drilled the one or more pilot holes, the surgeon may then install the anchor screw 102 into the first patient tissue. The actuation screw 104 may be disposed within the anchor screw 102 such that the surgeon may simultaneously drive each of the anchor screw 102 and the actuation screw 104 through the central hole of the distraction plate 106 and into the pilot hole disposed within the first patient tissue. When the anchor screw 102 is fully installed, the surgeon may then distract or retract the actuation screw 104 and thereby cause the actuation screw 104 to distract away from the anchor screw 102 (as shown in FIG. 1B) or retract toward the anchor screw 102. The system 100 is designed such that the distraction plate 106 will remain rotationally stationary when the actuation screw 104 is distracted and retracted. Thus, a distraction rotation of the actuation screw 104 causes the distraction plate 106 to lift away from the anchor screw 102 as shown in FIG. 1B but does not cause the distraction plate 106 to synchronously rotate with the actuation screw 104.

[0057] The anchor screw 102 is intended to be securely implanted within a tissue substrate, such as bone tissue. Thus, the anchor screw 102 remains stationary when the system 100 is distracted and retracted. The actuation screw 104 is configured to be fully disposed within the anchor screw 102 when the system 100 is in a fully retracted state (see, e.g., FIG. 6). The actuation screw 104 is configured to be partially exposed, and not fully disposed within the anchor screw 102, when the system 100 is in a distracted state as shown in FIG. 1B.

[0058] The system 100 includes the coupler 108 that is configured to axially couple the distraction plate 106 to the actuation screw 104 while ensuring the distraction plate 106 is not also rotationally coupled to the actuation screw 104. The coupler 108 includes an anchoring interface 120 and a rotational interface 126. The rotational interface 126 is attached to the anchoring interface 120, and the rotational interface 126 is located distal relative to the anchoring interface 120. The anchoring interface of the coupler 108 includes external threading 124 that corresponds with internal threading of a central threaded hole 144 of the distraction plate 106. The external threading 124 of the anchoring interface 120 thus enables the coupler 108 to be screwed into and secured to the distraction plate 106.

[0059] The rotational interface 126 includes a driver head configured to interface with the corresponding socket head 130 of the anchor screw 102. The rotational interface 126 may include a polygonal cross-sectional geometry that matches the polygonal cross-sectional geometry of the socket interface 130 of the anchor screw 102. In the example illustrated in FIGS. 1A-1B, the rotational interface 126 includes a hexagonal cross-sectional geometry, and may thus be referred to as a hex driver. The exemplary socket interface 130 illustrated in FIGS. 1A-1B corresponds with the rotational interface 126 and thus includes a hex socket. It should be appreciated that the rotational interface 126 and the socket interface 130 may include various numbers of sides as deemed appropriate, including, for example, a quadrilateral, pentagonal, hexagonal, octagonal, and so forth, polygonal cross-sectional geometry.

[0060] The coupler 108 comprises a hollow interior and a through hole, such that the coupler 108 is configured to receive the actuation screw 104. In the orientation illustrated in FIG. 1B, the actuation screw 104 extends up through the coupler 108 and then interfaces with the actuator linkage 110. The coupler 108 comprises a smooth hollow interior that enables the actuation screw 104 to freely rotate within the coupler 108. Thus, the coupler 108 enables the actuation screw 104 to rotate out of and into the anchor screw 102 without causing synchronous rotation of the distraction plate 106.

[0061] The coupler 108 enables the distraction plate 106 to be axially coupled to the actuation screw 104 such that distraction plate 106 moves vertically along the longitudinal axis of the system 100 while remaining rotationally stationary when the actuation screw 104 is screwed into and out of the anchor screw 102.

[0062] The distraction plate 106 includes a central threaded hole 144, one or more peripheral threaded holes 140, and a plurality of holes 142 disposed therethrough. The holes 142 may allow fluids, cells, molecules, and other components to pass between the upper and lower surfaces of the distraction plate 106, and this may improve patient outcomes from the distraction histogenesis and angiogenesis procedure. Each of the central threaded hole 144 and the one or more peripheral threaded holes 140 may include internal threading. The internal threading of the central threaded hole 144 corresponds with the external threading 124 of the anchoring interface 120 of the coupler 108. The internal threading of the one or more peripheral threaded holes 140 may corresponds with screws intended for anchoring the distraction plate 106 to patient tissue and may specifically be utilized to anchor the distraction plate 106 to osteotomized bone tissue.

[0063] The actuator linkage 110 is releasably coupled to a screw head (not visible in FIG. 1B) of the actuation screw 104. The actuator linkage 110 may thus be utilized to drive rotation of the actuation screw 104. The actuator linkage 110 serves as a bridge between the actuation screw 104 and an exterior of the patient's body. Thus, if the system 100 is utilized to perform a periosteal distraction procedure, the actuator linkage 110 percutaneously extends through the periosteum and other tissue layers located external to the periosteum, such as fat, skin, and other tissues.

[0064] The actuator linkage 110 includes an actuation screw coupling head 116, a shaft 114, and rotator coupling head 118. The actuation screw coupling head 116 has an internal recess socket feature which is configured to interface with a corresponding screw head (not visible in FIG. 1B) on the actuation screw 104, which serves as a torque drive component of the actuation screw 104. The rotator

coupling head **118** is configured to interface with the internal socket feature of the interface **120** of the coupler **108**. Through this interface coupling, the rotation of the coupling head **118** can rotate the coupler **108**. The rotator coupling head **118** is also configured to interface with a corresponding component utilized to rotate the actuator linkage **110**. This corresponding component may include, for example, a knob enabling a user to manually rotate the actuator linkage **110**, or a component for automatically rotating the actuator linkage **110** with an automated fixator adjustor. The rotator coupling head **118** may include a plurality of sides **112** forming a polygonal cross-sectional geometry, which may be utilized to rotate the actuator linkage more easily **108**.

[0065] In some cases, a knob (not shown in FIGS. **1**A-**1**B) may be releasably coupled to the actuator linkage **110** to enable a user to easily rotate the actuator linkage **110**, and thereby also rotate the actuation screw **104**. In other cases, a component of an automated fixator adjustor may be releasably coupled to the actuator linkage **110** to automatically rotate the actuator linkage **110** according to a treatment schedule.

[0066] FIG. **2** is an underside perspective view of the system **100** for performing a distraction histogenesis surgical procedure. Like in FIGS. **1**A-**1**B, FIG. **2** also illustrates wherein the actuation screw **104** is partially distracted (i.e., screwed out of) the anchor screw **102**, and thus, the distraction plate **106** is lifted away from the anchor screw **102**.

[0067] As shown in FIG. **2**, the external threading **124** of the coupler **108** may be screwed into a threaded hole of the distraction plate **106** to securely couple the coupler **108** to the distraction plate **106**. Further as shown in FIG. **2**, the rotational interface **126** of the coupler **108** may be directly attached to the outer screw shaft **122** of the actuation screw **104**.

[0068] FIG. **3** is a straight-on side view of the system **100** for performing a distraction histogenesis surgical procedure. Like in FIGS. **1**A-**1**B and **2**, FIG. **3** also illustrates wherein the actuation screw **104** is partially distracted (i.e., screwed out of) out of the anchor screw **102**, and thus, the distraction plate **106** is lifted away from the anchor screw **102**.

[0069] When the system **100** is implanted in a patient, the anchor screw **102** may be screwed into a first tissue of the patient while the actuation screw **104** is fully screwed into the anchor screw **102**. If the distraction plate **106** is being utilized, then a surgeon may first place the distraction plate **106** in a desired location on the patient, and then screw the anchor screw **102** through a hole disposed through the distraction plate **106**. The actuator linkage **110** may then be coupled to the actuation screw **104** through the hole disposed through the distraction plate **106**. Typically, a surgeon will close up the patient skin layer such that the actuator linkage **110** is the only component located external to the patient. The actuator linkage **110** thus serves as a bridge through one or more layers of patient tissue and enables a practitioner to distract or retract the actuation screw **104** without reopening the patient's skin layer. When the actuation screw **104** is distracted (i.e., lifted or screwed out of the anchor screw **102**, as shown in FIG. **3**), the actuation screw **104** and distraction plate **106** will lift a second patient tissue layer away from the first patient tissue layer. In practice, the anchor screw **102** may be screwed into bone tissue, and the actuation screw **104** and distraction plate **106** may lift a periosteum up and away from the bone tissue.

[0070] FIG. **4** is an overhead top-down perspective view of the system **100** for performing a distraction histogenesis surgical procedure. Like in FIGS. **1**A-**1**B and **2**-**3**, FIG. **4** also illustrates wherein the actuation screw **104** is partially distracted out of (i.e., screwed out of) the anchor screw **102**, and thus, the distraction plate **106** is lifted away from the anchor screw **102**.

[0071] As shown in FIG. **4**, the rotator coupling head **118** of the actuator linkage **110** may comprise a plurality of sides **112** such that the rotator coupling head **118** comprises a polygonal cross-sectional geometry. The exemplary rotator coupling head **118** illustrated in FIG. **4** includes a hexagonal cross-sectional geometry, but it should be appreciated that the rotator coupling head **118** may comprise other cross-sectional geometries without departing from the scope of the disclosure. The polygonal cross-sectional geometry of the rotator coupling head **118** enables a user or automated fixator adjustor to achieve sufficient torque to rotate the actuator linkage **110** and the actuation screw **104**.

[0072] FIG. **5** is an underside perspective view of the system **100** for performing a distraction histogenesis surgical procedure. Like in FIGS. **1**A-**1**B and **2**-**4**, FIG. **5** also illustrates wherein the actuation screw **104** is partially distracted out of (i.e., screwed out of) the anchor screw **102**, and thus, the distraction plate **106** is lifted away from the anchor screw **102**.

[0073] FIG. **6** is a perspective view of the system **100** for performing a distraction histogenesis procedure, wherein the actuation screw (see **104**, not visible in FIG. **6**) is fully retracted into the anchor screw **102** (i.e., fully screwed into the anchor screw **102**).

[0074] In practice, the system **100** may be disposed like in FIG. **6** when the system **100** is first installed into a patient and/or when the system **100** is about to be removed from the patient. After installation, a user or automated fixator adjustor may rotate the actuator linkage **110** to thereby rotate the actuation screw (see **104** as first illustrated in FIG. **1**). When the actuation screw **104** is unscrewed from the anchor screw **102**, the actuation screw **104** will lift away from the anchor screw **102**. If the optional distraction plate **106** is being utilized, then the distraction plate **106** will also lift away from the anchor screw **102**. The user or automated fixator adjustor may also rotate the actuator linkage **110** in the opposite direction to retract the actuation screw (i.e., screw the actuation screw into the anchor screw).

[0075] FIG. **7** is a perspective view of the system **100** for performing a distraction histogenesis procedure, wherein the actuation screw is fully retracted into the anchor screw **102**. As shown in FIG. **7**, the screw head (see **948** at FIG. **9**) of the actuation screw **104** may be disposed within the hollow interior defined by the sidewall of the anchor screw **102**. Thus, the screw head (see **948**) is not visible when the actuation screw **104** is fully retracted into the anchor screw. However, the sidewall of the anchor screw **102** is designed such that the actuation screw coupling head **116** of the actuator linkage **110** may still access the screw head (see **948**) to rotate the actuation screw **104**.

[0076] FIG. **8** is a straight-on aerial top-down view of the system **100** for performing a distraction histogenesis procedure. The aerial view of FIG. **8** provides further viewing of the various holes disposed through the distraction plate **106**, including the peripheral threaded holes **140** and the holes **142**.

[0077] FIG. **9** is a perspective cross-sectional view of the system **100** for performing a distraction histogenesis procedure, wherein the actuation screw is fully retracted into the anchor screw **102**. As shown in the cross-sectional view, the actuation screw **104** is disposed within a hollow interior space defined by the anchor screw **102**.

[0078] The cross-sectional view of FIG. **9** enables viewing of the full length of each of the anchor screw **102**, the actuation screw **104**, and the coupler **108**. As shown in FIG. **9**, the anchor tip **134** of the anchor screw **102** serves as the distal-most point of the device **100**. The actuation screw **104** is disposed within the anchor screw **102** and is further disposed through the coupler **108**. The coupler **108** extends through the distraction plate **106** and partially down into the anchor screw **102** when the device is in a fully retracted position as shown in FIG. **9**.

[0079] The cross-sectional view of FIG. **9** further enables viewing of various components of the actuation screw **104**. The actuation screw **104** may include each of the outer screw shaft **122** and an inner screw shaft **960**, wherein the inner screw shaft **960** is configured to be disposed at least partially within the outer screw shaft **122**.

[0080] The outer screw shaft **122** comprises the external threading **124**. The proximal end of the outer screw shaft **122** is located at a distal end of the coupler **108**. The distal end of the outer screw shaft **122** is formed by an outer actuation point **964**. The outer actuation point **964** is configured to be disposed within the anchor screw **102** and may nearly reach the distal-most end of the anchor screw **102**. The entirety of the outer screw shaft **122** is located distal relative to the coupler **108** and the distraction plate **106**.

[0081] A diameter of the outer screw shaft **122** is greater than an inner diameter of the through-holed defined by the coupler **108**. The diameter of the outer screw shaft **122** may additionally be greater than an inner diameter of the central threaded hole of the distraction plate **106**. Thus, the outer screw shaft **122** may not be disposed within the through-hole defined by the coupler **108**, and the outer screw shaft **122** is thus maintained in a position that is distal relative to the coupler **108** and the distraction plate **106**.

[0082] The external threading **124** of the outer screw shaft **122** is configured to interface with internal threading **954** attached to an interior surface of the sidewall **136** of the anchor screw **102**. At least a portion of the outer screw shaft **122** includes a sidewall that defines a hollow interior, and an interior surface of the outer screw shaft **122** may include internal threading **956**. The internal threading **956** is configured to interface with corresponding external threading **958** of the inner screw shaft **960** of the actuation screw.

[0083] The inner screw shaft **960** is configured to be disposed within at least a portion of the outer screw shaft **122**. The proximal end of the inner screw shaft **960** comprises a screw head **948** that may be located within a portion of the coupler **108** and/or the distraction plate **106**. The distal end of the inner screw shaft **960** comprises an inner actuation point **962** that is disposed within the hollow interior formed by the outer screw shaft **122**. The inner screw shaft **960** is configured to be disposed through the through-hole of the coupler **108**, and thus, in combination with the coupler **108**, the inner screw shaft **960** enables the actuation screw **104** to be axially coupled to the distraction plate **106** without also being rotationally coupled to the distraction plate **106**.

[0084] The inner screw shaft **960** includes a threaded portion that includes the external threading **958**. The inner screw shaft **960** may additionally include a smooth portion **946**. The smooth portion **946** is configured to be disposed within a hollow interior **952** defined by the rotational interface **126** of the coupler **108**. Thus, the smooth portion **946** may rotate freely within the rotational interface **126** of the coupler **108**.

[0085] The screw head **948** of the inner screw shaft **960** of the actuation screw **104** is configured to interface with the actuation screw coupling head **116** of the actuator linkage **110**. The screw head **948** is surrounded by the hollow interior defined by the anchoring interface **120** of the coupler **108**. The screw coupling head **116** may be disposed within the hollow interior space located in between the inner surface of the anchoring interface **120** of the coupler **108**, and the outer surface of the screw head **948** of the actuation screw **104**. When the screw coupling head **116** is located within that hollow interior space, the screw coupling head **116** may form an interference fit with the screw head **948** and then drive rotation of the inner screw shaft **960** of the actuation screw **104**. This may likewise drive rotation of the actuation screw **104** without driving synchronous rotation of the coupler **108** or the distraction plate **106**.

[0086] The rotational interface **126** of the coupler **108** includes a polygonal cross-sectional exterior geometry that enables the rotational interface **126** to form a torque coupling with the corresponding polygonal cross-sectional interior geometry of the socket interface **130** of the anchor screw **102**. This enables a user to simultaneously implant the actuation screw **104** and the anchor screw **102** into a patient as a single unit.

[0087] Further as shown in the cross-sectional view, the central threaded hole **144** of the distraction plate includes internal threading **950** that corresponds with the external threading **124** of the coupler **108**. This enables the coupler **108** to be securely screwed into the distraction plate **106**. Further as shown in the cross-sectional view, the anchor screw **102** includes internal threading **954** that corresponds with the external threading **128** of the actuation screw **104**.

[0088] FIG. **10** is a perspective cross-sectional view of the system **100** for performing a distraction histogenesis procedure, wherein the actuation screw is fully retracted into the anchor screw **102**. The cross-sectional view illustrated in FIG. **10** shows that the screw head **948** of the actuation screw **104** may have an external cross-sectional polygonal geometry that corresponds with an internal cross-sectional polygonal geometry of the actuation screw coupling head **116** of the actuator linkage **110**. This ensures the actuator linkage **110** may have sufficient torque to rotate the actuator screw **104**.

[0089] The brackets in FIG. **10** further illustrate how the combination of the outer screw shaft **122** and the inner screw shaft **960** make up the actuation screw **104**. As shown, the inner screw shaft **960** is partially disposed within the outer screw shaft **122**, and additionally passes through the coupler **108** and terminates within the central threaded hole of the distraction plate **106**.

[0090] FIG. **11**A is a schematic illustration of an exploded straight-on side view of an anti-rotation assembly, which is a component of the device **100** described herein. The anti-rotation assembly includes components of the actuation screw **104** (including the inner screw shaft **960** and the outer screw shaft **122**), the coupler **108**, and the distraction plate **106**. The anti-rotation assembly enables the distraction plate

106 to be axially coupled to the actuation screw 104 without also being rotationally coupled to the actuation screw 104.

[0091] The anti-rotation assembly includes the actuation screw 104, which includes the inner screw shaft 960 and the outer screw shaft 122. The outer screw shaft 122 comprises a diameter that is greater than a diameter of the rotational interface 126 of the coupler 108, and this prevents the outer screw shaft 122 from sliding up into the coupler 108 or the distraction plate 106. The inner screw shaft 960 comprises a diameter that is smaller than the diameter of the central threaded hole 144 of the distraction plate 106. The diameter of the inner screw shaft 960 is also smaller than the diameter of a through-hole extending through the entirety of the coupler 108, including the anchoring interface 120 and the rotational interface 126.

[0092] During assembly or installation, the inner screw shaft 960 is slid through the through-hole defined by the sidewall of the coupler 108. The inner screw shaft 960 is then securely coupled to the outer screw shaft 122 by screwing the external threading 958 of the inner screw shaft 960 into the internal threading 956 disposed within the hollow interior of the outer screw shaft 122. The inner screw shaft 960 will be fully installed within the outer screw shaft 122 when the screw head 948 is located approximately within the central threaded hole 144 of the distraction plate 106 and/or when the smooth portion 946 of the inner screw shaft 960 is aligned with the rotational interface 126 of the coupler 108. The outer screw shaft 122 may include stopper that prevents the inner screw shaft 960 from being screw in any deeper than desired.

[0093] As shown in FIG. 11A, the rotational interface 126 of the coupler 108 comprises a diameter that is greater than a diameter of the smooth portion 946 of the inner screw shaft 960. This aids in enabling the inner screw shaft 960 to rotate freely within the coupler 108. This consequently ensures the inner screw shaft 960 may rotate freely within the distraction plate 106, and this enables the distraction plate 106 to remain rotationally stationary even when the actuation screw 104 is screwed into or screwed out of the anchor screw 102.

[0094] The external threading 958 of the inner screw shaft may be tightly engaged with the internal threading 956 of the outer screw shaft 122 to prevent these two components of the actuation screw 104 from becoming separated. In some cases, the inner screw shaft 960 may be glued into the outer screw shaft 122 to ensure a tight and semi-permanent installation. This may help ensure that a loosening rotation of the actuation screw 104 to remove the actuation screw from the anchor screw 102 does not also loosen the inner screw shaft 960 from the outer screw shaft 122.

[0095] FIG. 11B is a schematic illustration of an exploded perspective view of a system 1100 for performing a distraction histogenesis procedure. The system 1100 includes the components of the system 100 first described in connection with FIGS. 1A-1B. The system 1100 additionally includes a knob 1102 for enabling easy rotation of the actuator linkage 110.

[0096] The knob 1102 may include a plurality of grooves 1104 to enable a user to rotate the knob 1102 more easily clockwise or counterclockwise. The knob 1102 may comprise various implementations without departing from the scope of the disclosure. For example, the knob 1102 may comprise a smooth cylindrical geometry without any grooves 1104. The knob 1102 may comprise a quadrilateral, pentagonal, hexagonal, octagonal, or other cross-sectional geometry to provide straight sides enabling a user to rotate the knob 1102 more easily. The knob 1102 may be constructed of any suitable rigid material, including, for example, a metallic material, a polycarbonate material, and so forth. The knob 1102 may be constructed of a material that may be easily cleaned to prevent the buildup or absorption of fluids within the knob 1102. The knob 1102 may also comprise a ball plunger which would provide tactile feedback to users when they rotate the knob.

[0097] The actuator linkage 110 may comprise a polygonal blind hole 1106 disposed within a surface of the rotator coupling head 118. The polygonal blind hole 1106 enables the actuator linkage 110 to interface with corresponding components disposed within a bottom surface of the knob 1102 or a corresponding component within an automated fixator adjustor. The blind hole 1106 may include polygonal cross-sectional geometries to provide the necessary torque to enable the knob 1102 or automated fixator adjustor to rotate the actuator linkage 110, and thereby enable the actuator linkage 110 to rotate the actuation screw 104.

[0098] The actuator linkage 110 may comprise male or female components for forming a coupling with the knob 1102 and the actuation screw 104. In some cases, the actuator linkage 110 may comprise a male component on the rotator coupling head 118 and a female component on the actuation screw coupling head 116, or vice versa.

[0099] The distraction plate 106 comprises the plurality of holes 142 disposed therethrough, and additionally includes the central hole 144 disposed through a center of the distraction plate 106. The central hole 144 may comprise internal threading such that one or more of a drill sleeve (not pictured) or the coupler 108 may be threaded through the central hole 144.

[0100] The distraction plate 106 may comprise various geometries without departing from the scope of the disclosure. The distraction plate 106 may comprise an irregular octagonal geometry as shown in FIG. 11A, wherein the distraction plate 106 includes two long sides 1112 oriented parallel to one another, two short sides 1108 oriented parallel to one another and perpendicular to the two long sides 1112, and four chamfered sides 1110. Each of the four chamfered sides 1110 is disposed in between one long side 1112 and one short side 1108 as shown in FIG. 11A. The two long sides 1112 may have substantially equivalent lengths, the short sides 1108 may have substantially equivalent lengths, and the four chamfered sides 1110 may have substantially equivalent lengths.

[0101] FIG. 12 is a schematic illustration of a perspective of the actuator linkage 110. As shown, the actuator linkage 110 comprises the rotator coupling head 118, the shaft 114, and the actuation screw coupling head 116. Each of the rotator coupling head 118 and the actuation screw coupling head 116 may comprise a polygonal cross-sectional geometry to enable the actuator linkage 110 to provide sufficient torque such that the knob (see 1102) or automated fixator adjustor can rotate the anchor screw 108.

[0102] The polygonal cross-sectional geometries of the rotator coupling head 118 and the actuation screw coupling head 116 may vary without departing from the scope of the disclosure. One or more of the rotator coupling head 118 or the actuation screw coupling head 116 may comprise a hexagonal cross-sectional geometry as shown in FIG. 11A. However, one or more of the rotator coupling head 118 or the actuation screw coupling head 116 may alternatively

comprise one or more of a triangular, quadrilateral, pentagonal, heptagonal, octagonal, or n-sided geometry, depending on the implementation.

[0103] FIG. **13** is a schematic illustration of a straight-on side view of the anchor screw **102**. As shown, the anchor screw **102** comprises a socket interface **130**, external threading **132**, and an anchor tip **134**. The external threading **132** and the design of the anchor tip **134** may be adjusted and optimized depending on the intended use-case based on factors such as the type of bone being operated upon, the patient's condition, the patient's age, and so forth.

[0104] FIG. **14** is a schematic block diagram of a system **1400** for manual distraction and retraction, and specifically illustrates wherein system components are installed in a patient. The system **1400** includes the distraction plate **106** disposed in between the bone **1402** and the periosteum **1404** of the patient. The system **1400** further includes the anchor screw **102** drilled into the bone **1402** of the patient, and the actuation screw **104** disposed within the anchor screw **102**. As shown, the skin **1406** is located external to the periosteum **1404**, but it should be appreciated that additional tissues and biological components may be disposed in between the periosteum **1404** and the skin **1406**. The actuator linkage **110** is coupled to the actuation screw **104** and the knob **1102**, and the shaft of the actuator linkage **110** is disposed through patient tissue. The knob **1102** is located external to the patient, such that a patient or practitioner may rotate the knob to rotate the actuation screw **104** and thereby distraction or retract the distraction plate **106**.

[0105] FIG. **15** is a schematic block diagram of a system **1500** for automated distraction and retraction through mechanical coupling, and specifically illustrates wherein system components are installed in a patient. The system **1500** includes the distraction plate **106** disposed in between the bone **1402** and the periosteum **1404** of the patient. The system **1500** further includes the anchor screw **102** drilled into the bone **1402** of the patient, and the actuation screw **104** disposed within the anchor screw **102**. As shown, the skin **1406** is located external to the periosteum **1404**, but it should be appreciated that additional tissues and biological components may be disposed in between the periosteum **1404** and the skin **1406**. The actuator linkage **110** is attached to the actuation screw **104** and an automated fixator adjustor **1502**, and the shaft of the actuator linkage **110** is disposed through patient tissue. The automated fixator adjustor **1502** is located external to the patient, such that a patient or practitioner may cause a motor within the automated fixator adjustor **1502** to automatically rotate the actuation screw **104**.

[0106] FIG. **16** is a schematic illustration of a straight-on wide view of a cannulated driver **1600** to be used in connection with the components of the systems described herein. The cannulated driver **1600** comprises a distal end **1602**, a shaft **1604**, and a proximal end **1606**. The distal end **1602** comprises a polygonal cross-sectional geometry configured to interface with the socket interface (see **130**) of the anchor screw (see **102**). This provides sufficient torque such that the cannulated driver **1600** may be utilized to screw the anchor screw (see **102**) into the bone of a patient and into the distraction plate **106** simultaneously. The proximal end **1606** is configured to interface with another device such as a screwdriver handle, drill, or other device.

[0107] The socket interface (see **130**) of the anchor screw (see **102**) includes a polygonal cross-sectional geometry on its bottom side that is configured to mate with the shaft of the anchor screw (see **102**). This enables torque to be transmitted from the cannulated driver **1600** to the socket interface (see **130**) and then to the shaft of the anchor screw (see **102**) to drive the anchor screw (see **102**) into patient tissue.

[0108] FIG. **17** is a schematic illustration of a perspective view of drill sleeve **1700** to be used in connection with the components of the system **100** described herein. The drill sleeve **1700** is configured to be utilized by a healthcare provider to enable the provider to drill a pilot hole into the patient bone. The drill sleeve **1700** includes a shaft **1704** that comprises a hollow interior **1702**. The drill sleeve **1700** further comprises threading **1706** that corresponds with the internal threading of the central hole of the distraction plate (see **106**). Thus, the drill sleeve **1700** may be securely screwed into the distraction plate (see **106**), and then a provider may dispose a drill bit through the hollow interior **1702** of the shaft **1704**. This guides the location of the drill bit and prevents the provider from drilling into the patient bone at an undesired location and also makes sure the anchor screw to be inserted will be perpendicular to the distraction plate.

[0109] FIGS. **18**A-**18**E are schematic block diagrams of a method **1800** for performing a distraction histogenesis surgical procedure utilizing the systems and devices described herein. In FIGS. **18**A-**18**E, the method **1800** 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. **18**A-**18**E. The systems described herein may additionally be utilized to perform distraction histogenesis procedures on other tissue types.

[0110] The method **1800** may begin with planning a distraction plate position at **1802** 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 (see **106**) would improve patient outcomes based on the patient's unique health circumstances. In some cases, the healthcare provider may determine that a distraction plate (see **106**) is not necessary, and that the patient may benefit from only the use of an anchor screw (see **102**) and actuation screw (see **104**) for distracting and retracting the patient's tissues such as bone or periosteum.

[0111] The method **1800** includes creating at **1804** a longitudinal or transverse skin incision and a transverse incision of the patient's periosteum layer. The method **1800** includes inserting at **1806** a periosteal elevator to prepare subperiosteal tunnel on both sides of the incision. The method **1800** 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 (see **106**). The method **1800** 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 (see **106**). The method **1800** includes inserting at **1812** the entire distraction plate (see **106**) under the periosteum on the distal side. The method **1800** includes pulling at **1814** the distraction plate (see **106**) back under the periosteum on the proximal side. The method **1800** include aligning at **1816** the central threaded hole of the distraction plate with the incision through the periosteum. The method **1800** includes inserting at **1818** a drill sleeve (see **1700**) into the central

threaded hole of the distraction plate. The method **1800** includes drilling at **1820** a hole into the patient's bone, wherein a drill bit is disposed through the drill sleeve. The method **1800** includes removing at **1822** the drill sleeve and inserting the anchor screw (see **102**) through the central threaded hole of the distraction plate (see **106**) and into the pilot hole drilled into the patient's bone. The method **1800** includes simultaneously driving at **1824** the anchor screw (see **102**) into both the bone and the distraction plate (see **106**) using cannulated driver (see **2400**) until the anchor screw (see **102**) is locked flush into the distraction plate (see **106**). The method **1800** includes inserting at **1826** the actuator linkage (see **108**) into the socket head of the anchor screw. The method **1800** includes attaching at **1828** the knob (see **1102**) or automated fixator adjustor (see **1502**) on to the top plate of the actuator linkage (see **108**). The method **1800** includes rotating at **1830** the knob (see **1102**) or the automated fixator adjustor (see **1502**) to distract or retract the actuation screw (see **104**), and accordingly lift up or relax the patient's periosteum.

[0112] FIGS. **19**A-**19**B are schematic block diagrams of a method **1900** for performing a distraction histogenesis surgical procedure utilizing the systems and devices described herein, and specifically for performing an osteogenesis surgical procedure. In FIGS. **19**A-**19**B, the method **1900** 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 additionally be utilized to perform distraction histogenesis procedures on other tissue types.

[0113] The method **1900** may begin with utilizing at **1902** a stencil or distraction plate as a guide to draw reference lines on patient skin for incision positions. The method **1900** includes dissecting at **1904** down to bone while preserving the periosteum. The method **1900** includes utilizing at **1906** the stencil or the distraction plate as a guide to place a drill sleeve in the desired location. The method **1900** includes inserting at **1908** the drill sleeve into the central hole of the stencil or distraction plate. The method **1900** includes drilling at **1910** a hole into the bone through the drill sleeve.

[0114] The method **1900** includes removing at **1912** the drill sleeve and inserting a distraction screw (including an anchor screw and actuation screw) into pilot hole drilled into the bone. The method **1900** includes utilizing at **1914** the stencil or distraction plate as a guide to drill osteotomy guide holes. The method **1900** includes utilizing at **1916** a saw to connect the osteotomy guide holes. The method **1900** includes repairing the periosteum at **1918** and closing the skin. The method **1900** includes rotating at **1920** the actuation screw to distract and retract the intercalary segment.

[0115] FIG. **20** is a schematic block diagram of a system **2000** for remotely monitoring and controlling a distraction device. The system **2000** may be utilized in connection with any of the systems, methods, or devices described herein. The system **2000** may specifically be utilized in connection with any of the distraction devices described herein, including the system **100** first described in connection with FIG. **1**, when the system **100** is actuated with an automated fixator adjustor. The system **2000** may further be used in connection with the system **1500** first described in connection with FIG. **15**. The system **2000** may be utilized in connection with a manual fixator adjustor or an automated fixator adjustor **1502**.

[0116] The system **2000** includes a health management server **2002** that processes operations for a health management platform **2006**. The health management server **2002** renders a graphical user interface (GUI) that is made accessible by way of the health management platform **2006**. The health management platform **2006** is made accessible to one or more personal devices **2014** by way of a computer-executed application, web browser, or other means. The health management platform **2006** may be accessed with a personal device **2014** that is in communication with a network, such as wide area network, local area network, LoRaWAN, the Internet, and so forth.

[0117] The health management server **2002** may optionally include an artificial intelligence and/or machine learning (AI/ML) engine **2004**. The AI/ML engine **2004** is trained upon a set of training data. The AI/ML engine **2004** may be trained to assess data output from any of the automated fixator adjustor **1502**, a temperature sensor **2016**, a biomarker sensor **2018**, or a camera **2020** to determine whether there is a likely issue with the patient. The temperature sensor **2016**, biomarker sensor **2018**, and/or camera **2020** may be implemented as separate components from the automated fixator adjustor **1502** or be integrated and part of the automated fixator adjustor **1502**. The AI/ML engine **2004** may further be trained on data from the automated fixator adjustor **1502** or from numerous orthopedic procedures, including osteotomy and distraction histogenesis procedures, to generate a proposed treatment protocol for adjusting a fixator with the automated fixator adjustor **1502**.

[0118] The health management platform **2006** may include modules for providing information regarding data monitoring **2008**, adjustment calculation **2010**, provider communication **2012**, and so forth. The health management platform **2006** may be rendered on an application that is run on a personal device **2014**, such as a mobile phone, a tablet, or other personal computer. The health management platform **2006** may be rendered on a web browser that is accessible by way of a personal device **2014** connected to the Internet or LoRaWAN.

[0119] Patients, healthcare providers, administrators, and other users may access the health management platform **2006** with a personal device **2014** to view up-to-date data provided by any of the automated fixator adjustor **1502**, temperature sensor **2016**, biomarker sensor **2018**, or camera **2020**. Additionally, the health management platform **2006** provides current and past information regarding adjustment calculations **2010** for a fixator that is currently or was previously fixated to a patient. The adjustment calculations **2010** may be utilized to change or maintain protocols to be implemented by the automated fixator adjustor **100**. The health management platform **2012** provides a means for secure bidirectional communication with patients and healthcare providers by way of the provider communication **2012** module. The health management platform **2012** additionally provides a means for secure bidirectional communication with devices such as the temperature sensor **2016**, biomarker sensor **2018**, camera **2020**, and automated fixator adjustor **1502**.

[0120] The automated fixator adjustor **1502** comprises one or more processors configured to execute instructions stored in non-transitory computer readable storage medium. The processors of the automated fixator adjustor **1502** may receive instructions from any of the health management server **2002**, a locally stored memory device with the

automated fixator adjustor **1502**, or from another source such as the personal device **2014**. The automated fixator adjustor **1502** may automatically lift or lower a 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 **2002** by way of the health management platform **2006**.

[0121] The automated fixator adjustor **1502** may include one or more Bluetooth® low energy chips and/or near-field communication chips that enable the automated fixator adjustor **1502** to wirelessly communicate with personal devices **2014** by way of Bluetooth® or near-field communication. The automated fixator adjustor **1502** may further be equipped with Wi-Fi® or LoRaWAN capability that enables the automated fixator adjustor **1502** to wirelessly communicate with the health management server **2002** directly.

[0122] The temperature sensor **2016** may be temporarily installed within a patient to monitor the real-time internal temperature of the patient. Data output by the temperature sensor **2016** may be assessed to determine if patient tissue is inflamed or if the patient may have an infection at the surgical site or there is enough blood flow on extremities of patient's body.

[0123] The biomarker sensor **2018** may be temporarily installed within a patient to monitor the real-time presence of certain biomarkers. The biomarker sensor **2018** 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 **2018** may be utilized to determine if the patient likely has an infection at the surgical site and requires additional care. The biomarker sensor **2018** may additionally be utilized to detect and measure growth factors or positive biomarkers associated with patient healing.

[0124] The camera **2020** 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. The camera **2020** may additionally or alternatively include a spectroscopy system, including, for example a Near Infrared Spectroscopy (NIRS) system utilized for measuring tissue oxygenation. The camera **2020** may thus be utilized to measure progress of perfusion to tissues. In some cases, a personal device **2014** comprising a camera communicates with the health management server **2002** by way of a computer-executed application. The health management server **2002** executes the application and may communicate directly with the camera **2020** to receive images and other data captured by the camera **2020**. In some cases, the camera **2020** may integrated with any of the systems described herein and may capture up-to-date pictures of a fixator installed on a patient.

[0125] The personal device **2014** is any personal computing device that can communicate with the health management server **2002**. The personal device **2014** may include a smart phone, a tablet, a laptop, a personal computer, virtual or augmented reality device, and so forth. The personal devices **2014** may communicate with the health management server **2002** by way of a local area network (LAN) connection, a wide area network (WAN) connection, or another network connection, 4G/5G data network, or satellite signals.

[0126] The personal device **2014** may include an application installed thereon for enabling streamlined 2-way communication with the health management server **2002**. 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 **2002**, the temperature sensor **2016**, the biomarker sensor **2018**, the camera **2020**, or the automated fixator adjustor **1502**. 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.

[0127] Referring now to FIG. **21**, a block diagram of an example computing device **2100** is illustrated. Computing device **2100** may be used to perform various procedures, such as those discussed herein. Computing device **2100** 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 **2100** 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. The computing device **2100** described herein can also embedded as part of the automated fixator adjustor **1502** instead of a separate standalone device.

[0128] Computing device **2100** includes one or more processor(s) **2112**, or microcontrollers, one or more memory device(s) **2104**, one or more interface(s) **2106**, one or more mass storage device(s) **2108**, one or more Input/output (I/O) device(s) **2110**, and a display device **2130** all of which are coupled to a bus **2112**. Processor(s) **2112** include one or more processors or controllers that execute instructions stored in memory device(s) **2104** and/or mass storage device (s) **2108**. Processor(s) **2112** may also include diverse types of computer-readable media, such as cache memory.

[0129] Memory device(s) **2104** include various computer-readable media, such as volatile memory (e.g., random access memory (RAM) **2114**) and/or nonvolatile memory (e.g., read-only memory (ROM) **2116**). Memory device(s) **2104** may also include rewritable ROM, such as Flash memory.

[0130] Mass storage device(s) **2108** 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. **21**, a particular mass storage device **2108** is a hard disk drive **2124**. Various drives may also be included in mass storage device(s) **2108** to enable reading from and/or writing to the various computer readable media. Mass storage device(s) **2108** include removable media **2126** and/or non-removable media.

[0131] I/O device(s) **2110** include various devices that allow data and/or other information to be input to or retrieved from computing device **2100**. Example I/O device (s) **2110** include cursor control devices, keyboards, keypads,

microphones, monitors, touchscreen devices, or other display devices, speakers, printers, network interface cards, modems, and the like.

[0132] Display device **2130** includes any type of device capable of displaying information to one or more users of computing device **2100**. Examples of display device **2130** include a monitor, display terminal, video projection device, and the like.

[0133] Interface(s) **2106** include various interfaces that allow computing device **2100** to interact with other systems, devices, or computing environments. Example interface(s) **2106** may include any number of different network interfaces **2120**, such as interfaces to local area networks (LANs), wide area networks (WANs), 4G/5G data network, satellite signals, wireless networks, and the Internet. Other interface(s) include user interface **2118** and peripheral device interface **2122**. The interface(s) **2106** may also include one or more user interface elements **2118**. The interface(s) **2106** 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.

[0134] Bus **2112** allows processor(s) **2112**, memory device (s) **2104**, interface(s) **2106**, mass storage device(s) **2108**, and I/O device(s) **2110** to communicate with one another, as well as other devices or components coupled to bus **2112**. Bus **2112** represents one or more of several types of bus structures, such as a system bus, PCI bus, IEEE bus, USB bus, and so forth.

[0135] 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 **1800** and are executed by processor(s) **2112**. 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

[0136] The following examples pertain to further embodiments.

[0137] 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, wherein the anchor screw comprises external threading attached to an external surface of the sidewall, and wherein the anchor screw comprises internal threading attached to an internal surface of the sidewall. The system includes an actuation screw comprising actuation threading attached to an exterior surface of the actuation screw. The system includes an actuator linkage configured to be coupled to the actuation screw. The system is such that the actuation screw is configured to be disposed within the hollow interior of the anchor screw such that the distraction threading interfaces with the internal threading of the anchor screw. The system is such that rotation of the actuator linkage causes rotation of the actuation screw such that the actuation screw is screwed into and out of the hollow interior of the anchor screw.

[0138] Example 2 is a system as in Example 1, further comprising a distraction plate configured to be disposed in between a first tissue and a second tissue of a patient, wherein the actuation screw is coupled to the distraction plate along a longitudinal axis of the actuation screw.

[0139] Example 3 is a system as in any of Examples 1-2, wherein the distraction plate comprises a hole defined by a sidewall that comprises internal threading, and wherein the hole is disposed through a thickness of the distraction plate.

[0140] Example 4 is a system as in any of Examples 1-3, wherein the internal threading of the sidewall of the hole of the distraction plate corresponds with external threading of a coupler such that the coupler may be screwed into the distraction plate.

[0141] Example 5 is a system as in any of Examples 1-4, further comprising an adjustor coupled to the actuator linkage, wherein the adjustor comprises a knob, and wherein the knob is configured to be coupled to the actuator linkage to enable a user to manually rotate the actuator linkage.

[0142] Example 6 is a system as in any of Examples 1-5, further comprising an adjustor coupled to the actuator linkage, wherein the adjustor comprises an automated fixator adjustor, and wherein the automated fixator adjustor comprises: a motor or gearmotor; and a driveshaft in mechanical communication with the motor; wherein the drive shaft drives the anchor screw via the actuator linkage.

[0143] Example 7 is a system as in any of Examples 1-6, wherein the automated fixator adjustor further comprises: a processor; and a wireless communication antenna or chip in RF communication with the processor; wherein the processor actuates the motor in response to receiving an instruction to actuate the motor, wherein the instruction is received via one or more of preloaded storage or the wireless communication antenna or chip.

[0144] Example 8 is a system as in any of Examples 1-7, wherein the anchor screw is configured to be screwed into a bone tissue of a patient, and wherein rotation of the actuator linkage in a first direction causes the actuation screw to lift away from an outer surface of the bone tissue.

[0145] Example 9 is a system as in any of Examples 1-8, wherein rotation of the actuator linkage in a second direction that is opposite to the first direction causes the actuation screw to lower toward the outer surface of the bone tissue.

[0146] Example 10 is a system as in any of Examples 1-9, wherein the anchor screw is configured to be screwed into a bone tissue of a patient, and wherein the actuator linkage is configured to be disposed through a skin layer and a periosteum layer of the patient.

[0147] Example 11 is a system as in any of Examples 1-10, further comprising an adjustor located external to a skin layer of the patient when the system is installed in a patient.

[0148] Example 12 is a system as in any of Examples 1-11, wherein the actuator linkage comprises: a top plate, wherein the top plate comprises a top polygonal cross-sectional geometry; a bottom plate, wherein the bottom plate com-

prises a bottom polygonal cross-sectional geometry; and a shaft disposed in between the top plate and the bottom plate.

[0149] Example 13 is a system as in any of Examples 1-12, wherein a length of the shaft is optimized based on a thickness of patient tissue from the outer surface of the bone to an exterior of a skin layer of the patient.

[0150] Example 14 is a system as in any of Examples 1-13, wherein one or more of the top polygonal cross-sectional geometry or the bottom polygonal cross-sectional geometry is a hexagonal geometry.

[0151] Example 15 is a system as in any of Examples 1-14, further comprising a distraction plate coupled to the actuation screw, wherein the distraction plate comprises an irregular octagonal geometry.

[0152] Example 16 is a system as in any of Examples 1-15, wherein the irregular octagonal geometry of the distraction plate comprises two long sides that comprise substantially equivalent length and oriented substantially parallel to one another, and wherein the substantially equivalent length of the two long sides is selected to perform periosteal distraction on a leg bone of a patient.

[0153] Example 17 is a system as in any of Examples 1-16, wherein the irregular octagonal geometry of the distraction plate comprises two long sides that comprise substantially equivalent length and oriented substantially parallel to one another, and wherein the substantially equivalent length of the two long sides is selected to perform periosteal distraction on an arm bone of a patient.

[0154] Example 18 is a system as in any of Examples 1-17, further comprising a distraction plate coupled to the actuation screw, wherein the distraction plate is configured to be disposed in between a circumferential lamellae of a bone and a periosteum layer of the bone such that a tightening rotation of the actuator linkage causes the distraction plate to lift the periosteum layer away from the circumferential lamellae.

[0155] Example 19 is a system as in any of Examples 1-18, further comprising a distraction plate coupled to the actuation screw, wherein the distraction plate is configured to be disposed in between a circumferential lamellae of a bone and the periosteum layer of the bone such that a loosening rotation of the actuator linkage causes the distraction plate to lower toward the circumferential lamellae.

[0156] Example 20 is a system as in any of Examples 1-19, further comprising a drill sleeve, wherein the drill sleeve comprises: external threading; and a hollow cylinder; wherein the external threading corresponds with internal threading of a hole disposed through the distraction plate; and wherein a diameter of the hollow cylinder is configured to receive a drill bit for drilling a pilot hole into the bone.

[0157] Example 21 is a system as in any of Examples 1-20, further comprising a cannulated driver, wherein the cannulated driver comprises a driver head configured to interface with a socket head of a coupler, wherein the coupler axially couples the distraction plate to the actuation screw without also rotationally coupling the actuation screw to the distraction plate.

[0158] Example 22 is a system for performing a distraction histogenesis surgical procedure. 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 external actuation threading attached to an exterior surface of the actuation screw. The system includes a distraction plate coupled to the actuation screw. The system is such that the external actuation threading corresponds with the internal actuation threading such that the actuation screw is configured to be screwed into the hollow interior of the anchor screw. The system is such that the distraction plate is rotationally independent of the actuation screw.

[0159] Example 23 is a system as in Example 22, wherein the distraction plate is axially coupled to the actuation screw such that: rotation of the actuation screw in a first rotational direction causes the actuation screw to screw into the anchor screw and further causes the distraction plate to lower toward the anchor screw; and rotation of the actuation screw in a second rotational direction causes the actuation screw to screw out of the anchor screw and further causes the distraction plate to lift away from the anchor screw.

[0160] Example 24 is a system as in any of Examples 22-23, wherein the distraction plate is rotationally independent of the actuation screw such that the distraction plate remains rotationally stationary in response to the rotation of the actuation screw in either of the first rotational direction or the second rotational direction.

[0161] Example 25 is a system as in any of Examples 22-24, further comprising a coupler that couples the distraction plate to the actuation screw such that the distraction plate is rotationally independent of the actuation screw, wherein the coupler comprises a sidewall that defines a hollow interior, and wherein the sidewall comprises: an anchoring interface portion that comprises external threading attached to an exterior surface of the sidewall; and a rotational interface portion attached to the anchoring interface portion.

[0162] Example 26 is a system as in any of Examples 22-25, wherein the sidewall of the coupler comprises a polygonal cross-sectional geometry at the rotational interface portion such that the rotational interface portion forms a polygonal socket driver head having a hollow interior.

[0163] Example 27 is a system as in any of Examples 22-26, wherein the anchor screw further comprises a polygonal socket interface comprising a polygonal cross-sectional geometry; and wherein the polygonal socket driver head of the rotational interface is configured to interface with the polygonal socket interface of the anchor screw to drive rotation of the anchor screw.

[0164] Example 28 is a system as in any of Examples 22-27, wherein the distraction plate comprises a threaded hole disposed therethrough; and wherein the external threading attached to the exterior surface of the coupler is configured to interface with corresponding internal threading disposed on the threaded hole of the distraction plate.

[0165] Example 29 is a system as in any of Examples 22-28, wherein the actuation screw comprises an outer screw shaft forming the exterior surface of the actuation screw, wherein the outer screw shaft comprises: a sidewall that defines an at least partially hollow interior, wherein the sidewall defines the exterior surface of the actuation screw and further defines an interior surface of the actuation screw; the external actuation threading attached to the exterior surface of the actuation screw; and internal coupling threading attached to the interior surface of the actuation screw.

[0166] Example 30 is a system as in any of Examples 22-29, wherein the actuation screw further comprises an

inner screw shaft configured to be disposed within the outer screw shaft and the coupler, wherein the inner screw shaft comprises: a screw head comprising a polygonal cross-sectional geometry; a smooth shaft portion attached to the screw head; and a threaded portion comprising external coupling threading.

[0167] Example 31 is a system as in any of Examples 22-30, wherein the external coupling threading is configured to interface with the internal coupling threading to couple the inner screw shaft to the outer screw shaft.

[0168] Example 32 is a system as in any of Examples 22-31, wherein the smooth shaft portion of the inner screw shaft is configured to be disposed within the rotational interface portion of the coupler; and wherein an internal diameter of the rotational interface portion is greater than an external diameter of the smooth shaft portion such that the inner screw shaft rotates freely within the coupler.

[0169] Example 33 is a system as in any of Examples 22-32, wherein the coupler is configured to axially couple the distraction plate to the actuation screw such that: driving the screw head of the inner screw shaft of the actuation screw in a first rotational direction causes the actuation screw to rotate in the first rotational direction to screw into the anchor screw, and further causes the distraction plate to lower toward the anchor screw; and driving the screw head of the inner screw shaft of the actuation screw in a second rotational direction causes the actuation screw to screw out of the anchor screw, and further causes the distraction plate to lift away from the anchor screw; wherein the distraction plate is rotationally independent of the actuation screw such that the distraction plate remains rotationally stationary in response to the rotation of the actuation screw in either of the first rotational direction or the second rotational direction.

[0170] Example 34 is a system as in any of Examples 22-33, wherein the distraction plate is configured to be disposed in between a first tissue and a second tissue of a patient.

[0171] Example 35 is a system as in any of Examples 22-34, wherein the actuation screw comprises a screw head comprising a polygonal cross-sectional geometry; wherein rotation of the screw head in a first rotational direction causes the actuation screw to screw into the anchor screw; and wherein rotation of the screw head in a second rotational direction causes the actuation screw to screw out of the anchor screw.

[0172] Example 36 is a system as in any of Examples 22-35, further comprising an automated adjustor coupled to the screw head of the actuation screw, wherein the automated adjustor comprises: one or more of a motor or gearmotor; and a driveshaft in mechanical communication with the one or more of the motor or the gearmotor; wherein the drive shaft drives rotation of the screw head.

[0173] Example 37 is a system as in any of Examples 22-36, wherein the automated adjustor further comprises: a processor; a motor driver; a power source comprising one or more of a battery or external power; and a wireless communication antenna or chip in communication with the processor; wherein the processor controls the one or more of the motor or the gearmotor via the motor driver in response to receiving an instruction to actuate the one or more of the motor or the gearmotor, and wherein the instruction is received via one or more of preloaded storage or the wireless communication antenna or chip.

[0174] Example 38 is a system as in any of Examples 22-37, wherein the external anchor threading of the anchor screw is configured to be screwed into a tissue substrate of a patient; wherein rotation of the actuation screw in a first rotational direction causes the actuation screw to screw into the anchor screw, and further causes the distraction plate to lower toward the anchor screw, without adjusting a position of the anchor screw within the tissue substrate; and wherein rotation of the actuation screw in a second rotational direction causes the actuation screw to screw out of the anchor screw, and further causes the distraction plate to lift away from the anchor screw, without adjusting a position of the anchor screw within the tissue substrate.

[0175] Example 39 is a system as in any of Examples 22-38, further comprising an adjustor located external to a skin layer of the patient when the system is installed in a patient.

[0176] Example 40 is a system as in any of Examples 22-39, 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 actuation screw within the hollow interior of the anchor screw.

[0177] Example 41 is a system as in any of Examples 22-40, further comprising an actuator linkage, wherein the actuator linkage comprises an actuation screw coupling head configured to interface with a screw head of the actuation screw, and wherein rotation of the actuator linkage causes synchronous rotation of the actuation screw when the actuator linkage is coupled to the actuation screw.

[0178] Example 42 is a system for performing a distraction histogenesis surgical procedure. The system includes a distraction device 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 head and external actuation threading attached to an exterior surface of the actuation screw; and a distraction plate coupled to the actuation screw; wherein the external actuation threading corresponds with the internal actuation threading such that the actuation screw is configured to be screwed into the hollow interior of the anchor screw; and wherein the distraction plate is rotationally independent of the actuation screw. The system includes an automated adjustor coupled to the screw head of the actuation screw and configured to drive rotation of the actuation screw, wherein the automated adjustor comprises: one or more of a motor or a gearmotor; a motor driver; a power source comprising one or more of a battery or an external power source; a driveshaft in mechanical communication with the one or more of the motor or the gearmotor; and a processor, wherein the processor controls the one or more of the motor or the gearmotor based upon a computer-readable instruction via the motor driver.

[0179] 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.

[0180] 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 external actuation threading attached to an exterior surface of the actuation screw; and

a distraction plate coupled to the actuation screw;

wherein the external actuation threading corresponds with the internal actuation threading such that the actuation screw is configured to be screwed into the hollow interior of the anchor screw; and

wherein the distraction plate is rotationally independent of the actuation screw.

2. The system of claim **1**, wherein the distraction plate is axially coupled to the actuation screw such that:

rotation of the actuation screw in a first rotational direction causes the actuation screw to screw into the anchor screw and further causes the distraction plate to lower toward the anchor screw; and

rotation of the actuation screw in a second rotational direction causes the actuation screw to screw out of the anchor screw and further causes the distraction plate to lift away from the anchor screw.

3. The system of claim **2**, wherein the distraction plate is rotationally independent of the actuation screw such that the distraction plate remains rotationally stationary in response to the rotation of the actuation screw in either of the first rotational direction or the second rotational direction.

4. The system of claim **1**, further comprising a coupler that couples the distraction plate to the actuation screw such that the distraction plate is rotationally independent of the actuation screw, wherein the coupler comprises a sidewall that defines a hollow interior, and wherein the sidewall comprises:

an anchoring interface portion that comprises external threading attached to an exterior surface of the sidewall; and

a rotational interface portion attached to the anchoring interface portion.

5. The system of claim **4**, wherein the sidewall of the coupler comprises a polygonal cross-sectional geometry at the rotational interface portion such that the rotational interface portion forms a polygonal socket driver head having a hollow interior.

6. The system of claim **5**, wherein the anchor screw further comprises a polygonal socket interface comprising a polygonal cross-sectional geometry; and

wherein the polygonal socket driver head of the rotational interface is configured to interface with the polygonal socket interface of the anchor screw to drive rotation of the anchor screw.

7. The system of claim **4**, wherein the distraction plate comprises a threaded hole disposed therethrough; and

wherein the external threading attached to the exterior surface of the coupler is configured to interface with corresponding internal threading disposed on the threaded hole of the distraction plate.

8. The system of claim **4**, wherein the actuation screw comprises an outer screw shaft forming the exterior surface of the actuation screw, wherein the outer screw shaft comprises:

a sidewall that defines an at least partially hollow interior, wherein the sidewall defines the exterior surface of the actuation screw and further defines an interior surface of the actuation screw;

the external actuation threading attached to the exterior surface of the actuation screw; and

internal coupling threading attached to the interior surface of the actuation screw.

9. The system of claim **8**, wherein the actuation screw further comprises an inner screw shaft configured to be disposed within the outer screw shaft and the coupler, wherein the inner screw shaft comprises:

a screw head comprising a polygonal cross-sectional geometry;

a smooth shaft portion attached to the screw head; and

a threaded portion comprising external coupling threading.

10. The system of claim **9**, wherein the external coupling threading is configured to interface with the internal coupling threading to couple the inner screw shaft to the outer screw shaft.

11. The system of claim **9**, wherein the smooth shaft portion of the inner screw shaft is configured to be disposed within the rotational interface portion of the coupler;

wherein an internal diameter of the rotational interface portion is greater than an external diameter of the smooth shaft portion such that the inner screw shaft rotates freely within the coupler.

12. The system of claim **11**, wherein the coupler is configured to axially couple the distraction plate to the actuation screw such that:

driving the screw head of the inner screw shaft of the actuation screw in a first rotational direction causes the actuation screw to rotate in the first rotational direction to screw into the anchor screw, and further causes the distraction plate to lower toward the anchor screw; and

driving the screw head of the inner screw shaft of the actuation screw in a second rotational direction causes the actuation screw to screw out of the anchor screw, and further causes the distraction plate to lift away from the anchor screw;

wherein the distraction plate is rotationally independent of the actuation screw such that the distraction plate remains rotationally stationary in response to the rotation of the actuation screw in either of the first rotational direction or the second rotational direction.

13. The system of claim **1**, wherein the distraction plate is configured to be disposed in between a first tissue and a second tissue of a patient.

14. The system of claim **1**, wherein the actuation screw comprises a screw head comprising a polygonal cross-sectional geometry;

wherein rotation of the screw head in a first rotational direction causes the actuation screw to screw into the anchor screw; and

wherein rotation of the screw head in a second rotational direction causes the actuation screw to screw out of the anchor screw.

15. The system of claim **14**, further comprising an automated adjustor coupled to the screw head of the actuation screw, wherein the automated adjustor comprises:

one or more of a motor or gearmotor; and

a driveshaft in mechanical communication with the one or more of the motor or the gearmotor;

wherein the drive shaft drives rotation of the screw head.

16. The system of claim **15**, wherein the automated adjustor further comprises:

a processor;

a motor driver;

a battery or an external power source; and

a wireless communication antenna or chip in communication with the processor;

wherein the processor actuates the one or more of the motor or the gearmotor via the motor driver in response to receiving an instruction to actuate the one or more of the motor or the gearmotor, and wherein the instruction is received via one or more of preloaded storage or the wireless communication antenna or chip.

17. The system of claim **1**, wherein the external anchor threading of the anchor screw is configured to be screwed into a tissue substrate of a patient;

wherein rotation of the actuation screw in a first rotational direction causes the actuation screw to screw into the anchor screw, and further causes the distraction plate to lower toward the anchor screw, without adjusting a position of the anchor screw within the tissue substrate; and

wherein rotation of the actuation screw in a second rotational direction causes the actuation screw to screw out of the anchor screw, and further causes the distraction plate to lift away from the anchor screw, without adjusting a position of the anchor screw within the tissue substrate.

18. The system of claim **1**, further comprising an adjustor located external to a skin layer of the patient when the system is installed in a 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 actuation screw within the hollow interior of the anchor screw.

20. The system of claim **1**, further comprising an actuator linkage, wherein the actuator linkage comprises an actuation screw coupling head configured to interface with a screw head of the actuation screw, and wherein rotation of the actuator linkage causes synchronous rotation of the actuation screw when the actuator linkage is coupled to the actuation screw.

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

a distraction device 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 head and external actuation threading attached to an exterior surface of the actuation screw; and

a distraction plate coupled to the actuation screw;

wherein the external actuation threading corresponds with the internal actuation threading such that the actuation screw is configured to be screwed into the hollow interior of the anchor screw; and

wherein the distraction plate is rotationally independent of the actuation screw; and

an automated adjustor coupled to the screw head of the actuation screw and configured to drive rotation of the actuation screw, wherein the automated adjustor comprises:

one or more of a motor or a gearmotor;

a driveshaft in mechanical communication with the one or more of the motor or the gearmotor; and

a processor;

a motor driver;

a battery or an external power source; and

wherein the processor actuates the one or more of the motor or the gearmotor based upon a computer-readable instruction.

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