

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

(19) World Intellectual Property

Organization

International Bureau

(43) International Publication Date

22 August 2019 (22.08.2019)



(10) International Publication Number

WO 2019/161100 A1

(51) International Patent Classification:

A61B 17/70 (2006.01)

A61B 17/72 (2006.01)

A61B 17/68 (2006.01)

(21) International Application Number:

PCT/US2019/018070

(22) International Filing Date:

14 February 2019 (14.02.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/630,300

14 February 2018 (14.02.2018) US

(71) Applicant: **DIGNITY HEALTH** [US/US]; 185 Berry Street, Suite 300, San Francisco, California 94107 (US).

(72) Inventor: **BOHL, Michael A.**; c/o DIGNITY HEALTH, 185 Berry Street, Suite 300, San Francisco, California 94017 (US).

(74) Agent: **FONTES, Timothy D.** et al.; POLSINELLI PC, One East Washington Street, Suite 1200, Phoenix, Arizona 85004 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,

DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Published:

— with international search report (Art. 21(3))

(54) Title: SYSTEMS AND METHODS FOR A PEDICLE SCREW ASSEMBLY WITH ANCHOR DEPLOYMENT

(57) Abstract: Various embodiments of a pedicle screw assembly disclosed herein include a pedicle screw configured for engaging with bone tissue. The pedicle screw includes a body defining a plurality of channels through the body of the screw and in communication with a plurality of respective distal openings defined along the screw body. The pedicle screw assembly further includes an anchor defining a plurality of anchor members which are configured to be received at least partially through the plurality of channels and the plurality of respective distal openings to further engage the pedicle screw to the bone tissue.

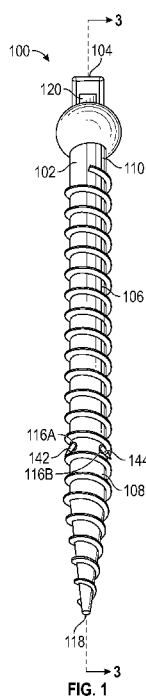


FIG. 1



WO 2019/161100 A1

SYSTEMS AND METHODS FOR A PEDICLE SCREW ASSEMBLY WITH ANCHOR DEPLOYMENT

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This is a PCT application that claims benefit to U.S. provisional application serial number 62/630,300 filed on February 14, 2018 which is incorporated by reference in its entirety.

FIELD

[0002] The present disclosure generally relates to surgical devices; and in particular, to systems and methods for pedicle screw assemblies.

BACKGROUND

[0003] Mechanical instability of the spine can result from many causes, including degenerative disease, trauma, infection, spinal deformity, or neoplastic processes. Left untreated, such spinal instability can result in pain, neurological compromise, and immobility. Spinal instability is treated surgically via fixation and fusion of the unstable spinal levels. Fixation of the spine is accomplished posteriorly through the insertion of screws through the vertebral pedicles, which are then segmentally connected by metal rods.

[0004] For patients undergoing spinal fixation and fusion surgery, pedicle screws are considered a standard of care. One of the most common complications associated with pedicle screw fixation, especially in long fixation constructs, is screw failure and pull-out with resultant pseudarthrosis or adjacent segment disease. Existing strategies for increasing the axial resistance required to pull out a pedicle screw include increased screw sizes, alternative core shapes, alternative thread shapes, and bone-cement augmentation. Each of these strategies comes with significant limitations, and none have proven to be a clinically reliable solution to the problem of pedicle screw failure.

[0005] It is with these observations in mind, among others, that various aspects of the present disclosure were conceived and developed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. 1 is a perspective view of a first embodiment of a pedicle screw assembly having a pedicle screw and a bone anchor with integral anchor ends, according to one aspect of the present disclosure;

[0007] FIG. 2 is an exploded view of the pedicle screw assembly of FIG. 1 depicting the pedicle screw and the bone anchor, according to one aspect of the present disclosure;

[0008] FIG. 3 is a cross-sectional view of the pedicle screw taken along line 3-3 of FIG. 1, according to one aspect of the present disclosure;

[0009] FIG. 4 is a cross-sectional view of the pedicle screw of FIG. 3 taken along line 4-4 showing the bone anchor disposed partially within a channel of the pedicle screw, according to one aspect of the present disclosure;

[0010] FIG. 5 is a cross-sectional view of the pedicle screw of FIG. 3 showing the bone anchor disposed fully within the channel of the pedicle screw and deployed through an opening formed at the distal end of the pedicle screw, according to one aspect of the present disclosure;

[0011] FIG. 6 is an anatomical perspective view of the pedicle screw partially engaged inside a pedicle of a vertebra with the bone anchor in a pre-deployment position, according to one aspect of the present disclosure;

[0012] FIG. 7 is an anatomical perspective view of the pedicle screw partially engaged inside a pedicle vertebra with the anchor in a post-deployment position, according to one aspect of the present disclosure;

[0013] FIG. 8 is a perspective view of a second embodiment of a pedicle screw assembly having a pedicle screw, a bone anchor, and anchor ends, according to one aspect of the present disclosure;

[0014] FIG. 9 is an exploded view of the pedicle screw assembly of FIG. 8 depicting the pedicle screw and the bone anchor, according to one aspect of the present disclosure;

[0015] FIG. 10 is a cross-sectional view of the pedicle screw of FIG. 9 taken along line 10-10, according to one aspect of the present disclosure;

[0016] FIG. 11 is a cross-sectional view of the pedicle screw of FIG. 8 taken along line 11-11 showing the bone anchor disposed partially within a channel of the pedicle screw, according to one aspect of the present disclosure;

[0017] FIG. 12 is a cross-sectional view of the pedicle screw of FIG. 8 showing the bone anchor disposed fully within the channel of the pedicle screw and deployed through an opening formed at the distal end of the pedicle screw, according to one aspect of the present disclosure;

[0018] FIG. 13 is an anatomical perspective view of the pedicle screw partially engaged inside a pedicle vertebra with the bone anchor in a pre-deployment position, according to one aspect of the present disclosure; and

[0019] FIG. 14 is an anatomical perspective view of the pedicle screw partially engaged inside a pedicle vertebra with the anchor in a post-deployment position, according to one aspect of the present disclosure.

[0020] Corresponding reference characters indicate corresponding elements among the view of the drawings. The headings used in the figures do not limit the scope of the claims.

DETAILED DESCRIPTION

[0021] Various embodiments of a pedicle screw assembly having one or more bone anchors that are engaged along a pedicle screw for securing the pedicle screw within a pedicle of a vertebra are disclosed. In some embodiments, the pedicle screw assembly includes a pedicle screw having external threads configured to allow the pedicle screw to be partially engaged within a pedicle vertebra. In addition, various embodiments of the pedicle screw may include one or more channels in communication with respective distal openings configured to accommodate passage of bone anchor ends through the body of the pedicle screw as described herein. In some embodiments, the bone anchor ends may extrude outwardly from the pedicle screw when the bone anchor is in a post-deployment configuration, thereby driving the anchor ends within bone, which further engages the pedicle screw to the pedicle vertebra.

[0022] In some embodiments, the bone anchor generally includes an elongated anchor body defining a base and a pair of anchor members extending from the base, with at least a portion of the anchor body being bendable and/or flexible. The anchor members of the bone anchor are configured for insertion within the channels of the pedicle screw and further configured to drive the anchor ends into the bone tissue as described herein.

[0023] In one method of engaging a pedicle screw to bone or other target location, the pedicle screw is inserted into a pedicle of the vertebra and the bone anchor is inserted through the respective channels of the pedicle screw such that the anchor ends associated with the bone anchor extend outwardly from the pedicle screw in a post-deployment position and engage bone tissue, thereby further engaging the pedicle screw to the pedicle vertebra. Referring to the drawings, embodiments of a pedicle screw assembly are illustrated and generally indicated as **100** and **200** in FIGS. **1-14**.

[0024] Referring to FIGS. **1-7**, a first embodiment of a pedicle screw assembly, designated **100**, is illustrated. As shown in FIGS. **1-3**, the pedicle screw assembly **100** includes a pedicle screw **102** that is configured to be mechanically coupled to a bone anchor **104** in a manner that is suitable for anchoring the pedicle screw **102** to bodily tissue, such as the bone tissue of a vertebra. In some embodiments, the pedicle screw **102** general includes an elongated screw body **106** defining a distal portion **108** (including a conical tip **118** defined at the free end thereof) and a proximal portion **110** that defines a pair of proximal openings **112** (shown in FIG. **3**); designated a first proximal opening **112A** and second proximal opening **112B**. As indicated in FIG. **3**, the first proximal opening **112A** is in communication with a first channel **114A** formed at least partially along a longitudinal axis **X1** of the pedicle screw **102**, and the second proximal opening **112B** is in communication with a second channel **114B** formed at least partially along the longitudinal axis **X1** of the pedicle screw **102**. In some embodiments as shown, at least a portion of the first channel **114A** is in parallel relation relative to the second channel **114B**. Further, the screw body **106** may define a threaded portion **115** defining external threads that extends substantially along the length of the screw body **106** configured to accommodate the pedicle screw **102** to engage and be retained within bone tissue.

[0025] Referring to FIG. **3**, along the distal portion **108** of the pedicle screw **102**, the first channel **114A** is in communication with a first distal opening **116A** formed through a first lateral side **117A** of the pedicle screw **102** along the distal portion **108** of the screw body **106**, and the second channel **114B** is in communication with a second distal opening **116B** formed through a second lateral side **117B** of the pedicle screw **102** along the distal portion **108** of the screw body **106**. In some embodiments, the first lateral side **117A** of the pedicle screw **102** is

generally defined opposite the second lateral side **117B** of the pedicle screw **102** such that the first distal opening **116A** is formed opposite the second distal opening **116B**, but the present disclosure is not limited in this regard. In addition, as indicated, the first channel **114A** may include a first portion **118A** extending from the proximal portion **110** of the screw body **106**, and a second portion **119A** adjacent the first distal opening **116A**. Similarly, the second channel **114B** may include a first portion **118B** extending from the proximal portion **110** of the screw body **106**, and a second portion **119B** adjacent the second distal opening **116B**. Each of the second portion **119A** and the second portion **119B** may be configured to be at least partially non-linear, and may define a curve as shown or a bend away from the longitudinal axis **X1** of the pedicle screw body **106**. In this manner, the first channel **114A** and the second channel **114B** may define a general partial C-shape or arcuate shape configuration, a general partial Y-shape configuration (not shown), or T-shape configuration (not shown). It is contemplated that the first channel **114A** and the second channel **114B** may take on any form so long as the first channel **114A** is in communication with the first distal opening **116A** and the second channel **114B** is in communication with the second distal opening **116B** so that portions of the bone anchor **104** can traverse through the first channel **114A** and extrude out the first distal opening **116A** and portions of the bone anchor **104** can similarly traverse through the second channel **114B** and extrude out the second distal opening **116B**, as further described herein. In some embodiments, the first and second distal openings **116A** and **116B** may be defined, respectively, directly adjacent the first portion **118A** and the first portion **118B** (not shown), above the first portion **118A** and the first portion **118B** (not shown), below the first portion **118A** and the first portion **118B** as shown in FIG. 3, such that the first distal opening **116A** the second distal opening **116B** are oriented closer to the conical tip **118** of the pedicle screw **102** than the first portion **118A** of the first channel **114A** and the first portion **118B** of the second channel **114B**.

[0026] In addition, as shown in FIGS. 1-5, in some embodiments the pedicle screw **102** may include a stopper **120** for obstructing the movement of at least a portion of the bone anchor **104** relative to the screw body **106** in order to allow the bone anchor **104** to be removed from the screw body **106**, as further described herein. The stopper **120** may generally define a block or ridge shaped-component formed along the proximal portion **110** of the screw body **106** between

the first proximal opening **112A** and the second proximal opening **112B** as shown, and may comprise rubber, plastic, steel or any biocompatible material. In some embodiments, the stopper **120** may further be removable from the screw body **106** where, e.g., it is desired to permanently engage the bone anchor **104** to the screw body **106** and bone tissue.

[0027] Referring back to FIG. 2, in some embodiments the bone anchor **104** includes an anchor body **130**, defining a proximal portion **131A** and a distal portion **131B**, with the anchor body **130** configured for at least partial insertion within the screw body **106** to engage the pedicle screw **102** to a pedicle or other target sites. In some embodiments, the anchor body **130** includes a base portion **132** along the proximal portion **131A** of the anchor body **130**, with the base portion **132** defining a first side **134** and a second side **136** opposite the first side **134**, as indicated. The base portion **132** may generally define a cuboidal or cylindrically shaped configuration and may be manufactured in any number of ways sufficient to receive a force (**F** in FIG. 4) for driving the bone anchor **104** partially through the screw body **106**, as further described herein. For example, the base portion **132** may include a handle or thumb print to receive a force applied by a human hand, or may define a rigid surface for receiving a force applied by a blunt instrument such as a hammer.

[0028] As shown, the anchor body **130** may further include a first anchor member **138** extending orthogonally from the first side **134** of the base portion **132** and configured for insertion within the first channel **114A** of the screw body **106**. Similarly, the anchor body **130** may include a second anchor member **140** extending orthogonally from the second side **136** of the base portion **132** and configured for insertion within the second channel **114B**. In some embodiments, the first anchor member **138** is in substantially parallel relation relative to the second anchor member **140**, as in the case where at least a portion of the first channel **114A** and the second channel **114B** define a similar parallel configuration, but the present disclosure is not limited in this regard. In general, the first anchor member **138** and the second anchor member **140** may define any shape suitable for insertion within the first channel **114A** and the second channel **114B** of the screw body **106**, respectively. For example, the first anchor member **138** and the second anchor member **140** may be generally cylindrical in shape, may define planar plates or tabs, may define spikes, etc., and may be formed with any biocompatible material, one or

more metals, plastics, or combinations thereof. In addition, while two anchor members (the first anchor member **138** and the second anchor member **140**) are shown, the anchor body **130** may define a sole anchor member (not shown) or any number of anchor members as desired (not shown). At least a portion of the anchor body **130**, including e.g., the first anchor member **138** and the second anchor member **140** may be at least partially bendable, biasable, and/or flexible to accommodate passage of the first anchor member **138** and the second anchor member **140** through the first channel **114A** and the second channel **114B**, respectively.

[0029] In addition, the first anchor member **138** may define an anchor end **142**, and the second anchor member **140** may define an anchor end **144** along the distal portion **131B** of the anchor body **130**. The anchor end **142** and the anchor end **144** may define any number of shapes or configurations, may be cylindrical in shape, may define planar plates or tabs, and/or may define spikes or blades, etc., such that the anchor end **142** and the anchor end **144** can penetrate bone tissue. In some embodiments, the anchor end **142** and the anchor end **144** are integral with the first anchor member **138** and the second anchor member **140**, respectively. In some embodiments, the anchor end **142** and the anchor end **144** define a general tapered shape configuration.

[0030] Referring to FIGS. **4-7**, one method of implanting the pedicle screw assembly **100** is illustrated. As shown in FIG. **6**, the pedicle screw **102** is first engaged into bone tissue, such as a pedicle of the vertebra, so that the proximal portion **110** of the pedicle screw **102** extends from the bone tissue. Once the pedicle screw **102** is implanted into the bone tissue, the first anchor member **138** and the second anchor member **140** of the bone anchor **104** are inserted into the first proximal opening **112A** and the second proximal opening **112B**, respectively, of the pedicle screw **102**, in the manner indicated in FIG. **4** to form a pre-deployment configuration **150** of the pedicle screw assembly **100**.

[0031] Once the pre-deployment configuration **150** is formed, the first anchor member **138** is at least partially disposed within the first channel **114A**, and the second anchor member **140** is at least partially disposed within the second channel **114B** as shown in FIG. **4**. Thereafter, in some embodiments, a force **F** may be applied as shown to drive the first anchor member **138** further through the first channel **114A** and simultaneously drive the second anchor member **140** further

through the second channel **114B** in the direction **D1**. In some embodiments, the force **F** may be applied to the base portion **132** of the anchor body **130** by a hammer or other blunt instrument (not shown).

[0032] Referring to FIG. **5** and FIG. **7**, the application of the force **F** shifts the pedicle screw assembly **100** from the pre-deployment configuration **150** to a post-deployment configuration **152**. In this post-deployment configuration **152**, the anchor end **142** of the first anchor member **138** is extruded from the first distal opening **116A**, and the anchor end **144** is extruded from the second distal opening **116B** as shown in FIG. **5**, which drives the anchor end **142** and the anchor end **144** into bone tissue as shown in FIG. **7**. In some embodiments, when the pedicle screw **102** includes the stopper **120**, the base portion **132** may contact the stopper **120** and limit the depth to which the first anchor member **138** and the second anchor member **140** can be passed within the first channel **114A** and the second channel **114B** respectively in the direction **D1**. In addition, in some embodiments, an axial gap **154** may be formed around the stopper **120**. In this manner, a pair of pliers, hook, hammer, or other such instrument (not shown) may be engaged to the base portion **132** by maneuvering around the axial gap **154** when the pedicle screw assembly **100** is in the post-deployment configuration **152**, and the bone anchor **104** may be pulled away from the pedicle screw **102** in a direction opposite **D1** (not shown), thereby removing the first anchor member **138** from within the first channel **114A** and removing the second anchor member **140** from within the second channel **114B**. Disengagement of the bone anchor **104** from the pedicle screw **102** in this manner may be advantageous where implementation of the pedicle screw assembly **100** is no longer desired or needs to be removed from the bone tissue for whatever reason.

[0033] Referring to FIGS. **8-14**, a second embodiment of the pedicle screw assembly, designated **200**, is illustrated. As shown in FIGS. **8-11**, the pedicle screw assembly **200** includes a pedicle screw **202** that is configured to be mechanically coupled to a bone anchor **204** in a manner that is suitable for anchoring the pedicle screw **202** to bodily tissue, such as the bone tissue of a vertebra. In some embodiments, the pedicle screw **202** generally includes an elongated screw body **206** defining a distal portion **208** (including a conical tip **218** at the free end thereof) and a proximal portion **210** that defines a pair of proximal openings **212**; including a first proximal opening **212A** and second proximal opening **212B**. As indicated, the first proximal opening **212A** is in communication with a first

channel **214A** formed at least partially along a longitudinal axis **X2** of the pedicle screw **202**, and the second proximal opening **212B** is in communication with a second channel **214B** formed at least partially along the longitudinal axis **X2** of the pedicle screw **202**. In some embodiments as shown, at least a portion of the first channel **214A** is in parallel relation relative to the second channel **214B**. Further, the screw body **206** may define a threaded portion **215** that extends substantially along the length of the screw body **206** configured to accommodate the pedicle screw **202** to engage and be retained within bone tissue.

[0034] Referring to FIG. **10**, along the distal portion **208** of the pedicle screw **202**, the first channel **214A** is in communication with a first distal opening **216A** formed through a first lateral side **217A** of the pedicle screw **202** along the distal portion **208** of the screw body **206**, and the second channel **214B** is in communication with a second distal opening **216B** formed through a second lateral side **217B** of the pedicle screw **202** along the distal portion **208** of the screw body **206**. In some embodiments, the first lateral side **217A** of the pedicle screw **202** is generally defined opposite the second lateral side **217B** of the pedicle screw **202** such that the first distal opening **216A** is formed opposite the second distal opening **216B**, but the present disclosure is not limited in this regard. In addition, as indicated, the first channel **214A** may include a first portion **218A** extending from the proximal portion **210** of the screw body **206**, and a second portion **219A** adjacent the first distal opening **216A**. Similarly, the second channel **214B** may include a first portion **218B** extending from the proximal portion **210** of the screw body **206**, and a second portion **219B** adjacent the second distal opening **216B**. Each of the second portion **219A** and the second portion **219B** may be at least partially non-linear, and may define a curve as shown or a bend away from the longitudinal axis **X2** of the pedicle screw body **206**. In this manner, the first channel **214A** and the second channel **214B** may define a general partial C-shape or arcuate shape configuration, a general partial Y-shape configuration (not shown), or T-shape configuration (not shown). It is contemplated that the first channel **214A** and the second channel **214B** may take on any form so long as the first channel **214A** is in communication with the first distal opening **216A** and the second channel **214B** is in communication with the second distal opening **216B** so that portions of the bone anchor **204** can traverse through the first channel **214A** and portions of the bone anchor **204** can traverse through the second channel **214B**, as further described herein. In some

embodiments, the first distal opening **216A** the second distal opening **216B** may be defined, respectively, directly adjacent the first portion **218A** and the first portion **218B** (not shown), may be defined above the first portion **218A** and the first portion **218B** (not shown), or may be defined below the first portion **218A** and the first portion **218B** as shown in FIG. 10, such that the first distal opening **216A** the second distal opening **216B** are oriented closer to the conical tip **218** of the pedicle screw **202** than the first portion **218A** of the first channel **214A** and the first portion **218B** of the second channel **214B**.

[0035] In addition, the pedicle screw **202** may include a stopper **220** for obstructing the movement of at least a portion of the bone anchor **204** relative to the screw body **206** in order to allow the bone anchor **204** to be removed from the screw body **206**, as further described herein. The stopper **220** may generally define a block or ridge shaped-component formed along the proximal portion **210** of the screw body **206** between the first proximal opening **212A** and the second proximal opening **212B** as shown, and may be formed from rubber, plastic, steel or any biocompatible material. In some embodiments, the stopper **220** may further be removable from the screw body **206** where, e.g., it is desired to permanently engage the bone anchor **204** to the screw body **206** and bone tissue.

[0036] Referring back to FIG. 9, in some embodiments the bone anchor **204** includes an anchor body **230**, defining a proximal portion **231A** and a distal portion **231B**, with the anchor body **230** configured for at least partial insertion within the screw body **206** to engage the pedicle screw **202** to a pedicle or other target site. In some embodiments, the anchor body **230** includes a base portion **232** along the proximal portion **231A** of the anchor body **230**, with the base portion **232** defining a first side **234** and a second side **236** opposite the first side **234** as indicated. The base portion **232** may generally define a cuboidal or cylindrically shaped configuration and may be manufactured in any number of ways sufficient to receive a force (**F** in FIG. 11) for driving the bone anchor **204** partially through the screw body **206**, as further described herein. For example, the base portion **232** may include a handle or thumb print to receive a force applied by a human hand, or may define a rigid surface for receiving a force applied by a blunt instrument such as a hammer.

[0037] As shown, the anchor body **230** may further include a first anchor member **238** extending orthogonally from the first side **234** of the base portion **232** and configured for insertion within the first channel **214A**. Similarly, the

anchor body **230** includes a second anchor member **240** extending orthogonally from the second side **236** of the base portion **232** and configured for insertion within the second channel **214B**. In some embodiments, the first anchor member **238** is in parallel relation relative to the second anchor member **240**, as in the case where at least a portion of the first channel **214A** and the second channel **214B** define a similar parallel configuration, but the present disclosure is not limited in this regard. In general, the first anchor member **238** and the second anchor member **240** define any shape suitable for insertion within the first channel **214A** and the second channel **214B** of the screw body **206**, respectively. For example, the first anchor member **238** and the second anchor member **240** may be generally cylindrical in shape, may define planar plates or tabs, may define spikes, etc., and may be formed with any biocompatible material, one or more metals, plastics, or combinations thereof. In addition, while two anchor members (the first anchor member **238** and the second anchor member **240**) are shown, the anchor body **230** may define a sole anchor member (not shown) for engaging a sole channel of the screw body **206** (not shown) or any number of anchor members as desired (not shown). At least a portion of the anchor body **230**, including e.g., the first anchor member **238** and the second anchor member **240** may be at least partially bendable or flexible to accommodate passage of the first anchor member **238** and the second anchor member **240** at least partially through the first channel **214A** and the second channel **214B**, respectively.

[0038] Referring to FIGS. **8-12** and FIG. **14**, the pedicle screw assembly **200** may further include an anchor end **242** staged within the second portion **219A** of the first channel **214A**, and a second anchor end **244** staged within the second portion **219B** of the second channel **214B**. In this embodiment of the pedicle screw assembly **200**, the anchor end **242** and the anchor end **244** are not formed integrally with the anchor body **130**, but are instead disposed within the first and second channels **214A** and **214B** of the screw body **206** as indicated. The anchor end **242** may be staged just inside the screw body **206** within the second portion **219A** directly adjacent to the distal opening **216A**, and the anchor end **244** may be staged just inside the screw body **206** within the second portion **219B** directly adjacent to the distal opening **216B** as shown in FIG. **10**. As further described herein, when the anchor **204** is engaged to the pedicle screw body **206** (i.e., the first anchor member **238** is driven through the first channel **214A** and the second anchor member **240** is concurrently driven through the second channel

214B), the first anchor member **238** drives the anchor end **242** at least partially through the first distal opening **216A**, and concurrently the second anchor member **240** drives the anchor end **244** at least partially through the second distal opening **216B**. The anchor end **242** and the anchor end **244** may define any number of shapes or configurations, may be cylindrical in shape, may define planar plates or tabs, and/or may define spikes or blades, etc., such that the anchor end **242** and the anchor end **244** can penetrate bone tissue. In some embodiments, the anchor end **242** and the anchor end **244** define a general tapered shape configuration.

[0039] As further indicated in FIG. **10**, the pedicle screw assembly **200** may include a first tether member **245A** and a second tether member **245B**. The first tether member **245A** may be engaged to the anchor end **242** and the screw body **206** within the channel **214A**, and the second tether member **245B** may be engaged to the anchor end **244** and the screw body **206** within the channel **214B**. The first tether member **245A** and the second tether member **245B** may comprise a rubber member or other such flexible component. In use, the first tether member **245A** restricts a predetermined degree of movement of the anchor end **242** relative to the screw body **206** so that the anchor end **242** does not merely fall outside the distal opening **216A** and the first channel **214A**, and the second tether member **245B** restricts a predetermined degree of movement of the anchor end **244** relative to the screw body **206** so that the anchor end **244** does not merely fall outside the distal opening **216B** and the second channel **214B**.

[0040] Referring to FIGS. **11-14**, one method of implanting the pedicle screw assembly **200** is illustrated. As shown in FIG. **13**, the pedicle screw **202** is first engaged into bone tissue, such as a pedicle of the vertebra, such that the proximal portion **210** of the pedicle screw **202** extends from the bone tissue. Once the pedicle screw **202** is implanted into the bone tissue, the first anchor member **238** and the second anchor member **240** of the bone anchor **204** are inserted into the first proximal opening **212A** and the second proximal opening **212B**, respectively, of the pedicle screw **202**, in the manner indicated in FIG. **11** to form a pre-deployment configuration **250** of the pedicle screw assembly **200**. In this manner, the terminal ends of the first anchor member **238** and the second anchor member **240** contact the anchor end **242** and the anchor end **244**, respectively, as shown.

[0041] Once the pre-deployment configuration **250** is formed, and the first anchor member **238** is at least partially received within the first channel **214A** as

indicated, and the second anchor member **240** is at least partially received within the second channel **214B**, a force **F** may be applied as shown to drive the first anchor member **238** against the first anchor end **242** and concurrently drive the second anchor member **240** against the second anchor end **244** in the direction **D1**, thereby causing the anchor end **242** and the anchor end **244** to at least partially extrude through the distal opening **216A** and the distal opening **216B**, respectively. The force **F** may be applied to the base portion **232** of the anchor body **230** by a hammer or other blunt instrument (not shown).

[0042] Referring to FIG. **12** and FIG. **14**, the application of the force **F** shifts the pedicle screw assembly **200** from the pre-deployment configuration **250** to a post-deployment configuration **252**. In this post-deployment configuration **252**, at least a portion of the anchor end **242** is extruded outside the first distal opening **216A**, and at least a portion of the anchor end **244** is extruded outside the second distal opening **216B** as shown in FIG. **12**, which drives the anchor end **242** and the anchor end **244** into bone tissue as shown in FIG. **14**. In some embodiments, when the pedicle screw **202** includes the stopper **220**, the base portion **232** may contact the stopper **220** and limit the depth to which the first anchor member **238** and the second anchor member **240** can traverse the first channel **214A** and the second channel **214B** respectively in the direction **D1**. In addition, in some embodiments, an axial gap **254** may be formed around the stopper **220**. In this manner, a pair of pliers, hook, hammer, or other such instrument (not shown) may be engaged to the base portion **232** by maneuvering around the axial gap **254** when the pedicle screw assembly **200** is in the post-deployment configuration **252**, and the bone anchor **204** may be pulled away from the pedicle screw **202** in a direction opposite **D1** (not shown), thereby removing the first anchor member **238** from within the first channel **214A** and removing the second anchor member **240** from within the second channel **214B**. Disengagement of the bone anchor **204** from the pedicle screw **202** in this manner may be advantageous where, e.g., it is desired to re-use the anchor **204** for other similar applications.

[0043] In some embodiments, the pedicle screw assemblies **100** and **200** are configured to be affixed to the larger vertebrae of the lumbar spine, or the smaller vertebrae of the thoracic or cervical spine.

[0044] In some embodiments, the pedicle screw assemblies **100** and **200** may be made from a metal, such as titanium, or a metal-based alloy, such as

titanium-based alloy. Alternatively, the pedicle screw assemblies **100** and **200** may comprise a reinforced polymer material. In some embodiments, the material used to manufacture the pedicle screw assemblies **100** and **200** can have a high bioactivity and high flexibility, and as a result, can improve ingrowth and mechanical fixation.

[0045] In some embodiments, the pedicle screws **102** and **202** may be engaged to a tulip structure (not shown) which is configured to interface with a longitudinal bar or a plate. In some embodiments, the tulip structure can be flexibly coupled to the pedicle screws **102** and **202** by way of a ball-joint or other type of flexible joint such that the pedicle screw assemblies **100** and **200** can account for any bending of the individual's spine while still exerting an axial force on the longitudinal bar, thereby stabilizing the spine of the individual.

[0046] It should be understood from the foregoing that, while particular embodiments have been illustrated and described, various modifications can be made thereto without departing from the spirit and scope of the invention as will be apparent to those skilled in the art. Such changes and modifications are within the scope and teachings of this invention as defined in the claims appended hereto.

CLAIMS

What is claimed is:

1. A pedicle screw assembly, comprising:
 - a pedicle screw, comprising
 - a screw body defining a proximal portion and a distal portion,
 - a first channel and a second channel defined within the screw body,
 - a first opening defined along a first lateral side of the screw body and in communication with the first channel,
 - a second opening defined along a second lateral side of the screw body and in communication with the second channel; and
 - an anchor defining an anchor body configured for being partially disposed within the screw body to engage the pedicle screw to a surgical site, the anchor body comprising:
 - a base portion defining a first side and a second side opposite the first side,
 - a first anchor member extending orthogonally from the first side of the base portion and configured for insertion within the first channel of the pedicle screw, and
 - a second anchor member extending orthogonally from the second side of the base portion and configured for insertion within the second channel of the pedicle screw.
2. The pedicle screw assembly of claim 1, wherein a portion of the first channel and a portion of the second channel is curved away from a longitudinal axis of the screw body.

3. The pedicle screw assembly of claim 1, further comprising:
 - a first anchor end oriented along the first anchor member, and
 - a second anchor end oriented along the second anchor member, the first anchor end and the second anchor end being configured for penetrating bone tissue.
4. The pedicle screw assembly of claim 3, wherein the first anchor end and the second anchor end are integral with the anchor body.
5. The pedicle screw assembly of claim 3, wherein the first anchor end and the second anchor end are separate from the anchor body, and engage the first anchor member and the second anchor member respectively as the first anchor member and the second anchor member are inserted within the first channel and the second channel.
6. The pedicle screw assembly of claim 1, wherein at least a portion of the first anchor member and at least a portion of the second anchor member is flexible such that the first anchor member and the second anchor member are flexible relative to the base portion to accommodate passage of the first anchor member and the second anchor member through the first channel and the second channel, respectively.
7. The pedicle screw assembly of claim 1, wherein the first channel includes a first portion aligned along a longitudinal axis of the screw body, and a second portion extending away from the first portion and the longitudinal axis of the screw body.
8. The pedicle screw assembly of claim 1, further comprising:
 - a first anchor end staged within the first channel; and
 - a second anchor end staged within the second channel,wherein the anchor is configured to drive the first anchor end partially through the first opening and further configured to drive the second anchor end partially through the second opening.

9. The pedicle screw assembly of claim 8, further comprising:
a tether member coupling the first anchor end to the screw body that
limits movement of the first anchor end relative to the screw
body.

1/8

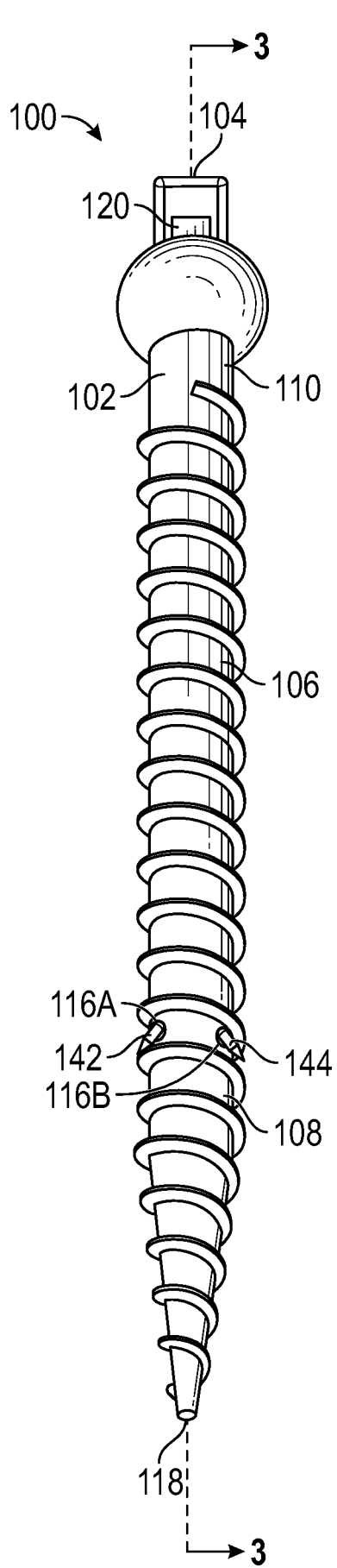


FIG. 1

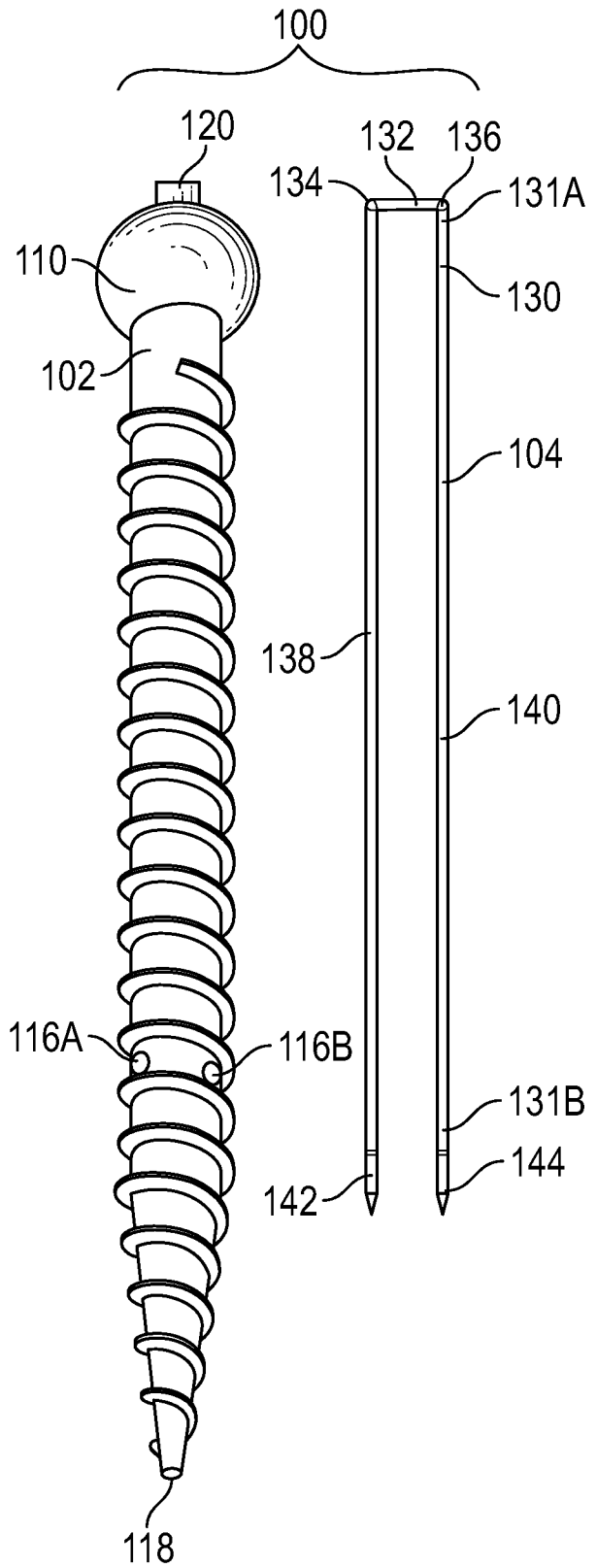


FIG. 2

2/8

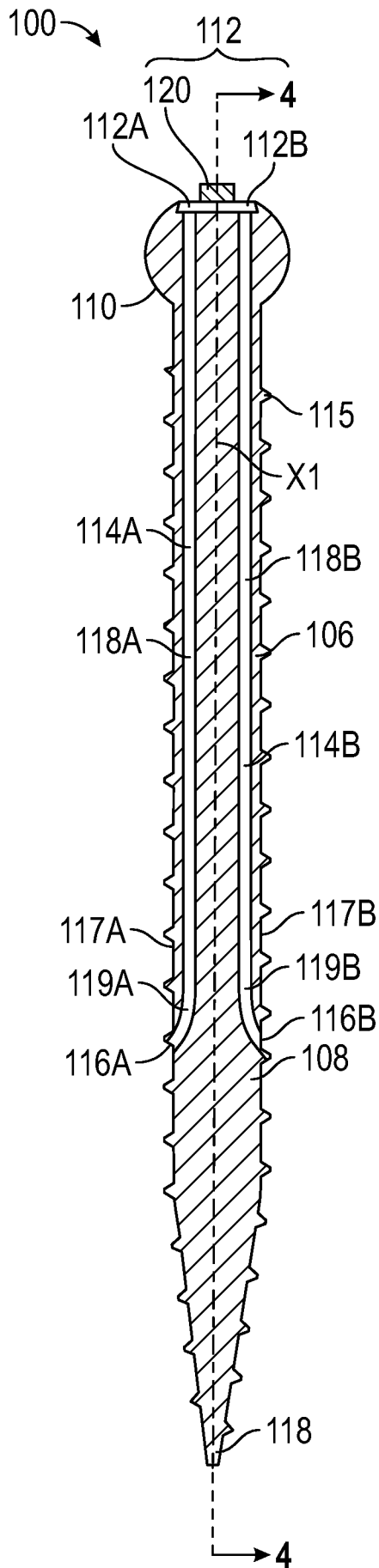


FIG. 3

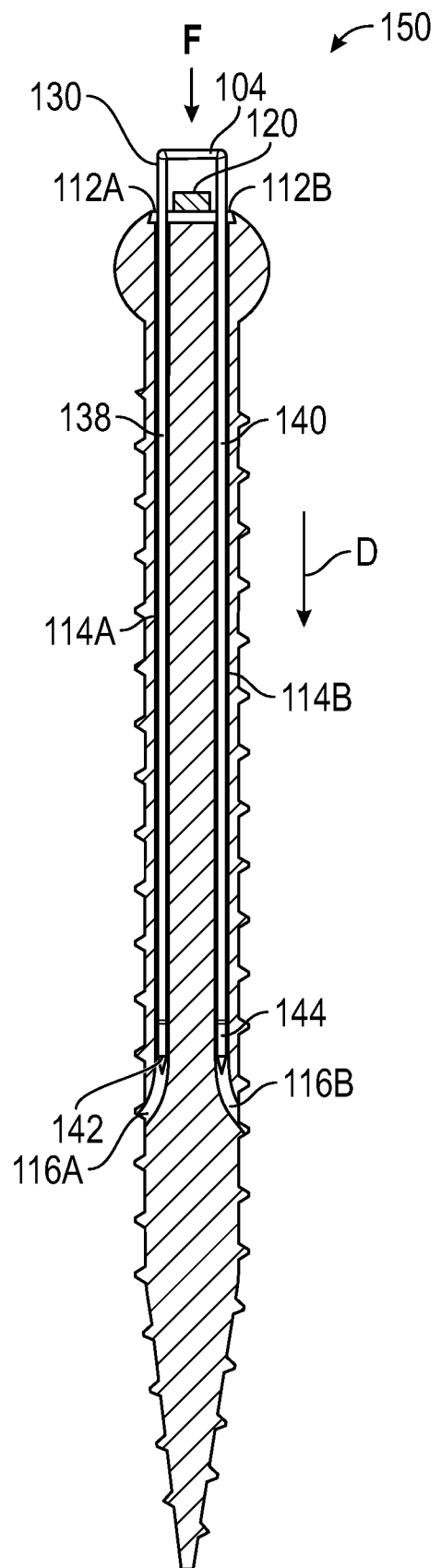


FIG. 4

3/8

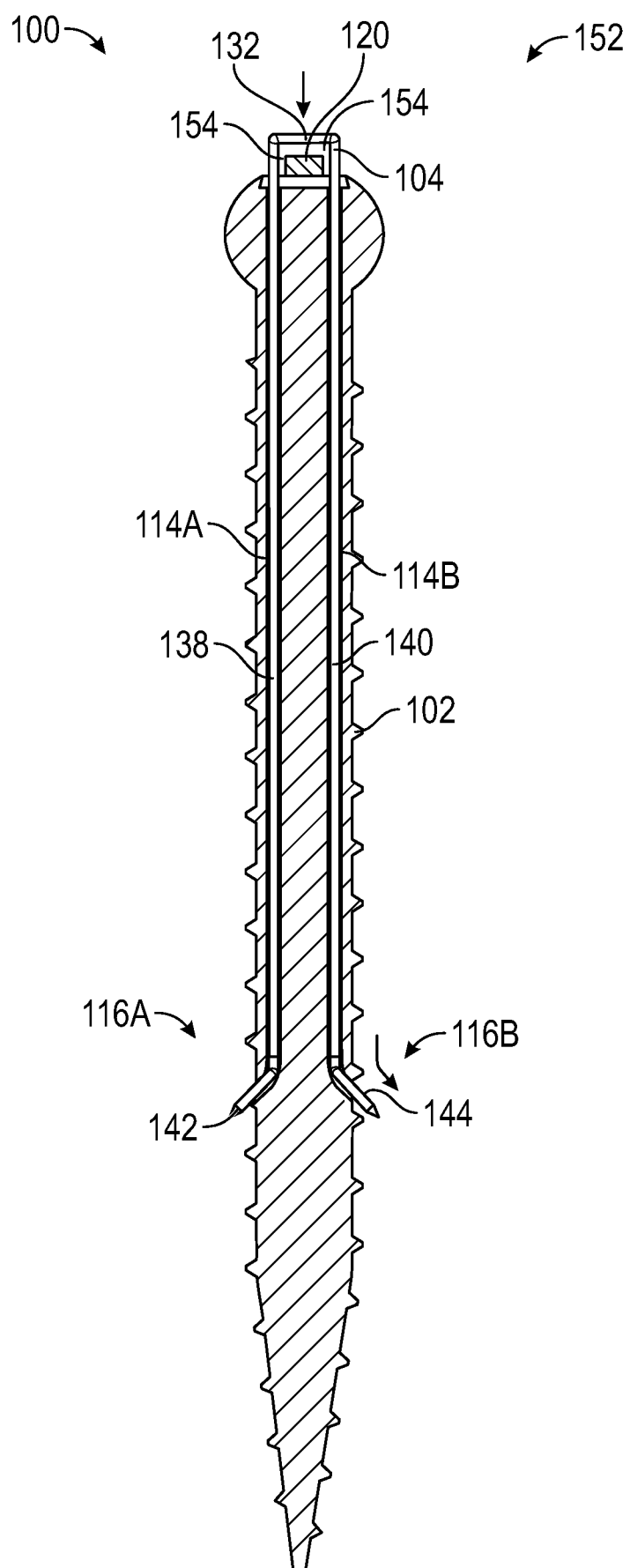


FIG. 5

4/8

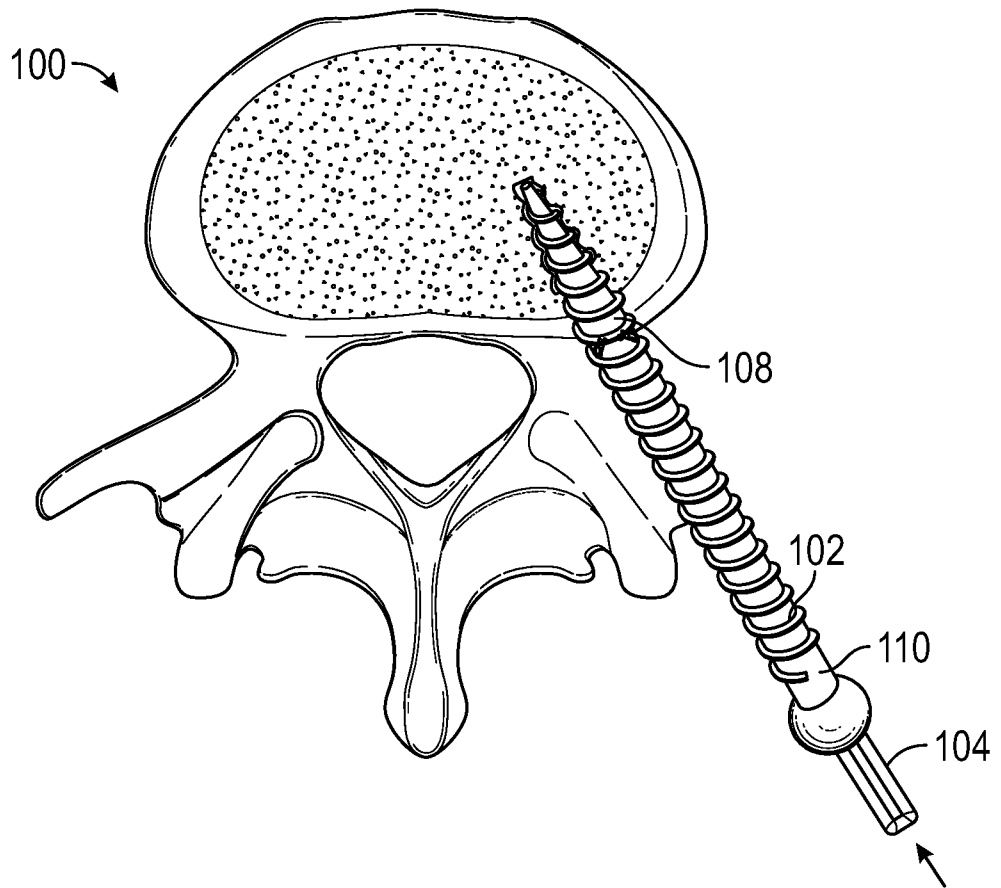


FIG. 6

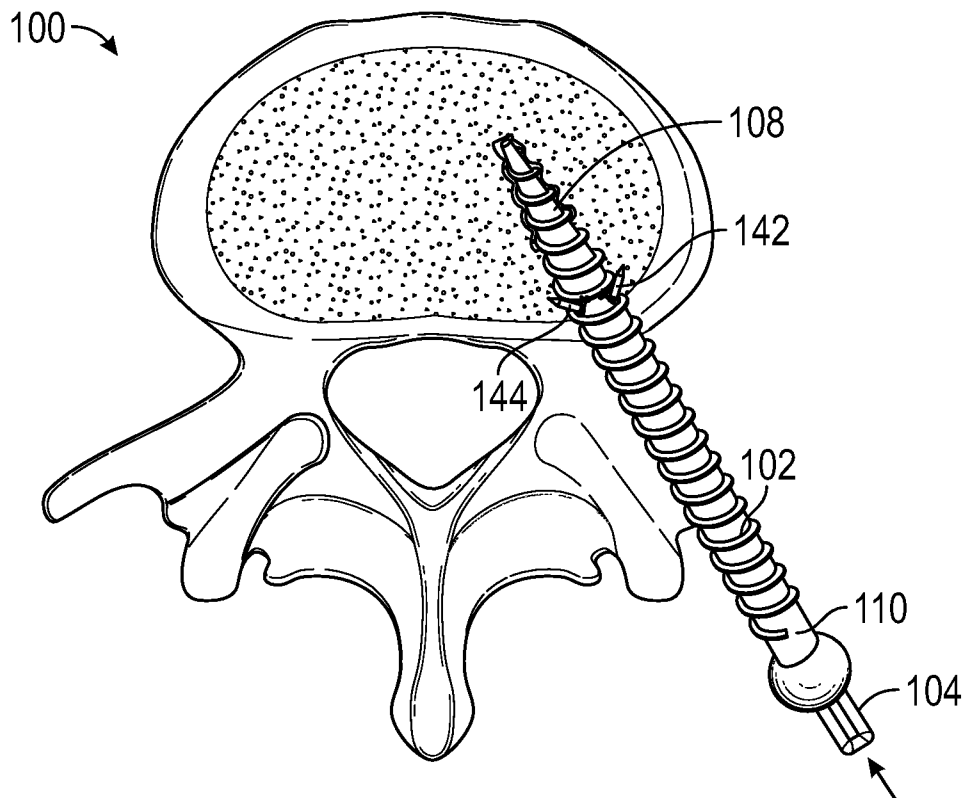
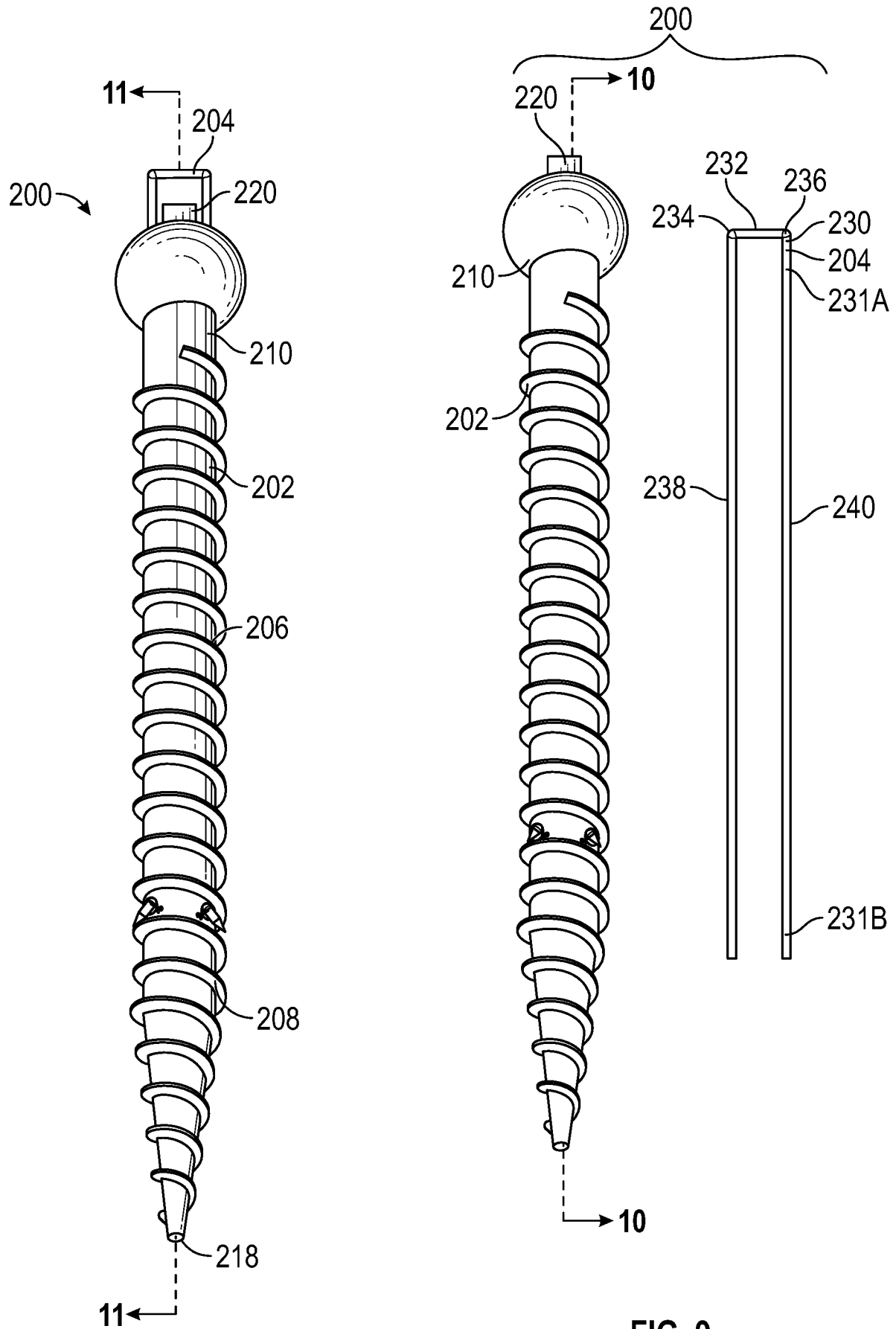


FIG. 7

5/8



6/8

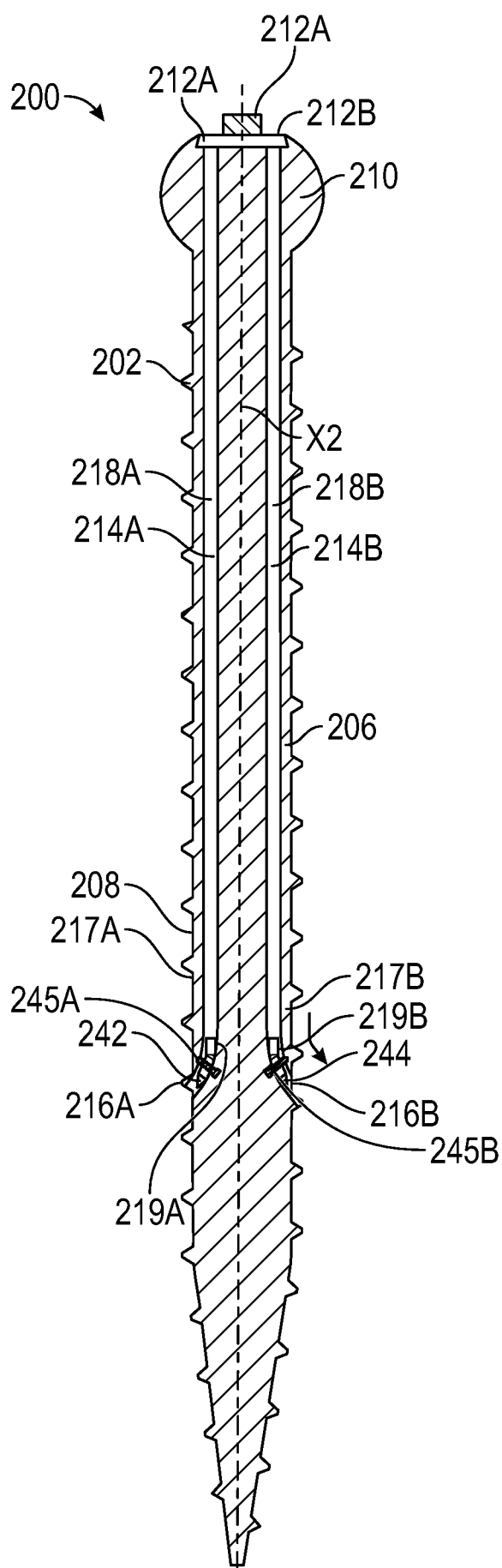


FIG. 10

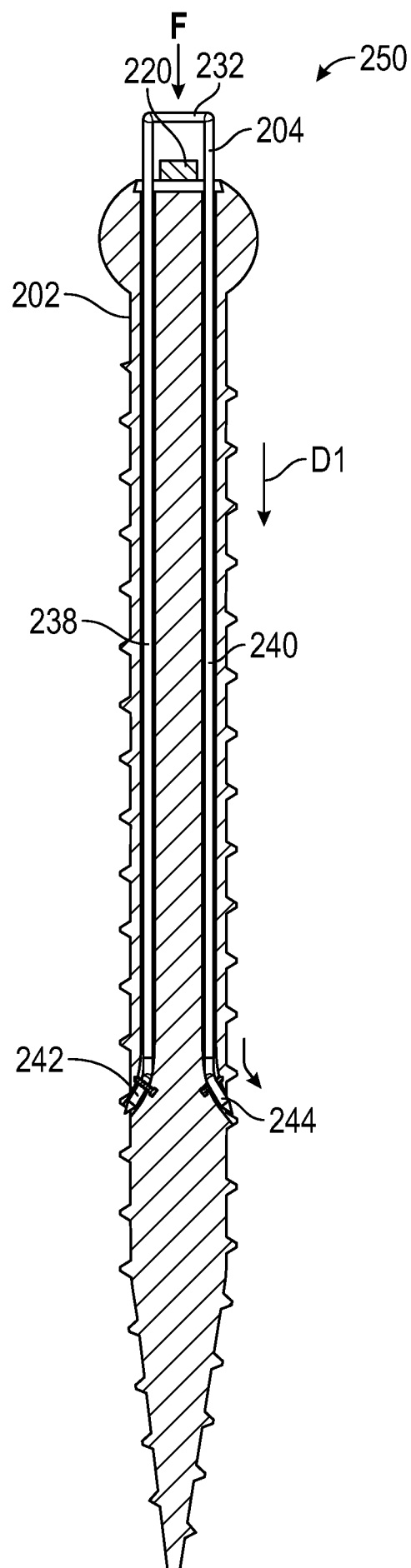


FIG. 11

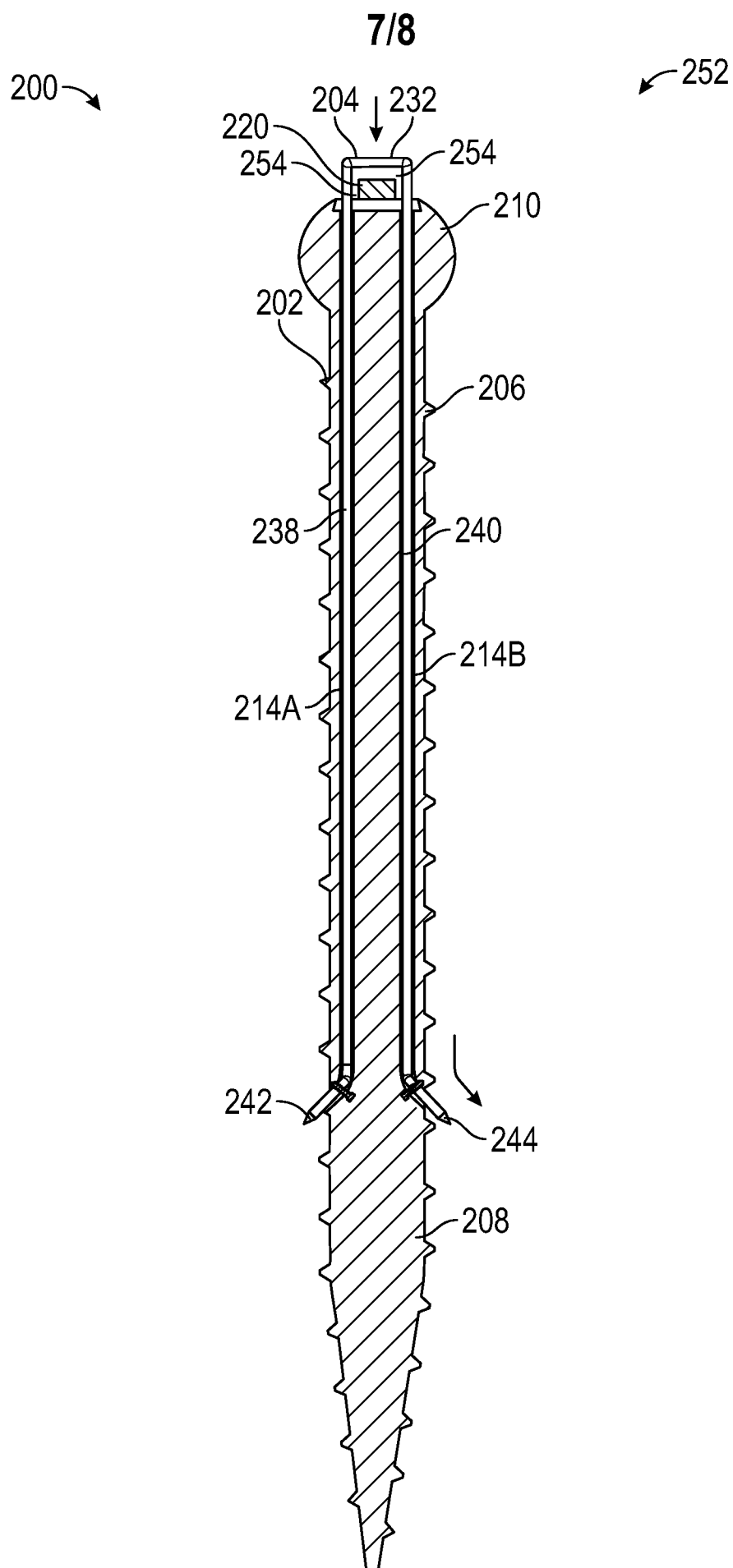


FIG. 12

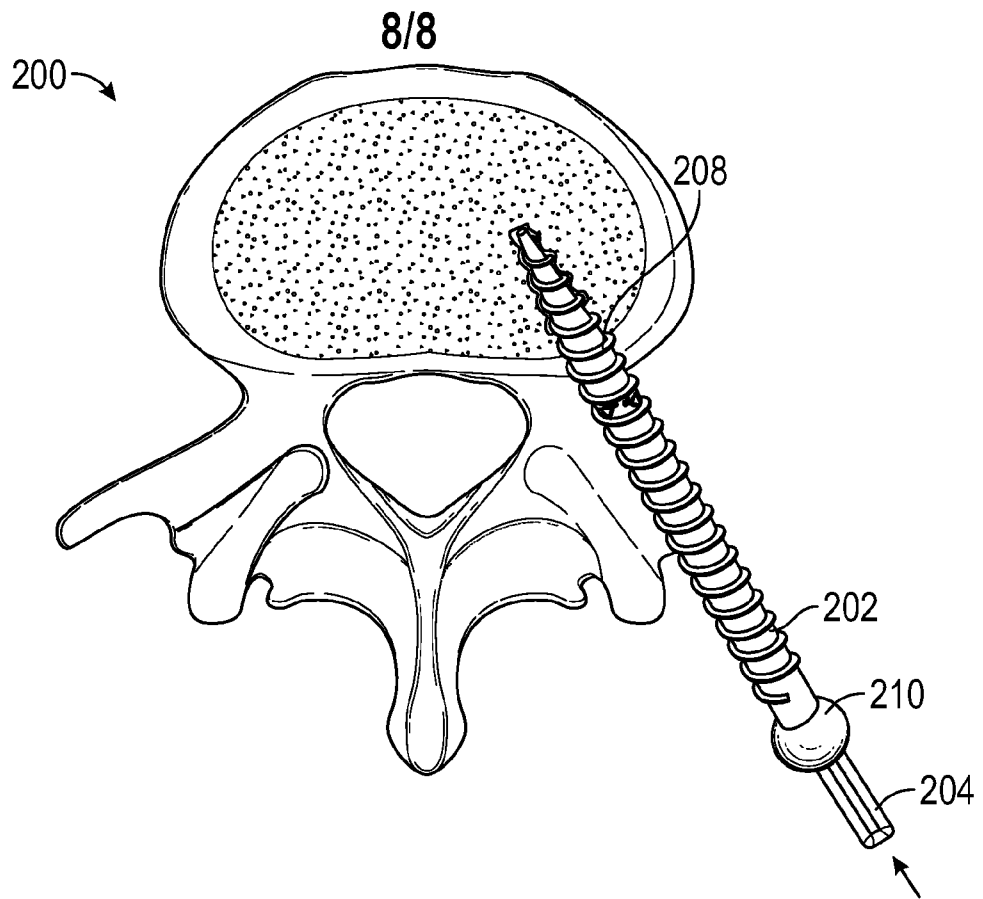


FIG. 13

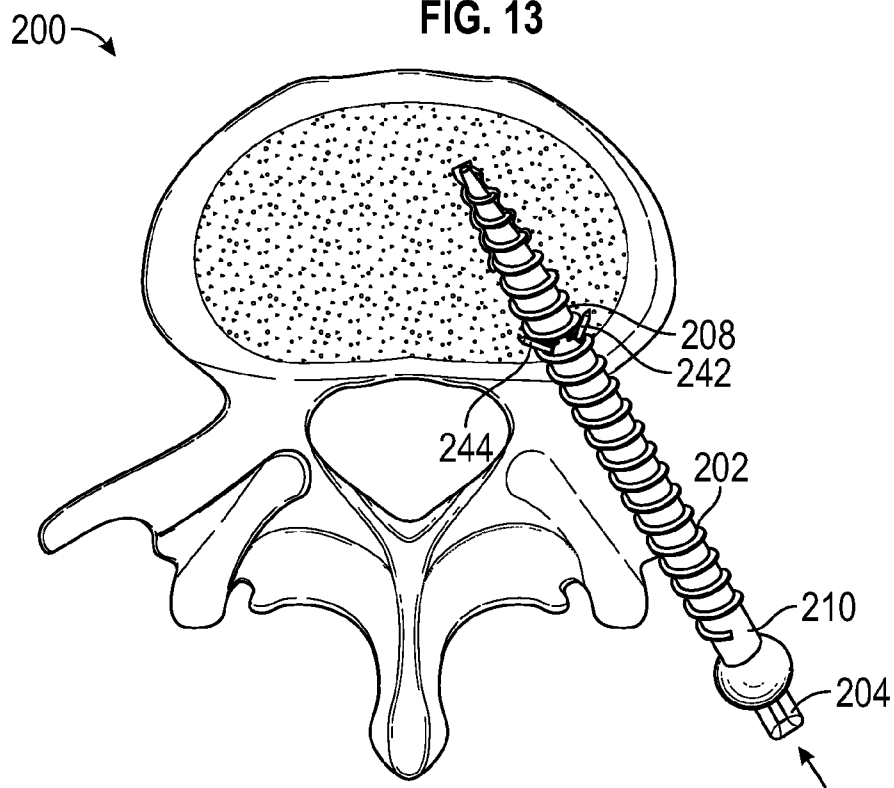


FIG. 14

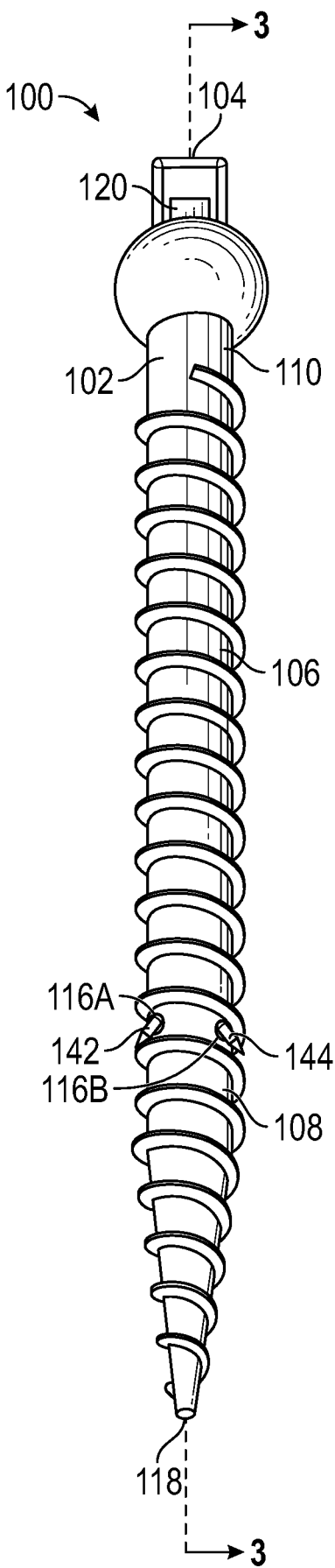


FIG. 1