



(51) International Patent Classification:

A61B 17/68 (2006.01) A61F 2/32 (2006.01)  
A61B 17/86 (2006.01)

(21) International Application Number:

PCT/US2014/048990

(22) International Filing Date:

31 July 2014 (31.07.2014)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

|            |                               |    |
|------------|-------------------------------|----|
| 61/860,185 | 30 July 2013 (30.07.2013)     | US |
| 61/914,409 | 11 December 2013 (11.12.2013) | US |
| 61/955,126 | 18 March 2014 (18.03.2014)    | US |
| 61/979,857 | 15 April 2014 (15.04.2014)    | US |

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, 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,

[Continued on next page]

(54) Title: SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT

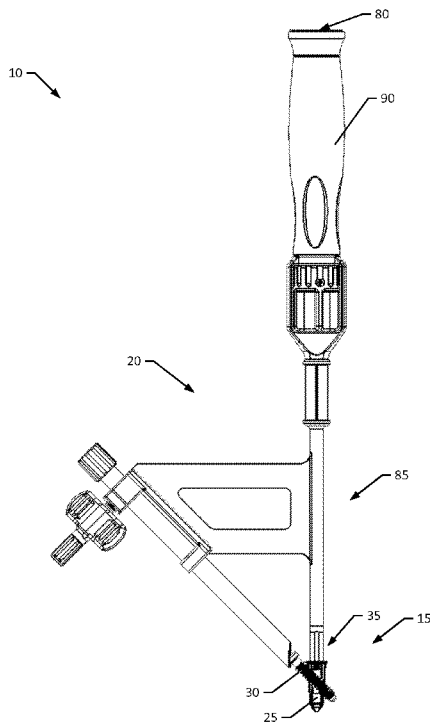


FIG. 1

(57) Abstract: A sacroiliac joint fusion system including a joint implant, an anchor element and delivery tool. The joint implant includes a bore extending non-parallel to the implant longitudinal axis. The anchor element is for receiving in the bore. The delivery tool includes an implant arm and anchor arm. The implant arm distal end is releasably coupled to the joint implant proximal end so the implant arm longitudinal axis is coaxial or parallel with the implant body longitudinal axis. An anchor arm distal end is engaged to the anchor element proximal end. The anchor arm is coupled to the implant arm such that the anchor element longitudinal axis is coaxially aligned with the bore longitudinal axis when the implant arm distal end is releasably coupled with the implant proximal end and the anchor arm distal end is engaged with the anchor element proximal end.

WO 2015/017593 A1



TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**(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, 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,

**Published:**

- *with international search report (Art. 21(3))*
- *with information concerning request for restoration of the right of priority in respect of one or more priority claims (Rules 26bis.3 and 48.2(b)(vii))*

**SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT****CROSS-REFERENCE TO RELATED APPLICATIONS**

**[0001]** The present application relates to U.S. Provisional Patent Application 61/914,409, which was filed December 11, 2013, entitled "SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT," and is hereby incorporated by reference in its entirety into the present application.

**[0002]** The present application also relates to U.S. Provisional Patent Application 61/860,185, which was filed July 30, 2013, entitled "SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT," and is hereby incorporated by reference in its entirety into the present application.

**[0003]** The present application also relates to U.S. Provisional Patent Application 61/955,126, which was filed March 18, 2014, entitled "SACROILIAC JOINT IMPLANT," and is hereby incorporated by reference in its entirety into the present application.

**[0004]** The present application also relates to U.S. Provisional Patent Application 61/979,857, which was filed April 15, 2014, entitled "SACROILIAC JOINT IMPLANT," and is hereby incorporated by reference in its entirety into the present application.

**FIELD OF THE INVENTION**

**[0005]** Aspects of the present invention relate to medical systems, devices, and methods for treating a sacroiliac joint. In particular, aspects of the present disclosure relate to systems, devices, and methods involving a sacroiliac joint implant for non-transverse placement between articular surfaces of a sacroiliac joint to dispose a sacrum and an ilium in a substantially immobilized relation.

**BACKGROUND OF THE INVENTION**

**[0006]** The sacroiliac joint is the joint between the sacrum and the ilium of the pelvis, which are joined by ligaments. In humans, the sacrum supports the spine and is supported in turn by an ilium on each side. The sacroiliac joint is a synovial joint with articular cartilage and irregular elevations and depressions that produce interlocking of the two bones.

**[0007]** Pain associated with the sacroiliac joint can be caused by traumatic fracture dislocation of the pelvis, degenerative arthritis, sacroiliitis, an inflammation or degenerative condition of the sacroiliac joint, osteitis condensans ilii, or other degenerative conditions of the sacroiliac joint. Currently, sacroiliac joint fusion is most commonly advocated as a surgical treatment for these conditions. Fusion of the sacroiliac joint can be accomplished by several different conventional methods encompassing an anterior approach, a posterior approach, and a lateral approach with or without percutaneous screw or other type implant fixation. However, while each of these methods has been utilized for fixation and fusion of the sacroiliac joint over the past several decades, substantial problems with respect to the fixation and fusion of the sacroiliac joint remain unresolved.

**[0008]** A significant problem with certain conventional methods for fixation and fusion of the sacroiliac joint including the anterior approach, posterior approach, or lateral approach may be that the surgeon has to make a substantial incision in the skin and tissues for direct access to the sacroiliac joint involved. These invasive approaches allow the sacroiliac joint to be seen and touched directly by the surgeon. Often referred to as an "open surgery", these procedures have the attendant disadvantages of requiring general anesthesia and can involve increased operative time, hospitalization, pain, and recovery time due to the extensive soft tissue damage resulting from the open surgery.

**[0009]** A danger to open surgery using the anterior approach can be damage to the L5 nerve root, which lies approximately two centimeters medial to the sacroiliac joint or damage to the major blood vessels. Additionally, these procedures typically involve fixation of the sacroiliac joint (immobilization of the articular surfaces of the sacroiliac joint

in relation to one another) by placement of one or more screws or one or more trans-sacroiliac implants or by placement of implants into the S1 pedicle and iliac bone.

**[0010]** Use of trans-sacroiliac and S1 pedicle-iliac bone implants can also involve the risk of damage to the lumbosacral neurovascular elements. Damage to the lumbosacral neurovascular elements as well as delayed union or non-union of the sacroiliac joint by use of these procedures may require revision surgery to remove all or a portion of the implants or repeat surgery as to these complications.

**[0011]** Another significant problem with conventional procedures utilizing minimally invasive small opening procedures can be that the procedures are technically difficult, requiring biplanar fluoroscopy of the articular surfaces of the sacroiliac joint and extensive surgical training and experience. Despite the level of surgical training and experience, there is a substantial incidence of damage to the lumbosacral neurovascular elements. Additionally, sacral anomalies can further lead to mal-placement of implants leading to damage of surrounding structures. Additionally, these procedures are often performed without fusion of the sacroiliac joint, which does not remove the degenerative joint surface and thereby does not address the degenerative condition of the sacroiliac joint, which may lead to continued or recurrent sacroiliac joint pain.

**[0012]** Another significant problem with conventional procedures can be the utilization of multiple trans-sacroiliac elongate implants, which do not include a threaded surface. This approach requires the creation of trans-sacroiliac bores in the pelvis and nearby sacral foramen, which can be of relatively large dimension and which are subsequently broached with instruments, which can result in bone being impacted into the pelvis and neuroforamen.

**[0013]** The creation of the trans-sacroiliac bores and subsequent broaching of the bores requires a guide pin, which may be inadvertently advanced into the pelvis or sacral foramen, resulting in damage to other structures. Additionally, producing the trans-sacroiliac bores, broaching, or placement of the elongate implants may result in damage to the lumbosacral neurovascular elements, as above discussed. Additionally,

there may be no actual fusion of the articular portion of the sacroiliac joint, which may result in continued or recurrent pain requiring additional surgery.

**[0014]** Another substantial problem with conventional procedures can be that placement of posterior extra-articular distracting fusion implants and bone grafts may be inadequate with respect to removal of the articular surface or preparation of cortical bone, the implant structure and fixation of the sacroiliac joint. The conventional procedures may not remove sufficient amounts of the articular surfaces or cortical surfaces of the sacroiliac joint to relieve pain in the sacroiliac joint. The conventional implant structures may have insufficient or avoid engagement with the articular surfaces or cortical bone of the sacroiliac joint for adequate fixation or fusion. The failure to sufficiently stabilize and fuse the sacroiliac joint with the conventional implant structures and methods may result in a failure to relieve the condition of sacroiliac joint being treated. Additionally, conventional methods of driving apart a sacrum and ilium may lead to mal-alignment of the sacroiliac joint and increased pain.

**[0015]** The inventive sacroiliac fusion system described herein addresses the problems associated with conventional methods and apparatuses used in fixation and fusion of the sacroiliac joint.

#### **BRIEF SUMMARY OF THE INVENTION**

**[0016]** 1. An implant assembly for the fusion of a sacroiliac joint of a subject, the implant assembly comprising:

**[0017]** a) an implant comprising:

**[0018]** an intraarticular element extending an implant length between an implant proximal end and an implant distal end, and further extending an implant height between an implant upper edge and an opposed implant lower edge, the intraarticular element comprising:

**[0019]** a first articular face and an opposed second articular face

extending the implant height and at least a portion of the implant length;

**[0020]** a graft window formed within at least a portion of the intraarticular element and extending through the intraarticular element from the first articular face to the second articular face; and

**[0021]** at least one keel attached to the intraarticular element along at least a portion of the implant length; and

**[0022]** b) an anchor comprising a proximal anchor end and a distal anchor end, wherein the proximal anchor end and the distal anchor end are positioned on opposite sides of a plane coincident with the first articular face or coincident with the second articular face;

**[0023]** wherein the intraarticular element is configured for implantation within a joint space of the sacroiliac joint with the first and second articular faces contacting articular surfaces of the sacroiliac joint, and the anchor is configured for insertion transversely across the joint space of the sacroiliac joint.

**[0024]** 2. The implant assembly of claim 1, wherein each keel of the at least one keels projects essentially perpendicularly outward from the first articular face and from the second articular face, ending in a first edge and a opposite second edge separated by a keel width.

**[0025]** 3. The implant assembly of claim 2, wherein the first edge and the second edge are in parallel alignment along the implant length.

**[0026]** 4. The implant assembly of claim 2, wherein the first edge and the second edge distally converge toward one another.

**[0027]** 5. The implant assembly of claim 4, wherein the at least one keel comprises a first keel extending from the implant proximal end to the implant distal end, wherein the first keel is attached along the implant upper edge or the implant lower edge.

**[0028]** 6. The implant assembly of claim 5, wherein the at least one keel further

comprises a second keel extending from the implant proximal end to the implant distal end, wherein the second keel is attached along the implant upper edge or the implant lower edge opposite to the first keel.

**[0029]** 7. The implant assembly of claim 6, wherein the keel width of the first keel is equal to the keel width of the second keel.

**[0030]** 8. The implant assembly of claim 6, wherein the keel width of the first keel is larger than the keel width of the second keel.

**[0031]** 9. The implant assembly of claim 1, wherein the at least one keel comprises a first keel extending from the implant proximal end to the implant distal end, wherein the first keel is attached to the intraarticular element between the implant upper edge and the implant lower edge.

**[0032]** 10. The implant assembly of claim 7, wherein the first keel further comprises a keel gap extending over an intersection of the first keel with the graft window.

**[0033]** 11. The implant assembly of claim 1, wherein the graft window extends through the intraarticular element along a window axis forming an angle ranging from about 45 degrees to about 90 degrees relative to a plane parallel to the first articular face or the second articular face.

**[0034]** 12. The implant assembly of claim 1, wherein the graft window further comprises a window length extending along a portion of the implant length, the portion ranging from about 40% to about 70% of the implant length.

**[0035]** 13. The implant assembly of claim 1, wherein the window length is situated between the implant proximal end and the implant distal end.

**[0036]** 14. The implant assembly of claim 1, wherein one end of the window length is coincident with the implant distal end.

**[0037]** 15. The implant assembly of claim 1, wherein the anchor passes through the graft window.



**[0038]** 16. The implant assembly of claim 1, wherein the anchor passes outside of the implant above the upper edge or below the lower edge.

**[0039]** 17. The implant assembly of claim 1, wherein the intraarticular element further comprises:

**[0040]** a proximal face situated at the implant proximal end; and

**[0041]** a threaded bore extending from the proximal face along the implant length toward the implant distal end and opening distally into the graft window.

**[0042]** 18. The implant assembly of claim 1, wherein the at least one keel and the intraarticular element taper distally into a distal edge situated at the implant distal end.

**[0043]** 19. The implant assembly of claim 1, wherein the implant length ranges from about 20 mm to about 50 mm.

**[0044]** 20. The implant assembly of claim 1, wherein the implant height ranges from about 10 mm to about 20 mm.

**[0045]** 21. The implant assembly of claim 1, wherein an intraarticular thickness between the first articular face and the second articular face ranges from about 5 mm to about 7 mm.

**[0046]** 22. The implant assembly of claim 2, wherein the keel width ranges from about 10 mm to about 20 mm.

**[0047]** 23. A sacroiliac joint fusion system comprising:

**[0048]** a) a joint implant comprising: a longitudinal axis extending between a proximal end and a distal end of the joint implant; and a first bore extending non-parallel to the longitudinal axis;

**[0049]** b) an anchor element configured to be received in the first bore; and

**[0050]** c) a delivery tool comprising:

**[0051]** i) an implant arm comprising a shaft extending between a proximal end and a distal end of the implant arm and a handle at the proximal end, the distal end of the implant arm configured to releasably couple to the proximal end of the joint implant; and

**[0052]** ii) an anchor arm rotatably coupled to the implant arm at a first end and comprising an anchoring guide at a second end that is configured to align the anchor element in a trajectory such that the anchor element will be received within the first bore when the anchor element is guided by the anchoring guide, wherein relative rotation of the anchor arm about a longitudinal axis of the implant arm is limited to trajectories of the anchor element that are configured to align the anchor element within the first bore,

**[0053]** wherein a final manufactured configuration of the delivery tool and the joint implant are such that, when the system is assembled such that the implant arm is releasably coupled to the joint implant, a delivery arrangement automatically exists such that the anchor arm is oriented to align the trajectory of the anchor element and to deliver the anchor element within the first bore.

**[0054]** 24. The system of claim 23, wherein rotation of the anchor arm relative to the implant arm is limited to about 60 degrees of rotation.

**[0055]** 25. The system of claim 24, wherein the first bore extends through a pair of planar faces that are opposite of each other, the pair of planar faces defining a first plane therein that also extends in a direction of the longitudinal axis of the joint implant, the first plane being substantially perpendicular to a second plane defined by the implant arm and the anchor arm in a neutral position, the neutral position orienting the anchor element substantially perpendicularly to the first plane.

**[0056]** 26. The system of claim 25, wherein the about 60 degrees of rotation includes about 30 degrees of rotation of the second plane relative to the first plane on either side of the neutral position.

**[0057]** 27. The system of claim 23, wherein the rotation of the anchor arm relative to the implant arm is limited to less than 360 degrees of rotation.

**[0058]** 28. The system of claim 23, wherein the rotation of the anchor arm relative to the implant arm is limited to less than 180 degrees of rotation.

**[0059]** 29. The system of claim 23, wherein the relative rotation of the anchor arm about a longitudinal axis of the implant arm is limited by a cam mechanism within a channel.

**[0060]** 30. The system of claim 29, wherein the implant arm includes the cam mechanism and the anchor arm includes the channel, wherein the cam mechanism includes a cam-shape that is configured to only partially rotate within the channel.

**[0061]** 31. The system of claim 29, wherein the cam mechanism is slidably coupled within the channel.

**[0062]** 32. A sacroiliac joint fusion system comprising:

**[0063]** a) a joint implant comprising: a longitudinal axis extending between a proximal end and a distal end of the joint implant; and a first bore extending non-parallel to the longitudinal axis;

**[0064]** b) an anchor element configured to be received in the first bore; and

**[0065]** c) a delivery tool comprising:

**[0066]** i) an implant arm comprising a shaft extending between a proximal end and a distal end of the implant arm and a handle at the proximal end, the distal end of the implant arm configured to releasably couple to the proximal end of the joint implant; and

**[0067]** ii) an anchor arm comprising an anchor guide coupled to the implant arm via a distal articulating member and a proximal articulating member, the distal articulating member rotatably coupled with implant arm at a first end and rotatably coupled with the anchor guide at a second end, the proximal articulating member slidably coupled with the implant arm at a third end and configured to slidably translate distal-proximal along the shaft of the implant arm, the proximal articulating member

rotatably coupled with anchor guide at a fourth end, the anchor guide configured to align the anchor element in a trajectory such that the anchor element will be received within the first bore when the anchor element is guided by the anchor guide,

**[0068]** wherein, when the third end of the proximal articulating member is positioned in a proximal-most position, the anchor guide is configured to align the anchor element in the trajectory, and when the third end of the proximal articulating member is positioned in a distal-most position, the anchor guide is configured to align the anchor element in the trajectory.

**[0069]** 33. The system of claim 32, wherein a final manufactured configuration of the delivery tool and the joint implant are such that, when the system is assembled such that the implant arm is releasably coupled to the joint implant, a delivery arrangement automatically exists such that the anchor arm is oriented to align the trajectory of the anchor element and to deliver the anchor element within the first bore.

**[0070]** 34. The system of claim 32, wherein the first end is positioned distally of the third end on the implant arm.

**[0071]** 35. The system of claim 34, wherein the second end is positioned distally of the fourth end on the anchor guide.

**[0072]** 36. The system of claim 32, wherein the implant arm further comprises an actuation assembly that is configured to releasably couple and decouple with the joint implant.

**[0073]** 37. The system of claim 32, wherein the actuation assembly is rotationally actuated.

**[0074]** 38. The system of claim 32, wherein an angle of the trajectory relative to the longitudinal axis of the joint implant is different when the third end is in the proximal-most position and the distal-most position.

**[0075]** 39. The system of claim 32, wherein, when the third end is in the proximal-most position, an angle between the trajectory and a longitudinal axis of the

shaft of the implant arm is about 34 degrees.

**[0076]** 40. The system of claim 32, wherein, when the third end is in the distal-most position, an angle between the trajectory and a longitudinal axis of the shaft of the implant arm is about 45 degrees.

**[0077]** 41. The system of claim 32, wherein the first end of the distal articulating member includes a stop feature that inhibits rotation of the first end beyond a certain point.

**[0078]** 42. The system of claim 41, wherein the stop feature is configured to contact the shaft of the implant arm when the third end of the proximal articulating member is in the proximal-most position.

**[0079]** 43. A sacroiliac joint fusion system comprising:

**[0080]** a) a joint implant comprising: a longitudinal axis extending between a proximal end and a distal end of the joint implant; and a first bore extending non-parallel to the longitudinal axis;

**[0081]** b) an anchor element configured to be received in the first bore; and

**[0082]** c) a delivery tool comprising:

**[0083]** i) an implant arm comprising a shaft extending between a proximal end and a distal end of the implant arm and a handle at the proximal end, the distal end of the implant arm configured to releasably couple to the proximal end of the joint implant; and

**[0084]** ii) an anchor arm rotatably coupled to the implant arm via a rotatable joint at a first end and comprising an anchoring guide at a second end that is configured to align the anchor element in a first trajectory such that the anchor element will be received within the first bore when the anchor element is guided by the anchoring guide, wherein the rotatable joint is configured to limit rotation of the anchor arm to predefined trajectories of the anchor element that are configured to align the anchor element within the first bore,

**[0085]** wherein a final manufactured configuration of the delivery tool and the joint implant are such that, when the system is assembled such that the implant arm is releasably coupled to the joint implant, a delivery arrangement automatically exists such that the anchor arm is oriented to align the first trajectory of the anchor element and to deliver the anchor element within the first bore.

**[0086]** 44. The system of claim 43, wherein a first angle is defined between the shaft of the implant arm and the anchor arm, wherein rotation of the anchor arm relative to the implant arm is limited to varying of only the first angle.

**[0087]** 45. The system of claim 43, wherein a relative decrease of the first angle causes the anchor element to angle towards a proximal portion of the first bore and wherein a relative increase in the first angle causes the anchor element to angle towards a distal portion of the first bore.

**[0088]** 46. The system of claim 43, wherein rotation of the anchor arm is limited to rotation about a longitudinal axis of the implant arm.

**[0089]** 47. The system of 43, wherein the anchoring guide comprises a plurality of laterally offset guides, each of the plurality of laterally offset guides configured to align a unique trajectory of an anchoring element.

**[0090]** 48. The system of claim 47, wherein the plurality of laterally offset guides comprises a first, a second, and a third guide, the first guide aligning a trajectory of a first anchoring element dorsal to the joint implant, the second guide aligning a trajectory of a second anchoring element within the first bore, the third guide aligning a trajectory of a third anchoring element ventral to the joint implant.

**[0091]** 49. The system of claim 43, further comprising an auxiliary guide arm rotatably coupled to the implant arm at a third end and comprising an auxiliary guide at a fourth end that is configured to align an auxiliary element in a second trajectory such that the auxiliary element will be delivered along the second trajectory when guided by the auxiliary guide, the auxiliary guide arm configured to adjust in at least one degree of freedom.

**[0092]** 50. The system of claim 49, wherein the auxiliary element is a needle.

**[0093]** 51. The system of claim 43, wherein the joint implant defines an I-beam shaped cross-section having a top keel, a bottom keel, and an intraarticular element extending between and coupling the top keel and the bottom keel, the first bore extending through the intraarticular element.

**[0094]** 52. A method of sacroiliac joint fusion, the method comprising:

**[0095]** a) approaching a sacroiliac joint space with a joint implant comprising: a longitudinal axis extending between a proximal end and a distal end; an intraarticular element extending between and coupling a first keel and a second keel; and a first bore extending between opposite faces of the intraarticular element, the intraarticular element, the first, and the second keel extending from the proximal end to the distal end;

**[0096]** b) delivering the joint implant into the sacroiliac joint space, the joint implant being oriented in the sacroiliac joint space such that the intraarticular element is generally coplanar with a plane defined by the sacroiliac joint space. While multiple embodiments are disclosed, still other embodiments of the present disclosure will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the disclosure. As will be realized, the invention is capable of modifications in various aspects, all without departing from the spirit and scope of the present disclosure. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0097]** The following figures illustrate various aspects of the disclosure.

**[0098]** **FIG. 1** is side view of the implant assembly mounted on a delivery tool.

**[0099]** **FIG. 2** is a side isometric view of an anchor and an implant of an implant assembly.

- [0100] FIG. 3 is a posterior view of an anchor and an implant secured within a sacroiliac joint of a subject.
- [0101] FIG. 4A is a side isometric view of an implant.
- [0102] FIG. 4B is a side view of an implant.
- [0103] FIG. 4C is a top view of an implant.
- [0104] FIG. 4D is a proximal view of an implant.
- [0105] FIG. 4E is a distal view of an implant.
- [0106] FIG. 4F is a longitudinal cross-section of an implant taken along A-A of FIG. 4A.
- [0107] FIG. 4G is a side view of an implant opposite to the side view illustrated in FIG. 4B.
- [0108] FIG. 5A is a posterior view of an implant secured within a sacroiliac joint of a subject in which the sacrum is hidden.
- [0109] FIG. 5B is a posterior view of an implant secured within a sacroiliac joint of a subject in which the ilium is hidden.
- [0110] FIG. 6A is a proximal perspective view of a single-keel implant.
- [0111] FIG. 6B is a side view of a single-keel implant.
- [0112] FIG. 6C is a proximal perspective view of a single-keel implant with an anchor through a graft window.
- [0113] FIG. 7A is a side view of a dual-keel implant with a graft window extending perpendicularly through an intraarticular element of the implant.
- [0114] FIG. 7B is a side view of a single-keel implant with a graft window extending at a 45° angle through an intraarticular element of the implant.
- [0115] FIG. 8 is a proximal view of a dual-keel implant with unequal keel widths and thicknesses.



[0116] FIG. 9A is a side view of a single keel implant with a monoaxial or polyaxial attachment fitting coupled to a proximal end of the implant.

[0117] FIG. 9B is a longitudinal cross-sectional view of a single keel implant with a polyaxial head attached at a proximal end of the implant.

[0118] FIG. 10 is a proximal perspective view of an implant with an extended graft window and an anchor inserted transversely through the extended graft window.

[0119] FIG. 11A is an exploded side view of a dual-keel implant separated from a distal end of a delivery tool.

[0120] FIG. 11B is a side view of a dual-keel implant mounted to a distal end of a delivery tool.

[0121] FIG. 12 is a proximal view of an implant with a halo of additional material surrounding a threaded bore formed within the proximal end of the implant.

[0122] FIG. 13 is a side view of an implant with additional reinforcing elements within a graft window.

[0123] FIG. 14 is a posterior view of an anchor, an additional anchor, and an implant secured within a sacroiliac joint of a subject.

[0124] FIG. 15A is a distal perspective view of a lag-type screw.

[0125] FIG. 15B is a distal perspective view of a fully threaded screw.

[0126] FIG. 16 is a side view of a fully threaded screw and a washer.

[0127] FIG. 14 is a posterior view of an anchor, an additional anchor, and an implant secured within a sacroiliac joint of a subject.

[0128] FIG. 15A is a distal perspective view of a lag-type screw.

[0129] FIG. 15B is a distal perspective view of a fully threaded screw.

[0130] FIG. 16 is a side view of a fully threaded screw and a washer.

[0131] FIG. 17 is a side view of an implant assembly.

- [0132] FIG. 18 is a proximal perspective view of an implant arm.
- [0133] FIG. 19A is a side cross-sectional view of an implant arm.
- [0134] FIG. 19B is a side cross-sectional view of a proximal end of an implant arm.
- [0135] FIG. 19C is a side cross-sectional view of a distal end of an implant arm.
- [0136] FIG. 20 is a perspective view of an adjustable delivery system with a slidable anchor arm.
- [0137] FIG. 21 is a perspective view of an adjustable delivery system with a rotating coupling to rotate the anchor arm around the implant arm axis.
- [0138] FIG. 22 is a perspective view of an adjustable delivery system with a rotating coupling to rotate the anchor arm around the implant arm and the implant arm about an axis mutually perpendicular to the implant arm and the anchor arm.
- [0139] FIG. 23 is a perspective view of an adjustable delivery system with a cam and channel coupling between the anchor arm and the implant arm.
- [0140] FIG. 24 is a section perspective view of an adjustable delivery system with a cam and channel coupling between the anchor arm and the implant arm.
- [0141] FIG. 25 is a side view of an adjustable delivery system with an articulating anchor arm.
- [0142] FIG. 26 is a perspective view of an delivery system with a modular anchor guide.
- [0143] FIG. 27 is a side view of an delivery system with a multi-position anchor arm.
- [0144] FIG. 28 is a perspective view of an delivery system with a multi-position anchor arm during an insertion of an implant assembly into a sacroiliac joint.
- [0145] FIG. 29 is a perspective view of an delivery system with an adjustavble auxiliary guide arm.

[0146] Corresponding reference characters and labels indicate corresponding elements among the views of the drawings. The headings used in the figures should not be interpreted to limit the scope of the claims.

## DETAILED DESCRIPTION

[0147] Implementations of the present disclosure involve a system for fusing a sacroiliac joint. Referring to **FIG. 1**, the system **10** includes a delivery tool **20** and an implant assembly **15** delivered to a sacroiliac joint (not shown) via the delivery tool **20**. The implant assembly **15** may include an implant **25** and an anchor **30** configured to fuse the sacroiliac joint once implanted at the joint. The elements of the delivery tool **20** are arranged and configured to quickly, accurately and reliably deliver the anchor **30** through a graft window (not shown) formed within the implant **25**. The implant **25** is supported off of a distal end **35** of the delivery tool **20**, thereby maintaining the implant **25** and the anchor **30** in an appropriate alignment relative to the anatomical features of the sacroiliac joint region as well as to one another. The alignment of the implant **25** and anchor **30** provided by the delivery tool **20** may reduce the potential for injury of sensitive tissues including, but not limited to, nerve tissue and vascular tissue. The alignment of the anchor **30** and implant **25** provided by the delivery tool **20** may further quickly, accurately, and reliably prevent mechanical interference between the implant **25** and anchor **30** during blind insertion of the anchor **30** during a surgical implantation procedure.

### *I. IMPLANT ASSEMBLY*

[0148] To begin a detailed discussion of components of an implant assembly **15**, reference is made to **FIG. 2**, a side isometric view of the implant assembly **15**. The implant assembly **15** may include an implant **25** and an anchor **30** in various aspects. The implant **25** may further include a graft window **40** formed within the implant **25** through which the anchor **30** may be inserted in an aspect.

[0149] Referring to **FIG. 3**, the implant assembly **15** may be implanted to stabilize a sacroiliac joint **1000** in one aspect. The implant **25** of the implant assembly **15** may be situated in a non-transverse placement within the sacroiliac joint space **1044** between the articular surfaces **1016** of the sacroiliac joint **1000**. The anchor **30** typically extends through the ilium **1005** and graft window **40** of the implant **25** and into the sacrum **1004** in a trajectory characterized as generally transverse to the sacroiliac joint **1000** and implant **25**. In this transverse trajectory, the anchor **30** may draw the ilium **1005** and sacrum **1004** together about the implant **25**, thereby enhancing the robust fixation of the implant **25** within the sacroiliac joint space **1044** by compressing the articular surfaces **1016** of the sacroiliac joint **1000** against the external surfaces of the implant **25**. With the implant **25** securely implanted in the sacroiliac joint **1000**, the articular surfaces **1016** may fuse together about the implant **25** as well as across the graft window **40** of the implant **25**.

[0150] In various other aspects (not shown) the implant assembly **15** may further include one or more additional anchors inserted along additional trajectories to further enhance the fixation of the implant **25** within the sacroiliac joint space **1044**. In other additional aspects, the anchor **30** and/or an additional anchor may be directed in an offset trajectory that is generally transverse to the sacroiliac joint **1000**, but offset from the trajectory illustrated in **FIG. 3** such that the anchor **30** passes above (cranially) or below (caudally) the implant **25**. By way of non-limiting example, this offset trajectory may be used to draw the ilium **1005** and sacrum **1004** together about the implant **25** when the design of the graft window **40** of the implant **25** precludes insertion of the anchor **30** through the implant **25**.

*a. Implant*

[0151] Referring again to **FIG. 3**, the implant assembly **15** includes an implant **25** for non-transverse placement between articular surfaces **1016** of a sacroiliac joint **1000** to dispose a sacrum **1004** and an ilium **1005** in a substantially immobilized relation.

[0152] **FIGS. 4A – 4E** are various views of an implant **25** in an aspect: a side isometric view (**FIG. 4A**); a side view (**FIG. 4B**); a top view (**FIG. 4C**); a proximal view (**FIG.**

**4D**); and a distal view (**FIG. 4E**). Referring to **FIG. 4A**, the implant **25** may have an implant length **402** extending from a proximal end **404** to a distal end **406**. Referring to **FIG. 4B**, the implant **25** may further have an implant height **426** extending from a top edge **428** to a bottom edge **430**. The distal end **406** may be introduced between the articular surfaces **1016** of a sacroiliac joint **1000** during implantation, as illustrated in **FIG. 3**. The implant **25** may include various features and elements to facilitate the insertion of the implant **25** into the sacroiliac joint **1000** of the subject, to enhance the fixation of the implant **25** within the sacroiliac joint **1000**, and to facilitate the fusion of the sacroiliac joint **1000** and implant **25** over extended use.

**[0153]** In various aspects, the implant length **402** may range from about 15 mm to about 60 mm. In various other aspects, the implant length **402** may range from about 15 mm to about 25 mm, from about 20 mm to about 30 mm, from about 25 mm to about 35 mm, from about 30 mm to about 40 mm, from about 35 mm to about 45 mm, from about 40 mm to about 50 mm, from about 45 mm to about 55 mm, and from about 50 mm to about 60 mm. In various additional aspects, the implant length **402** may be 15 mm, 20 mm, 25 mm, 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, 55 mm, and 60 mm.

**[0154]** In various aspects, the implant height **426** may range from about 10 mm to about 20 mm. In various other aspects, the implant height **426** may range from about 10 mm to about 12 mm, from about 11 mm to about 13 mm, from about 12 mm to about 14 mm, from about 13 mm to about 15 mm, from about 14 mm to about 16 mm, from about 15 mm to about 17 mm, from about 16 mm to about 18 mm, from about 17 mm to about 19 mm, and from about 18 mm to about 20 mm. In various additional aspects, the implant height **426** may be 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, and 20 mm.

**[0155]** Referring again to **FIGS. 4A – 4F**, the implant **25** may include an intraarticular element **408** extending at least a portion of the implant length **402**. The intraarticular element **408** may include a first articular face **410** and an opposed second articular face **412**. The first and second articular faces **410/412** may contact the articular surfaces **1016** of the sacroiliac joint **1000** when implanted, as illustrated in **FIG. 3**. Referring to **FIG. 5A**, the first articular face **410** may contact the articular surface **1016A**

of the ilium **1005**. Referring to **FIG. 5B**, the second articular face **412** may contact the sacrum **1004** or the articular surface **1016B** of the sacrum **1004**.

**[0156]** Referring to **FIG. 4E**, the intraarticular element **408** may include an intraarticular thickness **440** extending from the first articular face **410** and the second articular face **412**. The intraarticular thickness **440** may be influenced by any one or more of at least several factors including, but not limited to the width of the joint space **1044** at the region of the sacroiliac joint **1000** within which the implant **25** is to be inserted, the desired amount of taper at the distal end **406** of the implant **25**, the desired structural integrity of the implant, the length of the anchor **30** to be inserted transversely across the intraarticular element **408**, and the size of any holes, bores, windows, fittings, and the like to be formed at least partially within the intraarticular element **408**. In various aspects, the intraarticular thickness **440** may range from about 3 mm to about 10 mm. In various other aspects, the intraarticular thickness **440** may range from about 3 mm to about 5 mm, from about 4 mm to about 6 mm, from about 5 mm to about 7 mm, from about 6 mm to about 8 mm, from about 7 mm to about 9 mm, and from about 8 mm to about 10 mm. In various additional aspects, the intraarticular thickness **440** may be 3 mm, 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, and 10 mm.

**[0157]** In various embodiments, the first and second articular faces **410/412** of the implant **25** may be selected to match the contour of the joint space of the sacroiliac joint **1000** within which the implant **25** is to be inserted. For example, the first and second articular faces **410/412** of the implant **25** may be configured to be generally convex to match the contour of a sacral auricular bony surface or to match the contour of an extra-articular region of a sacrum **1004** (e.g., a sacral fossa). In one aspect, the sacral, medial or second articular face **412** of the implant **25** may be generally a surface negative of the articular surfaces **1016** of the extra-articular space **3007** and/or interarticular region **1044** of the sacrum **1004**. As another example, the lateral, iliac or second articular face **410** of the implant **25** may be configured to be generally concave to match the contour of an iliac auricular bony surface or to match the contour of an extra-articular region of an ilium (e.g., an iliac tuberosity). In one aspect, the lateral, iliac or second articular face **410** of the implant **25** may be generally a surface negative of the articular surfaces **1016** of the

extra-articular space **3007** and/or interarticular region **1044** of the ilium **1005**.

**[0158]** Referring again to **FIGS. 4A – 4F**, the intraarticular element **408** may further contain a graft window **40** extending in an essentially transverse direction through the first and second articular faces **410/412**. The graft window **40** may reduce the amount of an implant material including, but not limited to, a metal, within the joint space **1044** of the sacroiliac joint **1000**. The graft window **40** may further provide a space through which the bone tissues of the sacrum **1004** and ilium **1005** may grow and fuse during long-term residence of the implant **25** in the sacroiliac joint **1000**. In addition, the graft window **40** may provide a path through which the anchor **30** may pass transversely through the implant **25** in order to secure the implant **25** within the sacroiliac joint **1000**, as illustrated in **FIG. 2** by way of non-limiting example.

**[0159]** The graft window **40** may occupy at least a portion of the area of the first and second articular faces **410/412**. Without being limited to any particular theory, a relatively large graft window **40** may provide a wider range of fastener trajectories for any anchors **30** passing through the graft window **40**, may reduce the amount of material within the joint space **1044** or occupying the sacroiliac joint plane **1030** and associated risk of complications, and may enhance the potential fusion of the implant **25** with the surrounding bone tissue within the joint space **1044**. However, the size of the graft window **40** may be limited to a maximum size above which 1) the structural integrity of the implant **25** may be compromised due to the reduction in implant material associated with the graft window **40**, or 2) the surface area of the first and second articular faces **410/412** may have insufficient engagement or contact with the bone which may result in subsidence of the implant **25** into the bones. Referring to **FIG. 4B** and **FIG. 4G**, the graft window **40** may have a first window opening **468** on the first articular face **410** as illustrated in **FIG. 4B**. The first window opening **468** may be situated in close proximity to the ilium **1005**. Referring to **FIG. 4G**, the graft window **40** may have a second window opening **470** on the second articular face **412**. The second window opening **470** may be situated in close proximity to the sacrum **1004**. The first window opening **468** may be larger than the second window opening **470** due to a greater likelihood of subsidence of implant **25** into the sacrum **1004** due to lower bone density. An implant **25** with a larger

first window opening may have a first articular face **410** with an area that is less than the area of the second articular face **412**. In an aspect, the first window opening **468** and the second window opening **470** may be equal, yet the first articular face **410** may have an area which is less than the area of the second articular face **412**. Without being limited to a particular theory, this configuration may permit a greater dispersion of force upon the sacrum over a greater area, thereby lessening the possibility of subsidence.

**[0160]** Referring to **FIG. 4B**, the graft window **40** may include a window length **442** extending from a proximal edge to a distal edge of the graft window **40**. The window length **442** may vary based on a variety of factors, including the factors related to the overall size of the graft window **40** described herein previously, as well as the implant length **402**. In various aspects, the window length **442** may range from about 40% to about 70% of the implant length **402**. In various other aspects, the window length **442** may vary from about 40% to about 50%, from about 45% to about 55%, from about 50% to about 60%, from about 55% to about 65%, and from about 60% to about 70% of the implant length **402**. In various additional aspects, the window length **442** may be about 40%, about 45%, about 50%, about 55%, about 60%, about 65%, and about 70% of the implant length **402**. In various aspects, the window length **442** may range from about from about 10 mm to about 40 mm. In various other aspects, the window length **442** may range from about 10 mm to about 20 mm, from about 15 mm to about 25 mm, from about 20 mm to about 30 mm, from about 25 mm to about 35 mm, and from about 30 mm to about 40 mm. In various additional aspects, the window length **442** may be 10 mm, 12 mm, 14 mm, 15 mm, 16 mm, 18 mm, 20 mm, 22 mm, 24 mm, 25 mm, 26 mm, 28 mm, 30 mm, and 40 mm.

**[0161]** In various aspects, the graft window **40** may pass through the intraarticular element **408** at a range of angles relative to a plane parallel to the first and second articular faces **410/412**. In various aspects, the graft window **40** may pass through the intraarticular element **408** at a range of angles relative to a plane parallel to the first and second articular faces **410/412** ranging from about 45° to about 90° (i.e. normal to the first and second articular faces **410/412**). In various other aspects, the graft window **40** may pass through the intraarticular element **408** at a range of angles relative to a plane parallel



to the first and second articular faces **410/412** ranging from about 45° to about 55°, from about 50° to about 60°, from about 55° to about 65°, from about 60° to about 70°, from about 65° to about 75°, from about 70° to about 80°, from about 75° to about 85°, and from about 80° to about 90°. In various other aspects, the graft window **40** may pass through the intraarticular element **408** at an angle of 45°, 50°, 55°, 60°, 65°, 70°, 75°, 80°, 85°, and 90° angles relative to a plane parallel to the first and second articular faces **410/412**.

Referring to **FIG. 4F**, the graft window **40** may pass through the intraarticular element **408** at an angle of about 90° in an aspect. Referring to **FIGS. 7A** and **7B**, the graft window **40** may pass through the intraarticular element **408** at an angle of 90° (see **FIG. 7A**) in one aspect, and at an angle of 45° (see **FIG. 7B**) in another aspect.

**[0162]** In various aspects, the implant **25** may include a graft window **40** in which the perimeter of the graft window **40** may be provided with any known profile without limitation. Non-limiting examples of suitable profiles for the graft window **40** in various aspects include: a circular profile, an elliptical profile, a square profile, and a rectangular profile. In one aspect the profile of the graft window **40** may be provided in the form of an elliptical profile, as illustrated in **FIG. 4B** by way of non-limiting example.

**[0163]** Referring to **FIG. 13**, the graft window **40** of the implant **25** may further include at least one reinforcing element **464** to enhance the structural integrity of an implant **25** containing a graft window **40** in various aspects. In various aspects, the graft window **40** may further include a horizontal reinforcing element **464A** extending along the length of the graft window **40** and/or a vertical reinforcing element **464B** extending along the height of the graft window **40**. In these various aspects, the at least one reinforcing element **464** may occlude the anchor trajectory of an anchor **30** (not shown) through the graft window **40**, necessitating the use of additional anchors (not shown) directed along anchor trajectories that pass essentially transversely to the intraarticular element **408** of the implant **25** and caudad and/or cephalad relative to the implant **25**.

**[0164]** Referring to **FIG. 10**, in one aspect an implant **25B** may include an extended graft window **40A** that includes an open distal end **406**. In this aspect, the extended graft window **40A** may permit a wider range of potential anchor trajectories by eliminating the possibility of mechanical interference between the anchor **30** and the

distal end **406** of the implant **25B**. Further, the extended graft window **40A** may reduce the amount of implant material maintained within the joint space **1044** due to the elimination of the distal end **406** and associated structure of the implant **25B**. In addition, the extended graft window **40A** may be produced with any number of transverse keels while maintaining lateral symmetry, thereby simplifying the manufacturing and implantation of the implant **25B**. The extended graft window **40A** also permits the implant **25B** to be inserted into the joint space **1044** after the anchor **30** has been inserted in a transverse trajectory across the sacroiliac joint **1000**.

[0165] Without being limited to any particular theory, the surface area of all material introduced into the joint plane of the sacroiliac joint **1000** by the insertion of the implant **25** and associated anchor **30** may be associated with a risk of adverse effects, in particular if the implant **25** and anchor **30** are formed of a material which is not sufficiently osseointegrating. **FIG. 4F** is a cross-section of the implant **25** taken through a plane approximating the joint plane of the sacroiliac joint **1000**. As illustrated in **FIG. 4F**, a significant portion of the surface area of material within the joint plane comprises the intraarticular element **408**, and this area is significantly reduced by the inclusion of the graft window **40**. In one aspect, the total surface area of material introduced within the joint plane by the insertion of the implant **25** and anchor **30** may be less than about 400 mm<sup>2</sup>. In various other aspects, the total surface area of material introduced within the joint plane by the insertion of the implant **25** and anchor **30** may be less than about 380 mm<sup>2</sup>, less than about 360 mm<sup>2</sup>, less than about 340 mm<sup>2</sup>, less than about 320 mm<sup>2</sup>, less than about 300 mm<sup>2</sup>, less than about 280 mm<sup>2</sup>, less than about 260 mm<sup>2</sup>, less than about 240 mm<sup>2</sup>, less than about 220 mm<sup>2</sup>, less than about 200 mm<sup>2</sup>, less than about 180 mm<sup>2</sup>, less than about 160 mm<sup>2</sup>, less than about 150 mm<sup>2</sup>, less than about 145 mm<sup>2</sup>, and less than about 140 mm<sup>2</sup>.

[0166] Referring again to **FIG. 7A**, the distal end **406** of the implant **25** may further include various features to facilitate the insertion of the implant **25** into the joint space **1044** of the sacroiliac joint **1000** of the subject. In one aspect, the profile of the distal end **406** along the height **426** of the implant **25** may be tapered in order to provide a gradual increase in cross-sectional area as the distal end **406** is inserted into the joint space **1044**.

In one aspect, profile of the distal end **406** along the height **426** of the implant **25** may be provided in the form of a rounded leading edge **432**, as illustrated in **FIG. 4B**. In addition, the leading edge **432** may include a first lateral facet **434** and a second lateral facet **436** to provide a gradual transition from the relatively narrow leading edge **432** to the relatively wider remainder of the intraarticular element **408** situated proximal to the leading edge **432**.

**[0167]** In various aspects, the implant **25** may further include at least one transverse keel extending over at least a portion of the implant length **402**. Referring again to **FIGS. 4A – 4F**, the implant **25** may include a top keel **414** and a bottom keel **416** situated along the top edge **428** and bottom edge **430** of the implant **25**, respectively. The top keel **414** may project perpendicularly from the first and second articular faces **410/412**, ending in a first top lateral edge **418** and an opposed second top lateral edge **420**. The bottom keel **416** may project perpendicularly from the first and second articular faces **410/412**, ending in a first bottom lateral edge **422** and a second bottom lateral edge **424**.

**[0168]** Referring again to **FIG. 3**, each keel **414/416** may project transversely across the sacroiliac joint **1000** in various aspects. This transverse projection of the keels **414/416** may inhibit the cranial and/or caudal movements of the implant within the joint space **1044**. In addition, the keels **414/416** may provide additional contact area to facilitate the overgrowth of bone tissue over the implant **25**. Referring to **FIG. 5B**, the first top lateral edge **418** and the first bottom lateral edge **422** may project into an articular surface **1016B** of the sacrum **1004** in an aspect. Referring to **FIG. 5A**, the second top lateral edge **420** and the second bottom lateral edge **424** may project into an articular surface **1016A** of the ilium **1005** in an aspect.

**[0169]** In various aspects, the implant **25** may further include at least one transverse keel extending over at least a portion of the implant length **402**. In one aspect, the implant may be a dual keel implant **25**, as illustrated in **FIGS. 4A – 4F**. In another aspect, the implant may be a single keel implant **25A**, as illustrated in **FIGS. 6A – 6B**. In various aspects, the implant **25** may include 1 keel, 2 keels, 3 keels, 4 keels, 5 keels, 6 keels, and 7 keels.

[0170] Referring to **FIGS. 6A – 6B**, the implant **25** may include a single keel **414A** situated between the top edge **428** and bottom edge **430** of the implant **25**. The single keel **414A** may project perpendicularly from the first and second articular faces **410/412**, ending in a first top lateral edge **418** and an opposed second top lateral edge **420**.

[0171] Referring again to **FIGS. 4A – 4F**, the dual keel implant **25** in one aspect may include a top keel **414** and a bottom keel **416** situated along the top edge **428** and bottom edge **430** of the implant **25**, respectively. The top keel **414** may project perpendicularly from the first and second articular faces **410/412**, ending in a first top lateral edge **418** and an opposed second top lateral edge **420**. The bottom keel **416** may project perpendicularly from the first and second articular faces **410/412**, ending in a first bottom lateral edge **422** and a second bottom lateral edge **424**.

[0172] Referring again to **FIG. 3**, each keel **414/416** may project transversely across the sacroiliac joint **1000** in various aspects. This transverse projection of the keels **414/416** may inhibit the cranial and/or caudal movements of the implant within the joint space **1044**. In addition, the keels **414/416** may provide additional contact area to facilitate the growth of bone tissue about the implant **25**. Referring to **FIG. 5B**, the first top lateral edge **418** and the first bottom lateral edge **422** may project into the sacrum **1004** in an aspect. Referring to **FIG. 5B**, the second top lateral edge **420** and the second bottom lateral edge **424** may project into the ilium **1005** in an aspect.

[0173] **FIGS. 6A** and **6B** are rear isometric and side views, respectively, of an implant **25** that includes a single keel **414A** extending distally along at least a portion of the implant length **402** between the top edge **428** and the bottom edge **430** of the implant. In this aspect, the single keel **414** extends perpendicularly outward from the first and second articular faces **410/412**, and is typically situated transversely across a sacroiliac joint **1000** during use. In this aspect, the single keel **414** may extend distally across the graft window **40** of the intraarticular element **408**. As illustrated in **FIGS. 6A** and **6B**, the single keel **414** may include a proximal keel portion **414A'** and a distal keel portion **414A''** separated by a gap **438** over the graft window **40**. Referring to **FIG. 6C**, the gap **438** may provide a clear anchor trajectory for the insertion of an anchor **30** through the graft window **40** to secure the implant **25** within the sacroiliac joint **1000** (not shown).

[0174] Referring again to **FIGS. 4D** and **4E**, the at least one keel **414/416** projects transversely away from the intraarticular element **408** may end at a first lateral edge **418/422** and a second lateral edge **420/424**. The lateral edges **418/420/422/424** may have any cross-sectional profile without limitation. Non-limiting examples of suitable cross-sectional profiles for the lateral edges **418/420/422/424** include planar profiles, faceted or polygonal profiles such as triangular, square, octagonal and the like; rounded profiles such as semi-circular, semi-elliptical, parabolic, and the like.

[0175] In various aspects, the at least one keel **414/416** extends in a proximal direction along the length **402** of the implant **25** at any location on the implant **25** without limitation. In one non-limiting example, illustrated in **FIG. 4A**, the dual keels **414/416** may be situated at or near the top edge **428** and bottom edge **430** of the implant **25**. In another non-limiting example, illustrated in **FIG. 6A**, the single keel **414A** may be situated at a location between the top edge **428** and bottom edge **430** of the implant **25**. In yet another example, illustrated in **FIG. 9**, the single keel **414A** of a single keel implant **25A** may be situated at the top edge **428** of the implant **25A**.

[0176] In various aspects, the lateral edges **418/420/422/424**, first and second articular faces **410/412**, keels **414/414A/416**, and edges **428/430** may further include additional surface textures to enhance the securing of the implant **25** within the joint space **1044**. Non-limiting examples of suitable surface textures include: serrations, holes, furrows, and other depressions; and/or bumps, ridges, points, knurling, and other raised surface features. In one aspect, the lateral edges **418/420/422/424** may have a planar profile, as illustrated in **FIGS. 4D – 4E**.

[0177] Referring to **FIG. 4C**, the lateral edges **418** and **420** may define an overall profile of the implant **25** as viewed from above. In various aspects, the lateral edges **418** and **420** of a keel **414** as viewed from above may be linear, curved, or a combination of linear and curved. In one aspect (not shown), at least a portion of the first lateral edge **418** and at least a portion of the second lateral edge **420** may be parallel to one another along the length **402** of the implant **25**. In another aspect, the first lateral edge **418** and the second lateral edge **420** may taper inward toward the distal end **406** to enhance the ease of insertion of the implant **25** into the joint space **1044** or bone. Referring to **FIG. 4C**, a

distal portion **418A/420A** of the first and second lateral edges **418/420** may taper to a lesser extent than the taper of a proximal portion **418B/420B** of the first and second lateral edges **418/420**. Other pairs of lateral edges on opposite sides of the same keel may be similarly tapered in other aspects.

**[0178]** In one aspect, the keels may be sized according to the local region of the bone and joint space **1044** within which the keels are to be inserted. In one aspect, shown in **FIG. 8**, a bottom keel **416** to be situated in the vicinity of a sciatic notch **2008** (not shown) may be narrower than a top keel **414** situated further cephalad with respect to the sciatic notch **2008**. In one aspect, the narrower bottom keel **416** may enhance the compatibility of this keel **416** with the articular surfaces **1016** near the sciatic notch, which may include relatively thinner cancellous bone or lesser bone volume of the ilium or sacrum in close proximity to the anticipated placement of the narrower bottom keel **416**. In another aspect, shown in **FIG. 4D**, the top and bottom keels **414/416** may be of similar width; the width of the top and bottom keels **414/416** may be selected to be compatible with the thickness of cancellous bone near the sciatic notch **2008**. In this other aspect, the similar widths of the top and bottom keels **414/416** permit the implant **25** to be implanted with the top keel **414** facing upward or inverted with the top keel **414** facing downward without need to reconfigure the delivery tool **20**.

**[0179]** Referring to **FIGS. 4D** and **4E**, each keel **414** may include a width **444** extending between the lateral edges **418** and **420** of top keel **414** in an aspect. Referring to **FIG. 4C**, this width **444** typically defines an overall width of the implant **25** in various aspects. The width **444** may correspond to a maximum width if the keel **414** is tapered, as illustrated in **FIG. 4C** in one aspect. In another aspect (not shown) the width may be relatively constant if the lateral edges **418** and **420** extend distally in an essentially parallel manner.

**[0180]** In various aspects, the width **444** of each keel **414/414A/416** may range from about 8 mm to about 20 mm. In various other aspects, the width **444** of each keel **414/414A/416** may range from about 8 mm to about 10 mm, from about 9 mm to about 11 mm, from about 10 mm to about 12 mm, from about 11 mm to about 13 mm, from about 12 mm to about 14 mm, from about 13 mm to about 15 mm, from about 14 mm to about 16

mm, from about 15 mm to about 17 mm, from about 16 mm to about 18 mm, from about 17 mm to about 19 mm, and from about 18 mm to about 20 mm. In various additional aspects, the width **444** of each keel **414/414A/416** may be 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm, 15 mm, 16 mm, 17 mm, 18 mm, 19 mm, and 20 mm.

**[0181]** The keel width **444** of a keel **416** for insertion in the joint space **1044** near the sciatic notch **2008** may be slightly reduced as described herein previously to provide compatibility with the relatively thin cancellous bone in this region in an aspect. In this aspect, the keel width **444** may range between about 10 mm and about 16 mm, or within any of the subranges between about 10 mm and about 16 mm defined herein above. In various aspects, the keel width **444** of each keel **414/416** of a dual keel implant **25** (see, for example, **FIGS. 4A – 4E**) may be slightly narrower compared to a keel width **444** of a single keel implant **25A** with comparable implant length **402** and implant height **426**.

**[0182]** Referring again to **FIG. 4D**, the proximal end **404** of the implant **25** may include at least one or more features associated with reversibly attaching the implant **25** to a distal end **35** of a delivery tool **20**, as illustrated previously in **FIG. 1**. In various aspects, the proximal end **404** of the implant **25** may include a threaded bore **446** formed in the proximal end **404** and extending distally from the proximal face **454** of the proximal end **404** into the implant **25**. Referring to **FIG. 4F**, the threaded bore **446** may extend distally through the material of the intraarticular element **408**, and may open at a distal bore opening **450** into the graft window **40** opposite to a proximal bore opening **448** at the proximal face **454**. Referring to **FIG. 11A**, the threaded bore **446** may receive a distal end of an implant engagement feature in the form of a threaded shaft **220**. The threaded shaft **220** may be advanced into the threaded bore **446** and tightened to reversibly couple the proximal end **404** of the implant **25** to the distal end **35** of the delivery tool **20**, as illustrated in **FIG. 11B**.

**[0183]** In various aspects, the internal diameter of the threaded bore **446** may be matched to the diameter of the threaded shaft **220** and may range from about 3 mm to about 5 mm. The diameter of the threaded shaft **220** may be sufficiently large to secure the implant **25** to the delivery tool **20** without significantly increasing the thickness **440** of the intraarticular element **408**. In various aspects, the internal diameter of the threaded

bore **446** may range from about 3 mm to about 5 mm. In various other aspects, the internal diameter of the threaded bore **446** may range from about 3 mm to about 3.4 mm, from about 3.2 mm to about 3.6 mm, from about 3.4 mm to about 3.8 mm, from about 3.6 mm to about 4.0 mm, from about 3.8 mm to about 4.2 mm, from about 4 mm to about 4.4 mm, from about 4.2 mm to about 4.6 mm, from about 4.4 mm to about 4.8 mm, and from about 4.6 mm to about 5 mm. In various additional aspects, the internal diameter of the threaded bore **446** may be 3 mm, 3.2 mm, 3.25 mm, 3.5 mm, 3.75 mm, 3.8 mm, 3.9 mm, 4 mm, 4.2 mm, 4.25 mm, 4.5 mm, 4.75 mm, and 5 mm.

**[0184]** In various aspects, the desired thickness **440** of the intraarticular element **408** may be less than the internal diameter of the threaded bore **446**. Referring to **FIG. 12**, in one aspect, the proximal end **404** of the implant **25** may further include a halo **456** surrounding the threaded bore **446**. In this one aspect, the halo **456** may include an amount of material to contain the threaded bore **446** and maintain sufficient structural integrity during mounting of the implant **25** to the delivery tool **20**, as well as during subsequent insertion of the implant **25** into the joint space **1044** of the sacroiliac joint **1000**. In various aspect, the halo **456** may result in a minimum thickness of material surrounding the threaded bore **446** of at least about 1mm, at least about 1.2 mm, at least about 1.4 mm, at least about 1.5 mm, at least about 2 mm, and at least about 4 mm. In various other aspects, a diameter **458** of the halo **456** may range from about 5 mm to about 10 mm. In various other aspects, the diameter **458** of the halo **456** may range from about 5 mm to about 6 mm, from about 5.5 mm to about 6.5 mm, from about 6 mm to about 7 mm, from about 6.5 mm to about 7.5 mm, from about 7 mm to about 8 mm, from about 7.5 mm to about 8.5 mm, from about 8 mm to about 9 mm, from about 8.5 mm to about 9.5 mm, and from about 9 mm to about 10 mm. In various additional aspects, the diameter **458** of the halo **456** may be 5 mm, 5.5 mm, 6 mm, 6.5 mm, 7 mm, 7.5 mm, 8 mm, 8.5 mm, 9 mm, 9.5 mm, and 10 mm.

**[0185]** Referring again to **FIG. 11A**, the implant **25** may further include one or more alignment bores **452A/452B** configured to receive one or more corresponding alignment protrusions **255A/255B** extending distally from the distal end **35** of the delivery tool **20**. Referring to **FIG. 4F**, the one or more alignment bores **452A/452B** are blind bores



extending distally from the proximal face **454** into the material of the intraarticular element **408**. The alignment bores **452A/452B** are situated at a distance away from the threaded bore **446** corresponding to the positions of the alignment protrusions **255A/255B** on the distal end **35** of the delivery tool **20**. As the threaded shaft **220** is advanced into the threaded bore **446** and tightened, the alignment protrusions **255A/255B** are similarly advanced into the alignment bores **452A/452B**. The inner contour of the alignment bores **452A/452B** may be essentially matched to the outer contours of the alignment protrusions **255A/255B**, thereby reducing mechanical play of the alignment protrusions **255A/255B** within the alignment bores **452A/452B** upon insertion. In various aspects, the inserted alignment protrusions **255A/255B** may ensure that the implant **25** is properly aligned on the distal end **35** of the delivery tool **20**. In various other aspects, the inserted alignment protrusions **255A/255B** may prevent unwanted movements or shifts in position of the implant **25** and the delivery tool **20** including, but not limited to, twisting or torsional movements.

**[0186]** Alternatively, referring again to **FIG. 11A** and **FIG. 4F**, the distal end **35** of the delivery tool **20** may include one or more alignment bores (not shown) configured to receive one or more corresponding alignment protrusions (not shown) extending proximally from the proximal end **404** of the implant **25**.

**[0187]** Referring again to **FIG. 4D**, each alignment bore **452A/452B** may include a symmetrical contour in which an alignment protrusion **255** may be inserted in at least two different orientations in one aspect. Non-limiting examples of suitable symmetrical profiles include circular profiles, elliptical profiles, square profiles, rectangular profiles, and any other suitable profile with at least bilateral symmetry. In this one aspect, the implant **25** may have symmetrical features in which the implant **25** may be inserted either upright or inverted as described herein previously. Referring to **FIG. 6A**, the alignment bores **452A/452B** may include a non-symmetrical inner profile in one aspect such that the implant **25** may only be mounted in the distal end **35** of the delivery tool **20** in a single unique orientation to ensure that the implant **25** is properly inserted into the joint space **1044** of the sacroiliac joint **1000**. In another aspect, the proximal face **454** of the implant **25** may be provided with one or more alignment markings **466** to aid a practitioner in

mounted the implant **25** to the distal end **35** of the delivery tool **20**. In various aspects, any combination of non-symmetrical profiles within the alignment bores **452A/452B** and/or one or more alignment markings **466** on the proximal face **454** may be included to facilitate alignment of the implant **25** on the delivery tool **20**.

**[0188]** Referring again to **FIG. 11A**, the proximal face **454** of the implant **25** may include a contour that is matched to a corresponding contour (not shown) of the distal end **35** of the delivery tool **20**. In one aspect, the proximal face **454** may be essentially planar, thereby enhancing the degree of direct contact between the distal end **35** of the delivery tool **20** and the proximal end **404** of the implant **25**. In another aspect, the proximal face **454** of the implant **25** may have a non-planar contour that may be matched to a corresponding non-planar contour of the distal end **35** of the delivery tool **20**, including, but not limited to a spherical or hemispherical contour; an ellipsoidal contour, a saddle-shaped contour, and any other suitable contour. In one aspect, the contour of the proximal face **454** may be non-symmetrical and may function as a means of aligning the implant **25** on the distal end **35** of the delivery tool **20**.

**[0189]** Referring again to **FIGS. 9A** and **9B**, in various embodiments the implant engagement feature may be provided in forms other than a threaded shaft **220** as described herein previously. In one aspect, the implant **25A** may be provided with a monoaxial or polyaxial attachment fitting **460** attached at the proximal end **404** of the implant **25** via a ball joint-type fitting **462**. In this aspect, the implant **25** may be secured to the delivery tool **20** using standard tools used to install pedicle screws and other orthopedic devices outfitted with polyaxial heads that are well-known in the art. Once the implant **25** is secured within a sacroiliac joint **1000**, the monoaxial or polyaxial attachment fitting **460** may protrude from the sacroiliac joint **1000** and may be configured for use as an anchor for an orthopedic device such as a spinal stabilization appliance. In this embodiment, the delivery tool **20** may be modified to accommodate the monoaxial or polyaxial attachment fitting **460** during insertion of the implant **25**.

**[0190]** The monoaxial or polyaxial attachment fitting **460** may be attached to the proximal end **404** of the implant **25** using a ball joint-type fitting **462**, as illustrated in **FIG.**

**9B.** The resulting joint may be rotatable in any direction to a limited extent or may be uniplanar.

**[0191]** While reference is made to the embodiment of the implant **25** in **FIGS. 4A-4F**, the reference numerals are similarly applicable to the implant designs in the other figures.

**[0192]** In various aspects, the implant **25** may be machined, molded, formed, or otherwise manufactured from stainless steel, titanium, metallic implant alloys, ceramic, polymer, composite, bone or other biocompatible materials. In one aspect, the implant **25** may be machined from a metallic implant alloy including, but not limited to a titanium-aluminum-vanadium ELI (Extra Low Interstitial) alloy (ASTM F136). In another aspect, the implant **25** may be machined from a polymer including, but not limited to a polyetheretherketone (PEEK) polymer such as ZENVIA ZA-500. In yet another aspect, the implant **25** may further include a coating to improve osseointegration including, but not limited to, a commercially pure Ti coating (ASTM F1580).

*b. Anchor*

**[0193]** Referring again to **FIG. 3**, the implant assembly **15** may include an anchor **30** inserted transversely across the sacroiliac joint **1000** to hold the implant **25** in place within the joint space **1044** of the sacroiliac joint **1000**. The anchor **30** may be inserted along a generally lateral-medial fastener trajectory in which the anchor passes through the ilium **1005**, through the graft window **40** of the implant **25**, and penetrate the sacrum **1004**. In various aspects, the anchor **30** may be provided in the form of any suitable elongated body including, but not limited to: a nail, a rod, a pin, a threaded screw, an expanding body, a cable (e.g., configured with a ball end), and the like. In one aspect, the anchor **30** is configured to be received in the graft window **40** defined through intraarticular element **408** of the implant **25**. The graft window **40** extends through the implant **25** and is sized such that the anchor element **30** may extend through the implant **25** as illustrated in **FIG. 3**. In one aspect, the graft window **40** and at least one keel **414** may be sized to minimize toggling of the anchor **30** through a range of anchor trajectories through the graft window

**40** of the implant **25**.

[0194] Referring to **FIG. 14**, the implant assembly **15** may further include an additional anchor **30A**, also inserted transversely across the sacroiliac joint **1000** in a generally lateral-medial fastener trajectory. In one aspect, the second anchor **30A** may be inserted along a fastener trajectory situated caudad relative to the implant **25** such that the second anchor **30A** crosses the joint space **1044** without passing through the graft window. In one aspect, the additional anchor **30A** may be used instead of the anchor **30** to hold the implant **25** in place within the joint space **1044** as needed. In one non-limiting example, the additional anchor **30A** may be used if the articular surfaces **1016** are degraded in the region adjacent to the implant **25**, thereby limiting the effectiveness of an anchor **30** inserted through the implant **25**. In another non-limiting example, the additional anchor **30A** may be used in certain aspects of the implant in which the graft window **40** may be partially occluded by additional reinforcement elements **464**, as illustrated in **FIG. 13**.

[0195] In various aspects, the anchor **30** and additional anchor **30A** may be provided in the form of a screw. Referring to **FIGS. 15A** and **15B**, each anchor **30** may be a "lag" type screw (**FIG. 15A**) which serve to pull the SI joint together, or fully threaded (**FIG. 15B**) for capturing multiple cortices, enhancing stability. In other aspects, each anchor **30** may include a single lead or a dual lead. In yet other additional aspects, the anchor may be cannulated or non-cannulated. Referring to **FIG. 16**, the anchor **30** may be further provided with a washer **31** in various aspects. In various other aspects, the distal end **32** of the anchor **30** may include various features to enhance the function of the anchor **30** including, but not limited to, a self-tapping tip as illustrated in **FIG. 16**. In other aspects, each anchor **30** may include a single lead or a dual lead.

[0196] In various aspects, the anchor **30** may have an anchor diameter **33** ranging from about 4 mm to about 8 mm. In various aspects, anchor diameter **33** may range from about from about 4 mm to about 5 mm, from about 4.5 mm to about 5.5 mm, from about 5 mm to about 5.2 mm, from about 5.1 mm to about 5.3 mm, from about 5.2 mm to about 5.4 mm, from about 5.3 mm to about 5.5 mm, from about 5.4 mm to about 5.6 mm, from about 5.5 mm to about 5.7 mm, from about 5.6 mm to about 5.8 mm, from about 5.7 mm

to about 5.9 mm, from about 6.0 mm to about 6.2 mm, from about 6.1 mm to about 6.3 mm, from about 6.2 mm to about 6.4 mm, from about 6.3 mm to about 6.5 mm, from about 6.4 mm to about 6.6 mm, from about 6.5 mm to about 6.7 mm, from about 6.9 mm to about 7.1, and from about 7 mm to about 8 mm. In various additional aspects, the anchor diameter **33** may be 4 mm, 4.5 mm, 5 mm, 5.5 mm, 6 mm, 6.5 mm, 7 mm, 7.5 mm, and 8 mm.

**[0197]** In various other aspects, the anchor **30** may have an anchor length **34** ranging from about 20 mm to about 80 mm. In various aspects, anchor length **34** may range from about 20 mm to about 30 mm, from about 25 mm to about 35 mm, from about 30 mm to about 40 mm, from about 35 mm to about 45 mm, from about 40 mm to about 50 mm, from about 45 mm to about 55 mm, from about 50 mm to about 60 mm, from about 55 mm to about 65 mm, from about 60 mm to about 70 mm, from about 65 mm to about 75 mm, and from about 70 mm to about 80 mm. In various additional aspects, the anchor length **34** may be 20 mm, 25 mm, 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, 55 mm, 60 mm, 65 mm, 70 mm, 75 mm, and 80 mm.

**[0198]** In various other aspects, the anchor **30** may be provided in the form of a S2 alar iliac (S2AI) screw. In these aspects, the anchor **30** may be inserted in a medial-lateral fastener trajectory in which the anchor **30** may enter the bone of sacrum **1004** near the first sacral foramen (S2AI trajectory) then into or through graft window **40** and may further enter the bone of the ilium **1005**. In an aspect, the anchor **30** may enter the sacrum **1004** just lateral to the lateral edge of the S1 foramen and, in some instances, generally superiorly-inferiorly even with the superior edge of the S1 foramen so as to mimic an S2 alar iliac pelvic fixation. In other aspects, the anchor **30** may penetrate the sacrum **1004** just lateral to the lateral edge of the S2 foramen and, in some instances, generally superiorly-inferiorly even with the superior edge of the S2 foramen.

**[0199]** The anchor **30** may be machined, molded, formed or otherwise manufactured from similar biocompatible materials. In one aspect, the implant **25** may be machined from a metallic implant alloy including, but not limited to a titanium-aluminum-vanadium ELI (Extra Low Interstitial) alloy (ASTM F136). In another

aspect, the implant **25** may be machined from a polymer including, but not limited to a polyetheretherketone (PEEK) polymer such as ZENVIA ZA-500.

## **II. DELIVERY TOOL**

**[0200]** Referring again to **FIG. 1**, the system **10** for fusing a sacroiliac joint may include a delivery tool **20** to insert the implant assembly **15** into the sacroiliac joint (not shown) of a subject. The delivery tool **20** may include a distal end **35** and a proximal end **80**. The distal end **35** may detachably support the implant assembly **25** during insertion into the joint space of the sacroiliac joint of the subject. The proximal end **80** may be configured to be grasped and manipulated to facilitate the insertion of the implant **25** into the sacroiliac joint.

**[0201]** As illustrated in **FIG. 1**, the delivery tool **20** further includes an arm assembly **85** situated at the distal region of the tool **20**, and a handle **90** attached at the proximal end **80** of the tool **20**. Referring to **FIG. 17**, the arm assembly **85** may include an implant arm **110** and an anchor arm **115** supported off of the implant arm **110**. The implant arm **110** includes a distal end **120** and a proximal end **125**. Referring to **FIG. 18**, the proximal end **125** of the implant arm **110** may further include a proximal cylindrical opening **130** of a cylindrical bore **132**. The proximal end **125** may also include a faceted outer surface configuration **135** that facilitates a mechanical engagement arrangement with the handle **90** (not shown) similar to a mechanical arrangement that exists between a wrench and nut.

**[0202]** Referring to **FIGS. 19A – 19C**, the cylindrical bore **132** may extend the full length of the implant arm **110** from the proximal opening **130** to a distal opening **137**. In an aspect, the cylindrical bore **132** may contain an implant retainer **95** attached to a retainer knob **96** contained within a frame **97** situated near the proximal end **125**. In an aspect, the implant retainer **95** may extend distally along the cylindrical bore **132** and may end at a threaded shaft **220** protruding from the distal opening **137**. Referring to **FIGS. 11A** and **11B**, the threaded shaft **220** may be advanced into the threaded bore **446** of the implant **25** in order to retain the implant **25** on the distal end **35** of the delivery tool **20**.

[0203] As can be understood from **FIGS. 1** and **11B**, when the system **10** is assembled for the delivery of the implant assembly **15** to the sacroiliac joint **1000**, the proximal face **454** of the implant **25** is supported off of the implant arm distal end **120** (see **FIG. 11B**). Also, as shown in **FIGS. 11A** and **11B**, when the system **10** is assembled for the delivery of the implant assembly **15** to the sacroiliac joint, the planar extreme proximal face **454** of the implant **25** abuts against the planar extreme distal face **152** of the implant arm distal end **120**, the alignment protrusions **255A/255B** being received in a recessed fashion in the alignment bores **452A/452B**. The alignment protrusions **255A/255B** being received in the alignment bores **452A/452B** may prevent the implant **25** from pivoting relative to the implant arm **110**. The alignment protrusions **255A/255B** may be configured to have a rectangular, circular or any other cross section and the corresponding alignment bores **452A/452B** may also be configured to have corresponding cross-sectional shapes.

[0204] Referring again to **FIG. 17**, the anchor arm **115** may be supported off of the implant arm **110** at an angle and includes a proximal end **155** attached to the anchor arm **110** and a distal end **160** distally terminating in a sleeve or collar **165** defining an anchor axis  $LCA_1$  that is generally transverse to the longitudinal axis of the anchor arm **115**. The collar **165** may be configured to permit and maintain accurate alignment of the first sleeve **100** along  $LCA_1$  during the course of the procedure to install the implant assembly **15**. The anchor arm proximal end **155** intersects the implant arm **110** at a location between the proximal end **125** and the distal end **120** of the implant arm **110**.

[0205] As indicated in **FIGS. 17** and **19**, the implant arm **110** may also define an implant axis  $LCA_2$ . As shown in **FIGS. 11A** and **11B**, when the implant **25** is mounted on the distal end **120** of the implant arm **110**, the longitudinal center axis  $CA$  of the implant **25** is coaxially aligned with the longitudinal center axis  $LCA_2$  of the implant arm **110**. In addition, the anchor axis  $LCA_1$  defined within the anchor arm collar **165** projects through the graft window **40**, thereby assuring that the anchor **30** will pass through the graft window **40** without mechanical interference. Thus, the longitudinal center axis  $CA$  of the implant **25** and the implant axis  $LCA_2$  of the implant arm **110** exist on a first common longitudinally extending axis, and the anchor axis  $LCA_1$  of the anchor arm collar **165**

passes through the graft window **40** as a result of the orientation of the anchor arm collar **165** and the implant arm **110** of the delivery tool **20**. As a result, the delivery tool **20** enables the safe and accurate assembly of the implant assembly **15** within the sacroiliac joint **1000** of a subject without need for direct visual confirmation. By way of non-limiting example, the line of action for the insertion of the implant **25** into the sacroiliac joint **1000** is coaxial with the center axes of the implant **25**, implant arm **110** and handle **90**.

**[0206]** The use of the delivery tool **20** in various aspects results in a higher degree of accuracy and consistency in the implantation procedures, and further reduces invasiveness and potential for complications associated with performing an implantation procedure requiring direct visualization of the insertion of the anchor **30** through the implant **25**. The anchor arm collar **165** is oriented so as to guide drills and other tools in creating a channel through tissue and bone leading to the graft window **40** when the implant **25** is positioned in the sacroiliac joint space **1044** while the implant **25** is still attached to the distal end **120** of the implant arm **110**, as shown in **FIG. 17**. Additionally, the anchor arm collar **165** is oriented so as to guide the anchor member **30** into the graft window **40** when the implant **25** is positioned in the sacroiliac joint **1000** while the implant **25** is still attached to the distal end **120** of the implant arm **110**, as shown in **FIG. 1**.

**[0207]** In one embodiment, the longitudinal center axis  $LCA_1$  of the anchor arm collar **165** may form an angle  $A_{LCA1-LCA2}$  with the longitudinal center axis  $LCA_2$  of the implant arm **110**, as illustrated in **FIG. 17**. In various aspects, the angle  $A_{LCA1-LCA2}$  may range from about 15 degrees to about 135 degrees. In various other aspects, the angle  $A_{LCA1-LCA2}$  may range from about 15 degrees to about 25 degrees, from about 20 degrees to about 40 degrees, from about 30 degrees to about 50 degrees, from about 40 degrees to about 60 degrees, from about 50 degrees to about 70 degrees, from about 60 degrees to about 80 degrees, from about 70 degrees to about 90 degrees, from about 80 degrees to about 100 degrees, from about 90 degrees to about 110 degrees, from about 100 degrees to about 120 degrees, from about 110 degrees to about 130 degrees, and from about 115 degrees to about 135 degrees. In various other aspects, the angle  $A_{LCA1-LCA2}$  may be 15 degrees, 20 degrees, 25 degrees, 30 degrees, 35 degrees, 40 degrees, 45 degrees, 50 degrees, 55 degrees, 60 degrees, 65 degrees, 70 degrees, 75 degrees, 80



degrees, 85 degrees, 90 degrees, 95 degrees, 100 degrees, 110 degrees, 115 degrees, 120 degrees, 125 degrees, 130 degrees, and 135 degrees. In one aspect, the angle  $A_{LCA1-LCA2}$  may be 45 degrees.

**[0208]** As can be understood from **FIG. 17**, in one aspect, the above-described coaxial and angular relationships may be rigidly maintained due to the anchor arm **115** and its collar **165** being in a fixed, non-adjustable configuration, and the interconnection between the proximal end of the anchor arm **115** and the implant arm **110** being a fixed, non-adjustable configuration, at least with respect to the angle  $A_{LCA1-LCA2}$  between the longitudinal center axis  $LCA_1$  of the anchor arm collar **165** and the longitudinal center axis  $LCA_2$  of the implant arm **110**. Thus, in one embodiment, the delivery tool **20** may be provided to a practitioner in a fixed, non-adjustable configuration having the coaxial and angular relationships articulated above with respect to **FIG. 17**.

*a. Adjustable Anchor Arm*

**[0209]** In other aspects, the anchor arm **115** may be adjustable to accommodate patients of different sizes and/or fine-tune the anchor trajectory while still maintaining the angular relationships between the components of system **10** within a predefined range allow the anchor **30** to be delivered through the graft window **40** without any further adjustment to the delivery tool **20**. As illustrated in **FIG. 20**, the anchor arm **115** may be slideably attached at one end to a guide beam **102**. The guide beam **102** may be attached to the implant arm **110** at one end **103** and protrude from the implant arm **110** in a cantilevered configuration, wherein the protrusion angle of the guide beam **102** is configured to result in a predetermined anchor entry angle through the implant **25**. The anchor arm **115** may be provided with a slideable fitting **104** at an end **106** opposite to the anchor arm collar **165**. In this aspect, the slideable fitting **104** may be translated along the guide beam **102** to adjust the distance between anchor arm collar **165** and implant **25**, while maintaining the angular relationships maintained between the implant arm **110**, anchor arm **115**, anchor arm collar **165**, and the graft window **40**.

**[0210]** Another embodiment of an adjustable delivery tool **20** is illustrated in **FIG. 21**. Referring to **FIG. 21**, the delivery tool **20** may include an anchor arm **115** attached at one end to the implant arm **110** in a rotating joint **802** configured to rotate the anchor arm **115** about the longitudinal axis of the implant arm **110** while maintaining an anchor trajectory that includes passing an anchor **30** through the graft window **40** of the implant **25**. Opposite the rotating joint **802** is an anchoring guide that is configured to guide the insertion of an anchor **30** within the graft window **40**. The anchoring guide may, for example, include a plurality of slots or guide holes that guide an anchor **30** or a shaft of a tool that is coupled with an anchor **30**.

**[0211]** Stated another way, the anchor arm **115** may rotate or, conversely, the implant arm **110** may rotate within a range of trajectories that are each configured to pass an anchor **30** through the graft window **40**. Additionally, the anchor arm **115**, or, more particularly, the rotating joint **802** may restrict or limit the range of trajectories to a particular range of trajectories that will align the anchor **30** with the graft window **40** such that the anchor arm **115** may only rotate within the particular range. In this way, trajectories will not be chosen that result in errant placement of the anchor **30** in places other than the graft window **40**. The rotation can be mechanically restricted or limited with a stop element or other mechanical feature.

**[0212]** In various aspects, the angle **804** that the anchor trajectory makes relative to a perpendicular trajectory through the graft window may range from about -30 degrees to about +30 degrees. In other embodiments, however, the range may be from about -5 degrees to about +5 degrees or -10 degrees to about +10 degrees, among other ranges.

**[0213]** In this embodiment, the rotating joint **802** provides the capability to adjust the anchor trajectory within a predetermined envelope while restricting the anchor arm **115** from rotating to trajectories that are outside of the predetermined envelope. This predetermined envelope may be sized to ensure that the anchor trajectory passes through the graft window **40** while allowing a practitioner a limited amount of leeway to adjust the anchor trajectory as needed for each surgical procedure

[0214] Referring to **FIG. 22**, the proximal end **125** of the implant arm **110** may attach to the anchor arm **115** using a rotating joint **902** such that the implant arm **110** may pivot or rotate about an axis **904** perpendicular to the plane formed by the anchor arm **115** and implant arm **110** within a predetermined angular range **906**. In this way, the anchor arm **115** may pivot about the axis **904** such that the anchor **30** may be delivered through the graft window **40** in various orientations. For example, as seen in **FIG. 22**, the anchor **30** is substantially perpendicular to a plane formed by the graft window **40**. The anchor arm **30** may, however, be rotated clockwise about the axis **904** such that a distal end of the anchor **30** angles more towards a distal end of the graft window **40**. Conversely, the anchor arm **30** may be rotated counterclockwise about the axis **904** such that a distal end of the anchor **30** angles more towards a proximal end of the graft window **40**. In this embodiment, this angular range **906** may modify the trajectory of the anchor **30** or other fastener by inserting or withdrawing the anchor **30** slightly as well as changing the angle **804** of the anchor trajectory measured in the plane formed by the anchor arm **115** and implant arm **110**. Other rotating attachments between other elements of the delivery tool **20** may be incorporated in additional embodiments without limitation. For example, the rotating joint **902** may rotate about the axis **904** and the axis defined by the longitudinal axis of the implant arm **110**. Or, the rotating joint may only rotate about either the axis **904** or the axis defined by the longitudinal axis of the implant arm **110**.

[0215] While the anchor arm **115** of **FIGS. 21-22** is depicted as being arcuate, other designs are possible and contemplated herein. The anchor arm **115** may, for example, be a single straight member or may include multiple members of differing shapes. As another example, the anchoring arm **115** may include telescoping members that enable retraction and extension of an inner telescoping member.

[0216] Referring to **FIGS. 23 - 24**, in one aspect the rotating joint **902** may be provided in the form of a cam **910** engaged within a channel **912** formed within the proximal end **155** of the anchor arm **115**. In this aspect, the cam **910** may slide and pivot along the channel to effectuate rotations about an axis **904** perpendicular to the plane formed by the anchor arm **115** and implant arm **110**. In addition, the cam **910** may twist within the channel **912** to effectuate rotations **804** about the axis of the implant arm **110**.

The cam **910**, as seen in **FIG. 24**, has a limited ability to rotate within the channel because the cam-shape inhibits full rotation of the cam **910** within the channel **912**. And since the cam **910** is attached to the implant arm **110**, the implant arm correspondingly includes a limited range of rotation **804** relative to the anchor **30**. Additionally, the range of rotation about the axis **904** may be limited by the channel ends **914/916**. The range of rotation **804** may be limited by the mechanical interference of the cam outer wall **918** with the inner wall **920** of the channel **912**. The limited range of rotation is configured to allow an appropriate orientation of the anchor **30** relative to the graft window **40** in any of the limited ranges of rotation. Thus, the limited range of rotation limit the anchor **30** and graft window **40** to orientations that will not cause interference between the two.

**[0217]** It is noted that the embodiment of the insertion tool **20** in **FIGS. 23-24** is configured to allow for insertion of the anchor **30** prior to the insertion of the implant **25**. In certain implementations, however, the implant **25** may be inserted prior to the anchor **30**.

**[0218]** Another embodiment of an adjustable delivery tool **20** is provided in **FIG. 25**. Referring to **FIG. 25**, the anchor arm **115** may be provided in the form of two or more articulated members **602** and **604**. In this aspect, the articulating members **602** and **604** may be constrained to move between one of two locked positions: 1) a default position characterized by a 45 degree angle between the axes of the implant arm **110** and anchor arm **115**, respectively; and 2) a high BMI position characterized by a 35 degree angle between the axes of the implant arm **110** and anchor arm **115**, respectively and a higher lateral separation distance between the implant **25** and the anchor arm **115**. The articulated members **602** and **604** may be attached to the anchor arm **115** by rotatable pin joints at one end, and to the implant arm **110** by a lockable sliding joint **608** and a rotatable pin joint **606**, respectively. In use, the lockable sliding joint **608** may be unlocked and slid to a distal-most position to assume the default position, and slid to an proximal-most position to assume the high BMI position. Because of the coupling aspect of the articulating members **602** and **604**, as the lockable sliding joint **608** slides to the distal-most position, as seen in **FIG. 25**, the anchor arm **115** moves distally and rotates counterclockwise. Moving from the distal-most position, as seen in **FIG. 25**, the lockable

sliding joint **608** slides proximally and the anchor arm **115** moves proximally and rotates clockwise.

The articulating member **602** includes a tubular member with an inner diameter that is slightly larger than an outer diameter of the implant arm **110**. The relative difference in diameters facilitates the sliding of the sliding joint **608**. And, the articulating member **604** includes a partial tubular member that rotates about the rotatable pin joint **606** at one end of the partial tubular member. The partial tubular member acts as a stop that inhibits rotation of the member about the rotatable pin joint **606** past a point where the partial tubular member contacts the implant arm **110**. Thus, in the BMI position, the partial tubular member matingly contacts the tubular shaft of the implant arm **110** and inhibits further proximal sliding of the lockable sliding joint **608**. In this way, the angle of the anchor arm **115**, in the BMI position, is fixed by the inhibition of the partial tubular member to rotate further.

*b. Multiposition Anchor Guides*

[0219] Referring to **FIG. 26**, the anchor arm **115** may be configured to deliver the anchor **30** along a first predetermined anchor trajectory through the graft window **40** of the implant **25** as well as at least one additional anchor **30A** along at least one additional anchor trajectory. In one aspect, illustrated in **FIG. 26**, the delivery tool **20** may further include a modular anchor guide **302** attached to the anchor arm **115** of the delivery tool **20**. In this embodiment, the modular anchor guide **302** may include two or more collars **304** and **306** separated along the length of the anchor arm **115** such that the centerlines of the two or more collars **304** and **306** are laterally offset and aligned with the longitudinal axis **312** of the anchor arm **115**. In this aspect, the two or more collars **304** and **306** may provide a second trajectory **310** that may be aligned but offset from the longitudinal axis **312** of the anchor arm **115**. This second trajectory **310** may be used to guide the path of various surgical tools and/or components including, but not limited to: an additional anchor **30A**, a guidewire, a drill, a needle, a therapeutic compound, or any other surgical tool.

[0220] Referring to FIG. 27, the delivery tool 20 may further include an anchor arm 402 that distally ends in a multi-position anchor guide 400 in an aspect. The multi-position anchor guide 400 may include two or more guides 404, 406, and 408 that may be laterally offset and aligned along parallel trajectories. In use, the two or more anchor guides 404, 406, and 408 may be offset in an approximately dorsal-ventral direction to implement the insertion of an additional anchor dorsal to or ventral to the implant 25, as illustrated in FIG. 28 by way of non-limiting example. As illustrated in FIG. 28, the center guide 406 may define a center trajectory 406' directed through the graft window 40 of the implant 25 and the cephalad guide 408 may define a cephalad trajectory 408' that is aligned with the center trajectory 406' but passes cephalad to the implant 25. By way of non-limiting example, an anchor 30 and a second anchor 30A may be inserted along the center trajectory 406' and the cephalad trajectory 408' using the multi-position anchor guide 400 illustrated in FIG. 28, resulting in an implant assembly similar to that illustrated in FIG. 14. The multi-position guide 400 may be compatible with a variety of surgical tools and/or components including, but not limited to: an additional anchor 30A, a guidewire, a drill, a needle, a therapeutic compound, or any other surgical tool. Instruments and may be used to perform a variety of steps in a surgical procedure as described herein below.

*c. Auxiliary Guide Arm*

[0221] Referring to FIG. 29, the system 10 may further include an auxiliary guide arm 202 that may be used with one or more embodiments described herein. In one aspect, illustrated in FIG. 29, the auxiliary guide arm 202 may be attached at a proximal end 208 to a proximal portion of the implant arm 110. In various aspects, the auxiliary guide arm 202 may be adjustable in at least one degree of freedom. By way of non-limiting example, the auxiliary guide arm 202 may be attached to the implant arm 110 using a rotatable collar 210 that may permit the rotation of the auxiliary guide arm 202 about the longitudinal axis of the implant arm 110, and may further be provided with a locking mechanism such as a set screw 212 to lock the rotatable collar 210 in place. By way of another non-limiting example, the auxiliary guide arm 202 may be segmented with an adjustable joint between segments such as a sliding joint 206 that includes a post 216

projecting from a stationary element **220** situated within a channel **218** formed within a sliding element **222** that may be locked into place using a second locking mechanism such as a second set screw **214** to compress the sliding element **222** against the stationary element **220** when the second set screw is tightened down.

**[0222]** The auxiliary guide arm **202** may be further provided with an auxiliary guide collar **204** configured to guide a variety of tools and devices along a repeatable trajectory during a surgical procedure. In one non-limiting example, the auxiliary guide collar **204** may guide an additional anchor **40A** or other fastener along a trajectory suitable for facilitating the anchoring of the implant **25** during a surgical procedure. In another aspect, the auxiliary guide collar **204** may guide a needle or other device into a marrow region of surrounding bone tissue; in this example, the needle may be used to extract bone paste or other biocompatible materials for use in the surgical procedure as described herein below.

*d. Bone Paste Insertion Element*

**[0223]** Referring now to **FIG. 30**, the delivery tool **20** may be further configured to inject a bone paste material, or any other biocompatible material into an implant **25**. In one aspect, the implant arm **110** may be provided with a conduit **506** that opens into the graft window **40** of the implant **25**. As illustrated in **FIG. 30**, the proximal end of the conduit **506** may be provided with a plunger **508** that may be depressed distally within a close-fitting barrel **510** formed within the proximal end **80** of the implant arm **110**. The plunger **508** may provide a pressure that may cause the bone paste material or other biocompatible material to flow distally through the conduit **506** and out into the graft window **40** of the implant **25**.

**[0224]** Referring now to **FIG. 31**, the conduit **506** may terminate distally at a distal opening **512** that provides a path for the bone paste material to pass into the graft window **40** of the implant **25**. In an aspect, the conduit **506** may narrow in a nozzle **514** ending distally at the distal opening **512**. The nozzle **514** may be sized to fit within an orifice within the implant **25** including, but not limited to the threaded bore **446** illustrated, for example

at **FIG. 11B**. In this other aspect, the nozzle **514** may be sized to fit closely within the threaded bore **446**. In an aspect, the nozzle **514** may be provided with threads configured to mesh within the threads of the threaded bore **446**.

**[0225]** Referring now to **FIG. 32**, the barrel **516** may include a lumen **516** within which the bone paste material may be inserted prior to injection into the graft window **40**. The plunger **508** may further include a distal end **518** configured to fit closely within the lumen **516** in order to develop pressure within the lumen when the plunger **508** is advanced distally into the lumen **516**. In one aspect, the plunger **508** may be advanced by applying a distally directed force to the plunger handle **520**. In another aspect, the plunger **508** may further include a threaded portion **522** configured to mesh with corresponding threads **524** formed within the barrel **510**. In this aspect, the plunger may be advanced distally by twisting the threaded portion **522** into the corresponding threads **524**.

**[0226]** Referring to **FIG. 33**, the bone paste material may advance outward into the graft window **40** of the implant **25** at the initial of the injection process, along a path **526**. As the graft window **40** fills with bone paste material and the pressure within the graft window increases, additional bone paste material may enter the joint space (not shown) surrounding the implant **25**. In an aspect, the implant **25** may be provided with a plurality of channels **528** connecting the volume within the graft window **40** to the joint space surrounding the implant **25**. In this aspect, additional bone paste material may travel through the plurality of channel **528** to the joint space along a path **530**. In various aspects, an amount of bone paste material sufficient to fill the graft window as well as the joint space surrounding the implant may be introduced using the delivery tool in the various aspects described herein above.

### **III. METHOD OF FUSING SACROILIAC JOINT**

**[0227]** Various aspects of the delivery system **10**, delivery tool **20**, and implant assembly **15** may be used to fuse a sacroiliac joint of a subject.



**[0228]** Referring to FIG. 33, the patient may be put under under sedation and situated in a prone position on a translucent operating table or other suitable surface. The sacroiliac joint 1000 may be locally anesthetized to allow for injecting a radiographic contrast 1046 (as a non-limiting example, Isovium 300 radiographic contrast) under fluoroscopic guidance into the inferior aspect of the sacroiliac joint 1000 to outline the articular surfaces 1016 of the sacroiliac joint 1000 defined between the sacrum 1004 and ilium 1005 to visualize an interarticular region 1044 of the sacroiliac joint 1000. Injection of the radiographic contrast 1046 within the sacroiliac joint 1000 may be accomplished utilizing any suitable tubular member 1047 including but not limited to a syringe needle, the tubular member 1047 having a first tubular member end 1048 which may be advanced between the articulating surfaces 1016 of the sacroiliac joint 1000. The tubular member 1047 may have a second tubular member end 1049 that removably couples to a hub 1050. The hub 1050 may be configured to removably couple to a syringe barrel 1051 (or other suitable device to contain and deliver an amount of radiographic contrast 1046). In one non-limiting example, the syringe barrel 1051 may have an internal volume capable of receiving an amount of the radiographic contrast 1046 sufficient for outlining the articular surfaces 1016 of the sacroiliac joint 1000, for example, under lateral fluoroscopy. A plunger 1052 may be slidingly received within the barrel 1051 to deliver the radiographic contrast 1046 through the tubular member 1047 into the sacroiliac joint 1000. The tubular member 1047 may have a gauge ranging from about 16 gauge to about 20 gauge may be incrementally marked on the external surface to allow determination of the depth at which the first needle end 1048 has advanced within the sacroiliac joint 1000. As the first needle end 1048 advances into the sacroiliac joint 1000, the radiographic dye 1046 may be delivered from within the syringe barrel 1051 into the sacroiliac joint 1000 to allow visualization of the sacroiliac joint 1000 and location of the tubular needle 1047 within the sacroiliac joint 1000.

**[0229]** Referring now to FIG. 34, once the first tubular member end 1048 has been sufficiently advanced into the sacroiliac joint 1000 and the articular surfaces 1016 of the sacroiliac joint 1000 have been sufficiently visualized, the hub 1050 may be removed from the tubular member 1047, leaving the tubular member 1047 fixed within the sacroiliac joint 1000 as an initial guide for tools subsequently used to locate or place the

sacroiliac joint implant 25 non-transversely between the articulating surfaces 1016 of the sacroiliac joint 1000 (e.g., locate the implant 25 non-transversely to the joint plane 1030 generally defined by the articulating surfaces 1016 of the interarticular region 1044 of the sacroiliac joint 1000) or in removal of a portion of the sacroiliac joint 1000 within the region defined by the articular surfaces 1016 to generate an implant receiving space 1029. Alternately, one or more guide pins 1013 may be inserted along substantially the same path of the tubular member 1047 for fixed engagement within the sacroiliac joint 1000 and used in subsequent steps as a guide(s).

**[0230]** Now referring primarily to FIG. 35, a small incision 1053 can be made in the skin at the posterior superior (or as to certain embodiments inferior) aspect of the sacroiliac joint 1000, extending proximal and distal to the tubular member 1047 along the line of the sacroiliac joint 1000 to provide a passage to access the interarticular space between the articulating surfaces 1016 of the sacroiliac joint 1000. More specifically, the small incision 1053 can be made along the joint line 2019 of the sacroiliac joint 1000 in the tissue covering the posterior inferior access region 2016 of the sacroiliac joint articular region 1044. A cannulated probe 1054 may be slidingly engaged with the tubular member 1047 (or guide pin 1013) extending outwardly from the sacroiliac joint 1000 (while the sacroiliac joint may be shown in the figures as being substantially linear for illustrative purposes, it is to be understood that the normal irregular features of the sacroiliac joint have not been removed). The cannulated probe 1054 may have a probe body 1054 of generally cylindrical shape terminating in a spatulate tip 1055 at the end advanced into the sacroiliac joint 1000. A removable cannulated probe handle 1056 may couple to the opposed end of the probe body 1054. The spatulate tip 1055 may be guided along the tubular needle 1047 or guide wire 1013 into the posterior portion of the sacroiliac joint 1000 and advanced to the anterior portion of the sacroiliac joint 1000 under lateral fluoroscopic visualization. The cannulated probe handle 1056 may then be removed providing the generally cylindrical probe body 1054 extending outwardly from the sacroiliac joint 1000 through the incision 1053 made in the skin.

**[0231]** Alternatively, the probe 1054 may be used to guide, advance or place a needle, guide wire or other instrument up to, near, or into the sacroiliac joint 1000.

**[0232]** Additionally, in particular embodiments, probe handle 1056 or the opposed end of the probe body 1054, or both, can be configured to have an interference fit or a luer lock hub to communicate with a syringe barrel 1051 in order to advance contrast, in situ curable biocompatible materials, stem cells, or other suitable compounds through the cannulated probe 1054 or cannulated probe handle 1056.

**[0233]** Now referring primarily to FIG. 36, a passage from the incision 1053 to the sacroiliac joint 1000 can be generated by inserting a cannula 1057 into the incision. A soft tissue dilator 1058 having a blunt end 1059 can be advanced over the probe body 1054, or a plurality of soft tissue dilators of increasing size, until the blunt end 1059 of the soft tissue dilator 1058 and the corresponding cannula end contact the posterior aspect of the sacroiliac joint 1000. More specifically, in one embodiment, the ends of the dilator 1058 and cannula 1057 contact the joint line 2019 of the sacroiliac joint 1000 at the posterior inferior access region 2016 of the sacroiliac joint articular region 1044. The soft tissue dilator 1058 can be removed from within the cannula 1057. The external surface of the cannula 1057 can be sufficiently engaged with the surrounding tissue to avoid having the tissue locate within the hollow inside of the cannula 1057. A non-limiting embodiment of the cannula 1057 provides a tubular body having substantially parallel opposed side walls which terminate in a radius at both ends (lozenge shape) into which a plurality of different jigs can be inserted. Alternatively, as a non-limiting example, according to particular embodiments, cannula 1057 and corresponding dilators 1058 and alignment jigs 1060 can be configured to have tubular bodies with an elliptical or circular cross section.

**[0234]** In some embodiments, the cannula 1057 may be additionally configured to have within or near its walls a light source such as, for example, a fiber optic or a LED light source to assist in visualization of the working area. Also, in some embodiments, irrigation and suction tubing may communicate with the inside passage of cannula 1057.

**[0235]** Now referring to FIG. 37, a first drill jig 1067 can be advanced over the probe body 1054 (or guide pins 1013) and received within the cannula 1057. The probe body 1054 (or guide pins 1013) extending outwardly from the sacroiliac joint 1000 passes through a drill guide hole 1068 of the first drill jig 1067 (or a plurality of guide pins 1013 can extend through a corresponding plurality of guide pin holes 1069). The drill guide hole

1068 can take the form of a circular hole as shown in the Figures, a slot, or other configuration to restrict the movement of the drill bit 1062 within the drill jig 1060 and provide a guide for a drill bit 1062 in relation to the sacroiliac joint 1000. Guide pin holes 1069 can receive guide pins which can be positioned between the articular surfaces 1016 of the sacroiliac joint 1000 to demarcate the zone of desired treatment or safe working zones while using, for example, lateral fluoroscopy. As a non-limiting example, a first guide pin 1013 can be advanced through a first guide pin hole 1069, or alternatively a guide pin 1013 is first inserted into the sacroiliac joint 1000 and subsequently a guide jig 1067 is advanced over the guide pin 1013, the first guide pin 1013 can enter near inferior end 2022 of the posterior inferior access region 2016 of the sacroiliac joint articular region 1044 via the sacroiliac joint line 2019 to border a portion of the greater sciatic notch 2008 thereby allowing a medical person, computer guided surgical system, or other observer to more easily highlight under x-ray a border which should not be crossed during the procedure due to the presence of nerve and other structures. Additionally, as a non-limiting example, first guide pin 1013 can be configured as an electrode, insulated from the operator and the patient's soft tissues, and may be connected to a monitor to signal to an operator or surgeon when implant 25, configured with a stimulating electrode (NM), as discussed below, comes into contact with first guide pin. Similarly, a second guide pin 1013 can be placed in another guide pin hole 1069 to demarcate a second limit to a desired zone of treatment, or safe working zone. For example, a second guide pin 1013 can enter near the superior end 2018 of the posterior inferior access region 2016 of the sacroiliac joint articular region 1044 via the sacroiliac joint line 2019 to be positioned to border an area of the sacroiliac joint 1000 such as a transition zone between the extra-articular 3007 and the interarticular region 1044 which, for example, has been highlighted by contrast material as above described.

**[0236]** Now referring to FIG. 38, a cannulated drill bit 1070 can be advanced over the probe body 1054 and within a drill guide hole 1068 of the first drill jig 1067. The cannulated drill bit 1070 under fluoroscopic guidance can be advanced into the interarticular region 1044 between the articulating surfaces 1016 of the sacroiliac joint 1000 to produce a first bore 1071 (shown in broken line) to a determined depth. As to certain embodiments of the method, an amount of articular cartilage or other tissues from

between the articular surfaces 1016 of the sacroiliac joint 1000 can be removed sufficient to allow embodiments of the sacroiliac joint implant 25 to be implanted in replacement of the removed articular cartilage or tissue. Because the method removes the degenerative articular cartilage or tissue between the articular surfaces 1016 of the sacroiliac joint 1000, the articular surfaces 1016 of the sacroiliac joint 1000 can remain intact or substantially intact allowing the sacroiliac joint implant 25 to be non-transversely located between the articular surfaces 1016 of the sacroiliac joint 1000. Understandably, other instruments can be utilized separately or in combination with a cannulated drill bit 1062 for the removal of articular cartilage or tissue between articular surfaces 1016 such as: endoscopy tools, box chisels, side cutting router bits, burs, flexible burs and bits, hole saws, curettes, lasers (such as CO<sub>2</sub>, Neodymium/Y AG (yttrium-aluminum- garnet), argon, and ruby), electrosurgical equipment employing electromagnetic energy (the cutting electrode can be a fine micro-needle, a lancet, a knife, a wire or band loop, a snare, an energized scalpel, or the like) where the energy transmitted can be either monopolar or bipolar and operate with high frequency currents, for example, in the range of about 300kHz and about 1000 kHz whether as pure sinusoidal current waveform where the "crest factor" can be constant at about 1.4 for every sinus waveform, and a voltage peak of approximately 300 V to enable a "pure" cutting effect with the smallest possible coagulation effect or as amplitude modulated current waveforms where the crest factor varies between 1.5 and 8, with decreasing crest factors providing less of a coagulation effect. Electrosurgical waveforms may be set to promote two types of tissue effects, namely coagulation (temperature rises within cells, which then dehydrate and shrink) or cut (heating of cellular water occurs so rapidly that cells burst). The proportion of cells coagulated to those cut can be varied, resulting in a "blended" or "mixed" effect. Additionally, a fully rectified current, or a partially rectified current, or a fulguration current where a greater amount or lateral heat is produced can be employed to find the articular surfaces of the joint and aid in advancing a probe or guide wire into a position in between the articulating surfaces. These currents can effectively degrade the cartilage and allow advance into the joint without grossly penetrating much beyond the cartilage.

**[0237]** Now referring to FIG. 39, as to certain embodiments of the invention, the first drill jig 1067 can be removed from within the cannula 1057 and a second drill jig 1072

can be advanced over the probe body 1054 and received within the cannula 1057; however, the invention is not limited to any particular number of drill jigs and as to certain embodiments of the method the first drill jig 1067 can include all the required drill guide hole(s) 1068 (or slots or other configurations of the drill guide) and as to other embodiments of the method a plurality of drill jigs can be utilized in serial order to provide all the drill guide holes 1068. As to the particular embodiment of the invention shown by the Figures, the first drill jig 1067 can provide one or more additional drill guide holes 1068 which guide in relation to the first bore 1071 a second or more cannulated drills 1062 of the same or different configuration to be inserted within and advanced into the sacroiliac joint 1000 to produce a second bore 1073 (generally shown in broken line as 1071/1073) or a plurality of bores within the sacroiliac joint 1000 spaced apart in predetermined pattern to allow removal of sufficient articular cartilage 1016 or other tissue from the interarticular space of sacroiliac joint 1000 for placement of embodiments of the sacroiliac joint implant 25 within the region defined by and between the paired articular surfaces 1016 of the sacroiliac joint 1000. As to certain methods of the invention, the first drill jig 1067 or the second drill jig 1072 or a plurality of drill jigs can be utilized in serial order to remove a portion of the sacroiliac joint 1000 for generation of an implant receiving space 1029. As these embodiments of the method, articular cartilage or other tissues and sufficient subchondral bone can be removed from between the articular surfaces 1016 of the sacroiliac joint 1000 sufficient to allow placement of certain embodiments of the sacroiliac joint implant 25 and one or more radial member receiving channels 1074 can be cut into at least one of the articular surfaces 1016 of said sacroiliac joint 1000 sufficient to receive other embodiments of the sacroiliac implant 25. The one or more radial member receiving channels 1074 can be cut a depth into the subchondral, cortical bone or cancellous bone of the sacrum 1004 or ilium 1005.

**[0238]** Now referring primarily to FIG. 40, in a subsequent step, the last in the serial presentation of drill jigs 1067, 1072 can be removed from within the cannula 1057 and a broach jig 1075 can be advanced over the probe body 1054 to locate within the cannula 1057. The broach jig 1075 can include a broach guide hole 1076 which receives a first broach end 1077 of a cannulated broach 1078 advanced over the probe body 1054. The first broach end 1077 can have a configuration which can be advanced into the sacroiliac

joint 1000. As to certain embodiments of the method, the first broach end 1077 can be adapted to remove an amount of articular cartilage and other tissue from between the articular surfaces 1016 within the articular region 1044 of the sacroiliac joint 1000 for non-transverse placement of a sacroiliac joint implant 25 having an elongate body 45, or having an elongate body 45 and a first radial member 50, or an elongate body 45 having a first and second radial members 50 between the articular surfaces 1016 of the sacroiliac joint 1000. As to other embodiments of the method, the cannulated broach 1078 can remove a sufficient portion of the sacroiliac joint 1000 to generate an implant receiving space 1029 to receive embodiments of the sacroiliac joint implant 25 having an elongate body 45, an elongate body 45 and at least one radial member 50 adapted for non-transverse placement between the articular surfaces 1016 or at least one radial member 55 adapted to extend into the bone of the sacrum 1004 or the ilium 1005.

**[0239]** As a non-limiting example, FIG. 40 shows a broach 1078 configured to remove a portion of the sacroiliac joint 1000 to produce an implant receiving space 1029 to receive embodiments of the sacroiliac joint implant 25 having an elongate body 45 to which a first radial member 50 and a second radial member 50 extend along the longitudinal axis CA of the elongate body 45 in substantially opposed relation adapted to locate between the articular surfaces 1016 of the sacroiliac joint 1000 and further having a third radial member 55 and a fourth radial member 55 which extend along the longitudinal axis CA of the elongate body 45 in substantially opposed relation adapted to correspondingly extend correspondingly into the bone of the sacrum 1004 and the ilium 1005.

**[0240]** The implant receiving space 1029 and the sacroiliac joint implant 25 may be configured having related dimension relations such that placement of the sacroiliac joint implant 25 within the implant receiving space 1029 disposes the sacrum 1004 and the ilium 1005 in substantially immobilized relation and substantially avoids alteration of the positional relation of the sacrum 1004 and the ilium 1005 from the normal condition, or avoids driving together or driving apart the sacrum 1004 from the ilium 1005 outside of or substantially outside of the normal positional relation. An intention in selecting configurations of the sacroiliac joint implant 25 and the implant receiving space 1029

being immobilization of the sacrum 1004 in relation to the ilium 1005 while maintaining the sacroiliac joint 1000 in substantially normal or substantially normal positional relation, or returning the sacroiliac joint 1000 to a substantially normal positional relation to correct a degenerative condition of the sacroiliac joint 1000.

**[0241]** As a non-limiting example, configurations of an implant receiving space 1029 allow embodiments of the sacroiliac joint implant 25 to be placed non-transversely between the caudal portion 1086 of the articular surfaces 1016 of the sacroiliac joint 1000. While certain embodiments of the sacroiliac joint implant 25 may only provide an elongate body 45 which locates within a correspondingly configured implant receiving space 1029 to engage at least a portion of the bone of the ilium 1005 or sacrum 1004, the invention is not so limited. An anchor member 30 may be inserted through the graft window 40 in the implant 25 and into the sacrum 1004 and ilium 1005 to fix the location of the fixation fusion implant 25 within the implant receiving space 1029.

**[0242]** While the preceding discussion is given in the context of the implant 25 being implanted non-transversely in the caudal portion 1086 of the sacroiliac joint 1000, in other embodiments, the implant 25 may be implanted in other locations within the sacroiliac joint. For example, as disclosed in U.S. Patent Application 12/998,712, which is incorporated herein by reference, in some embodiments, the implant 25 may be implanted non-transversely in the cranial portion of the sacroiliac joint 1000 by the similar procedures or steps as above described with the incision and generation of the passage to the superior articular portion of the sacroiliac joint 1000. The implant may also be implanted in the sacroiliac joint in such a manner so as to extend between the cranial and caudal portions, as also disclosed in U.S. Patent Application 12/998,712.

**[0243]** Once the implant receiving space 1029 has been created, the implant 25 may be mounted to the delivery tool 20 as described herein previously and as illustrated in FIGS. 11A – 11B. The implant 25 may be supported off of the distal end 120 of the implant arm 110 of the delivery tool 20 and positioned such that the distal end 406 of the implant 25 begins to enter the sacroiliac joint articular region 1044 via the posterior inferior access region 2016, which is described in detail above. In entering the sacroiliac joint space 1044, the implant 25 may be oriented such that its intraarticular element 108 is



oriented generally parallel to, and aligned with, the sacroiliac joint space 1044 and the implant's keels 414/416 are generally transverse to the joint plane 1030. The longitudinal axis  $LCA_2$  of the implant arm 110 of the delivery tool 20 has a generally anterior trajectory that is located within the joint plane 1030. Alternatively, according to particular embodiments, as a non-limiting example, the longitudinal axis  $LCA_2$  of the implant arm 110 of the delivery tool 20 can have a trajectory which can be defined as being generally lateral or, in particular embodiments, generally posterior. In some embodiments, when the implant 25 is being delivered into the joint space, the implant arm 110 can be said to be at least one of generally superior or cephalad the sciatic notch.

**[0244]** The implant 25 may be inserted via the implant arm 110 of the delivery tool 20 into the caudal region 1086 of the sacroiliac joint articular region 1044. The implant 25 may enter the posterior inferior access region, and may be further advanced into the caudal region 1086 of the sacroiliac joint articular region 1044, in an orientation such that the implant arm 110 and wide planar members 50 are in the joint plane and the longitudinally extending edge 3050 of the wide planar member 50 next to the inferior boundary segment 3002 is generally parallel to, and immediately adjacent to, the inferior boundary segment 3002. The distal end 42 of the implant is heading generally perpendicular to, and towards, the anterior boundary segment 3004.

**[0245]** A depth gage may be used to determine the implant length. An appropriate trial may be used to determine the implant height and width for the prepared joint space. An appropriate broach may be used to finish preparing the implant receiving space. The cutting tools, trials and broaches should not be advanced beyond the anterior boundary of the sacroiliac joint or into the greater sciatic notch. Fluoroscopy may be used to obtain a lateral view to assist with boundary identification.

**[0246]** The implant may be inserted into the implant receiving space while monitoring the lateral view in order to not advance implant into the greater sciatic notch or beyond the anterior boundary of the sacroiliac joint. The anchor arm may be used align and advance anchor soft tissue protector up to the skin (either over the ilium for a generally lateral to medial trajectory, or, over the sacrum for a generally medial to lateral trajectory). The soft tissue may be dissected bluntly to the ilium or sacrum. The soft tissue protector may be

inserted up to the bone of the ilium or sacrum. A guide wire may be advanced using the drill sleeve held in place by the targeting arm aligned with the bore of the implant or alternatively aligned to place an anchor around the implant while avoiding hitting the implant.

**[0247]** Although various representative embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of the inventive subject matter set forth in the specification. All directional references (e.g., top, bottom) are only used for identification purposes to aid the reader's understanding of the embodiments of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention unless specifically set forth in the claims. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other.

**[0248]** In methodologies directly or indirectly set forth herein, various steps and operations are described in one possible order of operation, but those skilled in the art will recognize that steps and operations may be rearranged, replaced, or eliminated without necessarily departing from the spirit and scope of the present invention. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the spirit of the invention as defined in the appended claims.

**[0249]** The foregoing merely illustrates the principles of the invention. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. It will thus be appreciated that those skilled in the art will be able to devise numerous systems, arrangements and methods which, although not explicitly shown or described herein, embody the principles of the invention and are thus within the spirit and scope of the present invention. From the

above description and drawings, it will be understood by those of ordinary skill in the art that the particular embodiments shown and described are for purposes of illustrations only and are not intended to limit the scope of the present invention. References to details of particular embodiments are not intended to limit the scope of the invention.

**CLAIMS**

What is claimed is:

1. An implant assembly for the fusion of a sacroiliac joint of a subject, the implant assembly comprising:

a) an implant comprising:

an intraarticular element extending an implant length between an implant proximal end and an implant distal end, and further extending an implant height between an implant upper edge and an opposed implant lower edge, the intraarticular element comprising:

a first articular face and an opposed second articular face extending the implant height and at least a portion of the implant length;

a graft window formed within at least a portion of the intraarticular element and extending through the intraarticular element from the first articular face to the second articular face; and

at least one keel attached to the intraarticular element along at least a portion of the implant length; and

b) an anchor comprising a proximal anchor end and a distal anchor end, wherein the proximal anchor end and the distal anchor end are positioned on opposite sides of a plane coincident with the first articular face or coincident with the second articular face;

wherein the intraarticular element is configured for implantation within a joint space of the sacroiliac joint with the first and second articular faces contacting articular surfaces of the sacroiliac joint, and the anchor is configured for insertion transversely across the joint space of the sacroiliac joint.

2. The implant assembly of claim 1, wherein each keel of the at least one keels projects essentially perpendicularly outward from the first articular face and from the second articular face, ending in a first edge and a opposite second edge separated by a keel width.

3. The implant assembly of claim 2, wherein the first edge and the second edge are in parallel alignment along the implant length.
4. The implant assembly of claim 2, wherein the first edge and the second edge distally converge toward one another.
5. The implant assembly of claim 4, wherein the at least one keel comprises a first keel extending from the implant proximal end to the implant distal end, wherein the first keel is attached along the implant upper edge or the implant lower edge.
6. The implant assembly of claim 5, wherein the at least one keel further comprises a second keel extending from the implant proximal end to the implant distal end, wherein the second keel is attached along the implant upper edge or the implant lower edge opposite to the first keel.
7. The implant assembly of claim 6, wherein the keel width of the first keel is equal to the keel width of the second keel.
8. The implant assembly of claim 6, wherein the keel width of the first keel is larger than the keel width of the second keel.
9. The implant assembly of claim 1, wherein the at least one keel comprises a first keel extending from the implant proximal end to the implant distal end, wherein the first keel is attached to the intraarticular element between the implant upper edge and the implant lower edge.
10. The implant assembly of claim 7, wherein the first keel further comprises a keel gap extending over an intersection of the first keel with the graft window.
11. The implant assembly of claim 1, wherein the graft window extends through the intraarticular element along a window axis forming an angle ranging from about 45 degrees to about 90 degrees relative to a plane parallel to the first articular face or the second articular face.
12. The implant assembly of claim 1, wherein the graft window further comprises a

window length extending along a portion of the implant length, the portion ranging from about 40% to about 70% of the implant length.

13. The implant assembly of claim 1, wherein the window length is situated between the implant proximal end and the implant distal end.

14. The implant assembly of claim 1, wherein one end of the window length is coincident with the implant distal end.

15. The implant assembly of claim 1, wherein the anchor passes through the graft window.

16. The implant assembly of claim 1, wherein the anchor passes outside of the implant above the upper edge or below the lower edge.

17. The implant assembly of claim 1, wherein the intraarticular element further comprises:

a proximal face situated at the implant proximal end; and

a threaded bore extending from the proximal face along the implant length toward the implant distal end and opening distally into the graft window.

18. The implant assembly of claim 1, wherein the at least one keel and the intraarticular element taper distally into a distal edge situated at the implant distal end.

19. The implant assembly of claim 1, wherein the implant length ranges from about 20 mm to about 50 mm.

20. The implant assembly of claim 1, wherein the implant height ranges from about 10 mm to about 20 mm.

21. The implant assembly of claim 1, wherein an intraarticular thickness between the first articular face and the second articular face ranges from about 5 mm to about 7 mm.

22. The implant assembly of claim 2, wherein the keel width ranges from about 10 mm

to about 20 mm.

23. A sacroiliac joint fusion system comprising:

a) a joint implant comprising: a longitudinal axis extending between a proximal end and a distal end of the joint implant; and a first bore extending non-parallel to the longitudinal axis;

b) an anchor element configured to be received in the first bore; and

c) a delivery tool comprising:

i) an implant arm comprising a shaft extending between a proximal end and a distal end of the implant arm and a handle at the proximal end, the distal end of the implant arm configured to releasably couple to the proximal end of the joint implant; and

ii) an anchor arm rotatably coupled to the implant arm at a first end and comprising an anchoring guide at a second end that is configured to align the anchor element in a trajectory such that the anchor element will be received within the first bore when the anchor element is guided by the anchoring guide, wherein relative rotation of the anchor arm about a longitudinal axis of the implant arm is limited to trajectories of the anchor element that are configured to align the anchor element within the first bore,

wherein a final manufactured configuration of the delivery tool and the joint implant are such that, when the system is assembled such that the implant arm is releasably coupled to the joint implant, a delivery arrangement automatically exists such that the anchor arm is oriented to align the trajectory of the anchor element and to deliver the anchor element within the first bore.

24. The system of claim 23, wherein rotation of the anchor arm relative to the implant arm is limited to about 60 degrees of rotation.

25. The system of claim 24, wherein the first bore extends through a pair of planar faces that are opposite of each other, the pair of planar faces defining a first plane therein that also extends in a direction of the longitudinal axis of the joint implant, the first plane

being substantially perpendicular to a second plane defined by the implant arm and the anchor arm in a neutral position, the neutral position orienting the anchor element substantially perpendicularly to the first plane.

26. The system of claim 25, wherein the about 60 degrees of rotation includes about 30 degrees of rotation of the second plane relative to the first plane on either side of the neutral position.

27. The system of claim 23, wherein the rotation of the anchor arm relative to the implant arm is limited to less than 360 degrees of rotation.

28. The system of claim 23, wherein the rotation of the anchor arm relative to the implant arm is limited to less than 180 degrees of rotation.

29. The system of claim 23, wherein the relative rotation of the anchor arm about a longitudinal axis of the implant arm is limited by a cam mechanism within a channel.

30. The system of claim 29, wherein the implant arm includes the cam mechanism and the anchor arm includes the channel, wherein the cam mechanism includes a cam-shape that is configured to only partially rotate within the channel.

31. The system of claim 29, wherein the cam mechanism is slidably coupled within the channel.

32. A sacroiliac joint fusion system comprising:

a) a joint implant comprising: a longitudinal axis extending between a proximal end and a distal end of the joint implant; and a first bore extending non-parallel to the longitudinal axis;

b) an anchor element configured to be received in the first bore; and

c) a delivery tool comprising:

i) an implant arm comprising a shaft extending between a proximal end and a distal end of the implant arm and a handle at the proximal end, the distal end of the



implant arm configured to releasably couple to the proximal end of the joint implant; and

ii) an anchor arm comprising an anchor guide coupled to the implant arm via a distal articulating member and a proximal articulating member, the distal articulating member rotatably coupled with implant arm at a first end and rotatably coupled with the anchor guide at a second end, the proximal articulating member slidably coupled with the implant arm at a third end and configured to slidably translate distal-proximal along the shaft of the implant arm, the proximal articulating member rotatably coupled with anchor guide at a fourth end, the anchor guide configured to align the anchor element in a trajectory such that the anchor element will be received within the first bore when the anchor element is guided by the anchor guide,

wherein, when the third end of the proximal articulating member is positioned in a proximal-most position, the anchor guide is configured to align the anchor element in the trajectory, and when the third end of the proximal articulating member is positioned in a distal-most position, the anchor guide is configured to align the anchor element in the trajectory.

33. The system of claim 32, wherein a final manufactured configuration of the delivery tool and the joint implant are such that, when the system is assembled such that the implant arm is releasably coupled to the joint implant, a delivery arrangement automatically exists such that the anchor arm is oriented to align the trajectory of the anchor element and to deliver the anchor element within the first bore.

34. The system of claim 32, wherein the first end is positioned distally of the third end on the implant arm.

35. The system of claim 34, wherein the second end is positioned distally of the fourth end on the anchor guide.

36. The system of claim 32, wherein the implant arm further comprises an actuation assembly that is configured to releasably couple and decouple with the joint implant.

37. The system of claim 32, wherein the actuation assembly is rotationally actuated.

38. The system of claim 32, wherein an angle of the trajectory relative to the longitudinal axis of the joint implant is different when the third end is in the proximal-most position and the distal-most position.
39. The system of claim 32, wherein, when the third end is in the proximal-most position, an angle between the trajectory and a longitudinal axis of the shaft of the implant arm is about 34 degrees.
40. The system of claim 32, wherein, when the third end is in the distal-most position, an angle between the trajectory and a longitudinal axis of the shaft of the implant arm is about 45 degrees.
41. The system of claim 32, wherein the first end of the distal articulating member includes a stop feature that inhibits rotation of the first end beyond a certain point.
42. The system of claim 41, wherein the stop feature is configured to contact the shaft of the implant arm when the third end of the proximal articulating member is in the proximal-most position.
43. A sacroiliac joint fusion system comprising:
- a) a joint implant comprising: a longitudinal axis extending between a proximal end and a distal end of the joint implant; and a first bore extending non-parallel to the longitudinal axis;
  - b) an anchor element configured to be received in the first bore; and
  - c) a delivery tool comprising:
    - i) an implant arm comprising a shaft extending between a proximal end and a distal end of the implant arm and a handle at the proximal end, the distal end of the implant arm configured to releasably couple to the proximal end of the joint implant; and
    - ii) an anchor arm rotatably coupled to the implant arm via a rotatable joint at a first end and comprising an anchoring guide at a second end that is configured to align

the anchor element in a first trajectory such that the anchor element will be received within the first bore when the anchor element is guided by the anchoring guide, wherein the rotatable joint is configured to limit rotation of the anchor arm to predefined trajectories of the anchor element that are configured to align the anchor element within the first bore,

wherein a final manufactured configuration of the delivery tool and the joint implant are such that, when the system is assembled such that the implant arm is releasably coupled to the joint implant, a delivery arrangement automatically exists such that the anchor arm is oriented to align the first trajectory of the anchor element and to deliver the anchor element within the first bore.

44. The system of claim 43, wherein a first angle is defined between the shaft of the implant arm and the anchor arm, wherein rotation of the anchor arm relative to the implant arm is limited to varying of only the first angle.

45. The system of claim 43, wherein a relative decrease of the first angle causes the anchor element to angle towards a proximal portion of the first bore and wherein a relative increase in the first angle causes the anchor element to angle towards a distal portion of the first bore.

46. The system of claim 43, wherein rotation of the anchor arm is limited to rotation about a longitudinal axis of the implant arm.

47. The system of 43, wherein the anchoring guide comprises a plurality of laterally offset guides, each of the plurality of laterally offset guides configured to align a unique trajectory of an anchoring element.

48. The system of claim 47, wherein the plurality of laterally offset guides comprises a first, a second, and a third guide, the first guide aligning a trajectory of a first anchoring element dorsal to the joint implant, the second guide aligning a trajectory of a second anchoring element within the first bore, the third guide aligning a trajectory of a third anchoring element ventral to the joint implant.

49. The system of claim 43, further comprising an auxiliary guide arm rotatably

coupled to the implant arm at a third end and comprising an auxiliary guide at a fourth end that is configured to align an auxiliary element in a second trajectory such that the auxiliary element will be delivered along the second trajectory when guided by the auxiliary guide, the auxiliary guide arm configured to adjust in at least one degree of freedom.

50. The system of claim 49, wherein the auxiliary element is a needle.

51. The system of claim 43, wherein the joint implant defines an I-beam shaped cross-section having a top keel, a bottom keel, and an intraarticular element extending between and coupling the top keel and the bottom keel, the first bore extending through the intraarticular element.

52. A method of sacroiliac joint fusion, the method comprising:

a) approaching a sacroiliac joint space with a joint implant comprising: a longitudinal axis extending between a proximal end and a distal end; an intraarticular element extending between and coupling a first keel and a second keel; and a first bore extending between opposite faces of the intraarticular element, the intraarticular element, the first, and the second keel extending from the proximal end to the distal end;

b) delivering the joint implant into the sacroiliac joint space, the joint implant being oriented in the sacroiliac joint space such that the intraarticular element is generally coplanar with a plane defined by the sacroiliac joint space.

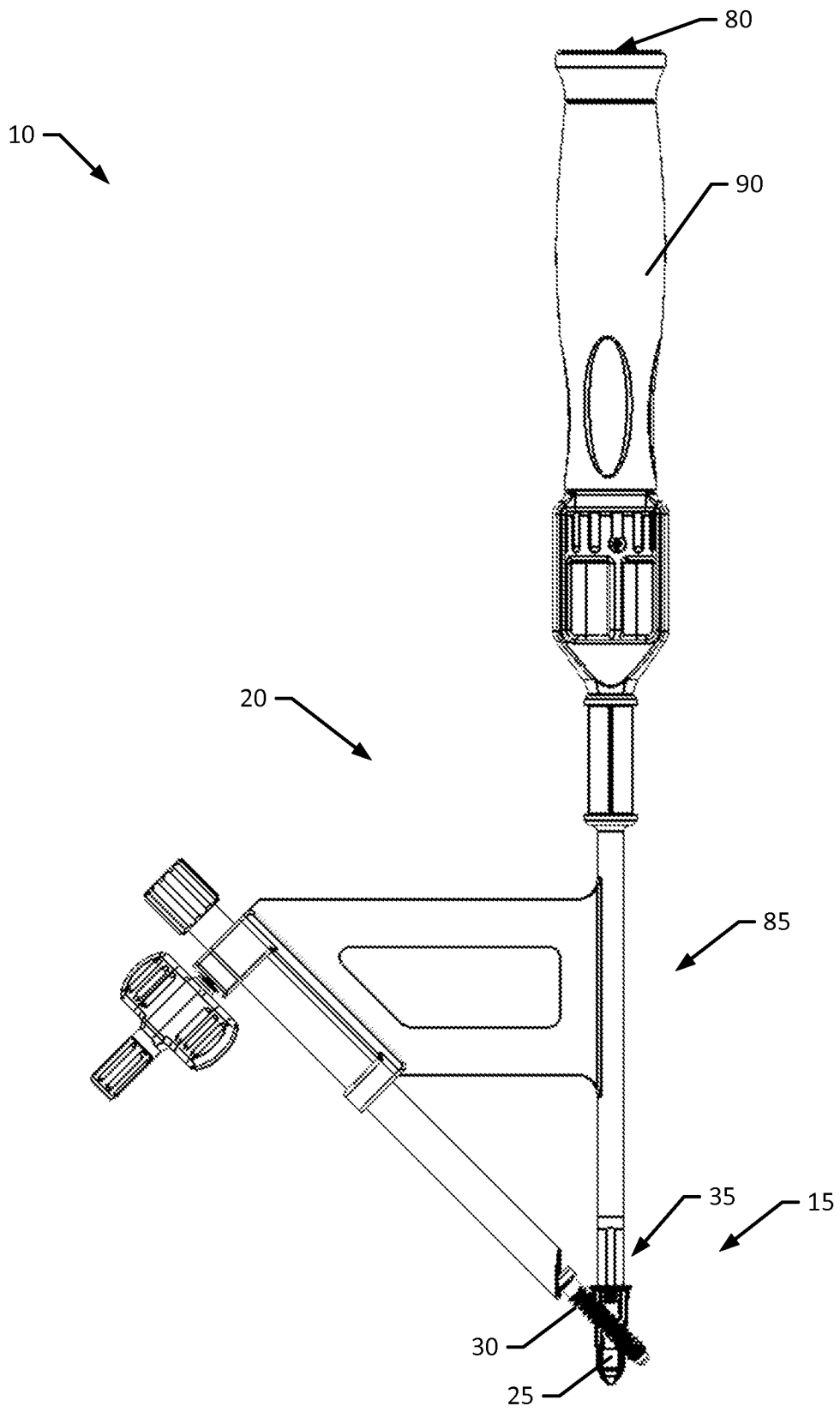


FIG. 1

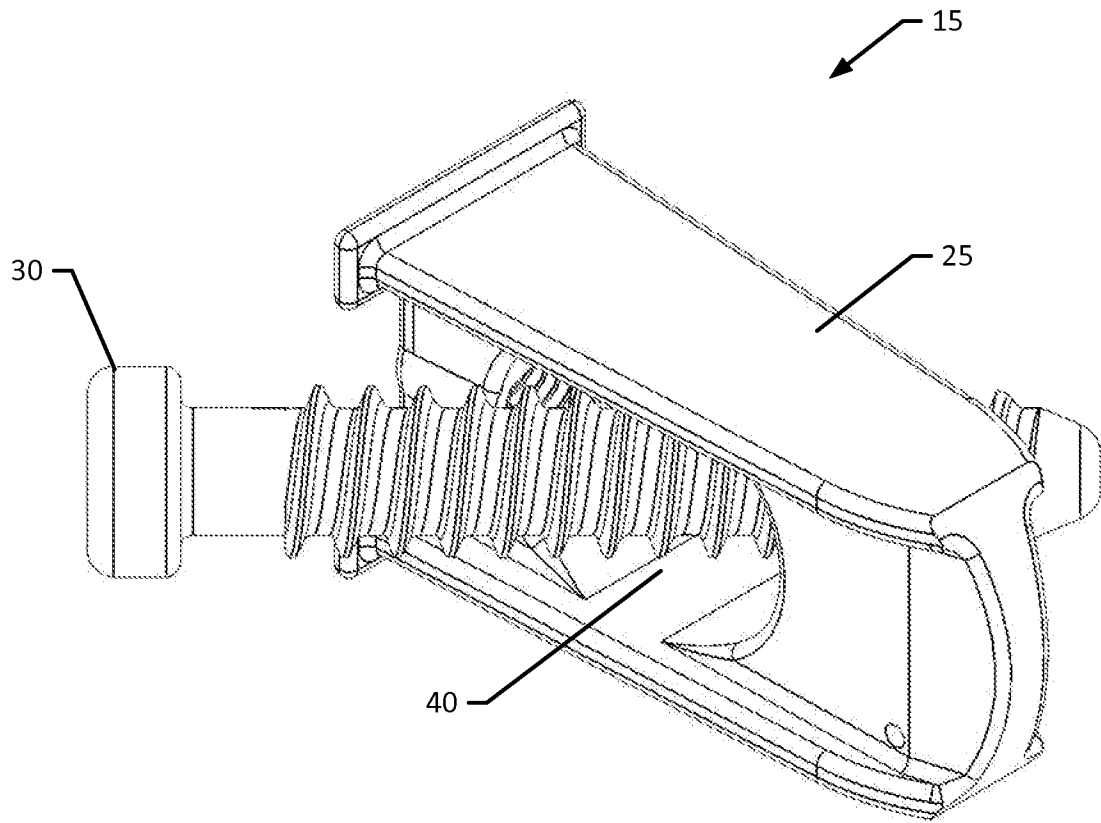


FIG. 2

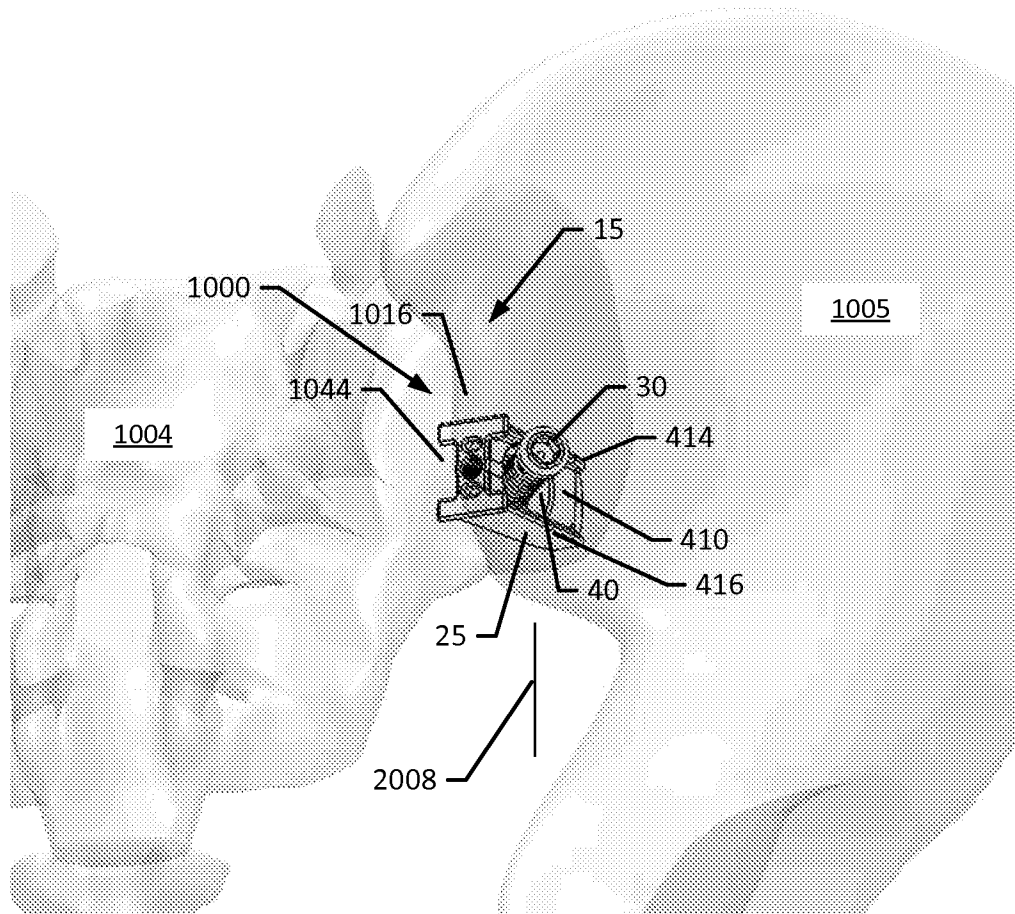


FIG. 3

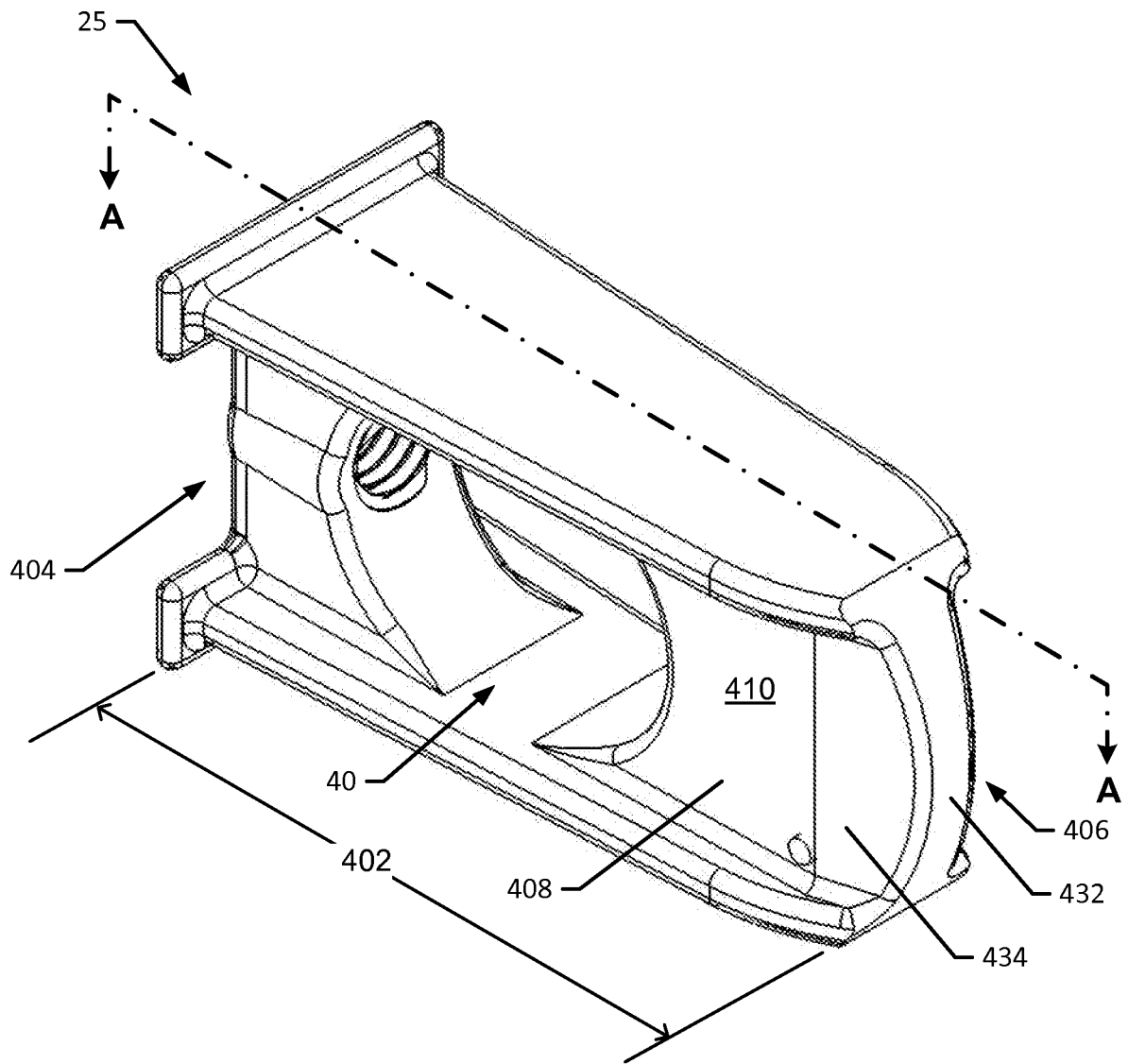


FIG. 4A



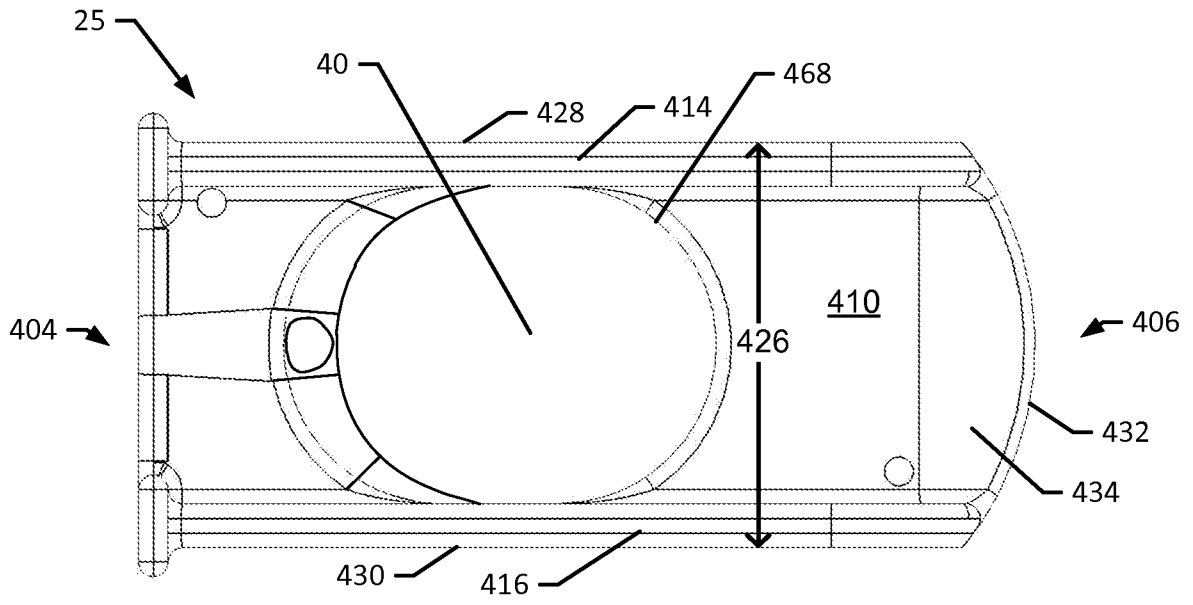


FIG. 4B

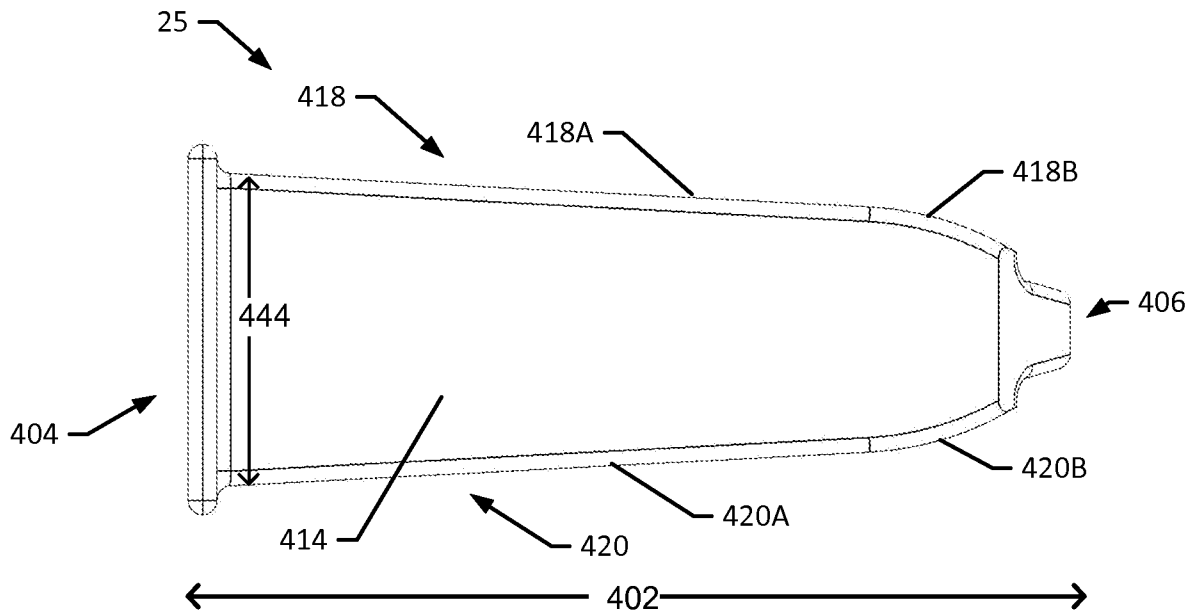
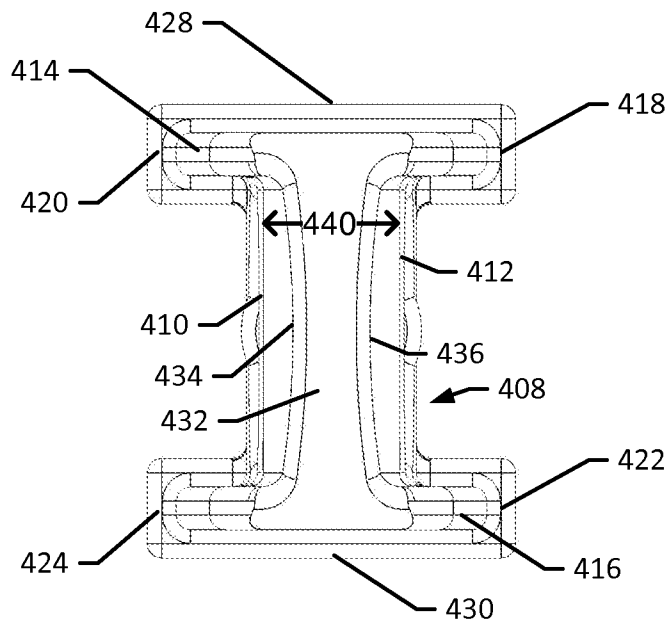
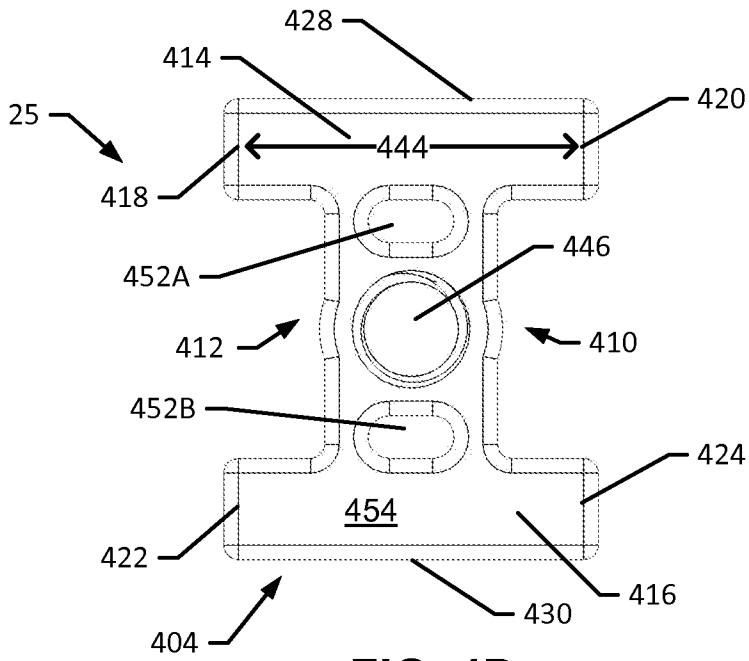


FIG. 4C



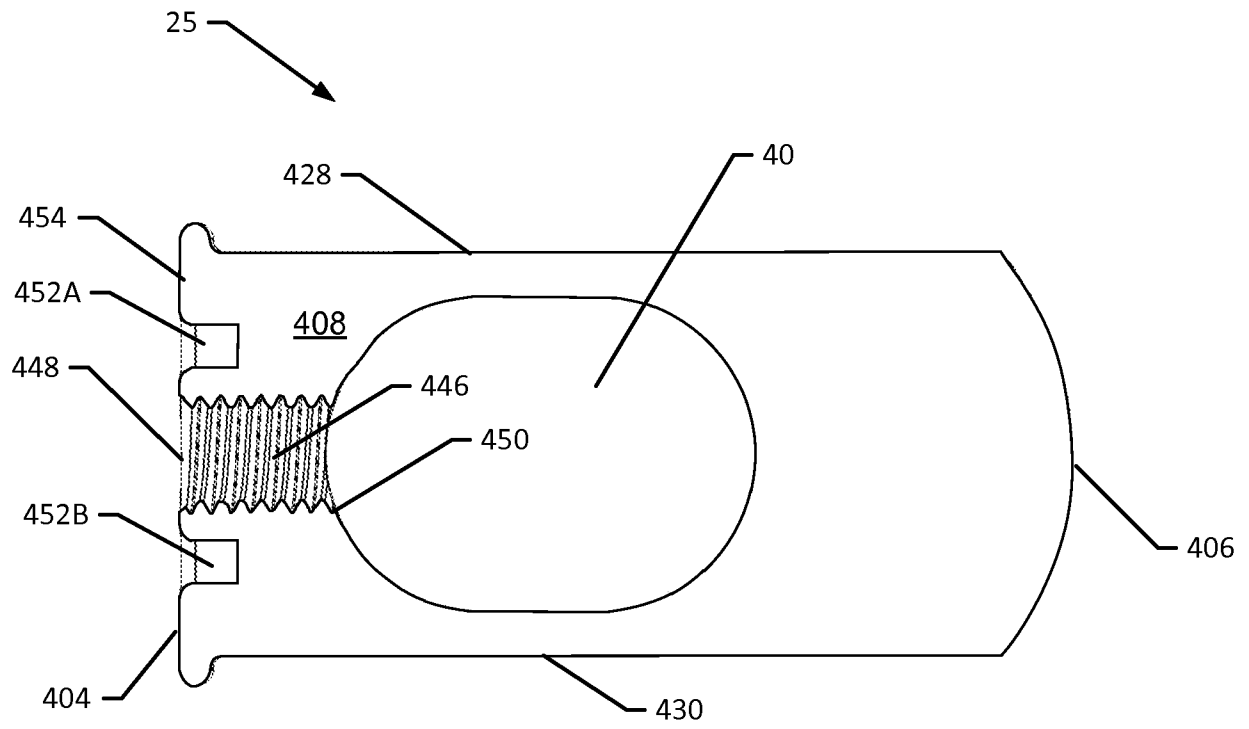


FIG. 4F

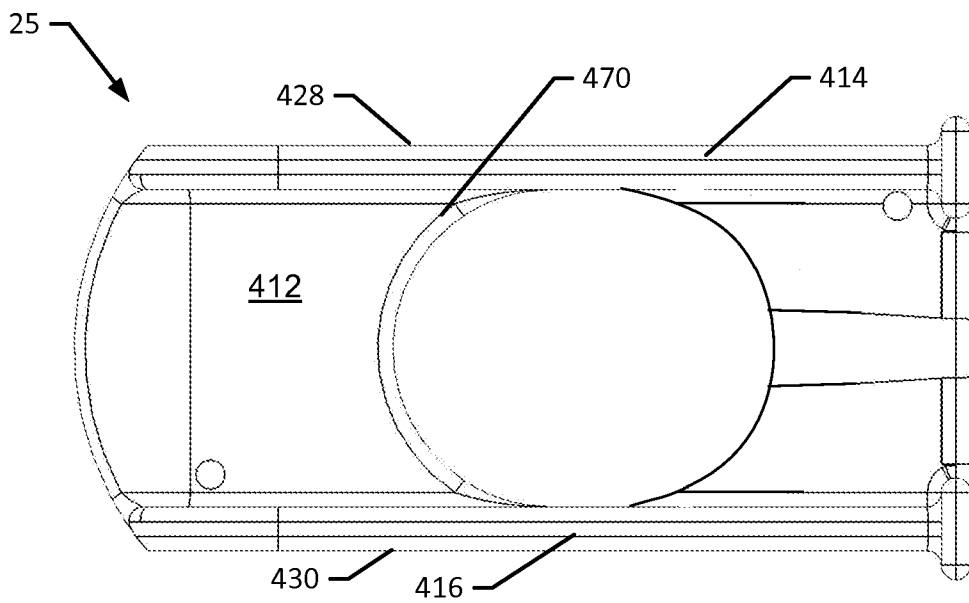


FIG. 4G

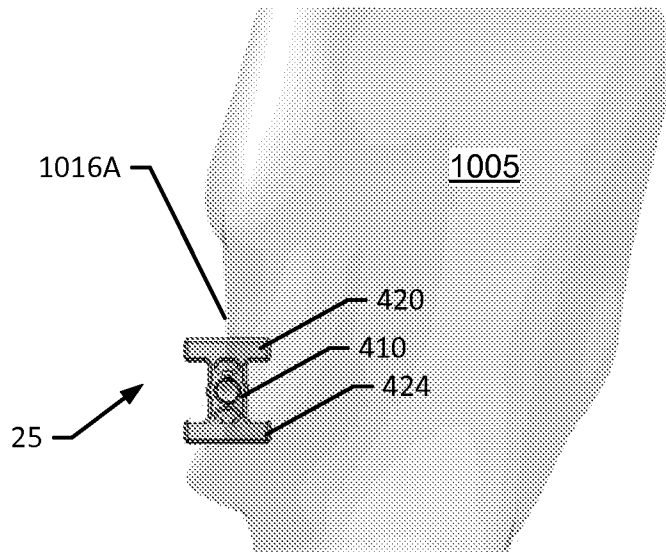


FIG. 5A

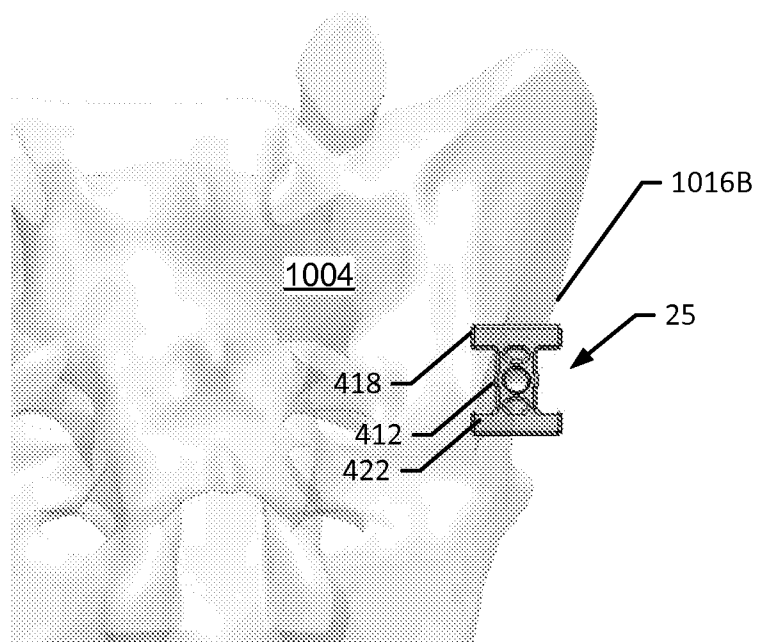
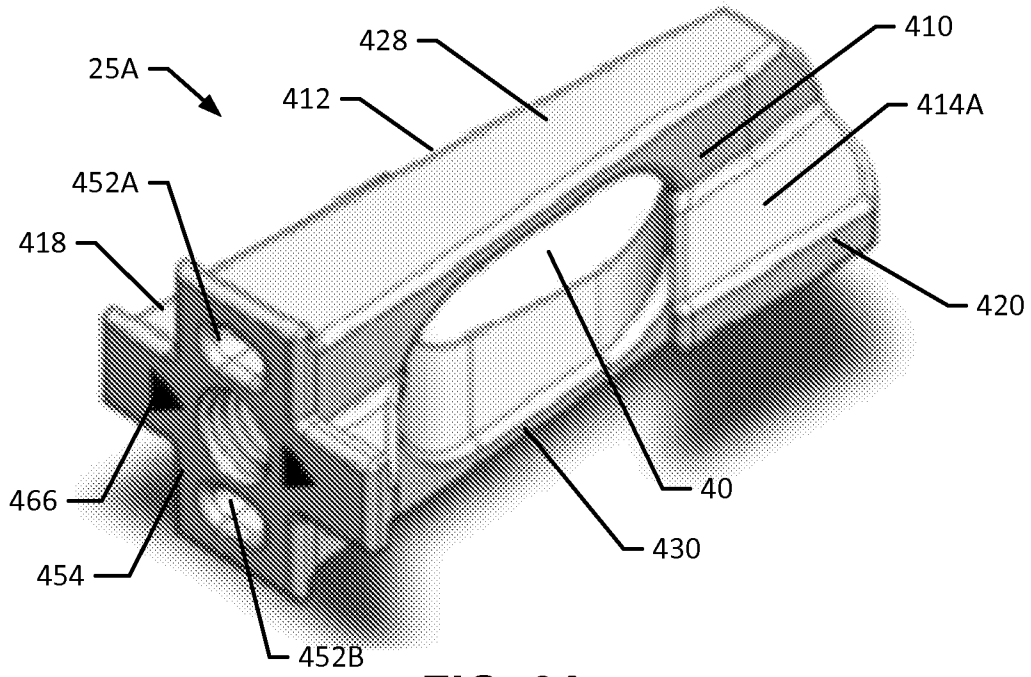
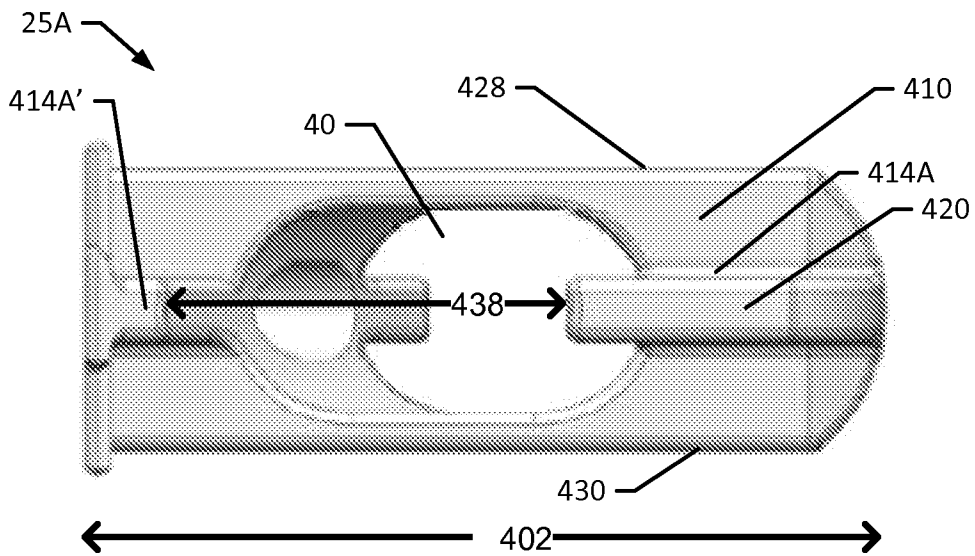


FIG. 5B



**FIG. 6A**



**FIG. 6B**

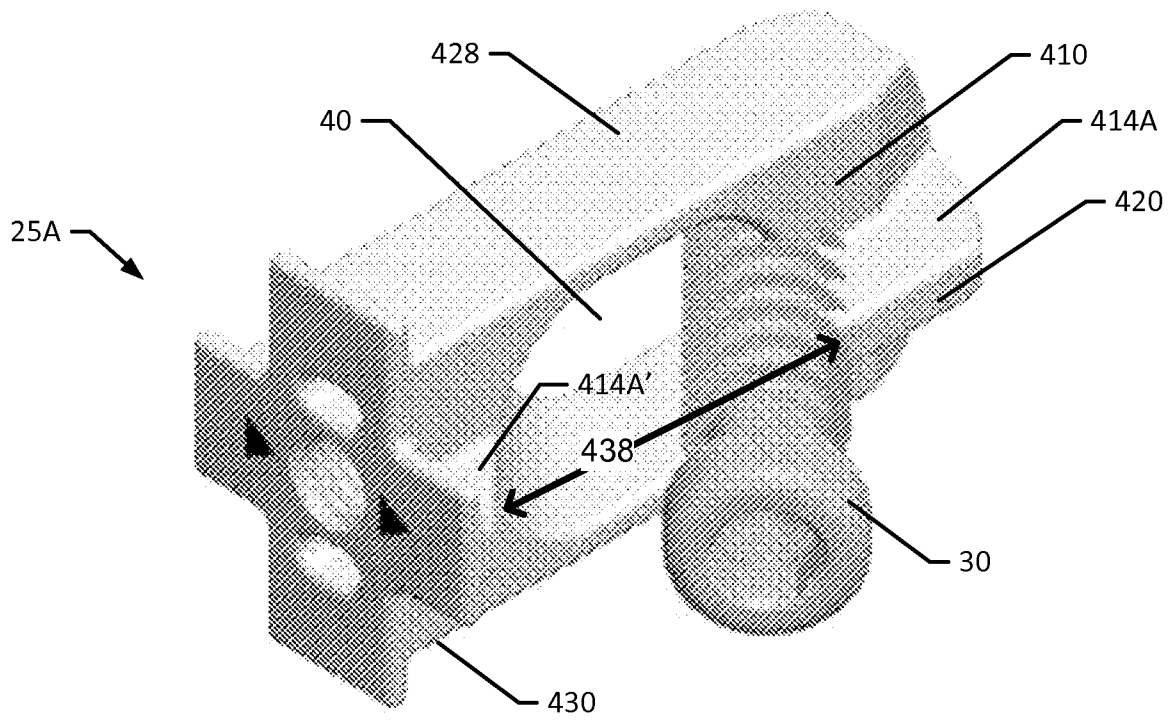
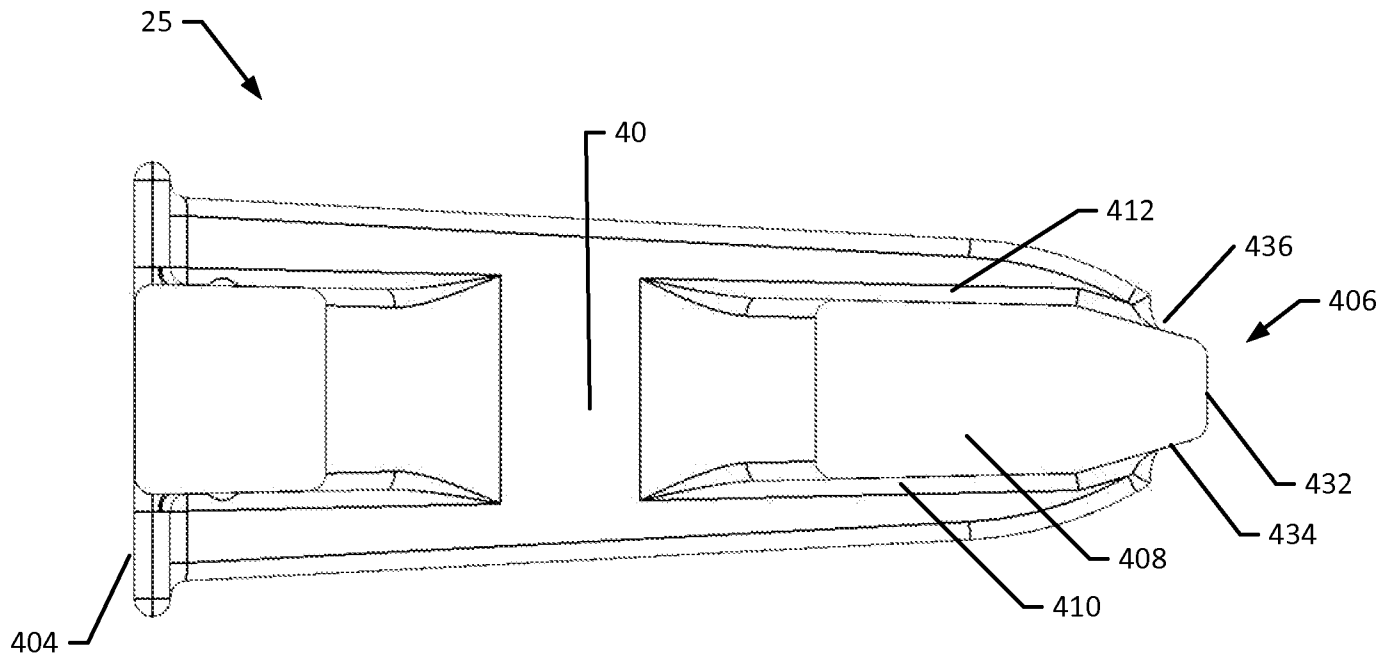
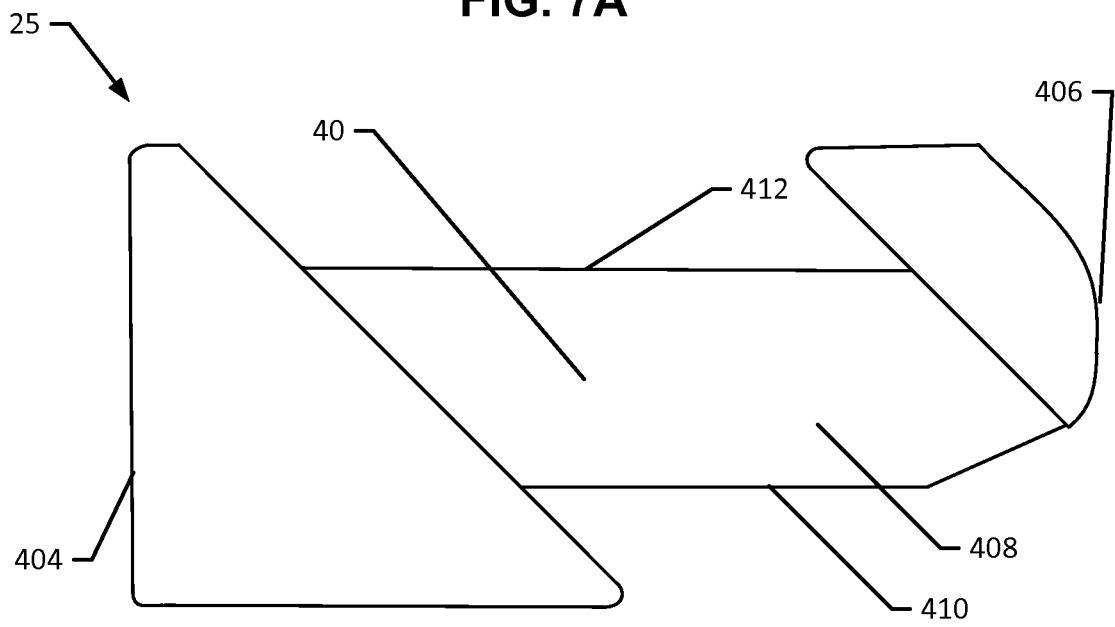


FIG. 6C



**FIG. 7A**



**FIG. 7B**

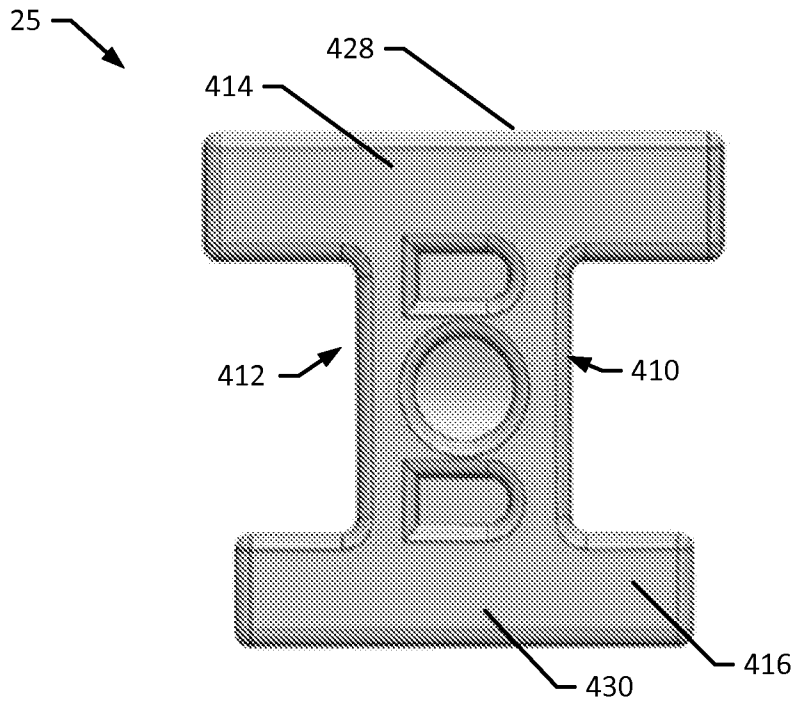


FIG. 8

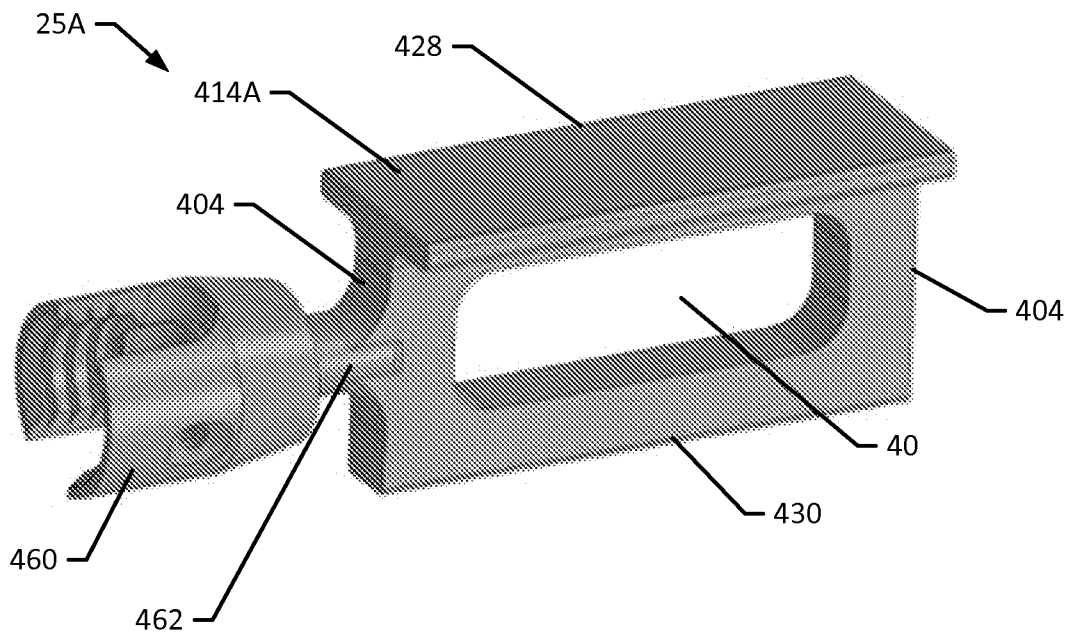
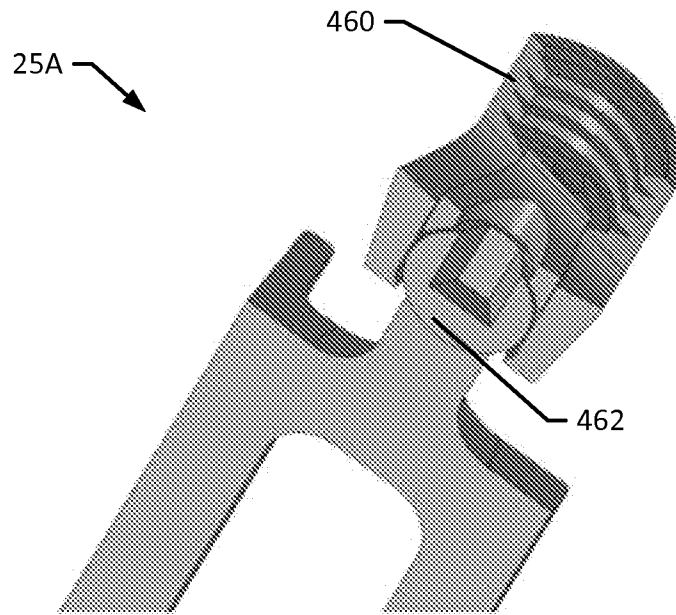
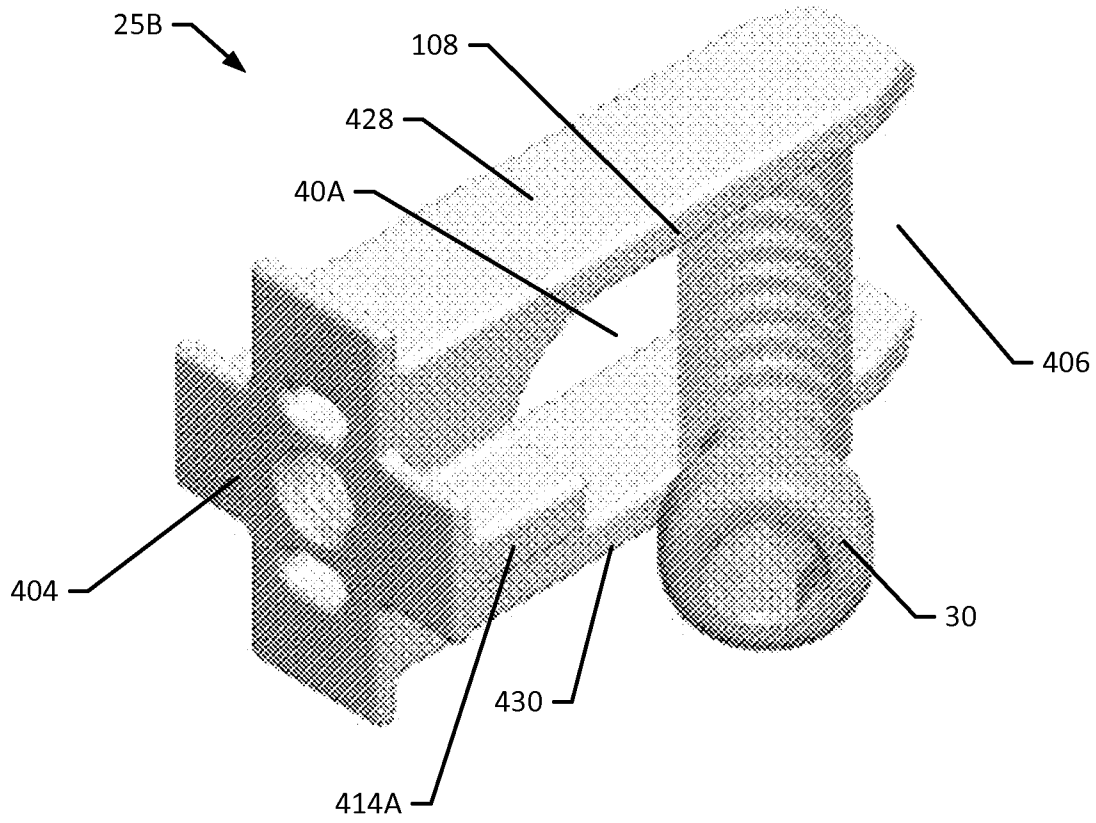


FIG. 9A





**FIG. 9B**



**FIG. 10**

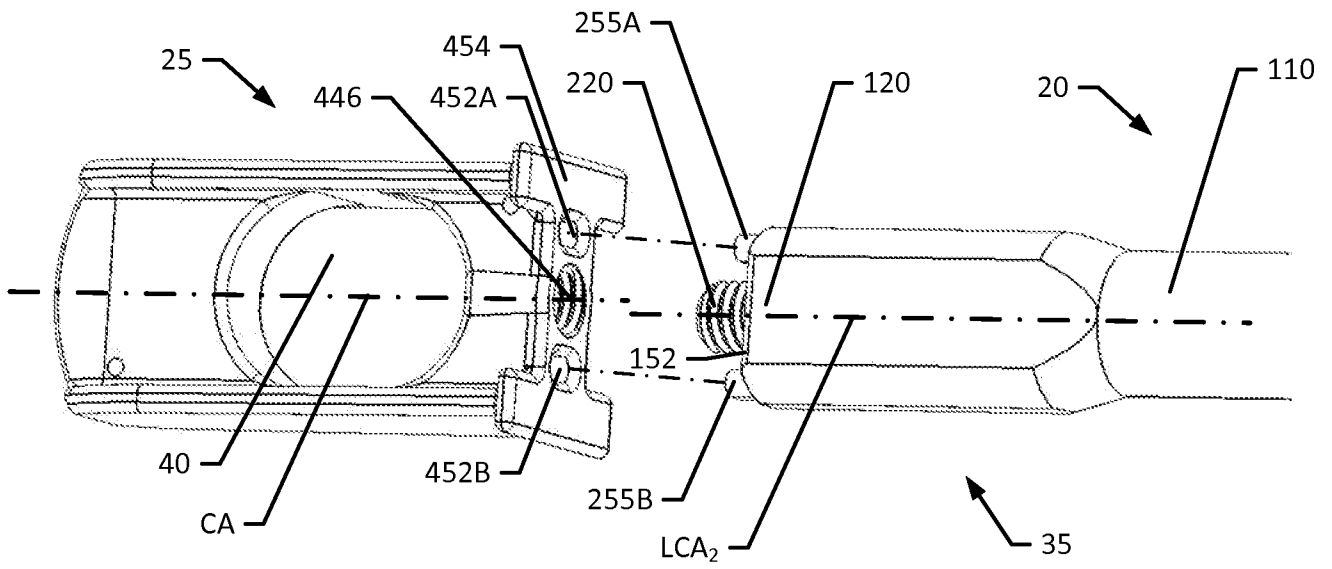


FIG. 11A

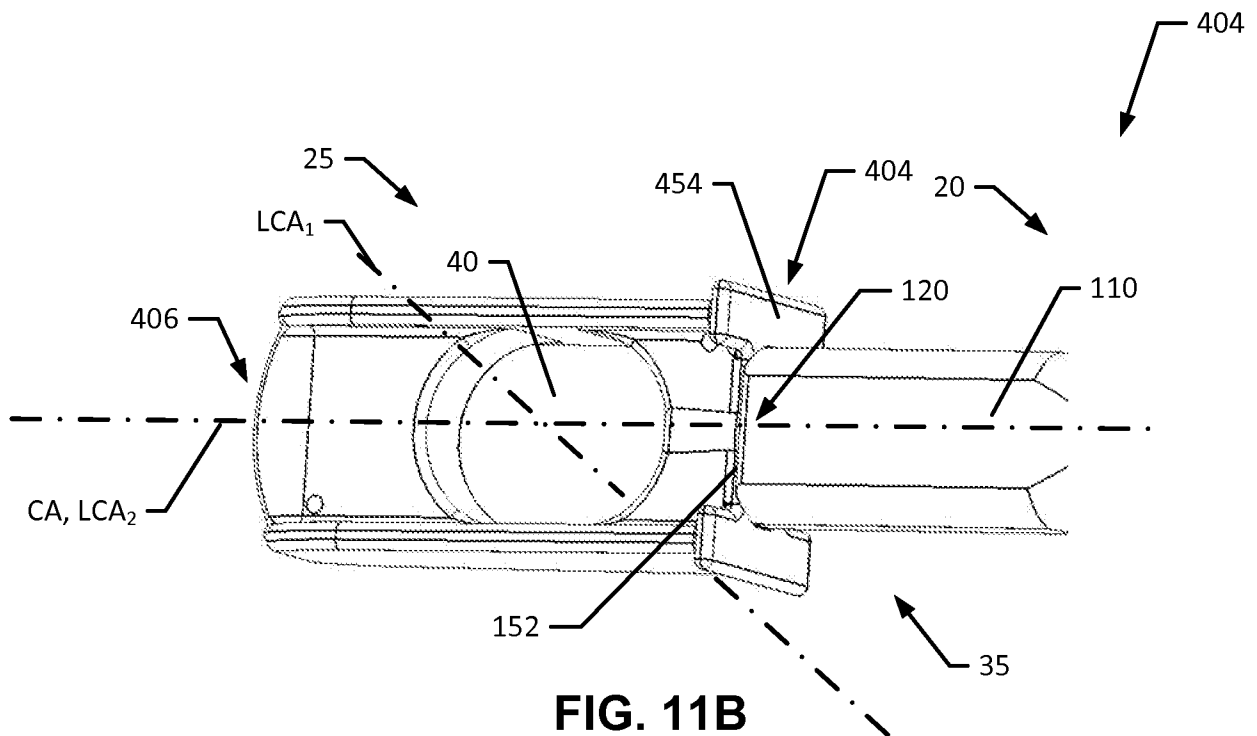


FIG. 11B

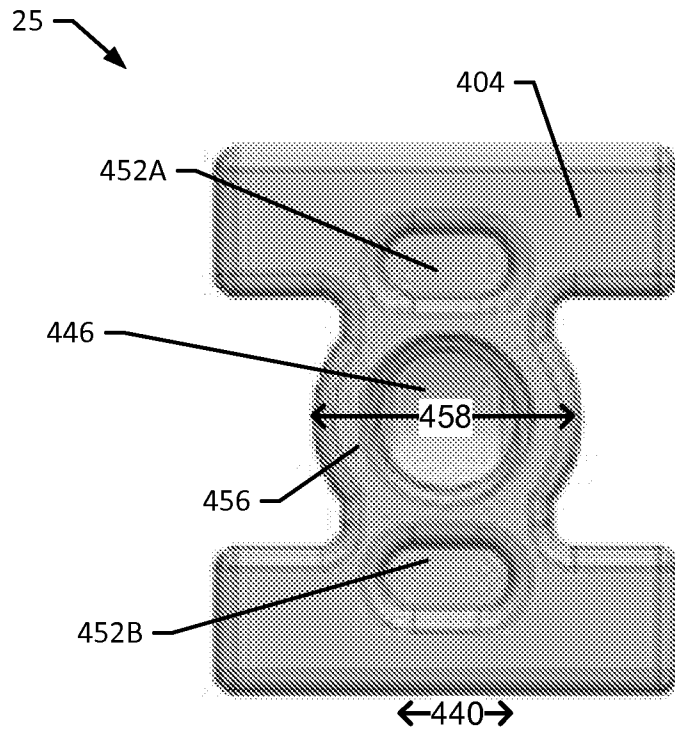


FIG. 12

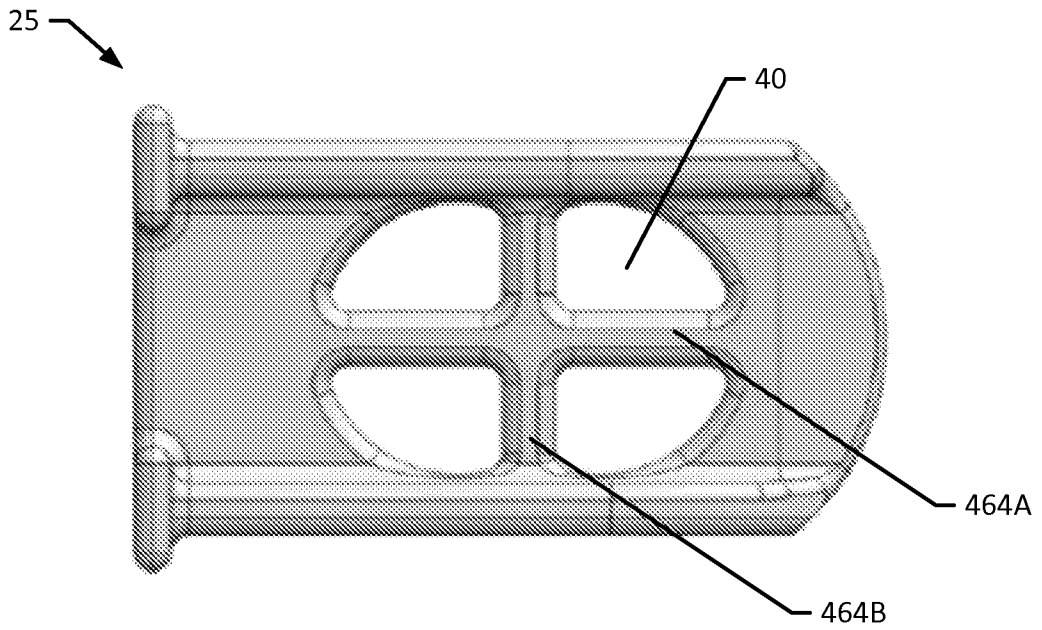
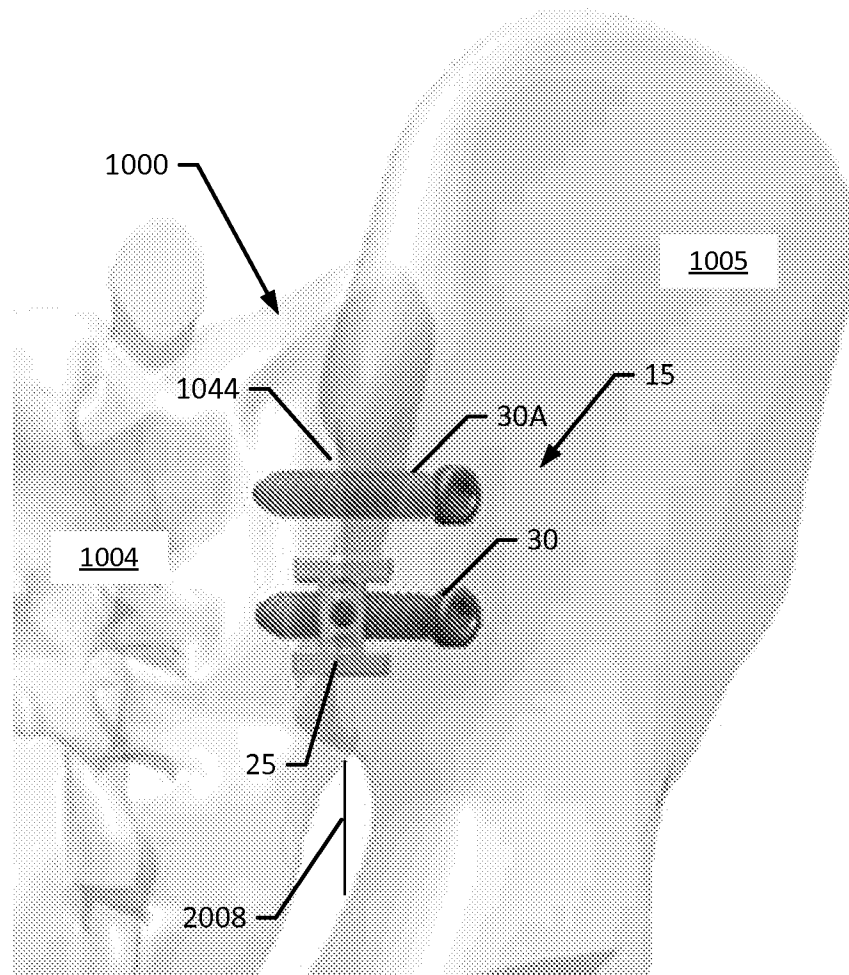
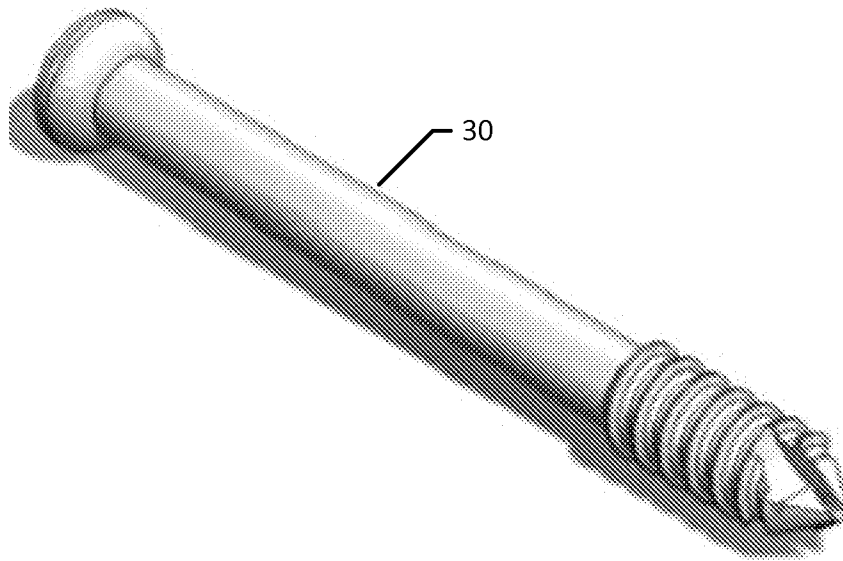


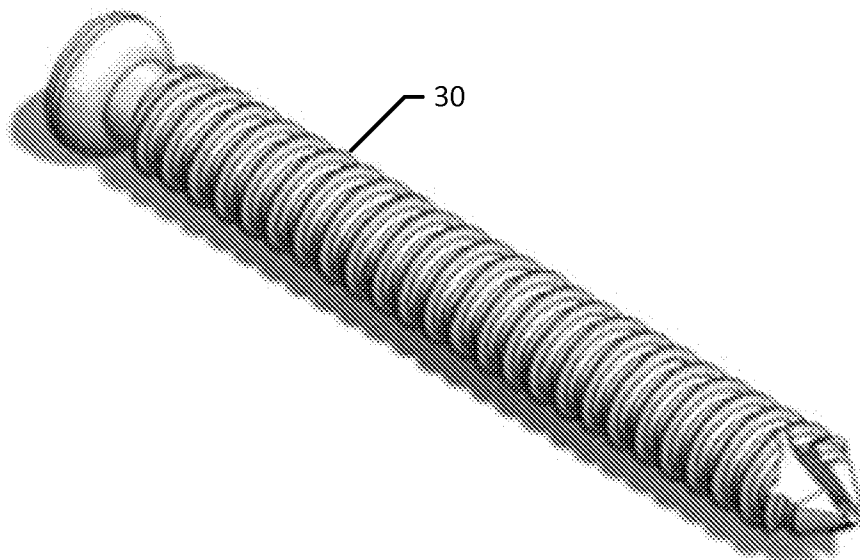
FIG. 13



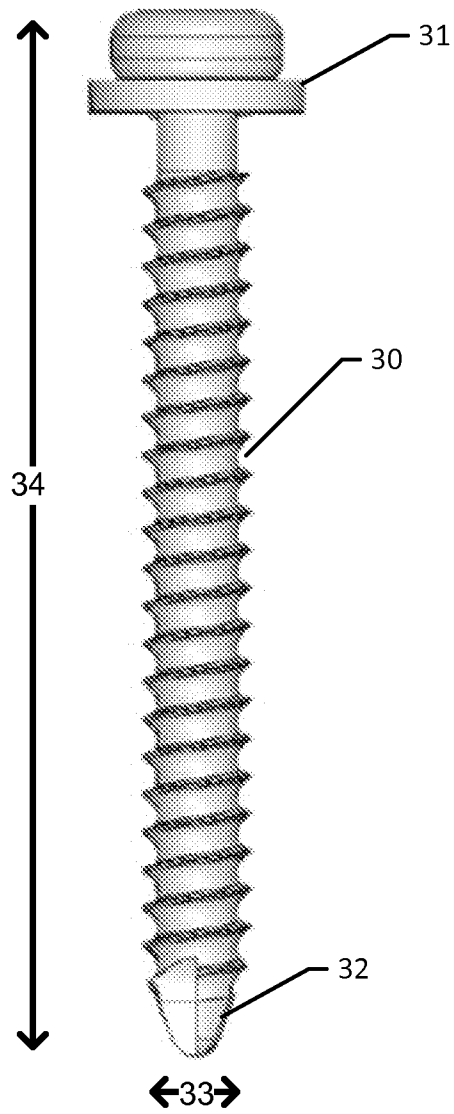
**FIG. 14**



**FIG. 15A**



**FIG. 15B**



**FIG. 16**

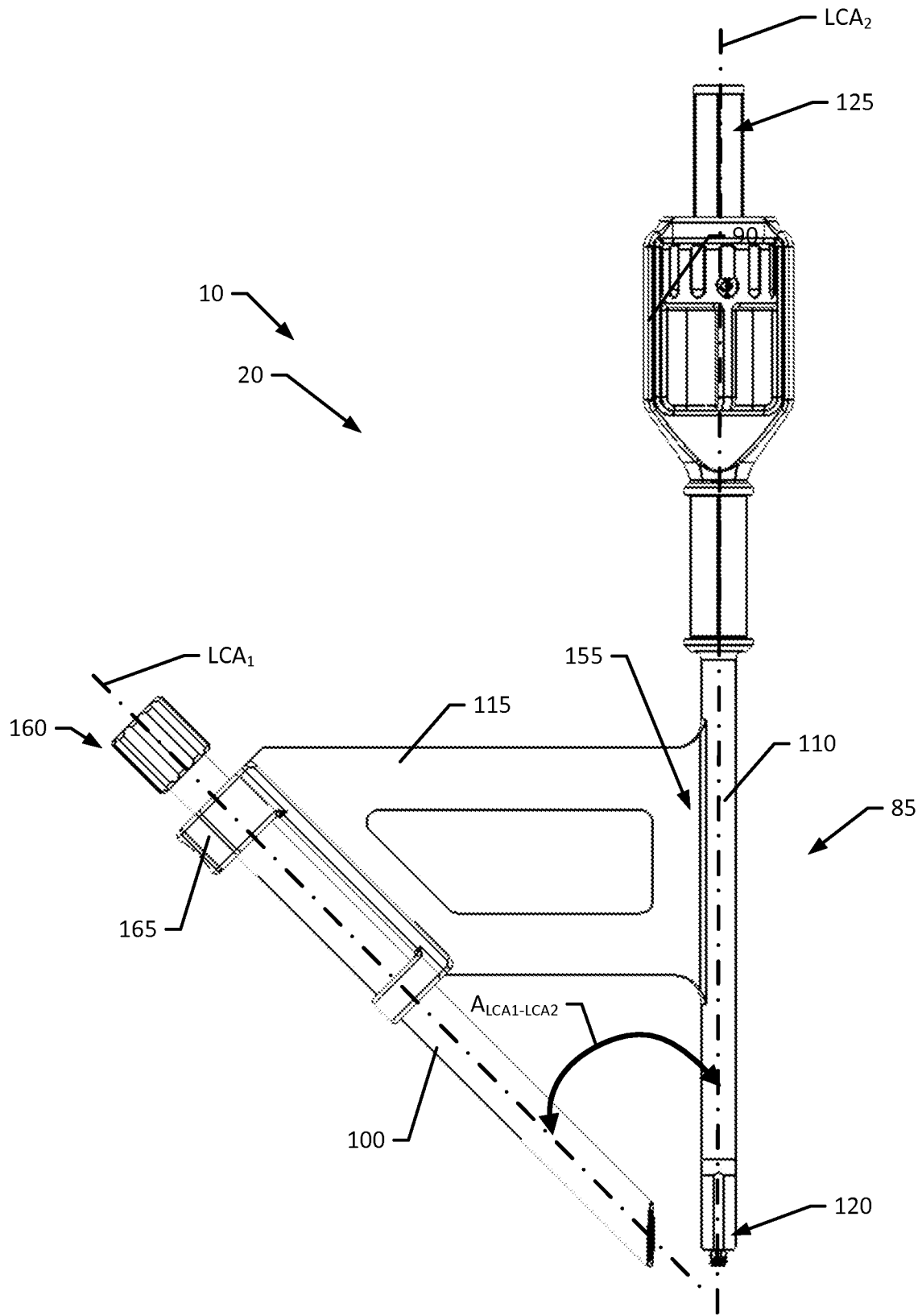


FIG. 17

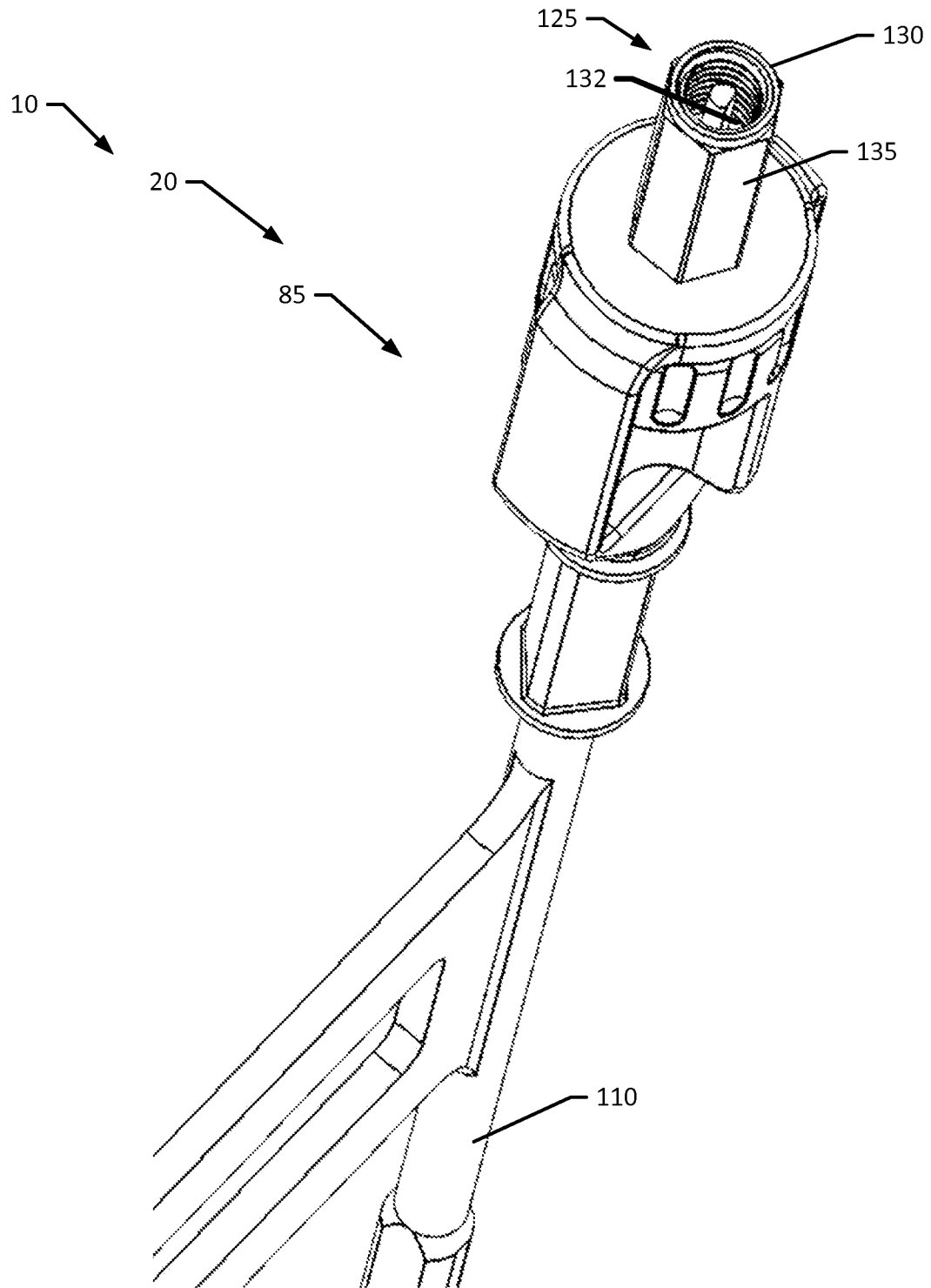
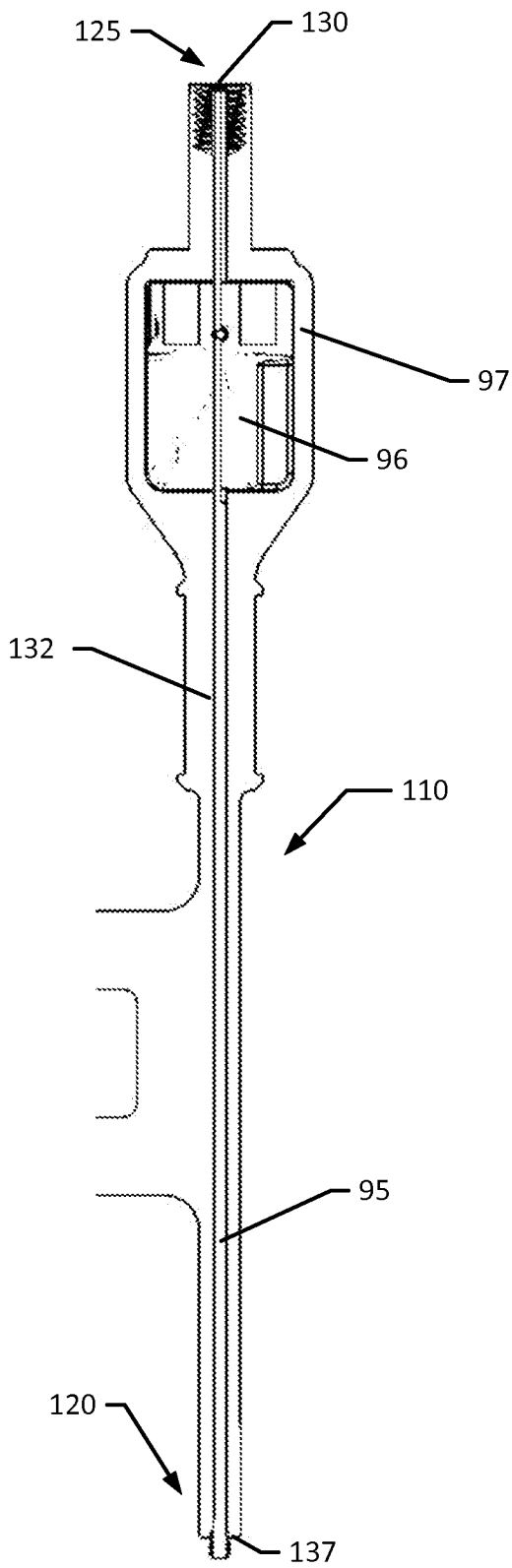
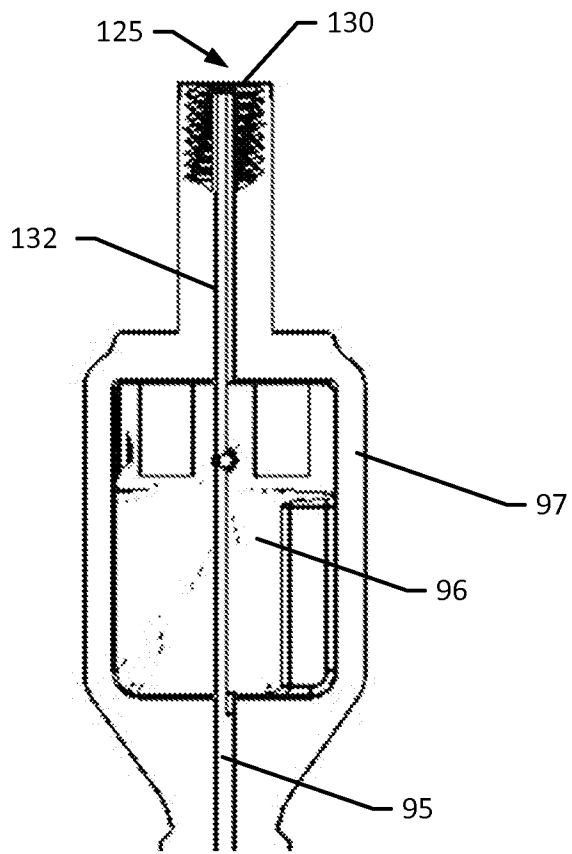


FIG. 18

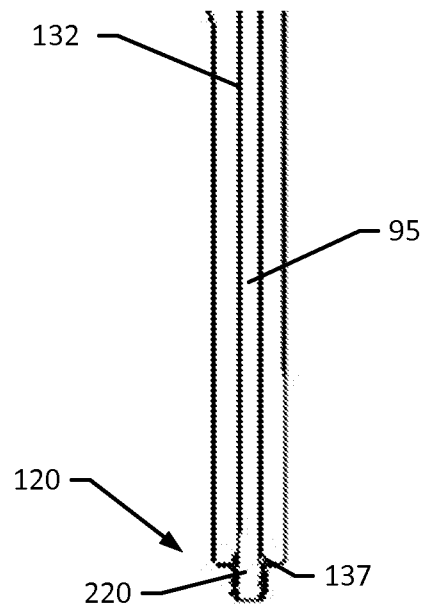




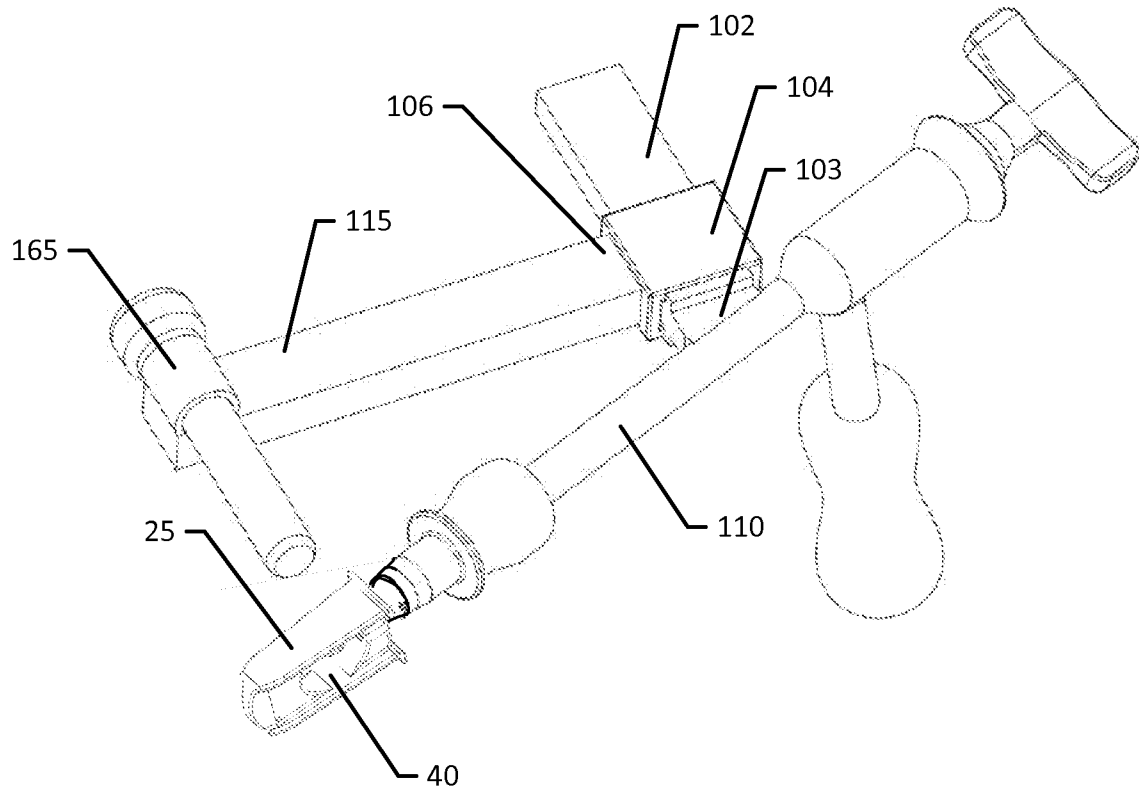
**FIG. 19A**



**FIG. 19B**



**FIG. 19C**



**FIG. 20**

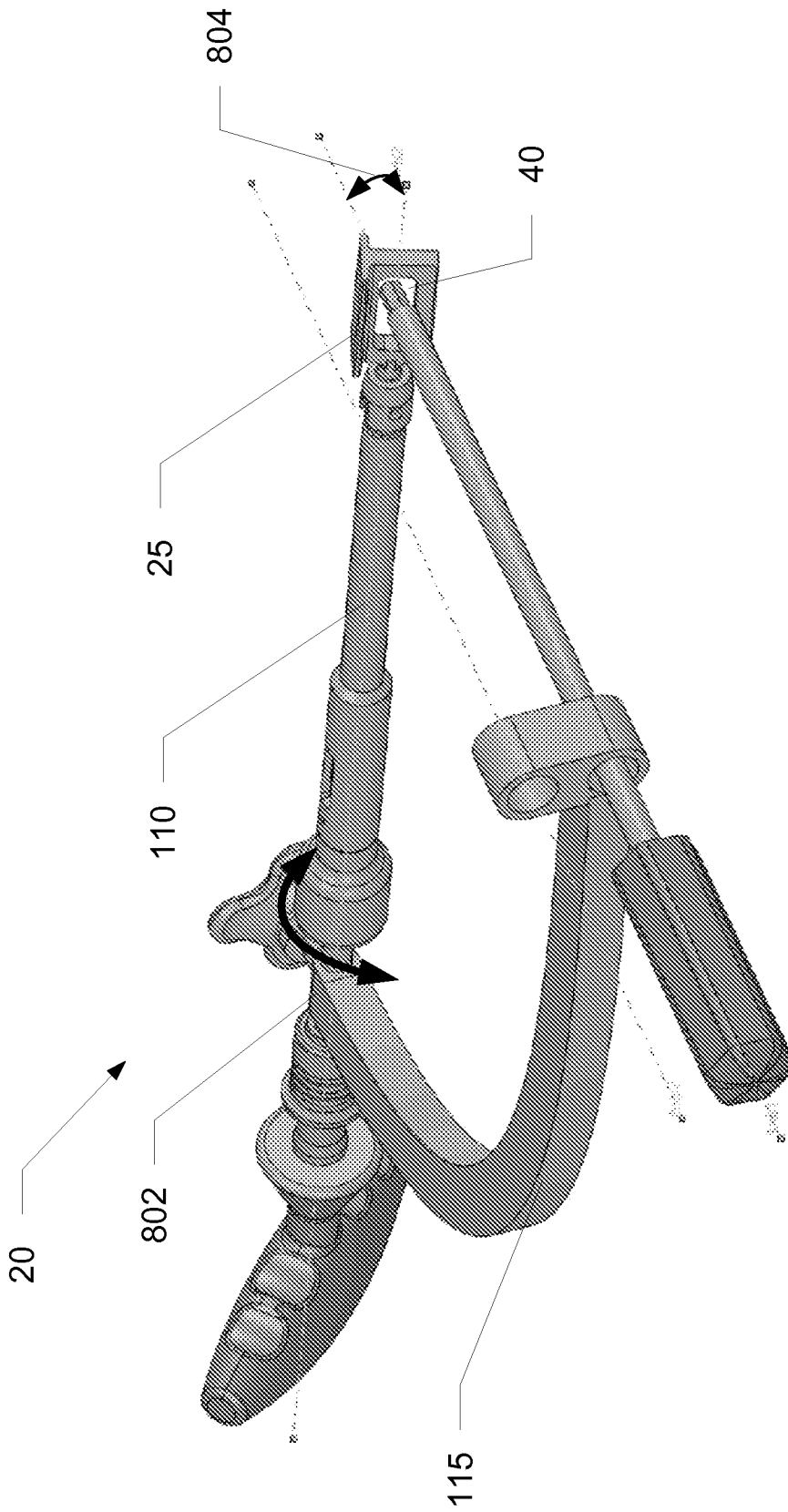
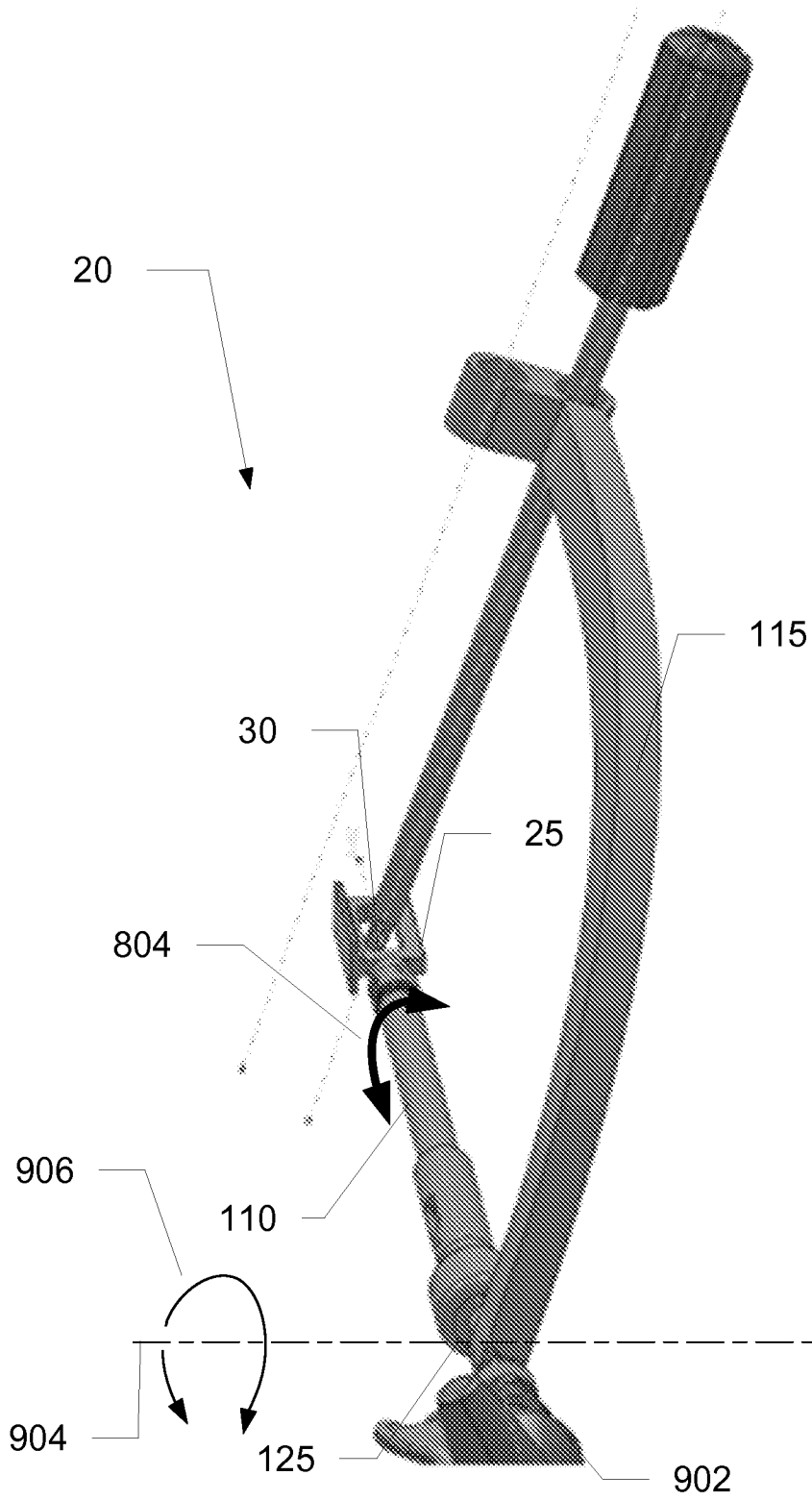


FIG. 21



**FIG. 22**

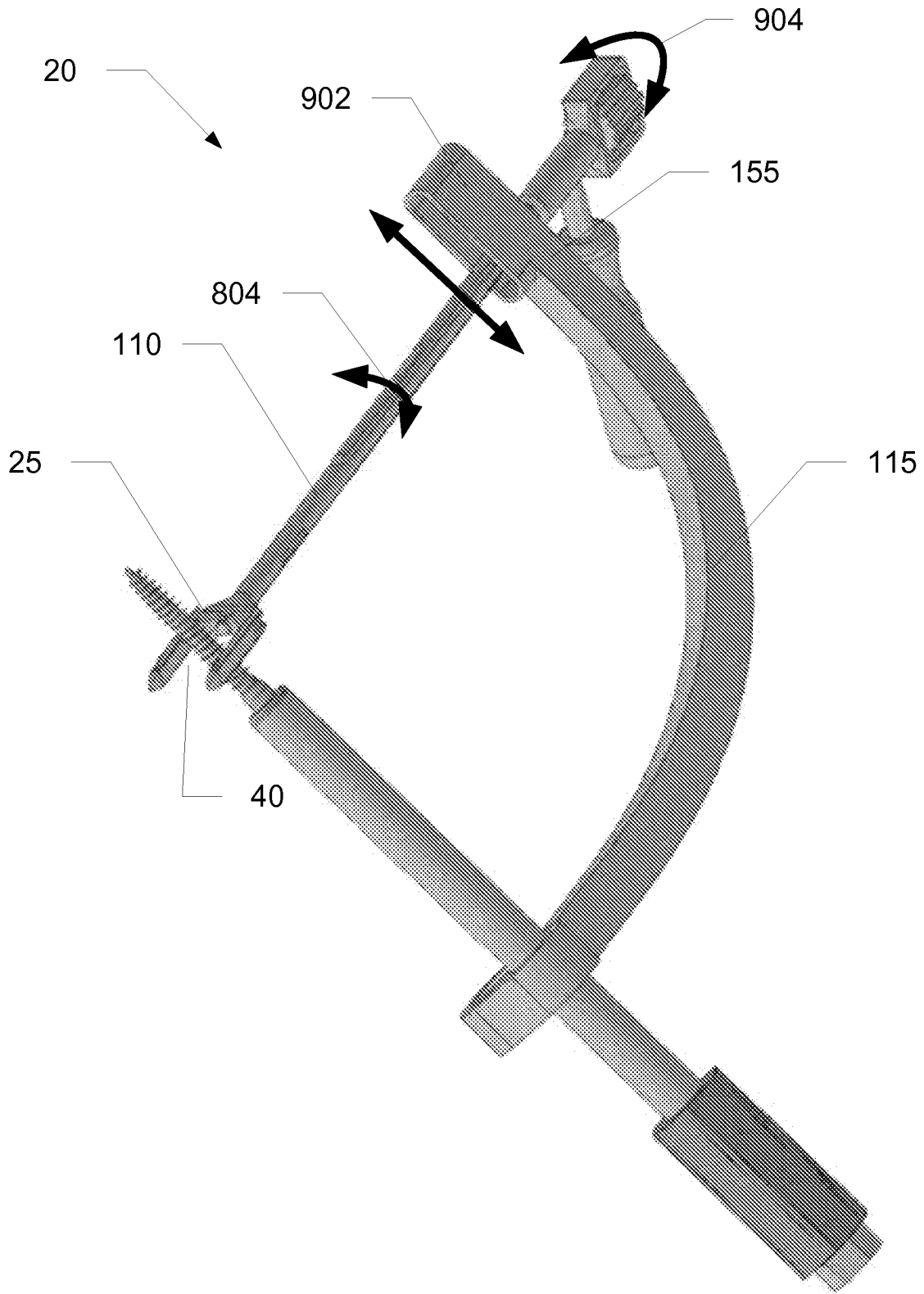


FIG. 23

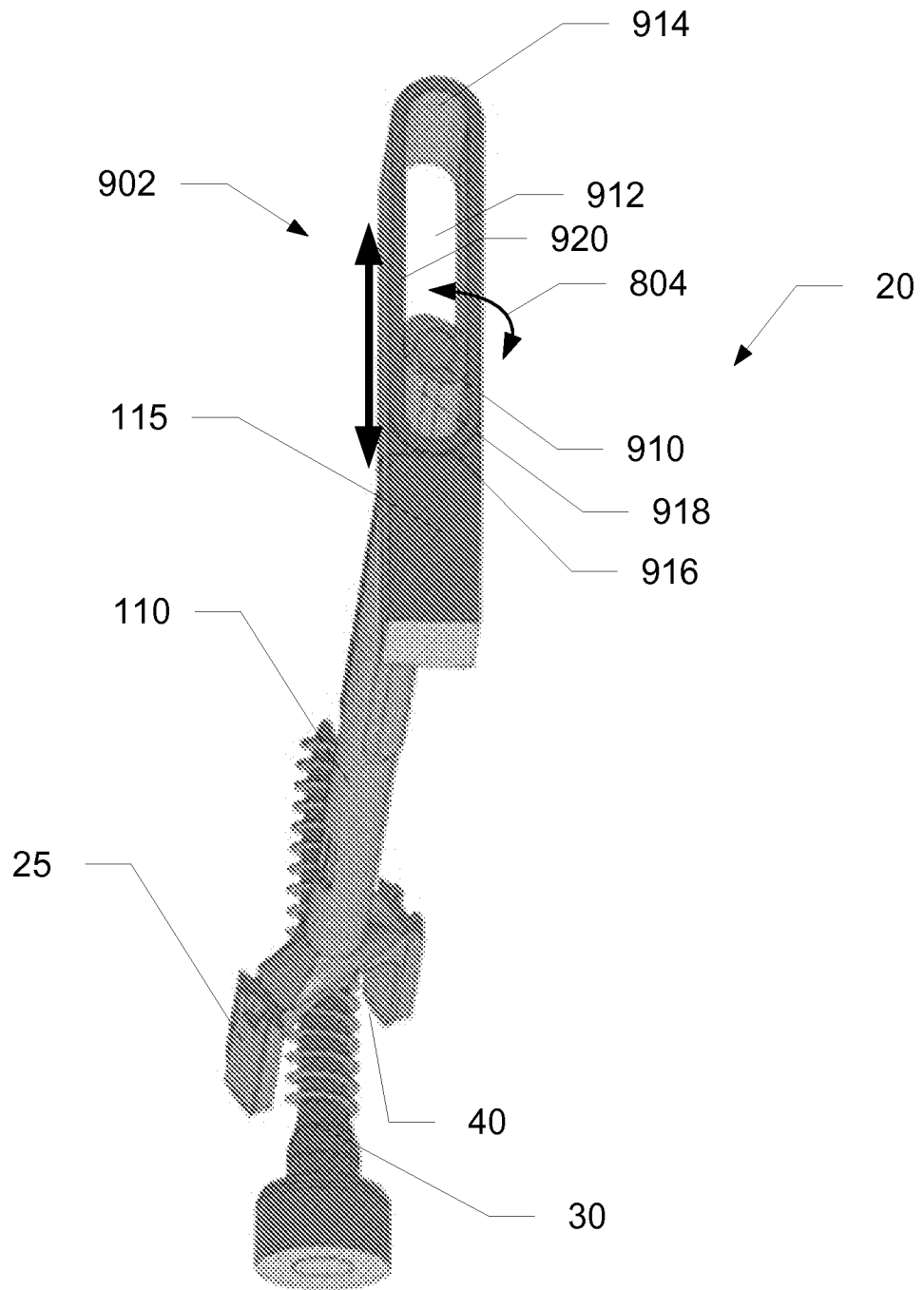


FIG. 24

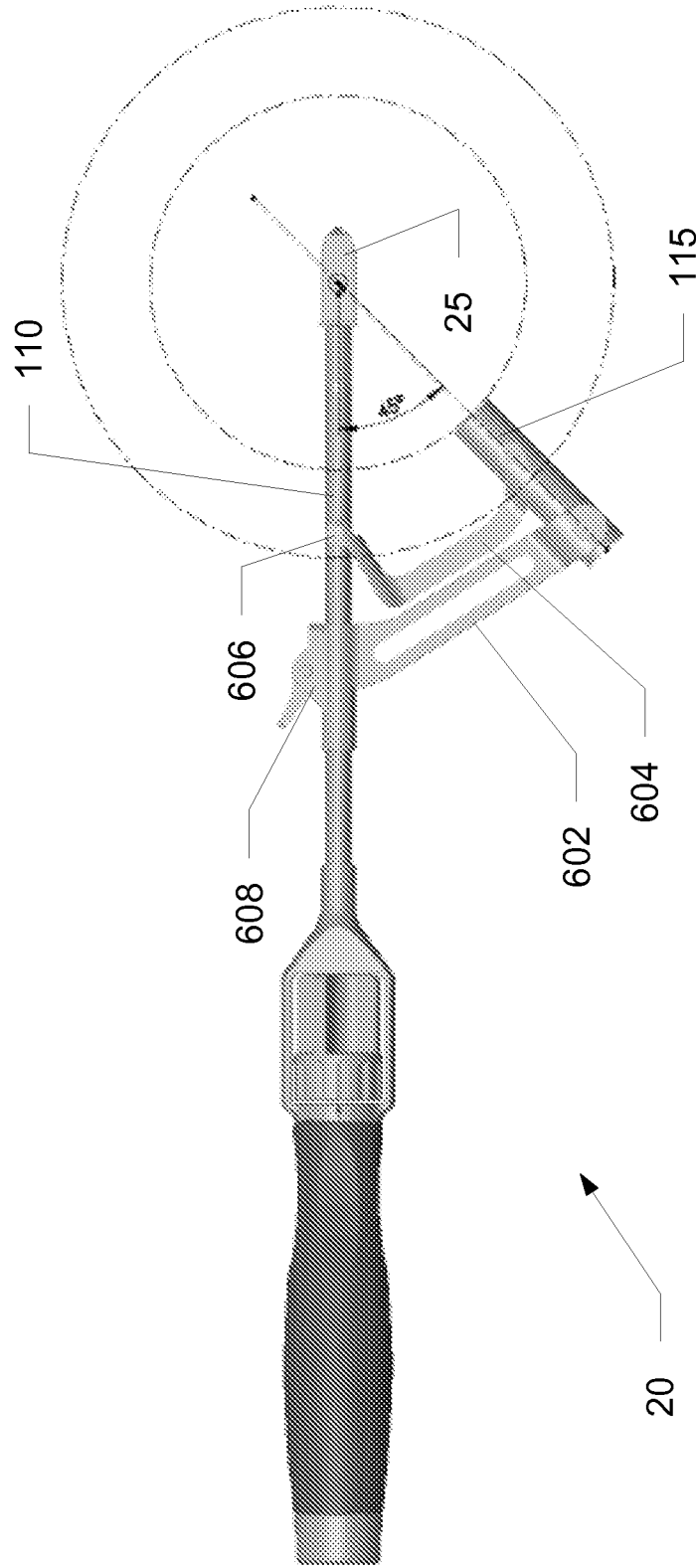


FIG. 25

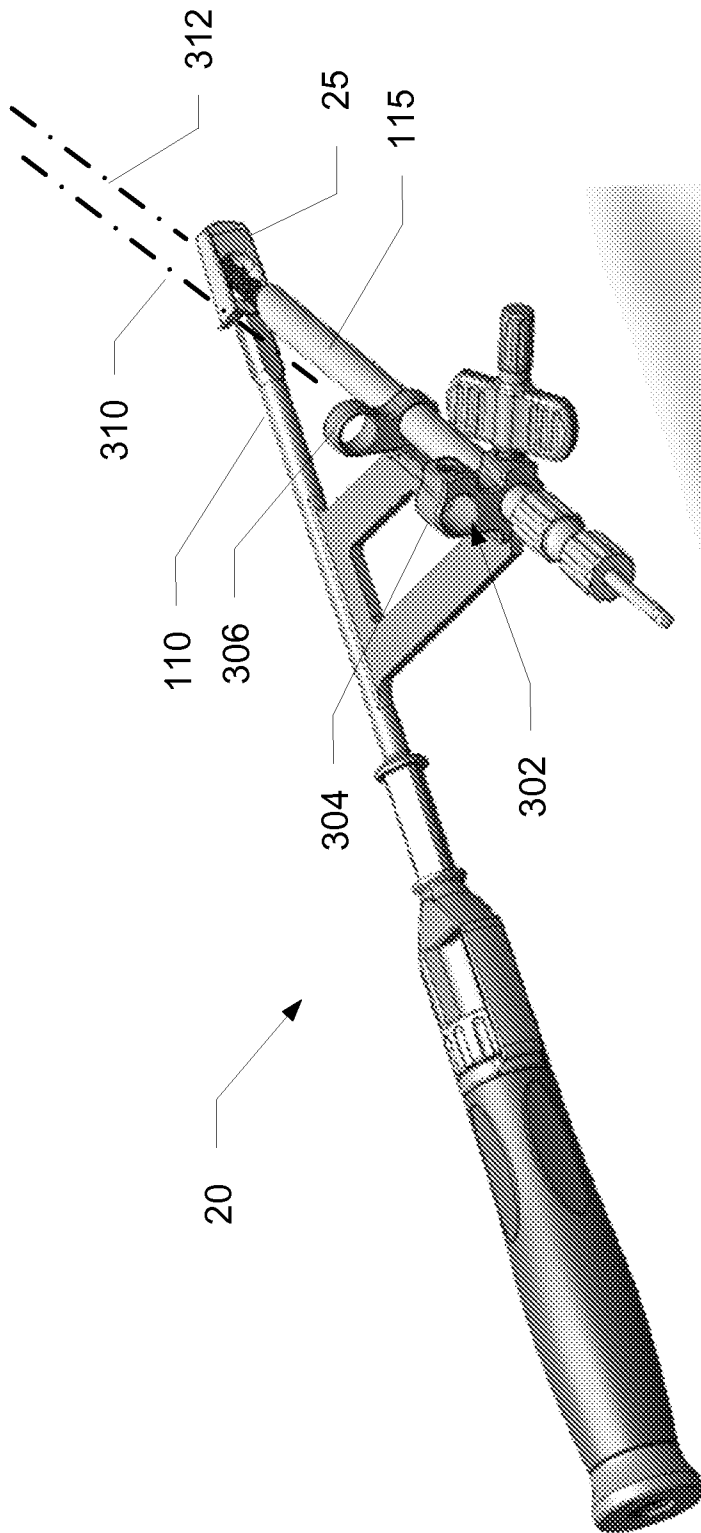


FIG. 26



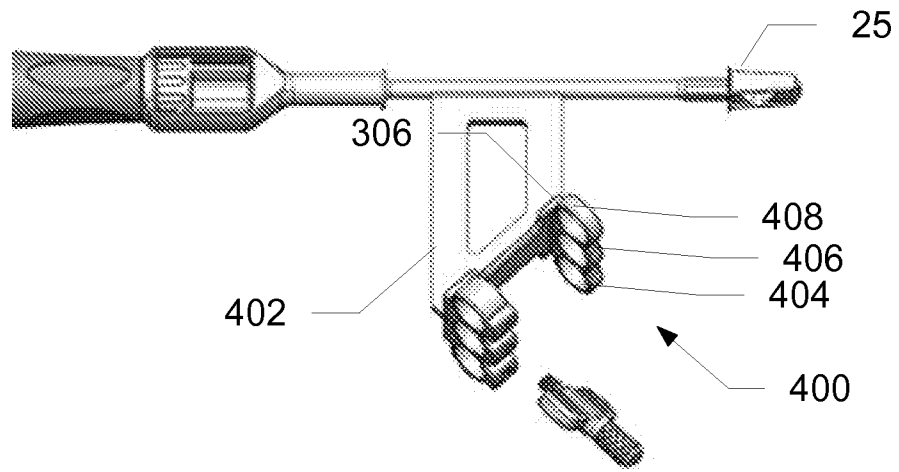


FIG. 27

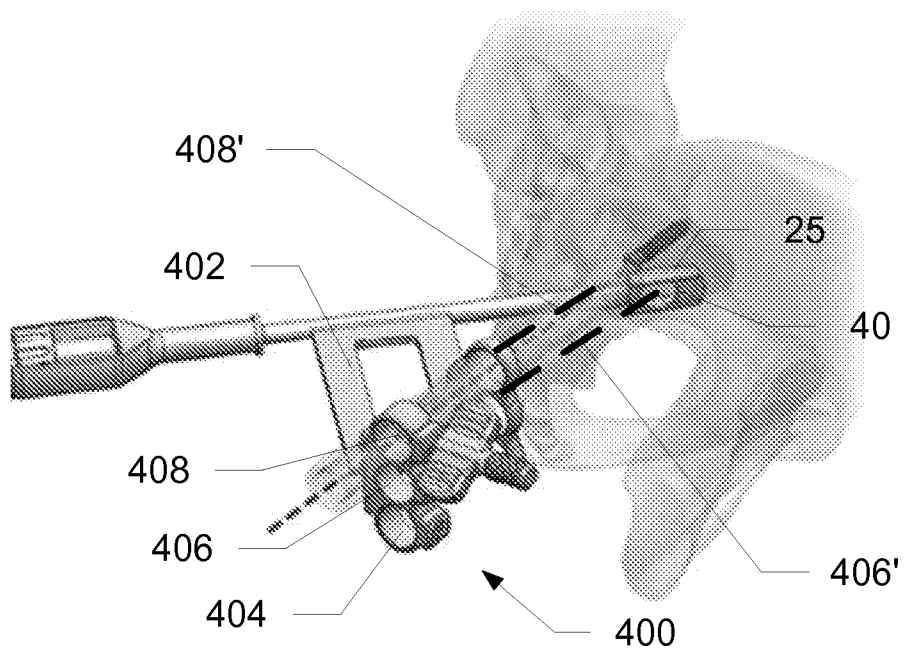


FIG. 28

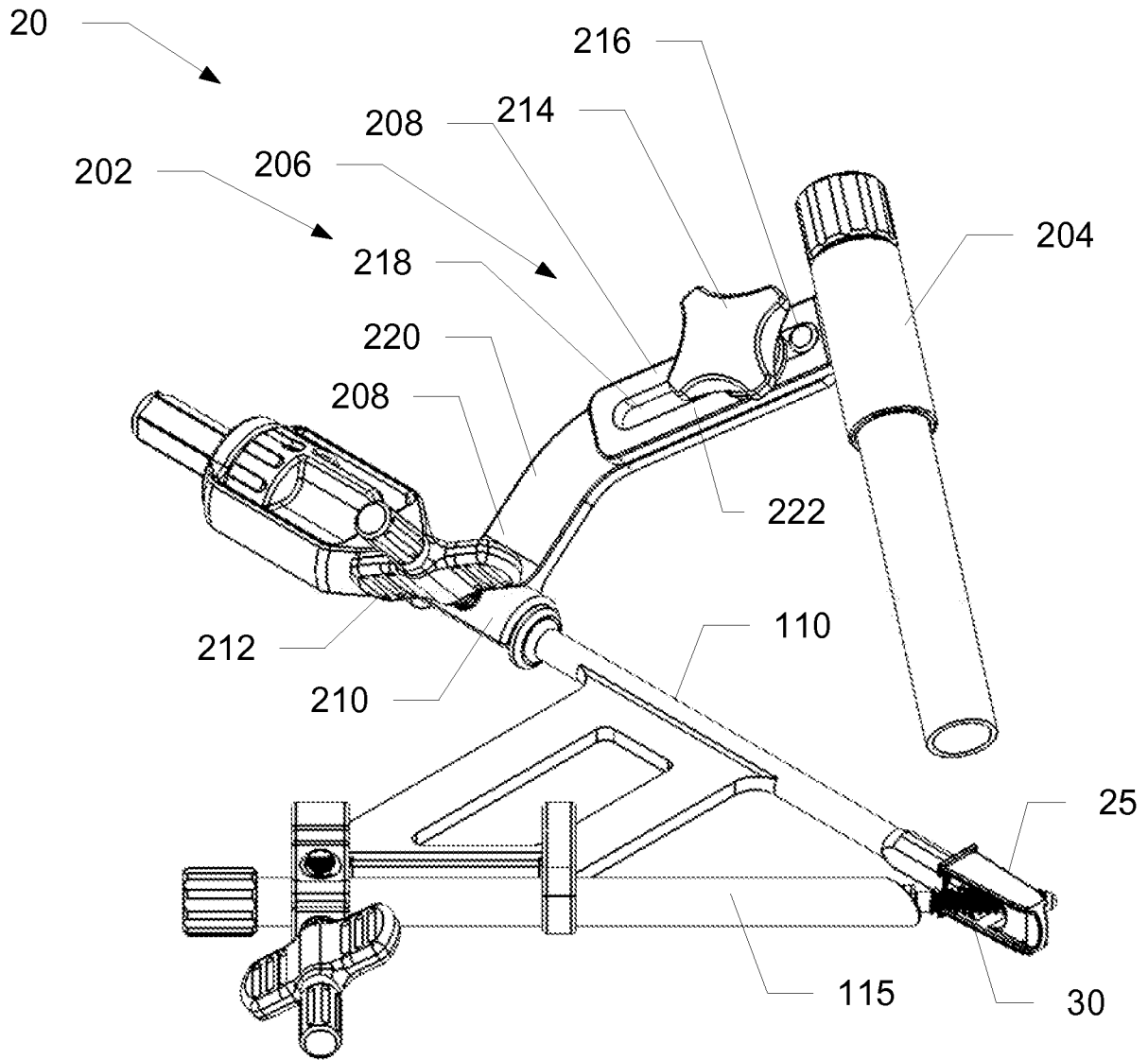


FIG. 29

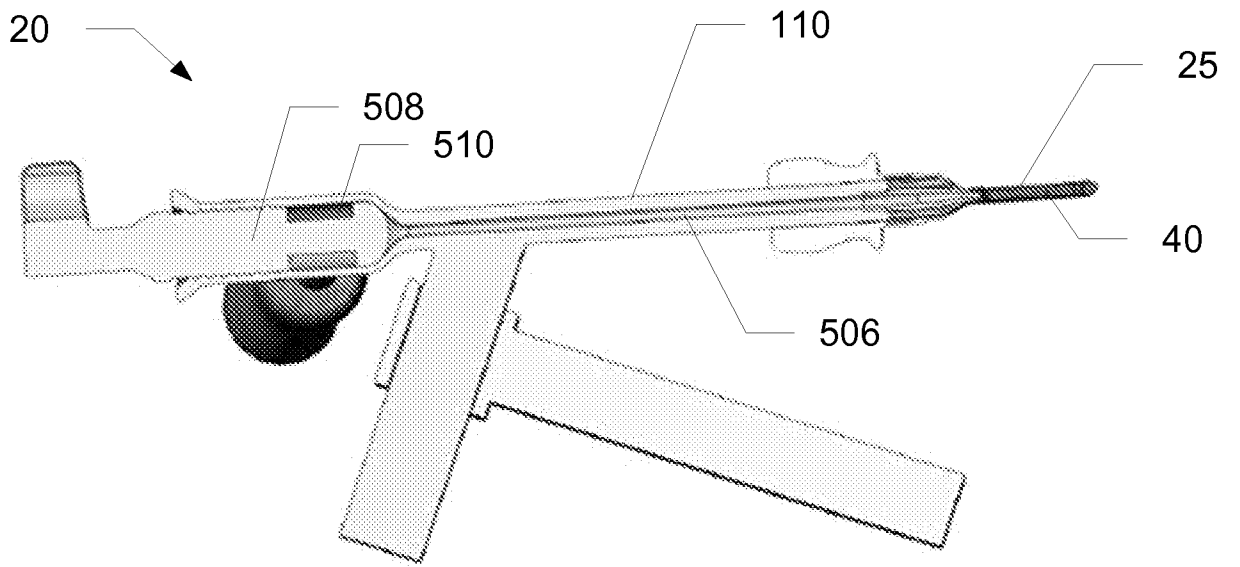


FIG. 30

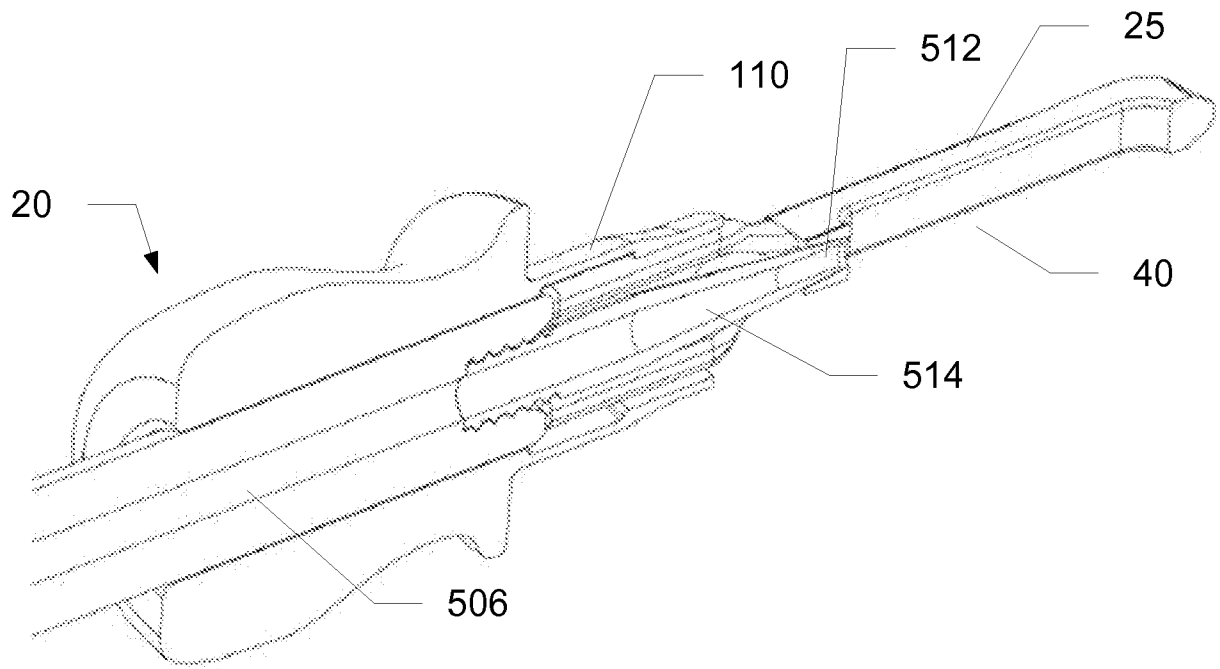


FIG. 31

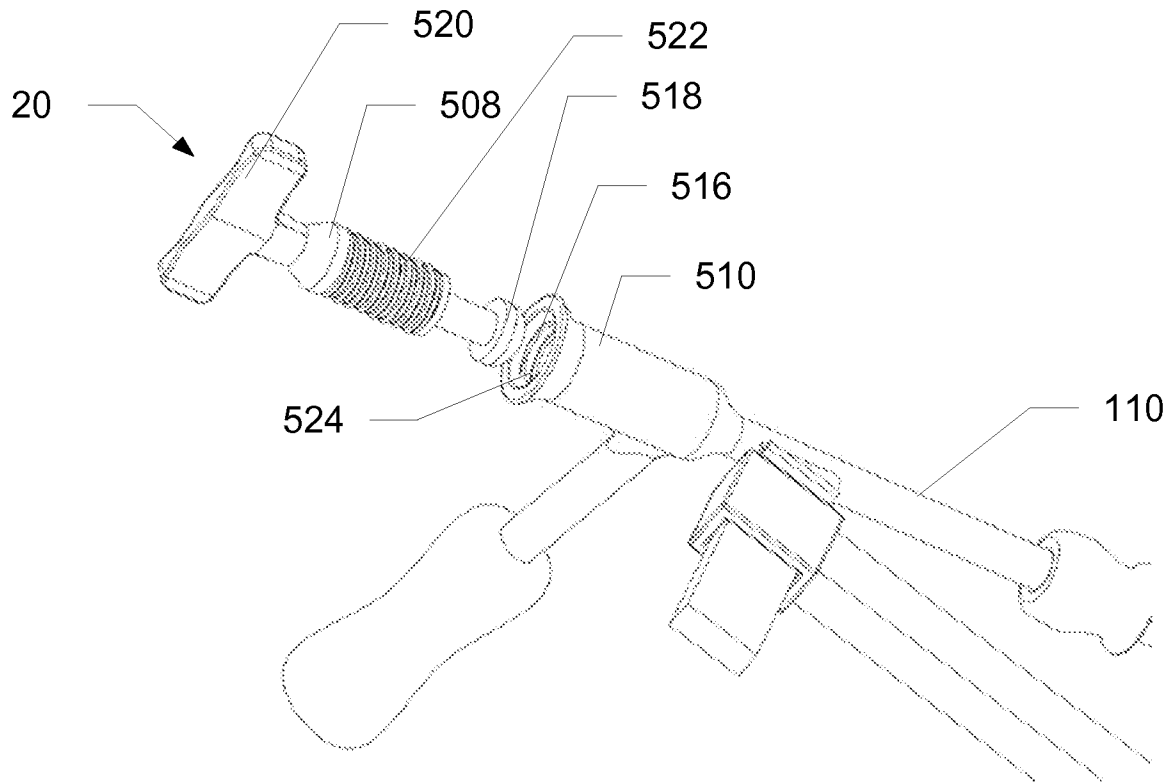


FIG. 32

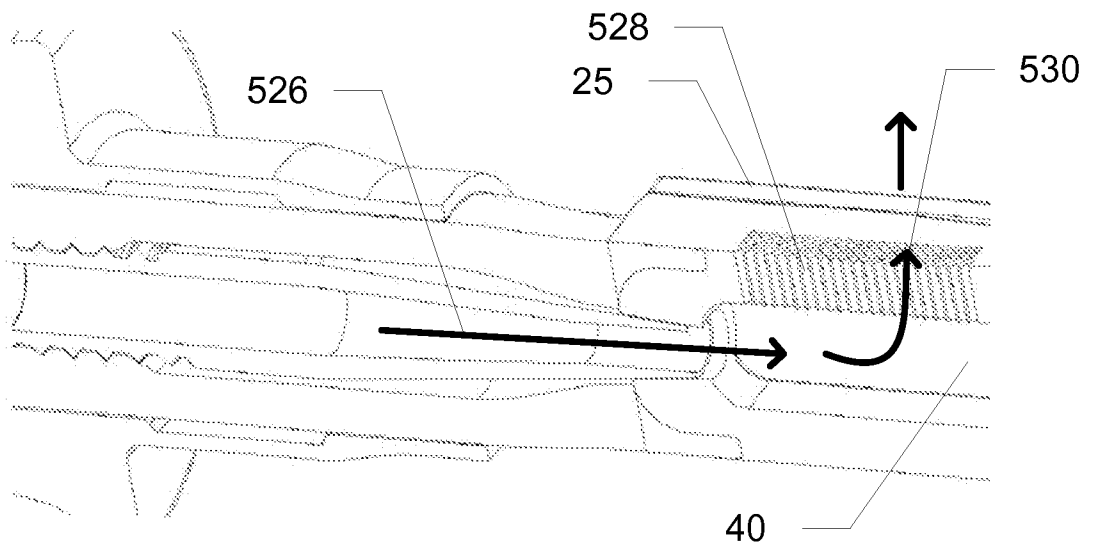


FIG. 33

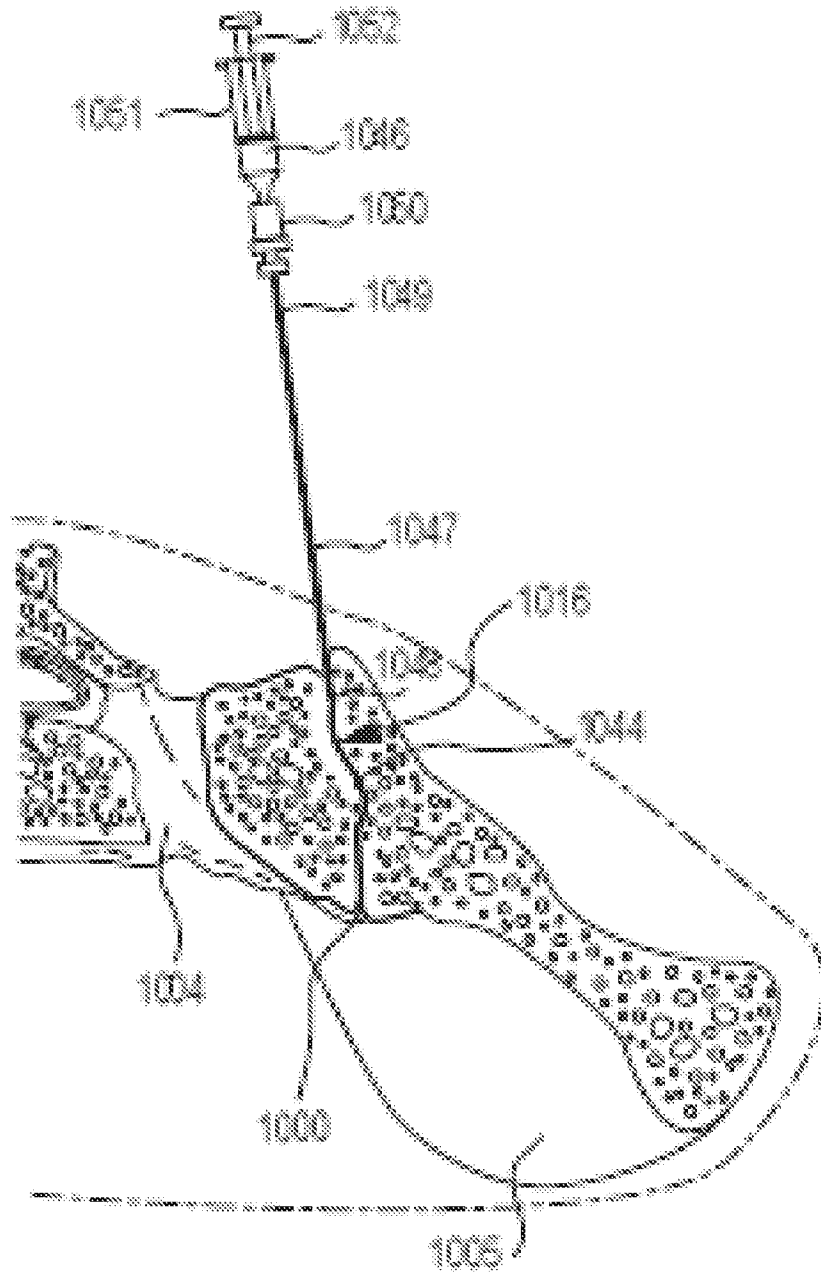


FIG. 33

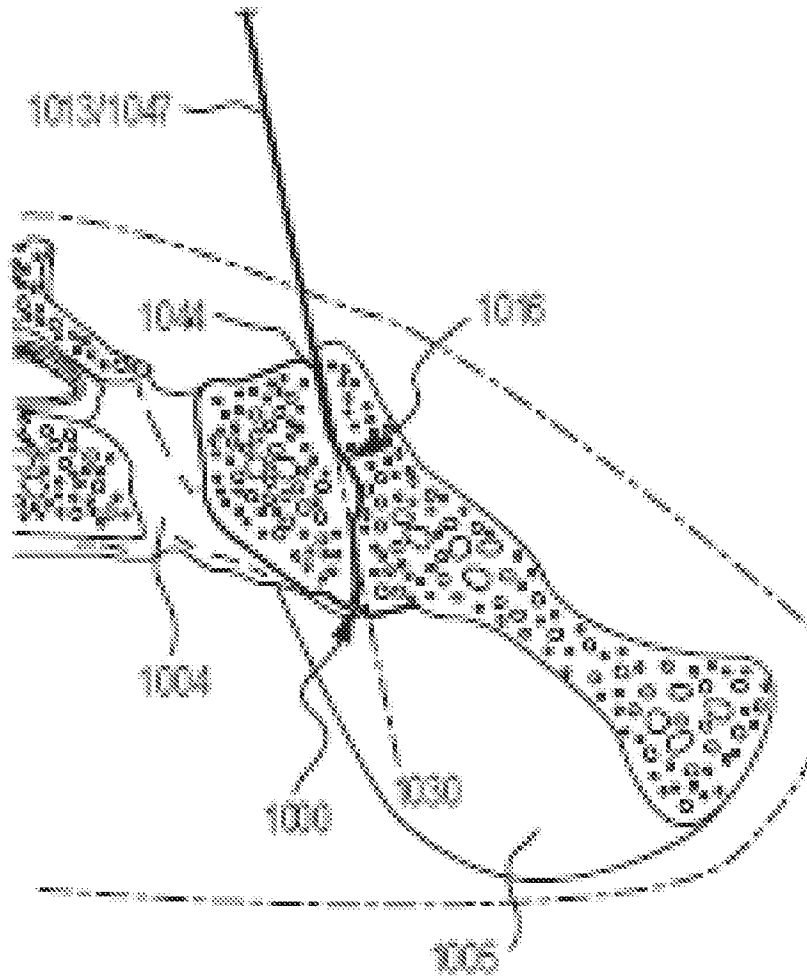


FIG. 34

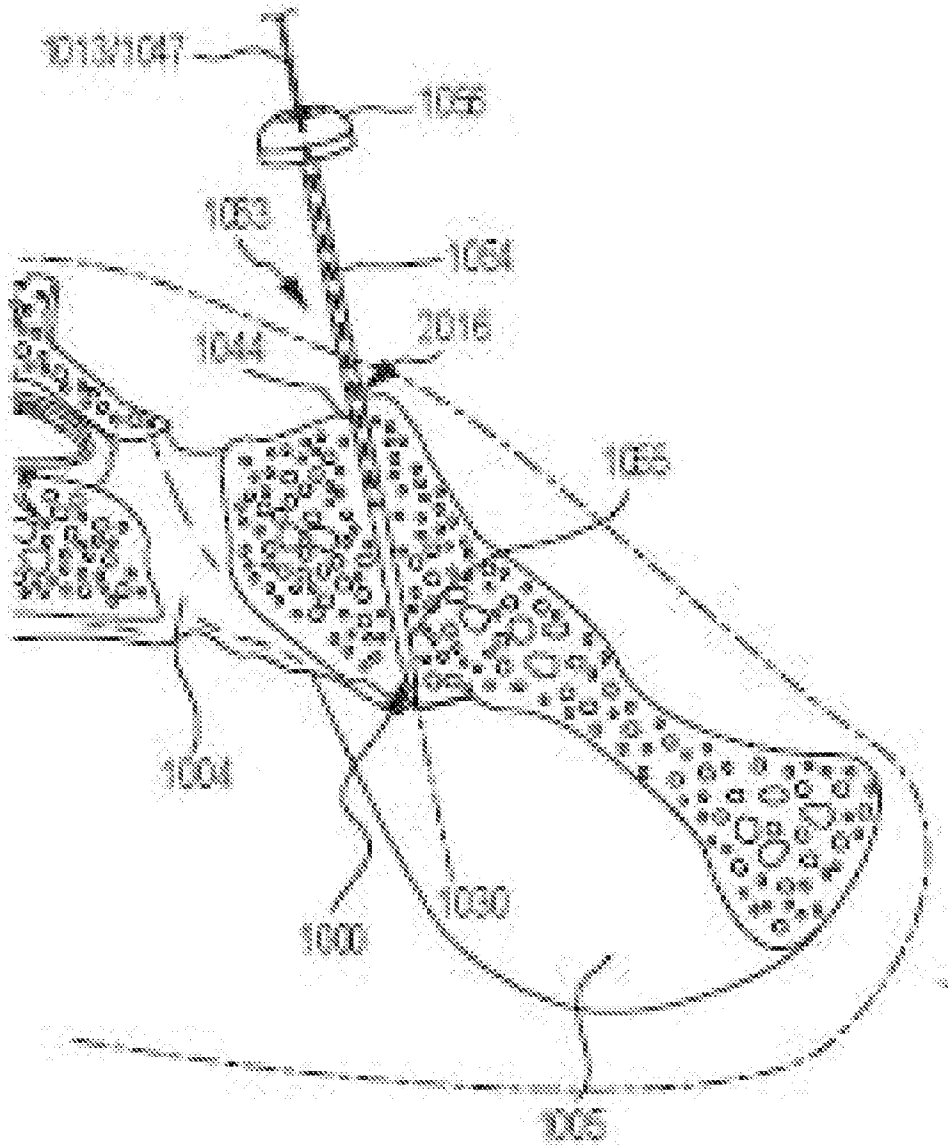


FIG. 35

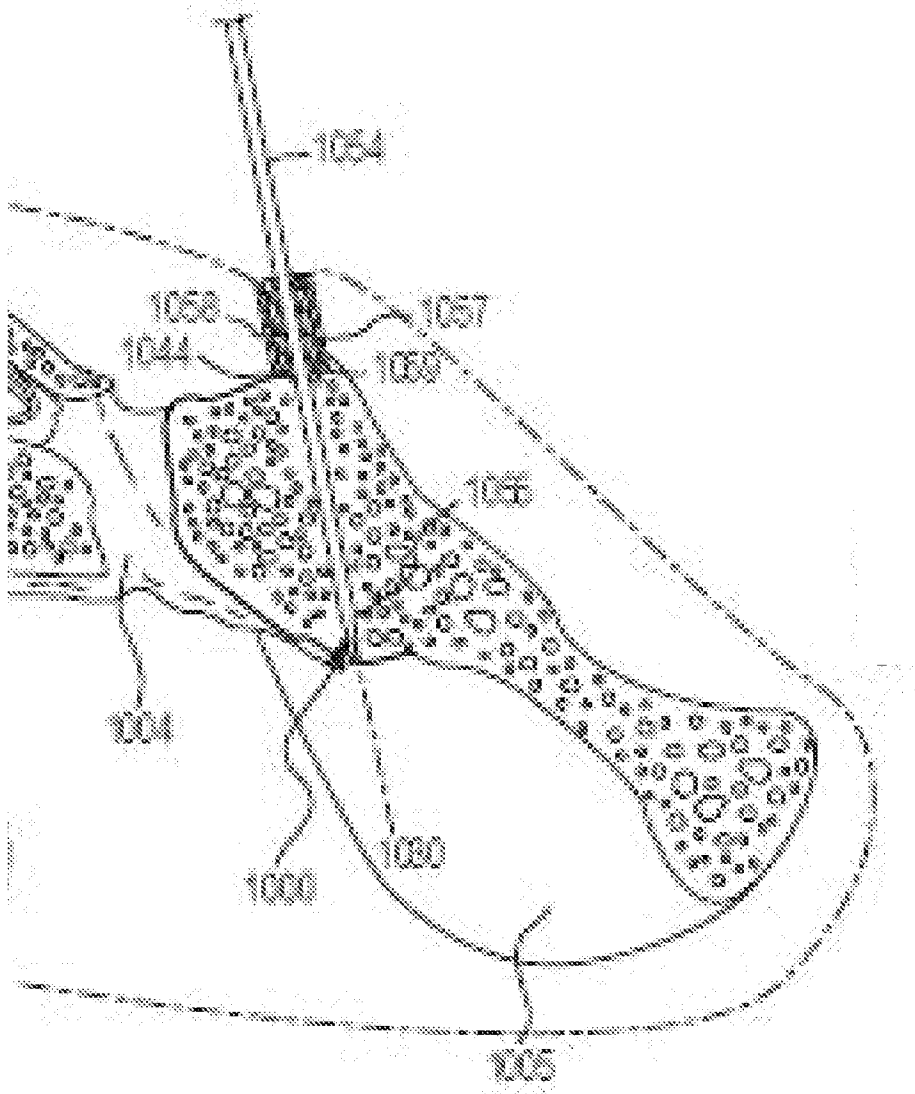


FIG. 36



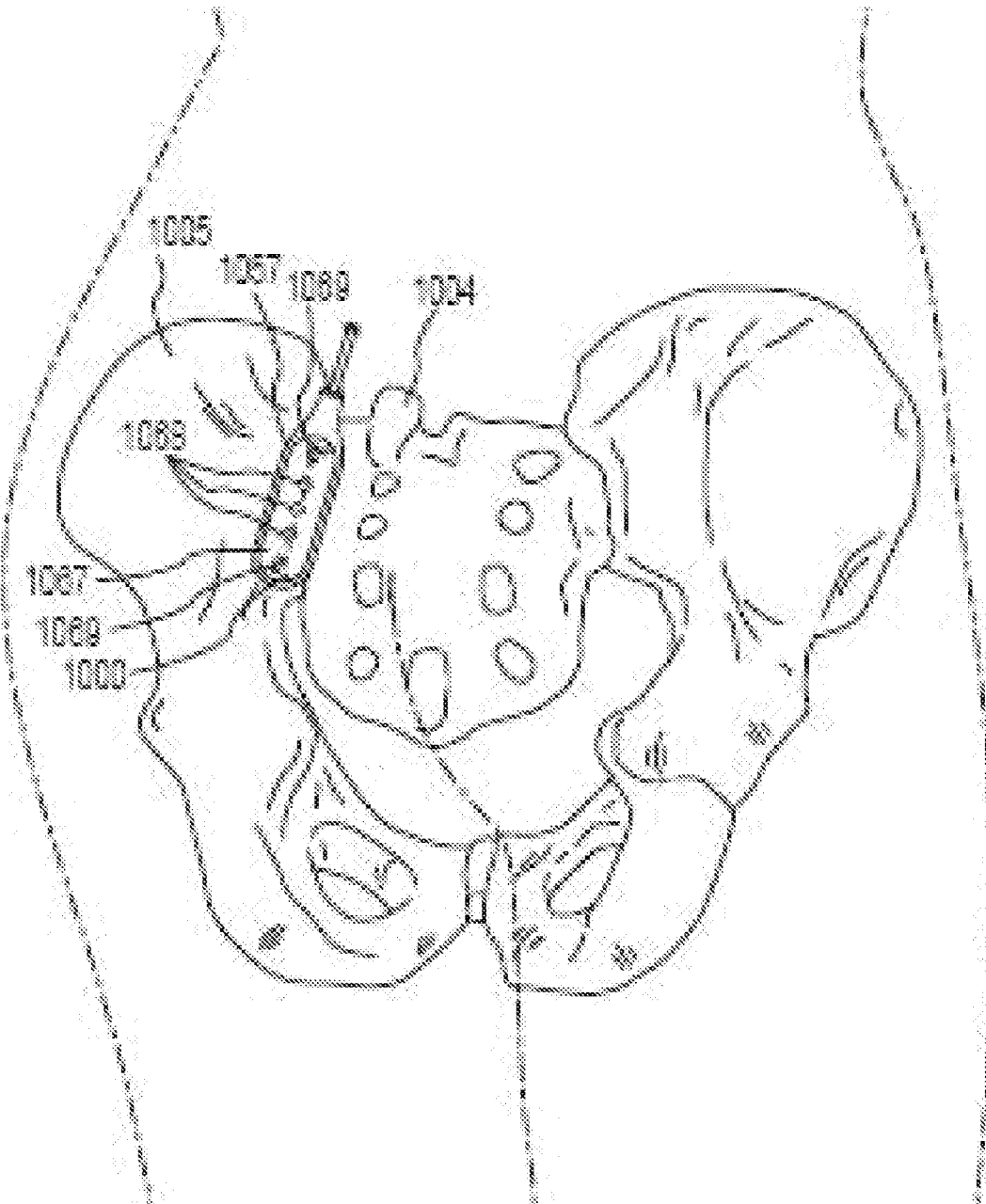


FIG. 37

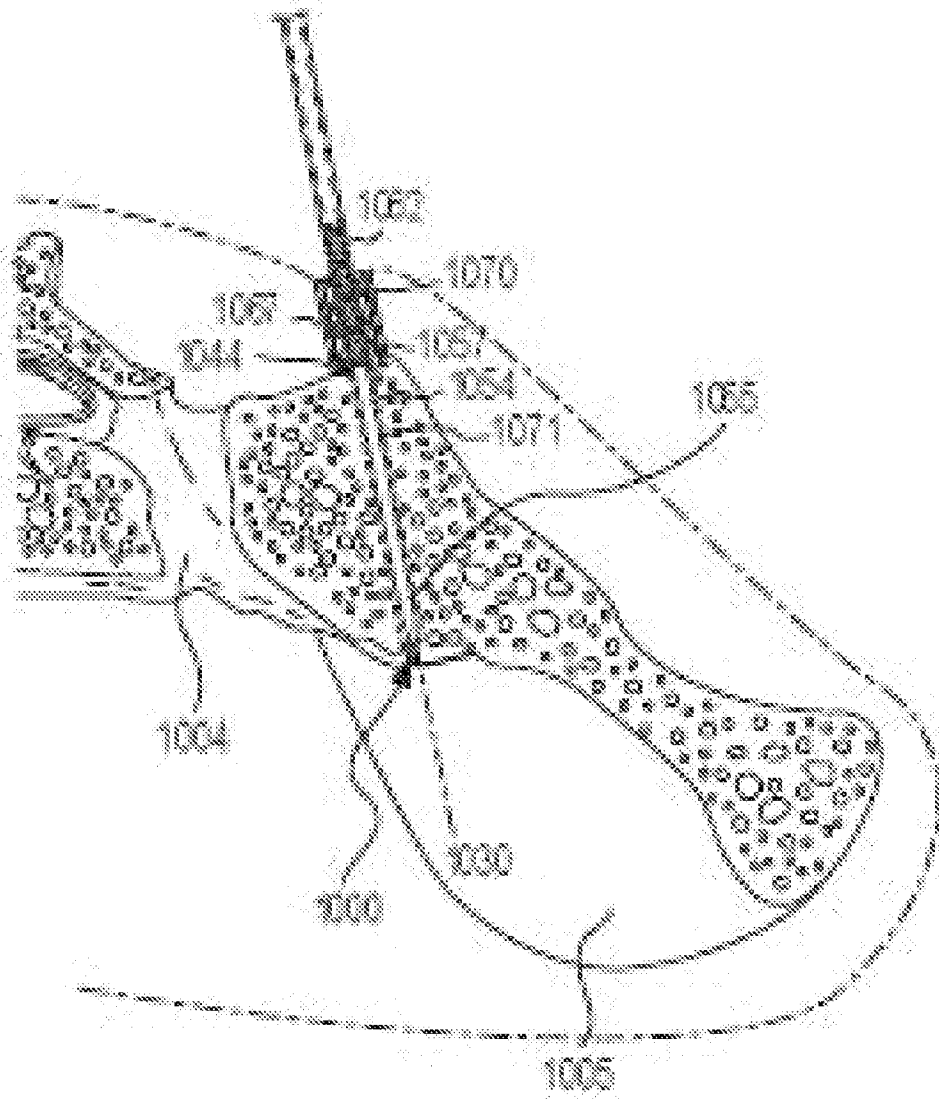


FIG. 38



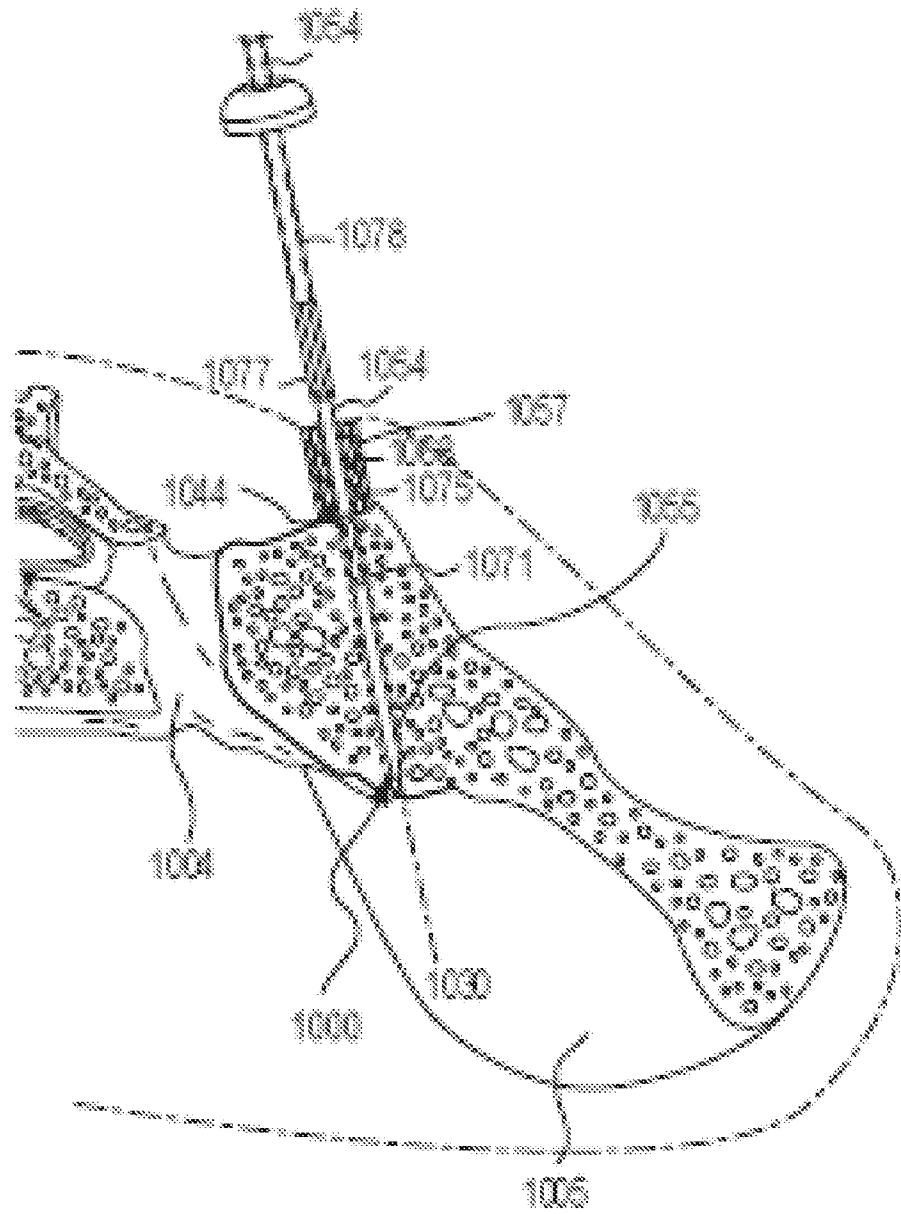


FIG. 40

**INTERNATIONAL SEARCH REPORT**

International application No.  
**PCT/US2014/048990**

**A. CLASSIFICATION OF SUBJECT MATTER**

**A61B 17/68(2006.01)i, A61B 17/86(2006.01)i, A61F 2/32(2006.01)i**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
A61B 17/68; A61F 2/08; A61F 2/46; A61F 2/44; A61F 5/04; A61B 17/56; A61B 17/86; A61F 2/32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
Korean utility models and applications for utility models  
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
eKOMPASS(KIPO internal) & Keywords: implant, fusion, sacroiliac joint, graft window, keel, anchor, delivery tool, implant arm, anchor arm, anchor guide, rotatable joint

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|-----------|---|-----------------------|
| X         | US 2012-0095560 A1 (DONNER, EDWARD JEFFREY) 19 April 2012<br>See paragraphs [0121], [0124], [0126], [0129]-[0133], [0135], [0136], [0158], [0159], [0161], [0162], [0164]-[0172], [0174], [0181]-[0194], [0226], [0242]; and figures 2A-24, 32-36, 102A-102D, 109, 110. | 1-22, 43-45, 47-51    |
| Y         |   | 23-28, 46             |
| A         |   | 29-42                 |
| Y         | US 2011-0009869 A1 (MARINO et al.) 13 January 2011<br>See paragraphs [0051]-[0054]; and figures 5A-5D.  | 23-28, 46             |
| A         | US 2011-0184519 A1 (TRIEU, HAI H.) 28 July 2011<br>See abstract; paragraphs [0053], [0066]-[0071], [0074]-[0089]; and figures 5A, 7, 8, 10.   | 1-51                  |
| A         | US 7837732 B2 (ZUCHERMAN et al.) 23 November 2010<br>See column 11, line 15 - column 13, line 17; and figures 28-30.  | 1-51                  |
| A         | US 5334205 A (CAIN, JAMES E.) 2 August 1994<br>See abstract; column 3, line 54-column 4, line 48; and figure 3.   | 1-51                  |
| A         | US 8317862 B2 (TROGER et al.) 27 November 2012<br>See column 3, line 16-column 4, line 35; and figures 1, 2.  | 1-51                  |

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance  
"E" earlier application or patent but published on or after the international filing date  
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  
"O" document referring to an oral disclosure, use, exhibition or other means  
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art  
"&" document member of the same patent family


Date of the actual completion of the international search

18 November 2014 (18.11.2014)

Date of mailing of the international search report

**18 November 2014 (18.11.2014)**

Name and mailing address of the ISA/KR

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Korean Intellectual Property Office  
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**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 52  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claim 52 pertains to a method for treatment of the human body by surgery, and thus relates to a subject-matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2014/048990**

| Patent document cited in search report | Publication date | Patent family member(s)   | Publication date   |
|--|------------------|---|--|
| US 2012-0095560 A1                     | 19/04/2012       | CA 2849095 A1<br>EP 2720628 A1<br>US 2012-0296428 A1<br>US 2014-0142700 A1<br>WO 2012-174485 A1<br>WO 2013-043584 A2<br>WO 2013-043584 A3 | 28/03/2013<br>23/04/2014<br>22/11/2012<br>22/05/2014<br>20/12/2012<br>28/03/2013<br>16/05/2013 |
| US 2011-0009869 A1                     | 13/01/2011       | US 8439925 B2   | 14/05/2013   |
| US 2011-0184519 A1                     | 28/07/2011       | US 8221428 B2   | 17/07/2012   |
| US 7837732 B2                          | 23/11/2010       | US 2005-0149193 A1<br>US 2011-0022176 A1<br>US 8491653 B2   | 07/07/2005<br>27/01/2011<br>23/07/2013   |
| US 5334205 A                           | 02/08/1994       | None  |  |
| US 8317862 B2                          | 27/11/2012       | AU 2009-222580 A1<br>US 2010-0121447 A1   | 29/04/2010<br>13/05/2010   |