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- (54) **IMPLANT PLACEMENT**
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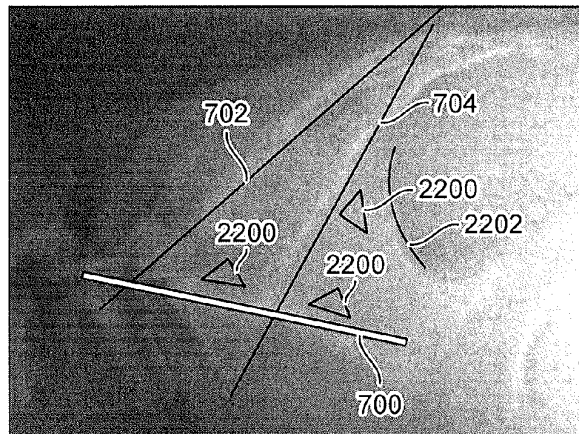
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(57) **ABSTRACT**
Embodiments of the present invention relate generally to implant placement into bone. More specifically, embodiments of the invention relate to implant placement across the sacro-iliac joint. Placement can be facilitated using various CT imaging views that allow the implants to be placed in bone associated with articular cartilage.

10 Claims, 33 Drawing Sheets



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2007/0270879	A1	11/2007	Isaza et al.	2011/0098747	A1	4/2011	Donner et al.
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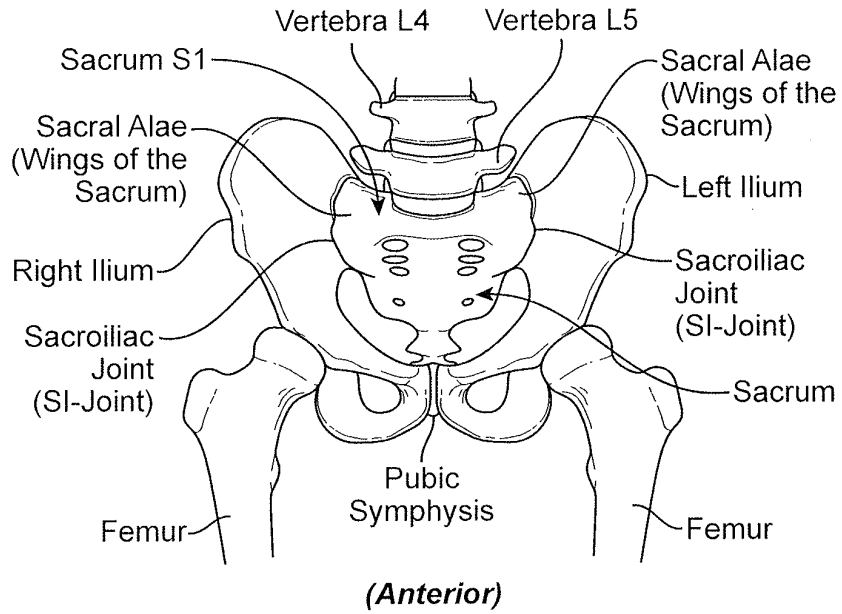


FIG. 1

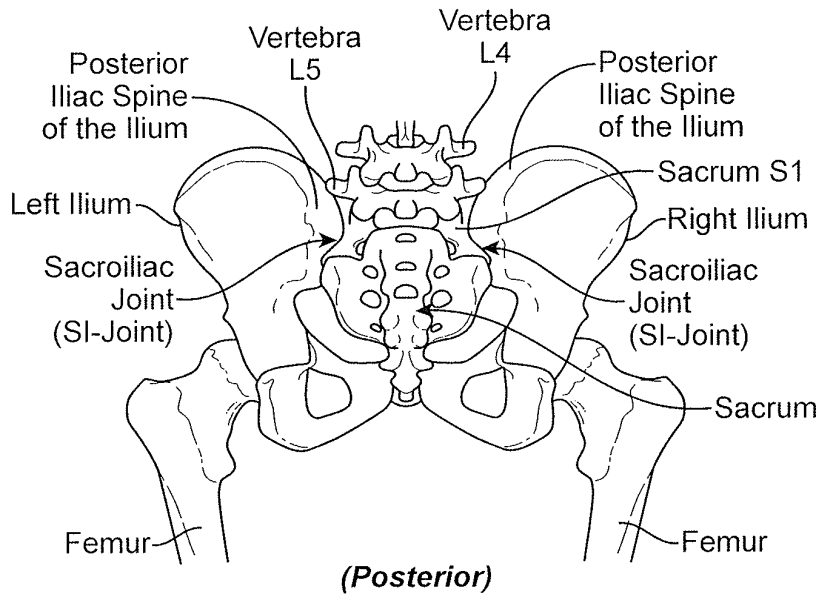


FIG. 2

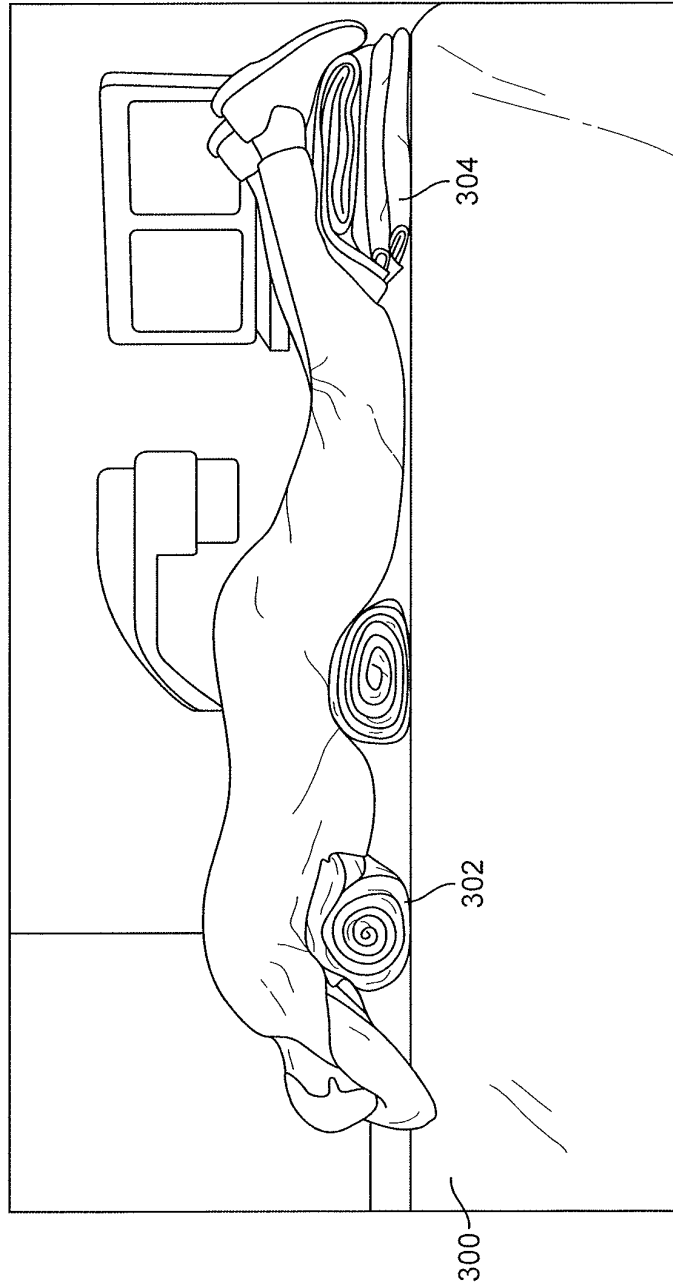


FIG. 3

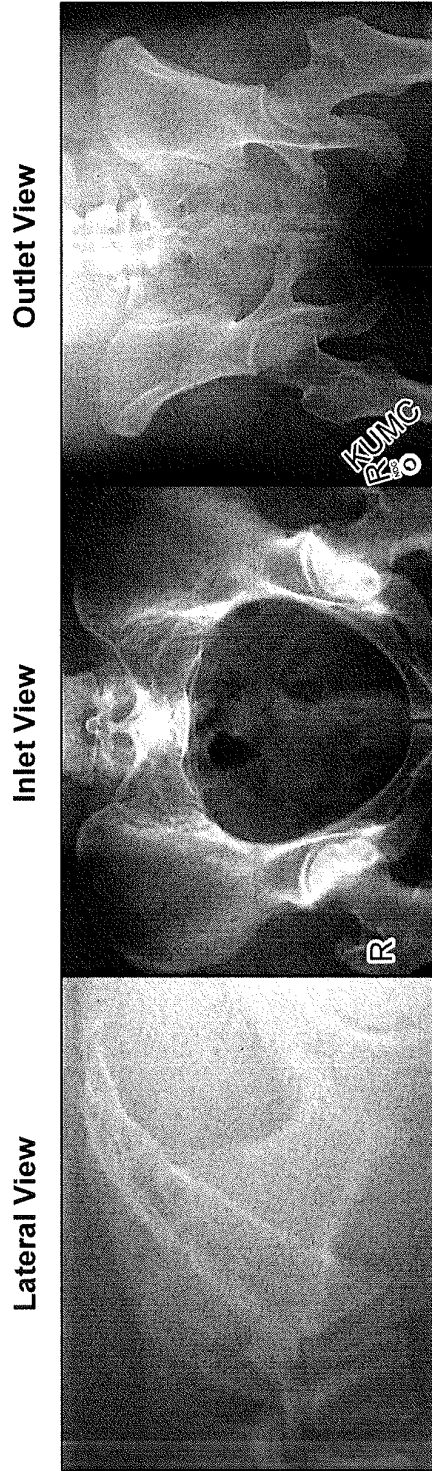
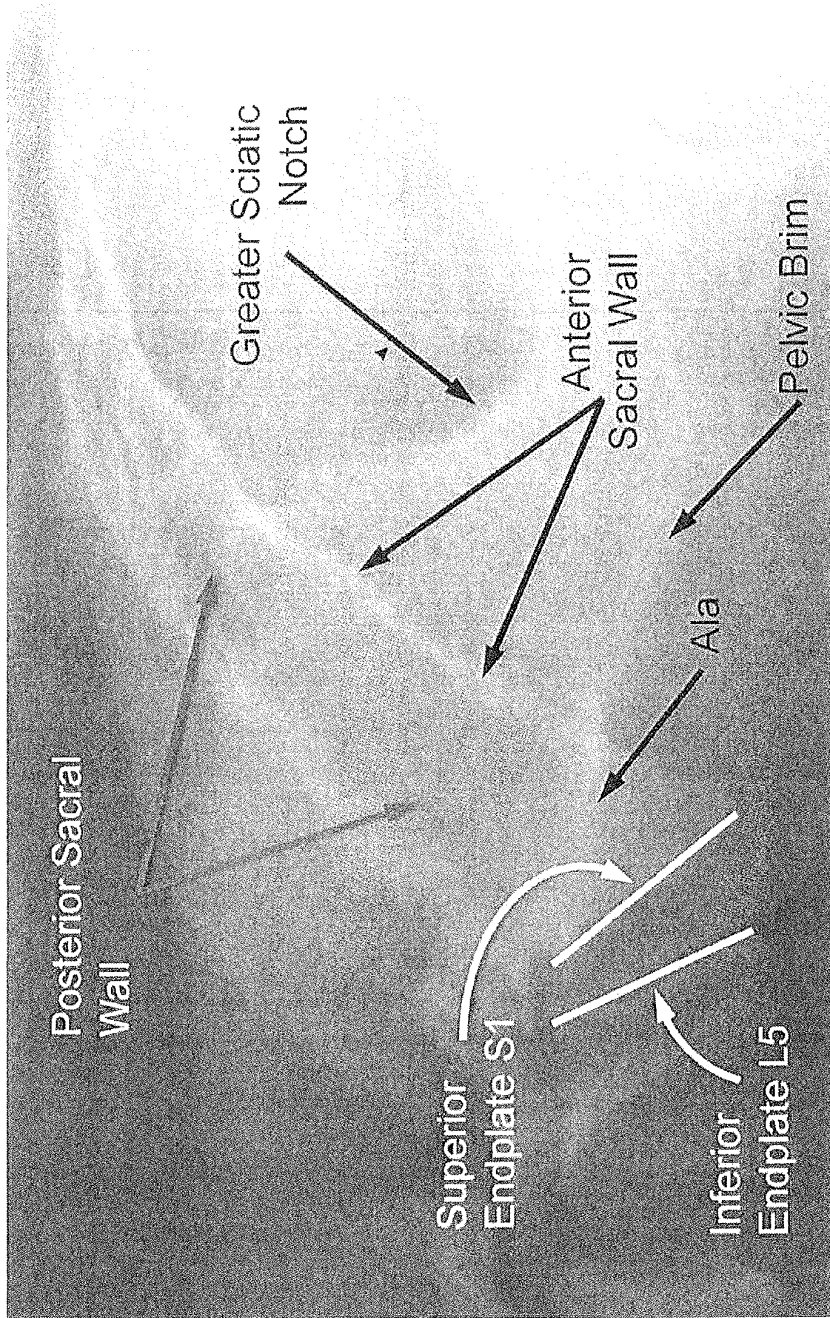


FIG. 4A

FIG. 4B

FIG. 4C

FIG. 5



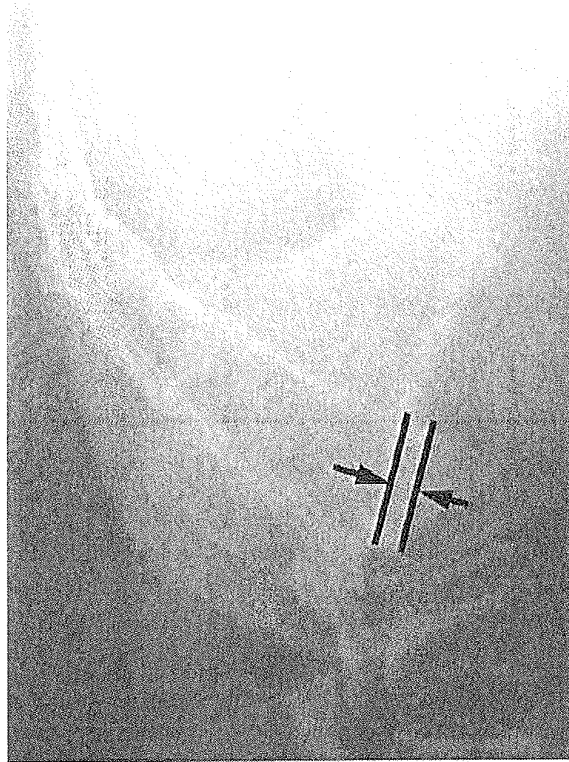


FIG. 6B

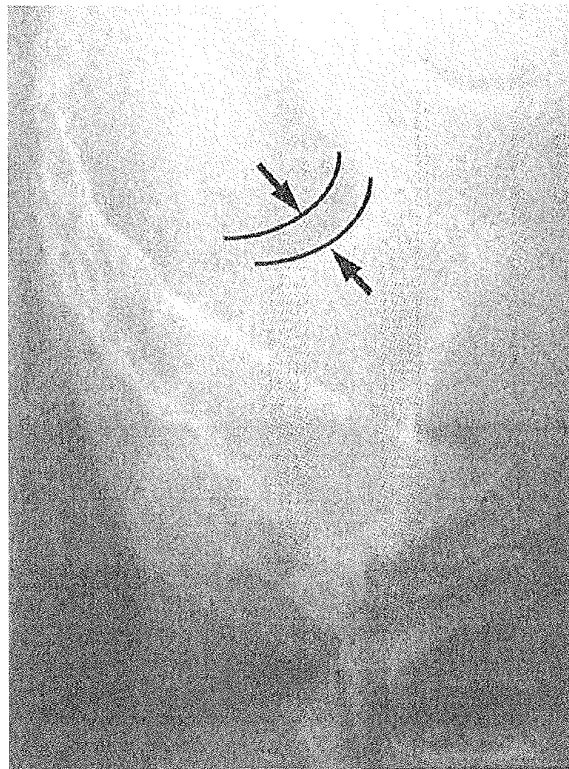


FIG. 6A

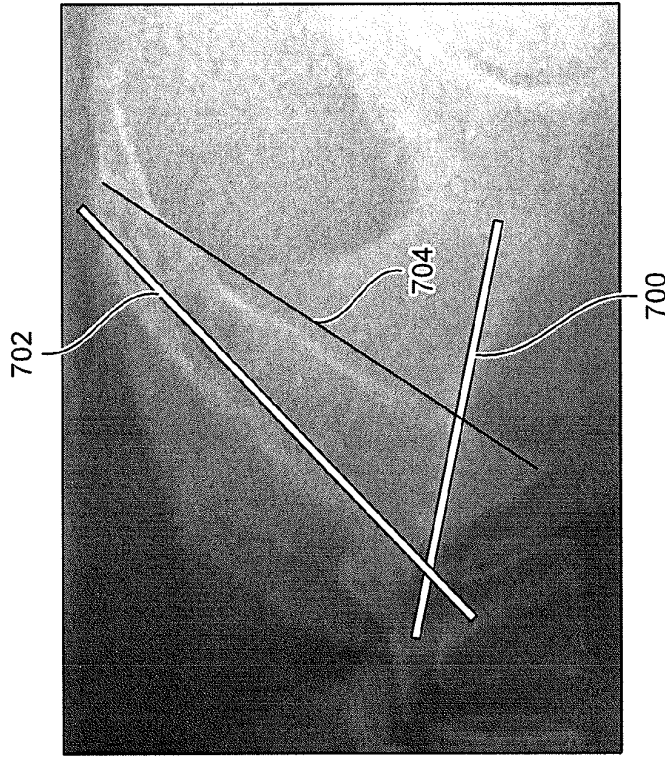


FIG. 7B

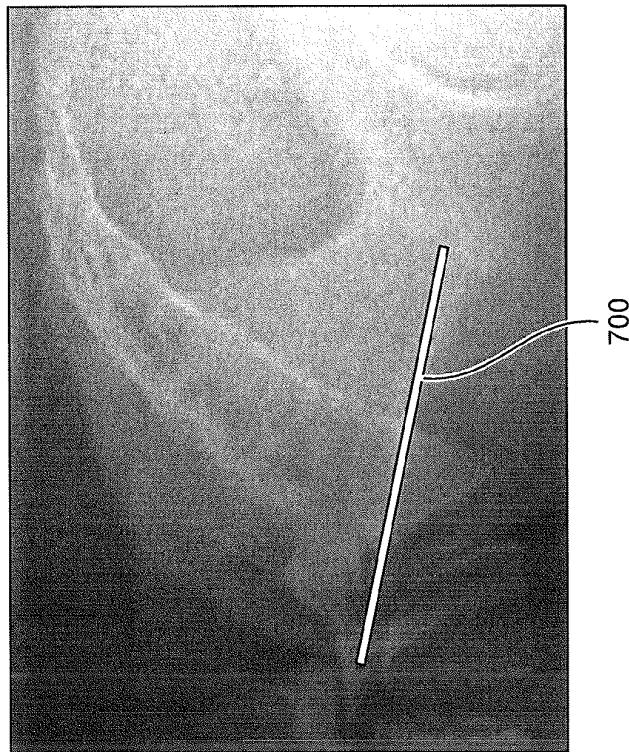


FIG. 7A

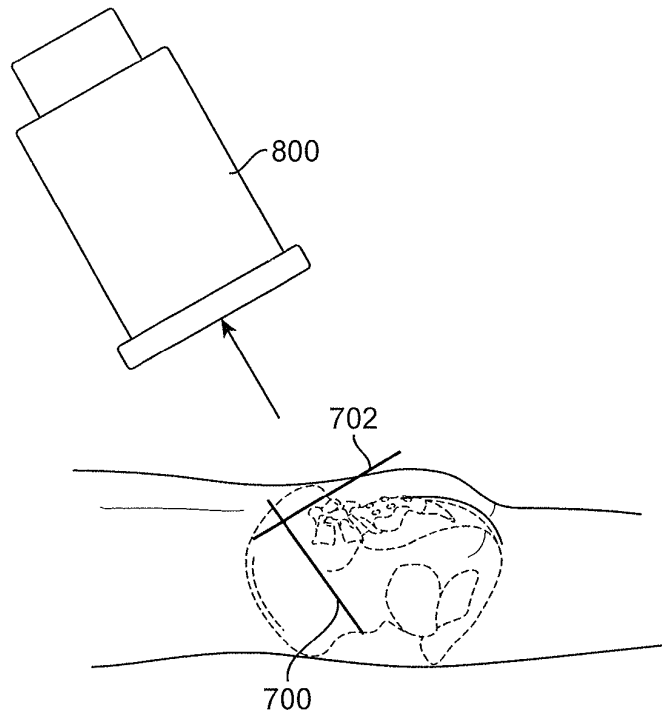


FIG. 8A

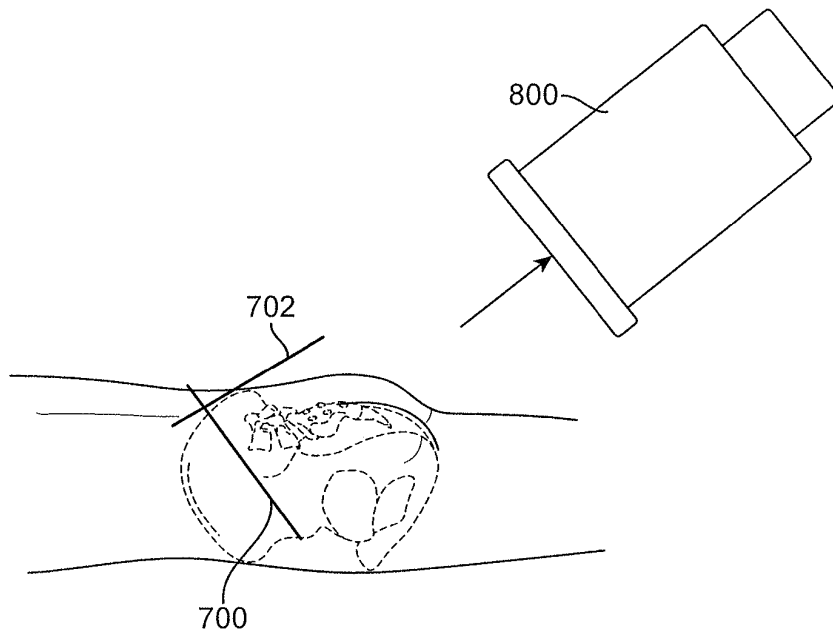


FIG. 8B

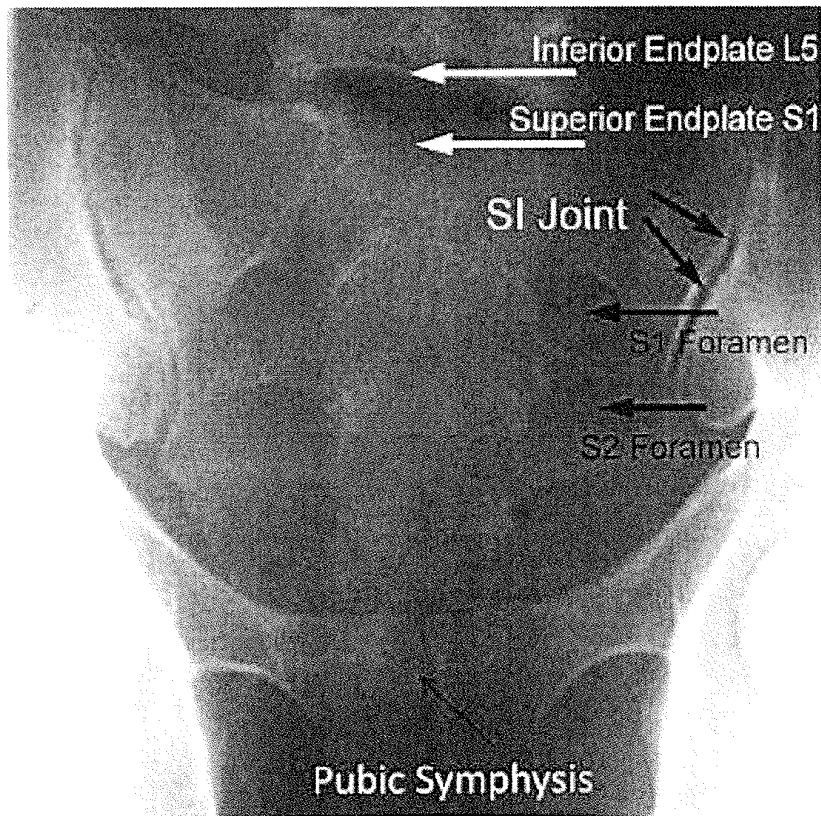


FIG. 9A

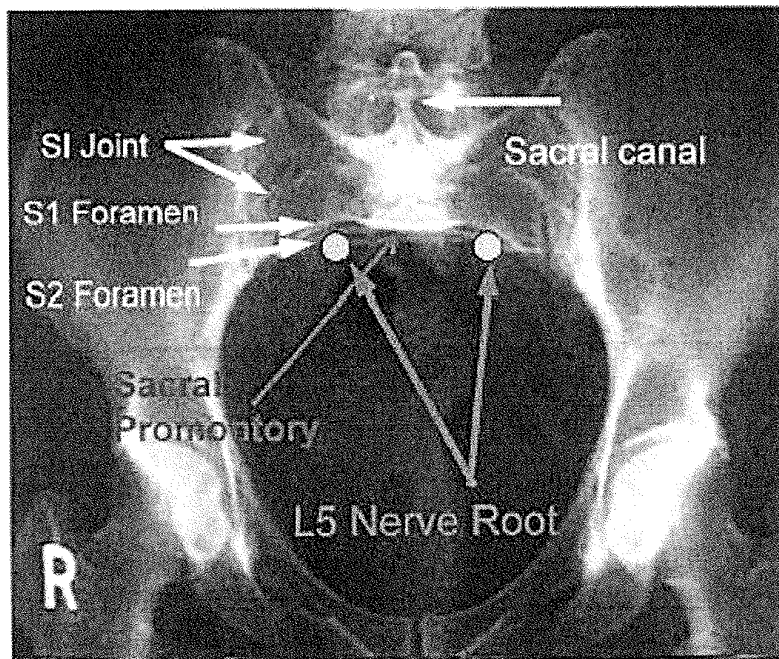


FIG. 9B

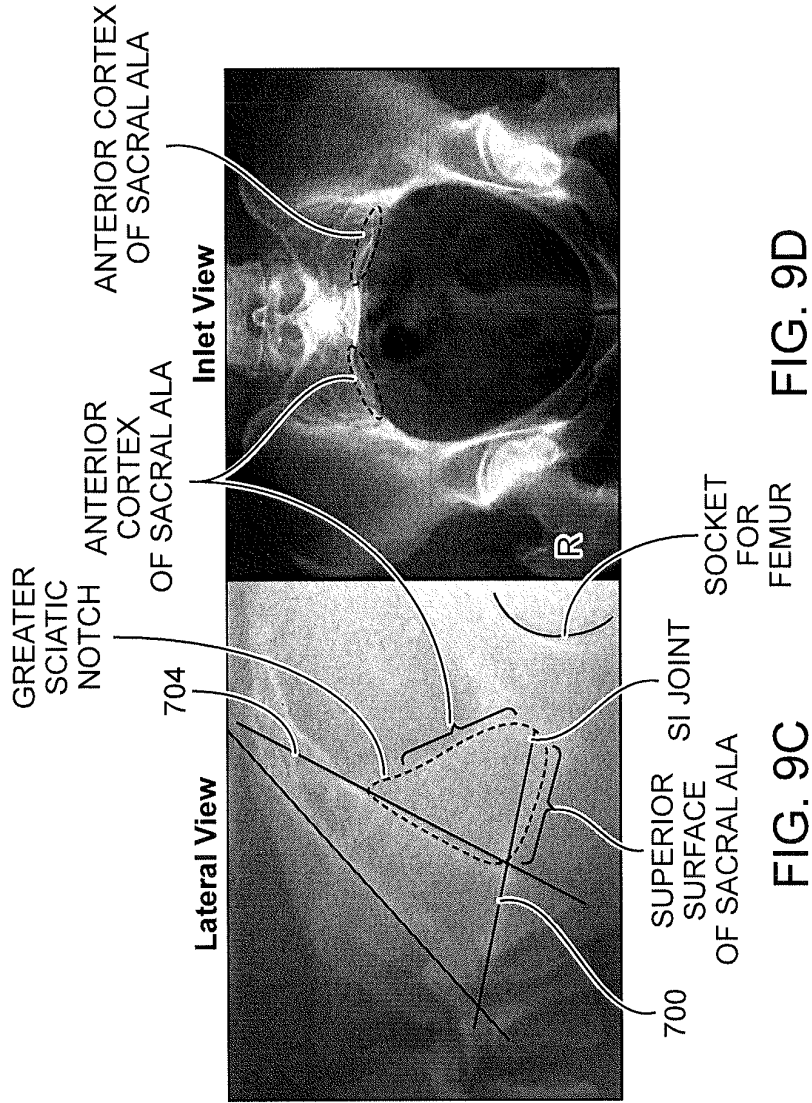


FIG. 9D

FIG. 9C

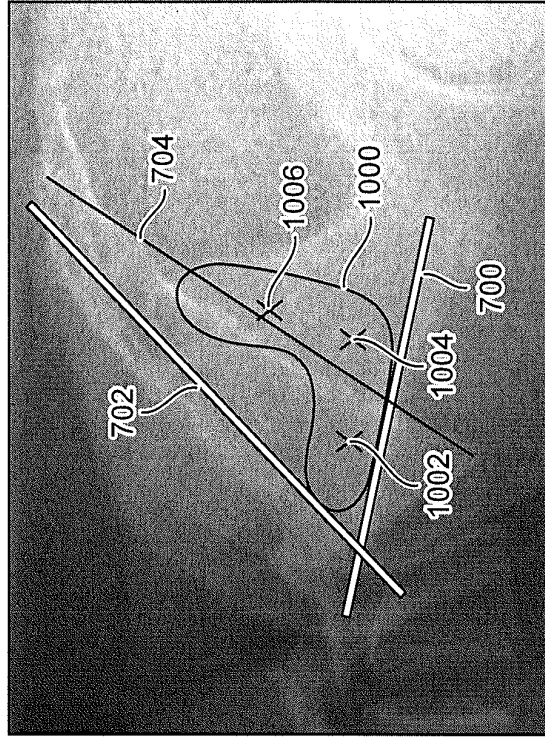


FIG. 10A

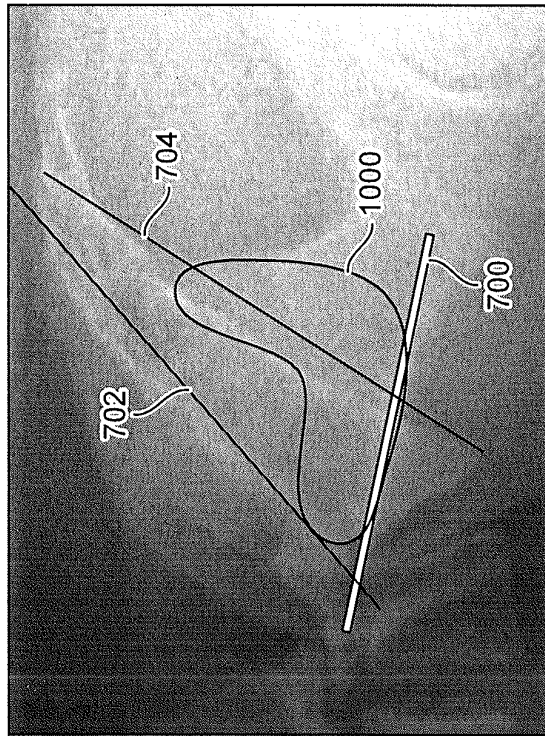


FIG. 10B

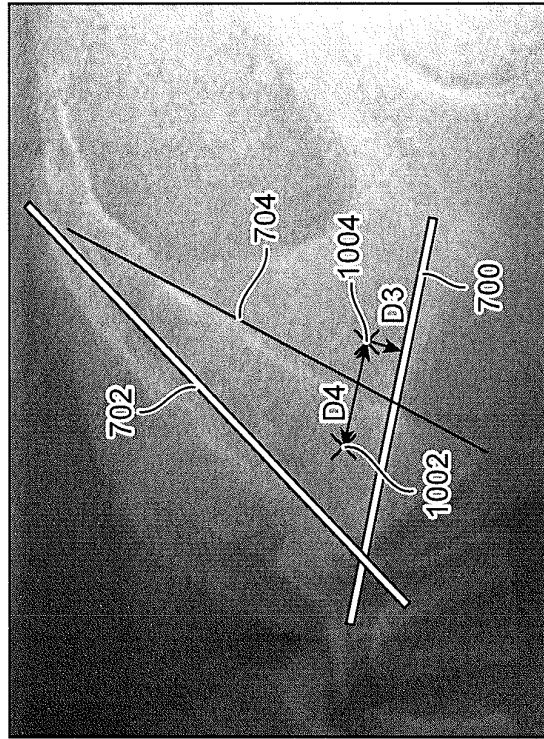


FIG. 10D

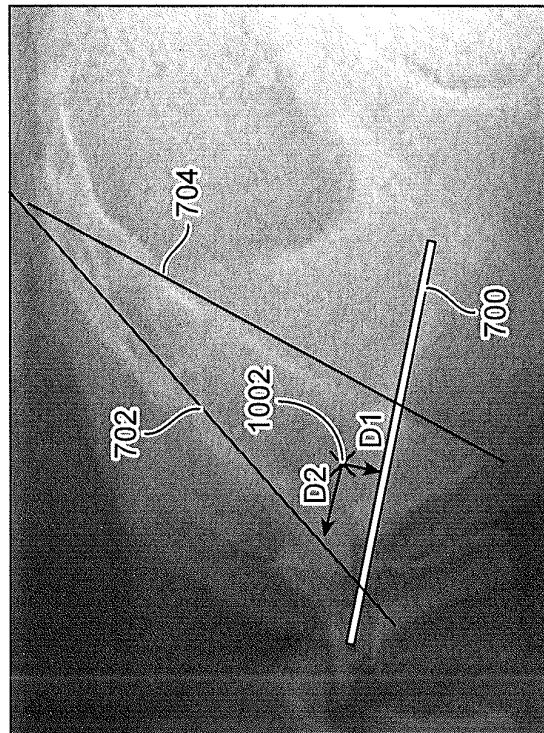


FIG. 10C

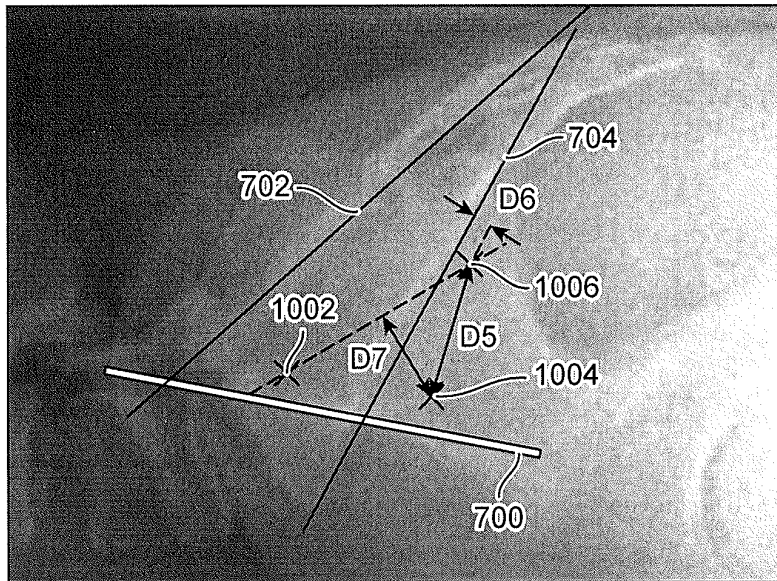


FIG. 10E

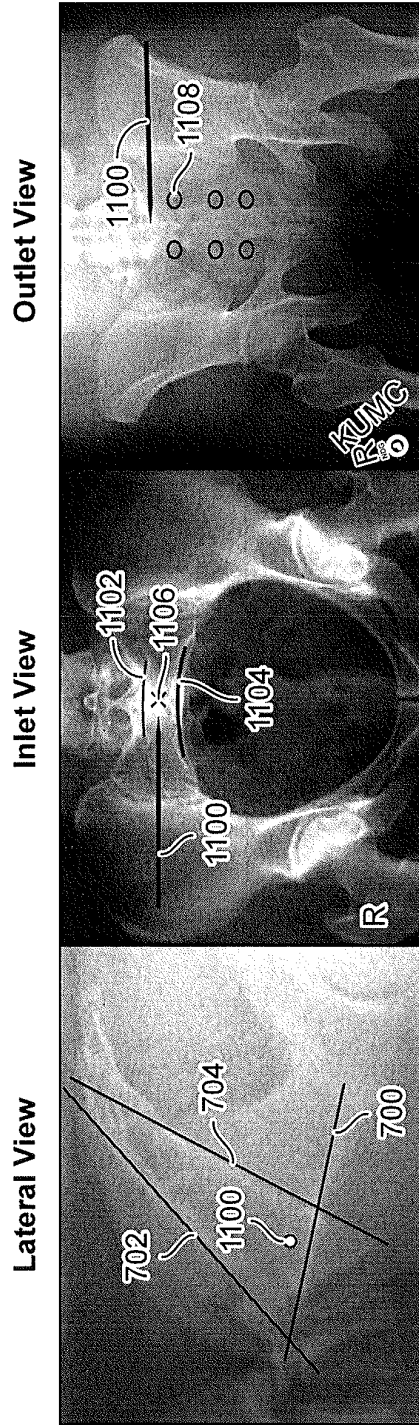


FIG. 11A

FIG. 11B

FIG. 11C

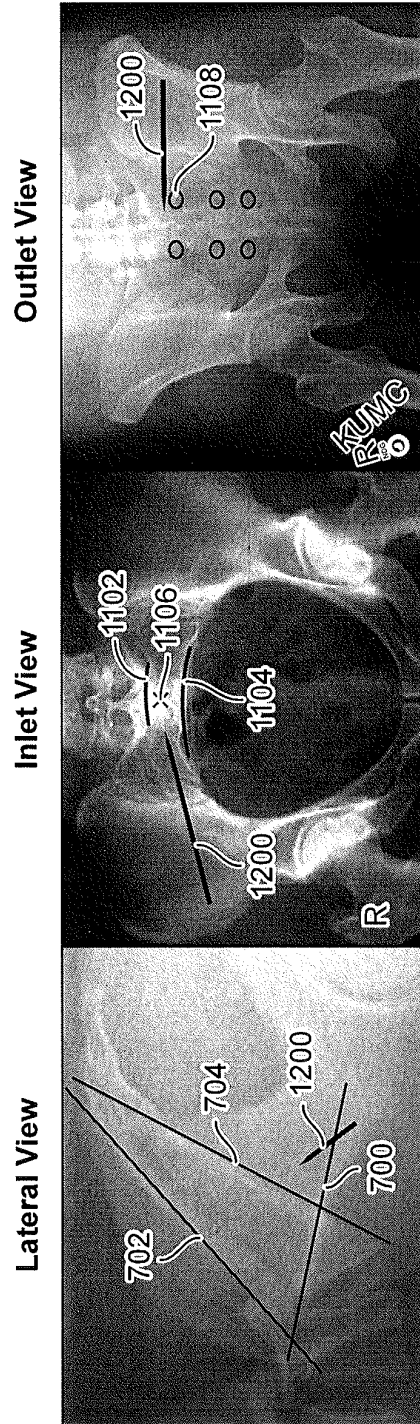


FIG. 12A

FIG. 12B

FIG. 12C

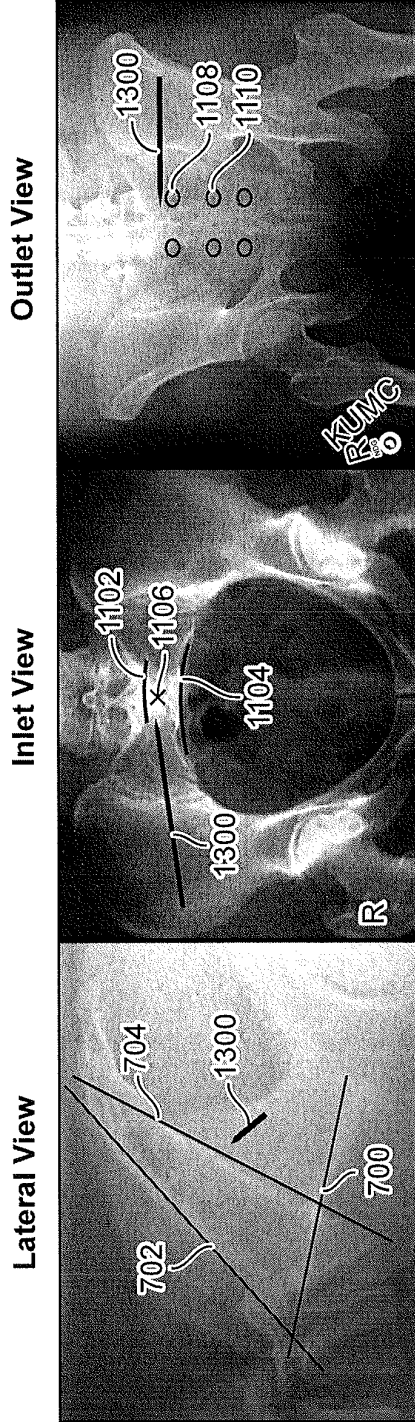


FIG. 13C

FIG. 13B

FIG. 13A

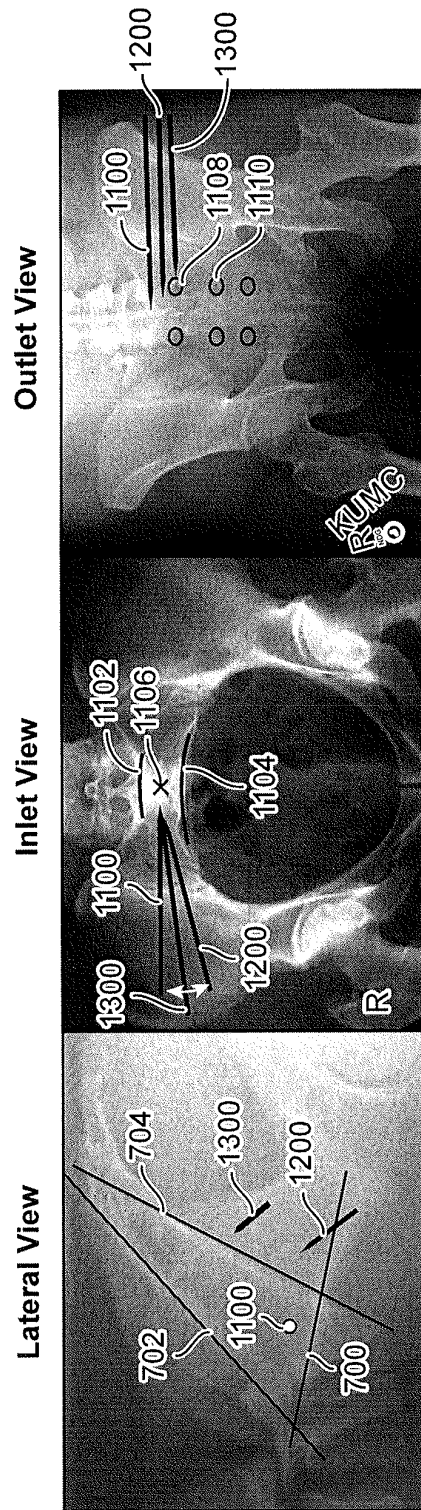


FIG. 14C

FIG. 14B

FIG. 14A

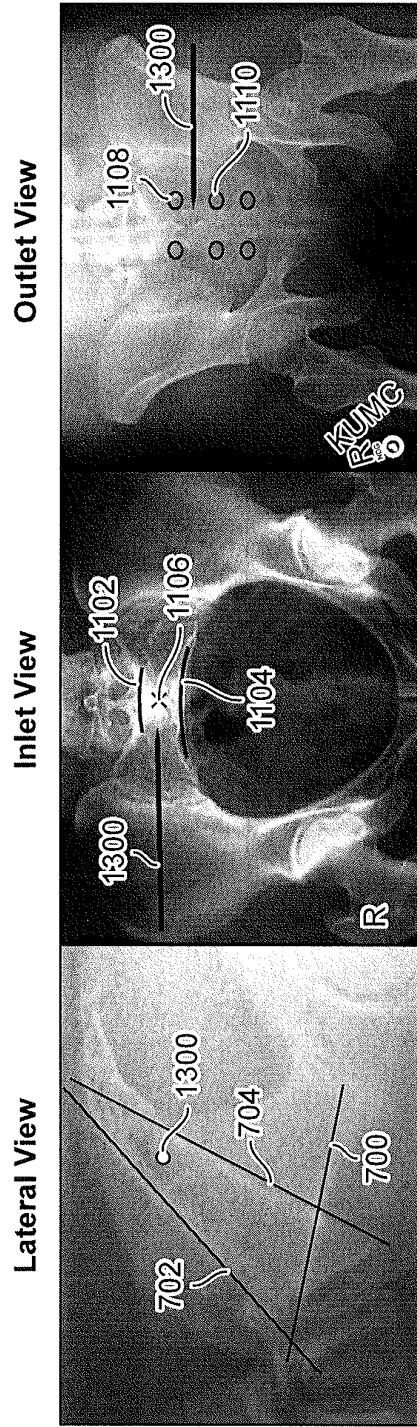


FIG. 15C

FIG. 15B

FIG. 15A

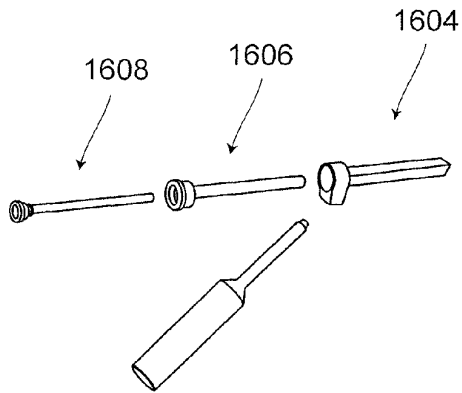


FIG. 16A

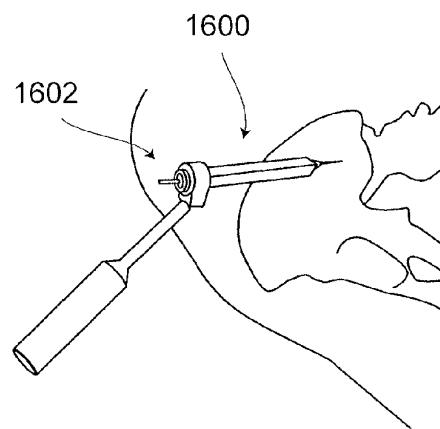


FIG. 16B

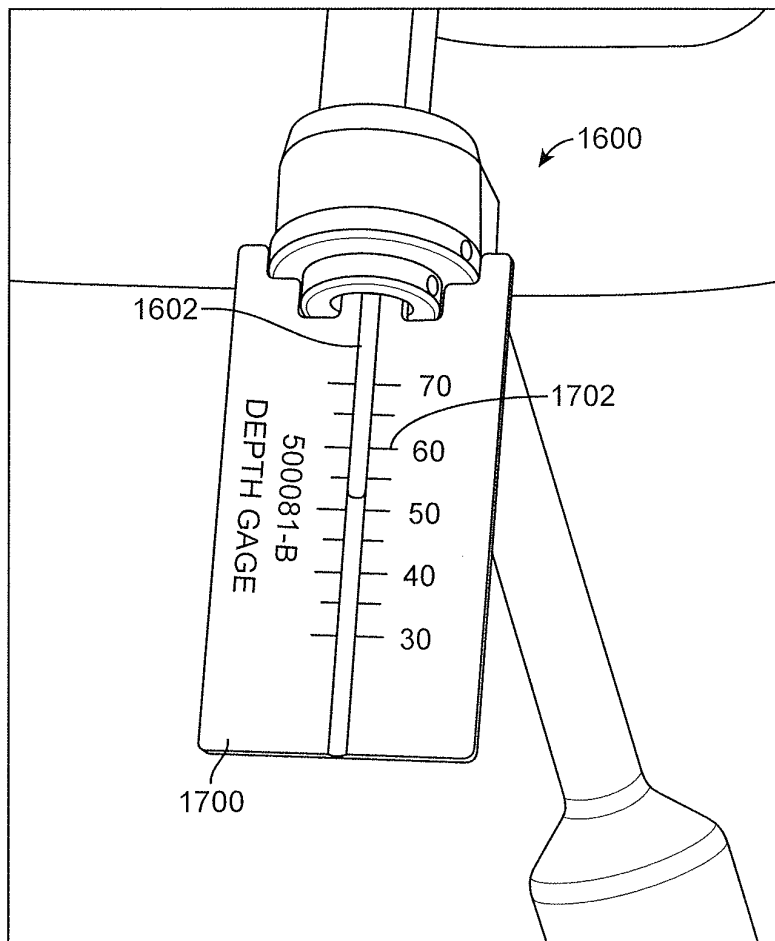


FIG. 17

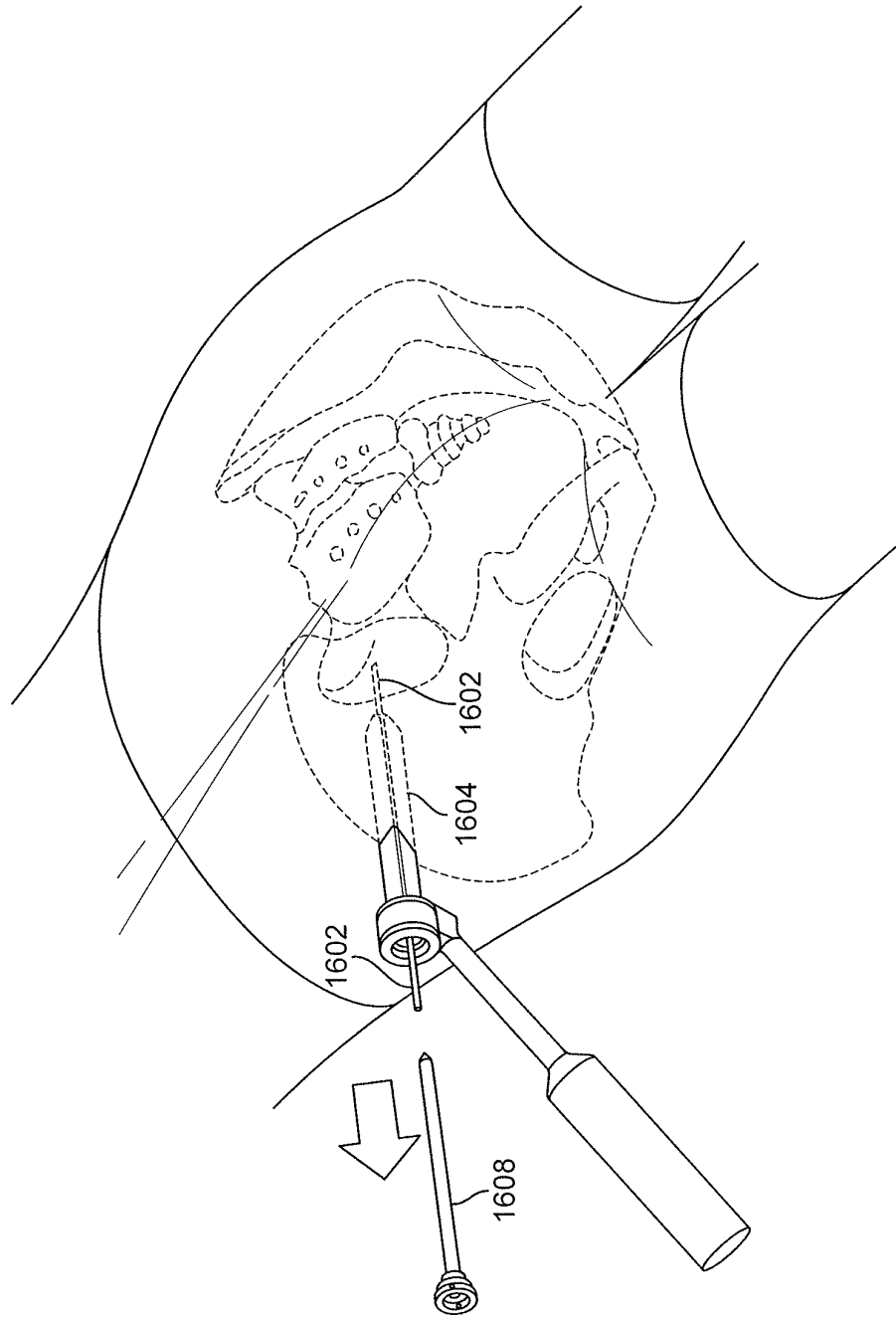


FIG. 18

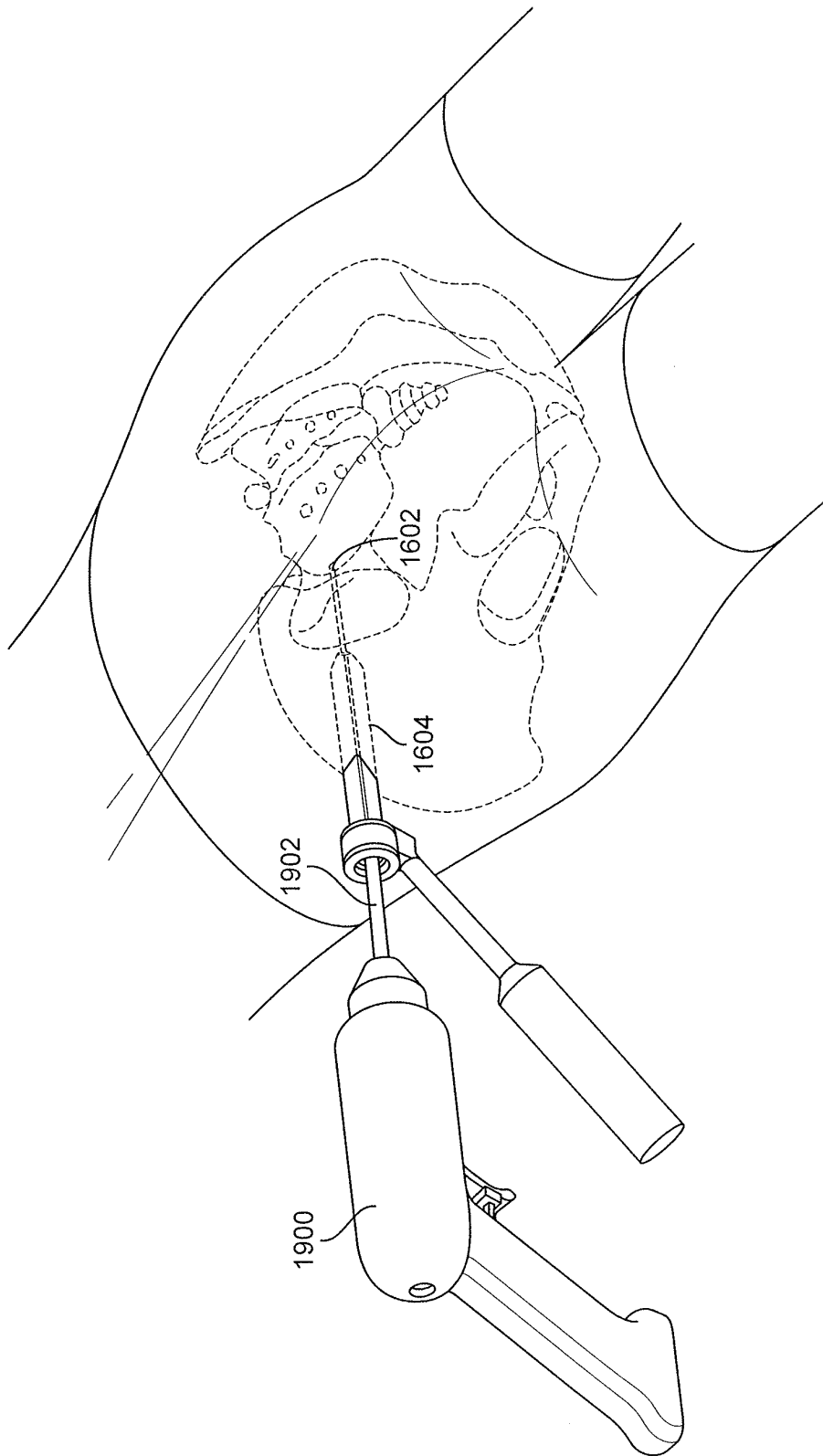


FIG. 19

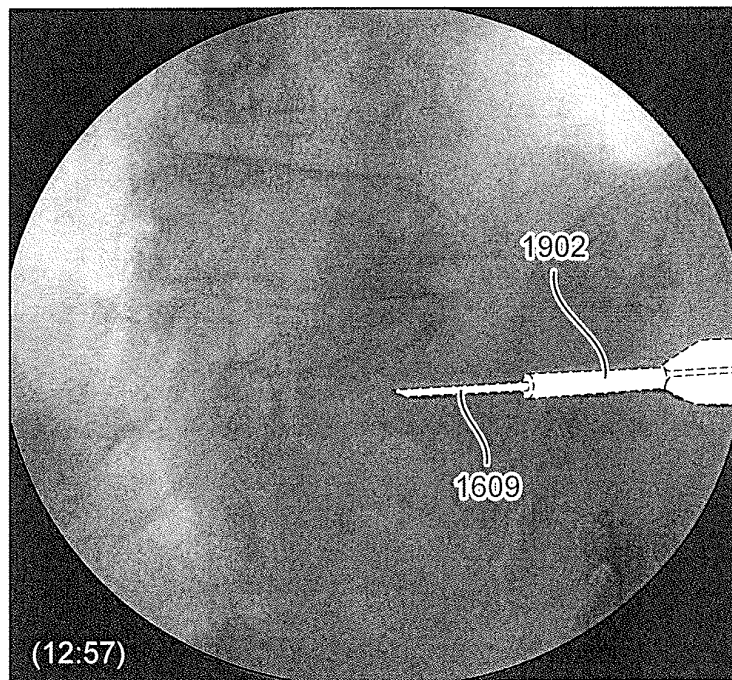


FIG. 20

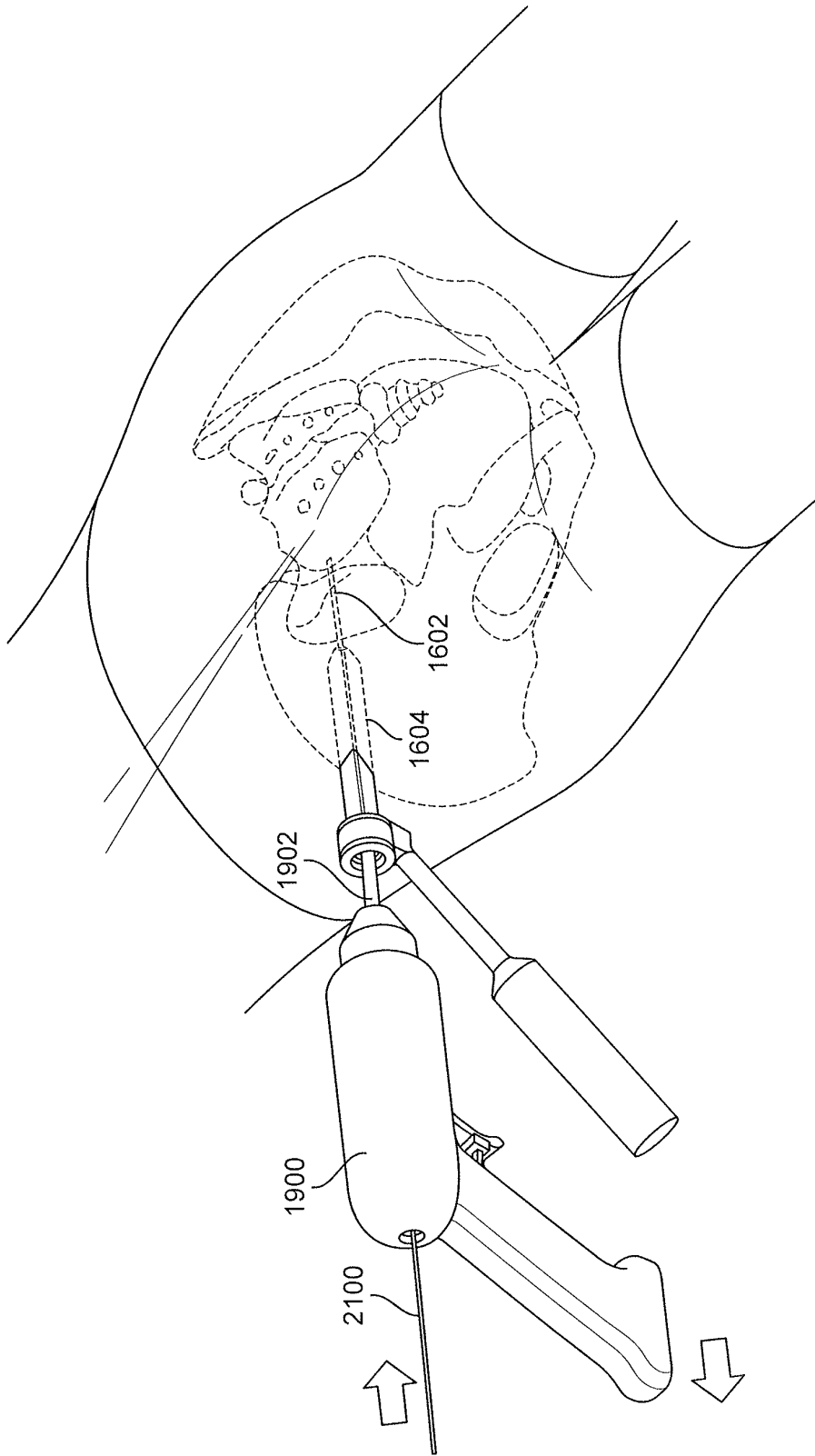


FIG. 21

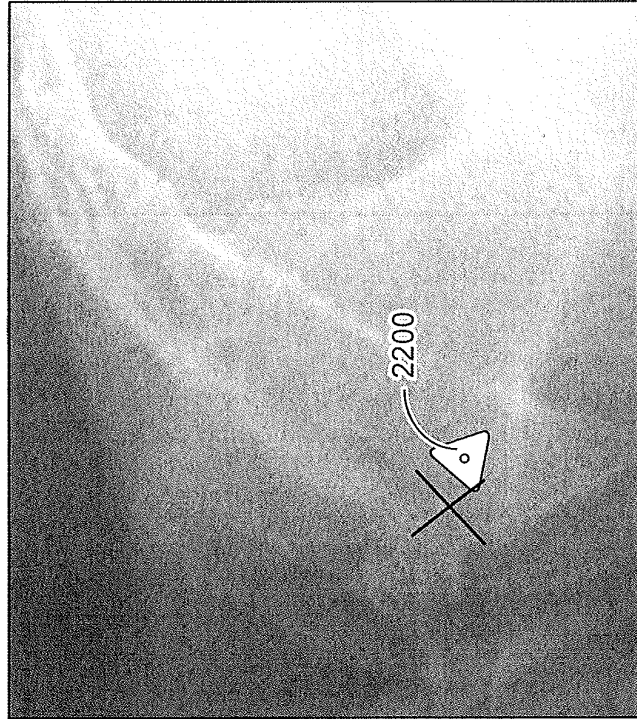


FIG. 22B

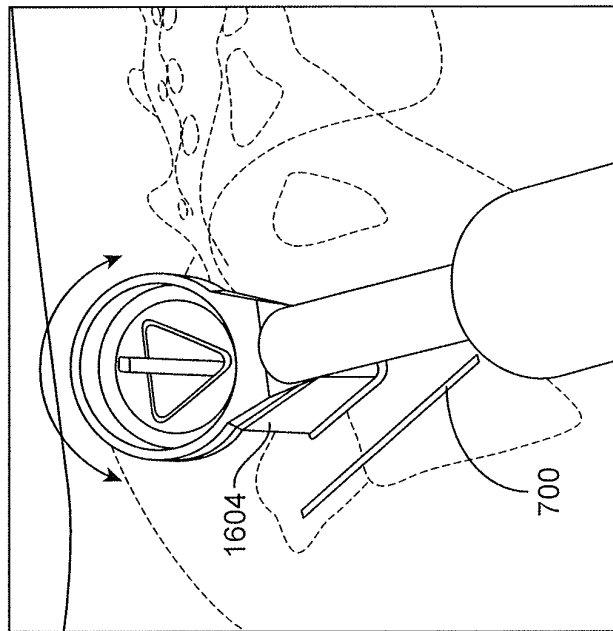


FIG. 22A

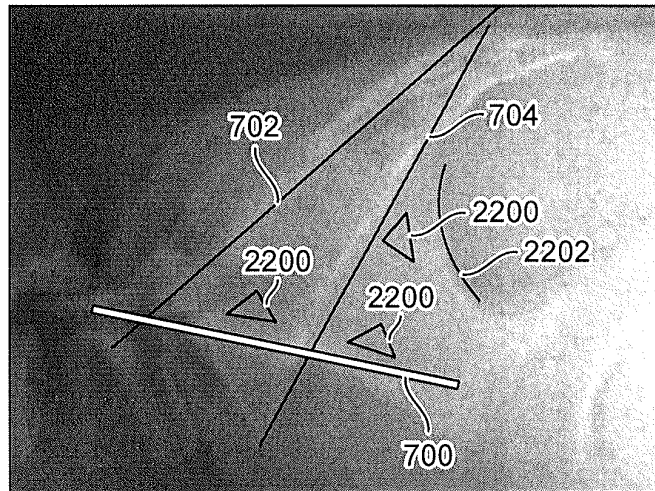
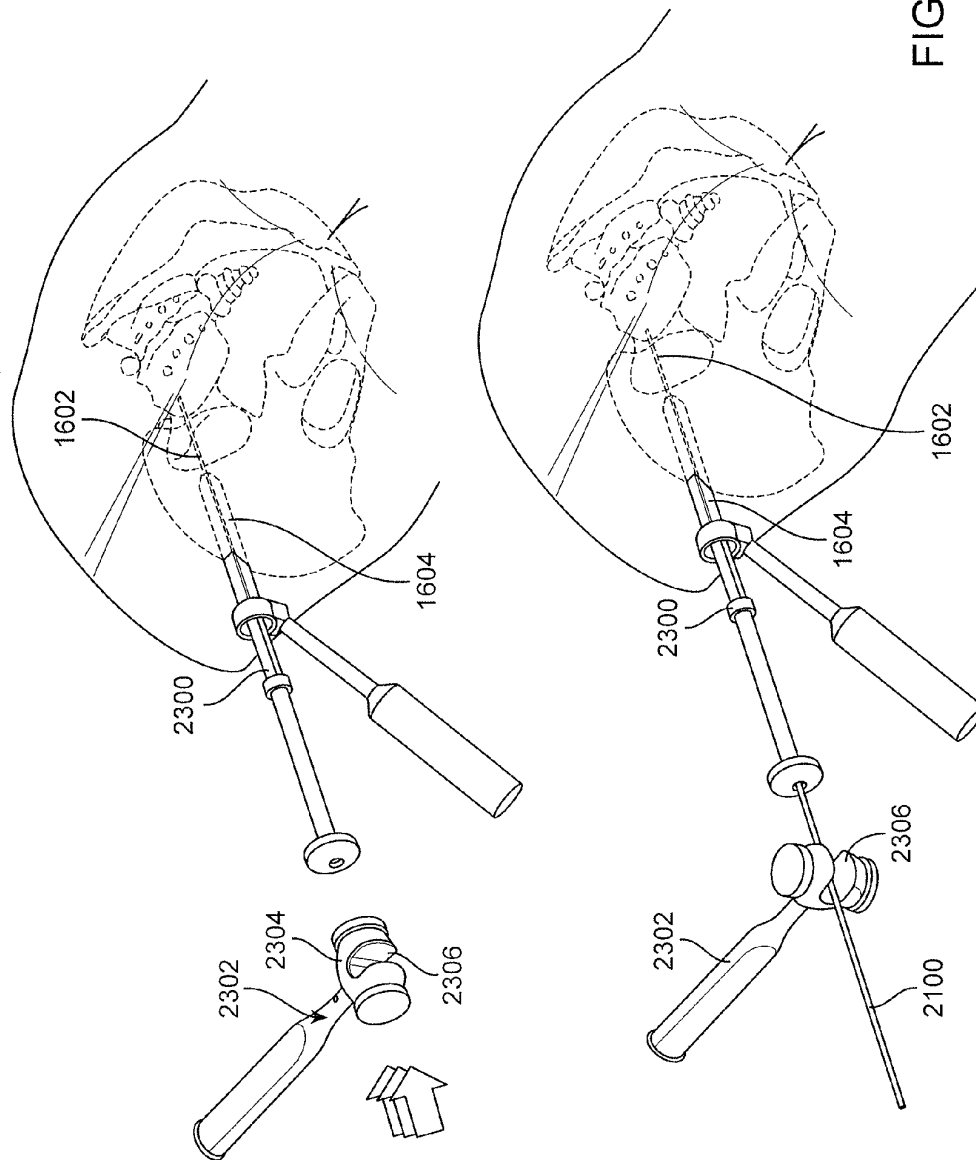


FIG. 22C



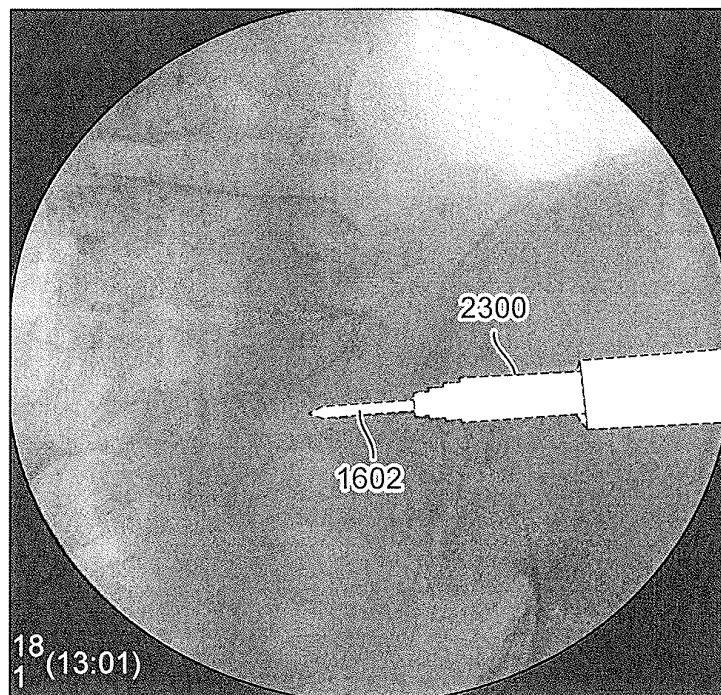


FIG. 24

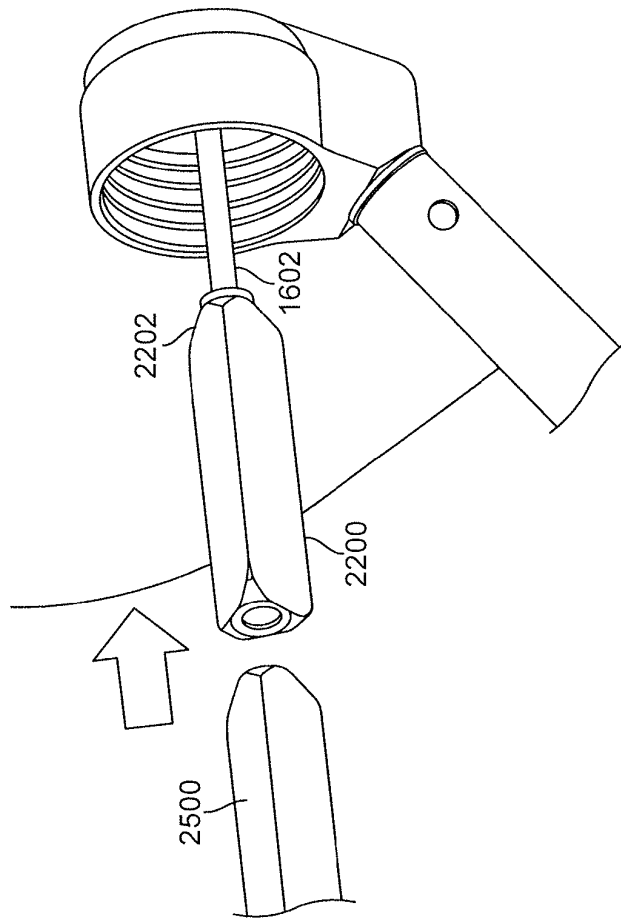


FIG. 25A

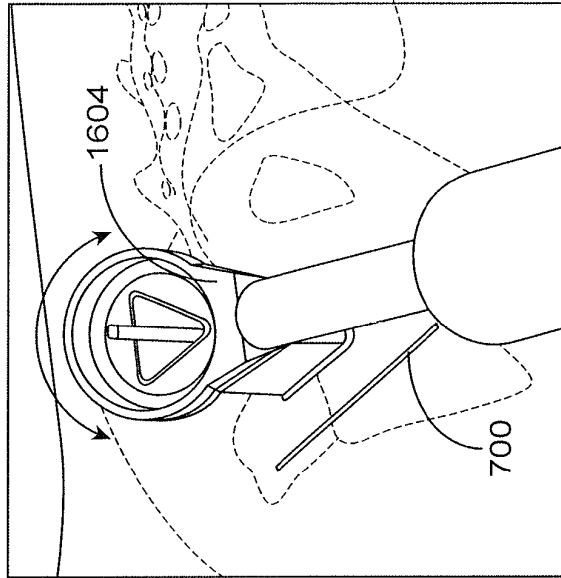
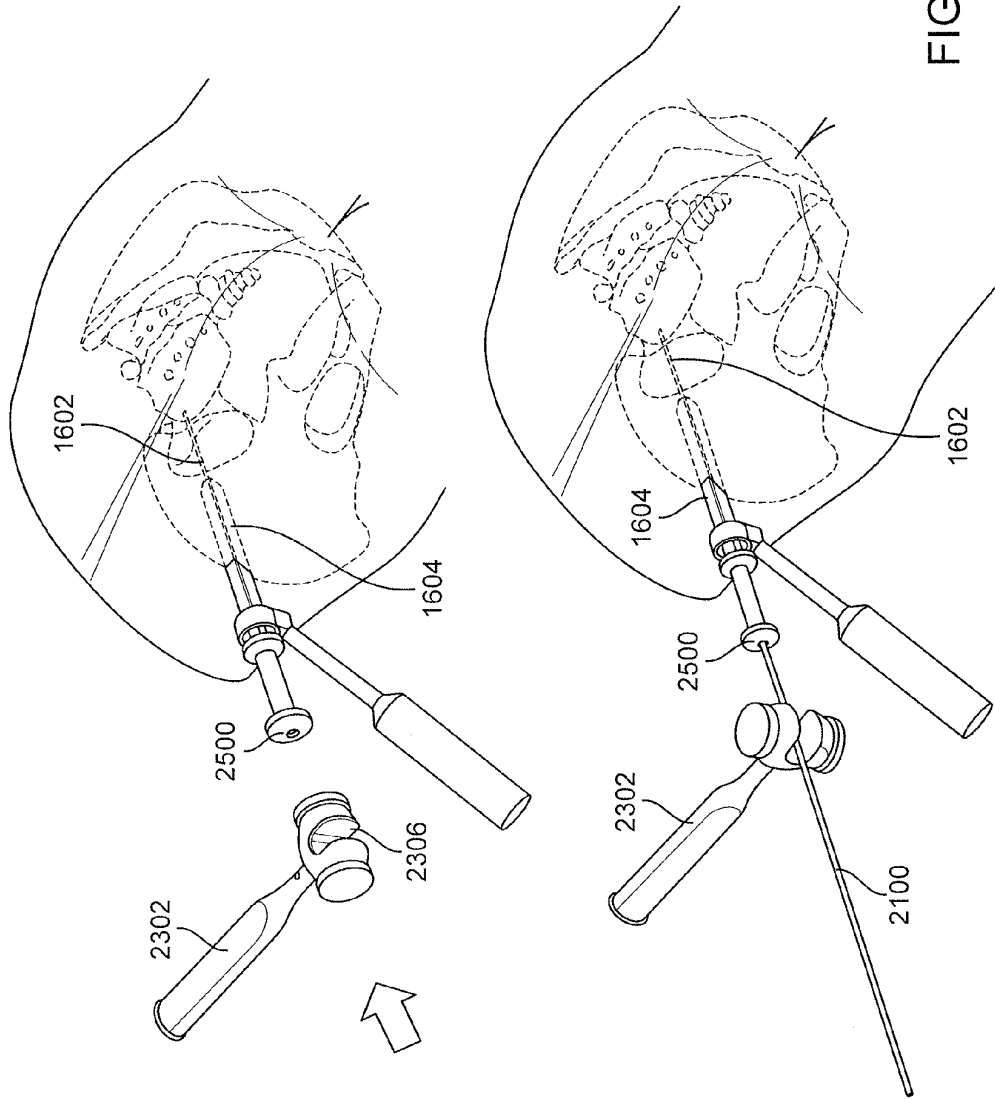


FIG. 25B



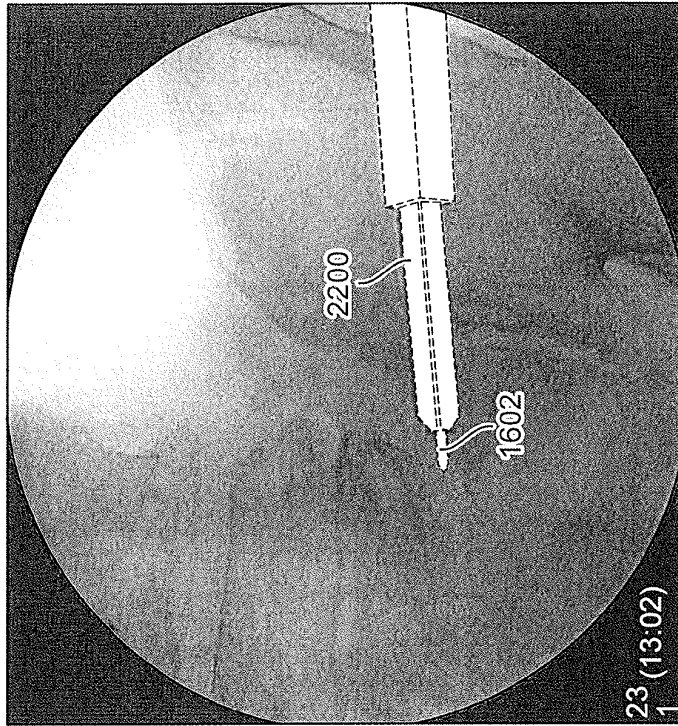


FIG. 27B

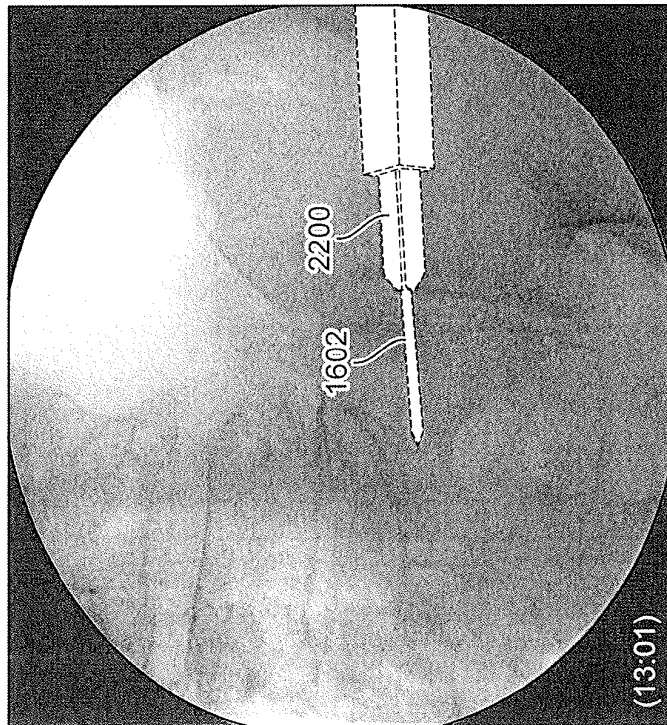


FIG. 27A

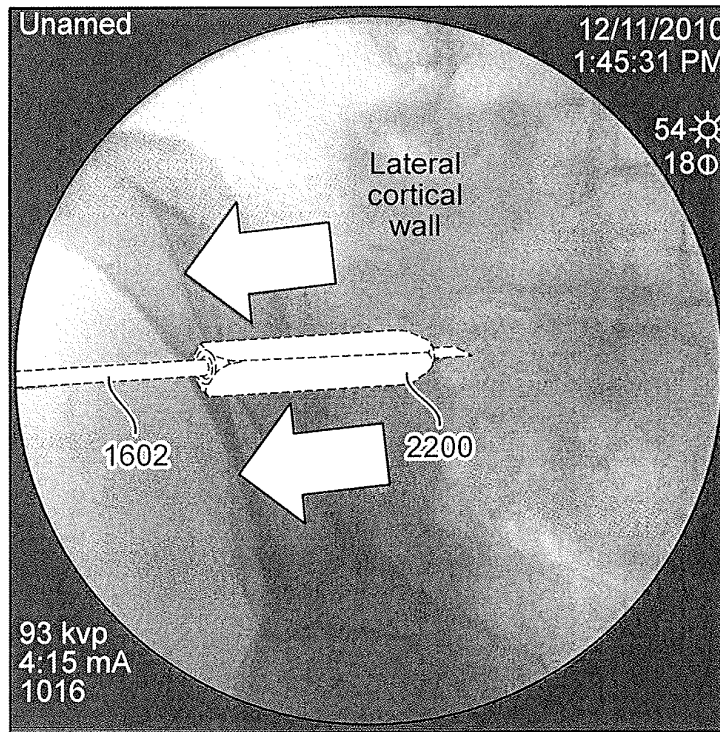


FIG. 28

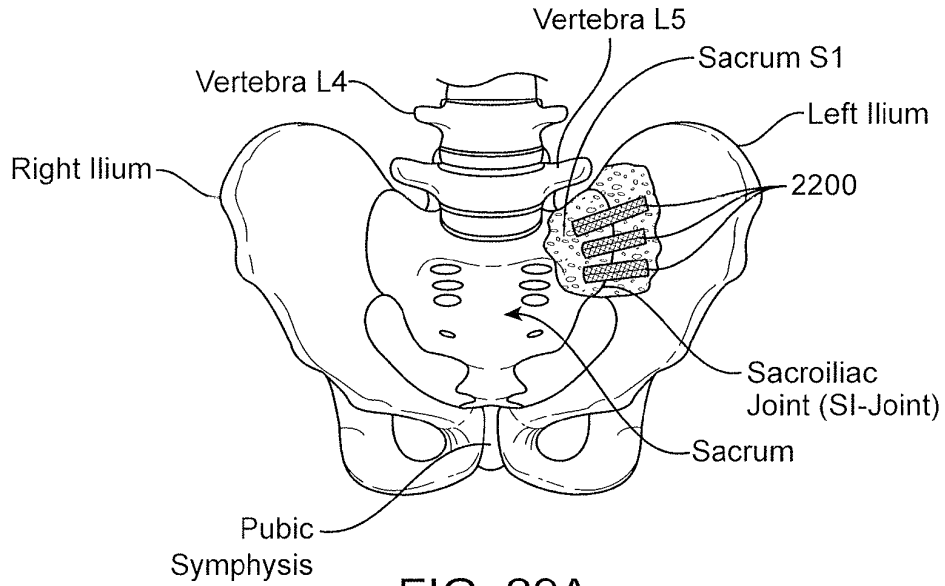


FIG. 29A

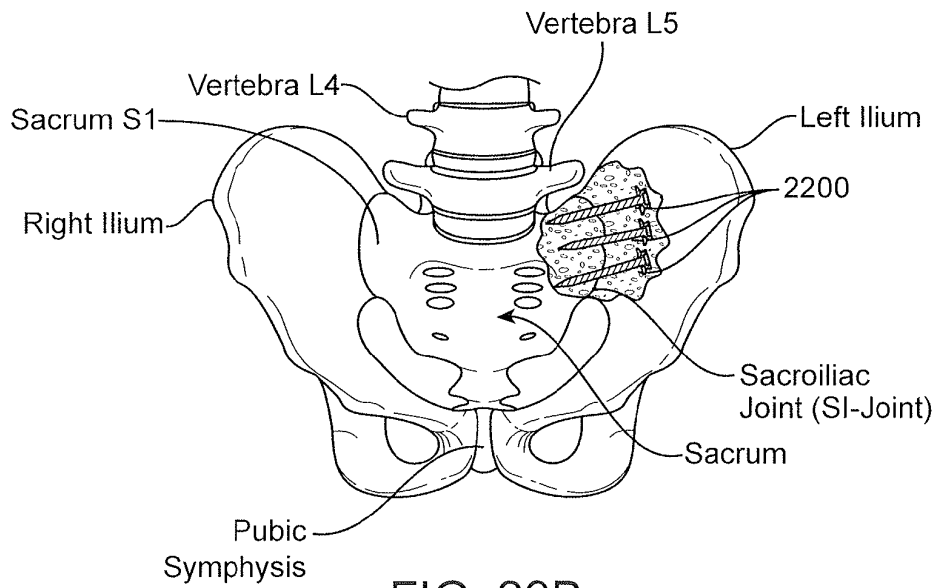


FIG. 29B

1

IMPLANT PLACEMENT**CROSS REFERENCE TO RELATED APPLICATIONS**

This application claims priority to U.S. Provisional Patent Application No. 61/891,326, filed Oct. 15, 2013, and titled "IMPLANT PLACEMENT," which is herein incorporated by reference in its entirety for all purposes.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

Embodiments of the invention relate generally to implant placement into bone. More specifically, embodiments of the invention relate to implant placement across the sacro-iliac joint.

BACKGROUND

Many types of hardware are available both for the fixation of bones that are fractured and for the fixation of bones that are to be fused (arthrodesed).

For example, the human pelvic girdle (see FIGS. 1 and 2) is made up of three large bones joined together by three relatively immobile joints. One of the bones is called the sacrum and it lies at the bottom of the lumbar spine, where it connects with the L5 vertebra. The other two bones are commonly called "pelvic bones" and are technically referred to as the right ilium and—the left ilium. The sacrum connects with both pelvic bones at the sacroiliac joint (in shorthand, the SI-Joint).

The SI-Joint functions to transfer forces from the spine to the lower extremities, and vice-versa. The SI-Joint has been identified as the pain generator in up to 22% of patients who present with lower back pain.

Sacroiliac joint fusion is a surgical procedure that is performed to alleviate pain coming from the SI joint in patients who have failed to receive adequate pain relief with non-surgical treatments of the SI joint. Some conditions of the SI joint that may be treated with SI joint fusion (arthrodesis) are: degenerative sacroiliitis, inflammatory sacroiliitis, iatrogenic instability of the sacroiliac joint, osteitis condensans ilii, or traumatic fracture dislocation of the pelvis. Currently, screws and screws with plates are used as the standard instrumentation for sacro-iliac fusion. Historically, an SI joint fusion consisted of an open surgical approach to the SI joint from an anterior, a posterior, or a lateral direction. The surgeon would then debride (remove) the cartilage from the articular portion of the joint and the interosseous ligament from the fibrous portion of the joint. These open approaches require a large incision and deep soft tissue dissection to approach the damaged, subluxed, dislocated, fractured, or degenerative SI joint.

A typical technique for placing implants involves placement of one or multiple implants from a lateral to medial direction across the SI-Joint. These implants are placed with a starting point on the lateral aspect of the ilium. The implants are then directed across the ilium, across the sacroiliac joint and into the sacrum. Regarding implant

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position, care is taken to avoid impinging on neural and vascular structures, including neural tissue within the neural foraminae or spinal canal. In addition, care must be taken to place the implants across the SI joint and avoid the leading tip(s) of the implant(s) violating the osseous envelope of the sacrum. However, the density of the bone in different portions of the sacrum is not typically a consideration during implant placement.

Accordingly, it would be desirable to provide systems and methods for placing multiple implants across the SI-Joint into those portions of the sacrum with relatively higher bone density. Implants placed into denser (stronger) bone will demonstrate improved short-term and long-term mechanical stability of the implant construct spanning the SI-Joint post implantation.

SUMMARY OF THE DISCLOSURE

The present invention relates generally to implant placement into bone. More specifically, embodiments of the invention relate to implant placement across the sacro-iliac joint.

In some embodiments, a method of implanting a plurality of implants in the SI-joint is provided. The method can include inserting a plurality of guide pins into an anterior portion of the SI-joint that is associated with articular cartilage; creating a bore around each of the plurality of guide pins; and inserting an implant into each bore such that each implant is located in an anterior portion of the SI-joint that is associated with articular cartilage.

In some embodiments, the method further includes obtaining a lateral view of the pelvis; and identifying a plurality of anatomical landmarks in the lateral view including the alar line, the posterior sacral body line, the anterior sacral body line, and the anterior cortex of the sacral alar, wherein the plurality of guide pins are inserted with reference to at least one anatomical landmark.

In some embodiments, at least one guide pin and implant are inserted anterior of the anterior sacral body line in the lateral view.

In some embodiments, at least two guide pins and implants are inserted anterior of the anterior sacral body line in the lateral view.

In some embodiments, the at least one guide pin and implant that is inserted anterior of the anterior sacral body line in the lateral view is angled with respect to the horizontal axis in the inlet view.

In some embodiments, at least two guide pins and two implants are placed parallel to the alar line.

In some embodiments, the plurality of guide pins are parallel in the outlet view.

In some embodiments, the method further includes identifying a target for the plurality of guide pins in the inlet view, wherein the target is located in the middle of the sacral body.

In some embodiments, the method further includes advancing the guide pins towards the target in the inlet view.

In some embodiments, the implants are non-collinear in the lateral view.

In some embodiments, the implants have an elongate body with a longitudinal axis and a rectilinear cross-sectional profile transverse to the longitudinal axis.

In some embodiments, the implants are screws.

In some embodiments, a system for fixation of the SI-joint is provided. The system can include a first elongate implant that is inserted into the SI-joint through a cephalad portion of the articular cartilage in the SI-joint; a second elongate

implant that is inserted into the SI-joint through a middle portion of the articular cartilage in the SI-joint, wherein the second elongate implant is caudal and anterior to the first elongate implant; and a third elongate implant that is inserted into the SI-joint through a caudal portion of the articular cartilage in the SI-joint, wherein the third elongate implant is caudal to the second elongate implant.

In some embodiments, the first elongate implant is inserted into the SI-joint caudal to the alar line and between the posterior sacral body line and the anterior sacral body line in a lateral view.

In some embodiments, the second elongate implant is inserted into the SI-joint caudal to the alar line and anterior to the anterior sacral body line in a lateral view.

In some embodiments, the third elongate implant is inserted into the SI-joint anterior to the anterior sacral body line in a lateral view.

In some embodiments, the first elongate implant is positioned horizontally in an inlet view and the second elongate implant is angled with respect to the first elongate implant in the inlet view.

In some embodiments, the first elongate implant, the second elongate implant, and the third elongate implant each have an elongate body with a longitudinal axis and a rectilinear cross-sectional profile transverse to the longitudinal axis.

In some embodiments, the first elongate implant, the second elongate implant, and the third elongate implant each are screws.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIGS. 1 and 2 illustrate anterior and posterior views of the pelvic girdle.

FIG. 3 illustrates the position of a patient on a Jackson table for CT imaging of the pelvic girdle.

FIGS. 4A-4C are three imaging views of the pelvis, a lateral view of the sacrum shown in FIG. 4A, an inlet view of the pelvis shown in FIG. 4B, and an outlet view of the pelvis shown in FIG. 4C.

FIG. 5 illustrates an annotated lateral radiographic view of the lower lumbar spine and sacrum that shows various anatomical landmarks.

FIGS. 6A and 6B illustrate landmarks in the lateral view that can be used to position and orient the C-arm to obtain a true lateral view.

FIGS. 7A and 7B illustrate locations on the patient's skin that may be marked to provide visual guidance or mapping that correlates with the position of various osseous landmarks identified using the lateral radiographic view.

FIGS. 8A and 8B illustrate how the skin marks in FIGS. 7A and 7B may be used as a guide to align the C-arm in the outlet view and the inlet view.

FIGS. 9A and 9B illustrate anatomical features and landmarks of the outlet view and the inlet view, respectively.

FIGS. 9C and 9D illustrate a lateral view and an inlet view that shows that the anterior cortex of the sacral ala is visible as the most anterior aspects of the sacrum.

FIGS. 10A and 10B are lateral views that illustrate an embodiment of an implant target zone that results in the

implants passing through the articular or hyaline cartilage portion of the SI-joint rather than the fibro cartilaginous portion of the SI-joint.

FIG. 10C illustrates a first implantation site placed with reference to both the alar line and the posterior sacral body line.

FIG. 10D illustrates a second implantation site that can be placed with reference to the alar line and the location of the first implantation site such that the second implantation site is inferior (caudal) and anterior to the first implantation site and placed in a middle portion of articular cartilage, near the vertex of the boomerang.

FIG. 10E illustrates a third implantation site that can be placed with reference to the anterior sacral body line and the second implantation site, so that the third implantation site is positioned in an inferior (caudal) portion of the articular cartilage.

FIGS. 11A-11C illustrate the orientation of a first guide pin inserted into the first implantation site in the lateral view, the inlet view, and the outlet view.

FIGS. 12A-12C illustrate the orientation of a second guide pin inserted into the second implantation site in the lateral view, the inlet view, and the outlet view.

FIGS. 13A-13C illustrate the orientation of a third guide pin inserted into the third implantation site in the lateral view, the inlet view, and the outlet view.

FIGS. 14A-14C illustrate the orientation of the three guide pins in the lateral view, the inlet view, and the outlet view.

FIGS. 15A-15C illustrate another embodiment of the third guide pin position and orientation when the third implantation site is located in between the posterior sacral body line and the anterior sacral body line in the inlet view.

FIGS. 16A and 16B illustrate an assembly for receiving the guide pin.

FIG. 17 illustrates a pin depth gage for determining the depth of insertion of the pin.

FIG. 18 illustrates removal of a pin sleeve from the guide pin.

FIG. 19 illustrates insertion of a drill over the guide pin.

FIG. 20 illustrates drilling a bore through the lateral cortex of the sacrum in the outlet view.

FIG. 21 illustrates removal of the drill after drilling the bore.

FIG. 22A-22C illustrate alignment of a soft tissue protector with reference to anatomical landmarks so that the faces of the rectilinear implant are properly oriented with respect to the anatomical landmarks.

FIG. 23 illustrates shaping the bore with a broach.

FIG. 24 illustrates broach advancement across the SI-joint.

FIGS. 25A and 25B illustrate implant insertion over the guide pin.

FIG. 26 illustrates implant advancement.

FIGS. 27A and 27B illustrates implant advancement under CT imaging.

FIG. 28 illustrates implant placement under CT imaging.

FIGS. 29A and 29B illustrate various types of implants that can be implanted across the SI-joint using the procedures described herein.

DETAILED DESCRIPTION

Pre-Op Preparation and Patient Setup

A computed tomography (CT) scan may be taken of the pelvis and SI-Joints prior to surgery to check for anatomic anomalies and to identify osseous landmarks useful for

implant placement. The patient may be placed on a flat radiolucent table, such as a Jackson table, to facilitate intra-operative imaging. Although one C-arm is typically employed, some surgeons may employ two C-arms, with one C-arm set in the lateral position and the other C-arm rotatable between the inlet and outlet positions, as further described below. As illustrated in FIG. 3, the patient may be placed on a flat Jackson type imaging table 300 with towel rolls 302 or other support structures placed transversely under the patient's chest and waist. This position allows the abdomen to hang free resulting in diminished intraabdominal pressure. Pillows 304 or other support structures can be placed under the patient's feet to relax the knees. After the patient has been properly positioned, a lateral view, an inlet view, and an outlet view may be taken of the SI-Joint and pelvis. The surgeon may identify any abnormalities that could interfere with the procedure and may also confirm that the anatomical landmarks used to guide implant placement are visible.

Intraoperative Imaging

As illustrated in FIGS. 4A-4C, three imaging views, a lateral view of the sacrum shown in FIG. 4A, an inlet view of the pelvis shown in FIG. 4B, and an outlet view of the pelvis shown in FIG. 4C, may be used to facilitate safe insertion and placement of instruments, tools and implants during the procedure. These fluoroscopic views allow the surgeon to identify various anatomical structures and landmarks, which may be used to assist the surgeon in placing the implants into a safe and biomechanically advantageous position. These intra-operative radiographic views may also be acquired using intra-operative CT scans and/or x-ray imaging.

FIG. 5 illustrates an annotated lateral radiographic view of the lower lumbar spine and sacrum. Various landmarks that may be used to facilitate implant placement are notated on this image. In the lateral view, the sacrum will appear as a curved wedge, with the posterior sacral cortical wall and the anterior sacral cortical wall being readily visible. In standard radiographic views denser tissues such as bone generally show up as white or light grey and the less dense soft tissues generally show up as black or dark grey. The posterior sacral cortical wall and the anterior sacral cortical wall appear as slightly curved dense white lines that define a triangular wedge shape on the lateral view. Other osseous anatomical landmarks useful for orientation and positioning include the sacral ala, the pelvic brim, the greater sciatic notch, the superior endplate of the S1 vertebrae and the inferior endplate of the L5 vertebrae.

The C-arm may be positioned to allow a true orthogonal lateral view of the sacrum and lower lumbar spine. FIGS. 6A and 6B illustrate landmarks in the lateral view that can be used to position and orient the C-arm to obtain this true lateral view. An initial lateral fluoroscopic image is obtained and then the C-arm positioning is adjusted until certain anatomic landmarks (left and right) are superimposed on the lateral image signaling that the C-arm is aligned correctly. For example, the disk space between the endplates of L5 and S1 may be aligned based on the initial lateral fluoroscopic imaging and subsequent adjusted images until the visualized endplates of L5 and S1 are parallel and in focus, which occurs when the disk space is perpendicular to the image plane. At this point the two sciatic notches, one from the right ilium and one from the left ilium, should overlap on the lateral fluoroscopic images. The alignment is considered final when the left and right iliac cortical densities, which are also known as the alar lines, are directly superimposed on

the lateral fluoroscopic image. The C-arm and the table are adjusted in multiple planes until the alignment described above is achieved.

As illustrated in FIGS. 7A and 7B, once a true lateral view has been obtained, the patient's skin may be marked to provide visual guidance or mapping on the patient's skin that correlates with the position of various osseous landmarks identified using the lateral radiographic view. For example, the skin may be marked along the sacral ala and pelvic brim to create a first mark 700, and the skin along the posterior cortex of the sacral body can be marked to create a second mark 702, as illustrated in FIGS. 7A and 7B. In addition, a third mark 704 may be placed overlying the anterior cortex of the sacral body. One or more guide pins, which are easily visible under the C-arm image generated by the fluoroscope, can be used to help locate the landmarks, such as the sacral ala and the posterior cortex of the sacral body. Other radiopaque markers may be used in place of the pin to help located the position of the landmarks. The surgeon may lay the pin against the skin over where the underlying osseous landmark is predicted or estimated to be located, and a C-arm image is used to confirm whether the pin is in the correct position. If the pin(s) are correctly positioned over the landmarks, the mark is then drawn on the skin. If the pin(s) are not correctly positioned, the surgeon may reposition the pin(s) and check pin placement under fluoroscopy until the pin(s) are correctly positioned.

As illustrated in FIGS. 8A and 8B, the skin marks 700, 702 may be used as a guide to align the C-arm in the outlet view and the inlet view. For example, in some instances, for an outlet view, the C-arm detector 800 is positioned over the patient's lower back and oriented perpendicular or normal to the mark 702 identifying the posterior sacral body, and for an inlet view, the C-arm detector 800 is positioned over the patient's legs and oriented parallel to the mark 702 identifying the anterior cortex of the sacral body. The C-arm may then be adjusted in both the outlet and the inlet views until the underlying osseous anatomy is clearly visualized. For example, in the outlet view the C-arm can be adjusted and oriented such that the pubic symphysis and S2 neural foramina are superimposed on the fluoroscopic image. In some embodiments, the neural foramina of S1, S2, S3 or S4 may be aligned with the pubic symphysis. In the inlet view the C-arm can be adjusted and oriented such that the sacral prominence of S1 appears as a thin line on the fluoroscopic image. In addition, in some embodiments, the C-arm detector 800 can be placed under the table (not shown) instead of above the patient.

FIGS. 9A and 9B illustrate anatomical features and landmarks of the outlet view and the inlet view, respectively. The outlet view is an anterior to posterior view of the pelvis and sacrum that provides a clear visualization of the sacral neuro-foramina, such as the S1 foramen and the S2 foramen, as well as other structures such as the inferior endplate L5 and the superior endplate S1. The inlet view is an anterior to posterior view of the pelvis that provides a clear visualization of the ventral (anterior) cortex of the sacrum. To obtain the inlet view, the C-arm of the fluoroscope is tilted towards the patient's feet until the dense cortical line of the S1-S2 vestigial disk directly overlies the dense cortical line of the sacral promontory. In the inlet view, the sacral canal, the ventral cortex of the sacral body and the sacral alar areas are visualized by the surgeon. Visualization of the osseous anatomy of the sacral ala and the sacral canal allows the surgeon to insert the implants across the SI-Joint, to keep the leading portion of the implants positioned within the sacral ala while avoiding damage to the neural tissues and vascular

structures. In addition, left and right oblique inlet and outlet views can be obtained to better visualize the sacroiliac joint and surrounding sacral foramina. With the C-arm in the inlet position, an oblique inlet image can be obtained by rotating the C-arm approximately 15 degrees to either side of the patient such that the C-arm's beam is approximately parallel to the SI-Joint and the lateral cortical walls of the S1 and S2 foramina. Similarly, with the C-arm in the outlet position, an oblique outlet image can be obtained by rotating the C-arm approximately 15 degrees to either side of the patient such that the C-arm's beam is approximately parallel to the SI-Joint and the lateral cortical walls of the S1 and S2 foramina.

Implant Placement

Proper implant placement across the SI-joint is determined by the surgeon selecting and maintaining the correct implant starting position, the correct implant insertion trajectory, and the correct implant length, which may all be determined with appropriate preoperative planning. Preoperative planning includes careful evaluation of osseous anatomy to identify the various landmarks described herein using CT scans and plane radiographs. Safe placement of implants involves placing the implants across the SI joint keeping the sacral portion of the implants within the osseous confine of the sacrum while avoiding the nerve tunnels of the spinal canal and neuroforamina, avoiding malposition of the implant in the dysplastic sacrum, and avoiding in-out-in positioning secondary to the concavity of the ventral surface of the sacral ala.

FIGS. 10A and 10B are lateral views that illustrate an embodiment of an implant target zone 1000 that results in the implants passing through the articular or hyaline cartilage portion of the SI-joint rather than the fibro cartilaginous portion of the SI-joint. The articular cartilage is associated with denser and stronger subchondral bone that can improve implant stability. Therefore, implants can be implanted into the denser and stronger subchondral bone by passing through the articular bone outlined by the implant target zone 1000. The location of the articular cartilage is shown as a boomerang or V-shaped outline that is located generally along the anterior portion of the SI-joint. The implant target zone 1000 is shown with reference to the various anatomical landmarks in the lateral view, including the alar line 700, the posterior sacral body line 702, and the anterior sacral body line 704. In addition, the anterior portion of the implant target zone 1000 is defined by the anterior cortex of the sacral ala, which is the curved portion of the anterior sacrum that extends from the sacral body to the ilium. In FIGS. 10A and 10B, the anterior portion of the implant target zone 1000 includes the portion of the implant target zone 1000 that is anterior the anterior sacral body line 704. In a lateral view and an inlet view, as illustrated in FIGS. 9C and 9D, the anterior cortex of the sacral ala is visible as the most anterior aspects of the sacrum. In the lateral view illustrated in FIG. 9C, the anterior cortex of the sacral ala is defined generally by the anterior sacral body line 704, the greater sciatic notch, and the superior surface of the sacral ala which forms the alar line 700. Three implantation sites 1002, 1004, 1006 are shown within the implant target zone 1000 in FIG. 10B, with two implantations sites 1004, 1006 located in the anterior portion of the implant target zone 1000 that corresponds to the anterior cortex of the sacral ala. The anterior cortex of the sacral ala can serve as a landmark for positioning those two implantation sites 1004, 1006.

In some embodiments, as shown in FIG. 10C, a first implantation site 1002 can be placed with reference to both the alar line 700 and the posterior sacral body line 702. In

some embodiments, the first implantation site 1002 can be placed with additional reference to the anterior sacral body line 704. For example, in some embodiments the first implantation site 1002 can be placed approximately 3 mm to 10 mm from the alar line, D1, and approximately 3 mm to 20 mm from the posterior sacral body line 702, D2, where the distance from the posterior sacral body line 702 is measured along a line parallel to the alar line 700. In some embodiments, the first implantation site 1002 can be placed approximately 5 mm from the alar line 700 and about 10 mm from the posterior sacral body line 702. The goal for the first implantation site 1002 is to place the implant in a superior (cephalad) portion of the articular cartilage by using the alar line 700 and the posterior sacral body line 702 for reference. In some embodiments, the first implantation site 1002 can be placed with additional reference to the anterior sacral body line 704, such that the first implantation site 1002 is positioned approximately in the midpoint of the posterior and anterior sacral body lines 702, 704. In some embodiments, the first implantation site 1002 is positioned anterior of the midpoint of the posterior and anterior sacral body lines 702, 704.

In some embodiments, as shown in FIG. 10D, the second implantation site 1004 can be placed with reference to the alar line 700 and the location of the first implantation site 1002 such that the second implantation site 1004 is inferior (caudal) and anterior to the first implantation site 1002 and placed in a middle portion of articular cartilage, near the vertex of the boomerang. In some embodiments, the second implantation site 1004 can be located anterior of the anterior sacral body line 704. In some embodiments, the second implantation site 1004 can be placed approximately 3 mm to 10 mm from the alar line 700, D3. In some embodiments, the second implantation site 1004 can be placed approximately the same distance from the alar line 700 as the first implantation site 1002, such that D1 and D3 are approximately equal and a line joining the first implantation site 1002 with the second implantation site 1004 is approximately parallel to the alar line 700. In some embodiments, the second implantation site 1004 can be positioned about 10 mm to about 40 mm from the first implantation site 1002, D4. The distance between the first implantation site 1002 and the second implantation site 1004 is generally, at a minimum, at least equal to the diameter of the implant so that the two implants do not overlap. In some embodiments, a guide pin jig can be used to help place the guide pin for the second implantation site 1004. The guide pin jig can have two holes for receiving guide pins that are separated by a predetermined distance, D4. In some embodiments, the guide pin jig can have a hole for the first guide pin and a slot for receiving the second guide pin, so that the distance between the two guide pins can be varied between about 10 mm to about 40 mm. In some embodiments, the slot can have distance markings showing the distance from the hole for the first guide pin. More generally, the guide pin jig can be used to place the next guide pin by using the position of a previously placed guide pin.

In some embodiments, as shown in FIG. 10E, the third implantation site 1006 can be placed with reference to the anterior sacral body line 704 and the second implantation site 1004, so that the third implantation site 1006 is positioned in an inferior (caudal) portion of the articular cartilage. In some embodiments, the distance between the third implantation site 1006 and the second implantation site 1004, D5, can be approximately equal to the distance between the first implantation site 1002 and the second implantation site 1004, D4. In some embodiments, D5 can

be between about 0.5 to 2 times the magnitude of D4. In some embodiments, the third implantation site **1006** can be about 0 to 5 mm anterior of the anterior sacral body line **704**, D6. In some embodiments, the third implantation site **1006** can be about 2 or 3 mm anterior to the anterior sacral body line **704**. As illustrated in FIG. 10E, the three implantation sites **1002**, **1004**, **1006** are located in the anterior articular portion of the SI-joint and are non-colinear. If a line is drawn through the first implantation site **1002** and the third implantation site **1006**, the second implantation site **1004** is offset from the first and third implantation site by a distance, D7, which can be about 1 to 15 mm.

The implantation sites described above specify the initial guide pin placement. In addition to the initial placement, guide pin and implant orientation can be specified to optimize the location of the implants across the SI-joint after initial guide pin placement. To orient the guide pins, in addition to the lateral views illustrated in FIGS. 10A-10E, the outlet and inlet views described above provide additional landmarks that facilitate guide pin orientation. Although the following description describes the various guide pins in terms of a first guide pin, a second guide pin, and a third guide pin, the actual order of insertion can be varied such that any one of the guide pins can be inserted first, second, or third.

For example, FIGS. 11A-11C illustrate the orientation of the first guide pin **1100** inserted into the first implantation site in the lateral view, the inlet view, and the outlet view. These illustrations and the other illustrations described herein are illustrative, and variations may occur depending on the particular orientations in which the various views are taken. As shown in FIG. 11A, the first guide pin **1100** is driven substantially axially in the lateral view such that the first guide pin **1100** appears to be driven into the page. In the inlet view shown in FIG. 11B, the first guide pin **1100** is advanced towards the middle of the space defined by the anterior sacral line **1104** and posterior sacral line **1102**. This target **1106** is illustrated by an X. In some embodiments, the first guide pin **1100** can be advanced proximate the target **1106** since the first guide pin **1100** should not encounter any neural structures in this orientation, allowing a longer implant to be used for the first implant. In addition, in some embodiments, the first guide pin **1100** is advanced substantially horizontally in the inlet view. As illustrated in FIG. 11C, in the outlet view the first guide pin **1100** is advanced substantially horizontally and is also usually advanced above the S1 foramen **1108**.

FIGS. 12A-12C illustrate the orientation of the second guide pin **1200** inserted into the second implantation site in the lateral view, the inlet view, and the outlet view. As shown in FIGS. 12A and 12B, the second guide pin **1200** is inserted at an angle α with respect to the horizontal axis of the inlet view. See also FIGS. 14A and 14B. To determine the correct angle of insertion, the distal end of the second guide pin **1200** is placed or docked at the second implantation site. Then the angle of the second guide pin **1200** is set by swinging out the proximal end of the second guide pin **1200** while keeping the distal end fixed until the second guide pin **1200** is pointed towards target **1106** illustrated in the inlet view of FIG. 12B, while keeping the second guide pin **1200** substantially horizontal in the outlet view shown in FIG. 12C. In some embodiments, the guide pin **1200** has a trajectory in the inlet view that is centered on the middle third of the body of S1 and aimed towards the target **1106**. In general, when the implantation site is located anterior of the anterior sacral body line **704** in the lateral view, the guide pin is angled by swinging out the proximal end of the guide

pin while keeping the distal end fixed until the guide pin is pointed towards target **1106** illustrated in the inlet view. This allows the guide pin to follow the anterior surface of the ala and sacrum without exiting the anterior surface. In some embodiments, the second guide pin **1200** is also advanced superior (cephalad) the S1 foramen but inferior (caudal) to the first guide pin in the outlet view. When the second guide pin **1200** is advanced superior (cephalad) the S1 foramen **1108**, it can be possible to advance the second guide pin **1200** all the way to target **1106** as above for the first guide pin. In other embodiments, the second guide pin **1200** can be advanced horizontally towards the S1 foramen **1108** in the outlet view, in which case the second guide pin **1200** is advanced up to but not into the S1 foramen **1108**.

FIGS. 13A-13C illustrate the orientation of the third guide pin **1300** inserted into the third implantation site in the lateral view, the inlet view, and the outlet view. As shown in FIG. 13A, the third guide pin **1300** is inserted at an angle in the lateral view, which is expected when the implantation site is anterior of the anterior sacral body line **704** as shown. As shown in FIG. 13B, the third guide pin **1300** is also advanced towards the target **1106** at an angle β to the horizontal axis. As described above, the angle of the guide pin is set by swinging out the proximal end of the guide pin while keeping the distal end fixed until the guide pin is pointed towards target **1106** illustrated in the inlet view of FIG. 13B, while keeping the guide pin substantially horizontal in the outlet view shown in FIG. 13C. As shown in FIG. 13C, the third guide pin **1300** is advanced substantially horizontally in the outlet view such that the third guide pin **1300** is directed towards the S1 foramen **1108**. In this case, the third guide pin **1300** is advanced up to but not within the S1 foramen **1108**. In other embodiments, the third guide pin **1300** can be directed between the S1 foramen **1108** and the S2 foramen **1110**, when the third implantation site is located more inferiorly (caudally) than illustrated in FIGS. 13A-13C. In this case, the third guide pin **1300** can be advanced past the S1 foramen **1108** and the S2 foramen **1110** to the medial portion of the sacrum, similar to the first guide pin.

FIGS. 14A-14C illustrate the orientation of the three guide pins in the lateral view, the inlet view, and the outlet view. As shown in FIG. 14B, the first guide pin **1100** is inserted horizontally in the inlet view. The second guide pin **1200** is oriented at an angle α with respect to the first guide pin **1100** or the horizontal axis in the inlet view. Angle α can vary depending on the particular implantation site chosen. In some embodiments, angle α can vary between about 0 degrees to about 45 degrees, or about 0 degrees to about 30 degrees. The third guide pin **1300** is oriented at an angle β with respect to the first guide pin **1100** or the horizontal axis in the inlet view. In some embodiments, angle β can also vary between about 0 degrees to about 45 degrees, or about 0 degrees to about 30 degrees. In some embodiments, as shown, the angle β is less than angle α . In other embodiments, angle α is approximately equal to angle β . As described in more detail below, implants can be advanced over the guide pins, resulting in implants having the same position and orientation as the guide pins across the SI-joint. By having the implants oriented at an angle with respect to each other and not parallel to each other, resistance to lateral separation of the SI-joint is increased.

FIGS. 15A-15C illustrate another embodiment of the third guide pin **1300** position and orientation when the third implantation site is located in between the posterior sacral body line **702** and the anterior sacral body line **704** in the inlet view. In this embodiment, the inlet view may demonstrate that the first and third guide pin are superimposed and

the outlet view may demonstrate that the first and third guide pin are substantially parallel. Because the implantation site is located between the posterior sacral body line 702 and the anterior sacral body line 704, the third guide pin can 1300 be inserted axially (into the page) in the lateral view and horizontally in the inlet view shown in FIG. 15B. FIGS. 15A and 15C illustrates the implantation site is located more inferior (caudal) than shown in FIGS. 13A-13C, and consequently, the third guide pin 1300 is advanced horizontally between the S1 foramen 1108 and the S2 foramen 1110 in the outlet view.

FIGS. 16A and 16B illustrate an assembly 1600 for receiving the guide pin 1602. The assembly can include a soft tissue protector 1604, a drill sleeve 1606 that is removably disposed within the soft tissue protector 1604, and a pin sleeve 1608 removably disposed within the drill sleeve 1606. The assembly 1600 can be slid over the guide pin 1602 until bony contact is achieved. FIG. 17 illustrates a pin depth gage 1700 that is placed against the proximal end of the assembly 1600 so that the proximal end of the guide pin 1602 is aligned with the depth gage markings 1702. The pin depth can then be read directly from the markings 1702 of the depth gage 1700, allowing the proper implant length to be selected. In some embodiments, the implant is left proud of the ilium's cortical wall by about 2 to 5 mm, so the implant size can be determined by adding 2 to 5 mm to the pin depth.

Next, as illustrated in FIGS. 18 and 19, the pin sleeve 1608 can be removed and a drill 1900 with a cannulated drill bit 1902 can be inserted over the guide pin 1602 to prepare a cavity for receiving the implant. Drilling can be monitored under fluoroscopy in the outlet view as illustrated in FIG. 20, allowing the user to monitor the depth of the drill and to watch for unwanted pin advancement. Drilling can be used to penetrate through the entirety of the ilium, to cross the SI joint and to penetrate the lateral cortex of the sacrum. Once the drill 1900 has reached the appropriate depth, the drill 1900 can be removed with the assistance of an exchange pin 2100, which can be inserted through the proximal end of the drill 1900 and drill bit 1902 until the exchange pin 2100 abuts against the guide pin 1602, as illustrated in FIG. 21. The exchange pin 2100 prevents the guide pin 1602 from withdrawing as the drill 1900 is removed. When placing the exchange pin 2100 against the guide pin 1602, care should be taken to avoid inadvertently advancing the guide pin 1602. After the drill 1900 is removed, the drill sleeve 1606 can also be removed from the assembly.

For an implant having a rectilinear cross-sectional profile or a cross-sectional profile defined by a plurality of apices and a plurality of sides, the soft tissue protector 1604 can have a matching cross-sectional profile, as shown in FIGS. 22A and 22B. For the first implant at the first implantation site, the soft tissue protector 1604 can be rotated so that one side of the soft tissue protector is parallel to the alar line 700. In some embodiments, for the second implant at the second implantation site, the soft tissue protector 1604 can also be rotated so that one side of the soft tissue protector is parallel to the alar line 700. This is appropriate when the second implantation site is located at the same distance from the alar line 700 as the first implantation site, as described above. Such a configuration allows the implant 2200 to be positioned close to the alar line without penetrating through the cortices. For the third implant, the soft tissue protector can be rotated so that one side of the soft tissue protector 1604 is facing the greater sciatic notch 2202. FIG. 22C illustrates the orientation of the faces of the implants 2200 to the anatomical landmarks in the lateral view.

FIG. 23 illustrates an embodiment of a broach 2300 and a mallet 2302 that can be used to create a rectilinear bore to match the shape of the implant. The broach 2300 has a distal end having a plurality of cutting edges and surfaces for removing bone. The mallet 2302 can have a slot 2306 in the mallet head 204 for receiving an exchange pin 2100 that allows the mallet 2302 to be used in conjunction with the exchange pin 2100. The broach 2300 can be inserted over the guide pin 1602 and into the soft tissue protector 1604 until it contacts the bone. As illustrated in FIG. 24, the broach 2300 can be tapped with the mallet 2302 across the SI-joint under visualization in the outlet view. The broach 2300 can be removed with the exchange pin 2100 in place in order to prevent the guide pin 1602 from withdrawing as the broach 2300 is removed.

After the broach 2300 has been removed, the implant 2200 can be placed over the guide pin 1602 and an impactor 2500 can be used to advance the implant 2200 into the broached bore, as illustrated in FIGS. 25A and 25B. The alignment of the soft tissue protector 1604 can be checked and adjusted as needed so that one side of the soft tissue protector is aligned with the alar line 700. In some embodiments, autograft or allograft bone derived materials, for example the bone materials generated by the drill and broach, can be applied to the implant surface before insertion. Other materials for coating the implant 2200 include growth factors such as bone morphogenetic protein. In some embodiments, the implant 2200 can have a tapered distal end 2202 that is inserted into the bore first. FIG. 26 illustrates a slotted mallet 2302, as described above, being used to strike and advance the impactor 2500 and implant 2200. The slot 2306 in the mallet 2302 can receive an exchange pin 2100 and allows the mallet 2302 to be used in conjunction with an exchange pin 2100, if desired. As illustrated in FIGS. 27A and 27B, implant advancement can be monitored under fluoroscopy in the outlet view to ensure that the implant avoids the foramen. The implant 2200 is advanced until about 2 to 5 mm of the implant remains proud of the surface of the ilium, as shown in FIG. 28.

SI-Joint Implants

Various implants 2200 can be used for the fixation and fusion of the SI-Joint, as illustrated in FIGS. 29A and 29B. These include screw like implants that are threaded or unthreaded implants or implants with both threaded and unthreaded portions. In some embodiments, the unthreaded implants can have a rectilinear cross-sectional profile transverse to the longitudinal axis of the implant, such as triangular or rectangular. In other embodiments, the unthreaded implants can have a cross-sectional profile defined by one or more apices joined by one or more sides which can be either rectilinear or curvilinear. Implants with a rectilinear cross-sectional profile or a cross-sectional profile defined by one or more apices can better resist rotation than a screw like implant with a circular cross-sectional profile.

Use of a round implant such as a screw type implant may require modifications to portions of the procedure described above including, for example, replacing the soft tissue protector with a standard tubular dilator system, and elimination of the broach and impactor.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions are incorporated herein by reference in their entirety. For example, features described in one embodiment may be combined with another embodiment. It is intended that the following claims define the scope of the invention

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and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method of implanting a plurality of implants across an SI-joint, the method comprising:

identifying a plurality of anatomical landmarks in the lateral view including the alar line, the posterior sacral body line, the anterior sacral body line, and the anterior cortex of the sacral alar;

inserting a plurality of guide pins across an anterior portion of the SI-joint and through hyaline cartilage, wherein the plurality of guide pins are inserted with reference to at least one anatomical landmark;

creating a bore around each of the plurality of guide pins; and

inserting an implant into each bore such that each implant crosses the anterior portion of the SI-joint and passes through hyaline cartilage, wherein at least one guide pin and implant are inserted anterior of the anterior sacral body line in the lateral view.

2. The method of claim 1, wherein at least two guide pins and implants are inserted anterior of the anterior sacral body line in the lateral view.

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3. The method of claim 1, wherein the at least one guide pin and implant that is inserted anterior of the anterior sacral body line in the lateral view is angled with respect to a horizontal axis in an inlet view.

4. The method of claim 1, wherein at least two guide pins and two implants are placed parallel to the alar line.

5. The method of claim 1, wherein the plurality of guide pins are parallel in an outlet view.

6. The method of claim 1, further comprising identifying a target for the plurality of guide pins in an inlet view, wherein the target is located in the middle of the sacral body.

7. The method of claim 6, further comprising advancing the guide pins towards the target in an inlet view.

8. The method of claim 1, wherein the implants are non-collinear in the lateral view.

9. The method of claim 1, wherein the implants have an elongate body with a longitudinal axis and a rectilinear cross-sectional profile transverse to the longitudinal axis.

10. The method of claim 1, wherein the implants are screws.

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