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(54) Title: SACRO-ILIAC JOINT STABILIZING IMPLANTS AND METHODS OF IMPLANTATION

(57) Abstract: Sacro-iliac joint stabilizing implants adapted for implanting across a SI joint from a dorsal approach. Methods of, and delivery tools adapted for implanting sacro-iliac joint stabilizing implants across a SI joint from a dorsal approach.

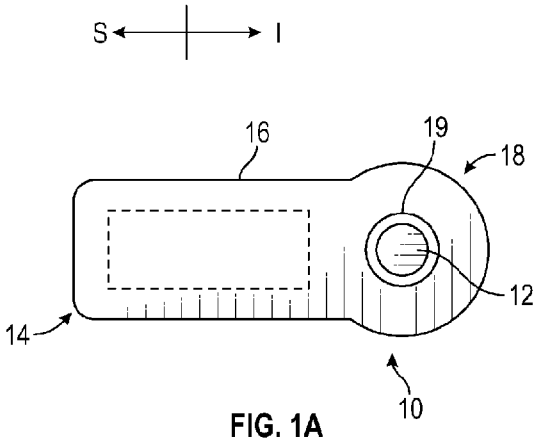


FIG. 1A

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SACRO-ILIAC JOINT STABILIZING IMPLANTS AND METHODS OF IMPLANTATION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Prov. No. 63/123,404, filed December 9, 2020, and U.S. Prov. No. 63/202,390 filed June 9, 2021, the disclosures of which are incorporated by reference herein in their entireties for all purposes.

INCORPORATION BY REFERENCE

[0002] This application incorporates by reference in its entirety for all purposes the entire disclosure of PCT publication WO2021/119126Al.

[0003] 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.

BACKGROUND

[0004] Implants may be positioned across a sacro-iliac ("SI") joint to help stabilize the joint. Portions of the ilium may have greater density than portions of the sacrum into which the implant is implanted. Depending on one or more of the delivery trajectories, the target location for implantation, and the configuration of the implant, the differences in bone density may present challenges while advancing some SI joint implants across the SI joint. Implants and methods of delivery are needed that accommodate for the differences in bone density and can facilitate the successful delivery of the SI joint implant from a dorsal approach across the SI joint. Additionally, implants are needed that are configured and sized to be safely implanted into a target anatomical region.

SUMMARY OF THE DISCLOSURE

[0005] This disclosure describes implants that are sized and configured to be implanted across an SI Joint from a dorsal trajectory to stabilize the joint.

[0006] This disclosure also describes delivery tools that are adapted to deliver and position implants across an SI Joint from a dorsal trajectory.

[0007] This disclosure also describes methods of implanting implants across an SI Joint from a dorsal trajectory.

[0008] One aspect of the disclosure is a sacro-iliac joint stabilizing implant for implanting across a SI joint from a dorsal approach, the implant having an implant body. The implant body has a central joint portion for placement across the SI joint, an ilium portion on a first lateral side of the central joint portion,

the ilium portion sized and configured for implanting into an ilium when the implant is implanted across a SI joint from a dorsal approach, and a sacrum portion on a second lateral side of the central joint portion, the sacrum portion sized and configured for implanting into a sacrum when the implant is implanted across the SI joint from the dorsal approach.

[0009] In this aspect, the implant body may have a wafer configuration with a width dimension greater than a height dimension.

[0010] In this aspect, the ilium portion may comprise and define an elongate ilium lumen that extends from a distal opening to a proximal opening and has an ilium lumen longitudinal axis, the ilium lumen sized and configured to receive therein an ilium positioning guide.

[0011] In this aspect, and with reference to a line that is orthogonal to an ilium lumen axis, the sacrum portion may extend further proximally than the ilium portion.

[0012] In this aspect, the implant body may include a distal portion that includes a sharpened distal end extending at least in the central joint portion, the sharpened distal end having a tapered configuration with a first surface that tapers downward and distally from a top portion of the implant body and a second surface that tapers upward and distally from a bottom portion of the implant body.

[0013] In this aspect, the implant body may have a proximal end having at least one surface feature configured to interface with a delivery tool (e.g., an impactor) to facilitate delivery of the implant body in a direction of implantation, and with reference to a line orthogonal to the direction of implantation, the sacrum portion may extend further proximally than the ilium portion.

[0014] In this aspect, a sharpened distal end of the implant body may have, in a top view, a concave curved configuration along at least a portion of the sharpened distal end. A curved configuration may be asymmetrical about a long axis of the implant body. A sharpened distal end may extend further distally in the ilium portion than in the sacrum portion.

[0015] In this aspect, a sharpened distal end of the implant body may extend laterally through the sacrum portion, the central portion, and the ilium portion.

[0016] In this aspect, a sharpened distal end may comprise a smooth curve.

[0017] In this aspect, a portion of the ilium portion may extend further distally than a sharpened distal end.

[0018] In this aspect, a portion of the sacrum portion may extend further distally than at least a portion of a sharpened distal end.

[0019] In this aspect, the implant body may comprise a distal portion, at least a portion of the distal portion comprising a curved distal end extending laterally from the ilium portion, through the central portion, and into the sacrum portion.

[0020] In this aspect, an ilium lumen may have a length that is greater than a length of a sacrum lumen.

[0021] In this aspect, an ilium lumen may have a length that is the same as a length of a sacrum lumen.

[0022] In this aspect, a sacrum lumen may have a length that is greater than a length of an ilium lumen.

[0023] In this aspect, an ilium lumen may be parallel with a sacrum lumen.

[0024] In this aspect, the ilium portion has an ilium length, and the sacrum portion has a sacrum length, and the ilium length may be greater than the sacrum length, the ilium length may be the same as the sacrum length, or the sacrum length may be greater than the ilium length.

[0025] In this aspect, a sacrum lumen may extend further proximally than an ilium lumen.

[0026] In this aspect, an ilium lumen may extend further distally than a sacrum lumen.

[0027] In this aspect, at least one distal opening of optional lumens may extend further distally than at least a portion of the central portion of the implant body. Distal openings of more than one lumen may extend further distally than the central portion.

[0028] In this aspect, the implant body may further comprise an inner frame, and an outer porous network of interconnected struts extending about at least a top portion and a bottom portion of the implant. A porous network of interconnected struts may further extend about the ilium portion and the sacrum portion. A porous network of interconnected struts may further extend about a plurality of side fenestrations in each of an ilium side of the implant body and a sacrum side of the implant body, wherein the plurality of fenestrations in the ilium side may be in communication with an ilium lumen and the plurality of fenestrations in the sacrum side may be in communication with a sacrum lumen. A porous network of interconnected struts may comprise pores in a central region of the implant body that are larger in size than pores that extend about the ilium portion and larger than pores that extend about the sacrum portion. An inner frame may have a slanted "digital eight" configuration that is slanted distally on the ilium side. An inner frame may include first and second axially extending elongate members and a plurality of axially spaced apart connecting elongate members extending from the first elongate member to the second elongate member, each two adjacent connecting elongate members, along with the first and second axially extending elongate members, defining one of a plurality of frame fenestrations.

[0029] In this aspect, the implant body may have a height dimension that is not greater than 70% of a width dimension of the implant body. The height dimension may not be greater than 60% of the width dimension of the implant body.

[0030] In this aspect, the implant body may have a length from 15 mm to 80 mm.

[0031] In this aspect, the implant body may have a width from 15 mm to 50 mm.

[0032] In this aspect, the implant body may have a height from 4 mm to 20 mm.

[0033] In this aspect, the implant body, in a top view, may have a parallelogram configuration that does not include right angles.

[0034] In this aspect, the implant body may have, in a top view, a rhomboid configuration or a rhombus configuration.

[0035] In this aspect, the implant body may have a height that is not constant across a width of the implant body. A height dimension may be greater in at least a portion of in the ilium portion than in the central region, and wherein the height dimension may be greater in at least a portion of in the sacrum portion than in the central region. At least one of a top portion or a bottom portion of the implant body may have a curvature therein. A height dimension of the implant body may be greater in at least a portion

of the central portion than in the ilium portion, and wherein the height dimension may be greater in at least the portion of the central portion than in the sacrum portion.

[0036] In this aspect, the ilium portion may comprise a cutting region proximally adjacent and disposed about the distal opening. A cutting region may comprise a plurality of axially-spaced cutting edges, which may be annular or circularly shaped.

[0037] In this aspect, the sacrum region may comprise a cutting region proximally adjacent and about the distal opening. A cutting region may comprise a plurality of axially-spaced cutting edges, which may be annular or circularly shaped.

[0038] In this aspect, a proximal end of the implant body may include a plurality of recessed members. A first recessed member may be in a first lateral half of the implant body, and a second recessed member may be in a second lateral half of the implant body.

[0039] In this aspect, a proximal end of the implant body may include a cylindrical channel (optionally extending along a long axis of the implant body) defining a lumen, wherein the channel comprises an inner thread.

[0040] One aspect of the disclosure is a method of positioning a sacro-iliac ("SI") joint stabilizing implant across an SI joint from a dorsal approach.

[0041] In this aspect, the method may include advancing an elongate sacrum pin from a dorsal starting point into a sacrum of a subject such that a distal end of the sacrum pin is in the sacrum and a proximal end of the sacrum pin is disposed outside of the subject.

[0042] In this aspect, the method may include advancing an elongate ilium pin from a dorsal starting point into an ilium of the subject such that a distal end of the ilium pin is in the ilium and a proximal end of the ilium pin is disposed outside of the subject.

[0043] In this aspect, the method may include advancing a distal opening of an ilium lumen that is in an ilium portion of an SI joint stabilizing implant over the ilium pin so as to restrict movement of the implant with respect to the ilium pin in at least one direction.

[0044] In this aspect, the method may include advancing a distal opening of a sacrum lumen that is in a sacrum portion of the SI joint stabilizing implant over the sacrum pin so as to restrict movement of the implant with respect to the sacrum pin in at least one direction.

[0045] In this aspect, the method may include advancing the implant distally over and relative to the sacrum pin and the ilium pin until the implant is across the SI joint with the ilium portion in the ilium and the sacrum portion in the sacrum.

[0046] In this aspect, the method may include removing the ilium pin and the sacrum pin from the subject, and leaving the implant positioned across the SI joint.

[0047] One aspect of this disclosure is a method of securing an SI-joint implant to an impactor.

[0048] In this aspect, the method may include causing a proximal end of the SI joint implant to be brought adjacent to a distal end of the impactor

[0049] In this aspect, the method may include engaging a first securing element on the impactor with a second securing element disposed in a proximal region of the implant to secure the implant to the

impactor and cause the implant to move axially with the impactor. In this aspect, a first securing element may be an elongate member with an external thread, and wherein the second securing element may be an internal channel with an internal thread. In this aspect, the method may include engaging a first impactor protrusion on a first lateral side of a first securing element with a first recess in the implant, and engaging a second impactor protrusion on a second lateral side of the first securing element with a second recess in the implant. In this aspect, the method may include causing a distal face of the impactor to be placed adjacent a proximal end of the implant, wherein, in a top view, the distal face and proximal end of the implant have complimentary shapes.

[0050] One aspect of the disclosure is a pin guide adapted for placing pin guides into an ilium and a sacrum in a dorsal approach.

[0051] In this aspect, the pin guide may include a pin guide body that includes at least one of a lateral ilium side with an axially extending ilium lumen and a lateral sacrum side with an axially extending sacrum lumen. If the pin guide body has first and second lumens, the lumens may be parallel.

[0052] In this aspect, an ilium side and an ilium lumen may extend further distally than a sacrum side and a sacrum lumen.

[0053] In this aspect, the pin guide may further comprise at least one lateral handle coupler that is adapted to be attached to an elongate handle so the handle and pin guide can be moved together by moving the handle.

[0054] In this aspect, the pin guide body may further comprise first and second central pins extending distally from the pin guide body, the first and second central pins disposed laterally inward relative to the ilium lumen and the sacrum lumen. Central pins may be permanently attached to a main portion of the pin guide body. Optional first and second central pins may be laterally aligned with each other. First and second central pins may extend between 10 mm and 20 mm from the pin guide body, optionally 15 mm.

[0055] One aspect of this disclosure is a pin guide adapted for placing pin guides into an ilium and a sacrum in a dorsal approach. The pin guide may include a pin guide body and a distal pin guide coupled to the guide body and extending distally from the pin guide body, wherein the distal pin guide may be movable relative to the pin guide body when the pin guide is in a first state and less movable relative to the pin guide body when the pin guide is in a second state.

[0056] One aspect of the disclosure is an impactor for advancing a bone implant. The impactor includes a proximal region, a distal region, and an elongate central region extending between the proximal region and the distal region.

[0057] In this aspect, the distal region may have a wafer configuration.

[0058] In this aspect, the distal region may include an implant securing element adapted to be releasable engaged with the bone implant.

[0059] In this aspect, the distal region may include a first protruding member on a first lateral side of the implant securing element and a second protruding member on a second lateral side of the implant securing element.

[0060] In this aspect, the distal region may include an ilium lumen in an ilium side of the distal region.

[0061] In this aspect, the distal region may include a sacrum lumen in a sacrum side of the distal region.

[0062] In this aspect, the distal region may include a distal face that is not orthogonal to a long axis of the central region. A distal face may extend further distally on the ilium side than on the sacrum side.

[0063] In this aspect, a first protruding member may extend further distally than a second protruding member.

[0064] In this aspect, an ilium lumen may extend further distally than a sacrum lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

[0065] Figures 1A and 1B illustrate an exemplary SI joint implant engaged with a positioning guide.

[0066] Figures 2A and 2B illustrate an exemplary SI joint implant engaged with first and second positioning guides.

[0067] Figures 3A and 3B illustrate an exemplary SI joint implant engaged with a positioning guide.

[0068] Figures 4A and 4B illustrate an exemplary SI joint implant engaged with first and second positioning guides.

[0069] Figures 5A and 5B illustrate an exemplary SI joint implant engaged with a plurality of positioning guides.

[0070] Figures 6A and 6B illustrate an exemplary SI joint implant engaged with a positioning guide.

[0071] Figure 7 illustrates an exemplary SI joint implant.

[0072] Figure 8 illustrates a portion of an exemplary SI joint implant engaged with a positioning guide.

[0073] Figure 9 illustrates a portion of an exemplary SI joint implant engaged with a positioning guide.

[0074] Figure 10 illustrates an exemplary SI joint implant engaged with a plurality of positioning guides.

[0075] Figures 11A and 11B illustrate an exemplary SI joint implant.

[0076] Figure 12 illustrates an exemplary SI joint implant.

[0077] Figure 13 illustrates an exemplary SI joint implant.

[0078] Figure 14 illustrates an exemplary SI joint implant.

[0079] Figures 15A, 15B and 15C illustrate an exemplary SI joint implant.

[0080] Figure 16 illustrates an exemplary SI joint implant.

[0081] Figures 17A, 17B and 17C illustrate exemplary cutting edges disposed about optional lumens.

[0082] Figures 18A, 18B and 18C illustrate an exemplary SI joint implant.

[0083] Figure 19 illustrates an exemplary SI joint implant.

[0084] Figure 20 illustrates an exemplary SI joint implant.

[0085] Figure 21 illustrates an exemplary SI joint implant.

[0086] Figures 22A, 22B and 22C illustrate an exemplary SI joint implant.

[0087] Figures 23A and 23B illustrate an exemplary SI joint implant.

[0088] Figure 24 illustrates an exemplary SI joint implant.

[0089] Figure 25 illustrates an exemplary SI joint implant.

[0090] Figure 26 illustrates an exemplary SI joint implant.

[0091] Figures 27A and 27B illustrate an exemplary SI joint implant.

[0092] Figure 28 illustrates an exemplary SI joint implant and an approximated quadrilateral shape or configuration of the implant in a top view of the implant body.

[0093] Figures 29, 30 and 31 illustrate exemplary proximal ends of exemplary SI joint implants.

[0094] Figure 32A illustrates a posterior view and exemplary locations for positioning guides.

[0095] Figure 32B illustrates an exemplary implantation location for a SI joint implant across a SI joint.

[0096] Figure 33 illustrates exemplary tools adapted for positioning one or more pins and for delivering implants from a dorsal approach.

[0097] Figure 34A, 34B, 34C, 34D, 34E and 34F illustrate exemplary radiograph imaging of an SI joint region and exemplary steps in a procedure.

[0098] Figures 35A, 35B and 35C illustrate an exemplary procedure that includes the use of a pin guide and one or more pins.

[0099] Figure 36 illustrates an exemplary impactor that is secured to an exemplary implant.

[0100] Figures 37A and 37B show exemplary radiograph imaging to confirm proper implant position.

[0101] Figure 38 illustrates an illustrative SI joint, ilium and sacrum.

[0102] Figures 39A, 39B, 39C and 39D illustrate exemplary 2D spaces characteristic of exemplary target envelopes.

[0103] Figures 40, 41A and 41B illustrate radiographic imaging of an exemplary process that includes injecting contrast media through a needle that is placed in the SI joint.

[0104] Figures 42A and 42B illustrate exemplary steps of placing an exchange pin and creating a linear skin marking along the exchange pin.

[0105] Figure 43 illustrates placement of a needle.

[0106] Figure 44 illustrates a nitinol wire after a needle has been removed.

[0107] Figure 45 illustrates an exemplary pin guide with a plurality of channels.

[0108] Figures 46A and 46B illustrate placing a central lumen of a pin guide over the wire from figure 44.

[0109] Figure 47 illustrates a pin being positioned through the sacral cortex with a mallet.

[0110] Figures 48A and 48B illustrate an ilium pin positioned through ilial cortex with a mallet.

[0111] Figures 49A and 49B illustrate taking a lateral radiographic image.

[0112] Figure 50 illustrates an optional step of drilling a hole through a center channel of an exemplary pin guide.

[0113] Figure 51 illustrates placement of a trephine over a pin.

[0114] Figure 52 is a radiographic image of an implant engaged with pins that have been placed in the sacrum and ilium.

[0115] Figures 53A and 53B shows an implant impacted to depth across the SI joint.

[0116] Figure 54 is a radiographic image showing the pins being removed from the sacrum and ilium.

[0117] Figure 55A is a lateral view and figure 55B is an outlet view showing the implant implanted across the joint.

[0118] Figures 56A, 56B, 56C and 56D illustrate exemplary pin guides.

[0119] Figures 57A and 57B illustrate an exemplary handle secured to an exemplary pin guide.

[0120] Figures 58A, 58B and 58C illustrates tool for and methods of positioning ilium and sacrum pins.

[0121] Figures 59A, 59B, 59C, 59D, 59E and 59F illustrate an exemplary impactor.

[0122] Figure 60 illustrates an exemplary impactor, an exemplary depth gauge, and an exemplary implant.

[0123] Figures 61A and 61B illustrate an implant secured to an impactor and implanted across an SI joint from the dorsal approach.

[0124] Figures 62A and 62B illustrate an implant implanted across an SI joint after pins have been removed.

[0125] Figures 63A, 63B and 63C illustrate an exemplary tool adapted for use with an impactor to remove pins from the patient.

[0126] Figure 64 illustrates an exemplary pin guide.

DETAILED DESCRIPTION

[0127] The disclosure herein is related to SI joint stabilizing implants ("implants") and methods of implanting SI joint stabilizing implants across an SI joint from a dorsal approach. Methods herein include implanting an implant from a dorsal approach across the SI joint with a first portion of the implant positioned in the ilium, a second portion of the implant positioned in the sacrum, and a third portion (e.g., a central portion) placed across the SI joint. The implants herein may be sized and configured to be implanted utilizing any of the suitable methods of implantation and delivery tools herein, unless indicated herein to the contrary. Similarly, method of implantation and delivery tools herein may be used to deliver any or all of the suitably configured implants across an SI joint, unless indicated herein to the contrary.

[0128] A region or portion of the ilium into which a first portion of the implant is positioned from a dorsal approach may have greater density than a region or portion of the sacrum into which a second portion or region of the implant is positioned. When positioning a SI joint implant across a SI joint from a dorsal approach, the implant may thus tend to deflect away from denser cortical iliac bone and migrate towards and into the less dense sacrum, which can prevent proper positioning of the implant across the SI joint. Implantation methods, delivery tools and implants are described herein that can maintain proper implant trajectory when advancing the SI joint implant across the SI joint from a dorsal approach described herein. The methods and approaches herein can account for the differences in bone density between the ilium and sacrum and prevent the implant from migrating away from denser iliac bone during implantation. Additionally, implants herein are sized and configured to be safely implanted into a target anatomical region when implanted from the dorsal approaches herein.

[0129] Methods of implanting the implants herein may include advancing one or more positioning guides, any of which may be referred to herein as a "guide," into an ilium from a dorsal approach, and in some embodiments between lateral and medial cortical walls of the ilium, which is described and shown

herein. Figure 32A illustrates a posterior view and a general dorsal approach for implanting the SI joint implants herein across an SI joint. Figure 32B illustrates an exemplary implant 1106 that has been implanted across an SI joint 1114' with a first region or portion of the implant disposed in the ilium 1110, a second region or portion of the implant disposed in the sacrum 1112, and a central region or portion extending across the SI joint 1114'. Figures 32A and 32B, which are described in more detail below, illustrate ilium 1110, sacrum 1112, the SI joints 1114 and 1114', and lumbar vertebrae 1116. Figure 32A also illustrates an optional anatomical region 1120 that is a starting point for advancing an ilium positioning guide into the ilium, and an optional exemplary anatomical region 1130 for a starting point for advancing a sacrum positioning guide into the ilium. Figure 32A further illustrates an exemplary and optional ilium starting point 1122 for an ilium positioning guide, as well as an exemplary and optional sacrum starting point 1132 for a sacrum positioning guide. Any of the ilium positioning guides herein may have a starting point in ilium region 1120, such as ilium starting point 1122. Any of the sacrum positioning guides herein may have a starting point in sacrum region 1130, such as sacrum starting point 1132. A radiographic view image may be obtained and utilized to help guide the positioning guide into the ilium between lateral and medial cortical walls of the ilium, which are illustrated generally in figures 32A and 32B. Methods herein may optionally include interfacing an ilium positioning guide herein with an ilium portion or region of the SI joint implant, such as an interface member of the implant, to guide the implant across the SI joint while maintaining a proper trajectory and achieving a desired implantation location. By positioning an ilium positioning guide in the relatively dense region of the ilium, and by interfacing and engaging the positioning guide with the ilium portion of the implant, the guide can help ensure a portion of or the entire implant will stay on course with a desired trajectory during advancement during implantation in the dorsal approach, rather than migrating away from the relatively dense cortical ilium bone and towards the sacrum. The optional positioning guides herein thus interface directly with the implant, and are sized and configured to act as a guide for the implant to ensure that an ilium portion or region of the implant is properly positioned in the ilium and that a joint region (which may be referred herein as a central region or portion) of the implant is properly implanted across the SI joint.

[0130] The positioning guides are sized and configured to, when engaged with the implant, generally restrict movement of the implant with respect to the positioning guide in at least one direction. The implant may be free to move relative to the positioning guide in other ways or directions. For example, once interfaced, the implant may still be able to rotate relative to the guide, such as in figures 1A and 1B, but the guide can still maintain the desired trajectory (relative axial movement) of the implant when the implant is advanced in the dorsal trajectory with respect to the engaged guide.

[0131] The methods herein include advancing the implant across the SI joint, while the optional guide(s) helps guide an ilium portion of the implant into the ilium. The methods may also include removing the positioning guide from the ilium after the implant has been positioned across the SI joint.

[0132] The methods herein may include positioning more than one positioning guide, optionally more than one ilium guide in the ilium, and optionally one or more guides into sacral bone. Any of the one or

more guides herein may be sized and configured to function as a positioning guide to help guide a portion of the implant into ilium bone or sacral bone.

[0133] In some alternative methods and implants described herein, the method of implantation may not require a position guide. For example, an implant may be advanced across an SI joint from a dorsal approach without using a positioning guide. For example, these methods may include radiographically visualizing a teardrop view of the ilium and advancing the implant while visualizing the teardrop view to ensure a portion of the implant stays sufficiently on course into the teardrop region of the ilium. Any of the methods herein may thus optionally exclude an ilium positioning guide, and may rely on a radiographic image, such as a teardrop view, to help maintain a desired implant trajectory into a teardrop region of the ilium. Implants implanted according to these methods may be implanted with or without a broach (described in more detail below), and if implanted without the use of a broach, the implants may have distal end regions that are configured to penetrate into bone, optionally having sharpened distal ends.

[0134] Some of the implants herein, such as any of those shown in figures 1A-31, are generally sized and configured to be able to interface with an elongate ilium positioning guide, and may be sized and configured to interface with one or more additional positioning guides, which may be ilium or sacrum guides.

[0135] Exemplary implants are described below. Even if the textual description of an exemplary implant does not expressly include it, it is understood that features shown with respect to different exemplary implants may be incorporated into other exemplary implants. For example, the implants shown in figures 1A, 1B, 2A and 2B each have an interface member with an annular inner surface that defines a lumen, even if the text does not expressly include a description thereof. Additionally, similar components may be similarly labeled in different embodiments. For example, it is understood that references to elements 10, 20, 30, 40, etc., in some of the figures may illustrate systems, even if the text related to any particular embodiment is silent with reference to a reference number shown in the figure.

[0136] Figure 1A is an end dorsal view (showing the proximal portion) and figure 1B is a perspective view of exemplary system 10 that includes SI joint stabilizing implant 14 and elongate ilium guide 12. Implant 14 includes an ilium guide interface member 18 interfacing, which may be also referred to herein as engaging, with ilium guide 12. Implant 14 includes main body or implant body 16, a central portion or region of which is disposed across the SI joint when the implant is implanted. The interface member 18 includes a surface 19 that has a configuration, in this example annular, that is sized and configured to interface with the corresponding configuration of ilium guide 12 to allow implant 14 to be axially advanced relative to guide 12. In these figures, the guide may or may not already be positioned in an ilium, such as at the exemplary general location shown in figure 32A. The interface between the guide and the interface member of the implant restricts the movement of the implant interface guide member with respect to the ilium guide in one or more directions. In this example, implant 14 may still be rotated relative to guide 12, but the interface restricts, for example, side-to-side (lateral) movement of 14 implant relative to guide 12. In this embodiment, the guide has a cylindrical configuration, with an annular outer profile in cross section along almost all of its length (except for the distal tip region, which may be

configured to penetrate and/or anchor (temporarily) into bone). Any of the guides herein may have a cylindrical configuration along all or substantially all of its length. Any of the guides herein may also include a sharpened or pointed distal end (e.g., as shown in figures 1B, 2B, 3B), which may be configured to help penetrate and/or anchor into bone (temporarily), such as iliac bone and/or sacral bone.

[0137] In figures herein, including figure 1A and 10, "S" refers to a sacrum and "I" refers to an ilium.

[0138] Figures 2A (end view) and 2B (perspective) illustrate exemplary system 20, which includes implant 24, ilium or iliac guide 22, and an optional elongate sacrum or sacral guide 21. In the figures shown, ilium guide 22 and the sacrum guide 21 may or may not yet be positioned within the ilium and sacrum, respectively. In some methods, the one or more guides may be inserted into bone, and then the implant may be advanced over the guides. In some embodiments, the implant is interfaced with the one or more guides, and subsequently the one or more guides can be inserted into bone. Interfacing the implant to a plurality of guides (in examples with more than one guide) before guide insertion may help prevent the guides from being inserted into bone and spaced apart at positions that prevent the implant from then be interfaced with the guides and successfully advanced along the guides and across the SI joint. Interfacing the implant with the guides first may help the guides being properly spaced apart to accommodate the implant during implantation. In merely exemplary embodiments herein, a method may include inserting an ilium guide into iliac bone, interfacing the guide with the implant, interfacing the implant with a sacrum guide, and inserting the sacrum guide into a sacrum. The implant may subsequently be advanced across the SI joint.

[0139] Any of the dashed lines in Figures 1A, 2A, 3A and 4A in an implant body indicates an optional axially extending bore or opening within a body portion of the implant, which may extend through distal and proximal implant body surfaces.

[0140] Figures 3A (end view) and 3B (perspective view) illustrate an exemplary system 30 that includes implant 34, which is configured to interface with ilium guide 32. Implant 34 includes guide interface member 33 that has a surface 35 sized and configured to interface with guide 32, which may be an ilium guide. Member 33 is in this embodiment curvilinear and has an almost completely annular configuration, but extends less than 360 degrees.

[0141] Figures 4A (end view) and 4B (perspective view) illustrate exemplary system 40 that includes implant 44 with first and second ilium guide interface members 43 and 45, each of which has a surface configured to interface with ilium guide 41 and ilium guide 42, respectively. Members 43 and 45 in this embodiment extend upward and downward from the main body region further than the guide interface members in figures 1A, 1B, 2A and 2B, for example.

[0142] Figures 5A (end view) and 5B (perspective view) illustrate an exemplary system 50 that includes exemplary implant 54, and exemplary ilium guides 51 and 52 and sacral guides 53 and 55. Implant 54 includes four guide members 56, 57, 58 and 59, each configured to interface with and be axially moveable relative to a separate guide. The implant body has a general "X" or crossing configuration in an end view, but could have other configurations, such as square, rectangular, oval, etc., and may still have four (or more) guide interface members.

[0143] Figures 6A (end view) and 6B (perspective view) illustrate an exemplary system 60 that includes implant 64 configured to interface with guide 62. In this embodiment guide 62 includes a recessed region that is configured to stably interface with interface member 63 that in this example is a lateral protrusion or extension from a main body region of the implant. This is an example of the implant having a guide interface member that extends within a portion of the guide, compared with guide interface members that extend around a portion of the guide, such as is shown in figures 1A-5B. The interface in this embodiment limits up and down movement of the implant relative to the guide, as well as right lateral movement relative to the guide, but allows guide 62 to act as a guide for implant 64 during implantation.

[0144] Figure 7 illustrates an exemplary implant 70 or broach 70 with a sharpened distal end, in this example extending laterally across the entire or substantially the entire width of the implant body, as shown. If used as a broach, the broach 70 may be configured with any of the guide members herein, and in methods of use can be guided over one or more guides (before the implant is implanted) to create a space across the SI joint for the implant. The broach can be removed, and an implant can then be advanced over the guides, which is described in more detail below.

[0145] If used as an implant, the implant 70 may comprise any of the guide members herein (e.g., one or more lumens), and in methods of use can be guided over one or more guides to position the implant across an SI joint. The sharpened region of the implant may create a space for the implant by penetrating or cutting into bone.

[0146] Figure 8 (end view) illustrates an exemplary implant 84 that includes guide interface member 86, which is configured to interface with guide 82. In this exemplary embodiment, guide 82 has a triangular configuration (which may have other rectilinear configurations), and member 86 includes an inner surface triangular configuration (which may have other rectilinear configurations), as shown. Implant 84 may also have any number of members 86, each of which can be configured to interface with a different guide.

[0147] Any of the implants herein may also have a guide interface member with a first configuration and a second guide interface member with a second configuration different than the first. For example, any of the implants herein may have one or more interface members that are the same or similar to member 23, the same or similar to member 33, the same or similar to member 63, and/or the same or similar to members 86.

[0148] Figure 9 (end view) illustrates an exemplary system 90 that includes implant 94. Implant 94 has a plurality of arms, and not all of the arms include a guide interface member at the respective arm end region. In this embodiment, only one of the arms has a guide interface member (in this embodiment member 96), but in other embodiments the implant may have any number of members less than the number of arms extending from a main body portion (e.g., two, three, four, etc.).

[0149] Figure 10 (end view) illustrates an exemplary system 100 that includes an implant 104 that includes ilium guide interface member 106 and sacrum guide interface member 108, each of which is configured to interface with guides 110 and 112, respectively. The position shown illustrates the implant as it may be implanted across an SI joint, illustrating that any of the implants herein may be implanted with one guide member (e.g., 106) in one type of bone superior to another guide member in a different

type of bone (e.g., ilium versus sacrum). For example, guide 110 may be positioned in iliac bone, and guide 112 may be positioned in a sacrum, either inferior to guide 110 as shown, or in other embodiments superior to guide 110, which is not shown, but which would be above guide 110 in figure 10.

[0150] Any of the implants herein may have one or more surfaces that are configured and adapted to facilitate at least one of bony ingrowth and ongrowth. For example, without limitation, any of the implants herein may include one or more of fenestrations, apertures, porous surfaces, irregular surfaces, etc., such as any that may be described in U.S. Pat. No. 9,044,321, U.S. Published Application 2013/0296953, U.S. Pat. No. 9,662,157, U.S. Pat. No. 10,166,033, U.S. Published Application 2016/0287171, the disclosures of which are incorporated by reference herein for all purposes.

[0151] As is set forth herein, SI joint implants herein may include one or more interface members, which may be configured as axially extending lumens or bores, and which may also be referred to as channels herein. The interface members are generally sized and configured to accommodate relative movement of one or more guides (such as an ilium guide), which are positioned in an ilium or a sacrum. In this way, implants may be moved axially relative to and guided by the positioning guides to the intended implantation location across the SI joint without migrating (or at least minimizing migration) away from the denser iliac bone.

[0152] In some embodiments, the implant may include interface members that are in opposing lateral side regions of the implant, an example of which is shown in figure 2A and 2B. In this arrangement, the implant is advanced over the guides to position the implant across the SI joint. The guides may be removed after the SI joint implant is delivered to its desired position, leaving the implant implanted across the SI joint.

[0153] Figures 11A and 11B illustrate in top and back end views, respectively, exemplary implant 1300. Implant 1300 may include any of the suitable features of other implants herein, such as interfacing members configured to interface with a positioning guide. Figures 11A and 11B illustrate implant 1300, which is sized and configured for implantation across a SI joint from a dorsal approach. Implant 1300 includes implant body 1302 that includes an ilium region or portion 1304 that is sized and configured for implanting into an ilium when the implant is implanted across a SI joint from the dorsal approach. Implant body 1302 also includes a sacrum region or portion 1306 that is sized and configured for implanting into a sacrum when the implant is implanted across the SI joint from the dorsal approach.

[0154] Height, Width and Length directions of the implant are also labeled to provide the relative dimensions of the implant body that are described herein. When the description herein refers to a general dimension (e.g., height, length) of the implant body, it refers to the greatest dimension of the implant body. For example, with reference to figure 11B, if the disclosure refers to a Height of implant body 1302, it refers to the greatest height dimension of the implant body, which in this embodiment is in lateral regions of the implant body. The disclosure herein may also, however, refer to dimension in a particular region of the implant (e.g., central region Height). The relative Distal and Proximal directions are also labeled in figure 11A.

[0155] As shown, ilium region 1304 includes and defines elongate ilium lumen 1305 therein that extends from a distal opening to a proximal opening, and is sized and configured to receive therein an ilium positioning guide. In this example, sacrum region 1306 extends further proximally than the ilium region 1304 with reference to the Length direction, as shown in figure 11A. Figure 38 illustrates an illustrative SI joint 1800, ilium 1802, and sacrum 1804. Implants herein may be advanced from a dorsal approach and into position across the SI joint, with the ilium region or portion of the implant in the ilium and the sacrum region or portion in the sacrum. The overall implant dimensions and configuration of exemplary implant 1300 (which may also be referred to herein as the implant outer profile) may provide one or more advantages when implanting the implant across the SI joint from the dorsal approaches described herein. As can be seen in figure 38, 39A and 39B, the sacrum may extend further proximally than the ilium, relative to the delivery trajectory. With implants that have an ilium region that extends as far proximally as a sacrum region, the ilium region of the implants may extend too far posteriorly when implanted, such that they are extending out of the ilium. Ilium region 1304 does not extend as far proximally as sacrum region 1306, such that when implanted there is less risk that the ilium region 1304 will extend outside of the ilium. The proximal end of the implant body in this example includes optional stepped region or portion 1308 between a sacral side and an ilium side of the implant body 1302, and in this example optionally includes three flat surfaces (shown in the top view of figure 11A), the central of which is tapered and extends further distally in the ilium portion of implant body. The tapered surface in this example extends between proximal sacrum and ilium surfaces that are orthogonal to a long axis of the implant (as shown), and are described in more detail with respect to an impactor, an example of which is shown in figures 33 and 36. In alternative implants, the proximal end may be a combination of one or more flat or curved surfaces, additional examples of which are described below.

[0156] Alternatively, implant 1300 may have a distal end in which ilium region 1304 extends further distally than sacrum region 1306, some examples of which are described below. For example, the configuration of implant body 1302 may approximate a general parallelogram shape that does not comprise four right angles, such as a rhomboid or rhombus configuration (in a top view of the implant). Implants for which sacrum regions do not extend as far distally as the ilium region may provide an advantage of preventing the sacrum region 1306 from being advanced too far distally in the patient, which may mitigate a risk of damaging tissue distal to the desired implantation location. Some implants herein thus may have ilium and sacrum regions that do not extend as far proximally or as far distally as one another, which may provide the exemplary advantages set forth herein.

[0157] Implant body 1302 is an example of an implant body that has a height dimension that is less than a width dimension, as shown. Implant body 1302 also includes a sacrum region 1306 that includes an optional elongate sacrum lumen 1307 therein that extends from a distal opening to a proximal opening and is sized and configured to receive therein a sacrum positioning guide (such as any of the sacrum guides herein). In this example, sacrum lumen 1307 has a length that is greater than a length of ilium lumen 1305, but in alternatives in which the sacrum region does not extend as far distally as is shown in figure 11A, the lumens may have lengths that are the same or substantially the same. In this example,

sacrum lumen 1307 is parallel to the ilium lumen 1305. The term parallel in this disclosure can include a very minor deviation from being strictly parallel, such as lumens or sides with corresponding axes that intersect at an angle that is five degrees or less, for example. Ilium lumen 1305 is also parallel to a longitudinal ("long") axis of the implant body, with the long axis in this example extending in the length direction.

[0158] As is set forth herein, the outer profile of the implant body is important to ensure the implant is positioned at a target implant location and generally within a patient's target anatomical envelope. A target envelope refers generally to an anatomical volume that is the target location for the implant, which may vary from patient to patient due to anatomical variability. For example, some implant configurations mitigate a risk of extending too far proximally out of the ilium, as described above. Additionally, some implant outer profiles may mitigate a risk of extending too far distally, such as too far distally in the sacrum and potentially damaging sensitive tissue. As such, the implant body generally has dimensions and profiles sized and configured to avoid these potential problems. The target envelope may optionally be characterized by two dimensional (2D) spaces and/or a three dimensional (3D) space. Figures 39A, 39B, 39C and 39D illustrate exemplary views that illustrate exemplary 2D spaces with exemplary dimensions that partially characterize exemplary target envelopes. As shown, there can be some patient-to-patient variability in sacral bone shape, iliac bone shape, and SI joint shape. While some implant shapes herein may be able to treat a wide range of patients, it may optionally be beneficial to customize an SI joint implant for a particular patient, such as by customization of one or more dimensions (e.g. angles), and/or the outer profile of the implant. A customization process can include characterizing the target envelope, such as obtaining one or more 2D views (e.g., figures 39A-3D) and/or constructing a 3D image of the target envelope, and designing or selecting an implant (optionally from a kit of implants with at least some different dimensions and/or outer profiles, for example) based on the target envelope characterization. For example, a patient from which the image in figure 39D is obtained may optionally be treated with an implant herein where ilium regions and sacrum regions extend to the same distal extent (e.g., figures 11A, 24, 25, 26 or 28A and 28B), whereas a patient from which the image in figure 39B is obtained may optionally be treated with an implant with a configuration that more closely approximates the general rhomboid 2D space annotated in figure 39D, such as (without limitation) any of the implants in figures 14, 15A, 16, 18A, or 23A).

[0159] The implant bodies herein may have a length from 15 mm to 80 mm (an example length of which is shown in figure 14, as "Length (implant body)"). For example, in figure 11A, the greatest proximal extent of implant body 1302 is in sacrum region 1306, and the greatest distal extent of implant body 1302 is in both sacrum region 1306 and ilium region 1304. In any of the embodiments herein, the ilium lateral side of the implant body may have a length from 35 mm to 70 mm, an exemplary dimension of which is shown in figure 14 as "Length (ilium lateral side)." In any of the embodiments herein, the sacrum lateral side may have a length from 25 mm to 60 mm. In any of the embodiments herein, the implant body may have a width from 15 mm to 50 mm, as example of which is shown in figure 16 ("Implant Width"). In any of the embodiments herein, the implant body may have a height from 4 mm to 15 mm in at least a

portion of the implant (such as one or both of an ilium region or a sacrum region), and the height may also vary across the width of the implant body, an example of which is shown in figure 11B.

[0160] Figure 28 illustrates an approximated shape of the implant body in a top view, including angles beta (the angle between the proximal end and the sacrum side of the approximated shape) and alpha (the angle between the ilium side and the distal or front end of the approximated shape). Figures 39A-39D also include exemplary angles alpha and beta for exemplary envelopes for particular patients. In some embodiments, the implant and/or the approximated shape (an example of which is shown in figure 28) may have an angle beta from 30 degrees to 85 degrees, including any subrange therein. In some more particular embodiments, the angle beta may be from 35 degrees to 80 degrees. In some embodiments, the angle alpha may be from 30 degrees to 90 degrees. The angle alpha may be slightly greater than 90 degrees (e.g., 90.2 degrees) and still be considered to be within the range from 30 degrees to 90 degrees, including any subrange therein. In some particular embodiments, angle alpha may be from 40 degrees to 90 degrees. It is understood that implants herein may have one or more right angles, such as having a rectangular shape in the top view (e.g., square). For example, some implants may be modified such that angles alpha and beta are 90 degrees. Any of the implants herein (including in any claims) may have any of the exemplary angles alpha and beta described herein.

[0161] The implant configuration may also be characterized by a top and/or bottom surface area of the implant, such as is shown in the top view of figure 11A. The surface area may refer generally to an area of an outer profile of the configuration of the implant (in a top view), even if there are a plurality of openings 1320 extending through the implant body (examples of which are shown in figure13A). In any of the embodiments herein, a surface area of a top portion and/or a bottom portion of the implant body may be from 400 to 3,000 mm^2.

[0162] As mentioned above, in some non-limiting embodiments the implant body have a quadrilateral configuration, such as a parallelogram configuration without right angles (e.g., rhomboid or rhombus), with the ilium portion extending further distally than the sacrum portion, and the sacrum portion extending further proximally than the ilium portion, many examples of which are shown and described herein.

[0163] In some embodiments, the implant body may have a quadrilateral shape (in a top view) with one or more right angles, such as a rectangle or square. For example, an implant body herein may have a rectangular shape with a sharpened distal region, an example of which is shown with implant 70 shown in figure 7. Figures 24-26 illustrate exemplary implant bodies with a quadrilateral shape or configuration, without any right angles.

[0164] As shown in figure 11B, implant body 1302 optionally has a height that is not constant across a width of the implant. In this example, the height is greater in at least a portion of the ilium and sacrum portions than in the central portion. The top and bottom portions or surfaces of the implant bodies herein may have a gradual curvature therein in an end view, as shown in the example in figure 11B.

[0165] As used herein, an implant body that has a wafer configuration or profile refers to an implant body with a width dimension that is greater than a height dimension. Implant body 1302 is an example of

an implant body that has a wafer or wafer-like configuration. The height dimension of any implant body herein may be not more than 70% of a width dimension of the implant body, not more than 65%, not more than 60%, not more than 55%, not more than 50%, not more than 45%, not more than 40%, not more than 35%, not more than 30%, not more than 25%, not more than 20%, not more than 15%, or not more than 10% of the implant body width. Implants herein are implanted across an SI joint from a dorsal approach, and if the implant body height is too great, the implant body may undesirably extend outside of the joint when implanted.

[0166] Wafer implants herein, may however, have relatively larger heights than those described in the ranges herein (absolute and/or relative) and may be able to safely stabilize and/or fuse an SI joint. For example, the implant bodies herein may be able to safely stabilize the SI Joint even if the height dimension is, for example, not more than 80% of the width dimension.

[0167] Implant body 1302 is also an example of a SI joint implant body wherein the ilium lateral side of the implant body has a length that is different than a length of the sacrum lateral side of the implant body. In this example, the ilium lateral side is shorter than the length of the sacrum lateral side, as shown. The lengths of the lateral sides in this context refers to the lengths of the lateral sides of the implant body, example of which are shown in figure 14 as "Length (ilium lateral side," and "Length (sacrum lateral side").

[0168] Implant body 1302 also includes a distal end region 1310 (which in this example is not the furthest distal extent of the entire implant body) that is sized and configured for one or more of penetrating through bony tissue as the implant is advanced or reducing the likelihood that the implant deviates from the intended trajectory. For example, distal end region 1310 is an example of a sharpened distal end at least a portion of which extends laterally inward or centrally relative to lateral sides of the implant, the sharpened distal end configured to help penetrate or cut through bony tissue as the implant is advanced. Additionally, end region 1310 has an optional concave curved configuration that can reduce the likelihood that the implant deviates from its intended trajectory when being distally advanced during implantation. A concave curved configuration (an example of which is shown in the top view of figure 11A) may be thought of as helping self-center the implant across the SI joint as the implant is being advanced. The degree of curvature may vary along the curve, as is shown in the example of figure 11A. The curve may be symmetrical about a long axis of the implant (even if the degree of curvature varies), of the curve may be asymmetrical about a long axis of the implant (such as if the ilium and sacrum regions have distal ends that do not extend distally to the same point, examples of which are described below). The sharpened distal end in this example has a tapered configuration, as shown, with a first surface tapering downward and distally from a top portion or surface of the implant body, and a second surface tapering upward and distally from a bottom portion or surface of the implant body, as shown. A sharpened region as that phrase is used herein does not require a configuration with a knife's edge, but rather may be a region with surfaces that taper towards one another or other configurations that facilitate cut or penetrating through bony tissue.

[0169] In this example, the sacrum and ilium lateral sides of the implant body extend further distally than distal region 1310 (distal region 1310 includes a central region of implant body), but in other embodiments the sacrum lateral side may not extend further distally than distal region 1310. The curvature of region 1310, in a top view, may optionally be symmetrical about a long axis of the implant body (such as is shown in the example in figure 11A), which may help maintaining the implant trajectory. Distal end region 1310 also extends laterally across a central region of the implant, wherein the central region is laterally inward relative to lateral sides of the implant body. A long axis of the implant body may extend through sharpened distal end region 1310.

[0170] Implant distal region 1310 is an example of a front region of the implant that has at least one surface sized and configured to at least help maintain the implant trajectory when implanted across the SI joint from a dorsal approach. In this example the region has an inwardly curved configuration. In this context, the term front, or forward, refers to the portion of the implant body that will typically engage tissue when the implant is advanced along a direction of implantation. The "front" of the implant body thus may extend laterally across the entire distal end of the implant body, and thus some front portions of the implant body (e.g., a central front portion) may be disposed proximally relative to other front regions of the implant. Distal region 1310 is an example of a front portion of implant body, at least a portion of which is proximal relative to distal ends of the ilium lateral side and the sacrum lateral side, as shown in figure 11A.

[0171] Alternatively, any of the implant bodies may have sacrum and ilium portions that have distal ends with surfaces that are configured to compress the SI joint as the implant is advanced, such as by having larger diameter regions, or one or more fins.

[0172] The central portion of implant bodies herein refers to a portion or region of the implant body that, in a top view of the implant, is laterally central or inward relative to lateral sides of the implant body, at least a portion of which is adapted or intended to be disposed in the SI joint when implanted. A long axis of the implant body may pass through central portions of implants herein. A central portion generally includes a lateral midpoint of the implant body, as measured laterally across one or both of distal and proximal ends of the implant body. Implant bodies herein do not necessarily have exact or definitive demarcations or delineations between an ilium portion and a central portion, or between a sacrum portion and central portion, but rather a central portion may include the portion or region of the implant that will be or is intended to be positioned across an SI joint when the implant body is implanted. In this regard, the use of the phrases ilium portion and sacrum portion herein refers generally to a lateral position of the portion relative to the central portion. For some or any of the implant bodies herein, it is understood that there may be some degree of lateral overlap between a central portion and at least one of the ilium portion and the sacrum portion. The phrase central portion or central region herein can thus refer to a lateral position relative to ilium and sacrum lateral sides of the implant body.

[0173] Figure 12 illustrates a proximal and top perspective view of implant 1200, which is sized and configured for implantation across an SI joint from the dorsal approaches described herein. Implant 1200 includes implant body 1202 that includes ilium portion 1204 that is sized and configured for implanting

into an ilium when the implant is implanted across a SI joint from the dorsal approach. Implant body 1202 also includes sacrum portion 1206 that is sized and configured for implanting into a sacrum when the implant is implanted across the SI joint from the dorsal approach. Any relevant description of figures 11A and 11B may be incorporated by reference into the description of figure 12, such as the relative proximal and distal directions. Ilium portion 1204 includes and defines an elongate ilium lumen therein (not labeled) that extends from a distal opening to a proximal opening, which is sized and configured to receive therein an ilium positioning guide. Sacrum portion 1206 includes and defines an elongate sacrum lumen 1207 therein that extends from a distal opening to a proximal opening, and is sized and configured to receive therein a sacrum positioning guide. In this example, sacrum portion 1206 extends further proximally than ilium portion 1204 with reference to the length direction, as shown in figure 12. Ilium portion 1204 extends further distally than sacrum portion 1206, as shown, exemplary advantages of which are described herein, such as preventing the sacrum region 1206 from being advanced too far distally in the patient, which may mitigate a risk of damaging tissue distal to the desired implantation location across the SI joint. Implant body 1202 is also an example of an implant body with a parallelogram configuration that does not have four right angles, and is generally rhomboid.

[0174] While an end view is not shown, implant body 1202 is an example of an implant body that has a wafer configuration, with a height dimension that is less than a width dimension, as can be appreciated from the perspective views that are shown. In this example, sacrum lumen 1207 has a length that is greater than a length of the ilium lumen, but may be at least substantially the same (optionally being exactly the same same) as a length of the ilium lumen. The guide lumens in implant body 1202 are examples of lumens that have axes that are parallel with each other, which again includes slight deviations from perfectly parallel (e.g., lumen axes intersecting with an angle of five degrees or less therebetween). Ilium lumen is also parallel to a long axis LA of the implant body, with the long axis LA in this example extending in the length direction.

[0175] Implant body 1202 is an example of an implant body comprising one or more porous networks of interconnected struts. Implant body 1202 includes top porous network of interconnected struts 1201, a bottom porous network of interconnected struts (not labeled, but defines part of the bottom portion of the implant body), and lateral side porous network of interconnected struts 1209 (only the sacrum side of which is shown and labeled). Top porous network of interconnected struts 1201 forms at least a portion of a top portion of the implant body, and lateral side porous network of interconnected struts 1209 form at least part of the lateral sides of the implant body. In the embodiment, implant body 1202 includes frame 1213, portions of which are connected or coupled by one or more discrete porous network of interconnected struts. For example, frame 1213 includes a plurality of axially extending frame members 1211a, 1211b, 1211c, and 1211d (1211d is not shown or labeled, but is one of the lower or bottom members), which may also be referred to as struts, and which may be a part of the framework providing much of the structural support of the implant body. Frame 1213 may also comprise a proximal frame portion 1215, which in this example extends laterally but obliquely (but not strictly laterally) across the width of implant body 1202, and generally obliquely to the axially extending members 1211a-1211d. In

this example, proximal frame portion 1215 forms a proximal side of the quadrilateral shape of the implant, which in this example is a parallelogram, and in particular a rhomboid. Implant body frame 1213 also comprises distal frame portion 1217, which in this example includes a sharpened distal end, which is described in more detail herein. Similar to proximal frame portion 1215, sharpened distal end 1217 extends generally laterally but not strictly orthogonally across implant body 1202 relative to long axis LA. Frame 1213 in this embodiment comprises distal frame portion 1217, proximal frame portion 1215, and a plurality of axially extending and linear frame members 1211a-1211d coupling the proximal 1215 and distal 1217 frame members.

[0176] A plurality of discrete porous networks of interconnected struts extend between and couple the frame members, as shown, forming most of the top, bottom, and lateral sides of the implant body. The top and bottom porous networks of interconnected struts each form most of the top and bottom portions, respectively, that, in an end view of the implant, define at least partially curved configurations for the top and bottom portions of the implant. In this example, each of the lateral side porous networks of interconnected struts 1209 partially define the ilium and sacrum lumens, as shown, and in particular, define a lateral section of each of the lumens, even though the lateral sides of the lumen have openings therein in between the struts.

[0177] Body 1202 is also an example of an implant body that has a quadrilateral configuration, and in this example has a parallelogram configuration that does not include four right angles. For example, body 1202 is an example of an implant body that has a rhomboid configuration, and may alternatively have a rhombus configuration, but in alternative embodiments it may have other quadrilateral configurations (including rectangular, square, etc.).

[0178] Implant bodies herein may have, in a top view of the implant body, a general quadrilateral configuration. In this context, the term quadrilateral does not require completely linear sides. Any side of implant bodies herein may have some minor degree of curvature while still approximating a quadrilateral configuration, such as the implant body in figure 26.

[0179] Additional details of porous networks of interconnected struts may be found in published PCT application WO2021/108590A1, the disclosure of which is incorporated by reference herein for all purposes. For example, any and all disclosure of porous networks of interconnected struts described in WO2021/108590A1 may be incorporated into the disclosure herein, including any examples that comprise one or more porous networks of interconnected struts. For example, a porous network of interconnected struts may also be referred to as a porous lattice, or mesh. Additionally, any of the individual struts herein may also be referred to as a beam. Additionally, the porous networks of interconnected struts may have and form a smooth outer surface, such as shown in the example in figure 12 (as opposed to struts or beams with free ends that extend outward). Additionally, in some embodiments the porous network may have an irregular configuration of struts, or it may have a regular pattern of struts, or a combination thereof. It is therefore understood that the term lattice or network as used herein does not require a regular or repeating pattern of struts. Additionally, struts of the porous network of interconnected struts may be interconnected at connections or nodal locations, which is

described in more detail in, for example, WO2021/108590A1. Connections or nodal locations herein may be the connection of two, three, four, or more individual struts or beams of the porous network of interconnected struts.

[0180] Implant bodies herein that include a porous network of interconnected struts may have added stability once implanted as the bone grows around the many struts.

[0181] Figure 13 is a distal and top perspective view illustrating exemplary implant 1350, which, like others herein, is sized and configured for implantation across an SI joint from the dorsal approaches herein. Implant 1350 includes implant body 1352 that includes ilium portion 1354 that is sized and configured for implanting into an ilium when the implant is implanted across an SI joint from the dorsal approach. Implant body 1352 also includes a sacrum portion 1356 that is sized and configured for implanting into a sacrum when the implant is implanted across the SI joint from the dorsal approach. Any relevant description of figures 11A-12B may be incorporated by reference to the description of figure 13. Ilium portion 1354 includes and defines an elongate ilium guide lumen 1358 that extends from a distal opening to a proximal opening, and is sized and configured to receive therein and move relative to an ilium positioning guide (not shown). Sacrum portion 1356 includes and defines an elongate sacrum lumen 1340 therein that extends from a distal opening to a proximal opening, and is sized and configured to receive therein a sacrum positioning guide. In this example, sacrum portion 1356 extends further proximally than ilium portion 1354 with reference to a length direction. Ilium portion 1354 extends further distally than sacrum portion 1356, as shown, exemplary advantages of which are described herein. Implant body 1352 is also an example of an implant body with, in a top view, a parallelogram configuration that does not include four right angles, and in this example has a rhomboid configuration (but may alternatively have a rhombus configuration). Implant body 1352 is also an example of an implant body that has a wafer configuration. In this example, sacrum lumen 1340 has a length that is slightly greater than a length of the ilium lumen 1358, but in alternatives it may be at least substantially the same or exactly the same as a length of the ilium lumen 1358. The guide lumens in implant body 1352 are examples of lumens that have long axes that are parallel, which includes slight deviations from perfectly parallel (described herein). Ilium lumen 1358 and sacrum lumen 1340 are also parallel to a longitudinal (or long) axis LA of the implant body, with the long axis in this example extending in the length direction. In this example, long axis LA extends through a lateral midpoint of the implant body (e.g., dividing the implant body laterally into halves). As shown in the examples herein, a long axis of the implant body may or may not be a line of symmetry of the implant body in a top view of the implant body. In figures 11A – 28, the long axis of the respective implant body is not a line of symmetry of the implant body in a top view. Implant body 1352 also includes a distal portion, at least a portion of which comprises sharpened distal end 1360, which is described in detail elsewhere herein. Sharpened or cutting distal end 1360 has a tapered configuration 1364, which tapers downward from a top portion 1362 of the implant body and that tapers upward from a bottom portion of the implant body. In this embodiment, tapering surface 1365 tapers downward and distally from top portion 1362, and a tapering surface (not shown but on the bottom side of implant body 1352) tapers upward and distally from the bottom portion

of the implant body. The sharpened distal end 1360 has some height dimension that is less than the height between the top and bottom portions of the implant body from which the tapered surfaces extend. The tapering surfaces help the distal end 1360 penetrate into bone during implantation. Distal end 1360, as shown, also has a concave curve configuration in a top view, and is recessed proximally relative to the distal ends of ilium portion 1354 and sacrum portion 1356, as shown.

[0182] Implant body 1352 also comprises frame 1373. Implant body 1352 may be monolithic (and may be 3D printed, for example), frame 1373 includes first and second axially extending elongate regions 1374a and 1374b, which are in ilium portion 1354 and sacrum portion 1356, respectively. Axially extending elongate regions 1374a and 1374b are connected or coupled together by generally oblique connecting members 1375a, 1375b and 1375c, which extend across the long axis, and extend from elongate region 1374b non-orthogonally relative to the elongate region 1374b, and in this example extend from elongate region 1374b partially distally such that they have a slanted configuration and are further distally in the ilium portion than in the sacrum portion. The distal most connector 1375c includes, in this example, top surface 1362 from which the tapered surface 1365 extends distally and downward. The distal connector 1375c also includes a corresponding bottom surface of the implant and a bottom tapered surface that extends distally and upward. Frame 1373 is an example of a frame that has a shape that, in a top view, resembles a digital eight configuration that is slanted further distally on the ilium side.

[0183] The implant will be subject to stresses when implanted across the SI joint with a portion of the implant in the sacrum and a portion of the implant in the ilium. Connectors 1375 of the frame are adapted to resist both bending and shear forces.

[0184] Frame 1373, in this embodiment, further defines a plurality of fenestrations (or openings) 1376a and 1376b, which as shown extend through the top and bottom portions or surfaces of the implant body. The fenestrations in any of the implant bodies herein can facilitate the ingrowth or ongrowth of tissue, while in some examples (such as figures 15A-15C) the fenestrations may be used to facilitate delivery of one or more agents into the patient. In alternative embodiments, any of the frames herein may include more than two fenestrations, such as from three to two hundred fenestrations. Implant body 1302 in figure 11A is, for example, an example of an implant body including nine fenestrations 1320 extending through top and bottom portions or surfaces of the implant. Elongate members 1374a and 1374b and connecting members 1375a, 1375b and 1375c, in this embodiment, define fenestrations 1376a and 1376b that extend through the top and bottom portions of implant body.

[0185] Figure 14 is a top view illustrating exemplary implant 1400, which, like others herein, is sized and configured for implantation across an SI joint from a dorsal approach. Implant 1400 includes implant body 1402, which is similar to implant 1350 in some ways. Implant body 1402 includes ilium portion 1404 that is sized and configured for implanting into an ilium when the implant is implanted across a SI joint from the dorsal approach. Implant body 1402 also includes sacrum portion 1406 that is sized and configured for implanting into a sacrum when the implant is implanted across the SI joint from the dorsal approach. Any relevant description of figures 11A-13 may be incorporated by reference to the description of figure 14. Ilium portion 1404 includes and defines an elongate ilium lumen therein (not labeled) that

extends from a distal opening to a proximal opening, and is sized and configured to receive therein an ilium positioning guide. Sacrum portion 1406 includes and defines an elongate sacrum lumen therein (not labeled) that extends from a distal opening to a proximal opening, and is sized and configured to receive therein a sacrum positioning guide. In this example, sacrum portion 1406 extends further proximally than ilium portion 1404, as shown. Ilium portion 1404 extends further distally than sacrum portion 1406, as shown. Implant body 1402 is also an example of an implant body with, in a top view, a parallelogram configuration without right angles, and in particular has a rhomboid configuration (which may alternatively have a rhombus configuration if all sides have the same length).

[0186] Implant body 1402 is an example of an implant body that has a wafer configuration. In this example, the sacrum lumen has a length that is slightly greater than a length of the ilium lumen, although in alterative embodiments they may be substantially the same. The guide lumens in implant body 1402 are examples of lumens that have axes (ilium lumen axis "ILA" and sacrum lumen axis "SLA") that are parallel with each other, which again includes slight deviations from perfectly parallel. ILA and SLA are also each parallel to a long axis LA of the implant body, as shown, which passes through a lateral midpoint of implant body.

[0187] Implant body 1402 also comprises frame 1413, which is similar in some ways to frame 1373 in figure 13, and which may have the same general configuration as frame 1373 in figure 13. Implant body 1402 also includes porous network of interconnected struts 1401, which may be additively manufactured with frame 1373, for example, to form implant body 1402. The disclosure that is incorporated by reference herein related to porous network of interconnected struts, such as the disclosure in WO2021/108590A1, may be incorporated into network 1401 of implant 1402. Network 1401 may extend over and about a portion of frame 1413, as shown, including over and about the lateral sides of the frame, as shown. As shown, network of interconnected struts 1401 may be at least partially continuous (or uninterrupted) laterally across portions of implant body, over a first lateral side, laterally across the bottom of implant body, and over the other lateral side. In some embodiments the network of struts may extend over and about a portion of frame 1413. In some ways, implant body 1402 in figure 14 includes aspects of frame 1373 from figure 13 and network of struts 1201 from figure 12.

[0188] All of the disclosure from figure 13 related to frame 1373 is incorporated by reference in its entirety into the disclosure of figure 14 with respect to frame 1401.

[0189] Implant body 1402 is also an example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration. In alternative embodiments, implant body 1402 may have a rhombus configuration, or it may have any other quadrilateral configuration (including rectangular, square, etc.). The proximal end of implant body 1402 is an example of a back or proximal side of an implant body that is considered a side, even though it does not have complete linearity.

[0190] Figures 15A-15C illustrate implant 1500, which is sized and configured for implantation across a SI joint from a dorsal approach, which is described herein. Implant 1500 includes implant body 1502 that includes ilium portion 1504 that is sized and configured for implanting into an ilium when the implant is

implanted across a SI joint from the dorsal approach. Implant body 1502 also includes a sacrum portion 1506 that is sized and configured for implanting into a sacrum when the implant is implanted across the SI joint from the dorsal approach. Any relevant description of figures 11A-14 may be incorporated by reference to the description of figures 15A-15C. Ilium portion 1504 includes and defines an elongate ilium lumen therein (not labeled) that extends from a distal opening 1501 to a proximal opening 1503, and is sized and configured to receive therein an ilium positioning guide. Sacrum portion 1506 similarly includes and defines an elongate sacrum lumen therein that extends from a distal opening to a proximal opening, and is sized and configured to receive therein a sacrum positioning guide. Exemplary lumens are described herein, and may each have a long axis. In this example, and as shown, sacrum portion 1506 extends further proximally than the ilium portion 1504. Ilium portion 1504 extends further distally than sacrum portion 1506, as shown, exemplary advantages of which are described herein. Implant body 1502 is also an example of an implant body with a parallelogram configuration without right angles, and in this example has a rhomboid configuration, exemplary benefits are described herein.

[0191] Implant body 1502 is an example of an implant body with a wafer configuration with a height dimension that is less than a width dimension. As shown, and in this example, the sacrum lateral side and sacrum lumen have lengths that are greater than corresponding lengths of the ilium lumen and ilium lateral side. The guide lumen axes in implant body 1502 are examples of lumens that have axes (ilium lumen axis ILA; sacrum lumen axis SLA) that are parallel to each other (as shown), which includes slight deviations from perfectly parallel. Ilium lumen axis ILA and sacrum lumen axis SLA are each also parallel to long axis LA of the implant body, as shown, which includes slight deviations from perfectly parallel.

[0192] Implant body 1502 further includes inner frame 1513, which may include the same general or similar configuration as the frame in the embodiment in figures 12 and 13. In this regard, the entire disclosure of the frame from the embodiments in figures 12 and 13 is incorporated by reference herein to the disclosure of frame 1513. For example, frame 1513 includes a plurality of axially extending frame members (not labeled but may be the same or similar to those in figure 13) and oblique or slanted connecting members (one of which is labeled, 1515) coupling and extending between the axially extending frame members. Connecting member(s) 1515 also extend obliquely across long axis LA, as shown. Implant body 1502 also comprises distal sharpened end 1517, which has a concave shape as shown, and which is described in more detail herein, and which extends generally laterally across implant body 1502, as shown.

[0193] Implant body 1502 is an example of an implant body comprising one or more porous network of interconnected struts, as shown. Implant body 1502 includes a porous network of interconnected struts 1511 that in this embodiment extends over and about a top implant body portion, a bottom implant portion, and lateral sides of the implant body. In this embodiment, porous network of interconnected struts 1511 define larger cells or pores in the central region than in the ilium and sacrum portions of the implant, as shown.

[0194] Implant body 1502 is an example of an implant body with a quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration. In alternative embodiment, implant body 1502 may have a rhombus configuration, but in alternative embodiments it may have any other quadrilateral configuration (including rectangular). The proximal end of implant body in figure 15 is an example of a proximal portion of an implant body that is considered to approximate a side of a quadrilateral even though it does not have complete linearity, as is shown.

[0195] Figure 15B illustrates implant 1500, and illustrates the exemplary length of the implant, measured axially from the distal end to the proximal end of the implant.

[0196] Figure 15C illustrates a perspective view of implant 1500, and also illustrates lateral side fenestrations 1550a and 1550b in the sacrum side of the implant, and which are in communication with the sacrum lumen as shown. Fenestrations 1550a and 1550b may be used to help facilitate delivery of an agent into the patient via delivery of the agent through the proximal opening of the sacrum lumen. Alternatively or additionally, fenestrations 1550a and 1550b may help tissue growth therethrough, which can help stabilize the implant. The ilium lateral side can similarly have fenestrations 1550a and 1550b therethrough. The lateral sides of the implant can optionally have one or more fenestrations 1550 therethrough, such as, without limitation, from one to ten, or more.

[0197] Figure 16 is a top view illustrating exemplary implant 1600, which, like others herein, is sized and configured for implantation across an SI joint from a dorsal approach. Implant 1600 may incorporate any suitable feature of any other implant body herein, such as those shown and described with respect to figures 11A-15. Implant 1600 includes implant body 1602 that includes ilium portion 1604 that is sized and configured for implanting into an ilium when the implant is implanted across an SI joint from the dorsal approach. Implant body 1602 also includes sacrum portion 1606 that is sized and configured for implanting into a sacrum when the implant is implanted across the SI joint from the dorsal approach. Ilium portion 1604 includes and defines an elongate ilium guide lumen (not labeled) that extends from a distal opening to a proximal opening, and is sized and configured to receive therein an ilium positioning guide. Sacrum portion 1606 includes and defines an elongate sacrum lumen therein that extends from a distal opening to a proximal opening, and is sized and configured to receive therein a sacrum positioning guide. In this example, sacrum portion 1606 extends further proximally than ilium portion 1604, as shown, exemplary advantages of which are described herein. Ilium portion 1604 extends further distally than sacrum portion 1606, as shown, exemplary advantages of which are described herein. Implant body 1602 is also an example of an implant body with, in a top view, a parallelogram configuration without right angles, as shown, which may be rhomboid or rhombus shaped. Implant body 1602 is also an example of an implant body with a wafer configuration that has a height dimension that is less than a width dimension. In this example, the sacrum lumen and sacrum side have lengths that are greater than length of the ilium lumen and ilium lateral side, respectively (as shown). The guide lumens are examples of lumens that have long axes that are parallel with each other (as shown), which includes slight deviations from perfectly parallel. Elongate ilium lumen axis ILA and sacrum lumen axis SLA are also

parallel to a longitudinal (or long) axis LA of the implant body, as shown. As shown in the examples herein, a long axis of the implant body LA may or may not be a line of symmetry of the implant body (in a top view), which in this case it is not. Implant body 1602 also includes a distal portion, at least a portion of which comprises sharpened distal end 1617, exemplary details of which are described herein, and which may be incorporated into this embodiment. For example, sharpened or cutting distal end 1617 has a tapered configuration that tapers downward from a top portion of the implant body and that tapers upward from a bottom portion of the implant body.

[0198] In this example, implant body 1602 includes a frame, which as shown does not comprise fenestrations through top and bottom portions of the implant body (e.g., such as fenestrations 1376a and 1376b). Any of the implants herein may not include fenestrations through top and bottom portions of the implant body, as is the case with implant body 1602.

[0199] Implant body 1602 is an example of an implant body with a wafer configuration with a height dimension that is less than a width dimension. As shown, and in this example, the sacrum side and sacrum lumen have lengths that are greater than corresponding lengths of the ilium lumen and ilium side, respectively. The guide lumen axes in implant body 1602 are examples of lumens that have axes (ilium lumen axis ILA; sacrum lumen axis SLA) that are parallel to each other (as shown), which includes slight deviations from perfectly parallel. Ilium lumen axis ILA and sacrum lumen axis SLA are each also parallel to long axis LA of the implant body, as shown, which includes slight deviations from perfectly parallel.

[0200] Implant body 1602 is an example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration, additional examples of which are shown herein. In alternative embodiment, implant body 1502 may have a rhombus configuration, but in alternative embodiments it may have any other quadrilateral configuration (including rectangular).

[0201] Implant 1600 may incorporate any other suitable feature of any of implant body herein.

[0202] Figures 17A and 17B illustrate an exemplary distal end 1720 of an ilium portion of an implant body, features of which may be incorporated into any of the distal ends of the ilium portions herein. Figure 17B is a front end view, also showing the ilium lumen. Figure 17C illustrates an exemplary distal end 1707 of a sacrum portion of an implant body, features of which may be incorporated into any of the distal ends of the sacrum portions herein. The distal end 1720 and 1707 both include a plurality of cutting edges 1750, which in each case progressively have larger dimensions moving proximally, as shown. The configuration of the cutting edges 1750 on each end acts like a broach to help both ends penetrate into bone as the implant is advanced distally. Cutting edges 1750 have annular configurations, as shown, which may be colinear with the lumen axes, which is also shown. Exemplary sharpened distal end 1717 is shown in figure 17B, exemplary details of which are described herein. In this example, the ilium distal end 1720 has three axially spaced annular cutting edges, while the sacrum region distal end 1707 has two axially spaced annular cutting edges. Each end may have more or fewer cutting edges. Cutting edges like

those shown in figures 17A-17C are shown in the implant bodies in figures 12, 13, 14, 15A-15C and 16, and thus the description of these other figures implicitly includes the description of figures 17A-17C.

[0203] Any of the ilium portions herein may have cutting edges, such as those shown in figures 17A and 17B. Any of the sacrum portions herein may have cutting edges, such as those shown in figure 17C.

[0204] Figures 18A-18C illustrate implant 1800, which include implant body 1802 that may be the same as implant body 1352 from figure 13 in all ways, except those described herewith. Implant body 1802 includes ilium portion 1804 that includes distal end 1820 with a configuration that helps penetrate or cut through tissue as the implant is being advanced distally. Figure 18B illustrates a close-up perspective view of distal end 1820 of ilium region 1804. Ilium region 1804 includes ilium lumen IL, additional details of which are described herein. Distal end 1820 includes first cutting region 1822 with a first cutting member 1823, and a second cutting region 1824 with a second cutting member 1825. Concave surfaces extend between the two cutting regions, as shown. Second cutting region 1824 extends further distally and is wider than first cutting region 1822. First cutting member 1823 has a height that is greater than a height of second cutting member 1825. Cutting edges of both first and second cutting members 1823 and 1825 are relatively sharp and help penetrate through tissue as implant 1800 is advanced.

[0205] Sacrum region 1806 includes distal end 1807, which may have the same configuration as any other sacrum or ilium portion distal end herein (including like distal end 1820). The sacrum portion may optionally include sacrum lumen SL as shown in figure 18C, but in alternative embodiments the sacrum portion may not include a lumen, as is described in examples herein. Implant body 1802 also has a sharpened distal end extending at least in the central portion of the implant body, examples of which are described herein and the disclosure of which is incorporated by reference into the description of figures 18A-18C.

[0206] Implant body 1802 is an example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration. In alternative embodiment, implant body 1802 may have a rhombus configuration, while in alternative embodiments it may have any other quadrilateral configuration.

[0207] Figure 19 shows a top view of implant 1900, which includes implant body 1902, which may be the same in any or all ways as implant body 1802 in figures 18A-18C except for those details described herewith. Implant body 1902 includes frame 1913 and one or more porous network of interconnecting struts 1930 extending from frame 1913. A porous network of interconnecting struts 1930 may by the same in any or all ways as porous network of interconnecting struts 1401 from figure 14. Implant body 1902 is an example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration. In alternative embodiment, implant body 1902 may have a rhombus configuration, but in alternative embodiments it may have any other quadrilateral configuration.

[0208] Figure 20 is a top view of implant 2000, which, like others herein, is sized and configured for implantation across an SI joint from a dorsal approach. Implant 2000 may incorporate any suitable feature

of any other implant body herein, such as those shown and described with respect to figures 11A-19. Implant body 2002 may be the same as implant body 1802 from figure 18A and 18B in any or all other ways except those described herewith. Implant body 2002 includes ilium portion 2004 with an ilium portion distal end 2020 that does not extend as far distally as some ilium portion distal ends described herein. Additionally, sacrum portion 2006 includes sacrum portion distal end 2007 that does not extend as far distally as some sacrum portion distal ends described herein. Distal end 2020 of ilium portion 2004 includes first cutting region 2022 and second cutting region 2024, and distal end 2007 of sacrum portion 2006 includes first cutting region 2009 and second cutting region 2011, all of which have pointed or sharpened configurations that help penetrate or cut into tissue as the implant is advanced distally. Each of the adjacent sharpened regions have concave surfaces therebetween in the top view, as shown.

[0209] Implant body 2002 includes a distal portion that includes sharpened distal end 2017 (which extends through the central region of the implant body. Any or all exemplary details of any of the sharpened distal ends herein may be incorporated by reference into sharpened distal end 2017 of figure 20. In this embodiment, due partially to the distal end of distal ends 2020 and 2007, sharpened distal end 2017 does not have as pronounced a concave curve as in other embodiments herein. In fact, as shown, sharpened distal end 2017 has a slight "S" shape curvature, as shown. Sharpened end 2017 thus has a convex curvature along a first portion of the front face, and is concave along a second portion of the front face, wherein the convex region is closer to the ilium side, as shown. Any of the implant bodies herein may be modified to include any or all of the features shown and described with respect to figure 20.

[0210] Implant body 2002 is an example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration. In alternative embodiment, implant body 2002 may have a rhombus configuration, but in alternative embodiments it may have any other quadrilateral configuration.

[0211] Figure 21 is a top view of implant 2100, which, like others herein, is sized and configured for implantation across an SI joint from a dorsal approach. Implant 2100 may be the same as implant 2000 in any or all ways except as described herewith. Implant body 2130 includes a plurality of porous networks of interconnecting struts 2130. While only one network 2130 is shown that extends over a portion of the top portion of the implant 2100 (the network similar have a slanted digital eight configuration), it is understood that a second network 2130' (not labeled) may similarly extend over the corresponding bottom portion of the implant body 2102. Network 2130 may be considered similar to network 1930 shown and described with respect to figure 19. Implant body 2102 is an example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration. In alternative embodiment, implant body 2102 may have a rhombus configuration, but in alternative embodiments it may have any other quadrilateral configuration.

[0212] Figures 22A-22C illustrate implant 2200, which may include any suitable feature from any of implant 1350 in figure 13, implant 1600 in figure 16, implant 1800 from figures 18A-18C, and/or implant 2000 from figure 20, except with respect to the features described herewith. Implant 2200 includes

implant body 2202, for which sacrum lumen SL does not have a distal opening, as shown. As such, delivery of implant 2200 does not include delivery over a sacrum guide, examples of which are described herein. Implant body 2202 includes a sacrum lumen SL, however, that includes a proximal opening, as shown, which may help facilitate growth on the lateral sacrum side via lateral sacrum side fenestrations 2240a and 2240b, as shown, or delivery of an agent therethrough as described herein. Additionally, as shown, distal end 2220 of the ilium region extends further distally than distal end 2207 of the sacrum region.

[0213] Implant body 2202 also includes a distal portion that comprises a sharpened distal end 2217, exemplary details of which are described herein and may be incorporated fully into the description of figures 22A-22C. The curvature of the sharpened distal end has a varying radius of curvature along the curve, and may include a concave section and a convex section, for example. In the embodiment in figures 22A-22C, the sharpened distal end comprises a convex section that is closer to the ilium lateral side than the sacrum lateral side, and includes a concave curve section that is closer to the sacrum side than the ilium side, as shown.

[0214] Implant body 2202 is an example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration. In alternative embodiment, implant body 2202 may have a rhombus configuration, but in alternative embodiments it may have any other quadrilateral configuration.

[0215] Figures 23A and 23B illustrate implant 2300 comprising implant body 2302, which may include any of the features of implant 2200 described with respect to figures 22A-22C. As with other examples herein, implant 2300 may include one or more network of struts 2130 extending about any portion of the implant body, examples of which are shown in figures 23A and 23B.

[0216] Implant body 2302 is an example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration. In alternative embodiment, implant body 2302 may have a rhombus configuration, but in alternative embodiments it may have any other quadrilateral configuration.

[0217] Figure 24 is a top view of an exemplary implant 2400 with implant body 2402. Any suitable feature (including the absence of any features, such as a lumen) from any other implant body herein may be incorporated into implant body 2402.

[0218] Implant body 2402 is an example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles. In alternative embodiments it may have any other quadrilateral configuration, such as a right trapezoid if the two lateral sides of implant body 2402 were modified to horizontal in figure 24 (parallel with the axes of the lumens).

[0219] Implant body includes a distal portion with sharpened distal end 2417, which may be configured as any of the sharpened ends described herein, all of which are incorporate by reference into the description of figure 24.

[0220] Figure 24 also conceptually illustrates exemplary lines L that are annotated in the top view of implant body 2402. Lines L are orthogonal to both a long axis LA of the implant body 1402, as well as to

lumen axes ILA and SLA, as shown. Lines L are also orthogonal to the direction of implantation, which refers to a direction in or trajectory along which the implant is implanted.

[0221] Figure 25 is a top view of an exemplary implant 2500 with implant body 2502. Any suitable feature (including the absence of any features, such as a lumen) from any other implant body herein may be incorporated into implant body 2502.

[0222] Implant body 2502 is an example of an implant body with a quadrilateral configuration with first and second parallel sides. In this example, the quadrilateral configuration does not include right angles. In alternative embodiments, it may have any other quadrilateral configuration.

[0223] Implant body includes a distal portion with a sharpened distal end 2517, which may be configured as any of the sharpened ends described herein, all of which are incorporate by reference into the description of figure 25.

[0224] Figure 25 also conceptually illustrates exemplary lines L that are annotated in the top view of implant body 2502. Lines L are orthogonal to both a long axis LA of the implant body 2502, as well as to lumen axes ILA and SLA, as shown.

[0225] Figure 26 is a top view of an exemplary implant 2600 with implant body 2602. Any suitable feature (including the absence of any features, such as a lumen) from any other implant body herein may be incorporated into implant body 2602.

[0226] Implant body 2602 is an example of an implant body with a quadrilateral configuration that does not include right angles. In alternative embodiments, it may have any other quadrilateral configuration.

[0227] Implant body includes a distal portion with sharpened distal end 2617, which may be configured as any of the sharpened ends described herein, all of which are incorporate by reference into the description of figure 26.

[0228] Figure 26 also conceptually illustrates exemplary lines L that are annotated in the top view of implant body 2602. Lines L are orthogonal to both a long axis LA of the implant body 2602, to lumen axes ILA and SLA, as shown, as well as to a direction or trajectory of implantation.

[0229] Figures 27A and 27B illustrate a top view and distal perspective view of exemplary SI joint stabilizing implant 2700, which may understandably incorporate any other feature of any implant herein even if not expressly described with respect to figures 27A and 27B. For example, implant 2700 includes implant body 2702 that includes ilium region 2704 and 2706, and sharpened distal end 2717 with a tapered configuration, as shown. In this embodiment, sharpened distal end 2717 has a general concave configuration, as shown. Sharpened distal end 2717 includes a top region that extends downward and distally from a top portion of the implant body, and a bottom region that extends upward and distally from a bottom portion of the implant body to form the tapered configuration. The top and bottom regions have general scallop configurations, as shown, as does the distal face of the sharpened distal end, both of which may enhance the ability of the sharpened distal end to cut or penetrate through bone.

[0230] Figure 28 illustrates a top view of implant 1402 shown in figure 14. Figure 28 illustrates conceptually how the outer profile of implant body 1402, in the top view, can be approximated to an approximated configuration 2802. Figure 28 illustrates how implant body 1402 is described herein as an

example of an implant body with a general quadrilateral configuration. In this example, the quadrilateral configuration does not include right angles, and is an example of an implant body with a rhomboid configuration, as shown by approximated configuration 2802. The general approximation shown in figure 28 is an example of how the implant bodies herein are described in terms of a general configuration, such as, without limitation, quadrilateral, rhomboid, parallelogram without right angles, etc.

[0231] Figures 29-31 illustrate exemplary proximal or back ends of implant bodies 2902, 3002 and 3102, respectively, which may be included in any of the implant bodies herein. The proximal ends in figures 29-31 are merely examples of proximal ends adapted to facilitate delivery of the implant with an impactor (examples of which are described below) Figure 31 illustrates an exemplary implant body wherein the SL does not include a distal opening, an example of which is shown in figures 22A and 22B.

[0232] Figure 29 illustrates recessed (or depressed) impactor stabilizers 2980a and 2980b on either lateral side of channel 2928, which includes an internal thread 2983. Impactor stabilizers 2980a and 2980b are each shaped and positioned to receive therein a protrusion on the distal end of an impactor or other delivery tool, such as protrusions 5960 shown in figure 59D. The interface and engagement between the impactor and implant on both sides prevents rotation therebetween when the implant is loaded onto the impactor and when the implant is impacted.

[0233] Channel 2982 includes an internal thread, which is configured to engage with the external thread on implant securing member 5958 of the impactor to facilitate the releasable coupling between the impactor and the implant. The releasable coupling therebetween allows the implant to be axially secured to the impactor for impaction across the SI joint, and also allows the implant to be retracted proximally if needed by pulling on the impactor.

[0234] Figures 30 and 31 illustrate exemplary proximal ends that include recessed impactor stabilizers 3080 and 3180, respectively, which are sized and configured to interface with protrusions on a distal end of a delivery tool, such as an impactor herein. Stabilizers 3080 and 3180 are examples of stabilizers that are centrally located (in a lateral direction), and may extend across the long axis of the implant.

[0235] One aspect of the disclosure is related to methods of positioning an SI joint stabilizing implant across a SI joint from a dorsal approach. In these methods, the SI joint implant may be any of the SI joint implants herein unless the method is limited to one or more implants herein. The methods may include advancing an elongate ilium positioning guide from a dorsal starting point, such as starting point 1122 shown in figure 32A, and into an ilium of a subject. For example only, figures 2A and 2B illustrate exemplary ilium guide 22, but other types of ilium guides may be positioned from a dorsal approach into an ilium of the subject. Figure 32A also illustrates a general region 1120 into which any of the ilium guides herein may be started and advanced into an ilium to function as a guide for the SI joint implant. The methods herein may include engaging a guide interface member of the SI joint implant with a positioning guide to restrict movement of the implant with respect to the positioning guide in at least one direction. For example only, figures 1A and 1B illustrate ilium guide interface member 18 of SI joint implant 14, but other interface members herein may be engaged with any of the guides herein to restrict movement of the SI joint implant with respect to the positioning guide in at least one direction. The

methods may include, at a time subsequent to the engaging step, advancing the implant across the SI joint while guiding the implant with the positioning guide to implant the implant across the SI joint. The methods further include removing the positioning guide from the ilium and leaving the implant implanted across the SI joint. The methods may include advancing a positioning guide into an ilium between lateral and medial cortical walls of the ilium, descriptions and locations of which are generally known and shown generally in figures 32A and 32B. In these methods, engaging the implant with an ilium positioning guide helps maintain the implantation trajectory and limits the extent to which the implant migrates towards the sacrum while advancing the implant across the SI joint.

[0236] Some methods may also include advancing a sacrum positioning guide into a sacrum of the patient, and further engaging a second guide interface member of the implant with the sacrum positioning guide. In these examples, the implant advancing step may occur while also guiding the implant with the sacrum positioning guide. In these examples, the method also includes removing the sacrum positioning guide from the sacrum. Any of the methods herein may include positioning a sacrum positioning guide into a sacrum before or after an ilium positioning guide is positioned in an ilium.

[0237] Methods herein may optionally include, prior to implanting the implant across the SI joint, interfacing a sharpened broach with one or more of the guides herein; advancing the sharpened broach over the one or more positioning guides towards the SI joint while guiding the broach with the one or more positioning guide; and creating a space for the SI joint implant with the sharpened broach. These methods may include removing the broach to allow dorsal access to the space. An implant may then be advanced over the one or more positioning guides as described elsewhere herein and implanted across the SI joint.

[0238] Depending on the implant being implanted across the SI joint, any of the methods herein may also include positioning a second ilium positioning guide from a dorsal approach into the ilium of a subject. These examples may also include engaging a second guide interface member of the implant with the second ilium positioning guide to further restrict movement of the implant with respect to the second ilium positioning guide in at least one direction.

[0239] Depending on the implant being implanted across the SI joint, any of the methods herein may optionally include positioning first and second sacral positioning guides from a dorsal approach into the sacrum of a subject. These examples may also include engaging first and second sacrum guide interface members of the implant with the first and second sacrum positioning guides to further restrict movement of the implant with respect to the first and second sacrum positioning guides in at least one direction.

[0240] Any of the individual method steps set forth herein may be combined with any other suitable method step or sequence of steps, unless the disclosure herein indicates to the contrary.

[0241] As is described above, an aspect of this disclosure is related to methods of positioning a sacro-iliac ("SI") joint stabilizing implant across a SI joint from a dorsal approach. An additional aspect of this disclosure is delivery tools that facilitate the delivery of one or more guides into the ilium and/or sacrum, and the methods of delivering the one or more guides into the ilium and/or sacrum. The disclosure that follows is related to those methods and delivery tools, and may be incorporated into any of the other

disclosure herein. For example, methods and delivery tools herein may include and be adapted for advancing an elongate ilium positioning guide from a dorsal approach into an ilium of a subject, engaging an ilium guide member of a SI joint stabilizing implant with the ilium positioning guide to restrict movement of the implant with respect to the ilium positioning guide in at least one direction, advancing the implant across the SI joint while guiding the implant with the ilium positioning guide, and removing the ilium positioning guide from the ilium. The disclosure that follows provides merely exemplary and illustrative additional steps that may be incorporated into any of these methods. It is fully understood that these steps are illustrative, may be optional, and are not limiting the general methods set forth herein. It is also fully understood that the order of one or more of the steps set forth herein may be changed. The method steps that follow may refer to one or more delivery devices, examples of which are shown in figure 33 (e.g., impactor, positioning template, pin guide, guide pins, trephines, etc.). It is understood that the names of these delivery devices are not necessarily limiting, and they instead may be described or characterized by the one or functions they provide during the procedure. For example, a guide pin may instead be considered more generally as a positioning guide or simply a guide for the implant. A parallel pin guide herein may also be referred to as a pin guide herein.

[0242] Methods herein may include one or more steps to ensure a proper trajectory for the implant. The one or more positioning guides (e.g., guide pins) herein may help facilitate the desired trajectory from the dorsal approach. Methods herein may also include one or more steps to properly determine a starting point or location for the one or more positioning guides. The methods herein may further include one or more steps to advance the positioning guides along a proper trajectory, which may help maintain a desired or proper trajectory for the implant when advanced distally relative to the positioning guide(s). Merely exemplary steps that may be performed to position one or more positioning guides and advance an implant in a dorsal approach are set forth below, and are made in reference to figures 34A-38.

[0243] A patient may be positioned in a prone position to facilitate the dorsal approach and dorsal entry. Radiograph imaging may be performed to obtain an A/P (anteroposterior) view of the SI joint region, as shown in figure 34A. The inferior joint aspect of the SI joint may be localized. A visual marking may be made on the skin (e.g., with a marker), optionally about 1 cm proximal to the end of the joint, which can generally indicate an implant insertion location, such as shown in figure 34B. A second visual skin marking may be made, which may be 3 cm long or about 3 cm long, in line with the SI joint bifurcating the transverse skin mark, such as shown in figure 34B. A skin incision may then be made along the second visual skin marking. An inlet oblique view may then be obtained, which may provide a view of the inferior limb of the articular joint, such as shown in figure 34C. A positioning template, such as the example shown in figure 33, may be placed in line with the transverse skin visual marking, and as represented in the view of figure 34D. It is of note that the methods herein may use only one positioning guide (e.g., pin), and the methods herein that use three are exemplary. The center hole or aperture in the positioning template may be positioned over the SI joint. The positioning template may be used to properly position one or more guide pins at one or more desired entry or starting point locations, and is illustrated in place in figure 34E (to illustrate the position relative to the view that is shown). Any of the

methods herein may further include positioning a guide pin through the positioning template into the Ilium, optionally through an ilium aperture in the template, which may be one or one, two, or three apertures in the template. The guide pin may have a sharpened distal end to help advance the guide pin. A sharp ilium guide pin may be replaced with a blunt ilium pin. The methods herein may further include aligning the pin, optionally in the inlet oblique view, so that it is parallel to the inferior aspect of the SI joint. The pin may be seated in the ilium and advanced, optionally 1 cm or about 1 cm. A lateral view may then be obtained, such as in figure 34F, and the ilium guide pin may be advanced, such as, for example only, 4 cm or about 4 cm.

[0244] The following steps are understood to be optional, and not all steps may need to be performed depending on the implant and the particulars of the procedure. For example, one or all of the following steps may not be performed if the method does not utilize more than a single guide pin (e.g., an ilium guide pin). The description that follows is made in reference to figures 35A-35C, but it is fully understood that one or more of these steps may occur in combination with one or more of the steps described with respect to figures 34A-34F. The methods may further include obtaining an Inlet Oblique View, and the positioning template may be removed from the patient. A pin guide, an example of which is shown in figure 33 and labeled parallel pin guide (which can also be seen in figures 35A-35C), may be advanced over the guide pin that is in the ilium. In the example in figure 33, the longer of the tubes of the pin guide may be advanced over the ilium pin, which can be seen in figure 35A. The methods herein may include advancing a guide pin (such as a stepped guide pin) into the sacrum through a sacrum guide tube of the pin guide, which can be seen in the view of figure 35A. The methods herein may include preparing a hole in the joint through a central lumen of the parallel pin guide, such as by drilling with a trephine through the center hole to a stop, such as into the joint approximately 30mm, which can be seen in figure 35B. A broach may be used instead of a drill, for example, and it is understood that any of the methods herein may be performed completely without electrical power (e.g., without power tools). If a trephine is used, the trephine may be removed, a guide pin may be advanced through the central lumen of the pin guide. Performing this optional step may help prevent the pin guide from rotating while placing a sacral trephine. The optional sacral guide pin may be removed and a hole may be prepared in the sacrum, such as by drilling into the sacrum with the trephine, such as about 30 mm, and example of which can be seen in figure 35C. The methods herein may include removing an optional sacral trephine and placing a blunt pin in the sacrum through the sacrum tube of the pin guide (not shown). The pin guide may be removed, and a central guide pin, if utilized, may be removed. A hole may optionally be prepared in the ilium, such as by drilling with a trephine over the iliac pin, such as up a line (e.g., 30 cm) on the trephine. A broach may alternatively be used without power to prepare an ilium hole. A trephine may be removed from the ilium, and in this merely exemplary embodiment, iliac and sacral guide pins are left behind in the patient to help guide the implant during implantation. It is again noted that any of the methods herein may utilize only one positioning guide (e.g., one guide pin), such as an ilium positioning guide.

[0245] With specific but not limiting reference to exemplary implant 1300 from figures 11A and 11B, the implant may then be engaged with the guides (e.g., pins) by advancing the lumens 1305 and 1307

over the respective guide pins. The ilium portion, which in this example does not extend as far proximally as the sacrum portion, is engaged with the ilium positioning guide and the implant 3610 is advanced over the pin guides, as shown in figure 36. An impactor 3600 (or other similar tool that can be used to advance the implant) can be advanced over the guide pins behind implant 3610 until it engages the implant at location 3620. As shown in figures 33 and 36, the distal end of the impactor can have a configuration that is shaped to mate with the configuration of the proximal end of implant 3610, and also to allow the impactor to apply a distally directed force to the implant. In this example, the impactor distal end is also stepped to match the configuration of the proximal end of implant 3610. Implant 3610 may include any of the features of any of the implants herein. Impactor 3600 includes a plurality of pin guides 3602 as well, sized and configured to receive therein the guide pins 3640, which in this embodiment are lumens extending axially along lateral portions of the impactor, as shown. This allows the impactor 3600 to be advanced over the guide pins and to be aligned with implant 3610 to facilitate distal advancement of the implant 3610 by applying a distally directed force on impactor 3600 (directly or indirectly applying the force). The implant may be advanced to the desired depth by applying the force on the impactor (e.g., with a mallet). The impactor and guide pins may be removed, leaving the implant behind implanted in the patient across the SI joint. A proper implant position may be confirmed, such as shown in the views of figures 37A, and 37B.

[0246] It is understood and stated again that the methods of implantation herein may include using as few as one, and optionally two, three or more guide pins.

[0247] Any of the methods of implantation herein may be performed solely under an inlet radiographic view. Any of the methods of implantation herein may be performed solely under an inlet or inlet oblique radiographic view.

[0248] Any of the methods of implantation herein may be performed without electric power (e.g., manual power only). Any of the methods of implantation herein may be performed with electric power (e.g., including use of an electric drill for one or more steps, examples of which are set forth herein).

[0249] Any of the methods steps herein that include preparing a hole may be performed by drilling a hole. Any of the methods steps herein that include preparing a hole may be performed by manually creating a hole, such as with a broach. Broaches herein may also be used to create a channel within the bones from one guide pin to the other to accept the entire implant.

[0250] Any of the methods herein may include a removable pin that threads into the sacral tube of the pin guide. This may provide an added advantage of not risking distal advancement beyond a desired location, which may reduce the risk of damaging sensitive tissue.

[0251] The disclosure that follows provides additional and exemplary methods and steps that may be included when preparing for the implantation and implanting any of the SI joint implants herein from a dorsal approach. The disclosure that follows describes a merely exemplary method, not all steps of which are necessarily required (and the order of some steps may be changed), and refers generally to figures 40-55B. Suitable method steps below may, however, be incorporated into alternative methods described herein, and vice versa. An exemplary method of placing a plurality of guide pins may include, in an inlet

oblique view such as is shown in figure 40, optionally placing a needle in the SI joint, as may occur in an SI joint injection. The method may optionally include injecting a contrast media such as Omnipaque with the needle to ensure the needle is in the SI joint, which can be viewed in, for example, an inlet oblique view and/or a lateral view as shown in figures 41A and 41B. As shown in the radiographic view of figure 42A, the method may include placing an exchange pin along the skin over the sacral promontory. The method may include creating a linear skin marking along the exchange pin, as shown in figure 42B. Additional skin markings may be made on either side of the SI joint, such as about 2 cm on either side of the SI joint, which may be used for creating an incision, which is described below. The method may include removing the back end of the needle, including the luer lock, and placing a Jamshidi™ needle over the needle, as represented in figure 43. The method may include removing the original needle and replacing it with a nitinol wire through the Jamshidi™ needle and into the SI joint. The Jamshidi™ may then be removed, leaving the nitinol wire in the SI joint, as shown in figure 44.

[0252] The method may also include making an incision along the linear marking between the additional markings that were made on either side of the SI joint, such as an incision about 4 cm in total length (e.g., 2 cm on either side of the joint). The method may also include placing a pin guide over the nitinol wire. Exemplary pin guides are shown in figures 33 and 45, both of which are examples of pin guides that include a plurality of tubes or channels as shown, and are also examples of pin guides that include three tubes, channels, or lumens. In an exemplary method, the center of three channels may be placed over the nitinol wire, which is shown in figures 46A and the radiographic image of figure 46B. Pin guide adjustment may be made under radiographic imaging such as fluoroscopy to obtain the appropriate pin guide positioning. The exemplary pin guide shown in figure 45 includes actuators that in this example include knobs that can individually be tightened against one of the three channels or tubes to prevent them from moving axially relative to the pin guide main body. Releasing the engagement can be performed to allow any of the tubes to be individually moved axially relative to the main body, after which time their relative axial positions can again be fixed by rotating the knobs until the threaded element engages the particular tube/channel. A variety of alternative mechanisms to both maintain axial position in a first configuration yet allow for axial movement in a second configuration may also be used. As used herein, any of the pin guide tubes may also be referred to herein as pin guide channels, both of which are understood to define a pin guide lumen therethrough.

[0253] The method may also include placing a sacral tube of the pin guide down to sacral bone. The sacral-side knob may then be tightened to secure the sacral tube of the pin guide on the sacrum. The method may include placing a pin (e.g., a 3.2 mm pin) through the sacral tube of the pin guide through sacral cortex, but not to depth. The pin may be positioned through the sacral cortex with a mallet, for example, as is shown in figure 47.

[0254] The method may also include distally advancing an ilium tube of the pin guide down and into contact with iliac bone, which may be performed before or after the sacral tube is advanced distally to sacral bone. The ilium-side knob on the pin guide may then be tightened to secure the ilium tube of the pin guide on the ilium. The method may include placing a pin (e.g., a 3.2 mm pin) through the ilium tube

of the pin guide through ilial cortex, but not to depth, which may be performed before or after the sacrum pin is advanced through sacral cortex. The ilium pin may be positioned through the ilial cortex with a mallet, for example, as shown in figure 48A and the radiographic image of figure 48B. At this exemplary embodiment, guide pins are positioned in both the sacrum and ilium (which may be positioned therein in either order).

[0255] The method may include providing or taking a lateral image, as shown in figures 49A and 49B, and distally driving the sacrum and ilium pins (in either order, or only one pin if the procedure utilizes only a single pin) to depth in the lateral view. The method may preferably include not distally advancing the guide pins passed the alar line, as shown. At this time, the elongate guiding wire (e.g., nitinol wire) may be removed from the optionally center channel of the pin guide.

[0256] A hole may optionally then be drilled through a center channel of the pin guide, as shown in figure 50. The pin guide may then be removed from the patient, leaving the ilium and sacrum pins in place in the ilium and sacrum, respectively. Ilium and sacrum bone may then be cut or removed using a cutting instrument such as a trephine placed over the ilium and sacrum pins, as shown in figure 51. Preferably only cortex bone is cut with the cutting instrument.

[0257] With guide pins in place in the ilium and sacrum, the SI joint implant can be engaged with the guide pins, details of which are described herein, an exemplary step of which is shown in the radiographic image of figure 52. The implant is then impacted to depth (e.g., using an impactor such as shown in figure 33 or other similar impactor) across the SI joint while being guided by the guide pins, as shown in figures 53A and 53B, and additional details of which are set forth above. After the implant is delivered to the desired position across the SI joint, the impactor and the guide pins may then be removed, which is shown in figure 54 when the guide pins are being removed. An additional lateral view (figure 55A) and an outlet view (figure 55B) may be obtained to visualize the implant position across the joint.

[0258] This exemplary method includes implanting an SI joint implant that comprises larger and fewer fenestrations than the implant in figure 11A, which can be seen in the radiographic image of figure 55B. This method also includes implanting an implant that includes a proximal region that does not include a sacrum region that extends further proximally than an ilium region, in comparison to the implant in figure 11A. As shown in figure 55B, the implant in this embodiment also includes a distal central region with at least some degree of curvature, which is described in more detail above with respect to the implant in figures 11A and 11B. Additionally, the implant shown in figure 55B also includes a sharpened distal central region, examples of which are described herein.

[0259] The disclosure that follows provides additional exemplary delivery tools (e.g., a pin guide) sized and configured for positioning one or more guides (e.g., guide pins) into an ilium and/or sacrum. The disclosure that follows additionally provides exemplary tools for advancing implants over the one or more guides and into position across the SI joint. It is understood that aspects of methods that follow may be incorporated into other methods of guide pin placement herein, and vice versa. It is also understood that features of delivery tools that follow may be incorporated into other suitable delivery tools herein, and vice versa. The methods and delivery tools that follow may be used to delivery one or more of the suitable

implants herein. The disclosure below describes delivery tools in the context of their methods of use with the exemplary methods.

[0260] In the dorsal approach with the patient prone (with their back facing up), an incision can first be made proximate the SI joint, followed by retracting soft tissue to expose the underling bone and provide access to the joint.

[0261] Figures 56A and 56B illustrate an exemplary pin guide 5600 that can be used in methods herein to place one or more guides (e.g., guide pins) into an ilium and/or a sacrum from a dorsal approach. Pin guide 5600 includes pin guide body 5602 with an ilium guide portion 5604 that is optionally longer than sacrum guide portion 5606. Ilium guide portion 5604 includes a lumen 5605 sized and configured (optionally cylindrical) to receive one or more elongate delivery tools, examples of which are described below. Sacrum guide portion 5606 includes a lumen 5607 sized and configured (optionally cylindrical) to receive one or more elongate delivery tools, examples of which are described below. Body 5602 further includes first and second laterally extending attachment members 5610a and 5610b, which are configured to interface with an optional elongate handle (described below), wherein the optional handle can be held by medical personnel and which can help maintain the position of pin guide 5600. The distal direction indicates the front of the pin guide 5600 that is first advanced into the patient. The pin guide may include a visual indicator that indicates if it should be used for right or left SI joint pin placement. For example, in this embodiment the pin guide includes a visual indicator that states Right or Left, but other indicators may be used.

[0262] Figures 56C and 56D illustrate perspective front and side views, respectively, of alternative pin guide 5600', which can be the same as pin guide 5600 in all other ways (and used in the same ways) except as described herewith. The same components are similarly labeled, such as body 5602 (figures 56A, 56B) and 5602' (figures 56C, 56D). Implant 5600' includes first and second central pins 5690a and 5690b, which may be permanently coupled with (attached to) body 5602'. Pins 5690a and 5690b are laterally aligned, with pin 5690a being superior to or above 5690b. Pins 5690a and 5690b extend to the same extent distally, as shown in figure 56D. Pins 5690a and 5690b are generally configured and positioned to be advanced across the SI Joint as pin guide is being moved distally towards the SI joint. Pins 5690a and 5690b extend further distally than other parts of pin guide and are the first portion of pin guide 5600' to engage with the SI joint. Pins 5690a and 5690b may, in some embodiments, extend from 10 mm to 20 mm distally from the pin lumens in body 5602'. Pins 5690a and 5690b have sharpened distal ends to pierce into joint tissue and help secure the pin guide relative to the Joint. As set forth herein, the pin guide may or may not include central joint pins 5690a and 5690b, although incorporating them may help secure the pin guide relative to the joint as the other one or more pins as advanced into bone.

[0263] Figures 57A and 57B illustrate exemplary handle 5700 after it has releasably secured to one of the laterally extending attachment members. Figure 57B is a close up view of the region where they are releasably coupled. Handle 5700 includes a channel at one end sized and configured to fit over and be secured to the attachment member. A variety of mechanisms may be used to secure the two components together, and in this example the attachment members include a detent or recessed region configured to

receive a locking element within the channel of the handle. The handle is configured to be gripped or grasped by medical personnel, which may make it easier to maintain the position of the pin guide during the pin placement procedure. Figures 57A and 57B illustrate pin guide 5600', which has a visual of Left to indicate it is configured for pin placement in a procedure on a patient's left SI joint. The left and right pin guides may have the same features, but which are mirror images of each other so they can be used on the right or left side. Additionally, pin guides 5600 and 5600' are optionally longer on the ilium side, as shown. The optional handle may be attached to the pin guide prior to the following exemplary steps.

[0264] Distal tips of the optional pins 5690a and 5690b may then be centered within the SI joint, and the starting point is optionally about 1 cm superior from the ventral SI joint surface. Pin guide 5600' (or any other pin guide herein) may be tapped into the SI joint at the target anatomy, optionally about 1cm superior from the ventral SI joint surface, and the distal tip of the pins 5690a and 5690b may be docked into the joint.

[0265] Figure 64 illustrates an exemplary pin guide 6400, which is similar to pin guides 5600 and 5600' but with differences set forth herein. Any suitable feature of pin guide 5600 or pin guide 5600' may be incorporated into the disclosure of figure 64 unless indicated to the contrary herein. Pin guide 6400 includes body 6402, ilium guide portion 6404 with lumen 6405, and sacrum guide portion 6406 with lumen 6407. Sacrum guide portion 6406 can extend as far distally as ilium guide portion 6404, as shown.

[0266] Unlike with pins 5690a and 5690b in figures 56C and 56D, which have a fixed orientation relative to pin guide 5602', pin guide 6400 is adapted such that distal pin 6470 can move relative to the pin guide body 6402 when pin guide 6400 is in a first state, and then can be locked in place relative to pin guide body 6402 (or at least become much more relative thereto) when pin guide 6400 is in a second state. Particularly, and in this embodiment, when stabilizer 6465 is in a first state, pin 6470 can be moved 360 degrees relative to the distal end of the body 6402 from which pin 6470 extends. By tightening stabilizer 6465 to a second state, however, the orientation of pin 6470 relative to body 6402 can be locked in place or at least becomes much more difficult to move relative to body 6402. By allowing more relative movement between the pin 6470 and body 6402 in a first state, yet allowing the orientation of the pin 6470 to be secured relative to the body 6402 in a second state, the pin 6470 can first be placed into the joint, and then the orientation of the pin guide body 6402 can be fine-tuned as desired by moving it relative to the already placed pin. The pin guide body 6402 can thus be moved relative to the set pin until the body lumens 6405 and 6407 are aligned with the desired trajectories for the ilium pin and the sacrum pin, which are subsequently placed as is set forth herein. When the pin guide body 6402 has been moved to the desired orientation relative to the joint and bones, stabilizer can then be actuated to cause the position of the pin guide body 6402 to be set in place (or least more secured) relative to the pin and the joint in which the pin is placed. This arrangement thus allows for fine tuning the position and orientation of the guide body relative to the pin and joint after the pin has already been placed in the joint, yet further allows the guide body position to be set once it's been moved into the desired orientation.

[0267] In this exemplary embodiment, distal pin 6470 in figure 64 may be fastened or coupled to pin guide 6400 via a spherical ball-and-socket that allows the user to place the pin 6470 in the joint, and then

fine tune the positioning of the sacrum guide portion 6406 and ilium guide portion 6404 over the respective bones as described above.

[0268] In use, the mounting pin 6470 may first be placed in the joint in approximately the correct location. The pin guide 6402 positioning can be further refined by decoupling the mounting pin 6470 from the pin guide 6402 by pulling the most proximal knob 6460 further proximally. The resistance of the ball-and-socket joint can be increased and decreased by turning the threaded stabilizer 6465 just distal to the proximal knob 6460. The sacrum and ilium guide portions 6406 and 6404 can be aligned over the respective bones, and the ball-and-socket joint resistance can be increased by turning threaded stabilizer 6465 clockwise, which limits movement between pin 6470 and body 6402. Ilium guide portion 6404 includes a lumen 6405 sized and configured (optionally cylindrical) to receive one or more elongate delivery tools, examples of which are described above with respect to figures 56A-56D. Sacrum guide portion 6406 includes a lumen 6407 sized and configured (optionally cylindrical) to receive one or more elongate delivery tools, examples of which are described above. After the sacrum and ilium guide portion positions are set, positioning of the guide pins such as 5830 and 5860 described herein may proceed, examples of which are described herein. All other uses of the pin guides herein may be applicable to pin guide 6400 shown in figure 64.

[0269] Figures 58A-58C illustrate a system of tools 5800 that can be to deliver one or more pins. Figures 58A-58C illustrate many components assembled, but the disclosure that follows describes an exemplary process starting with pin guide 5600 prior to assembly with any of the other components.

[0270] A sharp tipped guide tube 5810 can be placed through lumen 5607 in sacral side 5606 of pin guide 5600, as shown in figure 58A and 58B. Cap 5820 may then be placed on the back (proximal) end of sacrum tube 5810, as shown in figure 58A and 58C. In this example the two components are configured to allow cap 5820 to be rotated to cause rotation of sacrum tube 5810, and in this example they have a hex mating arrangement, as shown. Sacrum tube 5810 may then be rotated clockwise to advance sacrum tube 5810 through soft tissue. Once resistance is felt due to contact with the sacrum, sacrum tube 5810 may continue to be rotated until it is fully docked into the sacrum.

[0271] Sacrum pin 5830 (which may also be referred to an implant guide herein), which has a sharpened distal end, as shown, may then be placed into the proximal end of the lumen and through the lumen of sacrum tube 5810, as shown in figure 58A and 58B. Pin 5830 may then be docked into the sacrum using a mallet, such as about 1cm, without fully docking pin 5830 into the sacrum. Imaging in the outlet view, for example, may be used to ensure the trajectory of the sacrum pin 5830 will not intersect the foramina. Sacrum pin 5830 may then be further advanced into the sacrum to depth, such as about 2 cm short of the alar line in the lateral view. The sacrum pin at this time may be considered fully positioned in the sacrum.

[0272] As shown in figures 58A and 58B, sharpened distal tipped ilium tube 5840 can then be placed through lumen 5605 in the ilium guide portion 5604 of pin guide 5600. A cap may be placed on the proximal end of ilium tube 5840 (Similar to cap 5820 with the sacrum tube 5810). The cap may then be rotated to cause rotation of ilium tube 5840 to advance the tube through soft tissue. Once resistance is felt

due to contact with ilium bone, rotation of sharpened tube 5840 may continue until tube 5840 is fully docked in the ilium.

[0273] Ilium pin 5860 (see figures 58A and 58B) may then be placed through the lumen of ilium tube 5840. A cap 5850 may be placed on the proximal end of pin 5860, as shown in figure 58A and 58C, which allows rotation of the cap to cause rotation of pin 5860. Pin 5860 optionally includes a beveled distal end, as shown, which includes a pointed distal end and a flat beveled surface extending proximally and laterally from the pointed tip, as shown. In use, pin 5860 can be rotated (by rotating cap 5850) and oriented so that the flat beveled surface is facing laterally and the pointed surface is facing medially. The bevel causes the pin the better engage in the ilium and not skive along the lateral wall of the ilium without engaging the bone. Pin 5860 can then be docked into ilium bone with a mallet, about 1 cm. Imaging may be used to ensure the ilium pin 5860 is being advanced with the desired trajectory and is not skiving laterally, for example. The ilium pin can be advanced further, until it is about 2 cm short of the alar line in the lateral view. At this time, distal ends of sacrum pin 5830 and ilium pin 5860 are preferably in line, or aligned. Cap 5820 can then be placed over pin 5860 and slid onto the proximal end of ilium tube 5840. While holding pin 5860 with one hand, cap 5820 (which is rotationally secured to tube 5840) can be rotated counterclockwise with the other hand to remove ilium tube 5840 from the ilium. This can be repeated on the sacral side to remove sacral tube 5810. Once sacrum tube 5810 and ilium tube 5840 are free from bone, pin guide 5600 can be removed by sliding it proximally off pin 5830 and pin 5860, leaving sacrum pin 5830 in the sacrum and ilium pin 5860 in the ilium.

[0274] The above method is an example of positioning guide pins in an ilium and sacrum, and is an example of a set of tools that are adapted to do the same. Not all steps necessarily need to be performed, and one or more steps may occur out of sequence compared to the disclosure above. For example, an ilium pin may be fully docked in the ilium before the sacrum pin is fully docked in the sacrum.

[0275] The disclosure that follows provides exemplary methods and tools for implanting the implants herein across an SI joint from the dorsal approach, wherein a pin has been positioned in the ilium and a pin has been positioned in the sacrum. In alternative methods, only one pin may be positioned (in the ilium or the sacrum), and in other alternatives, the method of implanting the implant may not require any pin guides at all.

[0276] Figures 59A-59F illustrate an exemplary impactor 5900 that is configured to deliver the implant distally over the one or more pins and across the SI joint, with a portion of the implant in the ilium and a portion in the sacrum. Impactor 5900 includes distal region 5920 and proximal region 5904, and an elongate central region 5906 extending therebetween. Figure 59A is a side view and figure 59B is a perspective view. Figure 59C is a close up, side view of distal region 5902, figure 59D is a perspective view of distal region 5902, and figure 59E is a front end view. Figure 59F is a perspective view of proximal region 5904. Figure 59C also illustrates a relative distal position of implant 2100 from figure 21 to illustrate an exemplary implant relative to the distal region 5902 of impactor 5900. In figure 59C, the implant is not engaged or secured to the impactor.

[0277] As shown in figure 59D, distal region 5902 includes body 5950 that has, in this embodiment, a wafer configuration. Distal body 5950 has a distal face or surface 5959 with a configuration that is complimentary to the proximal end of the implant, as can be seen in figure 59C. The complimentary shaping helps the distal end of the impactor make contact with much or all of the proximal end of the implant, which provides an efficient transfer of the distally directed force from the impactor to the implant.

[0278] Distal portion 5950 includes an ilium portion 5954 that extends further distally than sacrum portion 5956, the general configuration of which, again, is complimentary to the proximal end of the implant, where the implant sacrum portion extends further proximally than the implant ilium portion (at least in this embodiment). Ilium portion 5954 includes ilium lumen 5955 that is sized and configured to receive therethrough the ilium pin (e.g., pin 5860), and sacrum portion 5956 includes sacrum lumen 5957 that is sized and configured to receive therethrough the sacrum pin (e.g., pin 5830). Impactor 5900 also includes an implant securing member 5958, which in this embodiment can have a threaded distal end that is configured to mate with an internal thread in the channel in the proximal end of the implant (e.g., figure 29). When implant securing member 5958 is secured to the implant via the threaded engagement, the implant can be moved by moving the impactor, which allows the implant to be removed from the patient if needed, or if the implant position needs to be adjusted. Implant securing member 5958 is in operational communication with implant control actuator 5970 in the proximal region 5904 of impactor 5900. In this embodiment implant control actuator 5970 is a rotatable member that can be rotated by the user to cause rotation of implant securing member 5958. Other mechanisms can be used to secure the impactor to the implant. The distal end of the impactor also includes a plurality of protrusions or fingers 5960, at least a first of which is on a first lateral half of distal region 5950 and a second of which is on a second lateral half of distal region 5950. The fingers on either side of the implant can help prevent rotational movement of the implant relative to the impactor as the impactor is used to distally advance the implant.

[0279] In use, and before the implant is implanted, the impactor may optionally be used to first deliver a cutting device such a broach to create a space where the implant will be implanted. A broach in this example may have a configuration that approximate the shape of the implant and/or has a proximal end that is complimentary to the distal face 5959 of the impactor. The broach can first be secured to the impactor, such as by engaging threads on securing member 5958 with internal threads in a channel in the proximal end of the broach. The broach and impactor assembly can then be advanced over the two pins, with the ilium pin passing through ilium lumen 5955 and the sacrum pin passing through sacrum lumen 5957. The broach can be impacted to near the ends of the pins. A broach (if used) and impactor can then be retracted proximally to remove the broach from the patient. The optional broach can then be removed from the impactor.

[0280] The implant can then be loaded onto the distal end of the impactor and secured to the impactor, such as with the threaded engagement between the two, examples of which are described herein. This allows the axial position of the implant to be controlled by axially moving the impactor. Loading the implant also comprises aligning the plurality of fingers (e.g., fingers 5960) with the recesses in the

proximal end of the implant, examples of which are described herein with respect to figures 29-31. The lumens of the impactor are now also aligned with implant lumens (if the implant has one or more lumens).

[0281] The implant (and impactor secured to the implant) is then advanced onto the proximal ends of the pins, and the implant-impactor assembly is slid distally over the pins. The pins will also extend into the two lumens of the impactor. The implant is then impacted with a distally directed force (e.g., with a mallet) to distally advance the implant. One option is to use imaging (e.g., fluoro imaging) and impact the implant to the desired depth while viewing the image (e.g., lateral view with fluoro). Alternatively (or additionally), a sacral impactor depth gauge can be used, which can be used to impact to a positive stop when using the sacral impactor depth gauge, an example of which is shown in figure 60 as depth gauge 6000. Depth gauge 6000 can be secured to the impactor, as shown in figure 60, and the implant can be impacted until the proximal end of sacral impactor depth gauge 6000 is aligned with marking 5907 on the impactor. The impactor will be advanced relative to the depth gauge when impacted. Other visual markings can be used to provide a visual indication that the impact has been sufficiently impacted.

[0282] Figure 61A illustrates a lateral model view showing an implant implanted across an SI joint, and still secured to impactor 5900. Figure 61B illustrates a model view of implant 6100 implanted across SI joint 6110, with a portion of implant 6100 implanted in the ilium and a portion in the sacrum. Pins 5860 and 5830 are shown, as is exemplary impactor 5900.

[0283] When the implant is in the desired position, the implant can be disengaged from the impactor, such as by rotating actuator 5970, which disengages the threaded engagement.

[0284] Figures 63A-63C illustrate an exemplary pin removal device 6300 that is adapted to be used in combination with impactor 5900 (or other impactors) to remove the ilium and sacrum pins. After the implant has been implanted, the pins remain extending through the lumens of the impactor (only one pin is shown in figures 63A-63C). To remove the pins, pin removal device 6300 can be placed over a pin and set on first and second impactor bosses 5999a and 5999b, as shown in figures 63-63C. As handles 6302 and 6304 of removal device 6300 are squeezed together, the pin is retracted proximally relative to the impactor until it has been removed from the bone and out of the patient. The mechanism may be similar to or the same as that found in wood clamps, such as the Irwin® QUICK-GRIP® clamp, the entire disclosure of which is incorporated by reference herein. Both pins can be removed from the bone in this manner, leaving the implant implanted in the SI joint.

[0285] Figure 62A illustrates a model view of implant 6100 implanted across SI Joint 6110 (left joint) after pin and impactor removal, and figure 62B illustrates a lateral model of implant 6100 across the SI joint after pin and impactor removal.

CLAIMS

1. A sacro-iliac joint stabilizing implant for implanting across a SI joint from a dorsal approach, comprising:

an implant body having a wafer configuration with a width dimension greater than a height dimension, the implant body including,

a central joint portion for placement across the SI joint;

an ilium portion on a first side of the central joint portion, the ilium portion sized and configured for implanting into an ilium when the implant is implanted across a SI joint from a dorsal approach,

a sacrum portion on a second side of the central joint portion, the sacrum portion sized and configured for implanting into a sacrum when the implant is implanted across the SI joint from the dorsal approach,

the ilium portion comprising an elongate ilium lumen extending from a distal opening to a proximal opening and having an ilium lumen longitudinal axis, the ilium lumen sized and configured to receive therein an ilium positioning guide, the sacrum portion comprising an elongate sacrum lumen extending from a distal opening to a proximal opening and having a sacrum lumen longitudinal axis, the sacrum lumen sized and configured to receive therein a sacrum positioning guide,

with reference to a line that is orthogonal to the ilium lumen axis and the sacrum lumen axis, the sacrum portion extends further proximally than the ilium portion, and the ilium portion extends further distally than the sacrum portion,

with reference to the line, the distal opening of the ilium lumen extends further distally than the distal opening of the sacrum lumen, and

a distal portion that includes a sharpened distal end, the sharpened distal end having a tapered configuration with a first surface that tapers downward and distally from a top portion of the implant body and a second surface that tapers upward and distally from a bottom portion of the implant body.

2. The implant of Claim 1, wherein the sharpened distal end has, in a top view, a concave curved configuration along at least a portion of the sharpened distal end.

3. The implant of Claim 2, wherein the curved configuration is asymmetrical about a long axis of the implant body.

4. The implant of Claim 2, wherein the sharpened distal end extends further distally in the ilium portion than in the sacrum portion.

5. The implant of Claim 1, wherein the sharpened distal end extends laterally through the sacrum portion, the central portion, and the ilium portion.

6. The implant of Claim 1, wherein the sharpened distal end comprises a smooth curve.

7. The implant of Claim 1, wherein a portion of the ilium portion extends further distally than the sharpened distal end.

8. The implant of Claim 1, wherein a portion of the sacrum portion extends further distally than at least a portion of the sharpened distal end.

9. The implant of Claim 1, wherein the implant body comprises a distal portion, at least a portion of the distal portion comprising a curved distal end extending laterally from the ilium portion, through the central portion, and into the sacrum portion.

10. The implant of Claim 1, wherein the ilium lumen has a length that is greater than a length of the sacrum lumen.

11. The implant of Claim 1, wherein the ilium lumen has a length that is the same as a length of the sacrum lumen.

12. The implant of Claim 1, wherein the sacrum lumen has a length that is greater than a length of the ilium lumen.

13. The implant of Claim 1, wherein the ilium lumen is parallel with the sacrum lumen.

14. The implant of Claim 1, wherein the ilium portion has an ilium length, and the sacrum portion has a sacrum length, wherein the ilium length is greater than the sacrum length.

15. The implant of Claim 1, wherein the ilium portion has an ilium length, and the sacrum portion has a sacrum length, wherein the ilium length is the same as the sacrum length.

16. The implant of Claim 1, wherein the ilium portion has an ilium length, and the sacrum portion has a sacrum length, wherein the sacrum length is greater than the ilium length.

17. The implant of Claim 1, wherein the sacrum lumen extends further proximally than the ilium lumen.

18. The implant of Claim 1, wherein the ilium lumen extends further distally than the sacrum lumen.

19. The implant of Claim 1, wherein at least one of the distal openings of the ilium and sacrum lumens extends further distally than at least a portion of the central portion of the implant body.

20. The implant of Claim 19, wherein both of the distal openings extend further distally than the central portion.

21. The implant of Claim 1, wherein the implant body further comprises an inner frame and an outer porous network of interconnected struts extending about at least a top portion and a bottom portion of the implant.

22. The implant of Claim 21, wherein the porous network of interconnected struts further extends about the ilium portion and the sacrum portion.

23. The implant of Claim 22, wherein the porous network of interconnected struts further extends about a plurality of side fenestrations in each of an ilium side of the implant body and a sacrum side of the implant body, wherein the plurality of fenestrations in the ilium side are in communication with the ilium lumen and the plurality of fenestrations in the sacrum side are in communication with the sacrum lumen.

24. The implant of Claim 22 wherein the porous network of interconnected struts comprises pores in a central region of the implant body that are larger in size than pores that extend about the ilium portion and larger than pores that extend about the sacrum portion.

25. The implant of Claim 21, wherein the inner frame has a slanted "digital eight" configuration, which is slanted distally on the ilium side.

26. The implant of Claim 21, wherein the inner frame includes first and second axially extending elongate members and a plurality of axially spaced apart connecting elongate members extending from

the first elongate member to the second elongate member, each two adjacent connecting elongate members, along with the first and second axially extending elongate members, defining one of a plurality of frame fenestrations.

27. The implant of Claim 1, wherein the implant body has a height dimension that is not greater than 70% of a width dimension of the implant body.

28. The implant of Claim 27, wherein the height dimension is not greater than 60% of the width dimension of the implant body.

29. The implant of Claim 1, wherein the implant body has a length from 15 mm to 80 mm.

30. The implant of Claim 1, wherein the implant body has a width from 15 mm to 50 mm.

31. The implant of Claim 1, wherein the implant body has a height from 4 mm to 20 mm.

32. The implant of Claim 1, wherein the implant body, in a top view, has a parallelogram configuration without right angles.

33. The implant of Claim 32, wherein the implant body has, in the top view, a rhomboid configuration or a rhombus configuration.

34. The implant of Claim 1, wherein the implant body has a height that is not constant across a width of the implant body.

35. The implant of Claim 34, wherein the height dimension is greater in at least a portion of in the ilium portion than in the central region, and wherein the height dimension is greater in at least a portion of in the sacrum portion than in the central region.

36. The implant of Claim 34, wherein, in an end view, at least one of a top portion or a bottom portion has a curvature therein.

37. The implant of Claim 34, wherein the height dimension is greater in at least a portion of the central portion than in the ilium portion, and wherein the height dimension is greater in at least the portion of the central portion than in the sacrum portion.

38. The implant of Claim 1, wherein the ilium portion comprises a cutting region proximally adjacent and disposed about the distal opening.

39. The implant of Claim 38, wherein the cutting region comprises a plurality of axially-spaced annular cutting edges.

40. The implant of Claim 1, wherein the sacrum region comprises a cutting region proximally adjacent and about the distal opening.

41. The implant of Claim 40, wherein the cutting region comprises a plurality of axially-spaced annular cutting edges.

42. The implant of Claim 1, wherein a proximal end of the implant body includes a plurality of recessed members, a first recessed member in a first lateral half of the implant body and a second recessed member in a second lateral half of the implant body.

43. The implant of Claim 1, wherein a proximal end of the implant body includes cylindrical channel therein defining a lumen, wherein the channel comprises an inner thread.

44. A method of positioning a sacro-iliac ("SI") joint stabilizing implant across an SI joint from a dorsal approach, comprising:

advancing an elongate sacrum pin from a dorsal starting point into a sacrum of a subject such that a distal end of the sacrum pin is in the sacrum and a proximal end of the sacrum pin is disposed outside of the subject;

advancing an elongate ilium pin from a dorsal starting point into an ilium of the subject such that a distal end of the ilium pin is in the ilium and a proximal end of the ilium pin is disposed outside of the subject;

advancing a distal opening of an ilium lumen that is in an ilium portion of an SI joint stabilizing implant over the ilium pin so as to restrict movement of the implant with respect to the ilium pin in at least one direction;

advancing a distal opening of a sacrum lumen that is in a sacrum portion of the SI joint stabilizing implant over the sacrum pin so as to restrict movement of the implant with respect to the sacrum pin in at least one direction;

advancing the implant distally over and relative to the sacrum pin and the ilium pin until the implant is across the SI joint with the ilium portion in the ilium and the sacrum portion in the sacrum; and

removing the ilium pin and the sacrum pin from the subject, and leaving the implant positioned across the SI joint.

45. The method of Claim 44, wherein the implant is any one of the implants of Claims 1-43 or is any of the implants described herein.

46. The method of Claim 44, wherein advancing the ilium pin comprises advancing the ilium pin into the ilium between lateral and medial cortical walls of the ilium.

47. The method of Claim 44, wherein advancing the sacrum pin occurs in time prior to advancing the ilium pin.

48. The method of Claim 44, wherein advancing the sacrum pin comprises preventing a distal end of the sacrum pin from extending beyond the alar line.

49. The method of Claim 44, wherein advancing the ilium pin comprises preventing a distal end of the ilium pin from extending beyond the alar line.

50. The method of Claim 44, further comprising securing an impactor to a proximal end of the implant.

51. The method of Claim 50, further comprising extending an impactor ilium lumen over the ilium pin and extending an impactor sacrum lumen over the sacrum pin.

52. The method of Claim 50, wherein securing the impactor to the proximal end of the implant comprises engaging an impactor threaded elongate member with an internally threaded channel in the implant.

53. The method of Claim 50, wherein advancing the implant distally over and relative to the sacrum pin and the ilium pin comprises applying a distally directed force on the impactor.

54. The method of Claim 44, further comprising bringing a distal end of an impactor adjacent to a proximal end of the implant, wherein the distal end of the impactor has a shape that is complimentary to a proximal end of the implant.

55. The method of Claim 44, wherein bringing a distal end of an impactor adjacent to a proximal end of the implant comprises causing an ilium side of the impactor to be further distally than a sacrum side of the impactor.

56. The method of Claim 44, further comprising, prior to advancing the distal openings over the ilium pin and sacrum pin, advancing a broach over and distally relative to the ilium pin and the sacrum pin, and advancing the broach into tissue across the SI joint.

57. The method of Claim 56, further comprising securing an impactor to a proximal end of the broach, and wherein advancing the broach comprises applying a distally directed force on the impactor.

58. A method of placing an ilium pin into an ilium and a sacrum pin into a sacrum from a dorsal approach,

in a patient in a prone position, making a dorsal incision proximate an SI joint and exposing tissue;

positioning a pin guide adjacent to the SI joint from the dorsal approach, the pin guide body comprising an ilium side lumen and a sacrum side lumen that are parallel to each other;

advancing a sacrum pin through the sacrum side lumen and into the sacrum; and

advancing an ilium pin through the ilium side lumen and into the ilium.

59. The method of Claim 58, further comprising, prior to advancing the sacrum pin, advancing a sacrum tubular member with a sharpened distal end through the sacrum side lumen and into contact with the sacrum, and cutting sacrum bone with the sharpened distal end of the sacrum tubular member.

60. The method of Claim 58, further comprising, prior to advancing the ilium pin, advancing an ilium tubular member with a sharpened distal end through the ilium side lumen and into contact with the ilium, and cutting ilium bone with the with the sharpened distal end of the ilium tubular member.

61. The method of Claim 58, further comprising attaching an elongate handle to a lateral side of the pin guide.

62. The method of Claim 58, wherein the ilium pin has a distal end with a different configuration than a sacrum pin distal end.

63. The method of Claim 62, further comprising orienting a sharped point of the ilium pin to be facing medially.

64. The method of Claim 63, further comprising orienting a flat beveled surface of the ilium pin distal end to be facing laterally.

65. A method of securing an SI-joint implant to an impactor, comprising:

causing a proximal end of the SI joint implant to be brought adjacent to distal end of the impactor; and

engaging a first securing element on the impactor with a second securing element disposed in a proximal region
of the implant to secure the implant to the impactor and cause the implant to move with the impactor.

66. The method of Claim 65, wherein the first securing element is an elongate member with an external thread, and wherein the second securing element is an internal channel with an internal thread.

67. The method of Claim 65, further comprising
engaging a first impactor protrusion on a first lateral side of the first securing element with a first recess in the implant, and
engaging a second impactor protrusion on a second lateral side of the first securing element with a second recess in the implant.

68. The method of Claim 65, further comprising causing a distal face of the impactor to be placed adjacent a proximal end of the implant, wherein, in a top view, the distal face and proximal end of the implant have complimentary shapes.

69. The method of Claim 65, further comprising, after the implant is implanted, disengaging the impactor from the implant so movement of the impactor no longer causes movement of the implant.

70. A pin guide adapted for placing pin guides into an ilium and a sacrum in a dorsal approach, comprising:

a pin guide body, the pin body comprising

a lateral ilium side with an axially extending ilium lumen,

a lateral sacrum side with an axially extending sacrum lumen that is parallel with the ilium lumen.

71. The pin guide of Claim 70, wherein the ilium side and the ilium lumen extend further distally than the sacrum side and the sacrum lumen.

72. The pin guide of Claim 70, further comprising at least one lateral handle coupler that is adapted to be attached to an elongate handle so the handle and pin guide can be moved together by moving the handle.

73. The pin guide of Claim 70, further comprising a second pin guide that is the same as the pin guide but has a mirror image configuration, wherein the pin guide is adapted for use with one of a patient's SI joints, and wherein the second pin guide is adapted for use with the other of the patient's SI joints.

74. The pin guide of Claim 70, further comprising first and second central pins extending distally from the pin guide body, the first and second central pins disposed laterally inward relative to the ilium lumen and the sacrum lumen.

75. The pin guide of Claim 74, wherein the first and second central pins are laterally aligned.

76. The pin guide of Claim 74, wherein the first and second central pins extend between 10 mm and 20 mm from the pin guide body, optionally 15 mm.

77. A pin guide adapted for placing pin guides into an ilium and a sacrum in a dorsal approach, comprising:

a pin guide body, the pin body comprising,

a lateral ilium side with an axially extending ilium lumen,

a lateral sacrum side with an axially extending sacrum lumen that is parallel with the ilium lumen, and

a distal pin guide coupled to the guide body and extending distally from the pin guide body, the distal pin guide movable relative to the pin guide body when the pin guide is in

a first state and less movable relative to the pin guide body when the pin guide is in a second state.

78. An impactor for advancing a bone implant, comprising:

a proximal region;

a distal region; and

an elongate central region extending between the proximal region and the distal region,

the distal region having a wafer configuration and including,

an implant securing element adapted to be releasable engaged with the bone implant,

a first protruding member on a first lateral side of the implant securing element,

a second protruding member on a second lateral side of the implant securing element,

an ilium lumen in an ilium side of the distal region, and

a sacrum lumen in a sacrum side of the distal region

79. The impactor of Claim 78, wherein the distal region has a distal face that is not orthogonal to a long axis of the central region.

80. The impactor of Claim 79, wherein the distal face extends further distally on the ilium side than on the sacrum side.

81. The impactor of Claim 78, wherein the first protruding member extends further distally than the second protruding member.

82. The impactor of Claim 78, wherein the ilium lumen extends further distally than the sacrum lumen.

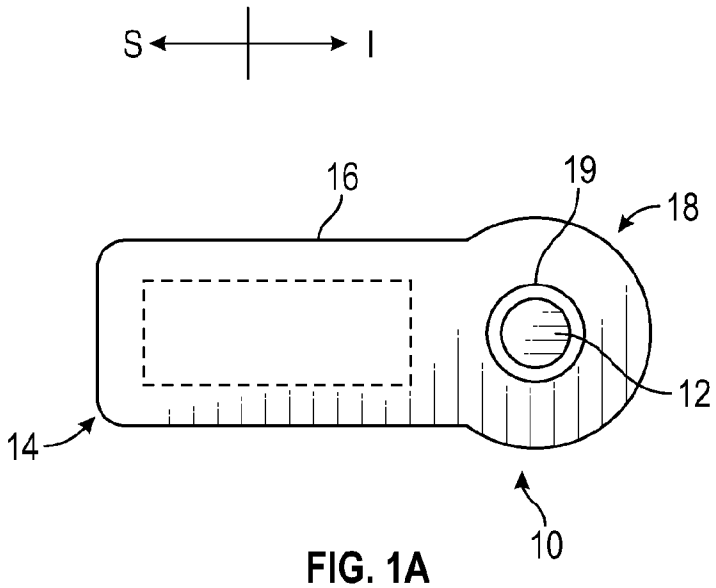


FIG. 1A

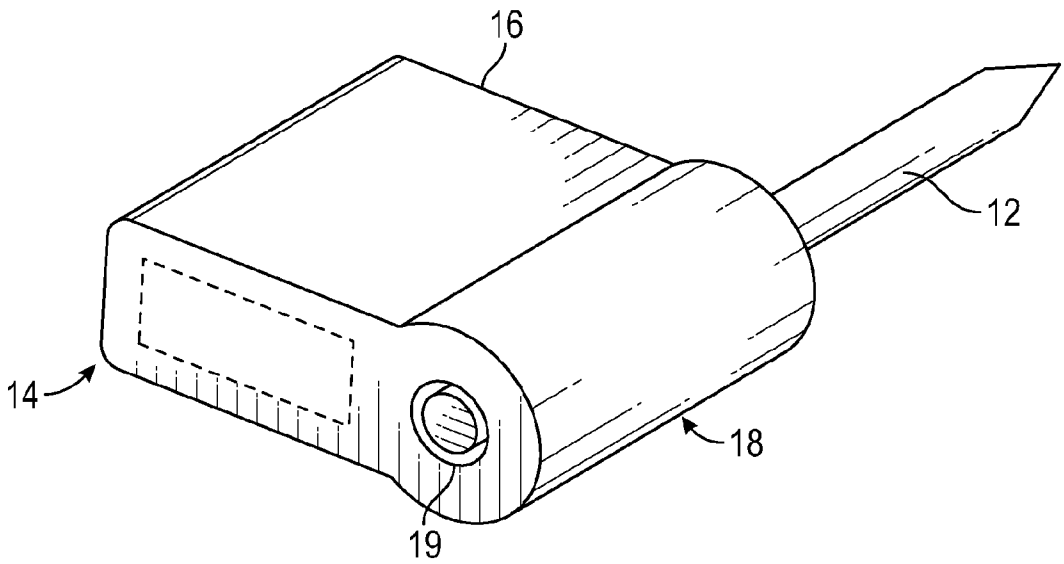


FIG. 1B

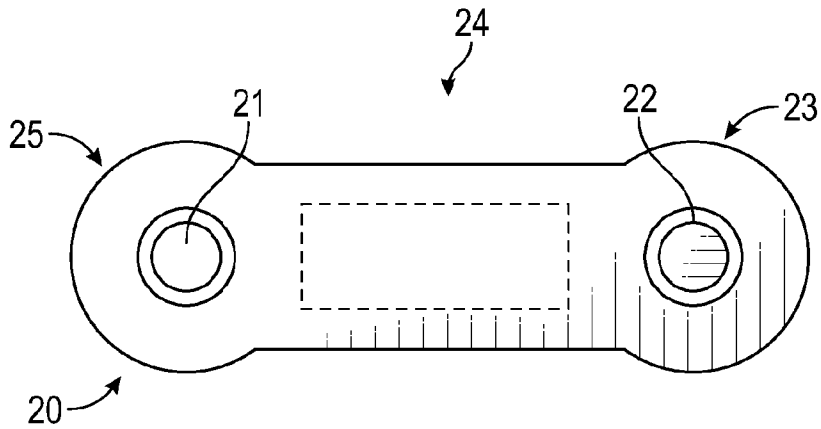


FIG. 2A

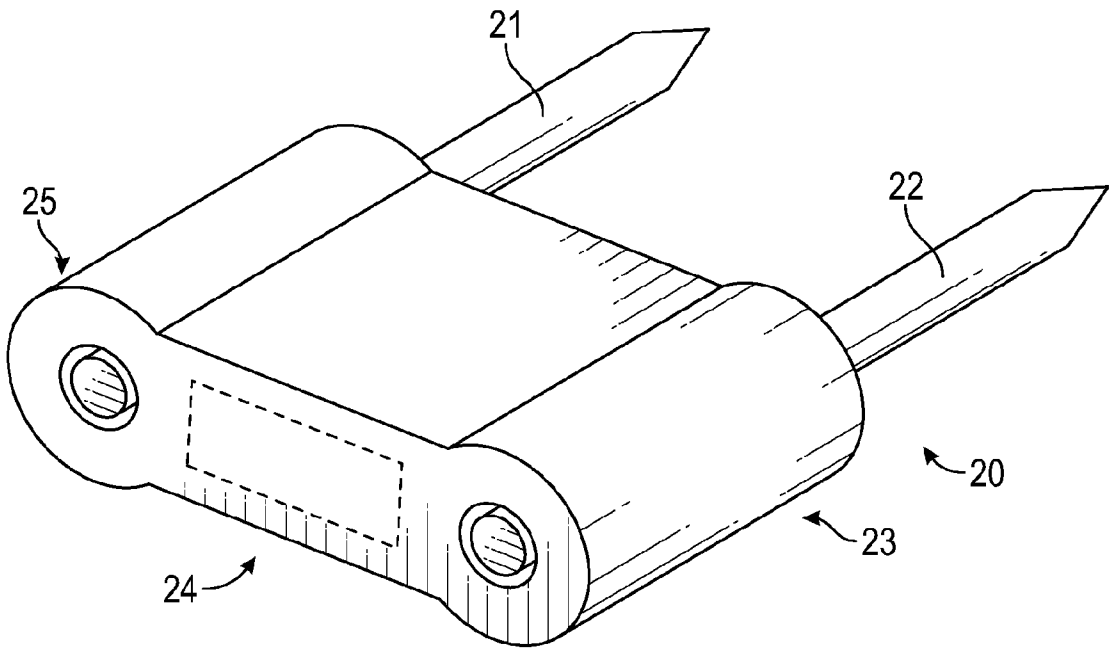


FIG. 2B

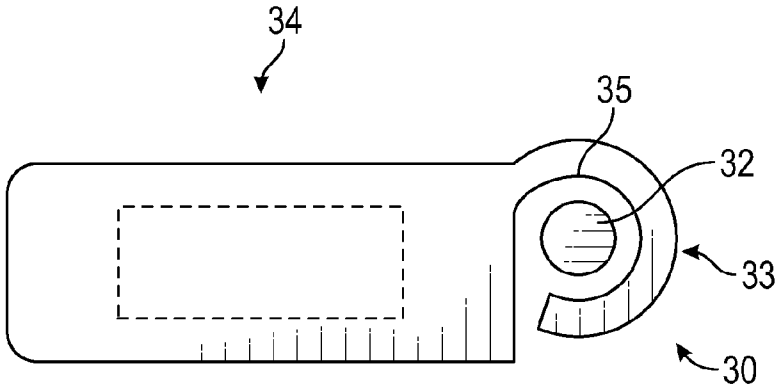


FIG. 3A

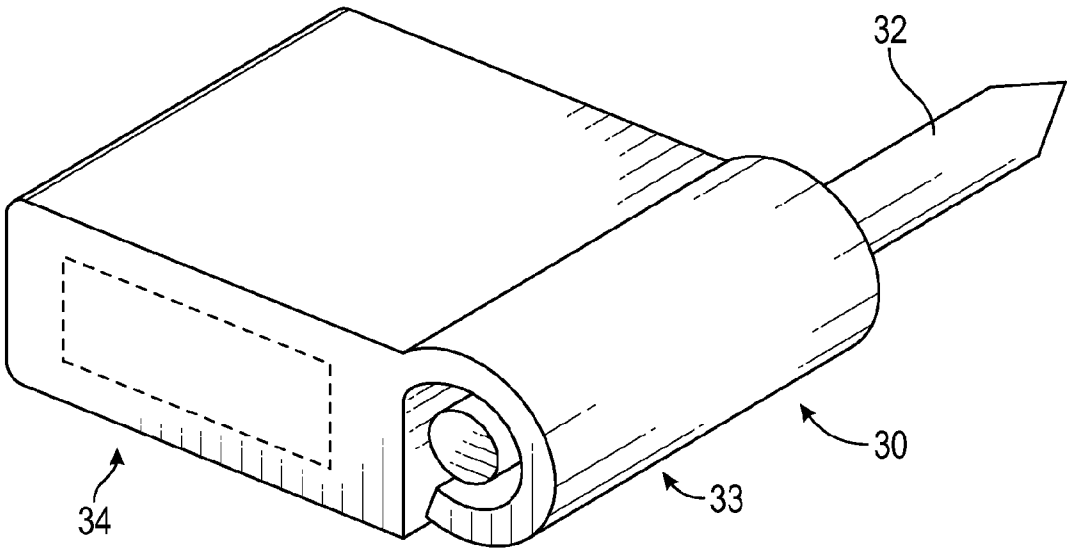


FIG. 3B

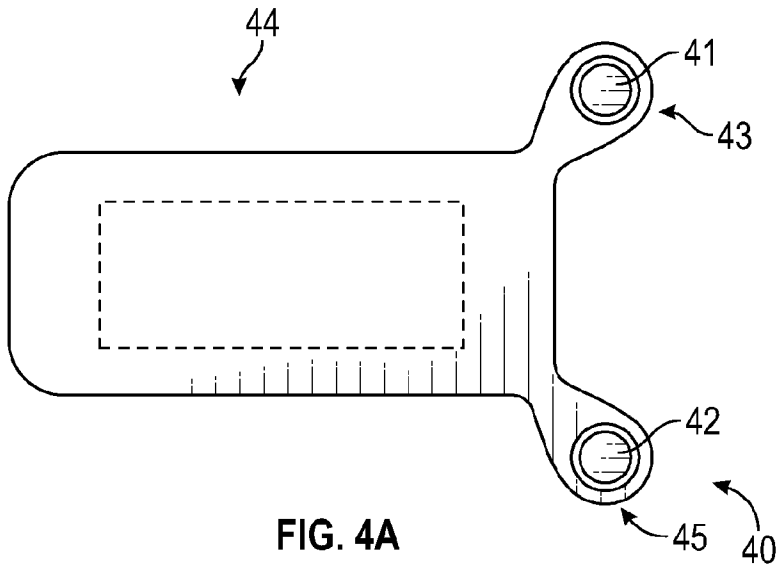


FIG. 4A

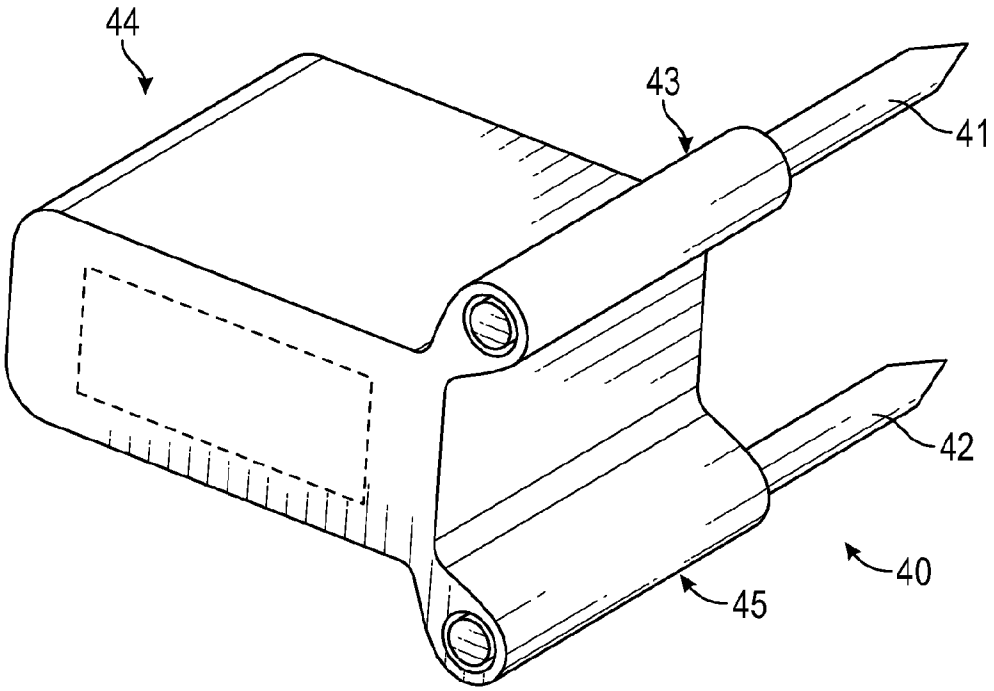


FIG. 4B

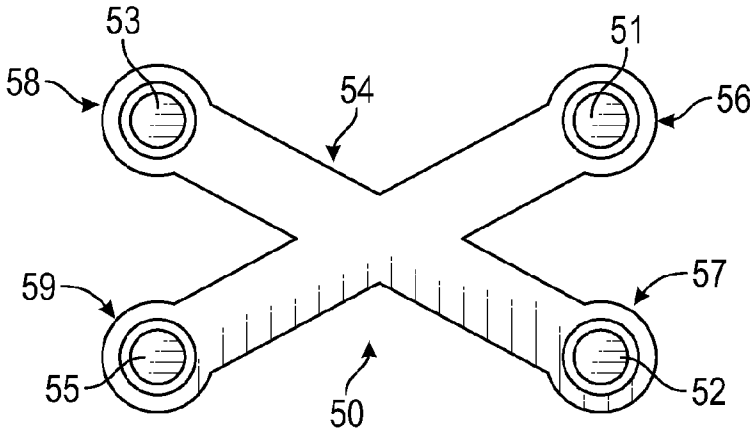


FIG. 5A

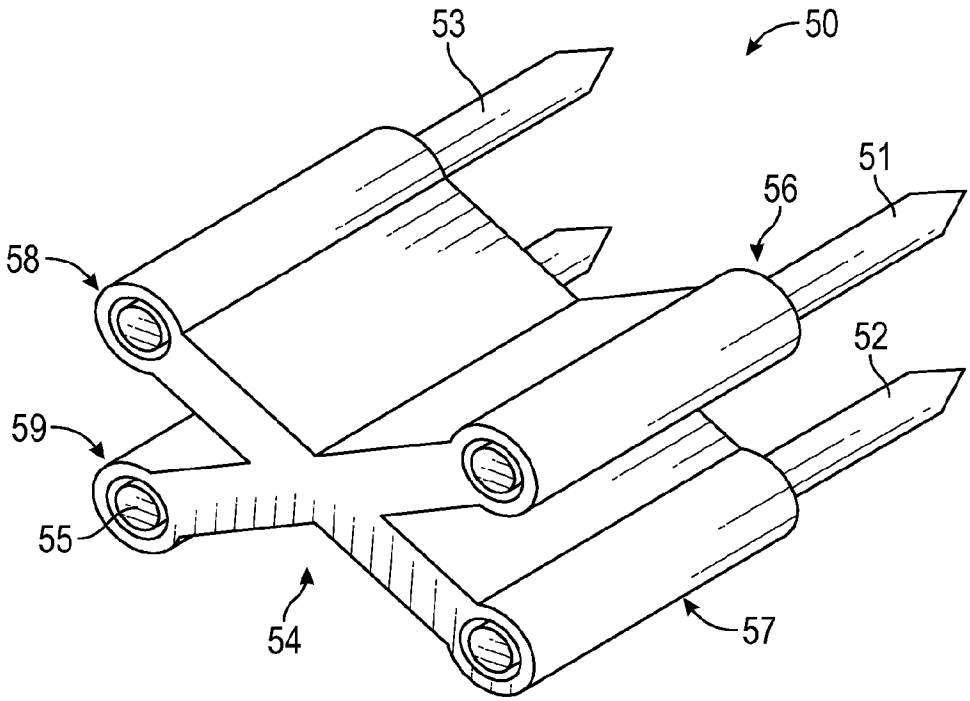


FIG. 5B

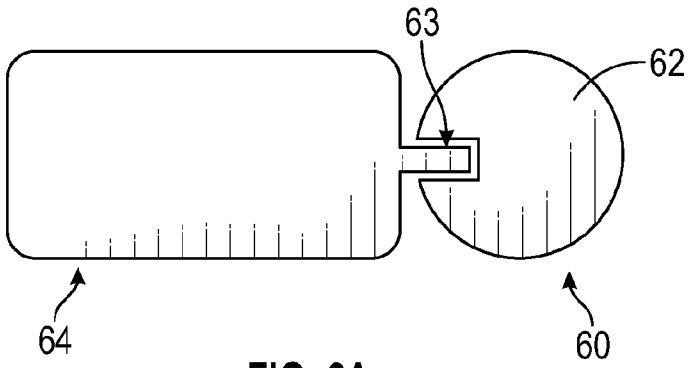


FIG. 6A

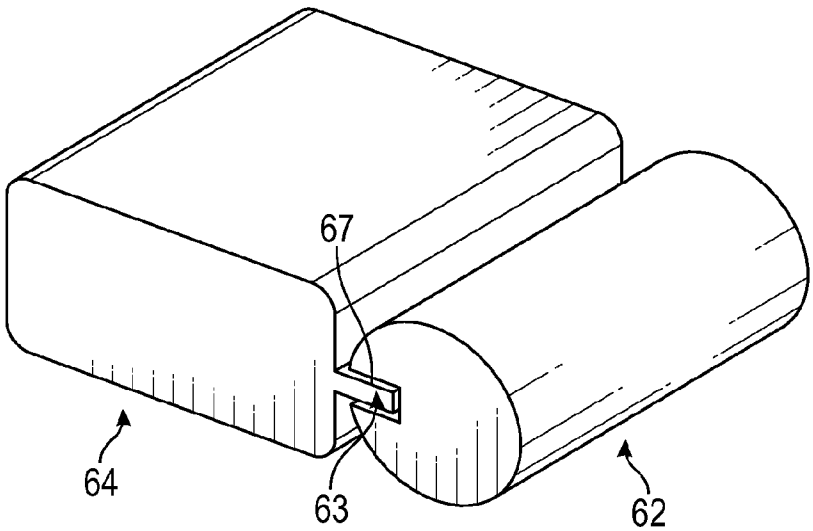


FIG. 6B

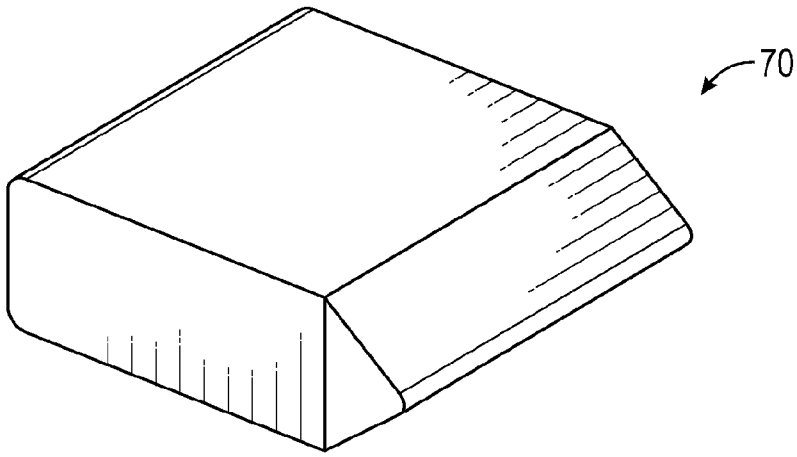


FIG. 7

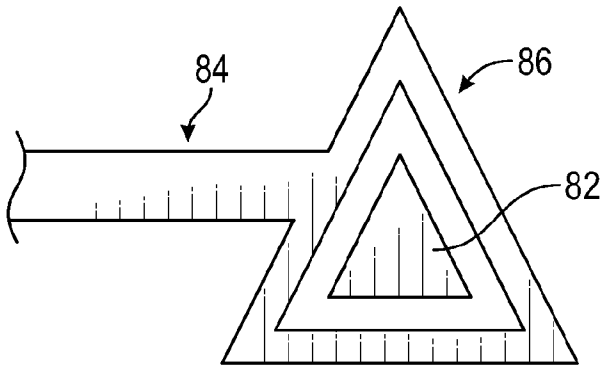


FIG. 8

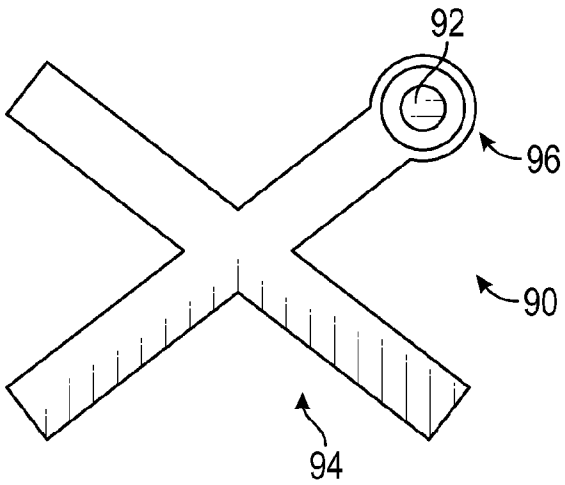


FIG. 9

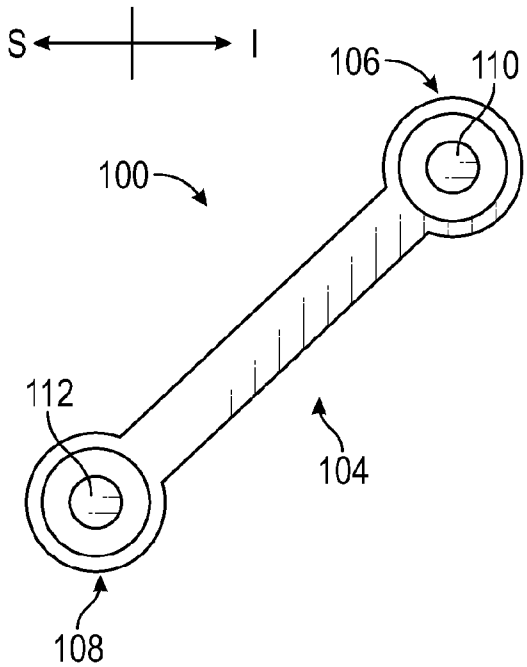


FIG. 10

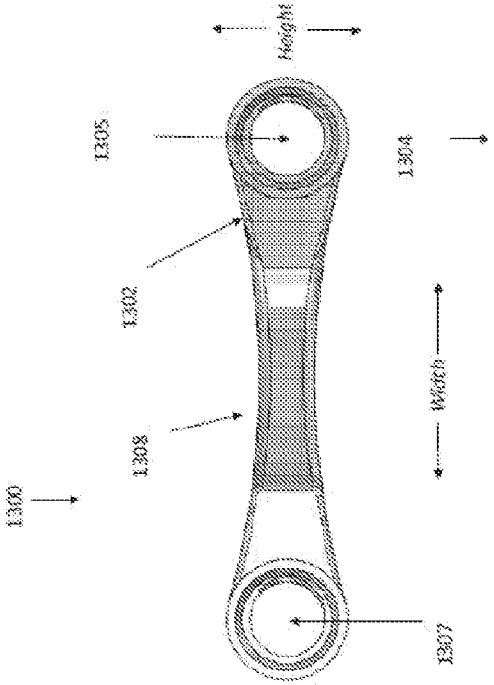


Figure 11B

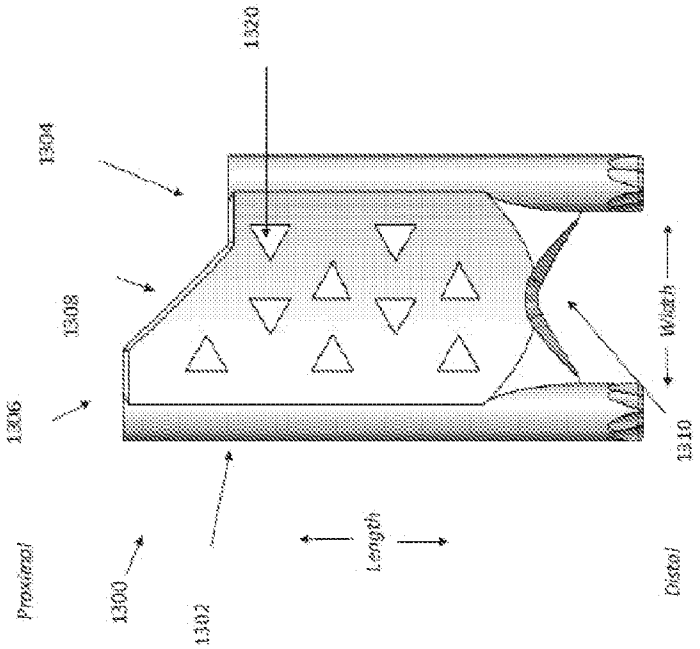


Figure 11A

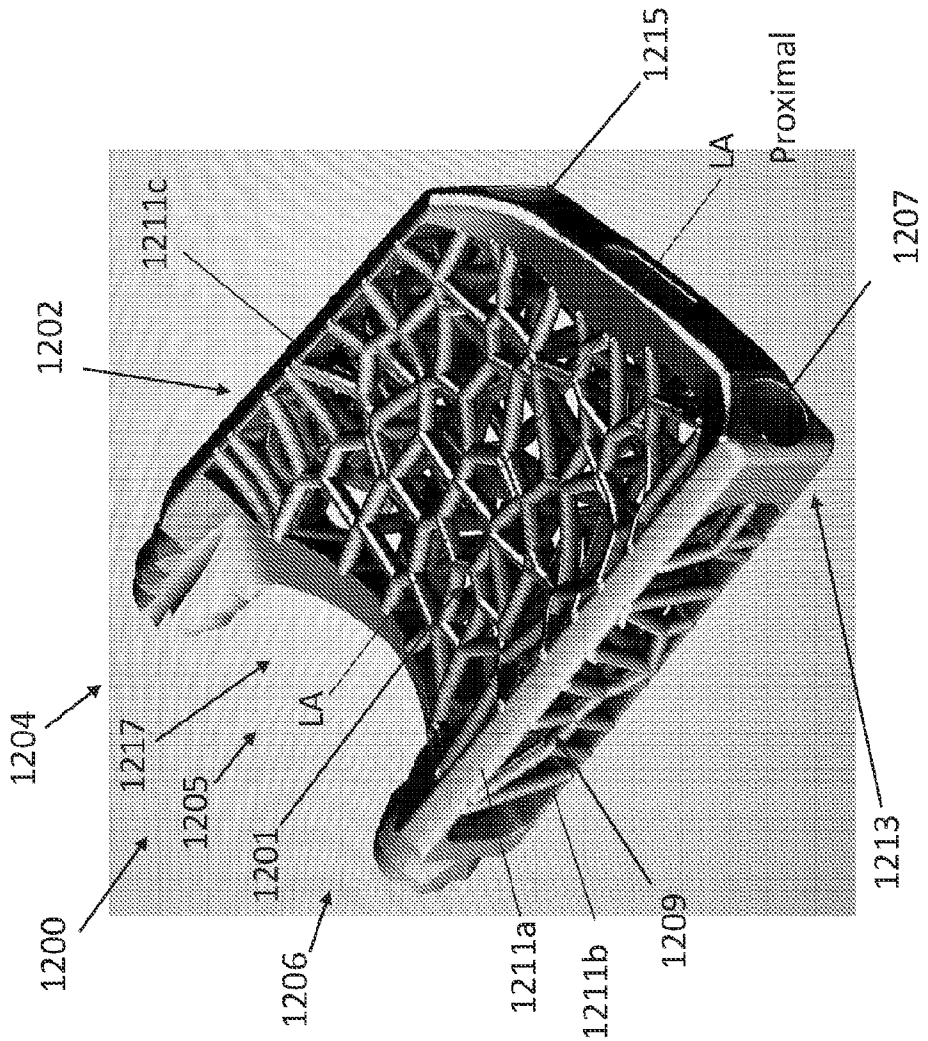

1215
Proximal
LA
1211c
1207
1202
1204
1217
1205
LA
1201
1200
1206
1211a
1211b
1209
1213

Figure 12

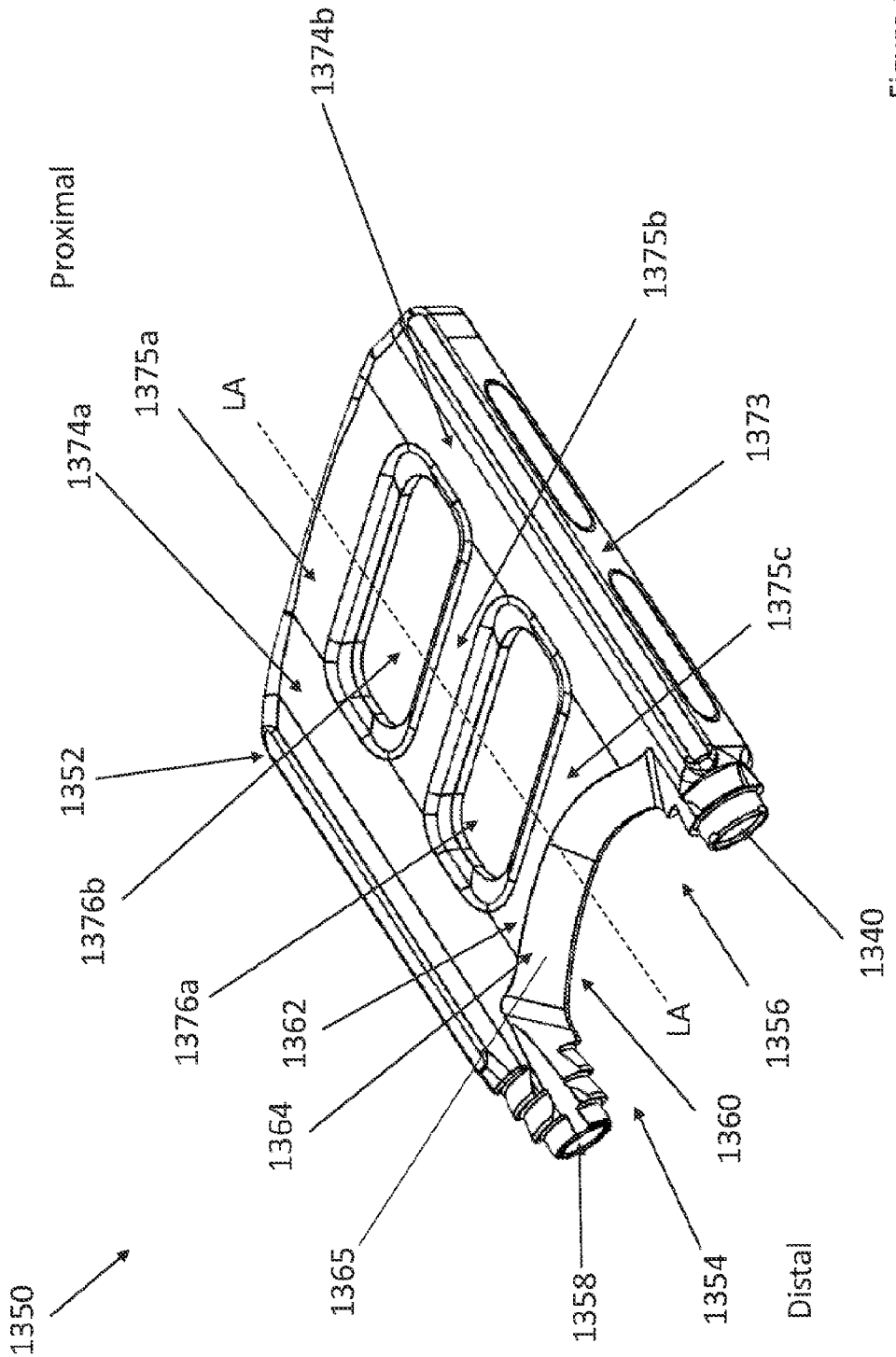

1350
1365
1358
1354
Distal
1364
1362
1376a
1376b
1352
1374a
1375a
LA
Proximal
1374b
1375b
1373
1375c
1340
1356
LA
1360

Figure 13

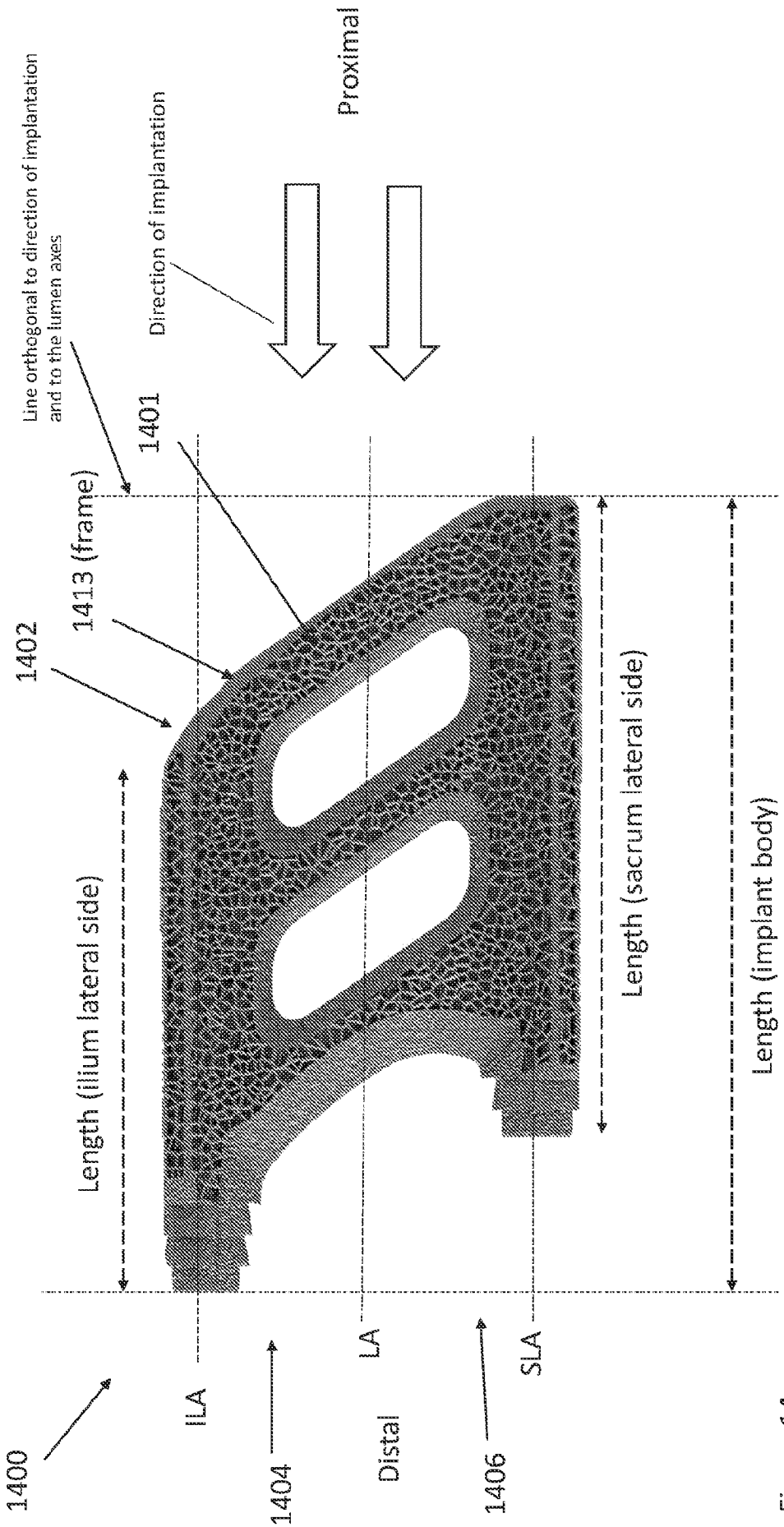

Proximal
Direction of implantation
Line orthogonal to direction of implantation and to the lumen axes
1401
1413 (frame)
1402
Length (ilium lateral side)
Length (sacrum lateral side)
Length (implant body)
1400
ILA
1404
LA
Distal
1406
SLA

Figure 14

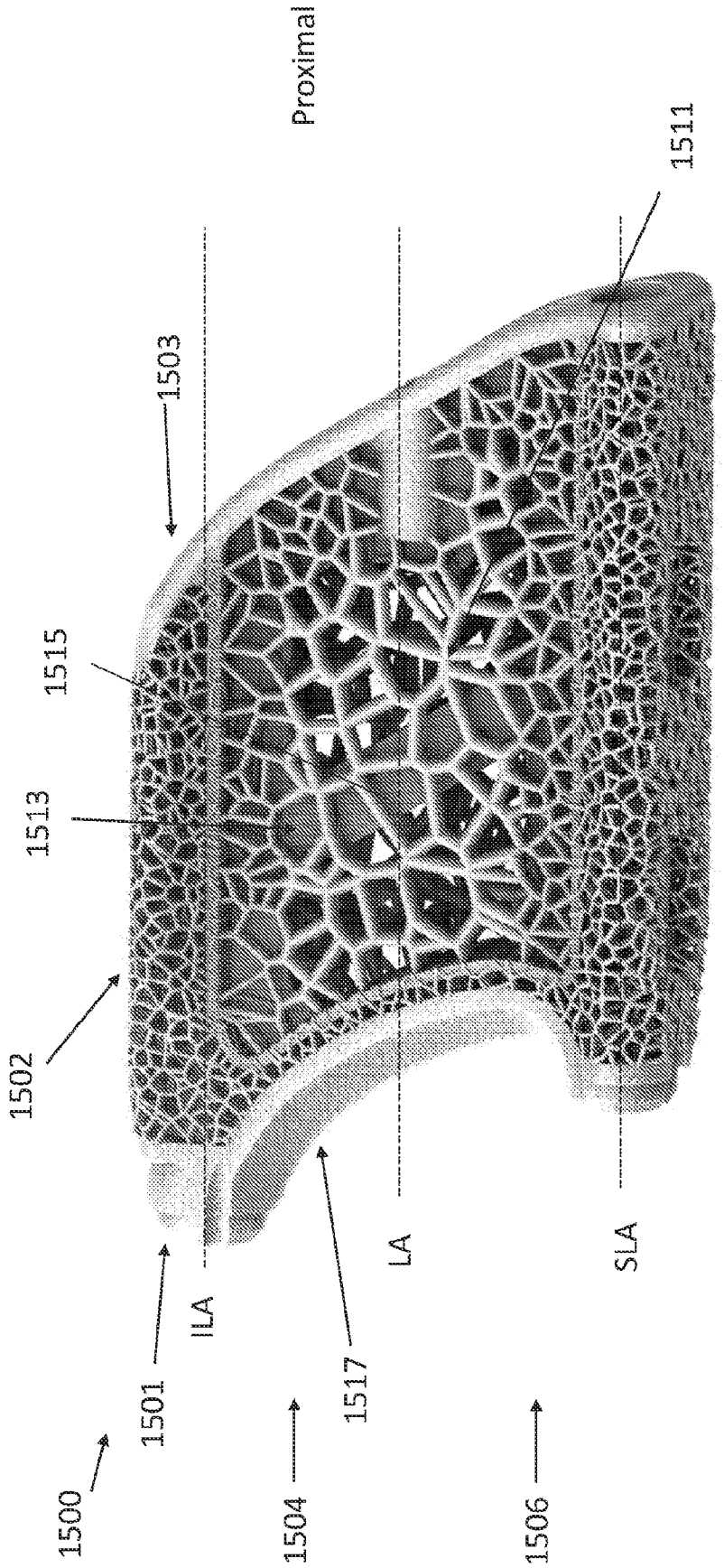

Proximal
1511
1503
1515
1513
1502
1500
1501
ILA
1517
LA
SLA
1504
1506
Distal

Figure 15A

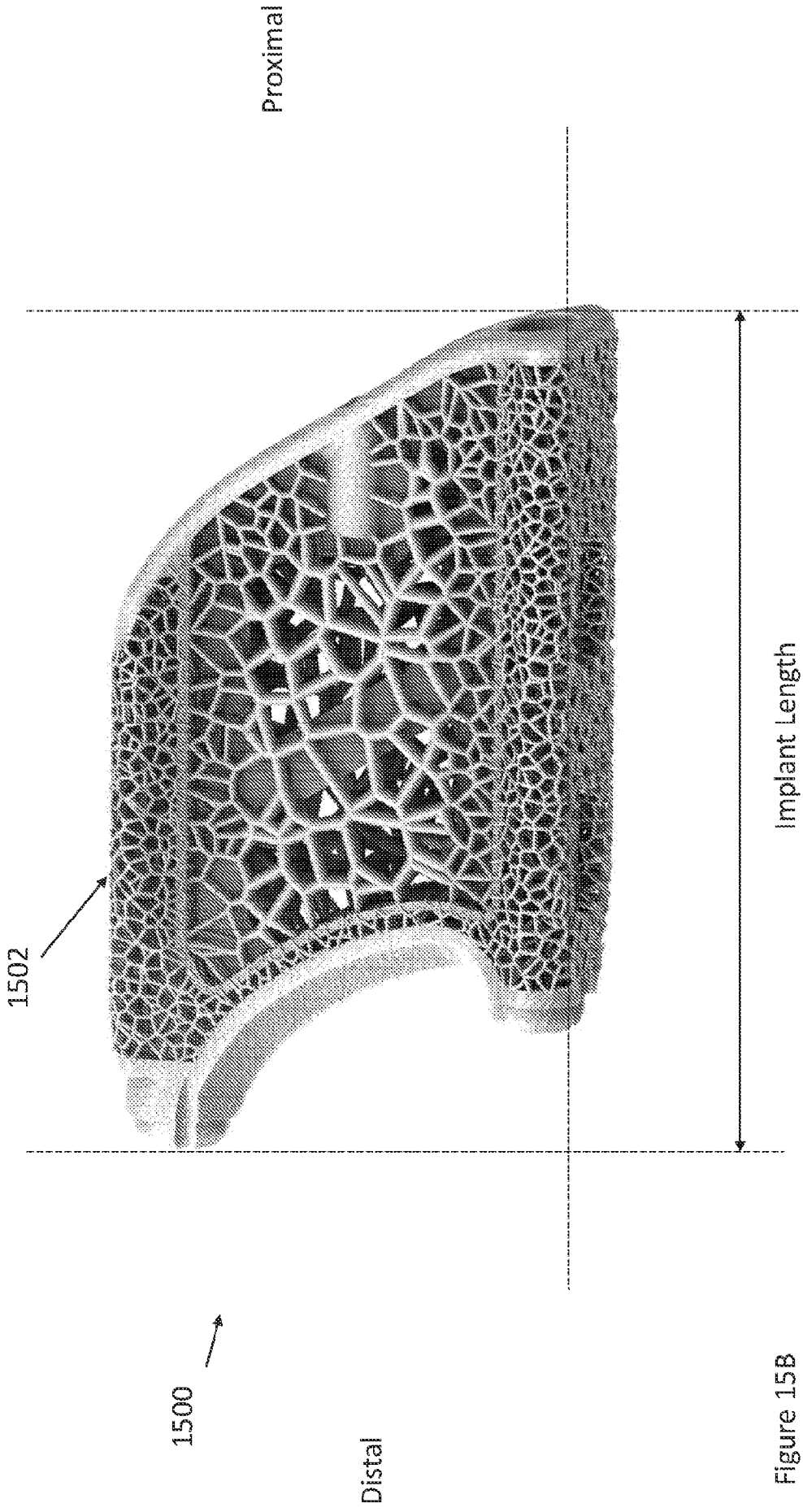


Figure 15B

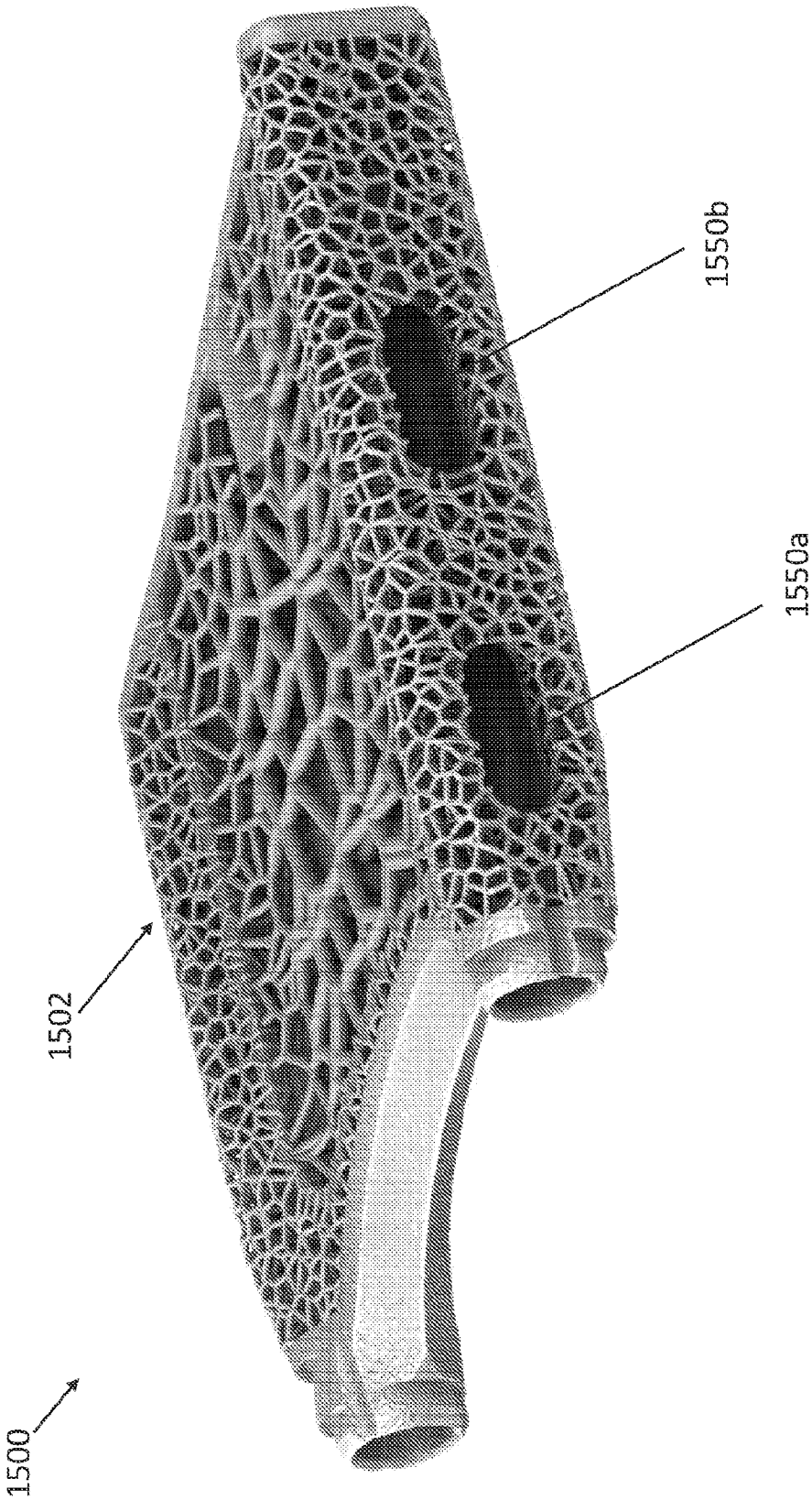


Figure 15C

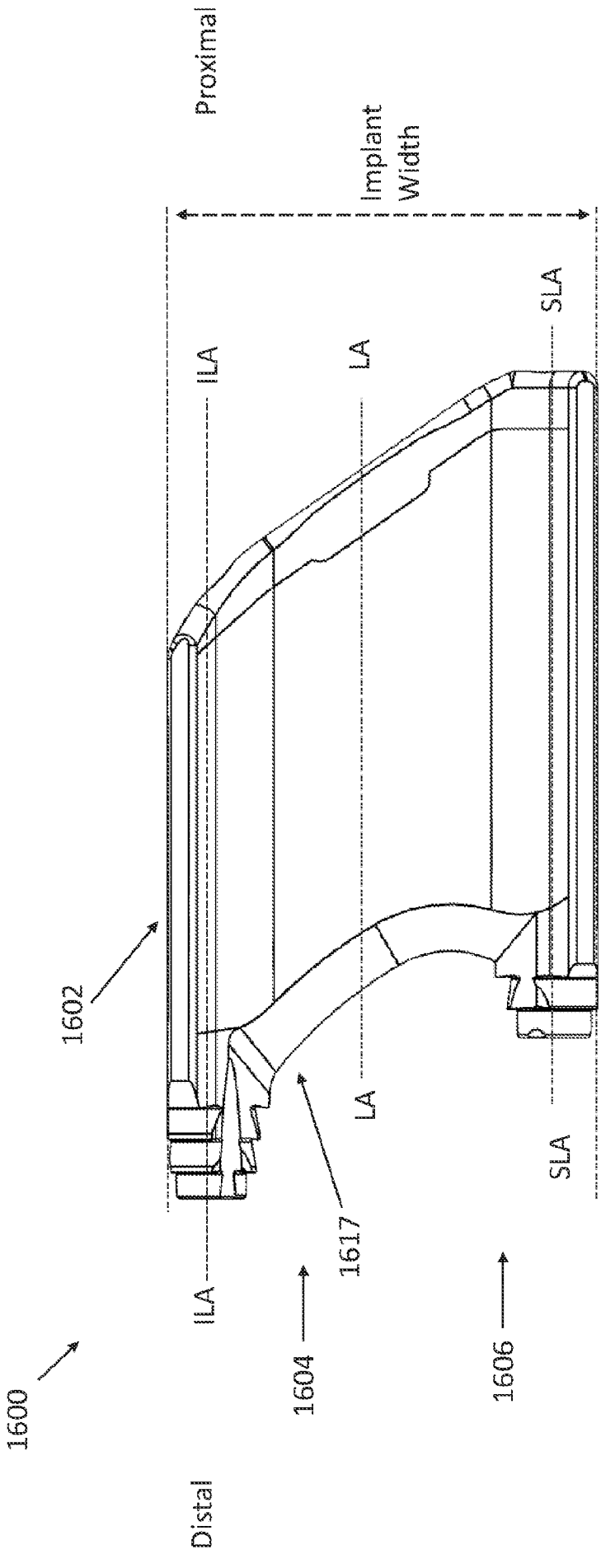

Proximal
Implant Width
ILA
LA
SLA
1602
LA
SLA
1617
ILA
1604
1606
1600
Distal

Figure 16

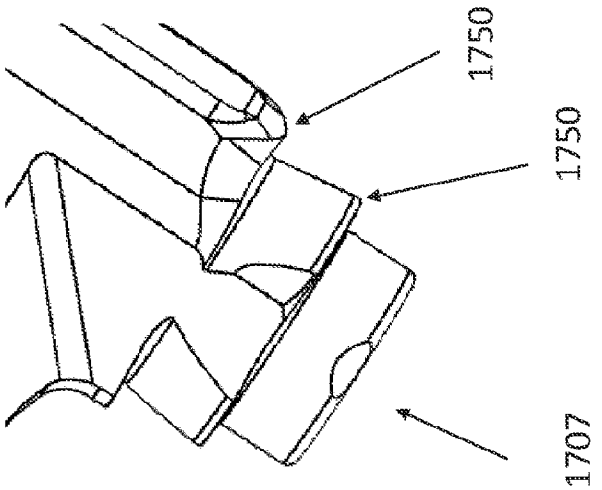


Figure 17C

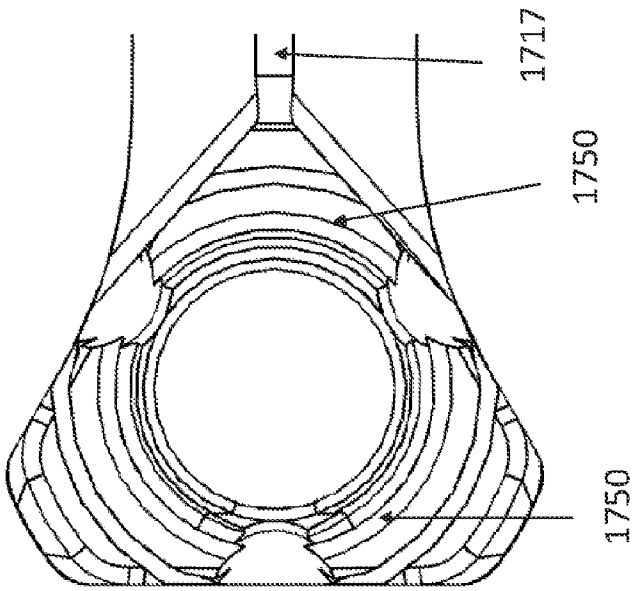


Figure 17B

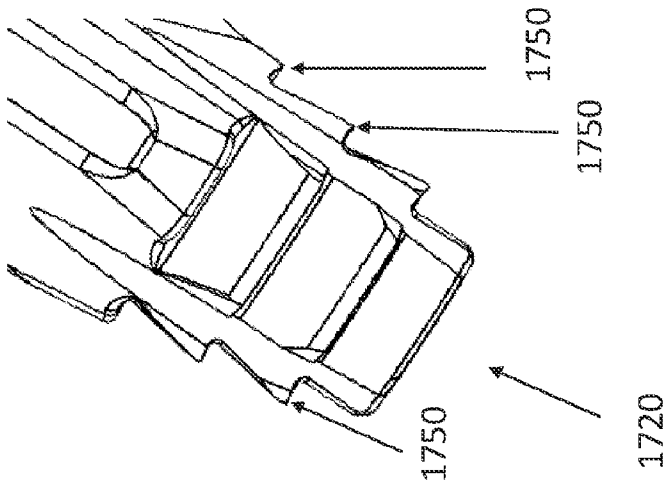


Figure 17A

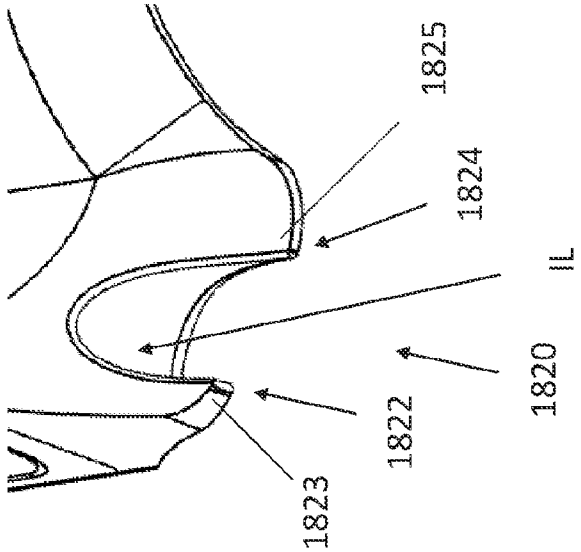


Figure 18B

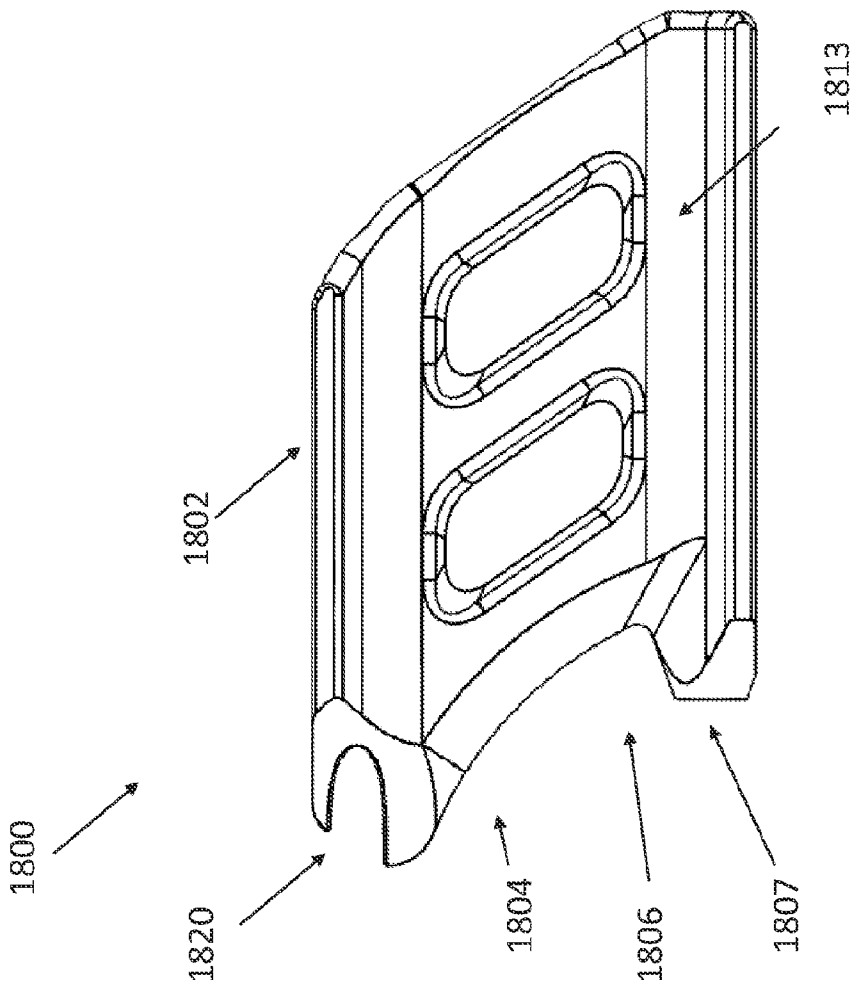


Figure 18A

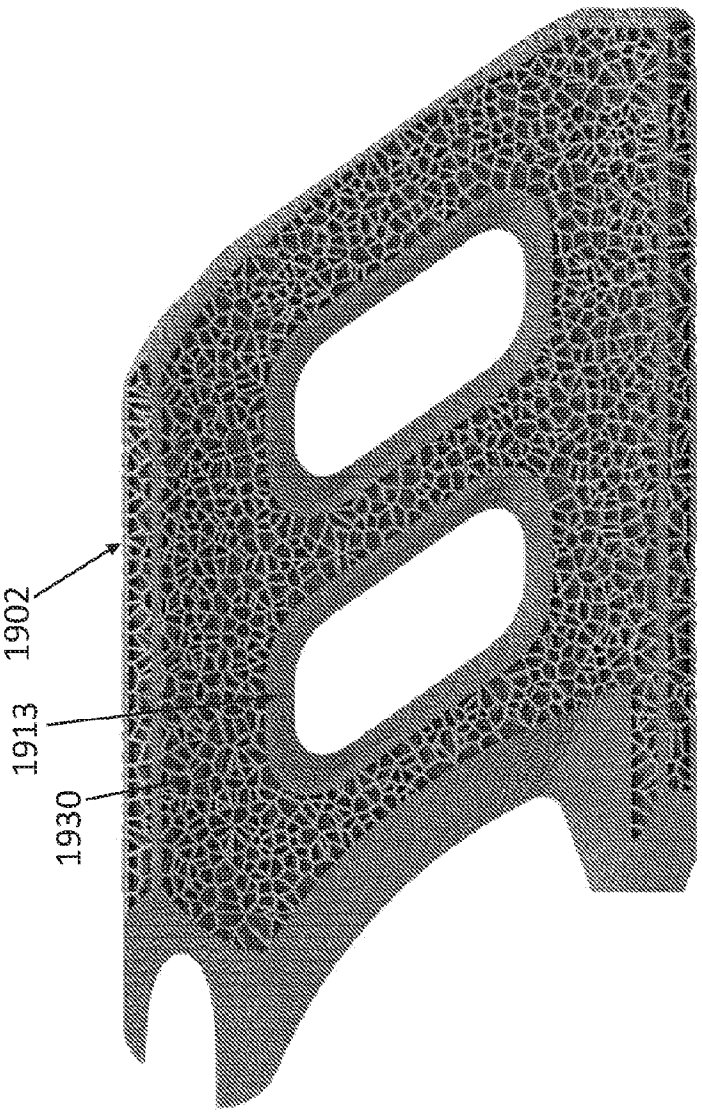


Figure 19

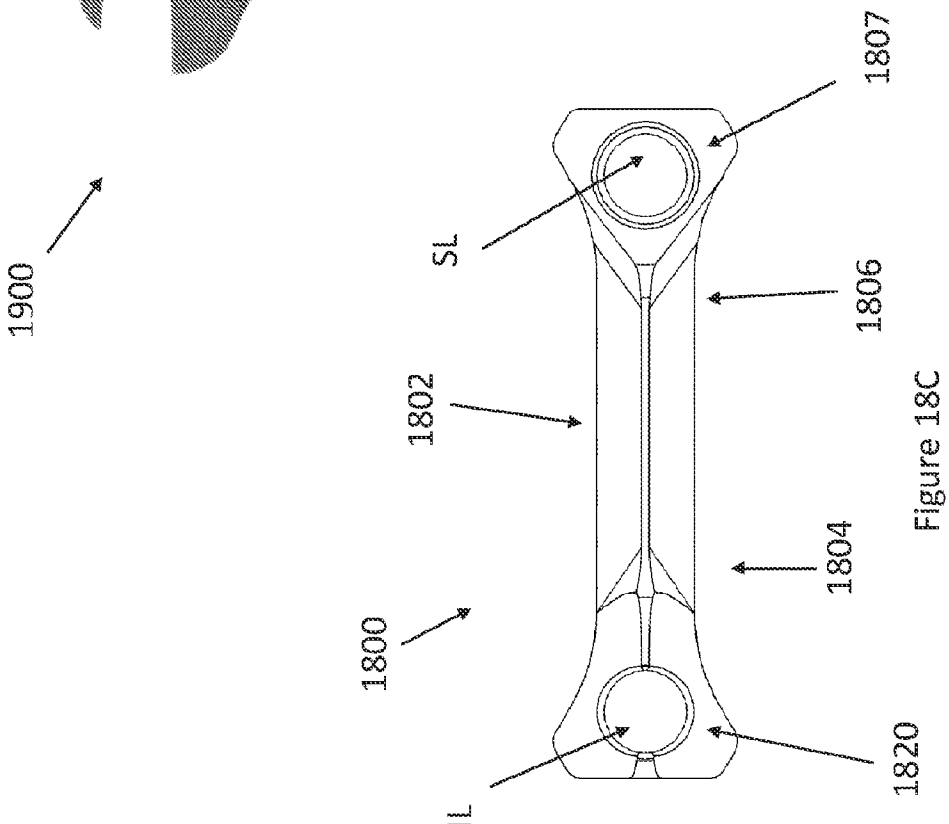


Figure 18C

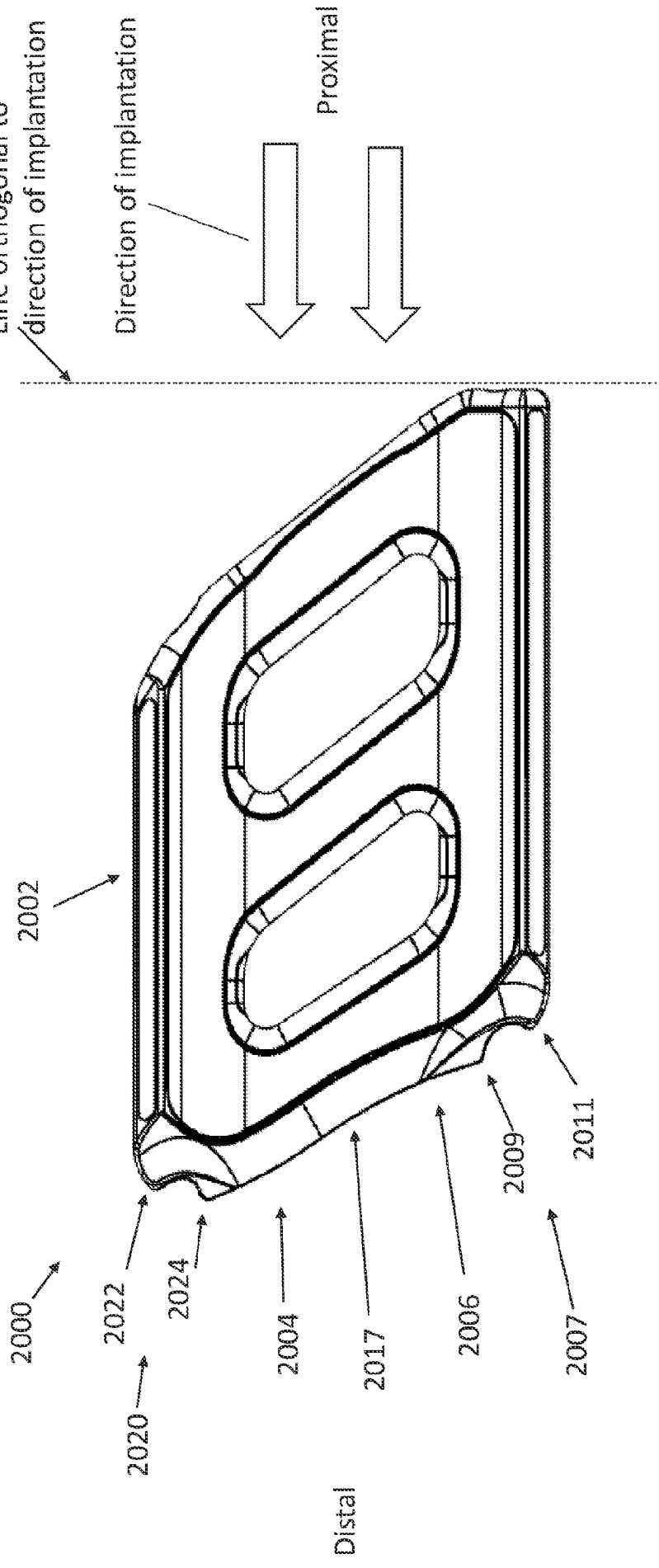

Line orthogonal to direction of implantation
Direction of implantation
Proximal
2002
2000
2022
2024
2004
2017
2006
2007
2009
2011
2020
Distal

Figure 20

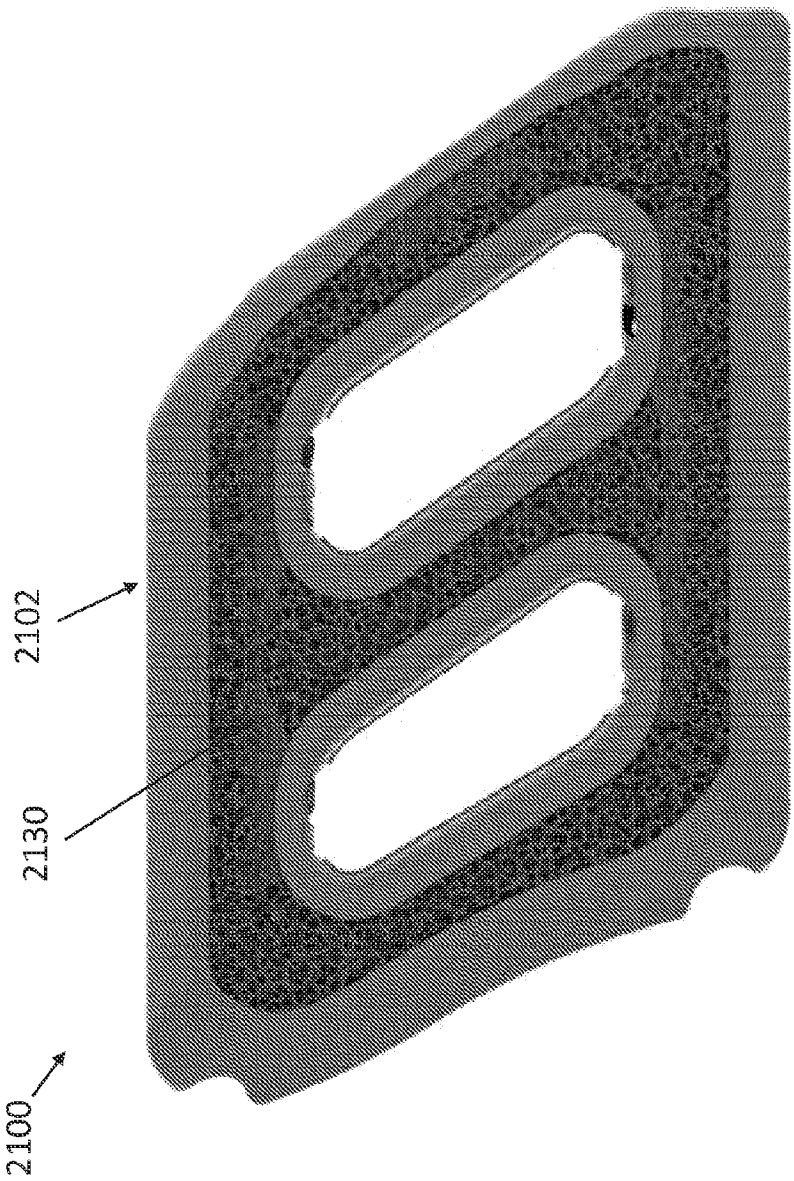


Figure 21

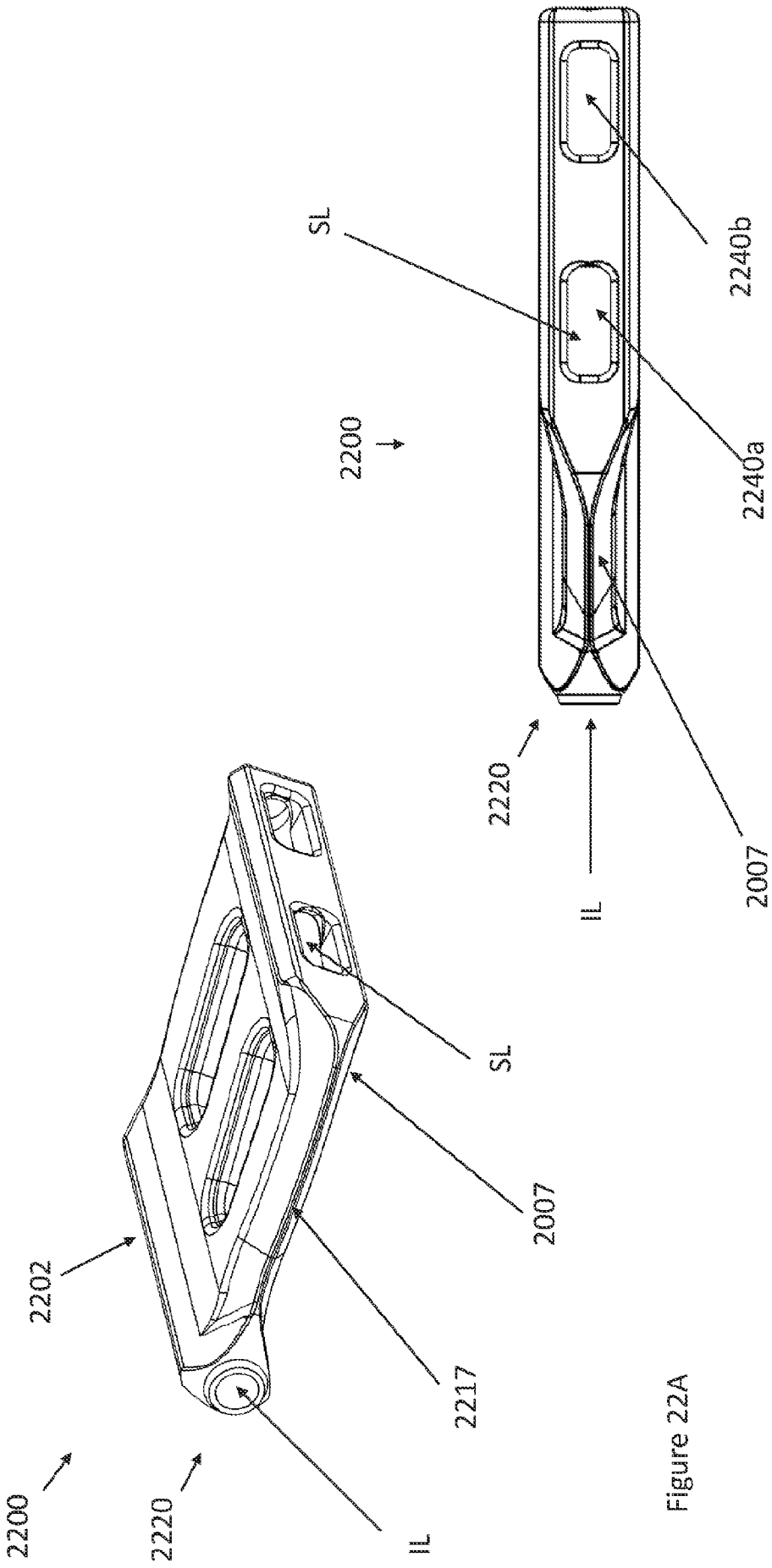


Figure 22A

Figure 22B

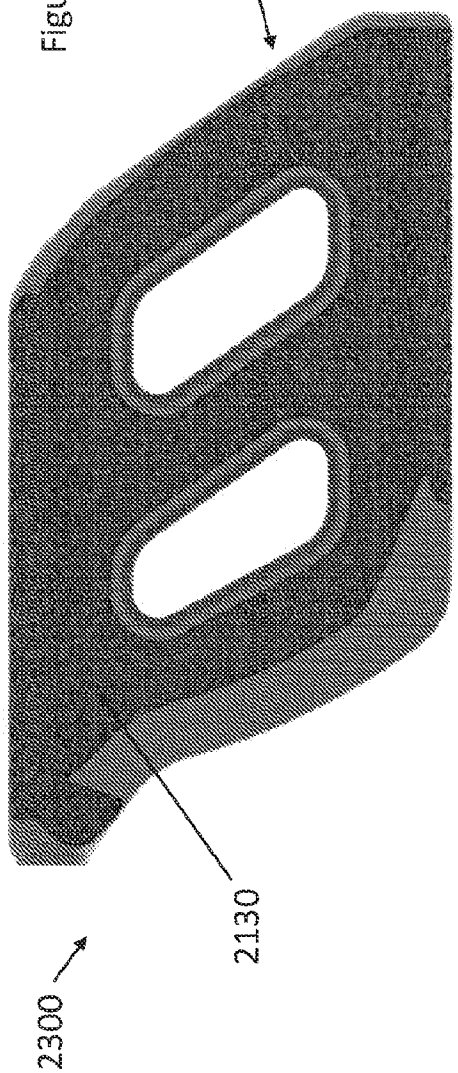


Figure 23A

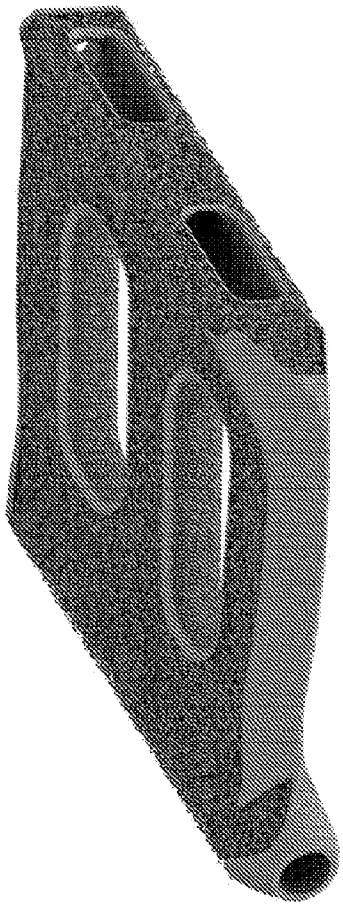


Figure 23B

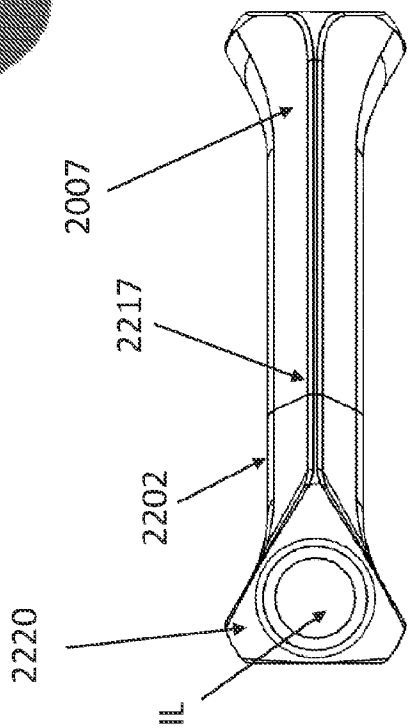


Figure 22C

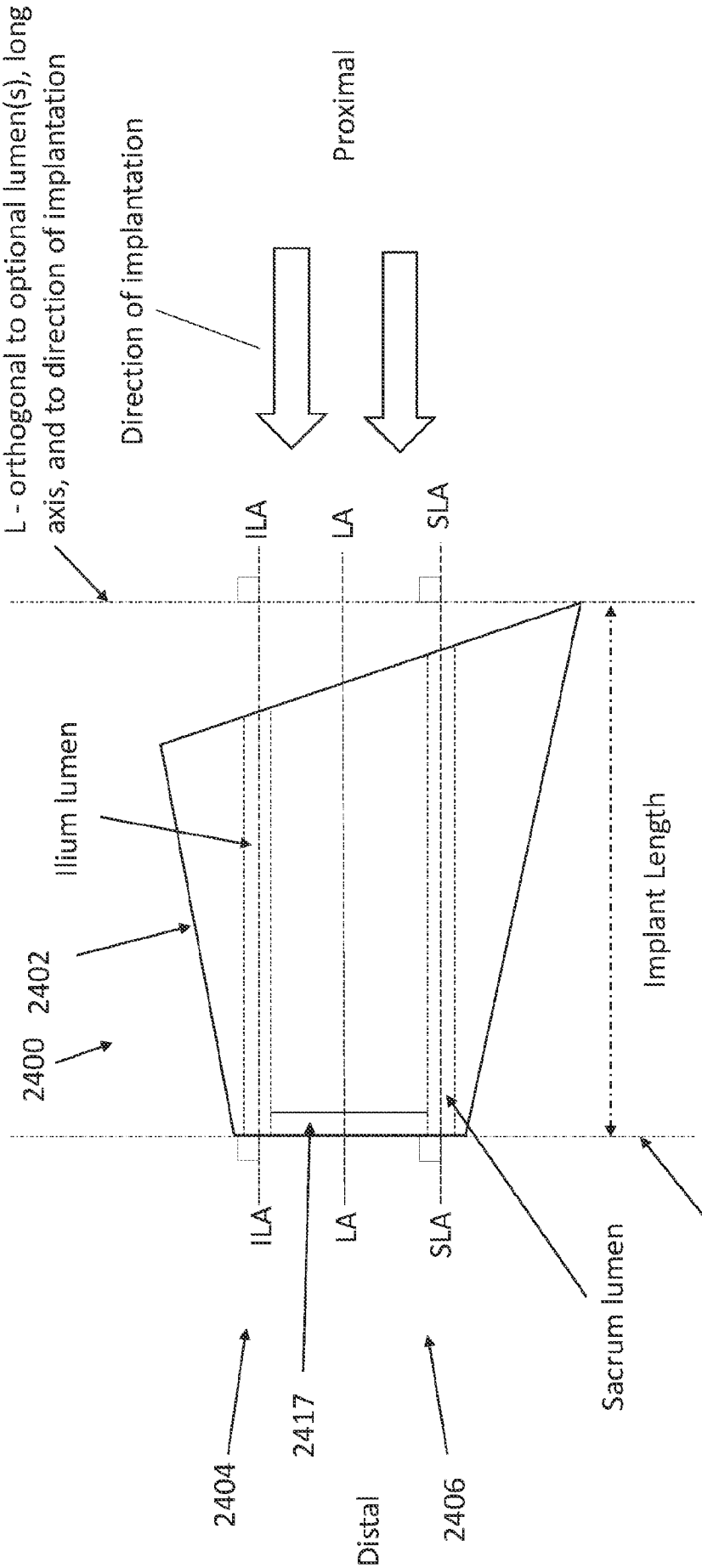

L - orthogonal to optional lumen(s), long axis, and to direction of implantation
Direction of implantation
Proximal
ILA
LA
SLA
Ilium lumen
2400
2402
Implant Length
ILA
LA
SLA
2404
2417
Distal
2406
Sacrum lumen
L - orthogonal to optional lumen(s), long axis and to direction of implantation

Figure 24

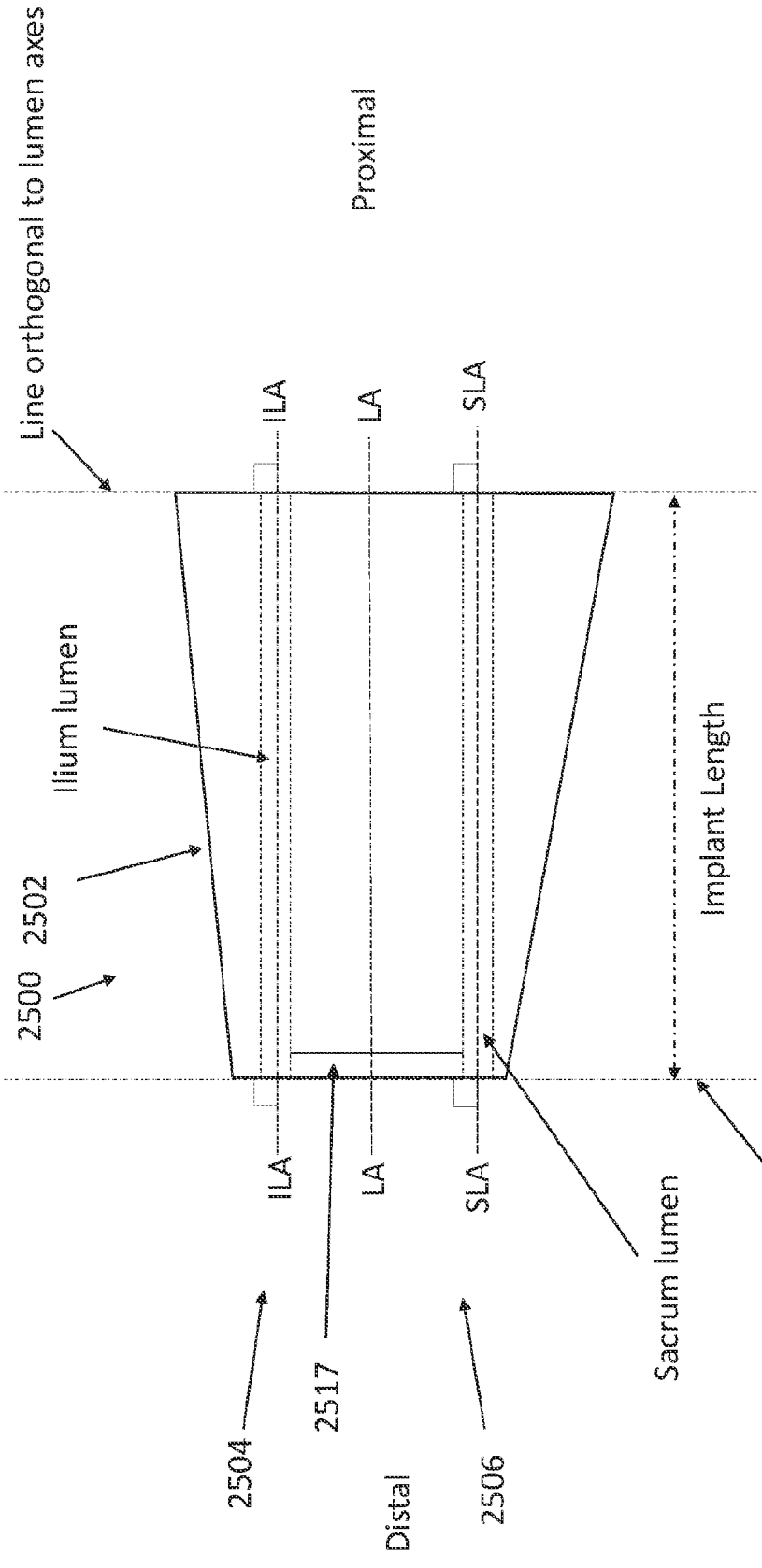

Line orthogonal to lumen axes
ILA
LA
SLA
Proximal
Ilium lumen
2500
2502
Implant Length
Sacrum lumen
ILA
LA
SLA
2504
2517
Distal
2506
Line orthogonal to lumen axes

Figure 25

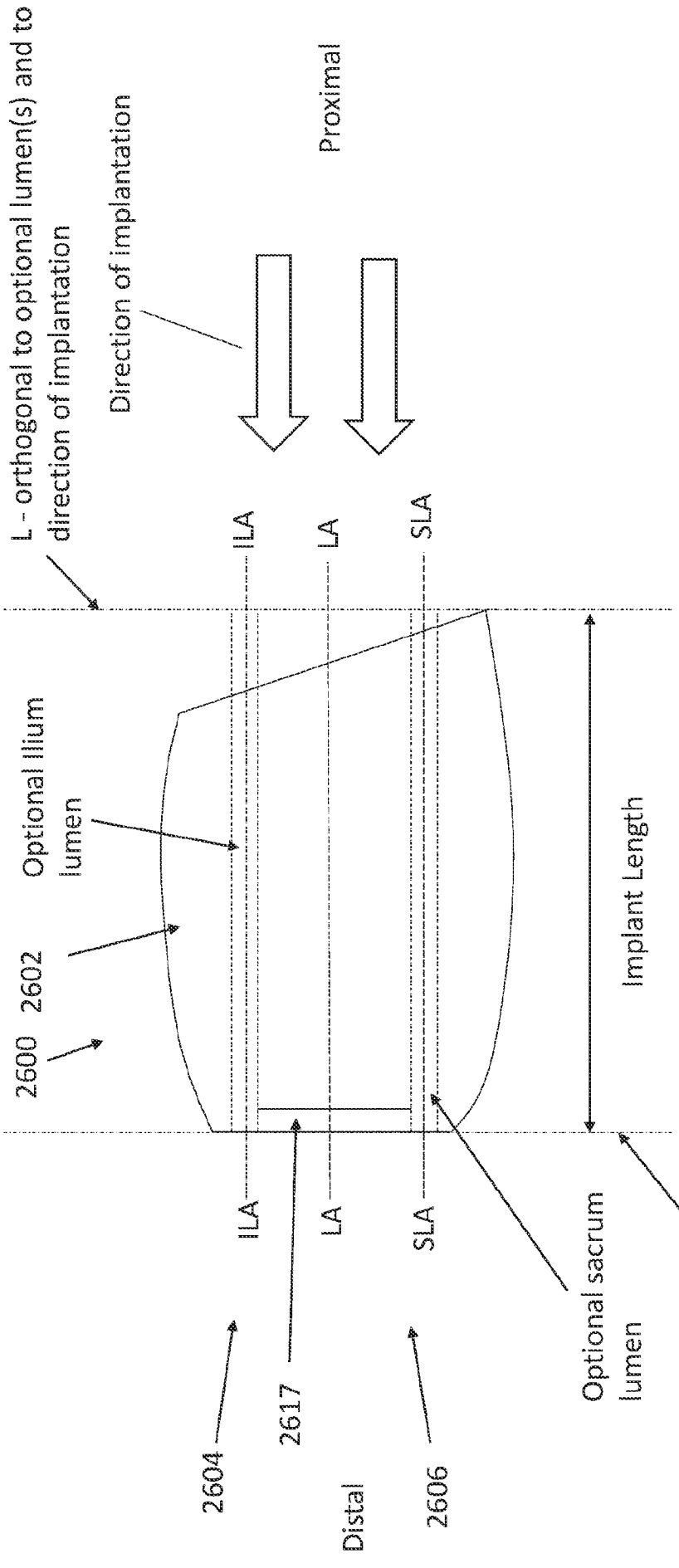

L - orthogonal to optional lumen(s) and to direction of implantation
Direction of implantation
Proximal
ILA
LA
SLA
Optional Ilium lumen
2602
2600
Implant Length
ILA
LA
SLA
2604
2617
Distal
2606
Optional sacrum lumen
L - orthogonal to optional lumen(s) and to direction of implantation

Figure 26

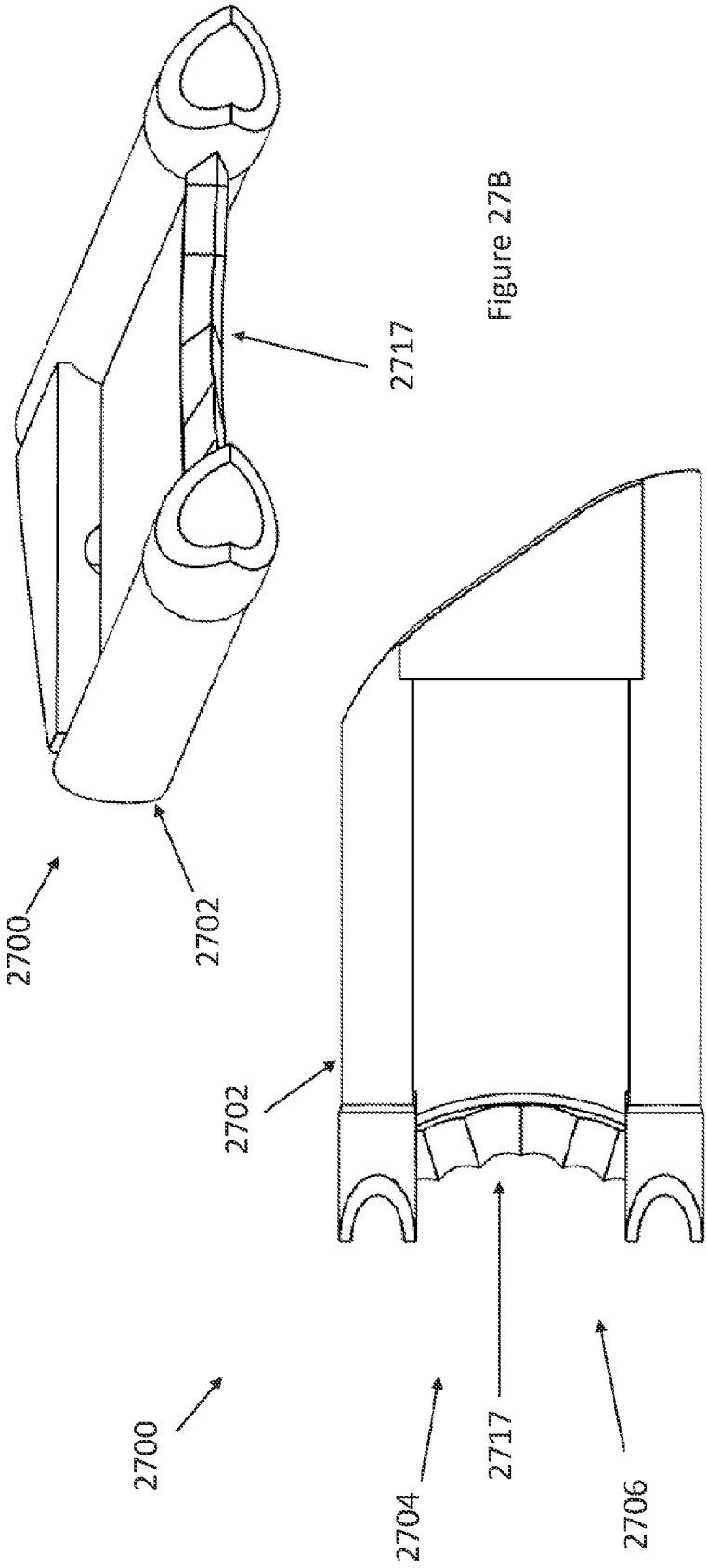


Figure 27A

Figure 27B

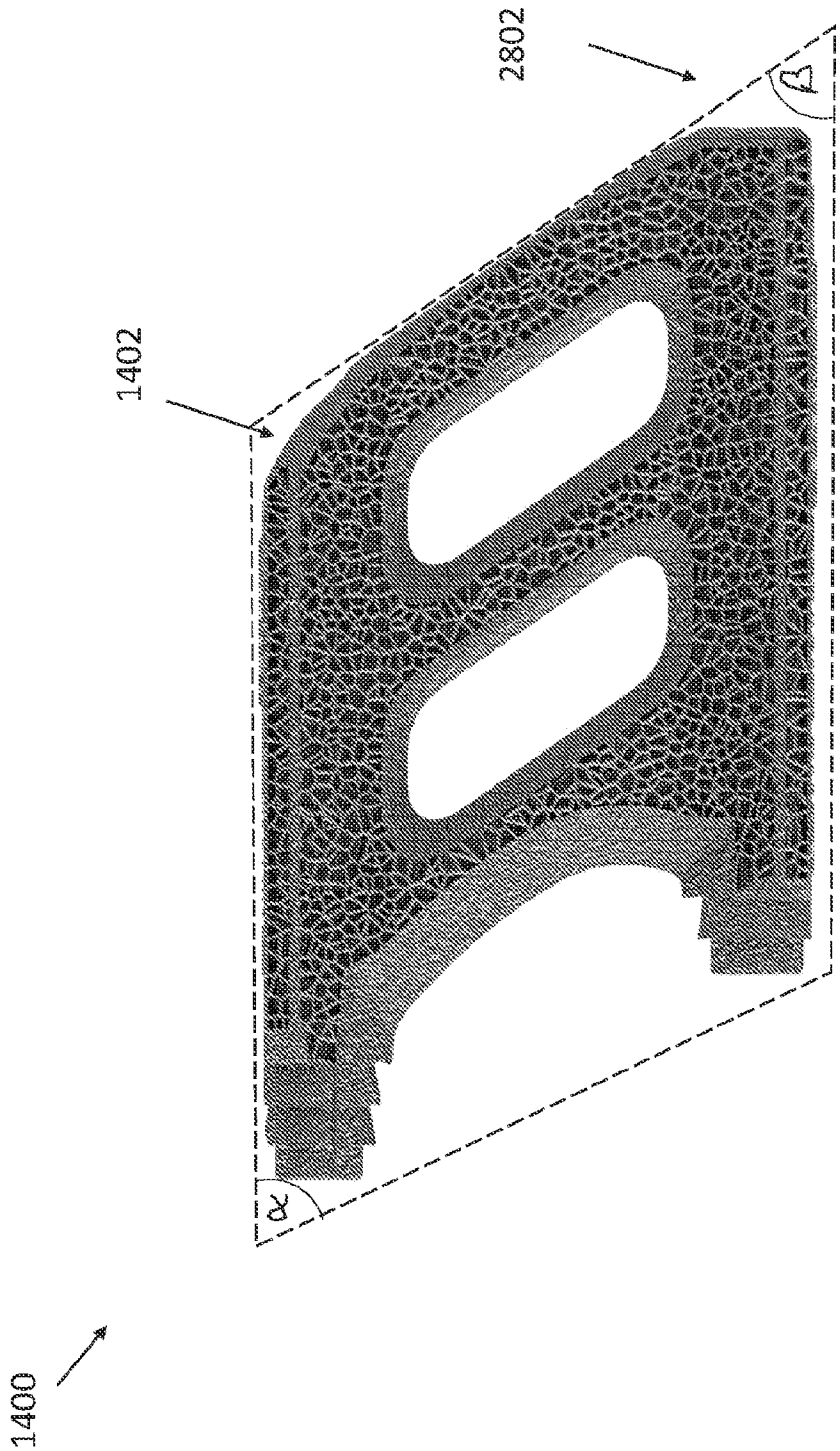


Figure 28

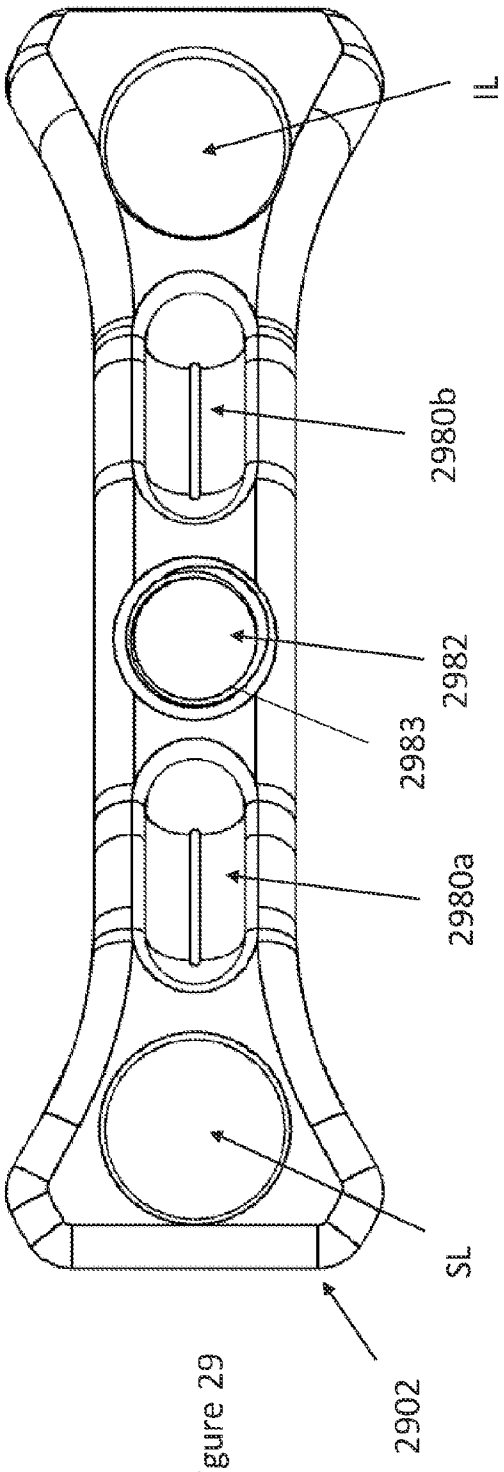


Figure 29

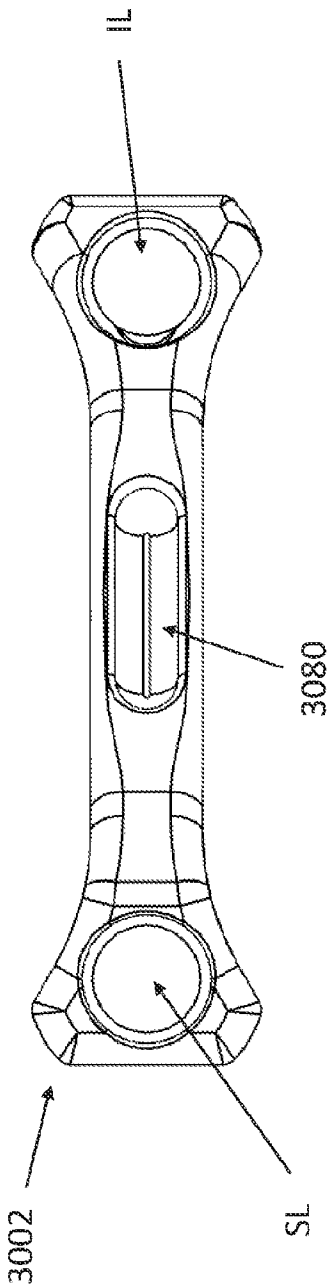


Figure 30

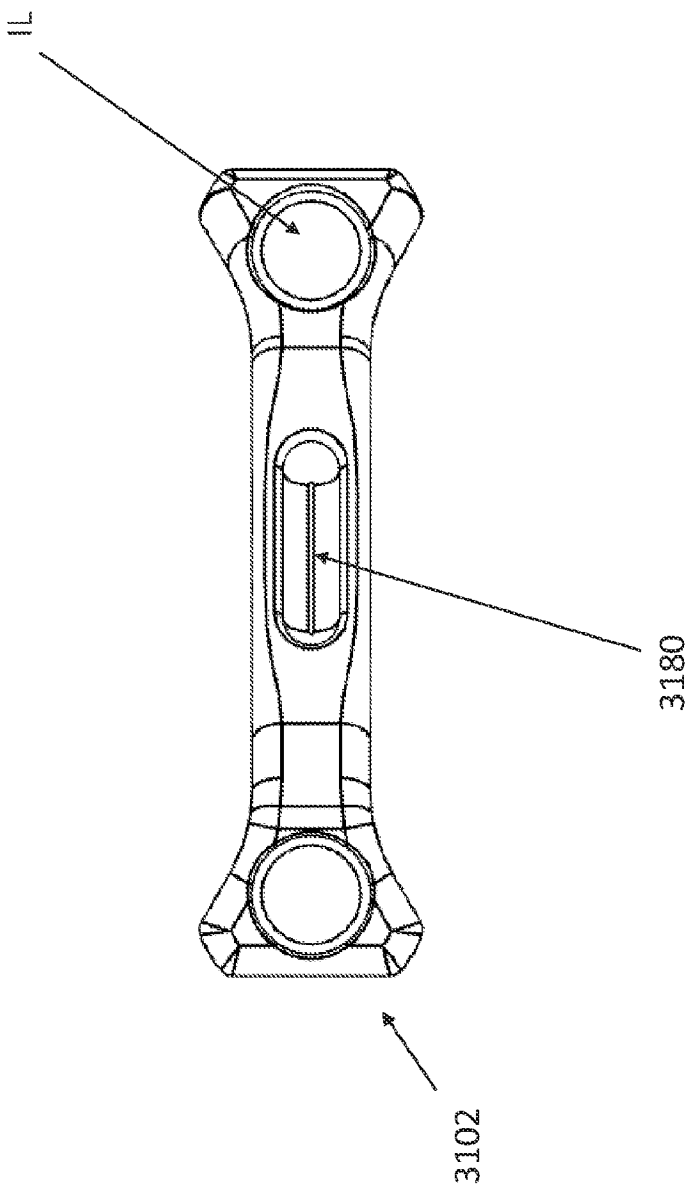


Figure 31

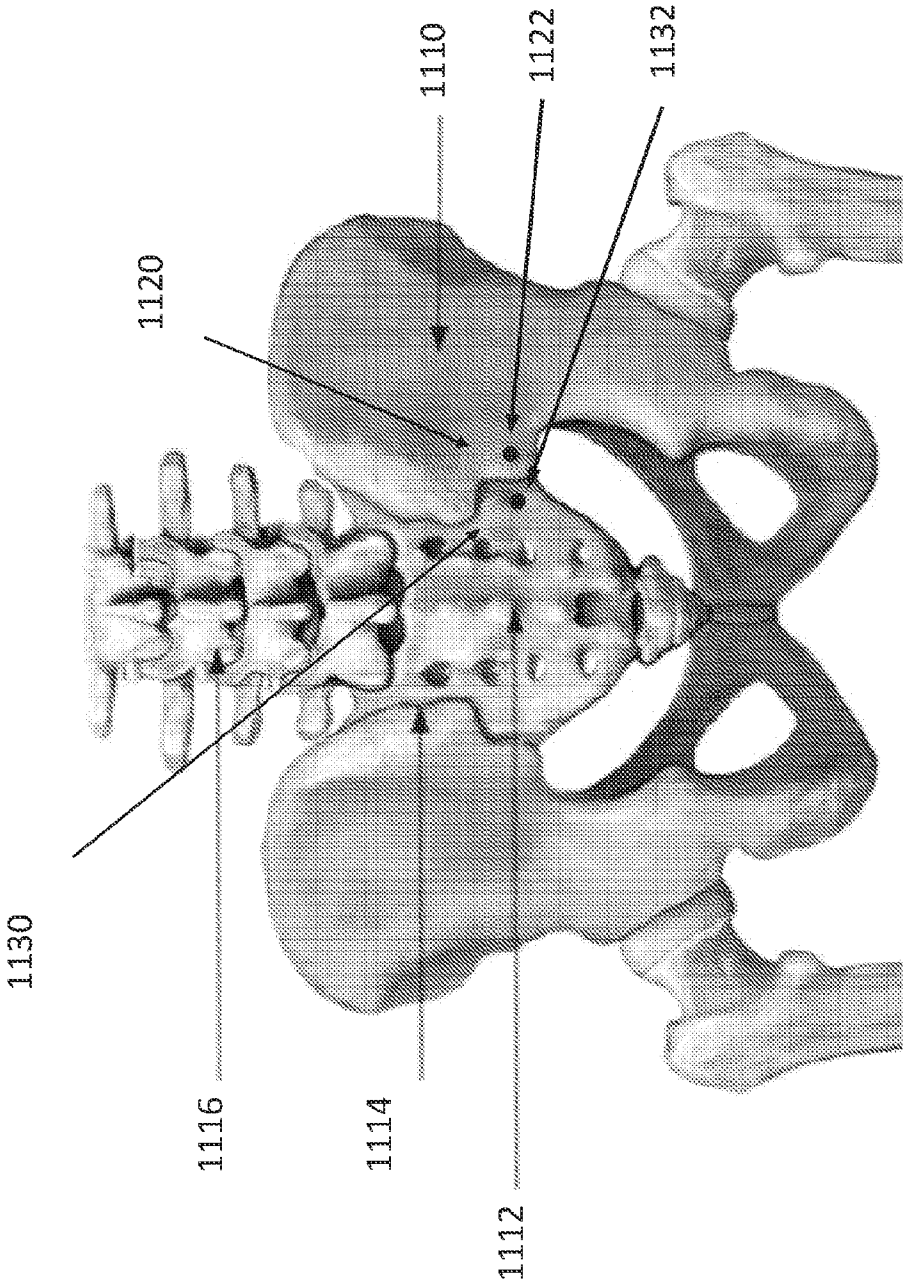


Figure 32A

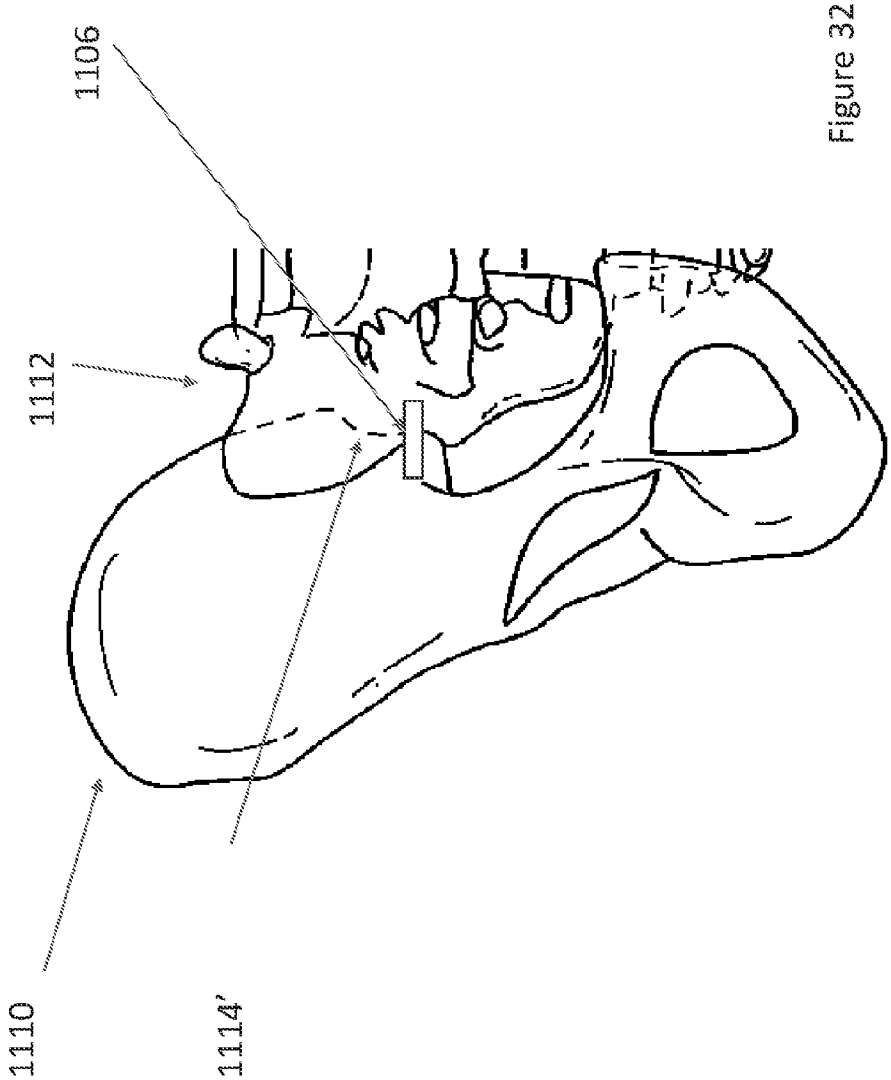


Figure 32B

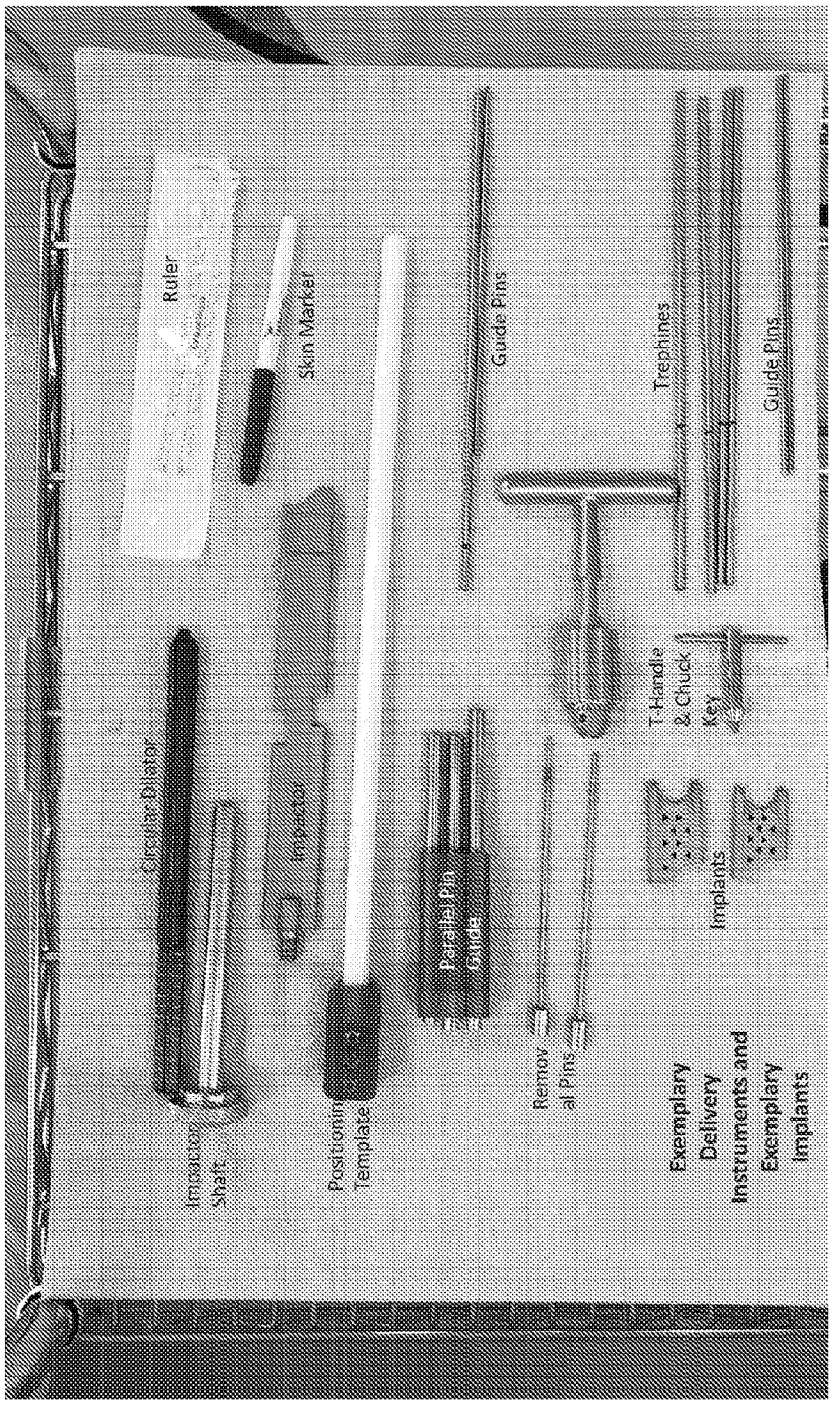

Exemplary Delivery Instruments and Exemplary Implants
Implantation Shaft
Circular Dilator
Ruler
Skin Marker
Introducer
Positioning Template
Removal Pins
Parallel Pin Tools
Guide Pins
Trephines
T-Handle & Chuck Key
Implants
Guide Pins

Figure 33

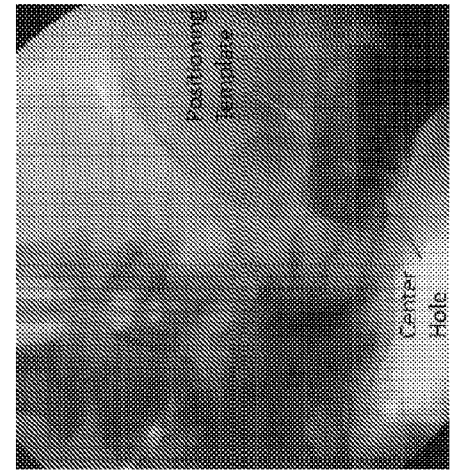


Fig. 34D

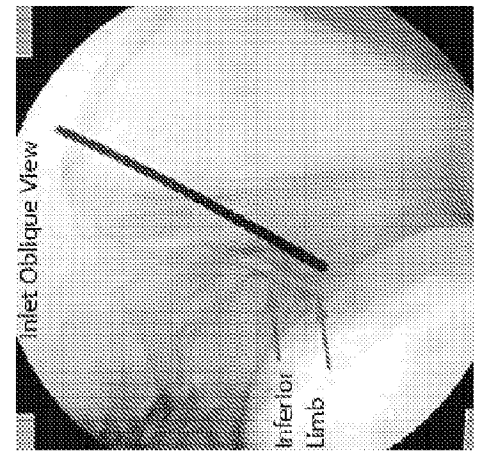


Fig. 34C

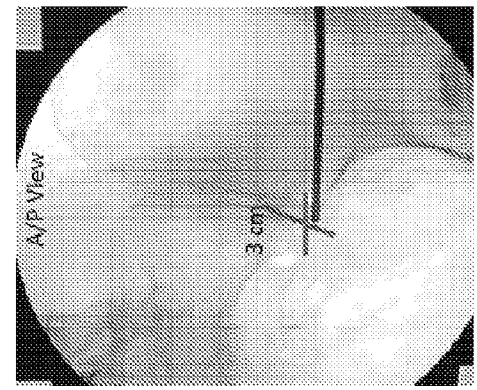


Fig. 34B

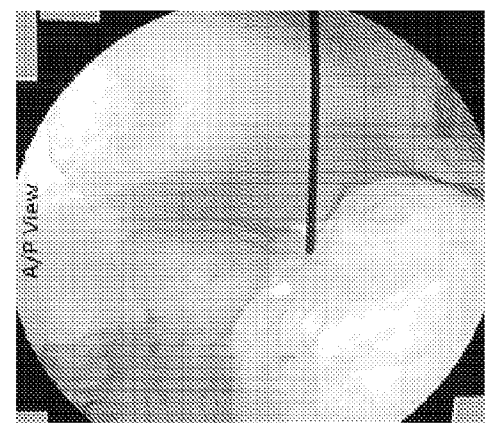


Fig. 34A

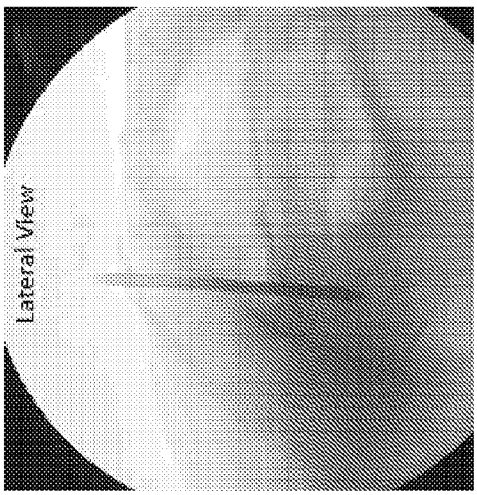


Fig. 34F

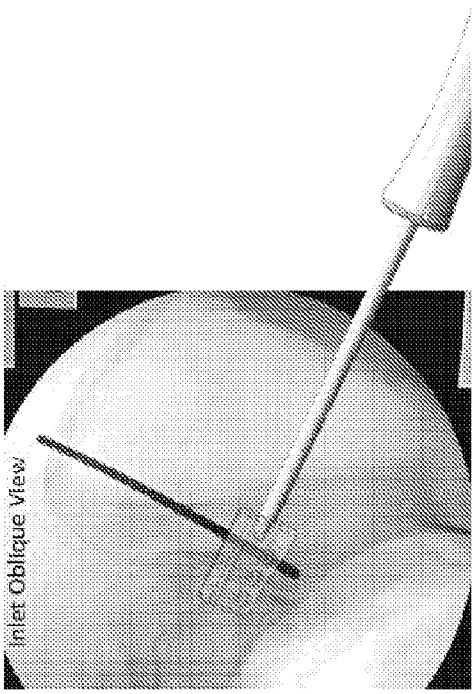


Fig. 34E

Fig. 35A

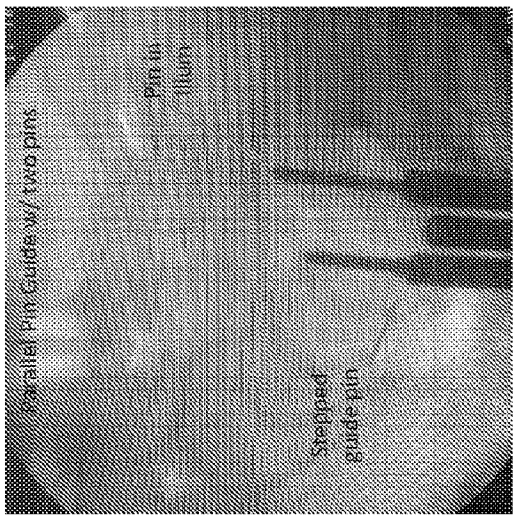


Fig. 35B

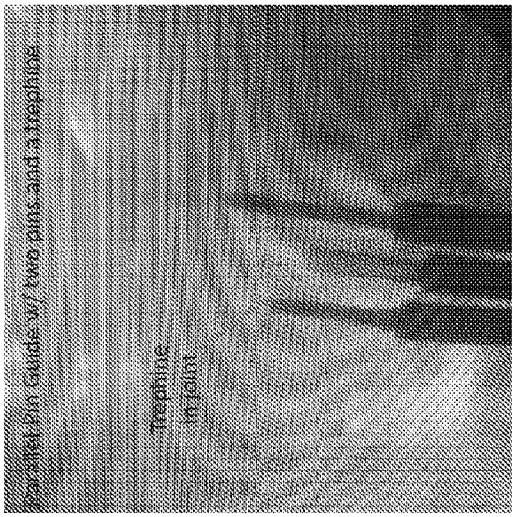
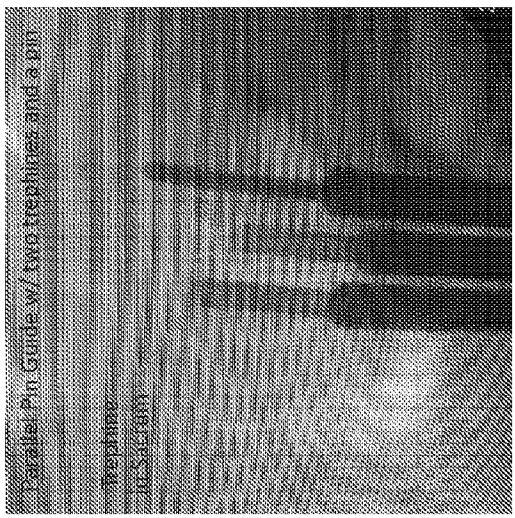


Fig. 35C



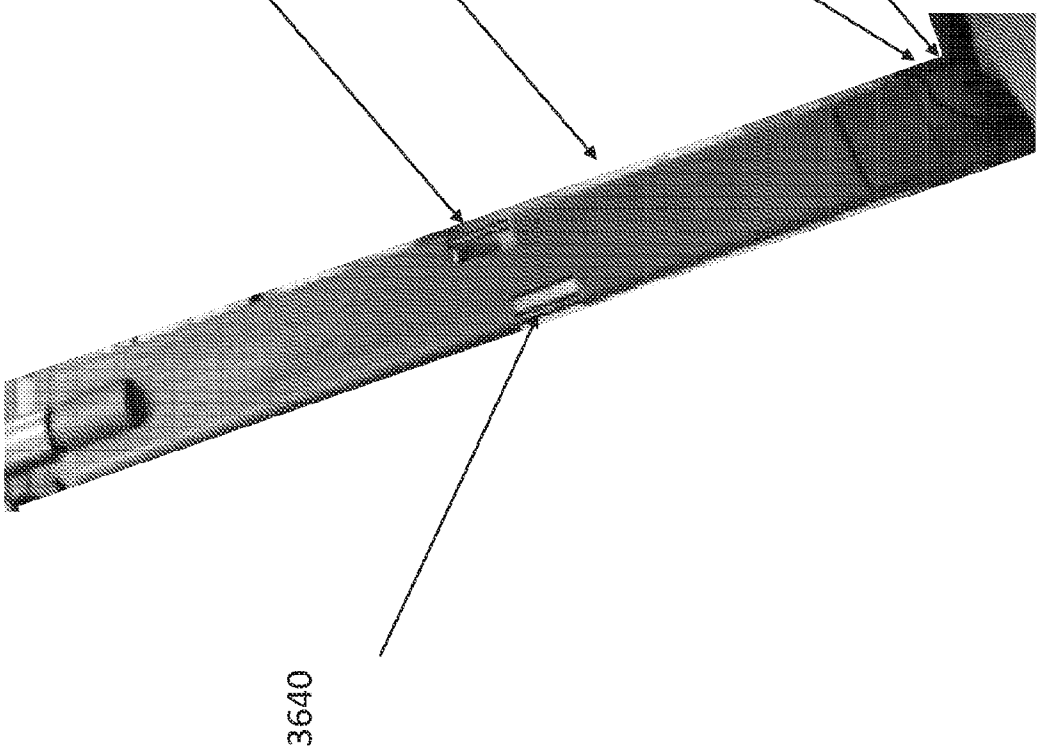


Fig. 36



Fig. 37B



Fig. 37A

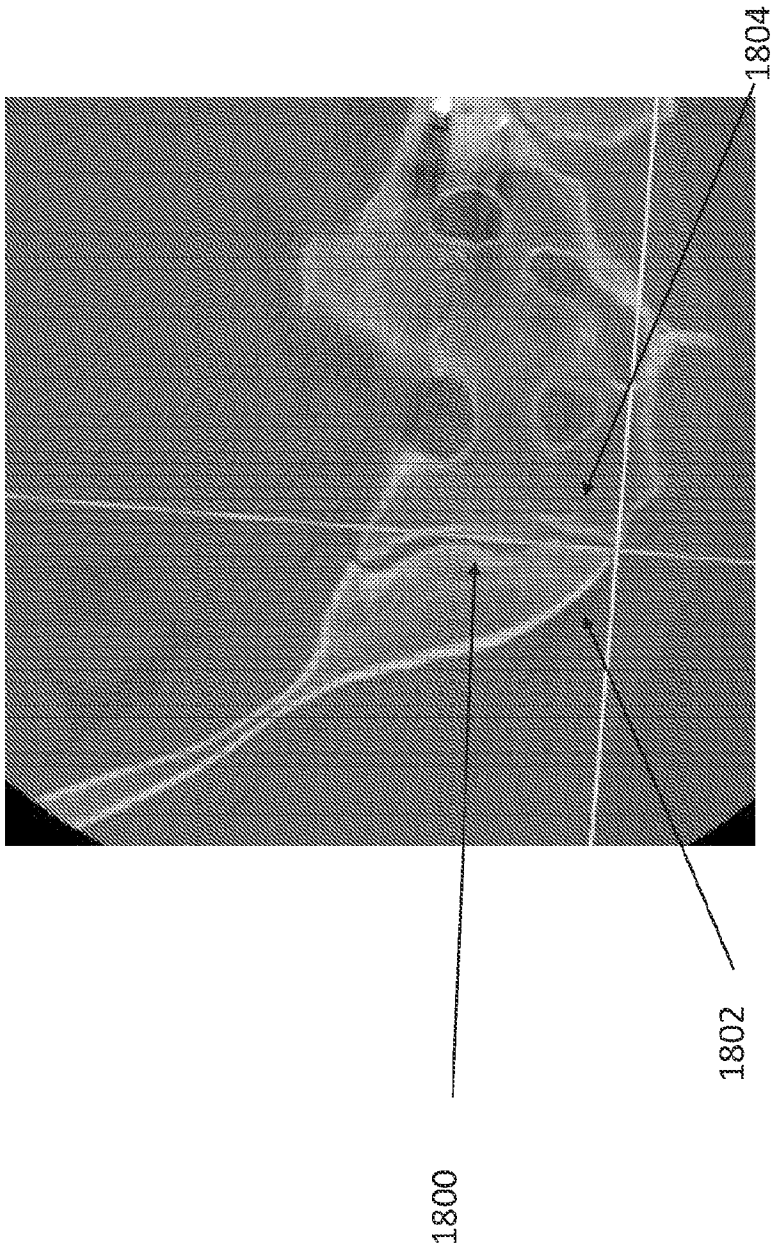


Fig. 38

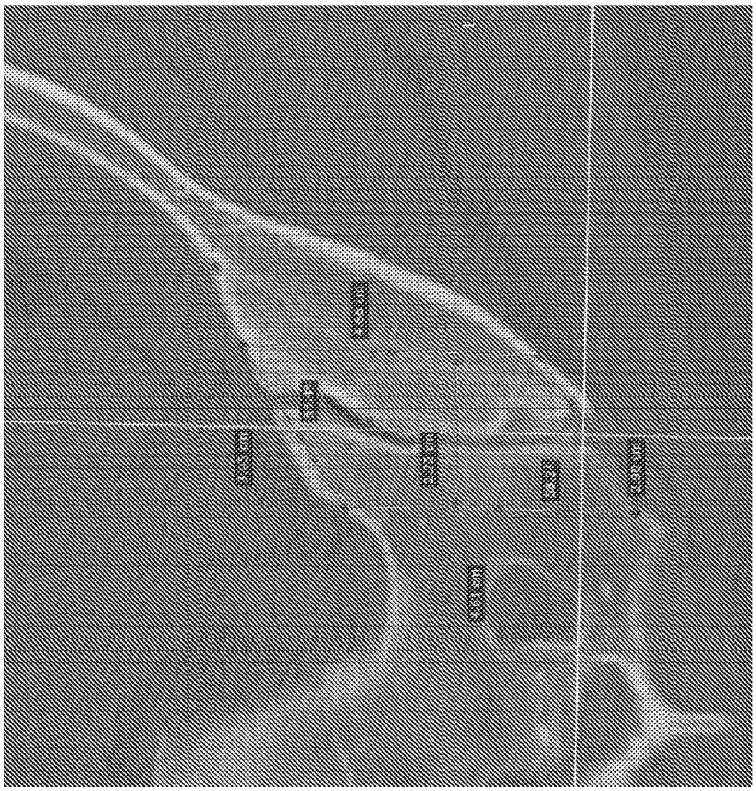


Figure 39B

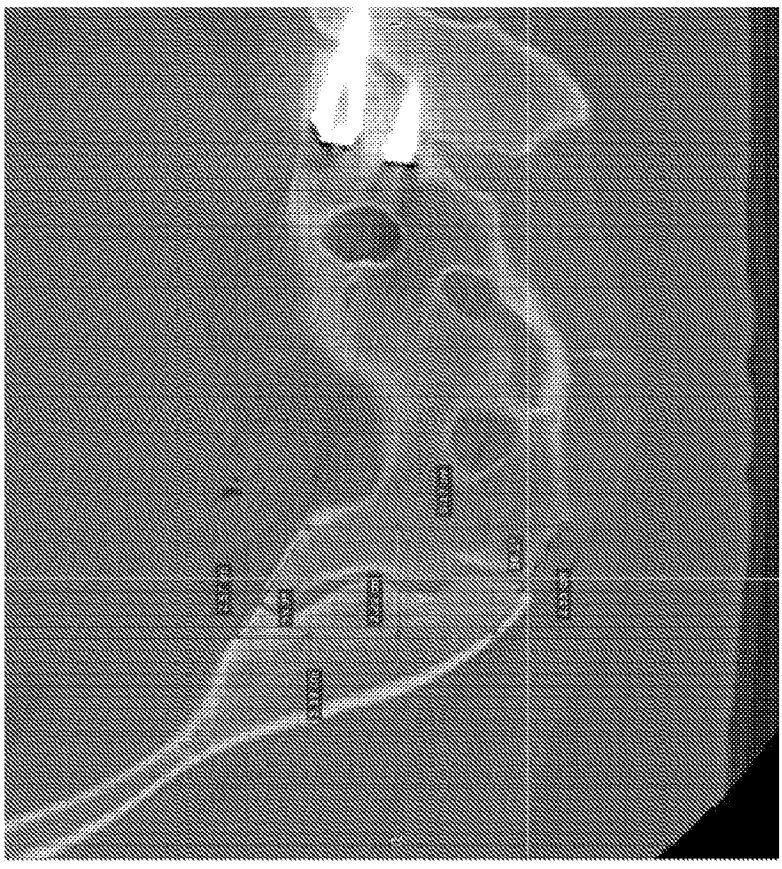


Figure 39A

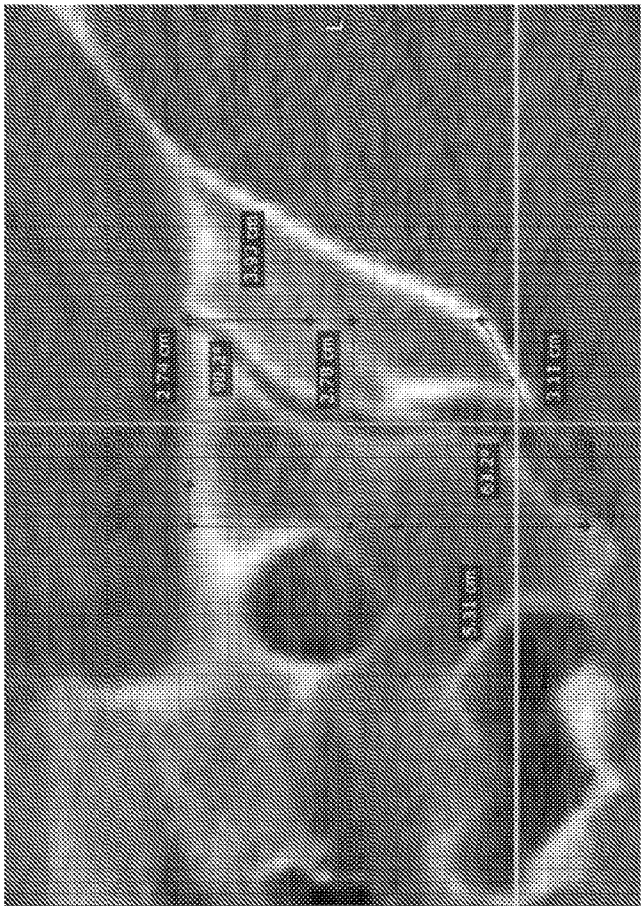


Figure 39D

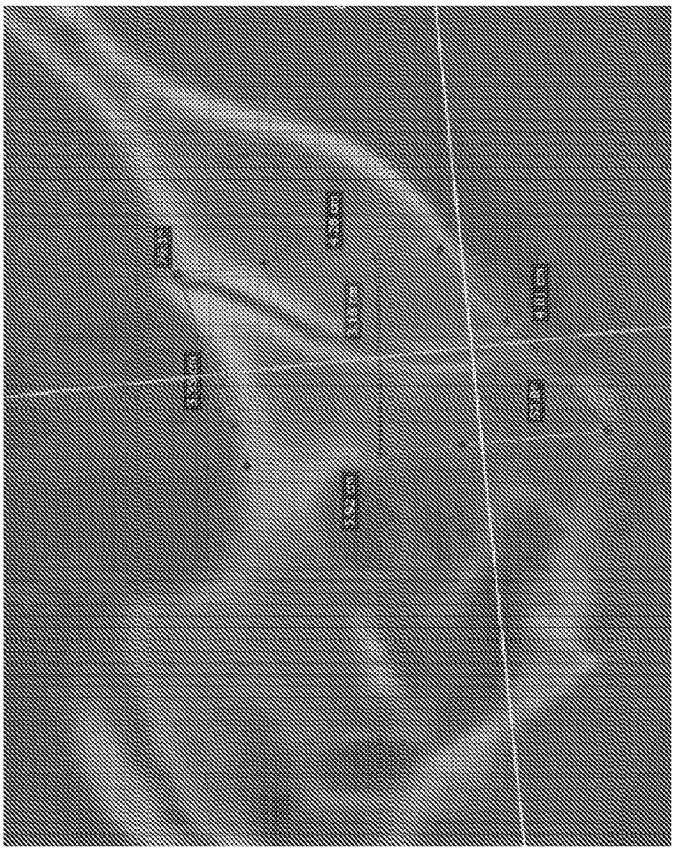


Figure 39C

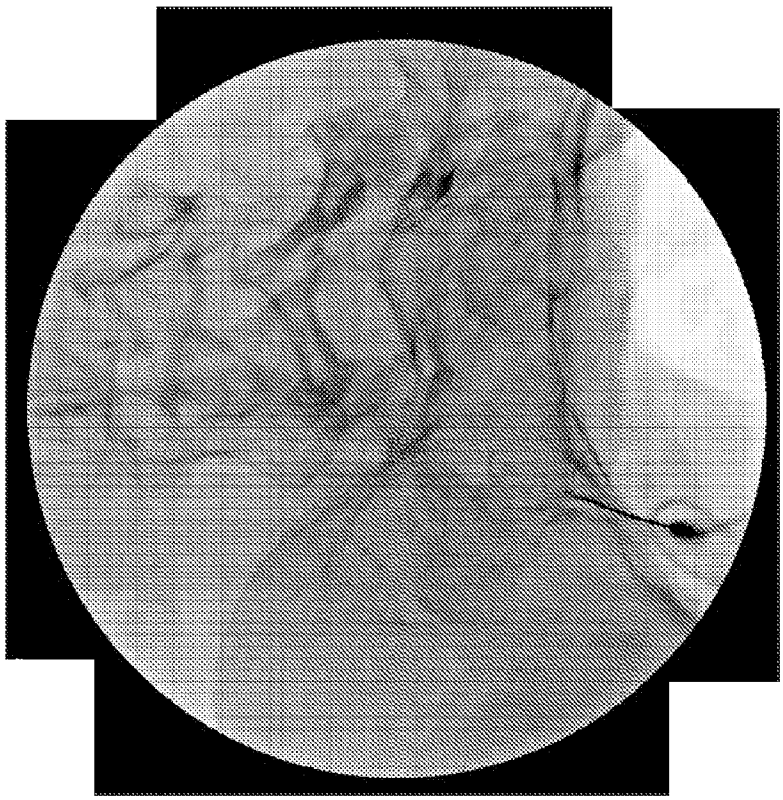


Figure 40



Figure 41B (lateral view)

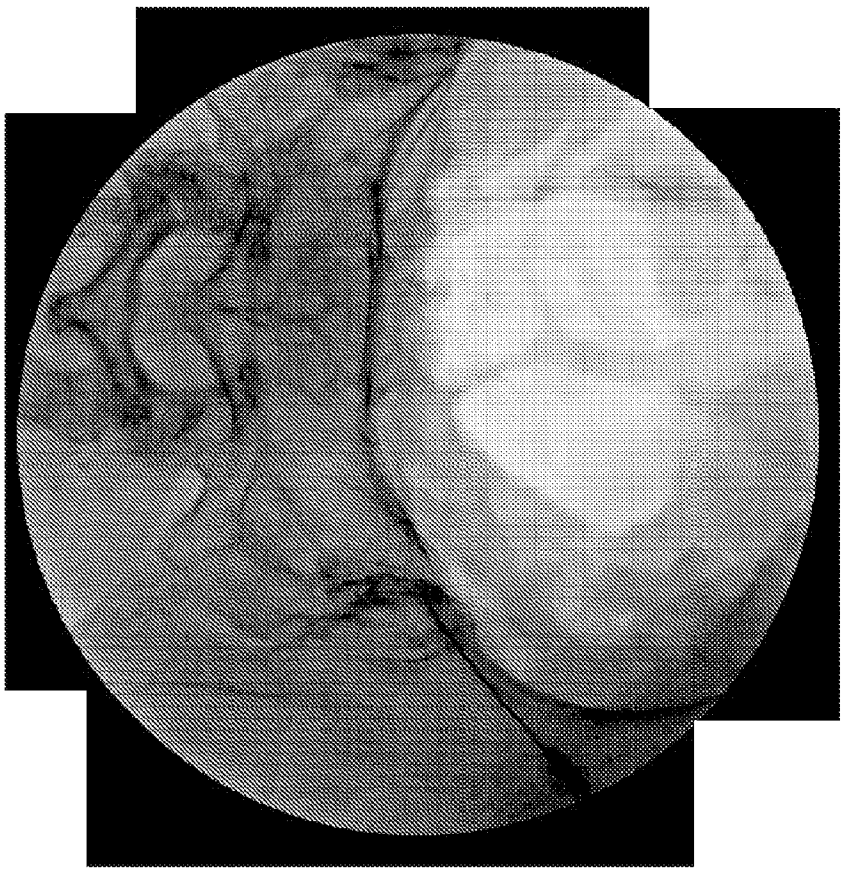


Figure 41A

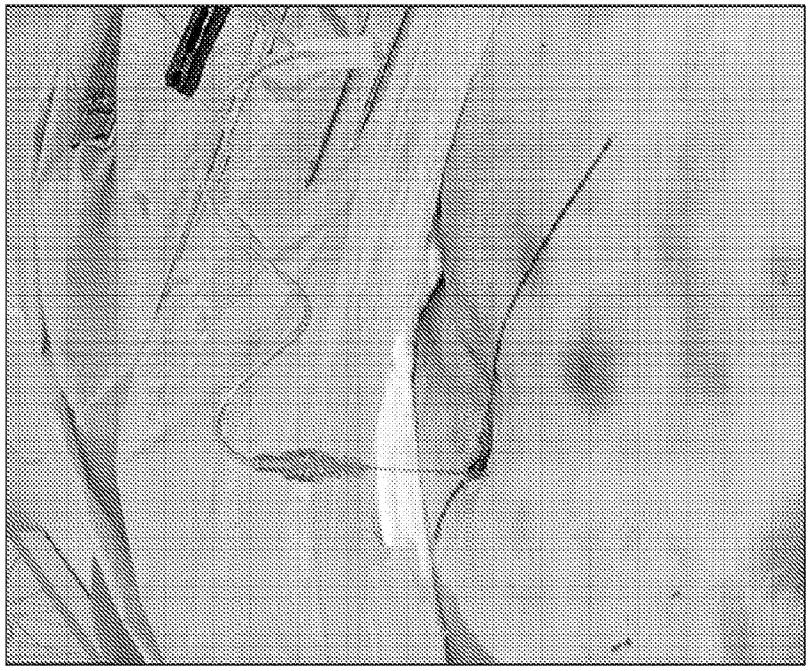


Figure 42B



Figure 42A

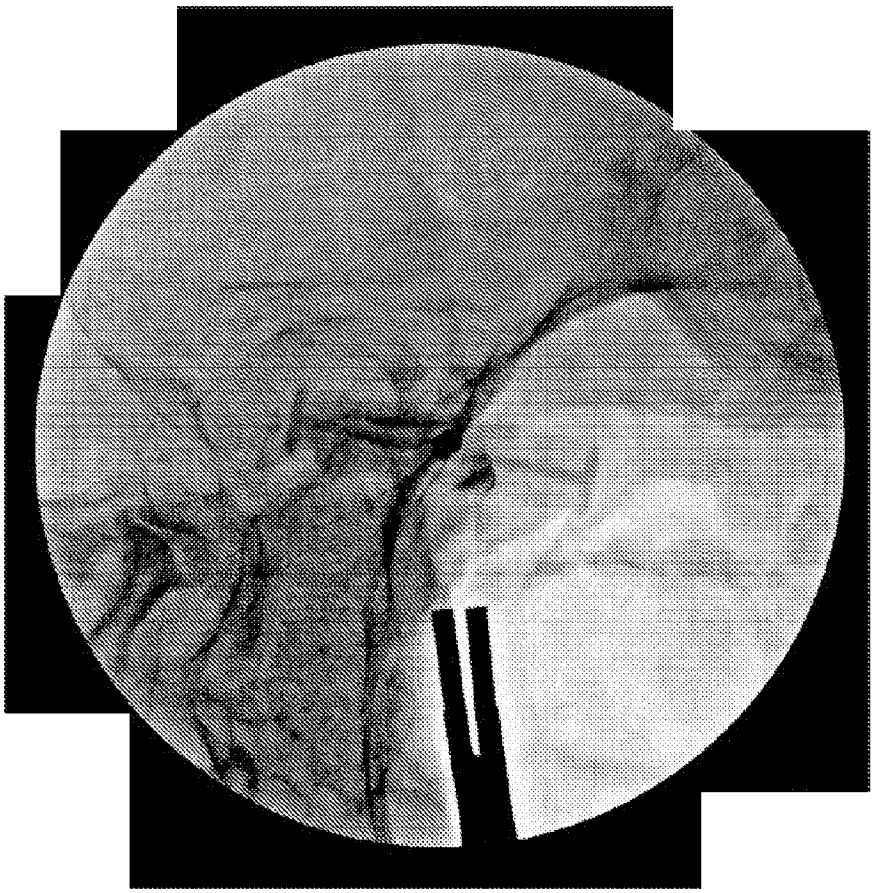


Figure 43

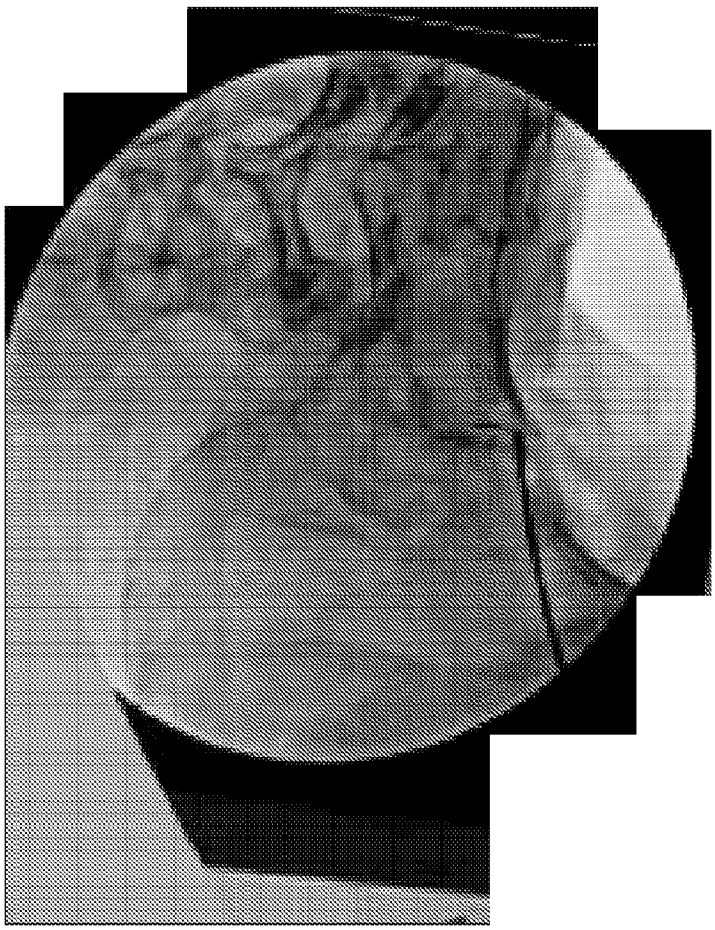


Figure 44

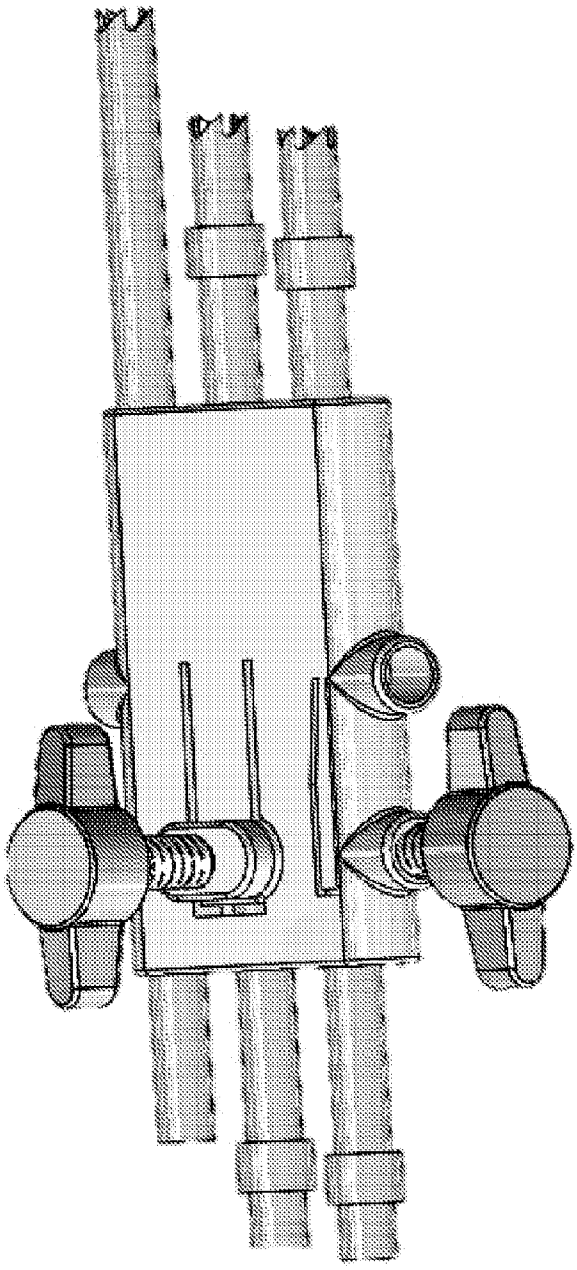


Figure 45

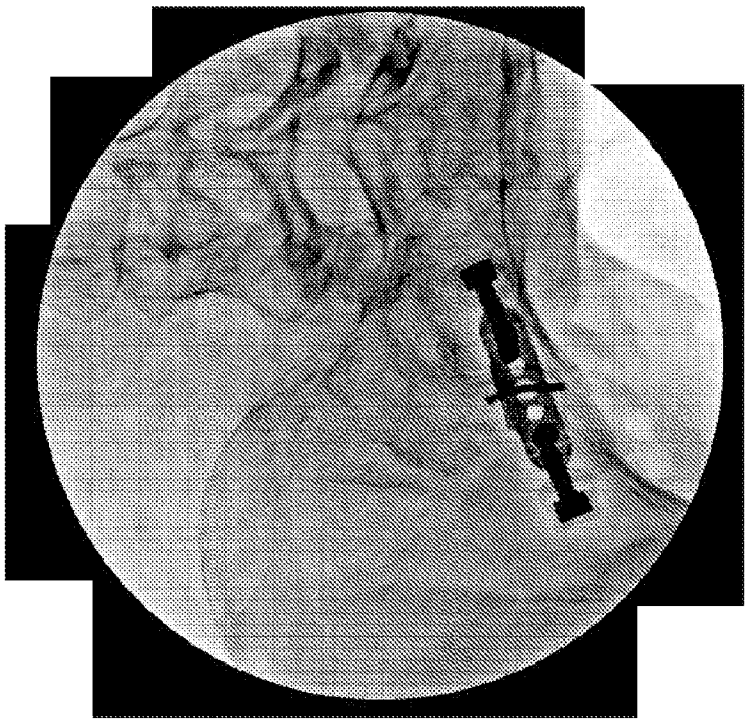


Figure 46B



Figure 46A

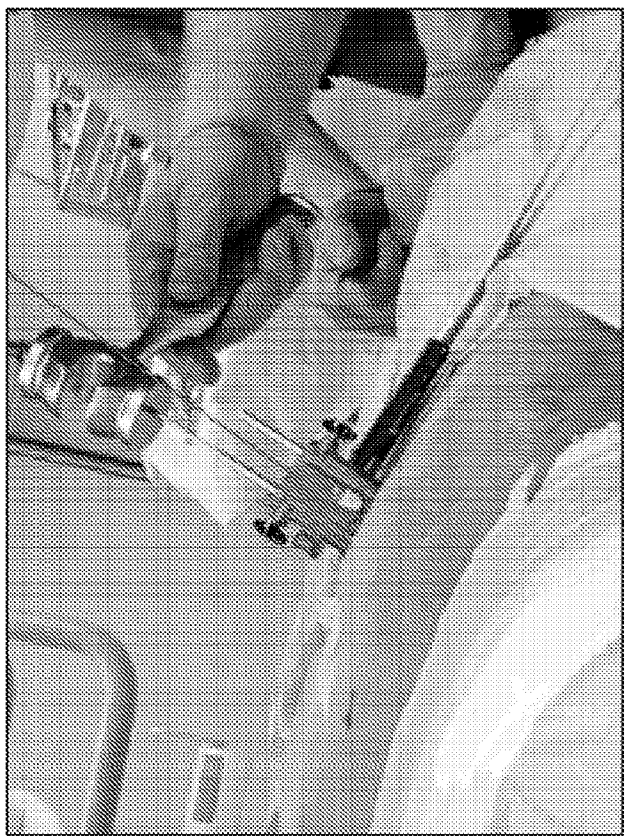


Figure 47

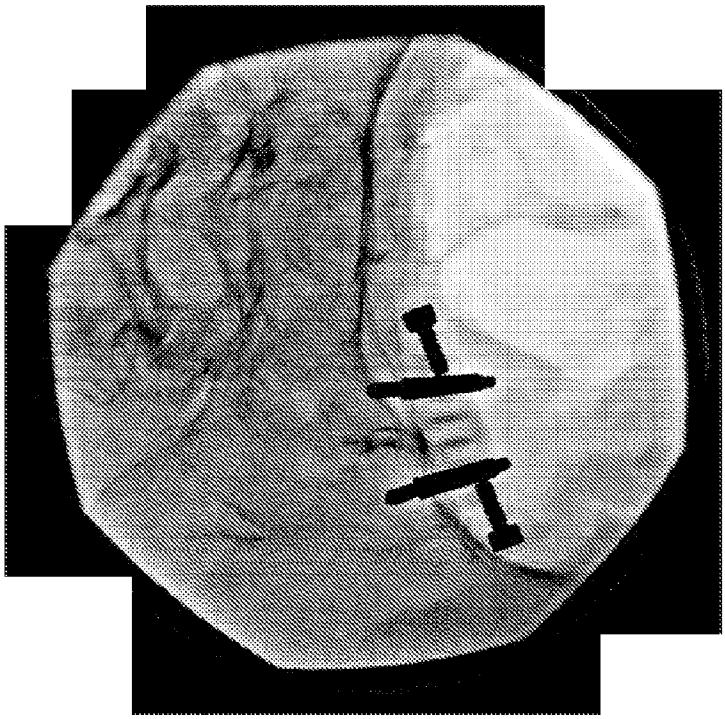


Figure 48B

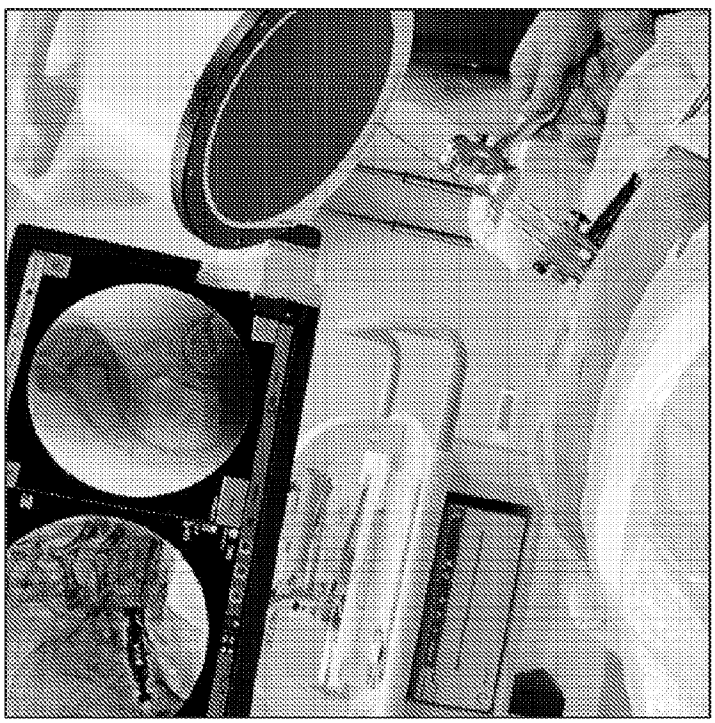


Figure 48A

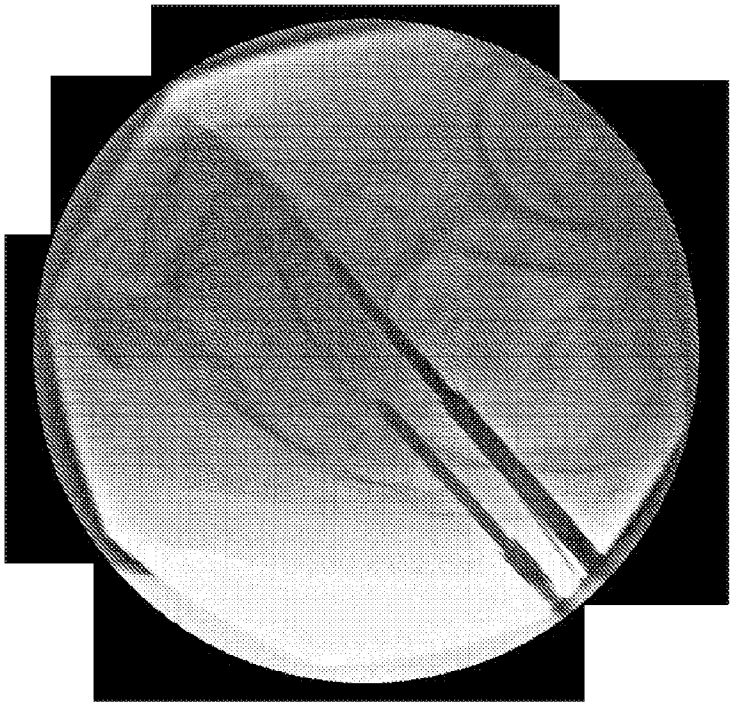


Figure 49B



Figure 49A



Figure 51



Figure 50

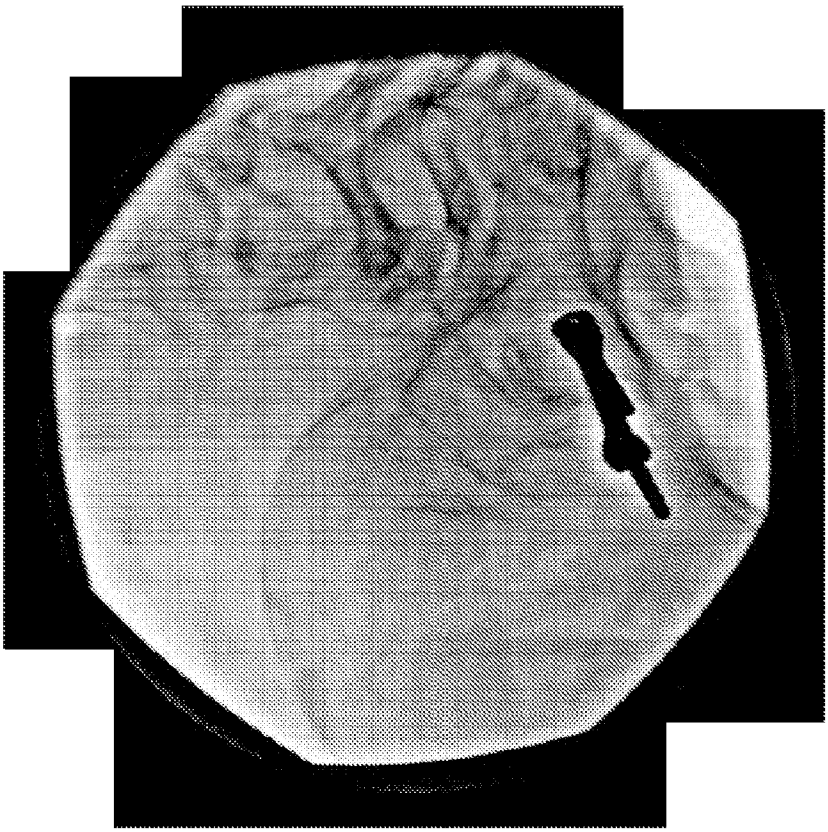


Figure 52

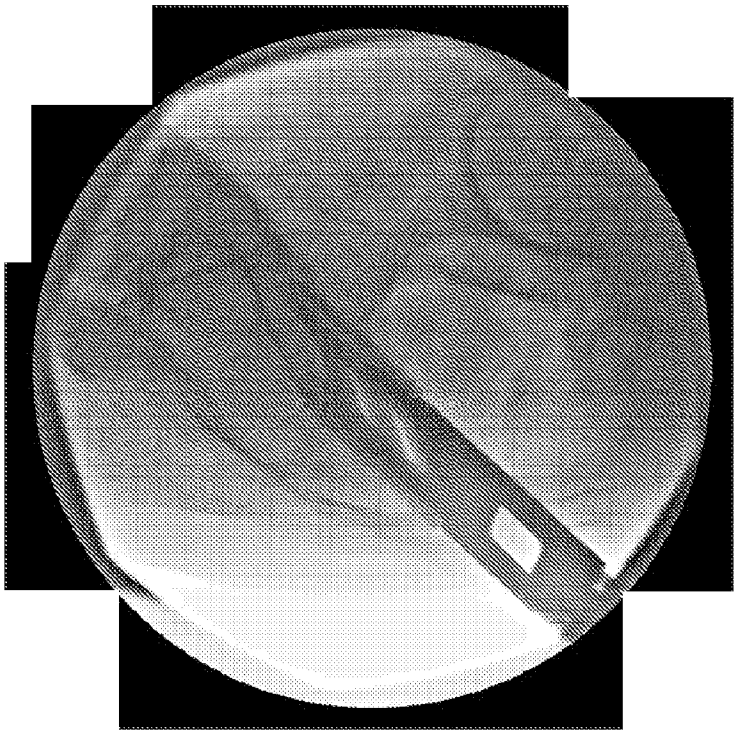


Figure 53B

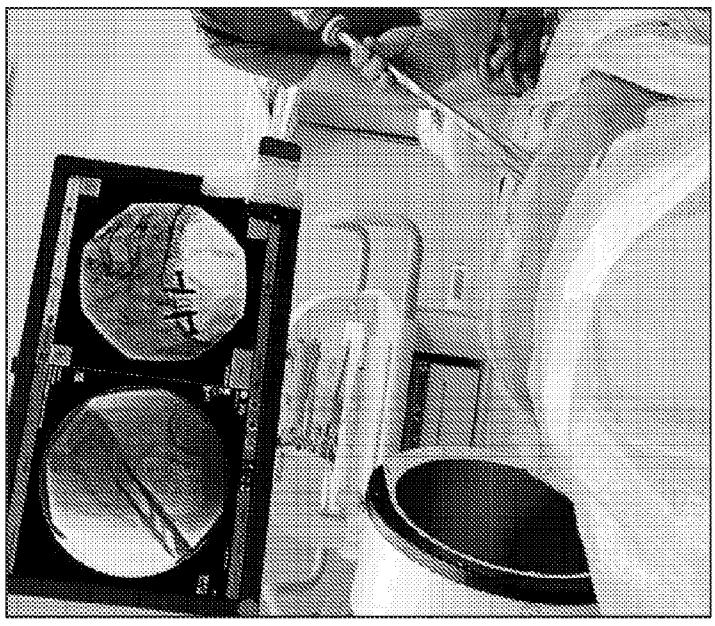


Figure 53A

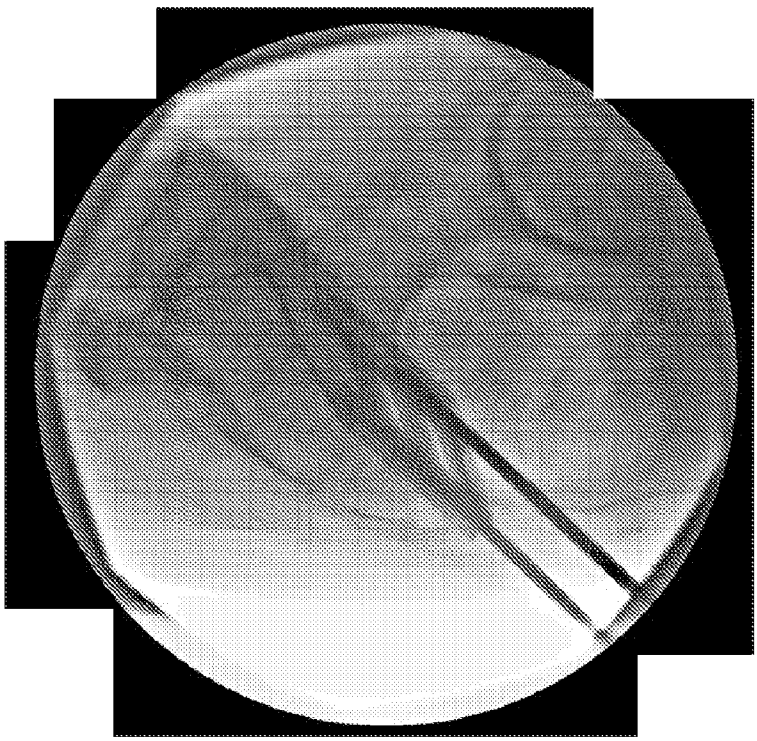


Figure 54

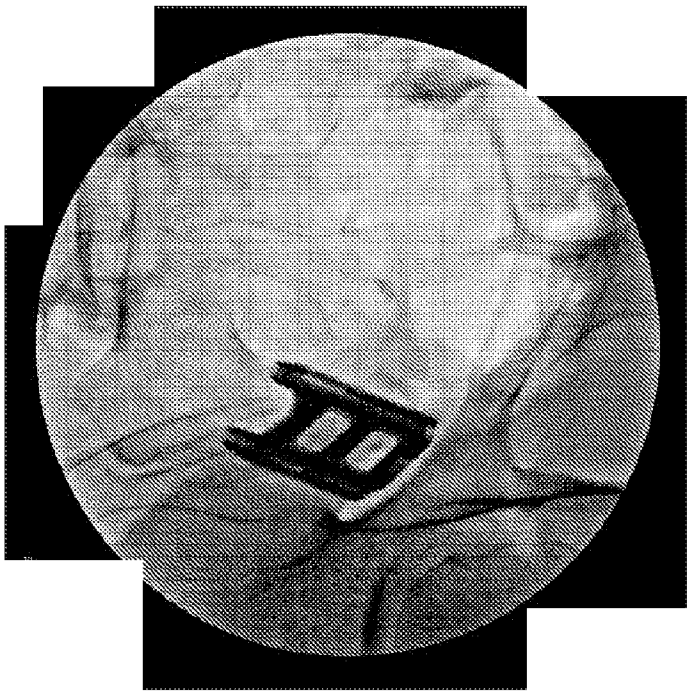


Figure 55B

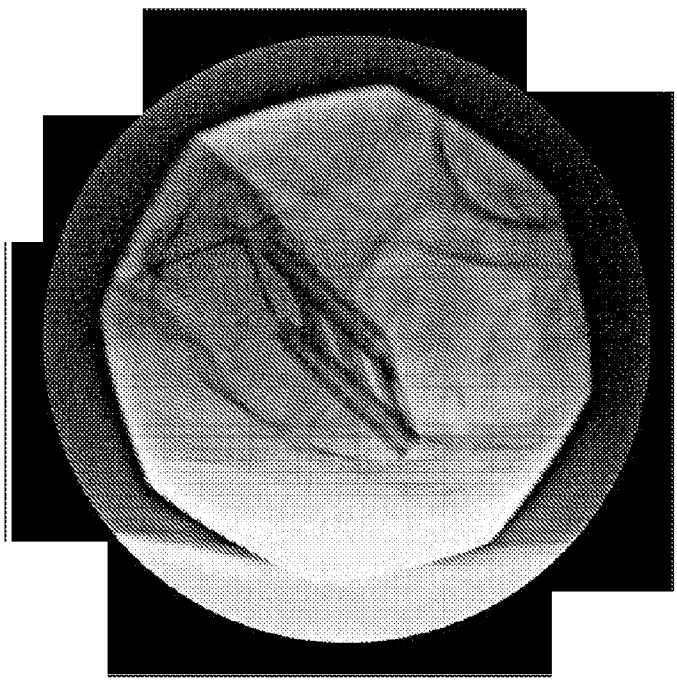


Figure 55A

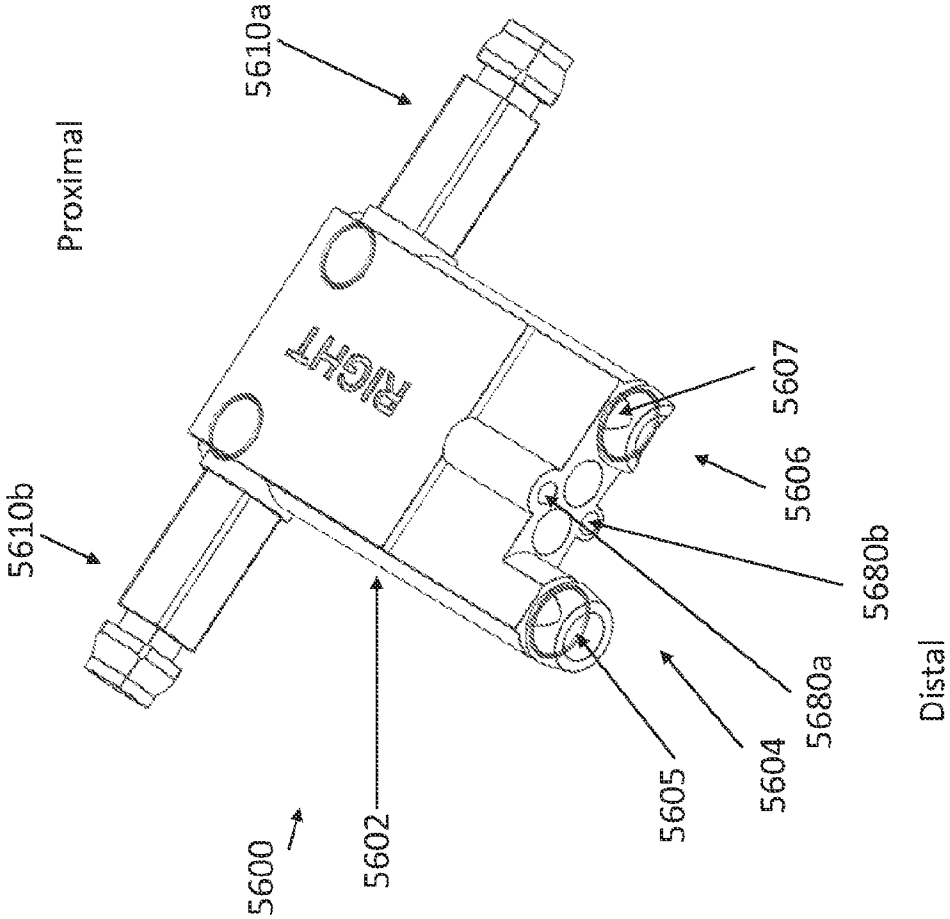


Figure 56B

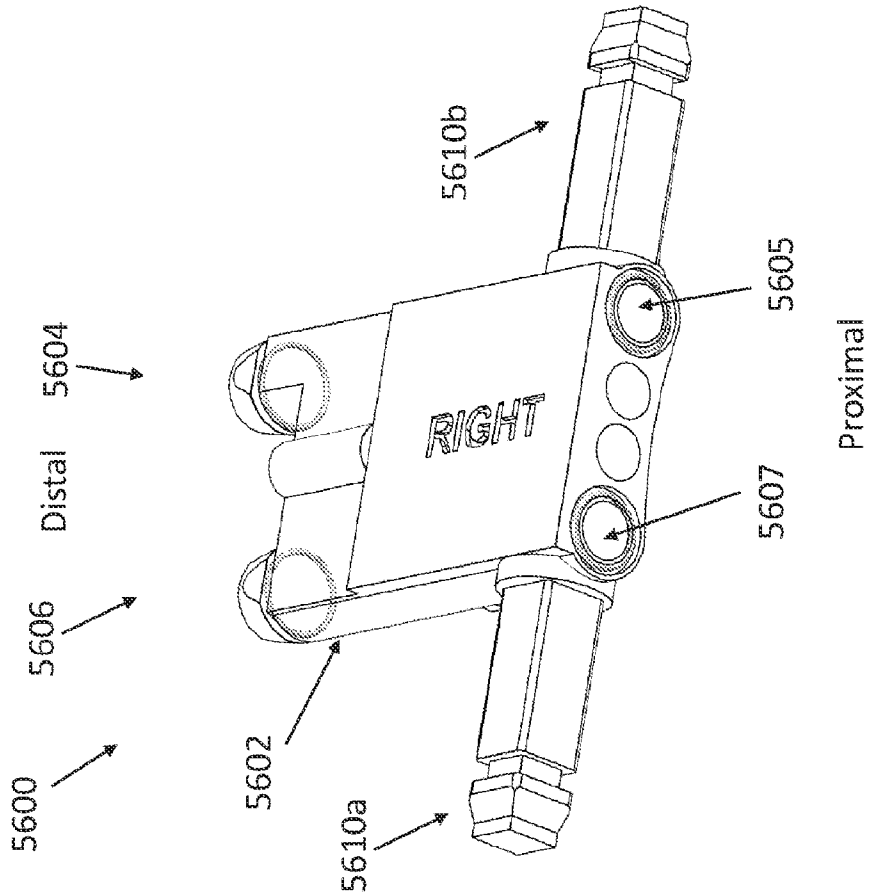


Figure 56A

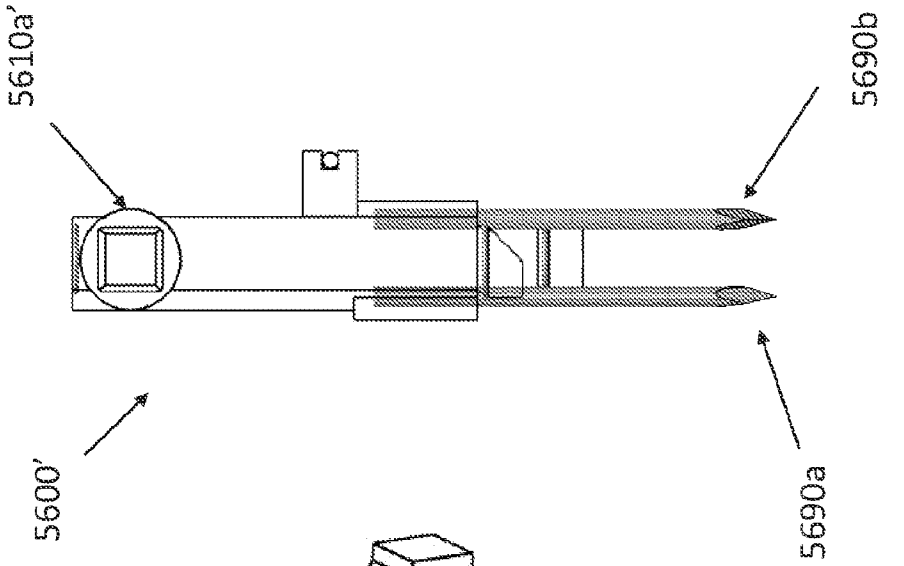


Figure 56D

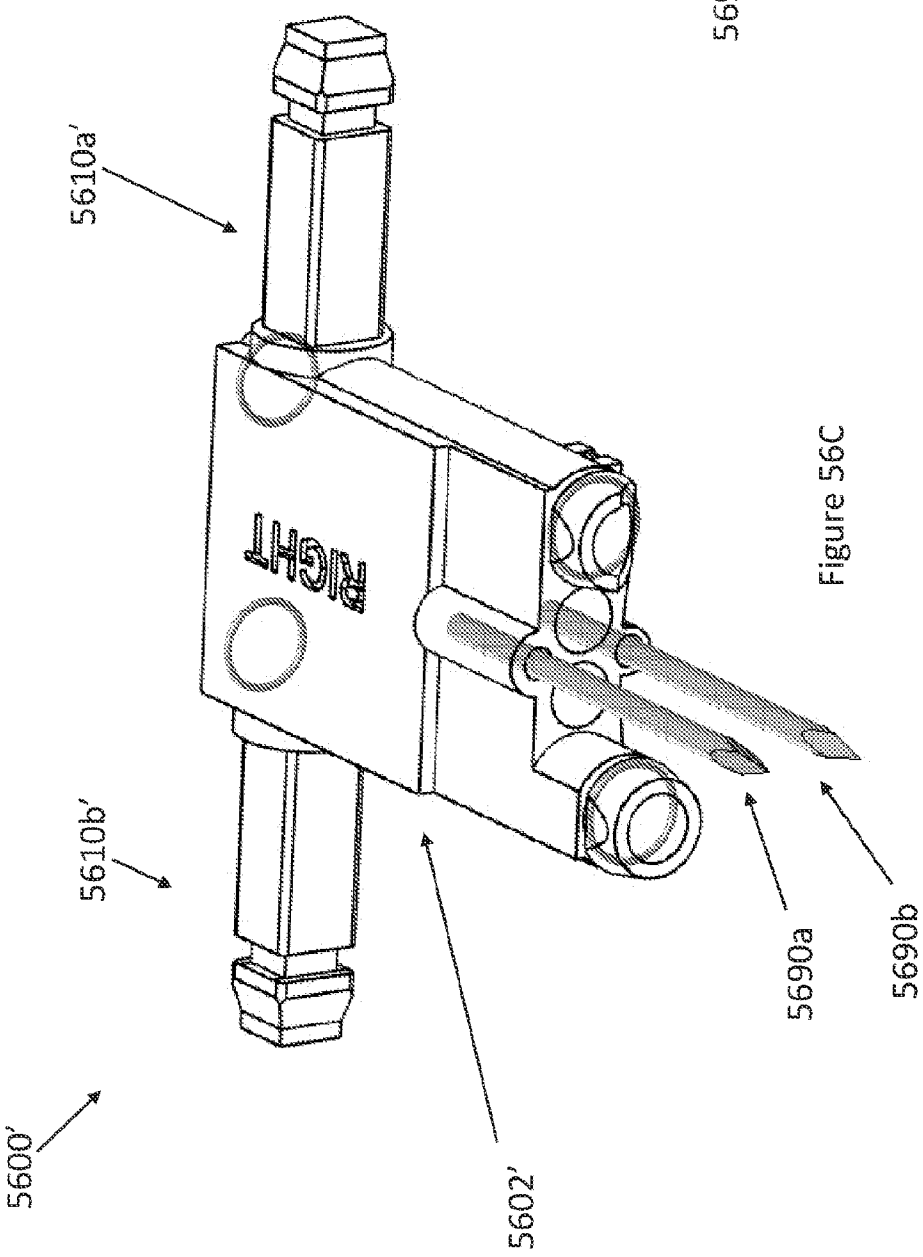


Figure 56C

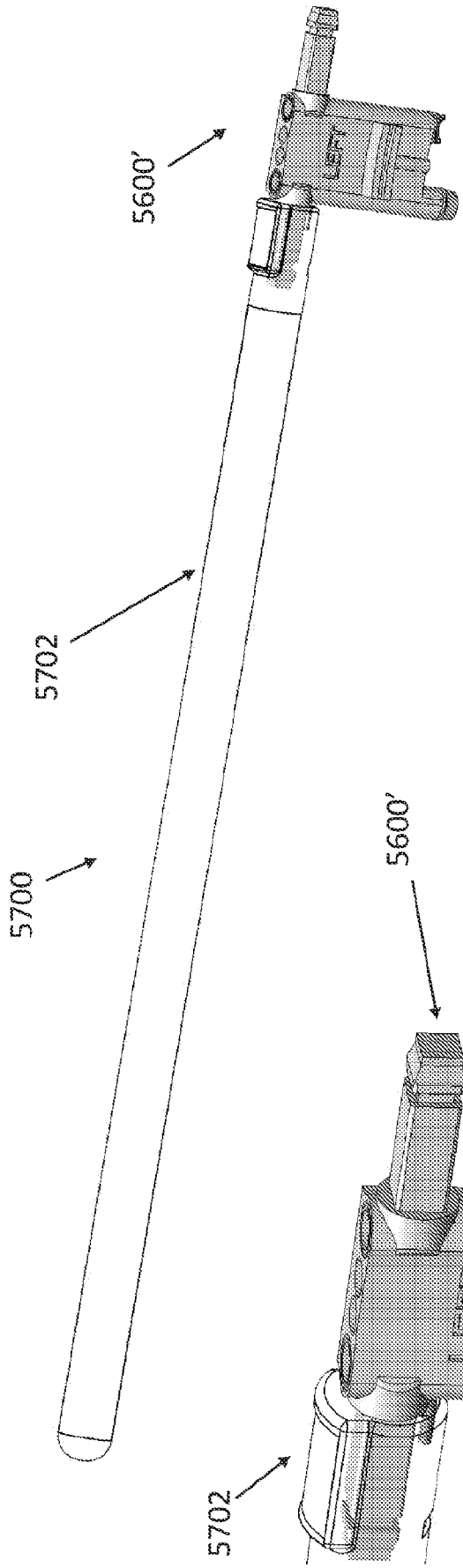


Figure 57A

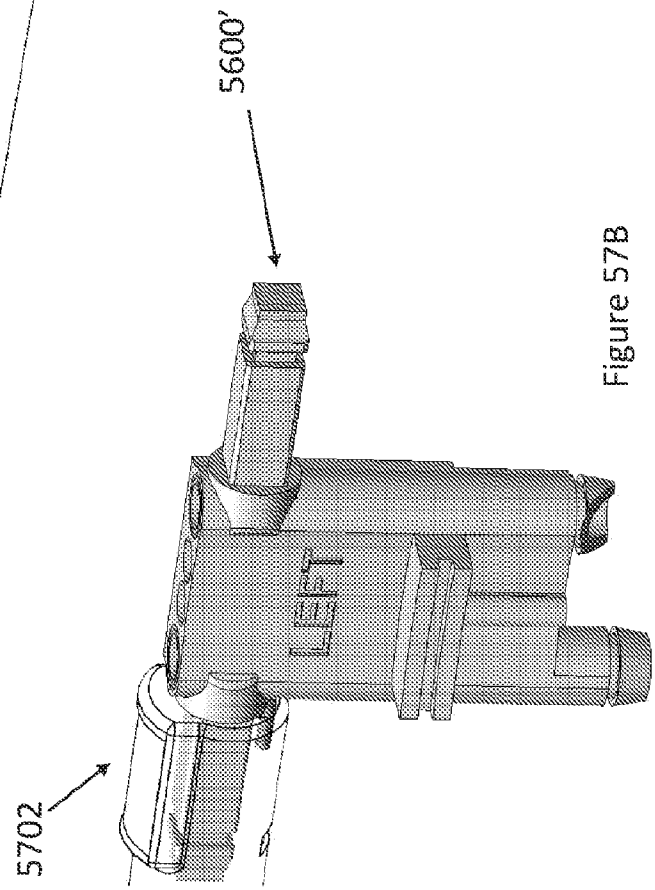


Figure 57B

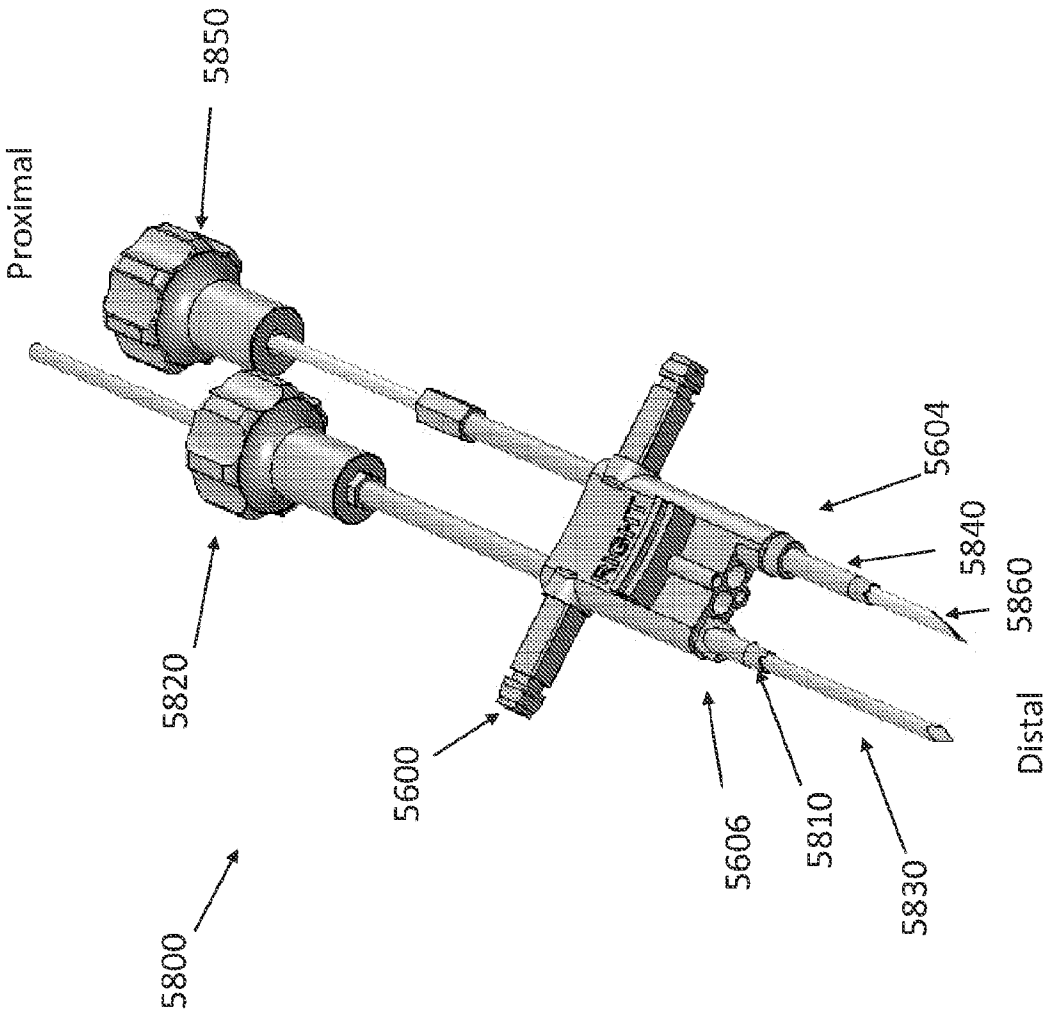

Proximal
5850
5820
5800
5600
5606
5810
5830
5604
5840
5860
Distal

Figure 58A

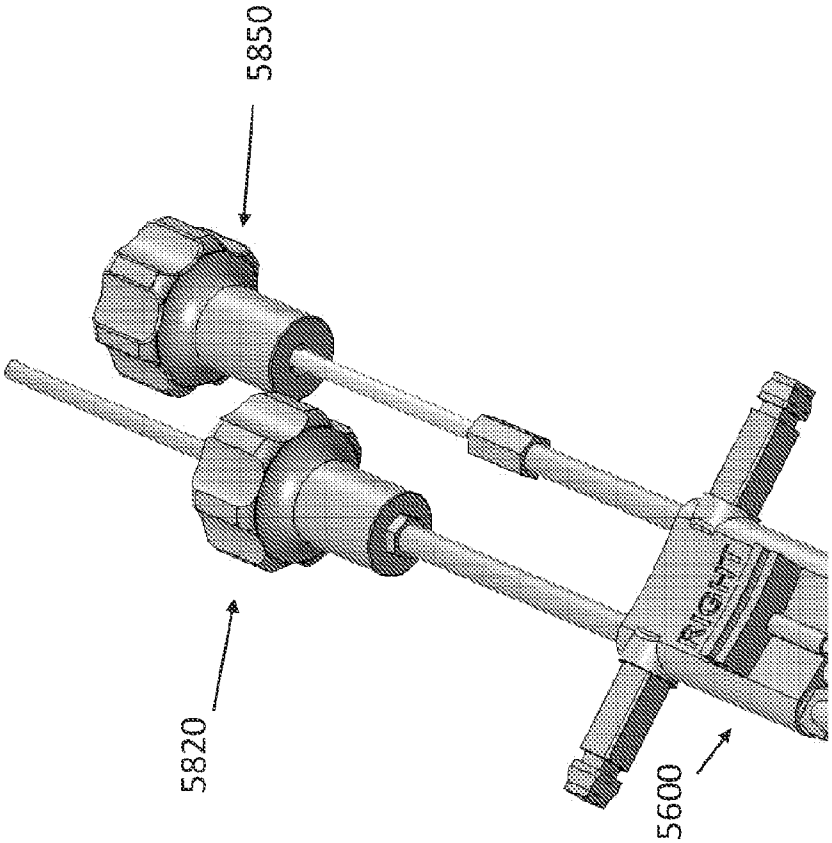


Figure 58C

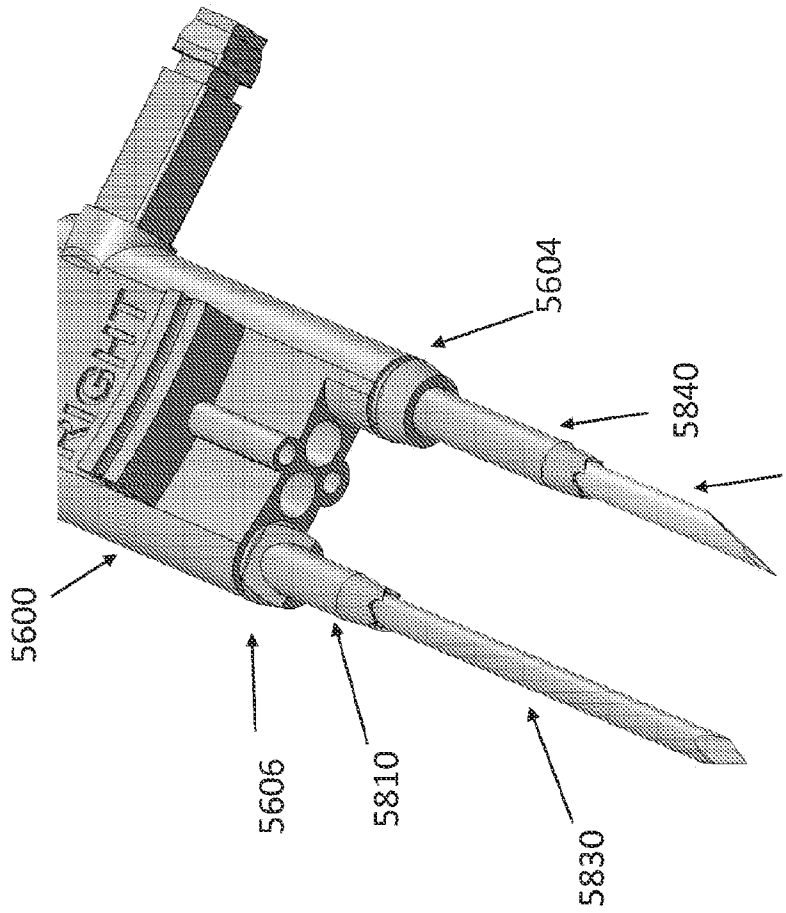


Figure 58B

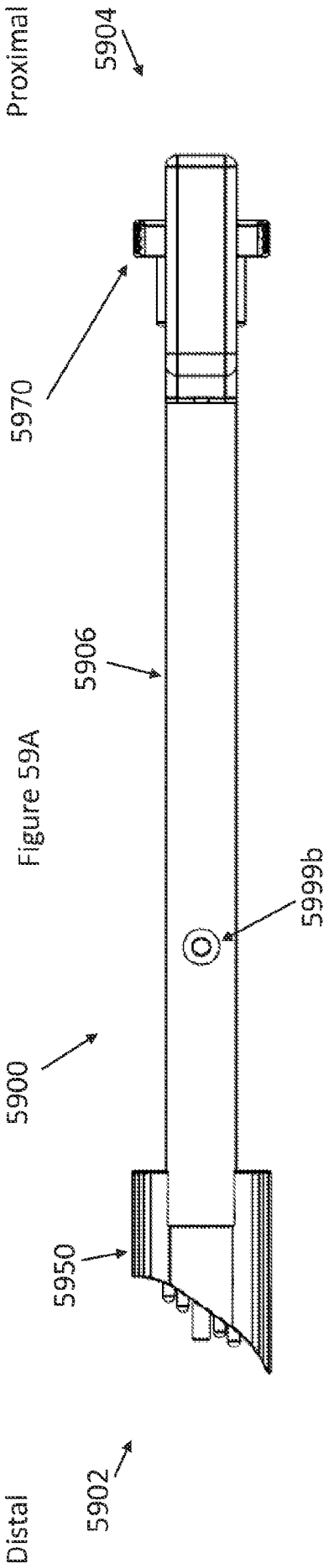


Figure 59A

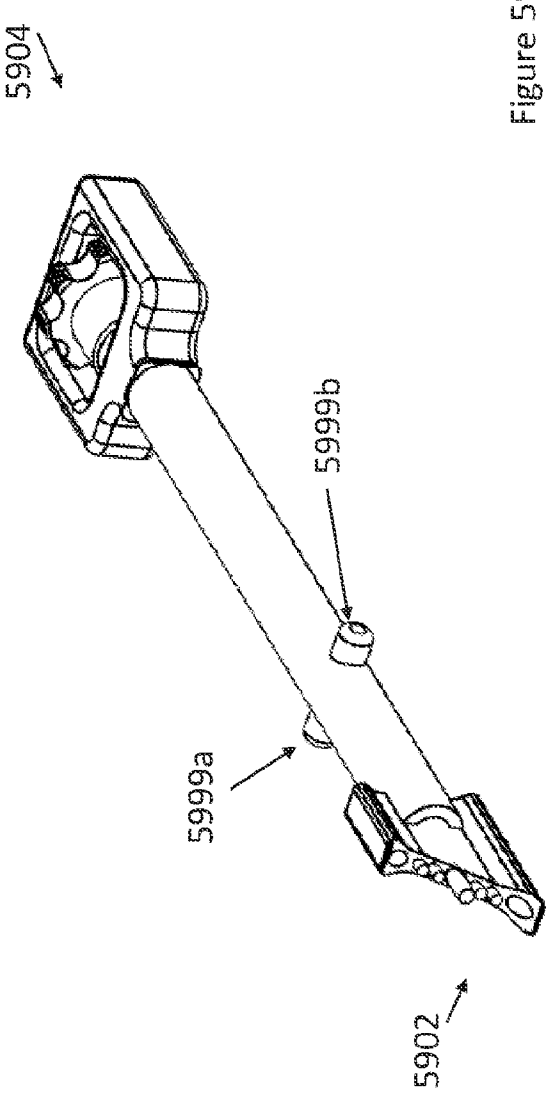


Figure 59B

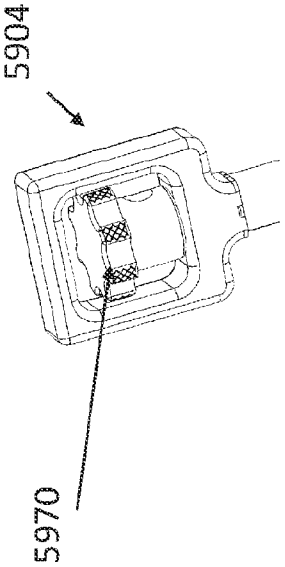


Figure 59F

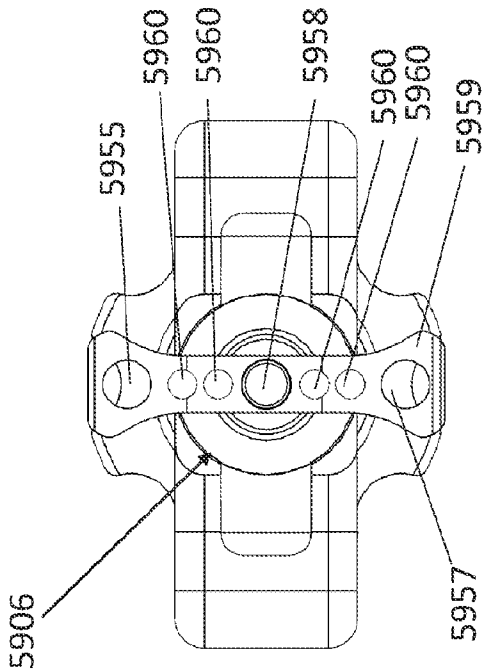


Figure 59E

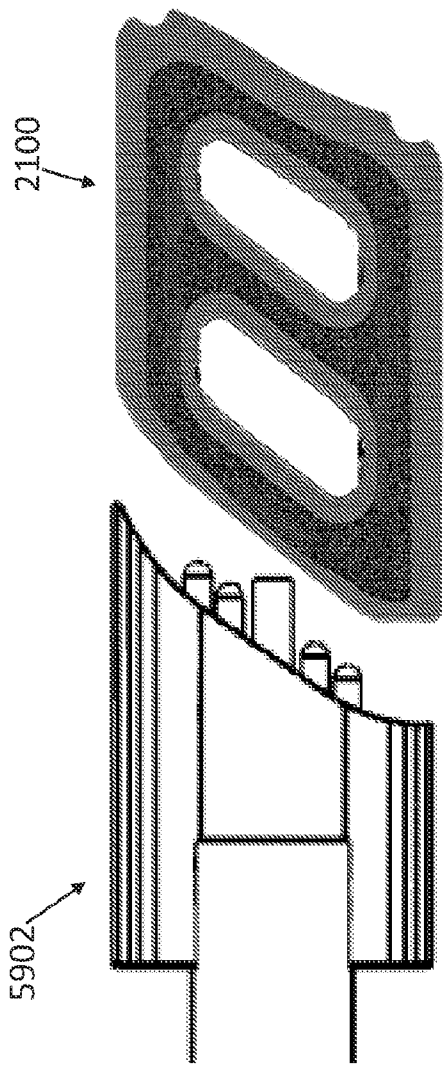


Figure 59C

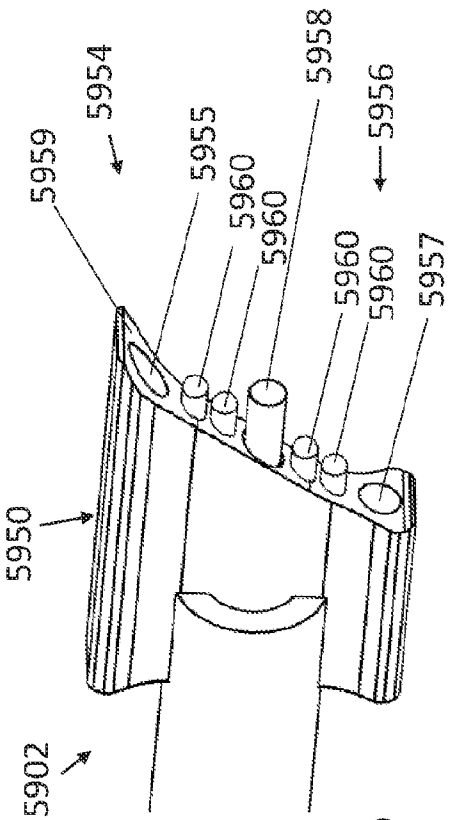


Figure 59D

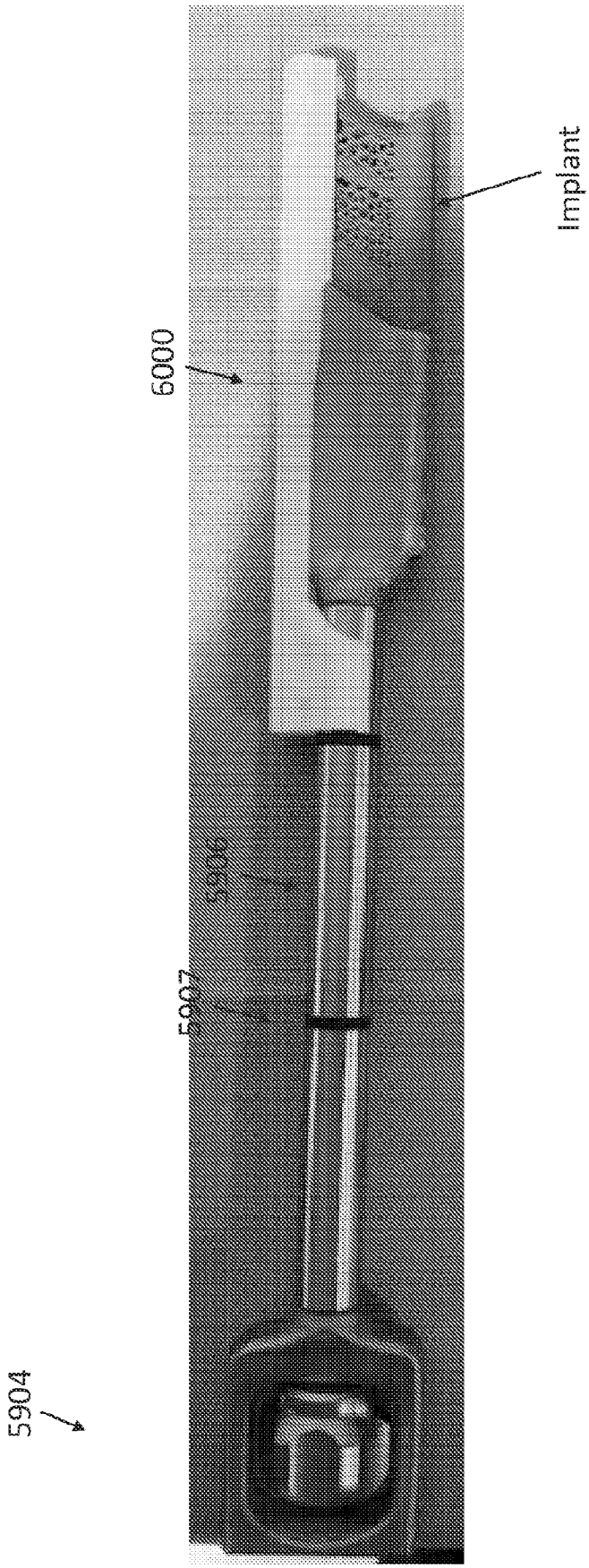


Figure 60

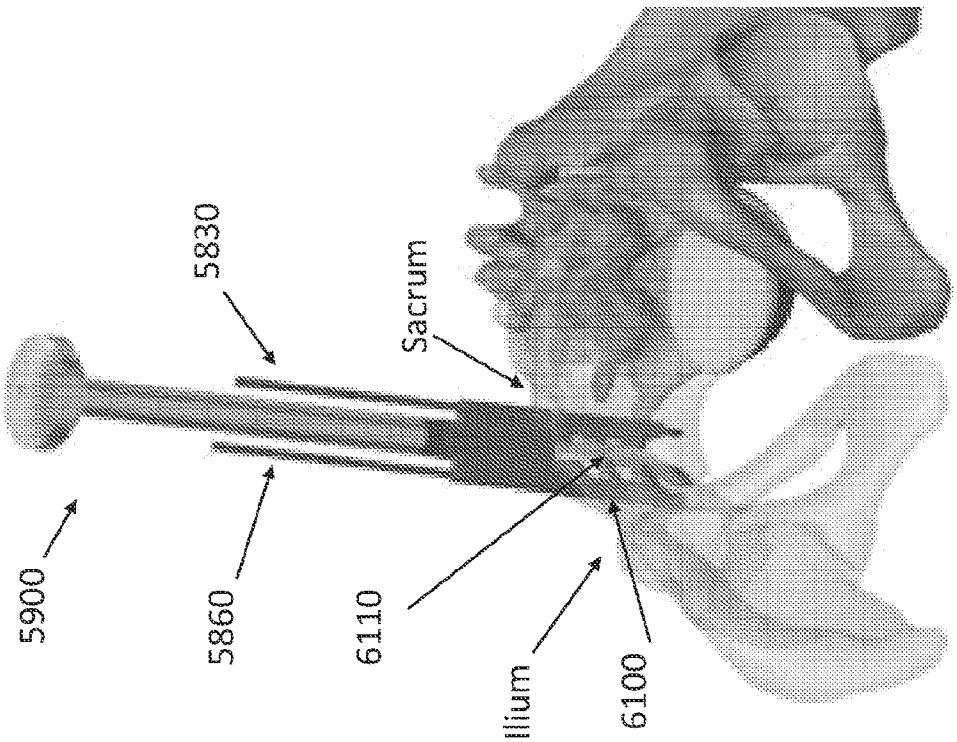


Figure 61B

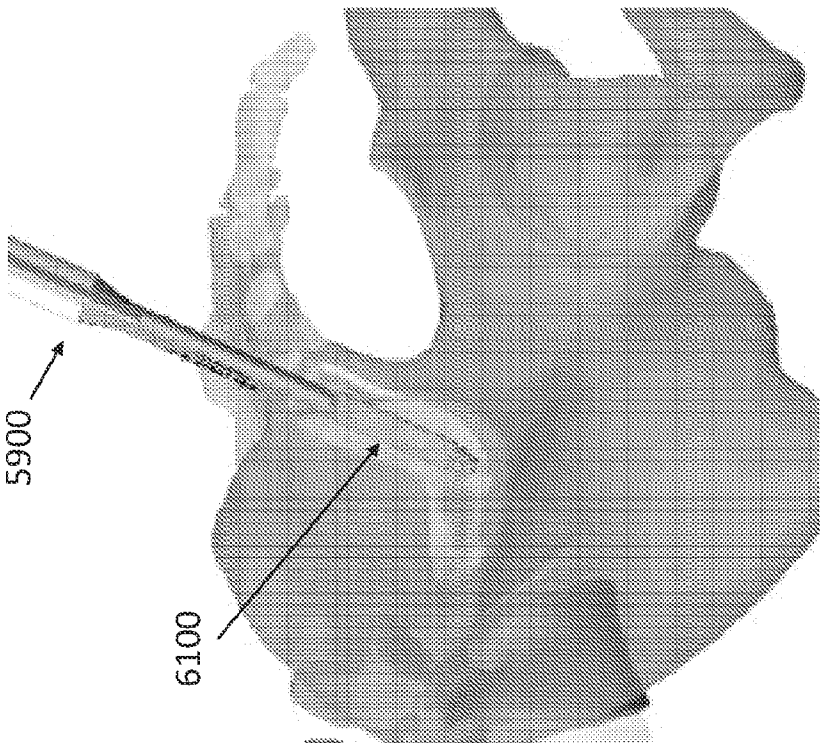


Figure 61A

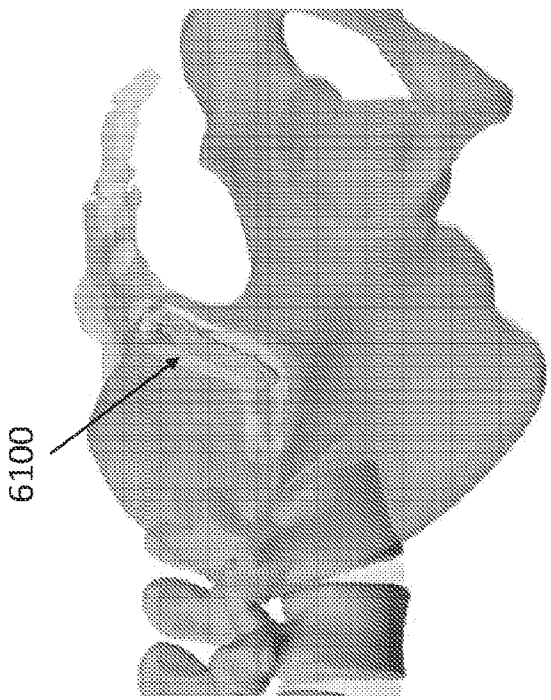


Figure 62B

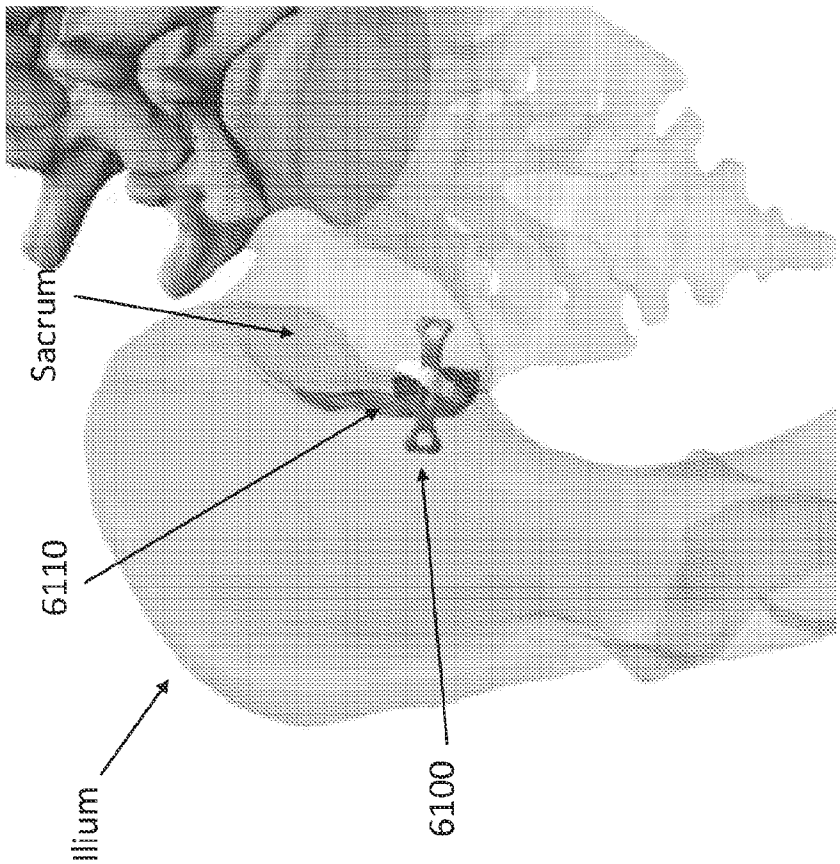


Figure 62A

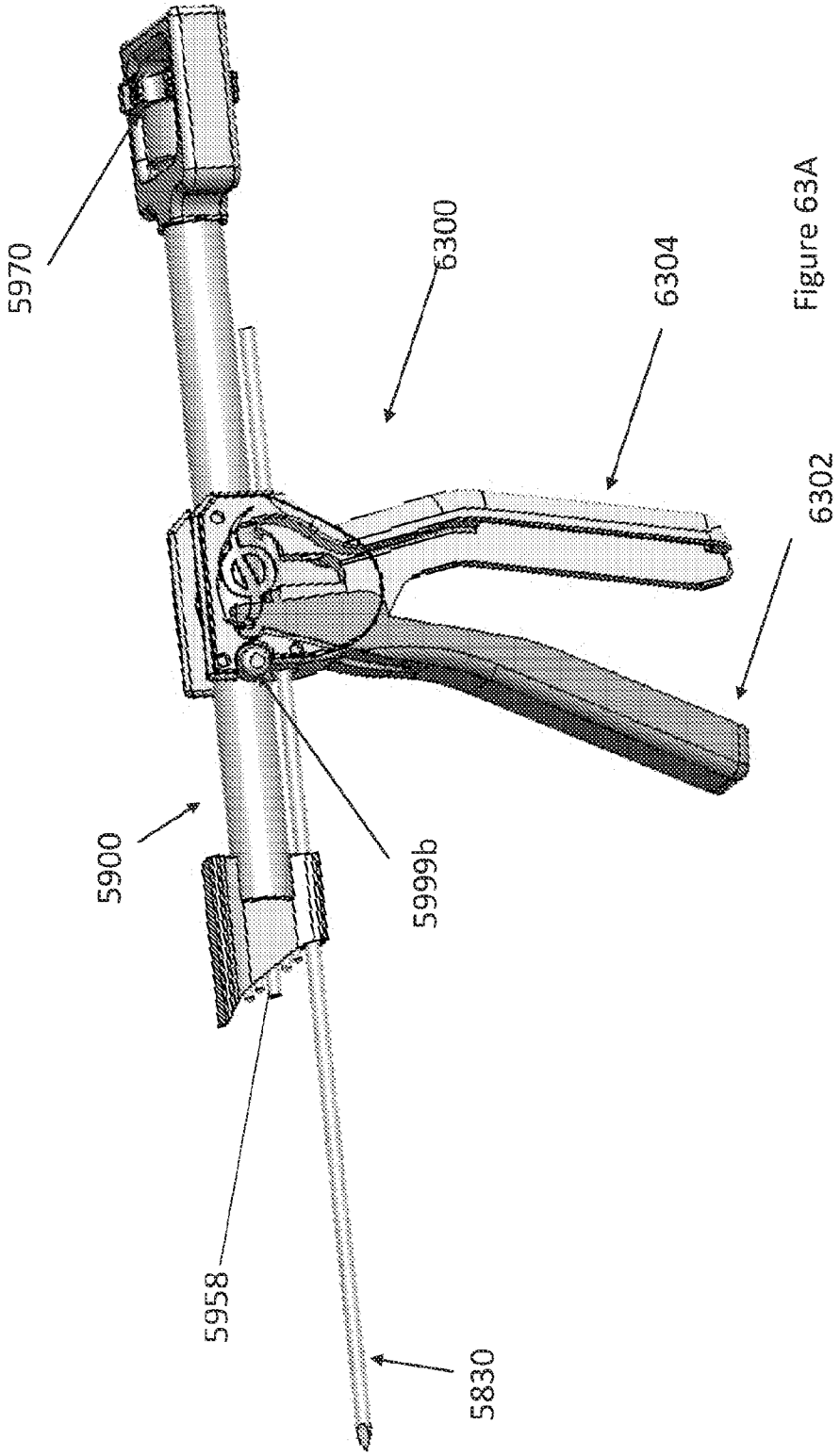


Figure 63A

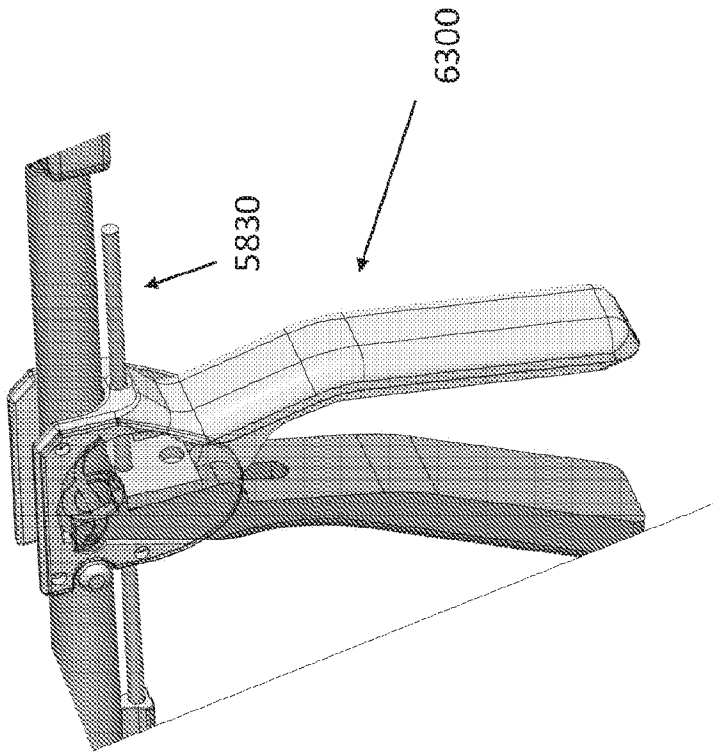


Figure 63C

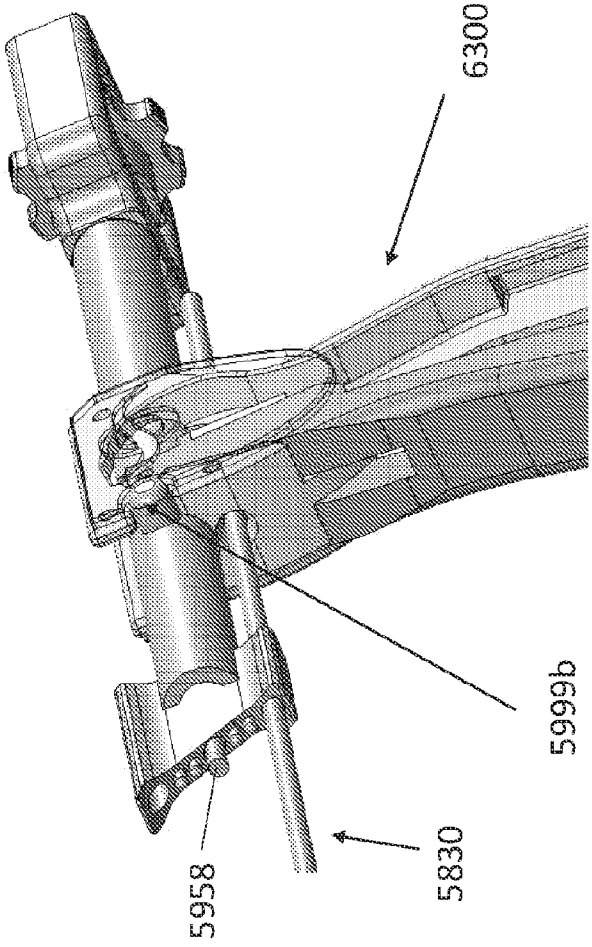


Figure 63B

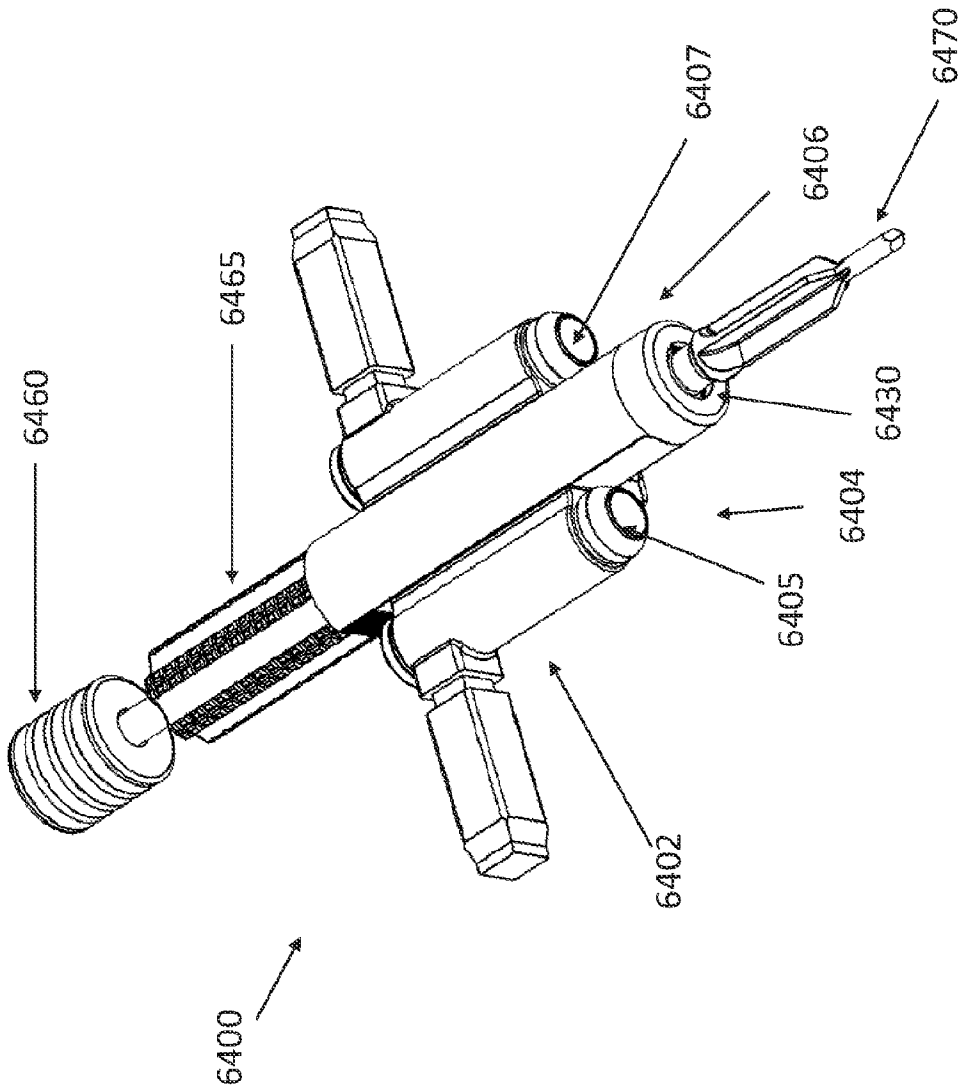


Figure 64

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/062337

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.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 45
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:

Claim 45 is held to be an omnibus claim because claim 45 fails to point out what is included or excluded by the claim language.

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:

See extra sheet(s).

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 additional fees, this Authority did not invite payment of 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.:

1-44, 46-64

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

International application No.
PCT/US2021/062337

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/68; A61B 17/70; A61B 17/88; A61B 17/90; A61F 2/28; A61F 2/30 (2022.01)
CPC - A61B 17/68; A61B 17/70; A61B 17/88; A61B 17/90; A61F 2/28; A61F 2/30 (2022.02)

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)
see Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
see Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2015/0342753 A1 (JCBD LLC) 03 December 2015 (03.12.2015) entire document	58, 61, 62 --- 44, 46, 47, 50, 52, 54, 56
Y	US 2011/0184478 A1 (REILEY) 28 July 2011 (28.07.2011) entire document	44, 46, 47, 50, 52, 54, 56
Y	US 2015/0080972 A1 (CHIN et al) 19 March 2015 (19.03.2015) entire document	50, 52, 54, 56
A	US 2018/0360608 A1 (AKSU) 20 December 2018 (20.12.2018) entire document	1-44, 46-64
A	US 2016/0184105 A1 (JCBD LLC) 30 June 2016 (30.06.2016) entire document	1-44, 46-64
P, A	US 2021/0169660 A1 (SI-BONE INC.) 10 June 2021 (10.06.2021) entire document	1-44, 46-64

☐ 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
"D" document cited by the applicant in the international application
"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	Date of mailing of the international search report
31 March 2022	APR 12 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Harry Kim Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/062337

Continued from Box No. III Observations where unity of invention is lacking

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-43, is drawn to a sacro-iliac joint stabilizing implant for implanting across a SI joint from a dorsal approach, comprising: an implant body having a wafer configuration with a width dimension greater than a height dimension.

Group II, claims 44-57, 58-64, is drawn to a method of positioning a sacro-iliac ("SI") joint stabilizing implant across an SI joint from a dorsal approach, comprising: advancing an elongate sacrum pin from a dorsal starting point into a sacrum of a subject such that a distal end of the sacrum pin is in the sacrum and a proximal end of the sacrum pin is disposed outside of the subject.

Group III, claims 65-69, 78-82, is drawn to a method of securing an SI-joint implant to an impactor, comprising: causing a proximal end of the SI joint implant to be brought adjacent to distal end of the impactor.

Group IV, claims 58-64, 70-77, is drawn to a pin guide adapted for placing pin guides into an ilium and a sacrum in a dorsal approach, comprising: a pin guide body.

The inventions listed as Groups I, II, III or IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention: an implant body having a wafer configuration with a width dimension greater than a height dimension, the implant body including, a central joint portion for placement across the SI joint; an ilium portion on a first side of the central joint portion, the ilium portion sized and configured for implanting into an ilium when the implant is implanted across a SI joint from a dorsal approach, a sacrum portion on a second side of the central joint portion, the sacrum portion sized and configured for implanting into a sacrum when the implant is implanted across the SI joint from the dorsal approach, the ilium portion comprising an elongate ilium lumen extending from a distal opening to a proximal opening and having an ilium lumen longitudinal axis, the ilium lumen sized and configured to receive therein an ilium positioning guide, the sacrum portion comprising an elongate sacrum lumen extending from a distal opening to a proximal opening and having a sacrum lumen longitudinal axis, the sacrum lumen sized and configured to receive therein a sacrum positioning guide, with reference to a line that is orthogonal to the ilium lumen axis and the sacrum lumen axis, the sacrum portion extends further proximally than the ilium portion, and the ilium portion extends further distally than the sacrum portion, with reference to the line as claimed therein is not present in the invention of Groups II, III or IV. The special technical feature of the Group II invention: advancing an elongate sacrum pin from a dorsal starting point into a sacrum of a subject such that a distal end of the sacrum pin is in the sacrum and a proximal end of the sacrum pin is disposed outside of the subject; advancing an elongate ilium pin from a dorsal starting point into an ilium of the subject such that a distal end of the ilium pin is in the ilium and a proximal end of the ilium pin is disposed outside of the subject; advancing a distal opening of an ilium lumen that is in an ilium portion of an SI joint stabilizing implant over the ilium pin so as to restrict movement of the implant with respect to the ilium pin in at least one direction; advancing a distal opening of a sacrum lumen that is in a sacrum portion of the SI joint stabilizing implant over the sacrum pin so as to restrict movement of the implant with respect to the sacrum pin in at least one direction; advancing the implant distally over and relative to the sacrum pin and the ilium pin until the implant is across the SI joint with the ilium portion in the ilium and the sacrum portion in the sacrum; and removing the ilium pin and the sacrum pin from the subject, and leaving the implant positioned across the SI joint as claimed therein is not present in the invention of Groups I, III or IV. The special technical feature of the Group III invention: causing a proximal end of the SI joint implant to be brought adjacent to distal end of the impactor; and engaging a first securing element on the impactor with a second securing element disposed in a proximal region of the implant to secure the implant to the impactor and cause the implant to move with the impactor as claimed therein is not present in the invention of Groups I, II or IV. The special technical feature of the Group IV invention: 70A pin guide adapted for placing pin guides into an ilium and a sacrum in a dorsal approach, comprising: a pin guide body, the pin body comprising a lateral ilium side with an axially extending ilium lumen, a lateral sacrum side with an axially extending sacrum lumen that is parallel with the ilium lumen as claimed therein is not present in the invention of Groups I, II or III.

Groups I, II, III, and IV lack unity of invention because even though the inventions of these groups require the technical feature of a sacro-iliac joint stabilizing implant for implanting across a SI joint from a dorsal approach, comprising: an implant body including an ilium portion and a sacrum portion, this technical feature is not a special technical feature as it does not make a contribution over the prior art.

Specifically, US 2017/0325845 to JCBD, LLC teaches a sacro-iliac joint stabilizing implant for implanting across a SI joint from a dorsal approach, comprising: an implant body including an ilium portion and a sacrum portion (FIG. 3 is a posterior view of an ilium 1005 and sacrum 1004 forming a sacroiliac joint 1000. The implant assembly 15 is installed in the sacroiliac joint 1000 and secured in place by the anchor 30, which extends from the sacrum 1004 to the ilium 1005 in this embodiment. A rod 2096 from a spinal stabilization system may be attached to an attachment fitting 500 of the implant system 15 and locked into place, thereby providing a robust anchor for the spinal stabilization system, para. 0122. the insertion angle Φ may be directed in any direction without limitation including, but not limited to anterior, lateral, medial, cranial, caudal, anterior, posterior, ventral, dorsal, para. 0183).

Since none of the special technical features of the Group I, II, III, or IV inventions are found in more than one of the inventions, unity of invention is lacking.