US011284798B2

(12) **United States Patent**
Donner et al.

(10) **Patent No.: US 11,284,798 B2**
(45) **Date of Patent: Mar. 29, 2022**

(54) **SYSTEMS FOR AND METHODS OF DIAGNOSING AND TREATING A SACROILIAC JOINT DISORDER**

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(72) Inventors: **Edward Jeffrey Donner**, Fort Collins, CO (US); **Christopher Thomas Donner**, Fort Collins, CO (US); **Hai Trieu**, Cordova, TN (US); **Taylor Davis**, Atlanta, GA (US); **Brian VanHiel**, Atlanta, GA (US)

(73) Assignee: **JCBD, LLC**, Fort Collins, CO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 267 days.

(21) Appl. No.: **16/282,114**

(22) Filed: **Feb. 21, 2019**

(65) **Prior Publication Data**

US 2019/0209011 A1 Jul. 11, 2019

Related U.S. Application Data

(63) Continuation-in-part of application No. 15/789,602, filed on Oct. 20, 2017, now Pat. No. 10,492,688,
(Continued)

(51) **Int. Cl.**

A61B 17/88	(2006.01)
A61B 17/17	(2006.01)
A61B 17/70	(2006.01)
A61B 5/00	(2006.01)
A61B 17/84	(2006.01)
A61B 17/02	(2006.01)

(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/0057*** (2013.01); ***A61B 5/4528*** (2013.01); ***A61B 5/4571*** (2013.01); ***A61B 17/1757*** (2013.01); ***A61B 17/7055*** (2013.01); ***A61B 17/7077*** (2013.01); ***A61B 17/84*** (2013.01); ***A61B 17/8872*** (2013.01); *A61B 5/6847* (2013.01); *A61B 5/6891* (2013.01); *A61B 17/90* (2021.08); *A61B 2017/0275* (2013.01); *A61F 2002/30995* (2013.01)

(58) **Field of Classification Search**
CPC ... A61B 5/0057; A61B 5/4528; A61B 5/4571; A61B 5/6847; A61B 5/6891; A61B 17/1757; A61B 17/7055; A61B 17/7077; A61B 17/84; A61B 17/8872; A61B 2017/0275; A61B 2017/90; A61F 2002/30995
USPC 623/17.11, 18.11; 606/279, 90, 102, 105
See application file for complete search history.

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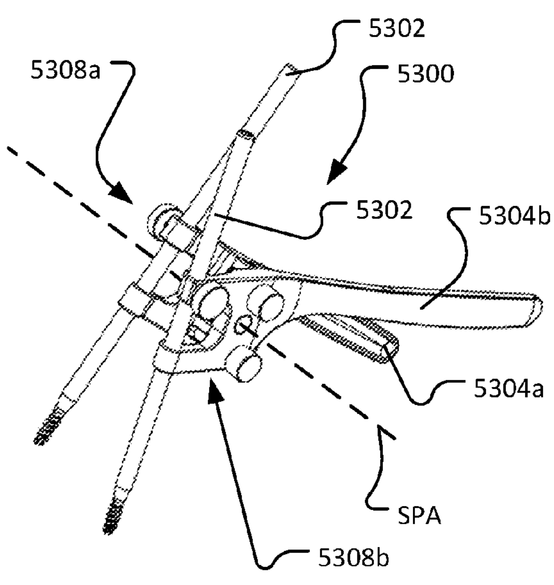
Primary Examiner — Eduardo C Robert
Assistant Examiner — David C Comstock
(74) *Attorney, Agent, or Firm* — Polsinelli PC; Joshua J. Pranckun; Samuel Wade Johnson

(57) **ABSTRACT**

A method of diagnosing and treating a sacroiliac joint of a patient involving delivering a first member into the ilium via a first posterior approach, delivering a second member into the sacrum via a second posterior approach, coupling the first and second members to a pliers, and manipulating the first member relative to the second member via the pliers to determine an ailment of the sacroiliac joint.

14 Claims, 91 Drawing Sheets



Related U.S. Application Data

which is a continuation of application No. 14/723,384, filed on May 27, 2015, now Pat. No. 9,801,546.

(60) Provisional application No. 62/633,205, filed on Feb. 21, 2018, provisional application No. 62/003,053, filed on May 27, 2014.

(51) **Int. Cl.**

A61F 2/30	(2006.01)
A61B 17/90	(2006.01)

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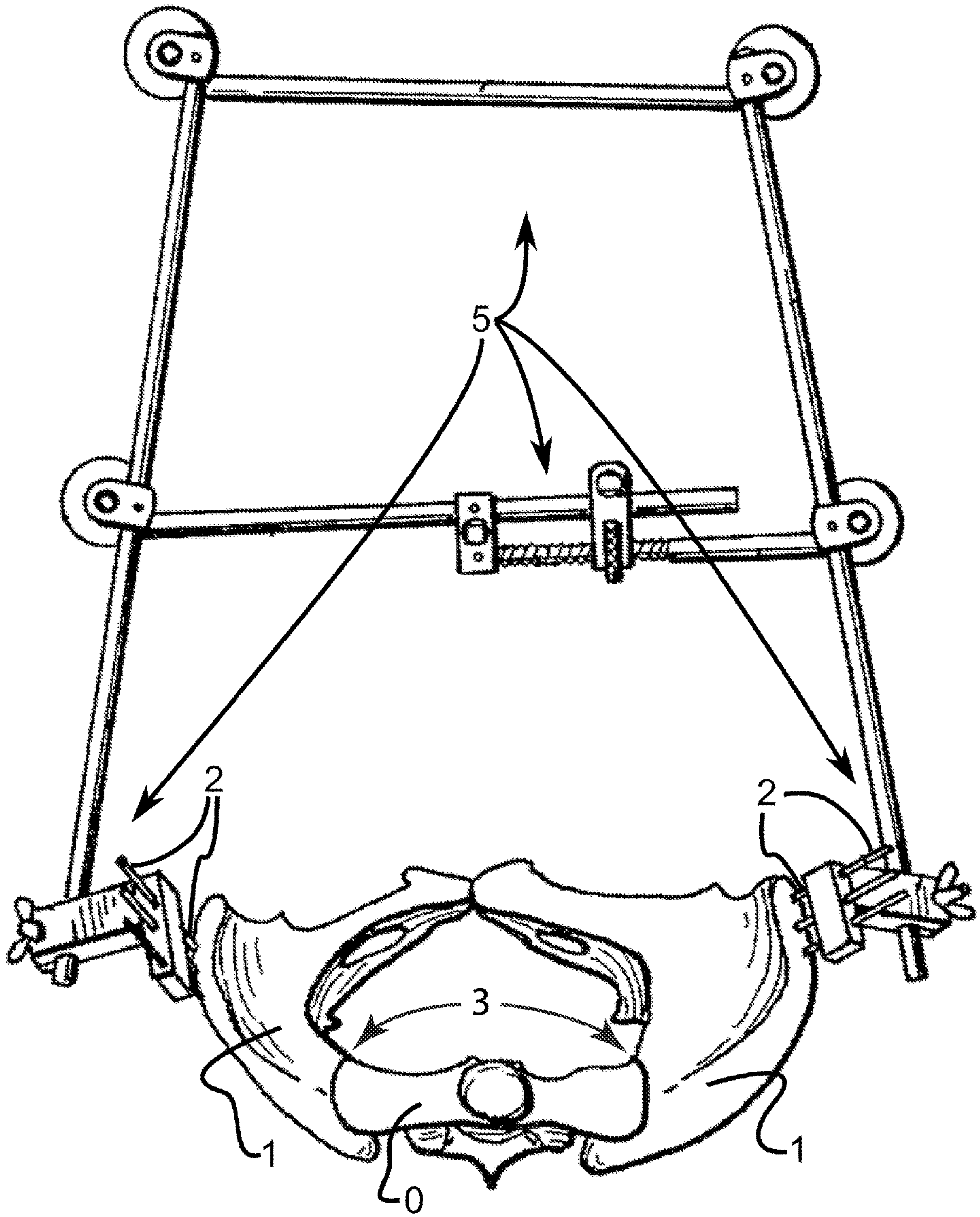

FIG.1A
(CONVENTIONAL ART)

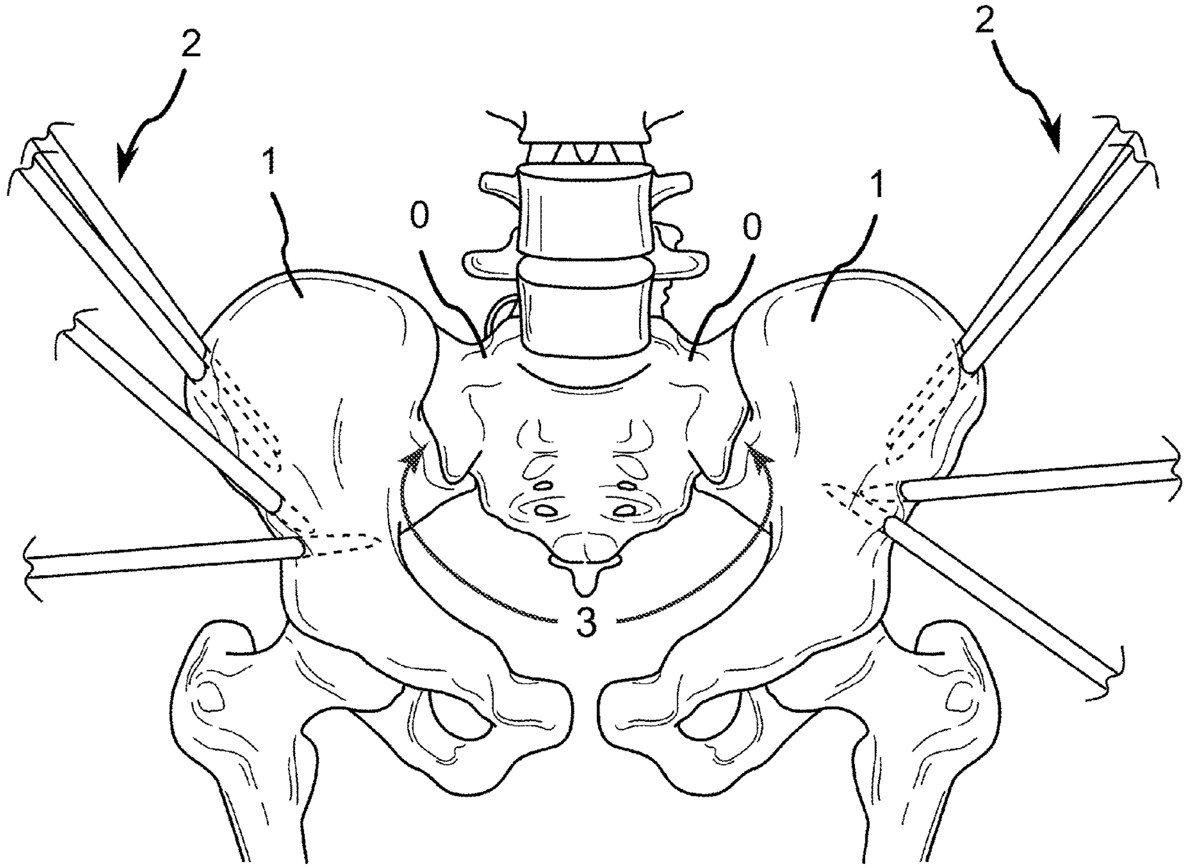

FIG.1B
(CONVENTIONAL ART)

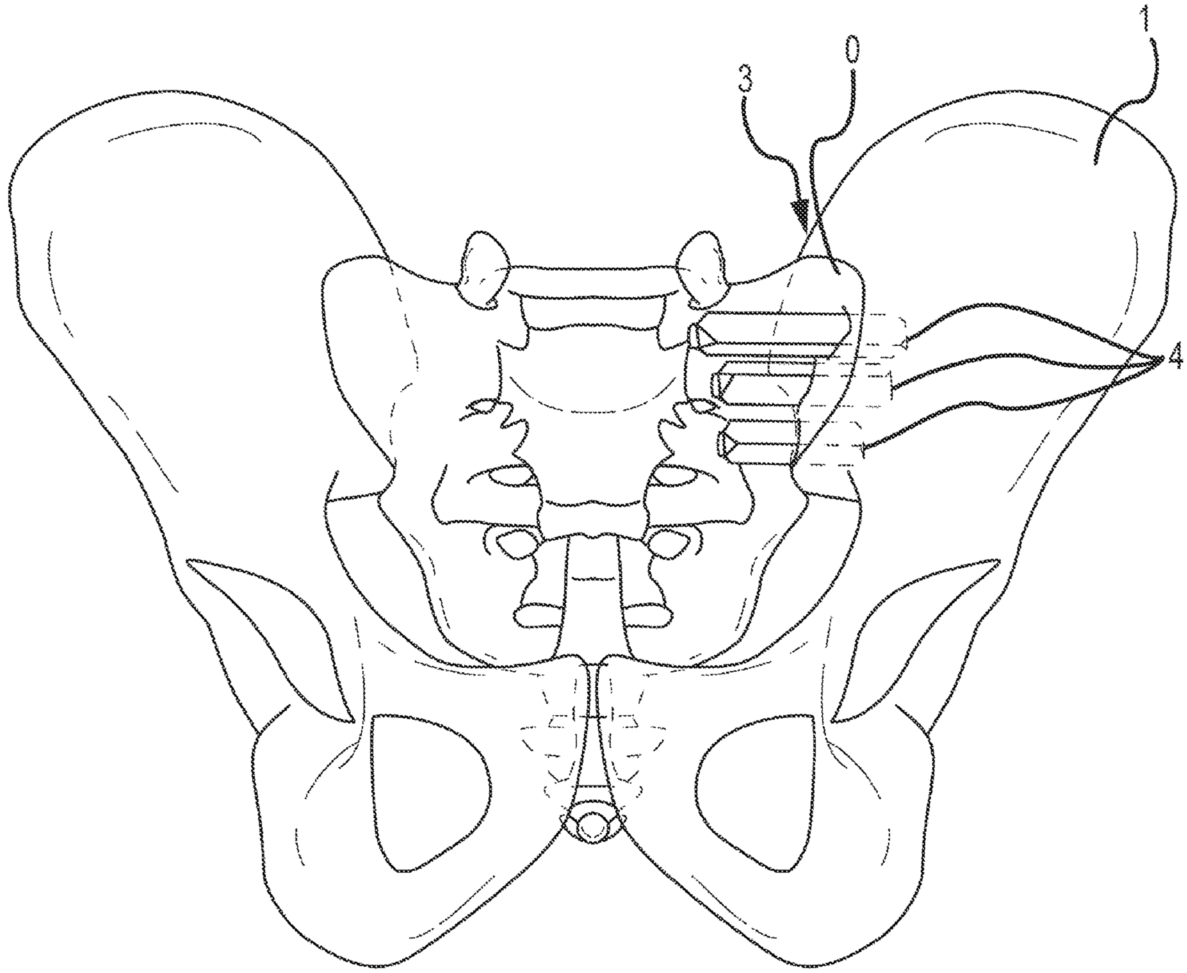

FIG.1C
(CONVENTIONAL ART)

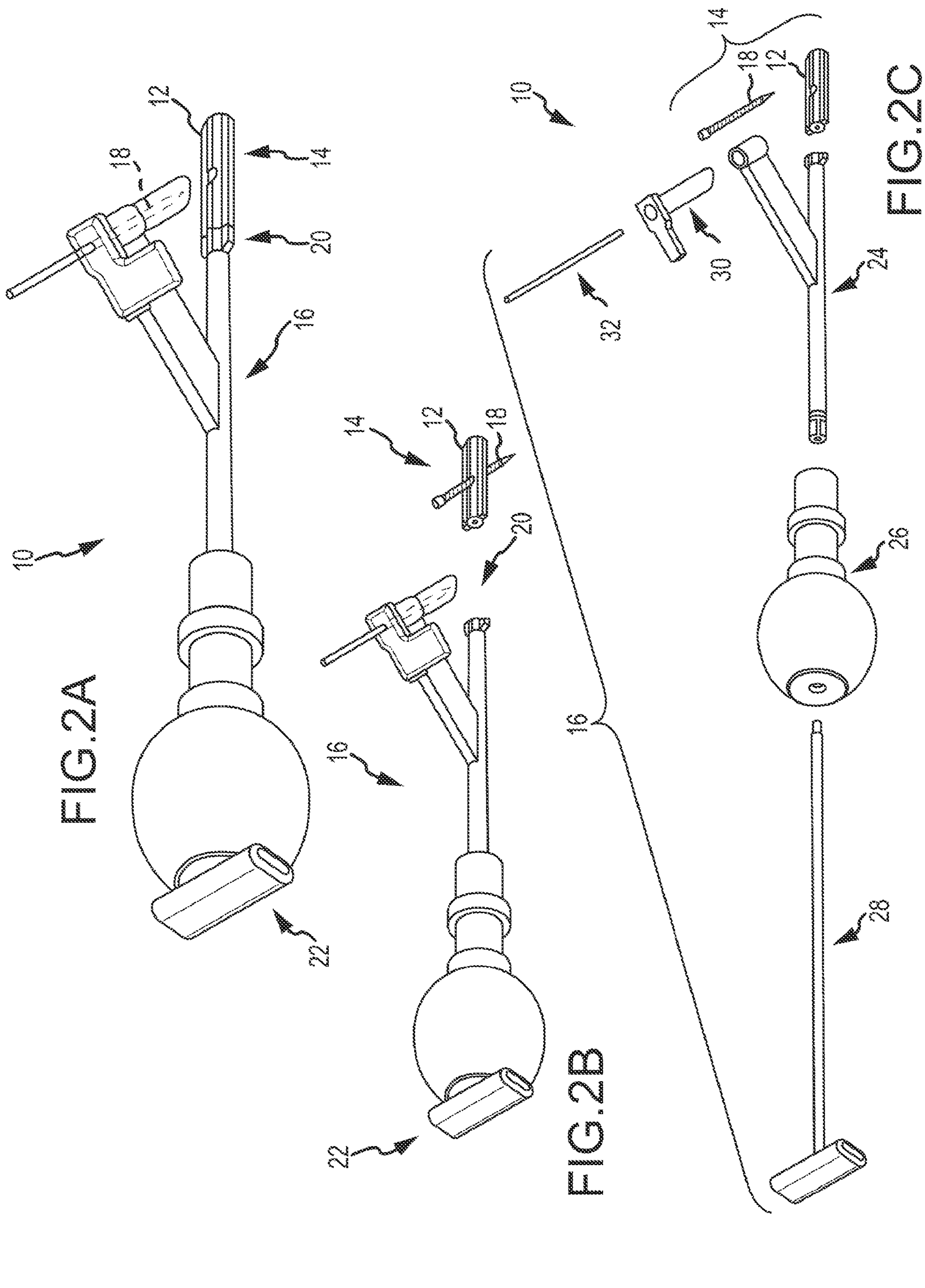

FIG.2A

FIG.2B

FIG.2C

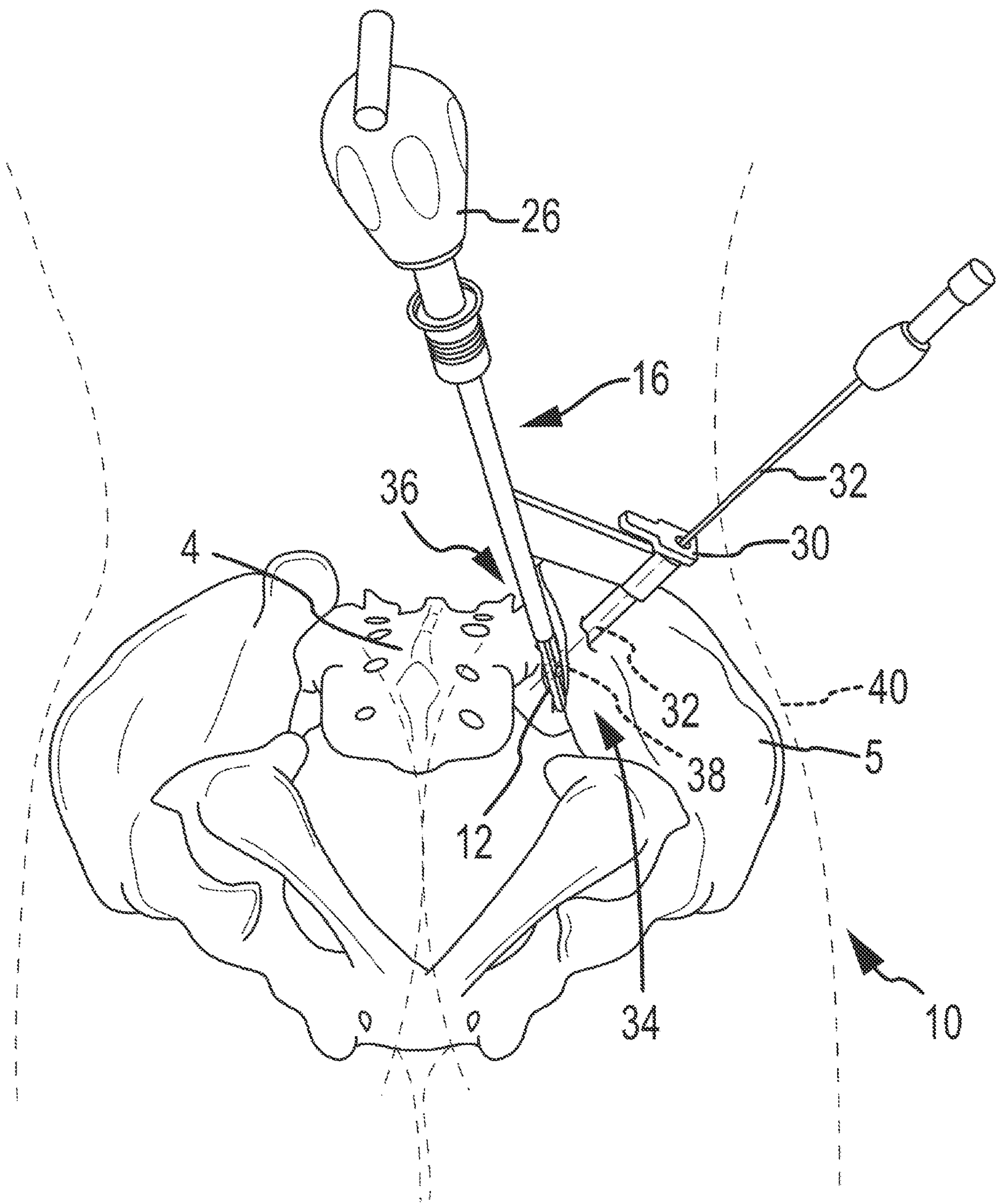

FIG. 3

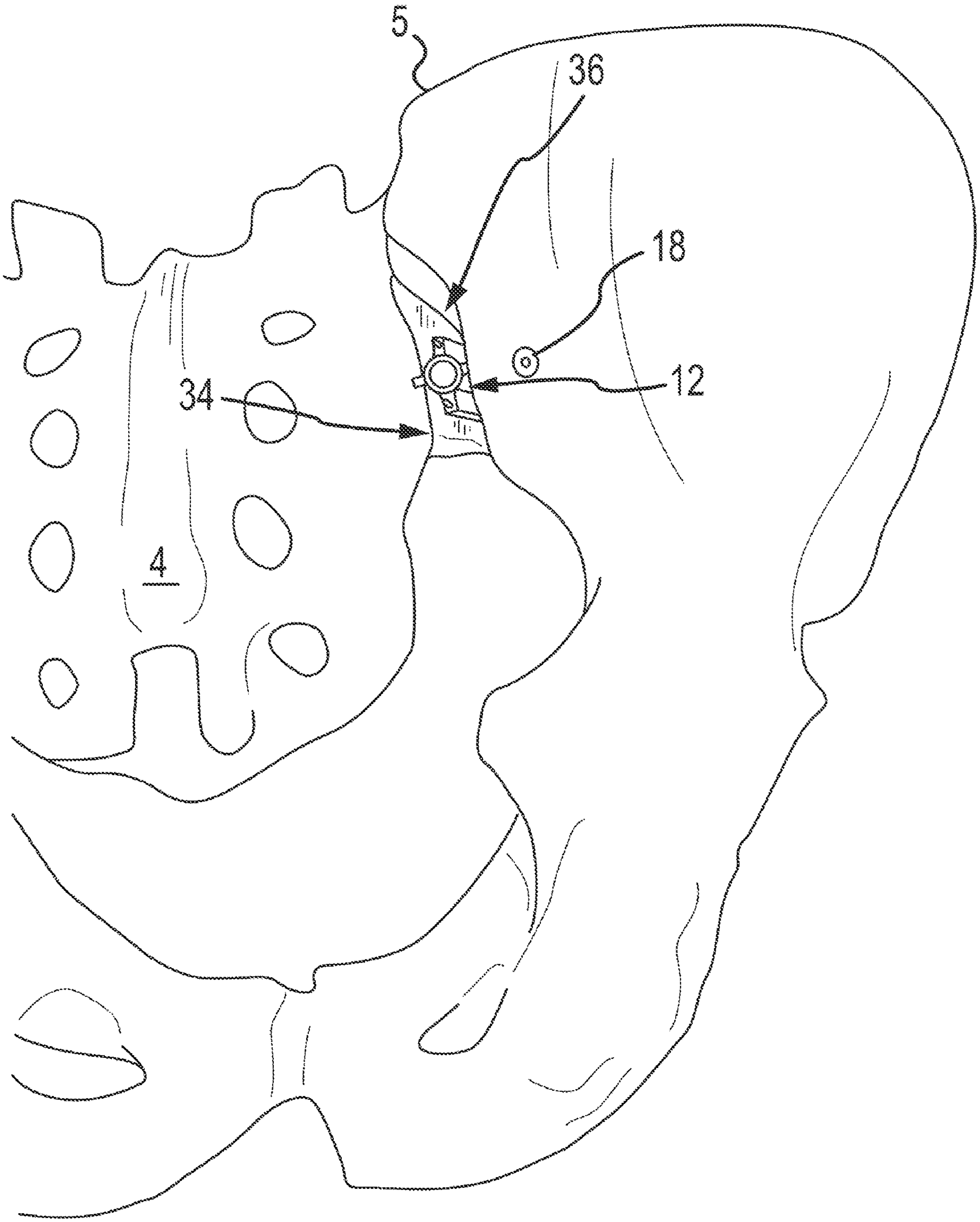

FIG. 4

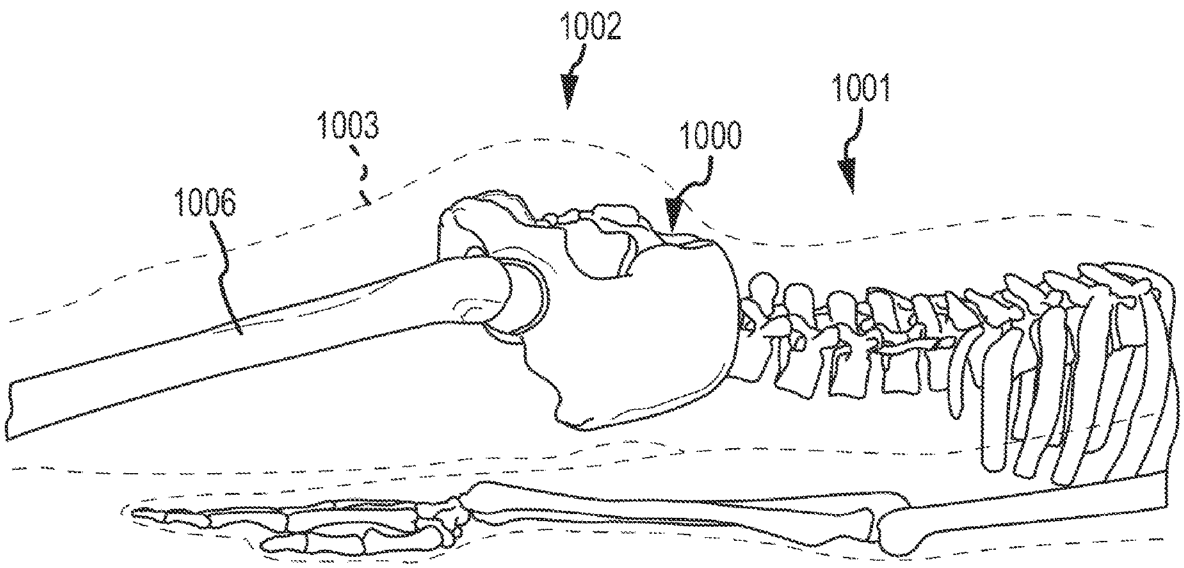

FIG. 5A

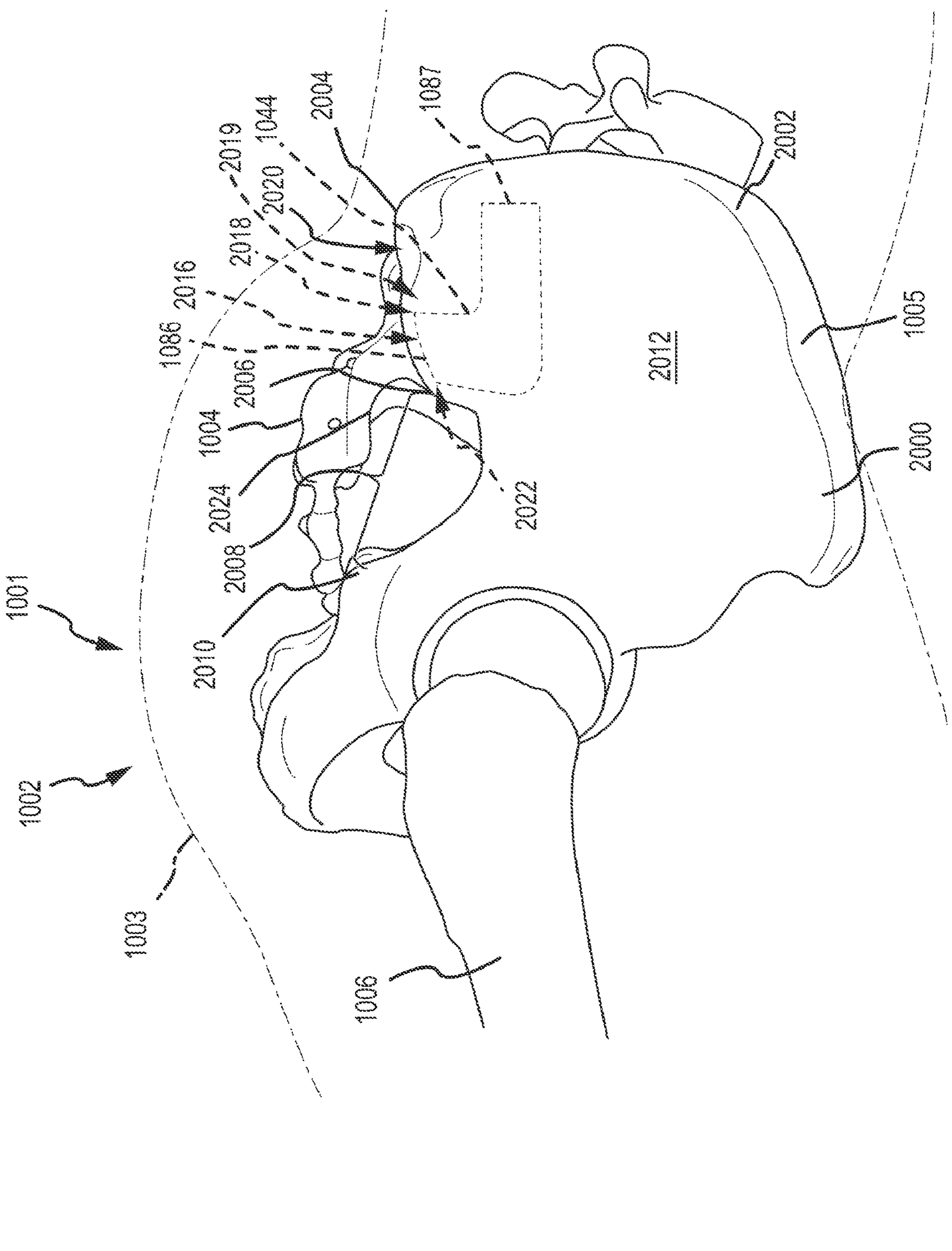

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FIG. 5B

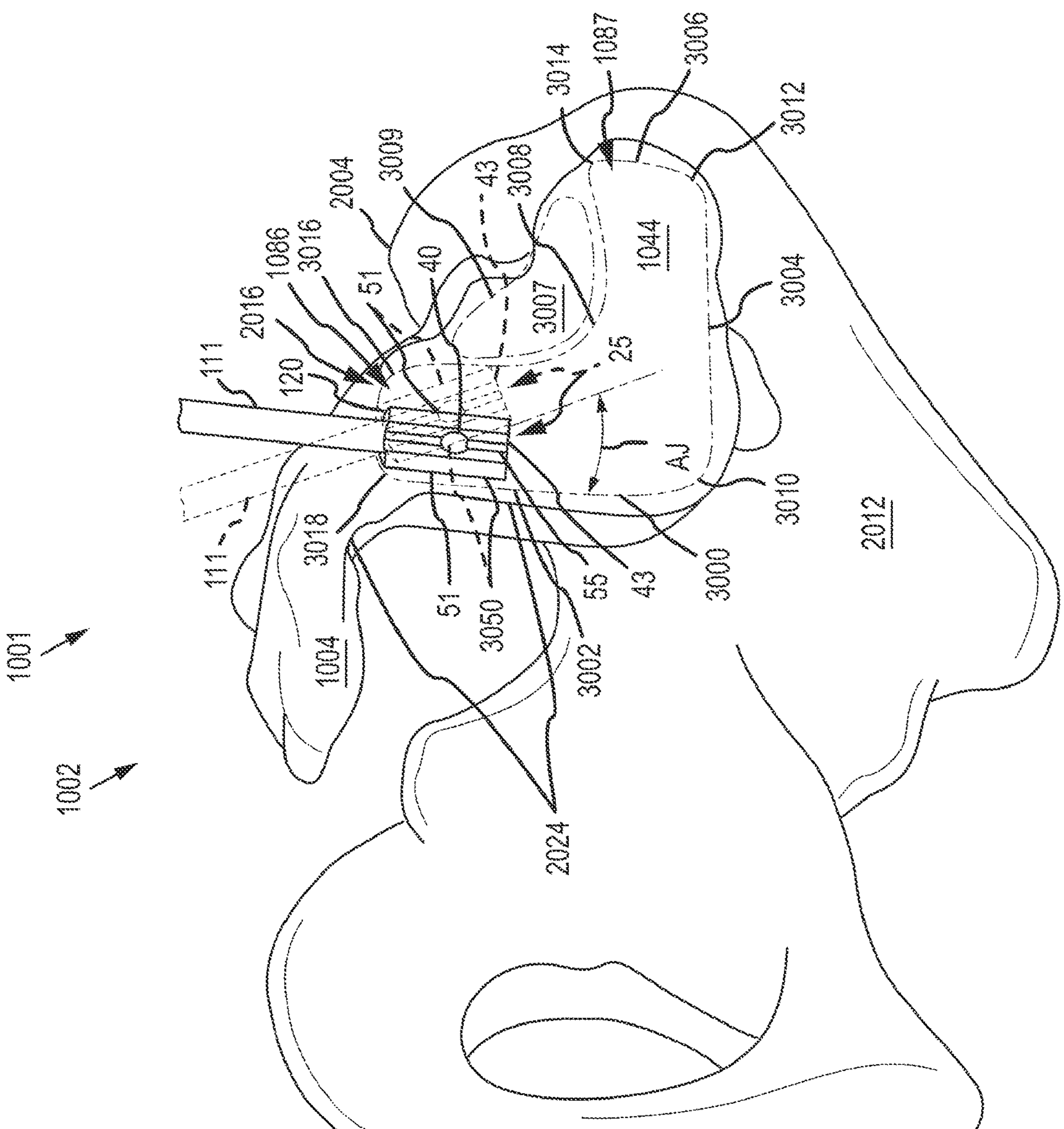
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FIG. 5C

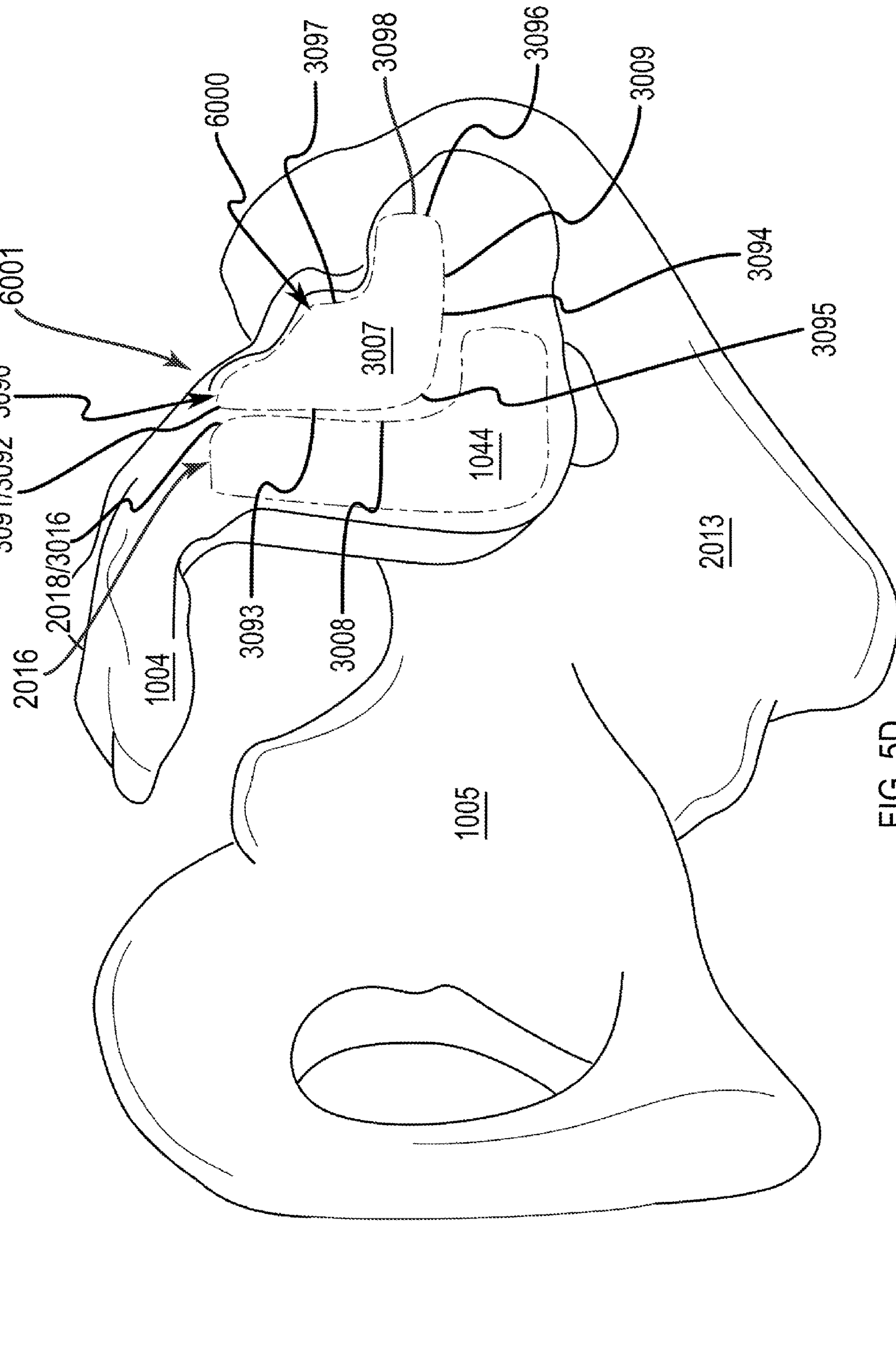
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FIG. 5D

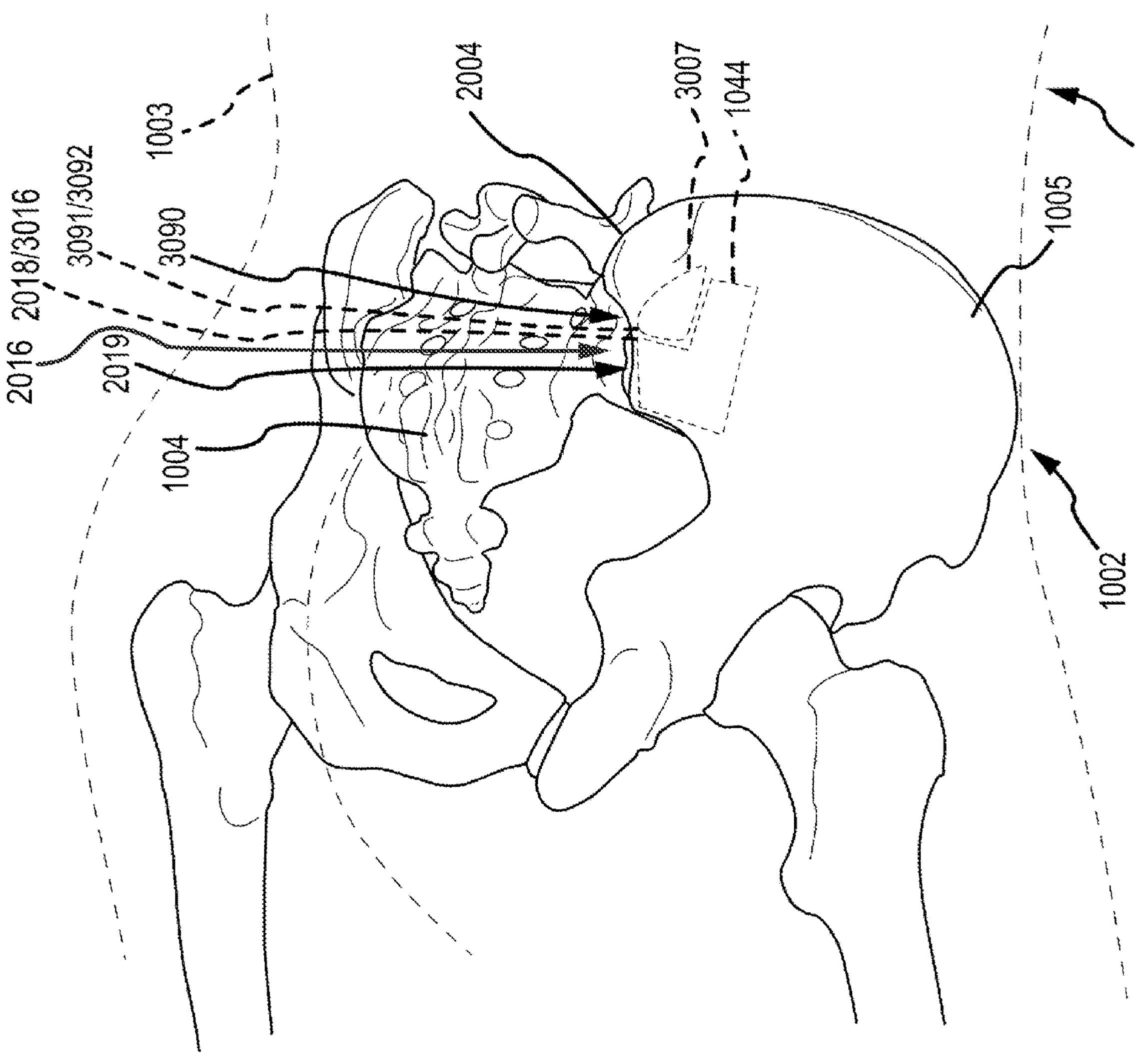

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FIG. 5E

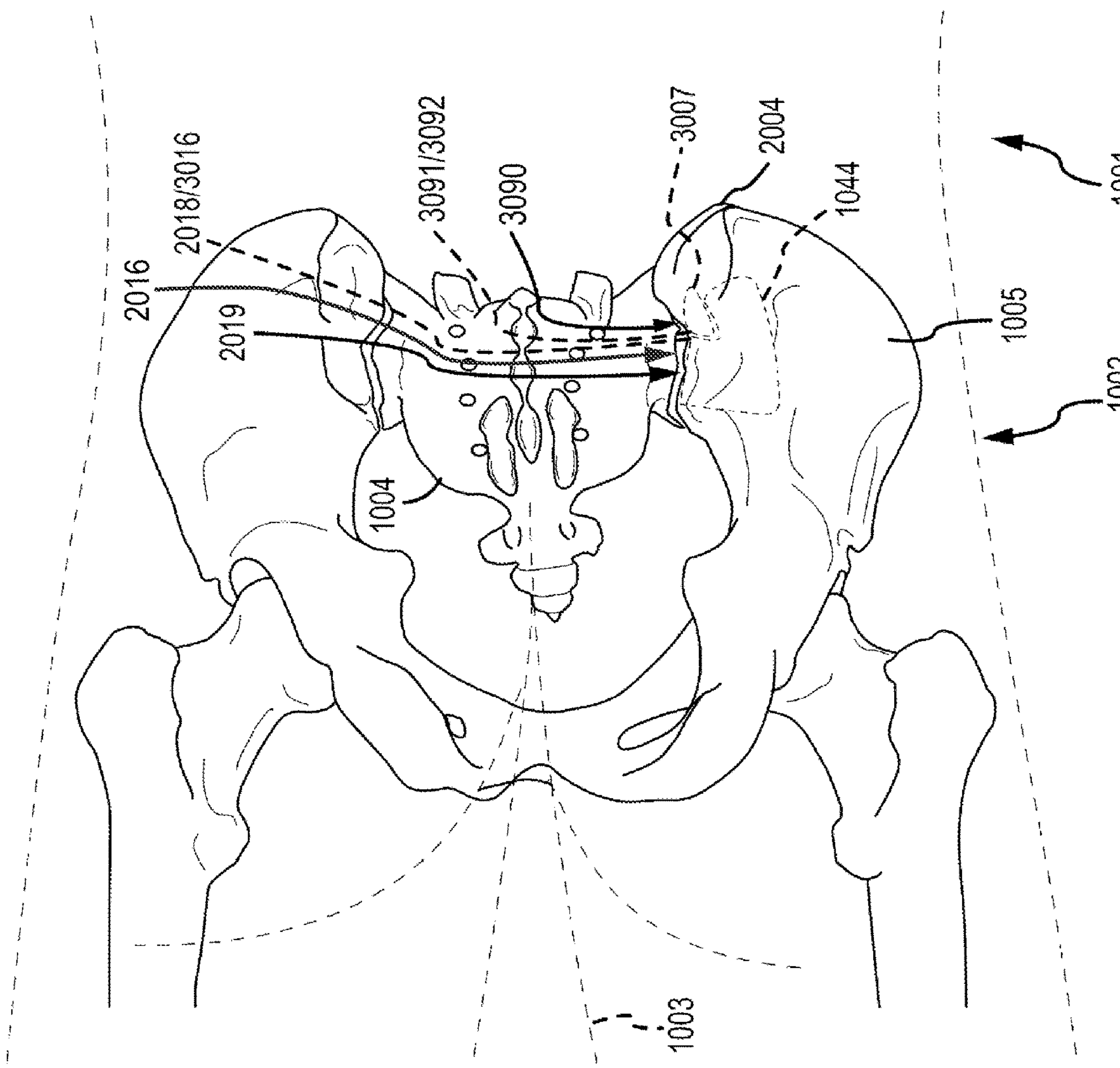
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FIG. 5F

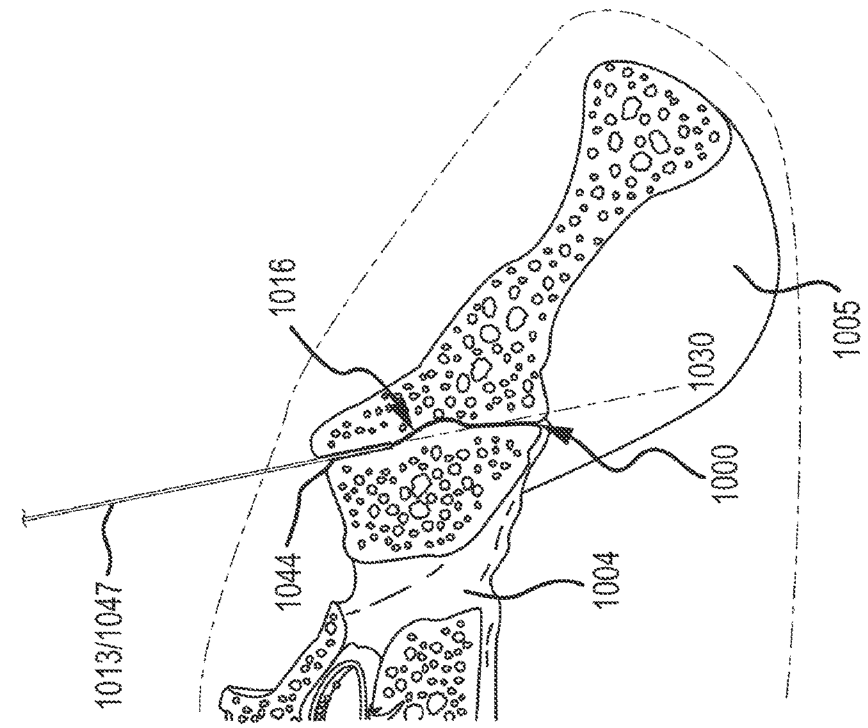
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FIG. 6B

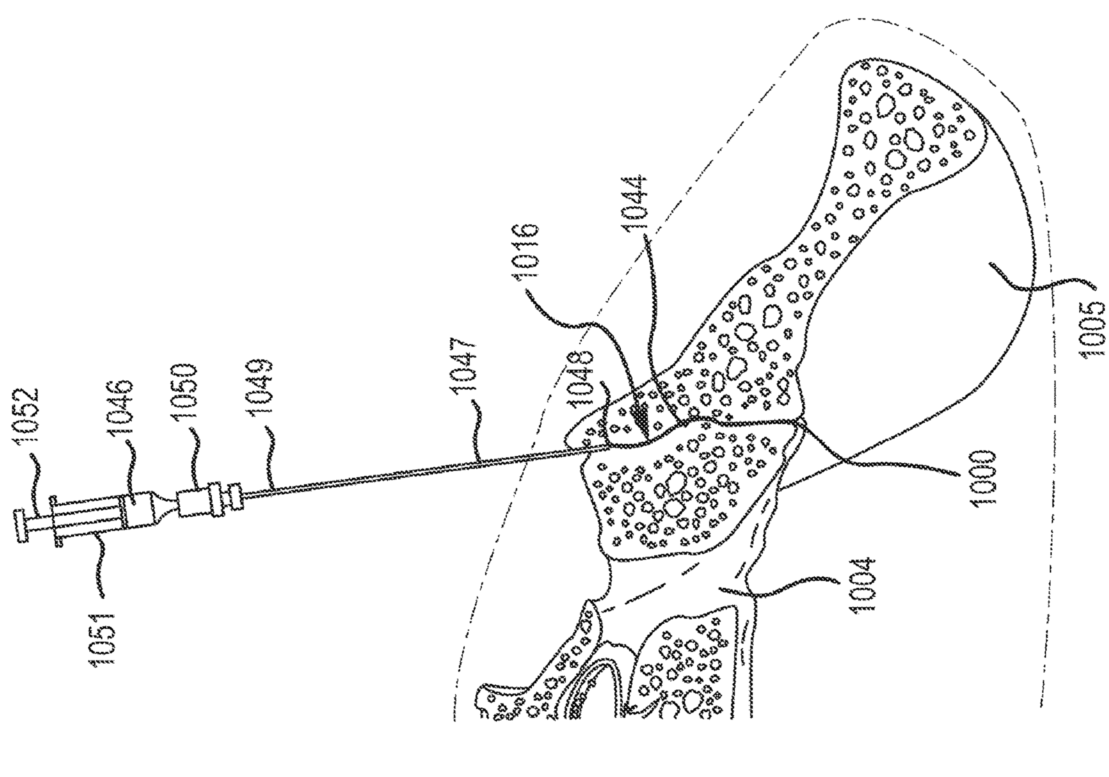
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FIG. 6A

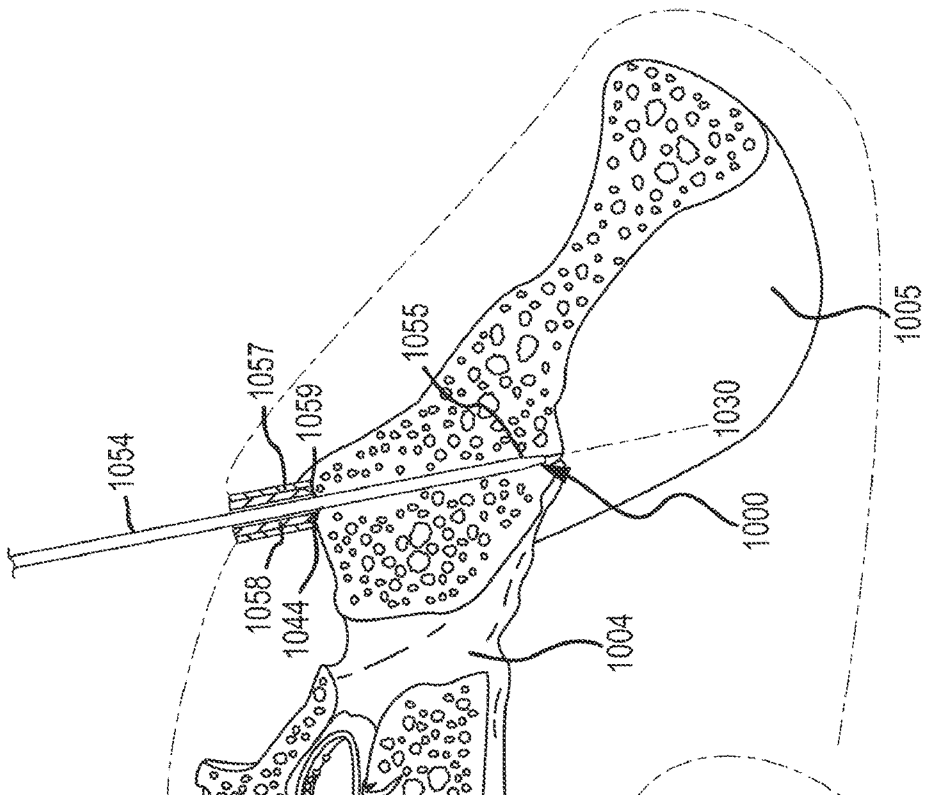
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FIG. 6D

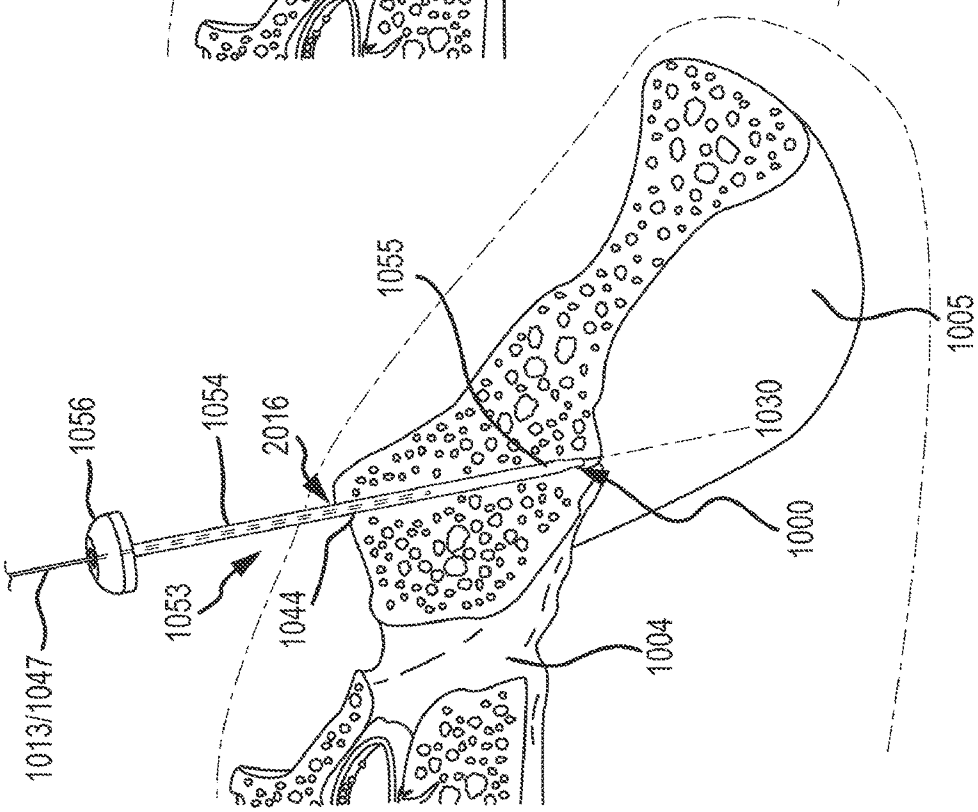
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FIG. 6C

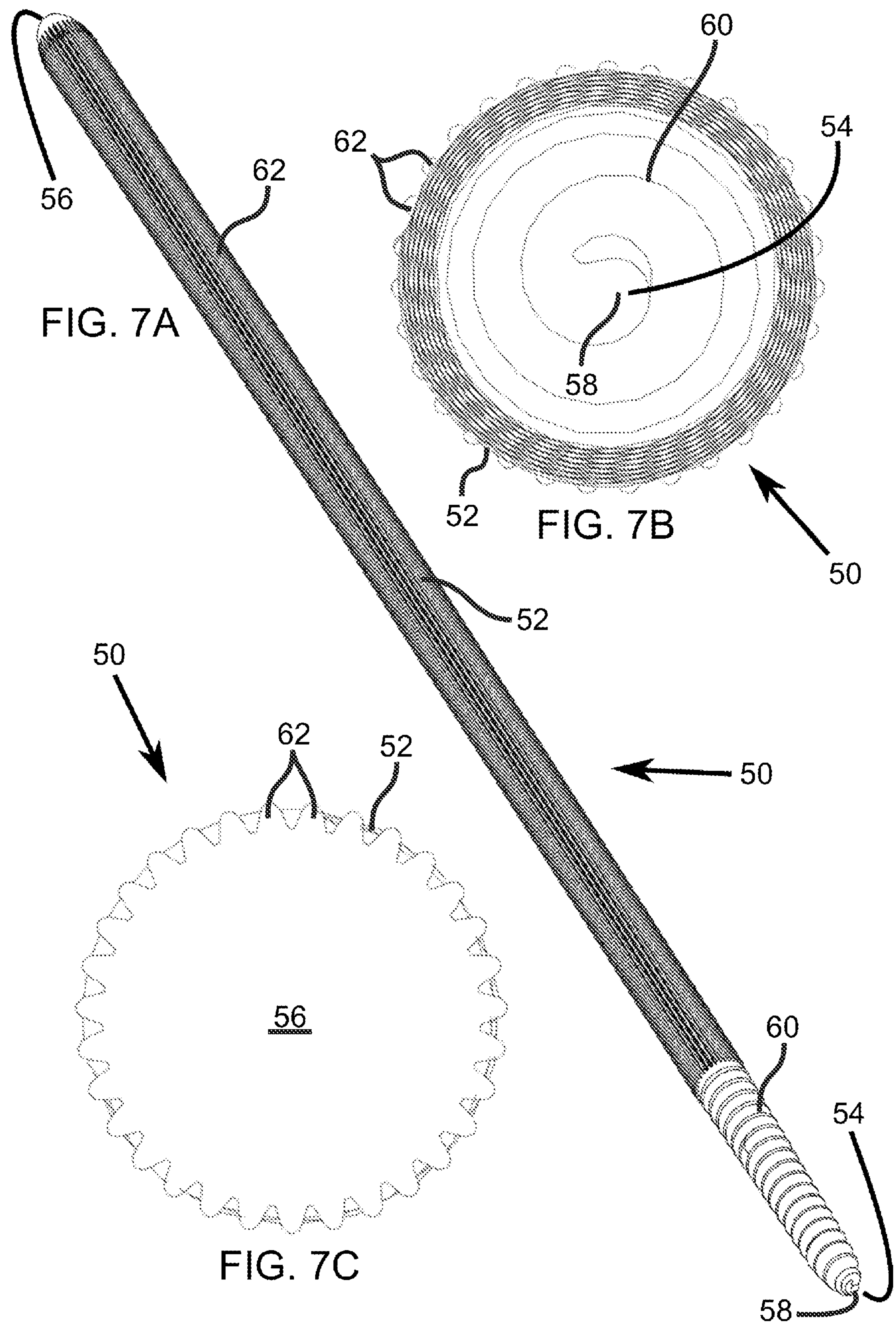


FIG. 7A

FIG. 7B

FIG. 7C

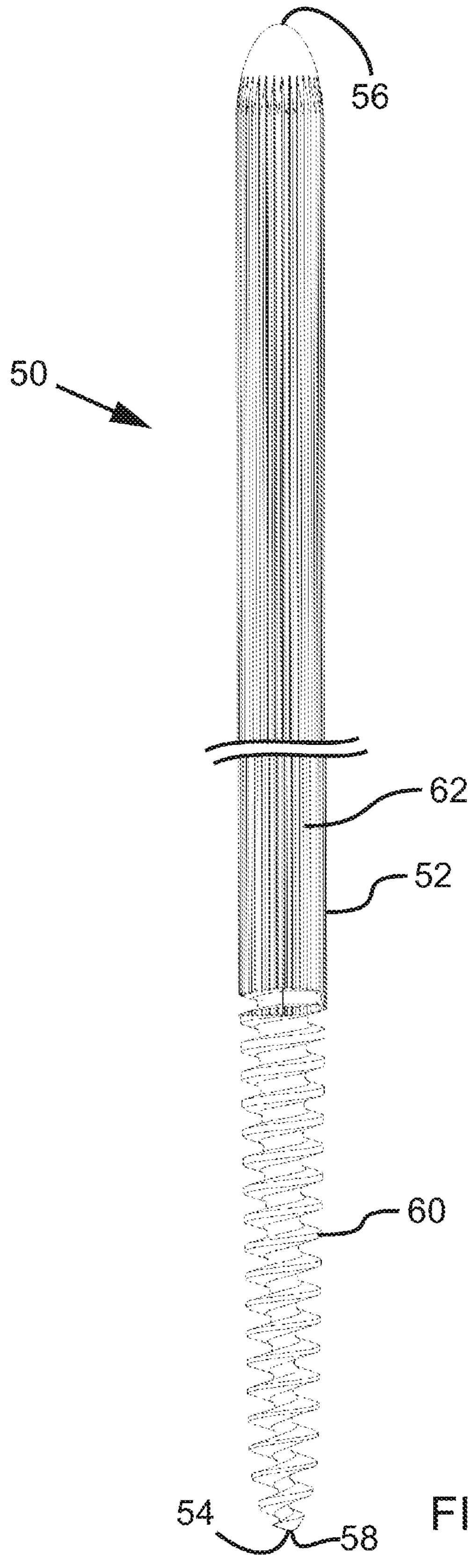


FIG. 7D

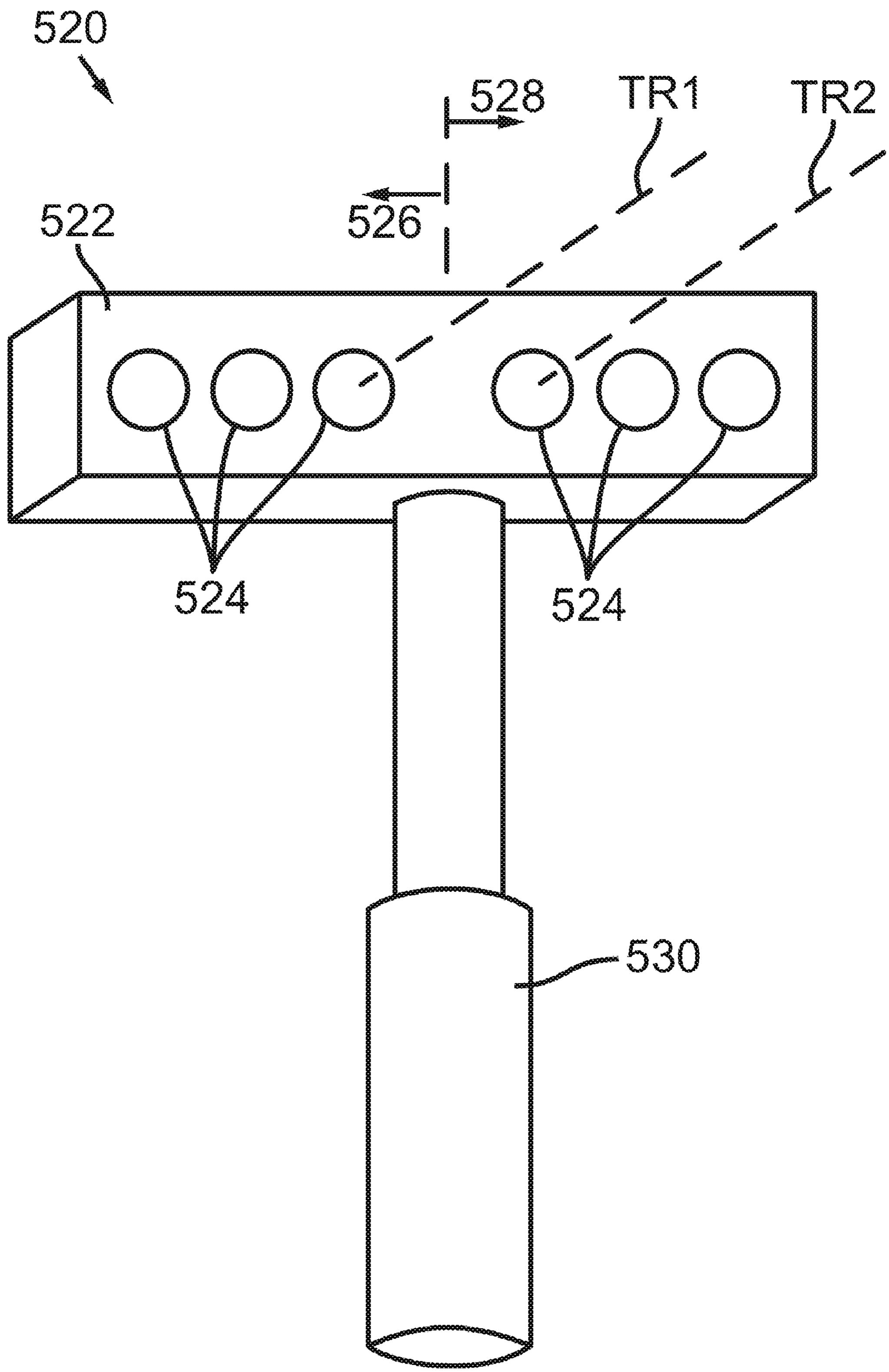
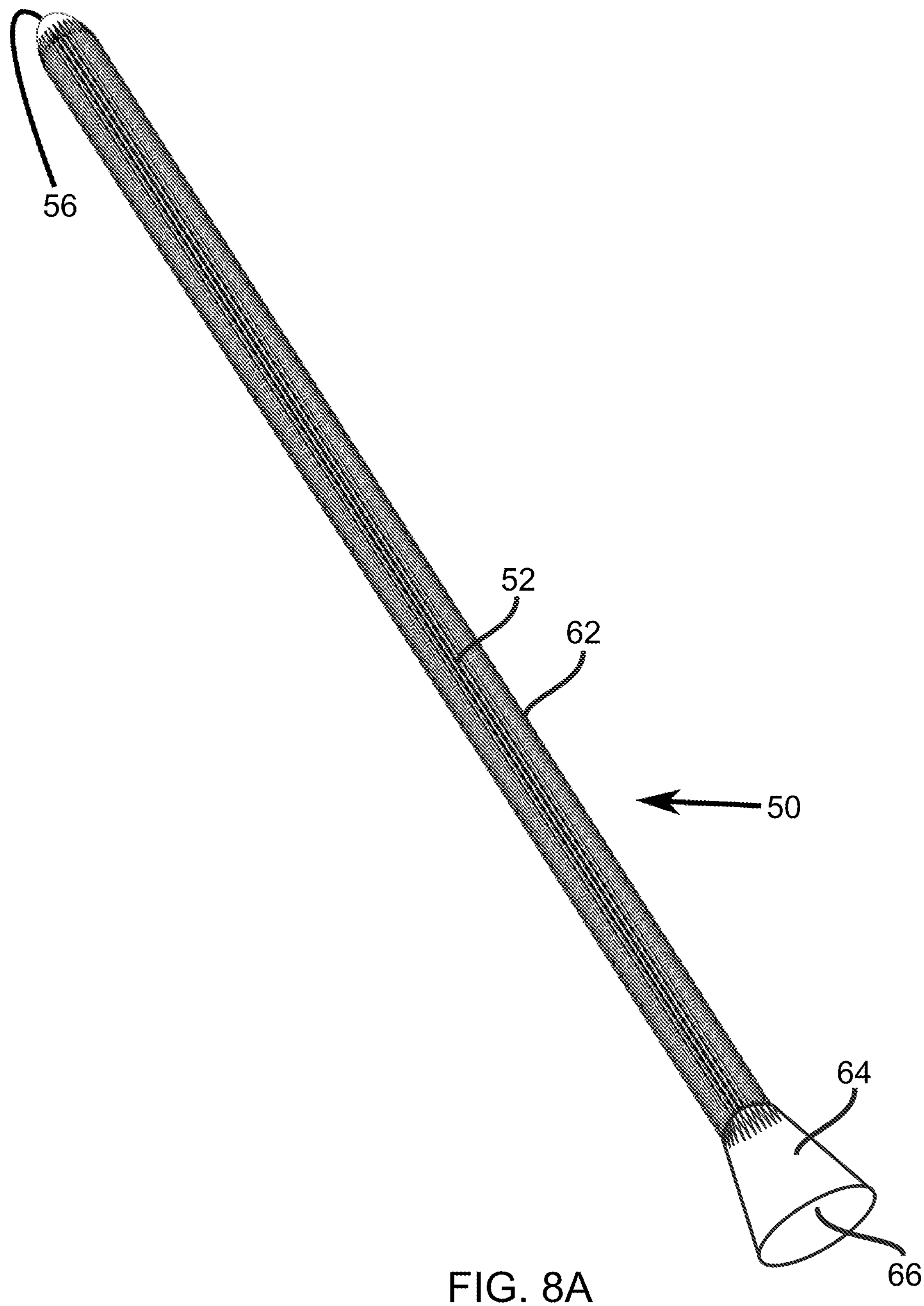


FIG. 7E



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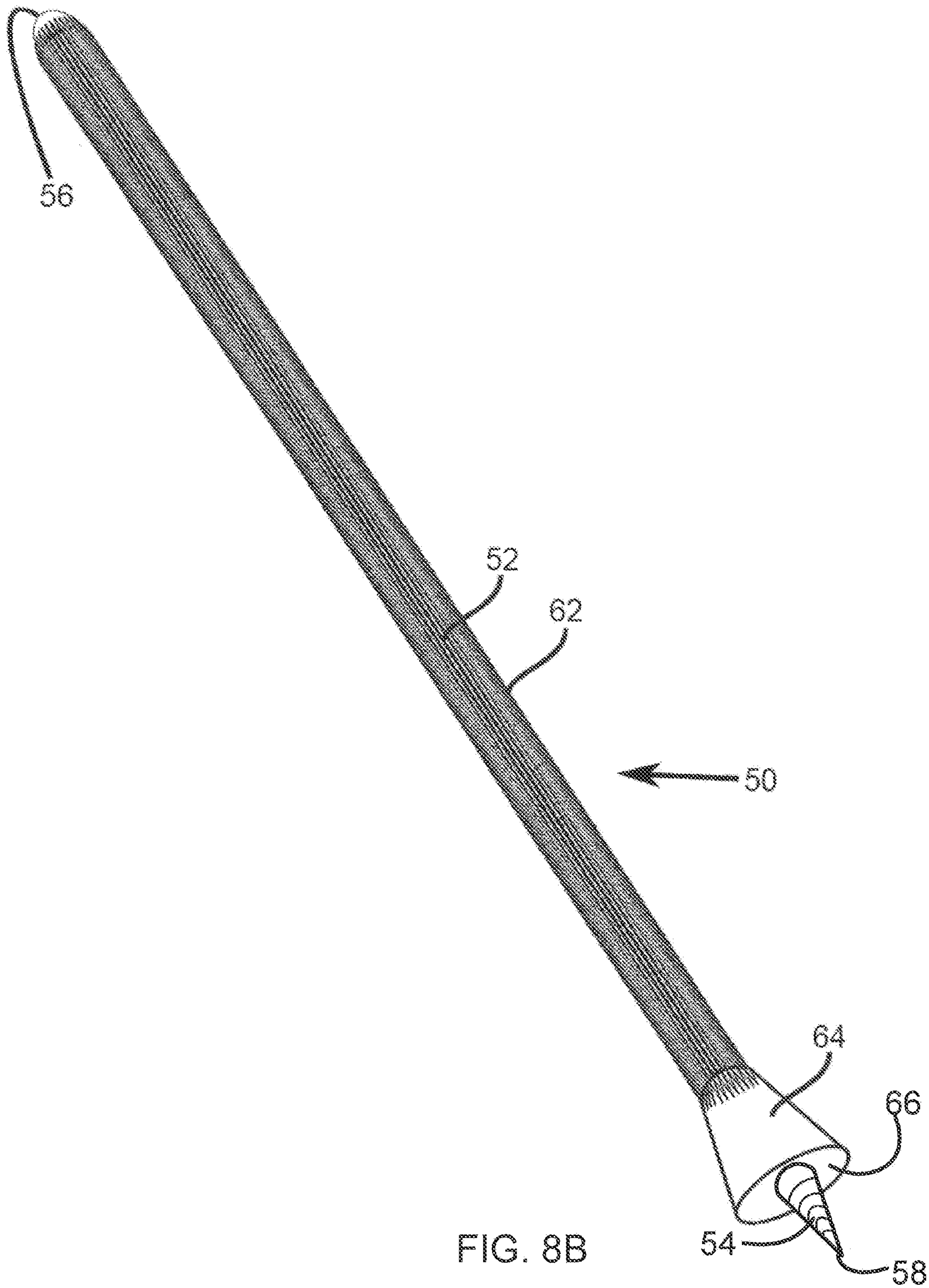

FIG. 8B

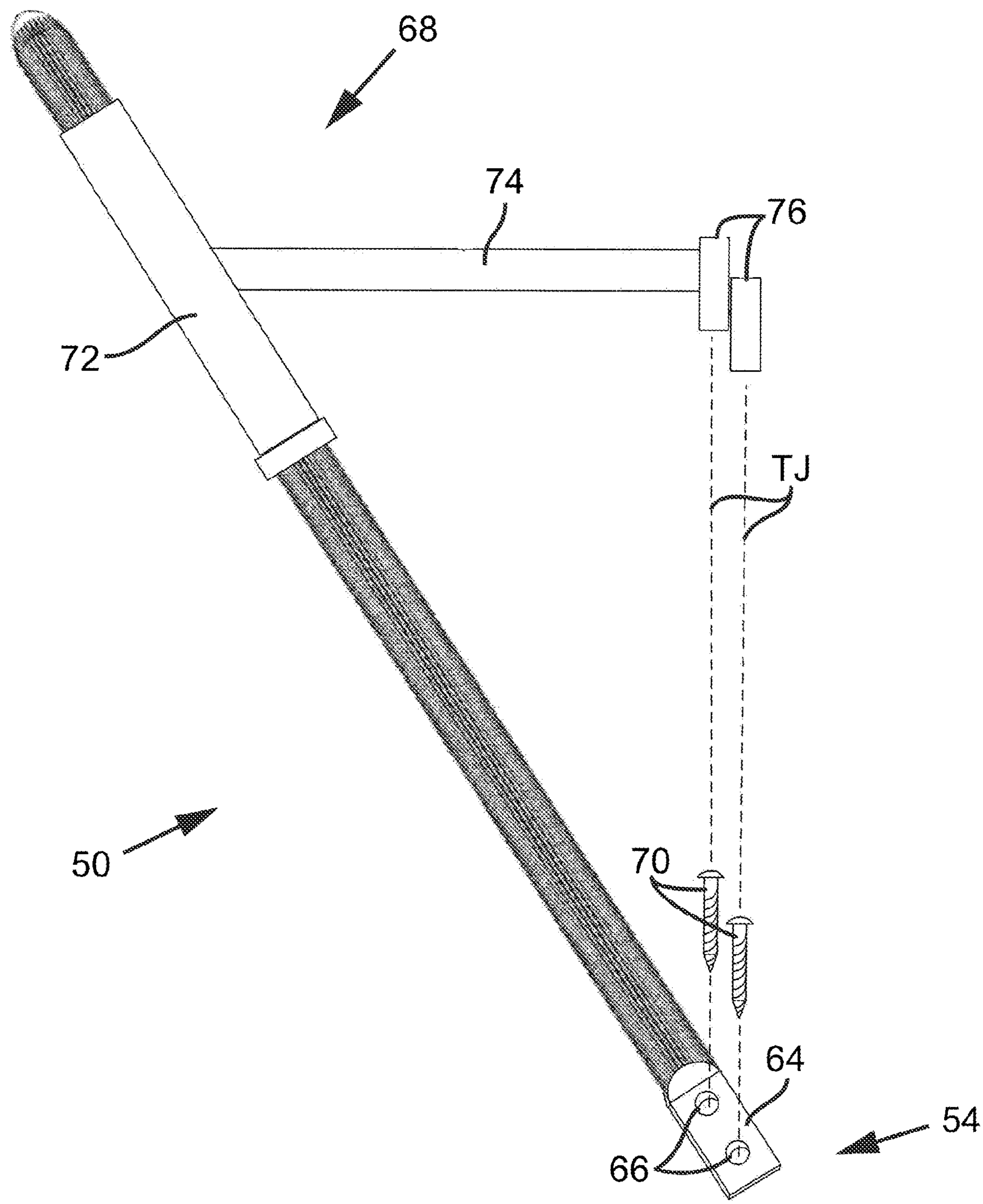

FIG. 9

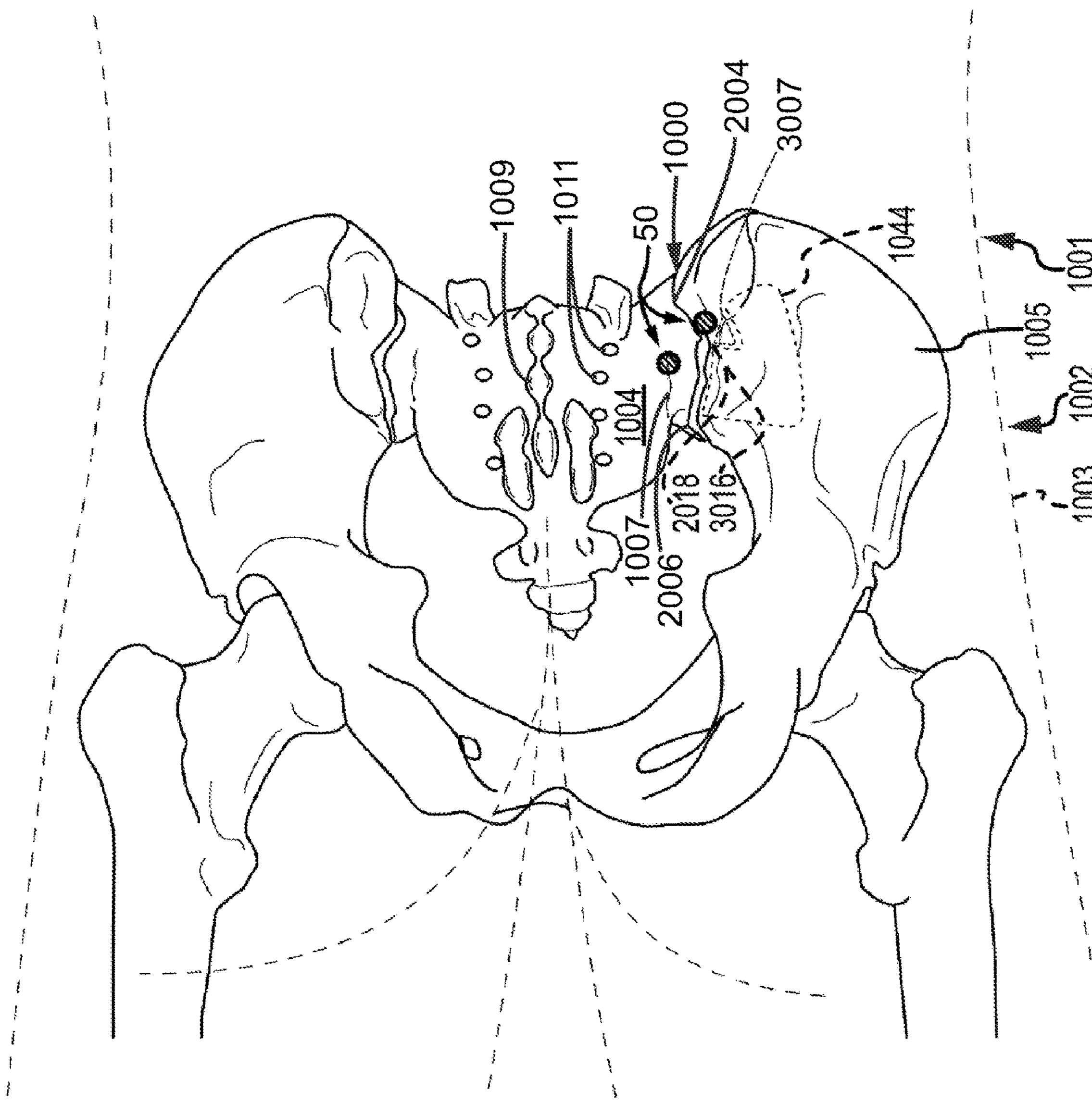
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FIG. 10A

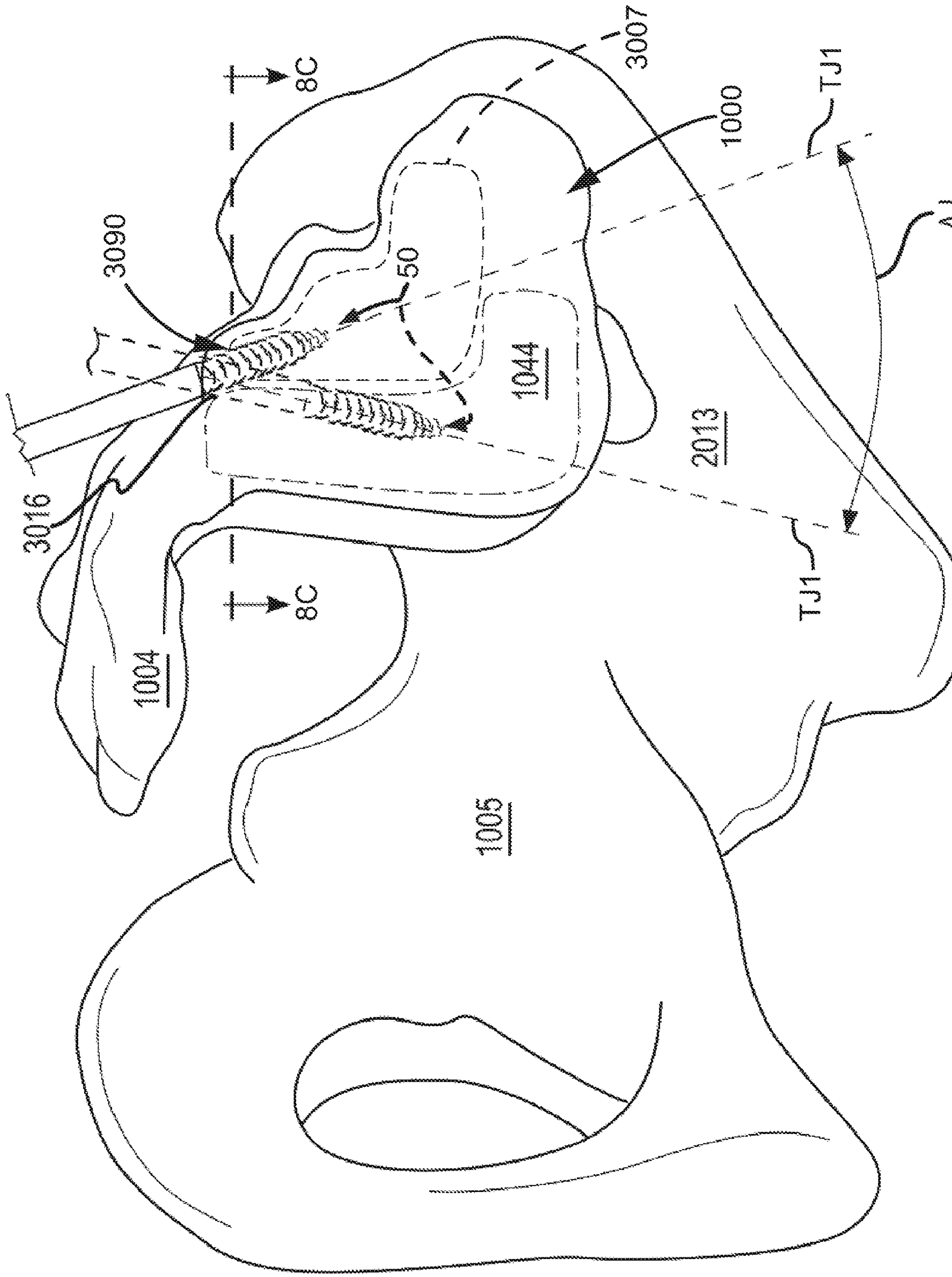

FIG. 10B

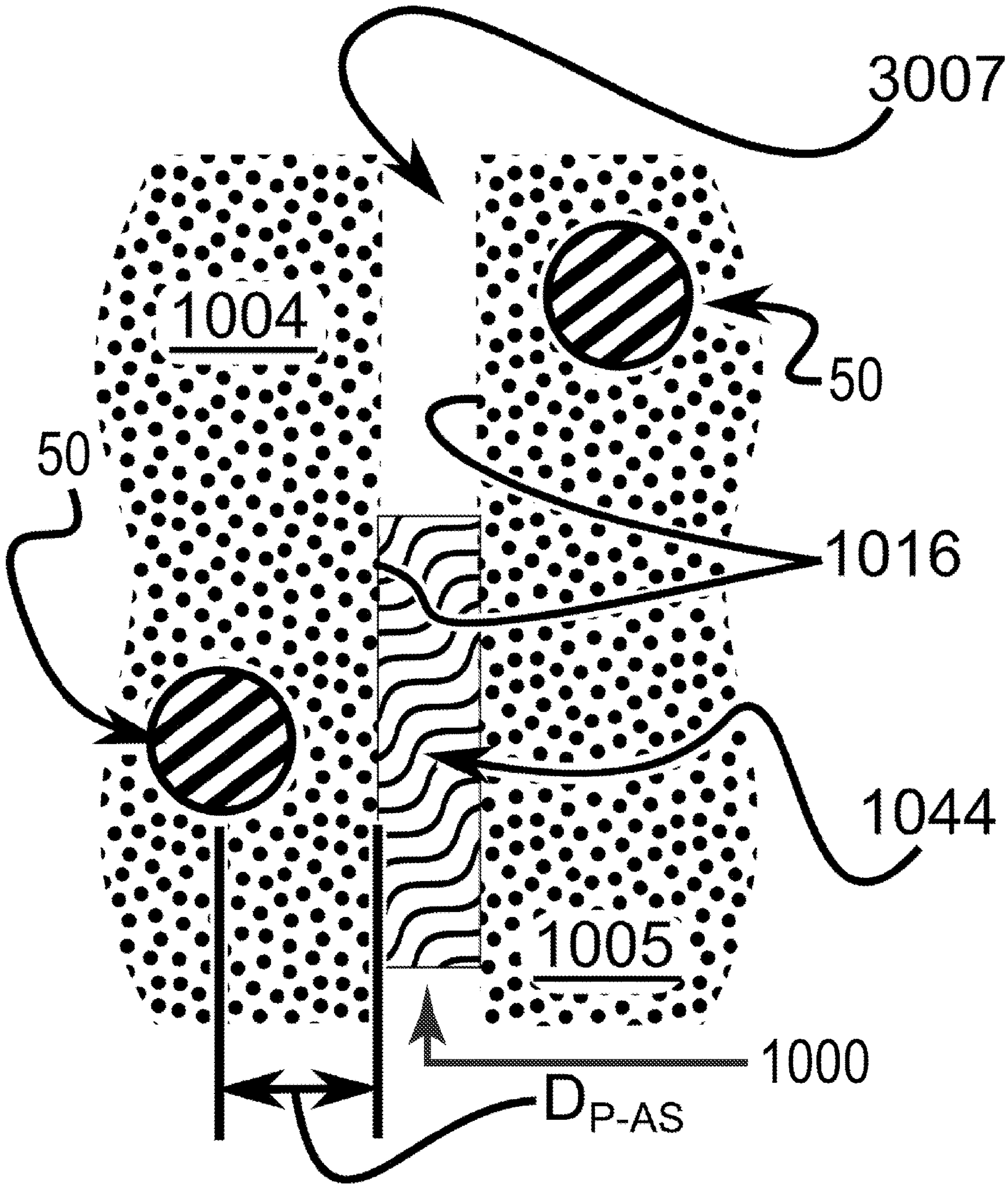

FIG. 10C

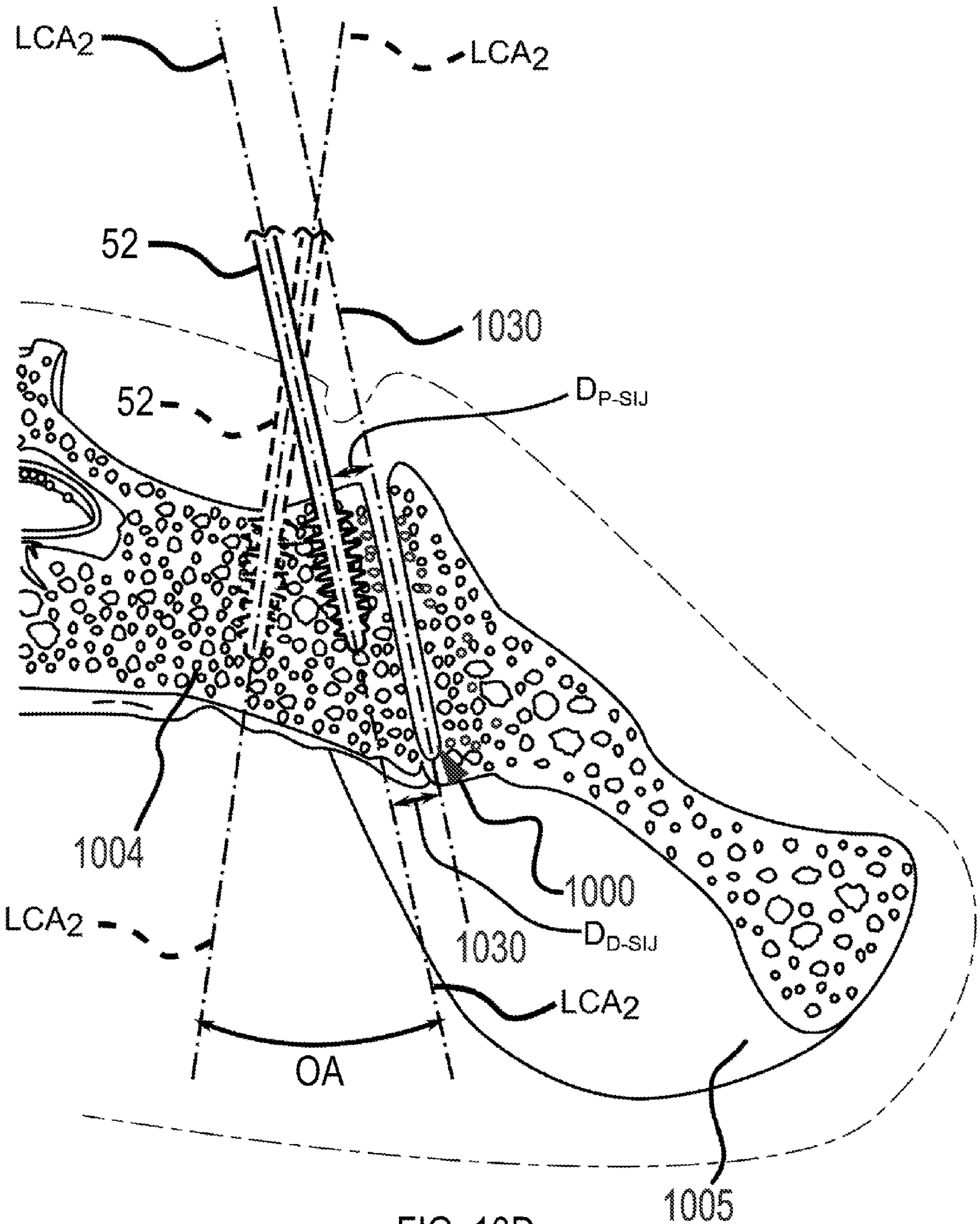
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FIG. 10D

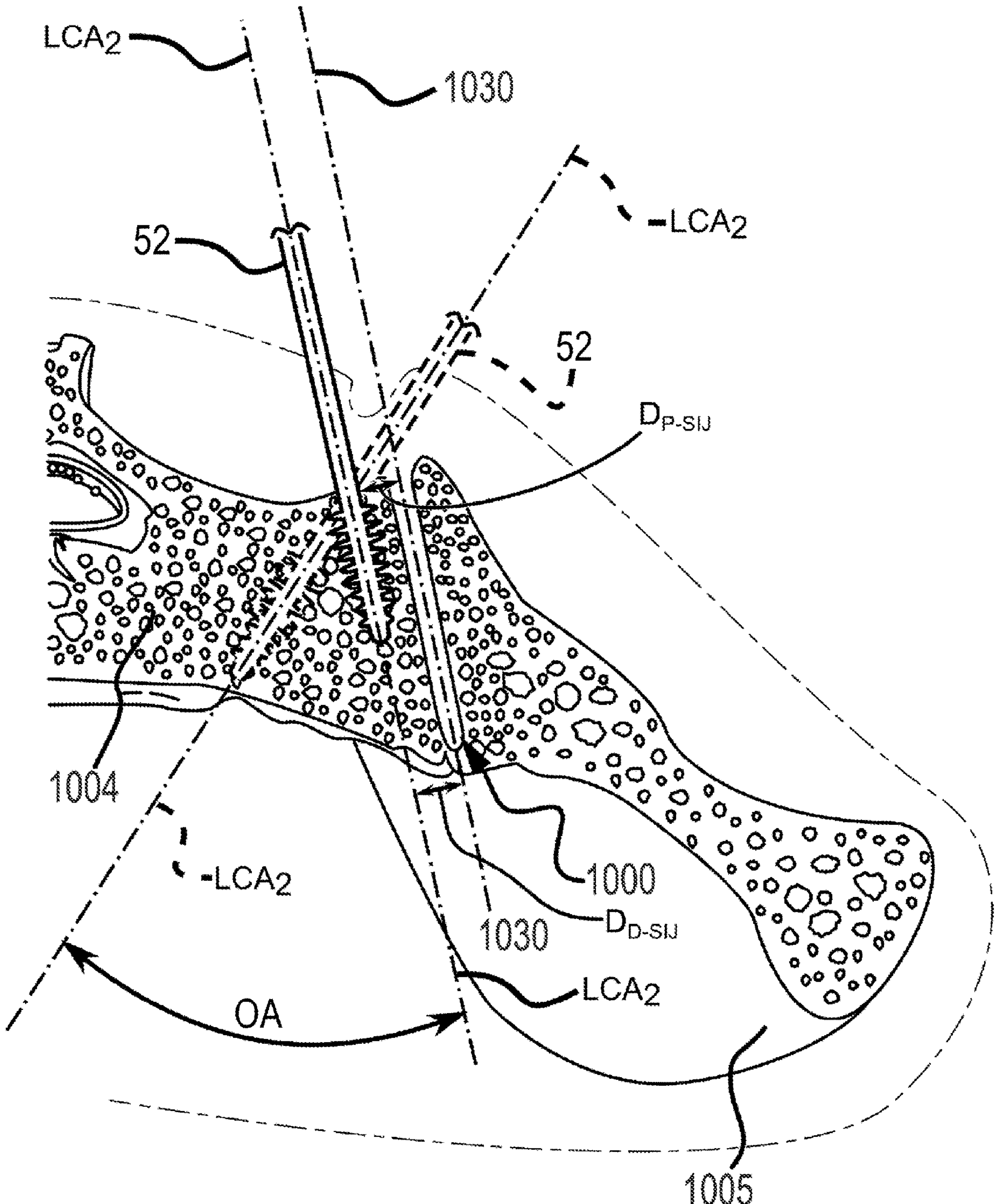
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FIG. 10E

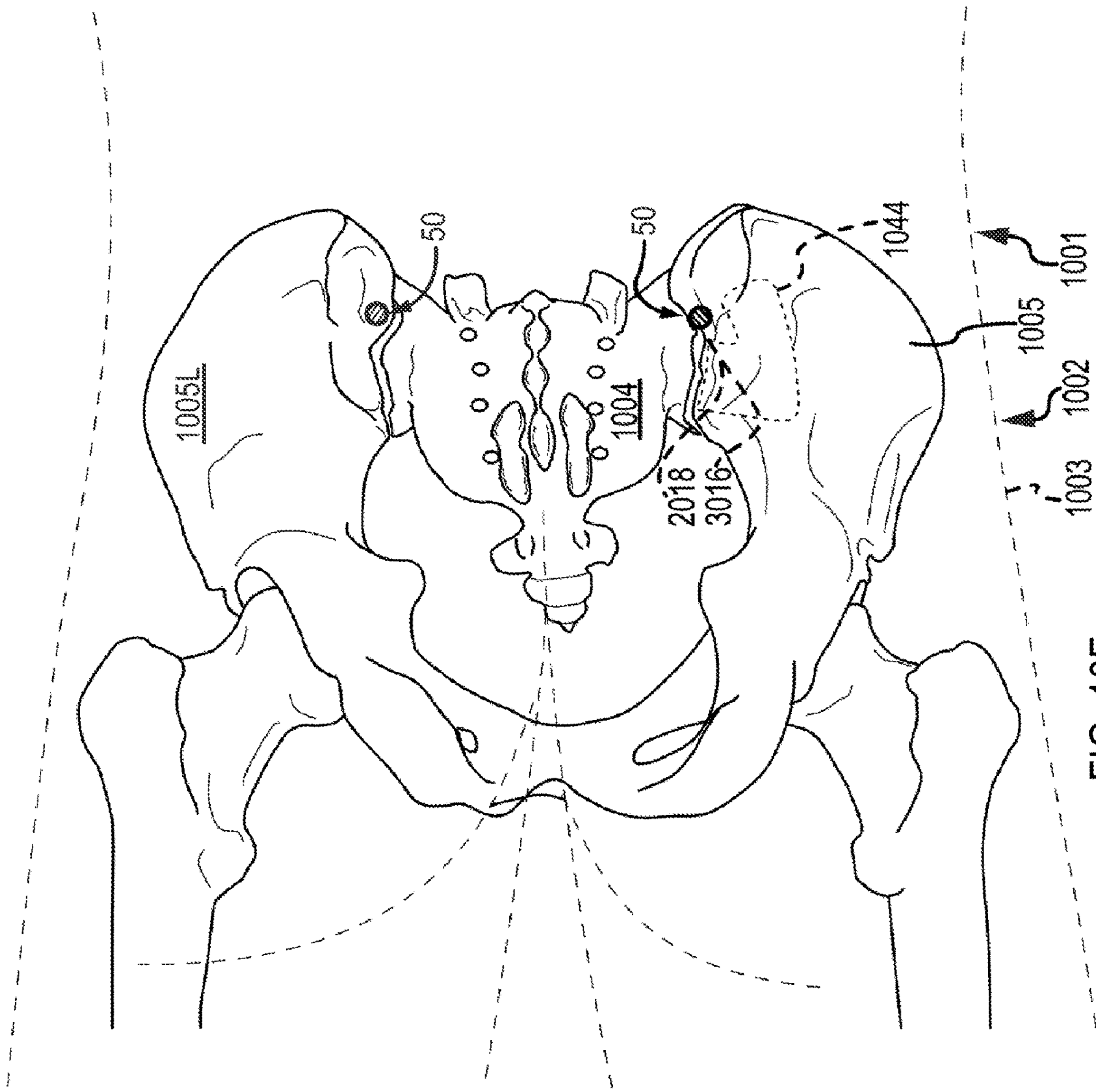

FIG. 10F

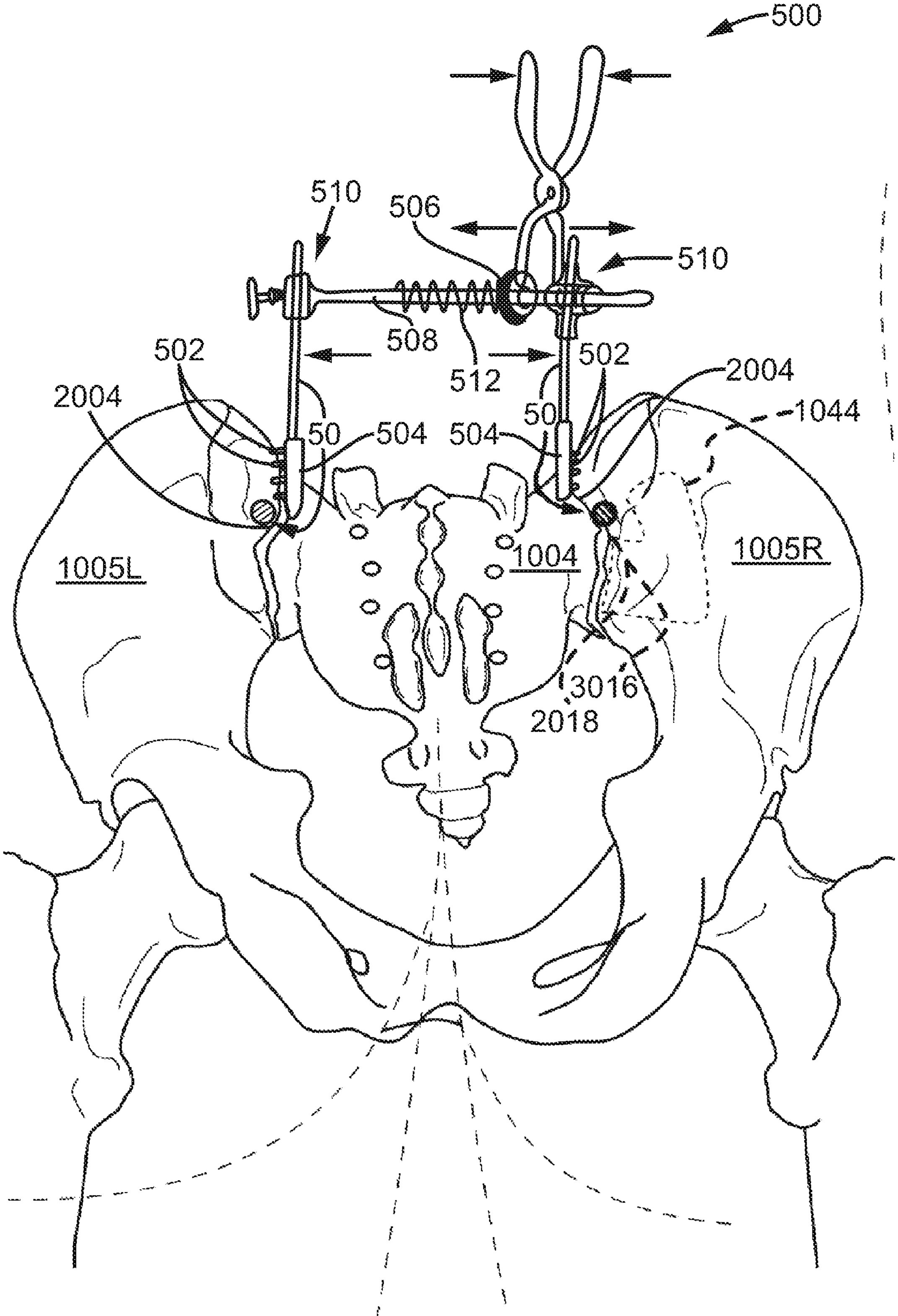
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FIG. 10G

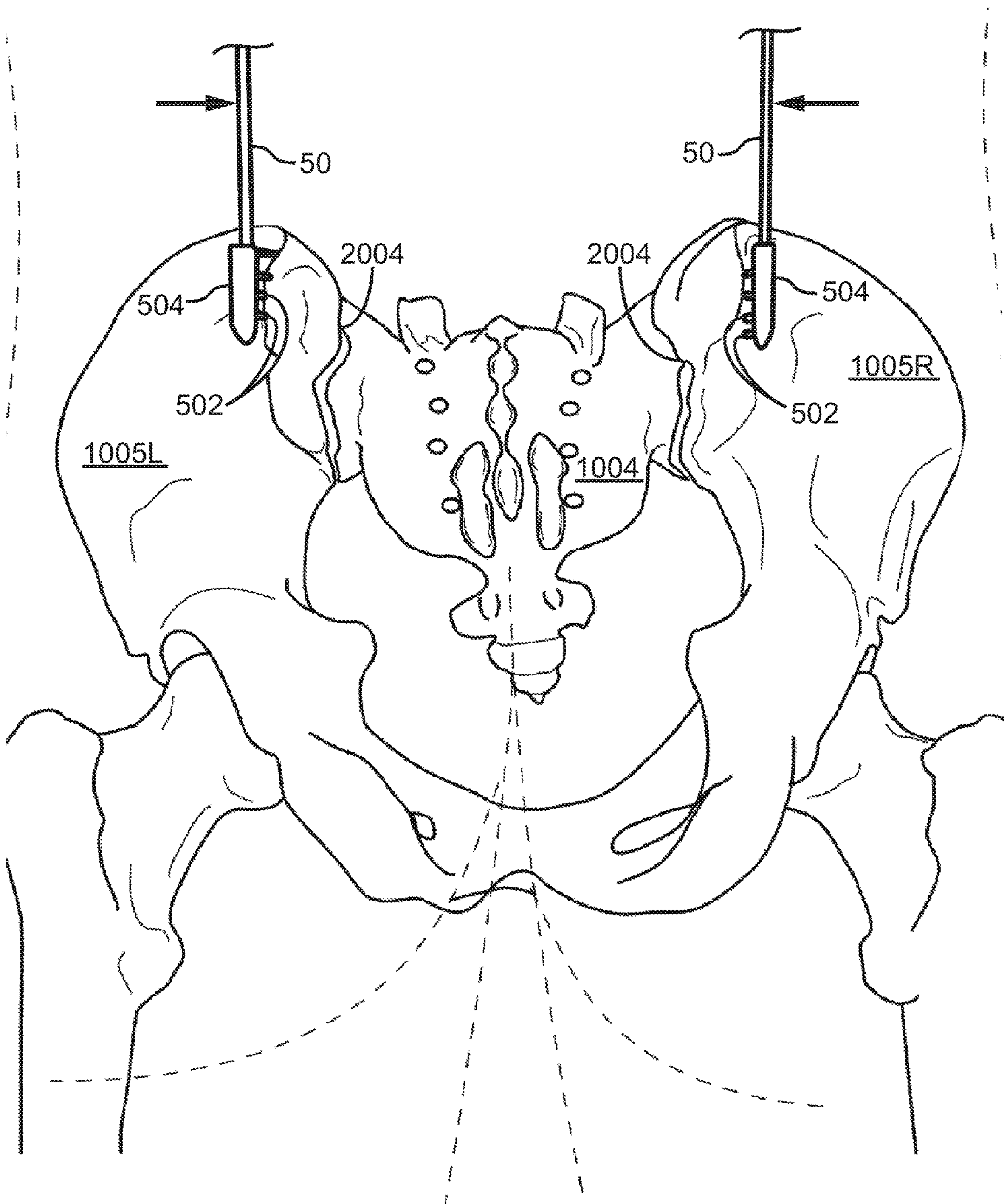


FIG. 10H

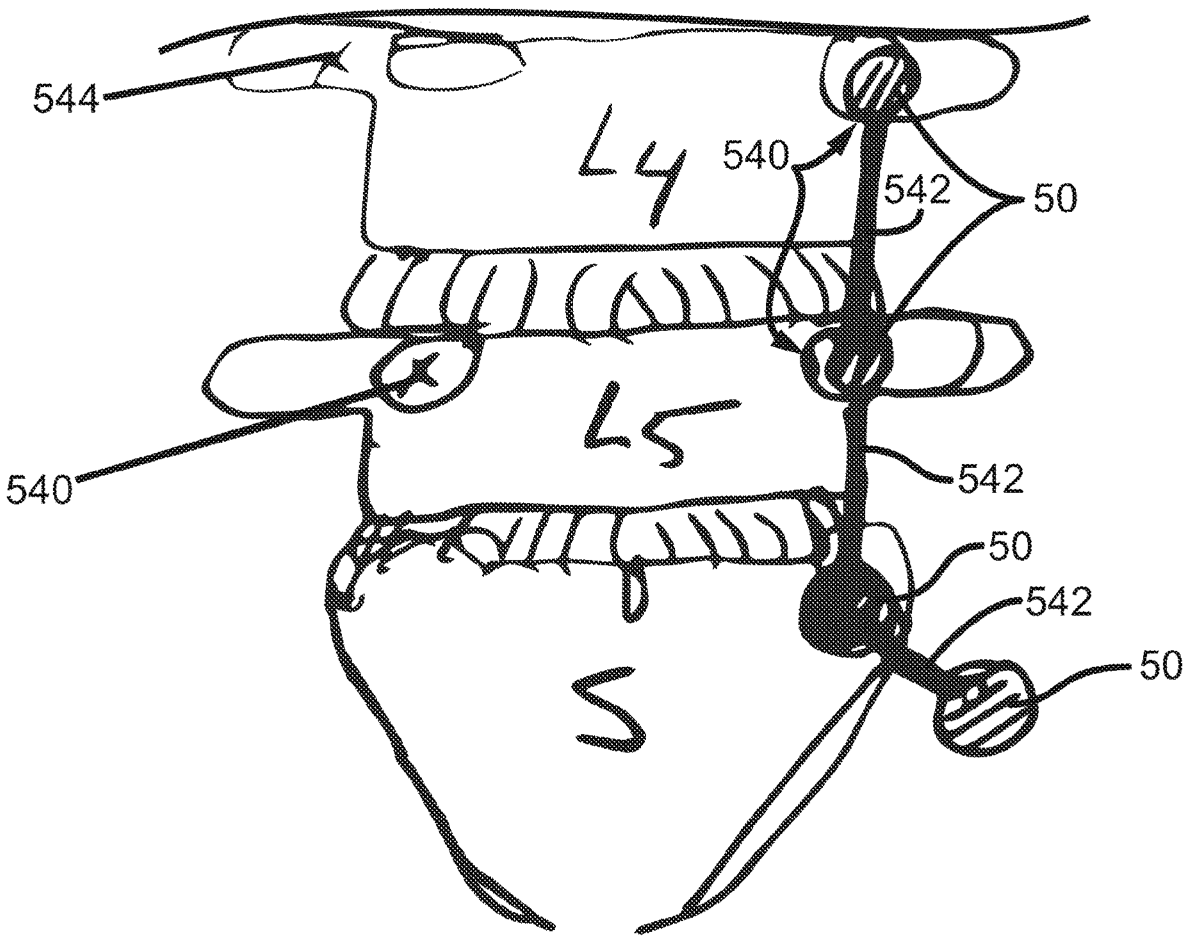


FIG. 10I

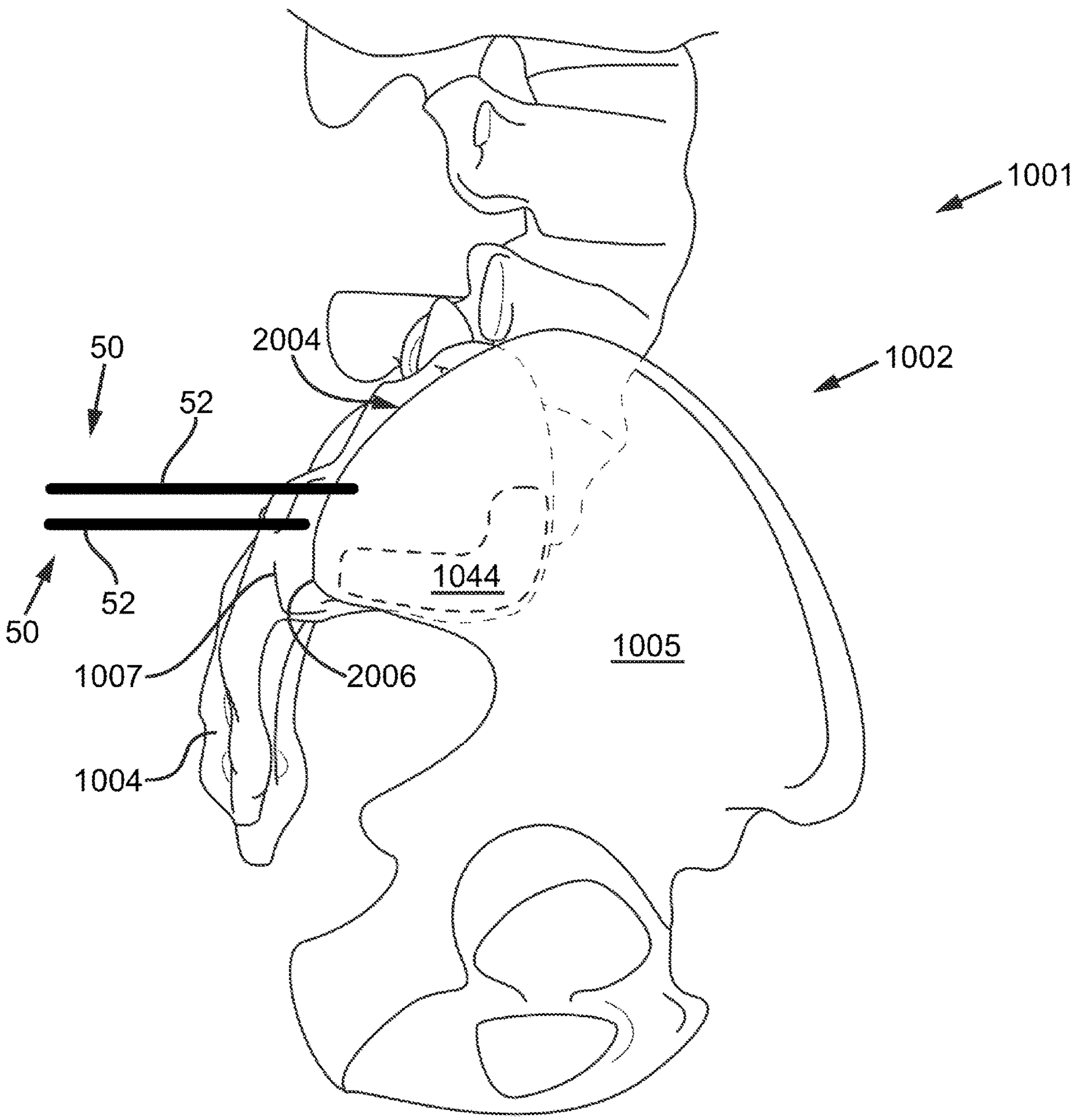


FIG. 11

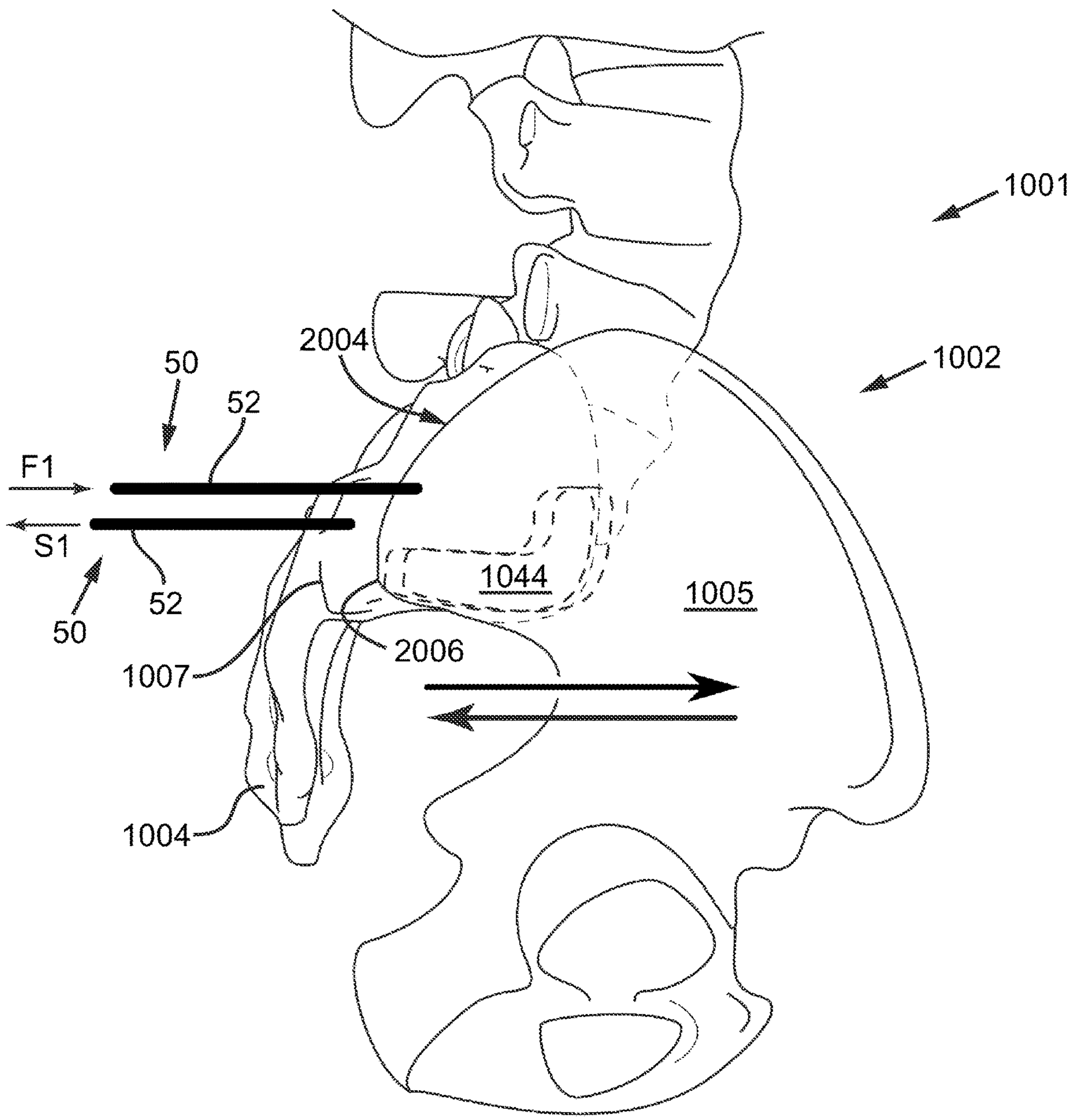


FIG. 12A

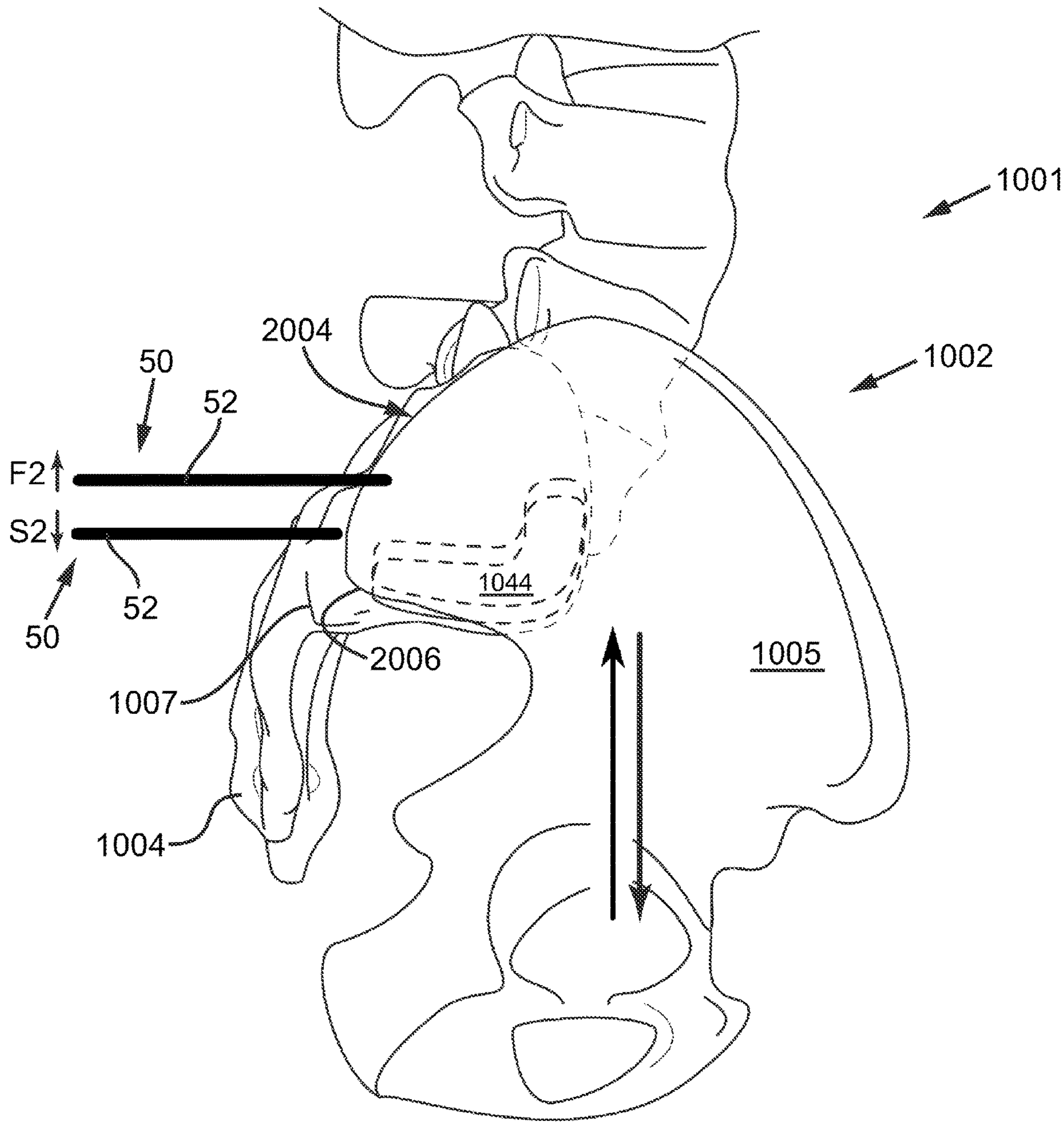


FIG. 12B

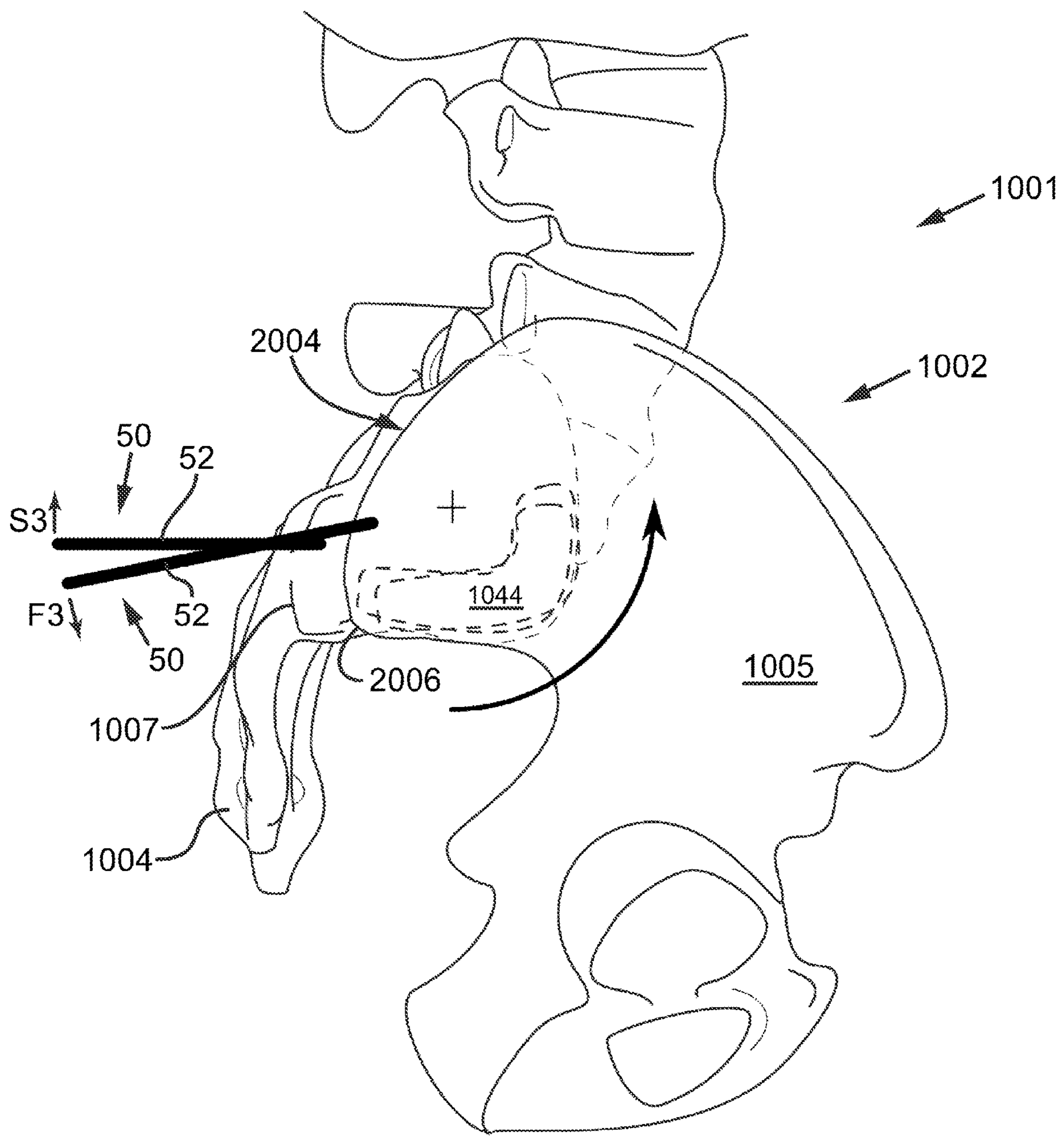


FIG. 12C

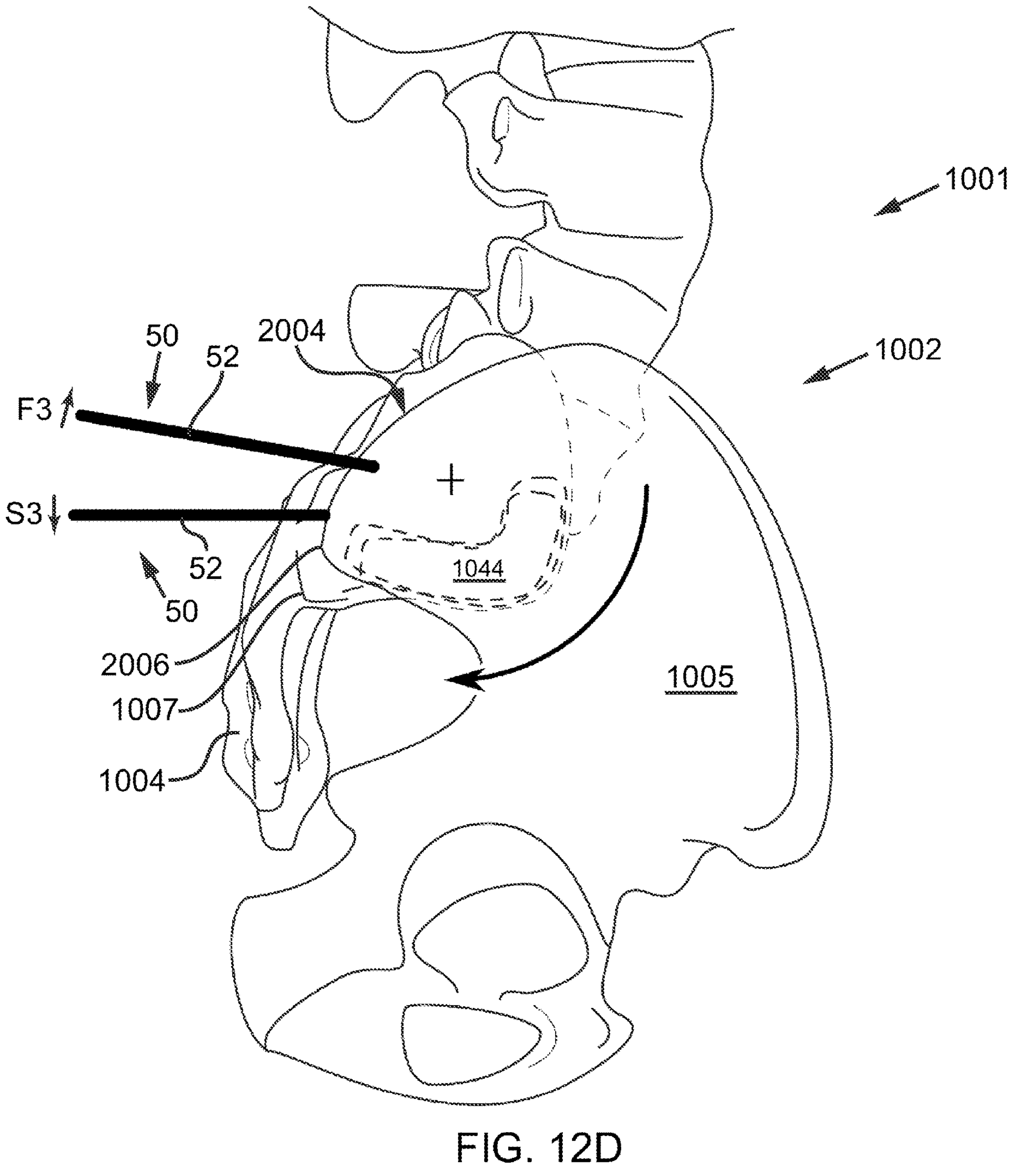
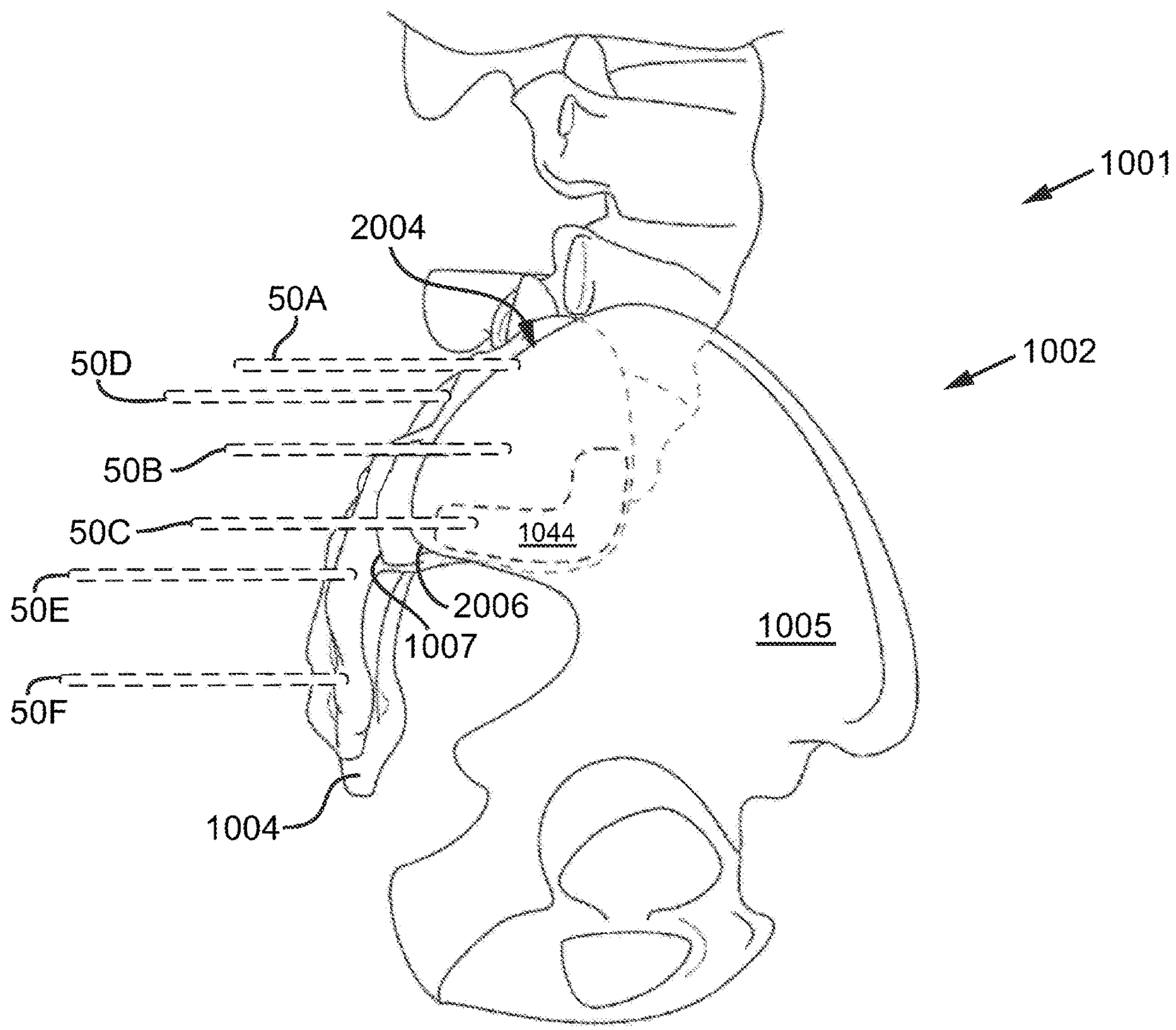


FIG. 12D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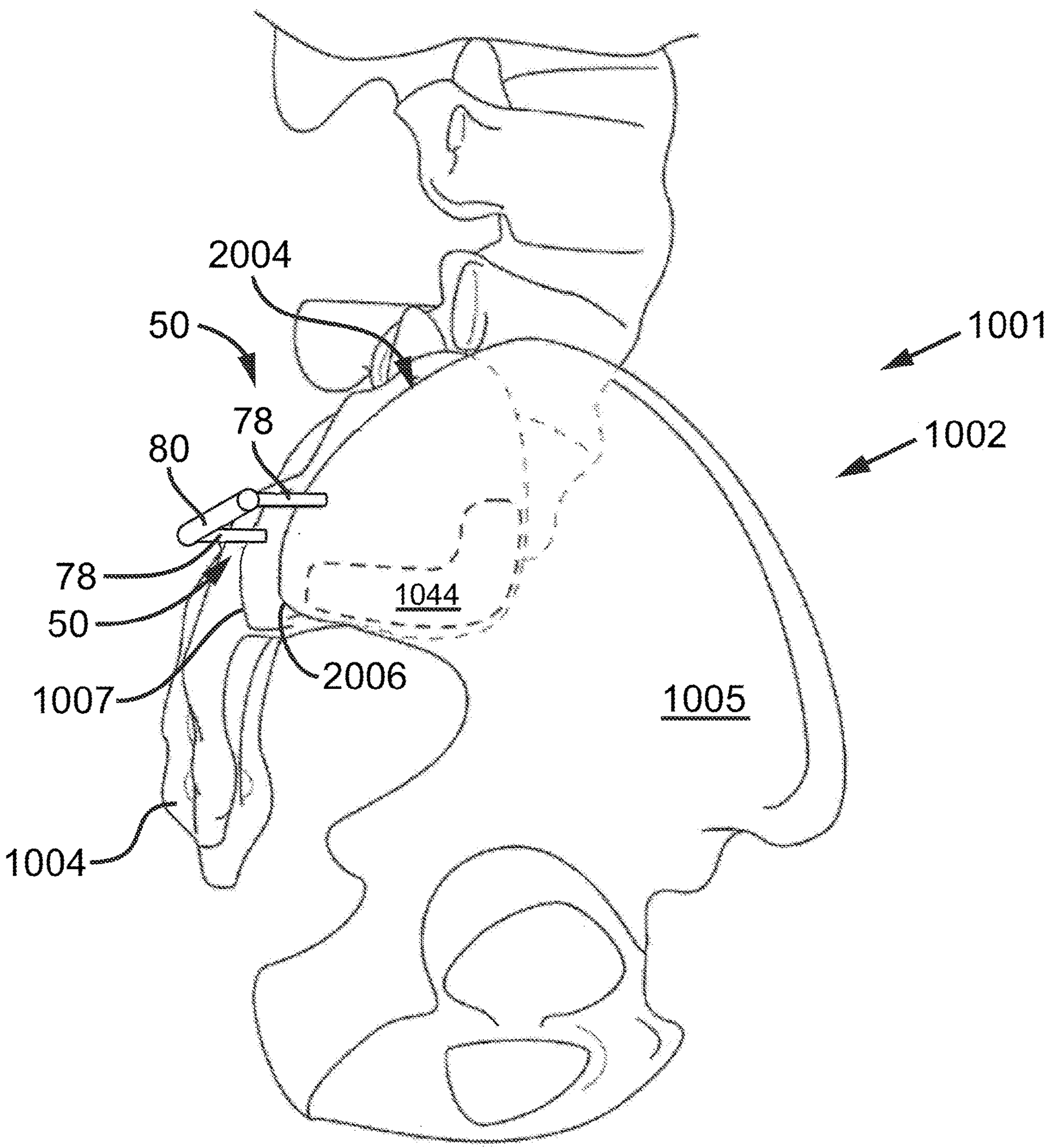

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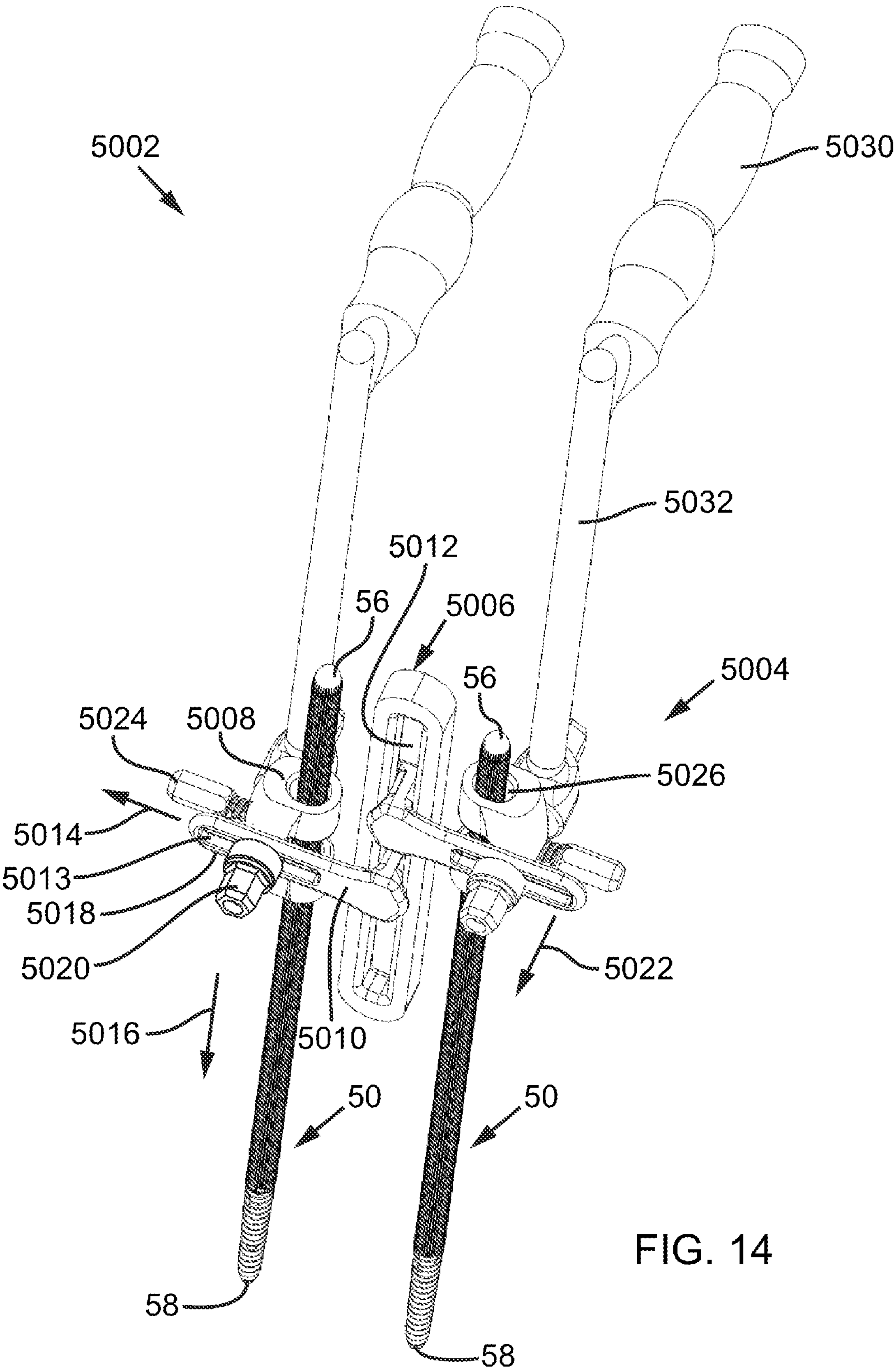
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FIG. 14

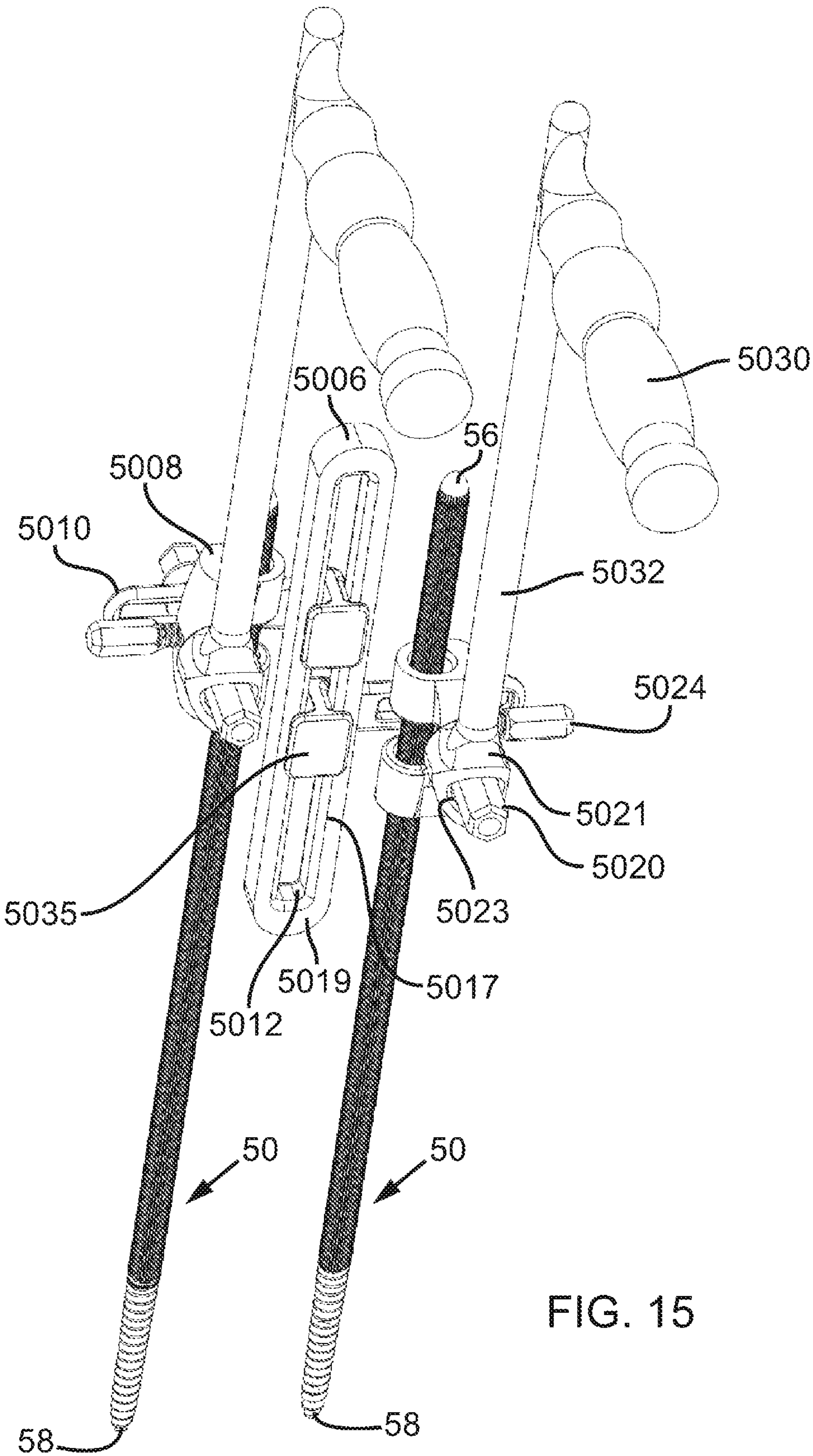
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FIG. 15

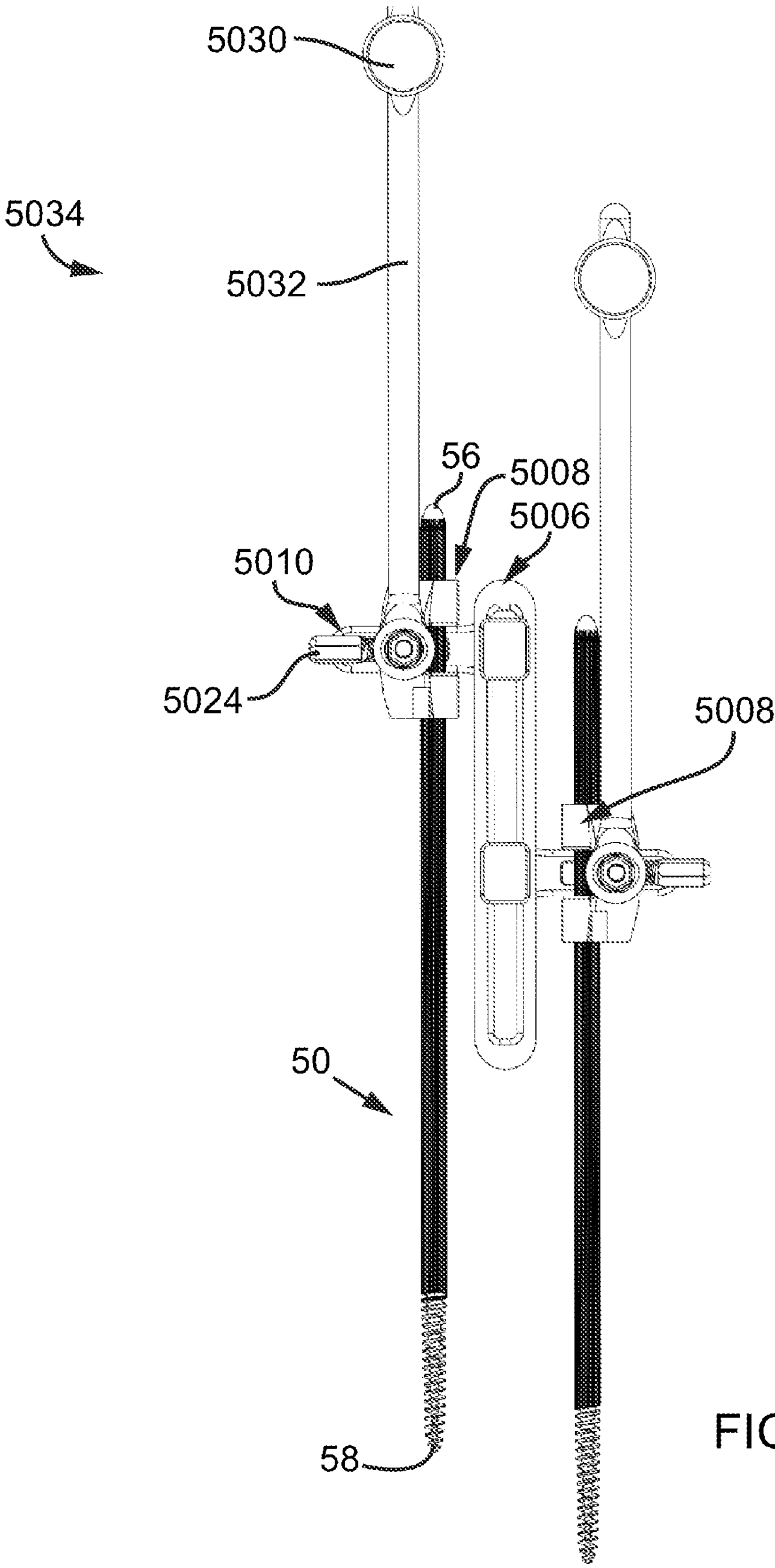


FIG. 16A

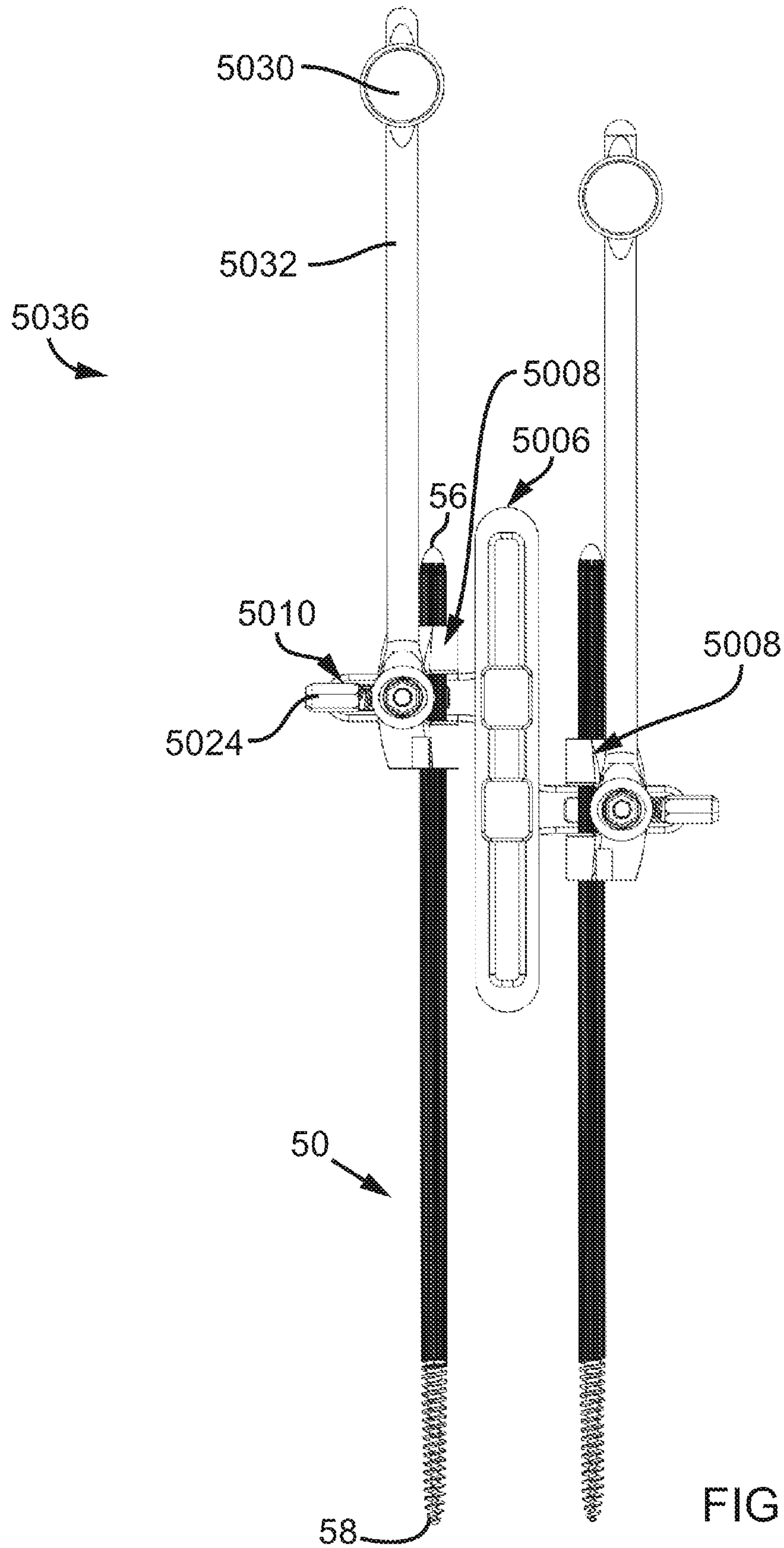


FIG. 16B

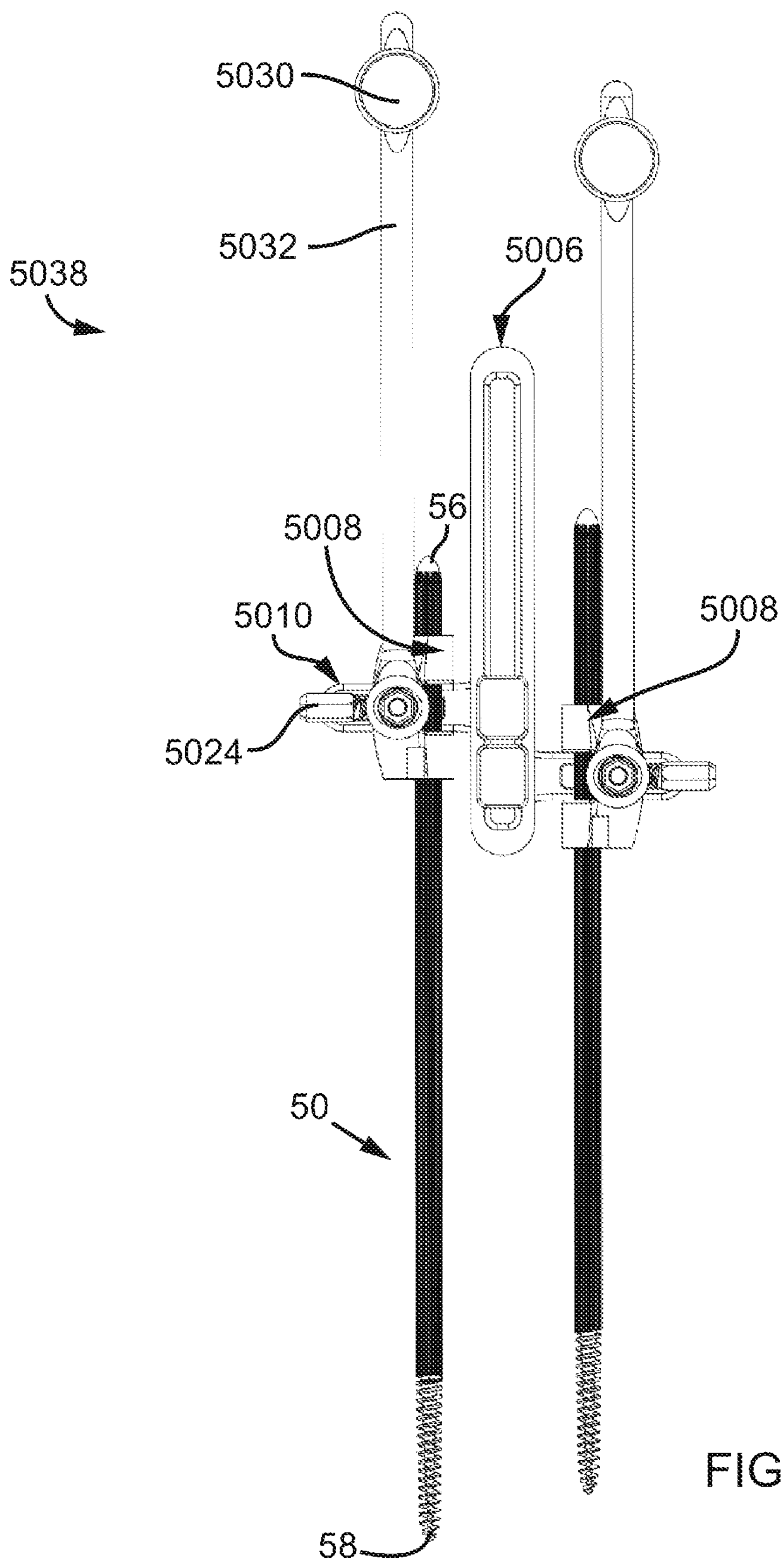


FIG. 16C

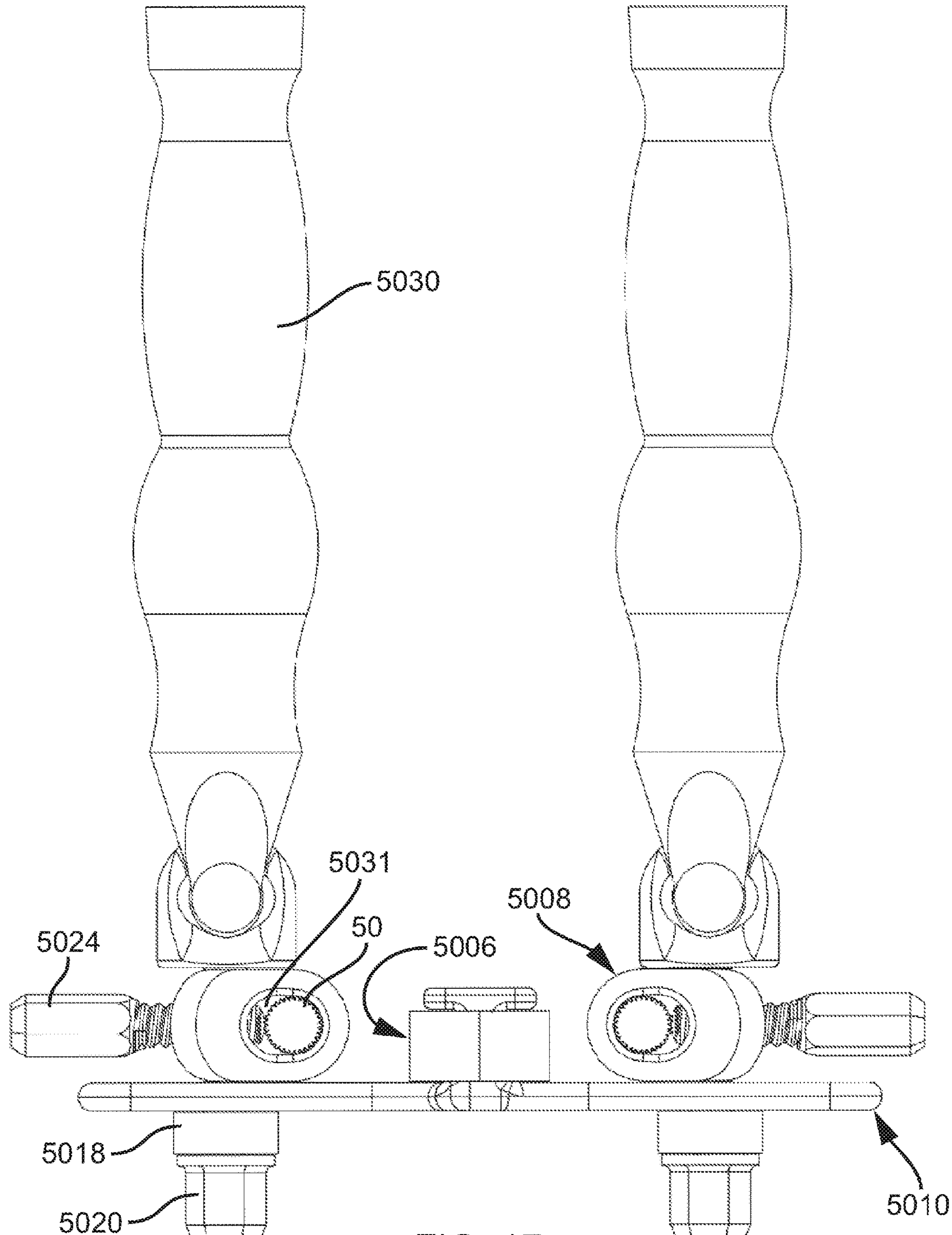


FIG. 17

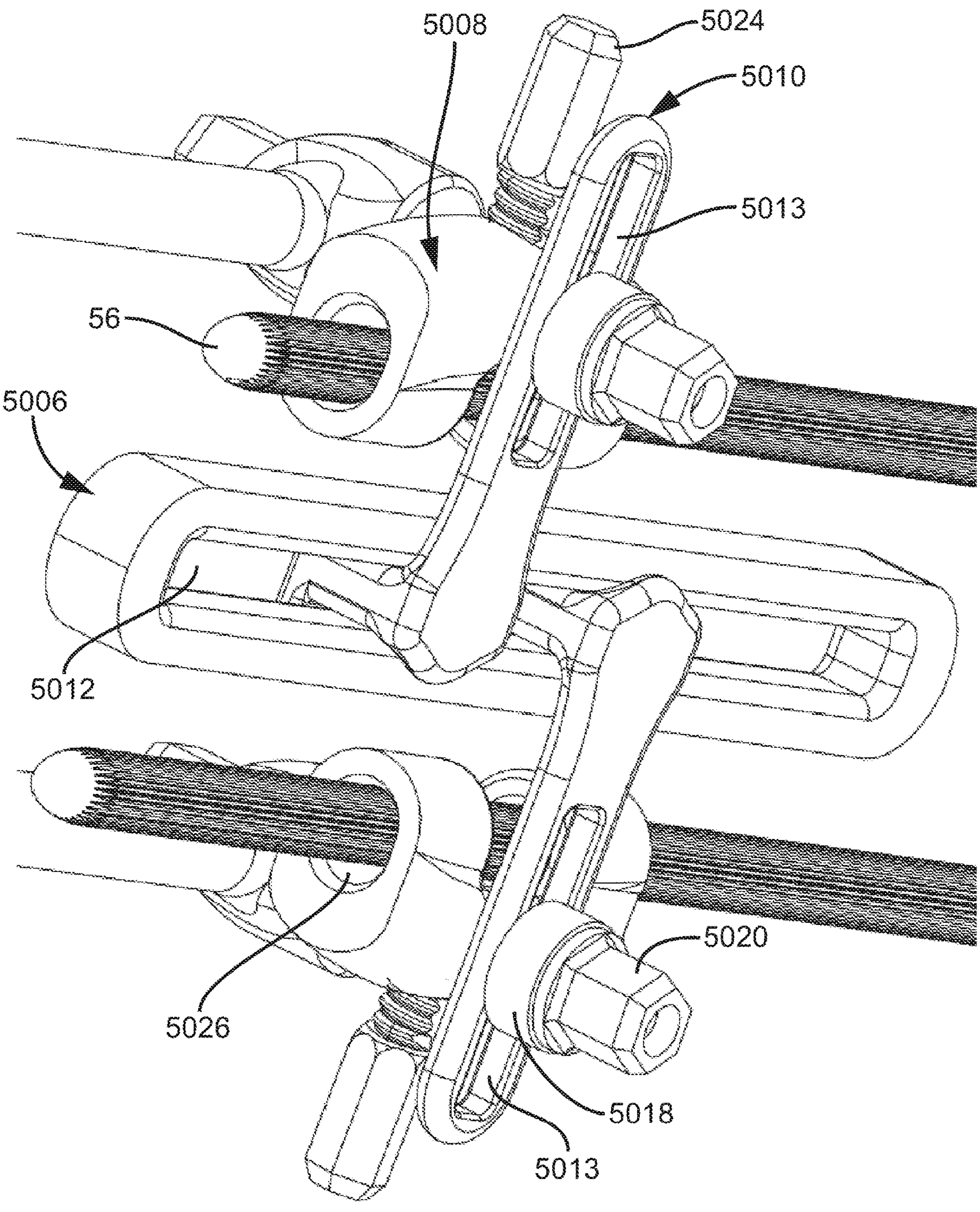


FIG. 18

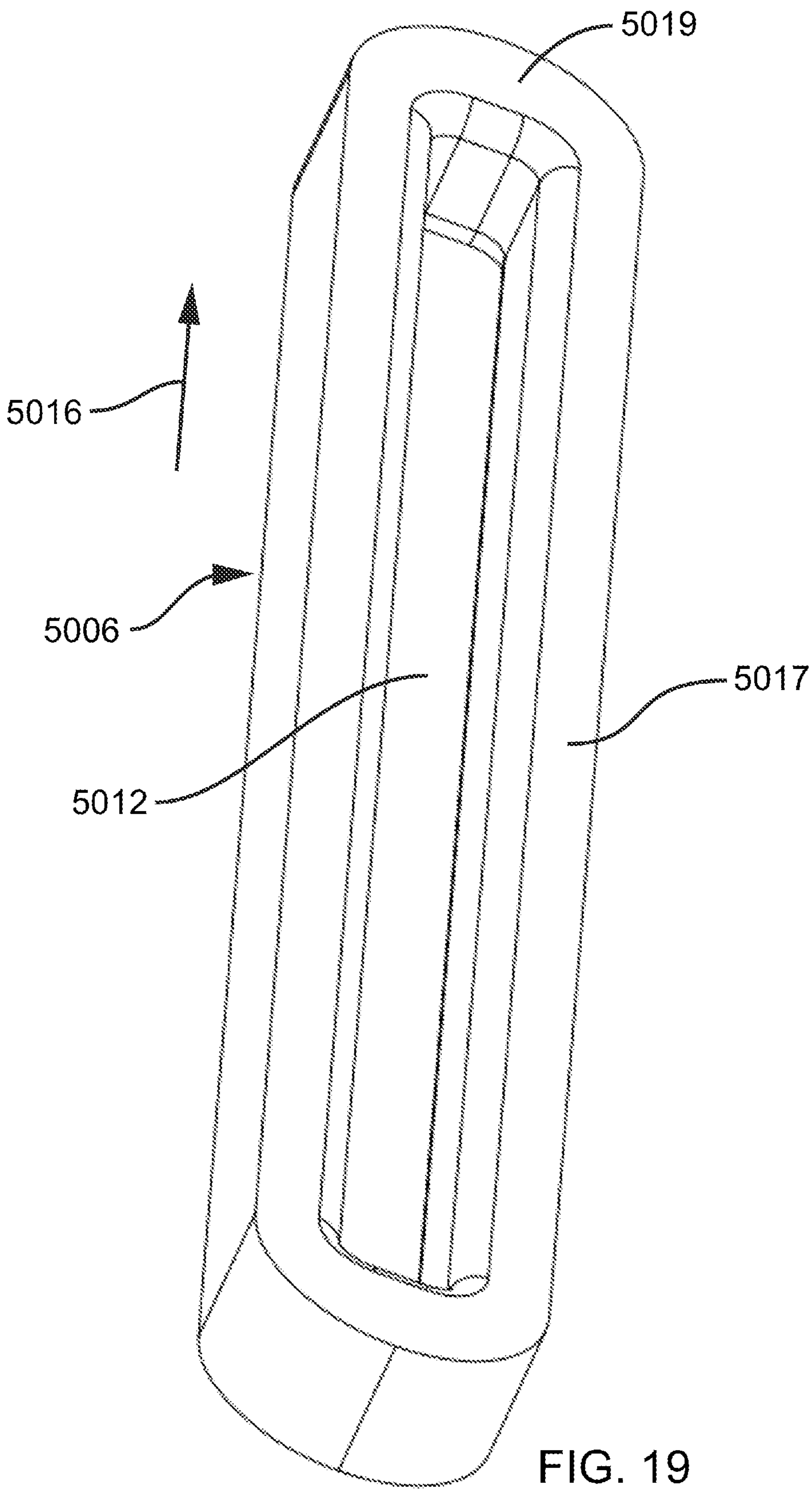


FIG. 19

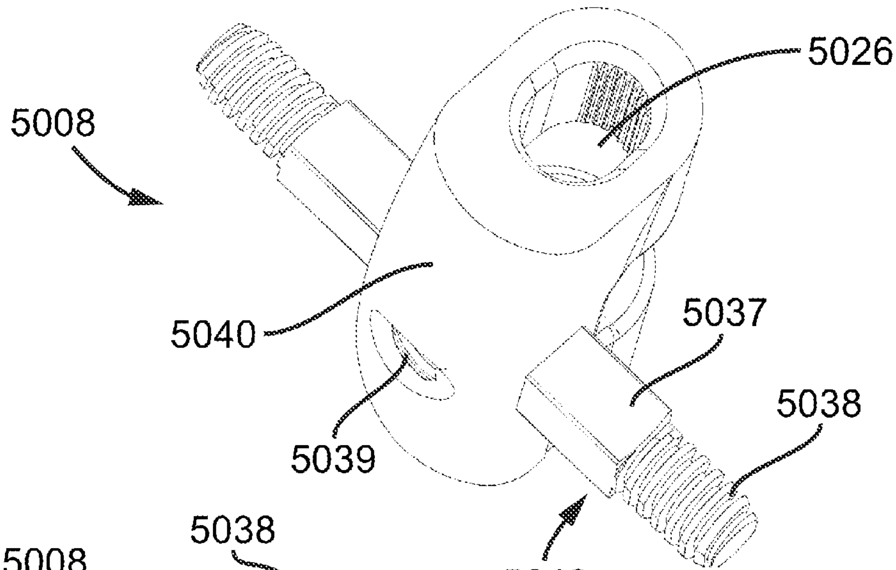


FIG. 20A

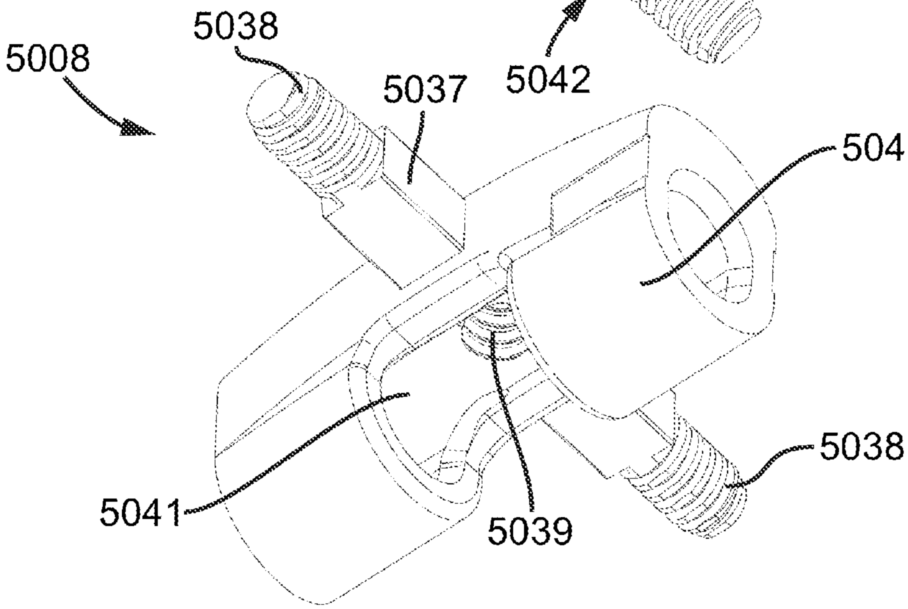


FIG. 20B

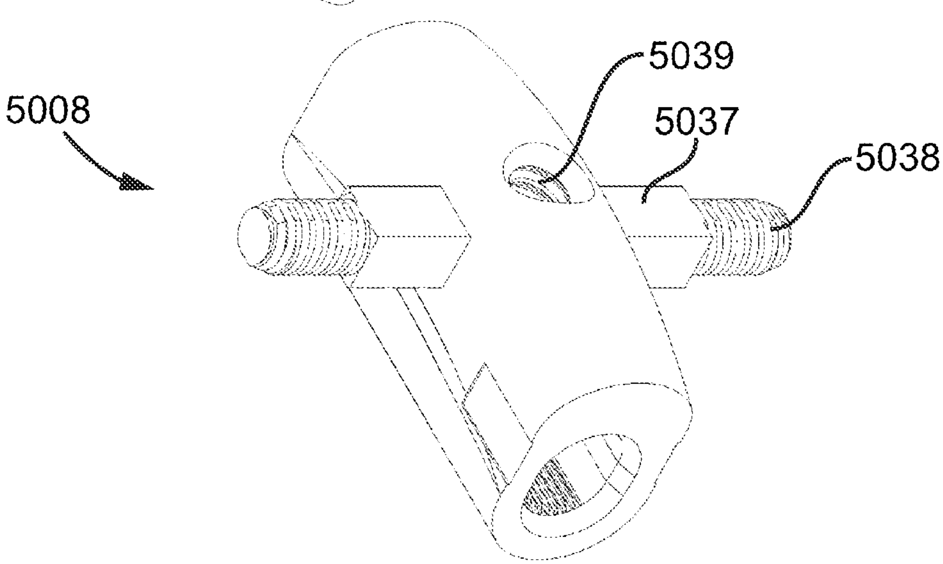


FIG. 20C

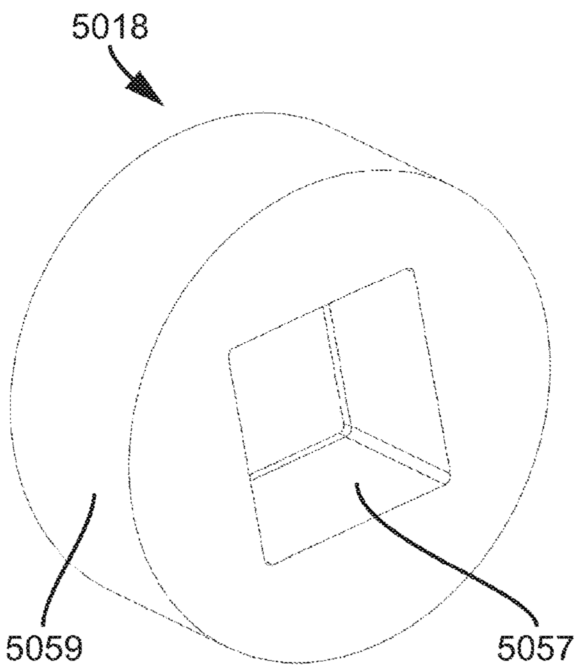


FIG. 22

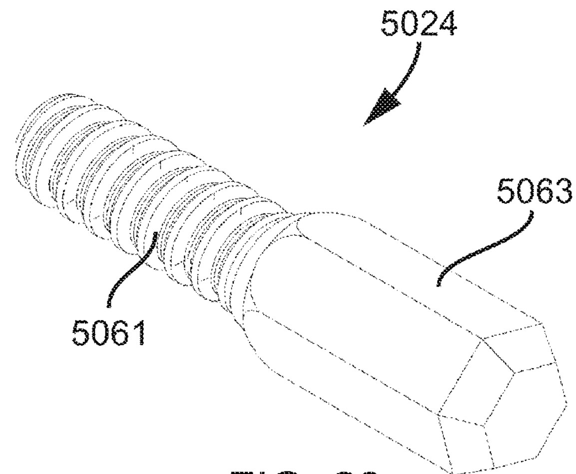


FIG. 23

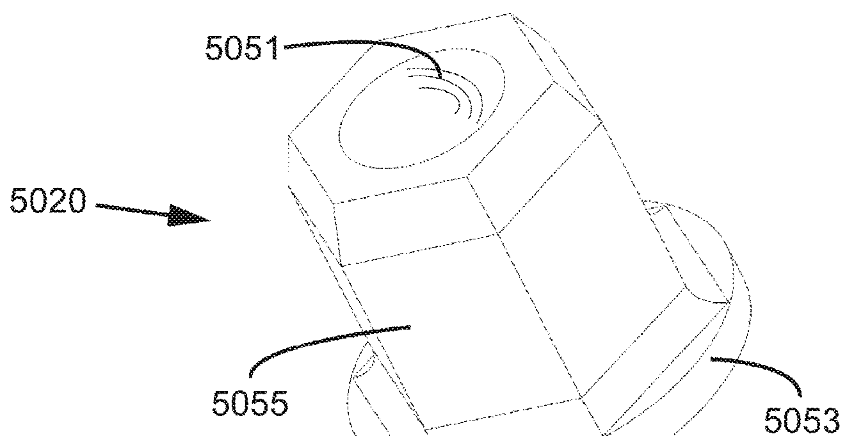


FIG. 21

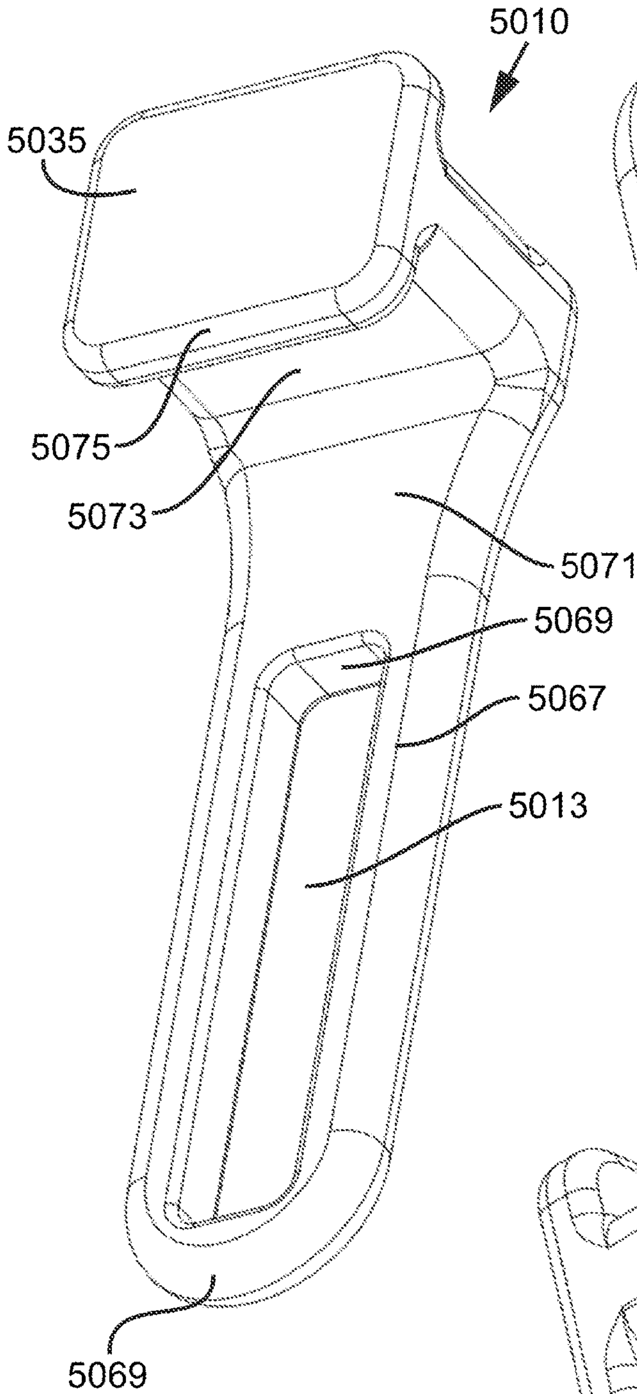


FIG. 24A

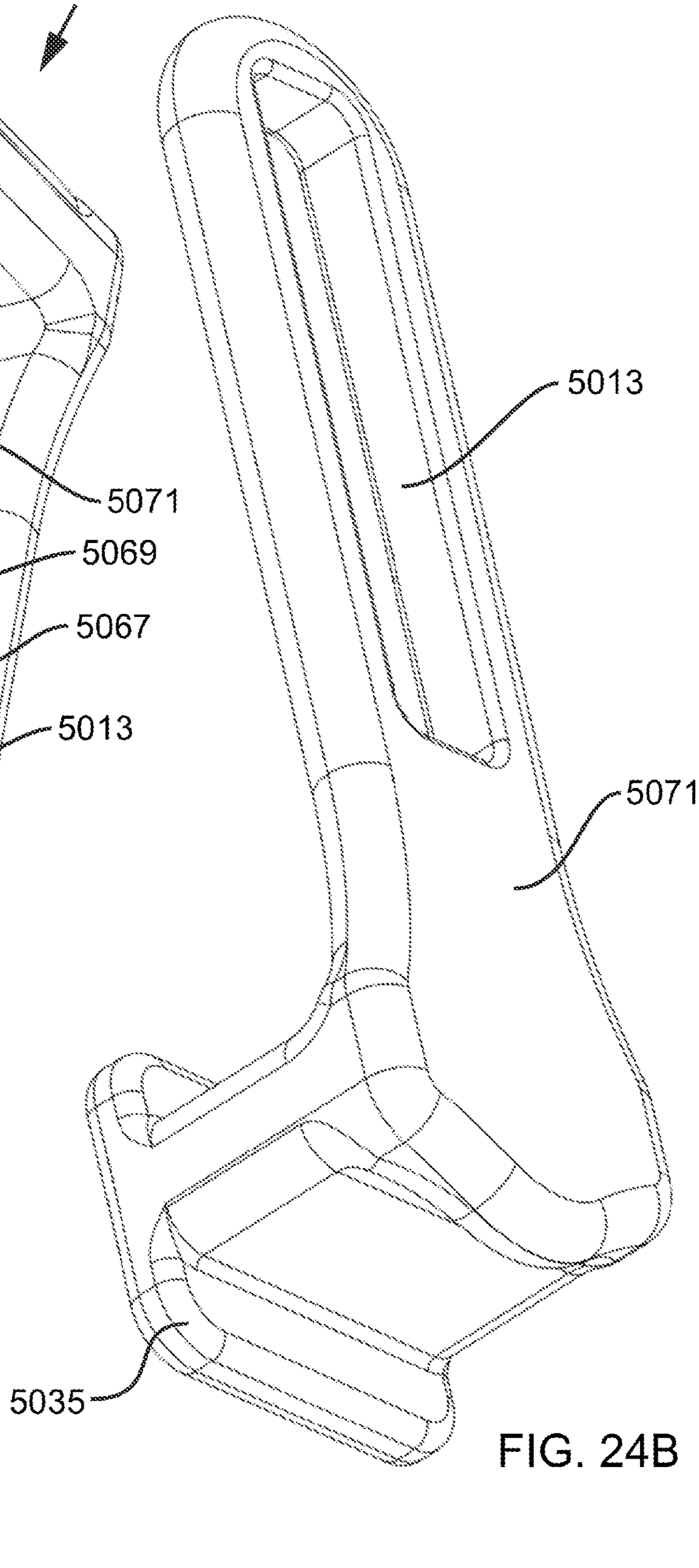


FIG. 24B

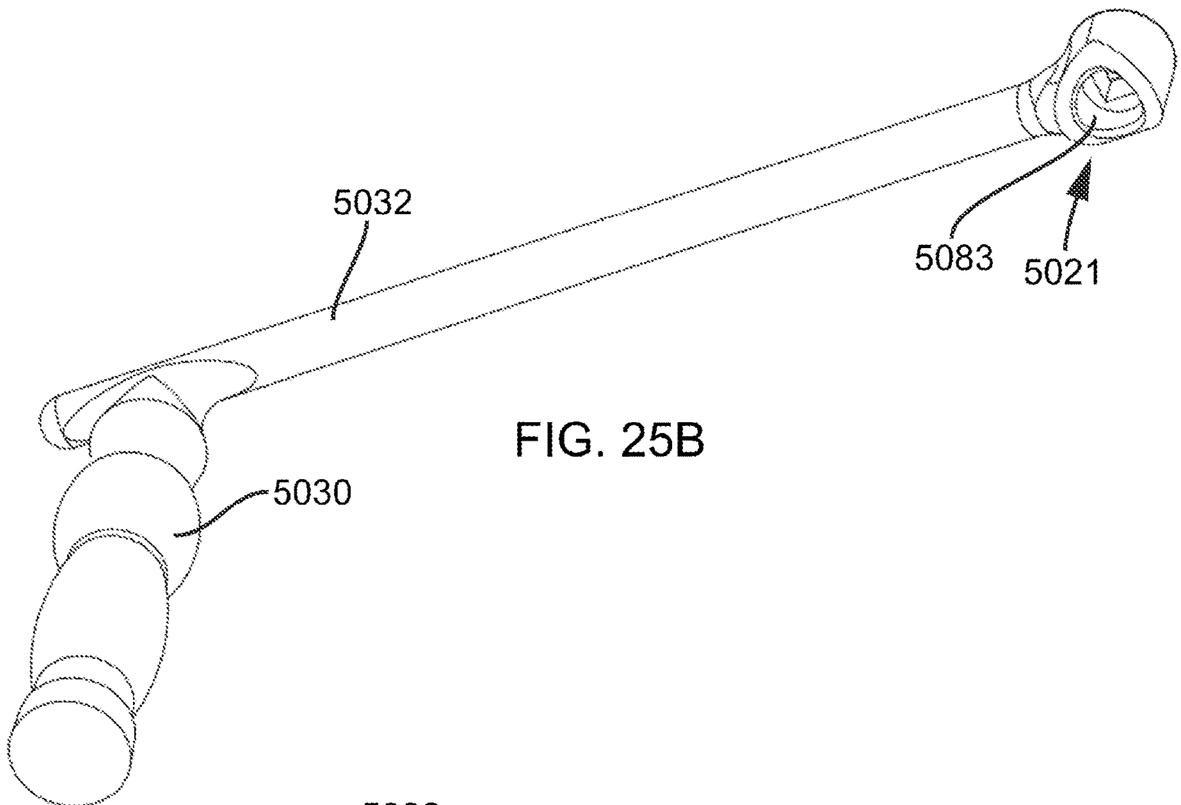


FIG. 25B

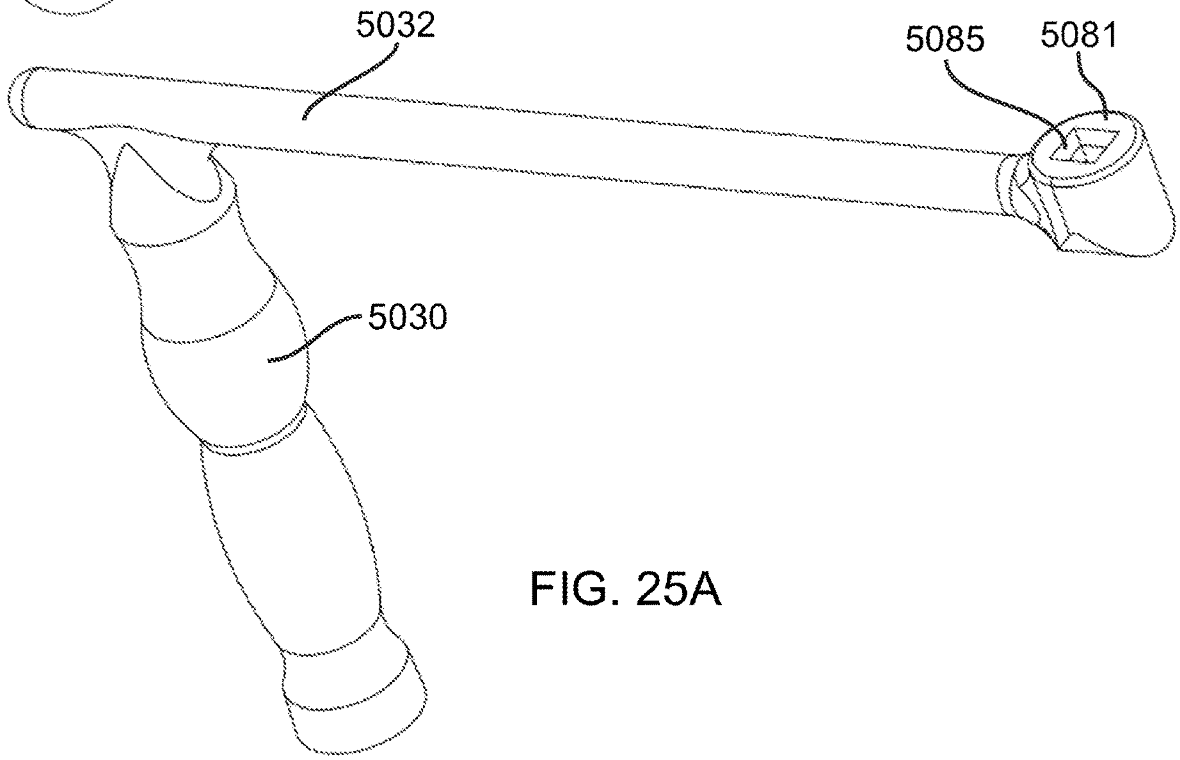
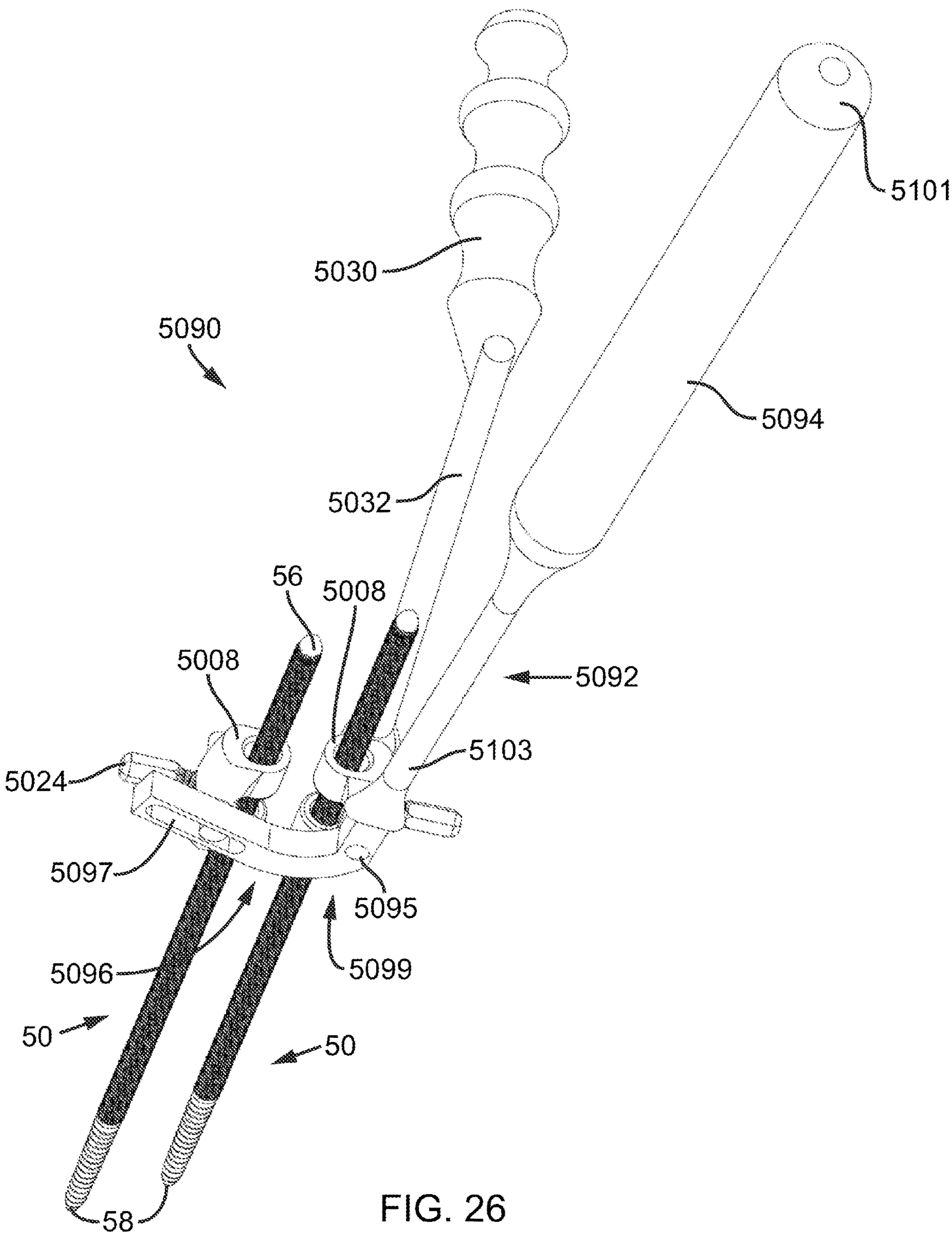


FIG. 25A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58

FIG. 26

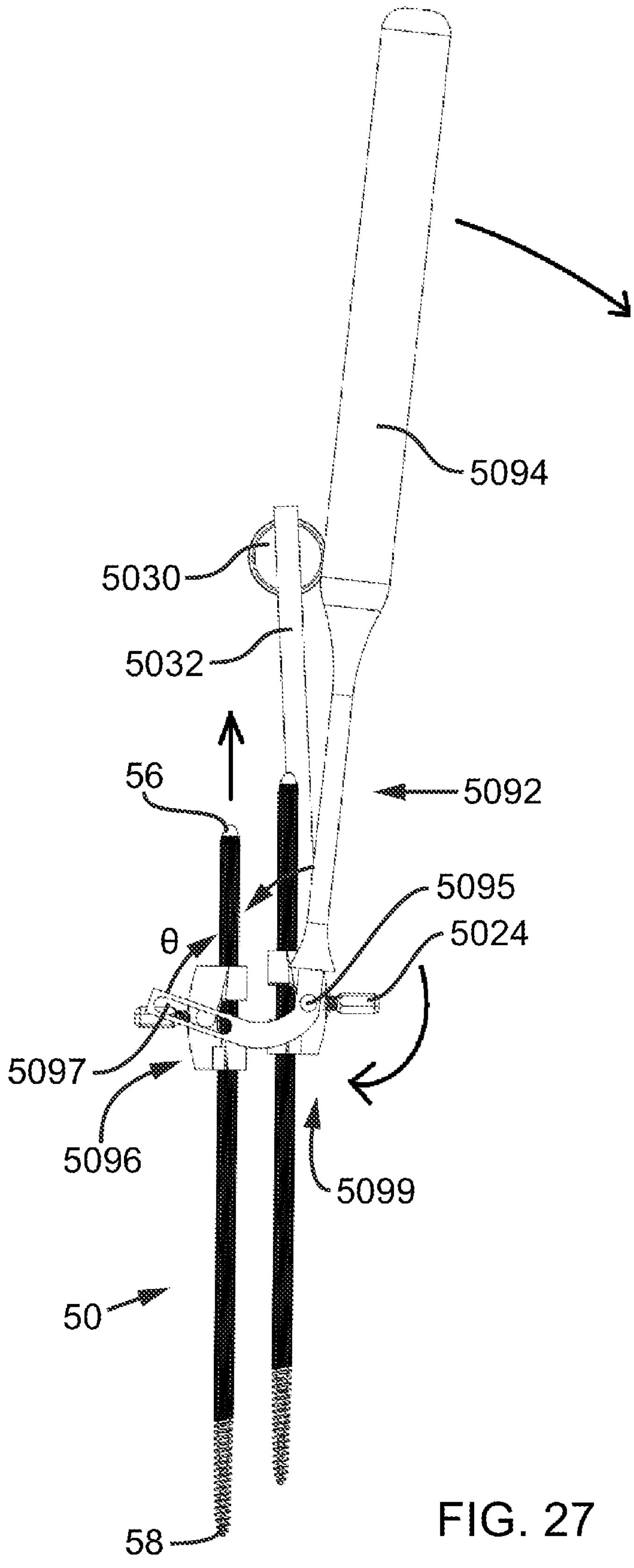


FIG. 27

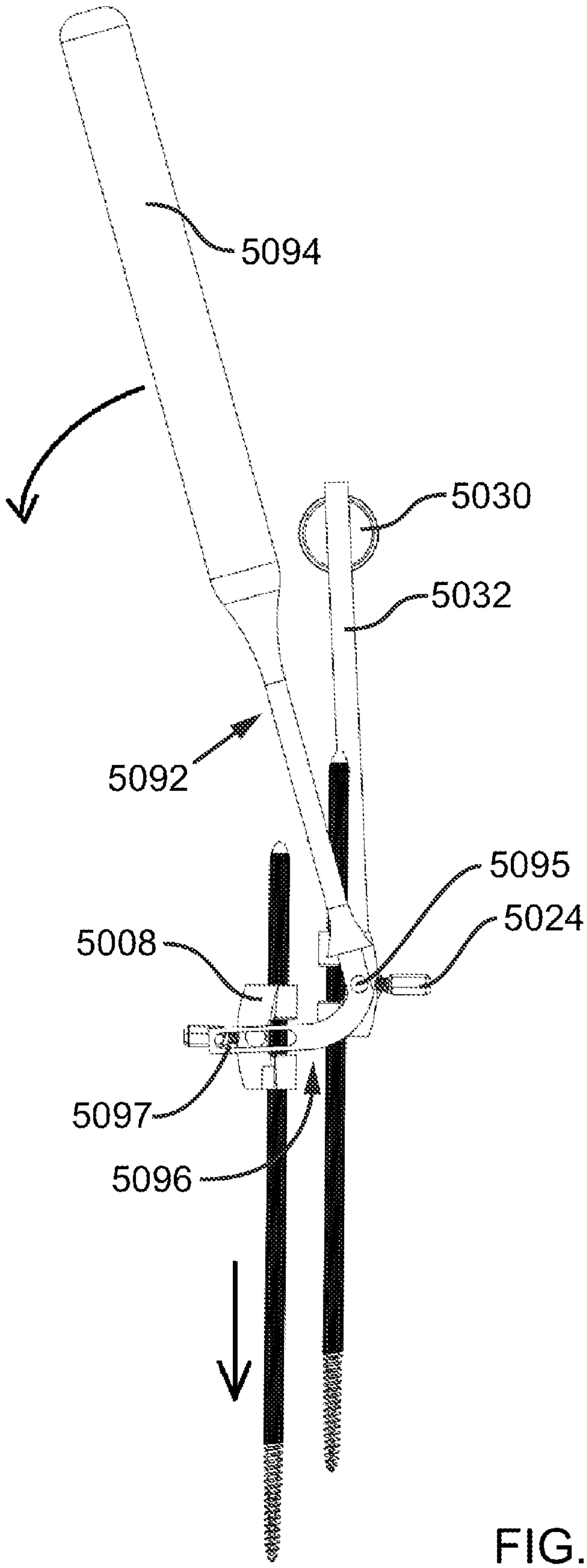
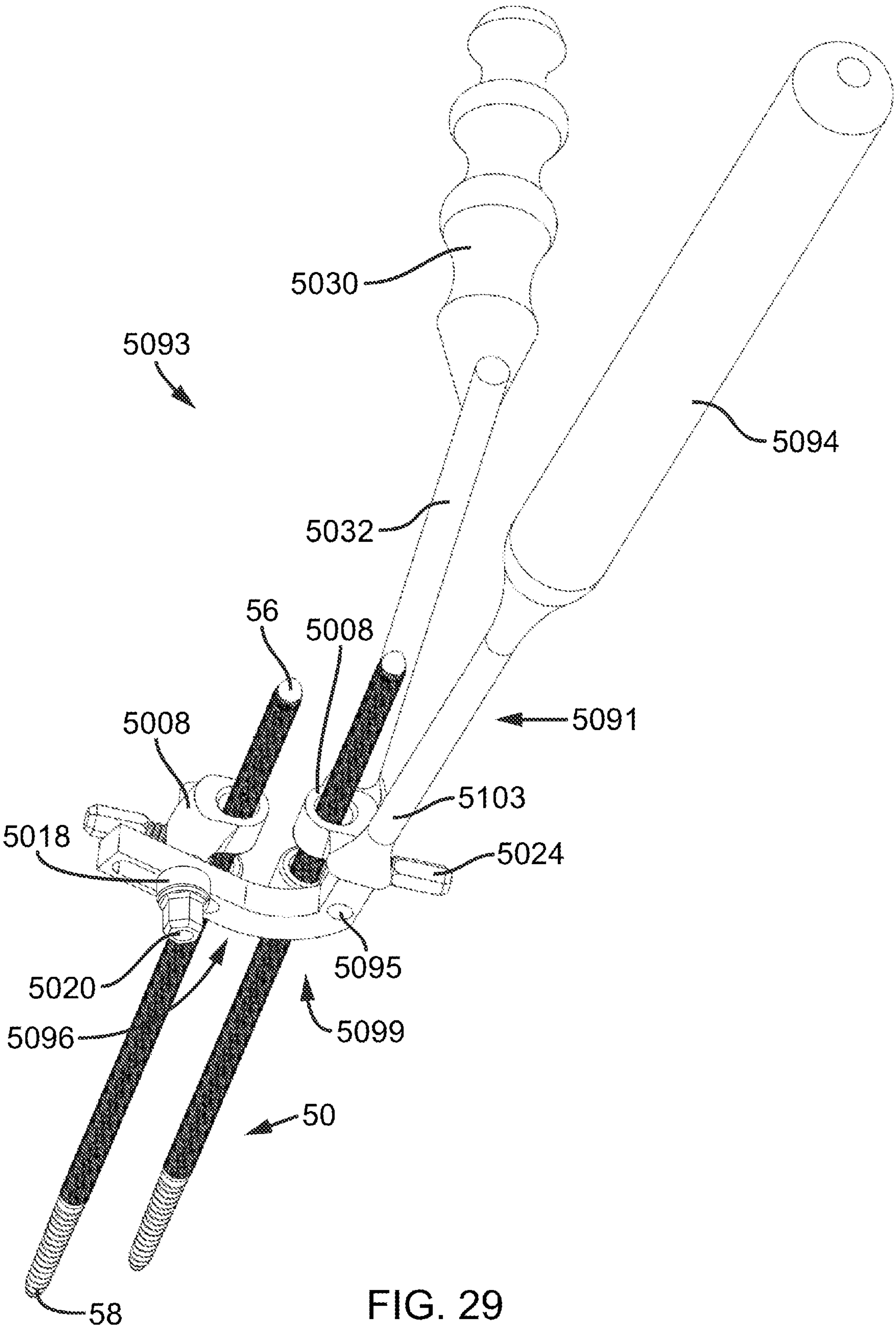


FIG. 28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5099
50
58

FIG. 29

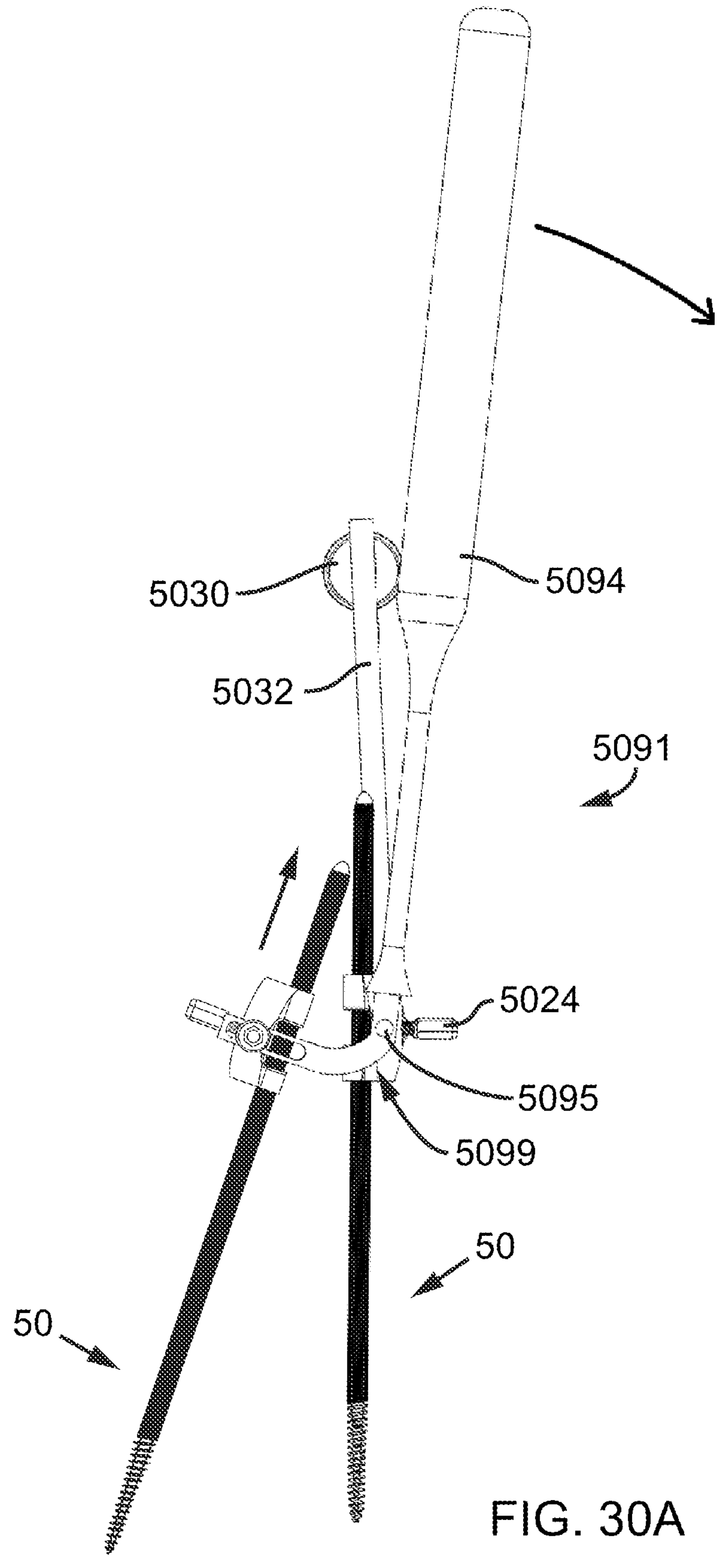


FIG. 30A

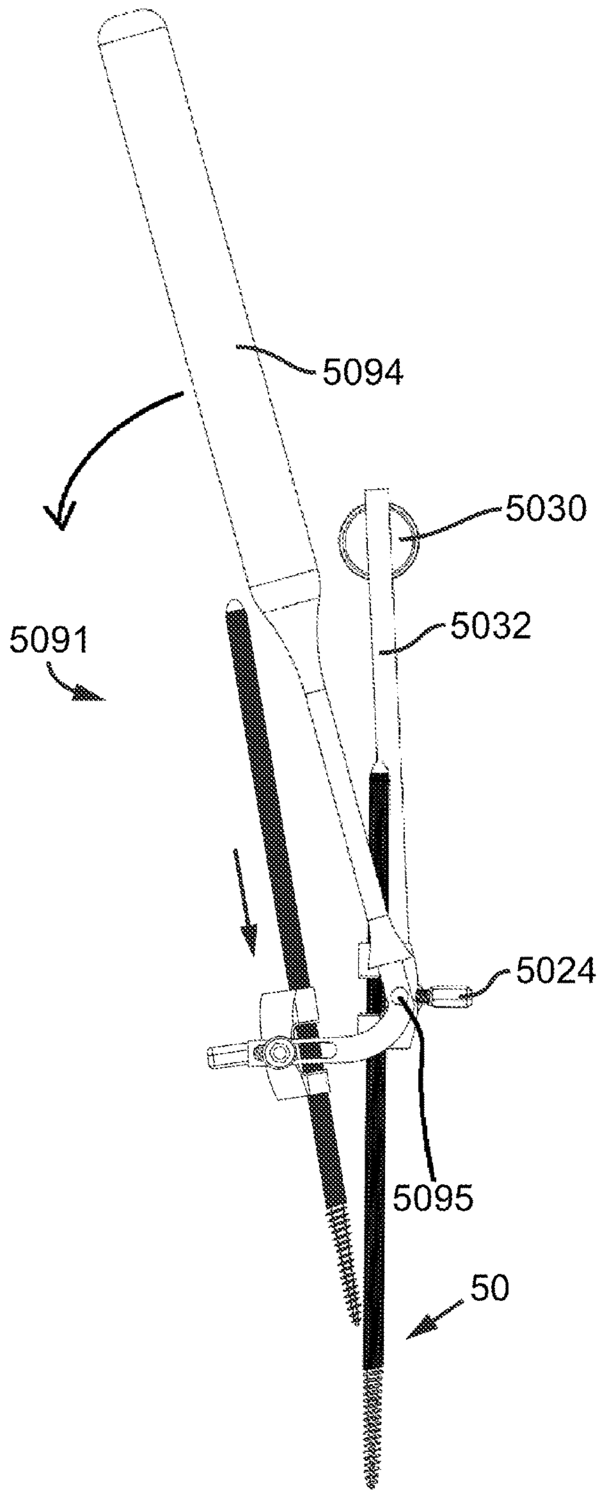


FIG. 30B

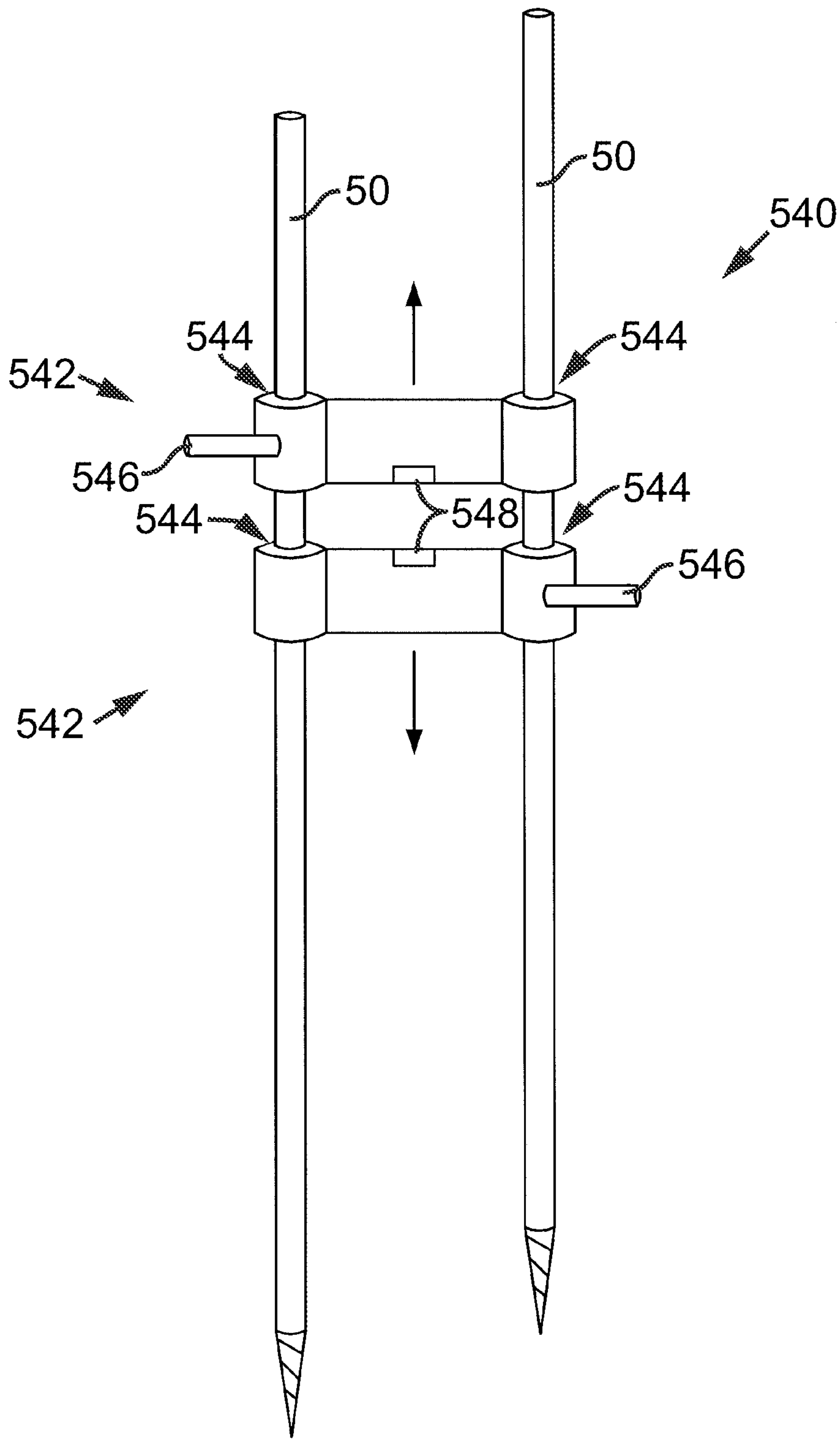
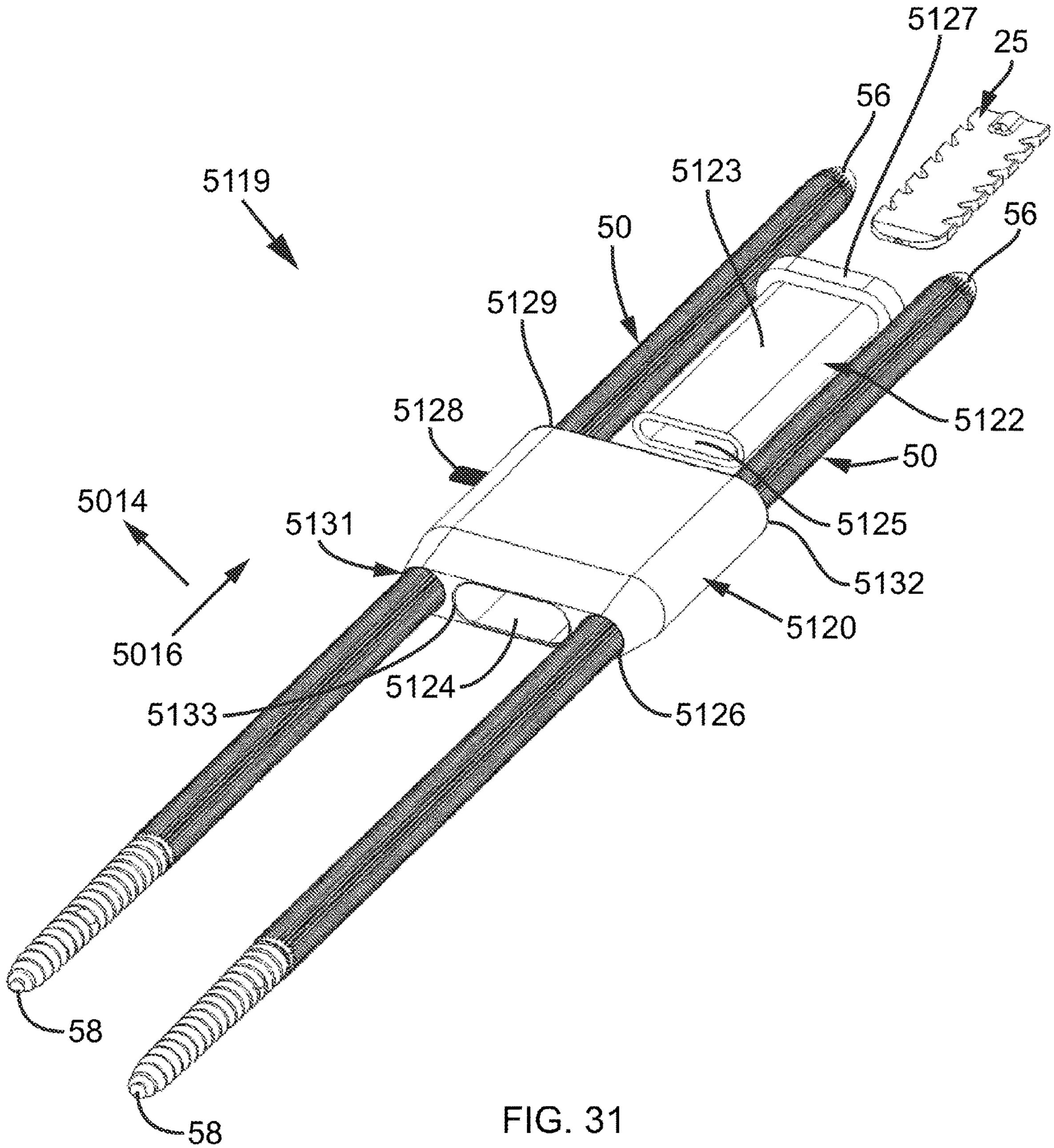


FIG. 30C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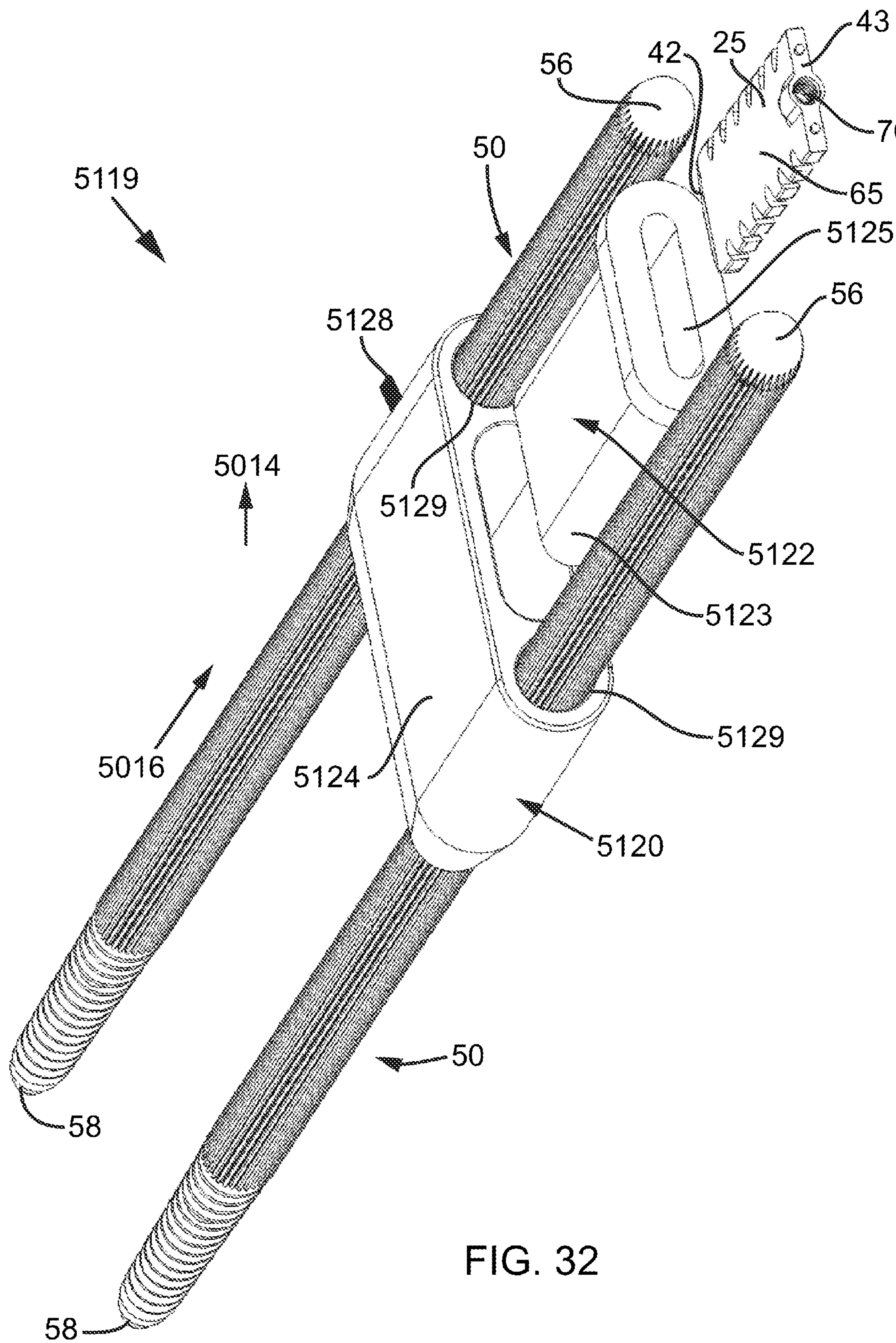
5120
5124
5133
5126
58
58

FIG. 31


43
42
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5016
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5120
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58
58

FIG. 32

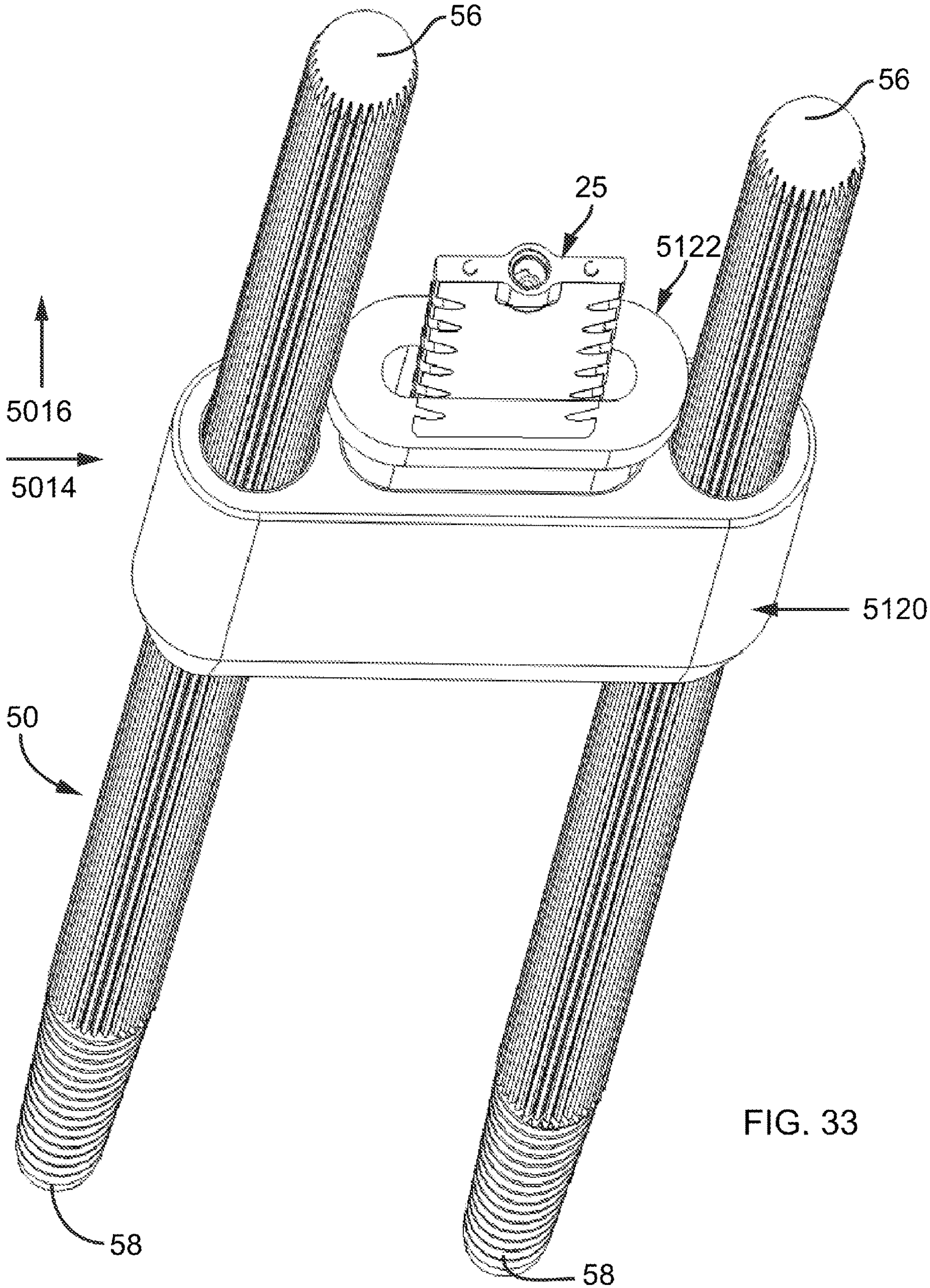


FIG. 33

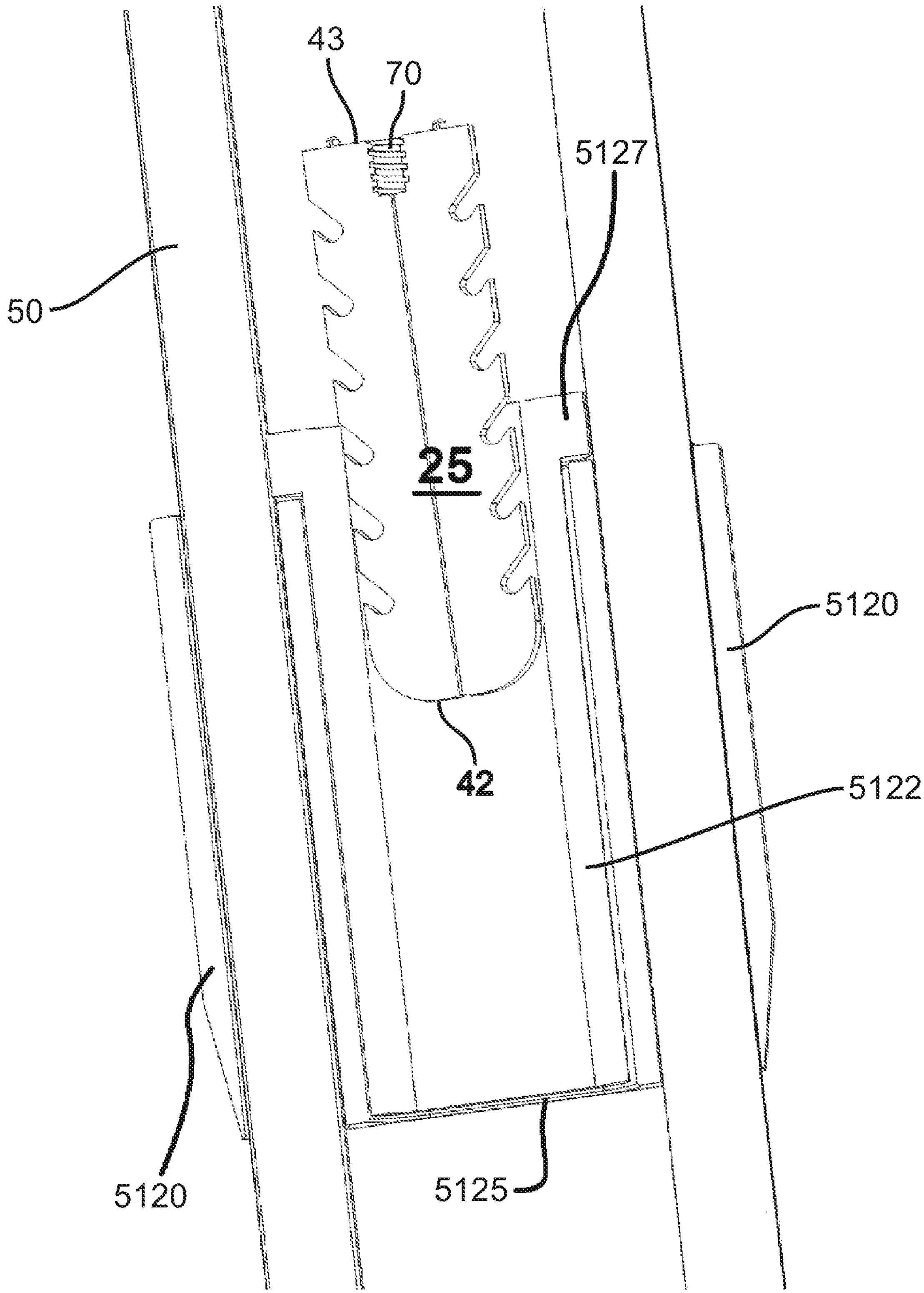


FIG. 34

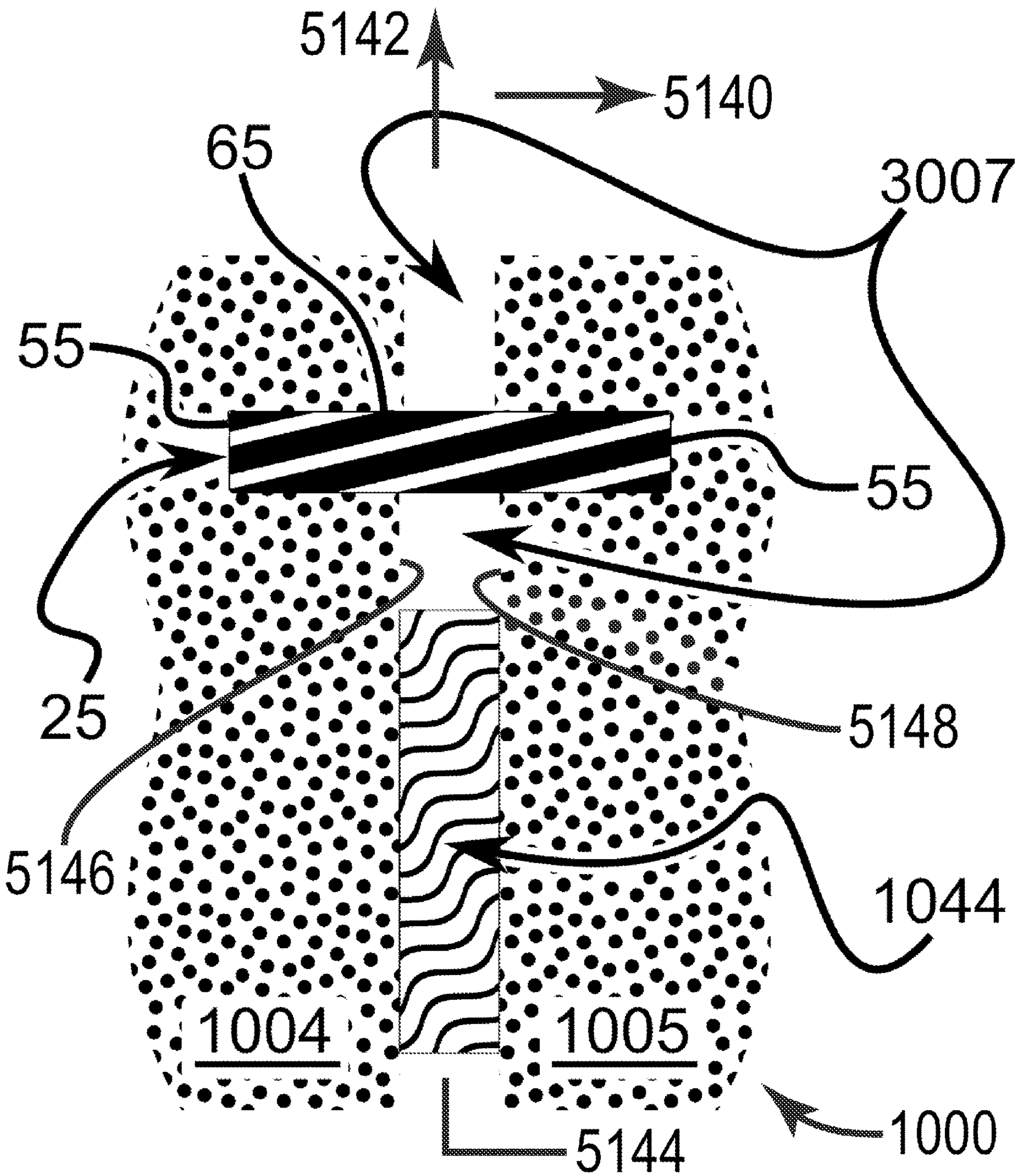


FIG. 35

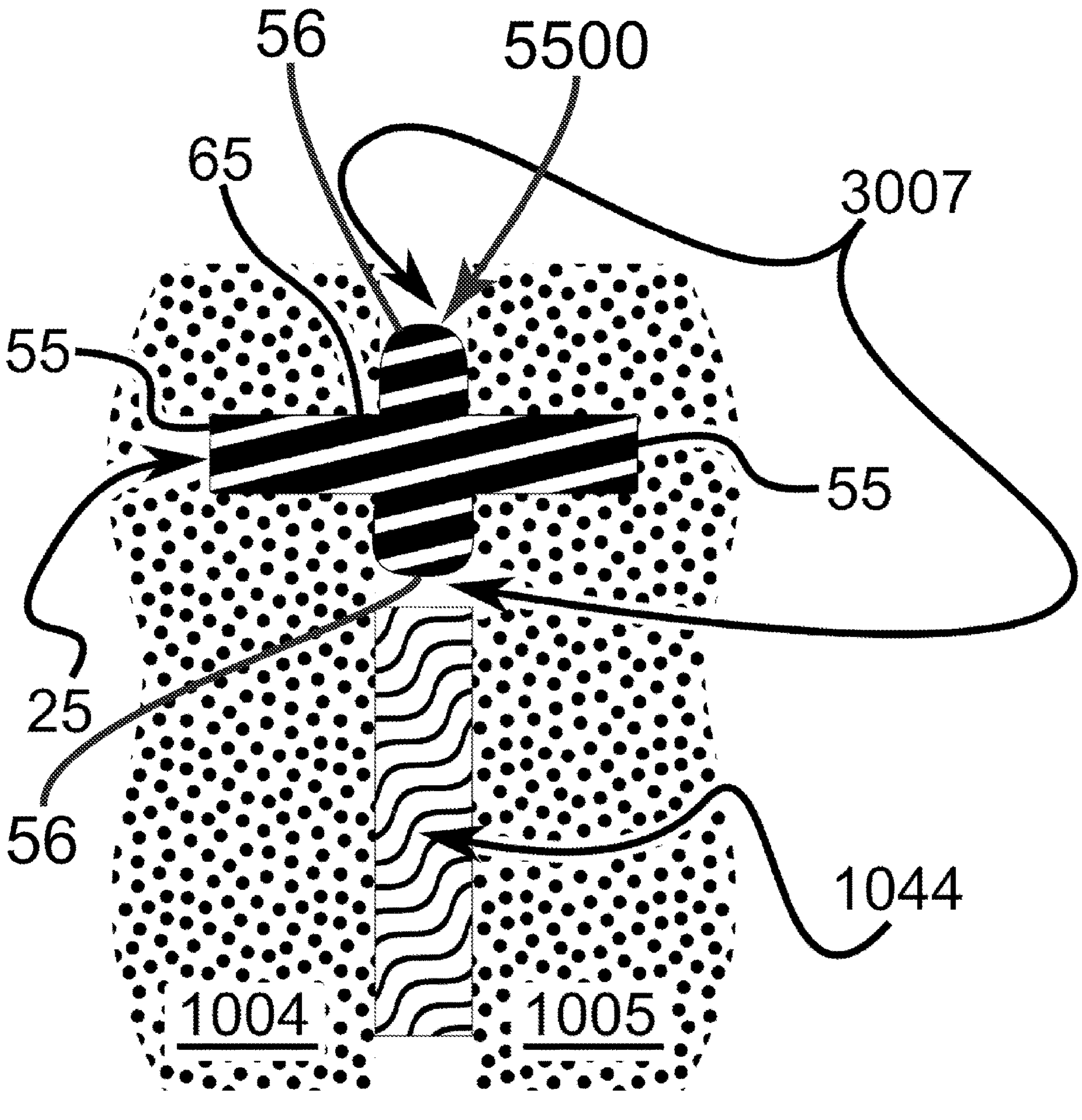


FIG. 36

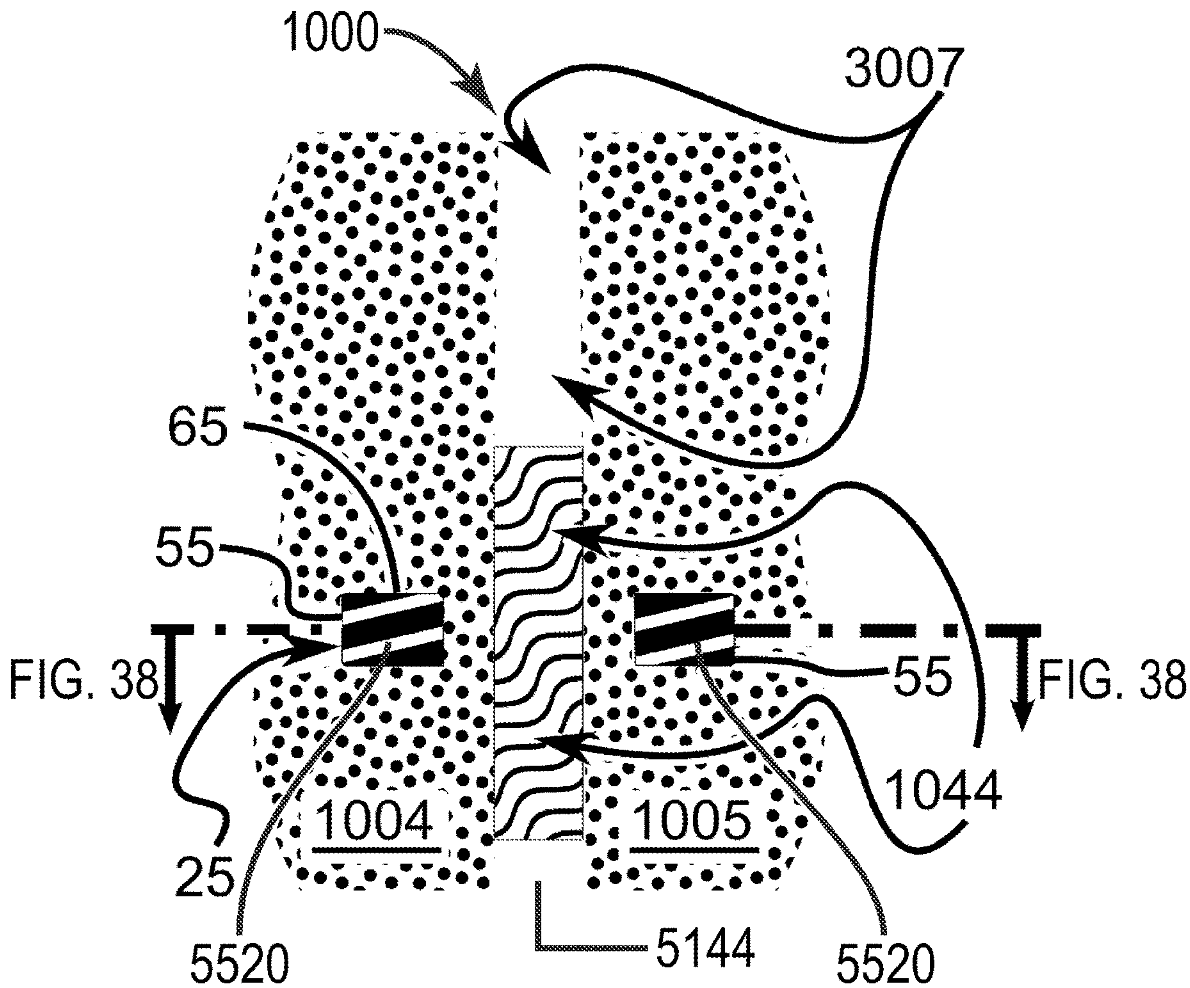
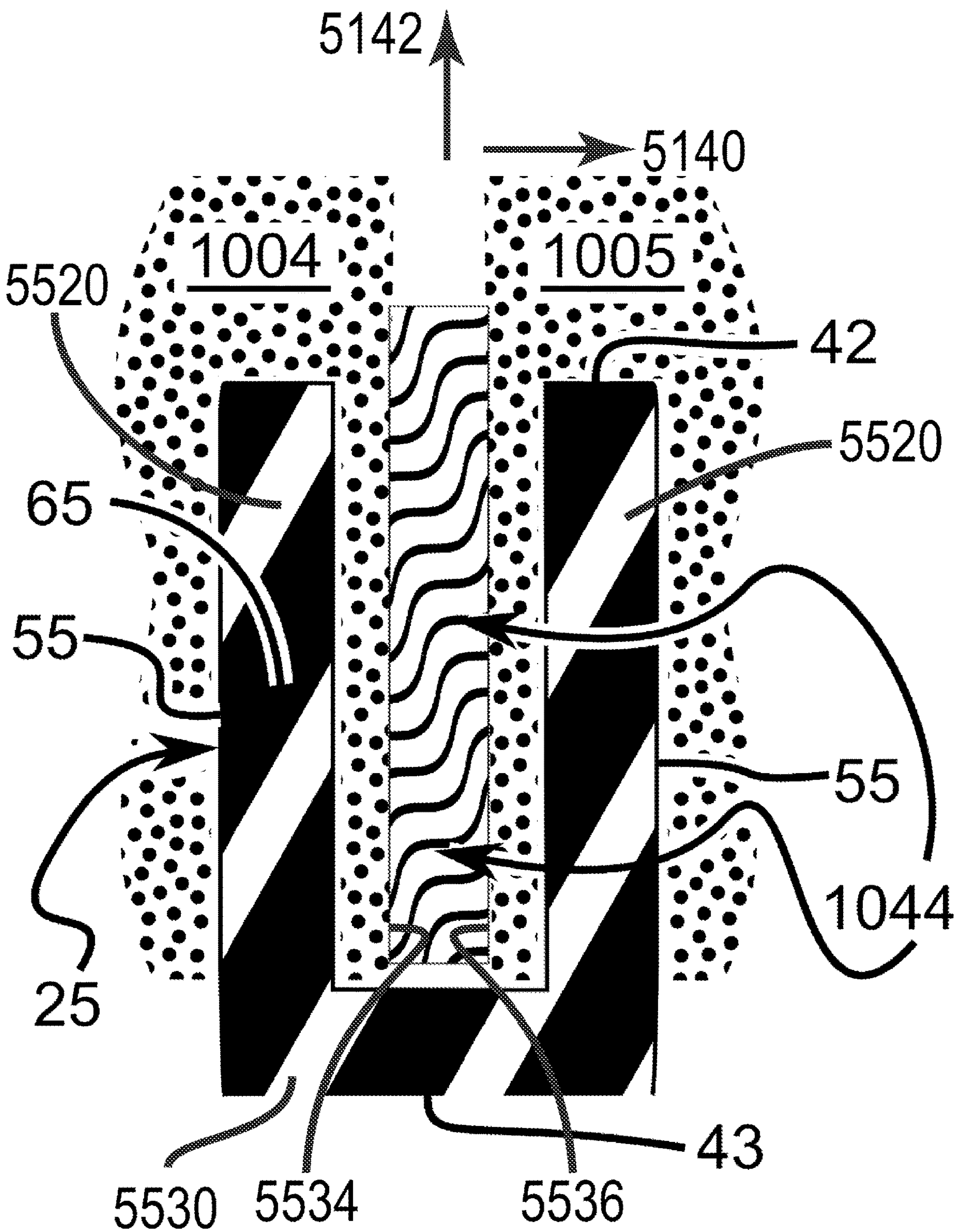

1000
3007
65
55
FIG. 38
55
FIG. 38
1044
25
1004
1005
5520
5144
5520

FIG. 37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1005
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55
1044
25
43
5530
5534
5536

FIG. 38

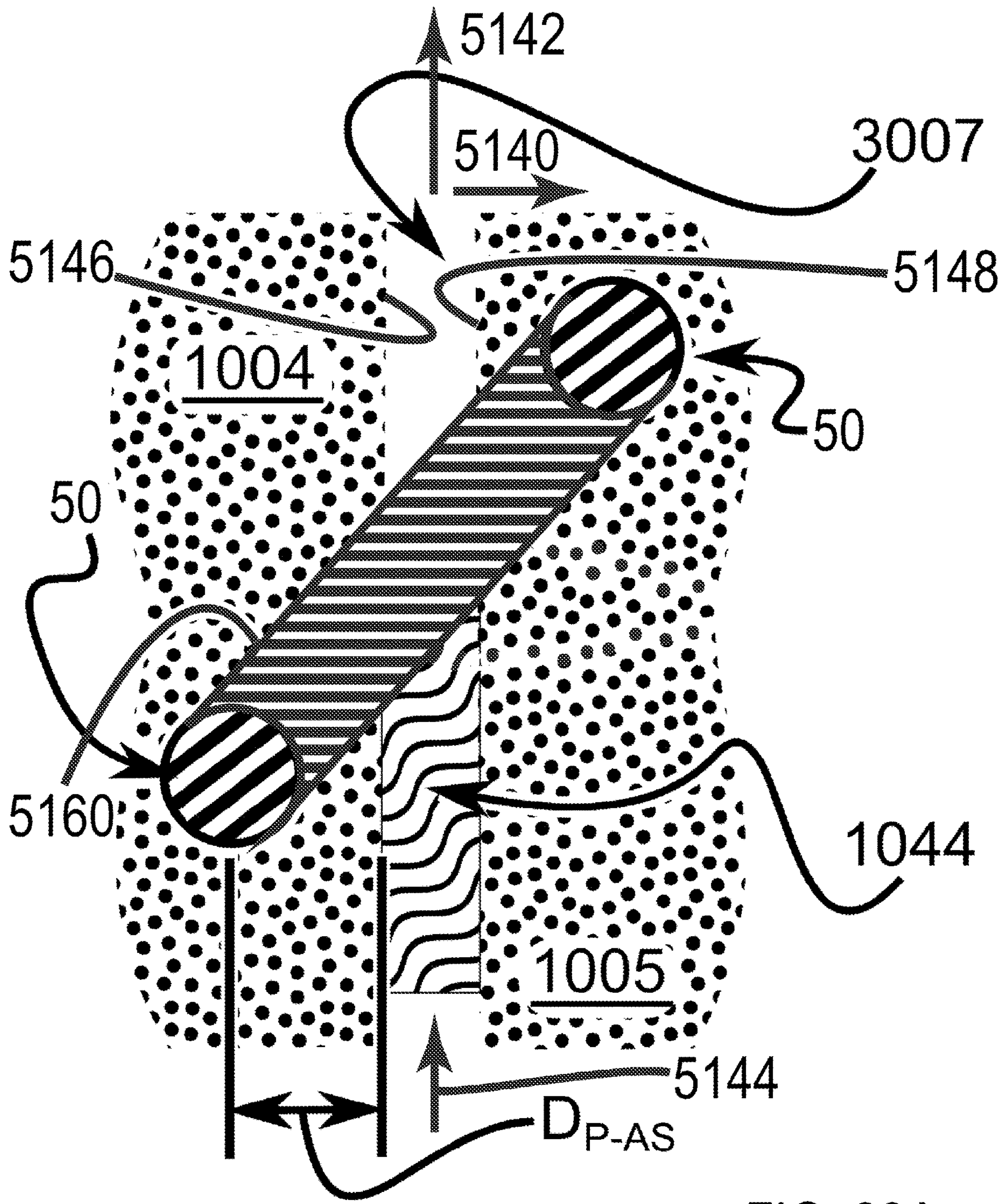


FIG. 39A

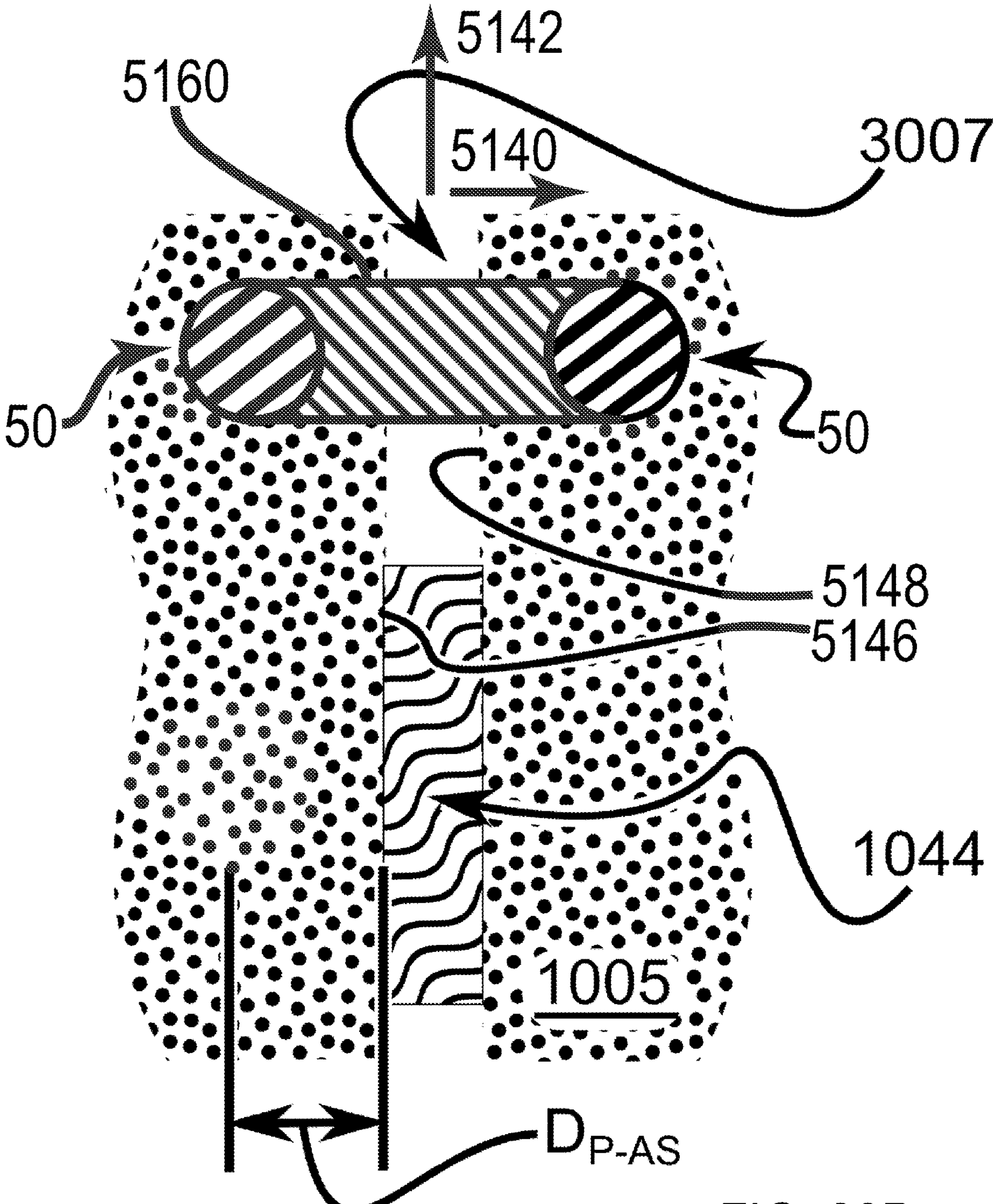


FIG. 39B

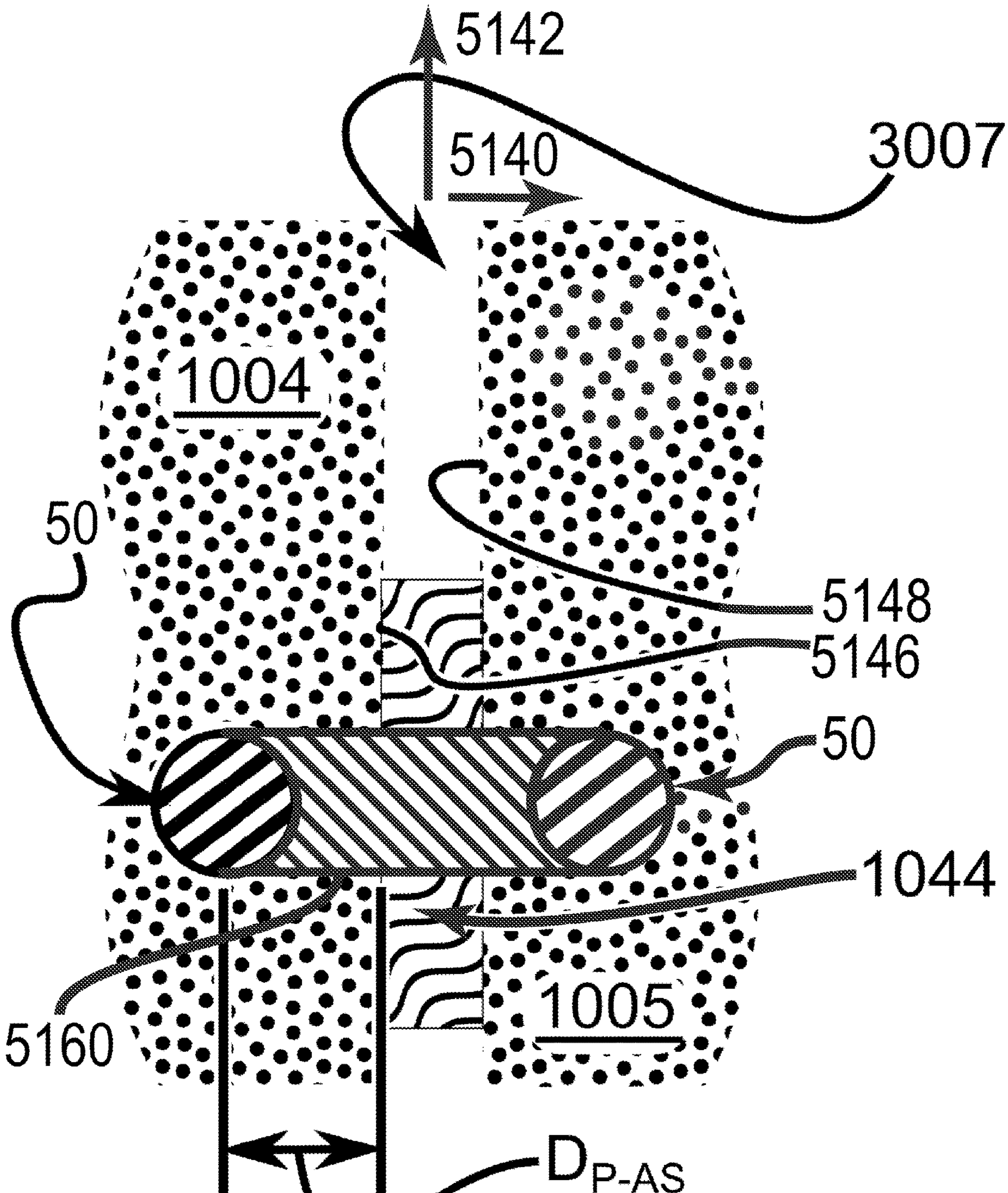


FIG. 39C

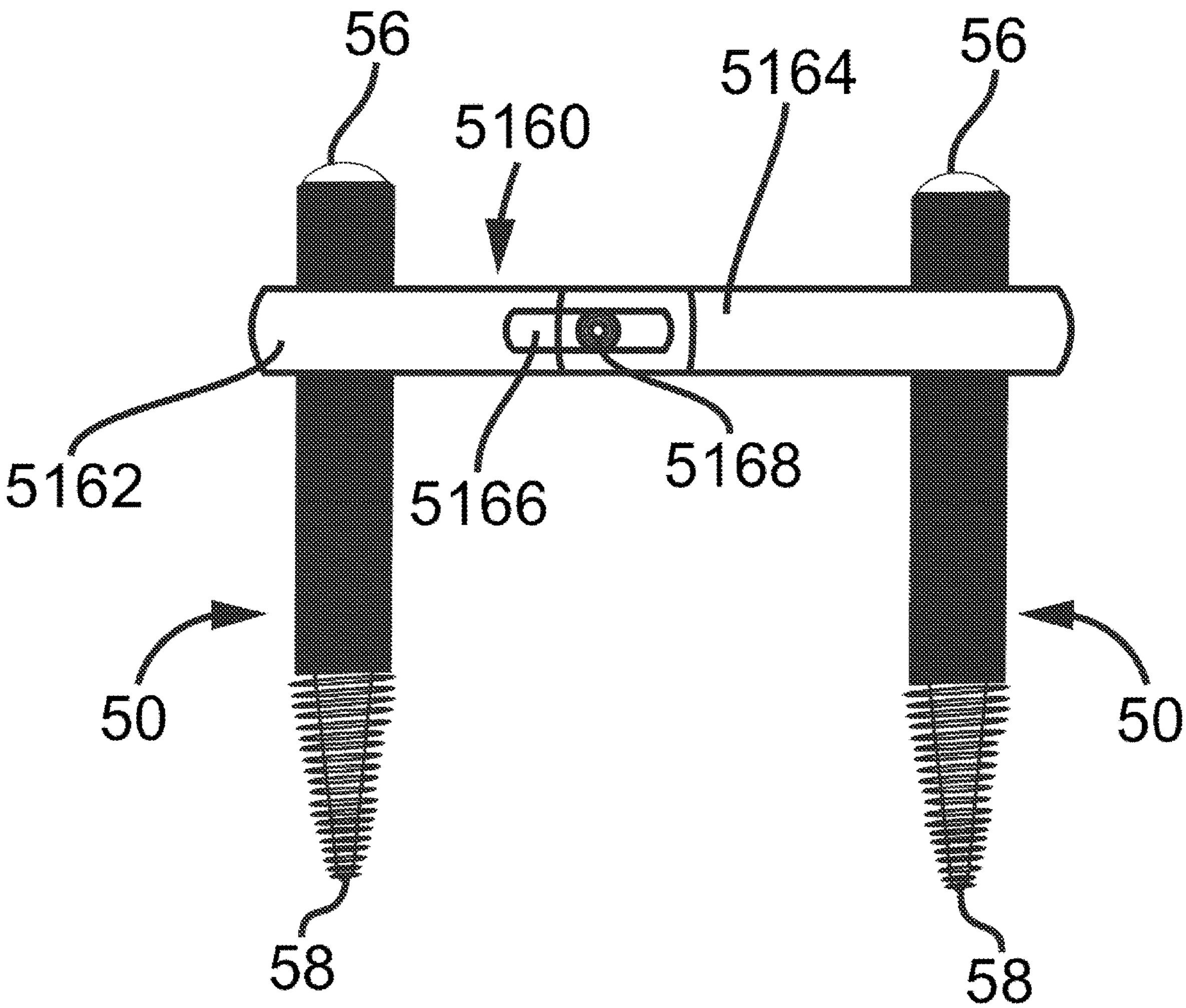
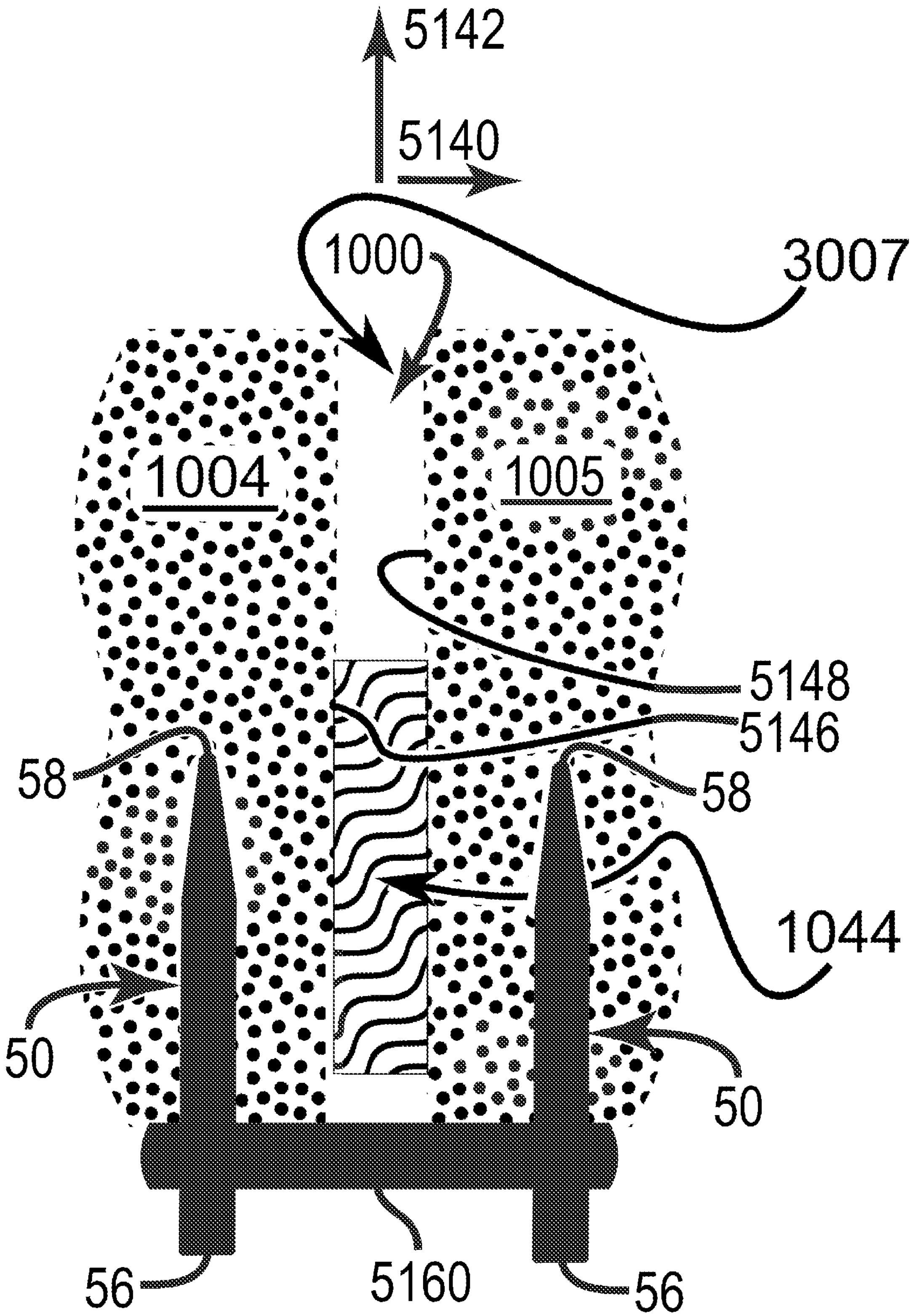


FIG. 40


5142
5140
1000
3007
1004
1005
5148
5146
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58
1044
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56
5160
56

FIG. 41

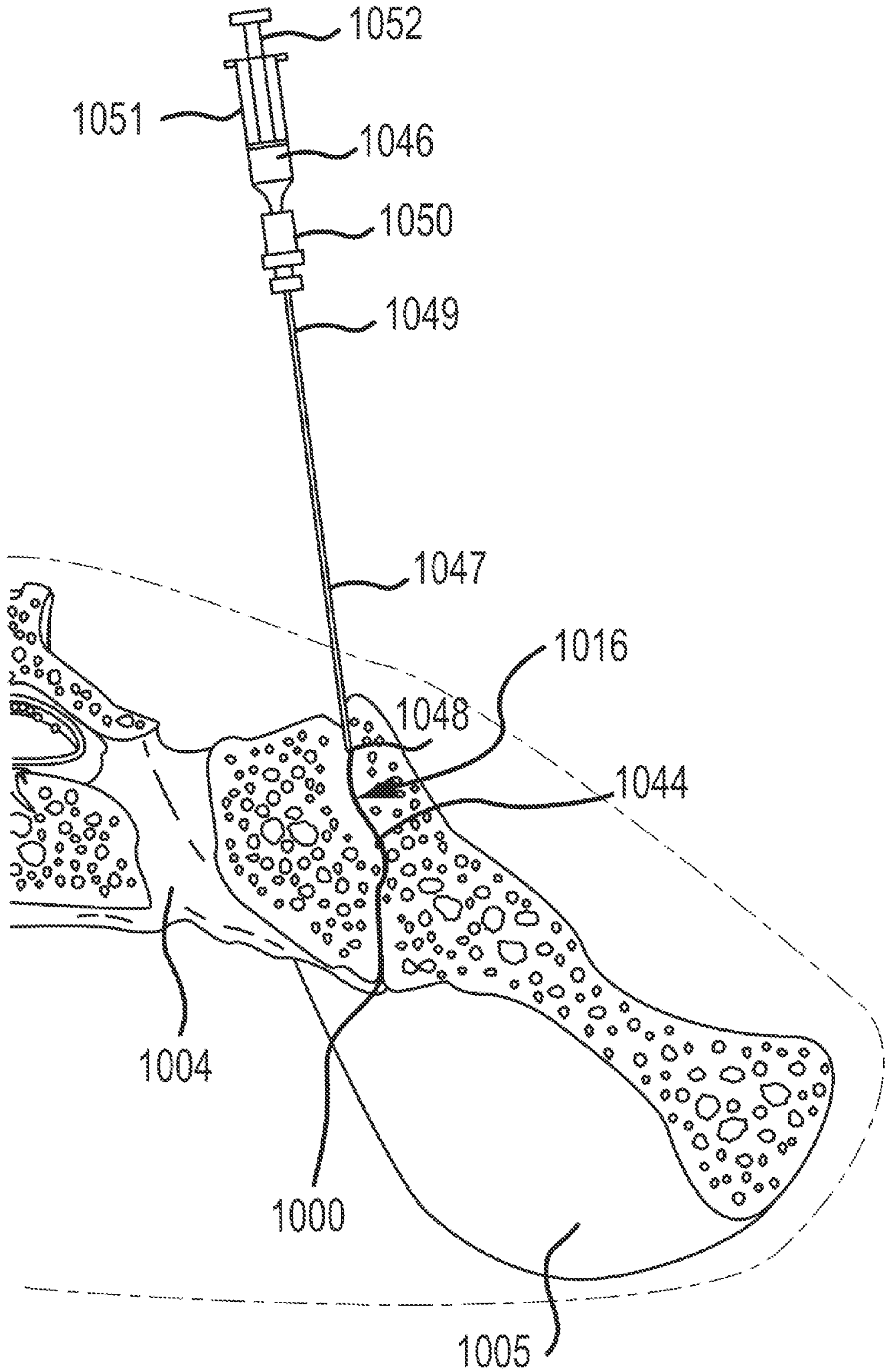


FIG. 42

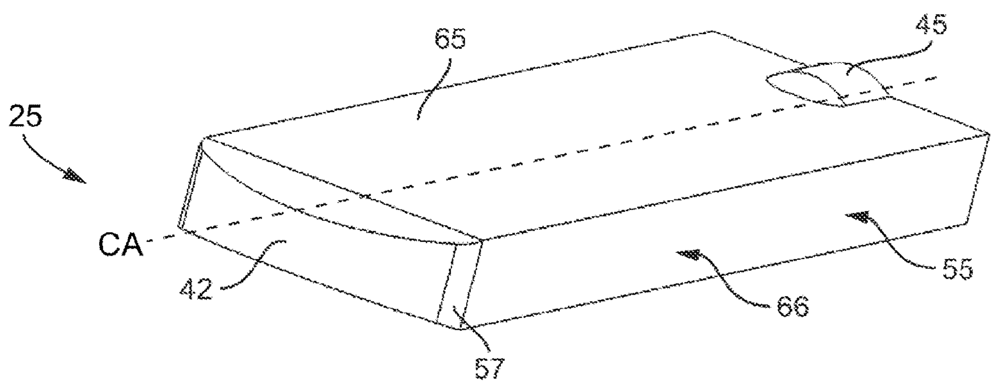


FIG. 43A

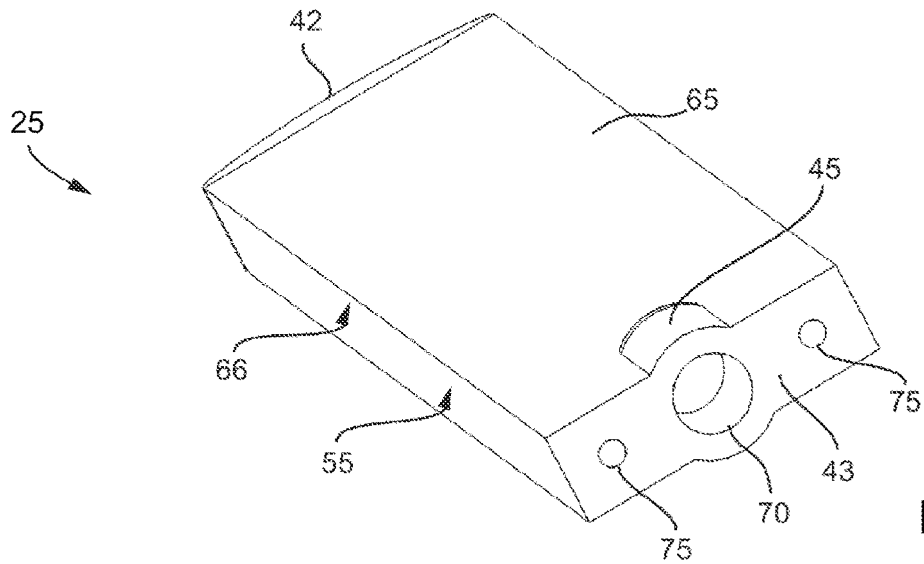


FIG. 43B

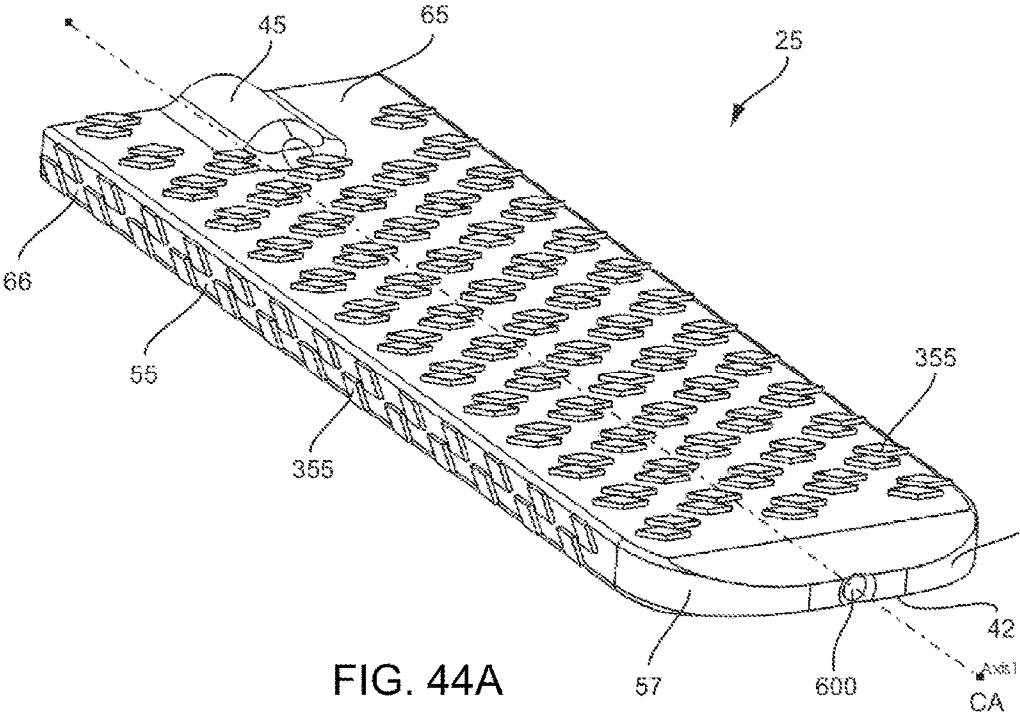


FIG. 44A

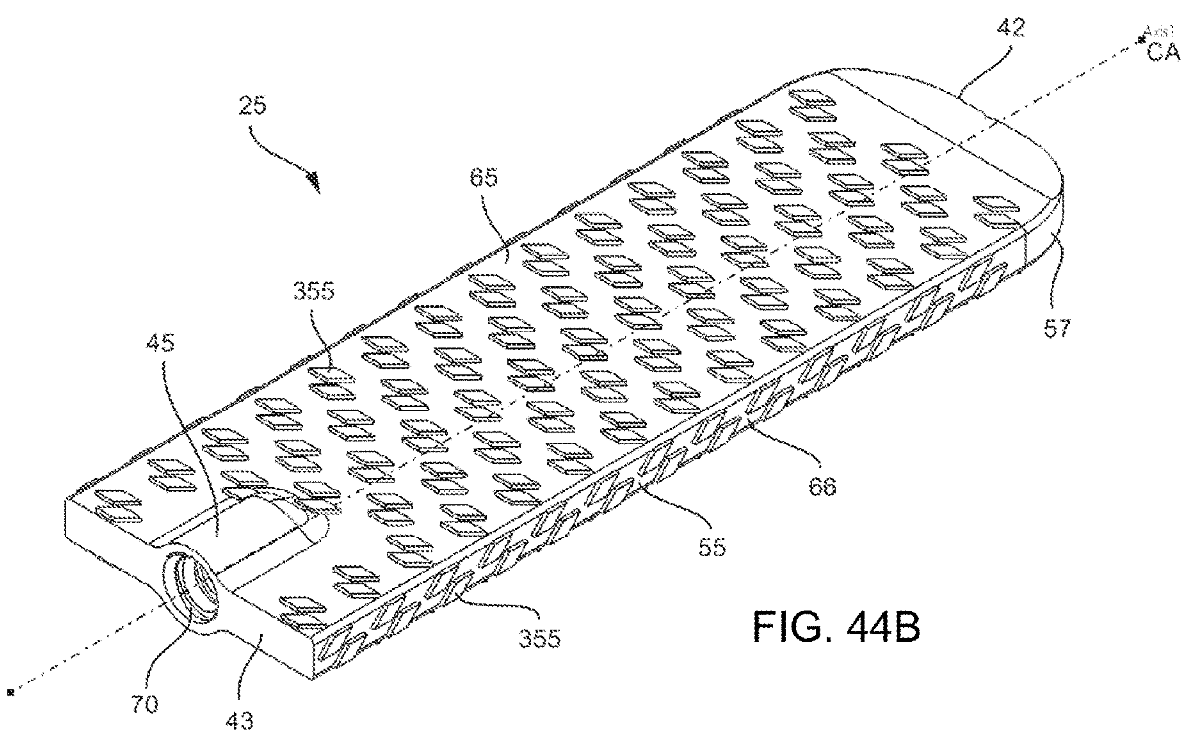


FIG. 44B

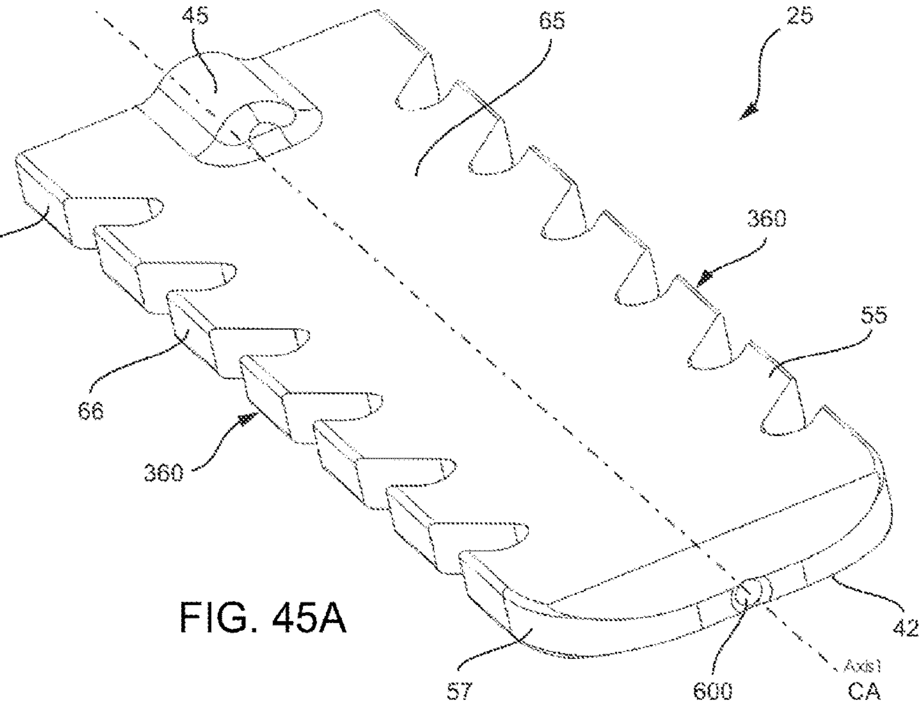


FIG. 45A

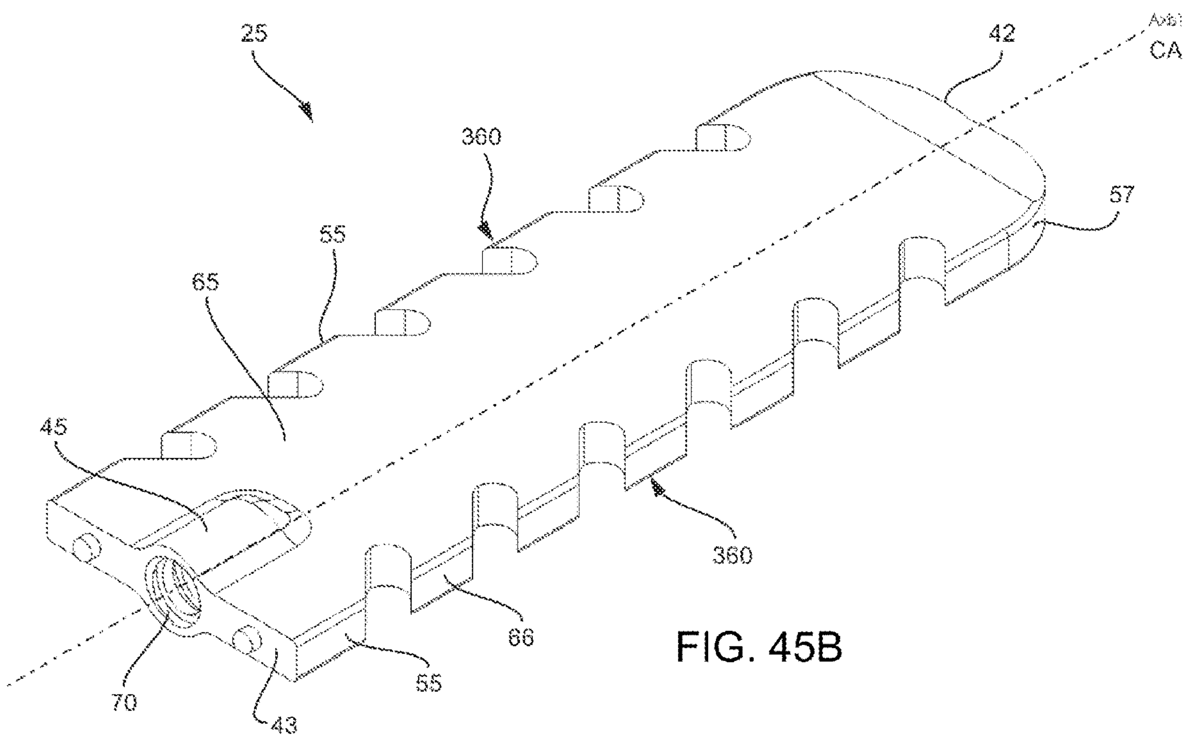


FIG. 45B

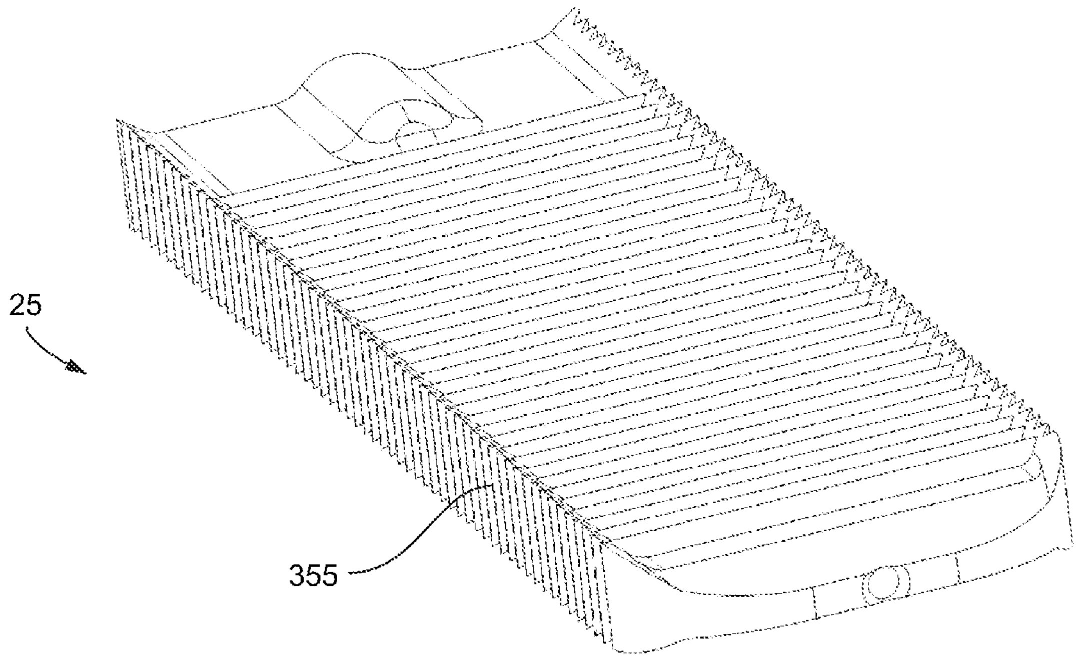


FIG. 46A

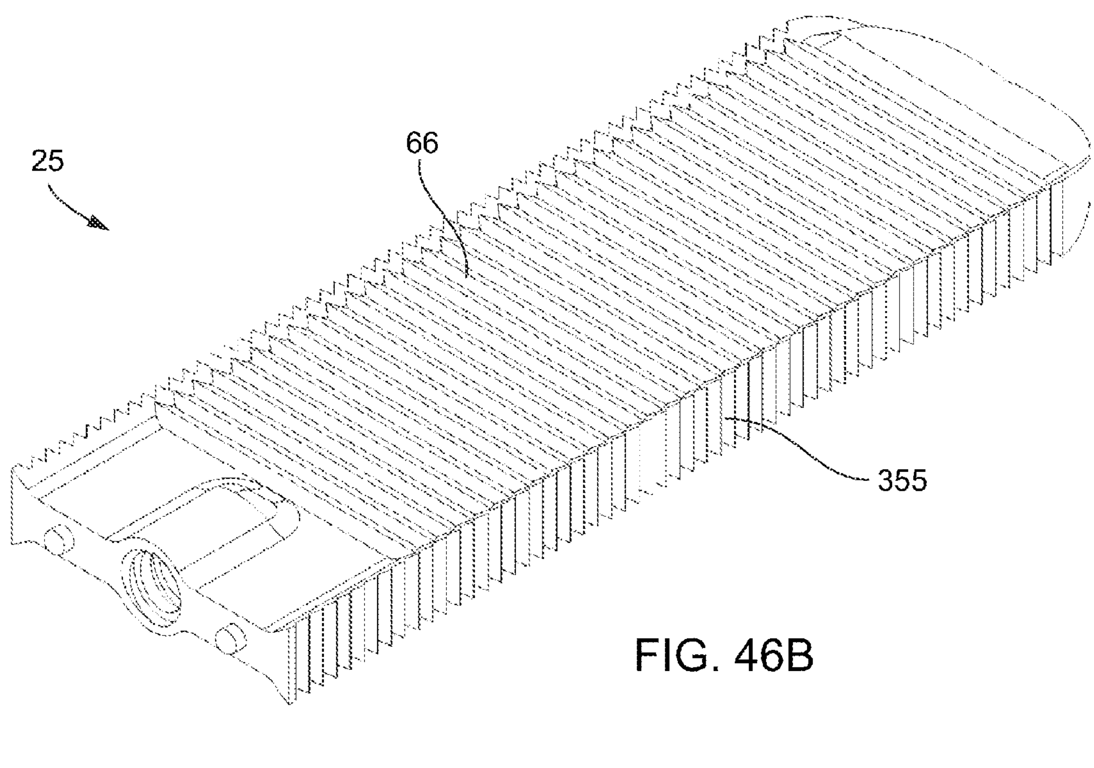


FIG. 46B

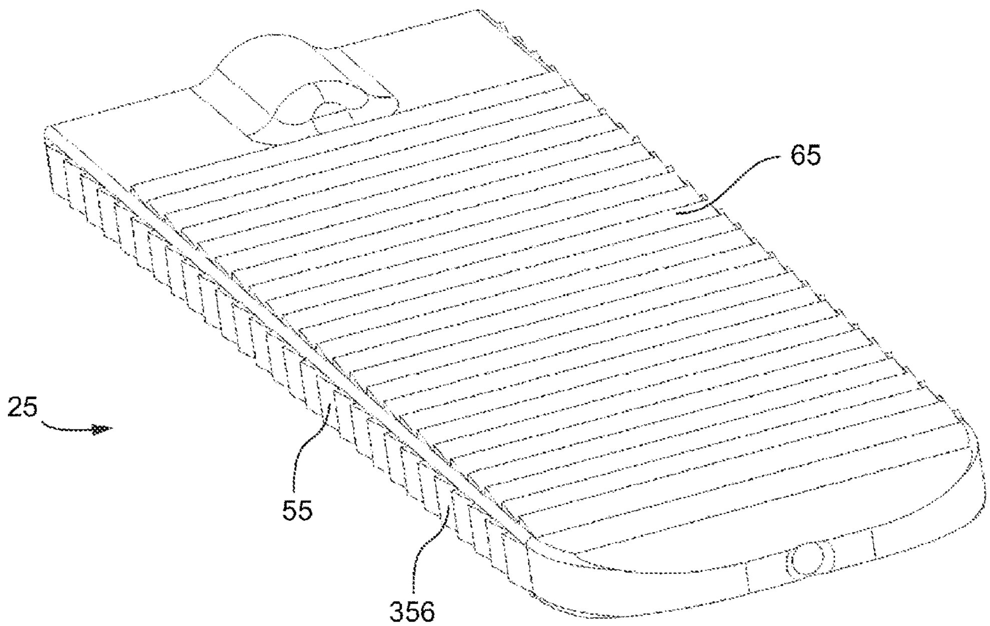


FIG. 47A

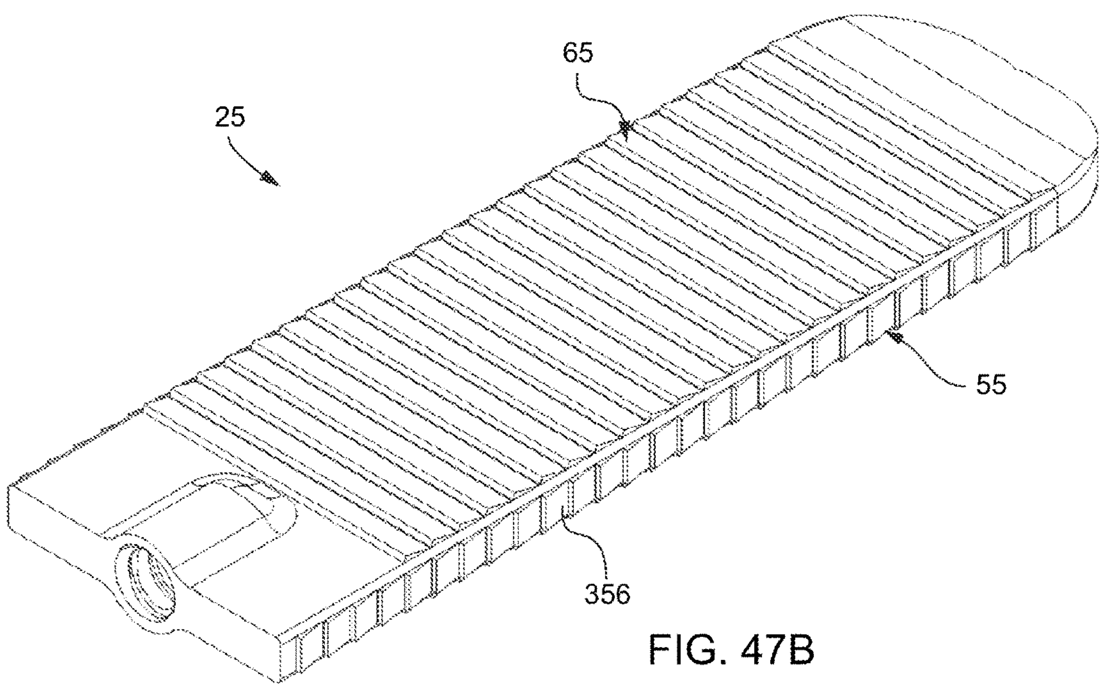


FIG. 47B

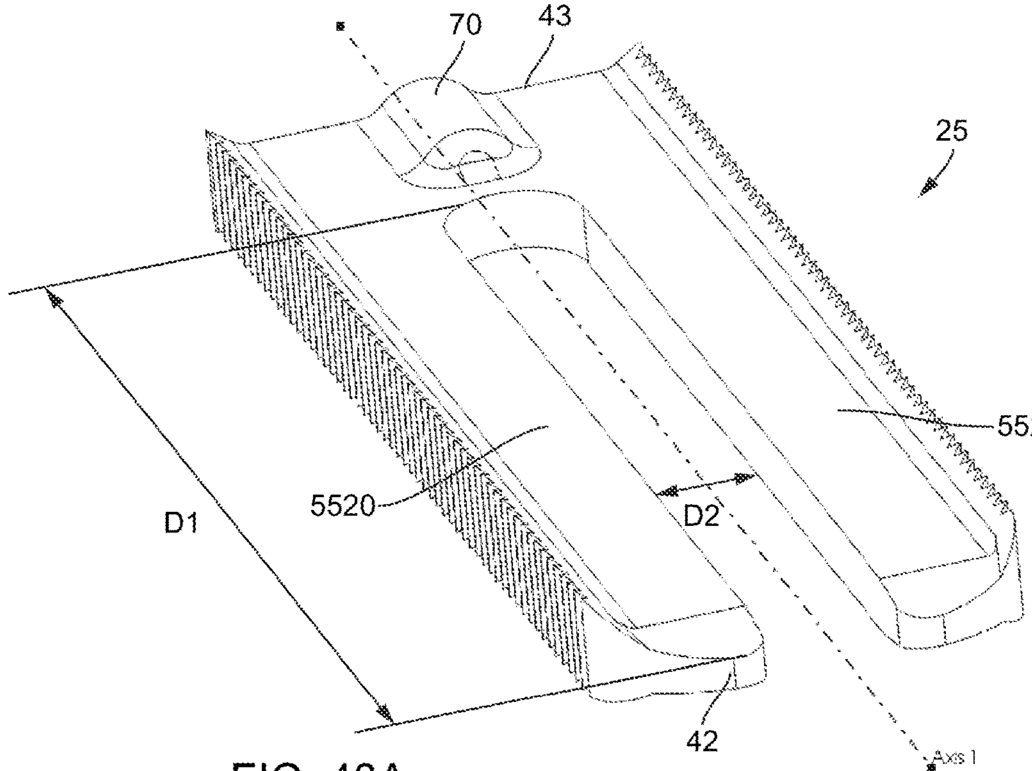


FIG. 48A

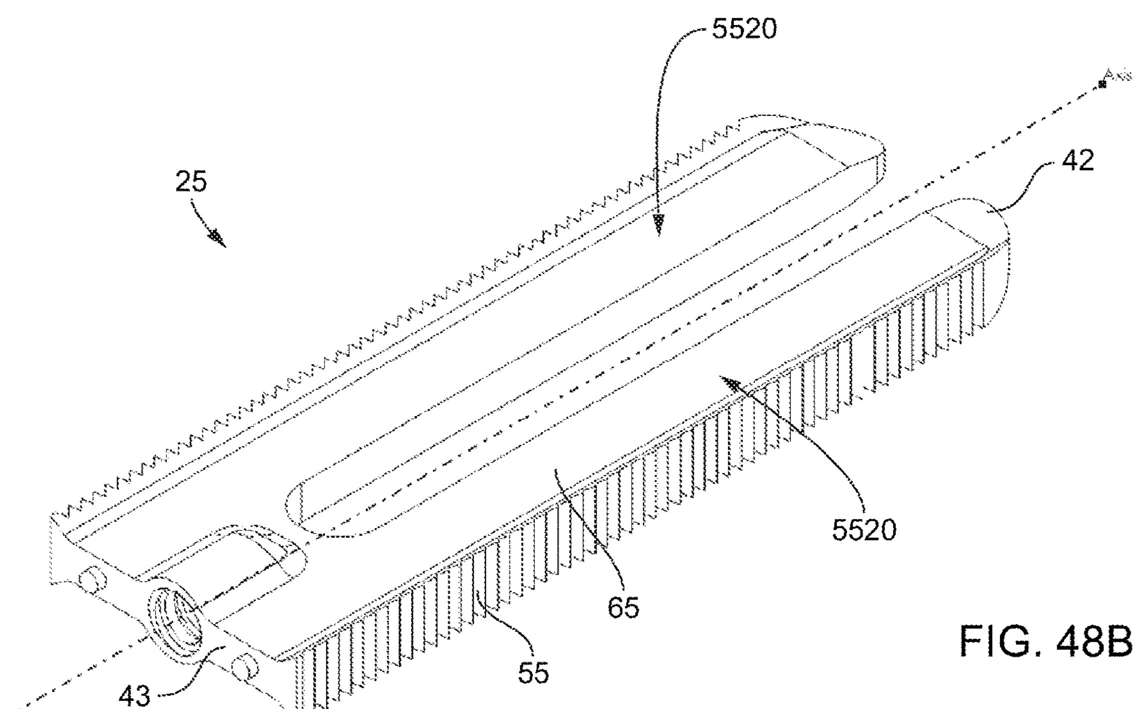


FIG. 48B

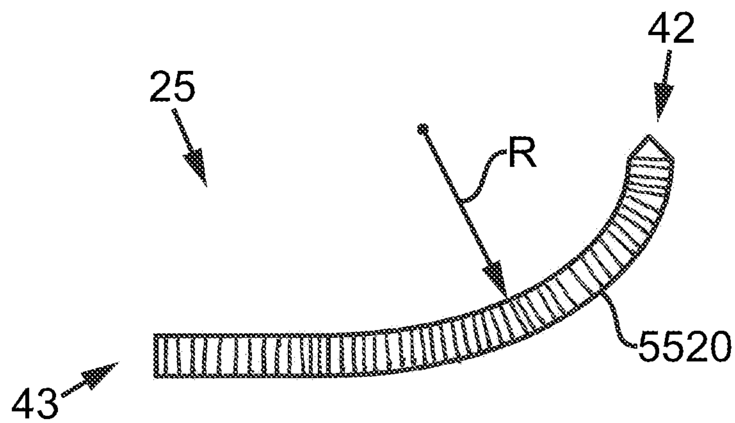


FIG. 48C

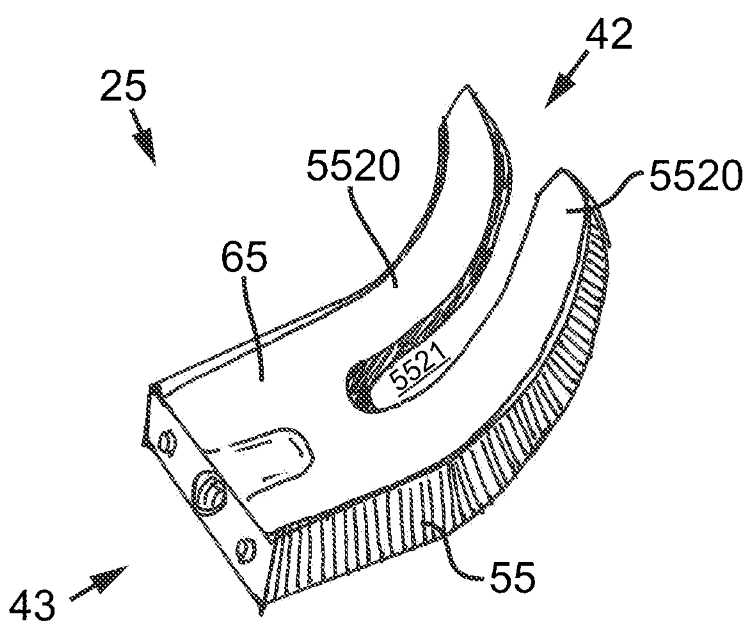
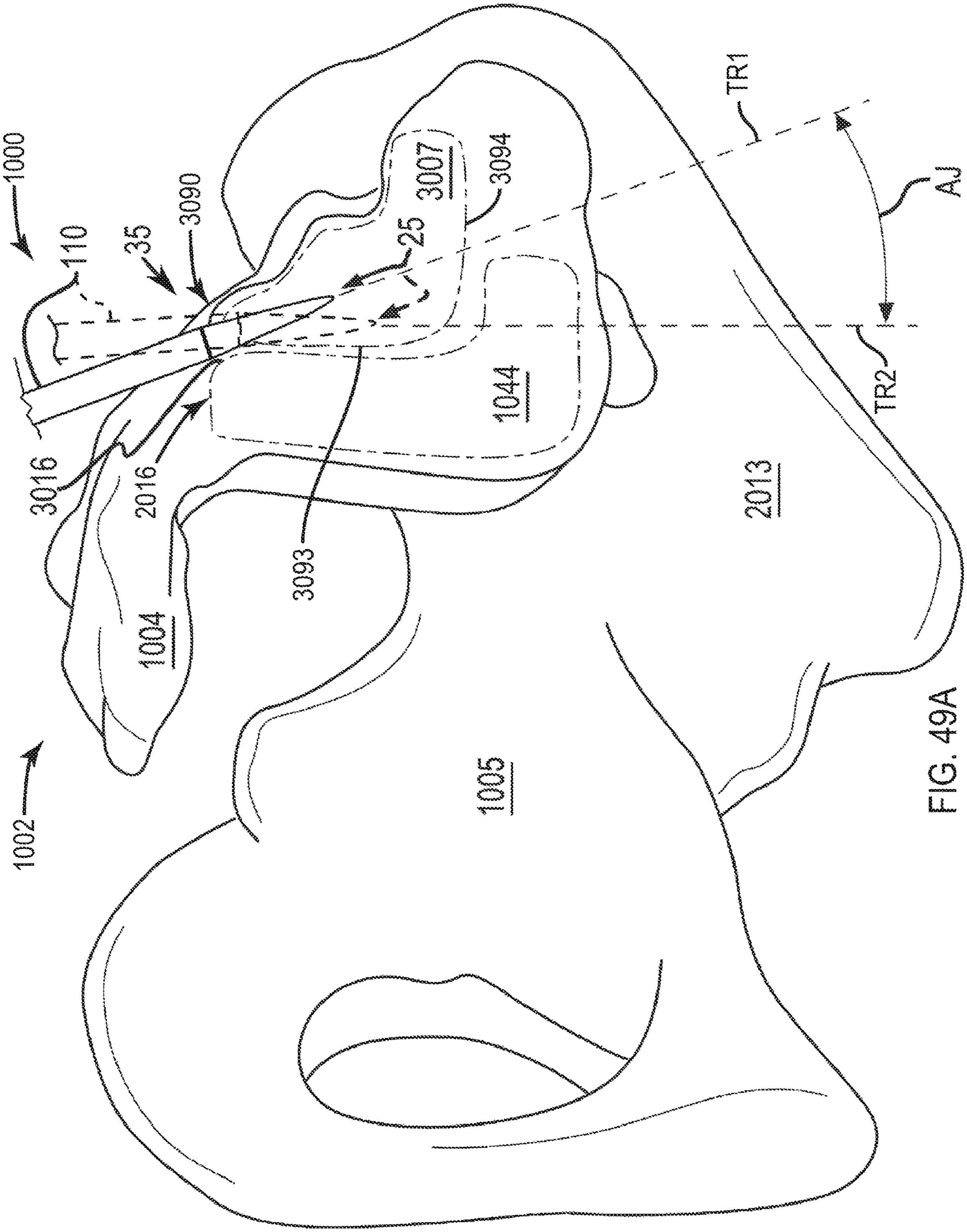


FIG. 48D


1000
110
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3090
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3007
3094
TR1
AJ
TR2
1044
2013
3016
2016
3093
1004
1005
1002

FIG. 49A

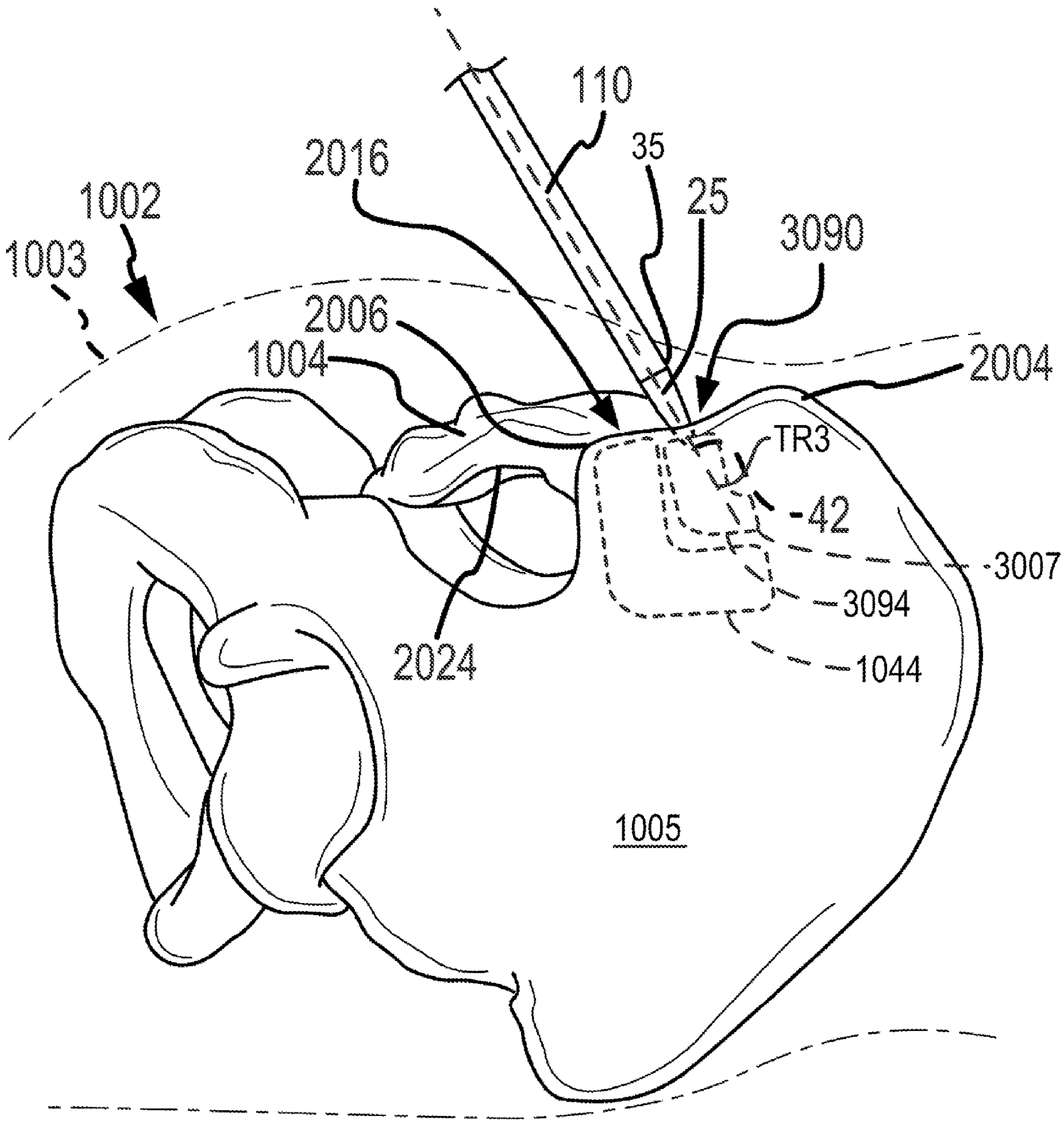
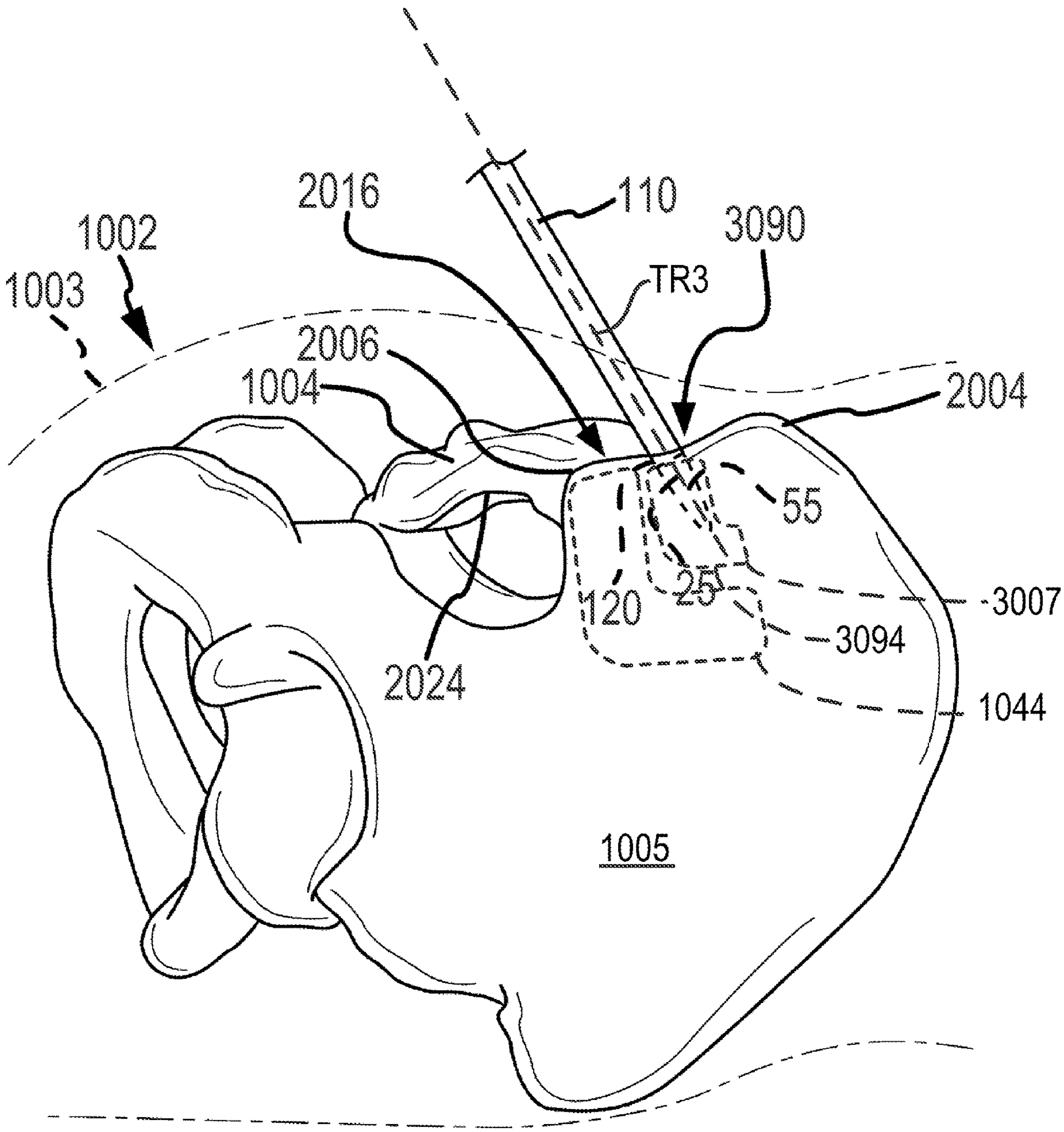

110
35
25
3090
2016
1002
1003
2006
1004
2004
TR3
42
3007
3094
2024
1044
1005

FIG. 49B



110
2016
3090
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TR3
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2004
1004
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120
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3007
3094
2024
1044
1005

FIG. 49C

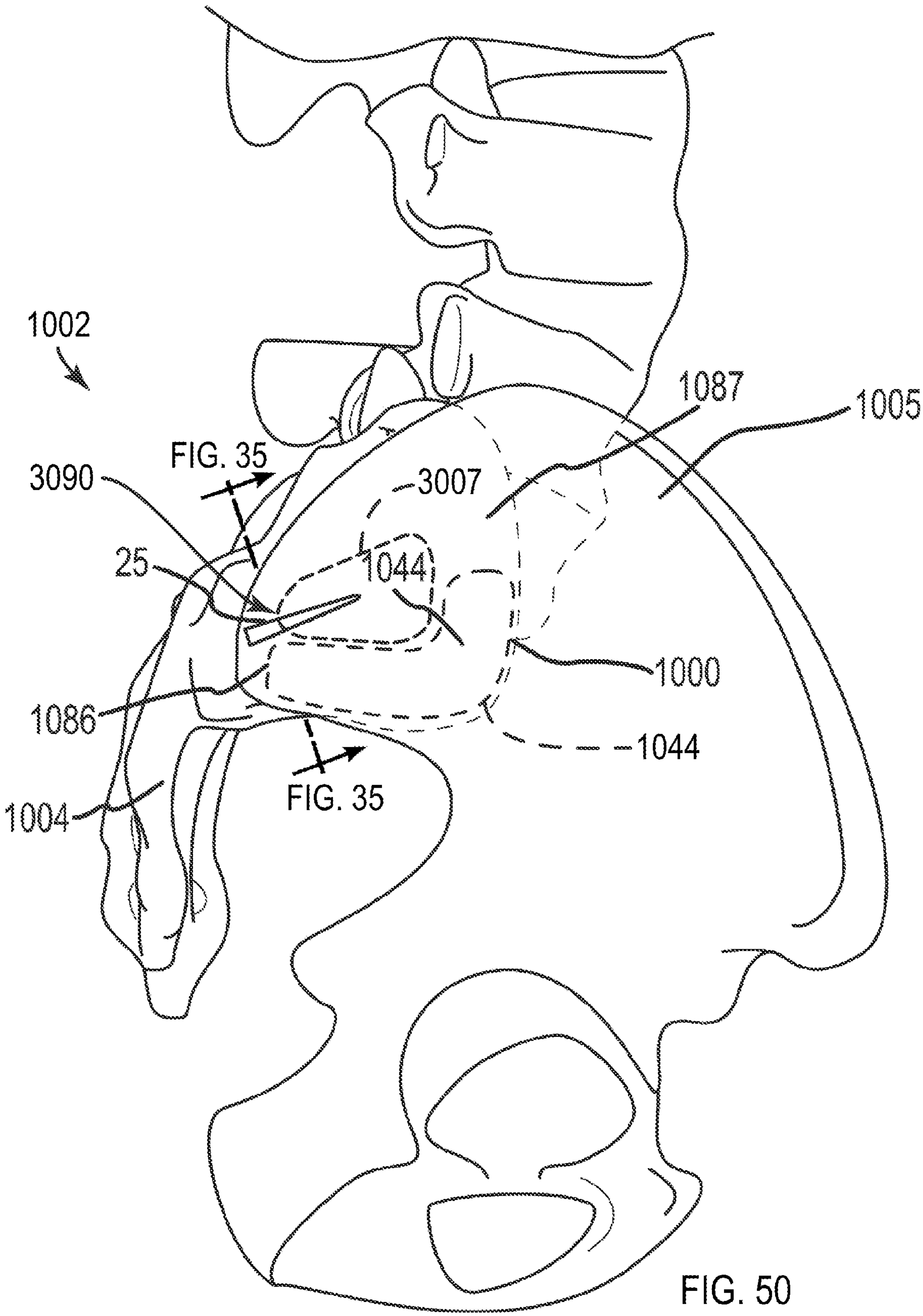

1002
FIG. 35
3090
3007
1087
1005
25
1044
1000
1086
1044
FIG. 35
1004

FIG. 50

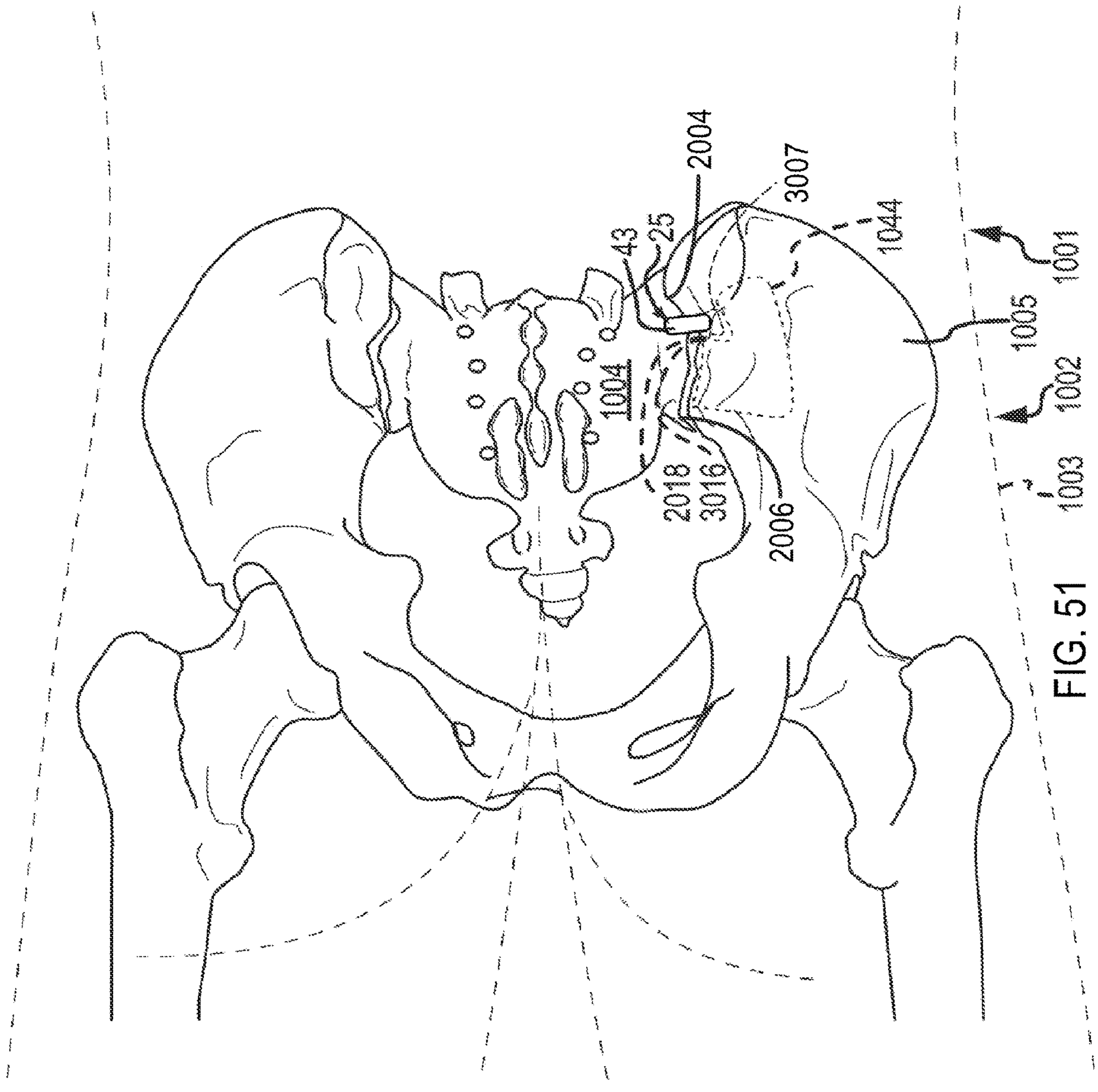


FIG. 51

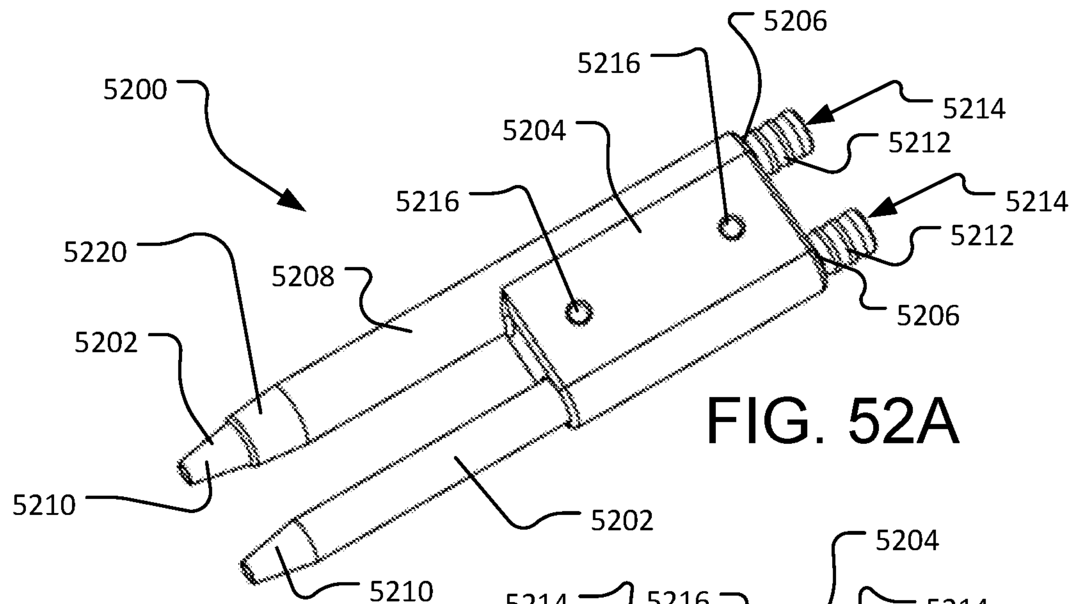


FIG. 52A

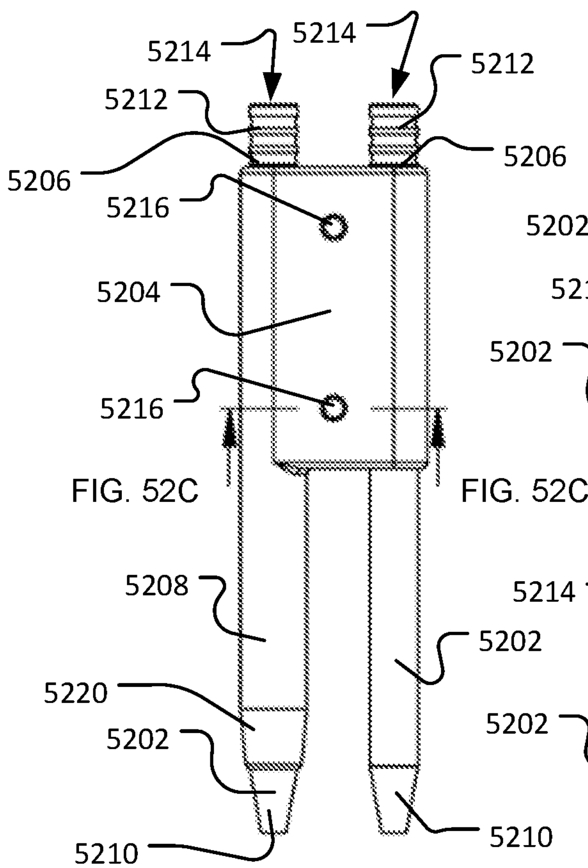


FIG. 52B

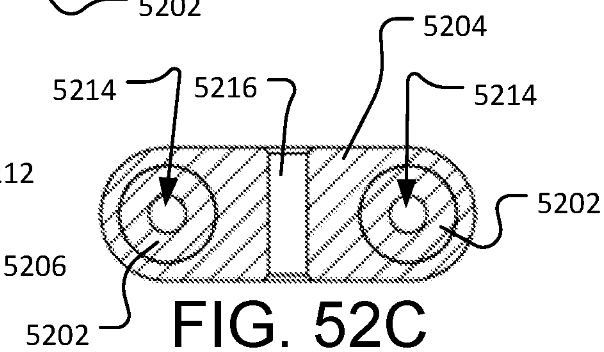


FIG. 52C

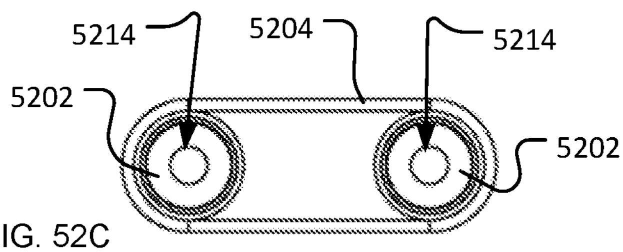


FIG. 52D

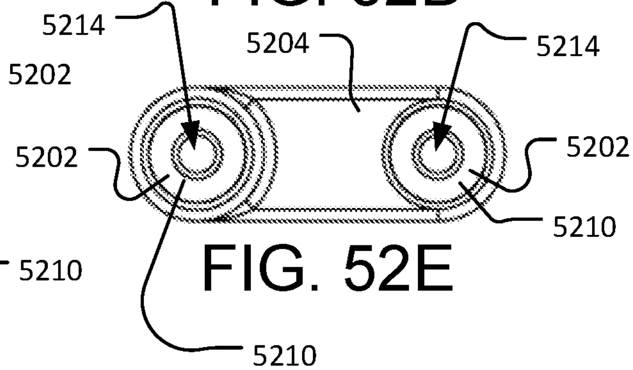


FIG. 52E

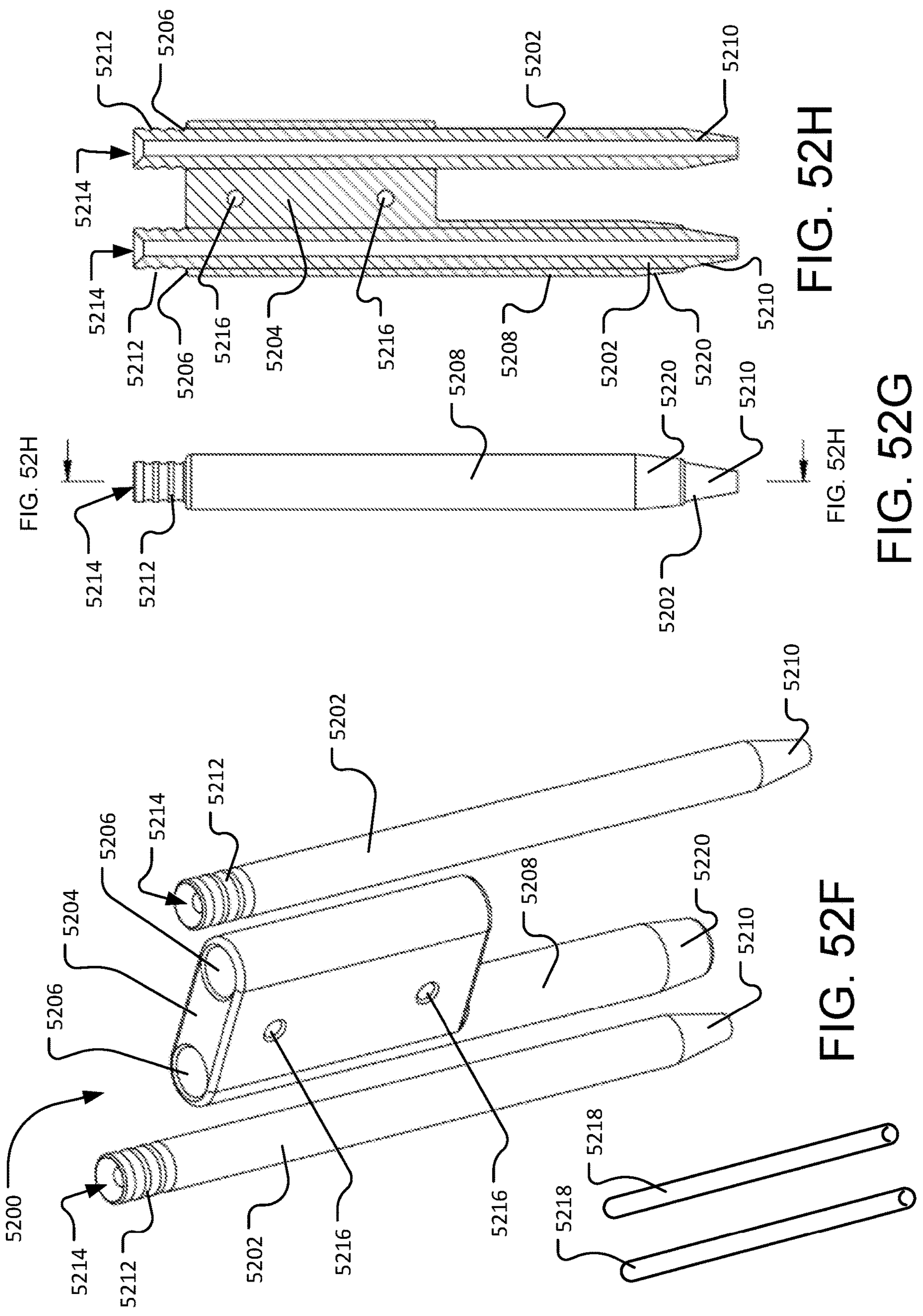


FIG. 52F

FIG. 52G

FIG. 52H

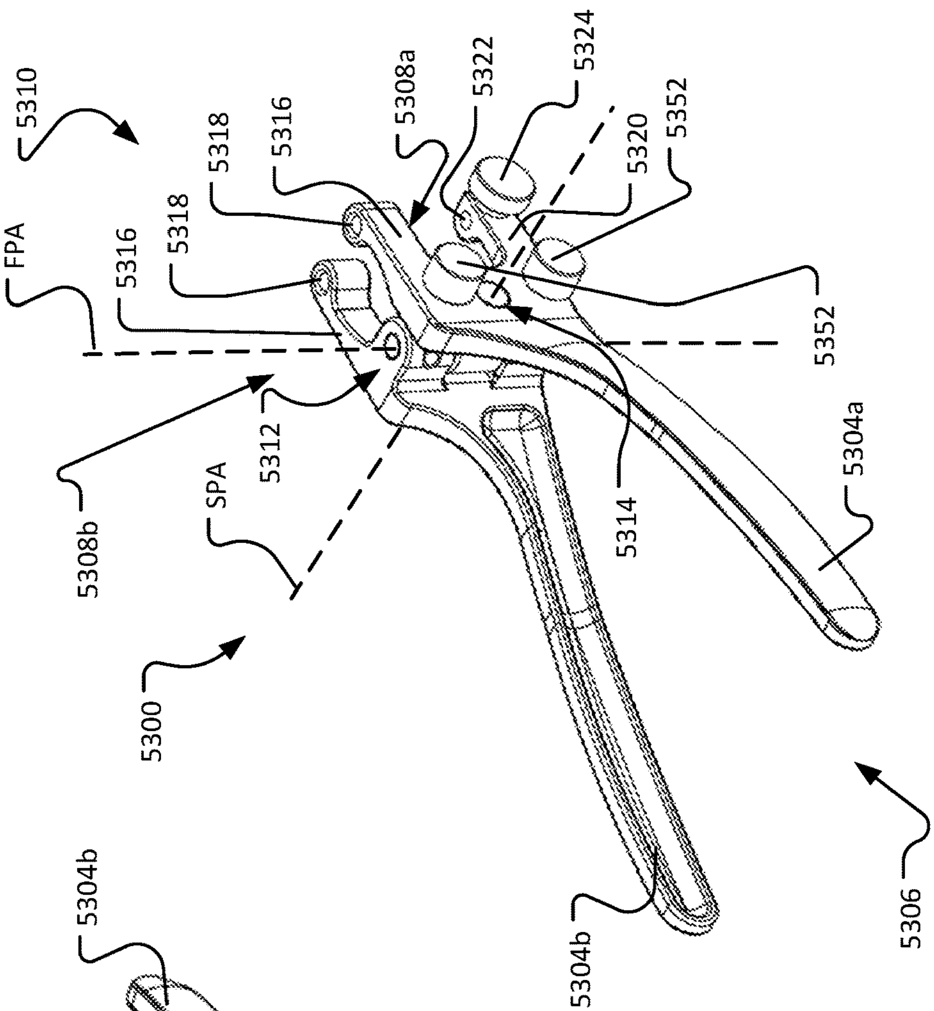


FIG. 53B

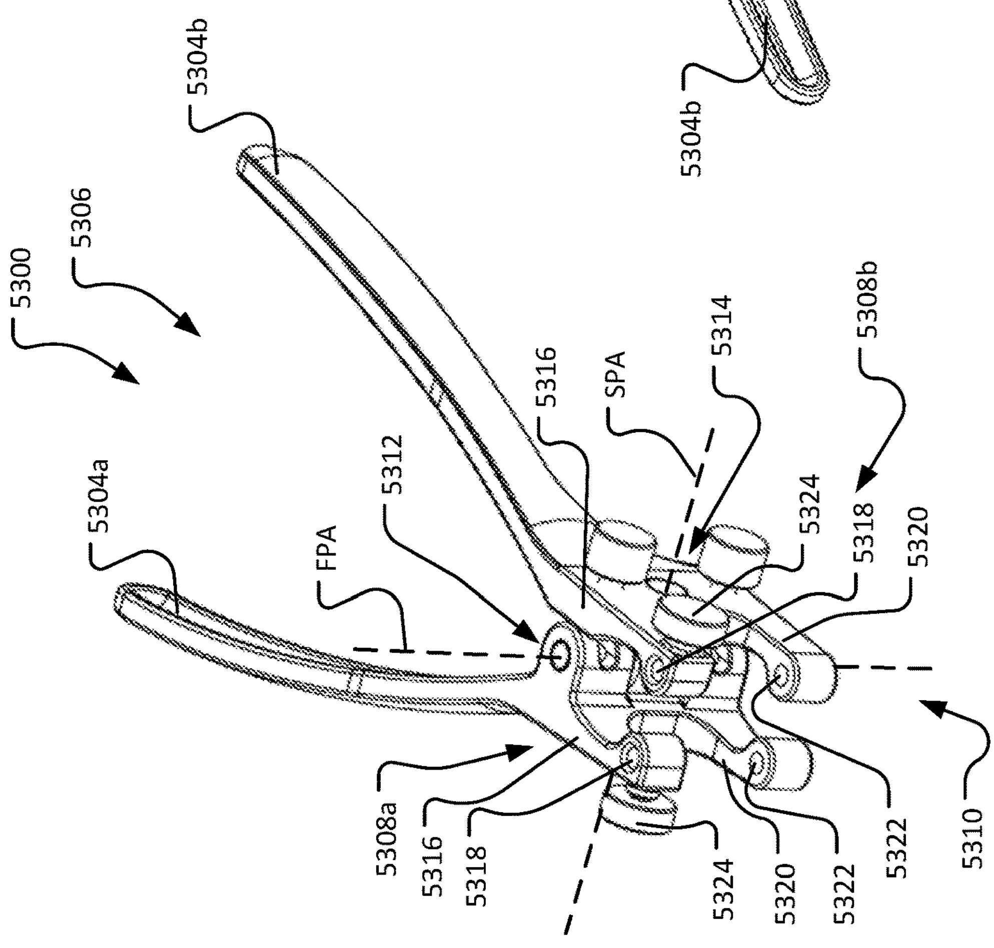


FIG. 53A

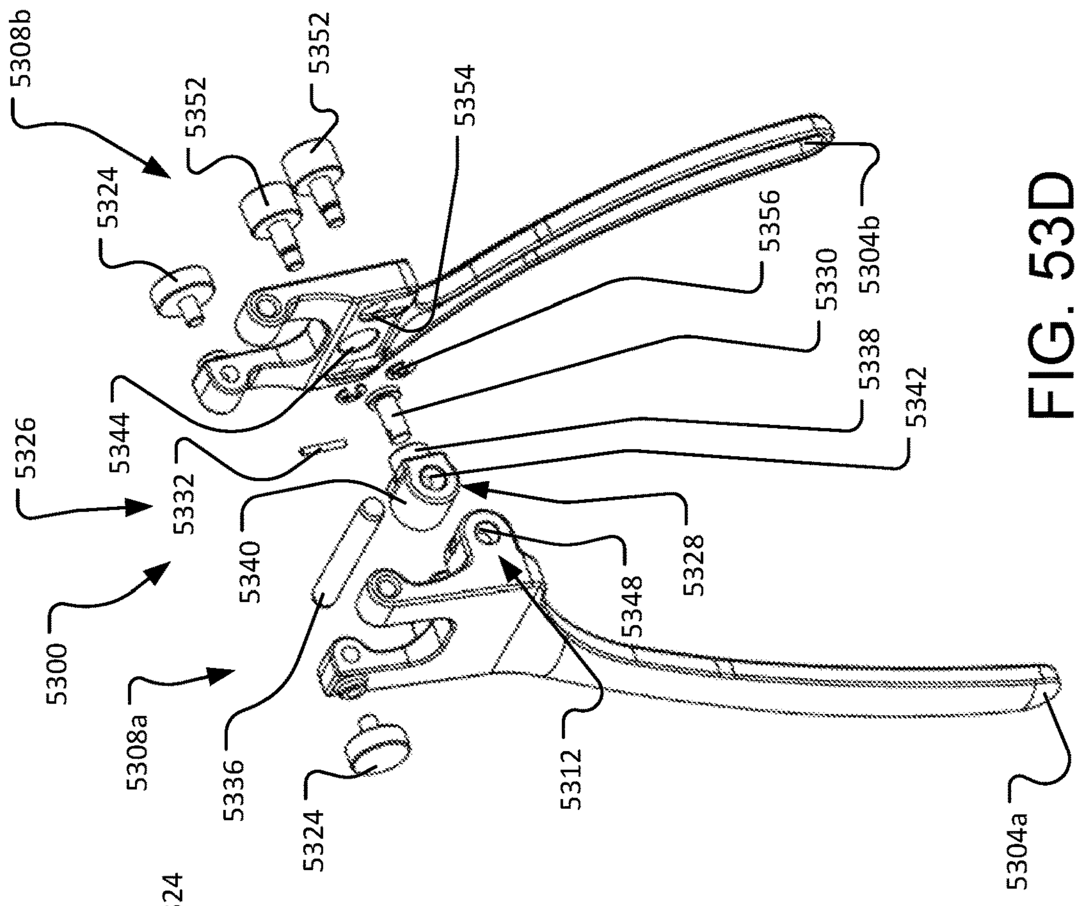


FIG. 53D

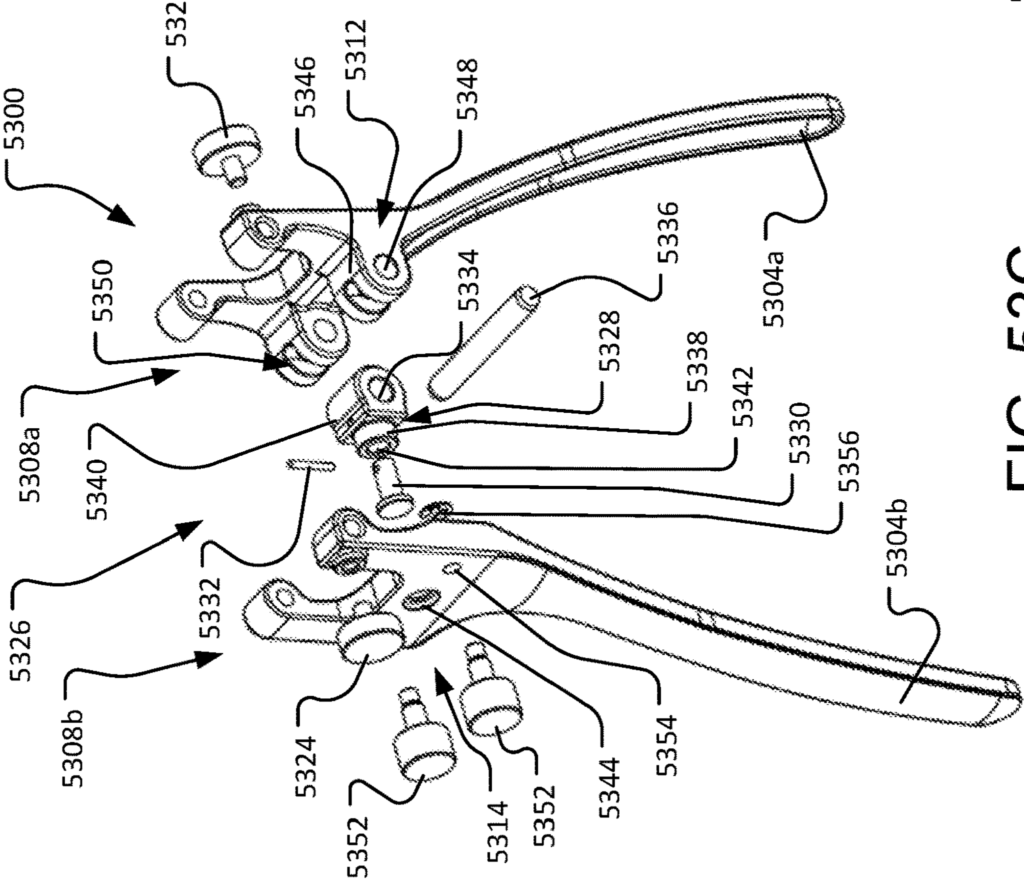


FIG. 53C

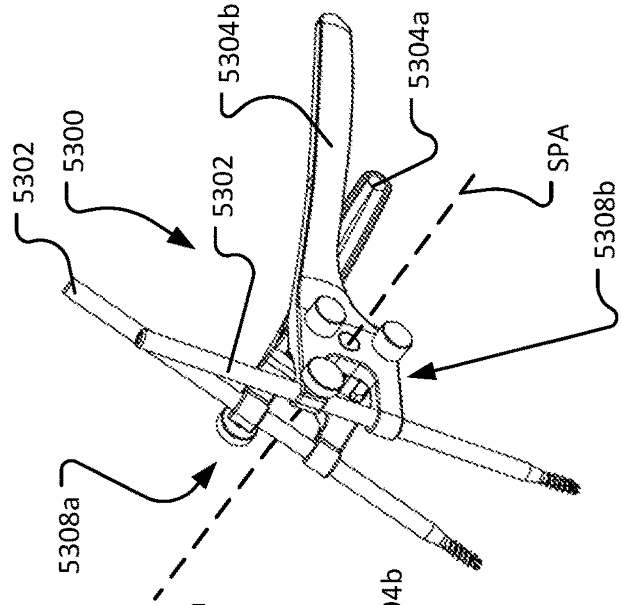


FIG. 53G

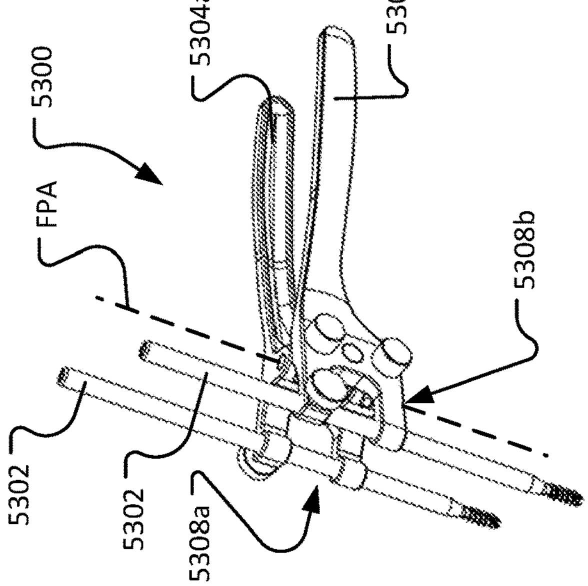


FIG. 53F

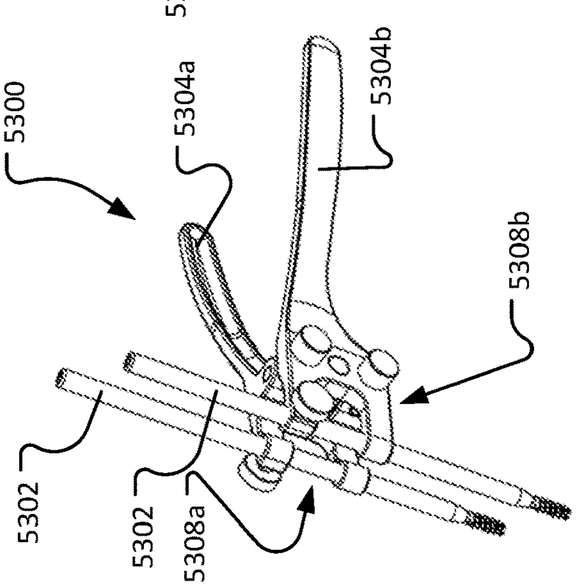


FIG. 53E

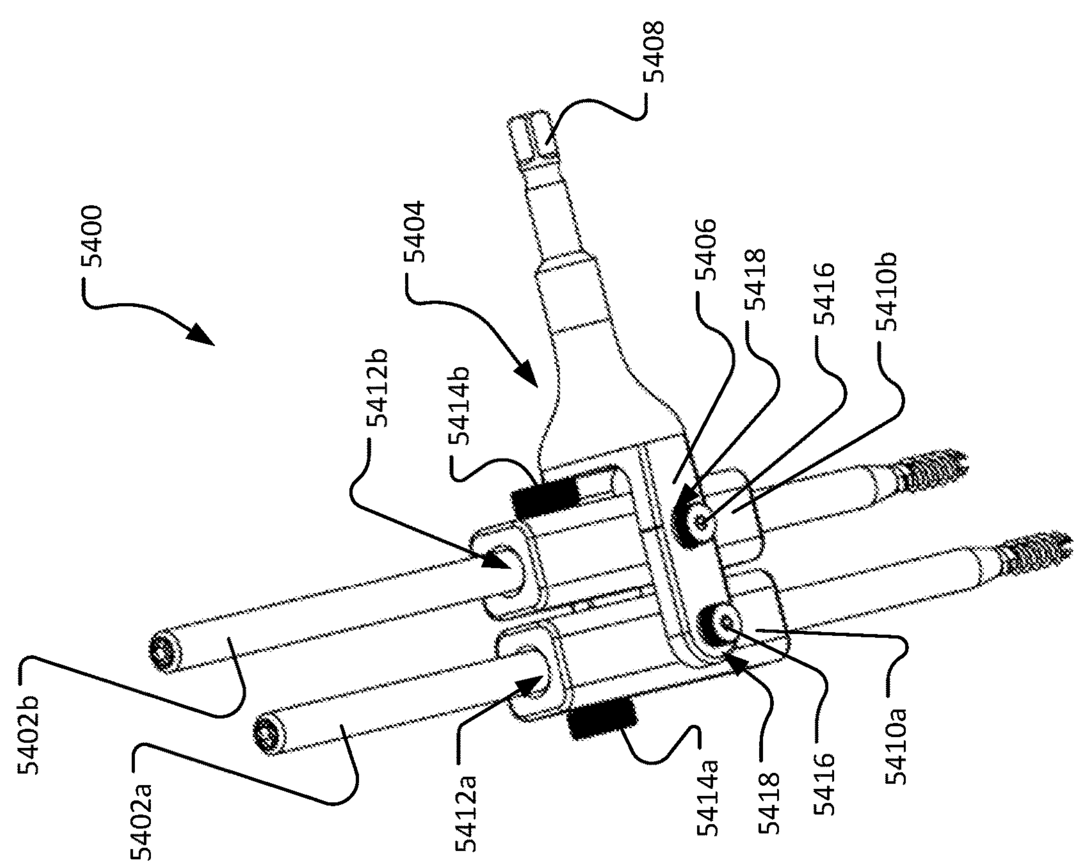


FIG. 54A

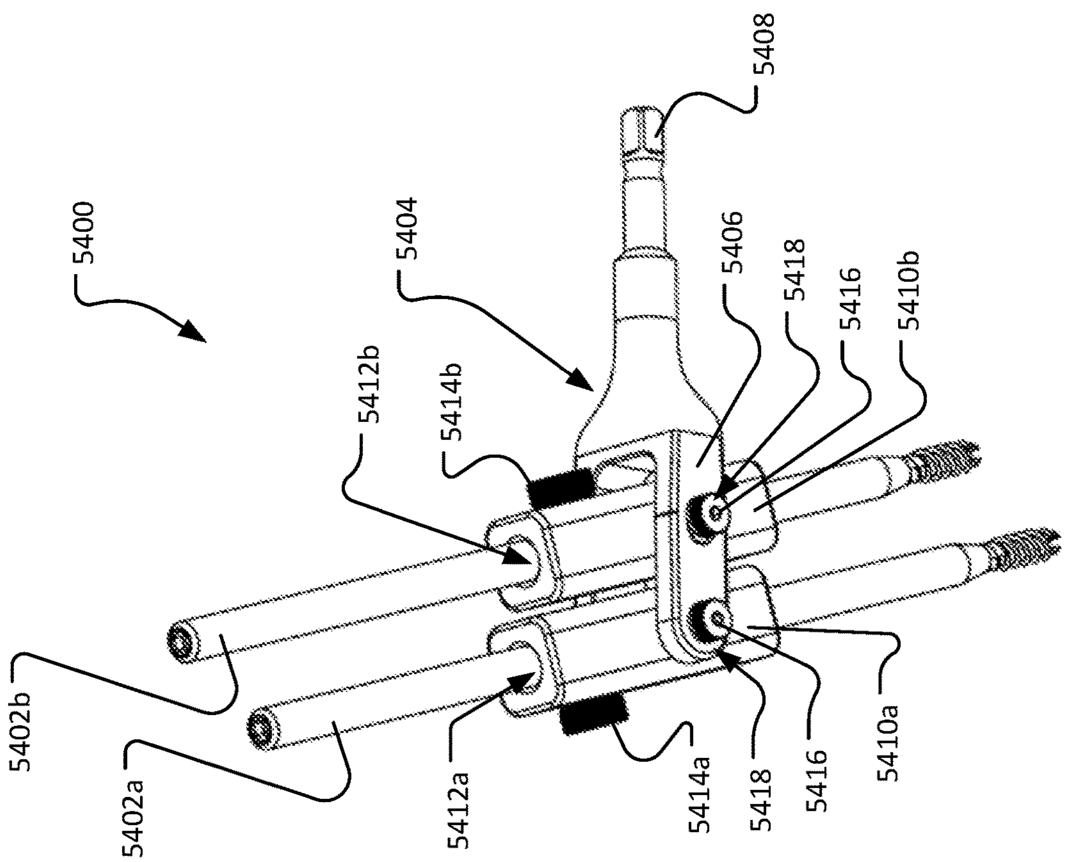
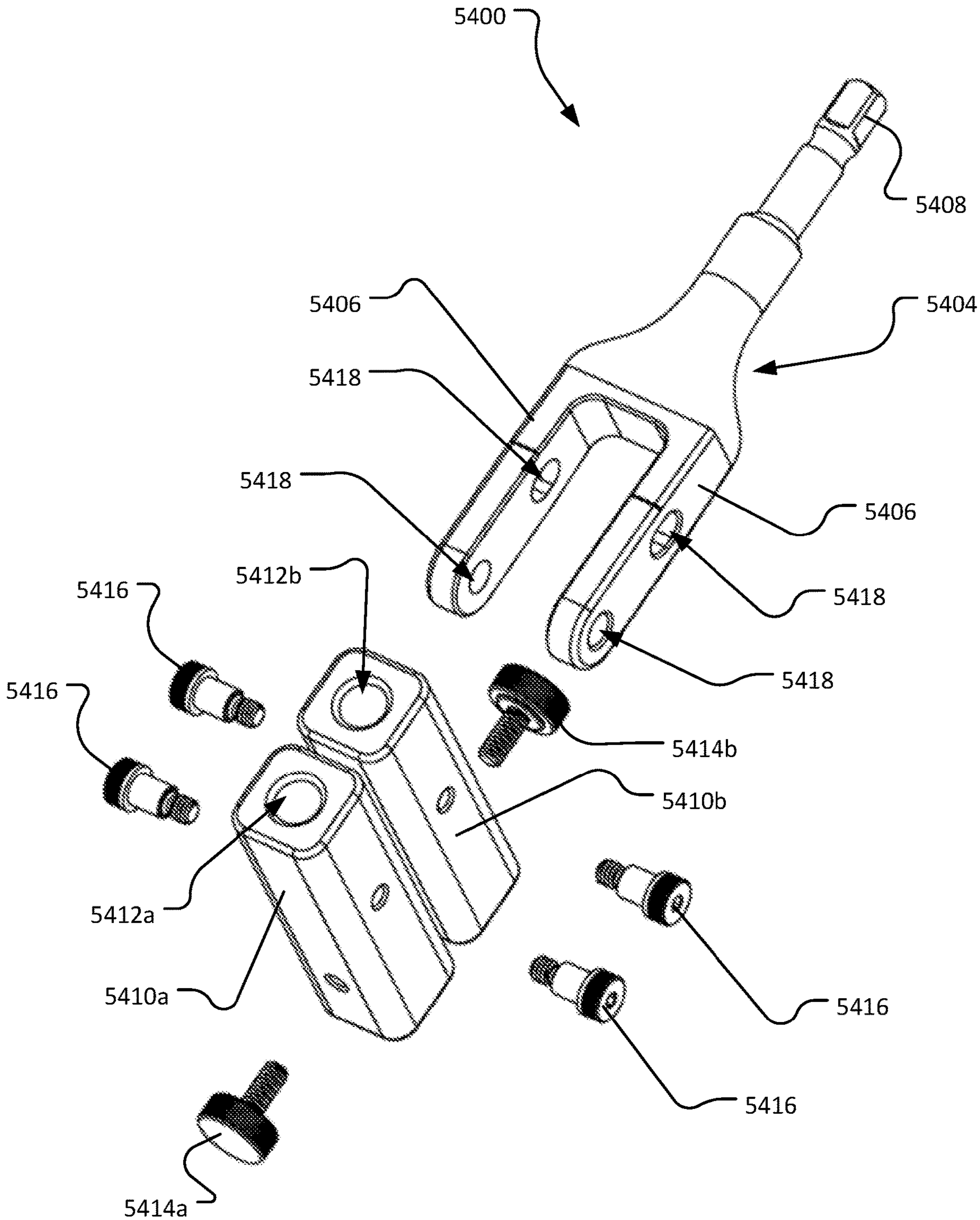


FIG. 54B


5400
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5416
5414b
5410b
5412a
5410a
5416
5416
5414a

FIG. 54C

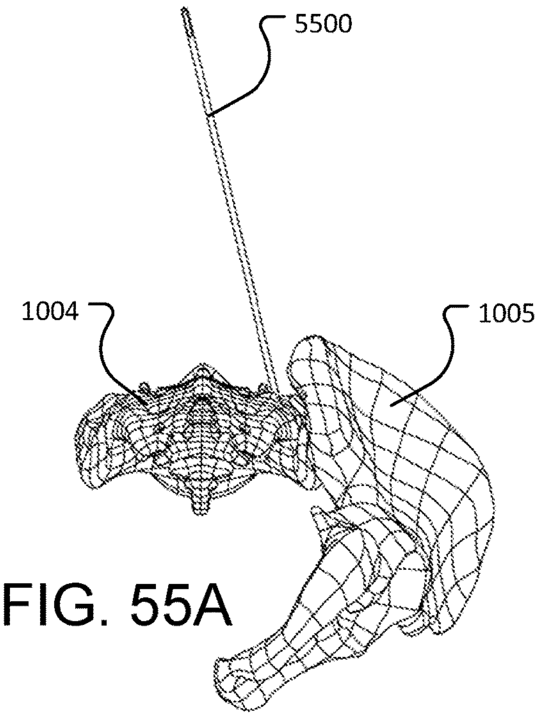

FIG. 55A

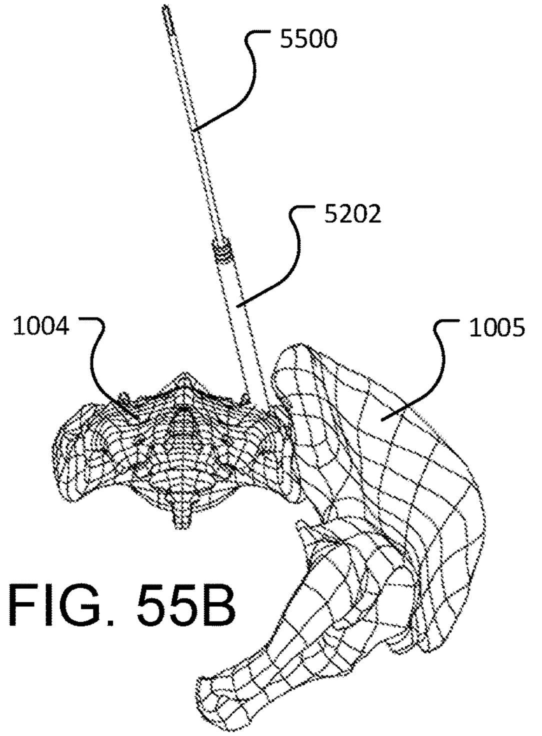

FIG. 55B

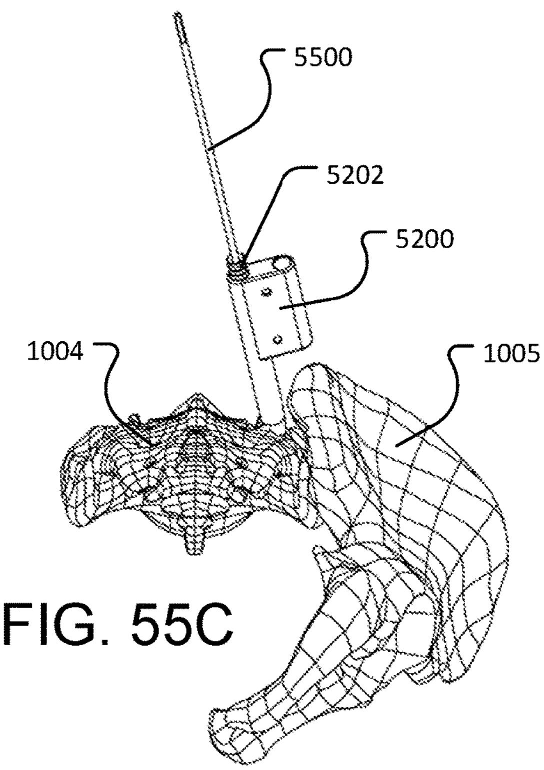

FIG. 55C

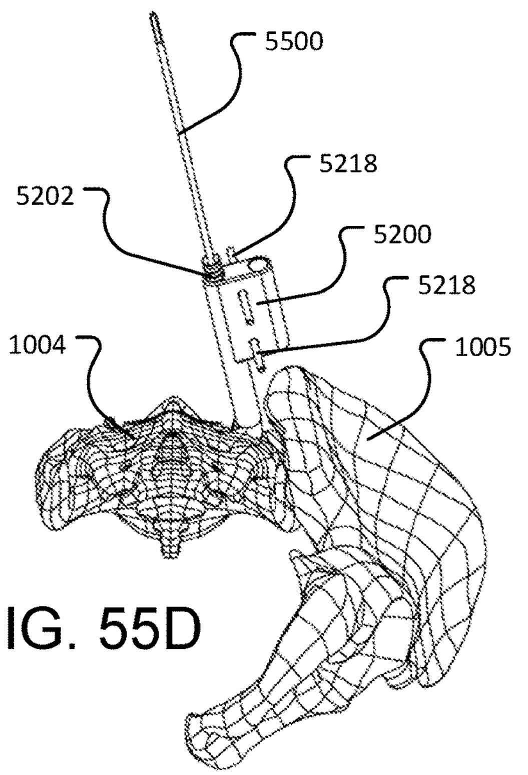

FIG. 55D

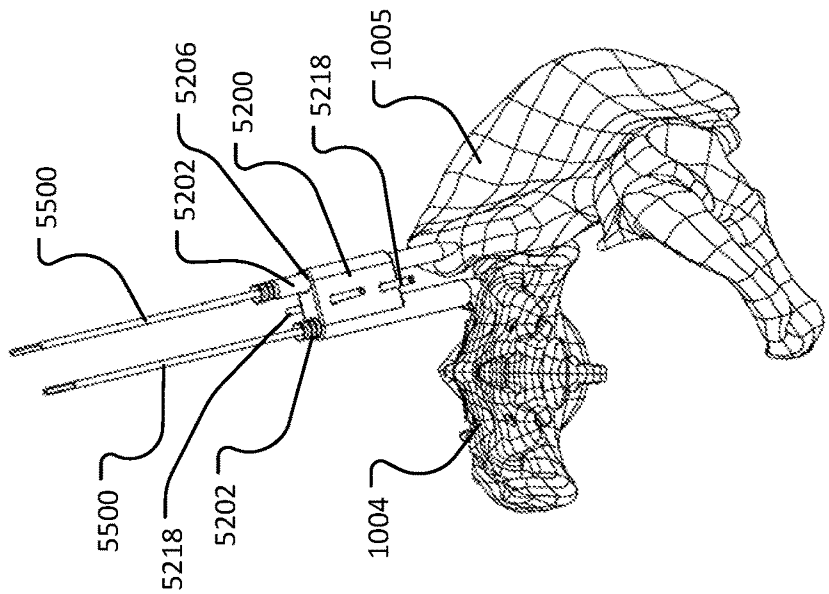

FIG. 55G

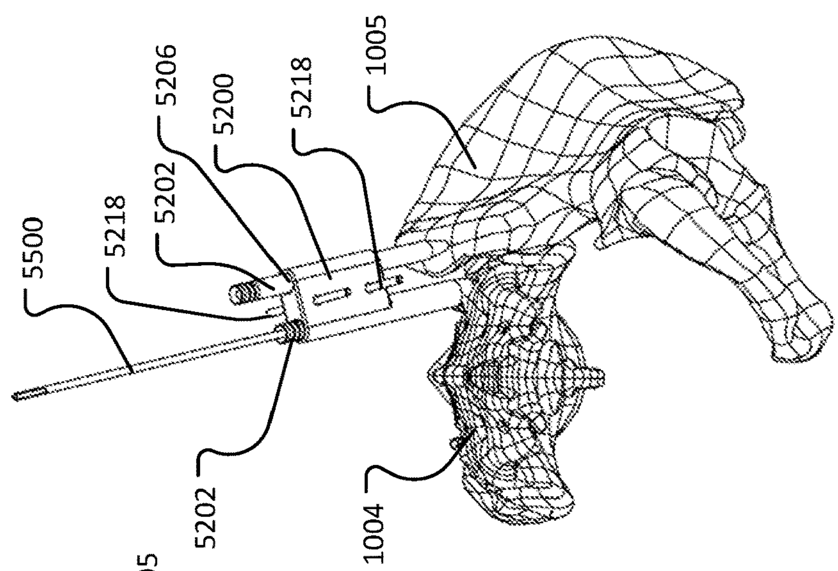

FIG. 55F

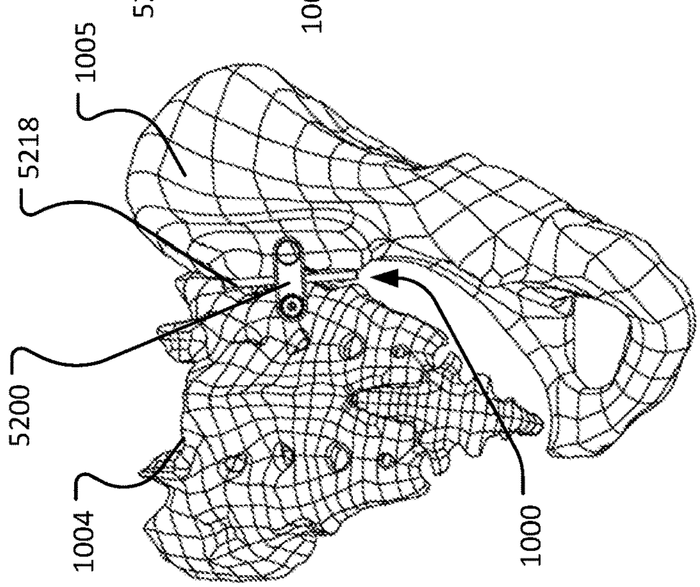

FIG. 55E

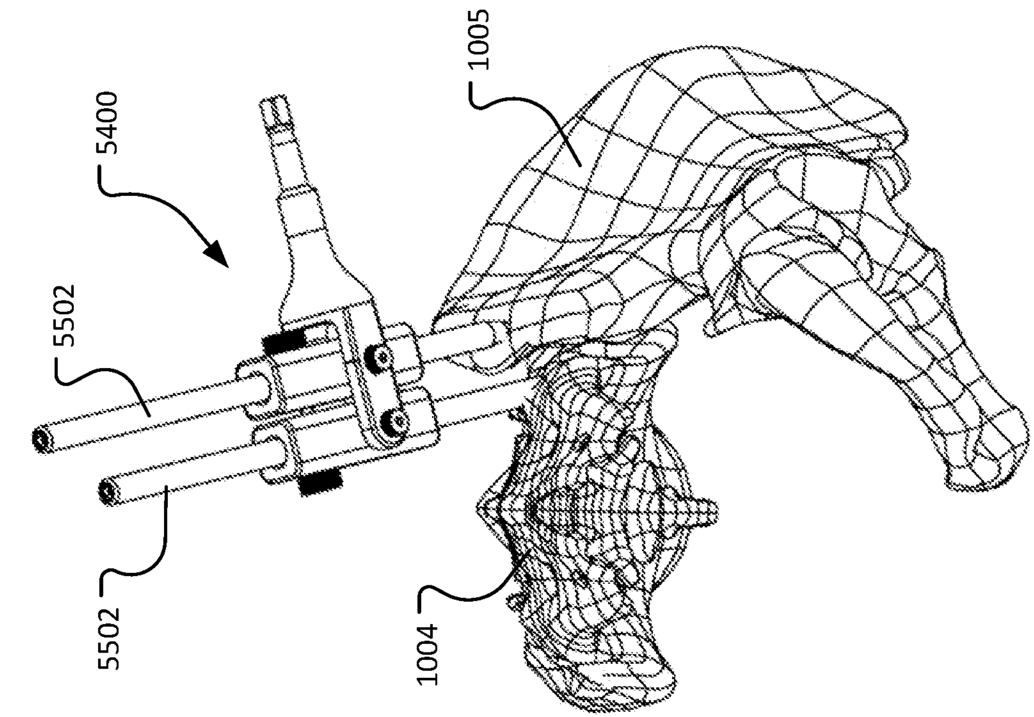

FIG. 55I

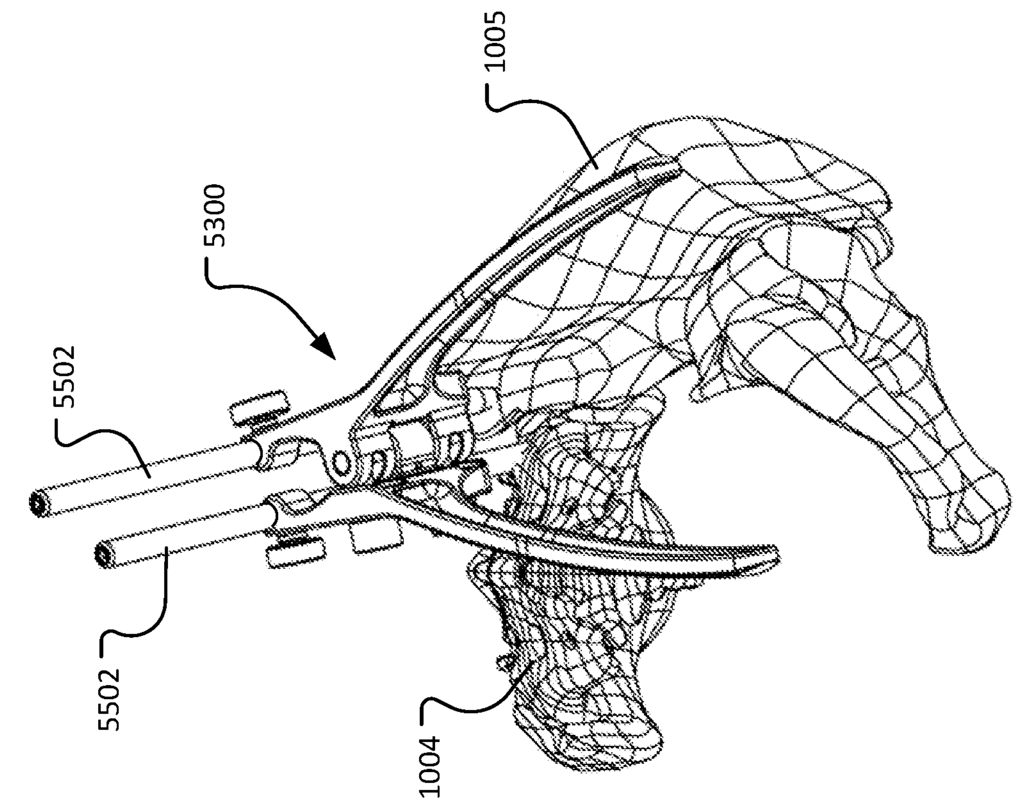

FIG. 55H

SYSTEMS FOR AND METHODS OF DIAGNOSING AND TREATING A SACROILIAC JOINT DISORDER

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part application of U.S. patent application Ser. No. 15/789,602, filed Oct. 20, 2017, which application is a continuation application of U.S. patent application Ser. No. 14/723,384 filed May 27, 2015, now U.S. Pat. No. 9,801,546, which application claims the benefit of U.S. Provisional Application 62/003, 053, which was filed May 27, 2014, entitled "SYSTEMS FOR AND METHODS OF TREATING A MUSCULOSKELETAL JOINT." The present application also claims the benefit of U.S. Provisional Application No. 62/633,205, filed Feb. 21, 2018. The contents of all the above-mentioned patent applications are hereby incorporated by reference in their entireties.

TECHNICAL FIELD

Aspects of the present disclosure relate to medical apparatus and methods. More specifically, the present disclosure relates to devices and methods for diagnosing and treating a sacroiliac joint.

BACKGROUND

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

Pain associated with the sacroiliac joint can be caused by traumatic fracture dislocation of the pelvis, degenerative arthritis, sacroiliitis an inflammation or degenerative condition of the sacroiliac joint, osteitis condensans ilii, or other degenerative conditions of the sacroiliac joint. Currently, sacroiliac joint fusion is most commonly advocated as a surgical treatment for these conditions. Fusion of the sacroiliac joint can be accomplished by several different methods encompassing an anterior approach, a posterior approach, and a lateral approach with or without percutaneous screw or other type implant fixation.

A general overview of anatomy, function, pathology and certain treatment options are shown and discussed in "Surgery for the Painful, Dysfunctional Sacroiliac Joint", copyrighted 2015 and edited by Drs. Bruce Dall, Sonia Eden, Michael Rahl and with chapters authored by Drs. E. J. Donner, Arnold Graham Smith, Michael Moore and David Polly. This book is hereby incorporated by reference in its entirety.

Improvements to sacroiliac joint fusion involve systems and methods for non-transverse delivery of an implant into the sacroiliac joint are described in U.S. patent application Ser. No. 12/998,712, filed May 23, 2011 entitled SACROILIAC JOINT FIXATION FUSION SYSTEM; Ser. No. 13/236,411, filed Sep. 19, 2011 entitled SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT; and Ser. No. 13/475,695, filed May 18, 2012, entitled SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT; and Ser. No. 13/945,053, filed Jul. 18, 2013, entitled SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT; and Ser. No. 13/946,790, filed Jul. 19, 2013, entitled SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT; and Ser. No. 14/216, 975, filed Mar. 17, 2014, entitled SYSTEMS AND METHODS FOR FUSING A SACROILIAC JOINT AND ANCHORING AN ORTHOPEDIC APPLIANCE; and Ser. No. 14/447,612, filed Jul. 31, 2014, entitled SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT; and Ser. No. 16/133,605, filed Sep. 17, 2018, entitled "SYSTEMS FOR AND METHODS OF PREPARING AND FUSING A SACROILIAC JOINT". All of application Ser. Nos. 12/998,712, 13/236,411, 13/475,695, 13/945,053, 13/946,790, 14/216,975, and 14/447,612 are herein incorporated by reference in their entirety.

To determine whether a sacroiliac joint is a source of pain, an injection of analgesics into a sacroiliac joint can be performed by a physician and a patient's subjective measurement of pain can be recorded before, during and for some time after the intervention. The injection may reduce or substantially eliminate pain temporarily. If the injection substantially reduces the pain then the physician could conclude that the sacroiliac joint is indeed a source of the patient's pain.

Other conventional methods for determining sacroiliac joint pain include physical manipulation of body parts within close proximity to the joint which can be meant to stress the sacroiliac joint and thereby provoke pain in hopes of eliciting a reproduction of the patient's accustomed pain. The sacroiliac pain provocation tests can include distraction, right or left sided thigh thrusts, right or left sided Gaenslen's test, compression, and sacral thrust.

The pain referral pattern associated with sacroiliac joint pain can be confused with other etiologies of the pain due to overlapping pain referral patterns. For example, lumbar spinal disc herniations, lumbosacral facet pathologies, femoral acetabular impingement and other musculoskeletal or medical conditions may cause confusingly similar pain referral patterns.

A significant problem with certain conventional methods, which include the injection of material within the joint, for determining sacroiliac pain may be that the physician has introduced an amount of analgesic or other combined substances into the joint which exceeds the capacity of the joint and the solution could then go beyond the joint and or affect other parts of the body. Similarly, without regard to the amount of solution injected, the solution can leave the joint and affect other structures. For example, if the analgesic solution affects the sciatic nerve, the lumbosacral trunk, the L4 nerve root, the sacral plexus, or the S1, S2 or S3 nerves, all of which are in close proximity to the sacroiliac joint, and, for example, if the patient's pain is due to some condition of one of these nerves which has a similar pain referral pattern as sacroiliac joint pain, the sensitivity and specificity of the diagnostic procedure can be grossly misleading.

Another substantial problem with conventional methods which include manipulation of body parts near the joint can be that the structures targeted by the provocative tests are not the only structures affected. One or more different innervated structures in close proximity to the sacroiliac joint could also be stressed by these tests and refer pain or other symptoms into the lower back, pelvis or lower extremities thereby complicating the diagnosis.

As seen in FIGS. **1**A-**1**B, external pelvic fixators **5** are conventionally used to stabilize and rest a traumatized sacroiliac joint **3** until healed or asymptomatic (e.g., 6-12 weeks). External pelvic fixators **5** are conventionally recommended to diagnose and determine whether sacroiliac joint fusion would be a treatment option if the patient received pain relief from temporary stabilization of the sacroiliac joint **3**.

However, the external pelvic fixators **5** require multiple pins **2** placed in, e.g., the ilium **1** bilaterally (i.e., in both ilia) which is associated with significant risk and morbidity including but not limited to pain, infection and the inconvenience to the patient and medical person due to a bulky external frame around the pelvis. Another problem with conventional procedures can be that there may be no or an insufficient reduction in the movements of a sacroiliac joint **3**. For example, an insufficient reduction in the movements of a sacroiliac joint **3** may be due to the extended distance from the fixation point provided by the external fixator relative to the sacroiliac joint **3** being evaluated. The complication rate for definitive and temporary conventional pelvic external fixation has been reported to be rather significant.

Referring to FIG. **1**C, other conventional techniques for fixation of the joint **3** may include placement of rods or screws **4** across a sacroiliac joint **3** within the ilium **1** and sacrum **0** defining the sacroiliac joint **3**. Yet further conventional techniques and implants may distract the joint and may thereby alter the tension of the surrounding ligamentous structure. Problems associated with these and other conventional techniques used primarily for sacroiliac joint fusion may include the difficulty of removal of the implants, namely, because the implants and the associated conventional methods of use are generally intended for insertion only. That is, the implants, rods, and screws described with reference to the conventional art are not configured for temporary use or for diagnostic purposes. Explanation of the implants, rods, or screws are generally not intended and is generally only utilized when complications arise. For example, the rods shown in FIG. **1**C may disrupt the interosseous ligament which the sacroiliac joint **3** depends on, in part, for stability in a healthy patient. As another example, other conventional implants and method may significantly disrupt the inner and outer table of the ilium, the cortical surface of the sacrum and may remove a significant volume of the bone of the sacrum and ilium.

Accordingly, there is a need in the art for systems and methods of diagnosing and treating a sacroiliac joint that minimally and temporarily disrupts the patient's anatomical structure and tissues. It is with these thoughts in mind, among others, that the present disclosure involving systems and methods of diagnosing and treating a sacroiliac joint were developed.

SUMMARY

Aspects of the present disclosure may involve a method of diagnosing and treating a sacroiliac joint of a patient, the method may include delivering a first member into the ilium via a first posterior approach, delivering a second member into the sacrum via a second posterior approach, coupling the first and second members to a pliers, and manipulating the first member relative to the second member via the pliers to determine an ailment of the sacroiliac joint.

In certain instances, the pliers are a dual-axis pliers may include first and second handles, first and second head portions, and a pair of joints adjustably coupling the first and second handles and the first and second head portions, the pair of joints facilitating rotation of the first and second head portions about first and second axes, the first and second axes are generally perpendicular to each other.

In certain instances, the pliers may include first and second handles, first and second head portions, and a first joint adjustably coupling the first and second handles and the first and second head portions, the pliers are expanding pliers such that movement of the first and second handles closer together via rotation about a first axis of the first joint causes the first and second head portions to move apart from each other.

In certain instances, the pliers further may include a second joint adjustably coupling the first and second handles and the first and second head portions, the second joint facilitates rotation of the first and second head portions about a second axis of the second joint, the second axis being generally perpendicular to the first axis.

In certain instances, the pliers further may include at least one stud member configured to be engaged and disengaged with the first joint, engagement of the stud member with the first joint limits rotation of the pliers to the first axis of the first joint, and disengagement of the stud member with the first joint permits rotation of the pliers to the first axis of the first joint and the second axis of the second joint.

Aspects of the present disclosure may involve a method of diagnosing and treating a sacroiliac joint of a patient, the method may include delivering a first member into the ilium via a first posterior approach, delivering a second member into the sacrum via a second posterior approach, coupling the first and second members to a first and second guide blocks, respectively, of a clevis guide, and manipulating the first member relative to the second member via the clevis guide to determine an ailment of the sacroiliac joint.

In certain instances, the clevis guide may include a pair of prongs adjustably coupled to the first and second guide blocks.

In certain instances, the first guide block may include rotationally coupled to the pair of prongs, and the second guide block may include rotationally and slidingly coupled to the pair of prongs so as to permit parallel alignment of the first and second guide blocks.

In certain instances, manipulation of the first member relative to the second member via the clevis guide may include relative longitudinal displacement of the first and second members.

In certain instances, the first guide block may include a first through-hole and a first screw-lock to secure the first member in a first position within the first through-hole, the second guide block may include a second through-hole and a second screw-lock to secure the second member in a second position within the second through-hole.

Aspects of the present disclosure may involve a method of diagnosing and treating a sacroiliac joint of a patient, the method may include delivering a first member into the sacrum via a first posterior approach, sliding a first dilator over the first member, sliding a sleeve of a first guide of a parallel pin guide over the first dilator, positioning a second guide of the parallel pin guide so as to target the ilium, inserting a second dilator into the second guide, and delivering a second member into the ilium via guidance by the second dilator.

In certain instances, the first and second members are guide wires, and the method further may include delivering first and second bone pins, respectively into the locations of the first and second members.

In certain instances, further may include manipulating the first and second bone pins relative to each other in order to determine a condition of the sacroiliac joint.

In certain instances, further may include using at least one of a pliers and a clevis guide to manipulate the first and

second bone pins relative to each other in order to determine a condition of the sacroiliac joint.

In certain instances, further may include inserting a pair of radiographic contrasting members into radiographic guide holes of the parallel pin guide, and aligning the radiographic contrasting members with the sacroiliac joint.

In certain instances, aligning the radiographic contrasting members with the sacroiliac joint may include done under radiographic imaging.

In certain instances, aligning the radiographic contrasting members with the sacroiliac joint causes the second guide of the parallel pin guide to target the ilium.

While multiple embodiments are disclosed, still other embodiments of the present disclosure will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the disclosure. As will be realized, the various embodiments of the present disclosure are capable of modifications in various aspects, all without departing from the spirit and scope of the present disclosure. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a superior view of a pelvic region and a conventional method and device for temporarily stabilizing the sacroiliac joint.

FIG. **1**B is an anterior view of the pelvic region and the conventional method and device for temporarily stabilizing the sacroiliac joint of FIG. **1**A.

FIG. **1**C is an anterior view of the pelvic region and a conventional method and device for permanently stabilizing the sacroiliac joint.

FIG. **2**A is an isometric view of an example system for fusing a sacroiliac joint.

FIG. **2**B is the same view as FIG. **2**A, except the delivery tool and implant assembly are decoupled from each other.

FIG. **2**C is the same view as FIG. **2**A, except the system is exploded to better illustrate its components.

FIG. **3** is a posterior-inferior view of a sacroiliac joint with a patient body shown in broken line.

FIG. **4** is a close-up view of the implant and anchor element in the sacroiliac joint.

FIG. **5**A is a right lateral view of a hip region of a patient lying in a prone position, wherein the soft tissue surrounding the skeletal structure of the patient is shown in dashed lines.

FIG. **5**B is an enlarged view of the hip region of FIG. **5**A.

FIG. **5**C is generally the same view as FIG. **5**B, except that the ilium is removed to show the sacroiliac joint space boundary defined along the sacrum and an implant positioned for implantation within the joint space.

FIG. **5**D is a lateral side view of the pelvic region of a patient with a nearest ilium removed to clearly show the regions of the sacroiliac joint.

FIG. **5**E is a lateral posterior view of the hip region of the patient showing the regions of the sacroiliac joint.

FIG. **5**F is a posterior view of the hip region of the patient showing the regions of the sacroiliac joint.

FIGS. **6**A-**6**D are each a step in the methodology and illustrated as the same transverse cross section taken along a plane extending generally medial-lateral and generally anterior posterior.

FIG. **7**A is an isometric view of a diagnostic pin.

FIG. **7**B is a bottom view of the diagnostic pin of FIG. **7**A.

FIG. **7**C is a top view of the diagnostic pin of FIG. **7**A.

FIG. **7**D is a side view of the diagnostic pin of FIG. **7**A.

FIG. **7**E is an isometric view of a diagnostic pin guidance tool.

FIG. **8**A is an isometric view of a diagnostic pin with a blunt distal end.

FIG. **8**B is an isometric view of a diagnostic pin with a blunt distal surface and a tapered tip extending distally of the blunt distal surface.

FIG. **9** is an isometric view of a diagnostic pin having a distal end with a pair of openings, the diagnostic pin coupled with an anchor guide.

FIG. **10**A is a posterior view of a hip region of a patient showing a diagnostic pin positioned in the sacrum and another diagnostic pin positioned in the ilium.

FIG. **10**B is a lateral side view of the hip region of the patient with a nearest ilium removed and a diagnostic pin positioned in the sacroiliac joint region.

FIG. **10**C is a posterior cross-sectional view of the sacroiliac joint with one pin positioned in the sacrum and one pin positioned in the ilium.

FIGS. **10**D-**10**E are transverse cross-sectional views of the sacrum and ilium showing various pin placements in the sacrum.

FIG. **10**F is a posterior view of the hip region of the patient showing pins in a right ilium and a left ilium.

FIG. **10**G is a posterior view of the hip region of the patient showing pins positioned in a right ilium and a left ilium for distracting the joint.

FIG. **10**H is a posterior view of the hip region of the patient showing pins positioned in a right ilium and a left ilium for compressing the joint.

FIG. **10**I is a posterior view of the lumbar spine showing pins to either stabilize or selectively allow motion between segments of the spine.

FIG. **11** is a lateral side view of the hip region of the patient in a neutral position with one pin in the sacrum and one pin in the ilium.

FIG. **12**A is a lateral side view of the hip region of the patient showing anterior-posterior movement of the ilium via the pins positioned in the sacrum and ilium.

FIG. **12**B is a lateral side view of the hip region of the patient showing cranial-caudal movement of the ilium via the pins positioned in the sacrum and ilium.

FIGS. **12**C-**12**D are lateral side views of the hip region of the patient showing rotational movement of the ilium via the pins positioned in the sacrum and ilium.

FIG. **13**A is a lateral side view of the hip region of the patient showing possible pin placements in the ilium and sacrum.

FIG. **13**B is a lateral side view of the hip region of the patient showing releasable distal portions of the pins being coupled with a coupling member.

FIG. **14** is a front isometric view of a diagnostic system including a mechanical coupling assembly coupled between a pair of diagnostic pins in accordance with embodiments of the present disclosure.

FIG. **15** is a back isometric view of the diagnostic system of FIG. **14**.

FIG. **16**A-**16**C are back views of the diagnostic system of FIG. **15**.

FIG. **17** is a top view of the diagnostic system of FIG. **14**.

FIG. **18** is an enlarged view of the mechanical coupling assembly of FIG. **14**.

FIG. **19** is an isometric view of the first coupling member of the diagnostic system of FIG. **14**.

FIG. **20**A is one isometric view from the side of the second coupling member **5008** of the diagnostic system of FIG. **14**.

FIG. **20**B is one isometric view from the bottom of the coupling member of the diagnostic system of FIG. **14**.

FIG. **20**C is one isometric view from the top of the coupling member of the diagnostic system of FIG. **14**.

FIG. **21** is an isometric view of the fastener of the diagnostic system of FIG. **14**.

FIG. **22** is an isometric view of the washer of the diagnostic system of FIG. **14**.

FIG. **23** is an isometric view of the side screw of the diagnostic system of FIG. **14**.

FIG. **24**A is an isometric view from the back of the third coupling member **5010** of the diagnostic system of FIG. **14**.

FIG. **24**B is an isometric view from the front of the third coupling member **5010** of the diagnostic system of FIG. **14**.

FIG. **25**A is an isometric view from the bottom of the connector at the end of the extension bar connected to the handle of the diagnostic system of FIG. **14**.

FIG. **25**B is an isometric view from the top of the connector at the end of the extension bar connected to the handle of the diagnostic system of FIG. **14**.

FIG. **26** is an isometric view of a diagnostic system including a pivot type mechanical coupling assembly for causing translational movements of the pins in accordance with embodiments of the present disclosure.

FIG. **27** is an isometric view of the diagnostic system of FIG. **26** in a position that one of the diagnostic pin moving upward in accordance with embodiments of the present disclosure.

FIG. **28** is an isometric view of the diagnostic system of FIG. **26** in a position that one of the diagnostic pin moving downward in accordance with embodiments of the present disclosure.

FIG. **29** is an isometric view of a diagnostic system including a pivot type mechanical coupling assembly for causing rotational movements of the pins in accordance with embodiments of the present disclosure.

FIG. **30**A is an isometric view of the diagnostic system that rotates one diagnostic pin clockwise with respect to another diagnostic pin.

FIG. **30**B is an isometric view of the diagnostic system that rotates one diagnostic pin counterclockwise with respect to another diagnostic pin.

FIG. **30**C is a front view of a diagnostic system that allows selective sliding of one pin relative to another pin.

FIG. **31** is an isometric view from a bottom of a surgical system for delivering an implant in accordance with embodiments of the present disclosure.

FIG. **32** is an isometric view from a top of the surgical system for delivering an implant of FIG. **31**.

FIG. **33** is an isometric view of the surgical system of FIG. **31** with the implant inserted partially.

FIG. **34** is a sectional view of the surgical system of FIG. **33** with the implant inserted partially.

FIG. **35** is an enlarged sectional view illustrating that the implant is inserted in the extra-articular region.

FIG. **36** is an enlarged sectional view illustrating that a cross type implant is inserted in the extra-articular region.

FIG. **37** is an enlarged sectional view illustrating that the fork-like shaped implant is inserted in the intra-articular region.

FIG. **38** is a sectional view of FIG. **37** as shown by arrows A-A.

FIG. **39**A is an enlarged sectional view illustrating that one pin is inserted in ilium near extra-articular region and one pin is inserted into the sacrum near the intra-articular region with coupling between the pins.

FIG. **39**B is an enlarged sectional view illustrating that one pin is inserted in ilium near extra-articular region and one pin is inserted into the sacrum near the extra-articular region with coupling between the pins.

FIG. **39**C is an enlarged sectional view illustrating that one pin is inserted in ilium near intra-articular region and one pin is inserted into the sacrum near the intra-articular region with coupling between the pins.

FIG. **40** is a simplified diagram illustrating an adjustable coupling member for the pins.

FIG. **41** is an enlarged sectional view illustrating that a temporary implant including coupled pins is inserted in the intra-articular region.

FIG. **42** illustrates a radiographic contrast tool that injects radiographic contrast under fluoroscopic guidance into the joint.

FIG. **43**A is an isometric view from a distal end of an implant in accordance with a first embodiment of the present disclosure.

FIG. **43**B is another isometric view from a proximal end of the implant of FIG. **43**A.

FIG. **44**A is an isometric view from a distal end of an implant in accordance with a second embodiment of the present disclosure.

FIG. **44**B is another isometric view from a proximal end of the implant of FIG. **44**A.

FIG. **45**A is an isometric view from a distal end of an implant in accordance with a third embodiment of the present disclosure.

FIG. **45**B is another isometric view from a proximal end of the implant of FIG. **45**A.

FIG. **46**A is an isometric view from a distal end of an implant in accordance with a fourth embodiment of the present disclosure.

FIG. **46**B is another isometric view from a proximal end of the implant of FIG. **46**A.

FIG. **47**A is an isometric view from a distal end of an implant in accordance with a fifth embodiment of the present disclosure.

FIG. **47**B is another isometric view from a proximal end of the implant of FIG. **47**A.

FIG. **48**A is an isometric view from a distal end of an implant in accordance with a sixth embodiment of the present disclosure.

FIG. **48**B is another isometric view from a proximal end of the implant of FIG. **48**A.

FIG. **48**C is a side view of a curved implant in accordance with a seventh embodiment of the present disclosure.

FIG. **48**D is an isometric view from a proximal end of the implant of FIG. **48**C.

FIG. **49**A is a lateral side view of the hip region of the patient with a nearest ilium removed and an implant positioned in the extra-articular region of the sacroiliac joint.

FIG. **49**B is a lateral side view of the hip region of the patient showing an implant coupled with a delivery tool positioned for delivery into the sacroiliac joint.

FIG. **49**C is the same view as FIG. **48**B, except the implant has been delivered into the extra-articular region of the sacroiliac joint.

FIG. **50** is a lateral side view of the hip region of the patient showing positioning of the implant within the extra-articular region of the sacroiliac joint.

FIG. **51** is a posterior view of the hip region of the patient showing the implant within the extra-articular region of the sacroiliac joint.

FIG. **52**A is an isometric front view of a parallel pin guide supporting a pair of dilators.

FIG. 52B is a front view of the parallel pin guide supporting the pair of dilators.

FIG. 52C is a cross-sectional view of the parallel pin guide supporting the pair of dilators.

FIG. 52D is a top view of the parallel pin guide supporting the pair of dilators.

FIG. 52E is a bottom view of the parallel pin guide supporting the pair of dilators.

FIG. 52F is an isometric front view of the parallel pin guide separated from the pair of dilators.

FIG. 52G is a side view of the parallel pin guide supporting the pair of dilators.

FIG. 52H is a cross-sectional view of the parallel pin guide supporting the pair of dilators.

FIG. 53A is an isometric front view of a dual-axis pliers.

FIG. 53B is an isometric rear view of the dual-axis pliers.

FIG. 53C is an isometric exploded view of the dual-axis pliers from a first side.

FIG. 53D is an isometric exploded view of the dual-axis pliers from a second side.

FIG. 53E is an isometric front view of the dual-axis pliers supporting a pair of bone pins in a first parallel orientation.

FIG. 53F is an isometric front view of the dual-axis pliers supporting a pair of bone pins in a second parallel orientation where the bone pins are spaced apart a farther distance than in the first parallel orientation.

FIG. 53G is an isometric front view of the dual-axis pliers supporting a pair of bone pins in a third orientation where the pair of bone pins are angled relative to each other but within parallel planes.

FIG. 54A is an isometric front view of a clevis guide supporting a pair of bone pins in a first parallel orientation.

FIG. 54B is an isometric front view of the clevis guide supporting the pair of bone pins in a second parallel orientation where the bone pins are moved longitudinally relative to each other relative to their positions in the first parallel orientation.

FIG. 54C is an isometric exploded view of the clevis guide.

FIG. 55A is an inferior view of a sacrum and an ilium with a guide wire delivered into the sacrum.

FIG. 55B is an inferior view of the sacrum and the ilium with a first dilator positioned over the guide wire.

FIG. 55C is an inferior view of the sacrum and the ilium with the parallel pin guide positioned over the first dilator.

FIG. 55D is an inferior view of the sacrum and the ilium with a pair of radiographic contrasting cylinders positioned through the radiographic guides of the parallel pin guide.

FIG. 55E is a posterior view of the sacrum and the ilium showing the pair of radiographic contrasting cylinders parallel with each other and generally parallel with a joint line of the sacroiliac joint.

FIG. 55F is an inferior view of the sacrum and the ilium with a second dilator positioned up against the ilium and through a guide hole of the parallel pin guide.

FIG. 55G is an inferior view of the sacrum and the ilium with a second guide wire positioned through the second dilator and into the ilium.

FIG. 55H is an inferior view of the sacrum and the ilium with the dual-axis pliers secured to a pair of pins (positioned in the sacrum and ilium where the guide wires were previously).

FIG. 55I is an inferior view of the sacrum and the ilium with the clevis guide secured to the pair of pins (positioned in the sacrum and ilium where the guide wires were previously).

DETAILED DESCRIPTION

Implementations of the present disclosure involve a system for diagnosing and treating a sacroiliac joint disorder or ailment. In particular, the system may include a diagnostic tool for manipulating a pair of rods temporarily implanted or engaged with the hip region of the patient. A first rod may engage with or be delivered into the sacrum and a second rod may be delivered parallel to the first rod and may engage with or be delivered into the ilium. The rods may span an intra-articular region or extra-articular region of the sacroiliac joint. The diagnostic tool may be used to grasp and manipulate the rods such that the sacrum and ilium are manipulated relative to each other. Through manipulation of the diagnostic tool, the ilium may be, for example, translated proximally, distally, cranial, or caudal relative to the sacrum. Additionally, the ilium may be, for example, rotated in various planes relative to the sacrum via the diagnostic tool. Alternatively and in certain embodiments, the rods may be manipulated by hand without the aid of the diagnostic tool. The manipulation of the sacrum and ilium via the rods may be beneficial for a medical professional to diagnose a sacroiliac joint disorder because, for example, the rods may isolate the forces exerted to specific areas of the hip region (e.g., sacrum, ilium or lumbosacral spine). In certain instances, the diagnosis may indicate that stabilization of the joint is necessary.

The joint may be stabilized in a number of ways. For example, the rods may be replaced by anchor or shorter rods and the rods may be coupled together, beneath the patient's skin. If a suitable amount of pain is reduced by this procedure, this may indicate that permanent fixation of the joint should alleviate or substantially reduce the pain.

As another example of joint fixation and while the rods are in place in the sacrum and ilium, the rods may act as an alignment system for the subsequent delivery of a temporary implant. More particularly, a sleeve may be fitted over the rods and an insert may be fitted within the sleeve to guide a particular implant for delivery into the sacroiliac joint. The implant may be delivered via a posterior approach into the sacroiliac joint and the implant may be delivered such that a portion of the implant bridges the joint and affixes into a portion of each of the sacrum and the ilium. In certain implementations, the implant may include an open distal end such that a majority of the body of the implant occupies the sacrum and the ilium with the open portion of the implant occupying the sacroiliac joint space so as to minimally disrupt the cartilage in the joint space.

The temporary implant may remain in the patient for a period of time to determine if a subsequent, permanent implant is needed. For example, if the temporary implant successfully treats the disorder, the implant may be removed in favor of implanting a permanent implant such as those described in U.S. patent application Ser. Nos. 14/447,612; 13/475,695; 13/236,411; 12/998,712; and Ser. No. 16/133,605, all of which are incorporated by reference in their entireties into the present application. Accordingly, if a subsequent implant is to be delivered into the joint space, the joint may be prepared according to the systems, tools, and methods described in U.S. patent application Ser. Nos. 14/514,221, and 16/133,605 which is hereby incorporated by reference into the present application in its entirety. Or, the implant may remain implanted and a subsequent implant may or may not be delivered into the sacroiliac joint.

In particular instances, a portion or entirety of a sacroiliac joint may be treated, stabilized, or replaced by an implant, system and/or method as described in U.S. patent application Ser. No. 14/127,119, filed Dec. 17, 2013, entitled "Sacroiliac Joint Implant System" and incorporated herein by reference in its entirety.

In certain instances, when a patient may have pain in the region near the sacroiliac joint, a fluid injection method may be used to inject pain medicine in the sacroiliac joint. When using the fluid injection method, it may be difficult to accurately determine if the pain arises from the sacroiliac joint or other regions, because the fluid may leak to other nearby regions. The pain medicine may leak in to other nearby regions and relieve the pain in those regions such that even if the pain is reduced, it is difficult to determine if the pain truly comes from the sacroiliac joint.

Current diagnostic procedures may not be accurate enough to determine whether the root cause of the pain comes from the sacroiliac joint. As a result, a surgeon may place an implant in the sacroiliac joint, which may not be necessary or helpful for relieving the patient's pain, or possibly subjecting the patient to unnecessary potential complications.

The present diagnostic system provides a diagnostic system that can generate localized forces to cause movement of the sacroiliac joint. The diagnostic system may assist to accurately determine the need of an implant in the sacroiliac joint (or other treatment), either by stabilizing the joint to reduce the pain in a patient or by reproducing the pain in the patient via the localized forces to mobilize the joint or cause movement of the joint. This diagnostic system and method may provide accurate diagnostics on whether an implant is needed, thus, reducing the possibility of an unnecessary implant being implanted into the sacroiliac joint.

The present disclosure provides a diagnostic system that can be used to mobilize the sacroiliac joint of a patient in order to reproduce or stimulate pain in the patient. The patient may provide feedback on whether the pain is similar to his or her familiar pain pattern. If the pain in the patient can be reproduced by manipulating the movement of the sacroiliac joint, this suggests that fusion, fixation, stabilization, or other treatment of the joint (e.g., with an implant) may be helpful to reduce the pain. Various methods and means may be used to mobilize the sacroiliac joint. For example, the diagnostic system may include pins, rods, or bars that may be inserted or engaged with the sacrum or ilium at different locations to cause particular movements of the sacroiliac joint. The pins or bars may have a distal end portion that can engage a larger region of the ilium or sacrum to cause the movement. For example, the distal end portion may extend from the pin in a radial direction such that the distal end portion may have a larger surface area. The distal end portion may be a 2D or 3D plate. The diagnostic system may also include screws that are inserted in the ilium or sacrum. One shaft may be used to couple to one screw while another shaft may be coupled to another screw. The shafts may be used to cause movements or stabilization of the joint. The distal portion may be a hook. The distal portion may be configured to reversibly expand (i.e., similar to a molly bolt or toggle bolt).

The present disclosure also provides a diagnostic system that can help determine if stabilizing the sacroiliac joint of a patient helps with reducing pain or other symptoms in the patient. The diagnostic system may include diagnostic pins coupled together that may be temporarily placed in the patient to stabilize the joint and to determine if the patient may have reduced pain. The pins may remain in the patient for a given period of time to determine if stabilization of the joint via the pins is effective at reducing pain. Instructions may be given to the patient to perform, e.g., single leg stands, squats, sitting, rolling on side, movement of leg in various directions, an activity which causes accustomed symptoms. The patient may do certain work out routines on a running machine or cycling machine to provide feedback on whether the pain is reduced. The patient may also be instructed to live a regular daily life to provide feedback on whether the pain is reduced. The diagnostic system may also include delivering tools for implanting into the joint.

I. System for Fusion of the Sacroiliac Joint

To begin a detailed discussion of a system **10** for delivering an implant **12** into the sacroiliac joint, reference is made to FIGS. **2**A-**2**C. FIG. **2**A is an isometric view of the system **10**. FIG. **2**B is the same view as FIG. **2**A, except an implant assembly **14** of the system **10** is separated from a delivery tool **16** of the system **10**. FIG. **2**C is the same view as FIG. **2**A, except the system **10** is shown exploded to better illustrate the components of the system **10**.

As can be understood from FIGS. **2**A and **2**B, the system **10** includes a delivery tool **16** and an implant assembly **14** for implanting at the sacroiliac joint via the delivery tool **16**, the implant assembly **14** being for fusing the sacroiliac joint. As indicated in FIG. **2**C, the implant assembly **14** includes an implant **12** and an anchor element **18** (e.g., a bone screw or other elongated body). As discussed below in greater detail, during the implantation of the implant assembly **14** at the sacroiliac joint, the implant **12** and anchor element **18** are supported by a distal end **20** of the delivery tool **16**, as illustrated in FIG. **2**A. The delivery tool **16** is used to deliver the implant **12** into the sacroiliac joint space. The delivery tool **16** is then used to cause the anchor element **18** to extend through the ilium, sacrum and implant **12** generally transverse to the sacroiliac joint and implant **12**. The delivery tool **16** is then decoupled from the implanted implant assembly **14**, as can be understood from FIG. **2**B. As illustrated in FIGS. **2**A-**2**C, the delivery tool **16** further includes a proximal end **22** opposite the distal end **20**, an arm assembly **24**, a handle **26**, an implant retainer **28**, a sleeve **30** and a trocar or guidewire **32**. While in the embodiment of FIGS. **2**A-**2**C, the delivery tool **16** is fixed and non-adjustable and configured to deliver the anchoring element **18** in a single orientation relative to the implant **12**, the delivery tool **16** may be adjustable and configured to deliver the anchoring elements **18** within a range of orientations relative to the implant **12** that will orient the anchoring element **18** either within a bore of the implant **12**, or adjacent implant **12** as described in U.S. patent application Ser. No. 14/447,612, filed Jul. 31, 2014, entitled SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT, which is hereby incorporated by reference in its entirety.

In particular embodiments, first and second articular faces of the implant **12** may be selected to match the contour of the joint space of the sacroiliac joint within which the implant **12** is to be inserted. For example, the sacral, medial or first articular faces of the implant may be configured to be generally convex to match the contour of a sacral auricular boney surface or to match the contour of an extra-articular region of a sacrum (e.g., a sacral fossa). In one aspect and referring to portions of the anatomy shown FIG. **5**C, the sacral, medial or first articular face of the implant **12** may be generally a surface negative of the articular surfaces **1016** of the extra-articular region **3007** and/or articular region **1044** of the sacrum **1004**. As another example, the lateral, iliac or second articular face of the implant **12** may be configured to be generally concave to match the contour of an iliac auricular boney surface or to match the contour of an extra-articular region of an ilium (e.g., an iliac tuberosity). In one aspect, the lateral, iliac or second articular face of the implant **12** may be generally a surface negative of the articular surfaces **1016** of the extra-articular region **3007** and/or articular region **1044** of the ilium **1005**.

A system as described in FIGS. **2**A-**2**C may be used in a surgical procedure via a posterior approach, as seen in FIGS. **3**-**4**. As can be understood from FIG. **3**, which is a posterior-inferior view of a sacroiliac joint **36** with a patient **40** shown in broken line, the delivery tool **16** is positioned to deliver the implant **12** into a caudal region **34** of the sacroiliac joint **36** and the anchoring element **18** through the ilium **5** and into the bore **38** of the implant **12**. Referring to FIG. **4**, the implant **12** and anchoring element **18** have been inserted into the caudal region **34** of the sacroiliac joint **36** and the delivery tool **16** has been removed.

With further reference to the boney anatomy shown in FIG. **5**C, a system as described herein may be used in a surgical procedure via an anterior approach (e.g., such that the surgical pathway includes traversing an anterior boundary segment **3004** and/or traversing an anterior-inferior corner **3010**) and may further include positioning an implant into a sacroiliac joint such that: 1) the implant longitudinal axis a) is generally parallel to a sacroiliac joint inferior boundary segment **3002**, or b) points towards a posterior superior iliac spine, or c) point towards a posterior inferior iliac spine, or d) points toward a sacroiliac extra-articular region; or, 2) the distal end of the implant generally lies within a) a caudal region of the sacroiliac joint articular region, or b) an extra-articular portion of the sacroiliac joint, or c) a cranial portion or cephalad region of the sacroiliac joint articular region.

Additionally, a system as described herein may be used in a surgical procedure via an approach which includes a surgical pathway which transverses a sacroiliac joint inferior boundary segment **3002**, e.g., as described in U.S. patent application Ser. No. 13/945,053, filed Jul. 18, 2013, entitled SYSTEMS AND METHODS OF FUSING A SACRO-ILIAC JOINT, which is hereby incorporated by reference in its entirety. A surgical procedure via this pathway may further include positioning an implant into a sacroiliac joint such that: 1) the implant longitudinal axis a) is transverse to a sacroiliac joint inferior boundary segment **3002**, or b) points towards a posterior superior iliac spine, or c) point towards a posterior inferior iliac spine, or d) points toward a sacroiliac extra-articular region, or e) points towards a sacroiliac joint anterior boundary segment **3004**, or f) points towards either superior boundary segment corner **3014** or **3012** or somewhere in-between; or, 2) the distal end of the implant generally lies within a) a caudal region of the sacroiliac joint articular region, or b) an extra-articular portion of the sacroiliac joint, or c) a cranial portion or cephalad region of the sacroiliac joint articular region.

Furthermore, in certain embodiments, an implant **12** may be inserted along a generally arcuate path. Accordingly, a surgical preparation technique and tools may be utilized while operating in an arcuate path. The implant arcuate path may follow and generally match the surgical preparation arcuate path and the path arc may include a radius of between approximately 3 cm to 6 cm. The portion of the path having an arcuate path including a radius of between approximately 3 cm to 6 cm may reside substantially in the plane of the sacroiliac joint or in a plane in close proximity and generally parallel thereto. Furthermore, the arcuate path may generally or substantially reside in sacroiliac joint articular region **1044**. Additionally, an implant may be selected for use during the procedure which substantially matches the radius or curvature of the arcuate or curved insertion path or surgical preparation path.

In certain embodiments, after drilling or otherwise producing an opening through an ilium (or sacrum) leading toward or into a sacroiliac joint, a sleeve may guide (alone or along with another cannulated tool, e.g., a needle) a bone paste, bone marrow aspirate, stem cells, allograft or any biocompatible material or substance into the sacroiliac joint space via a path with a trajectory which may be generally transverse to the plane of the sacroiliac joint. The sleeve may be caused to form a seal with a bone defining the sacroiliac joint, e.g. the ilium. The seal may be created by impacting a proximal end of sleeve which may, for example, cause the sleeve to slightly penetrate the cortex of the outer table of the ilium. Alternatively, a cannulated tool such as a large gauge needle or tube may either be interference fit within a hole in the ilium or the needle or tube may have a threaded distal end which may be threaded into the bore formed in the ilium. A plunger or bone tamp may be forced through a sleeve to advance the bone paste or other material into the sacroiliac joint space, adjacent/around the implant and/or into the bone graft window of the implant.

Subsequently, an anchor such as a bone screw may be advanced via the sleeve into engagement with an opening formed in the ilium and driven across the sacroiliac joint and further into the sacrum. Alternatively, a bone plug may be positioned into the opening formed in the ilium in order to occlude the passageway between the outer cortex of the ilium and the implanted bone paste or other material positioned generally in the plane of the joint.

II. Methods of Preparing the Sacroiliac Joint for Fusion

The following discussion will focus on various methods of diagnosing and treating a sacroiliac joint ailment utilizing the tools and devices discussed previously.

A. Preoperative Planning for a Diagnostic and/or Surgical Procedure

Prior to any joint treatment, preparation or fusion, a surgeon or other medical person may diagnose a particular ailment of the sacroiliac joint and select a suitable procedure to treat the sacroiliac joint, e.g., fusion, fixation, stabilization, replacement, resurfacing, restructuring, repairing, or altering of boney ligamentous or capsular tissue. The procedure may include fusing the joint with or without delivering an implant in the joint space. A diagnostic and/or treatment procedure may be planned and/or conducted (and, e.g., the surgeon may select an implant configuration for delivery into the sacroiliac joint region of the patient) based on preoperative or intraoperative data. The data may be the result of post-processing of raw or other imaging data (e.g. CT or MRI DICOM files). The post-processing may include the use of a software program (e.g., 3DSLICER available from http://www.slicer.org) that may be used for medical image processing and 3D visualization of image data. Other data may include the patient's weight, activity level, spinal alignment, posture and general health.

The preoperative or intraoperative data may assist in the planning and selecting of desirable implant and final anchor positioning, trajectories (e.g., starting and stopping points on patient's soft tissue and near or within bone tissue), anchor, number, configurations and dimensions (e.g., length, cannulation, apertures, cross sectional geometry, surface treatments, diameter, head size, washer, thread pitch), implant types, number, configurations and dimensions, and joint preparation tool types, dimensions, and configurations. A particularly system for preparing and fusing the sacroiliac joint may be selected, for example, for a hypermobile joint, which may include an implant or fusion system that is resistant to the expected forces (magnitude and vector) present at that particular patient's sacroiliac joint. The determination of fixation sufficiency may be calculated based on the patient's data and also on the performance results of various bench and/or finite element analysis ("FEA") tested implant assembly (or individual components) configurations. For example, a calculated anchor and/or implant trajectory may be considered and determined from certain patient imaging and post-processing data with an overlayed implant assembly. Further, the implant assembly footprint within the joint plane may be selected as a lower percent of total joint surface area to permit sufficient boney fusion across the joint while maintaining a sufficient implant sacral and iliac face surface area to prevent implant subsidence.

Specific measurements and characteristics of the patient's anatomy may influence the selection of a particular joint fusion system. For example, the patient's bone density may be measured at numerous locations in proximity to and surrounding the elements of the implant assembly. Lower bone density (e.g., osteopenia, osteoporosis) corresponding to a T-score lower than −1, sacroiliac joint instability, or hypermobility may require the use of an implant assembly with a greater amount of keel (or a particular keel configuration) (i.e., the material cross section as defined by thickness of the keel and its length along implant longitudinal axis and also keels extending a greater distance into both bones defining the sacroiliac joint) and anchor extending across the sacroiliac joint and into the ilium and sacrum. Additionally, the relative angles between the implant longitudinal axis and anchor or anchors, and also the relative angles between multiple anchors (e.g., parallel, divergent, convergent) may be preselected based on the patient's anatomy.

A comparison of the preoperative or intraoperative data (e.g., sacroiliac joint surface area, joint mobility, loading, bone density, desirable anatomic pathways) and the selected implant assembly and joint preparation tools may be conducted to ensure or validate compatibility before the manufacture ships the implant system and/or before the surgeon employs the system in a surgical procedure. After implant assembly and preparation tools validation, the selected assemblies may be shipped to the surgeon and the surgeon may proceed with the surgical fusion procedure utilizing the selected assemblies.

Similarly, various aspects of the diagnostic tools (discussed herein) may be selected based on the same or similar data and/or studies. Additionally, placement of the various components of the diagnostic systems in to the sacroiliac joint region and/or the amount of displacement of one bone relative to another may be chosen or guided by one or more of the following: the anchor trajectory and placement may be guided and confirmed with imaging studies before the end of the surgical procedure or afterwards. For example, a surgeon may use fluoroscopy (and/or arteriography) to obtain an anteroposterior view, lateral view, an inlet view, an outlet-oblique view, Judet views of the pelvis, an internal (obturator) oblique view, a Ferguson view, an external (iliac) oblique view or other relevant views and further use radiographic boney landmarks such as the superimposed greater sciatic notches, superimposed iliac cortical densities or alar slope, sacral promontory, first sacral endplate, sacral foramina, arcuate sacral lines, iliopectineal line, ilioishial line, acetabular teardrop lines bony corridors of S1 or S2, superimposed acetabula, ventral and dorsal surfaces of the sacrum, etc.; or using an angiogram to identify vascular structures such as the superior gluteal artery, internal iliac artery and vein, iliolumbar vein, etc.

B. Fusion of the Sacroiliac Joint Via Implant Delivery

The following is an overview of the anatomy and methods of fusing the joint. To begin, reference is made to FIGS. **5**A-**5**B, which depict various bone landmarks adjacent, and defining, the sacroiliac joint **1000** of a patient **1001**.

Reference is first made to FIG. **5**A, which is a right lateral view of a hip region **1002** of a patient **1001** lying prone, wherein the soft tissue **1003** surrounding the skeletal structure **1006** of the patient **1001** is shown in dashed lines. Delivery of an implant into the sacroiliac joint **1000** and, thus, preparing of the joint **1000** for delivery of the implant may be conducted via a posterior approach to the hip region **1002**. FIG. **5**B, which is an enlarged view of the hip region **1002** of FIG. **5**A, depicts a lateral view of the patient's hip region **1002** and reveals certain features of the ilium **1005**, including the anterior superior iliac spine **2000**, the iliac crest **2002**, the posterior superior iliac spine **2004**, the posterior inferior iliac spine **2006**, the greater sciatic notch **2008** extending from the posterior inferior iliac spine **2006** to the ischial spine **2010**, and the tubercle of the iliac crest **2012**.

The sacroiliac joint articular region or intra-articular region **1044** is shown in dashed lines. The articular region **1044** is a portion of the sacroiliac joint **1000** formed between articular surfaces of the ilium **1005** and sacrum **1004**. The articular region **1044** is typically covered in a thin plate of cartilage and is surrounded by a fibrous capsule containing synovial fluid.

Boundaries of the sacroiliac joint articular region **1044** are as follows. A posterior inferior access region **2016** of the sacroiliac joint articular region **1044** has a superior end **2018** on the sacroiliac joint line **2019** that is between approximately 0 mm and approximately 40 mm inferior the posterior inferior overhang **2020** of the posterior superior iliac spine **2004**. The posterior inferior access region **2016** of the sacroiliac joint articular region **1044** has an inferior end **2022** on the sacroiliac joint line that is at approximately the intersection of the posterior inferior iliac spine **2006** with the lateral anterior curved boundary **2024** of the sacrum **1004**. In other words, the posterior inferior access region **2016** of the sacroiliac joint articular region **1044** has an inferior end **2022** on the sacroiliac joint line that is at approximately the superior beginning of the greater sciatic notch **2008**.

Still referring to FIG. **5**B, the sacroiliac joint articular region **1044** roughly defines an L-shape or boot-shape that includes a caudal region **1086** and a cranial region **1087**. Access into the caudal region **1086** of the sacroiliac joint may be accomplished via the posterior inferior access region **2016** that extends between corners defined by the superior end **2018** and the inferior end **2022**. Access into the cranial region **1087** may be accomplished by continual, anterior travel in the caudal region **1086** until the articular region **1044** turns superiorly into the cranial region **1087**.

To begin a discussion of implant delivery into the sacroiliac joint articular region **1044**, reference is made to FIG. **5**C, which is a close-up lateral side view of the hip region **1002** of a patient **1001** with a nearest ilium **1005** removed in order to show the sacroiliac joint boundary **3000** defined along the sacrum **1004** and outlining the sacroiliac joint articular region **1044**, and an implant **25** positioned for implantation within the sacroiliac joint articular region **1044**.

As seen in FIG. **5**C, boundaries along the sacroiliac joint articular region **1044** include an inferior boundary segment **3002**, an anterior boundary segment **3004**, a superior boundary segment **3006**, and a posterior boundary segment **3008**. The inferior boundary segment **3002** is immediately adjacent, and extends along, the sciatic notch **2024**.

The inferior boundary segment **3002** and anterior boundary segment **3004** intersect to form an anterior-inferior corner **3010**. The anterior boundary segment **3004** and superior boundary segment **3006** intersect to form an anterior-superior corner **3012**. The superior boundary segment **3006** and posterior boundary segment **3008** intersect to form a superior-posterior corner **3014**. The posterior boundary segment **3008** and posterior inferior access region **2016** intersect to form a superior-posterior corner **3016** of the posterior inferior access region **2016**. The inferior boundary segment **3002** and posterior inferior access region **2016** intersect to form an inferior-posterior corner **3018** of the posterior inferior access region **2016**.

The inferior boundary segment **3002** extends between corners **3010** and **3018**. The anterior boundary segment **3004** extends between corners **3010** and **3012**. The superior boundary segment **3006** extends between corners **3012** and **3014** and provides an access into the cranial portion **1087** of the sacroiliac joint. The posterior boundary segment **3008** extends between corners **3014** and **3016**. The posterior inferior access region **2016** extends between corners **3016** and **3018** and provides an access into the caudal region **1086** of the sacroiliac joint.

The posterior boundary segment **3008** separates the articular region **1044** and the extra-articular region **3007**, which includes the sacral fossa on the sacrum **1004** and the corresponding iliac tuberosity on the ilium **1005** and defined by the extra-articular region boundary **3009**.

In one aspect and as seen in FIG. **5**C, the implant **25** may be delivered via an implant arm **111** of a delivery tool into the caudal region **1086** of the sacroiliac joint articular region **1044**. As shown via the implant **25** and implant arm **111** shown in solid lines, in one embodiment, the implant **25** enters the posterior inferior access region **2016**, and is further advanced into the caudal region **1086** of the sacroiliac joint articular region **1044**, in an orientation such that the implant arm **111** and wide planar members **51** are in the joint plane and the longitudinally extending edge **3050** of the wide planar member **51** next to the inferior boundary segment **3002** is generally parallel to, and immediately adjacent to, the inferior boundary segment **3002**. Thus, the distal end **43** of the implant is heading generally perpendicular to, and towards, the anterior boundary segment **3004**.

As shown in FIG. **5**C via the implant **25** and implant arm **111** shown in dashed lines, in one embodiment, the implant **25** enters the posterior inferior access region **2016**, and is further advanced into the caudal region **1086** of the sacroiliac joint articular region **1044**, in an orientation such that the implant arm **111** and wide planar members **51** are in the joint plane and the longitudinally extending edge **3050** of the wide planar member **51** next to the inferior boundary segment **3002** is somewhere between being generally parallel to the inferior boundary segment **3002** (as illustrated by the solid-lined implant **25** in FIG. **5**C) or forming an angle AJ with the inferior boundary segment **3002** of up to approximately 50 degrees. Thus, the distal end **43** of the implant shown in dashed lines can be said to head anywhere from generally perpendicular to, and towards, the anterior boundary segment **3004** to heading generally towards the superior-anterior corner **3012**, or points in between.

In one embodiment, the implant **25** may be first directed into the joint space as illustrated by the solid-lined implant **25** in FIG. **5**C after which the implant **25** is rotated within the joint space to be positioned somewhere between, and including, angled position depicted by the dashed-lined implant **25**. In other embodiments, the implant **25** may be first directed into the joint space as illustrated by the dashed-lined implant **25** in FIG. **5**C after which the implant **25** is rotated within the joint space to be positioned somewhere between, and including, the parallel position depicted by the solid-lined implant **25**. Thus, an implant **25** may be delivered non-transversely (i.e., within the joint and not across the joint) into the caudal region **1086**, the cranial portion **1087**, or partially within each of the caudal and cranial regions **1086**, **1087** of the sacroiliac joint articular region **1044**. Further details of the implant delivery can be found in related applications, mentioned previously, such as U.S. patent application Ser. No. 12/998,712, which is incorporated by reference herein in its entirety.

Reference is now made to FIG. **5**D, which depicts a close-up lateral view of the hip region **1002** of FIG. **5**C, except the implant is not shown. In particular, FIG. **5**D shows additional anatomical features of the extra-articular region **3007** of the joint. As seen in the figure, the extra-articular region boundary **3009** has a caudal boundary segment **3093**, an anterior boundary segment **3094**, and a posterior boundary segment **3097**. The caudal boundary segment **3093** and the anterior boundary segment **3094** separate the intra-articular region **1044** and the extra-articular region **3007**. The posterior boundary segment **3097** is immediately adjacent and extends along the sacroiliac joint line **2019**. The caudal and anterior boundary segments **3093**, **3094** intersect to form an anterior-inferior corner **3095**. The caudal boundary segment **3093** intersects with the posterior boundary segment **3097** to form a posterior-inferior corner **3091**. The anterior boundary segment **3094** of the extra-articular boundary **3009** intersects with the posterior boundary segment **3097** for form a posterior-anterior corner **3096**.

The sacroiliac extra-articular region **3007** has an extra-articular recess access region **6000**, which spans the posterior boundary segment **3097** and has an inferior end **3092** (i.e., generally coincident with posterior inferior corner **3091**) and a superior end **3098** located near the posterior anterior corner **3096** along the sacroiliac joint line **2019**.

The extra-articular access region **6000** has an extra-articular posterior-inferior access region **6001** that has an inferior end **3092** along the sacroiliac joint line **2019**. The inferior end **3092** is generally coincident with the posterior inferior corner **3091**. The inferior end **3092** is immediately adjacent both the superior-posterior corner **3016** and the superior end **2018** of the posterior inferior access region **2016**.

Reference is now made to FIGS. **5**E-**5**F, which depict, respectively, a lateral-posterior view and a posterior view of the hip region **1002** of the patient **1001**. These figures include many of the anatomical features referred to in FIGS. **5**B-**5**C and the some of the additional anatomical features described in FIG. **5**D. For example, the articular region **1044** and extra-articular region **3007** are shown in dashed line with many of their respective boundaries identified in each figure. FIG. **5**E depicts the posterior inferior access region **3090** of the sacroiliac joint extra-articular region **3007** and inferior end **3092** of the extra-articular posterior inferior access on the sacroiliac joint line **2019**. The posterior inferior access region **2016** of the intra-articular region **1044** has the superior end **2018** on the sacroiliac joint line **2019** that is immediately adjacent the inferior end **3092** of the caudal boundary segment **3093** of the extra-articular region **3007**.

C. Preparing the Sacroiliac Joint for Fusion

Now that an overview of the relevant anatomical landmarks and an example fusion procedure has been described, the discussion may now focus on preparing the sacroiliac joint for a fusion procedure. In doing so, reference will be made to FIGS. **6**A-**6**D, among additional figures, which are steps in the methodology and illustrated in the same transverse cross section taken in along a plane extending medial-lateral and anterior posterior. In this cross section, articular surfaces **1016** are covered by a thick layer of articular cartilage with a joint space existing between them, the FIGS. **6**A-**6**D are simplified for illustrative purposes and do not show these features to scale.

Now referring primarily to FIG. **6**A, an embodiment of the method can include the step of placing a patient under sedation prone on a translucent operating table (or other suitable surface). The sacroiliac joint **1000** can be locally anesthetized to allow for injecting a radiographic contrast **1046** (as a non-limiting example, Isoview **300** radiographic contrast) under fluoroscopic guidance into the inferior aspect of the sacroiliac joint **1000** to outline the articular surfaces **1016** of the sacroiliac joint **1000**) defined between the sacrum **1004** and ilium **1005**, the sacroiliac joint **1000** having an interarticular region **1044**. Injection of the radiographic contrast **1046** within the sacroiliac joint **1000** can be accomplished utilizing a tubular member **1047** (e.g., a syringe needle) having first tubular member end **1048** which can be advanced between the articulating surfaces **1016** of the sacroiliac joint **1000** and having a second tubular member end **1049** which removably couples to a hub **1050**. The hub **1050** can be configured to removably couple to a syringe barrel **1051** or other device to contain and deliver an amount of radiographic contrast **1046**. In the example of a syringe barrel **1051**, the syringe barrel **1051** can have an internal volume capable of receiving an amount of the radiographic contrast **1046** sufficient for outlining the articular surfaces **1016** of the sacroiliac joint **1000**, for example, under lateral fluoroscopy. A plunger **1052** can be slidingly received within the barrel **1051** to deliver the radiographic contrast **1046** through the tubular member **1047** into the sacroiliac joint **1000**. The tubular member **1047** can have a gauge in the range of about 16 gauge and about 20 gauge and can further be incrementally marked on the external surface to allow determination of the depth at which the first needle end **1048** has advanced within the sacroiliac joint **1000**. As the first needle end **1048** advances into the sacroiliac joint **1000** the radiographic dye **1046** can be delivered from within the syringe barrel **1051** into the sacroiliac joint **1000** to allow visualization of the sacroiliac joint **1000** and location of the tubular needle **1047** within the sacroiliac joint **1000**.

Now referring primarily to FIG. **6**B, once the first tubular member end **1048** has been sufficiently advanced into the sacroiliac joint **1000** and the articular surfaces **1016** of the sacroiliac joint **1000** have been sufficiently visualized, the hub **1050** can be removed from the tubular member **1047** leaving the tubular member **1047** fixed within the sacroiliac joint **1000** as an initial guide for tools subsequently used to locate or place the sacroiliac joint implant non-transversely between the articulating surfaces **1016** of the sacroiliac joint **1000** (e.g., locate the implant non-transversely to the joint plane **1030** generally defined by the articulating surfaces **1016** of the interarticular region **1044** of the sacroiliac joint **1000**) or in removal of a portion of the sacroiliac joint **1000** within the region defined by the articular surfaces **1016** to generate an implant receiving space **1029**. Alternately, one or more guide pins **1013** can be inserted along substantially the same path of the tubular member **1047** for fixed engagement within the sacroiliac joint **1000** and used in subsequent steps as a guide(s).

Now referring primarily to FIG. **6**C, a small incision **1053** can be made in the skin at the posterior superior, or as to certain embodiments inferior, aspect of the sacroiliac joint **1000**, extending proximal and distal to the tubular member **1047** along the line of the sacroiliac joint **1000** to provide a passage to access the interarticular space between the articulating surfaces **1016** (see FIG. **6**B) of the sacroiliac joint **1000**. More specifically, the small incision **1053** can be made along the joint line of the sacroiliac joint **1000** in the tissue covering the posterior inferior access region **2016** of the sacroiliac joint articular region **1044**. A cannulated probe **1054** can be slidingly engaged with the tubular member **1047** (or guide pin **1013**) extending outwardly from the sacroiliac joint **1000** (while the sacroiliac joint may be shown in the figures as being substantially linear for illustrative purposes, it is to be understood that the normal irregular features of the sacroiliac joint have not been removed). The cannulated probe **1054** can have a probe body **1054** of generally cylindrical shape terminating in a spatulate tip **1055** at the end advanced into the sacroiliac joint **1000**. A removable cannulated probe handle **1056** couples to the opposed end of the probe body **1054**. The spatulate tip **1055** can be guided along the tubular needle **1047** or guide wire **1013** into the posterior portion of the sacroiliac joint **1000** and advanced to the anterior portion of the sacroiliac joint **1000** under lateral fluoroscopic visualization. The cannulated probe handle **1056** can then be removed providing the generally cylindrical probe body **1054** extending outwardly from the sacroiliac joint **1000** through the incision **1053** made in the skin.

Alternatively, the probe **1054** can be used to guide, advance or place a needle, guide wire or other instrument up to, near, or into the joint.

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

Now referring primarily to FIG. **6**D, a passage from the incision **1053** (see FIG. **6**C) to the sacroiliac joint **1000** can be generated by inserting a cannula **1057** into the incision. A soft tissue dilator **1058** having a blunt end **1059** can be advanced over the probe body **1054**, or a plurality of soft tissue dilators of increasing size, until the blunt end **1059** of the soft tissue dilator **1058** and the corresponding cannula end contact the posterior aspect of the sacroiliac joint **1000**. More specifically, in one embodiment, the ends of the dilator **1058** and cannula **1057** contact the joint line **2019** of the sacroiliac joint **1000** at the posterior inferior access region **2016** of the sacroiliac joint articular region **1044**. The soft tissue dilator **1058** can be removed from within the cannula **1057**. The external surface of the cannula **1057** can be sufficiently engaged with the surrounding tissue to avoid having the tissue locate within the hollow inside of the cannula **1057**. A non-limiting embodiment of the cannula **1057** provides a tubular body having substantially parallel opposed side walls which terminate in a radius at both ends (lozenge shape) into which a plurality of different jigs can be inserted. Alternatively, as a non-limiting example, according to particular embodiments, cannula **1057** and corresponding dilators **1058** and alignment jigs **1060** can be configured to have tubular bodies with an elliptical or circular cross section.

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

At this stage, additional tools and methods may be employed to provide access to the sacroiliac joint **1000** as described in U.S. patent application Ser. No. 13/475,695 filed May 18, 2012 entitled "SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT", Ser. No. 14/514,221 filed Oct. 15, 2015 entitled "SYSTEMS FOR AND METHODS OF PREPARING A SACROILIAC JOINT FOR FUSION," and Ser. No. 16/133,605, filed Sep. 17, 2018, entitled "SYSTEMS FOR AND METHODS OF PREPARING AND FUSING A SACROILIAC JOINT", all of which are hereby incorporated by reference in their entireties. For example, drill jigs may be further advanced over the probe body **1054** to align a drill or other joint preparation tool. Accordingly, the discussion will now focus on employing the tools and devices described in previous sections of this application.

In certain embodiments of the method, an amount of articular cartilage or other tissues from between the articular surfaces of the sacroiliac joint **1000** can be removed sufficient to allow embodiments of the sacroiliac joint implant to be implanted in replacement of the removed articular cartilage or tissue. Because the method removes the degenerative articular cartilage or tissue between the articular surfaces of the sacroiliac joint **1000**, the articular surfaces of the sacroiliac joint **1000** can remain intact or substantially intact allowing the sacroiliac joint implant to be non-transversely located between the articular surfaces of the sacroiliac joint **1000**.

Understandably, other instruments can be utilized separately or in combination during the course of any of the steps of the methodology, e.g., for the removal of articular cartilage or tissue between articular surfaces, such as any of the tools previously described or any of: endoscopy tools, box chisels, side cutting router bits, burs, flexible burs and bits, hole saws, key hole saw, medical bone chainsaw osteotome, curettes, lasers (e.g., CO2, Neodymium/Y AG (yttrium-aluminum-garnet), argon, and ruby), electrosurgical equipment employing electromagnetic energy (the cutting electrode can be a fine micro-needle, a lancet, a knife, a wire or band loop, a snare, an energized scalpel, or the like) where the energy transmitted can be either monopolar or bipolar and operate with high frequency currents, for example, in the range of about 300 kHz and about 1000 kHz whether as pure sinusoidal current waveform where the "crest factor" can be constant at about 1.4 for every sinus waveform, and a voltage peak of approximately 300 V to enable a "pure" cutting effect with the smallest possible coagulation effect or as amplitude modulated current waveforms where the crest factor varies between 1.5 and 8, with decreasing crest factors providing less of a coagulation effect. Electrosurgical waveforms may be set to promote two types of tissue effects, namely coagulation (temperature rises within cells, which then dehydrate and shrink) or cut (heating of cellular water occurs so rapidly that cells burst). The proportion of cells coagulated to those cut can be varied, resulting in a "blended" or "mixed" effect. Additionally, a fully rectified current, or a partially rectified current, or a fulguration current where a greater amount or lateral heat is produced can be employed to find the articular surfaces of the joint and aid in advancing a probe or guide wire into a position in between the articulating surfaces. These currents can effectively degrade the cartilage and allow advance into the joint without grossly penetrating much beyond the cartilage.

III. Tools, Systems, and Methods for Diagnosing and Treating the Sacroiliac Joint

The following discussion will focus on various tools, systems, and methods of diagnosing and treating a sacroiliac joint ailment or disorder. The tools, systems, and methods may be useful in determining if fusion of the sacroiliac joint may be beneficial to a patient by, for example, alleviating pain. The tools and systems may be used to isolate the bones in the pelvic region such that manipulation of the bones (e.g., sacrum, ilium) can more easily, accurately, and efficiently diagnose the sacroiliac joint as a source of pain and discomfort. Upon diagnosing the sacroiliac joint as a source of pain and fusion as a possible solution, the joint may be temporarily or permanently fixated. The following discussion will focus on the tools, systems and methods of diagnosing and treating a sacroiliac joint disorder or ailment.

A. Diagnostic Pins, Rods, or Bars

FIGS. **7A-7F** illustrate diagnostic pins, rods, or bars **50** for use in diagnosing an ailment of a sacroiliac joint of a patient. The diagnostic pins **50** may be manipulated to cause movement of the sacrum and/or ilium, which may reproduce the pain in the patient or alleviate the pain in the patient (e.g., may realign the sacroiliac joint). In either scenario and depending on the particular manipulation, reproducing or alleviating the pain may suggest a need for fusing the joint via, for example, an implant. If the movement induced in the joint does not reproduce the pain in the patient, the diagnostics may suggest that the pain may come from areas other than the sacroiliac joint, such that fusion of the sacroiliac joint may not help to reduce the patient's pain. For these reasons, among others, the diagnostic method described herein may eliminate unnecessary implantation and trauma to the sacroiliac joint.

The diagnostic pins **50** may be caused to rotate or translate, which may cause movement of the sacrum and ilium about the joint. For example, one pin **50** may be placed in the sacrum while the other pin **50** may be placed in the ilium. The movement of the sacrum and ilium may vary depending upon the locations of the diagnostic pins or bars **50** and direction of the force. If the pin **50** is positioned on (or in) the caudal region of the sacrum and pushed anteriorly, the cephalad portion sacrum may rotate toward the posterior direction. If the pin is placed near the first sacral body (i.e., a cephalad portion of the sacrum) and a force is directed anteriorly, the cephalad portion of the sacrum may rotate toward the posterior direction. One pin may be placed in the ilium near the intra-articular region or extra-articular region of the joint.

Referring to FIGS. **7A-7D**, which are respective isometric, front, back, and side views of the pin **50**, the pin **50** may include an elongated body **52** extending between a distal end **54** and a proximal end **56**. In some embodiments, the distal end **54** may be tapered and include threads **60** that terminate at a point **58** such that the pin **50** may be rotationally driven into the bone. In certain embodiments, the threads **60** may be self-tapping threads. The distal end **54** may have a smaller cross-section than the proximal end **56**. It will be appreciated by those skilled in the art that the cross-section of pins or bars **50** may be generally circular, oval, square, rectangular or triangular in shape.

As seen in the figures, the elongated body **52** includes longitudinally extending and radially projecting ridges **62** that extend from the proximal end **56** to the threads **60** near the distal end **54** of the pins **50**. The ridges **60** provide grip for the pins **50** when grasped by a medical professional or a mechanical device. Alternatively, the pins may be configured with a high-friction surface.

As one non-limiting example, the elongate body **52** may have a diameter of in the range of about 3 millimeters ("mm") to about 8 mm (e.g., 6 mm) and a length disposed between the proximal and distal ends **56**, **54** in the range of about 2 centimeters ("cm") and about 20 cm. Pin length measurements may be marked along the length of the pin **50**.

The pin **50** proximal end **56** may have a tool interface configured to permit, e.g., a handle or other tool to couple to the elongate body **52**.

As to particular embodiments of the pin **50**, the elongate body **52** can further include a cannulation which communicates between the distal end **54** and the proximal end **56**. The cannulation allows for placement within the cannulation a guide pin (or other guide member) about which embodiments of the pins **50** can be guided for insertion and placement in the bones of the sacrum **1004** or ilium **1005**, or allow injection of analgesics.

Reference is made to FIG. **7**E, which is an isometric view of a pin guidance tool **520** for guiding the placement of the pins **50** within the sacrum and ilium, respectively. The tool **520** includes a guidance head **522** with three cylindrical openings **524** on a left side **526** of the head **522** and three cylindrical openings **524** on a right side **528** of the head **522**. The tool **520** further includes a handle **530** coupled and extending from the guidance head **522**. The tool **520** is configured to guide one or more pins **50** within the openings **524** into the sacrum or ilium. When used to guide multiple pins **50**, the pins will be delivered parallel to each other and with a predetermined amount of space or distance between the placements. For example, a first pin may be guided along trajectory TR**1** into the sacrum and a second pin may be guided along another trajectory TR**2** into the ilium. The doctor or medical professional can be assured that the pins are parallel to each other and spaced apart a certain, known, distance. While this example and the figure shows the trajectories TR**1**, TR**2** utilizing the most inner openings **524**, the tool **520** may be used with other combinations of openings **524** without limitation.

Referring to FIG. **8**A, which is an isometric view of another embodiment of the pin **50**, the pin **50** may include a similar proximal end **56** and elongated body **52** with ridges **62** that was previously described in reference to FIGS. **7**A-**7**D. The pin **50** of FIG. **8**A may, however, include a blunt distal end **64** instead of a threaded **60** distal end **54** that terminates at a point **58**. The blunt distal end **64** may include, for example, a planar distal surface **66** that may conform to the surface features of the bone or may simply be configured to not penetrate or minimally penetrate into the boney surfaces of the sacrum or ilium upon contact. The planar distal surface **66** may include surface features such as ridges or points that are configured to grip the bone surfaces upon contact. For example, as seen in FIG. **8**B, the planar distal surface **66** may include a threaded distal end **54** that extends through the planar distal surface **66** and distally terminates at a point **58**. Other variations to the pin **50** are contemplated herein and may include any type and kind of blunt distal end that is not designed to extend into the patient's bone upon application of a force. Alternatively, the distal end **64** may include surface contours that match the bones of the ilium and sacrum so as to provide a mating surface with which to apply force against.

With the blunt distal end **64**, the medical professional may position the pin **50** in various orientations and on various boney landmarks to manipulate the sacrum and ilium without boring multiple holes into the patient's bone. Thus, the medical professional can attempt multiple different kinds and styles of manipulation prior to or instead of boring holes into the patient's bone.

Another embodiment of the pin **50** is shown in FIG. **9**. As seen in the figure, the pin **50** includes a planar, plate member **64** at the distal end **54** with a pair of openings **66** extending transversely or across the plate member **64**. The pin **50** may be used in conjunction with an anchor guide **68** that may guide anchors **70**, such as bone screws, into the openings **66** of the plate member **64** when a sleeve **72** of the anchor guide **68** extends over the elongated body **52** of the pin **50**. The anchor guide **68** may further include an extension member **74** extending from the sleeve **72** to a pair of guides **76** that are configured to align a trajectory TJ of the anchors **70** across the plate member **64** and into the openings **66** when the sleeve **72** is positioned on the elongated body **52**. A shaft of a delivery tool (not shown) may be guided by the guides **76** to deliver the anchors **70** into the openings **66**.

The pin **50** and anchor guide **68** shown in FIG. **9** may be delivered into a patient's pelvic region and positioned such that the plate member **64** lies generally parallel with a posterior lateral surface of the ilium, for example. The openings **66** of the plate member **64** may be oriented on the ilium such that a trajectory of the anchors **70** is across either the intra-articular region or the extra-articular region of the sacroiliac joint and into the sacrum. Once positioned adjacent the ilium, the anchors **70** may be delivered via the anchor guide **68** into the openings **66** and into the ilium. At this point, the pin **50** may be manually manipulated by a medical professional with his or her hands or with the aid of a diagnostic tool that grasps the pin **50**. The pin **50** may, for example, facilitate nutation and counternutation of the ilium and sacrum, flexing and compression of the joint, or other manipulations of the bones and joint.

Upon determining that the joint requires fusion, the anchors **70** may be threadably released from the ilium and the pin **50** may be removed from the patient's pelvic region. If fusion by the anchors **70** is suitable for the particular patient and the ailment, the anchors **70** may be re-inserted into the ilium and further advanced across the sacroiliac joint and into the sacrum.

The plate member **64** may include a releasable feature (not shown) that releases the anchors **70** from being positioned within the openings **66** such that the anchors **70** do not need to be threadably released from the ilium prior to re-inserting them back into the ilium and, then, across the joint and into the sacrum. The releasable feature may be that the plate member **64** includes two longitudinally extending members that come together at the openings **66** in a scissor-like fashion. In a deployed state, the plate member **64** may close such that the member **64** appears as shown in FIG. **9**. In a non-deployed state, the plate member **64** may open in the scissor-like fashion such that two longitudinally extending members separate and, thus, the pin **50** and the plate member **64** may be retracted from the anchors **70** without removing the anchors **70** from the bone.

While the pin **50** in FIG. **9** is shown as having a plate member **64** at a distal end **54** of the pin **50**, the pin **50** may be differently configured. For example, the pin **50** may be as described with reference to FIGS. **7**A-**7**D and further include one or more openings **66** extending through a distal end **54** of the pin **50**. That is, the openings **66** would extend through a cylindrical portion of the pin **50**, either through the tapered threaded portion or the elongated body portion having the ridges **62**.

Alternatively, the plate may be releasably coupled to the pin **50** and left in place after the diagnostic procedure.

The pins **50** may be used individually, in pairs, or in other combinations. The following discussion will focus on the placement of the previously described pins **50** in the sacrum and ilium. Then, there will be a discussion of manipulating the pins to diagnose an ailment of the joint.

B. Positioning and Delivery of the Pins in the Sacrum and Ilium

Reference is now made to FIGS. **10**A-**10**E, which show multiple views of positioning and delivery the pins into the sacrum and ilium.

In certain instances, such as when the pins **50** may be used to guide a temporary implant into the extra-articular region **3007**, it may be beneficial to deliver the pins **50** into the sacrum and ilium in regions of the respective bone that are medial or lateral (i.e., immediately adjacent) of the extra-articular region **3007** of the sacroiliac joint. That is, the pins may be delivered into the sacrum and ilium superior of the intra-articular region **1044**. In other instances and possibly depending on the configuration of the temporary implant, it may be beneficial to deliver the pins **50** into the sacrum and ilium in regions of the bone that are immediately adjacent the intra-articular region **1044**. The ilium is generally harder in the region of the intra-articular region, so there may be advantages in certain instances to delivering the pins **50** in this region.

To begin, reference is made to FIG. **10**A, which is a posterior view of the hip region **1002** of the patient **1001** with a pin **50** in each of the sacrum **1004** and the ilium **1005**. As seen in the figure, the pin **50** may be posteriorly delivered into a patient **1001** with a generally anterior trajectory. In doing so, the pin **50** may extend through the soft tissue **1003** of the patient **1001** and extend into the hip region **1002** via tissue penetration in a superior region of the patient's buttock. The pin **50** in the ilium may be oriented immediately lateral of the posterior inferior access region of the extra-articular region **3007** of the joint **1000**. The pin **50** in the sacrum may be oriented inferior and lateral of the superior articular facet and lateral of the median sacral crest.

Turning to FIG. **10**B, which is a lateral side view of the hip region **1002** with a nearest ilium removed from view to more clearly see the intra-articular region **1044** and the extra-articular region **3077**, the pin **50** may be delivered into the sacrum **1004** or ilium **1005** immediately adjacent the posterior inferior access region **3090** of the extra-articular region of the joint **1000**. As seen in the figure, the pin may include a trajectory TJ**1** within a range of degrees AJ while still penetrating the bone immediately adjacent the posterior inferior access region **3090**. In certain embodiments, the range of degrees AJ may be 20 degrees, 30 degrees, 50 degrees, or 60 degrees, among others.

As seen in FIG. **10**C, which is a cross-sectional view, generally in a coronal plane, of the extra-articular region **3007** and the intra-articular region **1044** of the sacroiliac joint, one pin **50** is positioned in the ilium **1005** immediately adjacent the extra-articular region **3007** and one pin **50** is positioned in the sacrum **1004** immediately adjacent the intra-articular region **1044**. The pin **50** in the sacrum **1004** may also be positioned superiorly such that it would be parallel with the pin **50** in the ilium **1005** and a line connecting the pins would be generally perpendicular to a plane of the sacroiliac joint **1000**. Additionally, the pin **50** in the ilium **1005** may also be positioned inferiorly such that it would be parallel with the pin **50** in the sacrum **1004** and a line connecting the pins would be generally perpendicular to a plane of the sacroiliac joint **1000**.

Reference is now made to FIG. **10**D, which is a transverse cross-section of the sacrum **1004** and ilium **1005** viewed superiorly showing a pin **50** positioned in the sacrum **1004**. As seen in the figure, the longitudinal axis LCA**2** of the elongate body **52** of the pin **50** may be generally parallel to the joint line **1030** of the sacroiliac joint **1000**. In this embodiment, the longitudinal axis LCA**2** may be offset from the joint line **1030** by a distance at a proximal portion of the joint DP-SIJ. In certain embodiments, the distance DP-SIJ may be about 0.5 centimeter ("cm"), 1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm, 5 cm, or 6 cm, among others. And the distance DP-SIJ may be within a range of about 0.5 cm to about 6 cm. In this embodiment, the longitudinal axis LCA**2** may be offset from the joint line **1030** by a distance at a distal portion of the joint DD-SIJ. In certain embodiments, the distance DD-SIJ may be about 0.5 centimeter ("cm"), 1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm, 5 cm, or 6 cm, among others. And the distance DD-SIJ may be within a range of about 0.5 cm to about 6 cm.

Alternatively and as seen in the dashed line pin **50**, the longitudinal axis LCA**2** of the elongate body **52** of the pin **50** may be generally offset to the joint line **1030** of the sacroiliac joint **1000** by a certain degree OA. The certain degree may be between about 5 degrees and about 50 degrees, in certain embodiments. In other embodiments the certain degree may be about 5 degrees, 10 degrees, 15 degrees, 20 degrees, 25 degrees, 30 degrees, 35 degrees, 40 degrees, 45 degrees, or 50 degrees, among others and may include being directed medially (as shown in the figures) or laterally (while not crossing the sacroiliac joint).

As another alternative of an angled placement of the pin **50** relative to the joint line **1030**, as seen in FIG. **10**E, which is the same view of the sacrum **1004** and ilium **1005** as in FIG. **10**C, the pin **50** in dashed line may penetrate the sacrum **1004** such that the longitudinal axis LCA**2** of the elongate body **52** extends a greater angle relative to the pin **50** that is positioned parallel to the joint line **1030**.

Although not shown in FIGS. **10**D and **10**E, the pin **50** in the ilium may be parallel to the joint line, directed laterally or even medially, or generally parallel to an ilium outer cortex.

As an example of possible pin placements in the pelvic region, a first pin having a tapered and threaded distal end may be posteriorly delivered into the ilium just lateral of the extra-articular region of the sacroiliac joint (i.e., an upper or superior region defined between the posterior inferior iliac spine **2006** and the posterior superior iliac spine **2004**, as seen in FIG. **10**A). A second pin having a tapered and threaded distal end may be posteriorly delivered into the sacrum, between the lateral sacral crest (**1007** in FIG. **10**A) and the joint line of the joint.

As another possible example of pin placements in the pelvic region, a first pin having a tapered and threaded distal end may be posteriorly delivered into the ilium just lateral of the intra-articular region of the sacroiliac joint (i.e., a lower or inferior region defined between the posterior inferior iliac spine **2006** and the posterior superior iliac spine **2004**, as seen in FIG. **10**A). A second pin having a tapered and threaded distal end may be posteriorly delivered into the sacrum, between the lateral sacral crest (**1007** in FIG. **10**A) and the median sacral crest (**1009** in FIG. **10**A).

As another possible example of pin placements in the pelvic region, a first pin having a tapered and threaded distal end may be posteriorly delivered into the ilium just lateral of the intra-articular region of the sacroiliac joint (i.e., a lower or inferior region defined between the posterior inferior iliac spine **2006** and the posterior superior iliac spine **2004**, as seen in FIG. **10**A). A second pin having a blunt distal end may be posteriorly positioned against the sacrum, between the lateral sacral crest (**1007** in FIG. **10**A) and the posterior sacral foramina (**1011** in FIG. **10**A). Or, the second pin may be positioned against the lateral sacral crest.

As another possible example of pin placements in the pelvic region, as seen in FIG. **10**F, which is a posterior view of the hip region **1002** of the patient **1001**, a first pin **50** having a tapered and threaded distal end may be posteriorly delivered into a right side ilium **1005**R just lateral of the extra-articular region of the sacroiliac joint (i.e., an upper or superior region defined between the posterior inferior iliac spine **2006** and the posterior superior iliac spine **2004**, as seen in FIG. **10**A). A second pin **50** having a tapered and threaded distal end may be posteriorly delivered into a left side ilium **1005**L just lateral of the extra-articular region of the sacroiliac joint (i.e., an upper or superior region defined between the posterior inferior iliac spine **2006** and the posterior superior iliac spine **2004**, as seen in FIG. **10**A). In this example, the two pins **50** are delivered into opposite iliums **1005**R, **1005**L. Thus, the joints may be manipulated without delivering a pin **50** into the sacrum **1004**. Since the sacrum **1004** is a softer bone than the ilium **1005**R, **1005**L, this example of pin **50** placement may be useful in certain patients with an especially soft or brittle sacrum **1004**.

Reference is now made to FIG. **10**G, which is a posterior view of a pelvic region of a patient with a distractor **500** positioned between a pair of pins **50** positioned in opposing iliums **1005**L, **1005**R. As seen in the figure, the pins **50** may include anchors **502** extending through a plate member **504** at a distal end of the pins **50**. The pins **50** may be positioned such that the anchors **502** extend through openings in the plate member **504** and extend into an inner cortex of the ilium near the posterior superior iliac spine **2004**. The pins **50** may couple with an extension rod **508** spanning the sacrum **1004** via adjustable couplers **510** that may be variably fixed on the length of the pins **50**. The extension rod **508** may be a cylindrical rod having a spring **512** engaged with a thumb-wheel **506** that may be movably adjusted along the extension n rod **508**. The spring **512** may bias the thumb-wheel **506** to the right. One of the couplers **510** (on right ilium **1005**R) may slidably couple the extension rod **508** and the pin **50** such that as the distractor **500** is positioned between the coupler **510** on the right and the thumb-wheel **506**, outward distraction of the arms of the distractor **500** causes a distance between the thumb-wheel **506** and the coupler **510** on the right to increase so as to also increase a distance between the pins **50** (i.e., and the opposing ilium).

As opposed to distracting the joints via pins **50** positioned in the ilium **1005**, the pins **50** may be used to compress the joint. As seen in FIG. **10**H, which is a posterior view of a pelvic region of a patient with a pair of pins **50** positioned in opposing ilium **1005**R, **1005**L, the sacroiliac joint may be compressed with similar tools and methods as described with reference to FIG. **10**G, except the pins **50** may be positioned against the outer cortex of the ilium **1005**R, **1005**L or against both the inner and outer cortex ("sandwich PSIS"). As seen in FIG. **10**H, the pins **50** are similar to those described in reference to FIG. **10**G. That is, the pins **50** include the plate member **504** at a distal end and are secured to the ilium via anchors **502** extending through openings in the plate member **504** and into the bone. As seen in the figure, the anchors **502** extend into the ilium on the outer cortex. A device for compressing the joint is not shown in this figure, but may be similar to that shown in FIG. **10**G, except the tool may be configured to compress the joint, as opposed to distract the joint.

While not depicted in the figures, the system and methods described in reference to FIGS. **10**G-**10**H can be combined to sandwich the posterior superior iliac spine **2004** and provide for distraction or compression, as desired for the particular diagnosis.

Reference is now made to FIG. **10**I, which is a posterior view of the lumbar spine showing pins **50** to either stabilize or selectively allow motion between segments L**4**, L**5** of the spine. As seen in the figure, pins **50** or anchors may be delivered into the spinal segments at, for example, the pedicles **540**, which are medial of the transverse process **544**. Further, an extension member **542** may be coupled with the pins **50** via a coupler (not shown) to link the segments of the spine. In this way, upon manipulation of the patient's sacrum and ilium, the segments of the spine will be linked to either: stabilize the segments of the spine; or allow relative motion between certain segments of the spine. In stabilizing the spine, the pins **50** and extension members **542** may be rigidly coupled via the couplers such forces transferred via manipulation of the sacroiliac joint are not concentrated on any one spinal segment. Rather, the forces are distributed in order to further isolate the movements of the sacrum and ilium, respectively, for diagnosing purposes. Alternatively, certain segments of the spine may be allowed certain movements relative to each other.

As seen with the most inferiorly placed pin **50**, the pin **50** and extension member **542** construct may link with the a pin positioned in the ilium (not shown) for further manipulation of the sacroiliac joint.

C. Using the Pins to Mobilize the Sacroiliac Joint for Diagnostic Purposes

The sacroiliac joint or, more particularly, the sacrum and the ilium may be difficult to manipulate because of the vast array of ligaments surrounding the sacrum and ilium. Additionally, the joint may be difficult to diagnose as a source of pain since manual manipulating the joint may cause movement and pain or discomfort in other areas of the body.

With the diagnostic system described herein, the movements of the ilium and sacrum may be isolated from movement of other parts of the body (e.g., the spinal column) to provide for a more accurate diagnosis of a sacroiliac joint ailment. Additionally, the present disclosure provides a diagnostic system that may be effective in mobilizing the joint to determine if pain can be activated or alleviated, depending on the joint condition. The diagnostic system may include the use of the pins, previously described. The diagnostic system may also include one or more mechanical assemblies that assist in the movements of the pins or bars, including translational movements, rotational movements or combination of translational and rotational movements. The rotation of the diagnostic system may be controlled or limited to within a few degrees. The translational displacement or linear movement of the diagnostic system may be limited to within a few millimeters.

In some embodiments, the pins or bars described above may be inserted into the bones to cause the movement of the sacroiliac joint. In some embodiments, the pins may include a blunt distal end that is not inserted into the bones, but, rather, is pushed against the bones to cause the movement. In some embodiments, the screws may be used to cause the movement of the joint. In some embodiments, a combination of pins or screws may be used to cause the movement of the joint.

In some embodiments, opposing portions of a right and left ilium may be pushed or pulled against each other such that the joint is under tension or compression or rotation.

In some embodiments, the diagnostic system may also be used to cause movement of the sacroiliac joint to return to its natural position to release the pain of the patient.

Reference is made to FIGS. **11-12**D, which depict lateral side views of a hip region **1002** of a patient **1001** with a pin **50** positioned lateral of the lateral sacral crest **1007** of the sacrum **1004** and another pin **50** positioned in the ilium **1005** just lateral of and in an upper region of the iliac spine between the posterior superior iliac spine **2004** and the posterior inferior iliac spine **2006**. FIG. **11** depicts a neutral position of the pins **50**, just after delivery into the sacrum **1004** and ilium **1005** and before any manipulation has taken place. In this particular embodiment, the pins **50** are delivered parallel to each other, although the pin **50** in the sacrum **1004** is positioned slightly inferior to the pin **50** in the ilium. In this neutral position, the pins **50** may be manipulated in a variety of ways to determine if the patient's pain can be alleviated or reproduced.

As an example of how manipulation of the pins may alleviate pain while indicating that fusion of the joint may be helpful in reducing pain, a patient may have a compressed joint that is causing pain during normal activities (e.g., standing, walking). Upon inserting the pins into the patient's bones, the neutral position may be the compressed state of the joint. Thereby, when the doctor applies a force (e.g., distractive force) to relieve the compressive force on the joint, the pain may be alleviated. In that case, fusing the joint may alleviate the compression on the joint and, thus, alleviate the patient's pain.

As an example of how manipulation of the pins may reproduce a patient's pain while indicating that fusion of the joint may be helpful in reducing pain long term, the patient may only experience pain the in joint upon certain movements (e.g., flexing at the hips, decubital, prone, and standing positions). Upon inserting the pins into the patient's bones with the patient lying prone on an examining table, for example, the patient may not experience a significant amount of pain. When the doctor manipulates the joint, however, the doctor may be able to manipulate the joint in such a way that causes the same pain in the patient that is experienced upon doing those certain movements (e.g., flexing at the hips, decubital, prone, and standing positions). Thus, the doctor was able to manipulate the joint in order to reproduce the pain and diagnose that a fusion procedure may be helpful in alleviating the patient's pain.

Turning again to FIG. **11**, in the neutral state, the joint has not yet been manipulated by the doctor or medical professional. Upon manipulation of the sacrum or ilium, the joint will have a tendency to revert back to or spring back to the neutral state.

From the neutral state, the joint may be manipulated in a number of ways to either reproduce the patient's pain or alleviate the patient's pain. As seen in FIG. **12**A, which is the same view as FIG. **11**, except the ilium **1005** is caused to move or translate anteriorly, a force F**1** is applied to the pin **50** in the ilium **1005**. The force F**1** could be applied by the medical professional with his or her hands or with the aid of a diagnostic tool. Alternatively, the force F**1** could be applied via a surgical robot. In order to isolate the force F**1** to the pin **50** in the ilium **1005**, a stabilizing or holding force S**1**, acting counter to the force F**1**, may be exerted on the pin **50** in the sacrum **1004**. The stabilizing force S**1** need not be actively pulled posteriorly, but be held at a constant force so as to isolate the movement of the ilium **1005** with respect to the sacrum **1004** and the rest of the upper body (e.g., spine). In certain instances, translating or moving the ilium anteriorly from the neutral state may reproduce or alleviate a patient's pain and indicate to the medical professional that fusion of the joint may be helpful in alleviating or lowering the patient's pain long-term.

In certain instances, for example, the ilium **1005** may have been posteriorly jammed or knocked out of a natural alignment. Thus, moving the ilium **1005** anteriorly may reduce the patient's pain as such movement would restore the natural alignment.

The force F**1** may be applied in the opposite, posterior direction, as well and as similarly described with reference to applying the force F**1** in an anterior direction. Applying the force F**1** in a posterior direction by pulling on the pin **50** in the ilium **1005** may be helpful in reducing or reproducing pain in the joint.

Turning to FIG. **12**B, which is the same view as FIG. **11**, except the ilium **1005** is caused to move or translate in a cranial direction, a force F**2** is applied to the pin **50** in the ilium **1005**. The force F**2** could be applied by the medical professional with his or her hands or with the aid of a diagnostic tool. Alternatively, the force F**2** could be applied via a surgical robot. In order to isolate the force F**2** to the pin **50** in the ilium **1005**, a stabilizing or holding force S**2**, acting counter to the force F**2**, may be exerted on the pin **50** in the sacrum **1004**. The stabilizing force S**2** need not be actively pulled in a caudal direction, but be held at a constant force so as to isolate the movement of the ilium **1005** with respect to the sacrum **1004** and the rest of the upper body (e.g., spine). In certain instances, translating or moving the ilium **1005** in a cranial direction from the neutral state may reproduce or alleviate a patient's pain and indicate to the medical professional that fusion of the joint may be helpful in alleviating or lowering the patient's pain long-term.

In certain instances, for example, the ilium **1005** may have been jammed in a caudal direction so as to be out of a natural alignment. Thus, moving the ilium **1005** in a cranial direction may reduce the patient's pain as such movement would restore the natural alignment.

The force F**2** may be applied in the opposite, caudal direction, as well and as similarly described with reference to applying the force F**2** in the cranial direction. Applying the force F**2** in a caudal direction by pushing on the pin **50** in the ilium **1005** may be helpful in reducing or reproducing pain in the joint.

The pins **50** may be moved or translated apart while keeping them parallel by, for example, using a tool that grasps the pins at multiple points along the elongated body **52**. That is, the multiple contact points on each arm of the tool would counteract the bending moment caused by the joint resisting the movement.

Referring now to FIGS. **12**C-**12**D, the ilium **1005** may be pivoted or rotated relative to sacrum **1004** via the pins **50** placed in the ilium **1005** and sacrum **1004**. As seen in FIG. **12**C, which is the same view as FIG. **11**, except the ilium **1005** is caused to pivot or rotate in a posterior direction (i.e., nutation of sacrum **1004**), a force F**3** is applied to the pin **50** in the ilium **1005**. The force F**3** could be applied by the medical professional with his or her hands or with the aid of a diagnostic tool. Alternatively, the force F**3** could be applied via a surgical robot. In order to isolate the force F**3** to the pin **50** in the ilium **1005**, a stabilizing or holding force S**3**, acting counter to the force F**3**, may be exerted on the pin **50** in the sacrum **1004**. The stabilizing force S**3** need not be actively pulled or pushed in a cranial direction, but be held at a constant force so as to isolate the movement of the ilium **1005** with respect to the sacrum **1004** and the rest of the upper body (e.g., spine). In certain instances, pivoting or rotating the ilium **1005** in a posterior direction from the neutral state may reproduce or alleviate a patient's pain and indicate to the medical professional that fusion of the joint may be helpful in alleviating or lowering the patient's pain long-term.

In certain instances, for example, the ilium **1005** may have been jammed or damaged so as to be out of a natural alignment. Pivoting or rotating the ilium **1005** in a posterior direction may reduce the patient's pain as such movement would restore the natural alignment.

The force F**3** may be applied in the opposite, anterior direction (i.e., counternutation of sacrum **1004**), as seen in FIG. **12**D, as similarly described with reference to applying the force F**3** so as to rotate the joint in a posterior direction. Applying the force F**3** in an anterior direction by pushing on the pin **50** in the ilium **1005** may be helpful in reducing or reproducing pain in the joint.

The particular manipulations of the joint via the pins **50** described above in reference to FIGS. **11-12**D are merely exemplary of pin placements in the sacrum **1004** and ilium **1005** and are merely exemplary of possible manipulations to the joint. Other pin placements and manipulations are possible and contemplated herein. As seen in FIG. **13**A, which is the same view as FIG. **11**, except multiple possible pin placement locations are depicted, the pins **50** may be placed in a number of locations on the sacrum **1004** and ilium **1005** to manipulate the joint. As seen in the figure and referring first to the ilium **1005**, a pin **50**A may be positioned near the posterior superior iliac spine **2004**, a pin **50**B may be positioned prominently in the wing of the ilium (gluteal surface), or a pin **50**C may be positioned near the posterior inferior iliac spine **2006**, among other possible placements of the pin **50**.

Referring to placements of the pin **50** in the sacrum **1004**, a pin **50**D may be positioned near a superior region of the lateral sacral crest **1007** near the sacral tuberosity, a pin **50**E may be positioned near a middle region of the lateral sacral crest **1007**, or a pin **50**F may be positioned near an inferior region of the lateral sacral crest **1007**. It is noted that in regions of the sacrum **1004** with softer and/or thinner bone, it may be advantageous to use a pin **50** with a blunt distal end.

It is noted that the manipulations of the joint described in reference to FIGS. **11-12**D may be accomplished using any of the previously described pins **50** in FIGS. **7-9**.

D. Using the Pins to Stabilize the Sacroiliac Joint

Upon diagnosing the sacroiliac joint as a source of pain and determining that fusing the joint may be helpful in alleviating the pain, the doctor has a number of choices for the fusion procedure. A temporary or permanent implant may be implanted into the joint with or without the use of the pins as a guide. Another approach is to use the pins or a portion thereof as a temporary implant to assist in determining if the implant helps release the pain of the patient.

In some embodiments, the pins or merely a distal portion of the pins may be mechanically coupled together by a mechanical assembly to help stabilize the joint. The pins may be short enough such that they are less disturbing to the patient's activities, as the pins are not used for causing movements of the joint. The patient may monitor his or her reaction to pain with the temporary pins or implants. When the patient's pain is reduced, this may suggest that the joint movement may be a root cause for the pain and stabilization of the joint by using an implant may help to permanently reduce the pain.

Reference is made to FIG. **13**B, which is a lateral view of the hip region **1002** of the patient **1001** with a distal portion **78** of the pins **50** coupled together with a coupling member **80**. The proximal portion (not shown) of the pins **50** may be releasable or detachable from the distal portion **78** of the pins **50** such that after manipulation of the joint with both the distal and proximal portions of the pins **50**, the proximal portions may be removed from the pins **50** leaving the distal portion **78** still implanted in the sacrum **1004** and ilium **1005**. The distal portion **78** may release from attachment with the proximal portion via a threaded connection or other mechanisms. The coupling member **80** may couple the distal portions **78** together close to the patient's bones so that the pins **50** do not extend out of the patient's skin.

Temporarily stabilizing the joint in this way allows for a determination if permanent stabilization is likely to be effective in reducing pain in the long-term. Since this method does not destroy or otherwise alter the capsule or cartilage of the sacroiliac joint, the distal portion **78** of the pins **50** and the coupling member **80** can be utilized and later removed without damage to the joint.

E. Diagnostic Tools Utilizing the Pins, Rods, or Bars

1. Diagnostic Tools and Systems for Causing and Controlling Translational Movement

A diagnostic system may include a first elongated member and a second elongated member extending along a longitudinal axis. The elongate members may be the pins or bars, described previously. Each of the members has a distal end that can be delivered into the sacrum and the ilium via a posterior approach, as described above. The diagnostic system may also include a mechanical coupling assembly coupled between the elongated members. The mechanical coupling assembly may be configured to allow one of the elongated members to translate or rotate relative to the other elongated member, such that forces and directions of the forces applied by the elongated members to the sacrum and the ilium can be manipulated to determine a treatment plan.

The diagnostic system isolates manipulations of the sacrum and ilium such that a doctor can more accurately determine if the pain in a patient originates from the sacroiliac joint. If the joint causes the pain in the patient, the treatment plan or method may include inserting an implant into the joint to help temporarily stabilize the joint. The treatment plan or method may also include injecting a bio-based fusion material in the joint to aid in the fusion of the joint.

FIG. **14** is a front isometric view of a diagnostic system including a mechanical coupling assembly coupled between a pair of diagnostic pins in accordance with embodiments of the present disclosure. This diagnostic system can cause the diagnostic pins to move linearly within a plane defined by the pins by applying forces to the pins using the handles, as shown in FIGS. **12**A-**12**B. More particularly, the diagnostic system may be configured to move a pin linearly relative to the other pin, in a longitudinal direction of the pins. And, the diagnostic system may be configured to move a pin laterally away from the other pin while maintaining an orientation (e.g., parallel) with the other pin. The diagnostic system may control the forces of the pins and thus control the movement of the joint.

As shown in FIG. **14**, a diagnostic system **5002** may include a pair of elongated members or pins **50**, which were previously described with reference to FIGS. **7-9**. Each elongated member **50** may include a distal end **58** that can be inserted into the sacrum **1004** or ilium **1005** near the sacroiliac joint. Each elongated member **50** may also include a proximal end **56** where a mechanical coupling assembly **5004** may be coupled to the elongated member **50**. The elongated member **50** extends between the distal end **58** and the proximal end **56** along a longitudinal axis **5016**. The mechanical coupling assembly **5004** can be used to manipulate the translational movement of the elongated members **50** along the longitudinal axis **5016**. The mechanical coupling assembly **5004** may also be configured to align one elongated member **50** to be generally parallel to another elongated member **50**.

As shown in FIG. **14**, the mechanical coupling assembly **5004** may include a first coupling member **5006** positioned between the two elongated members **50**, a second coupling member **5008** that couples to the respective elongated member **50**, and a third coupling member **5010** that couples between the first coupling member **5006** and the respective second coupling member **5008**. The first coupling member **5006** may include a longitudinal slot **5012** that is elongated along the longitudinal axis **5016**. Each third coupling member **5010** may include an engagement element **5035**, as seen in FIG. **15**, which is configured to slidably engage with the slot **5012** of the first coupling member **5006**, such that the respective elongated member **50** may move up or down. In the example shown in FIG. **14**, the elongated member **50** on the right side may move up while the elongated member **50** on the left side may move down. The slot size may affect the translational displacement or movement of the elongated members **50**.

The third coupling members **5010** may include transverse slots **5013** that extend along a transverse axis that is perpendicular to the longitudinal axis **5016**, such that the third coupling member **5010** may be coupled to the second coupling members **5008**. The transverse slots **5013** in the third coupling members **5010** enable adjustment of the distance between the two elongated members **50**. The third coupling member **5010** may be fixedly attached to the second coupling member **5008** via a fastener **5020**. A washer **5018** may also be used between the fastener **5020** and the third coupling member **5010** to help tighten against the third coupling member **5010**. The fastener **5020** is attached to the elongated member **50** along a second transverse axis **5022**, which is generally perpendicular to the longitudinal axis **5016** and also generally perpendicular to the transverse axis **5014**.

The second coupling member **5008** may be fixedly attached to the elongated member **50** by a side screw **5024**, which may be generally parallel to the transverse slot **5013** of the third coupling member **5010** along the transverse axis **5014**. The second coupling member **5008** may include a hollow portion **5026** that is configured to allow the elongated member **50** to pass through to fixedly attach to the elongated member **50** by the side screw **5024**. The second coupling member **5008** may also include a side extension **5042** that may have a threaded end configured to be fastened to the fastener **5020**. The side extension **5042** may be perpendicular to the side screw **5024** for easily adjusting the third coupling member **5010** or the second coupling member **5008** independently without interference. The second coupling member **5008** may also include an opposite side extension **5042** that may be coupled to an extension bar **5032** extending away from the proximal end **56** of the elongated member **50** along the longitudinal axis **5016**. The extension bar **5032** may connect to a handle **5030** at an opposite end. The handle **5030** may be at an angle from the extension bar **5032** for easy manipulation by hand. The handle **5030** may vary in shape or geometry or size to be comfortable for user to grasp.

FIG. **15** is a back isometric view of the diagnostic system of FIG. **14**. As shown in this view, the engagement element **5035** extends beyond the slot **5012** toward sidewalls **5017** that surrounds the slot **5012**. The engagement element **5035** overlaps with portions of the sidewalls **5017** of the first coupling member **5006**. The engagement element **5035** may have a square shape, a circular shape, an oval shape, or a rectangular shape, among other shapes. This figure also illustrates that the extension bar **5032** has a coupling end portion or connector **5021** that includes a hollow portion **5023** that allows the side extension **5042** to pass through. A fastener **5020** including an inner threaded hole may be fastened to the side extension **5042**. The engagement element **5035** may move within the slot **5012** toward one or two ends walls **5019**. The end walls **5019** are connected between the sidewalls **5017** to surround the slot **5012**.

FIGS. **16A**-**16C** depict side views of the diagnostic system of FIG. **15** with the second coupling members **5008** on the right and left at different translational positions. As shown in the figures, the second coupling member **5008** on the right side is attached to the elongated member **50** at a lower position than the second coupling member **5008** on the left side.

FIG. **17** is a top view of the diagnostic system of FIG. **14**. As shown, the side screw **5024** is pressed against the elongated member **50** so as to fixedly attach the tool to the elongated member **50**. The second coupling member **5008** may have a hollow portion **5031** that is configured to conform to the elongated member **50** and to allow the side screw **5024** to extend into the hollow portion **5031** to tighten against the elongated member **50**. FIG. **18** is an enlarged view of the mechanical coupling assembly of FIG. **14**. The hollow portion may be generally oval shaped as shown, "pear" shaped or other shapes (not shown).

FIG. **19** is an isometric view of the first coupling member of the diagnostic system of FIG. **14**. As shown, the slot **5012** is enclosed by surrounding two opposing side walls **5017** along the longitudinal axis **5016** and two opposing end walls **5019** that connect between the two opposing side walls **5017**. In certain instances, the length of the slot **5012** may be configured to correspond to an amount of possible translational movement of the ilium relative to the sacrum. That is, the length of the slot **5012** may be limited so that a medical professional utilizing the tool will not injure the patient by forcing the ilium to move past a certain point relative to the sacrum. In certain instances, the length of the slot **5012** may be about 0.075 cm, 0.1 cm, 0.2 cm, 0.25 cm, 0.3 cm, 0.4 cm, 0.5 cm, 0.6 cm, 0.7 cm, 0.8 cm, 0.9 cm, or 1 cm. In certain instances, the length of the slot **5012** may be within a range of about 0.075 cm to about 1 cm.

FIG. **20**A is an isometric view from the side of the second coupling member **5008** of the diagnostic system of FIG. **14**. FIG. **20**B is another isometric view from the bottom of the second coupling member of the diagnostic system of FIG. **14**. FIG. **20**C is yet another isometric view from the top of the second coupling member of the diagnostic system in an alternative embodiment.

As shown in FIG. **20**A, the second coupling member **5008** may also include a non-threaded spacer **5037** between the main body **5040** and the threaded end **5038**. The non-threaded spacer **5037** may be configured to slide within the transverse slot **5013** of the third coupling member **5010**. In this particular embodiment, the non-threaded spacer **5037** has generally planar opposing surfaces that can slide within the slot of the third coupling member **5010**. The threaded end **5038** may include outer threads configured to be received in a matched fastener **5020**. According to other embodiments e.g., in FIGS. **26-30**B, the non-threaded spacer **5037** may be cylindrical.

As shown in FIG. **20**B, the second coupling member **5008** may include an inner threaded hole **5039** configured to receive the side screw **5024**. Although the main body **5040** includes an opening **5041** between two opposing end portions **5043** in this particular embodiment, a different embodiment may not have the opening **5041**. Instead, the opening may be solid side wall that connects the two end portions, as shown in FIG. **20**C.

FIG. **21** is an isometric view of the fastener **5020** of the diagnostic system of FIG. **14**. As shown, the fastener **5020** includes inner threaded hole **5051** that is configured to receive the threaded end **5038** of the side extension **5042** of the second coupling member **5008**. The fastener **5020** may also include a flange end portion **5053** that extends sideway from the main body **5055** of the fastener **5020**.

FIG. **22** is an isometric view of the washer of the diagnostic system of FIG. **14**. As shown in FIG. **22**, the washer **5018** may include a hollow portion **5057** that is shaped and sized to match to the spacer **5037** of the second coupling member **5008** as shown in FIG. **20**A. The hollow portion **5057** may have cross-section that is a square shape, among others. The washer **5018** may include an outer surface, which may be in a cylindrical shape.

FIG. **23** is an isometric view of the side screw **5024** of the diagnostic system of FIG. **14**. The side screw **5024** includes an end portion **5061** with outer threads and a non-threaded grasping portion **5063** that connects to the threaded end portion.

FIG. **24**A is an isometric view from the back of the third coupling member **5010** of the diagnostic system of FIG. **14**. As shown in FIGS. **24**A-**24**B, the third coupling member **5010** may include a generally planar main body connected to the engagement element **5035** at a first end. The planar main body includes two opposing side walls **5067** connected to two opposing end walls **5069**. The side walls **5067** and end walls **5069** are sandwiched between two generally planar opposing surfaces **5071**. The second end wall **5069** is at an opposing end to the first end wall **5069** near the engagement element **5035**. The planar main body also includes an elongated slot **5013** enclosed by the sidewalls **5067** and the end walls **5069**. The elongated slot **5013** allows adjustment of the distance between the two elongated members **50**. In certain instances, the length of the slot **5013** may be about 1 cm, 2 cm, 3 cm, 4 cm, 5 cm, 6 cm, 7 cm, 8 cm, 9 cm, 10 cm, 11 cm, 12 cm, 13 cm, 14 cm, or 15 cm. In certain instances, the length of the slot **5013** may be within a range of about 1 cm to about 15 cm.

The engagement element **5035** includes an extended portion that extends above one of the planar surfaces **5071** near the first end wall **5069** of the planar main body. The extended portion **5073** can fit within the slot **5012** of the first coupling member **5006**. The engagement element **5035** also includes an end flange portion **5075** extending sideway from the extended portion **5073**, such that the end flange portion can extend on sidewall of the first coupling member **5006** to hold the third coupling member **5010** within the slot **5012** of the first coupling member **5006**.

FIG. **25**A is an isometric view from the bottom of the connector **5021** at the end of the extension bar **5032** connected to the handle **5030** of the diagnostic system of FIG. **14**. FIG. **25**B is an isometric view from the top of the connector **5021** at the end of the extension bar **5032** connected to the handle **5030** of the diagnostic system of FIG. **14**. The handle **5030** is coupled to the second coupling member **5008**, and configured to ergonomically force the third coupling member **5010** to slide within the first coupling member **5006** to move one of the first or second members relative to the other of first or second member along the longitudinal axis **5016**.

As shown in FIGS. **25**A-**25**B, the handle **5030** is at one end of the extension bar **5032** and the connector **5021** is at an opposing end of the extension bar **5032**. The connector **5021** is configured to connect to the second coupling member **5008**. Specifically, the connector **5021** includes a first surface **5081** having a square shape opening **5085** and a second surface **5082** with a generally circular opening **5083**. The square shape opening **5085** is configured to fit to the spacer of the second coupling member **5008**. The circular opening **5083** is configured to be large enough to allow the fastener **5020** as shown in FIG. **21** to fasten against the threaded portion **5038** of the second coupling member **5008** as shown in FIG. **20**A. Again, the shapes of the opening may vary with the extension **5042** of the second coupling member **5008**.

The amount of movement of the ilium relative to the sacrum may depend on the particular ailment of the sacroiliac joint. When used to manipulate the sacroiliac joint, as shown in FIGS. **11**-**12**A, the ilium may have a small, moderate, or large amount of translational movement relative to the sacrum. In some embodiments, the translational movement may be less than 5 mm. In some embodiments, the translational movement may be less than 4 mm. In some embodiments, the translational movement may be less than 3 mm. In some embodiments, the translational movement may be less than 2 mm. In some embodiments, the translational movement may be less than 1 mm.

2. Diagnostic Tools and Systems for Causing and Controlling Translational and Rotational Movement

An alternative mechanical coupling assembly may be used to cause translational movement and/or rotational movement. The mechanical coupling assembly may include a pivot subassembly, which may be attached to one diagnostic pin and used to cause translational movement or rotational movement of another diagnostic pin.

FIG. **26** is an isometric view of a diagnostic system including a pivot type mechanical coupling assembly in accordance with embodiments of the present disclosure. As shown, a mechanical coupling assembly **5090** may include a first coupling component **5008** attached to a first elongated member **50**, such as a pin or bar described with reference to FIGS. **7**A-**9**, a handle **5030** coupled to the first coupling component **5008** attached to the first elongated member **50** by using a side screw **5024**, such as shown in FIG. **23**. The mechanical coupling assembly **5090** may also include a second coupling component **5008** attached to a second elongated member **50** by using the side screw **5024**, such as shown in FIG. **23**. The first and second coupling components **5008** may be similar to the second coupling member **5008** as shown in FIGS. **20**A-**20**C.

The mechanical coupling assembly **5090** may also include a pivot subassembly **5092**, which may include a handle bar **5094** with a free end **5101** and an opposite end **5103**, and a middle portion **5099** being pivotally attached to the first elongated member **50** and connected to the end **5103** of the handle bar **5094**. The middle portion **5099** is connected to an arm portion **5096**, which may be angled from the handle bar **5094**. The middle portion **5099** is a curved transition portion between the handle bar **5094** and an arm portion **5096**. The arm portion **5096** may extend from the transition portion and may be at an angle from the handle bar **5094**. This angle may vary for different pivot subassemblies. In some embodiments, the angle is less than 90°. In some embodiments, the angle is less than 80°. In some embodiments, the angle is less than 70°. In some embodiments, the angle is less than 60°. In some embodiments, the angle is less than 50°. In some embodiments, the angle is greater than 40°. In some embodiments, the angle is greater than 50°. In some embodiments, the angle is greater than 60°. In some embodiments, the angle is greater than 70°. In some embodiments, the angle is greater than 80°.

The arm portion may include an elongated slot **5097**, such that the position of the arm portion **5096** with respect to the second elongated member **50** can be adjusted with respect to the first elongated member **50**. The slot size and configuration may vary to allow translational movement of the second elongated member **50** or diagnostic pin. The arm portion **5096** may be slidably attached to the second elongated member **50** to cause translational movement of the second member.

FIG. **27** is an isometric view of the diagnostic system of FIG. **26** in a position such that one of the diagnostic pins is moving upward. As shown in FIG. **27**, the handle bar **5094** is rotated clockwise about the pivot joint **5095**, as indicated by the arrow, such that the pin **50** on the left moves upward. The arm portion **5096** may be caused to move relative to the slot **5097** toward a right end of the slot **5097**. The arm portion **5096** may now be slidably attached to the second elongated member **50** near the right end position of the slot **5097**.

FIG. **28** is an isometric view of the diagnostic system of FIG. **26** in a position such that one of the diagnostic pins is caused to move downward. As shown in FIG. **28**, the handle bar is rotated counterclockwise about the pivot joint **5095**, as indicated by the arrow, such that the second pin **50** moves downward. During this movement, the arm portion **5096** may move within the slot toward a left end of the slot **5097**. The arm portion **5096** may be slidably attached to the second elongated member **50** near the left end of the slot **5097**.

In some embodiments, the arm portion **5096** may be fixedly attached to the second member **50** by affixing the arm portion **5096** within the slot **5097**. For example, a fastener may be used affix the arm portion **5096** at a certain position within the slot. In this case, rotation of the handle bar **5094** about the pivot joint **5095** may cause rotational movement of the pins **50** relative to each other. FIG. **29** is an isometric view of a diagnostic system that is configured to rotate one of the diagnostic pins with respect to another diagnostic pin. As shown in FIG. **29**, the diagnostic system includes a first coupling component **5008** and a second coupling component **5008** that are respectively coupled to the first and second elongated members **50**, as similarly described above, with respect to FIG. **28**. The diagnostic system may also include a pivot subassembly **5091** including an arm portion **5096** that is fixedly attached to the second elongated member **50**, for example, by using the fastener **5020** such as shown in FIG. **21**.

The pivot subassembly **5091** may also include a middle portion that is pivotally joined to the first elongated member **50** around a pivot joint **5095** that may be cylindrically shaped. The pivot joint **5095** allows the middle portion **5099** or transition portion **5099** to rotate about such that the arm portion **5096** can cause rotation of the second elongated member **50** when the handle bar **5096** is rotated.

The transition portion **5099** may be attached to the end **5103** of the handle bar **5094**. The transition portion **5099** and the arm portion **5096** may be integrated together. Alternatively, the handle bar **5094** may be integrated with the transition portion **5099**, which may be integrated with the arm portion **5096**. The transition portion **5099** may include an opening that is configured to rotatably join to the pivot joint **5095**. The opening may be cylindrically shaped and sized to match to the pivot joint **5095**.

Still referring to FIG. **29**, the arm portion **5096** may be fixedly attached to the second member **50** by a fastener **5020**. The arm portion **5096** may include a slot **5097** for adjusting position of the fastener **5020** within the slot **5097**, which may vary the angle of the rotation of the second elongated member **50**. The other handle **5030** may be used to hold the first elongated member **50** in position such that the first elongated member **50** does not need to rotate or move while only the second elongated member **50** rotates, in this example.

In use and in one embodiment, the distal end of the first elongated member **50** may be inserted into the ilium **1005**, while the distal end of the second elongated member **50** may be inserted into the sacrum **1004**. In another embodiment, the first elongated member **50** may be inserted into the sacrum **1004**, while the second elongated member **50** may be inserted into the ilium **1005**.

FIG. **30**A is an isometric view of the diagnostic system that rotates one diagnostic pins **50** clockwise with respect to the other diagnostic pin **50**. As shown in FIG. **30**A, the second elongated member **50** is caused to rotate clockwise by rotating the handle bar **5094** clockwise. The position of the fastener **5020** within the slot **5097** remains the same as shown in FIG. **29**.

FIG. **30**B is an isometric view of the diagnostic system that rotates one diagnostic pin **50** counterclockwise with respect to the other diagnostic pin **50**. As shown in FIG. **30**B, the second elongated member **50** is caused to rotate counterclockwise by rotating the handle bar **5094** counterclockwise. The position of the fastener **5020** within the slot **5097** remains the same as shown in FIG. **29**.

In some embodiments, the ilium **1005** or sacrum **1004** may be caused to rotate by using the mechanical coupling including the pivot subassembly shown in FIGS. **29** and **30**A-B. In some embodiments, the rotation may be limited to less than 10°. In some embodiments, the rotation may be less than 5°. In some embodiments, the rotation may be less than 4°. In some embodiments, the rotation may be less than 3°. In some embodiments, the rotation may be less than 2°. In some embodiments, the rotation may be less than 1°.

Reference is now made to FIG. **30**C, which is a front view of another diagnostic system **540** for controlled manipulation of pins **50**. As seen in the figure, the system **540** includes a pair of coupling members **542** coupled between the pins **50**. The coupling members **542** are identical. A bottom coupling member **542** is merely flipped relative to the top coupling member **542**.

Each coupling member **542** includes a pair of through hole openings **544** that are configured to allow the pins **50** to slide through. One side of each coupling member **542** includes a set screw **546** extending into the opening to selectively affix a position of the pin **50** such that the pin **50** cannot slide within the opening **544**. The opposite side of the coupling member **542** does not include a set screw such that the pin within that side can freely slide. The coupling members **542** include a notch or void **548** for engaging a distractor (not shown), which can drive the coupling members **542** longitudinally away from each other (as seen by the arrows in FIG. **30**C).

In operation, a left side pin **50** can be affixed in a position via the set screw **546** relative to the top coupling member **542** and a right side pin **50** can be affixed in a position via the other set screw **546** relative to the bottom coupling member **542**. A distractor may be positioned within the notch **548** and engaged to drive apart the coupling members **542**. If, for example, the left pin **50** is in the sacrum and the right pin **50** in in the ilium, the distractor would drive the left pin **50** posteriorly and the right pin **50** anteriorly.

While reference is made to the previously described tools to manipulate the patient's bones, a physician may also manipulate the pins with his or her hands without the aid of the tools. Alternatively, a surgical robot may also manipulate the pins. Additionally, features of the various tools described herein may be incorporated into different and other embodiments without limitation.

F. Implant Delivery Device Utilizing the Pins, Rods, or Bars as a Guide

After diagnosing the patient's sacroiliac joint as a source of pain and diagnosing fusion of the joint as a possible solution to alleviate the pain, the diagnostic pins, described herein, may be used as a guide for the subsequent delivery of an implant (temporary or permanent) into or near the sacroiliac joint. The implant may be delivered by using a delivery tool that includes a shaft having an end configured to couple to a proximal end of the implant. The implant may also be delivered by using an implant delivery system as described below or as described in related U.S. Patent Applications incorporated by reference in this application. The implant delivery system may be configured to deliver the implant in a controlled manner (e.g., angle of delivery). The implant delivery system may include a pair of diagnostic pins connected by a guide coupling member, which guides the delivery of the implant.

To begin the discussion, reference is made to FIG. **31**, which is an isometric view from a bottom of an implant delivery system or a surgical system for delivering an implant. As shown in the figure, an implant delivery system **5119** may include a first guide member **50** and a second guide member **50**, as described previously, and a guide coupling member **5120** configured to be slidably positioned between the first and second guide members **50**. The first guide member **50** extends along a first longitudinal axis **5016** and has a distal end **58** configured to be delivered into the sacrum **1004** or ilium **1005** via a posterior approach. The second guide member **50** extends along a second longitudinal axis generally parallel to the first longitudinal axis and has a distal end **58** configured to be delivered into the ilium **1005** or sacrum **1004** via the posterior approach.

The guide coupling member **5120** can slide onto the first and second guide members **50** and can receive an implant **25** from the top of the guide coupling member **5120** to deliver the implant **25** into the sacroiliac joint along a predetermined trajectory. The guide coupling member **5120** may have a general planar body with a proximal end **5132**, a distal end **5131**, and an inner opening **5124** configured to allow the implant **25** to be delivered therethrough. The inner opening **5124** may be located in a center of the guide coupling member **5120** and may extend from the proximal end **5132** to the distal end **5131** along the longitudinal axis **5016**. The central opening **5124** may elongate along a transverse axis **5014**, which is generally perpendicular to the first and second guide members **50** to match to the shape of the implant **25**.

The guide coupling member **5120** may also include two opposite through-holes **5129** configured to attach to the first and second guide members **50**. The two opposite through-holes **5129** are positioned on opposite ends **5133** of the central opening **5124**. The through-holes **5129** may be sized to provide interference fitting to the first and second guide members **50**. Alternatively, a side screw **5128** may be used to fasten the guide coupling member **5120** to the first or second guide members **50**.

The implant delivery system **5119** may also include a guide spacer **5122** positioned between the guide coupling member **5120** and the implant **25** to accommodate various types of implants, which may vary in shape, geometry or dimension. The guide spacer **5122** may have an outer surface **5123** configured to fit inside the central opening **5124** of the guide coupling member **5120** from the proximal end **5132** to the distal end **5131**. The guide spacer **5122** may have an inner opening **5125** configured to fit to a size or shape of the implant **25**, such that the implant **25** can slide through the guide spacer **5122**.

The guide spacer **5122** member may also include an end portion **5127** configured to stop by the top surface **5129** near the proximal end **5132** of the guide coupling member **5120**. As shown in FIG. **31**, the end portion **5127** extends circumferentially to contact the top surface **5129** of the guide coupling member **5120**. The extended end portion **5127** still remains between the first and second guide members **50**.

Reference is now made to FIG. **32**, which is an isometric view from a top of the implant delivery system for delivering an implant of FIG. **31**. As shown in FIG. **32**, the implant **25** may include a generally planar body having a proximal end **43**, a distal end **42** opposite the proximal end **43**, and a pair of generally planar surfaces **65** extending between the proximal and distal ends **43**, **42**. The implant **25** may have a threaded opening **70** near the proximal end **43**. A delivery tool may be coupled to the threaded opening **70** to push the implant **25** through the guide spacer **5122**.

FIG. **33** is an isometric view of the implant delivery system of FIG. **31** with the implant **25** inserted partially. As shown, the implant **25** is pushed into the guide spacer **5122**. The guide coupling member **5120**, which may be distally driven in the patient's body until the distal end of the guide coupling member **5120** abuts the ilium **1005** and sacrum **1004**, the implant **25** may be delivered into a region of the joint defined between the diagnostic pins **50**, which may be in the intra-articular region or extra-articular region of the joint. That is, if the pins **50** are positioned such that they span the extra-articular region of the sacroiliac joint, the implant **25** will subsequently be delivered into the extra-articular region of the joint. On the other hand, if the pins **50** are positioned such that they span the intra-articular region of the sacroiliac joint, the implant **25** will subsequently be delivered into the intra-articular region of the joint. Accordingly, the physician may choose to position the pins **50** in a certain region of the sacrum **1004** and ilium **1005** during the diagnostic portion of the procedure while contemplating that, if an implant fusion procedure is necessary, the pins may be used to subsequently guide the implant into the joint.

As an example, a physician may choose to position a first pin **50** in a patient's ilium in a superior region of the iliac spine between the posterior superior iliac spine **2004** and the posterior inferior iliac spine **2006** (i.e., lateral of the extra-articular region of the joint). The physician may choose to position a second pin **50** in a patient's sacrum just medial of the first pin. Thus, after diagnosing the sacroiliac joint as a source of pain and fusion as a procedure for alleviating the pain, the physician may deliver the implant into the extra-articular region of the sacroiliac joint using the pins as a guide.

As another example, a physician may choose to position a first pin **50** in a patient's ilium in an inferior region of the iliac spine between the posterior superior iliac spine **2004** and the posterior inferior iliac spine **2006** (i.e., lateral of the intra-articular region of the joint). The physician may choose to position a second pin **50** in a patient's sacrum just medial of the first pin. Thus, after diagnosing the sacroiliac joint as a source of pain and fusion as a procedure for alleviating the pain, the physician may deliver the implant into the intra-articular region of the sacroiliac joint using the pins as a guide.

Moving on, reference is made to FIG. **34**, which is a sectional view of the implant delivery system of FIG. **33** with the implant inserted partially. As shown, the implant **25** slides down from the proximal end toward the distal end. The tolerance between the outer surface of the implant **25** and the inner surface of the guide spacer **5122** may be large enough to allow the implant **25** to slide down without resistance or friction, but small enough such that the implant **25** can be guided down along the longitudinal axis.

The guide members **50** may have any shaped cross section, including circular, oval, triangular, rectangular, square, diamond, or the like. As one non-limiting example, the generally cylindrical elongated guide member **50** may have a diameter of in the range of about 3 mm to about 8 mm and a length between the distal end and the proximal end may be in the range of about 2 cm to about 20 cm.

G. Implant Delivery Locations

During an implantation procedure, the implant or insertion element **25** may be positioned into a pelvic region of a patient through an incision in the patient's skin. A retractor may be used to open the incision and a trocar or other device may be used to provide a passageway into the surgical site. A medical person may grasp a delivery tool with a mechanically attached insertion element and advance the distal end of the insertion element to a sacroiliac joint region. Alternatively, a surgical robot may conduct the implantation procedure. The distal end of the insertion element may further be advanced into the bones defining a sacroiliac joint. The insertion element may be positioned to substantially or generally avoid the intra-articular portion of the sacroiliac joint. Alternatively, in order to capture the dense bone surrounding the intra-articular portion of the joint, the insertion element may be advanced to be positioned generally or substantially within the intra-articular portion of the sacroiliac joint.

A medical personal may apply a force along the longitudinal axis of the insertion element or the delivery tool to advance the insertion element. The force may cause the insertion element to translate or advance into the joint in a generally anterior direction.

FIG. **35** is an enlarged sectional view illustrating the implant being inserted in the extra-articular region **3007** of the sacroiliac joint. The sectional view is obtained from FIG. **50** as shown by arrows in that figure. As shown in FIG. **35**, the implant **25** is in a generally transverse direction **5140** across the joint line **5144** defining the sacroiliac joint **1000** and the sacrum **1004** and the ilium **1005**. As seen in the figure, the intra-articular region **1044** is shown inferior to the extra-articular region **3007** of the joint. The implant **25** may be positioned substantially perpendicular to the joint line **5144** of the ilium **1005** and sacrum **1004**. The joint line **5144** is along a vertical axis **5142** generally perpendicular to the transverse axis **5140**. The generally planar surface **65** of the implant **25** is generally perpendicular to the joint line **5144** along the vertical axis **5142**, as shown in FIG. **35**. The joint line **5144** is generally in a plane defined by an ilium plane **5148** and sacrum plane **5146**. The implant **25** may also be positioned to be generally symmetric across the joint line **5144** such that the implant **25** may stabilize the joint evenly from both the ilium **1005** and sacrum **1004**. Specifically, one edge **55** of the implant **25** may extend into the sacrum **1004** and one opposite edge **25** may extend into the ilium **1005**. The distance from the edge **55** to the joint line **5144** may be about the same as the distance from the opposite edge **55**.

In alternative embodiments, the implant **25** may be positioned non-symmetrically across the joint line **5144**. For example, the distance of the edge **55** extending into the sacrum **1004** may be smaller or larger than the distance of the opposite edge **55** extending into the ilium **1005**. The distance may vary in order to help temporarily stabilize the joint and to reduce the pain in a patient. In alternative embodiments, the implant **25** may be positioned across the joint line **5144** in a non-perpendicular manner. That is, the implant **25** may be positioned at an angle relative to the joint line **5144** that is less than or more than ninety degrees.

In some embodiments, two or more implants **25** may be used. For example, one fork type implant, such as shown in FIGS. **47**A-B, may be used in the intra-articular region **1044**, while another implant, such as shown in FIGS. **44-46** may be used in the extra-articular region.

FIG. **36** is an enlarged sectional view illustrating another type of implant **25** inserted in the extra-articular region **3007**. As shown in the figure, the implant **5500** may include a cross-shape cross-section with a pair of keels **55** extending into the sacrum **1004** and ilium **1005** and a pair of perpendicularly oriented keels **56** extending generally vertically or in-line with the joint line **5144** in a gap between the ilium **1005** and sacrum **1004** in the extra-articular region **3007**. The additional implant **5500** may be similar to implant embodiments described in related U.S. Patent Applications that are previously identified as being incorporated by reference in this application.

Other embodiments of the implant **25** include a fork or U-shaped implant **25**, as seen in FIGS. **37-38** and **48**A-**48**B. FIG. **37** is a cross-sectional view of the implant **25** taken along the cross-section line shown in FIG. **50**, except the implant **25** in FIGS. **37-38** depict the implant **25** spanning the intra-articular region **1044** instead of the extra-articular region of the sacroiliac joint **1000**. As seen in FIG. **38**, which is another cross-sectional view of the implant **25** taken along the cross-section line shown in FIG. **37**, the implant **25** may include a first longitudinally extending member or finger **5520** and a second longitudinally extending member or finger **5520** that are coupled together at a proximal end of the implant **25** by a coupling member **5530**.

In use, the first longitudinally extending member **5520** may be positioned in the sacrum **1004**, the second longitudinally extending member **5520** may be positioned in the ilium **1005**, and the coupling member **5530** may span the intra-articular region **1044** of the sacroiliac joint **1000**. In this way, the implant **25** may be used in the intra-articular region **1044**, which includes a harder portion of the ilium **1005** than in the extra-articular region **3007**. Although not shown in FIGS. **37-38**, the implant **25** may also be positioned such that the coupling member **5530** spans the extra-articular region **3007** of the joint **1000**.

When implanted in the joint **1000**, the fingers **5520** may be generally parallel to the joint line **5144**. When implanted in this way, the first and second longitudinally extending members **5520** may be fully positioned within the sacrum **1004** and ilium **1005**, respectively, such that an inner sacrum surface **5534** and an inner ilium surface **5536**, on opposing surfaces of the intra-articular region **1044**, are substantially or completely undisturbed by implantation and positioning of the implant **25**. As seen in FIG. **38**, the longitudinally extending member **5520** are aligned along a transverse axis **5141**. The transverse axis **5141** and the horizontal axis are in a transverse plane to a human body. Also, when implanted in the region of the intra-articular region **1044**, the coupling member **5530** does not contact the cartilage in the intra-articular region **1044**; rather, the coupling member **5530** remains positioned outside the joint **1000**. In some embodiments, the coupling portion **5530** may be outside within the patient's soft tissue, or inside a patient's body.

In some embodiments, a temporary implant may include two implant pins with a mechanical coupling that joins the two implant pins, as previously described with reference to FIG. **13**B. The implant pins **50** may be inserted into the sacrum **1004** and ilium **1005** near intra-articular region **1044** or extra-articular region **3007** to help temporarily stabilize the joint for a patient. The patient may carry the temporary implant for a period of time to evaluate if the temporary implant helps reduce the pain. Then, the temporary implant may be removed. A long term implant may be placed in the joint where the temporary implant locates.

FIG. **39**A is an enlarged posterior view of the sacroiliac joint **1000** illustrating that one implant pin is inserted in ilium **1005** near extra-articular region **3007** and one implant pin is inserted into the sacrum **1004** near the intra-articular region **1044**. As shown in FIG. **39**A, one implant pin **50** is inserted into the ilium **1005** near the extra-articular region, while another implant pin **50** is inserted into the sacrum **1004** near the intra-articular region. The pins **50** are respectively coupled together at a proximal end via a mechanical coupling **5160**.

FIG. **39**B is an enlarged posterior view of the sacroiliac joint **1000** illustrating that one pin is inserted in ilium **1005** near extra-articular region **3007** and one implant pin **50** is inserted into the sacrum **1004** near the extra-articular region **3007**. As shown in FIG. **39**B, one implant pin **50** is inserted into the ilium **1005** near the extra-articular region **3007**, while another implant pin **50** is inserted into the sacrum **1004** also near the extra-articular region **3007**. The pins **50** are respectively coupled together at a proximal end via a mechanical coupling **5160**.

FIG. **39**C is an enlarged posterior view of the sacroiliac joint **1000** illustrating that one pin is inserted in ilium **1005** near intra-articular region **1044** and one implant pin **50** is inserted into the sacrum **1004** near the intra-articular region **1044**. As shown in FIG. **39**C, one implant pin **50** is inserted into the ilium **1005** near the intra-articular region **1044**, while another implant pin **50** is inserted into the sacrum **1004** also near the intra-articular region **1044**. The pins **50** are respectively coupled together at a proximal end via a mechanical coupling **5160**.

The implant pins **50** as shown in FIGS. **39**A-C may be joined by a mechanical coupling **5160** to hold the two implant pins **50** in position, such that the coupling **5160** along with the two implant pins **50** can help stabilize the joint temporarily or permanently depending on the needs of the patient. The mechanical coupling **5160** may be like the guide coupling, as shown in FIG. **31**, which is positioned between the two implant pins **50** to connect them together. The coupling **5160** can hold the implant pins **50** in their positions such that the joint is effectively stabilized.

In some embodiments, the mechanical coupling **5160** may also be configured to adjust the distance between the two implant pins **50**, such that the implant pins **50** may be placed in various locations as shown in FIGS. **39**A-C. FIG. **40** illustrates a mechanical coupling **5160** that may include a first portion **5162** attached to the first implant pin **50** and a second portion **5164** attached to the second implant pin **50**. The first portion **5162** may include an elongated slot **5166** configured to allow the distance between the two pins **50** to be adjustable, while the second portion **5164** may include a protruded screw **5168** such that the screw **5168** may be fastened within the slot **5166** by a fastener. The mechanical coupling **5160** may be located outside of a patient's body or inside a patient's body. The mechanical coupling **5160** may be configured to join the implant pins **50**, fixedly or not fixed depending upon the need according to a medical person.

FIG. **41** is an enlarged sectional view illustrating that a temporary implant including coupled implant pins is inserted in the intra-articular region. As shown in FIG. **41**, a distal end **58** of one implant pin **50** is inserted into the ilium **1005** and a distal end **58** of another implant pin **50** is inserted into the sacrum **1004**. Both implant pins **50** are positioned near the intra-articular region **1044**. One implant pin **50** is inside the sacrum joint surface **5146** and another implant pin **50** is inside the ilium joint surface **5148**. Both proximal ends **56** of the implant pins **50** are outside the joint **1000**, thus, not disturbing the cartilage, capsule, and fluid within the intra-articular region **1044** of the joint **1000**. The implant pins **50** may be coupled together via the mechanical coupling **5160**, which is also positioned outside of the joint **1000**. The implant pins **50** are along a transverse axis **5141** which is generally perpendicular to the vertical axis **5142** as shown in FIG. **39**C, and also perpendicular to the horizontal axis **5140**. The transverse axis **5141** and the horizontal axis are in a transverse plane to a human body.

In some embodiments, the implant **25** may be inserted into the sacroiliac joint **1000** without using the guidance tool as shown in the previous figures.

H. Imaging and Radiographic Contrasting Agents

An imaging system may be used to assist in delivering the implant into the intra-articular region or extra-articular region of the sacroiliac joint. More particularly, the capsule of the intra-articular region of the sacroiliac joint, among other anatomical areas, may be injected with a radiographic contrasting agent such that delivery of the implant, in relation to the anatomical feature injected with the contrasting agent, may be viewed under X-ray or fluoroscopy, among other methods, to ensure proper implant placement. As an example, the intra-articular region of the joint may be injected with the radiographic contrasting agent. Then, the implant may be delivered into the extra-articular region of the joint while the joint is viewed under X-ray or fluoroscopy. In this way, with the intra-articular region of the joint clearly visible with the contrasting agent, the implant may be properly positioned and delivered into the extra-articular region.

FIG. **42** illustrates a radiographic contrast tool that injects radiographic contrast under fluoroscopic guidance into the joint. As shown in FIG. **42**, the sacroiliac joint **1000** can be locally anesthetized to allow for injecting a radiographic contrast **1046** (as a non-limiting example, ISOVIEW **300** radiographic contrast) under fluoroscopic guidance into the inferior aspect of the sacroiliac joint **1000** to outline the articular surfaces **1016** of the sacroiliac joint **1000**) defined between the sacrum **1004** and ilium **1005**, the sacroiliac joint **1000** having an interarticular region **1044**. Injection of the radiographic contrast **1046** within the sacroiliac joint **1000** can be accomplished utilizing a tubular member **1047** (such as a syringe needle) having first tubular member end **1048** which can be advanced between the articulating surfaces **1016** of the sacroiliac joint **1000** and having a second tubular member end **1049** which removably couples to a hub **1050**. The hub **1050** can be configured to removably couple to a syringe barrel **1051** (or other device to contain and deliver an amount of radiographic contrast **1046**). In the example of a syringe barrel **1051**, the syringe barrel **1051** can have an internal volume capable of receiving an amount of the radiographic contrast **1046** sufficient for outlining the articular surfaces **1016** of the sacroiliac joint **1000**, for example, under lateral fluoroscopy.

A plunger **1052** can be slidingly received within the barrel **1051** to deliver the radiographic contrast **1046** through the tubular member **1047** into the sacroiliac joint **1000**. The tubular member **1047** can have a gauge in the range of about 16 gauge and about 20 gauge and can further be incrementally marked on the external surface to allow determination of the depth at which the first needle end **1048** has advanced within the sacroiliac joint **1000**. As the first needle end **1048** advances into the sacroiliac joint **1000** the radiographic dye **1046** can be delivered from within the syringe barrel **1051** into the sacroiliac joint **1000** to allow visualization of the sacroiliac joint **1000** and location of the tubular needle **1047** within the sacroiliac joint **1000**.

By highlighting the intra-articular region **1044** of the sacroiliac joint **1000**, important landmarks for subsequent steps of the for implanting an insertion element via the posterior inferior access region **3090** of the sacroiliac joint extra-articular region **3007** (as described in greater detail below) may be more easily identified, e.g., the posterior inferior corner **3091** of the sacroiliac joint extra-articular region boundary **3009**, the inferior end **3092** of the posterior inferior access region **3090** of the sacroiliac joint extra-articular region **3007**, the inferior boundary segment **3093** of the sacroiliac joint extra-articular region boundary **3009**, the anterior boundary segment **3094** of the sacroiliac joint extra-articular region boundary **3009** or the superior-posterior corner **3016** and superior end **2018** of the posterior inferior access region **2016**.

I. Insertion Element or Implant Configurations

FIGS. **43**A-B-**48**A-B illustrate various embodiments of the insertion element or implant **25**. Each implant or insertion element **25** may have a generally planar body having a proximal end, a distal end opposite to the proximal end. The implants may vary in shape, surface features, for example, main surfaces or side surfaces, which may provide variation in friction or resistance to movements. Also, the implants may vary in edges or surface features to provide better bonding to the bones of the sacrum and ilium.

The insertion elements may be formed of biocompatible materials including biocompatible metals, such as stainless steel, titanium, biocompatible ceramics, biocompatible polymers or composite materials. The insertion element may be manufactured by processes including machining, injection molding, among others.

To begin, reference is made to FIGS. **43**A and **43**B. FIG. **43**A is an isometric view from a distal end of an implant **25**, in accordance with a first embodiment of the present disclosure. FIG. **43**B is another isometric view from a proximal end of the implant of FIG. **43**A. As shown in the figures, an insertion element **25** includes a planar member **66**, a distal or leading end **42**, a proximal or trailing end **43**. The planar member **66** has a length between the distal and proximal ends **42**, **43** along a longitudinal center axis CA. The planar members **66** include a pair of generally opposed main surfaces **65** and side edge surfaces **55**. The insertion element **25** also includes a longitudinally extending body **45**. The planar members **66** that extend the length between the distal end **42** and proximal end **43**. The planar members **66** may radially extend outwardly away from the body **45**.

In one embodiment, the radially extending planar members **66** may be grouped into pairs of planar members **66** that are generally coplanar with each other. For example, planar members **66** that are opposite the body **45** from each other, or opposite the longitudinal center axis CA, generally exist in the same plane. More specifically, the planar faces **65** of a first planar member **66** are generally coplanar with the planar faces **65** of a second planar member **66** opposite the body **45** from the first planar member **66**. The longitudinally extending body **45** can extend a greater distance outwardly or transversely from the longitudinal center axis CA than the planar faces **65** of the planar members **66** yet the body **45** does not extend beyond the side edge surfaces **55**.

The cylindrical body **45** may include a threaded hole **70** configured to connect to an implant delivery tool. The threaded hole **70** may be large enough such that the outer surface of the body **45** near the threaded hole may radially extend beyond the two generally opposed main surfaces **65**.

The distal end **42** may be rounded or tapered. For example, the distal end **42** may have a convex surface that may be less resistant when inserted into the sacroiliac joint. The distal end **42** may also be thinner than the general planar body **66** such that the distal end **42** may be easier to be placed into the sacroiliac joint.

The thickness of the planar member **66** may be between approximately 1 mm and approximately 10 mm. In a particular embodiment, the thickness may be approximately 3.5 mm. The length of the planar member may be between approximately 5 mm and approximately 30 mm. In a particular embodiment, the length of the planar member may be approximately 20 mm. The cylindrical body may have a radius between approximately 2 mm and approximately 4 mm. In a particular embodiment, the radius may be approximately 2.75 mm. The width of the planar member **66** may be between 1 cm and 5 cm.

FIG. **44**A is an isometric view from a distal end of an implant in accordance with a second embodiment of the present disclosure. FIG. **44**B is another isometric view from a proximal end of the implant of FIG. **44**A. As shown in FIGS. **44**A-**44**B, an insertion element **25** may include a generally planar body **66** with an anti-migration surface feature **355** on opposed main surfaces **65** and/or side edge surfaces **55**. The anti-migration surface feature **355** may increase the resistance to the movement of sacroiliac joint. The surface feature **355** may include protruded portions from the planar surfaces **65**. The protruded portions **355** may be spaced from each other.

The anti-migration features **355** are generally evenly distributed along the planar surfaces of the planar members in a rows and columns arrangement. The anti-migration features **355** may be in the form of trapezoids, squares, rectangles, etc. The anti-migration features **355** may have a rectangular cross sectional elevation with a thickness FT of between approximately 0.2 mm and approximately 5 mm, with one embodiment having a thickness FT of approximately 1 mm. The anti-migration features may be generally pyramidal.

FIG. **45**A is an isometric view from a distal end of an implant **25** in accordance with a third embodiment of the present disclosure. FIG. **45**B is another isometric view from a proximal end of the implant of FIG. **45**A. As shown in FIGS. **45**A-B, an insertion element **25** may include a generally planar body **66** having opposing planar surfaces **65**. The planar body **66** may include side edges **55** that may have a teeth-type or notch type pattern **360**, that are anti-migration edges. The teeth-type pattern **360** may include a number of protruded portions interleaved with a number of recessed regions. The teeth pattern or notches **360** may increase surface friction or resistance to movement of the sacroiliac joint. The notches **360** may generally be evenly distributed along longitudinally extending free edges or ends of the planar members **66**. The orientation of each notch **365** may be such that the center line NL of the notch **360** forms an angle with the center axis CA of the insertion element **25** that is between approximately 90 degrees and approximately 15 degrees, with one embodiment having an angle NA of approximately 45 degrees. As indicated in FIG. **45**A, each notch **365** may have a length LN between the extreme point on the arcuate end **375** and the outer edge boundary of the notch of between approximately 0.2 mm and approximately 10 mm, with one embodiment having a length LN of approximately 3 mm. Each notch **365** may have a width WN of between approximately 0.5 mm and approximately 20 mm, with one embodiment having a width WN of approximately 2 mm.

In some embodiments, the angles may be less than 80°. In some embodiments, the angles may be less than 70°. In some embodiments, the angles may be less than 60°. In some embodiments, the angles may be less than 50°. In some embodiments, the angles may be less than 40°. In some embodiments, the angles may be less than 50°. In some embodiments, the angles may be less than 30°. In some embodiments, the angles may be less than 20°. In some embodiments, the angles may be greater than 15°. The recessed regions may vary in the recessed depth from the outer edge surface. Similar to other insertion elements, this insert element **25** may also include a cylindrical body with a threaded hole at the proximal end.

FIG. **46**A is an isometric view from a distal end of an implant in accordance with a fourth embodiment of the present disclosure. FIG. **46**B is another isometric view from a proximal end of the implant of FIG. **46**A. As shown in FIGS. **46**A-**46**B, an insert element **25** may include anti-migration features that are in the form of unidirectional serrated triangular shaped teeth or ridges on opposed main surfaces and side surfaces. The ridges **355** may increase the resistance to movement of the implant when positioned in the sacroiliac joint. The triangular ridges **355** are generally evenly distributed along the planar surfaces **65** of the planar members **66** in ridges **355** that run transverse to the length of the insertion element **25**. The anti-migration features **355** are generally similarly distributed along the planar surfaces of the edges of the planar members **66**.

Although the anti-migration features **355** are depicted in the form of unidirectional serrated teeth or ridges **355** on each of the textured surfaces of the insertion device, the invention is not so limited and, as to particular embodiments, can be configured to have said features **355** arranged in multiple directions, unidirectional, or a combination of multiple direction on some surfaces of the insertion element and unidirectional on other surfaces of the insertion element. Accordingly, the features **355** can be so arranged on the various surfaces of the insertion element so as to prevent undesired migration in particular directions due to the forces present at the sacroiliac joint. Features **355** may be spike like or pyramidal.

FIG. **47**A is an isometric view from a distal end of an implant in accordance with a fifth embodiment of the present disclosure. FIG. **47**B is another isometric view from a proximal end of the implant of FIG. **47**A. As shown in FIGS. **46**A-**46**B, an insert element **25** may include anti-migration features that are in the form of unidirectional square shaped teeth or ridges **356** on opposed main surfaces **65** and side surfaces **55**.

FIG. **48**A is an isometric view from a distal end of an implant in accordance with a sixth embodiment of the present disclosure. FIG. **48**B is another isometric view from a proximal end of the implant of FIG. **48**A. As seen in the figures, the insertion element **25** may include a U-shaped or fork-like generally planar member having a pair of longitudinally extending members or fingers that are coupled together by a proximal end member or portion, which may include a cylindrical body with a threaded hole and a planar portion surrounding the cylindrical body. The cylindrical body has a radius larger than the thickness of the planar member. In some embodiments, the side surfaces may include patterns that may increase resistance to movement of the sacroiliac joint. In some embodiments, the main surfaces of the fingers may also include surface features that may that may increase resistance to movement of the sacroiliac joint.

Referring still to FIGS. **48**A and **48**B, the insertion element **25** includes a distal or leading end **42**, a proximal or trailing end **43**, a length between the distal and proximal ends **42**, **43**, a longitudinal center axis CA, a longitudinally extending body **45**, and two longitudinally extending members **5520** that extend the length between the distal end **42** and proximal end **43**. The longitudinally extending members **5520** include a pair of generally opposed faces **65** and side edge surfaces **55**. The longitudinally extending members **5520** may radially extend outwardly away from the body **45**. From the longitudinal center axis CA of the insertion element **25**, the longitudinally extending members **5520** project outwardly on opposite sides of the body **45** and extend distally beyond the most distal region of the body **45** forming the fork-like shape of planar finger members **5520**. The longitudinally extending members **5520** define an opening **5521** between the members **5520**. The width of the opening **5521** may correspond with a width of a portion of the sacroiliac joint. For example, a width of the opening **5521** may be slightly wider than a width of a widest portion of the intra-articular region of the joint. In this way, the implant **25** may be implanted in the joint **1000** in the intra-articular region such that the longitudinally extending members **5520** extend into the sacrum and ilium, respectively, while the opening **5521** spans the intra-articular region of the joint and, thus, avoids damaging the capsule, cartilage, and synovial fluid in the joint.

The distance D**1** spanned by the longitudinally extending members **5520** is between approximately 5 mm and approximately 25 mm, with one embodiment having a distance D**1** of approximately 14 mm. The distance D**2** of the planar members that project outwardly on opposite sides of the fingers **5520** is between approximately 1 mm and 5 mm, with one embodiment having a distance D**2** of approximately 4.5 mm. The distance D**3** of the cylindrical threaded opening is between approximately 3 mm and 8 mm, with one embodiment having a distance D**3** of 5 mm. Distance D**3** may vary along the length of the implant. The cylindrical threaded opening **70** has a radius R of between approximately 2 mm and approximately 4 mm, with one embodiment having a radius R of approximately 2.75 mm.

In one embodiment, the implant **25** has a length L of between approximately 5 mm and approximately 30 mm, with one embodiment having a length L of approximately 20 mm.

Reference is now made to FIGS. **48**C-**48**D, which are, respective, side and isometric views of the implant of FIG. **48**A-**48**B, except the longitudinally extending members **5520** of the implant **25** in FIGS. **48**C-**48**D is curved as it extends from the proximal end **43** to the distal end **42**. The curve of the members **5520** defines a radius R, which may be about 20 mm to about 60 mm. In certain embodiments the radius R may be about 60 mm. In certain embodiments the radius R may be about 55 mm. In certain embodiments the radius R may be about 50 mm. In certain embodiments the radius R may be about 45 mm. In certain embodiments the radius R may be about 40 mm. In certain embodiments the radius R may be about 35 mm. In certain embodiments the radius R may be about 30 mm. In certain embodiments the radius R may be about 25 mm. In certain embodiments the radius R may be about 20 mm. In certain embodiments, an arc of the curved portion of the implant **25** may be about 40, 50, 60, 70, 80, 90, 100, 110, or 120 degrees. In certain embodiments, the implant **25** has a length L that is similar to that of the implant **25** in FIGS. **48**A-**48**B. The implant **25** may include a ratio of length L to radius of curvature R or a ratio of radius of curvature R to length L as defined by the measurements given herein.

The implant **25** of FIGS. **48**C-**48**D would look similar to the cross-sectional views shown in FIGS. **37-38**, except the implant **25** would be curved along a longitudinal extension of the implant **25**. This type of implant **25** may be useful when implanted in the region of the intra-articular region of the sacroiliac joint because the opening **5521** in the implant **25** could span the articular region and follow the contour of intra-articular region as it transitions from the caudal region to the cranial region (i.e., because of the curved nature of the longitudinally extending members **5520**).

This type of implant may be used in the intra-articular region or extra-articular region. The intra-articular region has a higher bone density than the extra-articular region. This may make the intra-articular region a better implant location, for implants that can avoid damaging the intra-articular region, because the implant can anchor into stronger bone.

J. Materials, Coatings, and Agents

Embodiments of the sacroiliac joint insertion element can further include a coat coupled, generated or integral to all or a part of the external surface of the sacroiliac joint insertion element, elongate bodies, or pins. The coat can be of any composition that can be coupled to the sacroiliac joint insertion element capable of biocompatible osseointegration with the bone of the ilium **1005** and sacrum **1004**, such as pure alumina, titanium-dioxide, hydroxyapatite, calcium triphosphate, or the like. As a non-limiting example, the coat can be applied by plasma spraying with a plasma torch, plasmatron or a plasma gun. Alternately, the coat can be achieved by producing a surface roughness, porosity, or irregularity of the sacroiliac joint insertion element by sand blasting, bead blasting, molding, or the like. The coat can have a thickness in the range of about 40 micrometers and about 100 micrometers. Again, embodiments of the sacroiliac joint insertion element can be configured as a material having interconnecting pores throughout such as TRABECULAR METAL available from Zimmer, P.O. Box 708, 1800 West Center Street, Warsaw, Ind. 46581-0708 or a metallic foam such as a titanium foam available from the National Research Council Canada, 1200 Montreal Road, Bldg. M-58, Ottawa, Ontario, Canada or fully-engineered, porous, titanium structures such as TRABECULITE available from Tecomet, 115 Eames Street, Wilmington, Mass. 01887.

One or more biologically active agent(s) can be applied directly to the external surface of the sacroiliac joint insertion element or can be mixed with a biocompatible material or biocompatible biodegradable material or biocompatible osseointegratable material which can be applied to the external surface of the sacroiliac joint insertion element or otherwise made a part of the sacroiliac joint insertion element. As to particular embodiments of the insertion element, the biologically active agent(s) can be mixed with an amount of a biocompatible or biodegradable material or osseointegratable material and located within one or more of the aperture elements.

Biocompatible means the ability of any material to perform the intended function of an embodiment of the invention without eliciting any undesirable local or systemic effects on the recipient and can include non-biodegradable materials such as: ceramic; metals or steels such as titanium alloys or rigid polymeric materials or rigid laminate materials or composites which include suitably dimensioned particles of metals or steels dispersed within rigid laminate materials, or suitably sized particles of biocompatible materials suitably bound or formed to provide configurations, polyurethanes, polyisobutylene, ethylene-alpha-olefin copolymers, acrylic polymers and copolymers, vinyl halide polymers and copolymers, polyvinyl esters, polyvinylidene chloride, polyacrylonitrile, polyvinyl ketones, polyvinyl aromatics such as polystyrene, copolymers of vinyl monomers and olefins such as ethylene-methyl methacrylate copolymers, acrylonitrile-styrene copolymers, ABS resins, ethylene-vinyl acetate copolymers, polyamides such as Nylon 66 and polycaprolactone, alkyd resins, polycarbonates, polyoxyethylenes, polyimides, polyesters, epoxy resins, rayon-triacetate, cellophane, polyether ether ketone (PEEK), polyetherketoneketone (PEKK), bone-from-wood available from the Istituto di Scienza e Tecnologia dei Mareriali Ceramici, Faenza, Italy, or the like, or biodegradable materials, as herein described.

Biodegradable means the ability of any biocompatible material to breakdown within the physiological environment of the sacroiliac joint by one or more physical, chemical, or cellular processes at a rate consistent with providing treatment of a condition of the sacroiliac joint at a therapeutic level controllable by selection of a polymer or mixture of polymers (also referred to as polymeric materials), including, but not limited to: polylactide polymers (PLA), copolymers of lactic and glycolic acids (PLGA), polylactic acid-polyethylene oxide copolymers, poly(.epsilon.-caprolactone-co-L-lactic acid (PCL-LA), glycine/PLA copolymers, PLA copolymers involving polyethylene oxides (PEO), acetylated polyvinyl alcohol (PVA)/polycaprolactone copolymers, hydroxybutyrate-hydroxyvalerate copolymers, polyesters such as, but not limited to, aspartic acid and different aliphatic diols, poly(alkylene tartrates) and their copolymers with polyurethanes, polyglutamates with various ester contents and with chemically or enzymatically degradable bonds, other biodegradable nonpeptidic polyamides, amino acid polymers, polyanhydride drug carriers such as, but not limited to, poly(sebacic acid) (PSA), aliphatic-aromatic homopolymers, and poly(anhydride-co-imides), poly(phosphoesters) by matrix or pendant delivery systems, poly(phosphazenes), poly(iminocarbonate), crosslinked poly(ortho ester), hydroxylated polyester-urethanes, or the like.

Biologically active agents are those agents or mixture of agents which can be varied in kind or amount to provide a therapeutic level effective to mediate the formation or healing of bone, cartilage, tendon, or to reduce, inhibit, or prevent a symptom of a condition of the sacroiliac joint subsequent to placement of an embodiment of the fixation fusion insertion element within the sacroiliac joint such as infection or pain and without limitation can include agents that influence the growth of bone, demineralized bone matrix, stem cells, allografts, autografts, xenografts, bone forming protein whether naturally occurring, synthetic, or recombinate, growth factors, cytokines, bone morphogenetic protein **2**, bone morphogenetic protein **7**, analgesics, anesthetics, anti-inflammatory agents, antibacterials, antivirals, antifungals, antiprotozoals, anti-infectives, antibiotics such as aminoglycosides such as gentamicin, kanamycin, neomycin, and vancomycin; amphenicols such as chloramphenicol; cephalosporins, such as cefazolin HCl; penicillins such as ampicillin, penicillin, carbenicillin, oxycillin, methicillin; lincosamides such as lincomycin; polypeptide antibiotics such as polymixin and bacitracin; tetracyclines such as tetracycline, minocycline, and doxycycline; quinolones such as ciprofloxacin, moxifloxacin, gatifloxacin, and levofloxacin; anti-viral drugs such as acyclovir, gancyclovir, vidarabine, azidothymidine, dideoxyinosine, dideoxycytosine; analgesics, such as codeine, morphine, ketorolac, naproxen, an anesthetic, lidocaine; cannabinoids; antifungal agents such as amphotericin; anti-angiogenesis compounds such as anecortave acetate; retinoids such as tazarotene, steroidal anti-inflammatory agents such as 21-acetoxypregnenolone, alclometasone, algestone, amcinonide, beclomethasone, betamethasone, budesonide, chloroprednisone, clobetasol, clobetasone, clocortolone, cloprednol, corticosterone, cortisone, cortivazol, deflazacort, desonide, desoximetasone, dexamethasone, diflorasone, diflucortolone, difluprednate, enoxolone, fluazacort, flucloronide, flumethasone, flunisolide, fluocinolone acetonide, fluocinonide, fluocortin butyl, fluocortolone, fluorometholone, fluperolone acetate, fluprednidene acetate, fluprednisolone, flurandrenolide, fluticasone propionate, formocortal, halcinonide, halobetasol propionate, halometasone, halopredone acetate, hydrocortamate, hydrocortisone, loteprednol etabonate, mazipredone, medrysone, meprednisone, methylprednisolone, mometasone furoate, paramethasone, prednicarbate, prednisolone, prednisolone 25-diethylamino-acetate, prednisolone sodium phosphate, prednisone, prednival, prednylidene, rimexolone, tixocortol, triamcinolone, triamcinolone acetonide, triamcinolone benetonide, triamcinolone hexacetonide; or allograft cellular matrix containing viable mesenchymal stem cells such as OSTEOCEL PLUS available from NuVasive, Inc., 7475 Lusk Blvd., San Diego, Calif. 92121 USA, and any of their derivatives, whether separately or in combinations thereof.

The biologically active agent(s) can be dispersed throughout a biocompatible or biocompatible biodegradable material (or mixture of biocompatible materials or mixture of biocompatible biodegradable materials) by mixing biologically active agent(s) into the melted biocompatible or biodegradable polymer and then solidifying the resulting material by cooling, having the biologically active agent(s) substantially uniformly dispersed throughout. The biodegradable material or biocompatible material or mixture thereof can be selected to have a melting point that is below the temperature at which the biologically active agent(s) becomes reactive or degrades. Alternatively, the biologically active agent(s) can be dispersed throughout the biocompatible or biodegradable material by solvent casting, in which the biocompatible or biodegradable material is dissolved in a solvent, and the biologically active agent(s) dissolved or dispersed in the solution. The solvent is then evaporated, leaving the biologically active agent(s) in the matrix of the biocompatible or biodegradable material. Solvent casting requires that the biocompatible or biodegradable material be soluble in organic solvents. Alternatively, the insertion element can be placed in a solvent having a concentration of the biologically active agent(s) dissolved and in which the insertion element or the biocompatible or biocompatible biodegradable material located in the aperture elements, or applied to the external surface, swells. Swelling of the insertion element or portions thereof draws in an amount of the biologically active agent(s). The solvent can then be evaporated leaving the biologically active agent(s) within the biocompatible or biocompatible biodegradable material. As to each method of dispersing the biologically active agent(s) throughout the biocompatible or biodegradable biocompatible material of or coupled to the insertion element, therapeutic levels of biologically active agent(s) can be included in biocompatible biodegradable material to provide therapeutically effective levels of the biologically active agent to the sacroiliac joint to treat a particular sacroiliac joint condition.

Other non-active agents may be included in the biocompatible biodegradable material for a variety of purposes. For example, buffering agents and preservatives may be employed. Preservatives which may be used include, but are not limited to, sodium bisulfite, sodium bisulfate, sodium thiosulfate, benzalkonium chloride, chlorobutanol, thimerosal, phenylmercuric acetate, phenylmercuric nitrate, methylparaben, polyvinyl alcohol and phenylethyl alcohol. Examples of buffering agents that may be employed include, but are not limited to, sodium carbonate, sodium borate, sodium phosphate, sodium acetate, sodium bicarbonate, and the like, as approved by the FDA or other appropriate agencies in the United States or foreign countries, for the desired route of administration. Electrolytes such as sodium chloride and potassium chloride may also be included in the formulation.

K. Sensors and Display

The diagnostic system may include sensors for determining position changes from original positions of the pins or bars, which may give quantitative indication of the movement of the ilium **1005** or sacrum **1004** near the joint. The sensors may be placed near the joint. The pins or bars may be manipulated to cause either linear movement or angular movement of the joint. The pins or bars may be held at certain positions for a period of time to either reduce the pain or to cause or reproduce the pain in the patient. The system may include pressure sensors for measuring forces. The sensors may be placed near the joint. In particular, the sensor may be positioned in the plane of the joint, across the joint, or outside the joint.

If positioned in the plane of the joint, a portion of the joint may be removed for insertion of the sensor. In this instance, the sensor may be paddle shaped and may match a shape of a portion of the joint (e.g., intra-articular region). If positioned across the joint, a portion of the ilium and sacrum may be bored-out to provide a passageway for the sensor. If positioned outside the joint, the sensor may bridge the joint and be positioned partially on the ilium and partially on the sacrum. Or, the sensor may be positioned on the ligaments surrounding the joint.

The sensor may be a piezoelectric sensor or transducer. The sensor may sense and transmit measurements that correspond to movement (e.g., bending, twisting, elongation, compression) that may be further associated with pain or discomfort. The patient may, for example, log the points in time that correspond with pain and discomfort and the points may be correlated with the measurements of the sensor to diagnose the types of movements associated with the patient's pain. The sensor may transmit the measurements through an application on the patient's cell phone, for example. The movements associated with pain may be used by the doctor to diagnose an ailment of the sacroiliac joint.

The sensors or transducers may also be positioned on any of the devices described in this application. For example, the implant as shown in FIG. **13**B may include a sensor positioned on the coupling member **80** that is positioned outside the joint. Alternatively, any of the implants, for example as shown in FIGS. **43**A-**48**D may include a sensor or transducer on or integrated with the implant. In this way, the implant may be used, temporarily perhaps, while measurements of compression, distraction, and bending, among others, are taken during a period of time. The information associated with the measurements may be used by the doctor to further diagnose the need for a permanent fixation of the joint.

When used with the tools and systems described herein, the sensors and transducers may be useful in providing a vast amount of data across of a large span of time to the doctor for his or her use in diagnosing an ailment of the sacroiliac joint. Measuring distraction and compression, among other metrics, while in a doctor's office is certainly helpful, but obtaining more data over an extended period of time provides even more data that can be used in the diagnosis.

The system may also include a display that may reveal quantitative information, such as angle, displacement, or holding time. The sensors are in communication with the display to provide the quantitative information. The measured angles, displacements or holding time may be stored on a storage device.

Systems, devices and methods described herein may use oscillatory motion for the diagnosis of a sacroiliac joint ailment. In certain embodiments, a method of diagnosing a medical condition associated with a sacroiliac joint of a patient may include delivering a first member in close proximity to a sacroiliac joint region. The first member may be a pin as described herein an implant or anchor. Subsequently, a force may be applied to the first member. The force may include a periodic oscillation. The periodic oscillation may be applied through via an eccentric rotating mass actuator, a linear resonant actuator, a piezo module, or an electro-active polymer actuator, among others. The periodic oscillation may include a linear displacement comprising an amplitude within a range of about 0.25 mm to about 0.5 mm, about 0.4 mm to about 0.75 mm, about 0.6 mm to about 1 mm, about 0.8 mm to about 1.2 mm, or about 1 mm to about 2 mm. The periodic oscillation may include proportional amplitudes of displacement such that the periodic oscillation resembles a sinusoidal waveform. In certain instances, the displacement may occur in a direction along a longitudinal axis of the first member. In certain instances, the displacement may occur in a direction generally transverse to a longitudinal axis of the first member. And, in certain instances, the periodic oscillation is may be caused by an electrically or pneumatically driven motor comprising a drive shaft with an off-balanced mass coupled thereto.

Based on a patient's pain, discomfort, or alleviation of the pain or discomfort, a doctor may be able to diagnose a sacroiliac joint ailment based on the oscillatory vibrations delivered to the patient through the first member.

L. Delivery of the Implant

The following discussion will focus on delivering the implant into the sacroiliac joint region. The discussion will further focus on the implant and its relation to the various regions (e.g., intra-articular, extra-articular) of the sacroiliac joint. While the pins, described previously, are not shown in the following figures, it is intended that the implant may be delivered with or without the aid of the pins.

To begin, reference is made to FIG. **49**A, which is a lateral side view of a hip region **1002** of a patient showing a sacrum **1004** and an ilium **1005** with a nearest ilium **1005** removed to more clearly depict the intra-articular region **1044** and the extra-articular region **3007** of the sacroiliac joint **1000**. Preparing an access region from the patient's skin to the patient's bone is described in this and other applications, such as, U.S. patent application Ser. No. 12/998,712, filed May 23, 2011 entitled SACROILIAC JOINT FIXATION FUSION SYSTEM and Ser. No. 13/236,411, filed Sep. 19, 2011 entitled SYSTEMS FOR AND METHODS OF FUSING A SACROILIAC JOINT. These applications are hereby incorporated by reference in their entireties. As seen in FIG. **49**A, the implant **25** may include a distal end and be coupled with a distal end **35** of an implant arm **110**. The distal end of the implant **25** may be posteriorly delivered into the hip region **1002** with a general anterior trajectory. The implant in solid line is shown entering the posterior inferior access region **3090** of the extra-articular region **3007** of the sacroiliac joint **1000** along a trajectory TR**1**. Depending on the shape and configuration of the implant **25**, it may penetrate into both the ilium (nearest ilium not shown) and the sacrum **1004** and extend across the joint **1000**.

The dotted line depiction of the implant shows another trajectory TR**2** of the implant as it extends into the posterior inferior access region **3090** of the extra-articular region **3007** of the joint **1000**. In both trajectories TR**1**, TR**2**, the implant avoids penetration into the intra-articular region **1044** of the joint **1000**. The intra-articular region **1044** of the joint includes a capsule containing cartilage and synovial fluid. For this reason, implanting an implant within the extra-articular region **3007**, as opposed to the intra-articular region **1044**, avoids damaging to the capsule in the event that a permanent fusion procedure is unnecessary. That is, it may be desirable to avoid damaging the intra-articular region **1044** of the joint **1000** until a permanent fusion procedure within the intra-articular region **1044** occurs.

Accordingly, the doctor or medical professional may deliver the implant along trajectories TR**1**, TR**2** or at any points in between. Trajectory TR**1** is generally parallel to the caudal boundary segment **3093**. Trajectory TR**2** extends an angle AJ cranial of trajectory TR**1** towards a mid-section of the anterior boundary segment **3094**. In certain embodiments, the angle AJ may be between 5 degrees and 35 degrees. In certain instances, the angle AJ may be about 5 degrees. In certain instances, the angle AJ may be about 10 degrees. In certain instances, the angle AJ may be about 15 degrees. In certain instances, the angle AJ may be about 20 degrees. In certain instances, the angle AJ may be about 25 degrees. In certain instances, the angle AJ may be about 30 degrees. In certain instances, the angle AJ may be about 55 degrees.

Still referring to FIG. **49**A and in certain embodiments of the implant (shown in FIG. **48**A-**48**B), the implant may be delivered into the sacrum **1004** and ilium (nearest is hidden) in the region of the intra-articular region **1044** without damaging the capsule, cartilage, and synovial fluid of the joint. In these configurations, the distal opening of the implant occupies the joint space such that the capsule of the joint is not damaged or disturbed by the body of the implant. That is, the implant may be delivered such that it is in-line with the posterior inferior access region **2016** of the intra-articular region **1044**. A sacral side of the implant **25** may be delivered into the sacrum **1004** in the region just medial of the posterior inferior access region **2016** and an ilial side of the implant may be delivered into the ilium **1005** in the region just lateral of the posterior inferior access region **2016**. On the ilium **1005**, the ilial side of the implant may extend into the ilium between the posterior superior iliac spine **2004** and the posterior inferior iliac spine **2006**.

Turning to FIGS. **49**B-**49**C, which are lateral views of the hip region **1002** showing the patient's skin **1003** in dotted line, the implant **25**, being coupled with a distal end **35** of the shaft **110** of a delivery tool, is being delivered into the extra-articular region of the sacroiliac joint via a posterior approach. FIG. **49**B shows the distal end of the implant **25** entering the extra-articular region **3007** of the joint. A trajectory TR**3** of the implant is oriented to extend through the posterior inferior access region **3090** and extend superior-anterior towards a mid-section of the anterior boundary segment **3094** of the extra-articular region **3007**. FIG. **49**C shows the implant **25** extending into the caudal region of the extra-articular region **3007** of the joint.

FIG. **50**, which is a lateral side view of the hip region **1002** with a nearest ilium hidden from view to more clearly show the regions of the sacroiliac joint **1000**, depicts the implant **25** positioned in the extra-articular region **3007** of the sacroiliac joint **1000**. As seen in the figure, the implant is de-coupled from the shaft **110** of the delivery tool such that the implant **25** resides in the joint **1000**, extending into the posterior inferior access region **3090** of the extra-articular region **3007**. As stated previously, delivering the implant **25** in this region **3007** avoids disruption of the capsule, cartilage, and fluid within the intra-articular region **1044** of the joint **1000**. In this way, if it is determined that a permanent implant is not needed, the implant (i.e., in the extra-articular region **3007**) may be removed and the joint **1000** has not been irreparably damaged by, for example, removing the cartilage.

Reference is now made to FIG. **51**, which shows a posterior view of FIG. **50** showing the implant **25** positioned in the sacrum and ilium above the intra-articular region **1044**. As seen in the figure and as described previously, the implant **25** extends across the extra-articular region **3007** of the joint and extends into the ilium **1005** between the posterior superior iliac spine **2004** and the posterior inferior iliac spine **2006**.

Once the temporary implant is delivered into the patient and the delivery tool is removed from the implant, the various surgical tools may be removed from the incisions and the incision may be sterilized and closed. The patient may move about and simulate movements that would previously cause pain (e.g., flexing at hips). The implant may remain in the patient for a given period of time (e.g., minutes, hours, days) to determine if fusion of the joint is effective in eliminating or alleviating the pain. In certain patients, for example, a petite individual with a low activity level, if the temporary implant relieves the pain, it may be suitable to allow the implant to remain in the patient's body. Perhaps no other fusion procedure is necessary. Or, perhaps a subsequent implant may be delivered into the joint to permanently fuse the joint.

In certain instances, the temporary implant may be removed by coupling the shaft of the delivery tool with the implant and removing the implant from its position within the joint. This procedure may be done just prior to delivering a permanent implant into the joint in either the intra-articular region or the extra-articular region. If a permanent implant is to be delivered into the joint region, the joint may be prepped for the procedure according to U.S. patent application Ser. No. 14/514,221, filed Oct. 15, 2014, which is hereby incorporated by reference in its entirety. It is noted that the temporary implant positioned within the extra-articular region need not be removed prior to insertion of a permanent implant in the intra-articular region of the joint.

M. Tools, Systems, and Methods for Bone Pin Delivery and Manipulation

The following is a description of various tools, systems, and methods for bone pin delivery and manipulation. FIGS. **52**A-**52**H depict various views of a parallel pin guide **5200**.

More particularly, FIG. **52**A is an isometric front view of the parallel pin guide **5200** supporting a pair of dilators **5202**. FIG. **52**B is a front view of the parallel pin guide **5200** supporting the pair of dilators **5202**. FIG. **52**C is a cross-sectional view of the parallel pin guide **5200** supporting the pair of dilators **5202**. FIG. **52**D is a top view of the parallel pin guide **5200** supporting the pair of dilators **5202**. FIG. **52**E is a bottom view of the parallel pin guide **5200** supporting the pair of dilators **5202**. FIG. **52**F is an isometric front view of the parallel pin guide **5200** separated from the pair of dilators **5202**. FIG. **52**G is a side view of the parallel pin guide **5200** supporting the pair of dilators **5202**. And, FIG. **52**H is a cross-sectional view of the parallel pin guide **5200** supporting the pair of dilators **5202**.

As best seen in FIG. **52**F, among others, the parallel pin guide **5200** may include a guide body **5204** having a pair of spaced-apart guide holes **5206** extending in a distal-proximal direction. One of the guide holes **5206** may include a sleeve **5208** extending distally from the guide body **5204**. A distal tip **5220** of the sleeve **5208** may include a conical taper. The guide holes **5206** may define a passageway there through for receiving a dilator **5202**. The dilators **5202** may include a distal tip **5210** that may be conically tapered, a ribbed proximal end **5212** for grip, and passageway **5214** extending there through.

The guide body **5204** may additionally include a pair of radiographic guides or apertures **5216** extending transversely through the body **5204**. An axis extending through the radiographic guides **5216** may be generally perpendicular to an axis extending through the guide holes **5206**. The radiographic guides **5216** may receive radiographic contrasting cylinders **5218** therein for aligning relative to a joint line of the sacroiliac joint during the surgical procedure while under radiographic guidance (e.g., C-arm fluoroscopy). Alternatively or additionally, the guide body (or bone pins **5302**, a handle coupled to the bone pins, or any other component of the system described here or throughout the present application) may be configured for a navigated stereotactic procedure. As an example, the system may be configured to be used with a Medtronic StealthStation™ Navigation System and TeraTrackers or similar system (e.g., any system comprising optical or electromagnetic tracking) in order to assist the physician in precisely locating anatomical structures and accurately placing certain components of the system (e.g., the bone pins, guide wires or any other tool or implant) into or onto the patient. As such the guide body or other tool may have an attachment site configured to support a tracking array comprising active (transmits its own infrared light, e.g., via light-emitting diodes) or passive (reflects infrared light supplied by an external illumination source) markers.

As seen in FIGS. **52**A-**52**E and **52**G-**52**H, when the first and second dilators **5202** are positioned in the guide holes **5206** of the guide body **5204**, the ribbed proximal end **5212** of the dilators **5202** may extend from the proximal end of the guide body **5204**, and the distal tip **5210** of the first dilator **5202** extends beyond the distal tapered tip **5220** of the sleeve **5208**. The second dilator **5202** extends from the proximal end of the guide body **5204** in parallel alignment with the first dilator **5202**.

FIGS. **53**A-**53**G depict various views of a dual-axis pliers **5300**. More particularly, FIG. **53**A is an isometric front view of a dual-axis pliers **5300**. FIG. **53**B is an isometric rear view of the dual-axis pliers **5300**. FIG. **53**C is an isometric exploded view of the dual-axis pliers **5300** from a first side. FIG. **53**D is an isometric exploded view of the dual-axis pliers **5300** from a second side. FIG. **53**E is an isometric front view of the dual-axis pliers **5300** supporting a pair of bone pins **5302** in a first parallel orientation. FIG. **53**F is an isometric front view of the dual-axis pliers **5300** supporting a pair of bone pins **5302** in a second parallel orientation where the bone pins **5302** are spaced apart a farther distance than in the first parallel orientation. FIG. **53**G is an isometric front view of the dual-axis pliers **5300** supporting a pair of bone pins **5302** in a third orientation where the pair of bone pins **5302** are angled relative to each other but within parallel planes.

As seen in FIGS. **53**A and **53**B, the dual-axis pliers **5300** may include handles **5304** at a proximal end **5306**, a head **5308** at a distal end **5310**, and first and second pivot joints **5312**, **5314** intermediate of the handles **5304** and head **5308**. A first handle **5304***a* may be integrally formed with a first head portion **5308***a*, and a second handle **5304***b* may be integrally formed with a second head portion **5308***b*. The dual-axis pliers **5300** may function as expanding pliers where inward movement of the handles **5304***a*, **5304***b* relative to each other causes the head portions **5308***a*, **5308***b* to move away from each other, or expand, and thereby (depending on the arrangement of the bone pins to the sacroiliac joint) causing a distractive force at the sacroiliac joint, e.g., when a line drawn between the pins is substantially perpendicular to the sacroiliac joint line or when a line drawn between the pins forms an acute angle relative to the joint line such action may cause a shearing force or motion at the joint or a rotational force or motion at the joint. Conversely, outward movement of the handles **5304***a*, **5304***b* relative to each other causes the head portions **5308***a*, **5308***b* to move closer to each other, or to contract, and thereby (depending on the arrangement of the bone pins to the sacroiliac joint) causing a compressive force at the sacroiliac joint, e.g., when a line drawn between the pins is substantially perpendicular to the sacroiliac joint line or when a line drawn between the pins forms an acute angle relative to the joint line such action may cause a shearing force or motion at the joint or a rotational force or motion at the joint.

Each of the head portions **5308***a*, **5308***b* of the dual-axis pliers **5300** may include a proximal head member **5316** having a through-hole **5318** extending there through and a distal head member **5320** with a through-hole **5322** extending there through. The through-holes **5318**, **5322** are coaxial with each other and sized to accept a bone pin (e.g., schanz screw/pin) therein. The proximal head members **5316** may each include a thumb-screw **5324** with a portion of the shaft extending into the through holes **5318** so as to contact and retain the bone pin in a desired position relative to the head portion **5308***a*, **5308***b*. While the thumb-screw **5324** is shown on the proximal head member **5316**, the thumb-screw **5324** may additionally or alternatively be positioned on the distal head member **5320**.

The pliers **5300** are referred to as dual-axis plier because the first and second pivot joints **5312**, **5314** are oriented perpendicular to each other; the first pivot joint **5312** facilitates movement or rotation (e.g., expanding and contracting) of the head portions **5308***a*, **5308***b* about a first pivot axis FPA, and the second pivot joint **5314** facilitates movement or rotation (e.g., shearing) of the head portions **5308***a*, **5308***b* about a second pivot axis SPA. In this way, as seen in FIGS. **53**E-**53**F, the pliers **5300** may be used to expand a pair of bone pins secured to the pliers **5300** away from each other or closer to each other via rotation about the first pivot axis FPA. And, as seen in FIG. **53**G, the pliers **5300** may be used to rotation or shear a pair of bone pins secured to the pliers **5300** via rotation about the second pivot axis SPA.

Referring to FIGS. **53**C and **53**D, the first and second pivot joints **5312**, **5314** will be described. As seen in the figures, the dual-axis pliers **5300** may include a pivot assembly **5326** including a dual-cylinder body **5328**, a pivot pin **5330**, and a retention pin **5332** (similar to a cotter pin). The dual-cylinder body **5328** includes a barreled body **5340** with a first through-hole **5334** for receiving the first pivot pin **5336** there through. The dual-cylinder body **5328** may also include cylinder flange **5338** extending perpendicular to the barreled body **5340**. The cylinder flange **5338** may include a second through-hole **5342** perpendicular to the first through-hole **5334**. The second through-hole **5342** may receive the shaft of the pivot pin **5330** therein, and the retention pin **5332** may extend through the barreled body **5340** and into an opening in the tip of the pivot pin **5330** such that the pivot pin **5330** and dual-cylinder body **5328** are coupled to the second head portion **5308***b* of the pliers **5300**. As seen in FIG. **53**C, the second head portion **5308***b* includes a through-bore **5344** for receiving the pivot pin **5330** therein.

When the pivot pin **5330** is retained in the through-bore **5344** of the second head portion **5308***b*, and when the pivot pin **5330** is also coupled to the dual-cylinder body **5328** via the retention pin **5332**, the cylinder flange **5338** of the dual-cylinder body **5328** is received within an enlarged portion of the through-bore **5344** such that the dual-cylinder body **5328** can rotate about the pivot pin **5330**, which defines the second pivot axis SPA.

As seen in FIG. **53**C, the first head portion **5308***a* includes a pair of inwardly extending knuckles or barrels **5346** with through-holes **5348** for receiving the first pivot pin **5336** therein. Each of the pair of knuckles **5346** includes a slot **5350** jutting into the knuckle **5346**.

The pliers **5300** may function so as to pivot only about the first pivot joint **5312**, or function to pivot about both the first and second pivot joints **5312**, **5314**. To pivot about only the first pivot joint **5312**, a pair of thumb-studs **5352** may be selectively engaged with the slots **5350** of the knuckles **5346** so as to prevent rotation about the second pivot joint **5314** (the pivot pin **5330**). As seen in FIG. **53**C, the thumb-studs **5352** may extend through openings **5354** (e.g., threaded) in the second head portion **5308***b*, and may be retained from removal from the second head portion **5308***b* via e-clips **5356**. The thumb-studs **5352** may be pushed or threadedly advanced to contact the second head portion **5308***b*, and in doing so the unthreaded tips of the thumb-studs **5352** may enter the slots **5350** of the knuckles **5346** on the first head portion **5308***a*. With the tips of the thumb-studs **5352** within the slots **5350**, the pliers **5300** are permitted to pivot about the first pivot pin **5336** extending through the knuckles **5346** and the dual-cylinder body **5328** of the pivot assembly **5326** as the tips of the thumb-studs **5352** may slide within the slots **5350**; but, in this orientation, the pliers **5300** are prevented from rotating about the second pivot joint **5314** defined by the pivot pin **5330** by contact of the tips of the thumb-studs **5352** against the upper and lower walls defined by the slots **5350**.

By pulling back on or unthreading the thumb-studs **5352**, relative to the second head portion **5308***b*, the tips of the thumb-studs **5352** may disengage or pull-out from within the slots **5350** of the knuckles **5346**. In this orientation, the second head portion **5308***b* is permitted to rotate relative to the first head portion **5308***a* via the pivot pin **5330** and the cylinder flange **5338** of the dual-cylinder body **5328** (about the second pivot axis). It is noted, the second head portion **5308***b* may still rotate relative to the first head portion **5308***a* about the first pivot pin **5336** when the thumb-studs **5352** are disengaged from the slots **5350** of the knuckles **5346**.

As seen in FIG. **53**E, the dual-axis pliers **5300** is coupled to a pair of bone pins **5302** such that the bone pins **5302** are parallel to each other. As seen in FIG. **53**F, the handles **5304***a*, **5304***b* are moved closer to each other (rotated about the first pivot axis FPA of the first pivot joint **5312**) so as to cause the first and second head portions **5308***a*, **5308***b* to move farther apart from each other while the bone pins **5302** are still parallel to each other. And in FIG. **53**G, the thumb-studs **5352** are disengaged (pulled away from the second head portion **5308***b*) from the slots **5350** of the knuckles **5346** (not seen in FIG. **53**G) such that the pliers **5300** are pivotable about the second pivot axis SPA of the second pivot joint **5314**. As configured the dual-axis pliers allow the physician to selectively and reproducibly constrain manipulation or force delivery to certain desirable degrees of freedom.

FIGS. **54**A-**54**C illustrate various view of a clevis guide **5400**. More particularly, FIG. **54**A is an isometric front view of a clevis guide **5400** supporting a pair of bone pins **5402** in a first parallel orientation. FIG. **54**B is an isometric front view of the clevis guide **5400** supporting the pair of bone pins **5402** in a second parallel orientation where the bone pins **5402** are moved longitudinally relative to each other relative to their positions in the first parallel orientation. FIG. **54**C is an isometric exploded view of the clevis guide **5400**.

As seen in the figures, the clevis guide **5400** may include a clevis **5404** having a pair of prongs **5406** at one end and a tool engaging structure **5408** (e.g., square-end handle quick connect adapter) at the opposite end. The clevis guide **5400** may couple to a pair of guide blocks **5410***a*, **5410***b*, each of which may include a guide hole **5412***a*, **5412***b* extending longitudinally through the guide block **5410***a*, **5410***b*. The guide blocks **5410***a*, **5410***b* may include a thumb-screw **5414***a*, **5414***b* that, when engaged, causes a tip of the shaft to extend into the guide holes **5412***a*, **5412***b* so as to contact and retain the bone pins **5402***a*, **5402***b* positioned therein.

Each of the guide blocks **5410***a*, **5410***b* may be supported relative to the prongs **5406** via a pair of pins **5416** that extend through apertures **5418** in the prongs **5406**. It can be seen in FIGS. **54**B and **54**C that the aperture **5418** nearest the body of the clevis **5404** is elongated so as to permit the pins **5416** to slide slightly distal-proximal, which permits the guide blocks **5410***a*, **5410***b* to remain in a parallel orientation during use.

In use, the clevis guide **5400** may be used to displace the bone pins **5402***a*, **5402***b* longitudinally relative to each other. For example, FIG. **54**A depicts the guide blocks **5410***a*, **5410***b* in a neutral orientation where the blocks are parallel to each other and the tops and bottom surfaces of the blocks are, respectively, coplanar. From this orientation, the tool engaging structure **5408** may be moved down (assuming the bone pins **5402***a*, **5402***b* are secured to a patient's bone surface), which causes the most distal bone pin **5402***a* (the one farthest from the tool engaging structure **5408**) to move up relative to the other bone pin **5402***b*. With this type of movement, the proximal bone pin **5402***b* acts as a fulcrum. While not shown, the tool engaging structure **5408** may be moved upwards, which causes the most distal bone pin **5402***a* to move down relative to the other bone pin **5402***b*.

FIGS. **55**A-**55**G depict exemplary steps in a surgical procedure. FIG. **55**A is an inferior view of a sacrum **1004** and an ilium **1005** with a guide wire **5500** delivered into the sacrum **1004**. FIG. **55**B is an inferior view of the sacrum **1004** and the ilium **1005** with a first dilator **5202** positioned over the guide wire **5500**. FIG. **55**C is an inferior view of the sacrum **1004** and the ilium **1005** with the parallel pin guide **5200** positioned over the first dilator **5202**. FIG. **55**D is an inferior view of the sacrum **1004** and the ilium **1005** with a pair of radiographic contrasting cylinders **5218** positioned through the radiographic guides **5216** of the parallel pin guide **5200**. FIG. **55**E is a posterior view of the sacrum **1004** and the ilium **1005** showing the pair of radiographic contrasting cylinders **5218** parallel with each other and generally parallel with a joint line of the sacroiliac joint **1000**. FIG. **55**F is an inferior view of the sacrum **1004** and the ilium **1005** with a second dilator **5202** positioned up against the ilium **1005** and through a guide hole **5206** of the parallel pin guide **5200**. FIG. **55**G is an inferior view of the sacrum **1004** and the ilium **1005** with a second guide wire **5500** positioned through the second dilator **5202** and into the ilium **1005**. FIG. **55**H is an inferior view of the sacrum **1004** and the ilium **1005** with the dual-axis pliers **5300** secured to a pair of pins **5502** (positioned in the sacrum **1004** and ilium **1005** where the guide wires **5500** were previously). FIG. **55**I is an inferior view of the sacrum **1004** and the ilium **1005** with the clevis guide **5400** secured to the pair of pins **5502** (positioned in the sacrum **1004** and ilium **1005** where the guide wires **5500** were previously).

The systems disclosed above may include a digital and or analog indicators and readout. Additionally or alternatively, the systems may include various forms of motion control (e.g., between components of the system and or the patient or a frame in proximity to the patient) with accurate position/velocity/torque capabilities operating in either open or closed loop mode. For example, open loop stepping drives may send motion commands to stepper motors, but receive no information about the result while closed loop servo systems may have feedback devices at the motor shaft to verify or adjust the resulting motion. Additionally or alternatively, the systems may include: linear motion slides and actuators, drive couplings, sensors, encoders, rotary encoders for detecting position and speed, sensors for detecting proximity, pressure, temperature, level, flow, current and voltage, limit switches for detecting states such as presence or end-of-travel limits, discrete or analog outputs, optical rotary encoders, inductive proximity sensors, magnetic proximity sensors, capacitive proximity sensors, photoelectric sensors, laser sensors, area sensors, fiber optic sensors, color sensors, contrast sensors, fork sensors, ultrasonic proximity sensors, pressure sensors, pressure gauges, thermometers, temperature sensors and transmitters, level sensors and controllers, flow sensors, current & voltage sensors (ac & dc), ground fault sensors, limit switches, hmi (human machine interface) providing a textual or graphical view of system conditions and operations offering monitoring, control, status reporting and other functions, programmable controllers (providing accurate, reliable, easily-modified control with discrete and process functions including motion, data logging and web server access), mechanical power transmission components, mechanical drivetrains to create movement, gearboxes, timing belts/pulleys/bushings, shaft couplings, bore reducers, linear shafts, and linear shaft supports.

Neuromonitoring may be conducted simultaneously with the diagnostic procedure utilizing any of the systems or methods described herein in order to monitor the status of the nerves in proximity to the diagnostic or treatment site whether to assess the location of the pins or to assess the influence of joint movement or pin movement on the nerves.

The foregoing merely illustrates the principles of the embodiments described herein. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. It will thus be appreciated that those skilled in the art will be able to devise numerous systems, arrangements and methods which, although not explicitly shown or described herein, embody the principles of the embodiments described herein and are thus within the spirit and scope of the present disclosure. From the above description and drawings, it will be understood by those of ordinary skill in the art that the particular embodiments shown and described are for purposes of illustrations only and are not intended to limit the scope of the present disclosure. References to details of particular embodiments are not intended to limit the scope of the disclosure.

What is claimed is:

1. A method of diagnosing and treating a sacroiliac joint of a patient, the method comprising:

a) delivering a first member into the ilium via a first posterior approach;

b) delivering a second member into the sacrum via a second posterior approach, the second member not crossing the sacroiliac joint;

c) coupling the first and second members to a pliers; and

d) manipulating the first member in the ilium relative to the second member in the sacrum via the pliers.

2. The method of claim **1**, wherein the pliers are a dual-axis pliers comprising first and second handles, first and second head portions, and a pair of joints adjustably coupling the first and second handles and the first and second head portions, the pair of joints facilitating rotation of the first and second head portions about first and second axes, wherein the first and second axes are generally perpendicular to each other.

3. The method of claim **1**, wherein the pliers comprise first and second handles, first and second head portions, and a first joint adjustably coupling the first and second handles and the first and second head portions, wherein the pliers are expanding pliers such that movement of the first and second handles closer together via rotation about a first axis of the first joint causes the first and second head portions to move apart from each other.

4. The method of claim **3**, wherein the pliers further comprise a second joint adjustably coupling the first and second handles and the first and second head portions, wherein the second joint facilitates rotation of the first and second head portions about a second axis of the second joint, the second axis being generally perpendicular to the first axis.

5. The method of claim **4**, wherein the pliers further comprise at least one stud member configured to be engaged and disengaged with the first joint, wherein engagement of the stud member with the first joint limits rotation of the pliers to the first axis of the first joint, and wherein disengagement of the stud member with the first joint permits rotation of the pliers to the first axis of the first joint and the second axis of the second joint.

6. The method of claim **1**, further comprising: e) receiving feedback from the patient including whether or not manipulating the first member relative to the second member via the pliers at least one of reproduces, stimulates, and alleviates a symptom being investigated.

7. The method of claim **1**, wherein the pliers comprise at least one of an analog and a digital readout.

8. A method of diagnosing and treating a sacroiliac joint of a patient, the method comprising:

a) delivering a first member into the sacrum via a first posterior approach;

b) sliding a first dilator over the first member;

c) sliding a sleeve of a first guide of a parallel pin guide over the first dilator;

d) positioning a second guide of the parallel pin guide so as to target the ilium;

e) inserting a second dilator into the second guide; and

f) delivering a second member into the ilium via guidance by the second dilator.

9. The method of claim **8**, wherein the first and second members are guide wires, and the method further comprises delivering first and second bone pins, respectively into the locations of the first and second members.

10. The method of claim **9**, further comprising manipulating the first and second bone pins relative to each other.

11. The method of claim **10**, further comprising using at least one of a pliers and a clevis guide to manipulate the first and second bone pins relative to each other.

12. The method of claim **8**, further comprising inserting a pair of radiographic contrasting members into radiographic guide holes of the parallel pin guide, and aligning the radiographic contrasting members with the sacroiliac joint.

13. The method of claim **12**, wherein aligning the radiographic contrasting members with the sacroiliac joint is done under radiographic imaging.

14. The method of claim **12**, wherein aligning the radiographic contrasting members with the sacroiliac joint causes the second guide of the parallel pin guide to target the ilium.

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