

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

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(45) **Date of Patent:** **Jul. 2, 2019**

(54) **ORTHOPEDIC ANCHORING METHODS**

(71) Applicant: **JCBD, LLC**, Fort Collins, CO (US)

(72) Inventors: **Edward Jeffrey Donner**, Fort Collins, CO (US); **Christopher Thomas Donner**, Fort Collins, CO (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 152 days.

(21) Appl. No.: **15/385,446**

(22) Filed: **Dec. 20, 2016**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 14/413,318, filed as application No. PCT/US2013/051381 on Jul. 19, 2013, now Pat. No. 9,554,909.
(Continued)

(51) **Int. Cl.**
A61B 17/58 (2006.01)
A61B 17/17 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61B 17/58** (2013.01); **A61B 17/1757** (2013.01); **A61B 17/7055** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/1757; A61B 17/1742; A61B 17/7055; A61B 17/7076; A61B 17/58
See application file for complete search history.

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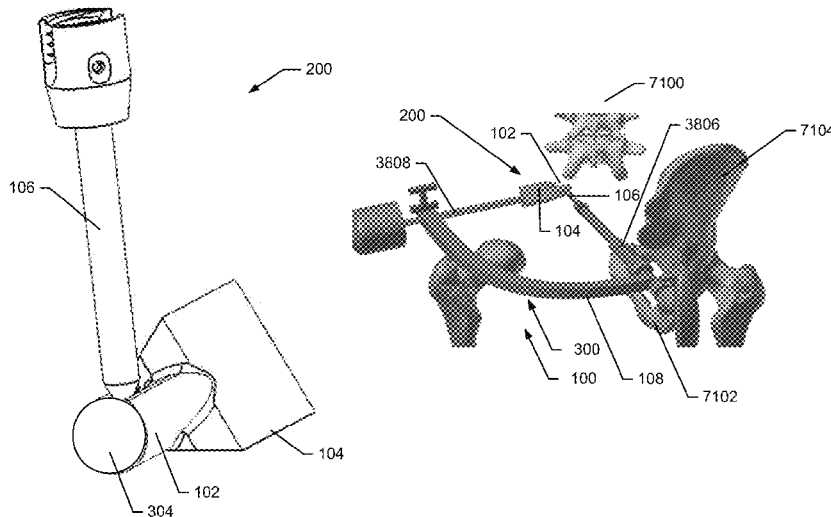
Primary Examiner — Olivia C Chang

(74) *Attorney, Agent, or Firm* — Polsinelli PC; Joshua J. Prackun; Samuel Wade Johnson

(57) **ABSTRACT**

Methods for performing orthopedic surgical procedures to treat a patient are presented herein. A method may include: positioning an implant assembly at the pelvic region, the implant assembly including an implant body including at least a portion of a locking element, an implant outer layer, and a fastener including a longitudinal axis and an attachment feature configured to mechanically interlock with the locking element in an interference mechanical engagement, the attachment feature comprising a distal end and a contracted neck region; delivering the implant outer layer into the ilium, across the sacroiliac joint, and into the sacrum such that a fastener opening of the implant outer layer resides within the sacrum; delivering the fastener through a posterior surface of the sacrum such that the distal end of the attachment feature is received within the implant outer layer; and interlocking the locking element and the attachment feature with each other.

29 Claims, 51 Drawing Sheets



Related U.S. Application Data

- (60) Provisional application No. 61/798,922, filed on Mar. 15, 2013, provisional application No. 61/674,233, filed on Jul. 20, 2012.
- (51) **Int. Cl.**
A61B 17/70 (2006.01)
A61F 2/30 (2006.01)
A61F 2/46 (2006.01)
A61B 17/88 (2006.01)
A61B 17/15 (2006.01)
- (52) **U.S. Cl.**
 CPC *A61B 17/7076* (2013.01); *A61B 17/88* (2013.01); *A61F 2/30* (2013.01); *A61F 2/30749* (2013.01); *A61F 2/4637* (2013.01); *A61B 17/15* (2013.01); *A61B 17/8875* (2013.01); *A61F 2002/30332* (2013.01); *A61F 2002/30378* (2013.01); *A61F 2002/30495* (2013.01); *A61F 2002/30617* (2013.01); *A61F 2002/4642* (2013.01)

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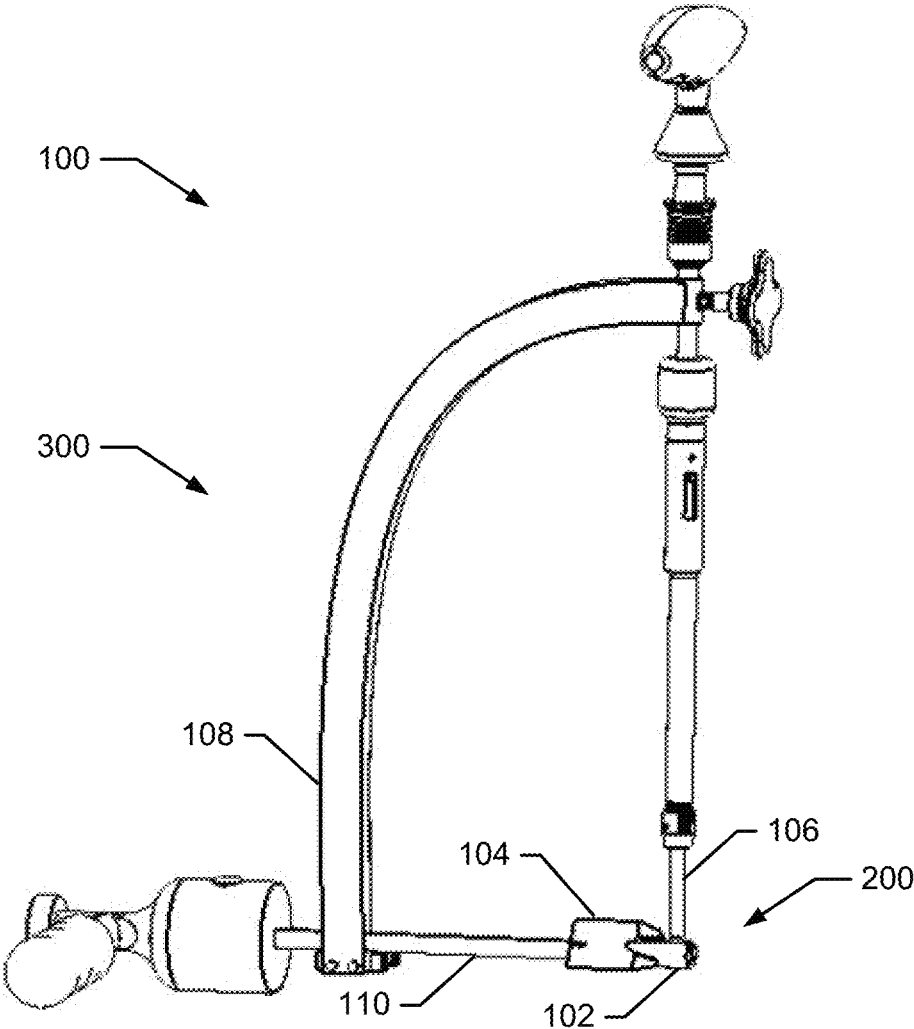


FIG. 1

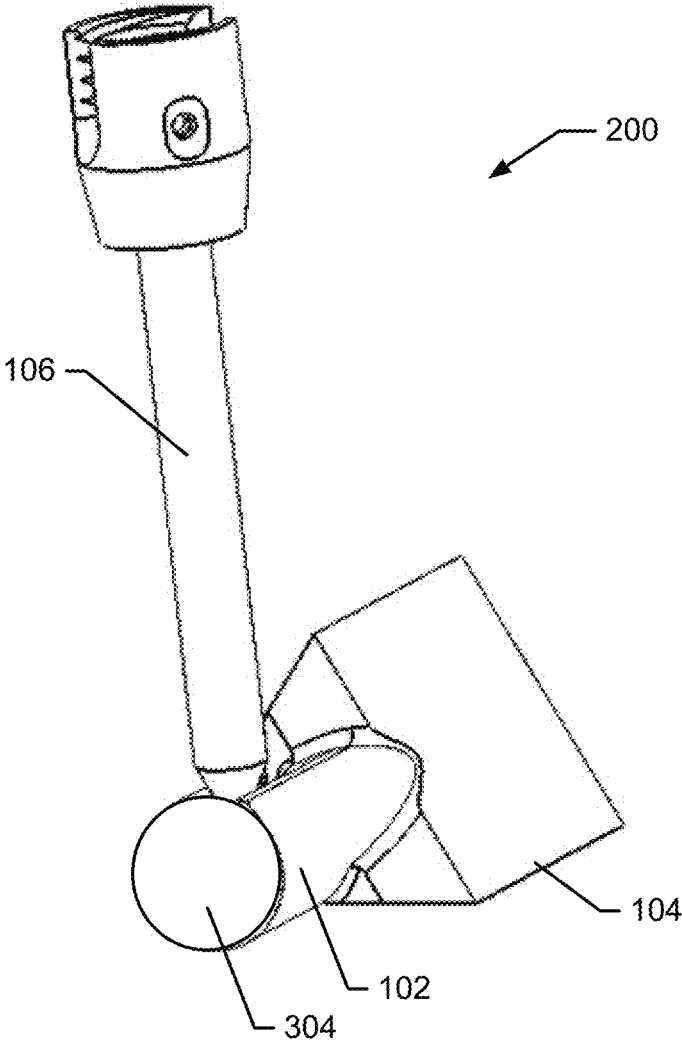


FIG. 2

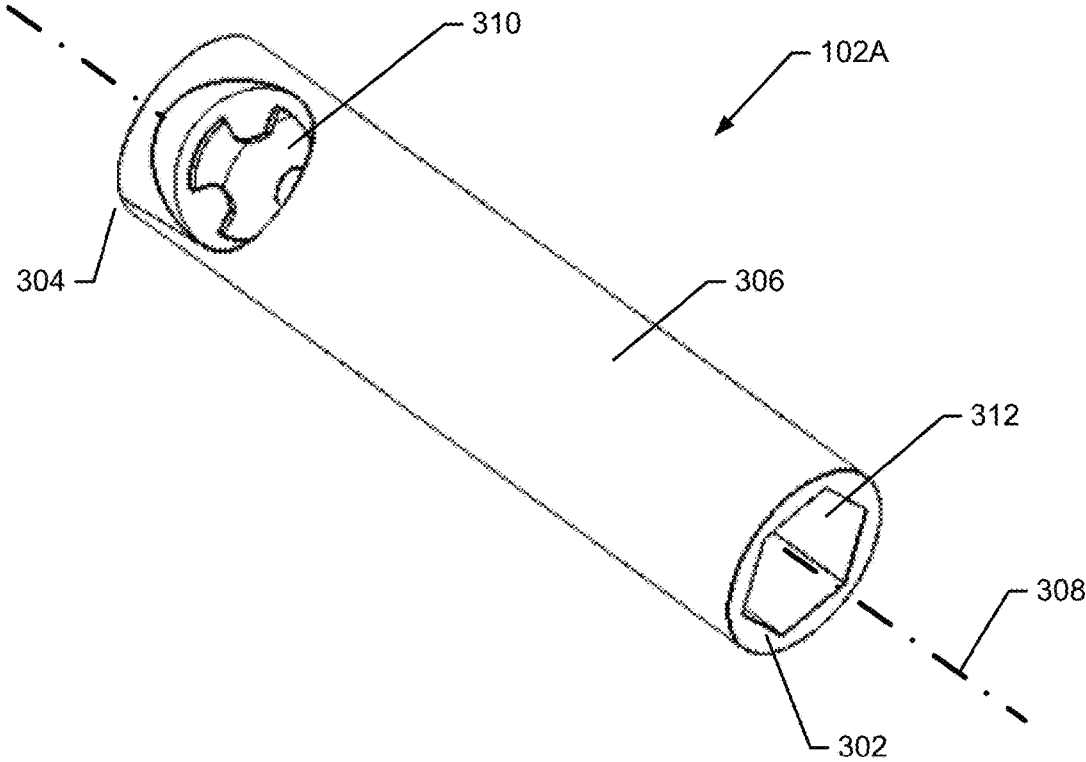


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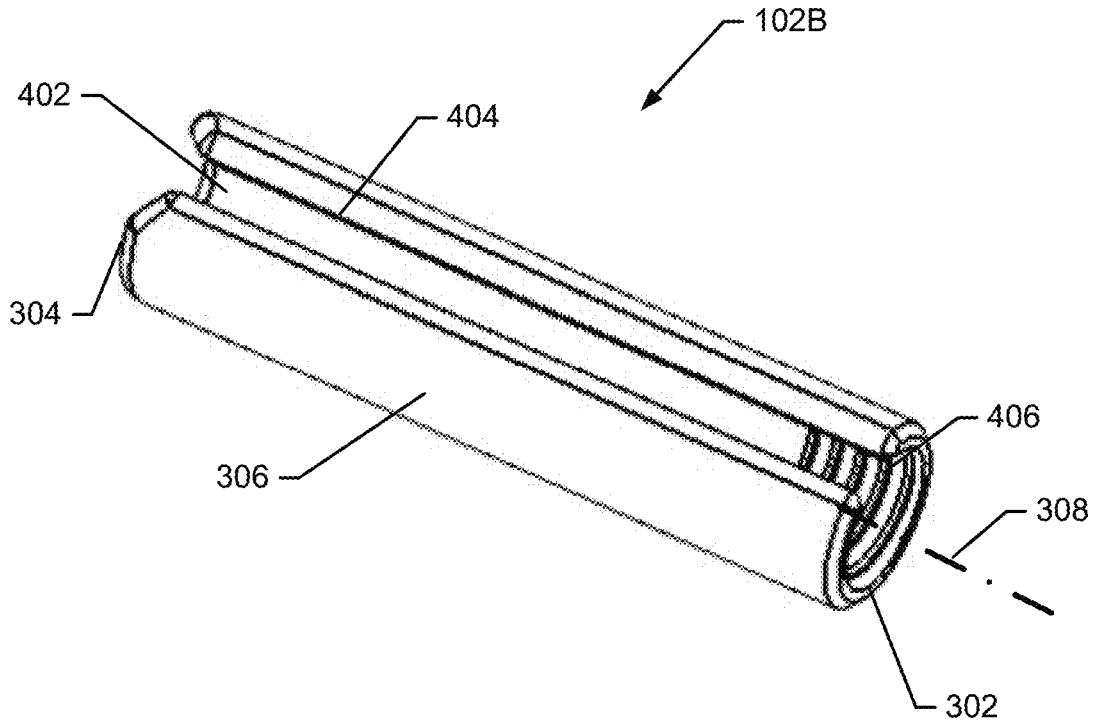


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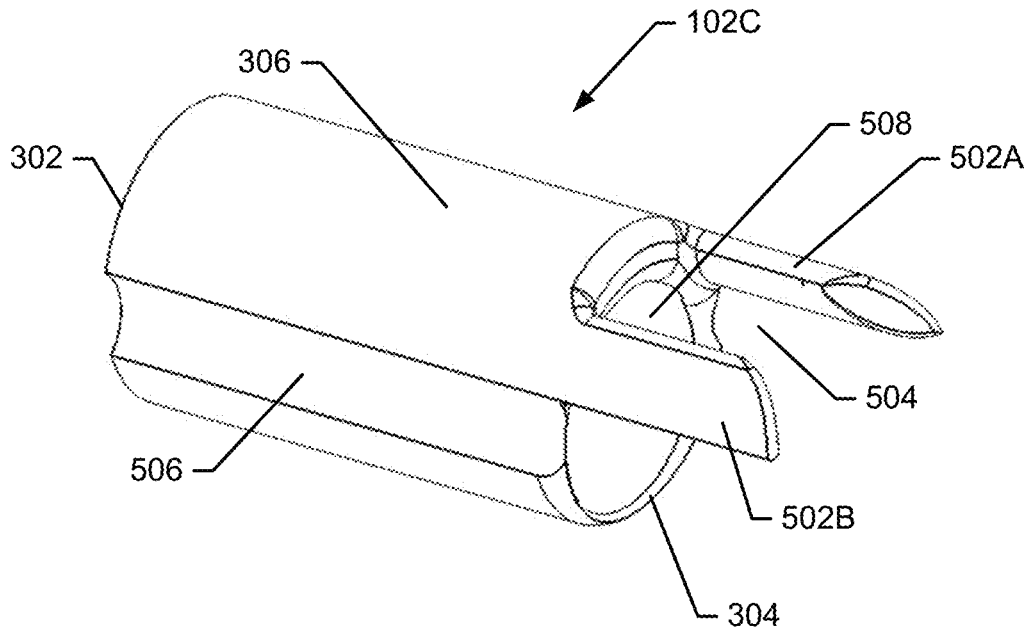


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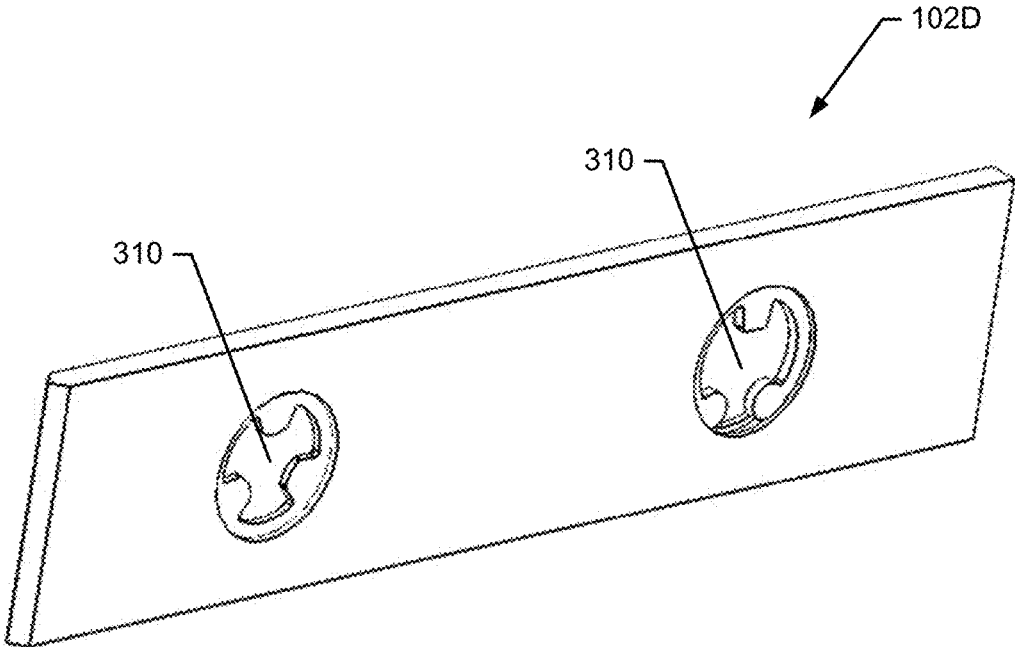


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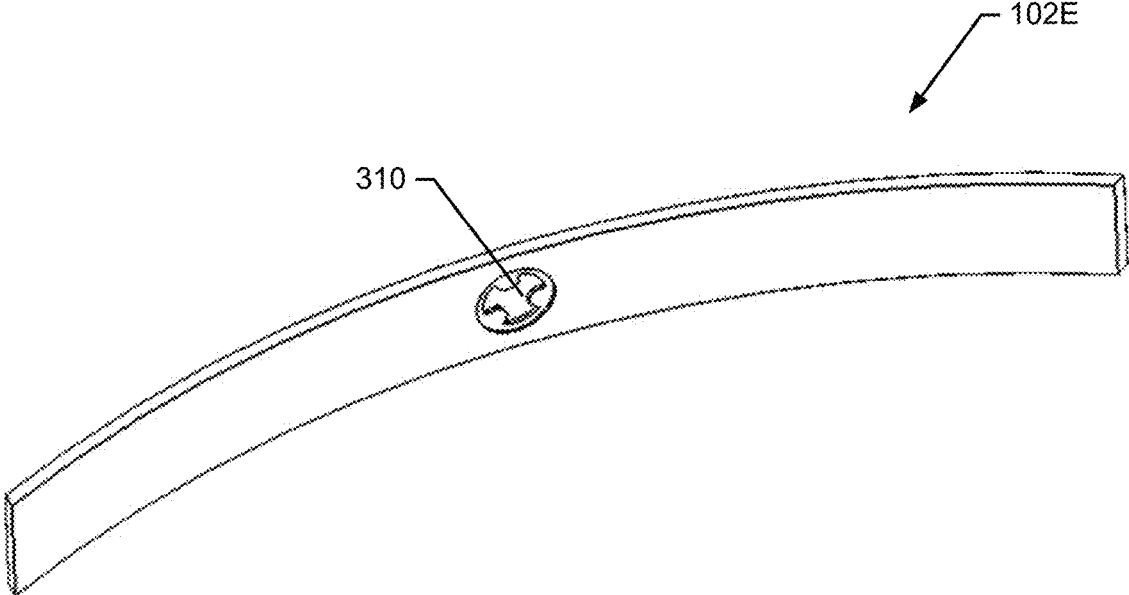
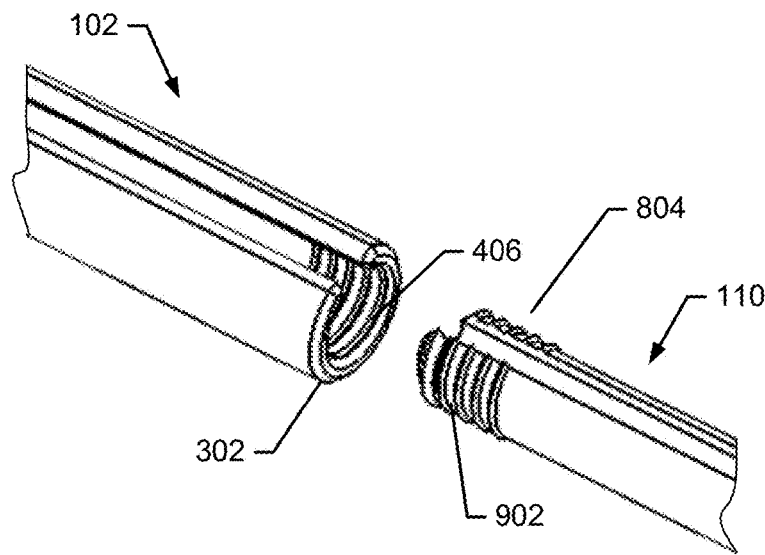
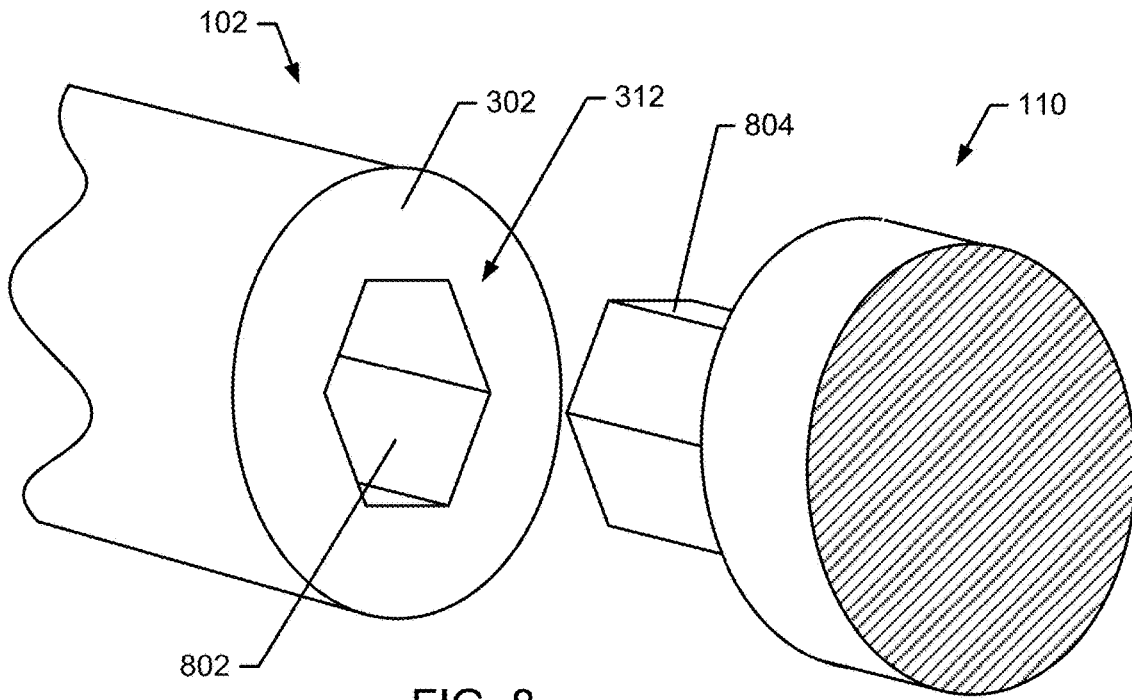


FIG. 7



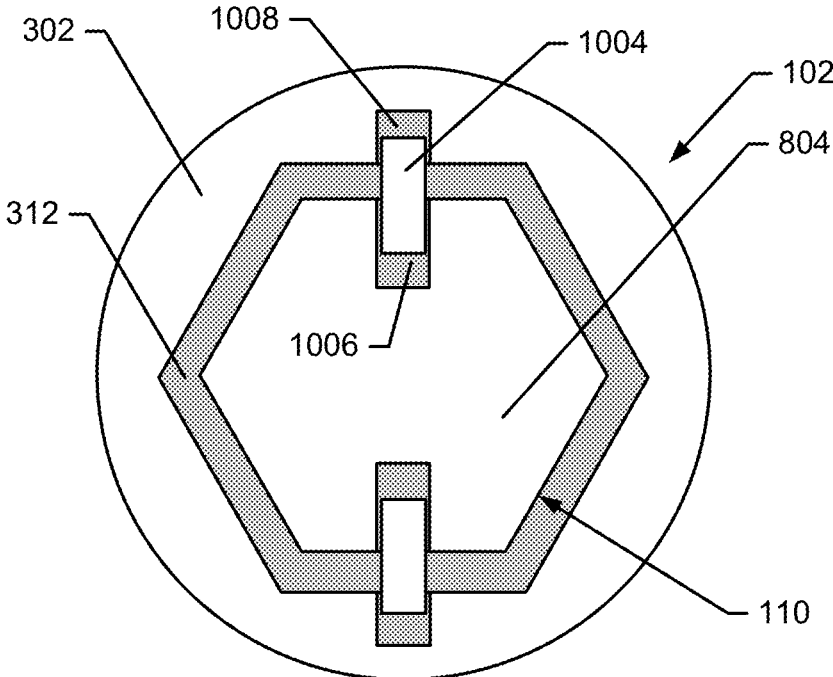


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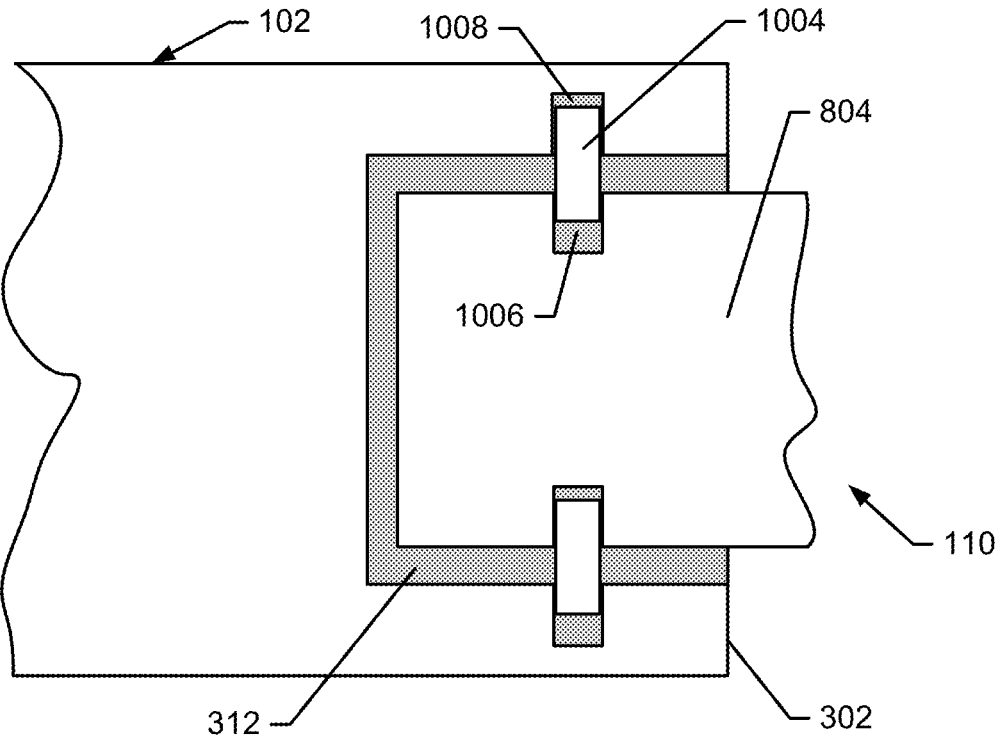


FIG. 11

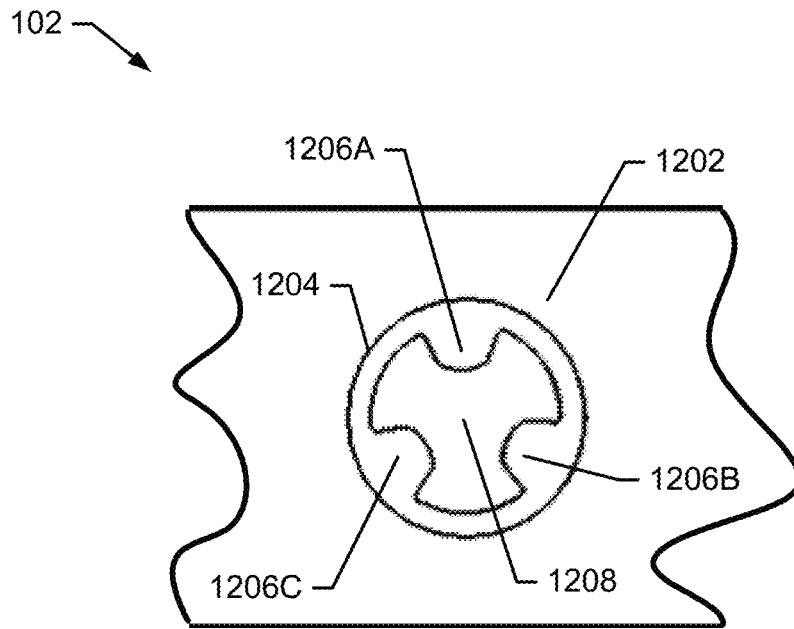


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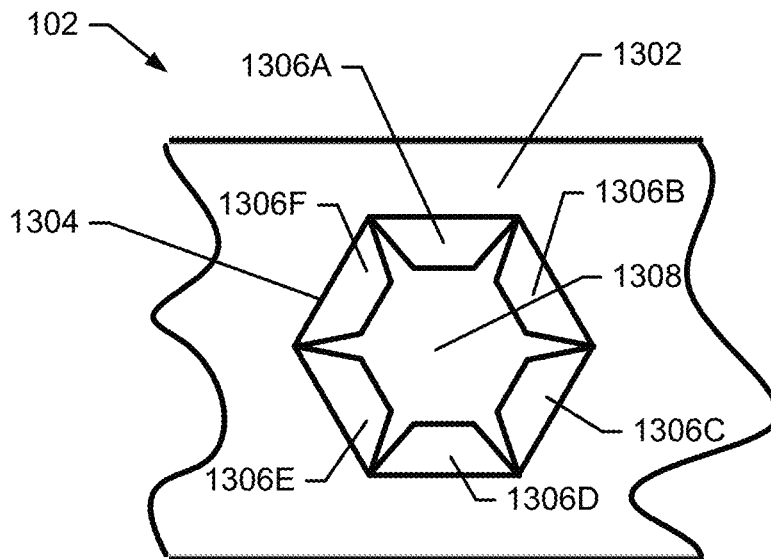


FIG. 13

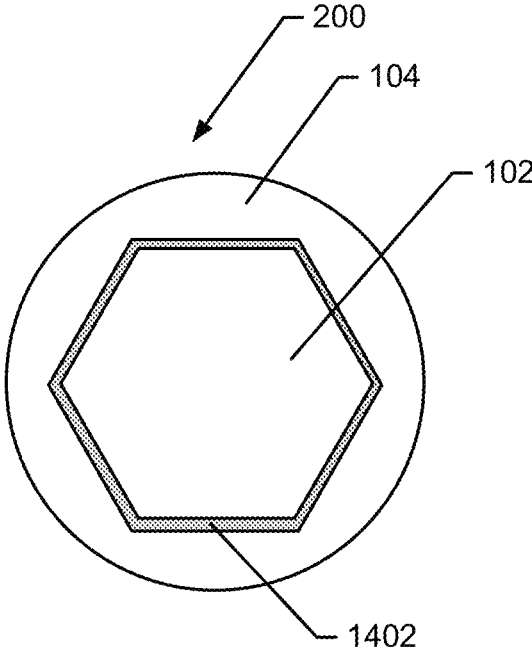


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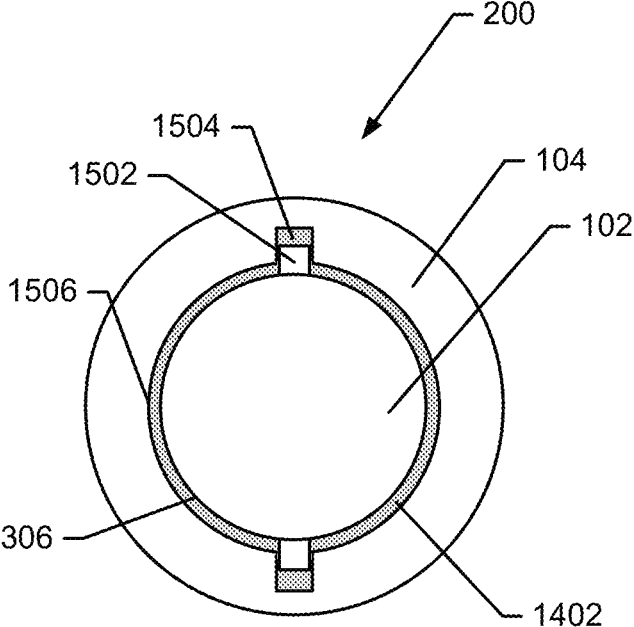


FIG. 15

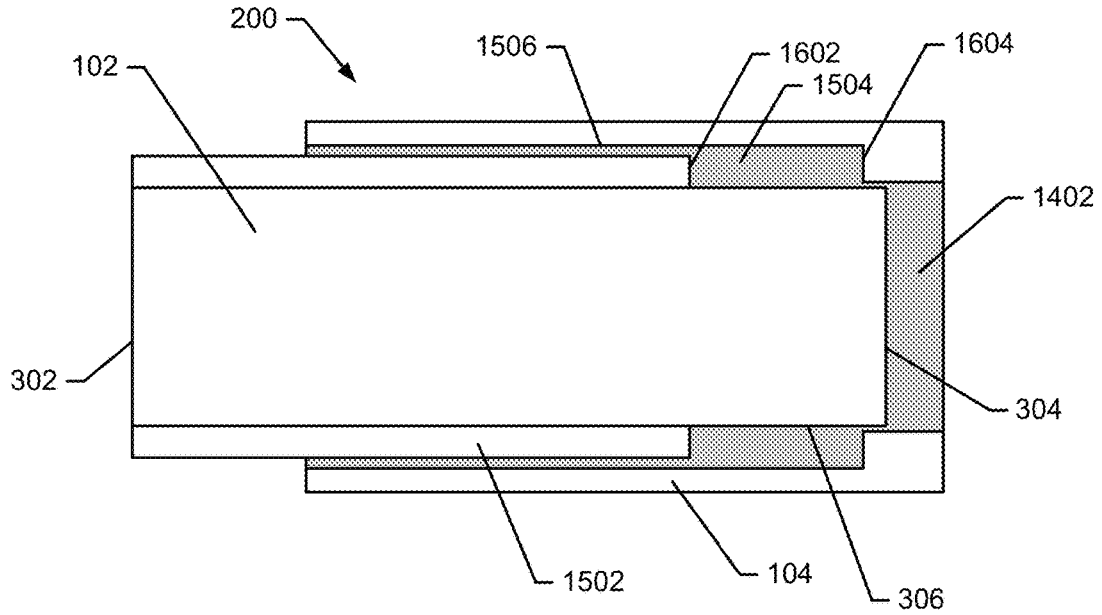


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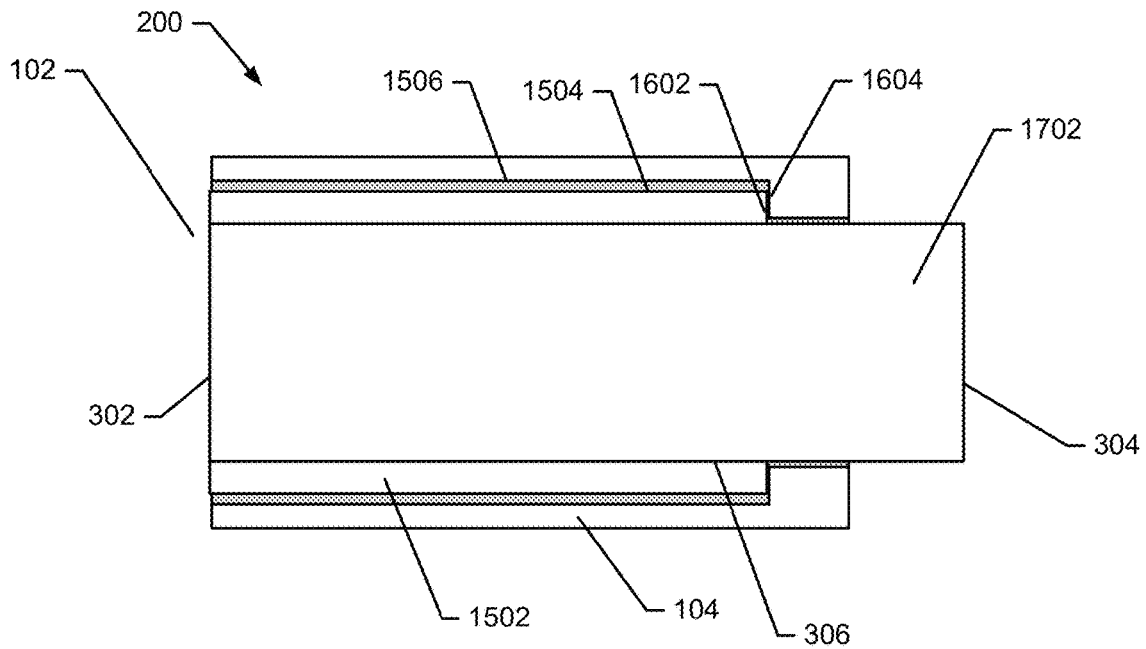


FIG. 17

FIG. 18A

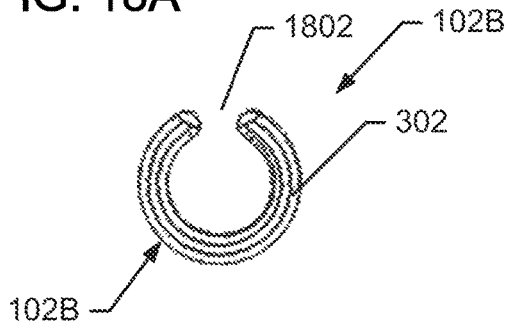


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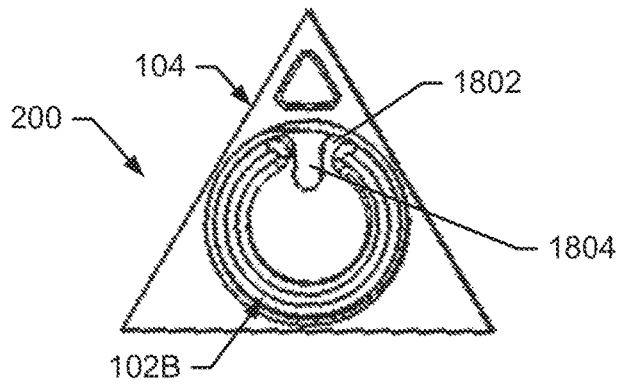
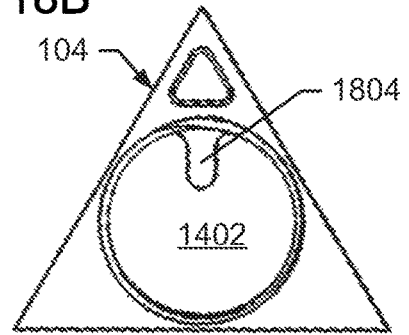


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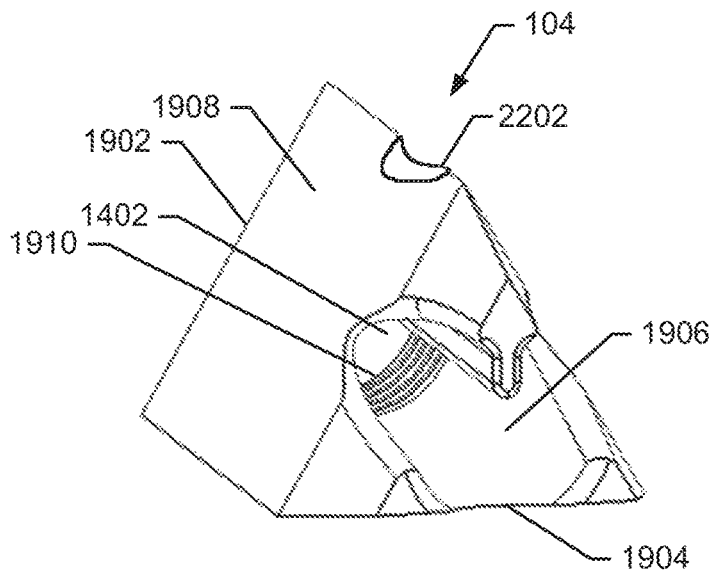


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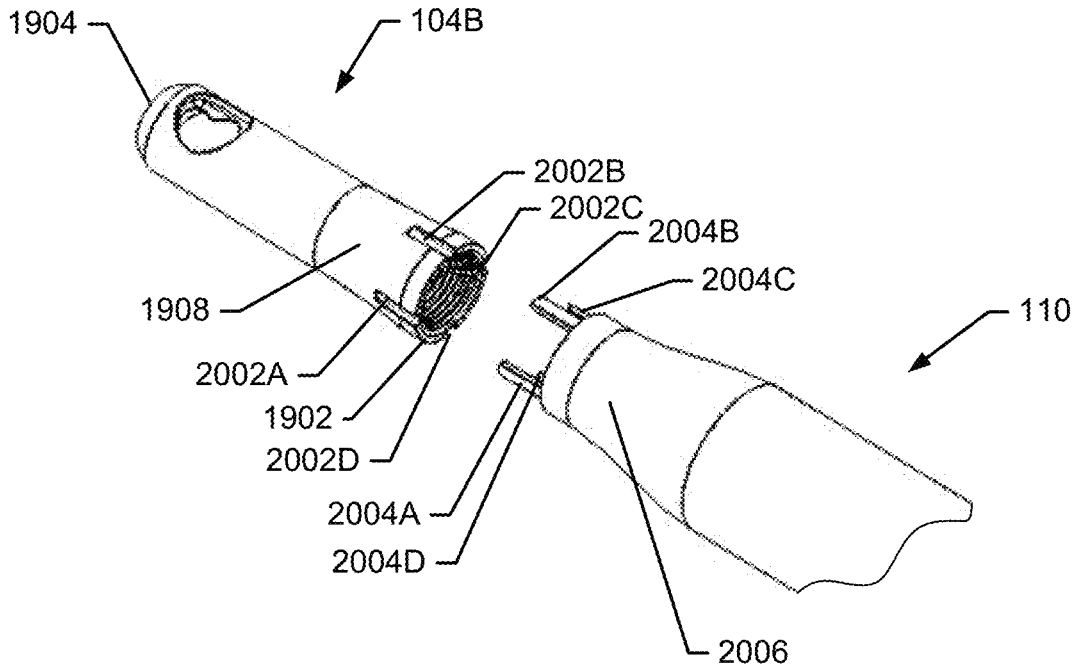


FIG. 20

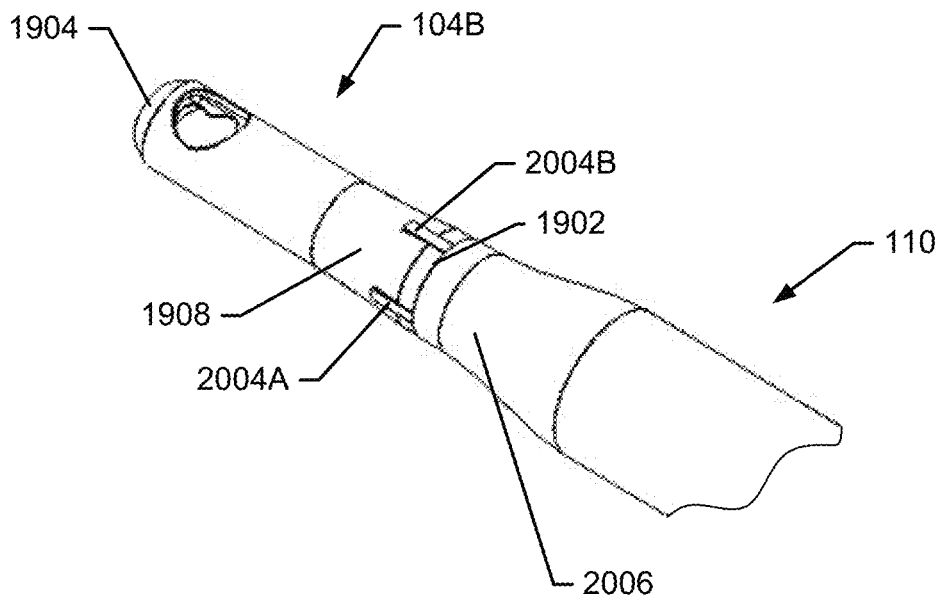


FIG. 21

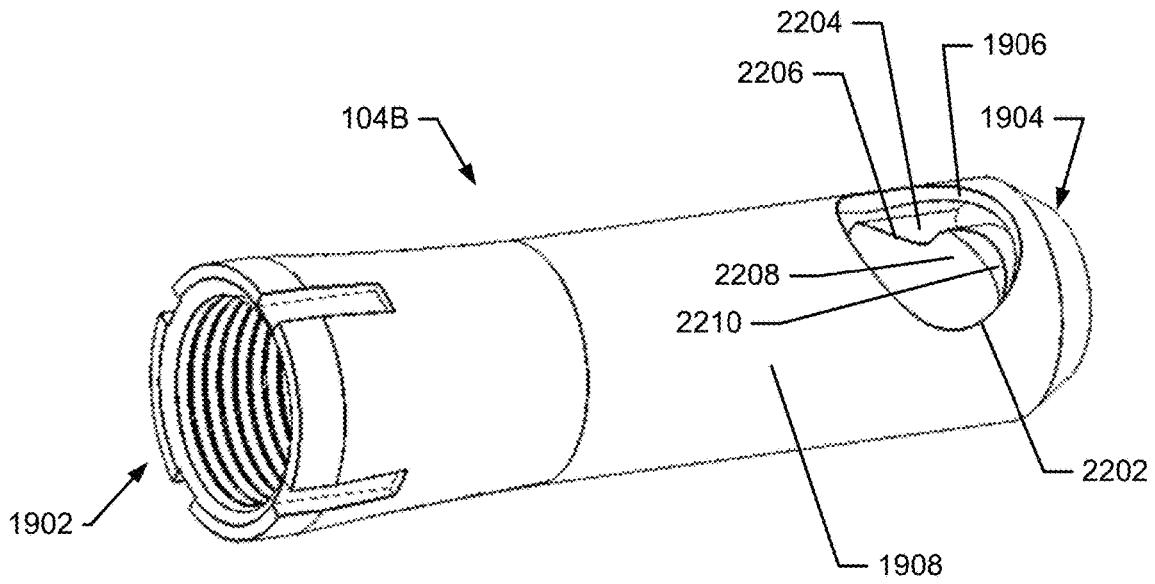


FIG. 22

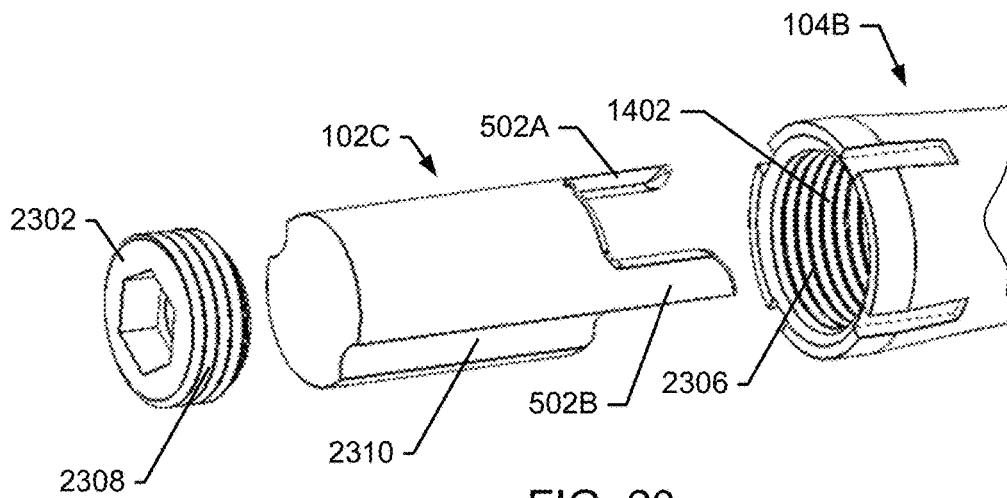


FIG. 23

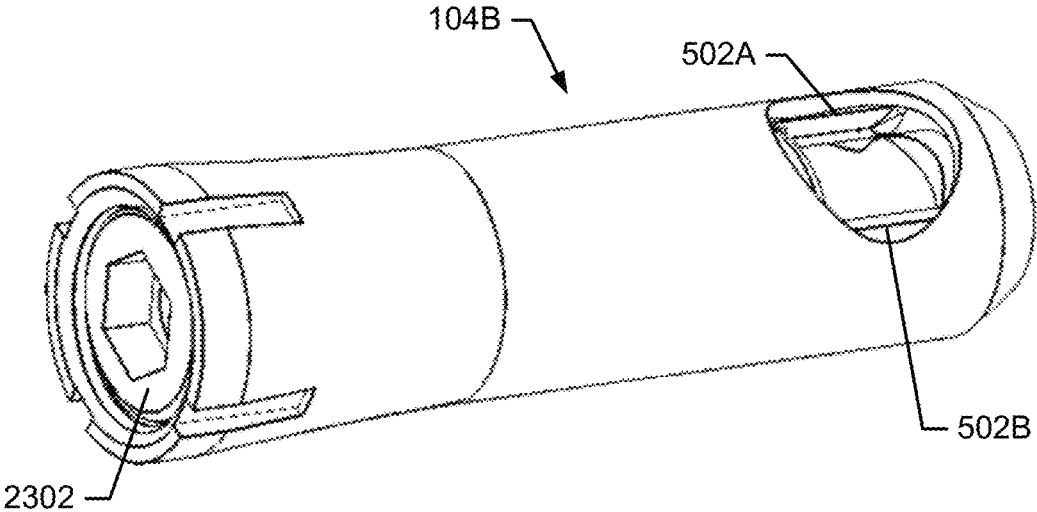


FIG. 24

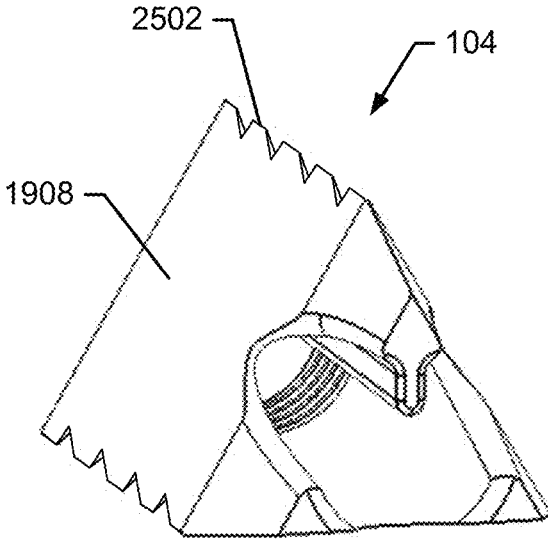


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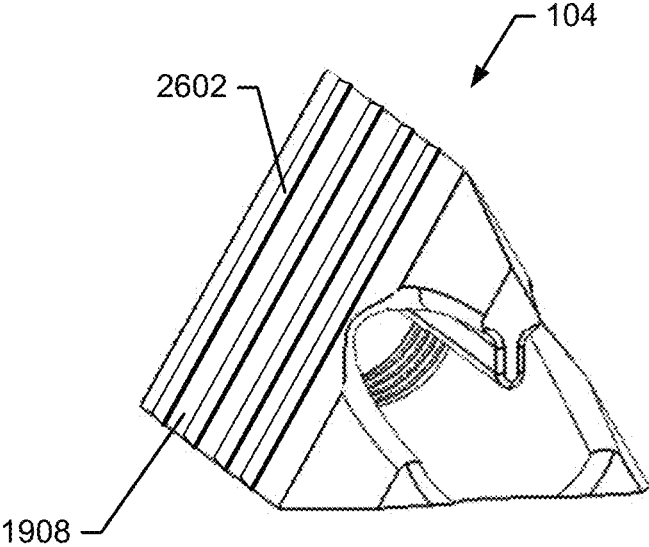


FIG. 26

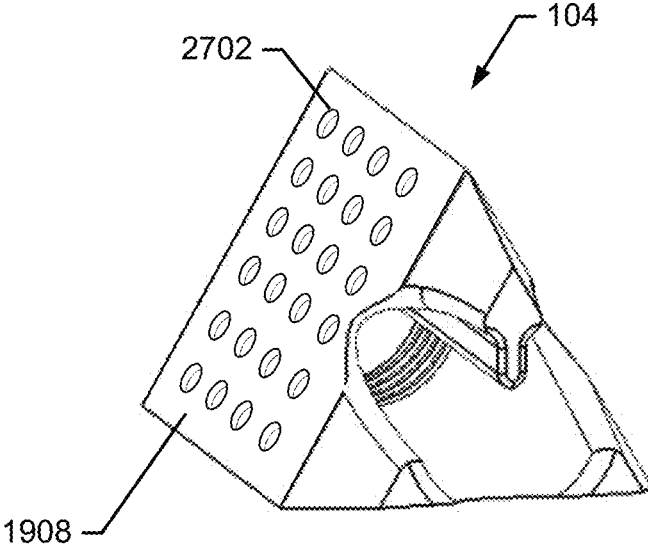


FIG. 27

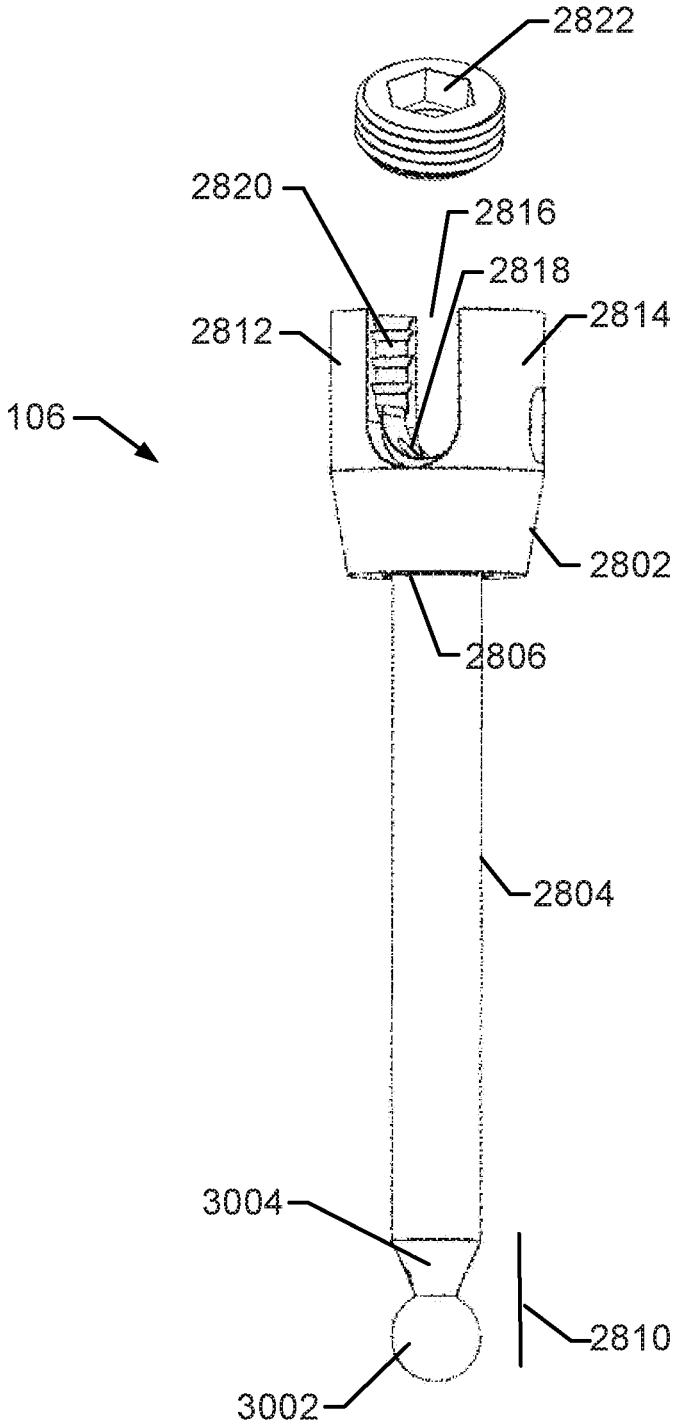


FIG. 28

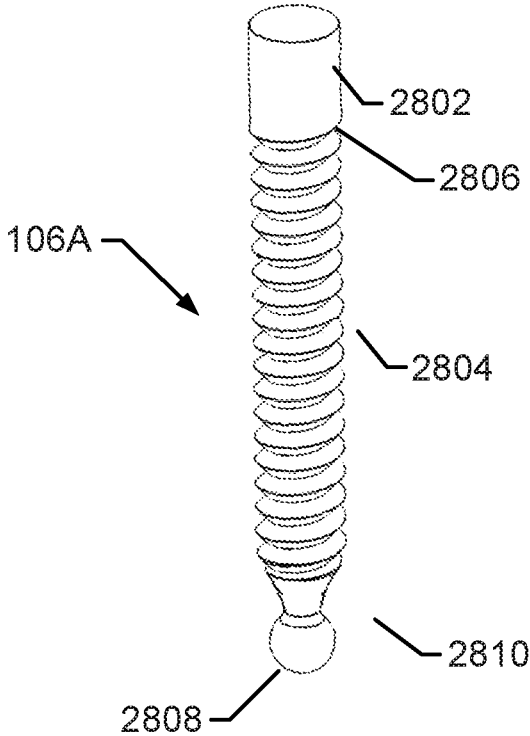


FIG. 29

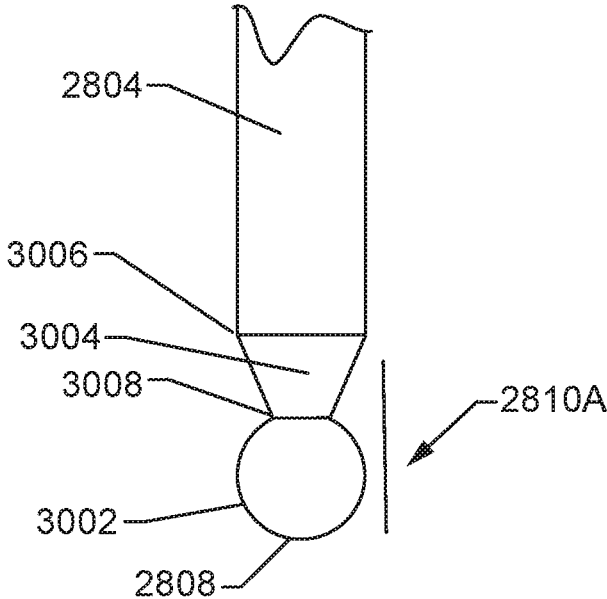


FIG. 30

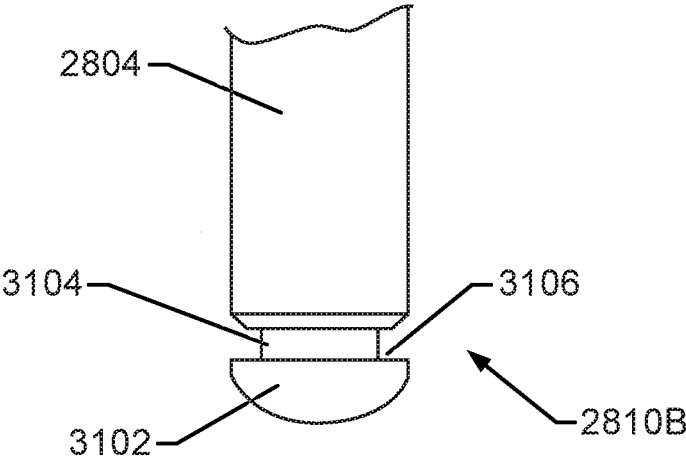


FIG. 31

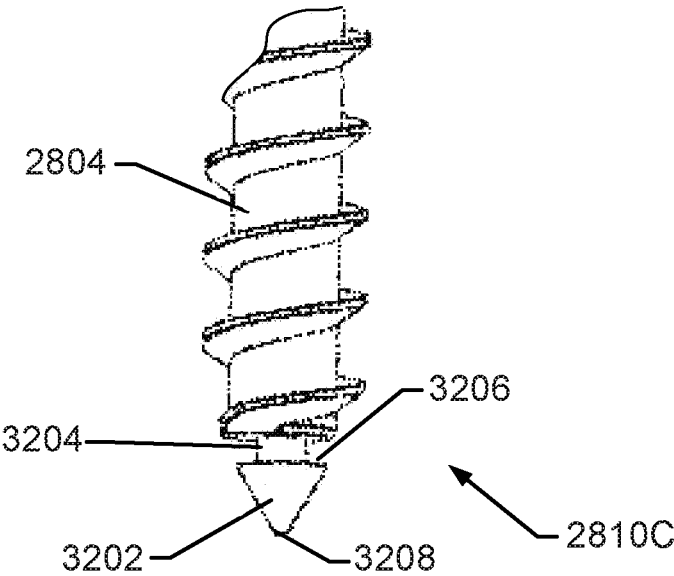


FIG. 32

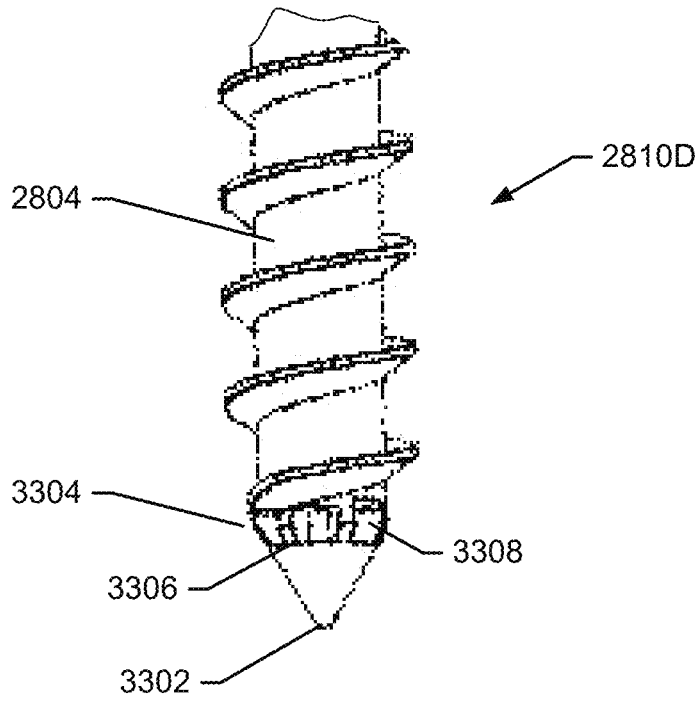


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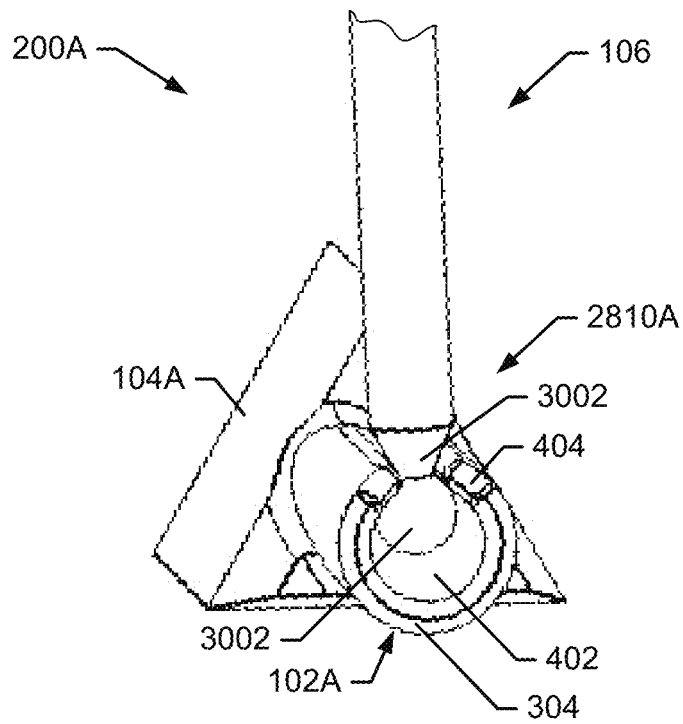


FIG. 34

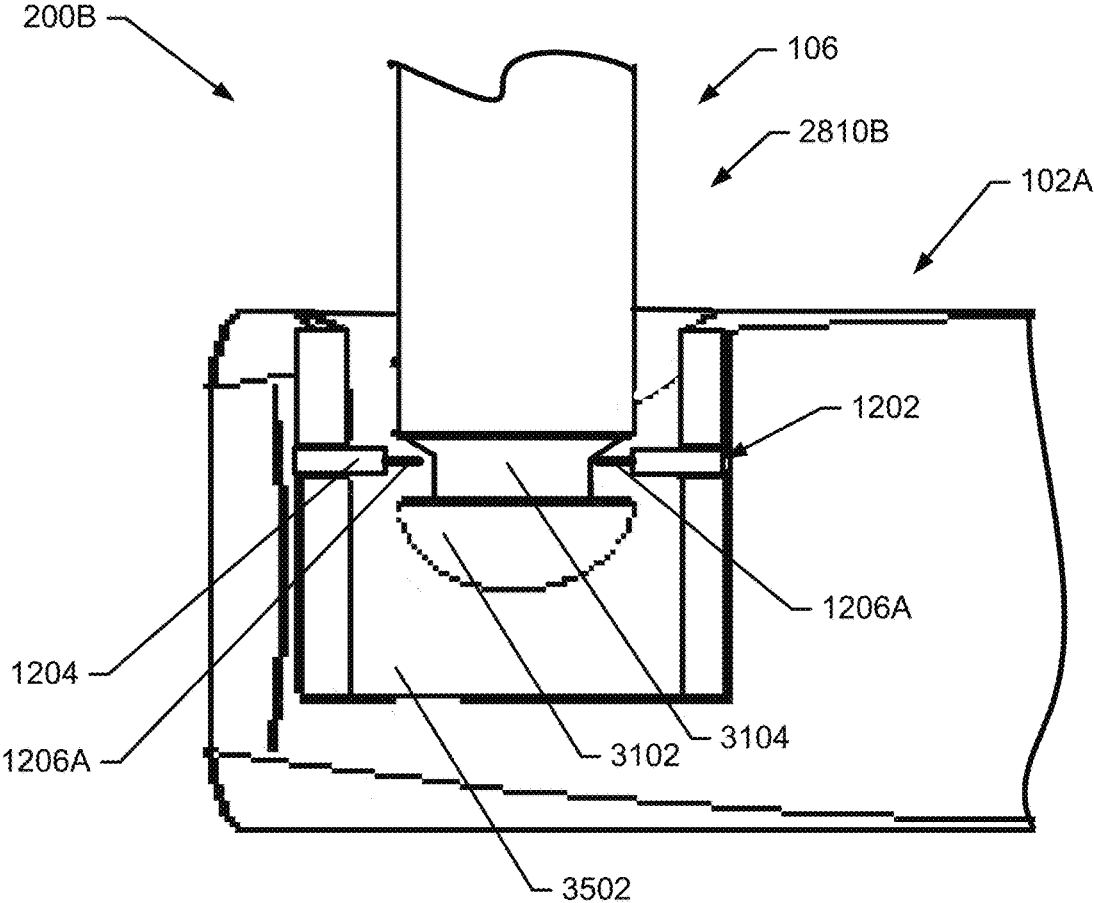


FIG. 35

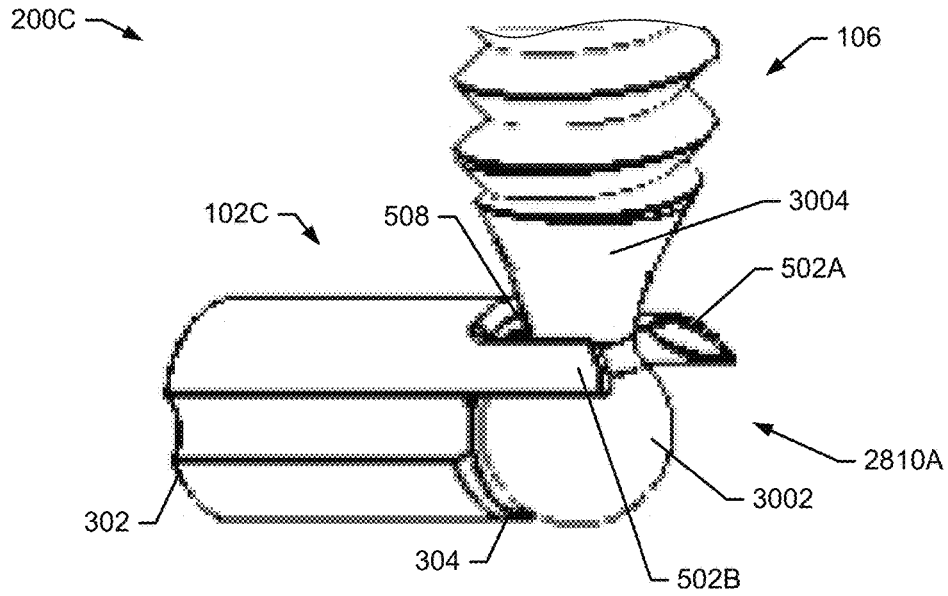


FIG. 36

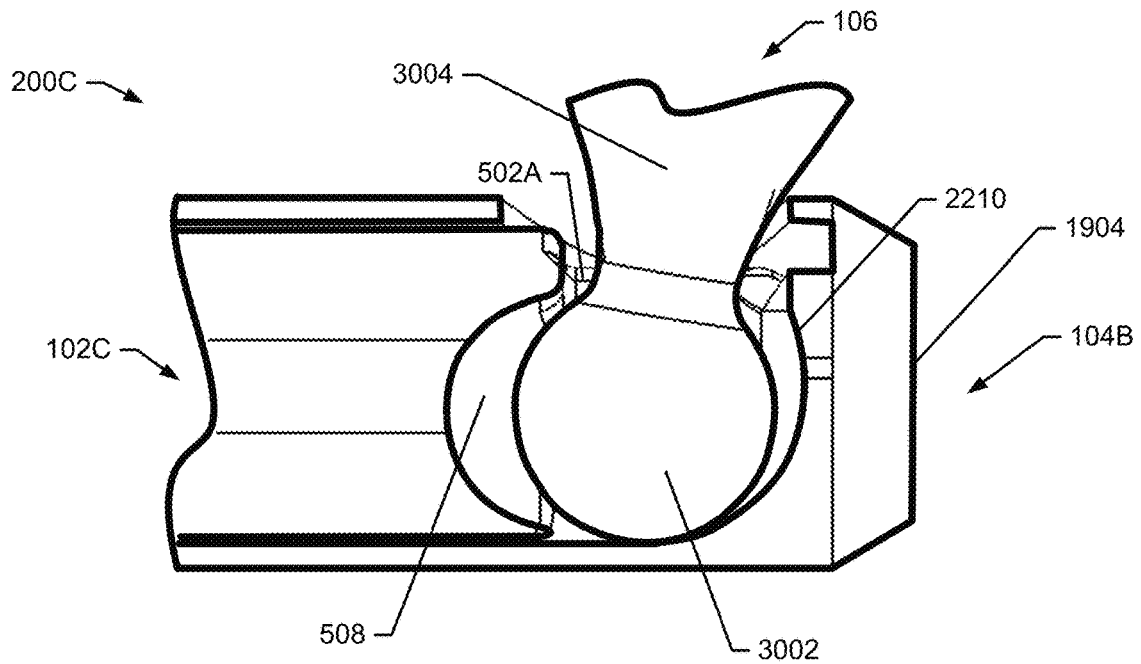


FIG. 37

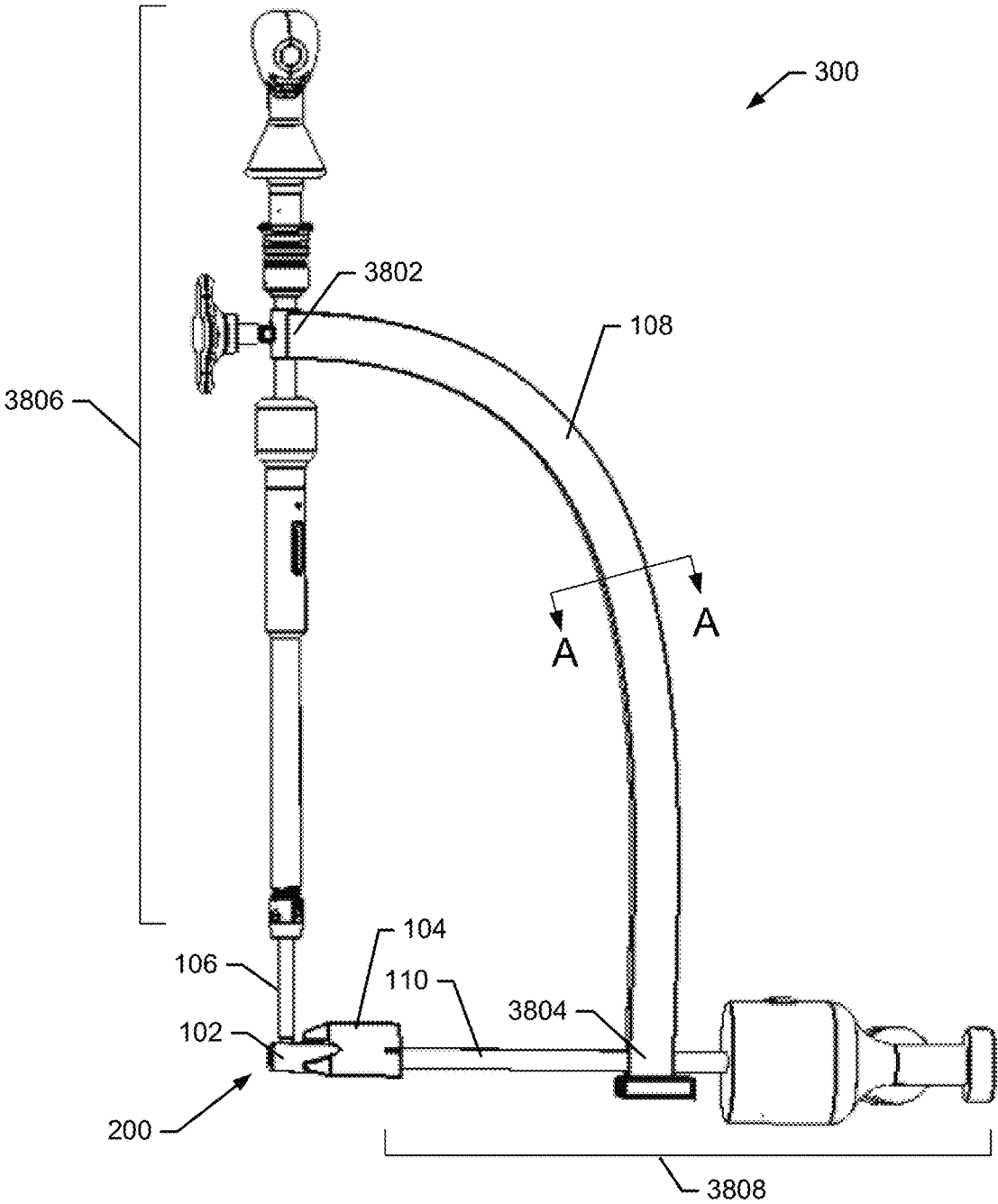


FIG. 38

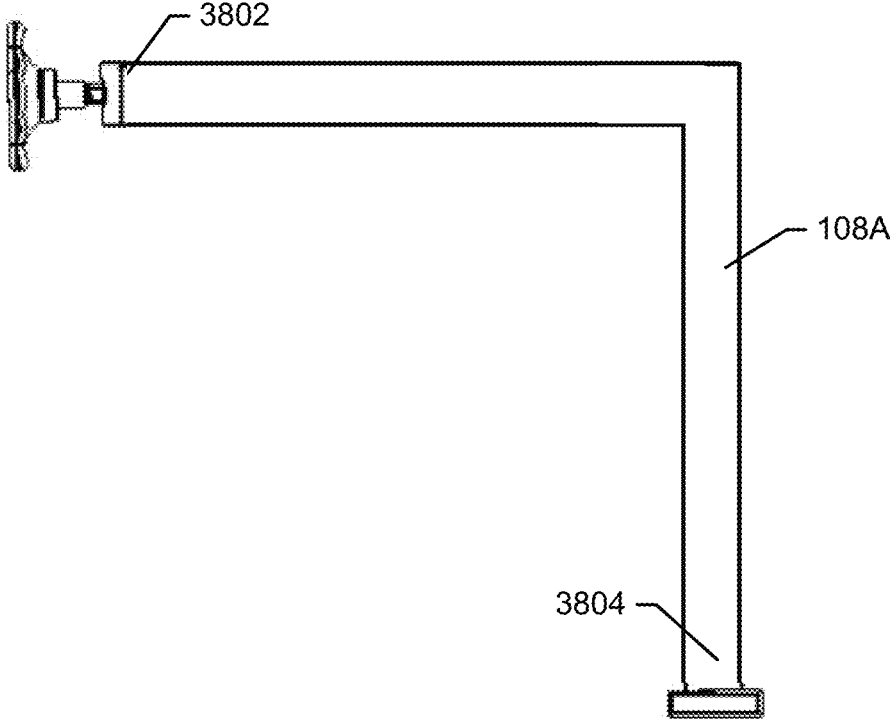


FIG. 39

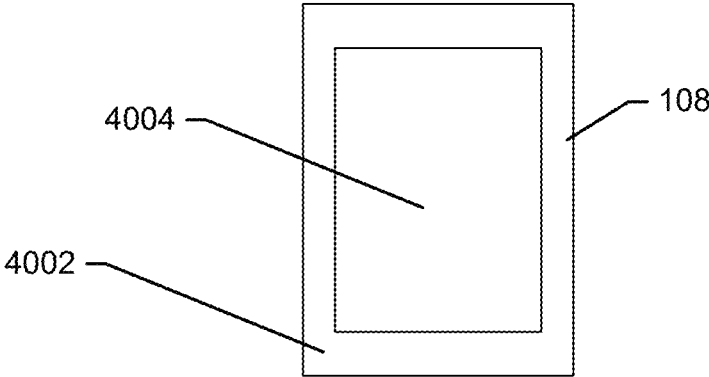


FIG. 40

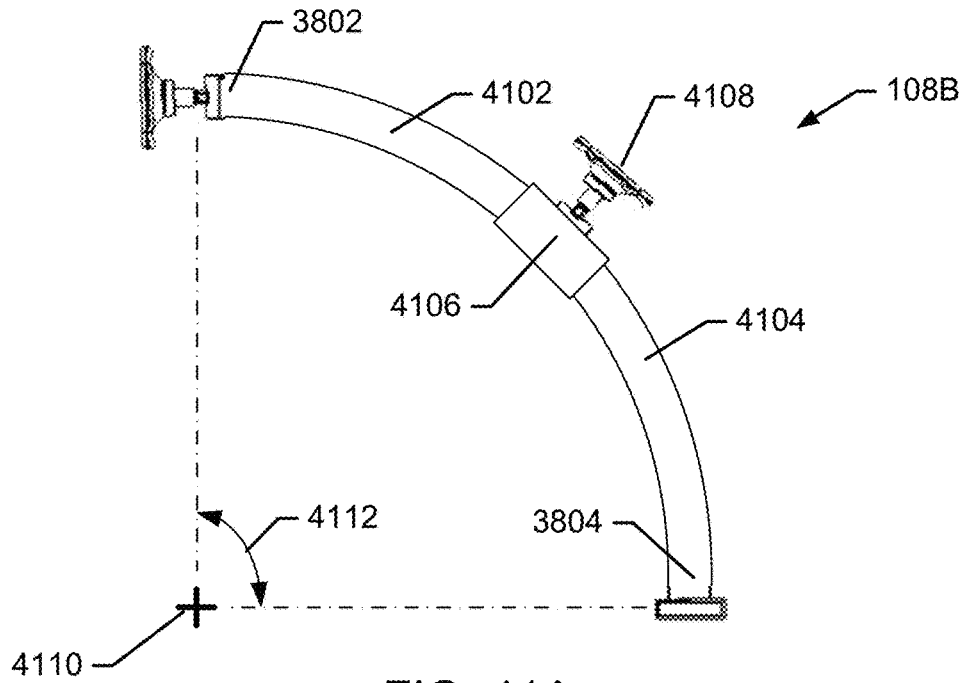


FIG. 41A

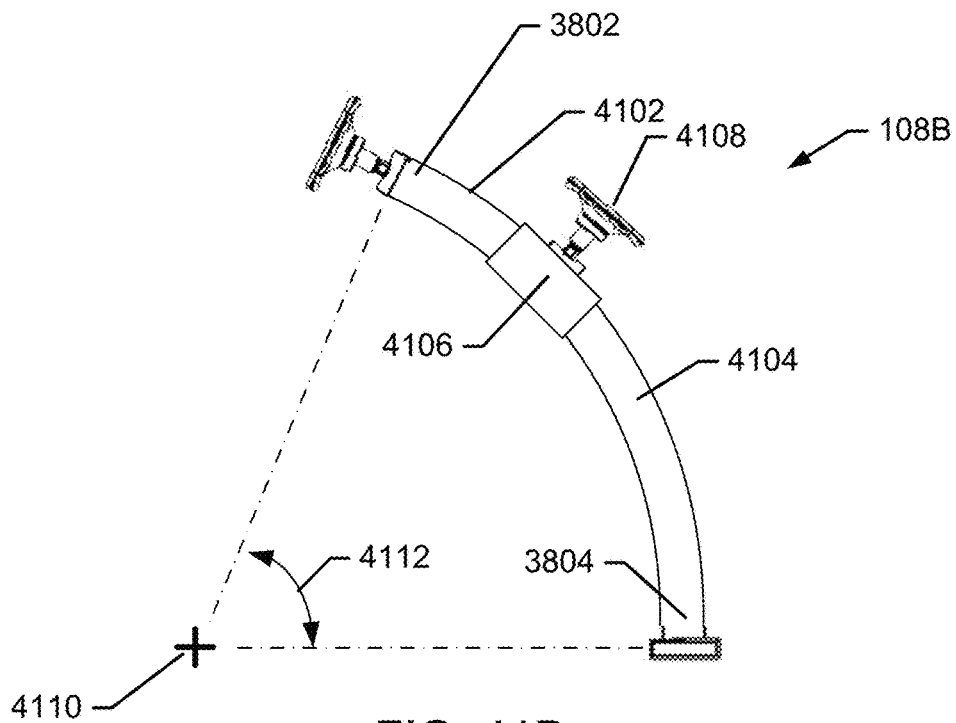


FIG. 41B

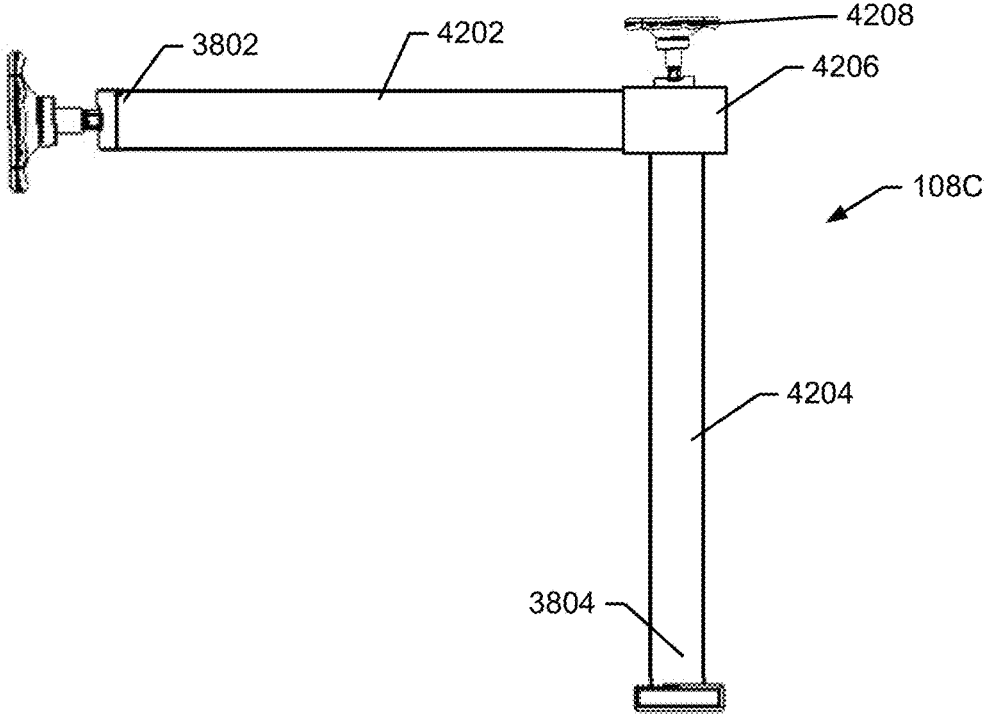


FIG. 42A

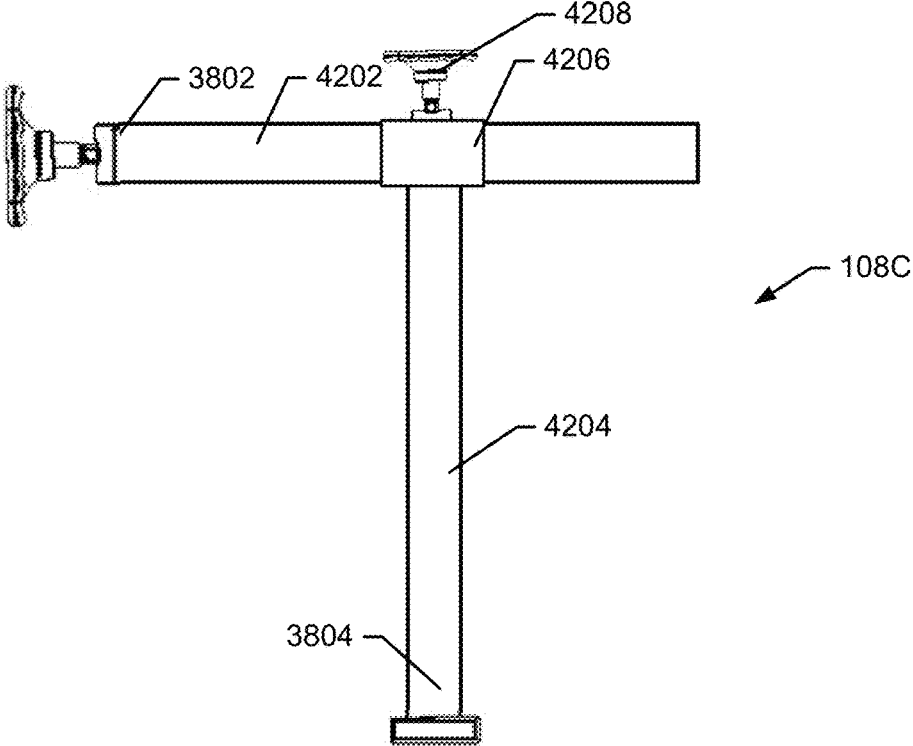


FIG. 42B

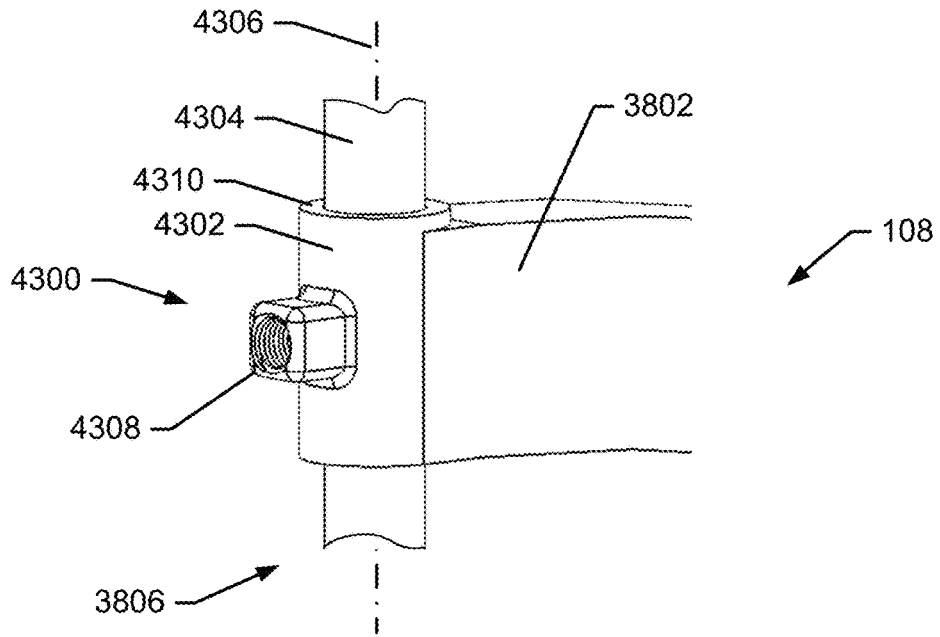


FIG. 43A

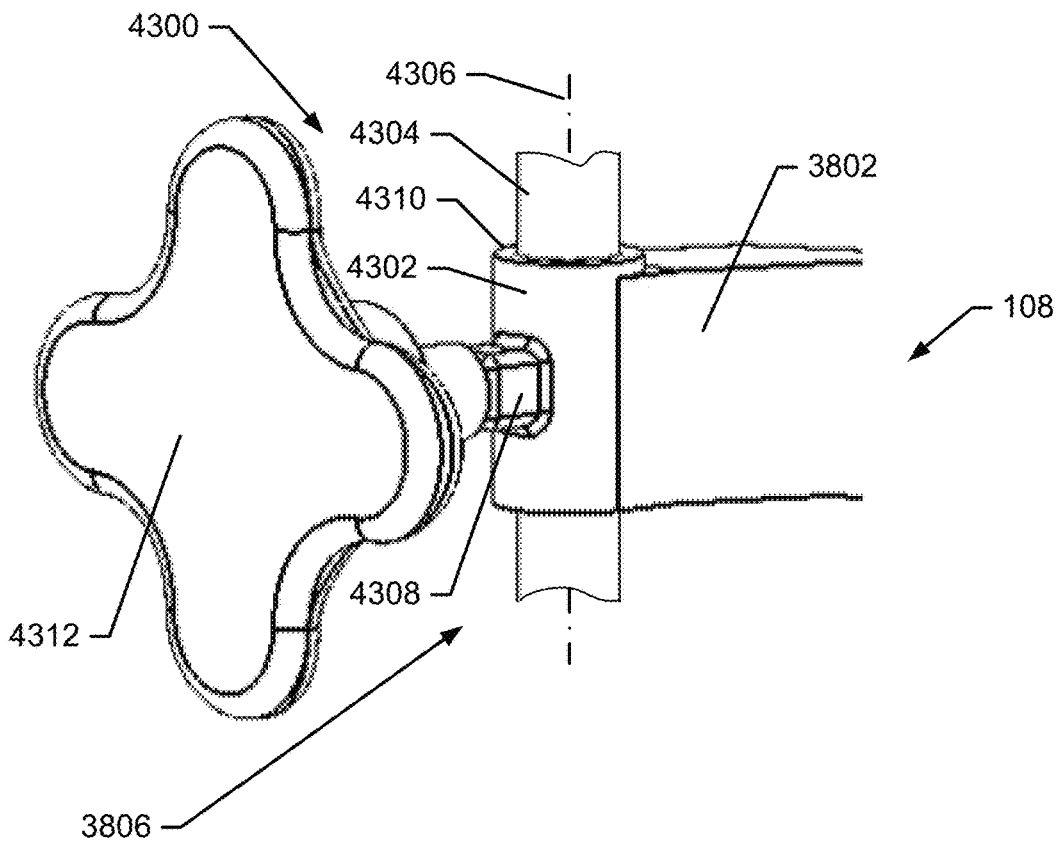


FIG. 43B

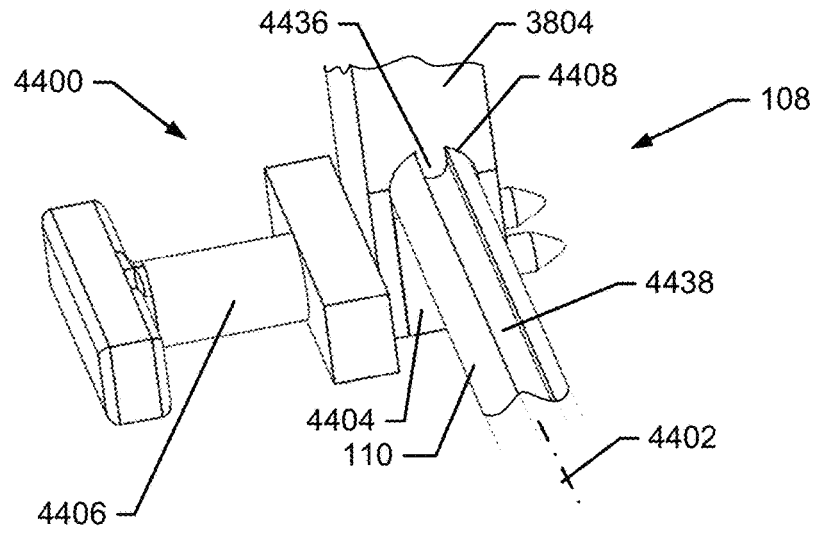


FIG. 44A

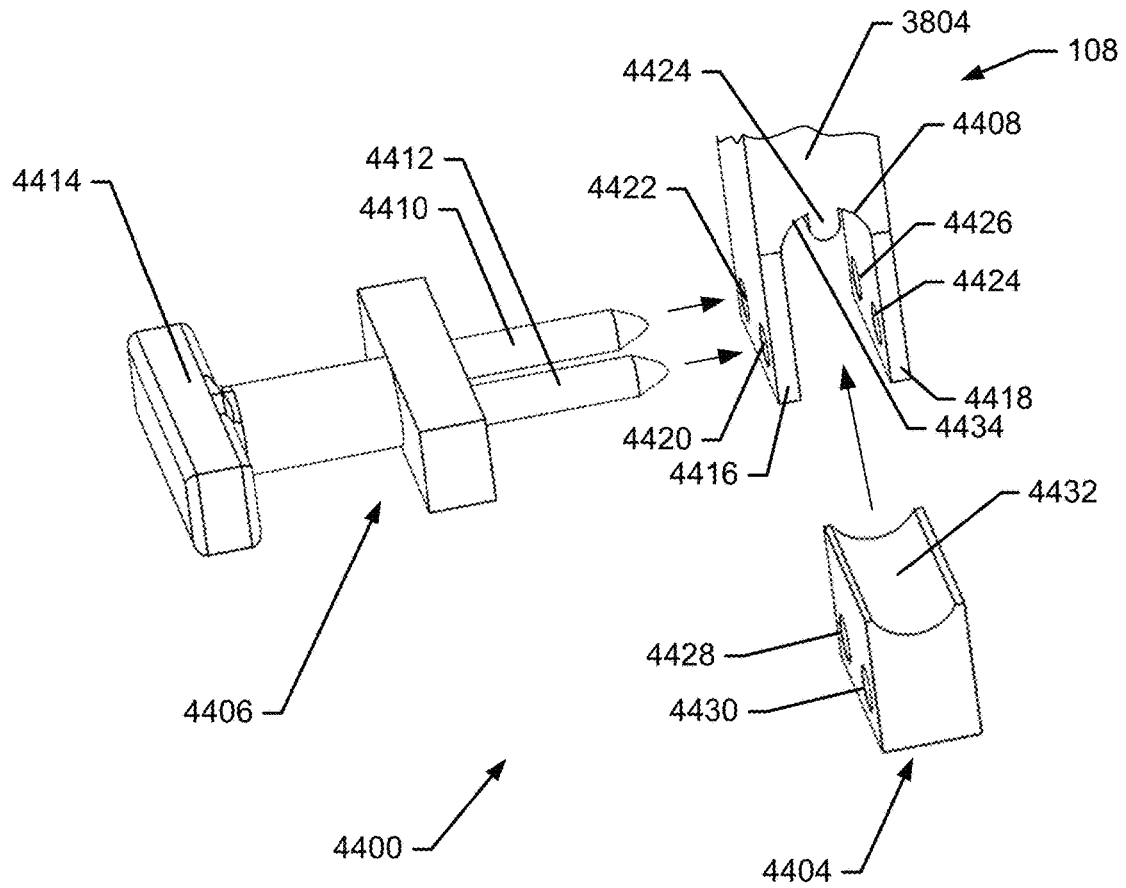


FIG. 44B

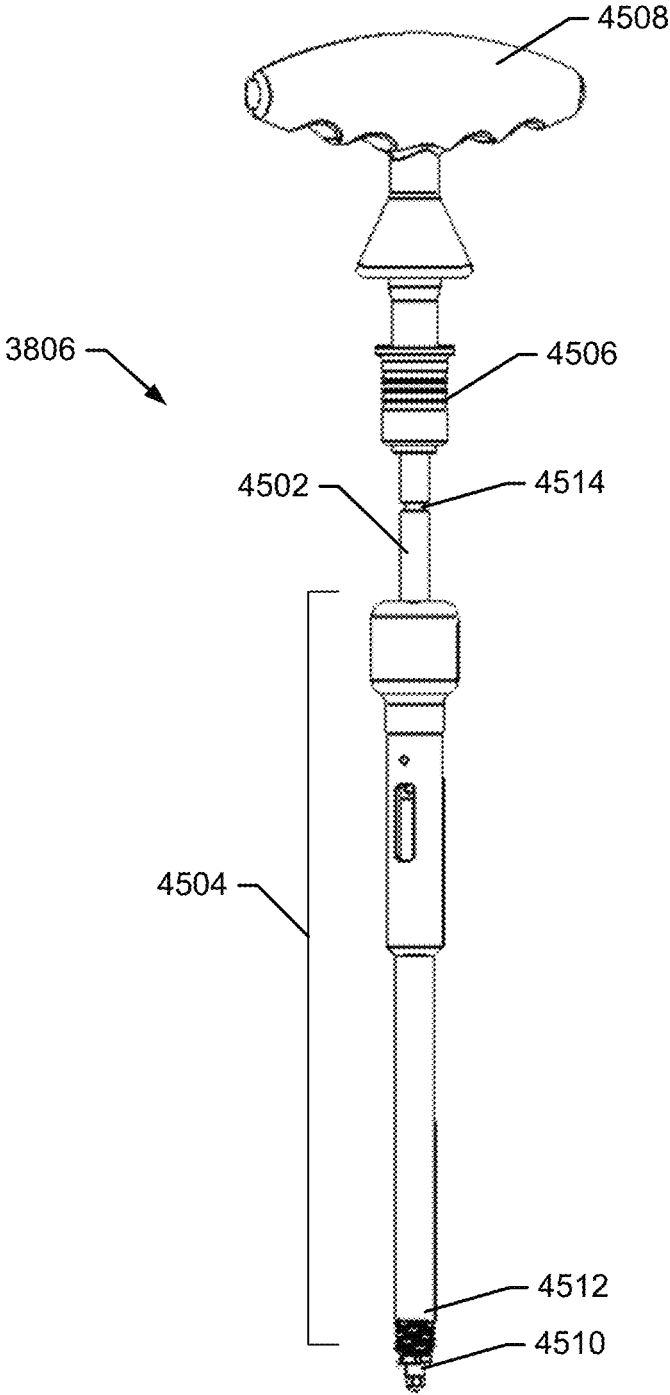


FIG. 45

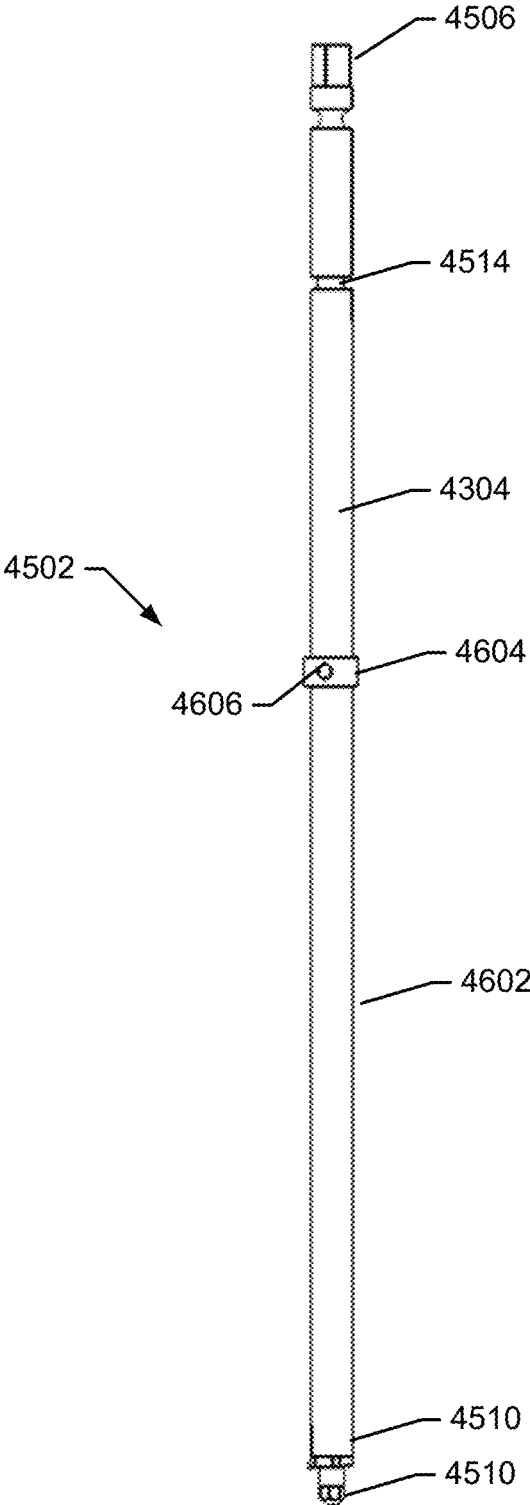


FIG. 46

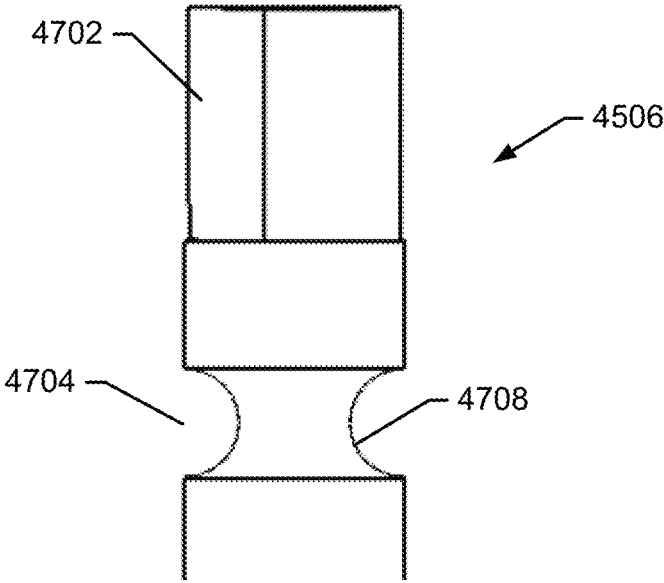


FIG. 47

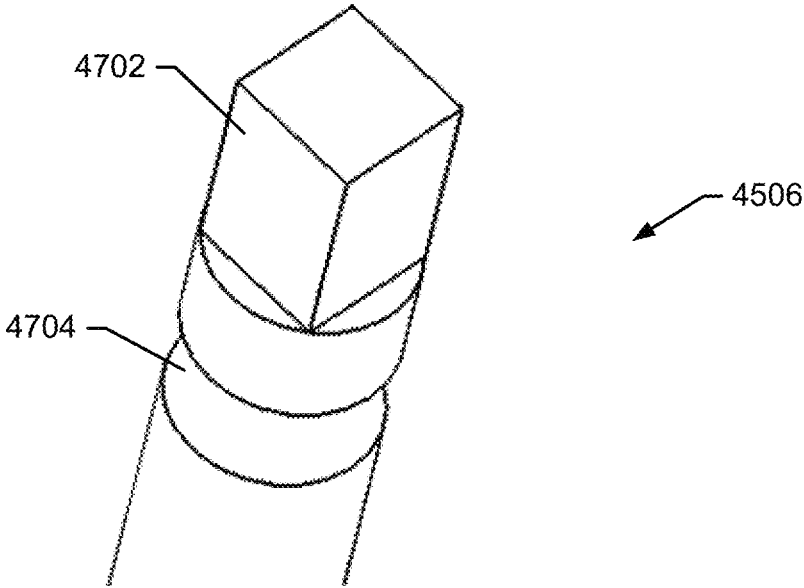


FIG. 48

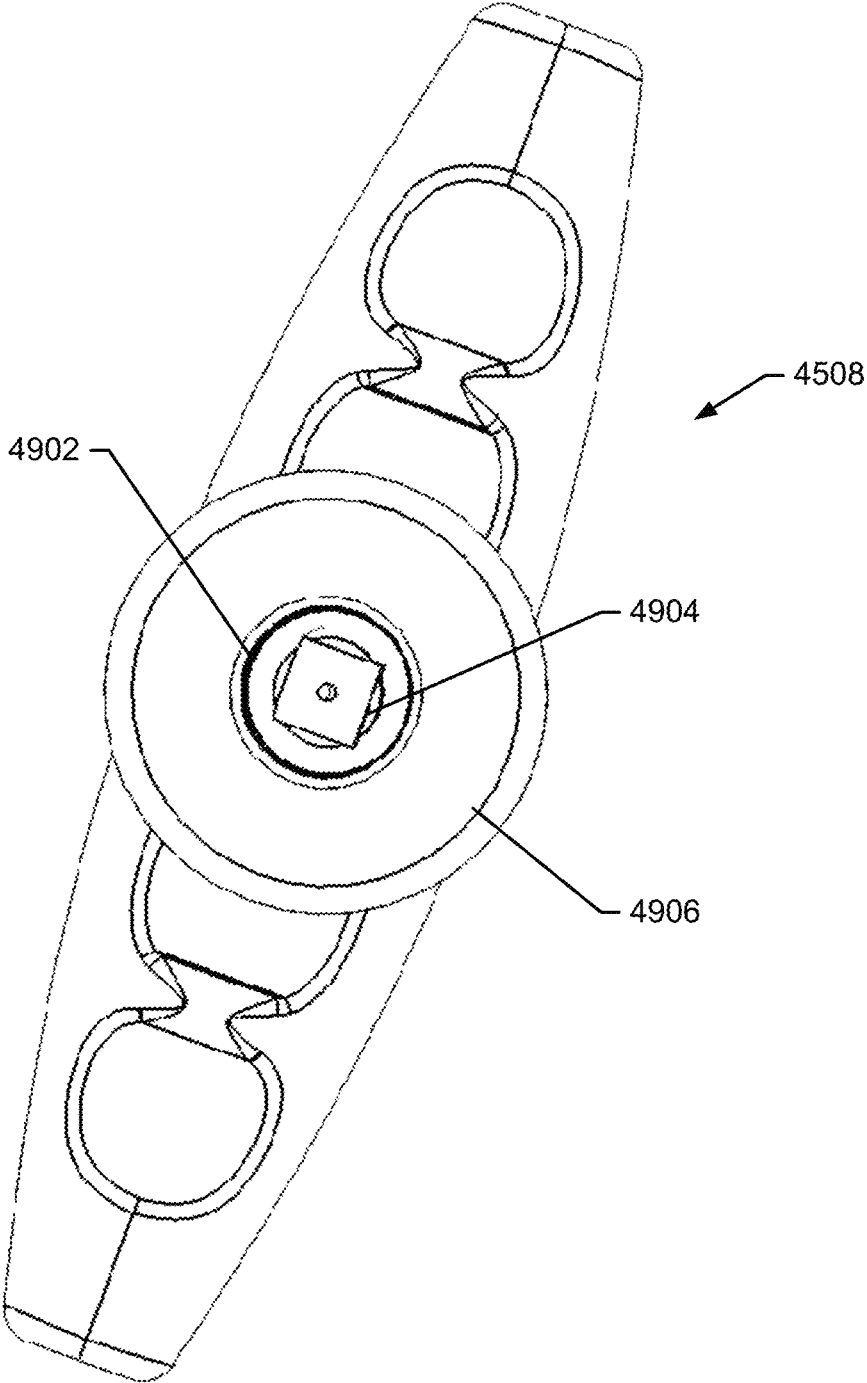


FIG. 49

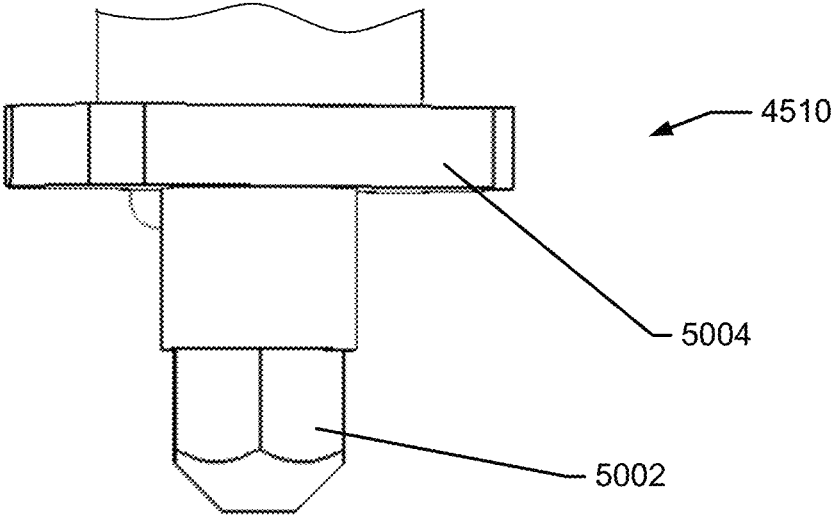


FIG. 50

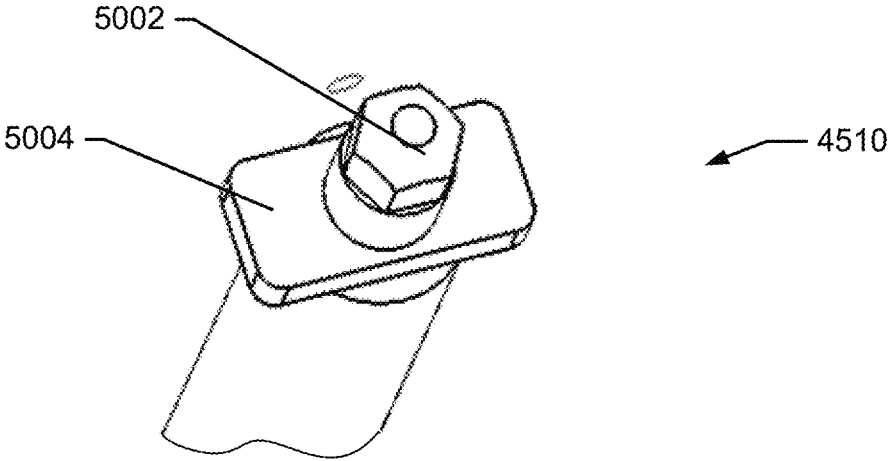


FIG. 51

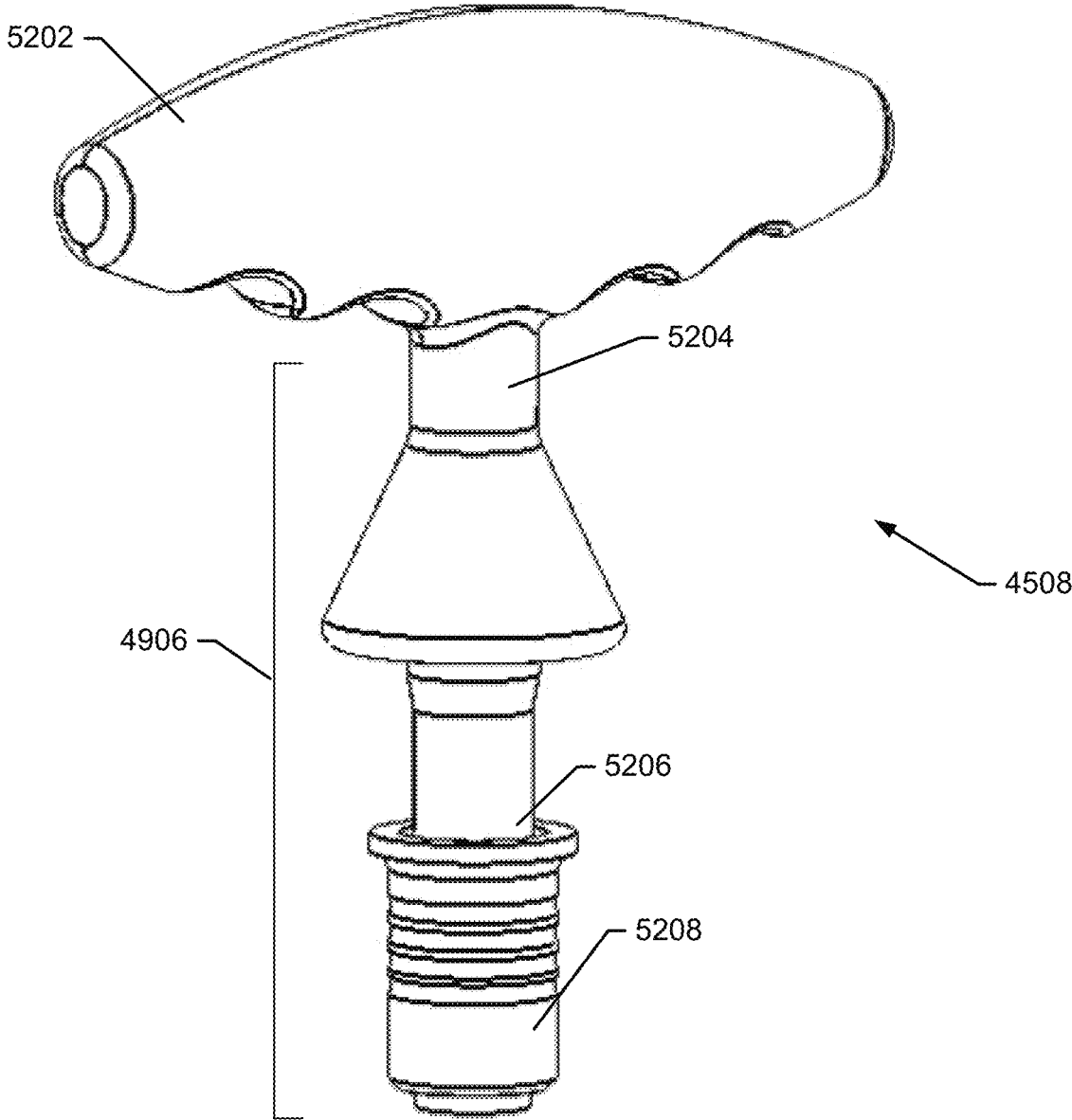


FIG. 52

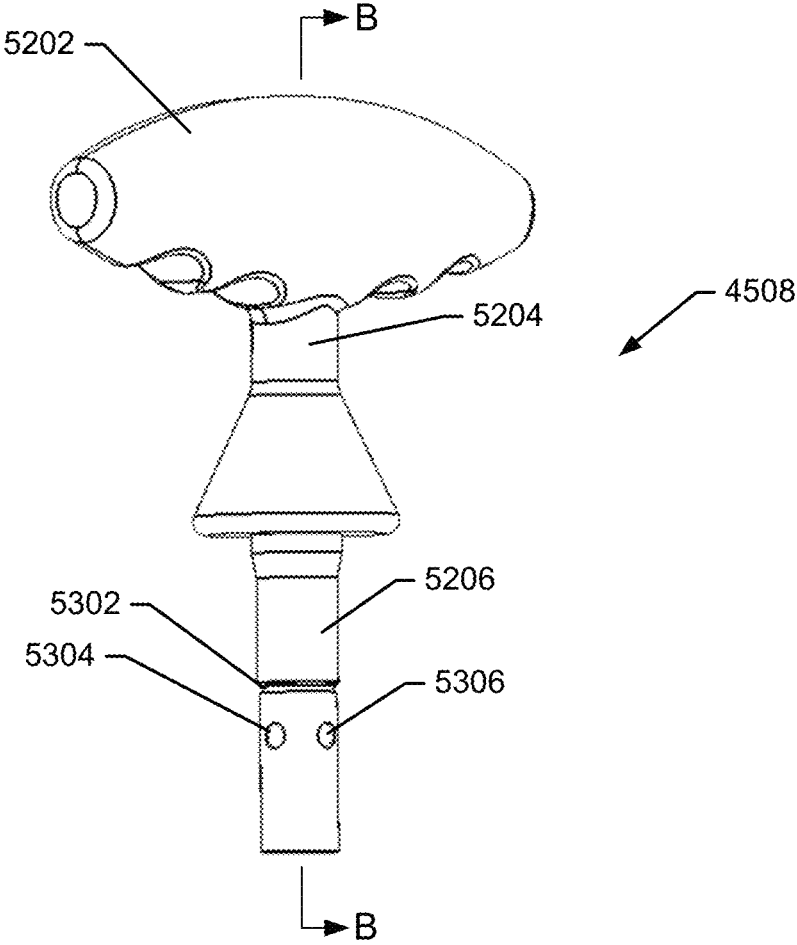


FIG. 53

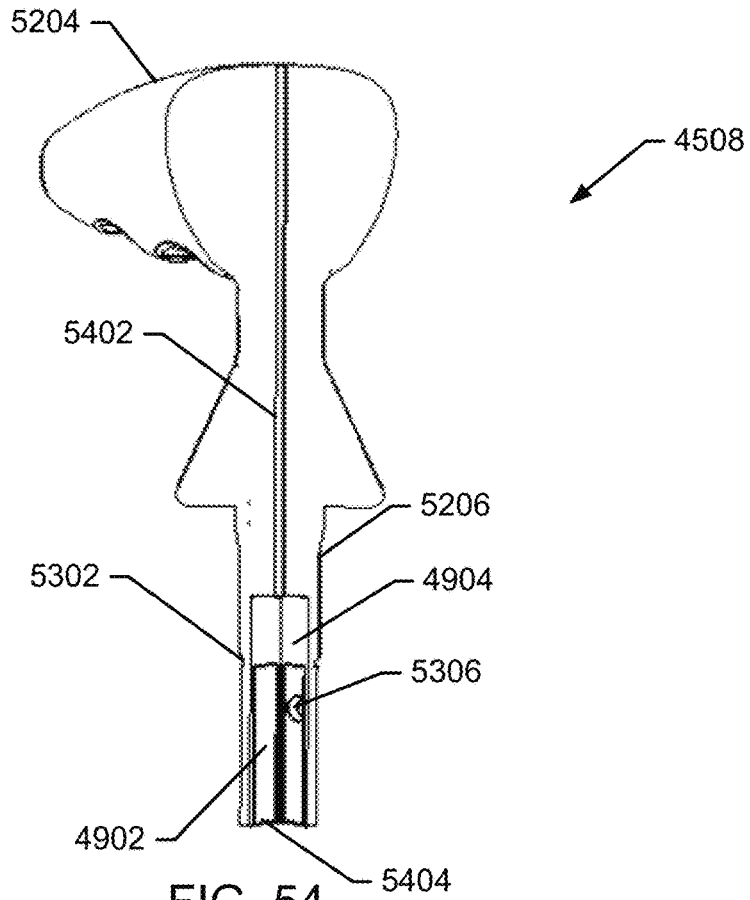


FIG. 54

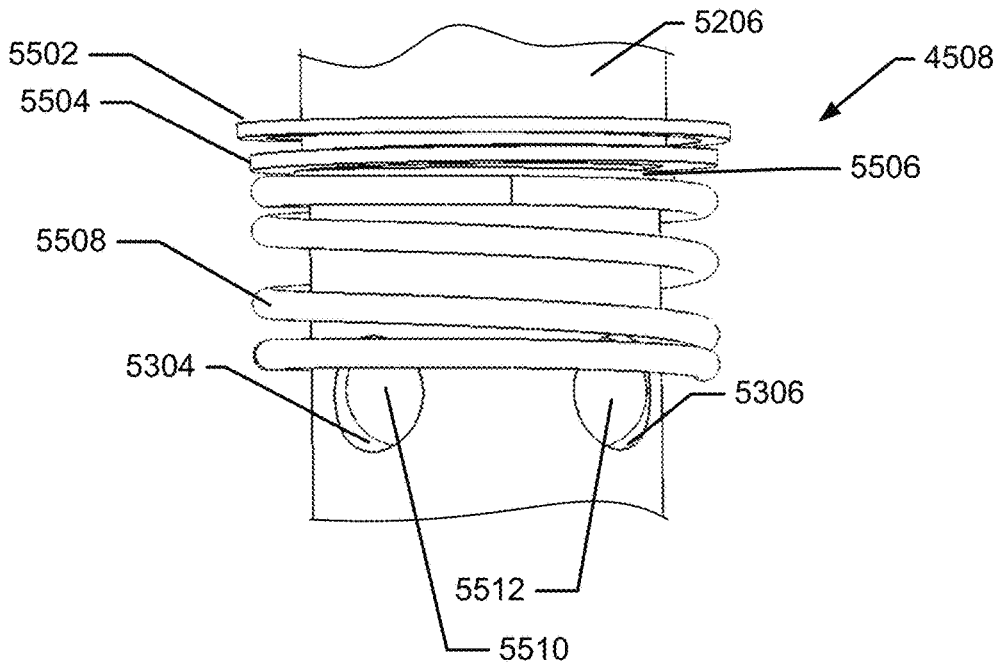


FIG. 55

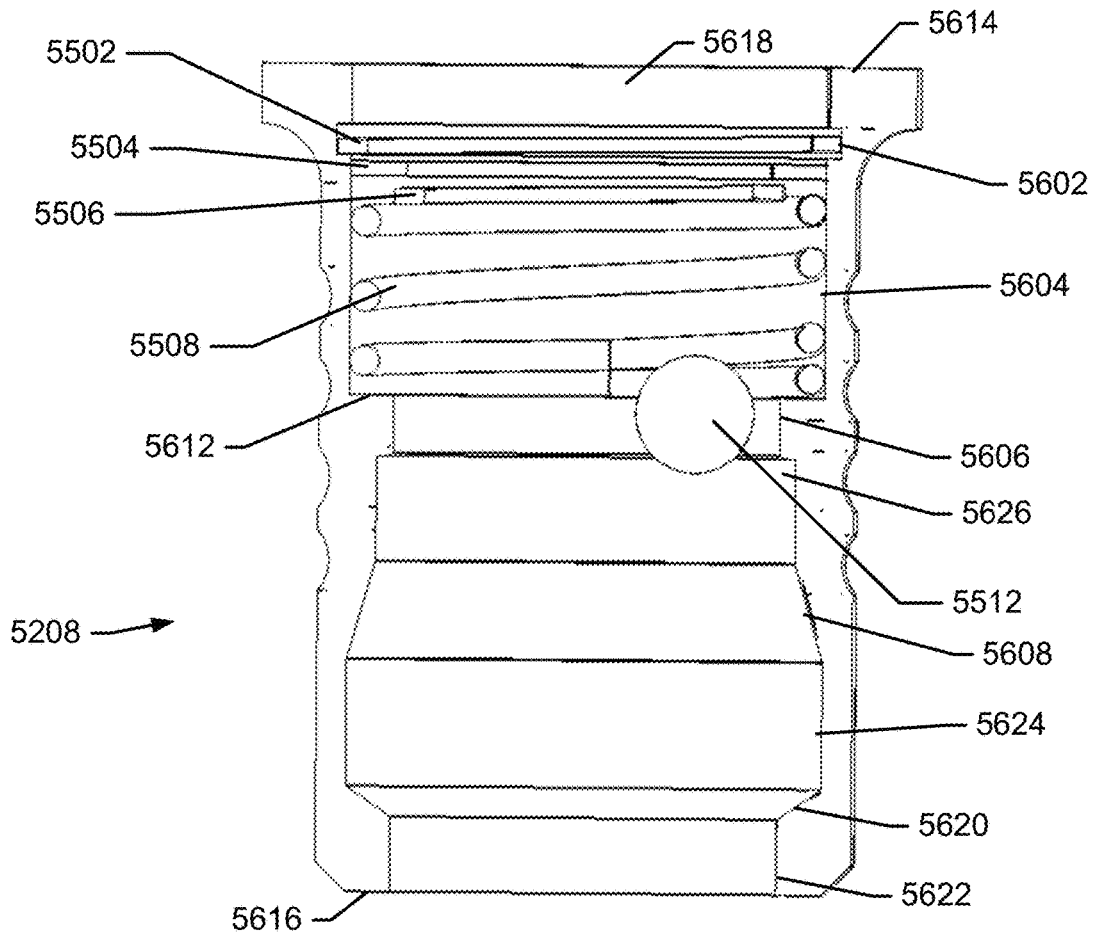


FIG. 56

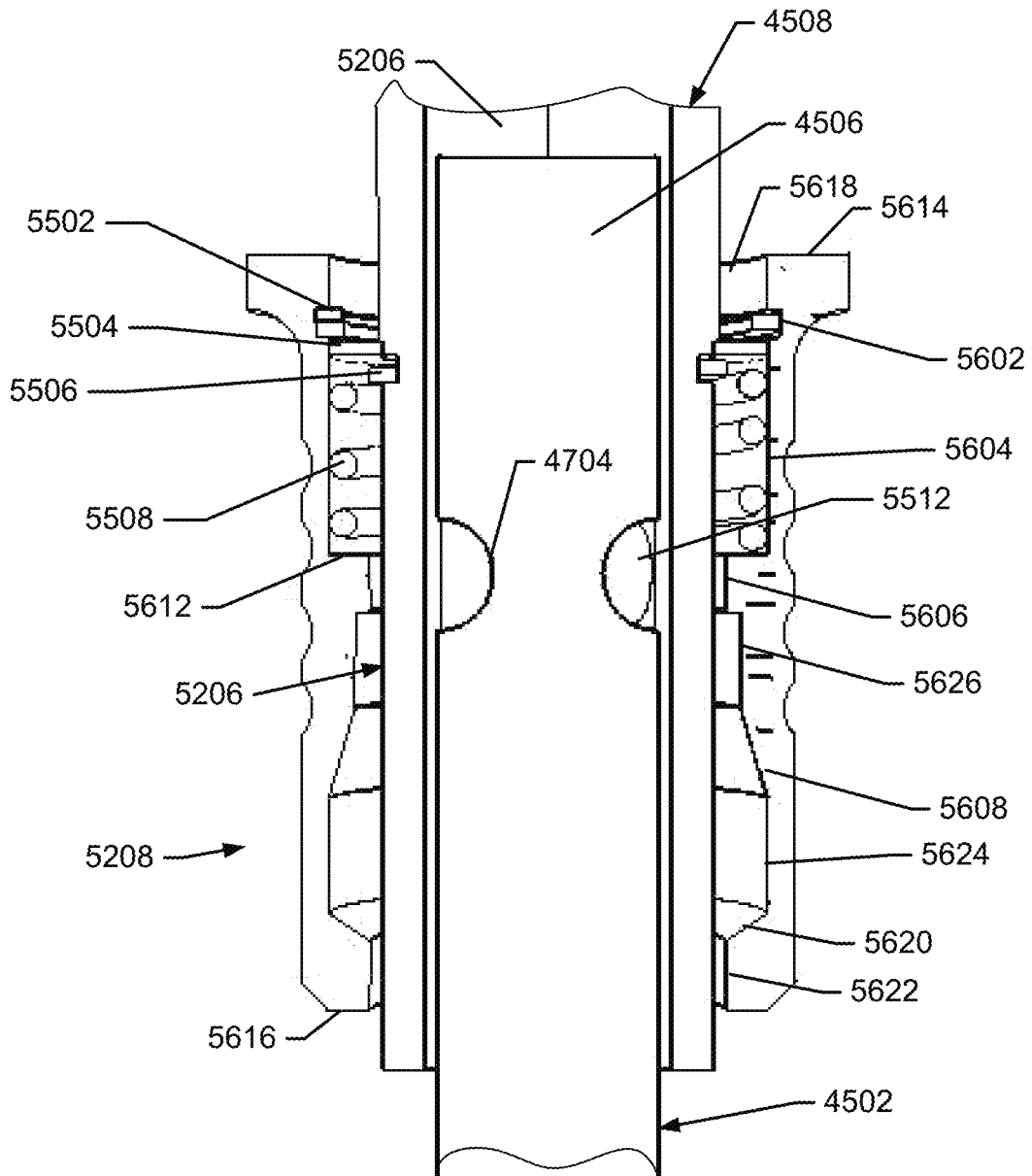


FIG. 57

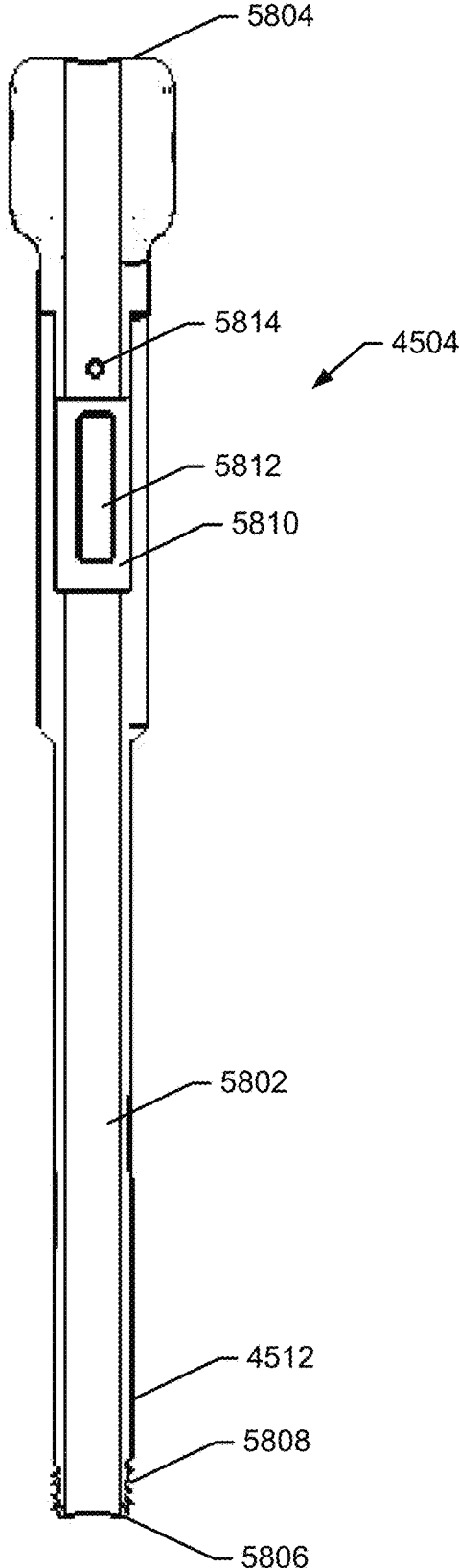


FIG. 58

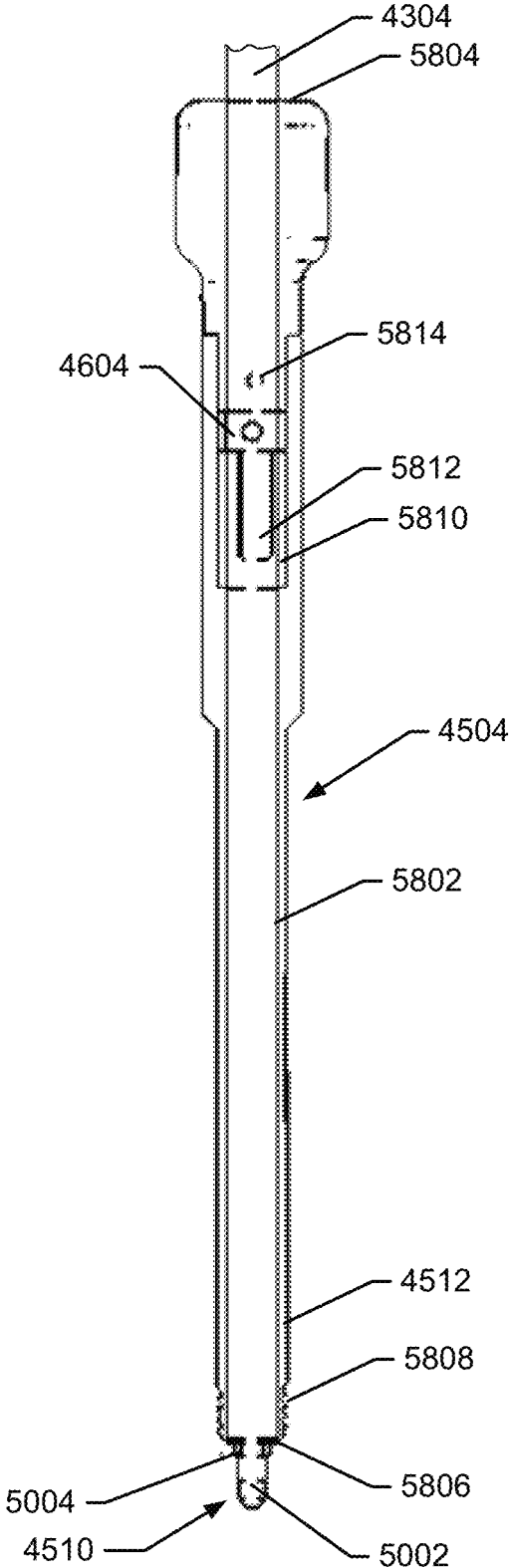


FIG. 59

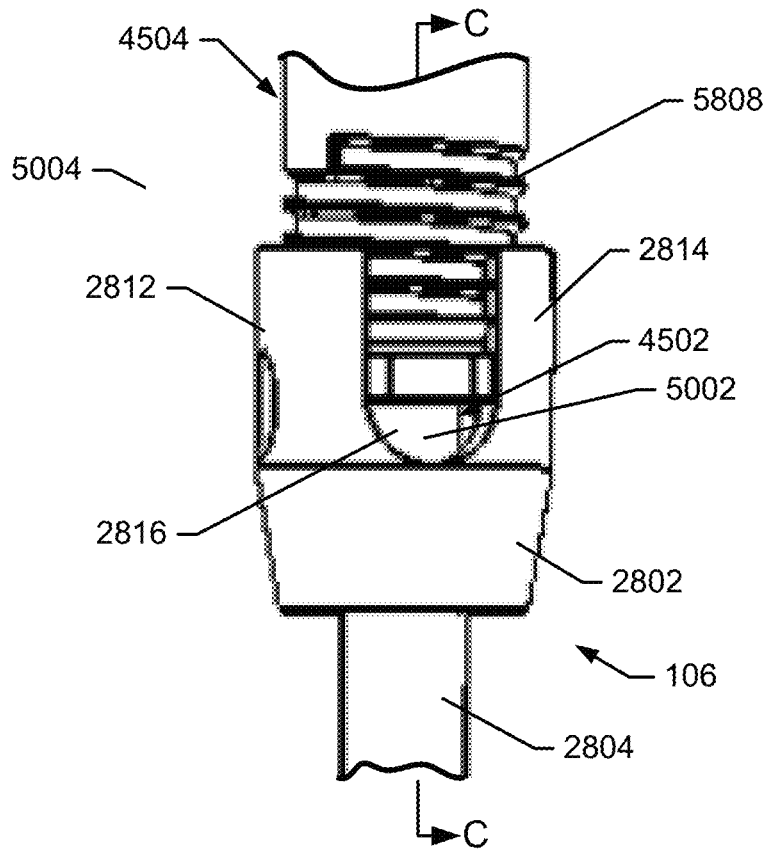


FIG. 60

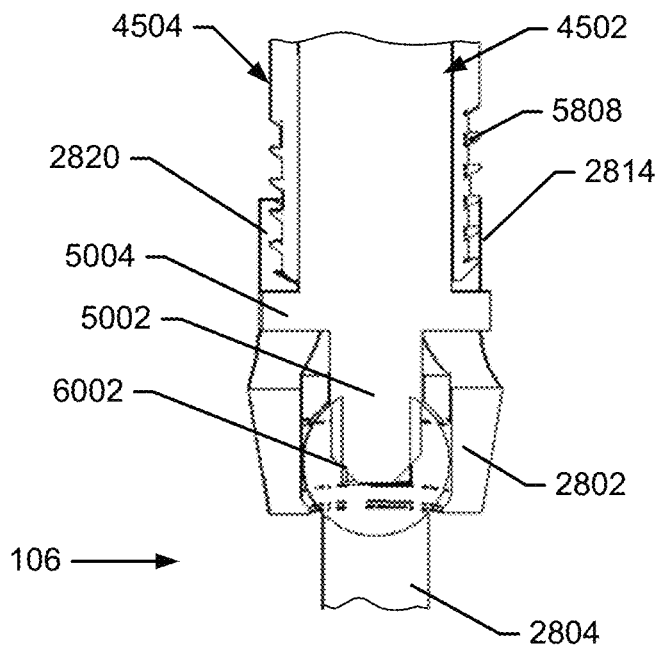


FIG. 61

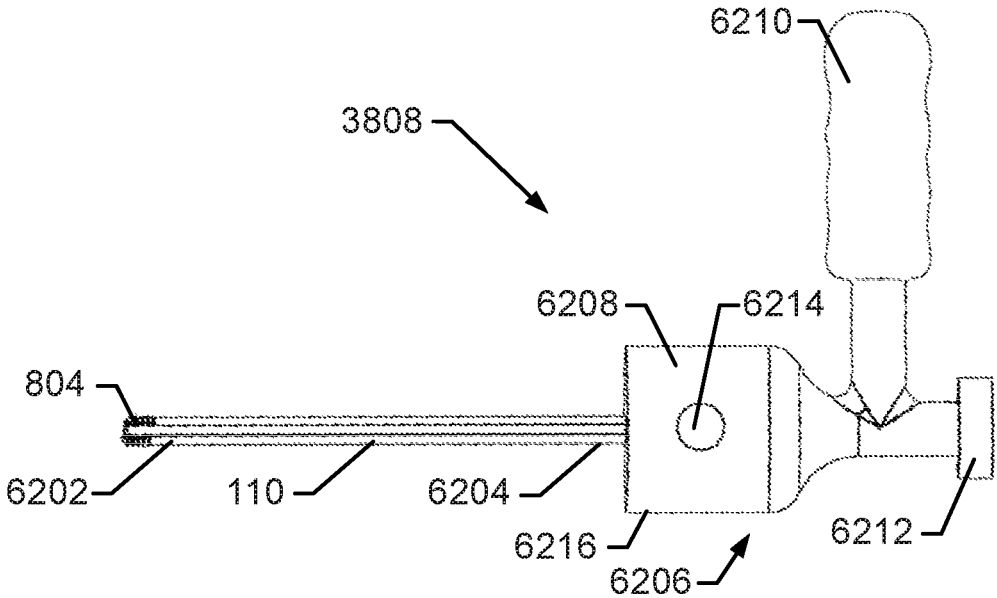


FIG. 62

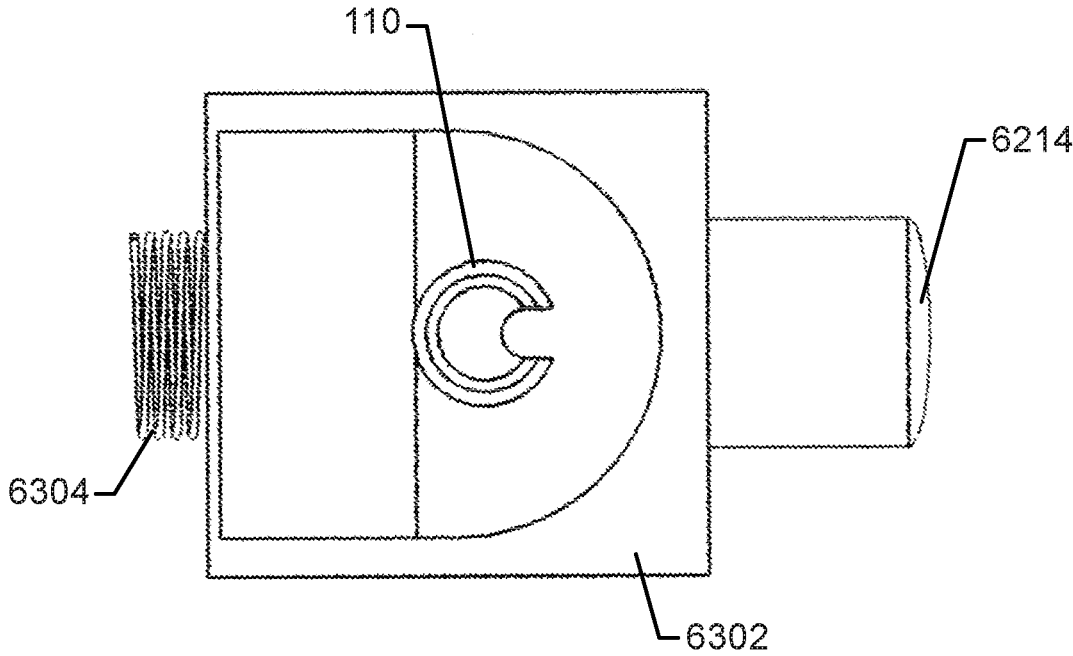


FIG. 63

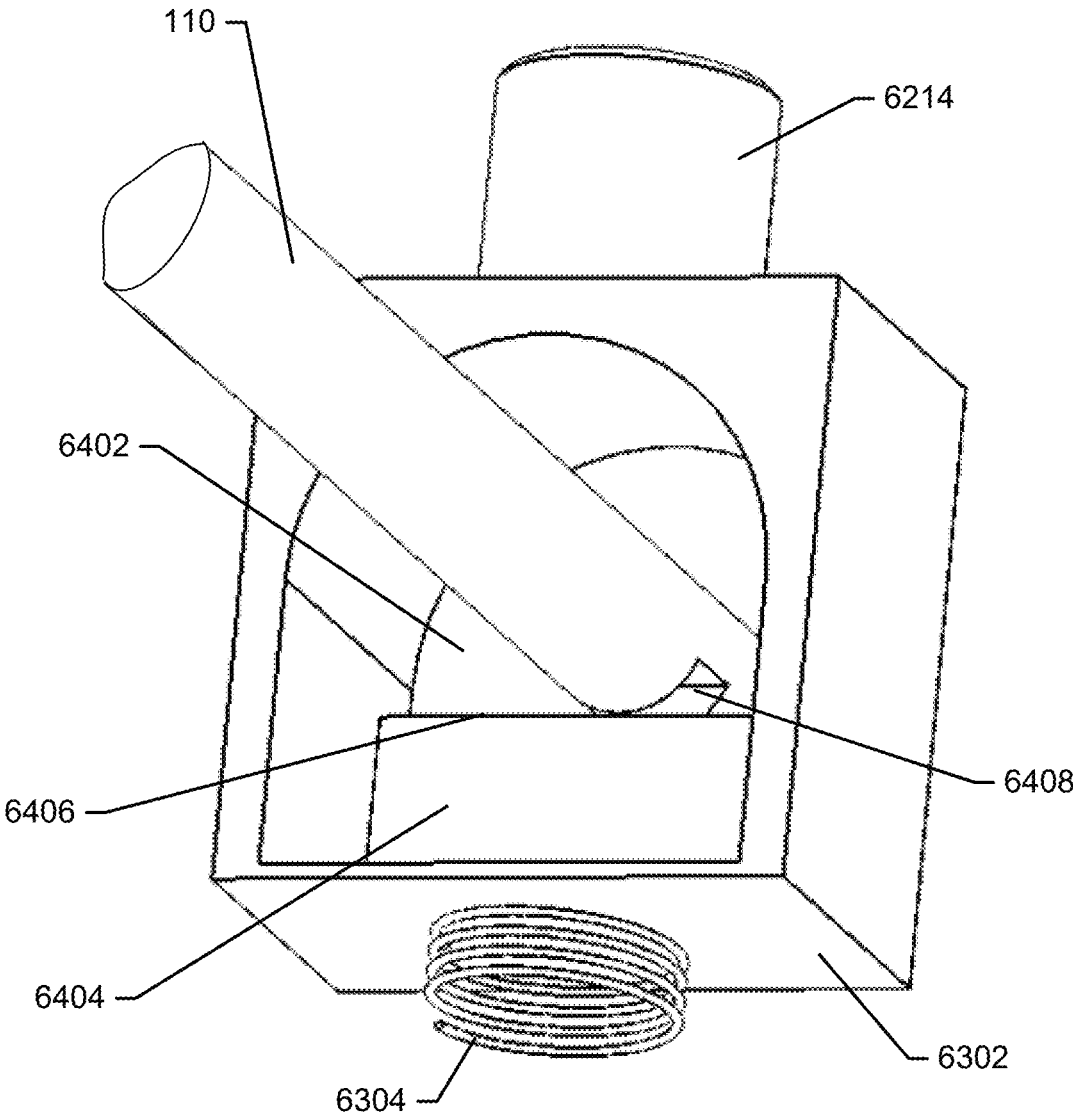


FIG. 64

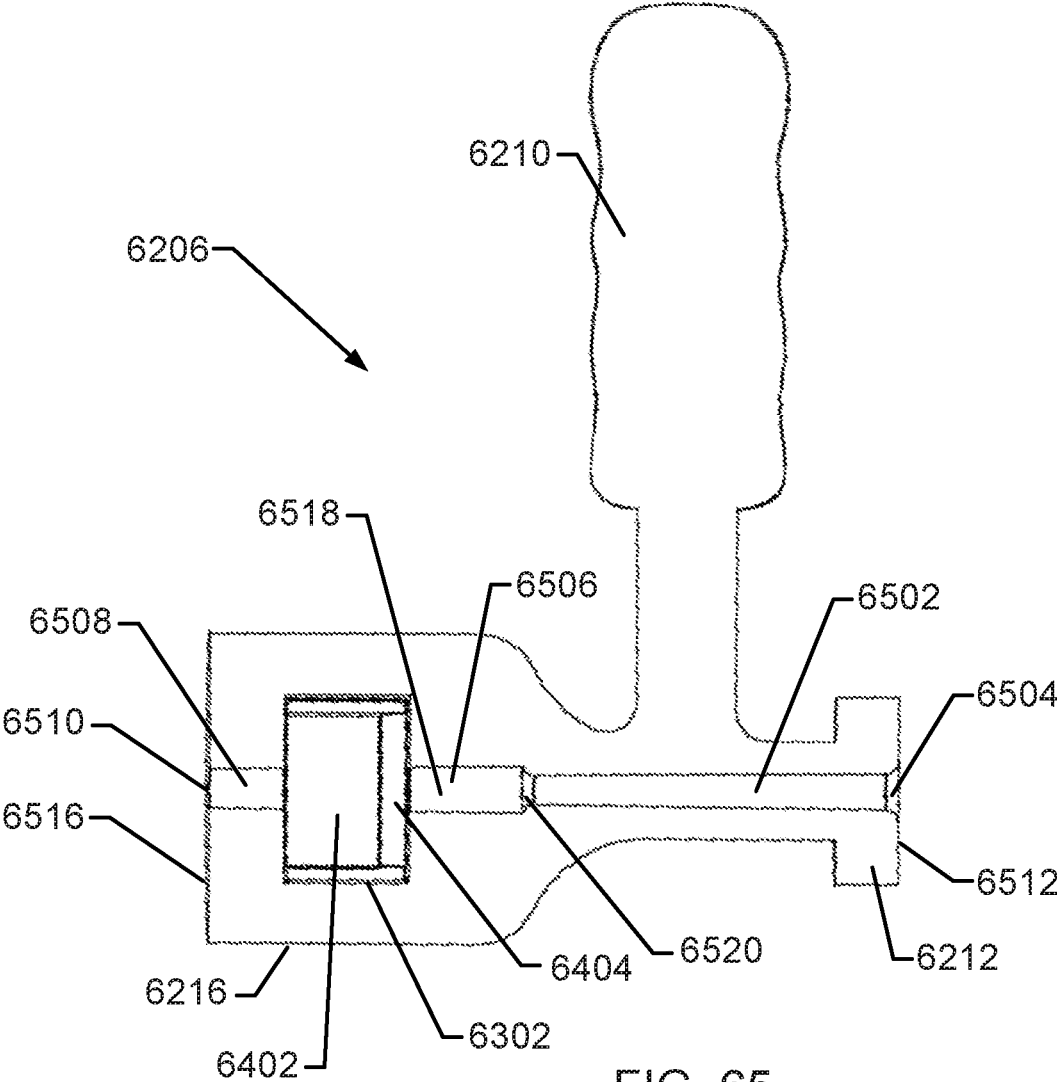


FIG. 65

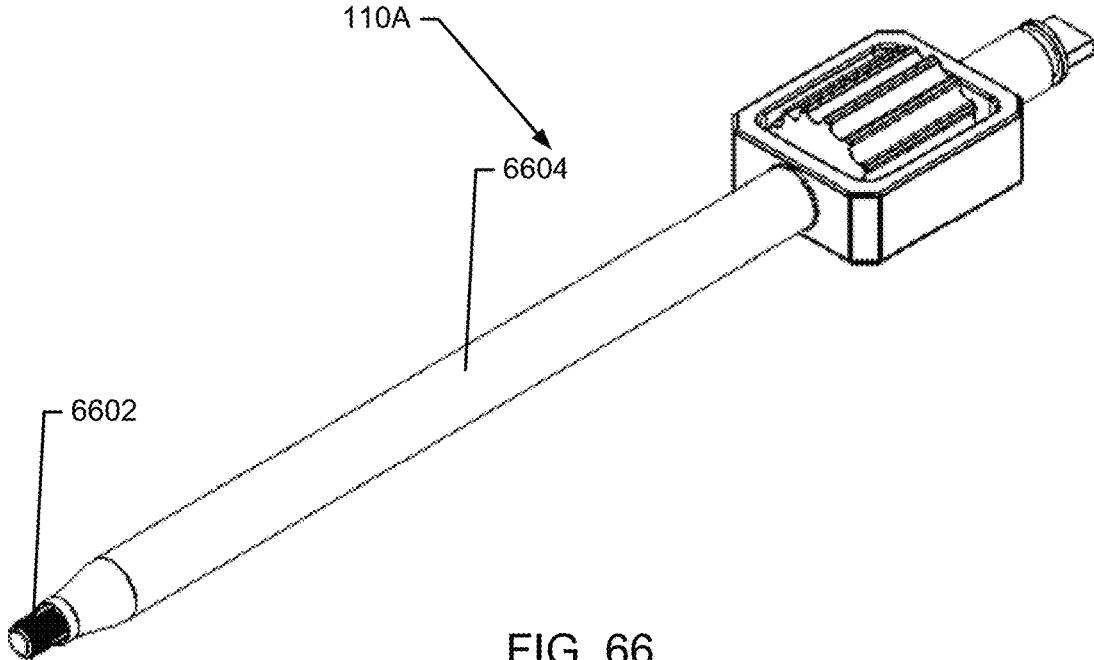


FIG. 66

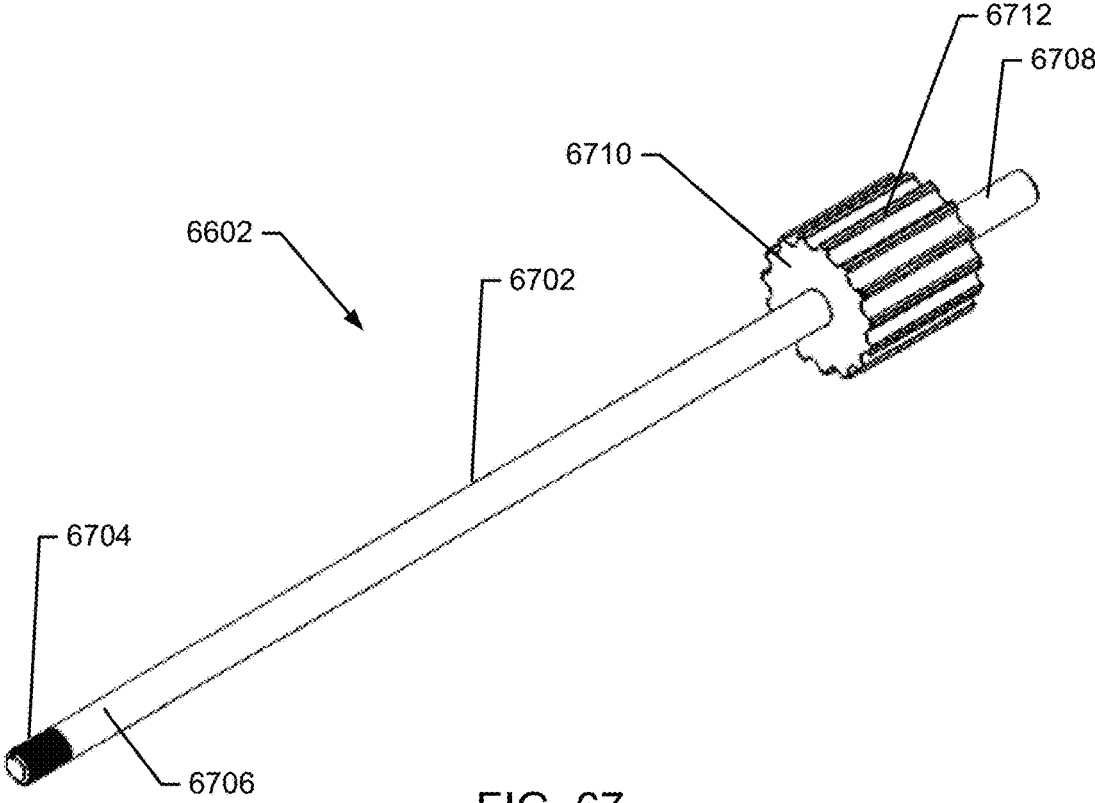


FIG. 67

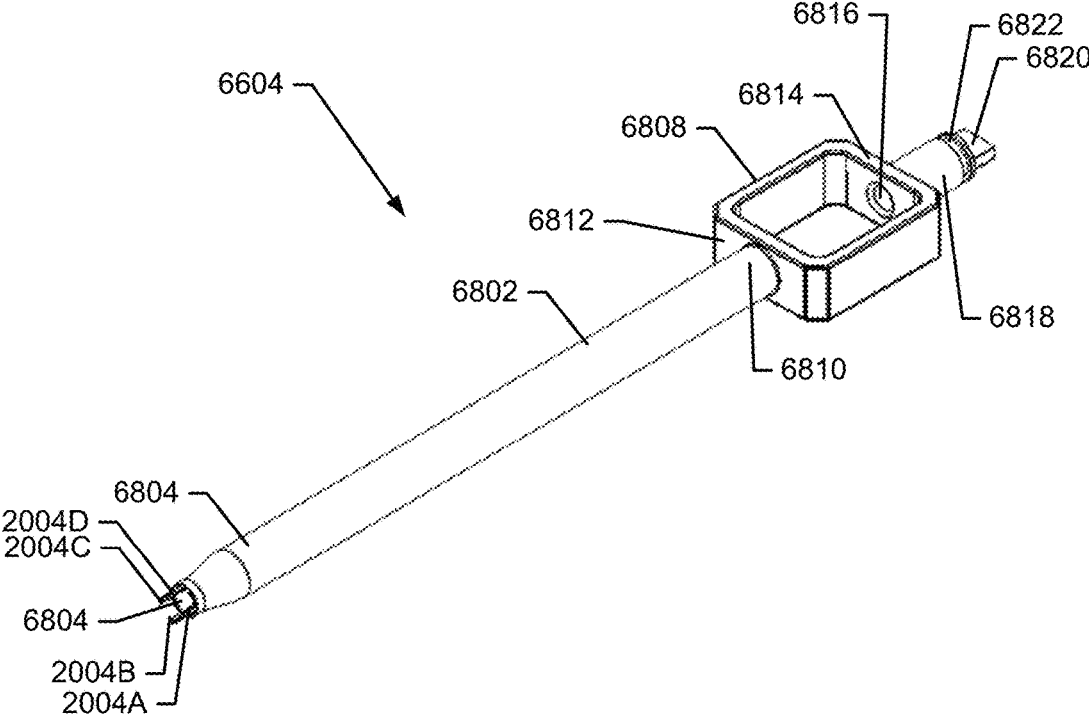


FIG. 68

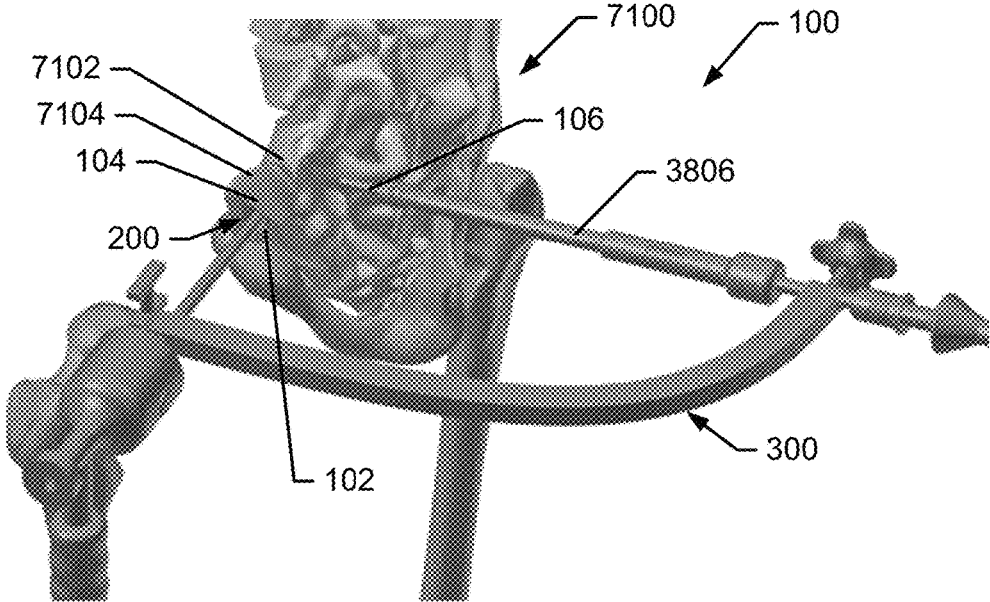


FIG. 69

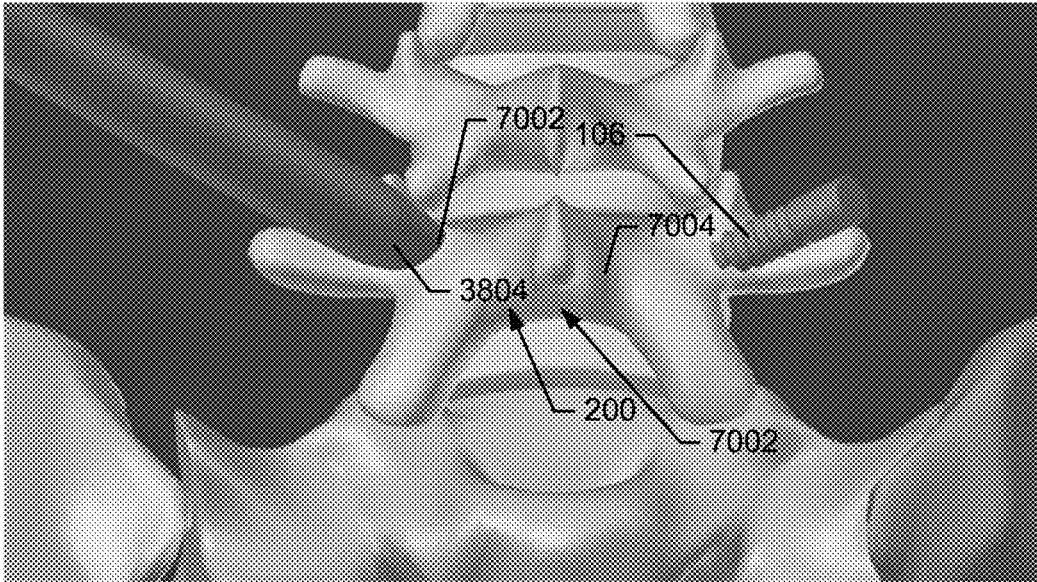


FIG. 70

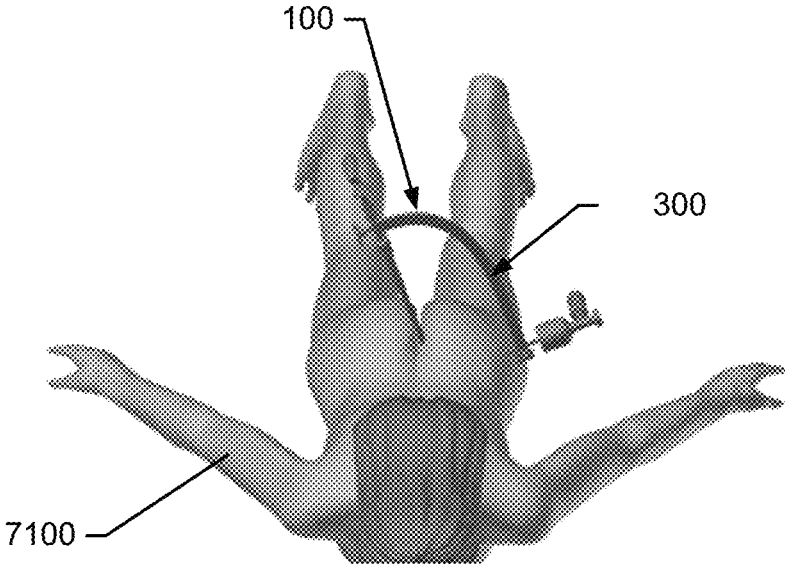


FIG. 71

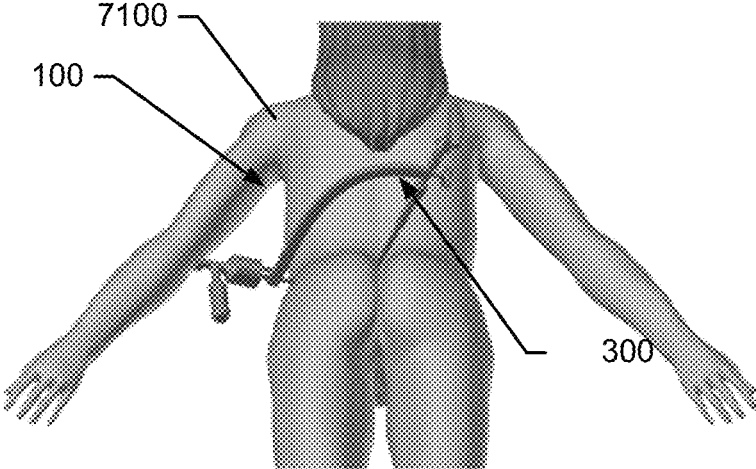


FIG. 72

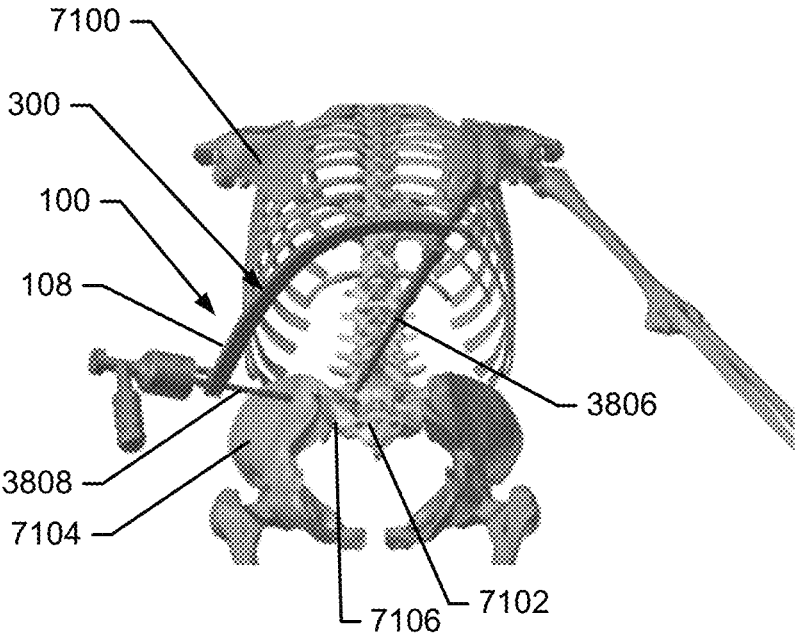


FIG. 73

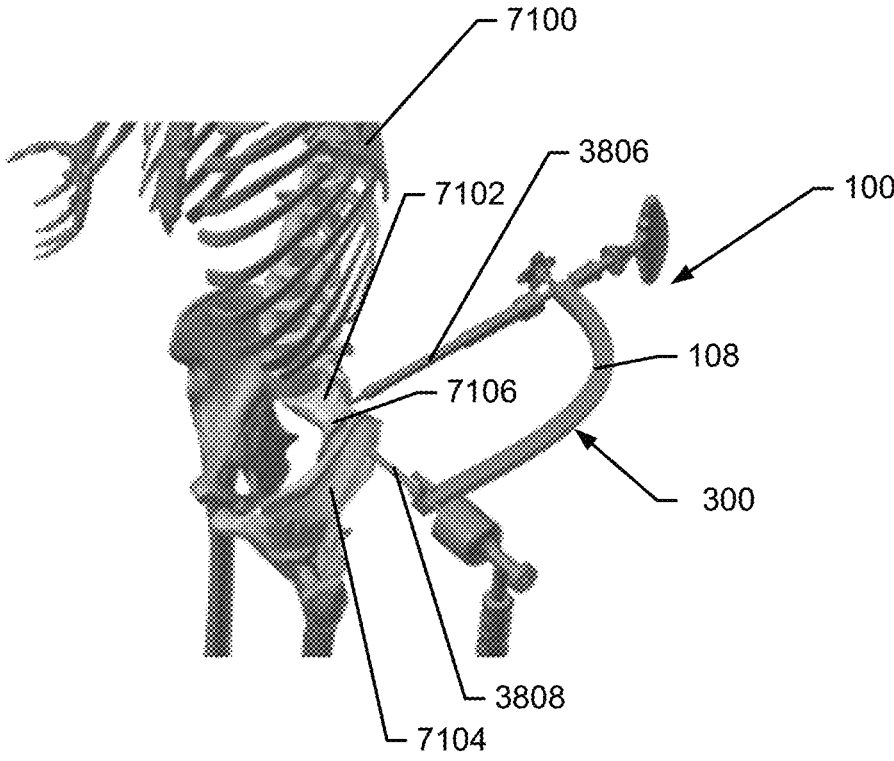


FIG. 74

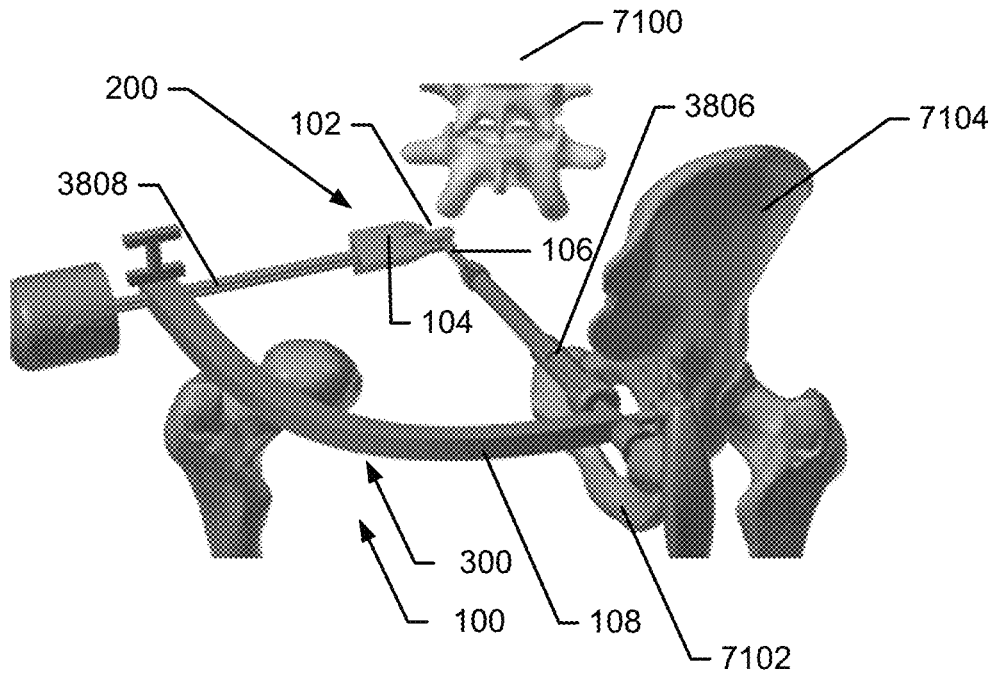


FIG. 75

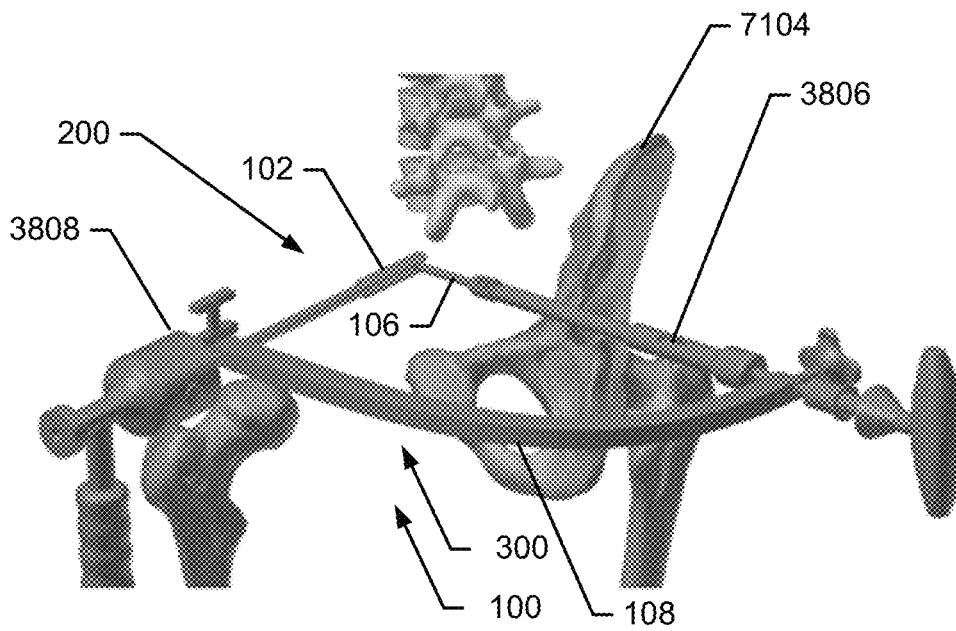


FIG. 76

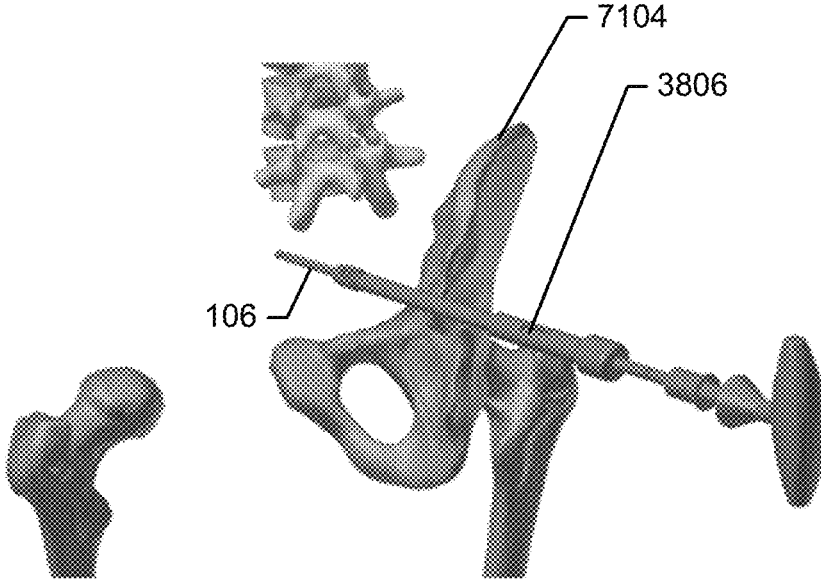


FIG. 77

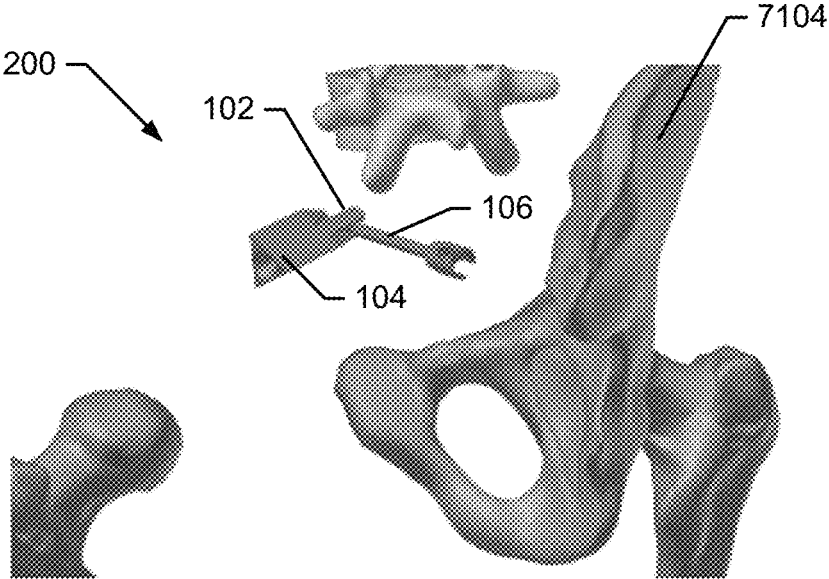


FIG. 78

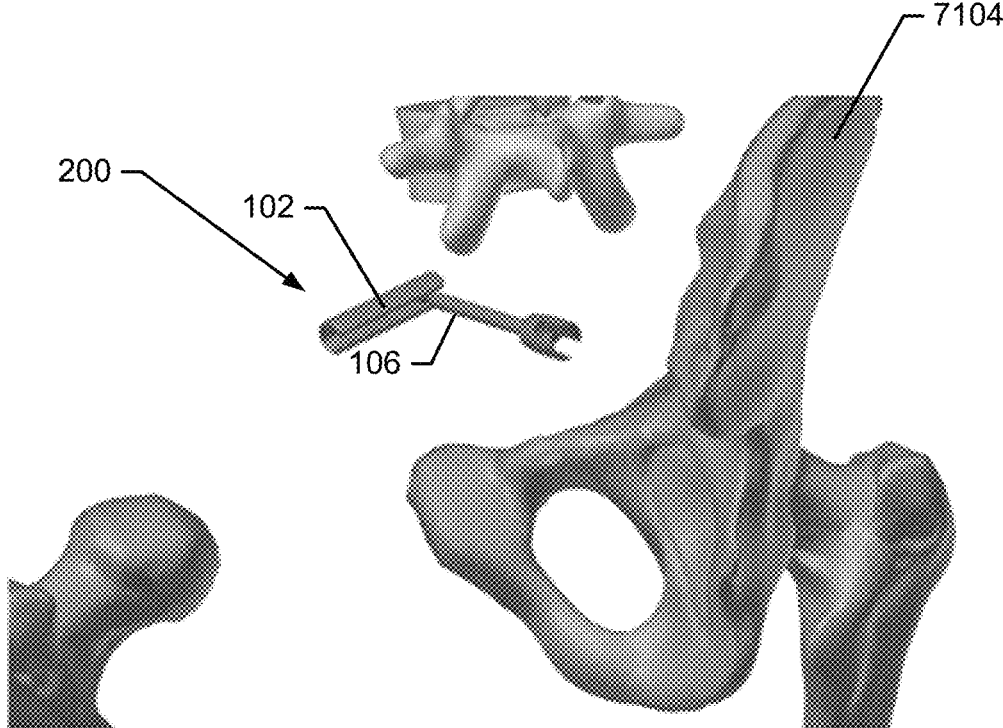


FIG. 79

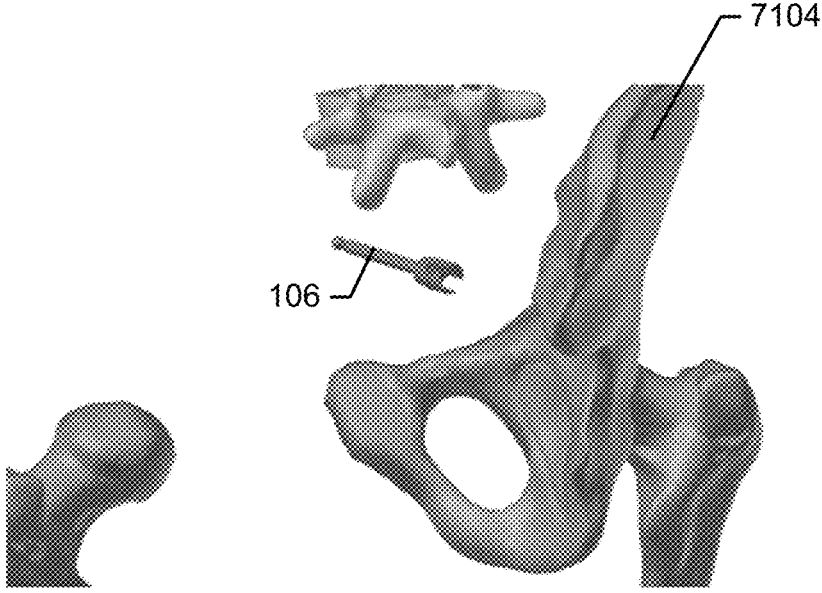


FIG. 80

ORTHOPEDIC ANCHORING METHODS**CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 14/413,318 filed Jan. 7, 2015, which application is a national stage entry of PCT Application No. PCT/US2013/051381 filed Jul. 19, 2013, which claims priority to U.S. Provisional Application No. 61/798,922 filed Mar. 15, 2013, which is entitled "Orthopedic Anchoring System and Methods", and also claims priority to U.S. Provisional Application No. 61/674,233, which is entitled "Orthopedic Anchoring System and Methods" filed Jul. 20, 2012.

All of the aforementioned applications are hereby incorporated by reference in their entireties into the present application.

FIELD OF THE INVENTION

Aspects of the present invention relate to systems and methods related to a medical apparatus. More specifically, the present invention relates to devices and methods for joint, vertebral or intervertebral joint reinforcement or immobilization.

BACKGROUND OF THE INVENTION

Reinforcement, stabilization, or fusion of a joint or vertebrae may be indicated as a treatment of an afflicted region of a patient. Examples of specific treatments include spinal stabilization, spinal fusion, posterolateral spinal fusion, vertebral immobilization or reinforcement, intervertebral joint immobilization or reinforcement, degenerative disk stabilization, repair of traumatic fracture or dislocation of the pelvis, treatment of degenerative arthritis, treatment of sacroiliitis (an inflammation or degenerative condition of the sacroiliac joint), osteitis condensans ilii, and treatments of other degenerative conditions of joints or vertebrae.

This reinforcement of intervertebral joints, sacroiliac joints, or other joint stabilizations may be accomplished by one or more existing methods, including inserting rods and/or other implants into the afflicted regions. These rods and/or other implants may be anchored in place using existing orthopedic fasteners such as pedicle screws. One limitation of many existing fusion procedures involves the challenge of situating a fusion implant in suitably close alignment with the removed tissues of the patient to achieve a stable fixation of the joint or vertebrae. Existing implant structures may have insufficient engagement with the articular surfaces or cortical bone of the joint for adequate fixation or fusion. This failure to sufficiently stabilize and fuse the joint with the conventional implant structures and methods may result in a failure to relieve the condition being treated.

It may be desirable to limit the movement and/or loosening over time of the anchoring implant and/or associated fasteners to enhance the long-term effectiveness of a fusion implant. Existing pedicle screws and/or implants may loosen, back out, or otherwise functionally degrade due to the cumulative effect of forces and torques experienced as a result of normal posture and/or movements including bending, sitting, walking, and any other typical movements. Therefore, there exists a need for a stabilized anchor that is resistant to these forces for applications in vertebral immobilization/stabilization, intervertebral immobilization/stabilization, sacroiliac joint immobilization, and other surgical interventions.

The inventive fusion system described herein addresses the problems associated with conventional methods and apparatuses used in fixation and fusion.

BRIEF SUMMARY OF THE INVENTION

Disclosed herein is an implant assembly for providing an anchor attached to a bone of a patient, the assembly comprising: a hollow elongate implant outer layer comprising a lumen wall defining a lumen; an elongate implant body comprising a locking element, wherein at least a portion of the implant body is situated within the lumen; and a fastener comprising an attachment fitting, wherein the attachment fitting is attached to the locking element in a locked mechanical engagement. The lumen opens to an outer layer proximal end opposite to an outer layer distal end of the implant outer layer. The outer layer is situated within a bore formed within the bone of the patient. The locking element is situated outside of the lumen of the implant outer layer. The locking element is situated within the lumen and the implant outer layer further includes a fastener opening aligned with the locking element, wherein the lumen opens to the fastener opening to provide access to the locking element through the lumen wall. The fastener opening may further include an additional locking element that engages in cooperation with the locking element of the implant body to form the locked mechanical engagement with the attachment fitting of the fastener. The fastener fitting may be chosen from: a ball fitting, a rounded fitting, a cone fitting, and a divoted fitting. The locking element may be chosen from: a self-locking retaining ring, a slot, a threaded fitting, a divoted fitting, one or more projections forming a slot. The fastener may be chosen from a screw, a nail, a pin, and a staple. The lumen may include a cross-sectional profile that is essentially matched to an external cross-sectional profile of the implant body.

Also disclosed herein is a delivery tool for performing an orthopedic surgical procedure, including: an elongate targeting arm including a first arm end and a second arm end; a fastener guide releasably attached to the first arm end, wherein the fastener guide includes a fastener guide longitudinal axis and a fastener guide distal end; and an implant guide releasably attached to the second arm end, wherein the implant guide includes an implant guide longitudinal axis and an implant guide distal end. The targeting arm maintains a fixed arrangement of the fastener guide longitudinal axis and the implant guide longitudinal axis during the orthopedic surgical procedure. The targeting arm may include a single rigid element formed into an elongate shape chosen from: a curved arcuate shape, a polygonal shape, a right-angle shape. The fixed arrangement maintained by the targeting arm may include a coplanar alignment of the fastener guide longitudinal axis and the implant guide longitudinal axis and a non-adjustable angle ranging from about 60° to 90° between the fastener guide longitudinal axis and the implant guide longitudinal axis. The targeting arm may also include a first element and a second element, wherein the first element and the second element are formed into elongate shapes chosen from: a linear shape, a curved arcuate shape, and a polygonal shape. The first element may include the first end and an opposite first joined end, the second element may include the second end and an opposite second joined end, and the first joined end and the second joined end are joined in an adjustable locked mechanical engagement. The fixed arrangement may include a coplanar alignment of the fastener guide longitudinal axis and the implant guide longitudinal axis and an adjustable angle

ranging from about 60° to 90° between the fastener guide longitudinal axis and the implant guide longitudinal axis. The targeting arm may include a first element and a second element, wherein the adjustable locked mechanical engagement is chosen from: a hinged engagement wherein a lockable hinged joint joins the first joined end and the second joined end; a clamped engagement wherein a first attachment device attached to the first joined end is removably attached to the second element at any position between the second end and the second joined end; and a telescoping arrangement wherein the first joined end is nested within the second joined end and the first joined end may be inserted into the second joined end or extended from the second joined end and then reversibly locked in place. The fastener guide may further include a tool releasably attached at the fastener guide distal end, wherein the tool is chosen from: a screwdriver head, a socket driver, a drill, a bone cutter, a fiber optic camera, a laser, a conduit, and any combination thereof. The implant guide may further include a tool releasably attached at the implant guide distal end, wherein the tool is chosen from: a screwdriver head, a drill, a bone cutter, a fiber optic camera, a laser, a conduit, and any combination thereof.

Also disclosed herein is an orthopedic anchoring system for providing a stable anchor attached to a bone of a patient, including an implant assembly. The implant assembly may further include a hollow elongate implant outer layer including an outer layer proximal end, an outer layer distal end opposite to the outer layer proximal end, and a lumen wall defining a lumen. The implant assembly may further include an elongate implant body including a body proximal end, and a locking element at a body distal end opposite to the body proximal end, wherein at least a portion of the implant body is situated within the lumen. The implant assembly may further include an elongate fastener including a fastener head at a fastener proximal end and an attachment fitting at a fastener distal end opposite to the fastener proximal end, wherein the attachment fitting is attached to the locking element in a locked mechanical engagement. The orthopedic anchoring system may further include a delivery tool including: an elongate targeting arm including a first arm end and a second arm end; a fastener guide releasably attached to the first arm end, wherein the fastener guide comprises a fastener guide longitudinal axis and a fastener guide distal end releasably attached to the fastener head; and an implant guide releasably attached to the second arm end, wherein the implant guide includes an implant guide longitudinal axis and an implant guide distal end releasably attached to the outer layer proximal end and/or the body proximal end. The targeting arm maintains a fixed arrangement of the fastener guide longitudinal axis and the implant guide longitudinal axis during the orthopedic surgical procedure. The lumen may open to the outer layer proximal end. The implant outer layer may be situated within a bore formed within the bone of the patient. The locking element may be situated outside of the lumen of the implant outer layer. The locking element may be situated within the lumen and the implant outer layer may further include a fastener opening aligned with the locking element, wherein the lumen opens to the fastener opening to provide access to the locking element through the lumen wall. The fastener opening may further include an additional locking element that engages in cooperation with the locking element of the implant body to form the locked mechanical engagement with the attachment fitting of the fastener. The fastener fitting may be chosen from: a ball fitting, a rounded fitting, a cone fitting, and a divoted fitting. The locking element may be chosen from: a self-locking

retaining ring, a slot, a threaded fitting, a divoted fitting, and one or more projections forming a slot. The fastener may be chosen from a screw, a nail, a pin, and a staple. The fixed arrangement may include a coplanar alignment of the fastener guide longitudinal axis and the implant guide longitudinal axis and a fixed angle ranging from about 60° to 90° between the fastener guide longitudinal axis and the implant guide longitudinal axis. The fastener guide may further include a tool releasably attached at the fastener guide distal end, wherein the tool is chosen from: a screwdriver head, a socket driver, a drill, a bone cutter, a fiber optic camera, a laser, a conduit, and any combination thereof. The implant guide may further include a tool releasably attached at the implant guide distal end, wherein the tool is chosen from: a screwdriver head, a drill, a bone cutter, a fiber optic camera, a laser, a conduit, and any combination thereof.

Also disclosed herein is a method for performing an orthopedic surgical procedure to treat an afflicted region of a patient, including providing a delivery tool including an elongate targeting arm comprising a first arm end and a second arm end, a fastener guide releasably attached to the first arm end, wherein the fastener guide includes a fastener guide longitudinal axis and a fastener guide distal end, and an implant guide releasably attached to the second arm end, wherein the implant guide includes an implant guide longitudinal axis and an implant guide distal end. The targeting arm maintains a fixed arrangement of the fastener guide longitudinal axis and the implant guide longitudinal axis during the orthopedic surgical procedure. The method also includes: forming a bore within a bone within the afflicted region by removing a portion of the bone using a bone removal tool reversibly attached to the implant guide distal end and reversibly attaching an outer layer proximal end of an implant outer layer to the implant guide distal end, wherein the implant outer layer further includes a lumen wall defining a lumen, the lumen opening to the outer layer proximal end situated opposite to an outer layer distal end. The method also comprises inserting the outer layer distal end into the bore to situate at least a portion of the implant outer layer within the bore and reversibly attaching a body proximal end of an implant body to the implant guide distal end, wherein the implant body further includes a locking element and a body distal end situated opposite to the body proximal end. The method also includes inserting the body proximal end into the lumen to situate at least a portion of the implant body within the lumen and reversibly attaching a fastener head of a fastener situated at a fastener proximal end to the fastener guide distal end, wherein the fastener further includes an attachment fitting situated at a fastener distal end opposite to the fastener proximal end. The method also includes engaging the attachment fitting of the fastener with the locking element of the implant body to form a locked mechanical engagement. The method may further include forming a fastener channel within the bone using a second bone removal tool reversibly attached to the fastener guide distal end. The bone removal tool and the second bone removal tool may be chosen from: a drill, a bone cutter, a fiber optic camera, a laser, a conduit, and any combination thereof.

Also disclosed herein is an orthopedic anchoring system including an implant assembly including: i) an implant body including at least a portion of a locking element; and ii) a fastener including an attachment feature configured to mechanically interlock with the locking element. The system also includes a delivery tool including: i) an implant guide configured to releasably couple to the implant body; and a fastener guide operably coupled to the implant guide

and configured to deliver the attachment feature of the fastener to the locking element. A final manufactured configuration of the delivery tool and a final manufactured configuration of the implant assembly are such that, when the system is assembled such that the implant guide is releasably coupled to the implant body, a delivery arrangement automatically exists such that the fastener guide is correctly oriented to deliver the attachment feature to the locking element. The system may further include an implant outer layer including a longitudinal axis and a lumen extending parallel to the longitudinal axis, wherein the lumen is configured to receive at least a portion of the implant body within the lumen. In being coupled together, the implant guide and fastener guide may form an angle relative to each other, and the angle is non-adjustable. The attachment feature may be configured to mechanically interlock with the locking element in a force-fit mechanical engagement. The locking element may be a self-locking retaining ring and the attachment feature may be a fastener distal end selected from a ball end, a rounded end, and a cone end attached to the fastener by a contracted neck region. The fastener distal end may be configured to be forced through the self-locking retaining ring to produce the force-fit mechanical engagement. The locking element may be situated near a distal end of the implant body. The distal end of the implant body may be configured to protrude from the lumen of the implant outer layer to expose the locking element. The implant outer layer may further include a fastener opening configured to provide a path through which the attachment feature passes to engage the locking element on a force-fit mechanical engagement. The attachment feature may be configured to mechanically interlock with the locking element in an interference mechanical engagement. The attachment feature may include a fastener distal end selected from a ball end, a rounded end, and a cone end attached to the fastener by contracted neck region; the locking element may include a slot formed within the implant body and extending from a distal end of the implant body in a direction parallel with the longitudinal axis, wherein the slot comprises a slot width between the diameter of the neck region and the diameter of the ball end; and the slot may be configured to receive the neck region of the attachment feature to retain the fastener distal end and to produce the interference mechanical engagement. The fastener may be situated in a final fastener position and the implant body may be advanced in a distal direction to form the interference mechanical engagement. The implant outer layer may further include a second locking element including a fastener opening configured to receive the attachment feature and to produce the interference mechanical engagement cooperatively with the locking element of the implant body when the implant body is advanced distally within the lumen of the implant outer layer. The implant outer layer may further include a first alignment feature and the implant body may further include a second alignment feature, wherein the first alignment feature is configured to operatively connect to the second alignment feature, resulting in a predetermined angular alignment of the implant body within the lumen about a rotational axis aligned parallel to the longitudinal axis and situated along a centerline of the implant body. The first alignment feature may include a first non-circular cross-sectional profile, the second alignment feature may include a second non-circular cross-sectional profile corresponding to the first non-circular cross-sectional profile, and the first cross-sectional profile and the second non-circular cross-sectional profile may be aligned only at the predetermined angular alignment. The first alignment feature may be cho-

sen from a longitudinal ridge or groove formed on an outer surface of the implant body and aligned with the longitudinal axis, the second alignment feature may be chosen from a corresponding longitudinal groove or ridge formed on an inner surface defining the lumen of the implant outer layer and aligned with the longitudinal axis; and the longitudinal ridge or groove may mesh with the corresponding longitudinal groove or ridge as the implant body is advanced distally into the lumen only at the predetermined angular alignment. The implant guide may be further configured to releasably couple with the implant outer layer. The delivery tool may further include a targeting arm including a first arm end and an opposite second arm end, wherein the first arm end is configured to releasably attach the fastener guide and the second arm end is configured to releasably attach the implant guide to operatively couple the fastener guide and the implant guide. The targeting arm may include a fixed structural element configured to operatively couple the fastener guide and the implant guide at a non-adjustable angle relative to each other. The targeting arm may include two or more linked structural elements configured to operatively couple the fastener guide and the implant guide at an adjustable angle relative to each other.

Also disclosed herein is a method of implanting an orthopedic anchor, including: a) approaching a bore formed within a bone tissue with an implant body including at least comprising at least a portion of a locking element; b) delivering the joint implant body into the bore, the joint implant body being oriented in the bore such that the locking element is aligned opposite to an opening of the bore at a surface of the bone tissue; and c) causing an attachment feature of a fastener to mechanically interlock with the locking element. The method may further include approaching a bore formed within the bone tissue with an implant outer body and situating the implant body within a lumen formed within the implant outer layer. The method may further include: a) releasably coupling the implant outer layer to an implant guide of a delivery tool prior to approaching the bore; b) releasably coupling the implant inner layer to the implant guide prior to situating the implant within the lumen; and c) releasably coupling the fastener to a fastener guide of the delivery tool to cause the attachment feature of the fastener to mechanically interlock with the locking element; wherein the implant guide and the fastener guide are operably coupled such that, when the implant guide is releasably coupled to the implant body, a delivery arrangement automatically exists such that the fastener guide is correctly oriented to mechanically interlock the attachment feature with the locking element.

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

BRIEF DESCRIPTION OF THE DRAWINGS

The following figures illustrate various aspects of the disclosure.

FIG. 1 is a side view of an orthopedic anchoring system.

FIG. 2 is side view of an implant assembly.

FIG. 3 is a proximal perspective view of a solid cylindrical implant body.

FIG. 4 is proximal perspective view of a hollow cylindrical implant body with a longitudinal groove.

FIG. 5 is a distal perspective view of a solid cylindrical implant body with longitudinal projections.

FIG. 6 is a top perspective view of a rectangular flat plate implant body with dual self-locking retaining rings.

FIG. 7 is a bottom perspective view of a rectangular arcuate plate implant body with a single self-locking retaining ring.

FIG. 8 is an exploded perspective view of a hexagonal tool receptacle and corresponding tool fitting.

FIG. 9 is an exploded perspective view of a threaded tool receptacle and corresponding tool fitting.

FIG. 10 is a transverse cross-sectional view of a hexagonal retaining rod with retractable pins.

FIG. 11 is a longitudinal cross-sectional view of a retaining rod end inserted within a tool fitting.

FIG. 12 is a top view of a self-locking retaining ring.

FIG. 13 is a top view of a hexagonal self-locking retaining ring.

FIG. 14 is a transverse cross-sectional view of a non-circular cross-sectioned implant body fitted within a non-circular cross-sectioned lumen of an implant outer layer.

FIG. 15 is a transverse cross-sectional view of a circular cross-sectioned implant body fitted within a circular cross-sectioned lumen of an implant outer layer.

FIG. 16 is a longitudinal cross-sectional view of a circular cross-sectioned implant body fitted within a circular cross-sectioned lumen of an implant outer layer.

FIG. 17 is a longitudinal cross-sectional view of a protruding end of an implant body limited by a distal stop formed within an implant outer layer.

FIG. 18A is a transverse cross-sectional view of a hollow cylindrical implant body with a longitudinal groove.

FIG. 18B is a transverse cross-sectional view of a longitudinal ridge projecting from a lumen of an implant outer layer.

FIG. 18C is a transverse cross-sectional view of an implant body with a longitudinal groove inserted in a lumen with a projecting longitudinal ridge situated within the longitudinal groove.

FIG. 19 is a distal perspective view of an implant outer layer with a triangular external cross-sectional profile.

FIG. 20 is an exploded perspective view of a tool fitting with indentations and a corresponding end of a retaining rod.

FIG. 21 is a proximal perspective view of an implant body and end of a retaining rod in an interlocked arrangement.

FIG. 22 is a proximal perspective view of an implant outer layer showing a fastener opening.

FIG. 23 is an exploded perspective view of an implant outer layer with a fastener opening and a solid implant body.

FIG. 24 is a proximal perspective view of an implant body mechanically locked in place within an implant outer layer.

FIG. 25 is a proximal perspective view of an implant outer layer with anti-migration serrated edges.

FIG. 26 is a proximal perspective view of an implant outer layer with anti-migration wedge-shaped ridges.

FIG. 27 is a proximal perspective view of an implant outer layer with a plurality of perforations.

FIG. 28 is an exploded side view of a fastener and threaded compression nut.

FIG. 29 is a side view of a fastener with a peg-like head.

FIG. 30 is a side detail view of a fastener with a ball fitting.

FIG. 31 is a side detail view of a fastener with a rounded fitting.

FIG. 32 is a side detail view of a fastener with a cone fitting.

FIG. 33 is a side detail view of a fastener with a divoted fitting.

FIG. 34 is a distal perspective view of an implant assembly that includes a slotted implant body and a fastener with a ball fitting, shown assembled to illustrate a locking mechanism.

FIG. 35 is a longitudinal cross-sectional view of an implant assembly that includes a solid implant body with a self-locking retaining ring and a fastener with a rounded fitting, shown assembled to illustrate a locking mechanism.

FIG. 36 is a side perspective view of an implant assembly that includes an implant body with longitudinal projections and a fastener with a ball fitting situated within the longitudinal projections.

FIG. 37 is a longitudinal cross-sectional view of the implant assembly illustrating the spatial relationships between a ball fitting, an implant body, and an implant outer layer in a locking mechanism.

FIG. 38 is a side view of a delivery tool attached to an implant assembly.

FIG. 39 is a side view of a targeting arm with a right-angle shape.

FIG. 40 is a transverse cross-sectional view of a targeting arm of the delivery tool illustrated in FIG. 38 taken at cross-sectional plane A-A.

FIGS. 41A and 41B are side views of a telescoping targeting arm with arcuate shape.

FIGS. 42A and 42B are side views of an adjustable targeting arm with a right-angle shape.

FIGS. 43A and 43B are detailed perspective views of a first end of the targeting arm illustrated in FIG. 38.

FIG. 44A is a detailed perspective view of a second end of a targeting arm and a retaining rod.

FIG. 44B is an exploded perspective view of the implant guide attachment fitting illustrated in FIG. 44A.

FIG. 45 is a side view of the fastener guide illustrated in FIG. 38.

FIG. 46 is a detailed side view of the bone screw inserter illustrated in FIG. 45 with the threaded sleeve and removable handle removed.

FIG. 47 is a detailed proximal perspective view of the proximal end of the bone screw inserter illustrated in FIG. 46.

FIG. 48 is a detailed perspective view of a proximal end of a bone screw inserter.

FIG. 49 is a bottom view of a removable handle.

FIG. 50 is a detailed side view of the distal end of the bone screw inserter illustrated in FIG. 46.

FIG. 51 is a distal perspective view of the distal end of the bone screw inserter illustrated in FIG. 46.

FIG. 52 is an enlarged side view of the removable handle illustrated in FIG. 45 with the threaded sleeve and bone screw inserter removed.

FIG. 53 is a side perspective view of a removable handle with the collar and underlying components removed.

FIG. 54 is a longitudinal cross-sectional view of a removable handle taken at the plane B-B denoted in FIG. 53 and with the collar and underlying components removed.

FIG. 55 is a detailed side view of a distal end of a handle with a sliding collar removed.

FIG. 56 is a longitudinal cross-sectional view taken through the collar and underlying components illustrated in FIG. 52 with the distal portion of the handle removed.

FIG. 57 is a longitudinal cross-sectional view taken through a collar and underlying components, a distal end of a handle, and a proximal end of a bone screw inserter.

FIG. 58 is a longitudinal cross-section of a threaded sleeve taken in a plane approximately parallel with the drawing plane of FIG. 45 and coincident with a longitudinal axis of a threaded sleeve.

FIG. 59 is a longitudinal cross-sectional view of FIG. 58 with the bone screw inserter included.

FIG. 60 is a side view of a head of a fastener attached to a bone screw inserter and threaded sleeve.

FIG. 61 is a detailed cross-sectional view of a head of a fastener attached to a bone screw inserter and threaded sleeve taken along the plane C-C illustrated in FIG. 60.

FIG. 62 is a side view of an implant guide.

FIG. 63 is a detailed proximal side view of an implant guide with handle body housing, grip, and proximal access port removed.

FIG. 64 is a detailed proximal perspective view of an implant guide with handle body housing, grip, and proximal access port removed.

FIG. 65 is a lateral cross-sectional view of the implant guide handle illustrated in FIG. 62 taken in the drawing plane of FIG. 62.

FIG. 66 is a distal perspective view of a dual-element retaining rod.

FIG. 67 is a distal perspective view of a central shaft of a dual-element retaining rod.

FIG. 68 is a distal perspective view of an outer sleeve of a dual-element retaining rod.

FIG. 69 is an illustration of a simulated orthopedic procedure to stabilize a sacroiliac joint using an orthopedic anchoring system, viewed from a craniolateral and posterior vantage.

FIG. 70 is an illustration of a simulated orthopedic procedure to provide an anchor for an orthopedic appliance using an orthopedic anchoring system viewed from a posterio-caudal vantage.

FIG. 71 is an illustration of an orthopedic anchoring system situated on a patient, viewed from a cranioposterior vantage.

FIG. 72 is an illustration of an orthopedic anchoring system situated on a patient, viewed from a posterio-caudal vantage.

FIG. 73 is an illustration of an orthopedic anchoring system situated on a patient, viewed from a posterio-caudal vantage, with all soft tissues removed.

FIG. 74 is an illustration of an orthopedic anchoring system situated on a patient, viewed from an anteriolateral/cranial vantage, with all soft tissues removed.

FIG. 75 is an illustration of an orthopedic anchoring system situated on a patient, viewed from a posteriolateral/cranial vantage, with all soft tissues and the patient's left ilium removed.

FIG. 76 is an illustration of an orthopedic anchoring system situated on a patient, viewed from a posteriolateral/cranial vantage, with all soft tissues and the patient's left ilium, sacrum, and L5 vertebra removed, and the implant outer layer of an implant assembly removed.

FIG. 77 is an illustration of an orthopedic anchoring system situated on a patient, viewed from a posteriolateral/cranial vantage, with all soft tissues and the patient's left ilium, sacrum, and L5 vertebra removed, as well as the targeting arm, implant guide arm, implant body and implant outer layer removed.

FIG. 78 is an illustration of an implant assembly situated on a patient, viewed from a posteriolateral/cranial vantage, with all soft tissues and the patient's left ilium, sacrum, and L5 vertebra removed.

FIG. 79 is an illustration of an implant assembly with the implant outer layer removed situated on a patient, viewed from a posteriolateral/cranial vantage, with all soft tissues and the patient's left ilium, sacrum, and L5 vertebra removed.

FIG. 80 is an illustration of a fastener of an implant situated on a patient, viewed from a posteriolateral/cranial vantage, with all soft tissues and the patient's left ilium, sacrum, and L5 vertebra removed.

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

DETAILED DESCRIPTION

Disclosed herein is an orthopedic anchoring system and method for providing structural support, reinforcement, and/or anchoring for a variety of orthopedic appliances. Non-limiting examples of orthopedic devices compatible with aspects of the orthopedic anchoring system include: vertebral reinforcement or immobilization devices; intervertebral joint reinforcement or immobilization devices; internal fixation devices; and any other orthopedic appliances or orthopedic applications known in the art.

A side view of the elements of an orthopedic anchoring system 100 is illustrated in FIG. 1. In an aspect, the system 100 includes an implant assembly 200 and a delivery tool 300. The implant assembly 200 may be situated and installed within a selected afflicted region of a patient, such as an intervertebral joint, using the delivery tool 300. In an aspect, the implant assembly 200 may include an implant body 102, an implant outer layer 104 and a fastener 106. The implant assembly 200 may provide a highly stable anchor that is resistant to loosening, backing out or otherwise functionally degrading due to the cumulative effect of forces and torques. In an aspect, the forces and torques may be experienced by the implant assembly 200 as a result of normal posture and/or movements including, but not limited to, bending, sitting, walking, and any other typical movements or postures. This stabilized orthopedic fastener 106 and other elements of the implant assembly 200 are particularly well-suited for a variety of orthopedic applications such as intervertebral joint immobilization, intervertebral joint stabilization, and other such surgical interventions.

The delivery tool 300 may facilitate the alignment and mechanical attachment of the fastener 106 to the implant body 102 in a safe and reliable manner. In an aspect, the delivery tool 300 may include a targeting arm 108 and a retaining rod 110. The retaining rod 110 may be releasably secured to the implant body 102 and/or the implant outer layer 104 when situating the implant assembly 200 within the afflicted region of the patient. The targeting arm 108 may situate and maintain the fastener 106 in precise alignment with the implant body 102 and/or implant outer layer 104 during insertion of the fastener 106 and the attachment of the fastener 106 to the implant body 102 and/or implant outer layer 104.

The implant body 102 may include additional features to provide additional functions to the implant body 102. Non-limiting examples of enhanced functions of the implant body 102 include: providing a receptacle and/or other means of mechanical attachment for the fastener 106; providing a

means of detachably fastening a component of the delivery tool **300** such as the retaining rod **110** to the implant body **102** during the placement of the implant body **102**; and facilitating the alignment and/or orientation of the implant body **102** within the implant outer layer **104** during the formation of the implant assembly **200**.

Aspects of the orthopedic anchoring system **100** described herein provide a robust anchoring element for orthopedic appliances and devices. Various elements of the implant assembly **200**, including the implant outer layer **104**, may facilitate the integration of surrounding bone tissue into the peripheral margins of the implant assembly **200**, further stabilizing the implant assembly **200**.

Detailed descriptions of various embodiments of the implant assembly **200**, delivery tool **300**, and methods of using the system **100** are provided herein below.

I. Implant Assembly

The elements of an implant assembly **200** in one aspect are illustrated in FIG. **2**. In this aspect, the implant assembly **200** may include an implant body **102**, an implant outer layer **104** and a fastener **106**. The implant outer layer **104** may house at least a portion of the implant body **102**; a remaining portion of the implant body **102** may protrude from the implant outer layer **104**, as illustrated in FIG. **2**. The fastener **106** may mechanically attach to the implant body **102** and/or the implant outer layer **104**. The implant outer layer **104** may be inserted within a bore (not shown) formed within bone tissue situated within or adjacent to an afflicted region of the patient to provide a stationary anchor for the implant body **102** and fastener **106**. In an aspect, the implant body **102** and/or the implant outer layer **104** may further incorporate additional features to engage the fastener **106** in a locked mechanical attachment.

a. Implant Body

In various aspects, the implant body **102** may provide structural support and anchoring for the fastener **106**. FIG. **3** is a drawing illustrating an implant body **102A** in one aspect. In this aspect, the implant body **102A** includes a body proximal end **302** and a body distal end **304**. The implant body **102** may have an elongate cylindrical form, as illustrated in FIG. **3**, or any other shape without limitation. Additional implant body **102** shapes in various aspects are described herein below.

The implant body **102** may further include a body external surface **306** and a body central axis **308** extending from the body proximal end **302** to the body distal end **304** of the implant body **102A** and aligned with a longitudinal axis of the implant body **102**. In various aspects, the implant body **102** may further include at least one locking element **310** for receiving the end of the fastener **106** (not shown), a tool fitting **312** for receiving an end of the retaining rod **110** (not shown) at the body proximal end **302** opposite the locking element **310**, as well as ridges and/or grooves associated with the body external surface **306** for alignment of the implant body **102A** within the implant outer layer **104** (not shown) during the process of assembling the implant assembly **200**.

In one aspect, the implant body **102** may be machined, molded, formed, or otherwise manufactured from stainless steel, titanium, ceramic, polymer, composite, bone or other biocompatible materials.

i. Implant Body External Shape and Cross-Sectional Shape

As indicated in FIGS. **3-7**, the implant body **102** may have a variety of external shapes and cross-sectional profiles depending upon the desired properties and uses of the implant body **102**. For example, different shapes, sizes,

and/or cross-sectional profiles of the implant body **102** may be selected to accommodate various orthopedic surgical areas and/or procedures, patient morphologies, shapes and types of orthopedic fasteners, and/or any other relevant criterion.

The implant body **102** may be provided as any external shape without limitation, so long as the implant body **102** is capable of performing all aspects of the implant body's function. For example, the external shape may be selected to fit either partially or entirely within an interior lumen **1402** of the implant outer layer **104** in various aspects. In another example, the external shape may be selected to have a non-circular cross-section in order to inhibit rotation of the implant body **102** within the lumen **1402** of the implant outer layer **104**. The external shape may be selected to include one or more longitudinal ridges or other features projecting outward or inward perpendicular to the body external surface **306** in an aspect. For example, the implant body **102** may include one or more longitudinal grooves **506** extending along the length of the implant body **102** and projecting inward relative to the body external surface **306**, as illustrated in FIG. **5**.

Non-limiting examples of suitable external shapes for the implant body **102** include: a solid cylinder, as illustrated in FIG. **3** and FIG. **5**; a hollow cylinder, as illustrated in FIG. **4**; a planar flat plate, as illustrated in FIG. **6**; or an arcuate flat plate, as illustrated in FIG. **7**. In various aspects, the external shapes of the implant body **102** may be generally elongate such that the length of the implant body **102** from the body proximal end **302** to the body distal end **304** is longer than the thickness of the implant body **102**. The implant body **102** may also be any length which allows a fastener **106** with a connection fitting to attach to the implant body **102** at the locking element **310**.

In another aspect, the cross-sectional shape of the implant body **102** may have any solid or hollow profile, without limitation. Non-limiting examples of suitable cross-sectional shapes of the implant body include circular, elliptical, semi-circular, rectangular, triangular, any other polygonal geometry, and any other non-circular geometry. In an additional aspect, the cross-sectional shape and size may be uniform along the full length of the implant body **102** to facilitate the insertion of the implant body **102** into the lumen **1402** of the implant outer layer **104**.

In yet another aspect, the implant body **102** may include a body lumen **402** contained within the interior of the implant body **102**. The body lumen **402** may extend the entire length of the implant body **102**, as illustrated in FIG. **4**. In this aspect, the body lumen **402** extends from the body proximal end **302** to the body distal end **304**. In other aspects, the body lumen **402** may extend only a portion of the length of the implant body **102**. For example, the body lumen **402** may open outward through the body proximal end **302**, but may be bounded somewhere between the body proximal end **302** and the body distal end **304** at a transition from a hollow body cross-section to a solid body cross-section. In another example, the body lumen **402** may open outward through the body distal end **304**, but may be similarly bounded somewhere between the body proximal end **302** and the body distal end **304** at a transition from a hollow cross-section to a solid cross-section.

The body lumen **402** may further open laterally through the body external surface **306** in one or more regions along the length of the implant body **102**. These one or more lateral openings may be in the form of discrete openings including, but not limited to, holes, slits, or any other discrete opening type. The one or more discrete openings may be arranged in

any distribution without limitation. In one aspect, the one or more lateral openings may take the form of a longitudinal groove 404, as illustrated in FIG. 4. The lateral openings may provide various functions to the implant body 102 including, but not limited to: an alignment guide for aligning the implant body 102 within the implant outer layer 104 during the process of assembling the implant assembly 200; a structural feature forming at least a portion of a locking element 310; and/or a structural feature forming at least a portion of a tool fitting 312.

In another aspect, the implant body 102 may include one or more longitudinal projections extending in a direction essentially parallel with the body central axis 308 in a proximal and/or distal direction. For example, the implant body 102 may include a pair of longitudinal projections 502A and 502B as illustrated in FIG. 5. The longitudinal projections 502A and 502B may define the lateral sides of a slot 504 in this aspect. The slot 504 may function in a variety of ways in the implant assembly 200 including, but not limited to, functioning as part of a locking element 310.

Specific examples of the function of the features of the implant body as a tool fitting, a locking element, and other functions are described in further detail herein below.

ii. Tool Fitting

In various aspects, the implant body 102 includes a tool fitting 312 to provide a means of releasably connecting an end of the retaining rod 110 to the body proximal end 302 during insertion of the implant body 102 into the implant outer layer 104 and/or securing the implant body 102 in a fixed alignment while the fastener 106 is mechanically connected to the implant body 102.

The tool fitting 312 may be situated at the body proximal end 302 of the implant body 102 in one aspect, as illustrated in FIG. 3. In this aspect, the tool fitting 312 may be provided in the form of a hexagonal recess within the body proximal end 302. As illustrated in FIG. 8, the hexagonal cross-sectional shape and dimensions of the recess 802 forming the tool fitting 312 are selected such that a corresponding end 804 of the retaining rod 110, which also has a hexagonal cross-section, fits closely within the hexagonal recess 804 in this aspect. Any cross-sectional shape for the recess 802 forming the tool fitting 312 may be selected without limitation, so long as this cross-sectional shape corresponds to the cross-sectional shape of the corresponding end 804 of the retaining rod 110.

In another aspect (not shown), the end 804 of the retaining rod 110 may include a recess within which a tool fitting 312 in the form of a protrusion extending from the body proximal end 302 may fit. In this aspect, any cross-sectional shape for the recess within the end of the retaining rod 110 may be selected without limitation, so long as this cross-sectional shape is matched to the cross-sectional shape of the tool fitting 312 extending from the body proximal end 302. Any non-circular cross-section may be selected for the tool fitting 312 of the retaining rod 110 and corresponding body proximal end 302 including, but not limited to: any non-circular polygonal cross-section such as triangular, square, and hexagonal; other non-circular cross-sections such as elliptical.

The tool fitting 312 may incorporate other features such as corresponding threaded fittings to releasably connect the end of the retaining rod 110 to the body proximal end 302. Referring to FIG. 9, the body proximal end 302 may include a threaded receptacle 406 that receives a corresponding threaded end 902 of the retaining rod 110. In this aspect, the threaded end 902 may be advanced into the threaded receptacle 406 until the threaded end 902 has advanced the full extent of the threads in the threaded receptacle 406. In

another aspect (not shown), the end of the retaining rod 110 may include a threaded recess into which a threaded end of the body proximal end 302 may be advanced to releasably connect the body proximal end 302 to the end of the retaining rod 110.

In additional aspects, the tool fitting 312 may incorporate features such as retractable pins or fins to releasably connect the end of the retaining rod to the body proximal end. In one additional aspect, illustrated in FIG. 10 as a transverse cross-section, the retaining rod end 1002 may include one or more retractable pins 1004 or fins (not shown) that project laterally outward from the surface of the retaining rod end 1002 in an extended position. These one or more retractable pins 1004 may be retracted into corresponding inner receptacles 1006 formed within the retaining rod end 1002 during the insertion of the retaining rod end 1002 into the tool fitting 312 in the body proximal end 302. Upon insertion, the retaining rod end 1002 may be reversibly locked into place within the tool fitting 312 by extending the retractable pins 1004 radially outward to engage corresponding outer pin receptacles 1008 formed within the wall surrounding the tool fitting 312. After the implant assembly 200 is installed within the afflicted region of the patient, the retaining rod 110 may be removed from the implant body 102 by retracting the one or more retractable pins 1004 and sliding the retaining rod end 1002 from the tool fitting 312. FIG. 11 is a longitudinal cross-section of the retaining rod end 1002 inserted within the tool fitting 312, showing the retractable pins 1004 engaged with the corresponding outer pin receptacles 1008, thereby locking the retaining rod end 1002 in place.

In another additional aspect (not shown) the retractable pins 1004 may retract outward into the corresponding outer pin receptacles 1008 during insertion and/or removal of the retaining rod end 1002 from the tool fitting 312. The retaining rod end 1002 may be locked into the tool fitting 312 by extending the retractable pins 1004 radially inward to engage corresponding inner pin receptacles 1006 formed within the retaining rod end 1002.

iii. Locking Element

The implant body 102 may further include at least one locking element 310 for receiving a fastener 106. In various aspects, the locking element 310 may reversibly or irreversibly engage a corresponding attachment fitting 2810 of the fastener 106 in a locked engagement to form an anchor for an orthopedic appliance, orthopedic procedure, or other treatment of an afflicted region of a patient.

FIG. 3 is a perspective view of an implant body 102 that includes a locking element 310 in one aspect. The location of the locking element 310 on the implant body 102 may include, but is not limited to, any position situated between the body distal end 304 and the body proximal end 302, as well as extending distally away from the body distal end 304. The locking element 310 may extend any portion of the length of the implant body 102 from the body proximal end 302 to body distal end 304 up to the entire length of the implant body 102. For example, the longitudinal groove 404, shown illustrated in the perspective view of an implant body 102B in FIG. 4, may function as a locking element 310 that extends the entire length of the implant body 102B. As an additional example, as illustrated in the perspective view of FIG. 5, a slot 504 formed between a pair of longitudinal projections 502A and 502B may function as the locking element 310.

Any known means of securing a fastener 106 to a locking element 310 may be suitable for use in the implant assembly 200. Due to the limited visibility inherent in many ortho-

pedic surgical procedures, a means of securing a blind fastener **106** may be particularly well-suited for use in the implant assembly **200**. The type of locking element **310** may be selected to be compatible with the particular attachment fitting **2810** of the fastener **106** used in the implant assembly **200**. The locking element **310** may further be selected to provide for limited movements of the fastener **106** in one or more predefined directions after the fastener is attached in a locked engagement with the locking element **310**.

Non-limiting examples of suitable locking elements include: self-locking retaining ring, slots, threaded fittings, divoted fittings, and one or more longitudinal projections forming slots. The locking elements **310** may be situated entirely within or upon the implant body **102** in one aspect. In another aspect, at least one locking element **310** may be situated within or upon the implant body **102** and one or more other locking elements may be situated within or upon the implant outer layer **104**. In this aspect, the locking elements of the implant body **102** and the implant outer layer **104** may interact in an interlocking manner to form the locked engagement with attachment fitting **2810** of the fastener **106**. In additional aspects, the implant body **102** may include a single locking element **310**, as illustrated in FIGS. 3-5 and FIG. 7, or the implant body **102** may include two or more locking elements **310**, as illustrated in FIG. 6.

In one aspect, the locking element **310** opens laterally outward in a direction generally perpendicular to the body central axis **308** of the implant body **102**. The opening formed by the locking element **310** may extend fully through the entire implant body, as illustrated in FIG. 6 and FIG. 7. In another aspect, the locking element **310** may extend from the body external surface **306** to the interior of the implant body **102**, which may be of solid cross-section, as illustrated in FIG. 3. In yet another aspect, illustrated in FIG. 4, the locking element **310**, provided in this aspect as a longitudinal groove **404**, may extend from the body external surface **306** into the body lumen **402** of the hollow implant body **102B**.

In another aspect, the locking element **310** may be a self-locking retaining ring **1202**. A top view of a self-locking retaining ring **1202** is illustrated in FIG. 12. The self-locking retaining ring **1202** may include a planar circular opening **1204** with at least three arcuate members **1206A**, **1206B**, and **1206C** distributed around a circumference of the planar circular opening **1204** and projecting radially inward toward a center **1208** of the planar circular opening **1204**. The at least three arcuate members **1206A**, **1206B**, and **1206C** may be separated by a distance corresponding to a narrowed region of the attachment fitting of the fastener **106** (not shown), described in detail herein below. The at least three arcuate members **1206A**, **1206B**, and **1206C** may be flexible to facilitate the deformation of the arcuate members **1206A**, **1206B**, and **1206C** to accommodate larger-diameter elements of the fastener **106** during its insertion into the self-locking retaining ring **1202**. The self-locking retaining ring **1202** allows an attachment fitting of a fastener **106** to be inserted into the locking element **310** of the implant body **102** but restricts the movement of the fastener **106** out of the locking element **310** once inserted. A detailed description of the attachment of the fastener **106** to the implant body **102** via the self-locking retaining ring **1202** is provided herein below.

In other aspects, the self-locking retaining ring **1202** may include a planar non-circular opening with at least three flexible arcuate or non-arcuate members projecting from a perimeter of the non-circular opening into a center of the non-circular opening. For example, the non-circular opening

may be provided as a polygonal shape such as a hexagonal opening **1302**, as illustrated in FIG. 13. In this aspect, six flexible non-arcuate members **1306A-1306F** project from a perimeter of the hexagonal opening **1304** toward the hexagon center **1308**. In other additional aspects, the self-locking retaining ring **1202** may be non-planar. For example, a locking element **310** such as a self-locking retaining ring **1202** may be provided as an arcuate shape to conform to the shape of an arcuate implant body **102E**, as illustrated in FIG. 7.

In additional aspects the locking element **310** may be provided in the form of a longitudinal groove **404**. Referring to FIG. 4, the longitudinal groove **404** may extend from the body distal end **304** to the body proximal end **302** of the implant body **102** and may be aligned parallel to the body central axis **308**. In general, the longitudinal groove **404** may have any intermediate length up to the full length of the implant body **102**. The dimensions of the longitudinal groove **404** including, but not limited to, groove width, groove depth, and any other groove dimension may be selected to provide a compatible fit with the corresponding attachment fitting of the fastener **106**. For example, the longitudinal groove **404** may have a minimum width corresponding to the narrowest region of the attachment fitting **2810** of the fastener **106**. This width may allow the attachment fitting **2810** of the fastener **106** to extend through the longitudinal groove **404** but retain the attachment fitting **2810** within the longitudinal groove **404** once the fastener **106** is inserted through the longitudinal groove **404**.

In another aspect, the locking element **310** may be provided in the form of a slot **504** formed between a pair of longitudinal projections **502A** and **502B** as illustrated in FIG. 5. The longitudinal projections **502A** and **502B** may have a minimum length that is essentially equal to the cross-sectional diameter of the attachment fitting of the fastener **106**. In this aspect, the longitudinal projections **502A** and **502B** may lock an attachment fitting of a fastener **106** using a meshing engagement with additional locking elements **310** formed within the implant outer layer **104**, as described herein below. To facilitate this meshing engagement, the distal end **304** of the implant body **102** may further contain additional features including, but not limited to, a distal body depression **508** contoured to the shape of the attachment fitting **2810** of the fastener **106** that projects through the slot **504** after insertion of the fastener **106**.

iv. Alignment Features

In an aspect, the implant body **102** may further include surface features on the body external surface **306** to guide the placement and/or orientation of the implant body **102** within the implant outer layer **104** during the formation of the implant assembly **200**. These surface features may facilitate the alignment of the locking element **310** with a corresponding fastener opening **2202** in the implant outer layer **104**. The surface features may limit the insertion depth of the implant body **102** through the implant outer layer **104** to ensure that the body distal end **304** protrudes from the implant outer layer **104** by an appropriate amount for purposes of alignment of the fastener **106** with the locking features of the implant outer layer **104** and/or locking element **310**. The surface features may ensure an appropriate alignment of the fastener **106** locked within the implant outer layer **104** and/or the implant body **102** for function as an anchor.

Any known method of aligning a pair of nested elements may be selected for use as alignment features for the implant body **102** so long as the alignment features are compatible with corresponding alignment features of the implant outer

layer 104. In one aspect, illustrated as a transverse cross-section in FIG. 14, the alignment feature may be provided in the form of a non-circular cross-sectional shape of the implant body 102 that may closely fit within a lumen 1402 of the outer layer 104 with a corresponding non-circular cross-sectional profile. In this aspect, the non-circular cross-sectional profile of the implant body 102 and lumen 1402 inhibit the rotation of the implant body 102 relative to the implant outer layer 104, thereby maintaining a predetermined alignment during the formation of the implant assembly 200.

In another aspect, the implant body 102 and implant outer layer 104 may have matching cross-sectional shapes including circular cross-sectional shapes, as illustrated in the transverse cross-sectional view of FIG. 15. In this aspect, the alignment feature may be provided in the form of at least one longitudinal ridge 1502 projecting outward from the body external surface 306 that may be situated within a corresponding groove 1504 formed within a lumen wall 1506 that defines the lumen 1402 of the implant outer layer 104.

A longitudinal cross-section of the implant assembly 200 of FIG. 15 is illustrated in FIG. 16. During the insertion of the implant body 102 within the lumen 1402 of the implant outer layer 104, each longitudinal ridge 1502 may slide within a corresponding groove 1504, ensuring proper alignment of the implant body 102 within the implant outer layer 104. Each longitudinal ridge 1502 and corresponding groove 1504 may extend the entire length of the implant body 102 and outer layer 104, respectively, or each longitudinal ridge 1502 and corresponding groove 1504 may extend only a partial length of the implant outer layer 104, as illustrated in FIG. 16.

Referring again to FIG. 16, each longitudinal ridge 1502 may end in a distal face 1602 and each corresponding groove 1504 may end in a distal stop 1604. In another aspect, illustrated in the longitudinal cross-section of FIG. 17, the distance at which the protruding end 1702 of the implant body 102 extends from the implant outer layer 104 may be limited by the mechanical interference of the distal stop 1604 with the distal face 1602. During the formation of the implant assembly 200, the implant body 102 may be inserted within the lumen 1402 of the implant outer layer 104 until the distal face 1602 contacts the distal stop 1604, preventing further insertion of the implant body 102.

In another aspect, illustrated in FIG. 18A as a transverse cross-section of the implant body 102B illustrated in FIG. 4, the alignment feature may be provided in the form of a longitudinal groove 1802 formed within the implant body 102B. In this aspect, the longitudinal groove 1802 may fit within a longitudinal ridge 1804 projecting inward toward the lumen 1402 of an implant outer layer 104, as illustrated in the transverse cross-section illustrated in FIG. 18B. When the implant assembly 200 is produced by inserting the implant body 102B into the lumen 1402 as illustrated in the transverse cross-section of FIG. 18C, the meshing of the longitudinal ridge 1804 within the longitudinal groove 1802 maintains the desired alignment of the implant body 102 within the implant outer layer 104.

In an additional aspect (not shown), the alignment feature may be provided in the form of at least one discrete extendable pin projecting from the body external surface 306 of the implant body 102. Each extendable pin may fit within a corresponding pin receptacle formed within the lumen wall 1506 of the implant outer layer 104 when the implant body 102 is situated in a predetermined alignment within the implant outer layer 104. In another additional aspect, the alignment feature may be provided in the form of

one or more pin receptacles formed within the body external surface 306 of the implant body 102 that receive corresponding extendable pins projecting inward from the lumen wall 1506 when the implant body 102 is situated in a predetermined alignment within the lumen 1402.

In yet other aspects (not shown), the alignment feature may be provided in the form of circumferential threads formed within the body external surface 306 of the implant body 102. In this aspect, the circumferential threads may extend from the body distal end 304 toward the body proximal end 302 up to the full length of the implant body 102. The circumferential threads may engage mechanically with a circumferential threaded fitting formed within the lumen wall 1506 of the implant outer layer 104. This circumferential threaded fitting may extend from the outer layer proximal end 1902 of the implant outer layer 104 in a distal direction up to the full length of the lumen 1402 of the implant outer layer 104. In this aspect, the length of the circumferential threads and/or circumferential threaded fitting may determine the degree of penetration of the implant body 102 through the lumen 1402 of the implant outer layer 104, thereby controlling the distance at which the implant body 102 projects from the implant outer layer 104.

b. Implant Outer Layer

The implant body 102 may be partially or fully contained within an implant outer layer 104 in various aspects. The implant outer layer 104 in one aspect is illustrated in FIG. 19. The implant outer layer 104 may be inserted within a bore (not shown) formed within the afflicted region of the patient to provide a stationary anchor for the implant body 102 and fastener 106 (not shown). The implant outer layer 104 may interact mechanically and/or biologically with the bone tissue within the bore and may provide features that may encourage bone growth, prevent migration and/or loosening of the implant assembly 200 within the bore, and/or otherwise stabilize the position of the implant assembly 200.

In an aspect, the implant outer layer 104 may include an outer layer proximal end 1902 and an outer layer distal end 1904. The implant outer layer 104 further contains a lumen 1402 bounded by a lumen wall 1906; the lumen 1402 extends from the outer layer proximal end 1902 to the outer layer distal end 1904. The implant outer layer 104 may further include a fastener opening 2202 formed through the lumen wall 1906 to provide access to the locking element 310 of the implant body 102. During the formation of the implant assembly 200, the implant body 102 may be inserted into the lumen 1402. In various aspects, the implant body 102 may be contained completely within the lumen 1402, or the body distal end 304 may protrude from the outer layer distal end 1904. In some aspects, the implant outer layer 104 may include one or more locking elements 310 that may help to secure the fastener 106 in a locked attachment during the formation of the implant assembly 200. In other additional aspects, the implant outer layer 104 may further include an external surface 1908 that contacts the inner surface of the bore formed in the bone tissue of the patient within an afflicted area. In these other additional aspects, the external surface 1908 of the implant outer layer 104 may further include surface textures, surface coatings, holes or pores, and any other surface features known in the art to encourage the incorporation of bone tissue; these surface features may inhibit the movement or loosening of the implant assembly 200 within the bore over extended post-implantation periods.

In one aspect, the implant outer layer 104 may be machined, molded, formed, or otherwise manufactured from

stainless steel, titanium, ceramic, polymer, composite, bone or other biocompatible materials.

i. Outer Layer External and Cross-Sectional Shape

The implant outer layer **104** may have a variety of cross-sectional shapes in various aspects. The cross-sectional shape of the implant outer layer **104** may facilitate the anchoring of the implant outer layer **104** within the bore, may provide one or more locking elements **310** to secure the attachment fitting of the fastener **106**, and/or may provide one or more corresponding alignment features to ensure the proper alignment and/or insertion depth of the implant body **102** within the lumen **1402**.

The implant outer layer **104** may have a variety of external shapes and cross-sectional profiles without limitation, depending upon the desired properties and uses of the implant outer layer **104**. For example, different shapes, sizes, and/or cross-sectional profiles of the implant outer layer **104** may be selected to accommodate various orthopedic surgical areas and/or procedures, patient morphologies, shapes and types of implant bodies **102**, shapes and types of fasteners **106**, and/or any other suitable criterion.

The implant outer layer **104** may be provided as any external shape without limitation, so long as the implant outer layer **104** is capable of performing all aspects of the outer layer's function. In one aspect, the external cross-sectional profile of the implant outer layer **104** may be selected to fit within the bore formed within the afflicted area of the patient. In this aspect, the external cross-sectional profile may be selected to match a cross-sectional profile of a bore formed using known orthopedic surgical techniques. For example, the external cross-sectional profile of the implant outer layer **104** may be circular to match a bore created by a drill-type surgical bone removal device. In other aspects, the external cross-sectional profile of the implant outer layer **104** may be a non-circular profile to enhance the stability of the outer layer within the bore; for example an implant outer layer **104** with a triangular external cross-sectional profile, as illustrated in FIG. **19**, may impart a resistance to twisting within the bore during subsequent use. Non-limiting examples of non-circular cross-sectional profiles include elliptical, semi-circular, rectangular, triangular, any other polygonal geometry, and any other non-circular geometry.

Referring again to FIG. **19**, the cross-sectional profile of the implant outer layer **104** includes the lumen **1402** for receiving the implant body **102** in various aspects. The cross-sectional profile of the lumen wall **1906** that forms the lumen **1402** may be selected independently of the external cross-sectional profile of the implant outer layer **104**. The cross-sectional profile of the lumen wall **1906** may be selected to match the cross-sectional profile of the implant body **102**. In an aspect, the cross-sectional profile of the lumen wall **1906** may be relatively constant along the length of the implant outer layer **104** to facilitate the insertion of the implant body **102** during the formation of the implant assembly **200**. In another aspect (not shown), the cross-sectional profile of the lumen wall **1906** may be wider at the outer layer proximal end **1902** and narrower at the outer layer distal end **1904**. In this aspect, the narrower cross-sectional profile at the outer layer distal end **1904** may limit the degree of insertion of the implant body **102** to a predetermined distance in the implant assembly **200**.

In another aspect, the lumen wall **1906** may include at least one alignment feature to ensure that the implant body **102** is contained within the implant outer layer **104** at a predetermined orientation and/or insertion distance. In this aspect, the alignment features included in the lumen wall

1906 may be selected to be compatible with the corresponding alignment features included on the body external surface **306** of the implant body **102**. Non-limiting examples of suitable alignment features included in or on the lumen wall **1906** include longitudinal ridges, longitudinal grooves, extendable pins, pin receptacles, threaded receptacles, and any other suitable alignment feature known in the art. For example, the lumen wall **1906** may include a longitudinal ridge **1804**, illustrated in FIG. **19**, which may be situated within the longitudinal groove **404** of the implant body **102B** when the implant body **102** is inserted and/or contained within the implant outer layer **104** to maintain the desired alignment.

ii. Tool Fitting

In an aspect, the implant outer layer **104** may include a tool fitting for releasably connecting an end of the retaining rod **110** to the outer layer proximal end **402** of the implant outer layer **104**. The tool fitting may include, but is not limited to a threaded fitting **1910**, a hexagonal connection, or indentations **2002A-2002D** for interlocking with corresponding tines **2004A-2004D** on the retaining rod **110**. The implant outer layer **104** may connect with the retaining rod **110** to accurately situate the implant outer layer **104** within the bore formed at the surgical site and to fix the implant outer layer **104** in place while the fastener **106** is implanted.

For example, the outer layer may include a tool fitting in the form of a threaded fitting **1910**, as illustrated in FIG. **19**. In another example, illustrated as a perspective view in FIG. **20**, the implant outer layer **104B** may include a tool fitting in the form of indentations **2002A-2002D** formed within the external surface **1908** of the implant outer layer **104B** to reversibly attach to the end **2006** of the retaining rod **110** during formation of the implant assembly **200**. In this aspect, the indentations **2002A-2002D** may be situated and dimensioned to engage corresponding tines **2004A-2004D** projecting from the end **2006** of the retaining rod **110** in a reversibly interlocked arrangement. FIG. **21** is a perspective view illustrating the implant body **102** and the end **2006** of the retaining rod **110** in the interlocked arrangement.

iii. Fastener Opening or Fitting

Referring back to FIG. **2**, the implant outer layer **104** may be open at both the proximal and distal ends. In this aspect, the distal end of the implant body **102** may project from the implant outer layer **104**, exposing the locking element **310** formed within the implant body **102**. The fastener **106** may attach directly to the exposed locking element **310** within the implant body **102** without mechanical interference from the implant outer layer **104**.

FIG. **22** is a perspective view of an implant outer layer **104B** showing a fastener opening **2202** in another aspect. In this aspect, the lumen **1402** of the outer layer **104B** is closed at the outer layer distal end **1904**. As a result, the implant body **102** (not shown) fits completely within the lumen **1402**. The implant outer layer **104B** may include a fastener opening **2202** formed through the lumen wall **1906** to provide access to the locking element **310** of the implant body **102**. The fastener opening **2202** may be formed near the outer layer distal end **1904** and extend from the external surface **1908** into the lumen **1402**. The fastener opening **2202** may be situated in alignment with the corresponding locking elements **310** on the implant body **102** (not shown) to allow the fastener **106** access to the corresponding locking element **310** of the implant body **102** through the implant outer layer **104**.

The implant outer layer **104** may further include additional locking elements that mechanically engage with the fastener **106** along with the locking elements **310** formed

within the implant body **102** to stabilize and/or immobilize the fastener **106** (not shown) within the implant assembly **200**. Referring back to FIG. **22**, the implant outer layer **104B** may further include additional locking elements in the form of a lock slot **2204** formed within the lumen **1402** of the implant outer layer **104B** in an aspect. The lock slot **2204** may define a wider region **2206** for receiving an attachment fitting of a fastener **106** at its widest diameter, as well as a narrower region **2208** to securely contain a narrower region of an attachment fitting of the fastener **106** in cooperation with the locking elements **310** of the implant body **102**. The additional locking elements may further include contoured surfaces, such as a curved face **2210** illustrated in FIG. **22** at the distal end of the lumen **1402**. In an aspect, the curved face **2210** may be shaped to correspond with the curvature of an attachment fitting **2810** of the fastener **106** to enhance the locked engagement formed between the attachment fitting **2810** of the fastener **106**, the locking element(s) **310** of the implant body **102**, and the additional locking element(s) of the implant outer layer **104**. A detailed description of the locked engagement of the fastener **106** within the implant outer layer **104** and/or the implant body **102** is provided herein below.

In other aspects, the fastener opening **2202** may include additional locking elements in additional forms including, but not limited to: threaded fittings, self-locking retaining rings, and divoted fittings similar to those described herein above in association with the locking element of the implant body **102**.

The implant outer layer **104** may further include a mechanism to lock the implant outer layer **104** to the implant body **102**. FIG. **23** is an exploded view illustrating the implant outer layer **104B** illustrated previously in FIG. **22**, as well as the implant body **102C** previously illustrated in FIG. **5**. In this aspect, the implant body **102C** may be inserted into the lumen **1402** of the implant outer layer **104B**, followed by a threaded plug **2302**. The threaded plug **2302** includes circumferential threads **2308** that mesh with the threads of a threaded receptacle **2306** within the implant outer layer **104B**. The threaded plug **2302** may be advanced within the threaded receptacle **2306** thereby pushing the implant body **102C** further within the lumen **1402** ahead of the threaded plug **2302**. The advancement of the threaded plug **2302** may be limited by the contact of the longitudinal projections **502A** and **502B** of the implant body **102C** with the closed distal end of the lumen **1402**. In this assembled configuration, illustrated as a perspective view in FIG. **24**, the implant body **102C** may be mechanically locked into place between the closed distal end of the lumen **1402** and the threaded plug **2302**.

iv. Alignment Features

The implant outer layer **104** may have features on the inner surface **1506** of the lumen **1402** for interacting with corresponding features on the body external surface **306** of the implant body **102**, as described previously herein above in association with the description of the alignment features of the implant body **102**. In one aspect, the cross-sectional contour of the lumen **1402** may be a non-circular polygon, ellipsoid or any other shape dimensioned to closely fit a correspondingly-contoured implant body **102**, as illustrated in FIG. **14**. In another aspect, the inner surface **1506** of the lumen **1402** may include ridges or grooves **1504** to interlock with corresponding grooves or ridges **1502** on the body external surface **306** of the implant body **102**, as illustrated in FIGS. **15-17**. In an additional aspect, the implant outer layer **104** include retractable pins and/or pin receptacles that mechanically interlock with corresponding pin receptacles

and/or retractable pins formed or attached to the body external surface **306** of the implant body **102**. In yet another aspect, the implant outer layer **104** may further include features such as circumferential threads or threaded receptacles that mechanically intermesh with corresponding threaded receptacles or circumferential threads included in the implant body **102**.

v. External Surface Texture

The implant outer layer **104** may further include surface features and/or textures on the external surface **1908**. This exposed external surface **1908** may interact with the bone tissue mechanically and/or biologically and may include anti-migration surface features. These anti-migration surface features may assist in preventing the implant assembly **200** from moving or migrating within the afflicted area during prolonged use by the patient.

The implant outer layer **104** may include an anti-migration texture projecting outward from the external surface **1908** and/or other anti-migration surface features. Non-limiting examples of anti-migration surface features include a plurality of projections, a plurality of serrated teeth or ridges, a plurality of perforations, or any other surface feature on the external surface **1908** which may reduce the migration of the implant body **102** and/or implant outer layer **104**. The surface features may be unidirectional in an aspect.

In various aspects, the external surface **1908** of the implant outer layer **104** may have a plurality of projections as an anti-migration texture. The plurality of projections may extend to a projection height ranging from about 0.2 mm to about 5 mm from the surface. The plurality of projections may be distributed essentially uniformly over the external surface **1908**. The plurality of projections may project essentially perpendicularly from the external surface **1908**.

In another aspect, the external surface **1908** may have a plurality of unidirectional serrated teeth or ridges. Each serrated tooth or ridge may include a right triangular cross-section with a base, a side, and an apex. The base of each serrated tooth or ridge may extend perpendicularly from the external surface **1908** to a height ranging from about 0.2 mm to about 5 mm. The side of each serrated tooth or ridge may be coincident with the external surface **1908**. The apex of each serrated tooth or ridge may be situated nearer to the outer layer distal end **1904** relative to the base. FIG. **25** is a perspective view of an implant outer layer **104** that includes an anti-migration texture in the form of serrated edges **2502** in one aspect. FIG. **26** is a perspective view of an implant outer layer **104** that includes an anti-migration texture in the form of wedge-shaped ridges **2602** on the external surface **1908** in another aspect.

The external surface **1908** of the implant outer layer **104** may have a plurality of perforations **2702** that may extend from the external surface **1908** into the lumen **1402**. FIG. **27** is a perspective view of an implant outer layer **104** that includes a plurality of perforations **2702** in the external surface **1908** in an aspect. The plurality of perforations **2702** may provide spaces for the incorporation of bone tissue. The plurality of perforations **2702** may be distributed essentially uniformly over the external surface **1908**, as illustrated in FIG. **27**, or the plurality of perforations **2702** may be distributed in a non-uniform pattern in another aspect. In this other aspect, the plurality of perforations **2702** may be spaced in a closer distribution in close proximity to edges of the outer layer such as the outer layer proximal end **1902**, outer layer distal end **1904**, or in any other suitable pattern known in the art. The plurality of perforations **2702** may further include a compound suitable for inducing or enhanc-

ing a variety of effects to reinforce the fixation of the implant outer layer **104** and associated implant assembly **200** within the bore. Non-limiting examples of suitable effects for reinforcing the fixation of the anchor assembly within the bore include: stimulating the incorporation of bone tissue into the perforations **2702**, enhancing the biocompatibility of the implant assembly, enhancing the bonding of the external surface **1908** to the surrounding bone tissue of the bore, and any combination thereof. Non-limiting examples of suitable compounds to include within the plurality of perforations **2702** include: a bone growth factor, a nutrient, bone tissue transplant cells, bone stem cells, anti-rejection compounds, biocompatible bone cement, and/or any other suitable compound in any combination.

In one aspect, the external surface **1908** of the implant outer layer **104** may be treated with a bone growth factor or other compounds to encourage bone tissue growth around the implant assembly **200**. In another aspect, the lumen **1402** may be filled with a bone paste material. In this aspect, the bone paste material may be pressed out through the plurality of perforations **2702** when the implant body **102** is inserted into the lumen **1402** during the formation of the implant assembly **200**; the bone paste material pressed out of the lumen **1402** may be situated within any voids between the bore and the external surface **1908** of the implant outer layer **104**.

c. Fastener

In various aspects, the implant assembly **200** of the orthopedic anchoring system **100** may include an fastener **106** attached at one end to the implant outer layer **104** and/or implant body **102**. The fastener **106** may attach in a locked engagement to the implant outer layer **104** and/or implant body **102** at one or more locking elements, forming a robust anchor for an orthopedic procedure, orthopedic device or appliance, or any other related treatment of an afflicted region of a patient.

FIG. **28** is a side view of a fastener **106** in one aspect. The fastener may include a head **2802**, a shaft **2804** including a top end **2806**, and an attachment fitting **2810** opposite to the top end **2806**. In an aspect, the attachment fitting **2810** may include an end **3002** and a neck **3004**. The attachment fitting **2810** may mechanically attach to a corresponding locking element **310** of an implant body **102** and/or a locking element of an implant outer layer **104**.

The fastener **106** may be any surgical fastener type suitable for and/or compatible with various orthopedic interventions and treatments known in the art. Non-limiting examples of suitable surgical fasteners include nails, pins, screws, pegs, staples, and any other known surgical fastener type. In one aspect, the fastener **106** may be an orthopedic pedicle screw with a tulip-like head suitable for a variety of orthopedic procedures either in isolation or in combination with other orthopedic devices, appliances, and/or implants including, but not limited to, reinforcing rods, reinforcing wires, reinforcing plates, and any other reinforcing structural element.

In one aspect, the fastener **106** may be machined, molded, formed, or otherwise manufactured from stainless steel, titanium, ceramic, polymer, composite, bone or other biocompatible materials. The material of the fastener **106** may be compatible for continuous contact with the implant body **102** and implant outer layer **104**.

i. Head

In one aspect, the fastener **106** may include a head **2802**. The head **2802** may be provided in any form known in the art. The particular form of the head **2802** may be selected to be compatible with the orthopedic device or appliance to be

implanted within the afflicted region of the patient as part of an orthopedic surgical procedure. Referring back to FIG. **28**, the head **2802** may be provided in the form of a tulip-like head in one aspect. In this aspect, the head **2802** may include at least two support elements **2812** and **2814** forming the sides of at least one upward-opening groove **2816**. The head **2802** may further include a compression element **2818** forming the bottom surface of the groove **2816**. The inner surfaces of the at least two support elements **2812** and **2814** may further form a threaded fitting **2820** into which a threaded compression nut **2822** may be inserted during use.

In this aspect, the head **2802** may be attached to the top end **2806** of the shaft **2804** such that the head **2802** may rotate freely about a longitudinal axis of the shaft **2804**, but may not otherwise translate or rotate. In use, an elongate reinforcing element such as a rod (not shown) may be situated within the groove **2816**. The compression nut **2822** may be situated within the threaded fitting **2820** and advanced until the reinforcing element is held fixed between the compression nut **2822** and the compression element **2818**. In another aspect, the introduction of a compressive force onto the compression element **2818** by the compression nut **2822** via the reinforcement element may further introduce a holding force within the attachment of the head **2802** to the top end **2806** of the shaft **2804** such that the head **2802** may no longer rotate freely.

FIG. **29** is a side view of a fastener **106A** in another aspect. In this aspect, the head **2802** of the fastener **106A** may be a peg-like head. In this aspect, the head **2802** may be in the form of a cylinder attached in a fixed engagement to the top end **2806** of the shaft **2804**. In other aspects, the peg-like head may be modified with raised circumferential rings, circumferential depressions (not shown), radial bores, or any other fitting suitable for forming an interlocked mechanical engagement with a corresponding element of an orthopedic device or appliance.

ii. Shaft

Referring back to FIG. **28**, the shaft **2804** of the fastener **106** includes the top end **2806** attached to the head **2802** and the tip **2808** with associated attachment fitting **2810**. The shaft **2804** may be unthreaded, as illustrated in FIG. **28**, or the shaft may be threaded, as illustrated in FIG. **29**. The shaft **2804** may have a transverse cross-sectional profile that is any known profile, including, but not limited to, circular as illustrated in FIG. **28**, semicircular, elliptical, polygonal including triangular, square, rectangular, and hexagonal.

In an aspect, the fastener **106** may be any suitable length for use in an orthopedic surgical procedure. The length of the fastener **106** may be selected based at least one of several factors including, but not limited to the individual patient's morphology, the particular type of surgical procedure in which the fastener is to be used, the anatomical location in which the fastener **106** is to be used, the desired strength or rigidity of the fastener, and any other related selection factor known in the art.

When attached to the implant outer layer **104** and/or implant body **102**, the shaft **2804** may extend away from the implant body **102** at any angle ranging from about 0° to about 20° relative to a plane perpendicular to the central axis **308**. The angle or range of angles at which the shaft **2804** extends away from the implant body **102** may be selected based on the desired surgical use of the fastener **106**. In one aspect, the shaft **2804** may extend away from the implant body **102** at a relatively fixed angle within the range described herein previously. In another aspect, the shaft **2804** may extend

away from the implant body at an angle that varies freely within any angular sub-range within the range described herein previously.

iii. Tip with Attachment Fitting

In various aspects, the fastener **106** includes an attachment fitting **2810** situated near the tip **2808** for mechanically attaching the fastener **106** to the implant locking element(s) of the implant outer layer **104** and/or implant body **102**. The attachment fitting **2810** may form a locked engagement with one or more locking elements within the implant body **102** and implant outer layer **104**. In an aspect, the attachment fitting **2810** is provided in a form that is compatible and/or capable of forming a locked engagement with the locking elements of the implant outer layer **104** and/or implant body **102**. The attachment fitting **2810** may allow the fastener **106** to lock into place in a fixed engagement or an engagement with limited movement once attached to the implant outer layer **104** and/or implant body **102**.

The attachment fitting **2810** may be provided in any known form without limitation, so long as the attachment fitting **2810** is compatible with the locking elements of the implant outer layer **104** and/or implant body **102**. Non-limiting examples of suitable attachment fittings include a ball end, a rounded end, and a cone end.

The attachment fitting **2810** may be provided in the form of a ball fitting in one aspect. FIG. **30** is a side view of a ball fitting **2810A**. The ball fitting **2810A** may include a spherically-shaped end **3002** and a tapered neck **3004** that includes a wide neck end **3006** and opposite narrow neck end **3008**. In this aspect, the wide neck end **3006** is attached to the shaft **2804** and the narrow neck end **3008** is attached to the spherically-shaped end **3002**. The wide neck end **3006** may have a diameter that is essentially equal to the cross-sectional diameter of the shaft **2804**, and the narrow neck end **3008** may have a narrow end diameter that may be at least 10% smaller than the cross-sectional diameter of the shaft **2804**. In other aspects, the neck may not be tapered but instead may have a constant diameter at least 10% smaller than the cross-sectional diameter of the shaft **2804**. The ball fitting **2810A** may be used in combination with any form of shaft **2804** including, but not limited to, a threaded shaft as illustrated in FIG. **28** and an unthreaded shaft as illustrated in FIG. **29**.

The attachment fitting **2810** may be a rounded fitting. FIG. **31** is a side view showing a rounded fitting **2810B** in one aspect. The rounded fitting **2810B** may include a rounded end **3102** and a neck **3104**. The neck **3104** may be a narrow cylindrical section attached to the flat face **3106** of the rounded end **3102** and to the shaft **2804** at opposite ends of the neck **3104**. The rounded end **3102** may include a spherical section and the flat face **3106**. The rounded end **3102** may have a maximum cross-sectional diameter that is essentially equal to the cross-sectional diameter of the shaft **2804**. The cross-sectional diameter of the neck **3104** may be at least 10% smaller than the cross-sectional diameter of the shaft **2804**.

The attachment fitting **2810** may be a cone fitting. FIG. **32** is a side view showing a cone fitting **2810C** in one aspect. The cone fitting **2810C** may include a conical tip **3202** with a flat face **3206** and a neck **3204**. The neck **3204** may be a cylindrical segment attached at one end to the flat face **3206** and attached at the opposite end to the shaft **2804**. The cylindrical neck **3204** may have a cross-sectional diameter of at least 10% less than the cross-sectional diameter of the shaft **2804**.

In another additional aspect, the attachment fitting **2810** may be a divoted fitting. FIG. **33** is a side view showing a

divoted fitting **2810D** in one aspect. The divoted fitting **2810D** may include a conical tip **3302** with a flat face **3306** and a divoted neck **3304**. The divoted neck **3304** may be a cylindrical segment attached at one end to the flat face **3306** and attached at the opposite end to the shaft **2804**. The cylindrical segment of the divoted neck **3304** may have a cross-sectional diameter that is essentially equal to the cross-sectional diameter of the shaft **2804**. From about one to about ten divots **3308** may be formed within the divoted neck **3304**. Each divot **3308** may extend from the one end to the opposite end of the divoted neck **3304**. The divots **3308** may fit within a divoted locking element (not shown) provided as part of the locking elements on the implant body **102** and/or implant outer layer **104** in an aspect. The divoted locking element may be contoured to mechanically intermesh with the one or more divots **3308** when the fastener **106** is inserted, providing a locked engagement with the divoted fitting **2810D**.

The attachment fitting **2810** may be provided in any other suitable form without limitation, so long as the attachment fitting **2810** is capable of forming a locked engagement with the one or more locking elements associated with the implant outer layer **104** and/or implant body **102**. For example, any attachment fitting **2810** with a non-circular cross-sectional profile, but with an overall tapered profile at the tip **2808** and a reduced-width neck segment similar to the ball fitting **2810A**, rounded fitting **2810B**, or cone fitting **2810C** may be used as an attachment fitting **2810**, depending on the particular configuration of the corresponding locking element(s). Non-limiting examples of suitable other attachment fittings include a pyramidal-tipped fitting and a tapered blade-like fitting. In addition, any other attachment fitting profile without limitation may be suitable for use in the fastener **106** so long as the attachment fitting **2810** is capable of forming the locked engagement with the one or more locking elements using any known locking mechanism.

d. Fastener Locking Mechanisms

Any suitable locking mechanism known in the art may be incorporated into the design of the implant assembly **200** without limitation. The locking mechanism may be selected based on any one or more of at least several factors including, but not limited to: the desired orientation of the fastener **106** within the implant assembly **200**, the desired degree of allowable movement of the fastener **106** within the implant assembly **200**, the ease of attaching the fastener **106** during the formation of the implant assembly **200**, and the needed strength of the locked mechanical engagement of the fastener **106** to the implant outer layer **104** and/or implant body **102** within the implant assembly **200**.

FIG. **34** is a perspective view of an implant assembly **200A** illustrating a locking mechanism in one aspect. The implant assembly **200A** in this aspect may include the slotted implant body **102B** illustrated previously in FIG. **4**, the triangular outer layer **104A** illustrated previously in FIG. **19**, and the fastener **106** with a ball fitting **2810A** illustrated previously in FIG. **30**. In this aspect, the fastener **106** and implant outer layer **104A** may be implanted into the afflicted region and then the implant body **102A** may be inserted such that the longitudinal groove **404** slides over the tapered neck **3004** of the fastener **106**. Upon formation of the implant assembly **200A**, the spherically-shaped end **3002** may be situated within the body lumen **402** of the implant body **102B**, and the tapered neck **3004** may be situated within the longitudinal groove **404**. Because the diameter of the spherically-shaped end **3002** is too large to pass through the longitudinal groove **404** and the body distal end **304** of the implant body **102A** is butted up against the bottom of the

bore formed within the afflicted region of the patient, the fastener **106** is locked into place. In this aspect, the implant outer layer **104A** may further limit the movement of the fastener **106** along the length of the implant body **102B**.

In this aspect, the rounded profile of the spherically-shaped end **3002** and the relatively open design of the longitudinal groove **404** along the length of the implant body **102B** may provide a limited envelope of movement of the fastener **106** within the implant assembly **200** during use. Without being limited to any particular theory, this limited movement may be well-suited for orthopedic surgical applications such as the reinforcement of spinal segments or intervertebral joints that ordinarily undergo limited movements during normal patient activities such as bending or walking. The degree of angular movement of the fastener **106** may be governed by any one or more of at least several factors including, but not limited to: the diameter of the spherically-shaped end **3002** relative to the diameter of the body lumen **402** and/or the width of the longitudinal groove **404**, the taper angle of the tapered neck **3004**, and various dimensions of the longitudinal groove **404** such as the groove width and the groove depth. The degree of translation of the fastener **106** along the length of the implant body **102B** may be governed by any one or more of at least several factors including, but not limited to the distance at which the implant body **102B** protrudes from the implant outer layer **104A** in the implant assembly **200A**. In addition, the fastener **106** may remain free to rotate about the longitudinal axis of the fastener **106** in this aspect.

FIG. **35** is a longitudinal cross-sectional view of an implant assembly **200B** illustrating a locking mechanism in another aspect. The implant assembly **200B** in this aspect may include the solid implant body **102A** illustrated previously in FIG. **3** with a self-locking retaining ring **1202**, illustrated previously in FIG. **12**, and an attached fastener **106** with a rounded fitting **2810B** illustrated previously in FIG. **31**. In this aspect, the implant outer layer **104** and implant body **102A** may be implanted into the afflicted region and the fastener **106** may then be inserted with a force sufficient to penetrate the self-locking retaining ring **1202** with the rounded end **3102**. Upon formation of the implant assembly **200B**, the rounded end **3102** may be situated within an inner volume **3502** of the implant body **102**, and the neck **3104** may be situated between the arcuate members **1206A**, **1206B** and **1206C** (not shown) of the self-locking retaining ring **1202**. During insertion of the rounded end **3102** into the self-locking retaining ring **1202**, the insertion force reversibly deforms the arcuate members **1206A**, **1206B** and **1206C** downward, resulting in a transient increase in the space between the arcuate members **1206A**, **1206B** and **1206C** to accommodate the insertion of the rounded end **3102**. Because the diameter of the rounded end **3102** is too large to pass through the undeflected arcuate members **1206A-1206C** without application of a sizeable removal force, the fastener **106** is locked into place. In other aspects, any fastener **106** having a tapered tip and a reduced-diameter neck may be locked into place in this manner including, but not limited to a ball fitting **2810A** and a cone fitting **2810C**.

In this aspect, the movement of the fastener **106** within the implant assembly **200B** may be more restrained relative to the degree of movement afforded by the implant assembly **200A** due to the relatively close fit of the self-locking retaining ring **1202** around the neck **3104** of the fastener **106**. The degree of movement of the fastener **106** within the implant assembly **200B** may be governed by any one or more of at least several factors, including but not limited to:

the height and diameter of the neck **3104**, the diameter of the opening of the self-locking retaining ring **1202**, and the thickness and stiffness of the arcuate members **1206A**, **1206B** and **1206C**. In addition, the fastener **106** may remain free to rotate about the longitudinal axis of the fastener **106** in this aspect.

FIG. **36** is a perspective view of an implant assembly **200C** illustrating a locking mechanism in another additional aspect. The implant assembly **200C** in this aspect may include the implant body **102C** with longitudinal projections **502A** and **502B** illustrated previously in FIG. **5**, the implant outer layer **104B** illustrated previously in FIGS. **20-24**, and the fastener **106** with a ball fitting **2810A** illustrated previously in FIG. **30**. The implant outer layer **104** is omitted in FIG. **36** to facilitate visualization of the locking mechanism. In this aspect, the fastener **106** and implant outer layer **104** may be situated within the afflicted area of the patient and then the implant body **102C** may be inserted into the implant outer layer **104** as discussed herein previously and illustrated in FIGS. **22-24**. The tapered neck **3004** of the fastener **106** may be situated within a slot **508** formed between the pair of longitudinal projections **502A** and **502B** of the implant body **102C**. In addition, the spherically-shaped end **3002** may fit closely within the distal body depression **508** of the implant body **102C**.

In this aspect, additional locking elements associated with the implant outer layer **104B** may further secure the ball fitting **2810A** in place. FIG. **37** is a longitudinal cross-section of the implant assembly **200C** illustrating the spatial relationships between the ball fitting **2810A**, the implant body **102C**, and the implant outer layer **104B**. During the formation of the implant assembly **200C**, the implant body **102C** is inserted within the lumen **1402** of the implant outer layer **104B** and shifted toward the outer layer distal end **1904** as illustrated in FIGS. **23-24**. When the implant body **102C** is fully inserted, the spherically-shaped end **3002** may be compressed between the distal body depression **508** of the implant body **102C** and the curved face **2210** of the implant outer layer **104B**. As a result, the spherically-shaped end **3002** is secured in a locked configuration within the space formed between the distal body depression **508**, the curved face **2210**, and the longitudinal projections **502A** and **502B**.

Prior to compression of the spherically-shaped end **3002** between the distal body depression **508** and the curved face **2210**, the fastener **106** may be positioned anywhere within a relatively wide range of movement comparable to the range of movement afforded by the implant assembly **200A** described previously. However, the compression of the spherically-shaped end **3002** may render the fastener relatively immobile, even with respect to rotational movements of the fastener **106** about the fastener's longitudinal axis. The tightly locked-in engagement of the fastener **106** in this aspect may be suitable for use in orthopedic surgical treatments in which the efficacy of the treatment may rely upon maintaining a fixed position within the afflicted area.

In another aspect, a fastener **106** with a divoted fitting **2810D** may be attached to any implant body that includes a self-locking retaining ring **1202** including, but not limited to implant body **102A** illustrated in FIG. **3**, implant body **102D** illustrated in FIG. **6**, and implant body **102E** illustrated in FIG. **7**. Referring to FIGS. **12** and **33**, the one or more divots **3308** may mesh with arcuate members **1206A**, **1206B** and **1206C**, forming a locked engagement. The arcuate members **1206A**, **1206B** and **1206C** may deform to permit insertion of the divoted fitting **2810D** into the self-locking retaining ring **1202**, but once inserted, the arcuate members **1206A**, **1206B**

and 1206C may mechanically resist the removal of the divoted fitting 2810D from the self-locking retaining ring 1202.

II. Delivery Tool

Referring back to FIG. 1, the orthopedic system 100 may include a delivery tool 300 to implement the preparation of the afflicted region of the patient and the formation of the implant assembly 200. The delivery tool 300 may be designed to perform a variety of surgical procedures associated with the formation of the implant assembly 200 within the afflicted region of the patient. The delivery tool 300 may be used to remove bone or other tissue within the afflicted region of the patient, to form a bore within which the implant outer layer 104 may be inserted, to form a guide hole through which the fastener 106 may be inserted, to obtain visual or other images of the afflicted region, to introduce one or more therapeutic compositions, and any combination thereof.

FIG. 38 is a side view of the delivery tool 300 attached to an implant assembly 200 in one aspect. The delivery tool 300 may include an elongate targeting arm 108 with a first arm end 3802 and a second arm end 3804 opposite to the first arm end 3802. A fastener guide 3806 may be attached to the targeting arm 108 at the first arm end 3802 and an implant guide 3808 may be attached at the second arm end 3804. The targeting arm 108 maintains the fastener guide 3806 and the implant guide 3808 in a fixed orientation relative to one another, thereby facilitating the preparation of the afflicted area of the patient to receive the implant assembly 200 and implementing the subsequent formation of the implant assembly 200.

Detailed descriptions of various aspects of the delivery tool 300 including the targeting arm 108, fastener guide 3806, and implant guide 3808 are provided herein below.

a. Targeting Arm

Referring again to FIG. 38, the targeting arm 108 in this aspect is an elongate element that may be fastened to the fastener guide 3806 at the first arm end 3802 and may further be fastened to the implant guide 3808 at the second arm end 3804. The targeting arm 108 in this aspect is an arcuate elongate element that functions as a robust structural member to maintain the fixed orientation of the fastener guide 3806 and the implant guide 3808 throughout an orthopedic surgical procedure. The targeting arm 108 may possess any known elongate shape without limitation including, but not limited to: a general curved arcuate shape as illustrated in FIG. 38, a circular arc shape, an elliptical arc shape, a polygonal shape, and a right-angle shape. FIG. 39 is a side view of a targeting arm 108A with a right-angle shape.

The cross-sectional profile of the targeting arm 108 may be any profile without limitation. FIG. 40 is a transverse cross-section taken across the cross-sectional plane A-A illustrated in FIG. 38. In this aspect, the cross-sectional profile may be a hollow rectangular profile that includes an outer layer 4002 enclosing an inner lumen 4004. In other aspects, the cross-sectional profile may be a solid section rather than a hollow section. Other non-limiting examples of suitable cross-sectional profiles for the targeting arm 108 include: circular, elliptical, polygonal, triangular, square, rectangular, hexagonal, and any other known closed cross-sectional profile.

In other additional aspects, the cross-sectional profile of the targeting arm 108 may be essentially constant in size and shape along the length of the targeting arm 108, or the cross-sectional shape may vary along the length of the targeting arm 108. For example, the cross-sectional profile of the targeting arm 108 may thicken at the first arm end

3802 and second arm end 3804 to provide structural reinforcement for the attachment of the fastener guide 3806 and the implant guide 3808.

i. Adjustable Targeting Arms

In one aspect, the targeting arm 108 may be provided as a single continuous structural element as illustrated in FIGS. 38 and 39, thereby providing a fixed elongate shape. In another aspect, the targeting arm 108 may be provided in the form of two or more linked structural elements thereby providing an adjustable elongate shape. For example, FIG. 41A and FIG. 41B are side views of a telescoping targeting arm 108B. Referring to FIG. 41A, the targeting arm 108B may include a first section 4102 ending in the first arm end 3802 and a second section 4104 ending in the second arm end 3804; both sections 4102 and 4104 may have matched circular arc shapes with a common center 4110 as illustrated in FIG. 41A. In an aspect, the second section 4104 may have a hollow cross-section with a central lumen (not shown), and the first section 4102 may be shaped and dimensioned to fit within the central lumen by sliding along the arc length of the second section 4104.

FIG. 41B illustrates the targeting arm 108B with a portion of the first section 4102 nested within the central lumen of the second section 4104, resulting in a shorter elongate shape. The second section 4104 includes the second arm end 3804 as well as a sliding attachment fitting 4106 at an end of the second section 4104 opposite to the second arm end 3804. The sliding attachment fitting 4106 may slide along the first section 4102 to adjust the relative position of the first arm end 3802 and second arm end 3804 as illustrated in FIG. 41B. The elongate shape of the targeting arm 108B and the sliding attachment fitting 4106 may be locked into a fixed position using a locking mechanism including, but not limited to, a set screw 4108 as illustrated in FIG. 41A. Any other known locking mechanism may be used to lock the adjustable targeting arm 108B into a locked position including, but not limited to clamps, pegs, compression fittings, and any combination thereof. In this aspect, the shorter elongate shape illustrated in FIG. 41B may result in a change in the angle 4112 between the fastener 106 and/or fastener guide 3806 and the implant body 102 and/or implant guide 3808 (not shown). The adjustability of the targeting arm 108B may further facilitate fine-tuning the entry paths of the various components during formation of the implant assembly 200 to account for variability in patient morphology and/or to avoid injury to vulnerable tissues including, but not limited to, neurons and/or blood vessels.

FIGS. 42A and 42B are side views of another adjustable targeting arm 108C in another aspect. In this aspect, the targeting arm 108C includes a straight horizontal segment 4202 and a straight vertical segment 4204. The vertical segment 4204 includes the second arm end 3804 as well as a sliding attachment fitting 4206 at an end of the vertical segment 4204 opposite to the second arm end 3804. The sliding attachment fitting 4206 may slide in a horizontal direction along the horizontal segment 4202 to adjust the relative position of the first arm end 3802 and second arm end 3804 as illustrated in FIG. 42B. The position of the sliding attachment fitting 4206 may be locked into place using any known locking mechanism described previously above including, but not limited to, a set screw 4208 as illustrated in FIG. 42B.

In various other aspects, the targeting arm 108 may be made adjustable by the incorporation of any other adjustable elements known in the art. Non-limiting examples of suitable adjustable elements include: two or more hinged or jointed subsections of the targeting arm 108, two or more

telescoping subsections of the targeting arm **108**, one or more bendable subsections of the targeting arm **108** having limited deformability, and any combination thereof. In other additional aspects, different sizes of fixed-geometry targeting arms **108** may be used to provide a suitable range of installation tool geometries to account for differences in patient morphologies, differences in orthopedic surgical procedures, and any other variable factor governing the selection of a targeting arm geometry.

ii. Fastener Guide Attachment Fitting

Referring again to FIG. **38**, the targeting arm **108** may be attached to the fastener guide **3806** at the first arm end **3802**. FIGS. **43A** and **43B** are close-up perspective views of the first arm end **3802** of the targeting arm **108** illustrated in FIG. **38**. As illustrated in FIG. **43A**, the first arm end **3802** may include a fastener guide attachment fitting **4300**. The fastener guide attachment fitting **4300** may be designed to receive a portion of the fastener guide **3806** such as a fastener guide shaft **4304** in a reversibly locked mechanical engagement. When unlocked, the fastener guide attachment fitting **4300** may allow limited movement of the fastener guide **3806** including, but not limited to, rotation of the fastener guide **3806** about the fastener longitudinal axis **4306** and/or translation of the fastener guide **3806** along the fastener longitudinal axis **4306**. However, even when unlocked, the fastener guide attachment fitting **4300** may maintain a fixed orientation between the fastener longitudinal axis **4306** and the implant longitudinal axis (not shown).

The fastener guide attachment fitting **4300** may incorporate any known mechanical attachment elements including a collar **4302** as illustrated in FIG. **43A**. In this aspect, the collar **4302** may further include a threaded fitting **4308** that extends through the entire thickness of the collar wall **4310**. A set screw **4312** may be advanced through the threaded fitting **4308** until the screw tip (not shown) compresses the fastener guide shaft **4304**, thereby locking the fastener guide shaft **4304** in a reversibly locked mechanical engagement.

In other aspects, any other known mechanical elements capable of forming a reversibly locked mechanical engagement may be incorporated into the fastener guide attachment fitting **4300**. Non-limiting examples of other mechanical elements suitable for incorporation into the fastener guide attachment fitting **4300** include: collars and one or more set screws; collars and one or more cotter pins, pegs, and or any other insertable elongate element; clamps; bands; compression fittings, and any combination thereof.

iii. Implant Guide Attachment Fitting

Referring again to FIG. **38**, the targeting arm **108** may be attached to the implant guide **3808** at the second arm end **3804**. FIG. **44A** is a close-up perspective view of the second arm end **3804** of the targeting arm **108** and the retaining rod **110**. As illustrated in FIG. **44A**, the second arm end **3804** may include an implant guide attachment fitting **4400**. The implant guide attachment fitting **4400** may be designed to receive a portion of the implant guide **3808** such as a retaining rod **110** in a reversibly locked mechanical engagement. When unlocked, the implant guide attachment fitting **4400** may allow limited movement of the implant guide **3808** including, but not limited to, the rotation of the retaining rod **110** about the implant longitudinal axis **4402**. However, even when unlocked, the implant guide attachment fitting **4400** may maintain a fixed orientation between the implant longitudinal axis **4402** and the fastener longitudinal axis **4306** (not shown).

As illustrated in FIG. **44A**, the implant guide attachment fitting **4400** may include a guide block **4404** locked into place by a pin assembly **4406**. Together, the guide block

4404 and the second arm end **3804** form a channel **4408** within which a section of the retaining rod **110** may be locked in place. The channel **4408** is typically shaped and dimensioned to closely fit the cross-sectional profile and dimensions of the retaining rod **110**. The channel **4408** may be any cross-sectional shape without limitation. In one aspect, the channel **4408** may include projections extending radially inward or depressions extending radially outward from the implant longitudinal axis **4402**, discrete pins and/or pin receptacles, or any other feature known in the art for securing a section of an elongate member and/or inhibiting translation and/or rotation of the elongate member. For example, the channel **4408** may include a downward-projecting finger **4436** formed within the second arm end **3804** of the targeting arm **108** that fits closely within a groove **4438** extending longitudinally along at least a section of the retaining rod **110** as illustrated in FIG. **44A**.

FIG. **44B** is an exploded perspective view of the implant guide attachment fitting **4400** illustrated in FIG. **44A**. The pin assembly **4406** may include a pair of pins **4410** and **4412** projecting from a pin handle **4414**. The second arm end **3804** may include a pair of flanges **4416** and **4418** projecting downward from the second arm end **3804**. A first pair of holes **4420** and **4422** may be formed in the first flange **4416** and a second pair of holes **4424** and **4426** may be formed in the second flange **4418** that extend through the full width of the flanges **4416** and **4418**. Holes **4420** and **4424** are aligned and dimensioned to receive pin **4412**; holes **4422** and **4426** are similarly aligned and dimensioned.

The guide block **4404** may be shaped and dimensioned to fit snugly between the flanges **4416** and **4418**. An upper surface **4432** may be shaped and dimensioned to match the cross-sectional profile of a lower portion of the retaining rod **110**. Together, the lower surface **4434** of the second arm end **3804** and the upper surface **4432** of the guide block **4404** may define the channel **4408**. In one aspect, the lower surface **4434** and/or upper surface **4432** may further include a surface texture to inhibit slipping of the retaining rod **110** when the implant guide attachment fitting **4400** is in a locked mechanical engagement with the retaining rod **110**.

The guide block **4404** may further include a pair of holes **4428** and **4430** that extend through the width of the guide block **4404** and align with holes **4422/4426** and **4420/4424** respectively to receive pins **4410** and **4412** during assembly of the implant guide attachment fitting **4400**. In one aspect, the holes **4428** and **4430** on the guiding block **4404** may be situated such that the upper surface **4432** may compress the retaining rod **110** against the lower surface **4434** of the second arm end **3804** when the pin assembly **4406** is inserted through the flanges **4416/4418** and the guide block **4404**. In this aspect, the compression may be sufficient to result in a friction fit to hold the retaining rod **110** locked into place.

In other aspects, any other known mechanical elements capable of forming a reversibly locked mechanical engagement may be incorporated into the implant guide attachment fitting **4400**. Non-limiting examples of other mechanical elements suitable for incorporation into the implant guide attachment fitting **4400** include: collars and one or more set screws; collars and one or more cotter pins, pegs, and or any other insertable elongate element; clamps; bands; compression fittings, and any combination thereof.

b. Fastener Guide

Referring again to FIG. **38**, the delivery tool **300** may include a fastener guide **3806** fastened to the first arm end **3802** of the targeting arm **108**. The fastener guide **3806** may be used to prepare the afflicted region of the patient for the insertion of a fastener **106** and to implement the delivery and

attachment of the fastener **106** as part of the formation of the implant assembly **200**. In various aspects, the preparation of the afflicted region of the patient may include drilling, cutting, grinding, or otherwise removing intervening tissues such as connective tissues and bone tissues to facilitate the subsequent insertion of the fastener **106**. The preparation of the afflicted region of the patient may further include obtaining images of the afflicted region before, during, and/or after the insertion of the fastener **106**. The delivery and attachment of the fastener **106** may further include standard surgical fastener insertion techniques known in the art including, but not limited to the insertion and withdrawal of a trocar, a guidewire, a drill, a screwdriver, a chisel, and/or any other known surgical tool associated with the delivery and attachment of surgical fasteners. In various aspects, the fastener guide **3806** may be used to perform the surgical procedures associated with insertion and attachment of the fastener **106** to the other elements of the implant assembly **200** while maintaining a precise alignment of the fastener **106** relative to these other elements of the implant assembly **200**.

By way of example, FIG. **45** is a side view of the fastener guide **3806** illustrated in FIG. **38**. In this aspect, the fastener guide **3806** may include a bone screw inserter **4502** nested within a threaded sleeve **4504**. The proximal end **4506** of the bone screw inserter **4502** may be reversibly attached to a removable handle **4508**. The distal end **4510** of the bone screw inserter **4502** may protrude from the distal end **4512** of the threaded sleeve **4504**. The bone screw inserter **4502** may further include a circumferential groove **4514** or other fitting element to which the fastener guide attachment fitting **4300** of the targeting arm **108** may attach in a reversible locked engagement. For example, the circumferential groove **4514** may be dimensioned and situated to receive the tip of the set screw **4312** of the fastener guide attachment fitting **4300** as illustrated in FIG. **43B**.

i. Bone Screw Inserter

FIG. **46** is a side view of the bone screw inserter **4502** illustrated in FIG. **45** with the threaded sleeve **4504** and the removable handle **4508** removed to expose the features of the bone screw inserter **4502**. The bone screw inserter **4502** may include a fastener guide shaft **4304** with the proximal end **4506** and the opposite distal end **4510**. The proximal end **4506** of the bone screw inserter **4502** may include features that mechanically interlock with corresponding features of the removable handle **4508**. FIG. **47** is an enlargement of the side view of the proximal end **4506** of the bone screw inserter **4502** illustrated in FIG. **46**.

The proximal end **4506** may include a proximal tip segment **4702** having a non-circular cross-sectional profile that transitions to a cylindrical segment **4706** situated between the proximal tip segment **4702** and a second circumferential groove **4704**. FIG. **48** is a perspective view of the proximal end **4506** at a scale comparable to the scale of the view illustrated in side view in FIG. **47**. FIG. **49** is a bottom view of the removable handle **4508**. Referring to FIGS. **48** and **49**, the proximal tip segment **4702** of the bone screw inserter **4502** fits within a corresponding four-sided fitting **4904** at the bottom of a central bore **4902** formed within a vertical portion **4906** of the removable handle **4508**.

Referring back to FIG. **47**, the second circumferential groove **4704** includes a groove wall **4708** with a semi-circular cross-sectional profile. This circumferential groove **4704** may be designed to accommodate additional corresponding elements of the removable handle **4508**, including but not limited to retaining balls (not shown). A more detailed description of the mechanical interaction of the

proximal end of the bone screw inserter **4502** and the removable handle **4508** are provided herein below.

Referring back to FIG. **46**, the bone screw inserter **4502** may further include a cylindrical collar **4604** attached to the fastener guide shaft **4304** using a reversibly locking mechanism such as a set screw **4606**. In an aspect, the collar **4604** may fit tightly within the threaded sleeve **4504** (not shown). The collar **4604** may inhibit lateral play of the bone screw inserter **4502** within the threaded sleeve **4504** during use, and/or may limit the range of motion of the bone screw inserter **4502** within the bone screw inserter **4502** in the proximal-distal direction. For example, the collar **4604** may be situated in a position on the fastener guide shaft **4304** such that the maximal distal protrusion of the distal end **4510** may be such that the fastener **106** (not shown) interlocks with corresponding locking element of the implant assembly **200** (not shown) without overshooting and/or damaging the corresponding locking element.

Again referring to FIG. **46**, the bone screw inserter **4502** may further include a distal end **4510** that includes elements that mechanically interact with the fastener **106** (not shown) during formation of the implant assembly **200** (not shown). As illustrated in FIG. **45**, the distal end **4510** of the bone screw inserter **4502** protrudes from the distal end **4512** of the threaded sleeve **4504**. The two distal ends **4510** and **4512** and associated features act in concert to situate and install a fastener **106** (not shown) as part of the formation of the implant assembly **200** (not shown). A detailed description of the mechanical interaction of the fastener **106** and distal ends **4510** and **4512** are provided herein below.

FIG. **50** is a close-up side view of the distal end **4510** of the bone screw inserter **4502** illustrated in FIG. **46**. FIG. **51** is a perspective view of the distal end **4510** at a similar scale to the distal end **4510** illustrated in FIG. **50**. Referring to FIGS. **50** and **51**, the distal end **4510** may include a screwdriver tip **5002** and an additional screw head fitting **5004** situated proximally relative to the screwdriver tip **5002**. The screwdriver tip **5002** may have a cross-sectional profile corresponding to any known screw head fitting **5004** including, but not limited to: flat blade profile, Phillips head profile, hexagonal profile as illustrated in FIGS. **50** and **51**, star profile, and any other known screwdriver profile.

ii. Removable Handle

Referring back to FIG. **45**, the fastener guide **3806** may include a removable handle **4508** in an aspect. In this aspect, the removable handle **4508** may be reversibly attached in a locked mechanical engagement to the proximal end **4506** any fastener guide tool such as the bone screw inserter **4502** as illustrated in FIG. **45**. When attached, the removable handle **4508** may be used to twist the bone screw inserter **4502** about the longitudinal axis of the bone screw inserter **4502**, to translate the bone screw inserter **4502** along its longitudinal axis in a proximal or distal direction, or to maintain the bone screw inserter **4502** and/or attached fastener **106** (not shown) in a fixed orientation relative to the other elements of the implant assembly **200** (not shown) during the formation of the implant assembly **200**.

FIG. **52** is an enlarged side view of the removable handle **4508** illustrated in FIG. **45** with the threaded sleeve **4504** and the bone screw inserter **4502** removed to better expose the features of the removable handle **4508**. The removable handle **4508** may include a vertical portion **4906** and a grip portion **5202**. The grip portion **5202** may be grasped by a single hand and/or two hands by an orthopedic surgeon or other practitioner performing an orthopedic procedure.

In another aspect (not shown), the grip portion **5202** may include additional adaptor elements that may interact with

powered actuators that may be used to situate and attach the fastener 106 during the formation of the implant assembly. Non-limiting examples of powered actuators include hydraulic and electromechanical pistons, electrical motors including stepper motors, screwjacks, and any other powered actuator known in the art. In this other aspect, the powered actuators may be operator-controlled and/or automatically controlled. Non-controlling examples of suitable additional adaptor elements include threaded fittings, projecting threaded and unthreaded shafts, gears, and any other adaptor element suitable for establishing a mechanical engagement with an actuator.

Referring back to FIG. 52, a proximal end 5204 of the vertical portion 4906 may be attached to the grip portion 5202. In addition, a distal end 5206 of the vertical portion 4906 may be situated within a sliding collar 5208; the sliding collar 5208 may be used to lock and unlock the removable handle 4508 from the proximal end 4506 of the bone screw inserter 4502. FIG. 53 is a perspective view of the removable handle with the collar 5208 and underlying components removed to expose the underlying distal end 5206 of the removable handle 4508. The distal end 5206 may further include a circumferential groove 5302 and a pair of holes 5304 and 5306 to contain a pair of retaining bearings (not shown). The external cross-sectional profile of the distal end 5206 may be any shape without limitation including, but not limited to the circular profile illustrated in FIG. 53 and FIG. 49.

FIG. 54 is a cross-sectional view taken at the plane B-B denoted in FIG. 53. The central bore 4902 is situated within the distal end 5206 that opens to a channel 5402 proximally and to the distal face 5404 distally. The most proximal region of the central bore 4902, situated most deeply within the bore, forms the four-sided fitting 4904 that receives the square proximal tip segment 4702 (not shown). In addition, the holes 5306 and 5304 (not shown) extend from the central bore 4902 to the outer surface of the removable handle 4508. The hollow channel 5402 is situated within the grip portion 5202 and may extend from the proximal end 5204 of the grip portion 5202 to the four-sided fitting 4904 within the central bore 4902. The channel 5402 may be used to introduce guidewires, optical fibers, drill bits, and any other known device or element suitable for use in an orthopedic procedure.

FIG. 55 is a close-up side view of the distal end 5206 of the removable handle 4508 with the sliding collar 5208 removed to expose the underlying elements of the locking mechanism of the removable handle 4508. In this aspect, a large lock washer coil 5502 is situated just proximal to the circumferential groove 5302 illustrated in FIGS. 53 and 54. A lock washer 5504 is situated within the circumferential groove adjacent in the distal direction to the large lock washer coil 5502. A small lock washer coil 5506 is situated adjacent to the lock washer 5504 opposite to the large lock washer coil 5502, and a spring 5508 is situated adjacent to the small lock washer coil 5506 opposite to the lock washer 5504. Retaining bearings 5510 and 5512 are situated within holes 5304 and 5406, respectively, such that the retaining bearings 5510 and 5512 protrude into the central bore 4902 distal to the four-sided fitting illustrated in FIG. 54.

FIG. 56 is a longitudinal cross-section taken through the collar 5208 and underlying components illustrated in FIG. 52 with the distal end 5206 of the removable handle 4508 removed to enhance the visualization of the orientation of the underlying components within the inner surface of the collar 5208. The collar 5208 in this aspect contains a series of lumen segments arranged in order from the proximal end

5614 to the distal end 5616 of the collar 5208, a large-diameter proximal opening segment 5618, an expanded circumferential groove segment 5602, a large-diameter spring segment 5604, a smaller-diameter restriction segment 5606, an expansion section 5608 with a smaller-diameter proximal end 5626 and a larger-diameter distal end 5624, a second distal restriction section 5620, and a smaller-diameter distal opening section 5622.

In this aspect, the large lock washer coil 5502 is situated within the circumferential groove segment 5602, and the lock washer 5504, the small lock washer coil 5506, and the spring 5508 are situated within the large-diameter spring segment 5604. The retaining bearings 5510 and 5512 (not shown) are situated in various segments depending on the locked or unlocked condition of the collar 5208 including, but not limited to, the smaller-diameter restriction segment 5606 in the locked condition and within the expansion section 5608 in the unlocked condition.

FIG. 57 is a longitudinal cross-section similar to FIG. 56 taken through the collar 5208 and underlying components as well as the distal end 5206 of the removable handle 4508 and the proximal end 4506 of the bone screw inserter 4502. In the locked position, the retaining bearings 5510/5512 may be situated within the smaller-diameter restriction segment 5606 of the collar 5208, thereby forcing the retaining bearings 5510/5512 into the circumferential groove 4704 of the bone screw inserter 4502, thereby locking the bone screw inserter 4502 in place within the removable handle 4508. To unlock the bone screw inserter 4502 from the removable handle 4508, the collar 5208 may be displaced in a proximal (upward) direction, thereby situating the retaining bearings 5510/5512 within the larger-diameter distal end 5624. When the bone screw inserter 4502 is slid distally (downward) out of the removable handle 4508, the retaining bearings 5510/5512 may now fall out of the circumferential groove 4704, allowing the removal of the bone screw inserter 4502. Because the spring 5508 is compressed between the lock washer 5504 and a shoulder 5612 within the large-diameter spring segment 5604, the collar 5208 passively returns to a locked position when the spring 5508 extends to the uncompressed position illustrated in FIG. 57.

iii. Threaded Sleeve

Referring back to FIG. 45, the fastener guide 3806 may include a threaded sleeve 4504 in an aspect. In this aspect, the bone screw inserter 4502 may be situated within the threaded sleeve 4504 such that the distal end 4512 of the bone screw inserter 4502 protrudes from the distal end 4512 of the threaded sleeve 4504. FIG. 58 is a longitudinal cross-section of the threaded sleeve 4504 taken in a plane approximately parallel with the drawing plane of FIG. 45 and coincident with the longitudinal axis of the threaded sleeve 4504. The bone screw inserter 4502 was removed from this cross-section to expose the internal features of the threaded sleeve 4504 in this aspect.

As illustrated in FIG. 58, the threaded sleeve 4504 encloses a constant-diameter channel 5802 that runs the full length of the threaded sleeve 4504 and opens at the proximal face 5804 and at the distal face 5806. The cross-sectional profile and diameter of the channel 5802 may be selected to closely fit the outer cross-sectional profile of the fastener guide shaft 4304 of the bone screw inserter 4502. The distal end 4512 of the threaded sleeve 4504 may end in a threaded end 5808.

The threaded sleeve 4504 further encloses a larger-diameter expanded channel segment 5810. The cross-sectional diameter of the expanded channel segment 5810 may be selected to accommodate the outer diameter of the collar

4604 attached to the fastener guide shaft 4304 of the bone screw inserter 4502. The smaller diameter of the channel 5802 situated proximally and distally to the expanded channel segment 5810 cannot accommodate the outer diameter of the collar 4604 thereby restraining the movement of the collar 4604 and the attached bone screw inserter 4502 to within the expanded channel segment 5810.

The expanded channel segment 5810 may further include one or more windows 5812 opening to the outside of the threaded sleeve 4504 to provide a visual indication of the position and movements of the collar 4604 within the threaded sleeve 4504. In an aspect, a pair of windows 5812 may be situated in a diametrically opposed orientation. In another aspect (not shown), the fastener guide shaft 4304 may include radially projecting arms that project through the one or more windows. For example, if an orthopedic nail is selected as the fastener 106, the projecting arms may be used to produce a significant distally-directed force on the fastener guide shaft 4304 to hammer the orthopedic nail into place in the implant assembly 200.

The channel 5802 may further include one or more holes 5814 opening to the outside of the threaded sleeve 4504. In one aspect (not shown), a pair of diametrically opposed holes may be included to provide access for a locking pin, set screw, or other mechanical locking element to lock the fastener guide shaft 4304 into a fixed position within the threaded sleeve 4504. In this aspect, the mechanical locking element would enter the threaded sleeve 4504 through a first hole 5814A, pass through a second hole formed within the fastener guide shaft 4304, and exit the threaded sleeve 4504 through a third hole 5814B situated diametrically opposite to the first hole 5814A.

FIG. 59 is the same longitudinal cross-sectional view of the threaded sleeve 4504 illustrated in FIG. 58 with the bone screw inserter 4502 included to illustrate the spatial relationship of the elements of the bone screw inserter 4502 within the threaded sleeve 4504. The fastener guide shaft 4304 of the bone screw inserter 4502 is situated within the central channel 5802 of the threaded sleeve 4504; the fastener guide shaft 4304 of the bone screw inserter 4502 protrudes proximally from the proximal face 5804 and the distal end 4510 of the bone screw inserter 4502 distally from the distal face 5806 of the threaded sleeve 4504. The collar 4604 attached to the bone screw inserter 4502 is situated within the expanded channel segment 5810 of the threaded sleeve 4504.

In an aspect, the threaded end 5808 of the threaded sleeve 4504 and the screwdriver tip 5002 and screw head fitting 5004 of the bone screw inserter 4502 cooperatively attach reversibly to the head of a fastener 106 (not shown) in a mechanically locked engagement during the formation of the implant assembly 200 (not shown). FIG. 60 is a side view of the head 2802 of a fastener 106 attached to the bone screw inserter 4502 and the threaded sleeve 4504. FIG. 61 is a cross-sectional view taken along the plane C-C illustrated in FIG. 60.

Referring to FIGS. 60 and 61, the screwdriver tip 5002 is situated within a corresponding screwdriver fitting 6002 formed within the head 2802 of the fastener 106, and the screw head fitting 5004 is situated within the upward-opening groove 2816 formed within the support elements 2812 and 2814 of the fastener head 2802. The threaded end 5808 of the threaded sleeve 4504 is advanced into the threaded fitting 2820 formed within the support elements 2812 and 2814 of the fastener head 2802.

c. Implant Guide

Referring again to FIG. 38, the delivery tool 300 may include an implant guide 3808 fastened to the second arm end 3804 of the targeting arm 108. The implant guide 3808 may be used to prepare a bore within the afflicted region of the patient, to insert the implant outer layer 104 and implant body 102 into the bore and to help implement the attachment of the fastener 106 as part of the formation of the implant assembly 200. In various aspects, the preparation of the bore within the afflicted region of the patient may include drilling, cutting, grinding, or otherwise removing intervening tissues such as connective tissues and bone tissues to facilitate the subsequent insertion of the implant outer layer 104 and implant body 102. The preparation of the bore within the afflicted region of the patient may further include obtaining images of the afflicted region before, during, and/or after the insertion of the implant outer layer 104 and implant body 102. The delivery and placement of the implant outer layer 104 and implant body 102 may further include standard surgical fastener insertion techniques known in the art including, but not limited to the insertion and withdrawal of a trocar, a guidewire, a drill, a screwdriver, a chisel, and/or any other known surgical tool associated with the delivery and attachment of surgical implants. In various aspects, the implant guide 3808 may be used to perform the surgical procedures associated with delivery and placement of the implant outer layer 104 and implant body 102 within the bore, and the attachment of the implant outer layer 104 and/or implant body 102 to the fastener 106 during the formation of the implant assembly 200 while maintaining a precise alignment of the fastener 106 relative to the implant outer layer 104 and implant body 102.

By way of example, FIG. 62 is a top view of the implant guide 3808 illustrated in FIG. 38. In this aspect, the implant guide 3808 includes a retaining rod 110 with a distal rod end 6202 and a proximal rod end 6204 attached to a robust implant guide handle 6206. In this aspect, the implant guide handle 6206 includes a handle body 6208, a grip 6210 projecting essentially perpendicularly from the handle body 6208, and a proximal access port 6212. The handle body 6208 may contain various internal locking elements (not shown) within a handle body housing 6216 to provide a reversible locked mechanical engagement of the proximal rod end 6204 within the handle body 6208. In this aspect, this reversible locked mechanical engagement may be unlocked by depressing a button 6214 and sliding the proximal rod end 6204 out of the handle body 6208.

FIG. 63 is a proximal side view of the implant guide 3808 in which the handle body housing 6216, grip 6210, and proximal access port 6212 are removed to expose the internal locking elements. In this aspect, the internal locking elements may include a sliding block 6302 attached to the button 6214 at one end and operably attached to a bias spring 6304 which biases the position of the sliding block 6302 in the direction of the button 6214, causing the button 6214 to protrude from the handle body housing 6216 as illustrated in FIG. 62.

FIG. 64 is a perspective view of the locking elements illustrated in FIG. 63. The sliding block 6302 may enclose an internal volume 6402 containing a blade element 6404 extending the width of the internal volume 6402. When the sliding block 6302 is biased toward the button 6214 by the force generated by the bias spring 6304, the blade edge 6406 is pressed into a notch 6408 formed into the material of the retaining rod 110 to form the locked engagement. When the button 6214 is depressed, the sliding block 6302 shifts toward the bias spring 6304, thereby shifting the blade edge

6406 out of the notch 6408, allowing the removal of the retaining rod 110 from the implant guide handle 6206.

In various other aspects, any other known reversible locking mechanism may be used attach the retaining rod 110 within the implant guide handle 6206. Non-limiting examples of suitable locking mechanisms include collars with one or more set screws, pins, pegs, and/or any other insertable elongate element; clamps; bands; compression fittings; and any combination thereof.

FIG. 65 is a cross-sectional view of the implant guide handle 6206 illustrated in FIG. 62 taken in the drawing plane. The retaining rod 110 is removed in FIG. 65 to expose the internal cavities of the implant guide handle 6206. The sliding block 6302 and blade element 6404 are contained within the handle body housing 6216 as described herein previously. In addition, the handle body housing 6216 contains a channel 6518 that extends the entire length of the implant guide handle 6206, opening at a proximal opening 6504 in the proximal handle face 6512 as well as at a distal opening 6510 in the distal handle face 6516. The channel 6518 may include one or more sections including, but not limited to: a distal channel segment 6508 situated between the distal face 6518 and the internal volume 6402 enclosed by the sliding block 6302; a central channel segment 6506 situated between the internal volume 6402 and a proximal channel segment 6502; and the proximal channel element 6502 ending at the proximal opening 6504. In this aspect, the distal channel segment 6508 and the central channel segment 6506 may have a cross-sectional profile that is matched to the exterior cross-sectional profile of the retaining rod 110 such that the retaining rod fits closely within the channel segments 6506 and 6508. The proximal channel segment may have a cross-sectional profile that is smaller than the corresponding exterior cross-sectional profile of the retaining rod 110; the proximal end of the central channel segment 6506 may end in a contraction 6520 that limits the insertion distance of the retaining rod 110.

Referring back to FIG. 62, the distal rod end 6202 of the retaining rod 110 may terminate in a retaining rod distal end 804 designed to operatively connect to various tool fittings (not shown) associated with the implant body 102 and/or implant outer layer 104 in a reversible locked engagement. Various aspects of the retaining rod distal end 804 were described herein previously in association with FIGS. 8-11 and FIGS. 20-21. For example, the retaining rod distal end 804 may be provided as a threaded tip that may be advanced into corresponding threaded receptacles formed within the implant body 102 and/or the implant outer layer 106 (not shown). Any other suitable reversible locking mechanism may be incorporated into the retaining rod distal end 804 without limitation.

FIG. 66 is a perspective view of a dual-element retaining rod 110A in another aspect. In this aspect, the dual-element retaining rod 110A includes a central shaft 6602 nested within an outer sleeve 6604. A perspective view of the central shaft 6602 only is illustrated in FIG. 67, and a perspective view of the outer sleeve 6604 only is illustrated in FIG. 68 expose the features of the individual elements. Referring to FIGS. 66-68, the central shaft 6602 may include an elongate rod 6702 with a threaded tip 6704 situated at the distal rod end 6706. A proximal end 6708 may be extend through a channel formed within a cylindrical knob 6710 attached using a set screw, pin, or any other known method of fixing a cylindrical knob to a shaft. The cylindrical knob may be provided with a surface texture such as raised ridges 6712 as illustrated in FIGS. 66-67, or other surface textures

such as knurling to facilitate the twisting of the central shaft 6602 within the outer sleeve 6604.

The outer sleeve 6604 includes a hollow cylindrical tube 6802 at with tines 2004A-2004D (see FIG. 20) projecting distally from the distal tube end 6804. The tines 2004A-2004D may interlock with corresponding indentations in the implant outer layer 104 as illustrated in FIGS. 20-21. Referring back to FIGS. 66-68, the hollow cylindrical tube 6802 encloses a central channel (not shown) that opens at the distal end in a distal opening 6806. The threaded tip 6704 of the central shaft 6602 protrudes distally from this distal opening 6806.

The outer sleeve 6604 also includes a frame 6808 attached at one end to a proximal end 6810 of the hollow cylindrical tube 6802. The distal edge 6812 of the frame 6808 contains an opening aligned with the central channel of the hollow cylindrical tube 6802 to allow the insertion of the proximal end 6708 of the central shaft 6602. The proximal edge 6814 of the frame 6808 contains a blind fitting 6816 to receive the proximal end 6708 of the central shaft 6602. The outer sleeve 6604 further includes a cylindrical proximal handle attachment fitting 6818 attached to the proximal edge 6814 of the frame 6808 opposite to the blind fitting 6816. The handle attachment fitting 6818 may include features for attaching to a handle (not shown) similar to the implant guide handle 6206 described previously herein in connection with FIGS. 62-65. The attachment features may include a blade-like element 6820 protruding proximally from the attachment fitting 6818, a circumferential groove 6822, and any other attachment feature known in the art in any combination.

III. Methods of Treatment Using Orthopedic Anchoring System

In various aspects, the orthopedic anchoring system 100 described herein may be used to implement a variety of orthopedic surgical methods. Non-limiting examples of suitable orthopedic surgical methods include: vertebral reinforcement or immobilization devices; intervertebral joint reinforcement or immobilization devices; internal fixation devices; and any other orthopedic appliances or orthopedic applications known in the art.

FIG. 69 is an illustration of a simulated orthopedic procedure to stabilize a sacroiliac joint using the orthopedic anchoring system 100 in an aspect. In this aspect, the delivery tool 300 is used to situate an implant outer layer 104 within a bore formed within the sacrum 6902 and ileum 6904 of a patient. A fastener 106 is then introduced through the ileum 6904 at a predetermined penetration distance and orientation by the fastener guide 3806. The implant body 102 is then inserted through the outer layer 104 to lock the fastener 106 in place to produce the implant assembly 200. The implant assembly 200 was described previously herein and was illustrated in FIG. 34.

FIG. 70 is an illustration of a simulated orthopedic procedure to provide an anchor for an orthopedic appliance using the orthopedic anchoring system 100. The implant assembly 200 was described herein previously and illustrated in FIGS. 22-24 and FIGS. 36-37. In this aspect, the implant outer layer (not visible) is inserted into a bore 7004 formed within a vertebral arch 7002 using the implant guide 3808. A fastener 106 is then introduced through the vertebral arch 7002 at a predetermined penetration distance and orientation by the fastener guide 3806 (not shown). The implant body 102 (not visible) is then inserted through the outer layer 104 followed by a threaded plug 2302 (not visible) using the implant guide 3808 to lock the fastener 106 in place to produce the implant assembly 200.

FIGS. 71 and 72 are posterio-caudal and posterio-cranial perspective views illustrating the orthopedic anchoring system 100 situated on a patient 7100 as part of the procedure used to produce the implant assembly 200 in an afflicted area. In various aspects, the implant outer layer 104 is situated into position on the patient 7100 for the desired procedure. The positioning of the delivery tool 300 may be confirmed using any suitable medical imaging method including, but not limited to fluoroscopy, CT scanning, X-ray imaging, and any other suitable medical imaging method. In various aspects, the delivery tool 300 may be adjusted to compensate for variations in the morphology of individual patients, using any of the targeting arm adjustment means described herein previously.

FIGS. 73 and 74 are posterio-cranial and anterio-lateral perspective views illustrating the orthopedic anchoring system 100 situated on a patient 7100 for which the soft tissue has been removed to reveal the positions and orientations at which the fastener guide 3806 and the implant guide 3808 enter the sacrum 7102 and ileum 7104, respectively during a procedure to stabilize the sacroiliac joint 7106 of the patient 7100 in one aspect of the method. Once in position, the delivery tool 300 maintains the fastener guide 3806 and the implant guide 3808 in a fixed geometric arrangement relative to one another, ensuring precise alignment of the fastener 106, the implant outer layer 104, and the implant body 102 during the surgical procedure. In addition, the cutting paths of various surgical tools used to prepare the bore to receive the implant outer layer and the hole to receive the fastener 106 are maintained in appropriate alignment with the eventual insertion paths of the components of the implant assembly 200 using the delivery tool 300.

FIG. 69 is an illustration of a simulated orthopedic procedure to stabilize an sacroiliac joint of a patient 7100 using the orthopedic anchoring system 100 in one aspect. The ileum 7104 has been partially removed in FIG. 69 to facilitate visualization of the arrangement of the elements of the orthopedic anchoring system 100. In this aspect, the delivery tool 300 may be used to situate an implant outer layer 104 within a bore formed within the sacrum 7102 and ileum 7104 of a patient 7100 using the implant guide 3808. A fastener 106 is then introduced through the ileum 7104 at a predetermined penetration distance and orientation by the fastener guide 3806. The implant body 102 may then be inserted through the outer layer 104 to lock the fastener 106 in place to produce the implant assembly 200. The implant assembly 200 was described previously herein previously and was illustrated in FIG. 34.

FIGS. 75-80 are additional illustrations of the simulated orthopedic procedure to stabilize an sacroiliac joint using the orthopedic anchoring system 100 in the preceding aspect; all figures are posterior perspective views. FIG. 75 is a view of the procedure with both the sacrum 7102 and the afflicted ileum 7104 of the patient 7100 removed to enhance the visualization of the spatial arrangement of the implant body 102, the implant outer layer 104, and the fastener 106 of the implant assembly 200. FIG. 76 is a similar view to FIG. 75, with the implant outer layer 104 removed to illustrate the mechanical link between the fastener 106 and the implant body 102, and the significance of the alignment of these elements made possible by the fastener guide 3806 and the implant guide 3808 of the delivery device 300. FIG. 77 is a similar view to FIG. 76, with the implant guide 3808 and targeting arm 108 of the delivery device 300 removed to show the fastener guide 3806 and attached fastener 106.

FIG. 78 is a similar view to previous FIGS. 75-77, but with the delivery device 300 removed to reveal the spatial

arrangement of the implant body 102, the implant outer layer 104, and the fastener 106 of the implant assembly 200. The implant outer layer 104 is additionally removed in FIG. 79 to reveal the spatial arrangement of the implant body 102 and attached fastener 106 of the implant assembly 200. FIG. 80 additionally removes the implant body 102, the implant outer layer 104, and the fastener 106 of the implant assembly 200 to reveal the alignment of the fastener 106 in this simulated orthopedic procedure.

In addition to stabilization of a sacroiliac joint or intra-vertebral joints, the implant assembly 200 may be used as a robust anchor to provide support for other orthopedic stabilization appliances. FIG. 70 is an illustration of a simulated orthopedic procedure to provide an anchor for an orthopedic appliance using the orthopedic anchoring system 100 in another aspect. The implant assembly 200 was described herein previously and illustrated in FIGS. 22-24 and FIGS. 36-37. In this aspect, the implant outer layer (not visible) is inserted into a bore 7004 formed within a vertebral arch 7002 using the implant guide 3808; in this aspect the vertebral arch 7002 is a part of the 5th lumbar vertebra 7006. A fastener 106 may then be introduced through the vertebral arch 7002 at a predetermined penetration distance and orientation by the fastener guide 3806 (not shown). The implant body 102 (not visible) is then inserted through the outer layer 104 followed by a threaded plug 2302 (not visible) using the implant guide 3808 to lock the fastener 106 in place to produce the implant assembly 200.

In the various aspects of the methods described previously herein, the fastener 106, the implant outer layer 104 and implant body 102 may be implanted in any possible sequence without limitation. The particular sequence of elements implanted in any aspect of the method may be influenced by one or more factors including, but not limited to: the particular orthopedic surgical procedure to be performed, the location and condition of the tissues in the afflicted area, and the particular design of the elements of the implant assembly 200 as described previously herein.

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

What is claimed is:

1. A method of performing an orthopedic surgical procedure on a pelvic region of a patient, the pelvic region including a sacrum, an ilium and a sacroiliac joint therebetween, the method comprising:

positioning an implant assembly adjacent the pelvic region, the implant assembly comprising:

- i) an implant body comprising at least a portion of a locking element;
- ii) an implant outer layer comprising a longitudinal axis, a lumen extending parallel to the longitudinal axis, an exterior surface, and a fastener opening including a fastener opening perimeter, and a fas-

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tener path, wherein the lumen is configured to receive at least a portion of the implant body within the lumen;

- iii) a fastener comprising a longitudinal axis and an attachment feature configured to mechanically interlock with the locking element in an interference mechanical engagement, the attachment feature comprising a distal end and a contracted neck region, wherein the attachment feature is configured to mechanically interlock with the locking element when the distal end of the attachment feature is received within the fastener opening of the implant outer layer, and when there is a predetermined alignment between the implant body relative to the implant outer layer and the locking element relative to the attachment feature, respectively,

delivering the implant body and the implant outer layer into the ilium, across the sacroiliac joint, and into the sacrum such that the fastener opening resides within the sacrum;

delivering the fastener through a posterior surface of the sacrum such that the distal end of the attachment feature is received within the implant outer layer; and interlocking the locking element and the attachment feature with each other.

2. The method of claim 1, wherein the implant outer layer further comprises a first alignment feature and the implant body further comprises an second alignment feature, wherein the first alignment feature is configured to operatively engage with the second alignment feature resulting in a first portion of the predetermined alignment of the implant body within the lumen of the implant outer layer.

3. The method of claim 1, wherein the exterior surface of the implant outer layer comprises a generally elongate triangular box.

4. The method of claim 1, wherein the locking element comprises a distal region and a slot formed through the implant body at the distal region, wherein the slot comprises a first end, a second end opposite the first end, a first slot side, a second slot side opposite the first slot side, and a slot width, the first and second slot sides attached to the first end and extending generally parallel to one another away from the first slot end and towards the second slot end, the slot width extending between the first slot side and second slot side and being between a diameter of the contracted neck region and a diameter of the distal end of the attachment feature of the fastener, the slot configured to receive the contracted neck region of the attachment feature to retain the distal end of the attachment feature and to produce the interference mechanical engagement.

5. The method of claim 1 further comprising:

orienting the fastener opening toward the posterior surface of the sacrum such that the fastener path permits the fastener to extend generally posterior to anterior; and

orienting the fastener with the implant outer layer such that the fastener longitudinal axis is aligned with the fastener path.

6. The method of claim 1, wherein the distal end of the attachment feature comprises a ball end.

7. The method of claim 1, wherein the distal end of the attachment feature comprises a rounded end.

8. The method of claim 1, wherein the distal end of the attachment feature comprises a cone end.

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9. The method of claim 1, wherein:

the fastener further comprises a proximal end, a distal end opposite the proximal end, a threaded shaft extending between the proximal and distal ends, and a head coupled to the proximal end and configured to rotate freely relative to the shaft and further configured to couple with an elongate reinforcing element.

10. The method of claim 9, comprising: coupling the elongate reinforcing element with the head of the fastener.

11. The method of claim 9, wherein:

the implant body further comprises a distal region comprising a body depression contoured to a shape of at least a portion of the attachment feature; and

wherein, when the body depression is compressed against the attachment feature, a meshing engagement therebetween comprises the interference mechanical engagement.

12. The method of claim 11, wherein:

the at least a portion of the attachment feature comprises at least a portion of a spherical shape and the body depression comprises a contour which is a general surface negative of the at least a portion of the spherical shape; and

wherein the at least a portion of the spherical shape of the at least a portion of the attachment feature is configured and dimensioned to fit at least partially within the body depression.

13. The method of claim 9, wherein:

the implant outer layer comprises a contoured surface shaped to correspond with a shape of the at least a portion of the attachment feature to enhance a locked engagement formed between the attachment feature of the fastener and the locking element of the implant body.

14. The method of claim 13, wherein:

the at least a portion of the attachment feature comprises a spherical shape and the contoured surface of the implant outer layer comprises a contour which is a general surface negative of the spherical shape; and wherein the spherical shape of the at least a portion of the attachment feature is configured and dimensioned to fit closely within the contoured surface of the implant outer layer.

15. The method of claim 1, further comprising:

positioning a delivery tool at the pelvic region, the delivery tool comprising:

an implant guide configured to releasably couple to at least one of the implant body or the implant outer layer; and

a fastener guide operably coupled to the implant guide and configured to deliver the attachment feature of the fastener to the locking element;

wherein a final manufactured configuration of the delivery tool and the implant assembly are such that, when the system is assembled such that the implant guide is releasably coupled to the at least one of the implant body or the implant outer layer, a delivery arrangement automatically exists such that the fastener guide is correctly oriented to deliver the attachment feature to the locking element.

16. The method of claim 15, wherein:

the fastener guide is operably coupled to the implant guide via a targeting arm comprising a single continuous structural element having a fixed elongate shape.

17. The method of claim 15, wherein:
the fastener guide is operably coupled to the implant
guide via a targeting arm comprising two or more
linked structural elements having an adjustable elongate
shape. 5

18. The method of claim 17, wherein:
the targeting arm comprises a telescoping arrangement via
the two or more linked structural elements.

19. The method of claim 18, wherein:
the targeting arm comprises a first section ending in a first
arm end and a second section ending in a second arm
end, the first and second sections including matching
circular arc shapes with a common center. 10

20. The method of claim 17, wherein:
the targeting arm further comprises a sliding attachment
fitting which permits sliding between the two or more
linked structural elements to adjust a relative position
thereof. 15

21. The method of claim 20, wherein:
the targeting arm comprises a first section ending in a first
arm end and a second section ending in a second arm
end, the first and second sections including matching
circular arc shapes with a common center. 20

22. The method of claim 15, wherein:
the targeting arm comprises two or more hinged or jointed
subsections resulting in the delivery arrangement. 25

23. The method of claim 15, wherein:
the targeting arm comprises one or more bendable sub-
sections having limited deformability resulting in the
delivery arrangement. 30

24. The method of claim 15, wherein:
the fastener guide is operably coupled to the implant
guide via a targeting arm, the targeting arm attached to
the fastener guide at a fastener guide attachment fitting,
the fastener guide attachment fitting configured to
receive a portion of the fastener guide in a reversibly
locked mechanical engagement; 35

wherein, when unlocked, the fastener guide attachment
fitting permits limited movement of the fastener guide
including at least one of rotation of the fastener guide
about the fastener longitudinal axis and translation of
the fastener guide along the fastener longitudinal axis
such that, when unlocked, the fastener guide attach-
ment fitting is configured to maintain a fixed orientation
between the fastener longitudinal axis and the longitu-
dinal axis of the implant outer layer. 40

25. The method of claim 24, wherein:
the fastener guide attachment fitting comprises a collar
having a locking mechanism configured to compresses
a fastener guide shaft, thereby locking the fastener
guide shaft in a reversibly locked mechanical engage-
ment, the locking mechanism selected from one or
more set screws, cotter pins, pegs, clamps, bands,
compression fittings, and any combination thereof. 45

26. The method of claim 15, wherein:
the fastener further comprises a proximal end, a distal end
opposite the proximal end, a threaded shaft extending
between the proximal and distal ends, and a head
coupled to the proximal end configured to rotate freely
relative to the shaft and further configured to couple
with an elongate reinforcing element; and, 50

the fastener guide includes a bone screw inserter nested
within a sleeve comprising a threaded distal end, a
distal end of the bone screw inserter configured to

protrude from the threaded distal end of the sleeve, the
distal end of the bone screw inserter comprising a
screwdriver tip, a screw head fitting positioned proximal
the screwdriver tip and wherein the threaded distal
end of the sleeve and the screw head fitting of the bone
screw inserter are configured to cooperatively reversibly
attach to the head of the fastener in a mechanically
locked engagement during a formation of the implant
assembly and wherein the screwdriver tip is configured
to be received within a corresponding screwdriver
fitting formed within a portion of the fastener at the
proximal end, the screw head fitting configured to be
received within an upward-opening groove formed
within support elements of the fastener head of the
fastener. 5

27. The method of claim 1, wherein the implant body is
at least partially within the lumen of the implant outer layer
upon delivery of the implant body and the implant outer
layer into the ilium, across the sacroiliac joint, and into the
sacrum.

28. A method of performing an orthopedic surgical pro-
cedure on a pelvic region of a patient, the pelvic region
including a sacrum, an ilium and a sacroiliac joint therebe-
tween, the method comprising:
positioning an implant assembly adjacent the pelvic
region, the implant assembly comprising:
i) an implant body comprising at least a portion of a
locking element;
ii) an implant outer layer comprising a longitudinal
axis, a lumen extending parallel to the longitudinal
axis, an exterior surface, and a fastener opening
including a fastener opening perimeter, and a fast-
ener path, wherein the lumen is configured to
receive at least a portion of the implant body within
the lumen;
iii) a fastener comprising a longitudinal axis and an
attachment feature configured to mechanically inter-
lock with the locking element in an interference
mechanical engagement, the attachment feature
comprising a distal end and a contracted neck region,
wherein the attachment feature is configured to
mechanically interlock with the locking element
when the distal end of the attachment feature is
received within the fastener opening of the
implant outer layer, and when there is a predeter-
mined alignment between the implant body rela-
tive to the implant outer layer and the locking
element relative to the attachment feature, respec-
tively,
delivering the implant outer layer into the ilium, across
the sacroiliac joint, and into the sacrum such that the
fastener opening resides within the sacrum;
delivering the implant body into engagement with the
implant outer layer;
delivering the fastener through a posterior surface of the
sacrum such that the distal end of the attachment
feature is received within the implant outer layer; and
interlocking the locking element and the attachment fea-
ture with each other. 15

29. The method of claim 28, wherein delivering the
implant body into engagement with the implant outer layer
comprises inserting the implant body at least partially within
the lumen of the implant outer layer. 20