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(54) Title: ORTHOPEDIC ANCHORING SYSTEM AND METHODS

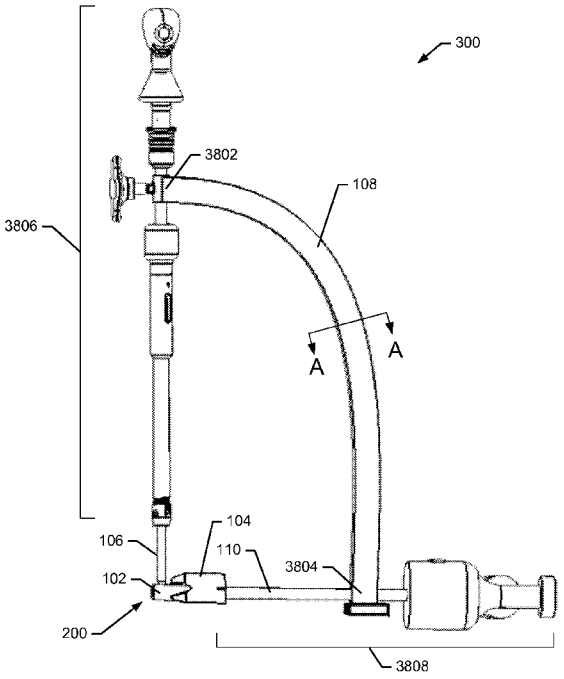

FIG. 38

(57) Abstract: Systems and methods for performing orthopedic surgical procedures to treat a patient are presented herein. The orthopedic anchoring system may include an implant assembly and a delivery tool to perform the orthopedic surgical procedure. The implant assembly may include an implant outer layer, an implant body situated within the implant outer layer, and a fastener attached to a locking element of the implant body. The delivery tool may include a targeting arm, a fastener guide removably attached at a first end of the targeting arm and an implant guide removably attached to a second end of the targeting arm. The delivery tool may maintain a fixed spatial relationship between a longitudinal axis of the fastener and a longitudinal axis of the implant outer layer and implant body. The orthopedic anchoring system may be used to perform orthopedic surgical procedures related to joint reinforcement or immobilization.

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ORTHOPEDIC ANCHORING SYSTEM AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 61/798,922 filed March 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 July 20, 2012.

[0002] All of the aforementioned applications are hereby incorporated by reference in their entireties into the present application.

FIELD OF THE INVENTION

[0003] 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

[0004] 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.

[0005] 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.

[0006] 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.

[0007] 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

[0008] 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 includes 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.

[0009] 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 60º to 90º 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 60º to 90º 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.

[0010] 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 60º to 90º 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.

[0011] 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.

[0012] 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 chosen 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 meshes 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.

[0013] 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.

[0014] 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

[0015] The following figures illustrate various aspects of the disclosure.

[0016] **FIG. 1** is a side view of an orthopedic anchoring system.

[0017] **FIG. 2** is side view of an implant assembly.

[0018] **FIG. 3** is a proximal perspective view of a solid cylindrical implant body.

[0019] **FIG. 4** is proximal perspective view of a hollow cylindrical implant body with a longitudinal groove.

[0020] **FIG. 5** is a distal perspective view of a solid cylindrical implant body with longitudinal projections.

[0021] **FIG. 6** is a top perspective view of a rectangular flat plate implant body with dual self-locking retaining rings.

[0022] **FIG. 7** is a bottom perspective view of a rectangular arcuate plate implant body with a single self-locking retaining ring.

[0023] **FIG. 8** is an exploded perspective view of a hexagonal tool receptacle and corresponding tool fitting.

[0024] **FIG. 9** is an exploded perspective view of a threaded tool receptacle and corresponding tool fitting.

[0025] **FIG. 10** is a transverse cross-sectional view of a hexagonal retaining rod with retractable pins.

[0026] **FIG. 11** is a longitudinal cross-sectional view of a retaining rod end inserted within a tool fitting.

[0027] **FIG. 12** is a top view of a self-locking retaining ring.

[0028] **FIG. 13** is a top view of a hexagonal self-locking retaining ring.

[0029] **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.

[0030] **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.

[0031] **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.

[0032] **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.

[0033] **FIG. 18A** is a transverse cross-sectional view of a hollow cylindrical implant body with a longitudinal groove.

[0034] **FIG. 18B** is a transverse cross-sectional view of a longitudinal ridge projecting from a lumen of an implant outer layer.

[0035] **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.

[0036] **FIG. 19** is a distal perspective view of an implant outer layer with a triangular external cross-sectional profile.

[0037] **FIG. 20** is an exploded perspective view of a tool fitting with indentations and a corresponding end of a retaining rod.

[0038] **FIG. 21** is a proximal perspective view of an implant body and end of a retaining rod in an interlocked arrangement.

[0039] **FIG. 22** is a proximal perspective view of an implant outer layer showing a fastener opening.

[0040] **FIG. 23** is an exploded perspective view of an implant outer layer with a fastener opening and a solid implant body.

[0041] **FIG. 24** is a proximal perspective view of an implant body mechanically locked in place within an implant outer layer.

[0042] **FIG. 25** is a proximal perspective view of an implant outer layer with anti-migration serrated edges.

[0043] **FIG. 26** is a proximal perspective view of an implant outer layer with anti-migration wedge-shaped ridges.

[0044] **FIG. 27** is a proximal perspective view of an implant outer layer with a plurality of perforations.

[0045] **FIG. 28** is an exploded side view of a fastener and threaded compression nut.

[0046] **FIG. 29** is a side view of a fastener with a peg-like head.

[0047] **FIG. 30** is a side detail view of a fastener with a ball fitting.

[0048] **FIG. 31** is a side detail view of a fastener with a rounded fitting.

[0049] **FIG. 32** is a side detail view of a fastener with a cone fitting.

[0050] **FIG. 33** is a side detail view of a fastener with a divoted fitting.

[0051] **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.

[0052] **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.

[0053] **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.

[0054] **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.

[0055] **FIG. 38** is a side view of a delivery tool attached to an implant assembly.

[0056] **FIG. 39** is a side view of a targeting arm with a right-angle shape.

[0057] **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.

[0058] **FIGS. 41A** and **41B** are side views of a telescoping targeting arm with arcuate shape.

[0059] **FIGS. 42A** and **42B** are side views of an adjustable targeting arm with a right-angle shape.

[0060] **FIGS. 43A** and **43B** are detailed perspective views of a first end of the targeting arm illustrated in **FIG. 38**.

[0061] **FIG. 44A** is a detailed perspective view of a second end of a targeting arm and a retaining rod.

[0062] **FIG. 44B** is an exploded perspective view of the implant guide attachment fitting illustrated in **FIG. 44A**.

[0063] **FIG. 45** is a side view of the fastener guide illustrated in **FIG. 38**.

[0064] **FIG. 46** is a detailed side view of the bone screw inserter illustrated in **FIG. 45** with the threaded sleeve and removable handle removed.

[0065] **FIG. 47** is a detailed proximal perspective view of the proximal end of the bone screw inserter illustrated in **FIG. 46**.

[0066] **FIG. 48** is a detailed perspective view of a proximal end of a bone screw inserter.

[0067] **FIG. 49** is a bottom view of a removable handle.

[0068] **FIG. 50** is a detailed side view of the distal end of the bone screw inserter illustrated in **FIG. 46**.

[0069] **FIG. 51** is a distal perspective view of the distal end of the bone screw inserter illustrated in **FIG. 46**.

[0070] **FIG. 52** is an enlarged side view of the removable handle illustrated in **FIG. 45** with the threaded sleeve and bone screw inserter removed.

[0071] **FIG. 53** is a side perspective view of a removable handle with the collar and underlying components removed.

[0072] **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.

[0073] **FIG. 55** is a detailed side view of a distal end of a handle with a sliding collar removed.

[0074] **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.

[0075] **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.

[0076] **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.

[0077] **FIG. 59** is a longitudinal cross-sectional view of **FIG. 58** with the bone screw inserter included.

[0078] **FIG. 60** is a side view of a head of a fastener attached to a bone screw inserter and threaded sleeve.

[0079] **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**.

[0080] **FIG. 62** is a side view of an implant guide.

[0081] **FIG. 63** is a detailed proximal side view of an implant guide with handle body housing, grip, and proximal access port removed.

[0082] **FIG. 64** is a detailed proximal perspective view of an implant guide with handle body housing, grip, and proximal access port removed.

[0083] **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**.

[0084] **FIG. 66** is a distal perspective view of a dual-element retaining rod.

[0085] **FIG. 67** is a distal perspective view of a central shaft of a dual-element retaining rod.

[0086] **FIG. 68** is a distal perspective view of an outer sleeve of a dual-element retaining rod.

[0087] **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.

[0088] **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 posteriocaudal vantage.

[0089] **FIG. 71** is an illustration of an orthopedic anchoring system situated on a patient, viewed from a cranioposterior vantage.

[0090] **FIG. 72** is an illustration of an orthopedic anchoring system situated on a patient, viewed from a posteriocaudal vantage.

[0091] **FIG. 73** is an illustration of an orthopedic anchoring system situated on a patient, viewed from a posteriocaudal vantage, with all soft tissues removed.

[0092] **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.

[0093] **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.

[0094] **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.

[0095] **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 .

[0096] **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.

[0097] **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.

[0098] **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.

[0099] 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

[00100] 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.

[00101] 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.

[00102] 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**.

[00103] 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.**

[00104] 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**.

[00105] 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

[00106] 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

[00107] 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.

[00108] 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**.

[00109] 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

[00110] 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.

[00111] 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**.

[00112] 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**.

[00113] 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.**

[00114] 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.

[00115] 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**.

[00116] 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**.

[00117] 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

[00118] 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**.

[00119] 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.**

[00120] 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.

[00121] 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.**

[00122] 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.

[00123] 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

[00124] 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.

[00125] **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**.

[00126] 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 orthopedic 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**.

[00127] 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**.

[00128] 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**.

[00129] 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.

[00130] 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**.

[00131] 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**.

[00132] 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

[00133] 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.

[00134] 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**.

[00135] 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**.

[00136] 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**.

[00137] 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**.

[00138] 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**.

[00139] 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**.

[00140] 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***

[00141] 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**.

[00142] 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**. 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.

[00143] 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

[00144] 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**.

[00145] 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.

[00146] 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.

[00147] 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**.

[00148] 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

[00149] 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.

[00150] 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

[00151] 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**.

[00152] **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**.

[00153] 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.

[00154] 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**.

[00155] 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

[00156] 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

[00157] 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.

[00158] 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.

[00159] 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**.

[00160] 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.

[00161] 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 enhancing 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.

[00162] 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

[00163] 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.

[00164] **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**.

[00165] 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

[00166] 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.

[00167] 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.

[00168] **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

[00169] 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.

[00170] 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 0º to about 20º 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

[00171] 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**.

[00172] 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.

[00173] 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**.

[00174] 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**.

[00175] 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**.

[00176] 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**.

[00177] 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

[00178] 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**.

[00179] **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**.

[00180] 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.

[00181] **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**.

[00182] 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.

[00183] **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**.

[00184] 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**.

[00185] 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.

[00186] 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

[00187] 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.

[00188] **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**.

[00189] 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

[00190] 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.

[00191] 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 if 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.

[00192] 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

[00193] In one aspect, the targeting arm **108** may be provided as a single continuous structural element as illustrated in **FIG. 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**.

[00194] **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.

[00195] **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**.

[00196] 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

[00197] 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).

[00198] 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.

[00199] 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

[00200] 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).

[00201] 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**.

[00202] **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.

[00203] 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**.

[00204] 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 though 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.

[00205] 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

[00206] 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**.

[00207] 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 4**300** 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 4**300** as illustrated in **FIG. 43B**.

*i. **Bone screw inserter***

[00208] **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**.

[00209] 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**.

[00210] 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.

[00211] 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.

[00212] Again referring to **FIG. 46**, the bone screw inserter **4502** may further include a distal end **4510** that includes elements to 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.

[00213] **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

[00214] 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**.

[00215] **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.

[00216] 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.

[00217] 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**.

[00218] **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.

[00219] **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**.

[00220] **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**.

[00221] 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.

[00222] **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

[00223] 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 **4510** 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.

[00224] 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**.

[00225] 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**.

[00226] 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**.

[00227] 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**.

[00228] **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**.

[00229] 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**.

[00230] 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

[00231] 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**.

[00232] 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**.

[00233] **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**.

[00234] **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**.

[00235] 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.

[00236] **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**.

[00237] 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.

[00238] **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**.

[00239] 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**.

[00240] 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

[00241] 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.

[00242] **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 previously and was illustrated in **FIG. 34**.

[00243] **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**.

[00244] **FIGS**. **71** and **72** are posteriocaudal and posteriocranial 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.

[00245] **FIGS**. **73** and **74** are posteriocranial and anteriolateral 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**.

[00246] **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.**

[00247] **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.**

[00248] **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.

[00249] In addition to stabilization of a sacroiliac joint or intravertebral 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**.

[00250] 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.

[00251] The foregoing merely illustrates the principles of the invention. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. It will thus be appreciated that those skilled in the art will be able to devise numerous systems, arrangements and methods which, although not explicitly shown or described herein, embody the principles of the invention and are thus within the spirit and scope of the present invention. From the above description and drawings, it will be understood by those of ordinary skill in the art that the particular embodiments shown and described are for purposes of illustrations only and are not intended to limit the scope of the present invention. References to details of particular embodiments are not intended to limit the scope of the invention.

CLAIMS

What is claimed is:

1. An implant assembly for 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.

2. The implant assembly of claim 1, wherein the lumen opens to an outer layer proximal end opposite to an outer layer distal end of the implant outer layer.

3. The implant assembly of claim 1, wherein the outer layer is situated within a bore formed within the bone of the patient.

4. The implant assembly of claim 1, wherein the locking element is situated outside of the lumen of the implant outer layer.

5. The implant assembly of claim 1, wherein the locking element is situated within the lumen and the implant outer layer further comprises 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.

6. The implant assembly of claim 5, wherein the fastener opening further comprises 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.

7. The implant assembly of claim 1, wherein the fastener fitting is chosen from: a ball fitting, a rounded fitting, a cone fitting, and a divoted fitting.

8. The implant assembly of claim 1, wherein the locking element is chosen from: a self-locking retaining ring, a slot, a threaded fitting, a divoted fitting, and one or more projections forming a slot.

9. The implant assembly of claim 1, wherein the fastener is chosen from a screw, a nail, a pin, and a staple.

10. The implant assembly of claim 1, wherein the lumen comprises a cross-sectional profile that is essentially matched to an external cross-sectional profile of the implant body.

11. A delivery tool for performing an orthopedic surgical procedure, the tool comprising:

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 comprises 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 comprises an implant guide longitudinal axis and an implant guide distal end;

wherein the targeting arm maintains a fixed arrangement of the fastener guide longitudinal axis and the implant guide longitudinal axis during the orthopedic surgical procedure.

12. The delivery tool of claim 11, wherein:

the targeting arm comprises a single rigid element formed into an elongate shape chosen from: a curved arcuate shape, a polygonal shape, and a right-angle shape;

the fixed arrangement comprises a coplanar alignment of the fastener guide longitudinal axis and the implant guide longitudinal axis and a non-adjustable angle ranging from about 60º to 90º between the fastener guide longitudinal axis and the implant guide longitudinal axis.

13. The delivery tool of claim 11, wherein:

the targeting arm comprises 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 comprises the first end and an opposite first joined end;

the second element comprises the second end and an opposite second joined end;

the first joined end and the second joined end are joined in an adjustable locked mechanical engagement;

the fixed arrangement comprises a coplanar alignment of the fastener guide longitudinal axis and the implant guide longitudinal axis and an adjustable angle ranging from about 60º to 90º between the fastener guide longitudinal axis and the implant guide longitudinal axis.

14. The delivery tool of claim 13, wherein the targeting arm comprises 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.

15. The delivery tool of claim 11, wherein the fastener guide further comprises 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.

16. The delivery tool of claim 11, wherein the implant guide further comprises 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.

17. An orthopedic anchoring system for providing a stable anchor attached to a bone of a patient, the system comprising:

an implant assembly comprising:

a hollow elongate implant outer layer comprising an outer layer proximal end, an outer layer distal end opposite to the outer layer proximal end, and a lumen wall defining a lumen;

an elongate implant body comprising 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; and

an elongate fastener comprising 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; and

a delivery tool comprising:

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 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 comprises 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;

wherein the targeting arm maintains a fixed arrangement of the fastener guide longitudinal axis and the implant guide longitudinal axis during the orthopedic surgical procedure.

18. The orthopedic anchoring system of claim 17, wherein the lumen opens to the outer layer proximal end.

19. The orthopedic anchoring system of claim 17, wherein the implant outer layer is situated within a bore formed within the bone of the patient.

20. The orthopedic anchoring system of claim 17, wherein the locking element is situated outside of the lumen of the implant outer layer.

21. The orthopedic anchoring system of claim 17, wherein the locking element is situated within the lumen and the implant outer layer further comprises 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.

22. The orthopedic anchoring system of claim 21, wherein the fastener opening further comprises 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.

23. The orthopedic anchoring system of claim 17, wherein the fastener fitting is chosen from: a ball fitting, a rounded fitting, a cone fitting, and a divoted fitting.

24. The orthopedic anchoring system of claim 17, wherein the locking element is chosen from: a self-locking retaining ring, a slot, a threaded fitting, a divoted fitting, one or more projections forming a slot.

25. The orthopedic anchoring system of claim 17, wherein the fastener is chosen from a screw, a nail, a pin, and a staple.

26. The orthopedic anchoring system of claim 17, wherein the fixed arrangement comprises a coplanar alignment of the fastener guide longitudinal axis and the implant guide longitudinal axis and a fixed angle ranging from about 60º to 90º between the fastener guide longitudinal axis and the implant guide longitudinal axis.

27. The orthopedic anchoring system of claim 17, wherein the fastener guide further comprises 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.

28. The orthopedic anchoring system of claim 17, wherein the implant guide further comprises 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.

29. A method for performing an orthopedic surgical procedure to treat an afflicted region of a patient, the method comprising:

providing a delivery tool comprising:

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 comprises a fastener guide longitudinal axis and a fastener guide distal end;

an implant guide releasably attached to the second arm end, wherein the implant guide comprises an implant guide longitudinal axis and an implant guide distal end;

wherein the targeting arm maintains a fixed arrangement of the fastener guide longitudinal axis and the implant guide longitudinal axis during the orthopedic surgical procedure;

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;

reversibly attaching an outer layer proximal end of an implant outer layer to the implant guide distal end, wherein the implant outer layer further comprises a lumen wall defining a lumen, the lumen opening to the outer layer proximal end situated opposite to an outer layer distal end;

inserting the outer layer distal end into the bore to situate at least a portion of the implant outer layer within the bore;

reversibly attaching a body proximal end of an implant body to the implant guide distal end, wherein the implant body further comprises a locking element and a body distal end situated opposite to the body proximal end;

inserting the body proximal end into the lumen to situate at least a portion of the implant body within the lumen;

reversibly attaching a fastener head of a fastener situated at a fastener proximal end to the fastener guide distal end, wherein the fastener further comprises an attachment fitting situated at a fastener distal end opposite to the fastener proximal end; and

engaging the attachment fitting of the fastener with the locking element of the implant body to form a locked mechanical engagement.

30. The method of claim 29, further comprising forming a fastener channel within the bone using a second bone removal tool reversibly attached to the fastener guide distal end.

31. The method of claim 30, wherein the bone removal tool and the second bone removal tool are chosen from: a drill, a bone cutter, a fiber optic camera, a laser, a conduit, and any combination thereof.

32. An orthopedic anchoring system comprising:

an implant assembly comprising:

an implant body comprising at least a portion of a locking element; and

a fastener comprising an attachment feature configured to mechanically interlock with the locking element;

a delivery tool comprising:

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;

wherein 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.

33. The system of claim 32, further comprising an implant outer layer comprising 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.

34. The system of claim 32, wherein in being coupled together, the implant guide and fastener guide form an angle relative to each other, and the angle is non-adjustable.

35. The system of claim 33, wherein the attachment feature is configured to mechanically interlock with the locking element in a force-fit mechanical engagement.

36. The system of claim 35, wherein the locking element is a self-locking retaining ring and the attachment feature is 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, and wherein the fastener distal end is configured to be forced through the self-locking retaining ring to produce the force-fit mechanical engagement.

37. The system of claim 36, wherein the locking element is situated near a distal end of the implant body.

38. The system of claim 37, wherein the distal end of the implant body is configured to protrude from the lumen of the implant outer layer to expose the locking element.

39. The system of claim 37, wherein the implant outer layer further comprises a fastener opening configured to provide a path through which the attachment feature passes to engage the locking element in a force-fit mechanical engagement.

40. The system of claim 33, wherein the attachment feature is configured to mechanically interlock with the locking element in an interference mechanical engagement.

41. The system of claim 40, wherein:

the attachment feature comprises 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 comprises 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 is configured to receive the neck region of the attachment feature to retain the fastener distal end and to produce the interference mechanical engagement.

42. The system of claim 41, wherein the fastener is situated in a final fastener position and the implant body is advanced in a distal direction to form the interference mechanical engagement.

43. The system of claim 42, wherein the implant outer layer further comprises a second locking element comprising 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.

44. The system of claim 33, 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 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.

45. The system of claim 44, wherein:

the first alignment feature comprises a first non-circular cross-sectional profile,

the second alignment feature comprises 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 are aligned only at the predetermined angular alignment.

46. The system of claim 44, wherein:

the first alignment feature is chosen 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 is chosen from 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 meshes with the corresponding longitudinal groove or ridge as the implant body is advanced distally into the lumen only at the predetermined angular alignment.

47. The system of claim 33, wherein the implant guide is further configured to releasably couple with the implant outer layer.

48. The system of claim 32, wherein the delivery tool further comprises a targeting arm comprising 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.

49. The system of claim 48, wherein the targeting arm comprises a fixed structural element configured to operatively couple the fastener guide and the implant guide at a non-adjustable angle relative to each other.

50. The system of claim 48, wherein the targeting arm comprises 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.

51. A method of implanting an orthopedic anchor, the method comprising:

approaching a bore formed within a bone tissue with an implant body comprising at least a portion of a locking element;

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

causing an attachment feature of a fastener to mechanically interlock with the locking element.

52. The method of claim 51, further comprising approaching the 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.

53. The method of claim 52, further comprising :

releasably coupling the implant outer layer to an implant guide of a delivery tool prior to approaching the bore;

releasably coupling the implant inner layer to the implant guide prior to situating the implant body within the lumen;

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.

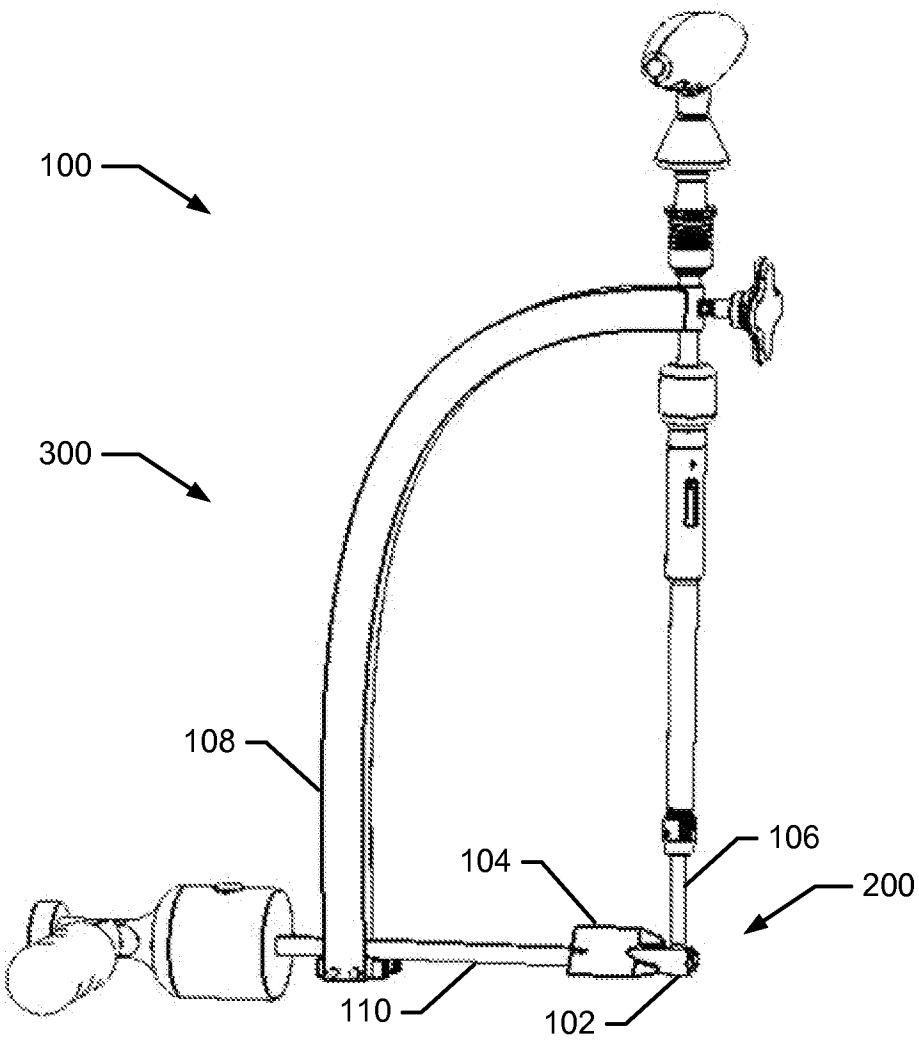

FIG. 1

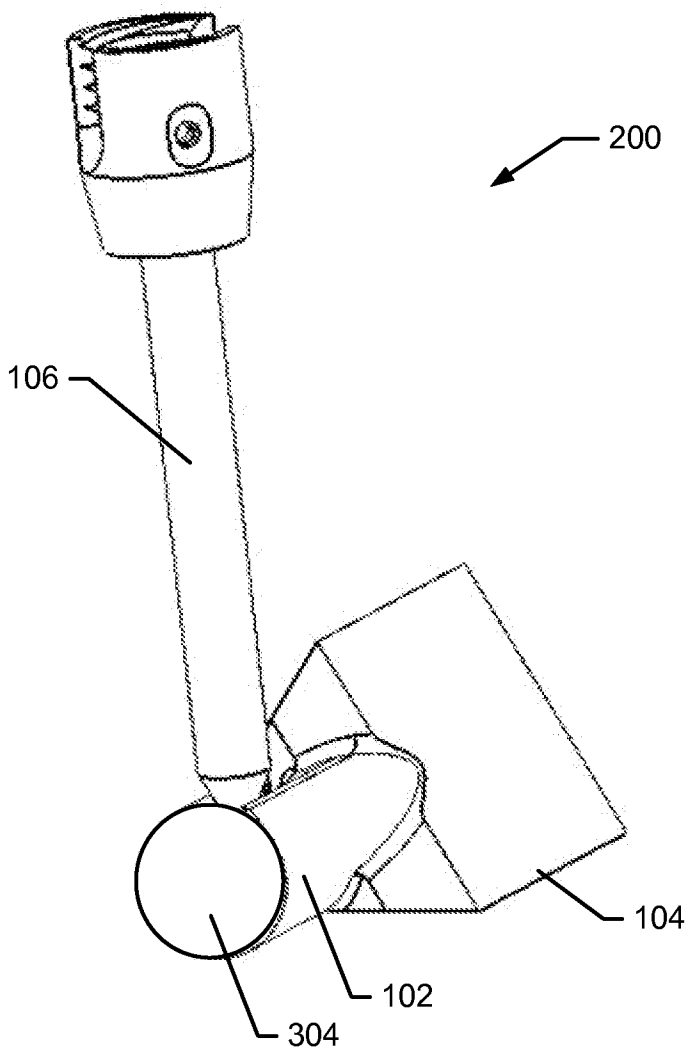

FIG. 2

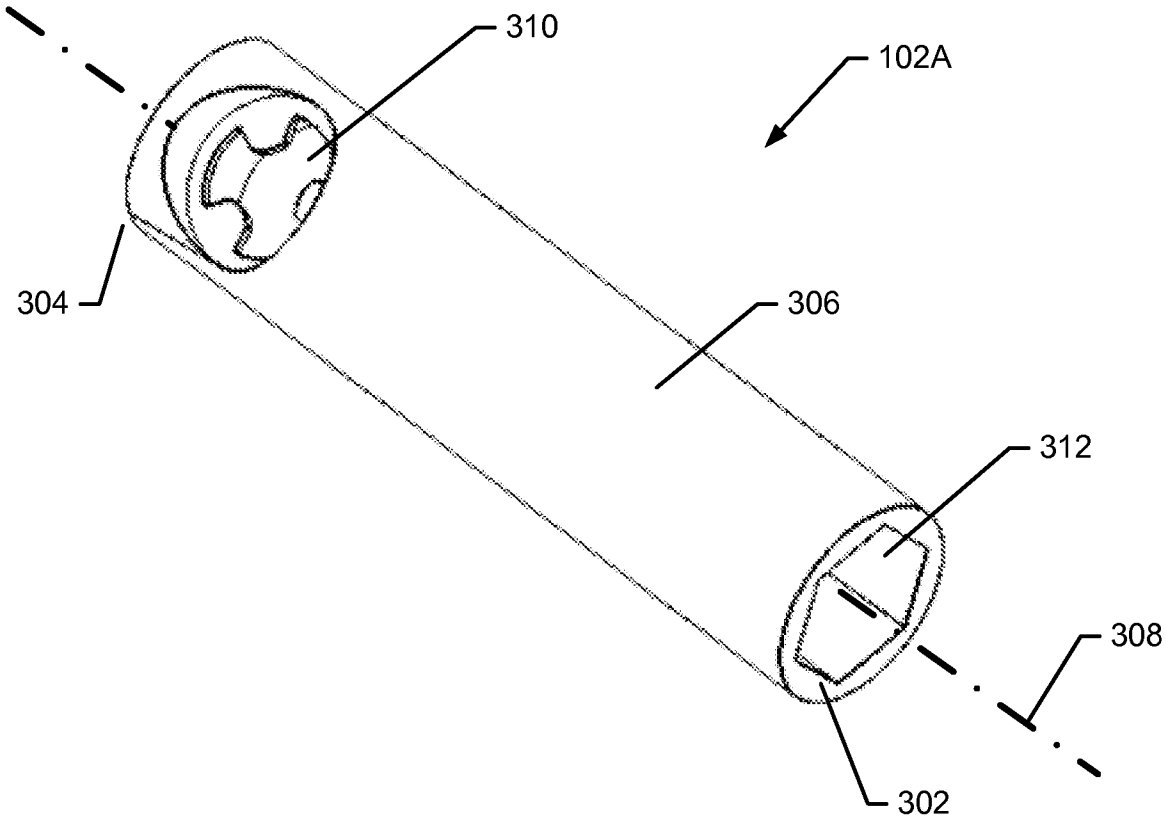

FIG. 3

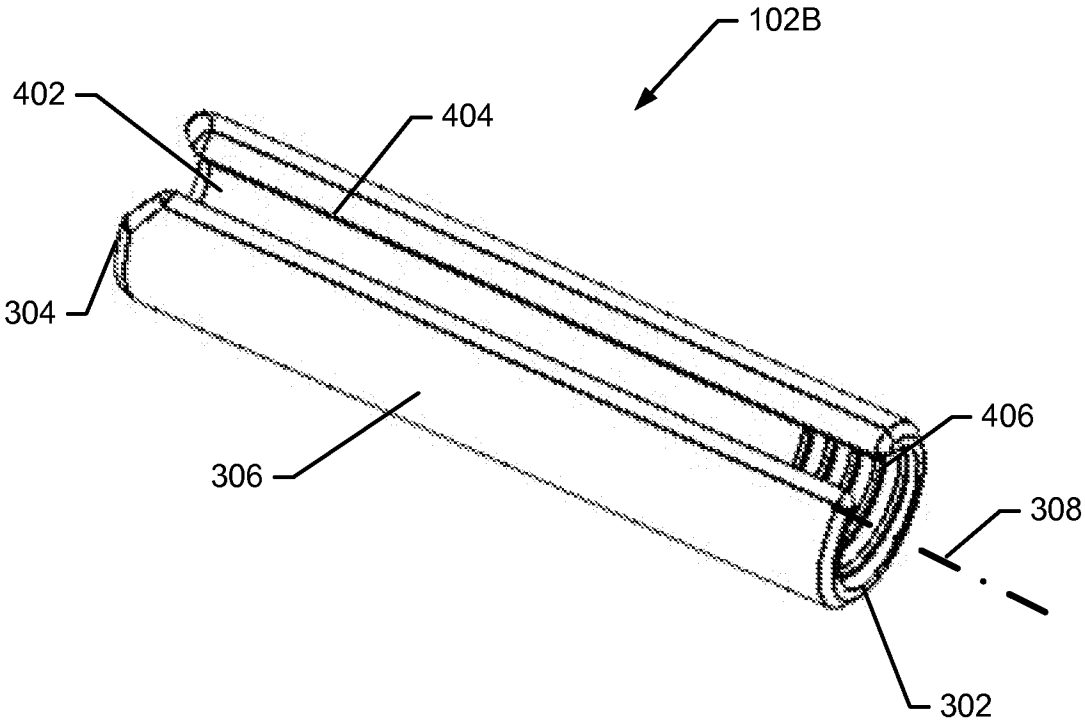
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FIG. 4

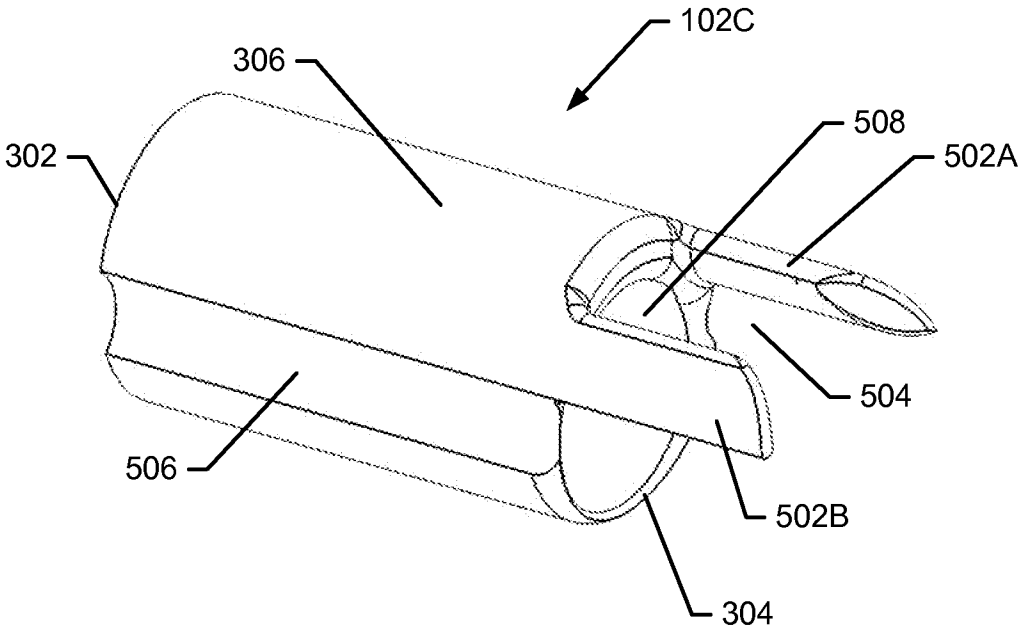
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FIG. 5

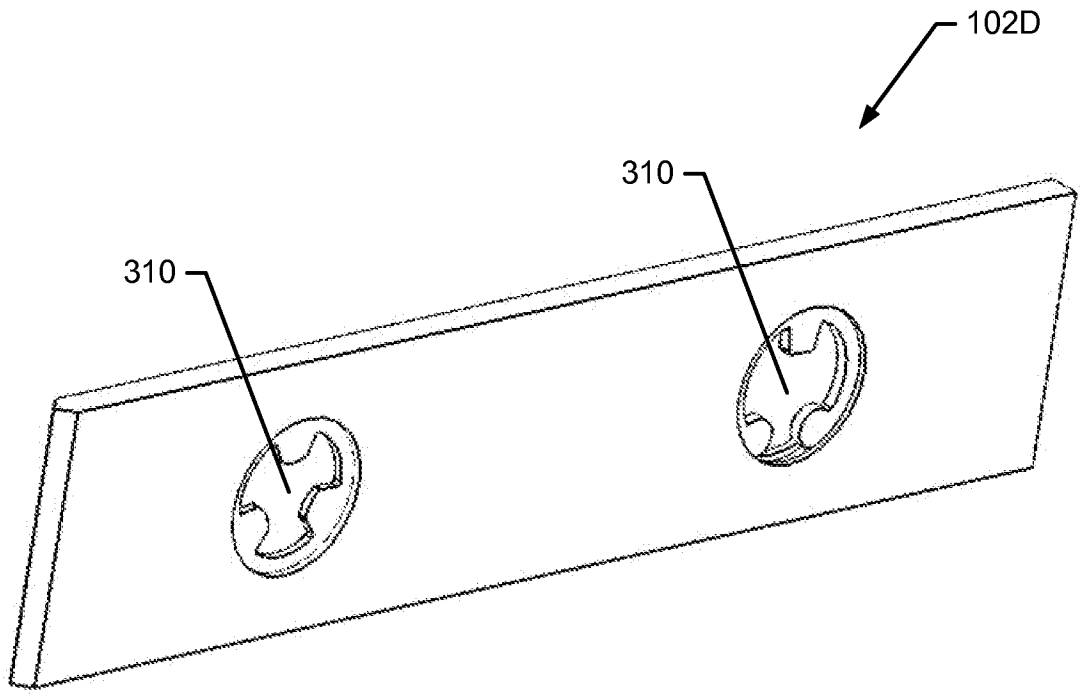

FIG. 6

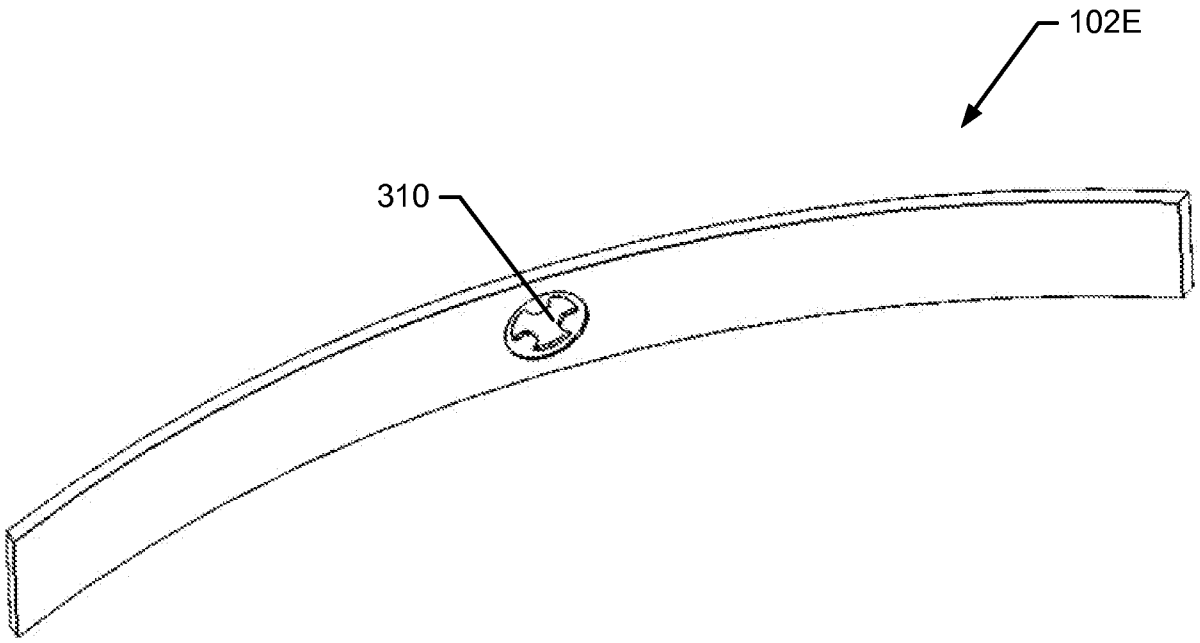

FIG. 7

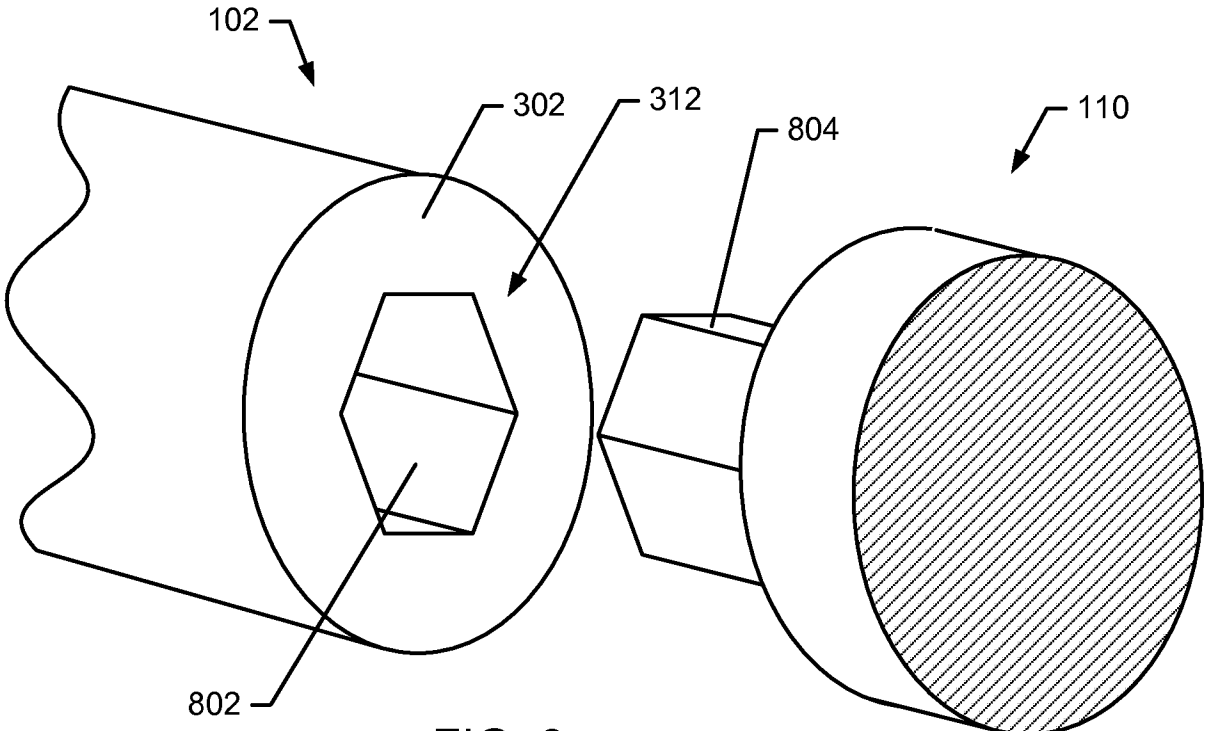

FIG. 8

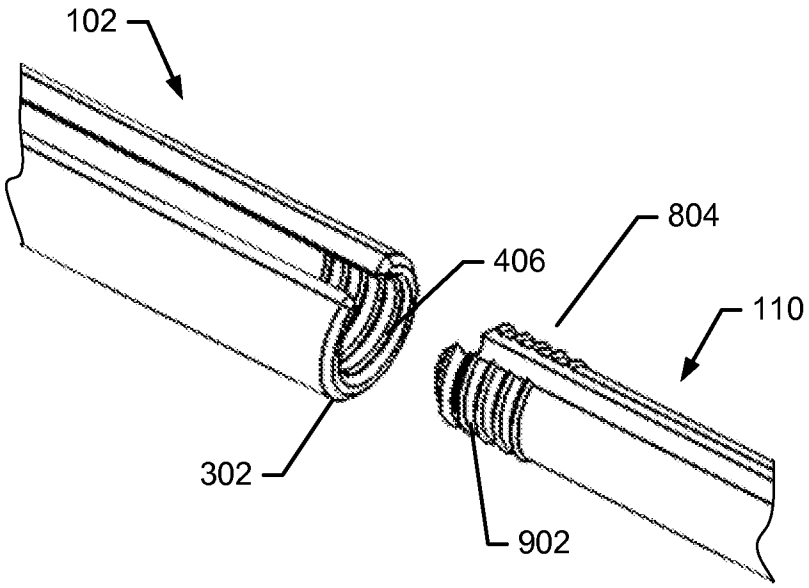

FIG. 9

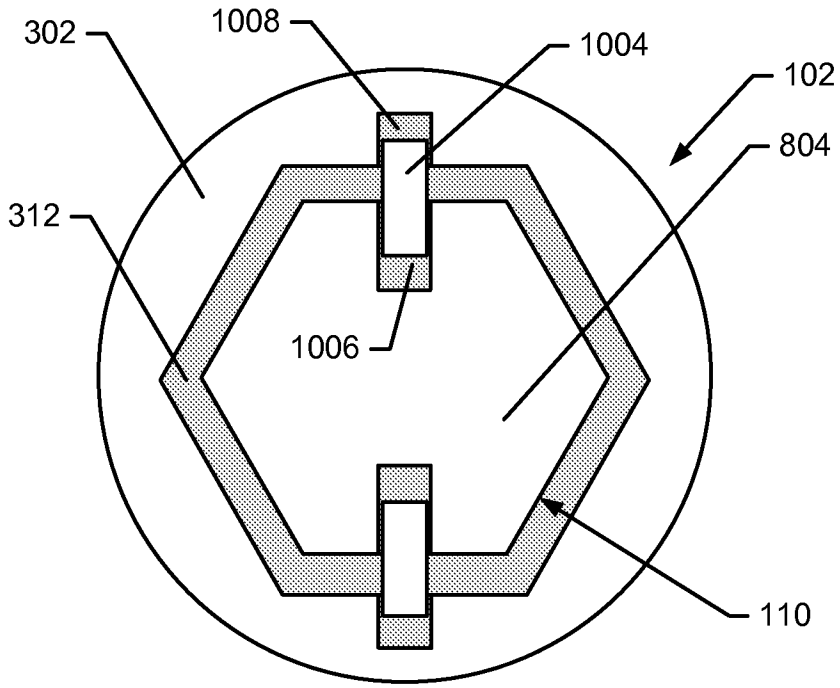
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FIG. 10

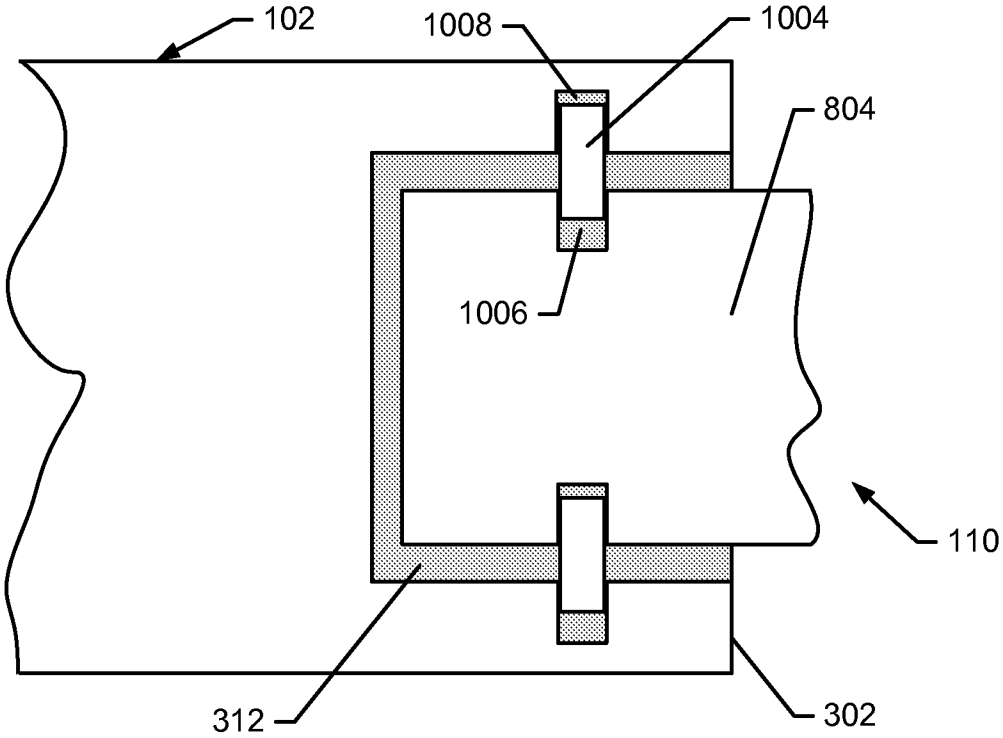
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FIG. 11

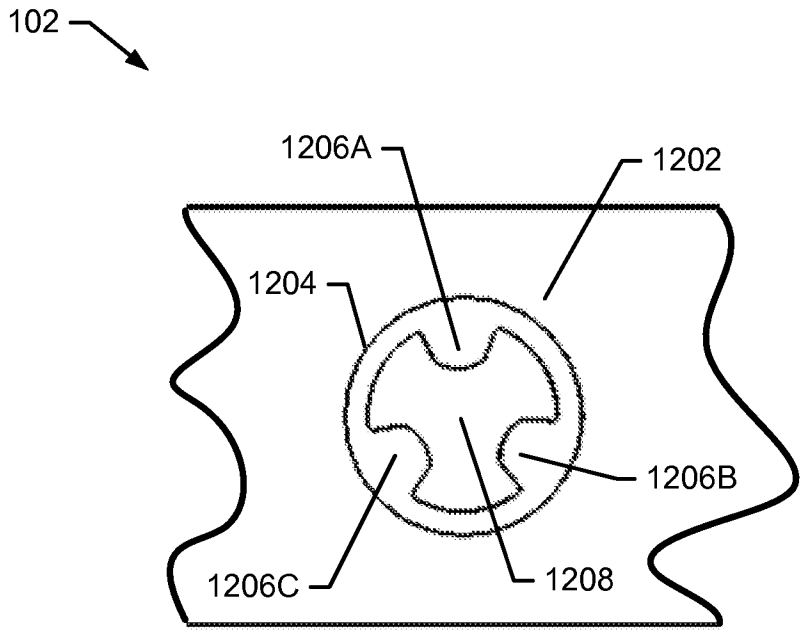
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FIG. 12

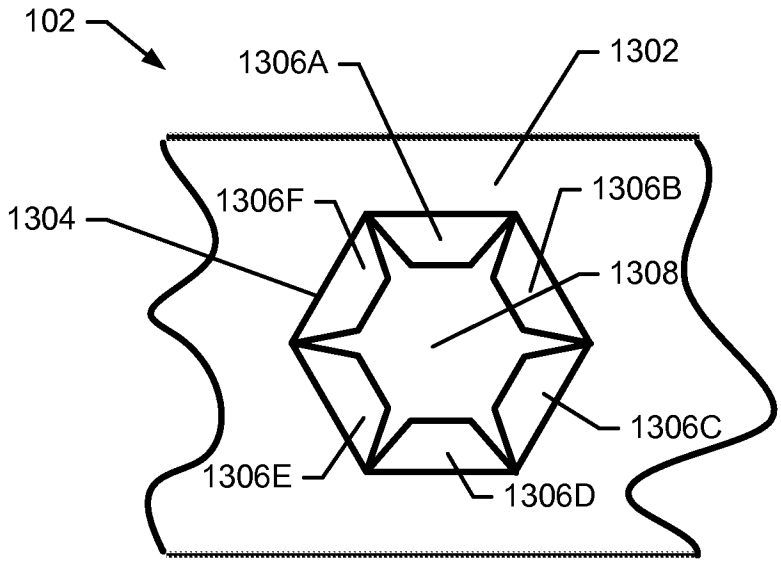
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FIG. 13

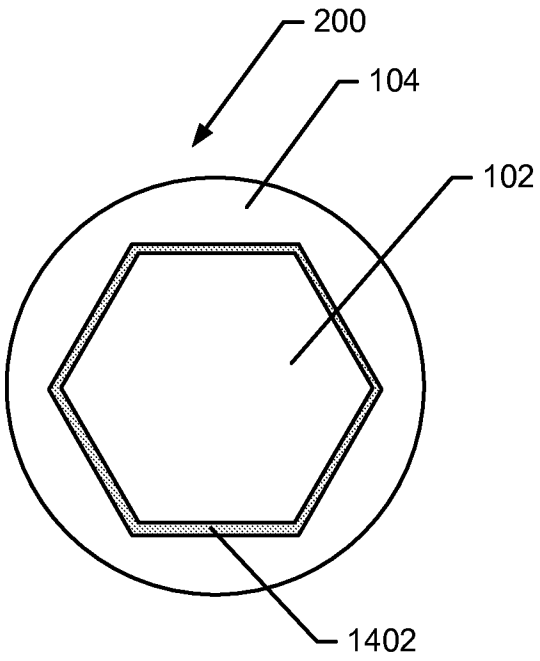

FIG. 14

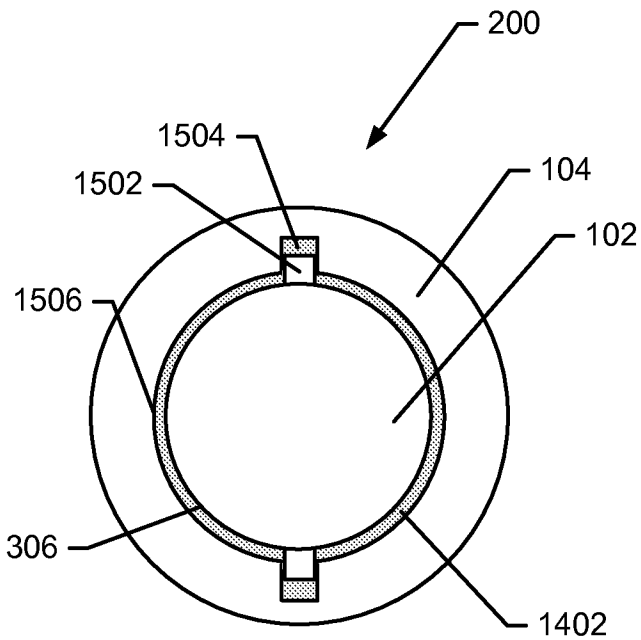

FIG. 15

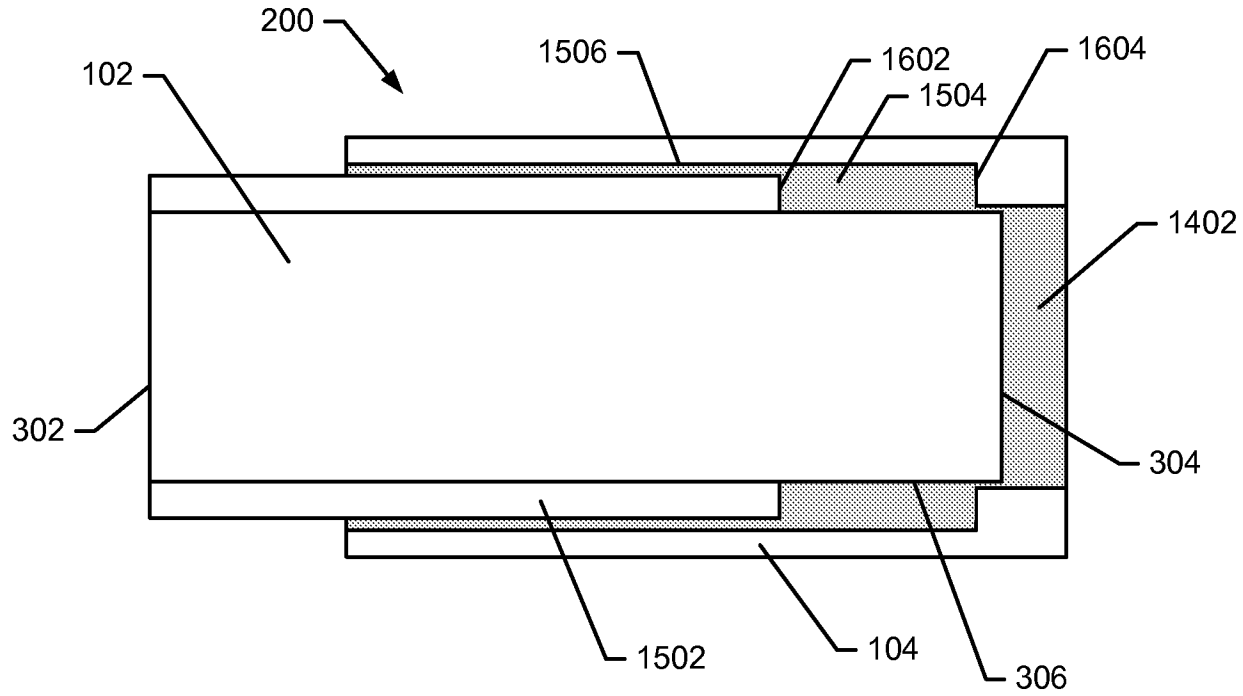
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FIG. 16

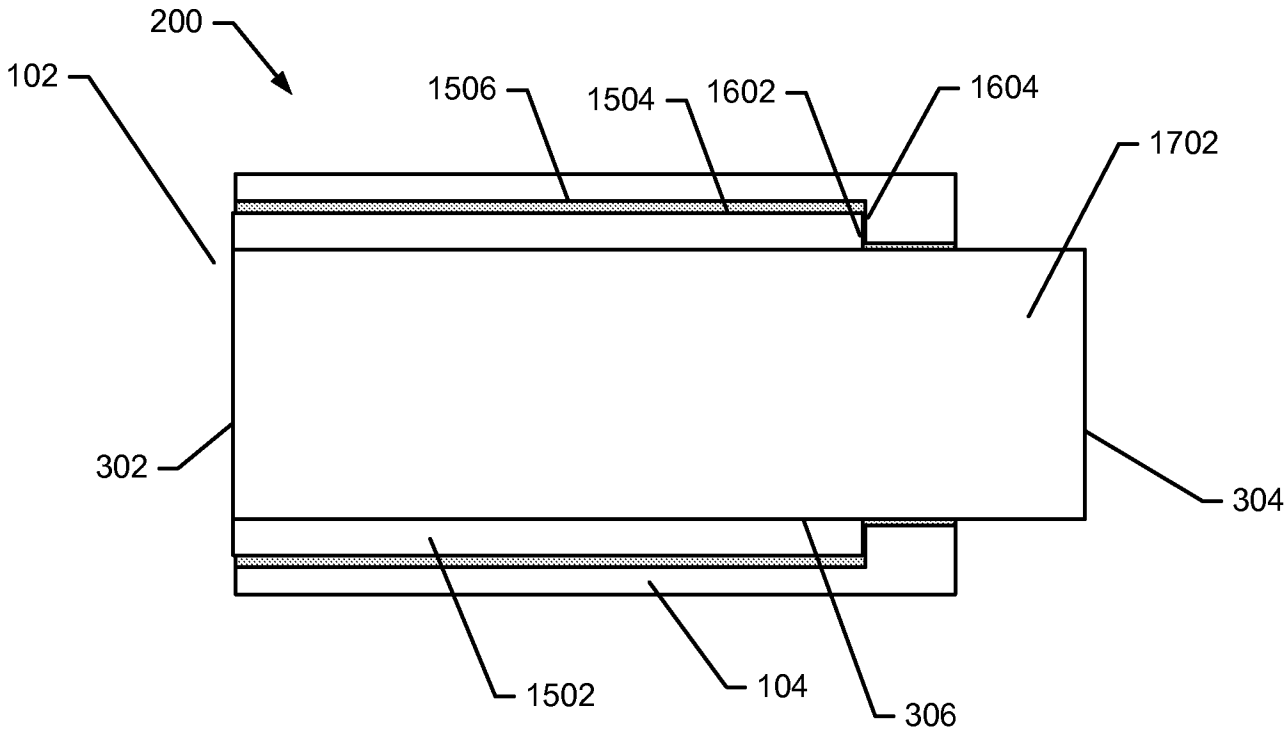
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FIG. 17

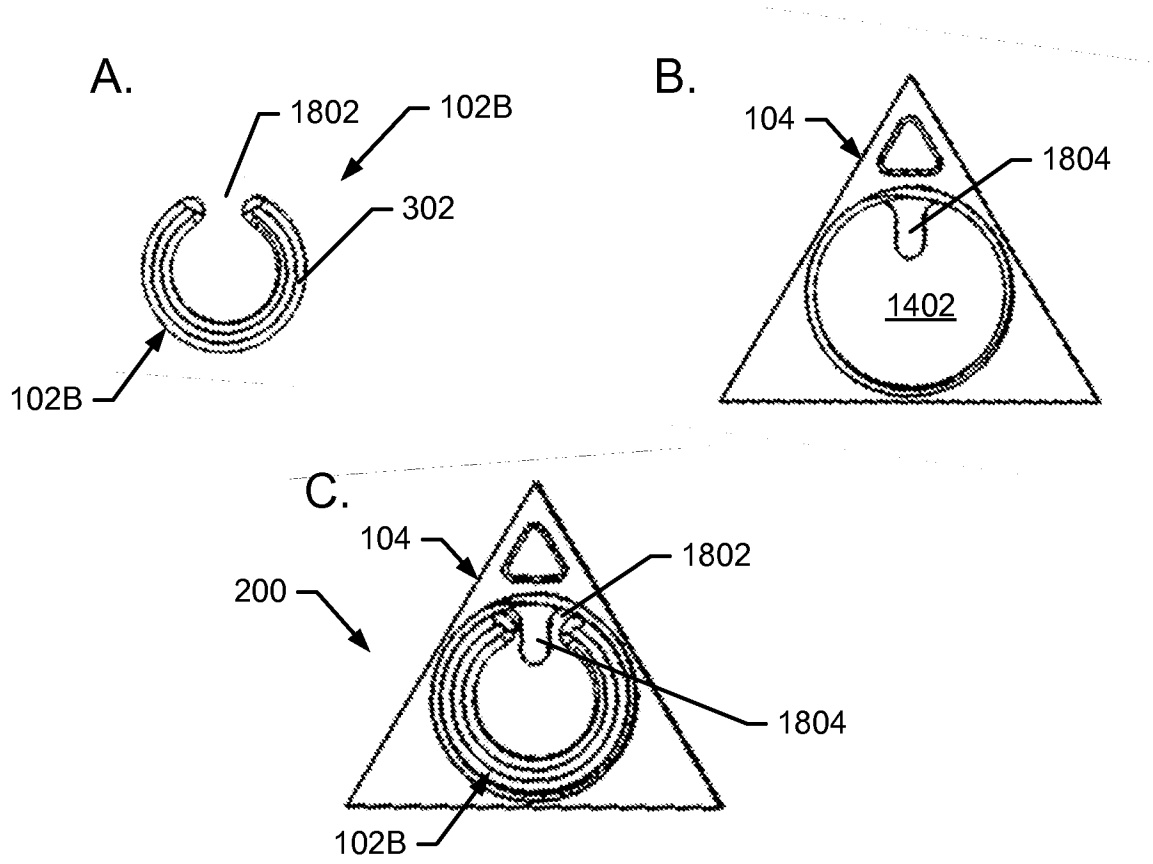
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FIG. 18

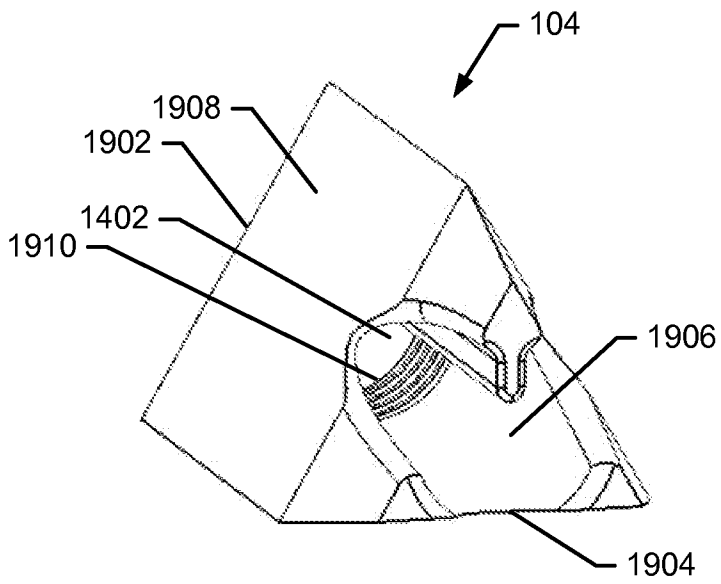
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FIG. 19

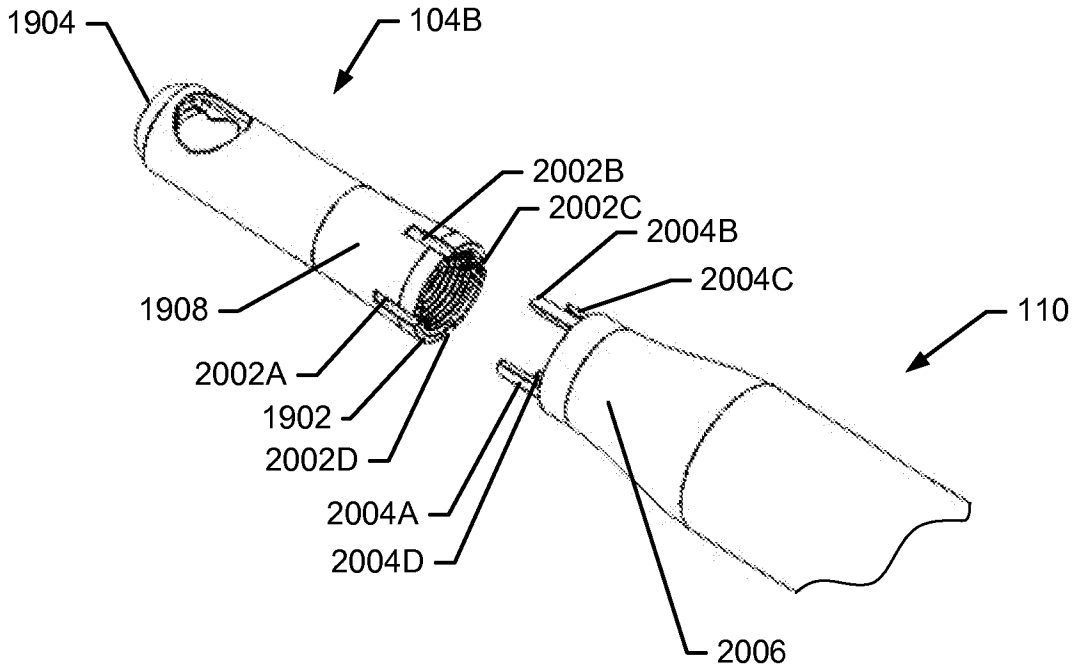
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FIG. 20

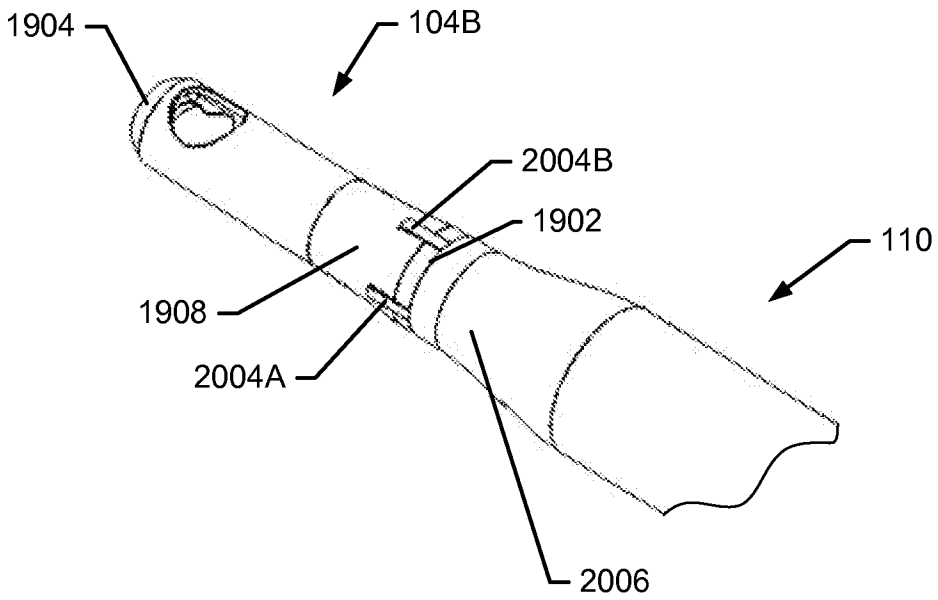
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FIG. 21

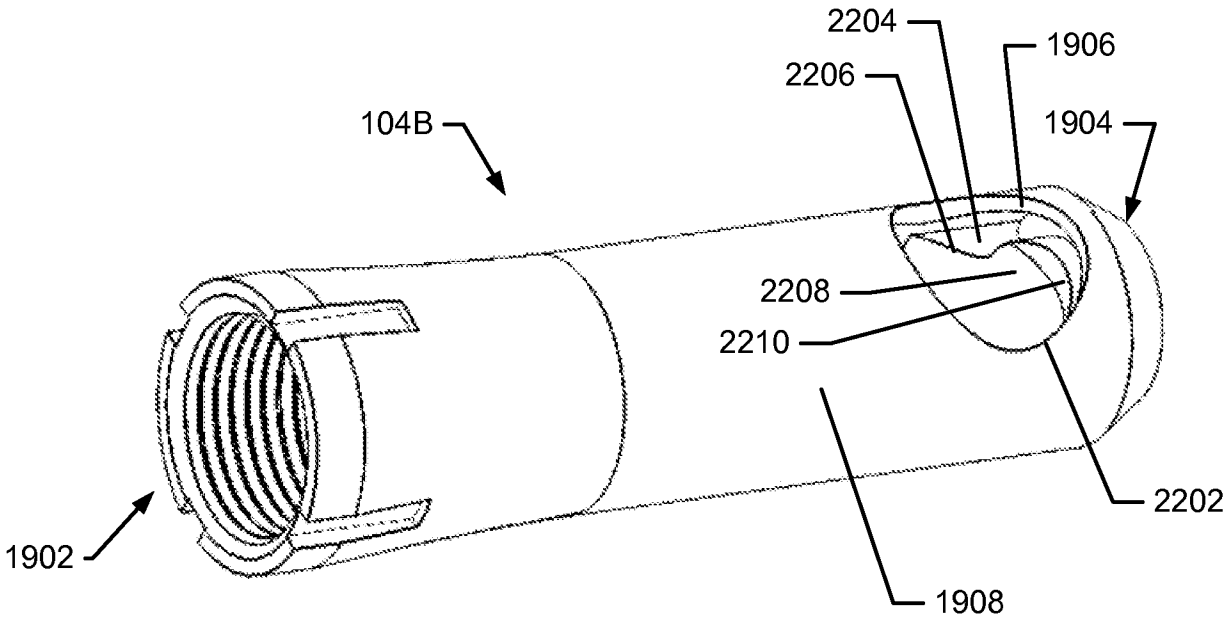
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FIG. 22

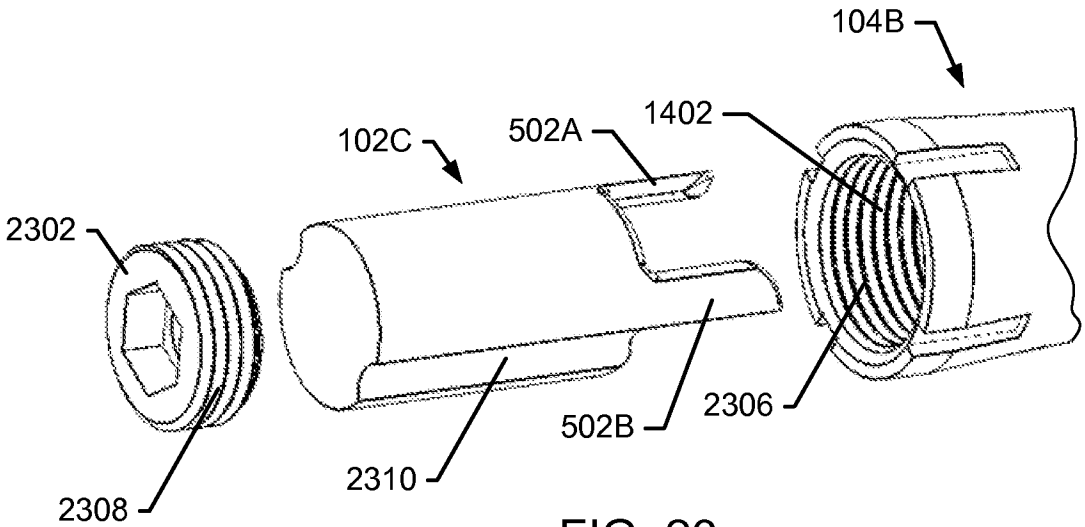
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FIG. 23

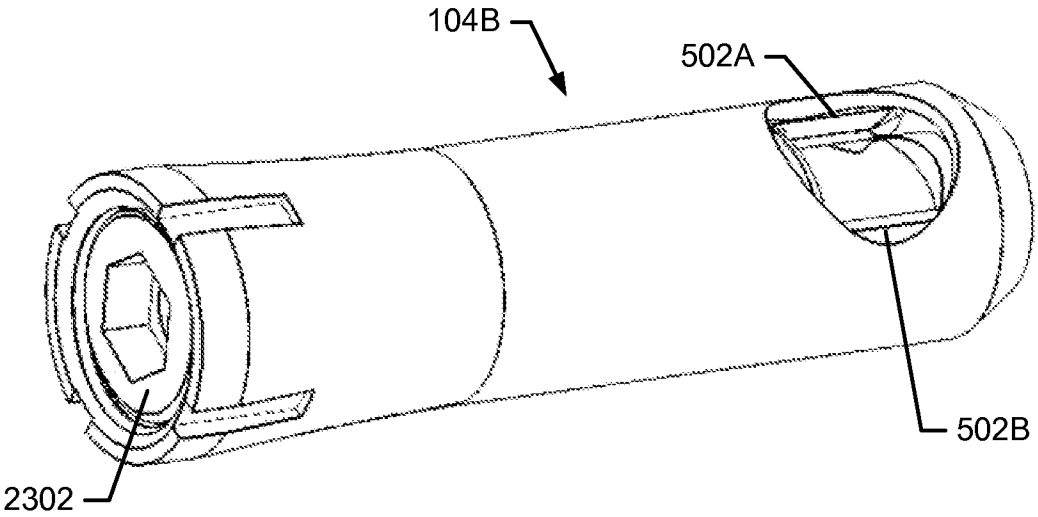

FIG. 24

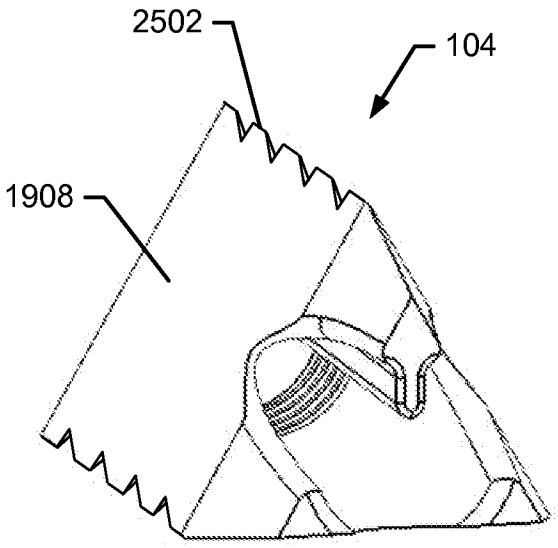

FIG. 25

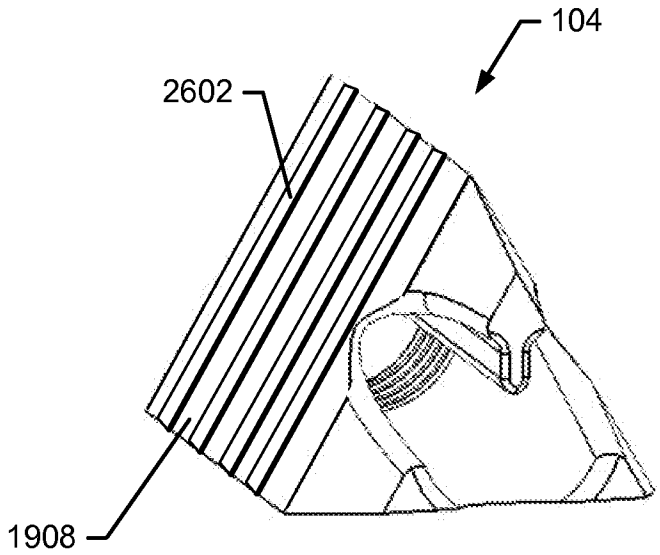

FIG. 26

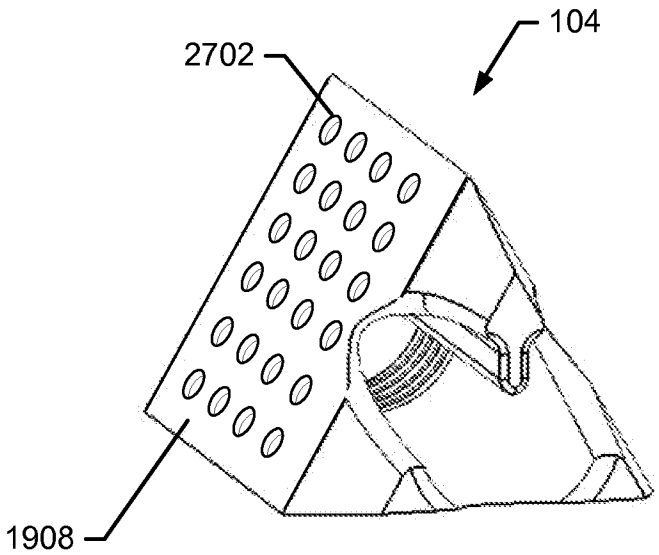

FIG. 27

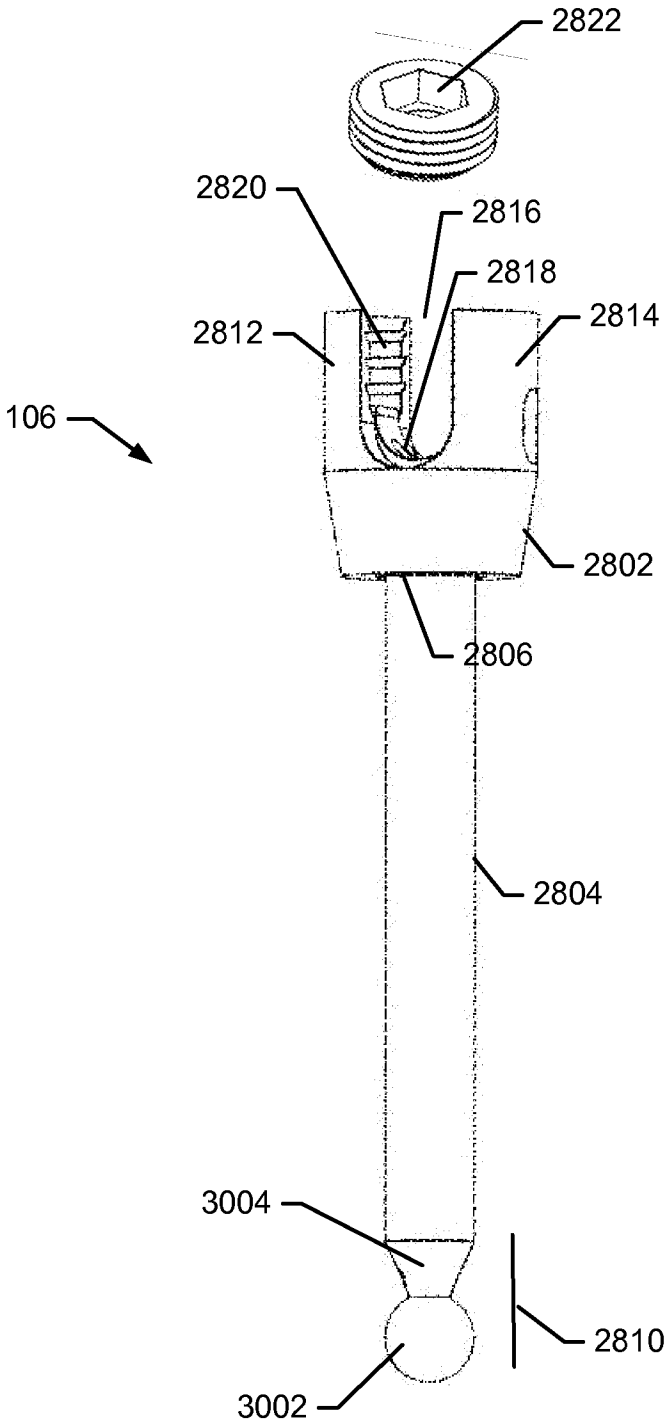
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FIG. 28

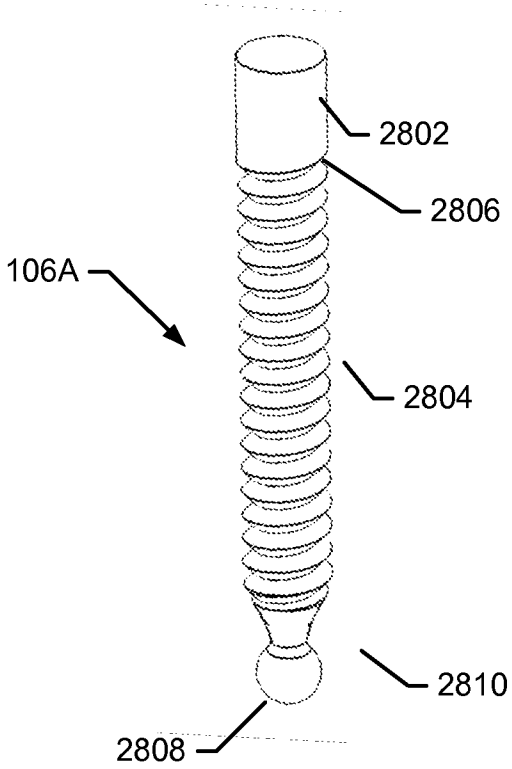
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FIG. 29

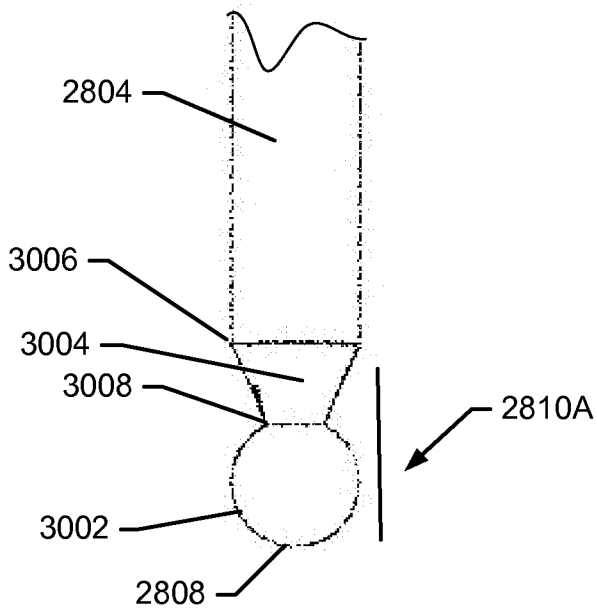
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FIG. 30

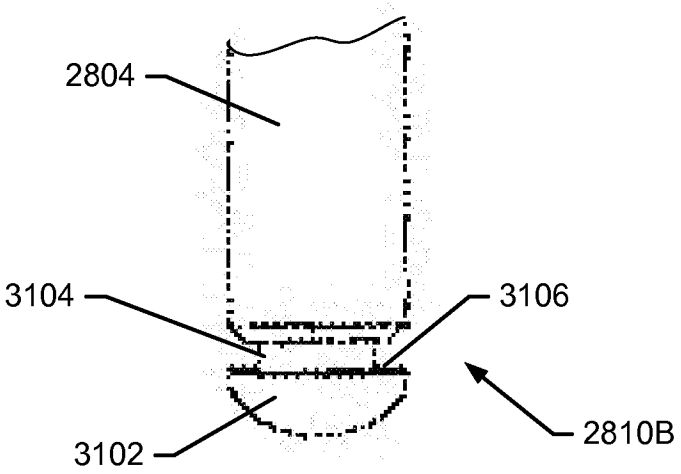

FIG. 31

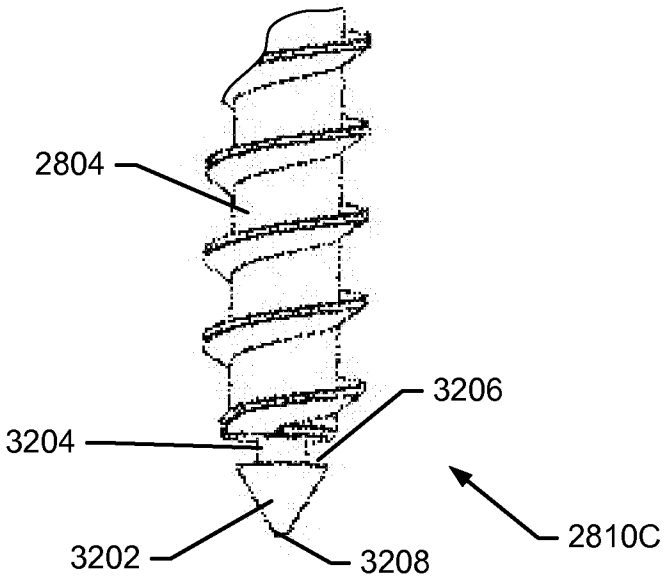

FIG. 32

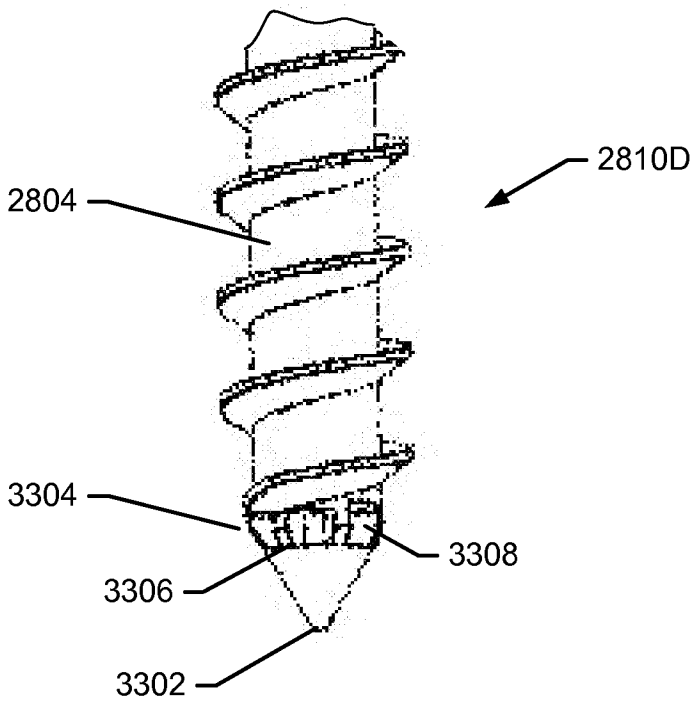
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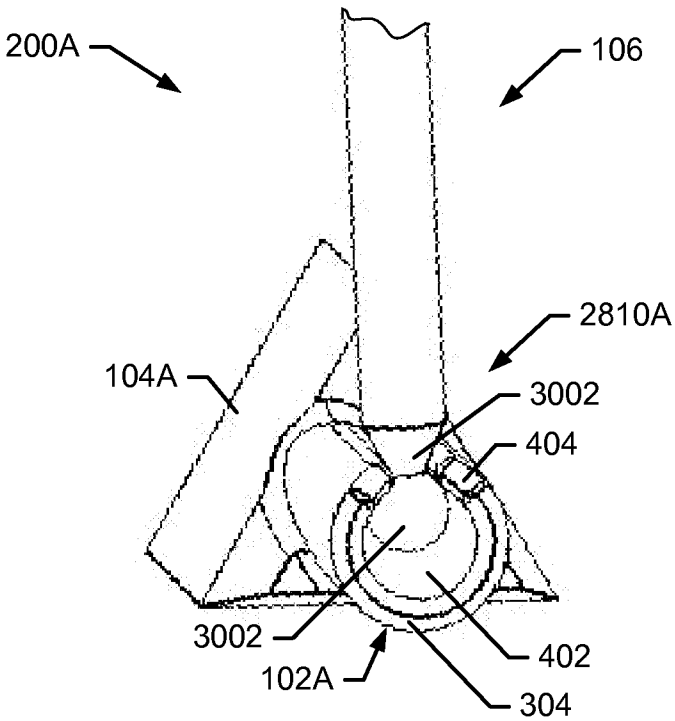
FIG. 33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104A
3002
404
3002
402
102A
304

FIG. 34

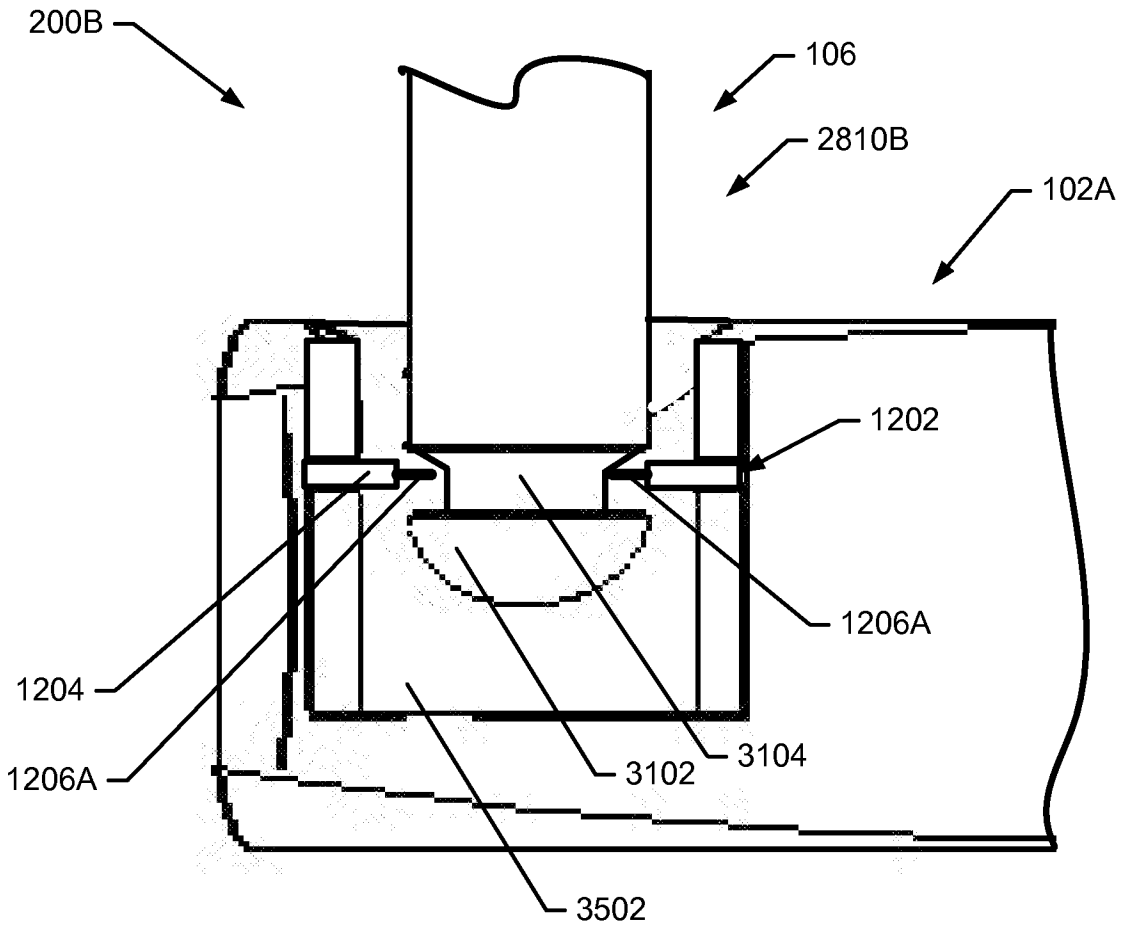


FIG. 35

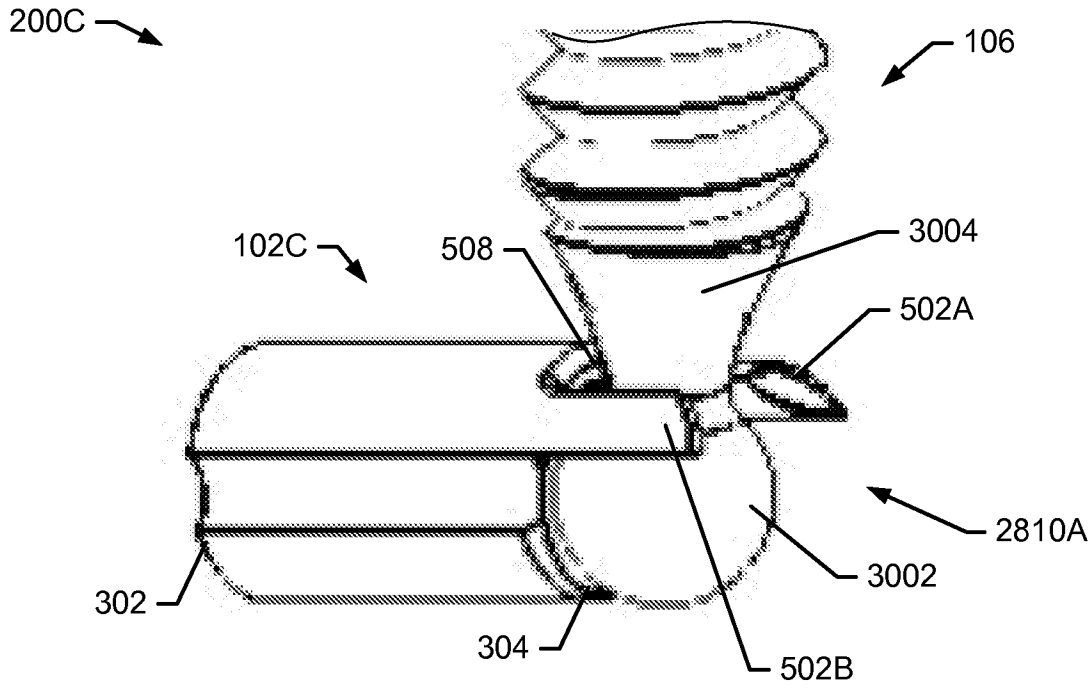

200C
106
102C
508
3004
502A
2810A
3002
302
304
502B

FIG. 36

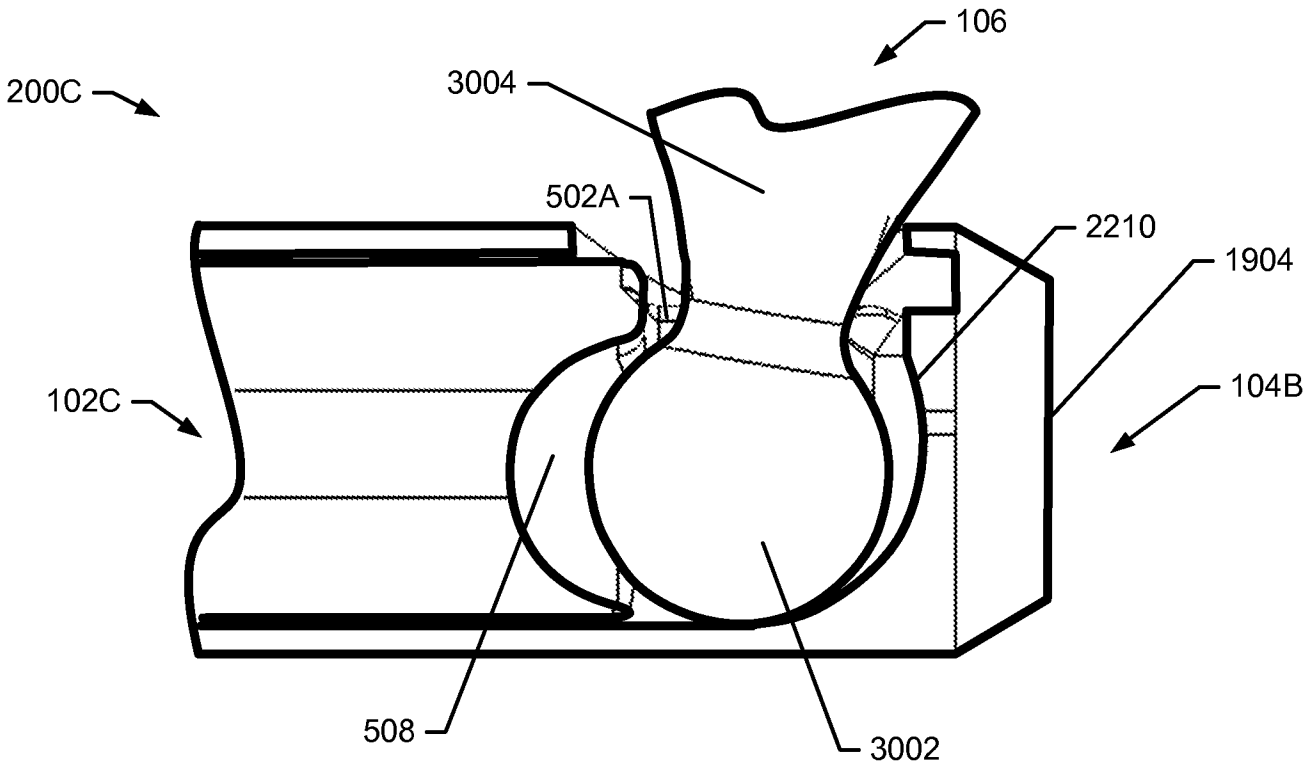

106
200C
3004
502A
2210
1904
104B
102C
508
3002

FIG. 37

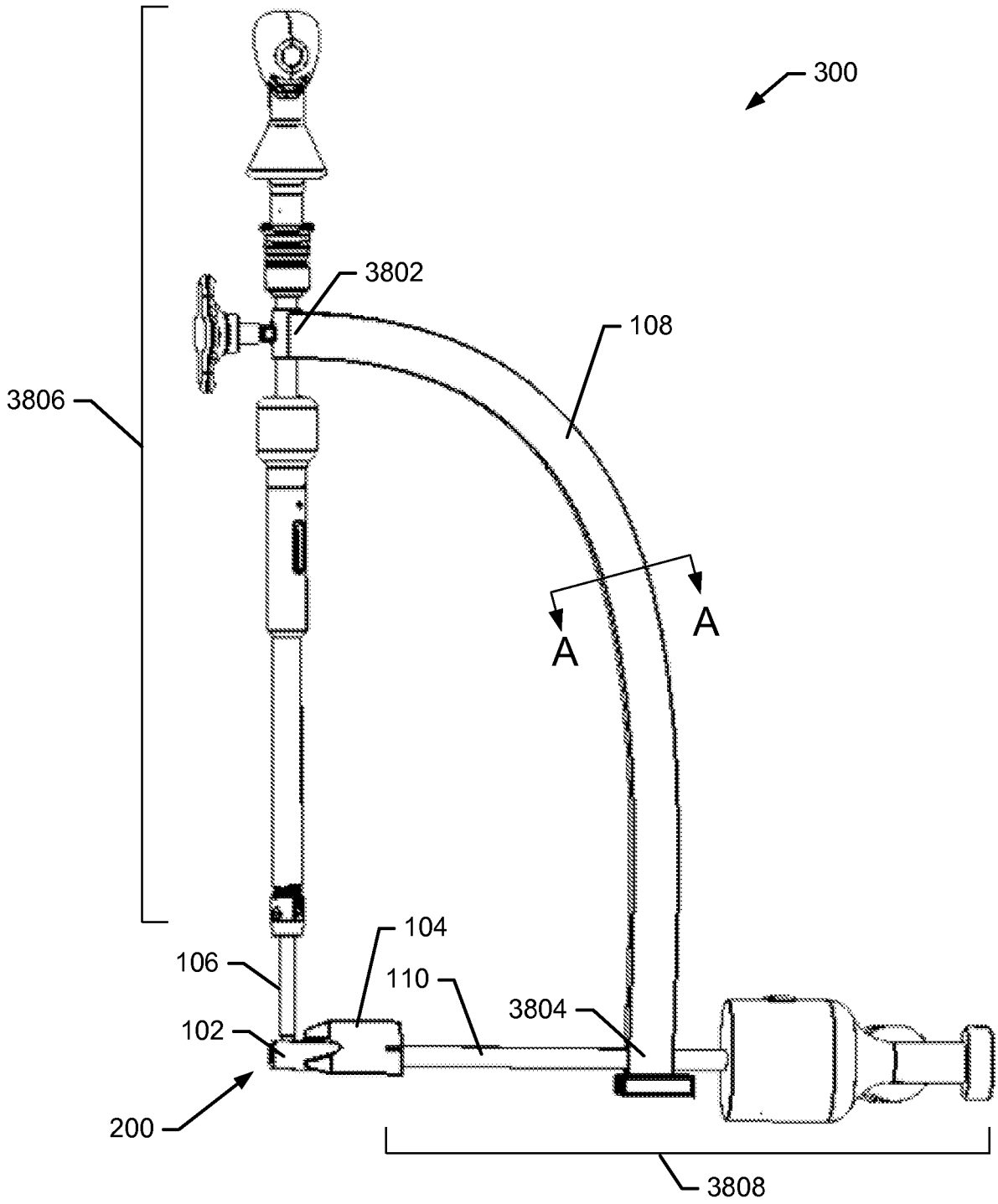


FIG. 38

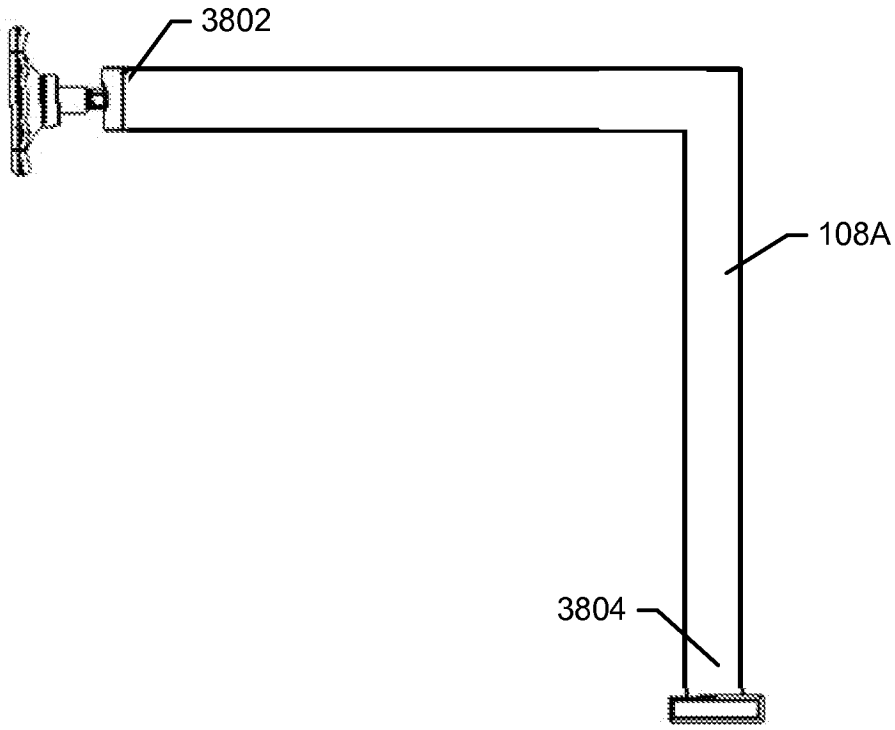


FIG. 39

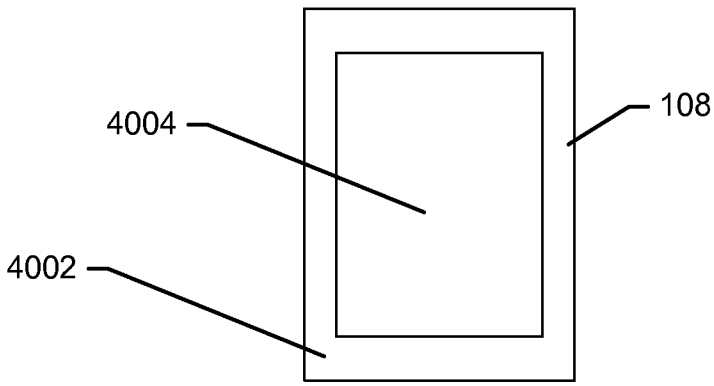


FIG. 40

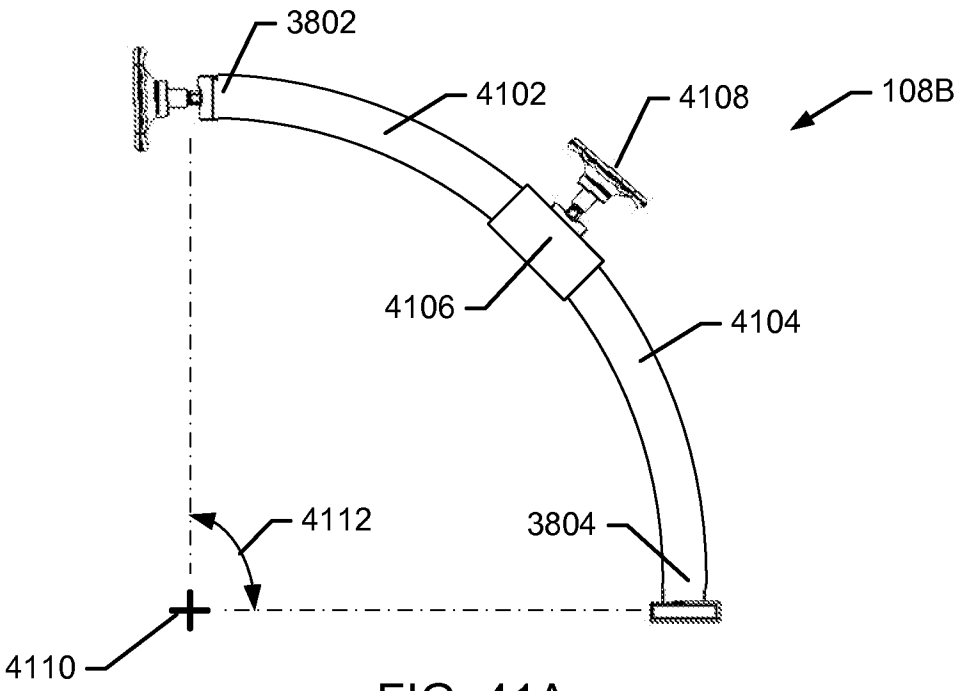


FIG. 41A

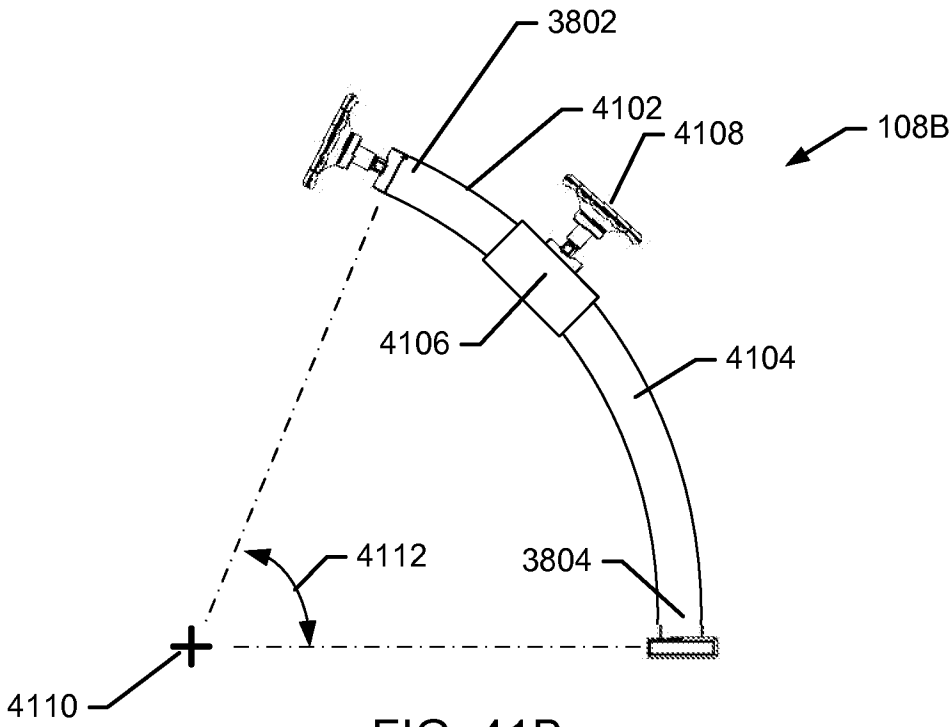


FIG. 41B

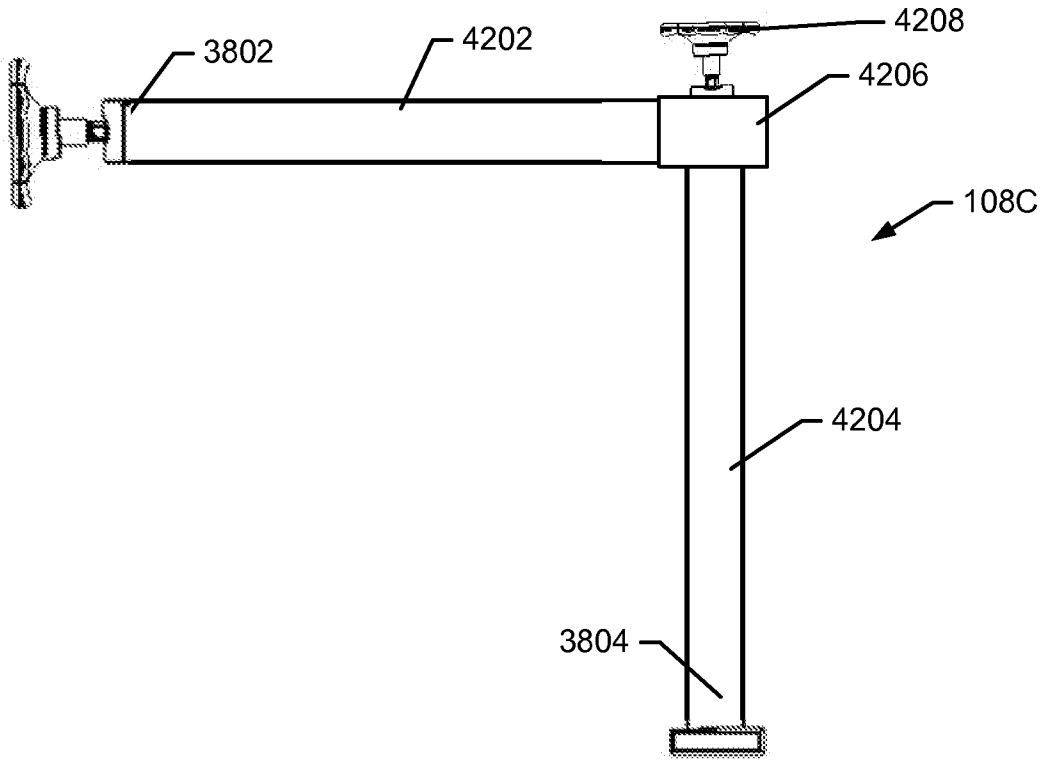


FIG. 42A

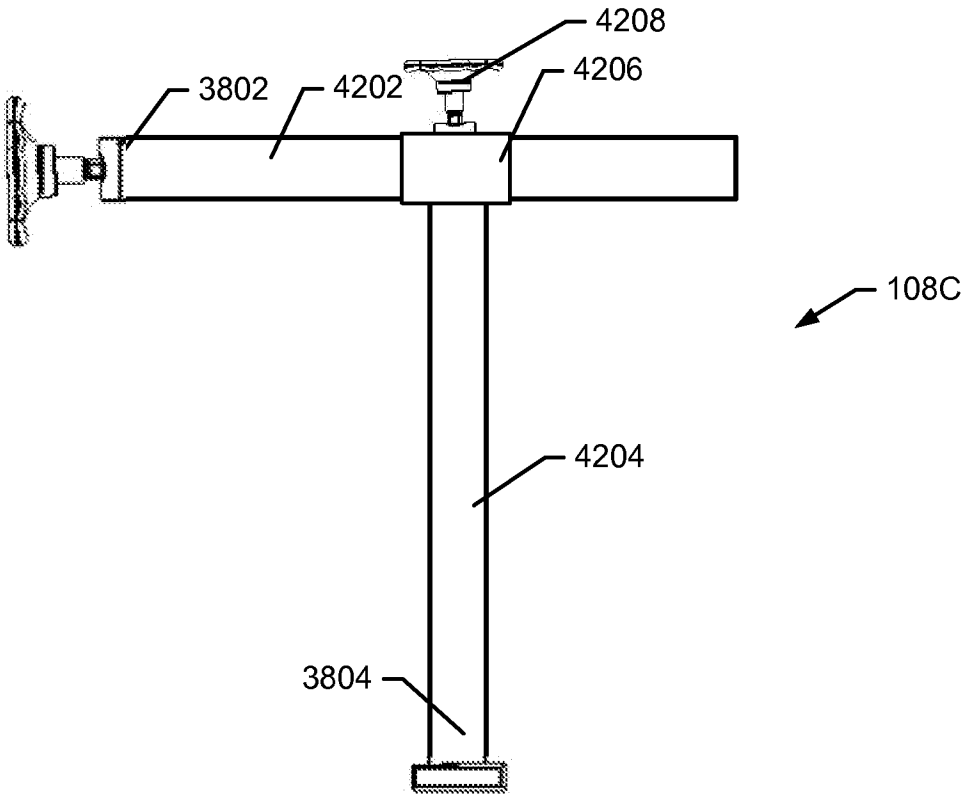


FIG. 42B

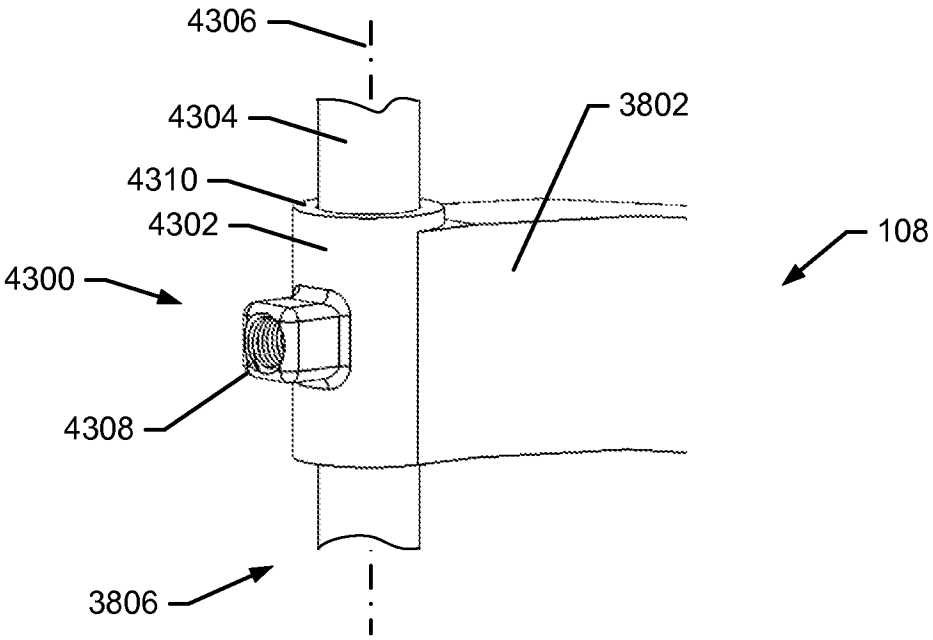


FIG. 43A

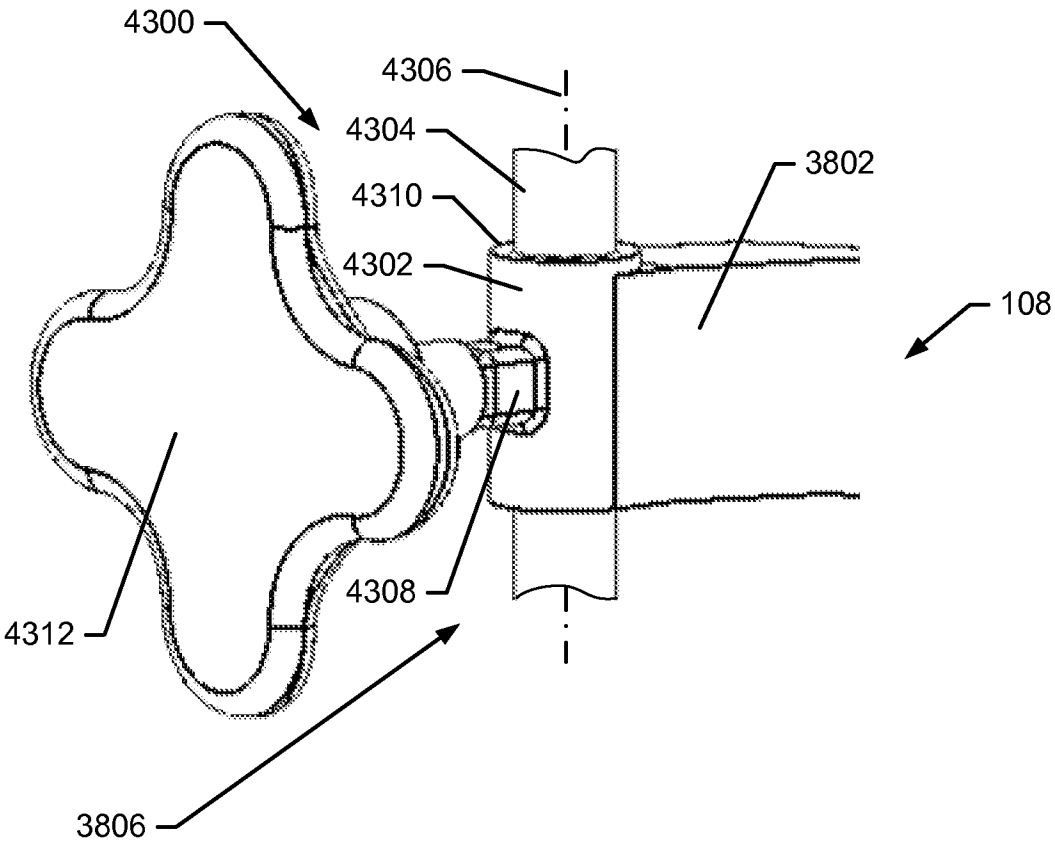


FIG. 43B

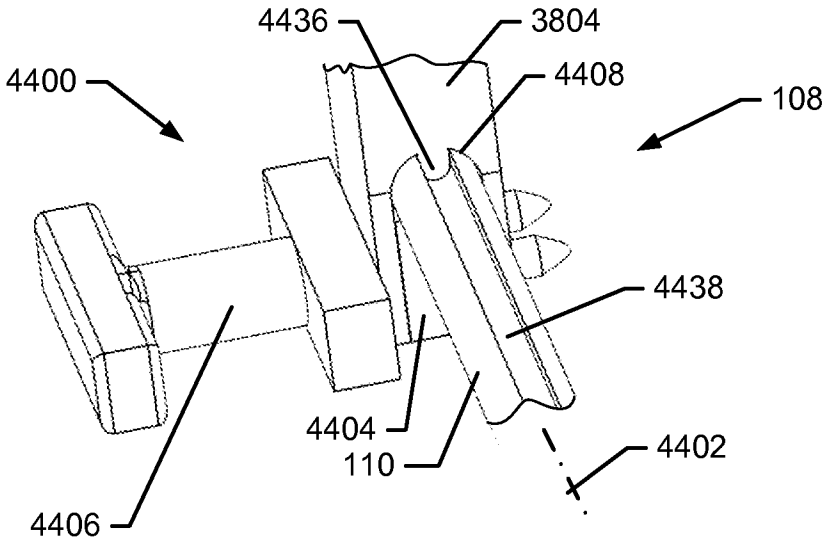


FIG. 44A

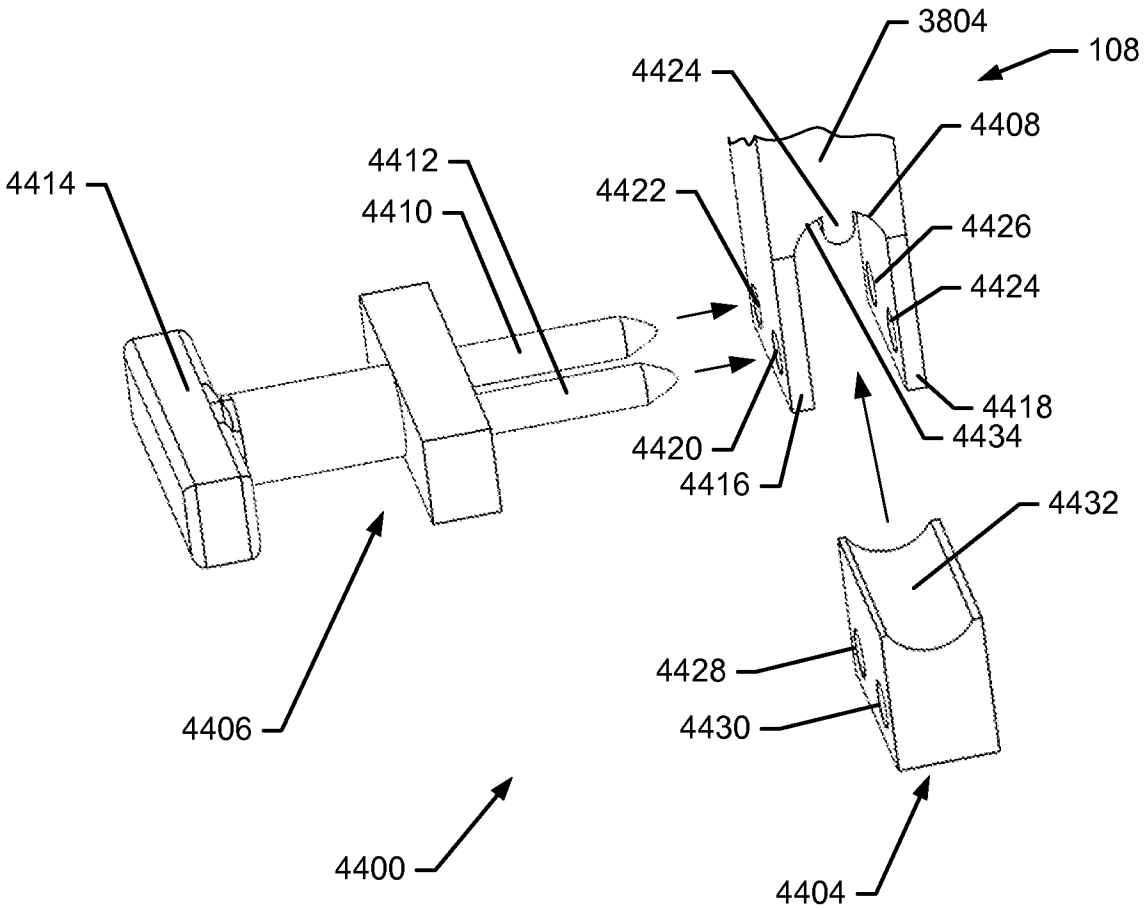


FIG. 44B

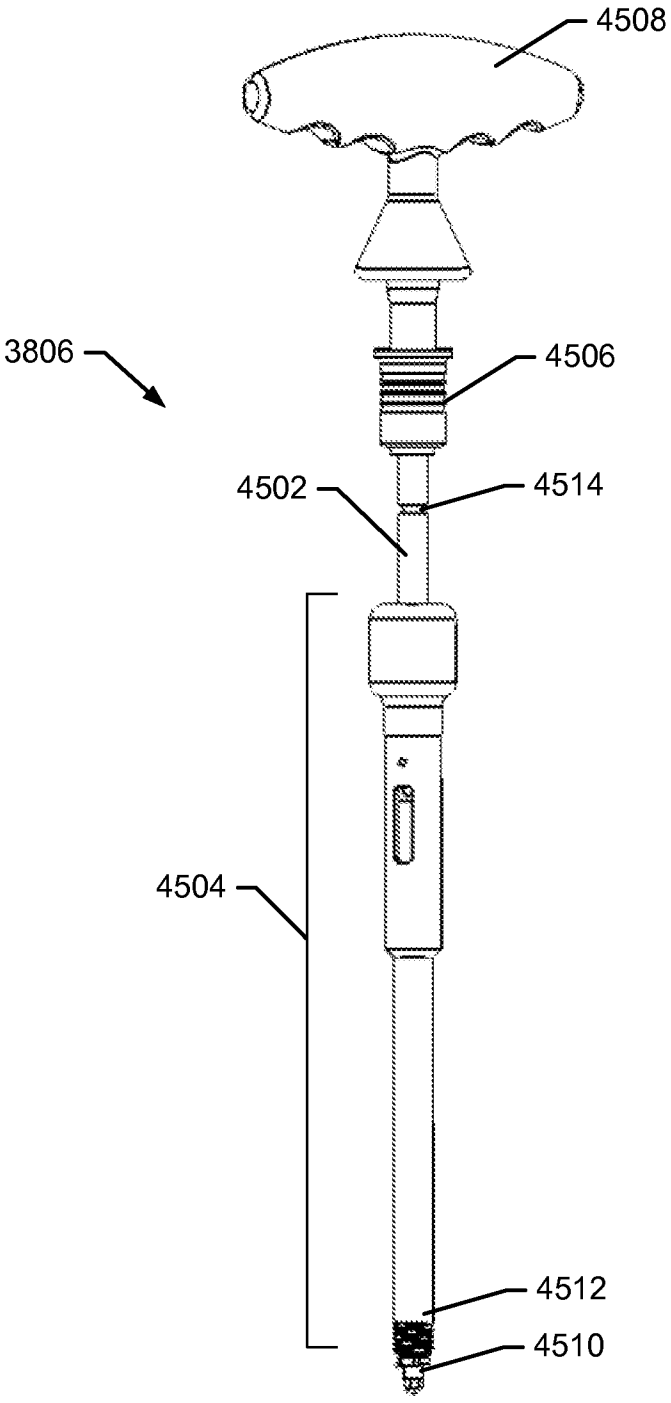


FIG. 45

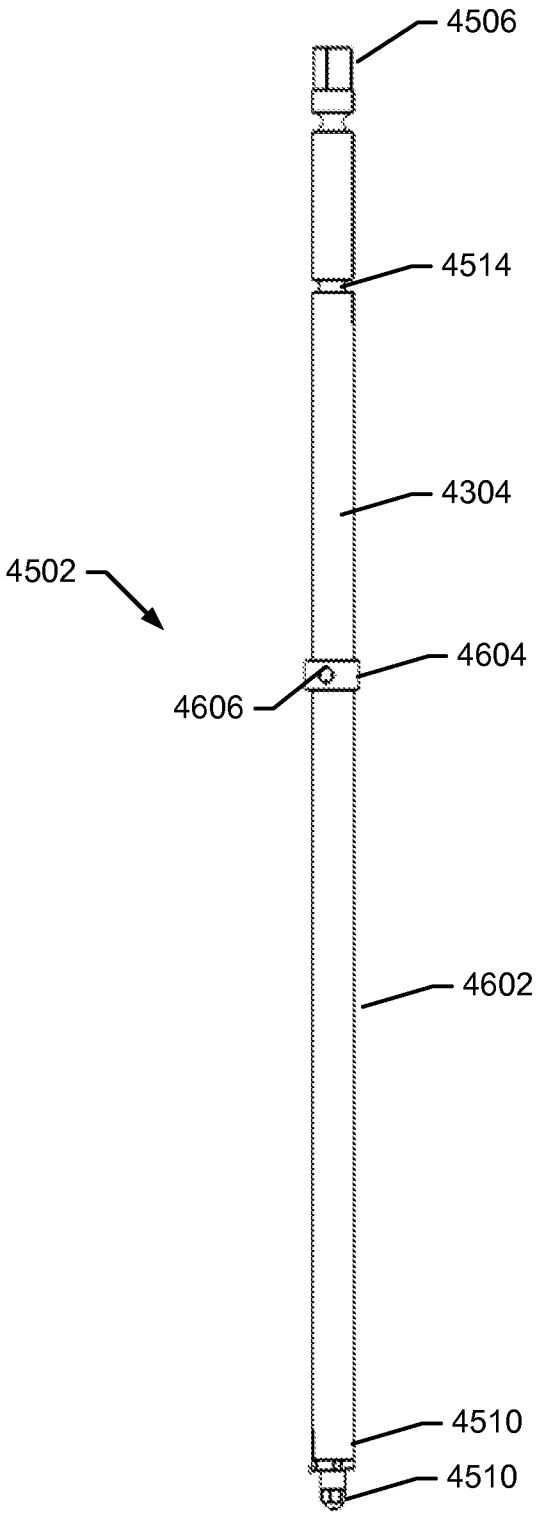


FIG. 46

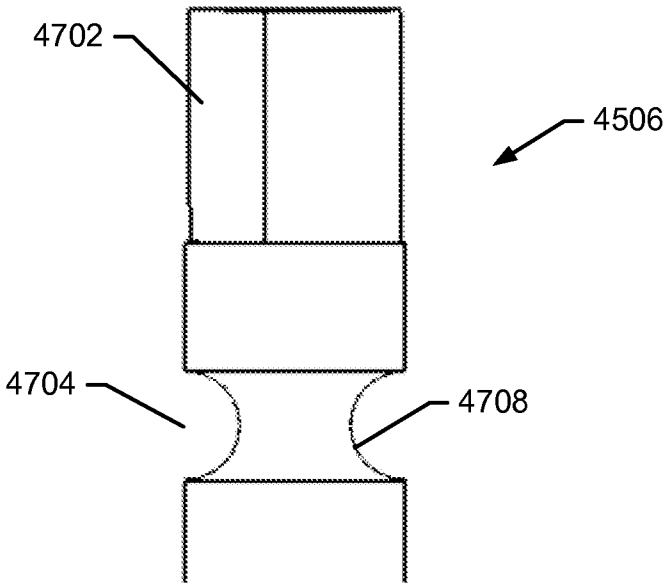


FIG. 47

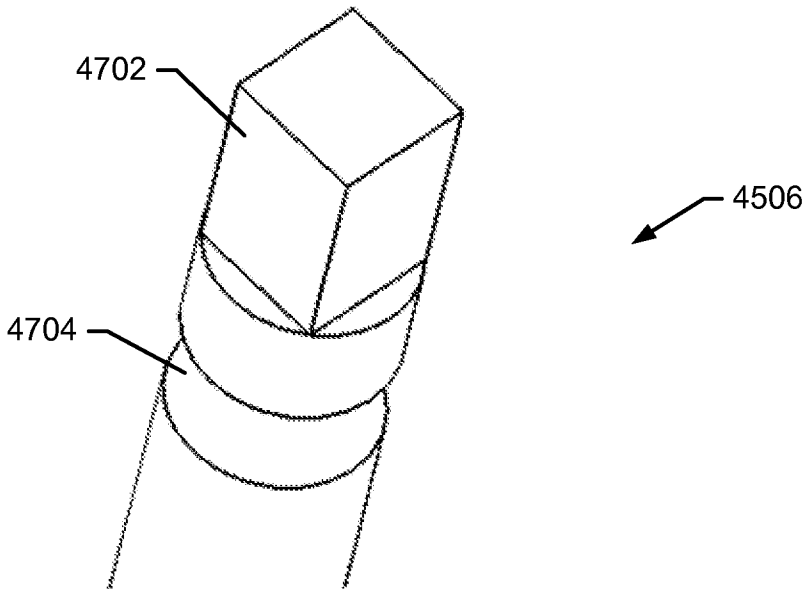


FIG. 48

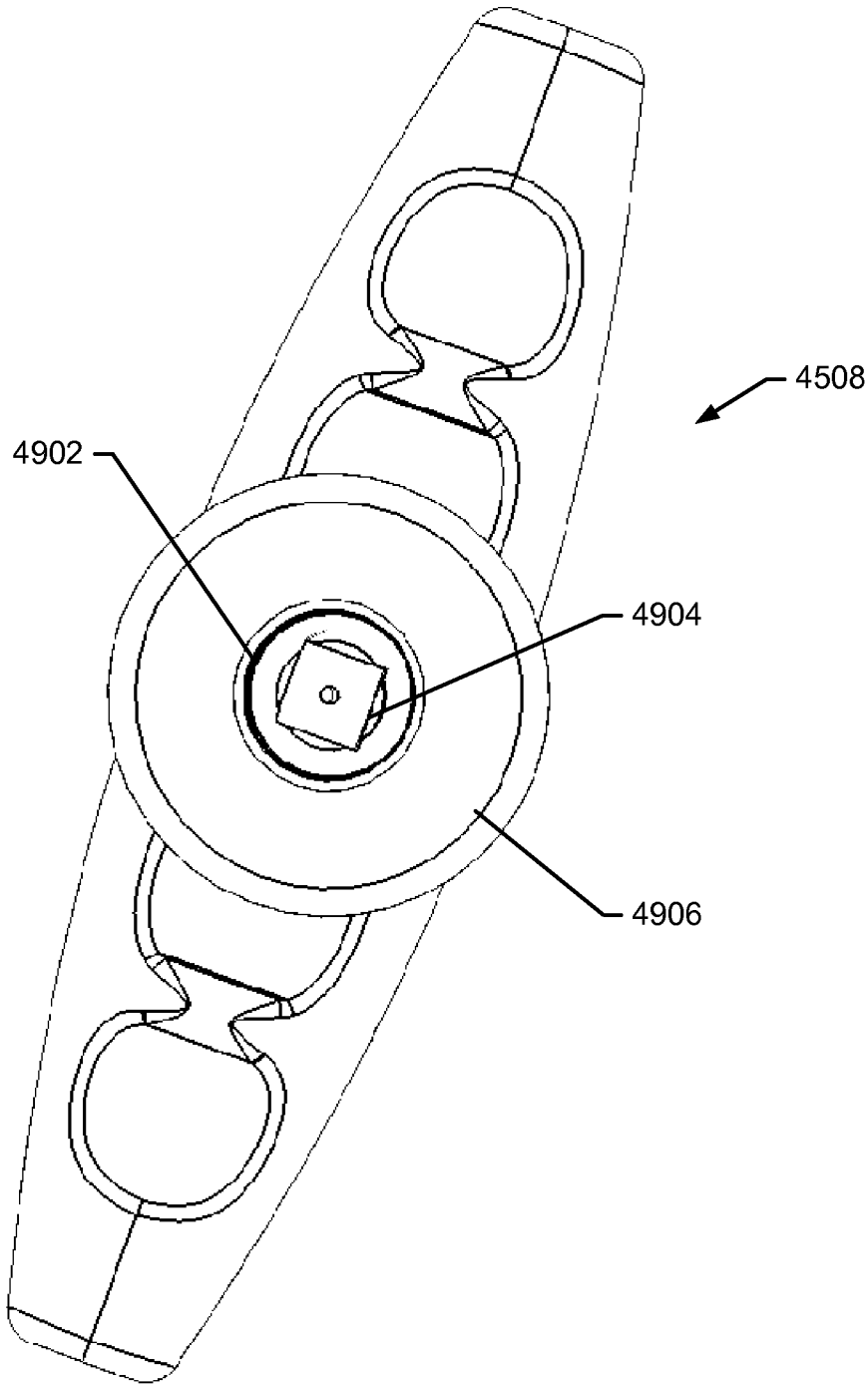


FIG. 49

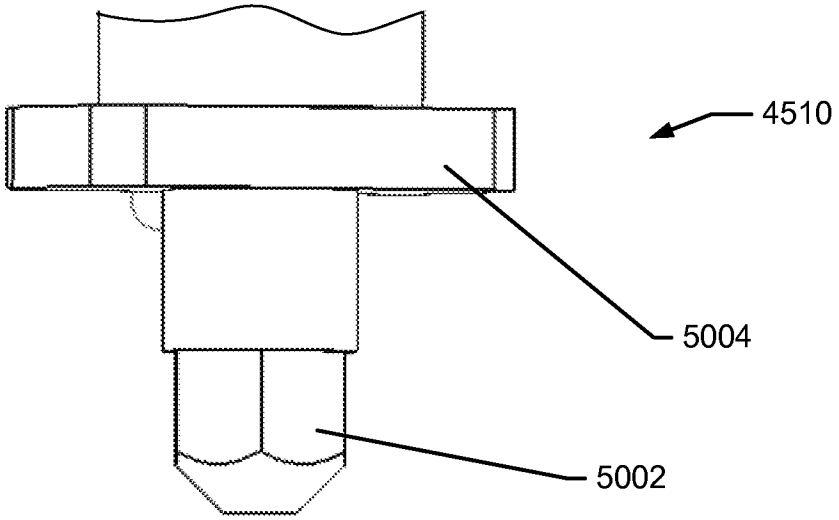


FIG. 50

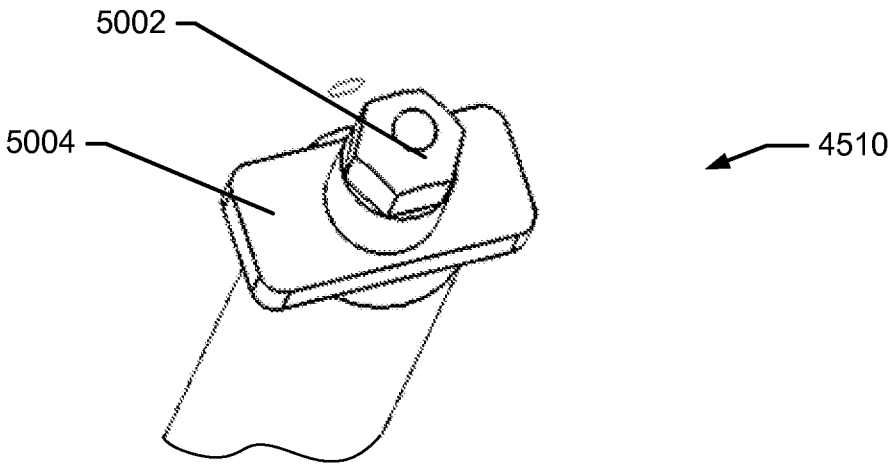


FIG. 51

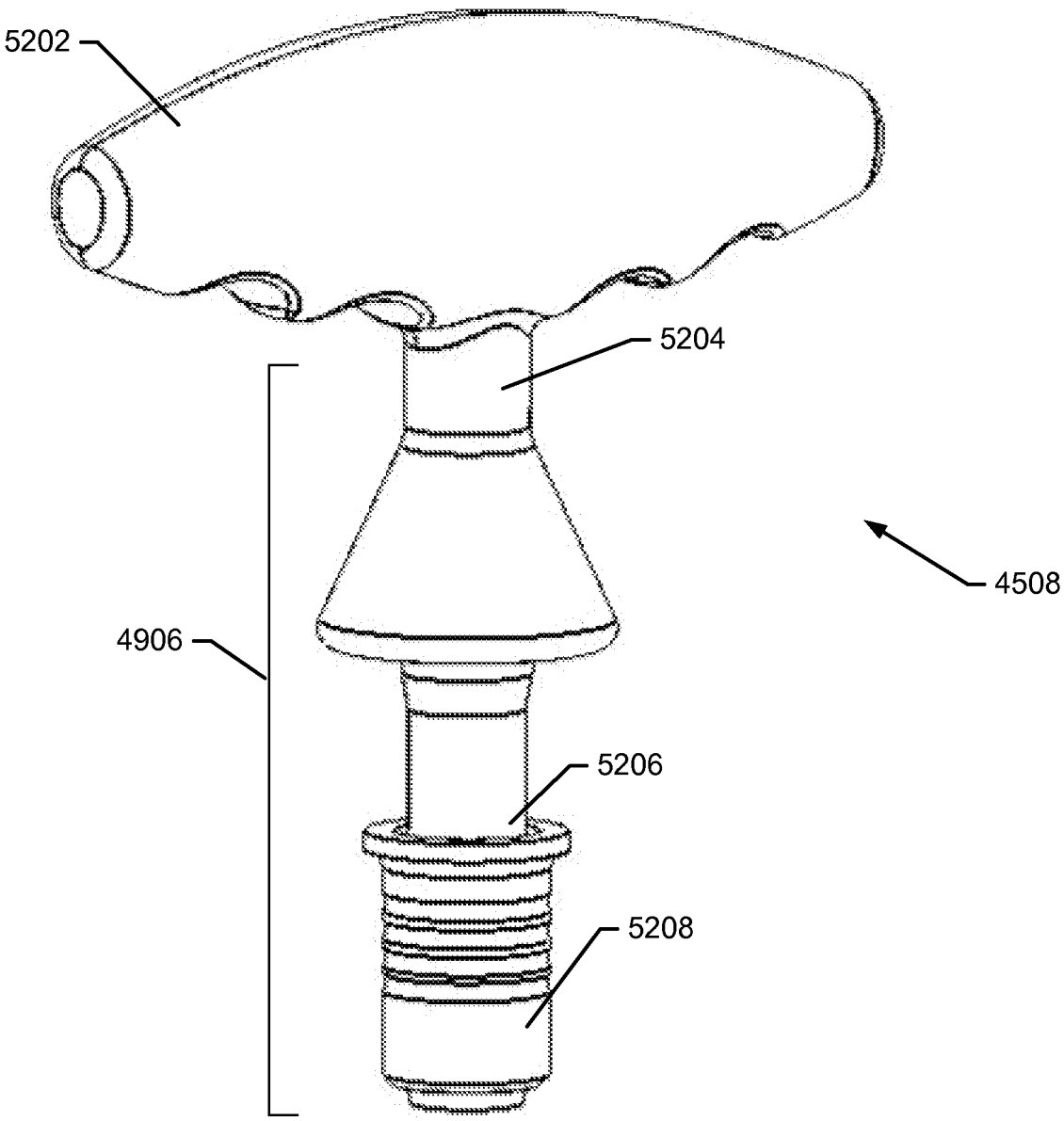


FIG. 52

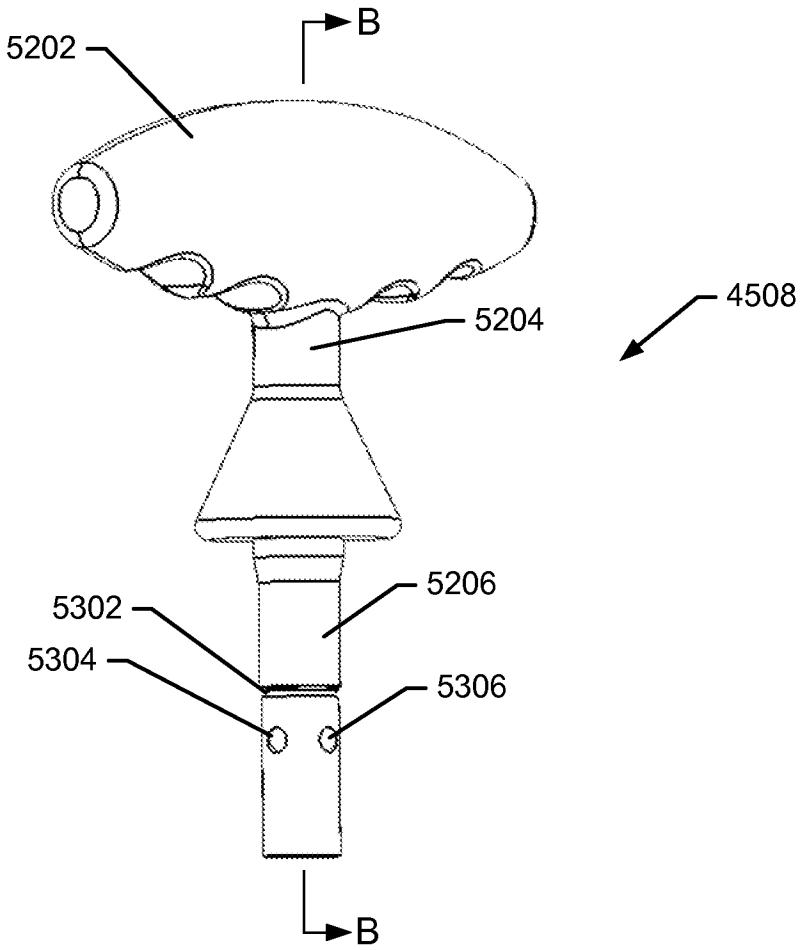
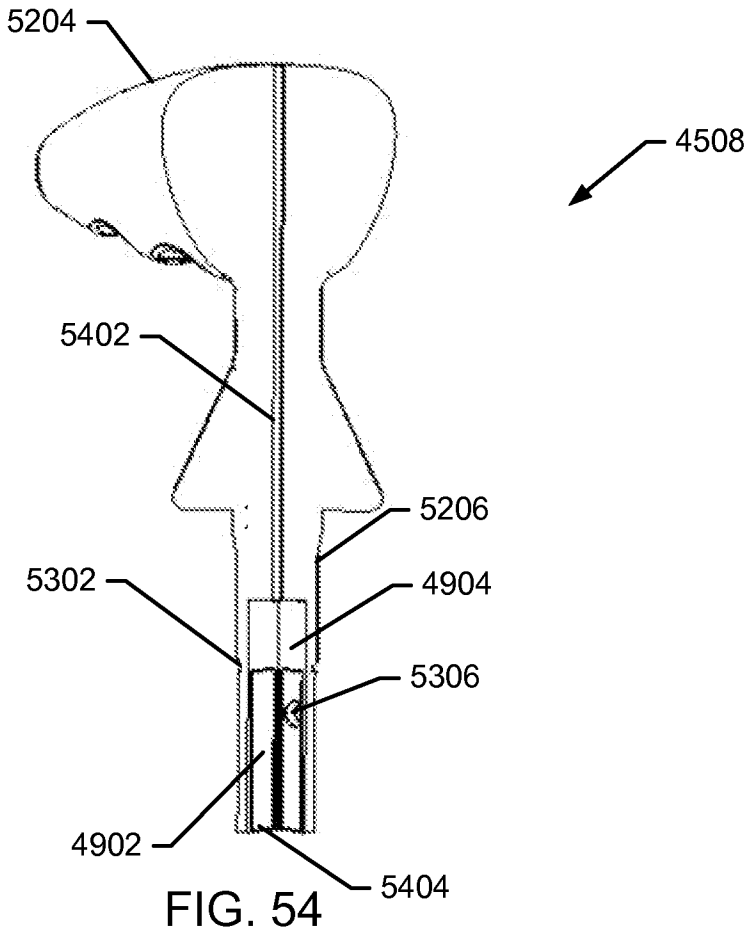


FIG. 53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4508
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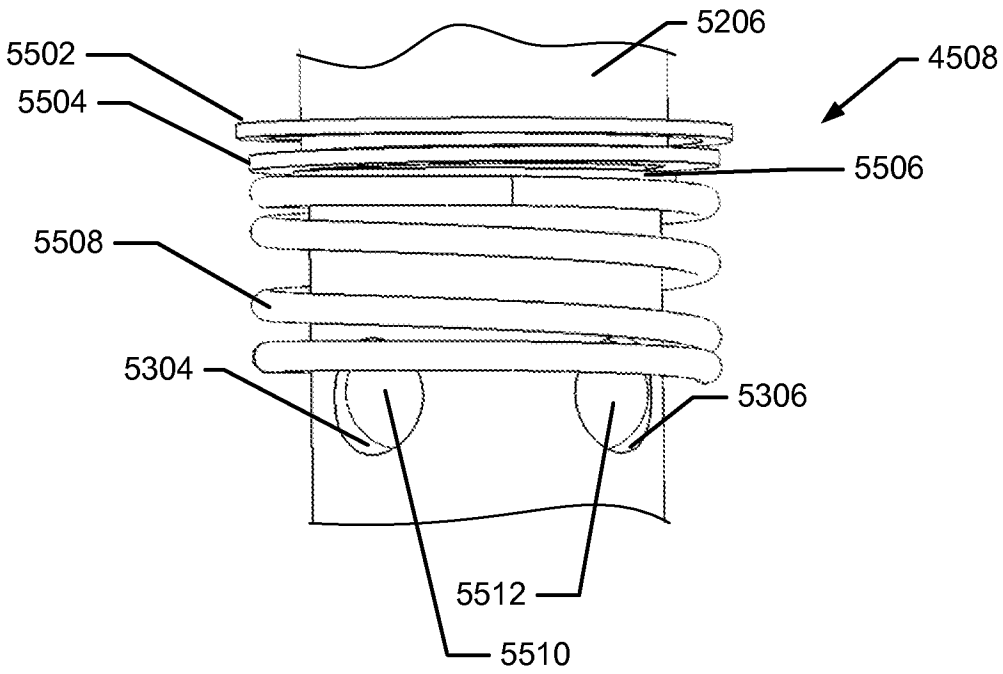
5206
5302
4904
5306
4902
5404

FIG. 54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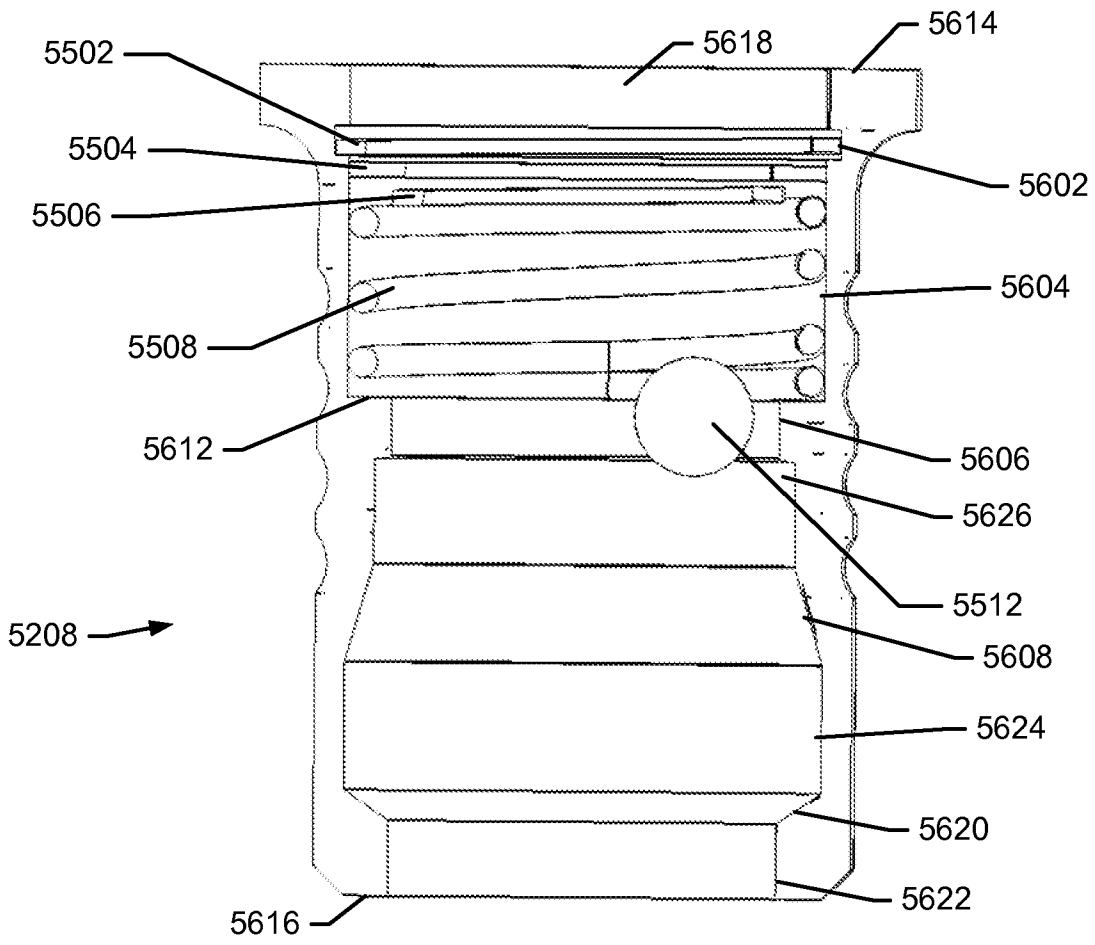
4508
5504
5506
5508
5304
5306
5512
5510

FIG. 55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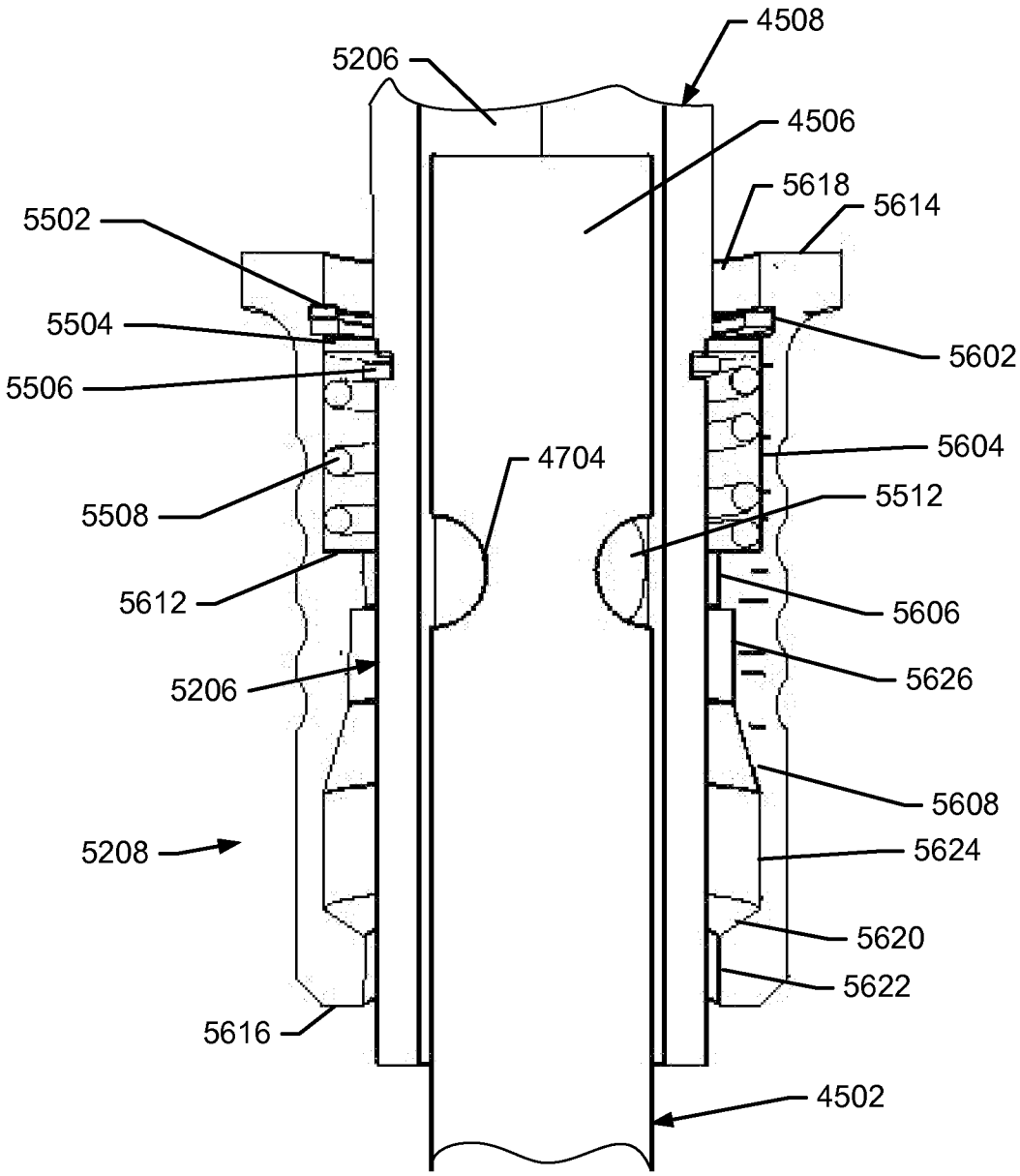
5622
5616

FIG. 56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5608
5208
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5620
5622
5616
4502

FIG. 57

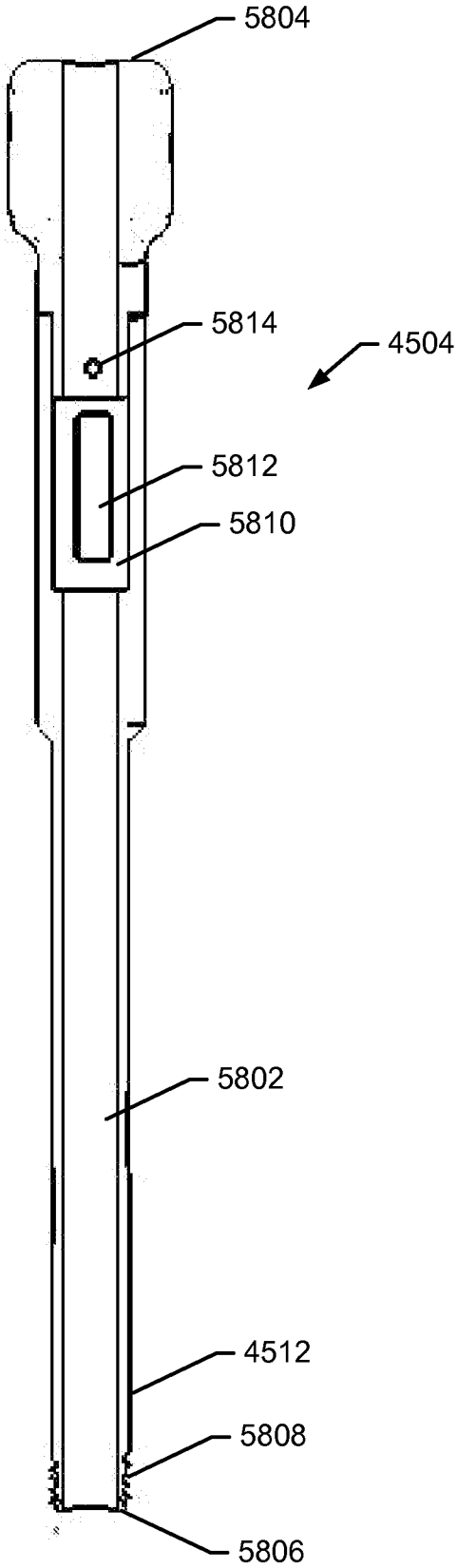
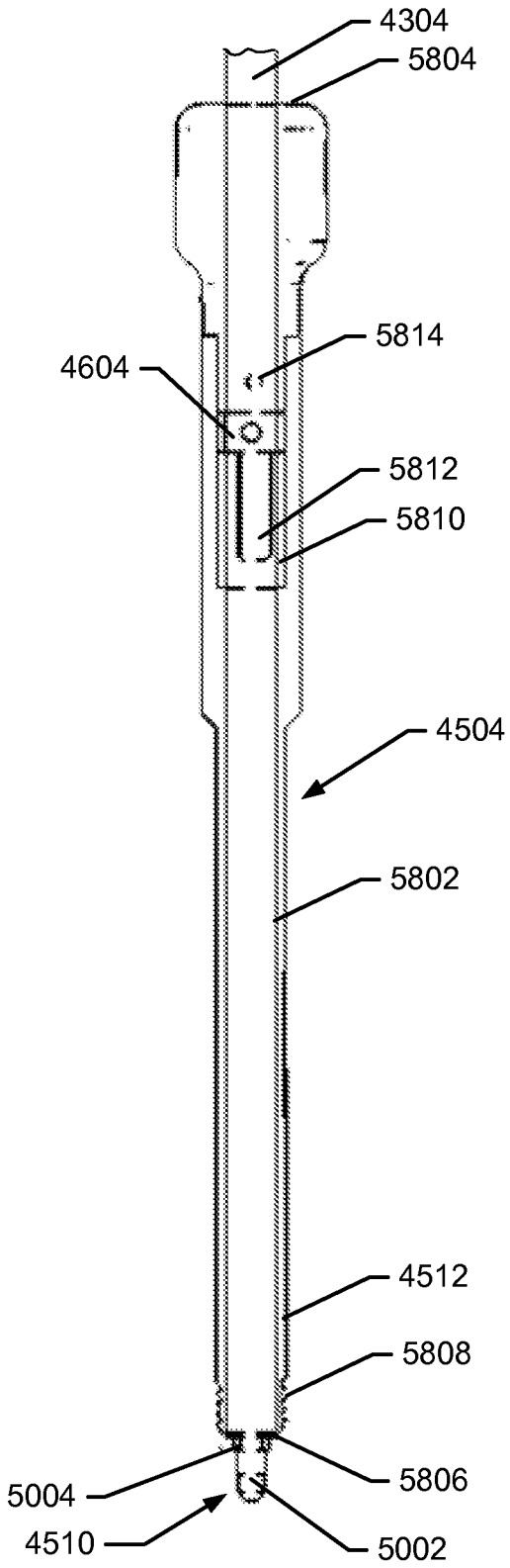


FIG. 58


4304
5804
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5812
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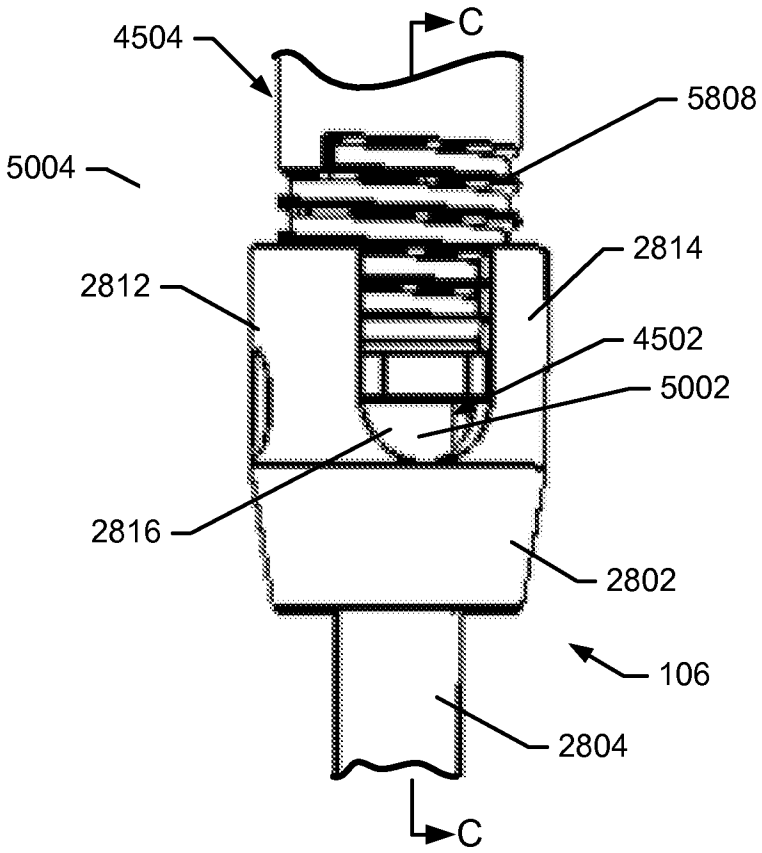
4504
5802
4512
5808
5806
5004
4510
5002

FIG. 59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C
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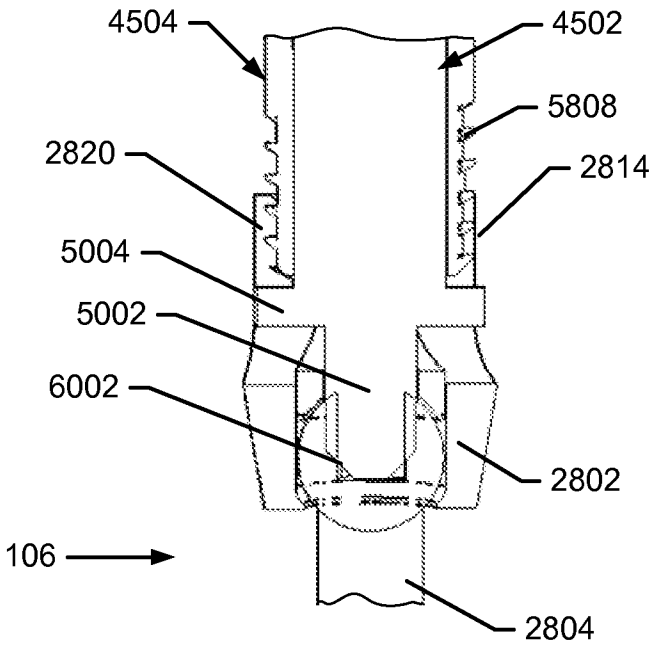
5004
2814
2812
4502
5002
2816
2802
106
2804
C

FIG. 60


4504
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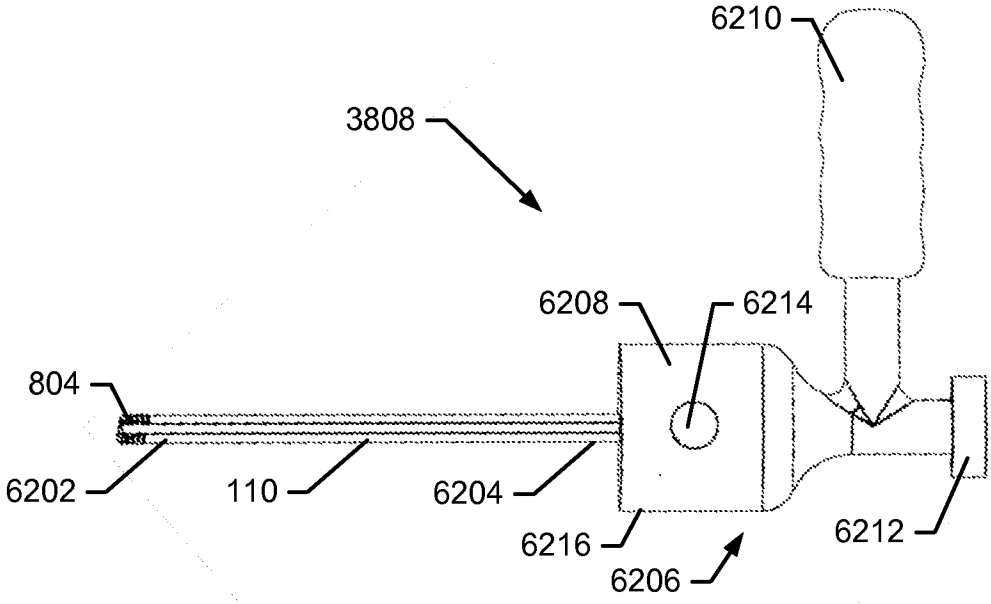
5002
6002
2802
106
2804

FIG. 61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6214
804
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110
6204
6216
6206
6212

FIG. 62

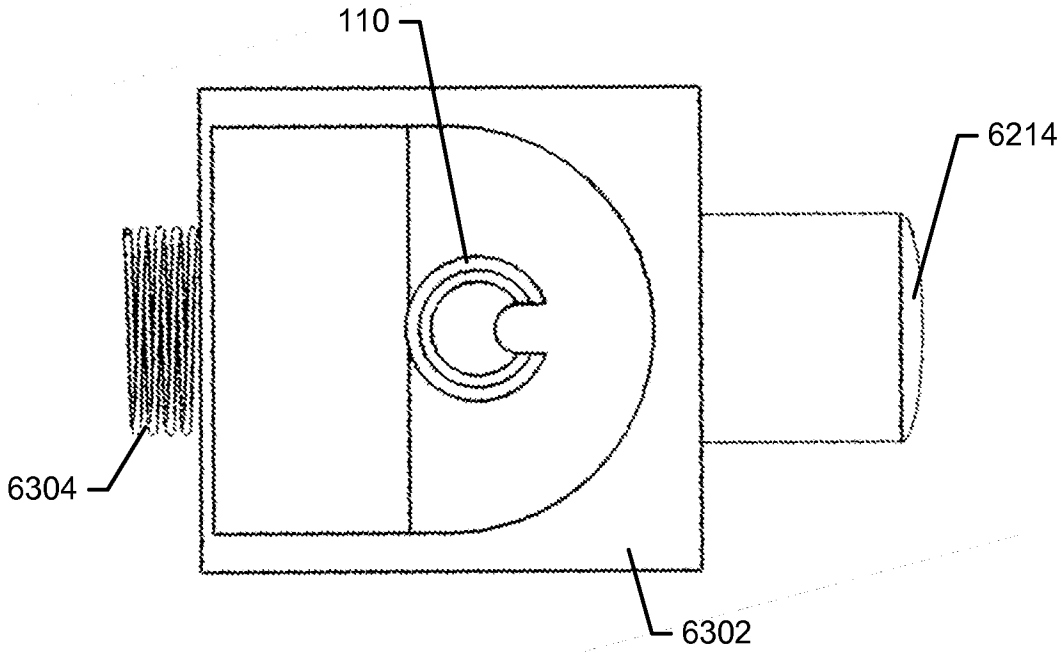

110
6214
6304
6302

FIG. 63

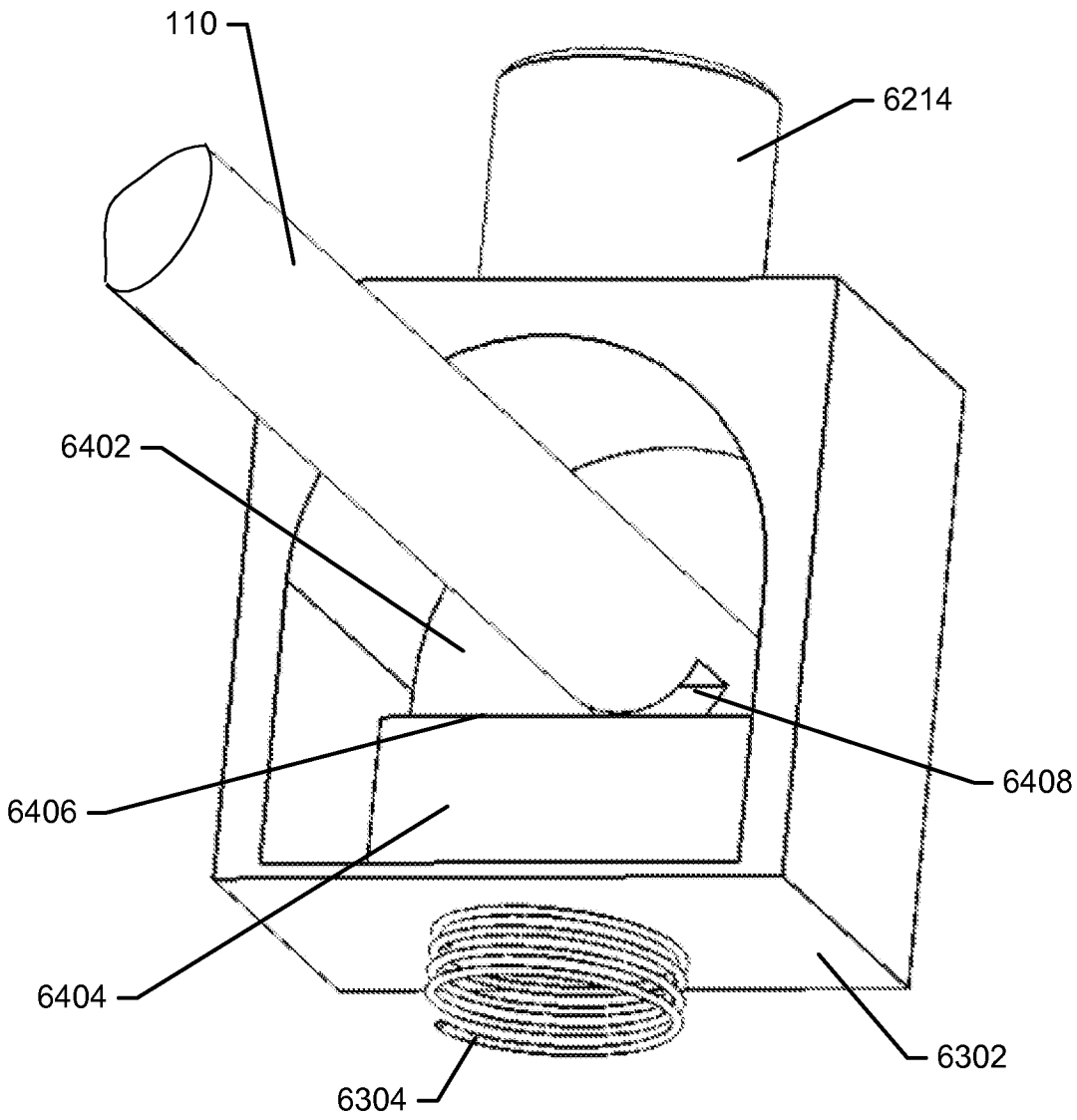
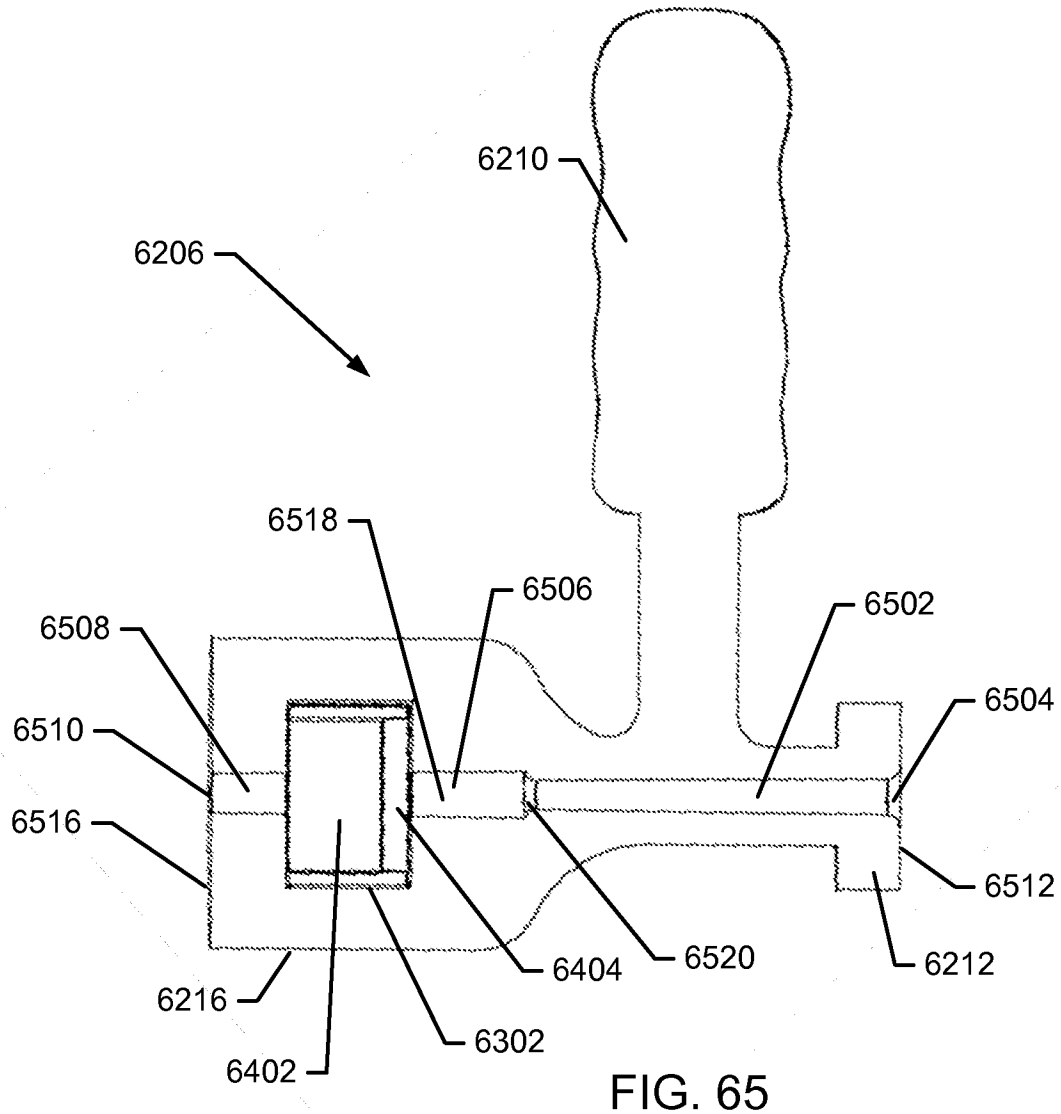


FIG. 64


6210
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6516
6512
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6212
6404
6216
6302
6402

FIG. 65

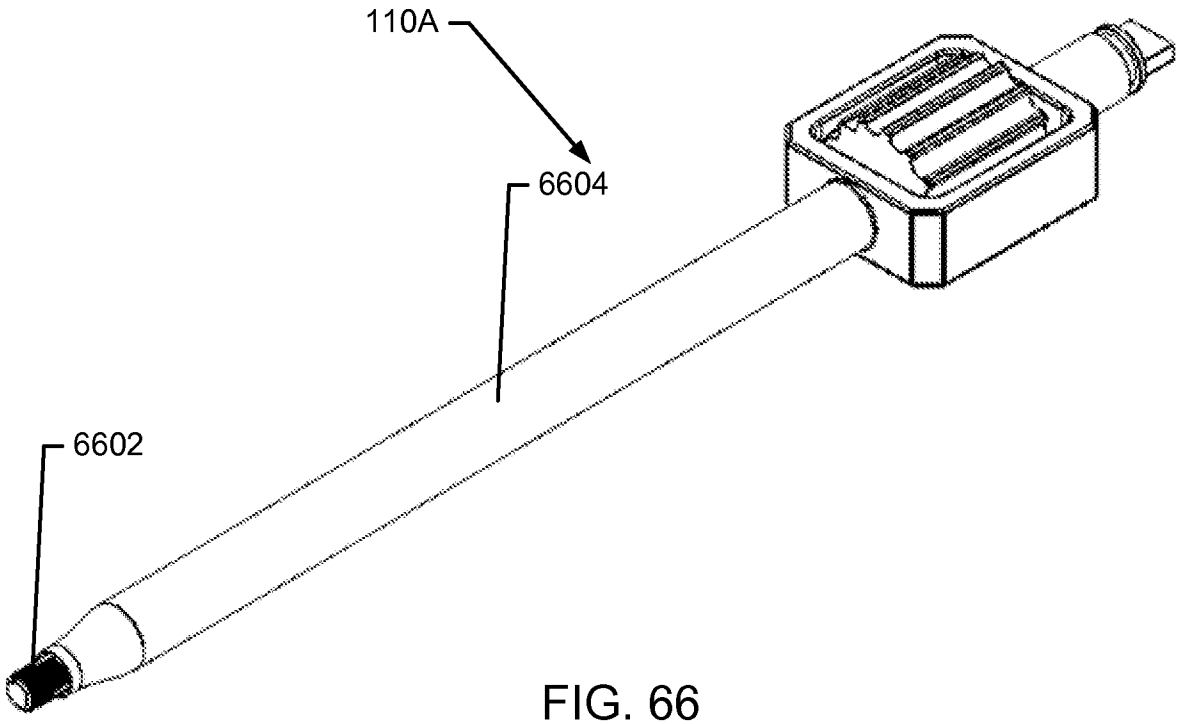


FIG. 66

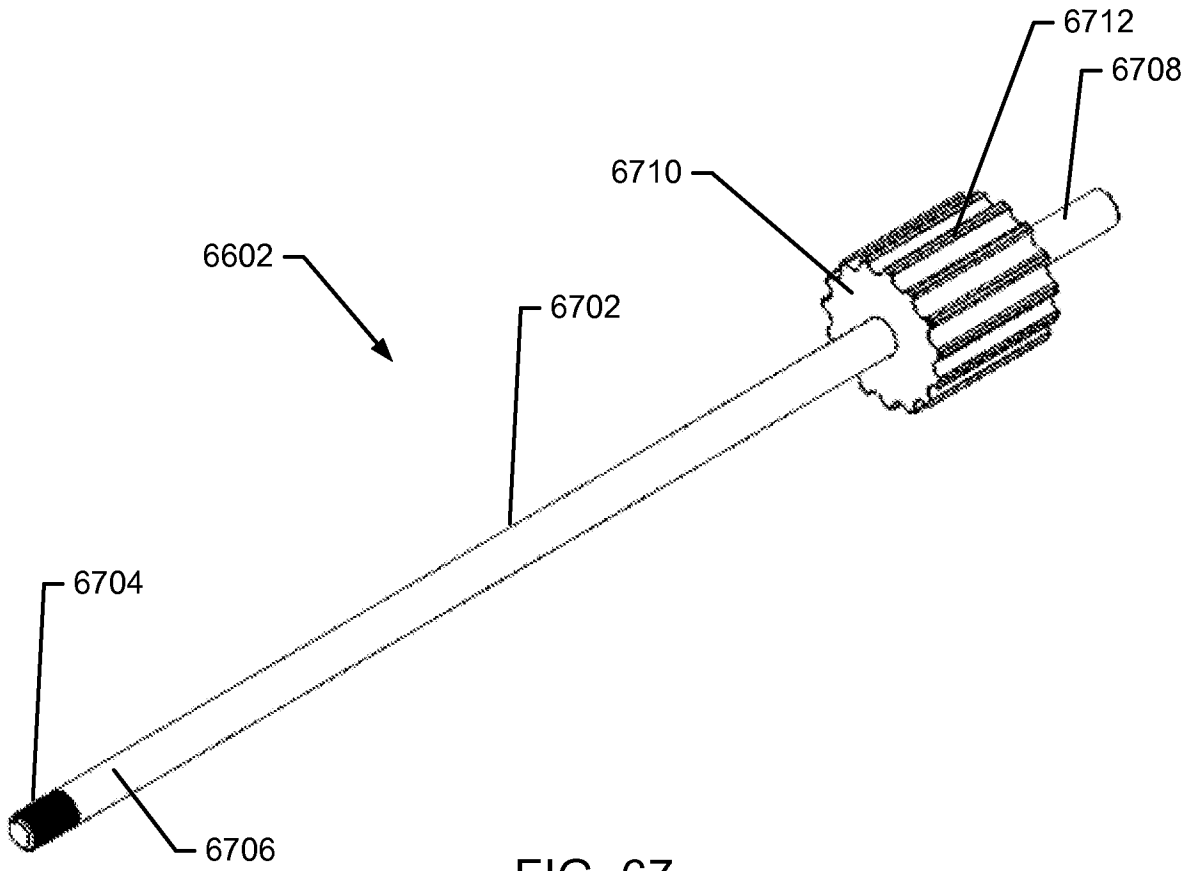
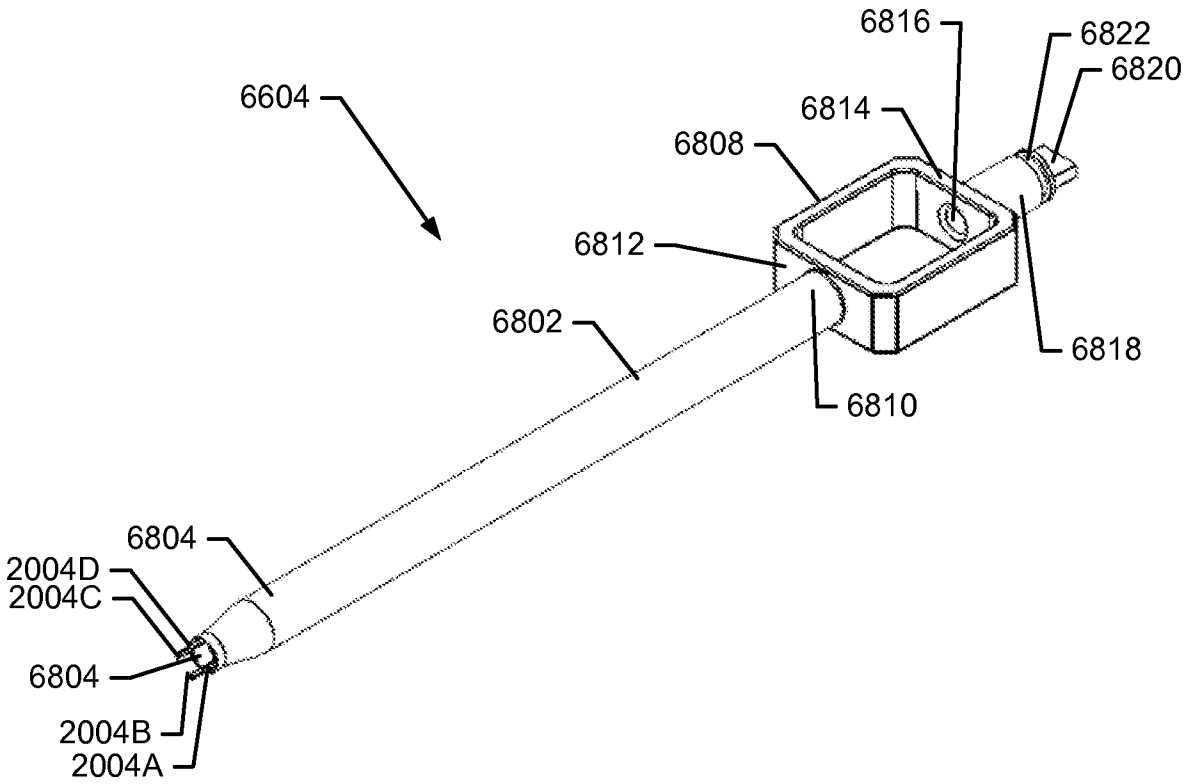


FIG. 67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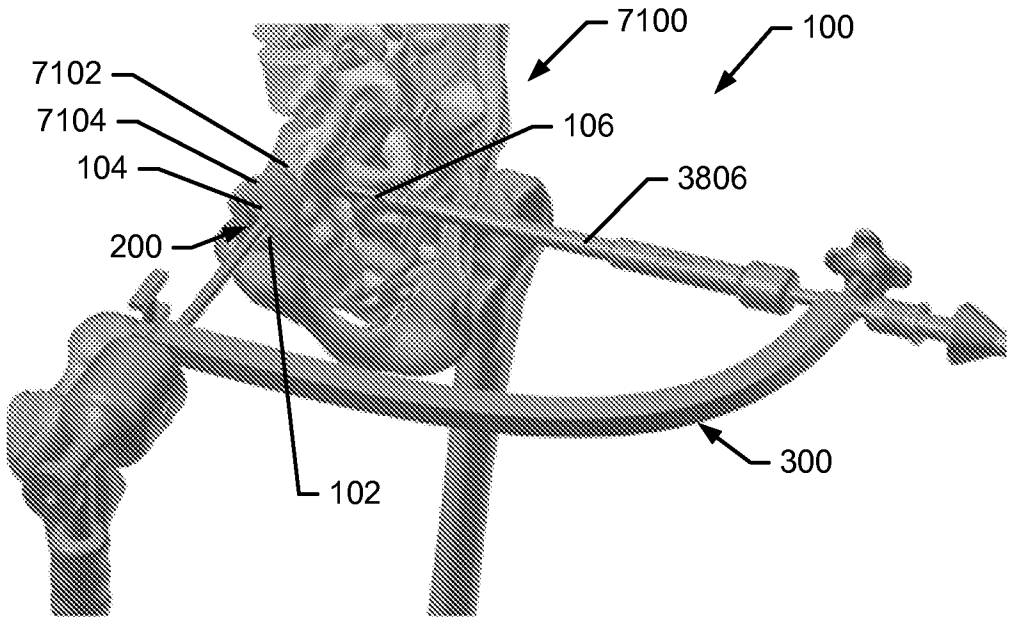
2004D
2004C
6804
2004B
2004A

FIG. 68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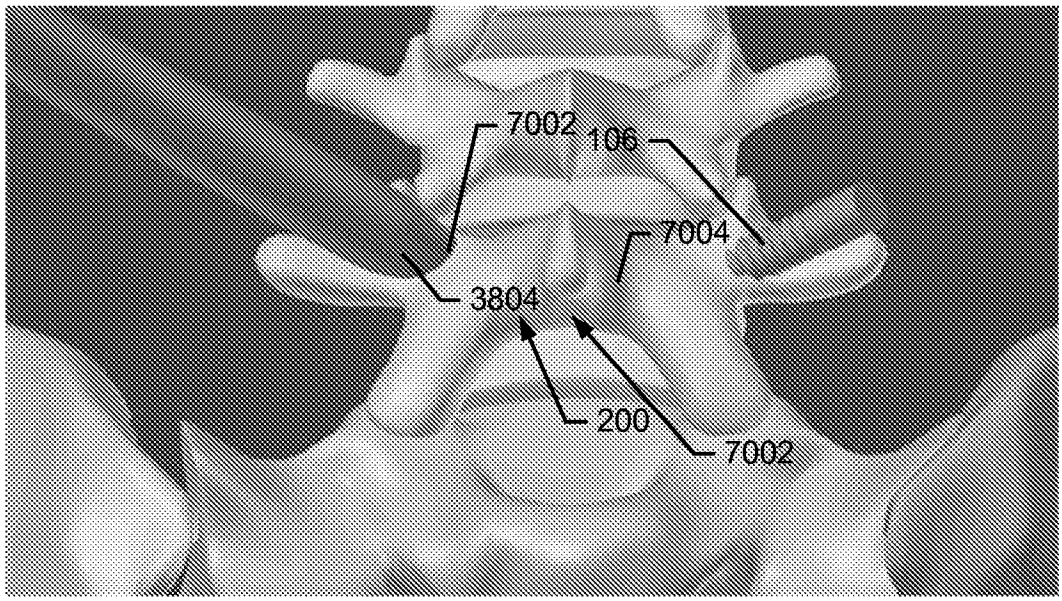
100
7102
7104
104
106
3806
200
300
102

FIG. 69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106
7004
3804
200
7002

FIG. 70

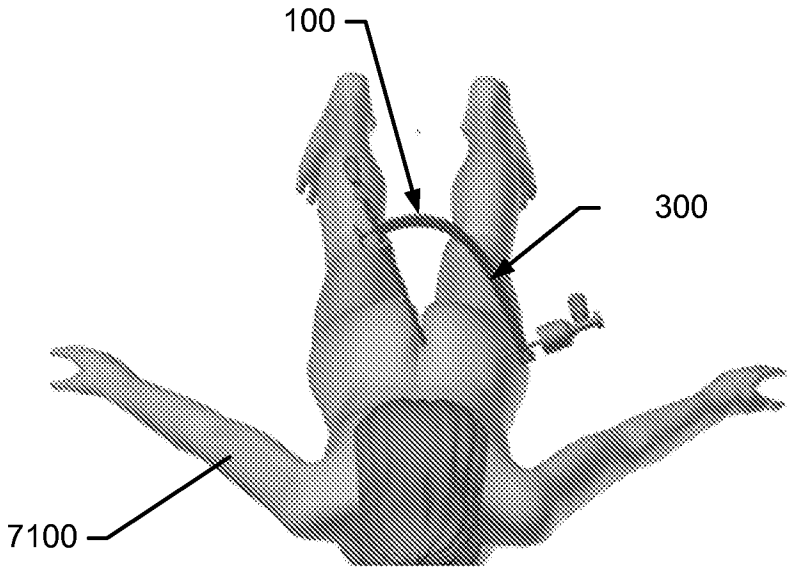


FIG. 71

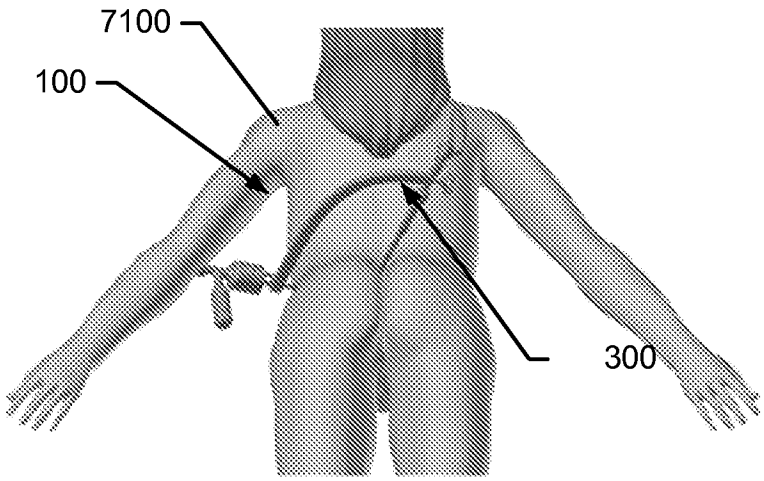


FIG. 72

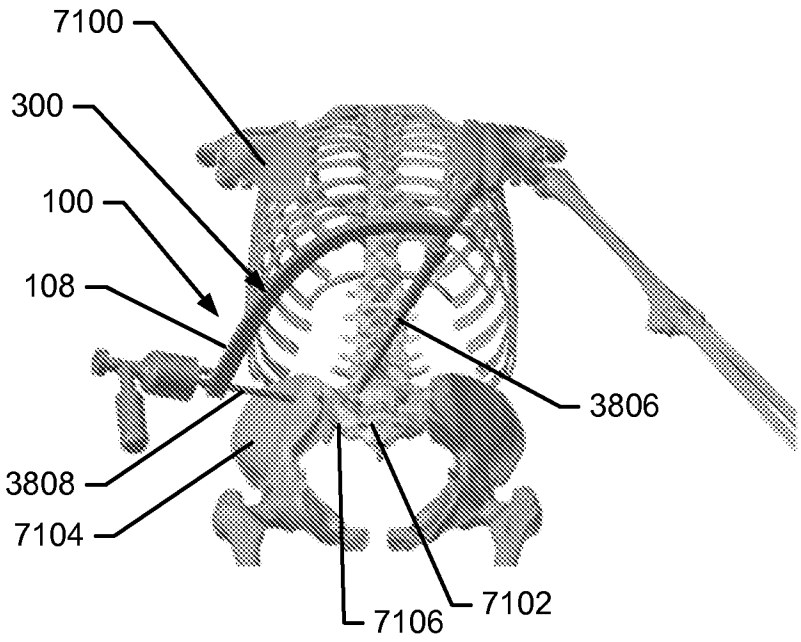

7100
300
100
108
3806
3808
7104
7106
7102

FIG. 73

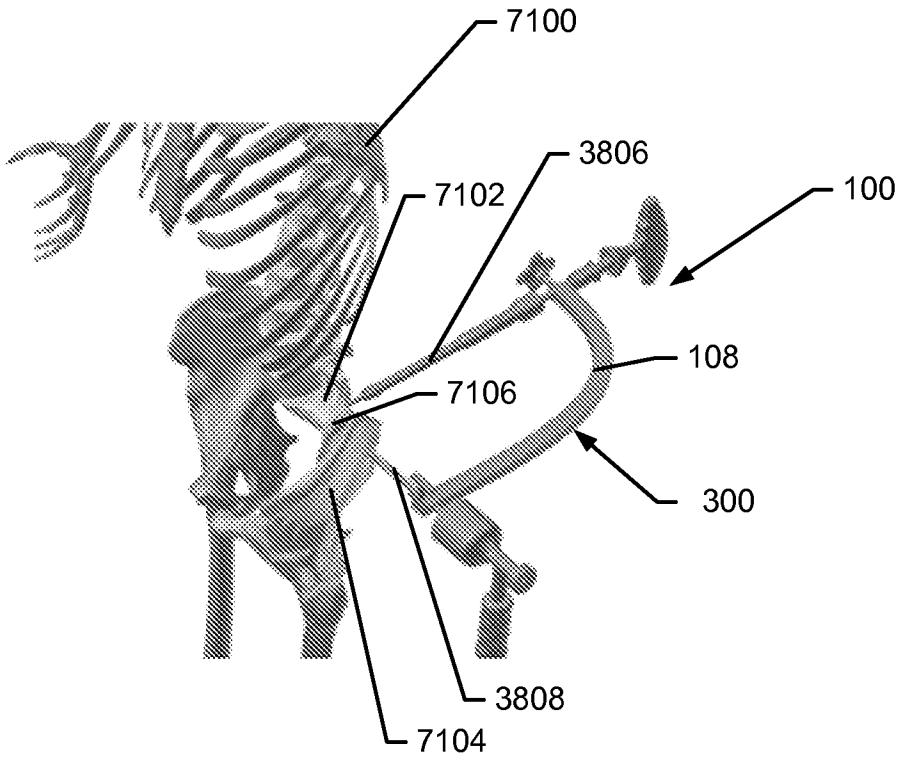
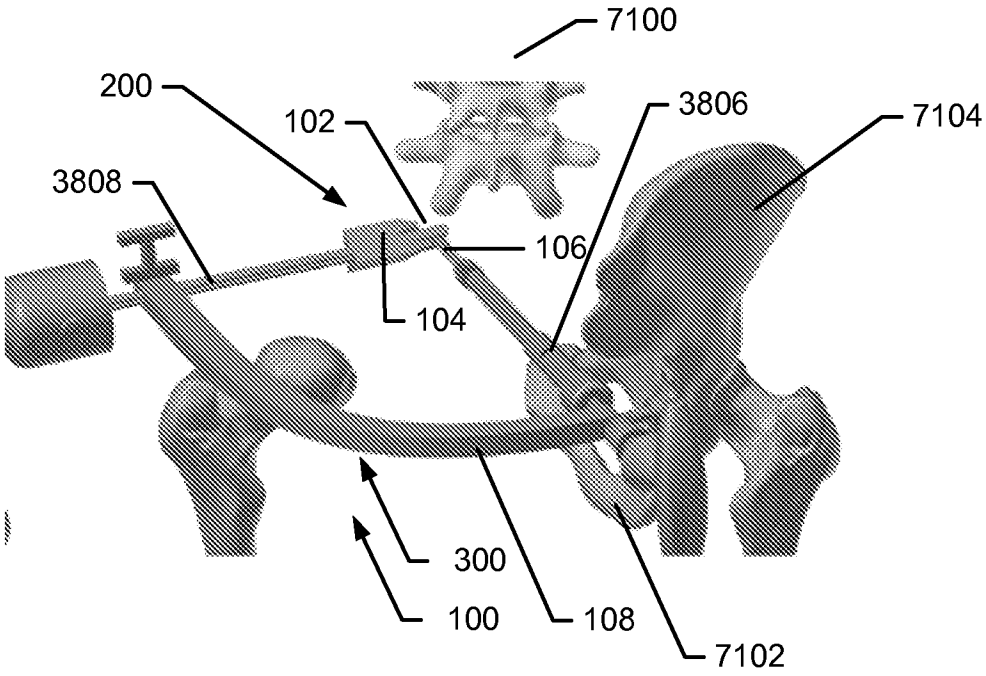

7100
3806
7102
100
108
7106
300
3808
7104

FIG. 74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200
102
3806
7104
3808
106
104
300
100
108
7102

FIG. 75

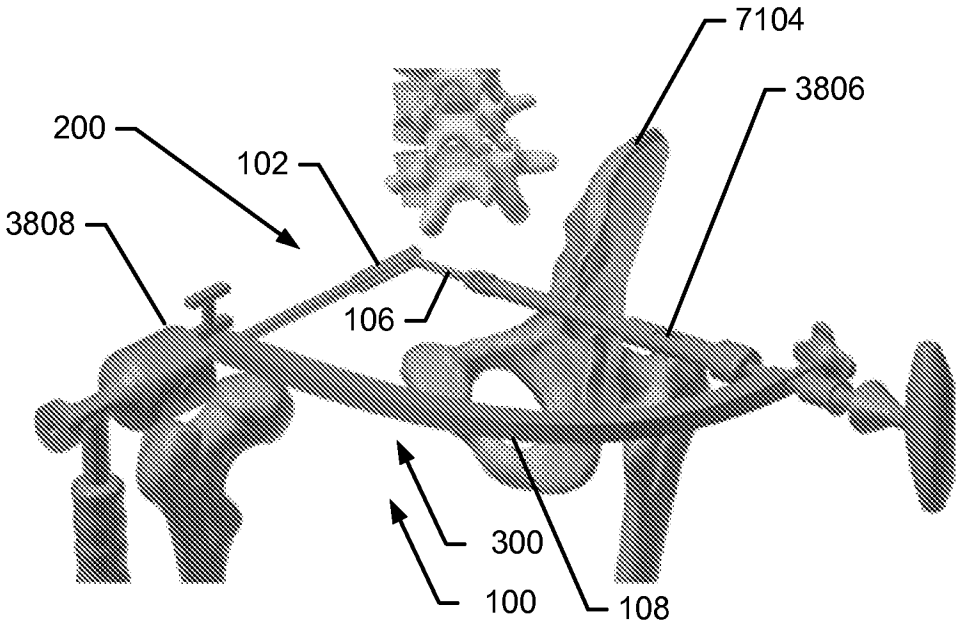
7104
3806
200
102
3808
106
300
100
108

FIG. 76

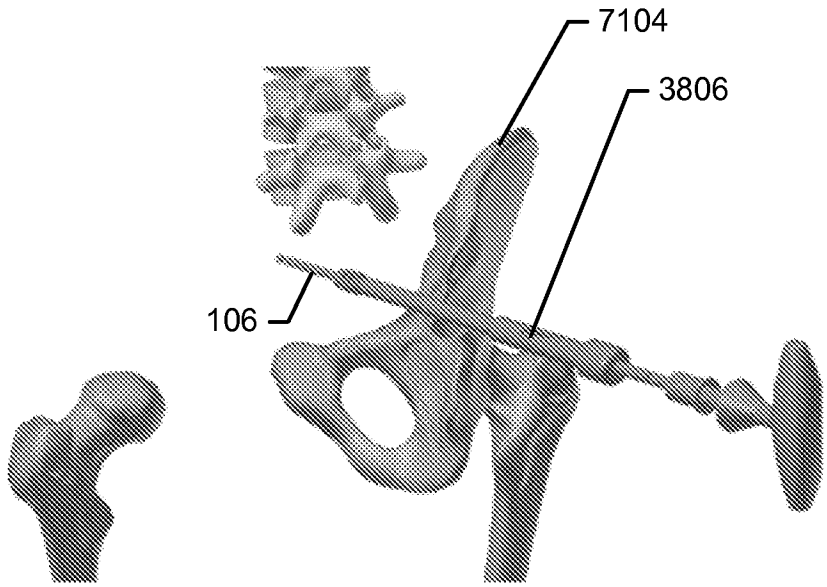

FIG. 77

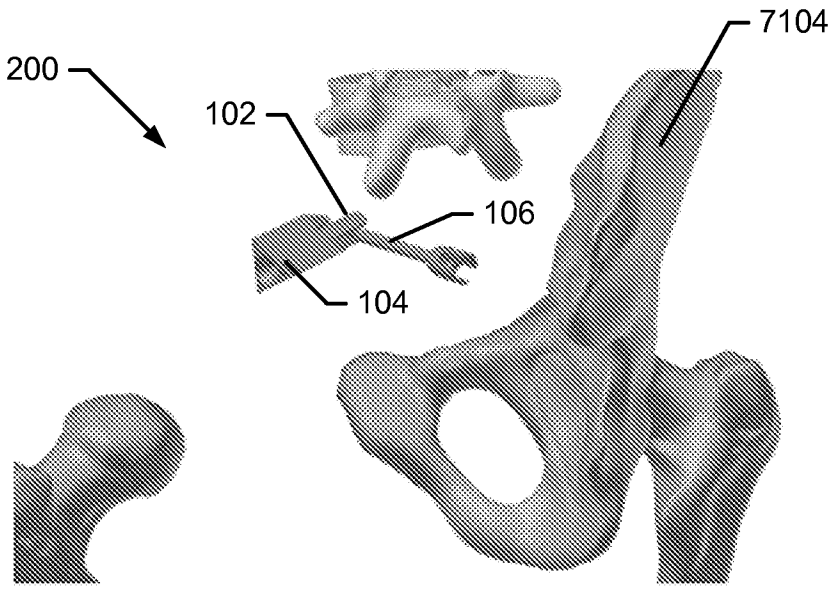

FIG. 78

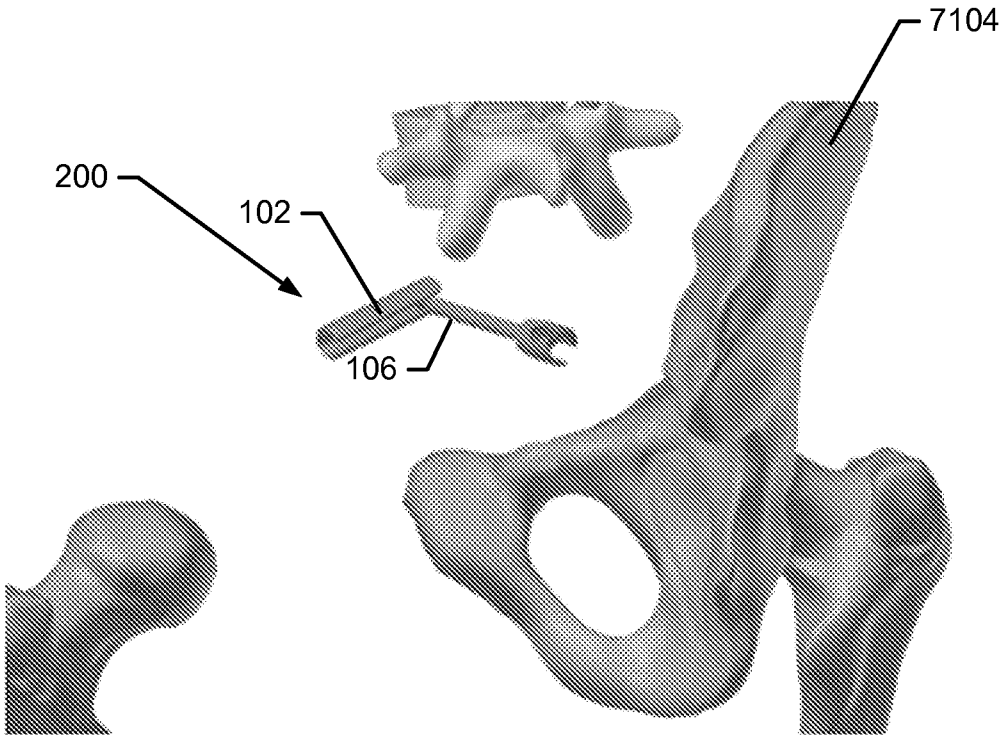

FIG. 79

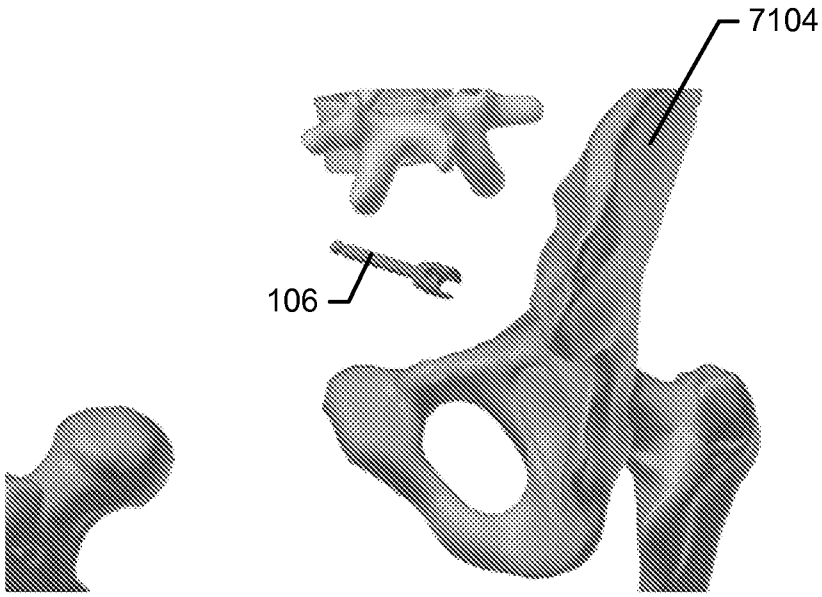

FIG. 80

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/051381

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/84(2006.01)i, A61B 17/86(2006.01)i, A61B 17/90(2006.01)i, A61B 17/70(2006.01)i, A61F 2/46(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 17/84; A61F 2/08; A61F 2/30; A61F 2/36; A61C 13/00; A61F 2/44; A61B 17/56; A61B 17/86; A61B 17/90; A61B 17/70; A61F 2/46

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: implant, deliver, guide, fastener, bone, hollow, tissue interaction, multi wall, fill cavity, anchor

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011-0184519 A1 (TRIEU, H. H.) 28 July 2011 See paragraphs [0031], [0032], [0044], [0076]-[0081]; figures 1, 3, 10.	11-16,32,34,48-50
Y		1-10,17-28,33,44-47
A		35-43
Y	US 2001-0018616 A1 (SCHWAB, J. M.) 30 August 2001 See paragraphs [0085], [0089], [0090], [0099], [0110]; figures 1, 3.	1-10,17-28,33,44-47
A	US 2003-0124486 A1 (MCDEVITT, D.) 03 July 2003 See the entire document.	1-28,32-50
A	US 2004-0127988 A1 (GOBLE, E. M. et al.) 01 July 2004 See the entire document.	1-28,32-50
A	US 5891150 A (CHAN, K. H.) 06 April 1999 See the entire document.	1-28,32-50

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 November 2013 (04.11.2013)	**04 November 2013 (04.11.2013)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/051381

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. ☒ Claims Nos.: 29-31, 51-53
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 29-31, 51-53 pertain to a method for treatment of the human body and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulation under the PCT, to search.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/051381

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011-0184519 A1	28/07/2011	US 8221428 B2	17/07/2012
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		US 6620195 B2	16/09/2003
		US 7229448 B2	12/06/2007
		US 7963984 B2	21/06/2011
US 5891150 A	06/04/1999	None	