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(54) **Title:** ORTHOPEDIC TETHERED IMPLANTS AND SYSTEM

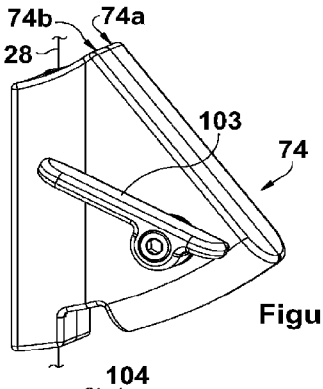


Figure 9a

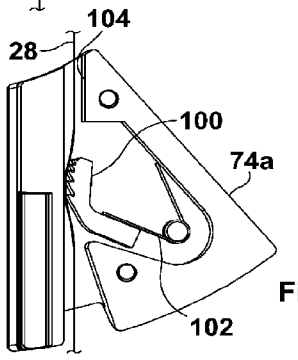


Figure 9b

(57) **Abstract:** A clamp assembly for orthopedic use having a housing that includes a top surface, a recess, a distal base and a bottom surface, the recess defining a longitudinal axis and extending through the housing from the top surface through the distal base and toward the bottom surface, and at least two through slots, each one of being disposed at a bottom or a side a surface of the housing. The assembly including a securement assembly positionable within the recess in a co-axial relationship to a mating surface on the recess, and a band sized for travel along a predetermined path defined in part by the through slots in the housing, wherein at least one of the through slots is a starting point for travel of the band along the predetermined path.

WO 2018/022769 A1

may present an abnormal curvature, such as for example, vertebrae inclined and rotated relative to one another and relative to the vertebral axis. In such a curvature, the lateral edges of the vertebrae situated on one side are closer to one another and form a concave curve, while the lateral edges on the other side are spaced apart from one another and form a convex curve. This condition can result in subsequent and serious conditions, such as for example, abnormalities of the cardiac, pulmonary, neuromuscular and gastrointestinal systems.

[004] An individual's spine may also be damaged by one or more fractured vertebrae. Spine osteosynthesis, the reduction (bringing together) and fixation of a bone fracture with implantable devices, is a known treatment of a spinal fracture. Specifically, osteosynthesis is a surgical procedure with an open or percutaneous approach to the fractured bone, which aims to bring the fractured bone ends together and immobilize the fracture site while healing takes place.

[005] To correct these and other conditions, conventional procedures have been developed using mechanical implants to straighten or otherwise hold successive vertebrae in a fixed position. To keep the vertebrae in the desired relative position, hardware, such as a screw, is inserted into the vertebrae. The screws include tulip heads and act as an anchoring point for a connecting member between vertebrae, such as a straight surgical rod.

[006] The use of screws introduces risk into the surgical procedure and may cause additional damage to the vertebrae. Spinal clamps have been developed that provide additional anchor points along the spine when the use of a screw is not possible or not optimal. Known exemplary spinal clamps introduce further risk and complexity into the surgery, including installation complexity, inadequate size offerings and additional parts.

[007] Similar risk and complexity exist in orthopedic surgery in other areas of the body adjacent or remote from the spine.

Summary

[008] The present application describes various exemplary methods and apparatus for tether clamps and tether clamp instruments and systems, together with methods for addressing orthopedic conditions using tether bands and associated implants and instruments.

[009] In various embodiments, a clamp assembly includes a clamp housing, a securement assembly selected from discrete locking and securement elements, and an integrated locking and securement element, and a flexible band or tether. The clamp housing is in some embodiments

unitary (one piece), have no moving parts, and defines at least one slot for passage of the band. The housing is adapted to receive the securement assembly, which may comprise a screw, snap or spring element, or a rod or other insert, in some embodiments without the use of a retaining clip or other hardware for retaining the securement assembly in the housing. The securement assembly provides at least the compressive force for retaining and fixing the tether band to the housing. And in some embodiments, the securement assembly is further used for providing securement, alignment, stabilization or other benefits within the clamp assembly.

[010] In various embodiments, the securement assembly is positioned within a recess in the clamp housing to provide compressive force onto the band to compress the band against an interior surface of the housing after tensioning to achieve fixed engagement of the band within the housing. In some embodiments, the housing and the securement assembly engage in each of a provisional and a fixed locking engagement, thereby enabling provisional (temporary) fixation of the band to the clamp in preparation for locking of the securement assemble once desired tether band tension and positioning have been achieved. In some embodiments, the housing defines an axis along the recess, and in some such embodiments, all or a portion of the housing is cylindrical, as well as all or a portion of the recess, and according to such embodiments, all or a portion of the securement assembly is engaged co-axial with one or both of the recess and the housing. During installation, the band is tightened around one or more of a bone and another implant and tensioned into a tightened position by use of a tensioning instrument.

[011] In some particular embodiments, as described herein, the securement assembly is retained within the housing. In yet other particular embodiments, as described herein, the securement element includes a locking set screw and a surgical rod that extends beyond the housing of a clamp assembly for attachment with one or more other implants, such as other clamp assemblies, screws, and plates.

[012] In some embodiments, a clamp system includes a clamp assembly, locking and tensioning tools, and a tensioning instrument, as described in some representative embodiments herein. The tensioning instrument has a distal end which engages the clamp assembly. The tensioning instrument further defines at least one slot which allows movement of a carriage between a non-tightened position and a tightened position, permitting a surgeon to tighten the band. A longitudinal cylinder of the tightening instrument permits the insertion of various tools,

e.g., to restrict movement of the vertebral structure relative to the securement assembly. In some embodiments, the base of the clamp assembly may include one or more surface features including elevating feet, knurling or other surface texturing, ribs, and apertures for receiving one or more of hooks, bone screws, nails, plugs or wires to affixing the clamp to bone.

[013] An embodiment of a method includes, by way of example, positioning a clamp assembly adjacent to a bone or portions of a bone (such as across a fracture), and includes: providing a clamp assembly including a clamp housing, a securement assembly comprising a locking element a securement element, and a band, wherein in some particular embodiments the locking element is a set screw and the securement element is a spinal rod. The method further includes positioning the housing along the rod at a desired location adjacent a bone, such as a fractured long bone; wrapping a band about the aligned portions of the fractured bone and through the housing; inserting the locking element within the housing to capture the securement element; provisionally locking the locking element; engaging a tensioning instrument with the clamp assembly; inserting the band through a carriage of the tensioning instrument; moving the carriage to a tightened position to secure the band; locking the locking element, and disengaging the tensioning instrument.

Brief Description of the Related Drawings

[014] Features and advantages of the general inventive concepts will become apparent from the following detailed description made with reference to the accompanying drawings.

[015] Figure A1 depicts positioning of a clamp assembly according to the invention for rib cerclage;

[016] Figure A2 depicts positioning of a clamp assembly according to the invention for fracture securement;

[017] Figure A3 depicts in six views a first embodiment of a clamp assembly according to the invention, including from top left to bottom right, a semitransparent top surface view, a top perspective view, a cross sectional side view, a side view, a semitransparent bottom view, and a bottom perspective view;

[018] Figure A4 depicts in five views a second embodiment of a clamp assembly according to the invention, including from top left to bottom right, a semitransparent top surface

view, a top perspective view, a cross sectional side view, a side view, and a semitransparent bottom view;

[019] Figure A5 depicts in five views a third embodiment of a clamp assembly according to the invention, including from top left to bottom right, a semitransparent top surface view, a top perspective view, a cross sectional side view, a side view, and a semitransparent bottom view;

[020] Figure A6 depicts in six views a fourth embodiment of a clamp assembly according to the invention, including from top left to bottom right, a semitransparent top surface view, a top perspective view, a cross sectional side view, a side view, a semitransparent bottom view, and a bottom perspective view;

[021] Figure A7 depicts in six views a fifth embodiment of a clamp assembly according to the invention, including from top left to bottom right, a semitransparent top surface view, a top perspective view, a cross sectional side view, a side view, a semitransparent bottom view, and a bottom perspective view;

[022] Figure A8 depicts in three panels, from left to right of cross sectional side and side views of embodiments of a clamp assembly according to the invention, where

[023] Figure A8 A1 is a cross sectional side view showing a first path for a band;

[024] Figure A8 A2 is a side view of the clamp assembly;

[025] Figure A8 B1 is a cross sectional side view showing a first path for a band;

[026] Figure A8 B2 is a side view of the clamp assembly;

[027] Figure A8 C1 is a cross sectional side view showing a first path for a band;

[028] Figure A8 C2 is a side view of the clamp assembly;

[029] Figure 1a is a front perspective view of a spinal clamp housing;

[030] Figure A9 shows on the left top and side views of an embodiment of a clamp assembly according to the disclosure, and on the right top and side views of a first embodiment of a securement assembly of the clamp assembly;

[031] Figure A10 shows on the left top and side views of another embodiment of a clamp assembly according to the disclosure, and on the right top and side views of a second embodiment of a securement assembly of the clamp assembly;

[032] Figure 1b is a side perspective view of the housing of Figure 1a;

[033] Figure 1c is a front view of a band wrapped about the housing of Figure 1a;

[034] Figure 1d is a bottom perspective view of the housing of Figure 1a;

[035] Figure 1e is a front cross-sectional view of a band engaged with the housing of Figure 1d;

[036] Figure 2 is a front perspective view of a spinal rod positioned within the housing and band assembly of Figure 1c;

[037] Figure 3 is a front cross-sectional view of a set screw positioned within the housing of Figure 1a, shown without a rod or band;

[038] Figure 4 is a top perspective view of a locking element of Figure 3;

[039] Figure 5a is a perspective view of a provisional locking tool engaged with a rod and spinal clamp assembly, shown without a band;

[040] Figure 5b is an enlarged perspective view of the designated circular area of Figure 5a;

[041] Figure 5c is a perspective view of the provisional locking tool of Figure 5a;

[042] Figure 6a is a front view of a tensioning instrument;

[043] Figure 6b is a rear view of the tensioning instrument of Figure 6a;

[044] Figure 7a is a front perspective view of the tensioning instrument of Figure 6a, shown engaged with the rod and spinal clamp assembly of Figure 5a;

[045] Figure 7b is an enlarged perspective view of the designated circular area of Figure 7a;

[046] Figure 7c is a front cross-sectional view of Figure 7a, shown without a tightening rod;

[047] Figure 7d is an enlarged perspective view of the designated circular area of Figure 7c;

[048] Figure 7e is a perspective cross-sectional view of a center portion of the tensioning instrument of Figure 7a;

[049] Figure 7f is an enlarged perspective view of a bearing ring of the tensioning instrument of Figure 7a;

[050] Figure 7g is a front perspective view of a tightening rod of the tensioning instrument of Figure 7a;

[051] Figure 8 is a perspective view of Figure 7a, shown with the band routed through a carriage of the tensioning instrument, with the carriage in a non-tightened position;

[052] Figure 9a is an enlarged perspective view of the carriage of Figure 8;

[053] Figure 9b is a front cross-sectional view of the carriage of Figure 9a;

[054] Figure 10a is a perspective view of Figure 8, shown with the carriage in a tightened position;

[055] Figure 10b is perspective view of a tightening tool of Figure 10a;

[056] Figure 11a is a perspective view of Figure 10a, shown with the carriage in a tightened position and a screwdriver tool inserted within the tensioning instrument;

[057] Figure 11b is an enlarged cross-sectional view of the screwdriver tool engaging the set screw;

[058] Figure 11c is a side view of the screwdriver tool of Figure 11a;

[059] Figure 12 is a front perspective view of another spinal clamp housing;

[060] Figure 13 is a bottom perspective view of the spinal clamp housing of Figure 12;

[061] Figure 14 is a front sectional view of the spinal housing of Figure 13, show with a pin and band installed in the housing;

[062] Figure 15 is a front view of a tensioning instrument;

[063] Figure 16 is a front sectional view of the tensioning instrument of Figure 15;

[064] Figure 17 is front view of a tightening rod of the tensioning instrument of Figure 15;

[065] Figure 18 is a perspective view of a bearing ring of the tensioning instrument of Figure 15;

[066] Figure 19 is a front cross-sectional view of the carriage of Figure 15;

[067] Figure 20 is a cross-sectional view of a center portion of the tensioning instrument of Figure 15;

[068] Figure 21 is a cross-sectional view of a center portion of the tensioning instrument of Figure 15, shown with the tightening rod installed and the carriage in a non-tightened position;

[069] Figure 22 is a cross-sectional view of a top portion of the tensioning instrument of Figure 15, shown with the tightening rod installed;

[070] Figure 23 is a cross-sectional view of a top portion of the tensioning instrument of Figure 15, shown with the screwdriver tool installed;

[071] Figure 24a is a perspective view of another embodiment of the invention, showing a dual tether band assembly;

[072] Figure 24b is a perspective view of The clamp assembly of Figure 24a, shown with a part of the dual tether band split into two individual bands;

[073] Figure 25 is a perspective view of another embodiment of the invention, showing a tether band/pedicle screw assembly;

[074] Figure 26 is a perspective view of another embodiment of the invention, showing a tether band/cross-connector assembly;

[075] Figure 27a is a perspective view of another embodiment of the invention, showing a tether band/hook assembly with the hook and the band in an opposite orientation;

[076] Figure 27b is a perspective view of another embodiment of the invention, showing a tether band/hook assembly;

[077] Figure 28 is a perspective view of another embodiment of the invention, showing a two housing assembly and a transverse tether band;

[078] Figure 29 is a perspective view of another embodiment of the invention, showing the installation of a tether band/pedicle screw assembly acting as a reduction device;

[079] Figure 30 is a perspective view of another embodiment of the invention, showing another tether/band/pedicle screw assembly;

[080] Figure 31a is a perspective view of another embodiment of the invention, showing a tether band/rod/hook assembly;

[081] Figure 31b is a perspective view of another embodiment of the invention, showing another tether band/rod/hook assembly; and

[082] Figure 32 is a front view of a tether band/pedicle screw assembly as used in a reduction process.

[083] Implants and instruments in accordance with these applications can include the features as described further herein in connection with the following disclosure:

Detailed Description

[084] This Detailed Description merely describes exemplary embodiments in accordance with the general inventive concepts and is not intended to limit the scope of the invention in any way. Indeed, the invention as described in the specification is broader than and unlimited by the exemplary embodiments set forth herein, and the terms used herein have their full ordinary meaning.

[085] The general inventive concepts will now be described with occasional reference to the exemplary embodiments of the invention. This general inventive concept may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the general inventive concepts to those skilled in the art.

[086] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art encompassing the general inventive concepts. The terminology set forth in this detailed description is for describing particular embodiments only and is not intended to be limiting of the general inventive concepts. As used in this detailed description and the appended claims, the singular forms “a,” “an,” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise.

[087] Unless otherwise indicated, all numbers expressing quantities of ingredients, properties such as molecular weight, reaction conditions, and so forth as used in the specification and claims are to be understood as being modified in all instances by the term “about.” Accordingly, unless otherwise indicated, the numerical properties set forth in the specification and claims are approximations that may vary depending on the suitable properties sought to be obtained in embodiments of the present invention. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the general inventive concepts are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any

numerical values, however, inherently contain certain errors necessarily resulting from error found in their respective measurements.

[088] The invention is directed a tether clamp assembly and implantation system for use in orthopedic surgery. The system provides a temporary or permanent implant intended to provide temporary stabilization during the development of solid bony fusion and aid in the repair of bone fractures. Exemplary indications for use include, but are not limited to: spine to rib fixation; cerclage banding for fractures and osteotomies, and, anterior spinal tethering, as well as spinal fixation applications, such as spinal trauma surgery, used in sub-laminar, interspinous, or facet wiring techniques, spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis, spinal degenerative surgery, as an adjunct to spinal fusions, and treatment of idiopathic and neuromuscular scoliosis in patients eight years of age and older.

[089] The inventive system may be used in conjunction with other medical implants made of metal, for example, titanium alloy or cobalt chromium alloy, whenever "wiring" or banding may help secure the attachment of other implants. Of course it will be appreciated that while many of the specific exemplary embodiments shown in this supplemental disclosure are directed to spinal applications, the invention herein is capable of application to any orthopedic subject matter in humans and animals, and there is no limitation as to the use hereof with other anatomical structures, such as long bones, ribs, major joints such as the shoulder, hip and knees, and aspects of the spine, to name a few.

[090] An embodiment of the invention which will now be discussed is an orthopedic clamp implant. Referring now to the drawings, Figures A1 and A 2 show representative examples of use of an orthopedic implant comprising a clamp assembly according to the disclosure, wherein Figure A1 shows an assembly in the context of use for rib cerclage, and Figure A2 shows an assembly in the context of use for bone fracture securement. With reference generally to Figures A1 –A10, in accordance with the various embodiments, a clamp assembly 500 includes a clamp housing 510, a securement assembly 600, and a flexible band 700.

[091] Referring again to the drawings, Figures A3 – A7 show alternate embodiments of a clamp housing 510 according to the disclosure. The housing is adapted for placement at a desired implantation point in contact with or generally adjacent to bone, such as but not limited to one or

more of a vertebra, a long bone, and a rib. The housing 510 may be constructed of suitable material, such as for example, stainless steel, cobalt chromium, or titanium.

[092] The housing includes a base 540 that may be generally cylindrical shaped, or plate like and one of round or square. The housing includes a top surface 550 that includes an opening 555 into a recess 560, and a bottom surface 590. In some embodiments, as show, the top surface 550 is generally cylindrical with a circular opening 555. The recess 560 defines a longitudinal axis L_A and the recess 560 extends from the top surface 550 towards the base 540. The housing 510 also includes a bottom surface 520 and a side surfaces 530. In some embodiments, as depicted in Figures 1A – 10A, the base 540 is generally square shaped and the side surfaces 530 form four discrete sides. An internal surface of the recess includes a mating engagement surface 570 comprising a locking feature 580, such as for example, a threaded surface. According to embodiments wherein the locking feature is adapted to engage with a threaded screw or set screw, the threaded surface mates with a locking element 620 component of a securement assembly 600, such as for example, a set screw. In some other embodiments, a locking element 620 us selected from other securement means, such as but not limited to, a blocking nut, or a blocker, and is engageable by snap or other fitting with one or more locking features 580 selected from flanges, grooves, ridges, teeth or the like on the mating surface 570 of the recess 560. It should be apparent to one with skill in the art that other styles, types, and sizes of surfaces for locking elements and tensioning instrument mating can be used in the practice of this invention.

[093] Generally, the clamp housing according to the various embodiments as disclosed herein includes structural features comprising one or more through slots 590 to permit a band to be wrapped securely about a bone or other structure or another implant, and secured to the housing by passage through one or more through slots. In certain embodiments, the band may be secured at one end by attachment through one or more through slots of the housing (shown, for example, in one possible clamp housing embodiment as depicted in Figure 1e). For example, one or more of a knot, stitching, and other form of bonding or fixation may formed at one end of the band to secure it to the housing. It should be understood by those with ordinary skill in the art that the number of slots used to secure the band, if any, as well as the shape and location of the slots, may vary in the practice of this invention. It will also be appreciated that in the various embodiments a slot is not limited to an elongate slit that is narrower in a width dimension than in a length

dimension, and that a slot may be round, elliptical, or some other shape. Moreover, a band that is fixed at one end to a through slot may partially or completely fill the slot and the slot may compress and end of the band as a means of securement thereto.

[094] The housing 10 further includes apertures 32. These apertures may be used by a surgeon for various purposes, such as for example, grasping the housing 10 during implantation, or insertion of a pin for a structural anchor for another assembly piece, such as for example, the tether band.

[095] Structural features of the bottom of the spinal clamp housing are best seen in Figures A3 – A7, wherein it is shown that the bottom surface 520. And various possible band paths defined by the through slots 590 are shown in Figure A8, panels A1, B1 and C1, which show, respectively, passage of the band 700 through each of two bottom and two side slots 590 and passing across the bottom surface 520 of the housing 510, passage of the band 700 through each of two bottom surface 520 slots 590 and passing across an interior surface within the base 540 below the recess 560, and passage of the band 700 through one of two bottom and two side slots 590 and passing over an interior surface within the base 540 below the recess 560 by looping around a side surface 530 of the housing 510.

[096] Referring again to Figures A9 and A 10, each shows alternate embodiments of securement assemblies according to the disclosure, wherein the securement assemblies comprise two parts, including a locking element and a securement element. It will be appreciated that in alternate embodiments, the securement assembly may be unitary and comprise a single component that includes features for engagement within the recess and also contacting the band 700 to enable engagement and fixation of band tensioning. As shown in Figure A9, the locking element 620 is a set screw and the securement element 610 is a plug that snap fits into the locking element 620. Referring now to Figure A10, the alternate embodiment of a securement assembly 600 includes a locking element 620 comprising a blocker or blocking nut that engages with one or more locking features 580 in the recess 560, and a securement element 610 similar to that of Figure A9. In accordance with the various embodiments, the securement element 610 may be provisionally engaged with the band 700 by actuation through an opening in the set screw and upon final tensioning of the band 700, the set screw and plug are actuated to fully engage with and lock within the housing to secure the band to the housing and secure the tightened band for therapeutic use.

[097] Generally, in some embodiments the securement assembly may include other fastener and engagement features, such as but not limited to a dowel pressed through set screw and into groove on a plug for actuation of the plug into engagement with the band, and it may include a flexible retaining ring assembled into a locking element such as a set screw that snaps into a groove on the plug. In yet other embodiments, the plug may have flexible or slotted ends that allow it to snap into the set screw. These alternate embodiments are but some of the ways by which the securement assembly components including locking and securement elements may be fixed to none another.

[098] According to various embodiments of methods as disclosed herein, the instruments described herein below may be adapted for use with one or more of the clamp assemblies described herein above and shown in the Figures A1-A10. As used, the instruments may engage the housing 510 to secure it in place while tensioning the band that is fixed at one end to the housing 510 via passage through one or more slots 590, and the various instruments can be used to insert and provisionally secure and finally lock the securement assembly upon final tensioning of the band.

[099] Another embodiment of the invention which will now be discussed is a spinal clamp implant. The spinal implant is used to aid in fusion and stabilization in one or more vertebrae during a posterior access surgery. The spinal clamp can be used with one or more similar spinal clamps to provide anchoring points for a surgical rod. The spinal clamp can further be used with conventional screw and tulip head implants. For example, the spinal clamp may be secured to third lumbar vertebra L3, while conventional screw and tulip head implants are secured to the second lumbar vertebra L2 and the fourth lumbar vertebra L4. When discussing the spinal clamp and implantation of the spinal clamp, the terms "proximal" and "distal" are used relative to the surgeon, and not the operating field, i.e., not relative the patient.

[0100] Referring again to the drawings, a spinal clamp housing 10 is shown in Figures 1a and 1b. The housing is adapted for placement at a desired implantation point adjacent to a vertebra. The housing 10 may be constructed of suitable material, such as for example, stainless steel, cobalt chromium, or titanium.

[0101] The housing is generally cylindrical shaped and defines a longitudinal axis L_A (best seen in Figure 3). More specifically, the housing includes a center recess 12 defined by opposing

arms 14, 16 extending from a base 17. An internal surface of the arms 14, 16 include a mating engagement surface, such as for example, a threaded surface 18. The threaded surface mates with a locking element, such as for example, a set screw, a blocking nut, or a blocker. An exterior of the exemplary arms 14, 16 include a flat surface 20. A tightening instrument engages the flat surface 20 to prevent housing 10 rotation while the set screw is rotated into a locked position. This operation will be discussed in further detail. It should be apparent to one with skill in the art that other styles, types, and sizes of surfaces for locking elements and tensioning instrument mating can be used in the practice of this invention.

[0102] The housing 10 includes structural features to permit a band to be wrapped securely about the housing. A first slot 22 is located at the bottom of the recess 12 and defines a passage for a band along a longitudinal axis of the housing. The first slot may allow use by a surgeon as a starting point for band travel within and in the vicinity of the housing 10. For example, a knot may be tied at the beginning of the band to prohibit one end of the band from entering the slot and passing through to the bottom side of the housing, or one end of the band may include a clip larger in size than the slot 22. A second slot 24 and a third slot 26 are formed in opposing positions on either side of the housing 10. These slots 24, 26 may permit band travel perpendicular to the longitudinal axis of the housing 10. An exemplary travel path of a band 28 is illustrated in Figure 1c. The band 28 is illustrated in an exemplary pattern, for example, routed in a pattern around a lamina (not shown).

[0103] The housing 10 further includes apertures 32. These apertures may be used by a surgeon for various purposes, such as for example, grasping the housing 10 during implantation, or insertion of a pin for a structural anchor for another assembly piece, such as for example, the tether band.

[0104] Structural features of the bottom of the spinal clamp housing are best seen in Figure 1d. In this embodiment, the housing 10a includes two slots 22a, 22b, separated by a bridge 23, at the bottom of the housing recess. The slots 22a, 22b may allow use by a surgeon as a starting point for band travel within and in the vicinity of the housing 10a. For example, a first end of the band 28 may be routed through both slots as shown in Figure 1e, and secured to a distal location 29 of the band, to secure the band to the housing 10a. In the exemplary embodiment, the band is integral to the housing and secured prior to surgery, for example, during surgery preparation or by a

manufacturer. In other embodiments, the surgeon may attach the first end of the band at the distal location 29 by one of several methods, including sewing the first end to the band. It should be understood by those with ordinary skill in the art that the number of slots used to secure the band, if any, as well as the shape and location of the slots, may vary in the practice of this invention.

[0105] Another embodiment of the invention includes a housing having different structural features. Specifically, the housing 210 illustrated in Figures 12-14 includes a single aperture 122 at the bottom of housing. The aperture as shown is a rectangular shaped slot. It may be of any suitable shape, width and length. As shown, the single slot 122 is wider than the double slots 22a, 22b shown in the housing 10 of Figure 1d.

[0106] The base of the housing 210 is absent any apertures oriented perpendicular to a position of an installed surgical rod. The housing 210 does include two holes 132 for supporting a pin 123 as seen in Figure 14. The holes are positioned co-axial with an installed position of a surgical rod. The end of the band is fixed to provide a loop for slipping over the pin, or the band may be fixed to the pin. As shown, a loop and the end of a tether band 128 is formed by fixing two band lengths 130a, 130b.

[0107] Referring now to Figure 2, a surgical rod 34 placed within the recess 12 of the housing is shown. The housing is concave-shaped to accept and laterally retain the rod 34 within the arms 14, 16. The weight of the rod 34 applies a force to pinch a portion of the band 28 against the housing 10. It will be appreciated that in alternate embodiments, a different securement element other than a rod may be used to secure the band within the housing. In some specific embodiments, the fixation element need not extend outside of the housing, and in some embodiments, the housing does not include opposing arms and may be overall cylindrical.

[0108] During implantation, the next step is to provisionally lock the rod in place with use of a set screw. A set screw 36 is shown engaged with a housing 10 in Figure 3. The rod 34 and band 28 are not shown for clarity. As shown in Figures 3 and 4, the set screw 36 has a threaded external circumferential surface 38 which engages the internal threaded surface 18 of the arms 14, 16. A top surface 40 of the set screw 36 includes a cut-out recess 42. The recess 42 is shaped to accept locking tools.

[0109] Figures 5a and 5b illustrate a provisional locking tool 50 engaged with a set screw 36. In the implantation of the spinal clamp, a surgeon uses the provisional locking tool 50 to tighten

the set screw enough to temporarily contain the rod 34. The set screw must not be locked in place until the band is sufficiently tightened about the target lamina. In a further surgical step, the set screw 36 is locked in a final position.

[0110] As shown in Figure 5c, the provisional locking tool 50 includes an instrument rod 52 and palm handle 54. The palm handle 54 may be separable from the instrument rod 52. The system may include multiple tools, each with specifically shaped instrument rods. For example, the instrument rod 52 includes a constant diameter shaft terminating in a socket head 56 sized to mate with the recess 42 of the set screw 36.

[0111] The spinal clamp installation system includes a tensioning instrument for use by a surgeon to tighten a band and securing the vertebral structure relative to the implant rod. The installation system is arranged for user ease of installation. As shown in the Figures, for example, Figures 3 and 7d, the housing 10, set screw 36 and tensioning instrument 60 are all positionable about a common longitudinal axis L_A. Any tools used in the installation, either prior to the engagement of the tensioning instrument, or inserted within the internal channel of the tensioning instrument from a proximal end to a distal end, are also positioned along the same common axis. This arrangement also promotes increased user flexibility, e.g., the user may easily incrementally tighten a band of a spinal clamp assembly, then by retract a tool from the set screw and then disengaging the tensioning instrument from the housing, move to the next sequential spinal clamp assembly along the surgical rod, and make a similar incremental adjustment.

[0112] Figures 6a and 6b illustrate front and rear views of a tensioning instrument 60. The instrument includes an elongated cylinder 62. The cylinder permits the insertion of tools from a proximal end 64 to a distal end 65 to manipulate the set screw 36, and further contains a hollow tightening rod 66. The tightening rod 66 is used by the surgeon to secure the band 28 in a final position.

[0113] The cylinder 62 is adapted for securing the spinal clamp in a final position relative the target vertebra. Figures 7a-7d illustrate various views of the tensioning instrument 60 engaged with a spinal rod. The cylinder 62 includes projections 68 at the distal end 65. An arched section 63a between two adjacent projections engage a top surface of the rod 34 (see Figure 7b). A flat portion 63b between other adjacent projections engage the flat portions 20 on the exterior of the housing 10, to prohibit movement of the housing. The cylinder further defines two opposing slots

70, 72. The slots permit travel of a carriage 74 within the slot, at least partially between a distal end 70a (see Figure 7a) and proximal end 70b (see Figure 10a). Two protruding tabs 76, 78 ride within the slots during movement of the carriage. The mechanics of this movement will be discussed in further detail.

[0114] The tensioning instrument is structured to tighten the band 28 to secure the housing 10 to the rod 34. As best seen in Figure 7e, the cylinder 62 includes an interior surface 80 defining a hollow chamber. Within the proximal portion of the chamber, the tightening rod 66 mates with internal threads of the cylinder. The tightening rod 66 is illustrated in Figure 7g and includes a knob 82, threaded portion 84, and a distal, non-threaded portion 86. The distal position 86 includes holes 88 for engagement by set screws (not shown) which secure a retaining ring 90 (see Figure 7e). The retaining ring 90 moves axially within the cylinder as the tightening rod 66 is manipulated by the surgeon.

[0115] A bearing ring 92 is disposed to the proximal side of the retaining ring 90, as best shown in Figure 7e. Further as shown in Figure 7f, the two tabs 76, 78 radially protrude from opposing sides of the bearing ring 92. A center aperture 94 permits passing of the distal portion 86 of the tightening rod 66. A top surface 96 of the bearing ring 92 may engage a shoulder 98 of the tightening rod to limit entry of the rod into the cylinder in a distal direction.

[0116] The bearing ring 92 is adapted for connection to the carriage 74. As shown in Figure 7e, a wing 98 extends radially from a base of the bearing ring into the carriage 74, which is constructed from two pieces 74a, 74b (see Figure 9a). The carriage may be constructed of a suitable material, such as for example, plastic or metal, and include two snap-fit pieces that enclose the wing 98. A carriage half 74a is illustrated in Figure 7e and includes a spur 100 which is biased in a direction toward the cylinder 62 by a torsion spring 102. The spur 100 is operated by a handle 103 (see Figure 9a) to permit threading of the band 28 in a proximal direction through a channel 104 in the carriage 74. Teeth on the spur 100 prohibit return movement of the band in the distal direction.

[0117] Figure 8 shows the band 28 inserted through the carriage 74 and properly positioned for use of the tensioning instrument. The carriage is in a non-tightened position in Figure 8. Front perspective and cross-sectional views of the carriage 74 are shown in Figures 9a and 9b,

respectively, with the band 28 in an inserted position. As shown in Figure 9b, teeth on the spur 100 press the band 28 against the wall of the channel 104.

[0118] As previously discussed, a surgeon may secure the housing 10 in place relative to the targeted vertebra by manipulation of the tightening rod 66. Referring now to Figure 10a, a tightening tool 110 is shown engaged with the knob 82 of the tightening rod 66. As shown, the rod 66 has been turned and axially moved in a proximal direction away from the housing 10. As such, the carriage has moved axially along the exterior of the cylinder 62, and within the range between the slot 70 distal end 70a and proximal end 70b, at the discretion of the surgeon. As the carriage moves proximally, the band 28 is tensioned in a proximal direction securing the vertebral structure relative to the implant rod. The carriage is in a tightened position in Figure 10a.

[0119] Figure 10b is perspective view of the tightening tool 110 of Figure 10a. The tightening tool includes a palm handle 54 and an instrument shaft 112, which terminates at a head 114 for engaging a recess in the knob 82. As previously discussed in regard to other tools, the palm handle 54 may separate from the instrument shaft 112 so that a single handle can accommodate multiple shafts for multiple purposes during implantation.

[0120] After the band 28 is sufficiently tensioned, the surgeon may lock the set screw 36 into a desired and final position. Figures 11a-11c detail aspects of this locking process. In Figure 11a, a perspective view of Figure 10a is shown with the carriage in a tightened position, the tightening tool 110 removed, and a screwdriver tool 120 inserted within the tensioning instrument 60. An enlarged cross-sectional view of the head 56 of the screwdriver tool 120 engaged with the set screw 36 is shown in Figure 11b. In this position, the surgeon may tighten the set screw as desired by turning the tool 120.

[0121] Figure 11c is perspective view of the screwdriver tool 120. The tool includes a palm handle 54 and an instrument shaft 122, which terminates at a head 56 for engaging the recess 42 in the set screw. As previously discussed in regard to other tools, the palm handle may separate from the instrument shaft. The exemplary shaft 122 shown includes a shoulder 124 to accommodate the internal dimensions of the cylinder 62 and tightening rod 66.

[0122] Another embodiment on the tensioning instrument will now be discussed. The tensioning instrument 160 and related parts are illustrated in Figures 15-23. The tensioning instrument 160 has similar features as the discussed embodiment of Figures 5a-11b. However, the

tensioning instrument 160 includes structural differences of certain components related to tensioning. The embodiment discussed is exemplary only, and other structural difference of the same or different components can be utilized in the practice of the invention.

[0123] Figures 15 and 16 illustrate front and sectional views, respectively, of a tensioning instrument. The tensioning rod 166 is fixed by one or more pins and moves only axially upon rotation. In other words, the tensioning rod does not translate along the longitudinal axis of the tensioning instrument. As seen in Figure 16, 17 and 18, the inside of the bearing ring is threaded, and no retaining ring or set screws are included in the assembly as in other embodiments. The cross-sectional view of Figure 21 shows detail of the tensioning rod, bearing ring and carriage assembly.

[0124] Referring specifically now to Figure 15, a front view of a tensioning instrument 160 is illustrated. The tensioning instrument includes a hollow cylinder 162. As best shown in the sectional view of Figure 16, the cylinder has a smooth internal surface 162 without female threads. With the internal surface being smooth, the threaded portion 184 of the tightening rod 166 does not engage the inside surface of the hollow cylinder 162. As shown in Figure 16-18 and 21, the tightening rod 166 engages a bearing ring 192. Specifically, a threaded surface 184 of the tightening rod engages an inside threaded surface 195 of the bearing ring 192.

[0125] The bearing ring 192 is adapted for connection to the carriage 174. As shown in Figure 18, a wing 198 extends radially from a base of the bearing ring. The wing extends into the carriage 174 as in a previously discussed embodiment. Two tabs 176, 178 are oval in shape and ride with a slot 170 on either side of the tensioning instrument 160 as the carriage travels from a lower non-tensioned position to a higher tensioned position, as previously discussed.

[0126] The carriage advantageously “auto-locks” in operation, prohibiting disengagement of the band in the distal direction, but allowing for easy slack removal by pulling in the proximal direction.

[0127] 174 illustrated in Figures 16 and 19 includes a lever 200 which is biased in a direction toward the cylinder 162 by a torsion spring 202. The lever 200 is operated by a handle 199 to permit threading of a tether band in a proximal direction through a channel 204 in the carriage 174. Teeth 200 on the lever 197 prohibit return movement of the band in the distal direction.

[0128] The invention can be utilized in various applications and techniques. Several other embodiments of the invention and methods of use as illustrated in Figures 24a-32. A dual housing assembly is illustrated in Figures 24a-24b. The figures illustrate two housings 210a, 210b with a dual tether band 300 fixed to the bottom of each housing. The strands are connected to the housing as by the arrangement shown in Figure 14, with the individual strands 302a, 302b of the band connected to a pin inserted through the housing. The proximal end of the band can be split in two ends 304a, 304b after being passed through as lot on another housing, or other device. After splitting and passing, each end 304a, 304b is secured independent of the other to each housing 210a, 210b, such as for example, under a surgical rod.

[0129] Other embodiments of the invention can include housings having pedicle screw capability, such as for example, the housing illustrated in Figure 25. The housing 310 includes a screw portion 314 having construction suitable for use as a pedicle screw. One or more slots allow for anchoring or passing of a tether band. As shown, a distal loop of a band 312 surrounds a mounting pin 320 and exits a lower slot 316b, and upon re-entry to the housing 310 passes through an upper slot 316a and over a surgical rod 318. This arrangement allows for additional fixation options, such as for example, to support resistance to screw pullout, e.g., in osteopenic bone. A similar arrangement is shown in Figure 26, in which a band surrounds a second surgical rod 320. In this embodiment, the band is mounted to a pin 320 and exits out an upper slot. In this arrangement with two surgical rods 318, 320, the assembly is used as a cross connector to add bi-lateral stability in rod/implant constructs.

[0130] Other embodiments of the invention can include housings with laminar hooks used to engage bone. Specifically, the housing along the combination of hook, rods and tethers to prevent dislodging of hook, for example, to prevent proximal junctional kyphosis. Figures 27a and 27b illustrate housing 330, 338 with hooks 336, 340, respectively. In Figure 27A, the rod 332 and tether 334 are positioned at opposing orientations, and with the tether above the rod. In contrast, the housing 338 of Figure 27b positions the rod above the tether and at the same orientation, i.e., in a co-axial position. Other combinations of rod and tether positions can be practiced with this invention.

[0131] Another exemplary assembly is shown in Figure 28. As shown, a pedicle screw housing 344 is implanted into a vertebrae 348. A second housing is fixed to a rod 346 and

positioned on an opposite side of the vertebrae 348 relative the pedicle screw housing 344.
A tether 350 stretches from a pin mounting in the housing 342, through a surgical created slot in the vertebrae, and to the pedicle screw housing 344. The use of tether band 350 in a transverse arrangement helps derotation of vertebral body and prohibits any creep of construct.

[0132] Multiple inventive housings and a tether band can also be advantageously used during surgery to help implant a rod. For example, Figure 29 illustrates an exemplary use of a first housing, a pedicle screw housing, and a tether 366 in which the tether band is used to laterally translate the pedicle screw housing to the implant rod. After the first housing 360 is mounted to a rod 368, the pedicle screw housing 362a (as shown in a first position) is translated to a second position 362b by use of the tether, in effect moving the vertebrae (from a first position 364a to a second position 364b) to an position engageable with the rod 368.

[0133] As discussed, the inventive housing include slots suitable for passing of a tether. For example, pedicle screws with slots for tether band may be used to allow additional fixation options by accommodating passage of a tether band thru the head of the screw. As shown in Figure 30, a pedicle screw housing 370 includes a screw portion 372, and a head 382 having a slot 374 in each arm. A tether 376 may pass above or below a surgical rod 378, and may be held in place by a set screw 380. Other examples using hooks 392 are illustrated in Figures 31a and 31b. These housings 394, 390 allow for additional fixation options by accommodating passage of a tether band 376 through the body of the housing transversely (as shown in Figure 31a) or along the axis of the rod 378 (as shown in Figure 31b). Other orientation combinations are possible in practice of invention.

[0134] Referring now to Figure 32, a tether band and pedicle screw housing is shown in use in a reduction process. Specifically, a tether 408 is used as a reduction device to seat a rod 404 into a pedicle screw housing 402. As shown, the housing is implanted into a vertebrae 400.
By use of tensioning instrument 406, the vertebrae 400 and housing 402 is moved in a direction A_2 to seat the rod in a desired position.

[0135] While various inventive aspects, concepts and features of the general inventive concepts are described and illustrated herein in the context of various exemplary embodiments, these various aspects, concepts and features may be used in many alternative embodiments, either individually or in various combinations and sub-combinations thereof. Unless expressly excluded

herein all such combinations and sub-combinations are intended to be within the scope of the general inventive concepts. Still further, while various alternative embodiments as to the various aspects, concepts and features of the inventions (such as alternative materials, structures, configurations, methods, circuits, devices and components, software, hardware, control logic, alternatives as to form, fit and function, and so on) may be described herein, such descriptions are not intended to be a complete or exhaustive list of available alternative embodiments, whether presently known or later developed. Those skilled in the art may readily adopt one or more of the inventive aspects, concepts or features into additional embodiments and uses within the scope of the general inventive concepts even if such embodiments are not expressly disclosed herein. Additionally, even though some features, concepts or aspects of the inventions may be described herein as being a preferred arrangement or method, such description is not intended to suggest that such feature is required or necessary unless expressly so stated. Still further, exemplary or representative values and ranges may be included to assist in understanding the present disclosure; however, such values and ranges are not to be construed in a limiting sense and are intended to be critical values or ranges only if so expressly stated. Moreover, while various aspects, features and concepts may be expressly identified herein as being inventive or forming part of an invention, such identification is not intended to be exclusive, but rather there may be inventive aspects, concepts and features that are fully described herein without being expressly identified as such or as part of a specific invention. Descriptions of exemplary methods or processes are not limited to inclusion of all steps as being required in all cases, nor is the order that the steps are presented to be construed as required or necessary unless expressly so stated.

CLAIMS

1. A clamp assembly for orthopedic stabilization, the assembly comprising:

a clamp housing, a top surface, a recess, a distal base and a bottom surface, the recess defining a longitudinal axis and extending through the housing from the top surface through the distal base and toward the bottom surface, the housing further comprising at least two through slots, each one of the at least two through slots disposed at a surface of the housing selected from the bottom surface of the housing and a side surface of the housing;

a securement assembly positionable within the recess in a co-axial relationship to a mating surface on the recess,

a band sized for travel along a predetermined path defined in part by the through slots in the housing;

wherein at least one of the through slots is a starting point for travel of the band along the predetermined path.

2. The clamp assembly of claim 1 wherein the mating surface on the recess comprises a locking feature for engaging with the securement assembly.

3. The clamp assembly of claim 2 wherein the securement assembly comprises a securement element and a locking element.

4. The clamp assembly of claim 3 wherein the housing is adapted to receive within the recess a compression assembly comprising a compression element positioned within the distal base and below and in a co-axial relationship to the locking element.

5. The clamp assembly of claim 2 wherein the securement assembly comprises an integrated locking and securement element.

6. The clamp assembly of claim 2 wherein the locking feature comprises one or more of threads and a groove.

7. The clamp assembly of claim 1 comprising one of two through slots and more than two through slots.

8. The clamp assembly of claim 2 comprising more than two through slots, wherein at least one of the more than two through slots is disposed at the bottom surface of the housing

and at least two through slots are disposed opposite one another, each on a side surface of the housing and positioned on the housing to define a path of the band below the securement assembly.

9. The clamp assembly of claim 4 comprising more than two through slots, wherein at least one of the more than two through slots is disposed at the bottom surface of the housing and at least two through slots are disposed opposite one another, each on a side surface of the housing and positioned on the housing to define a path of the band below the securement assembly.

10. The claim assembly of claim 10 wherein the housing comprises on first and second sides opposing elongate side arms that extend along the longitudinal axis defined by the recess, wherein two of each of the at least two through slots disposed on a side surface of the housing is, respectively, in one of each of the opposing elongate side arms.

11. The claim assembly of claim 12 wherein the securement element is a surgical rod, and wherein the at least two opposing through slots in the elongate side arms define a band path below the surgical rod, and wherein the locking element is a set screw and at least a portion of the housing recess is threaded for engagement with the set screw.

12. The clamp assembly of claim 11, the clamp housing comprising an elongate slot aperture on the bottom surface of the distal base, and two opposing coaxial holes and a pin insertable therein, the coaxial holes and inserted pin positioned to bisect the elongate slot aperture and form the starting point for travel of the band, and wherein a first end of the band is fixed to the clamp housing by engagement around the pin.

13. The clamp assembly of claim 11, the clamp housing comprising two elongate slot apertures on the bottom surface of the distal base that form the starting point for travel of the band, and wherein a first end of the band is fixed to the clamp housing by engagement through the two elongate slot apertures on the bottom surface.

14. The clamp assembly of claim 8, wherein the distal base of the housing has a shape that is one of square and circular, and wherein the top surface of the housing comprises a cylindrical extension having a circular opening to the recess.

15. The clamp assembly of claim 14 wherein the distal base is one of substantially planar and curved.

16. The clamp assembly of claim 1 wherein the distal base includes one or more features selected from the group of a hook extending from the bottom surface, a screw extending from the bottom surface, one or more apertures for receiving a bone fixation element selected from a screw, a rod, a pin, a plug, a bone anchor, and a wire, texturing on the bottom surface, ribs on the bottom surface, and knurling on the bottom surface.

17. The clamp assembly of claim 1 wherein the clamp housing is unitary.

18. A clamp assembly for providing orthopedic stabilization, the assembly comprising:

a unitary housing comprising a recess, a top surface, a distal base and a bottom surface, wherein the distal base of the housing has a shape that is one of square and circular, and wherein the top surface of the housing comprises a cylindrical extension having a circular opening to the recess;

a securement assembly positionable within the recess in a co-axial relationship to a mating surface on the recess, the securement assembly comprising one of

an integrated securement assembly selected from a snap fit blocking nut, a spring loaded blocking nut, and a blocker and

a securement element selected from a plug and a spring loaded plug, and a locking element selected from a set screw, a snap fit blocking nut, a spring loaded blocking nut, and a blocker,

a band sized for travel along a predetermined path defined in part by the slots in the housing;

wherein the housing comprises two or more through slots, wherein at least one of the through slots is disposed at the bottom surface of the housing and at least two through slots are disposed opposite one another, each on a side surface of the housing and positioned on the housing to define a path of the band below the securement assembly; and

wherein at least one of the through slots is a starting point for travel of the band along the predetermined path.

19. A clamp assembly of claim 18, wherein the securement assembly comprises a securement element comprising a plug and a locking element comprising a set screw.

20. A clamp assembly for providing stabilization as a bone anchor, the assembly comprising:

a unitary housing comprising a recess, a top surface, a distal base and a bottom surface, and comprising two opposing arms extending from the base, the recess extending through the housing between the opposing arms and toward the bottom surface, the housing further comprising at least one through slot in each of the two opposing arms, and two slots disposed at the bottom surface of the housing in a parallel orientation to each other and separated by a bridge extending therebetween;

a locking element positionable within the recess,

a securement element comprising a surgical rod positionable within the recess below the locking element, and

a band sized for travel along a predetermined path defined in part by the slots in the housing;

wherein the bridge and the two slots disposed at the bottom surface is a starting point for travel of the band along the predetermined path; and

wherein the slots in the arms are positioned on the housing to define the path of the band below the locking element.

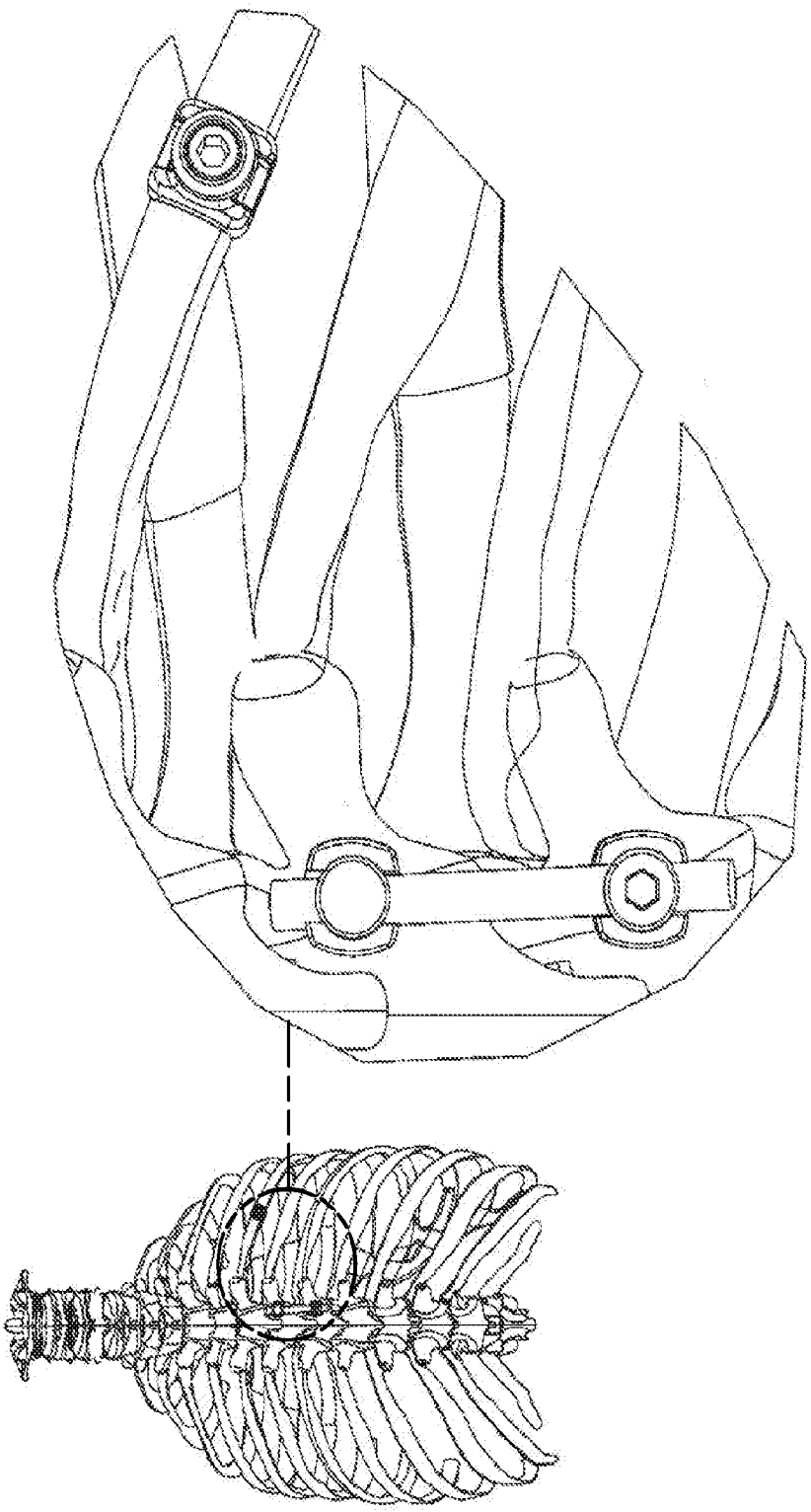
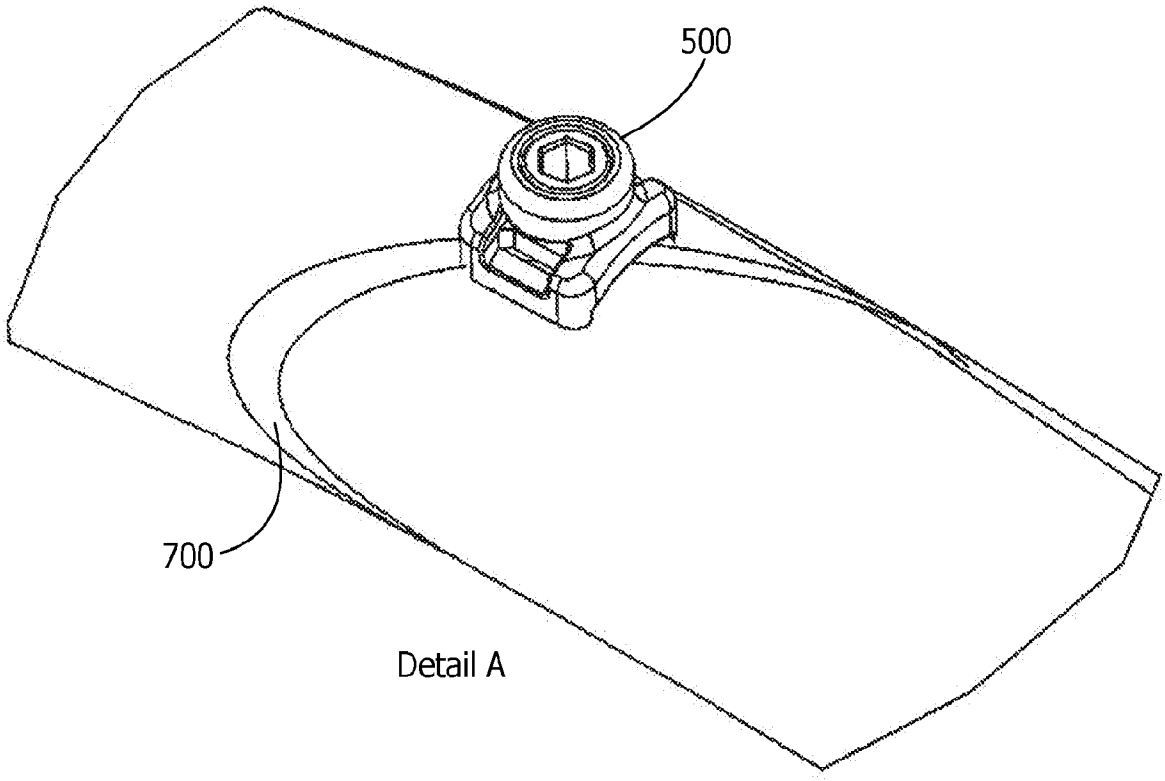


Figure A1



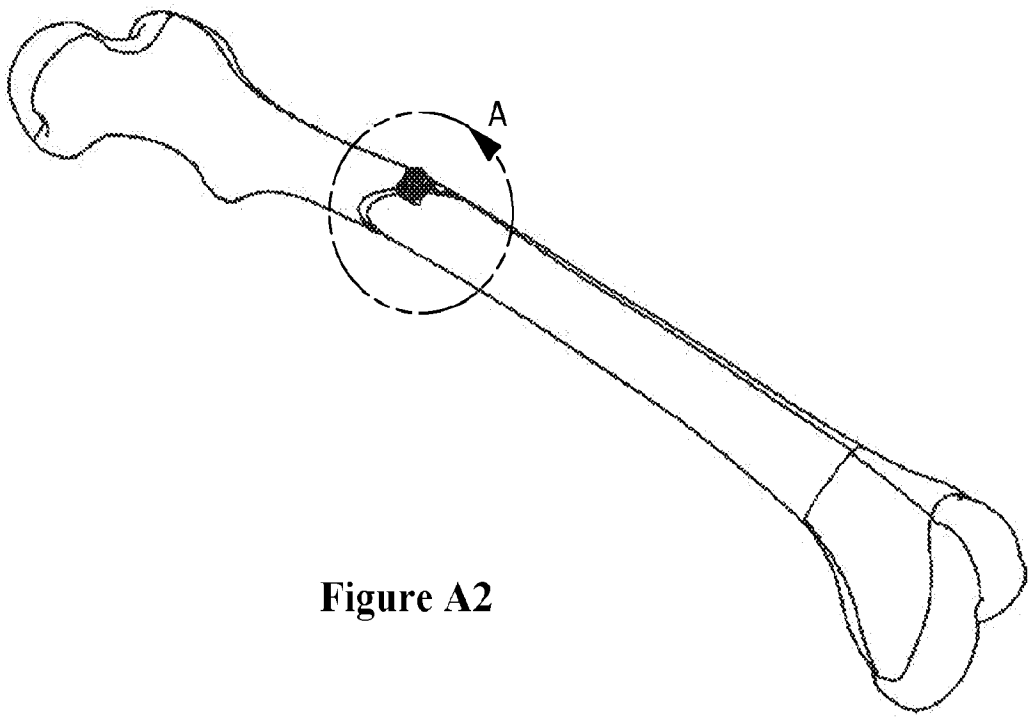
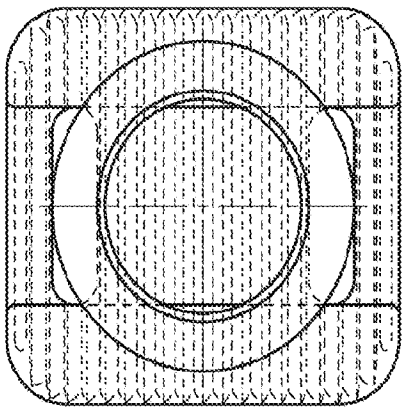
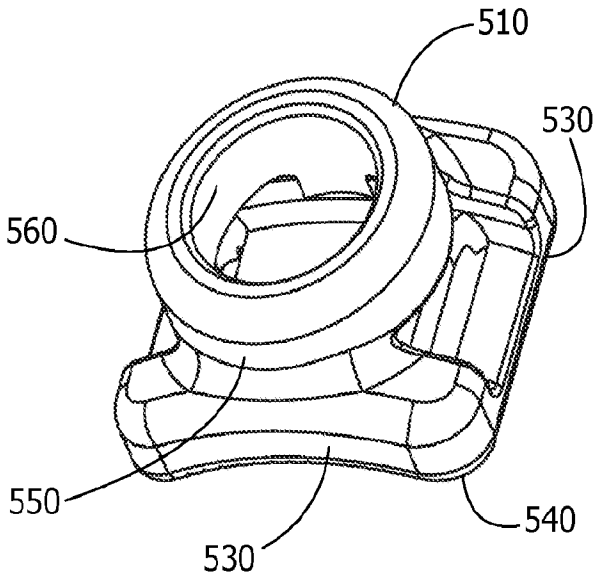
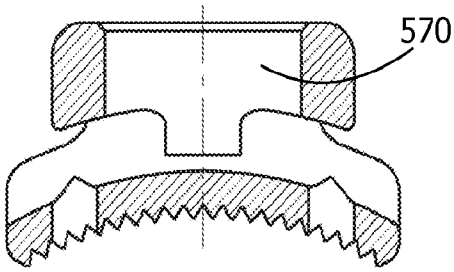


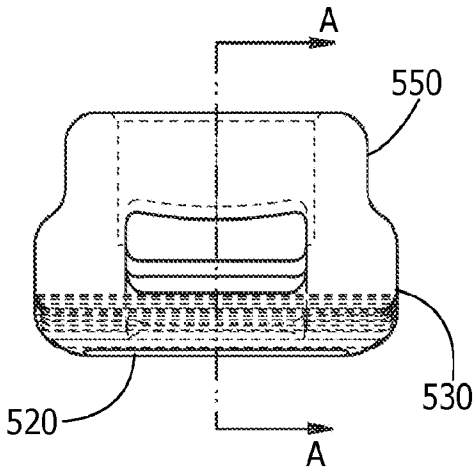
Figure A2

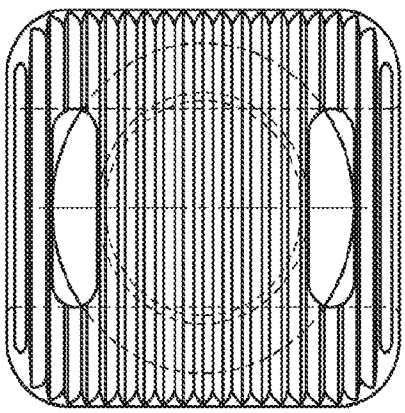






Section A-A





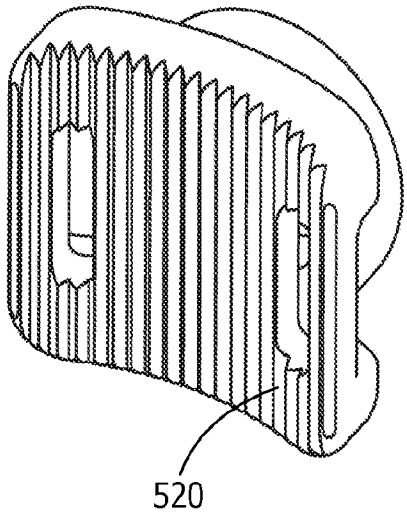


Figure A3

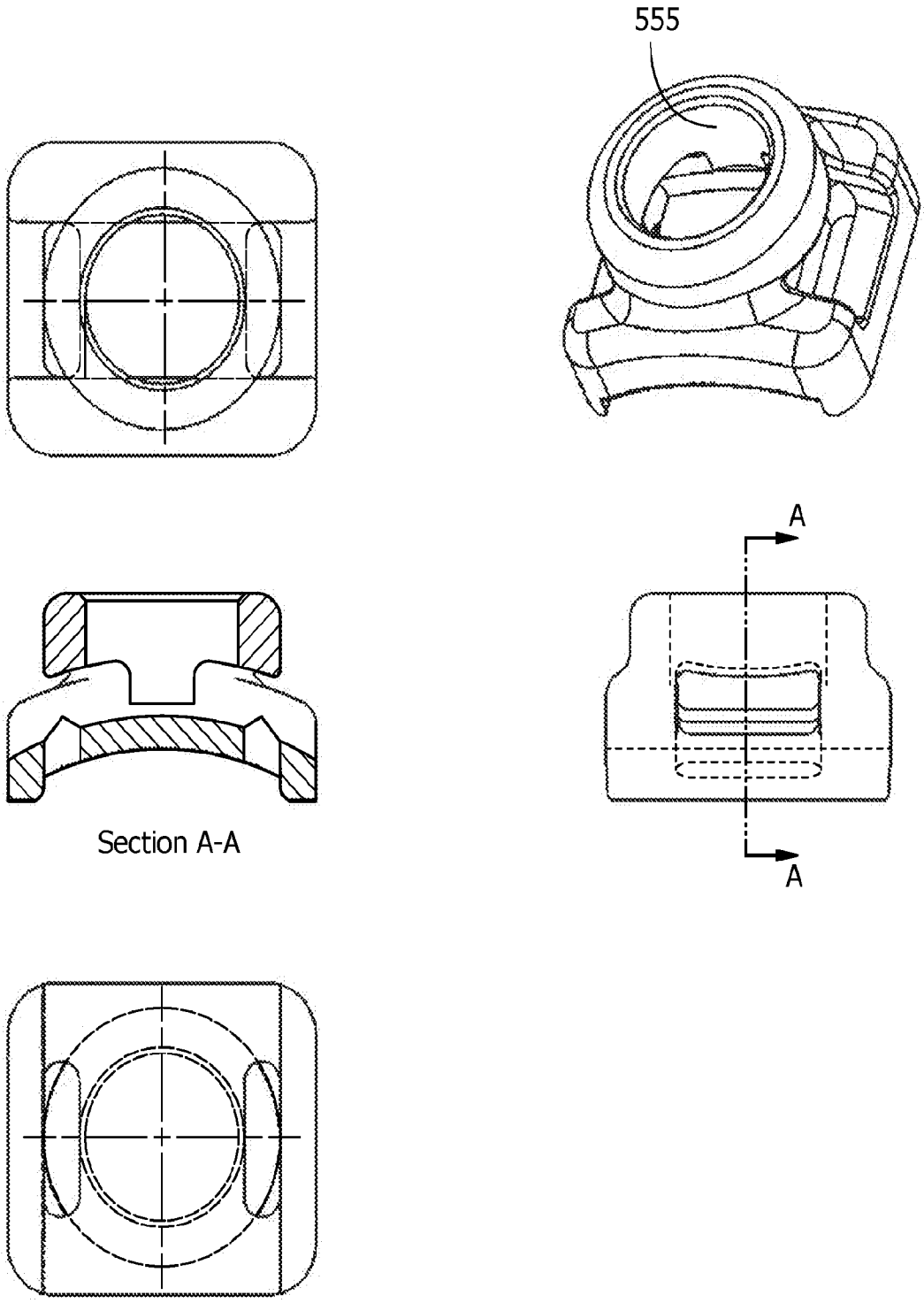


Figure A4

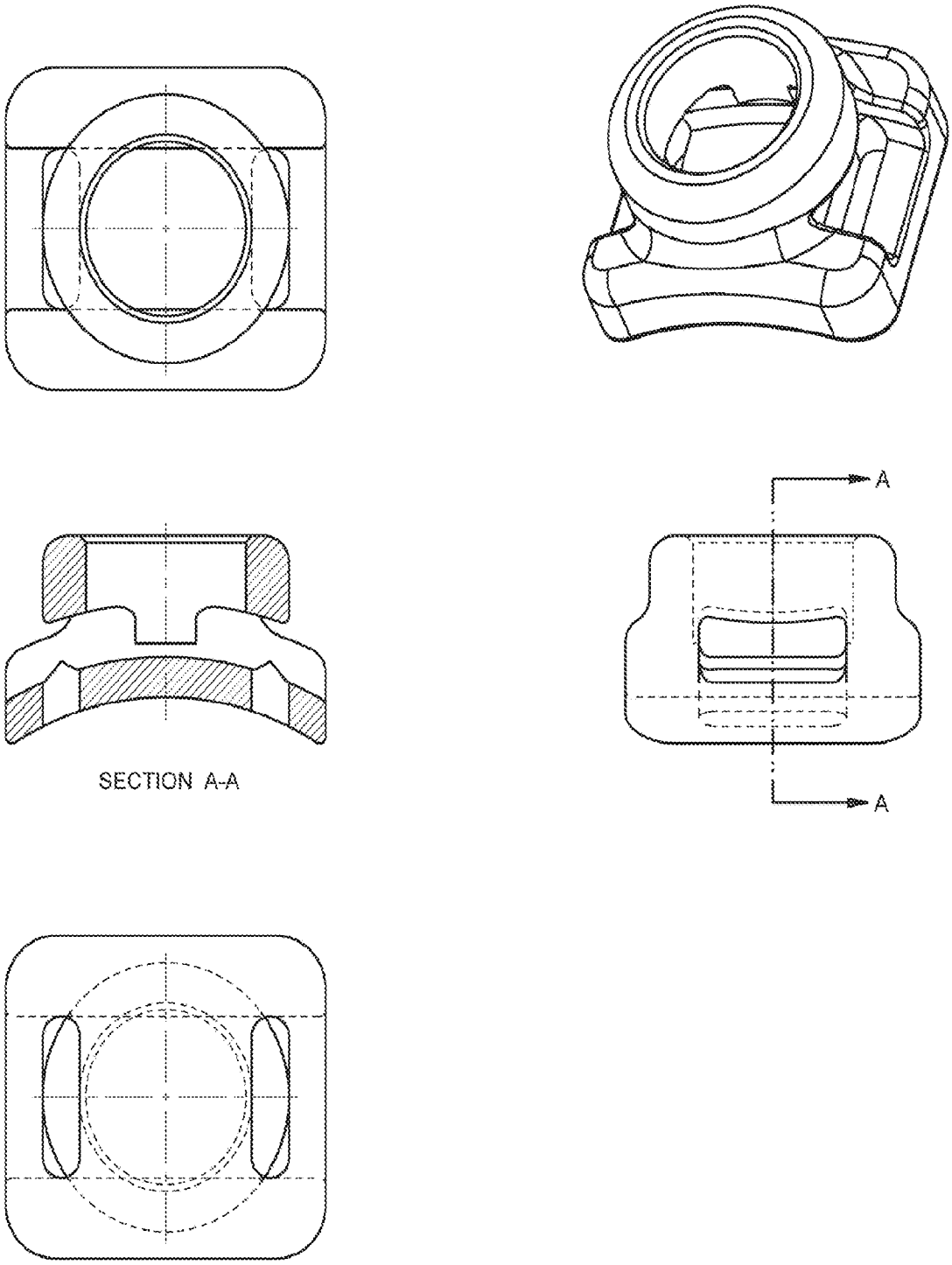


Figure A5

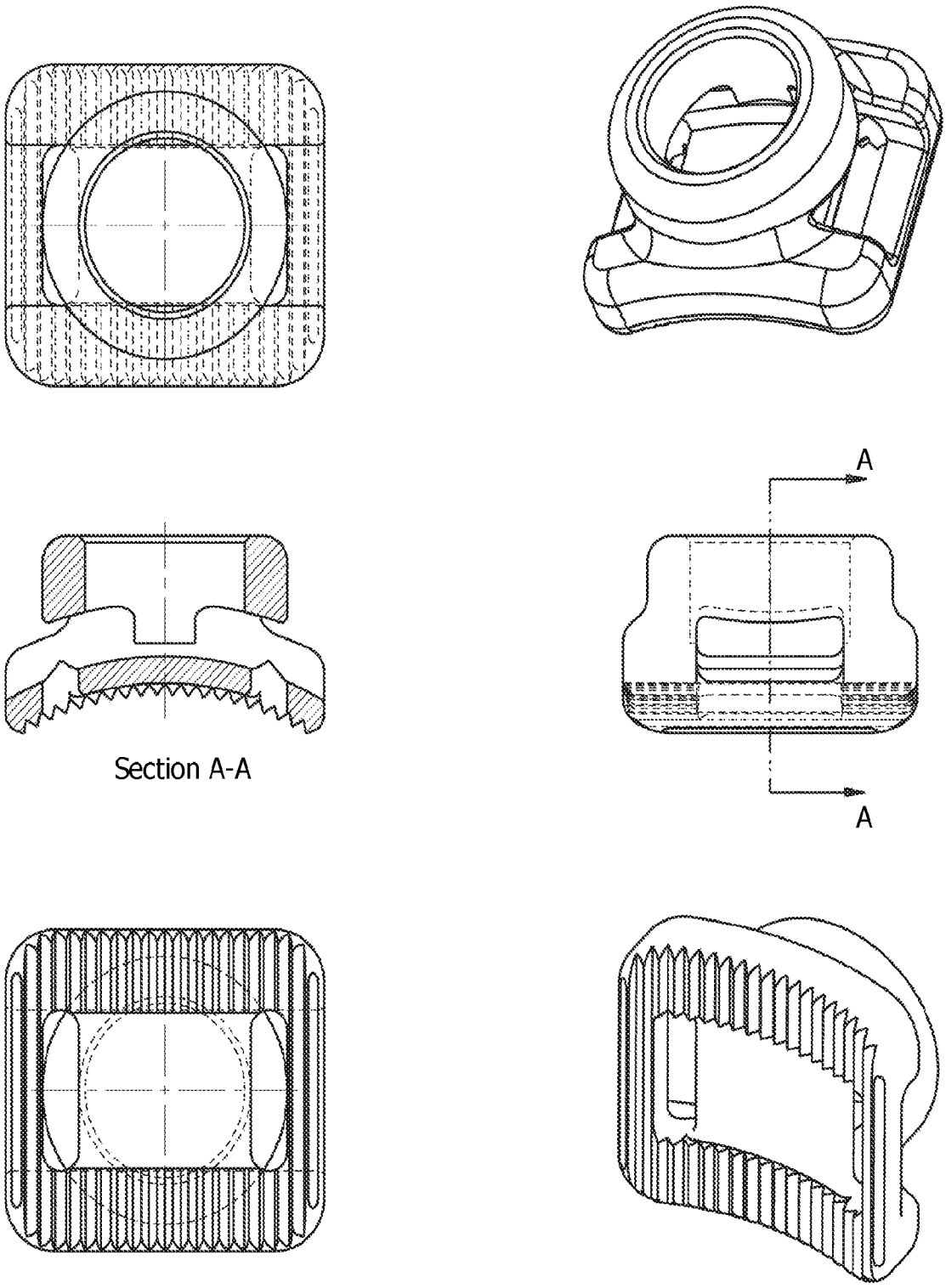


Figure A6

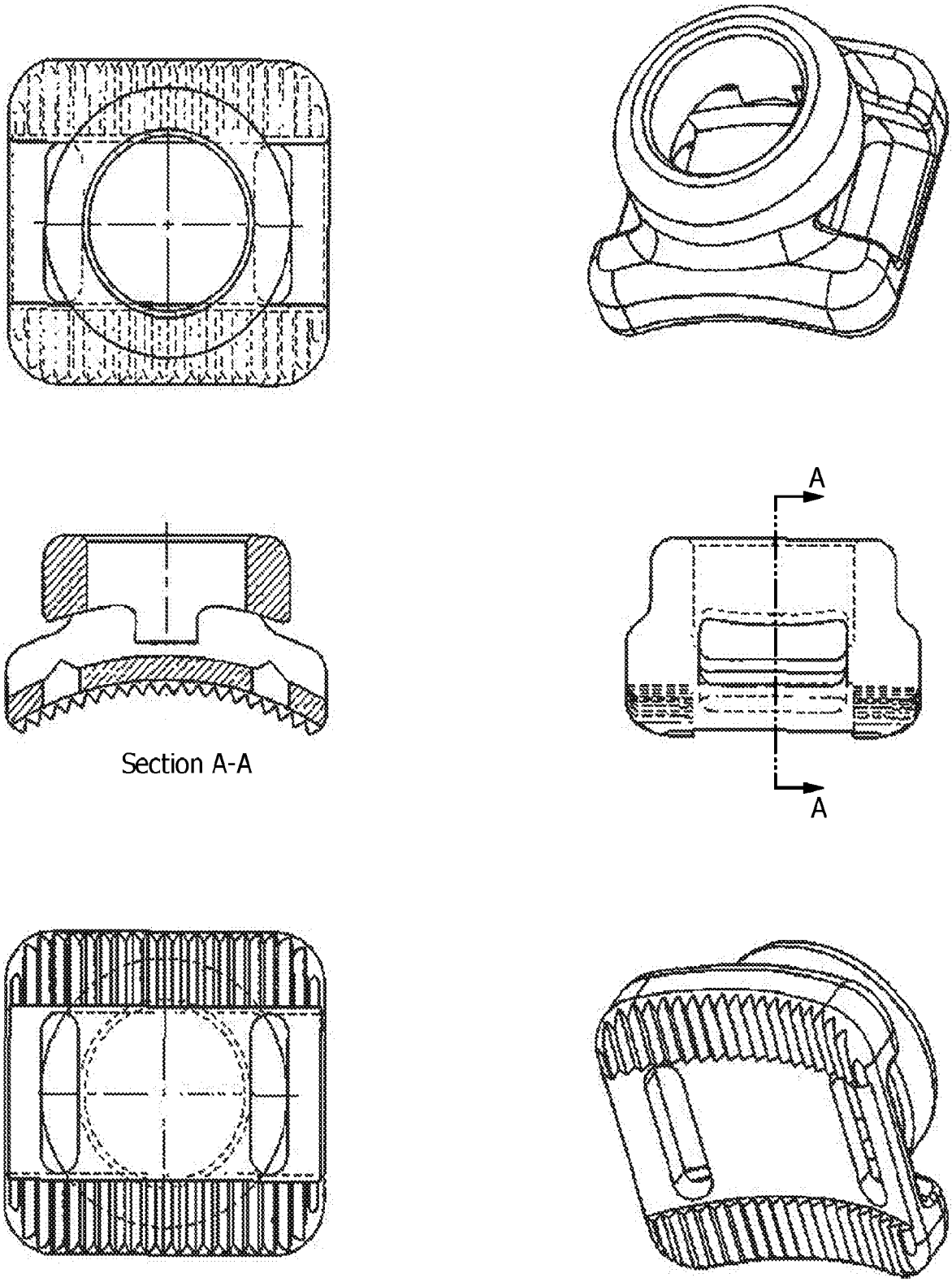
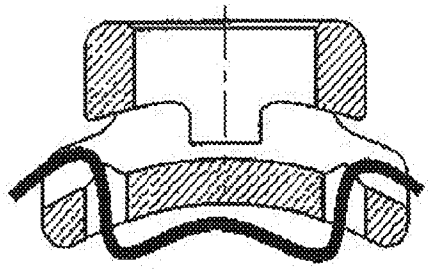


Figure A7



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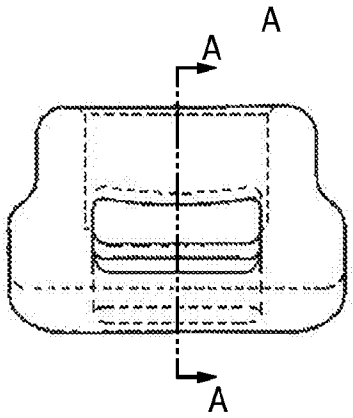

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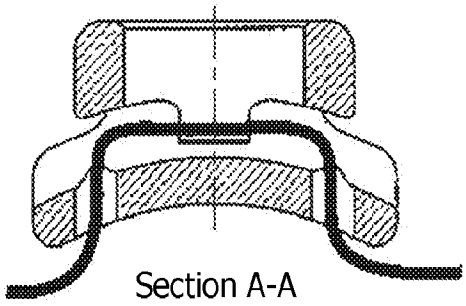

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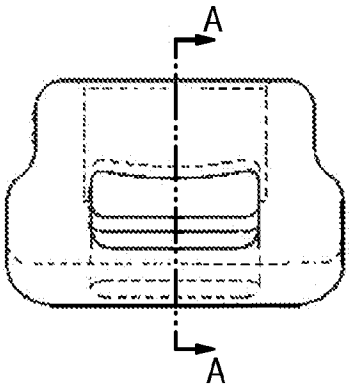

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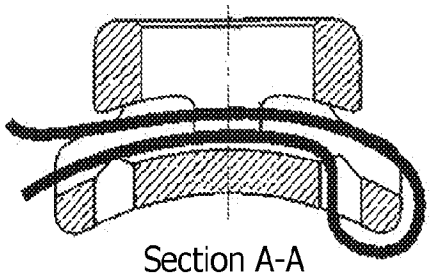
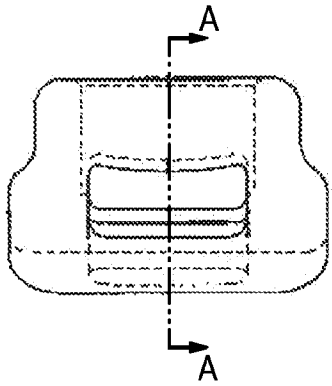
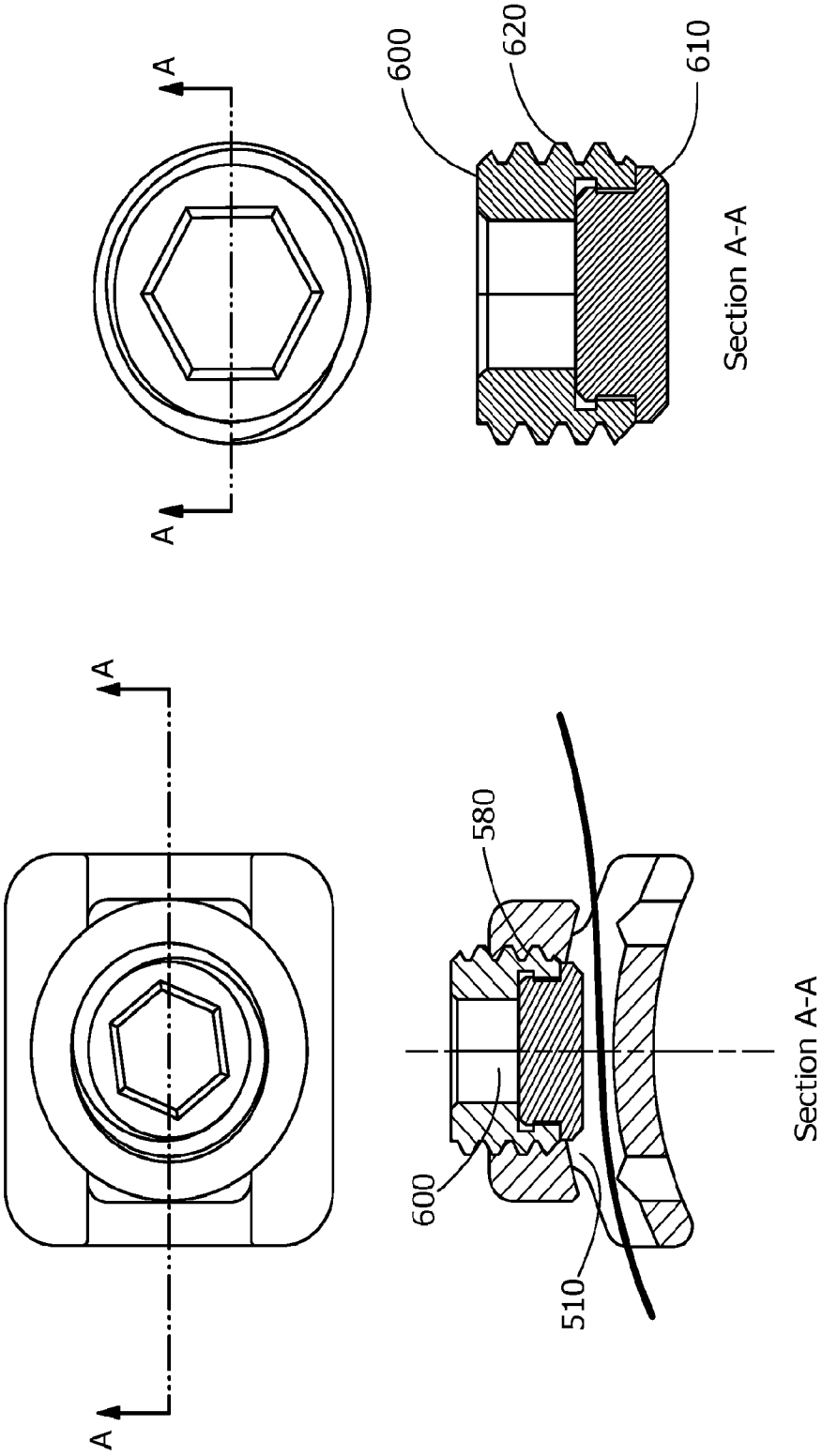


C1



C2

Figure A8



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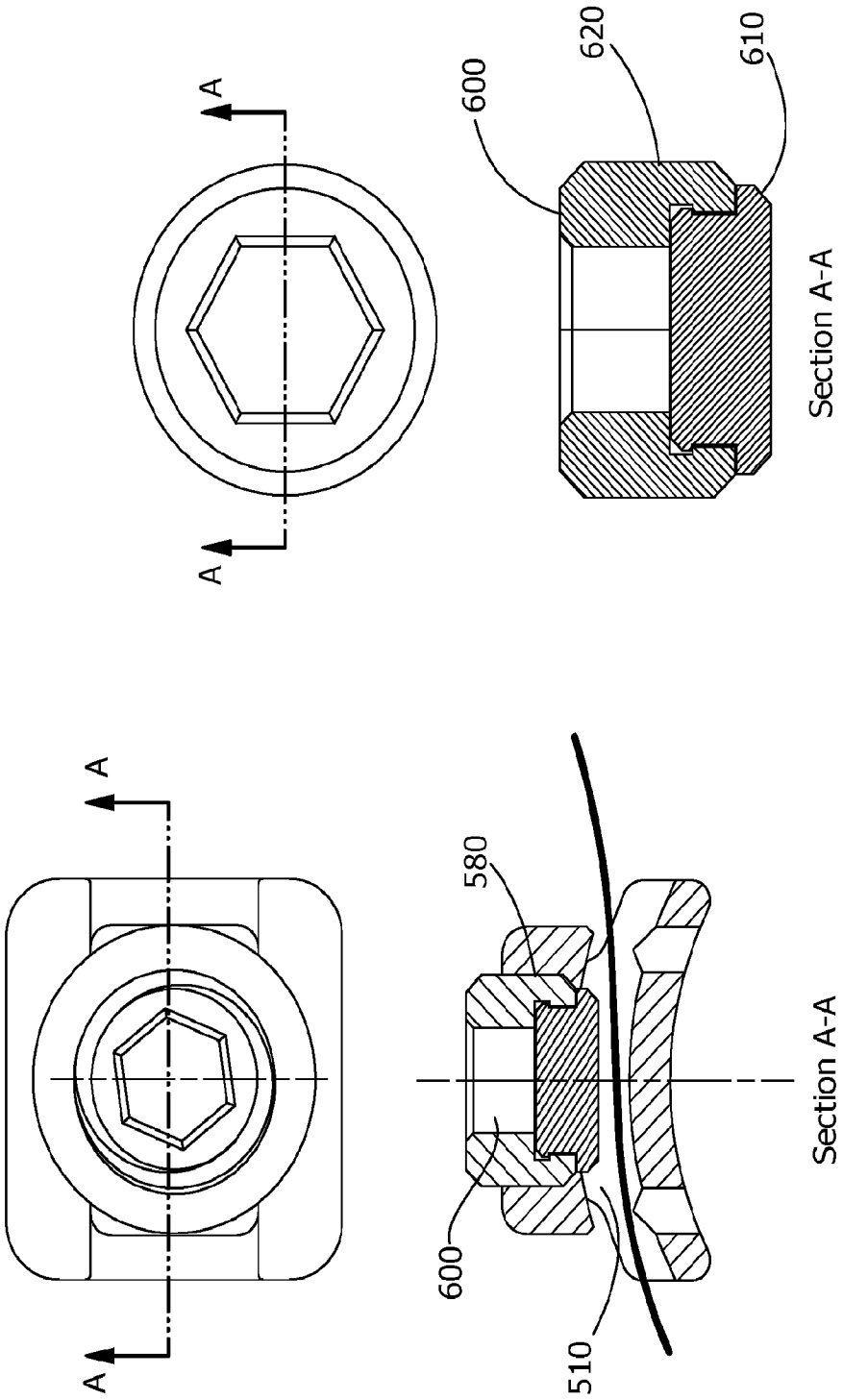

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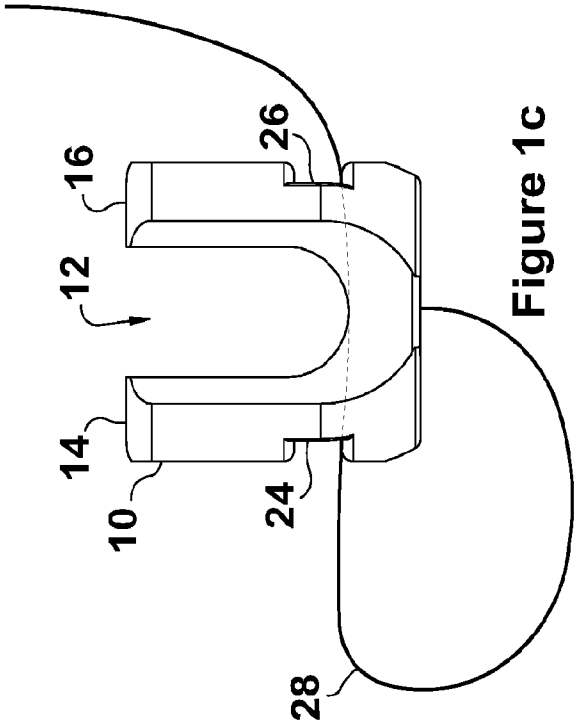
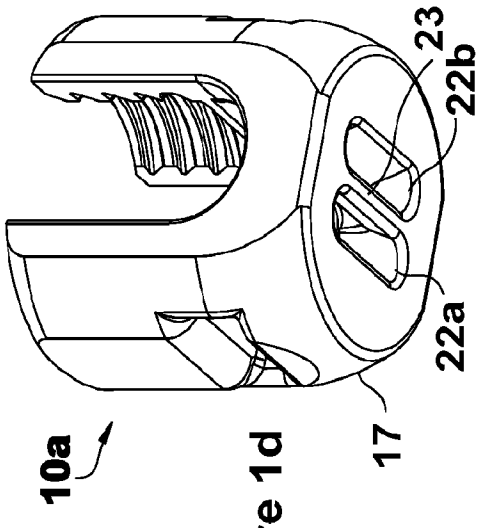


Figure 1c



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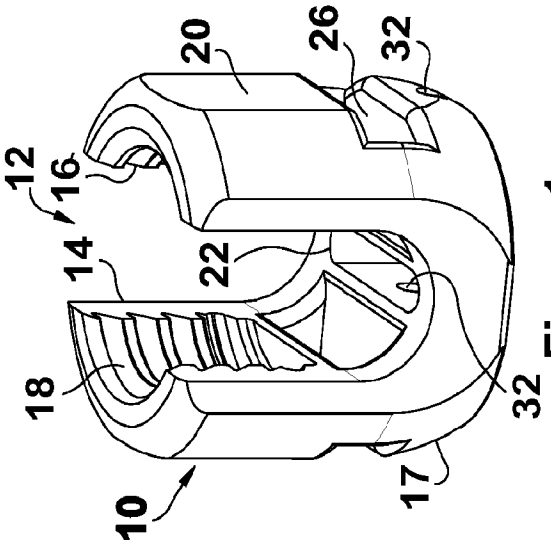


Figure 1a

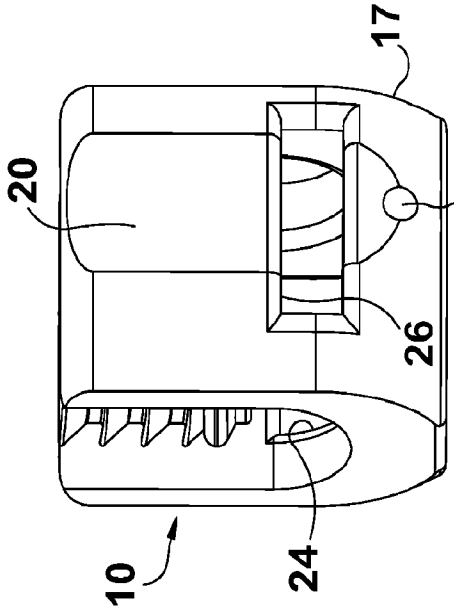
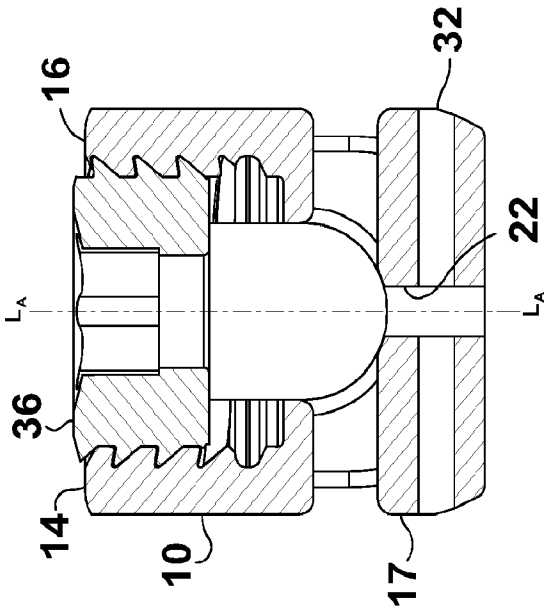


Figure 1b



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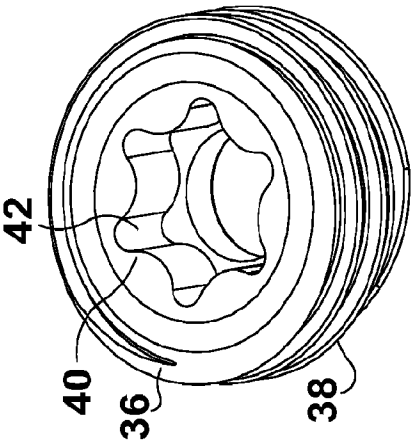

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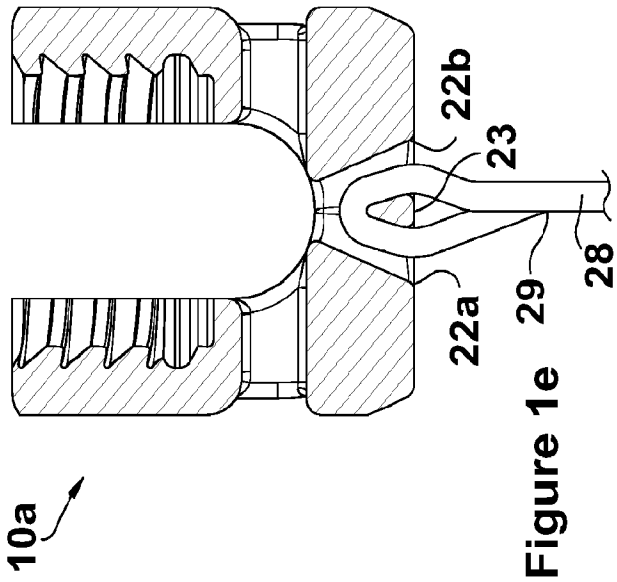

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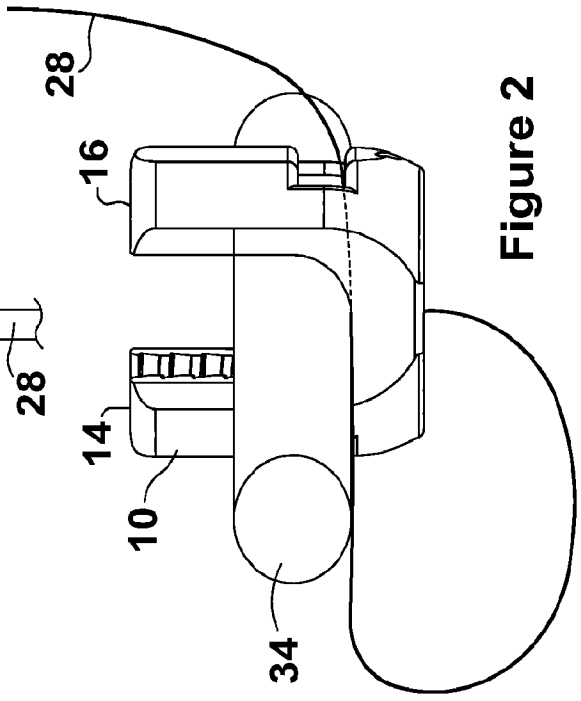

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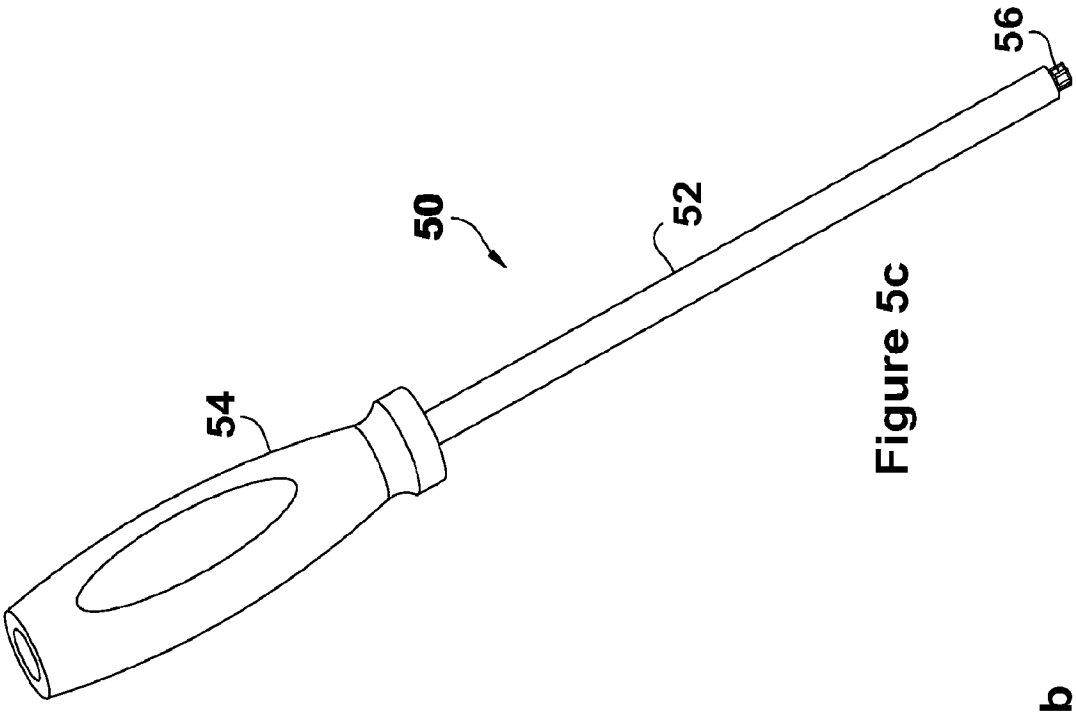

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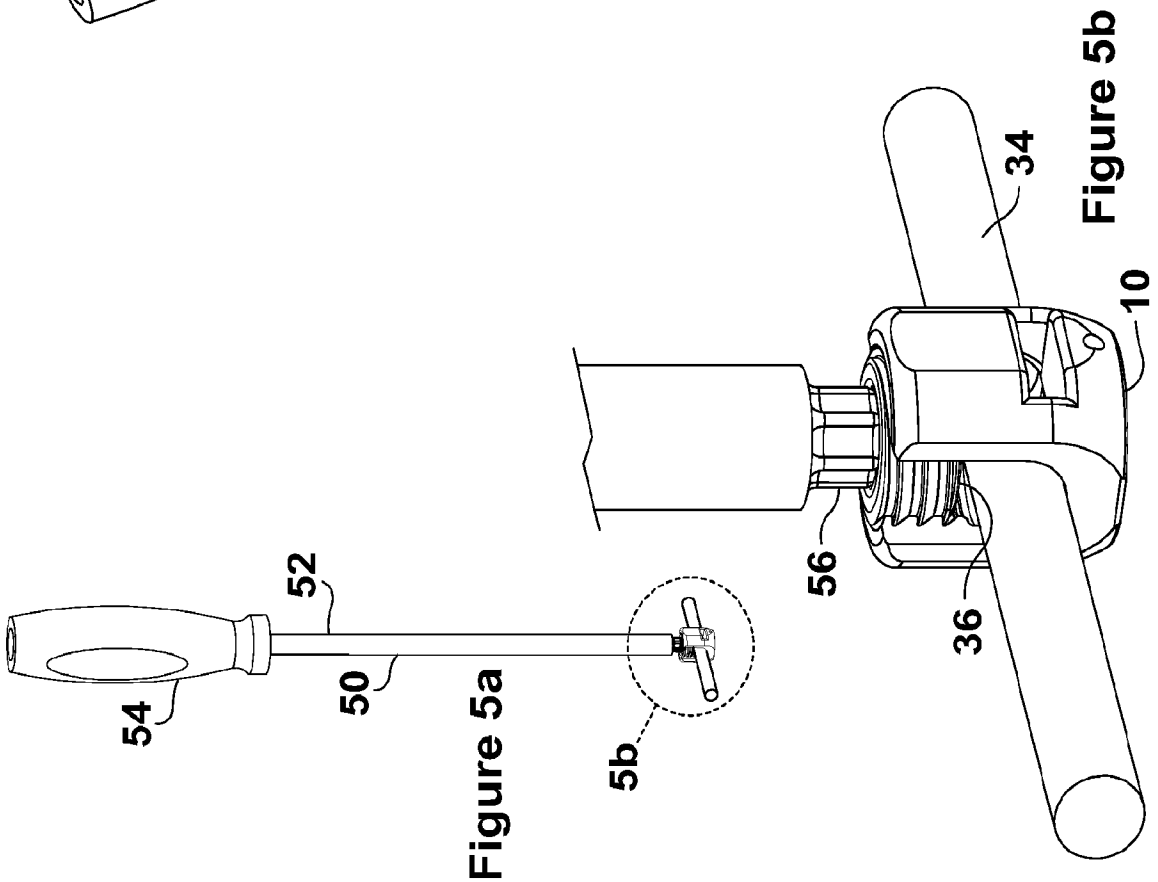


Figure 5b

Figure 5a

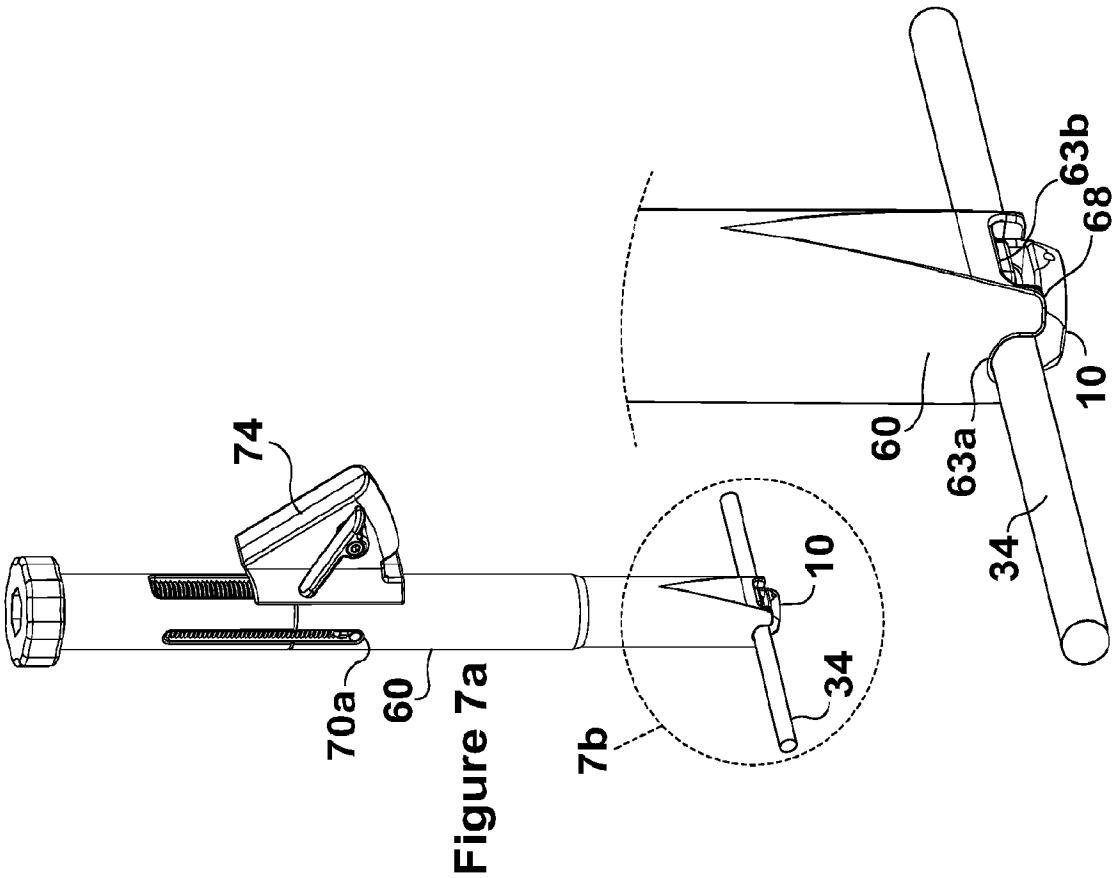


Figure 7a

Figure 7b

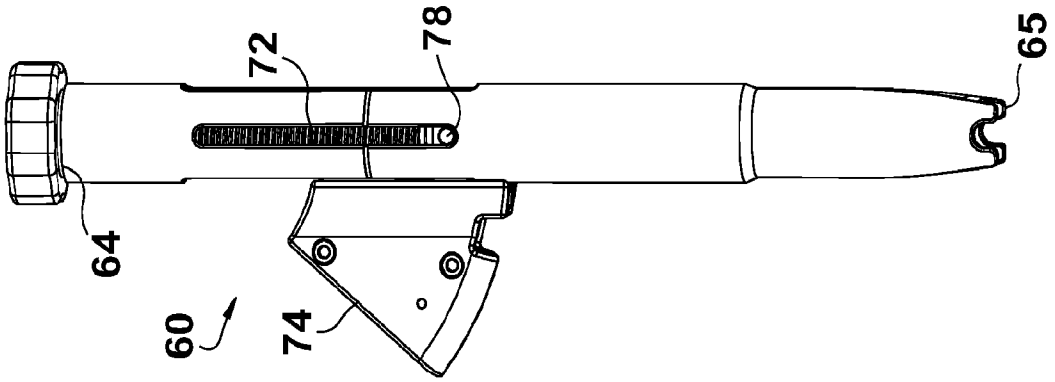


Figure 6b

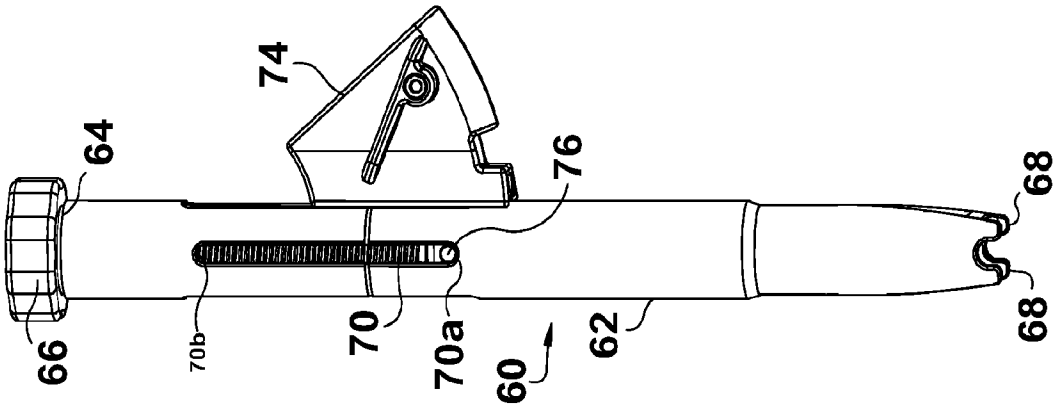


Figure 6a

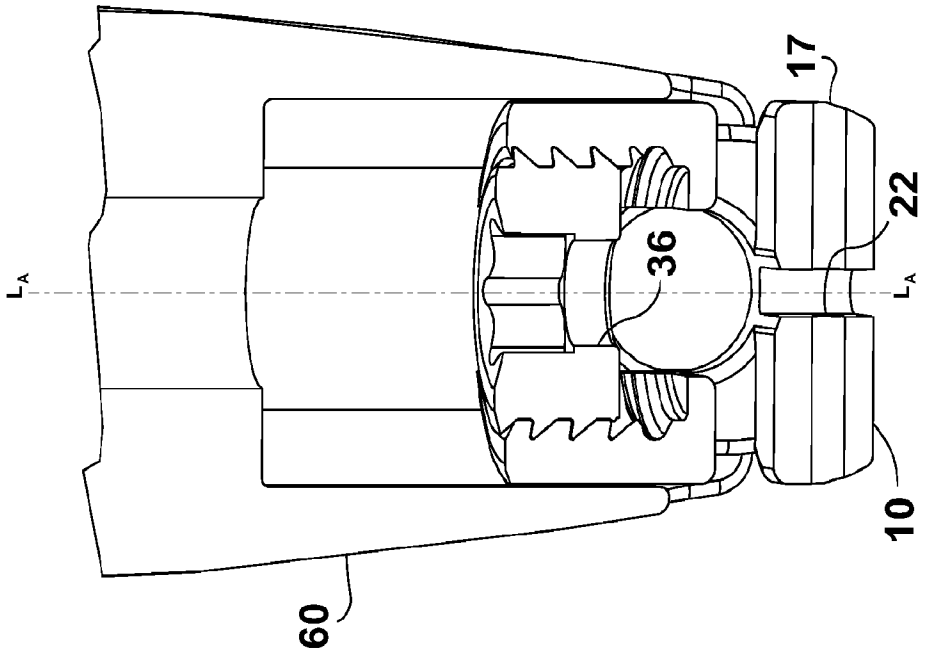
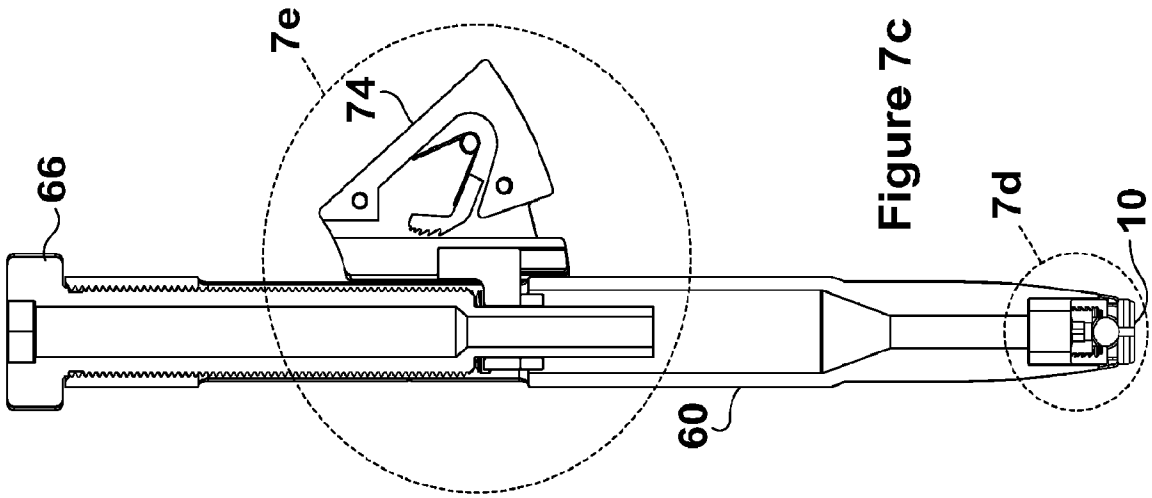


Figure 7d



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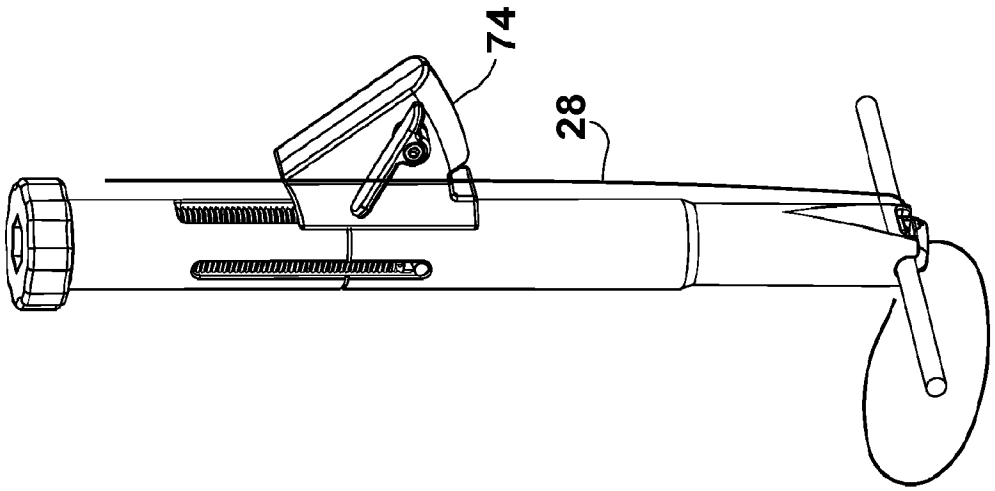

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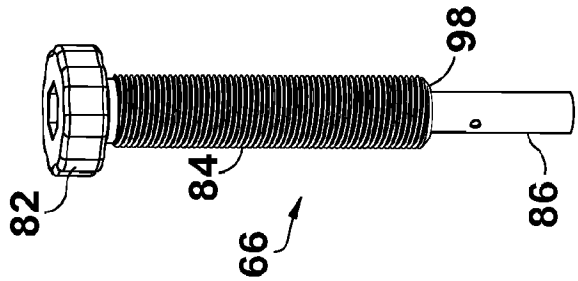

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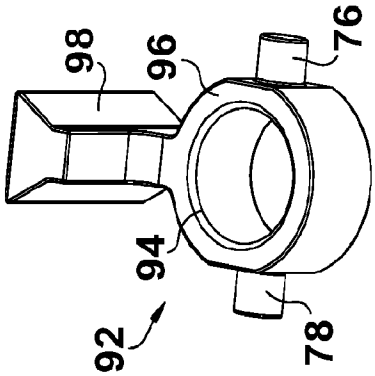


Figure 7f

Figure 7e

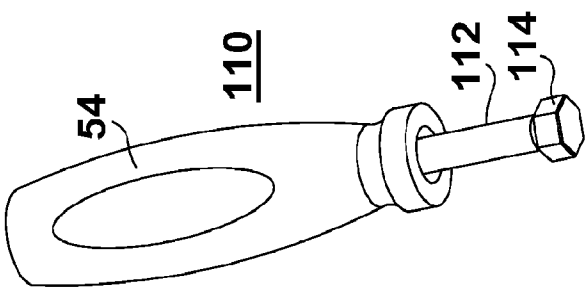
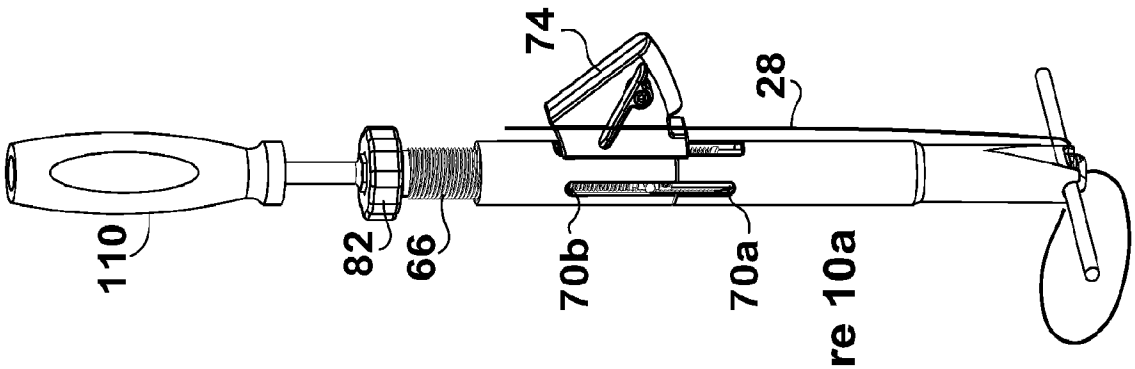


Figure 10b



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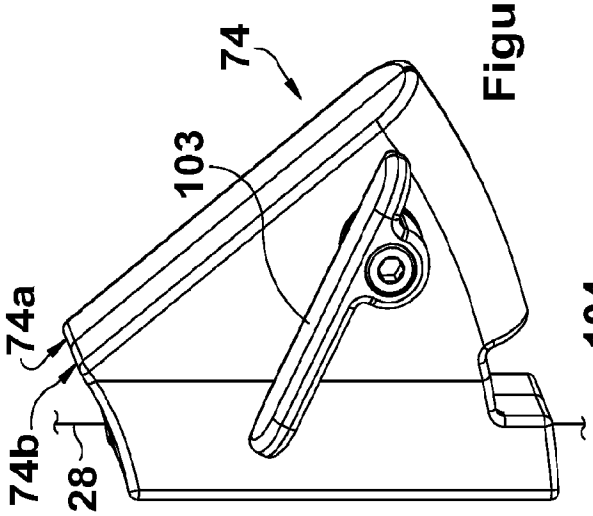

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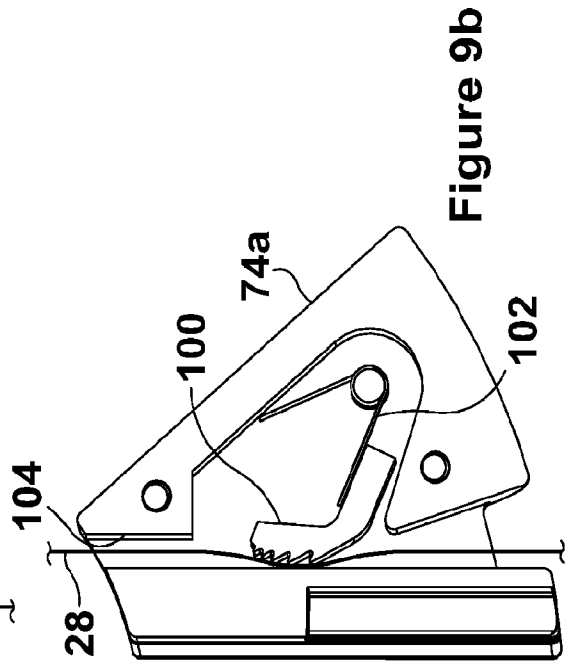

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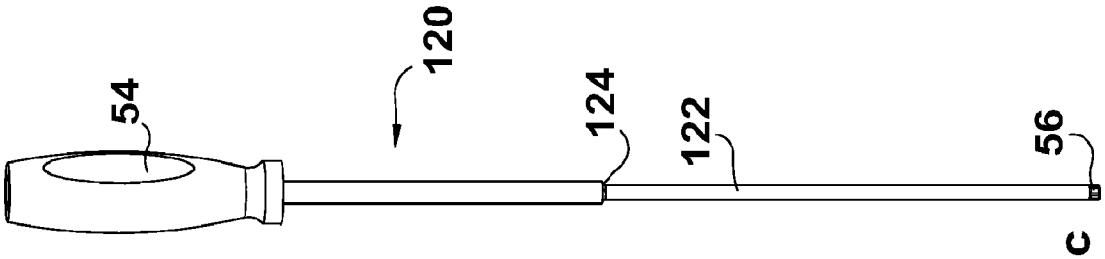
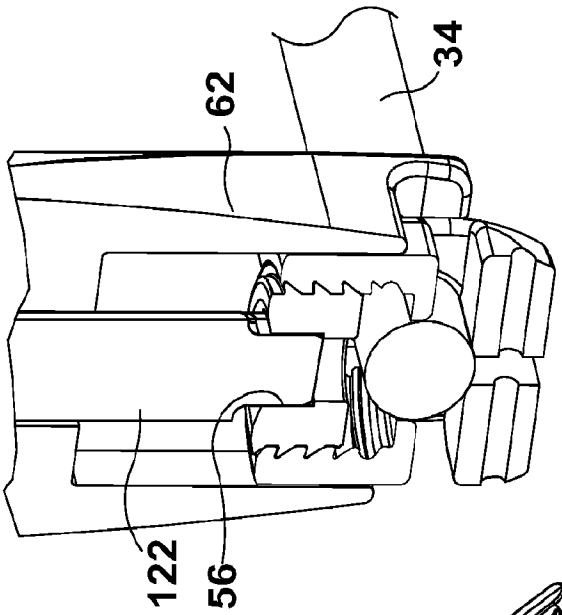


Figure 11c



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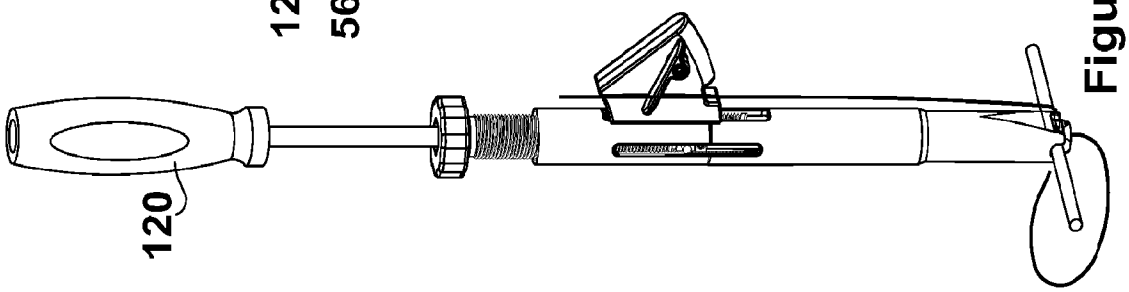

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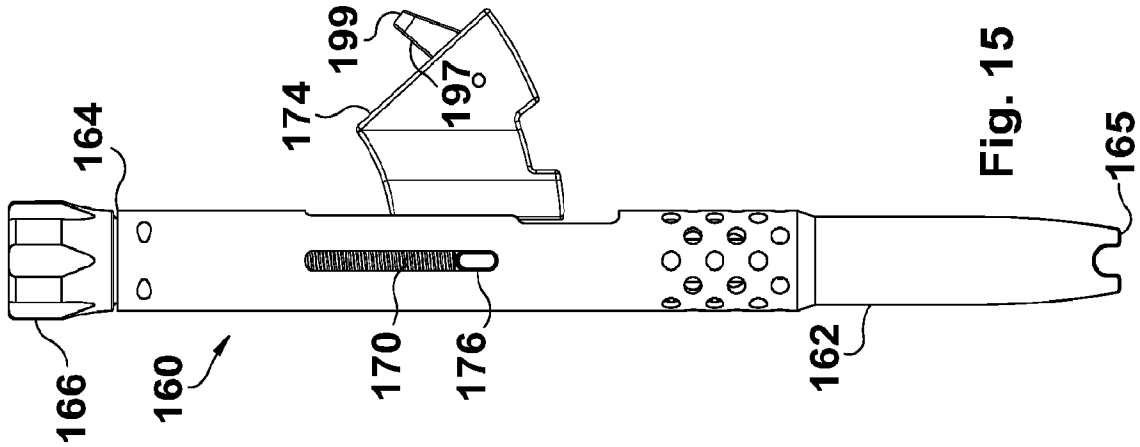

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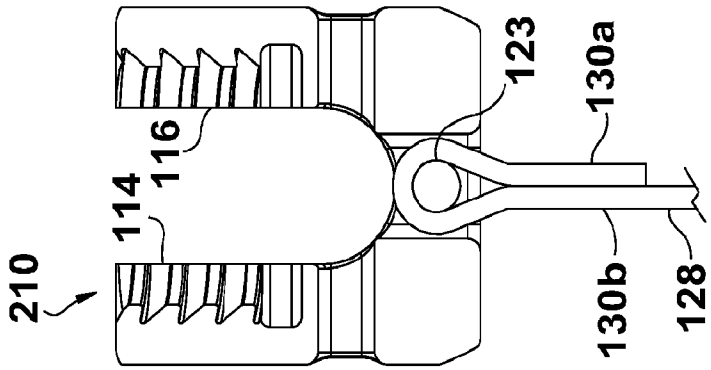

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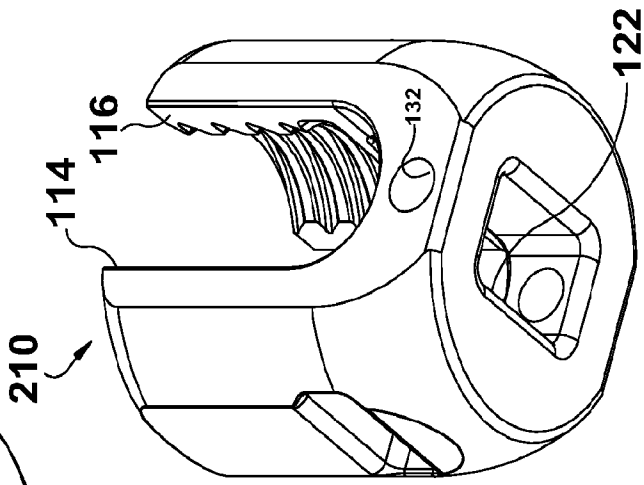

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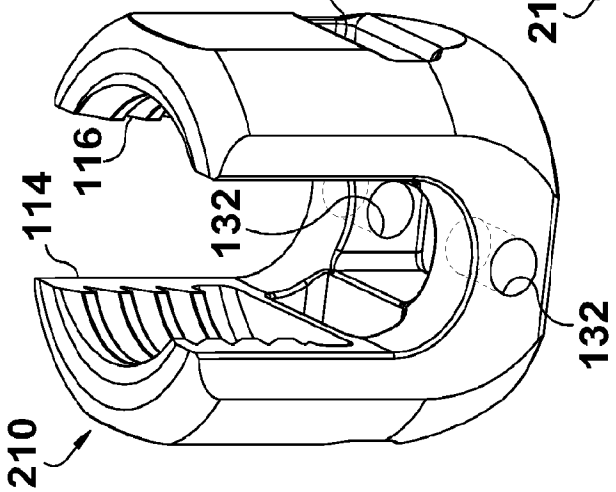

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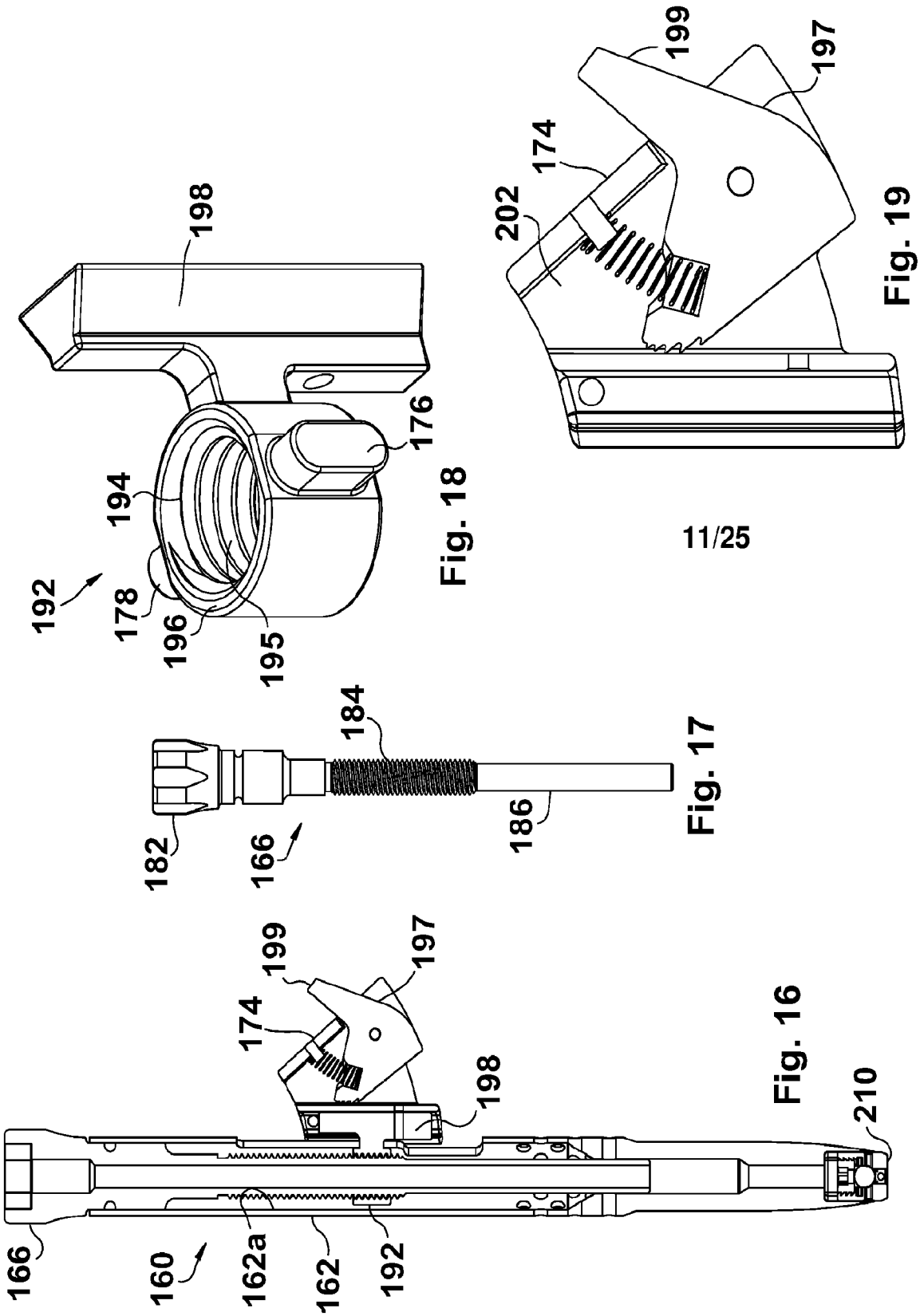


Fig. 19

Fig. 18

11/25

Fig. 17

Fig. 16

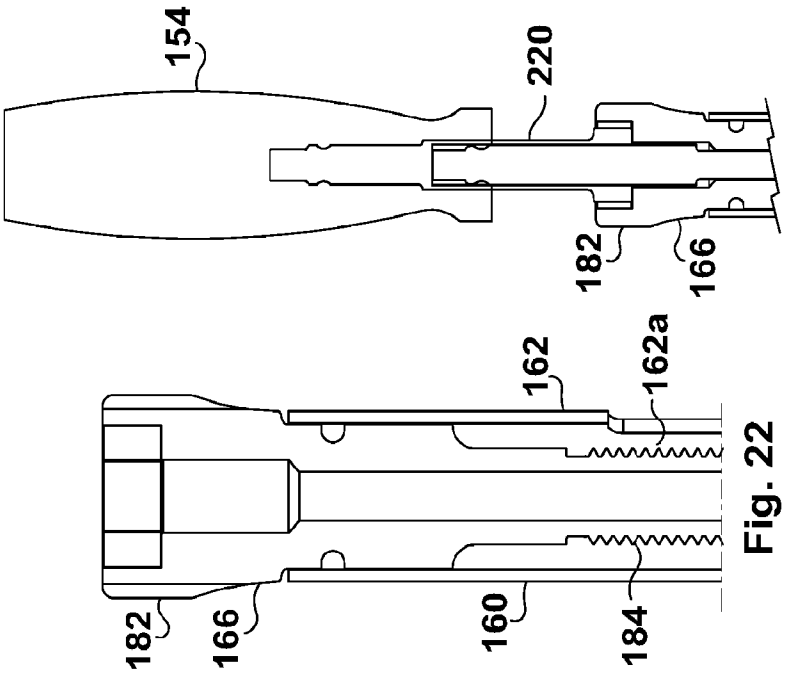


Fig. 23

Fig. 22

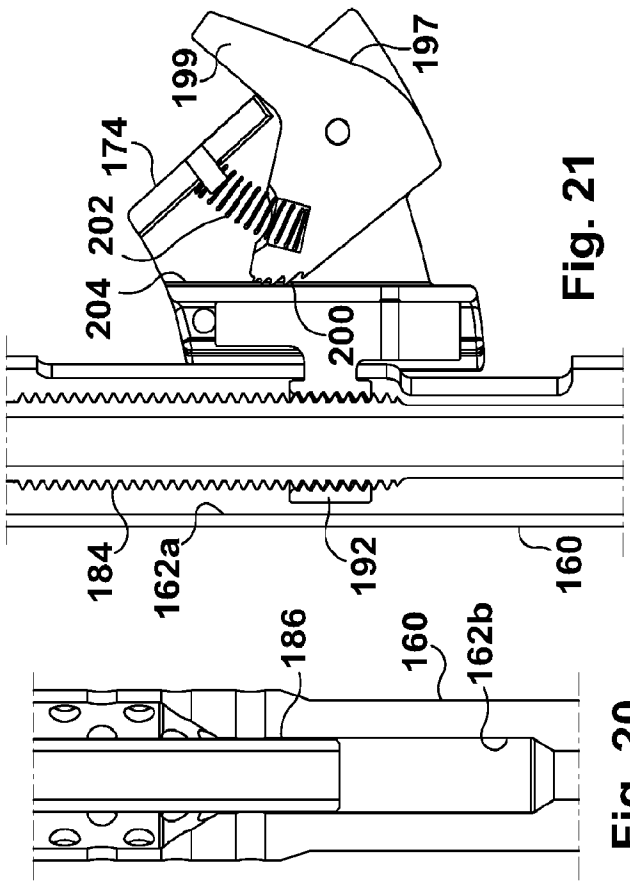


Fig. 21

Fig. 20

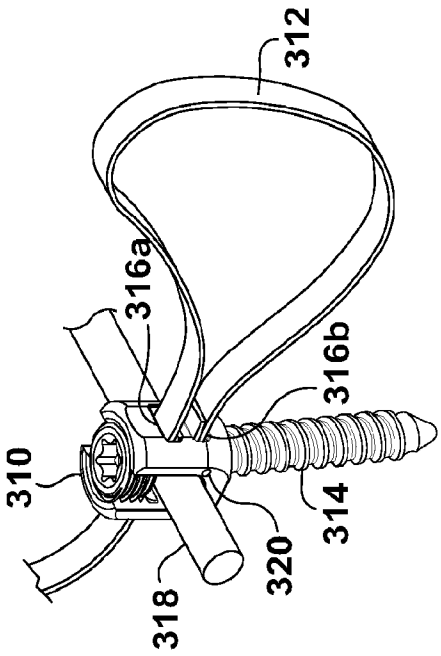
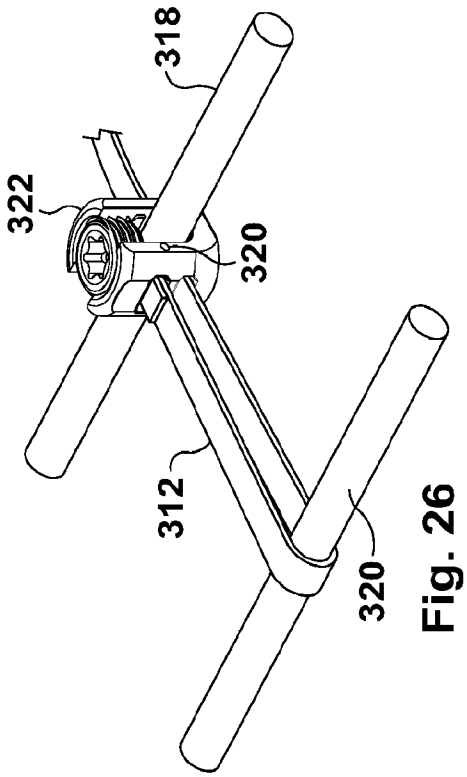


Fig. 25



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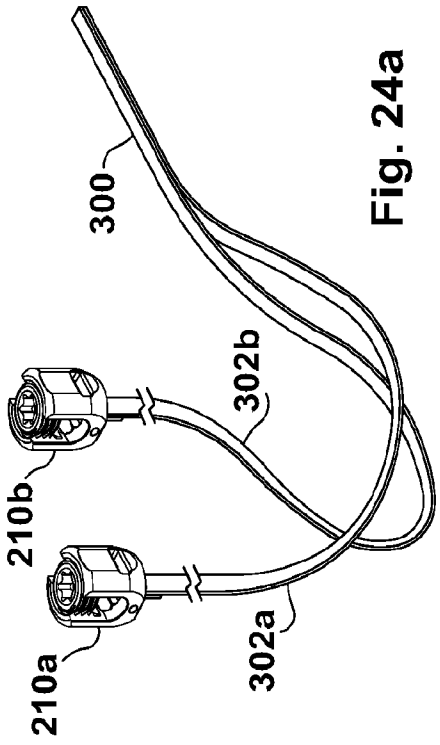


Fig. 24a

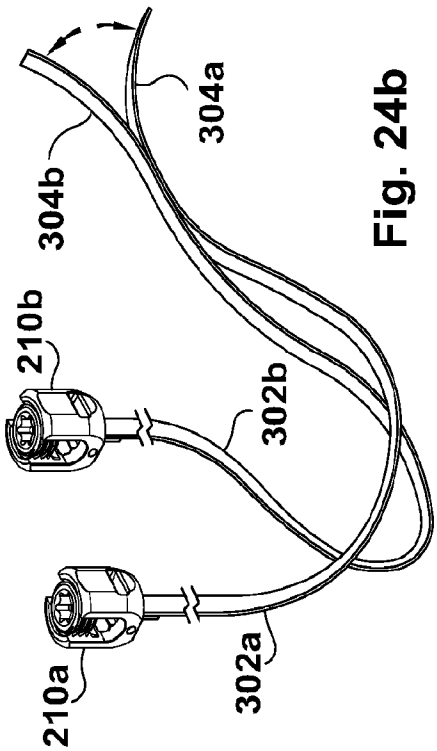


Fig. 24b

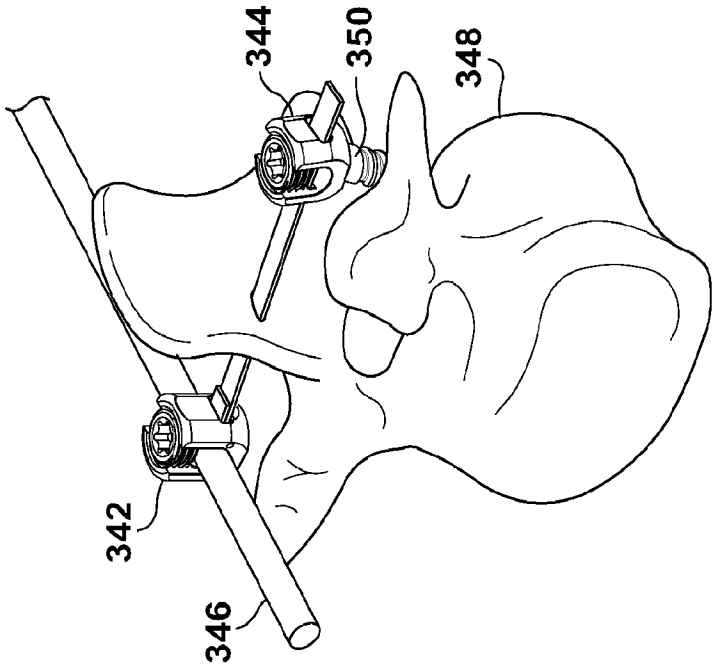


Fig. 28

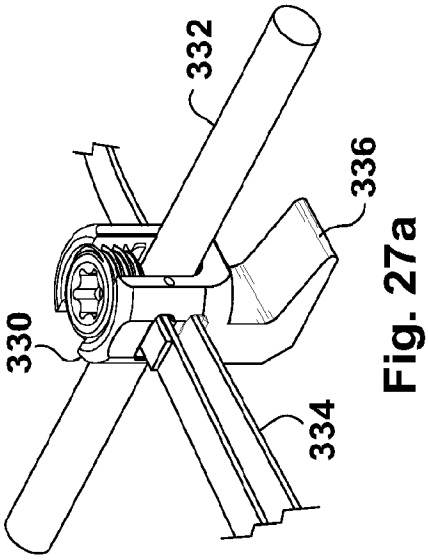


Fig. 27a

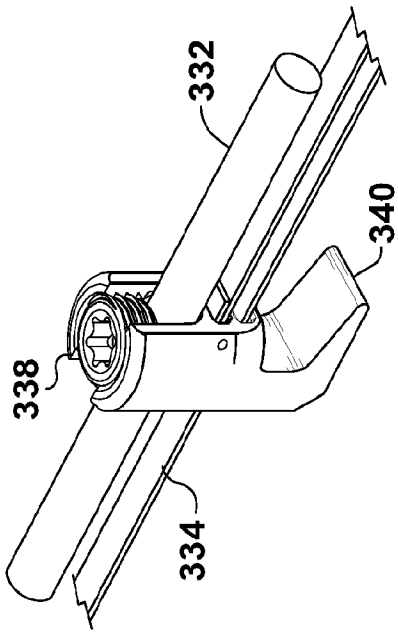


Fig. 27b

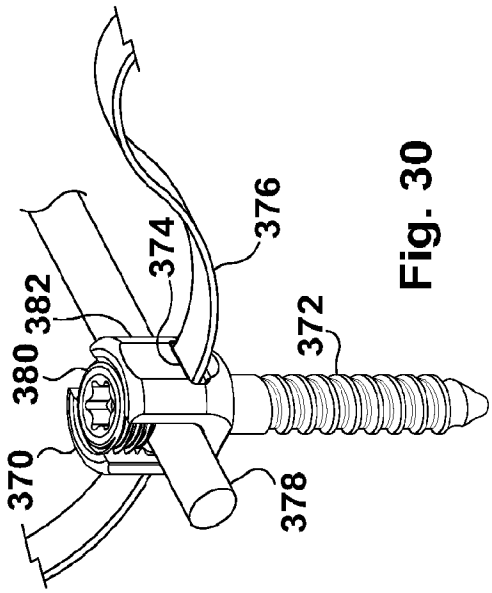
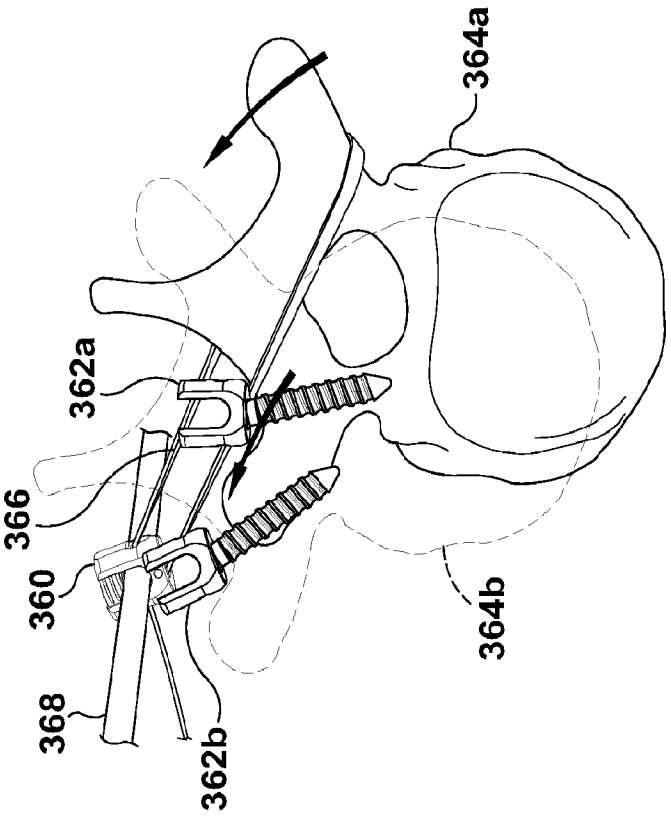


Fig. 30



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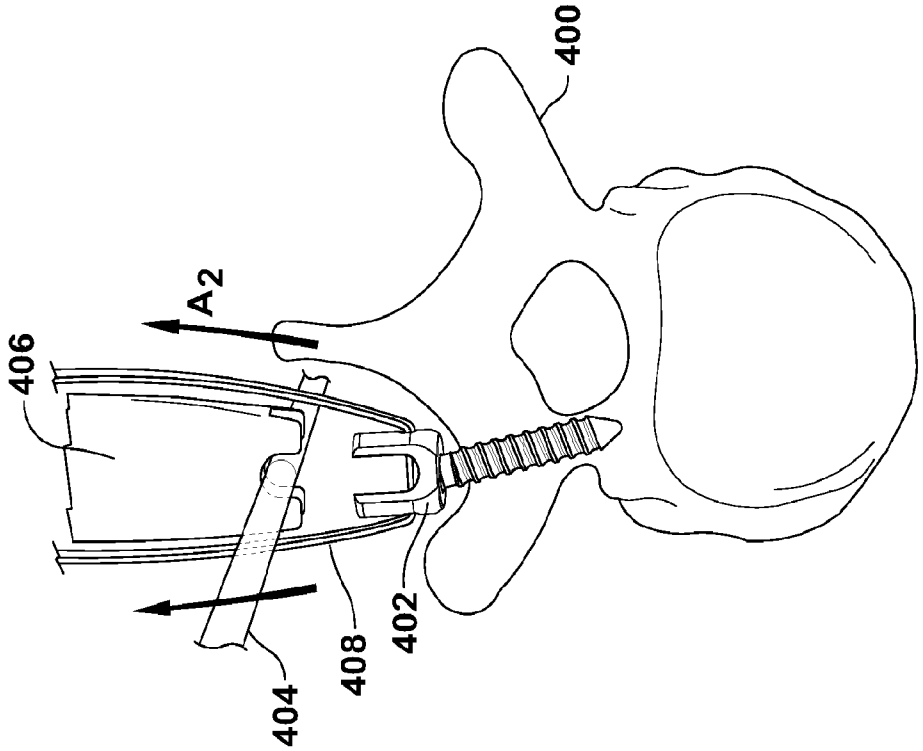

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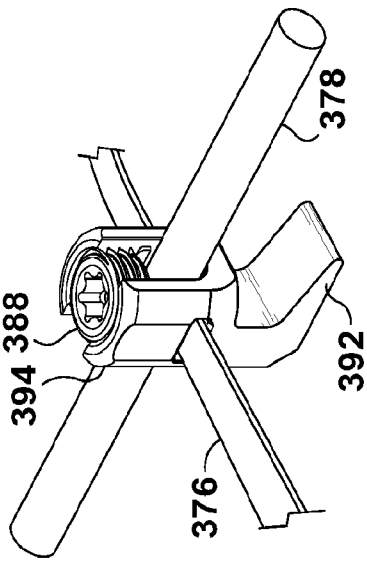

Fig. 31a

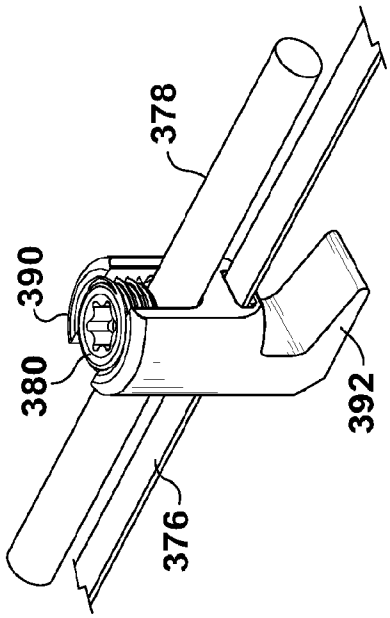

Fig. 31b

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2017/043976

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/70 *(2006.01)*

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 17/70

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

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

Patentscope, USPTO DB, Esp@cenet, DWPI, CIPO (Canada PO), SIPO DB, AIPN, DEPATISnet, VINITI.RU, SCSML.FSSI.RU, PatSearch (RUPTO internal), Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 2011/012690 A1 (ZIMMER SPINE et al.) 03.02.2011, fig. 1-4	1-8, 11, 14-15 9-10, 12, 13, 16, 17
X Y	US 2009/0292317 A1 (ZIMMER SPINE S.A.S.) 26.11.2009, fig. 4A-B, 13A-B, 18C	18-20 9-10, 12, 13, 16, 17
A	FR 2900561 A1 (TORNIER SOCIETE PAR ACTIONS SIPLIFIEE) 09.11.2007	1-20
A	US 5380326 A (CHIH-I LIN) 10.01.1995	1-20

☐ 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 document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 September 2017 (21.09.2017)	05 October 2017 (05.10.2017)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer Y. Skvortsova Telephone No. (495)531-64-81

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