(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 May 2016 (06.05.2016)

(10) International Publication Number
WO 2016/070191 A1

(51) International Patent Classification:
A61B 17/88 (2006.01)

(21) International Application Number:
PCT/US2015/058670

(22) International Filing Date:
2 November 2015 (02.11.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/073,968 1 November 2014 (01.11.2014) US

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(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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(54) Title: COMPRESSION FIXATION SYSTEM

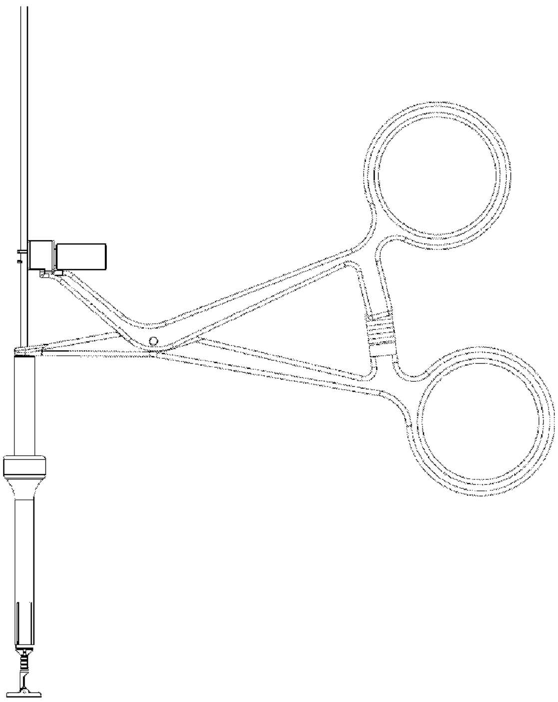

FIG. 1

(57) Abstract: The invention is directed in various aspects to a compression fixation system that includes coupling components and locking assemblies for connecting two or more separate elements in a fixed arrangement. For example, the system is useful for connecting and compressing two or more elements selected from bones and bone fragments. The system includes a substantially linear coupling component, such as, for example, a Kirschner Wire ("K- Wire") and locking assembly elements that engage with the coupling component in a coaxial orientation. The coupling component includes at least a linear portion and an anchor portion, the anchor portion configured to be fixed within or adjacent to a first one of the elements to be connected and the linear portion configured to be fixed adjacent to a second one of the elements to be connected, where the locking assembly is attached coaxially with and locked against the second element to achieve compression and fixation.

WO 2016/070191 A1

Published:

— *with international search report (Art. 21(3))*

TITLE: COMPRESSION FIXATION SYSTEM

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[001] RELATED APPLICATIONS

[002] This application claims the benefit under 35 U.S.C. §119 (e) to U.S. Provisional Application Ser. No. 62/073,968 filed Nov 01, 2015, the entirety of which is incorporated herein by reference.

[003] FIELD OF INVENTION AND BACKGROUND

[004] The invention relates generally to a locking assembly and a compression fixation system for fixing two or more elements together and to maintain, and optionally adjust a desired degree of compression across the two or more objects. The system is suitable, for example, for connecting and compressing two or more elements selected from bones and bone fragments. The system includes a substantially linear coupling component, and a locking assembly that engages with a locking assembly-receiving portion the coupling component in a generally coaxial orientation.

[005] The invention is described herein below in relation to bone fractures, which is but an example of the useful application of the invention. One skilled in the art will appreciate that the locking assembly and compression fixation system components and the methods of use thereof as described herein can be used without undue adaptation for applications that include, but are not limited to: connecting one or more medical devices or appliances to bone; connecting one or more medical or other devices together; repairing structural components, for example, household, building and construction components such as combinations of two or more pieces of wood, concrete, supports, beams, studs, joists, columns, wall boards; and the like.

[006] Devices and systems as disclosed herein are useful for a variety of applications, including with particularity, orthopedic fixation. There are many needs in orthopedics for the fixation of bones. In some instances, adjacent bones must be fixed together to allow for healing of damaged associated soft tissue, or to replace the function of such soft tissue, such as in the case of ligament damage between adjacent bones as well as tendon damage. In other instances, fractures of bones must be corrected by alignment, reduction of space between, and compression of the bone fragments to enable bone healing. Many approaches are known in the medical arts for achieving the attachment, fixation, and desired degrees of compression of bones and bone fragments. Generally, for example, threaded screws with and without heads, pins and rods, and wires may be used. There are challenges with all of these, which include, for example, imprecise compression and fixation, protrusion of the fixation element from bone into tissue (screw heads, twists of wires), bone loss/damage due to size of fixation element and damage to bone (for example, thread stripping of screws within bone), and costs associated with inventory to provide the number of components needed to meet size ranges of fractures.

[007] Included in the art are several examples of compression bone fixation systems that are aimed at overcoming the shortcomings of wires and screws for bone fixation. In many instances, such systems provide fixation that overcomes some of the limitations of bone screws and wires. However, it remains a problem in the art to achieve fixation of relatively small bones using low profile fixation components that are capable of fine adjustment to placement and tensioning, are relatively simple to manipulate and are adjustable and/or removable post fixation.

[008] Accordingly, there is a need for a fixation system that can fix, align and compress bone elements together wherein the system presents minimal risk of bone compromise and loss, and provides ease of use by the clinician, adjustability in size to minimize inventory needs, and highly reliable and precise and reversible locking to achieve reliable fixation and enable the clinically needed degree of compression between bone elements. Indeed, a particular advantage of the inventions provided herein is overcoming the challenges presented in the art with implant placement and subsequent adjustment or removal.

[009] BRIEF DESCRIPTION OF THE DRAWINGS

[010] Features and advantages of the general inventive concepts will become apparent from the following description made with reference to the accompanying drawings, including drawings represented herein in the attached set of figures, of which the following is a brief description:

[011] FIG 1 shows a side view of a first embodiment of a fully assembled compression fixation system engaged with coupling component tensioning and insertion tools;

[012] FIG 2 shows in the left panel an enlarged perspective view of an embodiment of a fully assembled compression fixation system engaged with coupling component locking assembly insertion tools, and in the upper right panel a close up perspective view of respective embodiments of a coupling component, and in the lower right panel an anchor and an anatomically correct model of a foot with a metatarsal fracture that is fixated with an embodiment of a compression fastening system according to this disclosure;

[013] FIG 3 shows alternate front, side, back, perspective, bottom, side and top views of an embodiment of a coupling component;

[014] FIG 4 shows in the upper left panel alternate front, bottom, side, top, side, perspective and end views of the embodiment of the anchor shown in FIG 2 the anchor comprising a toggle, and in the bottom left and right panels, respectively, cross sectional side views of respective embodiments of the anchor and coupling component;

[015] FIG 5 shows in the upper left panel a close up perspective view in color of the compression fixation assembly in an open configuration, and in the upper right panel a close up of the locking assembly, and in the lower left panel an enlarged cutaway perspective view of a locking assembly in a locked configuration engaged with a coupling component of the compression fixation assembly, and in the lower right panel, an enlarged side view of the embodiment of a fully assembled compression fixation system engaged with coupling component locking assembly;

[016] FIG 6 shows in the upper left panel side views of alternate split and slit embodiments of locking collets, and in the middle left panel cross sectional side views of alternate smooth and textured embodiments of locking collets, and in the lower left panel an embodiment of a locking assembly cap on the left and an embodiment of a securement ring on the right; in the upper right and lower right panels, respectively, show alternate open and locked configuration views of the locking assembly embodiment;

[017] FIG 7 shows in the left panel alternate front, perspective, top, side bottom, back, side, and bottom views of a split embodiment of a locking collet, and in the right panel alternate front, perspective, top, side bottom, back, side, and bottom views of a slit embodiment of a locking collet of the locking assembly;

[018] FIG 8 shows in the top panel alternate cross sectional side and perspective views of a locking cap, and in the middle panel, alternate top, side, bottom and side views of a locking cap, and in the bottom panel, alternate side, top/bottom, and perspective views of a securement ring of the locking assembly;

[019] FIG 9 shows in the upper panel, a perspective view of an embodiment of assembled insertion tools, and in the lower left and right panels, respectively, perspective views of the disassembled outer and inner sleeve components of the insertion tools;

[020] FIG 10 shows in the left panel a cross sectional perspective view of the assembled insertion tools, and in the right panel, an cross sectional side view of the embodiment of a fully assembled compression fixation system engaged with coupling component locking assembly;

[021] FIG 11 shows alternate top, side, front, side, back, bottom and perspective views of the outer sleeve of the insertion instrument shown in FIG 9;

[022] FIG 12 shows alternate top, perspective front, side, back, side and bottom views of the inner sleeve of the insertion instrument shown in FIG 9;

[023] FIG 13 shows alternate top, perspective front, side, back, cross sectional side, and bottom views of the inner sleeve of the insertion instrument shown in FIG 9;

[024] FIG 14 shows enlarged alternate perspective views of the assembly shown in FIG 1, the left panel showing the engagement of the tensioning instrument with the coupling component pre-tensioned, and the right panel showing the same assembly after an actuation of the tensioning instrument;

[025] FIG 15 shows alternate views of a tensioning instrument, the upper left panel showing a top view of the instrument, the upper right panel showing a side view, the middle panel showing a close up view of the coupling component engagement features, the lower left and right panels showing respective front end and back end perspective views of the tensioning instrument;

[026] FIG 16 shows in the upper panel a side view of a second embodiment of a fully assembled compression fixation system engaged with coupling component tensioning and insertion tools, and in the lower left panel a side view of the locking assembly and coupling components, and in the lower right panel a bottom perspective view of the locking assembly and coupling components;

[027] FIG 17 shows various views of components of an alternate exemplary embodiment of a locking assembly, including in the upper and middle panels, respectively, solid and cross sectional views of a collet (left), a collet seat (center), and a compression nut (right), and in the lower left panel the exemplary locking assembly assembled with the coupling component inserted through the central bore, and in the right panel the assembled locking assembly components form a channel there through for receiving a coupling component to achieve locking fixation with the coupling component;

[028] FIG 18 shows in the upper left panel an end view of the counter torque insertion tool engaged with an assembled locking assembly, showing the edges of the opposing pins, and in the upper right and lower left panels alternate cross sectional views of the assembly, and in the lower right panel a cutaway view of the outer sleeve of the counter torque insertion tool showing in a depicted embodiment opposing pins that are press fit into the outer sleeve;

[029] FIG 19 depicts respectively in the upper left, upper right, lower left and lower right panels alternate embodiments a compression fixation system comprising an first end having a anchor and a second end having a locking compression means for securing and locking an elongate coupling component; and,

[030] FIG 20 depicts respectively in the upper left and upper right panels alternate embodiments a compression fixation system comprising an first end having a anchor and a second end having a locking compression means for securing and locking an elongate coupling component, and in a lower panel an alternate embodiment of an anchor component.

[031] Features and advantages of the general inventive concepts will become apparent from the following description made with reference to the accompanying drawings, including drawings represented herein in the attached set of figures, of which the following is a brief description:

[032] This disclosure 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.

[033] DESCRIPTION

[034] This description 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.

[035] The general inventive concepts will now be described with occasional reference to the exemplary embodiments of the invention. 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.

[036] As used herein, the singular forms “a,” “an,” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. The term “proximal” as used in connection with any object refers to the portion of the object that is closest to the operator of the object (or some other stated reference point), and the term “distal” refers to the portion of the object that is farthest from the operator of the object (or some other stated reference point). The term “operator” means and refers to any professional or paraprofessional who delivers clinical care to a medical patient, particularly in connection with the delivery of care. More broadly, in connection with non-medical uses of the inventions described herein, the term refers to a user of one or more components of the compression fixation system.

[037] Unless otherwise indicated, all numbers expressing quantities, properties, 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 desired 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.

[038] Use of Compression Fixation System

[039] Generally in accordance with the embodiments described herein and depicted in the drawings, the invention is directed in various aspects to systems, components, instruments, and methods for fixing and /or compressing elements along a generally rectilinear path, using at least one of each of a coupling component and a locking assembly. As described herein, the locking assembly and the coupling component engage in a generally coaxial orientation, such that, at least a portion of the coupling component comprises a generally rectilinear configuration and is adapted to engage with the locking assembly.

[040] In certain particular embodiments, the system enables fixation of two or more traumatized, fractured, deformed, and/or otherwise displaced bones or bone fragments. Embodiments of compression fixation systems are disclosed herein that significantly enhance the surgical techniques for repairing damaged bones, such as fractured phalangeal and metatarsal bones, and provide improved and superior performance in the achievement and maintenance of fixation and desired bone compression as compared with use of conventional wires and screws. For example, in contrast to screws, certain embodiments of the systems described herein enable flexible and adjustable orientation and positioning of adjacent bones to be fixed, which cannot be achieved using conventional rigid screws. In particular, the adaptable sizing of the coupling components enables customized sizing without the need to have a wide array of sizes on hand such as is required when using screws. That is, the coupling components are adaptable for use with different locking assemblies, and the coupling components can be adjusted in a length dimension, thus obviating he need for alternate lengths. And in another example, in contrast to conventional K (Kirschner) wires which are also used in the medical arts for bone fixation whereby they are fixed into compression via crimping and twisting, certain embodiments of the systems described herein enable precise compression that can be finely and selectively adjusted without compromise to the healing bone or to the fixation system components. Moreover, the instant disclosure enables use of ancillary fixation devices such as flanges and plates that can be positioned and locked to bone using the adjustable locking assemblies described herein.

[041] Significant benefits can be realized in connection with surgical use of the fixation system, including, but not limited to: optimized patient experience and outcome as a result of controlled and precise compression to enhance healing and minimized bone damage/loss; improved time efficiency during surgery; and enhanced options for implant selection and customization. Time savings during surgery are realized in comparison to the current state of the art due to the elimination of need to precisely measure for and select a specific length of implant; the instant disclosure provides a system that can be customized in size without any compromise in fixation. Cost savings can also be realized through reduction of required implant sizes; the instant disclosure provides a system in which one implant fits all and can be easily sized to the specific patient, resulting in a significant reduction in the number and size of devices that must be stocked.

[042] While the examples provided herein pertain to the fixation/compression of bone material, it will be appreciated that other materials of relevance to the body, including biological and non-biological, implanted and non-implanted, can be fixed together and as desirable, compressed using the inventions disclosed herein. Examples herein include use of the compression fixation system for reduction, alignment, fixation and/or compression of bone fragments such as in the phalanges and metatarsal bones. Of course, it will be appreciated by one skilled in the art that the inventive components can be used in connection with most types of fractures, particularly such fractures that are typically treated by percutaneous insertion of pins and wires and screws. Further, the system is suitable for use with other bone element fixation indications.

[043] COMPONENTS, INSTRUMENTS AND TECHNIQUES FOR COMPRESSION/ FIXATION

[044] EXAMPLE 1: Snap Fit Compression Fixation System

[045] Referring now to the drawings, FIG 1 shows a side view of a fully assembled compression fixation system engaged with coupling component tensioning and locking assembly insertion instruments.

[046] The compression fixation system includes a coupling component that is selected from suitable wire and other bone pins and similar rod type devices, such as, for example K-wire. The coupling component is adapted at a first end, intended to be most distal to the operator, with an anchor portion for fixation within or on a distal outer surface of a first bone element. The coupling component is further adapted at a second end, intended to be most proximal to the operator, with a locking assembly receiver portion that is generally rectilinear. In various embodiments, at least the proximal portion of the coupling component is substantially rectilinear, and cylindrical, while the distal and a medial portion of the coupling component may be other than rectilinear or may be initially rectilinear and manipulated by the operator for optimal engagement and shape conformity with the two or more elements to be fixed.

[047] The distal anchor portion of the coupling component may be selected from any of a number of anchors known in the art, and generally selected from (i) those that are adapted to engage with and remain substantially within and anchor to a bone, and (ii) those that extend through bone and are adapted to engage with an outer surface of a bone or bone fragment, or a plate or other non-bone material that is intended to be held adjacent to the distal bone element. Some examples of anchors that are adapted to engage with and remain substantially within and anchor to a bone include self or non-self tapping threads, and bone engagement features that can engage by press fitting such as keels, ribs and fins. Some examples anchors that extend through bone and are adapted to engage with an outer surface include coils, barbs, and toggles.

[048] Referring now to FIG 2, an anatomically correct model of a foot with a metatarsal fracture is shown, wherein the fracture is fixated with an embodiment of a compression fastening system according to this disclosure. As shown, an untrimmed coupling component extends proximally out of the upper surface of the fractured bone, and a locking assembly is fixed on the coupling component and is in compression against the proximal (upper) bone element while the anchor (not shown) is oriented opposite from the locking assembly on the distal side of the distal (lower) bone fragment to achieve locked fixation between the bones.

[049] One of ordinary skill will appreciate that the depicted coupling component can be provided in variable lengths, with or without curves or bends, with or without surface texture and/or surface features. Moreover, while the depicted coupling component is generally cylindrical in shape from the proximal end and terminates at the exemplary anchor, one of ordinary skill will appreciate that the shape may be other than cylindrical (i.e., the cross section may be other than circular). Thus, in some alternate embodiments, the coupling component may have a cross section that is selected from one of the following non-limiting examples, including, scalloped, star shaped, hexagonal, square, and ovoid. Likewise, the coupling component may be uniform in cross sectional shape and width along its entire length, or it may comprise regions that vary and include combinations of different cross sectional shapes, widths/diameters, and textures.

[050] Thus, it will be appreciated that any particular portion of a coupling component which may be substantially rectilinear for receiving a locking assembly may be cylindrical or otherwise shaped and may be smooth or have any one of a variety of surface features such as grooves or notches and textures that comprise knurling or other non-smooth texturing. Further, while the exemplary embodiment of the coupling component shown in the drawings terminates as a cylinder at the proximal end, there may be alternate shapes and features at the proximal end that are suited for engagement with a tool or instrument. Thus, in some non-limiting examples, the coupling component may comprise at its proximal end a hemispherical, conical or frustoconical feature, or a star, scallop or hex cross-section, or combinations of these.

[051] Referring now to FIG 3, alternate views of an embodiment of a coupling component are shown, and in FIG 4 cross sectional views of the distal portion of a coupling component and a detached toggle anchor are shown. In the depicted embodiment, the coupling component comprises a series of spaced circumferential grooves along at least a portion of its length, the grooves adapted for receiving one or more ridge features on the inner surface of a locking component. It will be appreciated that in some embodiments, the number and spacing of the grooves may vary such that there are more or fewer, the grooves are narrower or wider, deeper or shallower, and are equidistant or variably spaced. In addition, in alternate embodiments, a coupling component may comprise other surface features to either enhance sliding between a coupling component or to enhance friction there between. Further, such textures and features may vary along the length of a coupling component to differentially enhance surface contact with various instruments, compression locking components, and bone.

[052] In some alternate embodiments, the coupling component may have a diameter that permits cannulation through at least a portion of the coupling component. In some examples such an embodiments would include cannulated bone wires and pins. In other such embodiments, examples include tubes, conduit, pipes, and other substantially hollow components that are suitable to receive a locking assembly along at least a portion of the component that is rectilinear.

[053] Referring again to the drawings, enlarged views of the distal portion of an exemplary embodiment of a coupling component are shown in FIG 2. As depicted, the anchor is a toggle, which is pivotal around an axis that is perpendicular to a long axis of the coupling component. In the depicted embodiment, the toggle is pivotal in only one direction, the coupling component being adapted to receive the toggle into a recess that receives a portion of the toggle body whereby the overall cross sectional area of the distal end of the closed toggle matches the cross sectional area of the distal portion of the coupling component allowing a minimal profile for insertion into bone. The cantilever design enables actuation of the toggle against tissue that is distal to the most distal bone fragment to facilitate engagement of the toggle anchor with the bone for achieving fixation between the bone fragments. Of course, it will be appreciated that other mating configurations of a toggle and coupling component are possible.

[054] Referring to FIG 2, the left panel shows a proximal to distal end perspective view of the assembly including insertion instruments with a toggle anchor at the distal end, and FIG 2 upper right panel shows a close up alternate distal to proximal end perspective view of a deployed toggle anchor. In each of FIG 1 and FIG 2 the toggle is in a securement configuration, such that the toggle is pivoted so that it is aligned perpendicular to the long axis of the coupling component to enable securement against bone through which the assembly is passed. In the insertion configuration (not shown) the toggle is pivoted 90 degrees so that its axis is in line with the axis of the proximal end of the coupling component, for insertion into the bone and allowing clean exit from a hole in the bone that traverses the bone from a proximal to a distal end of the bone.

[055] Actuation of the pivot feature of the toggle rotates its position so that it is perpendicular to the axis of the coupling component, and is deployed to operate as an anchor, thereby preventing back out of the coupling component from the bone. According to the instant embodiment shown in FIG 2, the toggle as shown attaches to and engages with the coupling component in a nested cantilever configuration, whereby actuation to close the toggle involves pivoting around a central pivot axis that is on the terminal end along the axis of the coupling component. In alternate embodiments as disclosed herein, the toggle component is attached in an alternate manner whereby the coupling component is split at its end, and the toggle rotates within the split end of the coupling component. And in accordance with the depicted embodiment, the toggle is attached to the distal end of the coupling component using a through pin that snap fits or may alternatively be welded or soldered in place. One of ordinary skill will understand that yet other embodiments, the toggle may be attached by any one of other possible means.

[056] In various exemplary embodiments of the locking assembly, as shown in the drawings, inter-engaging compression and collet components cooperate along a shared axis and inter-engage to form a locking assembly. Assembled locking assembly components form a through channel there for receiving a coupling component to achieve locking fixation with the coupling component. According to the various embodiments, the compression and collet components are constructed to slide over at least a first end of the coupling component while in an open configuration, can be held stably on the coupling component in a friction (engaged but not locked) configuration to enable positioning relative to the elements to be fixed, and can be actuated to achieve a locked configuration.

[057] Referring again to the drawings, FIG 5 shows an exemplary locking assembly assembled with the coupling component inserted through the central bore, the anchor in the form of a toggle in the open configuration for fixation to bone. The depicted embodiment of the locking assembly comprises a collet, a securement ring, and a locking cap. As shown, the locking cap is shown as transparent to reveal the relative inter-fitting between the respective collet, securement ring, and locking cap components. FIG 5 upper left panel shows the locking assembly in an open configuration and FIG 5 upper right panel shows the assembly in a locked configuration.

[058] Referring now to FIG 6, the discrete collet, securement ring and locking cap components are shown, wherein with respect to each of the securement ring and the cap, the components are shown with a perspective view from their proximal faces or tops, while with respect to the collet, it is shown with a perspective view from its distal face or bottom.

[059] An advantageous aspect of this embodiment of the locking assembly is that the connection and compression can be achieved without introduction of rotational insertion to the system; that is, the collet, securement ring and cap are designed to engage with the by compression and snap fitting, without rotating around the shared axis with the coupling component, thereby diminishing the risk of material stripping into patient tissue and ensuring optimal compression and purchase of the coupling component surface. In various embodiments, the compression fixation system may be provided for use by an operator in a pre-assembled state, completely disassembled, or in a state of sub-assembly.

[060] Referring again to FIG 6, alternate views of the locking assembly are shown in the right panel, wherein in the top view the assembly is in an open configuration, and in the lower panel, the assembly is in a closed, locked configuration. As will be described further herein, the locking components are fully movable along the length of a coupling component while in the open configuration. According to the instant embodiment, engagement of the securement ring around the collet provides sufficient force to maintain the collet in a slightly compressed state, thereby allowing free movement of the provisionally engaged locking assembly proximally and distally along the length of the coupling component. Applying axial compression to the locking assembly results in the translation of the cap distally, across the surface of the securement ring, whereby it encloses and compresses the ring against the collet to lock the assembly to the coupling component. In the closed configuration, the inner face of the collet is compressed firmly against the coupling component and this compressive force retains the position of the locking assembly to maintain compression on the bone. According to the depicted embodiment as shown in FIG 6, for example, the collet is adapted with ridges on its inner face which are spaced and sized to inter-fit in corresponding circumferential grooves on the surface of the coupling component. In the closed configuration, the compression fit of the locking assembly is enhanced through the inter-engagement between these ridges and grooves.

[061] Of course, as described elsewhere herein, both the collet and the coupling component may be devoid of any surface features, wherein retention of the locking assembly would rely on compressive force alone. And in other embodiments, one or more interacting surface features on either or both the collet and the coupling component may be provided to enhance locking. Notably, according to the embodiment shown in FIG 6, when the locking assembly is in the open configuration, the assembly can be adapted to move in either proximal or distal directions with the rounded ridges on the collet passing over and across the rounded grooves on the coupling component to enable precise positioning of the locking assembly prior to closure. As such, at least in the depicted embodiments, the assembly can be freely adjusted without the use of any additional tools such as would be required with a one way ratcheting mechanism.

[062] In the depicted embodiment of the collet, shown, for example, in FIG 6, the collet, as depicted, is generally cylindrical, having a central bore that is cylindrical and adapted to receive the coupling component, a tapered distal end that is generally frustoconical, a cylindrical proximal end, and is adapted in a center portion of its outer surface with a circumferential recess adapted to receive and retain the securement ring. The cap is adapted with internal engagement features to fit over and engage with the securement ring. In the open configuration, the distal opening of the cap rests on and is provisionally secured to the securement ring. In the closed configuration, the cap slides distally towards the distal end of the collet and thereby encloses the securement ring and engages with a distal end thereof to close the locking assembly.

[063] Referring again to FIG 6, the collet, as depicted, includes a generally frustoconical proximal end, with a central bore that is substantially cylindrical from its proximal to its distal end. Referring to the upper left panel, two representative alternate embodiments of collet are shown, wherein one embodiment is unitary with a single slit from the proximal to the distal end. In another embodiment as show, the collet is provided in two halves that are split along the proximal to distal dimension. As show in the lower left panel, a first embodiment of a collet has a smooth cylindrical inner face, and a second embodiment has a textured inner face comprising ridges. FIG 7 left panel shows alternate views of a split collet, and FIG 7 right panel shows alternate views of a slit collet. It will be appreciated by one of ordinary skill that in some yet further embodiments, a collet may be formed of more than two parts, and yet other embodiments of slit or slotted collets may be provided. Some alternate slotting embodiments of collet locking components are described herein.

[064] According to some embodiments, the collet comprises a series of spaced circumferential ridges along at least a portion of the length of its internal face from proximal to distal, the ridges adapted for resting in one or more groove features on the surface of a coupling component. It will be appreciated that in some embodiments, the number and spacing of the ridges on the inner face of the collet may vary such that there are more or fewer, the ridges are narrower or wider, sharper or shallower, and are equidistant or variably spaced. In addition, in alternate embodiments, a collet may comprise no surface features on its internal face, other surface features or combinations thereof to either enhance sliding between a collet and a coupling component or to enhance friction there between. Further, such textures and features may vary along the internal face of the collet to differentially enhance surface contact with a coupling component. It will be appreciated by those skilled in the art that other engagement features are possible and that the disclosed engagement feature is not to be limiting. In alternate embodiments, all or a portion of the interior face as well as the exterior surface of the collet may be textured by surface treatment or other features such as ridges, grooves, keels, fins, thread, dimples and the like to enhance engagement with and locking between the collet and the coupling component.

[065] In alternate embodiments, the collet may extend distally to form a sleeve that extends along at least a portion of a coupling component that is inserted there through wherein the length of the frustoconical portion is greater than in the embodiments shown in the aforementioned drawings. Referring to the drawings, FIG 19 and 20 depict some such embodiments. Of course, in yet other embodiments, the distal end of the collet may extend along substantially all of the length of the coupling component. In some such embodiments, a further locking component (not shown) may be provided which attaches to the distal end of the coupling component and extends proximally to receive and engage the distal end of the elongated collet. In some such embodiments, the extended sleeve closely contacts the surface of the coupling component providing enhanced locking engagement therewith. According to such specific embodiments, the extended sleeve may be adapted with a taper to allow insertion into the proximal surface of the bone to further enhance fixation and securement to the bone. Optionally, the distal sleeve may have on its exterior surface features or texture that further enhance engagement with bone, particularly when the taper is inserted therein.

[066] Referring again to FIG 6, the securement ring is sized to rest in the circumferential recess of the collet. The securement ring may be made of a minimally flexible material and used to act as the primary circumferential retaining force to secure the collet and its slidable engagement with the coupling component, used without the cap. The ring resides within the circumferential recess of the collet for both the open and closed configurations of the locking assembly, sliding from a proximal open (provisionally locked) position, and allowing movement along the axis to a distal closed/locked configuration, whereby the circumferential diameter compresses the ring and the collet into a locked states in compressive communication with the coupling component. According to the disclosure herein, the securement ring is formed with a material that is non-elastic to minimally elastic and slipped over the proximal end of the collet prior to assembly on the coupling component and will retain close engagement and assembly of collet embodiments that comprise two or more parts in a partially or provisionally closed configuration.

[067] In some examples, the securement ring is formed of silicone. In alternate examples, other suitable materials may be used to provide the needed elasticity and stiffness. In the various embodiments, the material, such as silicone, will be compressed by the inference of the cap with the ring in the open configuration to maintain the securement of the cap, and will remain sufficiently flexible to prevent compression and closure of the collet. Further, the material will be more fully compressed when in the closed position, thereby exerting compressive force on the collet to lock and close it. Thus, the material is capable of expanding in various directions when under compressive force, and can act as a spring closure to secure but not lock the collet except when the fully closed compressive force of the cap is applied. Of course it will be appreciated that other materials having the desired properties may be selected and that alternative materials may be selected from flexible and shape memory metals, such as nitinol, the selection of material being non limiting.

[068] In yet other embodiments, the securement ring may be formed of a more rigid material, such as, for example, polymers and metals as described further herein below, and according to such embodiments, the ring may be segmented, or wound like a spring, or it may comprise a plurality of circumferentially arranged slits that confer flexibility and spring like qualities. And in yet other embodiments, the securement ring may be formed with an array of multiple rings stacked and arranged in the recess of the collet formed of the same or different materials as described herein above. And in yet other embodiments, the ring may be formed of a fabric band or a stacked array of bands. It will be understood that combinations of the afore described embodiments may be employed to provide a securement ring.

[069] And in further embodiments, the securement ring may be formed of a contractile material that is responsive to application of an activator such as heat, electrical, chemical or other force or means such that in a pre activated form, the ring may be more pliable and or may have a circumferential dimension that is greater than the receiving recess of the collet, and in the activated form the ring is contracted so that it becomes more rigid and or contracts to assume a smaller circumferential diameter such that it fits within and compresses against the collet. According to some such embodiments, the contractile ring when activated does not operate to fully compress the collet, and locking of the assembly requires application of the locking cap. According to other such embodiments, the ring functions as both a provisional and a fix locking component wherein the application of activation of the contractile ring converts it from the provisional locking (open) configuration to the locked (closed) configuration, without application of the cap. Thus, according to such embodiments, the locking components are fully movable along the length of the coupling component. Engagement of the securement ring around the collet provides sufficient force to maintain the collet in a slightly compressed state thereby allowing free movement of the provisionally engaged locking assembly proximally and distally along the length of the coupling component. The securement ring, residing in a circumferential recess on the collet, and fashioned out of contractile material which may be activated by heat, electrical , chemical or other means, can be activated to apply a circumferential force to the collet whereby it compresses the ring against the collet to lock the assembly to the coupling component.

[070] In various embodiments, the securement ring may be smooth with rounded edges as depicted in the figures. In yet other embodiments, the securement ring may be squared at its edges, or may have combinations of square and rounded edges. Further, in alternate embodiments one or both of the internal and outer faces of a securement ring may have features or textures that enhance engagement with smooth or corresponding features and textures on the outer face of the collet and on the inner face of the locking cap. Thus, in alternate embodiments, all or a portion of the interior and/or the exterior surface of the securement ring may be textured with surface treatment or other features such as ridges, grooves, keels, fins, thread, dimples to enhance engagement with and locking between the securement ring and either or both the collet and the locking cap. FIG 8 lower panel shows alternate views of a securement ring according to the embodiment of the locking assembly shown in FIG 6. In various embodiments, the securement ring performs the functions of maintaining provisional closure of the collet in the open configuration (including also maintaining the contact and assembly of multi part collet), retention of the cap while the assembly is in the open configuration, and providing compression on the collet and securing the cap in the closed configuration. It will thus be appreciated that the collet.

[071] Referring again to FIG 6 and FIG 8, the locking cap, as depicted, has a cylindrical body with cylindrical interior and exterior surfaces, and comprising a circumferential recess on its inner surface defined by ridges on the distal and proximal interior surfaces. Referring now to FIG 8 upper and middle panels, alternate views of the cap are shown. As can be seen in the upper left panel, which is a cross sectional view of the cap, the proximal interior ridge is slightly more prominent than the distal interior ridge, to facilitate ease of passage of the distal end of the cap over the securement ring. As can be seen in the first and third lower panels, which depict the proximal and distal ends, respectively, the cap has a inner diameter that is greater at the distal end vs. the proximal end to further ensure that the cap can pass over the securement ring and not pass beyond the ring distally. In various embodiments, the locking cap may be smooth with rounded edges as depicted in the figures. In yet other embodiments, the locking cap may be squared at its edges, or may have combinations of square and rounded edges. Further, in alternate embodiments one or both of the internal and outer faces of a locking cap may have features or textures that enhance engagement with smooth or corresponding features and textures on the outer face of the securement ring. Further, it will be appreciated by one of skill in the art that the locking cap may be formed as a ring or as a unitary closed cap that is engageable with a collet and securement ring subassembly, thus, the term used herein to refer to the locking cap is not intended to be limiting. In alternate embodiments, all or a portion of the interior and/or the exterior surface of the locking cap may be textured with surface treatment or other features such as ridges, grooves, keels, fins, thread, dimples to enhance engagement with and locking between the locking cap and the securement ring.

[072] Example 2: Clinical Technique

[073] In alternate embodiments, one or more adaptations to the locking assembly and its components are contemplated to enable ready use with other stabilization implant, such as, for example, stabilization plates, such as bone plates. In accordance with one such embodiment, the locking assembly is adapted to be engaged within a through hole or seat in a stabilization implant, formed from a metal or other suitable implant material. In various embodiments, the stabilization implant comprises one or more locking assembly receivers that are shaped and comprise engagement features, such as threads, for achieving locking engagement with a locking assembly. In an exemplary embodiment, the seat in the stabilization implant is concave hemispherical and the outer base of the collet seat is correspondingly convex hemispherical, and each are threaded for engagement. In another exemplary embodiment, the seat in the stabilization implant is a cylindrical through hole and the collet seat is cylindrically shaped at least at a portion including or distal to its proximal end and its distal ends, and each is threaded for engagement.

[074] One of ordinary skill will appreciate that the corresponding shapes and engagement features may vary. Moreover, it will also be appreciated that a stabilization implant may comprise one or more types of engagement features for locking assemblies according to the instant invention, as well as for fasteners known in the art such as conventional screws. Further, it will be appreciated that stabilization implants may be provided preassembled with one or more locking assemblies according to the instant invention.

[075] In use by an operator, installation of the components of the exemplary compression fixation system for element fixation, including bone element fixation as described above, includes initial selection of a coupling component device that is to be inserted through the elements to be fixed. An anchor component of the coupling component is then actuated to engage with the element that is most distant from the operator, and a locking assembly is slid over the coupling component in a coaxial orientation towards the two or more elements and pressed against the element most proximal to the operator while at the same time the coupling component is held under tension until the desired compression is achieved. The locking assembly is then actuated into a locked configuration relative to the coupling component and the elements, to thereby fix the assembly and maintain the desired compression.

[076] When the elements being compressed are bone, then, consistent with suitable clinical practice, the system is retained intact so that compression is maintained over the clinically appropriate healing period. In some embodiments, the compression fixation system is adjusted during the healing to maintain, increase, or reduce compression. Optionally, the system may be removed from the bone after healing.

[077] Of course, it will be appreciated that the locking assembly may be used with other coupling components that lack an anchor and comprise other features that are not described herein. Indeed, in some embodiments, the locking assembly may be adapted and scaled to engage with coupling components that are substantially smaller than bone pins and wires, and with coupling components that are substantially larger scale. Accordingly, the references to "proximal" and "distal" in regards to the exemplary coupling components described herein are not intended to be limiting, and generically, the orientation of the locking assembly as used herein and as may be used in other applications is not in any way limiting.

[078] Example 3: Instruments for Engaging and Tensioning System Components

[079] The compression fixation system also includes instruments for assembling and locking the coupling component and locking assembly components.

[080] One exemplary instrument includes a locking assembly insertion tool, shown in perspective view in FIG 9. The insertion tool operates to maintain orientation and alignment of the locking assembly components and the coupling component and can be actuated to reduce and lock the locking assembly components, or loosen and unlock the locking assembly for adjustment during healing or post treatment removal of the system. Referring again to the drawings, FIG 9-FIG 13 show alternate views of the components of an exemplary embodiment of a locking assembly insertion tool for achieving placement, component reduction, friction tensioning, locking and unlocking of a locking assembly as described herein. Referring now to FIG 9, the insertion tool includes two nesting elongate sleeves, each having a substantially cylindrical interior, the inner sleeve having an internal and external cylindrical shape and dimensioned to closely interfit with the cylindrical interior of the outer sleeve. As depicted in FIG 10, which is a cross sectional view of the interfitted sleeves, the insertion tool includes at least one pin that may be press fit into the outer sleeve. The pin can be actuated to engage with and constrain the outer sleeve to the inner sleeve engagement in a slot in the body of the inner sleeve. Upon engagement of the at least one pin, the outer sleeve is able to freely rotate along the distance of the slot about the inner sleeve. The outer sleeve can also translate axially relative to the inner sleeve, but only a short distance defined but the proximal and distal boundaries of the pin engagement slot. This distance corresponds roughly to the amount of translation needed to engage the compression nut to the collet seat. FIG 11 – 13 each show in various views each of the outer sleeve, the inner sleeve, and the assembled insertion tool components.

[081] Referring again to FIG 10, each of the sleeves of the depicted locking assembly insertion tool inter-engages with at least a portion of the external surface of one or more of the collet and the locking cap. The outer sleeve is adapted with an interior groove feature that inter-engages with the outer proximal edge of the locking cap to stabilize it relative to the other components of the locking assembly. The inner sleeve is adapted to inter engage with the proximal frustoconical end of the collet. The engagement there between enables differential securement of the insertion tool to the collet to enable downward pressure on the collet for engagement of the collet with the bone without actuating downward pressure on the locking cap. As further described herein, use of the tensioning tool first reduces the bone and the locking component into engagement with the bone. Thereafter, engagement of the inserter pin enables discrete actuation of the outer sleeve to compress the locking cap against the collet and securement ring to snugly lock the locking assembly in tight engagement with the coupling component.

[082] Should removal and adjustment of the locking assembly be required, a flat driver or other instrument can be inserted between the distal end of the cap and the distal edge of the securement ring recess to disengage the cap from the securement ring. In some embodiments, such as shown in FIG 10, the distal edge of the locking cap and the opposing distal edge of the recess in the collet may be chamfered to facilitate insertion of a tool for disengagement. Of course, other instruments may be used to disengage the cap and the collet, such as a circumferential grip that can grasp and pull the components apart. FIG 10 right panel shows a cross sectional view of the insertion instrument inner and outer sleeves engaged with the compression fixation system. As can be seen, the inner sleeve of the insertion tool is engaged with features of the proximal end of the collet, and the edges of the outer sleeve are engaged with the outer edges of the cap.

[083] Another exemplary instrument includes a tensioning instrument that clamps the coupling component to stabilize it and enable maintenance of tension during locking assembly securement. The tensioning instrument is shown in FIG 1 and FIG 16, for example, and in various views in FIG 14 and FIG 16. Referring to FIG 1, the exemplary embodiment of the insertion instrument is shown engaged at its proximal end with the proximal end of the coupling component and is engaged at its distal end at a more distal locus on the coupling component near the proximal end of the insertion tool. Referring now to FIG 14, upper right panel, the exemplary embodiment of the tensioning instrument comprises a handle portion that actuates opposing gripping elements around a pivot axis, whereby actuation of the handle moves the opposing elements towards and away from one another.

[084] Referring now to FIG 15, close up detail in the center panel shows the tensioning tool comprises at its proximal grip element a clamp actuation sleeve with opposing clamping means extending therefrom and configured to receive the coupling component in a central channel defined through the clamping means. The proximal grip element of he insertion instrument locks onto the coupling component. The tensioning tool also comprises a distal grip element that engages with and articulates to push down on the top of the insertion tool, which in turn presses on the top of the locking assembly. In use, the instrument grips are affixed to a coupling component as shown, for example, in the upper panel of FIG 15, the tool handle is squeezed by the operator to rotate the proximal grip element away from the distal grip element, thereby actuating upward movement of the proximal end of the coupling component. This motion causes the lower grip element of the tool to displace downward into contact with the proximal end of the inner sleeve of the insertion tool. Repeated squeezes of the handle further actuate gripping and upward displacement of the coupling component, thereby driving the inner sleeve of the insertion tool assembly and locking assembly distally, and forcing the distal end of the collet against the proximal bone. The effect of actuation of the insertion instrument is to reduce the two or more bone elements (i.e., compress them against one another effectively reducing the space there between) and at the same time reduce the clearance between the distal end of the locking assembly and the proximal bone. Tensioning is complete when the collet at the distal end of the locking assembly is firmly pressed against the bone. The tensioning tool handle is locked to maintain tension on the coupling component while the locking assembly is engaged and secured. Engagement of at least one side pin of the insertion instrument enables securement of the inner sleeve to the outer sleeve of the insertion instrument, and downward compression on the insertion instrument drives engagement and final closure of the locking assembly.

[085] It will be appreciated that the instruments described herein are merely representative, and that more or fewer instruments comprising the same features may be provided. Thus, in some embodiments, the features of one ore more of the tensioner, insertion tool, and reducer may be integrated into a single instrument. Alternately, in other embodiments, the components of the instruments may be modular, such that, for example, the sleeves of the insertion tool may be sequentially assembled, or they may be provided in combination with the locking assembly such that the operate need only slip the locking assembly/insertion and reducer assembly on to the coupling component without the need to assemble them in series.

[086] The instruments, and the coupling component and one or more components of the locking assembly may be formed out of any suitable biocompatible material and combinations thereof, including those used conventionally in the art. Such materials include but are not limited to: metals such as, for example, stainless steel (such as 316 LVM, per ASTM F1350, electropolished and passivated), titanium alloys (such as TI-6AL-4V, per ASTM F136), cobalt alloys, superelastic metals, such as nitinol; polymers, such as polyester and polyethylene, polyether ether ketone (PEEK); and resorbable synthetic materials such as, for example, suture material and polylactic acid.

[087] EXAMPLE 4: Threaded Torsional Locking Compression Fixation System

[088] Referring now to FIG 16 – FIG 18, various views of an alternate embodiment of a compression fixation system are shown. FIG 16 shows a side view of a fully assembled compression fixation system engaged with coupling component tensioning and locking assembly inserter instruments.

[089] The compression fixation system includes a coupling component that is selected from suitable wire and other bone pins and similar rod type devices, such as, for example K-wire. The coupling component is adapted at a first end, intended to be most distal to the operator, with an anchor portion for fixation within or on a distal outer surface of a first bone element. The coupling component is further adapted at a second end, intended to be most proximal to the operator, with a locking assembly receiver portion that is generally rectilinear. In various embodiments, at least the proximal portion of the coupling component is substantially rectilinear, and cylindrical, while the distal and a medial portion of the coupling component may be other than rectilinear or may be initially rectilinear and manipulated by the operator for optimal engagement and shape conformity with the two or more elements to be fixed.

[090] The distal anchor portion of the coupling component may be selected from any of a number of anchors known in the art, and generally selected from (i) those that are adapted to engage with and remain substantially within and anchor to a bone, and (ii) those that extend through bone and are adapted to engage with an outer surface of a bone or bone fragment, or a plate or other non-bone material that is intended to be held adjacent to the distal bone element. Some examples of anchors that are adapted to engage with and remain substantially within and anchor to a bone include self or non-self tapping threads, and bone engagement features that can engage by press fitting such as keels, ribs and fins. Some examples anchors that extend through bone and are adapted to engage with an outer surface include coils, barbs, and toggles.

[091] Referring again to the drawings, enlarged views of the distal portion of an exemplary embodiment of a coupling component are shown in FIG 16. As depicted, the anchor is a toggle, which is pivotal around an axis that is perpendicular to a long axis of the coupling component. FIG 16 lower left panel shows a side view of the deployed toggle anchor, and FIG

16 lower right panel shows a distal to proximal end perspective view of a deployed toggle anchor. In an insertion configuration, the toggle is pivoted so that it is aligned with the long axis of the coupling component to enable insertion into the bone and allow clean exit from a proximal end of the bone. Actuation of the pivot feature of the toggle rotates its position so that it is perpendicular to the axis of the coupling component, and is deployed to operate as an anchor, thereby preventing back out of the coupling component from the bone. While the toggle as shown is engaged with the coupling component in a split end configuration, one of ordinary skill will understand that the toggle may be attached by any one of other possible means, such as a cantilever attachment to one side of the coupling component, as described herein above, and as shown in other drawings, specifically FIG 19 and FIG 20.

[092] One of ordinary skill will appreciate that the depicted coupling component can be provided in variable lengths, with or without curves or bends, with or without surface texture and surface features. Moreover, while the depicted coupling component is generally cylindrical in shape from the proximal end and terminates at the exemplary anchor, one of ordinary skill will appreciate that the shape may be other than cylindrical (i.e., the cross section may be other than circular). Thus, in some alternate embodiments, the coupling component may have a cross section that is selected from one of the following non-limiting examples, including, scalloped, star shaped, hexagonal, square, and ovoid. Likewise, the coupling component may be uniform in cross sectional shape and width along its entire length, or it may comprise regions that vary and include combinations of different cross sectional shapes, widths/diameters, and textures. Thus, it will be appreciated that any particular region which may be substantially rectilinear for receiving a locking assembly may be cylindrical or otherwise shaped and may be smooth or have any one of a variety of surface features such as grooves or notches and textures that comprise knurling or other non-smooth texturing. Further, while the exemplary embodiment of the coupling component shown in the drawings terminates as a cylinder at the proximal end, there may be alternate shapes and features at the proximal end that are suited for engagement with a tool or instrument. Thus, in some non-limiting examples, the coupling component may comprise at its proximal end a hemispherical, conical or frustoconical feature, or a star, scallop or hex cross-section, or combinations of these.

[093] In some alternate embodiments, the coupling component may have a diameter that permits cannulation through at least a portion of the coupling component. In some examples such embodiments would include cannulated bone wires and pins. In other such embodiments, examples include tubes, conduit, pipes, and other substantially hollow components that are suitable to receive a locking assembly along at least a portion of the component that is rectilinear.

[094] The compression fixation system also comprises a locking assembly. Referring again to FIG 17 lower right panel, a side view of a representative embodiment of a locking assembly is shown inserted on and arranged concentrically with the coupling component.

[095] The exemplary embodiments of the locking assembly, as shown in the drawings, includes inter-engaging collet (left), collet seat (middle), and compression nut (right) components, shown, respectively, in side and cut away views in FIG 17 upper and middle panels. Referring now to FIG 17 upper and middle panels, each of the compression nut, collet and collet seat components cooperate along a shared axis and inter-engage to form a locking assembly. As shown, the assembled locking assembly components form a channel there through for receiving a coupling component to achieve locking fixation with the coupling component.

[096] The collet seat, collet and compression nut components are constructed to slide over at least a first end of the coupling component while in an open configuration, can be held stably on the coupling component in a friction (engaged but not locked) configuration to enable positioning relative to the elements to be fixed, and can be actuated to achieve a locked configuration. FIG 17 lower left panel shows an exemplary locking assembly assembled with the coupling component inserted through the central bore. As shown, the collet seat is depicted as transparent to show the relative inter-fitting between the nut, collet, and collet seat components. The collet seat and collet have complimentary engagement surfaces that inter-fit and are adapted with features to enable precise locking and prevent sliding and rotation relative to the coupling component. Likewise, again with reference to FIG 17, the compression nut and the collet have complementary engagement surfaces that also inter-fit and are adapted to enable secondary locking to prevent sliding and rotation relative to the coupling component. An advantageous aspect of this system is that the connection and compression can be achieved without introduction of rotational insertion to the system; that is, the collet seat and collet are designed to engage with the compression screw without rotating around the shared axis with the coupling component, thereby diminishing the risk of material stripping into patient tissue and ensuring optimal compression and purchase of the coupling component surface. In various embodiments, the compression fixation system may be provided for use by an operator in a pre-assembled state, completely disassembled, or in a state of sub-assembly.

[097] Referring again to FIG 17, the collet seat, as depicted, is generally frustoconical, with a central bore that is substantially cylindrical at its most distal end, and proximal to the cylindrical portion a distal interior wall that is frustoconical in shape and adapted to receive and inter-fit with the collet when the collet is inserted therein. The collet seat also has a substantially cylindrical and threaded proximal interior wall for inter-engagement with the compression nut. The interior surface of the collet seat, as depicted, is generally smooth at the distal seat and the seat is generally conical in shape. The exterior surface of the collet seat is tapered and generally smooth from the proximal to the distal end, and includes on its proximal end an instrument engagement feature. The collet seat, as depicted, includes a hex nut configuration at its proximal end for engagement with a positioning and locking instrument. It will be appreciated by those skilled in the art that other engagement features are possible and that the disclosed engagement feature is not to be limiting. In alternate embodiments, all or a portion of the exterior surface as well as the interior surface of the collet seat may be textured by surface treatment or other features such as ridges, grooves, keels, fins, thread, dimples and the like to enhance engagement with and locking between the collet seat and the collet. Likewise, the shape of the interior distal wall of the collet seat may have a shape that is other than conical, for example, it may be hemispherical.

[098] In alternate embodiments, the collet seat extends distally to form a sleeve that extends along at least a portion of a coupling component that is inserted there through. Referring to the drawings, FIG 19 and FIG 20 depict some such embodiments. Of course, in yet other embodiments, the distal end of the collet seat may extend along substantially all of the length of the coupling component. In some such embodiments, a further locking component (not shown) may be provided that attaches to the distal end of the coupling component and extends proximally to receive and engage the distal end of the elongate sleeve end of the collet seat. In yet other embodiments, the extended sleeve closely contacts the surface of the coupling component providing enhanced locking engagement therewith. According to such specific embodiments, the extended sleeve may be adapted with a taper to allow insertion into the proximal fixed element. In such case where the element is bone, the tapered distal end of the collet seat sleeve may be inserted into the bone to further enhance fixation and securement to the bone. Optionally, the distal sleeve may have on its exterior surface features or texture that further enhance engagement with bone, particularly when the taper is inserted therein.

[099] Referring again to FIG 17, the collet, as depicted, is generally cylindrical, having a central bore that is cylindrical and adapted to receive the coupling component, a tapered distal end that is generally frustoconical a tapered proximal end, and a series of slots that are generally equally spaced circumferentially, and, as depicted, alternate in origination from the proximal and distal ends. It will be appreciated that the slots may, in alternate embodiments, be unequally spaced, there may be fewer or more slots, and they may all originate from one or the other of the proximal and distal end. As depicted, the collet has a circumferential groove or channel that is distal of the midpoint of the collet and defines the boundary between the tapers of the proximal and distal ends, referred to herein as the proximal lobe and the distal lobe, respectively, of the collet. The proximal lobe of the collet is shaped to inter-fit with the interior surface of the compression nut. The distal lobe of the collet is shaped to inter-fit with the interior distal wall of the collet seat. The exterior surface of the collet, as depicted, is generally smooth on each of the proximal and distal lobes. In alternate embodiments, all or a portion of the exterior surface as well as the interior surface of the collet may be textured surface treatment or other features such as ridges, grooves, keels, fins, thread, dimples to enhance engagement with and locking between the distal end of the collet and the collet seat, and between the proximal end of the collet and the compression screw.

[0100] Advantageously, referring again to FIG 17, the two lobed design of the collet enables uniform compression along its length and enhanced compression circumferentially against the coupling component inserted there through as a result of the combined compressive force of the collet seat on the distal lobe of the collet and the compressive force of the compression not on the proximal lobe of the collet.

[0101] Referring again to FIG 17, the compression nut, as depicted, has a tapered cylindrical interior surface, which is complementary to the taper of the proximal lobe of the collet. The compression nut has a substantially cylindrical exterior surface with threading at the distal end for engagement with the proximal interior wall of the collet seat, and includes on its proximal end an instrument engagement feature. The compression nut, as depicted, includes a hex nut configuration at its proximal end for engagement with a positioning and locking instrument. It will be appreciated by those skilled in the art that other engagement features are possible and that the disclosed engagement feature is not to be limiting. Likewise, it will be appreciated that the interior surface of the compression nut may have an inverted taper or no taper at all, and it may have surface texturing or other treatment or features as disclosed herein to enhance engagement with the coupling component. And in alternate embodiments, all or a portion of the non-threaded exterior surface of the compression screw may be textured with surface treatment or other features such as ridges, grooves, keels, fins, thread, dimples to enhance engagement with and locking between the proximal end of the compression screw and a feature that is proximal thereto.

[0102] As described herein above, various instruments are provided that facilitate use of the compression fixation system components. One exemplary instrument includes a tensioning grip that clamps the coupling component to stabilize it and enable maintenance of tension during locking assembly locking, as shown in FIG 1 and FIG 16.

[0103] Another exemplary instrument includes a locking assembly counter torque insertion tool. The counter torque insertion tool operates to maintain orientation and alignment of the locking assembly components and the coupling components and can be actuated to reduce and lock the locking assembly components, or loosen and unlock the locking assembly for adjustment during healing or post treatment removal of the system. Referring again to the drawings, FIG 18 depicts an alternate exemplary embodiment of a locking assembly tool, namely a counter torque insertion tool for achieving placement, component reduction, friction tensioning, locking and unlocking of a locking assembly as described herein. Referring now to FIG 18, the counter torque insertion tool includes two nesting elongate sleeves, each having a substantially cylindrical interior, the inner sleeve having an internal and external cylindrical shape and dimensioned to closely interfit with the interior cylindrical interior of the outer sleeve. As depicted in FIG 18 upper and lower right panels, cutaway views of the outer sleeve show that the counter torque insertion tool includes opposing pins that are press fit into the outer sleeve. These pins constrain the outer sleeve to the inner sleeve via the pins engaging a groove. The outer sleeve is able to freely rotate about the inner sleeve. The outer sleeve can also translate to relative to the inner sleeve, but only a short distance. This distance corresponds roughly to the amount of translation needed to engage the compression nut to the collet seat. FIG 18 upper left panel shows a distal end view of the assembly of the counter torque insertion tool and the locking assembly, showing the edges of the opposing pins.

[0104] The depicted locking assembly counter torque insertion tool is comprised of concentric inner and outer sleeves, each of which sleeves inter-engages with at least a portion of the external surface of one or more of the collet seat, the collet and the locking nut. Referring now to FIG 18 lower left panel, the outer sleeve is adapted with an interior groove feature that inter-engages with the outer proximal edge of the collet seat to lock it relative to the other components of the system. Likewise, the inner sleeve is adapted with notches to inter engage with corresponding features on the proximal rim of the compression nut. The engagement there between enables differential axial rotation of the nut by the counter torque insertion tool while the collet seat is held in place, thereby driving the mating threads of the nut and the collet seat into engagement.

[0105] In use, the threads of the collet seat and nut may be partially engaged to enable friction fixation of the locking assembly while tensioning is applied to tighten the coupling component and firmly place the locking assembly against the proximal element. Upon application of further torsional force to the counter torque insertion tool, the threads of the nut and collet seat are fully engaged, directing circumferential force against the upper lobe of the collet and forcing the lower lobe of the collet firmly into the collet seat thereby locking the lower lobe to achieve locked fixation of the fattener to the coupling component.

[0106] It will be appreciated that the instruments described herein are merely representative, and that more or fewer instruments comprising the same features may be provided. Thus, in some embodiments, the features of one ore more of the tensioner, torque reduction tool and reducer may be integrated into a single instrument. Alternately, in other embodiments, the components of the instruments may be modular, such that, for example, the sleeves of the torque tool may be sequentially assembled, or they may be provided in combination with the locking assembly such that the operate need only slip the locking assembly/torque and reducer assembly on to the coupling component without the need to assemble them in series.

[0107] 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, devices and components, 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.

[0108] 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. Further, while disclosed benefits, advantages, and solutions to problems have been described with reference to specific embodiments, these are not intended to be construed as essential or necessary to the invention.

CLAIMS

1. A compression fastener system comprising:

   a coupling component having proximal and distal ends, a locking assembly, and an anchor component that is integral with the coupling component at its distal end,

   the locking assembly engageable with the coupling component and comprising

      at least a first compressible collet, and

      at least a first collet compression component;

   wherein the locking assembly, when assembled, may be provisionally locked to enable free linear movement along the coupling component.

2. A compression fastener system according to claim 1, the coupling component comprising an elongate wire, the locking assembly also comprising a second compression component.

3. A compression fastener system according to claim 4, wherein the anchor component is selected from a threaded shank and a toggle.

4. A compression fastener system according to claim 3, wherein the first compression component operates to retain the collet, and wherein the second compression component operates in engagement with the first compression component in a first configuration to provisionally secure the locking assembly to the coupling component and in a second configuration to fixedly secure the locking assembly into compression locking with the coupling component.

5. A compression fastener system according to claim 4, the first collet compression component comprising a flexible securement ring that is engageable with the compressible collet, and the second collet compression component comprising a locking cap that is engageable with the collet and the securement ring, and actuatable between provisionally locked and locked configurations, wherein each of the collet, securement ring and cap are generally cylindrical, and wherein the collet is engageable and compressible directly with the coupling component, and wherein when the locking assembly and the coupling component are assembled they share a common center axis, and wherein engagement between the components is achieved by press fitting.

6. A compression fastener system according to claim 5, wherein the anchor is a toggle engageable with the coupling component in a cantilever pivotal arrangement, such that in one configuration, the toggle is pivoted into linear alignment with the coupling component and is nested within a recess therein, and in a second configuration, the toggle is deployed in a generally perpendicular orientation relative to the axis of the coupling component.

7. A compression fastener system according to claim 6, wherein at least one of (i) at least a portion of an outer surface of the distal end of the coupling component and (ii) at least a portion of an inner face of the compressible collet comprises a surface feature selected from one or a combination of ridges, grooves, keels, fins, threads, dimples, knurls, and surface texturing, and wherein the surface features of the at least one of the outer surface of the coupling component and the inner face of the compressible collet cooperate with the opposing surface of the assembly when the locking assembly is in a locked configuration to enhance the compressive securement of the locked compression fixture system.

8. A compression fastener system according to claim 7, wherein each of the at least a portion of an outer surface of the distal end of the coupling component and at least a portion of an inner face of the compressible collet comprises a surface feature, and wherein the securement ring comprises silicone.

9. A compression fastener system according to claim 8, wherein the collet is selected from (i) unitary slit form that comprises at least one slit selected from a through slit and a partial slit, and (ii) a multi piece form.

10. A compression fastener system according to claim 1, wherein the compression component comprises a securement ring that operates to retain the collet in a first configuration to provisionally secure the locking assembly to the coupling component and in a second configuration to fixedly secure the locking assembly into compression locking with the coupling component, wherein each of the collet and the securement ring are generally cylindrical, and wherein the collet is engageable and compressible directly with the coupling component, and wherein when the locking assembly and the coupling component are assembled they share a common center axis, and wherein engagement between the components is achieved by press fitting, wherein, the ring comprises a

contractile material that is responsive to application of an activator selected from one or more of heat, electrical, chemical and mechanical compressive force such that in a pre activated form, the ring is either or both pliable and has a circumferential dimension that is greater than the receiving recess of the collet, and in the activated form the ring is contracted so that it becomes more rigid and contracts to assume a smaller circumferential diameter such that it fits within and compresses against the collet thereby locking the assembly to the coupling component.

11. A compression fastener system according to claim 3, the first collet compression component comprising a collet seat that receives and is engageable with the compressible collet, and the second collet compression component comprising a compression nut that is engageable with the collet seat and is actuatable between provisionally locked and locked configurations, wherein each of the collet, collet seat and compression nut are generally cylindrical and when assembled share a common center axis, and wherein the collet is engageable and compressible directly with the coupling component.

12. A compression fastener system according to claim 11, wherein engagement between the components is achieved by one of press fitting and threaded engagement between the collet seat and the compression nut.

13. A compression fastener system according to claim 12, wherein the anchor is a toggle engageable with the coupling component in a cantilever pivotal arrangement, such that in one configuration, the toggle is pivoted into linear alignment with the coupling component and is nested within a recess therein, and in a second configuration, the toggle is deployed in a generally perpendicular orientation relative to the axis of the coupling component, and wherein the engagement between the locking assembly is by threaded engagement between the collet seat comprising interior threads and a threaded compression nut comprising corresponding threads for engagement with the collet seat.

14. A compression fastener system according to claim 13, wherein at least one of (i) at least a portion of an outer surface of the distal end of the coupling component and (ii) at least a portion of an inner face of the compressible collet comprises a surface feature selected from one or a combination of ridges, grooves, keels, fins, threads, dimples, knurls, and surface texturing, and wherein the surface features of the at least one of the outer surface of the coupling component and the inner face of the compressible collet cooperate with

the opposing surface of the assembly when the locking assembly is in a locked configuration to enhance the compressive securement of the locked compression fixture system.

15. A compression fastener system according to claim 14, wherein each of the at least a portion of an outer surface of the distal end of the coupling component and at least a portion of an inner face of the compressible collet comprises a surface feature.

16. A compression fastener system according to claim 15, wherein the collet is selected from (i) unitary slit form that comprises at least one slit selected from a through slit and a partial slit, and (ii) a multi piece form.

17. A compression fastener system according to claim 4, wherein the locking assembly components and the coupling component are preassembled in a provisionally locked configuration, the assembly further comprising an insertion tool that is engageable with the provisionally locked assembly, the insertion tool comprising nesting elongate sleeves, the outer sleeve adapted to engage with one of the collet and the first and second compression components and the inner sleeve adapted to engage with the other of the collet and the first and second compression components, the sleeves releasably engageable between free and limited degrees of freedom around and along a shared center axis, wherein when the sleeves are not engaged, one of the sleeves is actuatable along the axis to direct translation of the assembly distally, and wherein when the sleeves are engaged, at least one sleeve is actuatable either around or along the axis to drive fixed engagement between the first and second compression components.

18. A compression fastener system according to claim 17, the first collet compression component comprising a flexible securement ring that is engageable with the compressible collet, and the second collet compression component comprising a locking cap that is engageable with the collet and the securement ring, and actuatable between provisionally locked and locked configurations, wherein each of the collet, securement ring and cap are generally cylindrical, and wherein the collet is engageable and compressible directly with the coupling component, and wherein when the locking assembly and the coupling component are assembled they share a common center axis, and wherein engagement between the components is achieved by press fitting, wherein the anchor is a toggle engageable with the coupling component in a cantilever pivotal arrangement, such that in one configuration, the toggle is pivoted into linear

alignment with the coupling component and is nested within a recess therein, and in a second configuration, the toggle is deployed in a generally perpendicular orientation relative to the axis of the coupling component

wherein at least one of (i) at least a portion of an outer surface of the distal end of the coupling component and (ii) at least a portion of an inner face of the compressible collet comprises a surface feature selected from one or a combination of ridges, grooves, keels, fins, threads, dimples, knurls, and surface texturing, and wherein the surface features of the at least one of the outer surface of the coupling component and the inner face of the compressible collet cooperate with the opposing surface of the assembly when the locking assembly is in a locked configuration to enhance the compressive securement of the locked compression fixture system,

wherein each of the at least a portion of an outer surface of the distal end of the coupling component and at least a portion of an inner face of the compressible collet comprises a surface feature, and wherein the securement ring comprises silicone,

wherein the collet is selected from (i) unitary slit form that comprises at least one slit selected from a through slit and a partial slit, and (ii) a multi piece form,

wherein the inner sleeve of the insertion tool engages with the collet and the outer sleeve engages with the cap, and wherein upon engagement of the sleeves the outer sleeve is actuated by displacement in a distal direction to lock the cap to the securement ring and thereby compress and lock the collet into compressive engagement with the coupling component.

19. A compression fastener system according to claim 17, the first collet compression component comprising collet seat that receives and is engageable with the compressible collet, and the second collet compression component comprising a compression nut that is engageable with the collet seat and is actuatable between provisionally locked and locked configurations, wherein each of the collet, collet seat and compression nut are generally cylindrical and when assembled share a common center axis, and wherein the collet is engageable and compressible directly with the coupling component,

wherein engagement between the components is achieved by one of press fitting and threaded engagement between the collet seat and the compression nut,

wherein the anchor is a toggle engageable with the coupling component in a cantilever pivotal arrangement, such that in one configuration, the toggle is pivoted into linear alignment with the coupling component and is nested within a recess therein, and in a second configuration, the toggle is deployed in a generally perpendicular orientation relative to the axis of the coupling component, and wherein the engagement between the locking assembly is by threaded engagement between the collet seat comprising interior threads and a threaded compression nut comprising corresponding threads for engagement with the collet seat,

wherein at least one of (i) at least a portion of an outer surface of the distal end of the coupling component and (ii) at least a portion of an inner face of the compressible collet comprises a surface feature selected from one or a combination of ridges, grooves, keels, fins, threads, dimples, knurls, and surface texturing, and wherein the surface features of the at least one of the outer surface of the coupling component and the inner face of the compressible collet cooperate with the opposing surface of the assembly when the locking assembly is in a locked configuration to enhance the compressive securement of the locked compression fixture system,

wherein each of the at least a portion of an outer surface of the distal end of the coupling component and at least a portion of an inner face of the compressible collet comprises a surface feature,

wherein the collet is selected from (i) unitary slit form that comprises at least one slit selected from a through slit and a partial slit, and (ii) a multi piece form, and

wherein the inner sleeve of the insertion tool engages with the nut and the outer sleeve engages with the collet seat, and wherein upon engagement of the sleeves the inner sleeve is actuated by rotation around the shared axis to drive further engagement of the engaged threads of the collet seat and the nut in a distal direction to lock the nut to the collet seat and thereby compress and lock the collet into compressive engagement with the coupling component.

20. A method for achieving compression fixation of a plurality of bone elements, comprising:

inserting an elongate coupling component having distal and proximal ends into a through hole in each of the bone elements, the bone elements arranged for fixation along a generally linear path from a proximal to a distal position,

actuating an anchor at the distal end of the coupling component into engagement with a distal face of the most distal bone element,

sequentially engaging each of locking assembly components, and tensioning and insertion tools into engagement with the coupling component, the tensioning tool engaged fixedly with the proximal end of the coupling component and also engaged loosely with a more distal portion of the coupling component; each of the locking assembly and the insertion tool engaged along an axis that is shared with the coupling component, the insertion tool positioned between the more distal engagement position of the tensioning tool and the proximal fragment of the aligned bone fragments, and the locking assembly positioned between the distal end of the insertion tool and the proximal fragment of the aligned bone fragments,

actuating the tensioning tool to displace the coupling component in a proximal direction thereby exerting distally directed pressure on the proximal end of the insertion tool whereby distally directed pressure is also exerted on the locking assembly to direct it into compressive contact with the proximal bone fragment, and,

actuating the insertion tool to engage the locking assembly into a locked configuration.

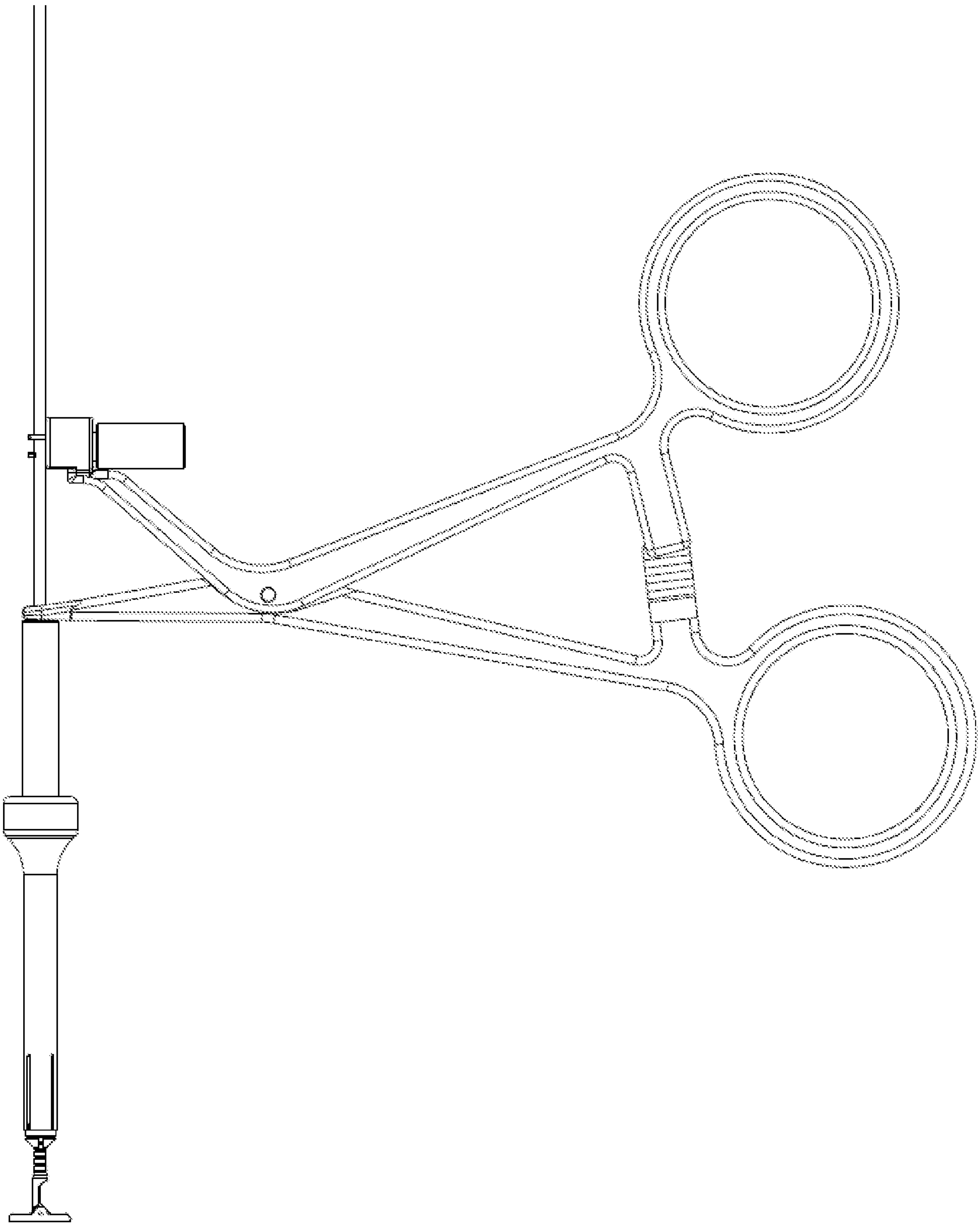


FIG. 1

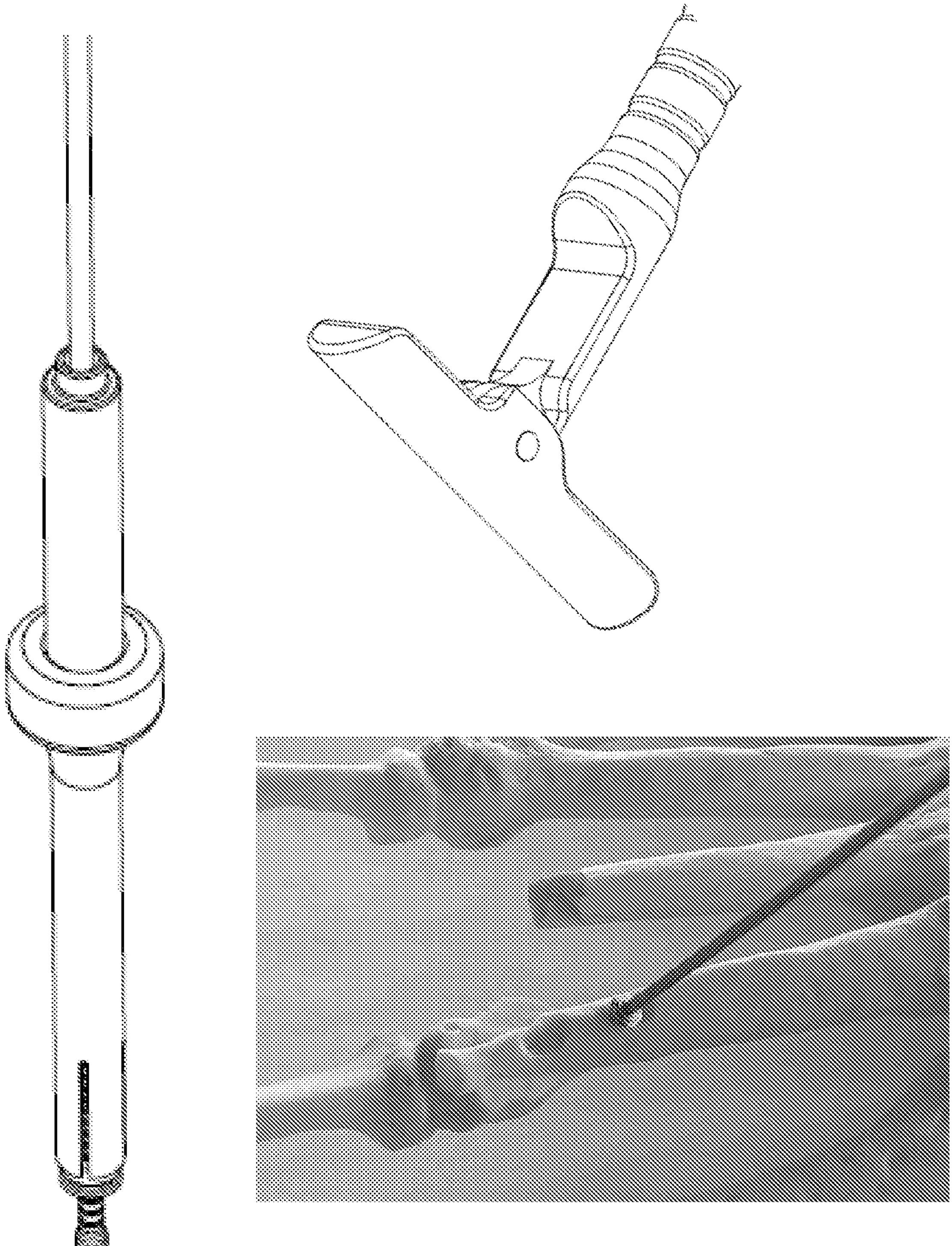


FIG. 2

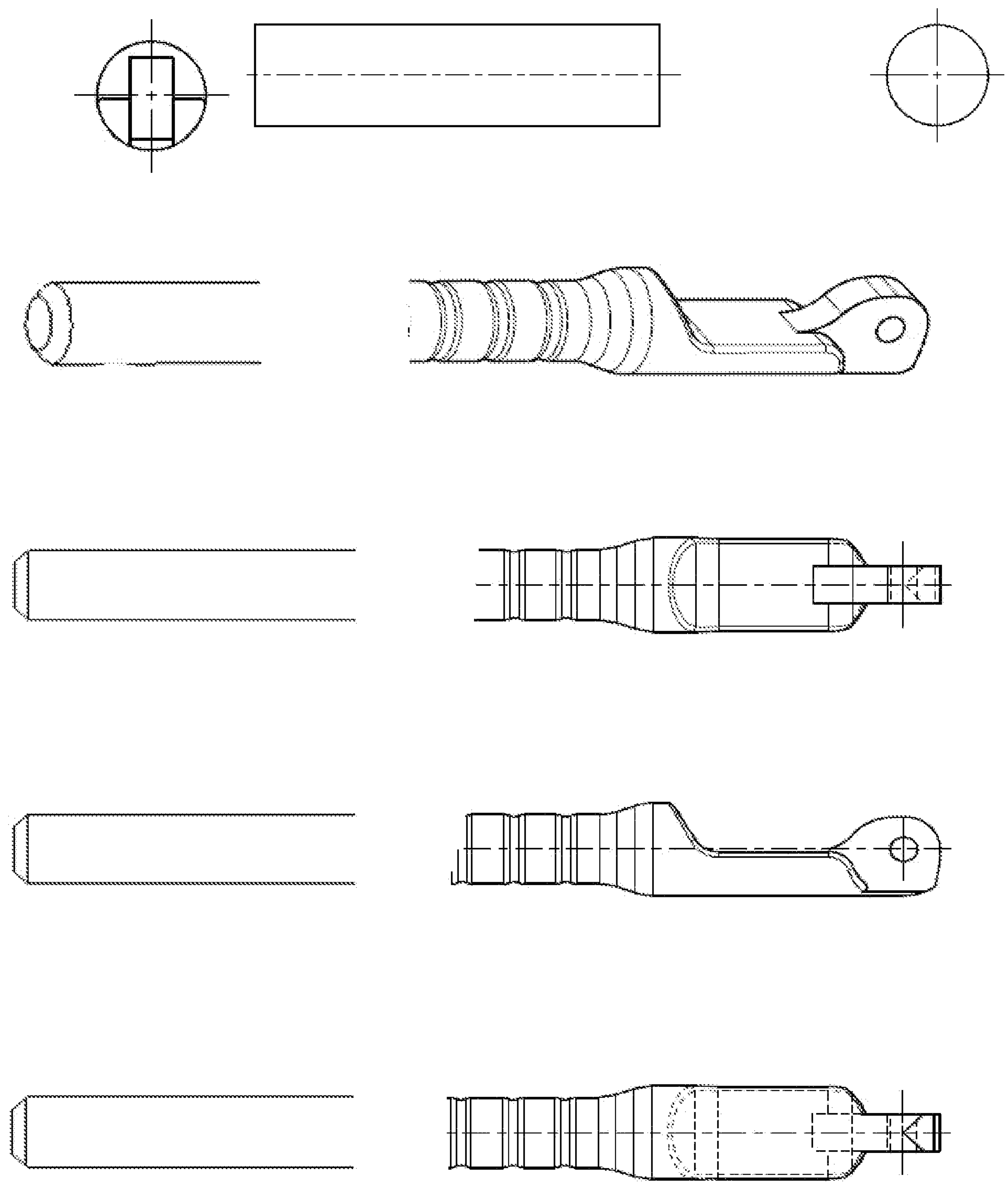


FIG. 3

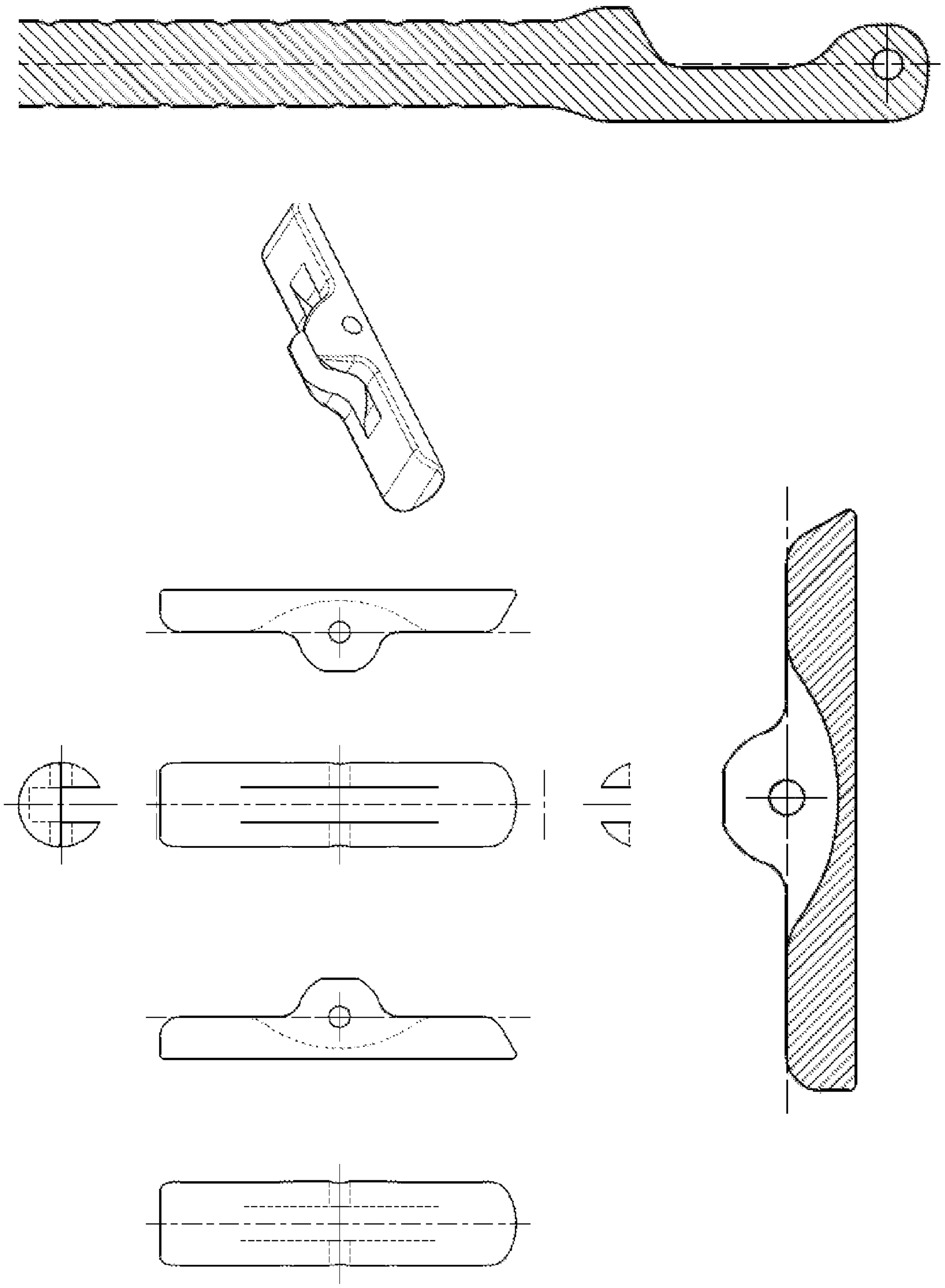


FIG. 4

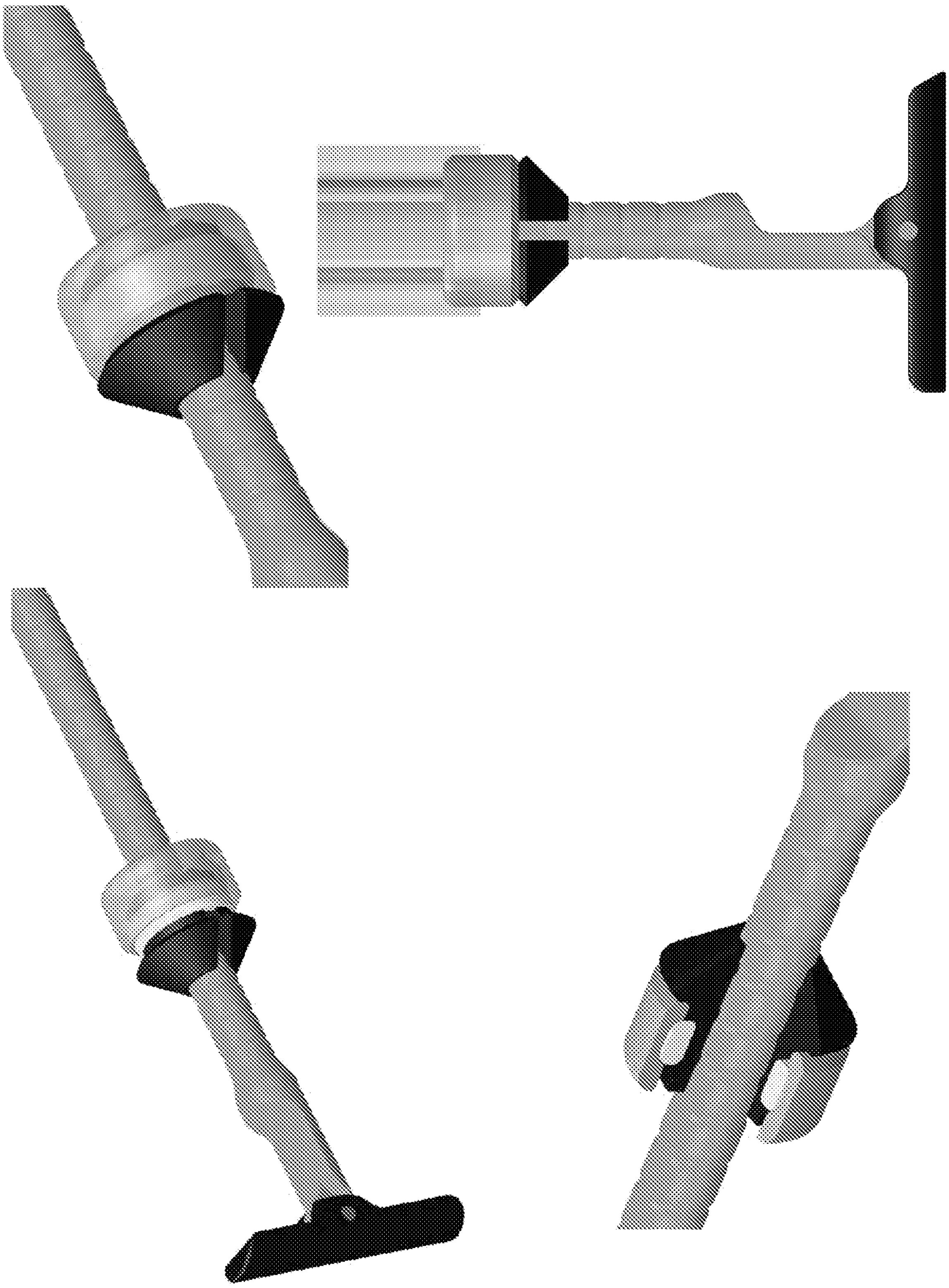


FIG. 5

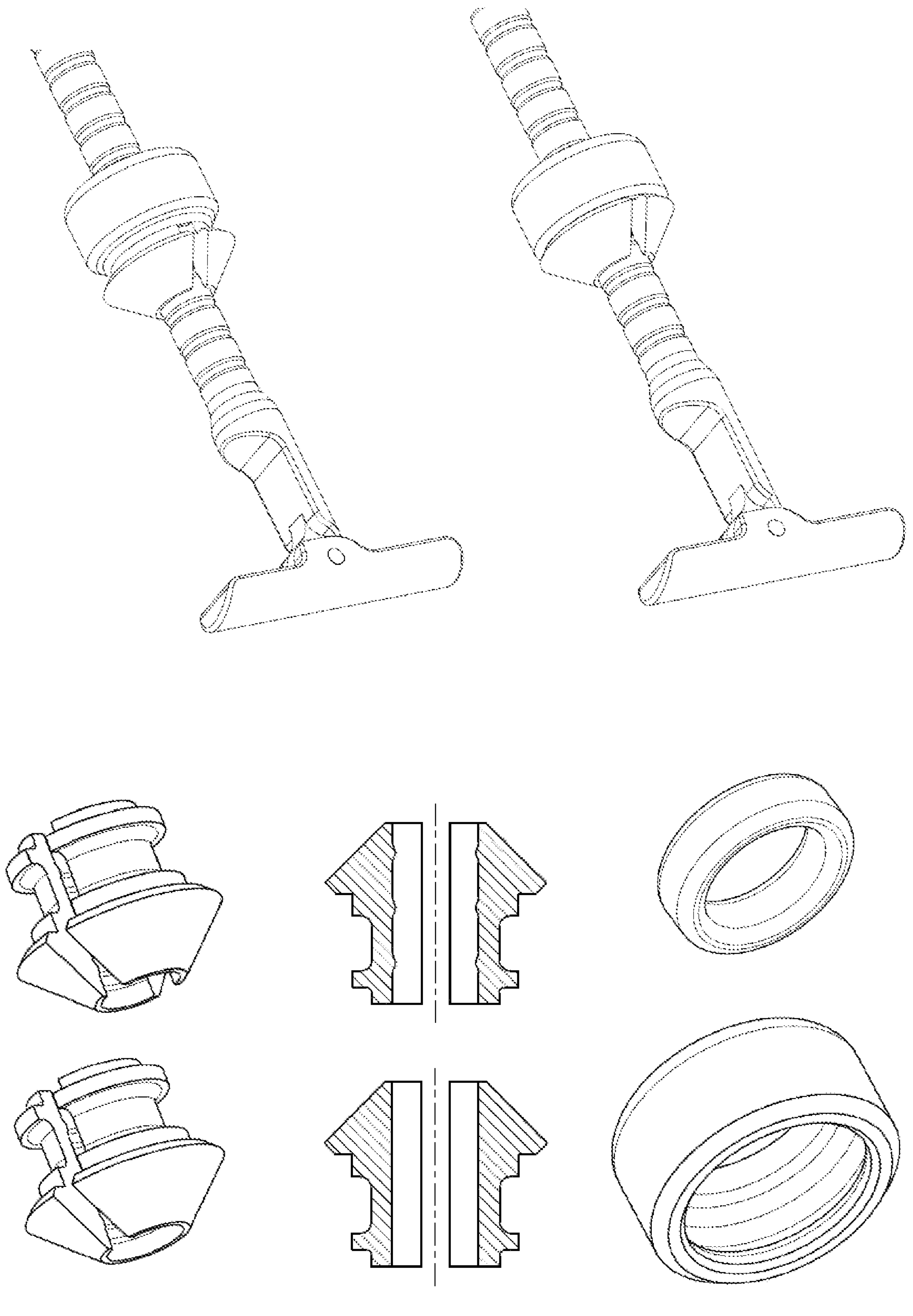


FIG. 6

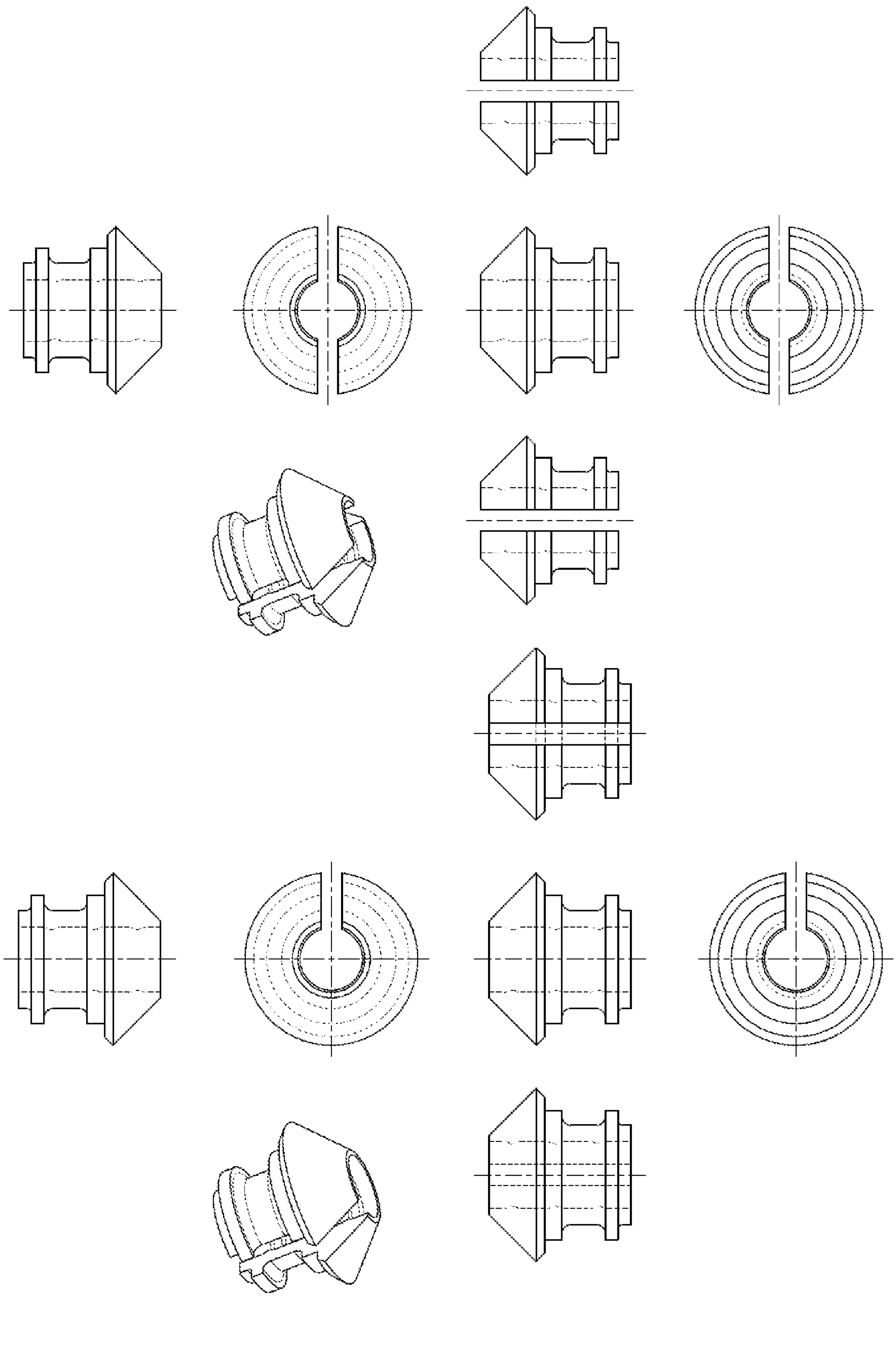


FIG. 7

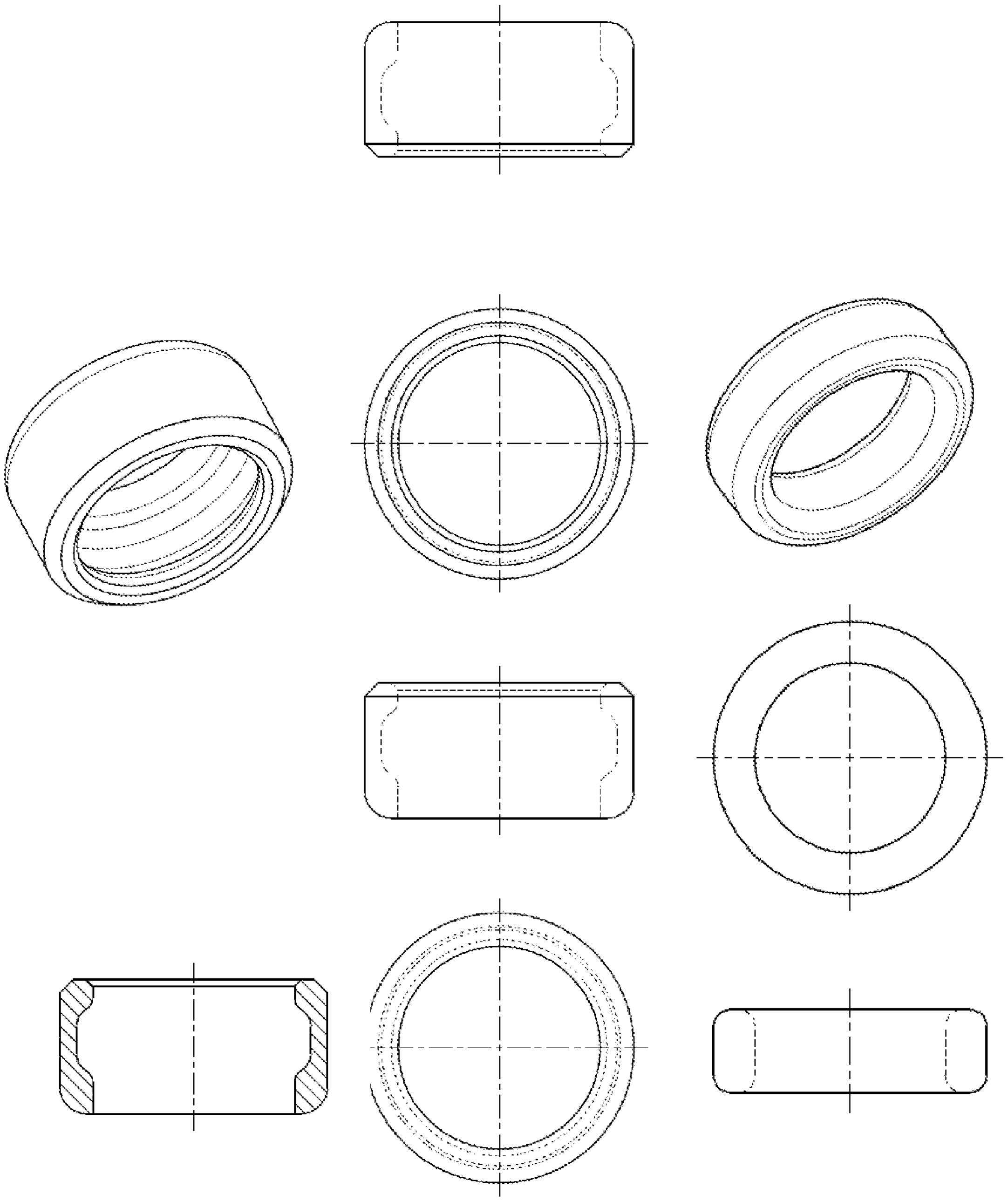


FIG. 8

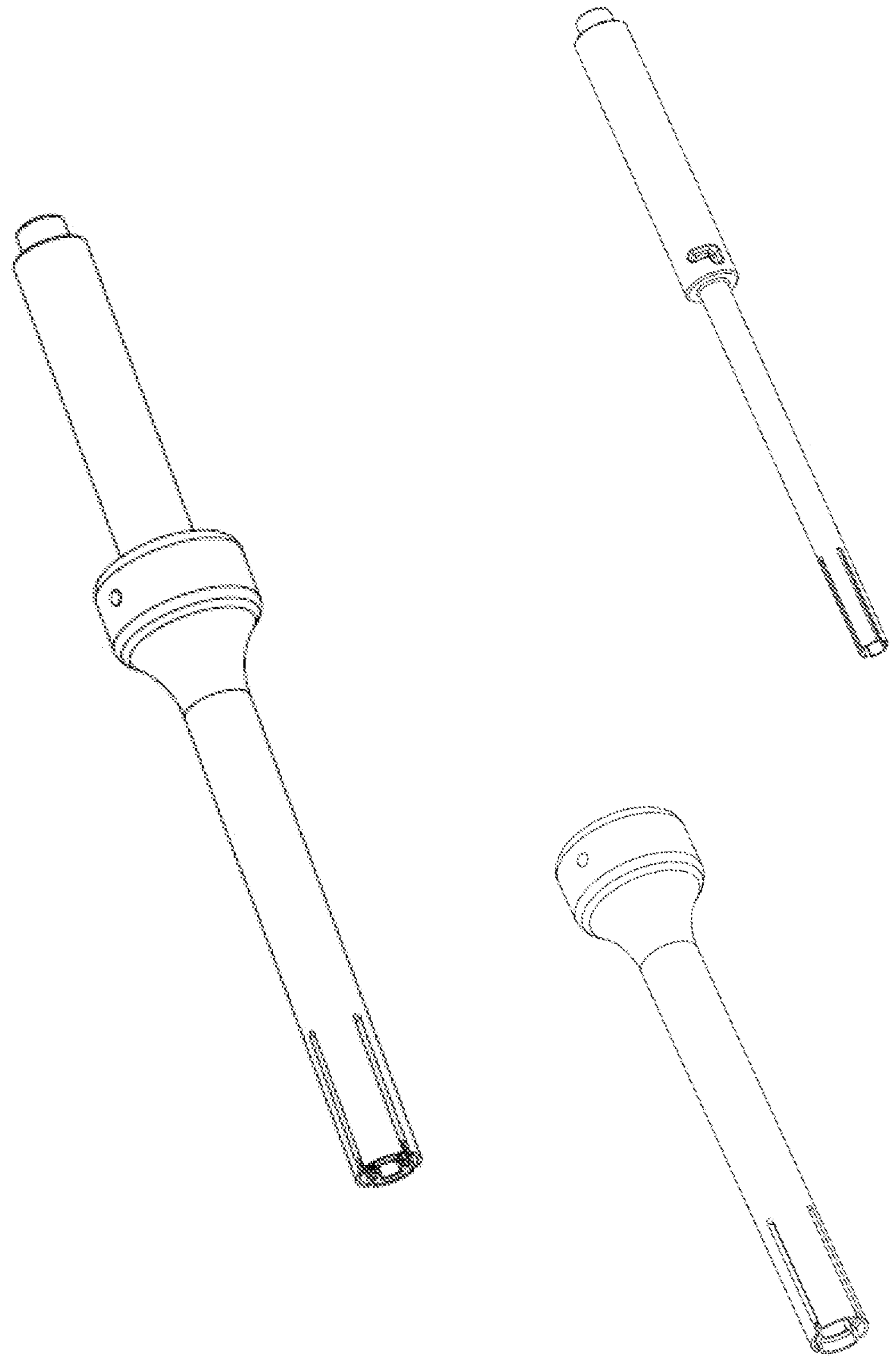
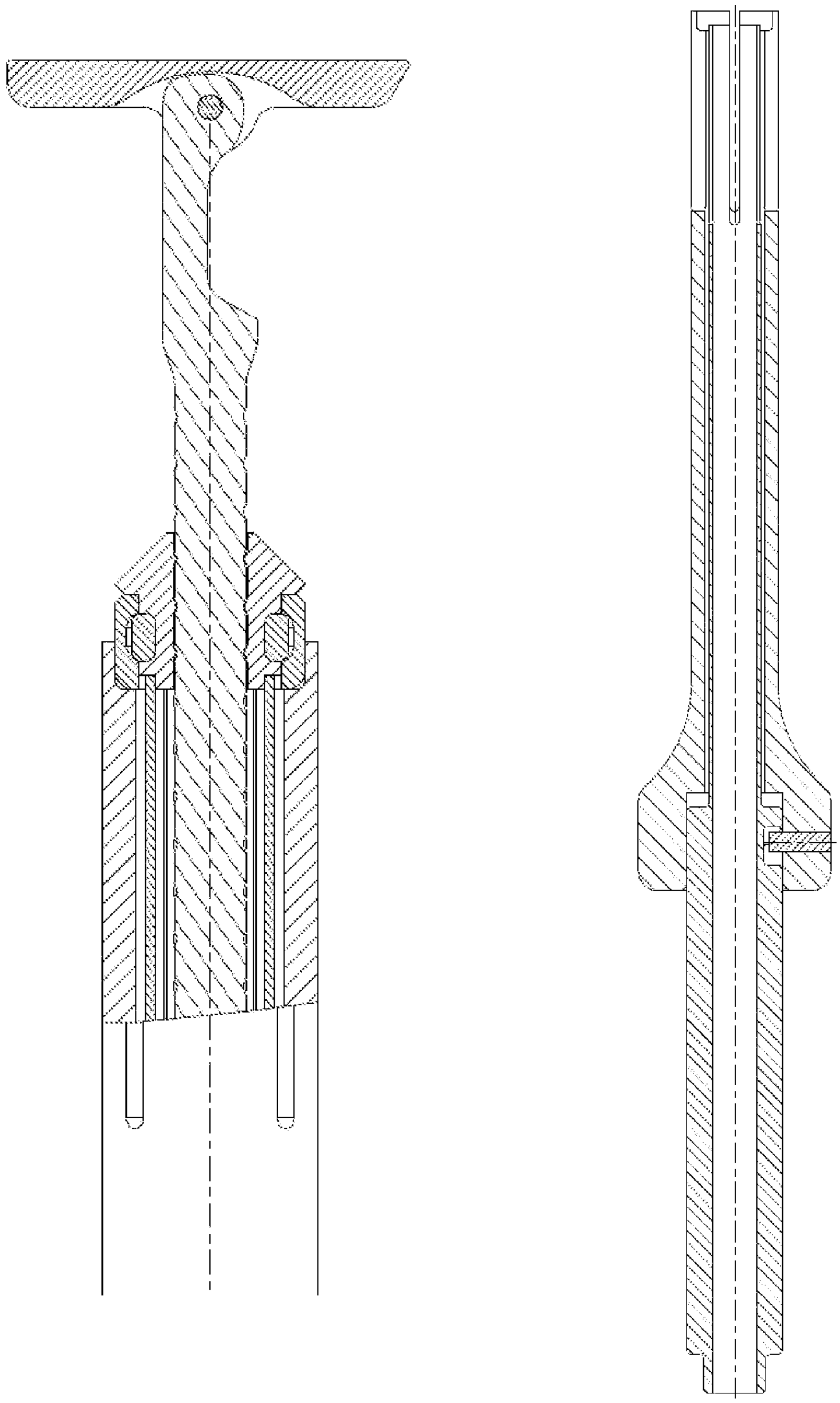


FIG. 9

FIG. 10



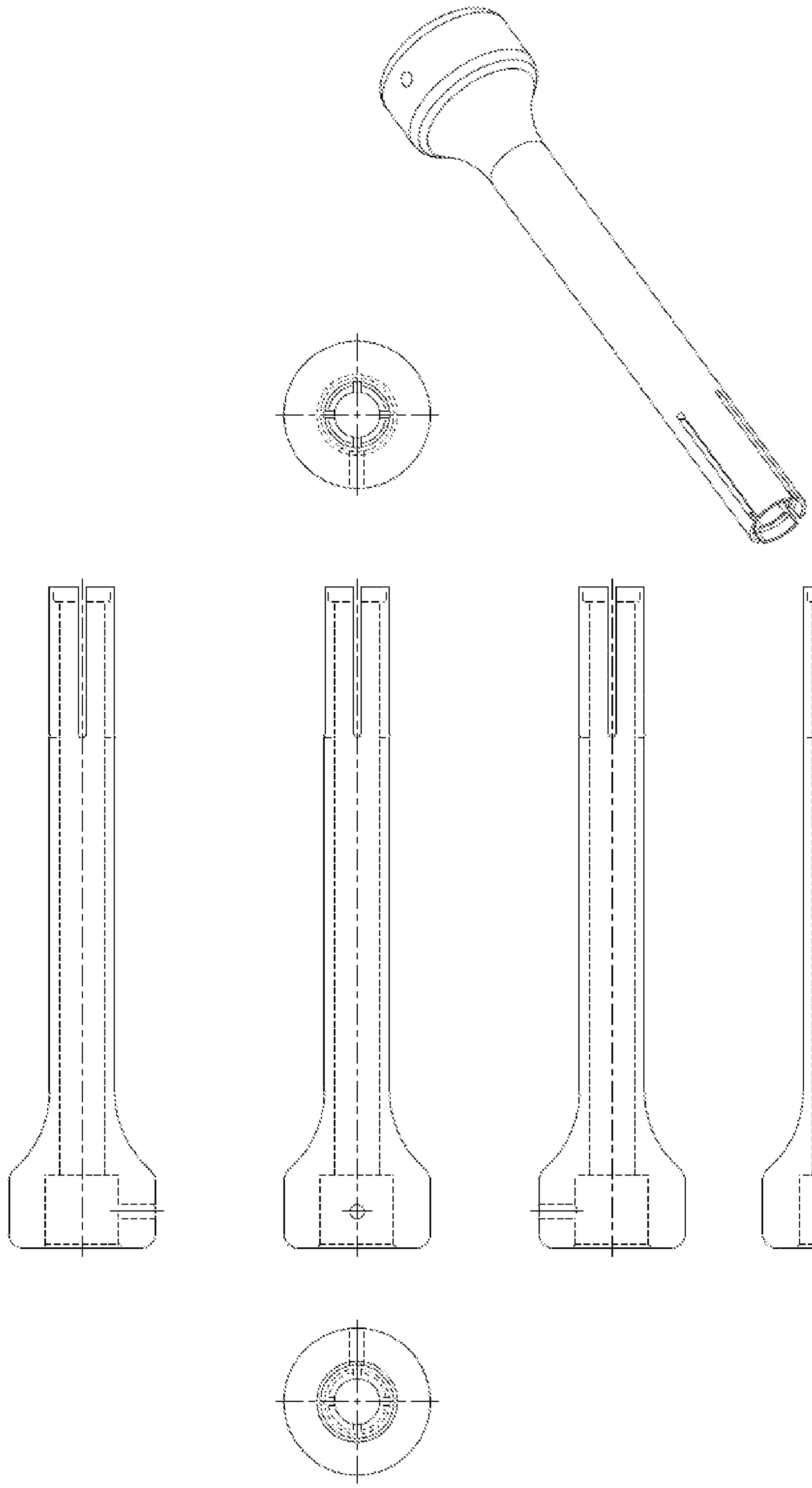


FIG. 11

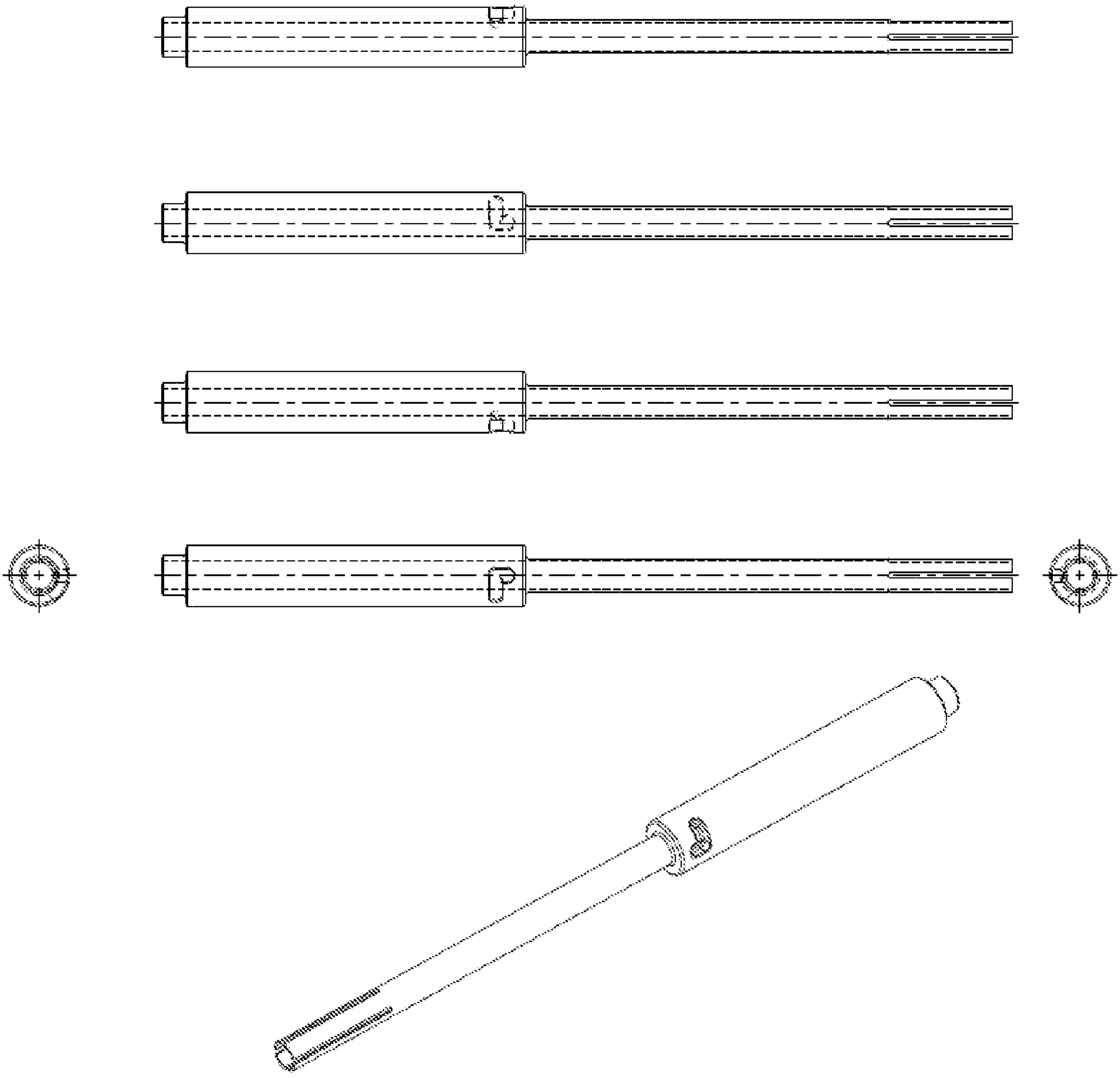


FIG. 12

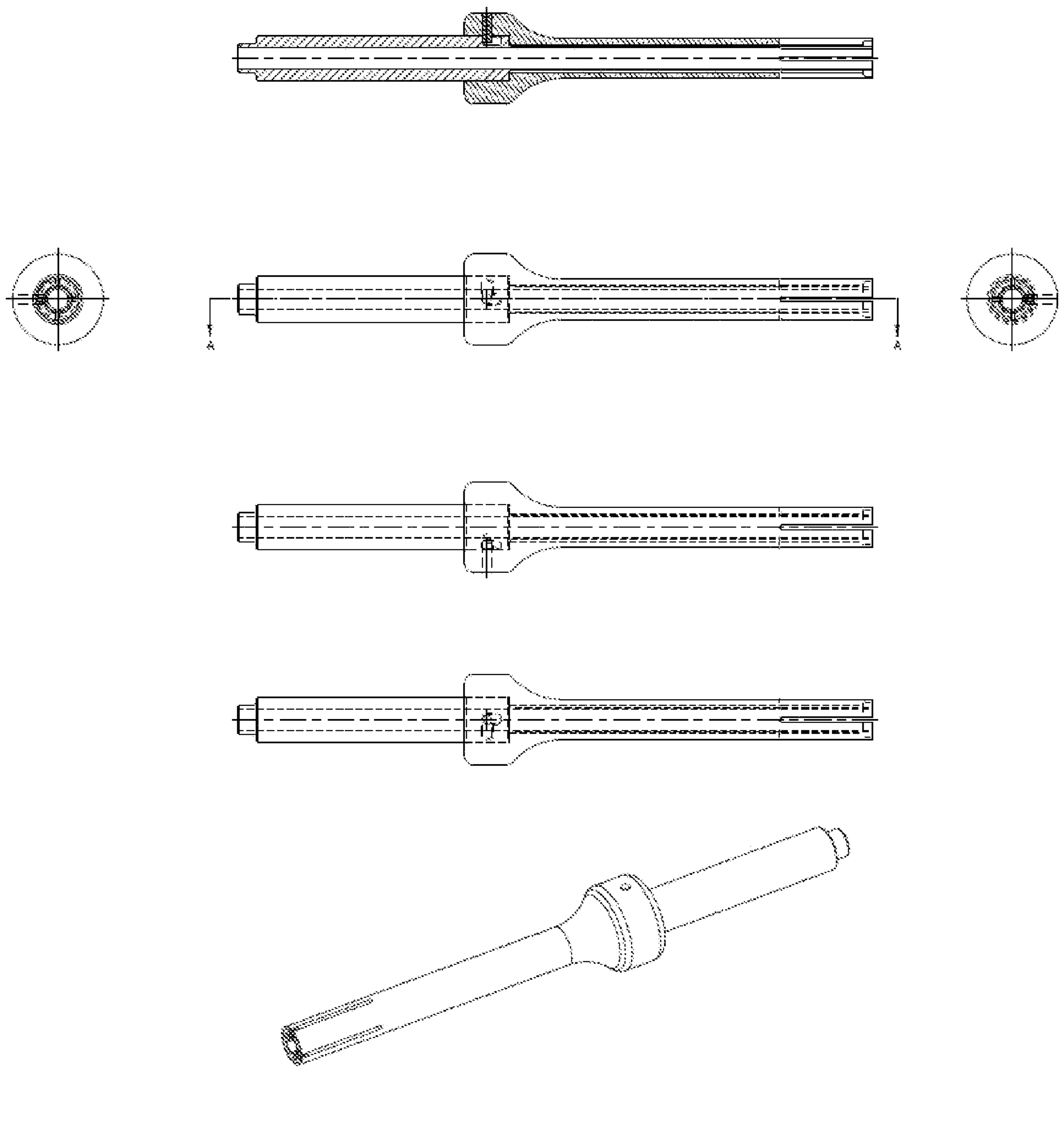


FIG. 13

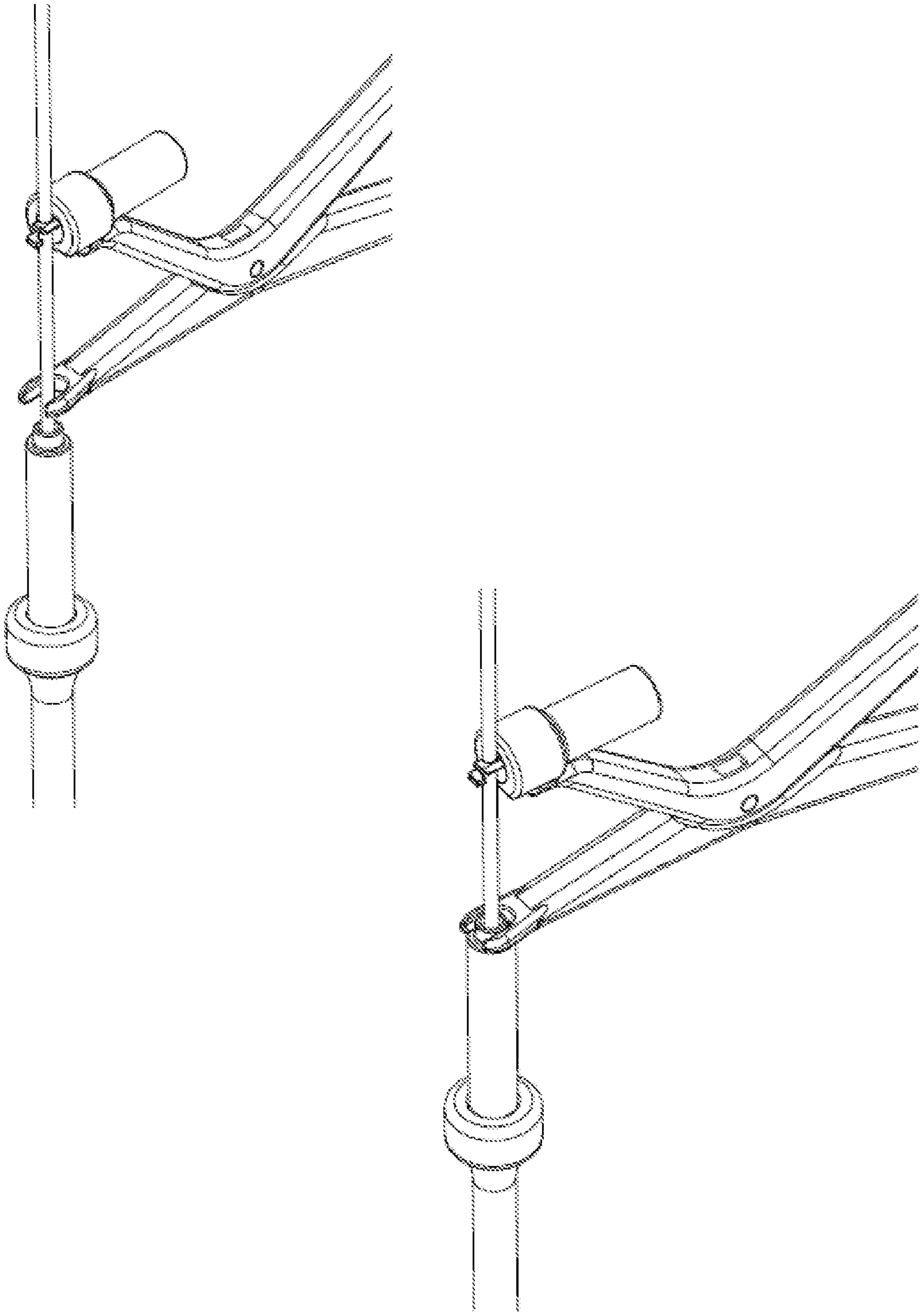


FIG. 14

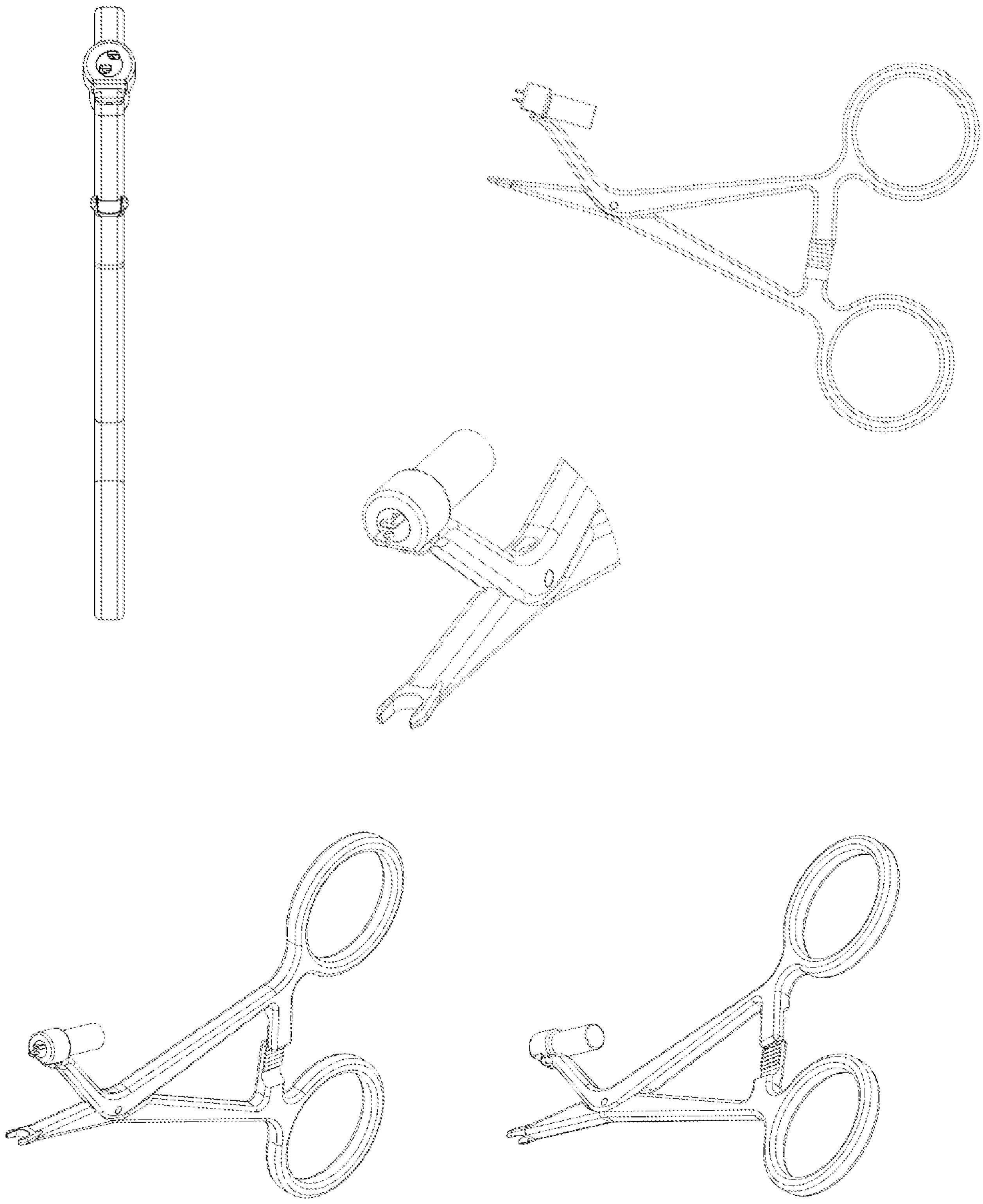


FIG. 15

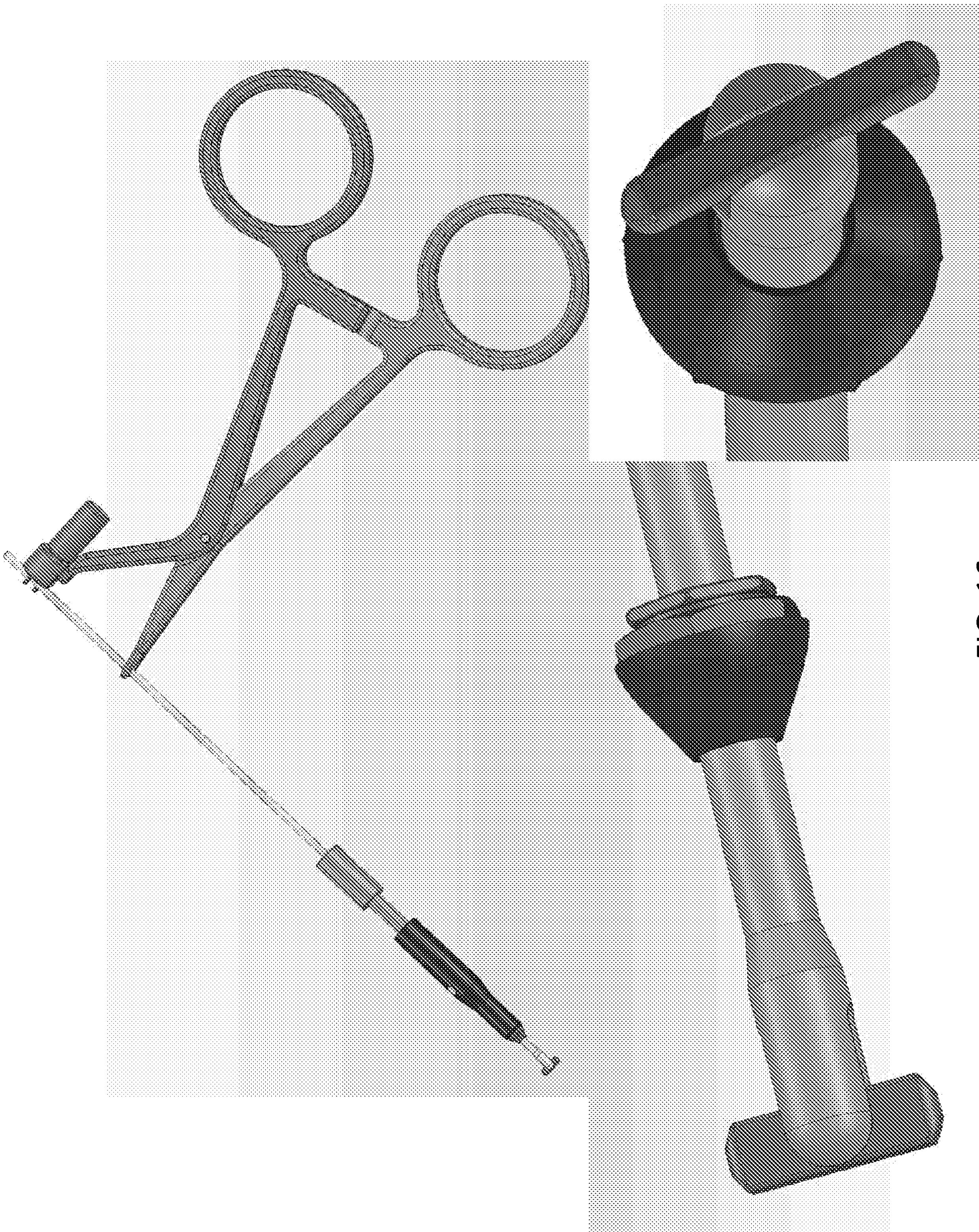


FIG. 16

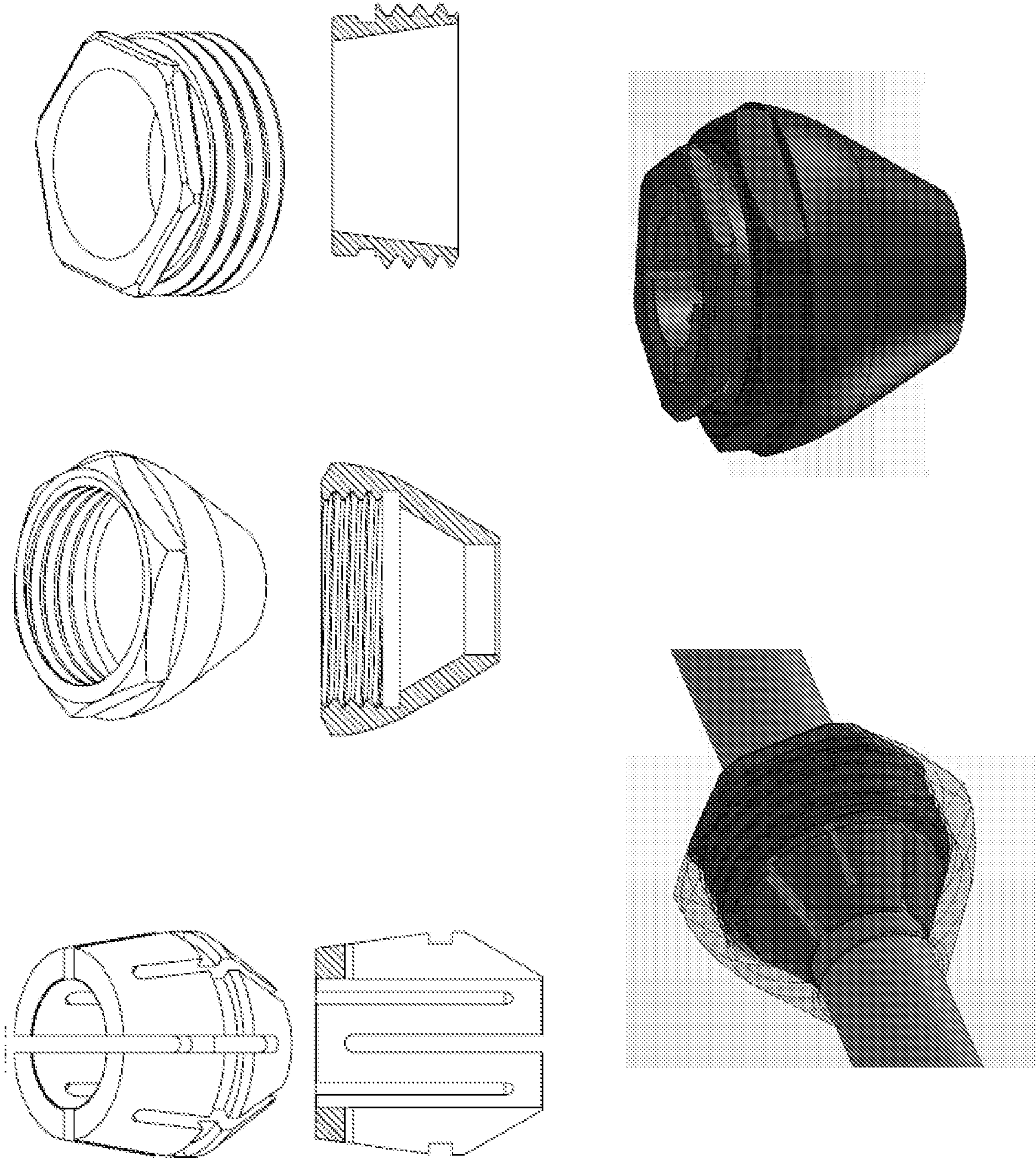


FIG. 17

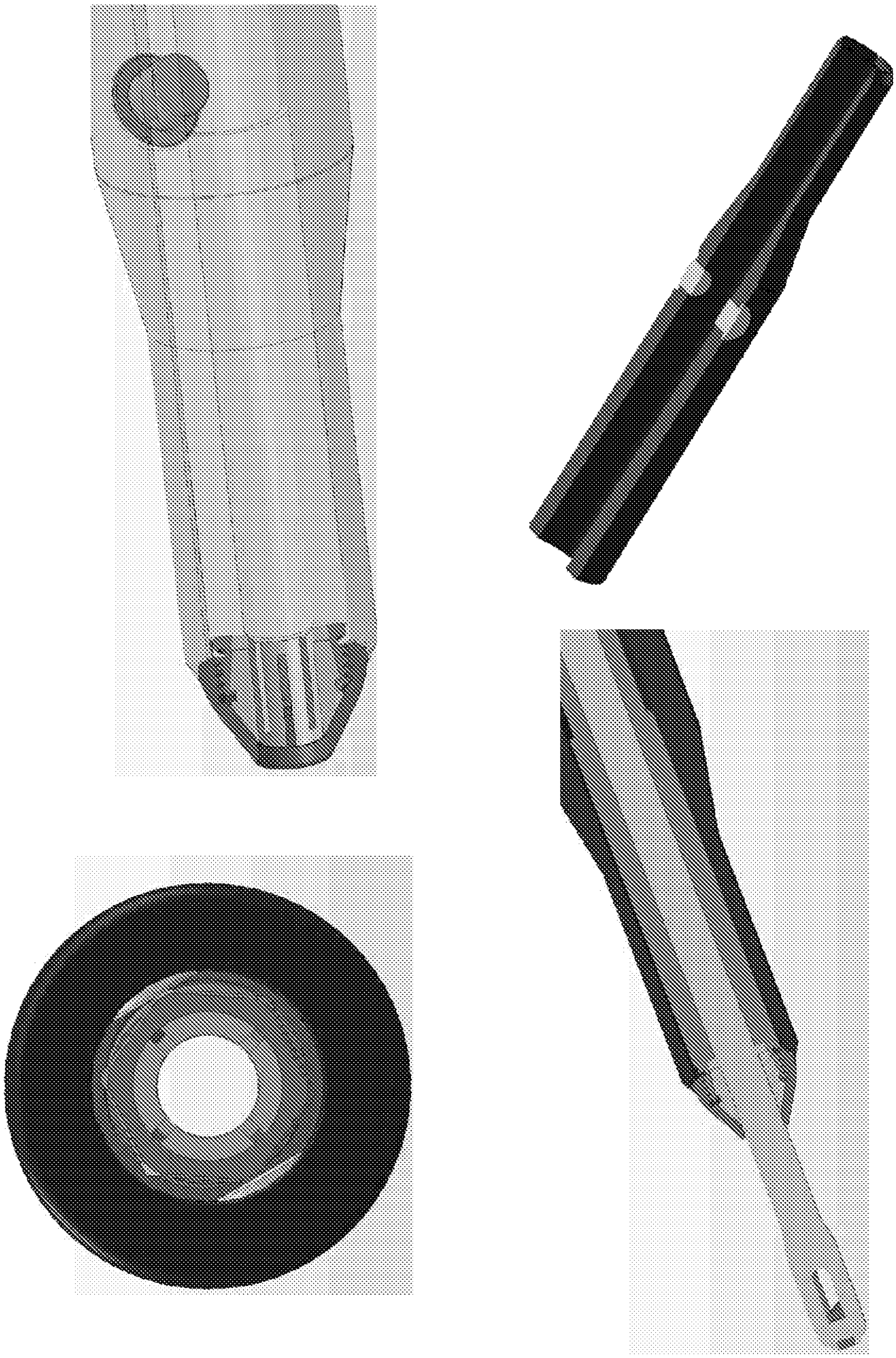


FIG. 18

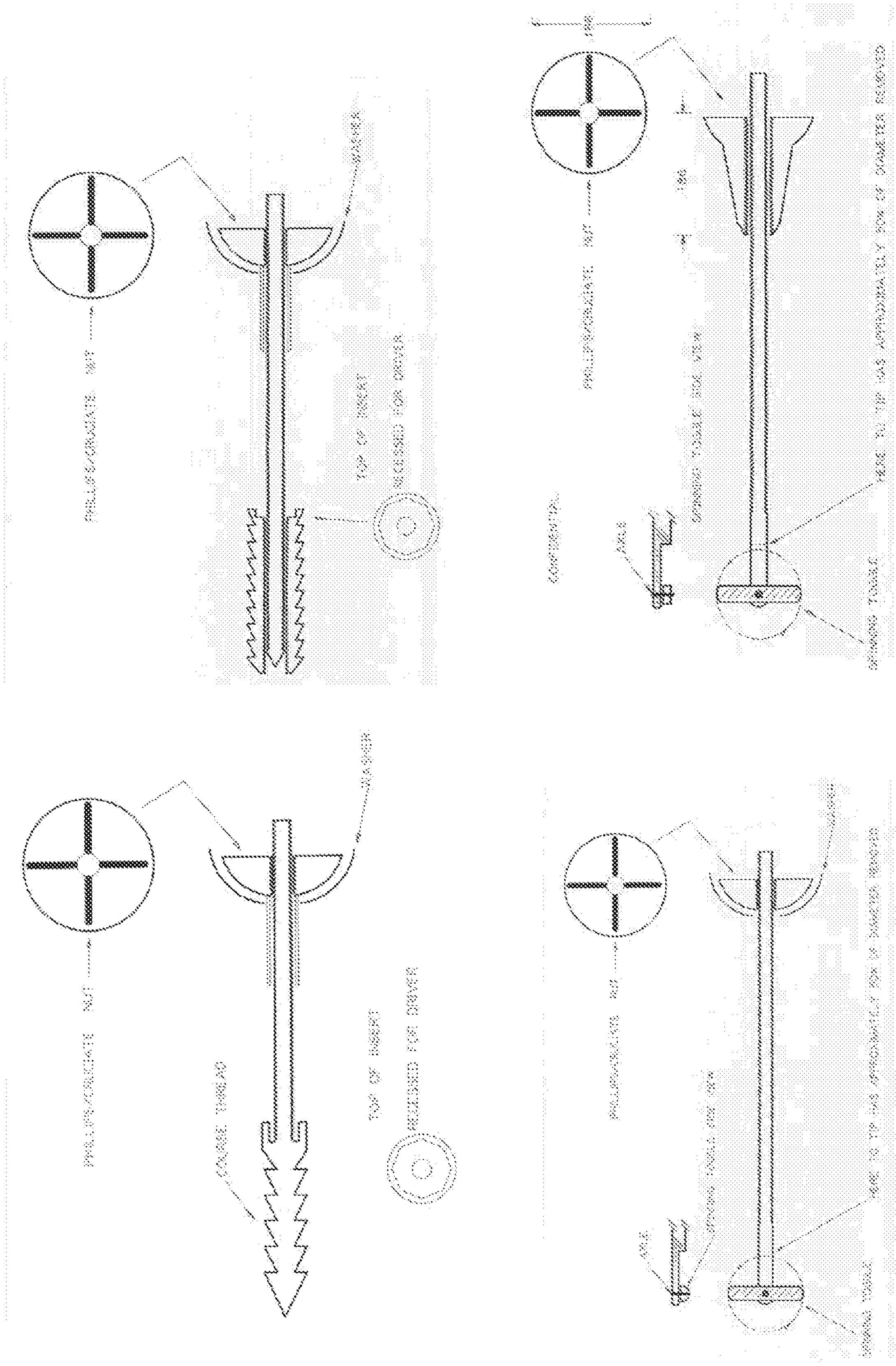
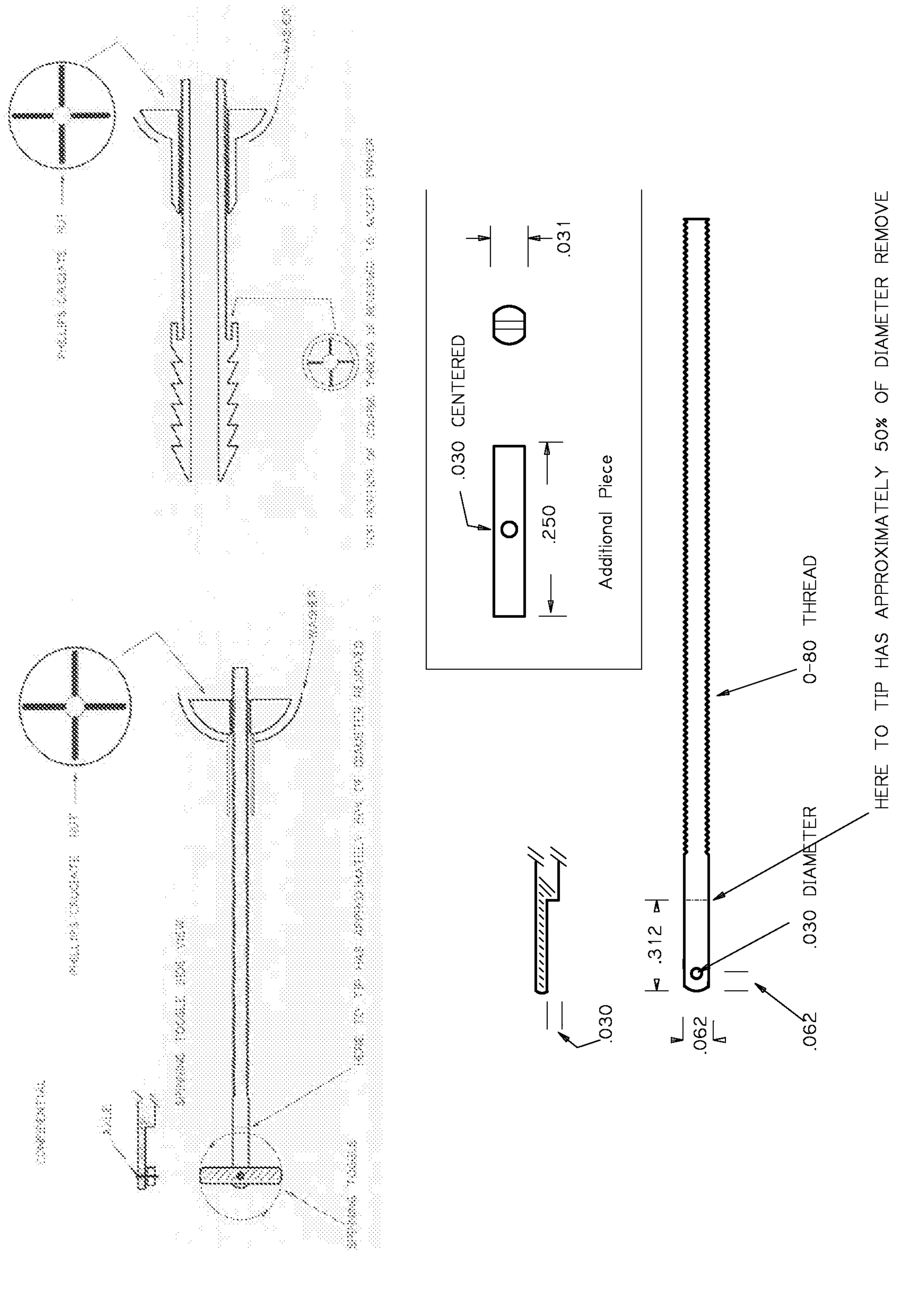


FIG. 19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.250
Additional Piece
.031
0-80 THREAD
HERE TO TIP HAS APPROXIMATELY 50% OF DIAMETER REMOVE
.030 DIAMETER
.312
.062
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.030

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2015/058670

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/88 *(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 17/84, F16B 37/08, A61B 17/04, 17/56, 17/90, 17/88

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)

PatSearch (RUPTO internal), PubMed, NCBI, Rambler, Yandex

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 7981143 B2 (SPINAL LLC) 19.07.2011, fig. 10, 11, 12, 17, claims 1, 2, 6, 9, 10, paragraphs [0005], [0008], [0012], [0019], [0050]	1-5, 10-12, 17-20 6-9, 13-16
Y	EP 1491148 A1 (DEPUY MITEK, INC.) 29.12.2004, abstract, p. 1	6-9, 13-16
Y	US 5944726 A (SCIMED LIFE SYSTEMS, INC.) 31.08.1999, abstract, p. 1	8-9

☐ 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
28 December 2015 (28.12.2015)	28 January 2016 (28.01.2016)

Name and mailing address of the ISA/RU:	Authorized officer
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	A. Amelin Telephone No. (495)531-64-81