



(43) International Publication Date
1 September 2016 (01.09.2016)

- (51) International Patent Classification:
A61B 17/60 (2006.01) *A61B 17/64* (2006.01)
- (21) International Application Number:
PCT/US2016/019486
- (22) International Filing Date:
25 February 2016 (25.02.2016)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
62/121,904 27 February 2015 (27.02.2015) US
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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

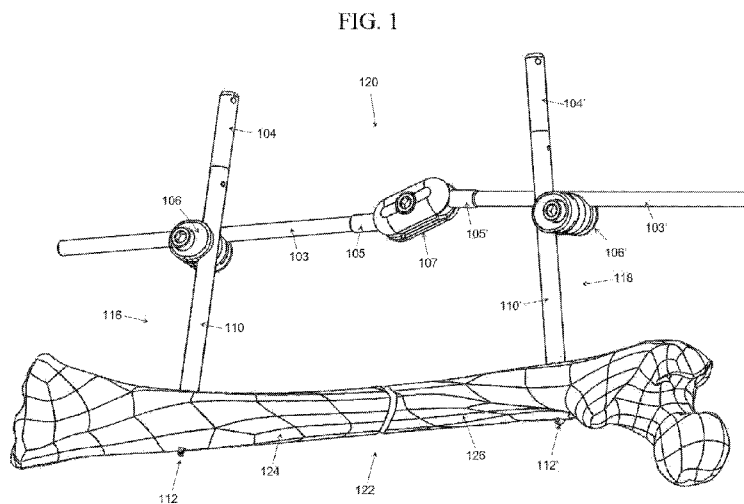
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- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, 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).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: ORTHOPEDIC EXTERNAL FIXATION DEVICE



(57) Abstract: Devices for the fixation of a bone fracture and methods of using the devices are provided. The devices comprise at least one distal pin assembly configured to engage a first bone fragment, at least one proximal pin assembly configured to engage a second bone fragment, and a pin connector assembly configured to connect the distal and proximal pin assemblies together across the bone fracture.

WO 2016/138220 A1

ORTHOPEDIC EXTERNAL FIXATION DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims priority to U.S. Provisional Patent Application No. 62/121,904 that was filed on February 27, 2015, the entire contents of which is hereby incorporated by reference.

BACKGROUND

[0002] Bone fractures are debilitating injuries that affect millions of people around the world each year. Many of these fractures involve the long bones of the extremities including the femur, tibia, fibula, humerus, radius, and ulna. Fractures to these bones can be particularly painful, difficult to heal, and may require multiple surgeries with months of recovery.

[0003] When a patient enters the emergency room with a severe bone fracture, it is often accompanied by many other serious injuries. For instance, bone fractures are a frequent occurrence after a serious car accident, where often times the individual will also have head and respiratory trauma that is of primary concern. Though the critical injuries must be addressed first, once the patient is stable in the emergency department any serious fractures must be stabilized. The patient may need to be transported throughout the emergency department for various imaging and surgical procedures, so it is important to have the injured limb temporarily stabilized to reduce pain and prevent improper healing. Temporary stabilization may be required until the patient and his or her injuries are stable enough for a surgical procedure in the operating room to repair and permanently fixate the fracture. This temporary period can be anywhere from a few hours to a few weeks, depending on the injuries. Once placed, a permanent device may remain affixed for a number of weeks or even months, until the fracture is adequately healed.

[0004] There are several forms of temporary fracture stabilization methods including splinting, traction, and external fixation. Splinting may provide support along a fracture until the patient's other critical injuries are stabilized; however, such temporary devices

are not always compatible with certain imaging techniques, such as magnetic resonance imaging (MRI), and don't actually fixate the fracture.

[0005] Traction is a method for temporary fracture stabilization used in many hospitals and emergency departments. Traction systems separate the two major bone fragments, properly aligning them (reduction) and facilitating proper healing. However, traction is a bulky procedure and can subject the patient to an uncomfortable position without the ability to move for an extended period of time. Bed transfers with this type of fixation are highly impractical, and very difficult to orchestrate.

[0006] External fixators have been used for over a century and have two widespread uses: temporary fixation and more permanent applications intended for a longer term treatment (permanent external fixation). Methods for permanent external fixation may utilize multi-pin circular frames and unilateral pin-bar systems. Though effective in stabilizing the fracture and keeping the fragments aligned for healing, the installation of these permanent fixation devices can take hours, and the complexity involved with unilateral and pin-point bone screw affixation can be complicated.

[0007] Temporary fixation involves the rapid temporary fixation of bone fractures using primarily unilateral pin-bar fixators to provide temporary stability while the patient is stabilized and care is provided during hospitalization. Current temporary fixators employ, at a minimum, four separate pins to achieve fixation. Such devices can take critical time to be applied and pose an increased risk for infection at the exposed sites of pin entry.

SUMMARY

[0008] Devices for the fixation of bone fractures are provided. Also provided are methods of using the devices for the fixation of bone fragments. The device comprises at least one distal pin assembly configured to engage a first bone fragment, at least one proximal pin assembly configured to engage a second bone fragment, wherein the second bone fragment is at least partially separated from the first bone fragment by a bone fracture, and a rod-clamp system configured to connect the distal and proximal pin assemblies together to create a bridge across the bone fracture.

[0009] Pin assemblies for engaging a bone fragment, orthopedic external fixation devices comprising the pin assemblies, and methods for using the orthopedic external fixation devices to stabilize the bone fragments of a fractured bone are provided.

[0010] One embodiment of an orthopedic external fixation device includes: (a) a distal pin assembly configured to engage a first bone fragment; (b) a proximal pin assembly configured to engage a second bone fragment; and (c) a pin assembly connector configured to connect the distal pin assembly to the proximal pin assembly. One embodiment of the the distal pin assembly includes: (i) a screw portion having a distal end configured to engage the first bone fragment and a proximal end; and (ii) a support sheath portion having a distal end configured to engage the first bone fragment, a proximal end, and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed. Similarly, one embodiment of the the proximal pin assembly comprises: (i) a screw portion having a distal end configured to engage the second bone fragment and a proximal end, and (ii) a support sheath portion having a distal end configured to engage the second bone fragment, a proximal end, and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed. One embodiment of the pin assembly connector comprises: a first clamp; a second clamp; and a connecting rod assembly comprising one or more rods, wherein the first clamp is configured to connect to the outer surface of the support sheath portion of the distal pin assembly and to a rod of the connecting rod assembly; the second clamp is configured to connect to the outer surface of the support sheath portion of the proximal pin assembly and to a rod of the connecting rod assembly.

[0011] One embodiment of a method of using the above-described device to stabilize a fractured bone comprising a first bone fragment and a second bone fragment includes the steps of: (a) engaging the first bone fragment with the distal pin assembly; (b) engaging the second bone fragment with the proximal pin assembly; and (c) connecting the distal pin assembly to the proximal pin assembly with the pin assembly connector.

[0012] Another embodiment of an orthopedic external fixation device comprises one or more pin assemblies, each configured to engage a bone fragment and comprising: (i) a

screw portion having a distal end configured to engage the bone fragment and a proximal end; and (ii) a support sheath portion having a distal end configured to engage the bone fragment; a proximal end; and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed, and further wherein the distal end of the support sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the bone fragment when the pin assembly is in place stabilizing a fractured bone.

[0013] One embodiment of an orthopedic external fixation device incorporating the above-described pin assemblies includes: (a) a distal pin assembly configured to engage a first bone fragment; (b) a proximal pin assembly configured to engage a second bone fragment; and (c) a pin assembly connector configured to connect the distal pin assembly to the proximal pin assembly. One embodiment of the distal pin assembly comprises: (i) a screw portion having a distal end configured to engage the first bone fragment and a proximal end; and (ii) a support sheath portion having a distal end configured to engage the first bone fragment; a proximal end; and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed, and further wherein the distal end of the support sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the first bone fragment. One embodiment of the proximal pin assembly comprises: (i) a screw portion having a distal end configured to engage the second bone fragment and a proximal end; and (ii) a support sheath portion having a distal end configured to engage the second bone fragment, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed, and further wherein the distal end of the support sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the second bone fragment.

[0014] One embodiment of a method of using the above-described device to stabilize a fractured bone comprising a first bone fragment and a second bone fragment includes the steps of: (a) engaging the first bone fragment with the distal pin assembly; (b)

engaging the second bone fragment with the proximal pin assembly; and (c) connecting the distal pin assembly to the proximal pin assembly with the pin assembly connector.

[0015] Other principal features and advantages of the invention will become apparent to those skilled in the art upon review of the following drawings, the detailed description, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Illustrative embodiments of the invention will hereafter be described with reference to the accompanying drawings, wherein like numerals denote like elements.

[0017] FIG. 1 shows a perspective view of an embodiment of an external fixation device fixated to a fractured bone.

[0018] FIG. 2 shows a perspective view of an embodiment of an external fixation device fixated to a fractured bone.

[0019] FIG. 3 shows a perspective view of an embodiment of an external fixation device fixated to a fractured bone.

[0020] FIG. 4 shows an exploded perspective view of an embodiment of an external fixation device.

[0021] FIG. 5 shows a front view of an embodiment of an external fixation device.

[0022] FIG. 6 shows a front view of an embodiment of an external fixation device.

[0023] FIG. 7 shows a side view of an embodiment of an external fixation device.

[0024] FIG. 8 shows a side view of an embodiment of an external fixation device.

[0025] FIG. 9 shows an exploded perspective view of an embodiment of a pin assembly for an external fixation device.

[0026] FIG. 10 shows an exploded perspective view of an embodiment of a pin assembly for an external fixation device.

[0027] FIG. 11 shows a close-up view of an embodiment of the pin assembly including multiple sharp extension (tine) features.

[0028] FIG. 12 shows a close-up view of an embodiment of the pin assembly including multiple sharp elongated blade features.

[0029] FIG. 13 shows a close-up view of an embodiment of the pin assembly including multiple sharp elongated blade features, expansion slots, and a threaded section of the screw with a conical section above it.

[0030] FIG. 14 shows a close-up view of an embodiment of the pin assembly including multiple sharp elongated blade features and a threaded section of the screw with a cutting section above it.

[0031] FIG. 15 shows a close-up view of an embodiment of the support sheath including multiple sharp elongated blade features and cutting edges, wherein the bladed section and the cutting section are separated by a tapered, conical section.

[0032] FIG. 16 shows a cross-section view of an embodiment of the pin assembly affixed to a fractured portion of bone, including multiple sharp extension (tine) features.

[0033] FIG. 17 shows a cross-section view of an embodiment of the pin assembly affixed to a fractured portion of bone, including multiple sharp elongated blade features.

DETAILED DESCRIPTION

[0034] The following description of the embodiments of the devices and methods is merely illustrative and is not intended to limit the invention to a specific embodiment or its use to a specific application.

[0035] The terms “distal end” and “proximal end” are used throughout this disclosure in reference to the screw portion, the support sheath portion and the cap portion of each pin assembly. As used herein the “distal end” refers to the end of the component that is nearest the bone fragment when the pin assembly is in place and the “proximal end” refers to the end of the component that is disposed opposite, or substantially opposite, the distal end.

[0036] One embodiment of an orthopedic external fixation device **120** is shown in FIG. 1, FIG. 4, FIG. 5, and FIG. 7. FIG. 5 and FIG. 7 show orthopedic external fixation device **120** alone. FIG. 4 is an exploded view of the orthopedic external fixation device

120. FIG. 1 shows orthopedic external fixation device **120** in combination with fractured bone **122**. The orthopedic external fixation device **120** includes distal pin assembly **116** configured to engage with first bone fragment **124**; proximal pin assembly **118** configured to engage with second bone fragment **126**; first rod **103** connecting first connector clamp **106** to center clamp **107**; and second rod **103'** connecting second connector clamp **106'** to center clamp **107**. First and second rods **103, 103'** may be solid or hollow and need not have a circular cross-section. The connections between first and second rods **103, 103'** and center clamp **107** may be ball-and-socket type connections, as shown in FIG. 4. For example, as shown in FIG. 4 and discussed in more detail below, a first ball-and-socket connection is formed between a spherical surface (i.e., a "ball") **650** at an end of first rod **103** and a mating spherical cavity defined in one end of center clamp **107** and a second ball-and-socket connection is formed between a spherical surface (i.e., a "ball") **650'** at an end of second rod **103'** and a mating spherical cavity defined in an opposing end of center clamp **107**. Spherical surfaces **650, 650'** can be an integral part of the end of the rods, or can be part of an end piece **105, 105'** fitted on the end of a rod, as shown in FIG. 4.

[0037] The rod-clamp connections provide a pin assembly connector that is configured to connect distal pin assembly **116** to proximal pin assembly **118**. Distal pin assembly **116** comprises cap portion **104** attached to the proximal end **160** of screw portion **112**. Proximal pin assembly **118** also comprises a cap portion **104'** attached to the proximal end **160** of screw portion **112'**. Cap portions **104, 104'** are configured such that, when their respective pin assemblies **116, 118** are engaged with their respective bone fragments **124, 126** and cap portions **104, 104'** are tightened onto the proximal ends of their respective screw portions **112, 112'**, the distal ends of the cap portions engage with (e.g., press against) the proximal ends of their respective support sheath portions **110, 110'**, thereby exerting a compressive force on said support sheath portions.

[0038] As shown in this embodiment, each support sheath portion has a distal end configured to engage a bone fragment, wherein the support sheath portion defines an elongated channel in which the proximal end of a screw portion is disposed and out of which the distal end of the screw portion extends. For example, the support sheath portion may comprise a distal end, an oppositely disposed proximal end and a body (e.g.,

a hollow shaft) connecting the distal and proximal ends, wherein the elongated channel extends through the body from the distal end to the proximal end. The engagement between a bone fragment and the distal end of the support sheath portion may be provided, for example, by extensions **701** (e.g., tines) extending outwardly from the leading edge **702** of the distal end of the support sheath portion that are configured to anchor the support sheath portion to a bone fragment and hold the support sheath portion in a given position and alignment along the bone fragment. The support sheath portion fits over the screw portion to allow the support sheath portion to slide over the proximal end of the screw portion and engage the bone fragment.

[0039] In the present embodiment, as best seen in FIG. 4, connector clamps **106, 106'** can be seen to be comprised of compression screws **501, 501'**; outer sheath clamp plates **502, 502'**; inner sheath clamp plates **503, 503'**; inner rod clamp plates **504, 504'**; and outer rod clamp plate **505, 505'**. Clamp plates **502, 503,** and **504** each define a bore hole **507, 508,** and **510** through which compression screw **501** can be placed, and clamp plate **505** defines a tapped bore hole (i.e., a threaded screw hole) **512** into which compression screw **501** can be screwed. Similarly, clamp plates **502', 503',** and **504'** each define a bore hole **507', 508', 510'** through which compression screw **501'** can be inserted, and clamp plate **505'** defines a tapped bore hole (i.e., a threaded screw hole) **512'** into which compression screw **501'** can be screwed. Outer sheath clamp plate **502** and inner sheath clamp plate **503** clamp support sheath portion **110** between them to provide a clamping grip on an outer surface (e.g., the circumference) of support sheath portion **110** when compression screw **501** is tightened. Similarly, outer sheath clamp plate **502'** and inner sheath clamp plate **503'** clamp support sheath portion **110'** between them to provide a clamping grip on an outer surface (e.g., the circumference) of support sheath portion **110'** when compression screw **501'** is tightened. Inner rod clamp plate **504** and outer rod clamp plate **505** provide a clamping grip on rod **103** when compression screw **501** is tightened. Similarly, inner rod clamp plate **504'** and outer rod clamp plate **505'** provide a clamping grip on rod **103'** when compression screw **501'** is tightened. The effective result is a clamping grip between pin assembly **116** and rod **103** and a clamping grip between pin assembly **118** and rod **103'**.

[0040] The inner surfaces of the clamp plates (i.e., the surfaces that make contact with a support sheath portion or a rod) may be contoured to match the contour of the outer surface of the support sheath portion or rod, as illustrated by grooves **509**, **509'**, **511**, **511'**, **513**, **513'**, **515**, and **515'**. In addition, inner sheath plate **503** and inner rod plate **504** need not be separate pieces, but can be a single integral piece, such that one face of the piece provides the inner sheath plate and the opposing face provides the inner rod plate.

[0041] In the present embodiment, as best seen in FIG. 4, center clamp **107** can be seen to be comprised of compression screw **601**; upper center clamp **602**; and lower center clamp **603**. Upper center clamp **602** defines a bore hole **656** through which compression screw **601** can be inserted and lower center clamp **603** defines a tapped bore hole (i.e., a threaded screw hole) **658** into which compression screw **601** can be screwed. Hemispherical cavities **652**, **654**, **652'**, and **654'** are defined in the opposing ends of both the upper and lower center clamps **602** and **603**. When compression screw **601** is inserted through the screw holes **656** and **658** in upper and lower center clamps **602** and **603** and tightened, hemispherical cavities **652** and **652'** come together to form a spherical cavity that provides a clamping force on spherical surface **650** and hemispherical cavities **654** and **654'** come together to form a spherical cavity that provides a clamping force on spherical surface **650'**. The effective result is ball-and-socket joint between center clamp **107** and rod **103** and a ball-and-socket joint between center clamp **107** and rod **103'**.

[0042] In the presented embodiment, as best seen in FIG. 9, the distal end of cap portion **104** defines a bore hole **170**, the inner surface of which comprises internal screw threads configured to engage with the threaded proximal end **160** of screw portion **112**. The distal end of cap portion **104** further comprises a surface **172** configured to engage with the proximal end of support sheath portion **110** and provide compression onto support sheath portion **110** when cap portion **104** is tightened onto screw portion **112**. Cap portion **104** can engage with support sheath portion **110** simply by pressing against it. Cap portion **104** further comprises a proximal end disposed opposite its distal end and a body, such as a hollow shaft, extending between the proximal and distal ends. Support sheath portion **110** of distal pin assembly **116** slides over screw portion **112**, such that the

distal end of screw portion **112** extends out of the distal end of support sheath portion **110**.

[0043] FIG. **11** shows only the distal end of distal pin assembly **116** in the presented embodiment. Support sheath portion **110** has a distal end configured with multiple sharp extensions **701** (e.g. tines) protruding from leading edge **702** meant to engage bone fragment **124**. FIG. **16** shows a cross-section view of the distal pin assembly **116** installed in bone fragment **124**. As shown in this figure, a threaded section at the tip of the distal end of screw portion **112** extends out of the distal end of support sheath portion **110** and is engaged with bone fragment **124** via extensions **701**.

[0044] Although only the distal pin assembly and the first bone fragment are shown in FIGs. **9**, **11**, and **16**, the proximal pin assembly and second bone fragment can have equivalent components and configurations. Similarly, although only the distal pin assembly and the first bone fragment are shown in FIGs. **10**, **12-15**, and **17** (described below), the proximal pin assembly and second bone fragment can have equivalent components and configurations.

[0045] Another embodiment of an orthopedic external fixation device **220** is shown in FIG. **2**, FIG. **6**, and FIG. **8**. FIG. **6** and FIG. **8** show the orthopedic external fixation device alone. FIG. **2** shows orthopedic external fixation device **220** in combination with fractured bone **122**. This embodiment of the orthopedic external fixation device uses the same cap portions **104**, **104'**, connector clamps **106**, **106'**, and screw portions **112**, **112'** as the device of FIG. **1**, but uses only one rod **103** to connect connector clamps **106**, **106'**. In addition, the support sheath portions **211**, **211'** in this embodiment of the device have a bladed configuration at their distal ends, as discussed in greater detail below. The orthopedic external fixation device **220** includes distal pin assembly **216** configured to engage with first bone fragment **124**; proximal pin assembly **218** configured to engage with second bone fragment **126**; and rod **103** connected to first connector clamp **106** and to second connector clamp **106'**, such that it bridges the first and second connector clamps. More specifically, a first end of rod **103** is clamped between inner rod clamp plate **504** and outer rod clamp plate **505** and a second end of rod **103** is clamped between inner rod clamp plate **504'** and outer rod clamp plate **505'**.

[0046] The rod-clamp connections are configured to connect distal pin assembly **216** to proximal pin assembly **218**. Distal pin assembly **216** comprises cap portion **104** attached to the proximal end of screw portion **112**. Proximal pin assembly **218** also comprises a cap portion **104'** attached to the proximal end of its screw portion **112'**. The structure of the screw portion, illustrated in FIG. **10**, is the same as that of the screw portion shown in FIG. **9**. As in the embodiment of the external fixation device depicted in FIG. **1**, cap portions **104, 104'** are configured such that, when their respective pin assemblies **216, 218** are engaged with their respective bone fragments **124, 126** and cap portions **104, 104'** are tightened onto the proximal ends of their respective screw portions, the distal ends of the cap portions engage with (e.g., press against) the proximal ends of their respective support sheath portions **211, 211'**, thereby exerting a compressive force on said support sheath portions.

[0047] As in the device shown in FIG. **1**, the orthopedic external fixation device of FIGs. **2, 6, and 8** comprises pin assemblies, each of which includes a support sheath portion having a distal end configured to engage a bone fragment, wherein the support sheath portion defines an elongated channel in which the proximal end of a screw portion is disposed and out of which the distal end of the screw portion extends. For example, the support sheath portion may comprise a distal end, an oppositely disposed proximal end and a body (e.g., a hollow shaft) connecting the distal and proximal ends, wherein the elongated channel extends through the body from the distal end to the proximal end. However, the alternative embodiments of support sheath portions **211, 211'** shown in FIGs. **2, 6, and 8** include a plurality (for example, at least two, at least three, or at least four) of blades **801, 801'** running lengthwise along an outer surface of the distal end of the support sheath portions. In this embodiment, the blades have a parallel, or substantially parallel, arrangement with each other and with the longitudinal axes of the support sheath portions. The engagement between a bone fragment and the distal end of the bladed support sheath portion may be provided, for example, by blades **801, 801'**, each of which has a sharp leading edge **821** (or "point"), as seen in FIGs. **12, 13, 14, 15, and 17**, and is configured to be inserted into a bone fragment in order to anchor the support sheath portion to said bone fragment and hold the support sheath portion in a given position along the bone fragment. As illustrated in this embodiment, the sharp

leading edges **821** of the blades may terminate at the leading edge of the support sheath portion.

[0048] In the presented embodiment, as best seen in FIG. **10**, the distal end of cap portion **104** defines a bore hole **170**, the inner surface of which comprises internal screw threads configured to engage with the threaded proximal end **160** of screw portion **112**. The distal end of cap portion **104** further comprises a surface **172** configured to engage with the proximal end of bladed support sheath portion **211** and provide compression onto bladed support sheath portion **211** when cap portion **104** is tightened onto screw portion **112**. Cap portion **104** can engage with bladed support sheath portion **211** simply by pressing against it. Cap portion **104** further comprises a proximal end disposed opposite its distal end and a body, such as a hollow shaft, extending between the proximal and distal ends. Bladed support sheath portion **211** of distal pin assembly **216** slides over screw portion **112**, such that the distal end of screw portion **112** extends out of the distal end of bladed support sheath portion **211**.

[0049] FIG. **12** shows only the distal end of a pin assembly in the presented embodiment. As discussed above, bladed support sheath portion **211** has a distal end configured with multiple sharp elongated blades **801** arranged around the circumference of its outer surface. The blades are configured to (i.e., designed to) penetrate bone fragment **124** when the orthopedic external fixation device is stabilizing fractured bone **122**. This penetration can be facilitated by the sharp leading edges **821** at the distal end of each blade **801**. In addition, the blades may have a triangular cross-section with an upward facing point in order to facilitate their insertion into a bone fragment. Optionally, the faces of the triangular blades may be hollow ground, as illustrated in FIG. **12**. The triangular blades with hollow ground faces are considered to fall within the category of blades having a triangular cross-section for the purposes of this disclosure. FIG. **17** shows a cross-sectional view of the pin assembly of the presented embodiment installed in bone fragment **124**. As illustrated in this view, blades **801** extend at least partially through the width of the bone fragment when the device is stabilizing the bone. Screw portion **112** is also engaged in bone fragment **124** and is disposed within bladed support sheath portion **211**. The leading edge **805** of the distal end of bladed support sheath portion **211** may be tapered so that the outer diameter at the tip of the support sheath

portion is only slightly larger than the diameter of the bore hole formed by the threaded end of screw portion **112** as it is installed into bone fragment **124**. This facilitates the insertion of leading edge **805** into bone fragment **124**.

[0050] FIG. **13** shows only the distal end of a pin assembly in an additional embodiment. Like the support sheath portion shown in FIG. **12**, the support sheath portion **311** in this embodiment has a distal end configured with multiple sharp elongated blades **801** arranged around the circumference of its outer surface. Bladed support sheath portion **311** further includes multiple elongated expansion slots **802** extending into its distal end from its leading edge. The elongated slots are configured to allow the distal end of the support sheath portion to expand outwardly when the support sheath portion is passed over the screw portion to engage bone fragment **124**. This design makes it possible for the threaded section of the screw portion to have a diameter that is the same as, or larger than, the diameter of the slotted section at the distal end of the support sheath portion. As a result, the bore hole created in bone fragment **124** by the threaded section of screw portion **1312** can have a diameter that is the same or larger than the outer diameter of the slotted section of support sheath portion **311** (for the purposes of this description, the blades are not taken into account when determining the outer diameter of the slotted section of the support sheath portion). This facilitates the insertion of the distal end of support sheath portion **311** into bone fragment **124**. Screw portion **1312** may also include a conical section **902** above its threaded section. Conical section **902** is tapered toward support sheath portion **311** and configured to force the expansion of the distal end of the support sheath portion **311**. In addition, as shown in FIG. **13**, the leading edge **1305** of bladed support sheath portion **311** can also be tapered to further facilitate the insertion of the support sheath portion into bone fragment **124**.

[0051] FIG. **14** shows only the distal end of a pin assembly in an additional embodiment. Here, again, bladed support sheath portion **211** has a distal end configured with multiple sharp elongated blades **801** arranged around the circumference of its outer surface. In this embodiment, screw portion **1412** includes a cutting section comprising one or multiple cutting edges **901** extending outwardly from its circumference above the threaded section, wherein cutting edge(s) **901** are configured to engage and bore a hole through the outer portion of bone fragment **124** as screw portion **1412** is installed into

bone fragment **124**. Tapered front edge **805** of bladed support sheath portion **211** can then be inserted into the resulting bore hole.

[0052] FIG. **15** shows only the distal end of a bladed support sheath portion **1511** in an additional embodiment. As in previous embodiments, support sheath portion **1511** has a distal end configured with multiple sharp elongated blades **801** arranged around the circumference of its outer surface. The leading edge **1505** of the distal end of bladed support sheath portion **1511** is flanked by multiple cutting edges **803** around its circumference. Cutting edges **803** are configured to engage and bore a hole through the outer portion of bone fragment **124** when the cutting section is drilled into the bone fragment. The trailing part of support sheath portion **1511** can then follow leading edge **1505** into the resulting bore hole.

[0053] In an additional embodiment, as best seen in FIG. **3**, two rods **103**, **103'** connect distal pin assembly **116** to proximal pin assembly **118** by use of clamping grip provided by each clamp **106**, **106'**, as previously described. Additional rods and clamps can be used to further stabilize the orthopedic external fixation device.

[0054] As shown in FIGS **1-8**, the two pin assemblies of each embodiment can be spaced apart along the rod-clamp system, such that the rod-clamp system forms a bridge between the pin assemblies. The rod-clamp system is desirably designed such that the spacing between the two pin assemblies can be adjusted and need not be planar or unilateral.

[0055] While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination. Therefore, the present invention is not limited to only the specific embodiments depicted herein.

[0056] The word "illustrative" is used herein to mean serving as an example, instance, or illustration. Any aspect or design described herein as "illustrative" is not necessarily to be construed as preferred or advantageous over other aspects or designs. Further, for the purposes of this disclosure and unless otherwise specified, "a" or "an" means "one or more".

[0057] The foregoing description of illustrative embodiments of the invention has been presented for purposes of illustration and of description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and modifications and variations are possible in light of the above teachings or may be acquired from practice of the invention. The embodiments were chosen and described in order to explain the principles of the invention and as practical applications of the invention to enable one skilled in the art to utilize the invention in various embodiments and with various modifications as suited to the particular use contemplated. It is intended that the scope of the invention be defined by the claims appended hereto and their equivalents.

WHAT IS CLAIMED IS:

1. A device for fixation of a bone fracture comprising:
 - a. a distal pin assembly configured to engage a first bone fragment, the distal pin assembly comprising: (i) a screw portion having a distal end configured to engage the first bone fragment and a proximal end; and (ii) a support sheath portion having a distal end configured to engage the first bone fragment, a proximal end, and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed;
 - b. a proximal pin assembly configured to engage a second bone fragment, the proximal pin assembly comprising: (i) a screw portion having a distal end configured to engage the second bone fragment and a proximal end; and (ii) a support sheath portion having a distal end configured to engage the second bone fragment, a proximal end, and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed; and
 - c. a pin assembly connector configured to connect the distal pin assembly to the proximal pin assembly, the pin assembly connector comprising: a first clamp; a second clamp; and a connecting rod assembly comprising one or more rods, wherein the first clamp is configured to connect to the outer surface of the support sheath portion of the distal pin assembly and to a rod of the connecting rod assembly; the second clamp is configured to connect to the outer surface of the support sheath portion of the proximal pin assembly and to a rod of the connecting rod assembly.
2. The device of claim 1, wherein the first clamp comprises:
 - an outer sheath clamp plate and an inner sheath clamp plate, wherein the outer and inner sheath clamp plates are configured to clamp the support sheath portion of the distal pin assembly between them; and
 - an outer rod clamp plate and an inner rod clamp plate, wherein the outer and inner rod clamp plates are configured to clamp a rod of the connecting rod assembly between them;and further wherein the second clamp comprises:

an outer sheath clamp plate and an inner sheath clamp plate, wherein the outer and inner sheath clamp plates are configured to clamp the support sheath portion of the proximal pin assembly between them; and

an outer rod clamp plate and an inner rod clamp plate, wherein the outer and inner rod clamp plates are configured to clamp a rod of the connecting rod assembly between them.

3. The device of claim 1, wherein the pin assembly connector comprises at least two rods that are connected together at a joint.

4. The device of claim 3, wherein the joint is a ball-and-socket type joint.

5. The device of claim 1, wherein the pin assembly connector has only a single rod.

6. The device of claim 1, wherein the distal end of the support sheath portion of the distal pin assembly comprises multiple elongated tines extending outwardly from its leading edge and configured to engage the first bone fragment and the distal end of the support sheath portion of the proximal pin assembly comprises multiple elongated tines extending outwardly from its leading edge and configured to engage the second bone fragment.

7. The device of claim 1, wherein the distal end of the support sheath portion of the distal pin assembly comprises multiple elongated blades running lengthwise along its outer surface and configured to engage the first bone fragment and the distal end of the support sheath portion of the proximal pin assembly comprises multiple elongated blades running lengthwise along its outer surface and configured to engage the second bone fragment.

8. The device of claim 1, wherein the distal pin assembly further comprises a cap portion attached to the proximal end of its screw portion and engaged with the proximal end of its support sheath portion; and

further wherein the proximal pin assembly further comprises a cap portion attached to the proximal end of its screw portion and engaged with the proximal end of its support sheath portion.

9. A method of using the device in claim 1 to stabilize a fractured bone comprising a first bone fragment and a second bone fragment, the method comprising:

- a. engaging the first bone fragment with the distal pin assembly;
- b. engaging the second bone fragment with the proximal pin assembly; and
- c. connecting the distal pin assembly to the proximal pin assembly with the pin assembly connector.

10. A pin assembly for an orthopedic external fixation device, wherein the pin assembly is configured to engage a bone fragment, the pin assembly comprising: (i) a screw portion having a distal end configured to engage the bone fragment and a proximal end; and (ii) a support sheath portion having a distal end configured to engage the first bone fragment; a proximal end; and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed, and further wherein the distal end of the support sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the first bone fragment.

11. The pin assembly of claim 10, further comprising: (iii) a cap portion attached to the proximal end of the screw portion and engaged with the proximal end of the support sheath portion.

12. A device for fixation of a bone fracture comprising:

- a. a distal pin assembly configured to engage a first bone fragment, the distal pin assembly comprising: (i) a screw portion having a distal end configured to engage the first bone fragment and a proximal end; and (ii) a support sheath portion having a distal end configured to engage the first bone fragment; a proximal end; and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed, and further wherein the distal end of the support

sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the first bone fragment;

b. a proximal pin assembly configured to engage a second bone fragment, the proximal pin assembly comprising: (i) a screw portion having a distal end configured to engage the second bone fragment and a proximal end; and (ii) a support sheath portion having a distal end configured to engage the second bone fragment, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed, and further wherein the distal end of the support sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the second bone fragment; and

c. a pin assembly connector configured to connect the distal pin assembly to the proximal pin assembly.

13. The device of claim 12, wherein the elongated blades have a triangular cross-section.

14. The device of claim 12, wherein: the distal end of the screw portion of the distal pin assembly has a tip comprising a threaded section; and a plurality of elongated slots are defined in the distal end of the support sheath portion of the distal pin assembly, the elongated slots being configured to allow the distal end of the support sheath portion to expand outwardly when it is passed over the threaded section of the screw portion; and

further wherein: the distal end of the screw portion of the proximal pin assembly has a tip comprising a threaded section; and a plurality of elongated slots are defined in the distal end of the support sheath portion of the proximal pin assembly, the elongated slots being configured to allow the distal end of the support sheath portion to expand outwardly when it is passed over the threaded section of the screw portion .

15. The device of claim 12, wherein the distal end of the screw portion of the distal pin assembly has a tip comprising a threaded section and the screw portion further comprises a cutting section above the threaded section, the cutting section comprising multiple outwardly extending cutting edges, wherein the multiple outwardly extending cutting edges are configured to bore a hole in the first bone fragment as the threaded section is installed into the first bone fragment; and

further wherein the distal end of the screw portion of the proximal pin assembly has a tip comprising a threaded section and the screw portion further comprises a cutting section above the threaded section, the cutting section comprising multiple outwardly extending cutting edges, wherein the multiple outwardly extending cutting edges are configured to bore a hole in the second bone fragment as the threaded section is installed into the second bone fragment.

16. The device of claim 12, wherein the distal end of the support sheath portion of the distal pin assembly has a tip comprising a cutting section comprising multiple outwardly extending cutting edges, wherein the multiple outwardly extending cutting edges are configured to bore a hole in the first bone fragment when the cutting section is drilled into the first bone fragment; and

further wherein the distal end of the support sheath portion of the proximal pin assembly has a tip comprising a cutting section comprising multiple outwardly extending cutting edges, wherein the multiple outwardly extending cutting edges are configured to bore a hole in the second bone fragment when the cutting section is drilled into the second bone fragment.

17. The device of claim 12, wherein the distal pin assembly further comprises a cap portion attached to the proximal end of its screw portion and engaged with the proximal end of its support sheath portion; and

further wherein the proximal pin assembly further comprises a cap portion attached to the proximal end of its screw portion and engaged with the proximal end of its support sheath portion.

18. A method of using the device in claim 12 to stabilize a fractured bone comprising a first bone fragment and a second bone fragment, the method comprising:

- a. engaging the first bone fragment with the distal pin assembly;
- b. engaging the second bone fragment with the proximal pin assembly; and
- c. connecting the distal pin assembly to the proximal pin assembly with the pin assembly connector.

FIG. 1

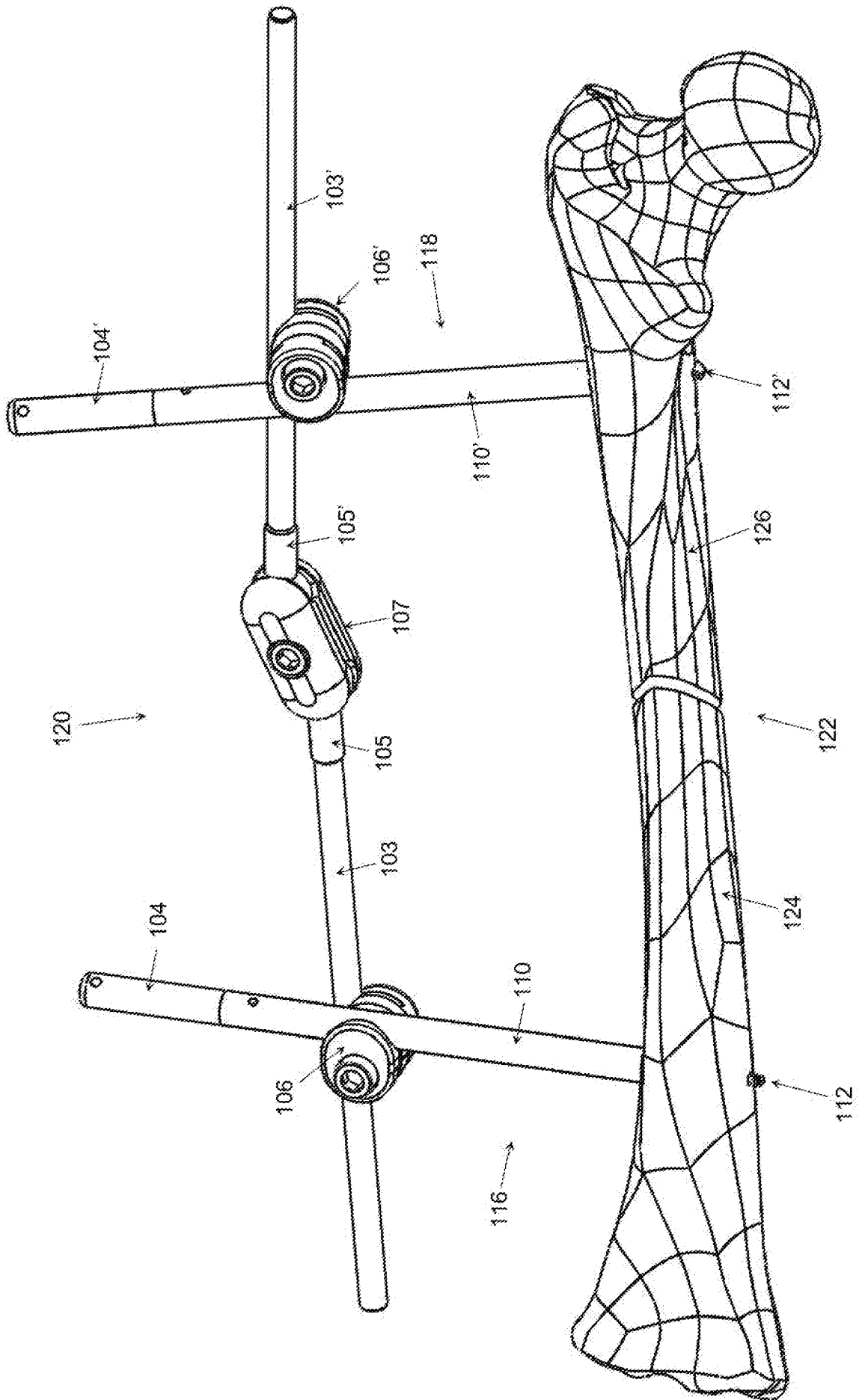


FIG. 2

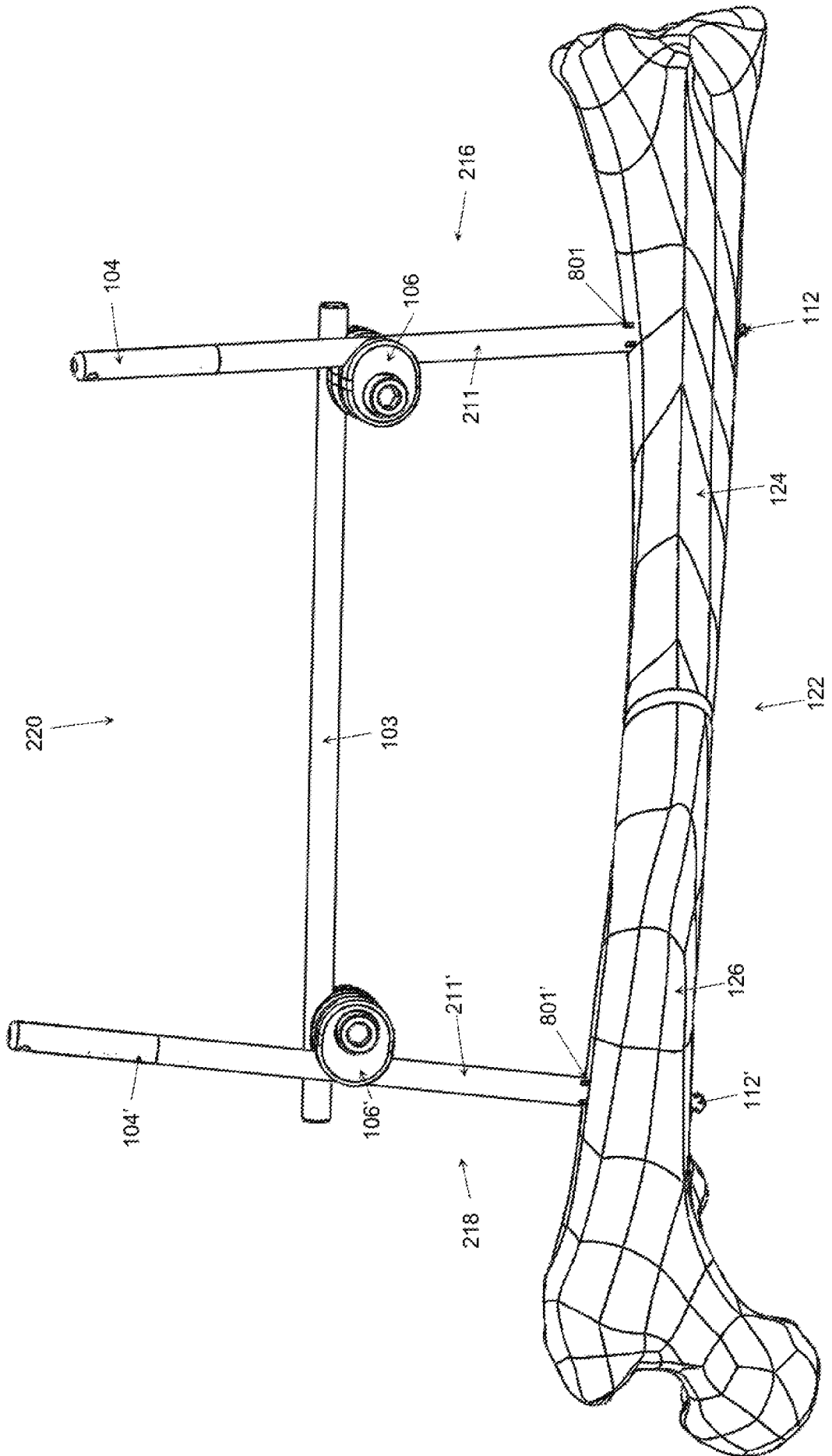


FIG. 3

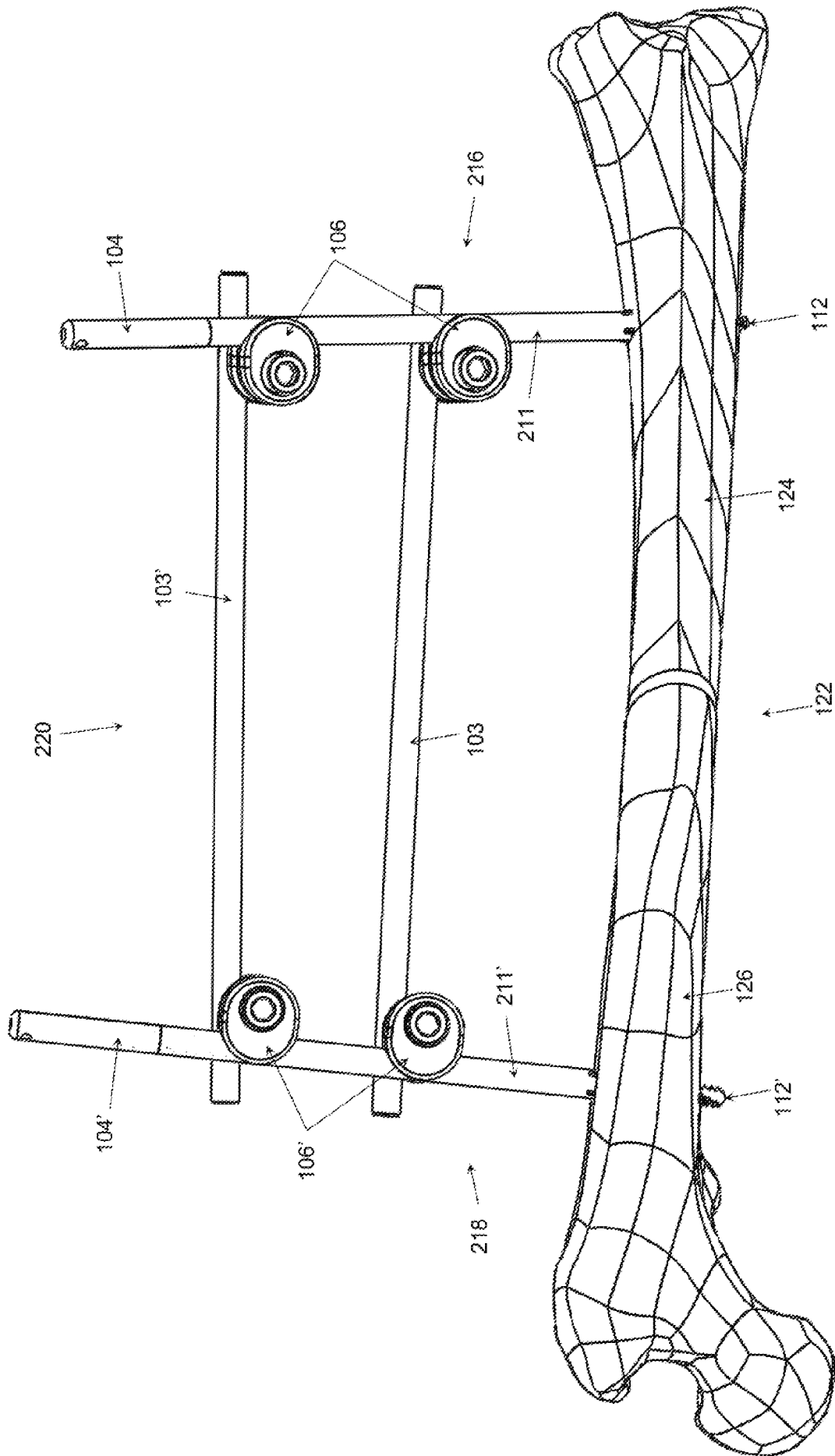


FIG. 4

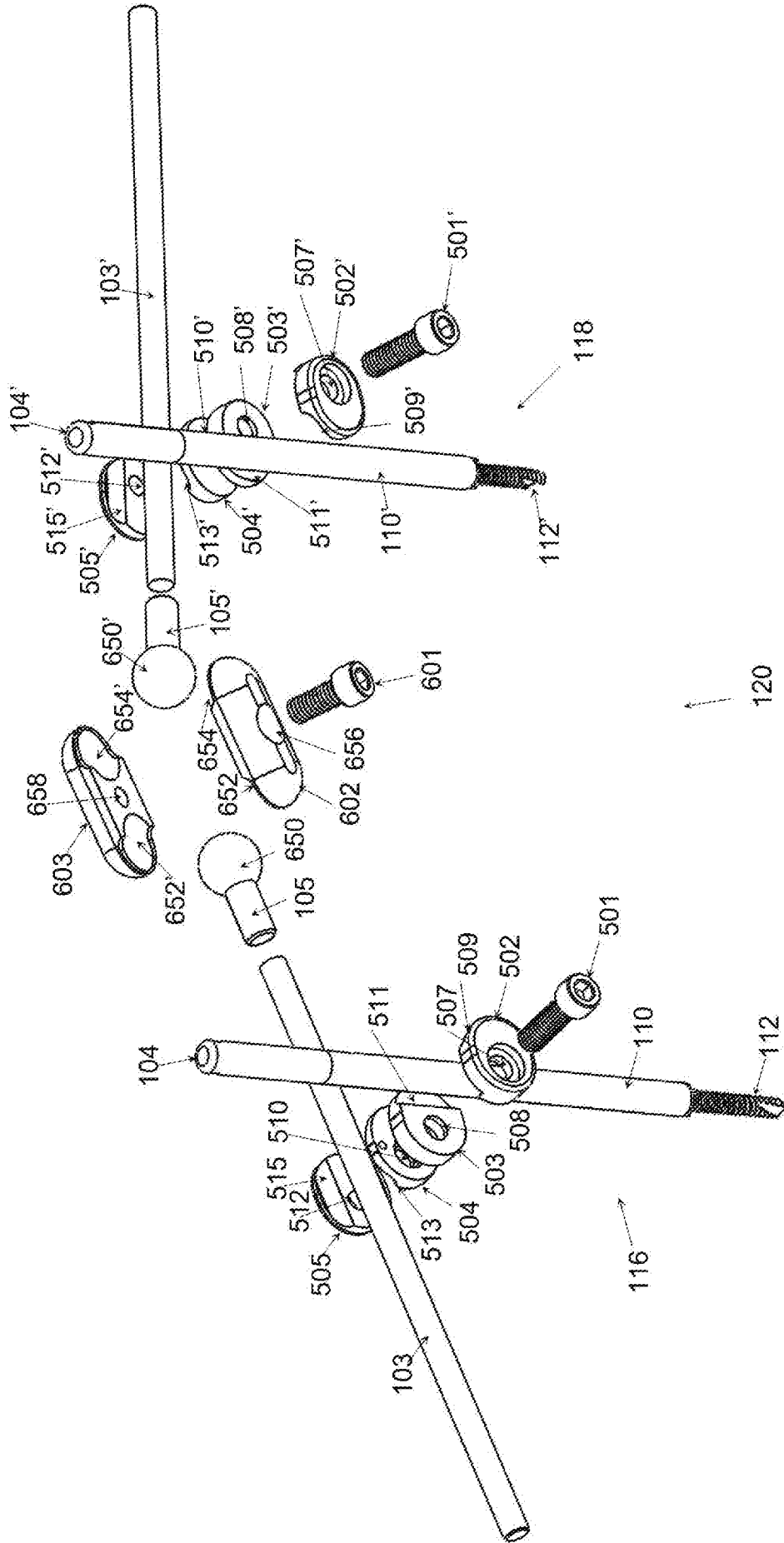


FIG. 5

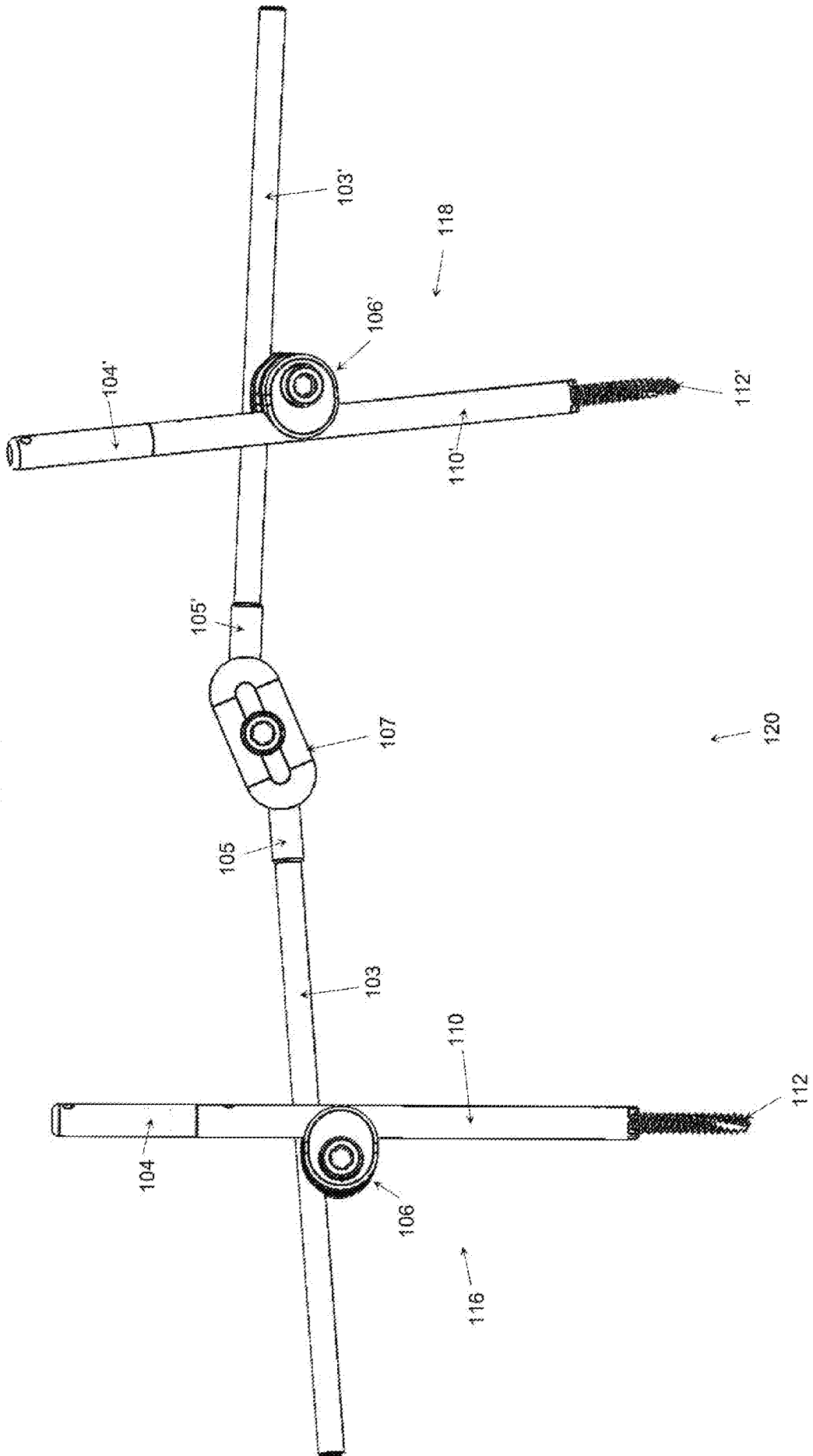


FIG. 6

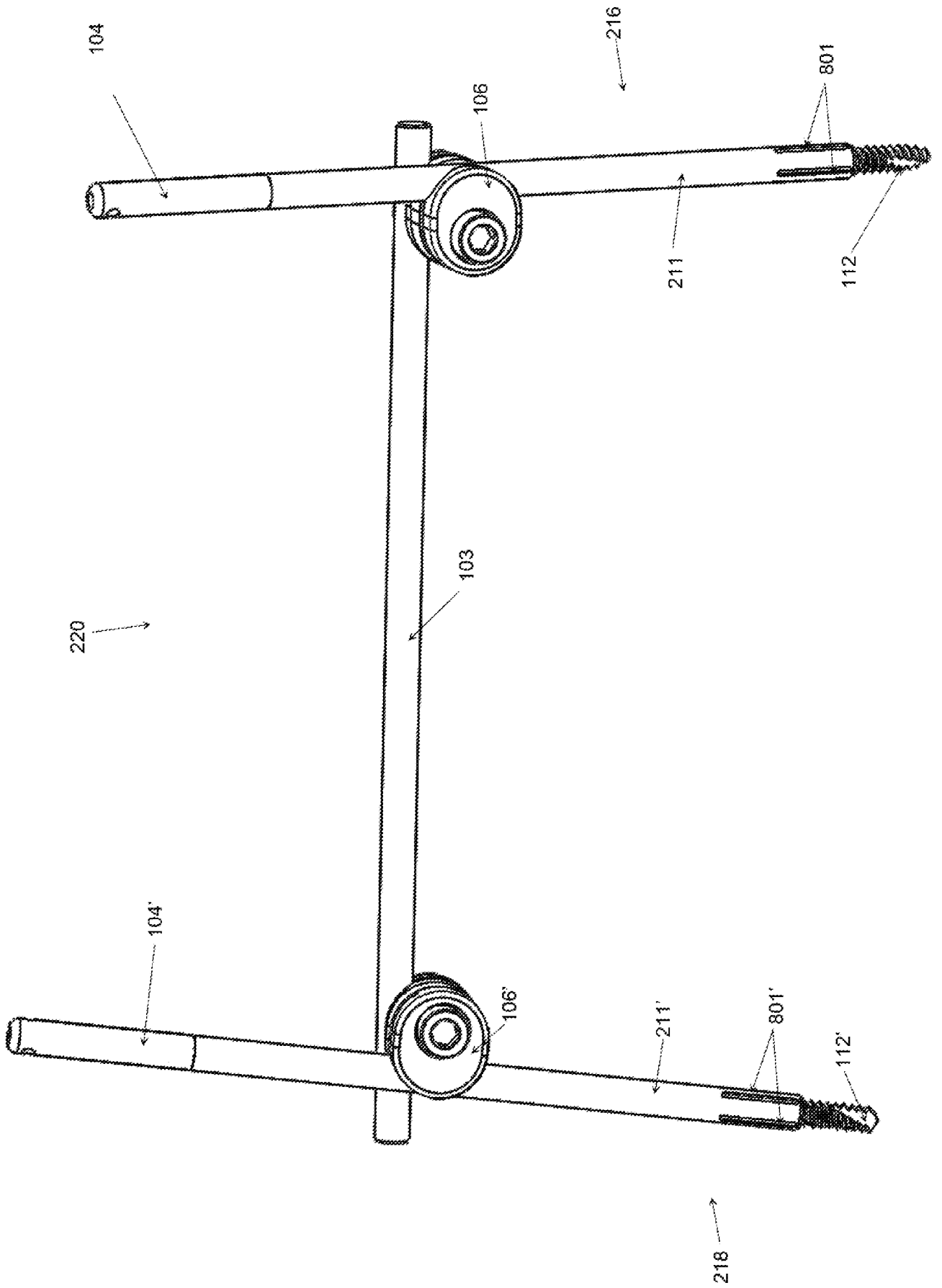


FIG. 8

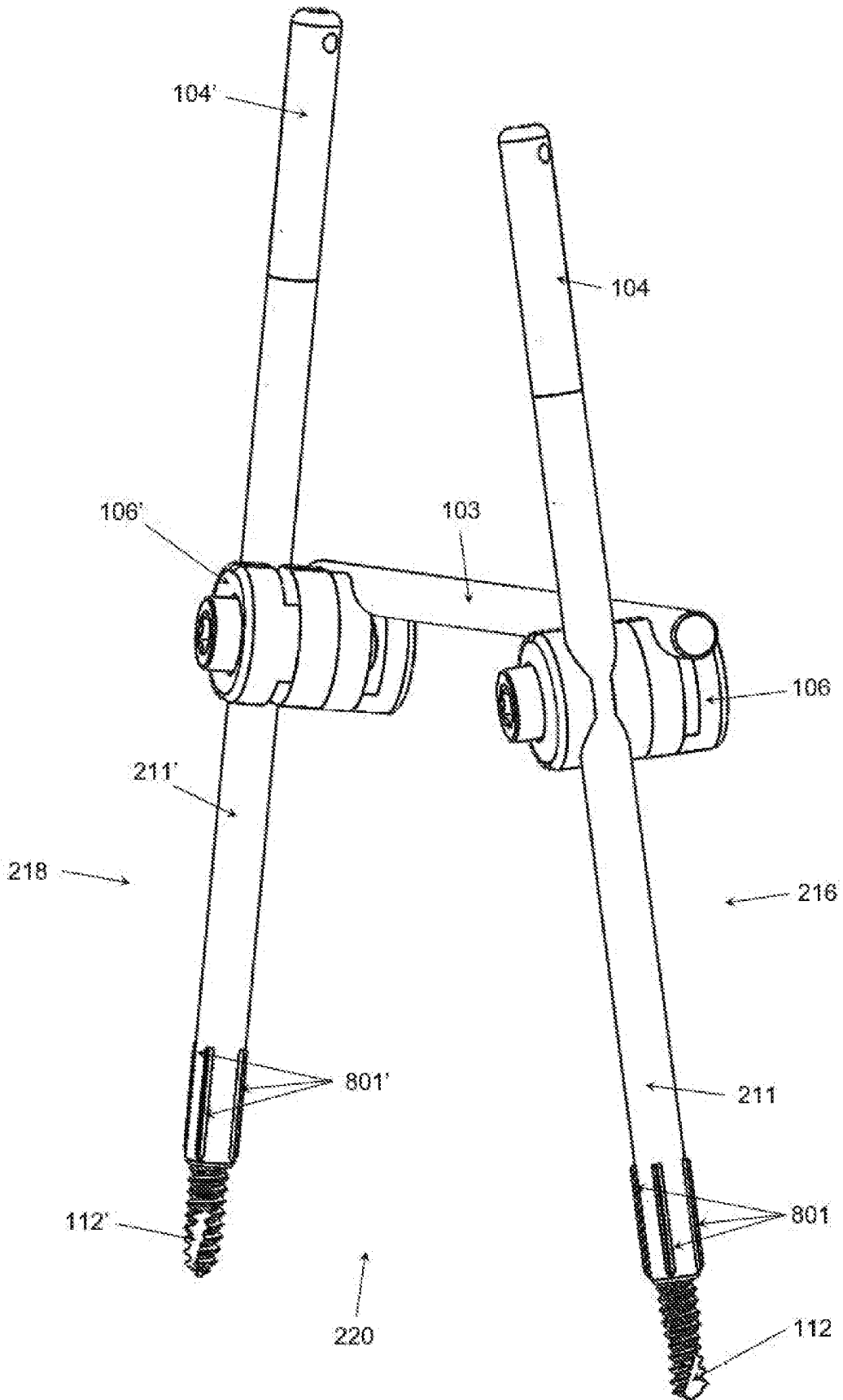


FIG. 9

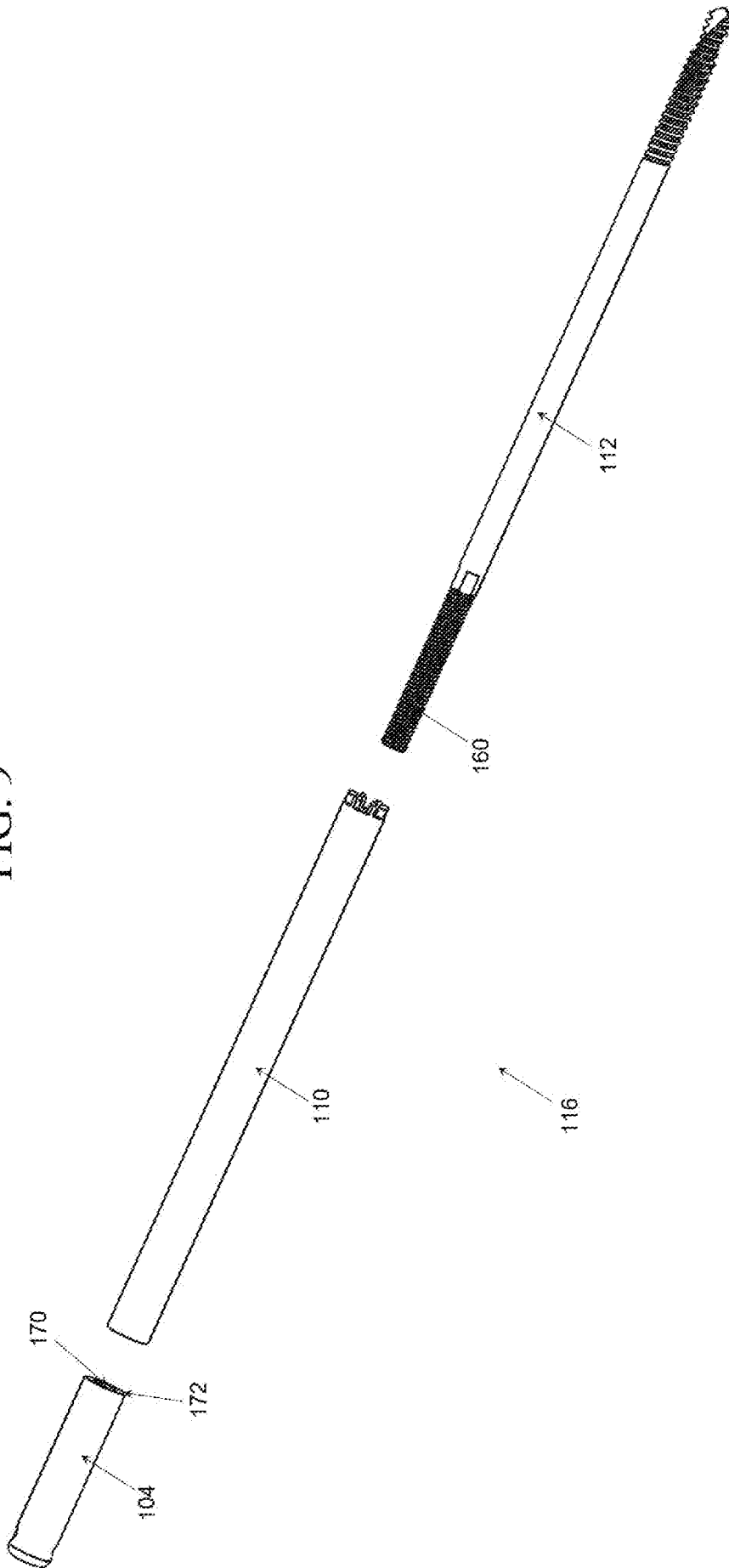


FIG. 10

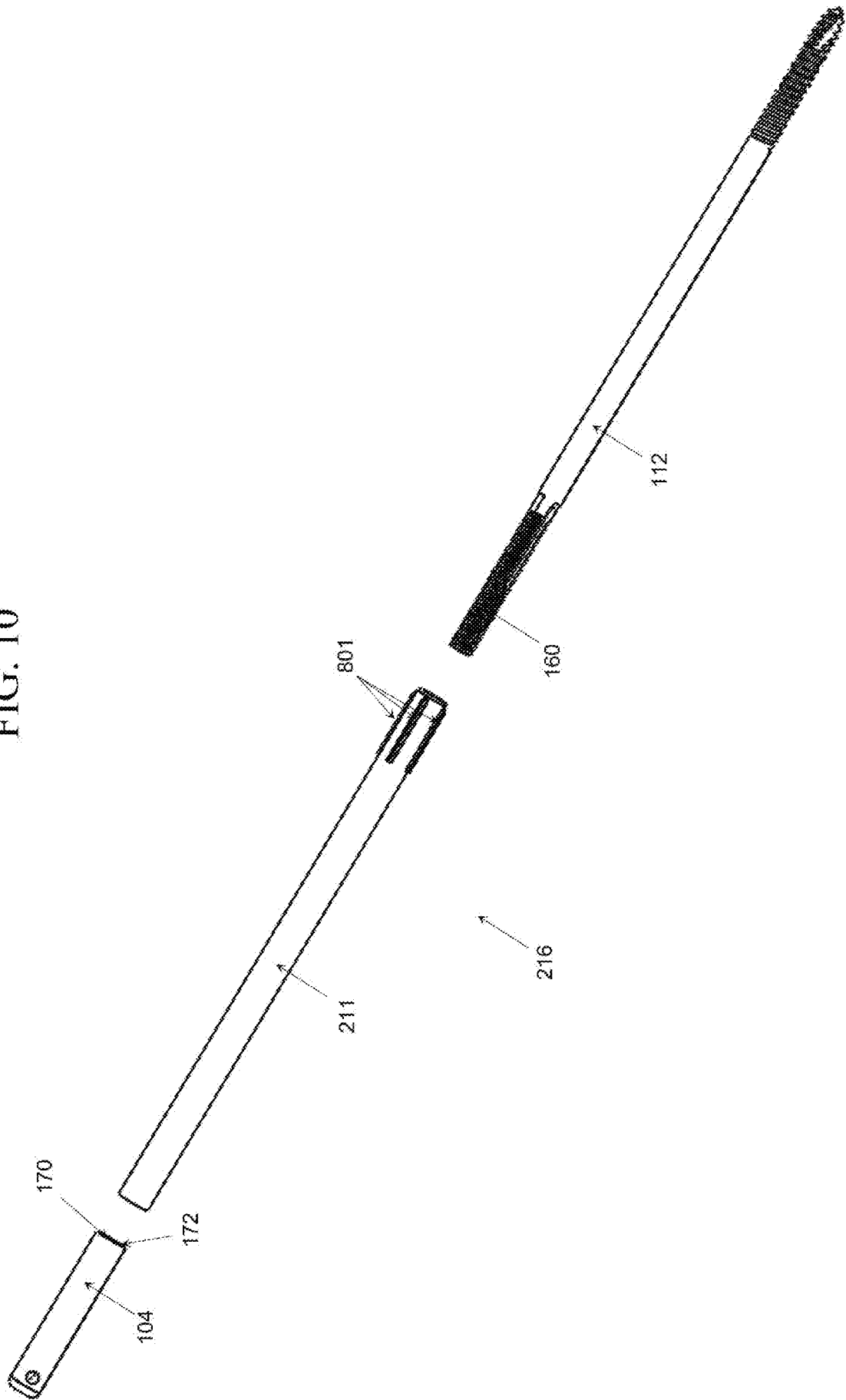


FIG. 11

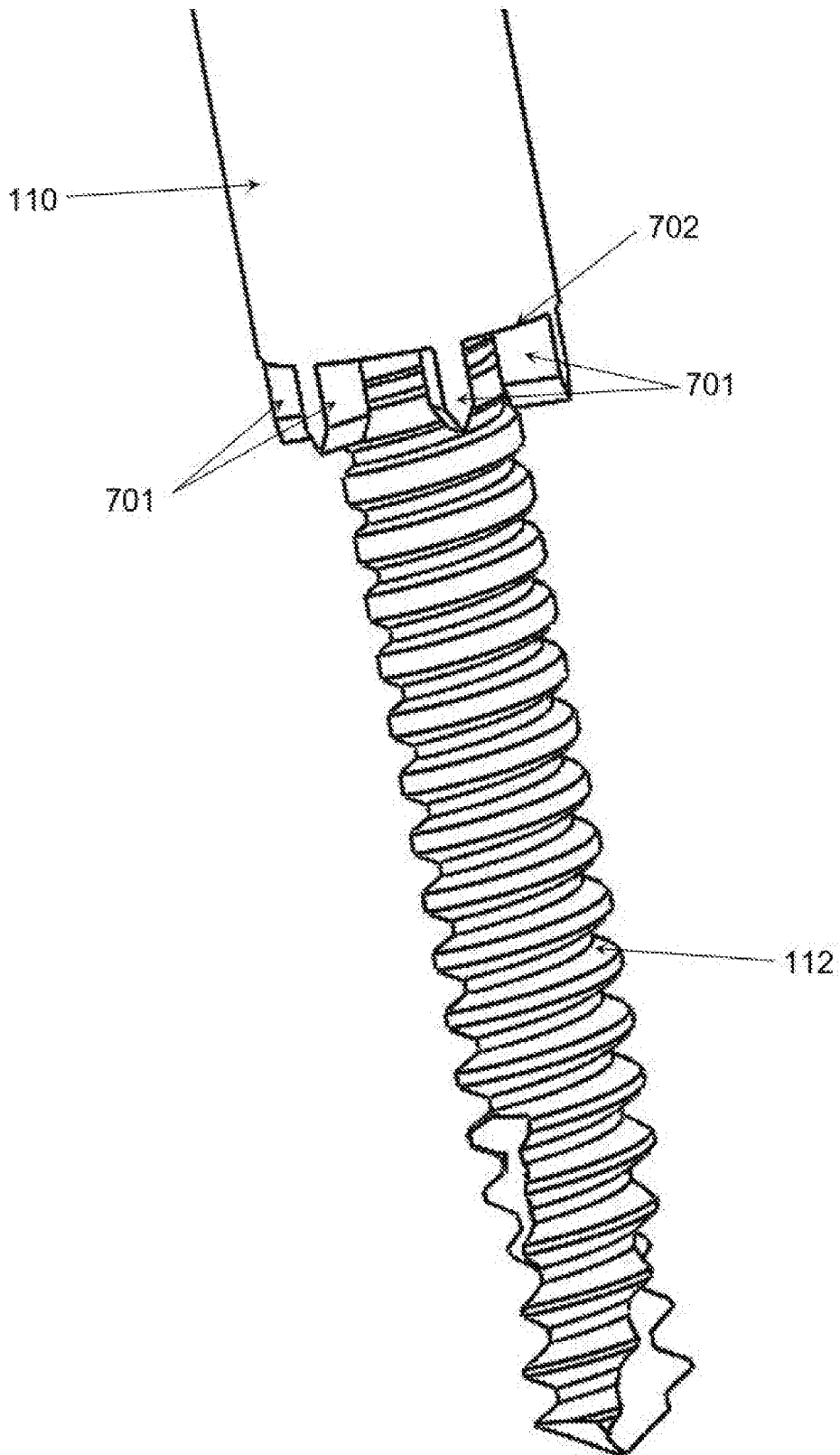


FIG. 12

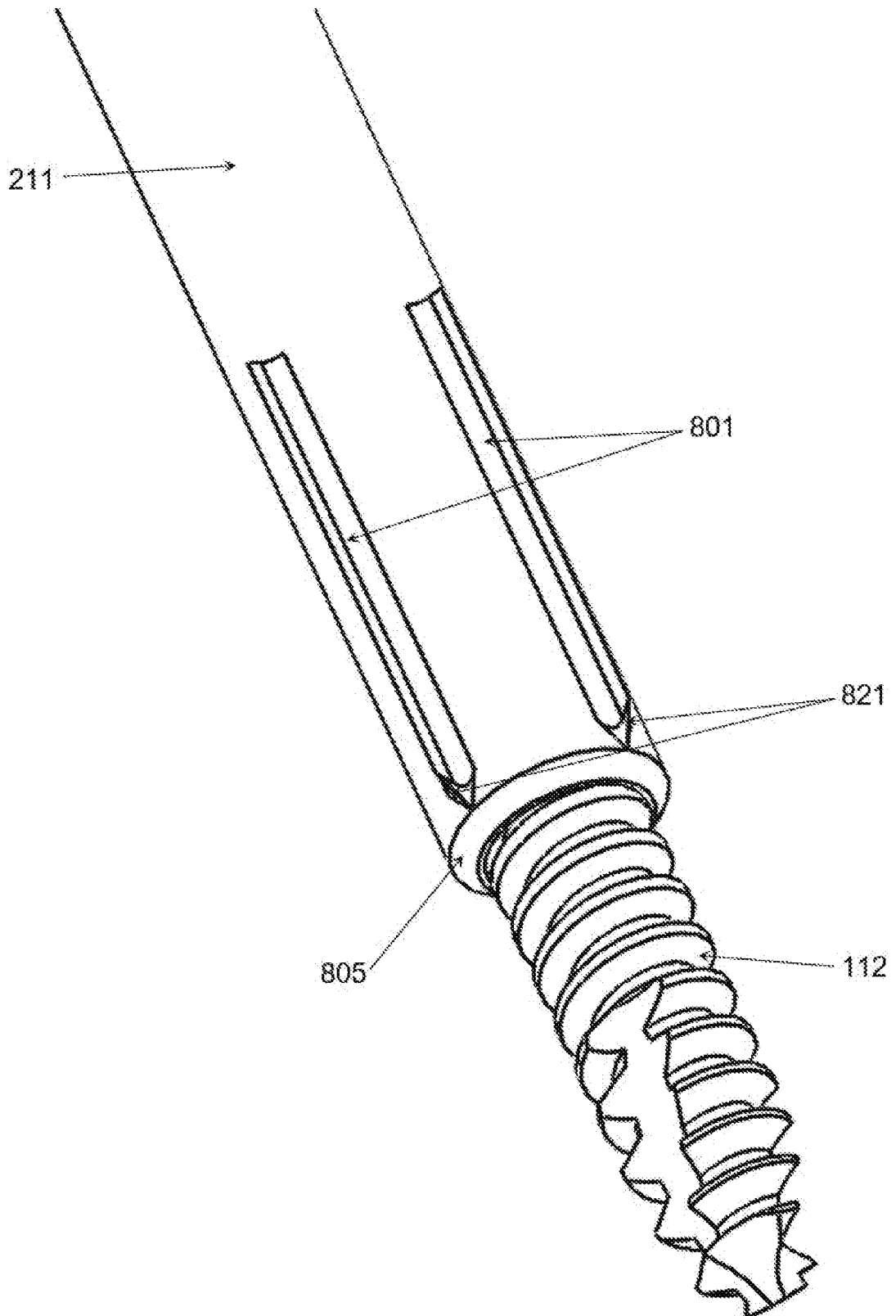


FIG. 13

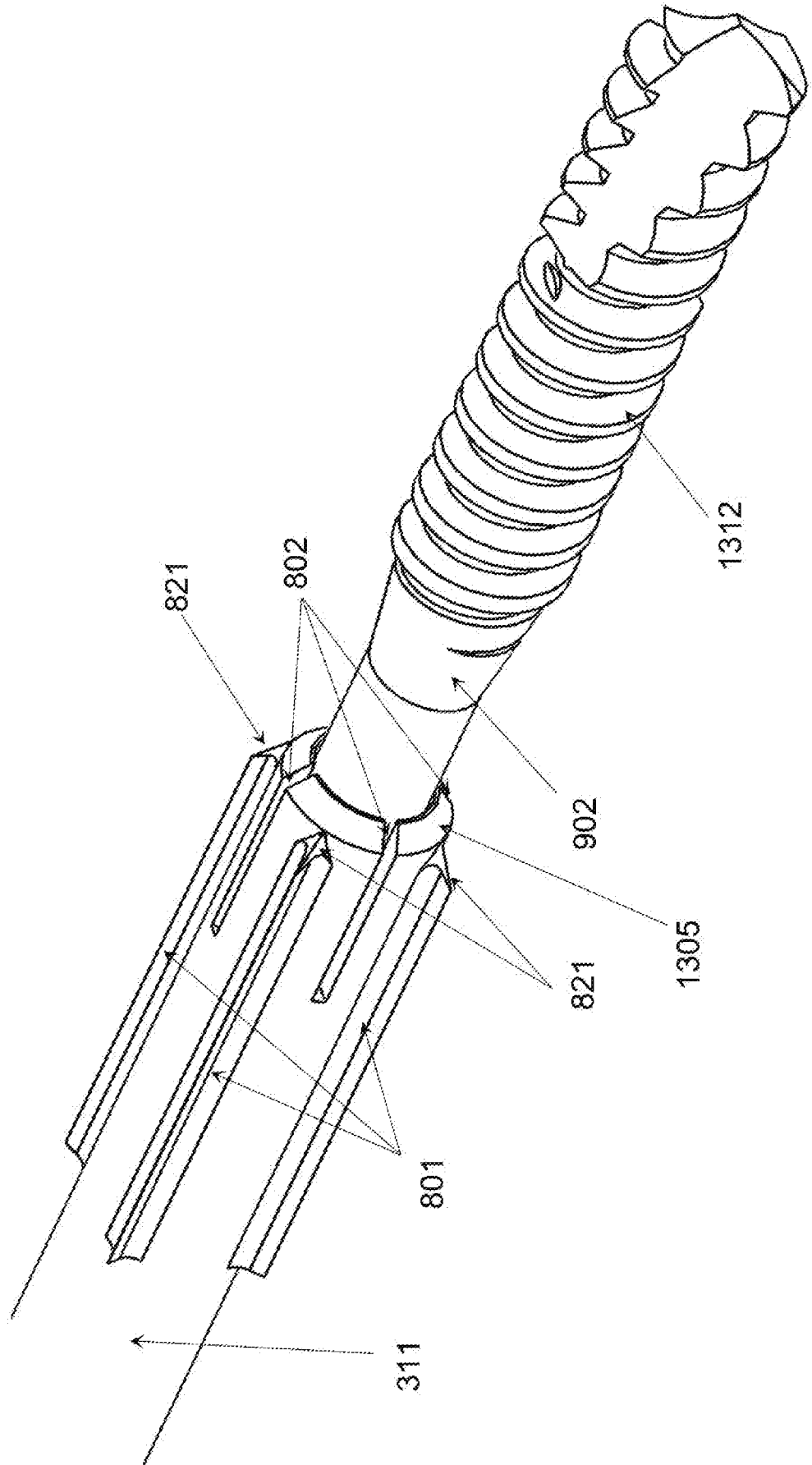


FIG. 14

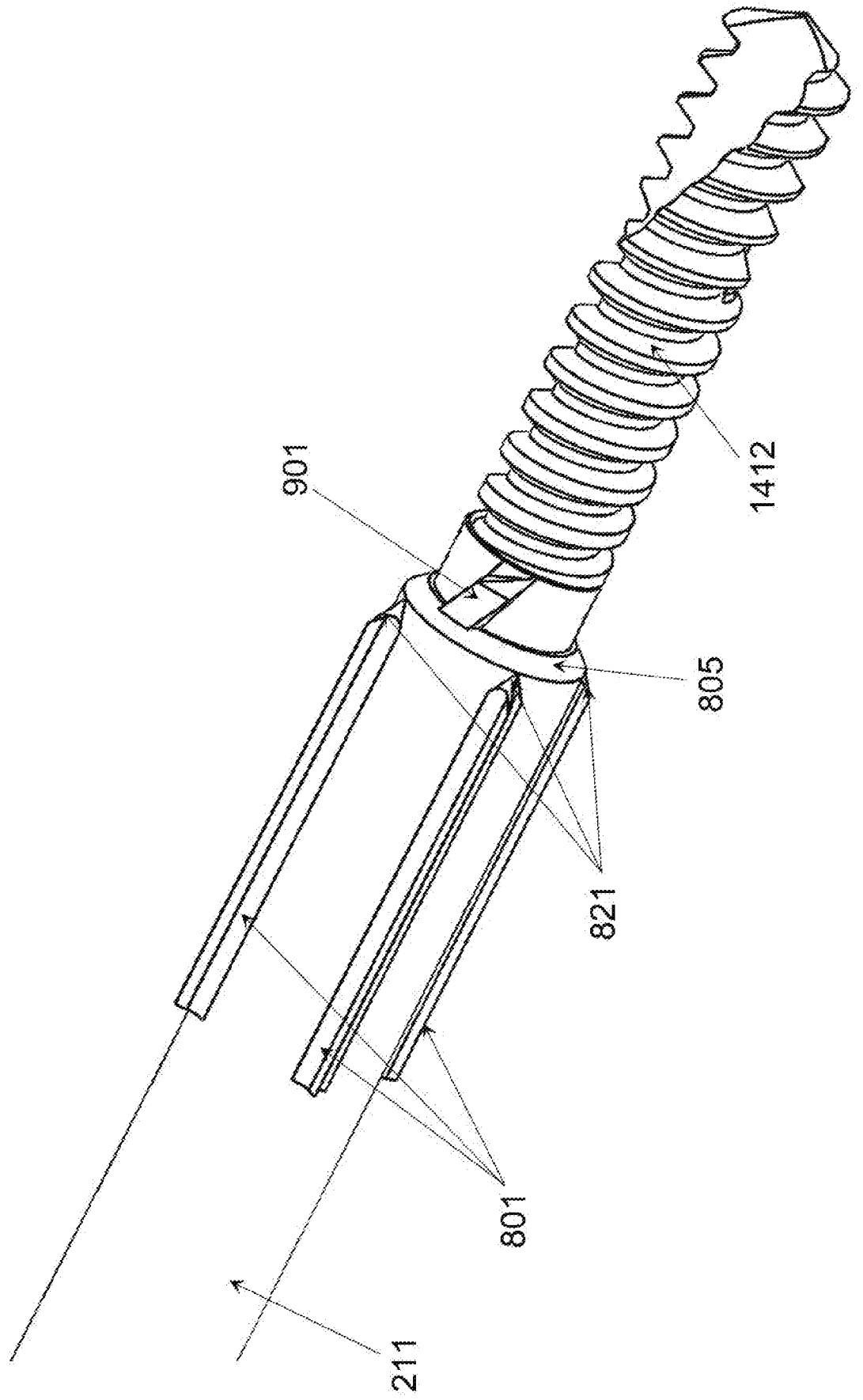


FIG. 15

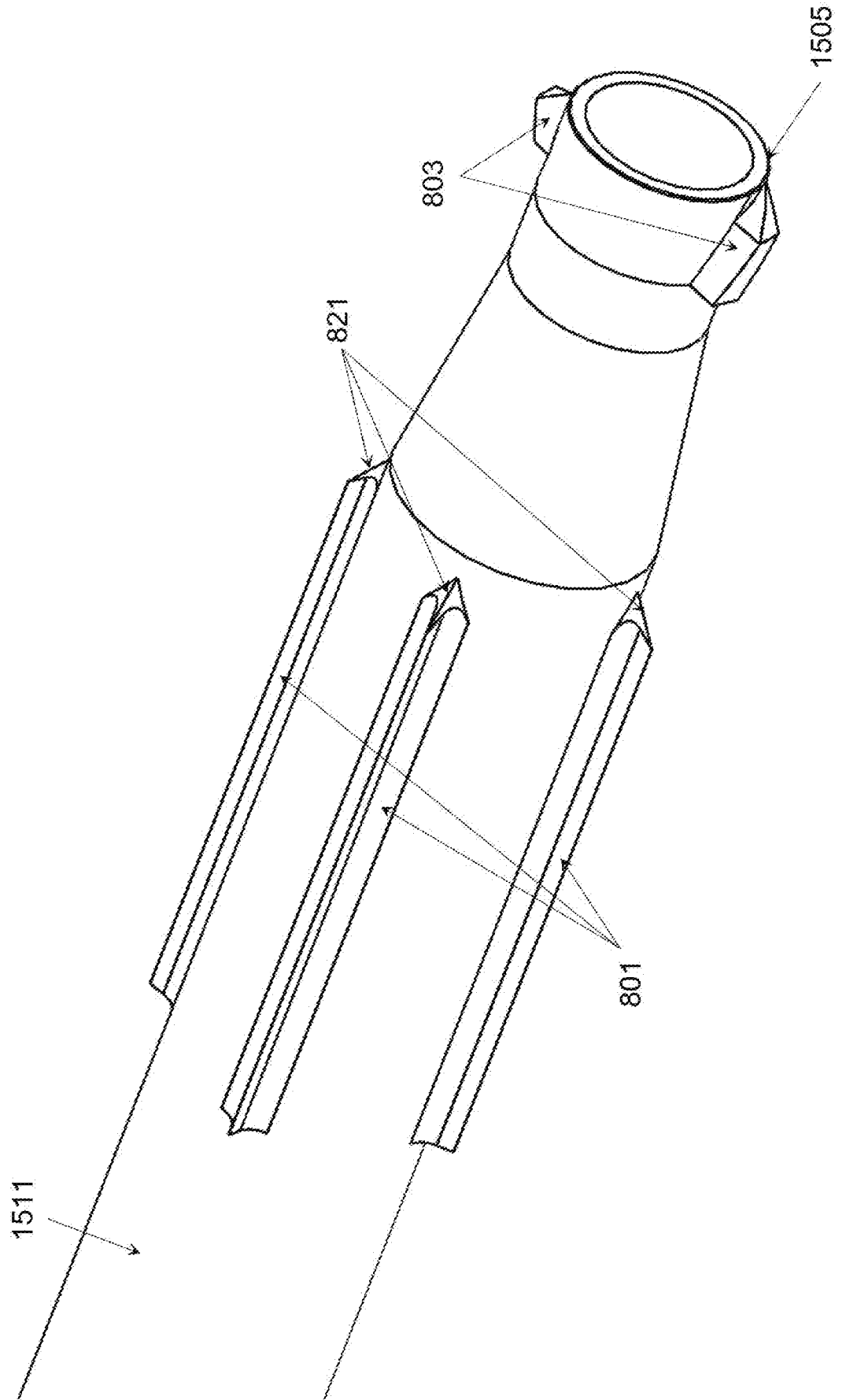


FIG. 16

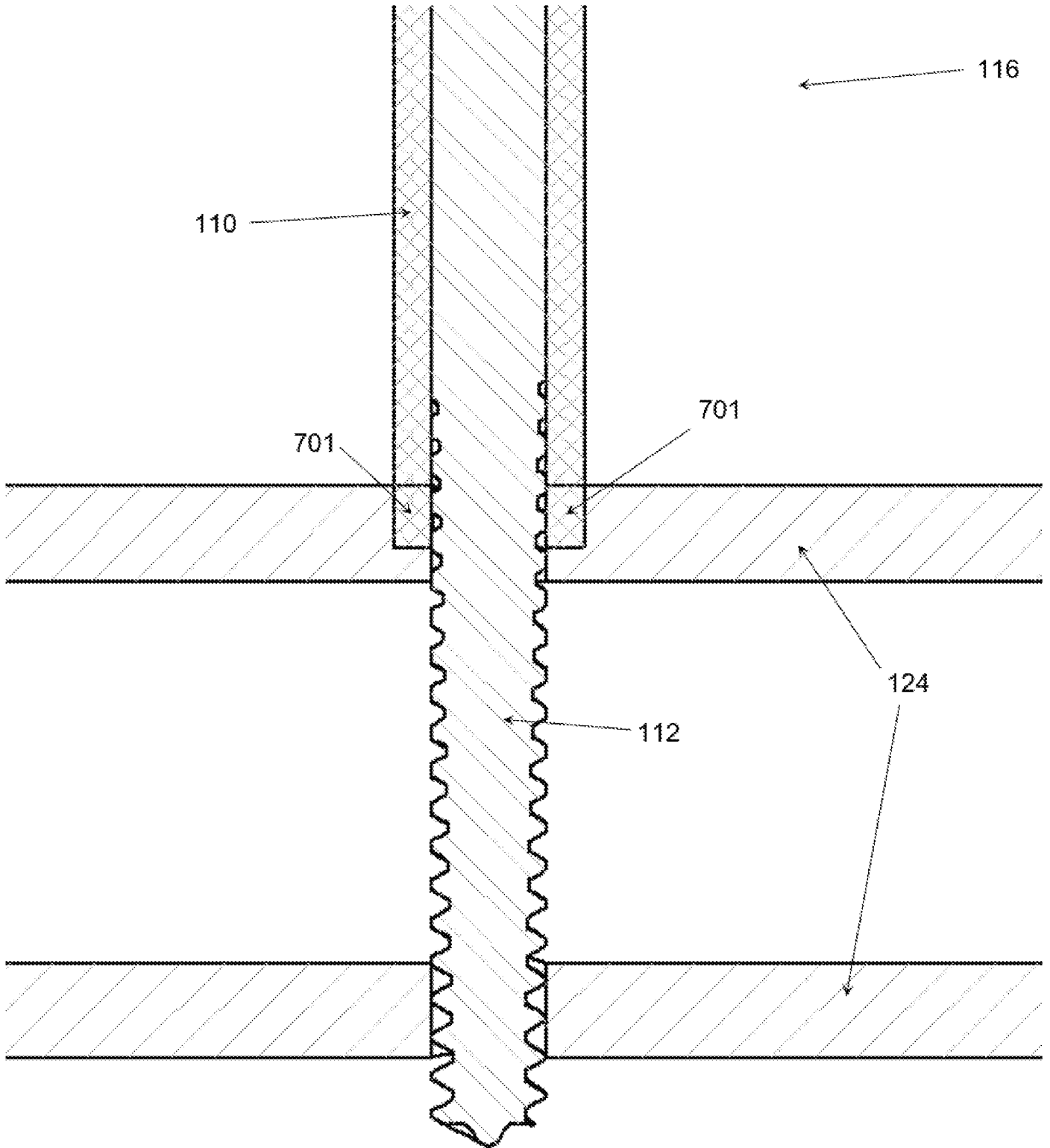
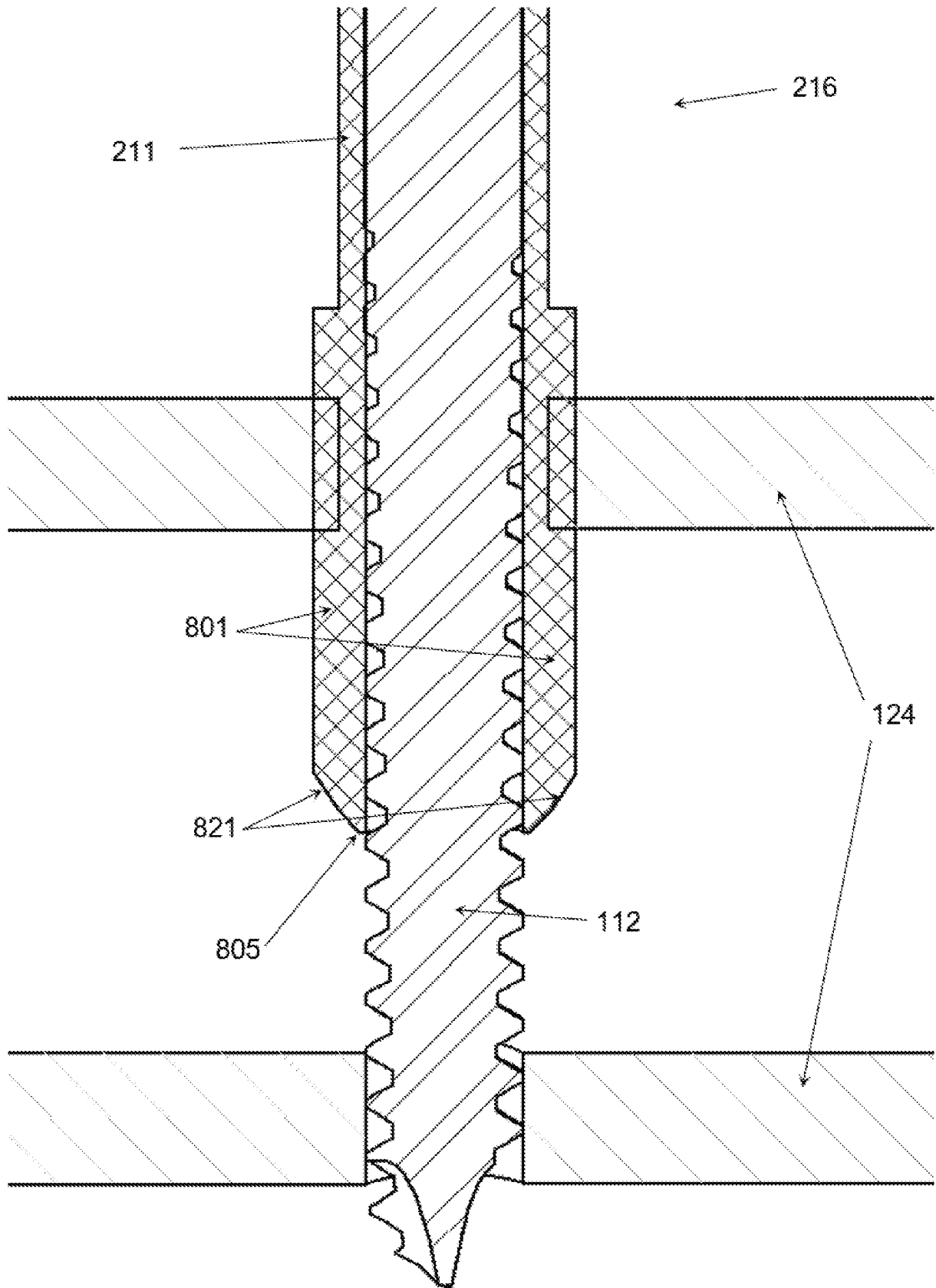


FIG. 17



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US16/19486

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/60, 17/64 (2016.01)

CPC - A61B 17/60, 17/6466, 17/66

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)

IPC(8) Classifications: A61B 17/56, 17/58, 17/60, 17/64, 17/66 (2016.01)

CPC Classifications: A61B 17/60, 17/62, 17/6416, 17/6466, 17/66

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

USPC Classifications: 606/54, 59

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

PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); bone, external fixation, threaded, fastener, pin, screw, multiple, plural, two, connect, rod, bar, linkage, clamp, anchor, sheath, sleeve, hollow, tube, slide, translate, axial, move, through, within, inside, interior, spine, tine, teeth, blade, ball, socket

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 4,848,368 A (KRONNER R. F.) July 18, 1989; figures 4, 6; column 5, lines 58-65	1, 3 --- 4
X	FR 2,674,120 A (HARDY J. M. D.) September 25, 1992; figures 1, 2, 17-20; lines 5-15 of page 7	1, 5, 9
X	US 4,620,533 A (MEARS D. C.) November 4, 1986; figures 1-3; column 7, lines 15-20	1, 2
X	US 2008/0300630 A1 (BONNEMA T. A. X. et al.) December 4, 2008; figures 2, 5	1, 6-8
Y	US 2014/0303621 A1 (FIXX ORTHOPEDICS LLC) October 9, 2014; figure 9; paragraph [0040]	4
A	US 2014/0364853 A1 (ZIMMER INC) December 11, 2014; entire document	1-9
A	US 2012/0203225 A1 (MINGOZZI F. et al.) August 9, 2012; entire document	1-9
A	US 5,891,144 A (MATA J. et al.) April 6, 1999; entire document	1-9
A	US 4,920,959 A (WITZEL U. et al.) May 1, 1990; entire document	1-9

 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 application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of 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

13 June 2016 (13.06.2016)

Date of mailing of the international search report

11 JUL 2016

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US16/19486

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

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

- 1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

This International Searching Authority found multiple inventions in this international application, as follows:
-***-Continued Within the Next Supplemental Box-***-

- 1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
- 2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
- 3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
- 4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Group I: claims 1-9

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

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US16/19486

-***-Continued from Box No. III Observations where unity of invention is lacking-***-

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: claims 1-9 are directed toward the pin assembly connector comprising: a first clamp; a second clamp; and a connecting rod assembly comprising one or more rods, wherein the first clamp is configured to connect to the outer surface of the support sheath portion of the distal pin assembly and to a rod of the connecting rod assembly; the second clamp is configured to connect to the outer surface of the support sheath portion of the proximal pin assembly and to a rod of the connecting rod assembly.

Group II: claims 10-18 are directed toward wherein the distal end of the support sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the first bone fragment; and further wherein the distal end of the support sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the second bone fragment.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical features of Group I include the pin assembly connector comprising: a first clamp; a second clamp; and a connecting rod assembly comprising one or more rods, wherein the first clamp is configured to connect to the outer surface of the support sheath portion of the distal pin assembly and to a rod of the connecting rod assembly; the second clamp is configured to connect to the outer surface of the support sheath portion of the proximal pin assembly and to a rod of the connecting rod assembly (which are not present in Group II).

The special technical features of Group II include wherein the distal end of the support sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the first bone fragment; and further wherein the distal end of the support sheath portion comprises multiple elongated blades running lengthwise along its outer surface, the elongated blades being configured to engage the second bone fragment (which are not present in Group I).

The common technical features of Groups I-II include a device for fixation of a bone fracture comprising: a distal pin assembly configured to engage a first bone fragment, the distal pin assembly comprising: a screw portion having a distal end configured to engage the first bone fragment and a proximal end; and a support sheath portion having a distal end configured to engage the first bone fragment, a proximal end, and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed; a proximal pin assembly configured to engage a second bone fragment, the proximal pin assembly comprising: a screw portion having a distal end configured to engage the second bone fragment and a proximal end; and a support sheath portion having a distal end configured to engage the second bone fragment, a proximal end, and an outer surface, wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed; and a pin assembly connector configured to connect the distal pin assembly to the proximal pin assembly.

These common technical features are disclosed by US 2008/0300630 A1 (BONNEMA); a device (medical device; abstract; figure 2) for fixation of a bone fracture (for fixation of vertebrae 12, 14, i.e., could also be used for fixation of fractures; abstract; figure 5; paragraph [0020]) comprising: a distal pin assembly (left anchor 20, left element 24, collectively; figure 2) configured to engage a first bone fragment (12; figure 5), the distal pin assembly comprising: a screw portion (20) having a distal end (lower end) configured to engage the first bone fragment (12) and a proximal end (20e); and a support sheath portion (24) having a distal end (lower end including teeth 24') configured to engage the first bone fragment (12; figure 5), a proximal end (upper end of element 24), and an outer surface (outer surfaces of element 24), wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed (the upper end of anchoring element 20 extends through (defines elongated channel) element 24 as shown; figures 2, 3c); a proximal pin assembly (right anchor 20, right element 24, collectively; figure 2) configured to engage a second bone fragment (14), the proximal pin assembly comprising: a screw portion (20) having a distal end (lower end) configured to engage the second bone fragment (14; figure 5) and a proximal end (20e); and a support sheath portion (24) having a distal end (lower end including teeth 24') configured to engage the second bone fragment (14), a proximal end (upper end of element 24), and an outer surface (outer surfaces of element 24), wherein the support sheath portion defines an elongated channel in which the proximal end of the screw portion is disposed (the upper end of anchoring element 20 extends through (defines elongated channel) element 24 as shown; figures 2, 3c); and a pin assembly connector (18) configured to connect the distal pin assembly to the proximal pin assembly (as shown; figure 2).

Because the common technical features are disclosed by BONNEMA, the inventions are not so linked as to form a single general inventive concept. Therefore, Groups I-II lack unity.