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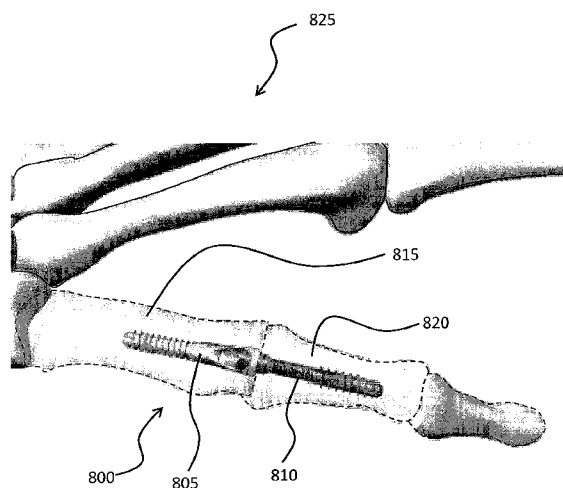
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(54) **Title:** AN INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE



**FIG. 8**

(57) **Abstract:** A method for applying compression to a joint includes providing an intramedullary fixation assembly having a proximal screw member positioned at a proximal end of the intramedullary fixation assembly and a lag screw member positioned at a distal end of the intramedullary fixation assembly. Medullary canals are drilled in a first and second bone and the medullary canals are reamed. The proximal screw member is inserted into the first bone and a drill is used create a dorsal hole in the first bone. The lag screw member is slideably coupled to the dorsal hole and to the proximal screw member and into the second medullary canal. A torque is applied to the lag screw member to apply compression to the joint.

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**AN INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE****FIELD OF THE INVENTION**

5 This invention relates to the field of orthopedic implant devices, and more particularly, to an intramedullary fixation assembly used for internal fixation of angled joints, bones and deformity correction, such as the metacarpal phalangeal joint in the hand.

**BACKGROUND OF THE INVENTION**

10 Orthopedic implant devices, such as intramedullary nails, plates, rods and screws are often used to repair or reconstruct bones and joints affected by trauma, degeneration, deformity and disease, such as Charcot arthropathy caused by diabetes in some patients. As an example, charcot arthropathy (or Charcot Foot) is a destructive process affecting many regions including joints of the foot and ankle in diabetics. This condition causes bony fragmentation, dislocation  
15 and fractures that eventually progresses to foot deformity, bony prominences, ulceration and instability of the foot. Charcot arthropathy can affect any joint in the body but is often seen in the feet affecting the metatarsal, tarsometatarsal and tarsal joints and frequently causes the foot to lose its arch or curvature, thus resulting in “flat footedness” in the mid-foot region.

Early treatment for Charcot Foot includes the use of therapeutic footwear, immobilization  
20 of the foot and/or non-weight bearing treatment. Surgical treatments include orthopedic fixation devices that fixate the bones in order to fuse them into a stable mass. These orthopedic implant devices realign bone segments and hold them together in compression until healing occurs, resulting in a stable mass.

Various implants have been utilized for surgical treatment, including bone screws. While  
25 these devices allow fixation and promote fusion, they do not deliver restoration of the arch in a Charcot Foot. Instead, the physician must estimate the arch and manually align the bones and

deliver the screws to hold the bones in place, while reducing bone purchase. Intramedullary nails and/or a plate with a lag screw too have deficiencies. These intramedullary nails also do not reconstruct an arch that is lost due to Charcot foot disease.

Moreover, infections and wound complications are a major concern in aforementioned  
5 procedures. Wound closure is technically demanding for the surgeon, and devices that add surface prominence, such as plates or exposed screws, add to the difficulty by requiring greater tissue tension during incision reapproximation. This increases the risk of postoperative wound infections and dehiscence that may ultimately result in limb amputation.

There is therefore a need for an intramedullary fixation assembly and method of use that  
10 overcomes some or all of the previously delineated drawbacks of prior fixation assemblies.

#### **SUMMARY OF THE INVENTION**

An object of the invention is to overcome the drawbacks of previous inventions.

Another object of the invention is to provide a novel and useful intramedullary fixation  
15 assembly that may be utilized to treat any bones in human body.

Another object of the invention is to provide a novel and useful intramedullary fixation assembly that may be utilized to treat bones in a mid-foot region.

Another object of the invention is to restore the arch by utilizing an intramedullary  
assembly.

20 Another object of the invention is to provide a system for treating deteriorating bones in a mid-foot region.

Another object of the invention is to provide a method for restoring the arch of the foot by delivering a fixator that can be coupled in a patient's foot.

Another object of the invention is to provide a connecting mechanism for generating  
25 compression in a patient's hand and foot bones.

Another object of the invention is to utilize a torque in the connecting mechanism to transmit compression to the bones in a patient's hand and foot bones.

In a first non-limiting aspect of the invention, a fixation assembly comprising two members is provided. A first member, positioned at a proximal end of the fixation assembly, has an elongated portion and a tapered bulbous end. A second member, positioned at a distal end of the fixation assembly, has an internal tapered aperture, wherein the elongated portion resides within the internal tapered aperture. The first member forms a fixed angle with the second member, thereby selectively coupling the first member to the second member.

In a second non-limiting aspect of the invention, a method for reconstructing an arch in a mid-foot region comprises eight steps. Step one includes making an incision in the mid-foot region of a patient's foot. Step two includes gunstocking the foot to expose the articular surface. Step three includes reaming the intramedullary canal and inserting a distal member. Step four includes coupling the instrument to the distal member. Step five includes assessing the position of the proximal member with a guide wire. Step six includes pre-drilling a hole through the joints selected for fusion. The seventh step includes inserting the proximal member over the guide wire until rigid connection with the tapered aperture is made that compresses the joint and wherein the proximal member is at an angle to the distal member. The eighth step includes removing the instrument and closing the incision, thereby causing the arch to be formed in the mid-foot region.

In a third non-limiting aspect of the invention, an instrument is combined with a fixation assembly for reconstructing an arch in a mid-foot region. The instrument has a handle, a "U-shaped" recess having two sides and a tapered bore. The intramedullary fixation assembly has a first member and a second member. The first member is positioned at a proximal end of the intramedullary fixation assembly. The first member has an elongated portion and a bulbous portion. The second member is positioned at a distal end of the intramedullary fixation assembly. The second member has an internal tapered aperture, a plurality of grooves and a

threaded portion. The elongated portion resides within the internal tapered aperture, and a “U-shaped” recess having two sides that couple the first member to the second member, and further coupling the instrument to the intramedullary fixation assembly for reconstructing the arch in the mid-foot region.

5 In a fourth non-limiting aspect of the invention, a method for joint compression in a human hand comprises eight steps. Step one includes providing an intramedullary fixation assembly. Step two includes drilling a first medullary canal in a first bone and drilling a second medullary canal in a second bone. Step three includes reaming the first medullary canal of the first bone and the second medullary canal of the second bone. Step four includes inserting the proximal screw  
10 member into the first bone. Step five includes inserting a drill in the proximal screw member at creating a dorsal hole in the first bone at a predetermined angle. Step six includes slideably coupling the lag screw member into the dorsal hole and into the proximal screw member to lock the lag screw member to the proximal screw member. Step seven includes threadably coupling the lag screw member into the second medullary canal. Step eight includes applying torque to  
15 the lag screw member to cause compression of the joint.

In a fourth non-limiting aspect of the invention, a method for applying compression to a joint includes eight steps. Step one includes providing an intramedullary fixation assembly, where the intramedullary fixation assembly further includes a proximal screw member positioned at a proximal end of the intramedullary fixation assembly and a lag screw member  
20 positioned at a distal end of the intramedullary fixation assembly, where the proximal screw member is slideably coupled to the lag screw member and makes a fixed angle with the lag screw member. Step two includes drilling a first medullary canal in a first bone and drilling a second medullary canal in a second bone. Step three includes reaming the first medullary canal of the first bone and the second medullary canal of the second bone. Step four includes inserting  
25 the proximal screw member into the first bone. Step five includes inserting a drill in the proximal screw member and creating a dorsal hole in the first bone at a predetermined angle.

Step six includes slideably coupling the lag screw member into the dorsal hole and into the proximal screw member to lock the lag screw member to the proximal screw member. Step seven includes threadably coupling the lag screw member into the second medullary canal. Step eight includes applying torque to the lag screw member to cause compression of the joint.

5 In a fifth non-limiting aspect of the invention, an intramedullary fixation assembly for bone fusion includes a proximal screw member positioned at a proximal end of the intramedullary fixation assembly and a lag screw member positioned at a distal end of the intramedullary fixation assembly. The proximal screw member includes a tapered aperture aligned at a predetermined angle, where the proximal screw member is slideably coupled to the  
10 lag screw member at the predetermined angle.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

A further understanding of the invention can be obtained by reference to a preferred embodiment set forth in the illustrations of the accompanying drawings. Although the illustrated  
15 embodiment is merely exemplary of systems and methods for carrying out the invention, both the organization and method of operation of the invention, in general, together with further objectives and advantages thereof, may be more easily understood by reference to the drawings and the following description. The drawings are not intended to limit the scope of this invention, which is set forth with particularity in the claims as appended or as subsequently amended, but  
20 merely to clarify and exemplify the invention.

For a more complete understanding of the invention, reference is now made to the following drawings in which:

Figure 1 is a perspective view of a fixation system according to a preferred embodiment of the invention.

25 Figure 2 is a perspective view of a proximal screw member used in the fixation system shown in Figure 1 according to the preferred embodiment of the invention.

Figure 3A is a perspective view of a distal member used in the fixation system shown in Figure 1 according to the preferred embodiment of the invention.

Figure 3B is a perspective cross-sectional view of the distal member shown in Figure 3A according to the preferred embodiment of the invention.

5 Figure 4 is a perspective view of the instrument member used in the fixation system shown in Figure 1 according to the preferred embodiment of the invention.

Figure 5 is a perspective view of the assembled intramedullary fixation assembly inserted into the bones of a patient's foot according to the preferred embodiment of the invention.

10 Figure 6 is a side view of the assembled intramedullary fixation assembly shown in Figure 5 according to the preferred embodiment of the invention.

Figure 7 is a flow chart illustrating the method of coupling the intramedullary fixation assembly shown in Figures 1-6 to tarsal and metatarsal bones in a human foot according to the preferred embodiment of the invention.

15 Figure 8 is a perspective view of an assembled intramedullary fixation assembly inserted into the metacarpal and proximal phalangeal bones of a patient's hand according to an alternate embodiment of the invention.

Figure 9A is a perspective view of the intramedullary fixation assembly shown in Figure 8 according to an embodiment of the invention.

20 Figure 9B is another perspective view of the intramedullary fixation assembly shown in Figures 8 and 9A according to an embodiment of the invention.

Figure 10A is a perspective view of the surgical process being utilized on the metacarpal and phalangeal bones of a human hand using the intramedullary fixation assembly according to an embodiment of the invention.

25 Figure 10B is a perspective view of the surgical process of reaming the metacarpal bone of a human hand according to an embodiment of the invention.

Figure 10C is a perspective view of the surgical process of inserting the metacarpal screw member in the metacarpal bone of a human hand according to the embodiment of the invention.

Figure 10D is a perspective view of the surgical process of creating a dorsal window in the metacarpal bone of a human hand according to an embodiment of the invention.

5 Figure 10E is a perspective view of the surgical process of measuring the lag screw member depth in the phalangeal bone of a human hand according to an embodiment of the invention.

Figure 10F is a perspective view of the surgical process of reaming the phalangeal bone of a human hand according to an embodiment of the invention.

10 Figure 10G is perspective view of the surgical process of inserting the lag screw member into the metacarpal screw member according to an embodiment of the invention.

Figure 10H is a perspective view of the inserted intramedullary fixation assembly shown in Figure 8 according to an embodiment of the invention.

15 Figure 11 is a flow chart illustrating the method of coupling the intramedullary fixation assembly shown in Figures 8-10H to the metacarpal and phalangeal bones in a human hand according to an embodiment of the invention.

## **DETAILED DESCRIPTION OF THE INVENTION**

The invention may be understood more readily by reference to the following detailed  
20 description of preferred embodiment of the invention. However, techniques, systems and operating structures in accordance with the invention may be embodied in a wide variety of forms and modes, some of which may be quite different from those in the disclosed embodiment. Consequently, the specific structural and functional details disclosed herein are merely  
representative, yet in that regard, they are deemed to afford the best embodiment for purposes of  
25 disclosure and to provide a basis for the claims herein, which define the scope of the invention.

It must be noted that, as used in the specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly indicates otherwise.

Referring now to Figure 1, there is shown a fixation system 100 which is made in accordance with the teachings of the preferred embodiment of the invention. As shown, the fixation system 100 includes an intramedullary fixation assembly 110, comprising a proximal screw member 130 and a distal member 140. Proximal screw member 130 is provided on proximal end 135 of assembly 110 and is coupled to a distal member 140 that is provided on the distal end 145 of the fixation assembly 110. Also, proximal screw member 130 makes a fixed angle 150 with distal member 140 and this angle 150 determines the angle for arch restoration. Moreover, fixation system 100 includes instrument 120 that is utilized to couple intramedullary fixation assembly 110 to the bones, in one non-limiting example, in the mid-foot region (not shown). It should be appreciated that in one non-limiting embodiment, intramedullary fixation assembly 110 may be made from a Titanium material, although, in other non-limiting embodiments, intramedullary fixation assembly 110 may be made from SST, PEEK, NiTi, Cobalt chrome or other similar types of materials. It should also be appreciated that intramedullary fixation assembly 110 may be utilized for the internal fixation of other bones in the human body.

As shown in Figure 2, proximal screw member 130 is generally cylindrical in shape and extends from first bulbous portion 202 to second tapered end 204. End 204 has a diameter that is slightly smaller than diameter 226 of bulbous portion 202. Additionally, bulbous portion 202 has a taper, such as a Morse taper, with a width that decreases from end 211 to end 212. The taper allows for a locked interference fit with tapered aperture 316 when tapered bulbous portion 202 is combined with tapered aperture 316, shown and described below. Moreover, bulbous portion 202 is generally circular and has a generally hexagonal torque-transmitting aperture 208 that traverses length 210 of bulbous portion 202. However, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope

of the invention. Torque transmitting aperture 208 is utilized to transmit a torque from bulbous portion 202 to tapered end 204 by rotating bulbous portion 202.

Further, proximal screw member 130 has a first smooth exterior portion 206 extending from end 212 of bulbous portion 202. Portion 206 comprises an internal aperture 214 that  
5 longitudinally traverses portion 206 in direction 201. Portion 206 terminates into a second generally tubular portion 216. Portion 216 may comprise internal circular aperture 220 that longitudinally traverses inside portion 216. Internal circular aperture 220 is aligned with apertures 214 and 208 along axis 203 to form a continuous opening (i.e., a cannula) from bulbous portion 202 to end 204. The continuous opening or cannula is provided to interact with  
10 a guide wire (not shown) by receiving the guide wire within the continuous opening thereby positioning and locating the proximal member 130. In other non-limiting embodiments, the proximal member 130 may be provided without apertures 220 and 214 (i.e., the proximal member is solid).

Furthermore, tubular portion 216 has a plurality of circular threads, such as threads 218,  
15 which are circumferentially disposed on the external surface of portion 216 and, with threads 218 having an external diameter 224. Portion 216 may also be provided with a self-tapping leading edge 222 to provide portion 216 with the ability to remove bone material during insertion of proximal screw member 130 into bone. It should be appreciated that the length of the proximal member 130 may be selected of varying lengths to allow a surgeon to fuse different joints in a  
20 foot (not shown).

As shown in Figures 3A-3B, distal member 140 of the preferred embodiment is generally tubular in shape and tapers from a first end 302 to a second end 304 (i.e. end 302 has a diameter 306 that is slightly larger than diameter 308 of end 304). However, in another non-limiting embodiment, distal member 140 has a constant width from first end 302 to second end 304.  
25 Further, first end 302 is generally semi-spherical in shape and has an internal circular aperture 316, which traverses end 302 along direction 301 (i.e. end 302 is generally “donut” shaped).

Additionally, circular aperture 316 emanates from surface 322, such that portion 310 has a generally tapered aperture 316 provided in portion 310. Circular aperture 316 comprises slope 320 from first end 302 to end 322 of portion 310. Further, aperture 316 is aligned along axis 303, which is offset from horizontal axis 305 of distal member 140. Axis 303 forms an angle 150 with horizontal axis 305 that determines the angle for arch restoration, as shown in figure 3A. Angle 150 may be any angle greater than 90 degrees and less than 180 degrees. Tapered aperture 316 when combined with tapered bulbous portion 202, shown in Figure 2, creates a locked interference fit between proximal member 130 and distal member 140. First end 302 has a plurality of substantially similar grooves 326 and 328, which form an "L-shape" with surface 330 of end 302. Grooves 326 and 328 are provided to receive instrument 120 of fixation system 100, which is later described. In other non-limiting embodiments, other similar instruments may be provided to be received within grooves 326 and 328.

Distal member 140 further comprises a generally smooth portion 310 coupled to end 302. Portion 310 has a generally hexagonal shaped aperture 312, which opens into aperture 316 and which longitudinally traverses through portion 310 in direction 301. In other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized. Circular aperture 316 has a diameter 314 that is slightly larger than external diameter 224 of portion 216 and 206 of proximal screw member 130, with portions 216 and 206 being slidably received within aperture 316 of portion 310. Aperture 316 has a diameter that is smaller than diameter 226 of bulbous portion 202.

Portion 310 of distal member 140 terminates into a second generally cylindrical portion 318 which has a plurality of threads 324, which are circumferentially disposed on the external surface of portion 318. Portion 318 has an internal circular aperture 326 which is longitudinally coextensive with portion 318 in direction 301. Circular aperture 326 aligns with aperture 312 to form a continuous opening from end 302 to end 304.

As shown in Figure 4, instrument 120 is illustrated for coupling proximal screw member 130 to distal member 140. Particularly, instrument 120 includes a handle portion 402 coupled to a rod portion 404. Rod portion 404 emanates from handle portion 402 at end 406 and terminates into a rectangular planar portion 408 at end 410. Planar portion 408 is aligned along axis 401 and is fixably coupled to a generally cylindrical tubular portion 412 (i.e., an aiming device).  
5 Portion 412 traverses portion 408 from top surface 414 to bottom surface 416. Further, tubular portion 412 is aligned along dissimilar axis 403, forming an angle 405 with axis 401. Also, tubular portion 412 has a through aperture 420 that longitudinally traverses portion 412 along axis 403.

10 Planar portion 408 is coupled to planar portion 422, with portion 422 having a width slightly smaller than width of portion 408. Portion 422 terminates into a generally “U-shaped” portion 424 with portion 424 being orthogonal to portion 422. Further, portion 424 has a plurality of substantially similar sides 426 and 428 which are provided to be slidably coupled to grooves 326 and 328 of distal member 140.

15 In operation, sides 426 and 428 of instrument 120 are received in respective grooves 326 and 328 of distal member 140, of Figures 3A-3B, thereby slidably coupling distal member 140 to instrument 120. In this position, axis 303 of aperture 316 is aligned along substantially the same axis as axis 403 of instrument 120. Proximal screw member 130 is coupled to distal member 140 by slidably coupling portions 206 and 216 through aperture 420 of tubular portion 412.

20 Tubular portion 412 guides proximal screw member 130 through internal aperture 420 and into aperture 316 on surface 322 and may also guide a Kirschner wire (K wire) or a drill. Proximal screw member 130, of Figure 2, travels into bone as portions 216 and 206 travel further through aperture 316 at end 302 until bulbous portion 202 is restrained by surface 322 and end 302.

Aperture 316, being tapered along axis 303, causes proximal screw member 130 to form an angle  
25 150 with distal member 140, with proximal member 130 being aligned along an axis 303, which is substantially the same axis as axis 403 of tubular portion 412 of instrument 120.

In operation, and as best shown in Figures 5, 6 and 7, the fixation system 100 utilizes the intramedullary fixation assembly 110 for treating and fixating the deteriorated and damaged or fractured bones in the human foot 500. This restores the arch in a human foot 500 by coupling the intramedullary fixation assembly 110 to the human foot 500 of a left leg. In one non-limiting example, and as shown in Figure 5, the intramedullary assembly 110 is coupled to the medullary canals of the first metatarsal 502, medial cuneiform 504, navicular 506 and talus bone 508. Talus bone 508 makes up part of the ankle joint where the threaded portion 216 of the proximal screw member 130 of the intramedullary assembly 110 is threadably coupled. The medial cuneiform 504 and navicular 506 bones are most affected by Diabetic Charcot foot disorder that causes deterioration and collapse of the arch of the foot 500. It should be appreciated that the intramedullary assembly 110 may be used within each of the five rays, with a ray representing a line drawn from each metatarsal bone to the talus. The angulation in the smaller rays will be smaller than the two rays (i.e., a line from the first and second metatarsal bones to the talus bone). Also, the diameter of distal member 140 will decrease from the large ray to the small ray. In one non-limiting example, the angulation may be any angle greater than 90 degrees and less than 180 degrees. For example, the angle for the first ray may be 150-170 degrees and the angles for the other rays may be 160-175 degrees.

As shown in Figures 6 and 7, the intramedullary fixation assembly 110 may be utilized to reconstruct an arch in a mid-foot region of a human foot 500. As shown, the method starts in step 700 and proceeds to step 702, whereby a Dorsal Lis Franc incision (i.e., mid-foot incision) (not shown) is made in foot 500 in order to gain access to the joint. In step 704, the joint capsule is separated by "Gunstocking" foot 500 in direction 601 (i.e., the foot 500 is bent mid-foot) to expose the articular surface 602 and the articulating cartilage is removed. Next, in step 706, the intramedullary canal is reamed and the distal member 140 is inserted into the intramedullary canal (not shown) of the metatarsal 502. In other non-limiting embodiments, the distal member

140 may be inserted by impaction, by press fit, by reaming a hole in the intramedullary canal (not shown) or substantially any other similar strategy or technique.

Next, in step 708, the instrument 120 is coupled to the distal member 140 by coupling sides 426 and 428 of instrument 120 to respective grooves 326 and 328. In step 710, initial  
5 positioning of the proximal member 130 is assessed with the use of a guide wire through portion 412 (i.e., aiming device). Next, in step 712, a countersink drill is inserted through portion 412 and the proximal cortex is penetrated. In this step, a cannulated drill or guide wire is used to pre-drill the hole through the joints selected for fusion. In step 714, the proximal screw member 130 is inserted over the guide wire and into the distal member 140. Particularly, the proximal  
10 member 130 is inserted through tubular portion 412 (i.e., aiming device), causing proximal member 130 to travel through internal longitudinal aperture 420, into distal member 140 and further into bones 504, 506 and 508 until rigid connection with the tapered aperture 316 is made, thereby compressing the joint. In one non-limiting embodiment, a locking element (not shown) such as a plate or a washer is coupled to end 302 of the intramedullary fixation assembly 110 to  
15 further secure proximal threaded member 130 to distal member 140. Next, in step 716 the instrument 120 is removed and the dorsal Lis Franc (i.e., mid-foot) incision is closed. The method ends in step 718.

It should be appreciated that a plurality of intramedullary fixation assemblies, such as intramedullary fixation assembly 110, may be inserted into any of the bones of a foot 500 such  
20 as, but not limited to the metatarsal, cuneiform, calcaneus, cuboid, talus and navicular bones, in order to restore the natural anatomical shape of the arch of the foot 500. Thus, the fixation system 100, in one non-limiting embodiment, is utilized to couple the intramedullary fixation assembly 110 to the foot 500, which causes the metatarsal 504, medial cuneiform 504, navicular 506 and talus 508 bones to be aligned to the proper anatomical shape of an arch when assembled  
25 within foot 500. It should be appreciated that the intramedullary fixation assembly 110 is delivered through a dorsal midfoot incision, thereby reducing the disruption to the plantar tissues

and/or the metatarsal heads while at the same time minimizing the tension on the skin. This allows for improved wound closure, reduced operating room time, reduction in the number of incisions required and reduction in the total length of incisions. It should also be appreciated that in other non-limiting embodiments, the intramedullary assembly 110 may be utilized with graft material (i.e., autograft, allograft or other biologic agent).

In an alternate embodiment, as shown in Figure 8, an intramedullary fixation assembly 800 may comprise interconnected members for applying compression to, in one example, the metacarpal bone 815 and the first proximal phalange bone 820 in the human hand 825 or any other appropriate use for the internal fixation of the other bones in the human body. Particularly, the interconnected members include a metacarpal screw member 805 inserted into the medullary canal of the first metacarpal bone 815 and being coupled to a lag screw member 810 inserted into the first proximal phalange bone 820 for the internal fixation of the bones in the human hand 825. It should be appreciated that in one non-limiting embodiment, intramedullary fixation assembly 800 may be made from a Titanium material, although, in other non-limiting embodiments, intramedullary fixation assembly 800 may be made from SST, PEEK, NiTi, Cobalt chrome or other similar types of materials.

As shown in Figures 9A-9B, the intramedullary fixation assembly 800 includes metacarpal screw member 805 coupled to the lag screw member 810 through a frictional interference fit, with the metacarpal screw member 805 provided on the proximal end 900 of the fixation assembly 800 and the lag screw member 810 provided on the distal end 905. As shown in Figure 9A, metacarpal screw member 805 is substantially similar to the distal member 140 shown in Figure 1 and includes a generally tubular shaped body 910 having a threaded portion 930 terminating in a generally tubular portion 935. Threaded portion 930 has a generally uniform width from end 915 to end 940 and includes a plurality of circumferentially disposed threads 932 on the exterior surface of portion 930. Also, tubular portion 935 has a generally smooth exterior surface 950 and tapers from end 940 to end 920 (i.e., end 920 has a

circumference that is slightly larger than circumference at end 940), although in another non-limiting embodiment, portion 935 may have a constant width from end 940 to end 920. Further, end 920 is inclined at 25-degrees (Figure 9B) in order to align the metacarpal screw member 805 along the metacarpal phalangeal (MCP) joint, however in another non-limiting example, end 920 may be straight. Further, and as shown in Figure 9B, tubular portion 935 has an internal aperture 925, which is aligned along axis 952 (Figure 9B), which is offset from horizontally axis 945 of metacarpal screw member 805. Internal aperture 925 is generally circular, however, any other shaped aperture may be utilized without departing from the scope of the invention. Axis 952 forms a predetermined angle 955 with horizontal axis 945, causing aperture 925 to be tapered at the predetermined angle 955 and which determines the angle for fixation of the lag screw member 810 within the metacarpal screw member 805 (i.e., the predetermined angle 955 determines the angle for fusing the MCP joint). In one non-limiting embodiment, angle 955 may be fixed at 25 degrees although, in other non-limiting embodiments, the angle may be fixed at 20 degrees or substantially any other angle for the other rays of the human hand.

Also as shown in Figures 9A-9B, lag screw member 810 is generally cylindrical in shape and extends from bulbous portion 965 to a tapered end 968 on generally cylindrical portion 975. Portion 965 has a diameter that is slightly larger than the diameter of cylindrical portion 975. End 960 of bulbous portion 965 has a generally hexagonal torque transmitting aperture 980 (Figure 9A), which is provided to transmit a torque from bulbous portion 965 to tapered end 968, although, in other non-limiting embodiments, aperture 980 may include a star-shaped aperture, a square-shaped aperture or any other shaped aperture may be utilized without departing from the scope of the invention. Also, portion 975 includes a self-tapping and self drilling leading edge 970, although in other non-limiting embodiments, a self-drilling edge may be provided in lieu of the self-tapping edge to provide the surgeon with the ability to remove bone material during insertion of lag screw member 810 into bone. Bulbous portion 965 has a taper, such as a Morse taper, which provides for a locked interference fit with internal aperture 925. Torque

transmitting aperture 980 is utilized for transmitting a torque from bulbous portion 965 to self-tapping end 970 by rotating bulbous portion 965, causing the morse taper to lock within aperture 925 and convert the torque to a compressive force between the metacarpal screw member 805 and lag screw member 810 causing the underlying metacarpal joint to be compressed in the  
5 process.

Furthermore, lag screw member 810 may comprise an internal aperture (not shown) that is longitudinally coextensive with lag screw member 810 and form a continuous opening from end 960 to end 968 (i.e., lag screw member 810 is cannulated). The continuous opening or cannula is provided to interact with a guide wire (not shown) by receiving the guide wire within  
10 the continuous opening thereby positioning and locating the lag screw member 810. In other non-limiting embodiments, the lag screw member 810 may be solid). Also, lag screw member 810 has a plurality of circular threads, such as threads 980, which are circumferentially disposed on the external surface of portion 975 in order to facilitate traversal of lag screw member 810 into bone and apply compression by preventing linear motion being converted to rotary. It  
15 should be appreciated that the length of the lag screw member 810 may be selected of varying lengths to allow a surgeon to fuse different metacarpal joints in a hand or any other joints in the body (not shown).

As shown in Figures 8, 10A-H and 11, the intramedullary fixation assembly 800 may be utilized to selectively apply compression to the bones in a human hand 825, such as, for  
20 example, the first metacarpal bone 815 and the first proximal phalange bone 820. As shown, the method starts in step 1100 and proceeds to step 1102, whereby a Medial incision (not shown) is made in hand 825 in order to gain access to the metacarpalphalangeal (MCP) joint. In step 1104, the joint capsule is separated by distracting the MCP joint (Figure 10A) to expose the articular surfaces of the first metacarpal 815 and the first proximal phalange 820 and the articulating  
25 cartilage may be removed prior to insertion of the guidewire.. Next, in step 1106, a guide wire is inserted into the first metacarpal bone 815 in order to predrill a hole through the intramedullary

canal and, in step 1108, the intramedullary canal of the first metacarpal bone 815 is reamed at a predetermined depth with a reamer 1000 (Figure 10B). Next, in step 1110, the metacarpal screw member 805 is inserted into the intramedullary canal (not shown) of the first metacarpal bone 815 and threadably connected at a predetermined depth in the intramedullary canal of the  
5 metacarpal bone 815 with aperture 925 (Figure 9A) positioned in a dorsal position (Figure 10C) or desired fusion angle in the intramedullary canal. It should be appreciated that in other non-limiting embodiments, the metacarpal screw member 805 may be inserted by impaction, by press fit, or by substantially any other similar strategy or technique. It should also be appreciated that the metacarpal screw member 805 may be inserted into the metacarpal bone 815 until the screw  
10 member 805 is flush with or slightly recessed below the cut surface of the metacarpal bone 815.

Next, in step 1112, the metacarpal joint is prepared for fusion by creating a dorsal window in the metacarpal bone 815 (Figure 10D) for receiving the lag screw member 810 (not shown) by using instrument 1005. The instrument 1005 is utilized to penetrate the dorsal surface of the metacarpal bone 815 at the predetermined angle 955, which determines the angle for joint  
15 fusion. Next, in step 1114, a guide wire is used to pre-drill a hole through the first proximal phalange bone 820 and the proximal cortex is penetrated. In step 1116, the size of the lag screw member 810 is chosen by inserting a lag screw depth gauge 1010 (Figure 10E) over the lag screw and into the intramedullary canal of the first proximal phalange bone 820. Also, a lag screw rasp (not shown) may be utilized to create a flattened surface of bleeding bone by  
20 advancing the rasp over the guide wire (Figure 10F) and removing bone material from the articulating surface. The rasp is removed and the guide wire is left in the first proximal phalange bone 820. Next, in step 1118, the proximal phalange bone 820 is prepared for joint fusion by reaming the dorsal window of the proximal phalange bone 820 (Figure 10G). In step 1120, lag screw member 810 is inserted into the metacarpal screw member 805 through the dorsal window  
25 and into the first proximal phalange bone 820, aligning the bone 820 and compressing the

metacarpal joint. Next, in step 1122, the metacarpal joint is verified (Figure 10H) for proper alignment of the intramedullary fixation assembly 800. The method ends in step 1122.

5 It should be understood that this invention is not limited to the disclosed features and other similar method and system may be utilized without departing from the spirit and the scope of the invention.

10 While the invention has been described with reference to the preferred embodiment and alternative embodiments, which embodiments have been set forth in considerable detail for the purposes of making a complete disclosure of the invention, such embodiments are merely exemplary and are not intended to be limiting or represent an exhaustive enumeration of all aspects of the invention. The scope of the invention, therefore, shall be defined solely by the following claims. Further, it will be apparent to those of skill in the art that numerous changes may be made in such details without departing from the spirit and the principles of the invention. It should be appreciated that the invention is capable of being embodied in other forms without departing from its essential characteristics.

15

**IN THE CLAIMS:**

1. An intramedullary fixation assembly for bone fusion, comprising:  
a metacarpal screw member positioned at a proximal end of the intramedullary fixation  
5 assembly; and  
a lag screw member positioned at a distal end of the intramedullary fixation assembly;  
wherein the metacarpal screw member comprises a tapered aperture aligned along a  
predetermined angle; and  
wherein the lag screw member is configured for coupling with the metacarpal screw  
10 member at the predetermined angle.
2. The intramedullary fixation assembly of claim 1, wherein the metacarpal screw member  
comprises a first elongated body from a first end to an opposed second end, wherein the first  
elongated body comprises a first threaded portion coupled to a tapered portion.  
15
3. The intramedullary fixation assembly of claim 2, further comprising a taper on an  
external surface of the tapered portion.
4. The intramedullary fixation assembly of claim 3, wherein the tapered portion comprises  
20 the tapered aperture.
5. The intramedullary fixation assembly of claim 4, wherein the second end is inclined at a  
fixed angle.
- 25 6. The intramedullary fixation assembly of claim 5, wherein the second end causes an  
interference fit with the lag screw member.

7. The intramedullary fixation assembly of claim 5, wherein the second end causes an interference lock with the lag screw member.
8. The intramedullary fixation assembly of claim 3, further comprising a first aperture  
5 partially disposed along a longitudinal axis of the metacarpal screw member.
9. The intramedullary fixation assembly of claim 8, wherein the first aperture comprises a hexagonal shape, a star shape, or a square shaped end.
- 10 10. The intramedullary fixation assembly of claim 9, wherein the first aperture is provided to receive a complementary shaped end of an instrument.
11. The intramedullary fixation assembly of claim 2, wherein the first threaded portion comprises a plurality of bone threads on an outer surface of the first threaded portion.  
15
12. The intramedullary fixation assembly of claim 11, wherein the plurality of bone threads comprises a self-tapping or a self-drilling edge for removing bone material during insertion of the metacarpal screw member.
- 20 13. The intramedullary fixation assembly of claim 1, wherein the lag screw member comprises a second elongated body, a second threaded portion, and a bulbous portion.
14. The intramedullary fixation assembly of claim 13, wherein the bulbous portion comprises a second aperture partially disposed in the bulbous portion.  
25

15. The intramedullary fixation assembly of claim 14, wherein the second aperture comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening.

16. The intramedullary fixation assembly of claim 15, wherein the second aperture is  
5 provided to receive a complementary shaped end of an instrument.

17. The intramedullary fixation assembly of claim 14, wherein the bulbous portion is received in the tapered aperture, and wherein the bulbous portion abuts an opening at the second end.

10

18. The intramedullary fixation assembly of claim 1, wherein the predetermined angle determines the angle for joint fusion.

19. The intramedullary fixation assembly of claim 13, wherein the second threaded portion  
15 contains a plurality of threads on an outer surface of the second threaded portion.

20. The intramedullary fixation assembly of claim 19, wherein the second threaded portion includes a self-tapping or a self-drilling edge for removing bone material during insertion of the lag screw member.

20

21. The intramedullary fixation assembly of claim 1, wherein the predetermined angle is an acute angle.

25

**22.** A method for applying compression to a joint, comprising:

forming a first medullary canal in a first bone and forming a second medullary canal in a second bone;

reaming the first medullary canal of the first bone and reaming the second medullary

5 canal of the second bone;

inserting a metacarpal screw member into the first bone, wherein the metacarpal screw member is positioned at a proximal end of an intramedullary fixation assembly and further wherein the metacarpal screw member comprises a tapered aperture aligned along a predetermined angle;

10 creating a dorsal hole in the first bone at the predetermined angle;

slideably coupling a lag screw member into the dorsal hole and into the metacarpal screw member, wherein the lag screw member is positioned at a distal end of the intramedullary fixation assembly;

coupling the lag screw member into the second medullary canal; and

15 applying torque to the lag screw member to cause compression of the joint.

**23.** The method of claim 22, wherein the metacarpal screw member comprises a first elongated body from a first end to an opposed second end, wherein the first elongated body comprises a first threaded portion coupled to a tapered portion.

20

**24.** The method of claim 23, wherein the intramedullary fixation assembly further comprising a taper on an external surface of the tapered portion.

**25.** The method of claim 24, wherein the tapered portion comprises a tapered aperture

25 aligned along the predetermined angle.

26. The method of claim 25, wherein the second end is inclined at a fixed angle.
27. The method of claim 26, wherein the second end causes an interference fit with the lag screw member.
- 5
28. The method of claim 26, wherein the second end causes an interference lock with the lag screw member.
29. The method of claim 24, wherein the intramedullary fixation assembly further comprises  
10 a first aperture partially disposed along a longitudinal axis of the metacarpal screw member.
30. The method of claim 29, wherein the first aperture comprises a hexagonal shape, a star shape, or a square shaped end.
- 15 31. The method of claim 30, wherein the first aperture is provided to receive a complementary shaped end of an instrument.
32. The method of claim 23, wherein the first threaded portion comprises a plurality of bone threads on an outer surface of the first threaded portion.
- 20
33. The method of claim 32, wherein the plurality of bone threads comprises a self-tapping or a self-drilling edge for removing bone material during insertion of the metacarpal screw member.
34. The method of claim 22, wherein the lag screw member comprises a second elongated  
25 body, a second threaded portion, and a bulbous portion.

35. The method of claim 34, wherein the bulbous portion comprises a second aperture partially disposed in the bulbous portion.

36. The method of claim 35, wherein the second aperture comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening.

37. The method of claim 36, wherein the second aperture is provided to receive a complementary shaped end of an instrument.

38. The method of claim 35, wherein the bulbous portion is received in the tapered aperture, and wherein the bulbous portion abuts an opening at the second end.

39. The method of claim 22, wherein the predetermined angle determines the angle for joint fusion.

40. The method of claim 34, wherein the second threaded portion comprises a plurality of threads on an outer surface of the second threaded portion.

41. The method of claim 40, wherein the second threaded portion includes a self-tapping or a self-drilling edge for removing bone material during insertion of the lag screw member.

42. The method of claim 22, wherein the predetermined angle is an acute angle.

43. An intramedullary fixation assembly for compressing bones, comprising:  
a metacarpal screw member adapted for coupling with an intramedullary canal of a first  
bone; and

a lag screw member adapted for coupling with an intramedullary canal of a second bone;

5 wherein the metacarpal screw member includes an aperture adapted for coupling with the  
lag screw member.

44. The intramedullary fixation assembly of claim 43, wherein the lag screw member is  
coupled to the metacarpal screw member at a predetermined angle.

10

45. The intramedullary fixation assembly of claim 44, wherein the predetermined angle  
determines the angle for bone fusion.

46. The intramedullary fixation assembly of claim 43, wherein the metacarpal screw member  
15 comprises a first elongated body from a first end to an opposed second end, wherein the first  
elongated body comprises a first threaded portion coupled to a tapered portion.

47. The intramedullary fixation assembly of claim 46, wherein the tapered portion comprises  
a tapered aperture aligned along the predetermined angle.

20

48. The intramedullary fixation assembly of claim 46, wherein the second end causes an  
interference fit with the lag screw member.

49. The intramedullary fixation assembly of claim 46, wherein the second end causes an  
25 interference lock with the lag screw member.

50. The intramedullary fixation assembly of claim 47, further comprising a first aperture partially disposed along a longitudinal axis of the metacarpal screw member.
51. The intramedullary fixation assembly of claim 50, wherein the first aperture comprises a  
5 hexagonal shape, a star shape, or a square shaped end.
52. The intramedullary fixation assembly of claim 51, wherein the first aperture is provided to receive a complementary shaped end of an instrument.
- 10 53. The intramedullary fixation assembly of claim 46, wherein the first threaded portion comprises a plurality of bone threads on an outer surface of the first threaded portion.
54. The intramedullary fixation assembly of claim 53, wherein the plurality of bone threads comprises a self-tapping or a self-drilling edge for removing bone material during insertion of  
15 the metacarpal screw member.
55. The intramedullary fixation assembly of claim 43, wherein the lag screw member comprises a second elongated body, a second threaded portion, and a bulbous portion.
- 20 56. The intramedullary fixation assembly of claim 55, wherein the bulbous portion comprises a second aperture partially disposed in the bulbous portion.
57. The intramedullary fixation assembly of claim 56, wherein the second aperture comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening.

**58.** The intramedullary fixation assembly of claim 57, wherein the second aperture is provided to receive a complementary shaped end of an instrument.

**59.** The intramedullary fixation assembly of claim 56, wherein the bulbous portion is received in the tapered aperture, and wherein the bulbous portion abuts an opening at the second end.

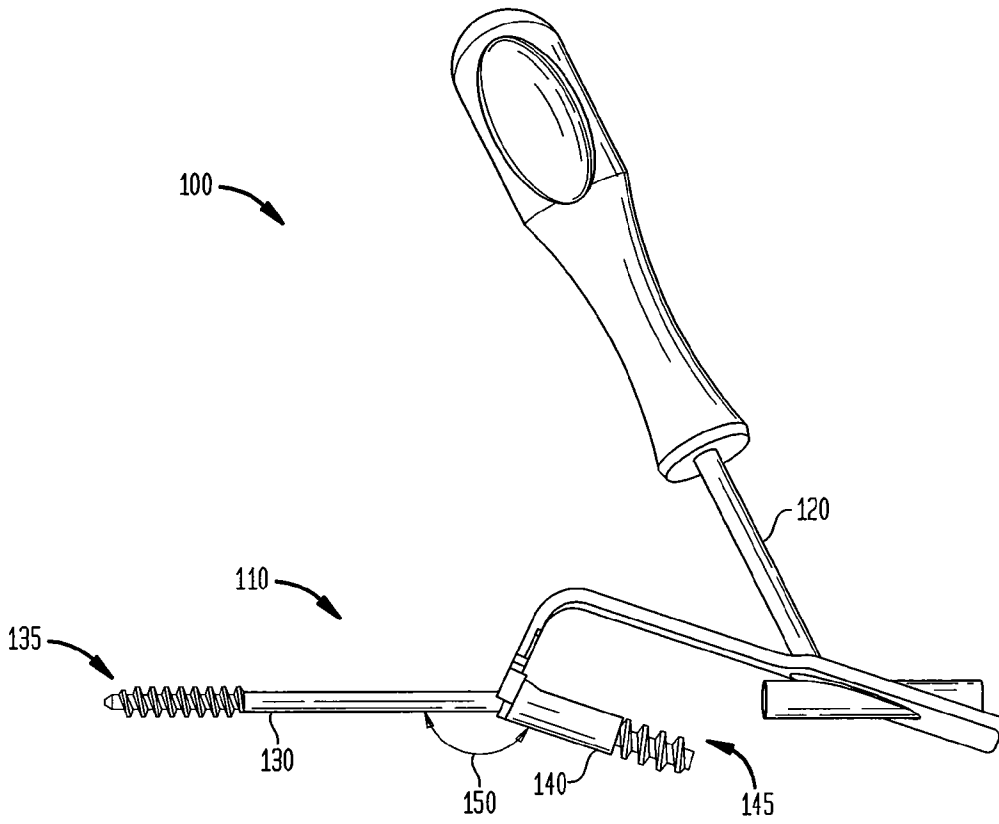
**60.** The intramedullary fixation assembly of claim 55, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

10

**61.** The intramedullary fixation assembly of claim 60, wherein the second threaded portion includes a self-tapping or a self-drilling edge for removing bone material during insertion of the lag screw member.

**62.** The intramedullary fixation assembly of claim 43, wherein the predetermined angle is an acute angle.

FIG. 1



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FIG. 2

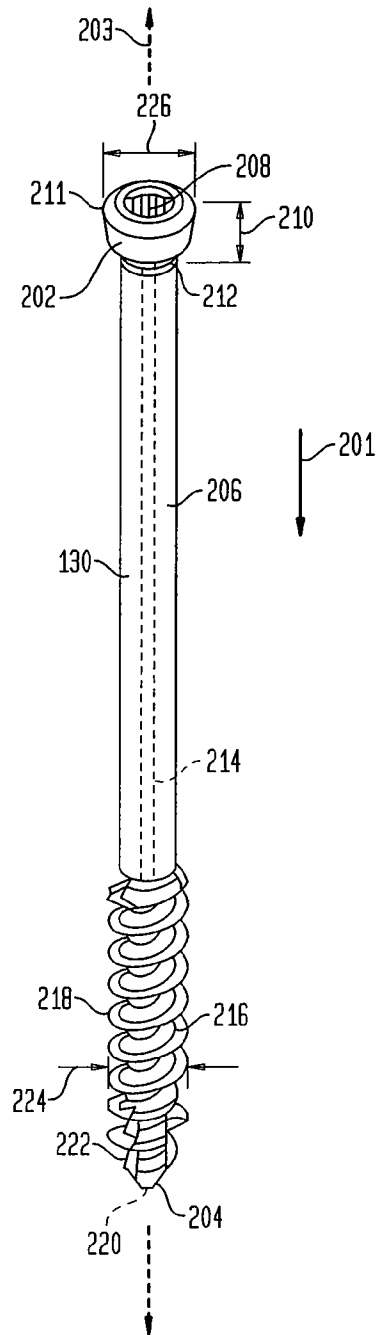


FIG. 3A

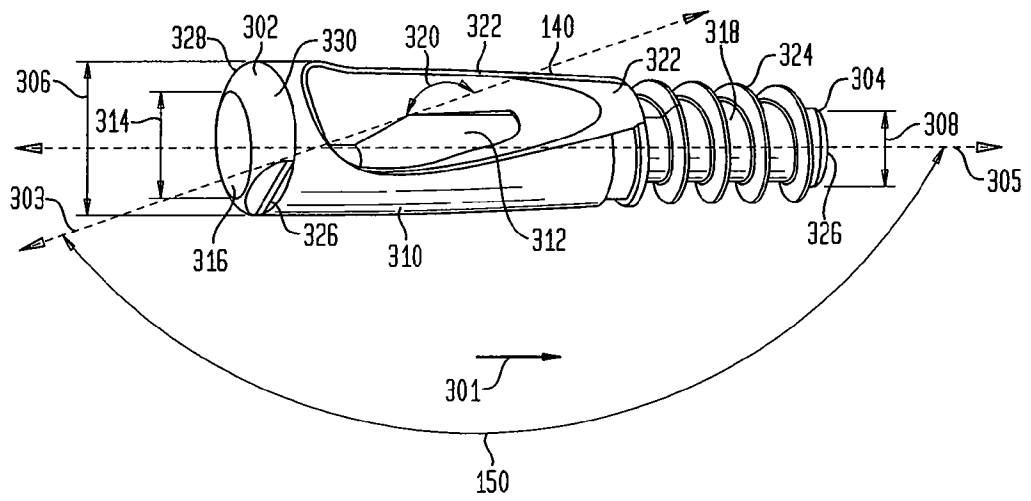


FIG. 3B

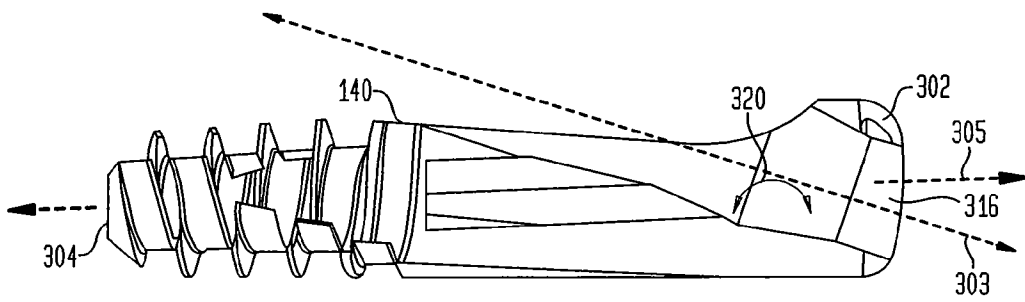
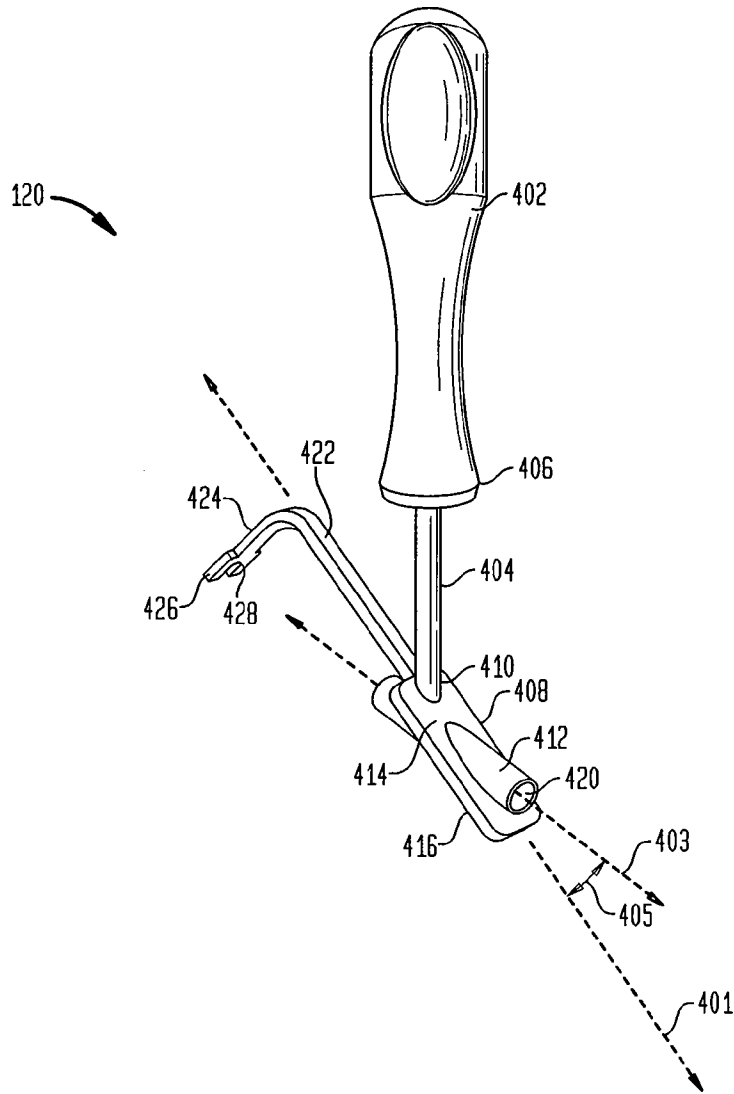


FIG. 4



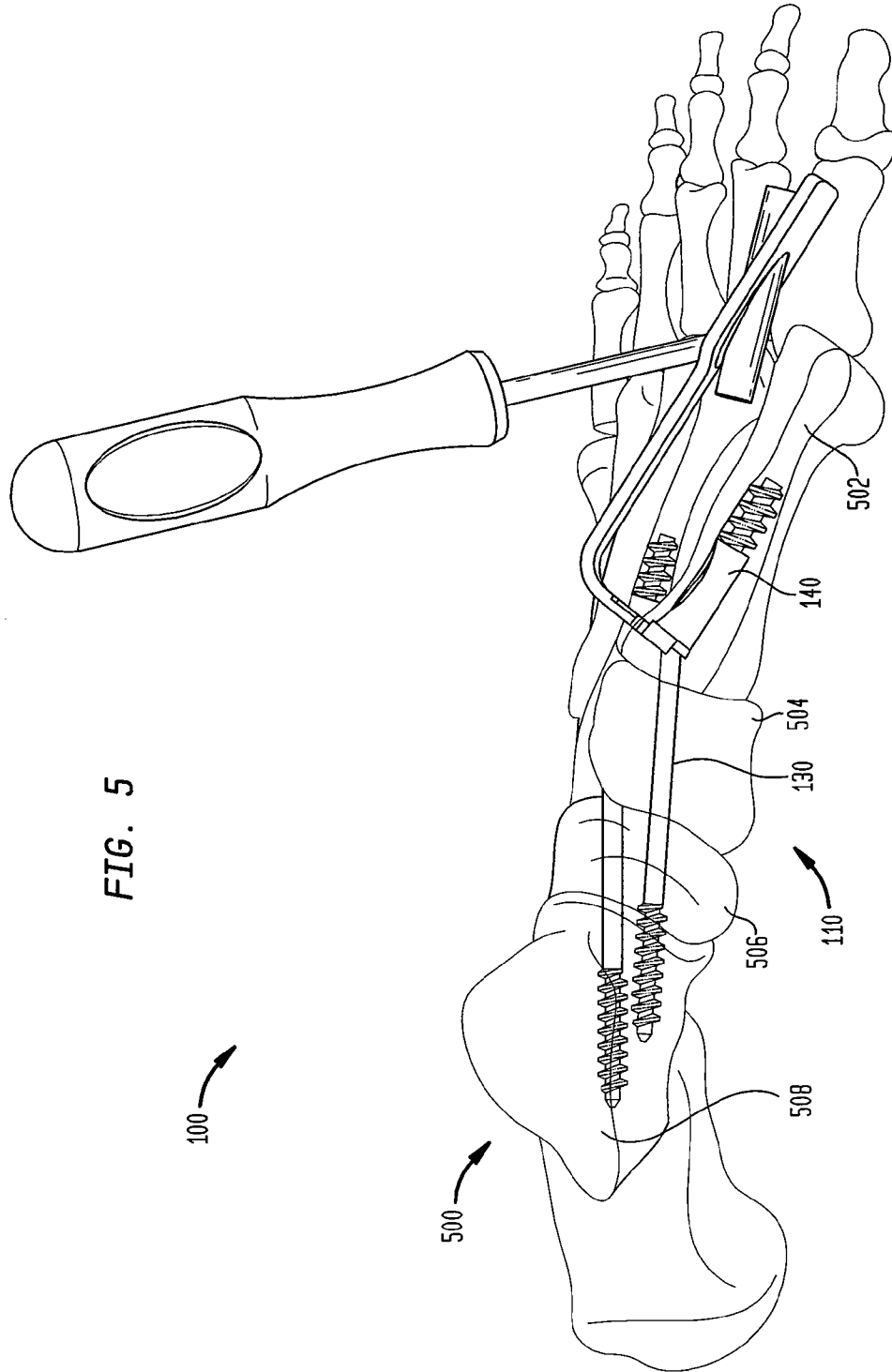
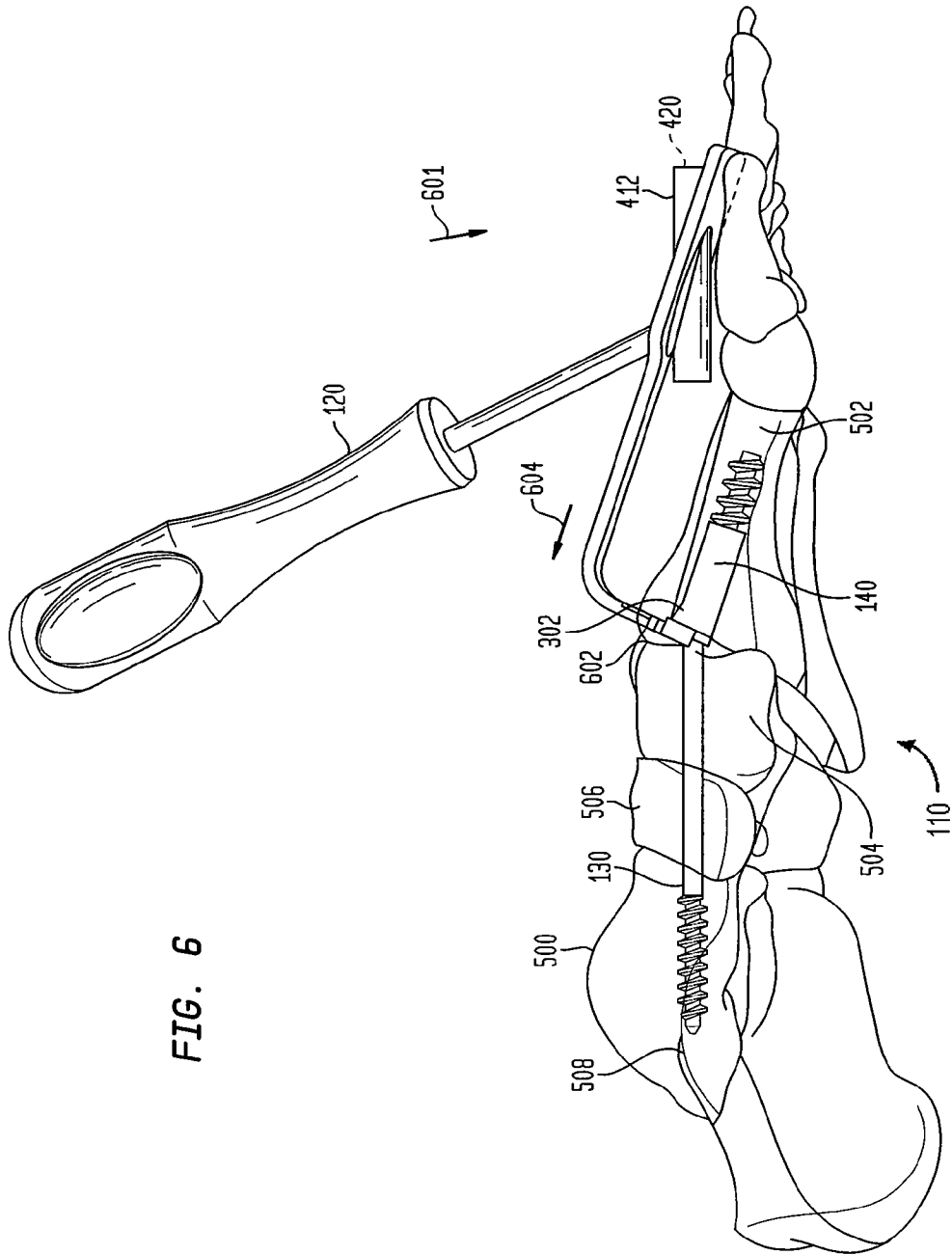
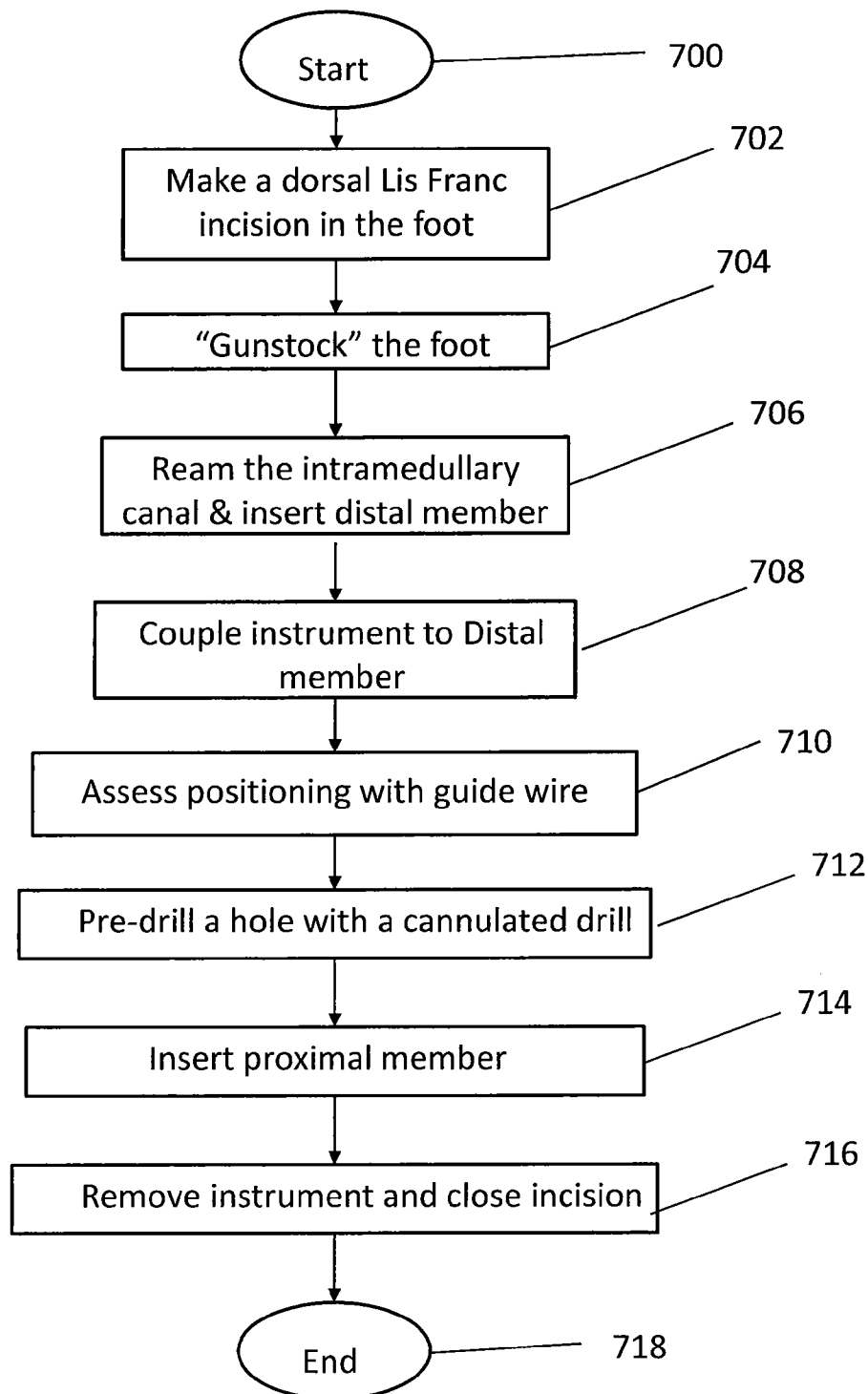


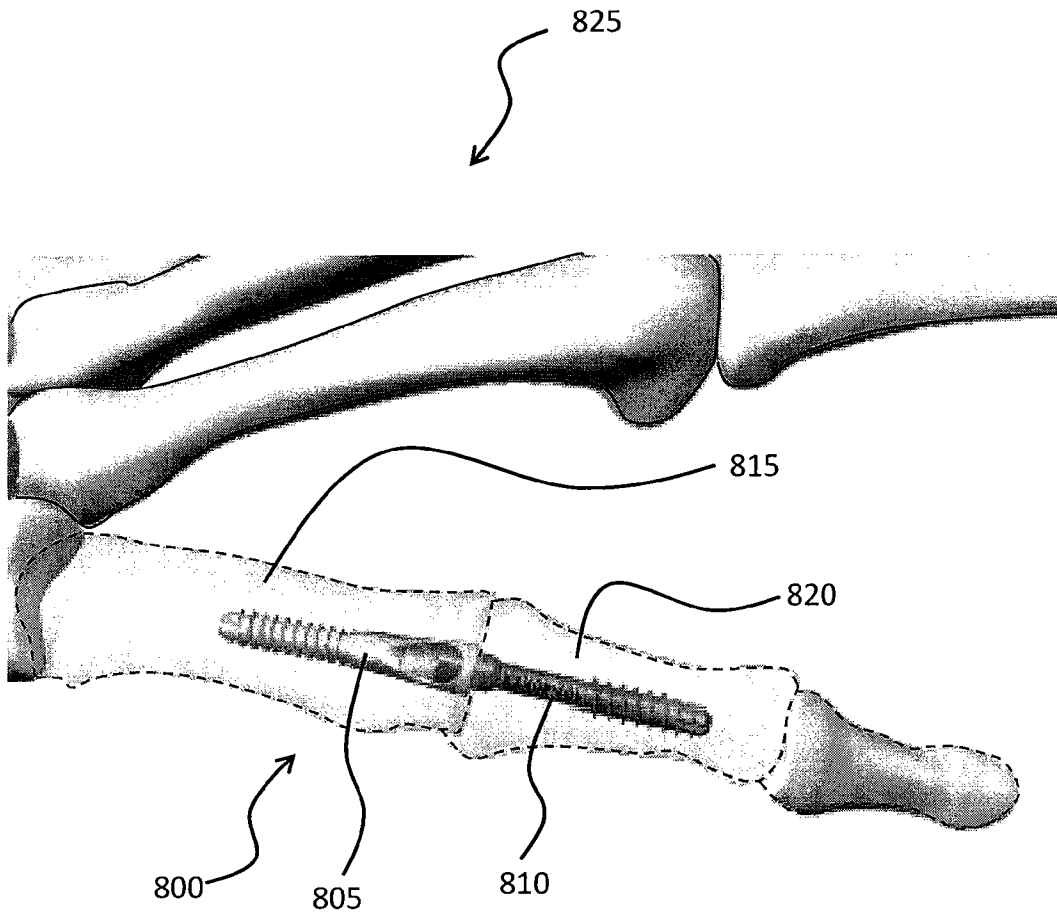
FIG. 5



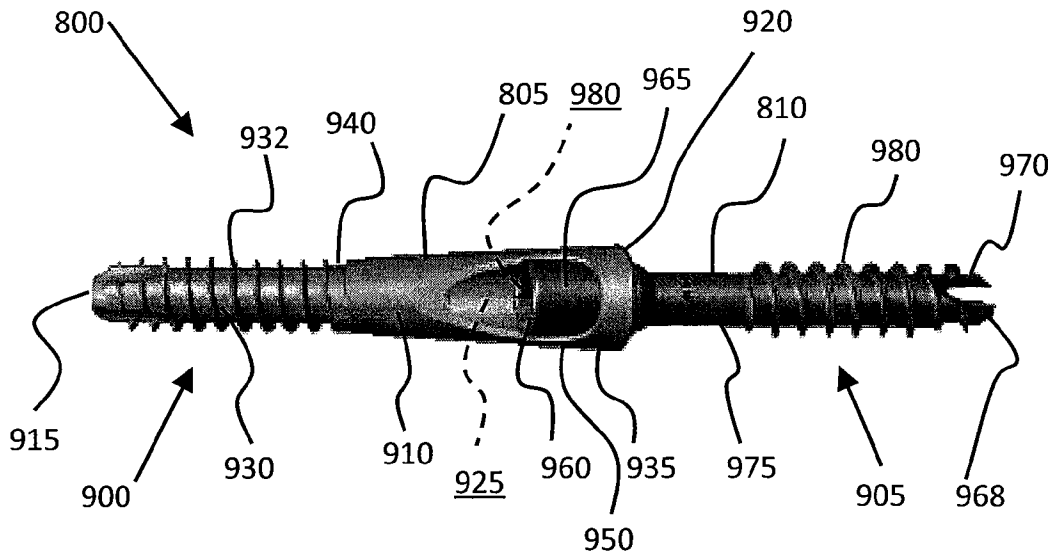
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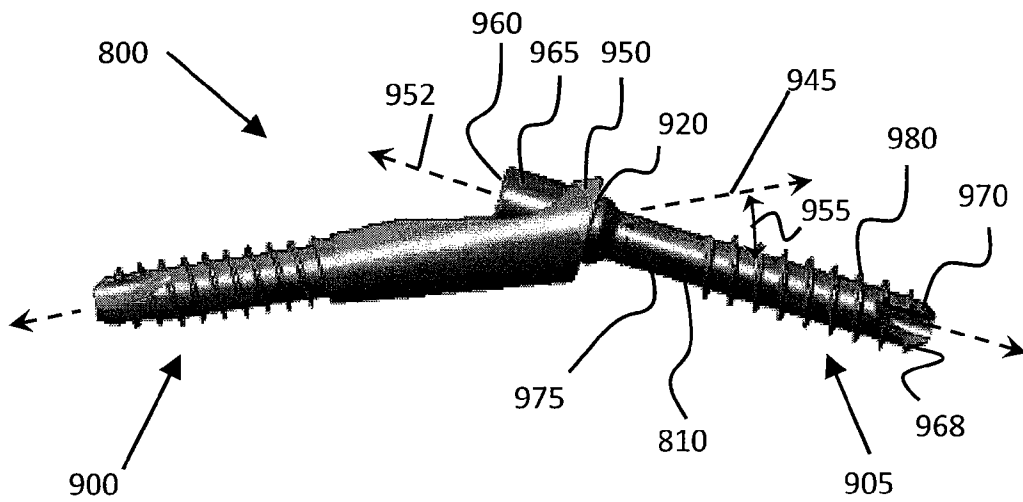
**FIG. 7**



**FIG. 8**

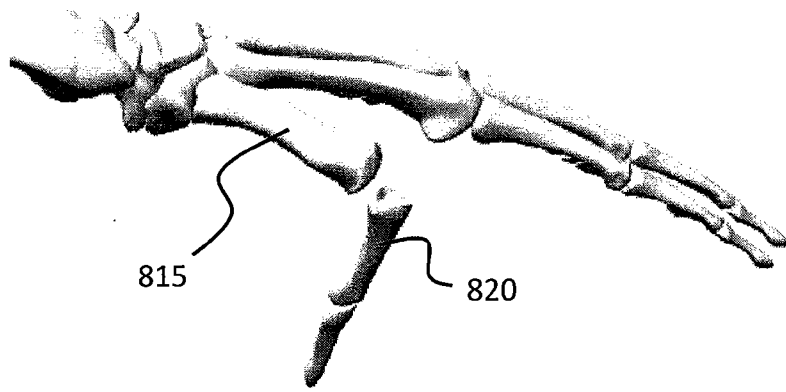


**FIG. 9A**

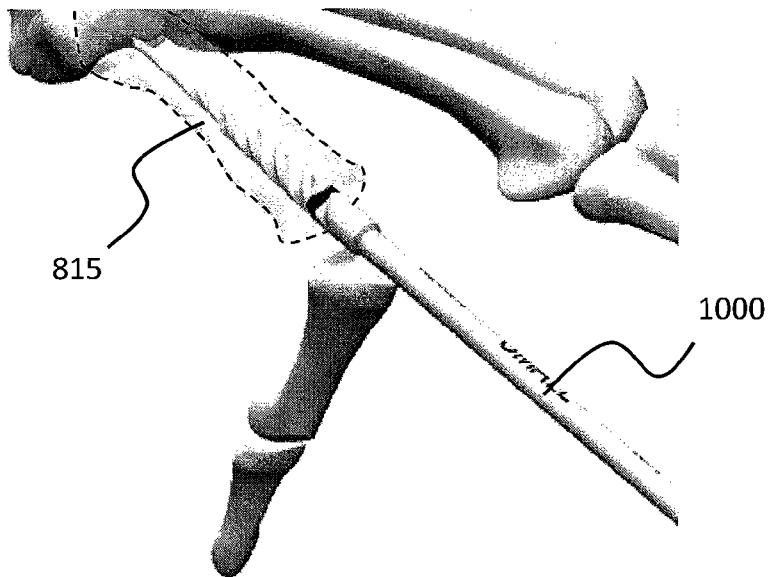


**FIG. 9B**

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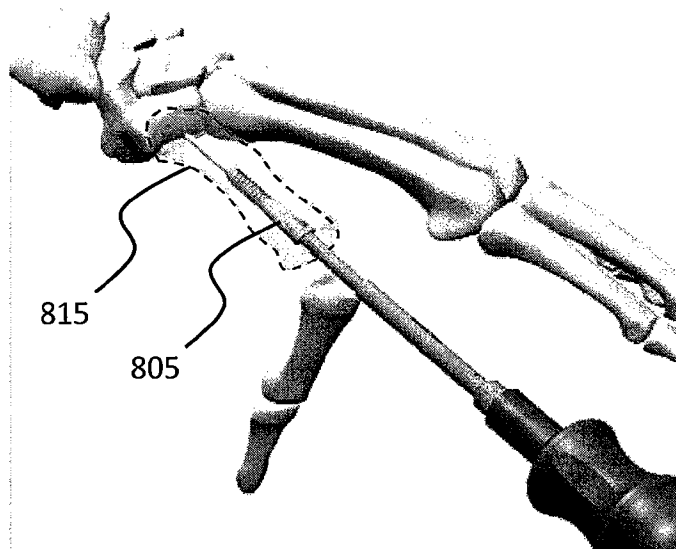


**FIG. 10A**

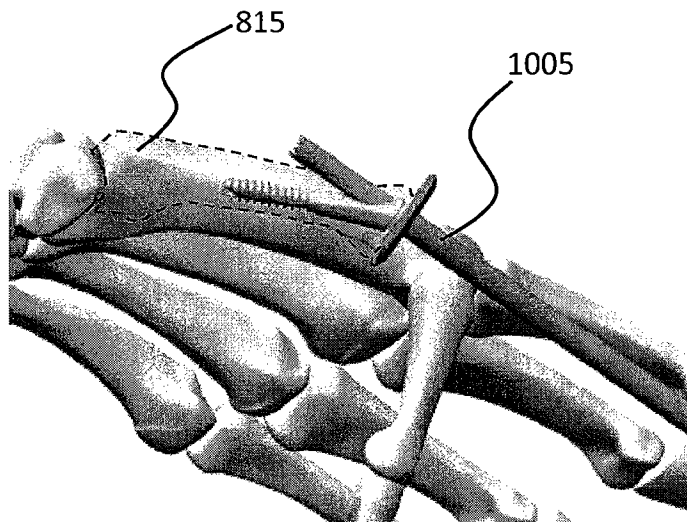


**FIG. 10B**

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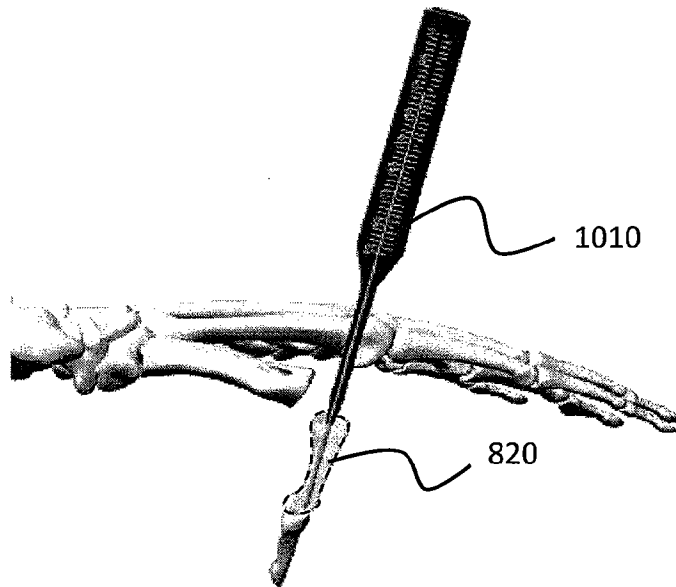


**FIG. 10C**

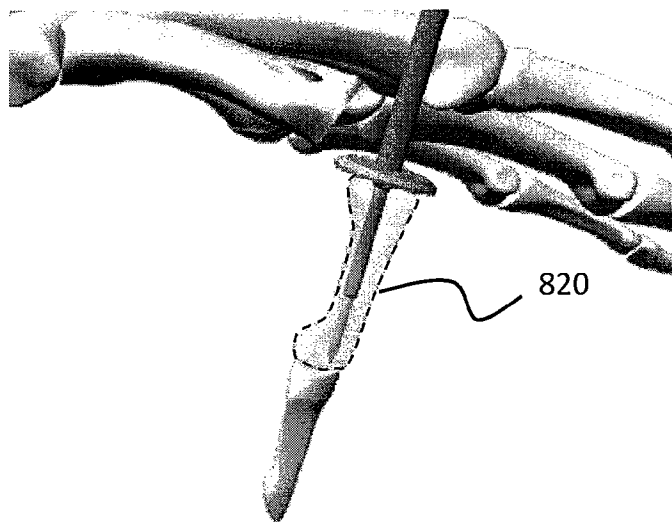


**FIG. 10D**

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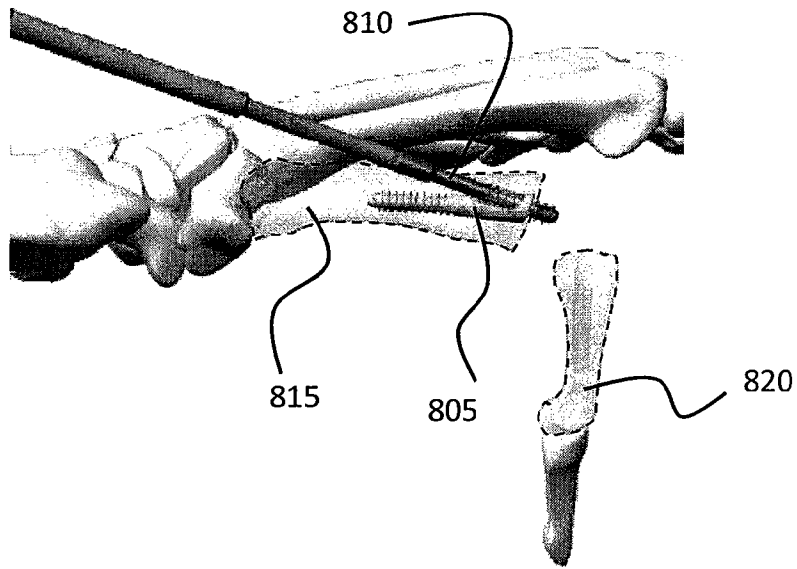


**FIG. 10E**

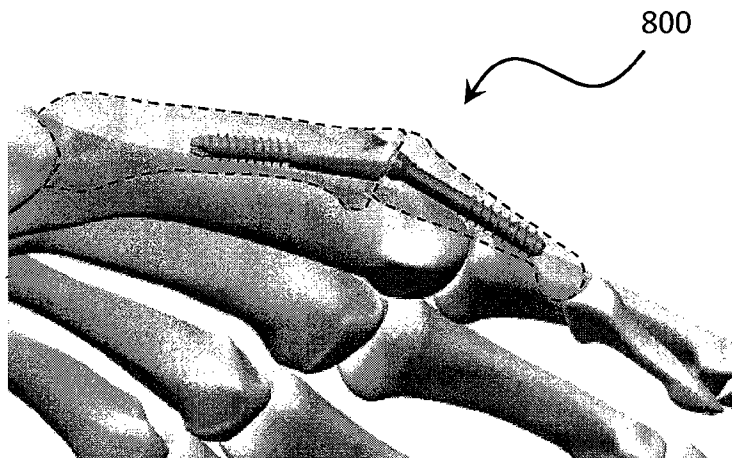


**FIG. 10F**

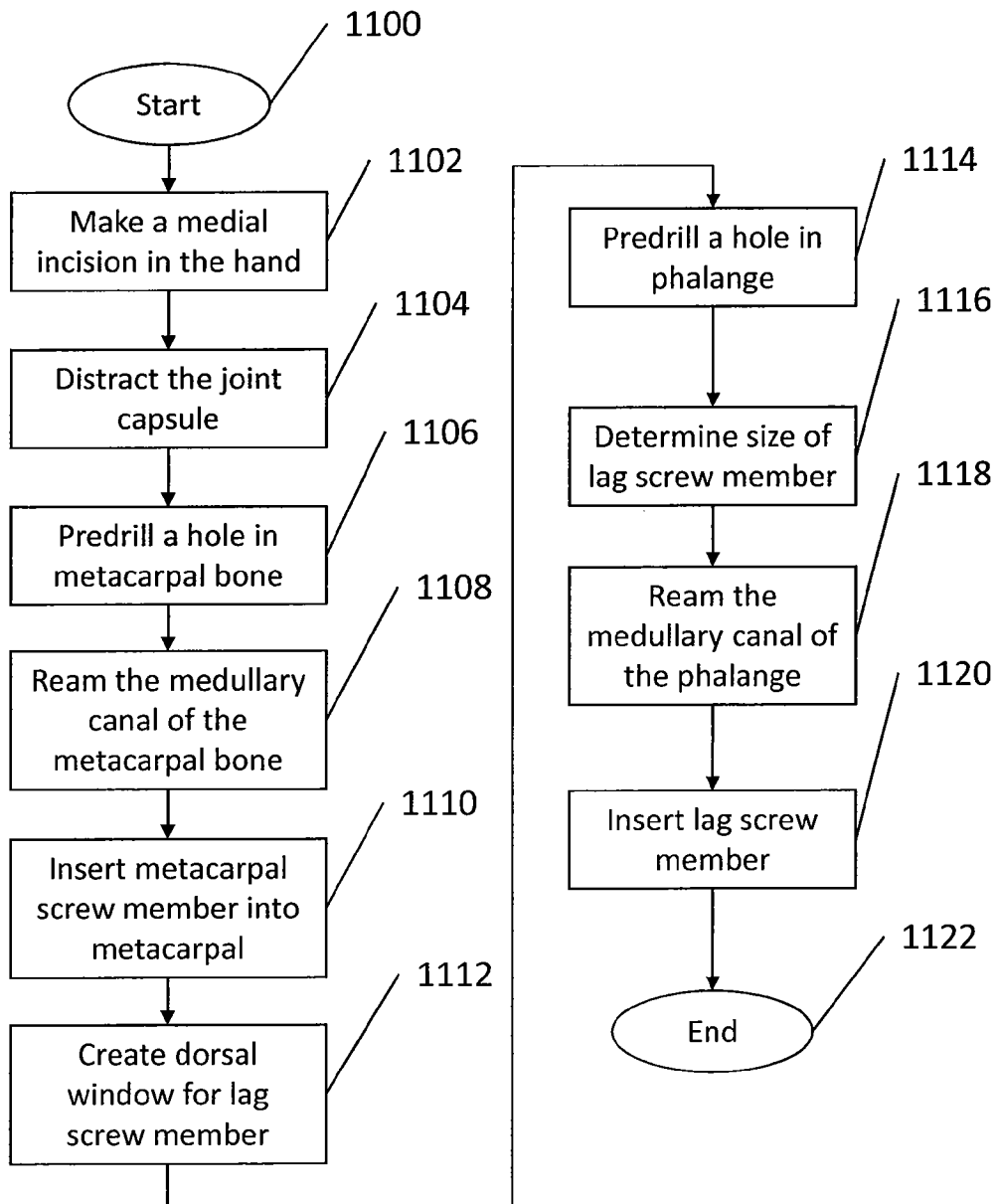
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**FIG. 10G**



**FIG. 10H**



**FIG. 11**

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2011/038785

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/56 (2011.01)

USPC - 606/62

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) - A61B 17/16, 17/56, 17/72, 17/82, 17/86, 17/88; A61F 2/30, 2/42 (2011.01)

USPC - 606/62, 65, 80, 86, 96, 104, 291, 297, 300, 301, 311, 312, 315; 623/18.11

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)

PatBase, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/0121324 A1 (TYBER et al) 13 May 2010 (13.05.2010) entire document	1-62
Y	US 2008/0065224 A1 (REIGSTAD et al) 13 March 2008 (13.03.2008) entire document	1-62
P	US 2011/0004255 A1 (WEINER et al) 06 January 2011 (06.01.2011) entire document	1-62

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search

21 October 2011

Date of mailing of the international search report

31 OCT 2011

Name and mailing address of the ISA/US

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