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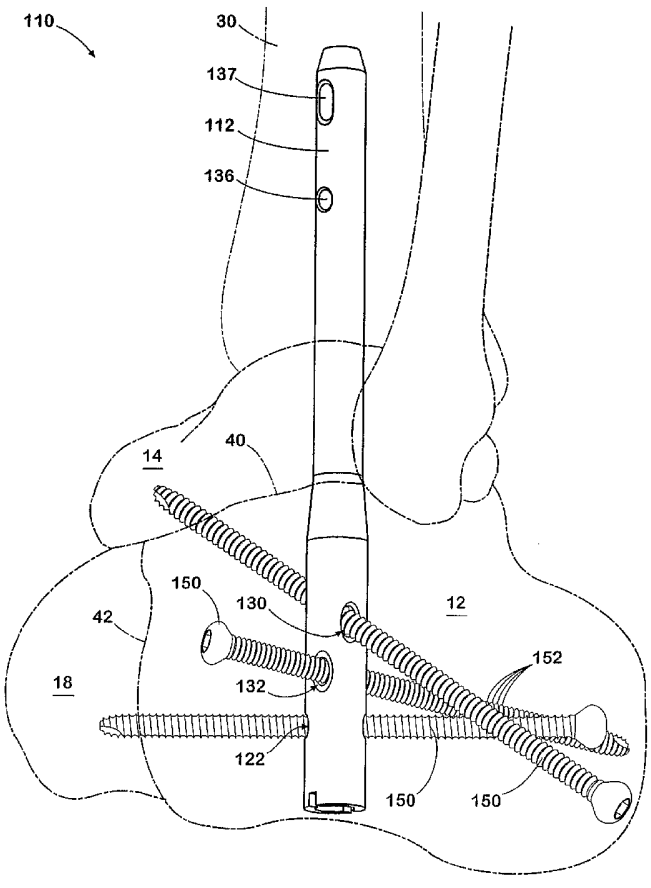
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(54) Title: HINDFOOT NAIL




(57) Abstract: The present invention relates to a nail and fastener assembly for use in providing a stable construct for optimal fixation of the hindfoot and to methods for implanting the nail and fastener assembly. One embodiment of the nail and fastener assembly provides additional fixation, for example, in the form of one or more threaded bores, to hold the fasteners in a fixed position. Another embodiment provides angled bores to allow multiplanar and multi-axial implantation of the fasteners. In some instances, the fasteners may cross one or more articulating surfaces of the foot. For example, the fastener may traverse one or more of the calcaneo-cuboid and the talo-calcaneal articulating surfaces to aid in more secure stabilization of the hindfoot.

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# HINDFOOT NAIL

## CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Patent Application Serial No. 11/061,699 entitled "Hindfoot Nail" filed February 18, 2005, the contents of which are incorporated herein by reference.

## FIELD OF THE INVENTION

The invention relates to nail and fastener assemblies that provide stable fixation of the hindfoot.

## BACKGROUND

Serious ankle problems can be caused by a number of conditions, such as arthritis (e.g., osteoarthritis, rheumatoid arthritis), diabetes, trauma, accidents, or severe deformation. One solution is to replace the ankle joint with an implant or ankle prosthesis. However, prostheses often fail due to subsidence, wear, and loosening within a few years following implantation. There are also anatomical considerations that make such implants non-feasible in some cases. Poor results with prostheses have led many surgeons to abandon implant arthroplasty in more serious cases and return to ankle arthrodesis – fusing the joint to ultimately result in bone fusion. Often, by the time fusion is selected as the best option, there is minimal motion at the joint prior to surgery.

Ankle fusion typically involves using screws and pins to hold the bone together. In a typical fusion surgery, the ankle joint is fused, allowing the tibia (shinbone) to grow together or fuse with the talus bone, the bone of the ankle that articulates with the tibia and fibula, and the calcaneus, the bone that forms the ankle joint. A long ankle arthrodesis "nail" may be inserted through the heel and fixed into place with screws or pins. Often, one or more screws or pins are inserted into the calcaneus, the bone at the lower back part of the foot forming the heel, which provides more stability.

Many of the currently available ankle fusion systems are less than optimal. One reason is because the screws or pins used to fuse the foot bones are secured only into the foot bones themselves; they are not secured to the ankle arthrodesis nail through which they are received. In some instances, an unsecured screw or pin can dislodge itself from the patient's bone and migrate out over years of use. Thus, there is a need in the art to provide a better solution to reduce the risk of migration.

Another reason that many of the currently available fusion systems are less than optimal is because they do not have angled fastener-receiving holes that allow for multi-planar fixation. Alternatively, if angled holes are present, they are not provided at optimal angle ranges for securing and immobilizing the ankle.

In some commercially available systems, the center of the fastener-receiving hole opening(s) in the ankle arthrodesis nail is perpendicular to the longitudinal axis of the nail, such that when the fastener is inserted, it is also perpendicular to the nail. This does not allow the surgeon to achieve purchase into preferred bones of the foot, but instead, limits the surgeon to securing the fastener into the calcaneus (the heel bone). Such systems also fail to provide the option of inserting fasteners in multiple axes to provide a more stable fixation system.

Moreover, fusion systems typically include one or more fasteners that engage only one foot bone in use. The fasteners do not cross articulating surfaces. It would be advantageous to provide a system that allows one or more fasteners to cross one or more articulating surfaces of the bones in the foot in order to provide more stability.

Another disadvantage of some fusion systems is that they do not provide nails with reinforced distal portions. If the nail is the same diameter throughout its length, but there are fastener holes in the distal portion, the implant may be weaker at that portion due to increased stresses from the patient's weight. Thus, there is a need for a fusion system that provides greater rigidity and stability in use.

Accordingly, it would be advantageous to provide a nail and fastener assembly that addresses many of the problems that have not been solved by currently-available systems.

## SUMMARY

The present invention comprehends various embodiments of nail and fastener assemblies, which may be employed, among other things, for use in providing a stable construct for optimal fixation of the hindfoot. It also comprehends various methods for implanting the nail and fastener assemblies.

Because bone quality is typically poor in patients who are candidates for this procedure, it is beneficial for a system to include a nail that provides additional fixation to hold the fasteners, which may be screws, pins, partially threaded screws, fasteners having a surface with threads or blades of various pitches, shapes, and rotations about the fastener, helical blades, bolts, or any other structure capable of holding and/or engaging bone, in a

fixed position. It is also beneficial for a system to provide the option of stabilizing various articulating surfaces of the foot.

Accordingly, certain embodiments of the present invention provide fusion systems with fixation features between the nail and fastener that secure the fastener into the nail. Other embodiments provide a fusion system with one or more openings of the nail that receive fasteners at various angles, allowing one or more fastener to cross one or more articulating surfaces of the foot to provide for multi-planar and multi-axial implantation of the fasteners. Certain structures provide a fusion system with a fastener that crosses one or more of the talo-calcaneal and the calcaneo-cuboid articulating surfaces. Other embodiments combine these features or aspects of them.

One structure according to certain embodiments of the invention includes a hindfoot nail with a threaded fastener-receiving hole. Other structures include angled fastener-receiving bores, and further structures include assemblies adapted to fuse articulating surfaces of a patient's foot. Even further versions include an implant assembly for a hindfoot, comprising a hindfoot nail having a proximal portion, a distal portion, and a central longitudinal axis, and a fastener adapted to be received by the hindfoot nail; characterized in that the distal portion of the hindfoot nail comprises a fastener-receiving hole that is at least partially threaded. Methods of the invention provide methods for at least partially fusing certain bones of the patient's hindfoot.

Certain devices of the present invention accomplish these results in a number of ways, some of which are discussed in detail below, with reference to the drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG 1 shows a dorsal view of the anatomy of the foot.

FIG. 2 shows a side view of a foot having an implanted nail according to one embodiment of the invention.

FIG. 3 shows a perspective view of one embodiment of a nail and fastener assembly.

FIG. 3A shows a perspective hind view of a foot having an implanted nail and fastener assembly according to another embodiment of the invention.

FIG. 4 shows a side view of a nail according to one embodiment of the invention.

FIG. 4A shows a cross-sectional view of the nail of Figure 4.

FIG. 5 shows another cross-sectional view of the nail of Figure 4.

FIG. 6 shows a cross-sectional schematic view of the threaded angled bores of the nail of Figure 4 showing fasteners (in phantom) inserted.

## DETAILED DESCRIPTION OF THE DRAWINGS

Anatomy of the Foot and Ankle:

There are twenty-six bones in the human foot 10, shown in FIGS. 1 and 2. There are seven tarsal bones: the bone that forms the heel is the calcaneus 12; the talus 14 connects to and supports the tibia 30 (shown in FIG. 2) at the ankle. The five other tarsal bones are the navicular 16, the cuboid 18, and three cuneiforms 20, which form the middle of the foot. Next, five metatarsals 22 form the lower portion of the instep of the foot. The metatarsals 22 radiate out to the phalanges 24, which are the toe bones.

Of the tarsal bones, the talus 14 and the calcaneus 12 are the largest and are adjacent to each other. Also adjacent to the calcaneus 12 is the cuboid 18. The calcaneus 12 and the talus 14 define an articulating surface 40 between the two bones (the talo-calcaneal articulating surface), and the calcaneus 12 and the cuboid 18 also define an articulating surface 42 (the calcaneo-cuboid articulating surface). Some or all of these, or combinations of them, are the foot bones and articulating surfaces that can be of particular interest to certain embodiments of the present invention.

Fusion System:

Figures 3 and 3A each show a fusion assembly 110 according to embodiments of the invention. Assembly 110 features a nail 112 and one or more fasteners 150. In Figure 3, some fasteners 150 are shown as partially threaded and partially smooth or fully threaded. In Figure 3A, all fasteners 150 are shown having threads 152. In short, a surgeon may choose to use a combination of any type of fasteners.

As shown in Figure 2, nail 112 is adapted to be implanted into a patient's tibial canal. The fasteners 150 are adapted to be inserted through and received by the nail 112 and secure to particular bones of the foot. Different nails 112 are typically provided for the left and right sides of a patient's body to account for differing angles.

As shown in Figure 4, nail 112 has a distal portion 114 and a proximal portion 116. Nail 112, as is the case with other components of embodiments disclosed herein, can be formed of Titanium, Titanium alloys, Surgical Steel alloys, or other desired material. Distal portion 114 is shown having a greater outer diameter relative to the proximal portion 116 and may be considered, if desired, also to include a frustoconical transition segment between the portion with the greater outer diameter and the smaller outer diameter. However, distal portion 114 need not necessarily have a greater outer diameter than other portions of the nail 112.

Nail 112 can be also cannulated, if desired. One form of such cannulation is shown in Figs. 4 – 5 and can be accomplished by gundrilling or other appropriate techniques. Such cannulation enhances the ability of the nail 112 to be inserted using a closed surgical procedure, such as over a guide wire or rod. Cannulation in the distal portion 114 or portions of it, can be of greater diameter than cannulation in the proximal portion 116 or portions of it, as desired.

At the distal portion 114 is a driving end 118 that has an instrument-receiving portion 120. Instrument-receiving portion 120 may include any type of connecting portion, such as a threaded bore 119 (shown in Figure 5) that is adapted to receive and fasten to implantation instruments. Instrument-receiving portion 120 may also have an optional keyway 121 (shown in Figure 6) that can provide additional stabilization with respect to implantation instruments. Other options for connecting the instrument-receiving portion 120 to implantation instruments may be a ball and detent mechanism, a dovetail and slot configuration, a lock and key configuration, or any other stable locking mechanism.

Because distal portion 114 of nail 112 (which again may, if desired, contain some or all of the frustoconical transition shown in Figs. 4 – 5) may include one or more angled fastener holes 122, 130, distal portion 114 may be provided with an outer diameter that is larger than the diameter at proximal portion 116. In the particular embodiment shown in Figs. 4 – 5, the greater outer diameter can in some ways be considered to provide favorable properties such as any or all of increased resistance to bending, rigidity, strength, stability, durability and enhanced reception and / or retention of fasteners.

One aspect of embodiments of the present invention is that one or more fasteners are received by and secured to a nail, as well as being secured to the patient's bone. See, e.g., Figure 3A. One structure used to accomplish the securing of the fastener to the nail can be a threaded bore and threaded fastener combination. In this example, the nail can have a threaded bore 128 and the fastener can have corresponding threads 152 at or near the portion received by the nail.

In the specific embodiment shown in Figure 3A, the fastener is a threaded screw 150. Threads 152 may be provided in any number of shapes (e.g., trapezoidal teeth, triangular teeth, square teeth), pitches, and rotations (e.g., tightly wound around fastener or "loosely" wound such that there is a greater distance between each thread). The screw threads and the threads of the nail need not have the same shape, pitch, or rotation, although they typically will.

In an alternate embodiment (not shown), the fastener is a partially threaded screw. Again, the threads may be provided in any number of shapes, pitches, and rotations. In this example, the threads are preferably located at or near the portion where the threads are secured into nail to prevent their migration.

In a further embodiment, the fastener has a series of cutting edges that engage a patient's bone. Cutting edges may be cutting blades, helical blades, spikes, or any other structure capable of holding and/or engaging bone. Cutting edges may cover all or just a portion of the fastener. Alternatively, the fastener may feature a bolt, a moly bolt, a tension spring, or any other structure capable of holding and/or engaging bone.

In use, the threaded bore 128 is adapted to receive and secure a corresponding structure on the fastener with respect to nail 112, as well as allow fastener to engage with bone. One or more openings in the nail 112 may be provided as threaded bores. It is also possible to provide a nail 112 having a combination of threaded and non-threaded bores (the non-threaded bore structure is described below). It is also possible to provide openings in the nail that are partially threaded and partially non-threaded.

One optional feature that may be provided with assembly 110 is an insert or bushing (not shown) to prevent rotation of the fastener. *See* pending S&N Application Serial No. 10/999572, filed November 30, 2004 and titled "Humeral Nail," the entire contents of which are hereby incorporated by this reference. This feature may provide a function similar to fastener anchors that can be used to hang a picture on a wall, i.e., the insert interferes with the rotation of the fastener in the nail and can prevent it from wobbling or threading out, without interfering with the ability of the fastener to insert into the nail at a range of angles. The insert may be used in connection with a threaded or non-threaded bore. It may be secured with respect to nail by the threads, by a rib and locking ring configuration, by injecting a biologic or bone cement through the cannulation as each fastener is inserted, by an interference fit, or any other securing means.

A further aspect of some embodiments of the present invention is that fusion of the hindfoot can be established by connecting and stabilizing certain articulating surfaces of the foot. In one specific embodiment, the talus 14 and the calcaneus 12 are connected to one another by a fastener that crosses the talo-calcaneal articulating surface when implanted. In another specific embodiment, the cuboid 18 and the calcaneus 12 are connected to one another by a fastener that crosses the calcaneo-cuboid articulating surface when implanted. This may be done by specifically targeting these bones using an assembly 110 with angled

holes or bores according to one embodiment of the present invention, as shown in Fig. 3A. This particular embodiment provides for multi-planar (and if desired, multi-axial) fixation. The nail may also be adapted to be secured to the tibia 30 for additional stability.

One particularly beneficial aspect of providing angled fastener holes 122, 130 is that they are provided such that any fastener received therein can target specific bones. In one structure according to certain embodiments of the invention, the fasteners are pin-like or substantially smooth. In another structure, the fasteners may have a portion that is threaded (or that contains cutting blades, helically shaped structures having any angle relative to the fastener axis, or other fastening structure to engage bone) that are adapted to secure to a patient's bone, and a portion that is at least partially smooth. These fasteners may be referred to as compression screws, an example of which is shown in Figure 3.

Compression screws have a portion adapted to attach to a patient's bone, as well as an at least partially smooth portion that articulates with the nail for sliding compression. The at least partially smooth surface is allowed to "slide" within the nail, such that when the patient applies pressure to the implant (for example, if the implant is a weight-bearing implant in the foot, the patient applies pressure when stepping down), the fastener compresses the bones together. The bone fragments are allowed to slide and bear on each other for better healing and fusion of the site.

In certain embodiments, the portion that cooperates with a patient's bone is adapted to cooperate with the calcaneus, and in other embodiments, the portion that cooperates with a patient's bone is adapted to cross one or more articulating surfaces of the foot.

Alternatively, angled fastener holes may have internal threads 128. In use, internal threads 128 of nail 112 cooperate with fastener threads 152 of fasteners 150 to secure the fasteners into the nail 112, as well as into the patient's bone. For ease of reference, fasteners will be referred to as fasteners 150 (which are shown as threaded screws) throughout the remainder of this application, although it is understood that fasteners may take any of the above-described forms, such as compression screws, pins, partially threaded screws, and so forth. *See e.g.* Figure 3.

In embodiments in which the fastener is adapted to cross articulating surfaces, fastener holes 122, 130 are provided at optimal angles that allow the surgeon to achieve fastener attachment into particular bones of the foot, such as the calcaneus 12, the talus 14, and the cuboid 18. Angled fastener holes 122, 130 are oriented so that fasteners 150 can be

inserted into the nail 112 and cross one or more of the articulating surfaces 40 and 42 of the foot bones.

For example, consider nail 112 having a central longitudinal axis 124 as shown in Figures 4-5. At least one angled fastener hole 122 is positioned at an angle θ that is between about 45° and about 135° off of the central longitudinal axis 124. (In other words, when a fastener is inserted through the hole 122, the fastener itself creates an axis 160 that forms an angle of between about 45° and about 135° with the central longitudinal axis 124, as shown in Figure 4A.) In a particular embodiment, at least one angled fastener hole 122 is positioned at an angle between about 65° and about 115° off of the central longitudinal axis 124. In an even more preferred embodiment, the angled fastener hole 122 is positioned at an angle between about 80° and about 90° off of the central longitudinal axis 124, and most preferably, at about 85° off of the central longitudinal axis 124.

Central longitudinal axis 124 also intersects a plurality of planes. One cross-section defined by central longitudinal axis 124 is central plane 125, which is the plane in the page of the paper. This cross-sectional view is shown in Figure 4A. In addition to its angled orientation with respect to central longitudinal axis 124, angled fastener hole 122 may also be disposed at an angle that is rotated off of the plane 125 of the paper. (In other words, when a fastener is inserted through hole 122, the fastener forms a second plane that is not aligned with plane 125 and would either extend from or retreat into plane 125 of the paper.) In one embodiment, fastener 150 may either be rotated about 0-45° into the plane 125 of the page or rotated about 0-45° out of the plane 125 of the page. In one embodiment, angled fastener hole 122 is rotated about 2-30° off of plane 125. In a further embodiment, it is rotated about 5-15 ° off of plane 125, and is most preferably, about 10° off of plane 125. (This angle may be in either the medial or the lateral direction.)

In certain embodiments, angled fastener hole 122 is adapted to receive a fastener that targets the cuboid 18 in use, or that at least partially traverses the calcaneo-cuboid articulating surface 42, as shown in Figure 3.

A second angled fastener hole 130 may also positioned on the distal portion 144 of nail 112. This angled fastener hole 130 may be positioned at an angle α that is between about 25° and about 135° off of the central longitudinal axis 124, such that a fastener inserted therein forms axis 162. In a particular embodiment, second angled fastener hole 130 is positioned at an angle between about 45° and about 115° off of the central longitudinal axis 124. In an even more preferred embodiment, second angled fastener hole 130 is positioned at

an angle between about 50° and about 75° off of the central longitudinal axis 124, and most preferably, second angled fastener hole 130 is positioned at about 55° off of the central longitudinal axis 124.

In addition to its angled orientation with respect to central longitudinal axis 124, second angled fastener hole 130 may also be rotated at an angle off of plane 125. For example, angled fastener hole 130 may be rotated about 0-45° off of plane 125, as shown in Figure 6. In one embodiment, angled fastener hole 130 is rotated about 2-30° off of plane 125. In a further embodiment, it is rotated about 5-15 ° off of plane 125, and is most preferably, about 10° off of plane 125. (Again, this angle may also be in either the medial or the lateral direction. It is preferred, although not required, that angled fastener hole 122 be about 10° in the opposite direction of angled fastener hole 130.)

In certain embodiments, second angled fastener hole 130 is adapted to receive a fastener that targets the talus 14 in use, or that at least partially traverses the talo-calcaneal articulating surface 40, as shown in Figure 3.

There may be provided a third fastener hole 132, which also has internal threads 128, but that may or may not be provided at an angle. Consider nail 112 with a horizontal axis 127 that is perpendicular to the central longitudinal axis 124 and that defines a horizontal plane perpendicular to plane 125 (i.e., extending out from the page). Figure 5 shows the nail of Figure 4 cut through a plane that extends perpendicular to plane 125 and then rotated 90° to illustrate the threaded bore of fastener hole 132.

In one embodiment, fastener hole 132 is disposed through distal portion 114 of nail 112 in the horizontal plane, give or take a few degrees. When fastener 150 is inserted through fastener hole 132, the fastener creates an axis that forms an angle of between about 80° - 100°, and preferably about 90° with the central longitudinal axis 124, as shown in Figure 3. In certain embodiments, the third fastener hole 132 is a transverse fastener that targets the calcaneus 12.

In use, a surgeon may choose to use one or more of threaded holes 122, 130, 132, or any combination thereof. For example, a surgeon may only need to use hole 122. In other cases, for example, if more stability is needed, the surgeon will also use 130 and/or hole 132. Alternatively, a surgeon may only use hole 132, but again, may use additional holes for additional stability.

Fasteners 150 may be provided in any number of lengths, although it is preferable that at least one fastener be provided in a length that allows it to cross one of more of articulating surfaces 40 and 42. Exemplary fastener lengths may be between 50 to 110 mm.

There may also be one or more static locking holes 136 or a dynamic compression slots 137 at the proximal portion 116 of nail 112. These openings 136, 137 are provided for rotational stability of assembly 110 and are typically not threaded or angled, although they can be angled and / or threaded as desired. Although the present inventors believe that it would not be good surgical practice to fix the fasteners to the holes in the proximal portion of nail 112 by threads because the nail 112 should not be overconstrained, it is understood that there could be instances when such fixation would be desired, and threaded upper holes are considered within the scope of this invention.

The surgeon may choose between static or dynamic locking by placing a fastener, pin, or small nail through either a static hole 136 or dynamic slot 137 and into the tibia 30. It is preferred that one of each opening 136, 137 be provided in order to give the surgeon the most flexibility, although this is not required.

Method:

A surgeon first chooses the properly-sized nail 112. (Nails are typically provided in 10-50 cm lengths.) The choice is based on the length of the ankle from the bottom of the calcaneus to a suitable fixation point on the tibia. In essence, the goal is to fuse the nail 112 with the calcaneus 12 and the tibia 30 to immobilize the ankle joint. Typically, the surgeon will remove cartilage from the ankle to encourage the bones to fuse.

Although the surgery may be performed as a closed procedure (i.e., minimally invasive) and it is often preferable for it to be that way due to ease of healing, some surgeons may also wish to remove cartilage from between the bones prior to the procedure, which is often performed using open surgical techniques. In short, embodiments of the invention lend themselves to use during ether type of procedure.

In one embodiment of the procedure, the surgeon makes an incision into the non-weight bearing part of the sole of the foot (i.e., the fatty tissue part of the heel) in line with the tibial planar axis. The surgeon may insert a guide wire into the tibial canal to assist reaming and the placement of nail 112. Once the canal has been reamed to an appropriate diameter and depth, the nail 112 is driven into the center (marrow) portion of the tibia 30, typically using one or more of the instrument-receiving portion 120 or the keyway 121 for securing the implant instrumentation. Preferably, the surgeon uses a C-arm or other image

intensifier to insert the nail 112 over a guide wire or rod in a closed surgical procedure as well as to insert the related fasteners.

Instrumentation may also be used to hold and guide drill bits to prepare other bones for receiving fasteners. Similar instrumentation may be used to hold and place a fastener. The fastener can be rotated into place, hammered, or otherwise inserted as desired. In some instances, guide wires may be used to place the fastener as well.

If the surgeon plans to aid the fusion process by inserting a fastener that will cross the calcaneo-cuboid articulating surface 42, the surgeon will insert the fastener through the posterior aspect of the calcaneus, through the opening in the nail, and into the cuboid to target that junction. In the embodiment shown, the surgeon would place fastener 150 into the most inferior angled fastener hole 122. The threads of fastener 150 cooperate with internal threads 128, as well as achieve purchase into the calcaneus 12 and cuboid 18. Alternatively, a compression screw, a pin, an at least partially threaded screw, or other embodiments may be used. In any event, this fastener will typically have a relatively "shallow" angle, being inserted at the calcaneus and at least partially crossing the calcaneo-cuboid articulating surface 42.

Once the first fastener is inserted, the surgeon may gently tap the driving end 118 of the nail 112 to achieve compression of the ankle. If the surgeon plans to place a transverse fastener (in this case, a fastener that will cooperate with the calcaneus 12), the fastener may be inserted through third fastener hole 132 in either the medial to lateral or lateral to medial direction. Even though this fastener is not necessarily strictly horizontal, it tends to be the most horizontally-located of the fasteners.

Next, if the surgeon plans to aid the fusion process by inserting a fastener that will cross the talo-calcaneal articulating surface 40, the surgeon will insert a fastener into the posterior of the calcaneus, through an opening of the nail, and into the talus to target that junction. In the embodiment shown, the surgeon would place fastener 150 into the superior angled fastener hole 130. The threads of fastener 150 will cooperate with internal threads 128, as well as achieve purchase into the calcaneus 12 and talus 14. Alternatively, a compression screw, a pin, an at least partially threaded screw, or other embodiments may be used. In any event, this fastener tends to be the most steeply angled of the three (assuming that all three fasteners are used). Assuming the patient's foot is standing on a horizontal surface, this fastener will have a relatively steep "upward" angle to at least partially cross the talo-calcaneal articulating surface 40.

This procedure has been described as if the surgeon is using three fasteners, although it should be understood that a surgeon may choose to use fewer or more fasteners and that nails according to structures of this invention may also have fewer or more fastener-receiving bores.

After the nail and junction fasteners have been properly placed in the patient's foot, the surgeon will secure the nail 112 with a fastener at the proximal portion 116 of the nail 112. The surgeon may choose between static or dynamic locking by placing the fastener through either a static hole 136 or a dynamic slot 137 in nail 112.

Changes and modifications, additions and deletions may be made to the structures and methods recited above and shown in the drawings without departing from the scope or spirit of the invention and the following claims.

What is claimed is:

1. A nail for a hindfoot implant assembly, comprising a proximal portion, a distal portion, and a central longitudinal axis, characterised in that the distal portion comprises a fastener-receiving hole that is at least partially threaded.

2. An implant assembly for a hindfoot, comprising: a nail according to claim 1; and a fastener adapted to be received by the nail.

3. An implant assembly according to claim 2, wherein the fastener has corresponding structures adapted to be received in the at least partially threaded fastener-receiving hole.

4. The nail of claim 1, wherein the at least partially threaded fastener-receiving hole has an axis disposed at an angle off of the central longitudinal axis.

5. The nail of claim 4, wherein the axis of the at least partially threaded fastener-receiving hole is provided at an angle between about 45° and about 135° off of the central longitudinal axis.

6. The nail of claim 4, wherein the axis of at the least partially threaded fastener-receiving hole is provided at an angle between about 80° and about 90° off of the central longitudinal axis.

7. The nail of claim 4, wherein the axis of the at least partially threaded fastener-receiving hole is provided at an angle between about 50° and about 75° off of the central longitudinal axis.

8. The nail of claim 1, wherein the nail comprises at least two at least partially threaded fastener-receiving holes, each having an axis, wherein the axes of the at least two holes are provided at differing angles off of the central longitudinal axis, such that the assembly is adapted to provide multi-axial fixation.

9. The nail of claim 1, wherein the central longitudinal axis defines a central plane, wherein the nail comprises at least two at least partially threaded fastener-receiving holes, and wherein the at least two holes are rotated at angles off of the central plane, such that the assembly is adapted to provide multi-planar fixation.

10. The nail of claim 1, wherein the central longitudinal axis defines a central plane, wherein the nail comprises at least two at least partially threaded fastener-receiving holes, each having an axis, wherein the axes of the at least two holes are (a) provided at differing angles off of the central longitudinal axis and (b) rotated at angles off of the central plane, such that the assembly is adapted to provide multi-axial and multi-planar fixation.

11. The nail of claim 10, further comprising a third at least partially threaded fastener-receiving hole having an axis that is substantially perpendicular to the central longitudinal axis.

12. The nail of claim 1, wherein the distal portion of the nail has first and second fastener-receiving bores; wherein the first fastener-receiving bore is disposed at an angle between about 65° and 115° off the central longitudinal axis; wherein the second fastener-receiving bore is disposed at an angle between about 45° and 135° off the central longitudinal axis; and wherein the fastener is adapted to be received in one of the first or the second fastener-receiving bores.

13. The nail of claim 12, wherein the central longitudinal axis defines a central plane, and the first and second fastener-receiving bores are angled at about 2-30° off of the central plane.

14. The nail of claim 12, further comprising a third fastener-receiving bore disposed at an angle of about 80-100° off of the central longitudinal axis.

15. The implant assembly for a hindfoot of claim 2, wherein the distal portion of the nail has at least two angled, threaded fastener-receiving holes that are disposed at angles off of the central axis; wherein the fastener is adapted to be received by the nail and

achieve at least partial purchase into a patient's calcaneus and cuboid bones; and further comprising a second fastener adapted to be received by the nail and achieve at least partial purchase into a patient's calcaneus and talus bones.

16. The implant assembly for a hindfoot of claim 2, wherein the assembly is adapted for use in stabilizing a patient's hindfoot by at least partially stabilizing the patient's calcaneo-cuboid and talo-calcaneal articulating surfaces.

17. The nail of claim 1, wherein the distal portion and the proximal portion each have a diameter, with the distal portion diameter being larger than the proximal portion diameter.

18. The nail of claim 1, further comprising one or more of a static locking hole and a dynamic compression slot at the proximal portion of the nail.

19. A method for at least partially fusing a patient's calcaneo-cuboid articulating surface, talo-calcaneal articulating surface, or both, in a hindfoot fusion process, comprising:

(a) providing a nail having a proximal portion and a distal portion, the distal portion having at least one angled fastener-receiving hole;

(b) providing at least one fastener adapted to be received in the angled fastener-receiving hole;

(c) implanting the nail into a patient's tibial canal;

(d) inserting the fastener through the angled fastener-receiving hole in the nail, such that the fastener at least partially crosses one or more of (a) the patient's calcaneo-cuboid articulating surface, (b) the talo-calcaneal articulating surface, or (c) both, and at least partially fuses the articulating surface therebetween.

20. The method of claim 19, wherein the fastener-receiving hole is at least partially threaded.

21 The method of claim 19, wherein the nail has a central longitudinal axis and the fastener-receiving hole is provided at an angle offset from that axis.

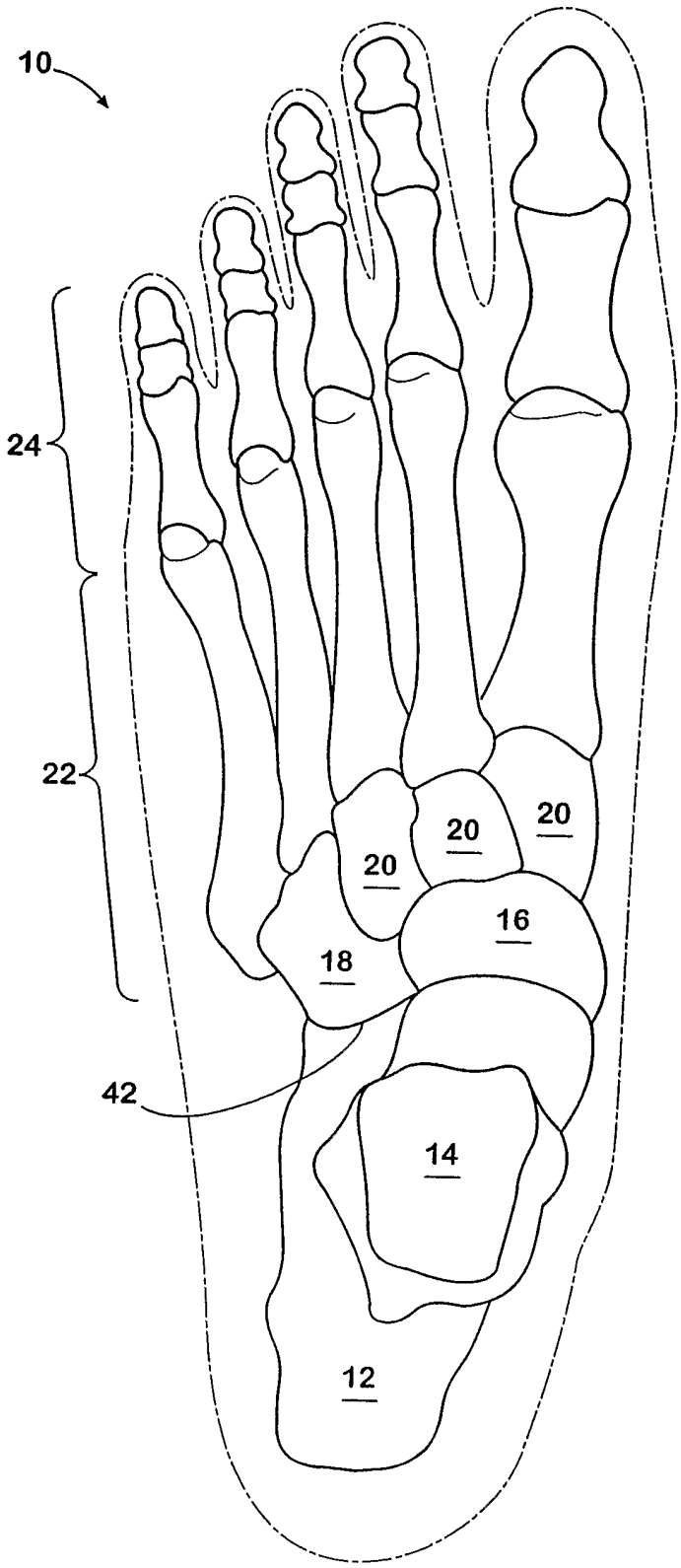



FIG 1

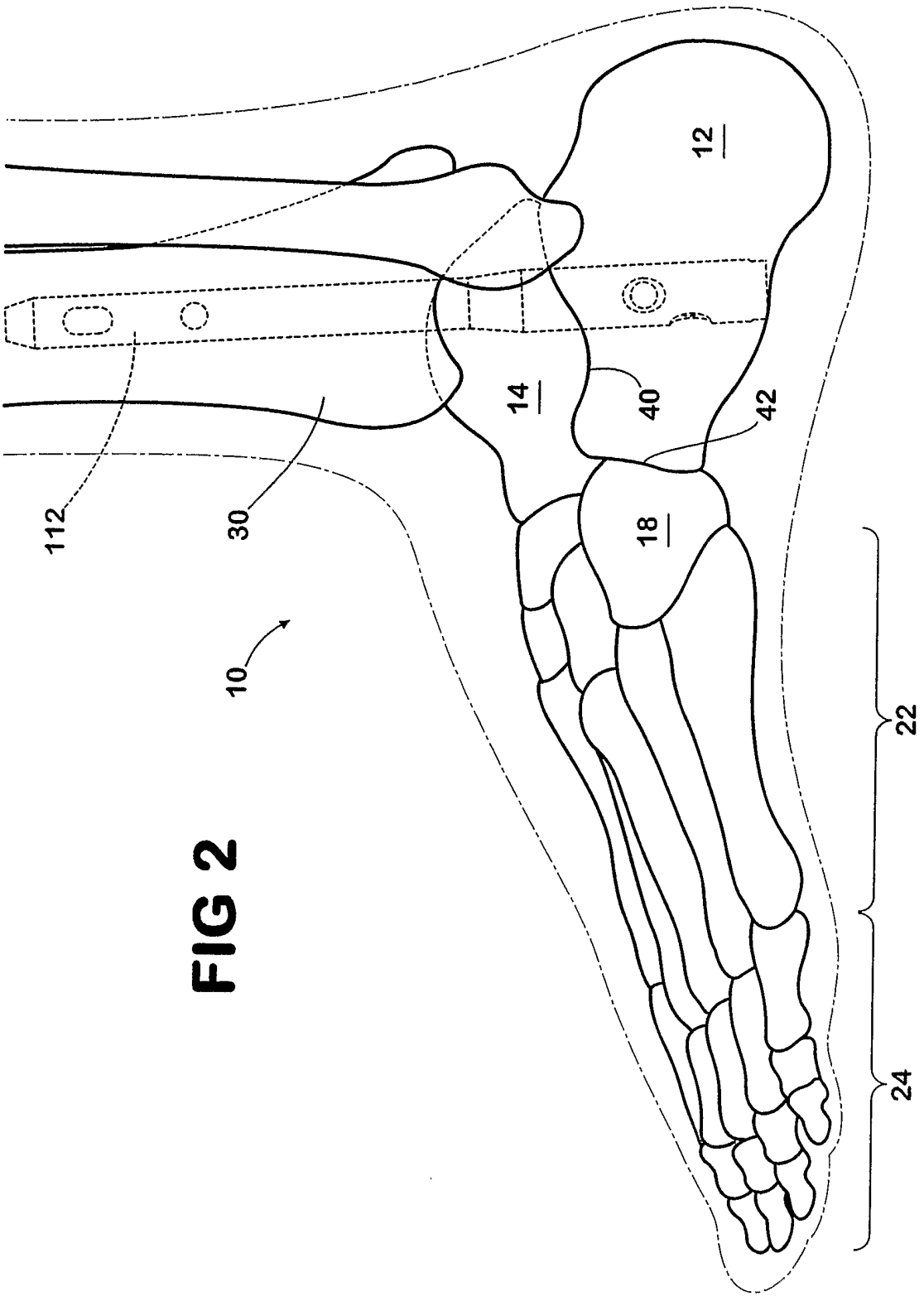



FIG 2

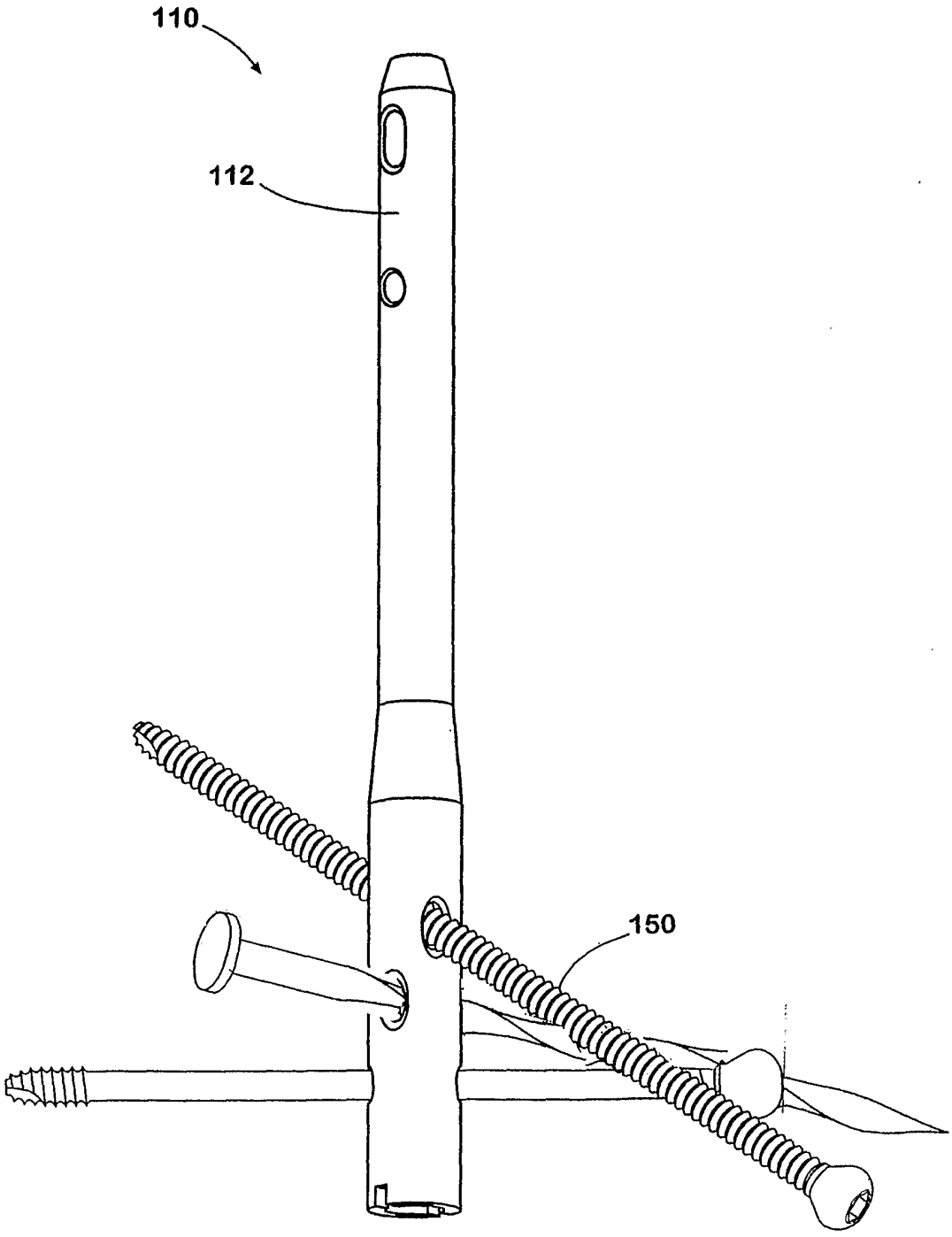



FIG 3

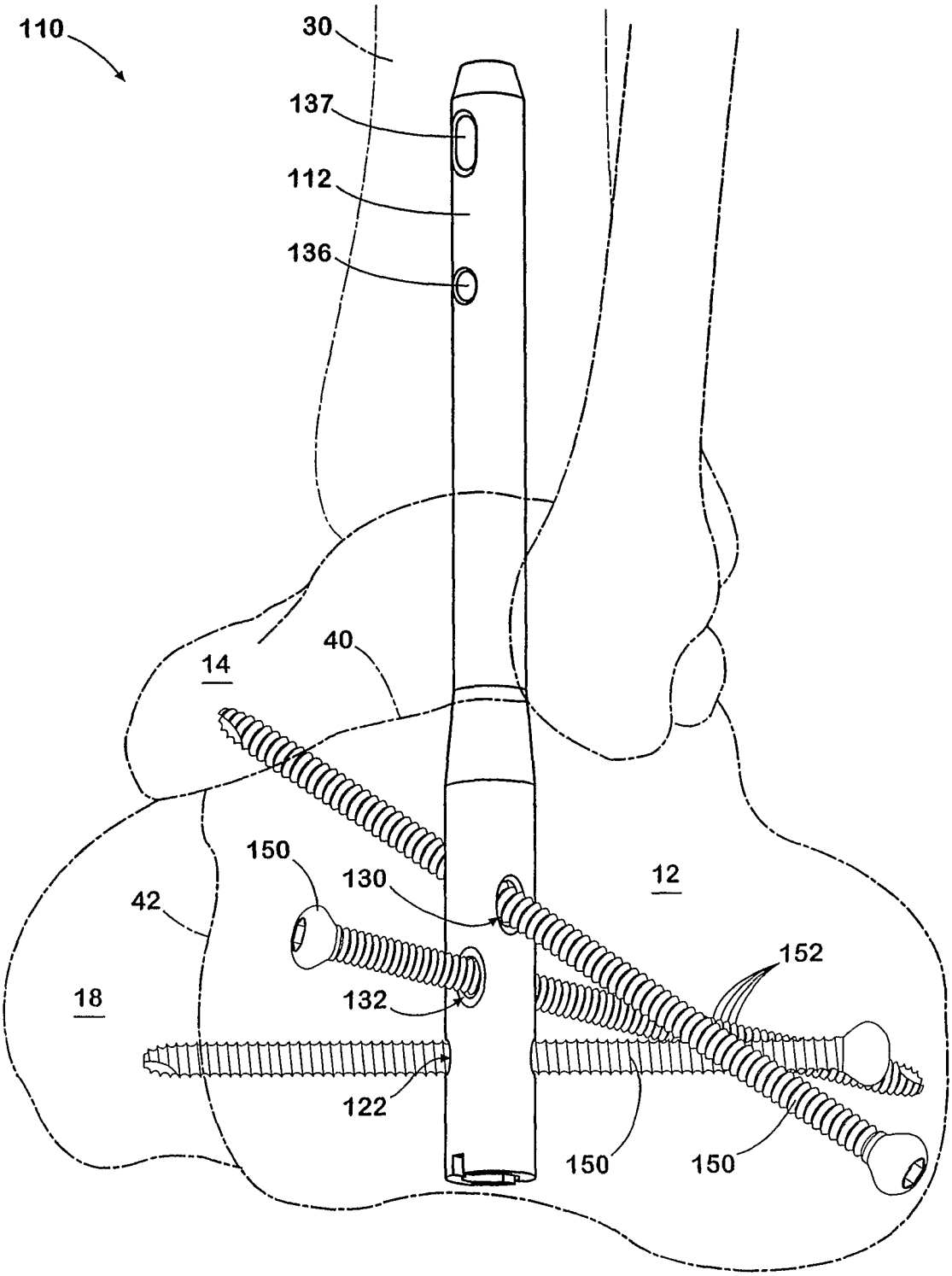



FIG 3A

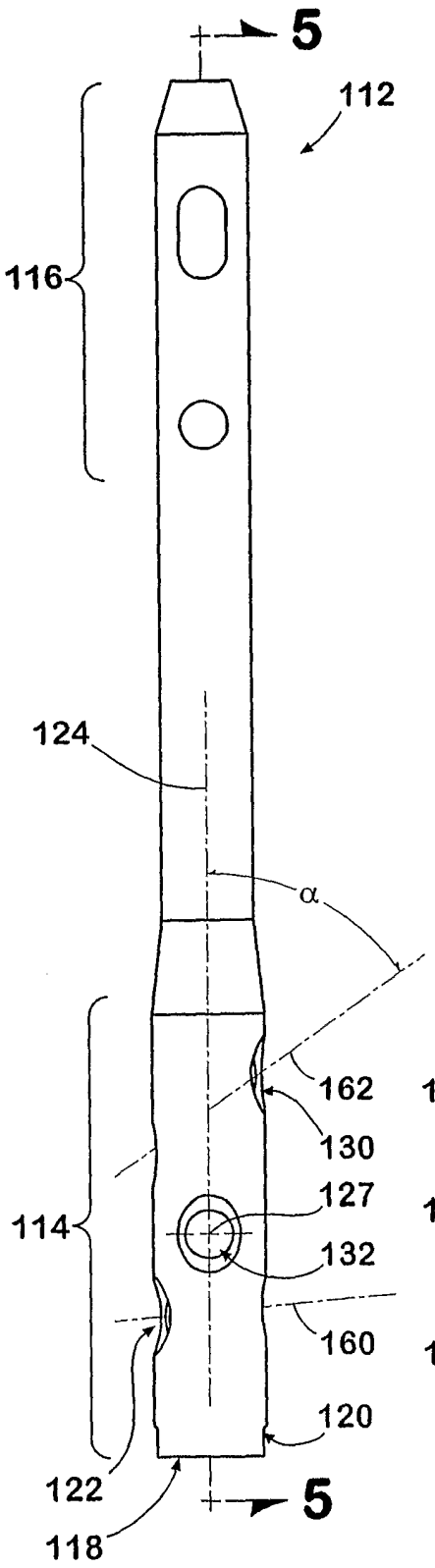



FIG 4

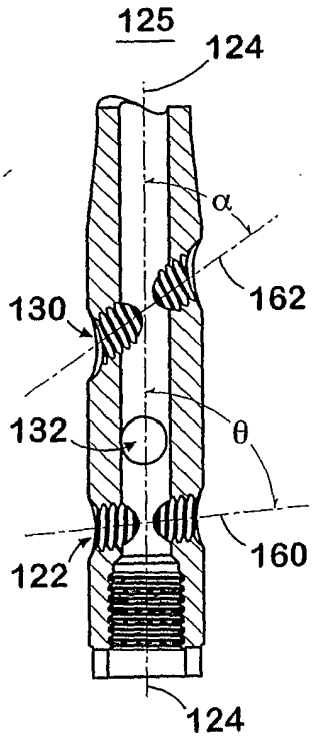



FIG 4A

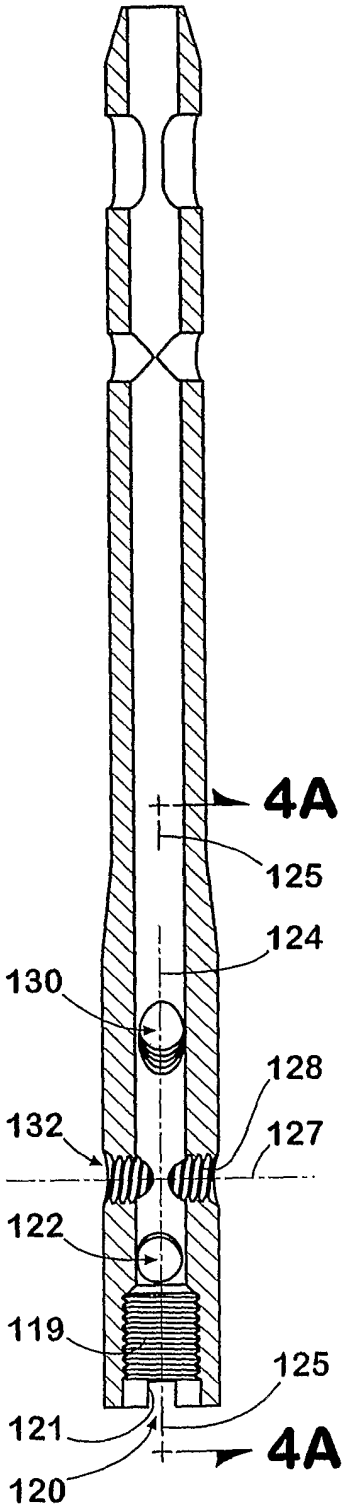



FIG 5

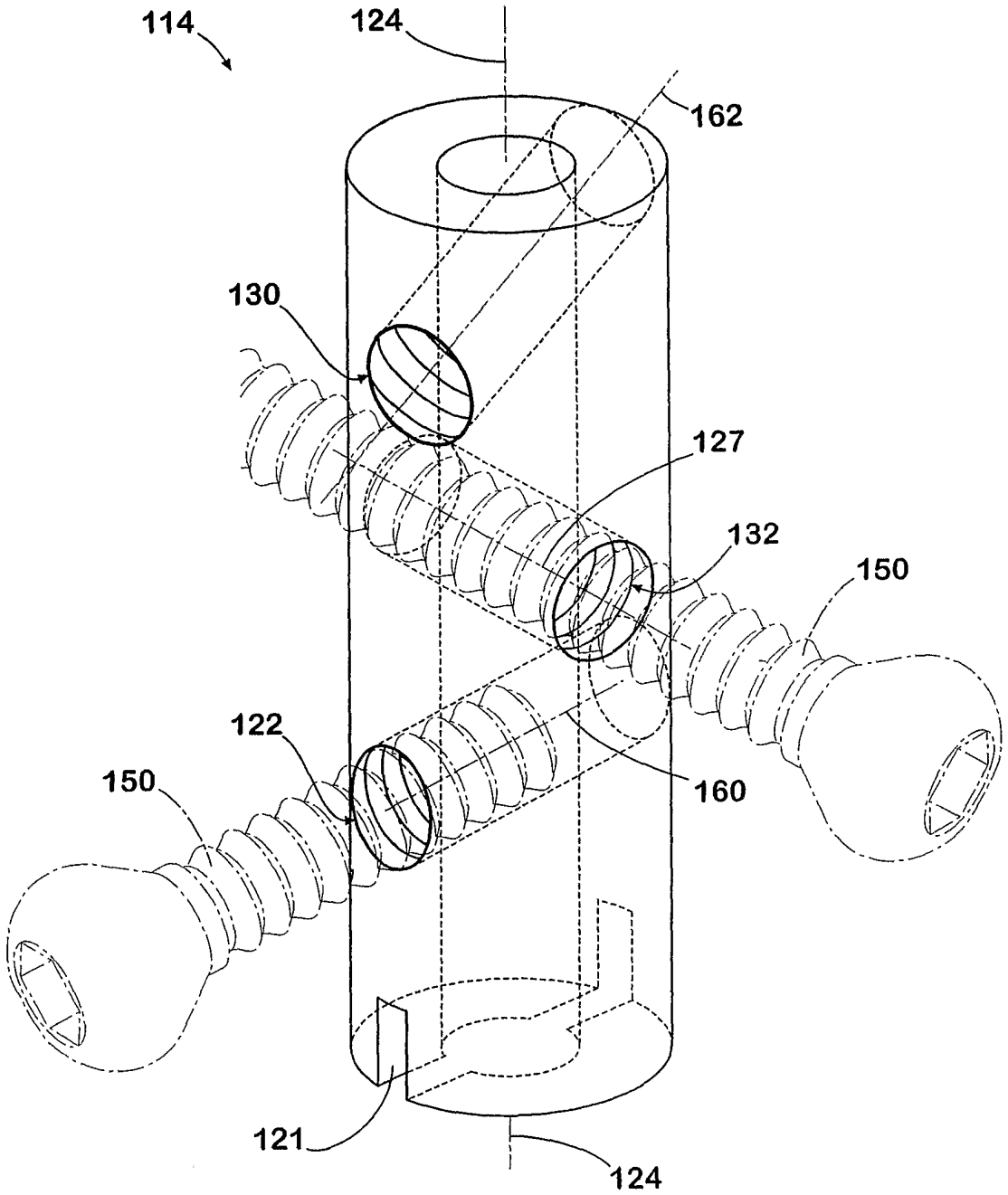



FIG 6

# INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/005396

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/76

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 6 579 293 B1 (CHANDRAN R.E.)<br>17 June 2003 (2003-06-17) | 1-14,18 |
| Y | column 3, line 66 - column 4, line 13<br>column 5, line 39 - line 64<br>column 6, line 31 - line 46<br>figures 2,3 | 17 |
| Y | US 4 875 474 A (BORDER R.)<br>24 October 1989 (1989-10-24) | 17 |
| A | column 1, line 34 - line 61<br>column 2, line 3 - line 20<br>column 2, line 28 - line 33<br>column 5, line 25 - line 30<br>figures 1,10 | 18 |
| A | US 2003/097131 A1 (SCHON C.L. ET AL)<br>22 May 2003 (2003-05-22) | |

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 19 June 2006 | 27/06/2006 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Nice, P |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/005396

## Box 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. [X] Claims Nos.: 19-21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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 III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required 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 an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/005396

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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