US007785326B2

(12) **United States Patent**
Green et al.

(10) **Patent No.: US 7,785,326 B2**
(45) **Date of Patent: Aug. 31, 2010**

(54) **SYSTEM FOR INTRAMEDULLARY ROD FIXATION AND METHOD THEREFOR**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1254 days.

(21) Appl. No.: **11/250,498**

(22) Filed: **Oct. 14, 2005**

(65) **Prior Publication Data**

US 2007/0100342 A1 May 3, 2007

(51) **Int. Cl.**
A61B 17/56 (2006.01)

(52) **U.S. Cl.** **606/64**; 606/62; 606/304

(58) **Field of Classification Search** 606/62–68, 606/300, 304, 309, 314, 318, 87, 96, 98, 606/104; 411/383, 393, 395, 315
See application file for complete search history.

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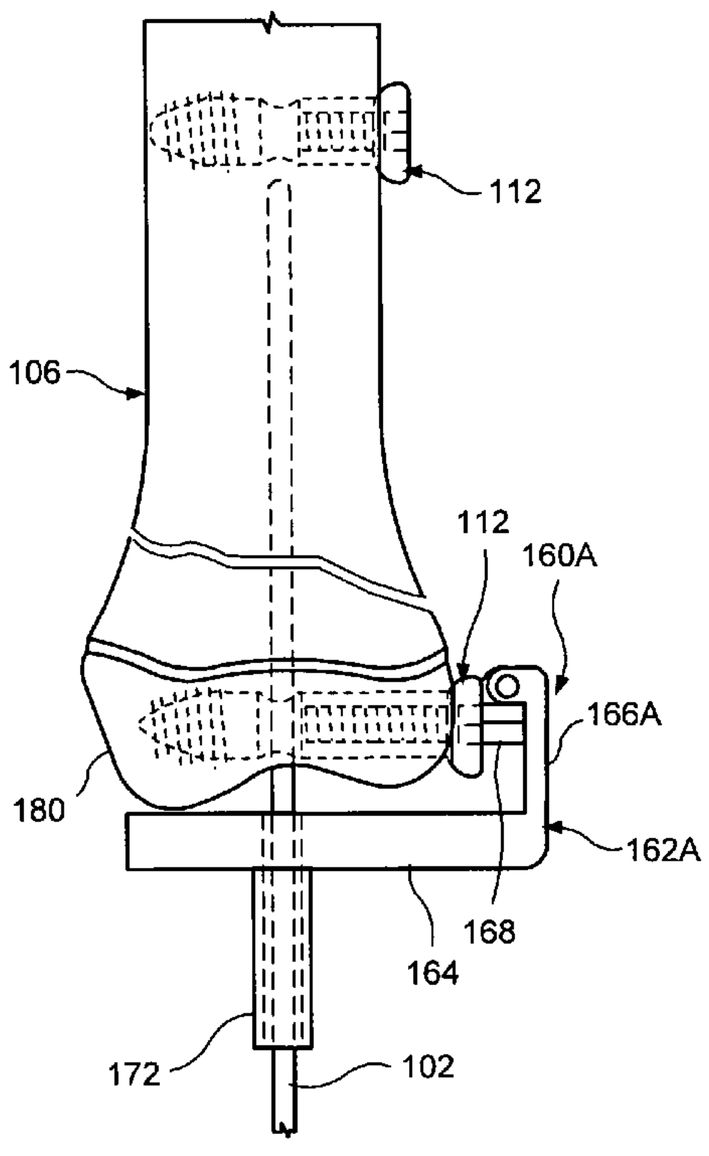
(57) **ABSTRACT**

A system and method for securing an intramedullary rod in a medullary canal of a long bone is provided. The system includes an intramedullary rod and a screw assembly for receiving the rod. The screw assembly has a transverse receiving bore for receiving the intramedullary rod and a securing member movable toward the bore for securing the rod to the screw assembly. An alignment jig may also be provided for aligning the rod with the receiving bore during installation.

5 Claims, 8 Drawing Sheets



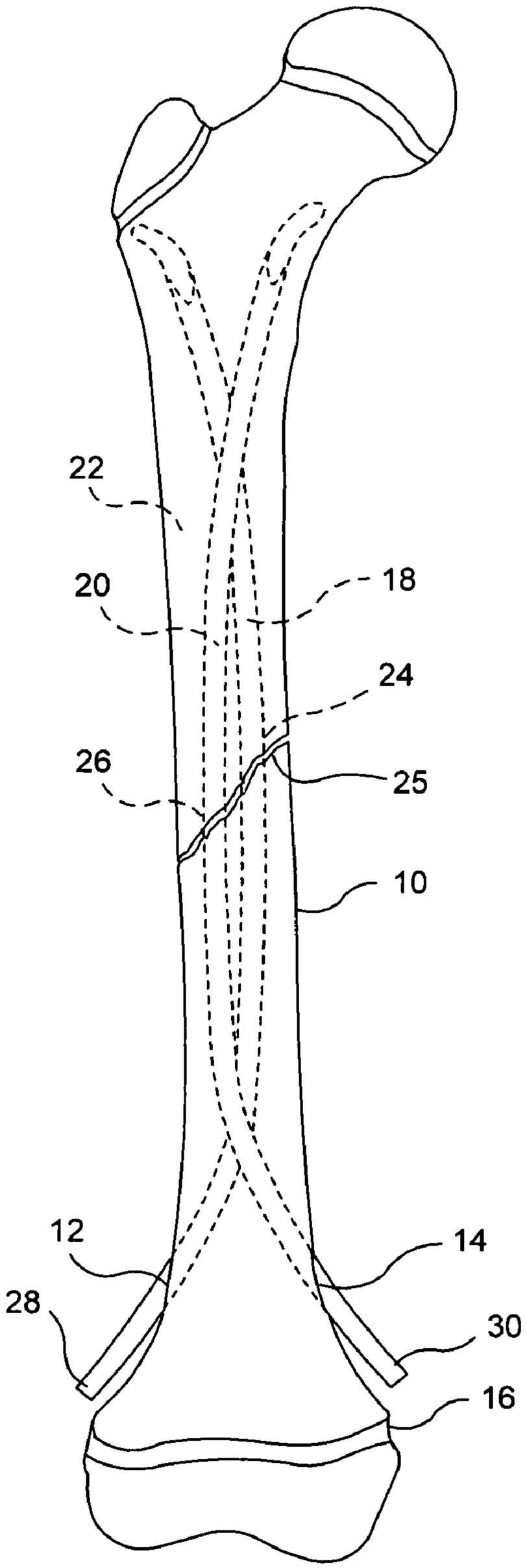


FIG. 1
PRIOR ART

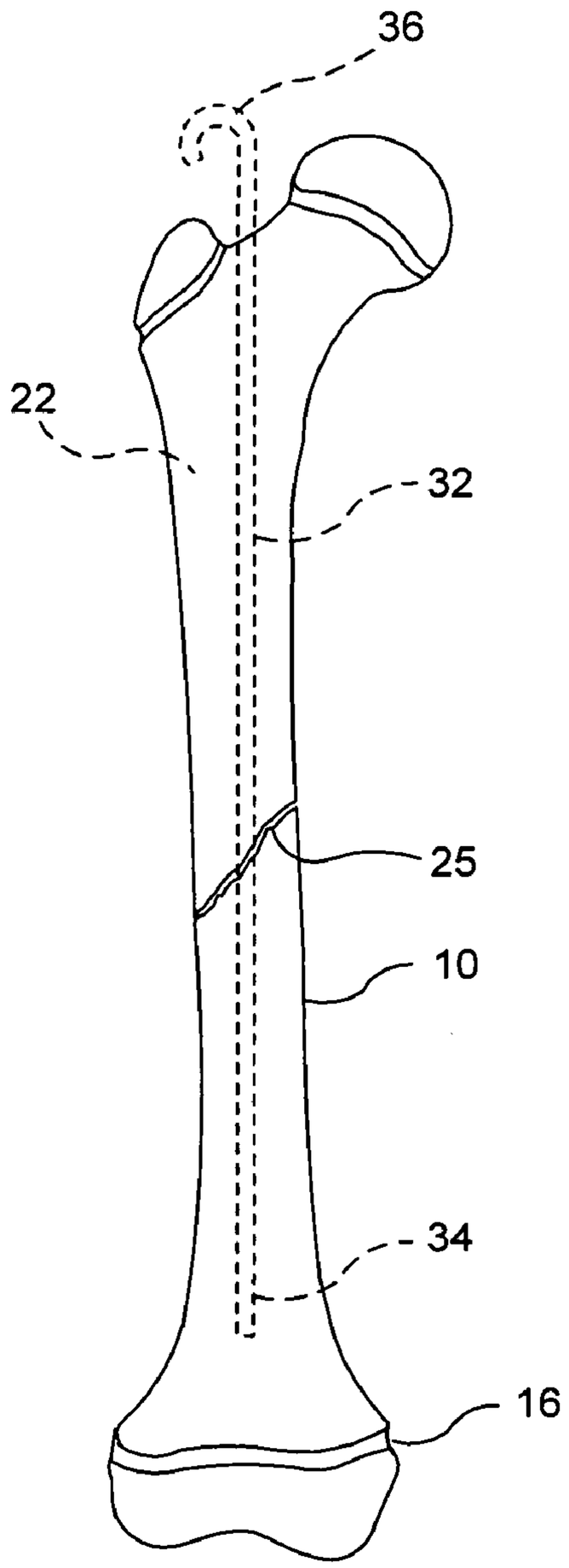


FIG. 2
PRIOR ART

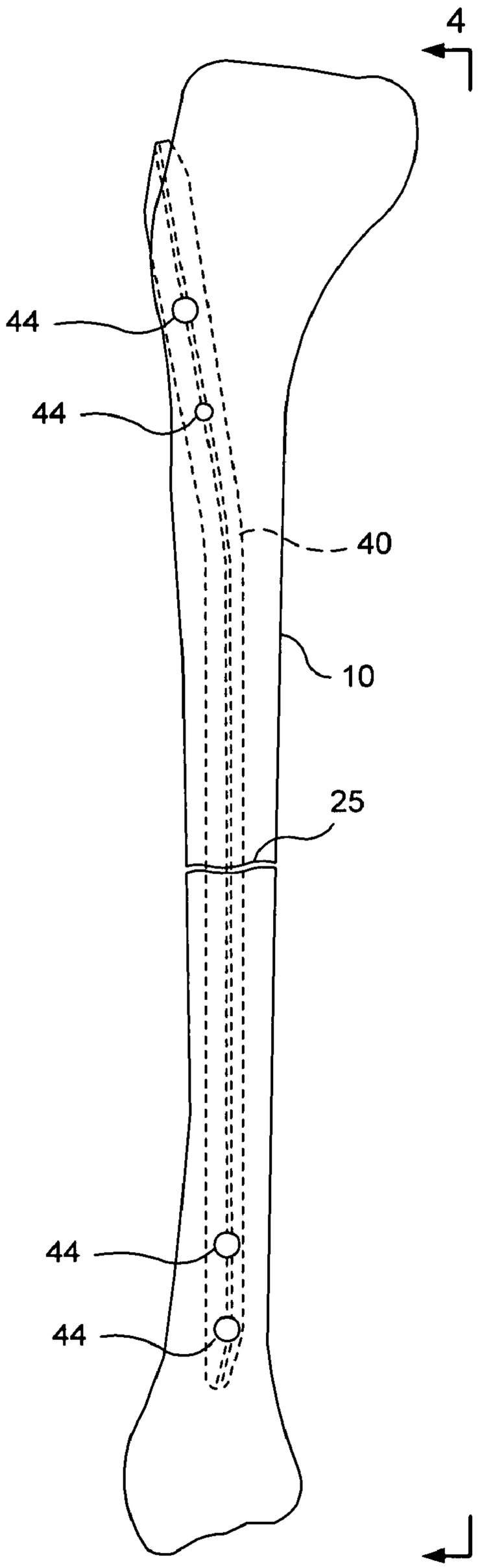


FIG. 3
PRIOR ART

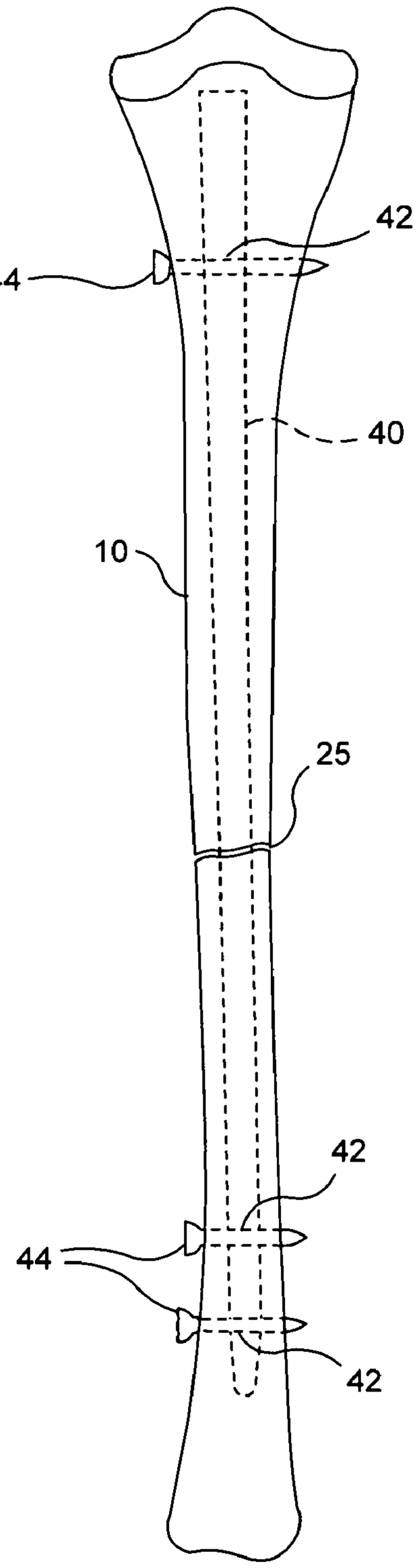


FIG. 4
PRIOR ART

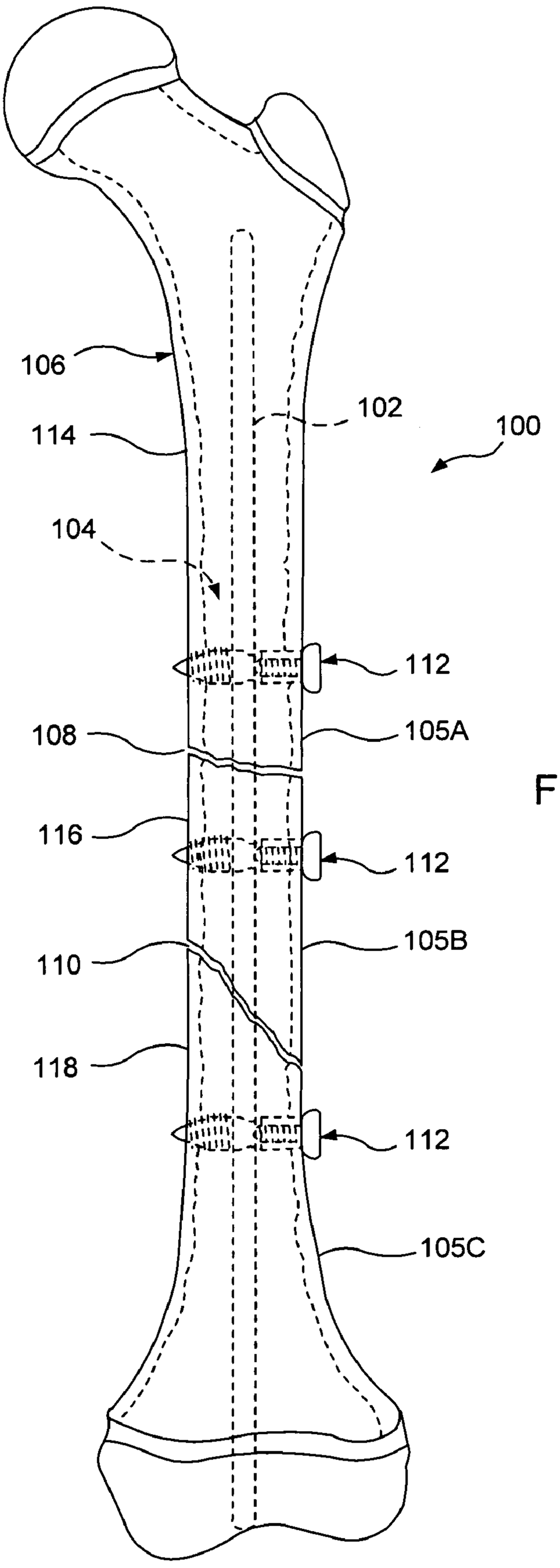


FIG. 5

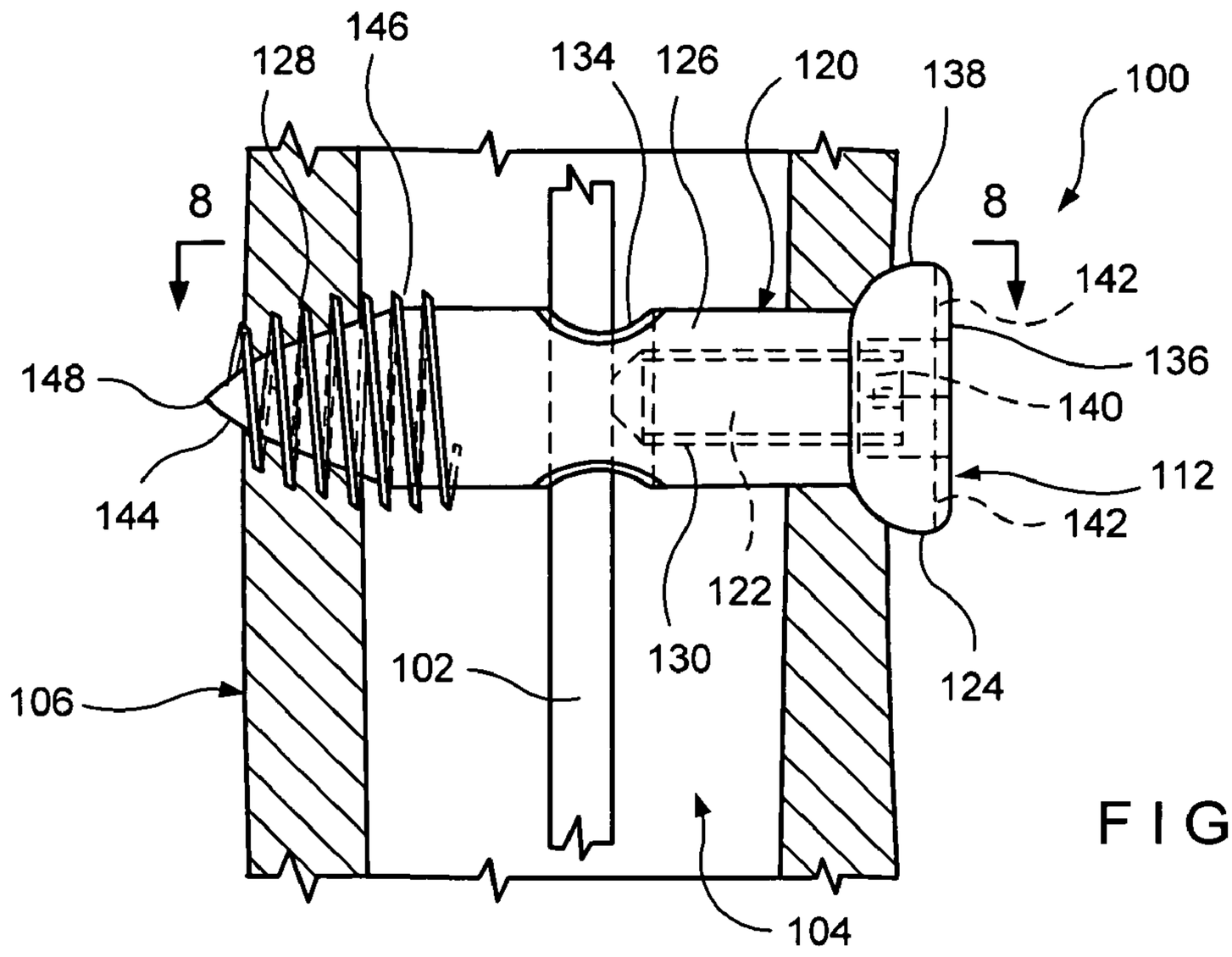


FIG. 6

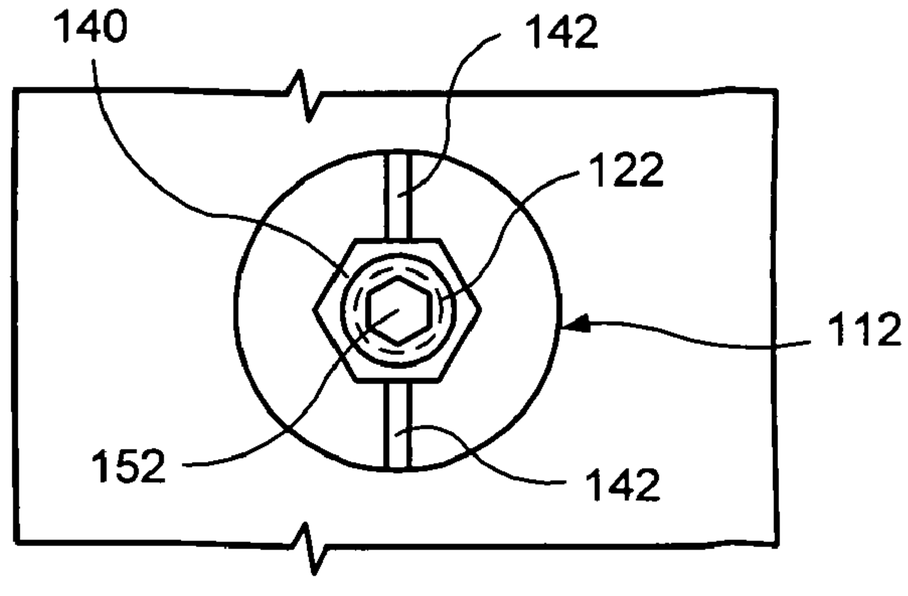


FIG. 7

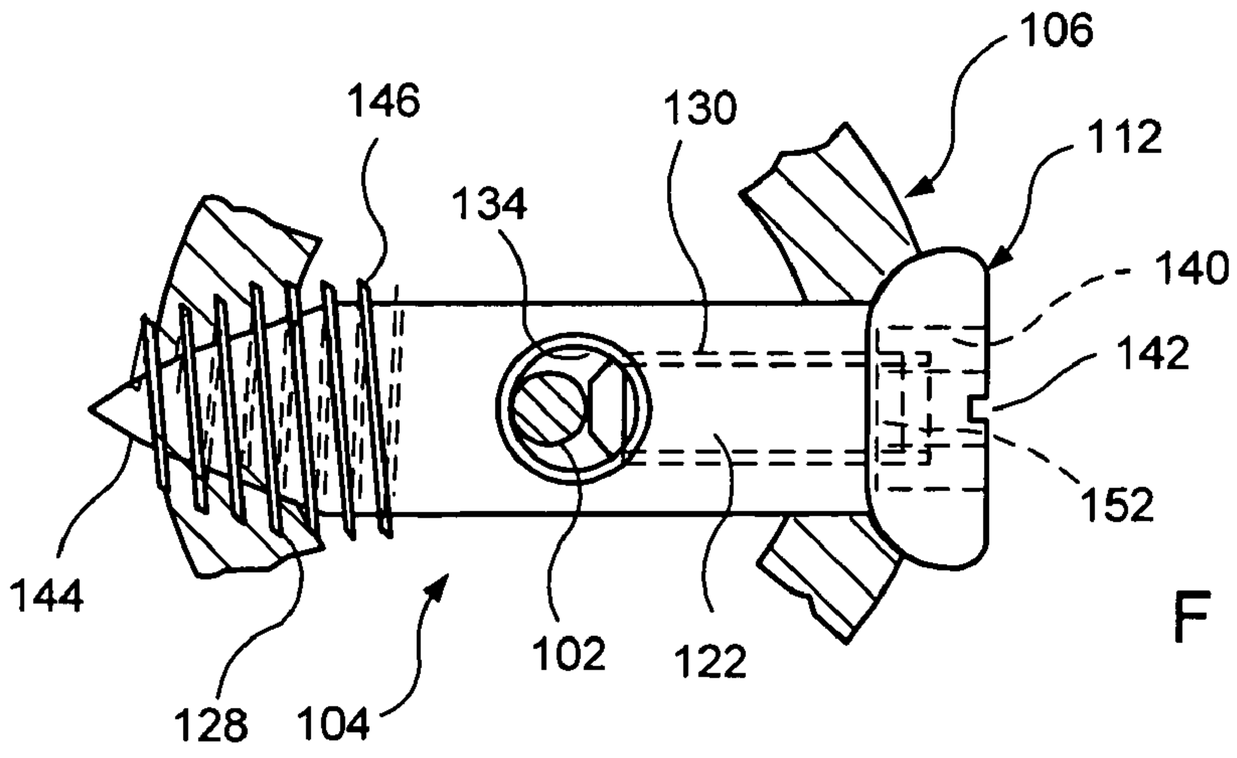


FIG. 8

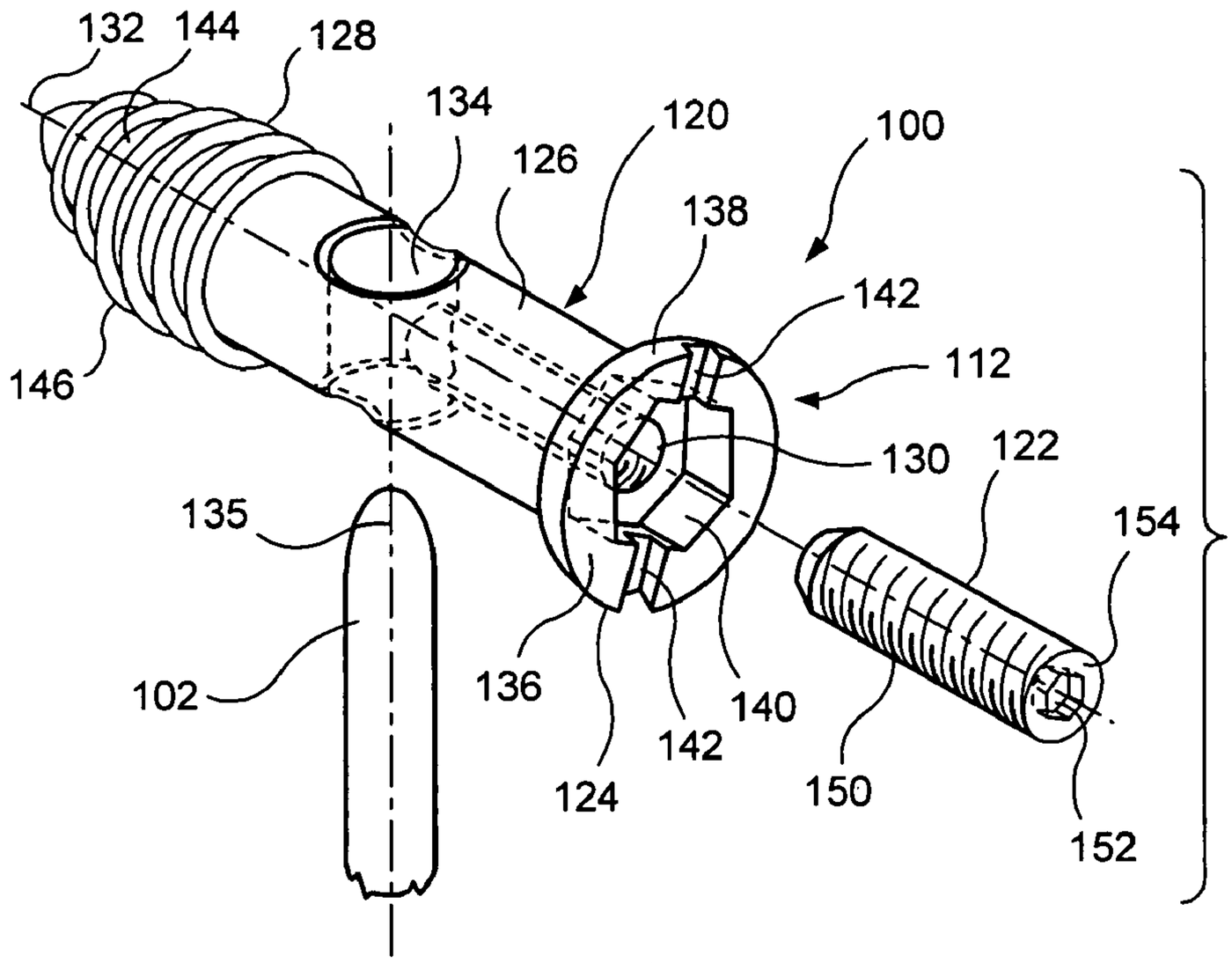

132
144
128
134
120
126
100
138
142
112
146
130
122
154
135
102
136
140
142
124
150
152

FIG. 9

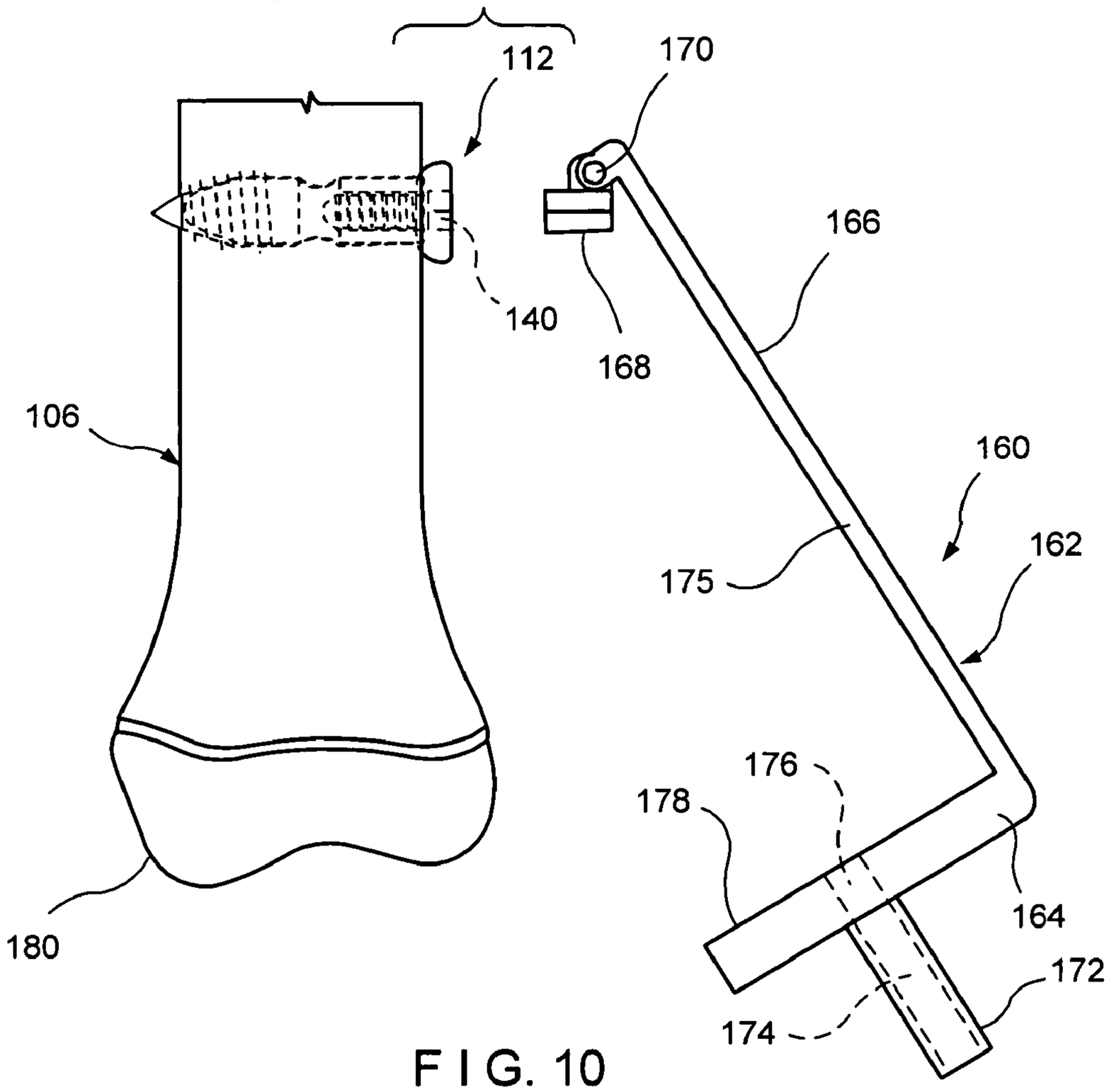

112
170
166
140
168
106
160
162
175
176
178
164
172
174
180

FIG. 10

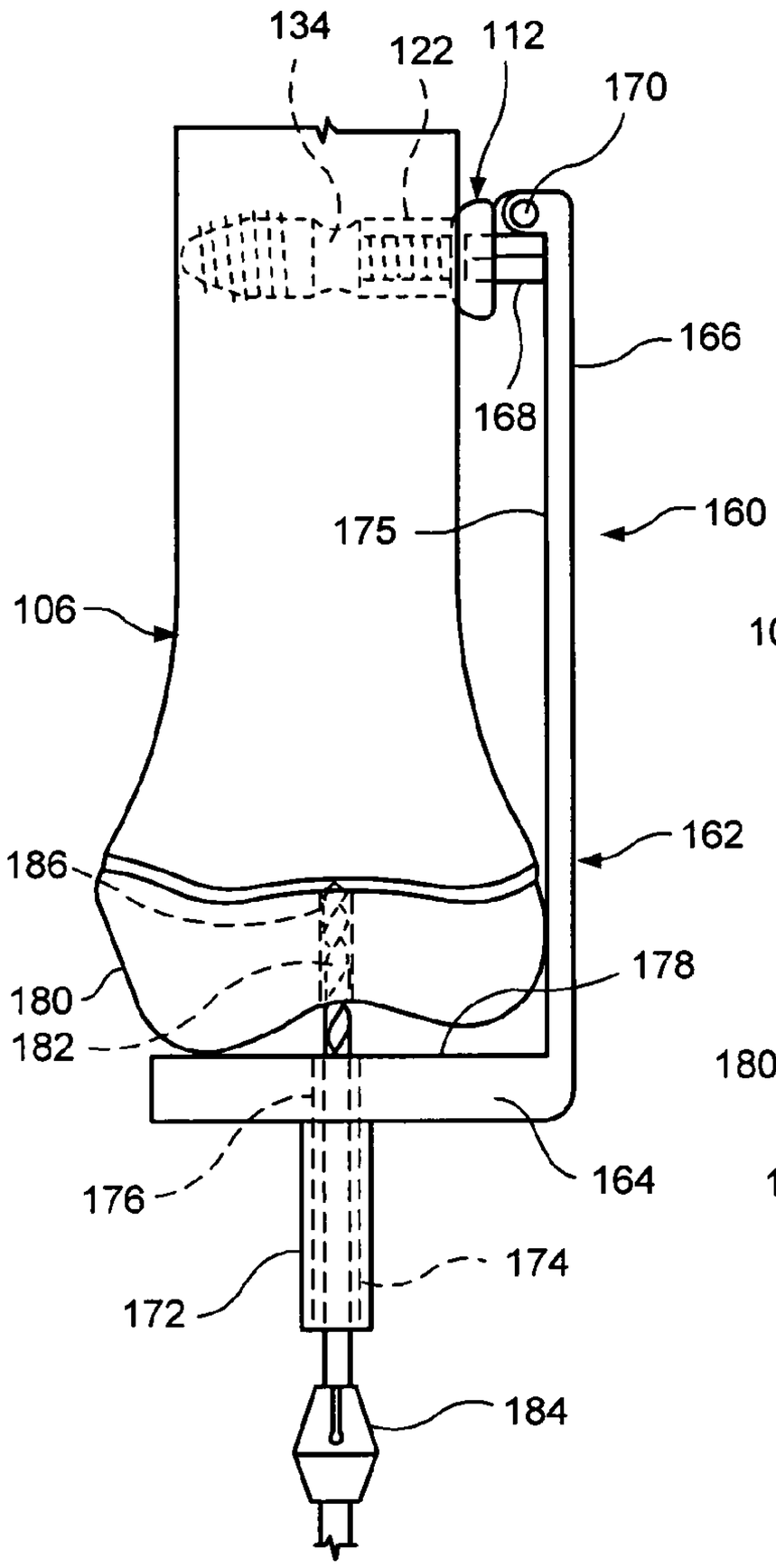
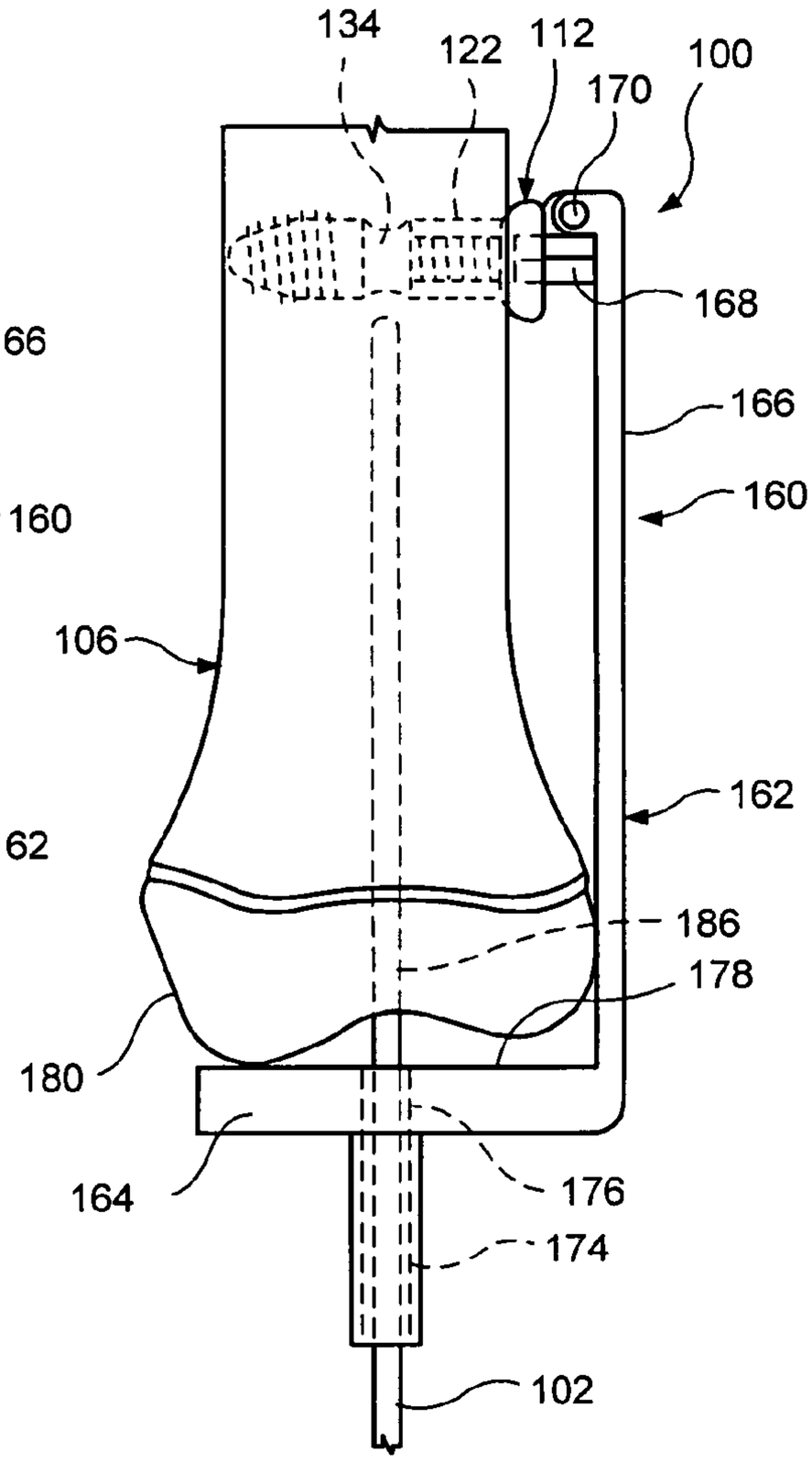

134
122
112
170
166
168
175
160
106
162
186
180
178
182
176
164
174
172
184

FIG. 11


134
122
112
170
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168
166
160
106
162
186
178
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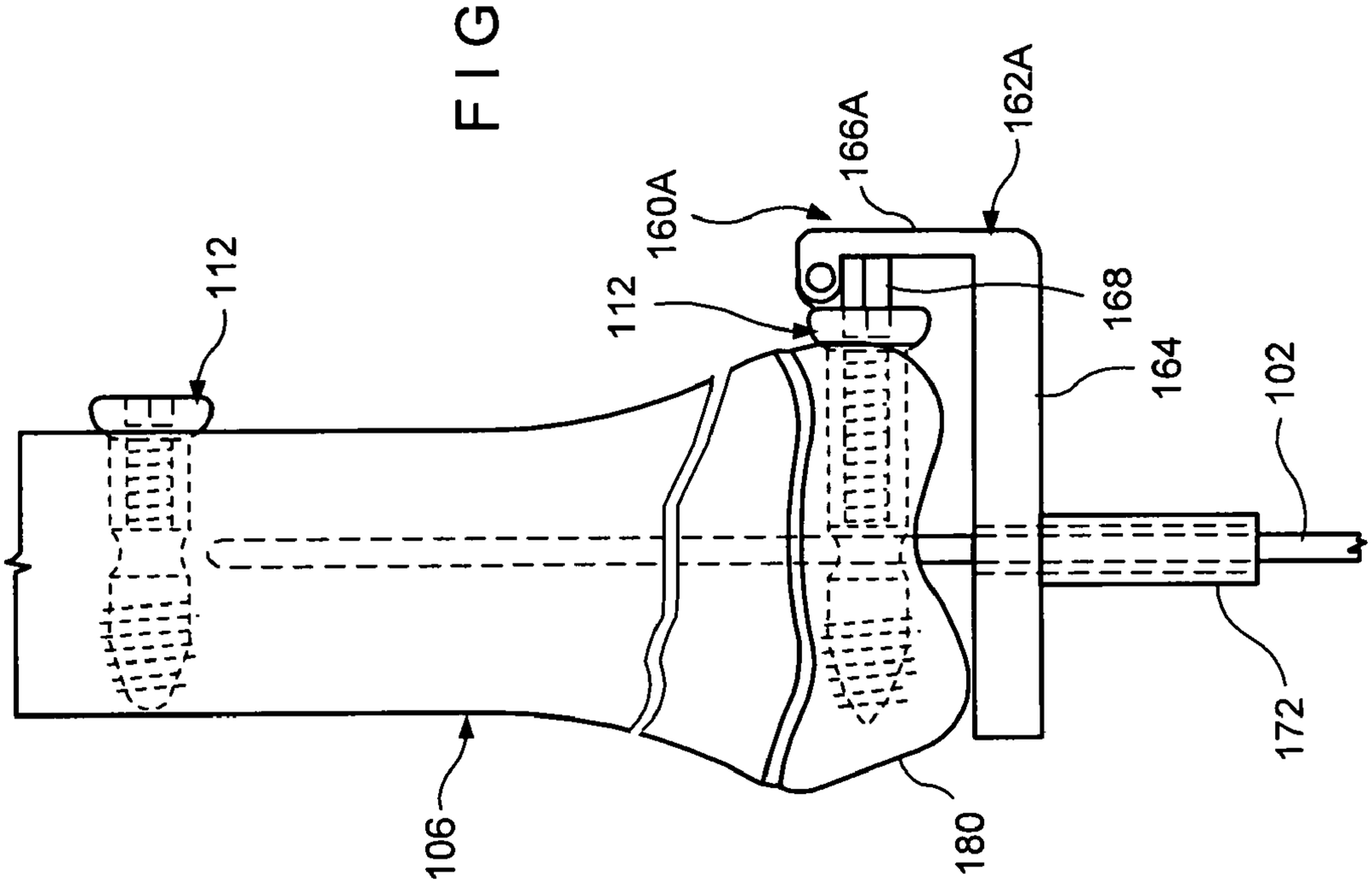
164
176
174
102

FIG. 12

FIG. 14


112
160A
166A
162A
112
168
164
102
172
106
180

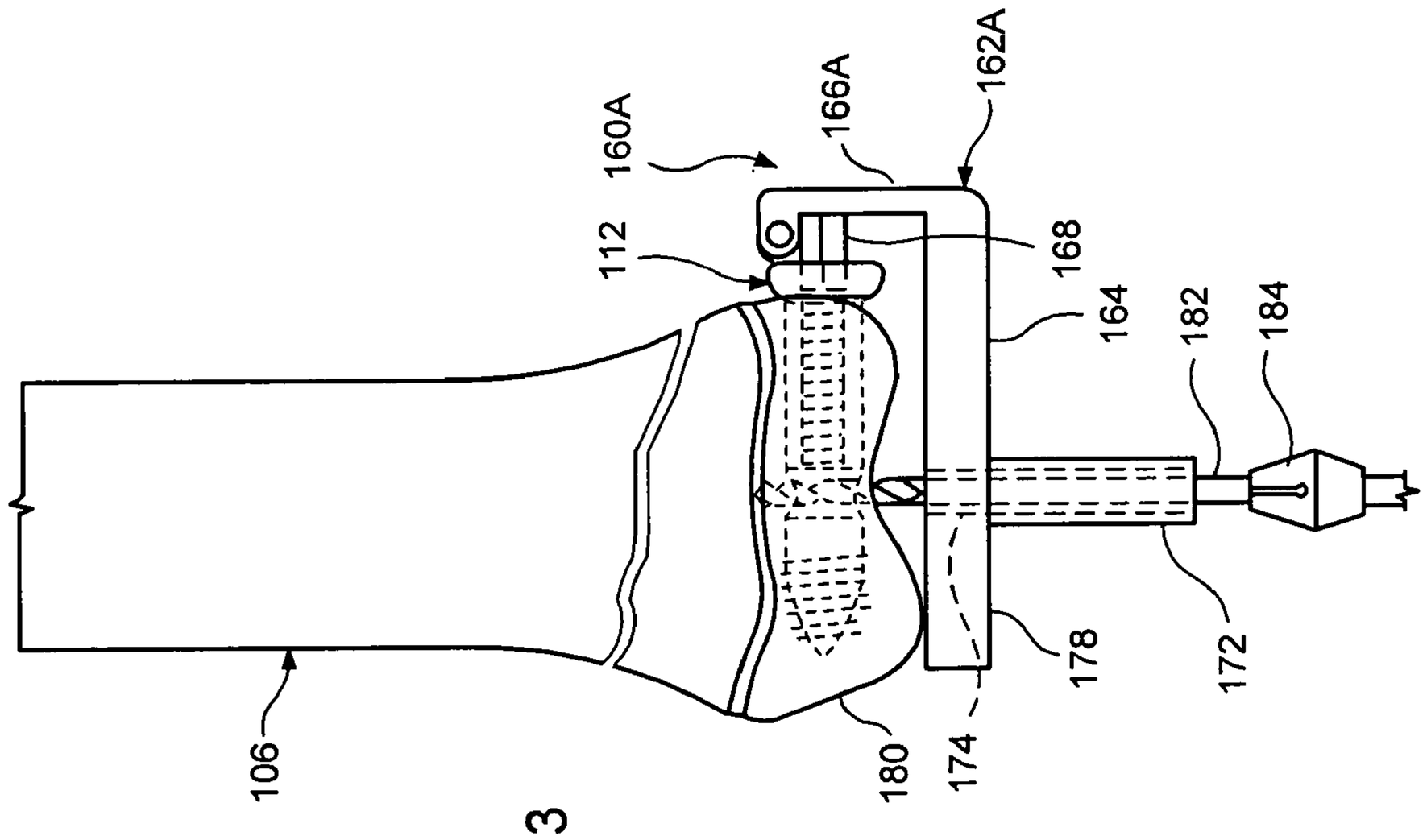

160A
166A
162A
112
168
164
182
184
178
172
106
180
174

FIG. 13

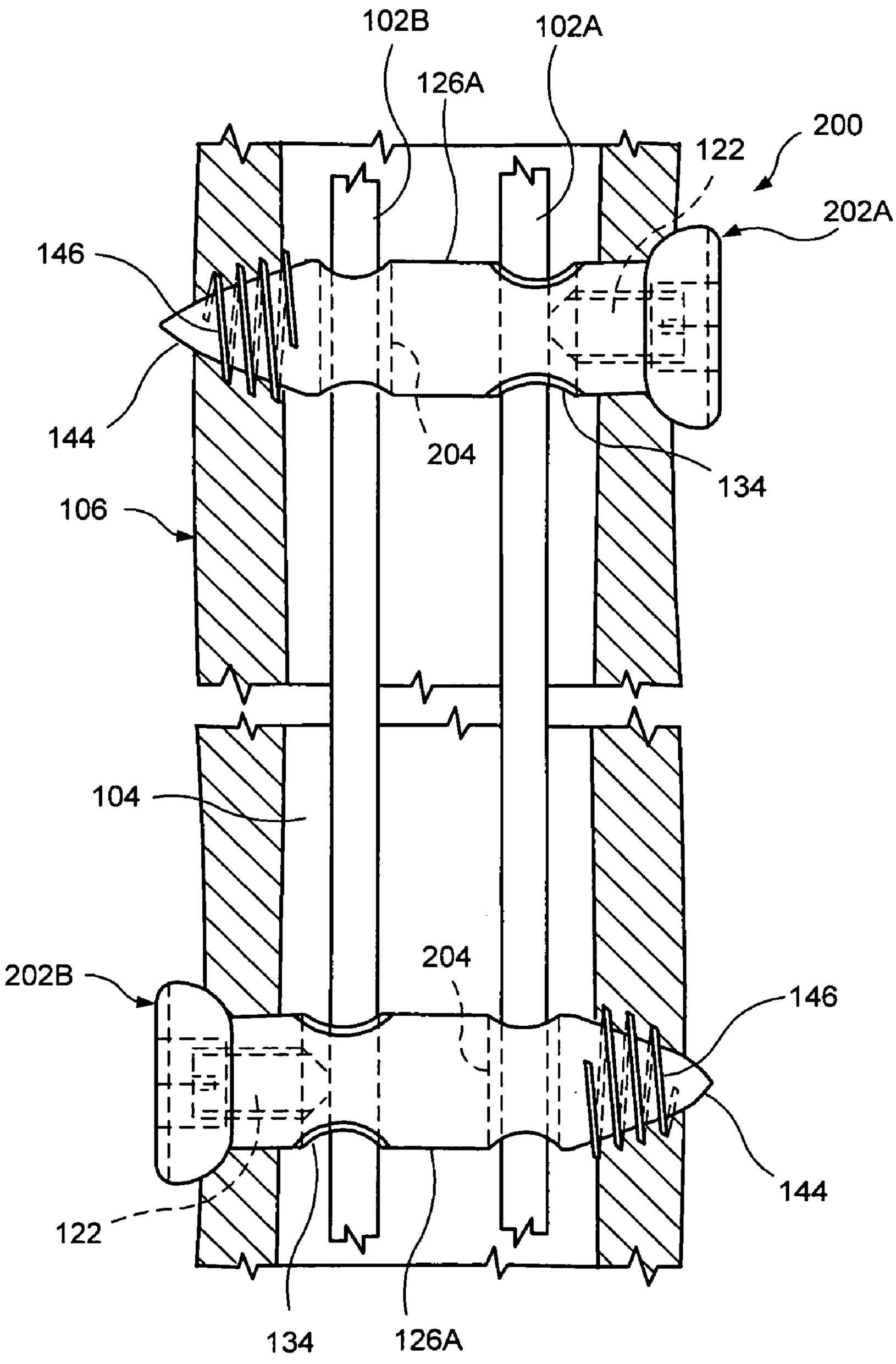

102B
102A
126A
200
122
202A
146
144
106
204
134
104
202B
204
146
144
122
134
126A

FIG. 15

SYSTEM FOR INTRAMEDULLARY ROD FIXATION AND METHOD THEREFOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to the treatment of bone fractures or abnormal bone conditions which require osteotomies, and more particularly to an intramedullary rod system for stabilizing bone segments.

2. Description of Prior Art

The fracture of certain bones, such as the femur, tibia, ulna, radius and humerous, requires substantial immobilization of the fractured bone sections in an abutting relationship during the healing process. Any longitudinal, transverse, or rotational movement of one fractured bone section relative to the other may cause a substantial delay in healing time or improper healing of the bone itself. In general, prior art provides various internal fixation approaches that have been used to immobilize the area surrounding the fracture site.

One approach involves driving metallic pins through the two sections of bone to be joined and connecting them to one or more plates bearing against the external surface of the bones. However, such an arrangement may cause injury to the surrounding outer layer and decrease blood supply and delay or inhibit bone healing. Plates also tend to shield the bone from stress and decrease the strength of the underlying bone.

Another approach for treating fractures involves the use of an intramedullary nail or rod which is inserted into the medullary canal of the bone, so as to be affixed therein. After complete healing of the bone at the fracture site, the rod may be removed through a hole drilled in the proximal or distal end of the bone.

A prior art flexible intramedullary nailing technique for affixing and mobilizing bone segments is illustrated in FIG. **1**. This technique includes drilling oblique lateral and medial openings **12**, **14** in the fractured bone **10** above the physis **16**, then inserting pre-bent flexible stainless steel or titanium nails **18** and **20** (shown in dashed line), which are typically 2-4 mm in diameter, into the bone interior or canal **22** through the openings in a retrograde manner. Prior to insertion, each nail **18**, **20** must be bent or curved such that their apexes **24**, **26** are at the level of the fracture **25**. Since the fracture may be oblique to a central axis of the bone as shown in FIG. **1**, the nails **18**, **20** may be bent at different locations. Using fluoroscopy to visualize rod progression and placement, the nails are advanced through the bone until they cross the fracture. The nails are then cut to length. Distal ends **28** and **30** of the nails are left extending slightly into the soft tissue surrounding the bone **10**.

Although flexible nails have been utilized by some doctors (primarily in pediatric patients with small diameter long bones), there are drawbacks to their use. For instance, the nails are not securely fixed within the intra medullary canal. Moreover, flexible nails lack the rotational stability of rigid nails and normally cannot be used in highly unstable or comminuted fractures.

FIG. **2** depicts another prior art solution that makes use of a flexible rod **32** (shown in dashed line). The rod **32** is inserted into the medullary canal **22** of the tibia **10**. The rod **32** is inserted manually as far as possible. An image intensifier is used to locate the distal end **34** of the rod. The proximal end **36** of the rod is then bent over in an attempt to anchor the rod to the bone area. The distal end **34** may be left unanchored to allow for growth of the bone, resulting in unpredictable positioning of the rod. Alternatively, the distal end **34** may also be bent over and fixedly attached to the distal end of the bone, but is nevertheless haphazard and imprecise.

FIGS. **3** and **4** show another prior art solution involving an unreamed tibial nail **40** (shown in dashed line). The nail **40** is inserted into the medullary canal **22** of the tibia **10**, medial to the patellar tendon and as superior as possible. The nail **40** includes a plurality of openings **42** for receiving screws **44**. Once in position, the location of the openings **42** are determined by fluoroscopy and the screws **44** are inserted transversely through the bone and openings **42** for anchoring the nail **40** in place. Although this type of system may be acceptable for bones having relatively large cross sections, it is difficult to implement in smaller bone structures due to size restraints. This is especially typical pediatric cases. For example, a typical nail may have a diameter in the range of 8-9 mm and the screws may have a thread diameter of approximately 4 mm in order to properly secure the nail to the bone. For pediatric situations or other cases where it may be impractical to insert a large diameter nail into a small bone, a suitable nail may have a diameter in the range of 2-4 mm and thus would require a screw with a substantially smaller thread diameter. However, forming a hole in the 2-4 mm nail would be quite difficult, and the provision of a substantially smaller screw to fit in the hole would not provide sufficient cross-pinning to isolate movement of the nail or to fix it in a desired position.

BRIEF SUMMARY OF THE INVENTION

According to one aspect of the invention, a screw assembly for securing an intramedullary rod in a medullary canal of a bone is provided. The screw assembly includes a screw body with a shaft and at least one receiving bore that extends transversely through the shaft. The bore is adapted to receive an intramedullary rod. A securing member is movable toward the bore to thereby secure the rod to the screw assembly.

According to a further aspect of the invention, a system for securing an intramedullary rod in a medullary canal of a bone is provided. The system includes an intramedullary rod and a screw assembly for receiving the rod. The screw assembly has a receiving bore extending transversely therethrough for receiving the intramedullary rod and a securing member movable toward the receiving bore for securing the rod to the screw assembly. An alignment jig may also be provided for aligning the rod with the receiving bore during installation.

According to yet a further aspect of the invention, a method for installing an intramedullary rod within a medullary canal of a bone is also provided. The method comprises providing a screw with a transverse bore, installing the screw into the bone such that the transverse bore is within the medullary canal, and inserting an intramedullary rod into the medullary canal and through the transverse bore. The intramedullary rod may then be secured to the screw.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary as well as the following detailed description of the preferred embodiments of the present invention will be best understood when considered in conjunction with the accompanying drawings, wherein like designations denote like elements throughout the drawings, and wherein:

FIG. **1** is a front elevational view of a prior art intramedullary nailing system for affixing and mobilizing separated bone segments of a bone structure;

FIG. **2** is a front elevational view of a further prior art intramedullary nailing system;

FIG. **3** is a front elevational view if yet a further prior art intramedullary nailing system;

FIG. **4** is a side elevational view as viewed from section plane **4-4** of FIG. **3**;

FIG. **5** is a front elevational view of an intramedullary nailing system in accordance with an exemplary embodiment of the present invention for affixing and/or mobilizing separated bone segments of a bone structure;

FIG. **6** is an enlarged front view of a portion of the nailing system of FIG. **5** showing a bone segment in cross section;

FIG. **7** is a side elevational view of the nailing system of FIG. **6**;

FIG. **8** is a top plan view of the nailing system taken along section plane **8-8** of FIG. **6**;

FIG. **9** is an exploded perspective view of the nailing system in accordance with the present invention;

FIG. **10** is a front elevational view of an alignment jig together with an installed bone screw for aligning an intramedullary rod with a transverse opening in the screw in accordance with the present invention;

FIG. **11** is a view similar to FIG. **10** with the alignment device in proper position for boring a hole through the bone;

FIG. **12** is a view similar to FIG. **10** and illustrating insertion of the intramedullary rod through the bored hole in alignment with the bore of the screw;

FIG. **13** is a front elevational view of an alignment jig in accordance with a further embodiment of the invention in proper position for boring a hole through the bone;

FIG. **14** is a view similar to FIG. **13** and illustrating insertion of the intramedullary rod through the bored hole and screws; and

FIG. **15** is an enlarged front view of a nailing system in accordance with a further embodiment of the invention.

It is noted that the drawings are intended to depict only typical embodiments of the invention and therefore should not be considered as limiting the scope thereof. It is further noted that the drawings are not necessarily to scale. The invention will now be described in greater detail with reference to the accompanying drawings.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings, and to FIG. **5** in particular, an intramedullary nailing system **100** in accordance with an exemplary embodiment of the present invention for affixing and/or mobilizing two or more separated bone segments, such as segments **114**, **116**, and **118**, of a bone structure **106** is illustrated. The system **100** preferably includes an intramedullary nail or rod **102** (shown in hidden line) that is adapted to extend into the medullary canal **104** (also shown in hidden line) of the bone structure **106** with one or more fractures **108**, **110** and a screw assembly **112** that anchors the rod **102** within the medullary canal to secure the bone segments together during the treatment process.

The system **100** of the present invention is especially suitable in pediatric orthopedics for fixation of fractured bones such as the tibia, femur and humerus, complications caused by osteogenesis imperfecta, pseudoarthrosis of the tibia, and so on. However, it will be understood that the present invention is not limited to treatment of the afore-mentioned bones for the afore-mentioned conditions, but is also applicable to a wide variety of bone structures (such as the fibula, ulna and radius), bone sizes and conditions for both pediatric and general orthopedics.

The intramedullary rod **102** is preferably of conventional construction and can be formed of various materials, such as titanium or stainless steel. The rod **102** is also preferably

circular in cross section, and of a sufficiently small diameter to fit within the medullary canal of the particular bone structure to be treated. By way of example, rods with diameters of 2, 2.5, 3, and 4 mm are commonly used for pediatric applications. It will be understood that the intramedullary rod **102** is not limited to the particular sizes, cross sectional shape or materials mentioned above, but may be constructed of different sizes, different cross sectional shapes such as square, triangular, oval, and so on, and different materials such as metals, ceramics, plastics, composites, or combinations thereof.

Referring now to FIGS. **6-9**, the screw assembly **112** preferably includes a screw body **120** with a locking member **122** positionable within an internal cavity **130** of the screw body for fixing the rod **102** to the screw assembly **112**. The screw body **120** has a shaft **126** with a head portion **124** formed at one end thereof and an auger portion **128** formed at an opposite end.

The shaft **126** includes a transversely extending receiving bore **134** and the longitudinally extending internal cavity **130** that substantially coincides with a central axis **132** of the shaft and that intersects the internal cavity. Preferably, a central axis **135** of the receiving bore **134** and the central axis **132** of the shaft **126** (see FIG. **9**) are substantially perpendicular to each other. However, it will be understood that the angle between the receiving bore and the internal cavity can vary, depending on the particular orthopedic application. The internal cavity **130** is preferably internally threaded for receiving and engaging the locking member **122**. The receiving bore **134** can have a smooth inner surface and is sized to receive the intramedullary rod **102**.

The head portion **124** preferably has a generally flat front surface **136** and a curved rear surface **138** that extends between the front surface **136** and the shaft **126**. In one embodiment of the invention, the diameter of the head portion **124** is approximately 1.5 times the diameter of the shaft **126**. However, it will be understood that the relative dimensions of the head portion and shaft can greatly vary. A hexagonally-shaped depression **140** extends into the head portion **124** from the front surface **136** and intersects with the front end of the internal cavity **130**. The depression **140** is adapted to receive a corresponding suitably shaped or hexagonally-shaped tool (not shown) for turning the screw assembly **112** during installation and removal as well as for alignment purposes, as will be described in greater detail below.

Alignment indicator marks **142**, preferably in the form of slots, are formed in the front surface **136** of the head portion **124** at opposite sides of the depression **140**. The slots **142** are preferably parallel with the central axis **135** of the receiving bore **134** so that the bore can be properly oriented during installation of the screw assembly **112**. It will be understood that the slots **142** can be replaced with other marks, ticks, protrusions, or any other visually distinguishable indicating means for specifying the orientation of the receiving bore **134**. It will be further understood that the head portion **124**, including the depression **140**, is not limited to the particular shape as shown and described, but may assume a wide variety of shapes and tool engaging configurations.

The auger portion **128** includes a conical section **144** with a spiral thread **146** that gradually diminishes in thread diameter toward the tip **148** to form a self-tapping configuration that facilitates boring into the bone structure as well as attachment of the screw assembly to the bone structure during installation. It will be understood that the auger portion **128** is not limited to the conical shape, but may alternatively be cylindrical with a uniform screw thread diameter or of any other suitable configuration.

As best illustrated in FIG. **9**, the locking member **122** is preferably in the form of a set screw with outer threads **150** that engage the inner threads of the internal cavity **130**. A hexagonally-shaped, for example, depression **152** is formed in an end face **154** of the locking member **122**. The depression **152** is adapted to receive a corresponding or hexagonally-shaped tool (not shown) for turning the locking member **122** inside the internal cavity **130** toward or away from the receiving bore **134** to thereby clamp or release the intramedullary rod **10** within the receiving bore.

In order to facilitate alignment of the intramedullary rod **102** with the receiving bore **134** of the screw assembly **112** during installation, an alignment jig **160** in accordance with the present invention is provided, as shown in FIGS. **10-12**. The alignment jig **160** includes a base member **162** with a first leg **164** and a second leg **166** that extends upwardly from the first leg. Preferably, the first and second legs are substantially perpendicular to each other. A hexagonally-shaped, for example, bar **168** is pivotally connected to an outer free end of the second leg **166** at a pivot joint **170**. The bar **168** is sized and shaped to be received within the respective or hexagonal depression **140** of the screw head portion **120**. A tubular guide member **172** extends downwardly from the first leg **164** and includes a central bore **174** (shown in hidden line) that substantially coincides with an opening **176** (shown in hidden lines) in the first leg **164**. Preferably, a proximal surface **178** of the first leg **164** is planar. The distance between a centerline of the central bore **174** and an inner surface **175** of the second leg **166** (or outer end of the hexagonal bar **168**) is preferably chosen so that when the alignment jig **160** is in the position shown in FIG. **11**, the central bore **174** will be aligned with the medullary canal of the bone and the receiving bore **134** of the screw assembly **112**.

In use, the particular number of screw assemblies **112** and their location along the length of the bone structure **106** can be determined by fluoroscopy or other techniques, and may be based on the type and size of the bone structure, the age of the injured person, the number of breaks, and so on. The screw assemblies **112** can then be installed at the determined locations by directly boring through the bone with the screw assemblies with an appropriate tool, such as a hex key connected to the chuck of a drill (not shown) or the like. In some circumstances, it may be desirable to drill pilot holes prior to transverse installation of the screw assemblies in the bone structure. Once in place, the screw assembly **112** is rotated until the alignment indicator slots **142** are aligned with the longitudinal direction of the bone structure **106** such that the receiving bore **134** is centered in the medullary canal **104** and also in alignment with the longitudinal direction of the bone structure, as shown in FIG. **8**. Since the receiving bore **134** is within the bone structure **106**, it may be difficult to view and align the receiving bore using fluoroscopy only. Accordingly, the alignment indicator slots **142** facilitate blind alignment of the first receiving **134** in the medullary canal.

Once the screw assembly **112** is in proper position, the hex rod **168** of the alignment jig is inserted into the hexagonal depression **140**. The base member **162** is then rotated about the pivot joint **170** until the proximal surface **178** of the first leg **164** is in contact with the distal end **180** of the bone structure **106**. In this manner, the exposed end of the hex rod **168** is in contact with the inner surface **175** of the second leg **166**. In this position, the hex rod **168** is preferably substantially perpendicular to the second leg **166** and parallel to the first leg **164**, as shown in FIGS. **11** and **12**. The central bore **174** of the tubular guide member **172** is thus automatically aligned with the central axis **135** of the receiving bore **134** of the screw assembly **112**. A drill bit **182** (shown in hidden line) is then inserted through the central bore **174** and the opening **176**. Upon rotation by a rotary tool **184**, such as a drill or the like, the drill bit **182** forms a hole **186** in the distal end **180** of the bone structure **106**. It will be understood that the hole may additionally or alternatively be formed at the proximal end of the bone structure.

When the medullary canal has been reached, the drill bit is removed and an intramedullary rod **102** is inserted through the central bore **174**, the opening **176**, the hole **186**, the medullary canal **104** (see FIGS. **6** and **12**), and finally the receiving bore **134** of the screw assembly **112**.

When multiple screw assemblies are to be placed at different positions along the length of the bone, a plurality of alignment jigs with different leg sizes and guide member positions can be used, as illustrated in FIGS. **13** and **14**. The alignment jig **160**A as shown is substantially similar in construction to the alignment jig **160** previously described, with the exception that the second arm **166**A is shorter than the second arm **166**, and the position of the tubular guide member **172** and opening **176** are at a different location on the first leg **164**A to accommodate the extra width of the distal end **180** of the bone structure **106**. The embodiment of FIGS. **13** and **14** is specifically adapted to accommodate bone growth of a patient.

In accordance with a further embodiment of the invention, the first leg **164** and/or the second leg **166** may be telescopic or otherwise adjustable in length for adapting to any bone size and screw assembly placement. In this manner, a single alignment jig can be used for a variety of different alignment requirements.

If multiple screw assemblies have been placed, the rod **102** is inserted through the receiving bore of each screw assembly as shown in FIG. **5**. The particular position of the rod **102** with respect to the screw assemblies **112** can be verified through radiographic studies. The alignment jig **160** is then removed and the locking member **122** of each screw assembly is rotated until the rod **102** is clamped between the locking member **122** and the inner wall of the receiving bore **134** (see FIG. **8**). In this manner, the intramedullary rod is securely fixed to the bone segments. In circumstances where bone growth may be impeded by multiple clamping positions of the screw assembly along the intramedullary rod, one or more of the screw assemblies may be left unclamped to provide for bone movement.

With the above-described arrangement, long bone structures with one or more breaks can be securely supported during the healing process. The system of the present invention is especially advantageous for small bone structures where it is impractical to insert a large diameter rod into a small bone or securely anchor a small diameter rod to the bone segments with an even smaller diameter screw since insufficient cross-pinning to isolate movement of the rod or to fix it in a desired position would result. By way of example, a screw assembly **112** in accordance with the present invention with a shaft diameter of 5 mm can be fixedly attached to a 2 mm diameter rod. Likewise, a screw assembly **112** with a shaft diameter of 6 mm can be fixedly attached to a 3 mm diameter rod, and so on. The particular sizes of screw assemblies and rod diameters can be adjusted to accommodate a wide variety of bone structures and conditions. The relatively large diameter of the screw assembly **112** enables it to span the medullary canal **104** and be securely fastened to opposite sides of a bone structure and to the intramedullary rod to thereby securely hold the bone segments together.

In addition, the present invention may be used in treatments involving both compression and non-compression modes. The compression mode would include fixing the intramedul-

lary rod at multiple positions for maximum bone stability that in many cases may allow at least partial weight bearing on the affected limb. The non-compression mode would include fixing the intramedullary rod at a single position (or even no fixation at all) to the screw assembly while allowing longitudinal guided motion of the rod through the receiving bore of a second screw assembly. The receiving bore would thus serve as a guide to ensure only linear movement of the rod during bone growth or treatment procedures.

Turning now to FIG. **15**, an intramedullary nailing system **200** in accordance with a further embodiment of the invention is illustrated. The system **200** is similar in construction to the system **100** previously described, with the exception that two intramedullary nails or rods **102**A, **102**B are secured within a medullary canal **104** of a bone structure **106** by a pair of screw assemblies **202**A and **202**B, respectively. As shown, the screw assemblies **202**A and **202**B extend through the bone structure **106** from opposite directions. Each screw assembly **202**A, **202**B is similar in construction to the screw assembly **112**, with the exception that a second receiving bore **204** is provided in the shaft **126**A between the receiving bore **134** and the conical section **144** to accommodate the extra intramedullary rod. The second receiving bore **204** is preferably parallel to the receiving bore **134**. With this configuration, the rod **102**A is secured to the screw assembly **202**A in a manner previously described, and is adapted to slide freely through the screw assembly **202**B via the second receiving bore **204**. Likewise, the rod **102**B is secured to the screw assembly **202**B and is adapted to slide freely through the screw assembly **202**A via the bore **204**. As illustrated in FIG. **15**, the rod or nail **102**A is secured within the receiving bore of the screw assembly **202**A. However, this rod can slide freely within a second receiving bore **204** of the second screw assembly **202**B. In a similar manner, the nail or rod **102**B is fixedly positioned within the first receiving bore **134** of the screw assembly **202**B and can slide freely within the second receiving bore **204** of the screw assembly **202**A. Such arrangement compensates for possible movement of one segment of the broken bone with respect to another bone segment, while assuring the required stability of the bone structure.

It will be understood that the term "preferably" as a used throughout the specification refers to one or more exemplary embodiments of the invention and therefore is not to be interpreted in any limiting sense.

In addition, terms of orientation and/or position as may be used throughout the specification, such as but not limited to: lateral, medial, longitudinal, inner, outer, front, rear, upwardly, downwardly, as well as their derivatives and equivalent terms, relate to relative rather than absolute orientations and/or positions.

It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It will be understood, therefore, that this invention is not limited to the particular embodiments disclosed, but is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

What is claimed is:

1. A system for securing an intramedullary rod adapted for positioning at a medullary canal of a human bone in an orthopedic procedure, the system comprising:

an intramedullary rod;

a screw having a screw body extending between distal and proximal ends thereof, the screw body comprising a shaft with at least one receiving bore extending through the shaft transversely to its longitudinal axis and an internal cavity extending from the proximal end of the body along the longitudinal axis and intersecting said at least one receiving bore, said at least one receiving bore being adapted to receive the intramedullary rod,

an alignment jig operably associated with the screw and the intramedullary rod, the alignment jig comprises a base member with a first leg and a second leg extending from the first leg, the second leg being adapted for engaging the internal cavity of the screw at the proximal end of the body, the first leg being adapted to contact a bone structure and having an opening coincident with the at least one receiving bore of the screw to thereby align the intramedullary rod with the at least one receiving bore within a medullary canal of the bone structure;

whereby in an assembled condition said at least one receiving transverse bore is adapted for positioning within the medullary canal so as to receive the intramedullary rod which passes through said canal in such a manner that longitudinal axes of the intramedullary rod, said at least one receiving bore and the opening of the first leg coincide.

2. A system according to claim **1**, wherein the alignment jig further comprises a tubular guide member extending from the first leg and coincident with the opening, the tubular guide member being adapted to receive a drill bit adapted for forming a hole in the bone structure in alignment with the at least one receiving bore and to receive the intramedullary rod for guiding the rod toward the at least one receiving bore.

3. A system according to claim **2**, wherein the alignment jig further comprises a bar connected to the second leg, the bar being adapted to fit within the internal cavity of the screw.

4. A system according to claim **3**, wherein the bar is pivotally connected to the second leg.

5. A system according to claim **4**, wherein the first and second legs are substantially perpendicular to each other.

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