



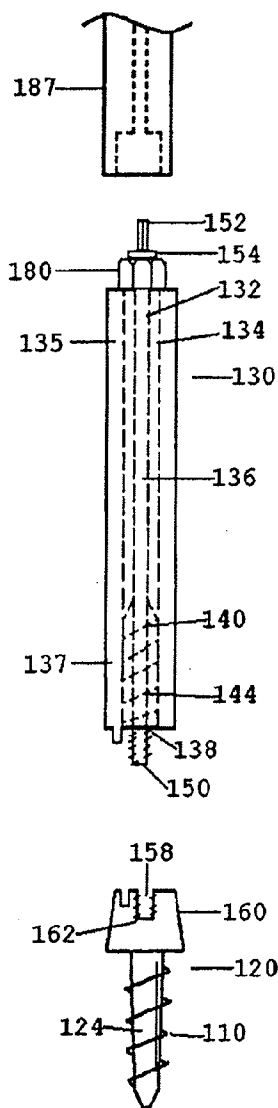
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(19) **United States**(12) **Patent Application Publication**
Abdou(10) **Pub. No.: US 2009/0177238 A1**(43) **Pub. Date: Jul. 9, 2009**(54) **DISTRACTION SCREW FOR SKELETAL
SURGERY AND METHOD OF USE**(60) Provisional application No. 60/417,776, filed on Oct.
11, 2002.(76) Inventor: **M. Samy Abdou**, San Diego, CA
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BOSTON, MA 02111 (US)**(57) **ABSTRACT**

An improved distraction bone screw and a method for its use are described. The distraction screw is comprised of an implantable distal segment and a detachably secured proximal segment. The distal segment includes a head portion and a threaded shank portion. The proximal segment is represented as an elongated body having an internal bore that extends through its length. A deployable member is disposed within the bore, which is extendible outside the internal bore to securely couple to the distal segment.

(21) Appl. No.: **12/351,736**(22) Filed: **Jan. 9, 2009****Related U.S. Application Data**(63) Continuation of application No. 10/683,325, filed on
Oct. 10, 2003, now Pat. No. 7,476,228.

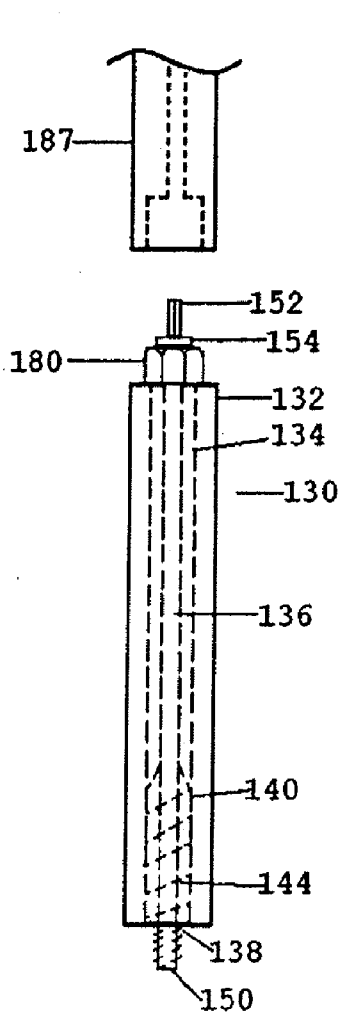


Fig. 1

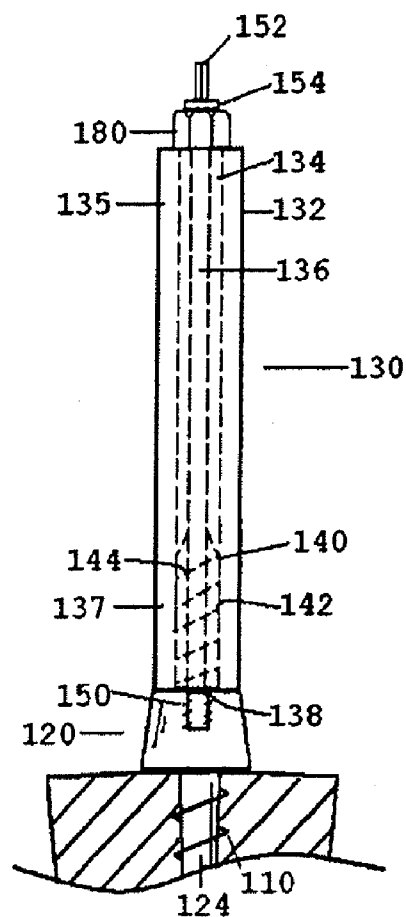
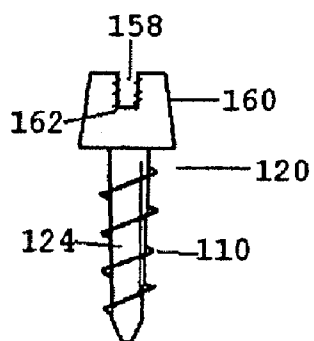


Fig. 2

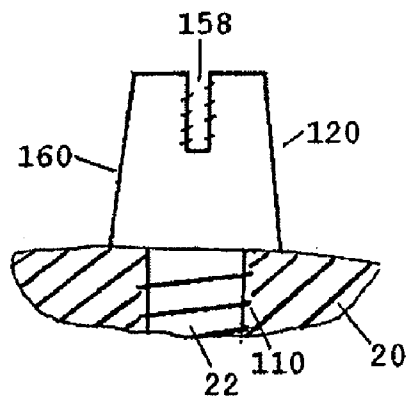


Fig. 3

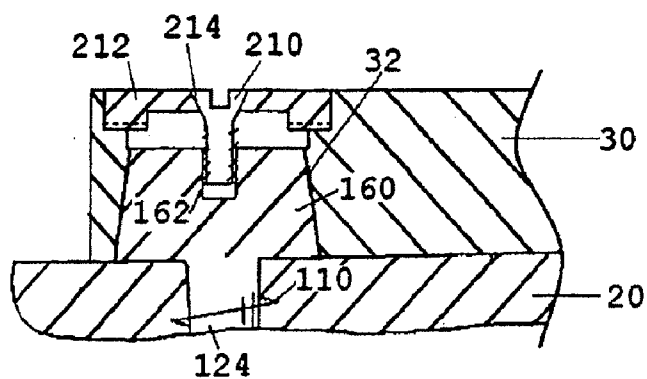


Fig. 4

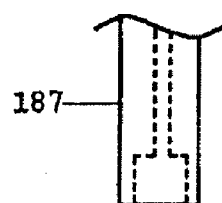
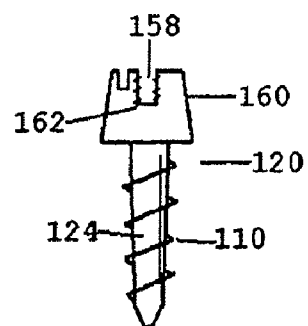
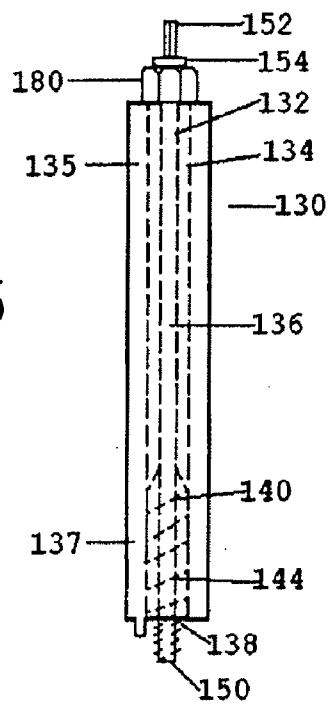


Fig. 5



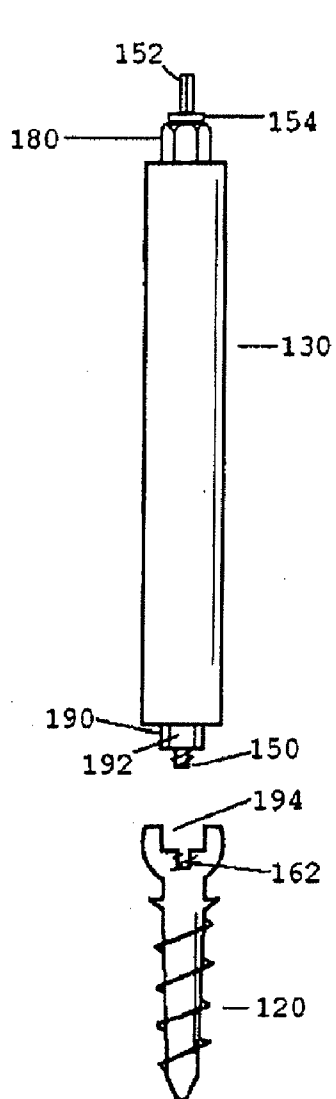


Fig. 6a

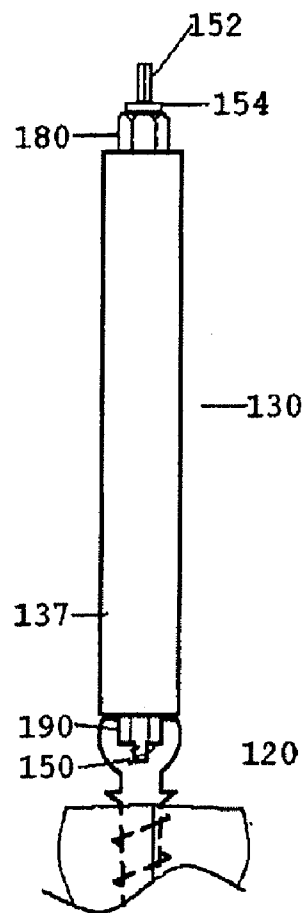


Fig. 6b

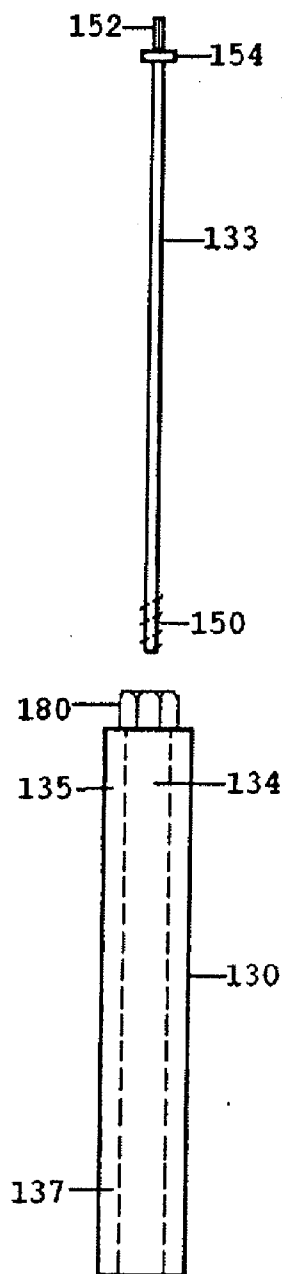


Fig. 7a

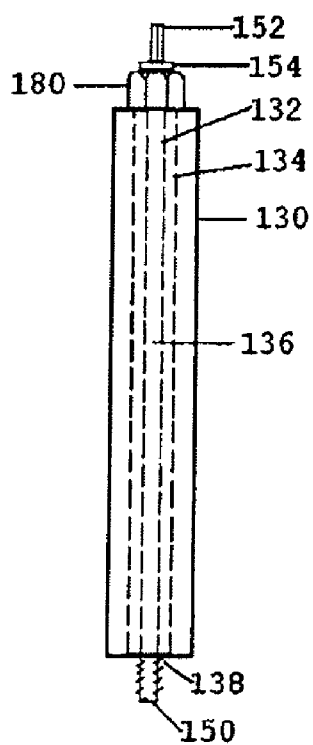


Fig. 7b

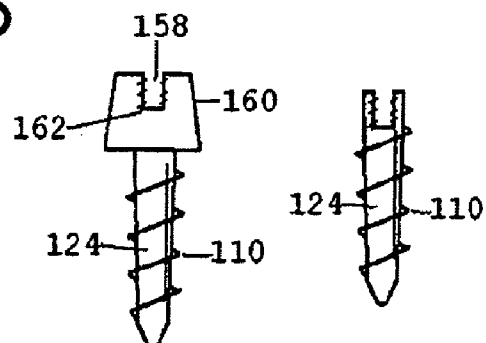
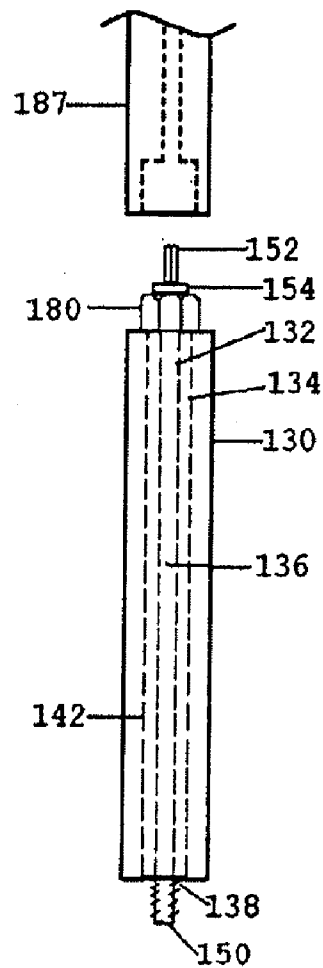


Fig. 7c

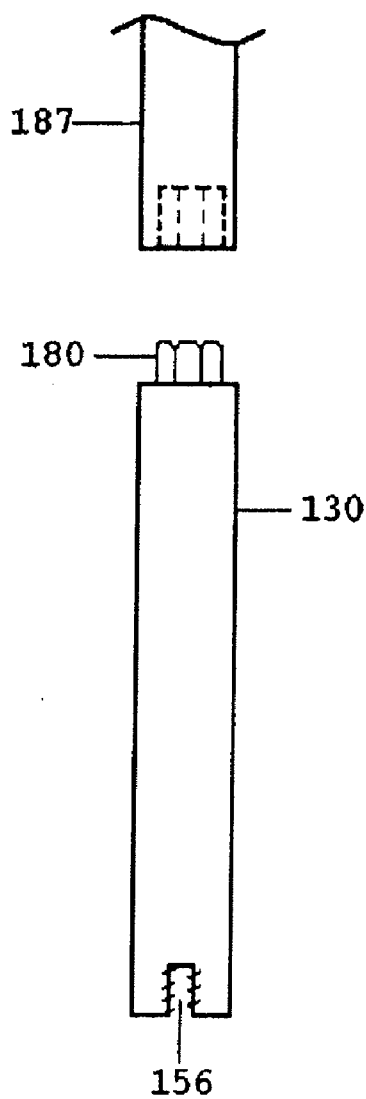


Fig. 8a

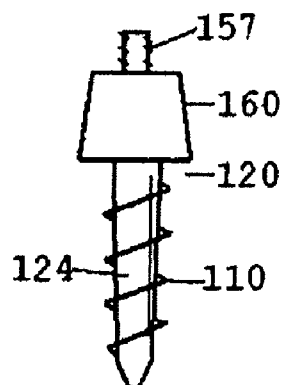


Fig. 8b

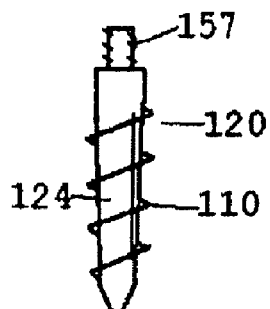


Fig. 8c

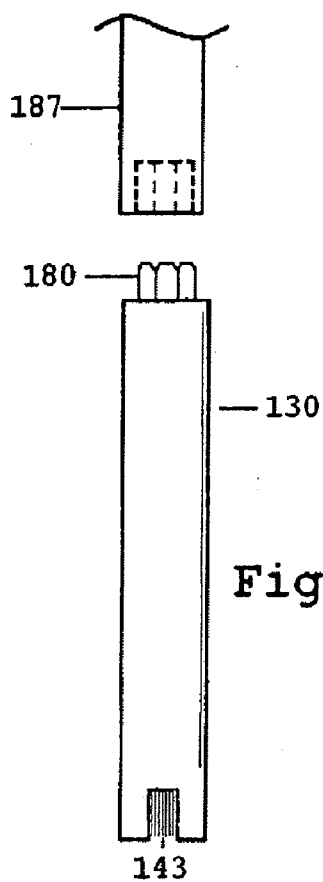


Fig. 9a

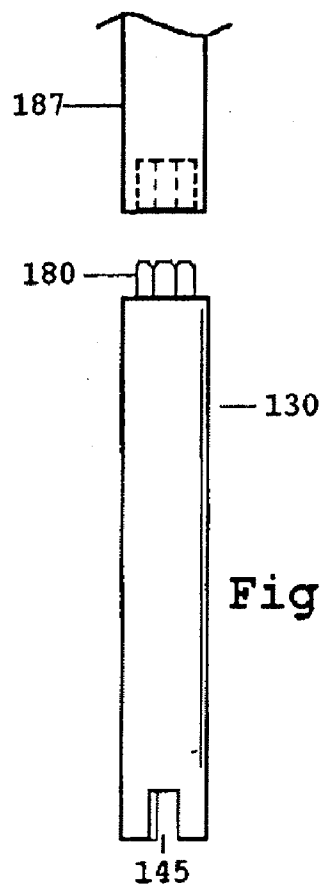


Fig. 10a

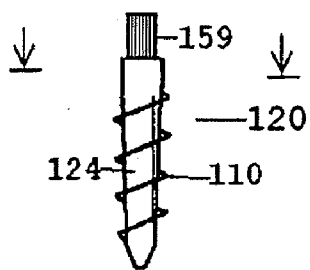


Fig. 9b

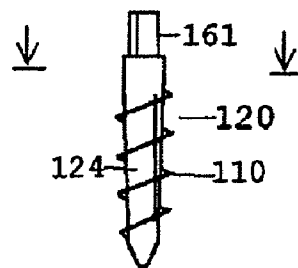
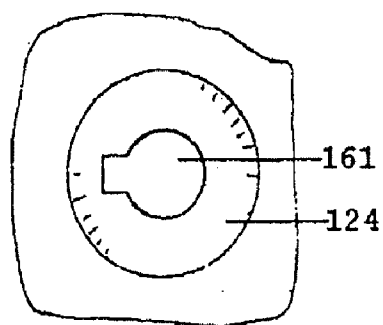
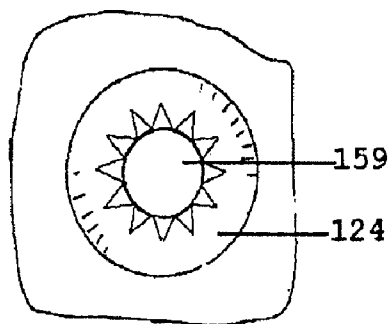


Fig. 10b



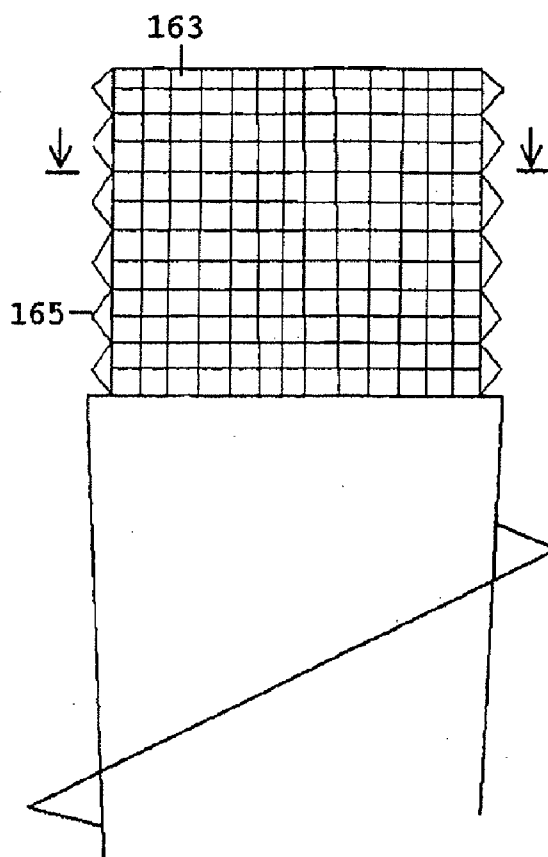
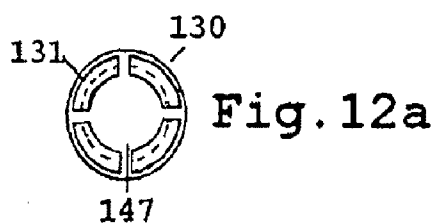
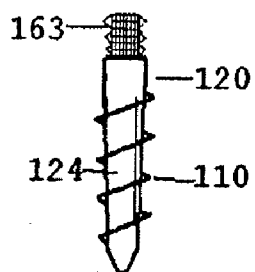
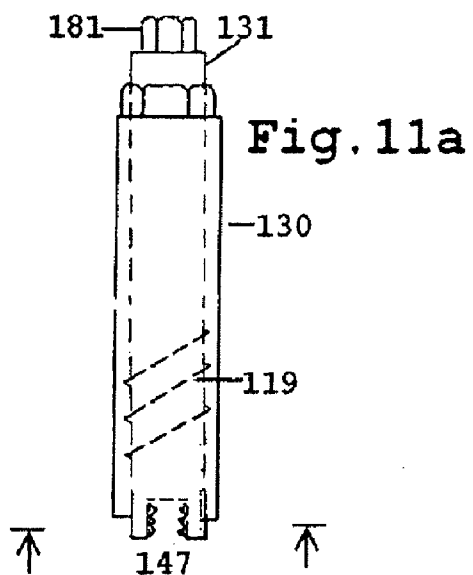
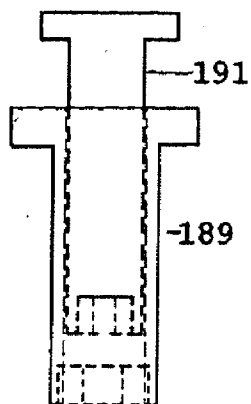


Fig. 11b

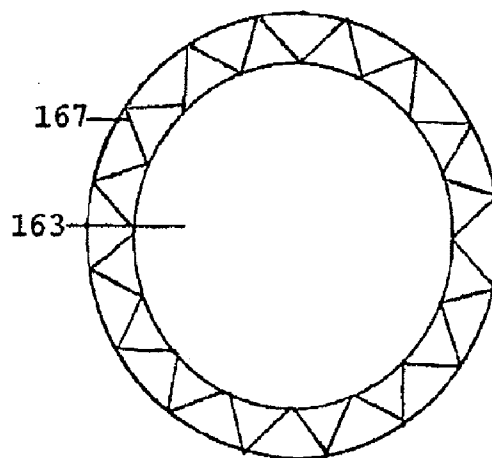


Fig. 12b

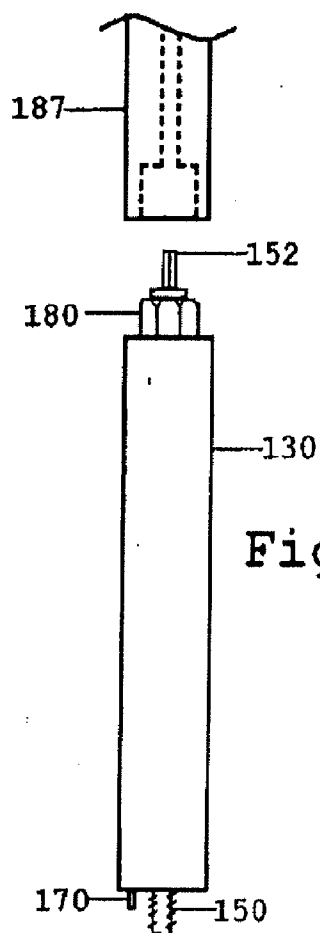


Fig. 13

Fig. 14

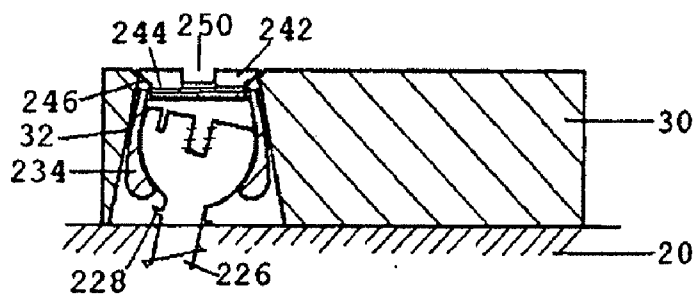
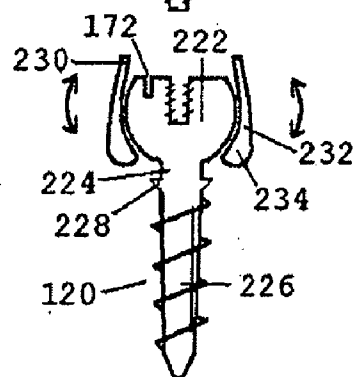
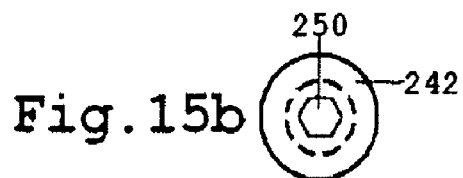
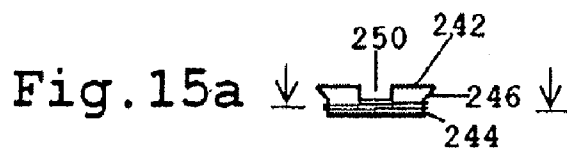
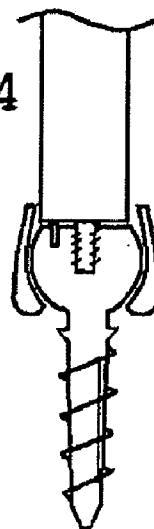


Fig. 15

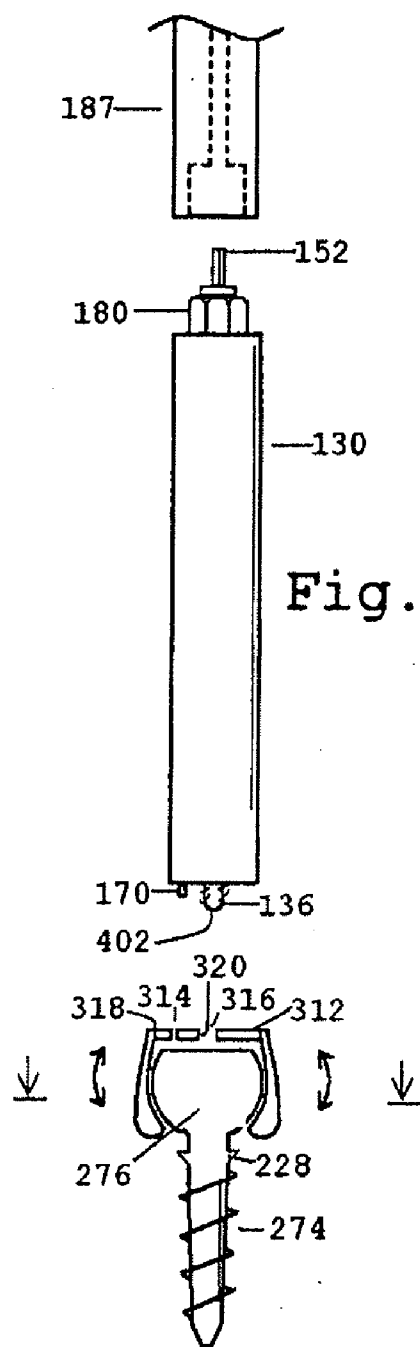


Fig. 16a

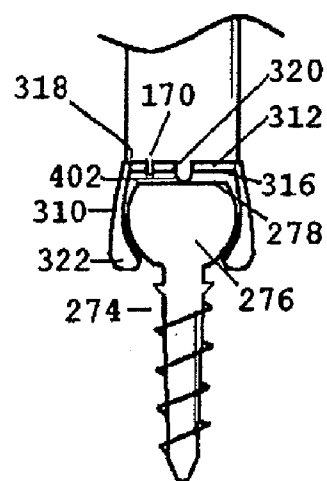


Fig. 17

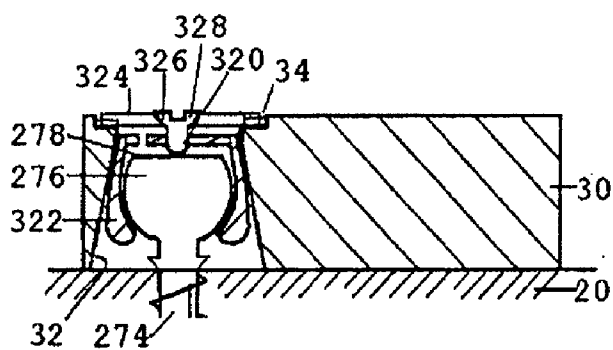


Fig. 18

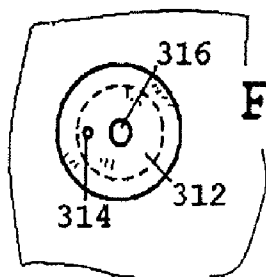


Fig. 16b

DISTRACTION SCREW FOR SKELETAL SURGERY AND METHOD OF USE

REFERENCE TO PRIORITY DOCUMENT

[0001] This application is a continuation of co-pending U.S. patent application Ser. No. 10/683,325 filed on Oct. 10, 2003, which claims the benefit of U.S. Provisional Application No. 60/417,776 filed Oct. 11, 2002. The disclosures of the patent applications are hereby incorporated by reference in their entirety.

BACKGROUND

[0002] The surgical removal of a herniated disc, whether from degenerative disease or traumatic disruption, is a common procedure in current medical practice. In the cervical spine, the procedure involves placement of a large temporary bone screw, which is also known as the distraction screw, into each of the vertebral bones above and below the diseased disc space. These screws are used to realign the vertebral bones into the desired anatomical relationship and to temporarily distract them so as to permit work within the intervening disc space. The disc is removed and a bone graft or suitable graft substitute is placed into the evacuated space. The temporary distraction screws are then removed from the vertebrae and a metallic skeletal plate is used to maintain the position of the vertebral bones while bone healing occurs. The bones are fixed to the skeletal plate using implantable bone screws (usually two screws per vertebrae), which are separate and distinct from the distraction screws.

[0003] Removal of the distraction screws from the vertebral bodies usually produces robust bone bleeding and requires that the bone holes be filled with a hemostatic agent. The empty bone holes also act as stress concentration points within the vertebral bodies, as would any empty opening or crack within a rigid structural member, and predispose the vertebral bodies to bone fracture, screw/plate migration and construct failure. Further, the empty holes often interfere with proper placement of the implantable screws and the associated skeletal plate, making proper alignment of the plate along the anatomically desired plane more difficult. This is especially problematic since the plate is placed at the end of the operative procedure and the preceding surgical steps have distorted the anatomical landmarks required to ensure proper plate alignment.

[0004] Lastly, once placed, the plate will effectively cover the vertebral bodies of the reconstructed segment. Extension of the operation to an adjacent level at a future date will require placement of a distraction screw within a covered vertebrae and, thus, necessitate plate removal. The latter requires re-dissection through the scarred operative field of the initial procedure and significantly increases the operative risk of the second procedure for the patient.

[0005] In view of the above, it would be desirable to design an improved distraction screw. The new device should minimize blood loss, reduce the potential for stress concentration, maximize the likelihood of proper plate alignment, provide an additional point of fixation for the skeletal plate and provide a ready mechanism for distraction screw replacement at the time of surgical revision without obligatory plate removal.

SUMMARY

[0006] The present invention is one of an improved distraction screw and a method for its use. The design substantially

enhances the functional capability of distraction screws used in the surgical reconstruction of mammalian bones. In this invention, the multi-segmental distraction screw comprises an implantable distal segment and a detachably secured proximal segment. The distal segment includes a head portion and a threaded shank portion. The proximal segment is represented as an elongated body having an internal bore that extends through its length. A deployable member is disposed within the proximal segment, which is extendable beyond the distal end of the internal bore to engage and secure the distal segment, thus forming a unitary distraction screw. Once assembled, the screw is used to realign and distract the bones during surgical reconstruction of a degenerated skeletal segment. Upon completion of that work, the proximal and distal segments are disengaged leaving the latter attached to bone. Securely affixed, the distal segment provides an additional point of anchoring and/or fixation for the skeletal plate and facilitates its proper placement. It also provides a ready mechanism for distraction screw replacement at the time of surgical revision without obligatory plate removal.

[0007] In other embodiments of the present invention, different proximal and distal segment designs are provided as well as an optional rotational locking means to inhibit the rotational movement of the proximal and distal segments relative to each other. Further, where the distal segment is affixed to the underlying bone at an inclined angle, a poly-axial head adapter is provided to ensure proper alignment during placement of the skeletal plate.

[0008] The distraction screw design of the present invention provides significant advantages over the current and prior art. These and other features of the present invention will become more apparent from the following description of the embodiments and certain modifications thereof when taken with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 is a partial side view of a distraction screw of the present invention, together with a tool driver to effect a rotational movement therefor;

[0010] FIG. 2 is a partial sectional side view of an assembled distraction screw of the present invention affixed onto a mammalian bone substrate;

[0011] FIG. 3 is a partial sectional side view of a distal segment of the distraction screw implanted onto a mammalian bone substrate;

[0012] FIG. 4 is a sectional side view of the distal segment affixing a skeletal plate onto the mammalian bone substrate;

[0013] FIG. 5 is a partial sectional side view of another embodiment of the present invention, which incorporates a rotational locking means as represented by a key-receptacle arrangement;

[0014] FIG. 6a is a partial sectional side view of a further embodiment of the present invention, which incorporates another variation of a rotational locking means as represented by a hex insert-socket arrangement;

[0015] FIG. 6b is a partial sectional side view of the assembled distraction screw shown in FIG. 6a affixed onto a mammalian bone substrate;

[0016] FIG. 7a is a sectional side view of another embodiment of the proximal segment;

[0017] FIG. 7b is a sectional side view of the assembled proximal segment shown in FIG. 7a;

[0018] FIG. 7c is a sectional side view of the assembled proximal segment shown in FIG. 7a, together with the distal segments and a tool driver to effect the rotational movement thereof;

[0019] FIG. 8a is a partial sectional side view of another embodiment of the proximal segment, together with a tool driver used to effect its rotation;

[0020] FIG. 8b is a sectional side view of one embodiment of the distal segment used with the proximal segment shown in FIG. 8a;

[0021] FIG. 8c is a sectional side view of another embodiment of the distal segment used with the proximal segment shown in FIG. 8a;

[0022] FIG. 9a is a partial sectional side view of another embodiment of the proximal and distal segments, together with a tool driver used to effect their rotation;

[0023] FIG. 9b is a top view of the distal segment illustrated in FIG. 9a;

[0024] FIG. 10a is a partial sectional side view of another embodiment of the proximal and distal segments, together with a tool driver used to effect their rotation;

[0025] FIG. 10b is a top view of the distal segment illustrated in FIG. 10a;

[0026] FIG. 11a is a partial sectional side view of another embodiment of the proximal and distal segments, together with a tool driver used to effect their rotation;

[0027] FIG. 11b is a partial top view of the distal segment illustrated in FIG. 11a;

[0028] FIG. 12a is a partial sectional side view of the distal segment of the embodiment illustrated in FIG. 11a;

[0029] FIG. 12b is a partial top view of the distal segment of the embodiment illustrated in FIG. 11a;

[0030] FIG. 13 is a partial sectional side view of another embodiment of the present invention, which incorporates a poly-axial feature;

[0031] FIG. 14 is a partial sectional side view of the embodiment of FIG. 13 shown as an assembly;

[0032] FIG. 15 is a partial sectional side view of a distal segment with a poly-axial feature implanted onto a mammalian bone substrate on which a skeletal plate is affixed;

[0033] FIG. 15a is a partial top view of a mounting plate used to secure the skeletal plate onto the distal segment;

[0034] FIG. 15b is a side view of the mounting plate of FIG. 15a;

[0035] FIG. 16a is a partial sectional side view of another embodiment of the present invention incorporating another variation of the poly-axial feature;

[0036] FIG. 16b is a top view of the screw cap shown in FIG. 16a;

[0037] FIG. 17 is a partial sectional side view of the assembled distraction screw of the embodiment shown in FIG. 16a; and

[0038] FIG. 18 is a partial sectional side view of a distal segment with poly-axial feature implanted onto a mammalian bone substrate on which a skeletal plate is affixed.

DETAILED DESCRIPTION

[0039] The present invention provides an improved distraction screw and a method for its use. FIG. 1 shows an embodiment of the present invention, as represented by a distraction screw 10, which comprises a distal segment 120 and a removable proximal 130 segment. The distal segment 120 is implantable on a vertebral bone as part of the surgical procedure. The distal segment 120 has a head portion 122, and a

threaded shank portion 124 which can be securely fastened unto the bone structure and which may be self-tapping and/or self-drilling.

[0040] As shown in FIGS. 1 and 2, the proximal segment 130 has an elongated body 132 with an internal bore 134 extending through its length from its proximal end portion 135 to its distal end portion 137. The elongated body 132 houses a deployable member 136, which is disposed within the internal bore 134. The deployable member 136 is adapted to be retractably deployed beyond the opening 138 of the internal bore 134 at the distal end portion 137 of the elongated body 132.

[0041] Along the wall 140 of the interior bore 134 of the elongated body 132 are cooperating threads 142, which complement threads 144 of the deployable member 136 such that rotation of the deployable member 136 relative to the elongated body 132 in one direction extends it beyond the opening 138 of the internal bore 134 in a deployed position, as shown in FIGS. 1 and 2. Conversely, rotation of the deployable member 136 in the opposite direction effects its retraction from the deployed position. Thus the deployable member 136 can be rotated independently of the elongated member 130.

[0042] For the embodiment shown in FIG. 1, the threads are made as right-hand thread, that is, viewing from the proximal end portion 135 of the elongated body 132, a clockwise rotation of deployable member 136 causes it to extend beyond the opening 138 of the internal bore 134. Conversely, a counter-clock wise rotation of the deployable member 136 effects its retraction into the internal bore 134.

[0043] The proximal segment 130 is adapted to be attached to the distal segment 120. As shown in FIGS. 1 and 2, the deployable member 136 has a threaded end portion 138, with threads 150, which are adaptably securable to interfit and interlock with complementary threads 162 of the threaded well 158 of the distal segment 120. Threads 150 and 162 are oriented in the same turn direction and have the same pitch (number of threads per unit length) as those of threads 142 and 144. This enables the threaded portion 138 to advance into the threaded well 158 when turned clockwise.

[0044] Construction of the threads 142 and 150, and their respective counterpart complementary threads 144 and 162 can be accomplished by various means. For example, threads 142 and 144 can be constructed as a screw drive arrangement to facilitate the relative movement between the elongated body 132 and the deployable member 136 in deployment or retraction. Likewise, threads 150 and 162 can be constructed for effective mutual engagement. As a matter of design preference, threads 142 and 144 may be of any length and may be placed at any point throughout the internal bore of the elongated member. In addition, though not necessary, threads 150 of the deployable member 136 can be an extension of its threads 144.

[0045] At its proximal end portion 152, the deployable member 136 is adapted to be manipulated to effect its extension beyond the opening 138 of the internal bore 134 in a deployed position or retraction. For the embodiment as shown in FIGS. 1 and 2, the rotational movement of the deployable member 136 can be effected by tools such as a wrench, socket wrench, screwdriver, or the like. In one embodiment of the present invention as shown in FIG. 1, the proximal end portion 152 of the deployable member 136 has a hex-shaped configuration, which is engageable by a socket or a wrench to effect a rotational action. In alternative

embodiments, proximal end portion **152** has an intersecting depression (not shown) adapted to accommodate the driving tip of a “Phillips” screwdriver to effect a rotational action. Any alternative means and arrangements for engaging and rotating the deployable member **136** can be employed including, but not limited to, a driver or “Allen” wrench configuration.

[0046] As referenced above, rotation of the deployable member **136** relative to the elongated body **130** extends the deployable member for its threads **150** to engage the threads **162** of the head portion **160** of the distal segment **120**. Once threads **150** are engaged with threads **162**, both the proximal and the distal segments are coupled as a unit.

[0047] The deployable member **136** can be removed from the elongated body **132**, allowing for different sizes, threads and/or shapes for the head portion and/or tool attachment portions. Thus, the attachment and/or arrangement of the elongated body **132** and the deployable member **136** can be a screw-fit, or snap-fit arrangement, which does not interfere with the rotation of the deployable member **136**.

[0048] The proximal segment **130** is provided with a tool attachment end portion **180** that is adaptable to receive a rotational torque to effect a rotational action of the elongated body **132**. As shown in FIG. 1, a “hex-head” end configuration is provided, on which a socket **187** can be fitted to effect the rotational action of the elongated body **132**. Optionally, the proximal end can incorporate a flange **154** to limit the extension of the deployable member **136** beyond the distal end of the proximal segment.

[0049] The coupled proximal and distal segments employing the above-described means of engagement provide a detachably coupled distraction screw, which functions as a unitary device. In a surgical application, a socket (coupled to a wrench, not shown) **187** is attached to the tool attachment portion **180**, and the distraction screw is positioned at a site of a bone structure **20**. By applying a rotational torque to the elongated body **132** in a clockwise direction, both the proximal and distal segments rotate in unison so that thread **110** of the distal segment **120** may engage opening **22** of the underlying bone. Shank **124** is advanced and secured onto the bone structure as shown in FIG. 2.

[0050] As shown in FIGS. 1 and 2, the distal segment **120** comprises a threaded shank portion **124** and a head portion **160**. As referenced above, threads **110** of the shank portion **124** would preferably, but not necessarily, be self-tapping and/or self-drilling. The threads **110** would also follow the same turn direction as those of threads **150** and **144**. Depending on the particular application, the shank portion **124** can be of variable lengths and threads **110** may be of any known configurations. One of ordinary skill in the art would understand that the threads can be of any design that is understood and well known to be applicable for screwing and inserting into mammalian bone. In the embodiment shown in FIGS. 1, 2 and 3, the internal diameter of the threaded shank portion is progressively tapered from the head portion to the distal tip.

[0051] The shape of the head portion **160** may be of any geometric design, including but not limited to, rectangular, trapezoidal, cylindrical, circular, spherical, hybrid configurations and the like. Further, the head may be absent altogether, placing the engagement adapter directly into the body of the screw shank (FIG. 7c). In the embodiment as shown in FIGS. 1, 2 and 3, the head portion **160** is mono-axial, remaining in a fixed plane relative to the threaded shank. As used herein, “mono-axial” refers to rotation of the head portion and shank

along a common arbitrary axis. This is defined by the placement of the head portion in a fixed geometric relationship to the threaded shank such that when the shank is rotated, the head portion also rotates along the same axis. Thus, in the embodiment as shown in FIGS. 1, 2 and 3, the head portion is arranged with its diameter perpendicular to the length of the shank, which defines a common mono-axial relationship.

[0052] The distal segment **120** can be made of any biologically adaptable or compatible materials. Materials considered acceptable for biological implantation are well known and include, but are not limited to, stainless steel, titanium, combination metallic alloys and the like, various plastics, ceramics, biologically absorbable materials and the like. It would be understood by one of ordinary skill in the art that the distal segment **120** can be made of any materials acceptable for biological implantation and capable of withstanding the torque required for insertion and the load encountered during use. Any components may be further coated/made with osteo-conductive (such as demineralized bone matrix, hydroxyapatite, and the like) and/or osteo-inductive (such as Transforming Growth Factor “TGF- β ,” Platelet-Derived Growth Factor “PDGF,” Bone-Morphogenic Protein “BMP,” and the like) bio-active materials that promote bone formation. The proximal segment **130** may be made from any non-toxic material capable of withstanding the torque required for insertion and the load encountered during use. Materials used in the proximal segment **130** need not be limited to those acceptable for implantation, since it functions to deliver the implantable distal segment **120** but is not, itself, implanted.

[0053] As shown in FIG. 2, the distraction screw **10** is placed at a predefined location of the vertebral bone. As rotational torque is applied to the distal segment **120** by the tool attachment, both the segments rotate in unison, which inserts the threaded portion **110** of the distal segment into the bone opening **22**. The coupling of the proximal and distal segments provides the longitudinal stability and the structural integrity of the coupled segments as a distraction device. In another embodiment of the present invention as shown in FIGS. 5, 6a and 6b, in addition to coupling the deployable member **136** with the distal segment **120**, the elongated body **132** of the proximal segment **130** is also engageable to the distal segment **120** to prevent their relative rotational movement by a rotation locking means.

[0054] As shown in FIG. 5, at the distal end portion **137** of the proximal segment **130**, a key **170** is provided. The key **170** is fitted to be inserted into a receptacle **172** as defined by a depression located at the head portion **160** of the distal segment **120**. When the key **170** is inserted into receptacle **172**, the elongated body **132** of the proximal segment **130** is engaged with the distal segment **120**, which prevents the relative rotational movement between the two segments. FIGS. 6a and 6b show another embodiment of the present invention in which a variation in the design of the rotation locking means is presented. The distal end portion **137** of the proximal segment **130** incorporates a hex extension **190**, which can be fitted into the well **158** of the head portion **160** with a complementary hex socket receptacle **194**. When so fitted, rotation of the distal segment **120** proximal segment **130** relative to each other is inhibited. As shown in FIGS. 6a and 6b, hex extension **190** has an internal bore **192** through which the deployable member **150** passes for engagement with the distal segment by way of their cooperating threads **150** and **162**.

[0055] While the rotation locking means is illustrated in a key-receptacle arrangement and hex extension-socket configuration, it is not limited to these examples. It is understood that any engageable arrangement can be used as a rotational locking means. These include, but are not limited to, one or more extended protuberances of the elongated body 132 to seat within complementary bored depressions on the head portion of the distal segment 120. Similarly, square-jaw or spinal jaw clutch arrangements, and serrated or saw tooth edges can be incorporated to mate or interlock with similar features on the head portion (not shown).

[0056] In embodiments that incorporate such rotation locking means, assembly of the proximal and distal segments can be easily accomplished. The deployable member 136 is fitted within the internal bore 134 of the elongated body 132 in a retracted configuration by effecting a relative rotational movement between elongated body and the deployable member along their cooperating threads. The proximal segment 130 is then held adjacent to the head portion 160 of the distal segment 120 to insert key 170 into the receptacle 172. For the embodiment shown in FIGS. 6a and 6b, the hex extension 190 is seated within the socket 194 of the head portion 160. A suitable tool such as a screw driver, wrench, pliers, or the like is used to engage the proximal end portion 152 of the deployable member 136 in a rotating action to extend the threaded end portion 152 beyond the end opening 138 of the bore 134 (or bore 192 of the hex extension) to engage the internal threads 162 of the head 160 of the distal segment 120. Their actions secure the proximal and distal segments in a coupled relationship and inhibits any relative longitudinal and rotational movements between the segments.

[0057] As discussed above, the proximal segment 130 is securely coupled to the distal segment 120 as a distraction device while being anchored onto the bone structure. After the need for the distraction has been met, the proximal segment 130 is detached from the distal segment 120. From the coupled configuration, the elongated body 132 is held stationary and, using segment 152, the deployable member 136 is rotated in a direction opposite to that which was used to effect its coupling to the internal threads 162 of the head 160. This rotation disengages threads 150 from threads 162 of the distal segment 120. The rotation also releases the friction between the distal portion of the elongated body and the head portion of the distal segment. Detachment of the proximal and the distal segment is thus effected, leaving the latter securely implanted onto the vertebral structure, as shown in FIG. 3.

[0058] The deployable member can be retracted and stowed into the internal bore 134 of the proximal segment. For the embodiment as shown in FIG. 5, once the complementary threads 150 and 162 are disengaged, the proximal segment 130 can be dislodged with the key 170 disengaged from the receptacle 172 to separate from the distal segment 120. In a similar manner, for the embodiment shown in FIGS. 6a and 6b, once threads 150 and 162 are de-coupled, the hex extension 190 can be withdrawn from hex socket 194 of the distal segment. In this way, the use of the rotation locking means further ensures that the distal segment 120 would not be inadvertently rotated and de-coupled from the skeletal bone while rotating the deployable member 136 during detachment of the proximal and distal segments.

[0059] FIGS. 7a-7c, 8a-8c, 9a, 9b, 10a, 10b, 11, 12a, 12b illustrate other embodiments of the modular distraction screw. Since a thorough description of the device has been

presented above, only the relevant design differences of the other embodiments will be described in detail.

[0060] FIG. 7a demonstrates another embodiment of the proximal segment. This embodiment employs an elongated proximal segment 130 with a smooth internal bore 134 and no internal threads. A deployable member 133 has a threaded tip 150 on its distal end and proximal segment 152 which is adapted so as to be engaged by a screw driver, wrench or the like in order effect its rotation. A flange 154 is placed immediately distal to the engageable proximal end. FIG. 7b demonstrates the assembled proximal segment wherein the outer elongated body and the deployable member are each independently rotatable from the other. FIG. 7c shows the proximal segment 130, distal segment 160 and the wrench 187. As threads 150 of the proximal segment are engaged with threads 162 of the distal segment, flange 154 limits the extension of the deployable member and applies a compressive force across the elongated element 130, thus forming a rigid distraction screw. As before, the screw is inserted into bone by application of a rotational force onto element 180 using wrench 187. Rotation may be achieved by any engageable means and is in no way limited to the hex-wrench arrangement illustrated. After completion of the bone work, the distal segment is disengaged from the proximal segment by rotation of element 152 in the direction opposite to that used for engagement while segment 130 is held stationary using element 180. Optionally, a rotation locking means can be incorporated as part of the distal tip of the proximal segment in order to ensure that the distal segment 120 does not inadvertently rotate and de-couple from the skeletal bone during distraction screw disassembly.

[0061] FIGS. 8a-8c shows another embodiment of the present invention in which a proximal/distal interface is defined by a threaded extension 157 disposed on the head portion of the distal segment. The threaded extension 157 is fitted within the complementary threaded female receptacle 156 of the proximal segment. It is understood that the head of the distal segment beneath extension member 157 may be of any geometric configuration. Further, in these or any of the other embodiments presented herein, the proximal/distal interface is not limited to the screw and screw receptacle arrangement depicted. Thus, for example, FIGS. 9a and 9b demonstrate a sprocket arrangement 159 (male member) and a complementary receptacle 143 (female member), and FIGS. 10a and 10b show a smooth male member 161 with a key which is used to engage the complementary receptacle 145. These two design arrangements demonstrate the adaptation that any engageable means can be used.

[0062] FIGS. 11a, 11b, 12a and 12b demonstrate a sprocket arrangement which permits a locking engagement with the complementary receptacle. As illustrated in FIGS. 12a and 12b, the cylindrical head 163, which is a smaller-diameter continuation of the screw shank 124, is fitted with engageable teeth 167 in the parallel plane (along the long axis of shank 124) and engageable teeth 165 in the perpendicular plane. The distal end portion of the elongated body 132 is provided with a receptacle 147 which is complementary to the cylindrical head 163 of the distal segment 120. Receptacle 147 has a central bore and engageable teeth in both the parallel and perpendicular planes relative to the long axis of the proximal segment to accommodate and engage teeth 163 and 165 of the distal element 120.

[0063] The elongated body 132 of the proximal segment 130 has an engageable proximal end portion 181, which is

adapted to be rotated, as for example, by means of a wrench **191**. Similarly, the proximal segment **130** is rotatable by means of a wrench **189**. With rotation, the proximal segment **130** advances along threads **119** to the receptacle **147** of the proximal segment around the cylindrical head **163** of the distal segment to produce a rigid distraction screw.

[0064] Wrench **191** is used to engage the end portion **181** of the proximal segment **132** to effect its rotation. The teeth within receptacle **147** of the proximal segment engage the complimentary teeth **165** and **167** of the distal segment, which rotates the distal segment and drive threads **111** into the underlying bone. Once the bone work has been completed, wrench **189** is used to rotate the proximal segment **130** in the direction opposite to that used during engagement causing it to retreat along threads **119**. In this way, the head portion **163** can be disengaged from the receptacle **147** thus leaving the distal segment **120** attached to the bone. One of ordinary skill in the art will understand that the engageable arrangements described herein are illustrative and not restrictive, and that any engageable means may be alternatively used at any of these points of contact.

[0065] The distal segment **120** of the distraction screw **10**, which remains securely affixed onto the vertebral bone, provides enhanced structural integrity of the bone by reducing the stress concentration generally expected of an empty opening in a structural member. Leaving the distal segment **120** in place further eliminates the robust bone bleeding encountered after removal of current, commercially-available distraction screws and obviates the need to fill the holes with a hemostatic agent.

[0066] The distal segment **120** can also provide a point of anchoring for a skeletal plate **30** or other prosthetic devices to adjust, align and maintain the spatial relationship(s) of adjacent bones or bony fragments during healing and fusion after surgical reconstruction, as shown in FIG. 4. Since placement of the distraction screws is performed as the first step in the surgical procedure, the anatomical landmarks required to ensure proper alignment of the plate or other prosthetic device in the desired anatomical plane are still intact.

[0067] Plate fixation using the affixed distal segment is largely similar for the many mono-axial embodiments illustrated. For simplicity, it will be described in detail for the first embodiment alone. As shown in FIG. 4, a skeletal plate **30** is mounted onto the distal segment, where head portion **160** is adapted with peripheral surface contour to fit an opening **32** of the skeletal plate. A mounting plate **212** having a tapered opening **214** centers the screw **210** in alignment and engagement with the threads **162** of the head portion. The mounting plate **212** also serves as a washer to assert the necessary force onto the skeletal plate **30** to be secured onto the bone substrate **20**. In this way, the distal segment guides the placement of the plate and maximize the likelihood of correct anatomical alignment. It will also provide an additional point of attachment for the plate or device and enhances the structural integrity of bone/plate interface.

[0068] It is accepted that fusion of a specific spinal level will increase the load on the disc space immediately above and below the fused segment. Over time, the increased load will promote degeneration of the adjacent discs and may ultimately require that they be removed and the fusion extended to the adjacent bony level. In that event, the mounting plate **212** can be removed, permitting access to the distal segment **120**. The proximal segment **130** and the elongated member **136** can be reattached to the distal segment **120** and, thus, reconstitute the distraction screw without removal.

[0069] A second distraction screw is placed into the bone of the new operative level and the surgical reconstruction is

performed. After the necessary work, the proximal segments **130** are removed from each distraction screw, leaving distal segments **120** securely affixed to the vertebral bodies. A bone plate or device is affixed to maintain the spatial relationships of the new operative level while bone healing and fusion progress. Again, each distal segment **120** so affixed provides an additional point of attachment for the plate or device.

[0070] In other embodiments of the present invention, the distal segment incorporates a poly-axial design feature, which further facilitates the mounting of the skeletal plate **30** onto the vertebral bone. As used herein, "poly-axial" refers to the ability for the head portion of the distal segment to rotate about an axis that is other than that of the longitudinal axis of the threaded shank. This design provides a ready mechanism through which a skeletal plate may be affixed onto an implantable distal segment that has been placed into the skeletal bone at an angle other than the perpendicular. This situation arises when the degenerated bony elements have suffered significant mal-alignment, requiring that the distraction screws be placed at an angle to the bone surface in order to achieve the trajectory needed to realign the bones.

[0071] Examples of the poly-axial head design are illustrated in FIGS. 13, 14, 15 a-c, 16a, 16b, 17 and 18. With such a feature, a poly-axial distal segment **220** incorporates a head portion **222**, which generally assumes the geometric shape of a spherical segment, or cup shape, and a neck portion **224** with a narrower cross-sectional profile that tapers to the shank portion **226**. A poly-axial head adapter **230** is swivelably fitted over the head portion **222**. The poly-axial head adapter **230** has a ring body **232**, which has an internal ring opening with a smaller internal diameter at its lower portion **234** than its upper portion thus forming a socket arrangement. The lower portion **234** also has a smooth concave external contour **236**.

[0072] Poly-axial head adapter **230** is installed over the head portion **222** by way of the opening at its lower ring portion. A rotational space between the poly-axial head adapter **230** and the head portion **222** is provided to allow the poly-axial head adapter to move. This type of connection can be considered a ball joint, or socket connection, though other means for providing a connecting relationship between the poly-axial head adapter and the head portion while permitting varying degrees of rotational flexibility (swivelability) can also be adapted.

[0073] A flange **228** is located between the neck portion **224** and the shank portion **226**, on which the poly-axial head adapter **230** can be rested. Flange **228** also provides as a stop when the shank **226** is inserted onto the bone structure, as well as a measure of the depth of the shank implant. A concave curvature in the lower portion of the flange **228** allows the maximum thread/bone contact and support when the distal segment **220** is affixed in an inclined angle relative to the surface of the bone **20**.

[0074] Coupling of the proximal segment **130** and the distal segment **220** in this embodiment can employ any of the coupling designs described in detail for the mono-axial distal segment. These methods include, but are not limited to, the design illustrated in FIGS. 13 and 14. Once coupled, the segments will function as a unitary device. By applying a rotational force to the proximal segment **130**, the threaded shank of the distal segment **226** can be advanced and secured into the underlying bone, as described for the mono-axial design.

[0075] Following the distraction work and detachment of the proximal segment from the implantable distal segment, the skeletal plate **30** can be mounted onto the implantable

distal segment. As shown in FIG. 15, the adapter ring 230 is peripherally contoured for it to be fitted within an opening 32 of the skeletal plate 30.

[0076] Poly-axial head adapter 230 has an open top with internal circumferential thread 238 for receiving a mounting plate 242 with complementary threads 244. As shown in FIGS. 15, 15a and 15b, mounting plate 242 has a circular-shaped top flange 246, which is seated on the rim 34 of the opening 32 of the skeletal plate 30. After the skeletal plate 30 is mounted onto the adapter ring 230, the mounting plate 242 is threaded onto its internal thread 238, thus forming a unitary piece. Before the threads 242 and 238 are completely engaged, the skeletal plate can be tilted or rotated for it to be aligned in proper placement. Since the adapter ring 30 is swivelable in relation to the head portion 222, skeletal plate 30 can be easily manipulated to assume the desired position in relation to the bone structure despite the other than normal or vertical entry of the distal segment onto the bone structure.

[0077] After placement of the bone plate 30, the mounting plate 242 is tightened against the thread 238. The force asserted by the thread engagement draws the head adapter close to the mounting plate, which in turn closes the space between the lower portion 234 of the adapter ring and the head portion 222 and to firmly secure the head adapter onto the distal segment as well as the skeletal plate. As shown in FIG. 15a, the mounting plate has a central opening 250 into which a turning device can be inserted to facilitate its turning. Although illustrated as a hexagonal opening into which an "Allen" wrench driver may be deployed, any engagement method consisting of a driver and complementary receptacle can be employed.

[0078] FIGS. 16a, 16b, 17 and 18 show another variation in the poly-axial design feature. The poly-axial head adapter 310 is provided with a cap 312, which is coupled to the head adapter by means of threads 318. In assembly, screw 274 is fitted into the poly-axial head adapter 310 and cap 312 is used to engage threads 318. The screw 274 has a head portion 276 and a flat top 278. The cap 312 has a central opening 316 with internal threads 320, which is adapted to receive the threaded, rounded distal end 402 of the deployable member 136. Cap 312 may be further adapted to receive an optional rotation locking means. While the key design (opening 314) is illustrated for simplicity, it is understood that the rotation locking means may be of any engageable configuration.

[0079] After key 170 is fitted into the key opening 314, the deployable member is extended to pass through the threaded opening 316 and to push against the top surface 278 of the screw 274. As the threaded distal portion is rotated further in relation to threads 320, the force exerted by the rounded end 402 on surface 278 causes the under surface of the screw head 276 to firmly engage portion 322 of head adapter 310, forming a unitary distraction screw. With distraction screw assembly, it is important that the long axis of the proximal segment 130 be the same as the long axis of screw 274, permitting uniform rotation of both segments along a common axis. In use, a rotational torque is applied to the proximal segment 130, which is translated by the key 170 to the head adapter 310 and, in turn, to screw 274. The shank rotates and engages the underlying bone.

[0080] Following distraction and bony realignment, the proximal portion is detached from the poly-axial head adapter, leaving the implantable distal segment affixed to

bone. The skeletal plate 30 is mounted with its opening 32 to fit over the peripherally contour of the distal segment and is manipulated to assume the desired position. The swivel action of the poly-axial head adapter permits proper placement of the skeletal plate even with angled placement of bone screw 274. A mounting plate 324 is seated on the stepped rim 34 of the opening 32 of the skeletal plate 30. It has a central opening 326 through which a mounting screw 328 can be passed to engage threads 320 of screw cap 312. As the threads are tightened, force is exerted onto surface 278 by the rounded end of screw 328 causing the under surface of the screw head 276 to firmly engage portion 322 of head adapter 310, and locking the poly-axial head portion to screw 274. The same action also effects a force on the mounting plate, bearing against the step rim 34 of the skeletal plate 30 for it to be securely anchored. For this embodiment, it is understood that a space is provided between the screw cap and the mounting plate to provide for the engagement of the poly-axial head adapter and the head portion.

[0081] From the above, it is apparent that the poly-axial design will produce a highly versatile distraction screw and can be used even with significantly mal-aligned bony structures. The ability of adapter ring 310 to rotate and swivel permit it to accommodate and orient the skeletal plate 30, thus ensuring proper alignment and correct plate fixation.

[0082] As described above, the present invention is that of a distraction screw and its use. It provides a significant design advantage over existing art by decreasing the bone stress encountered at the empty bone holes and reducing the extent of operative bleeding. The present design also provides an additional point of fixation for the implantable plate/prosthesis, maximizes the likelihood of proper plate/prosthesis alignment, and provides a ready mechanism for modular extension of the surgical reconstruction to adjacent levels at a future date. While the different embodiments of the present invention have been illustrated as consisting of a proximal and distal segment, it is understood that a modular distraction screw may be constructed from more than two components. The preceding descriptions and accompanying drawings are to be considered as illustrative and not restrictive in character. Further understanding of the present invention, and other embodiments as described herein can be obtained through a review of the claims.

1. A method for implanting a prosthetic device onto a mammalian bone structure comprising:

- (a) assembling a distraction screw, which comprises a proximal segment having an elongated body with an internal bore extending through the length of the elongated body; a deployable member disposed within the internal bore of the elongated body and adapted to be retractably deployed outside the internal bore and a prosthetic device including a head portion and a threaded shank portion and being detachably coupled to the elongated body; rotatably manipulating the distraction screw to effect the threading of the shank portion onto the mammalian bone structure; and
- (b) detaching the elongated member segment from the prosthetic device onto the mammalian bone structure.

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