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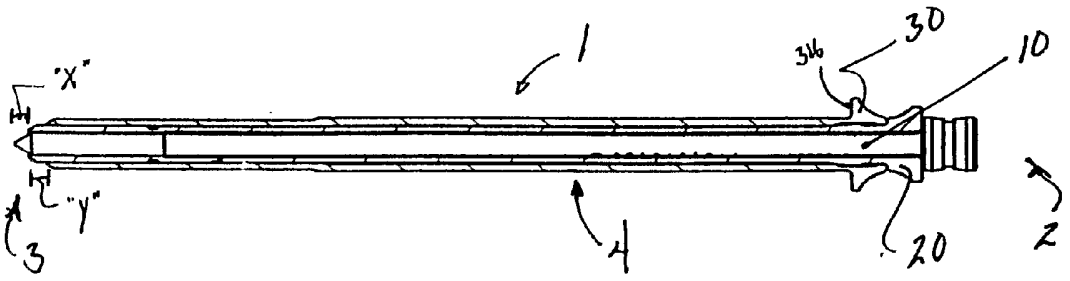
(54) Title: SNAP-LOCK FOR DRILL SLEEVE



(57) Abstract: A device for drilling a hole in bone and for inserting bone screws into the drilled hole is provided. The device comprises a trocar, drill sleeve and protection sleeve in a telescopically nested configuration. The drill sleeve and protection sleeve may have an axial locking feature that allows the two pieces to be handled together as a unit by preventing inadvertent separation. The axial locking feature may comprise an integral annular ridge provided on one sleeve that cooperates with an annular groove provided on the other sleeve. One sleeve may also have at (east one slot allowing the locking feature to be disengaged prior to separation of the sleeves. The sleeves may be easily separated with one hand by the user by the application of an axial separation force between a pair of flanges provided with the sleeves, and by a radial compression force applied to at least a portion of the drill sleeve.

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SNAP-LOCK FOR DRILL SLEEVE

FIELD OF THE INVENTION

[0001] The present invention is related to a drill sleeve system. More particularly, the invention is related to a snap lock design for provisionally retaining a drill sleeve to a screw insertion sleeve.

BACKGROUND OF THE INVENTION

[0002] Orthopedic fixation devices such as plates are frequently coupled to bone with fasteners inserted through holes in the device. For fractures of the long bones such as the humerus or the femur, fractures may be treated by inserting an elongated member into a channel reamed in the intramedullary canal. This elongated member, or "intramedullary nail" as it is known in the art, may provide stability to the bone until the fractured bone segments heal together. Intramedullary nails may be fastened to the bone in which they reside using screws inserted through pre-formed holes in the nail. Corresponding holes may be drilled in the adjacent bone to allow easier insertion of the screws in the bone. These holes can be formed with the aid of a drill guide aligned with the targeted screw hole. A drill may be introduced through the drill guide is thus guided through the screw hole to drill a hole in the bone underlying the screw hole.

[0003] In an effort to reduce the total number and length of incisions created when installing the intramedullary nail and inserting the securing fasteners, the drilling and screw insertion process can be performed percutaneously. Thus, an incision may be made in the skin overlying the bone, and a trocar may be inserted into the incision and used to separate the soft tissue to create an initial passage down to the bone. A drill may be inserted through the drill sleeve and used to form

a hole in the bone as previously described. A screw insertion sleeve may thereafter be inserted through the passage and used to facilitate engagement of the screw with the screw hole and bone. Advantageously, these three pieces (trocar, drill sleeve, screw insertion sleeve) may be provided as a single unit to facilitate handling and use by the surgeon. Thus, the three pieces may be nested within each other and inserted as a single unit.

[0004] To further facilitate use of these three-piece units, at least two of the pieces may be provided with features aimed at preventing separation of the individual pieces while they are being handled by the user. For example, snap rings, ball detents, or threads may be used to secure the pieces together. To remove one piece from the other (*e.g.* to remove the drill sleeve from the screw-insertion sleeve), the user may pull the pieces apart (in the case of a snap-ring or ball-detent) or may unthread the pieces (where threaded pieces are provided).

[0005] Snap-ring locking devices may be difficult to sterilize, and threaded pieces may be difficult to handle in the surgical environment. Thus there exists a need for a multiple piece drill sleeve system having a simple, easy to sterilize design for provisionally retaining at least two pieces of the system with respect to each other, and which allows easy separation of those pieces when desired by the user.

SUMMARY OF THE INVENTION

[0006] An orthopedic system is disclosed comprising a first sleeve member having an outer surface and an inner surface defining a longitudinal bore and a surface; and a second sleeve member having an outer surface and an inner surface defining a longitudinal bore, where the second sleeve member may further be configured to be at least partly received within the bore of the first sleeve member. The longitudinal bore of one of the first and second sleeves may be

configured to receive a drill bit therethrough to drill a hole in bone. Further, one of the first and second sleeve members may further comprise a protrusion and the other may comprise a corresponding recess, the protrusion and recess being co-operable to provisionally axially lock the first and second sleeve members together when the second sleeve member is at least partly received within the bore of the first sleeve member. The second sleeve may be dis-engageable from the first sleeve through the application of an axial separation force between the first and second sleeves and a radial compression force to at least a portion of the second sleeve.

[0007] The system may also comprising a trocar configured to be received within the longitudinal bore of the second sleeve. The first and second sleeve members further may each have a proximal end comprising a flange member and a distal end comprising a tapered tip region. The longitudinal bore of the first sleeve may further be configured to receive a driver and bone fastener therethrough to allow insertion of the fastener into bone in a direction along the longitudinal axis of the bore. Moreover, the tapered tip of at least one of the first or second sleeve members configured to align with a fastener hole in a bone fixation element. The bone fixation element may be a bone plate or an intramedullary nail.

[0008] The protrusion may be integrally formed with the associated sleeve, and in one embodiment may comprise at least one circumferential ridge. The recess may comprise at least one circumferential groove corresponding to the at least one ridge. The protrusion further may comprise first and second tapered surfaces.

[0009] The second sleeve may comprise at least one longitudinal slot disposed between the inner and outer surfaces of the sleeve, the slot running from

at least one end of the sleeve and having a length, the slot further configured to render at least a portion of the sleeve radially flexible.

[0010] The at least one slot may divide a first end of the sleeve into first and second halves, wherein pressing the first and second halves toward each other may disengage the ridge from the recess, thereby allowing the first and second sleeves to be axially engaged with, or disengaged from, each other.

[0011] The second sleeve may have two longitudinal slots diametrically disposed with respect to each other about the circumference of the sleeve. The protrusion may comprise at least one tapered surface configured to facilitate radial compression of the second sleeve when the sleeve is inserted into the bore of the first sleeve.

[0012] The first and second sleeves and the trocar may be color coded to provide a visual indication of the size of a bone screw that can be received through the bore of the first sleeve.

[0013] The outer surface of the first sleeve may be configured to be received within the bore of an aiming arm of an intramedullary nail to align the sleeve with a targeted fastener hole in a portion of the intramedullary nail.

[0014] An orthopedic system is provided comprising a first sleeve having proximal and distal ends, a longitudinal axis and inner and outer surfaces.

[0015] A second sleeve may be provided having proximal and distal ends, a longitudinal axis, and inner and outer surfaces, where the inner surface is configured to receive at least a portion of the first sleeve. The inner surface may further be configured to receive a bone fastener and driver for inserting the fastener into the hole drilled in bone. The inner surface of at least one of the first and second sleeves may be configured to receive a drill bit for drilling a hole in bone. At

least a portion of the first sleeve may be slidably receivable within at least a portion of the second sleeve.

[0016] One of the second sleeve inner surface and the first sleeve outer surface may comprise a projection, and the other may comprise a corresponding recess so that when the first sleeve is received within the second sleeve, the projection and recess may cooperate to releasably axially engage the first sleeve with the second sleeve.

[0017] The projection may be integrally formed with the associated sleeve. The protrusion may also comprise at least one circumferential ridge, or a plurality of discrete protruding elements. The recess may comprise at least one circumferential groove corresponding to the at least one ridge. The protrusion may comprise first and second tapered surfaces configured to engage a portion of the inner surface of the second sleeve.

[0018] The sleeves may be disengageable from each other by applying an axial separation force between the first and second sleeves and a radial compression force to at least a portion of the first sleeve.

[0019] The system may further comprise a trocar configured to be received within the longitudinal bore of the first sleeve. The sleeves further may each have a proximal end comprising a flange member and a distal end comprising a tapered tip region. The tapered tip of at least one of the first or second sleeves may be configured to align with a fastener hole in a bone fixation element. The bone fixation element may be a bone plate or an intramedullary nail.

[0020] The first sleeve may comprise at least one longitudinal slot disposed between the inner and outer surfaces of the sleeve, the slot running from at least one end of the sleeve and having a length, the slot further configured to render at least a portion of the sleeve radially flexible. The at least one slot may divide a first

end of the first sleeve into first and second halves, wherein when the first sleeve is fully received within the second sleeve, pressing the first and second halves toward each other disengages the ridge from the recess, thereby allowing the first sleeve to be removed from the second sleeve.

[0021] When the first sleeve is inserted into the second sleeve, the first tapered surface may cooperate with the inner surface of the second sleeve to radially compress the first and second halves together. The first sleeve may have two longitudinal slots diametrically disposed with respect to each other about the circumference of the sleeve. The protrusion may comprise at least one tapered surface configured to facilitate radial compression of the first sleeve when the sleeve is inserted into the bore of the second sleeve.

[0022] The first and second sleeves and the trocar may be color coded to provide a visual indication of the size of a bone screw that can be received through the bore of the first sleeve.

[0023] Moreover, the outer surface of the first sleeve may be configured to be received within the bore of an aiming arm of an intramedullary nail to align the sleeve with a targeted fastener hole in a portion of the intramedullary nail.

[0024] A method of drilling a hole in bone is provided, comprising: (a) providing a drill sleeve and protection sleeve combination, the drill sleeve telescopically receivable within at least a portion of the protection sleeve, the drill sleeve having an inner surface for receiving a drill bit for drilling a hole in a bone, the drill sleeve having an outer surface comprising one of a projection and a recess configured to engage a corresponding recess or projection disposed on an inner surface of the protection sleeve to provisionally axially lock the sleeves together; wherein the drill and protection sleeve are separable from each other through the application of an axial separation force between the sleeves and a radial

compression force to at least a portion of the drill sleeve; (b) advancing the drill sleeve and protection sleeve combination through an incision in a patient; (c) advancing the drill sleeve and protection sleeve to align with a bone fixation element overlying a portion of the bone; (d) inserting a drill bit through the drill sleeve and advancing the drill bit to engage bone; (e) rotating the drill to produce a hole in the bone; (f) removing the drill bit from the drill sleeve; and

(g) applying an axial separation force between the drill sleeve and the protection sleeve and applying a radial compression force to a portion of the drill sleeve to disengage the two.

[0025] The drill sleeve and protection sleeve further may comprise a trocar configured to be received within the longitudinal bore of the drill sleeve. The sleeves further each have a proximal end comprising a flange member and a distal end comprising a tapered tip region. The bone fixation element may be a bone plate or an intramedullary nail. The projection may be integrally formed with the associated sleeve. The projection may comprise a plurality of discrete protruding elements. The projection may comprise at least one circumferential ridge. The recess may comprise at least one circumferential groove corresponding to the at least one ridge. The protrusion may comprise first and second tapered surfaces configured to engage a portion of the recess.

[0026] The drill sleeve may comprise at least one longitudinal slot disposed between the inner and outer surfaces of the sleeve, the slot running from at least one end of the sleeve and having a length, the slot further configured to render at least a portion of the sleeve radially flexible. the at least one slot may divide a first end of the drill sleeve into first and second halves so that when the drill sleeve is fully received within the screw insertion sleeve, pressing the first and

second halves toward each other may disengage the protrusion from the recess, thereby allowing the drill sleeve to be removed from the screw insertion sleeve.

[0027] The method may comprise the additional steps of: (g) inserting a bone fastener and screwdriver through the protections sleeve; and (h) driving the bone fastener into the hole in the bone to fix the bone fixation element to the bone.

[0028] The method may further comprising the step, between steps (a) and (b), of: inserting the outer surface of the protection sleeve into a bore in an aiming arm attached to an intramedullary nail; step (c) may further comprise advancing the protection sleeve and drill sleeve through the bore in the aiming arm to align with a fastener hole in the bone fixation element; and step (e) comprises drilling a hole in the bone through the fastener hole in the intramedullary nail.

[0029] The method may further comprising the steps of: (h) inserting a bone fastener and screwdriver through the protection sleeve; (i) driving the bone fastener into the hole in the bone to fix the bone fixation element to the bone; and (j) removing the protection sleeve from the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] Preferred features of the present invention are disclosed in the accompanying drawings, wherein similar reference characters denote similar elements throughout the several views, and wherein:

[0031] **FIG. 1** is a cross sectional assembled view of a protection sleeve, drill sleeve and trocar device of the present invention.

[0032] **FIGS. 2a** and **2b** are side and detail views of the trocar element of the device of **FIG. 1**;

[0033] **FIGS. 3a** through **3e** are side, top, partial detail and detail views, respectively, of the drill sleeve of the device of **FIG. 1**;

[0034] **FIGS. 4a**, **4b** and **4c** are side, cross-section and detail cross-section views, respectively, of the protection sleeve of the device of **FIG. 1**;

[0035] **FIGS. 5a** and **5b** are side and cross-section views of the drill sleeve of **FIG. 3a** employing an alternative retention feature design;

[0036] **FIGS. 6a** and **6b** are side and cross-section views of the protection sleeve of **FIG. 4a** for use with the drill sleeve retention feature design of **FIGS. 5a** and **5b**;

[0037] **FIG. 7** is a side view of an exemplary drill bit for use with the device of **FIG. 1**;

[0038] **FIG. 8** is a side view of an exemplary bone screw for use with the device of **FIG. 1**;

[0039] **FIG. 9** is a cross-section view of the device of **FIG. 1** without the trocar, and with the drill bit of **FIG. 7** inserted through the drill sleeve;

[0040] **FIG. 10** is a cross-section view of the system of **FIG. 1** without the trocar and drill sleeve, and with a screw and screwdriver inserted through the protection sleeve;

[0041] **FIGS. 11a** through **11c** are perspective views of the device of **FIG. 1** being used with an aiming arm of an intramedullary nail assembly inserted in a femur;

[0042] **FIGS. 12a** and **12b** are side and cross section views of a wire guide sleeve for use with the protection sleeve of **FIGS. 4a-c**;

[0043] **FIG. 13** is a partial cross section view of a drill used with the protection sleeve of **FIGS. 4a-c**;

[0044] **FIG. 14** is a side view of a guide wire for use with the protection sleeve of **FIGS. 4a-c** and the wire guide sleeve of **FIGS. 12a-b**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0045] A drilling and screw insertion sleeve device is disclosed for use in installing fasteners for securing orthopedic fixation devices, such as bone plates, intramedullary nails, and the like, to bone segments of the human anatomy. Such fixation devices may be used to repair fractured bones or may be installed to protect against the fracturing of weak bones. **FIG. 1** shows an exemplary device **1** for such use, comprising a trocar **10**, a drill sleeve **20** and a protection sleeve **30**. As illustrated, the trocar **10**, drill sleeve **20** and protection sleeve **30** are in a nested configuration which allows them to be introduced through a surgical incision as a single unit. Thus, when the device **1** is used for drilling holes and placing screws in bone, the device **1** may be inserted through a single incision made through the patient's skin immediately overlying one or more bone screw holes of a plate, nail, etc. The individual elements of the system may then be removed as necessary to perform the desired procedure. For example, the trocar **10** may be removed after the device **1** has been appropriately placed in contact with the patient's bone or the screw hole of a fixation device.

[0046] As shown in **Fig. 1**, the device **1** has a proximal user end **2**, a distal incision end **3**, and a generally cylindrical longitudinal central portion **4** generally formed by the outer surface of the protection sleeve **30**. The proximal end **2** is configured for easy grasping by the user, and the distal end **3** may have a tapered configuration to facilitate insertion into an incision in the patient.

[0047] Referring to **Figs. 2a** and **2b**, the trocar **10** comprises a rod-like member having proximal and distal ends **110, 120** and a cylindrical center portion **130** having an outer diameter **"td,"** a longitudinal axis **"A-A,"** and a length **"tl."** The proximal end **110** may comprise a flange element **112** having an increased diameter **"tfd,"** and an outer gripping surface **114** configured to be easily grasped

by a user. The flange element **112** may further comprise a proximal end face **116** and a distal face **118.** The proximal end face **116** may be configured to receive a user input force, such as may be applied by the thumb or palm of the hand, while the distal face **118** may be configured to engage a proximal face **214** of the drill sleeve flange **212** to transmit the applied user input force thereto.

[0048] The trocar flange element **112** may have one or more annular grooves **119** that have a band of color applied to distinguish the trocar as being of a particular size. That is, since the inventive system may be provided in any of a variety of sizes, it may be advantageous to provide a simple color-coding of the device elements to provide a clear visual indication to the user of the system size. Thus, groove **119** may be provided with a band of color that matches similar color bands provided on the drill sleeve **20,** protection sleeve **30**, and drill **40** of the same system size. Color may be applied to the groove **119** by painting or other appropriate technique.

[0049] The trocar distal end **120** may be tapered to allow easier insertion into the incision in the patient. The taper may form an angle **θ** with respect to the longitudinal axis "**A-A**," which in the illustrated embodiment is about 30°, although other angles may be provided. The distal end **120** may have a tip portion **122** forming a sharp point to further facilitate movement of the trocar **10** (as well as drill sleeve **20** and protection sleeve **30**) **1** through the surrounding tissue. In use, the tip portion **122** may be used to separate the soft tissue as it is being pressed into and through the incision.

[0050] Referring to **Figs. 3a** through **3e**, an exemplary drill sleeve **20** is shown having proximal and distal ends, **210**, **220,** a central cylindrical portion **230** having a longitudinal axis "**B-B**", and a length "**dsl**." The drill sleeve **20** further may have an outer cylindrical surface **232** having a diameter "**dod,**" and an inner

cylindrical surface **234** having a diameter "**did**" defining a longitudinal bore **236** running along the length "**dsl.**"

[0051] The drill sleeve bore **236** may be sized to accept the cylindrical center portion **130** of trocar **10** during insertion of the sleeve **20** into the patient as part of system **1,** and as illustrated in **Fig. 1**. The bore **236** may also be sized to accept an appropriately sized drill bit **40 (Figs. 7, 9)** to allow drilling of underlying bone through the drill sleeve **20** along longitudinal axis "**B-B**" once the sleeve **20** has been introduced through the incision.

[0052] The proximal end **210** of the drill sleeve **20** may comprise a flange **212** having a diameter "**dsfd**" that is greater than the sleeve outer diameter "**dod.**" The flange **212** may further have a proximal end face **214** configured to engage the distal end face **118** of the trocar **10** when the trocar is fully inserted into the drill sleeve **20 (*see* Fig. 1).** The flange **212** may further have a distal end face **216** configured to engage a proximal annular end face **314** of the protection sleeve **30** (***see* Figs. 1** and **4b**), as will be described in more detail later.

[0053] As shown in **Fig. 3a**, to facilitate insertion of the trocar **10** within the drill sleeve **20,** bore **236** may taper slightly outward at a point immediately adjacent the sleeve proximal end **210.**

[0054] The drill sleeve flange **212** may have an outer gripping surface **218** configured to allow easy grasping by a user. In the illustrated embodiment, the outer diameter of the proximal end face **214** is larger than the outer diameter of distal end face **216,** such that gripping surface **218** disposed therebetween is angled to face slightly in the distal direction. Gripping surface **218** is also slightly concave to more closely conform to the user's fingers as they may be applied to pull the drill sleeve **20** out of engagement with protection sleeve **30.**

[0055] The drill sleeve distal end **220** may be tapered to allow easier insertion into the incision in the patient. The taper may form an angle **α** with respect to the longitudinal axis "**B-B**," which in the illustrated embodiment is about 30°, and which substantially matches angle **θ** of the trocar distal end **120**. The length "**dsl**" may be such that when the trocar **10** is inserted through the bore **236** of the drill sleeve, the distal tip **122** extends a distance "**x**" distally beyond the distal end **220** of the drill sleeve **20** (***see* Fig. 1**). This distance "**x**" may be selected so that the tapered ends **122, 220** of the trocar **10** and drill sleeve **20** correspond to form one relatively smooth tapered surface which may facilitate the insertion and advancement of the two pieces into a patient incision.

[0056] The drill sleeve **20** may further incorporate a locking feature to provisionally axially retain the drill sleeve within the protection sleeve **30** during handling and installation. This locking feature may be easily overcome by the application of finger pressure between the drill and protection sleeve flanges **212, 312 (Fig. 4a)**, as previously noted. In the embodiment illustrated in **Figs. 3a** & **3c**, the locking feature comprises a circumferential ridge **2000** located adjacent proximal end flange **212.** As illustrated in **Fig. 3c**, ridge **2000** may have first and second tapered surfaces **2010, 2020** and a top surface **2030** having a height "**rh**" . The first and second tapered surfaces **2010, 2020** may be oriented at taper angles **γ, σ** with respect to the longitudinal axis "**B-B**" of the drill sleeve **20.** The tapers **2010, 2020** may allow smooth engagement and disengagement of the circumferential ridge with an internal recess **3000** (**Fig. 4c**) of the protection sleeve **30,** as will be described in more detail later. To further facilitate engagement/disengagement, one or both of the tapered surfaces may also be slightly concave. Thus, when the drill sleeve **20** is inserted into the protection sleeve **30,** the first tapered surface **2010** may engage the inner surface **334** of the

protection sleeve **30** to provide a smooth compression of the proximal end **210** of the drill sleeve **20**. Once the ridge **2000** is fully engaged with the recess **3000**, the second tapered surface **2020** may contact the proximal end wall **3010** of the recess **3000** in the protection sleeve **30** to prevent the drill sleeve **20** from falling out of the proximal end **210** of the protection sleeve **30** during normal handling.

[0057] In one embodiment **(Fig. 3c)**, the second surface taper angle σ may be greater than the first surface taper angle γ to result in a relatively low required engagement force between the pieces **20, 30** and a slightly higher disengagement force for separation of the pieces. It is noted that although the ridge **3000** is illustrated as having unequal first and second taper angles γ, σ, the drill sleeve **20** could be provided with equal taper angles (***see* Fig. 5b**).

[0058] γ may be from about **5** degrees to about **90** degrees, and in one embodiment, γ is about **30** degrees. σ may be from about **1** degree to about **90** degrees, and in one embodiment, σ is about **5** degrees. Ridge height "**rh**" may be from about **0.2** mm to about **1.0** mm, and in one embodiment is about **0.4** mm.

[0059] As shown in **Fig. 3a**, a pair of longitudinal slots **2050, 2060** may be provided in diametrically opposed relationship in the drill sleeve proximal end **210** to allow compression of the drill sleeve **20** so that the circumferential ridge **2000** may engage the protection sleeve recess **3000**. Thus, the slots **2050** may divide the proximal end **210** of the drill sleeve into first and second opposing halves **2110, 2120** that may be flexed toward each other to temporarily reduce the outer dimension of the circumferential ridge **2000** during installation and removal of the drill sleeve **20** from the protection sleeve **30.**

[0060] As shown **in Fig. 3a**, the slots **2050, 2060** may run from the drill sleeve proximal end **210** to a location between the sleeve proximal and distal ends **210, 220.** The slots **2050, 2060** may have a length "**sl**" and a width "**sw**," and at

their distal ends may be provided with a stress-reducing enlarged cutout **2070**, which in the illustrated embodiment is a circular cutout. Slot length "**sl**" may be from about **20** mm to about **150** mm, and in one embodiment is about **65** mm. Slot width "**sw**" may be from about **0.5** mm to about **3.0** mm, and in one embodiment is about **1.0** mm.

[0061] It is noted that while the drill sleeve of **Fig. 3a** has been described as having a pair of slots **2050, 2060**, drill sleeve **20** could be provided with one or more slots, as desired. Further, where more than one slot is employed, the slots may have different lengths and/or different widths. Furthermore, the slots may have varying widths along their respective lengths.

[0062] As shown in **Figs. 3a** and **3e**, side flats **2080, 2090** may be provided on the outer surface **232** of the drill sleeve adjacent the drill sleeve proximal end **210**. These flats **2080, 2090** may be disposed at 180 degree intervals, and may be centered on the slots **2050, 2060** to further facilitate insertion of the drill sleeve **20** into the protection sleeve **20.** Since the slots **2050, 2060** only allow compression of the drill sleeve **20** in one dimension, the flats **2080, 2090** eliminate the remaining interference between the circumferential ridge **2000** and the inner surface **334** of the protection sleeve **30** adjacent **to** the slots **2050, 2060.** It is noted that providing the drill sleeve **20** with more than two slots may allow the sleeve to be compressed in two dimensions, and thus the side flats **2080, 2090** may not be required.

[0063] As with the trocar **10,** the drill sleeve **20** may be color-coded to distinguish the sleeve as corresponding to a particularly sized drill bit. Thus, the central cylindrical portion **230** may have an annular groove **232** formed in the outer surface **232** into which a band of color may be applied. The color applied may match the color applied to a trocar **10** that is sized to be received within the bore **236** of the drill sleeve **20**.

[0064] Referring to **Figs. 4a** through **4c**, an exemplary protection sleeve **30** is shown having proximal and distal ends, **310**, **320**, a central cylindrical portion **330** having a longitudinal axis "**C-C**", and a length "**psl**." The protection sleeve **30** further may have an outer cylindrical surface **332** having a diameter "**pod,**" and an inner cylindrical surface **334** having a diameter "**pid**" defining a longitudinal bore **336** running along the length "**psl.**"

[0065] The protection sleeve bore **336** may be sized to accept the cylindrical center portion **230** of drill sleeve **20** during insertion of the sleeves **20, 30** into the patient as part of system **1,** and as illustrated in **Fig. 1**. The bore **336** may also be sized to accept an appropriately sized screw **50** and screwdriver **60 (Fig. 10)** to facilitate insertion of the screw into the underlying bone through the protection sleeve **30** along the sleeve longitudinal axis "**C-C**" once the sleeve **30** has been introduced through the incision. Thus, the inner diameter "**pid**" may be about **1.0** mm to about **17.0** mm to allow insertion of screws, spiral blades or helical blades therethrough. Further description regarding such blades is provided in co-pending United States nonprovisional patent application serial number 10/269,976 to Roth et al., filed October 15, 2002 and titled "Orthopedic Implant Insertion Instruments," the entirety of which application is incorporated herein by reference. Specifically, the protection sleeve 30 may receive screws having major diameters of from about 1 mm to about 8 mm and having head diameters of about 1.0 mm to about 12.0 mm.

[0066] The proximal end **310** of the protection sleeve **30** may comprise a flange **312** having a diameter "**psfd**" that is greater than the sleeve outer diameter "**pod**." The flange **312** may further have a proximal end face **314** configured to engage the distal end face **216** of the drill sleeve **20** when the drill sleeve is fully

inserted into the protection sleeve **30** (*see* **Fig. 1**). The flange **312** may further have a distal end face **316** configured to allow gripping by a user.

[0067] The protection sleeve flange **312** may further have an outer gripping surface **318** disposed between the proximal and distal end faces **314, 316** and configured to allow easy grasping by a user. In the illustrated embodiment, the outer diameter of the proximal end face **314** is smaller than the outer diameter of distal end face **316,** such that gripping surface **318** disposed therebetween is angled to face slightly in the proximal direction. Gripping surface **318** also may be slightly concave to more closely conform to the user's fingers as they may be applied to hold the protection sleeve **30** while pulling the drill sleeve **20** out of engagement with protection sleeve **30.**

[0068] As shown in **Figs. 4b** and **4c**, and previously described in relation to the circumferential ridge **2000** of drill sleeve **20,** the protection sleeve **30** may further have a recess **3000** disposed in the bore **336** adjacent the sleeve proximal end **310.** This recess **3000** may be configured to engage the circumferential ridge **2000** of the drill sleeve **20** when the drill sleeve is fully inserted into the protection sleeve **30.** The recess **3000** may have a diameter "**rd,**" and proximal and distal end surfaces **3010, 3020** that provide a transition between the recess **3000** and the bore **336.** Recess diameter may be sized to provide a recess depth "**rd**" of from about **0.2** mm to about **1.0** mm to provide the desired interference and locking with circumferential ridge **2000.** In one embodiment, the recess depth "**rd**" is about **0.6** mm. Further, to facilitate insertion of the drill sleeve **20** into the protection sleeve **30,** the bore **336** may taper slightly outward immediately adjacent the sleeve proximal end **310.**

[0069] The protection sleeve distal end **320** may be tapered to allow easier insertion into the incision in the patient. The taper may form an angle β with

respect to the longitudinal axis "**C-C**," which in the illustrated embodiment is about 30°, and which substantially matches angles **θ** and **α** of the trocar and drill sleeve distal ends **120, 220**. Further, the length "**psl**" may be such that when the drill sleeve **20** is inserted through the bore **336** of the protection sleeve, the distal end **220** extends a distance "**y**" distally beyond the distal end **320** of the protection sleeve **30 (see Fig. 1)**. This distance "**y**" may be selected so that the tapered ends **122, 220, 320** of the trocar **10,** drill sleeve **20** and protection sleeve correspond to form one relatively smooth tapered surface which may facilitate the insertion and advancement of the two pieces into a patient incision.

[0070] **Figs. 5a - 5c** show a drill sleeve **1200** having an alternative provisional retention feature comprising a raised circumferential ridge **1222** configured to engage a corresponding recess **1322** in an alternative protection sleeve **1300 (see Figs. 6a, 6b).** The ridge **1222** may be disposed on the outer surface **1232** of the sleeve **1200** adjacent the distal end face of flange **1212.** As shown in **Figs. 5a-5c** the drill sleeve **1200** may have a longitudinal slot **1224** formed in the proximal end **1210** and extending distally to intersect with an elongated window **1226** disposed between the inner and outer surfaces **1232, 1234** of the sleeve. This combination of slot **1224** and window **1226** provides the desired flexibility to the proximal end **1210** of the drill sleeve **1200** to allow it to be compressed so that the drill sleeve **20** can be received within the protection sleeve **30** as described previously in relation to the drill sleeve **20** of **Fig. 3a.**

[0071] **Figs. 6a - 6c** show a protection sleeve **1300** for use with the drill sleeve **1200** of **Figs. 5a - 5c** in which circumferential recess **1322** is disposed in inner surface **1334** adjacent proximal end flange **1312.** Recess **1322** may be configured to receive ridge **1222** of the drill sleeve **1200** when the drill sleeve is

inserted fully into the protection sleeve **1300** as described previously in relation to the drill sleeve **20** and protection sleeve **30** of **Figs. 3a** and **4a**.

[0072] Furthermore, it should be noted that the drill sleeve **1200** of **Figs. 5a - 5c** and the protection sleeve **1300** of **Figs. 6a-6c** may further incorporate any or all of the other features previously described in relation to the drill sleeve **20** and protection sleeve **30** of **Figs. 3a and 4a** (*e.g.* distal end taper, dimensions, color-coding, flange configurations, etc).

[0073] It should also be noted that although the invention has been described as having the projection formed on the drill sleeve and the recess formed in the protection sleeve, this arrangement may be reversed. Thus, a projection or projections may be provided on the inner surface of the protection sleeve and the corresponding recess or recesses may be provided on the drill sleeve outer surface.

[0074] Furthermore, the projection provided on the drill sleeve (or alternatively on the protection sleeve) may be formed by machining. Thus, if the sleeve itself is machined from a single piece of material, the projection may be formed during the general machining process. Alternatively, the projection may be provided by depositing a weld bead or fillet about the circumference of the drill sleeve/protection sleeve and then machining or grinding the bead or filled to the desired shape. Further, the projection may comprise a series of raised rivets or applied nubs integrated into the surface of the drill guide/protection sleeve and configured to engage the recess of the protection sleeve.

[0075] In yet another alternative embodiment, the projection could be formed using a short sleeve or annular ring applied to the drill sleeve or protection sleeve. Such an arrangement may simplify the machining of the drill sleeve/protection sleeve, since instead of being machined-in, the ring could be fixed in place using an

appropriate means, including welding, brazing, bonding, shrink fit or press fit to the associated sleeve.

[0076] **Fig. 7** shows an exemplary drill bit **40** for use with the device **1.** The drill bit **40** may have a proximal coupling end **410,** a distal drilling end **420** and a central cylindrical shaft portion **430** disposed therebetween. A set of calibration marks **440** may be provided along at least a portion of the shaft **430.** These calibration marks may be used to determine the depth to which the drill has been driven into bone. Thus, when the drill bit **40** is inserted into the drill sleeve **20** as shown in **Fig. 9**, the user may read the calibration mark **440** located directly adjacent the drill sleeve flange proximal face **214** to determine the distance beyond the distal end **220** of the drill sleeve **20** that the distal cutting end **420** of the drill **40** has been extended. This arrangement thus allows a quick and easy manner of determining drilling depth.

[0077] **Fig. 8** shows an exemplary fastener for use with the device **1** in which bone screw **50** has a head **510** and a threaded shank **520,** the head having a maximum diameter "**msd**" that is slightly smaller than the inner diameter "**pid**" of protection sleeve **30.** The head may further have a drive recess **530** configured to receive the driving tip **610** of screwdriver **60** (***see* Fig. 10**) to drive the bone screw **50** into bone. Thus, as illustrated in **Fig. 3,** protection sleeve **30** is sized to receive bone screw **50** and screwdriver **60** to allow the screw **50** to be driven into the underlying bone via protection sleeve **30** and along axis **"C-C."**

[0078] A method of using the invention to engage a bone fastener with a fixation device and underlying bone is also provided. To assemble the device **1,** drill sleeve **20** may be inserted into protection sleeve **30** until the circumferential ridge **2000** of the drill sleeve engages the proximal end **310** of the protection sleeve. Thereafter, the application of force against the drill sleeve **20,** while holding

the protection sleeve **30** steady, may cause the proximal end **210** of the drill sleeve to compress along slots **2050, 2060** allowing the circumferential ridge **2000** to pass into engagement with recess **3000** in the protection sleeve **30.** Once the ridge **2000** and recess **3000** are engaged, the sleeves **20, 30** are provisionally axially locked together. The trocar **10** may then be inserted into the drill sleeve **20.**

[0079] The assembled device **1 (Fig. 1)** may then be inserted into an incision in the patient overlying a targeted bone screw hole of a fixation element. The user may insert the pointed end **3** of the device **1** into the incision, pressing the device down through the tissue by applying force to the device flanges **112, 212, 312.** The tapered distal end surfaces **122, 220, 320** may serve to separate the tissue, facilitating passage of the device therethrough. Once the distal end **3** of the device **1** contacts the bone, the trocar **10** may be removed, and a drill bit may be **40** inserted through the bore **236** of the drill sleeve. The drill bit **40** may be advanced until the cutting end engages bone, and drilling may be performed until a desired depth is reached, as indicated by calibration marks **440** on the drill bit. The drill bit **40** may be removed from the drill sleeve **20,** and drill sleeve **20** may be removed from the protection sleeve by squeezing together the arms **2110, 2120** of the proximal flange **212** and pulling the drill sleeve **20** up and away from the protection sleeve **30.** An appropriately sized bone screw **50** may then be engaged with the end of a screwdriver **60** and the two may be inserted into the bore **336** of the protection sleeve **30** via the sleeve proximal end **310.** The screw **50,** and screwdriver **60** may then be advanced through the sleeve to engage the fixation device and/or the drilled hole in the bone. The screwdriver **60** may then be used to drive the bone screw into the bone hole, fixing the fixation device to the bone. Thereafter, the screwdriver **60** and protection sleeve **30** may be removed from the incision and the incision may be sutured closed.

[0080] Figs. **11a - 11c** illustrate the use of the invention for installing locking screws in the shaft of an intramedullary nail. As illustrated, intramedullary nail **70** is inserted in the intramedullary canal of a patient femur **80.** Aiming arm **90** is engaged with the nail **70**, and is used to guide the trajectory of the locking screw **50** to precisely align with one or more pre-formed fixation holes **72** in the nail **70**. Further description of the aiming arm and associated instruments is provided in co-pending non-provisional United States patent application serial number 09/978,002 to Roth filed October 17, 2001 and titled "Bone Fixation Systems," the entirety of which application is incorporated herein by reference.

[0081] Thus, the device **1** may be inserted into an appropriate bore **92** in the aiming arm **90** corresponding to a fixation hole **72** in the nail **70.** The outer surface **332** of the protection sleeve **30** may slide within the aiming arm bore **92** to align the device **1** with the fixation hole **72.** An incision may be made in the skin over the insertion point for the device **1**, and by applying a force to the device flanges **112, 212, 312,** the device may be driven through the incision and into alignment with the targeted fastener hole. The trocar **10** may be removed, and drilling and screw insertion functions may be performed as previously described.

[0082] Shown in **Figs. 12a & b** is a wire guide sleeve **400** that may be used together with the protection sleeve **30** of **Figs. 4a-c** to create an initial opening in bone for insertion of an intramedullary nail. Alternatively, the sleeves **400, 30** may be used for inserting a spiral blade or helical blade into a fractured femoral head to connect the head to the associated femoral shaft. A large pre-drilled bone hole may be required to receive such large fixation devices (*e.g.* from about 8 mm to about 17 mm), and thus the protection sleeve may be used for receiving and guiding the large sized drill bit **500** (see **Fig. 13**) for drilling the hole in the bone. The wire guide sleeve **400** may be used for engaging a guide wire **600** (*see* **Fig.**

14) for aligning the sleeves **400, 30** with the bone segments to be fixed. The guide wire **600** may be pre-inserted in at least one bone segment to provide precise alignment of the sleeves **400, 30** to ensure the drilled bone hole will have the precise trajectory desired by the surgeon. A bone hole thus prepared may ensure that the installed fixation device engages the bone portions in a manner that will best facilitate fusion of the fractured bone segments.

[0083] The wire guide sleeve **400** may have any or all of the features of the drill sleeve **20** described in relation to **Figs. 3a - e** (e.g. tapered distal end **401**, proximal flange element **402**, generally cylindrical body portion **403**, color coding, etc.). The wire guide sleeve **400** may also comprise any of the locking features as described in relation to **Figs. 3a - e** for provisionally axially locking the wire guide sleeve **400** to the protection sleeve **30**. In the illustrated embodiment, the wire guide sleeve **400** has a circumferential ridge **404** having all of the features described in relation to circumferential ridge **2000** of drill sleeve **20** (*see* **Fig. 3c**), and also has longitudinal slots **406, 407** having all the features described in relation to slots **2050, 2060** of the drill sleeve **20** (*see* **Fig. 3a**). Further, the wire guide sleeve **400** may have a distal inner surface portion **405** sized and configured to coaxially receive the guide wire **600**. In the illustrated embodiment, the distal inner surface portion may have an inner diameter "**wgid**" of about 3.3 mm, which may accept a standard 3.0 mm guide wire. The outer surface diameter "**wgod**"of the wire guide sleeve **400** may be from about 4 mm to about 17 mm, to allow it to be slidably received within the longitudinal bore **336** of the protection sleeve **30**. Thus, the wire guide sleeve 400 may be received within the protection sleeve **30** and the assembled sleeves may thus receive the guide wire **600**. It is noted that the indicated dimensions are provided for purposes of illustration only, and that other sizes, both larger and smaller, are also contemplated.

[0084] To use the combination of the protection sleeve **30**/wire guide sleeve **400** for forming an opening in a femur into which an intramedullary nail may be inserted, the surgeon may first make an incision in the patient's skin to the depth of the bone. The protection sleeve **30**, guide sleeve **400** and trocar **10** may be nested together as previously described in relation to **Fig. 1** and driven through the incision down to the bone. The trocar **10** may then be removed and a guide wire inserted through the cannulation **405** in the wire guide sleeve **400** and advanced into the bone under x-ray or fluoroscopic observation. The guide wire **600** may have a threaded or drilling tip **602** that may allow the surgeon to positively engage the guide wire **600** to the bone. Once the guide wire is properly positioned, the wire guide sleeve **400** may then be disengaged from the protection sleeve **30** by radially compressing the flange **402** to disengage the locking feature, and may be slipped off the free end **604** of the guide wire **600**. A drill **500** having a cannulation **502** may be placed over the free end **604** of the guide wire **14** and inserted into the bore **336** of the protection sleeve **30**. The drill **500** may be advanced through the protection sleeve **30** until the tip **504** contacts bone and then may be rotated to drill the desired hole in the bone. Once the bone hole has been formed, the drill **500** and protection sleeve **30** may then be removed from the incision. The guide wire **600** may be removed or it may be left in place to be used as part of a subsequent procedure.

[0085] To use the combination of the protection sleeve **30**/wire guide sleeve **400** for installing a helical blade, the surgeon may undertake the same steps as described above, with the exception that instead of removing the protection sleeve **30** and guide wire **600** after the hole has been drilled, the surgeon may retain both elements in place and remove only the drill bit **500**. Thereafter, a cannulated helical blade or spiral blade may be slipped over the free end **604** of the guide wire

and inserted into the bore **336** of the protection sleeve **30**. A cannulated driving tool may follow the helical or spriral blade over the guide wire **600** and may be used to drive the blade into to the hole in the bone.

[0086] The protection sleeve **30**, drill sleeve **20**, wire guide sleeve **400**, trocar **10** and any or all of the other described instruments may be provided as part of an orthopedic kit for use during surgical procedures in which percutaneous placement of fasteners will be performed. Thus, the kit may comprise one or more device, and each device may comprise a trocar, drill sleeve, and protection sleeve sized to correspond to a different screw size. Likewise, if the kit includes a wire guide sleeve 400, it as well as the trocar and protection sleeve may be sized to correspond to different nail or spiral/helical blade sizes.

[0087] In an exemplary embodiment for use with an intramedullary nail, the kit may contain three separate devices sized to correspond to screw sizes of 3.2 mm, 4.0 mm and 5.0 mm, respectively. Other device sizes may be provided as desired.

[0088] The trocar **10,** drill sleeve **20,** wire guide sleeve **400** and protection sleeve **30** may be made of stainless steel, titanium, polymer or any other appropriate material. In one embodiment, the trocar, drill sleeve and protection sleeve are manufactured from a martinsitic stainless steel.

[0089] The trocar 10, drill sleeve 20, wire guide sleeve 400 and protection sleeve 30 also may be manufactured from a radiolucent or partially radiolucent materials such as ultra high molecular weight polyethylene (UHMWPE), poly-ether-ether-ketone (PEEK), extruded carbon fiber or other such material. Any or all of the components of the system may also be disposable.

[0090] It will be appreciated that although the invention has been described in relation to its use with an intramedullary nail system, that the invention may be

applied to any orthopedic application in which a stabilizing device, such as a bone plate, rod, nail, etc., is to be applied to a bone. Thus, the invention may find application in maxillofacial indications where small-sized plates are applied to portions of the cranio-facial skeleton and where screw sizes may be as small as 1.0 mm. Likewise, the invention may be used in large-scale applications, accepting up to 17 mm drills used for installation of spiral blades, helical blades, or for facilitating opening the insertion site for an intramedullary nail.

WHAT IS CLAIMED:

1. An orthopedic system comprising:

a first sleeve member having an outer surface and an inner surface defining a longitudinal bore and a surface;

a second sleeve member having an outer surface and an inner surface defining a longitudinal bore, the second sleeve member further configured to be at least partly received within the bore of the first sleeve member;

wherein the longitudinal bore of one of the first and second sleeves is configured to receive a drill bit therethrough to drill a hole in bone, and wherein one of the first and second sleeve members further comprises a protrusion and the other comprises a corresponding recess, the protrusion and recess being co-operable to provisionally axially lock the first and second sleeve members together when the second sleeve member is at least partly received within the bore of the first sleeve member, the second sleeve being dis-engageable from the first sleeve through the application of an axial separation force between the first and second sleeves and a radial compression force to at least a portion of the second sleeve.

2. The system of **claim 1**, further comprising a trocar configured to be received within the longitudinal bore of the second sleeve.

3. The system of **claim 2**, the first and second sleeve members further each having a proximal end comprising a flange member and a distal end comprising a tapered tip region.

4. The system of **claim 3**, the longitudinal bore of the first sleeve further configured to receive a driver and bone fastener therethrough to allow insertion of the fastener into bone in a direction along the longitudinal axis of the bore.

5. The system of **claim 4**, the tapered tip of at least one of the first or second sleeve members configured to align with a fastener hole in a bone fixation element.

6. The system of **claim 5**, wherein the bone fixation element is a bone plate or an intramedullary nail.

7. The system of **claim 1**, wherein the protrusion is integrally formed with the associated sleeve.

8. The system of **claim 7**, wherein the protrusion comprises at least one circumferential ridge.

9. The system of **claim 8**, wherein the recess comprises at least one circumferential groove corresponding to the at least one ridge.

10. The system of **claim 9**, wherein the protrusion comprises first and second tapered surfaces.

11. The system of **claim 9**, wherein the second sleeve comprises at least one longitudinal slot disposed between the inner and outer surfaces of the sleeve, the slot running from at least one end of the sleeve and having a length, the slot further configured to render at least a portion of the sleeve radially flexible.

12. The system of **claim 11**, wherein the at least one slot divides a first end of the sleeve into first and second halves, wherein pressing the first and second halves toward each other disengages the ridge from the recess, thereby allowing the first and second sleeves to be axially engaged with, or disengaged from, each other.

13. The system of **claim 11**, wherein the second sleeve has two longitudinal slots diametrically disposed with respect to each other about the circumference of the sleeve.

14. The system of **claim 8**, wherein the protrusion comprises at least one tapered surface configured to facilitate radial compression of the second sleeve when the sleeve is inserted into the bore of the first sleeve.

15. The system of **claim 14**, wherein the first and second sleeves and the trocar are color coded to provide a visual indication of the size of a bone screw that can be received through the bore of the first sleeve.

16. The system of **claim 1**, wherein the outer surface of the first sleeve is configured to be received within the bore of an aiming arm of an intramedullary nail to align the sleeve with a targeted fastener hole in a portion of the intramedullary nail.

17. An orthopedic system comprising:

a first sleeve having proximal and distal ends, a longitudinal axis and inner and outer surfaces;

a second sleeve having proximal and distal ends, a longitudinal axis, and inner and outer surfaces, the inner surface configured to receive at least a portion of the first sleeve, the inner surface further configured to receive a bone fastener and driver for inserting the fastener into the hole drilled in bone;

wherein the inner surface of at least one of the first and second sleeves is configured to receive a drill bit for drilling a hole in bone; and wherein at least a portion of the first sleeve is slidably receivable within at least a portion of the second sleeve; and wherein one of the second sleeve inner surface and the first sleeve outer surface comprises a protrusion, and the other comprises a corresponding recess so that when the first sleeve is received within the second sleeve, the protrusion and recess cooperate to releasably axially engage the first sleeve with the second sleeve; the sleeves being disengageable from each other

by applying an axial separation force between the first and second sleeves and a radial compression force to at least a portion of the first sleeve.

18. The system of **claim 17**, further comprising a trocar configured to be received within the longitudinal bore of the first sleeve.

19. The system of **claim 18**, the sleeves further each have a proximal end comprising a flange member and a distal end comprising a tapered tip region.

20. The system of **claim 19**, the tapered tip of at least one of the first or second sleeves being configured to align with a fastener hole in a bone fixation element.

21. The system of **claim 20**, wherein the bone fixation element is a bone plate or an intramedullary nail.

22. The system of **claim 21**, wherein the protrusion is integrally formed with the associated sleeve.

23. The system of **claim 21,** wherein the protrusion comprises a plurality of discrete protruding elements.

24. The system of **claim 17**, wherein the protrusion comprises at least one circumferential ridge.

25. The system of **claim 24**, wherein the recess comprises at least one circumferential groove corresponding to the at least one ridge.

26. The system of **claim 25**, wherein the protrusion comprises first and second tapered surfaces configured to engage a portion of the inner surface of the second sleeve.

27. The system of **claim 26**, wherein the first sleeve comprises at least one longitudinal slot disposed between the inner and outer surfaces of the sleeve, the slot running from at least one end of the sleeve and having a length, the slot further configured to render at least a portion of the sleeve radially flexible.

28. The system of **claim 27**, wherein the at least one slot divides a first end of the first sleeve into first and second halves, wherein when the first sleeve is fully received within the second sleeve, pressing the first and second halves toward each other disengages the ridge from the recess, thereby allowing the first sleeve to be removed from the second sleeve.

29. The system of **claim 28,** wherein when the first sleeve is inserted into the second sleeve, the first tapered surface cooperates with the inner surface of the second sleeve to radially compress the first and second halves together.

30. The system of **claim 27**, wherein the first sleeve has two longitudinal slots diametrically disposed with respect to each other about the circumference of the sleeve.

31. The system of **claim 30**, wherein the protrusion comprises at least one tapered surface configured to facilitate radial compression of the first sleeve when the sleeve is inserted into the bore of the second sleeve.

32. The system of **claim 31**, wherein the first and second sleeves and the trocar are color coded to provide a visual indication of the size of a bone screw that can be received through the bore of the first sleeve.

33. The system of **claim 17**, wherein the outer surface of the first sleeve is configured to be received within the bore of an aiming arm of an intramedullary nail to align the sleeve with a targeted fastener hole in a portion of the intramedullary nail.

34. A method of drilling a hole in bone, comprising:

(a) providing a drill sleeve and protection sleeve combination, the drill sleeve telescopically receivable within at least a portion of the protection sleeve, the drill sleeve having an inner surface for receiving a drill bit for drilling a hole in a bone, the drill sleeve having an outer

surface comprising one of a protrusion and a recess configured to engage a corresponding recess or protrusion disposed on an inner surface of the protection sleeve to provisionally axially lock the sleeves together;

wherein the drill and protection sleeve are separable from each other through the application of an axial separation force between the sleeves and a radial compression force to at least a portion of the drill sleeve;

(b) advancing the drill sleeve and protection sleeve combination through an incision in a patient;

(c) advancing the drill sleeve and protection sleeve to align with a bone fixation element overlying a portion of the bone;

(d) inserting a drill bit through the drill sleeve and advancing the drill bit to engage bone;

(e) rotating the drill to produce a hole in the bone;

(f) removing the drill bit from the drill sleeve; and

(g) applying an axial separation force between the drill sleeve and the protection sleeve and applying a radial compression force to a portion of the drill sleeve to disengage the two.

35. The method of **claim 34**, wherein the drill sleeve and protection sleeve further comprise a trocar configured to be received within the longitudinal bore of the drill sleeve.

36. The method of **claim 35**, wherein the sleeves further each have a proximal end comprising a flange member and a distal end comprising a tapered tip region.

37. The method of **claim 34**, wherein the bone fixation element is a bone plate **or** an intramedullary nail.

38. The method of **claim 34**, wherein the protrusion is integrally formed with the associated sleeve.

39. The method of **claim 34,** wherein the protrusion comprises a plurality of discrete protruding elements.

40. The method of **claim 34**, wherein the protrusion comprises at least one circumferential ridge.

41. The method of **claim 40**, wherein the recess comprises at least one circumferential groove corresponding to the at least one ridge.

42. The method of **claim 41**, wherein the protrusion comprises first and second tapered surfaces configured to engage a portion of the recess.

43. The method of **claim 42**, wherein the drill sleeve comprises at least one longitudinal slot disposed between the inner and outer surfaces of the sleeve, the slot running from at least one end of the sleeve and having a length, the slot further configured to render at least a portion of the sleeve radially flexible.

44. The method of **claim 43**, wherein the at least one slot divides a first end of the drill sleeve into first and second halves, wherein when the drill sleeve is fully received within the screw insertion sleeve, pressing the first and second halves toward each other disengages the protrusion from the recess, thereby allowing the drill sleeve to be removed from the screw insertion sleeve.

45. The method of **claim 34,** further comprising the steps of:

(g) inserting a bone fastener and screwdriver through the protections sleeve; and

(h) driving the bone fastener into the hole in the bone to fix the bone fixation element to the bone.

46. The method of **claim 34**, further comprising the step, between steps (a) and (b), of: inserting the outer surface of the protection sleeve into a bore in an aiming

arm attached to an intramedullary nail; step (c) comprises advancing the protection sleeve and drill sleeve through the bore in the aiming arm to align with a fastener hole in the bone fixation element; and step (e) comprises drilling a hole in the bone through the fastener hole in the intramedullary nail.

47. The method of **claim 46**, further comprising the steps of:

(h) inserting a bone fastener and screwdriver through the protection sleeve; and

(i) driving the bone fastener into the hole in the bone to fix the bone fixation element to the bone; and

(j) removing the protection sleeve from the patient.

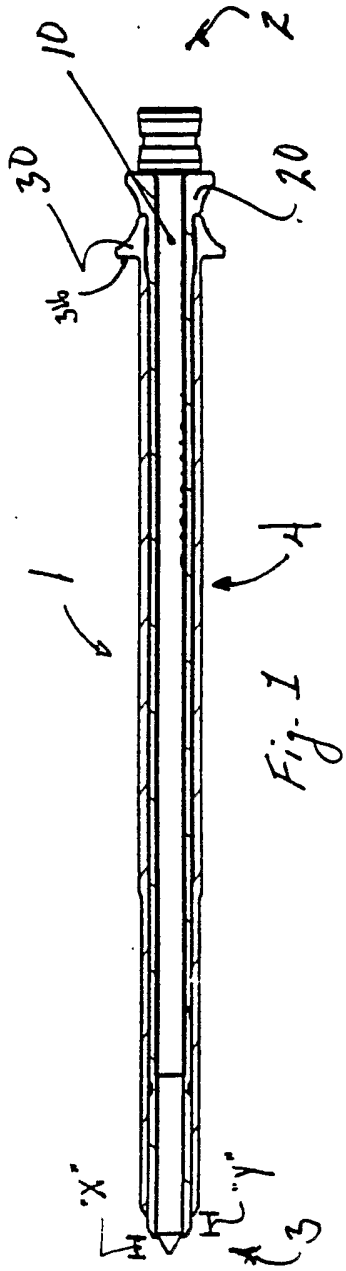

Fig. 1

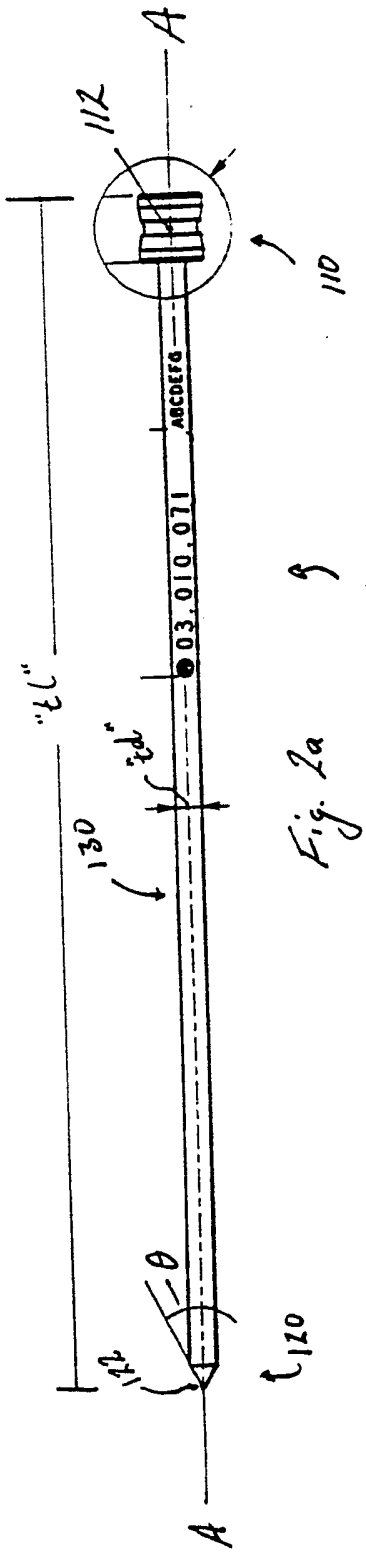
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Fig. 2a

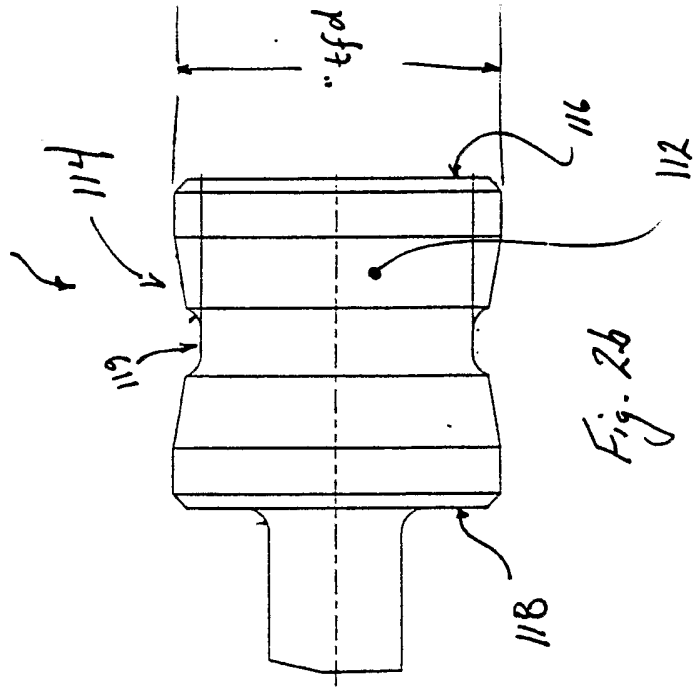
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Fig. 2b

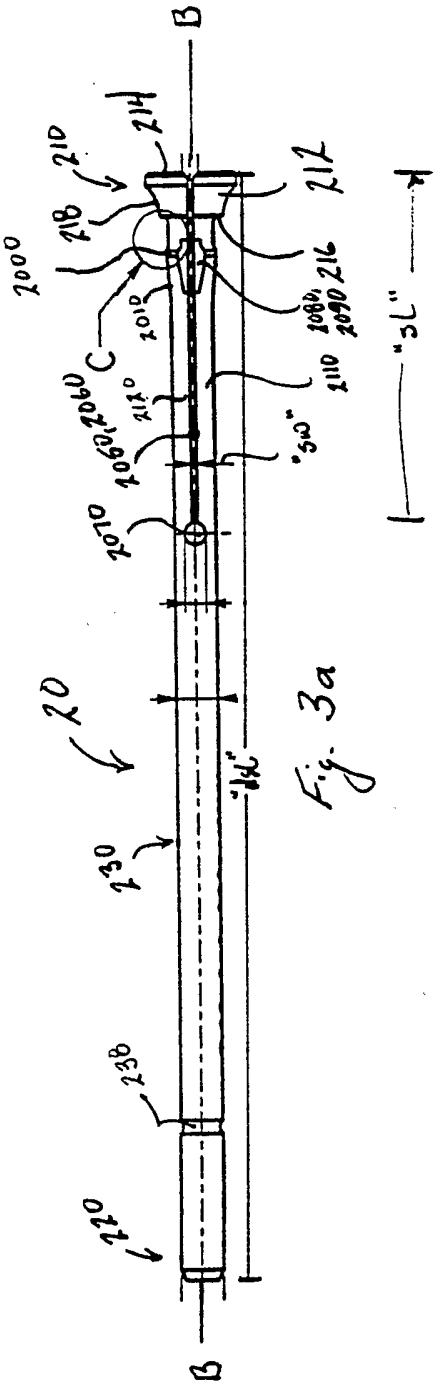

Fig. 3a

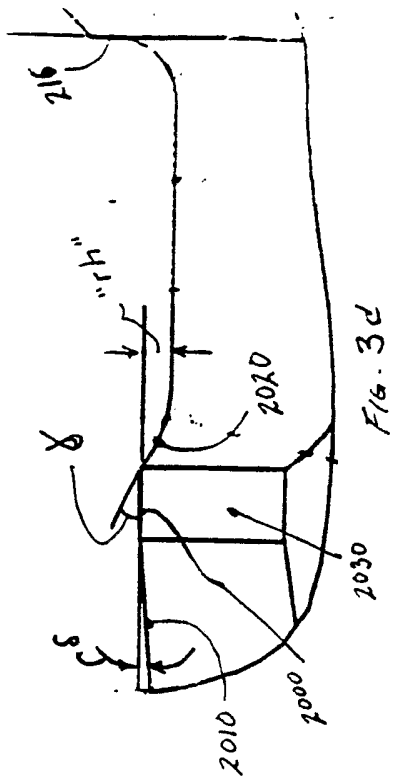

Fig. 3d

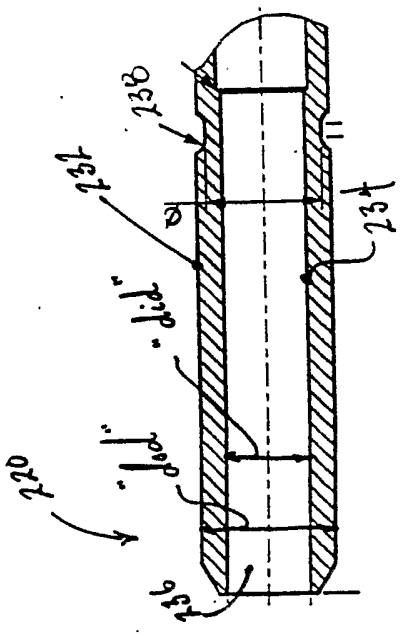

Fig. 3b

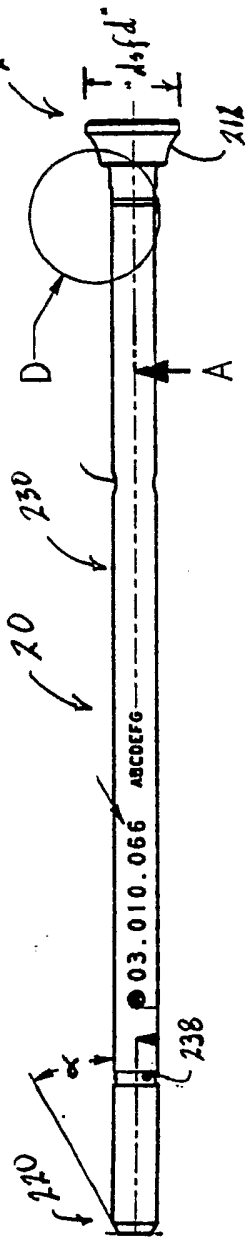

Fig. 3d

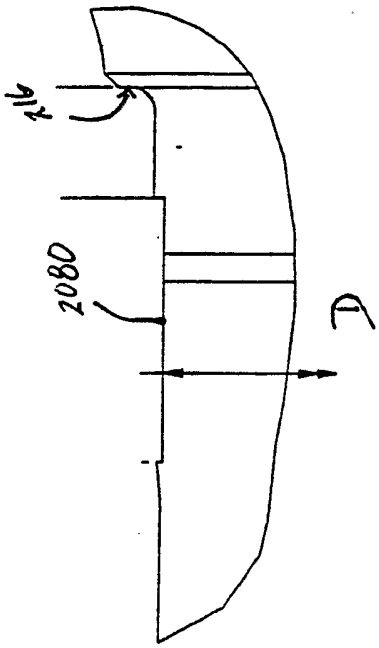

Fig. 3e

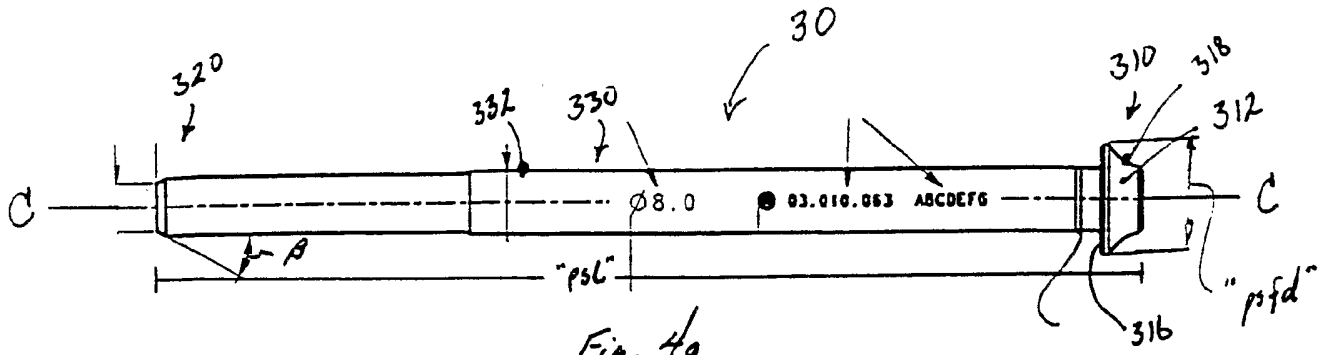

Fig. 4a

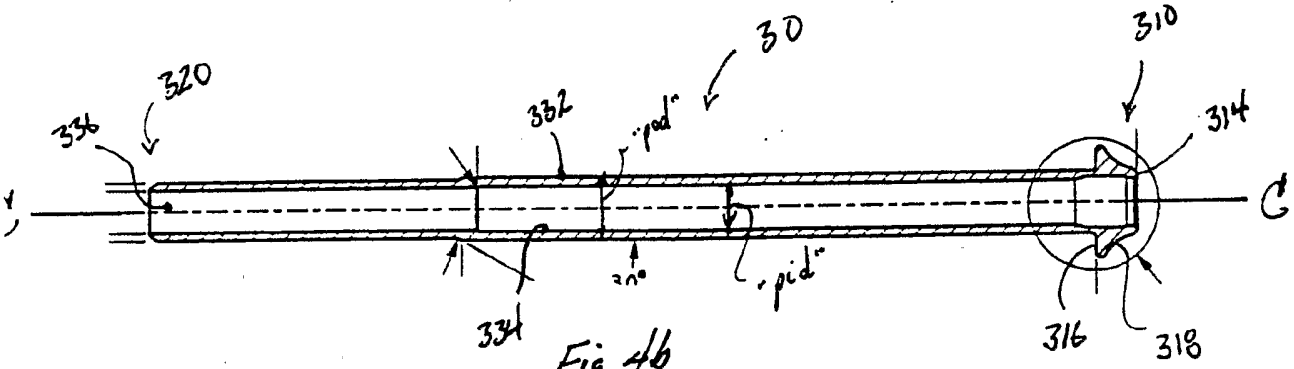

Fig. 4b

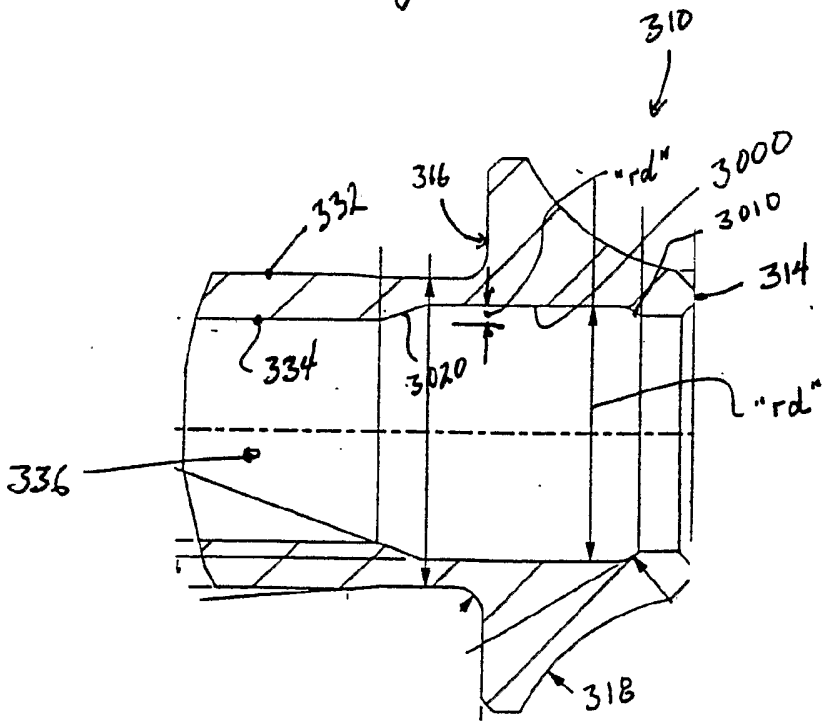

Fig. 4c

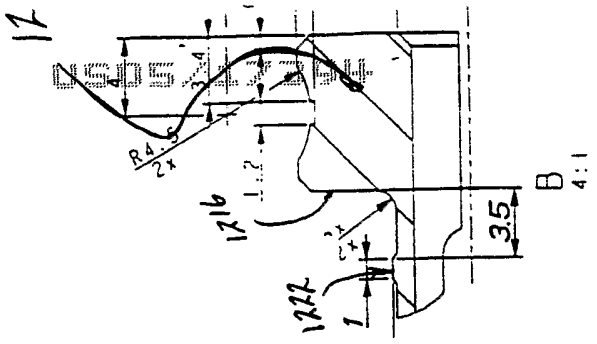

Fig. 5c

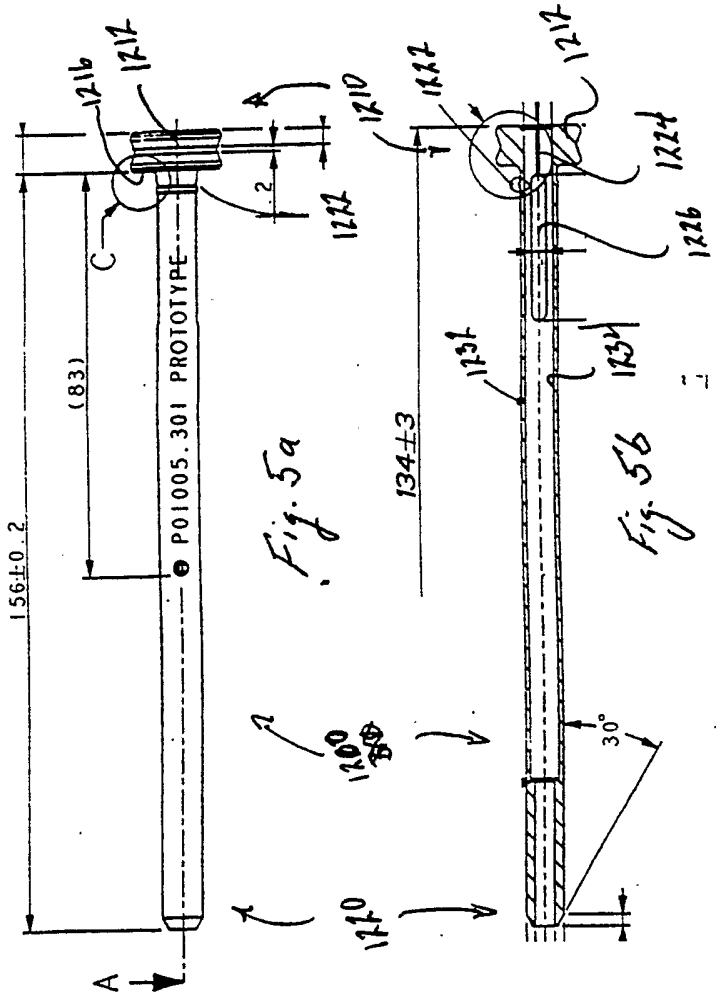

Fig. 5a

Fig. 5b

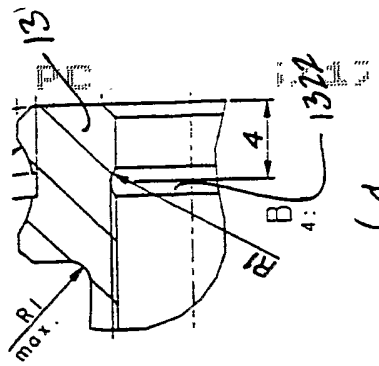

Fig. 6d

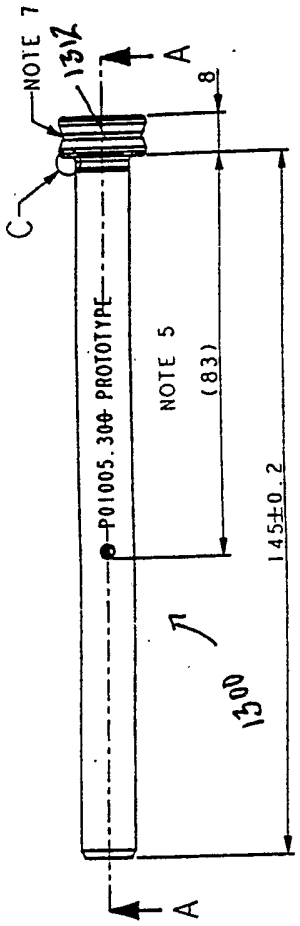

Fig. 6a

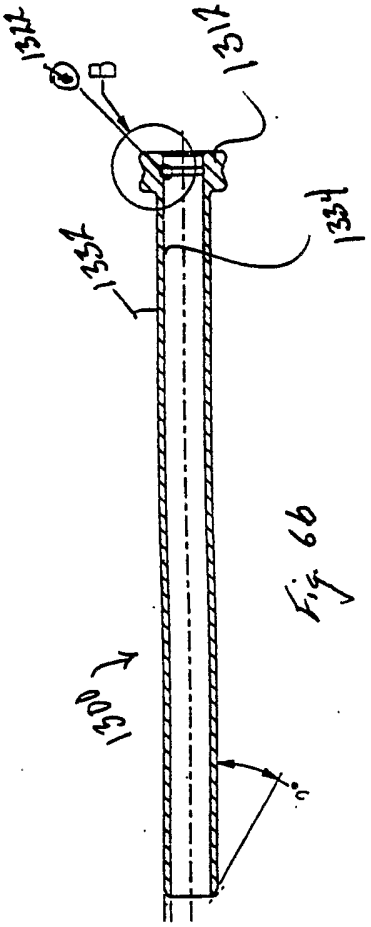

Fig. 6b

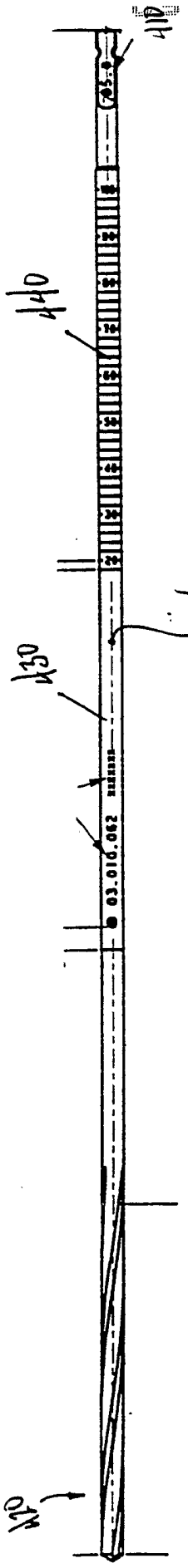

Fig. 7

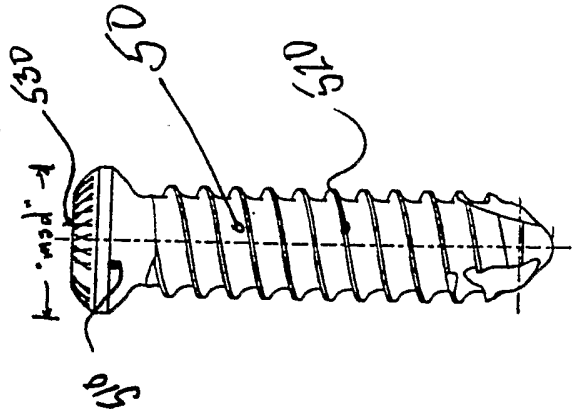

Fig. 8

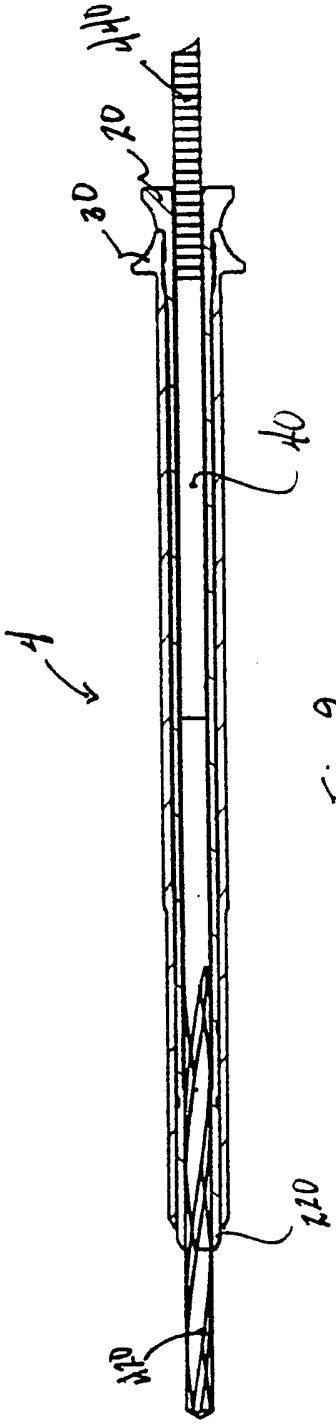

Fig. 9

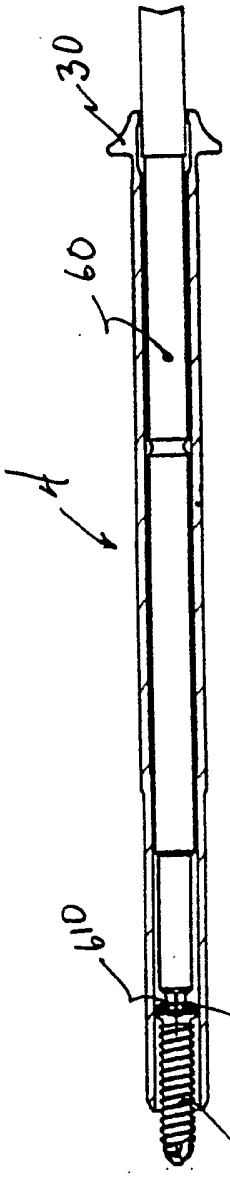

Fig. 10

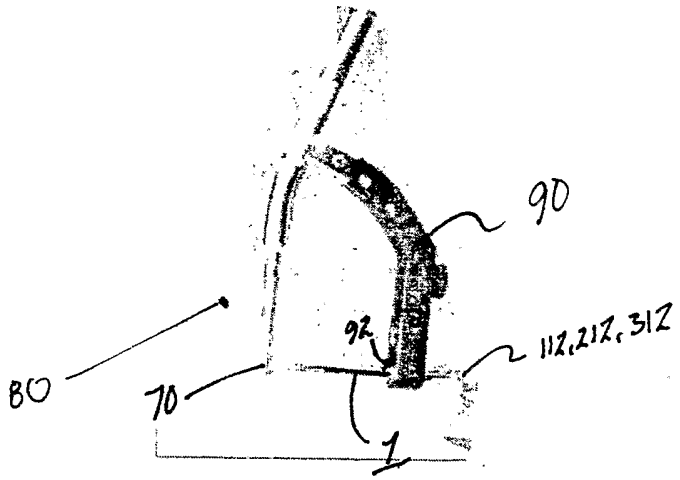

Fig. 11a

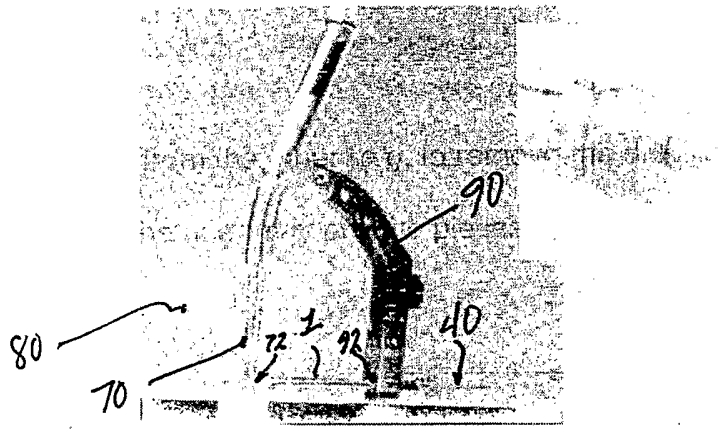

Fig. 11b

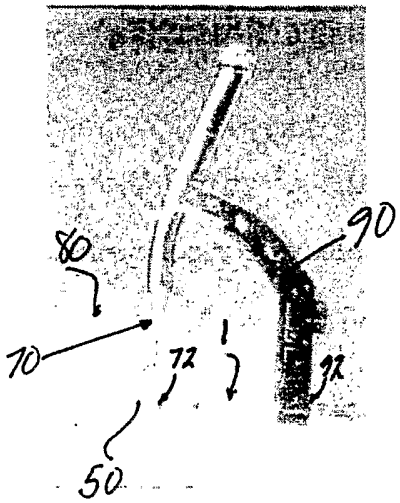

Fig. 11c

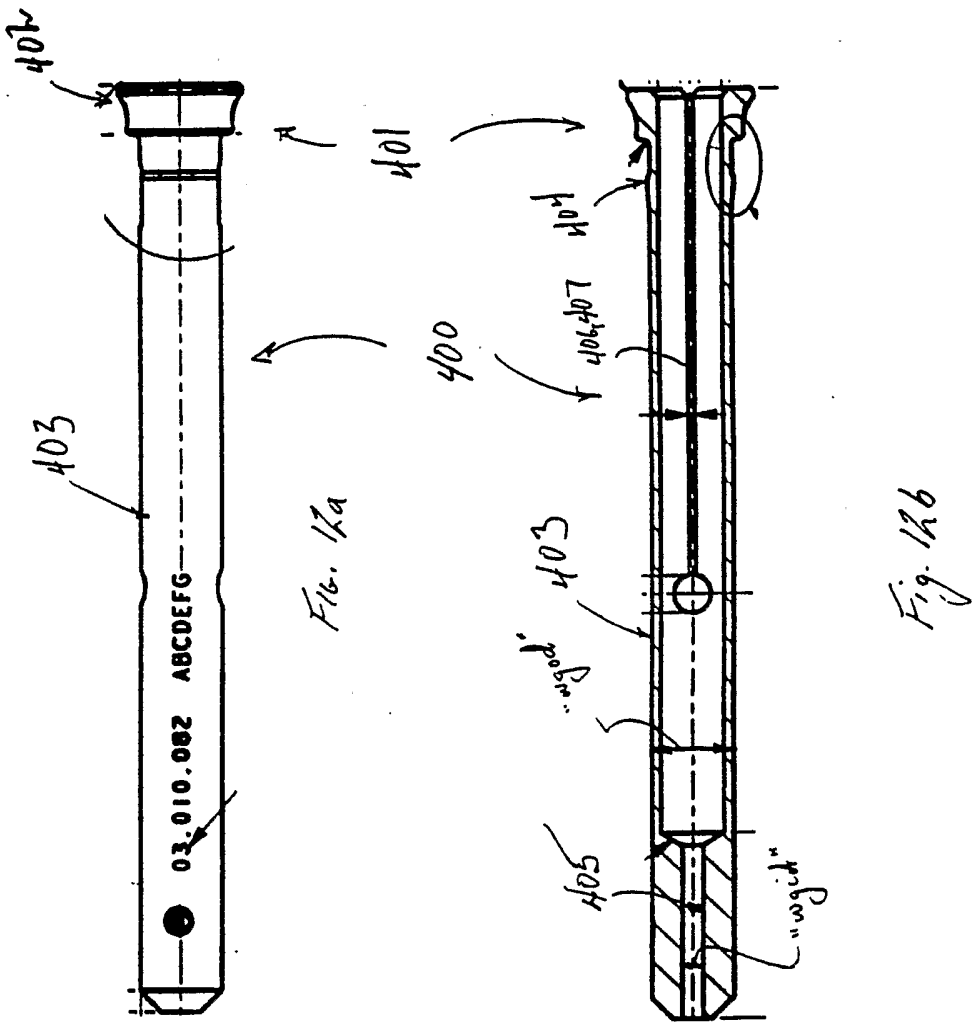

Fig. 12a

Fig. 12b

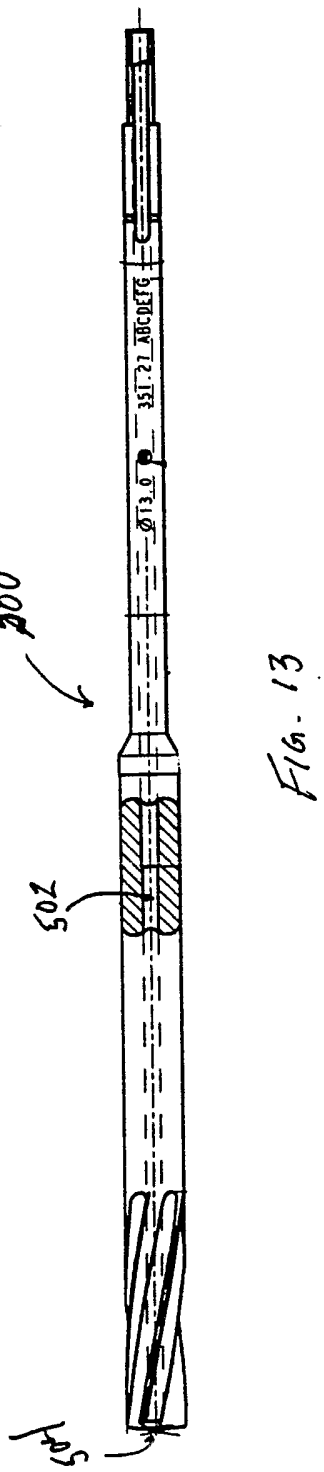

FIG. 13

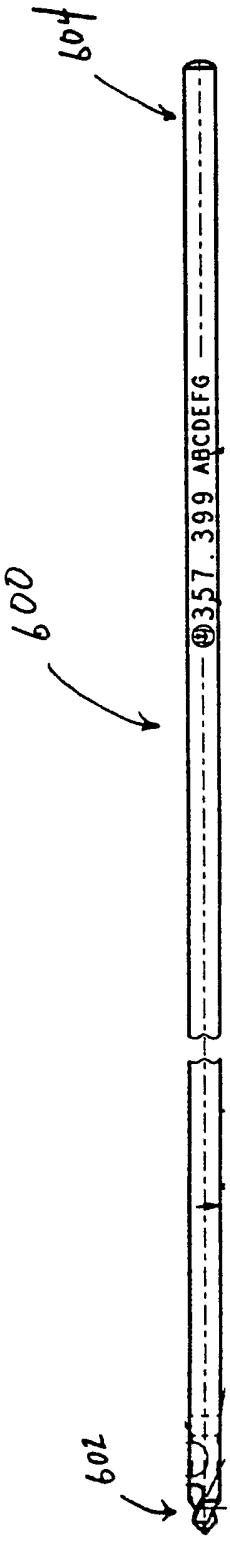

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/17394

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/17

US CL : 606/96

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)

U.S. : 606/80, 96-98, 104, 185

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,755,721 A (HEARN) 26 May 1998 (26.05.1998).	
A	US 5,112,337 A (PAULOS et al) 12 May 1992 (12.05.1992).	

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"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

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Date of the actual completion of the international search

20 July 2005 (20.07.2005)

Date of mailing of the international search report

26 AUG 2005

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Form PCT/ISA/210 (second sheet) (January 2004)