



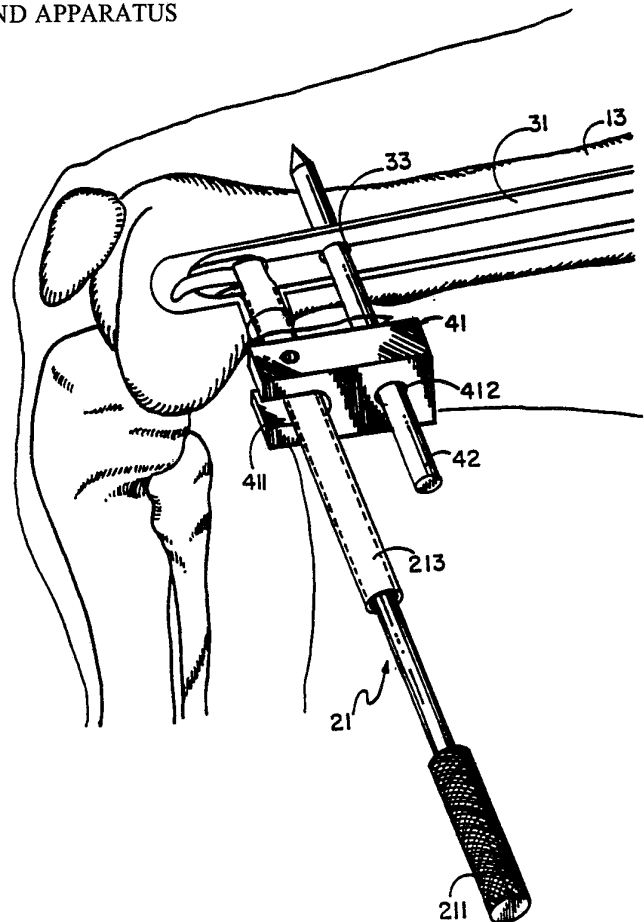
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<p>(21) International Application Number: PCT/US91/02259 (22) International Filing Date: 2 April 1991 (02.04.91) (30) Priority data: 577,366 4 September 1990 (04.09.90) US (71) Applicant: BETH ISRAEL HOSPITAL [US/US]; 330 Brookline Avenue, Boston, MA 02215 (US). (72) Inventor: HAYES, Wilson, C. ; 161 Tower Road, Lincoln, MA 01773 (US). (74) Agents: SUNSTEIN, Bruce, D. et al.; Bromberg & Sunstein, 10 West Street, Boston, MA 02111 (US).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), NO, SE (European patent). Published <i>With international search report.</i></p>

(54) Title: INTRAMEDULLARY NAILING METHOD AND APPARATUS

(57) Abstract

The present invention provides a method and apparatus for achieving the fixation of a bone having medullary canal, and permits the secure and highly repeatable location of the distal locking screws used in intramedullary nailing of long bone fractures. The distal end of an intramedullary nail (31) is locked to the distal portion of a bone by inserting a guide wire (11) into the medullary canal of the bone, drilling a pilot hole through the near cortex of the bone, and using a suitable locator tool (21) that has an arrangement for grabbing the guide wire. The intramedullary nail is then inserted until it engages with the locator. A distal alignment fixture (41) engaged with the locator can then be used to determine the location of the first distal locking hole. After insertion of the first distal locking screw, the second distal locking screw can be located.



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INTRAMEDULLARY NAILING METHOD AND APPARATUS

5

DESCRIPTIONTechnical Field

The present invention relates to methods and apparatus for achieving the fixation of long bone fractures utilizing intramedullary nails.

10

Background Art

One approach to the internal fixation of long bone fractures is to insert a relatively flexible intramedullary nail into the medullary canal so that it crosses the fracture site and provides increased rigidity to the fracture fragments. Until recently, such devices have been viewed as gliding splints, allowing the fracture fragments to collapse slightly as weightbearing loads are applied and fracture healing proceeds. Under these conditions, fixation rigidity depends on close-fitting frictional load transmission between intramedullary nail and bone and on adequate contact between the proximal and distal fracture fragments. As a result, intramedullary nails have not traditionally been used with fractures near the bone ends or with severely comminuted central shaft fractures where bone collapse and marked shortening could occur.

In attempts to expand the indications for intramedullary nailing to these fracture types, a number of manufacturers have developed "locking" systems, which are designed to provide secure attachment between the intramedullary nail and the most proximal and distal fracture fragments. Such locking systems prevent collapse of severely comminuted fractures, allow weightbearing relatively early, and increase the torsional, flexural and axial rigidity and strength of the bone-implant system. The availability of these locking systems has resulted in a dramatic increase in the use of intramedullary nailing, to the point that it is the treatment of choice for most long bone fractures of the lower extremity.

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Several approaches are used to provide proximal and distal locking of intramedullary nails. These include the use of expanding bolts (U.S. patent 4,590,930 for an invention of Kurth et al.), fins (West German patent application laid open as number 24 40 045 on April 10, 1975; U.S. patent 4,519,100 for an invention of Wills et al.), and multiple protruding pins, all operated by screw-type insertions along the length of the nail. (See also the discussion in column 1 of U.S. patent 4,733,654 for an invention of Marino and columns 1-2 of U.S. patent 4,697,585 for an invention of Williams.) By far the most popular approach, however, is to employ transverse screws or bolts, which are inserted through transverse holes in the intramedullary nail and corresponding holes drilled in the bone cortices. Such locking screws can be perpendicular or oblique to the longitudinal axis of the bone and can be used singly or in pairs to provide a rigid connection between nail and bone fragment.

In the process of intramedullary nailing, it is common to insert initially, into the medullary canal from the proximal end thereof, a ball-ended guide wire and then to pass this guide wire down the canal to locate the distal fracture fragment. Thereafter a series of flexible intramedullary reamers are passed in succession over the guide wire. The guide wires are also intended to allow withdrawal of the reamer tip in the unlikely case that the reamer breaks during the reaming process. Once reaming is completed, the ball-ended guide wire is usually replaced with a smooth-tipped guide wire and the hollow intramedullary nail is inserted over the guide wire. Once successful positioning of the intramedullary nail is achieved, the guide wire is withdrawn and proximal and distal locking screws are inserted. See U.S. patent 4,913,137, for an invention of Azer et al.

The prior art has frequently attempted to address the problem of positioning holes, drilled in the most proximal and distal bone fragments, in proper relation to the

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corresponding holes in the intramedullary nail, so that the locking screws can be inserted to fix the position of the nail vis-a-vis these bone fragments. For proximal locking, it is straightforward to design fixtures that can be used
5 intraoperatively as drill guides for locating the position of the proximal screw or screws. Typically, such devices attach temporarily to the proximal end of the nail, allow the transverse holes to be drilled through a special guide, and are then removed after screw insertion. See United
10 States patent 4,733,654 for an invention of Marino. However, such an approach (described in U.S. patents 4,881,535 for an invention of Sohngen and 4,913,137 for an invention of Azer et al.), has proven unworkable with the distal transverse locking screws. Invariably some twisting
15 and bending of the nail occurs during insertion and thus the geometric relationship between the proximal and distal ends of the nail cannot be determined with certainty.

As a consequence, there have been many attempts to develop locating devices for the distal locking screws that
20 allow holes to be drilled through the bony cortices at the precise location of the distal holes in the intramedullary nail. Approaches have ranged from special radiographic targeting devices (much like bomb sights) to capture mechanisms which depend on prior insertion of the locking
25 screw and a special configuration of the distal end of the nail. For the latter, see U.S. patents 4,817,591 and 4,705,027 for inventions of Klaue. The radiographic approaches are time-consuming, expose the surgeon to excess radiation and do not achieve proper location with absolute
30 certainty. Capture mechanisms have proven unworkable, primarily because of nail deformation and an inability to hit the already inserted screw, and have thus never been marketed. Thus targeting and location of the distal locking screws remain the most time-consuming and problematic phase
35 of the surgical procedure. While highly experienced surgeons eventually learn to accomplish this step successfully, it is considerably more difficult for

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inexperienced surgeons or for those who do not do intramedullary nailing with considerable frequency.

Summary of the Invention

The present invention provides a method and apparatus
5 for achieving the fixation of a bone having a medullary canal, and in particular permits the secure and highly repeatable location of the distal locking screws used in intramedullary nailing of long bone fractures. In
10 accordance with a preferred embodiment of a method of the invention the distal end of an intramedullary nail is locked to the distal portion of a bone by inserting a guide wire into the medullary canal of the bone, drilling a pilot hole through the near cortex of the bone, and using a suitable locator tool that has an arrangement for grabbing the guide
15 wire. The locator tool also has an arrangement for engaging with a suitably configured intramedullary nail. The intramedullary nail is then inserted until it engages with the locator. A distal alignment fixture engaged with the locator can then be used to determine the location of the
20 first distal locking hole. After insertion of the first distal locking screw, the second distal locking screw can be located. The invention also provides apparatus for achieving the foregoing, as well as methods and apparatus for adjusting the compression of distal and proximal bone
25 fragments and placement of the proximal locking screw or screws.

Brief Description of the Drawings

The foregoing features of the present invention may be more readily understood by reference to the following
30 detailed description taken with the accompanying drawings, in which:

Fig. 1 presents an elevation of a bone and guide wire of the types to which the invention is applicable, and Fig. 2 illustrates in vertical section the use of an
35 intramedullary nail with the guide wire of Fig. 1 in accordance with an embodiment of the invention;

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Fig. 3 shows in a cut away perspective view the use of a locator in accordance with a preferred embodiment of the invention grabbing the guide wire of Fig. 1;

Fig. 4 shows the locator of Fig. 3 engaged with the
5 distal end of an intramedullary nail in accordance with a preferred embodiment of the invention;

Fig. 5 shows a distal alignment fixture, in accordance with a preferred embodiment of the invention, engaged with the locator of Fig. 4;

10 Fig. 6 shows placement of the first distal locking screw following use of the distal alignment fixture of Fig. 5;

Figs. 7 and 8 illustrate in a partial vertical section the use, in accordance with a preferred embodiment of the
15 invention, of a compression nut and compression washer and bolt system at the proximal end of the intramedullary nail of Fig. 6 to achieve controlled compression of the bone fragments;

Fig. 9 is a perspective view of a proximal alignment
20 fixture in accordance with a preferred embodiment of the invention; Fig. 10 shows use of the fixture in a partial vertical section; and Fig. 11 is a vertical section illustrating placement of the proximal locking screw following use of the fixture;

25 Fig. 12 is an elevation view of a femur experiencing fixation in accordance with the embodiments of the previous figures showing placement of the intramedullary nail and locking screws;

Figs. 13 and 14 are elevation views of the locator of
30 Figs. 3-5 with sleeve retracted and extended respectively;

Fig. 15 shows front and side elevations of the locator of Figs. 3-5 and shows detail of the sleeve;

Fig. 16 is a front elevation of the distal end of the intramedullary nail of the previous figures; Fig. 17 shows
35 in detail the engagement opening of the nail of Fig. 16; Fig. 18 is a side elevation of the nail of Fig. 16; and Fig.

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19 is a cross section through the plane A-A of the nail of Fig. 16;

Fig. 20 shows bottom and side elevations of the distal alignment fixture of Fig. 5;

5 Fig. 21 illustrates inserts used in connection with the distal alignment fixture of Fig. 20;

Fig. 22 is a partial perspective view of the distal alignment fixture of Fig. 5; and

10 Fig. 23 is an elevation of a slap hammer in accordance with a preferred embodiment of the invention.

Detailed Description of Specific Embodiments

In a preferred embodiment, the method and apparatus of the invention utilize the prior art guide wire that allows passage of the intramedullary nail. Fig. 1 illustrates such
15 a guide wire 11, which, as described in the Background Art section above, is used after reaming of the medullary canal of a long bone such as femur 13. Fig. 2 shows an intramedullary nail 12, disposed concentrically around the guide wire 11, being guided through the canal 14.

20 As shown in Fig. 3, in accordance with a preferred embodiment of the invention, before the intramedullary nail is positioned in the canal, there is drilled a pilot hole 22 in the near cortex of the bone through which is inserted the hook tip 212 of a locator 21. (As used in this description
25 and in the following claims, the term to "drill" a hole refers to any method of forming a hole, regardless whether by means of a conventional drill or laser apparatus or otherwise.) The location of the pilot hole may be determined using anatomical markers and radiographic
30 techniques. If desired the guide wire may be provided with a suitable radio-opaque marker for determination of longitudinal placement of the hole. The locator may be held by its handle 211 and is manipulated until the tip 212 grabs the guide wire 11. The locator has a sleeve 213 (which is
35 initially held in the retracted position illustrated here) that is slidably mounted on the locator.

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As shown in Fig. 4, after the guide wire 11 has been grabbed, the sleeve 213 is then moved to the extended position both to maintain the grasp of the hook on the guide wire and to present a feature that may be engaged with the distal end of the intramedullary nail 31. The locator 21 may be held with one hand while the nail is then inserted and manipulated until the engagement opening 32 at its distal end is engaged with the tip of sleeve 213 of the locator.

10 The location for drilling in the bone a hole corresponding to the locking aperture 33 at the distal end of the nail 31 may then be determined in a manner illustrated in Fig. 5. As shown in Fig. 5, a distal alignment fixture 41 has an engagement region 411 that is
15 engaged against the sleeve 213 of locator 21. The alignment hole 412 of the fixture 41 is used to guide drill 42 in drilling the hole, corresponding to locking aperture 33 of the nail, in the near and far cortices. To assure reliability in identifying a suitable location for the hole,
20 the engagement region 411 may be keyed to sleeve 213 in the manner described below in connection with the distal alignment fixture of Fig. 20. Preferably, drilling of the hole is commenced before removal of the guide wire, so that the distal alignment fixture then has an orientation that is
25 effectively fixed with respect to the guide wire.

As shown in Fig. 6, after the drilling has been completed, the fixture may be removed, and first locking screw 51 is inserted through the hole and through locking aperture 33, thus fixing the distal end of the nail 31 in
30 relation to the distal bone fragment. The locator 21 may then be disengaged from the nail and removed from the pilot hole. Thereafter a second locking distal locking screw may be inserted using one of a variety of alternatives. In accordance with one embodiment, the same fixture 41 may be
35 reversed and engaged with locking screw 51 (which initially is not screwed in quite completely) to provide alignment hole 412 as a guide for drilling to extend the pilot hole

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through the far cortex. (In such an instance the intramedullary nail 31 has a corresponding locking aperture--shown as item 139 in Figs. 16 and 17--situated beneath the pilot hole.) In accordance with another embodiment, however, a fixture (which may but need not be distinct from fixture 41) engaged with locking screw 51 may be used to determine the location of third distinct hole corresponding to the location of a separately located locking aperture in the nail 31; this aperture may be either distal or proximal of the aperture 33.

After placement of the distal locking screws, the proximal screw or screws may be inserted in a manner known in the art. Alternatively, as shown in Fig. 7, a concentric bolt system including inner and outer bolts 64 and 63 is employed. Outer bolt 63 includes a proximal flange 631 used to mount the alignment fixture in the manner discussed below. Inner bolt 64 is screwed into mating threads formed in the proximal end of the intramedullary nail 31. If controlled compression of the fracture fragments in relation to one another is desired, compression nut 62 and compression washer 61 are included on the outer bolt 63; then as shown in Fig. 8, the nut 62 is turned by wrench 71 so as to urge proximal fragment 77 in the relative downward direction 771 and distal fragment 78 in the upward direction 781 to a desired extent.

Outer bolt 63 of Fig. 7 is also used to hold the proximal alignment fixture 81 in place. This fixture, shown in Fig. 9, has a drilling guide hole 83 and mounting aperture 82. As shown in Fig. 10, the fixture is positioned with the head of bolt 63 snugly disposed in the aperture 82, and the bottom surface 811 of the fixture 81 surrounding the aperture 82 rests on the flange 631 of the head of bolt 63 to hold the fixture in place. Set screw 64 locks the fixture to the head of bolt 63. The drilling guide 83 is used for guiding the drill 91 to drill the hole for the proximal locking screw 101, which is shown inserted in Fig. 11.

Fig. 12 shows the relative positions of the intramedullary nail 31, the proximal locking screw 101 and the distal locking screws 51 and 79 placed in accordance with the embodiments herein described.

5 Figs. 13 and 14 show the locator 21 in further detail with the sleeve 213 respectively retracted and extended along the longitudinal axis of the locator. The sleeve 213 is slidably mounted on the core 129. The hook tip 212 is formed on the rod 128 that is affixed to the core 129.

10 Fig. 15 shows the sleeve 213 in further detail. At the distal end of the sleeve are formed a U-shaped receiving region 127 for receiving the hooked tip 212 when the sleeve is extended and annular recess 126 for engagement in the engagement opening 32 at the distal end of the
15 intramedullary nail 31.

The distal end of the intramedullary nail 31 is shown in Figs 16 through 19. In addition to first distal locking aperture 33, a second distal locking aperture 139 is provided. This aperture is formed only in the rear half of
20 the wall forming the nail, since the front half is in this region absent on account of the presence of engagement opening 32.

The shape of the engagement opening 32 is illustrated in detail in Fig. 17 from the front and in Fig. 18 from the
25 side. As can be seen in Fig. 18 the end of the wall of the intermedullar nail generally defines an opening in the front of the member lying generally in the plane Y-Y. The effect of this geometry is shown in Fig. 17, in which it can be seen that the tip of the locator sleeve 213 may be inserted
30 into the opening with the sleeve disposed perpendicularly to the longitudinal axis X-X of the interior channel of the nail. The end of the wall is shaped so as to facilitate positioning of the nail and to cause its rotation to the extent necessary, on encountering the locator in an
35 approximately correct position, to become positively engaged in the opening.

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The shape of the end of the wall of the nail has bilateral symmetry with respect to the plane perpendicular to the page passing through the longitudinal axis. The shape can be analyzed in terms of the axial position of a
5 projection of a location on the end of the wall onto the longitudinal axis as a function of the angular orientation of the location about the longitudinal axis. The most distal axial position 1331 is associated with an angular orientation at the rear of the nail. As the angular
10 orientation of a location on the end of the wall moves toward the front on regions 1381 and 1382, the axial position associated with such location becomes smoothly and progressively less distal until axial position 1332 associated with symmetrical points 1333 and 1334 on the end
15 of the wall. Here the distance between the points 1333 and 1334 is approximately equal to the diameter of the sleeve 213 at its recess 126 shown in Fig. 15, and the wall is here on each side approximately parallel to the longitudinal axis. In the angular orientations lying predominantly
20 between the points 1333 and 1334, the wall defines a region into which the locator may be positively engaged by gripping in the recess 126 of sleeve 213 (of Fig. 13). This region lies in front of the locking aperture 139. The maximum spacing between opposing points on the wall increases
25 slightly in this region beyond the spacing between points 1333 and 1334 in order to provide kinesthetic indication that the locator has been properly engaged in the nail. Also as shown in Fig. 18, the slot 137 along the side of the nail is closed in the most distal region 136 of the nail,
30 for example, by soldering or welding. In order to facilitate centering of the guide wire 11 within the channel of the nail 31 (and therefore grabbing of the guide wire 11 by the locator 21), the cross section of the nail in the region marked by plane A-A in Fig. 16 is narrowed somewhat,
35 for example, by silver soldering. The cross section is shown in Fig. 19 as item 134 and the narrowed cross section is item 135. The cross section must not be narrowed,

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however, so much that the tip of the guide wire cannot readily be removed from the channel within the nail.

Fig. 20 shows detail of the distal alignment fixture 41, which is provided with teeth 141 on the underside for 5 facilitating stabilization of the fixture. Although the sleeve 213 has been shown as cylindrical in shape, it may have one or more flat sides that are keyed to the engagement region 411 of the fixture 41 for further stabilization.

Fig. 21 illustrates inserts used with the fixture 41, 10 including a bushing 151 for a K-wire inserted through channel 152, which fits concentrically within drill guide 153.

Fig. 22 is a partial perspective view of the distal alignment fixture of Fig. 5.

Fig. 23 illustrates a slap hammer for use in inserting 15 the nail 31, including handle 161, insertion tip 162, and lower stop 163. The slapper 164 is slidably mounted on the rod 165 and travels between the handle 161 and lower stop 163.

20

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What is claimed is:

1. A method, of locking the distal end of an intramedullary nail to a distal portion of a bone, comprising:

5 (A) inserting a guide wire into the medullary canal of the bone;

(B) obtaining a locator that includes grab means for grabbing the guide wire;

10 (C) inserting the locator through a pilot hole in the near cortex of the bone in a suitable distal location and causing the grab means to grab the guide wire; and

(D) inserting an intramedullary nail along the guide wire into the medullary canal until it contacts the locator.

2. A method according to claim 1,

15 wherein the locator includes engagement means for engaging with the distal end of a suitably configured intramedullary nail,

the method further comprising, prior to step (D), the step of obtaining an intramedullary nail configured at its 20 distal end to engage with the engagement means;

wherein step (D) further includes inserting the intramedullary nail into the medullary canal until it engages with the engagement means of the locator.

3. A method according to claim 1, further comprising:

25 (E) engaging a first region of a distal alignment fixture with the locator and using the distal alignment fixture for determining the location of a first distal locking hole.

4. A method according to claim 2, further comprising:

30 (F) engaging a first region of a distal alignment fixture with the locator and using the distal alignment fixture for determining the location of a first distal locking hole.

5. A method according to claim 2, further comprising:

35 (G) drilling the first distal locking hole in the location determined in step (E); and

(H) using a suitable fixture mounted to a member inserted in the first distal locking hole for determining the location of a second distal locking hole.

6. A method according to claim 4, further comprising:

5 (I) drilling the first distal locking hole in the location determined in step (E); and

(J) using a suitable fixture mounted to a member inserted in the first distal locking hole for determining the location of a second distal locking hole.

10 7. A method according to claim 3, further comprising, immediately prior to step (E), the step of removing the guide wire from the intramedullary canal.

8. A method according to claim 6, further comprising, immediately prior to step (E), the step of removing the
15 guide wire from the intramedullary canal.

9. An apparatus for fixation of a bone having a medullary canal, comprising:

a locator, for insertion into a pilot hole drilled transversely with respect to the axis of the medullary
20 canal, the locator having (i) grab means for grabbing a guide wire inserted into the medullary canal and (ii) engagement means for engaging with the distal end of a suitably configured intramedullary nail that has been inserted along the guide wire into the intramedullary canal.

25 10. An apparatus according to claim 9, wherein the locator has a longitudinal axis and proximal and distal ends,

the grab means is disposed at the distal end, and the engagement means includes an annular recess in the
30 locator.

11. An apparatus according to claim 10, wherein the locator includes a sleeve slidably mounted on the longitudinal axis of the locator, and the annular recess in the locator is formed in the distal end of the sleeve.

35 12. An apparatus according to claim 11, wherein the grab means includes a hook and the sleeve is formed in such a way as to substantially surround the hook when the sleeve

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is slid to its most distal location along the longitudinal axis.

13. An apparatus according to claim 12, wherein the sleeve includes a U-shaped receiving region for receiving
5 the hook.

14. An apparatus according to claim 9, further comprising:

a distal alignment fixture engagable against the locator, the fixture including an alignment hole for
10 locating a hole to be drilled in the bone.

15. An apparatus according to claim 11, further comprising:

a distal alignment fixture engagable against the sleeve of the locator, the fixture including an alignment
15 hole for locating a hole to be drilled in the bone.

16. An intramedullary nail comprising:

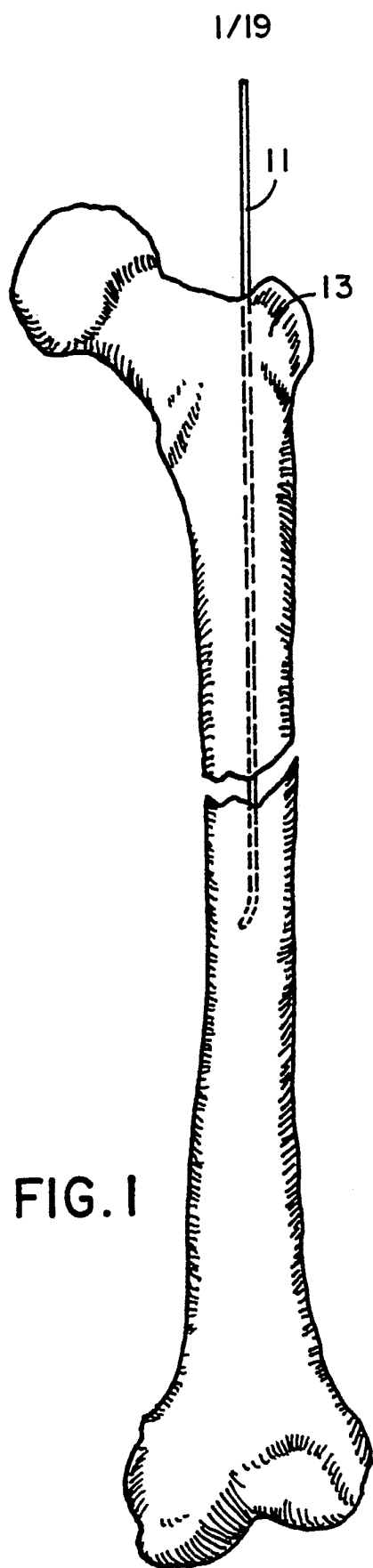
a prolonged member having (i) a wall forming an interior channel, (ii) a longitudinal axis in the channel, and (iii) a distal end thereof at which the end of the wall
20 defines an opening in the front of the member, lying generally in a plane that is obliquely disposed with respect to the longitudinal axis so as to enable the tip of a locator, disposed perpendicularly to the longitudinal axis, to enter the channel from the front of the member; and

25 wherein the end of the wall is further shaped in such a manner that, to facilitate positioning of the nail and to cause its rotation, to the extent necessary on encountering the locator thus disposed for engaging the location, the axial position of a projection of a location on the end of
30 the wall onto the longitudinal axis, as a function of angular orientation of the location about the longitudinal axis, varies smoothly with bilateral symmetry from the most distal axial position, associated with an angular orientation at the rear of the member, to a pair of shorter
35 axial positions associated with angular orientations of locations on the wall at points spaced apart by a distance approximately equal to the diameter of the locator's tip, at

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which points the wall is approximately parallel to the longitudinal axis; and

wherein, in the angular orientations lying predominantly between such points, the wall defines a region
5 into which the locator may be positively engaged.



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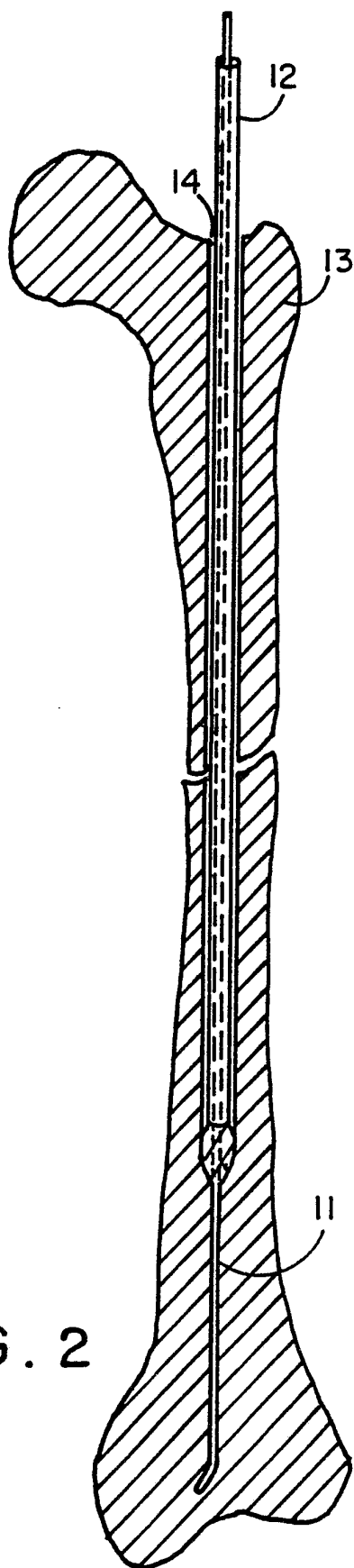


FIG. 2

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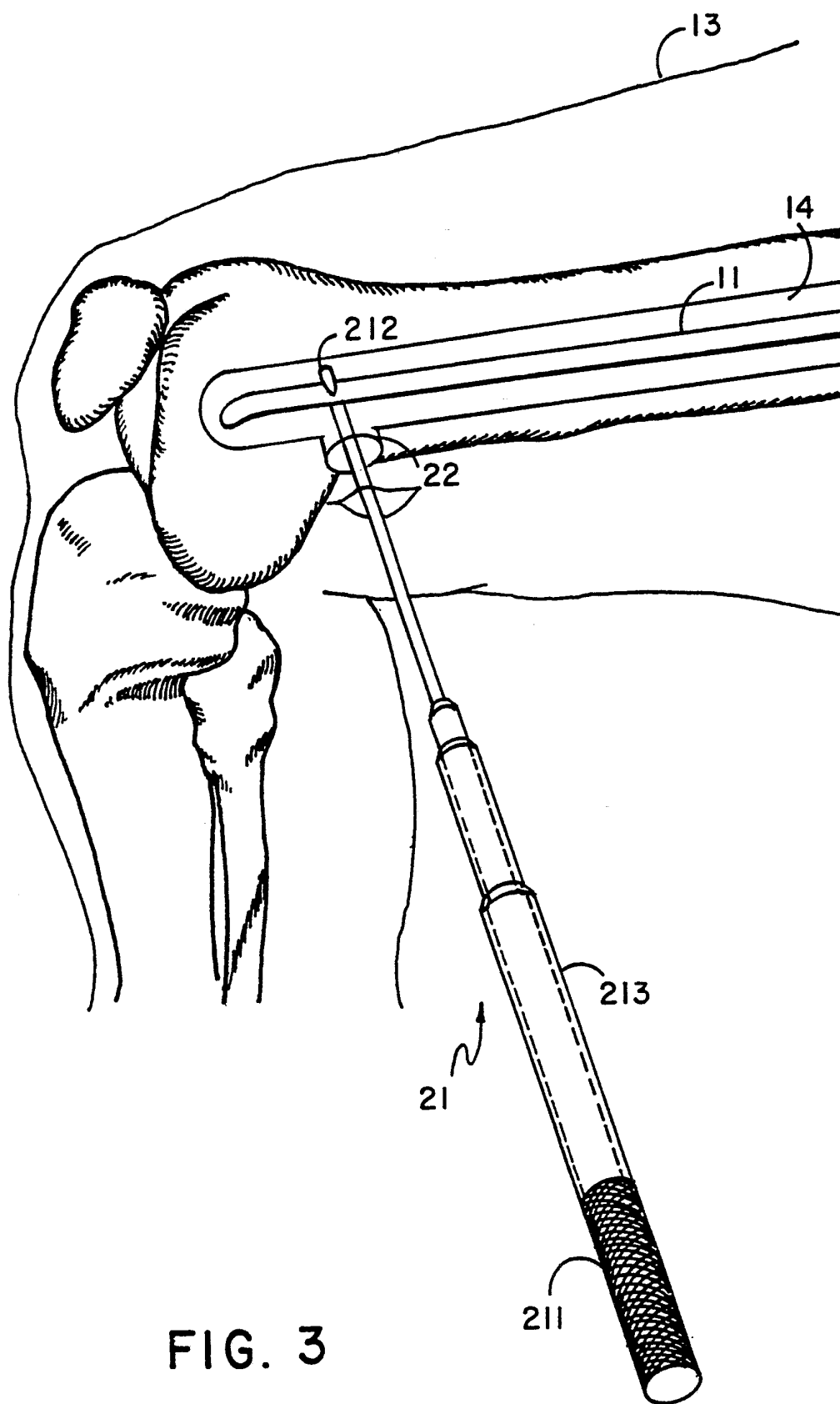


FIG. 3

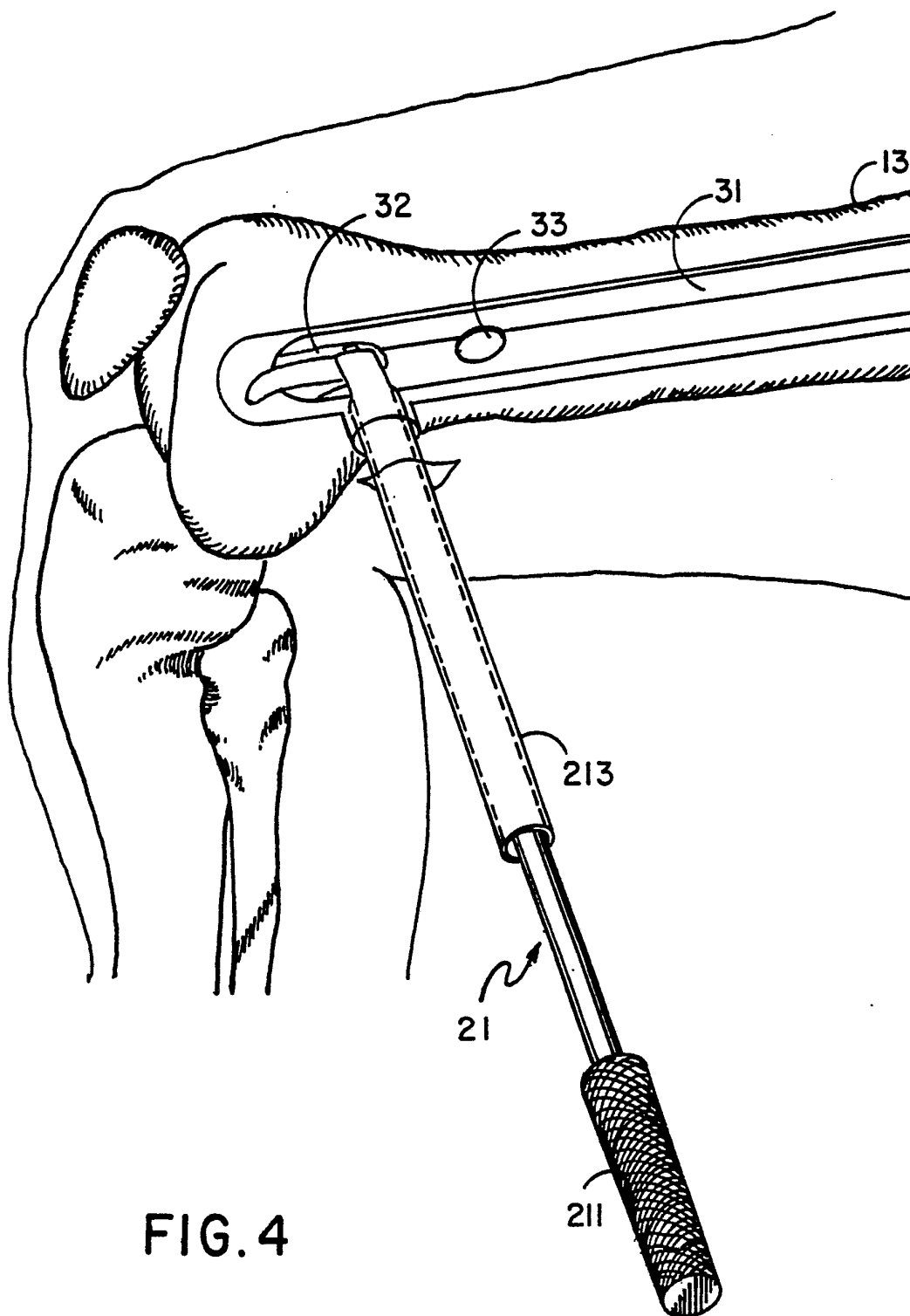
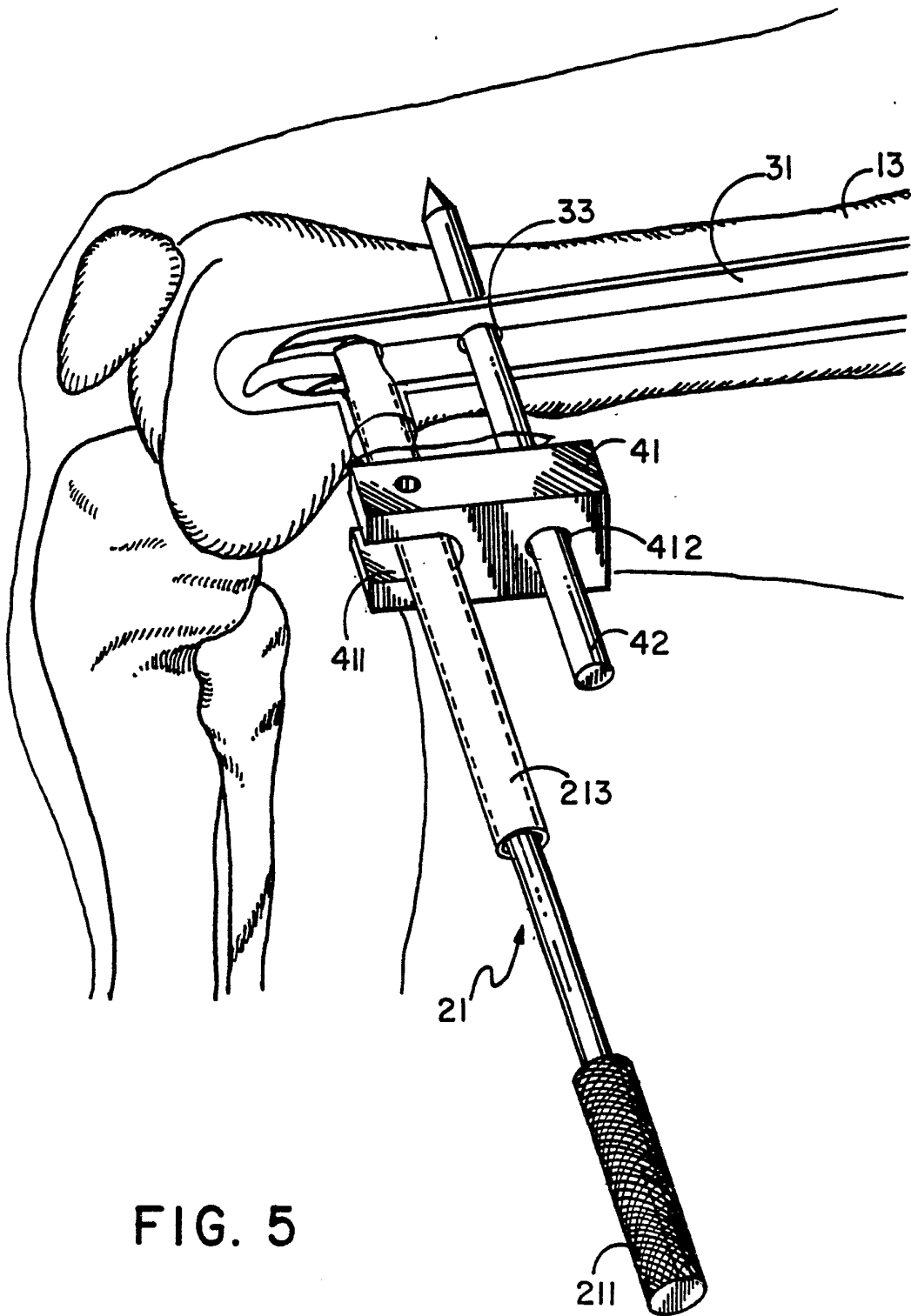


FIG. 4



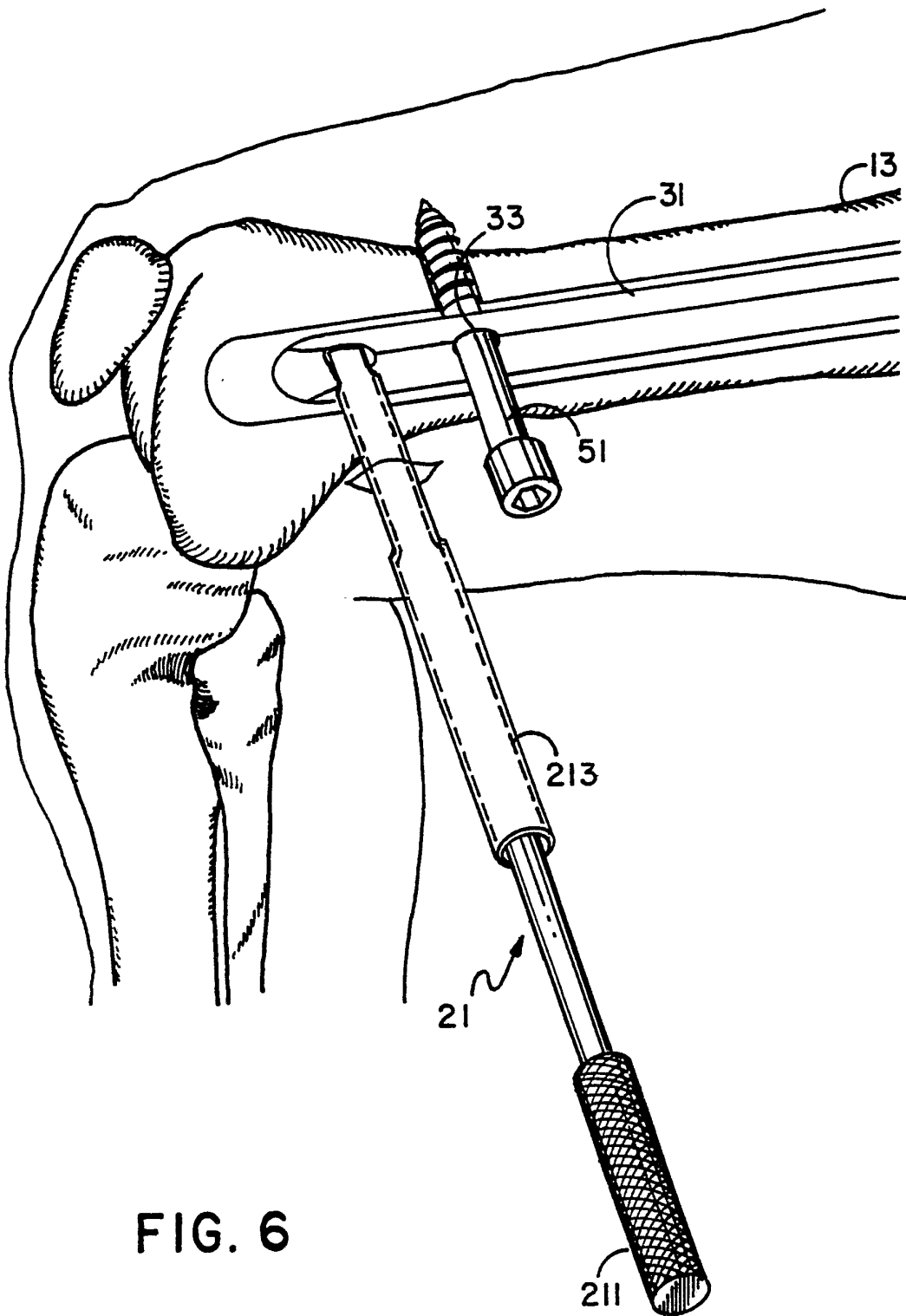


FIG. 6

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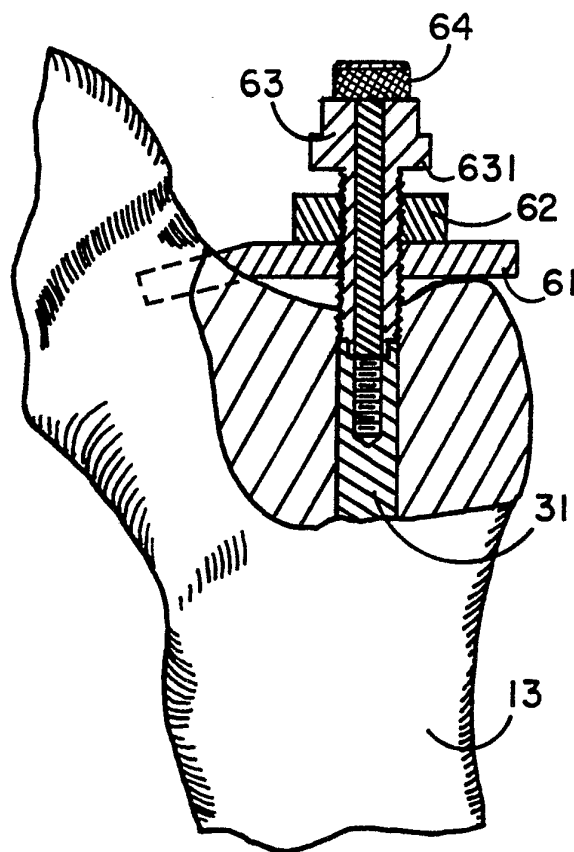


FIG. 7

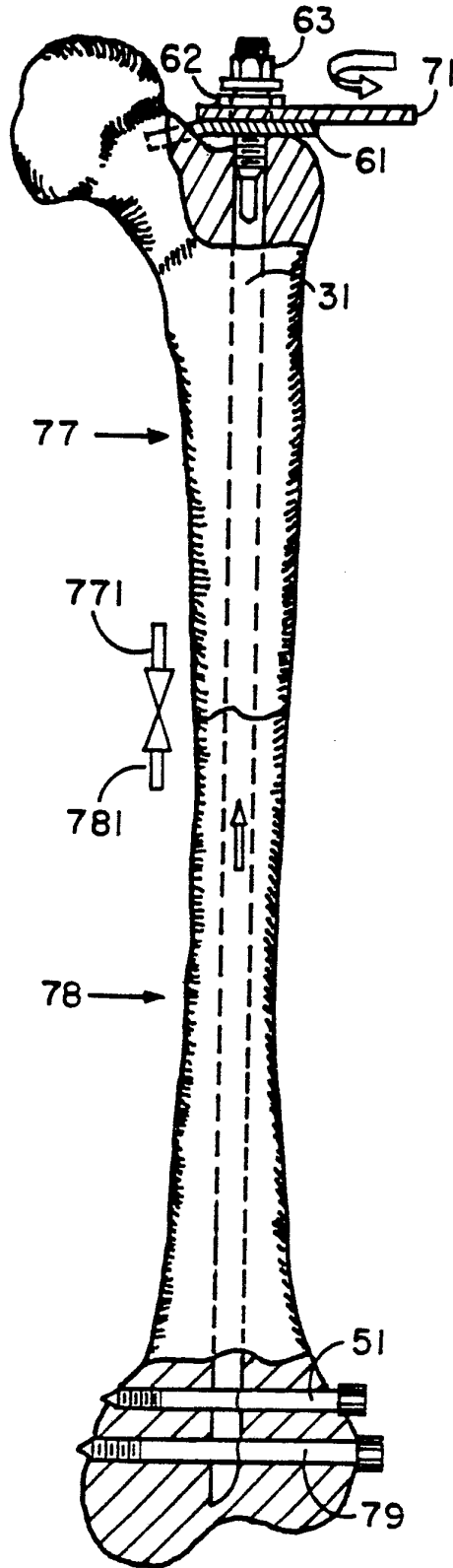


FIG. 8

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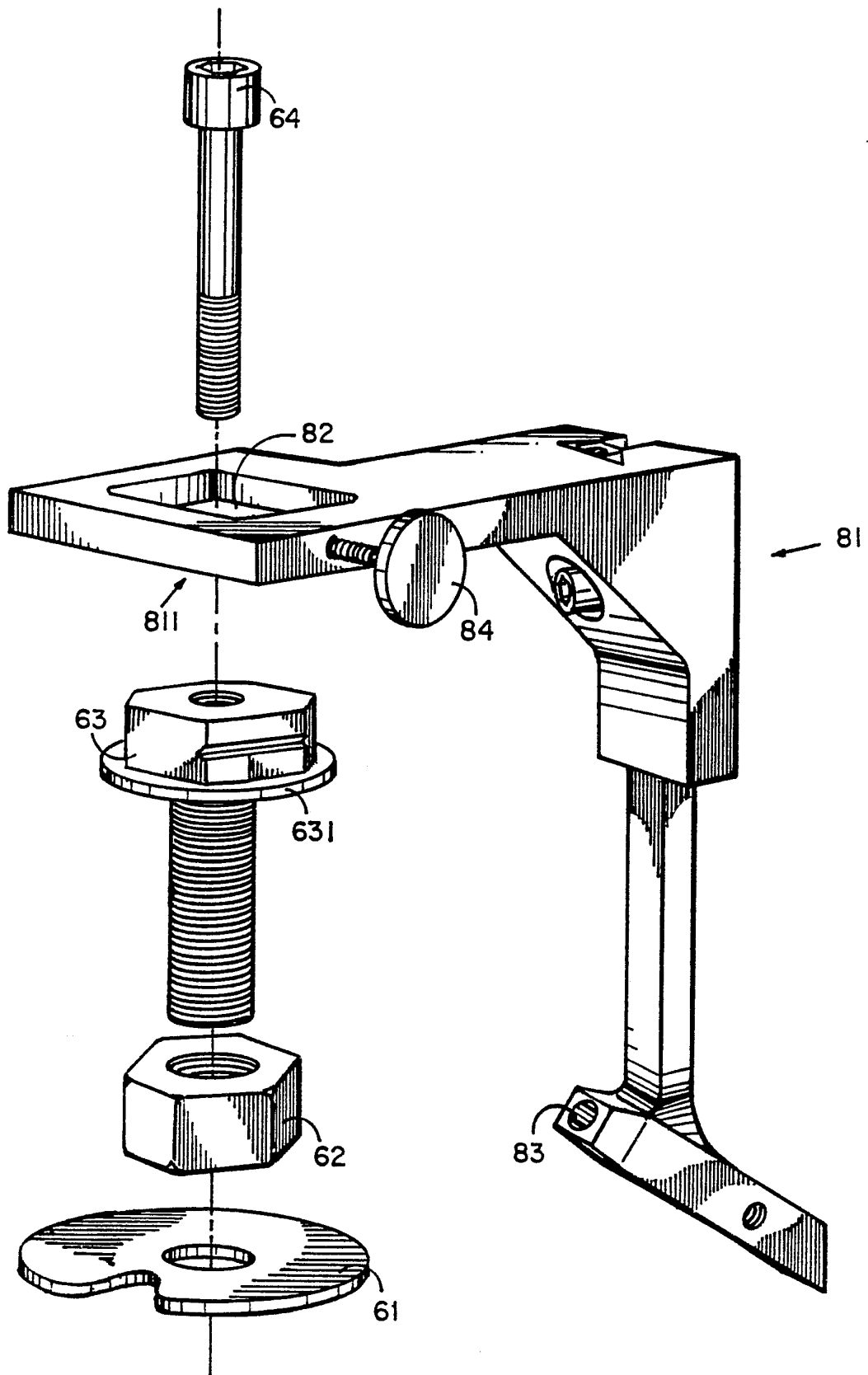
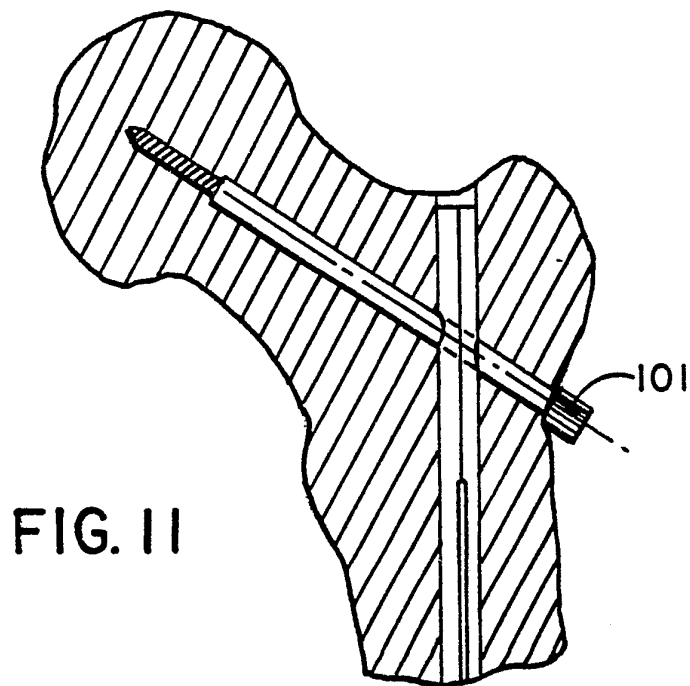
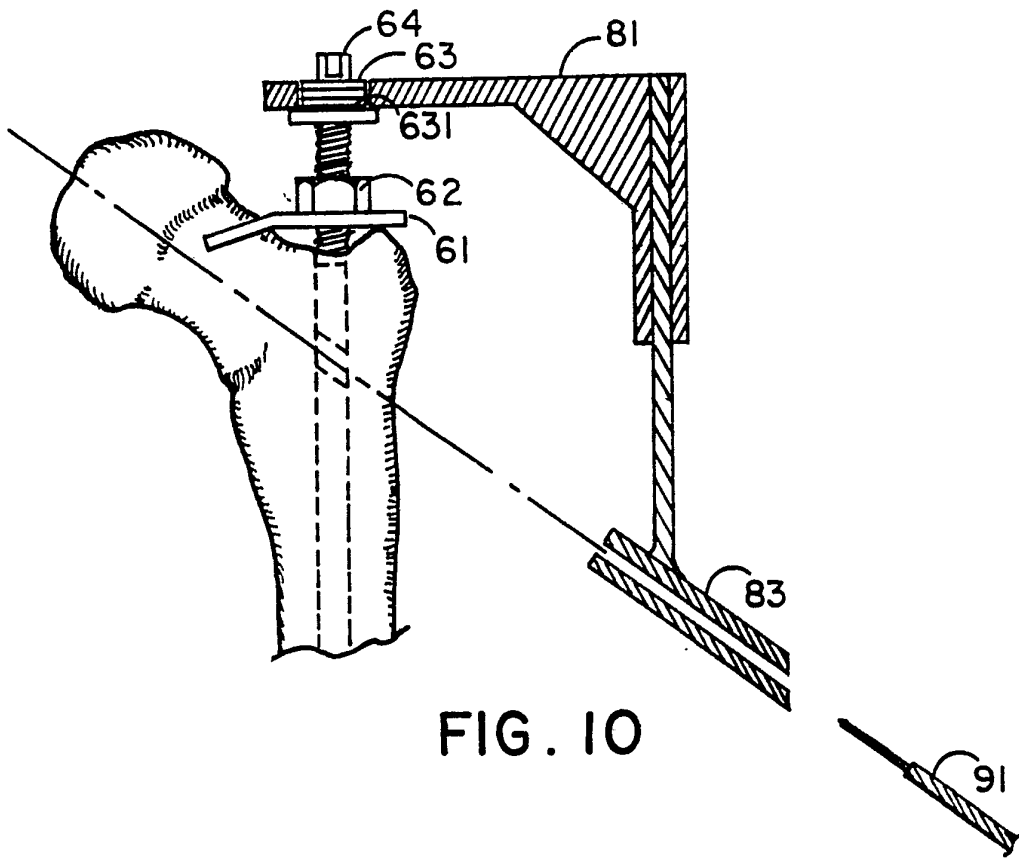


FIG. 9

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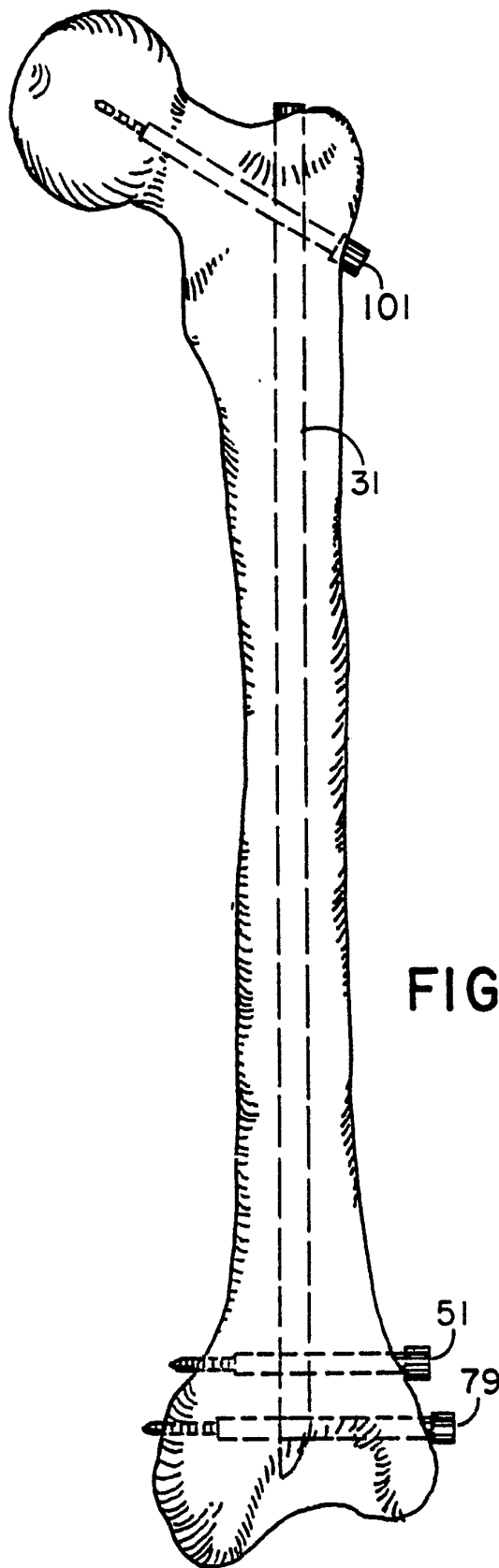


FIG. 12

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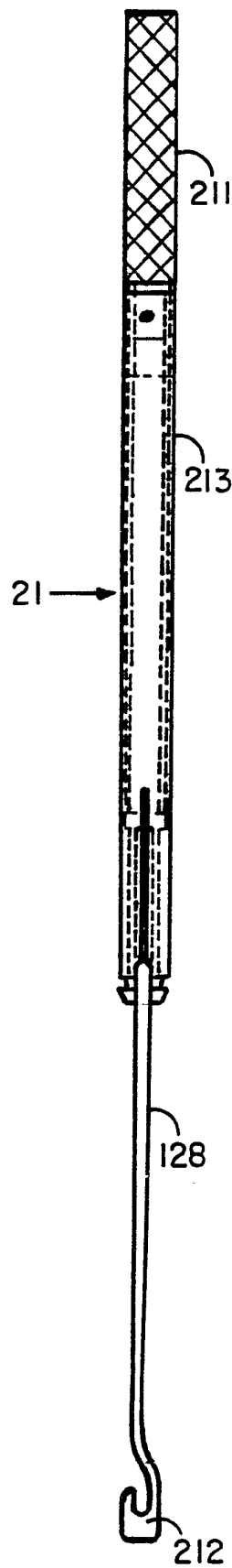


FIG. 13

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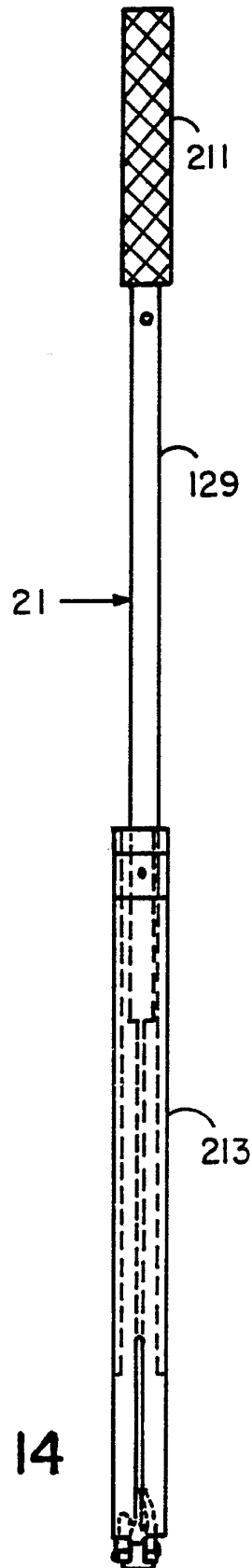


FIG. 14

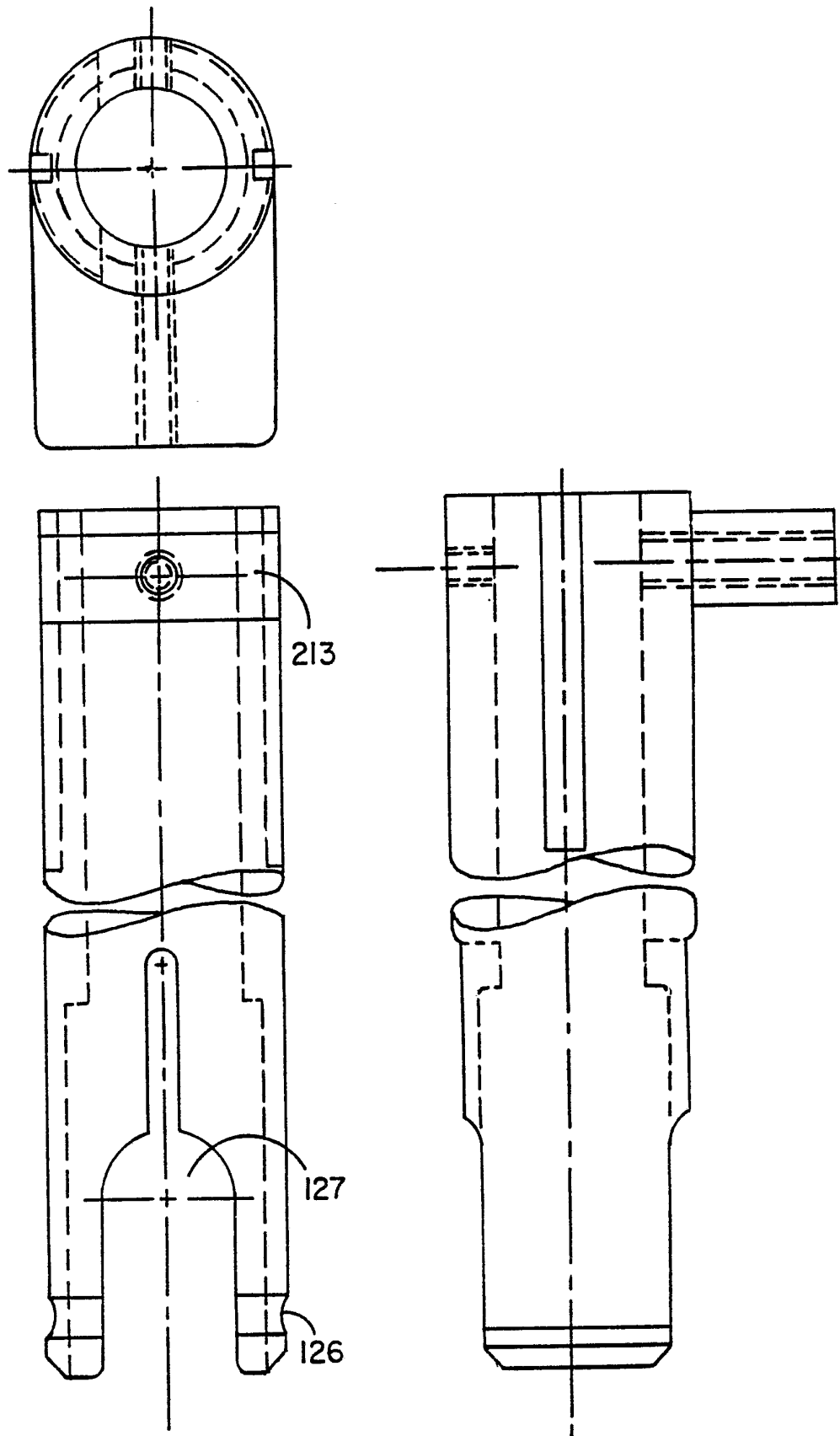


FIG. 15

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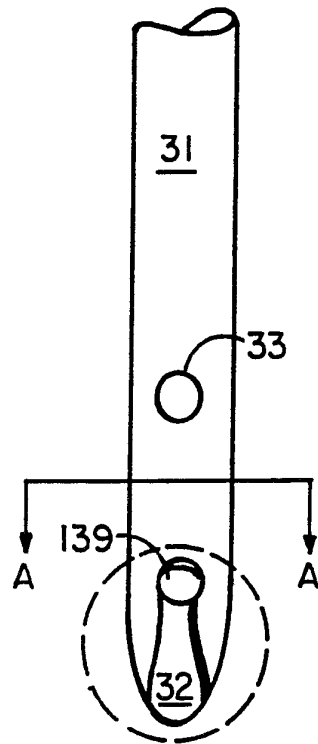


FIG. 16

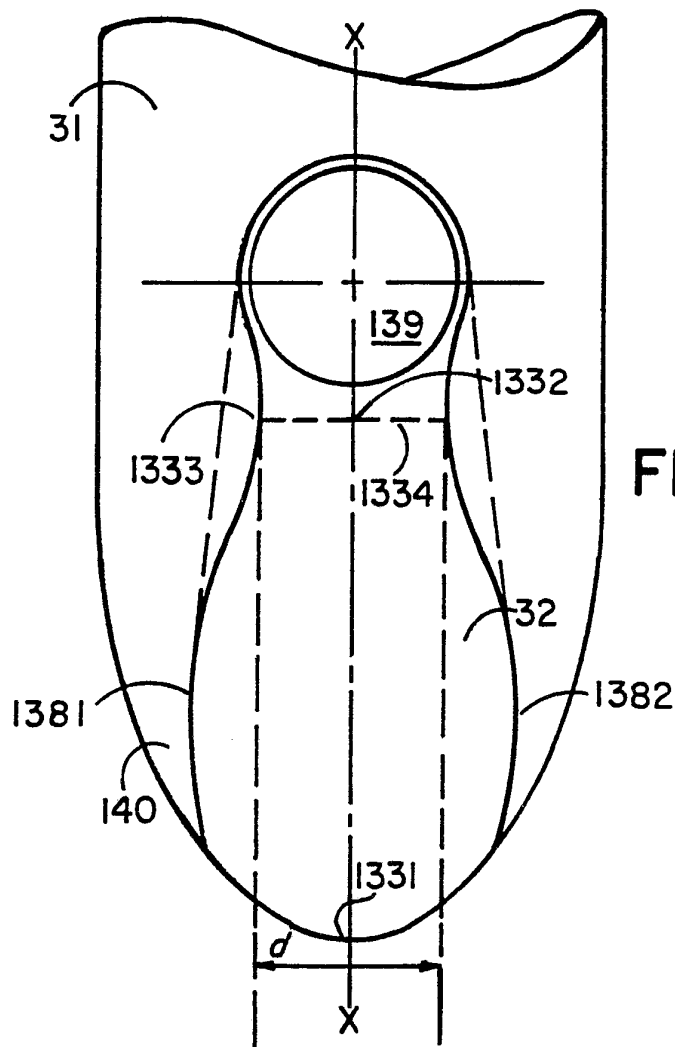


FIG. 17

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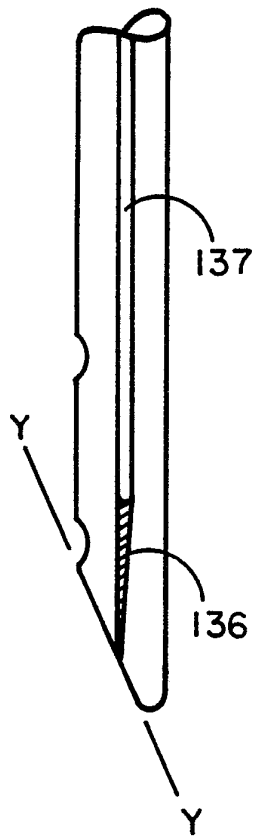


FIG. 18

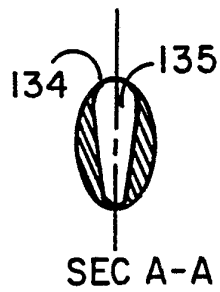
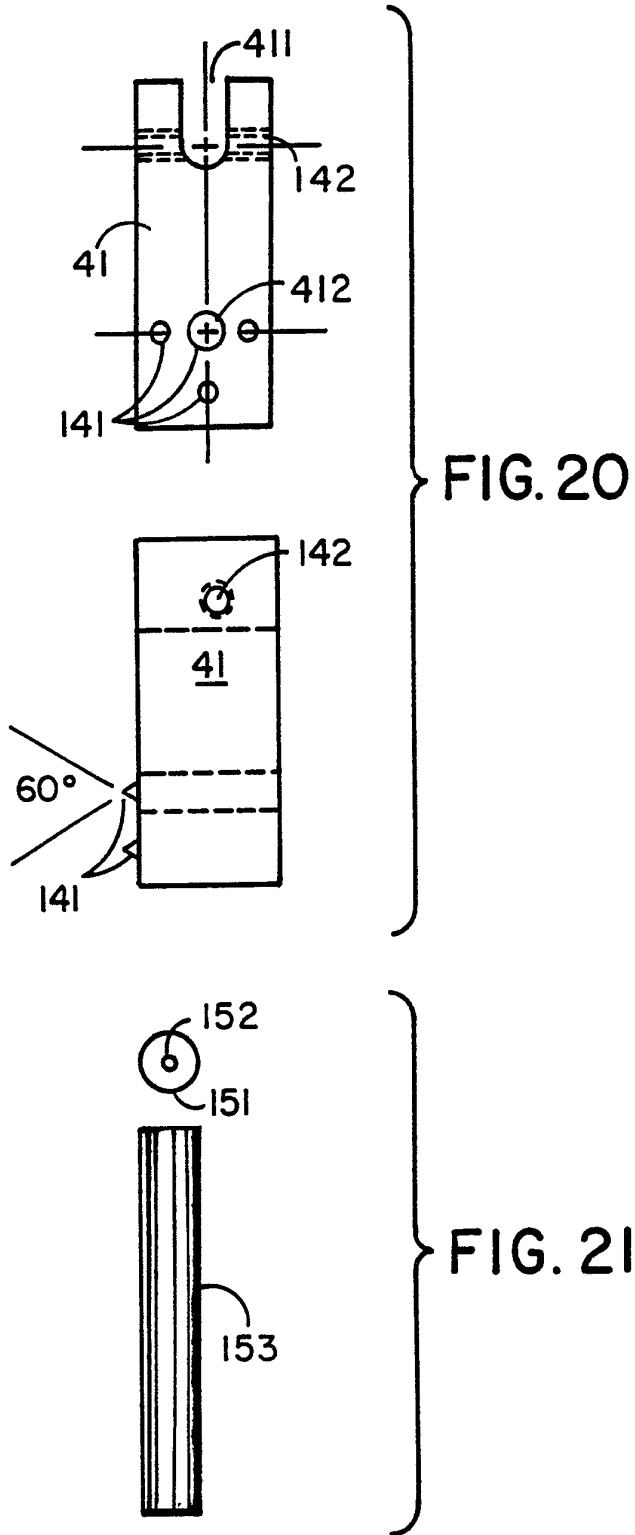


FIG. 19

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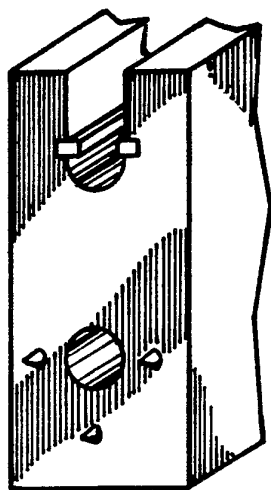


FIG. 22

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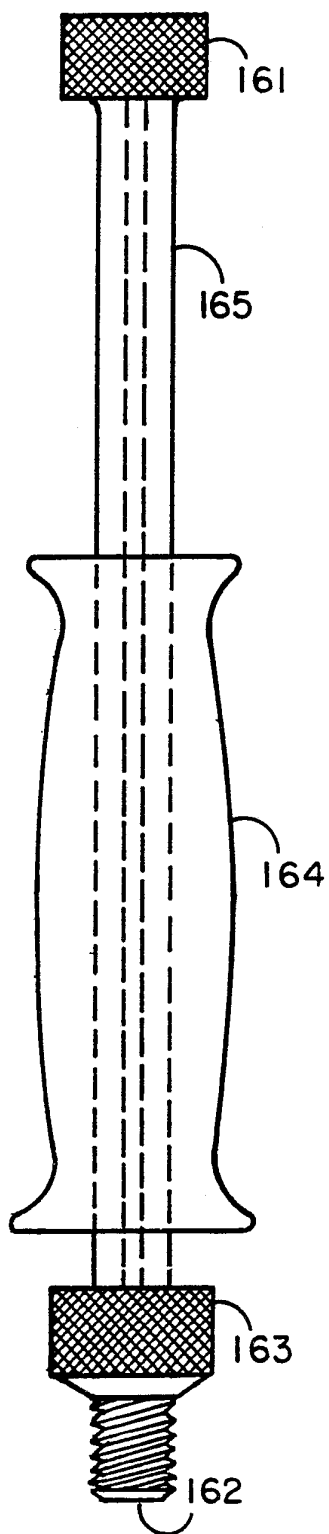


FIG. 23

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/02259

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁵ : A 61 B 17/58		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁵	A 61 B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ¹⁰	Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	US, A, 4846162 (MOEHRING) 11 July 1989 see column 3, line 40 - column 4, line 65; figures 1-6 --	9,16
A	EP, A, 0273872 (G. CREMASCOLI) 6 July 1988 see column 3, line 14 - column 4, line 36; figures 1-12 --	9,16
A	DE, A, 3347333 (MECRON) 28 June 1984 see page 6, line 29 - page 7, line 15; figure 4 --	9,16
A	DE, U, 8702208 (HOWMEDICA) 16 July 1987 see page 9, lines 7-19; figure 6 -----	
<p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
10th July 1991	- 2. 09. 91	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	M. PEIS M. Peis	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. OBSERVATION WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim numbers 1-8 because they relate to subject matter not required to be searched by this Authority, namely:

Pls. see Rule 39.1 (iv) - PCT:

Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

2. Claim numbers because they relate to parts of the International application that do not comply with the prescribed requirements to such an extent that no meaningful International search can be carried out, specifically:

3. Claim numbers because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

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

1. As all required additional search fees were timely paid by the applicant, this International search report covers all searchable claims of the International application
2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the International application for which fees were paid, specifically claims:
3. No required additional search fees were timely paid by the applicant. Consequently, this International search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- The additional search fees were accompanied by applicant's protest.
- No protest accompanied the payment of additional search fees.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9102259
SA 46578

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 27/08/91. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4846162	11-07-89	None	
EP-A- 0273872	06-07-88	US-A- 4877019	31-10-89
DE-A- 3347333	28-06-84	US-A- 4574795	11-03-86
DE-U- 8702208	04-06-87	None	