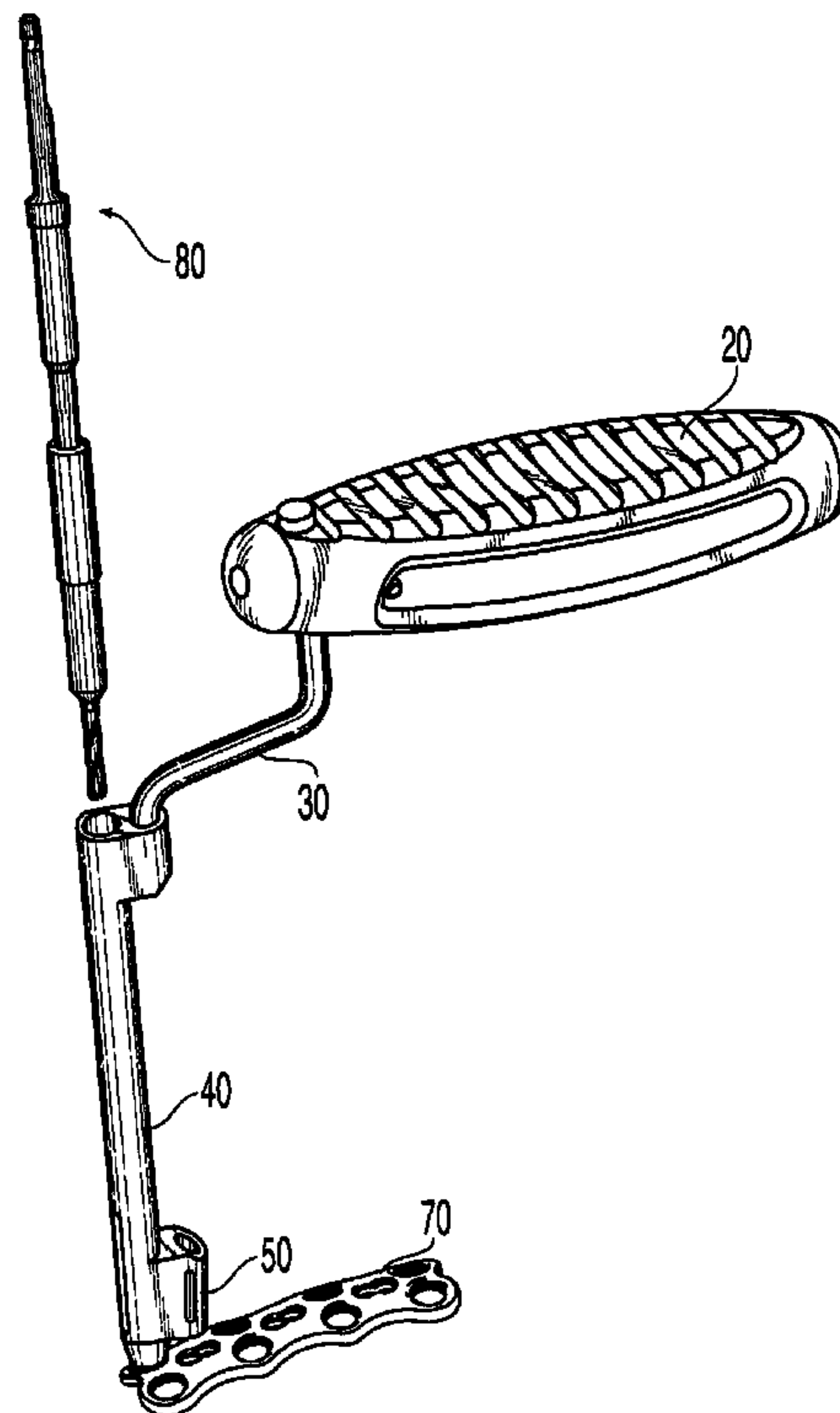




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A surgical drill guide for use with a bone plate having fastener holes oriented at predetermined angles with respect to the plate, the surgical drill guide having at least one alignment drill guiding barrel that is aligned with the respective fastener holes in the bone plate for drilling the holes at the desired range of angles permitted by the plate hole.

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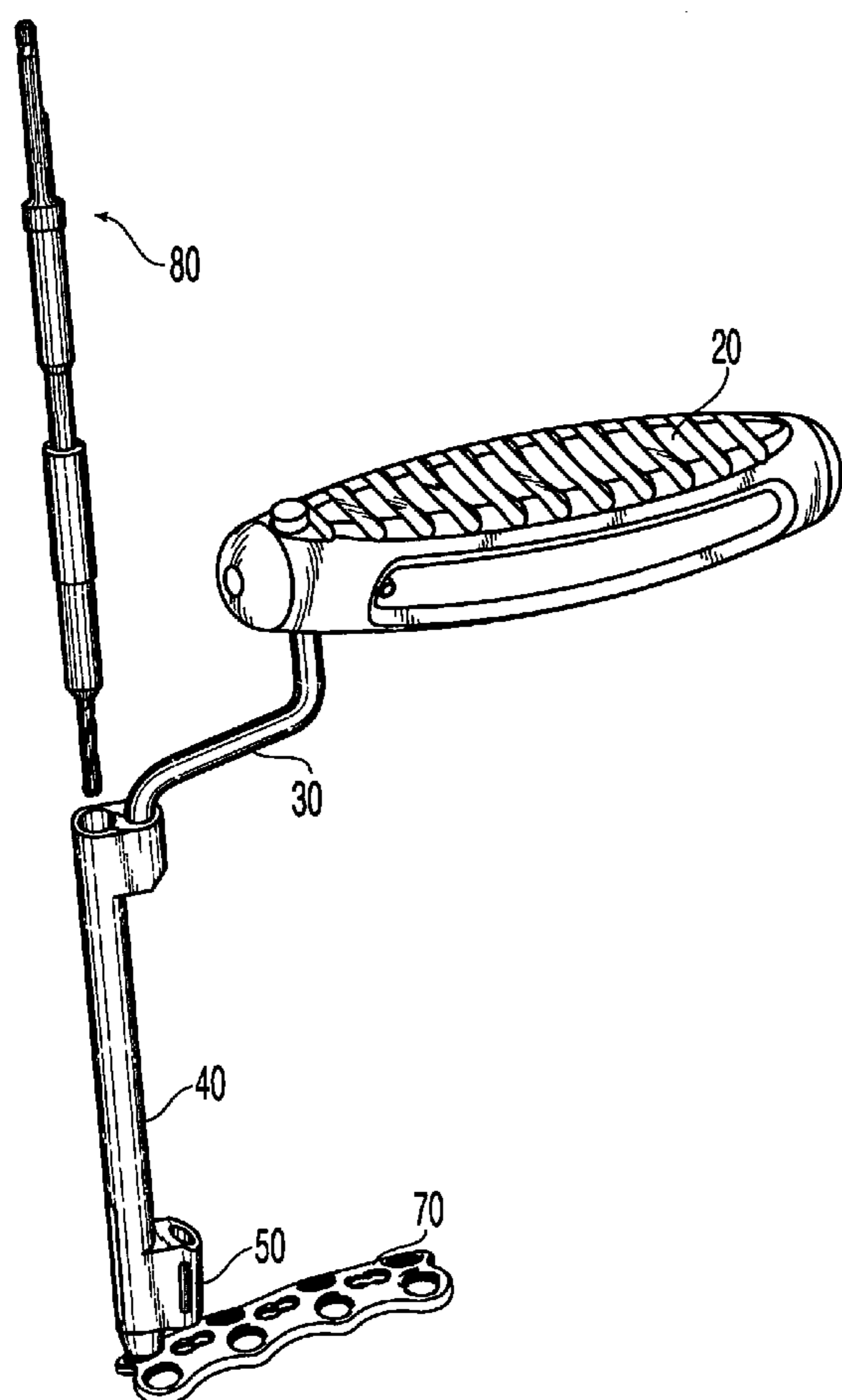
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FREE HAND DRILL GUIDE**FIELD OF THE INVENTION**

[0001] The present invention relates to the field of surgical drill guides, and in particular relates to drill guides that may be associated with a bone plate for providing precise alignment of hole forming tools with the bone screw holes of the plate. More particularly, the surgical drill guide assembly provides soft tissue protection and precise alignment of at least one drill tube with bone screw holes of a bone plate, such as for example, a spinal bone plate.

BACKGROUND OF THE INVENTION

[0002] The use of surgical fixation plates for a variety of orthopedic applications is widely accepted. The plates are used by surgeons to stabilize, mend, or align a patient's bone as well as alter compression of patient's bones, and are typically fastened to the bones with a plurality of fasteners, such as, screws that are installed through holes in the plate. Proper orientation and alignment of fasteners and secure surgical fixation of the plate can mitigate some of the potential complications after implantation.

[0003] Locking bone plates used in spinal applications must be installed with special care, as the plates may be used for long term, intervertebral fixation, bone-fragment fixation, and anterior decompression of vertebra of the spine. The margin for error in spinal surgery is small, particularly because of the sensitivity of the spinal cord and the risk inherent with invasive procedures around the spinal cord. Furthermore, the dimensions of vertebral bone available for setting fasteners are fairly constrained.

[0004] Screws, used to secure the plate to the bone, should be properly aligned with the associated fixation plate hole so that each screw is seated correctly

~~within the plate. Any misalignment of the screw within the plate hole risks tissue~~

damage. In addition, improperly seated screws may result in an unstable or insecure connection of the plate to the bony material, thus potentially defeating the usefulness of the plate. Locking plates, in particular, demand precise fastener
5 alignment.

[0005] Drill guides are often used to assist the surgeon in aligning the screws with the plate holes. Drill guides for locking plates attach or abut to the plate and generally include a guide tube for guiding hole-forming tools, such as a drill bit.

10

SUMMARY OF THE INVENTION

[0006] A drill guide is provided comprising a guide barrel for receiving a bone tool for creating a hole in bone and an alignment assembly associated with the guide barrel for aligning the bone tool with a selected first or second fastener hole of a bone plate. The alignment assembly may comprise a location post configured
15 to be at least partially received within a recess in the bone plate. Further, the location post may be pivotable about the bone plate recess to allow the guide barrel to be selectively aligned with the first and second fastener holes. The location post alternatively may be configured to axially lock the drill guide to the bone plate.

[0007] The location post may further comprise a plurality of resilient finger
20 elements configured to frictionally engage the bone plate recess to thereby axially lock the drill guide to the bone plate. The resilient finger elements also may have at least one ridge configured to engage threads in the bone plate recess.

[0008] The alignment assembly further may comprise a housing having a first axial bore configured to slidably receive at least a portion of the location post.
25 The location post and housing further each may have a distal end. The location post may have a retracted position in which the location post distal end is located a

first distance from the distal end of the housing. The location post may also have

an extended position in which the location post distal end is located a second distance from the distal end of the housing, where the second length is greater than the first length. The alignment assembly further comprising a spring element
5 disposed at least partially within a second axial bore in the housing to bias the location post to the extended position.

[0009] The guide barrel further may comprise a bore with a bore axis, and a distal plate-engaging end, wherein the distal plate-engaging end comprises a nose portion configured to be received within the first or second fastener hole to align the
10 bore with the bone screw hole.

[0010] The nose portion may comprise a conical shape. Further, the housing first axial bore and the guide barrel bore forming an acute angle therebetween. Thus, when the location post received within the bone plate recess and the location post is in the extended position, the guide barrel distal end may be located a first
15 distance from the top surface of the bone plate. Further, when the location post is received within the bone plate recess and the location post is in the retracted position, the guide barrel distal end may contact the selected bone screw hole. In an alternative embodiment, the location post may be axially fixed to the alignment assembly.

20 [0011] The drill guide may further comprise a handle associated with the guide barrel, and the handle may be configured to be selectively rotatable with respect to the guide barrel in a first plane. The first plane may be substantially perpendicular to the longitudinal axis of the guide barrel bore. A handle swivel assembly may also be provided having a locked position in which the handle can
25 not rotated with respect to the guide barrel, and an unlocked position in which the handle is freely rotatable with respect to the guide barrel. The swivel assembly

~~may comprise at least one non-metallic bearing, and may also comprise a drain~~

hole configured to allow fluid to drain from the assembly subsequent to sterilization of the drill guide.

[0012] A surgical drill guide may be provided comprising a handle, a guide
5 barrel having a proximal end associated with the handle and a distal end configured to engage an inner surface of a fastener hole of a bone plate. The guide barrel further may comprise a bore configured to receive a bone cavity forming tool. An alignment assembly may be associated with the guide barrel for aligning the bone tool with a selected first or second fastener hole, the alignment assembly
10 comprising a location post configured to be at least partially received within a recess in the bone plate;

[0013] The location post may be pivotable within the recess to allow the guide barrel to be selectively aligned with the first and second fastener holes so that the tool may be extended through the guide barrel to form a cavity in a bone
15 underlying the selected fastener hole. The location post may be configured to axially lock the drill guide to the bone plate. The location post further may comprise a plurality of resilient finger elements configured to frictionally engage the bone plate recess to thereby axially lock the drill guide to the bone plate. The resilient finger elements may further comprise at least one ridge configured to engage
20 threads in the bone plate recess. The alignment assembly may further comprise a housing having a first axial bore configured to slidably receive at least a portion of the location post.

[0014] The location post may have a retracted position in which a first length of the location post is received within the bore and an extended position in which a
25 second length of the location post is received within the bore, wherein the first length is greater than the second length.

[0015] The alignment assembly further may comprise a spring element

disposed at least partially within a second axial bore in the housing to bias the location post to the extended position. The guide barrel further may comprise a bore with a bore axis, and a distal plate-engaging end, wherein the distal plate-engaging end comprises a nose portion configured to be received within the first or second fastener hole to align the bore with the bone screw hole. The nose portion may comprise a conical shape. Further, the housing first axial bore and the guide barrel bore may form an acute angle therebetween.

[0016] The location post may be received within the bone plate recess so

that when the location post is in the extended position, the guide barrel distal end is located a first distance from the top surface of the bone plate. Further, when the location post is received within the bone plate recess and the location post is in the retracted position, the guide barrel distal end may contact second bone screw hole. Alternatively, the location post may be axially fixed to the alignment assembly.

[0017] The drill guide further may comprise a handle associated with the guide barrel, where the handle is configured to be selectively rotatable with respect to the guide barrel in a first plane. The first plane may be substantially perpendicular to the longitudinal axis of the guide barrel bore. The swivel assembly may have a locked position in which the handle can not rotated with respect to the guide barrel, and an unlocked position in which the handle is freely rotatable with respect to the guide barrel. The swivel assembly may further comprise at least one non-metallic bearing. The swivel assembly further may comprise a drain hole configured to allow fluid to drain from the assembly subsequent to sterilization of the drill guide.

[0018] A drill guide assembly is provided comprising a guide barrel having a tool receiving portion comprising a longitudinal bore having a bore axis, and an

~~aligning assembly portion.~~ An aligning assembly may be provided comprising a guide barrel engaging portion, a housing and a location post having a post axis. A bone plate may further be provided comprising at least two bone screw holes and a positioning recess, and the positioning recess may be configured to receive at least a portion of the location post, the center of the positioning recess being separated from the center of at least one of the bone screw holes by a first distance. The bore axis may be located a second distance from the location post axis, the first and second distances being substantially equal so that when the location post engages the bone plate recess, the bore is substantially coaxial with the at least one fixation hole.

[0019] The drill guide may further comprise a handle member associated with a proximal end of the guide barrel, and the handle member may be pivotable in relation to the guide barrel.

[0020] The guide barrel may have at least one depth stop surface configured to coact with a corresponding stop surface of a bone cavity forming tool when the tool is received within the bore to prevent the tool from passing completely through the guide barrel bore. The handle further may have a locked position in which the handle is rotationally coupled to the guide barrel, and an unlocked position in which the handle is freely rotatable with respect to the barrel. The handle may further comprise a locking button having an actuation end and a locking end, the locking end having at least one radial projection, the button further having an unactuated position and an actuated position.

[0021] The handle may further comprise a bore configured to slidably receive at least a portion of the button, the bore further comprising a radial recess configured to receive the radial projection. A handle extension may be provided having a handle engaging end and a guide barrel engaging end, the handle

~~engaging end having at least one radial groove configured to receive the radial~~

projection; wherein when the handle is in the unactuated position, the radial projection engages the radial recesses of the handle bore and the handle extension to configure the handle in the locked position. Further, when the handle is in the actuated position, the radial projection may engage the radial recess of only one of the handle bore and the handle extension to configure the handle in the unlocked position.

[0022] The location post further may comprise a plate engaging end having a plurality of resilient fingers configured to axially lock the drill guide to the bone plate when the location post is engaged with the recess. The location post plate engaging end may have at least one circumferential ridge configured to engage a bottom surface of the bone plate when the location post is engaged with the recess.

[0023] A drill guide assembly may further be provided comprising a guide barrel having a tool receiving portion comprising a longitudinal bore having a bore axis, and an aligning assembly portion. An aligning assembly may be provided comprising a guide barrel engaging portion, a housing and a location post having a post axis. A bone plate further may be provided having at least two fastener receiving holes and a drill guide positioning recess, the recess configured to receive at least a portion of the location post, the center of the recess being separated from the center of at least one of the bone screw holes by a first distance. Further, the bore axis may be located a second distance from the location post axis as measured between the distal ends of the guide barrel and the location post, the first and second distances being substantially unequal so that when the location post engages the bone plate recess, the bore is not coaxial with the at least one fixation hole.

[0024] The difference between the first and second distances may be from

~~about 0 millimeters (mm) to about 0.8 mm.~~ Alternatively, the second distance may be about .0.5 mm longer than the first distance.

- [0025] A method for drilling a hole in bone may be provided, comprising the steps of: providing a bone plate having at least a first pair of fastener receiving holes and a drill guide aligning recess; applying the plate to the bone surface; providing a drill guide having a guide bore for receiving a tool and an alignment mechanism associated with the guide bore and including a location post having a proximal alignment mechanism engaging end and a distal plate engaging end; inserting the plate engaging end of the location post into the recess in the bone plate; rotating the location post within the recess in the bone plate to align the guide bore with a first selected one of the pair of fastener receiving holes; inserting and advancing a tool through the guide bore to contact the bone surface underlying the selected fastener receiving hole; and applying rotational and/or axial force to the tool to creating a cavity in the bone underlying the selected fastener receiving hole.
- [0026] The alignment mechanism may further comprise a spring element to bias the location post distally axially away from the alignment mechanism, the guide bore further comprising a distal end adjacent the distal end of the location post, the guide bore distal end comprising a conical nose portion configured to engage an inner surface of at least one of the pair of fastener receiving holes, wherein the step of aligning the guide bore with a selected one of the pair of fastener receiving holes further comprises engaging the guide bore nose with the inner surface of the at least one of the pair of fastener receiving holes.

- [0027] The method may further comprise the step of rotating the location post within the hole, slot, or indentation in the bone plate to align the guide bore with the second one of the pair of fastener receiving holes; inserting and advancing the tool through the guide bore to contact the bone surface underlying the second

~~fastener receiving hole~~ and applying rotational and/or axial force to the tool to

create a cavity in the bone underlying the second fastener receiving hole. The tool may be an awl, drill or tap.

[0028] The method may further comprising the steps of disengaging the

5 location post from the recess in the plate to disassociate the drill guide from the bone plate, inserting a bone fastener through one of the first and second fastener receiving holes and into the cavity in the bone underlying the fastener receiving hole, and engaging the fastener with the fastener receiving hole and the bone to fix the plate to the bone.

10 [0029] The drill guide bore and alignment mechanism may be offset from each other so that when the location post is rotated within the bone plate recess to align the guide bore with a first selected one of the pair of fastener receiving holes, the guide bore axis is offset from the center of the fastener receiving hole.

[0030] The method may further comprise the steps of inserting and
15 advancing a tool through the guide bore to contact the bone surface underlying the selected fastener receiving hole; and applying rotational and/or axial force to the tool to creating a cavity in the bone underlying the selected fastener receiving hole comprise creating a cavity having an axis that is not collinear with the axis of the fastener receiving hole.

20

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] 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:

25 [0032] FIG. 1 is a perspective view of a first embodiment of the free hand drill guide assembly, an exemplary bone plate, and an exemplary drill bit;

~~[0033] / US~~ FIGS. 2A, 2B and 2C are top, side cross section and end cross

section views, respectively, of the bone plate of FIG. 1;

[0034] FIGS. 3A and 3B are a side view and cross sectional detail view, respectively, of the drill guide of FIG. 1, while FIG. 3C is a cross sectional view of

5 the drill guide of FIG. 1 engaged with the plate of FIG. 2A;

[0035] FIG. 4 is a cross sectional detail view of an embodiment of the drill guide of FIG. 1 incorporating an alternative plate-retaining feature;

[0036] FIGS. 5A and 5B are cross-sectional detail and exploded views, respectively, of the swivel handle mechanism of the drill guide of FIG. 1;

10 [0037] FIGS. 6A and 6B are cross-sectional detail and exploded views, respectively, of an alternative embodiment of the swivel handle mechanism of FIGS. 5A and 5B.

[0038] FIG. 7 is a cross-sectional view of the guide barrel portion of the drill guide of FIG. 1;

15 [0039] FIG. 8 is a side view of an alternative embodiment of the guide barrel portion of FIG. 7;

[0040] FIG. 9 is a side view of the location post of the drill guide of FIG. 1;

[0041] FIG. 10 is a side view of an alternative embodiment of the location post of FIG. 4;

20 [0042] FIG. 11 is a side view of an exemplary drill bit for use with the drill guide of FIG. 1;

[0043] FIG. 12 is a side view of an exemplary bone screw for use with the bone fixation plate of FIG. 2A;

[0044] FIG. 13 is a side sectional view of the bone fixation plate of FIG. 2A;

25 [0045] FIGS. 14A and 14B are side and cross-sectional detail views, respectively, of an awl for use with the drill guide of FIG. 1;

[0046] ~~US FIG. 15~~ FIG. 15 is a side view of a tap for use with the drill guide of FIG. 1;

[0047] FIG. 16 is a perspective view of a bone plate fixed to adjacent vertebra using two pairs of bone screws, where the bone screws have been placed in holes drilled off-center of the fastener holes of the plate;

5 [0048] FIG. 17 is a top view of the bone plate of FIG. 2A, illustrating an offset bone screw hole;

[0049] FIG. 18 is a cross-sectional view of the location post of FIG. 10 engaged with the plate of FIG. 2A;

[0050] FIG. 19 is a perspective cutaway view of an exemplary bone screw
10 engaged with a bone screw hole of a plate having a locking clip.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0051] Referring to **FIG. 1**, there is shown an exemplary drill guide assembly **10**, which is adapted for use with a spinal fixation device, such as for example, a
15 spinal fixation plate **70**. An exemplary spinal fixation plate may be that disclosed in co-pending United States non-provisional patent application Serial No. 10/653,164, filed September 3, 2003, entitled "Bone Plate with Captive Clips," by Duong, *et al.*, the entire disclosure of which is expressly incorporated by reference herein. It is noted, however, that while the drill guide assembly is disclosed in conjunction with
20 a spinal fixation plate it is contemplated that the drill guide assembly may be used in conjunction with bone plates used on any portion of the body. Alternatively, in some instances the drill guide may be used without a bone plate. Drill guide assembly **10** generally includes a handle **20**, an offset handle extension **30**, a guide barrel **40**, and a plate aligning mechanism **50**. In general, to operate the drill guide
25 assembly **10**, a surgeon grasps the handle **20** of the drill guide assembly **10** and aligns the plate aligning mechanism **50** (**FIGS. 3A, 3B**) with a bone plate **70** such

that the location post 52 of the plate aligning mechanism 50 is received within a slot end-hole 72 (FIG. 2A, 2C) in bone plate 70. When the location post 52 is received within the end hole 72, the drill guide barrel 40 may then be swiveled about the location post 52 to bring the barrel 40 into rough alignment with one of a pair of bone screw holes 74R, L in the bone plate 70. A downward force may then be applied to the handle 20 to force the nose portion 42 of the guide barrel 40 to engage the targeted bone screw hole 74R, L. This engagement serves to precisely align the guide barrel 40 within the bone screw hole 74R, L to assure the hole in the bone will be drilled in the desired location and with the desired trajectory, since the hole will largely control the location of the bone screw placed therein.

[0052] With the nose portion 42 of the drill guide barrel 40 engaged with the targeted bone screw hole 74R, L, an awl, drill and tap may be individually and sequentially inserted through the guide barrel 40 to prepare the hole in the bone for receipt of a bone screw. Once preparation of the hole is complete, the guide barrel nose portion 42 may be removed from the bone screw hole 74R, L, and the guide barrel 40 swiveled within the slot end-hole 72 to align with the barrel with the other bone screw hole of the "pair." The second hole may then be prepared in the same manner as the first. After drilling is complete, the drill guide may be lifted off the plate and similarly aligned with another "pair" of bone screw holes. Since the location post is not affirmatively retained within the end hole, unwanted movement of the plate is minimized during removal of the drill guide from the plate.

[0053] In an alternative embodiment, illustrated in FIGS. 4 & 10, the plate aligning mechanism 50 may have a location post 152 with a plate-retaining feature comprising a plurality of axial slots 1152 which may form a plurality of resilient fingers 154. This arrangement may allow the plate aligning mechanism 50 to axially retain the bone plate which may allow the surgeon to use the drill guide 10

~~As a plate holder.~~ As the location post **152** is inserted into the slot end-hole **72** of

the plate **70**, the fingers **154** are compressed together, causing the them exert an expansion spring force against the inner surface of the end-hole **72** in the bone plate, thereby axially locking the drill guide **10** to the plate **70**. Although the
5 expansion force may be sufficient to axially lock the drill guide to the plate, the location post may remain rotatable within the hole **72**, thus allowing the guide barrel **40** to be swiveled to align with a pair of bone screw holes **74R, L**, as described with respect to the previous embodiment.

[0054] To increase the locking strength of the location post **152** within the
10 slot end-hole **72** of the bone plate **70**, the resilient fingers **154** may comprise one or more circumferential ridges **1154** which may engage the inner surface of the slot end-hole **72**. This arrangement may be particularly effective where the slot end-hole **72** is threaded, because the circumferential ridges may engage a portion of the slot end-hole threads. Further, as illustrated in **FIG. 18**, an end portion **1155** of
15 each of the locking post fingers **154** may comprise a circumferential ridge that may engage an underside surface (**FIGS. 13 & 18**) of the bone plate **70** when the post is engaged with the slot end hole **72**.

[0055] This locking post arrangement of **FIGS. 4 & 10** may eliminate the need for a separate tool to place and hold the bone plate in place within the
20 surgical site. The remaining features of the drill guide of this embodiment are the same as that described in relation to the previous embodiment. Thus, once the locking post **152** is engaged with the slot end hole **72**, the guide barrel **40** of this embodiment may be aligned within a targeted screw hole **74R, L** and used with an awl, tap and drill in the same manner as the drill guide of **FIG. 1**. After use,
25 however, the drill guide may be disconnected from the plate by pulling up on the handle with sufficient force to disengage the resilient fingers **154** from the plate slot

~~end-hole 72~~ 05/12/16

[0056] With reference to **FIG. 2A**, an exemplary bone plate **70** is illustrated. The plate **70** may have a plurality of “pairs” of bone screw holes **74R, L** disposed along the length of the plate, and each “pair” of bone screw holes may correspond to a pair of bone screws used to engage a single vertebra. The bone screw holes **74R, L** may have at least an upper portion **174R, L (FIG. 2B)** that is conical in cross section, and this portion may be configured to receive the conical nose portion **42** of guide barrel **40**. A slot **76** may be provided between successive bone screw hole “pairs,” and this slot may take the shape of a “dog-bone” (*i.e.* it may comprise a slot with an expanded portion **72** located at either end). In the illustrated embodiment the expanded portions are circular holes **72 (FIG. 2C)**. Each hole **72** may be configured to receive the location post **52 (FIGS. 3A, 3B)** of drill guide **10** to couple the drill guide and bone plate. The slot **76** may have a longitudinal axis that is substantially parallel to the longitudinal axis “**A-A**” of the plate **70**, and in the illustrated embodiment the slot is also centered on the plate axis. The inner surface **172** of each end hole **72** may be smooth, threaded or ribbed, and a counterbore **173** may also be provided at the top of the hole to provide a flat surface for embodiments of the plate **70** in which the plate top surface **78** is curved. The end holes **74** may have parallel sides, or the holes may be fully or partially conical in cross-section. It is noted that the end-holes may be provided in any appropriate configuration or combination of configurations known in the art.

[0057] As shown in **FIG. 3A**, the drill guide **10** may have a handle **20** with a gripping portion **22** and an extension-engaging portion **24**. The gripping portion **22** may assume any appropriate configuration, and in the illustrated embodiment is provided with an elongated ergonomic shape having a plurality of surface slots **26** to maximize gripping by the user during operation. The extension-engaging

~~portion 24 may be configured to receive the proximal extension 32 of a handle~~

extension element **30** which itself may have a distal extension **34** that engages the drill guide barrel **40**. The extension-engaging portion **24** of the handle may further comprise a swivel assembly **28** to allow the handle **20** to be swiveled about the extension **30** and the guide barrel **40** during use. This swiveling function may allow the user to adjust the rotational position of the handle **20** with respect to the guide tube **40** to provide the most convenient approach of the device to the bone plate **70** and to the surgical site, and also may allow the handle to be rotated away from the work site once the plate **70** has been placed on the bone and the drill guide **10** has been positioned on the plate. The swivel assembly **28** may further be provided with a selective locking feature to allow the user to lock the handle in a desired rotational position with respect to the handle extension **30** and guide barrel **40**.

[0058] Referring to **FIGS. 5A-6B**, the swivel assembly **28** will be described in more detail. The handle swivel assembly **28** may comprise a button cam **280** having a set of radial detents **282 (FIG. 5B)**, a cam spring **284**, a bearing **286**, a locking element **288** and a handle sleeve **290**. The radial detents **282** may be configured to engage corresponding sets of detent grooves **292, 294 (FIG. 5B)** formed in the handle proximal extension **32** and the handle sleeve **290**, respectively. The handle sleeve **290** may have inner and outer surfaces **296, 298**, with the outer surface **298** configured to be received within a bore **200** in the extension engaging portion **24** of the handle **20**. The handle sleeve **290** may further comprise an upper shoulder region **300** configured to abut an inner axial stop surface **202** of the handle **20**. The upper shoulder region **300** may comprise a series of radially-disposed detent grooves **294** configured to receive radial detents **282** of button cam **280**. The inner surface **296** of the handle sleeve **290** may further be configured to receive the proximal handle extension **32** for sliding

~~rotational movement therein.~~ A bearing **286** may be provided between the proximal handle extension **32** and the handle sleeve inner surface **296** to facilitate smooth rotational movement between the pieces to reduce the amount of force required to rotate the handle about the handle extension and to reduce wear of the

5 components. The handle sleeve **290** and proximal handle extension **32** may be axially locked together by means of a locking element **288** positioned within respective radial grooves **306**, **308** formed in the sleeve **290** and handle extension **32**, respectively. In the embodiment of **FIGS. 5A & 5B**, the bearing **286** may comprise a sleeve element fabricated from a polymer, such as Teflon, PEEK

10 (polyether-ether-ketone), or other suitable bearing material. Likewise, the locking element **288** may comprise a C-shaped clip formed of Teflon, PEEK or other suitable material. Using non-metallic bearing and locking elements **296**, **288** may increase the useful life of the swivel assembly which, along with the other components of the drill guide **10**, may undergo high temperature steam sterilization

15 after each use. This exposure to steam, coupled with the difficulty in completely drying the swivel assembly components after exposure, may lead to corrosion of assembly components. In particular, galvanic corrosion of individual components may occur where the assembly components are made of different metals and are not separated by a non-metallic material. Thus, a non-metallic bearing and a non-

20 metallic locking clip may be provided. It is noted that the use of a non-metallic bearing and locking clip material may provide the advantage of preventing galvanic corrosion between the metallic components of the swivel assembly **28** when these components are subjected to the high-moisture environment of the sterilization process. Such corrosion is undesirable because it may reduce the efficiency of the

25 swivel assembly after only a few uses due to the presence of corrosion particles between bearing surfaces.

~~[0059] US To further facilitate~~ minimize the chance for corrosion of the swivel

assembly pieces, drain holes **1280**, **1032** may be provided in the button cam **280** and proximal extension **32**, respectively to facilitate drainage of any condensation remaining after sterilization of the drill guide **10**. Hole **1032** may exit the handle extension **30** at port **1034**, thus providing a drainage path between the top portion of the button cam **280** and the handle extension **30**. High pressure air may also be applied to either end of the drainage path to blow out remaining fluid.

[0060] In an alternative embodiment, shown in **FIGS. 6A & 6B**, the bearing may comprise a series of balls **306** configured to move within corresponding circumferential grooves **308**, **310** in the handle sleeve **200** and proximal handle extension **32**, respectively. With the balls **306** in place within the grooves **308**, **310**, the handle sleeve **200** may further be axially locked to the proximal handle extension **32**. To facilitate introduction of the balls **306** into the grooves **308**, **310**, the handle **20** may have an axial bore **1312** through which the balls may be loaded between the grooves **308**, **310** once the proximal handle extension **32** has been fit within the handle sleeve **200**. A set screw **312** may then be threaded into the bore **1312** to prevent the balls **306** from escaping. The balls **306** may be made from stainless steel, chrome plated steel, or other metal (coated or uncoated) suitable for use as a bearing material. Alternatively, the balls **306** may be made from a suitable non-metallic material, such as a polymer (*e.g.* ultra-high molecular weight polyethylene). The swivel assembly of this embodiment further may incorporate a drain hole arrangement similar to that described above in relation to **FIGS. 5A and 5B**, to reduce or eliminate corrosion of the swivel assembly pieces.

[0061] Referring again to **FIGS. 5A & 5B**, the proximal extension **32** of handle **30** may comprise first and second axial bores **316**, **318** configured to receive the button cam **280** and the cam spring **284**, respectively. When

~~Assembled, cam spring 284~~ may be positioned within the second bore 316 and may abut the lower surface 291 of the button cam 280 to bias the button upwardly toward a top surface 204 of the handle 20. The handle 20 may have a second bore 206, positioned coaxial with the bore formed by the circumferential inner surface 296 of the handle sleeve 290, and may be configured to receive the button portion 320 of the button cam 280 therethrough, so that the upward bias of the cam spring 284 may force the button portion 320 up through the handle portion so that it protrudes above the top surface 204 of the handle 20. Thus, the button cam 280 may be conveniently thumb-actuated by the user while a grip is maintained on the drill guide handle 20.

[0062] In the unactuated "neutral" position, the handle 20 is axially and radially locked to the handle extension 30 via the engagement of the radial detents 282 of the button cam 280 with detent grooves 292, 294 of the proximal extension 32 and the handle sleeve 290, respectively. To rotationally unlock the handle 20 from the handle extension 30 to allow the handle to be swiveled with respect to the remainder of the drill guide assembly, button cam 280 is pressed downward against the bias of cam spring 284. This downward axial movement of the button cam 280 within the first bore 316 of the proximal extension 32 may cause the radial detents 282 to move out of engagement with the detent grooves 294 of the handle sleeve 290 thus rotationally decoupling the handle 20 from the handle extension 30, and allowing handle member 20 to be rotated with respect to the handle extension 30. Releasing pressure on the button cam 280 causes cam spring 284 to return detents 282 of button cam 280 into engagement with detent grooves 294 of handle sleeve 290 to again prevent rotation of handle member 20 in relation to handle extension 30.

[0063] As shown in FIG. 3A, the handle 20 may be offset from drill guide

~~barrel 40 by offset handle extension 30~~, thus allowing greater visibility and access to bone plate **70** and the vertebra. Distal extension **34** may be mechanically attached to the proximal portion **44** of drill guide barrel **40** at an extension receiving section **144**, for example by welding, brazing, a threaded connection, friction fit or
5 pinned connection. Extension receiving section **144** may comprise a bore into which a cylindrical portion of distal extension **34** is inserted, or handle extension **30** may be associated with the guide barrel **40** in any appropriate manner. For example, the distal extension **34** may comprise a bore configured to engage at least a portion of the outer surface of the guide barrel proximal portion **44**, and
10 which may be attached by welding, brazing, a threaded connection or friction fit. Alternatively, the handle extension **30** may be formed integrally with the guide barrel **40**.

[0064] Referring to **FIG. 7** an exemplary guide barrel **40** is illustrated. The drill guide barrel **40** may have a proximal handle engaging end **44** and a distal plate
15 engaging end **46**. The guide barrel may further comprise a longitudinal bore **48** having a bore axis “**B-B**.” The guide barrel bore **48** may be configured and dimensioned to slidably receive therethrough a number of bone hole preparation tools, such as an awl, tap and/or drill. The guide barrel bore **48** may comprise a proximal portion **148** having a first diameter “**D1**” and a distal portion **149** having a
20 second diameter “**D2**,” and the first diameter “**D1**” may be greater than the second diameter “**D2**.” Where the drill guide **10** is used with an awl **90** (**FIG. 14A, B**), “**D1**” may be sized to accept a proximal middle portion **92** of the awl, and “**D2**” may be sized to slidably accept a distal barrel portion **94** of the awl. Furthermore, the guide barrel distal end **46** may have a conical inner surface **1252** configured to
25 receive the conical nose portion **96** of the awl barrel portion **94**.

[0065] The proximal handle engaging end **44** of the barrel **40** may have an

~~end face 150 that may function~~ as a stop surface for the drill bit **80**, which may limit

the total depth of penetration of the drill tip **88** into the bone, thus limiting the ultimate bone hole to a predetermined depth. In the illustrated embodiment, end face **150** may cooperate with shoulder **810** on drill bit **80** (**FIG. 11**) to perform this
5 depth limiting function.

[0066] Where the drill guide **10** is used with a tap **100** (**FIG. 15**), the guide barrel bore **48** may comprise a stop surface **1250** configured to engage a corresponding shoulder **106** of tap **100**. These corresponding stop surfaces may cooperate to limit the distance that thread tapping surface **104** may penetrate into
10 the bone hole.

[0067] The drill guide barrel distal end **46** may further have a conical nose portion **42** configured and dimensioned to be received within the conical bone screw holes **74R, L** of bone plate **70**. In one embodiment, the conical nose portion may have a taper angle α configured to substantially match the taper of the
15 corresponding conical portion **174R, L** of bone screw hole **74R, L**. Alternatively, the taper angle α may be greater than or less than that of the bone screw hole conical portion **174R, L**. It is noted that any appropriate taper angle α may be provided, as long as the taper functions to center the guide barrel within the bone screw hole to precisely align the barrel with the bone screw hole to ensure the
20 appropriately placed and angled hole is drilled in the underlying bone. In one embodiment, the taper angle α of the conical nose portion may be about 12 degrees.

[0068] The end surface **460** of the guide barrel distal end **46** may be non-orthogonal with respect to the guide barrel bore axis "**B-B**," and may be configured
25 to be substantially parallel to the underside surface of the bone plate **70** when the conical nose portion **42** of the guide barrel **40** is received within the bone screw

~~FIG. 74R, L~~ In one embodiment, the angle γ formed between the end surface **460**

and the guide bore axis “B-B” may be about 85 degrees.

- [0069] Providing an angled end surface **460** may allow a protruding side **462** of the drill guide conical nose portion **42** to “catch” (and thus align with) at least a portion of the bone screw hole **74R, L** even if the conical nose portion **42** is slightly out of alignment with the hole (*i.e.* where the axis “B-B” of the drill guide barrel is not coaxial with the trajectory of the bone screw hole). This may occur when the surgeon is initially attempting to align the guide barrel **40** with the bone screw hole **74R, L**.
- 10 [0070] The angled end surface **460** also may allow the surgeon to make slight adjustments to the trajectory of the guide barrel **70** with respect to the bone screw hole **74R, L** while still engaging at least the protruding side **462** of the conical nose portion **42** of the guide barrel **40** within the conical portion **174R, L** of the hole trajectory. This feature may allow the surgeon to customize the trajectory of the
- 15 drilled hole to ensure the bone screw is ultimately seated in a portion of the vertebral body that is sufficiently thick to reliably retain the bone screw. For example, depending on the anatomy of the particular patient, when the plate **70** is placed on the targeted vertebrae one or more pairs of bone screw holes **74R, L** may be located directly adjacent to a vertebral end plate. In such a case the bone
- 20 underlying the bone screw holes **74R, L** may not provide the most secure long-term purchase for the bone screw because there may be little bone thickness between the screw shank and the end plate once the screw is seated in the vertebral body. Thus the surgeon may modify the trajectory of the drilled hole slightly to shift the trajectory of the drilled hole (and ultimately the screw) toward the centroid of the
- 25 vertebral body, thus providing more bone thickness between the screw shank and the end plate.

~~[0071] US The angled end surface 460~~ may also be configured to limit such

slight adjustments to the guide barrel trajectory to within a predetermined range.

Such a limitation may be appropriate, for example, where the drill guide is used with bone screw and plate combinations that have a locking feature, where the

5 trajectory of the screw with respect to the plate may affect the efficacy of the locking engagement of the screw and plate. One example of such a locking screw/plate combination is disclosed in co-pending U.S. nonprovisional patent application

Serial No. 10/653,164, filed September 3, 2003, entitled "Bone Plate with Captive

Clips," by Duong, *et al.*. Such a system is shown in **Figure 19**, and includes a bone

10 screw **740**, fixation plate **70** and locking clip **750**. The locking clip **750** is disposed within a groove **752** in the bone screw hole **74R, L** of the plate **70**. The bone screw

head **742** has a circumferential groove **748** configured to engage at least a portion

of the clip **750** when the bone screw **740** is engaged with the plate **70**. The

engagement between the bone screw head **742** and the locking clip **750** thus

15 prevents the screw **740** from backing out of the plate hole **74R, L** during use.

[0072] With such a screw-locking arrangement, the locking interaction

between the screw head **742** and the clip **750** may depend on proper relative

orientation of the screw **740** and clip **750**. Thus, in the illustrated embodiment, if

the bone screw **740** is oriented at an angle of less than about 12 degrees with

20 respect to the bone screw hole trajectory, the screw groove **748** and locking clip

750 will normally be engaged sufficiently to prevent back-out of the screw in use.

Where the bone screw **740** is oriented at an angle of greater than about 12 degrees

with respect to the bone screw hole trajectory, the groove **748** and clip **750** may not

be sufficiently aligned to allow proper engagement, and thus the locking feature of

25 the screw and plate may not be effective in preventing screw back-out.

[0073] Thus, it may be advantageous to limit the maximum allowable

~~adjustment to the guide barrel trajectory~~ within the bone screw hole **74R, L** to

ensure that the bone screw head **742** may still be positively retained by the locking clip **750**. Thus, the angle γ may be selected to allow the surgeon a positive “catch” between the protruding side **462** of the guide barrel nose **42** and the conical portion **174R, L** of the bone screw hole, only in so far as the resulting hole trajectory does not adversely affect the locking interaction between the screw head **742** and the locking clip **750**.

[0074] Thus, the angle γ may be selected to ensure engagement between the guide barrel conical nose portion **42** and the bone screw hole **74R, L** only where the guide barrel **40** axis and the screw hole trajectory are misaligned within a certain predetermined range. In the illustrated embodiment, this range is from about 0 degrees to about 5 degrees (the complement of the angle between the end surface **460** and axis “B-B”). The angled end surface **460** feature thus may provide the surgeon with immediate feedback to ensure the ultimate bone screw alignment will be within the predetermined range to ensure proper locking of the screw to the plate. If the protruding side **462** engages at least a portion of the bone screw hole **74R, L**, then the trajectory is within the allowable range. Likewise, If the protruding side **462** does not engage a portion of the bone screw hole **74R, L**, then the hole alignment is outside the range and should be adjusted accordingly.

[0075] Corresponding to this conical nose portion **42**, the guide barrel bore **48** may comprise an internal reduced diameter portion **1252** that has an inner diameter less than the diameter “D2” of bore distal portion **149**, and which is only slightly greater than the outer diameter of the fluted portion **84** of drill bit **80** (FIG. **11**). This reduced diameter portion **1252** of bore **48** may also serve as a stop surface for the tool to prevent the tool from penetrating farther into the bone than desired. The reduced diameter portion **1252** may also act as bearing surface to

~~support and guide the fluted portion 84 of the drill.~~ It may also serve to reduce the amount of drilling debris drawn up into the drill guide during use.

[0076] In an alternative embodiment, shown in **FIG. 8**, guide barrel **40** may have a distal nose portion **142** having a non-conical end portion. With this alternative nose design, the guide barrel distal end may not be received within the bone screw hole, thus the surgeon may not use the bone screw hole to automatically align the guide barrel with the bone screw hole. The surgeon may, however, use one of the cavity forming tools to precisely align the drill guide barrel with the targeted bone screw hole. For example, when using the awl of **FIG. 14A, B**, the awl barrel **94** may be placed through the guide barrel **40** until the conical nose portion **96** extends beyond the guide barrel distal end **46** and engages the conical portion **174R, L** of the targeted bone screw hole **74R, L**. The rotational position of the drill guide barrel **40** may then be adjusted to nest the tapered nose **96** of the awl within the conical portion **174R, L** of the bone screw hole. The awl tip **98** may then be used to form an entry hole through the cortex of the bone in the desired location. Thereafter, the drill **80 (FIG. 11)** and tap **100 (FIG. 15)** may simply be aligned with the entry hole.

[0077] Since the flat-nosed end **142** of the guide barrel is not engageable with a bone screw hole **74R, L**, the location post **52** may be fixed within the guide barrel housing **156**, rather than being slidable and spring biased as with the previously described embodiments. The post **52** may be fixed within the barrel using any appropriate joining method (*e.g.* brazing, welding, adhesive), or it may be formed as an integral part of the housing.

[0078] Since the nose portion **142** of the guide barrel of this embodiment does not have a reduced-diameter conical nose portion (and thus the attendant reduction in inner bore diameter at the guide barrel nose), the guide barrel bore

~~may allow placement of a bone screw 740~~ and screwdriver therethrough, in addition to the awl, tap and drill of the previous embodiment.

- [0079] Referring again to **FIG. 7**, the distal end of guide barrel **40** may further comprise a viewing slot **352** disposed in the barrel wall. This viewing slot may be used by the surgeon to visually verify the location of the distal tip of a tool inserted through the guide barrel (for example, tip **88** of drill bit **80**). In the illustrated embodiment the viewing slot **352** comprises an elongated channel having an axis parallel to the axis of the guide barrel bore **48**. The viewing slot may, however, assume any appropriate shape, configuration, or orientation known in the art.
- [0080] The distal end of guide barrel **40** may also comprise a housing **156** which encloses a plate engaging mechanism **50**. This housing **156** may be formed integrally with the guide barrel or it may be a separate piece that is attached by welding, brazing, adhesive, etc. The housing **156** may comprise a bore **158** configured to slidably receive a location post **54** of the plate engaging mechanism **50**. The bore may have an axis “**C-C**” that forms an acute angle β with respect to longitudinal axis “**B-B**” of the guide barrel. When the drill guide is installed on bone plate **70**, the plate engaging mechanism **50** may be oriented so that axis “**C-C**” is substantially perpendicular to the top surface **78** of the bone plate **70**. Thus, angle β may be the angle at which the awl, tap and drill will be inserted into the bone, and so it may also be the angle at which the bone screws will ultimately be installed in the bone. To ensure proper engagement between the bone screw **740** and the screw hole, **74R, L**, angle β may be selected to correspond to the trajectory of the associated bone screw hole **74R, L** in the plate **70**, which in an exemplary embodiment is about 4 degrees.
- [0081] The housing **156** may further comprise a slot **160** oriented substantially parallel to axis “**C-C**” and configured to receive a pin **162** used to

retain location post 54 within the housing 156. This feature will be described in more detail below.

[0082] Referring to **FIG. 3B**, plate engaging mechanism 50 will be described in greater detail. Plate engaging mechanism 50 is designed to stabilize the drill
5 guide 10 on the bone plate 70 and to provide a pivot point about which the guide may be rotated so as to bring the guide barrel 40 into alignment with a targeted pair of bone screw holes 74R, L, thus allowing two bone screw holes to be drilled with only a single placement of the drill guide on the bone plate.

[0083] The plate engaging mechanism 50 may comprise a location post 52
10 (**FIG. 9**) configured to cooperate with a slot-end hole 72 of a bone plate to stabilize the drill guide on the bone plate. The location post 52 may have a proximal end 522 configured to slide within bore 158 of guide barrel housing 156 (**FIG. 7**), and a distal end 524 configured to cooperate with slot-end hole 72 of bone plate 70. A spring element 502 may be provided within guide barrel housing 156 and may be
15 configured to engage the location post on its proximal end surface 526 to axially bias the location post 52 in the distal axial direction (*i.e.* in the direction of the bone plate 70). The location post 54 may be axially retained within the housing bore by a pin 504 which may be passed transversely through a bore 528 in the proximal portion of the post 52 and which may also engage slot 162 of the guide barrel
20 housing 156 (**FIG. 7**). Thus, when the plate engaging mechanism is assembled, the spring 502 may force the location post to move in the axial distal direction until the pin 504 abuts the distal most end of the slot 162 in the housing 156, whereupon further axial movement of the post 52 is prevented.

[0084] The distal end of location post 52 may comprise a nose section 530
25 configured to sit within the slot end-hole 72 of the bone plate 74. In the illustrated embodiment, the nose section 530 has rounded sides 532 and a flat end 534. In

~~this embodiment, the rounded sides 532~~ are configured to contact the inner surface

172 of slot end-hole 72 to seat the post within the hole, but without axially retaining the post therein (*i.e.* lifting the drill guide up off the bone plate will not cause the plate to move upward with the drill guide).

5 [0085] This configuration of the nose section 530 and the slot end-hole 72 may allow the location post 52 to “toggle” within the hole, thus allowing the surgeon to adjust the drill guide barrel 40 trajectory slightly within the targeted bone screw hole 74R, L while still maintaining the connection between the location post 52 and the plate end-hole 72. This “toggling” feature may allow the surgeon to customize
10 the trajectory of the hole (*i.e.* alter it from the trajectory of the bone screw hole 74R, L) that will be drilled into the bone, thereby customizing the trajectory of the bone screw that will be placed in the hole. As previously described, this feature may provide the surgeon with an important degree of flexibility in placing screws where the bone screw holes 74R, L are located very close to an end plate of one of the
15 vertebral bodies. In such a case, a slight adjustment in the guide barrel trajectory (while still maintaining the nose 42 engaged with the bone screw hole 74R, L) may allow the surgeon the option of placing the hole (and thus the screw) closer to the centroid of the vertebral body.

[0086] This “toggling” feature may also allow the surgeon greater flexibility in
20 drilling holes in vertebra that may be difficult to access, such as the cervical vertebra C1 through C3, and C7. Anterior access to these vertebra may be partially obstructed by the chin (C1-C3) or the sternum (C7), and thus, it is an advantage to allow the surgeon the option of adjusting the guide barrel trajectory to avoid the obstruction, while maintaining the contact between the plate slot end hole 72 and
25 the location post 54.

[0087] The nose section may be used with slot end-holes having various

~~inner surface configurations~~ (e.g. smooth, threaded, ribbed, conical, etc.). This

configuration minimizes the chance that the bone plate position on the bone will be affected when the drill guide is disengaged from the plate (e.g. when the drill guide is repositioned on the bone plate to access a second pair of bone screw holes).

5 [0088] The spring-biased feature of the location post 52 may allow the drill guide barrel 40 to assume a “neutral” position with respect to the bone plate 70 when the location post is received within the slot end-hole 72. In this “neutral” position, the nose portion of the guide barrel may be axially offset from the top surface of the bone plate 70, and may in such condition be freely pivotable about
10 the location post to allow the barrel 40 to be brought into alignment with a right or left bone screw hole of a targeted bone screw hole pair 74R, L. Final alignment/engagement of the guide barrel 40 with the bone screw hole 74R, L may then be achieved by pressing downward on the drill guide handle 20, compressing the location post spring 502, and allowing conical nose portion 42 of the guide
15 barrel 40 to be received within the targeted bone screw hole 74. Bone hole preparation tools may then be introduced through the guide barrel 40. Once bone hole preparation is complete for the first of the pair of bone screw holes 74R, L, the handle may be lifted slightly, aided by the spring 502, to move the drill guide up and away from the plate 70. The guide barrel 40 may then be pivoted about the
20 location post to bring the barrel into alignment with the second bone screw hole of the pair 74R, L.

[0089] The spring 502 may also facilitate uninterrupted contact between the conical nose portion 42 of the drill guide barrel 40 and the bone screw hole 74R, L regardless of the relative trajectory of the two. Thus, when the conical nose 42
25 engages the bone screw hole 74R, L such that the guide barrel trajectory is coaxial with the trajectory of the bone screw hole, the spring 502 will compress by a first

amount, extending the location post 52 from the end of the housing 156 by a

distance "D1." By comparison, when the drill guide barrel nose 42 engages the bone screw hole 74R, L such that the guide barrel trajectory is tilted out of alignment with respect to the trajectory of the bone screw hole, the spring 502 may compress by a second amount, retracting the location post 52 slightly into the housing 156, thus allowing the guide barrel nose 42 to remain engaged with the bone screw hole 74R, L. In this tilted configuration, the location post 52 may extend out of the end of the housing 156 by a distance "D2," which is less than "D1."

[0090] Thus, the spring-biased location post 52 may serve the additional purpose of ensuring continued engagement of the guide barrel 40 and bone screw hole 74R, L, which in turn may ensure that the resulting hole in the bone will support a bone screw at a desired trajectory with respect to the plate. As previously discussed, this may be particularly important where the bone screw 740 is configured to be axially retained by the plate 70 and the retention feature may be adversely affected by too great an angular offset between screw and hole, such as when using the previously described locking clip 750.

[0091] An alternative location post design is shown in FIG. 10, in which distal portion 524 comprises a plate-retaining feature, which is illustrated as a plurality of resilient fingers 154 configured to engage the slot-end hole 72 of the bone plate 70. This arrangement may allow the plate aligning mechanism 50 to axially retain the bone plate which may allow the surgeon to use the drill guide 10 as a plate holder. As the location post 152 is inserted into the slot end-hole 72 of the plate 70, the fingers 154 are forced together, causing them to exert an expansion spring force against the inner surface 172 of the slot end-hole 72, thereby locking the drill guide 10 to the plate 70. Although the expansion force may be sufficient to axially lock

~~the drill guide to the plate~~ the location post remains rotatable within the hole **72**,

thus allowing the guide barrel **40** to be swiveled to align with a pair of bone screw holes **74R, L**, as described with respect to the previous embodiment.

[0092] To increase the locking strength of the location post **152** within the slot end-hole **72** of the bone plate **70**, the resilient fingers **154** may comprise one or more circumferential ridges **1154** which may engage the inner surface of the slot end-hole **72**. This arrangement may be particularly effective where the slot end-hole **72** is threaded, because the circumferential ridges may engage a portion of the slot end-hole threads. Further, as illustrated in **FIG. 18**, the distal-most circumferential ridge **1155** of each resilient finger **154** may be configured to engage an underside surface **79** of the plate **70**, thus providing an additional axial retention feature between the plate to the drill guide **10**.

[0093] As shown in **FIG. 11**, drill bit **80** may comprise a proximal coupling end **802** and a distal drilling end **804**. The proximal coupling end **802** may be configured to couple to an appropriate source of rotational motion, either hand or powered, and may assume any appropriate configuration known in the art. The distal drilling end **804** likewise may comprise drilling flutes **84** configured to drill into bone. Intermediate the proximal and distal ends **802, 804** the drill body **806** may comprise at least one shoulder region **810** configured to cooperate with an internal shoulder **150** of the drill guide barrel bore **48** to control the maximum distance which the drill is allowed to advance beyond the nose portion **42** of the guide barrel **40**. This maximum distance may correspond to a maximum desired drilling depth, and may controlled by locating the cooperating shoulder regions **810, 150** of the drill **80** and guide barrel **40** appropriately.

[0094] In an alternative embodiment, the drill guide barrel **40** and plate attachment mechanism **50** may be arranged so that the hole drilled in the bone

~~may be slightly longitudinally offset~~ from the center of the bone screw holes **74R, L** located on one end of the bone plate **70**. Drilling a hole in the bone which is offset from the bone screw hole **74R, L** of the plate **70** may result in the head **742** of the bone screw **740** (**FIG. 12**) overhanging one side **744** (**FIG. 13**) of the screw hole **74R, L** when the screw is initially inserted into the hole in the bone (**FIG. 16**). Thus, as the bone screw **740** is driven into the vertebra, the angled lower surface **746** of the screw head **742** may contact the side **744** of the screw hole, and as the bone screw **740** is driven further into the vertebra, the screw head may force the plate **70** to move longitudinally relative to the screw **740** until the screw is centered within the bone screw hole **74R, L**. This arrangement may be used to move adjacent vertebra nearer to each other simply by tightening the bone screws that are drilled into the offset holes (*i.e.* compression of the intermediate disc space may be achieved). To effect such a compression, a first pair of bone screws may be inserted through a first pair of bone screw holes **74R, L** and fully engaged with the underlying vertebra to lock the plate **70** to the first vertebra. Thereafter, the drill guide of the present embodiment may be used to prepare two bone screw holes that are longitudinally offset from the center of an adjacent pair of bone screw holes in the plate **70**. A second set of bone screws then may be driven into the offset holes to achieve the above-described longitudinal movement between the plate and the screws. To achieve the desired offset, the distance between the guide barrel **40** and the guide barrel housing **156** may be varied as appropriate.

[0095] As shown in **FIG. 17**, an exemplary offset bone hole insertion point is indicated as “X,” while the center point of the bone screw hole **74R, L** is indicated as “Y.” The distance from the bone plate slot end-hole **72** to the center of the bone screw hole **74R, L** is designated “L1,” while the distance from the bone plate slot end-hole **72** to the center of the offset bone hole insertion point “X” is designated

FIG. 12. An axis **"D-D"** formed by points **"X"** and **"Y"** may be oriented substantially parallel to the longitudinal axis **"A-A"** of the bone plate **70**. A bone screw **740** (**FIG. 12**) inserted into a hole formed at point **"X"** will, when tightened into the bone, move toward point **"Y"** due to the previously described interaction of the bone screw head **742** with the side **744** of the fastener hole **74R, L**. This movement of the bone screw **740** along axis **"D-D"** will also move the attached bone segment **2002** along axis **"D-D"** toward the adjacent bone segment **2004**, thus drawing the two bone segments closer together along axis **"D-D."**

[0096] In the embodiment illustrated in **FIG. 16**, the bone plate may be attached to adjacent vertebra **2002, 2004** of the spine such that the plate axis **"A-A"** may be substantially aligned with the longitudinal axis of the spine. Thus, compression of the disc space **2006** between the adjacent vertebra **2002, 2004**, may be achieved substantially along the axis of the spine. Compression of the disc space in a direction substantially along the longitudinal axis of the spine may be important for a number of reasons, including the need to maintain the patient's anatomy in as normal a post-operative condition as possible. Additionally, where an Intervertebral spacer (*e.g.* a fusion spacer) has been installed between the vertebral end plates, compression along the spine axis serves to provide proper initial seating and loading of the spacer between the end plates.

[0097] To achieve this compression vector, the guide barrel **40** and location post **52** may be configured so that the center of the guide barrel **40** distal end **44** and center of the location post **52** may be separated by a distance equal to length **"L2"** so that when the drill guide barrel is rotated about the location post **52** it may be aligned with offset bone hole insertion point **"X."**

[0098] In one embodiment, the guide barrel **40** and barrel housing **156** may be configured so that the distance between points **"X"** and **"Y"** along axis **"D-D"** is

~~about 0.5 mm, thus allowing~~ approximately 0.5 mm of longitudinal compression of

adjacent bone segments. In one embodiment, the drill guide barrel and housing may be configured so that the distance between points “X” and “Y” may be from about 0 mm to about 0.8 mm, thus allowing longitudinal compression of bone segments of from about 0 mm to about 0.8 mm when the fasteners are tightened within the appropriate bone screw holes.

[0099] While the bone plate, drill bit, and drill guide assembly are shown and described for use in fixing adjacent vertebra of the spine, it will be appreciated that the drill guide assembly may be utilized with any suitable bone plate or other structure that may be secured to bone using bone fasteners. Alternatively, the drill guide may be used without a bone plate to guide the drilling of fastener holes in bone at any appropriate location in the body.

[00100] The method of drilling holes in vertebrae with the system disclosed above will now be described. The surgeon may introduce a bone plate 70 through an incision in the patient's skin and move the plate to a desired location on the patient's spine. In an exemplary embodiment, the plate may have at least two pairs of bone screw holes 74R, L configured to engage two adjacent vertebra in the cervical region of the spine. After the plate has been appropriately placed on the spine, the drill guide 70 may be introduced through the incision and the location post 52 may be seated within a slot-end hole 72 associated with one of the two pairs of bone screw holes of the bone plate. The drill guide 10 may then be pivoted about the location post 52 to align the guide barrel with the first bone screw hole of the targeted pair of bone screw holes 74. Once the guide barrel 40 has been substantially aligned with a bone screw hole 74, downward pressure may be applied to the handle 20 to move the nose 42 of the guide barrel into engagement with the bone screw hole, thus precisely aligning the guide barrel with the screw

~~hole 74. The surgeon may then~~ sequentially insert, in any combination, an awl, tap

and/or drill through the guide barrel bore to prepare a hole in the bone for receipt a bone screw. Preparing the hole in the bone using the drill guide **10** ensures that the hole is drilled in a vertebra at the proper angle coaxial with the fixation hole.

5 After the first bone hole has been prepared, the drill guide may be rotated within the slot in the bone plate until the drill guide barrel is positioned above the second of the pair of bone screw holes. The process of applying pressure to engage the fixation hole and inserting the drill bit is then repeated. Holes coaxial with other pairs of fixation holes in the plate **70** may then be drilled by lifting the drill guide off
10 the plate and seating the location post **52** in the slot-end hole **72** adjacent the next pair of targeted bone screw holes.

[00101] For embodiments of the drill guide **10** in which the location post **152** has an axial retention feature (*e.g.* resilient fingers) to retain the drill guide to the plate, the drill guide may be used to insert the plate through the incision in the
15 patient and to align the plate at the desired location on the spine. Furthermore, once a pair of bone screw holes have been accessed and the appropriate holes drilled, a separating force must be applied between the drill guide of this embodiment and the plate to overcome the retaining force of the location post.

[00102] Additionally, when using the embodiment of the drill guide having a
20 guide barrel without a conical nose portion, the step of pressing the guide barrel into the bone screw hole is omitted, and proper alignment of the drill guide barrel and the targeted screw hole may be achieved by simply pivoting the guide barrel into alignment over the screw hole. Alternatively, the user may employ the awl **90** (**FIG. 15A, B**) to align the guide barrel **40** with the bone screw hole **74R, L**. The
25 awl **90** (**FIG. 15A, B**) may be inserted through the guide barrel **40** so that the tapered nose portion **96** of the awl extends beyond the distal end **44** of the guide

~~barrel and engages the tapered portion~~ **174R, L** of the targeted bone screw hole

74R, L. Once the awl tip **98** has been used to break the cortex of the underlying bone to form the initial entry hole, the drill **80** may thereafter be aligned within the initial entry hole, thus maintaining the proper drilling location. An exemplary awl
5 may be that disclosed in co-pending United States non-provisional patent Serial No. 10/642,608, filed August 19, 2003, entitled "Spring Loaded Awl," by Christopher J. Ryan, the entire disclosure of which is expressly incorporated by reference herein.

[00103] While the invention has been shown and described herein with
10 reference to particular embodiments, it is to be understood that the various additions, substitutions, or modifications of form, structure, arrangement, proportions, materials, and components and otherwise, used in the practice and which are particularly adapted to specific environments and operative requirements, may be made to the described embodiments without departing from the spirit and
15 scope of the present invention. For example, various means may be used to attach the plate holder to the bone plate or to the drill guide assembly. In addition, the plate may be of various thicknesses, shapes, and contours; and have various fixation hole configurations. Accordingly, it should be understood that the embodiments disclosed herein are merely illustrative of the principles of the
20 invention. Various other modifications may be made by those skilled in the art which will embody the principles of the invention and fall within the spirit and the scope thereof.

1. A drill guide comprising:
a guide barrel for receiving a bone tool for creating a hole in bone; and
an alignment assembly associated with the guide barrel for aligning the
bone tool with a selected first or second fastener hole of a bone plate, the alignment assembly
comprising a location post configured to be at least partially received within a recess in the bone plate;
wherein the location post is pivotable about the bone plate recess to allow the guide barrel to
be selectively aligned with the first and second fastener holes.
2. The drill guide of **claim 1**, wherein the location post is configured to axially lock the drill
guide to the bone plate.
3. The drill guide of **claim 2**, wherein the location post further comprises a plurality of resilient
finger elements configured to frictionally engage the bone plate recess to thereby axially lock the drill
guide to the bone plate.
4. The drill guide of **claim 3**, wherein the resilient finger elements further comprise at least one
ridge configured to engage threads in the bone plate recess.
5. The drill guide of **claim 1**, the alignment assembly further comprising a housing having a first
axial bore configured to slidably receive at least a portion of the location post.
6. The drill guide of **claim 5**, the location post and housing further each comprising a distal end,
the location post having a retracted position in which the location post distal end is located a first
distance from the distal end of the housing, and an extended position in which the location post distal
end is located a second distance from the distal end of the housing, wherein the second length is
greater than the first length.
7. The drill guide of **claim 6**, the alignment assembly further comprising a spring element
disposed at least partially within a second axial bore in the housing to bias the location post to the
extended position.
8. The drill guide of **claim 7**, the guide barrel further comprising a bore with a bore axis, and a
distal plate-engaging end, wherein the distal plate-engaging end comprises a nose portion configured
to be received within the first or second fastener hole to align the bore with the bone screw hole.
9. The drill guide of **claim 8**, wherein the nose portion comprises a conical shape.

10. The drill guide of **claim 8**, the housing first axial bore and the guide barrel bore forming an acute angle therebetween.

11. The drill guide of **claim 7**, wherein when the location post is received within the bone plate recess and the location post is in the extended position, the guide barrel distal end is located a first distance from the top surface of the bone plate.

12. The drill guide of **claim 7**, wherein when the location post is received within the bone plate recess and the location post is in the retracted position, the guide barrel distal end contacts the selected bone screw hole.

13. The drill guide of **claim 1**, the drill guide further comprising a handle associated with the guide barrel, the handle configured to be selectively rotatable with respect to the guide barrel in a first plane.

14. The drill guide of **claim 13**, wherein the first plane is substantially perpendicular to the longitudinal axis of the guide barrel bore.

15. The drill guide of **claim 13**, further comprising a handle swivel assembly having a locked position in which the handle can not rotated with respect to the guide barrel, and an unlocked position in which the handle is freely rotatable with respect to the guide barrel.

16. The drill guide of **claim 15**, wherein the swivel assembly comprises at least one non-metallic bearing.

17. The drill guide of **claim 15**, wherein the swivel assembly comprises a drain hole configured to allow fluid to drain from the assembly subsequent to sterilization of the drill guide.

18. The drill guide of **claim 1**, wherein the location post is axially fixed to the alignment assembly.

19. A surgical drill guide comprising:
 a handle,
 a guide barrel having a proximal end associated with the handle and a distal end configured to engage an inner surface of a fastener hole of a bone plate, the guide barrel further comprising a bore configured to receive a bone cavity forming tool; and
 an alignment assembly associated with the guide barrel for aligning the bone tool with a selected first or second fastener hole, the alignment assembly comprising a location post configured to be at least partially received within a recess in the bone plate;

wherein the location post is pivotable within the recess to allow the guide barrel to be selectively aligned with the first and second fastener holes so that the tool may be extended through the guide barrel to form a cavity in a bone underlying the selected fastener hole.

20. The drill guide of **claim 19**, wherein the location post is configured to axially lock the drill guide to the bone plate.

21. The drill guide of **claim 20**, wherein the location post further comprises a plurality of resilient finger elements configured to frictionally engage the bone plate recess to thereby axially lock the drill guide to the bone plate.

22. The drill guide of **claim 21**, wherein the resilient finger elements further comprise at least one ridge configured to engage threads in the bone plate recess.

23. The drill guide of **claim 19**, the alignment assembly further comprising a housing having a first axial bore configured to slidably receive at least a portion of the location post.

24. The drill guide of **claim 23**, the location post having a retracted position in which a first length of the location post is received within the bore and an extended position in which a second length of the location post is received within the bore, wherein the first length is greater than the second length.

25. The drill guide of **claim 24**, the alignment assembly further comprising a spring element disposed at least partially within a second axial bore in the housing to bias the location post to the extended position.

26. The drill guide of **claim 25**, the guide barrel further comprising a bore with a bore axis, and a distal plate-engaging end, wherein the distal plate-engaging end comprises a nose portion configured to be received within the first or second fastener hole to align the bore with the bone screw hole.

27. The drill guide of **claim 26**, wherein the nose portion comprises a conical shape.

28. The drill guide of **claim 26**, the housing first axial bore and the guide barrel bore forming an acute angle therebetween.

29. The drill guide of **claim 25**, wherein when the location post is received within the bone plate recess and the location post is in the extended position, the guide barrel distal end is located a first distance from the top surface of the bone plate.

30. The drill guide of **claim 25**, wherein when the location post is received within the bone plate recess and the location post is in the retracted position, the guide barrel distal end contacts second bone screw hole.

31. ~~The drill guide of claim 19, the drill guide further comprising a handle associated with the guide barrel, the handle configured to be selectively rotatable with respect to the guide barrel in a first plane.~~

32. The drill guide of **claim 31**, wherein the first plane is substantially perpendicular to the longitudinal axis of the guide barrel bore.

33. The drill guide of **claim 31**, further comprising a handle swivel assembly having a locked position in which the handle can not rotated with respect to the guide barrel, and an unlocked position in which the handle is freely rotatable with respect to the guide barrel.

34. The drill guide of **claim 33**, wherein the swivel assembly comprises at least one non-metallic bearing.

35. The drill guide of **claim 33**, wherein the swivel assembly comprises a drain hole configured to allow fluid to drain from the assembly subsequent to sterilization of the drill guide.

36. The drill guide of **claim 19**, wherein the location post is axially fixed to the alignment assembly.

37. A drill guide assembly comprising:

a guide barrel having a tool receiving portion comprising a longitudinal bore having a bore axis, and an aligning assembly portion;

an aligning assembly comprising a guide barrel engaging portion, a housing and a location post having a post axis,

a bone plate having at least two bone screw holes and a positioning recess, the positioning recess configured to receive at least a portion of the location post, the center of the positioning recess being separated from the center of at least one of the bone screw holes by a first distance,

wherein the bore axis is located a second distance from the location post axis, the first and second distances being substantially equal so that when the location post engages the bone plate recess, the bore is substantially coaxial with the at least one fixation hole.

38. The surgical drill guide assembly of **claim 37**, further comprising a handle member associated with a proximal end of the guide barrel.

39. The surgical drill guide assembly of **claim 38**, wherein the handle member is pivotable in relation to the guide barrel.

40. The surgical drill guide assembly of **claim 37**, wherein the guide barrel has at least one depth stop surface configured to coact with a corresponding stop surface of a bone cavity forming tool when

the tool is received within the bore to prevent the tool from passing completely through the guide barrel bore.

41. The surgical drill guide assembly of **claim 39**, the handle further having a locked position in which the handle is rotationally coupled to the guide barrel, and an unlocked position in which the handle is freely rotatable with respect to the guide barrel.
42. The surgical drill guide assembly of **claim 41**, further comprising:
 a locking button having an actuation end and a locking end, the locking end having at least one radial projection, the button further having an unactuated position and an actuated position;
 the handle comprising a bore configured to slidably receive at least a portion of the button, the bore further comprising a radial recess configured to receive the radial projection; and
 a handle extension having a handle engaging end and a guide barrel engaging end, the handle engaging end having at least one radial groove configured to receive the radial projection;
 wherein when the handle is in the unactuated position, the radial projection engages the radial recesses of the handle bore and the handle extension to configure the handle in the locked position.
43. The drill guide of **claim 42**, wherein when the handle is in the actuated position, the radial projection engages the radial recess of only one of the handle bore and the handle extension to configure the handle in the unlocked position.
44. The drill guide of **claim 42**, the location post further comprising a plate engaging end having a plurality of resilient fingers configured to axially lock the drill guide to the bone plate when the location post is engaged with the recess.
45. The drill guide of **claim 44**, the location post plate engaging end having at least one circumferential ridge configured to engage a bottom surface of the bone plate when the location post is engaged with the recess.
46. A drill guide assembly comprising:
 a guide barrel having a tool receiving portion comprising a longitudinal bore having a bore axis, and an aligning assembly portion;
 an aligning assembly comprising a guide barrel engaging portion, a housing and a location post having a post axis,
 a bone plate having at least two fastener receiving holes and a drill guide positioning recess, the recess configured to receive at least a portion of the location post, the center of the recess being separated from the center of at least one of the bone screw holes by a first distance,

wherein the bore axis is located a second distance from the location post axis as measured between the distal ends of the guide barrel and the location post, the first and second distances being substantially unequal so that when the location post engages the bone plate recess, the bore is not coaxial with the at least one fixation hole.

47. The drill guide assembly of **claim 46**, wherein the difference between the first and second distances is from about 0 millimeters (mm) to about 0.8 mm.

48. The drill guide assembly of **claim 46**, wherein the second distance is about .0.5 mm longer than the first distance.

49. A method for drilling a hole in bone, comprising the steps of:
 providing a bone plate having at least a first pair of fastener receiving holes and a drill guide aligning recess;
 applying the plate to the bone surface;
 providing a drill guide having a guide bore for receiving a tool and an alignment mechanism associated with the guide bore and including a location post having a proximal alignment mechanism engaging end and a distal plate engaging end;
 inserting the plate engaging end of the location post into the recess in the bone plate,
 rotating the location post within the recess in the bone plate to align the guide bore with a first selected one of the pair of fastener receiving holes;
 inserting and advancing a tool through the guide bore to contact the bone surface underlying the selected fastener receiving hole; and
 applying rotational and/or axial force to the tool to creating a cavity in the bone underlying the selected fastener receiving hole.

50. The method of **claim 49**, wherein the alignment mechanism further comprises a spring element to bias the location post distally axially away from the alignment mechanism, the guide bore further comprising a distal end adjacent the distal end of the location post, the guide bore distal end comprising a conical nose portion configured to engage an inner surface of at least one of the pair of fastener receiving holes, wherein the step of aligning the guide bore with a selected one of the pair of fastener receiving holes further comprises engaging the guide bore nose with the inner surface of the at least one of the pair of fastener receiving holes.

51. The method of **claim 49**, further comprising the step of rotating the location post within the hole, slot, or indentation in the bone plate to align the guide bore with the second one of the pair of fastener receiving holes; inserting and advancing the tool through the guide bore to contact the bone

~~surface underlying the second fastener receiving hole; and applying rotational and/or axial force to the tool to create a cavity in the bone underlying the second fastener receiving hole.~~

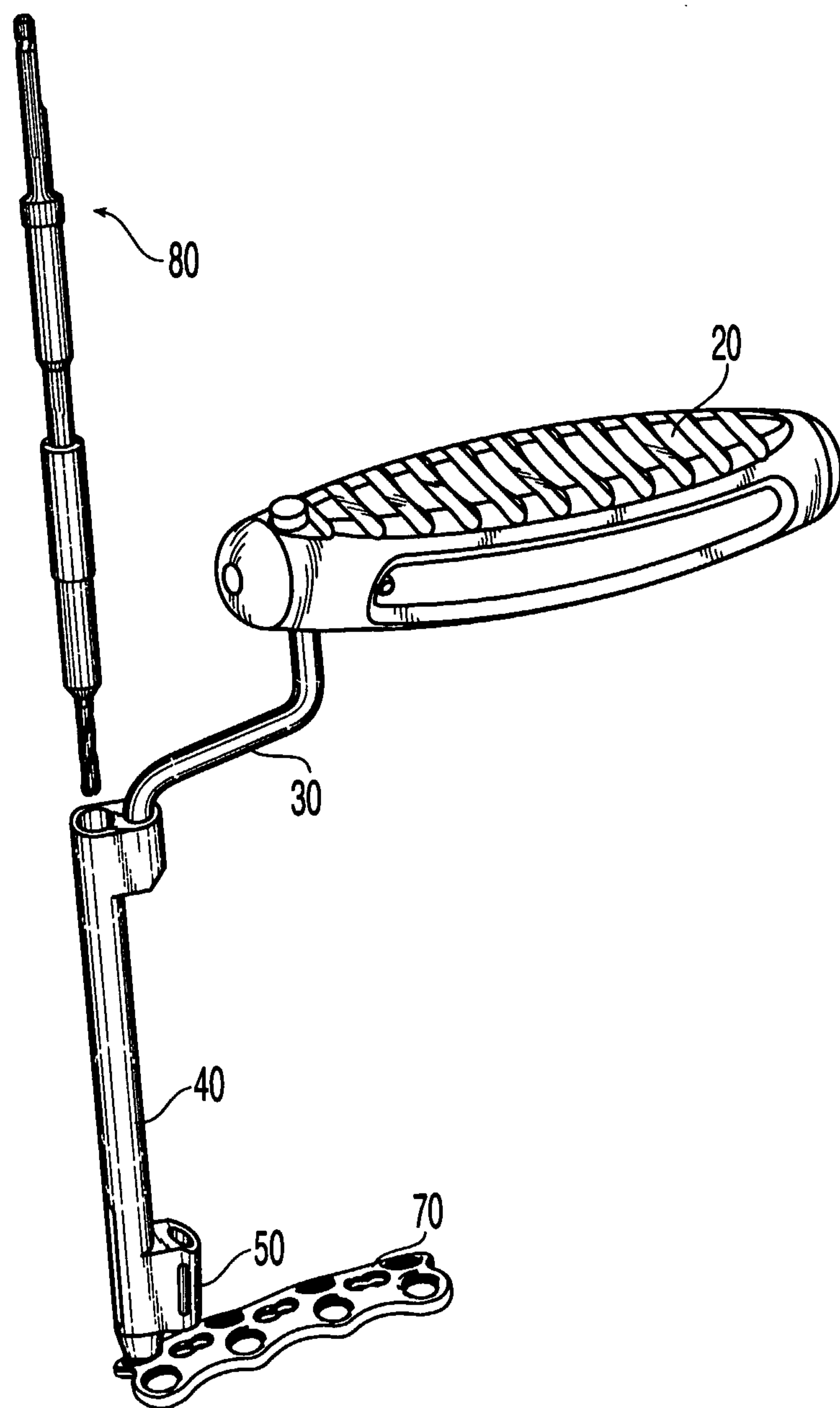
52. The method of **claim 51**, wherein the tool is an awl, drill or tap.

53. The method of **claim 51**, further comprising the steps of disengaging the location post from the recess in the plate to disassociate the drill guide from the bone plate, inserting a bone fastener through one of the first and second fastener receiving holes and into the cavity in the bone underlying the fastener receiving hole, and engaging the fastener with the fastener receiving hole and the bone to fix the plate to the bone.

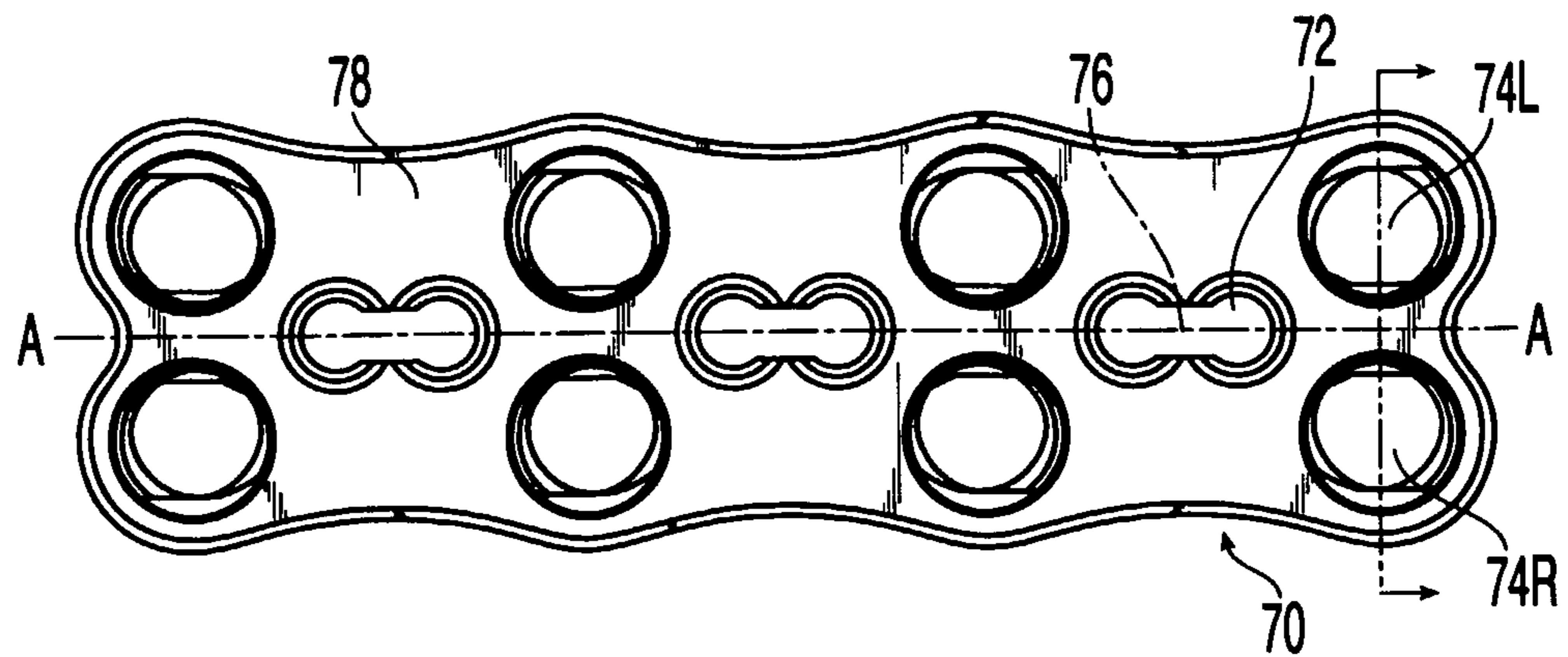
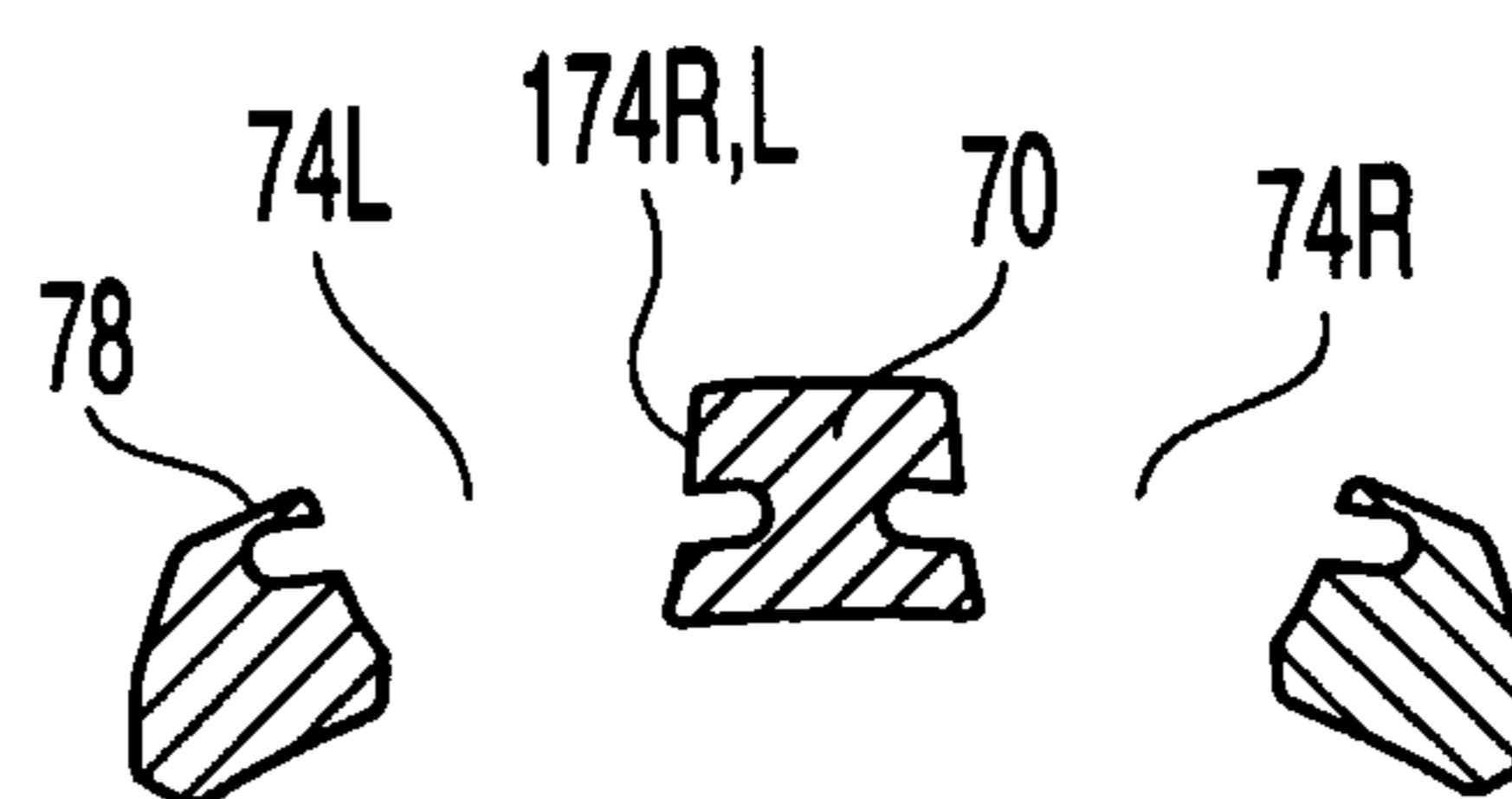
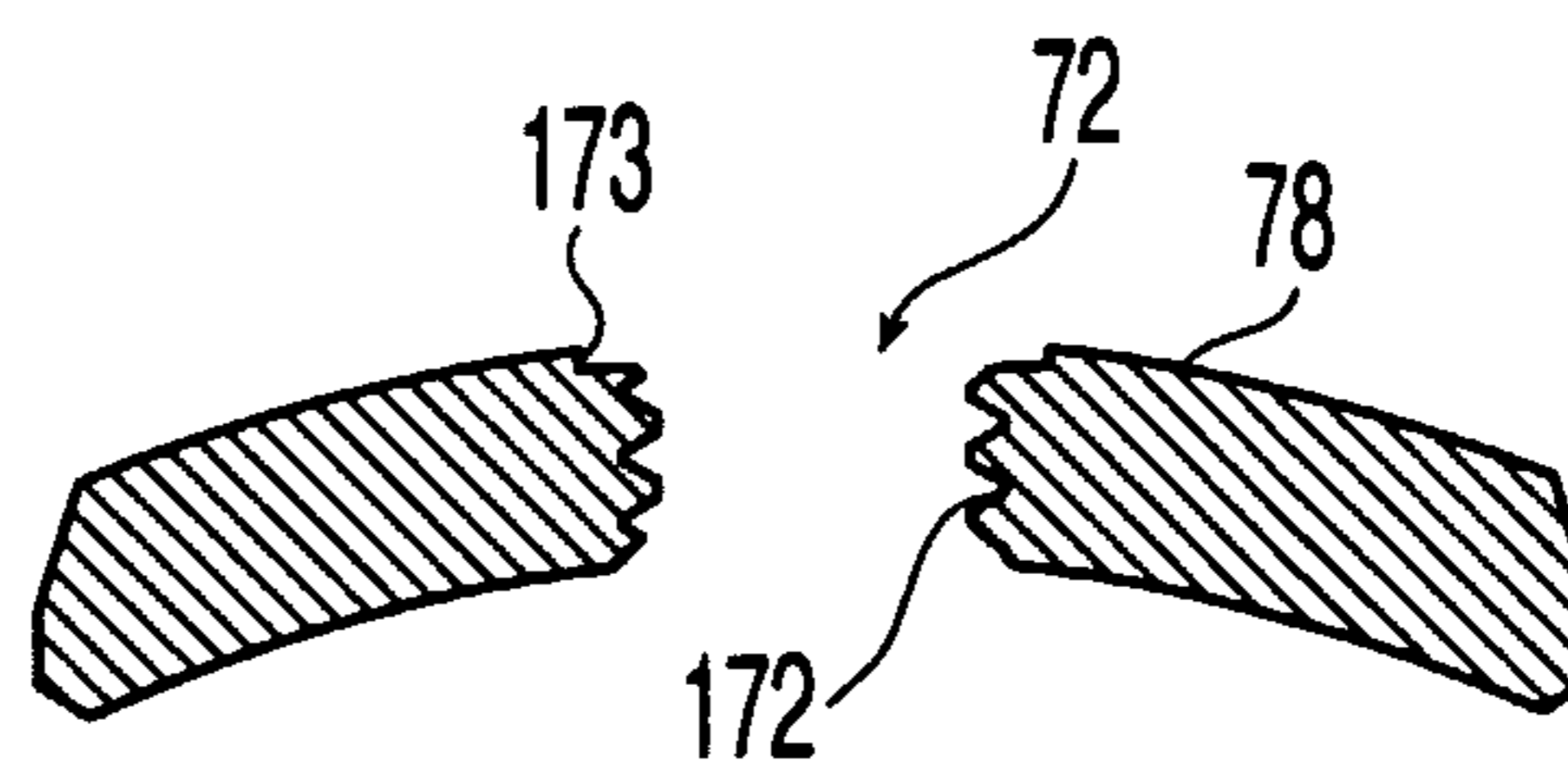
54. The method of **claim 49**, wherein the drill guide bore and alignment mechanism are offset from each other so that when the location post is rotated within the bone plate recess to align the guide bore with a first selected one of the pair of fastener receiving holes, the guide bore axis is offset from the center of the fastener receiving hole.

55. The method of **claim 54**, wherein the steps of inserting and advancing a tool through the guide bore to contact the bone surface underlying the selected fastener receiving hole; and applying rotational and/or axial force to the tool to creating a cavity in the bone underlying the selected fastener receiving hole comprise creating a cavity having an axis that is not collinear with the axis of the fastener receiving hole.

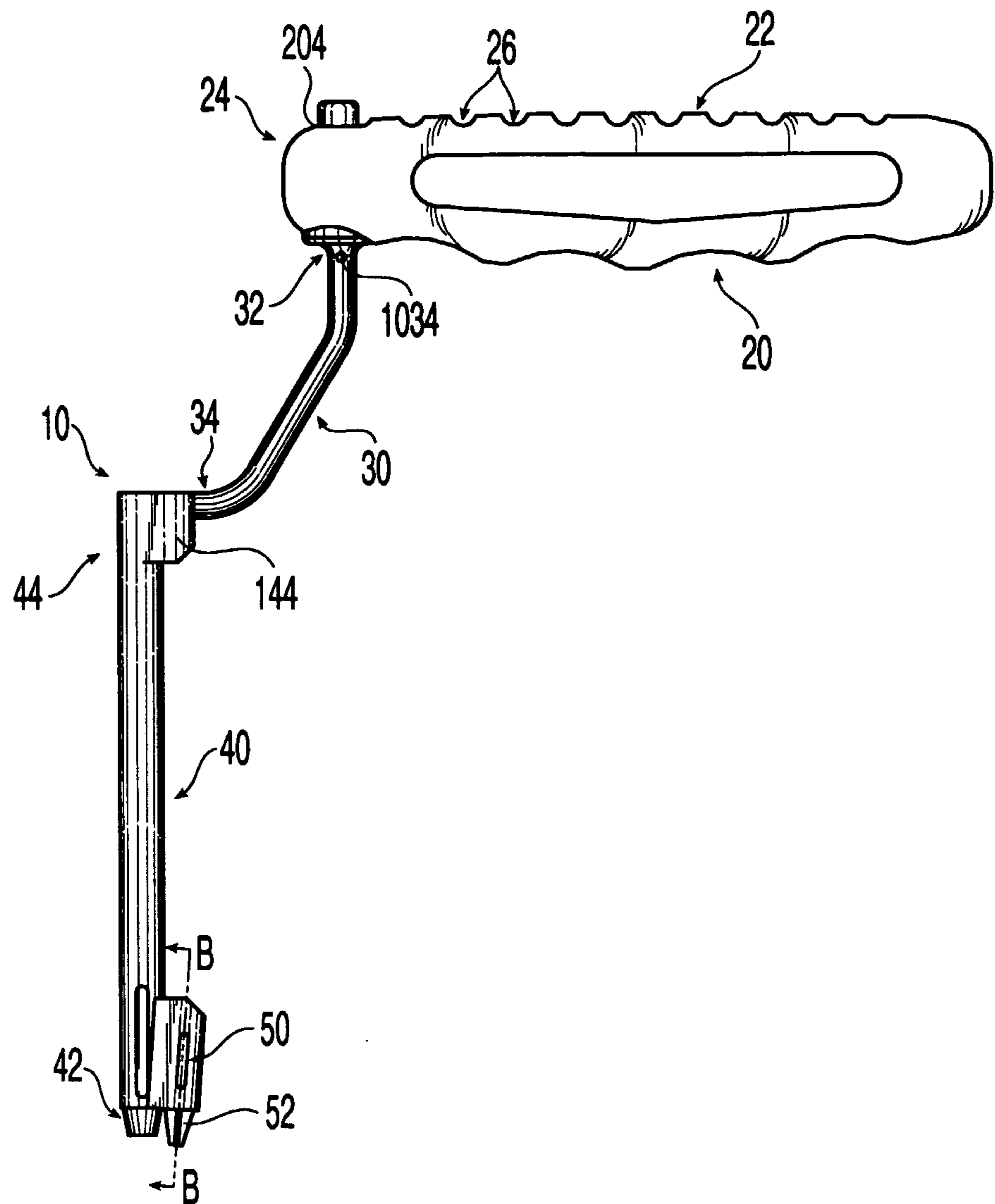
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*Fig. 1*

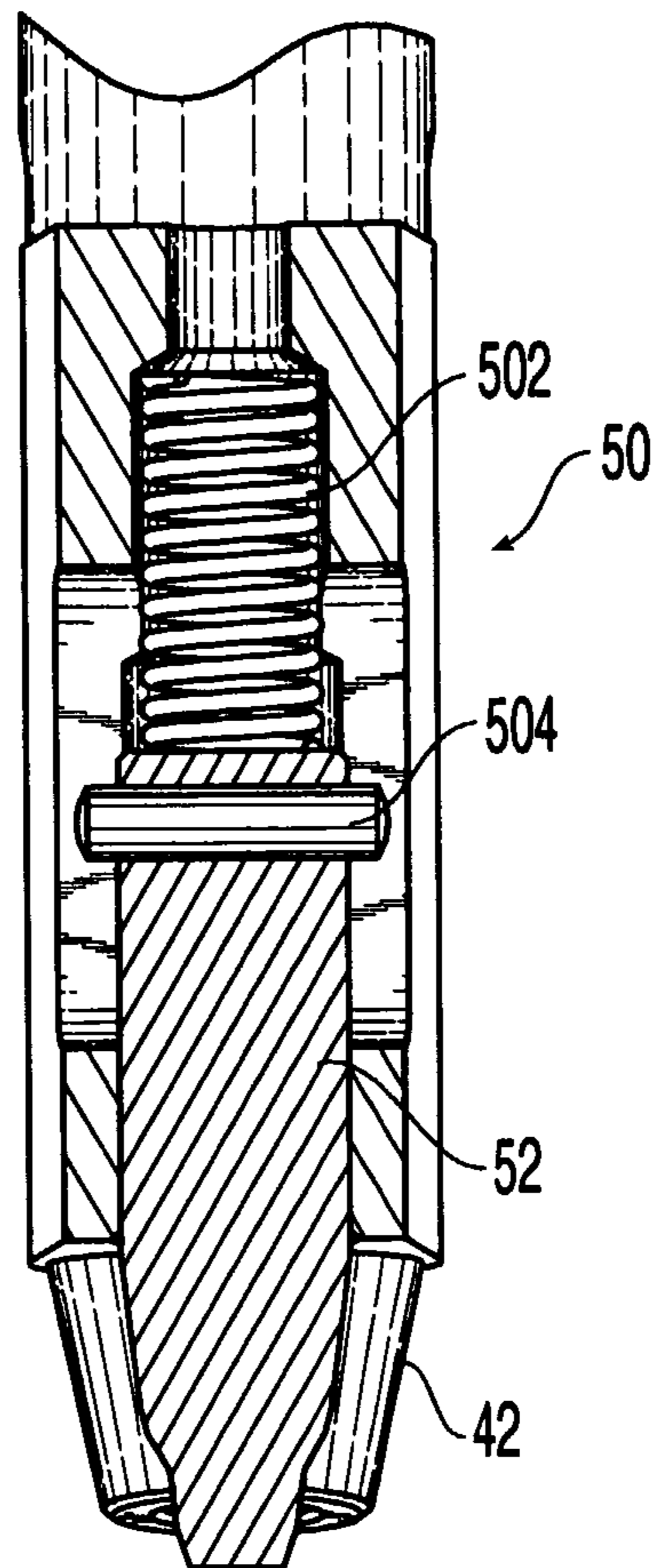
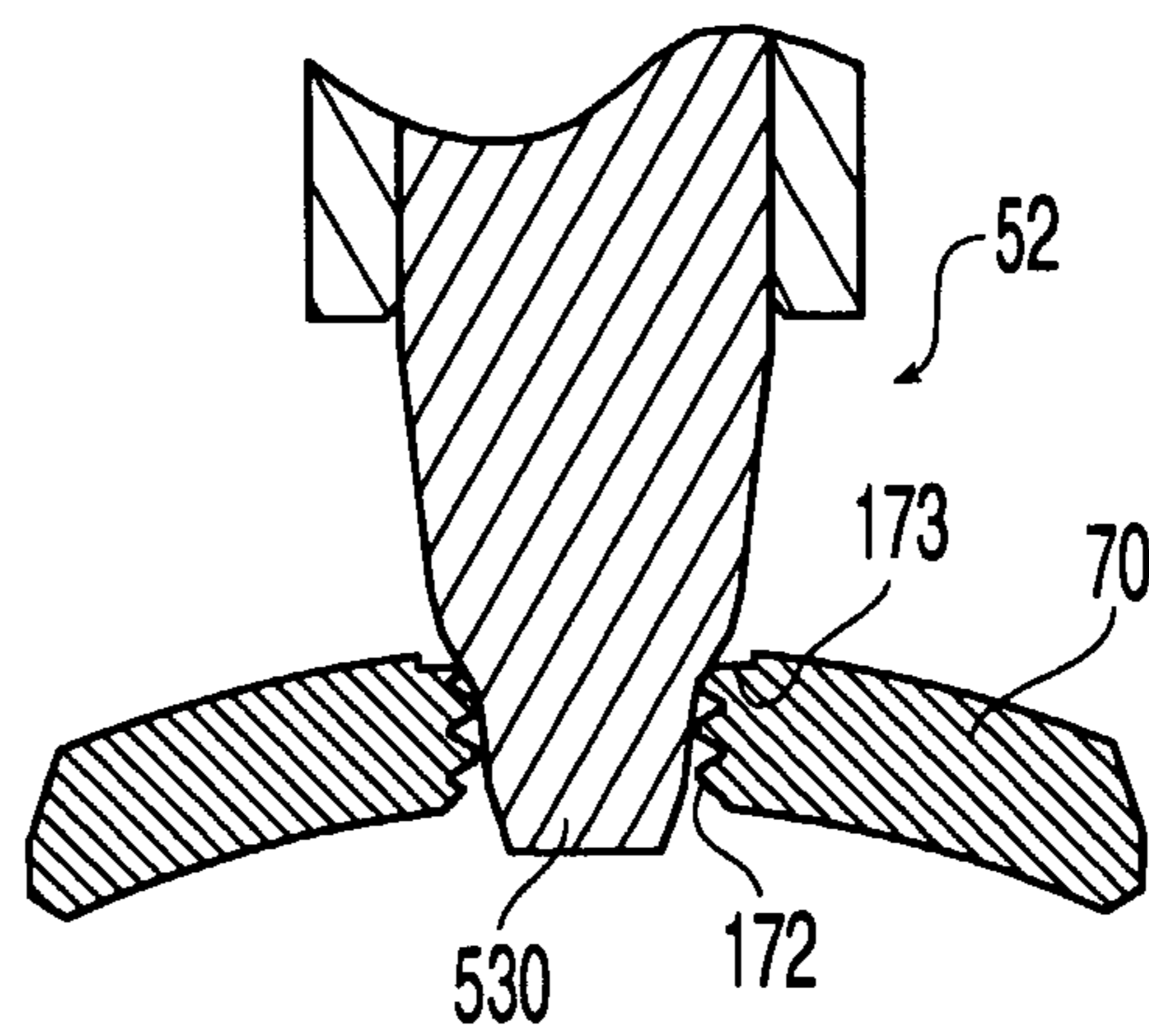
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*Fig. 2**Fig. 2B**Fig. 2C*

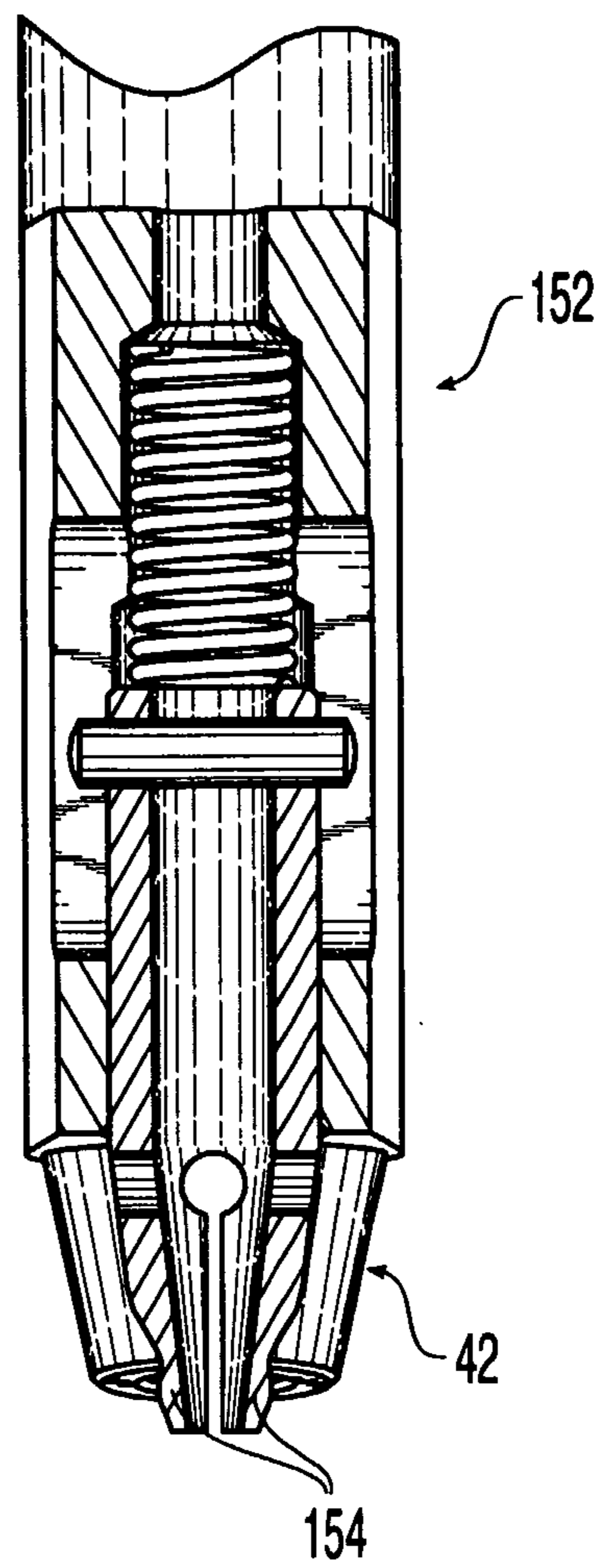
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*Fig. 3A*

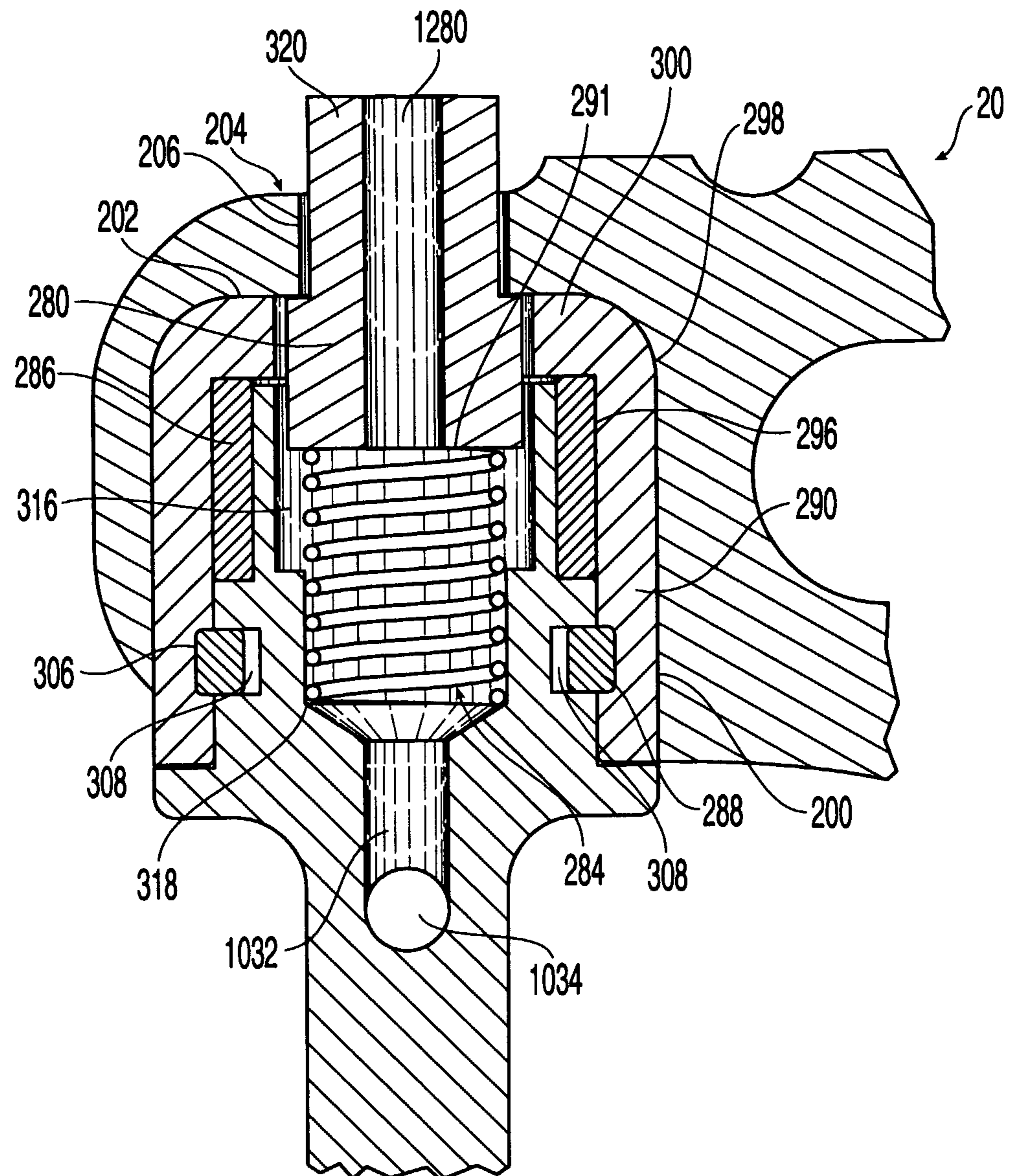
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*Fig. 3B**Fig. 3C*

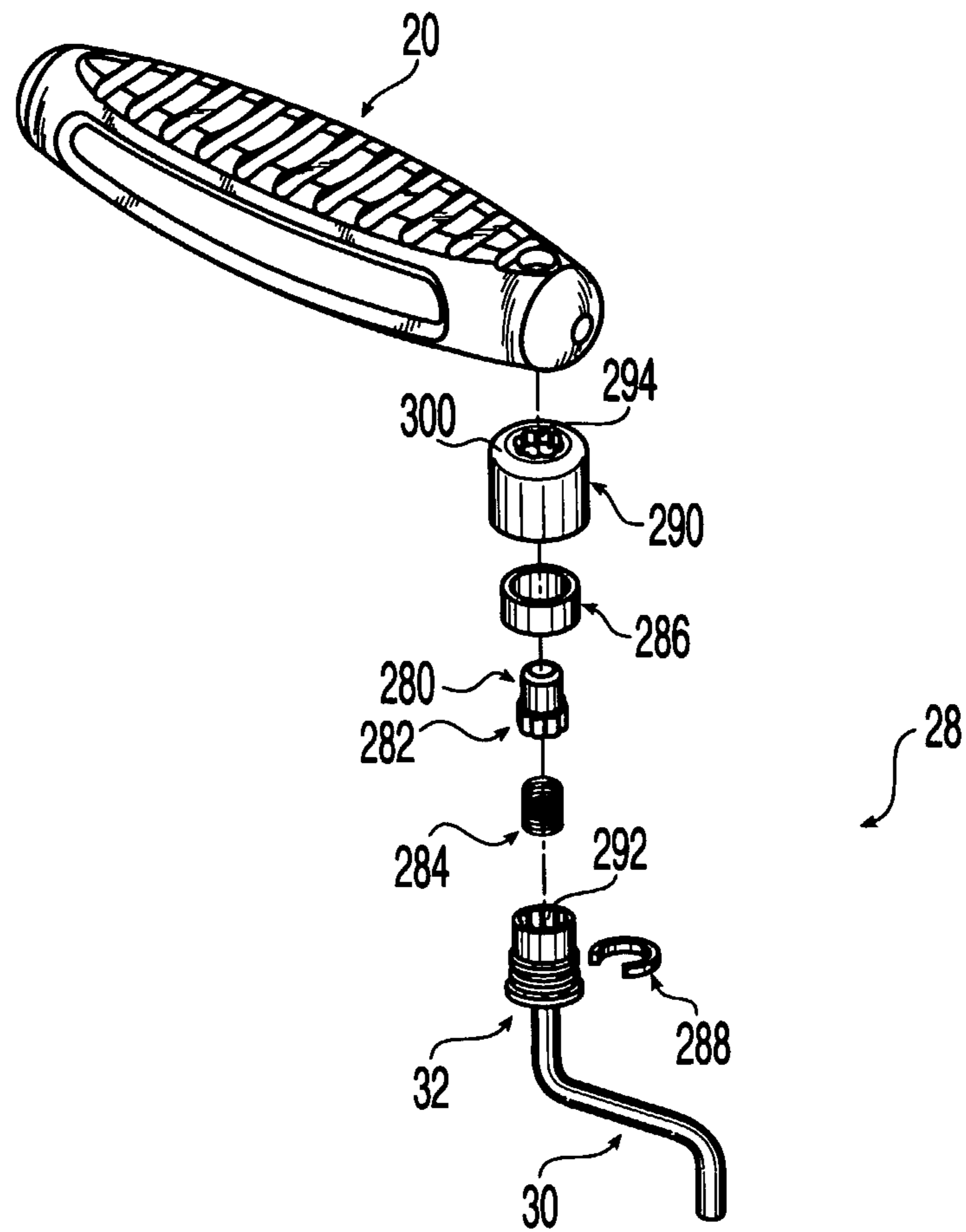
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*Fig. 4*

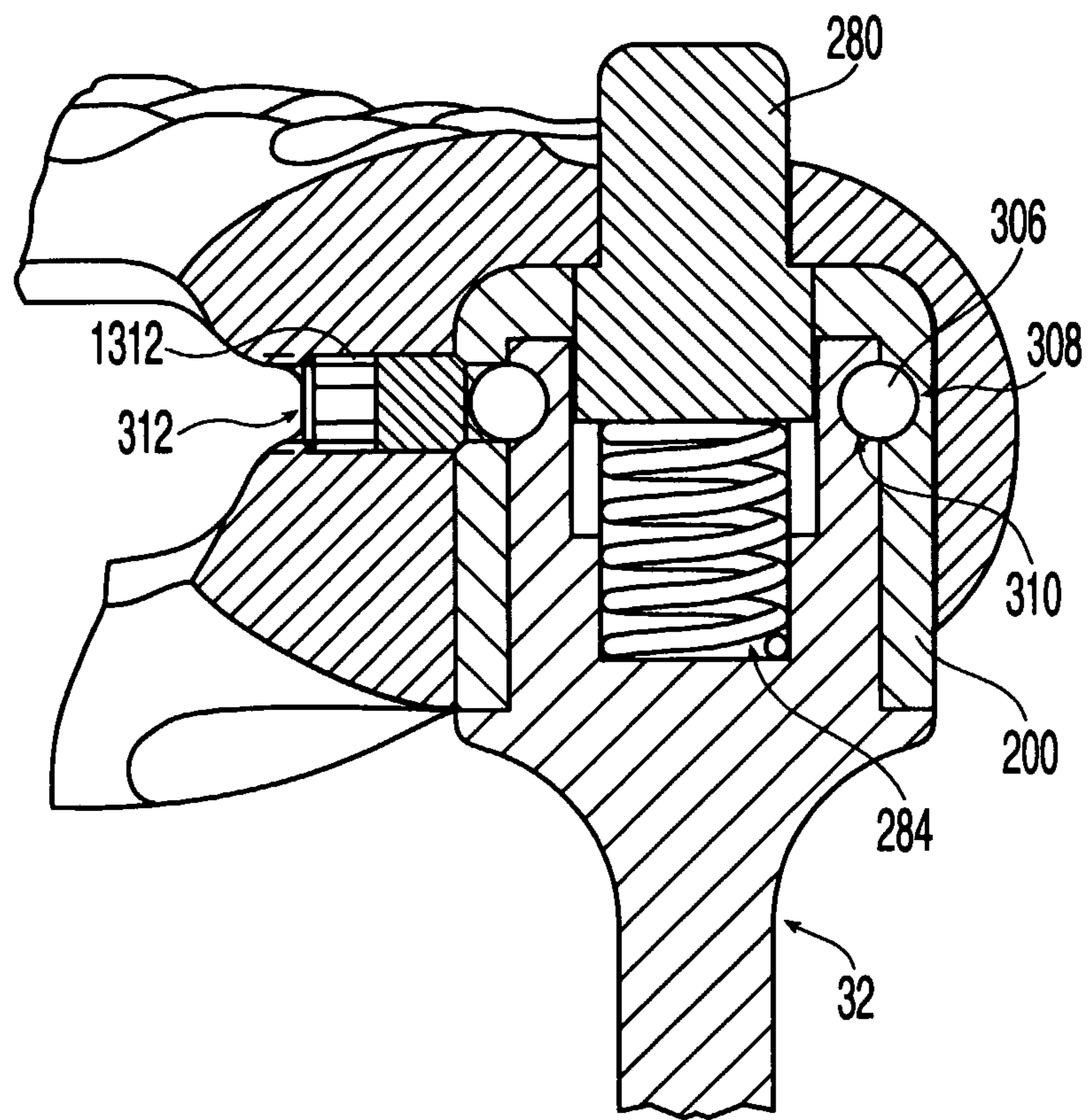
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*Fig. 5A*

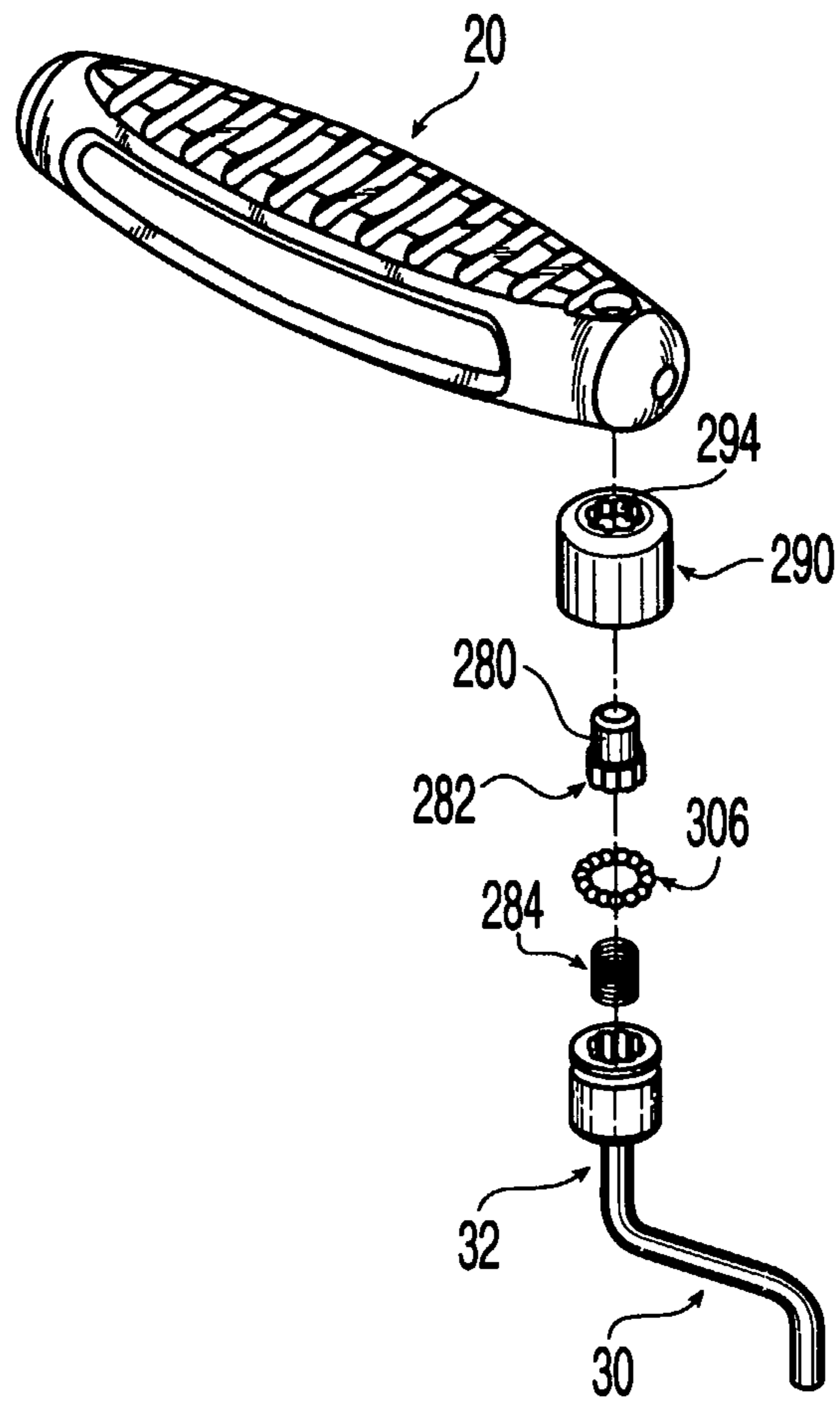
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*Fig. 5B*

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*Fig. 6A*

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*Fig. 6B*

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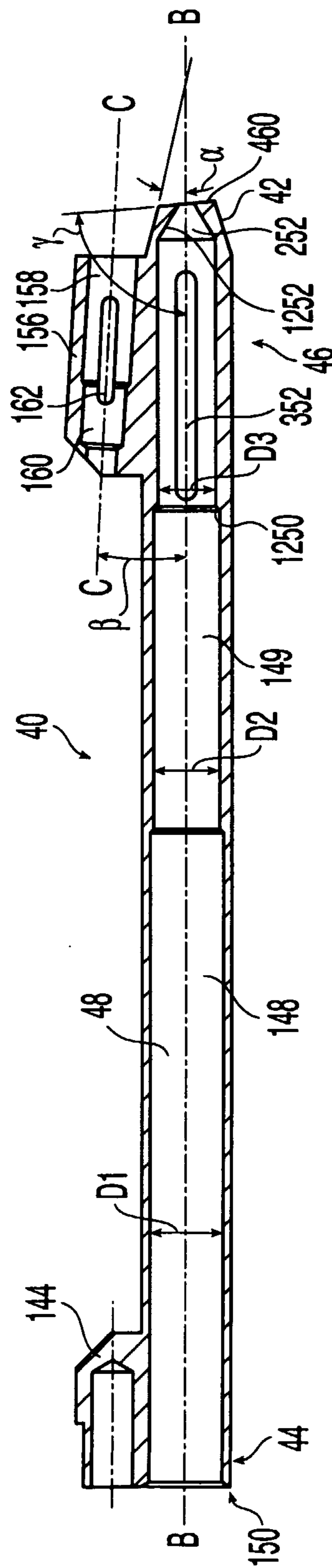
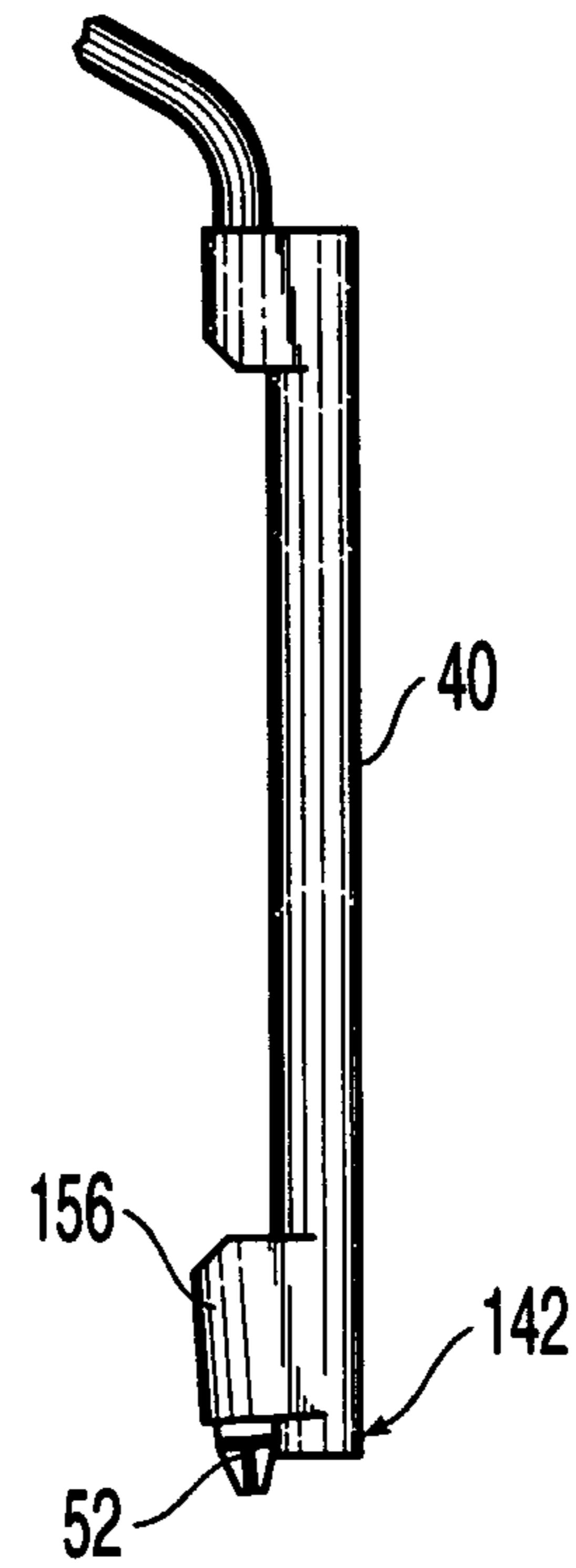
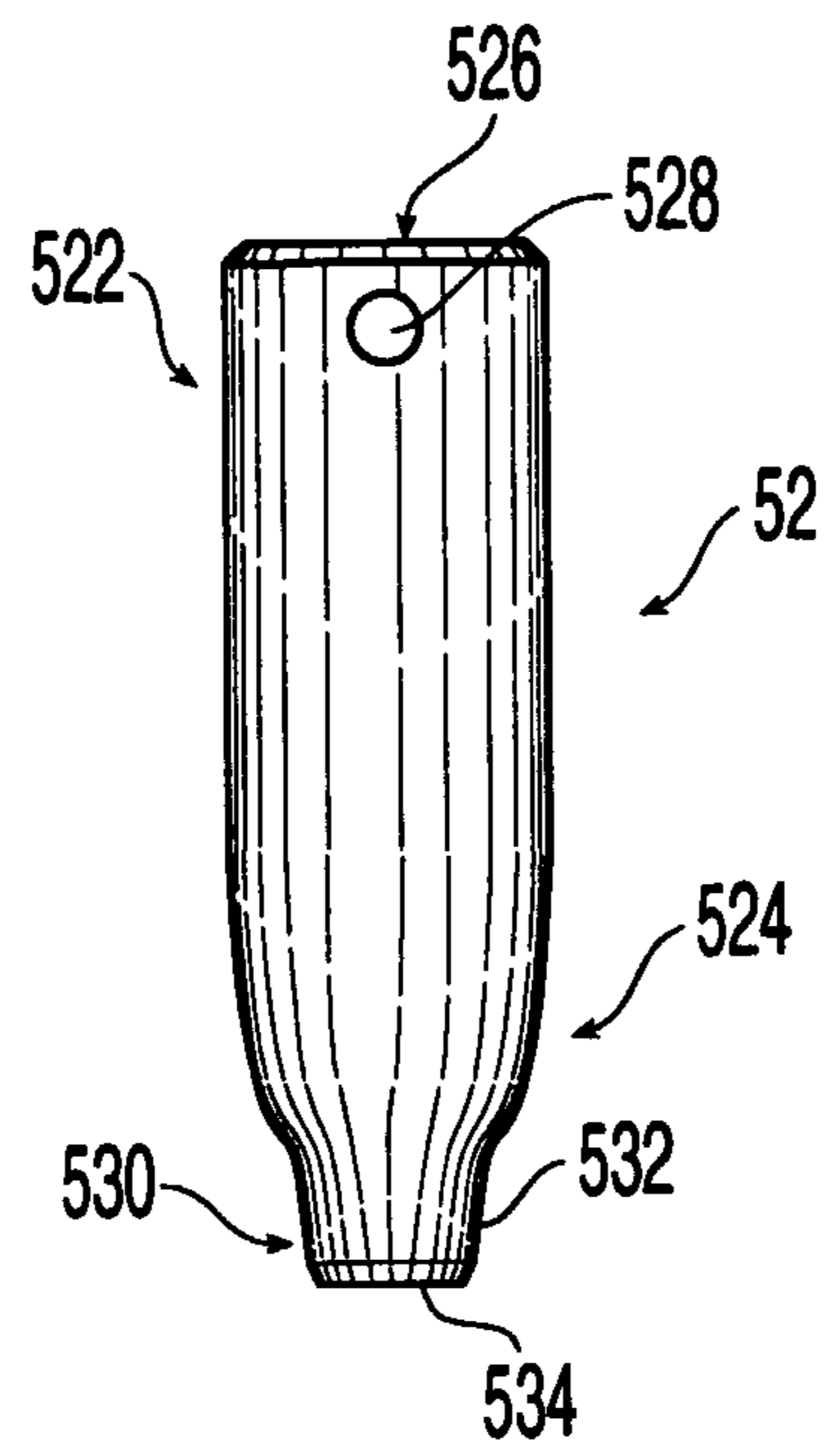
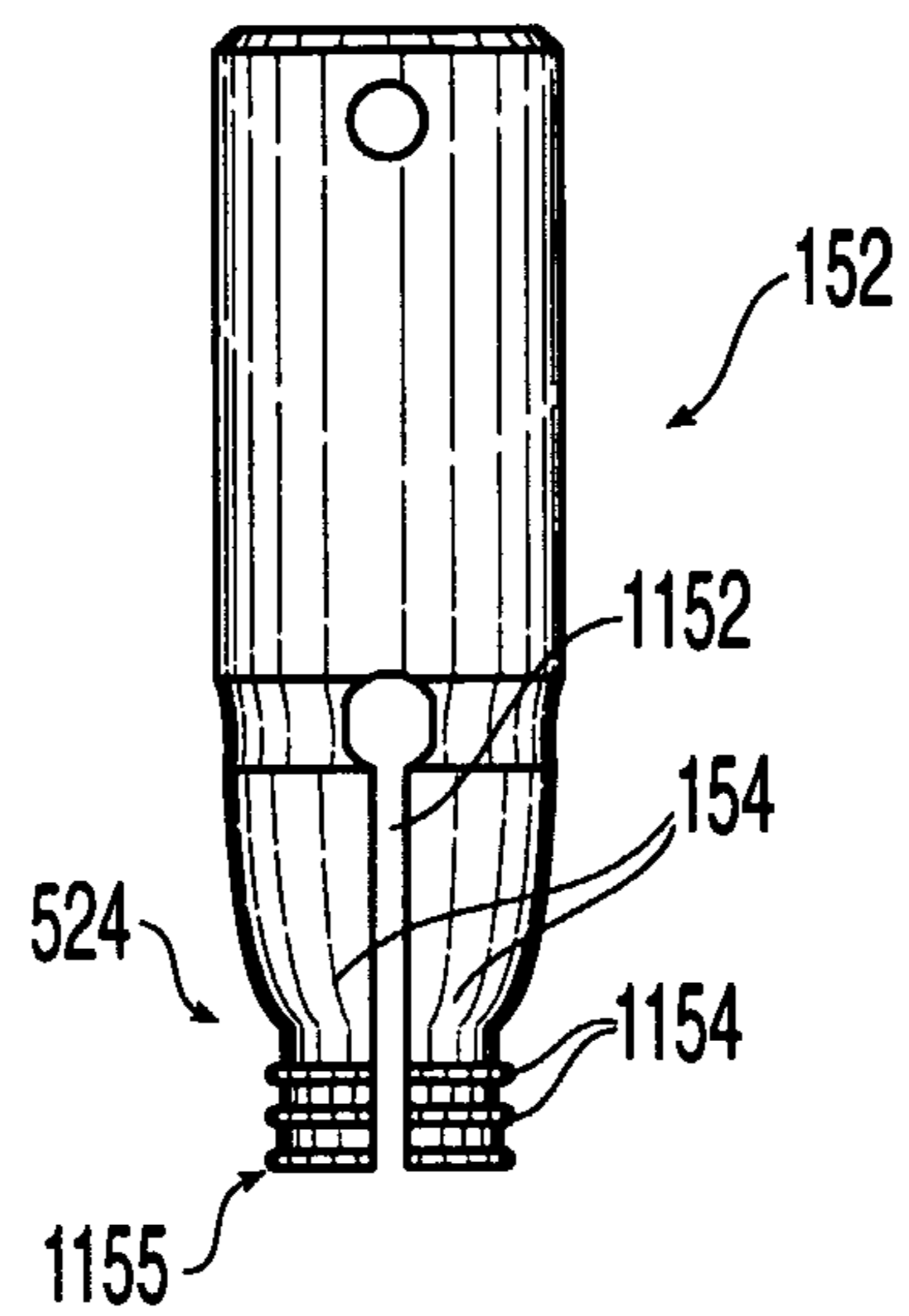


Fig. 7

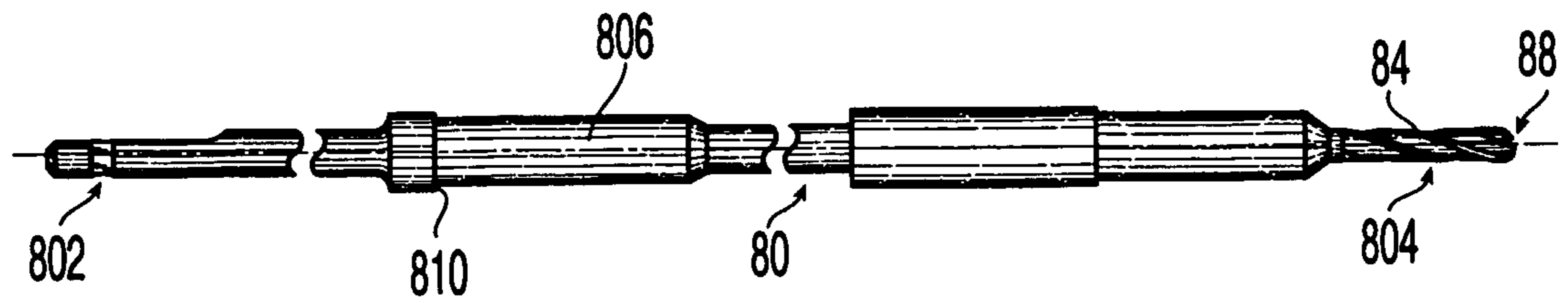
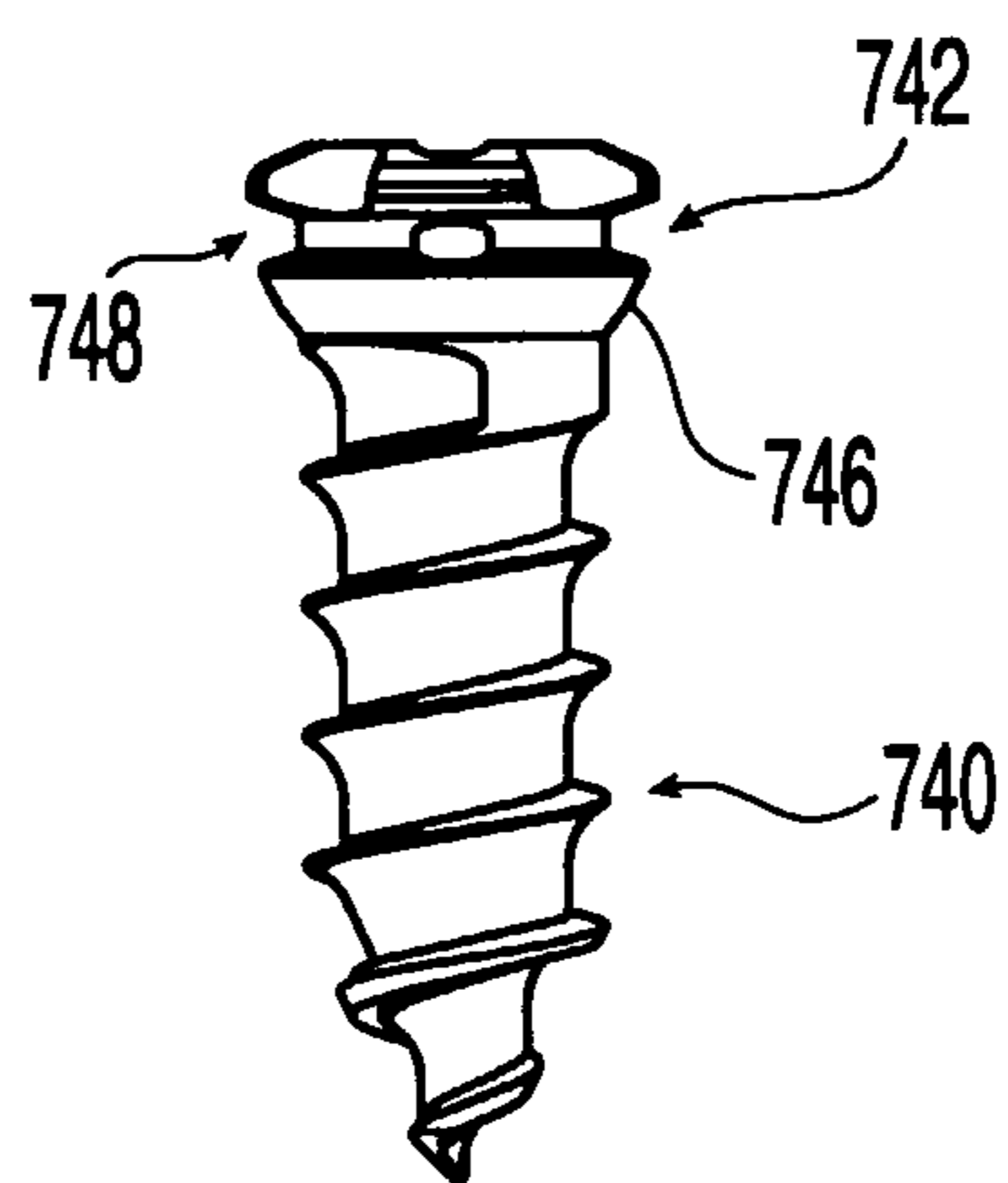
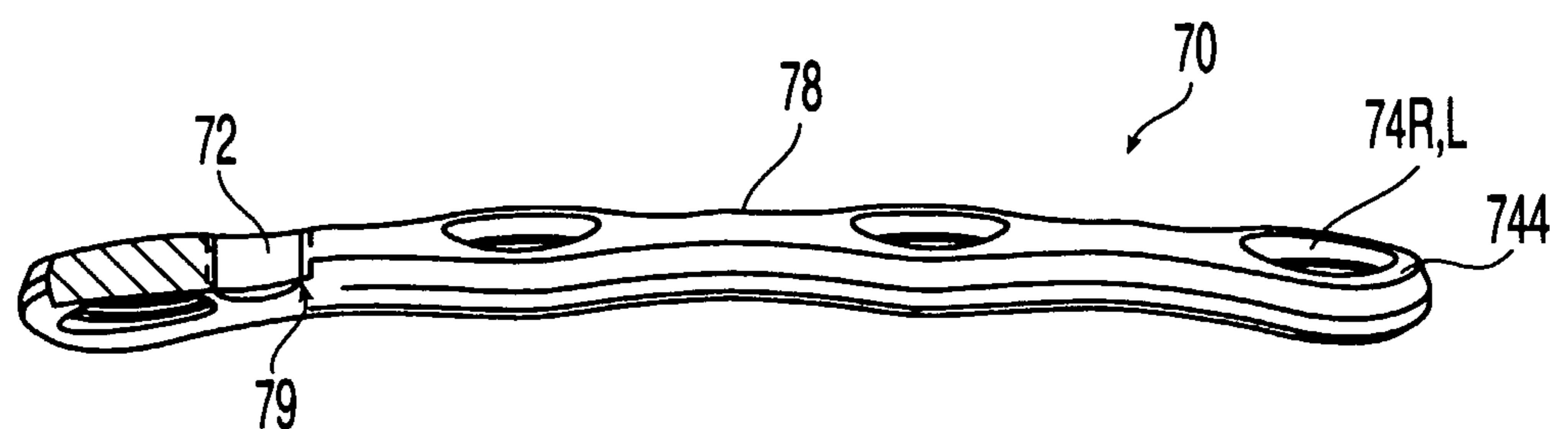
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*Fig. 8*

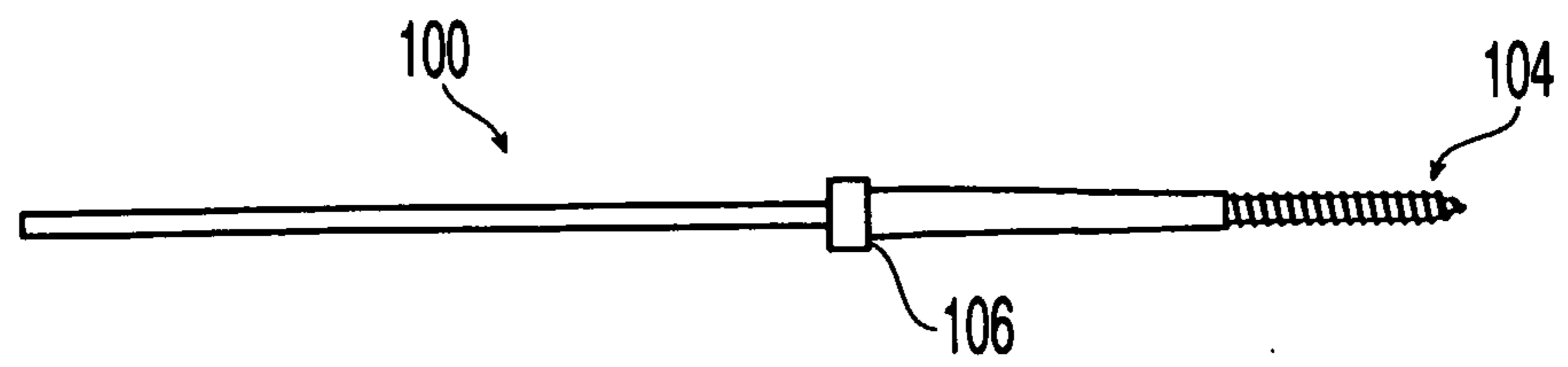
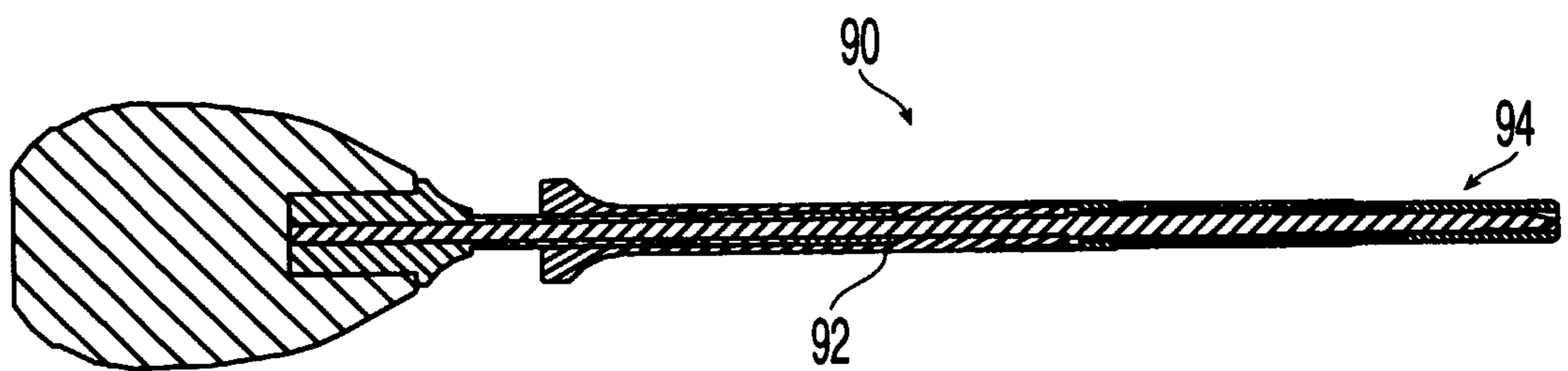
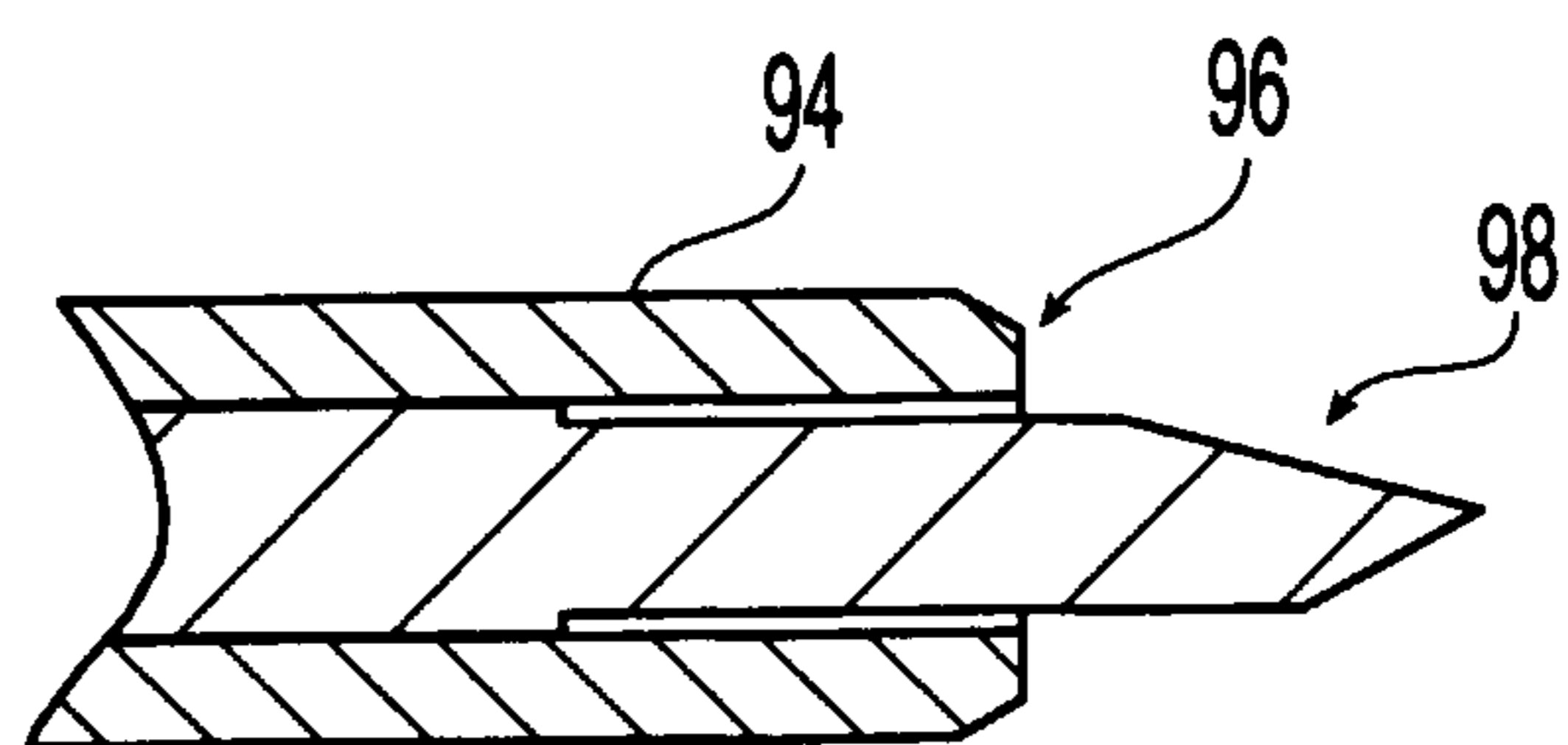
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*Fig. 9**Fig. 10*

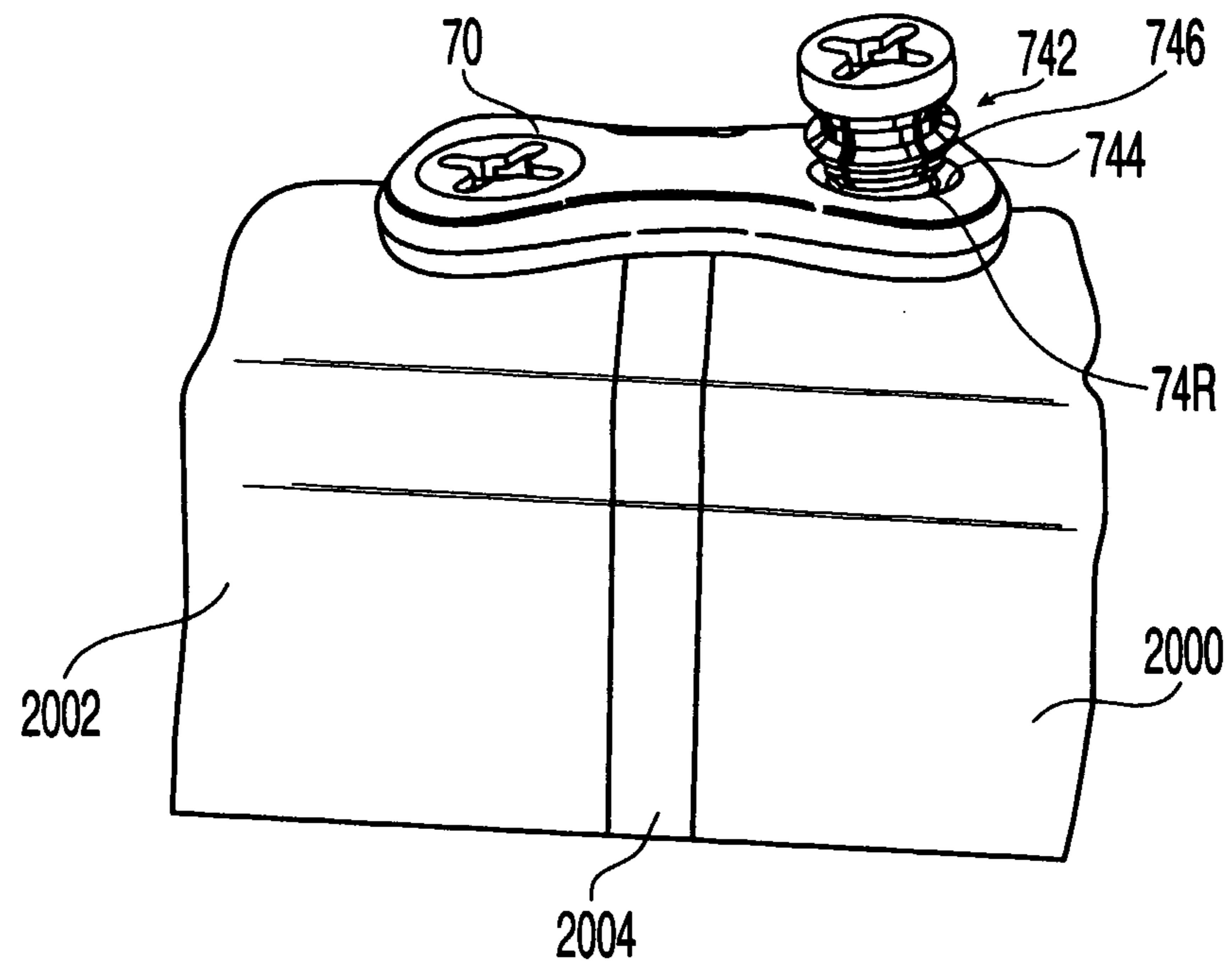
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*Fig. 11**Fig. 12**Fig. 13*

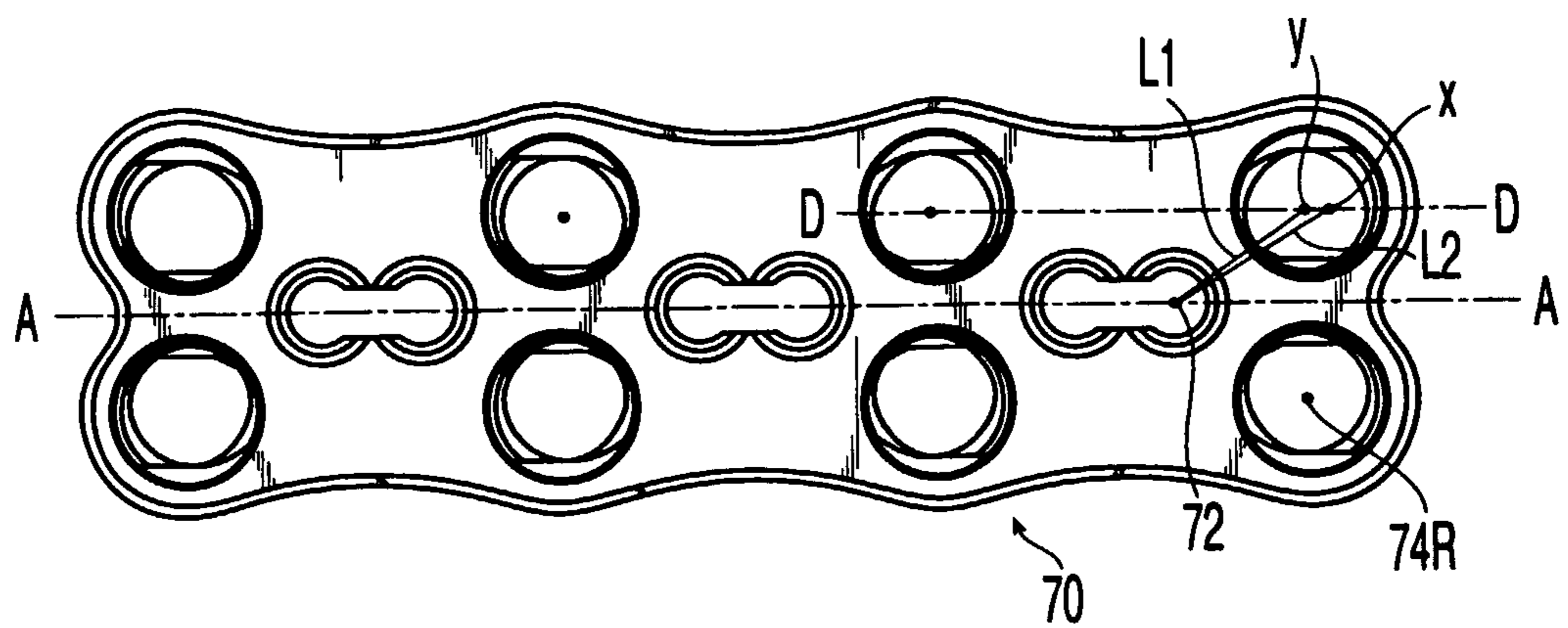
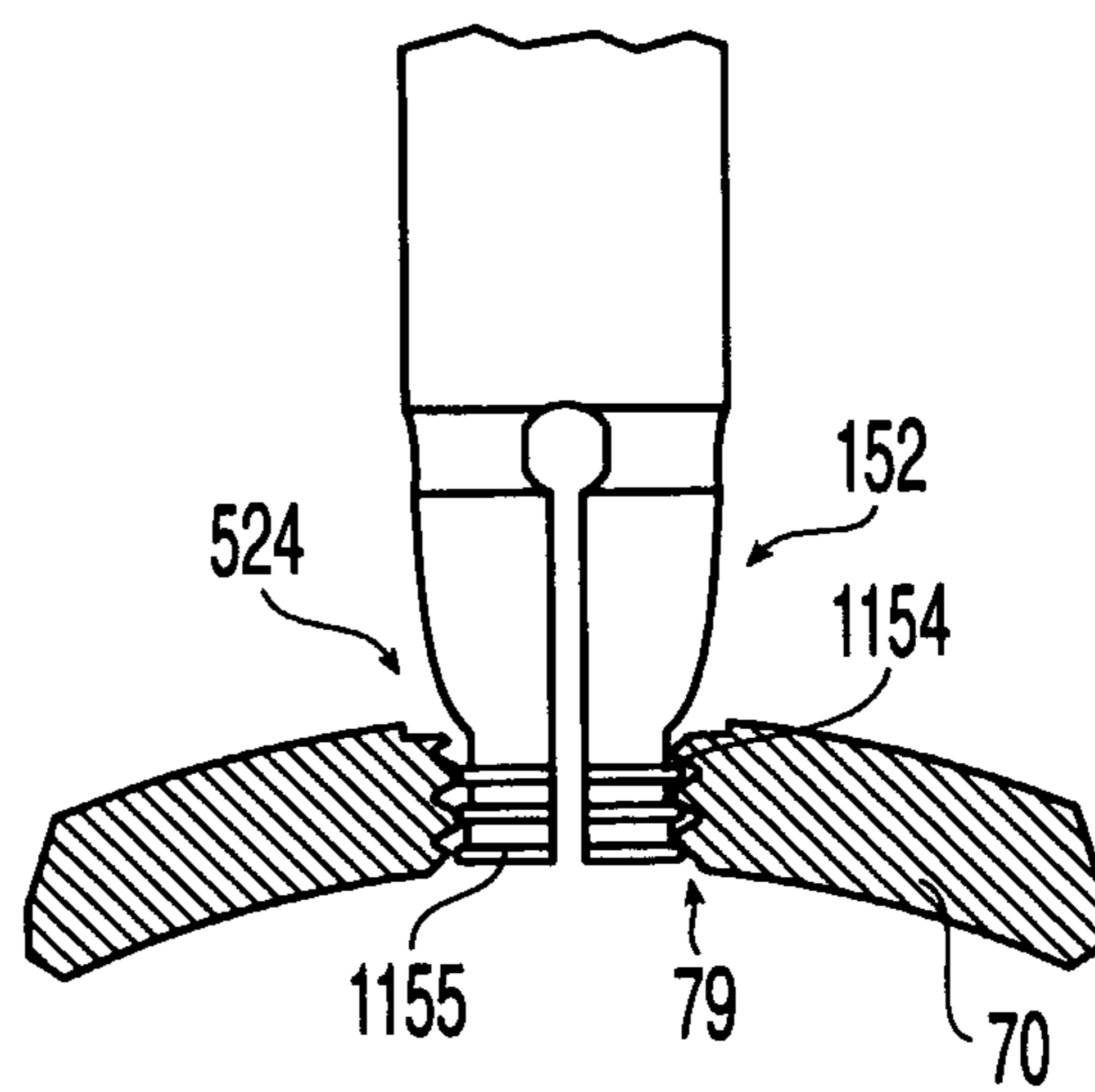
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*Fig. 15**Fig. 14A**Fig. 14B*

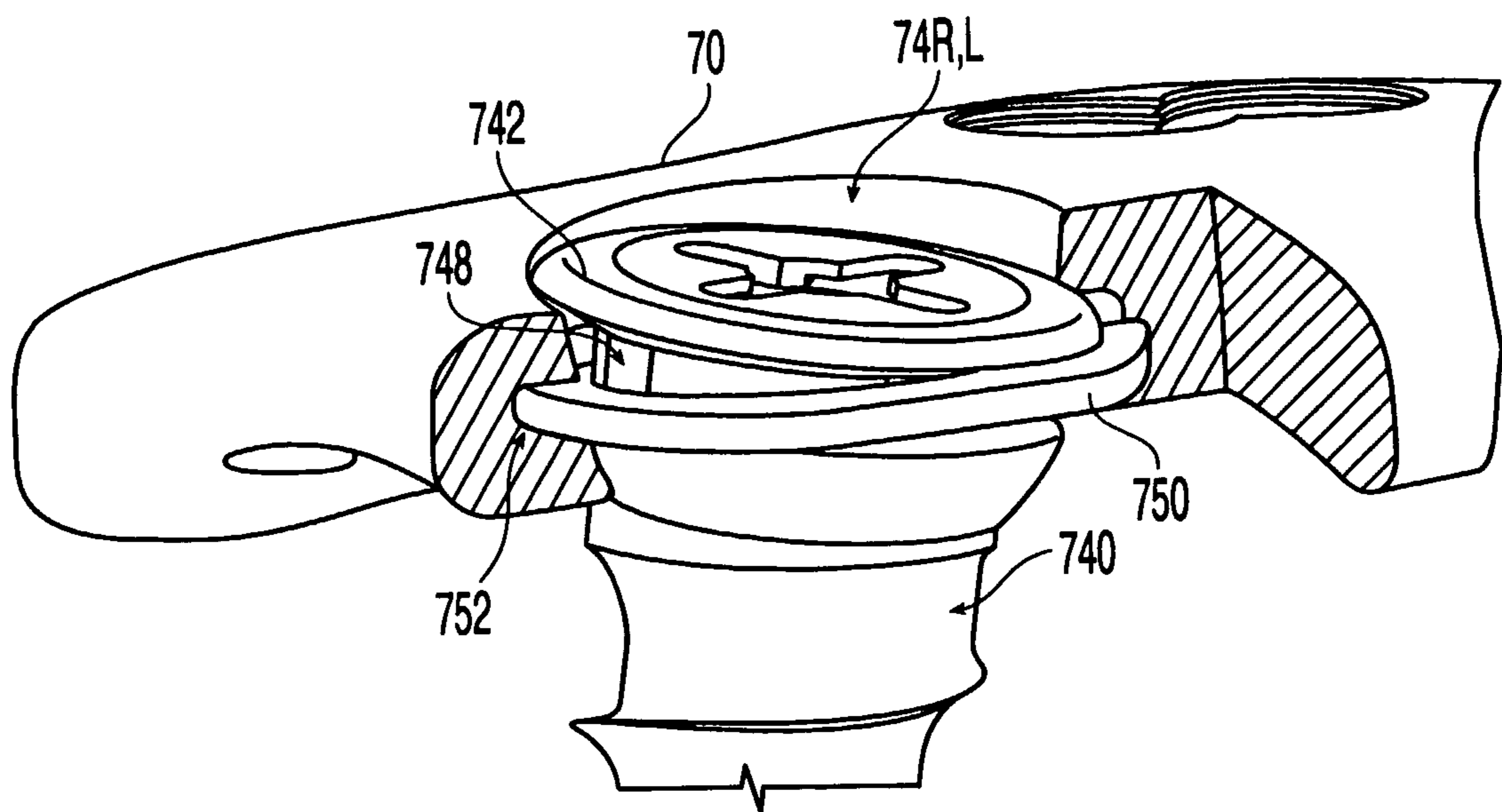
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*Fig. 16*

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*Fig. 17**Fig. 18*

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*Fig. 19*

