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71	FULL NAME(S) OF APPLICANT(S)
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SDGI Holdings, Inc.

72	FULL NAME(S) OF INVENTOR(S)
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RAY III, Eddie F.

DUNCAN, James P.

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54	TITLE OF INVENTION
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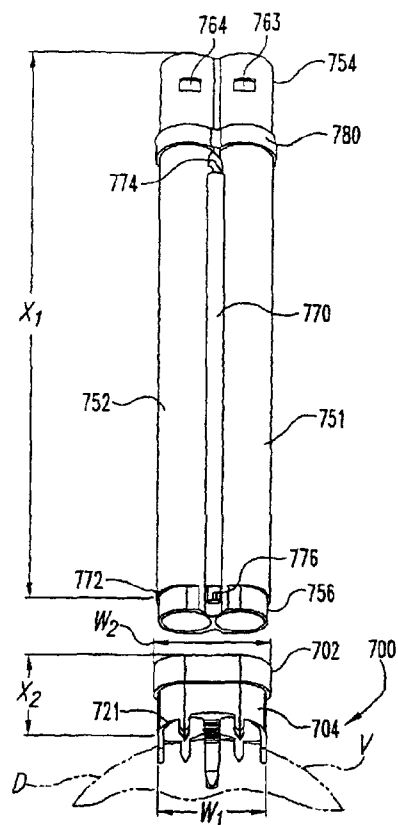
Methods and instrumentation for vertebral interbody fusion

57	ABSTRACT (NOT MORE THAN 150 WORDS)
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The sheet(s) containing the abstract is/are attached.

If no classification is furnished, Form P.9 should accompany this form.
The figure of the drawing to which the abstract refers is attached.



(57) **Abstract:** Methods and instrumentation for vertebral interbody fusion are provided. Sleeve assemblies can be provided with a reduced width portion adjacent the distal end to limit the amount of retraction of the surrounding vascular and neural structures required for the procedure. A sleeve assembly can be provided with a guide sleeve removably engaged to a guide sleeve housing. The guide sleeve can be removed during surgery to improve the surgeon's viewing of the operative site while the guide sleeve housing maintains disc space distraction. Methods and instruments for inserting and using the guide sleeve housing are also provided.

METHODS AND INSTRUMENTATION FOR VERTEBRAL INTERBODY FUSION

BACKGROUND OF THE INVENTION

5 The present invention relates generally to surgical procedures for spinal stabilization and more specifically to instrumentation adapted for inserting a spinal implant within the intervertebral disc space between adjacent vertebra. More particularly, while aspects of the invention may have other applications, the present invention is especially suited for disc space preparation and implant insertion into a disc space from a generally anterior approach
10 to the spine.

 Various surgical methods have been devised for the implantation of fusion devices into the disc space. Both anterior and posterior surgical approaches have been used for interbody fusions. In 1956, Ralph Cloward developed a method and instrumentation for anterior spinal interbody fusion of the cervical spine. Cloward surgically removed the disc
15 material and placed a tubular drill guide with a large foot plate and prongs over an alignment rod and then embedded the prongs into adjacent vertebrae. The drill guide served to maintain the alignment of the vertebrae and facilitated the reaming out of bone material adjacent the disc space. The reaming process created a bore to accommodate a bone dowel implant. The drill guide was thereafter removed following the reaming
20 process to allow for the passage of the bone dowel which had an outer diameter significantly larger than the reamed bore and the inner diameter of the drill guide. The removal of the drill guide left the dowel insertion phase completely unprotected.

 More recent techniques have advanced this concept and have provided further protection for sensitive tissue during disc space preparation and dowel insertion. Such
25 techniques have been applied to an anterior approach to the lumbar spine. In one approach, a unilateral template has been provided to evaluate the space in the disc space. For bilateral implant placement, the template entire device must be rotated and visually aligned to approximately 180° from the previous position. Thus, there is the chance for operator error in rotating the device to the correct position.

Further, there is little guidance to ensure proper alignment of cutting instruments extending through the template.

One approach to provide such alignment is the use of a guide wire extending through a cannulated cutting instrument, such as a trephine. However, for instruments with hollow cutting heads, there is typically no engagement between the inner walls of the hollow cutting head and the guide wire. Thus, the guide wire may bend between the portion extending into the tissue and the guide wire entrance into the cannula of the instrument. As a result, the hollow cutting head may not remain in substantial alignment with the guide wire, resulting in improper opening formation. Therefore, there remains a need for improved guiding mechanisms for cutting instruments.

Once an initial opening or openings have been made in the disc space, the height of the disc space is normally distracted to approximate the normal height. Typically, a first distractor with a height estimated by CT or MRI examination is inserted. If additional distraction is required, the first distractor is removed and a second, larger distractor is inserted. However, since the positioning of the distractors is usually performed without the benefit of protective guide sleeves, the switching of distractors increases the potential for damage to neurovascular structures and may increase the time of the procedure.

For bilateral procedures, a double barrel sleeve may be inserted over a pair of previously placed distractors with a central extension extending into the disc space to maintain distraction. One limitation on guide sleeve placement is the amount of neurovascular retraction that must be achieved to place the guide sleeves against the disc space. For some patients, a double barrel sleeve may not be used because there is insufficient space to accept the sleeve assembly. Further, although the distal end of the sleeve assembly may be configured to engage the vertebral surface, if material has been removed from the disc space, there is the potential that adjacent neurovascular structures may encroach on the working channels in the disc space, resulting in damage to these structures caused by contact with instruments. While visualization windows on the guide sleeve may assist in better visualization of procedure steps and verifying unobstructed working channels prior to tool insertion, the windows themselves may allow tissue to come into contact with instruments in

the working channels. Thus, there remains a need for guide sleeves requiring reduced neurovascular retraction for proper placement and providing greater protection to adjacent tissue.

While the above-described techniques are advances, improvement is still needed in the instruments and methods. The present invention is directed to this need and provides more effective methods and instrumentation for achieving the same.

SUMMARY OF THE INVENTION

The present invention relates to methods and instrumentation for vertebral interbody fusion. The present invention provides a guide sleeve having first and second working channels. The guide sleeve is removably engageable to a guide sleeve housing positioned in an operative location with respect to the disc space. The guide sleeve can be removed to enhance surgeon visualization while the guide sleeve housing maintains disc space distraction.

Sleeve assemblies according to the present invention can be provided with a reduced width portion adjacent the distal end to limit the amount of retraction of the surrounding vascular and neural structures required for the procedure. According to one aspect of the invention, a sleeve assembly is provided that includes a central distraction flange having a first height and an opposing pair of lateral flanges having a second height, less than the first height. The lateral flanges provide protection from encroachment of tissue into the working area in the disc space. The lateral flanges are provided on a guide sleeve housing removably mounted on the distal end of a guide sleeve. The central distraction flange can be provided as part of the guide sleeve housing or as part of the guide sleeve. It is further contemplated that neither the guide sleeve nor the guide sleeve housing is provided with a central distraction flange. With the guide sleeve removed from the guide sleeve housing, visualization by the surgeon of the working space in the disc space is enhanced.

In another aspect, the guide sleeve has first and second working channels and is removably attached to a guide sleeve housing at its distal end. The first and second working channels can be isolated by a central wall or are in communication with another to provide a reduced profile configuration.

In a further aspect of the invention, a guide sleeve housing is removably mounted to a housing inserter. The guide sleeve housing and housing inserter are movably mounted along a central distractor positioned in a spinal disc space. The guide sleeve housing is advanced along the distractor to insert at least lateral flanges of the guide sleeve housing into the disc space. The housing inserter is then uncoupled from the guide sleeve housing and removed. The central distractor is then removed with the guide sleeve housing remaining in the disc space. A guide sleeve can then be mounted to the guide sleeve housing and surgical procedures performed in the disc space through the guide sleeve and the guide sleeve housing. The guide sleeve is removable from the guide sleeve housing to enhance surgeon visualization of the operative site in the disc space. In one form, the central distractor is rotatable from a reduced height insertion and removal configuration to an increased height distraction configuration.

Related aspects, embodiments, forms, features, objects and advantages of the present invention will be apparent from the following brief description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1a is a perspective view of an expandable template according to the present invention.

Fig. 1b is a side elevational view of the template of Fig. 1a.

Fig. 1c is front view of the template of Fig. 1a.

Fig. 1d is a top view of the template of Fig. 1a.

Fig. 1e is a bottom view of the template of Fig. 1a.

Fig. 1f is an enlarged perspective view of the engaging end of the template of Fig. 1a.

Fig. 2a is a perspective view of the template of Fig. 1a in an expanded condition.

Fig. 2b is a top view of the template of Fig. 2a.

Fig. 3a is a side view of another embodiment of an expandable template according to the present invention with a trephine disposed therein.

Fig. 3b is a top view of the expandable template of Fig. 3a showing the locking mechanism.

Fig. 4a is a perspective view of a guide member and trephine according to the present

invention.

Fig. 4b is an enlarged perspective view of a portion of Fig. 4a.

Fig. 5a is a perspective view of a distractor according to the present invention.

Fig. 5b is an enlarged front view of the tip of the distractor of Fig. 5a.

Fig. 5c is an enlarged side view of the tip of the distractor of Fig. 5a.

Fig. 6 is a perspective view of a guide sleeve assembly according to another aspect of the present invention.

Fig. 7 is a front view of the guide sleeve assembly of Fig. 6.

Fig. 8 is a side view of the guide sleeve assembly of Fig. 6.

Fig. 9 is a partial cross-sectional side view of a guide sleeve assembly with a removable tip or housing at its distal end.

Fig. 10 is a perspective view of a guide sleeve assembly with a cover according to the present invention.

Fig. 11 is an end view of the guide sleeve assembly of Fig. 10.

Fig. 12 is a front view of one embodiment of a guide sleeve window cover according to the present invention.

Fig. 13 is a front view of a guide sleeve assembly with the cover of Fig. 12 mounted thereon.

Fig. 14 is a perspective view of an engaging end of a guide sleeve assembly with another embodiment of a window cover according to the present invention.

Fig. 15a is a side view of a window cover.

Fig. 15b is an end view of the window cover of Fig. 15a.

Fig. 16a is still a further embodiment of a window cover in accordance with the present invention.

Fig. 16b is an end view of the window cover of Fig. 16a.

Fig. 17 is an anterior to posterior view of a guide sleeve assembly with window covers according to Fig. 15 disposed thereon, the guide sleeve assembly is positioned in relation to a pair of adjacent vertebral bodies and blood vessels.

Fig. 18 is a partial cross-sectional top view of a guide sleeve assembly with only one

window cover positioned thereon, a portion of the guide sleeve assembly extending into the disc space.

Fig. 19 is a side view of a hollow headed reamer in accordance with another aspect of the present invention.

Fig. 20 is the reamer of Fig. 19 rotated 90 degrees about the shaft longitudinal axis.

Fig. 21 is an enlarged partial cross-sectional view of the head of the reamer of Fig. 19.

Fig. 22 is a side view of a clean out tool for use with the hollow reamer head of Fig. 19.

Fig. 23 is a top view of the clean out tool of Fig. 22.

Fig. 24 is a side view of a tap in accordance with the present invention.

Fig. 25 is a side view of a tap having a removable tap head in accordance with another aspect of the present invention.

Fig. 26a is a side view of a reamer having a removable reamer head in accordance with another aspect of the present invention.

Fig. 26b is a partial cross-sectional view of the connection mechanism of Fig. 26a.

Fig. 27 is a perspective view of a depth stop according to the present invention with the collar partially retracted to expose the locking fingers.

Fig. 28 is a side view of the depth stop of Fig. 27.

Fig. 29 is a cross sectional view taken along line 29-29 of Fig. 28.

Fig. 30 is a front view of the depth stop of Fig. 27 with the collar fully extended.

Fig. 31 is a side view of an alternative embodiment of a depth stop in accordance with the present invention.

Fig. 32 is a partial side view illustrating the depth stop of Fig. 31 in engagement in with a tool shaft.

Fig. 33 is a perspective view looking proximally of another embodiment removable guide sleeve tip or housing according to the present invention.

Fig. 34 is a perspective view looking distally of the guide sleeve housing of Fig. 33.

Fig. 35 is a perspective view of a guide sleeve according to the present invention removably attachable to the guide sleeve housing of Fig. 33.

Fig. 36 is a perspective view of the guide sleeve of Fig. 35 adjacent to the guide sleeve

housing of Fig. 33 in its operative position with respect to the disc space.

Fig. 37 is an enlarged perspective view of the distal end of the guide sleeve of Fig. 35.

Fig. 38 is a perspective looking proximally at the guide sleeve of Fig. 35 attached to another embodiment guide sleeve housing according to the present invention.

5 Fig. 39 is a perspective view of an alternate embodiment guide sleeve adjacent to and before attachment to the guide sleeve housing of Fig. 38.

Fig. 40 is a perspective view of a central distractor in the disc space and a guide sleeve housing mounted to a housing inserter positioned over a proximal portion of the shaft of the central distractor.

10 Fig. 41 is a perspective view of the central distractor, guide sleeve housing, and housing inserter of Fig. 40 with the guide sleeve housing advanced along the distractor shaft to position the guide sleeve housing in its operative position with respect to the disc space.

Fig. 42 is a perspective view of the central distractor, guide sleeve housing, and housing inserter of Fig. 40 with the guide sleeve housing in its operative position with respect to the disc space and the housing inserter uncoupled from the guide sleeve housing and withdrawn proximally along the shaft of the central distractor.

Fig. 43 is a perspective view of the central distractor, guide sleeve housing, and housing inserter of Fig. 40 with the guide sleeve housing in its operative position with respect to the disc space and the housing inserter withdrawn from the shaft of the central distractor.

20 Fig. 44 is a perspective view of the central distractor and guide sleeve housing of Fig. 40 with the guide sleeve housing in its operative position with respect to the disc space and the central distractor withdrawn from the disc space.

Fig. 45 is a perspective view of a guide sleeve according to the present invention before it is attached to the guide sleeve housing of Fig. 40 in its operative position with respect to the disc space.

25 Fig. 46 is a perspective view of a guide sleeve according to the present invention attached to the guide sleeve housing of Fig. 40 in its operative position with respect to the disc space.

Fig. 47 is an enlarged perspective view of the distal end of housing inserter of Fig. 40.

Fig. 48 is a perspective view of a rotatable central distractor according to the present invention in a reduced height configuration.

Fig. 49 is a perspective view of the rotatable central distractor of Fig. 48 in a distraction configuration.

5 Fig. 50 is a perspective view of the central distractor of Fig. 48 in its distraction configuration and removably coupled to a guide sleeve housing according to the present invention with the distractor and guide sleeve housing in their operative position with respect to the disc space.

10 Fig. 51 is a perspective view of the central distractor and guide sleeve housing of Fig. 50 with the distractor in a reduced height configuration and uncoupled from the guide sleeve housing.

Fig. 52 is a perspective view of the central distractor and guide sleeve housing of Fig. 51 with the central distractor removed from the guide sleeve housing.

15 DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no
20 limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

25 The present invention relates to methods and instrumentation for performing vertebral interbody fusion. Specifically, although aspects of the present invention may have other uses either alone or in combinations, the instruments and methods disclosed herein are particularly useful for anterior lumbar interbody fusion. Provisional application 60/081,206 filed April 9, 1998 is incorporated herein by reference.

Referring now to Figs. 1(a) through (f), there is shown an intraoperative template 10 for

use in interbody fusion. Intraoperative template 10 includes a central anchoring pin 12 and two supplemental anchoring pins 14 and 16. These pins are adapted to be driven into vertebral bodies or other tissue adjacent a disc space to anchor the intraoperative template 10 in the proper location. Template 10 includes an outer shaft 18 interconnected with handle 22 and an inner shaft 20 disposed within outer shaft 18. Inner shaft 20 extends to encompass pin 12. Outer shaft 18 is rotatable with respect to inner shaft 20. Disposed adjacent the distal end of template 10 are guide members 24 and 26 connected to inner shaft 20 and outer shaft 18, respectively. Preferably, guide members 24 and 26 are substantially circular plates having an aperture therein. Guide members 24 and 26 define openings 28 and 30, respectively, adapted to receive a trephine tool therethrough. Trephine guides 34 and 36 are positioned along outer shaft 18 and have openings 40 and 42, respectively, in alignment along axis 31 and are sized to receive a trephine tool shaft. In an alternative embodiment, it is contemplated that inner shaft 20 may be connected to guide member 26 and outer shaft 18 may be connected to guide member 24.

In a first reduced size configuration for unilateral templating and guiding, shown in Fig. 1a, guide members 24 and 26 are axially aligned along axis 31 with openings 28 and 30, respectively, in similar alignment. In this reduced size configuration, the expandable template may be inserted into the body through a relatively small opening and the template may be used for unilateral templating and guiding of a trephine. In this position, a trephine may be guided through guides 34 and 36 and guide members 24 and 26 to engage the tissue below. Moreover, referring to Fig. 3a, a trephine according to the present invention may have a uniform diameter along most of its shaft such that it is a close fit within guides 34 and 36. The close fit in guides 34 and 36 maintains axial alignment, while permitting trephine shaft rotation. Thus, a single template 10 may be used with a variety of sizes of trephine head diameters, provided the shaft has a substantially uniform diameter.

Referring now to Fig. 1a, handle 22 is connected to outer tube 18 and may be rotated in the direction of arrow 32 to a bilateral templating and guiding position. This action rotates outer shaft 18 with respect to inner shaft 20. Guiding member 26, guide 34 and guide 36 are connected to outer shaft 18 and therefore rotate when handle 22 is moved. In contrast, first

guide member 24 is interconnected with inner shaft 20 and remains stationary upon rotation of handle 22. As shown in Fig. 2a, handle 22 is rotated approximately 180 degrees to align second template 26 approximately 180 degrees from first template 24 and thereby expand the template to its bilateral trephining position. Thus, a trephine procedure may be conducted along axis 33 through guides 34 and 36 and second member 26 to cut an opening in the disc space. Axis 33 is spaced from axis 31 by a distance "D" representing the distance of spacing of the midpoints between implants to be inserted. Figs. 2a and 2b show the first and second templates rotated 180 degrees with respect to one another. Fig 2b shows a top view of a bilateral templating and guiding configuration. In this expanded configuration, the outer edges of guide members 24 and 26 define the total area necessary for placement of implants and instruments having a specific configuration and size. While in a preferred embodiment, cylindrical implants having diameters of 16mm, 18mm or 20mm may be used, it is contemplated that other diameters may be used and other shapes such as, but without limitation, squares and rectangles.

Shown in dashed line in Fig. 2b is a groove 39 formed in guide member 24 and projection 37 defined on guide member 26 and extending into groove 39. It will be understood that the engagement between groove 39 and projection 37 maintains alignment and limits rotation to 180 degrees. Thus, template 10 may be moved between the reduced size configuration and expanded configuration, but the groove and projection engagement limit further movement and will provide a positive indication of 180° rotation, thereby eliminating the requirement for visual alignment with the first position.

Referring now to Fig. 3a, there is illustrated a further embodiment of an expandable template according to the present invention. Template 600 is substantially identical to template 10 previously disclosed above, with the exception that template 600 includes a locking mechanism 613. Expandable template 600 includes a handle 626 connected to outer shaft 622. As in the previous embodiment, template 600 includes a first guide member connected to inner shaft 624 and a second guide member 606 connected to outer shaft 622. First guide member 608 includes spike 612 and inner shaft 624 extends to form central spike 610. Outer shaft includes guides 602 and 604. As shown in Fig. 3a, a trephine 601 may be

positioned through guides 602 and 604, and through guide member 606. The cutting head 605 includes cutting teeth 611, a series of index markings 607 and a window 609 to visualize the contents in the hollow interior. Preferably, trephine 601 includes a central cannula 603 extending from the handle to the cutting head.

5 A locking mechanism 613 is disposed between the inner and outer shafts to prevent rotation. Referring to Fig. 3b, locking arm 614 is pivotally attached to inner shaft 624 by pivot pin 620. The locking arm may be pivoted to extend through slot 616 in the outer shaft and slot 618 in the inner shaft. It will be understood that with locking arm disposed in the slots the inner and outer shaft will be prevented from rotation. In a first locked position, the
10 shafts are aligned as shown in Fig. 1a in the reduced size configuration. In a second locked position, the shafts are aligned as shown in Fig. 3a in the expanded bilateral templating configuration. It will be understood that the expandable, rotatable template of the present invention permits insertion of the device through a smaller opening than would have been permitted with a fixed relation double trephine opening template. Further, the expandable
15 template may be locked in either a unilateral or a bilateral position. Locking engagement in the bilateral position insures accurate bilateral placement with consistency that would not be readily achievable with a unilateral template particularly where the surgeon must reposition the device by visual alignment. Subsequently, the device may be rotated to an expanded configuration suitable for trephine guiding to form bilateral openings without removing the
20 instrument.

In use, access to an anterior portion of the spinal column is achieved by known method. Blood vessels, particularly the aorta, vena cava, and branches thereof are mobilized to provide space for bilateral implant placement. With the template in the reduced size configuration of Fig. 1a, the template is inserted into the body and advanced until the pins are
25 disposed adjacent a disc space. The circumference of the template guide member is selected to the circumference needed for bilateral placement of a pair of implants. More specifically, the area of the guide members of Fig. 2b closely approximate the area needed for placement of the double barrel guide sleeve disclosed herein, see for example Fig. 11. Central pin 12 is disposed centrally between the intended location of the implants. In either the unilateral or

expanded bilateral condition, the template may be disposed adjacent the disc space to measure the space available for implant and instrument placement. If the space appears too small, a smaller sized template may be inserted to evaluate the space. In the bilateral condition, the template approximates the area needed for implant and instrument placement.

5 Vessels disposed within the templated area may need to be mobilized outside the area or an alternative implant size or approach may be utilized. Further, osteophytes that appear within the templated area may be removed to prepare for engagement with a guide sleeve. Once the area is cleared, the pins are inserted into the tissue of the disc space and/or adjacent vertebra to anchor the template, thereby maintaining its position during subsequent steps. As shown

10 in Fig. 3a, a trephine is inserted into the guides and through the guiding members. The trephine is cuttngly advanced into the disc tissue to form an opening therein. The trephine may then be at least partially removed from the template to permit movement between the first and second guide members. If a lock mechanism is used, the locking arm must be moved to an unlocked position and the handle rotated to rotate the upper guide member to the

15 expanded bilateral templating position. The trephine is reinserted and advanced through the upper guide member to form a second opening aligned with and offset a distance D from the first opening. Thus, the template permits controlled bilateral opening formation through an expandable and collapsible template. The template may be collapsed into its reduced size form and withdrawn after completion of the trephining operation.

20 Referring now to Figs. 4a and 4b, there is shown a further guiding device according to the present invention. Guiding member 450 includes an elongated shaft 430 having a substantially uniform diameter over most of its length. Shaft 430 includes a distal portion adapted for guiding a cutting instrument having a hollow cutting head. The distal portion of shaft 430 includes distal end 432 having a sharpened tip 434 adapted to penetrate tissue,

25 specifically tissue disposed in the disc space. Distal end 432 includes markings 444 which indicate the extent of shaft 430 disposed in the disc space. Although guide member is preferably formed of stainless steel, other bio-compatible materials are contemplated. Specifically, shaft 430 may be formed of a radiolucent material and markings 444 may be radiopaque. Adjacent distal end 432 is enlarged portion 436 having a diameter substantially

greater than the shaft diameter. Enlarged portion 436 is adapted to prevent further advancement of guiding member 450 into the tissue and to guide the cutting of the cutting tool. Enlarged portion 436 preferably includes a planar surface 442 substantially perpendicular to the longitudinal axis of shaft 430. A substantially spherical surface 440 is disposed adjacent planar surface 442. This is followed by a tapering conical surface 438 that is adapted to align the cutting head over enlarged end 436. It will be understood that the internal surface of cutting head 426 defining opening 428 engages the transition line 448 between spherical surface 440 and taper surface 438. The diameter of transition line 448 substantially matches the internal diameter of cutting head 426 to provide a close fit for maintaining alignment.

In use, guide member 450 is inserted into the body with distal end 432 fully inserted into the tissue of interest, preferably disc tissue although other uses are contemplated. Cutting tool 420 is advanced over guide member 450 with shaft 422 in substantial alignment with shaft 430 extending through channel 427. While a trephine is illustrated, other cutting tools such as, but without limitation, reamers and non-rotary cutting tools may be used with guide members according to the present invention. Cutting teeth 425 are positioned adjacent enlarged portion 436 and are advanced until the cutting teeth surround the enlarged portion. It will be understood that if cutting teeth are offset with respect to enlarged portion 436, the teeth will engage a portion of conical surface 438 and thereby be urged into alignment. Enlarged portion 436 is received within chamber 428 and cutting teeth 425 are advanced along distal portion 432 until conical surface 428 abuts internal conical surface 429 to prevent further advancement. The assembly may be withdrawn with the cut tissue impaled by distal portion 432. The tissue may be removed from chamber 428 by advancing the guide member with respect to the cutting head such that the enlarged portion urges the tissue out of the hollow interior. This may be particularly helpful where the cutting tool is used to extract a bone graft. The depth of cutting teeth penetration may be adjusted by placement of the enlarged portion. Additionally, while only a single enlarged portion is shown, more than one may be positioned on the shaft to further adjust the guide member depth and cutting depth of the tool.

Referring now to Figs. 5a-c, there is shown a disc space distracter 50 according to one aspect of the present invention. Distracter 50 includes a proximal end 53 configured as an enlarged end for engagement with a conventional Hudson connection on a T-handle (not shown). Shaft 54 is joined with a distracter tip 56. While an integral shaft and head are shown, head 56 may be removably attached to shaft 54. One such removable attachment is more fully disclosed in provisional application 60/081,206 incorporated herein by reference. Distracter tip 56 is designed such that it can be inserted in a disc space to establish a first working distraction height 72 (see Fig. 5b), which is less than a second working distraction height 70 (see Fig. 5c). More specifically, distracter tip 56 has a rounded leading edge 62 that extends to opposing inclined surfaces 58 and 59 which extending more proximally blend into substantially planar opposing surfaces 60 and 61, respectively. Planar surfaces 60 and 61 extend in parallel alignment along the longitudinal axis of the distracter to establish height 72. It will be understood that the inclined surfaces 58 and 59 cooperate to ease insertion into the disc space and to initially distract the disc space to at least a height 72. If first height 72 is sufficient, further procedures as known in the art may then be carried out to accomplish implant insertion. Alternatively, rounded leading edge 62 permits the distracter to be inserted to directly achieve second distraction height 70.

In an alternative aspect, should first height 72 be insufficient, head 56 may be rotated a quarter turn, or 90 degrees, to the position shown in Fig. 5c. Rounded surfaces 64 and 66 engage the bone to urge it apart and into a second larger distracted height 70. It will be understood that utilization of a distracter tip as disclosed in the present invention, permits a two-height distraction of the disc space that may be carried out with a single instrument and without removing the instrument from the disc space. This offers an advantage to the surgeon of a single instrument offering multiple useful distraction heights. Thus, a surgeon may initially believe a disc space will need a first amount of distraction. After insertion of the distracter, the surgeon may discover that further distraction is required. In this situation, a distracter according to the present invention allows further distraction without instrument withdrawal. Moreover, distracter head 56 limits the number of instruments that must be made available to surgeon to accomplish a surgical procedure by providing two working

distraction heights on a single tool. Specifically, but without limitation, the distraction heads may be formed with first heights 72 ranging from 6mm to 12mm and second heights ranging from 7mm to 13mm. Preferably, heights 70 and 72 vary by 2mm increments. More preferably, height 72 is 8mm and height 70 is 10mm. In another form, height 72 is 10mm and height 70 is 12mm. Other variations may be utilized that provide multiple working distraction heights that approximate the disc height in a normal spine.

Referring now to Fig. 6, there is shown a double-barrel guide sleeve assembly 100 having a first sleeve 140 connected to a second sleeve 142. Sleeves 140 and 142 each define working channels 130 and 132 extending in a substantially unobstructed manner from the proximal end 102 to distal end 104. Assembly 100 includes upper windows 106 and 108 formed in sleeves 142 and 140, respectively, that are adapted for engagement by a removal tool. The sleeves also include lower elongated visualization windows 110 and 112.

Adjacent distal end 104, the material thickness along the outer edge of each tube 140 and 142 is reduced in order to provide a smaller cross-sectional area for the sleeve assembly as well as a reduced width extending transverse to the longitudinal axis of assembly. The reduced cross-sectional area and smaller width reduces the amount of retraction of vessels adjacent the disc space that would be required without the reduction. Side wall 114 is shown as an indication of the reduced thickness of the device in the distal area 104.

Distal end 104 includes a central distracting flange 116 which may be inserted into the disc space to achieve or maintain a height H1 of distraction between two vertebral bodies. Lateral flanges 118 and 120 also extend partially into or adjacent to the disc space. However, in a preferred embodiment, lateral flanges 118 and 120 have a height H2 that is less than height H1. Thus, they do not provide distraction of the disc space but are provided primarily to protect surrounding vessels and neurological structures from damage during the procedures. Although that is the function of the lateral flanges in the preferred embodiment, it is contemplated that they could be sized to provide distraction within the disc space in conjunction with central flange 116. Additionally, distal end 104 includes spikes 122, 124, 126, and a fourth spike which is not seen in the view of Fig. 10. These spikes may be urged into the bone of the adjacent vertebral bodies to hold the double-barrel guide sleeve 100 in a

fixed position relative to the vertebral bodies. It will be understood that windows 110 and 112 provide the medical staff with the opportunity to visualize the instruments as well as the openings in the disc space and vertebral bodies, without entirely removing instrumentation from guide sleeve 100.

Referring more specifically to Fig. 7, double-barrel guide sleeve 100 is shown in a front view to further illustrate an additional aspect of the invention. Opposite vertebrae engaging end 104, the guide sleeve has a width W1 approximately twice the diameter of one of the sleeves. Adjacent vertebrae engaging end 104 of the sleeve, each of the outer portions of the sleeves has a reduced wall thickness at side walls 114 and 113. The walls are not entirely flat but have a substantially greater radius of curvature (see Fig. 11) giving the appearance of substantially flat walls but providing a reduction in wall thickness over a greater area and tapering to the full wall thickness at the termination of side walls 113 and 114. The reduced wall thickness on the lateral portion of each tube reduces the overall width of the device to a width W2. The reduction in width decreases the amount of retraction that vessels in the area must be moved. The desirable reduction in width is accomplished with little reduction in the strength of the device since much of the structural integrity, particularly resistance to axial compression during insertion of the sleeves, is carried by the much thicker central portion where the two sleeves are joined to each other. Preferably, the central portion may have a thickness equal to two tube wall thickness.

As a further alternative, Fig. 9 shows that guide sleeve assembly 190 may be provided with removable barrel housings or tips 191 having different distraction heights, lateral extensions, or spike patterns. Barrel tips may also have different diameters corresponding to the placement of implants with different diameters. Removable tips 191 may be held in place by any of a variety of known connection mechanisms. However, in a preferred embodiment, guide sleeve assembly 190 includes a pair of opposing flexible fingers 192 and 193 having projections 194 and 195, respectively. Projections 192 and 193 on the flexible fingers extend into grooves 196 and 197, respectively, defined in the removable tip. To limit proximal movement of tip 191 during insertion, tapered surface 198 abuttingly engages shoulder 199 and the central portion between the upper guide tubes. Use of a removable tip according to

the present invention not only allows use of interchangeable tips to suit a specific application, it also permits removal of the outer sleeve after placement in the body. With only tip 101 in place, the posterior aspect of the disc space or spinal canal may be more easily visualized and accessed.

5 Referring now to Figs. 10 and 11, there is shown a further embodiment of a double-barrel guide sleeve similar in most respects to outer sleeve 100 of Fig. 6. The further embodiment of Fig. 12 differs from that of Fig. 6 in that guide sleeve 100 included only a single elongated visualization window for each sleeve. In double-barrel guide sleeve 150, each sleeve has a total of four windows, two on an upper surface and two on a lower surface. Thus, as shown in Fig. 10, windows 152, 154, 156, 158 provide the surgeon with the opportunity for visualization along the majority of each working channel. The back side of guide sleeve 150 has a similar configuration.

10 Guide sleeve 150 is used in a similar fashion to the outer sleeve 100. In a preferred embodiment, outer sleeve 100 is provided with a cover 160 having a length 162 sufficient to cover all four windows disposed on at least one side of the device. Cover 160 is provided to prevent possible damage to tissues which may invade the working channel through the windows and be damaged by the operation, insertion or removal of tools in the working channels. It is contemplated that cover 160 may be transparent to allow visualization directly through the cover or that it could be opaque, requiring that the cover be repositioned prior to visualization. It is further contemplated that the cover may have a length 162 sufficient to extend over all the windows on one side and it may be able to selectively cover either proximal windows 156 and 158 or all of the windows. Leading edge 163 is tapered to prevent damage to tissue, particularly when moving forward to cover the windows. The taper should urge the tissue out and away from the guide sleeve. Further, cover 160 includes a dip 171 substantially following the contour between the pair of guide sleeves.

20 Although other attachment mechanisms are contemplated, as shown in Fig. 11, cover 160 is held in place by retaining pin 170 connected through cover 160 to a lower dovetail portion 172. Dovetail portion 172 is slidable along a dovetail groove defined by grooves 168 and 169 defined within the outer body of guide sleeve 150.

Figs. 10 and 11 show one embodiment of a cover for slidably and selectively covering a plurality of windows in outer sleeve 150. Figs. 12 through 16b illustrate yet further embodiments of a cover which may be displaced to expose underlying windows in one of the double-barrel tubes. Further, although the covers are disclosed for use with double barrel assemblies, it is contemplated that they may be used with single tube guide sleeves without undue modification. In the further embodiments, the working channel and visualization windows of one barrel may be exposed while a cover remains in place on the alternate barrel.

Referring to Fig. 12, partially cylindrical cover 182 consists of elongated portions 183 and 185 which are sized to cover underlying visualization windows. The elongated portions are retained on the guide sleeve by connectors 184 and 186 that are sized to extend around the exterior of the outer tube and guiding portion 188. It is contemplated that connectors 184 and 186 may engage a cover portion on the opposite side of the guide sleeve identical to that shown in Fig. 12. While cover 182 is disclosed as having elongated members 183 and 185 interconnected, it is contemplated that each of the covers 183 and 185 could be separate to allow visualization of the windows only on an upper or lower surface of the working tube without opening the opposing window.

Referring to Figs. 14 through 16b, there are shown still further embodiments of window covers according to the present invention. Fig. 14 shows a cover 510 that covers approximately 200° of a single sleeve 502 of a guide sleeve assembly 501 similar to that of Fig. 6. The cover includes an internal passage 515 and is slidable along sleeve 502. In a further aspect, cover 510 includes an enlarged flange 512 adjacent bone engaging end 504. Tapered surface 513 extends between flange 512 and the outer diameter of cover 510. Referring to Figs. 15a and 15b, cover 514 includes a flange 516 that extends along the entire leading edge of the cover. The cover extends in a partial cylinder lacking material over angle 517.

Angle 517 is approximately 160°, thus material extends around approximately 200° of the cylindrical shape. It will be understood that covers 510, 514, and 520 may be configured to have material extending less than 200° around the cylinder to allow rotation of the cover in relation to a guide sleeve such that the cover may be rotated to uncover a window. Thus, for

covers 510 and 514, the flanges may continue to hold the vessels away from the guide sleeve even when moved to allow access through one of the windows.

An alternative embodiment shown in Figs. 16a and 16b does not include the enlarged flange 512. Cover 520 has a uniform end 524 and defines an internal channel 522 adapted to receive a guide sleeve. However, in certain surgical procedures it is desirable to use the embodiment having the flange to protect closely adjacent vessels and to urge them away from the distal end of the guide sleeve where it might be possible to contact instruments disposed therein. Without the use of a cover, the outer sleeves may not match the shape of the surface of the vertebral body thereby allowing the potential for contact between instruments in the outer sleeves and closely adjacent vessels. This is particularly dangerous when operating close to the vena cava and aorta. However, as shown in Figs. 17 and 18, the flanges on the covers act as a retractor to urge the vessels away from the outer sleeves.

Referring more specifically to Fig 17, guide assembly 550 is illustrated as being inserted into a disc space D between two adjacent vertebra V1 and V2. Disposed adjacent the guide assembly 550 are vessels 562 and 560 graphically representing portions of the aorta or vena cava. Covers 556 and 558 are mounted on guide tubes 552 and 554, respectively. Flanges on the covers, shown more clearly in Fig. 15a, urge the vessels away from the guide tube and more importantly, away from working channels 553 and 555 where tools would be inserted. Vessels 560 and 562 are most closely adjacent guide tubes 552 and 554 near V₁. Thus, lateral extensions on the guide assembly may be insufficient to prevent contact between vessels and tools in all applications.

Referring now to Fig. 18, there is shown a top view of a guide assembly 580 positioned in the disc space adjacent a vertebral body 591. The guide assembly 580 includes a central distractor 582 and lateral extensions 584 and 586. Spikes 590 and 592 may be inserted into the bone of the vertebral body. For the purposes of illustration, cover 596 has been positioned over a first guide tube, while guide tube 595 with window 593 remains uncovered. Bone engaging end 594 does not entirely conform to vertebra surface 589, thus allowing the possibility of vessel migration into the working channels. Cover 596 with flange 598 urges vessel 599 away from the engagement between bone engaging end 594 and bone surface 589.

In contrast, vessel 597 is positioned adjacent the interface between the guide tube and bone, resulting in the potential for vessel migration into the working channel via the space between the bone engaging end 594 and bone surface 589. Thus, covers according to the present invention may also be useful to further retract vessels away from the interface between the bone engaging end of the guide assembly and the bone surface.

Referring now to Figs. 19 through 21, there is shown a reamer 200 according to the present invention. Fig. 20 shows the reamer 200 of Fig. 19 rotated 90 degrees. Reamer 200 includes a cutting head 202 having cutting flutes 203 with troughs 205 disposed therebetween. Disposed in trough 205 is an aperture 204 extending to interior channel 209. A series of apertures 204 are defined in the cutting troughs and communicate with interior channel 209. The interior of cutting head 202 is hollow and forms interior channel 209. Interior channel 209 has a first portion with side walls substantially parallel to the longitudinal axis and a second portion defined by side walls extending at an angle to the longitudinal axis. Preferably the second portion extends at a non-orthogonal angle to permit easy cleaning. The second portion is connected to aperture 208 formed on the outer surface of the shaft and spaced from the cutting head. It will be understood that aperture 208 permits material cut by reaming head 202 to move through the interior channel 209 to exit at aperture 208. Moreover, the reduced diameter segment 211 defines an area between the shaft and outer sleeve where debris from the cutting operation may collect prior to removal of the device. This collection area has a length 214 in a preferred embodiment, although it is understood that this could be extended to increase the volume of material that may be collected. This configuration permits completion of the cutting operation without a requirement to remove the reamer to clean the collected debris. Additionally, the debris may be visualized through outer sleeve windows for evaluation.

Reduced diameter shaft 211 extends proximally to tapered region 210 which expands to a larger diameter guiding portion 212. Tapered region 210 assists ease of insertion and guiding of the shaft of the reamer within an outer working sleeve as previously disclosed. Larger diameter guiding portion 212 is sized to have a reasonably close fit within an outer working sleeve to permit rotation of the device, yet limit the amount of transverse movement

within the tube to insure accurate reaming within the bone. Reamer 200 may thereby be guided by a guide sleeve. Shaft 216 interconnects the proximal end to the enlarged area 212.

Disposed on shaft 216 are a series of numbers 218, which indicate the depth the reamer extends into the bone beyond the edge of a cooperable guide sleeve. As can be appreciated from examining Figs. 19 and 20, the numbers are displayed in a stepped arrangement around the circumference of shaft 216. This stepped arrangement permits each number to be larger, in the preferred embodiment three times larger, than they could be if all numbers were listed in a single column along the device. Thus, this arrangement permits easy visualization of the number by the surgeon despite the small incremental adjustment of the device, preferably 1mm increments. Extending more proximally along the shaft 216 are a series of grooves 221 which are adapted to engage a depth stop mechanism (described further below) to adjust the reaming depth of the device. On the proximal end 220 is a Hudson-type connection for engagement with a T-handle or other type of handle.

Referring now to Figs. 22 and 23, there is shown a clean out tool 1000 adapted for use with the hollow reamer head described above. Clean out tool 1000 includes a head 1002 having a diameter substantially matching the diameter of internal chamber 209. Clean out tool 1000 includes a flexible portion 1004. Flexible portion 1004 is connected to shaft 1008 which is connected to handle 1006. Flexible portion 1004 allows the device to enter through opening 208 in the reamer and force material out open end 201 of the reamer head as end 1010 is advanced. This is an improvement over hollow head reamers that do not provide a clean out channel.

Referring now to Fig. 24, there is shown a thread tap 230 for tapping a reamed out bone space. Tap 230 includes a cutting head 232, and a reduced diameter shaft 233 adjacent head 232 for providing space around the shaft between the outer tube for the collection of debris from the tapping operation. A tapered surface 234 extends to an increased outer diameter area 236. As previously explained with respect to reamer 200, tapered surface 232 permits guiding of the tap within a guide sleeve and enlarged area 236 by providing a reasonably close fit with the guide sleeve to maintain the axial alignment of tap 230. Tap 230 includes incrementally stepped depth markings 240 and a Hudson connection 242 as previously

disclosed with respect to reamer 200. Referring now to Figs. 25 through 26b, there are shown modular cutting tools joined to a shaft. Fig. 25 shows a shaft 250 releasably coupled to tap head 252 by coupler 254. Similarly, shaft 250 is coupled to reamer head 256 by coupler 254. In Fig. 26a reaming head 256 may be removed from shaft 250 at the connection 254. The reamer includes a reaming head 256 having only six cutting apertures disposed around the head and a hollow internal chamber connected to aperture 258. While any number of known connection mechanisms may be used, Fig. 26b shows the use of an axially displaceable collar 260 to release balls 262 and 263 from grooves 264 and 265 of the reamer head. Shaft 250 includes a hollow extension 268 having apertures 270 and 271 to hold balls 263 and 262, respectively. Collar 260 includes a reduced diameter portion 276 adapted to urge balls 262 and 263 into grooves 264 and 265 to lock the cutting head and shaft together. Collar 260 may be axially displaced away from the cutting head to dispose an enlarged internal diameter portion 278 adjacent the balls to allow them to disengage grooves 264 and 265, thereby allowing the cutting head to be disengaged from the shaft. The same mechanism may be used with a variety of cutting heads.

Referring now to Figs. 27 through 31, there is disclosed a depth stop mechanism cooperable with the shaft of a tool and guide sleeve such as previously disclosed. Such tools can include, without limitation, a reamer, a tap, and an implant inserter. Depth stop 326 includes an enlarged circumferential abutment shoulder 330 adapted to engage the proximal end of an outer working sleeve to prevent further advancement of the stop and any interconnected shaft. Stop 326 further includes viewing windows 328 to permit visualization of depth markings on a shaft extending within the stop. Stop 326 includes a manually operated collar 332 which may be axially displaced to allow flexing of fingers 334. Collar 332 is normally urged into an extended position by spring 342.

Referring specifically to Fig. 29, fingers 334 include projections 336 extending internally and bearing surface 337 extending externally. The internal projections 336 are configured for engagement within grooves 221 (Fig. 20) defined along a tool shaft of a working tool, and bearing surface 337 is configured to engage collar 332. Additionally, each finger includes an external taper portion 339 adapted for engagement with bearing surface

340 of collar 332 to urge the fingers inwardly as the collar is advanced. It will be understood that in a retracted position, bearing surface 340 of collar 332 will be substantially disengaged from taper 339 and permit fingers 334 to disengage from groove 221 of a working shaft (Fig. 20). With collar 332 in the extended position shown in Fig. 29, bearing surfaces 340 will
5 bear against bearing surface 337 of each finger to urge projections 336 into grooves 221 of a tool shaft. To release fingers, collar 332 may be moved in the direction of arrow R until bearing surface 340 moves beyond tapered surface 339. The flexible fingers may then spring outward. In this manner, a user may quickly and easily disengage the locking mechanism of the stop to advance or retract a working tool and then re-engage the stop at the desired
10 position. Preferably, distal end 333 of collar 332 will extend beyond fingers 334 to limit the possibility that surgical staff may snag protective apparel on exposed fingers.

In a first embodiment shown in Fig. 30, collar 332 is retained on housing member 334 by retaining pin 342 extending into the housing member and through a slot 344. Retaining pin 342 prevents rotation of collar 332 with respect to housing member 334. In an alternate
15 embodiment shown in Fig. 31, collar 332 defines an L-shaped slot 346 which permits axial displacement of collar 332 with respect to body 334, as well as a slight amount of rotation within the slot. It will be understood that the L-shaped slot 346 permits the depth stop mechanism to be locked in a disengaged position which permits free movement of the tool shaft through the depth stop. This is a desirable construction in some instances for easy
20 removal of the depth stop from the tool shaft, as well as for utilization of the tool without the constraints of a depth stop mechanism.

Fig. 32 shows a depth stop 326 engaged with a tool shaft having grooves 360 and marking 362 to show the depth of the distal end of the tool out of the guide sleeve 370. Abutment shoulder 330 is sized to engage the guide sleeve to prevent further movement. It
25 will be understood that the depth of penetration may be adjusted between a number of positions defined by engagement of the fingers 336 in grooves 360 of the tool shaft. The adjustment is easily accomplished by axial movement of collar 332. Engagement with the tool shaft is indexed by the spacing of grooves 360 on the tool shaft so the exact location of the stop may be easily known. The tool shaft may be rotated with respect to the stop

mechanism to display the appropriate depth numeral 362 in window 328.

Referring now to Figs. 33-52, further embodiments of guide sleeve tips or housings according to the present invention will be described along with methods and instruments useable with the guide sleeve housings. In Figs. 33-34, guide sleeve housing 700 includes a proximal portion 702 and a distal portion 704. Proximal portion 702 has an inner wall 703 that defines a proximal chamber 706 sized to receive a distal end of a guide sleeve, such as guide sleeve 750 of Fig. 35. Housing 700 further includes a first working channel port 708 and a second working channel port 710, each of which extend through distal portion 704 and are in communication with proximal chamber 706. A medial wall 715 extends between first and second working channel ports 708, 710, but does not extend into proximal chamber 706. Inner wall 703 can have an oval or racetrack shape as illustrated, or can have any other shape configured to receive the distal end of guide sleeve 750. Working channel portions 708, 710 are illustrated as having circular cross-sections; however, other shapes are also contemplated. A groove 712 is provided in inner wall 703, the purpose of which will be described further below.

As shown in Fig. 36, distal portion 704 has a width W1 transverse to the axis of the spinal column that is less than width W2 of proximal portion 702. The reduced cross-sectional area and smaller width reduces the amount of retraction of vessels adjacent the disc space than would be required without the reduction in width. In the illustrated embodiment, a lip 726 is provided completely around guide sleeve housing 700 at the junction between proximal portion 702 and distal portion 704, providing an external indication of the relative location of these portions and their internal configurations.

Distal portion 704 has a first lateral flange 714 and an opposite second lateral flange 715. A central distracting flange 716 extends distally from medial wall 715 between lateral flanges 714, 715. Central distracting flange 716 can be provided with teeth 718a on its upper surface 716a and teeth 718b on its lower surface 716b. The sidewalls 716c, 716d of central distractor flange 716 can also be concave in order to accommodate rotation of cylindrical instruments or implants therebeside. Similarly, lateral flanges 714, 715 can be concave along their respective medially oriented surfaces to accommodate rotation of cylindrical

instruments or implants therebeside. The lateral outer surfaces of lateral flanges 714, 715 can be flat or have a slight convexity.

Guide sleeve housing 700 has one operative position with respect to disc space D in which central distracting flange 716 is inserted into disc space D (Fig. 36) to achieve or maintain a distraction height H1 between two vertebral bodies. Lateral flanges 714 and 715 also extend at least partially into disc space D. Distal end wall 721 is positioned adjacent to or in contact with the vertebral bodies V on either side of the disc space. In one embodiment it is contemplated that lateral flange 714 has a height H2 between upper surface 714a and lower surface 714b that is less than height H1, and lateral flange 715 has a height H2 between upper surface 715a and lower surface 715b that is less than height H1. Thus, lateral flanges 714, 715 do not provide distraction of the disc space but are provided primarily to protect surrounding vessels and neurological structures from damage during the procedures. It is also contemplated that lateral flanges 714, 715 could be sized to provide distraction within the disc space in conjunction with central flange 716. Additionally, distal portion 704 can be provided with spikes 720a, 720b, 722a, 722b extending distally from end wall 721. These spikes may be urged into the bone of the adjacent vertebral bodies to hold the housing and a sleeve attached to it in a fixed position relative to the vertebral bodies.

In Figs. 35-37, there is shown a guide sleeve 750 having a first sleeve 751 connected to a second sleeve 752. First and second sleeves 751, 752 each define working channels 761, 762, respectively, extending in a substantially unobstructed manner from proximal end 754 to distal end 756. Guide sleeve 750 includes upper windows 763 and 764 formed in sleeves 751 and 752, respectively, adapted for engagement by removal and insertion tools or driving caps. Sleeves 751, 752 can also include lower visualization windows such as described above. A collar 780 is provided adjacent proximal end 754 around sleeves 751, 752 to provide further rigidity to the sleeve assembly.

Adjacent distal end 756, the material thickness about the outer edge of each sleeve 751, 752 is reduced in order to provide a recessed portion for positioning in chamber 706 of guide sleeve housing 700. The recessed portion allows proximal portion 702 to not protrude beyond the sidewalls of guide sleeve 750, providing the assembled guide sleeve and guide

sleeve housing with a smooth wall profile that minimizes or eliminates protrusions that could snag or catch the adjacent tissue. Guide sleeve 750 further includes an actuator housing 770 extending along the junction between first sleeve 751 and second sleeve 752. Actuator housing 770 can be recessed into an actuator channel 778 formed along the junction between first sleeve 751 and second sleeve 752. An actuator 772 extends through and is rotatably received in actuator housing 770. Actuator 772 includes a handle 774 at its proximal end and a finger 776 at its distal end that projects outwardly from actuator 772 and at least beyond the distal recessed portion of guide sleeve 750.

In order to attach guide sleeve 750 to guide sleeve housing 700, distal end 756 of guide sleeve 700 is placed in chamber 706. The surgeon uses handle 774 to rotate actuator 772 in the direction of arrow R and position finger 776 in groove 712 of guide sleeve housing 700, engaging guide sleeve 750 to guide sleeve housing 700. In this configuration, first working channel 761 is aligned with first working channel port 708 and second working channel 762 is aligned with second working channel port 710. Surgical procedures can then be completed through guide sleeve 750 and guide sleeve housing 700. Guide sleeve 750 can be easily and quickly removed from guide sleeve housing 700 to provide the surgeon the ability to better view the operative site in spinal disc space D. Guide sleeve 750 can be reattached as needed for completion of subsequent procedures through guide sleeve 750 and guide sleeve housing 700.

It is contemplated that the ratio of the length X1 of guide sleeve 750 extending proximally from guide sleeve housing 700' to the length X2 of guide sleeve housing 700' extending proximally from the vertebral bodies is more than about 2:1. In one specific embodiment, the ratio of X1 to X2 is about 5:1. Other embodiments contemplate other ratios for X1 to X2 that range from 2:1 to about 10:1.

Referring now to Fig. 38, there is shown another embodiment guide sleeve housing 700' removably engaged to guide sleeve 750. Except as described below, guide sleeve 700' is generally the same as guide sleeve 700. In Fig. 38, actuator handle 774 is shown rotated to its engaged position such that finger 776 is positioned in a groove formed in the inner wall of proximal portion 702' such as is provided with guide sleeve housing 700. Guide sleeve 700'

does not have a central distracting flange, but is provided with lateral flanges 714', 715' that each have a distraction height H3 between upper surfaces 714a', 715a' and lower surfaces 714b', 715b', respectively. The leading proximal ends of lateral flanges 714', 715' can be tapered to a reduced height from H3 to facilitate insertion into the disc space. It is also contemplated that lateral flanges 714', 715' extend distally further than non-distracting lateral flanges in order to provide greater penetration depth into the disc space and more bearing support area for the distracted disc space. Guide sleeve housing 700' has one operative position with lateral flanges 714', 715' positioned in the disc space and in contact with the adjacent vertebral endplates, and distal end wall 721' positioned adjacent to or in contact with the vertebral bodies on either side of the disc space. Upper surfaces 714a', 715a' can be provided with teeth 717a', 719a', respectively, and lower surfaces 714b', 715b' can be provided with teeth 717b', 719b', respectively. These teeth extend transversely across the lateral flanges to engage the vertebral endplates and resist movement of guide sleeve housing 700' from its operative position. Other engaging means on the lateral flanges are also contemplated, such as knurlings, spikes or barbs, to name a few.

Another feature of guide sleeve housing 700' is that its distal portion 704' is provided with working channel ports 708', 710' that are in communication with another through distal portion 704', forming an overall oval or racetrack shaped working channel port. Such a configuration allows guide sleeve housing 700' to be used to prepare the spinal disc space for positioning of spinal implants adjacent to or in contact with one another, or for using reduced profile instruments and implants. Such reduced profile instruments and implants are disclosed in PCT Publication no. WO 00/45709, published August 10, 2000, and also in the publication entitled Reduced Profile Instrumentation Surgical Technique by J. Kenneth Burkus, M.D. and John D. Dorchak, M.D. Each of these publications is incorporated herein by reference in its entirety.

Referring now to Fig. 39, there is shown a perspective view of an alternate embodiment guide sleeve 750 'adjacent to and before attachment to guide sleeve housing 750'. Except as discussed below, guide sleeve 750' is identical to guide sleeve 750. Guide sleeve 750' includes a central distracting member 790' extending from a distal end thereof. Central

distracting member 790' can be centrally located between first sleeve 751' and second sleeve 752', and is positionable through guide sleeve housing 700' when guide sleeve 750' is engaged thereto.

5 Central distracting member 790' has a height H1 between upper distracting surface 790a' and lower distracting surface 790b' sufficient to distract the spinal disc space. Central distracting member 790' also separates the spinal disc space into bi-lateral working spaces and also distracts and maintains distraction of the adjacent vertebrae as surgical procedures are performed in the disc space. When used in combination with distracting lateral flanges 714', 715' the surface area supporting the distracted vertebrae is increased as compared with
10 embodiments having only one or two distracting members or flanges. Central distracting member can also be provides with teeth 791a' on upper distracting surface 790a' and teeth 791b' on lower distracting surface 790b'. The sidewalls between the upper and lower distracting surfaces of central distracting member 790' can be concave to accommodate rotation of surgical instruments and implants therebeside. Further embodiments contemplate
15 a guide sleeve having a central member that is not distracting, but rather only guides implants and instruments in the disc space and maintains separation of the working spaces in the disc space.

Referring now to Figs. 40 and 47, a housing inserter according to the present invention will be described. While housing inserter 850 is described with respect to guide sleeve
20 housing 700', it should be understood that housing inserter 850 could be used with any other embodiment guide sleeve housing described herein. Housing inserter 850 has a handle 852, a housing engaging portion 854 on the distal end of handle 852, and a passageway 856 opening at the distal face of housing engaging portion 854 and extending proximally through housing engaging portion 854 and handle 852 adjacent to or through the proximal end of handle 852.
25 Housing engaging portion 854 is sized and shaped to fit in chamber 706' defined by proximal portion 702' of guide sleeve housing 700'. A close interfit between housing engaging portion 854 and guide sleeve housing 700' ensures a rigid assembly and minimizes relative movement therebetween. In one form, housing engaging portion 854 is in the form of a boss extending outwardly from handle 852.

Housing inserter 850 further includes an actuator 872 rotatably received in actuator housing 870. Actuator 872 extends from a surgeon accessible location adjacent the proximal end of handle 852 to the housing engaging portion 854. Actuator 872 has a proximal actuator handle 874 and a distal finger 876, and actuator 872 functions in the manner described above with respect to actuator 772 to engage guide sleeve housing 700' to housing inserter 850 when housing engaging portion 854 is positioned in chamber 706'. Actuator 872 and actuator housing 870 can be recessed in a trough 858 formed along housing inserter 850 to prevent actuator 872 and actuator housing 870 from interfering with insertion of housing engaging portion into the guide sleeve housing.

With references to Figs. 40-46, methods and techniques for inserting the guide sleeve housings according to the present will be described. In Fig. 40, a central distractor 800 having a shaft 802 is centrally located along the spinal midline with its distal distractor tip 804 inserted into disc space D and in contact with the endplates of vertebrae V. It should be understood that central distractor 800 can be any of the distractors described herein or a distractor known in the art. Housing inserter 850 is engaged to guide sleeve housing 700', and the assembly is advanced over shaft 802 by placing passageway 856 over the proximal end of shaft 802. An example of a technique for accessing the disc space and inserting distractor 800 is provided in the publication entitled Anterior Instrumentation Surgical Technique as described by Scott H. Kitchel, M.D., which is incorporated herein by reference in its entirety.

In Fig. 41, housing inserter 850 and housing 700' have been advanced along shaft 802 of central distractor 800 to position lateral flanges 714', 715' in disc space D and end wall 721' adjacent to or in contact with the adjacent vertebrae V. If housing 700' were provided with spikes, such as those provided with guide sleeve housing 700, housing inserter 850 could be impacted on its proximal end to drive the spikes into vertebrae V. Impacting may also be necessary to insert lateral flanges 714', 715' into disc space D, particularly if the lateral flanges have a distraction height.

In Fig. 42, actuator 872 has been rotated to disengage housing inserter 850 from guide sleeve housing 700'. Housing inserter 850 is then withdrawn proximally along shaft 802

until it is completely removed, as shown in Fig. 43. A removal instrument or the like can be attached to proximal end 806 of distractor 800 and, as shown in Fig. 44, distractor tip 804 is withdrawn from disc space D and through guide sleeve housing 700', leaving guide sleeve housing 700' in its operative position with respect to disc space D. Surgical procedures can be performed in the disc space through guide sleeve housing 700', or the surgeon can attach a guide sleeve, such as guide sleeve 750. In Fig. 45, guide sleeve 750 is oriented so that distal end 756 is adjacent guide sleeve housing 700'. In Fig. 46, guide sleeve 750 is advanced to insert distal end 756 into chamber 706' of proximal portion 702'. Actuator 772 is rotated to position finger 776 in a groove formed in the inner wall of proximal portion 702'.

Surgical procedures, such as cutting, reaming, tapping, and implant insertion can be completed through guide sleeve 750. Examples of such techniques through guide sleeve 750 are described in the aforementioned Anterior Instrumentation Surgical Technique. With the guide sleeve housing of the present invention, the surgeon can remove the guide sleeve to better visualize the operative site while the guide sleeve housing maintains disc space distraction. It should be understood that guide sleeves other than guide sleeve 750 could be attached to guide sleeve housing 700', including those guide sleeves with working channels in communication with one another such as the reduced profile instruments disclosed above.

Referring now to Figs. 48 and 49, there is shown a rotatable distractor 900 according to another aspect of the present invention. Rotatable distractor 900 includes a shaft 902 extending between a proximal end 904 and a distal end 906. Proximal end 904 can include a standard connector arrangement for coupling distractor 900 to pullers, driving caps, inserters and the like. Distal end 906 includes an inner shaft (not shown) rotatably received through collar 908 and housing engaging portion 910. A distractor tip 916 is coupled to the distal end of the inner shaft. Distractor tip 916 includes an upper distracting surface 916a and an opposite lower distracting surface 916b, each of which can include teeth or other vertebral endplate engaging surface. Distractor tip 916 extends distally of housing engaging portion 910 and is rotatable with respect thereto in the direction of arrow R from a reduced height configuration (Fig. 48) to a distraction configuration (Fig. 49.)

Housing engaging portion 910 is sized and shaped to fit within inner chamber 706' of

guide sleeve housing 700'. Housing engaging portion 910 includes a receptacle 912 which houses a finger 914 keyed to the inner shaft extending through housing engaging portion 910. When distractor tip 916 is rotated to its reduced height configuration of Fig. 48, finger 914 is recessed into housing engaging portion 910 and guide sleeve housing 700' can be positioned about housing engaging portion 910. When distractor tip 916 is rotated to its distraction configuration of Fig. 49, finger 914 extends from housing engaging portion 910 and is positioned in a groove formed in the inner wall defining chamber 706' to engage guide sleeve housing 700' to rotatable distractor 900.

An example of a technique for accessing the disc space and preparing it for insertion of rotatable distractor 900 is provided in the aforementioned Anterior Instrumentation Surgical Technique. With guide sleeve housing 700' engaged to rotatable distractor 900 as shown in Fig. 50, distractor tip 916 extends through distal portion 704' and is in its distraction configuration. Distractor tip 916 is inserted into disc space D along with lateral flanges 714', 715' to distract the disc space and place guide sleeve housing in its operative position with respect to disc space D. When guide sleeve housing 700' is in its operative position, shaft 902 is rotated in direction R' as shown in Fig. 51 to move distractor tip 916 to its reduced height configuration. This withdraws finger 914 into housing engaging portion 910, disengaging rotatable distractor 900 from guide sleeve housing 700'. As shown in Fig. 52, rotatable distractor 900 can then be withdrawn from the disc space with guide sleeve housing 700' remaining in its operative position.

Surgical procedures can be performed in the disc space through guide sleeve housing 700', or the surgeon can attach a guide sleeve, such as guide sleeve 750, to housing 700'. Surgical procedures, such as cutting, reaming, tapping, and implant insertion can be completed through guide sleeve 750. Examples of such techniques through guide sleeve 750 are described in the aforementioned Anterior Instrumentation Surgical Technique. With the guide sleeve housing of the present invention, the surgeon can remove the guide sleeve to better visualize the operative site while the guide sleeve housing maintains disc space distraction. It should be understood that guide sleeves other than guide sleeve 750 could be attached to guide sleeve housing 700', including those guide sleeves with working channels

in communication with one another such as the reduced profile instruments discussed above.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

Claims

1. A spinal instrument assembly, comprising:
a central distractor having a distractor tip coupled to a shaft, said distractor tip having upper and lower distraction surfaces defining a distraction height therebetween to maintain distraction of a spinal disc space;
a guide sleeve housing having a distal portion and a proximal portion, said guide sleeve housing defining a working channel in which said central distractor is centrally located, wherein said guide sleeve housing is positionable in an operative position with respect to the spinal disc space; and
a guide sleeve having a distal end and a proximal end, said distal end of said guide sleeve removably engageable to said guide sleeve housing.
2. The instrument assembly of claim 1, wherein said central distractor is rotatable from a reduced height configuration whereby said upper and lower distraction surfaces are oriented away from vertebral endplates of a spinal disc space to a distraction configuration whereby said upper and lower distraction surfaces are oriented toward vertebral endplates of the spinal disc space.
3. The instrument assembly of claim 2, wherein said central distractor is engaged with said guide sleeve housing when in said distraction configuration and disengaged with said guide sleeve housing when in said reduced height configuration.
4. The instrument assembly of claim 1, wherein said guide sleeve housing is removably engageable to a housing inserter.
5. The instrument assembly of claim 4, wherein said housing inserter and said guide sleeve housing are positionable over a proximal end of said shaft of said central distractor and movable therealong to position said guide sleeve housing in said operative position.

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6. The instrument assembly of claim 1, wherein said guide sleeve housing includes a proximal portion and a distal portion, said proximal portion having an inner wall defining a chamber and said distal portion defining working channel ports therethrough in communication with said chamber.

7. The instrument assembly of claim 6, wherein said inner wall defines a groove therein.

8. The instrument assembly of claim 7, wherein:
said central distractor includes a housing engaging portion having an actuatable finger;
said central distractor has a reduced height configuration whereby said upper and lower distraction surfaces are oriented away from vertebral endplates of a spinal disc space and said finger is not actuated; and
said central distractor is rotatable to a distraction configuration whereby said upper and lower distraction surfaces are oriented toward vertebral endplates of a spinal disc space and said finger is actuated and received in said groove thereby coupling said guide sleeve housing to said central distractor.

9. The instrument assembly of claim 7, wherein said guide sleeve housing is removably engageable to housing inserter, said housing inserter having an actuatable finger positionable in said groove to engage said housing inserter to said guide sleeve housing.

10. The instrument assembly of claim 9, wherein said housing inserter and said guide sleeve housing are positionable over a proximal end of said shaft of said central distractor and movable therealong to position said guide sleeve housing in said operative position.

11. The instrument assembly of claim 9, wherein said finger is removed from said groove to disengage said housing inserter from said guide sleeve housing when said guide sleeve housing is in said operative position.

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12. The instrument assembly of claim 1, wherein said central distractor is withdrawable from the spinal disc space and said guide sleeve housing when said guide sleeve housing is in said operative position.

13. The instrument assembly of claim 1, wherein:
said guide sleeve has a first length extending proximally from said guide sleeve housing when engaged thereto;
said guide sleeve housing has a second length extending proximally from the operative site; and
a ratio of said first length to said second length is more than about 2:1.

14. The instrument assembly of claim 13, wherein said ratio is in the range of about 5:1 to about 10:1.

15. A guide sleeve assembly for defining a protected passageway to a disc space, comprising:
a guide sleeve extending between a distal end and a proximal end, said guide sleeve defining a first working channel and a second working channel extending therethrough between said distal and proximal ends; and
a guide sleeve housing have a first working channel port and a second working channel port extending therethrough alignable with a respective one of said first working channel and said second working channel of said guide sleeve with said guide sleeve housing removably engaged to said distal end of said guide sleeve wherein:

a proximal portion of said guide sleeve housing includes an outer wall;
said distal end of said guide sleeve includes a recessed portion positionable in said proximal portion of said guide sleeve housing;
said guide sleeve includes an outer wall proximal said recessed portion; and
said outer wall of said proximal portion of said guide sleeve and said proximal outer wall of said guide sleeve are aligned when said

guide sleeve is engaged to said guide sleeve housing.

16. The guide sleeve assembly of claim 15, wherein said first working channel and said second working channel are in communication with one another.

17. The guide sleeve assembly of claim 15, wherein said first working channel port and said second working channel port of said guide sleeve housing are in communication with one another through said guide sleeve housing.

18. The guide sleeve assembly of claim 15, wherein said guide sleeve housing includes a medial wall between said first working channel port and said second working channel port.

19. The guide sleeve assembly of claim 15, wherein said guide sleeve housing includes a central distracting flange extending distally therefrom positioned between said first working channel port and said second working channel port.

20. The guide sleeve assembly of claim 19, wherein said guide sleeve housing includes a pair of lateral flanges extending distally therefrom on opposite lateral sides of said guide sleeve housing.

21. The guide sleeve assembly of claim 20, wherein each of said lateral flanges has a non-distracting height between upper and lower surfaces thereof.

22. The guide sleeve assembly of claim 19, wherein said central distracting flange include an upper distracting surface an a lower distracting surface, each of said distracting surfaces including teeth formed thereacross.

23. The guide sleeve assembly of claim 15, wherein said guide sleeve housing includes a pair of lateral flanges extending distally therefrom on opposite lateral sides of said guide sleeve housing.

24. The guide sleeve assembly of claim 23, wherein said lateral flanges each include upper and lower distracting surfaces defining a distraction height therebetween.

25. The guide sleeve assembly of claim 24, wherein said upper distracting surface and said lower distracting surface of each of said lateral extensions include teeth formed thereacross.

26. The guide sleeve assembly of claim 23, wherein said first working channel port and said second working channel port are in communication with one another through said guide sleeve housing.

27. The guide sleeve assembly of claim 15, wherein said guide sleeve housing includes a distal end having spikes extending distally therefrom for engaging vertebral bodies.

28. The guide sleeve assembly of claim 15, wherein said guide sleeve housing includes a proximal portion having a first width transverse to the spinal column axis and said distal portion having a second width transverse to the spinal column axis, said first width greater than said second width.

29. The guide sleeve assembly of claim 28, wherein said guide sleeve housing defines a lip therearound between said proximal portion and said distal portion.

30. The guide sleeve assembly of claim 15, wherein said first working channel and said second working channel are each formed by respective ones of a first sleeve and a second sleeve.

31. The guide sleeve assembly of claim 15, wherein said guide sleeve includes an a actuator having a finger at a distal end thereof, said actuator rotatable between a first position wherein said finger engages said guide sleeve housing to said guide sleeve and a second position wherein said guide sleeve housing is disengaged from said guide sleeve.

32. The guide sleeve assembly of claim 31, wherein a proximal portion of said guide sleeve housing has an inner wall defining a groove therein, said finger positionable in said groove to engage said guide sleeve housing to said guide sleeve.

33. The guide sleeve assembly of claim 31, wherein said guide sleeve includes an actuator housing extending between said distal end and said proximal end of said guide sleeve, said actuator being rotatably received in said actuator housing with said finger at said distal end and a handle at said proximal end.

34. The guide sleeve assembly of claim 31, wherein said actuator is recessed in a trough formed along said guide sleeve between said proximal end and said distal end.

35. A guide sleeve assembly for defining a protected passageway to a disc space, comprising:

a guide sleeve extending between a distal end and a proximal end, said guide sleeve defining a first working channel and a second working channel extending therethrough between said distal and proximal ends; and

a guide sleeve housing have a first working channel port and a second working channel port extending therethrough alignable with a respective one of said first working channel and said second working channel of said guide sleeve

with said guide sleeve housing removably engaged to said distal end of said guide sleeve, wherein said guide sleeve includes a central distracting member extending distally therefrom and through said guide sleeve housing.

36. The guide sleeve assembly of claim 35, wherein said guide sleeve housing includes a pair of lateral flanges extending distal therefrom on opposite lateral sides of said guide sleeve housing.

37. The guide sleeve assembly of claim 36, wherein said lateral flanges each have upper and lower distracting surfaces defining a distraction height therebetween.

38. The guide sleeve assembly of claim 37, wherein said upper distracting surface and said lower distracting surface of each of said lateral extensions include teeth formed thereacross.

39. The guide sleeve assembly of claim 35, wherein said guide sleeve housing includes a distal end having spikes extending distally therefrom for engaging vertebral bodies.

40. The guide sleeve assembly of claim 35, wherein said guide sleeve housing includes a proximal portion having a first width transverse to the spinal column axis and said distal portion having a second width transverse to the spinal column axis, said first width greater than said second width.

41. The guide sleeve assembly of claim 40, wherein said guide sleeve housing defines a lip therearound between said proximal portion and said distal portion.

42. The guide sleeve assembly of claim 35, wherein said first working channel and said second working channel are each formed by respective ones of a first sleeve and a second sleeve.

43. The guide sleeve assembly of claim 35, wherein said guide sleeve housing includes a pair of lateral flanges extending distally therefrom on opposite lateral sides of said guide sleeve housing.

44. The guide sleeve assembly of claim 43, wherein each of said lateral flanges has a non-distracting height between upper and lower surfaces thereof.

45. The guide sleeve assembly of claim 35, wherein said central distracting member include an upper distracting surface and a lower distracting surface, each of said distracting surfaces including teeth formed thereacross.

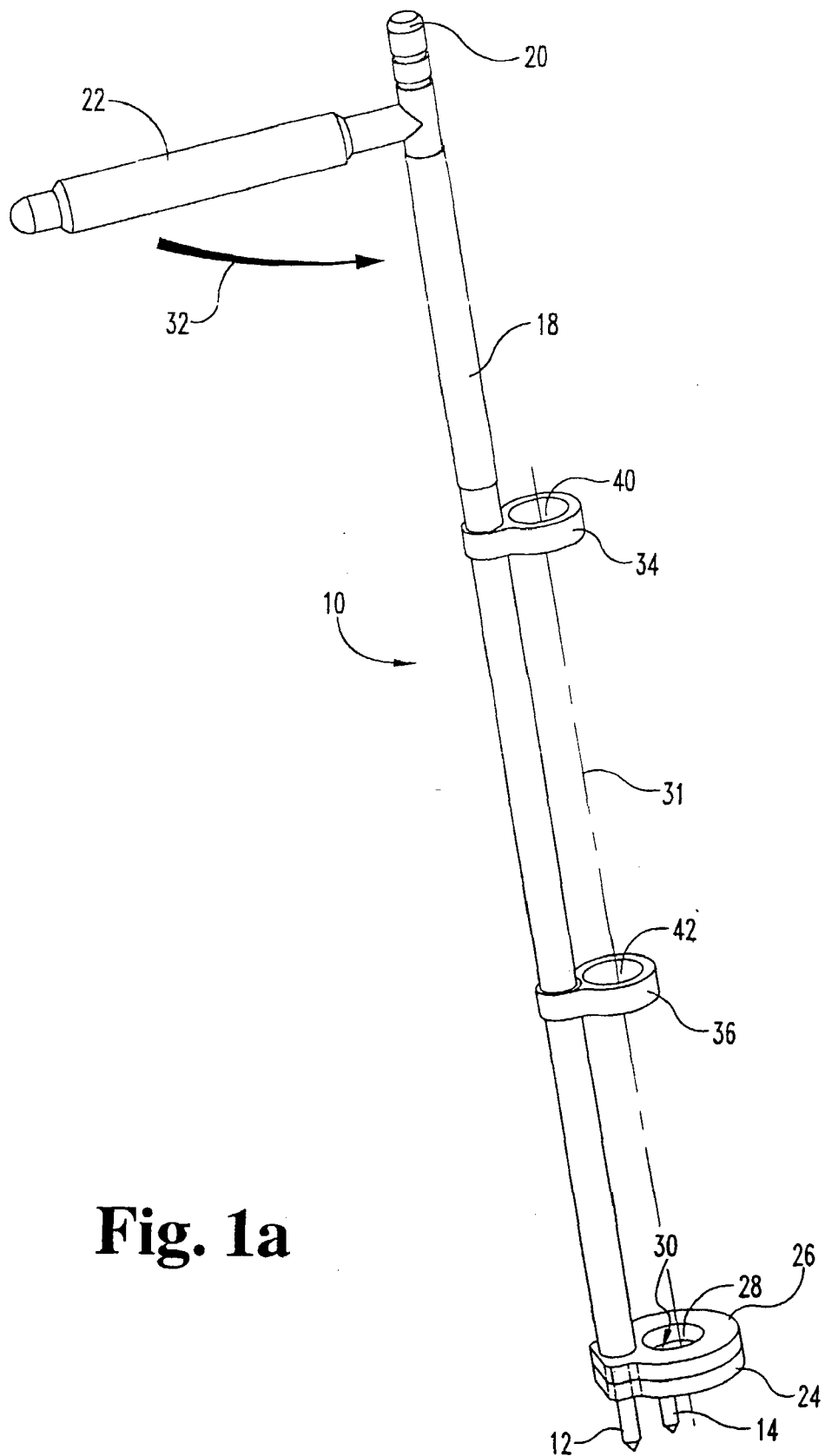
46. The guide sleeve assembly of claim 45, wherein:
said guide sleeve has a first length extending proximally from said guide sleeve housing when engaged thereto:
said guide sleeve housing has a second length extending proximally from the operative site; and
a ratio of said first length to said second length is more than about 2:1.

47. The guide sleeve assembly of claim 46, wherein said ratio is in the range of about 5:1 to about 10:1.

48. An instrument assembly according to claim 1, substantially as herein described and illustrated.

49. A guide assembly according to claim 15, or claim 35, substantially as herein described and illustrated.

50. A new instrument assembly, or a new guide assembly, substantially as herein described.



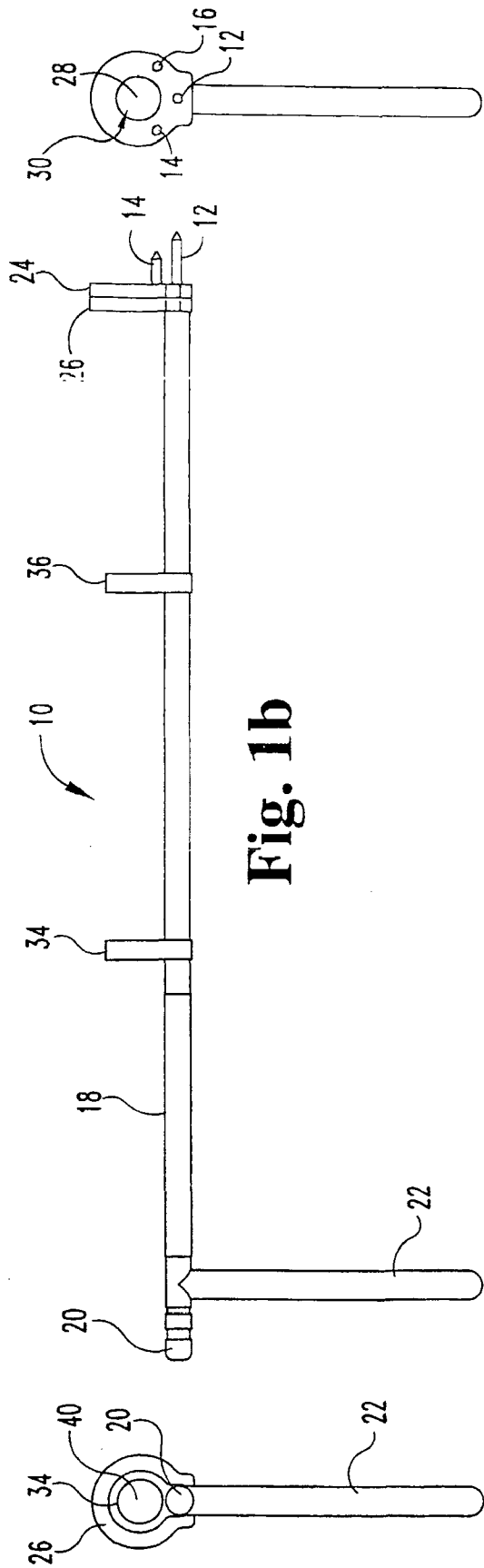
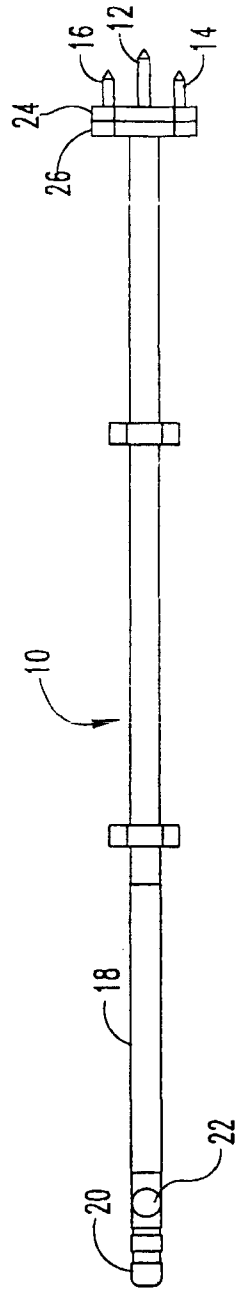
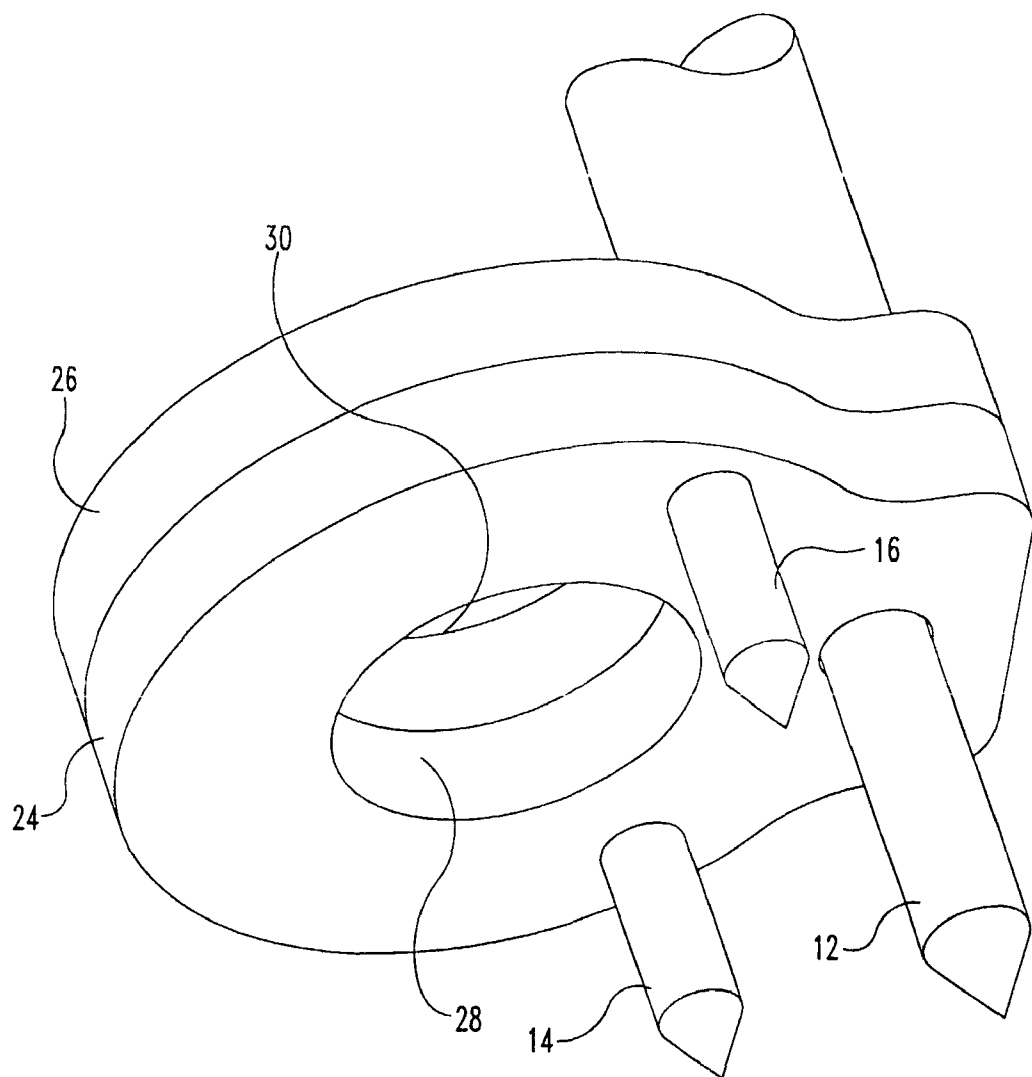


Fig. 1d

Fig. 1e



**Fig. 1f**

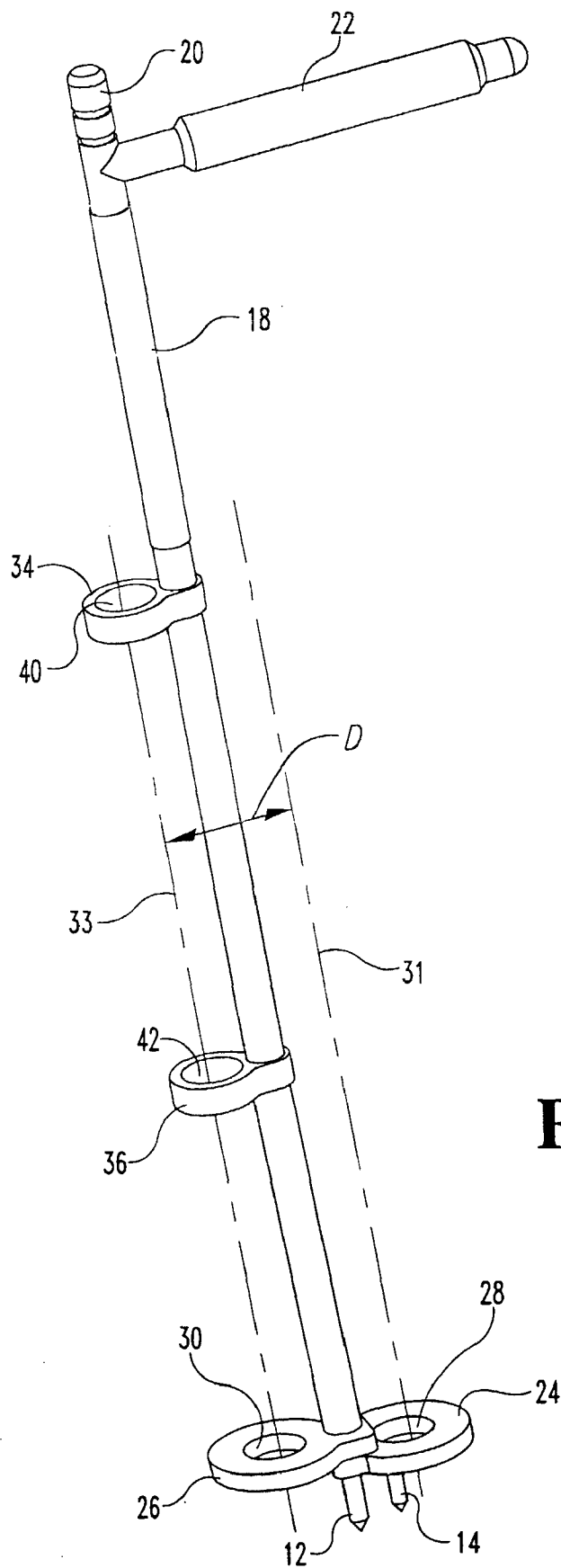


Fig. 2a

5/39

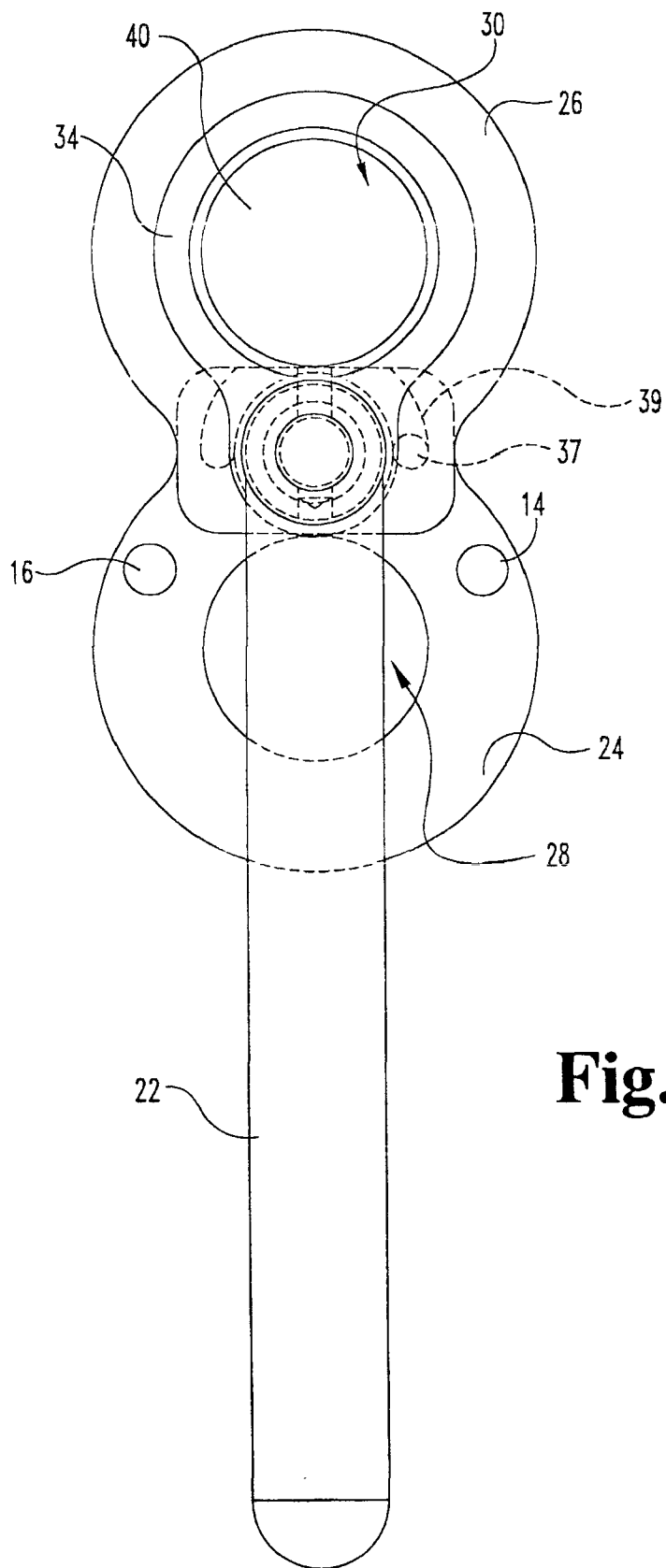
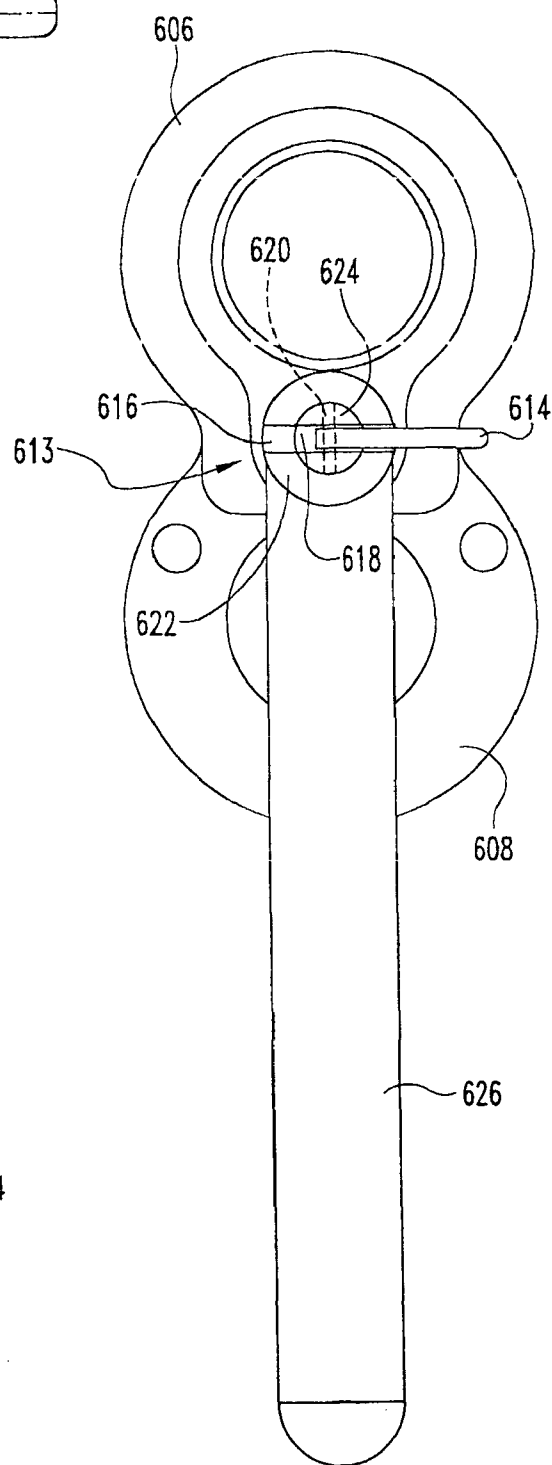
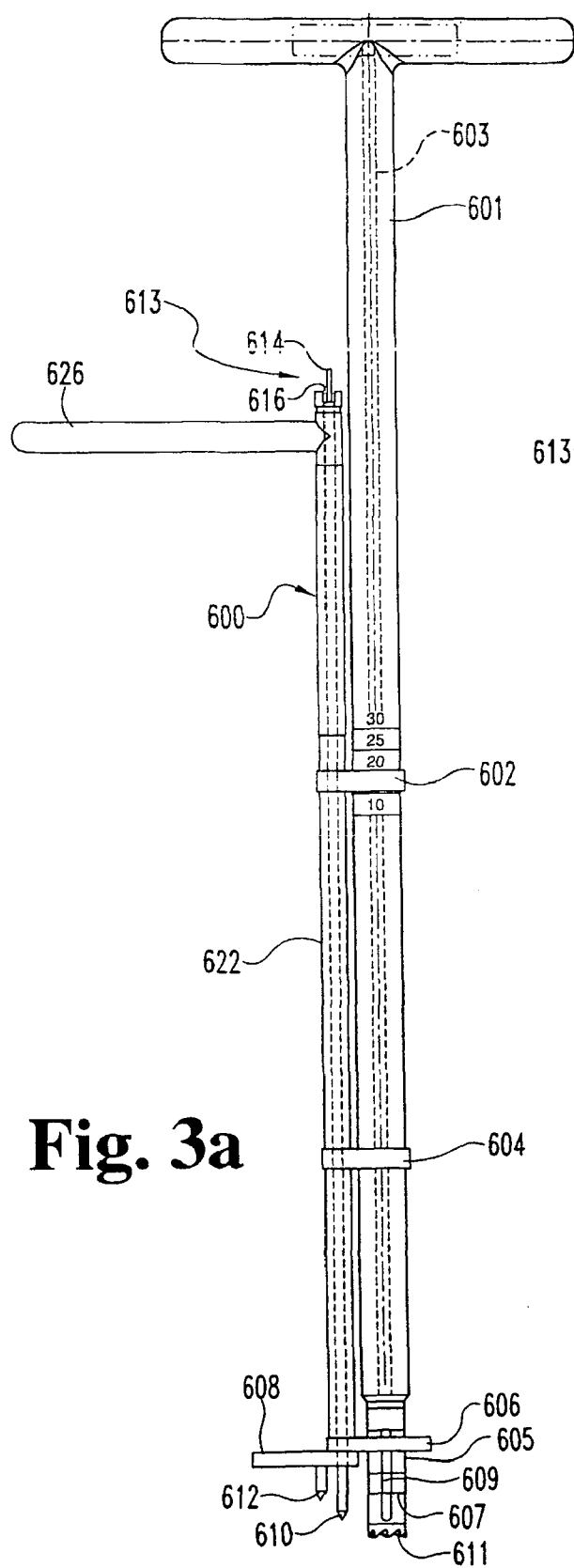


Fig. 2b



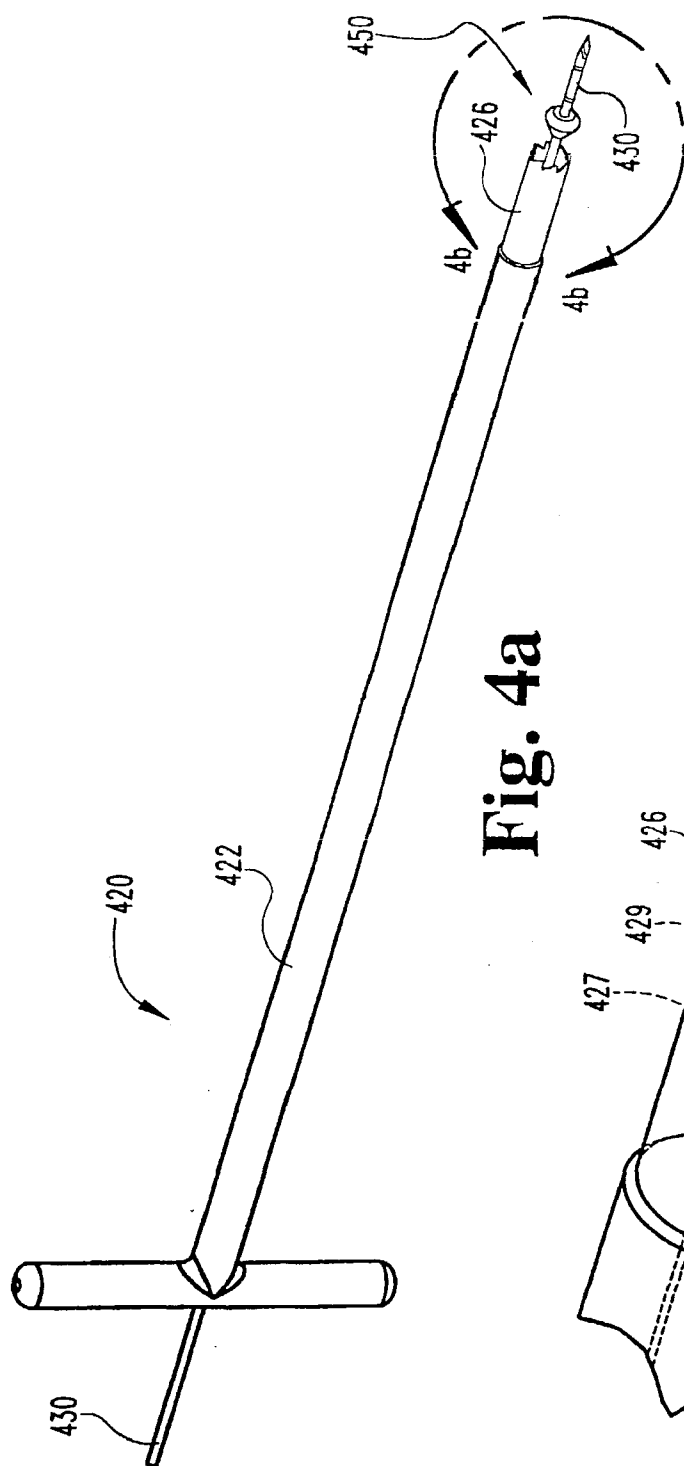


Fig. 4a

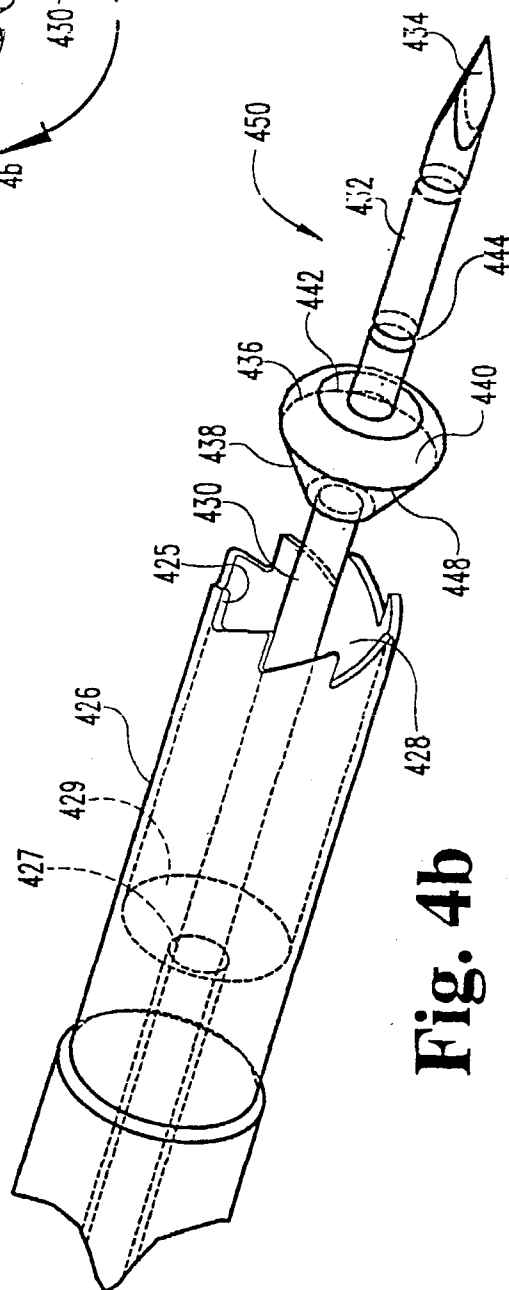


Fig. 4b

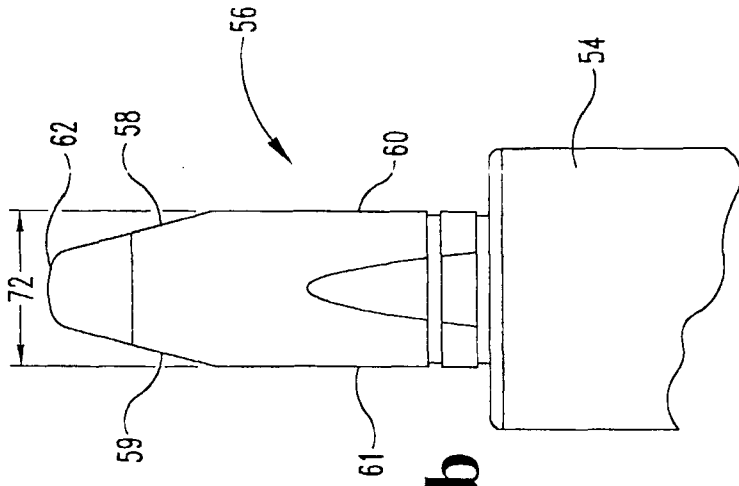


Fig. 5b

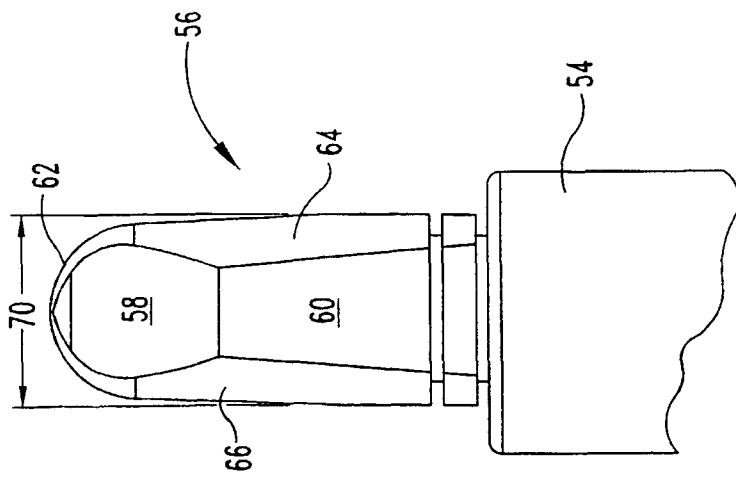


Fig. 5c

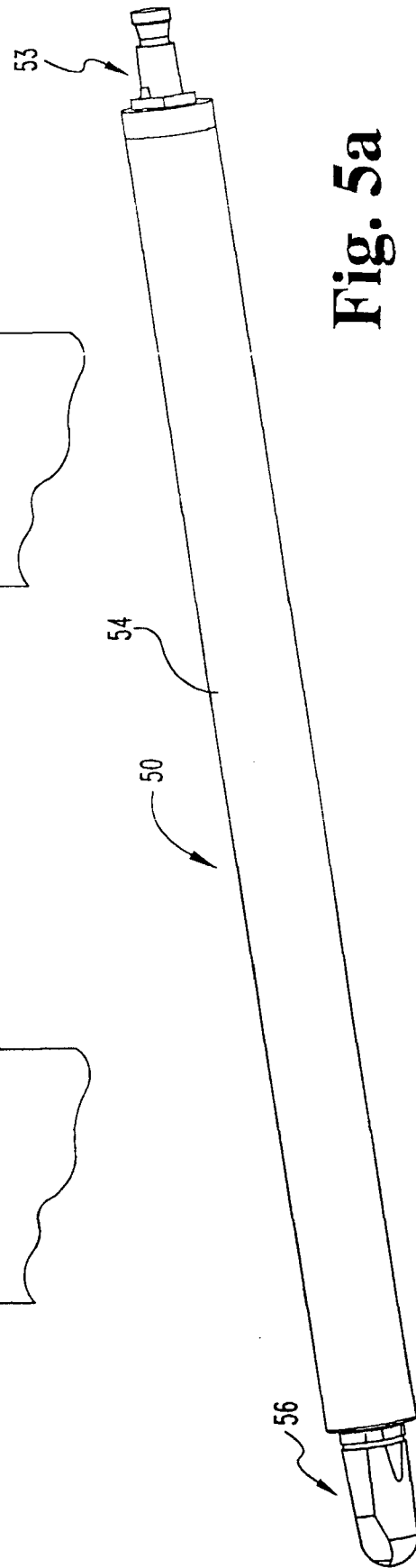
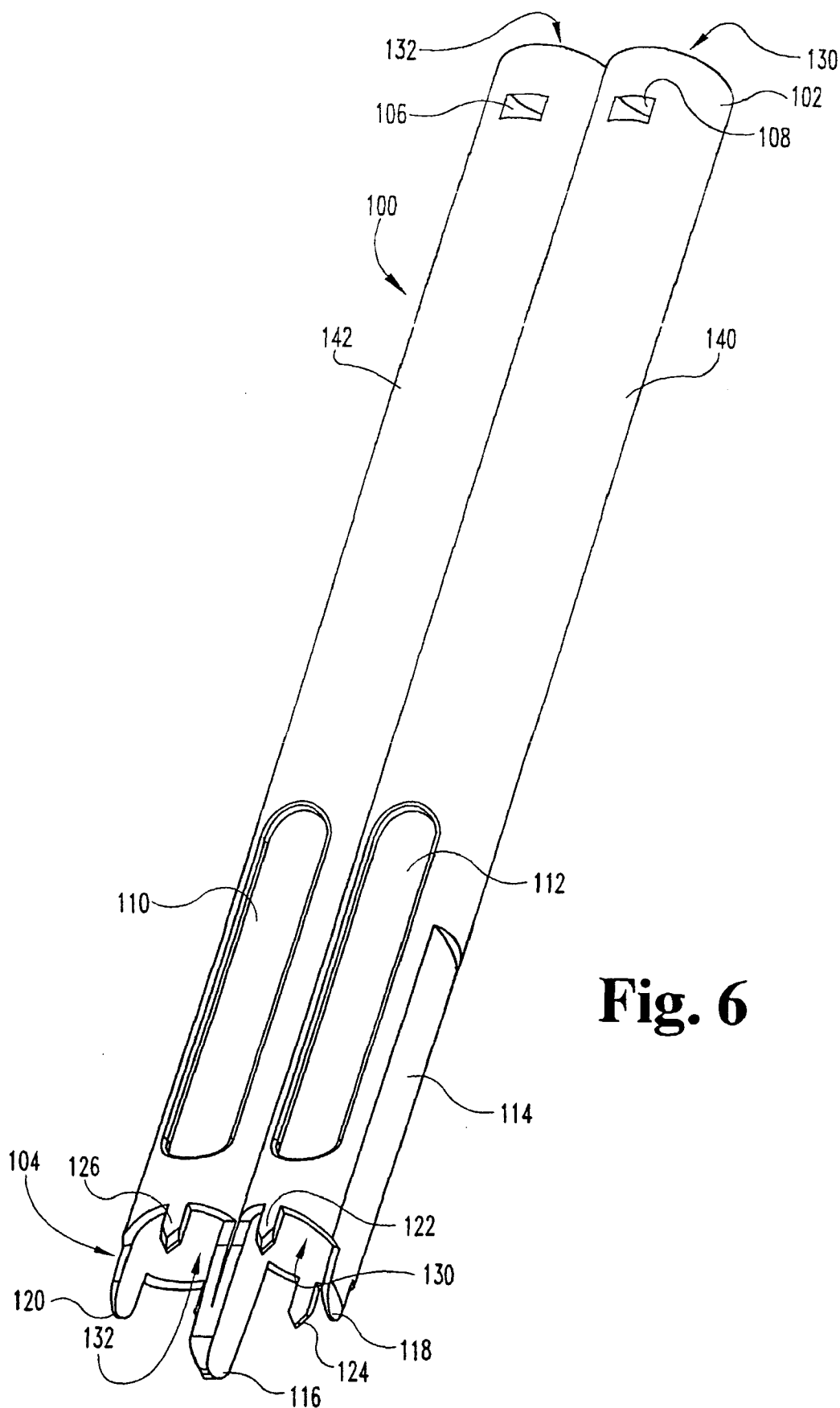


Fig. 5a



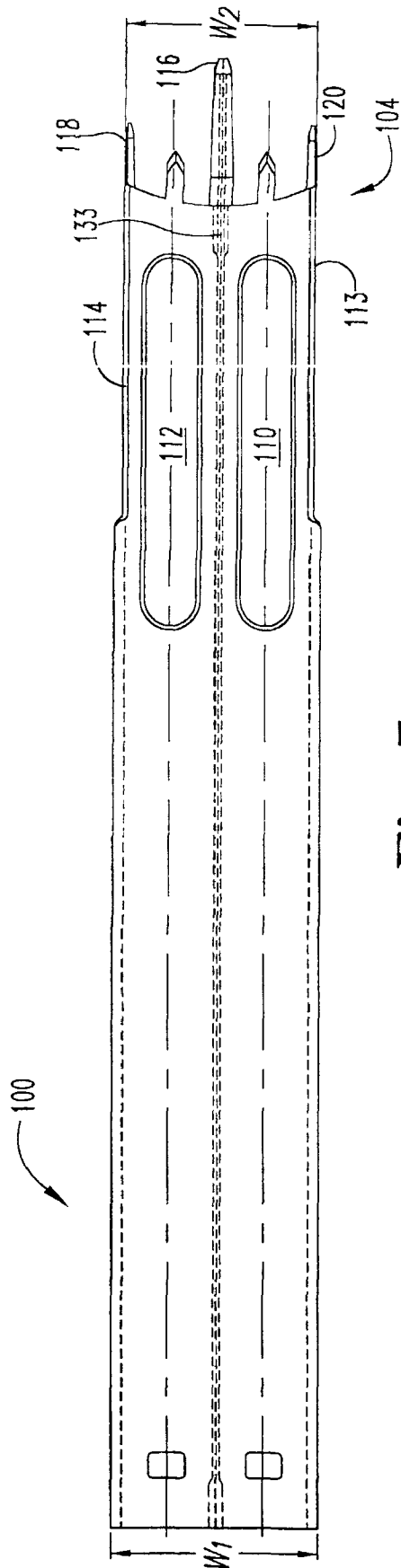


Fig. 7

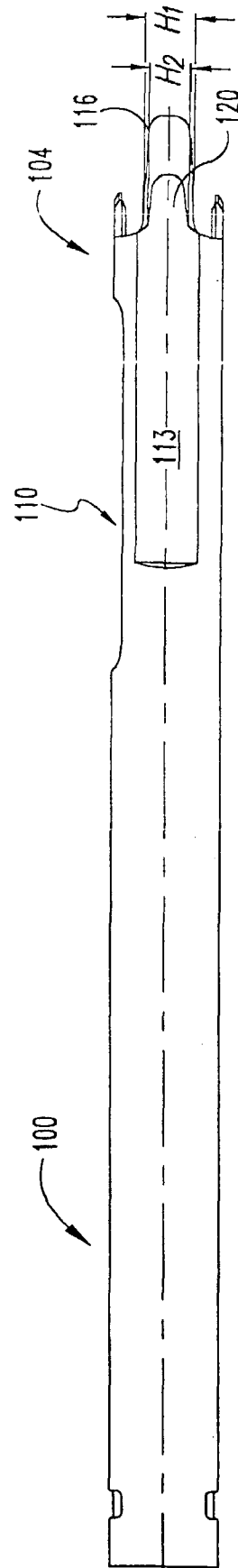


Fig. 8

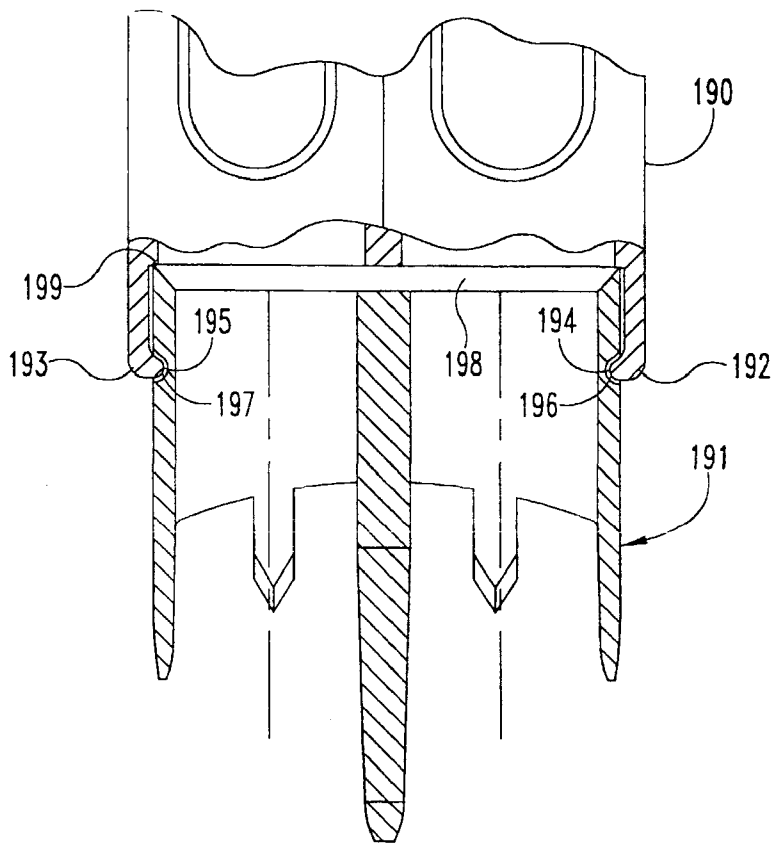
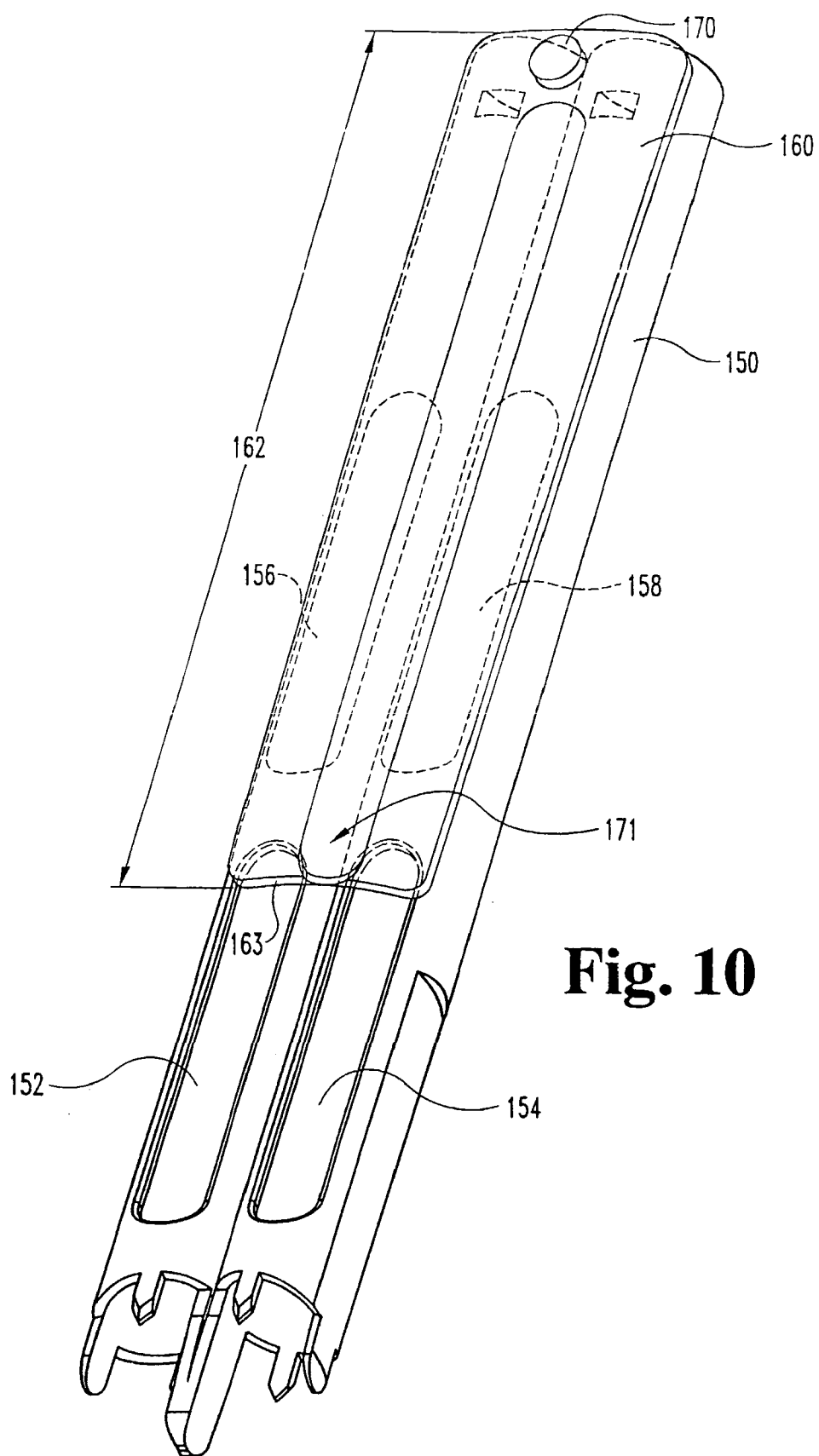


Fig. 9

**Fig. 10**

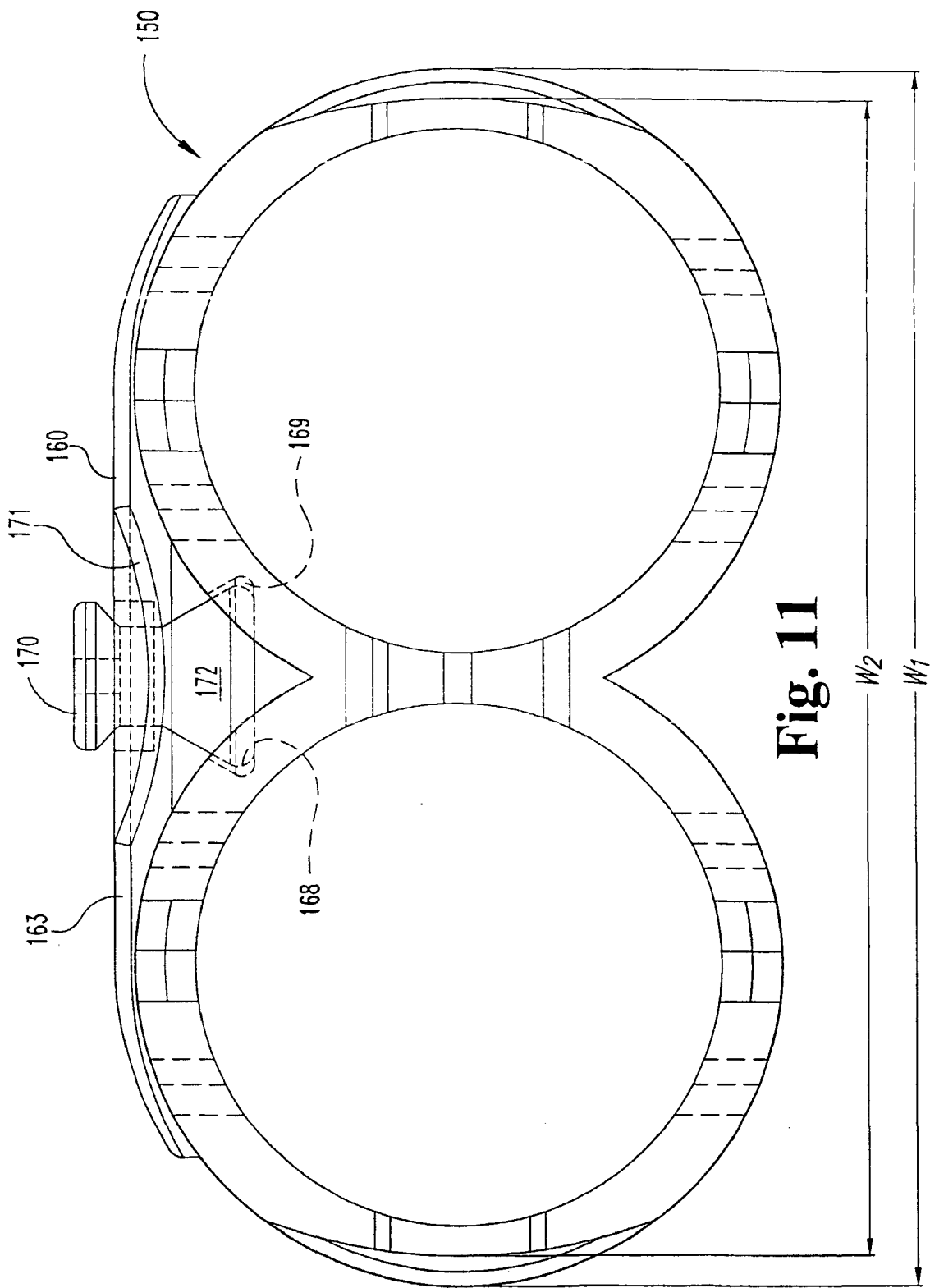


Fig. 11

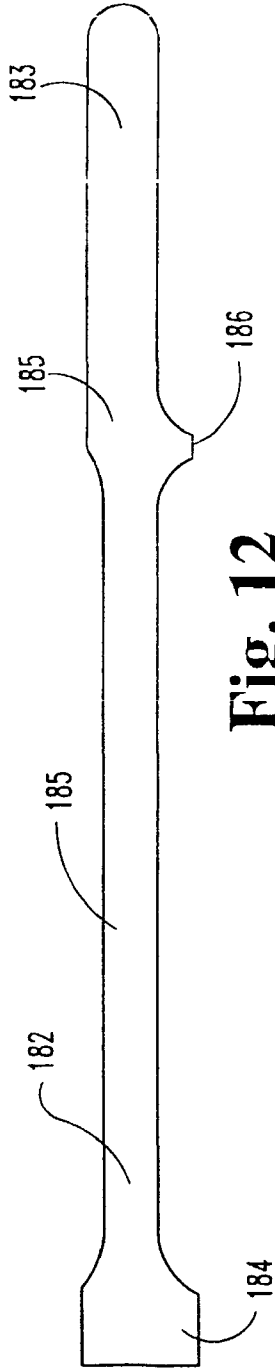


Fig. 12

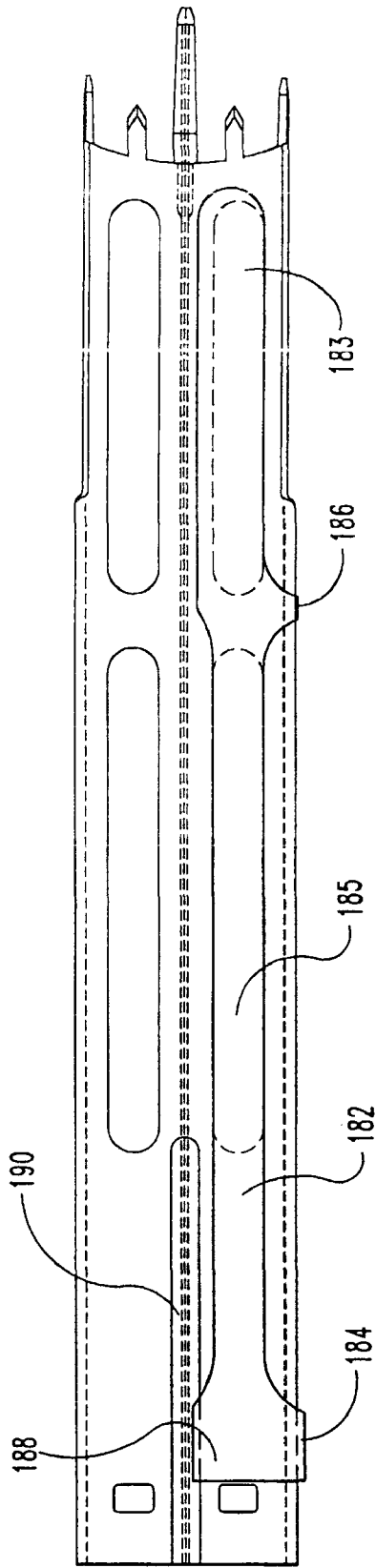
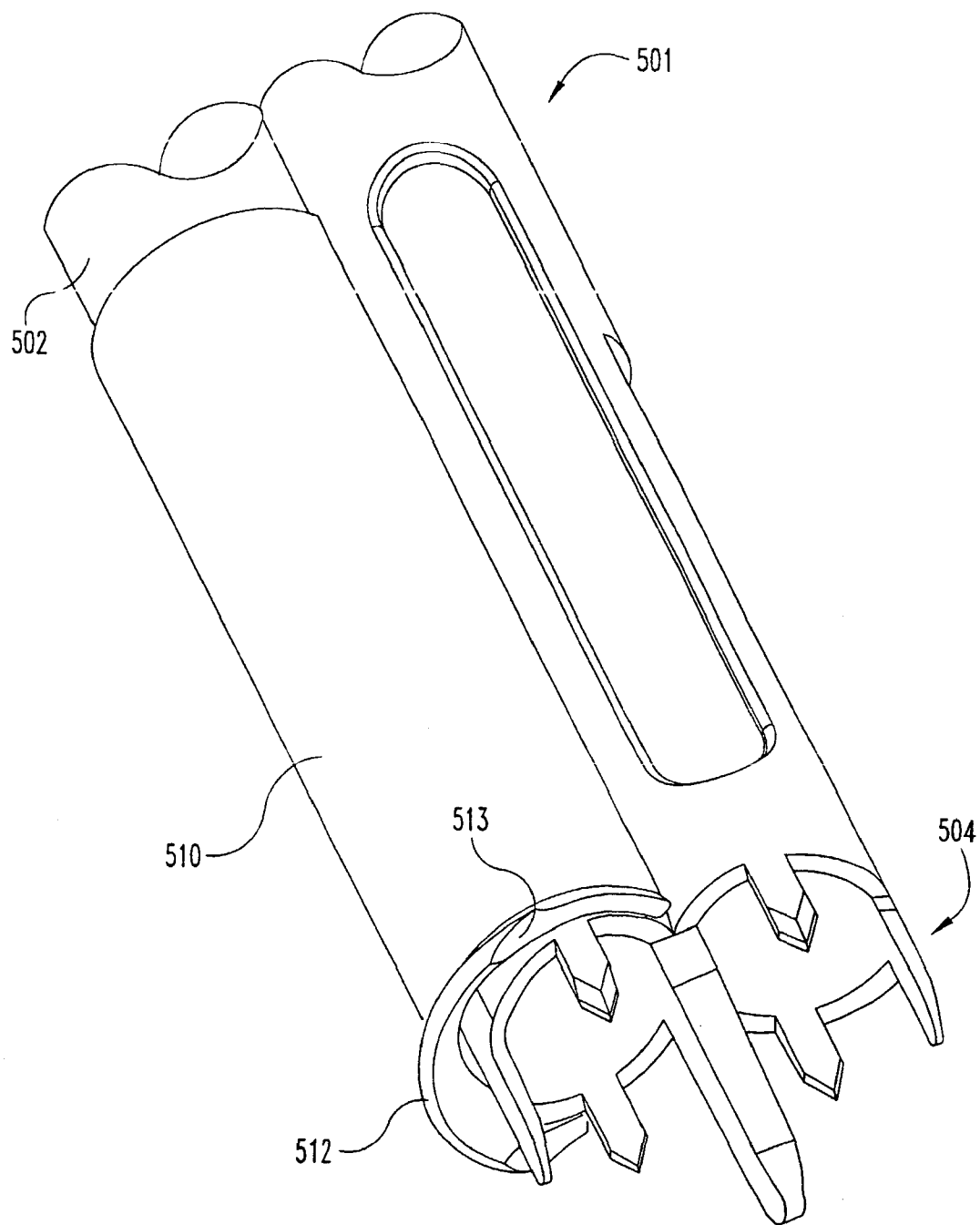


Fig. 13

**Fig. 14**

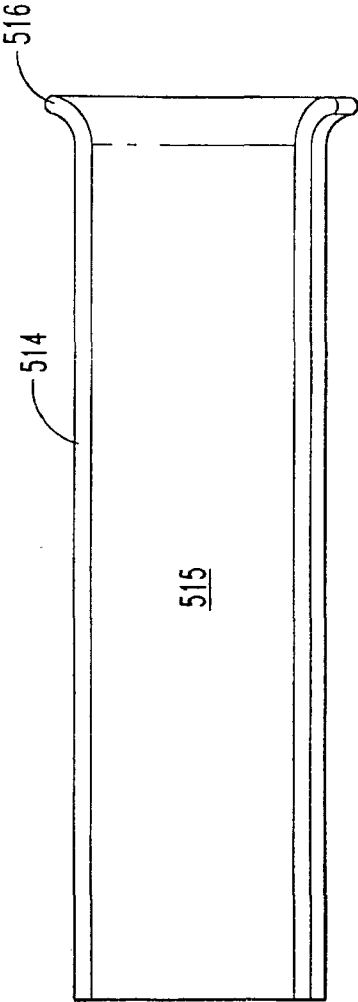


Fig. 15a

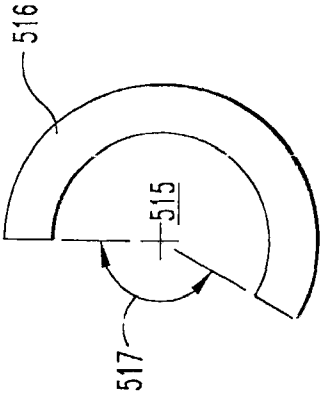


Fig. 15b

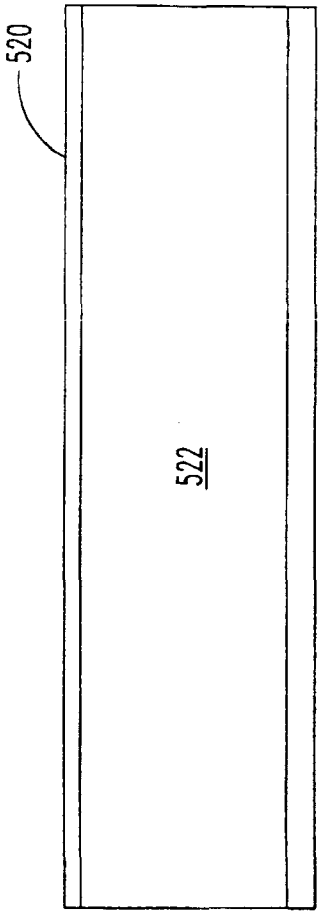


Fig. 16a

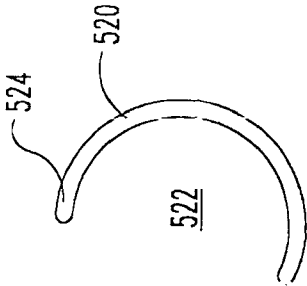
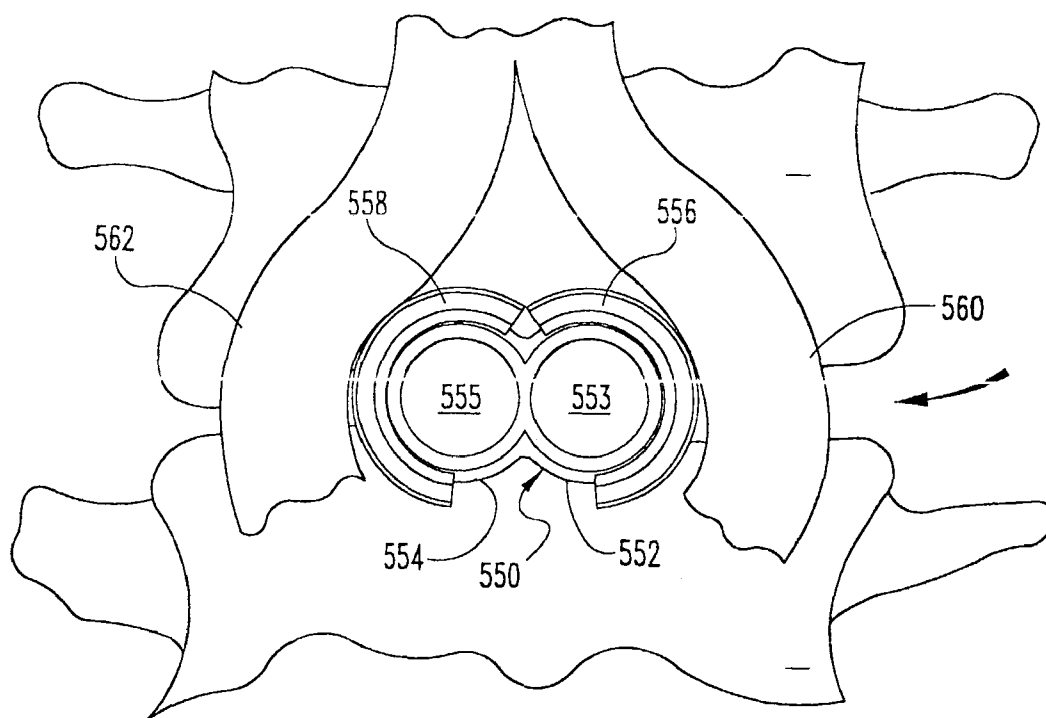
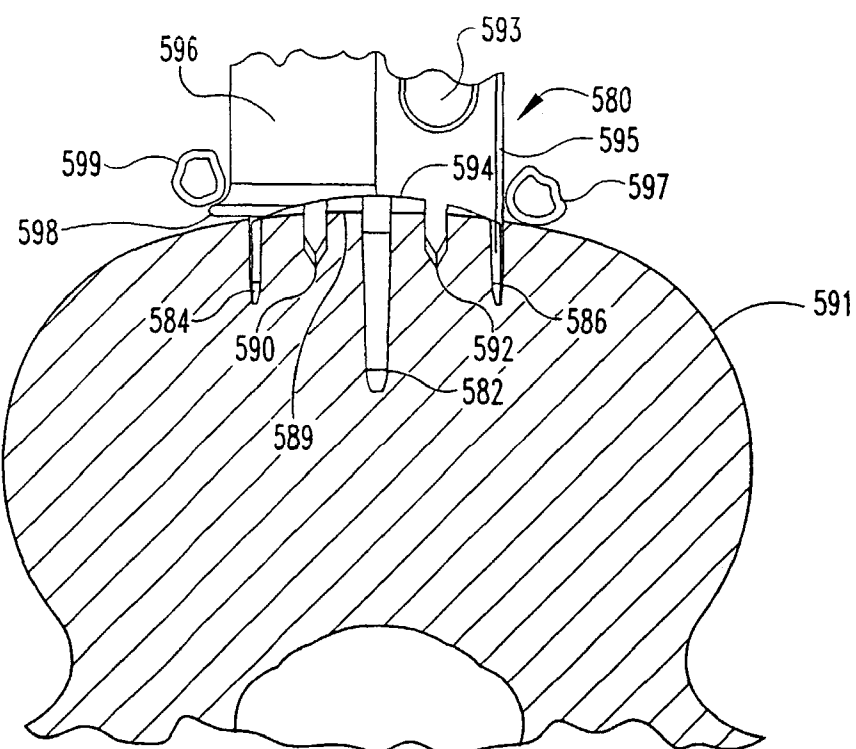


Fig. 16b

**Fig. 17****Fig. 18**

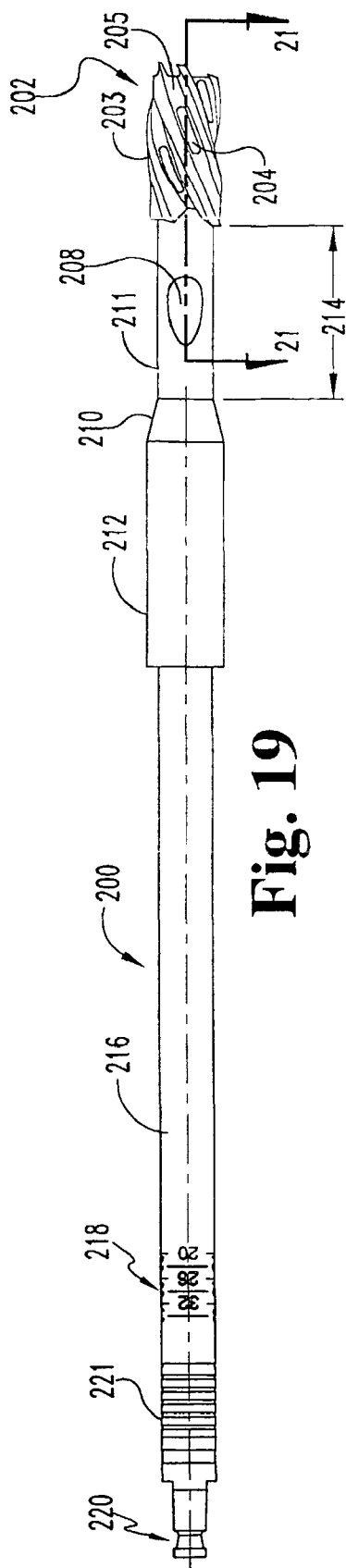


Fig. 19

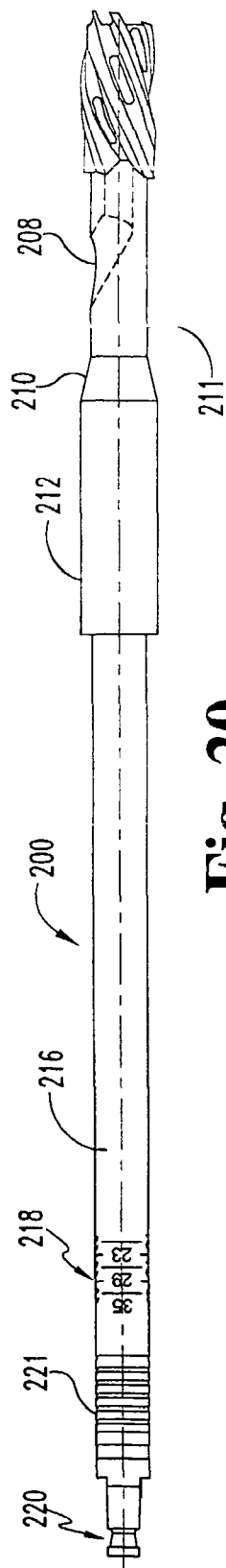


Fig. 20

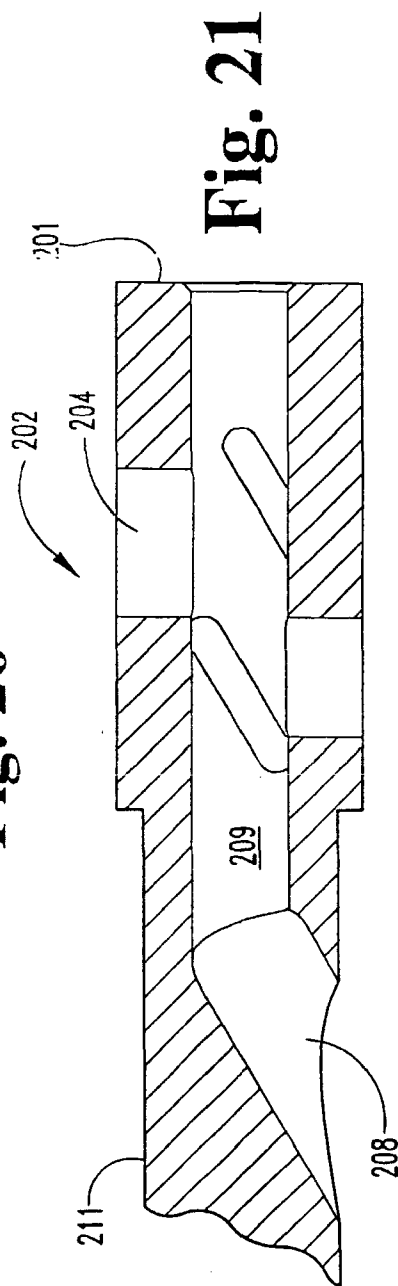


Fig. 21

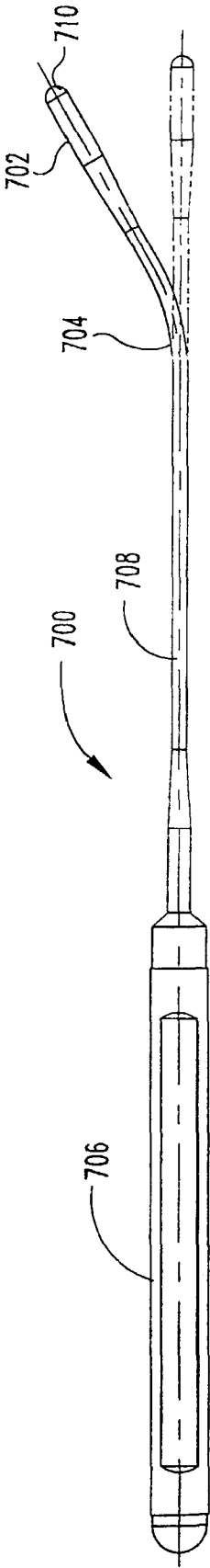


Fig. 22

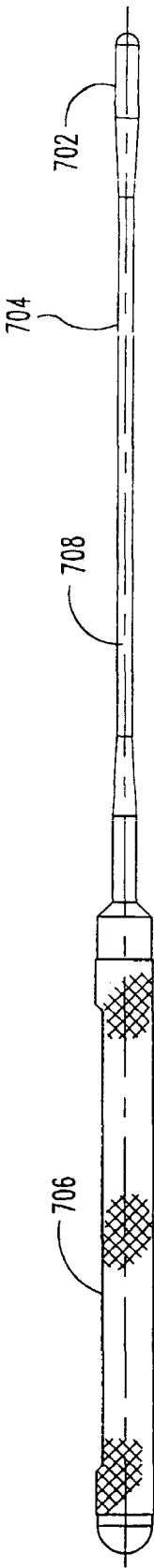


Fig. 23

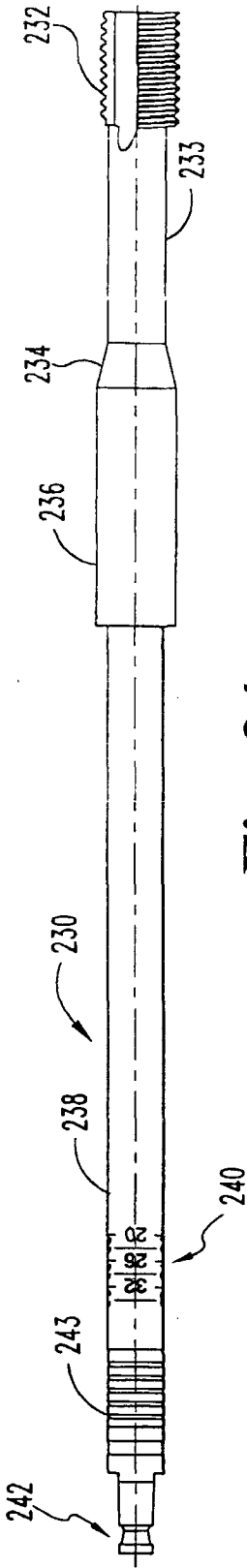


Fig. 24

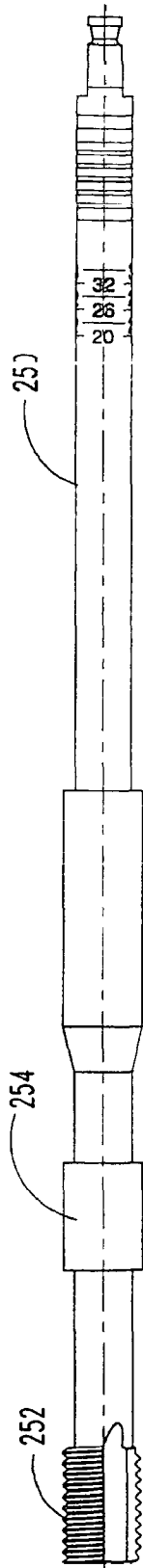


Fig. 25

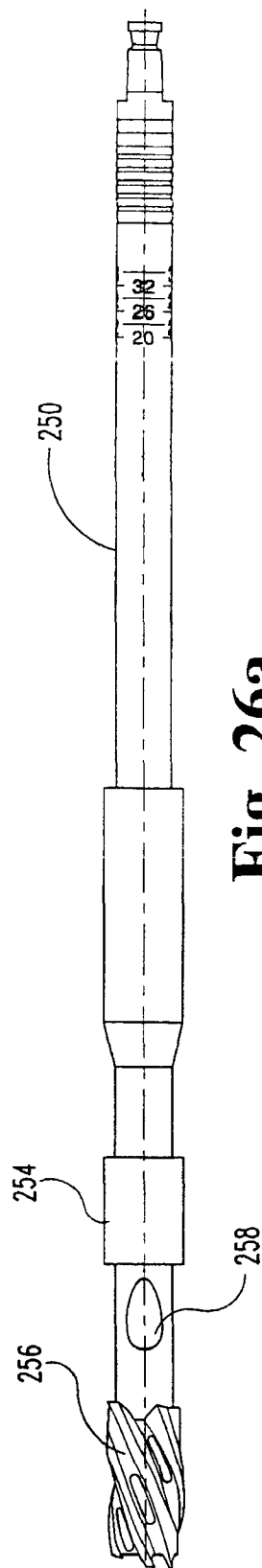


Fig. 26a

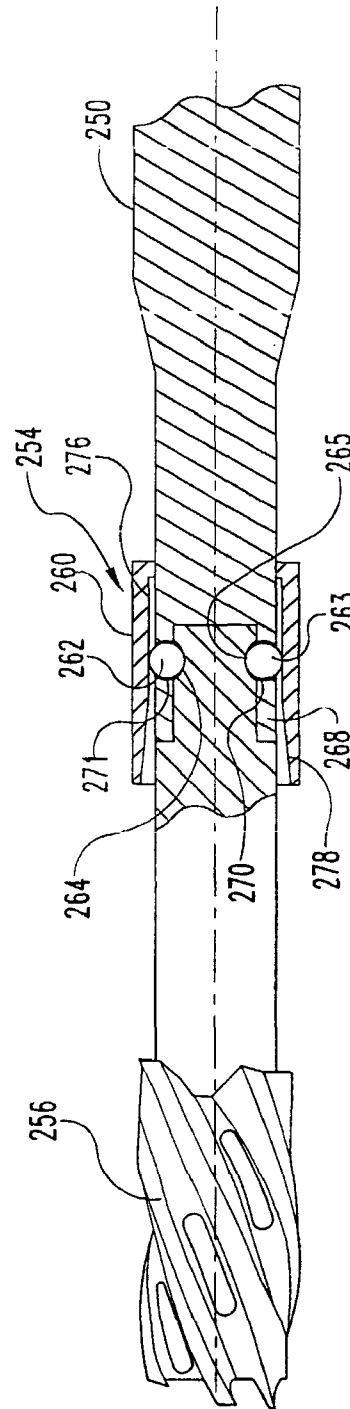
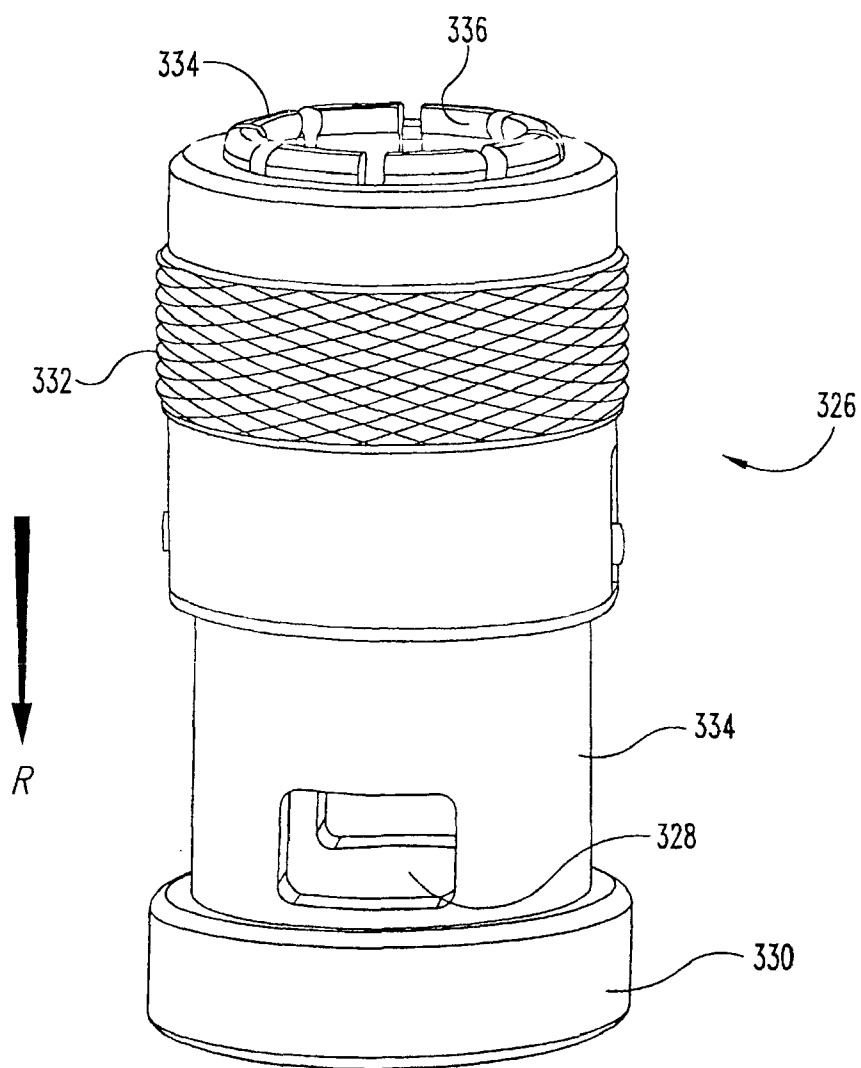


Fig. 26b

**Fig. 27**

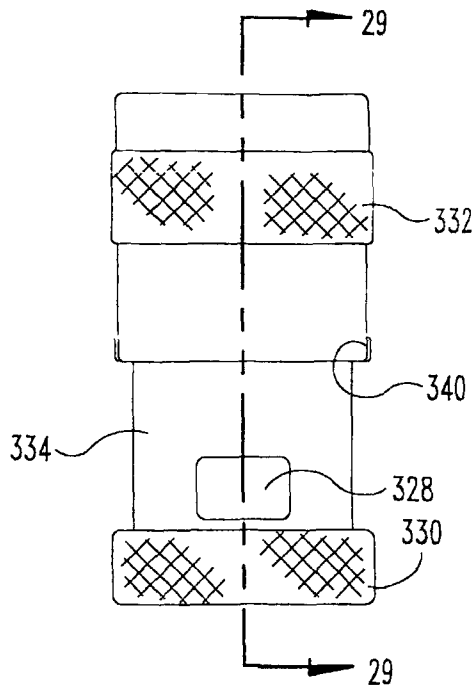


Fig. 28

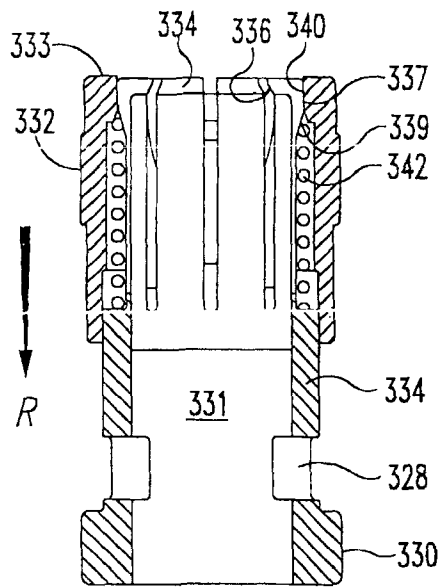


Fig. 29

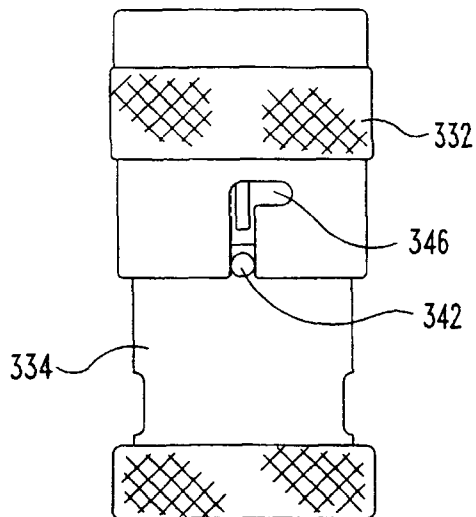


Fig. 31

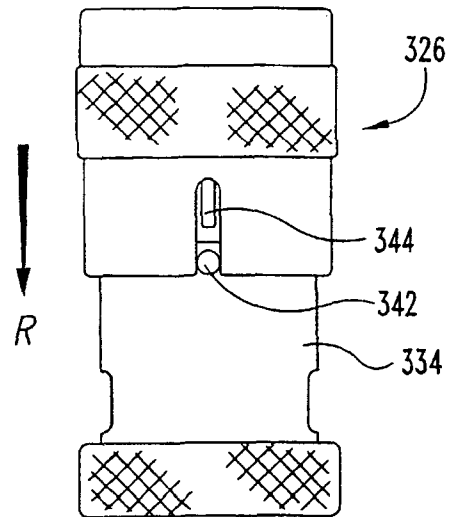


Fig. 30

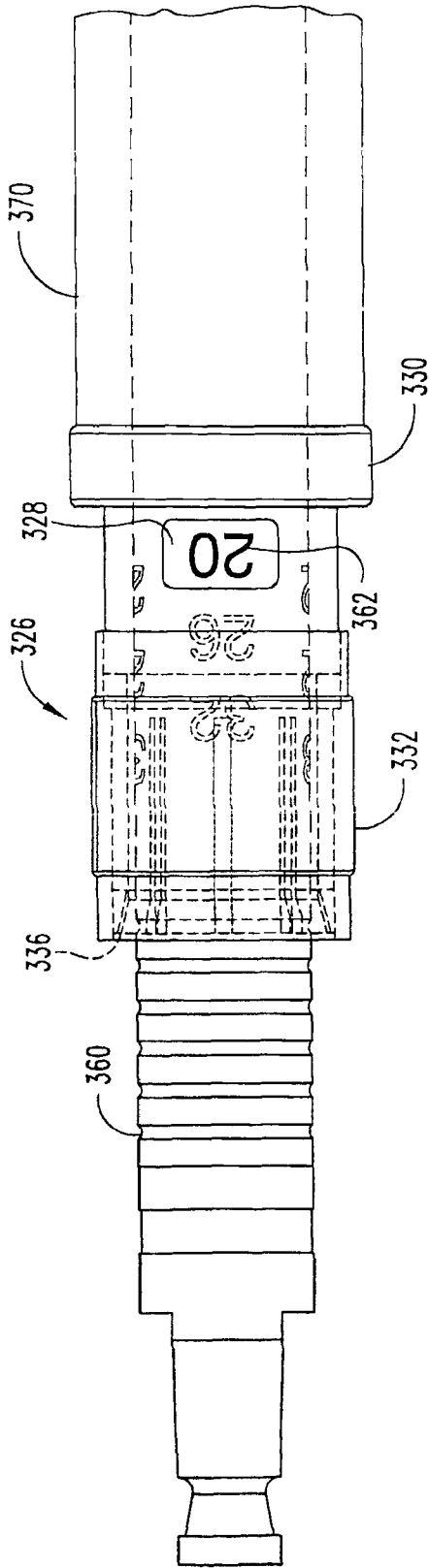


Fig. 32

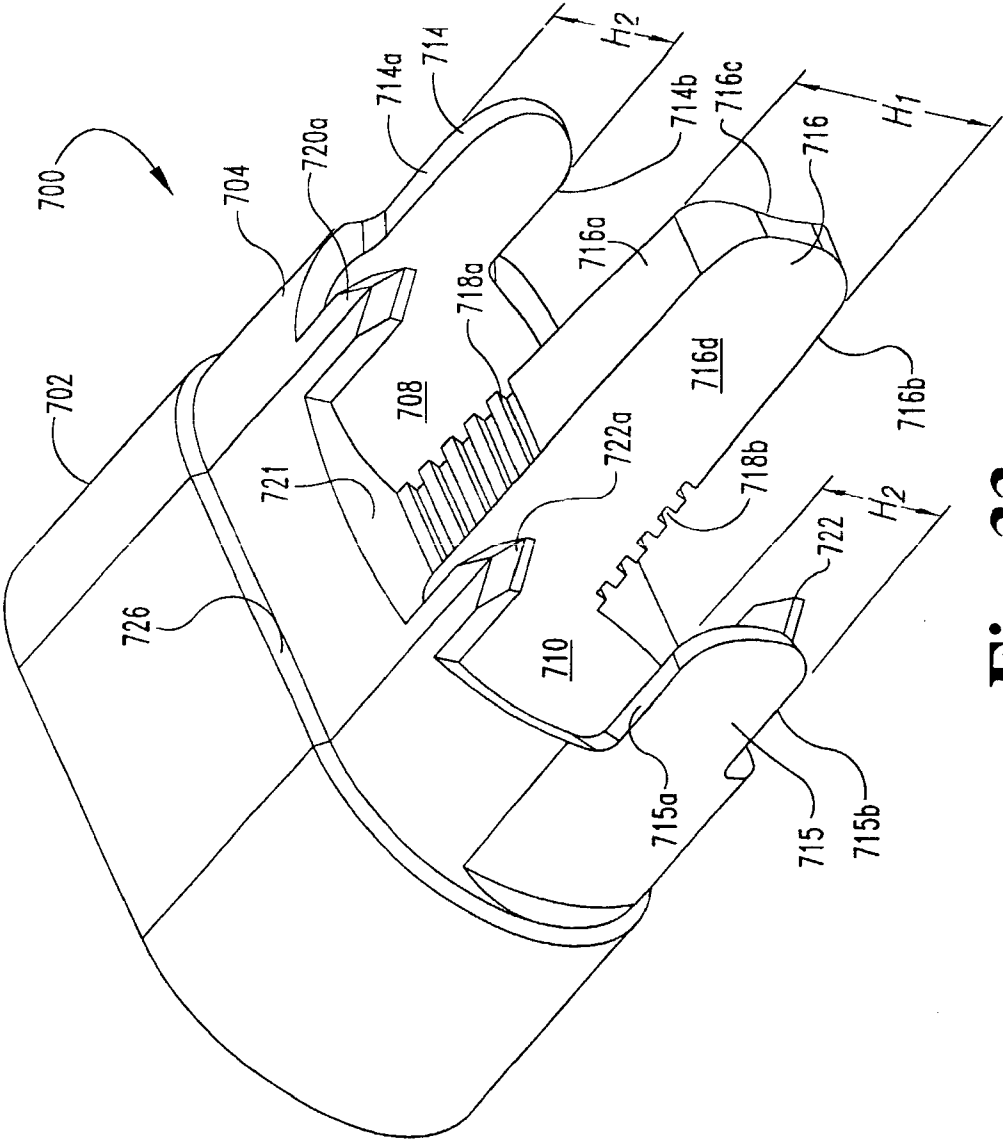


Fig. 33

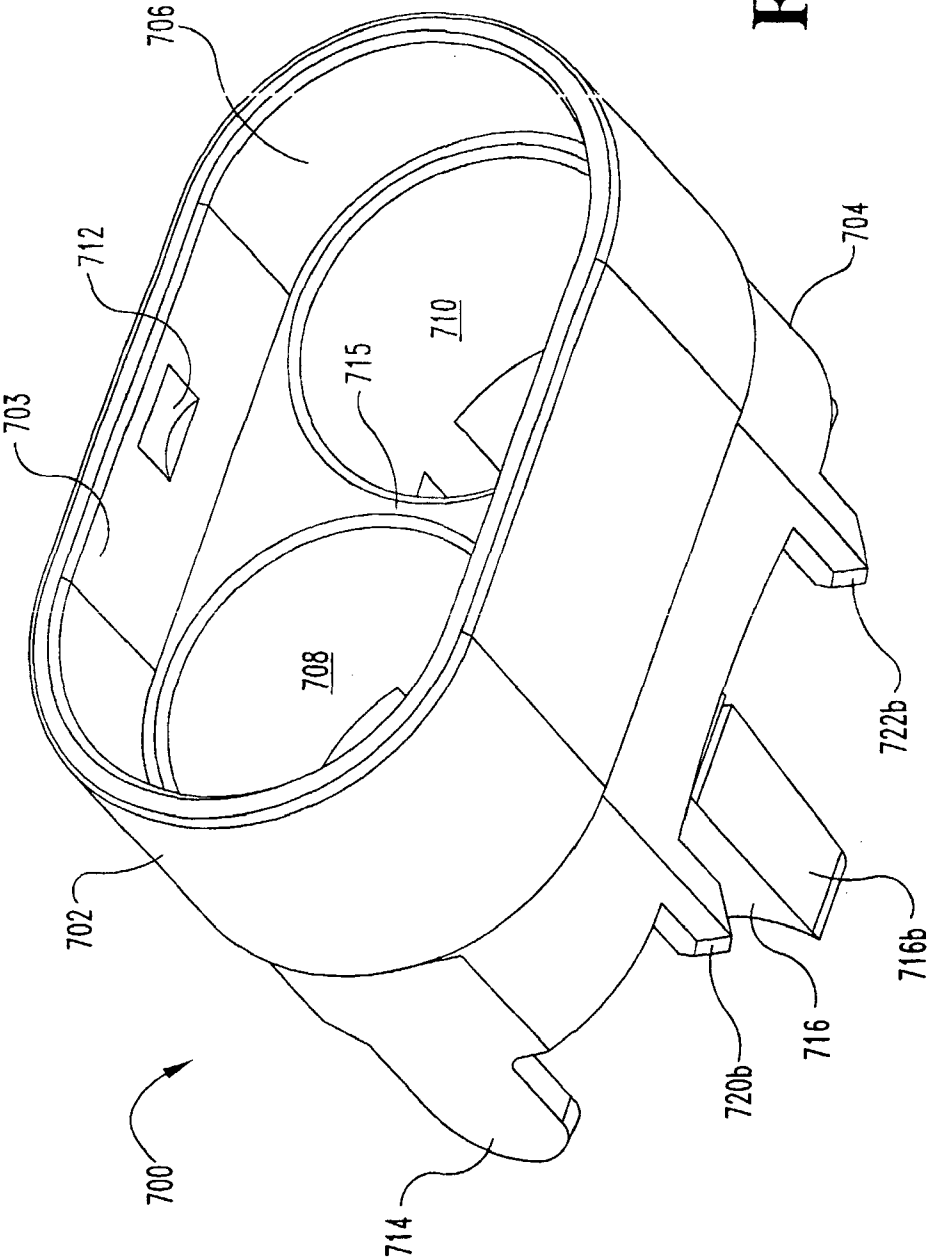


Fig. 34

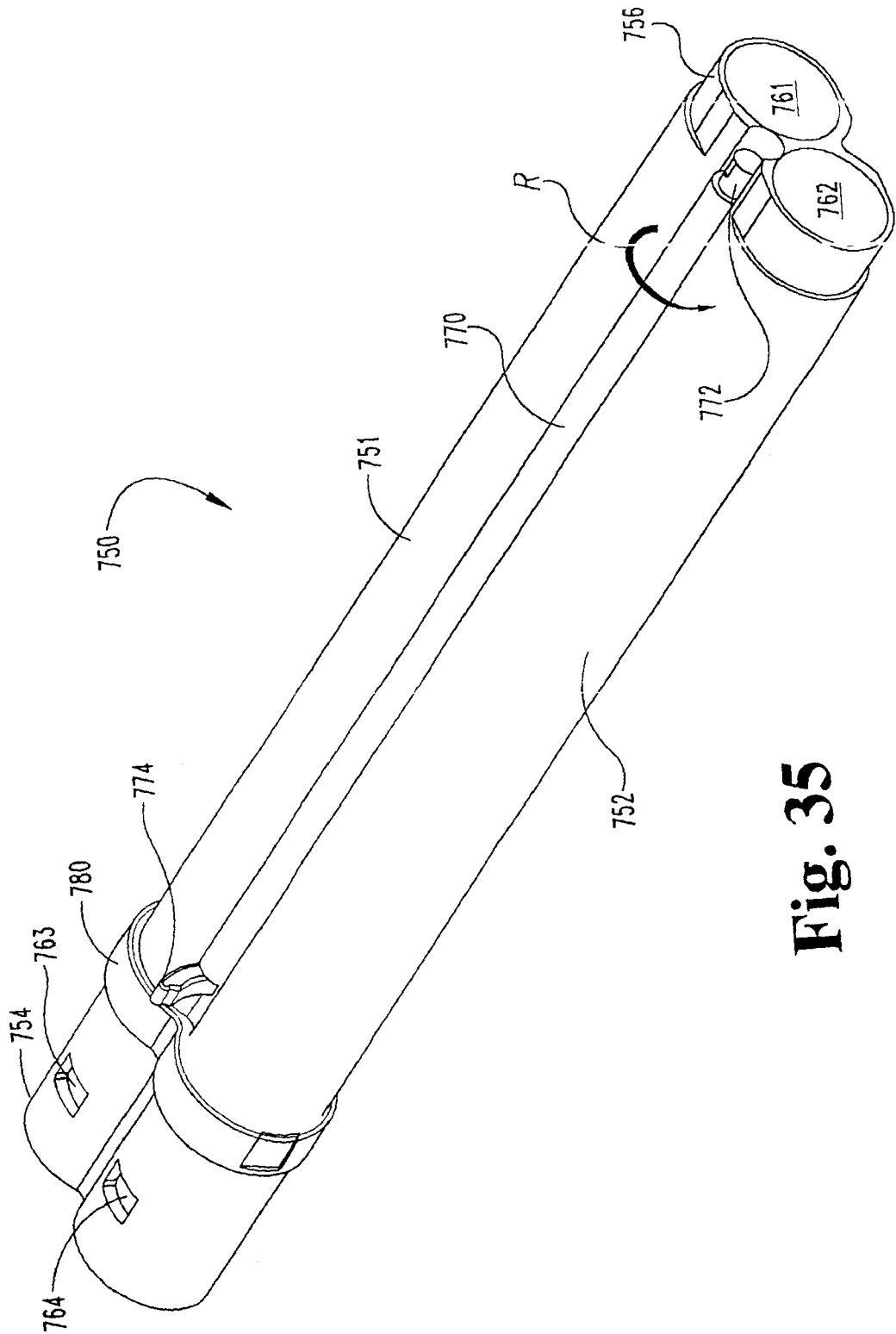
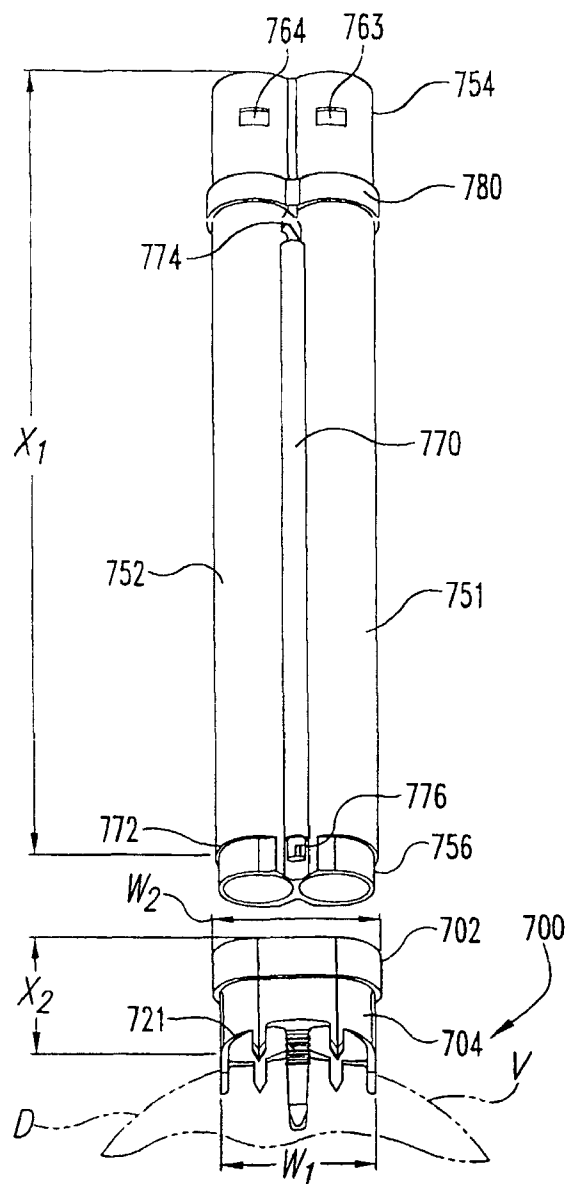


Fig. 35

**Fig. 36**

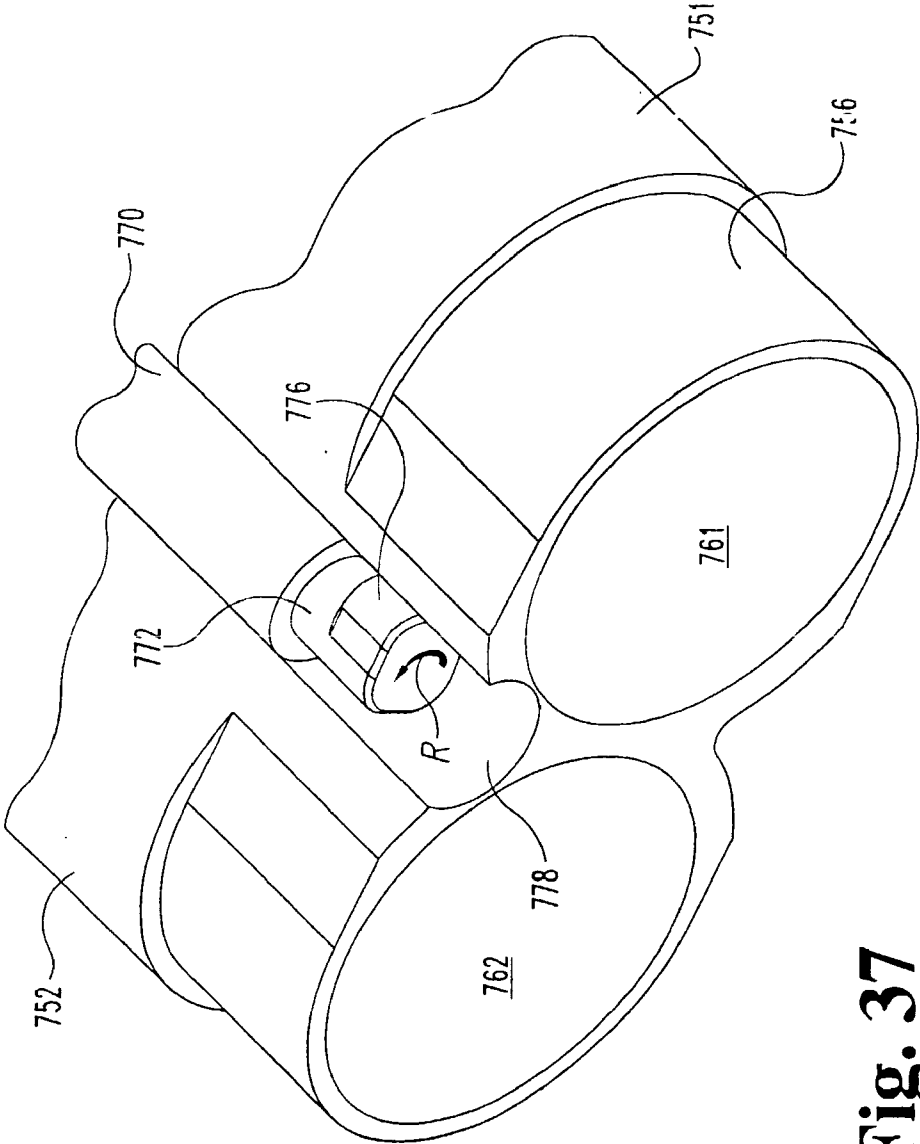


Fig. 37

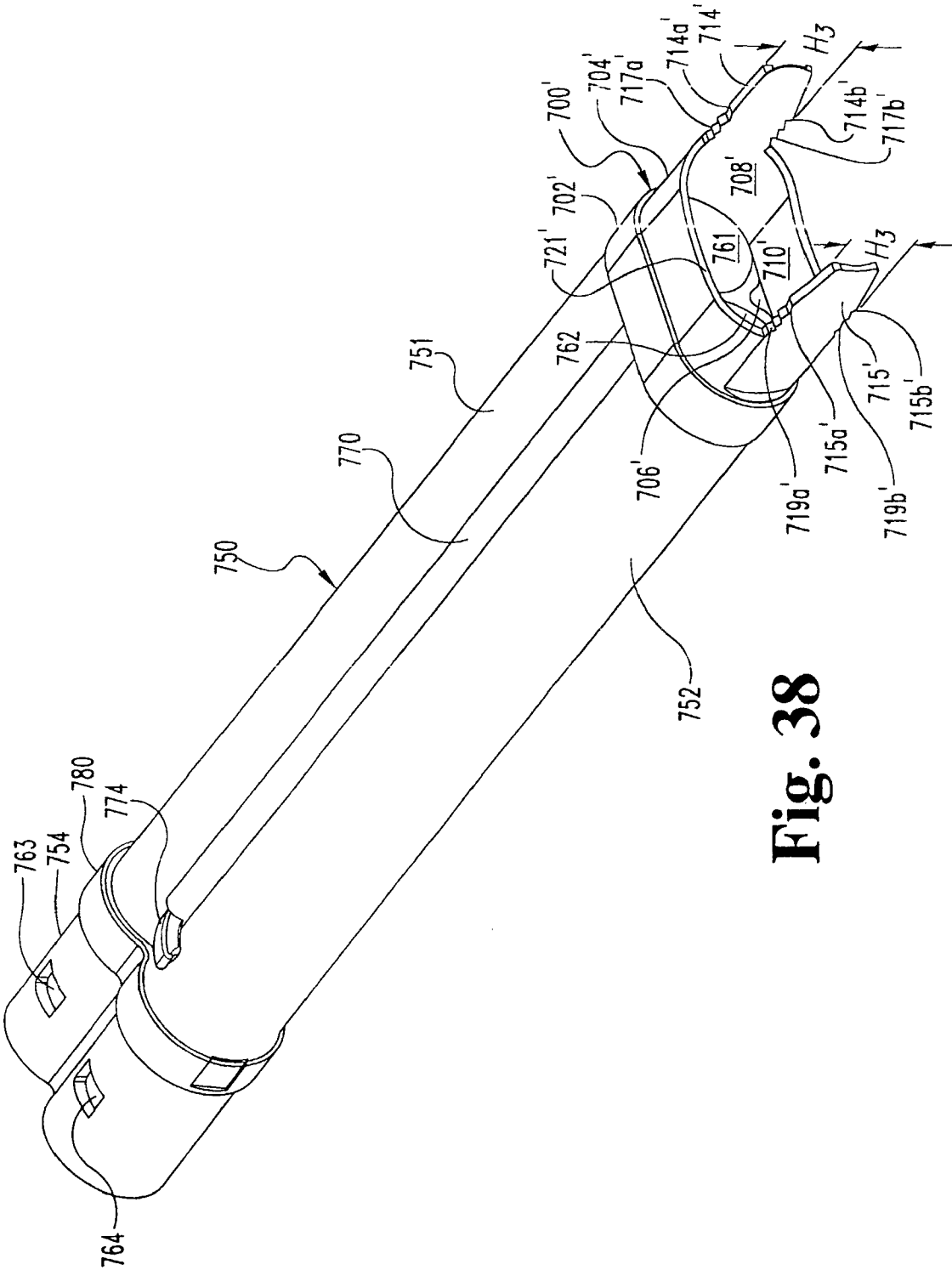


Fig. 38

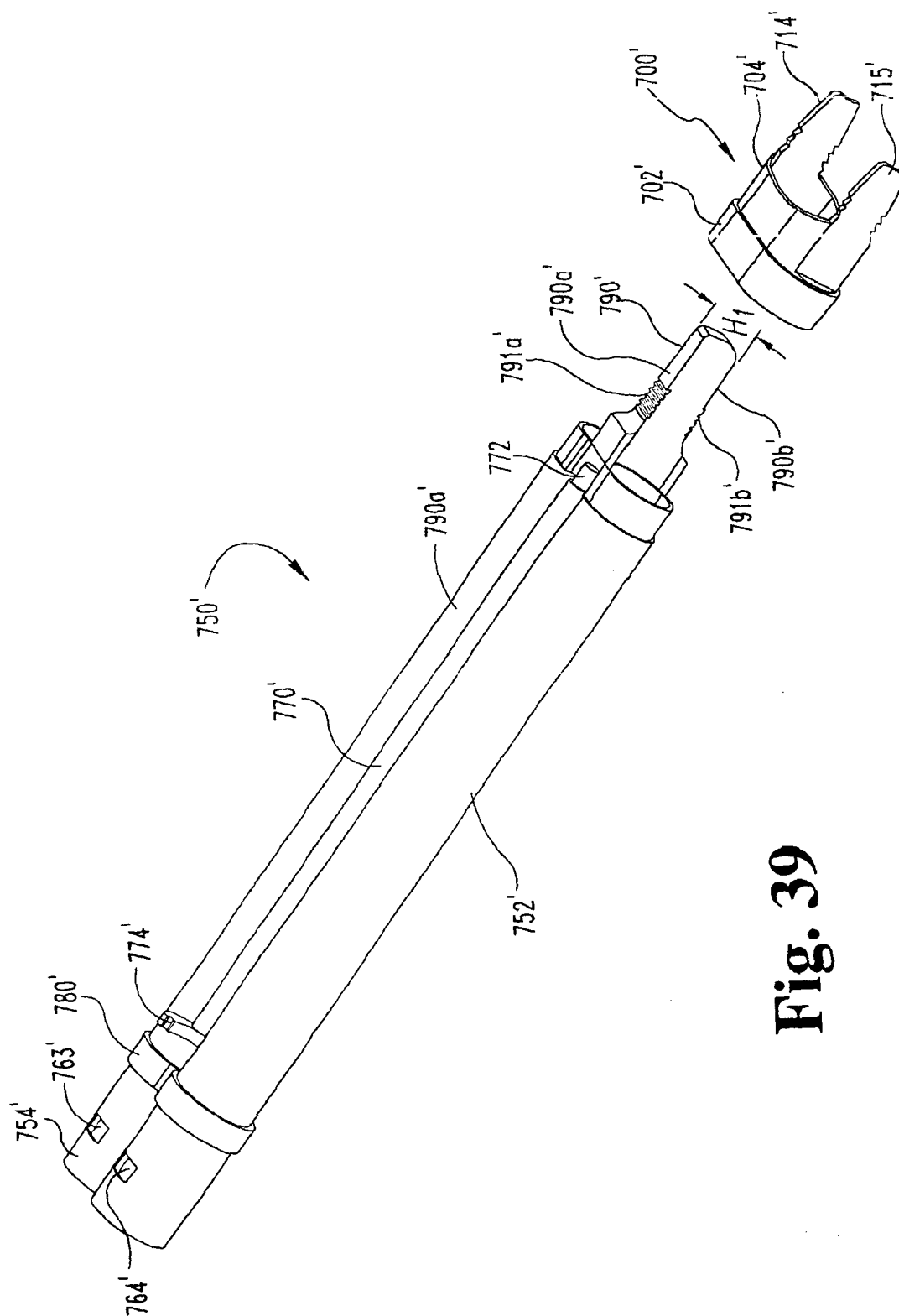


Fig. 39

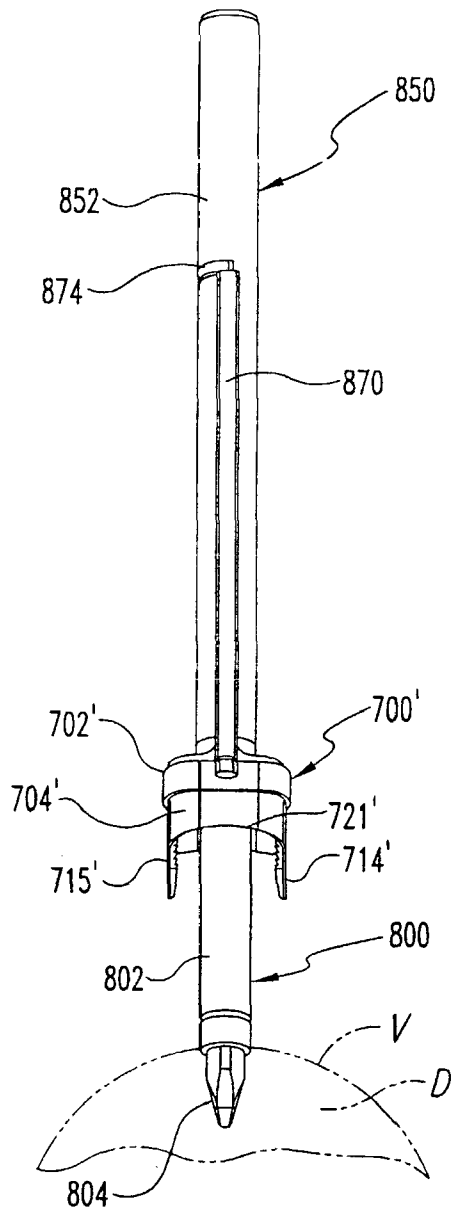


Fig. 40

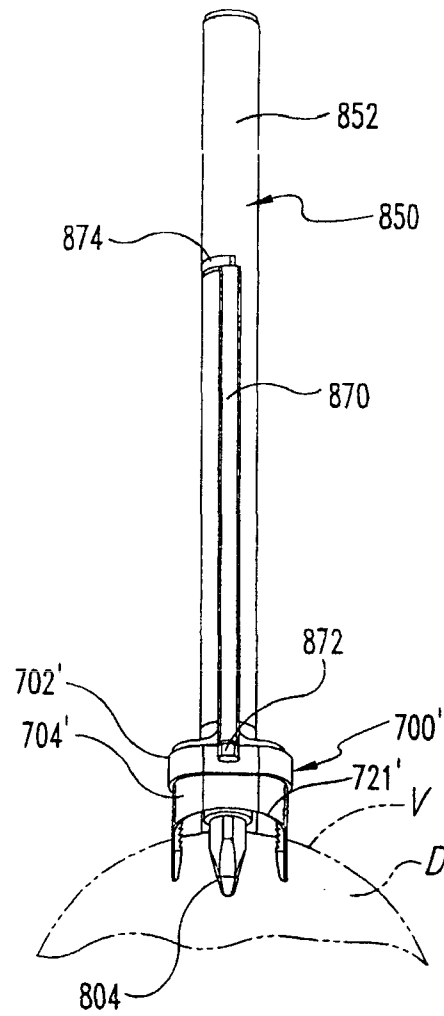


Fig. 41

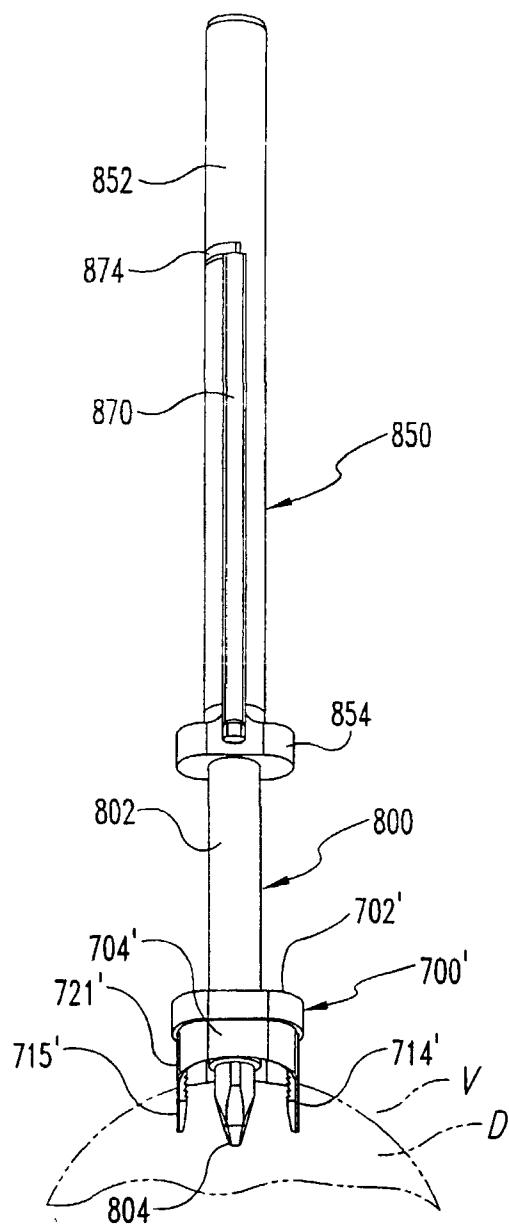


Fig. 42

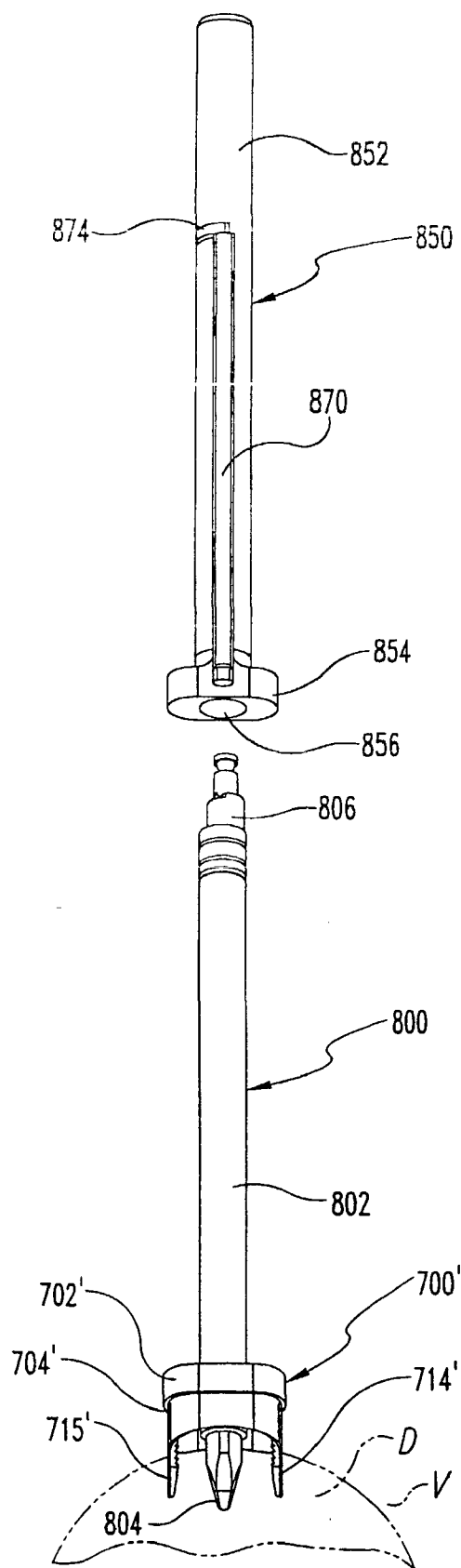


Fig. 43

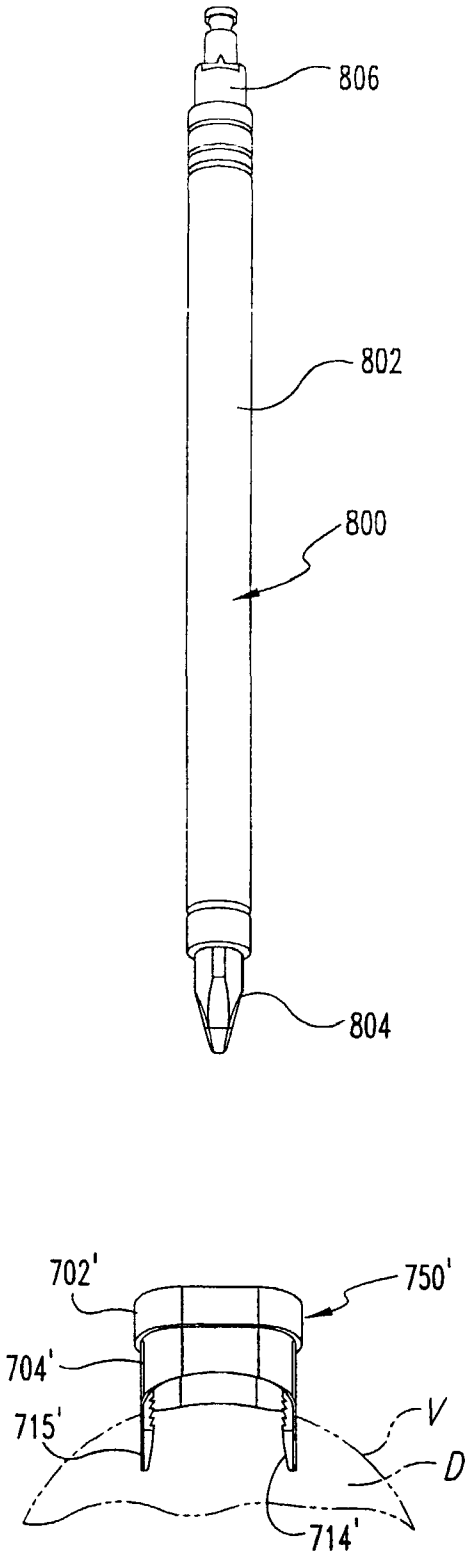
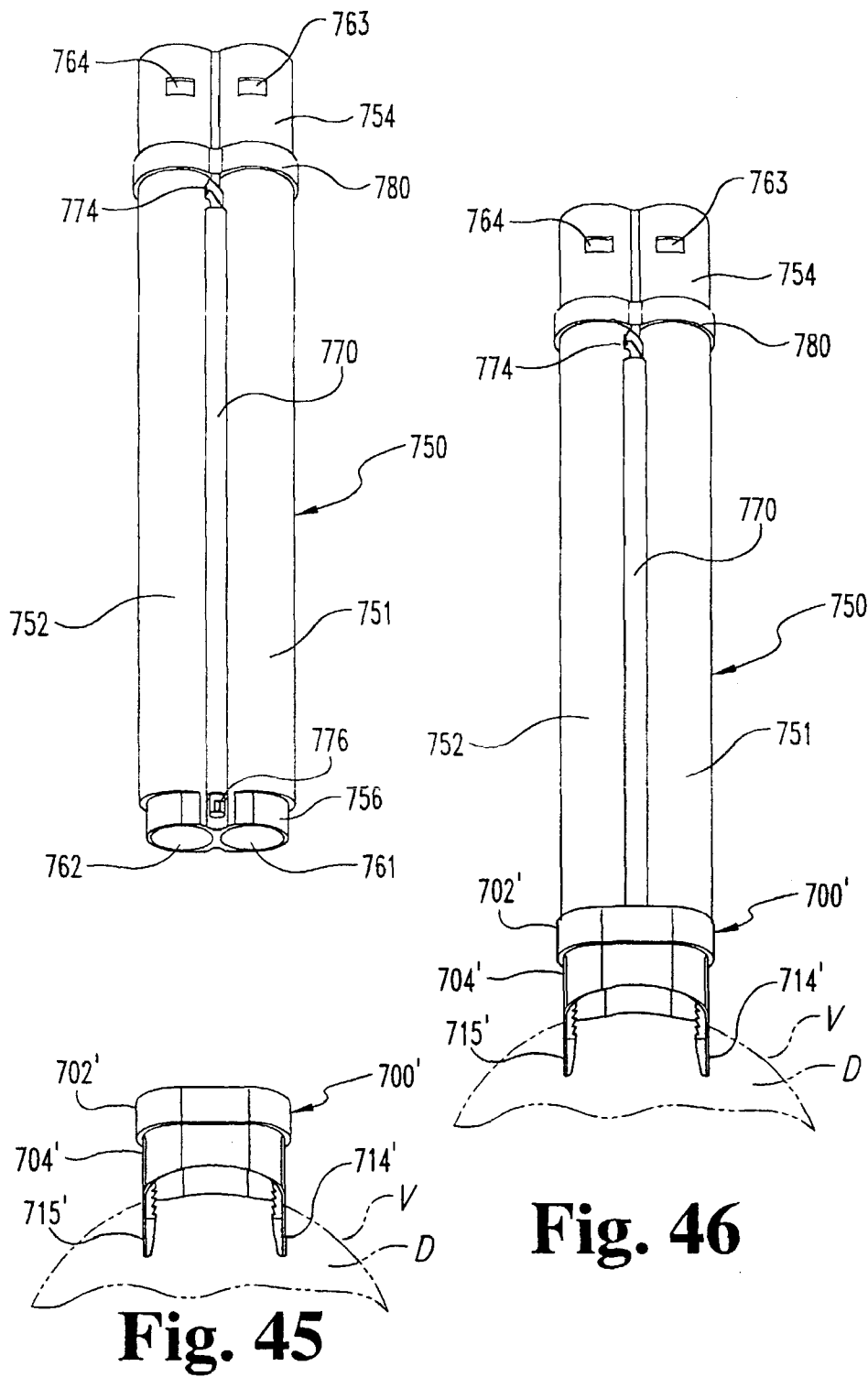
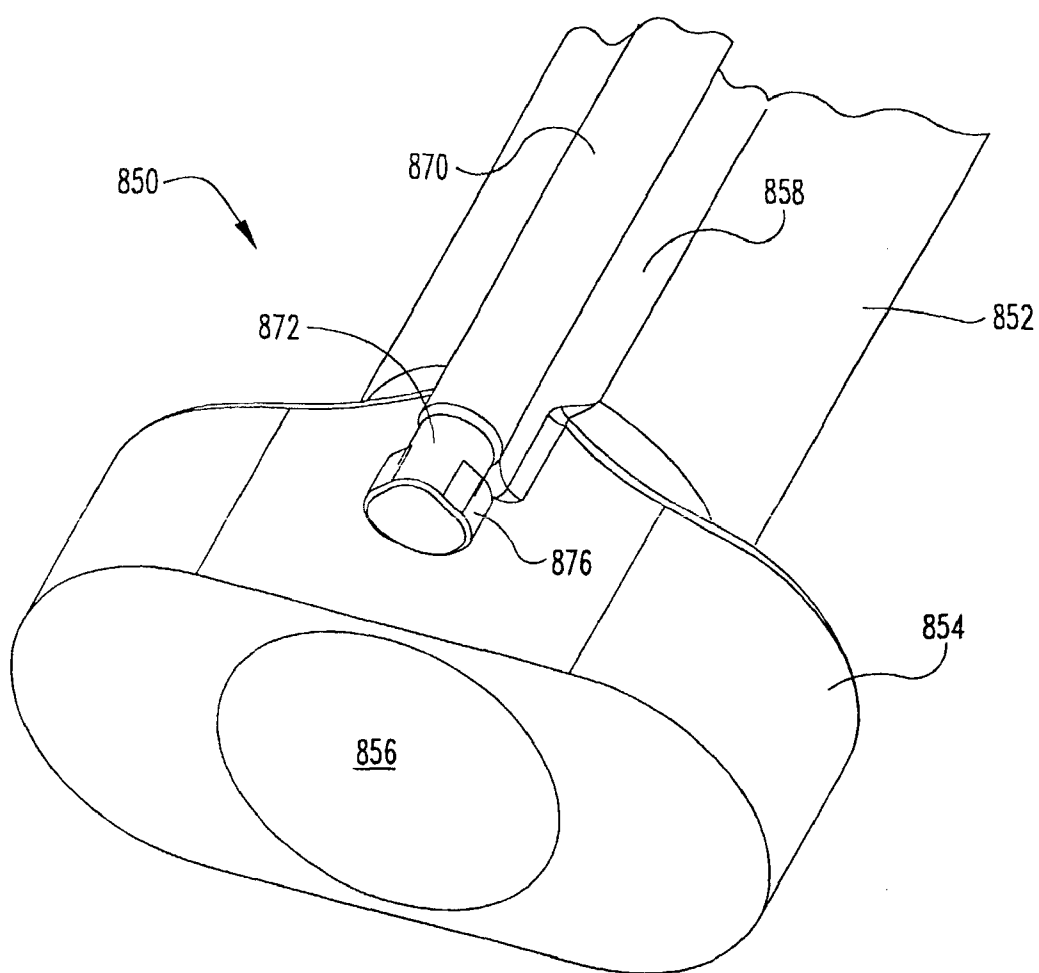
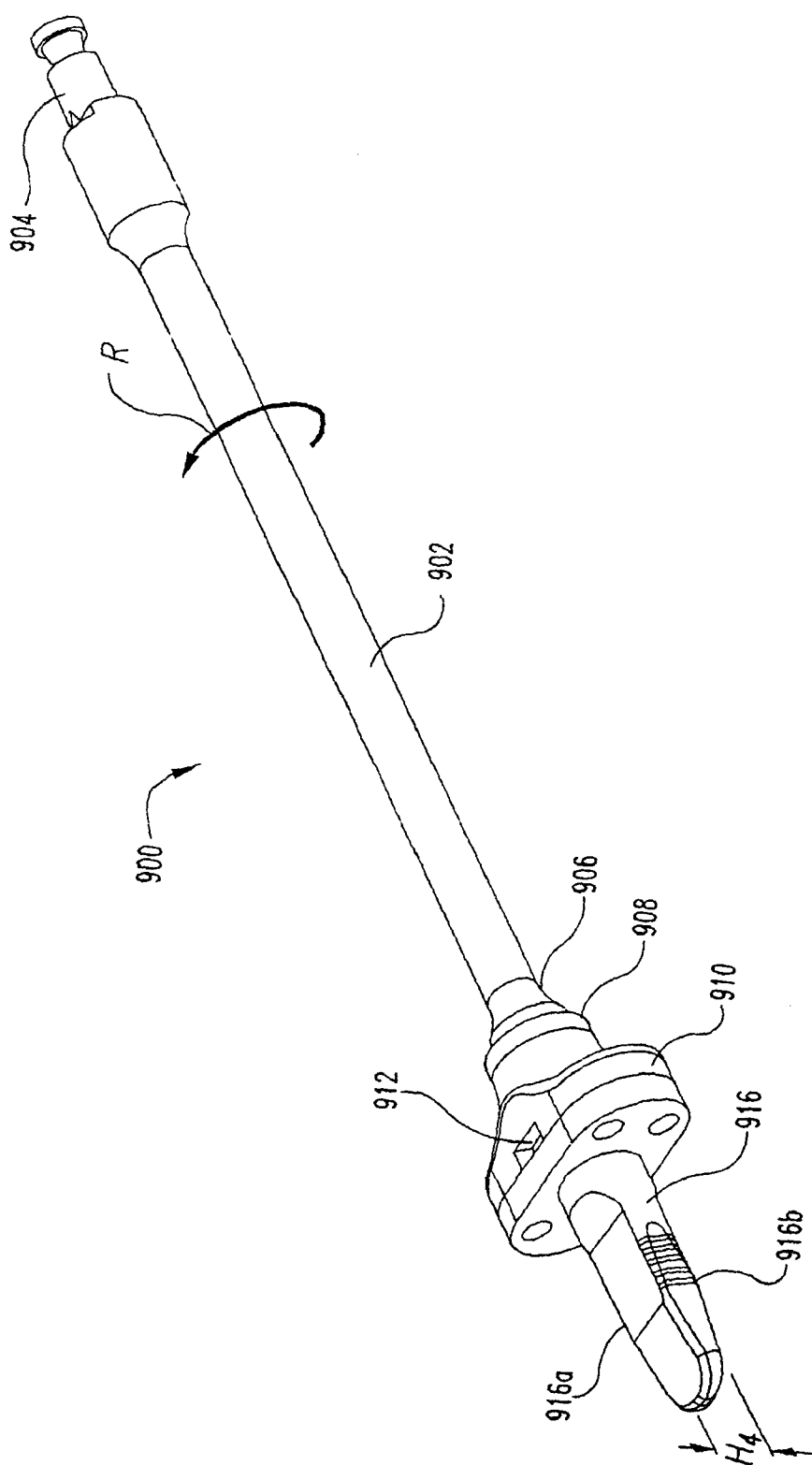


Fig. 44



**Fig. 47**

**Fig. 48**

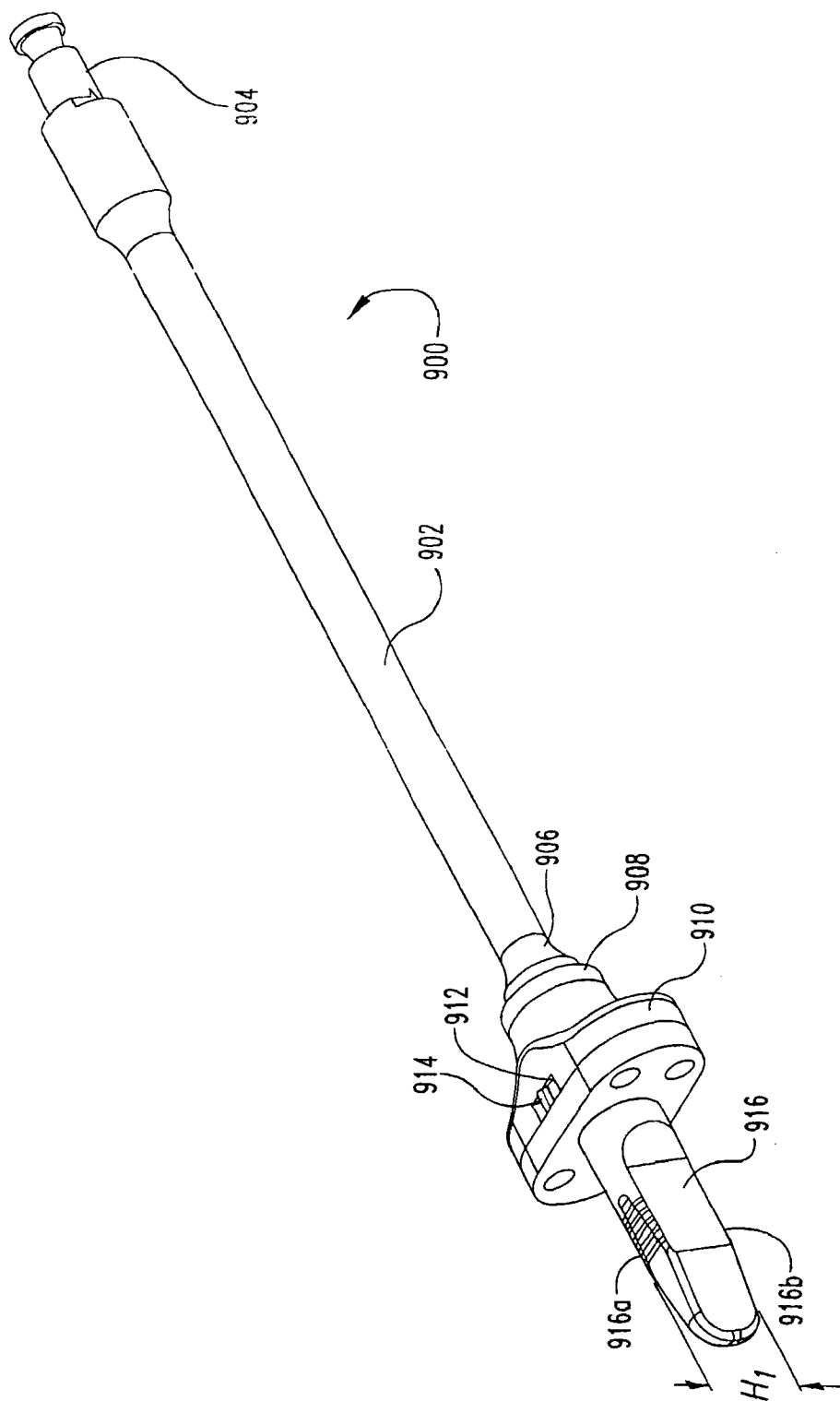


Fig. 49

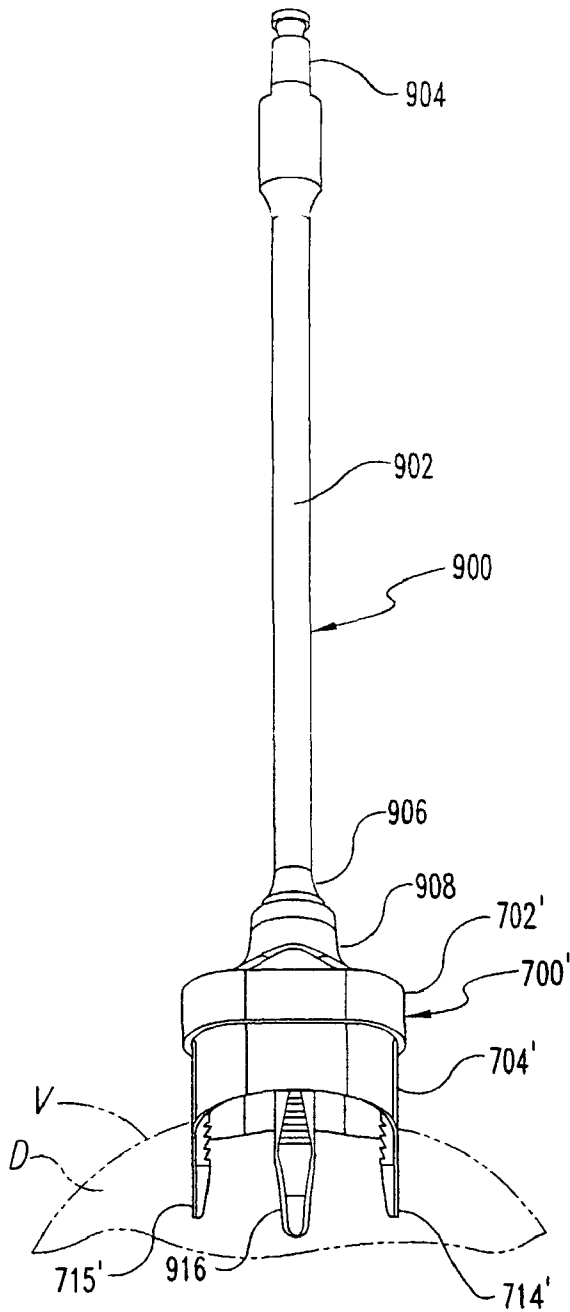


Fig. 50

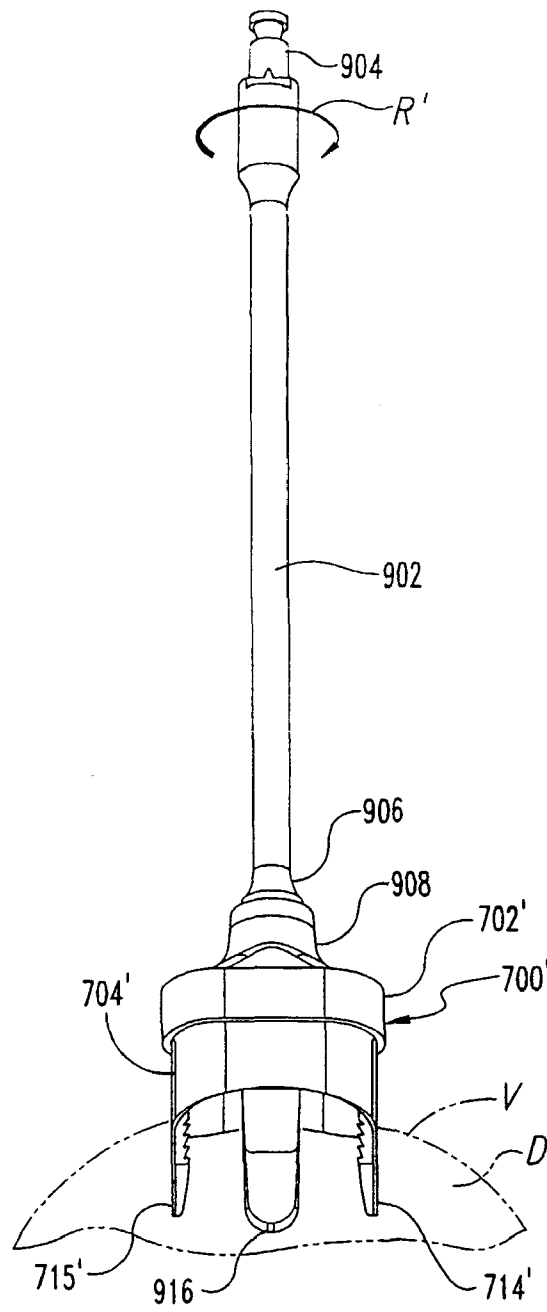
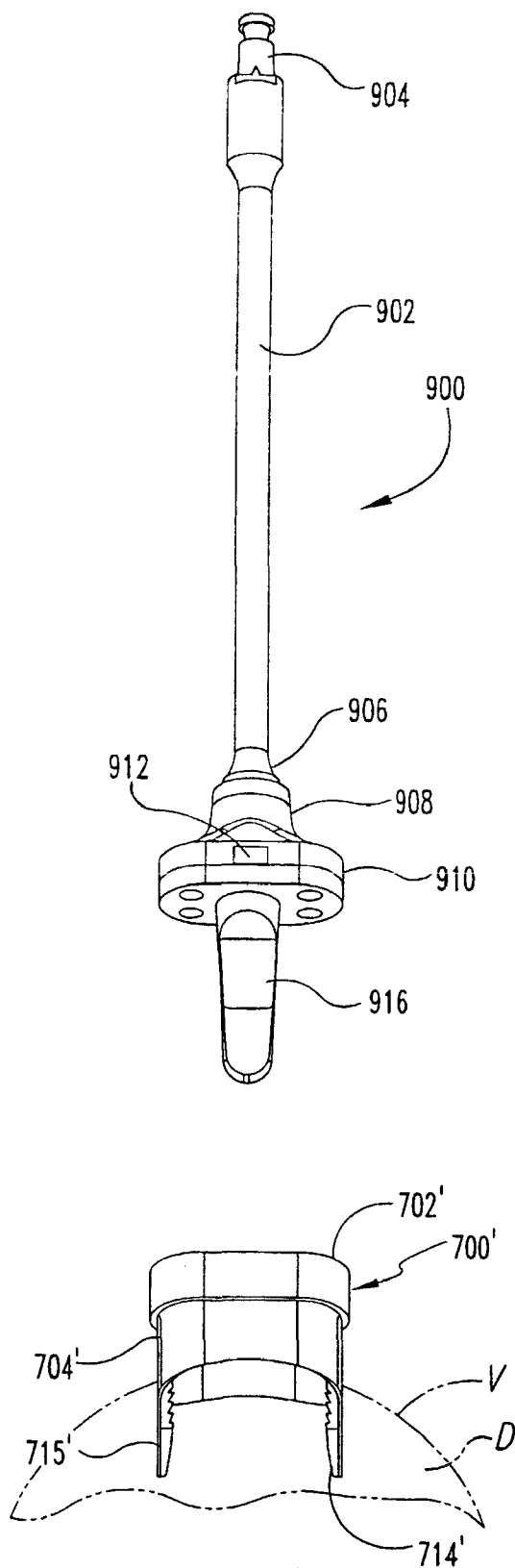


Fig. 51

**Fig. 52**