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(54) INTERVERTEBRAL DISC AND INSERTION METHODS THEREFOR

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DISQUE INTERVERTEBRAL ET LEURS METHODES D'INSERTION

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Description

BACKGROUND OF THE INVENTION

[0001] The present invention is directed to a template for making score lines on a spinal segment during spinal disc surgeries.

[0002] As is well known to those skilled in the art, the structure of the intervertebral disc disposed between the cervical bones in the human spine comprises a peripheral fibrous shroud (the annulus) which circumscribes a spheroid of flexibly deformable material (the nucleus). The nucleus comprises a hydrophilic, elastomeric cartilaginous substance that cushions and supports the separation between the bones while also permitting articulation of the two vertebral bones relative to one another to the extent such articulation is allowed by the other soft tissue and bony structures surrounding the disc. The additional bony structures that define pathways of motion in various modes include the posterior joints (the facets) and the lateral intervertebral joints (the unco-vertebral joints). Soft tissue components, such as ligaments and tendons, constrain the overall segmental motion as well.

[0003] Traumatic, genetic, and long term wearing phenomena contribute to the degeneration of the nucleus in the human spine. This degeneration of this critical disc material, from the hydrated, elastomeric material that supports the separation and flexibility of the vertebral bones, to a flattened and inflexible state, has profound effects on the mobility (instability and limited ranges of appropriate motion) of the segment, and can cause significant pain to the individual suffering from the condition. Although the specific causes of pain in patients suffering from degenerative disc disease of the cervical spine have not been definitively established, it has been recognized that pain may be the result of neurological implications (nerve fibers being compressed) and/or the subsequent degeneration of the surrounding tissues (the arthritic degeneration of the facet joints) as a result of their being overloaded.

[0004] Traditionally, the treatment of choice for physicians caring for patients who suffer from significant degeneration of the cervical intervertebral disc is to remove some, or all, of the damaged disc. In instances in which a sufficient portion of the intervertebral disc material is removed, or in which much of the necessary spacing between the vertebrae has been lost (significant subsidence), restoration of the intervertebral separation is required.

[0005] Unfortunately, until the advent of spine arthroplasty devices, the only methods known to surgeons to maintain the necessary disc height necessitated the immobilization of the segment. Immobilization is generally achieved by attaching metal plates to the anterior or posterior elements of the cervical spine, and the insertion of some osteoconductive material (autograft, allograft, or other porous material) between the adjacent vertebrae of the segment. This immobilization and insertion of osteoconductive material has been utilized in pursuit of a fusion of the bones, which is a procedure carried out on tens of thousands of pain suffering patients per year.

[0006] This sacrifice of mobility at the immobilized, or fused, segment, however, is not without consequences. It was traditionally held that the patient's surrounding joint segments would accommodate any additional articulation demanded of them during normal motion by virtue of the fused segment's immobility. While this is true over the short-term (provided only one, or at most two, segments have been fused), the effects of this increased range of articulation demanded of these adjacent segments has recently become a concern. Specifically, an increase in the frequency of returning patients who suffer from degeneration at adjacent levels has been reported.

[0007] Whether this increase in adjacent level deterioration is truly associated with rigid fusion, or if it is simply a matter of the individual patient's predisposition to degeneration is unknown. Either way, however, it is clear that a progressive fusion of a long sequence of vertebrae is undesirable from the perspective of the patient's quality of life as well as from the perspective of pushing a patient to undergo multiple operative procedures.

[0008] While spine arthroplasty has been developing in theory over the past several decades, and has even seen a number of early attempts in the lumbar spine show promising results, it is only recently that arthroplasty of the spine has become a truly realizable promise. The field of spine arthroplasty has several classes of devices. The most popular among these are: (a) the nucleus replacements, which are characterized by a flexible container filled with an elastomeric material that can mimic the healthy nucleus; and (b) the total disc replacements, which are designed with rigid baseplates that house a mechanical articulating structure that attempts to mimic and promote the healthy segmental motion.

[0009] Among these solutions, the total disc replacements have begun to be regarded as the most probable long-term treatments for patients having moderate to severe lumbar disc degeneration. In the cervical spine, it is likely that these mechanical solutions will also become the treatment of choice. At present, there are two devices being tested clinically in humans for the indication of cervical disc degeneration. The first of these is the Bryan disc, disclosed in part in U.S. Pat. No. 6,001,130. The Bryan disc is comprised of a resilient nucleus body disposed in between concaval-covex upper and lower elements that retain the nucleus between adjacent vertebral bodies in the spine. The concaval-convex elements are L-shaped supports that have anterior wings that accept bones screws for securing to the adjacent vertebral bodies.

[0010] The second of these devices being clinically tested is the Bristol disc, disclosed substantially in U.S. Pat. No. 6,113,637. The Bristol disc is comprised of two L-shaped elements, with corresponding ones of the legs of each element being interposed between the vertebrae and in opposition to one another. The other of the two

legs are disposed outside of the intervertebral space and include screw holes through which the elements may be secured to the corresponding vertebra; the superior element being secured to the upper vertebral body and the inferior element being attached to the lower vertebral body. The opposing portions out each of the elements comprise the articulating surfaces that include an elliptical channel formed in the lower element and a convex hemispherical structure disposed in the channel.

[0011] As is evident from the above descriptions, the centers of rotation for both of these devices, which are being clinically tested in human subjects, is disposed at some point in the disc space. More particularly with respect to the Bryan disc, the center of rotation is maintained at a central portion of the nucleus, and hence in the center of the disc space. The Bristol disc, as a function of its elongated channel (its elongated axis being oriented along the anterior to posterior direction), has a moving center of rotation which is at all times maintained within the disc space at the rotational center of the hemispherical ball (near the top of the upper element). Document EP 1 488 747 discloses a device according to the preamble of claim 1.

[0012] Thus, there remains a need for improved intervertebral discs, as well as new and improved methods for safely and efficiently implanting intervertebral discs.

SUMMARY OF THE INVENTION

[0013] Disclosed herein are intervertebral discs or implants, surgical instruments and procedures.

[0014] In a preferred embodiments of the present invention, a template for marking score lines on a spinal segment includes a shaft having a proximal end and a distal end, and a template marker provided at the distal end of the shaft. The template marker preferably includes a cruciform-shaped structure having a first vertical arm and a second vertical arm that extends away from the first arm, the first and second vertical arms being aligned with one another along a first axis. The cruciform-shaped structure also preferably includes a first lateral arm and a second lateral arm extending away from the first lateral arm, the first and second lateral arms being aligned with one another along a second axis, whereby distal surfaces of the first and second lateral arms form a concave curved surface that conforms to an anterior surface of a disc between superior and inferior vertebral bodies.

[0015] The template may include a central pin or a plurality of pins provided at the distal end of the lateral arms for being inserted into the natural disc for stabilizing the template adjacent the disc space, and the vertical arms and the lateral arms spread outwardly from the distal end of the shaft. The first vertical arm desirably includes a first distally extending tack for engaging an anterior surface of the first vertebral body and the second vertical arm desirably includes a second distally extending tack for engaging an anterior surface of the second vertebral body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016]

FIG. 1 shows a perspective view of an intervertebral disc implant.

FIGS. 2A-2H show a top element of the intervertebral disc implant shown in FIG. 1.

FIGS. 3A-3H show a bottom element of the intervertebral disc implant shown in FIG. 1.

FIGS. 4A-4H show other views of the intervertebral disc implant shown in FIG. 1.

FIG. 5 shows a perspective view of the top and bottom elements of the intervertebral disc implant shown in FIG. 1.

FIG. 6A shows an anterior end view of the intervertebral disc implant shown in FIG. 1.

FIG. 6B shows a side elevational view of the intervertebral disc implant shown in FIG. 1.

FIGS. 7A-7D show a template in accordance with the present invention.

FIGS. 8A-8D show a template marker, in accordance with other preferred embodiments of the present invention.

FIGS. 9A-9B show the template marker of FIG. 8A being attached to a template handle, in accordance with certain preferred embodiments of the present invention.

FIGS. 10A-10D show the template marker and the template handle shown in FIGS. 9A-9B.

FIGS. 11A-11D show a reference pin drill guide.

FIG. 12 shows a drill bit used with the reference pin drill guide shown in FIGS. 11A-11D.

FIGS. 13A-13B show the reference pin drill guide of FIGS. 11A-11D inserted into an intervertebral disc space.

FIGS. 14A-14C show a reference pin insertion guide.

FIGS. 15A-15C show a reference pin.

FIG. 16 shows a reference pin.

FIGS. 17A-17C show a reference pin driver.

FIGS. 18A-18B show a sleeve used with the reference pin insertion guide of FIGS. 14A-14C.

FIGS. 19A-19C show a distractor, in accordance with certain preferred embodiments of the present invention.

FIGS. 20A-20D show a drill guide.

FIGS. 21A-21D show a chisel guide.

FIGS. 22A-22D show a chisel used in cooperation with the chisel guide of FIGS. 21A-21D.

FIG. 23 shows the chisel of FIGS. 22A-22D, coupled with the chisel guide of FIGS. 21A-21D.

FIGS. 24A-24B show a mallet.

FIGS. 25A-25D show a sizer.

FIGS. 26A-26E show the sizer of FIGS. 25A-25D, coupled with a sizer handle.

FIGS. 27A-27D show a trial.

FIGS. 28A-28F show an implant dispenser.

FIGS. 29A-29E show the implant dispenser of FIGS. 28A-28F, coupled with the intervertebral disc implant shown in FIG. 1.

FIGS. 30A-30F-1 show an inserter head for inserting an intervertebral disc into a disc space.

FIG. 31 shows the inserter head of FIG. 30A and an exploded view of an inserter handle.

FIGS. 32A-32B show the inserter head and inserter handle of FIG. 31 assembled together.

FIGS. 33A-33B show an intervertebral disc implant being transferred from an implant dispenser to an inserter head.

FIGS. 34A-34B show an intervertebral disc implant, coupled with an inserter head.

FIGS. 35A-35B show an intervertebral disc implant being disengaged from a distal end of an inserter head.

FIGS. 36A-36B show a tamp.

FIGS. 37A-37D show an extractor.

FIGS. 38-74 show a method of inserting an intervertebral disc implant.

FIG. 75A shows a side view of the intervertebral disc implant shown in FIG. 72.

FIG. 75B shows an anterior end view of the intervertebral disc implant shown in FIG. 73.

DETAILED DESCRIPTION

[0017] Referring to FIG. 1, an intervertebral disc implant 100 includes a top element 102 and a bottom element 104. As will be described in more detail below, the top and bottom elements 102, 104 have opposing articulating surfaces that engage one another. The intervertebral disc implant is adapted to be inserted into a disc space between adjacent vertebrae.

[0018] Referring to FIGS. 2A-2H, the top element 102 includes a first bone engaging surface 106 having protrusions 108A, 108B and a second articulating surface 110. Referring to FIGS. 2C and 2D, the top element has a posterior end 112 and an anterior end 114. As shown in FIGS. 2A and 2C, the two protrusions 108 are interconnected by an anterior wall 116 that extends along the anterior end 114 of the top element. The anterior wall preferably serves as a vertebral body stop to prevent over insertion of the intervertebral disc implant and/or posterior migration of the implant. The anterior wall of the top element 102 preferably provides an engagement surface to be engaged by instruments, including but not limited to tamps and extraction or repositioning instruments. In certain embodiments, the anterior wall may have a curved posterior face adapted to sit flush against a curved anterior face of a vertebral body. In certain embodiments, one or more surfaces of the anterior wall may be coated with an osteoconductive material to facilitate long-term fixation to an endplate surface.

[0019] Referring to FIGS. 2E and 2H, the articulating surface 110 preferably defines a convex curve extending between the sides 118, 120 of the top element 102. Referring to FIGS. 2F and 2G, the articulating surface 110 also defines a concave curve or surface extending between the posterior and anterior ends 112, 114 of the top element 102. In certain embodiments, the articulating surface 110 defines a toroidal saddle-shaped surface.

[0020] Referring to FIG. 2C, each protrusion 108 preferably has an engagement feature, or depression 121 formed in an outer surface thereof. In certain embodiments, the depressions 121 are vertically extending. In other embodiments, the protrusions may have one or more holes extending at least partially or completely therethrough. The holes may receive or be suitable for receiving a bone-growth inducing material. As will be described in more detail below, the depressions 121 facilitate engagement of the top element with instruments, and specifically preferably facilitate securing and handling of the top element 102 during an intervertebral disc insertion operation. The depressions 121 on the two protrusions 108 are preferably in alignment with one another. In other words, the depressions 121 are preferably at the

same distance between the posterior end 112 and the anterior end 114 of the top element 102.

[0021] As shown in FIGS. 2A, 2C, and 2F, each protrusion 108 preferably includes teeth 122 having sloping surfaces 124 (e.g., having a low point nearer to the posterior end 112 of the top element 102 and a high point nearer to the anterior end 114 of the top element 102) that facilitate insertion of the posterior end 112 of the top element 102. Referring to FIG. 2F, the sloping surfaces 124 of the teeth 122 facilitate insertion of the implant in a direction indicated by arrow D_1. The vertical surfaces 126 of the teeth 122 hinder or prevent dislodgement of the implant in the direction indicated by arrow D_2.

[0022] Referring to FIG. 2H, the teeth 122 on protrusions 108 preferably also include laterally sloping surfaces 126 that slope downwardly from apexes close to axis A_1 to the lateral sides 118, 120 of the top element 102. Thus, the sloping surfaces 126 slope away from axis A_1.

[0023] Referring to FIGS. 3A-3H, the intervertebral disc implant preferably includes a bottom element 104 having a first bone engaging surface 128 and a second articulating surface 130 that engages the articulating surface 110 of the top element 102 (FIG. 2A). The bottom element 104 includes a posterior end 132, an anterior end 134, and lateral sides 136, 138. Referring to FIGS. 3A and 3C, the first bone engaging surface 128 includes first and second protrusions 140A, 140B. Each protrusion preferably has an engagement feature or depression 142 formed in an outer surface thereof. In certain embodiments, the depressions 142 are vertically extending. In other embodiments, the protrusions may have one or more holes extending at least partially or completely therethrough. The holes may receive or be suitable for receiving a bone-growth inducing material. As will be described in more detail below, the depressions 142 facilitate engagement of the bottom element with instruments, and specifically preferably facilitate securing and handling of the bottom element 104 during an intervertebral disc insertion operation. The depressions 142 on the two protrusions 140A, 140B are preferably in alignment with one another. In other words, the depressions 142 are preferably at the same distance between the posterior end 132 and the anterior end 134 of the bottom element 104. Referring to FIGS. 3F and 3G, each protrusion 140A, 140B preferably also includes teeth 144 having sloping surfaces 146 having a low point nearer to the posterior end 132 of the bottom element 104 and a high point nearer to the anterior end 134 of the bottom element 104. Similar to the sloping surfaces of the teeth of the top element 102 described above, the sloping surfaces 146 on the teeth 144 facilitate insertion of the bottom element 104 in the direction indicated by arrow D_3. The vertical surfaces 147 of the teeth 144 hinder or prevent dislodgement of the implant in the direction indicated by arrow D_4 (FIG. 3).

[0024] Referring to FIGS. 3E and 3H, the teeth 144 preferably also include laterally sloping surfaces 148 that slope downwardly toward axis A_2 (FIG. 3H). More specifically, the sloping lateral surfaces have apexes or high points closer to the lateral sides 136, 138 and low points that are closer to axis A_2.

[0025] Referring to FIGS. 3A and 3C, the bottom element 108 also include an anterior wall 150 that extends between the protrusions 140A, 140B. The anterior wall preferably serves as a vertebral body stop to prevent over insertion of the intervertebral disc and/or posterior migration of the implant. The anterior wall preferably provides an engagement surface that can be engaged by instruments, including but not limited to tamps and extraction or repositioning instruments. In certain embodiments, the anterior wall may have a curved posterior face adapted to sit flush against a curved anterior face of a vertebral body. In certain embodiments, one or more surfaces of the anterior wall may be coated with an osteoconductive material to facilitate long-term fixation to an endplate surface.

[0026] Referring to FIGS. 3F and 3G, the articulating surface 130 preferably defines a convex curve or surface extending between the posterior 132 and anterior ends 134 of the bottom element 104. Referring to FIGS. 3E and 3H, the articulating surface 130 preferably defines a concave curve or surface extending between the lateral sides 136, 138 of the bottom element 104. As will be described in more detail herein, the articulating surface 130 preferably defines a toroidal saddle-shaped surface that engages the articulating surface of the top element 102 (FIG. 2G).

[0027] FIGS. 4A and 4B show the top element 102 of FIG. 2A being coupled with the bottom element 104 of FIG. 3A. Referring to FIG. 4B, each of the top and bottom elements 102, 104 desirably has a respective anterior wall 116, 150 that extends between protrusions. The anterior walls 116, 150 preferably extend along the anterior ends 114, 134 of the respective top and bottom elements.

[0028] FIG. 4D shows top element 102 including posterior end 112, anterior end 114, and lateral sides 118, 120. The top element 102 includes first bone engaging surface 106 and protrusions 108A, 108B having depressions 121 formed in outer surfaces thereof. The top element 102 includes anterior wall 116 extending between protrusions 108A, 108B.

[0029] Referring to FIG. 4C, bottom element 104 has a posterior end 132, anterior end 134, and lateral sides 136, 138. The bottom element 104 includes bone engaging surface 128 and protrusions 140A, 140B. The protrusions include depressions 142 formed in outer surfaces thereof. The bottom element 104 also includes anterior wall 150 extending between protrusions 140A, 140B.

[0030] Referring to FIGS. 4E and 4H, the opposing articulating surfaces 110, 130 of the top element 102 and the bottom element 104 are adapted to engage one another. The teeth 122 on the top element 102 slope downwardly toward the posterior end 112 thereof. Similarly, the teeth 144 on the bottom element 104 slope downwardly toward the posterior end 132 thereof.

[0031] Referring to FIGS. 4F and 4G, the teeth 122 on

the top element 102 have lateral sloping surfaces 126 that slope downwardly toward the sides 118, 120. In contrast, the teeth 144 on the bottom element 104 include lateral sloping surfaces 148 that slope inwardly toward axis A_3 (FIG. 4F). As a result, the lateral sloping surfaces 126 of the teeth 122 on the top element 102 slope in a different direction than the lateral sloping surfaces 148 of the teeth 144 on the bottom element 104. Thus, the apex of the teeth 122 on the top element 102 is closer to axis A_3 than the apex of the teeth 144 on the bottom element 104. It has been observed that stacking two implants in successive disc spaces may result in cracking of vertebral bone between the implants because the apexes on the teeth of the two implants are in alignment. To avoid this cracking problem the apexes of the teeth on the top element 102 are offset from the apexes of the teeth on the bottom element 104. It is believed that providing teeth having off-set apexes enables two or more intervertebral disc implants to be inserted into two or more successive disc spaces, while minimizing the likelihood of cracking the vertebral bodies between the disc spaces.

[0032] Referring to FIG. 5, prior to insertion into an intervertebral space, the articulating surface 110 of the top element 102 opposes the articulating surface 130 of the bottom element 104. In preferred embodiments, the articulating surface 110 of the top element 102 defines a toroidal saddle-shaped surface including a concave surface extending between proximal and anterior ends thereof and a convex surface extending between the sides of the top element 102. The articulating surface 130 of the bottom element 104 also includes a toroidal saddle-shaped surface having a convex surface extending between the posterior and anterior ends and a concave surface extending between the sides of the bottom element 104.

[0033] The articulating surfaces may be similar to the articulating surfaces disclosed in commonly assigned U.S. Patent No. 6, 997, 955. In certain embodiments the longitudinally inwardly directed articulation surface of the top element 102 forms a constant radii saddle-shaped articulation surface. More particularly, the saddle surface is defined by a concave arc that is swept perpendicular to and along a convex arc. The articulation surface has a cross-section in one plane that forms a concave arc, and a cross-section in another plane (perpendicular to that plane) that forms a convex arc. The concave arc has a respective constant radius of curvature about an axis perpendicular to the one plane. The convex arc has a respective constant radius of curvature about an axis perpendicular to the other plane.

[0034] In an embodiment, the concave arc has a constant radius of curvature A about an axis perpendicular to the anterior-posterior plane, and the convex arc has a constant radius of curvature B about an axis perpendicular to the lateral plane. Preferably, radius A is less than radius B.

[0035] The longitudinally inwardly directed articulation surface of the bottom element 104 also preferably forms a constant radii saddle-shaped articulation surface. More particularly, the saddle surface is defined by a convex arc that is swept perpendicular to and along a concave arc. The articulation surface has a cross-section in one plane that forms a convex arc, and a cross-section in another plane (perpendicular to that plane) that forms a concave arc. The convex arc has a respective constant radius of curvature about an axis perpendicular to the one plane. The concave arc has a respective constant radius of curvature about an axis perpendicular to the other plane.

[0036] In an embodiment, the convex arc has a constant radius of curvature C about an axis perpendicular to the anterior-posterior plane, and the concave arc has a constant radius of curvature D about an axis perpendicular to the lateral plane. Preferably, radius C is less than radius D.

[0037] The constant radii saddle shaped articulation surfaces are configured and sized to be nestable against one another and articulatable against one another, to enable adjacent vertebral bones (against which the top and bottom elements are respectively disposed in the intervertebral space) to articulate in flexion, extension, and lateral bending. More particularly, the intervertebral disc is assembled by disposing the top and bottom elements so that the vertebral body contact surfaces are directed away from one another, and the articulation surfaces are nested against one another such that the concave arcs accommodate the convex arcs.

[0038] Accordingly, movement of the adjacent vertebral bones relative to one another is permitted by the movement of the top and bottom elements relative to one another. In flexion and extension, the concave arcs of the top element 102 ride on the convex arcs of the bottom element 104 about a center of rotation below the articulation surfaces. In lateral bending, the concave arcs of the bottom element 104 ride on the convex arcs of the top element 102 about a center of rotation above the articulation surfaces. During these articulations, the elements are maintained at constant relative distraction positions, i.e., the elements do not move in directions that are directed away from one another (for example, do not move in opposing axial directions from one another (e.g., along a longitudinal axis of the spine)). Accordingly, in certain embodiments, the present invention provides a pair of articulation surfaces that have a center of rotation above the surfaces in one mode of motion (e.g., lateral bending), and below the surfaces in another (e.g., flexion/extension), consistent in these regards with a natural cervical intervertebral joint. Preferably, the articulation surfaces are sized and configured so that the respective ranges of angles through which flexion/extension and lateral bending can be experienced are equal to or greater than the respective normal physiologic ranges for such movements in the cervical spine.

[0039] It is preferable that, in addition to the flexion, extension, and lateral bending motions described above, the adjacent vertebral bones be permitted by the interver-

tebral disc implant to axially rotate relative to one another (e.g., about the longitudinal axis of the spinal column) through a small range of angles without moving in opposite (or otherwise directed away from one another) directions (e.g., along the longitudinal axis) within that range, and then to engage in such opposite (or otherwise directed away from one another) movement once that range is exceeded. Preferably, the articulation surfaces are accordingly configured and sized to permit such movements. Because of the differing radii of the opposing articulation surfaces, the top and bottom elements are able to axially rotate relative to one another about the longitudinal axis of the spinal column through a range of angles without causing the vertebral body contact surfaces to move away from one another along the longitudinal axis. Once the axial rotation exceeds that range, the articulation surfaces interfere with one another as the concave arcs move toward positions in which they would be parallel to one another, and the distance between the vertebral body contact surfaces increases with continued axial rotation as the concave arcs ride up against their oppositely directed slopes. Thus, the articulation surfaces are configurable to permit normal physiologic axial rotational motion of the adjacent vertebral bones about the longitudinal axis through a range of angles without abnormal immediate axially opposite (or otherwise directed away from one another) movement, and to permit such axially opposite (or otherwise directed away from one another) movement when under normal physiologic conditions it should occur, that is, outside that range of angles.

[0040] The articulation surfaces preferably maintain contact over a range of normal physiologic articulating movement between the adjacent vertebral bones. That is, through flexion, extension, lateral bending, and axial rotation, the articulation surfaces are in contact with one another. Preferably, the surface area dimensions of the articulation surfaces are selected in view of the selected radii of curvature to prevent the edges of the saddle surfaces (particularly the edges of the concave arcs) from hitting any surrounding anatomic structures, or other portions of the opposing upper or lower element, before the limit of the normal physiologic range of an attempted articulation is reached.

[0041] FIGS. 6A and 6B show, an intervertebral disc implant 100 including top element 102 and bottom element 104. The articulating surface of the top element 102 preferably engages the articulating surface of the bottom element 104. The articulating surface of the top element 102 preferably defines a convex surface extending between lateral sides 118, 120 thereof. The articulating surface of the bottom element 104 defines a concave surface extending between the lateral sides 136, 138 thereof. Each of the top and bottom elements 102, 104 include respective anterior walls 116, 150 that prevent over insertion and/or posterior migration of the intervertebral disc implant 100. The teeth 122 on the protrusions of the top element 102 include laterally sloping surfaces 124 that slope downwardly toward the sides 118, 120. In contrast, the teeth 144 on the protrusions of the bottom element 104 include laterally sloping surfaces 148 that preferably slope downwardly toward a central region of the bottom element 104. The opposite sloping configuration of the teeth on the respective top and bottom elements 102, 104 preferably permits stacking of two intervertebral disc implants in two successive disc spaces, while minimizing the likelihood of cracking the vertebral bone between the adjacent disc spaces. In other embodiments, the opposite sloping configuration of the teeth enable three or more intervertebral discs to be stacked atop one another over three or more successive disc spaces. In still other embodiments, the teeth of the top and bottom elements may slope laterally in the same direction.

[0042] Referring to FIG. 6B, the articulating surface of the top element 102 defines a concave surface extending between posterior 112 and anterior 114 ends thereof. The articulating surface of the bottom element 104 defines a convex surface extending between the posterior 132 and anterior 134 ends of the bottom element 104. The teeth 122 on the protrusions of the top element 102 include sloping surfaces 124 that slope downwardly toward the posterior end 112 of the top element 102. The teeth 144 on the protrusions of the bottom element 104 have sloping surfaces 146 that slope downwardly toward the posterior end 132 of the bottom element 104. As a result, the sloping surfaces 124, 146 of the respective teeth 122, 144 slope in the same direction, i.e., toward the posterior ends of the top and bottom elements 102, 104. The respective sloping surfaces 124, 146 facilitate insertion of the implant 100 into a disc space. The respective vertical surfaces 122, 144 hinder or prevent expulsion or migration of the implant from the disc space after it has been inserted.

[0043] Referring to FIGS. 7A-7D in certain preferred embodiments of the present invention, a template 154 has a distal end 156 and a proximal end 158. The template 154 includes a shaft 160 extending between the distal and proximal ends and a handle 162 secured to a proximal end of the shaft. The template includes a template marker 164. As shown in FIG. 7D, the template marker 164 has a cruciform-like structure with a first vertically extending arm 166, a second vertically extending arm 168, a first lateral arm 170 and a second lateral arm 172. The upper and lower ends of the respective first and second vertically extending arms 166, 168 preferably have apexes that may be used for aligning scoring of the anterior faces of the adjacent vertebral bodies. The score marks may later be used for aligning other tools and/or the intervertebral disc. The template marker 164 includes a central pin 174, a first tack 176 on the first vertical arm 166 and a second tack 178 on the second vertical arm 168. The central pin 174 is adapted to engage a natural disc and the tacks 176, 178 are adapted to engage bone, such as vertebral bone. The central pin 174 may also be replaced or supplanted by a plurality of pins positioned on the lateral arms 170, 172. Referring to FIG. 7D, the

lateral arms 170, 172 preferably define a distal surface 180 that is curved for matching the curve of the anterior surface of a natural intervertebral disc.

[0044] FIGS. 8A-8D show a template marker for a template, in accordance with another preferred embodiment of the present invention. The template marker 164' is substantially similar to the template marker shown in FIG. 7D. However, the template marker 164' shown in FIGS. 8A-8D includes first and second engagement features or projections 182A' and 182B' projecting from top and bottom surfaces of adapter shaft 184'.

[0045] Referring to FIGS. 9A and 9B, the template marker 164' may be attached to a distal end 156' of a template handle 162'. The adapter shaft 184' of the template marker 164' is inserted into an opening at the distal end 156' of the template handle 162'. The projections 182A', 182B' on the adapter shaft 184' are inserted into opposing grooves 186' formed in the template handle 162'.

[0046] FIGS. 10A-10B show the template marker 164' secured to the distal end 156' of the template handle 162'. Referring to FIGS. 10A-10C, after the projections 182A' and 182B' on the template marker 164' have been received within the grooves at the distal end of the template handle 162', a rotatable handle 188' is rotated for advancing shaft 190' relative to outer shaft 192' so as to lock the template marker 164' to the distal end 156' of the template handle 162'. In certain preferred embodiments, the template handle 162' is rotated to seat the projections 182A', 182B' in the grooves 186' and the rotatable handle 188' is rotated to hold the projections 182A', 182B' forward in the grooves 186'.

[0047] FIGS. 11A-11B show a reference pin drill guide 194 having a distal end 196, a proximal end 198, a shaft 200 extending between the distal and proximal ends and a handle 202 at the proximal end of the shaft 200. The distal end 196 of the reference pin drill guide includes a main body 204 having an upper end 206 and a lower end 208. The main body includes a first opening 210 extending therethrough adjacent upper end 206 and a second opening 212 extending therethrough adjacent lower end 208. The main body includes a head 214 that projects from a distal side thereof. The head includes a tapered nose 216, a top surface 218, and a bottom surface 220. The head 214 also includes a first vertebral body stop 222 projecting upwardly from top surface 218 and a second vertebral body stop 224 projecting below second surface 220.

[0048] Referring to FIGS. 11A and 11C, the shaft 200 of the reference pin drill guide 194 is preferably angled or curved so that the working end of the tool may be observed by a surgeon. As shown in FIGS. 11A-11C, a distal end 226 of a drill bit 228 may be passed through openings 210, 212 for forming holes in the vertebral bone. As will be described in more detail below, the threaded ends of reference pins may be inserted into the holes. Referring to FIG. 11A, the main body 204 preferably includes an upper alignment flange 230 projecting from upper end 206 thereof and a lower alignment flange 232 projecting from lower end 208 of main body 204, for use in aligning the flanges with alignment marks previously scored on the vertebral bones.

[0049] The drill bit 228 includes a distal end 226 and a proximal end 234 adapted to be secured by a drill. The drill bit 228 includes a shoulder 236 that limits advancement of the drill bit through the openings 210, 212 of the main body 204.

[0050] Referring to FIG. 13A and 13B, in order to make holes in the vertebral bone for alignment or reference pins, the head 214 of the reference pin drill guide 194 is inserted into the disc space between the vertebral bodies. The head is advanced until the vertebral body stops abut the anterior faces of the respective vertebral bodies. The distal end of the drill bit 228 is then inserted through the openings 210, 212 in the main body 204. The distal end of the drill bit 228 is advanced into bone to form the openings for the reference pins.

[0051] Referring to FIGS. 14A-14C, a reference pin insertion guide 236 has a distal end 238, a proximal end 240, a shaft 242 extending between the distal and proximal ends and a handle 244 secured to the distal end of the shaft 242. The reference pin insertion guide 236 includes alignment guide body 246 having an upper end including a first opening 248 and a lower end including a second opening 250. The distal end also includes a head 252 insertable into an intervertebral disc space. The head 252 has a tapered nose 254, a top surface 256 terminating at a first vertebral body stop 258 and a bottom surface 260 terminating at a second vertebral body stop 262. The first and second vertebral body stops 258, 262 preferably prevent over insertion of the tool into an intervertebral disc space.

[0052] FIGS. 15A-15C show an alignment or reference pin 264. Referring to FIGS. 15A and 15B, the reference pin 264 has a distal end 266 and a proximal end 268. Referring to FIG. 15B, the distal end 266 includes a threaded portion 270 that is threadable into vertebral bone. The distal end of reference pin 264 also preferably includes a flange 272 that limits insertion of the reference pin. A proximal side of the flange 272 includes a feature or hex nut 274 engageable by a driver.

[0053] FIG. 16 shows a rescue reference pin 264'. The rescue pin 264' is substantially similar to the reference pin 264 shown in FIG. 15B and includes a threaded shaft 276' located on a posterior side of flange 272'. The rescue pin 264' is preferably used if the reference pin 264 shown in FIG. 15B does not remain anchored to bone or pulls out of the bone. The rescue pin 264' preferably has larger diameter threading (than the reference pin 264) at the leading end thereof.

[0054] Referring to FIGS. 17A-17C, a reference pin driver 280 is utilized for driving reference pins into bone. The reference pin driver 280 includes a distal end 282 having an opening adapted to receive a reference pin 264 (or a rescue pin 264') and a proximal end 284 including a handle 286. The reference pin driver 280 also in-

cludes a shaft 288 that extends between the distal end 282 and the proximal end 284. The shaft 288 preferably has an opening including at least one hexagonal surface that matches the hexagonal nut 274 on the reference pin 264 (FIG. 15A).

[0055] FIGS. 18A and 18B show a sleeve 290 insertable into the openings in the reference pin drill guide 194. The sleeve 290 includes a distal end 292 having an opening 294 and a proximal end 296 including a stop flange 298. Referring to FIG. 18B, the distal end 292 of sleeve 290 includes opening 294 extending therethrough and larger opening 296 at the distal-most end. The enlarged opening 296 preferably has a circular counterbore that freely slides over the hex nut on the reference pin 264 described above. The smaller opening 294 preferably forms a sliding fit with an outer surface of the reference pin 264. The sleeve 290 preferably stabilizes the reference pin insertion guide 236 after the first reference pin has been inserted into bone and during insertion of the second reference pin.

[0056] FIGS. 19A-19C shows a distraction instrument 300 including support element 302 and first and second distracting arms 304, 306 that travel over the support element 302. Each distracting arm 304, 306 has a curved section 308 and openings 310 at distal ends of the arms 304, 306. The distracting element 300 also includes adjustment element 312 that interacts with support body 302 and arms 304, 306 for adjusting the distance between the arms. As will be described in more detail herein, after reference pins 264 are inserted into vertebral bone, the distractor arms 304, 306 are slid over the reference pins. Once the distractor element 300 is coupled with the reference pins 264, the adjusting element 312 may be operated for separating the distractor arms 304, 305 so as to distract adjacent vertebrae and allow for removal of disc material.

[0057] Referring to FIGS. 20A-20D, a drill guide 314 has a distal end 316, a proximal end 318, a shaft 320 extending between the distal and proximal ends and a handle 322 adjacent the distal end 318. The drill guide includes a main body 324 attached to the distal end of the shaft 320. Referring to FIG. 20D, the main body 324 includes first and second openings 326, 328 for engaging the reference pins. The main body 324 also includes four drill guide openings 330A-330D for guiding a distal end 332 of a drill bit 334. The four drill guide openings 330A-330D are positioned to coincide with the protrusions of an intervertebral disc implant. Referring to FIGS. 20A and 20C, the main body 324 also includes a head 336 insertable into an intervertebral disc space. The head 336 includes a tapered nose 338, a top surface 340, a bottom surface 342, and first and second vertebral body stops 344, 346 extending above and below the top and bottom surfaces 340, 342. As will be described in more detail herein, the alignment openings 326, 328 are slid over the reference pins and the tool is advanced until the head 336 is positioned in the intervertebral disc space. The distal end 332 of the drill bit 334 is then passed in series through the drill alignment openings 330A-330D for at least partially forming protrusion openings for the protrusions of an intervertebral disc implant.

[0058] Referring to FIGS. 21A-21D, a chisel guide 350 includes a distal end 352, a proximal end 354 with a handle 356 and a shaft 360 extending from the proximal end toward the distal end. The shaft 360 includes on one side a left track 362 having an opening 364 at the proximal end 354 and extending toward the distal end 352, and, on an opposite site, a right track 362' having an opening 364' at the proximal end 354 and extending toward the distal end 352. The chisel guide 350 includes a head 366 at the distal end 352. Referring to FIGS. 21C and 21D, the head 366 includes alignment grooves 368 formed in top and bottom surfaces thereof. The alignment grooves are adjacent the left and right tracks of the shaft 360.

[0059] Referring to FIGS. 21B and 21D, the chisel guide also includes first and second reference pins openings 370, 372. In operation, the reference pin openings 370, 372 are slid over the reference pins described above, and the head 366 is inserted into an intervertebral disc space.

[0060] Referring to FIGS. 22A-22D, a chisel 374 has a distal end 376 with first and second cutting blades 378, 380, and a proximal end 382 having a handle 384 and a striking surface 386. The chisel 374 includes a shaft 388 extending between the distal and proximal ends of the tool. The shaft 388 includes projections extending therefrom for guiding the chisel in the tracks of the chisel guide shown in FIGS. 21A-21D. Referring to FIGS. 22B and 22D, the projections 390 guide the chisel along the track while maintaining alignment of the chisel. Referring to FIG. 22C, the distal end of the chisel includes an opening extending between cutting blades 378, 380. The opening 394 allows the cutting blades 378, 380 to slide over the grooves 368 formed in the top and bottom surfaces of the head 366 (FIG. 21D).

[0061] Referring to FIG. 23, the chisel guide 350 described in FIGS. 21A-21D is slid over the reference pins 264 secured to bone. The chisel 374 of FIGS. 22A-22D is then slideably advanced along one of the tracks of the chisel guide for forming protrusion openings in the bone. The same or a second chisel 374 is then slideably advanced along the other of the tracks to form additional protrusion openings in the bone.

[0062] FIGS. 24A-24B show a mallet 396 including a handle 398 having a lower end 400 and an upper end 402 with a striking element 404 secured to the upper end. The striking element 404 includes a U-shaped opening 406 formed therein so that the mallet may be used as a slap hammer.

[0063] FIGS. 25A-25D show a sizer 408. The sizer 408 includes a main body 410 having a distal end 412, a top surface 414, and a bottom surface 416. The body 410 includes sloping surfaces 418 extending between the distal end 412 and the top and bottom surfaces 414, 416 to ease insertion of the sizer between the vertebrae. The sizer 408 also includes an adapter shaft 420 and first and

second projections 422A, 422B.

[0064] The sizer also includes vertebral body stops 424 and 426 for limiting insertion of the sizer. Referring to FIGS. 25A and 25B, the sizers are preferably provided in variable heights (e.g., 5-9 mm) and variable base plate widths (e.g., 14 and 16 mm). Sequentially larger sizers are used to determine the desired implant height that will best fit into the disc space without over-tensioning the annulus. In their preferred usage, the sizer that fits snugly into the disc space with mild to moderate resistance to pull-out should indicate the proper height of the disc to be implanted.

[0065] Referring to FIGS. 26A-26E, a sizer 408 may be attached to a distal end 430 of a handle 432 by sliding the projections 422A, 422B into grooves extending from the distal end 430 of the handle 432. After the sizer 408 is coupled with the handle 432, a rotatable element 434 may be rotated for locking the sizer 408 to the handle 432. In certain preferred embodiments, the handle 432 is rotated to seat the projections 422A, 422B in the grooves extending from the distal end 430 of the handle and the rotatable element 434 is rotated to hold the projections 422A, 422B forward in the closed ends of the grooves.

[0066] Referring to FIGS. 27A-27D, a trial 436 includes a distal end 438, a proximal end 440, a shaft 442 extending between the distal and proximal ends, and a striking surface 444 located at the proximal end 440 of the shaft 442. The trial also includes a trial implant 446 secured at distal end 438. The trial implant 446 includes protrusions 448 having teeth 450 that are positioned to coincide with the protrusions of a intervertebral implant. The size of the trial implant 446 is selected based upon the largest sizer that safely fit within the intervertebral disc space. The trial 436 also includes reference pin alignment openings 452, 454. The reference pin alignment openings 452, 454 are adapted to slide over the reference pins secured to vertebral bone.

[0067] Referring to FIGS. 28A-28F, an implant dispenser 456 is adapted to hold the top and bottom elements of an intervertebral disc implant as a single unit with the articulating surfaces held together. Referring to FIGS. 28A-28C, the implant dispenser 456 is preferably flexible and includes a superior arm 458 for engaging a top element of an intervertebral disc implant and an inferior arm 460 for engaging a bottom element of an intervertebral disc implant. The superior and inferior arms preferably have lateral notches 462 formed therein for receiving the teeth of the top and bottom elements, as will be described in more detail herein. The implant dispenser also preferably includes a central support 464 that enables the superior and inferior arms 458, 460 to move away from one another for releasing an intervertebral disc implant.

[0068] Referring to FIG. 28E, the superior arm 458 preferably has indicia such as a text or a symbol 466 indicating that the arm 458 overlies the top element of the implant. The indicia on the superior arm may also preferably include the size 468 of the implant. FIG. 28F shows the inferior arm 460 including indicia such as a text or a symbol 470 indicating that the arm 460 overlies the bottom element of the implant. The inferior element indicia may also include size information 472 as shown.

[0069] FIGS. 29A-29E show the intervertebral disc implant of FIG. 1 secured in the implant dispenser 456 of FIGS. 28A-28F. The intervertebral disc implant includes top element 102 engaged by superior arm 458 and central element 464. The bottom element 104 is engaged by inferior arm 460 and central element 464. The teeth of the implant extend through the notches 462 in the superior and inferior arms.

[0070] FIGS. 30A to 30F-1 show an inserter head for inserting an intervertebral disc implant. Referring to FIGS. 30A-30B, the inserter head 474 includes a main body 476 having a distal end 478 and a proximal end 480. The distal end 478 of the main body 476 includes four spaced arms 482 having inwardly facing surfaces with projections 484 that are adapted to fit within the depressions formed within the protrusions of the top and bottom elements of the intervertebral disc implant. The main body includes a central opening 486 extending from the proximal end 480 to the distal end 478 thereof. Referring to FIGS. 30C and 30D, the main body 476 also includes an upper alignment groove 488 and a lower alignment groove 490. The alignment grooves 488, 490 are adapted to engage the reference pins for guiding advancement of the inserter head. In certain embodiments, the alignment grooves 488, 490 taper toward one another so that the grooves are closer to one another at distal ends thereof and farther away from one another at proximal ends thereof.

[0071] FIGS. 30E and 30E-1 show the projection 484 on one of the four arms 482. As noted above, the projections 484 on the arms 482 engage the depressions in the protrusions of the top and bottom elements of the intervertebral discs.

[0072] FIG. 31 shows the inserter head 474 of FIG. 30A prior to assembly with an inserter handle 492. The inserter handle 492 includes a pusher rod 494 that may be advanced by a rotatable handle 496 coupled with the pusher rod 494. The handle includes a shaft 496 that is insertable into opening 486 of the inserter head. Referring to FIGS. 32A and 32B, after the inserter head 474 has been coupled with the inserter handle, the element 496 may be rotated for advancing the pusher rod 494. As will be described in more detail below, advancing the pusher rod 494 will disengage the top and bottom elements of an intervertebral disc with the arms 482 of the inserter head 474.

[0073] FIGS. 33A and 33B show the implant dispenser 456 of FIG. 29A holding an intervertebral disc implant 100. Referring to FIG. 33B, the depressions in the protrusions are coupled with the projections in the arms 482 of the inserter head 474. Referring to FIGS. 34A and 34B, after the implant 100 has been secured to the arms 482 of the inserter head 474, the implant dispenser may be

removed. Referring to FIG. 34B, at this point, the implant 100 is held by the arms 482 of the inserter head. Referring to FIGS. 35A-35B, the pusher rod 494 may be advanced toward the distal end of the inserter head 474 for decoupling the implant 100 from the inserter head 474.

[0074] Referring to FIGS. 36A and 36B, a tamp 500 includes a distal end 502, a proximal end 504, a shaft 506 extending between the distal and proximal ends and a handle 508 adjacent the proximal end 504. The distal end 502 includes an abutting surface 510 that is adapted to engage the anterior end of an intervertebral disc implant. The tamp 500 also includes a striking surface 512 at the proximal end. A device such as the mallet shown and described above may be impacted against the striking surface 512 for applying force to the striking surface 510 of the tamp.

[0075] FIGS. 37A-37D show an extractor 514, in accordance with certain preferred embodiments of the present invention. The extractor 514 includes a distal end 516 having a hook 518, a proximal end 520, and a shaft 522 extending between the distal and proximal ends. The extractor 514 also preferably includes a handle 524 adjacent the proximal end 520 thereof. FIGS. 37C and 37D show shaft 522 with a hook 518 at a distal end of the shaft.

[0076] Prior to implanting the intervertebral disc implant, a review of X-rays, MRI or CT-myelogram is preferably conducted to assess the level to be treated for osteophytes and to compare the intervertebral disc height with the adjacent levels. Referring to FIG. 38, the patient is preferably positioned in the supine position to provide for an anterior surgical approach to the cervical spine. Steps should preferably be taken to stabilize the patient's spine in a neutral position and to prevent rotation during the procedure. In certain embodiments, it may be preferable to place a towel or bean bag underneath the patient's shoulders. Tape, a halter or skeletal traction may be used to prevent rotation. Referring to FIGS. 38 and 39, a transverse skin incision is preferably made at the appropriate level to expose the targeted spinal segment including the discs above and below the target spinal segment. Care should be taken to avoid prolonged retraction pressure on vital structures, such as the esophagus.

[0077] Another step in the intervertebral disc implantation procedure involves identifying and marking a midline on the target segment of the spine. In preferred embodiments, a template, such as the template shown and described above in FIGS. 7A-10D, is utilized to mark the midline. In certain preferred embodiments, the size and dimensions of the template may vary. The exact template selected may be based upon initial estimation of the appropriate implant size from pre-operative X-rays and/or MRI/CT. The template is preferably attached to the template handle, as described above in reference to FIGS. 9A-9B and 10A-10D. The template may have different sizes whereby the lateral arms of the template attachments approximate the width options of the implant (i.e., 14 mm and 16 mm). Referring to FIG. 40 and FIG. 9A, the central pin at the distal end of the template is inserted into the middle of the disc so that the upper and lower vertically extending arms are approximately aligned with the midline axis of the vertebral column. The tacks on the upper and lower vertical arms engage the vertebral bone to stabilize the template. The handle at the proximal end of the template handle may be tapped, such as by using a mallet, to push the tacks into the vertebral bone. The template handle may then be disengaged from the template, which remains attached to the vertebral bone. At this stage, fluoroscopy may be used to verify the midline and lateral margins of the disc space. In addition, the spinous processes are preferably centered.

[0078] Referring to FIG. 41, a tool such as a scalpel or an electrocautery tool is preferably utilized to score the midline points on the anterior surfaces of the superior and inferior vertebral bodies. Care is preferably taken to ensure that the midline is well defined for all subsequent endplate preparation and implant insertion steps. Referring to FIGS. 41 and 42, after the midline points have been scored, the template handle may be reattached to the template for removing the template from engagement with the target area. FIG. 42 shows the target area of the spine with an opening formed in the disc space by the central pin of the template, and two smaller openings being formed in the respective superior and inferior vertebral bodies by the tacks of the template. In addition, the scoring of the midline points is evident at the anterior surfaces of the superior and inferior vertebral bodies.

[0079] Referring to FIG. 43, a cutting tool such as a scalpel may be used to dissect a window in the annulus of the targeted disc. The size of the window dissected in the annulus preferably approximates the width of an intervertebral disc implant to be inserted therein. In certain embodiments, radiographic imaging such as fluoroscopy may be used to identify osteophytes that extend anteriorly. Any osteophytes that extend anteriorly are preferably resected back to the vertebral body so that the surfaces of the superior and inferior vertebral bodies are flattened. Moreover, techniques such as radiographic imaging should be used to identify any osteophytes extending downwardly or upwardly into the anterior region of the disc space. Such osteophytes should be resected to the endplates. FIG. 44 shows the targeted disc space after the initial discectomy has been completed including resection of any anterior osteophytes present in the targeted disc area.

[0080] Referring to FIG. 45, after initial preparation of the disc space, reference pins may be attached to the anterior faces of the superior and inferior vertebral bodies. The midline score marks and the tack openings in the superior and inferior vertebral bodies are preferably used for proper placement of the reference pins. Care is preferably taken to ensure proper placement and alignment of the reference pins, which will guide subsequent steps of the procedure. Referring to FIG. 45, the reference pin drill guide described in FIGS. 11A-11D is inserted into the dissected disc space. Specifically, the head

at the distal end of the reference pin drill guide is inserted into the disc space between the vertebral bodies. The head at the distal end is inserted until the vertebral body stops abut against the anterior faces of the superior and inferior vertebral bodies. At this stage, one of the openings in the main body of the reference pin drill guide is preferably in alignment with the superior vertebral body and another one of the openings is in alignment with the inferior vertebral body. The reference pin drill guide is preferably aligned with the midline of the vertebral bodies as marked by the score line markings. The alignment of the reference pin drill guide is preferably checked such as by using fluoroscopy. Referring to FIG. 46, with the reference pin drill guide in place, holes are drilled in the superior and inferior vertebral bodies using a drill bit, such as the drill bit shown in FIG. 12 above. FIG. 46 shows a hole being drilled in the superior vertebral body. FIG. 47 shows a hole being drilled in the inferior vertebral body. FIG. 48 shows the target spinal segment after holes have been drilled in both the superior and inferior vertebral bodies.

[0081] Referring to FIG. 49, after the holes are drilled, the reference pin drill guide is removed from the targeted disc segment. At this stage, a first hole for a first reference pin has been formed in the superior vertebral body and a second hole for a second reference pin has been formed in the inferior vertebral body. The first and second holes in the vertebral bodies are preferably in alignment with the score marks formed previously.

[0082] Referring to FIG. 50, the reference pins may be inserted using the reference pin insertion guide shown and described above in FIGS. 14A-14C. Preferably, the head at the distal end of the reference pin insertion guide is inserted into the disc space until the vertebral body stops abut against the anterior surfaces of the superior and inferior vertebral bodies. As shown in FIG. 50, the reference pin insertion guide preferably has a first opening in alignment with the opening formed in the superior vertebral body and a second opening aligned with the opening formed in the inferior vertebral body. A reference pin, such as the reference pin shown and described above in FIGS. 15A-15C is inserted into the first opening of the reference pin insertion guide. The threading at the distal end of the reference pin is threaded into the opening in the superior vertebral body. The reference pin driver shown in FIG. 17A-17C may be utilized for threading the reference pin into the vertebral body. The threads on the reference pins may be self-tapping threads.

[0083] Referring to FIG. 51, after the first reference pin is inserted into bone, the second reference pin is passed through the lower opening in the reference pin insertion guide and driven into the inferior vertebral body using the reference pin driver. In other preferred embodiments, a first reference pin may be attached to the inferior vertebral body before attaching a second reference pin to the superior vertebral body. Thus, the insertion of the reference pins can be accomplished in any particular order.

[0084] Referring to FIG. 52, in certain embodiments, after a first reference is inserted into bone, a sleeve such as the sleeve shown and described in FIGS. 18A-18B may be slid over the attached reference pin so as to stabilize the reference pin insertion guide. As shown in FIG. 52, the sleeve preferably remains in place to prevent movement of the reference pin insertion guide during insertion of the second reference pin into the other vertebral body.

[0085] Different sized reference pins may be used. These different sized reference pins may include shafts having different diameters and/or lengths. In certain preferred embodiments, a small and a large set of reference pins is provided in an instrument tray. The smaller of the pair of reference pins should be inserted initially. If the smaller pair of reference pins proves unsatisfactory, the larger pair of reference pins may be utilized. As shown in FIG. 53, the reference pins are preferably parallel to each other and in alignment with the midline of the superior and inferior vertebral bodies.

[0086] Once the reference pins are in place, a surgeon may preferably apply distraction to the disc space by using a distraction tool, such as a distractor as shown and described in FIGS. 19A-19C. Once distraction has occurred, the disc space may be cleared of any extraneous matter and restored to a desired height. Prior to distraction, the facets of the targeted spinal segment should be reviewed under fluoroscopy in order to monitor facet orientation during distraction. The distractor shown in FIGS. 19A-19C is preferably placed over the reference pin shown in FIG. 53. FIG. 54 shows the distractor after it has been placed over the reference pins. If the reference pins loosen at any time during the distraction procedure, the reference pins may be removed and replaced with the larger reference pins provided in the instrument set.

[0087] The distractor is then utilized to apply distraction to the targeted spinal segment. During the distraction procedure, the facets and the disc space are preferably monitored under fluoroscopy to ensure a complete distraction. The amount of distraction should not exceed the height of the adjacent disc space. As noted above, fluoroscopy should be used to monitor the distraction height so as to prevent over-distraction. As is well known to those skilled in the art, over-distraction may cause nerve and/or facet damage.

[0088] After the targeted spinal segment has been distracted, the discectomy procedure is completed. In preferred embodiments, the posterior and lateral margins of the disc space are cleared of any extraneous matter. The clearing of the posterior and lateral margins preferably extends to the uncinate processes and all the way back to the nerve root and canal. In certain embodiments, lateral fluoroscopy is utilized to check the anterior aspects of the vertebral body for osteophytes. A cutting tool, such as a burr, may be used to further prepare the endplates of the opposing superior and inferior vertebral bodies. The cutting tool may be utilized to smooth out the curvature of the superior endplate. After the discectomy has been completed, the endplates of

the adjacent vertebral bodies are preferably parallel to one another and relatively uniform, thereby preventing undersizing of the implant.

[0089] In certain embodiments, the decompression of the targeted disc space may be completed by removing any posterior osteophytes or soft tissue material that may inhibit the full distraction of the posterior portion of the targeted disc space. In certain embodiments, it may be necessary to remove the posterior longitudinal ligament (PLL) to achieve optimal restoration of the disc height, decompression and release for post-operative motion. In addition, the posteriolateral corners of the endplates may be resected as needed to provide neural decompression. In certain instances, it may be necessary to remove the posteriolateral uncovertebral joints. The lateral uncovertebral joints are preferably not removed unless they are causing nerve root compression. In addition, in certain embodiments it may be necessary to perform a foraminotomy if there are symptoms of neural/foraminal stenosis.

[0090] In certain embodiments, another stage of the intervertebral disc implantation method involves initial endplate preparation including drilling pilot grooves in the superior and inferior vertebral bodies. After complete distraction has taken place, the distractor shown in FIG. 54 is removed. Referring to FIG. 55, the protrusion drill guide of FIGS. 20A-20D is inserted into the prepared disc space. The openings at the upper and lower ends of the drill guide are aligned with the proximal ends of the reference pins. As shown in FIG. 55, the reference pins engage the openings for guiding the drill guide toward the prepared disc space. The head at the distal end of the drill guide is inserted into the prepared disc space until the vertebral body stops abut against the anterior faces of the superior and inferior vertebral bodies. The surgeon should visually check that the vertebral body stops of the drill guide come into full contact with the superior and inferior vertebral bodies. The handle of the drill guide is preferably parallel with the inferior and superior endplates and aligned in the sagittal plane.

[0091] As shown in FIG. 55, a drill bit is utilized to drill four pilot holes for the implant protrusions at precise locations in the vertebral bodies. As shown in FIG. 55, the drill guide includes two openings for drilling a pair of pilot holes in the superior vertebral body and two openings for drilling pilot holes in the inferior vertebral body. In certain embodiments, the drill includes a stop to limit the length of the pilot holes. There is preferably a stop on the drill so as to ensure that the pilot holes are no more than 10 mm in length.

[0092] Referring to FIG. 56, after the pilot holes have been formed in the superior and inferior vertebral bodies, the drill guide is retracted from the targeted disc space and decoupled from the two reference pins. As shown in FIG. 56, two pilot holes are formed in the superior vertebral body and two pilot holes are formed in the inferior vertebral body. The two pilot holes on the left of the adjacent vertebral bodies are preferably in vertical alignment with one another and the two pilot holes on the right of the vertebral bodies are preferably in vertical alignment with one another.

[0093] In certain embodiments, channels for the protrusions of the intervertebral disc implant are formed in the endplates of the superior and inferior vertebral bodies. Referring to FIG. 57, the chisel guide shown and described in FIGS. 21A-21D is inserted into the targeted disc space. The alignment openings in the chisel guide are slid over the reference pins. The head at the distal end of the chisel guide is inserted into the targeted disc space until the vertebral body stops come into contact with the anterior surfaces of the vertebral bodies. The handle of the chisel guide is preferably parallel with the superior and inferior endplates and aligned in the sagittal plane. As shown in FIG. 55, the chisel described in FIGS. 22A-22D is coupled with one of the tracks of the chisel guide and advanced toward the disc space. The cutting blades of the chisel are preferably advanced toward the superior and inferior vertebral bodies while positive pressure is applied to the chisel guide to ensure that it does not back out of the disc space. FIG. 23 shows the chisel 374 coupled with the chisel guide 350 with the cutting blades at the distal end of the chisel opposing the superior and inferior vertebral bodies. A striking instrument, such as the mallet shown and described in FIGS. 24A-24B, may be utilized to strike the distal end of the chisel so as to cut channels in the superior and inferior vertebral bodies.

[0094] Referring to FIG. 58, after the first chisel has cut the channels on one side of the chisel guide, a second chisel is preferably utilized in the same manner as described above with respect to the first chisel to cut a second set of channels in the vertebral bodies. FIG. 59 shows the targeted spinal segment after a set of channels has been cut into the superior and inferior vertebral bodies. FIG. 60 shows the targeted spinal segment after the channels have been cut in the vertebral bodies and the chisel guide has been removed from the reference pins.

[0095] In certain embodiments, a sizing operation is conducted to determine the proper size of the intervertebral disc that will be placed into the targeted disc space. Referring to FIG. 61, a sizer such as the sizer shown and described above in FIGS. 25A-26B may be inserted into the disc space. The sizers may have different heights (e.g., 5-9 mm) and different base plate widths (e.g., 14 mm and 16 mm). In preferred embodiments, a sizer having a height of 5 mm is used initially. The sizer is preferably attached to the handle shown and described above in FIGS. 26A-26D. The sizer is then advanced into the disc space as shown in FIG. 62. The sizer is preferably advanced until the vertebral body stops on the sizer abut against the anterior surfaces of the superior and inferior vertebral bodies.

[0096] After starting with a sizer having a height of 5 mm, sequentially larger sizers are utilized to determine the desired implant height that will best fit into the disc space without over tensioning the annulus. The correct

height for the sizer is preferably determined when the sizer fits snugly into the disc space with mild to moderate resistance to retraction of the sizer. The width of the disc space may also be checked by using a sizer having a different width and inserting the sizer into the disc space. In certain preferred embodiments, the sizer may include alignment openings that engage the reference pins for guiding the sizer as it is advanced toward the disc space.

[0097] In certain embodiments, a trial is inserted into the disc space to complete preparation of the channels for the protrusions of the intervertebral disc. Referring to FIG. 63, a trial such as that shown and described above in FIGS. 28A-28D is advanced toward the disc space. As described above, the trial includes alignment openings that are slid over the reference pins for guiding advancement of the trial. The particular size of the trial is selected based upon the corresponding size of the sizer that produced the best fit within the disc space. In certain embodiments, the particular trial selected is based upon the following chart:

Sizer	Trial Size
5-6 mm height 14 mm x 12 mm baseplate	Small, 14 mm
7-9 mm height 14 mm x 12 mm baseplate	Large, 14 mm
5-6 mm height 16 mm x 14 mm baseplate	Small, 16 mm
7-9 mm height 16 mm x 14 mm baseplate	Large, 16 mm

[0098] Referring to FIG. 64, the trial is advanced along the reference pins and into the intervertebral space. The protrusions on the trial are preferably aligned with the channels previously formed in the opposing endplates. A mallet may be impacted against the proximal end of the trial for advancing the trial into the disc space. If necessary, a slap hammer may be utilized to remove the trial from the disc space. In certain embodiments, the trial is inserted at an angle that is parallel to the endplates so as to prevent damage to the endplates and avoid creating bone fragments. One or more trials may be inserted into the disc space until a proper fit is achieved.

[0099] In certain embodiments, an appropriately sized intervertebral disc implant is then selected and inserted into a targeted disc space. Referring to FIG. 65, in certain embodiments, the intervertebral disc implant is provided as a single unit with the top and bottom elements of the implant being held together by an implant dispenser 456. In certain embodiments, the implant dispenser is color coded to correspond to the height of the implant. In addition, the implant dispenser is preferably marked with the height of the implant and the width of the top and bottom elements. The outer surface of the implant may also be marked with the height and width of the implant. In certain embodiments, the anterior face of the implant is marked with the height and width of the implant.

[0100] In certain embodiments, prior to insertion of the intervertebral disc implant, the size label on the implant is inspected and the size label on the implant dispenser is also inspected to ensure that the correctly sized implant was selected and that the top or superior element of the implant is oriented for proper insertion. In certain embodiments, an implant is selected having a height and baseplate dimensions that match the corresponding sizer that restored the desired height of the disc space without overtensioning the annulus or damaging the facets.

[0101] After an appropriately sized intervertebral disc implant has been selected, an inserter head, such as the inserter head shown and described above in FIGS. 30A-30B, is selected. The selected inserter head preferably has a height and/or dimensions that match the particular dimensions of the selected implant and selected implant dispenser. Thus, the inserter head may also be color coded to correspond to the height of the implant and the particular dimensions of the implant dispenser. The inserter head may be a single use component that is discarded after the implantation procedure. In certain certain embodiments, each inserter head may be used for either a 14 mm or 16 mm width implant that is preferably matched to the implant height.

[0102] Referring to FIGS. 66 and 67, the implant and implant dispenser are juxtaposed with the distal end of the inserter head.

[0103] In certain certain embodiments, the inserter head is attached to a handle. The attachment may include a threaded attachment whereby a t-bar or handle is rotated to threadably engage the inserter head with the handle.

[0104] Referring to FIG. 67, in certain certain embodiments, the implant is attached to the inserter head by first matching the superior and inferior labels on the implant dispenser with the inserter head. The four arms of the inserter head are then slid along the outer lateral sides of the implant protrusions. The inwardly extending projections on the arms are preferably engaged with the depressions formed in the outer lateral sides of the protrusions. The implant is preferably secured to the inserter head when the projections are seated in the depressions in the outer lateral sides of the protrusions. Once the implant has been secured to the inserter head, the implant dispenser may be decoupled from the implant. Once secured, the posterior part of the implant preferably extends beyond the ends of the arms of the inserter head. The implant dispenser may then be detached from engagement with the implant.

[0105] In certain certain embodiments, the intervertebral disc implant is inserted into a prepared disc space. Referring to FIGS. 68 and 69, the inserter head is properly oriented with the disc space. In certain embodiments, the inserter head includes at least one label or marking that is oriented relative to the superior or inferior vertebral bodies. Preferably, a superior label of the inserter head

is oriented on top and an inferior label is oriented on the bottom. The reference pins are then utilized to guide the inserter head toward the disc space. The guide channels formed at the top and bottom of the inserter head preferably engage the reference pins. Referring to FIG. 69, as the intervertebral disc is advanced toward the disc space, the implant protrusions are preferably aligned with the protrusion channels previously formed in the endplates. In certain embodiments, fluoroscopy is utilized to check the angle of insertion of the implant. The inserter head is preferably advanced toward the disc space until the four arms of the inserter head come into contact with the anterior surfaces of the vertebral bones.

[0106] Referring to FIG. 70, a T-handle 496 (FIG. 31) may then be rotated for advancing a pusher rod 494 which pushes the implant off the distal end of the inserter head. This procedure is shown and described above with respect to the description of FIGS. 33A-35B. FIG. 35B shows pusher rod 494 decoupling intervertebral disc 100 from the distal end of inserter head 474.

[0107] In certain embodiments, the T-handle may be rotated approximately three or four turns for advancing the intervertebral disc implant 100 into the disc space. The proximal end of the handle for the inserter head may be impacted to ensure that the intervertebral disc implant continues into the disc space as the four arms of the inserter head remain in contact with the vertebral bodies. FIG. 71 shows further advancement of the intervertebral disc implant into the disc space. In certain embodiments, immediately prior to insertion of the intervertebral disc implant, the disc space may be distracted approximately 2 mm wider than the base plates of the implant to facilitate insertion. The distraction may result from the grooves on the inserter head being angled relative to one another, as described above in certain preferred embodiments.

[0108] Referring to FIG. 72, insertion is completed when the implant is fully disengaged from the inserter head and the posterior faces of the anterior walls of the intervertebral disc's top and bottom elements are in contact with the anterior surfaces of the superior and inferior vertebral bodies. The anterior/posterior positioning of the implant and the baseplate size are preferably confirmed to be satisfactory using fluoroscopy. Referring to FIG. 73, if more posterior positioning of either the top element or the bottom element of the intervertebral disc implant is required, a tamp such as that shown and described above in FIG. 36A may be utilized for adjusting the position of the implant. In certain embodiments, the tamp may be impacted to adjust the anterior/posterior depth of the top and bottom elements of the implant. The anterior walls of the top and bottom elements serve as vertebral body stops to prevent the implant from being impacted too far posteriorly. After final insertion and adjustments have been completed, the posterior faces of the anterior walls should be flush with the anterior faces of the respective vertebral bodies.

[0109] Referring to FIG. 72, once all relevant tests have been performed to ensure that the intervertebral disc is properly positioned within the disc space, the reference pins may be removed. A biocompatible material, such as a small amount of bone wax, may be applied to the reference pin openings remaining in the anterior surfaces of the superior and inferior vertebral bodies.

[0110] Referring to FIGS. 75A and 75B, an intraoperative lateral and anterior/posterior image of the implant is preferably obtained to observe its final position. If the implant is not properly positioned, it may be removed such as by using the extractor shown and described above in FIGS. 37A-37D. In FIG. 74, a hook of the extractor is engaged with an anterior wall of a top element of the intervertebral disc implant. Once it has been confirmed that the intervertebral disc is properly positioned within the disc space, a standard surgical closure procedure for anterior spinal surgery may be performed. Prior to discharge from the hospital, a lateral and anterior/posterior X-ray with the patient in the standing and/or sitting position is preferred.

[0111] Following surgery, in certain embodiments, a goal of post-operative rehabilitation is to return the patient to normal activity as soon as possible without jeopardizing soft and hard tissue healing. Preferably, the patient should wear a soft collar for approximately 1-2 weeks to support healing of the incision. The patient's rehabilitation program may be modified under the direction of a surgeon to take into consideration the patient's age, stage of healing, general health, physical condition, lifestyle, and activity goals. Adherence to a recommended rehabilitation program is highly desirable.

[0112] Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the scope of the present invention as defined by the appended claims.

INDUSTRIAL APPLICABILITY

[0113] The present invention has applicability in the medical arts.

Claims

1. A template (154) for marking score lines on a spinal segment including a superior vertebral body, an inferior vertebral body and a disc between the superior and inferior vertebral bodies, said template comprising:

   a shaft (160) having a proximal end and a distal end;

   a template marker (164) provided at the distal end of said shaft, said template marker compris-

ing a structure including:

a first vertical arm (166),
a second vertical arm (168) that extends away from said first arm (166), said first (166) and second (168) vertical arms being aligned with one another along a first axis,

chracterized in that said structure is cruciform-shaped and also includes :

a first lateral arm (170),
a second lateral arm (172) extending away from said first lateral arm (170), said first (170) and second (172) lateral arms being aligned with one another along a second axis, wherein distal surfaces of said first (170) and second (172) lateral arms form a concave curved surface that conforms to an anterior surface of the disc between the superior and inferior vertebral bodies.

2. The template (154) as claimed in claim 1, further comprising a central pin (174) provided at said distal end of said shaft (160) for being inserted into the disc.

3. The template (154) as claimed in claim 1, further comprising a plurality of pins extending along the lateral arms for being inserted into the disc.

4. The template (154) as claimed in claim 2, wherein said vertical arms and said lateral arms (170,172) spread outwardly from said distal end of said shaft (160).

5. The template (154) as claimed in claim 1, wherein said first vertical arm (166) includes a first distally extending tack (176) for engaging an anterior surface of the first vertebral body and said second vertical arm (168) includes a second distally extending tack (178) for engaging an anterior surface of the second vertebral body.

Patentansprüche

1. Schablone (154) zum Markieren von Schneidriefen auf einem Wirbelsäulensegment, welches einen oberen Wirbelkörper, einen unteren Wirbelkörper und eine Bandscheibe zwischen dem oberen und dem unteren Wirbelkörper umfasst, wobei die Schablone folgendes umfasst:

- einen Schaft (160) mit einem proximalen Ende und einem distalen Ende;
- eine Schablonenmarker (164), die an dem distalen Ende des Schaftes angeordnet ist, wobei die Schablonenmarker eine Struktur umfasst mit

- einem ersten vertikalen Arm (166),
- einem zweiten vertikalen Arm (168), der sich von dem ersten Arm (166) weg erstreckt, wobei der erste (166) und der zweite (168) vertikale Arm entlang einer ersten Achse miteinander fluchtend ausgerichtet sind,

dadurch gekennzeichnet, dass die Struktur kreuzförmig ist und ferner umfasst:

- einen ersten lateralen Arm (170),
- einen zweiten lateralen Arm (172), der sich von dem ersten lateralen Arm (170) weg erstreckt, wobei der erste (170) und der zweite (172) laterale Arm entlang einer zweiten Achse miteinander fluchtend angeordnet sind, wobei distale Oberflächen des ersten (170) und zweiten (172) lateralen Arms eine konkav gekrümmte Oberfläche bilden, die an eine vordere Oberfläche der Bandscheibe zwischen dem oberen und dem unteren Wirbelkörper angepasst ist.

2. Schablone (154) nach Anspruch 1, ferner umfassend einen zentralen Dorn (174), der an dem distalen Ende des Schaftes (160) vorgesehen ist, um in die Bandscheibe eingeführt zu werden.

3. Schablone (154) nach Anspruch 1, ferner umfassend eine Mehrzahl von Dornen, die sich entlang der lateralen Arme erstrecken, um in die Bandscheibe eingeführt zu werden.

4. Schablone (154) nach Anspruch 2, wobei die vertikalen Arme und die lateralen Arme (170, 172) sich von dem distalen Ende des Schaftes (160) nach außen ausbreiten.

5. Schablone (154) nach Anspruch 1, wobei der erste vertikale Arm (166) einen ersten, sich distal erstreckenden Stift (176) für den Eingriff mit einer vorderen Oberfläche des ersten Wirbelkörpers umfasst, und der zweite vertikale Arm (168) einen zweiten, sich distal erstreckenden Stift (178) für den Eingriff mit einer vorderen Oberfläche des zweiten Wirbelkörpers umfasst.

Revendications

1. Gabarit (154) pour marquer des lignes de repère sur un segment vertébral comprenant un corps vertébral supérieur, un corps vertébral inférieur et un disque entre les corps vertébraux supérieur et inférieur, ledit gabarit comprenant :

une tige (160) ayant une extrémité proximale et

une extrémité distale ;
un marqueur de gabarit (164) prévu au niveau de l'extrémité distale de ladite tige, ledit marqueur de gabarit comprenant une structure comprenant :

un premier bras vertical (166),
un second bras vertical (168) qui s'étend à distance dudit premier bras (166), lesdits premier (166) et second (168) bras verticaux étant alignés l'un par rapport à l'autre le long d'un premier axe,

caractérisé en ce que ladite structure est cruciforme et comprend également :

un premier bras latéral (170),
un second bras latéral (172) s'étendant à distance dudit premier bras latéral (170), lesdits premier (170) et second (172) bras latéraux étant alignés l'un par rapport à l'autre le long d'un second axe, dans lequel les surfaces distales desdits premier (170) et second (172) bras latéraux forment une surface incurvée concave qui se conforme à la surface antérieure du disque entre les corps vertébraux supérieur et inférieur.

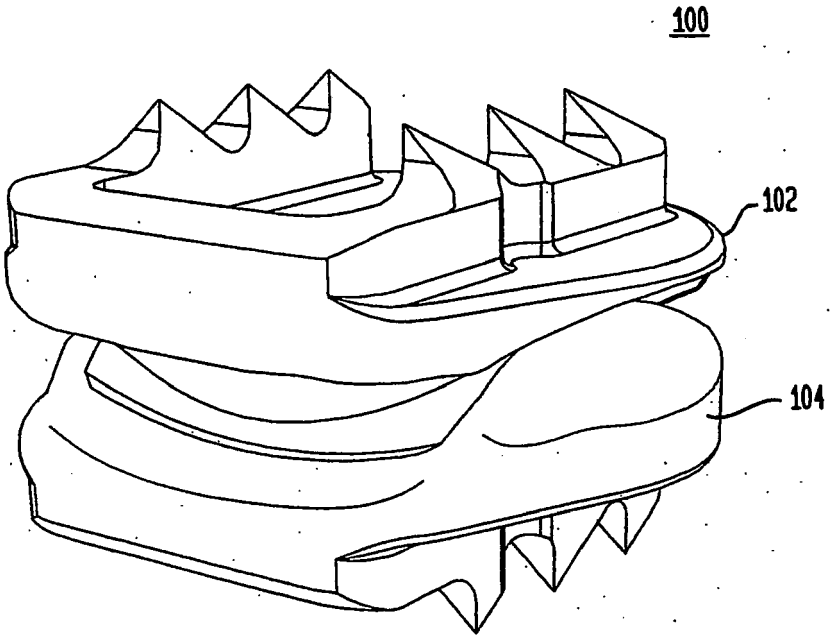
2. Gabarit (154) selon la revendication 1, comprenant en outre une broche centrale (174) prévue au niveau de ladite extrémité distale de ladite tige (160) pour être insérée dans le disque.

3. Gabarit (154) selon la revendication 1, comprenant en outre une pluralité de broches s'étendant le long des bras latéraux pour être insérées dans le disque.

4. Gabarit (154) selon la revendication 2, dans lequel lesdits bras verticaux et lesdits bras latéraux (170, 172) s'écartent vers l'extérieur à partir de ladite extrémité distale de ladite tige (160).

5. Gabarit (154) selon la revendication 1, dans lequel ledit premier bras vertical (166) comprend une première pointe (176) s'étendant de manière distale pour mettre en prise une surface antérieure du premier corps vertébral et ledit second bras vertical (168) comprend une seconde pointe (178) s'étendant de manière distale pour mettre en prise une surface antérieure du second corps vertébral.

FIG. 1



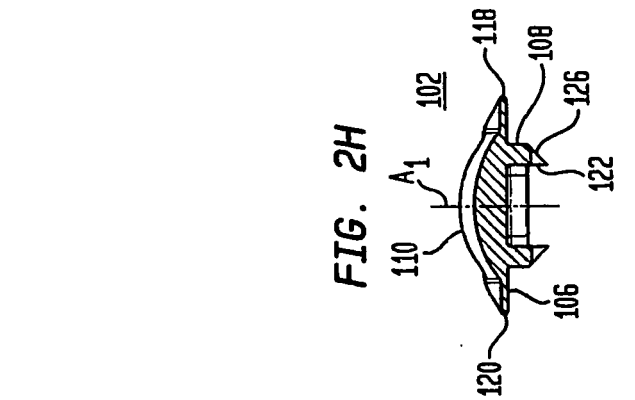


FIG. 2H

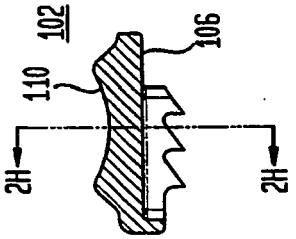


FIG. 2G

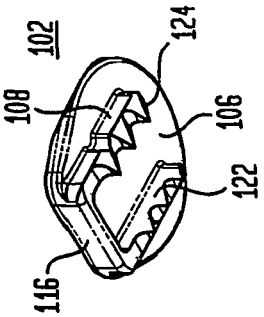


FIG. 2A

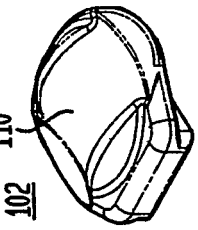


FIG. 2B

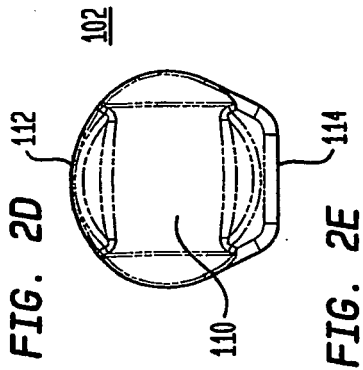


FIG. 2D

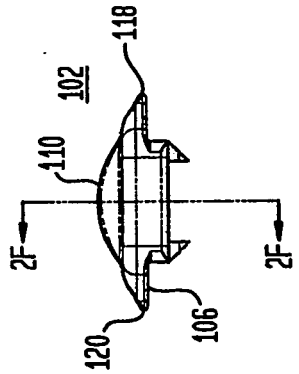


FIG. 2E

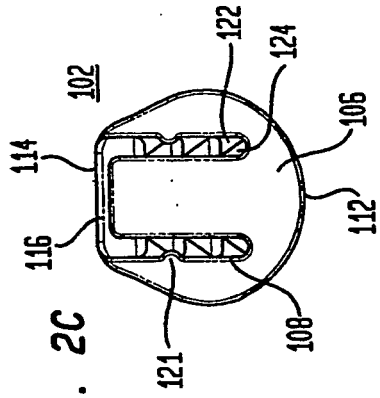


FIG. 2C

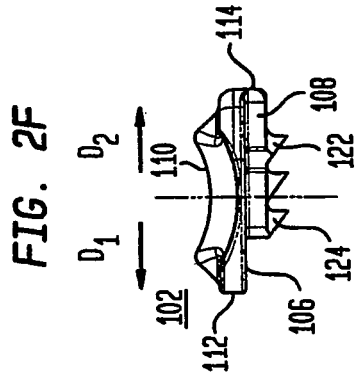
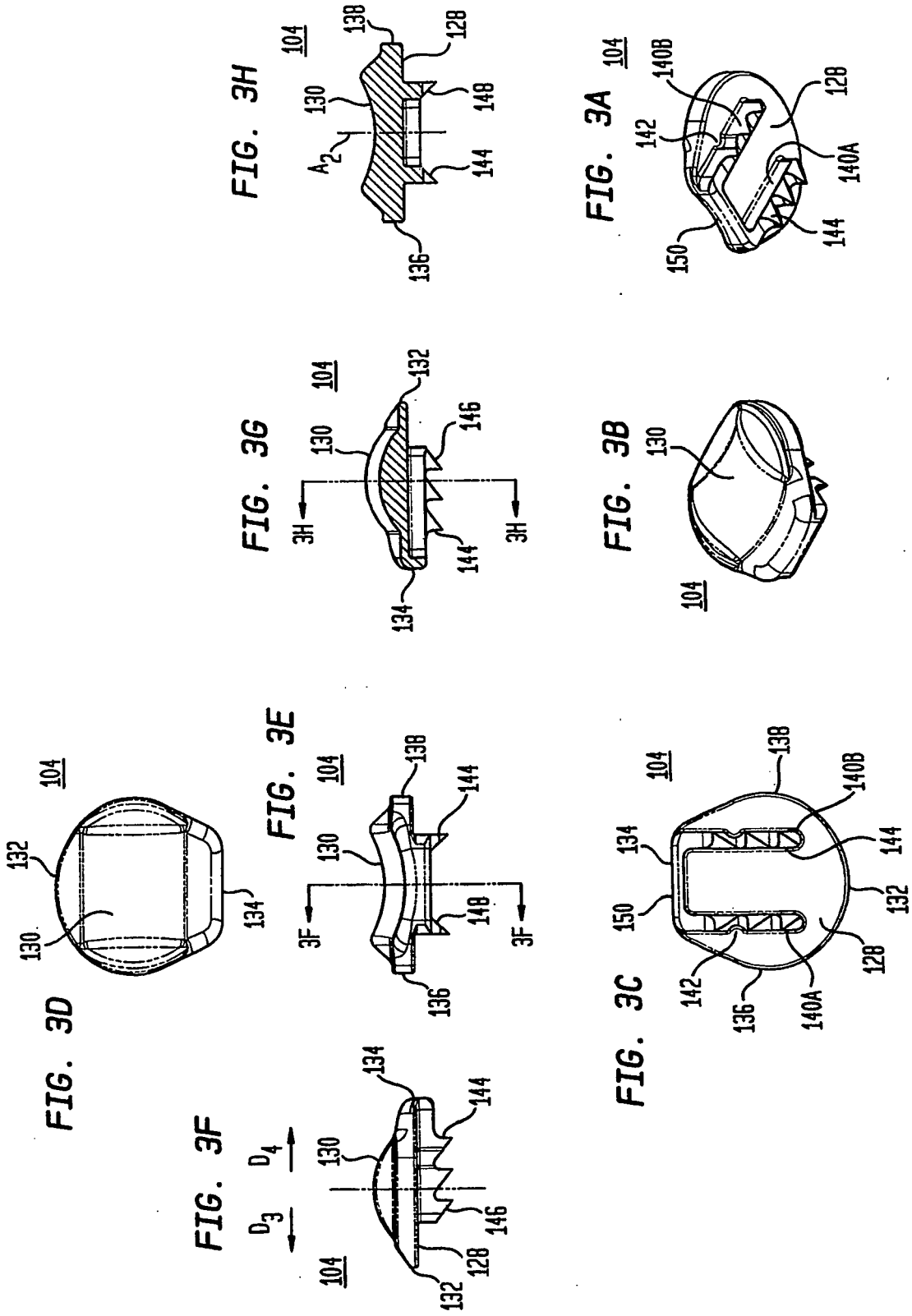


FIG. 2F


FIG. 3H
104
138
128
130
148
A_2
144
136
FIG. 3A
104
140B
128
142
140A
144
150
FIG. 3G
104
132
130
146
3H
3H
144
134
FIG. 3B
130
104
FIG. 3D
104
132
130
134
FIG. 3E
104
138
144
130
3F
3F
148
136
FIG. 3C
104
138
140B
134
144
150
132
128
142
136
140A
FIG. 3F
D_3
D_4
130
134
144
146
104
128
132

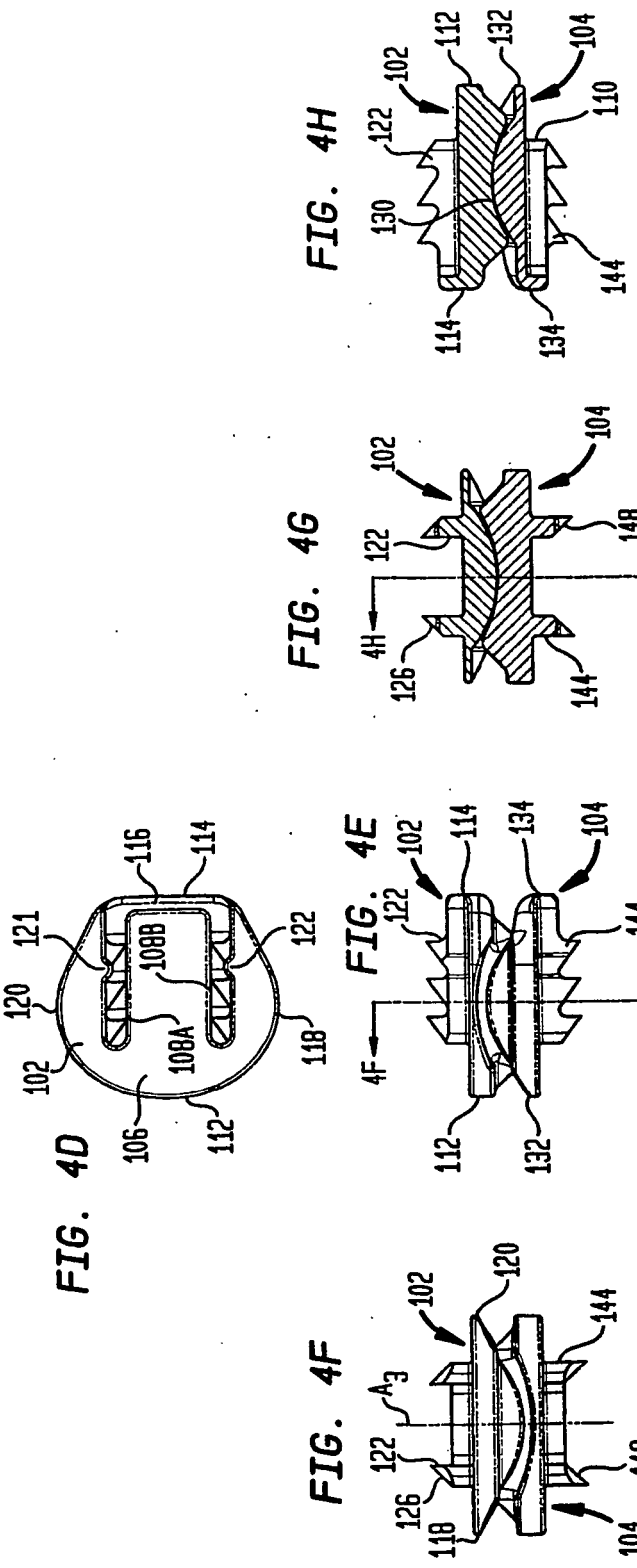

FIG. 4A
100
102
104
FIG. 4B
116
114
134
150
102
104
100
FIG. 4C
134
150
142
136
138
104
140A
132
128
140B
FIG. 4D
116
114
121
108B
122
120
108A
102
118
106
112
FIG. 4E
102
114
134
104
122
144
4F
4F
112
132
FIG. 4F
102
120
A_3
144
122
148
126
118
104
FIG. 4G
102
104
122
148
4H
4H
126
144
FIG. 4H
112
132
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102
110
122
130
144
114
134

FIG. 5

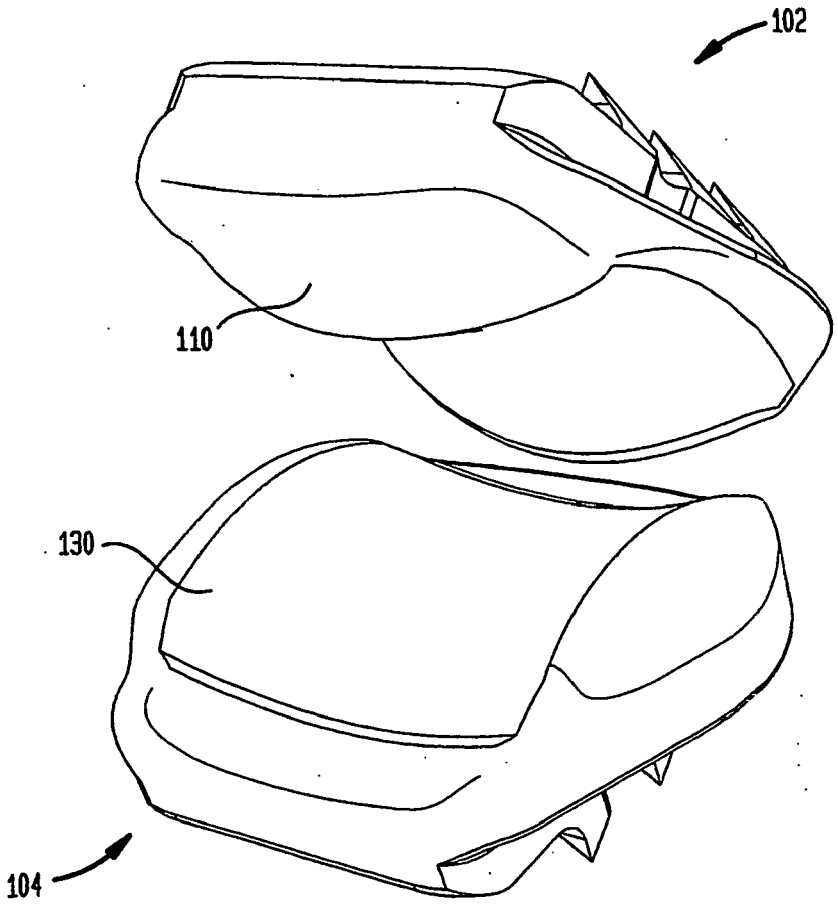


FIG. 6A

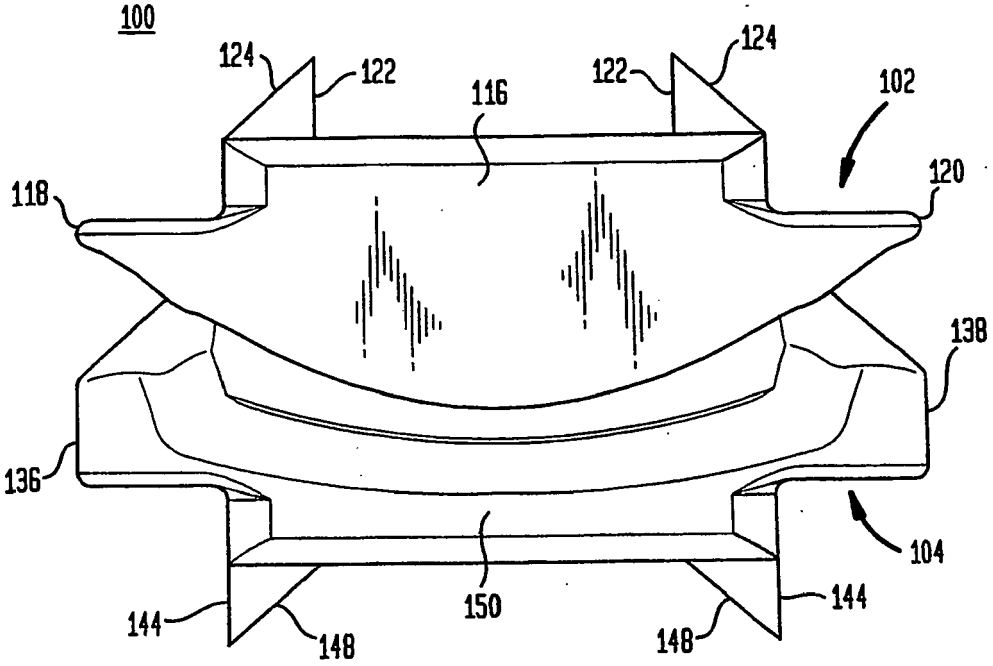
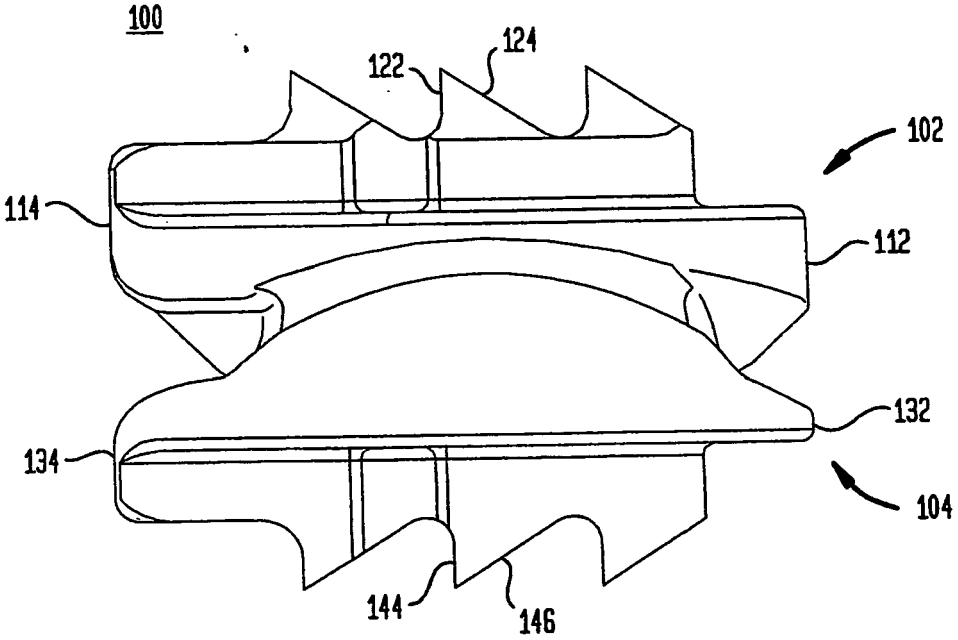

100
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116
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118
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104
144
148
150
148
144

FIG. 6B



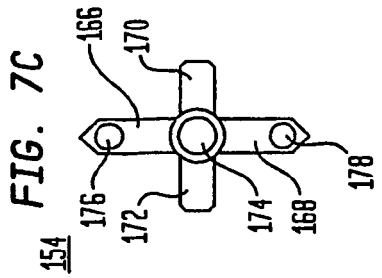


FIG. 7C

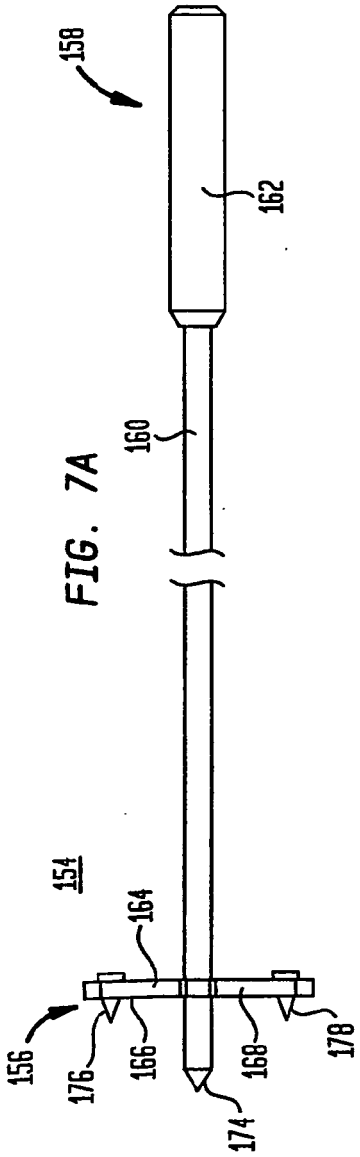


FIG. 7A

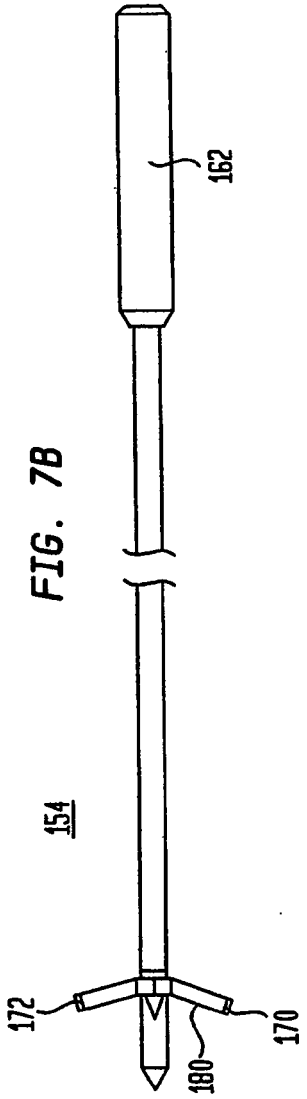


FIG. 7B

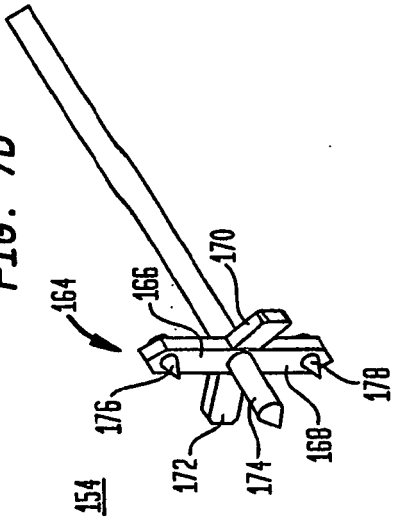


FIG. 7D

FIG. 8D

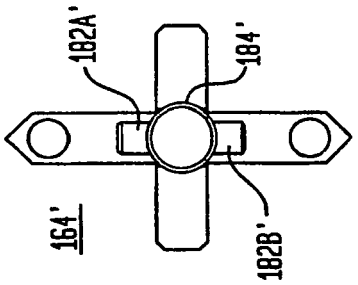


FIG. 8A

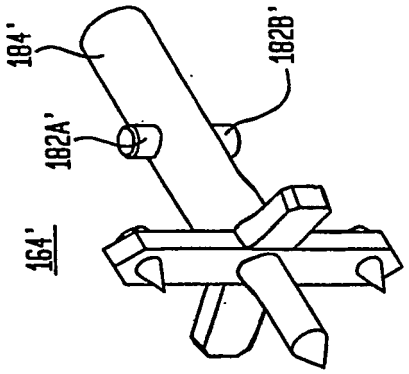


FIG. 8B

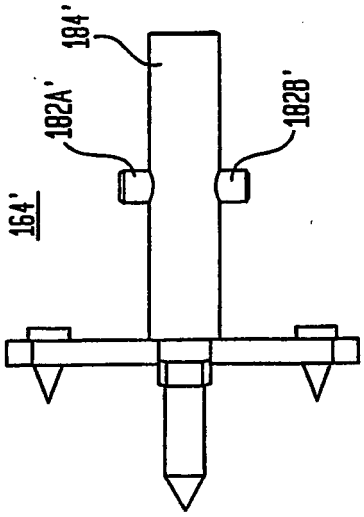
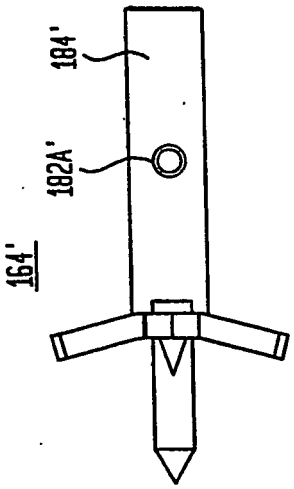


FIG. 8C



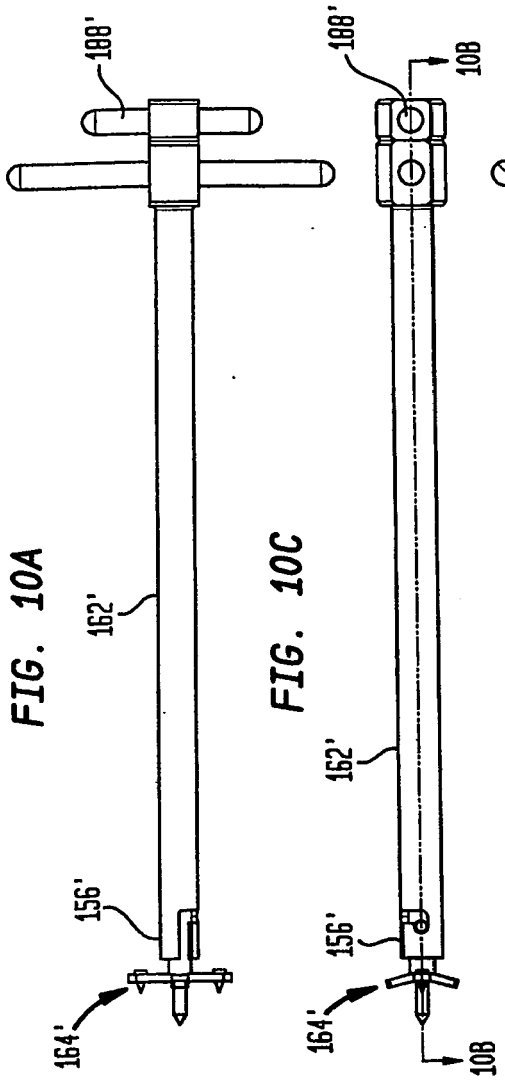


FIG. 10A

FIG. 10C

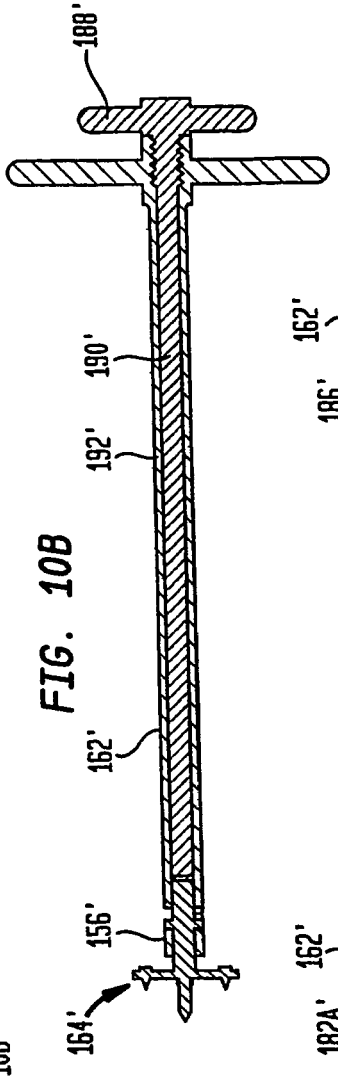


FIG. 10B

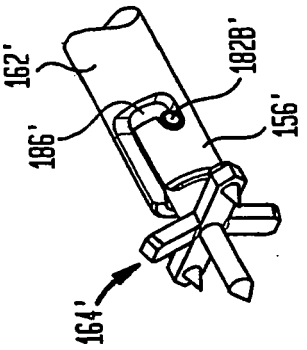


FIG. 9B

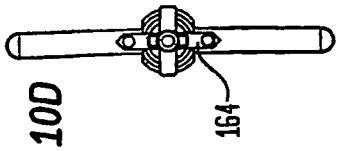


FIG. 10D

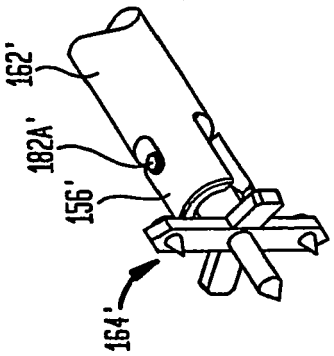


FIG. 9A

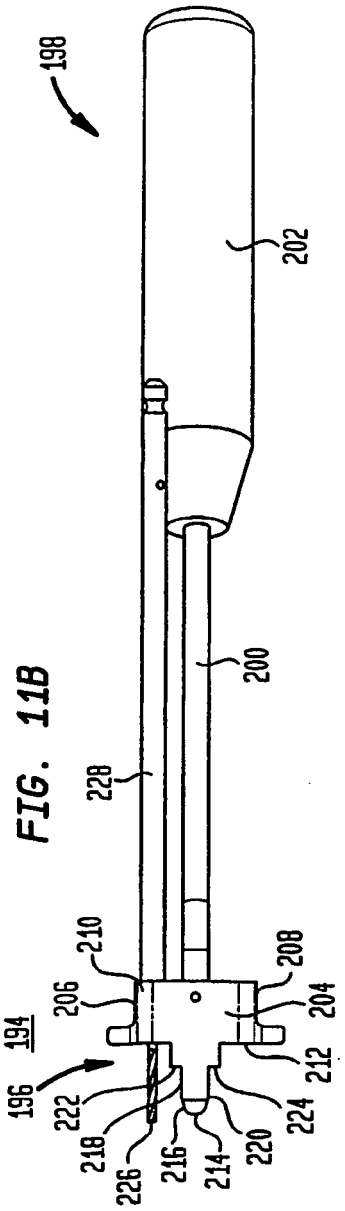


FIG. 11B

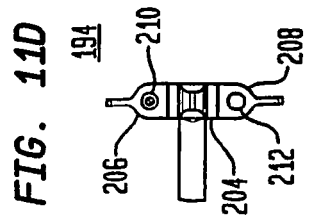


FIG. 11D

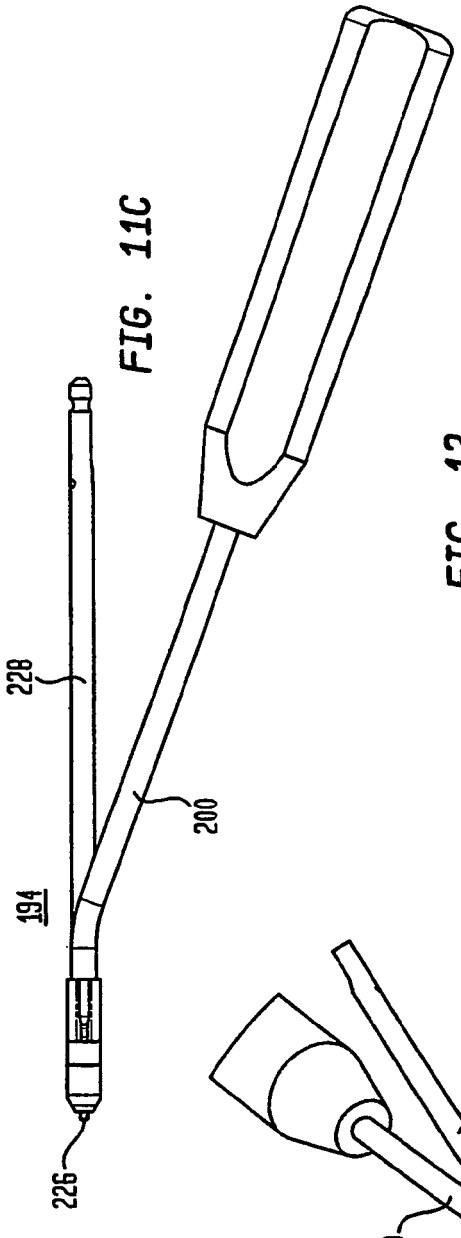


FIG. 11C

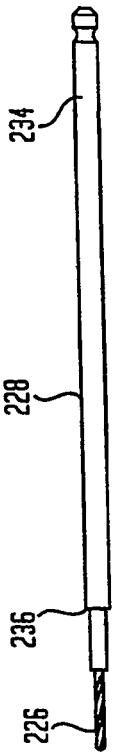


FIG. 12

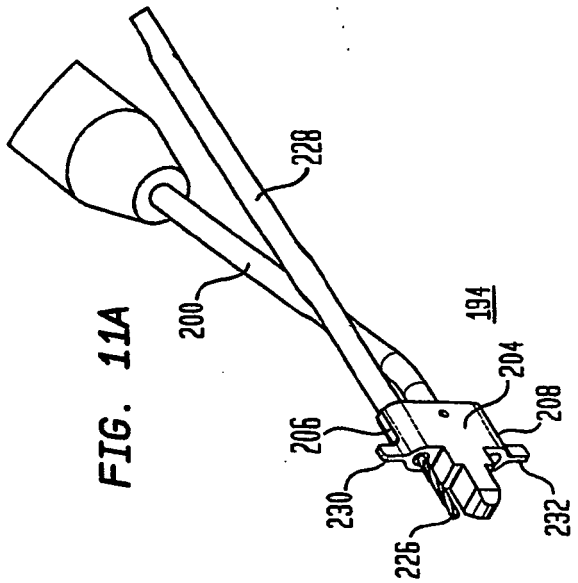


FIG. 11A

FIG. 13A

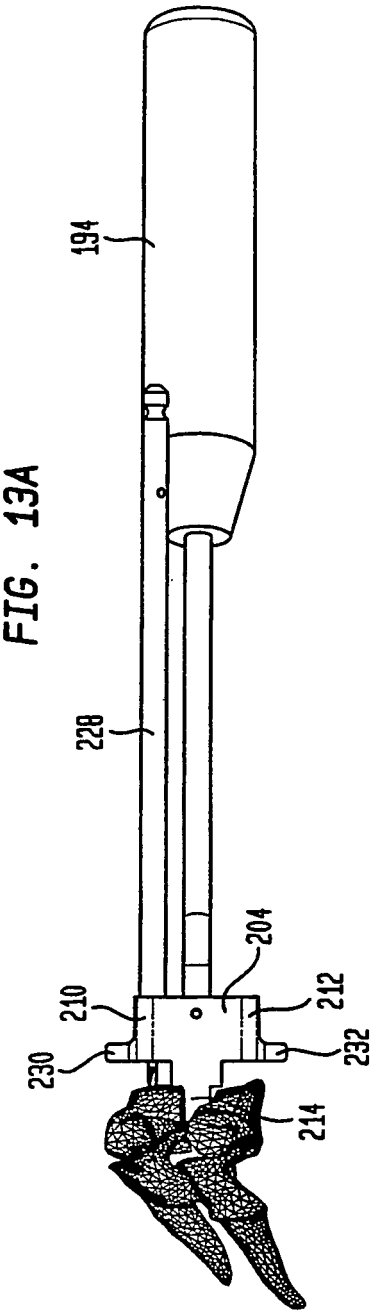
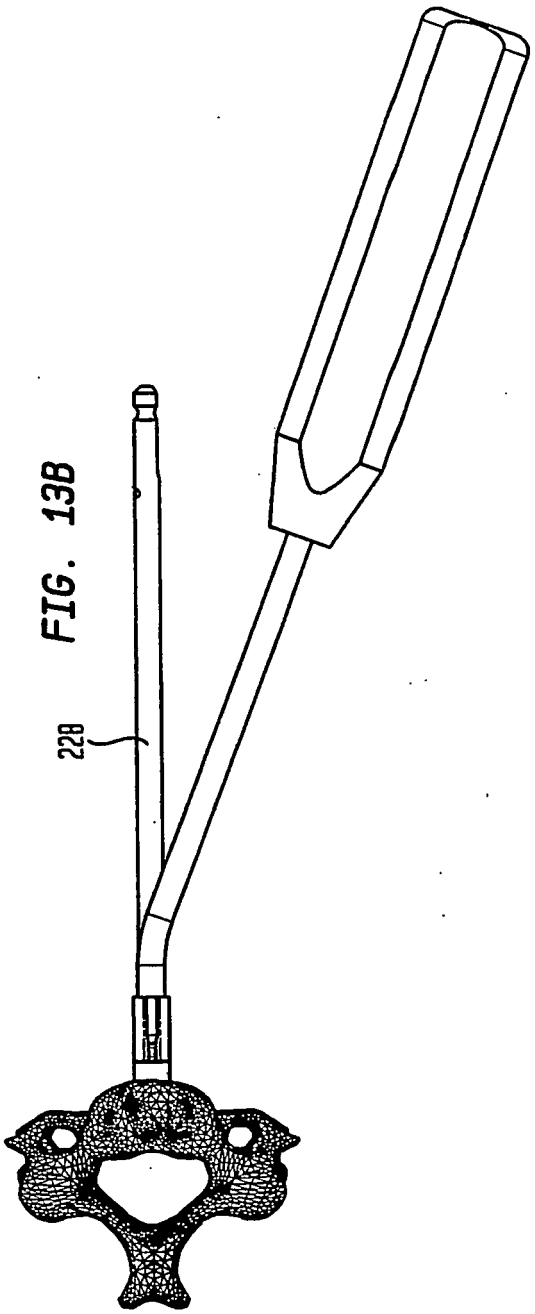


FIG. 13B



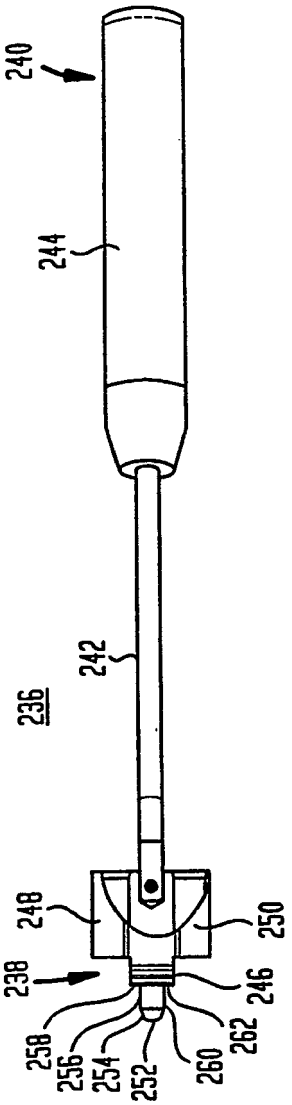


FIG. 14A

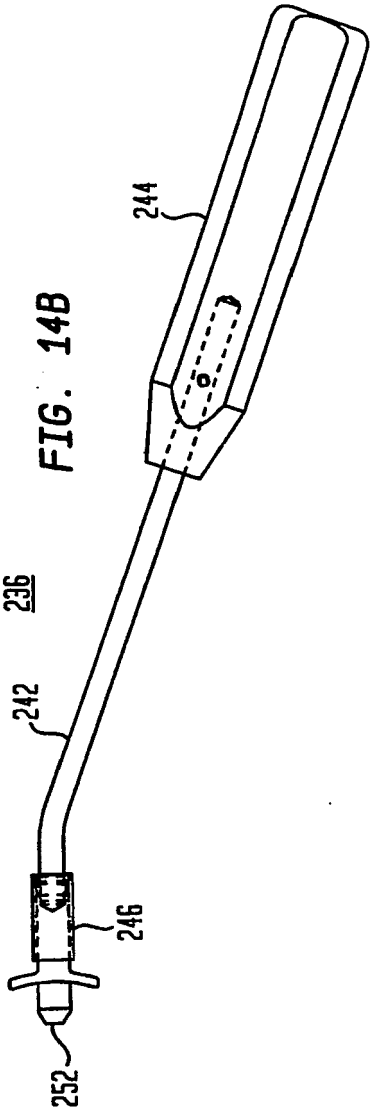


FIG. 14B

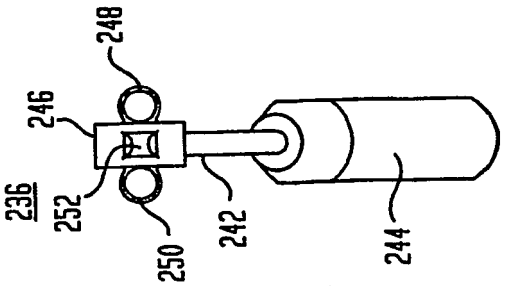


FIG. 14C

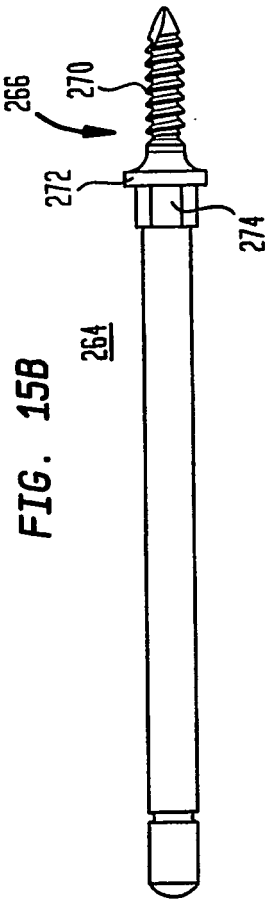


FIG. 15B

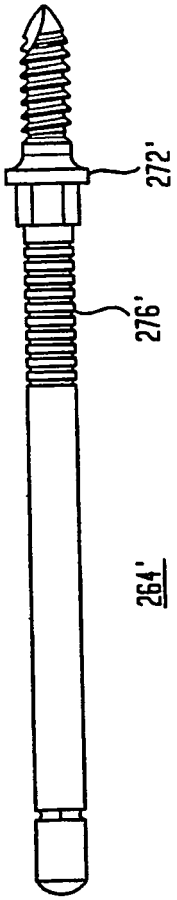


FIG. 16

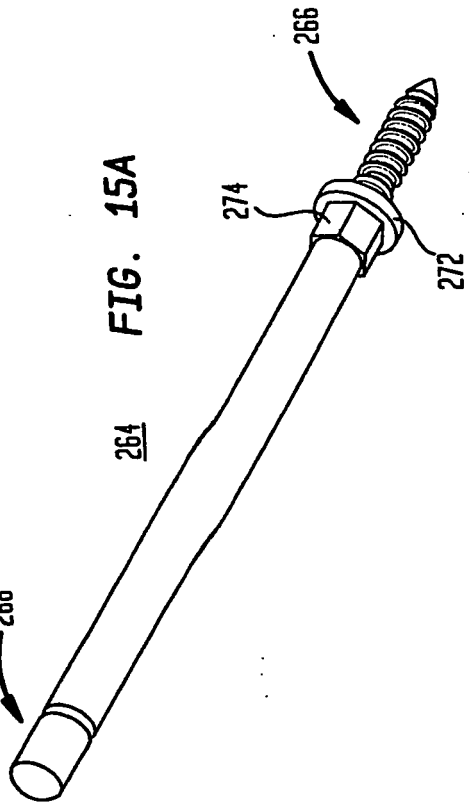


FIG. 15A

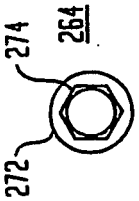


FIG. 15C

FIG. 17C

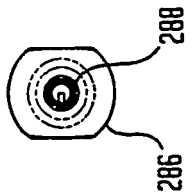


FIG. 17A

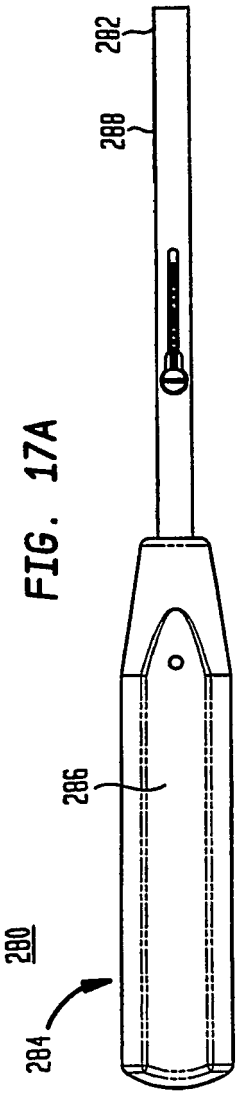


FIG. 17B

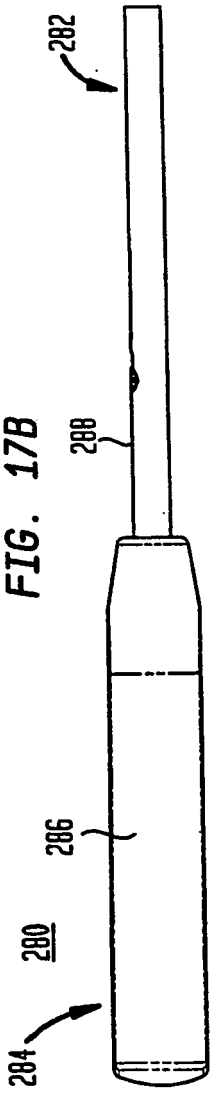


FIG. 18A

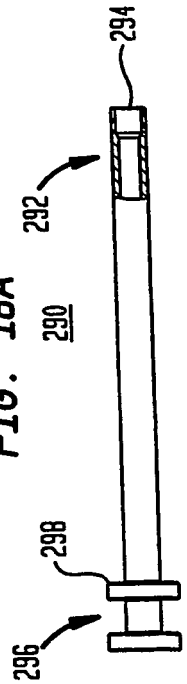


FIG. 18B

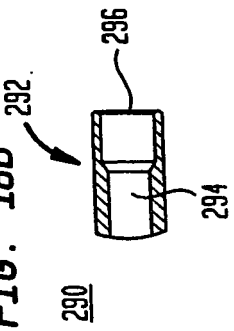


FIG. 19A

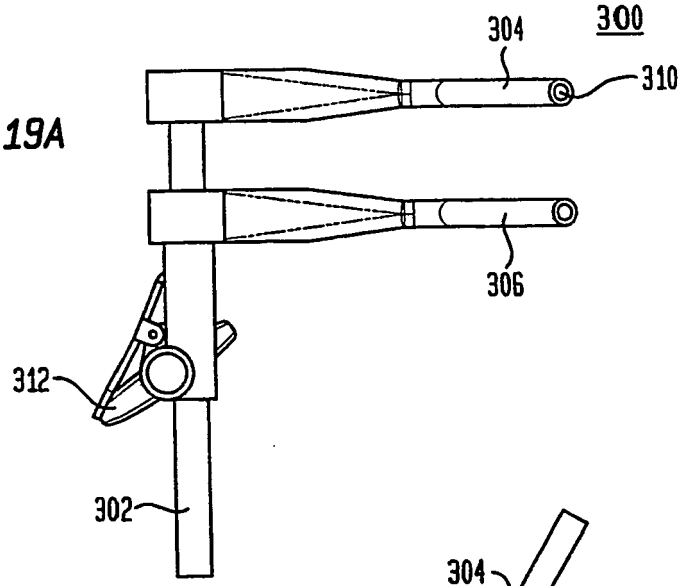


FIG. 19B

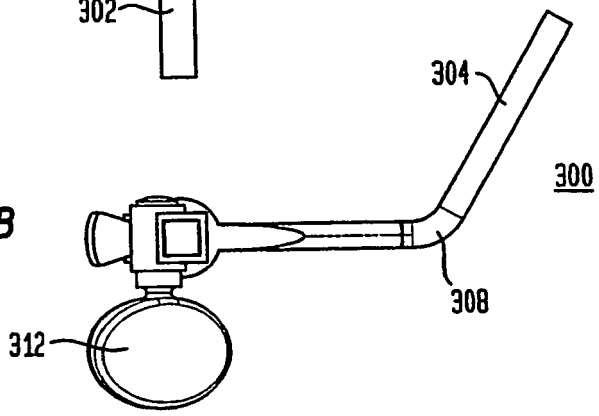
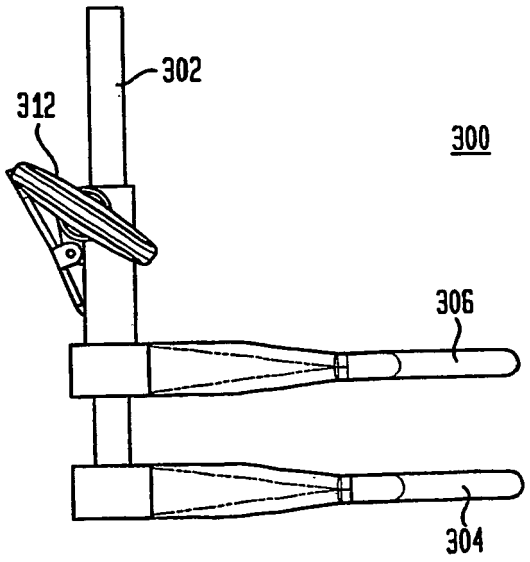


FIG. 19C



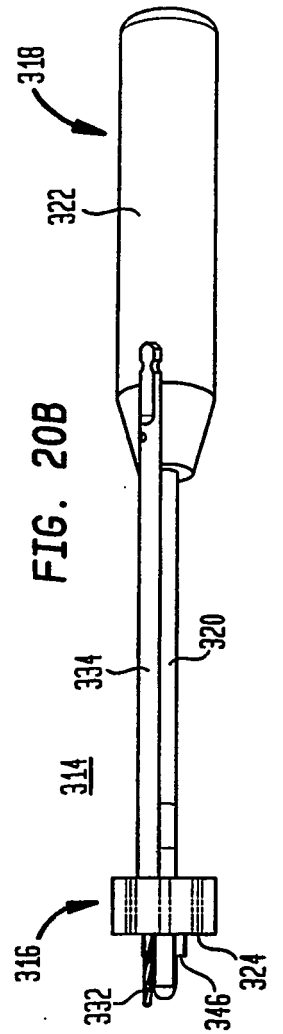


FIG. 20B

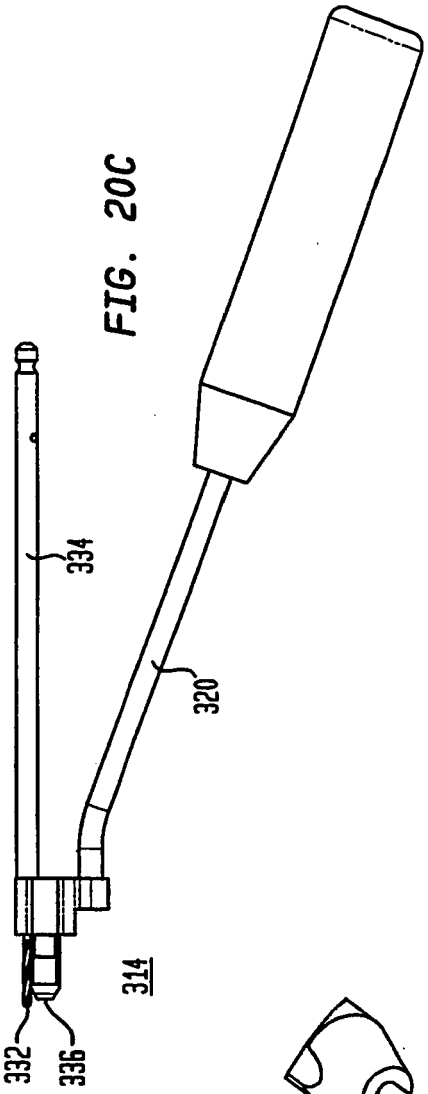


FIG. 20C

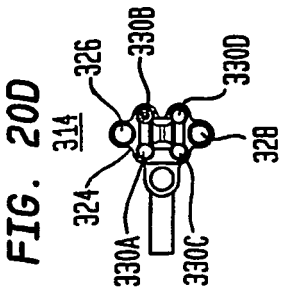


FIG. 20D

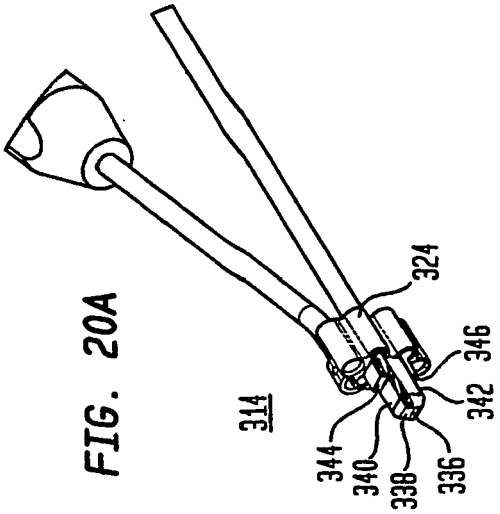


FIG. 20A

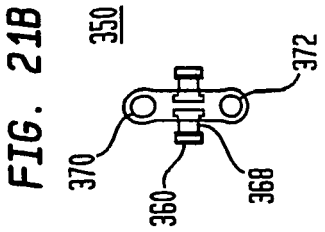


FIG. 21B

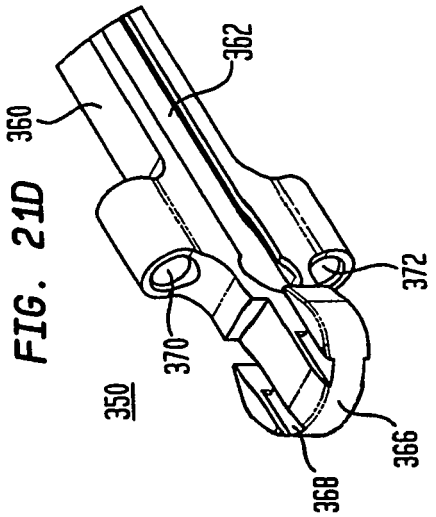


FIG. 21D

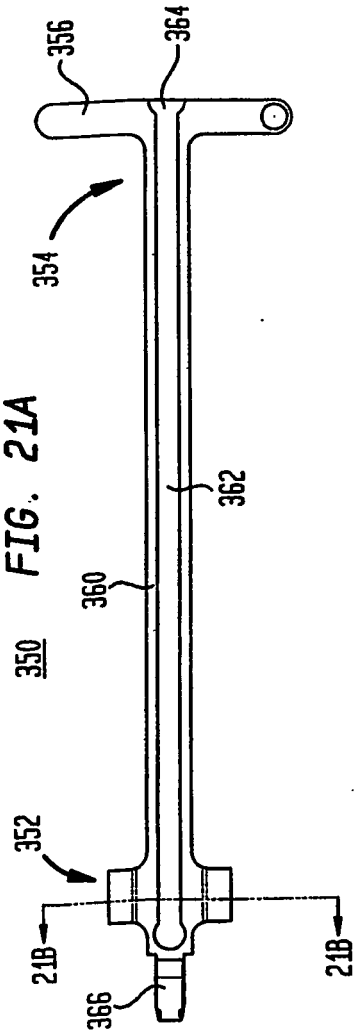


FIG. 21A

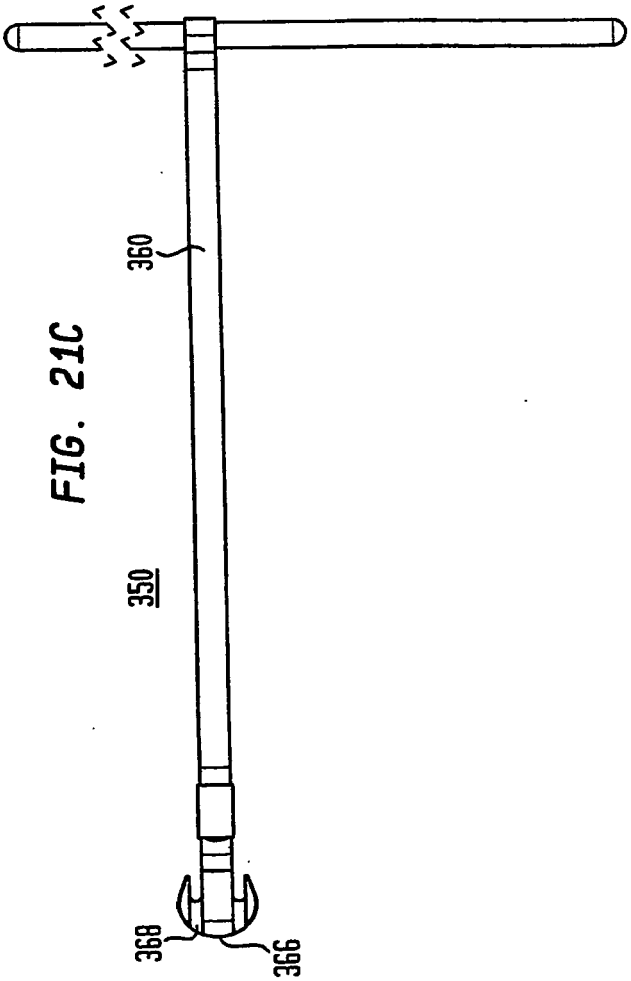


FIG. 21C

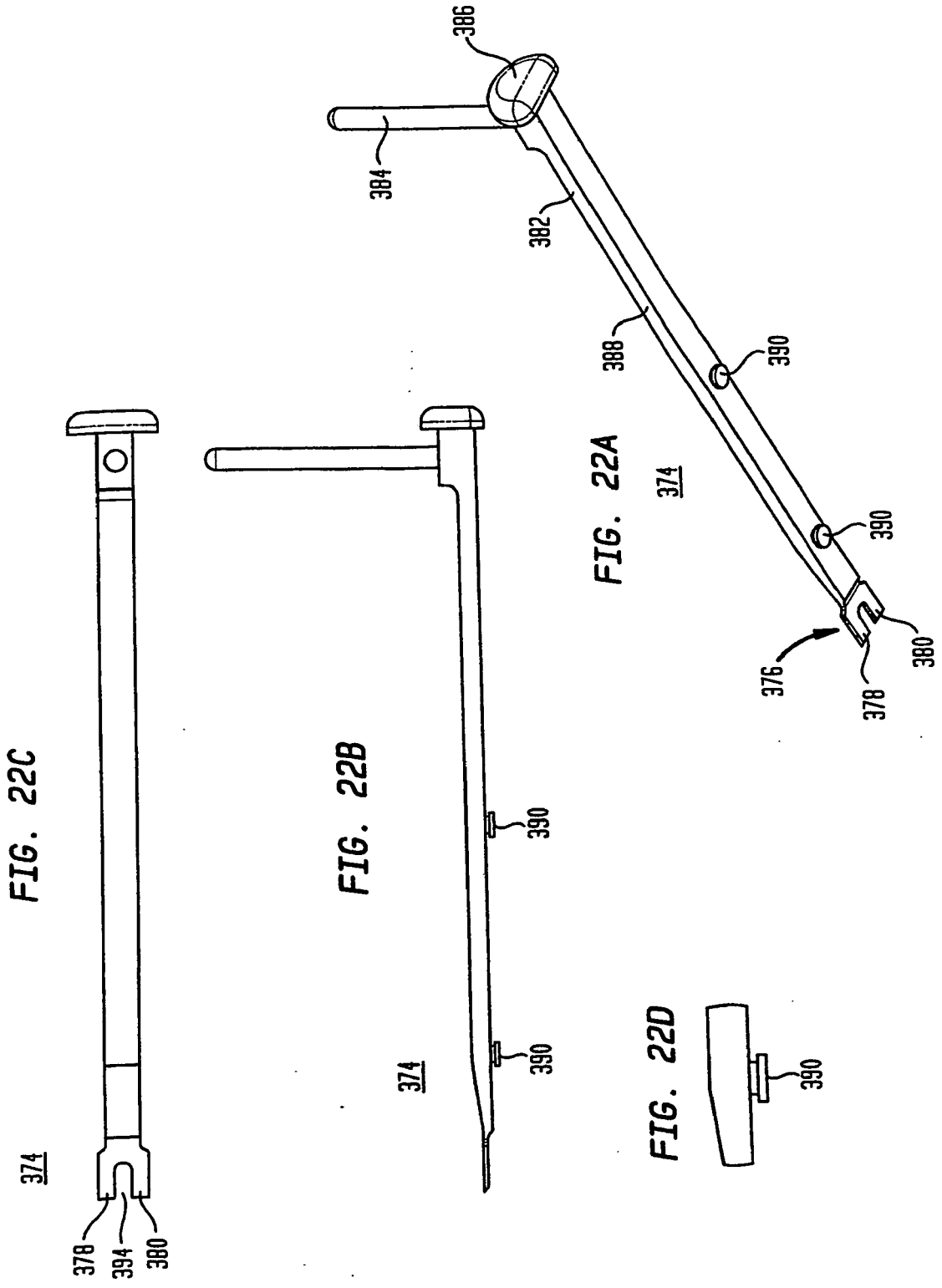


FIG. 22A

FIG. 22B

FIG. 22C

FIG. 22D

FIG. 23

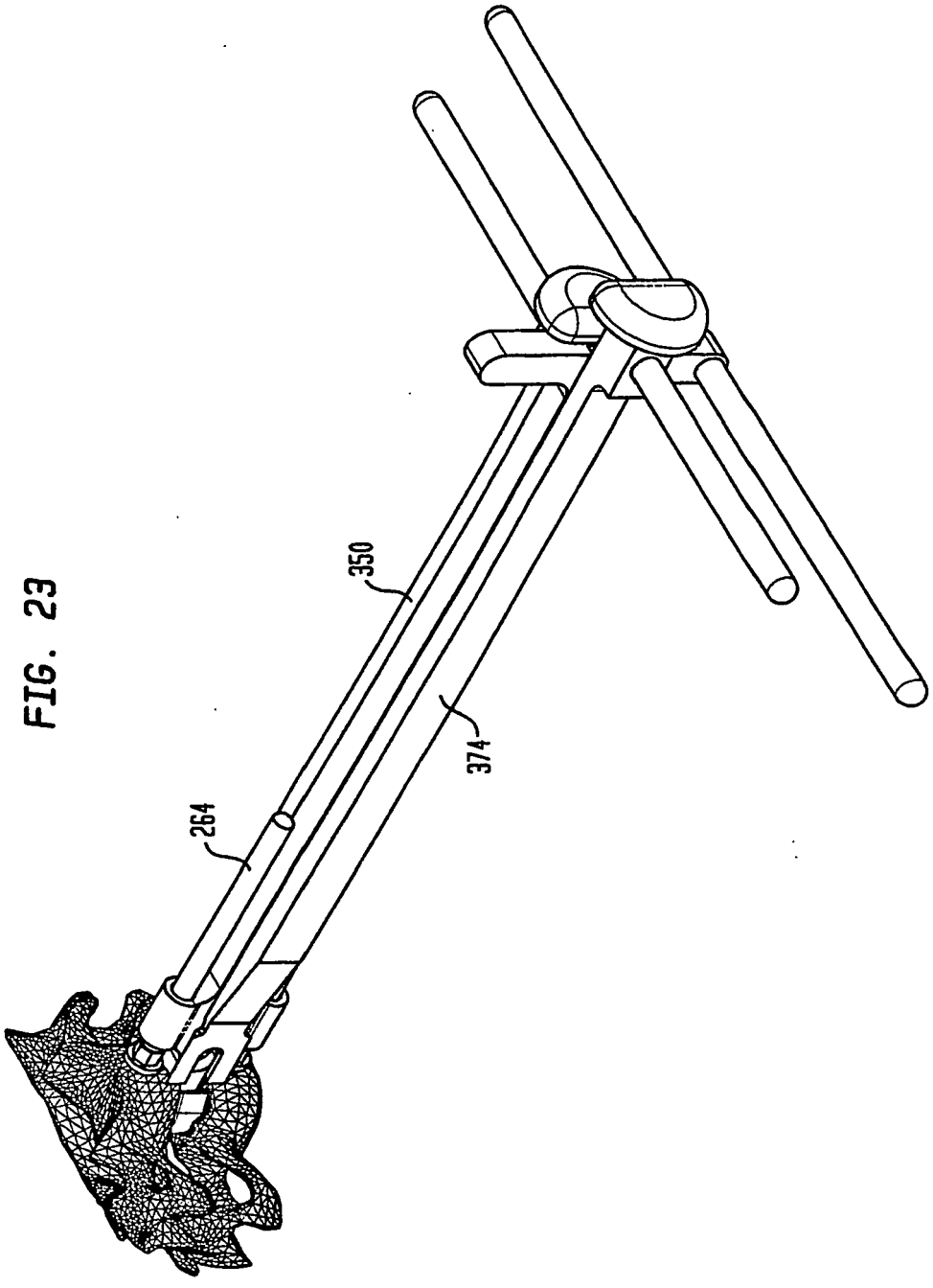


FIG. 24A

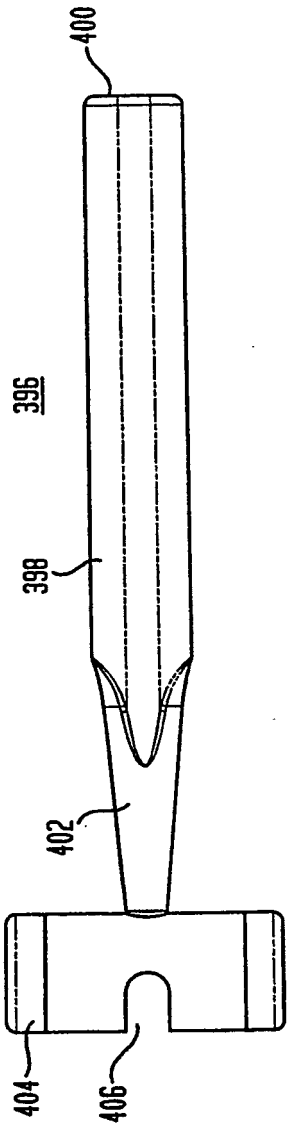


FIG. 24B

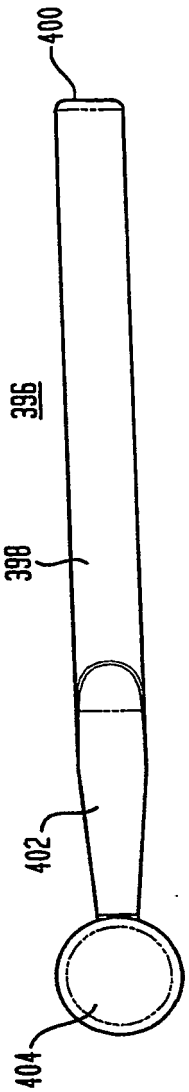


FIG. 25A

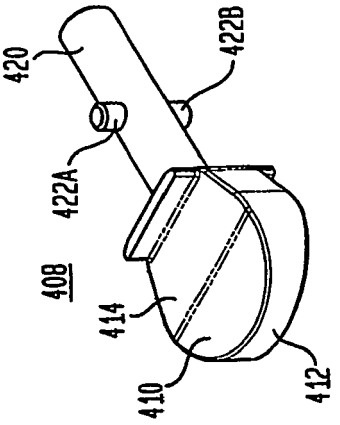


FIG. 25B

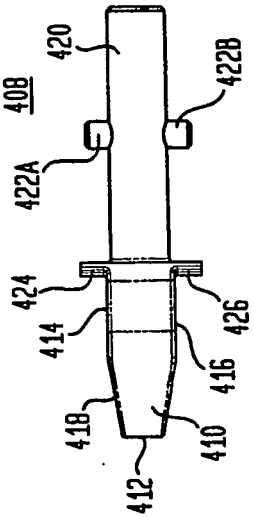


FIG. 25C

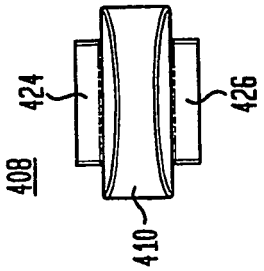
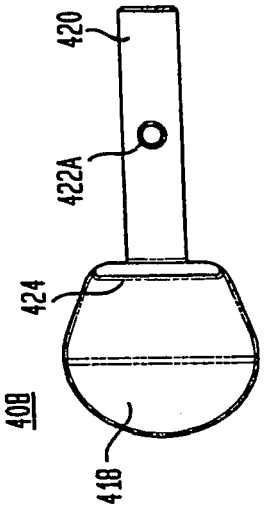
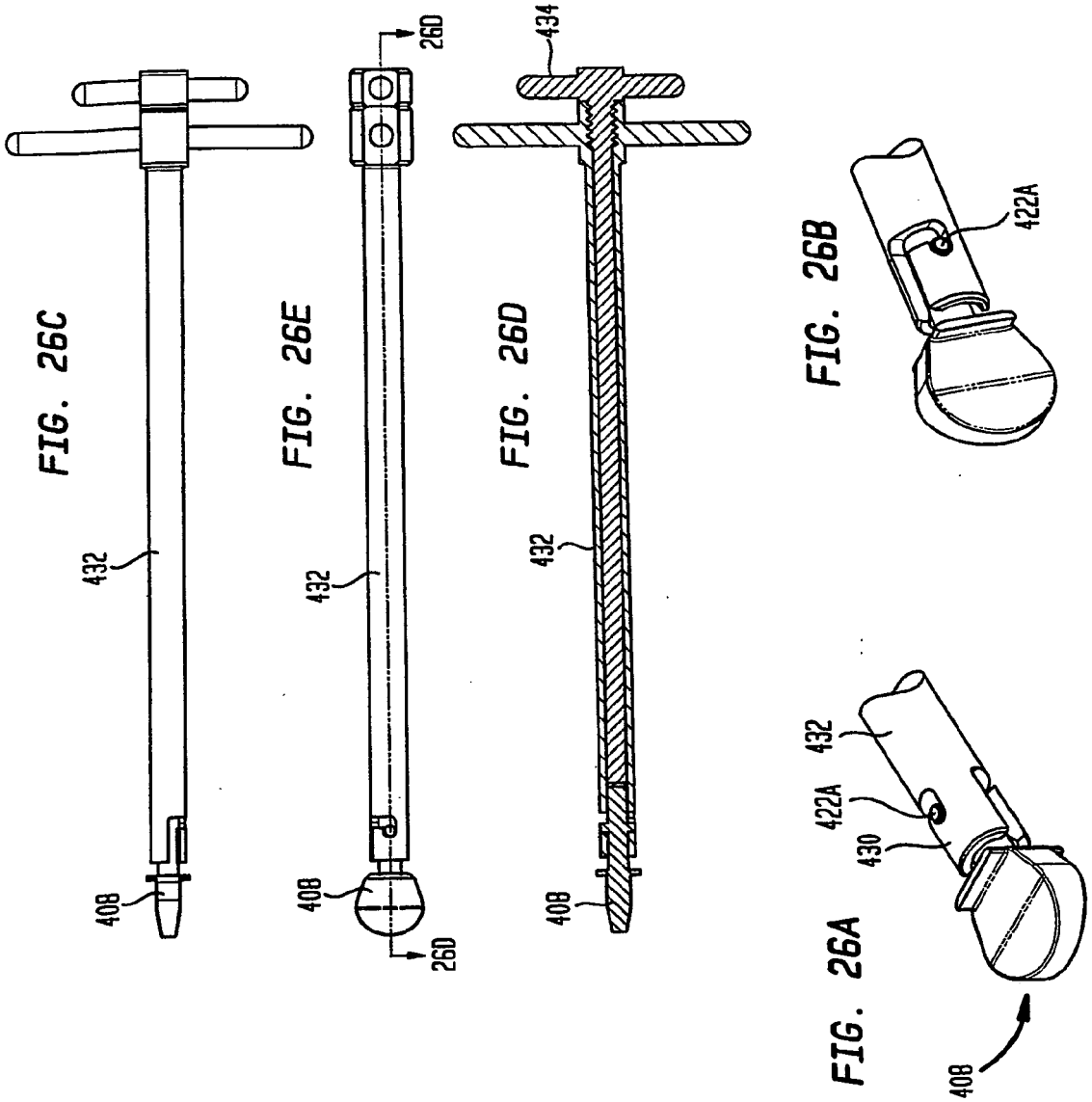


FIG. 25D




FIG. 26C
432
408
FIG. 26E
26D
432
408
26D
FIG. 26D
434
432
408
FIG. 26B
422A
FIG. 26A
432
422A
430
408

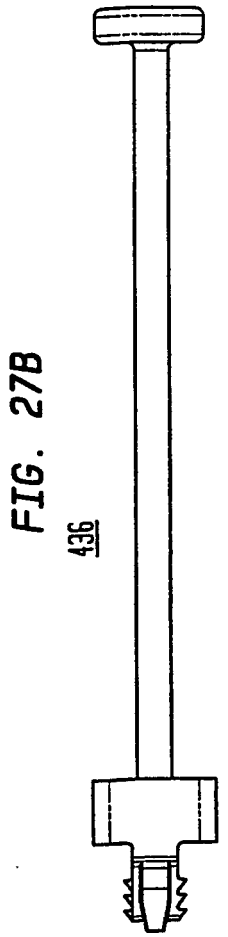


FIG. 27B



FIG. 27C

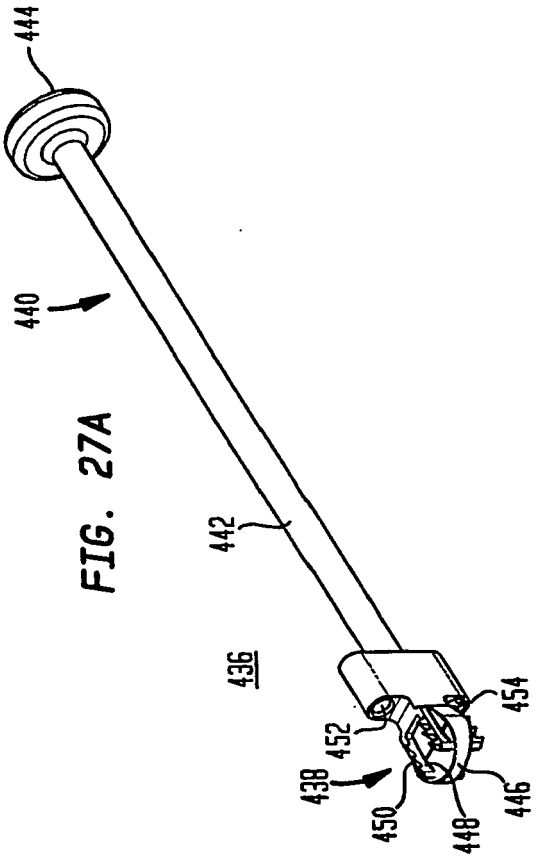


FIG. 27A

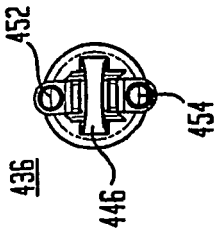


FIG. 27D

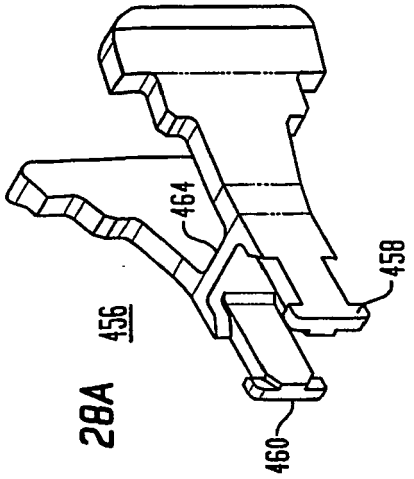


FIG. 28A

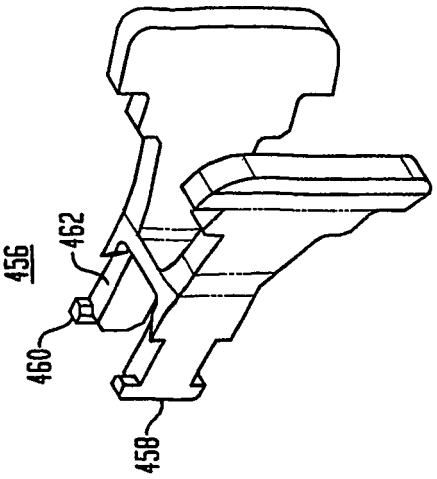


FIG. 28B

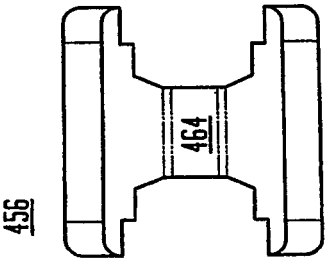


FIG. 28D

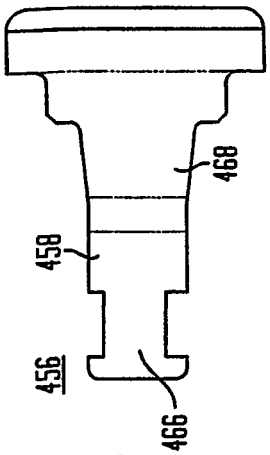


FIG. 28E

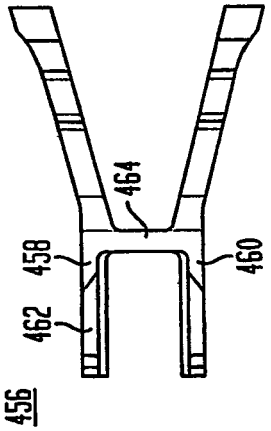


FIG. 28C

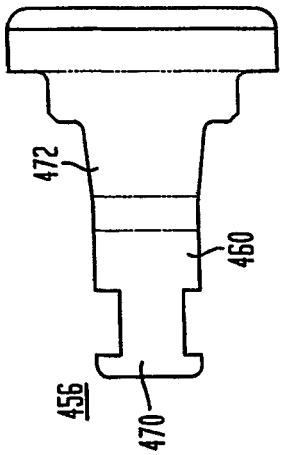


FIG. 28F

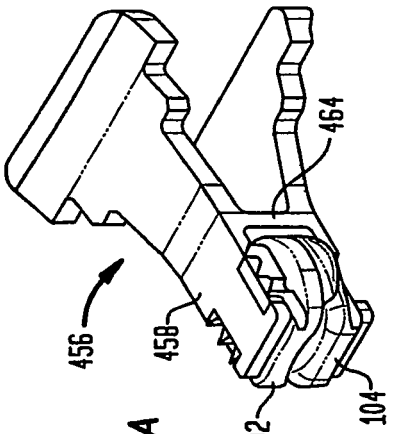


FIG. 29A

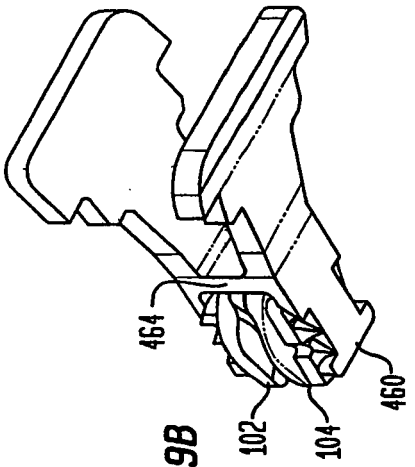


FIG. 29B

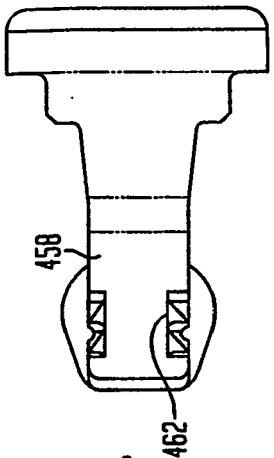


FIG. 29C

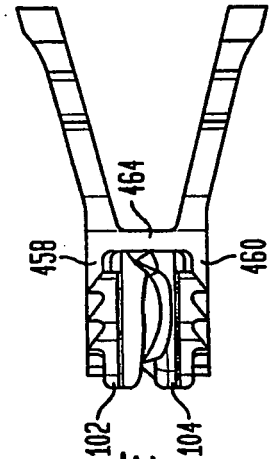


FIG. 29E

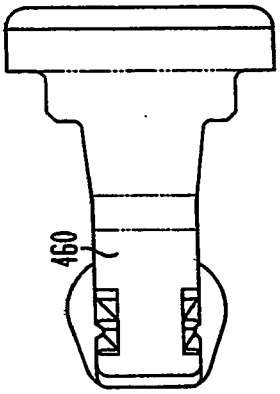


FIG. 29D

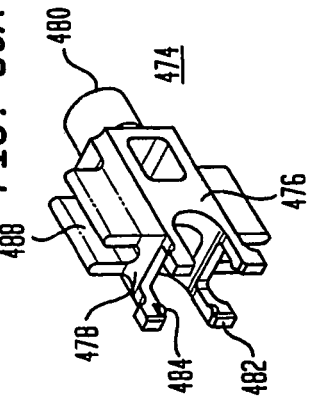


FIG. 30A

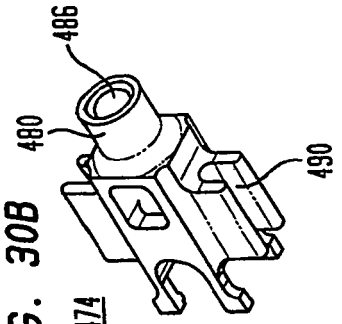


FIG. 30B

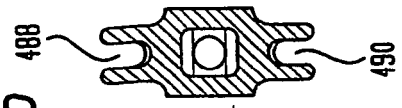


FIG. 30D

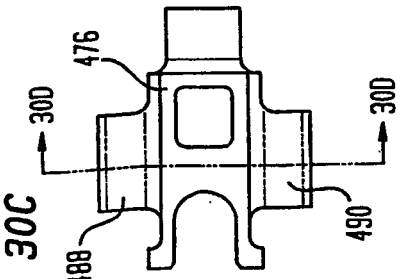


FIG. 30C

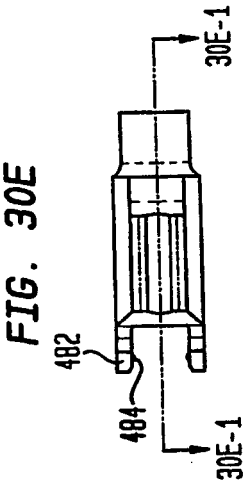


FIG. 30E

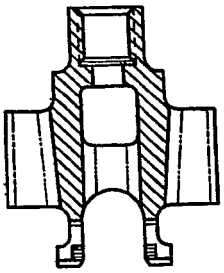


FIG. 30F

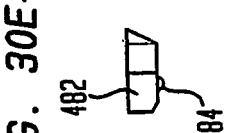


FIG. 30E-1



FIG. 30F-1

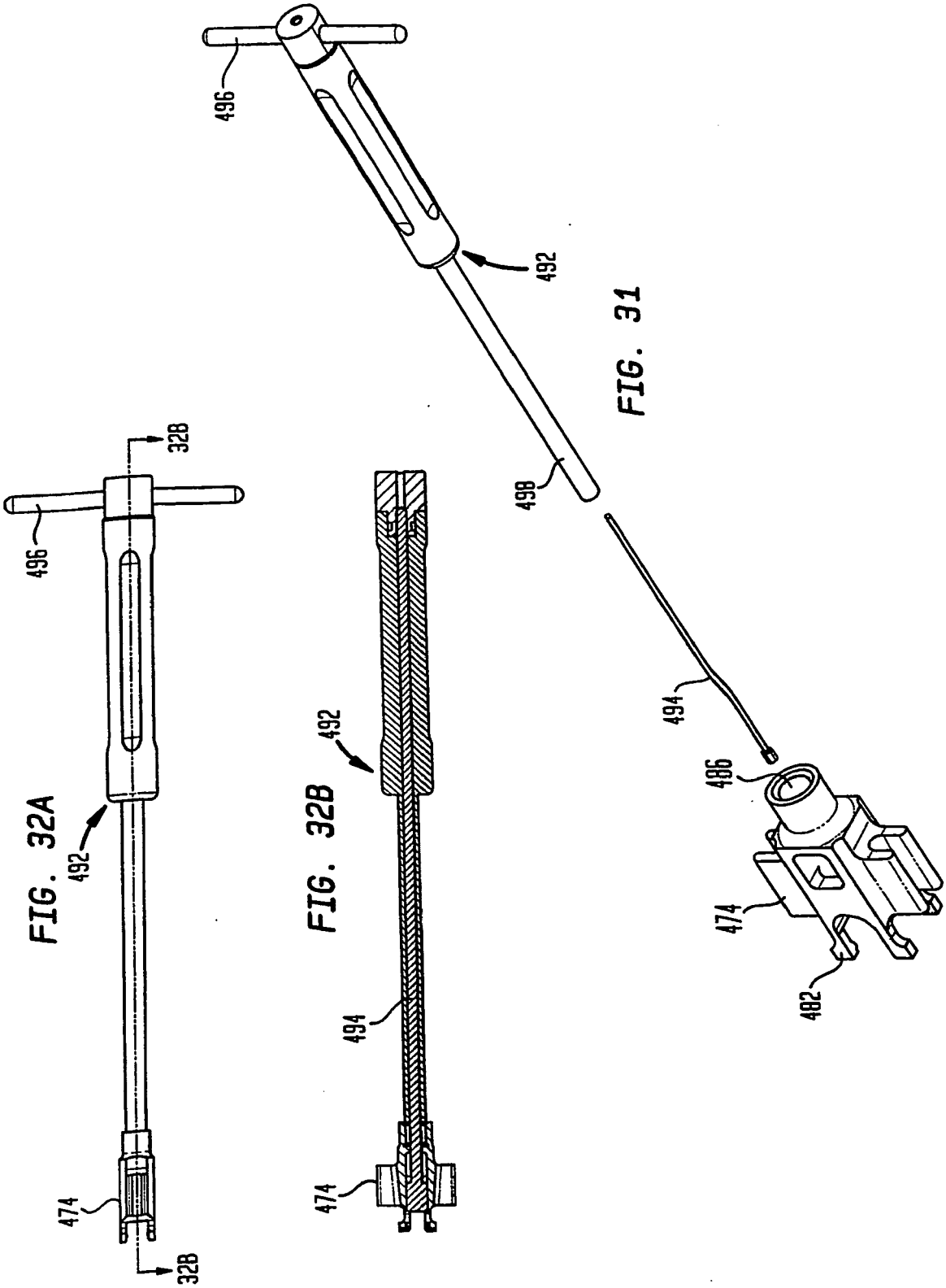

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FIG. 31
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32B
FIG. 32A
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FIG. 32B

FIG. 33B

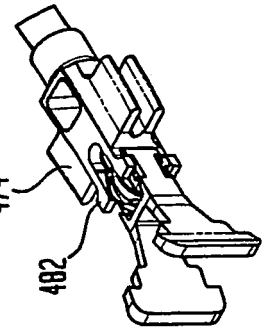


FIG. 34B

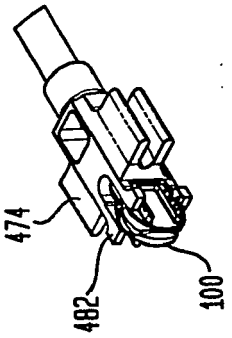


FIG. 35B

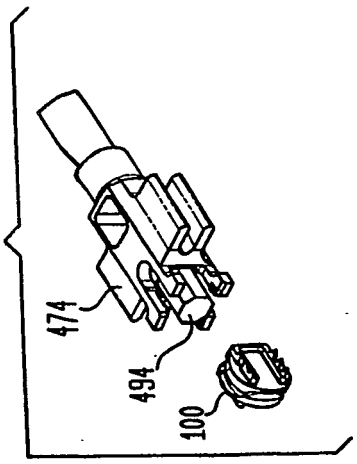


FIG. 33A

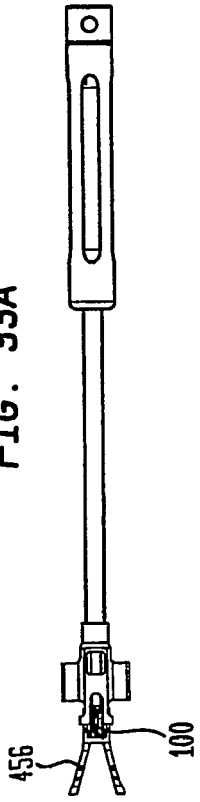


FIG. 34A

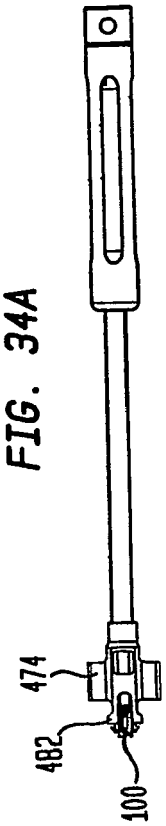
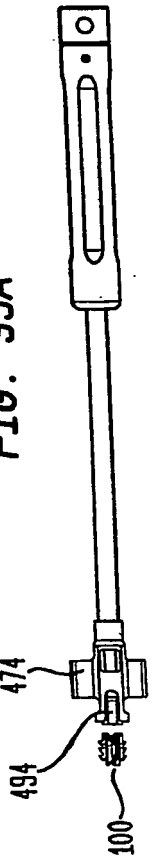


FIG. 35A



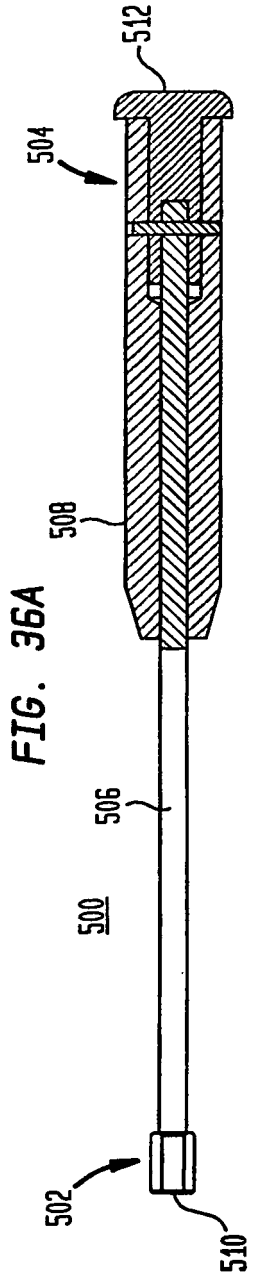


FIG. 36A

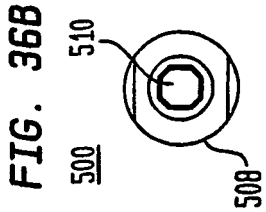


FIG. 36B

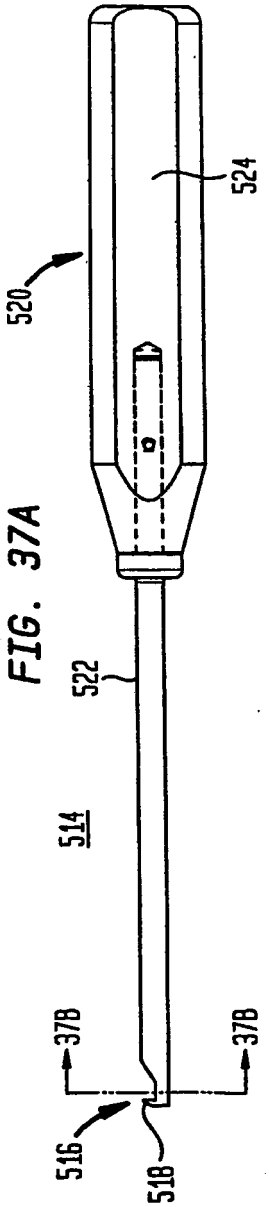


FIG. 37A

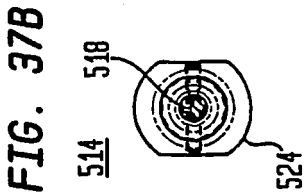


FIG. 37B

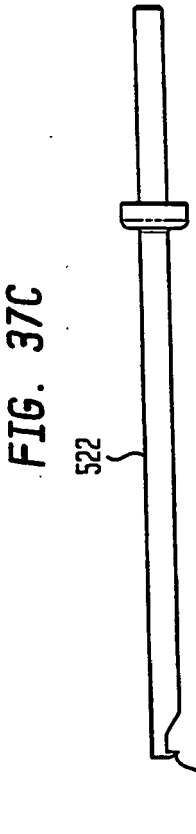


FIG. 37C

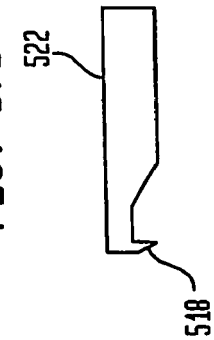


FIG. 37D

FIG. 38



FIG. 39

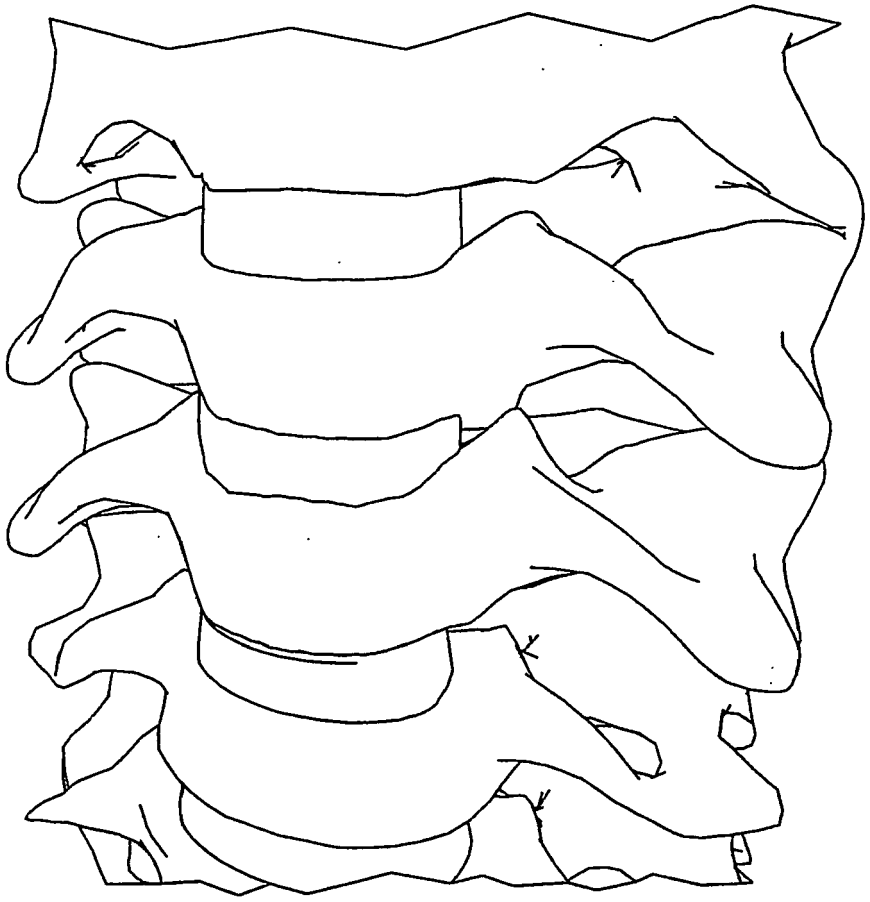


FIG. 40

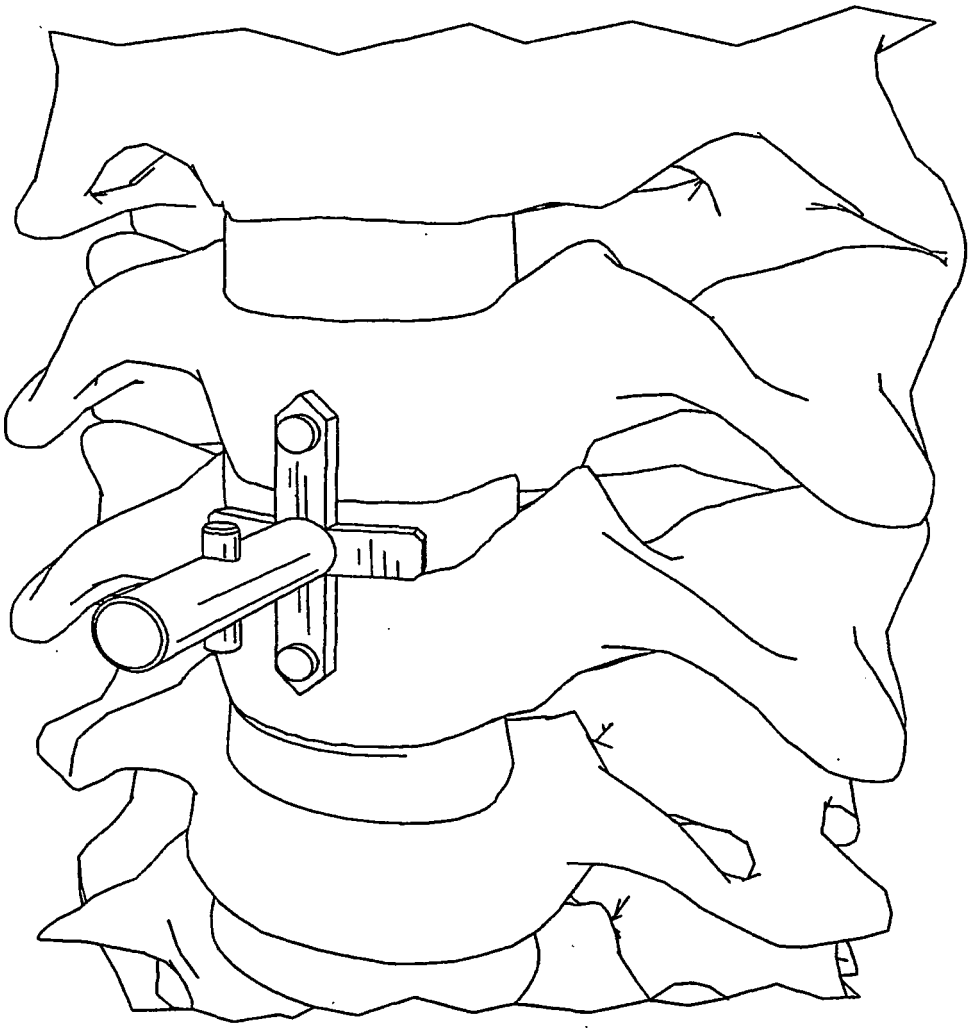


FIG. 41

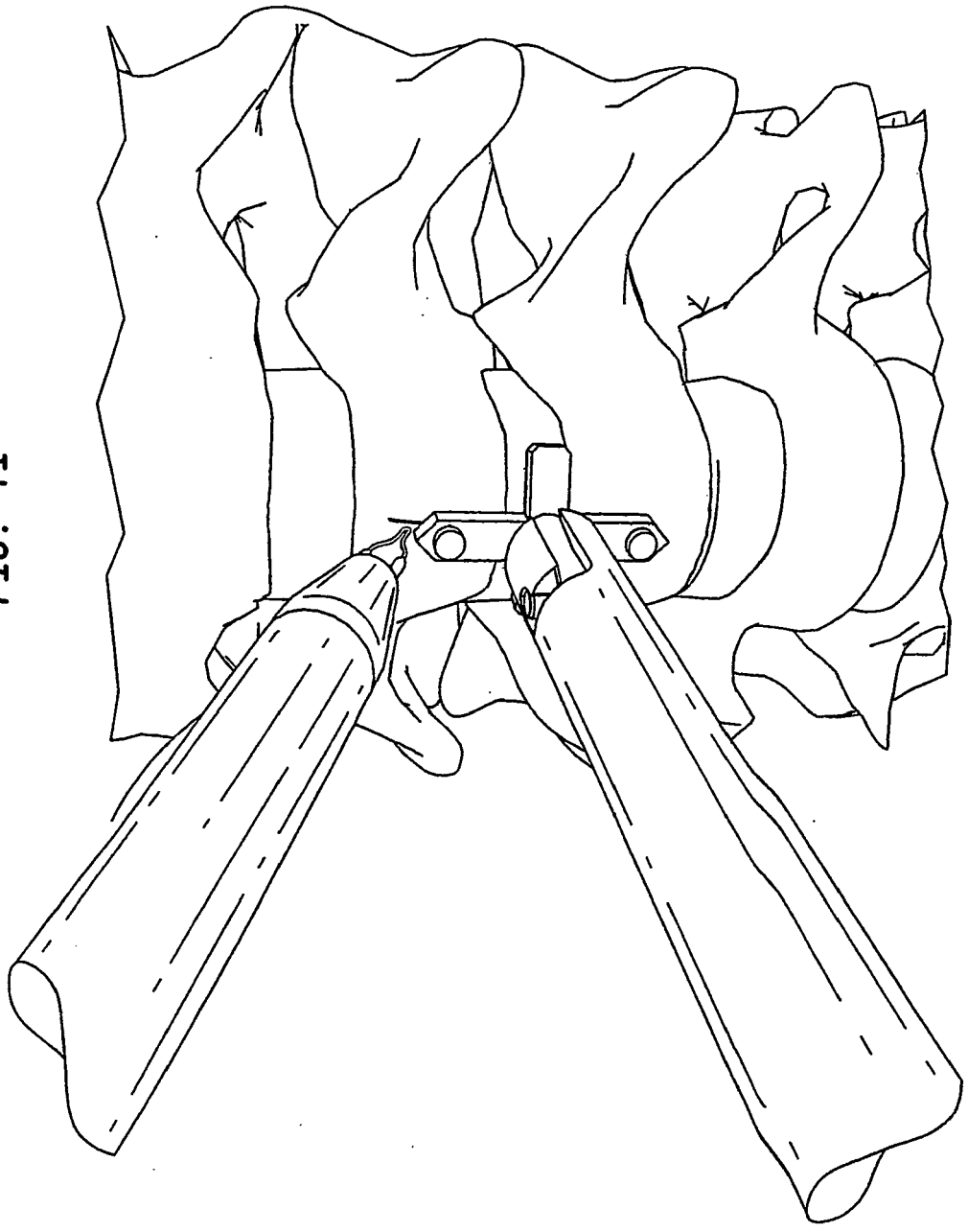


FIG. 42

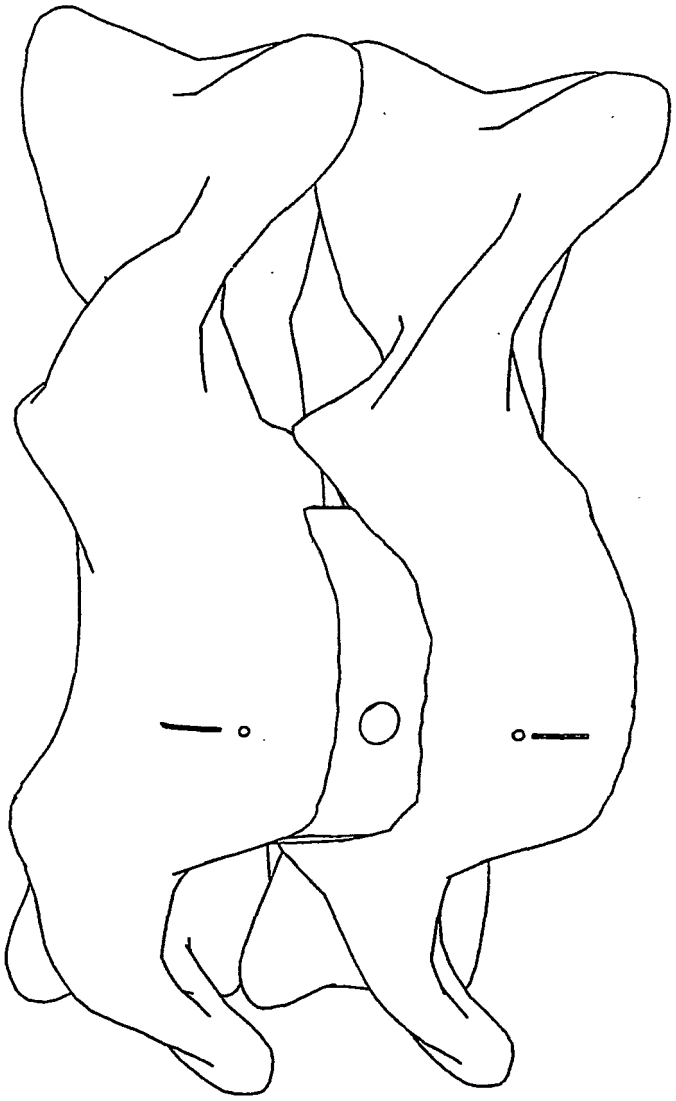


FIG. 43

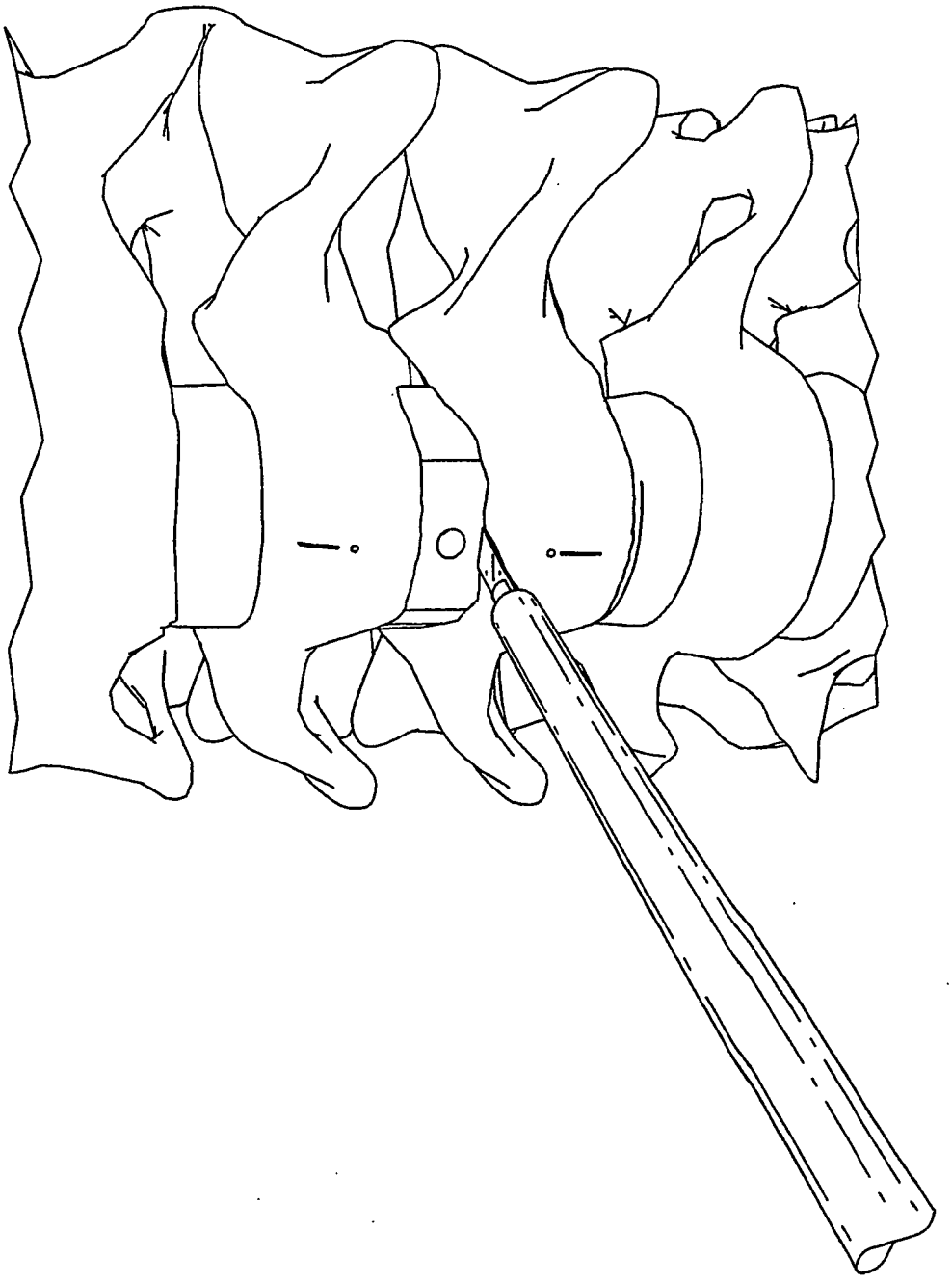


FIG. 44

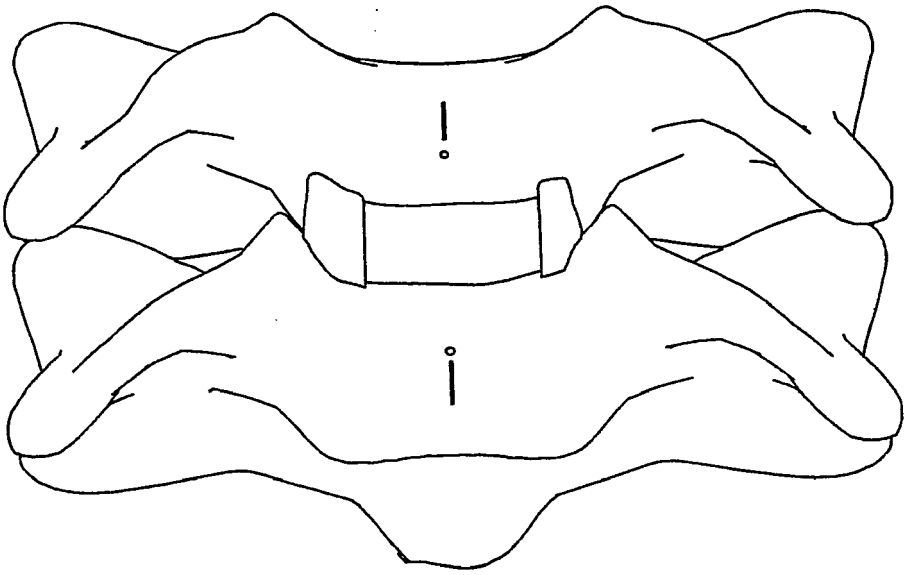


FIG. 45

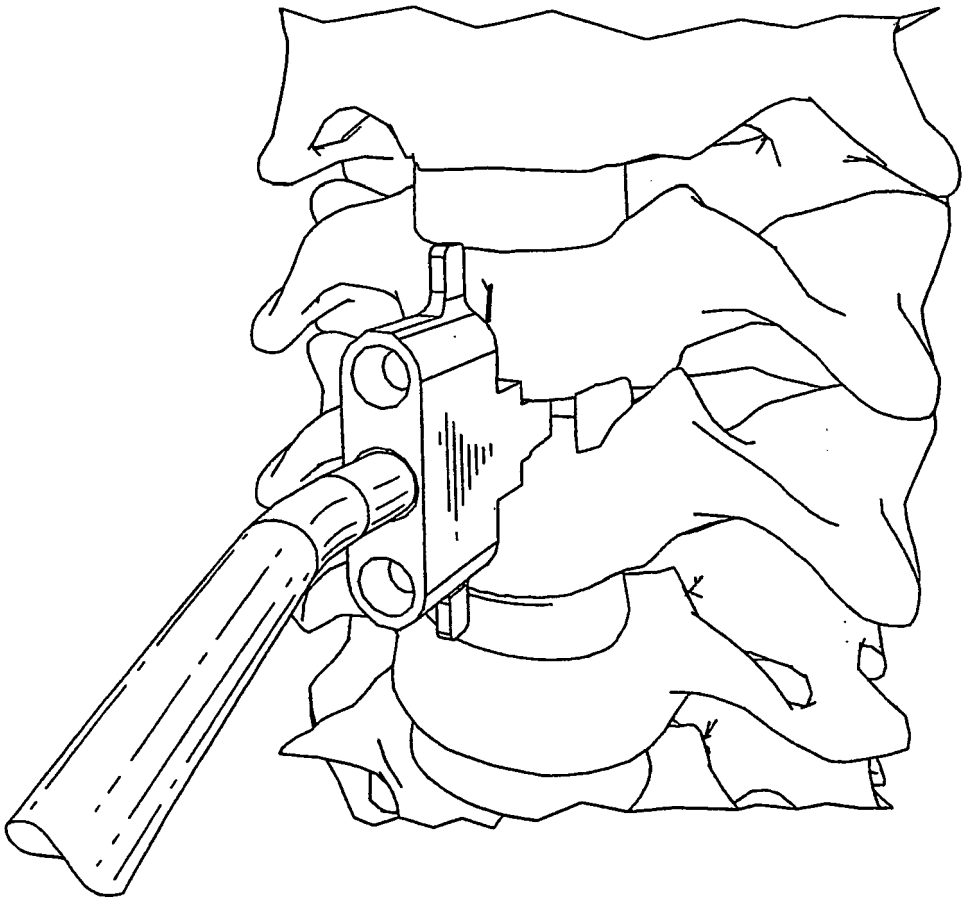


FIG. 46

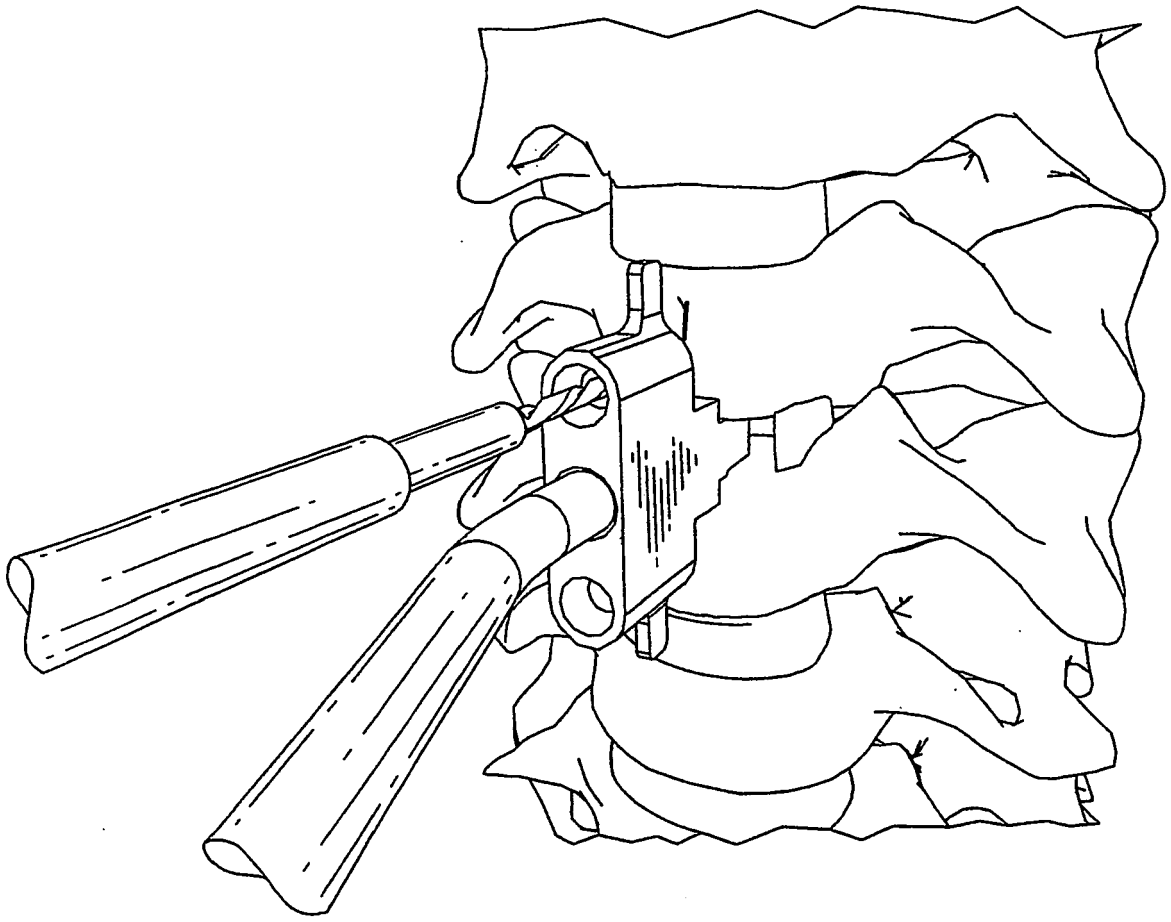


FIG. 47

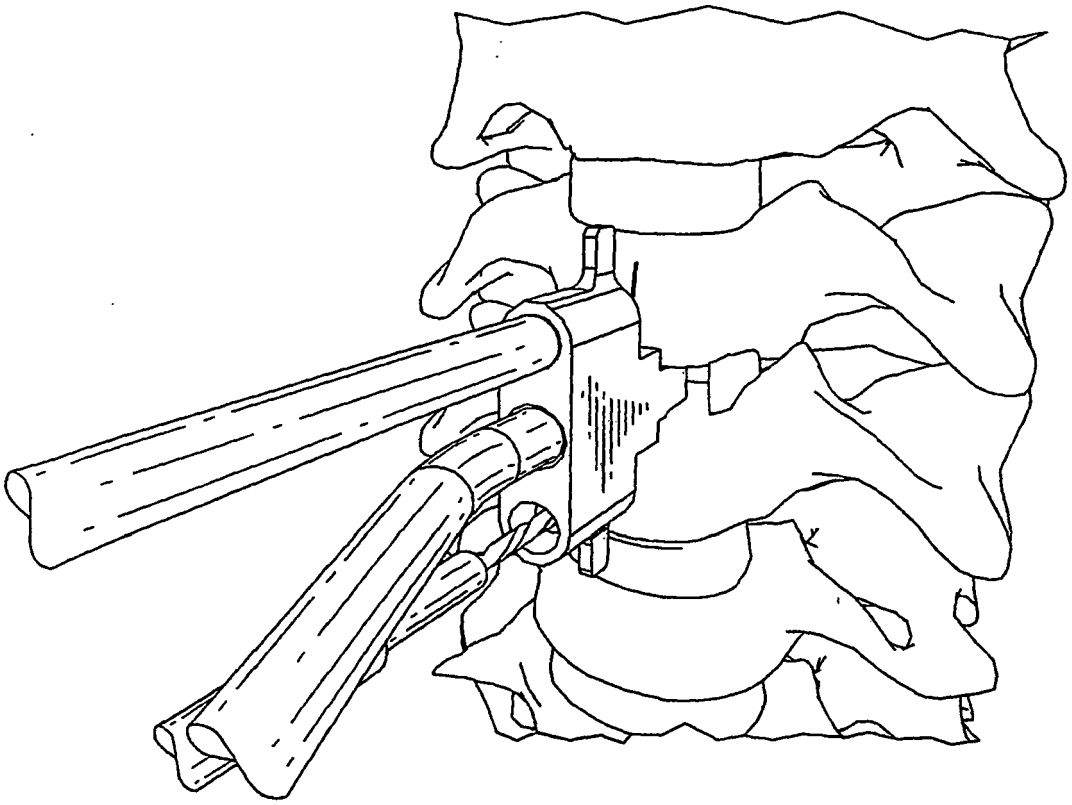


FIG. 48

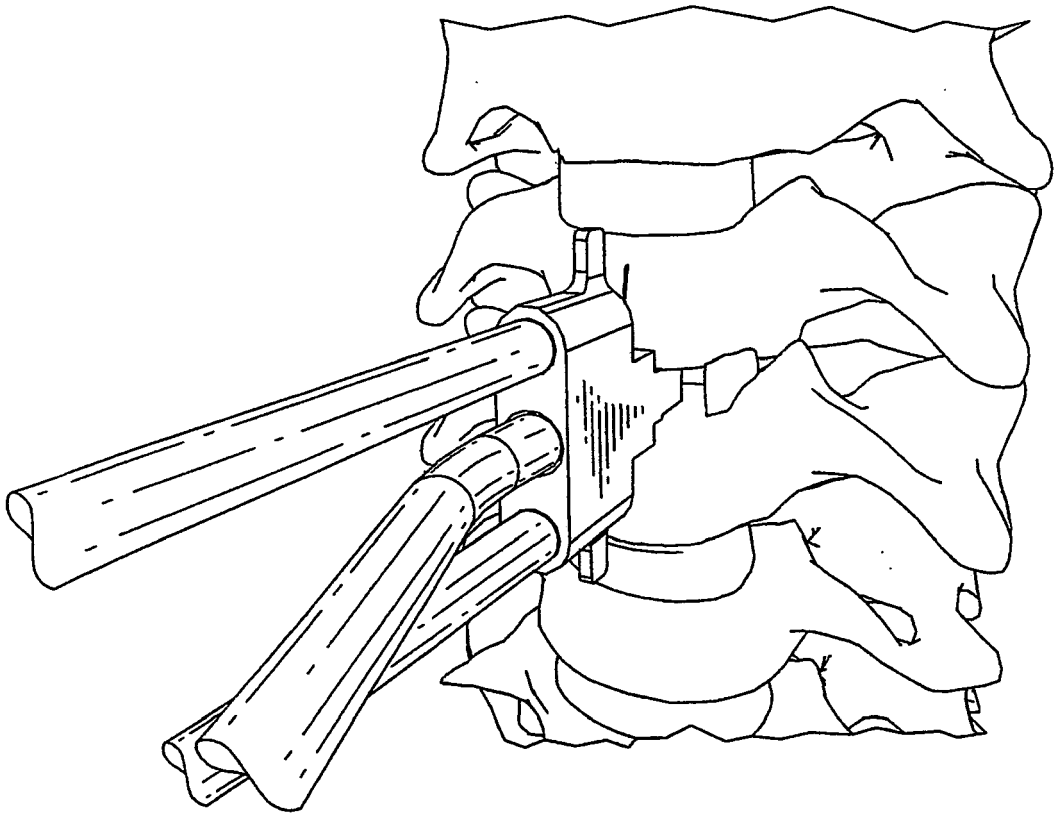


FIG. 49

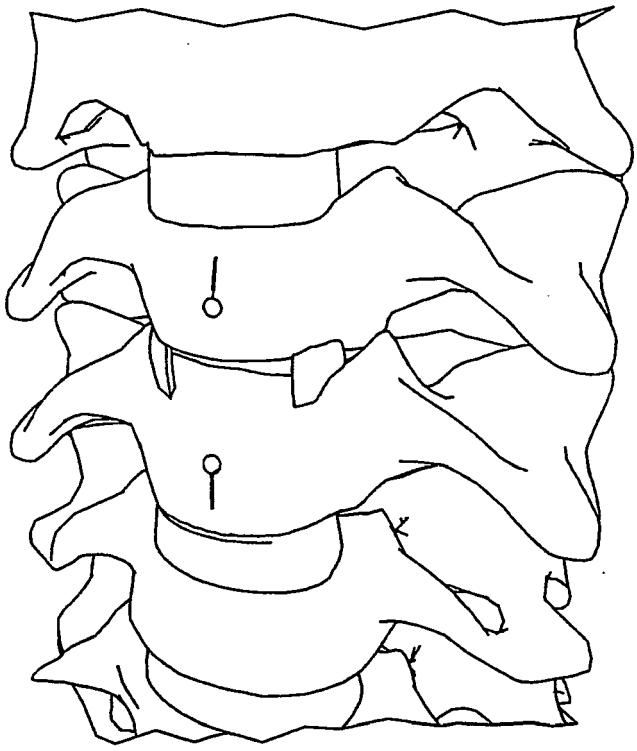


FIG. 50

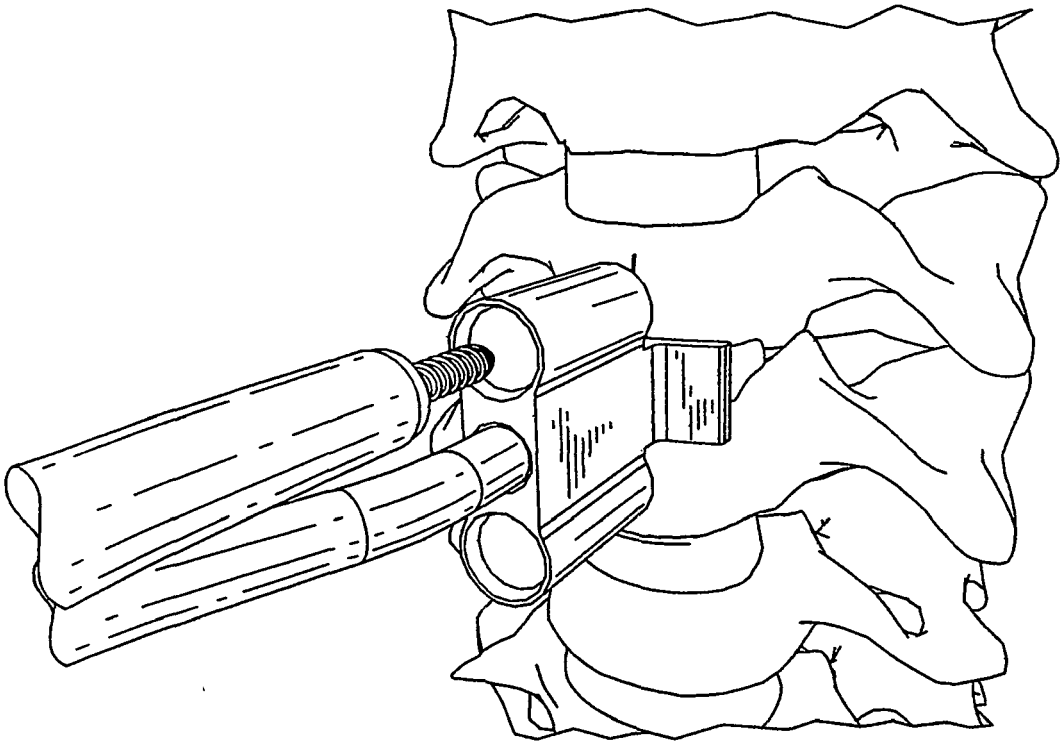


FIG. 51

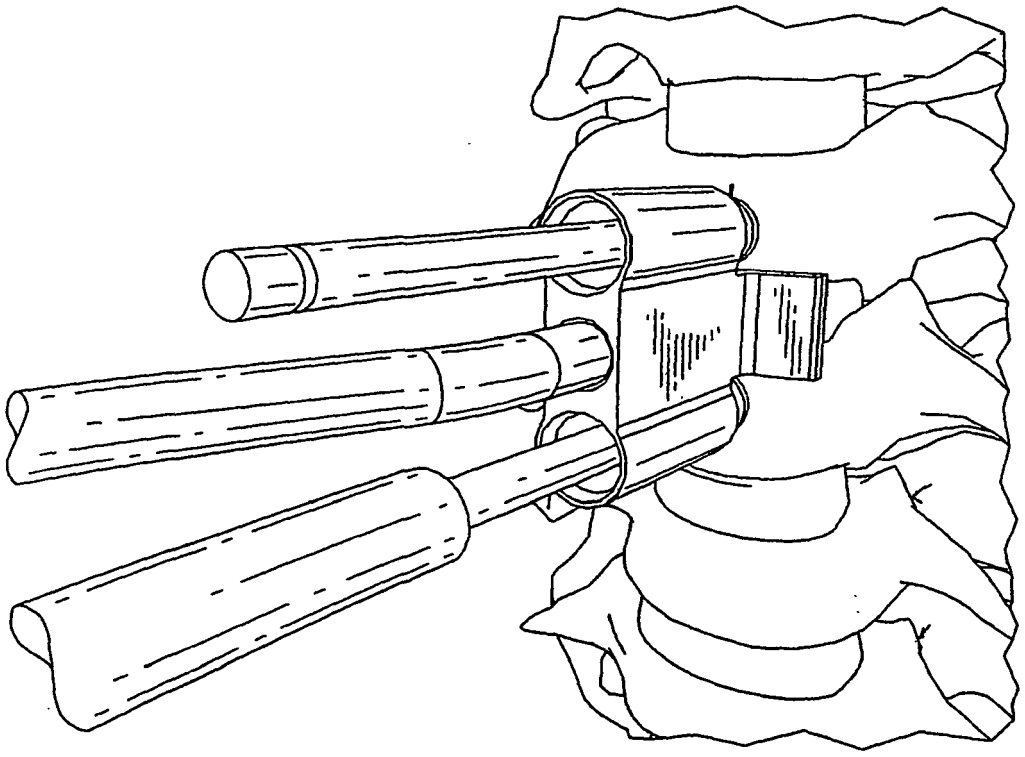


FIG. 52

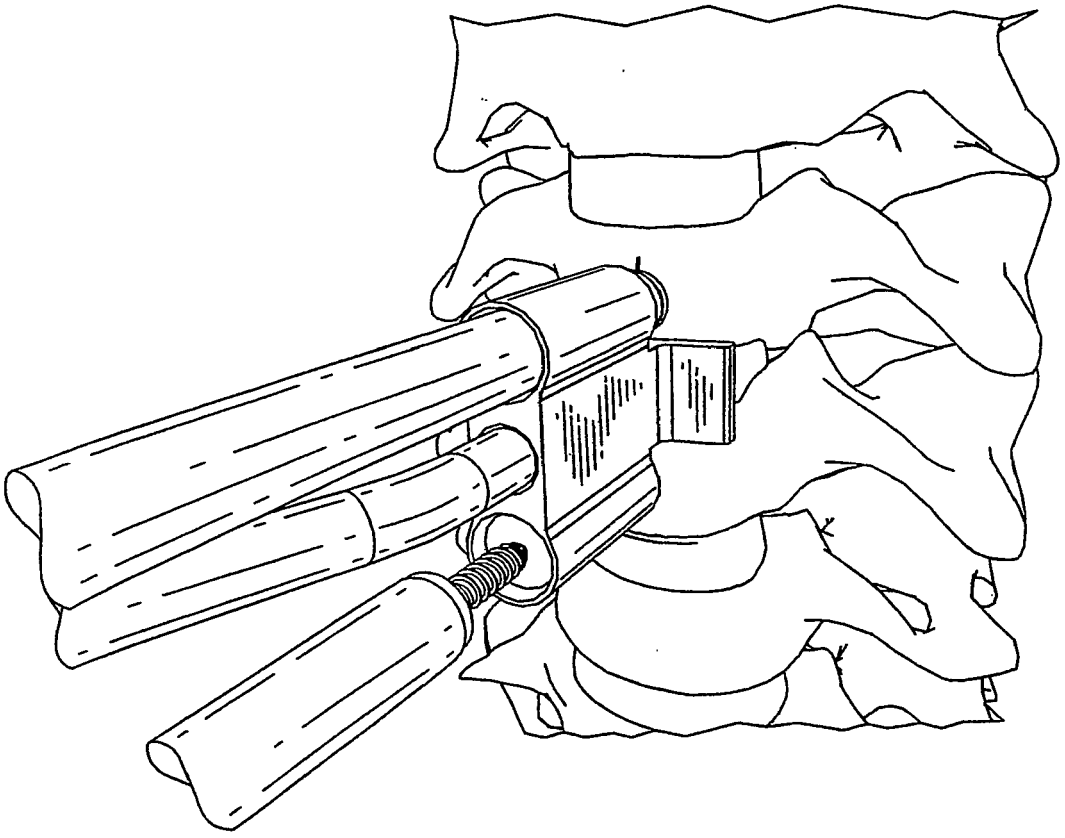


FIG. 53

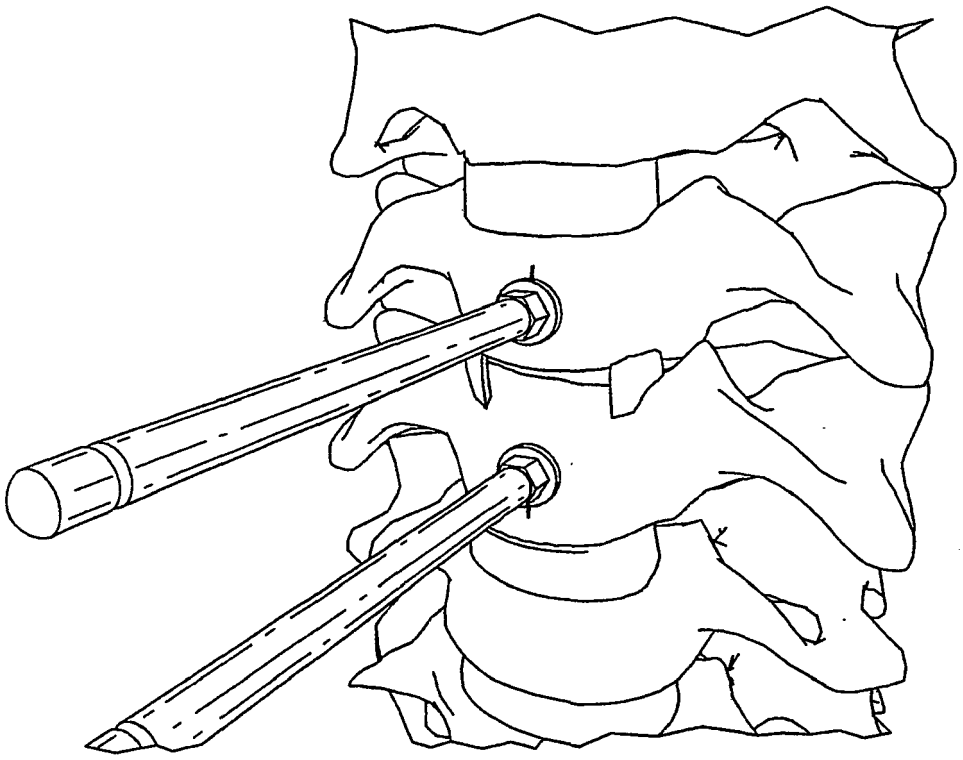
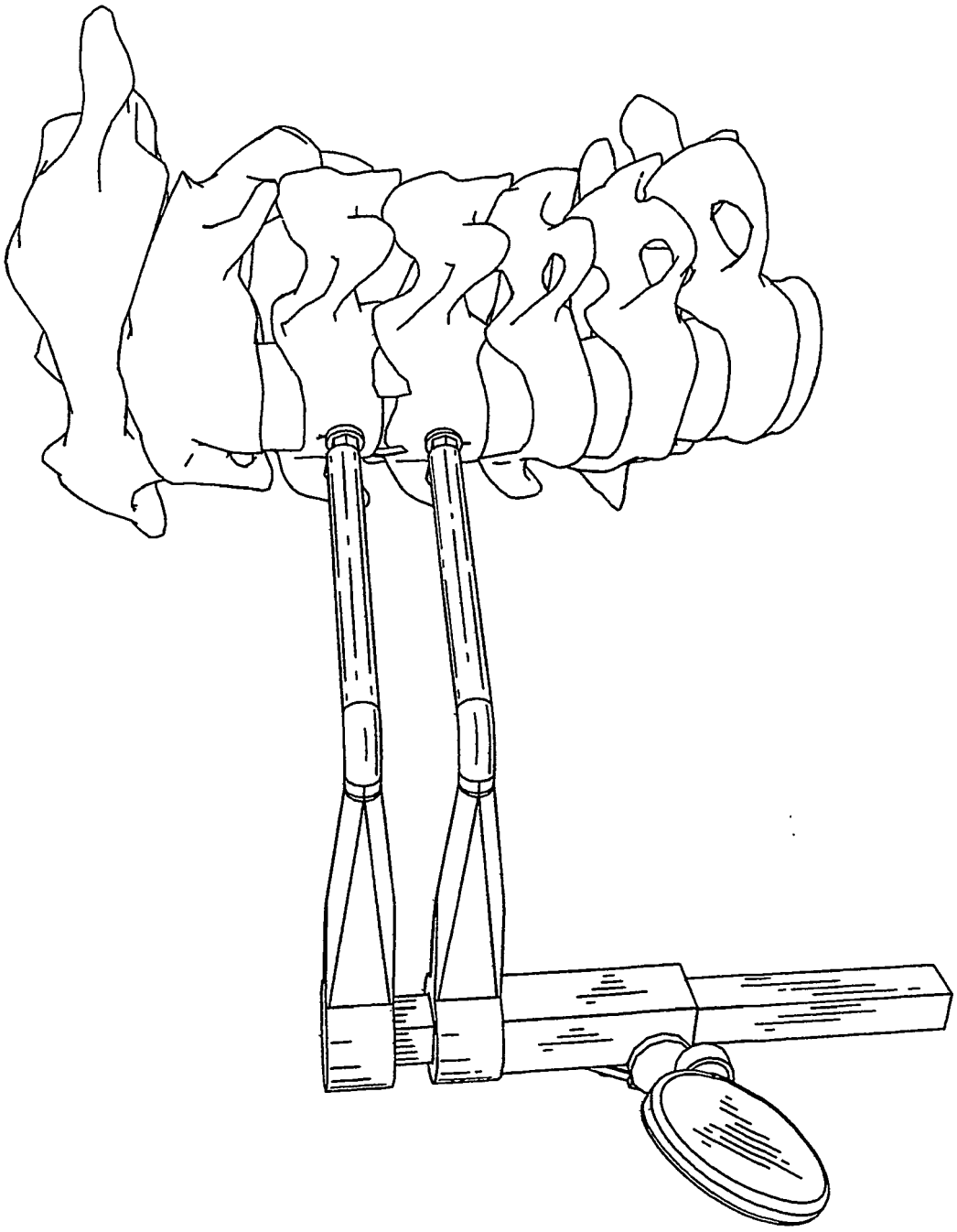


FIG. 54



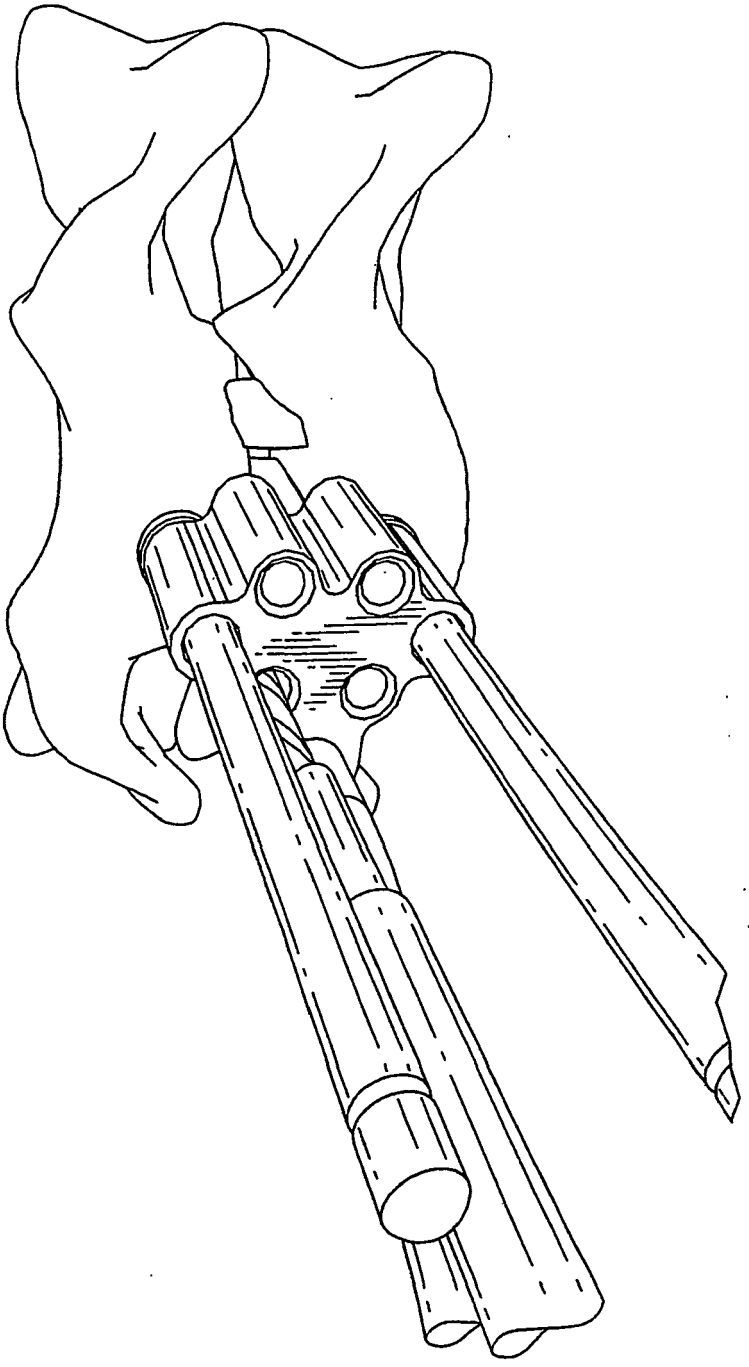


FIG. 55

FIG. 56

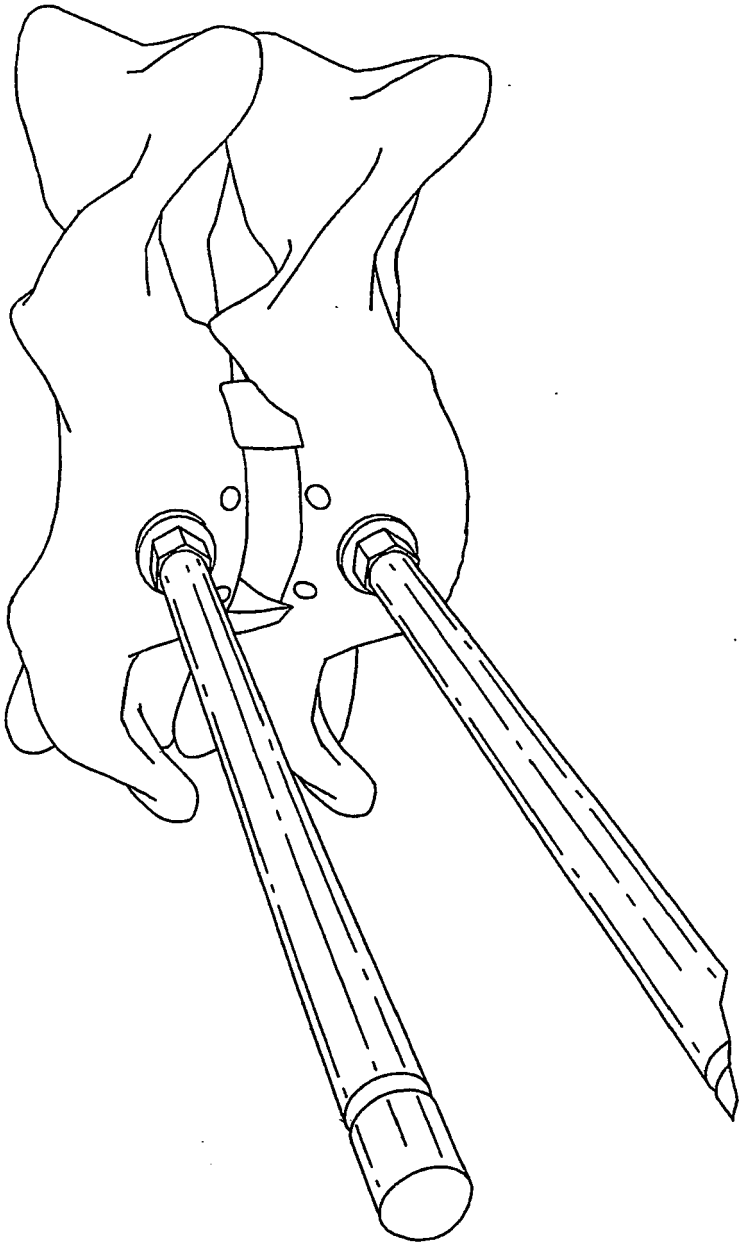


FIG. 57

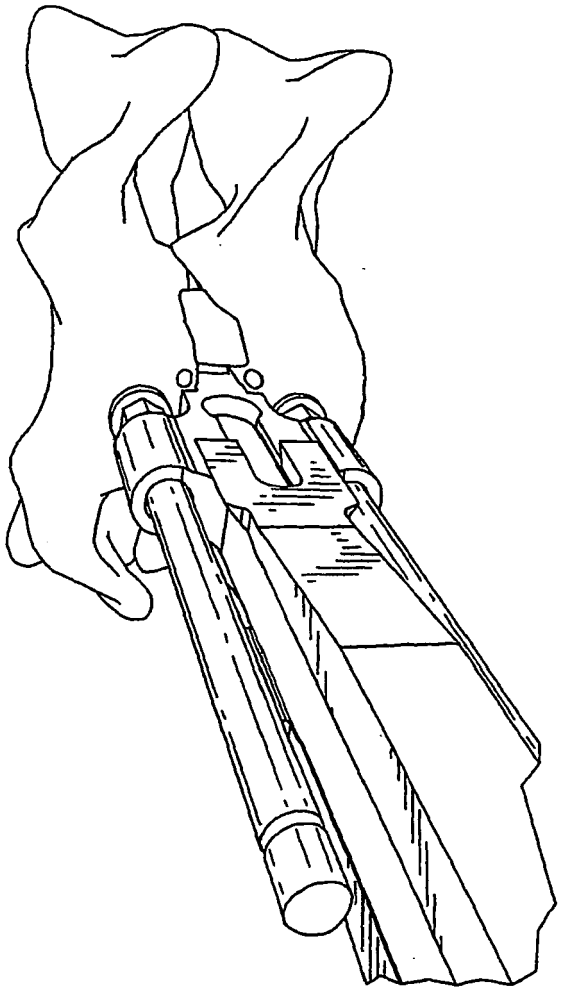


FIG. 58

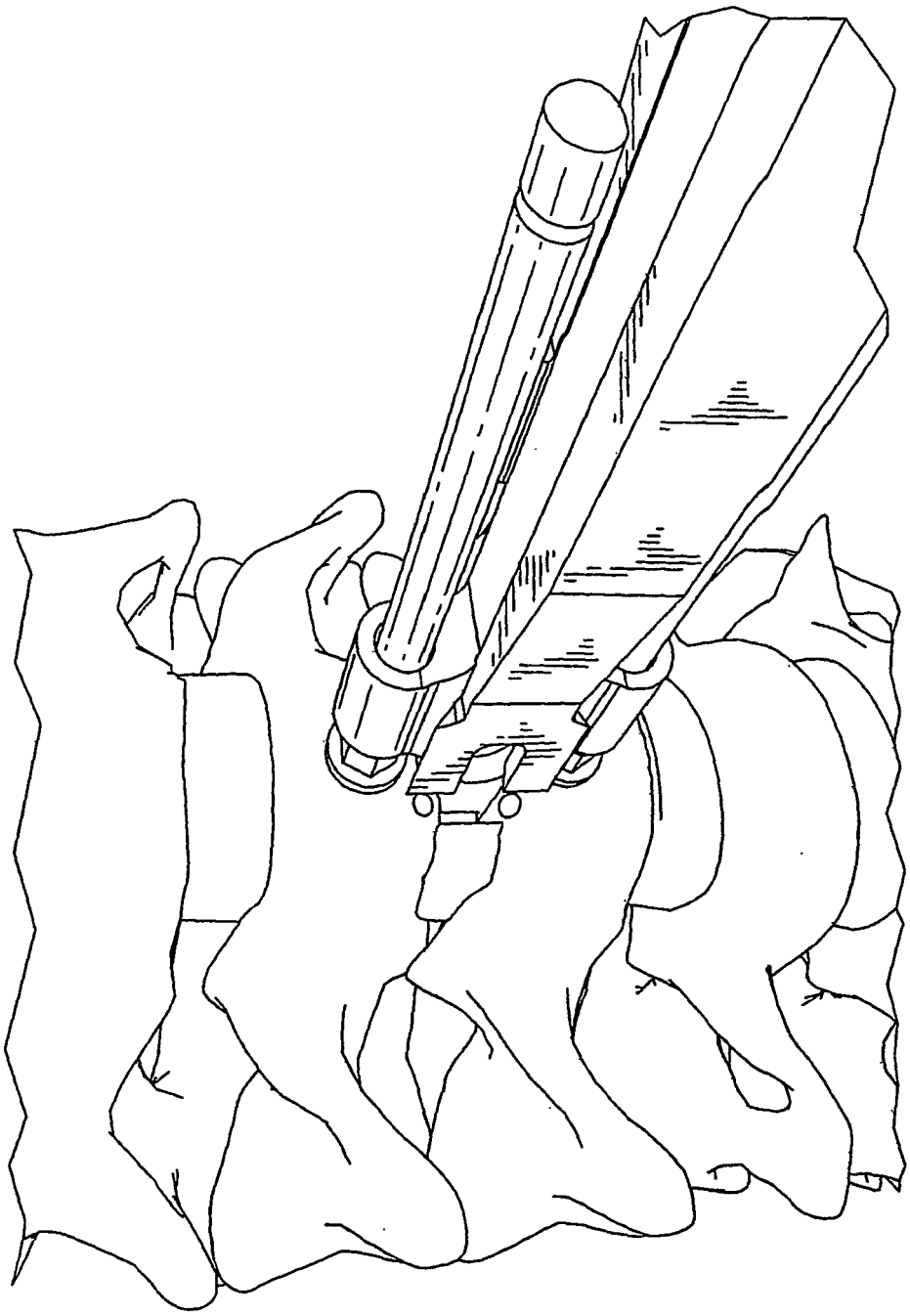


FIG. 59

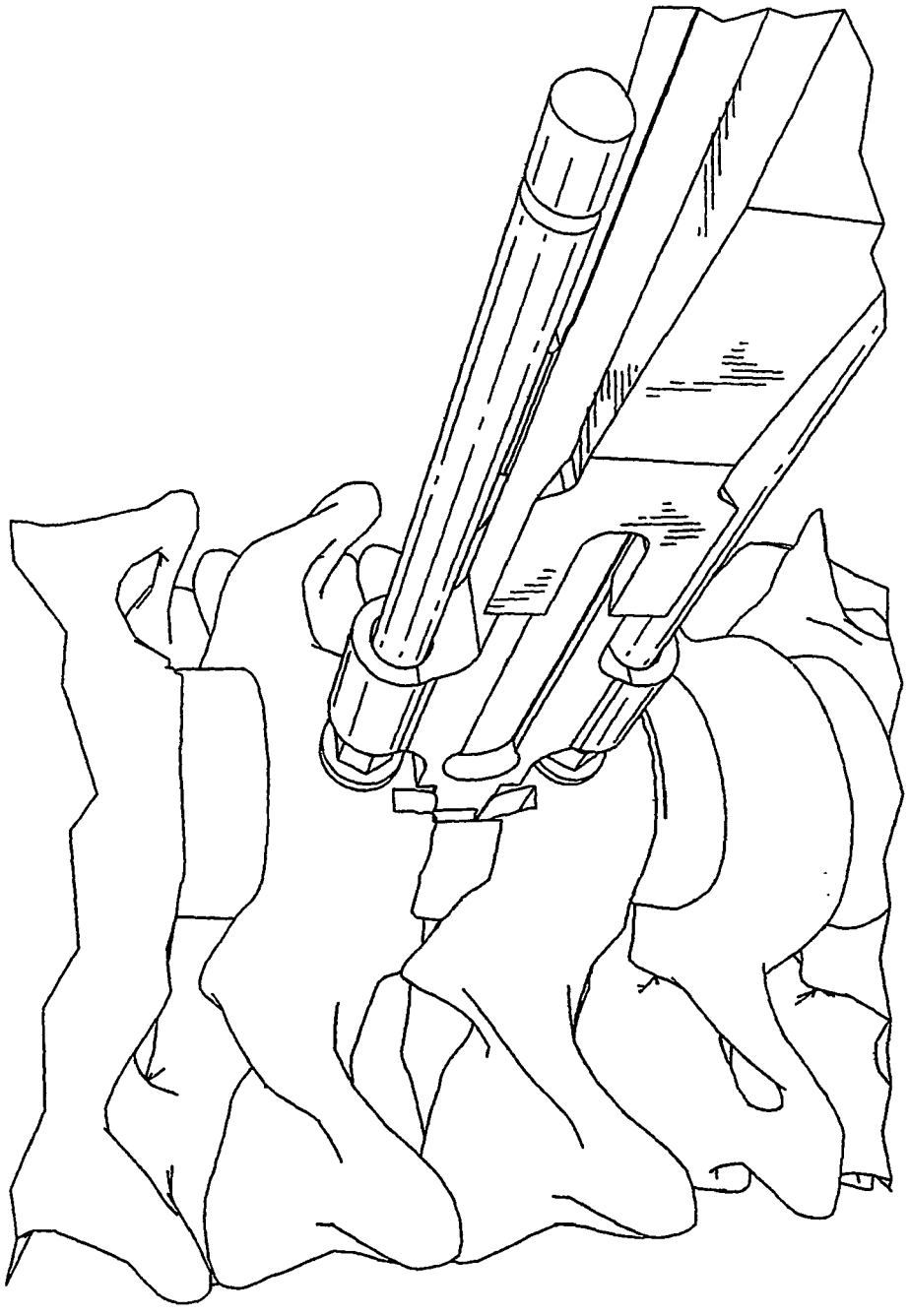


FIG. 60

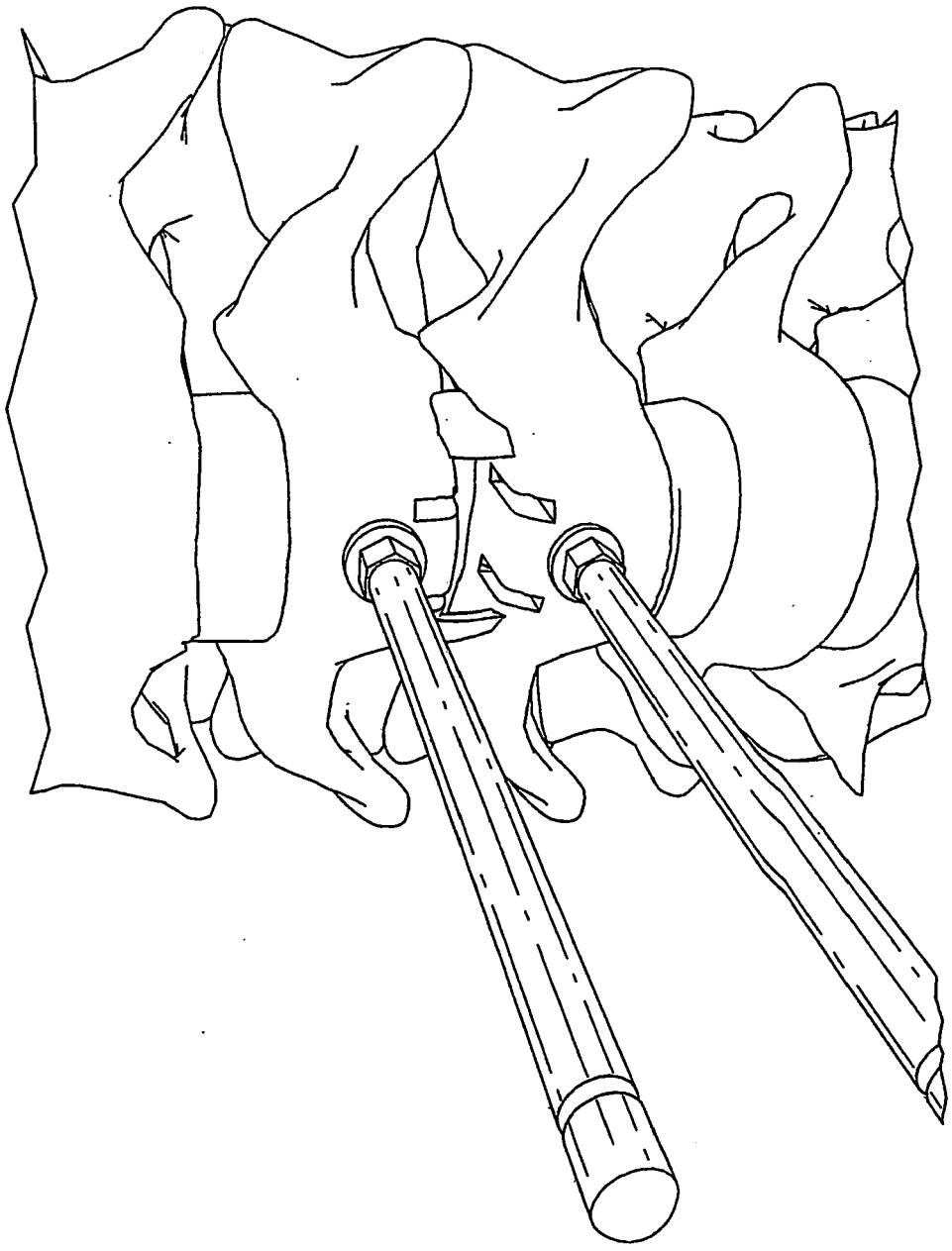


FIG. 61

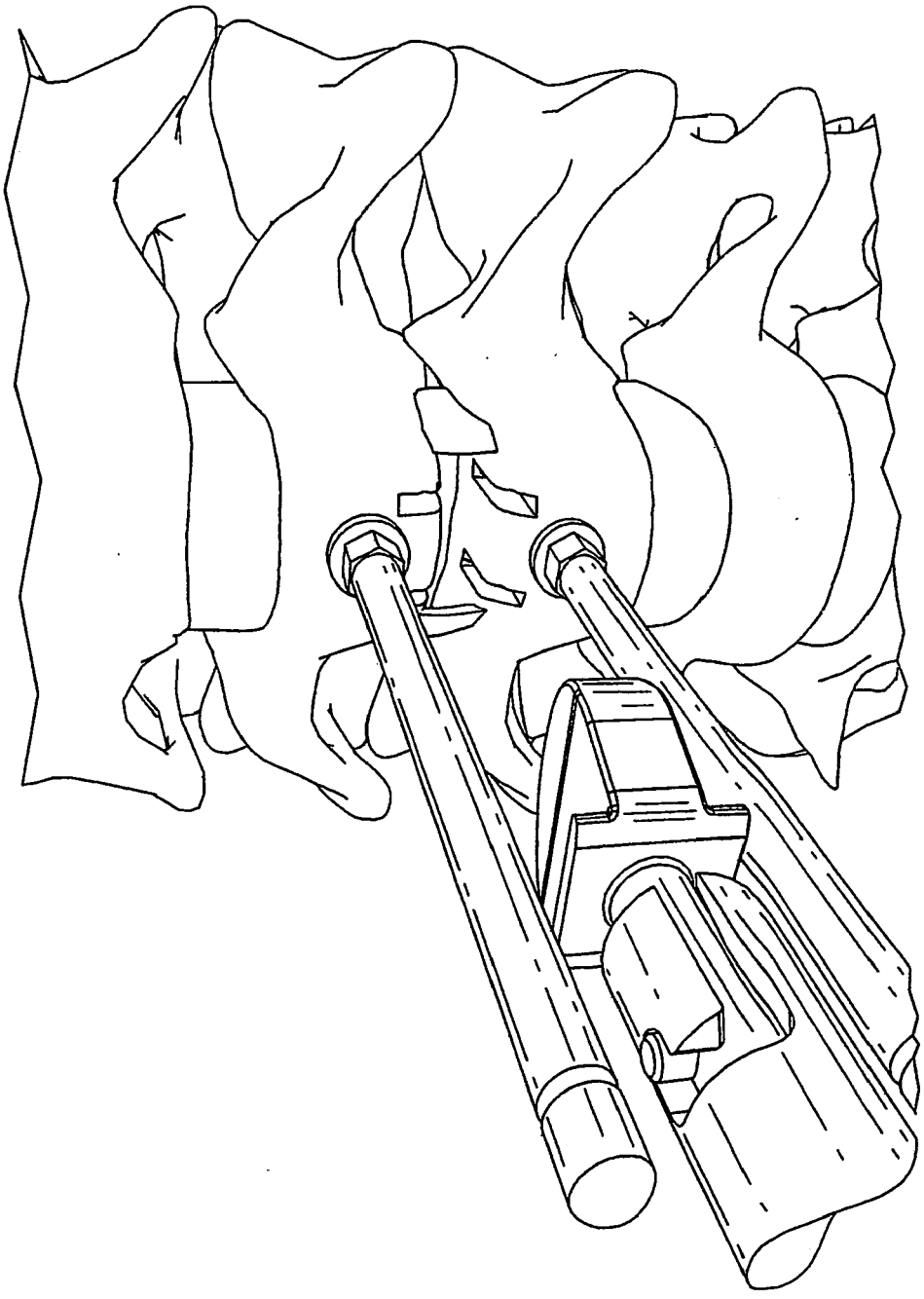


FIG. 62

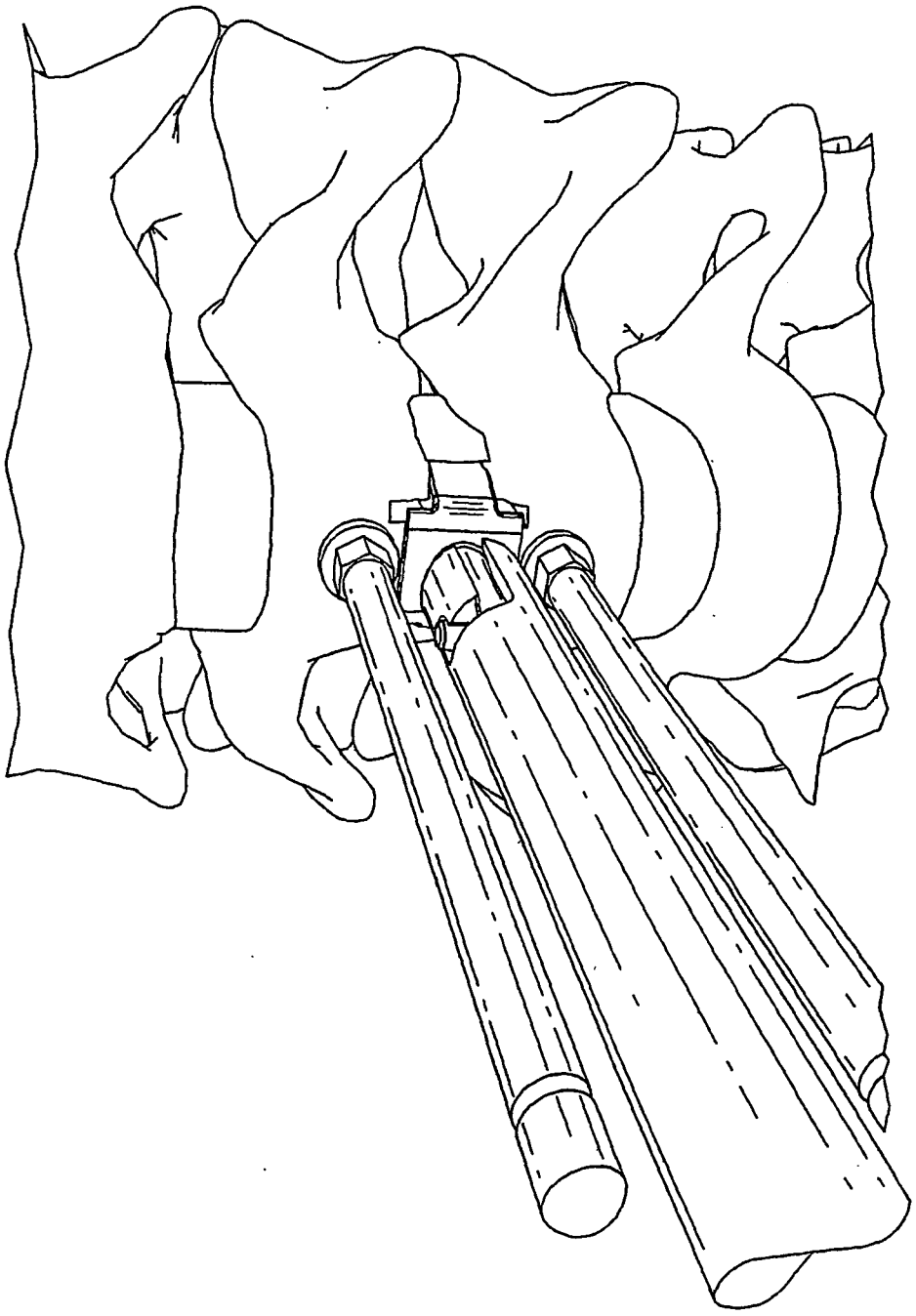


FIG. 63

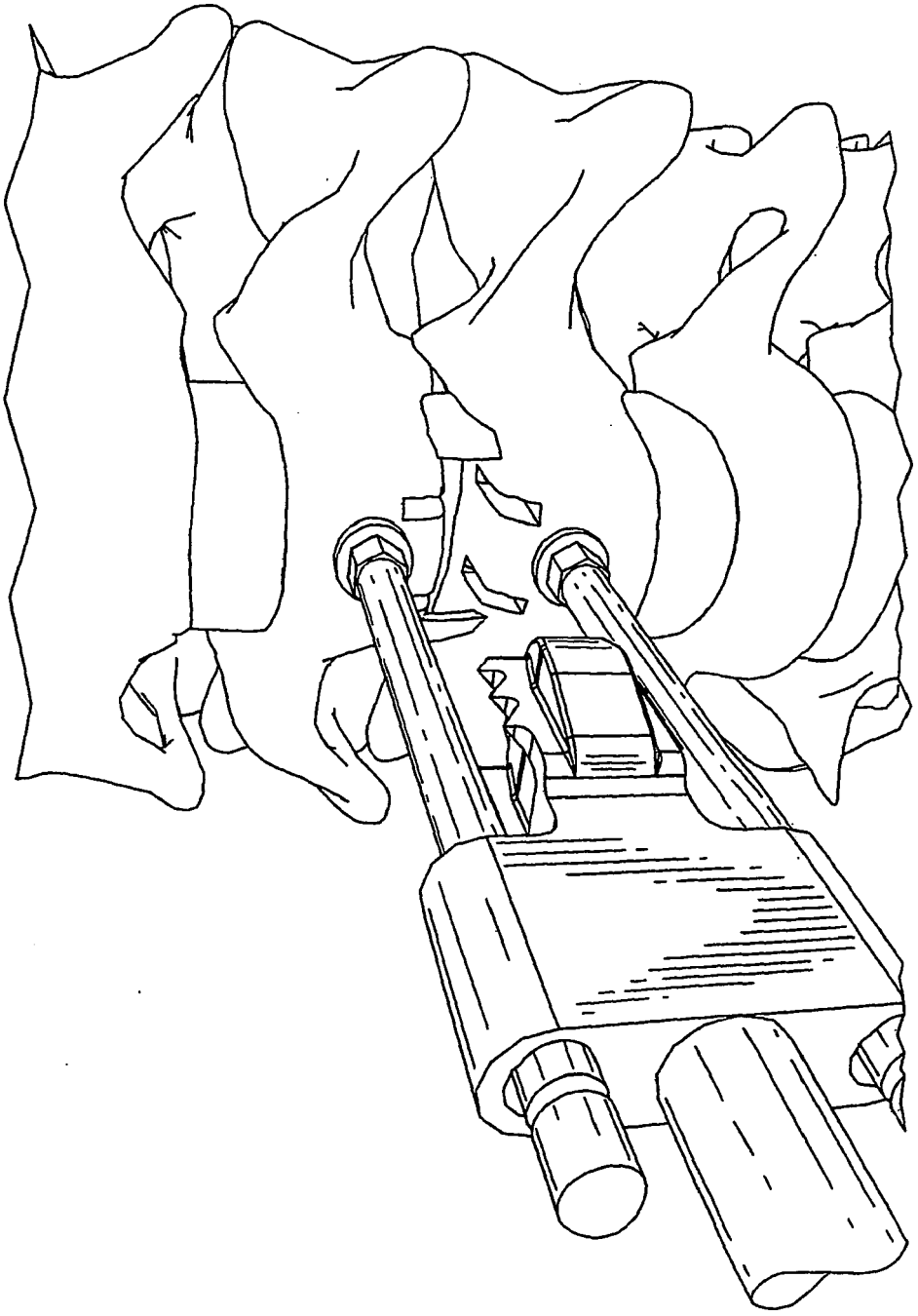


FIG. 64

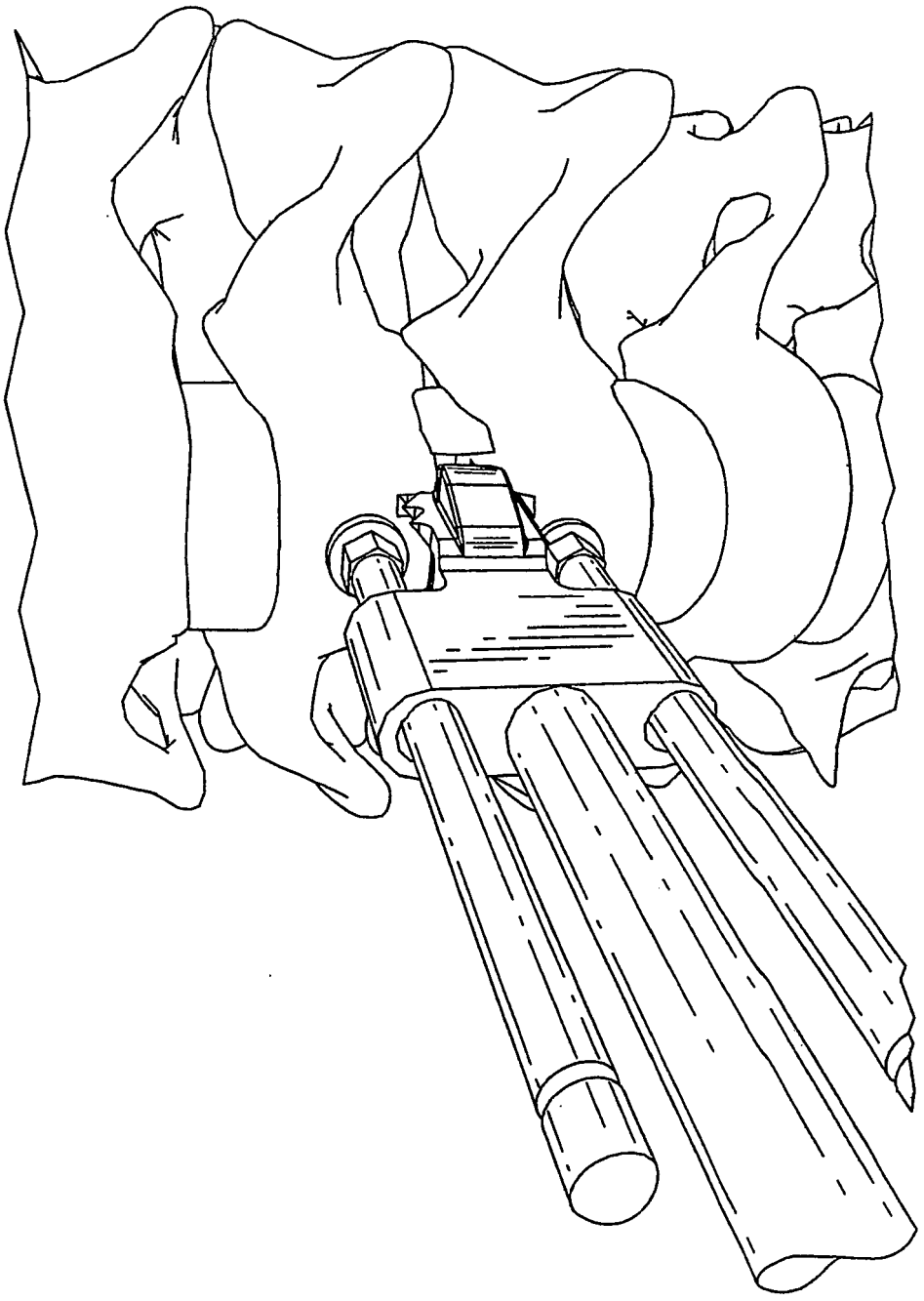
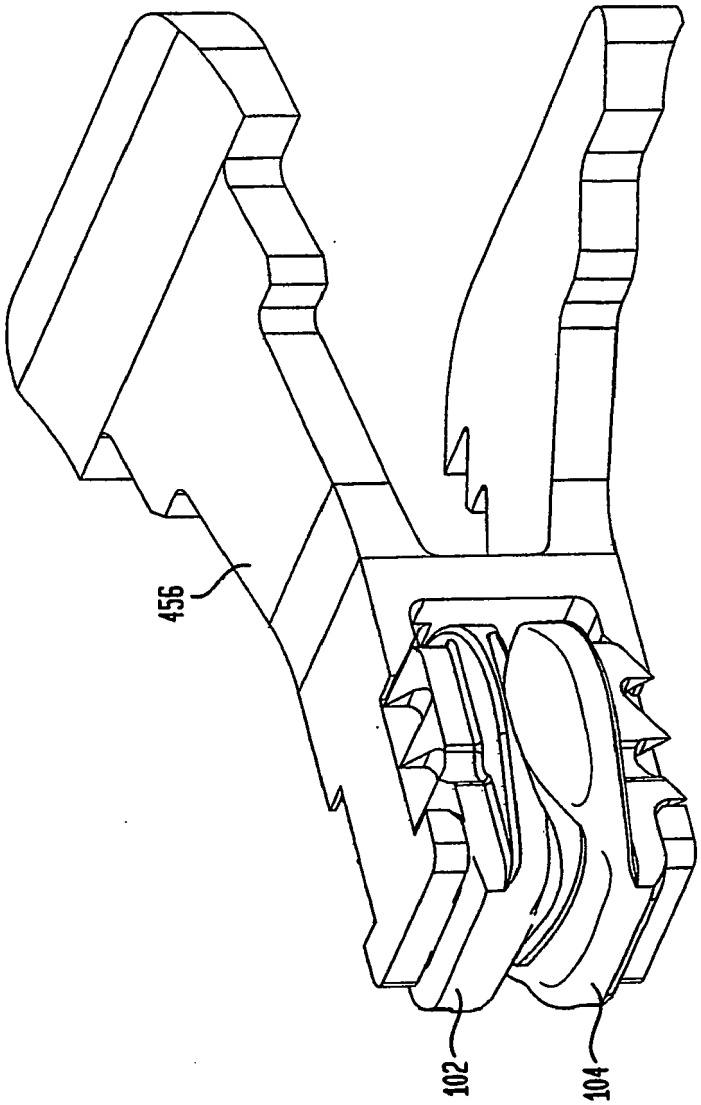


FIG. 65



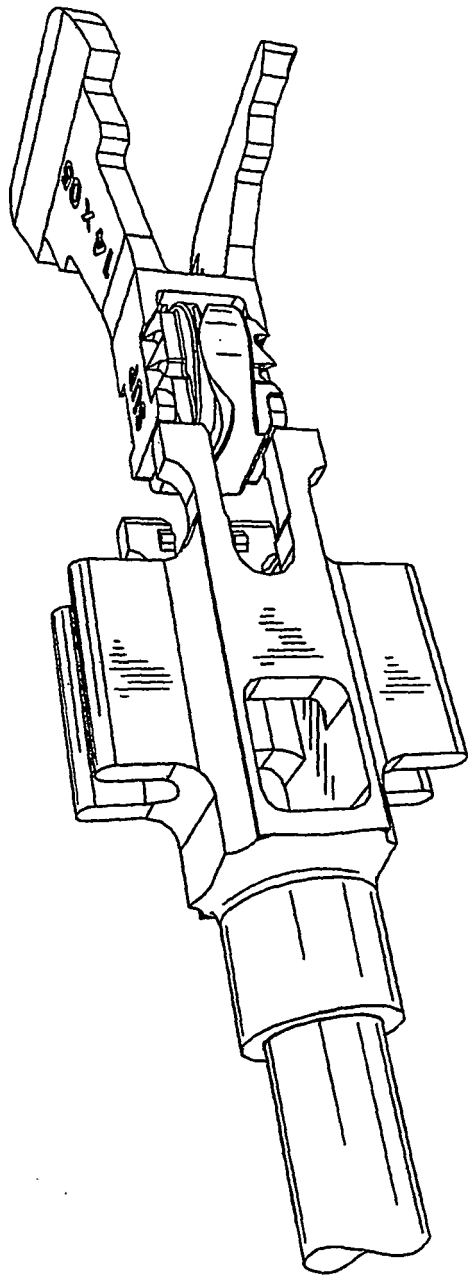


FIG. 66

FIG. 67

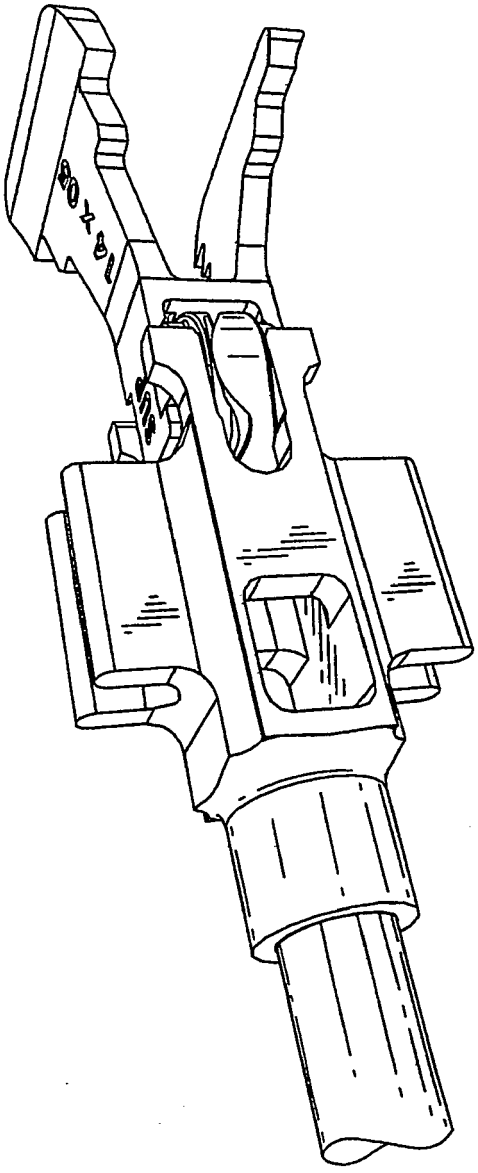


FIG. 68

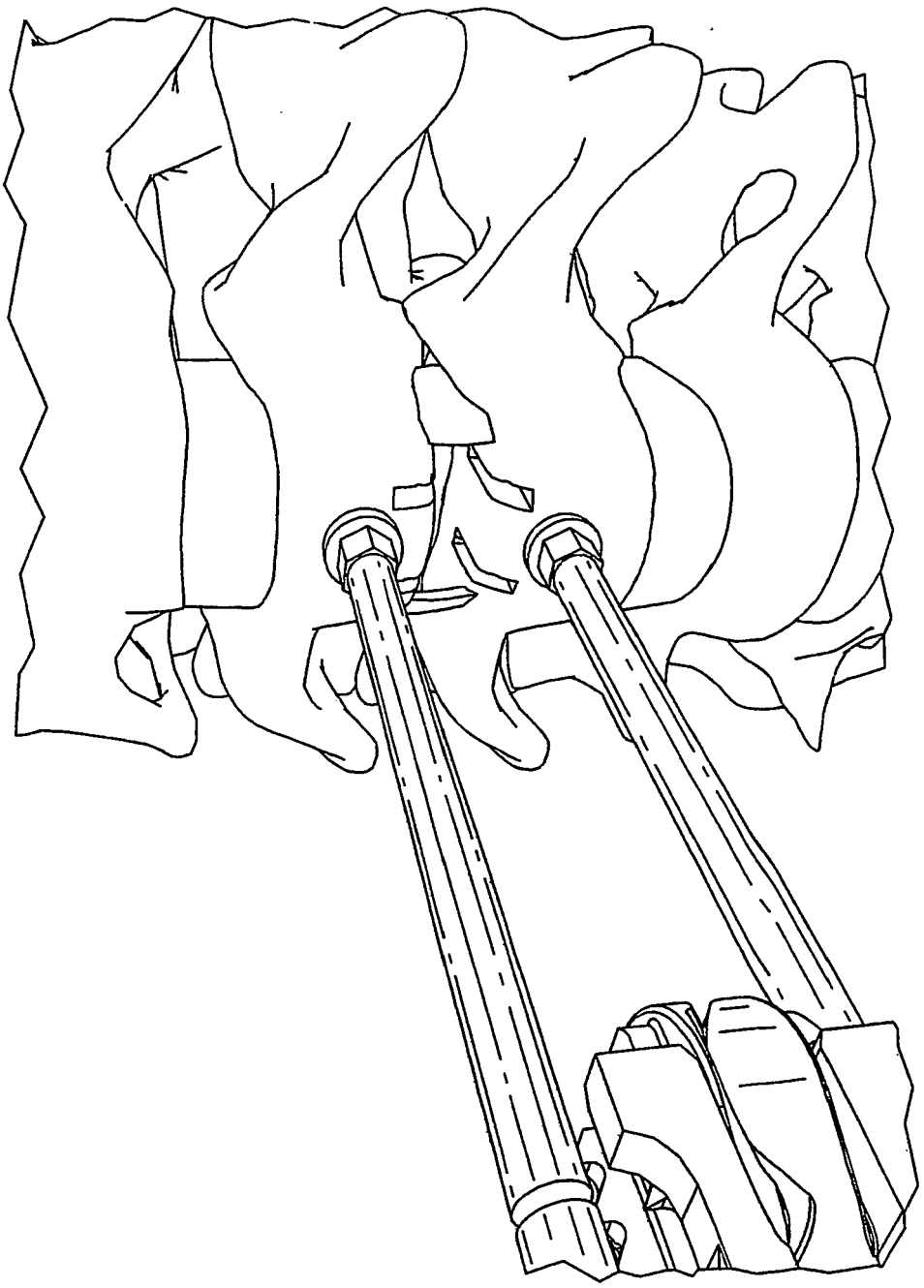


FIG. 69

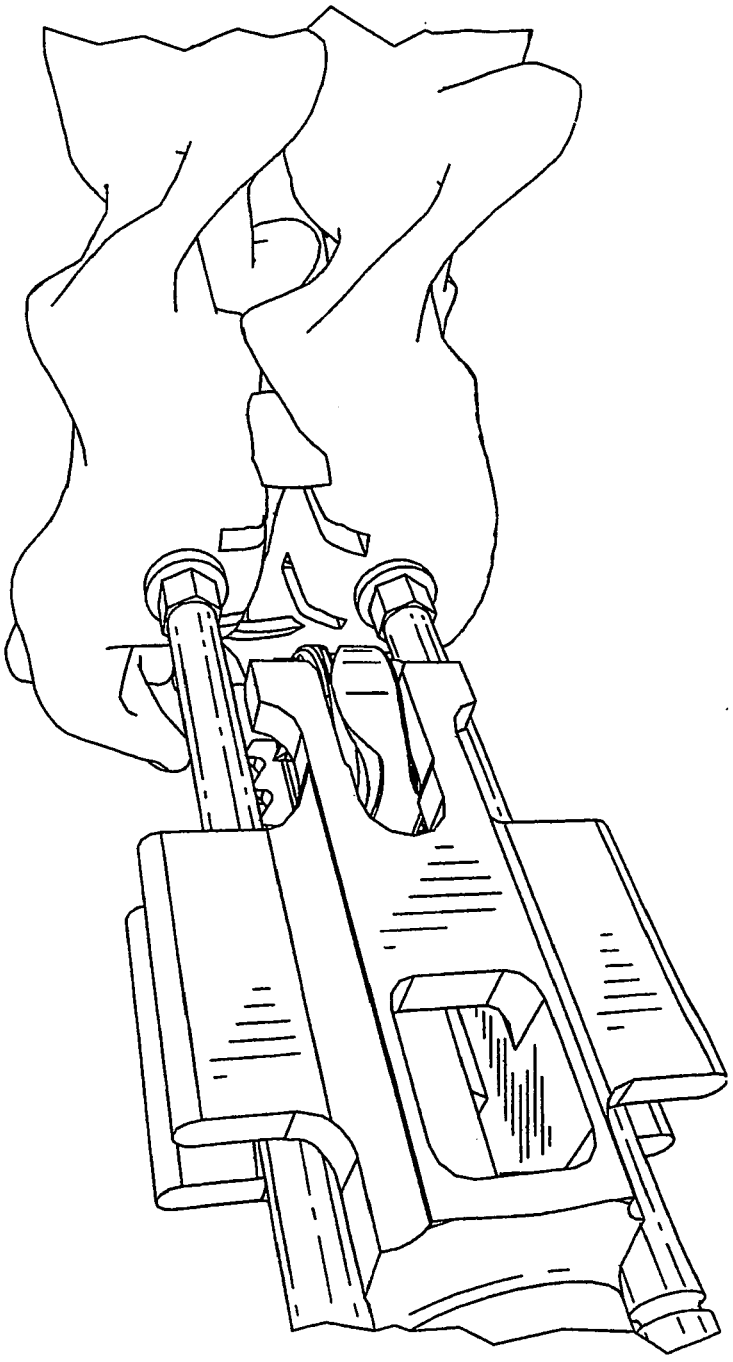


FIG. 70

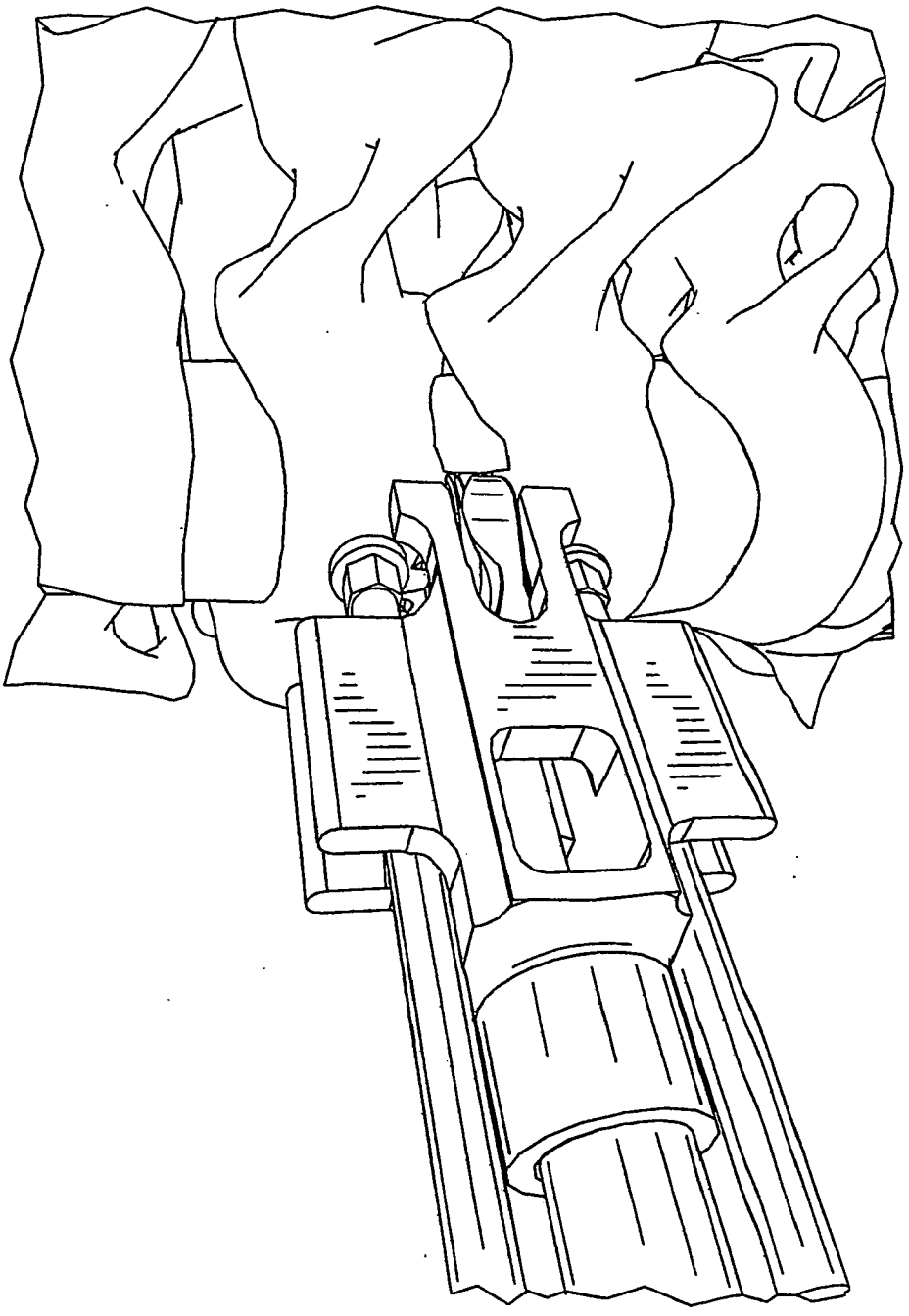


FIG. 71

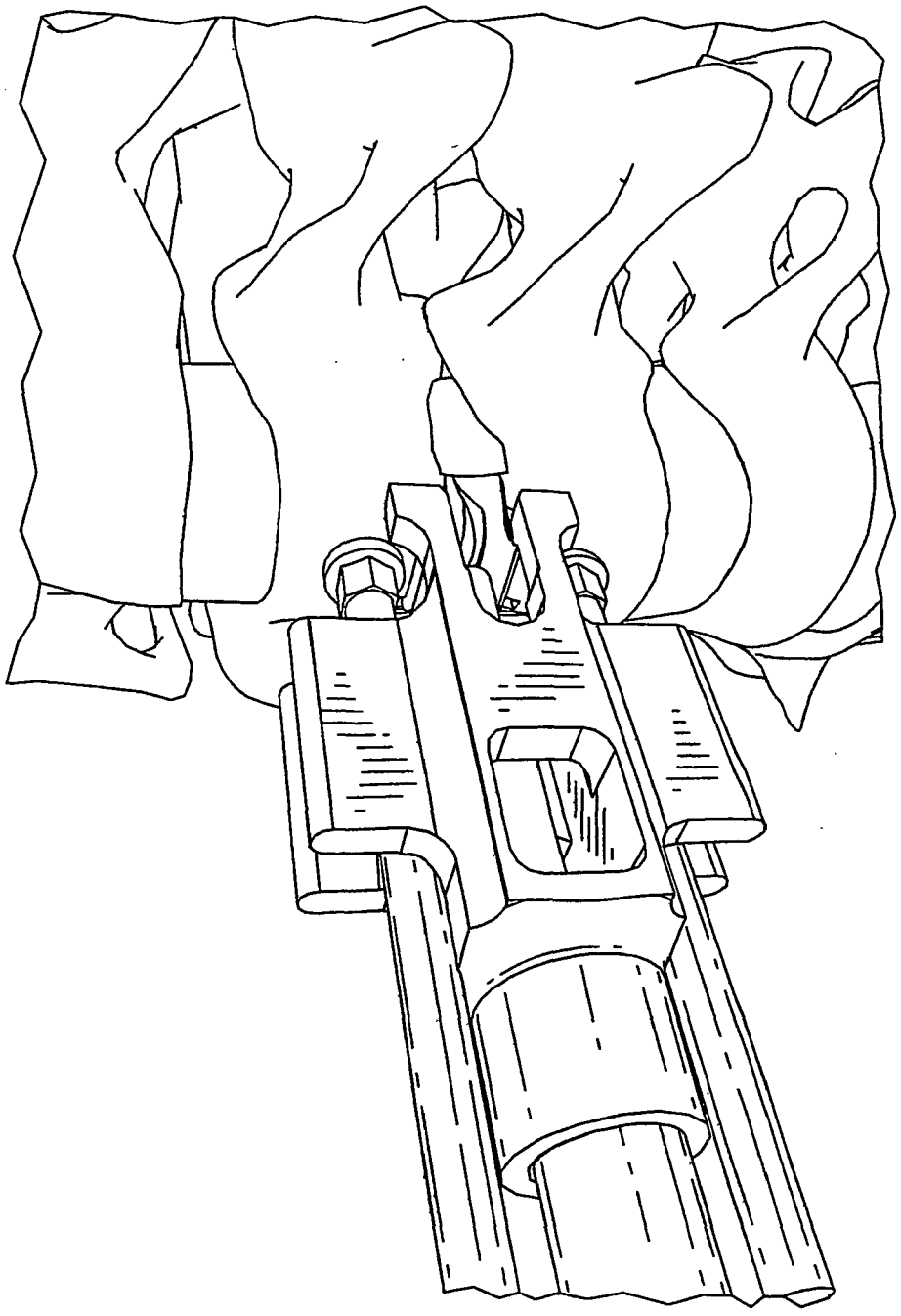
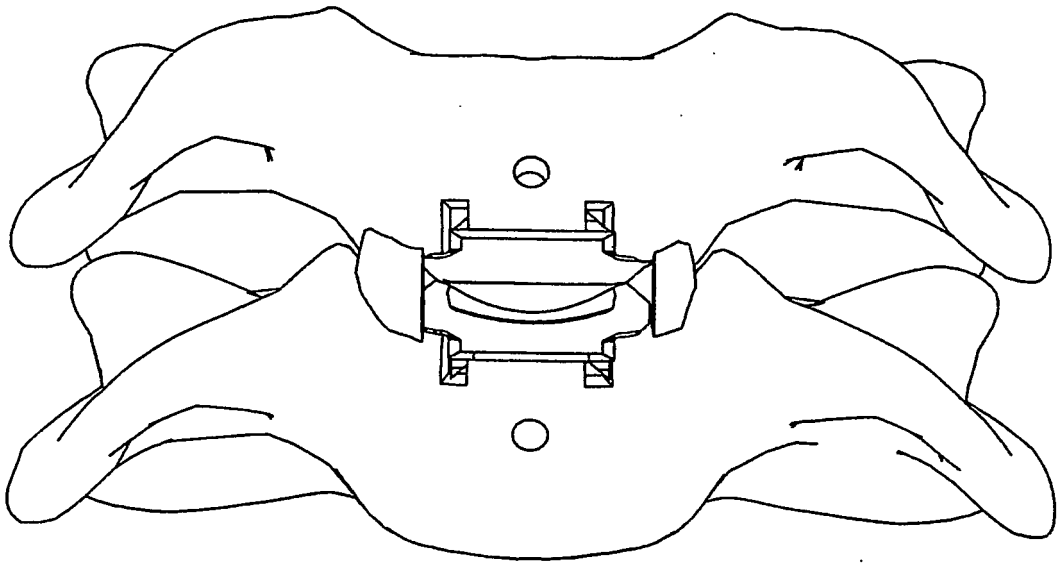


FIG. 72



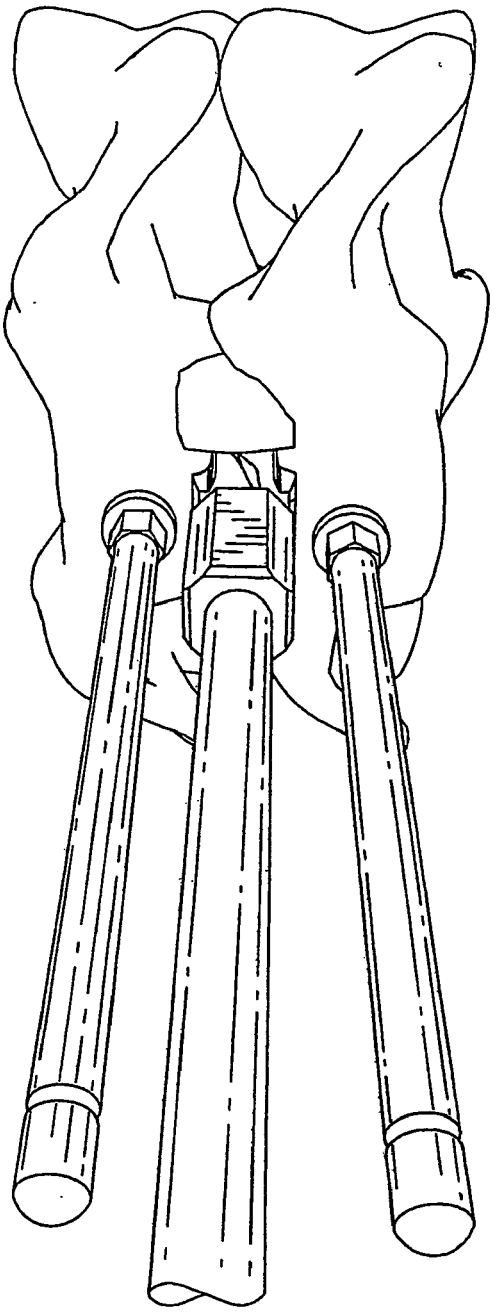


FIG. 73

FIG. 74

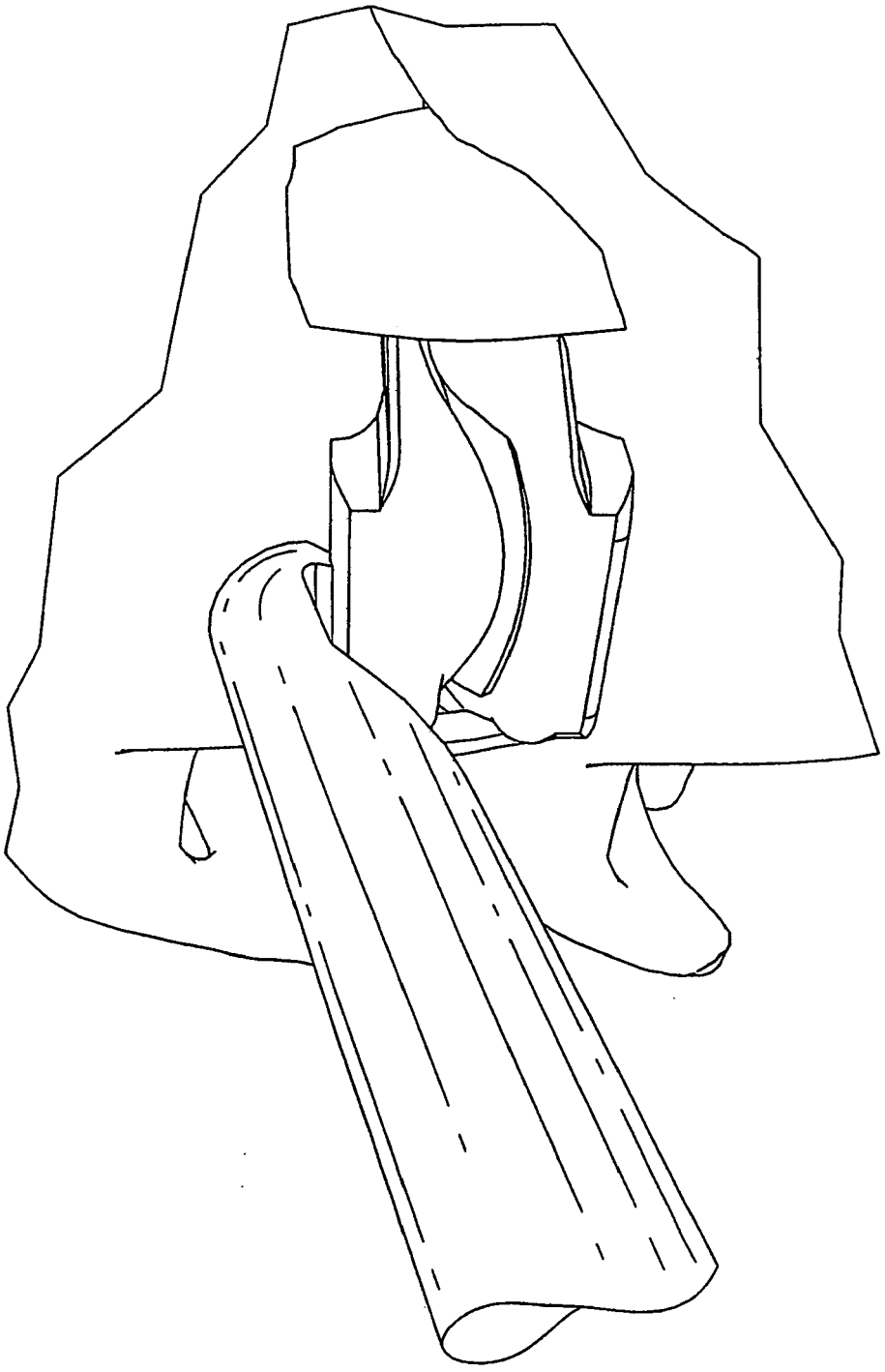
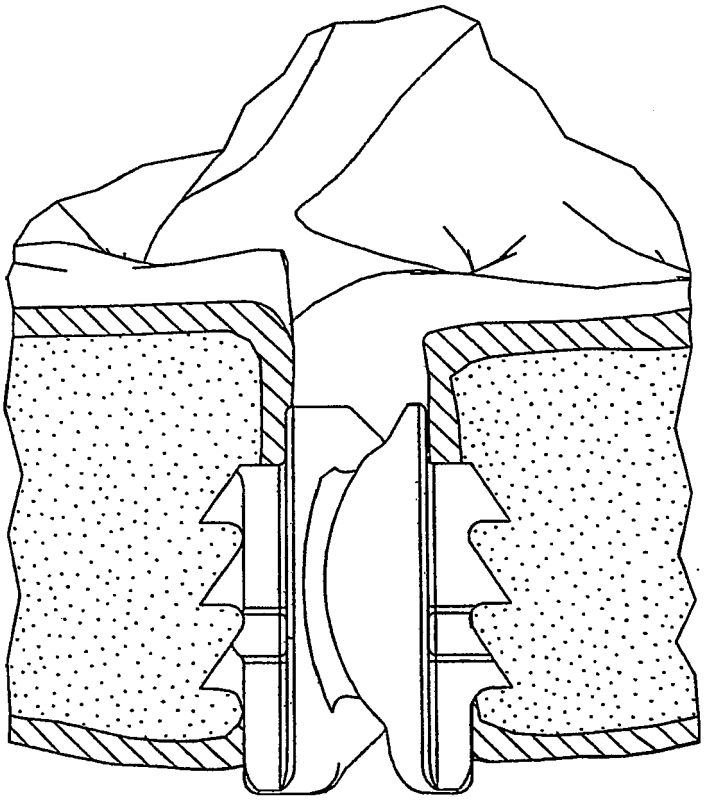


FIG. 75A



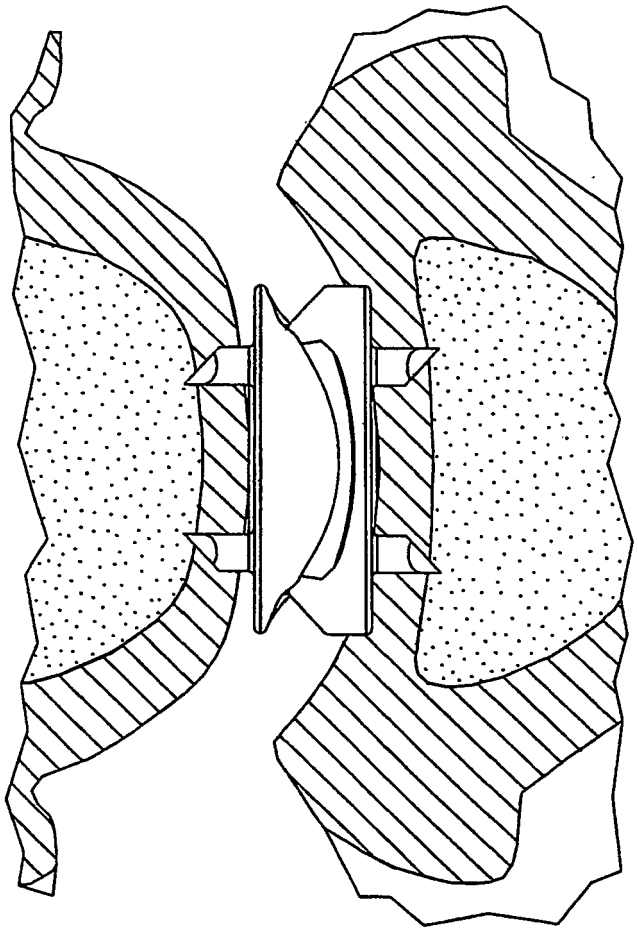


FIG. 75B

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 6001130 A **[0009]**
- US 6113637 A **[0010]**
- EP 1488747 A **[0011]**
- US 6997955 B **[0033]**