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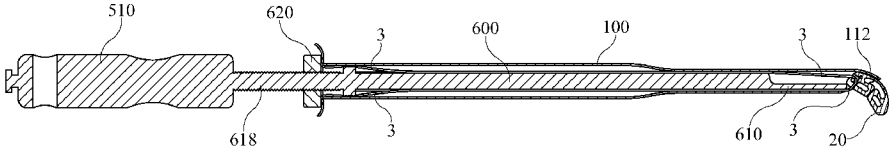


FIG. 58

(57) Abstract: A system for implanting an inter-body device (20) between adjacent vertebrae comprises an inter-body device having a plurality of cans secured to a flexible bridge and having a relief portion therebetween. An inserter tube (100) and complementary bullnoses (600) are advantageously secured to the vertebrae by an extension arm for securing the assembly precisely in place. A plurality of articulating trial implants are provided to test fit a disc space for the proper sized inter-body device.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES UTILITY PATENT APPLICATION

FOR

FLEXIBLE INTER-BODY IMPLANT

OF

DR. ROLANDO PUNO

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This international application claims the benefit of co pending U.S. Provisional Patent Application Serial Number 61/224,333 filed July 9, 2009 and entitled "Improved Inter-Body Implantation System and Method".

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[002] The present invention relates generally to an inter-body device for intervertebral disc replacement or inter-body spinal fusion and more specifically to a system including a device for disc replacement or an inter-body device for spinal fusion and an insertion system and method for placing the aforementioned devices in an intervertebral space utilizing a plurality of surgical approaches.

DESCRIPTION OF THE RELATED ART

[003] The normal human spine is comprised of seven cervical, twelve thoracic, and five lumbar vertebrae. Intervertebral discs are interposed between adjacent vertebrae with the exception of the first two cervical vertebrae. The spinal vertebrae are supported by ligaments, tendons and muscles which allow movement such as flexion, extension, lateral bending and rotation.

[004] Motion between vertebrae occurs through the relative motion of the disc and two facet joints. The disc lies in the front or anterior portion of the spine. The facet joints lie laterally on either side of the posterior portion of the spine. The basic shape of a human intervertebral disc is oval, having a depression in a longitudinal side thereof to form a kidney bean shape.

[005] The spine is a flexible structure that is capable of great curvature and twist in a plurality of directions. However, developmental or genetic irregularities, trauma, chronic stress and degeneration due to wear may result in the need for surgical intervention to effect repair. In cases of degeneration (or injury and disease) it may be necessary or desirable to remove a disc that is no longer performing the function of separation between adjacent vertebrae. This is particularly desirable in cases of degeneration or herniation, which often result in chronic and debilitating back pain.

[006] A damaged disc may be replaced with a prosthetic disc that is intended to be functionally identical to the natural disc. Some prior art replacement discs are shaped to approximate the shape of the natural disc that is being replaced, and further are comprised of a flexible material having a shape memory such that the disc may be deformed for insertion through a small area in the spine, then expand to its normal shape once insertion is completed. One of the major difficulties with many prior art discs is that they are most easily inserted utilizing an anterior surgical insertion due to the structure of the spine and arrangement of nerves proximate the spine. The anterior surgical approach to disc replacement is, however, quite invasive.

[007] Furthermore, many prior art disc replacements are complex devices made of a combination of materials and are also bulky and difficult to place properly between adjacent vertebrae. The implantation of these prior art devices requires invasive surgery for proper placement. Additionally, some disc replacements utilize materials such as hydrogels to simulate the gelatinous texture of the natural disc nucleus. However, these materials tend to be easily damaged during implantation and also tend to migrate into undesired areas of the body.

[008] A number of prior art inter-body devices to effect the fusion of adjacent vertebrae to each other are also employed to alleviate the pain and discomfort caused by disc degeneration. Implantation of these prior art devices is typically quite unwieldy and invasive due primarily to their complex structure and the complex geometry of the human spine.

[009] Accordingly, a need exists for an inter-body disc device or a disc replacement device and an implantation system for inserting the inter-body fusion or disc replacement device that are robust and surgically minimally invasive for the efficacious replacement of damaged or degenerated intervertebral discs.

SUMMARY OF THE INVENTION

[010] The present invention obviates the aforementioned difficulties in the prior art by providing an improved inter-body device that more closely resembles natural disc physiology and by providing a system and method for deploying improved inter-body devices that enables a surgeon to accurately and quickly place an inter-body device of appropriate size in a disc space, thereby minimizing surgery times and greatly enhancing recovery times for disc replacement surgeries.

[011] The improved inter-body devices of the present invention comprise a plurality of cans, or generally annular bodies, that extend from a flexible bridge that permits the cans to flex independently and compress together for ease of deployment in said disc space, while relaxing to their natural shape once deployed. The cans may further include a plurality of apertures for accepting bone graft material to aid in the fusion process, as well as corrugated upper and lower surfaces that act to guide the inter-body devices upon entry into the disc space and engage the adjacent vertebrae.

[012] The inter-body insertion system of the present invention includes an inserter tube that is shaped to guide a plurality of instruments into the disc space in the same orientation throughout the process. Once inserted, the inserter tube may be secured to the spine by means of an extension arm that locks the tube in place. A plurality of bullnose instruments having distal tips of varying shapes are used to prepare the disc space for entry of the inter-body device as well as to aid in inserting the inter-body device into the disc space.

[013] Additionally, the system of the present invention includes a plurality of articulating trial implants that may be inserted to determine the proper implant length prior to deployment of an inter-body device. The trial implants of the invention may articulate with respect to an implant rod that aids in positioning them in the disc space, thereby providing for relatively easy trial implant insertion and removal.

[014] The invention further comprises a novel inserter tube handle that is capable of being secured to a complementary handle that attaches to a plurality of bullnose instruments for insertion into the disc space. A box cutter having a distal tip with opposed cutting edges is provided to shave the posterior endplates of adjacent vertebrae in preparation for implant insertion.

[015] The invention also includes a bone graft insertion system that utilizes a novel bone graft plunger for distributing morselized bone graft material throughout the anterior disc space.

[016] Other features, advantages, and objects of the present invention will become apparent from the detailed description of the invention herein below, taken in conjunction with the appended drawing Figures.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

[017] Fig. 1 is a perspective view of a an inter-body device and an inserter tube in accordance with one embodiment of the present invention;

[018] Fig. 2 is a perspective view of a an inter-body device and an inserter tube in accordance with one embodiment of the present invention;

[019] Fig. 3 is a perspective view of a an inter-body device and an inserter tube in accordance with one embodiment of the present invention;

[020] Fig. 4 is a top view of an inter-body device in accordance with one embodiment of the present invention;

[021] Fig. 5 is a top view of an inter-body device in accordance with one embodiment of the present invention;

[022] Fig. 6 is a top view of an inter-body device in accordance with one embodiment of the present invention.

[023] Fig. 7 is a top view of an inter-body device in accordance with one embodiment of the present invention;

[024] Fig. 8 is a top view of an inter-body device in accordance with one embodiment of the present invention;

[025] Fig. 9 is a perspective view of an inter-body device in accordance with one embodiment of the present invention;

[026] Fig. 10 is a perspective view of an inter-body device in accordance with one embodiment of the present invention;

[027] Fig. 11 is a top view of an inter-body device in accordance with one embodiment of the present invention;

[028] Fig. 12 is a top view of an inter-body device in accordance with one embodiment of the present invention;

[029] Fig. 13 is a top view of an inter-body device in accordance with one embodiment of the present invention;

[030] Fig. 14 is a perspective view of an inter-body device in accordance with one embodiment of the present invention;

[031] Fig. 15 is a perspective view of an inter-body device in accordance with one embodiment of the present invention;

[032] Fig. 16 is a perspective view of an inter-body device in accordance with one embodiment of the present invention;

[033] Fig. 17 is top view of an inter-body device in accordance with one embodiment of the present invention;

[034] Fig. 18 is a top view of an inter-body device in accordance with one embodiment of the present invention;

[035] Fig. 19 is a top view of an inter-body device being advanced into a disc space in accordance with one embodiment of the present invention;

[036] Fig. 20 is a perspective view of an inter-body device push rod in accordance with one embodiment of the present invention;

[037] Fig. 21 is a perspective view of an insertion tool in accordance with one embodiment of the present invention;

[038] Fig. 22 is an exploded view of an insertion tool in accordance with one embodiment of the present invention;

[039] Fig. 23 is a perspective view of a trial implant in accordance with one embodiment of the present invention;

[040] Fig. 24 is a perspective view of a bullnose and trial handle in accordance with one embodiment of the present invention;

[041] Fig. 25 is a partial view of a bullnose and inserter in accordance with one embodiment of the present invention;

[042] Fig. 26 is a perspective view of a trial implant in accordance with one embodiment of the present invention;

[043] Fig. 27 is a partial view of a bullnose and inserter in accordance with one embodiment of the present invention;

[044] Fig. 28 is an exploded view of a bullnose and trial handle in accordance with one embodiment of the present invention;

[045] Fig. 29 is a perspective view of an assembled bullnose and trial handle in an inserter tube in accordance with one embodiment of the present invention;

[046] Fig. 30 is a side view of an inserter tube in accordance with one embodiment of the present invention;

[047] Fig. 31 is a side view of an inserter tube in accordance with one embodiment of the present invention;

[048] Fig. 32 is a perspective view of a trial implant and trial handle in accordance with one embodiment of the present invention;

[049] Fig. 33 is a side view of a trial implant in accordance with one embodiment of the present invention;

[050] Fig. 34 is a perspective view of a trial handle in accordance with one embodiment of the present invention;

[051] Fig. 35 is an exploded view of a trial handle in accordance with one embodiment of the present invention;

[052] Fig. 36 is a perspective view of a trial implant and implant rod in accordance with one embodiment of the present invention;

[053] Fig. 37 is a perspective view of a trial implant in accordance with one embodiment of the present invention;

[054] Fig. 38 is a top view of an inserter tube and trial implant advancing into a disc space in accordance with one embodiment of the present invention;

[055] Fig. 39 is a top view of an inserter tube and trial implant advancing into a disc space in accordance with one embodiment of the present invention;

[056] Fig. 40 is a top view of an inserter tube and trial implant advancing into a disc space in accordance with one embodiment of the present invention;

[057] Fig. 41 is a top view of an inserter tube and trial implant advancing into a disc space in accordance with one embodiment of the present invention;

[058] Fig. 42 is a top view of an inserter tube and trial implant advancing into a disc space in accordance with one embodiment of the present invention;

[059] Fig. 43 is a top view of an inserter tube and trial implant advancing into a disc space in accordance with one embodiment of the present invention;

[060] Fig. 44 is a partial side view of an inter-body device and bullnose inside an inserter tube in accordance with one embodiment of the present invention;

[061] Fig. 45 is a partial side view of an inter-body device and bullnose inside an inserter tube in accordance with one embodiment of the present invention;

[062] Fig. 46 is a partial top view of a bullnose in accordance with one embodiment of the present invention;

[063] Fig. 47 is a partial bottom view of a bullnose in accordance with one embodiment of the present invention;

[064] Fig. 48 is a partial top view of a bullnose in accordance with one embodiment of the present invention;

[065] Fig. 49 is a partial bottom view of a bullnose in accordance with one embodiment of the present invention;

[066] Fig. 50 is a top view of an inserter tube in a disc space, with an inter-body device and bullnose advancing into said disc space in accordance with one embodiment of the present invention;

[067] Fig. 51 is a top view of an inserter tube in a disc space, with an inter-body device and bullnose advancing into said disc space in accordance with one embodiment of the present invention;

[068] Fig. 52 is a top view of an inserter tube in a disc space, with an inter-body device and bullnose advancing into said disc space in accordance with one embodiment of the present invention;

[069] Fig. 53 is a perspective view of a box cutter in accordance with one embodiment of the present invention;

[070] Fig. 54 is a side view of a box cutter in accordance with one embodiment of the present invention;

[071] Fig. 55 is a side view of an inserter tube advanced into a disc space in accordance with one embodiment of the present invention;

[072] Fig. 56 is a perspective view of a trial handle and a bullnose in accordance with one embodiment of the present invention;

[073] Fig. 57 is a perspective view of a trial handle and a bullnose in accordance with one embodiment of the present invention;

[074] Fig. 58 is a cross-sectional side view of a bullnose and inter-body device being advanced through an inserter tube in accordance with one embodiment of the present invention;

[075] Fig. 59 is a perspective view of an inter-body device insertion tool in accordance with one embodiment of the present invention;

[076] Fig. 60 is a perspective view of an inter-body device insertion tool in accordance with one embodiment of the present invention;

[077] Fig. 61 is a perspective view of a bone graft funnel secured to an inserter tube in accordance with one embodiment of the present invention;

[078] Fig. 62 is a perspective view of a bone graft funnel in accordance with one embodiment of the present invention;

[079] Fig. 63 is a perspective view of a bone graft funnel in accordance with one embodiment of the present invention;

[080] Fig. 64 is an exploded perspective view of a bone graft plunger in accordance with one embodiment of the present invention;

[081] Fig. 65 is a perspective view of a bone graft plunger in accordance with one embodiment of the present invention;

[082] Fig. 66 is a perspective view of a bone graft plunger in accordance with one embodiment of the present invention;

[083] Fig. 67 is a side view of a bone graft plunger in accordance with one embodiment of the present invention;

[084] Fig. 68 is a perspective view of a bone graft plunger in accordance with one embodiment of the present invention;

[085] Fig. 69 is a cross-sectional side view of a bone graft plunger being advanced through an inserter tube into a disc space in accordance with one embodiment of the present invention;

[086] Fig. 70 is a side view of a bone graft plunger being advanced through an inserter tube into a disc space in accordance with one embodiment of the present invention;

[087] Fig. 71 is a cross-sectional side view of a bone graft plunger being advanced through an inserter tube in accordance with one embodiment of the present invention;

[088] Fig. 72 is a perspective view of an extension arm in accordance with one embodiment of the present invention;

[089] Fig. 73 is a side view of an extension arm in accordance with one embodiment of the present invention;

[090] Fig. 74 is a perspective view of an extension arm in accordance with one embodiment of the present invention;

[091] Fig. 75 is a perspective view of an extension arm in accordance with one embodiment of the present invention;

[092] Fig. 76 is a perspective view of an extension arm in accordance with one embodiment of the present invention;

[093] Fig. 77 is a perspective view of an extension arm in accordance with one embodiment of the present invention;

[094] Fig. 78 is a perspective view of an extension arm in accordance with one embodiment of the present invention;

[095] Fig. 79 is a perspective view of an extension arm in accordance with one embodiment of the present invention;

[096] Fig. 80 is a perspective view of the system of the present invention in place in the environment of a human spine in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

[097] Referring now to the drawing Figures, and in particular Figs. 1-3, and in accordance with a preferred constructed embodiment of the system 10 of the present invention, there is depicted an inter-body device 20 and an inserter tube 100 for orienting and inserting said inter-body device 20 into a disc space of a human spine. Drawing Figs. 50 and 55 depict one example of the insertion of inter-body device 20 into a disc space 2 of a spine 1 between vertebrae 4, and may be referred to throughout this specification for reference to the human anatomy to which the present invention is applied. Furthermore, it should be noted that the disc to be replaced by the inter-body device 20 of the present invention is first removed by a surgeon performing a thorough discectomy. Typically, it is desirable to extend the discectomy to a contralateral half of the disc space to allow placement of the longest inter-body device 20 possible and to maximize bony surface exposure for fusion to

occur. If there is significant disc space 2 collapse, a complete discectomy may not be possible until disc space 2 distraction is performed utilizing one of many known in the art distraction tools.

[098] As seen in Fig. 1, inter-body device 20 may comprise a plurality of lobes or cans 30, each spaced one from another and depending from a flexible bridge 60 that permits independent flexure and motion of each can 30 to facilitate entry into disc space 2. Flexible bridge 60 may be comprised of a memory metal such as nitinol or other flexible plastic material that has shape memory so that the overall shape of inter-body device 20 is retained once device 20 is implanted. In the embodiments of the invention depicted in Figs. 1-3 each can 30 includes a pair of generally parallel passageways 32 therein, through which a suture 3 may be threaded to aid in positioning of inter-body device 20, as well as to enable retrieval device 20 should its' placement prove unsatisfactory. Once inter-body device 20 is properly inserted into disc space 2, suture 3 may be manipulated to aid in implant positioning by pulling on either end thereof. Once device 20 is properly positioned, suture 3 may simply be pulled through both passageways 32 and thus removed from inter-body device 20.

[099] Inter-body device 20 cans 30 may further comprise an upper surface 34 and a lower surface 36 that contact upper and lower surfaces of adjacent vertebrae 4 once inter-body device 20 is properly positioned in disc space 2. Inter-body device 20 may further comprise an anterior wall 40 that may be integral with bridge 60, and may be generally convex in shape. Anterior wall 40 may terminate in distal and proximal cans 30. Anterior wall 40 includes an interior wall portion 42 that extends between adjacent cans 30. Additionally, each can 30 includes a posterior wall 44

that extends generally between upper 34 and lower 36 portions of cans 30 on a posterior portion thereof.

[0100] While many embodiments of the inter-body device 20 of the present invention are shown to have a generally anterior curvature, it should be recognized that inter-body devices 20 having a posterior curvature are within the scope of the present invention. Additionally, inter-body device 20 is preferably formed of a material that is durable and non-reactive. A wide variety of biocompatible materials may be utilized to manufacture the inter-body device 20 of the present invention, including but not limited to biocompatible polymers, elastomeric materials, hydrogels, hydrophilic polymers, shape memory polymers, and shape memory metals. It is understood that one of ordinary skill in the art would be aware of a variety of materials suitable for such implantation. In one embodiment of the invention, inter-body device 20 is comprised of a carbon fiber material while in another, device 20 is comprised of a polyetherketone (PEK) material.

[0101] As shown in Fig. 1, proximal can 30 may include a hitch 50, depicted in this embodiment of the invention as a generally annular protrusion extending outwardly from proximal can 30, which may be grasped or secured to various insertion tools as will be discussed in greater detail herein below.

[0102] Figs. 1-3 also depict an inserter tube 100 shown with one wall removed to show the path of suture 3 through inserter tube 100. Inserter tube 100 comprises a pair of opposed upper and lower walls 102, 104 and opposed medial and lateral walls 106, 108 that define a hollow tubular member through which inter-body device 20 may be deployed. Inserter tube 100 includes a distal end 110 wherein lateral wall 108 forms a curved portion 112 that guides the deployment of inter-body device 20 as it is advanced through inserter tube 100. In this embodiment of the present

invention lateral wall 108 curved portion 112 has a length greater than that of medial wall 106 to allow inter-body device 20 to curve into disc space 2 as it is advanced through inserter tube 100.

[0103] Cans 30 of each inter-body device 20 are spaced such that a relief area 38 is defined by the void space between cans 30. Relief area 38 permits inter-body device 20 and cans 30 to flex and compress during insertion and placement into disc space 2 while returning to its relaxed shape once it is properly positioned. Fig. 2 depicts an inter-body device 20 having only two cans 30, thereby providing for a much larger relief area 38. Fig. 3 depicts an inter-body device 20 wherein suture 3 is knotted at a terminal end for retrieval of device 20 back through inserter tube 100.

[0104] Fig. 4 is a top view of an embodiment of the present invention whereby each can 30 of inter-body device 20 includes an aperture 46 therein for accepting a morselized bone graft material to enhance the spinal fusion process. Additionally,as seen in Fig. 4 hitch 50 may comprise a generally annular aperture 52 therein for accepting a pin (not shown) or other instrument for inserting, retrieving and positioning inter-body device 20 in disc space 2.

[0105] Figs. 5 and 6 depict a further embodiment of the present invention whereby relief portion 38 of inter-body device 20 proximate interior wall 42 defines an elongated slot that enables bridge 60 to flex while each can 30 flexes independently of the other and is capable of motion in three planes. This feature of the invention enables accurate positioning of device 20 in disc space 2 by allowing device 20 to deform during insertion into disc space 2 and expand back to its relaxed shape once properly inserted. The embodiment of the invention shown in Fig. 5 depicts upper surfaces 32 having a plurality of corrugated ridges 33 thereon. Lower surfaces 34 may also include a plurality of corrugated ridges 33 to allow inter-body

device 20 to engage the upper and lower surfaces of adjacent vertebrae when inserted in disc space 2, which also assists in device 20 positioning within disc space 2.

[0106] Fig. 7 depicts a yet further embodiment of inter-body device 20 whereby flexible bridge 60 is secured to a pair of opposed cans 30, the proximal one of which includes a hitch 50 depending therefrom to facilitate insertion and removal. Fig. 8 depicts a similar embodiment to that of Fig. 7 wherein flexible bridge 60 extends around can 30 posterior wall 44 to firmly secure can 30 to bridge 60 while still permitting independent movement of each can 30.

[0107] Fig. 9 shows an additional exemplary embodiment of inter-body device 20 having a pair of spaced opposed flexible bridges 60, each secured to a pair of spaced cans 30 providing a relatively large relief area 38. In this embodiment of the invention, a hitch 50 is provided having a pair of spaced flanges 54 extending from proximal can 30, each with an aperture 52 therein to accept a pin (not shown) for connecting inter-body device 20 to an insertion and removal tool as will be discussed in greater detail herein below.

[0108] Referring now to Figs. 10-14 there are depicted a plurality of articulating inter-body devices 200 in accordance with a yet further embodiment of the present invention. Inter-body device 200 comprises a distal half 210 and a proximal half 220 connected by a central hinge 230. Each half 210, 220 of trial implant 200 includes a passageway 232 into which a segment of flexible spine 240 is inserted. Flexible spine 240 may be comprised of a memory metal to permit halves 210, 200 to flex with respect to each other then return to a relaxed position. A hitch 50 is also provided extending from proximal half 220 of trial implant 200 to facilitate insertion and removal thereof form disc space 2.

[0109] Figs. 10 and 11 depict central hinge 230 disposed approximately in the center of distal and proximal halves 210, 220, while Fig. 12 depicts hinge 230 disposed on the anterior edges of distal and proximal halves 210, 220 to permit flexure in the anterior direction. Fig. 13 depicts hinge 230 disposed on the posterior edges of distal and proximal halves 210, 220 to permit flexure in the posterior direction. Finally, Fig. 14 depicts a further embodiment of the invention having a plurality of apertures 234 therein to accept bone graft material to aid in vertebral fusion.

[0110] It should be noted that the embodiments of inter-body device 20 depicted in Figs. 10-14 may also be employed as trial implants, whereby they are inserted into disc space 2 prior to insertion of a permanent implant to test fit disc space 2 for proper size and positioning, and to determine that disc space 2 is properly prepared to receive inter-body device 20. Where inter-body devices 20 are employed as trials, they may be manufactured of a suitable material capable of reuse after proper sterilization, as is well known in the surgical arts.

[0111] Referring now to Figs. 15-17, an exemplary embodiment of inter-body device 20 is shown formed of a single piece of material, whereby flexible bridge 60 is integral with a pair of spaced elongated cans 30, each having upper 34 and lower 36 surfaces with an aperture 46 therein for accepting bone graft material. The embodiment of the present invention depicted in Figs. 15 and 17 further comprises a plurality of ridges 33 on upper 34 and lower 36 surfaces to facilitate vertebral engagement of device 20. Additionally, in this embodiment of the invention a portion of one can 30 comprises a void or slot 56 therein, that extends around an end of said can 30 and into posterior wall 44 thereof. Additionally, a pair of opposed apertures 58 communicate with slot 56 to accept a pin 59 that is secured in apertures

58. Pin 59 can then easily be accessed by an insertion and removal tool as discussed below.

[0112] Furthermore, in this embodiment of the invention flexible bridge 60 extends outwardly towards the distal and proximal ends, respectively, of cans 30 to define a relief area 38 that permits considerable flexure and straightening of device 20 as it is deployed through inserter tube 100. In a yet further embodiment of the invention, distal can 30 may comprise a beveled distal edge portion 31, best seen in Figs. 15 and 16, that facilitates smooth entry of device 20 into disc space 2 since the height of distal can 30 is slightly less than the height of inter-body device 20 along the remainder of its length.

[0113] It is to be understood from the teachings of this specification that the embodiments of inter-body device 20 shown and described herein may be produced in a wide variety of sizes, varying in both overall length and height, as well as varying in spacing between cans 30 and bridge 60 such that the invention may be adapted for use in nearly any size disc space as required by a surgeon. Furthermore, it is to be understood that the inter-body devices 20 described herein may include a plurality of radiographic markers disposed at a plurality of points in or on said inter-body devices 20, to enable a surgeon to ensure proper placement of said devices 20 by conventional radiographic techniques.

[0114] Referring now to Fig. 19 there is shown a flexible implant guide sleeve 140 that is sized to be inserted through inserter tube 100 into disc space 2. In this embodiment of the invention inter-body device 20 is carried by a distal end 142 of guide sleeve 140 until it is properly positioned in disc space 2 then guide sleeve 140 is retracted back into inserter tube 100. Guide sleeve 140 may advantageously be formed of a thin memory metal or equivalent flexible material capable of curving

into disc space 2. Furthermore, in one embodiment of the invention the relaxed shape of guide sleeve 140 distal end 142 approximates that of inter-body device 20 and disc space 2 to facilitate placement of device 20 therein.

[0115] Fig. 20 depicts an inter-body device push rod 160 adapted to be inserted into the interior of inserter tube 100, having a clasp 162 at a distal end 164 thereof. Clasp 162 may be actuated by known-in-the art means to engage and release a pin 59 of an inter-body device 20, for example the device 20 depicted in Fig. 15. Distal end 164 of push rod 160 may be sized to fit into slot 56 of inter-body device 20, thereby enabling device 20 to rotate into disc space 2 before being release by disengagement of clasp 162.

[0116] Referring now to Figs. 21 and 22, there is depicted an alternative inter-body insertion tool 300 in accordance with one embodiment of the present invention. Insertion tool 300 comprises an elongated central body 310 having a handle 312 secured thereto and extending upwardly therefrom, and a lock button 314 that is inserted through an aperture 316 in an upper surface of central body 310. Central body 310 further includes a channel 318 that extends longitudinally through central body 310, shaped to accept an elongated shaft 320 having a clasp 322 at a distal end 324 thereof for engaging an inter-body device 20. Shaft 320 further comprises a pair of spaced apertures 326 therethrough that align with a complementary pair of spaced apertures 330 in central body 310, and into which a pair of locking pins 328 are inserted to secure shaft 320 into central body 310.

[0117] Insertion tool 300 further comprises a stationary member 340 that includes a handle 342 secured thereto and extending outwardly therefrom, and an elongated slot 344 that is shaped to engage elongated central body 310. Stationary member 340 comprises a distal tip 346 shaped to direct an inter-body device 20 into a disc

space, as well as an elongated groove 348 in a portion thereof. Central body 310 fits closely into slot 344 of stationary member 340, and is slidable therein to enable central body 310 to be advanced forward such that clasp 22 extends into disc space 2 to position inter-body device 2.

[0118] Insertion tool 300 further comprises a sliding member 360, having a handle 362 extending therefrom and including a tongue 364 extending longitudinally on a portion of sliding member 360 that engages groove 348 of stationary member 340. Sliding member 360 further comprises a distal tip 366 that is generally flat. When assembled, and as best seen in Fig. 21, sliding member 360 and stationary member 340 form a channel into which an inter-body device 20 may be inserted, secured by clasp 322 of central body 310 shaft 220. Sliding member 360 is capable of moving forward relative to stationary member 340, thereby enabling distal tip 366 to enter and distract disc space 2 to facilitate device 20 delivery. Once so inserted, stationary member 340 and central body 310 are also inserted into disc space 2 for delivery of inter-body device 20. This feature of the instant invention provides an insertion tool 300 that assists in disc space distraction for ease of implant insertion.

[0119] Referring now to Figs. 23, 32, 33, 36, and 37 the present invention further comprises a trial implant 400 for determining the proper size of a permanent inter-body device 20 to be deployed, having a distal end 402 and a proximal end 404 secured together via a central hinge 406 that enables ends 402, 404 to rotate in a single plane relative to each other. Trial implant 400 is shaped to generally conform to the shape of inter-body device 20 that will be deployed for permanent use in disc space 2. Proximal end 404 of trial implant 400 includes a slot 408 therein, and a pin 410 secured transversely to slot 408 for securing trial implant 400 in an articulating fashion to a trial implant rod 420.

[0120] Trial implant rod 420 comprises an elongated body 421 terminating in a pair of spaced distal tips 422 that abut trial implant 400 at their distal ends. Trial implant rod further comprises a pin hinge 424 that extends through and is secured to both spaced distal tips 422 and a proximal end 426 having a threaded aperture therein for engagement with a trial implant insertion tool. An articulating arm 430 having an aperture at a distal end 432 thereof is rotatably secured to pin 410 of trial implant 400. Articulating arm 430 further comprises a proximal end 434 having a slot 436 therein that is engaged by hinge pin 424 of implant rod 420 so that articulating arm 430 is capable of both rotational and longitudinal movement with respect to implant rod 420. Furthermore, since trial implant 400 rotates around pin 410, both implant 400 and articulating arm 430 are capable of rotational motion with respect to implant rod 420.

[0121] Fig. 32 depicts trial implant 400 and implant rod 420 secured to an insertion tool 500 having a trial handle 510 secured to a threaded shaft 502. It should be noted that trial handle 510 is designed to connect to a plurality of components of the present invention, as will be discussed further herein below. Fig. 36 depicts an alternative embodiment of trial implant rod 420 wherein distal tips 422 include hinge 424 at a distal portion thereof such that articulating arm 430 extends outwardly toward trial implant 400. As seen in Fig. 37 trial implants 400 may further include a flexible spine 412 inside distal and proximal ends 402, 404, similar to those embodiments shown in Figs. 10-14.

[0122] Fig. 24 depicts a trial handle 510 secured to a bullnose 600 designed to aid in distraction of disc space 2 as well as insertion of inter-body devices 20 therein. Bullnose 600 comprises an elongated shaft 602 capable of engaging and being secured to handle 510 at a proximal end 604 thereof, and a distal end 606 having a

tapered distal tip 610 thereon, for inserting into and distracting disc space 2. Fig. 25 depicts bullnose 600 distal tip 610 exiting distal end 110 of inserter tube 100.

[0123] Figs. 26-29 depict an alternative embodiment of bullnose 600 utilized for inter-body device 20 insertion having a blunt distal tip 610 at distal end 606. Shaft 602 includes a suture 3 guide groove 612 along a substantial portion thereof that terminates in a wide groove end 614 proximate distal end 606 of bullnose 600. Guide groove 612 provides a space in which suture 3 is disposed when bullnose 600 is inserted through inserter tube 100, as shown in Fig. 29. Bullnose 600 proximal end 604 further includes an annular groove 616 that is engaged by a latch (such as a pin or spring-loaded ball, not shown) interior to handle 510. In operation, suture 3 may be secured to inter-body device 20 as shown in Figs. 1-3 and may ride in groove 612 of bullnose 600 as it is advanced through inserter tube 100 into disc space 2.

[0124] Referring again to Fig. 28 and to Figs. 34 and 35, trial handle 510 is shown in further detail. Handle 510 includes a distal end 512 having an aperture 514 therein for engaging a proximal end 604 of bullnose 600. A locking flange 520 is also disposed on distal end 512 of handle 510 for engaging a complementary flange of, for example, inserter tube 100. Handle 510 may also include lock 524 and unlock 522 marks on an exterior surface thereof indicating that inserter tube 100 is locked onto handle 512 when a corresponding mark on tube 100 is aligned with lock mark 524, and alternatively unlocked with a corresponding mark on tube 100 is aligned with unlock mark 522. Handle 522 may include a release button 530 that is biased by spring 532 to engage (or disengage) a locking pin 516 extending through the distal end 512 thereof, for releasing bullnose 600 from engagement with handle 510.

[0125] Figs. 29-31 depict one exemplary embodiment of inserter tube 100 and its engagement with handle 510. Inserter tube 100 includes a distal end 100 terminating in a curved portion 112 and a proximal end 114 terminating in a hollow handle 120 that communicates with tube 100, said handle 120 having a locking flange 122 on an interior circumference thereof that engages complementary locking flange 520 of trial handle 510. Inserter tube 100 handle 120 may also include an alignment arrow 124 that, when aligned with one of the lock/unlock markings 524, 522 of handle 510 indicate that locking flange 122 of inserter tube 100 is engaged or disengaged with locking flange 520 of handle 110. In a further embodiment of the invention, inserter tube handle 120 may comprise a small groove in a proximal edge thereof to accommodate suture 3 as it exits handle 120 when inter-body device 20 is being deployed.

[0126] Fig. 29 additionally shows bullnose 600 inserted into inserter tube 100 and extending through distal end 110 thereof. As can be seen from this drawing Figure, bullnose 600 may be secured to handle 510 thence inserted into inserter tube 100, which is then locked onto handle 510. By carefully positioning inserter tube 100 into disc space 100, bullnose 600 may then be inserted to an exact depth into disc space 2 necessary for suitable placement of inter-body device 2. Accordingly, inserter tube 100 may be provided with a plurality of depth markings along the exterior surfaces thereof (for example on upper and lower walls 102, 104 and on medial and lateral walls 106,108) to assist a surgeon in proper placement of inserter tube 100, as will be discussed in further detail herein below.

[0127] Figs. 38-43 depict the deployment of trial implant 400 through inserter tube 100 into disc space 2. Firstly, inserter tube 100 and concomitant bullnose 600 are inserted into disc space 2 through an annulotomy as far laterally in the disc space

as possible. This first step is typically practiced with bullnose 600 having a tapered tip 610 to aid in disc space distraction. In one embodiment of the present invention, the tapered tip 610 extends approximately 15 mm past beyond the distal end 110 curved tip 112 of inserter tube 100. A surgeon may note the depth of the inserter tube in the annulotomy at this stage of the procedure.

[0128] Secondly, a blunt tip 610 bullnose is assembled to trail handle 510 and inserter tube 100 and reinserted in disc space 2 In one embodiment of the present invention, the blunt tip 610 extends approximately 10 mm past beyond the distal end 110 curved tip 112 of inserter tube 100. The blunt tip 610 and concomitant inserter tube 100 are advanced into disc space 2 until distal tip 610 of bullnose 600 touches the anterior annulus 5 of disc space 2. At this point, bullnose 600 may be withdrawn and inserter tube 100 locked into place, as will be discussed further herein below.

[0129] A trial implant 400 is now secured to trial handle 510 and is advanced into disc space 2, as shown sequentially in Figs. 38- 43. The ability of trial implant 400 to articulate coupled with the curved portion 112 of inserter tube 100 enable accurate and easy placement of trial implant 400 in disc space 2. Furthermore, differing lengths and heights of trial implants 400 may be employed to determine the proper size inter-body device 20 to be used. The longest trial implant 400 that can be successfully deployed in disc space 2 will determine the length of inter-body device 20 to be used. Typically, the height of a distractor used to distract the disc space will determine the height of the inter-body device 20 to be deployed.

[0130] Referring now to Figs. 44, 46 and 47, an exemplary deployment of inter-body device 20 through inserter tube 100 utilizing suture 3 to secure device 20. In this embodiment of the invention, bullnose 600 comprises a single longitudinal suture guide groove 612 and wide groove end on one side of bullnose 600. Fig. 44

depcits distal tip 610 advancing device 20 through inserter tube 100 until it is properly positioned in disc space 2.

[0131] In contradistinction, Figs. 45, 48 and 49 depict a bullnose 600 having a longitudinal suture guide groove 612 and wide groove end on two sides of bullnose 600, whereby suture 3 is routed both above and below bullnose 600 shaft 602, as best seen in Fig. 45. This embodiment of the invention facilitates manipulation and placement of inter-body device 20 in disc space 2.

[0132] Referring now to Figs. 50-52, there is depicted the deployment of inter-body device 2 through inserter tube 100 into disc space 2. Apertures 46 of cans 30 may be filled with morselized bone graft material prior to inserting inter-body device 20 into inserter tube 100. A suture 3 is secured to hitch 50 of device 20 prior to insertion in inserter tube 100 as well. The suture guide groove 612 of bullnose 600 may also be aligned with the groove in inserter tube handle 120 to provide clearance for suture 3. The looped suture 3 shown in Figs. 50- 52 is disposed in groove 612 and bullnose 600 is then inserted into inserter tube 100, pushing inter-body device 20 into place as it advances into tube. It should be noted that blunt distal tip 610 bullnose 600 is used for insertion of inter-body device 20. Once properly positioned, radiographical techniques may be used to verify the positioning of inter-body device 20, whereupon suture 3 is removed, as is bullnose 600 and concomitant handle 510. Inserter tube 100 may remain in place in disc space 2 for application of bone graft material as described below.

[0133] Figs. 53 and 54 depict a box cutter 300 used to shave posterior endplates of adjacent vertebrae 4 in preparation for inter-body device 20 deployment. Box cutter 700 comprises a central shaft 702 secured to a handle 704 at a proximal end thereof. Handle 704 may have an option slap hammer flange 706 at a proximal end

thereof for attaching a known-in-the art slap-hammer device to aid in use of box cutter 700. A detachable head 708 is secured to shaft 702 at a distal end thereof, having a tapered distal tip 710 to facilitate distraction as head 708 enters the disc space 2. Head 708 may be provided in varying widths and heights to accommodate variable spinal geometry, and further may be provided with depth markers (not shown) along the exterior surfaces thereof to enable a surgeon to determine how far distal tip 710 advances into disc space 2. In one embodiment of the present invention box cutter head 708 height may be provided by a marking on the surface thereof. Additionally, box cutter head 708 may include exterior markings indicating the distance from distal tip 710.

[0134] Box cutter 700 further comprises a pair of spaced cutting edges 714 that facilitate the shaving of the posterior endplates with box cutter 700. In operation, box cutter 700 head 708 is selected having an appropriate width for a given application, and the posterior endplates of adjacent vertebrae 4 are shaved by advancing cutting edges 714 into disc space 2, utilizing a slap-hammer attachment if necessary.

[0135] Figs. 55-58 depict an alternative embodiment of the inserter tube 100 of the instant invention wherein the proximal end 114 is slightly wider than distal end 110 and wherein no handle is present. Fig. 56 depicts an alternative embodiment of bullnose 600 having a proximal end 604 that includes a threaded shaft 618 for engaging a handle 510, as well as a threaded stop 620 that is rotatable along threaded shaft 618 that abuts distal end 114 of inserter tube 100 when bullnose 600 is inserted therein. Fig. 56 further depicts a conventional "slap-hammer" 6 device secured to handle 510 to apply additional longitudinal force to bullnose 600 where necessary.

[0136] Fig. 57 is a view of bullnose 600 from the opposite side as Fig. 56, depicting a second suture guide groove 612 extending longitudinally into distal tip 610 of bullnose 600 for positive placement of suture 3. Fig. 58 is a cross-sectional view of bullnose 600 deploying inter-body device 20 through inserter tube 100, wherein suture 3 is guided in grooves 112 both above and below bullnose 600, as suture 3 loops through hitch 50 of inter-body device 20. This feature of the invention further aids in positioning of implants as they are deployed into disc space 20.

[0137] Figs. 59 and 60 depict two inter-body device 20 insertion and retrieval tools 750, each having a distal end 752 having a pair of spaced furcations 754 extending therefrom to engage pin 59 of inter-body device 20, or a similar hitch 50. In the embodiment of Fig. 59, furcations 754 are spaced to snap-fit onto pin 59 of hitch 50. In the retrieval tool embodiment shown in Fig. 60, a longitudinally slidable sleeve 756 is provided over distal end 752 of tool 750 that forces furcations 754 together to grasp pin 59 as sleeve 756 is advanced toward distal end 752.

[0138] Figs. 61 and 62 depict a bone graft funnel 800 that is operatively secured to inserter tube 100 handle 100 having an aperture 802 therein for supplying bone graft material through inserter tube 100 to disc space 2, as well as a flat edge 804 for ease of use, thereby facilitating use of bone graft funnel with other instruments or structures employed in spinal surgery. As best seen in Fig. 63, and in an alternative embodiment of bone graft funnel 800, a locking flange 806 is provided on one edge thereof for engaging a complementary flange on inserter tube 100 handle 120.

[0139] Fig. 64 depicts a bone graft plunger 820 designed for use with bone graft funnel 800 and inserter tube 100, having an angled plunger tip 822 on a distal end thereof. Angled plunger tip 822 may be formed of, for example, a flexible material

such as a silastic elastomer that enables plunger tip 822 to flex as it extends through inserter tube 100. In one embodiment of the present invention plunger tip 822 is disposable after each use. Furthermore, and in accordance with one embodiment of the invention, angled tip 822 is sized to be slightly larger than the interior profile of inserter tube 100 to tightly engage inserter tube 100 and enable angled tip 822 to force all the bone graft material deposited in inserter tube 100 into disc space 2. Bone graft plunger 820 further comprises a central shaft 824 having a distal end 826 that is shaped to snap-fit onto a complementary aperture 828 of angled tip 822, thereby securing tip 822 to shaft 824. A proximal end 830 of shaft 824 may include a threaded aperture 832 for securing bone graft plunger to a handle 510. While plunger tip 822 is be comprised of an elastomeric material, making it both flexible and disposable after use, plunger shaft 824 may be comprised of elastomer, but may also be produced from more durable alloys for repeated use after sterilization.

[0140] Fig. 66 depicts an alternative embodiment of bone graft plunger 820 that includes an elongated angled flexible tip 822 (shown in its relaxed state) that is secured to a plunger shaft 824. This embodiment of the invention enables bone graft material to be deposited further into disc space 2 since plunger 820 assumes a relaxed shape that approximates that of anterior disc space 2.

[0141] Figs. 67 and 68 show an alternative bone graft plunger 820 that is a single-piece plunger having an integral angled tip 822 and plunger shaft 824. Bone graft plunger 820 angled tip 822 may include a curved surface 823 designed to push bone graft material through complementary curved portion 112 of inserter tube 100. Plungers 820 constructed in accordance with this embodiment of the present invention can be manufactured of an elastomer or metal alloy without departing from the scope of the present invention.

[0142] Fig. 69 is a cross-section of bone graft funnel 800, plunger 820, and inserter tube 100 in operation. Funnel 800 is secured to inserter tube 100 handle 120 and provides a convenient mechanism for depositing bone graft material 7 into inserter tube 100. Plunger 820 is then inserted into aperture 802, and through handle 120 into inserter tube 100, thereby forcing all bone graft material 7 deposited therein into inserter tube 100 and disc space 2. Funnel 800 is then removed from handle 120 and plunger 820 is once again used to force the remaining bone graft material in inserter tube 100 into disc space 2. Flexible angled tip 822 enables plunger 820 to curve into disc space 2 as it is advanced, thereby providing superior delivery of bone graft material 7.

[0143] Figs. 70 and 71 depict an alternative embodiment of bone graft plunger 820, wherein angled tip 822 and shaft 824 are comprised of a single piece of memory metal that is curved to approximate the curvature of an anterior portion of disc space 2 in its relaxed shape. In this embodiment of the invention, bone graft plunger 820 is straightened to insert its distal tip 822 into funnel 800 and inserter tube 100, and it assumes its curved or relaxed shape when inserted into disc space 2.

[0144] Referring now to Figs. 72 -79, and in accordance with a constructed embodiment of the invention, an extension arm 900 is depicted for securing various components of the present system 10 to a plurality of pedicle screws 9 that are secured to a human spine by known-in-the-art surgical techniques. With specific reference to Figs. 72 and 73, extension arm 900 comprises an arm body 902 that engages a central threaded rod 910 having a proximal end that may be turned by, for example, a wrench, nut driver, or like mechanical device. Rod 910 also includes a distal end 914, which is shown in the present embodiment having a plurality of

helical threads thereon for engaging a pedicle screw having complementary threads therein.

[0145] An adjustable clamp 920 is secured to extension arm body 902 by a conventional adjustment knob 921 and concomitant threaded member (not shown). Clamp 920 includes a pair of spaced clamp arms 922 extending outwardly from body 902 that are adjustable with respect to one another by conventional means, for example a clamp adjustment knob 924 secured to a threaded member 926, that engages complementary threads 928 in each clamp arm. Extension arm 900 is secured to a complementary pedicle screw by rotating central rod 910 to engage distal end 914 with the pedicle screw. Clamp 920 is then adjusted to position arms 922 to secure, for example, inserter tube 100 to extension arm 900 in a precise location for delivery of inter-body device 20.

[0146] Figs. 74 and 75 depict additional embodiments of extension arm 900 that include an extension arm body 902 that has a distal end 914 having a transverse pin 906 secured thereto for engaging a complementary hook of a pedicle screw (not shown).

[0147] Figs. 76 and 78 depict an alternative embodiment of extension arm 900 having a body 902 that is shaped like an elongated channel, having a pair of spaced edges 907 along its length. Distal end 914 includes a cut-out portion 916 that engages a head of a pedicle screw 9, as shown in Fig. 78. Clamp 920 is secured to a clamp guide 930 that includes a pair of spaced arms 932, each having a groove 934 therein for engaging edges 907 of extension arm 900 body 902. In this embodiment of the invention, clamp guide 930 arms 932 slide onto body 902 edges 907, thereby providing a clamp guide 930 and claim 920 that is slidable along the length of extension arm body 902.

[0148] Figs. 77 and 79 depict a similar extension arm embodiment to those shown in Figs. 76 and 78, except that distal end 914 includes a vertical pin 918 that engages an aperture in pedicle screw 9, as best seen in Fig. 79.

[0149] Fig. 80 depicts the system 10 of the present invention secured to vertebrae 4 of spine 1 in an exemplary fashion. A plurality of pedicle screws are secured to spine 1 in a conventional fashion, as is known to one of ordinary skill in the art. Extension arm 900 is secured to pedicle screw 9 at its distal end 914. Clamp 920 of extension arm 900 is positioned via clamp guide 930 to engage handle 120 of inserter tube 100. Inserter tube 100 is positioned to be inserted through the annulotomy into disc space 2. Finally, trial handle 510 is secured to bullnose 600 and inserted through inserter tube 100.

[0150] In operation, the present system 10 and the components thereof may be employed by a surgeon to effect disc replacement in the following fashion. Initially, a surgeon makes a longitudinal midline incision in the area of pathology, through skin, subcutaneous tissue and fascia. Radiologic confirmation of vertebral level is then obtained through conventional radiographic techniques. Next, the lumbar spine is exposed through subperiosteal dissection, extending exposure only to the base of the transverse processes to permit identification of the entry points for insertion of pedicle screws 9. If TLIF (transforaminal lumbar inter-body fusion) is planned in conjunction with posterolateral fusion, dissect to the tips of the transverse processes of the levels included in the fusion. Pedicle screws are then applied in the conventional manner, as is known to one of ordinary skill in the art.

[0151] Next, a total ipsilateral facetectomy is performed, using an osteotome or drill. Additional bony removal may be carried out using a Kerrison Rongeur or drill to create a bigger space for insertion of appropriate sized implants and instruments.

At this point, a surgeon may perform any additional neural decompression, if the determination is made that the particular case requires it. The posterolateral corner of the annulus is exposed maximally to allow an annulotomy as far lateral as possible. Next, a 1cm-wide annulotomy incision is made.

[0152] Once the above-mentioned preparatory steps are completed, a thorough discectomy is performed. It is desirable in one embodiment of the present invention to extend the discectomy to the contralateral half of the disc space to allow for placement of the longest inter-body device 20 possible and to maximize bony surface exposure for fusion to occur. If there is significant disc space 2 collapse, a complete discectomy may not be possible until disc space 2 distraction is complete.

[0153] Next, the surgeon distracts the disc space sequentially with conventional distraction instruments, for example distractors ranging in height from 6mm to 16mm, until a snug fit is achieved. The surgeon may note the insertion depth and the height of the distractor used since the insertion depth gauges the depth of disc space 2. The height of the distractor employed in this step will determine the height chosen for the box cutter 700, bullnoses 600, inserter tube 100, trial implants 400, and inter-body device 20.

[0154] Next, the surgeon may apply a conventional contralateral distractor to maintain disc height and perform any additional discectomy, as necessary to prepare disc space 2. In one embodiment of the invention, a surgeon may employ a standard Penfield Elevator to palpate the vertebral endplate and then feel the anterior edge of the vertebral body. Once the anterior edge is felt and the Penfield Elevator dips, then adequate discectomy up to the anterior annulus has been achieved.

[0155] With a known-in-the art nerve root retractor the surgeon next protects the exiting and traversing nerve roots. At this point, box cutter 700 is inserted to shave the posterior endplate by utilizing a box cutter head of the same size as the tallest distractor used to achieve a snug fit as discussed above. Box cutter head 708 height may be provided on the surface thereof. It also has markings indicating the distance from distal tip 710. The surgeon then decorticates the remaining endplate surfaces of the superior and inferior vertebral bodies to enhance formation of bony fusion.

[0156] In the next step, the surgeon secures the extension arm 900 loosely to the inferior pedicle screw 9. Trial handle 510 is next secured to an appropriately sized bullnose 610, with a tapered distal tip 610 and this assembly is inserted into an identically sized inserter tube 100. Bullnose 600 and inserter tube 100 heights may marked on the instruments, as necessary.

[0157] Next, the assembled bullnose 600 and inserter tube 100 is advanced into disc space 2 through the annulotomy, by directing inserter tube 100 distal end 100 five to ten degrees laterally. The assembly orientation is then slowly manipulated to 0 degrees in the sagittal plane, keeping inserter tube 100 as far lateral in disc space 2 as possible.

[0158] Once the above assembly is inserted to the desired depth (as determined from the distractor placement mentioned above, bullnose 600 is removed. The surgeon should note the insertion depth of inserter tube 100 by the markings on the superior, medial and inferior surfaces thereof to indicate the distance from distal tip 110.

[0159] Next, the surgeon assembles handle 510 with the correct sized bullnose 600 having a blunt tip 610. Again, bullnose 600 height may be marked on the

surface of the main shaft. Next, bullnose 600 is inserted into inserter tube 100 by engaging inserter tube handle 120 with trial handle 510. In one embodiment of the invention, bullnose 600 having a tapered distal tip 610 extends 15mm beyond the inserter tube distal aperture 110. Furthermore, bullnose 600 having a blunt distal tip 610 extends only 10mm beyond inserter tube 100 distal tip 110. The surgeon advances the handle 510, bullnose 600, and inserter tube 100 assembly deeper into disc space 2 until bullnose 600 distal end 610 touches the anterior annulus thereof.

[0160] Next, the surgeon secures inserter tube 100 handle 120 to extension arm 900 and extension arm 900 distal end 914 is secured tightly to pedicle screw 9. Next, the surgeon can remove bullnose 600, while remembering that in this position, there is 10 mm of free space between inserter tube 100 distal tip 110 and the anterior annulus of disc space 2, to allow smooth deployment of the bullnose 600 having a blunt distal tip 610 and inter-body device 20 into the anterior disc space 2.

[0161] In the next step, the surgeon assembles handle 510 to the determined trial implant 400 height size. Each trial implant 400 may be marked with its length and height to facilitate assembly in the operating room. Through inserter tube 100, the surgeon next sequentially attempts to deploy three different trial implant 400 lengths (of the chosen trial implant 400 height), starting with the shortest (for example, 20mm), then with an intermediate (for example, 25mm) to the longest (for example, 30mm). Saline may be used to lubricate the inserter for easier deployment.

[0162] The longest trial implant 400 length that can be successfully deployed into disc space 2 determines the inter-body device length to be used. After radiologic confirmation of satisfactory trial implant 400 position within disc space 2, remove trial implant 400 from disc space 2 and inserter tube 100.

[0163] In the next step, the surgeon secures handle 510 to the previously determined bullnose 600 height. At this stage, bullnose 600 having blunt distal end 610 will be employed to push inter-body device 20 through inserter tube 100. Each inter-body device 20 may be marked with its height and length to facilitate assembly. The inter-body device should be visually inspected by the surgeon for any damage. Next, a standard No. 2 suture 3 may be looped through hitch 50 of inter-body device 20. Suture 3 will allow the inter-body device 20 to be retrieved, if necessary, before complete passage through inserter tube 100. If inter-body device 20 is retrieved it should again be visually inspected for any damage.

[0164] The surgeon next fills apertures 46 within the inter-body device 20 cans 30 with morselized bone graft material. The relief area 38 between cans 30 and anterior wall 40 should not be filled to permit inter-body device 20 bridge 60 and cans 30 to flex. Doing so may affect the proper deployment of inter-body device 20 through inserter tube 100 and disc space 2.

[0165] Nest, the surgeon inserts inter-body device 20 through inserter tube 100 with the concavity of the inter-body device 20 directed medially and hitch 50 directed proximally. Inserter tube 100 medial and lateral sides may be labeled on the instrument for ease of insertion. The surgeon positions looped suture 3 into the suture groove in inserter tube 100 handle 120. The groove in inserter tube 100 handle 120 should align with suture guide groove 612 in bullnose 600. This prevents suture 3 from being caught between the sliding surfaces of bullnose 600 and the interior wall of inserter tube 100.

[0166] Using the bullnose 600 handle 510 the surgeon next advances the inter-body device 20 along inserter tube 100 and into anterior disc space 2. Saline may be

used to lubricate inserter tube 100 for easier deployment. Once inserted, the surgeon verifies device 20 position by conventional radiography.

[0167] Next, the surgeon pulls looped suture 3 out of hitch 50 and inserter tube 100. Inserter tube 100 is next unlocked from extension arm 900 and handle 510, and bullnose 600 and inserter tube 100 assembly is withdrawn from disc space by approximately 10mm in preparation for application of bone graft material. A slap hammer may be used to aid withdrawal. This assembly is then secured back to extension arm 900 utilizing clamp 920.

[0168] Next, the surgeon disengages handle 510 from inserter tube 100 handle 120 and pulls bullnose 600 out of inserter tube 100. Bone graft funnel 800 is then placed on the proximal end of inserter tube 100 handle 120. The surgeon then assembles the appropriate size bone graft plunger 820 tip 822 to handle 510. In one embodiment of the invention, each plunger tip 822 is marked with its height. Next, the surgeon deposits morselized bone graft material 7 into bone graft funnel 800, and pushes it down inserter tube 100 using the bone graft plunger 820. Once this step is completed, the bone graft funnel 800 is disconnected from inserter tube handle 120. The bone graft material 7 may then be pushed further into disc space 2 using bone graft plunger 820 again.

[0169] Finally, the surgeon may remove the bone graft plunger 820, disconnect extension arm 900 from pedicle screw 9, and remove extension arm 900 and inserter tube 100 as an assembled unit to complete the procedure.

[0170] While the present invention has been shown and described herein in what are considered to be the preferred embodiments thereof, illustrating the results and advantages over the prior art obtained through the present invention, the invention is

not limited to those specific embodiments. Thus, the forms of the invention shown and described herein are to be taken as illustrative only and other embodiments may be selected without departing from the scope of the present invention, as set forth in the claims appended hereto.

I claim:

1. A system for insertion of an inter-body device into a disc space between adjacent vertebrae, said disc space being accessible through an annulotomy, said disc having been removed from said disc space through a discectomy, and said vertebrae having a plurality of pedicle screws secured thereto, comprising:

a first bullnose having a distal end shaped to distract said disc space, a central shaft, and a proximal end for engaging a handle to which said bullnose may be secured;

an inserter tube having a distal end for placement in said annulotomy space, and a proximal end comprising a hollow handle, and a channel therebetween; and

a second bullnose having a distal end shaped to advance into said disc space, a longitudinal shaft, and a proximal end shaped to engage a handle, whereby said second bullnose is sized to be accepted through the channel of said inserter tube.

2. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

an inserter tube having a distal end comprising a curved lateral wall and a straight medial wall to facilitate delivery of said inter-body device into said disc space.

3. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

an inserter tube comprising a pair of opposed upper and lower walls and a pair of opposed medial and lateral walls and having a distal end comprising a curved lateral wall having a predetermined length and a straight interior wall having a length less than that of the curved lateral wall to facilitate delivery of said inter-body device into said disc space.

4. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

an inserter tube having a hollow handle at a proximal end thereof in communication with said tube, through which said bullnose and said inter- body device may be inserted.

5. A system for insertion of an inter-body device into a disc space as claimed in claim 4 comprising:

an inserter tube having a locking flange on a proximal end of said hollow handle for engaging a complementary locking flange.

6. A system for insertion of an inter-body device into a disc space as claimed in claim 2 comprising:

an inserter tube having a plurality of depth indicators on an exterior surface thereof proximate said distal end for determining the depth of said inserter tube in said disc space.

7. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

a trial implant secured to an articulating arm for insertion through said inserter tube into said disc space to determine proper sizing for an inter-body device.

8. A system for insertion of an inter-body device into a disc space as claimed in claim 2 comprising:

a plurality of trial implants having a plurality of lengths, heights, and widths for insertion in said disc space to determine proper sizing for an inter-body device.

9. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

a second bullnose having a longitudinal groove disposed in one side of said longitudinal shaft from the proximal end to the distal end thereof, for accepting a suture used to manipulate said inter-body device.

10. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

a second bullnose having a distal end shaped to advance said inter-body device into said disc space.

11. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

a second bullnose having a distal end shaped to advance into said disc space, a longitudinal shaft, a proximal end shaped to engage a handle, and a pair of opposed longitudinal grooves along two sides of said shaft for permitting clearance of a suture secured to said inter-body device.

12. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

a plurality of bullnoses having distal ends comprising a plurality of different heights for distracting said disc space.

13. A system for insertion of an inter-body device into a disc space as claimed in claim 12 wherein the distal ends of said plurality of bullnoses comprise a plurality of insertion depth marks.

14. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

a box cutter having a head with a distal end comprising a shaped tip for advancing into said disc space and a pair of opposed cutting edges spaced longitudinally from said tip for shaving a posterior endplate of said adjacent vertebrae as said box cutter head is advanced through said annulotomy.

15. A system for insertion of an inter-body device into a disc space as claimed in claim 5 comprising:

a trial handle for engaging a proximal end of said first and second bullnoses, said trial handle adapted to be secured to said inserter tube handle.

16. A system for insertion of an inter-body device into a disc space as claimed in claim 5 comprising:

a trial handle having a locking flange on a distal end thereof for engaging said inserter tube handle and securing said trial handle thereto, wherein a one of said bullnoses is secured to said trial handle, inserted in said inserter tube, and secured to said inserter tube handle.

17. A system for insertion of an inter-body device into a disc space as claimed in claim 7 comprising:

an articulating arm having a distal end and a proximal end having a longitudinal slot therein;

a trial implant having a distal end and a proximal end connected by a central hinge, said implant proximal end rotatably secured to the distal end of said articulating arm; and

a trial implant rod having a pair of spaced distal tips and a proximal end for securing to an insertion tool, said distal tips connected by a hinge pin at a proximal end thereof, wherein said slot of said articulating arm is engaged by said hinge pin, and whereby said trial implant pivots around said central hinge, said distal end of said articulating arm, and said proximal end of said articulating arm for effective placement into said disc space.

18. A system for insertion of an inter-body device into a disc space as claimed in claim 17 comprising:

a plurality of trial implants having a plurality of lengths, heights, and widths for insertion in said disc space to determine proper sizing for an inter-body device.

19. A system for insertion of an inter-body device into a disc space as claimed in claim 17 comprising:

an insertion tool shaft having a distal end secured to said trial implant rod, and a proximal end; and

a trial handle for engaging said proximal end of said first insertion tool shaft, said trial handle adapted to be secured to said inserter tube handle.

20. A system for insertion of an inter-body device into a disc space as claimed in claim 4 comprising:

a bone graft funnel having a central aperture therein, said funnel adapted to be secured to said inserter tube hollow handle for delivering a bone graft material to said disc space through said inserter tube.

21. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

a bone graft plunger having a flexible angled tip at a distal portion thereof and a plunger shaft connected to said angled tip, said bone graft plunger capable of being inserted through said inserter tube to force a bone graft material into said disc space.

22. A system for insertion of an inter-body device into a disc space as claimed in claim 21 wherein said flexible angled tip is shaped to fit tightly in said inserter tube, thereby forcing any bone graft material therein into said disc space.

23. A system for insertion of an inter-body device into a disc space as claimed in claim 21 wherein said flexible angled tip is comprised of an elastomer.

24. A system for insertion of an inter-body device into a disc space as claimed in claim 21 wherein said plunger shaft is comprised of an elastomer.

25. A system for insertion of an inter-body device into a disc space as claimed in claim 21 wherein said flexible angled tip is elongated to advance into said disc space, and wherein said flexible angled tip is curved in a relaxed state.

26. A system for insertion of an inter-body device into a disc space as claimed in claim 21 wherein said bone graft plunger is comprised of a flexible metal alloy.

27. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

an extension arm having an elongated body having a distal end and a proximal end, said arm adapted to be secured to at least one of said pedicle screws at a distal end thereof, and having a clamp secured to the proximal end thereof for securing said inserter tube thereto.

28. A system for insertion of an inter-body device into a disc space as claimed in claim 4 comprising:

an extension arm having an elongated body having a distal end and a proximal end, said arm adapted to be secured to at least one of said pedicle screws at a distal end thereof, and having a clamp secured to the proximal end thereof for securing said inserter tube handle thereto.

29. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

an extension arm having an elongated channel having a distal end and a proximal end, said channel secured at a distal end thereof to at least one of said pedicle screws, and having a clamp secured to an adjustable clamp guide, said clamp guide movable along said channel to secure said clamp at a point thereon, wherein said clamp secures said inserter tube to said extension arm in a precise location.

30. A system for insertion of an inter-body device into a disc space as claimed in claim 4 comprising:

an extension arm having an elongated channel having a distal end and a proximal end, said channel secured at a distal end thereof to at least one of said pedicle screws, and having a clamp secured to an adjustable clamp guide, said clamp guide movable along said channel to secure said clamp at a point thereon, wherein said clamp secures said inserter tube handle to said extension arm in a precise location.

31. A system for insertion of an inter-body device into a disc space as claimed in claim 1 comprising:

a flexible sleeve capable of being inserted into said inserter tube and advanced into said disc space.

32. A method for replacement of a disc between adjacent vertebrae, said disc having been removed from a disc space between said adjacent vertebrae, said vertebrae having a plurality of pedicle screws secured thereto, and said disc space being accessible by an annulotomy procedure comprising the steps of:

a.) distracting the disc space with a distractor of a predetermined height;

b.) noting the depth of insertion of said distractor and the height thereof;

c.) applying a contralateral distractor to vertebrae adjacent to said disc space to maintain disc height;

d.) removing said distractor;

e.) inserting a box cutter instrument into the disc space, said box cutter having the same height as said distractor, thereby shaving a posterior endplate of said adjacent vertebrae;

f.) securing an extension arm capable of holding an instrument loosely to an inferior pedicle screw;

g.) inserting a first bullnose having first bullnose tip and a height the same as said distractor into an inserter tube having a distal end for entering said disc space;

h.) inserting said inserter tube and first bullnose into said disc space through said annulotomy in an orientation of approximately zero degrees in the saggittal plane until said first bullnose reaches the depth of said distractor;

i.) removing said first bullnose from said inserter tube;

j.) inserting a second bullnose having a blunt bullnose tip and a height the same as said distractor into said inserter tube and advancing said second bullnose and said inserter tube deeper into said disc space until said second bullnose tip touches the anterior annulus of said disc space;

k.) securing said inserter tube to said extension arm to fix its position in said disc space;

l.) tightening said universal extension arm to said inferior pedicle screw to secure said inserter tube and said extension arm securely in their respective positions;

m.) removing said second bullnose;

n.) assembling a trial impant having a height the same as said distractor height and a predetermined first length to a handle, and deploying said implant into said disc space through said inserter tube;

o.) repeating step n with a plurality of trial implants having differing lengths and identical heights to determine the longest trial implant that can be deployed in said disc space;

p.) confirming acceptable position of the longest trial implant in said disc space using a conventional imaging technique and removing said trial implant from said disc space;

q.) selecting an inter-body device having the same height and length as said trial implant from step p.) and threading a suture through a hitch on said implant;

r.) inserting said implant through said inserter tube with the curvature therof directed medially and inserting said second bullnose into said inserter tube behind said implant;

s.) advancing said implant through said inserter tube and into said anterior disc space;

t.) confirming acceptable implant position in said disc space using a conventional imaging technique;

u.) removing said suture by pulling said suture through said inserter tube; and

v.) removing said bullnose from said inserter tube.

33. A method for replacement of a disc between adjacent vertebrae, as claimed in claim 1 comprising the further steps of:

a.) placing a bone graft funnel on a proximal end of said inserter tube;

b.) depositing morselized bone graft material into said bone graft funnel;

c.) advancing said bone graft material into said inserter tube utilizing a bone plunger tip until said bone graft material is as far into said disc space as possible;

d.) detaching said extension arm from said pedicle screws; and

e.) removing said inserter tube from said disc space.

34. A method for replacement of a disc between adjacent vertebrae, as claimed in claim 1 comprising the further steps of:

a.) providing a plurality of handles for engaging said trial implants, said first and second bullnoses, said distractors, said box cutters, said implants and said bone plunger tips.

35. A method for replacement of a disc between adjacent vertebrae, as claimed in claim 3 comprising the further steps of:

a.) providing a slap hammer attachment for said plurality of handles for applying a longitudinal force along a longitudinal axis of said inserter tube.

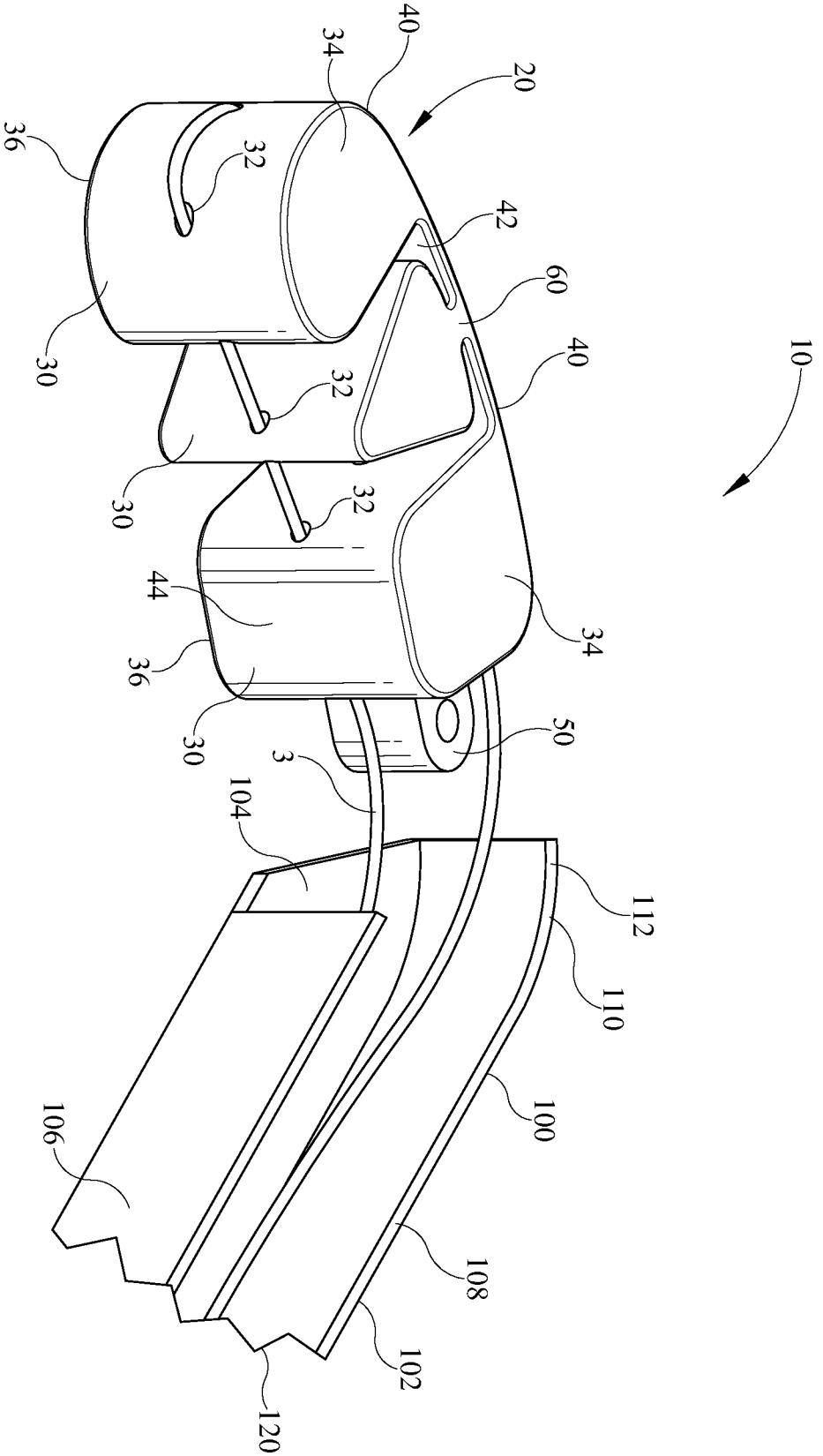


FIG. 1

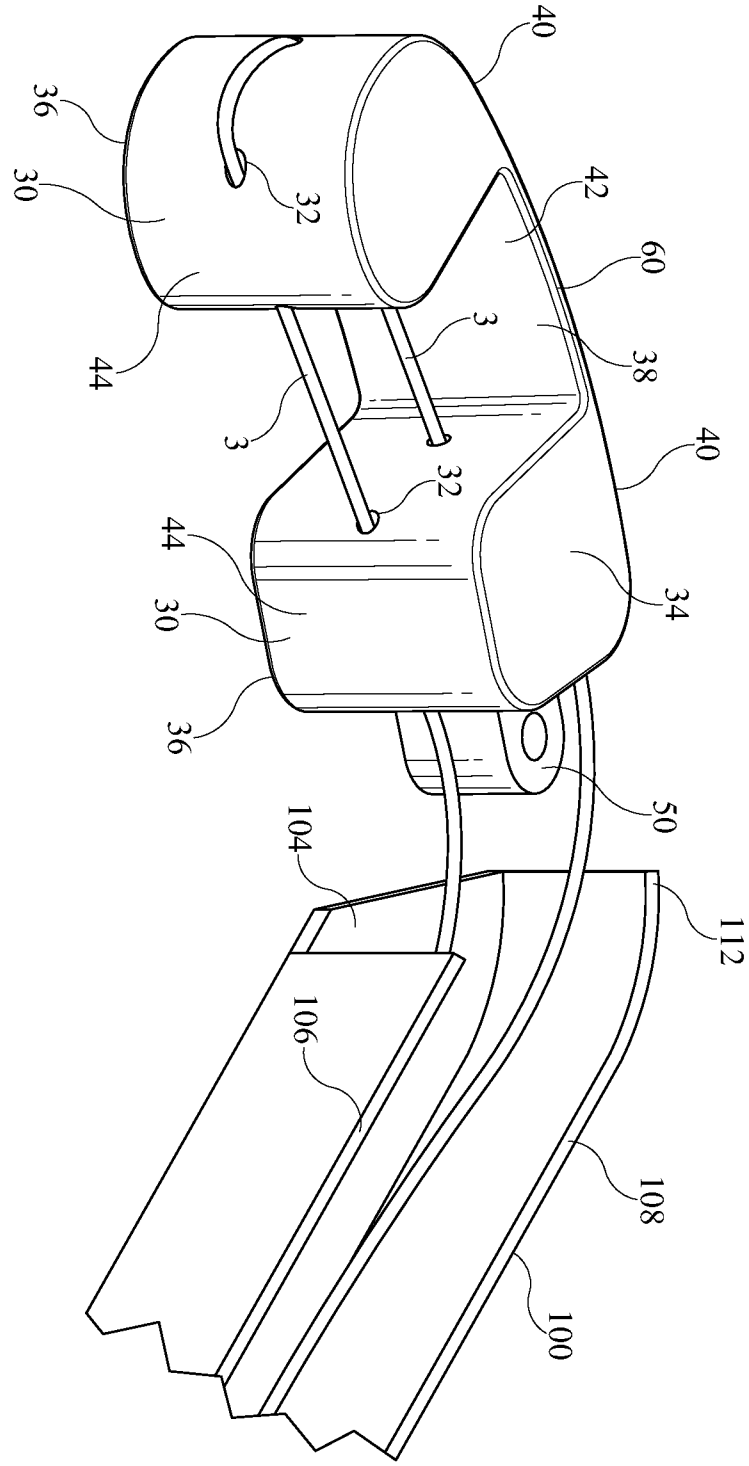


FIG. 2

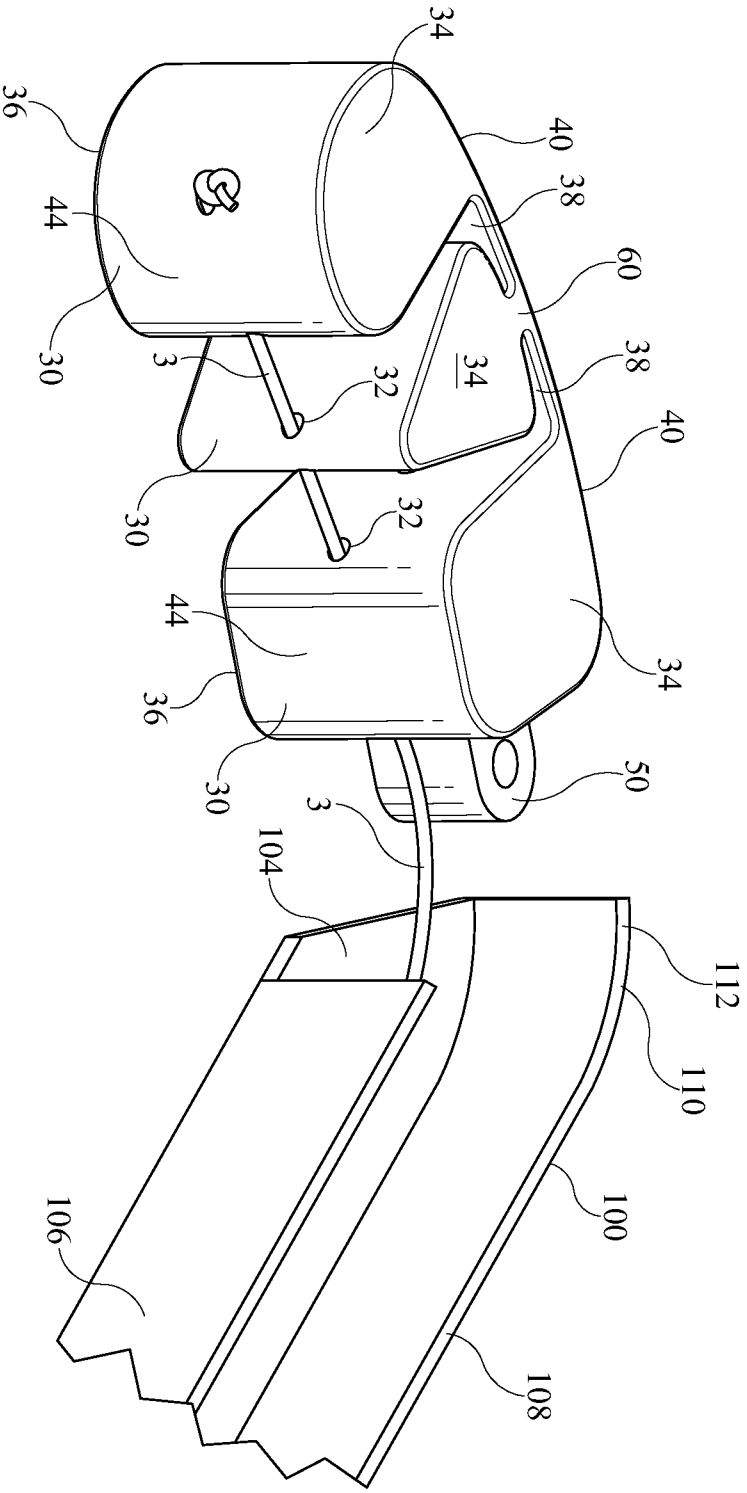

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FIG. 3

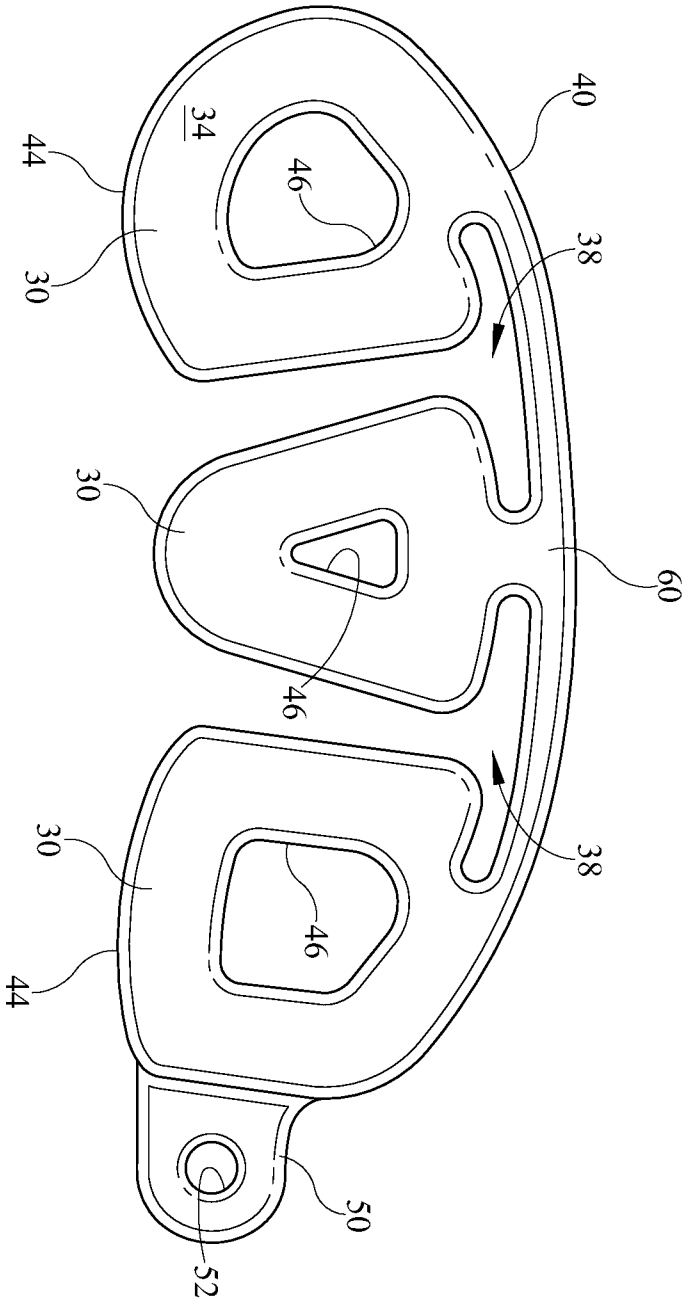


FIG. 4

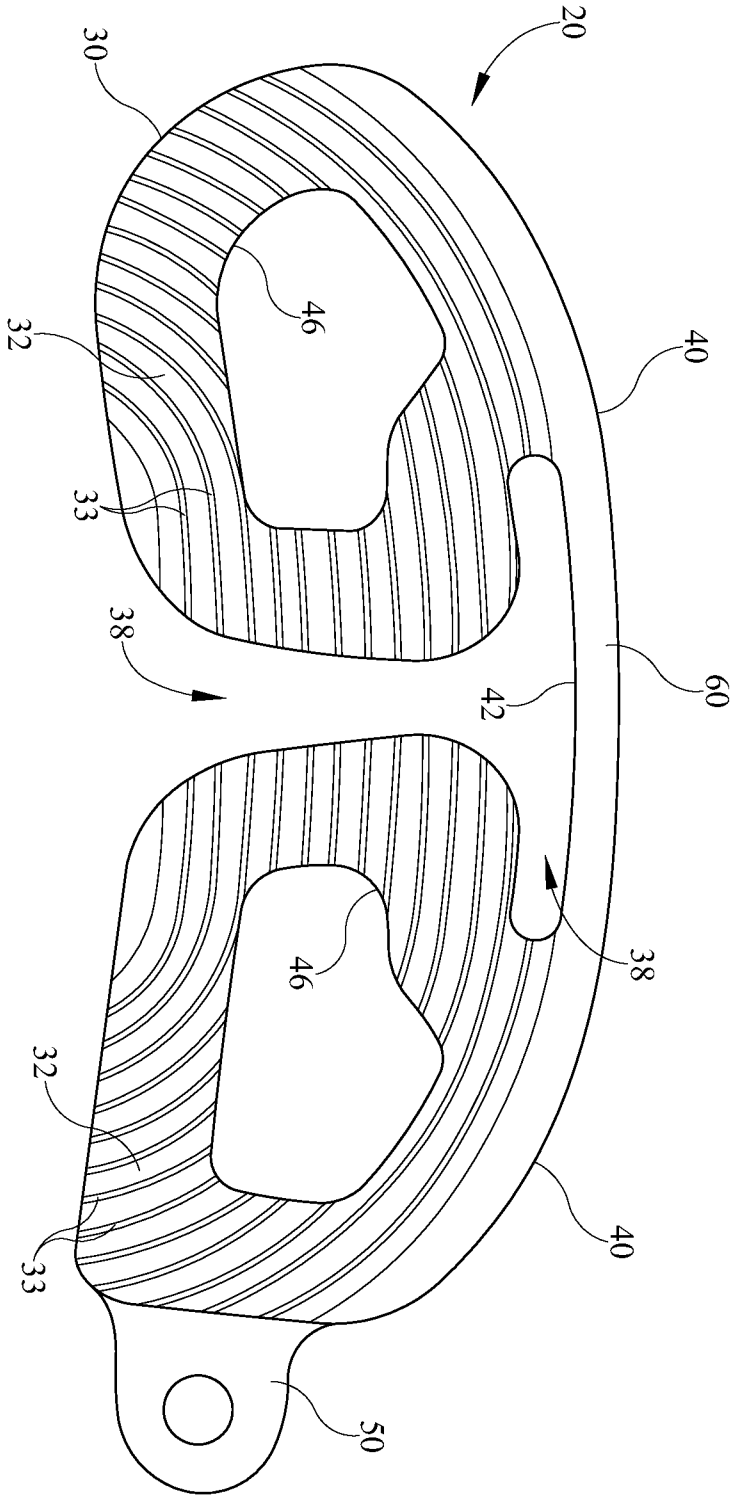


FIG. 5

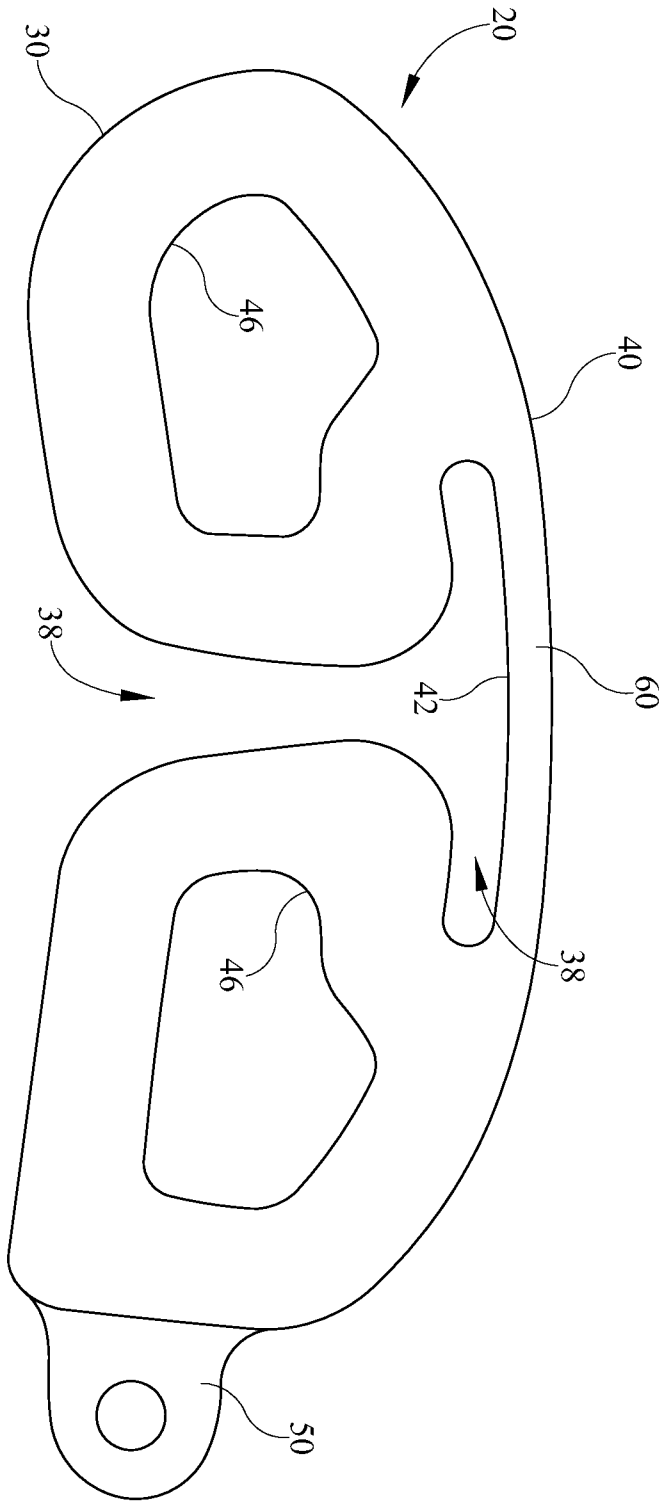


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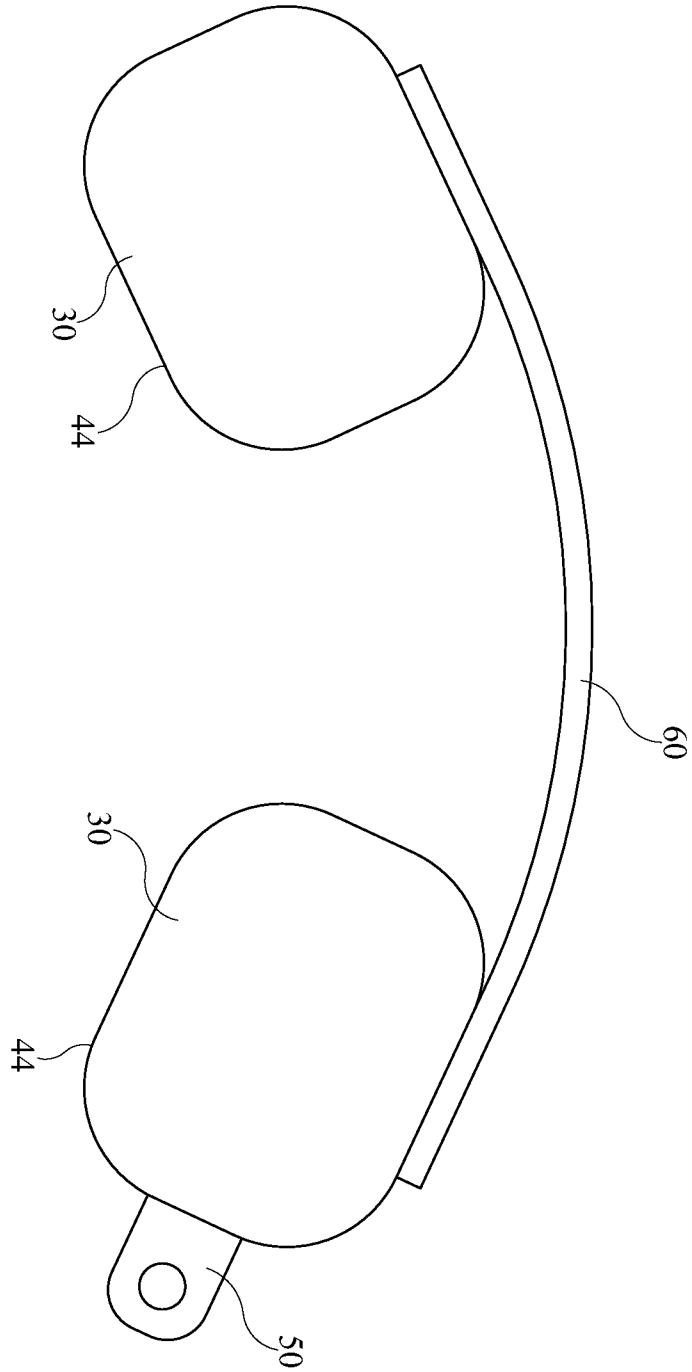


FIG. 7

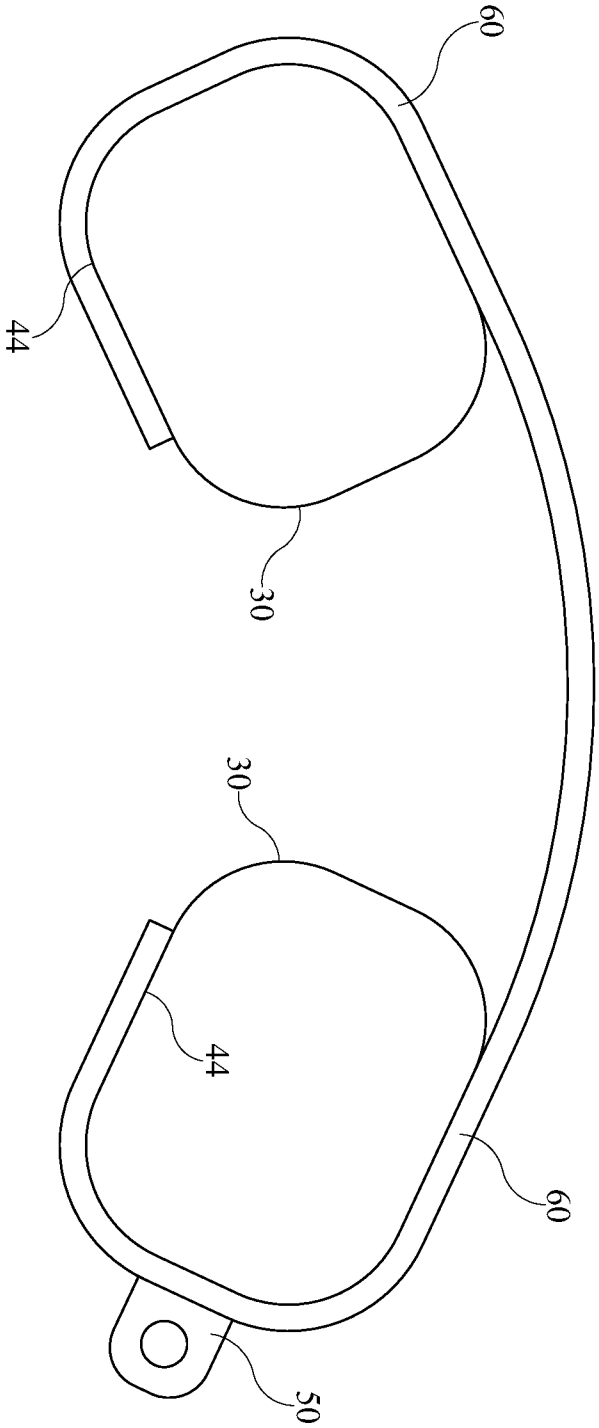


FIG. 8

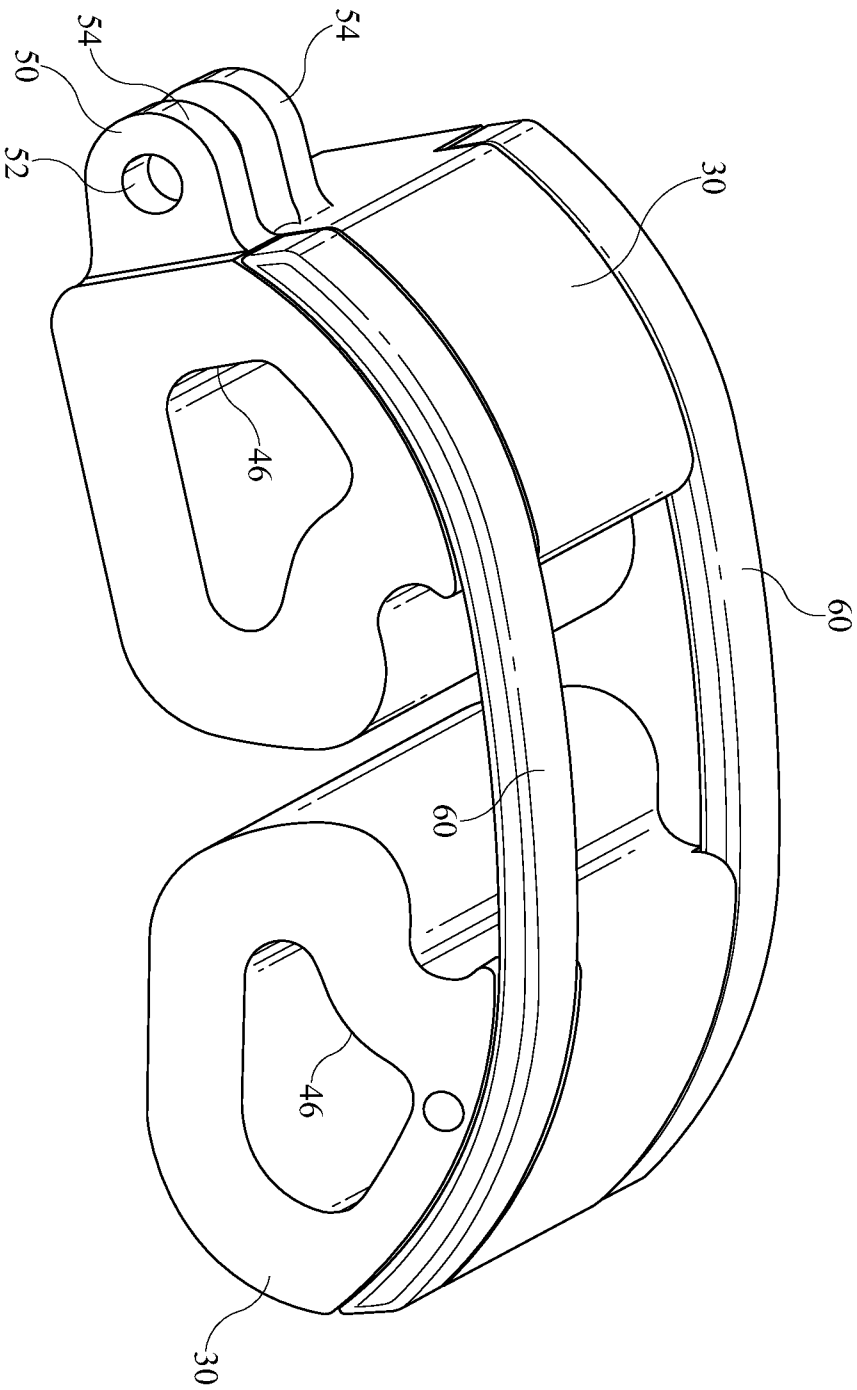


FIG. 9

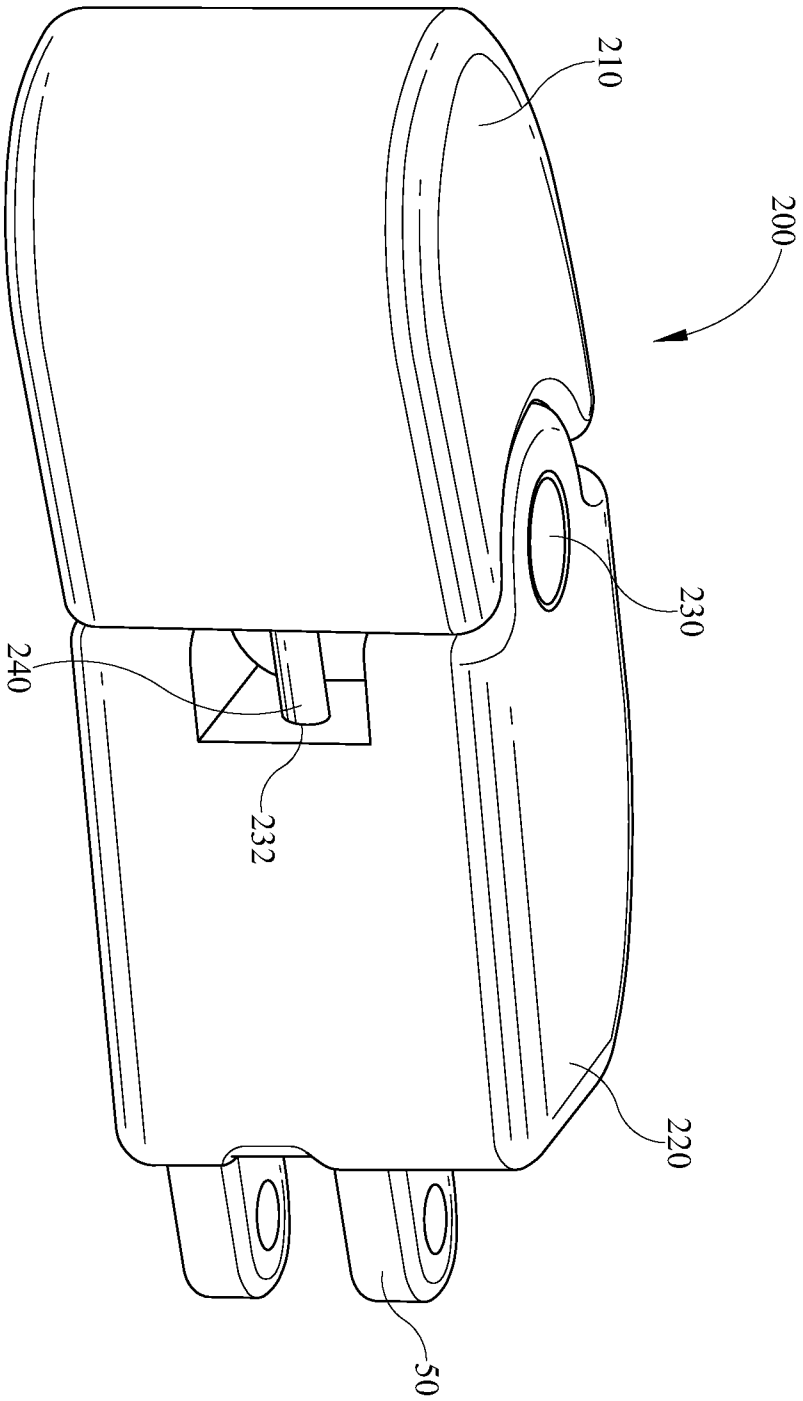


FIG. 10

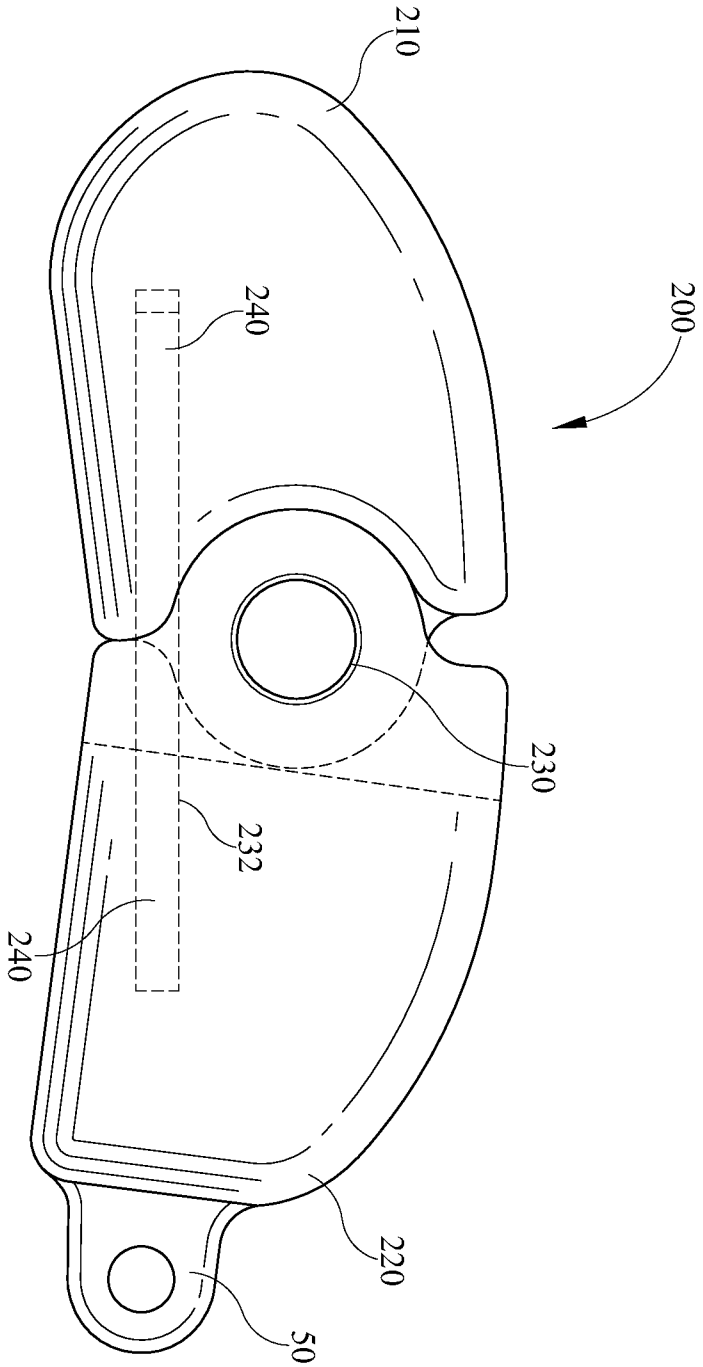


FIG. 11

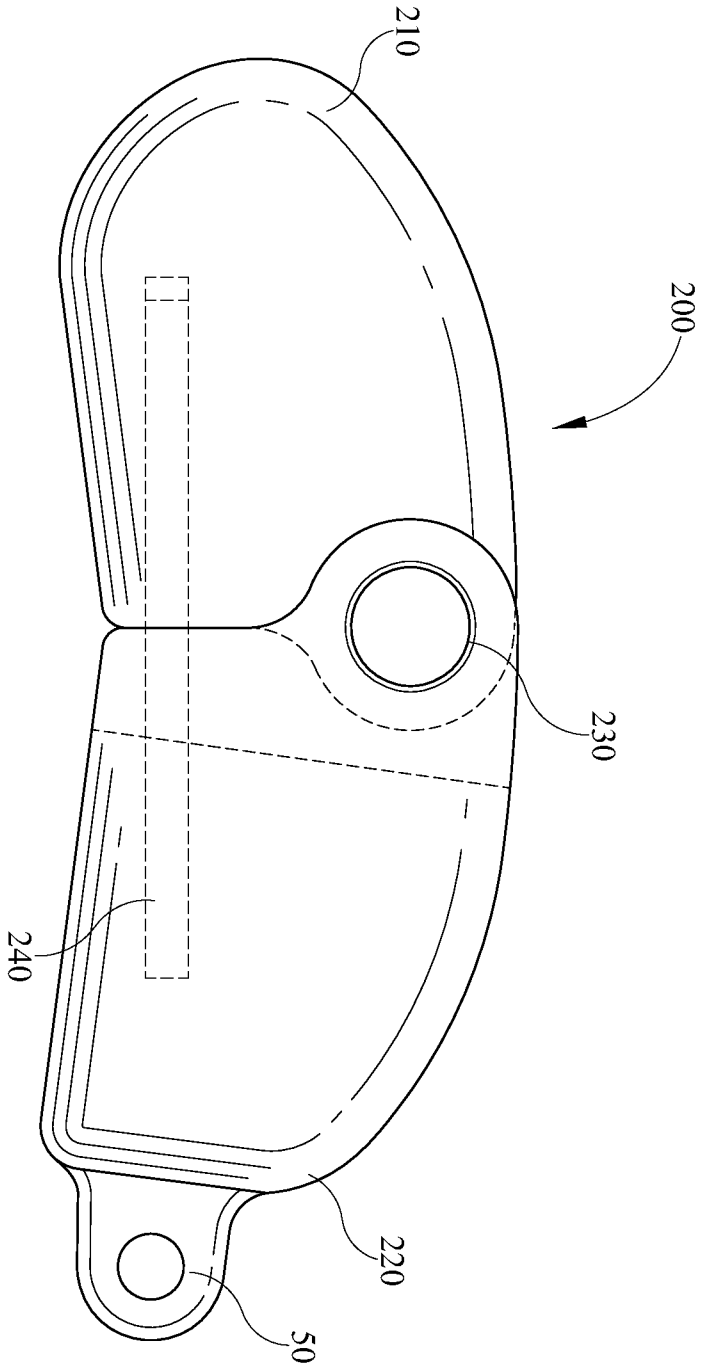


FIG. 12

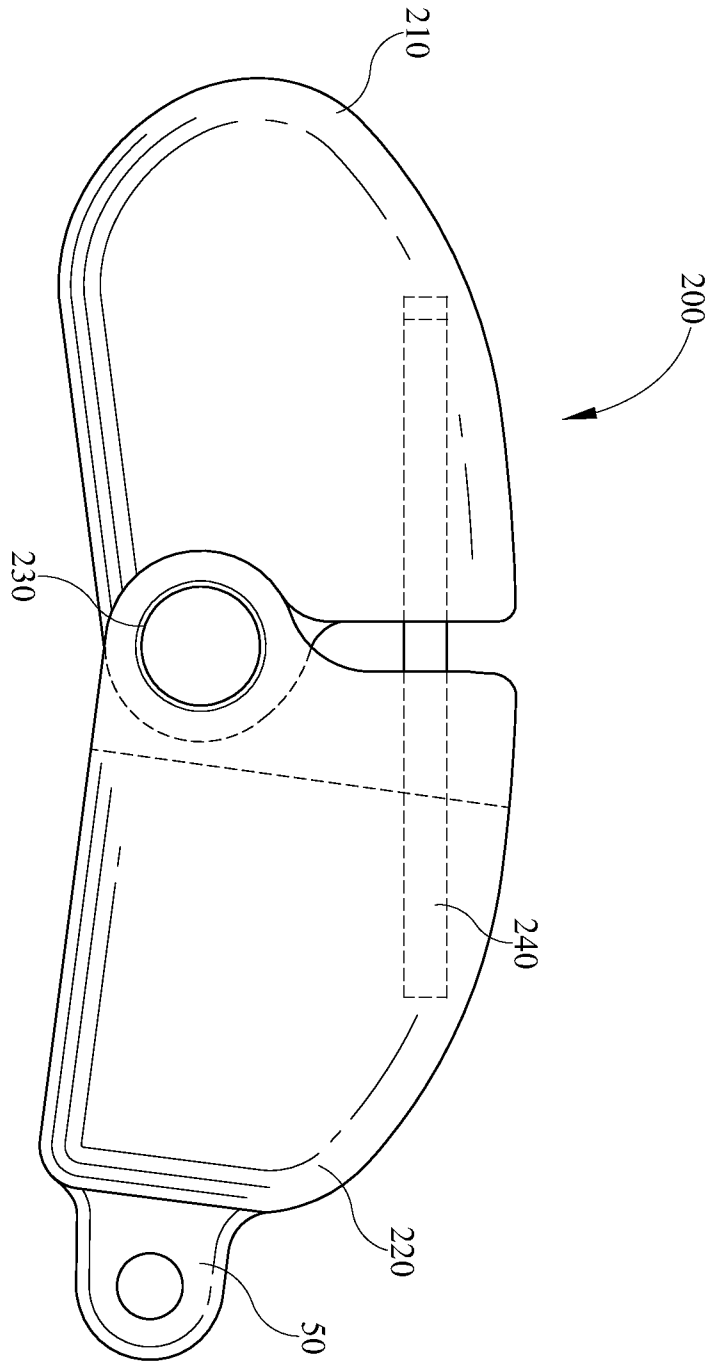


FIG. 13

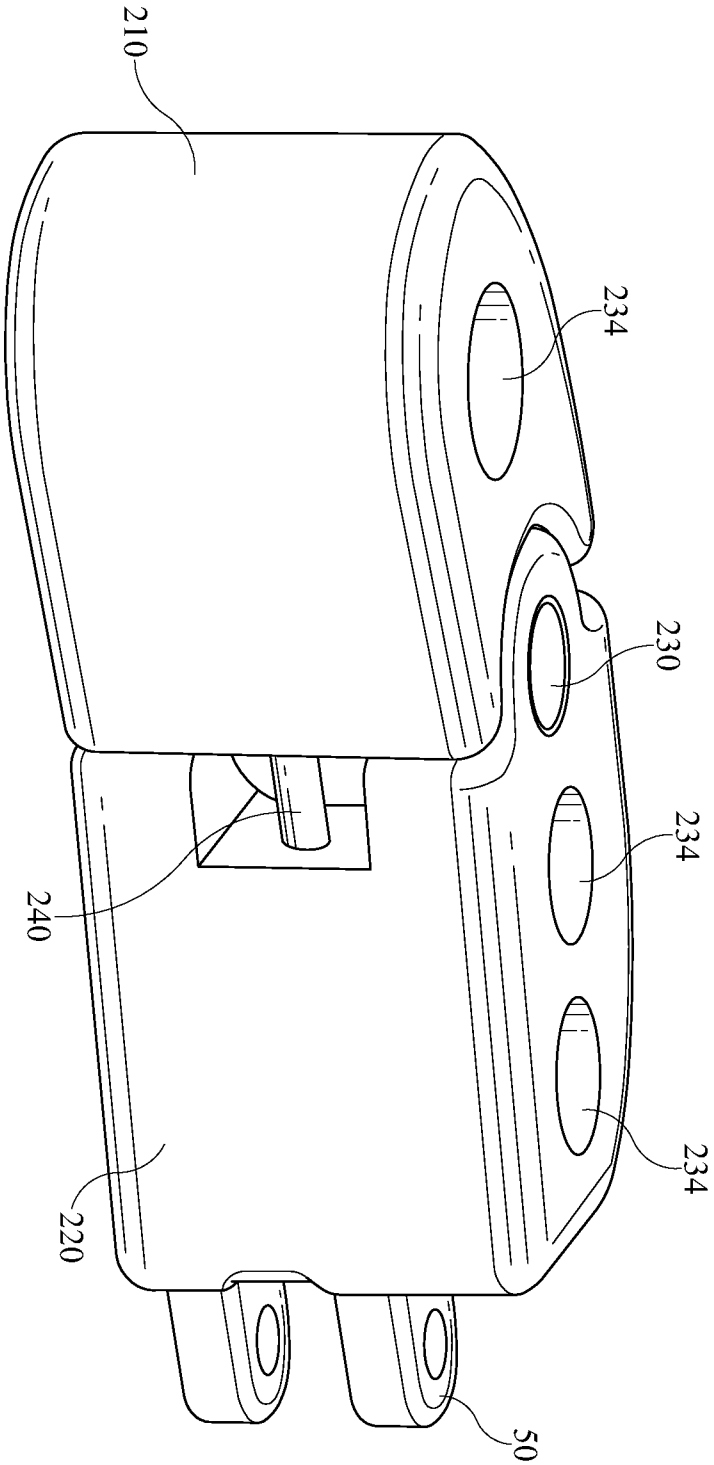


FIG. 14

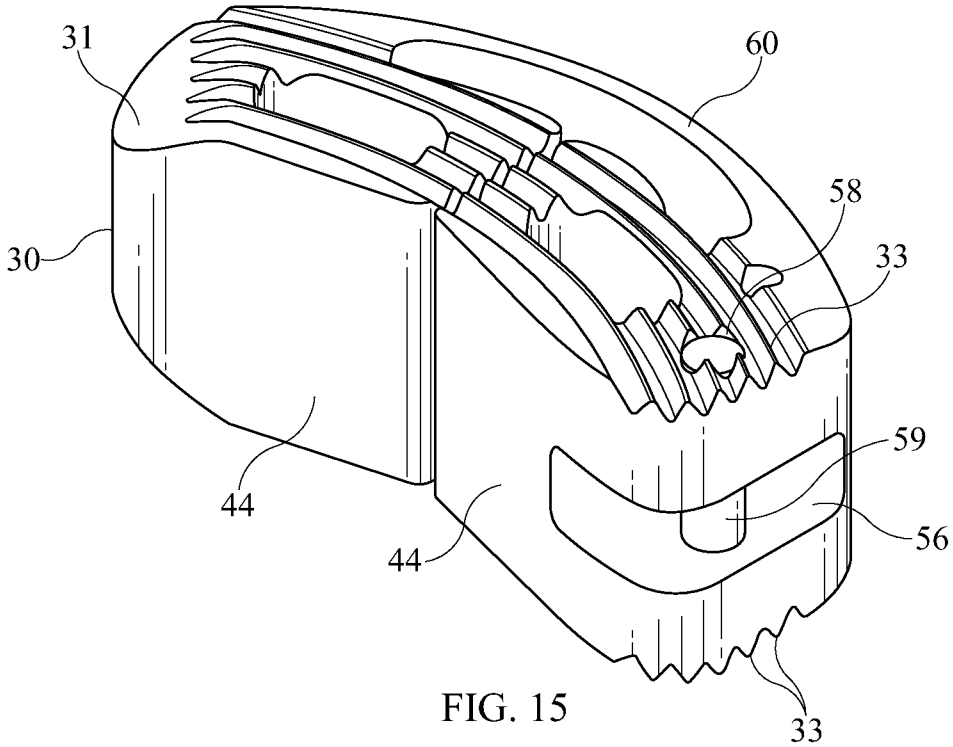


FIG. 15

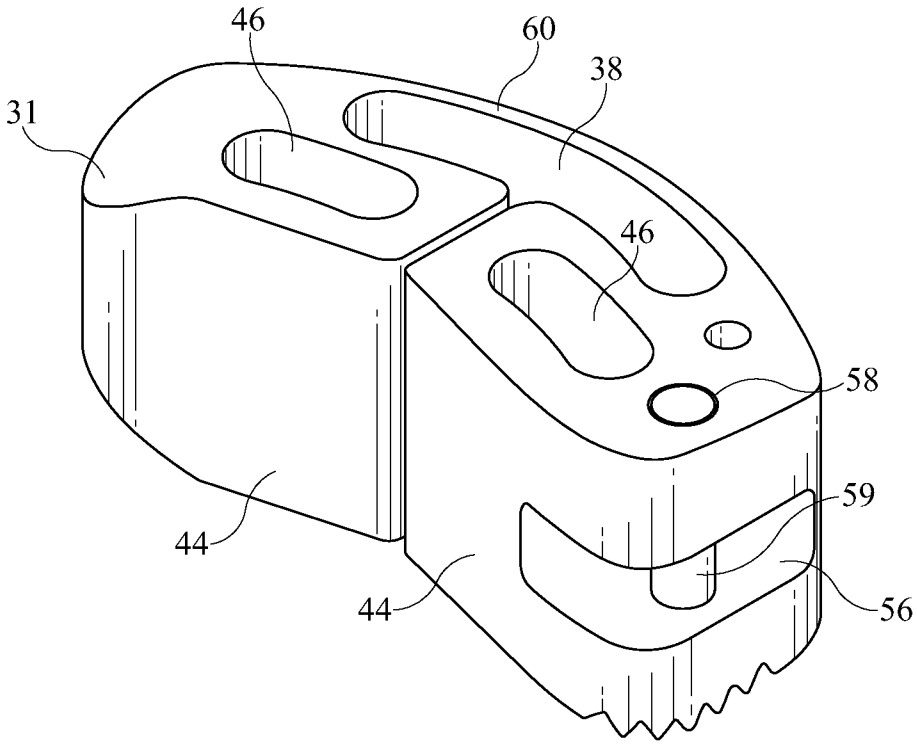


FIG. 16

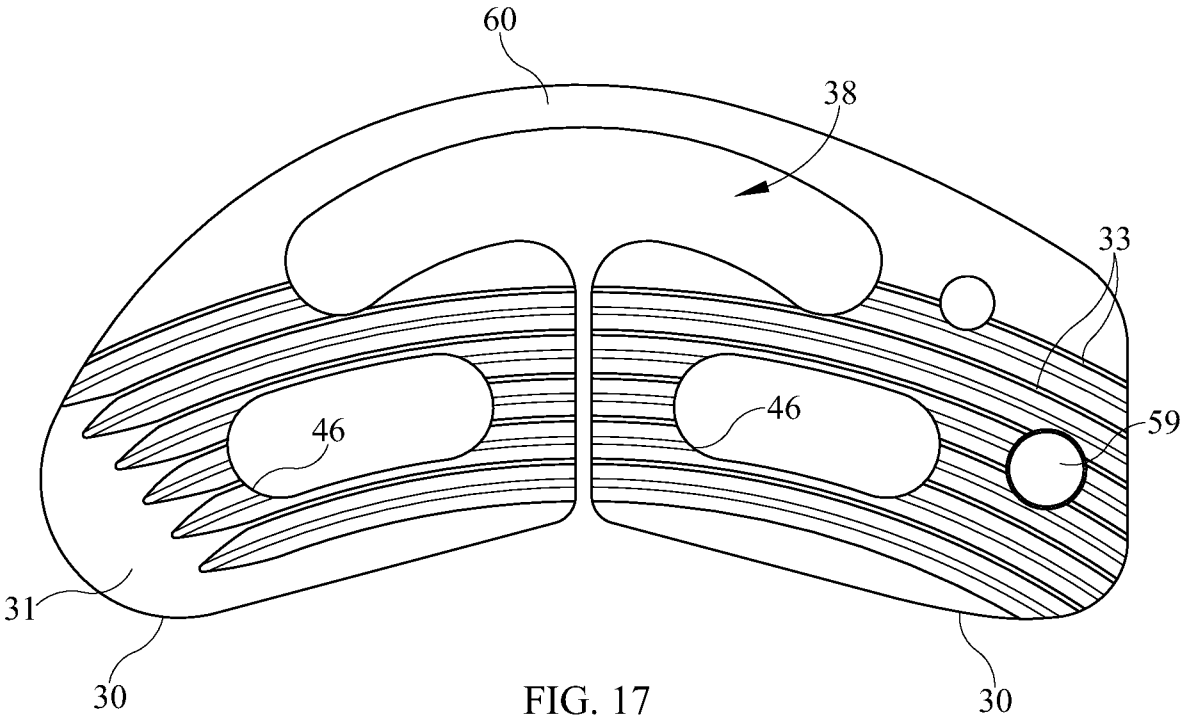


FIG. 17

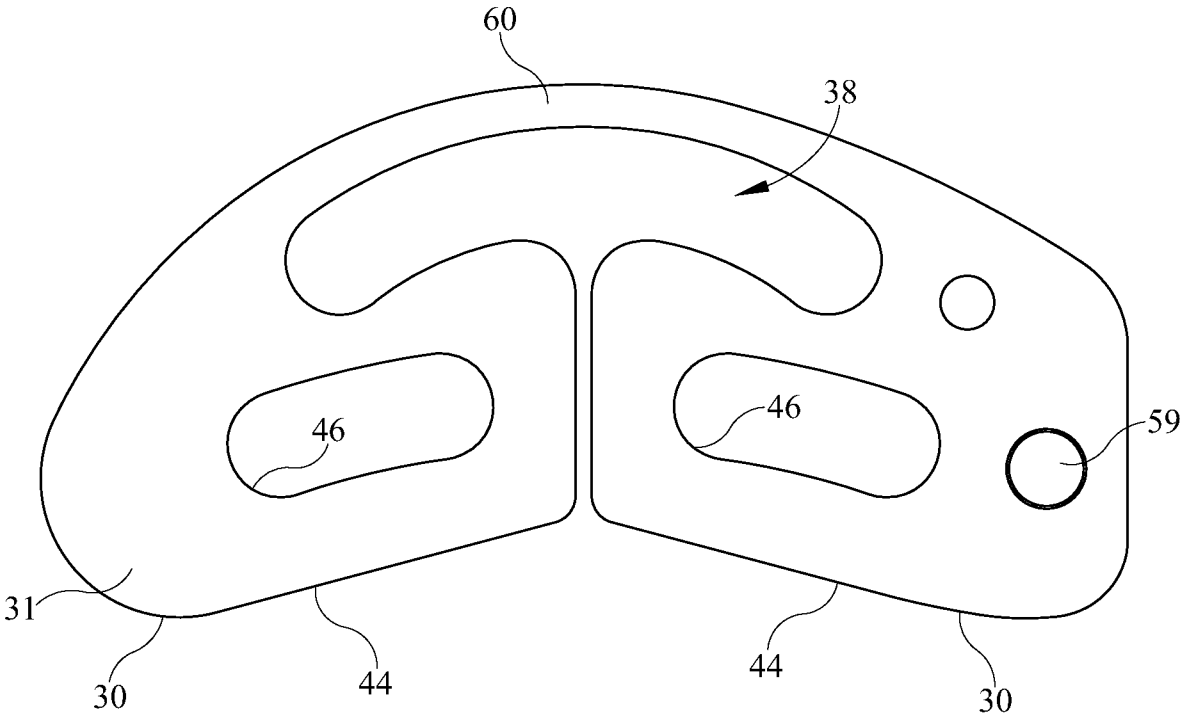


FIG. 18

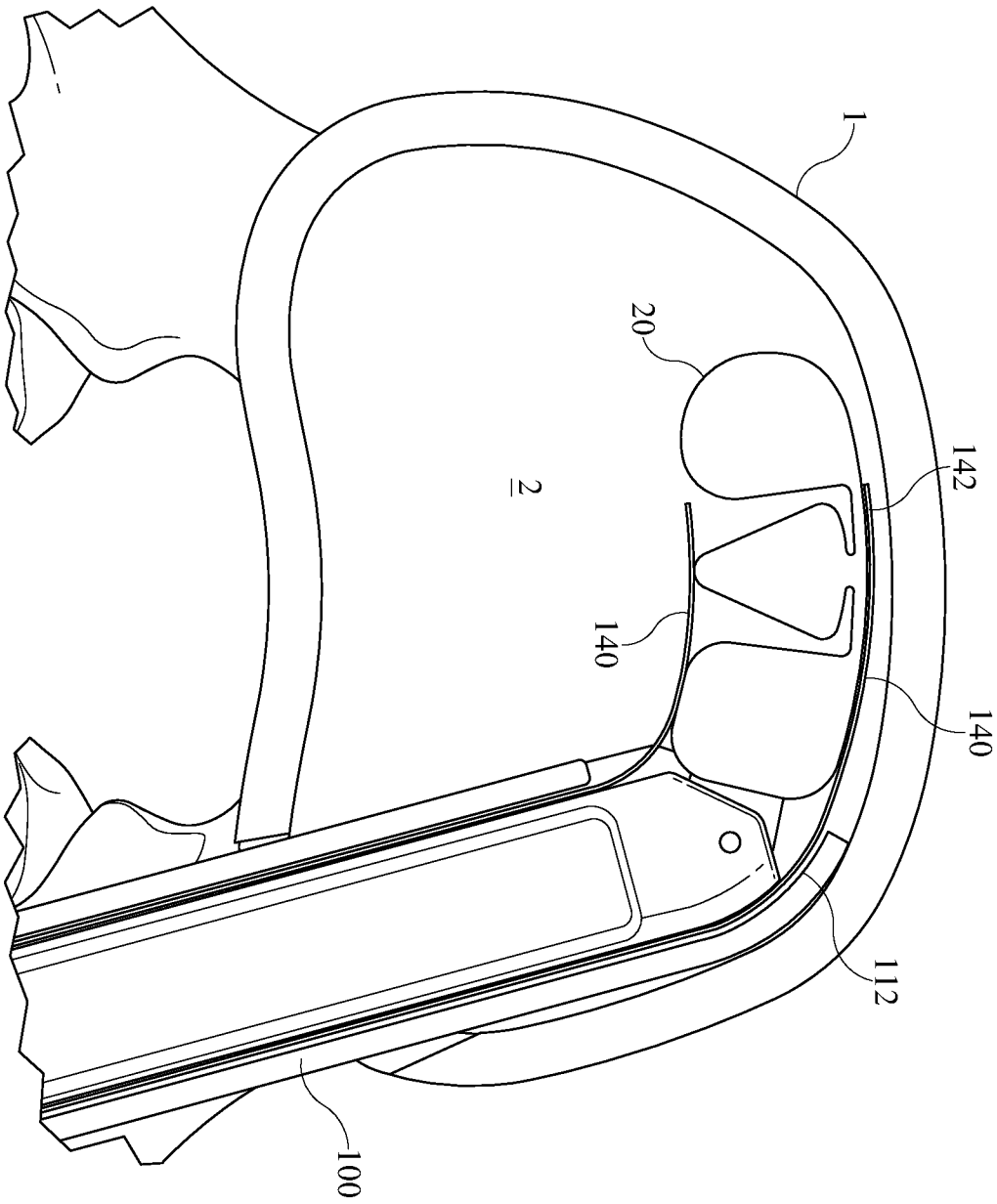


FIG. 19

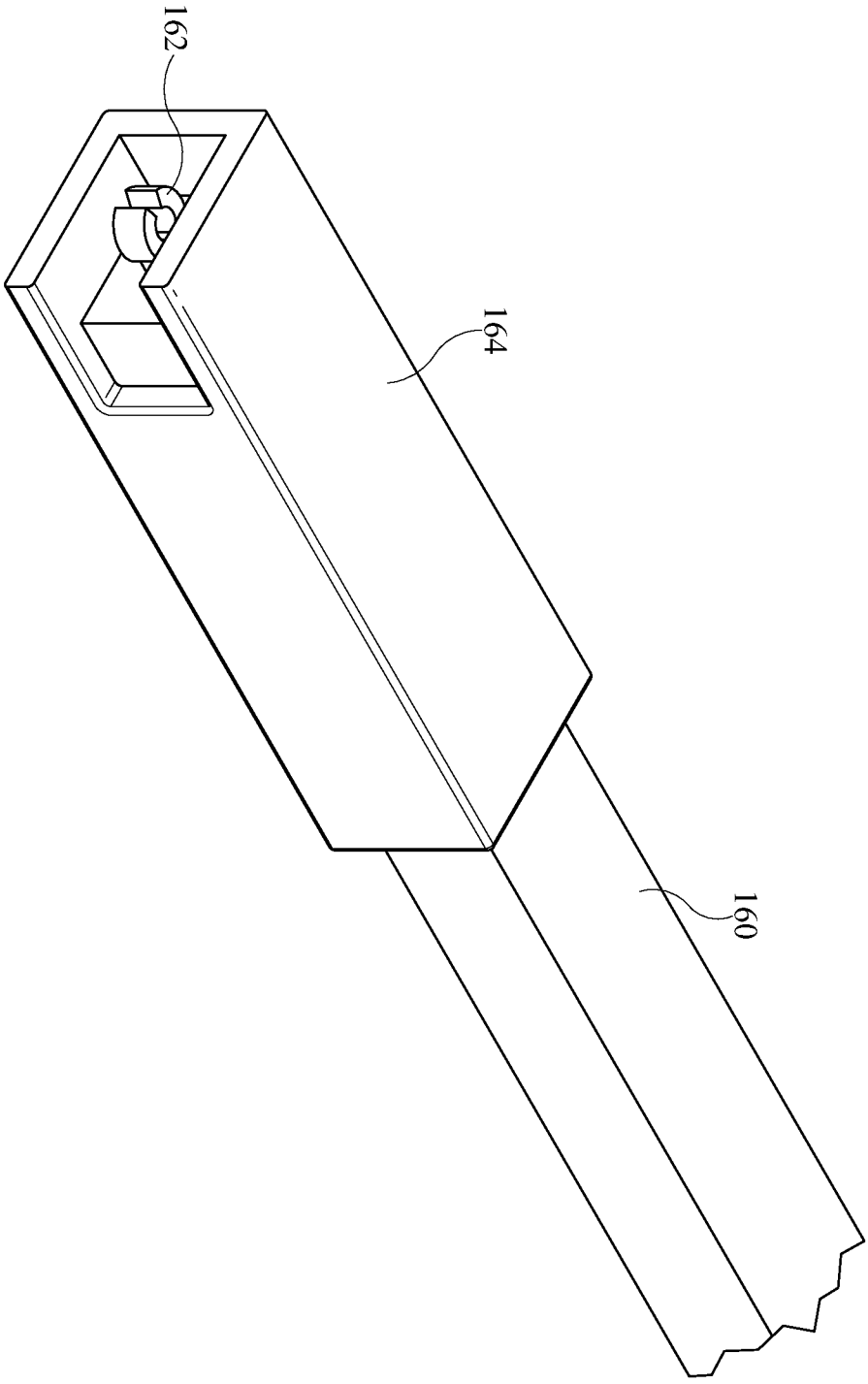


FIG. 20

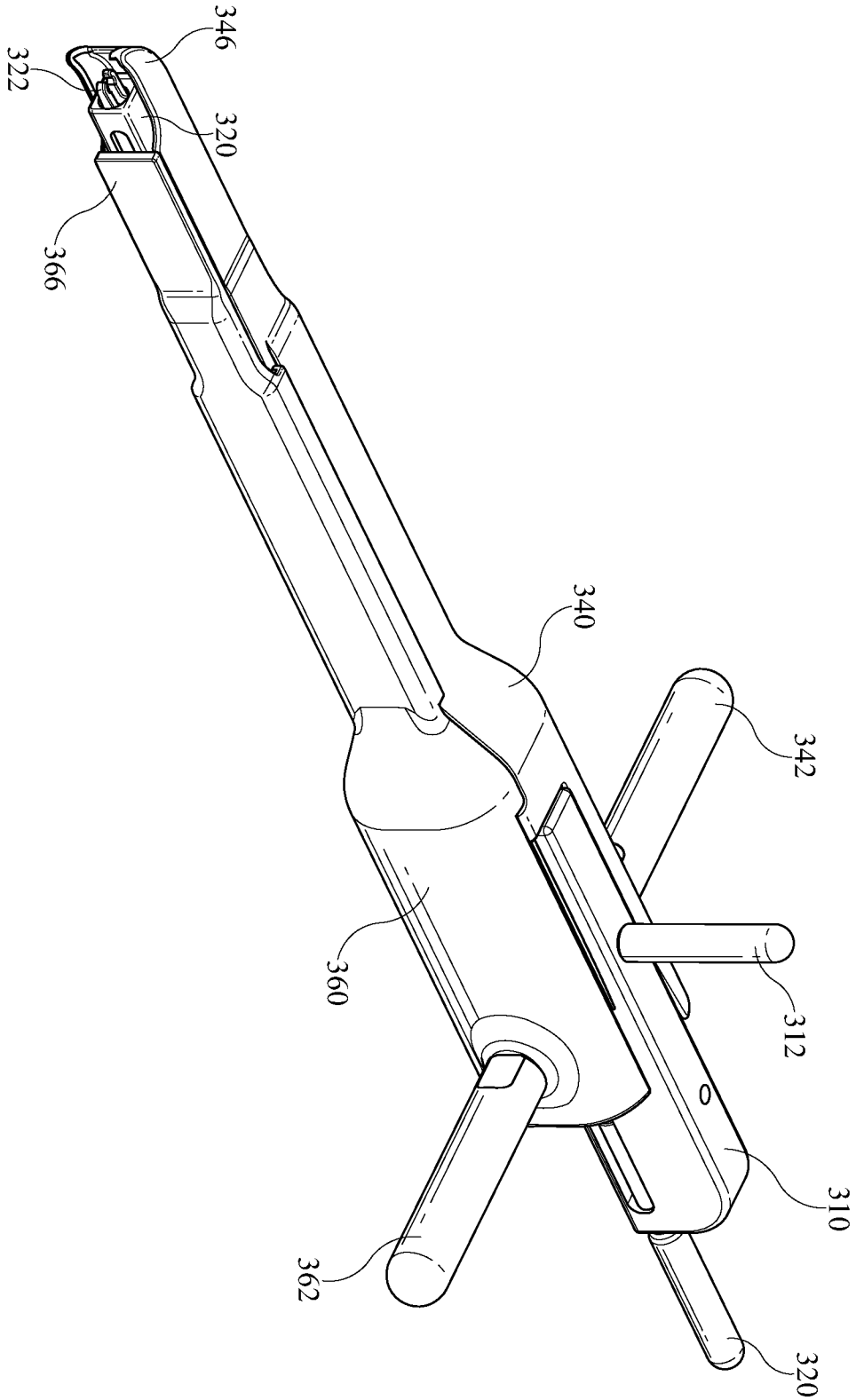


FIG. 21

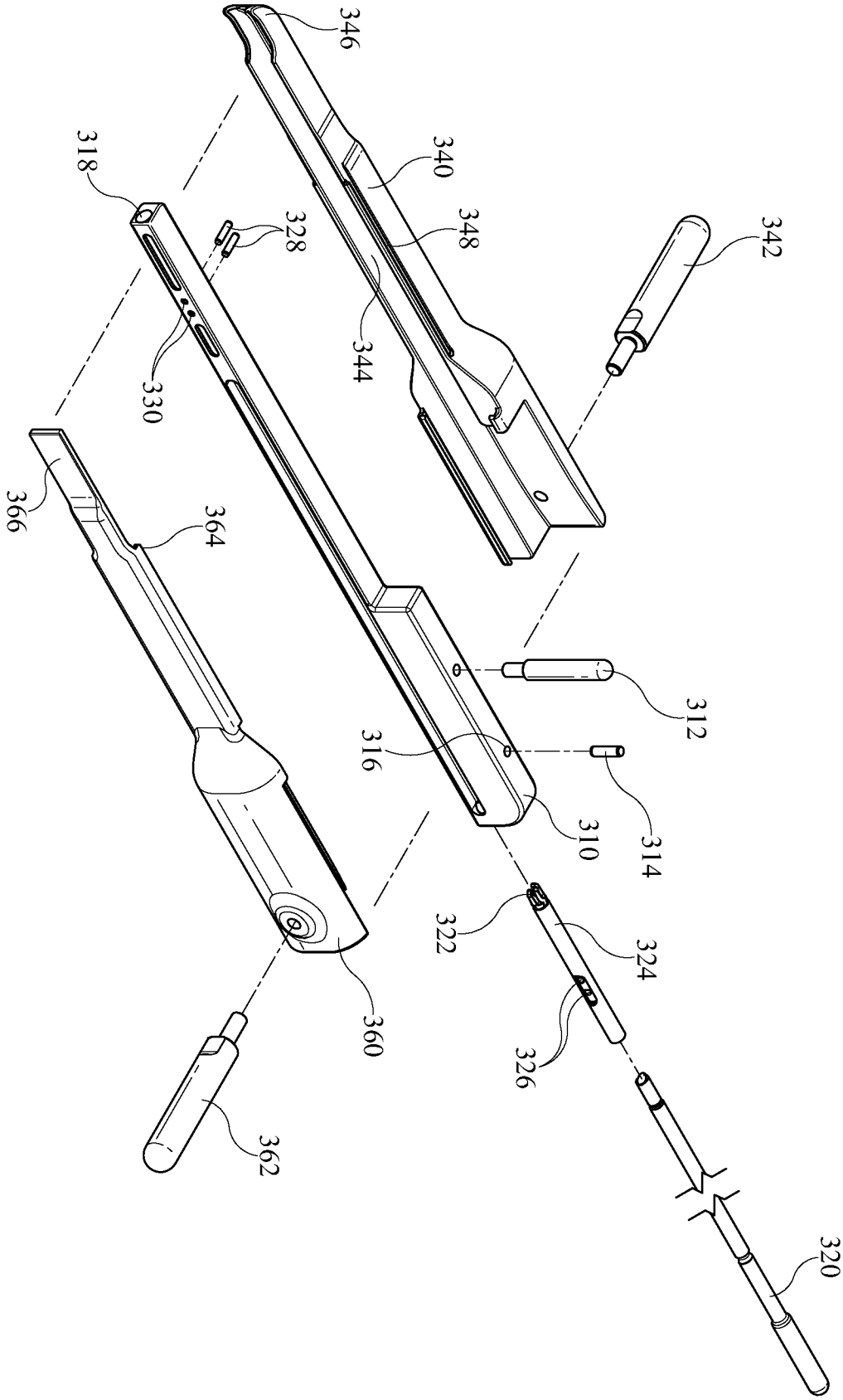

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FIG. 22

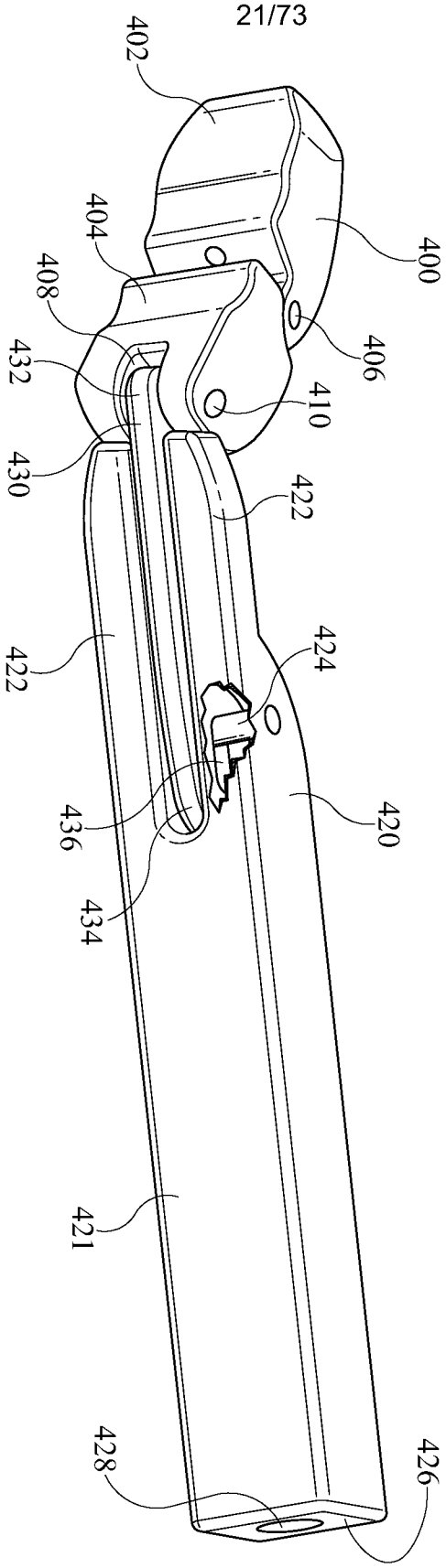

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FIG.23

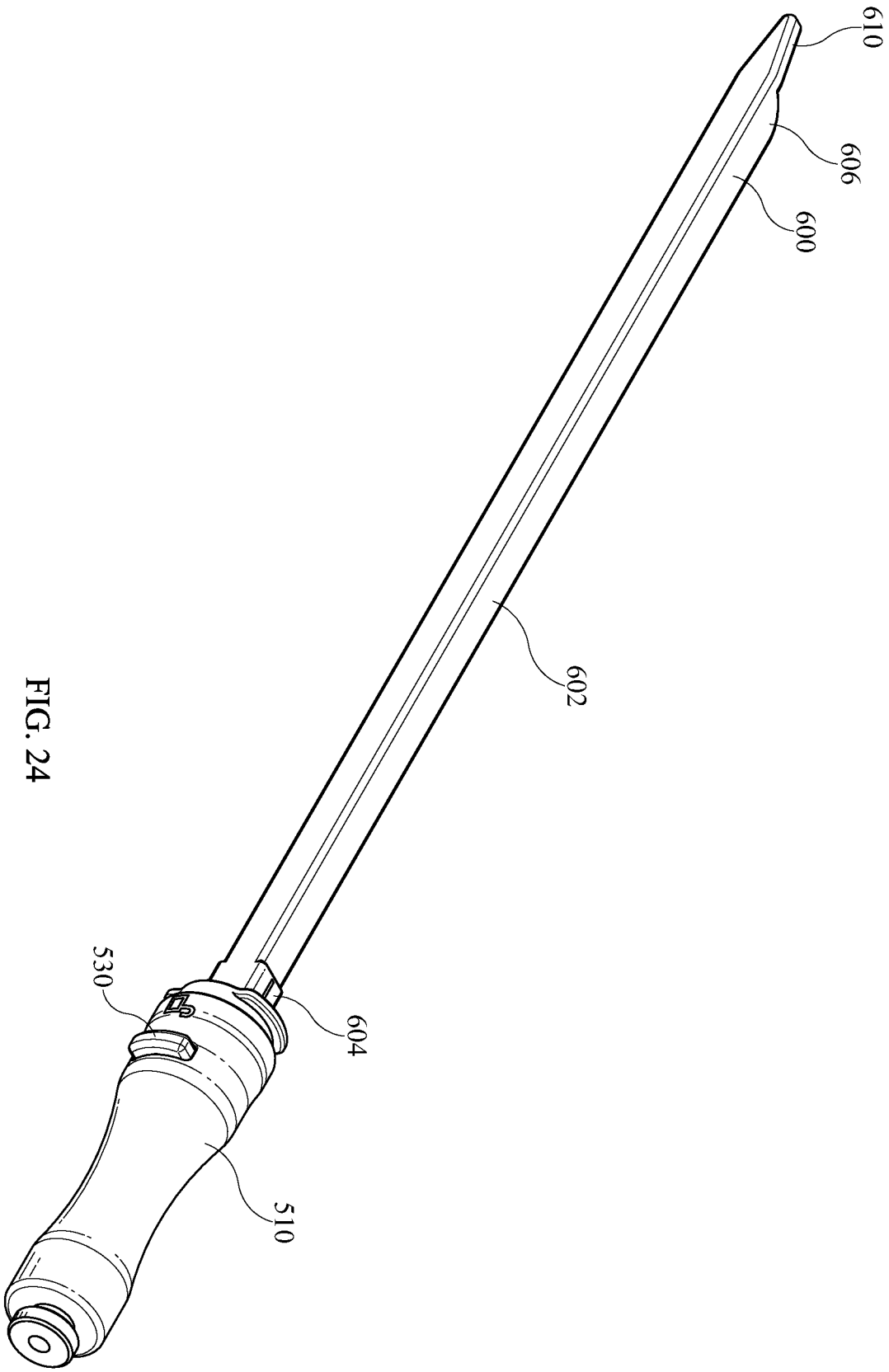


FIG. 24

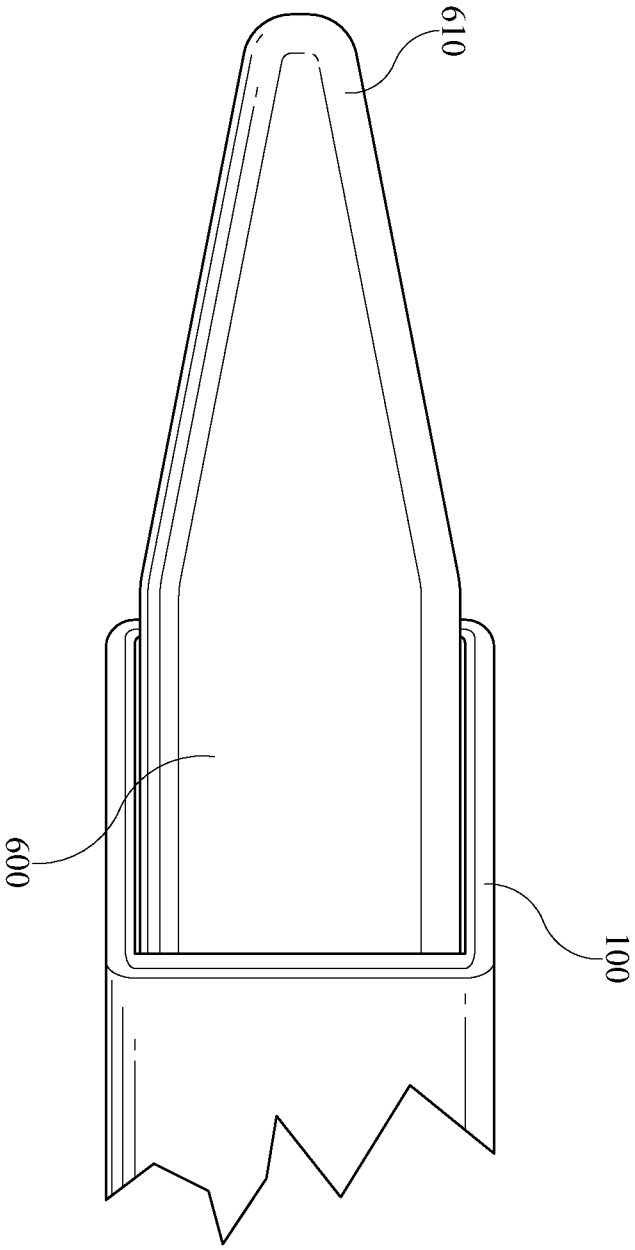


FIG. 25

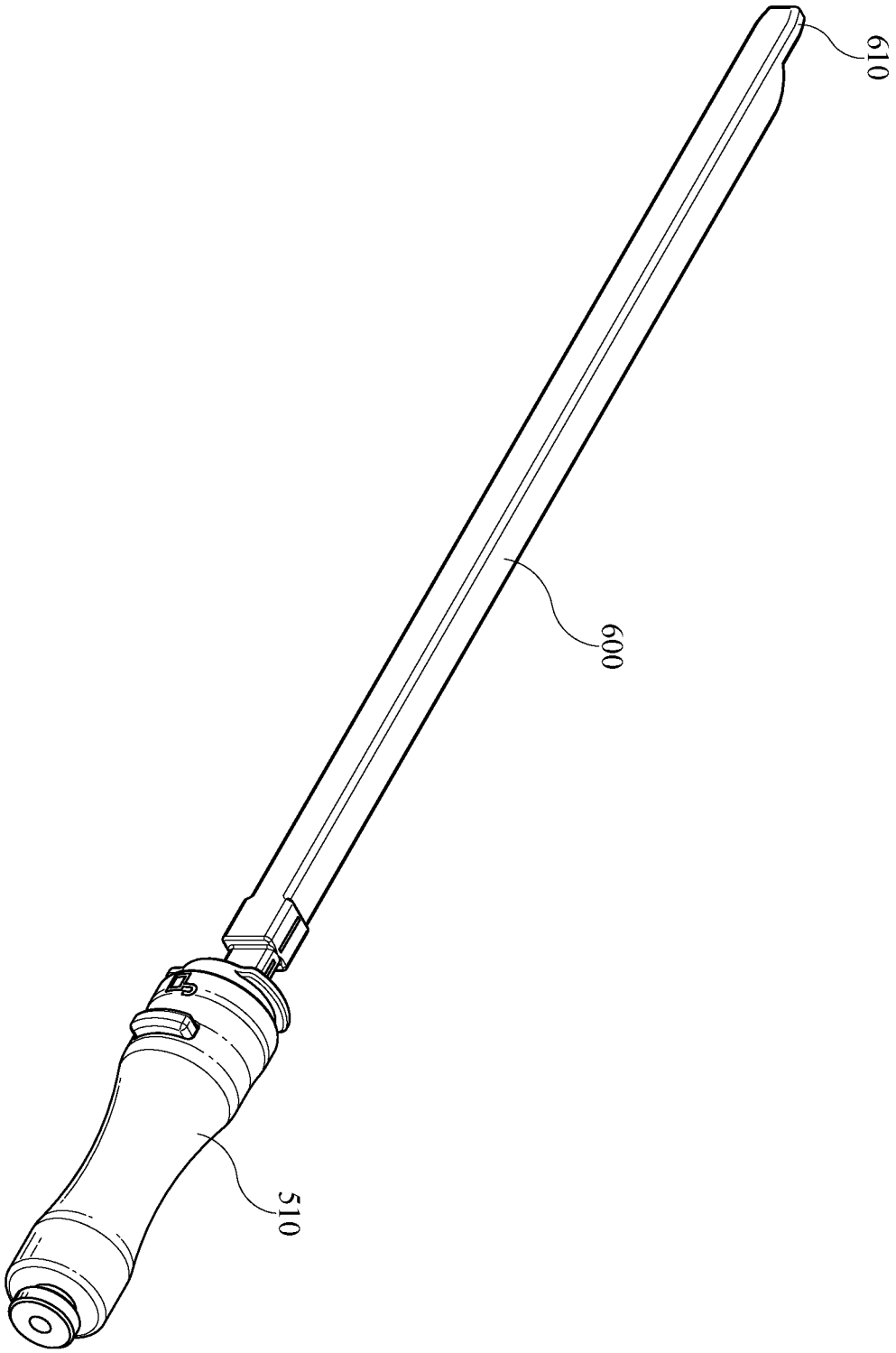


FIG. 26

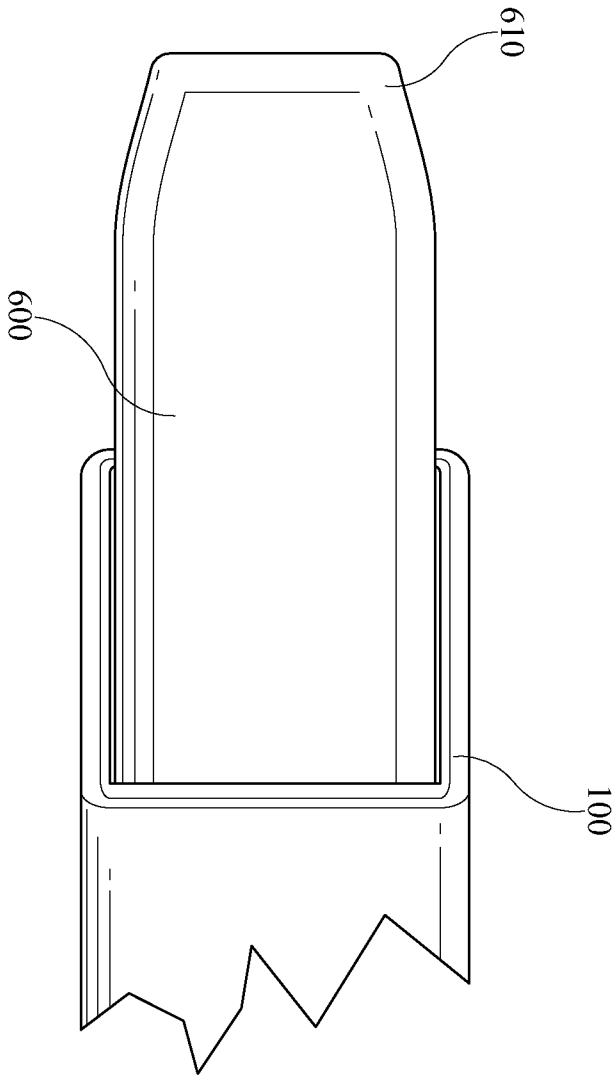


FIG. 27

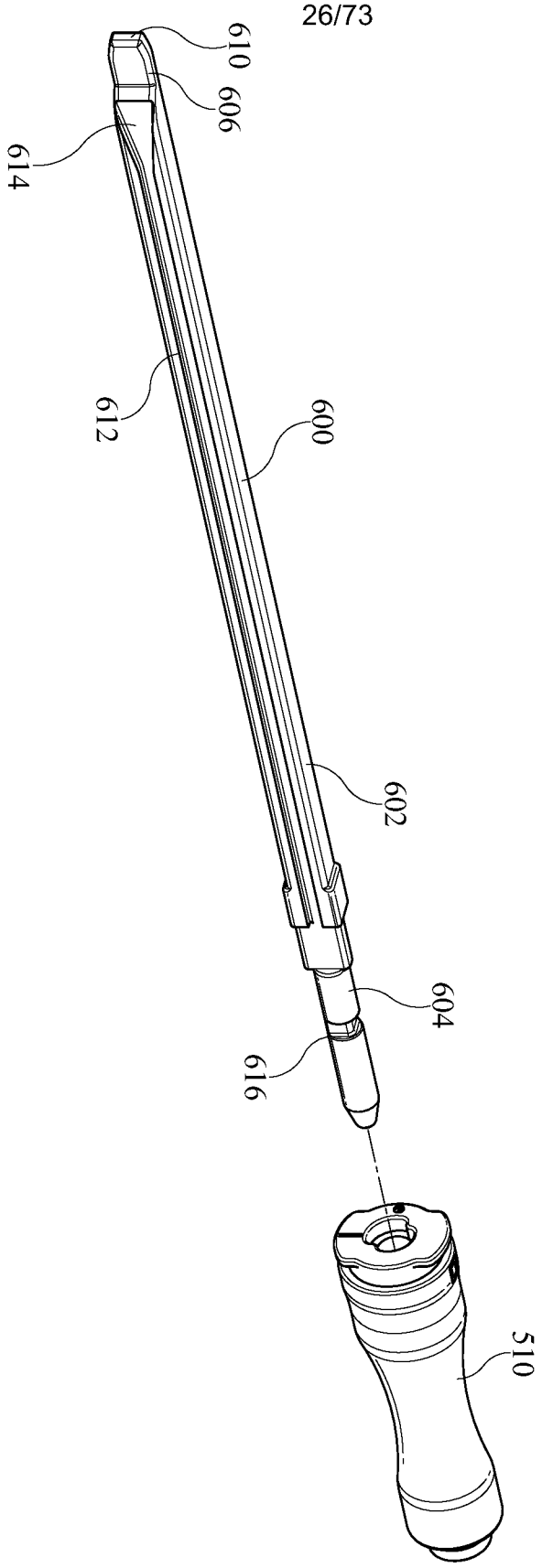


FIG. 28

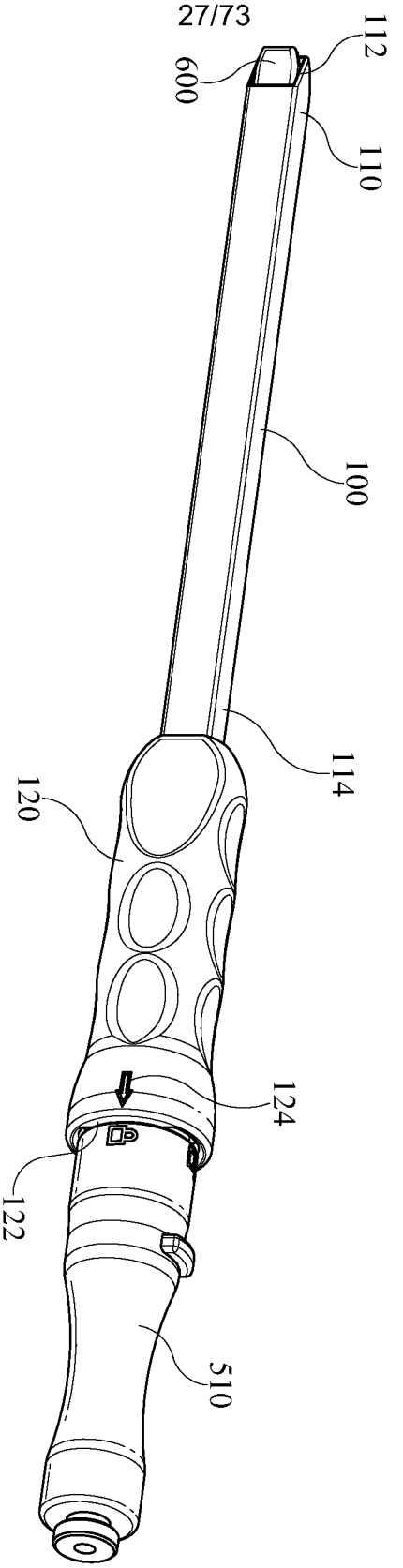


FIG. 29

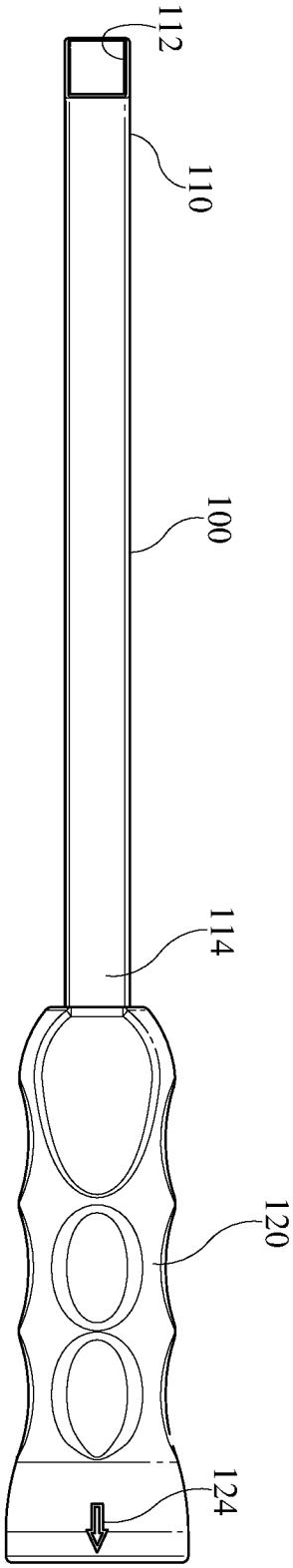


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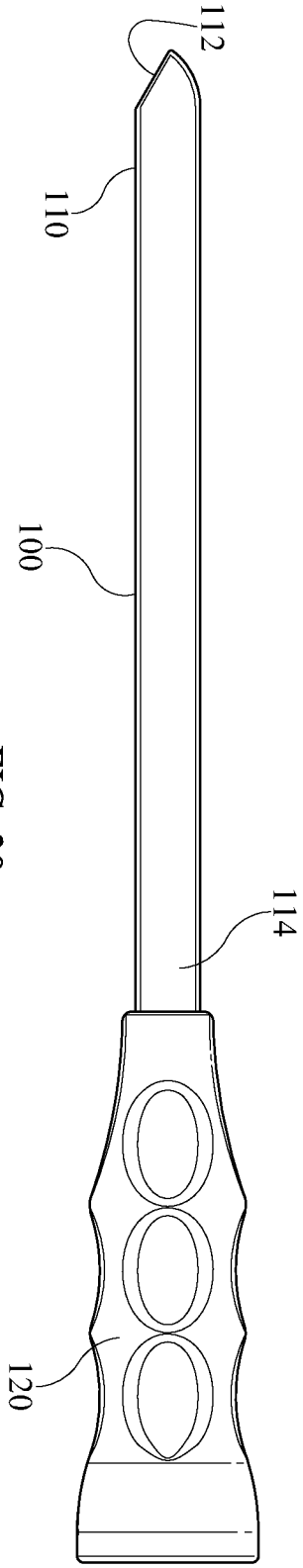


FIG. 30

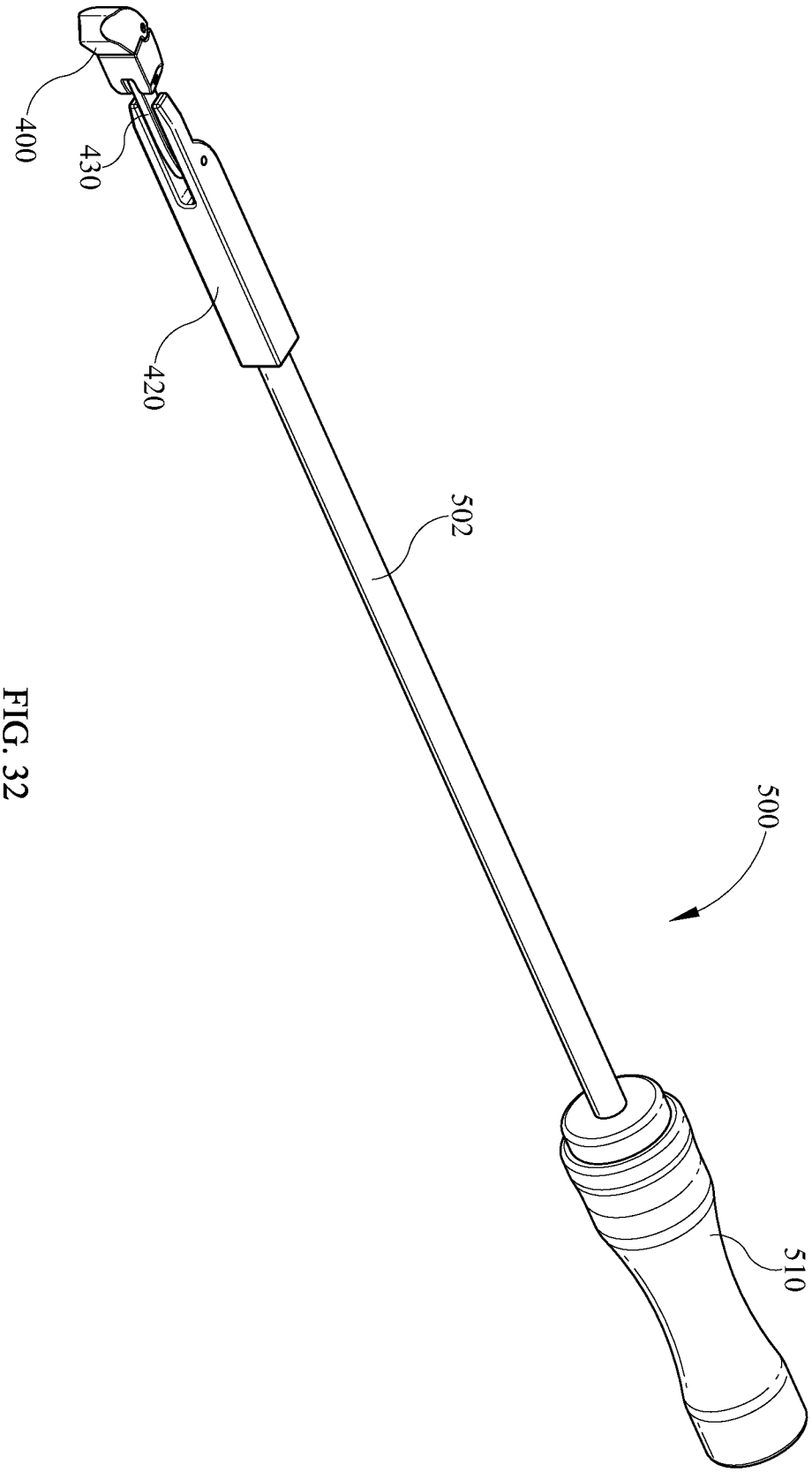


FIG. 32

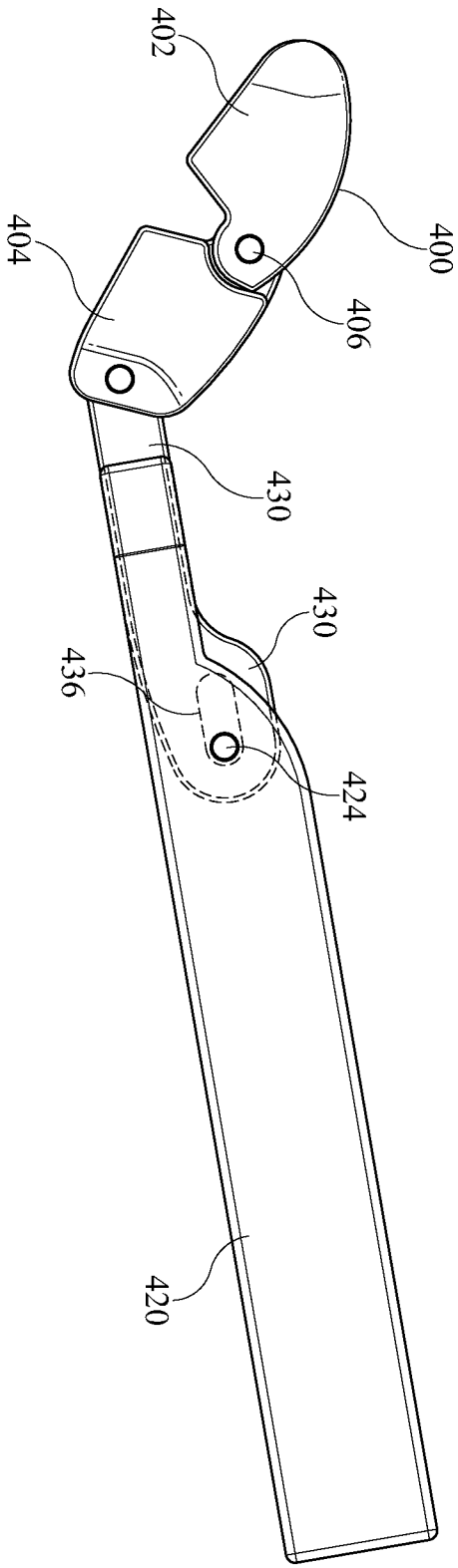


FIG. 33

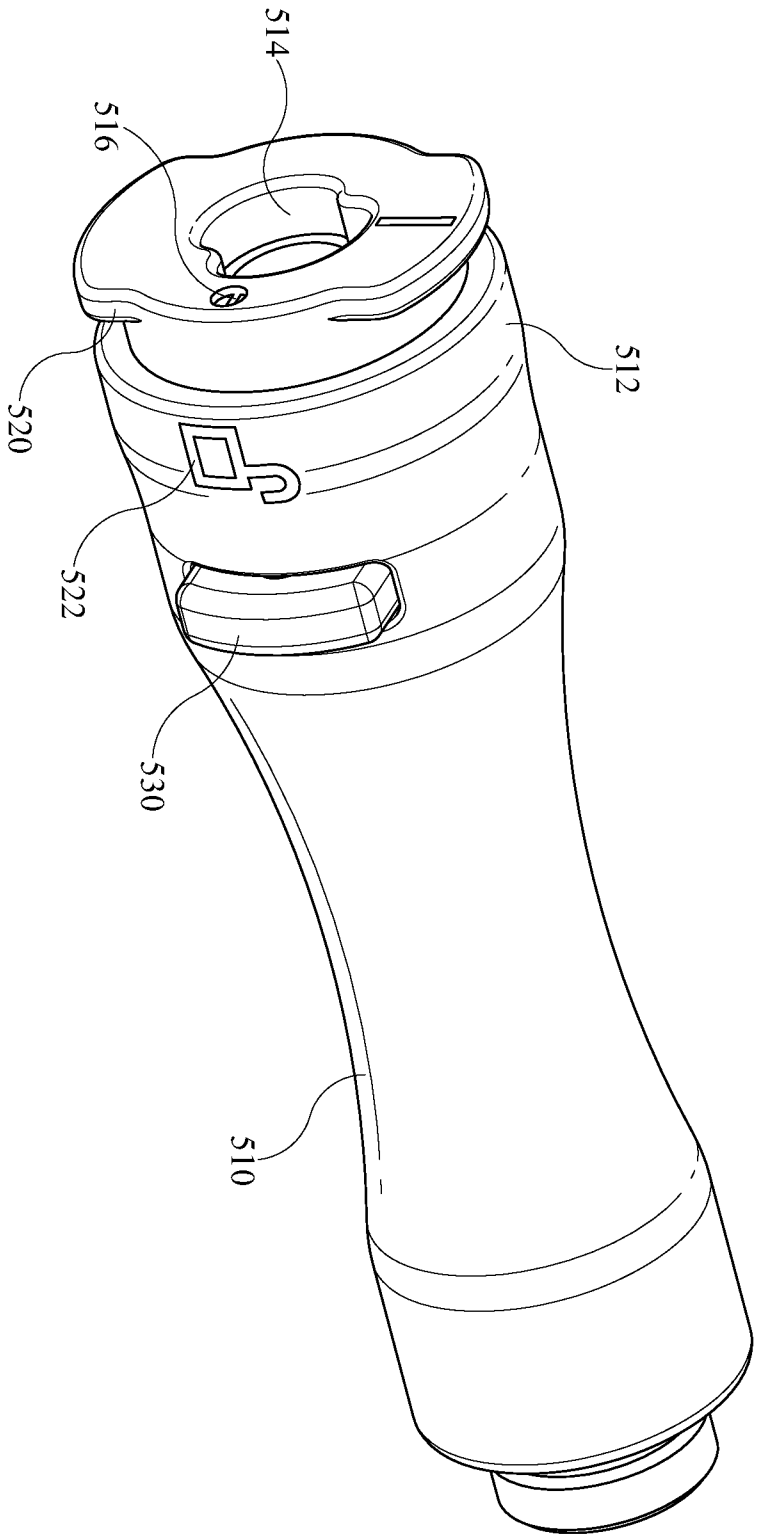


FIG. 34

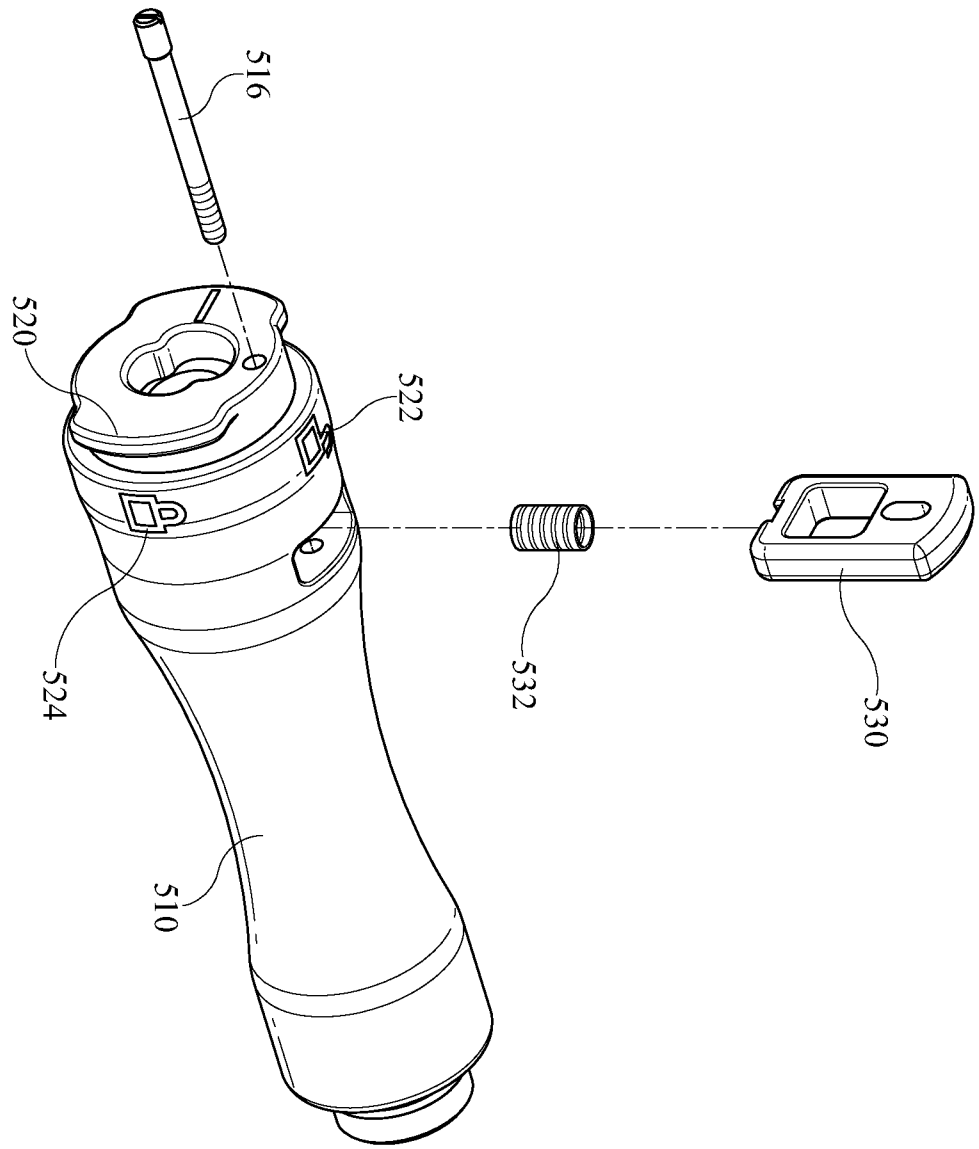


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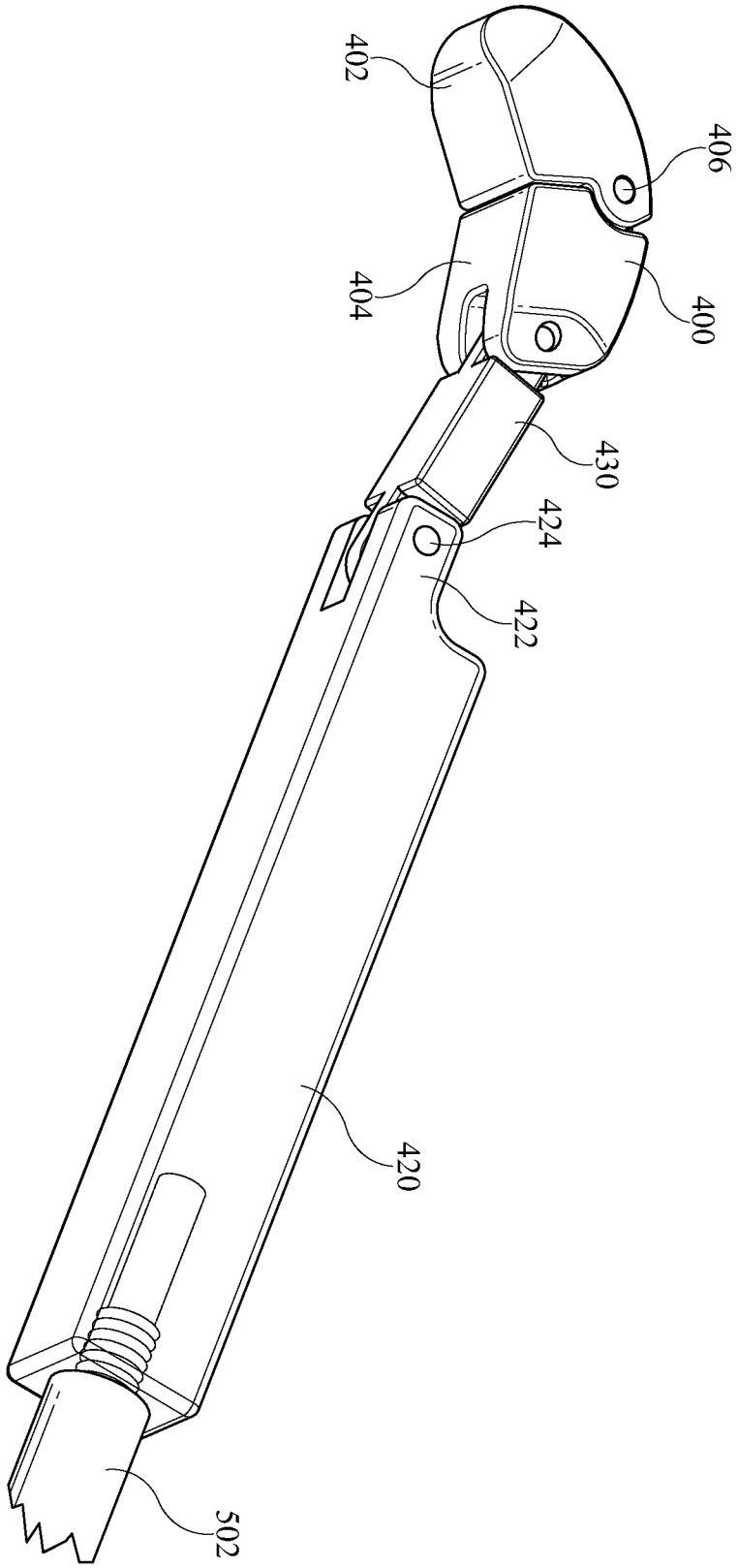


FIG. 36

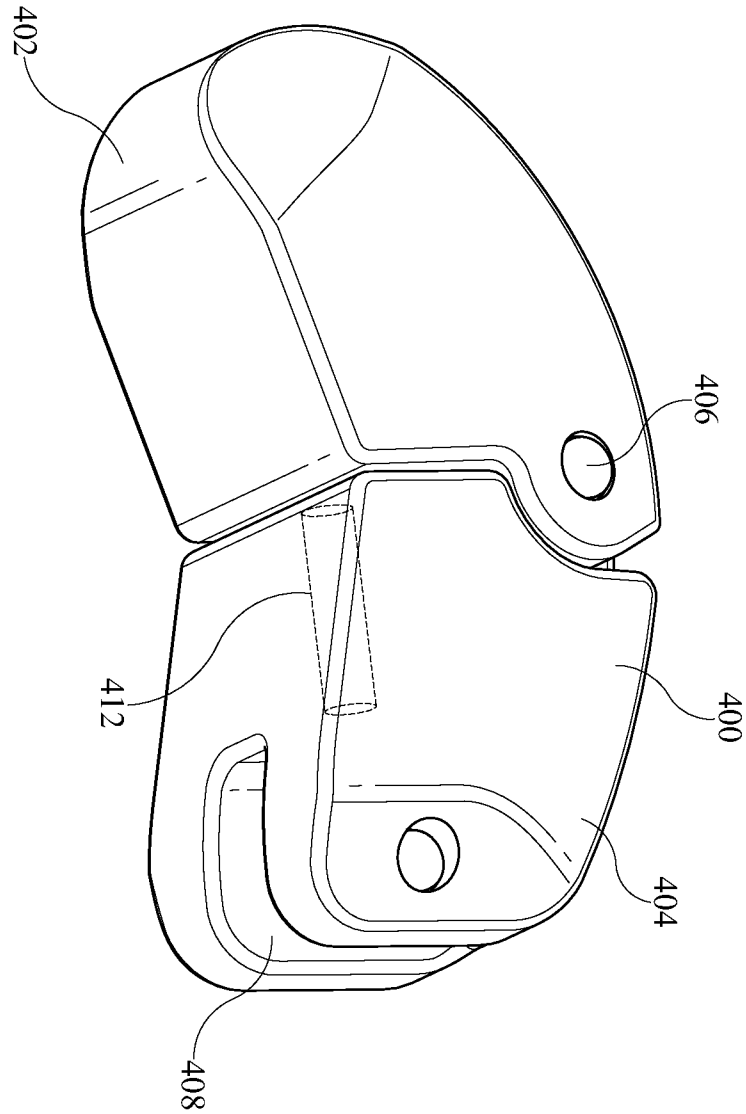


FIG. 37

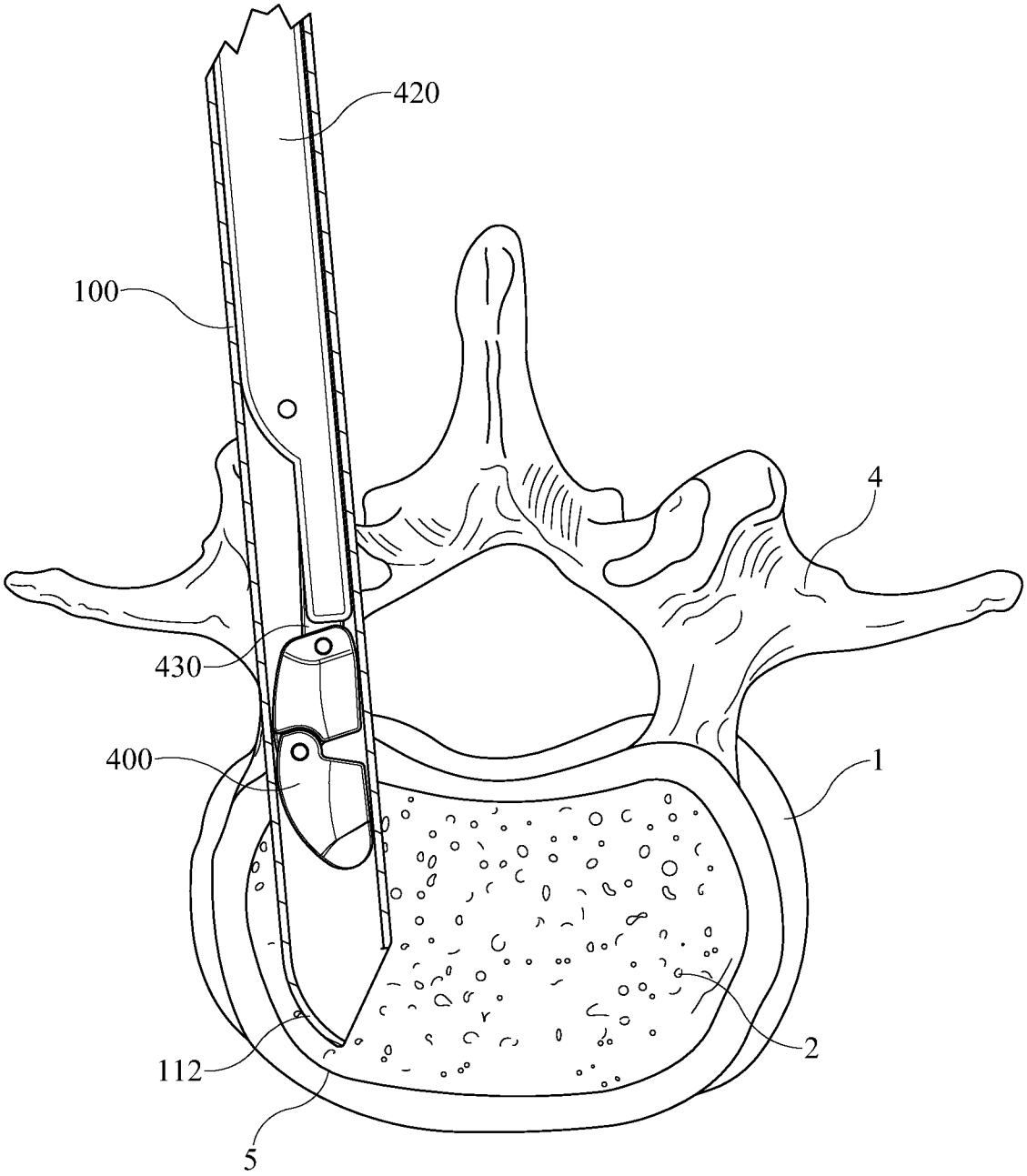


FIG. 38

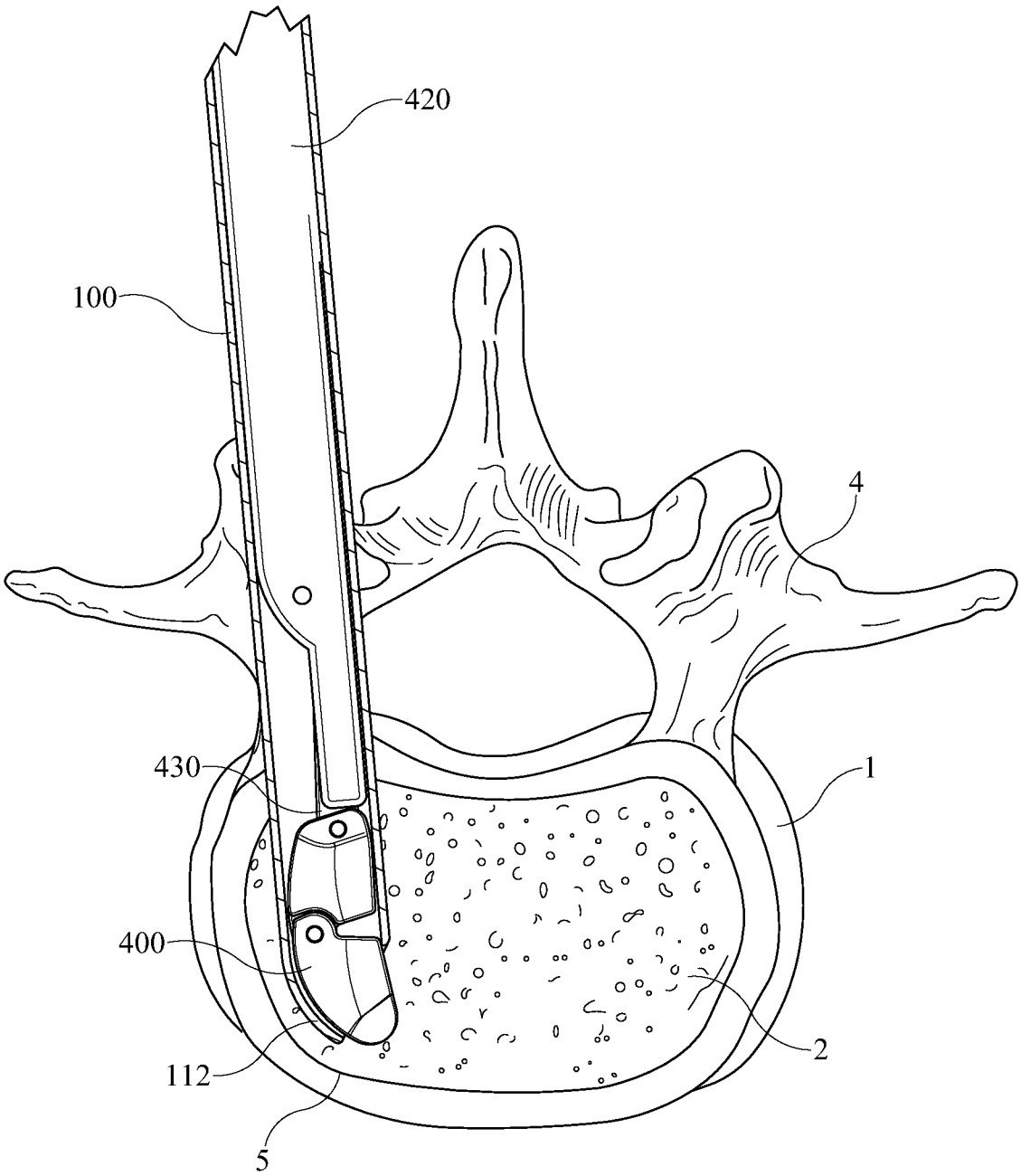


FIG. 39

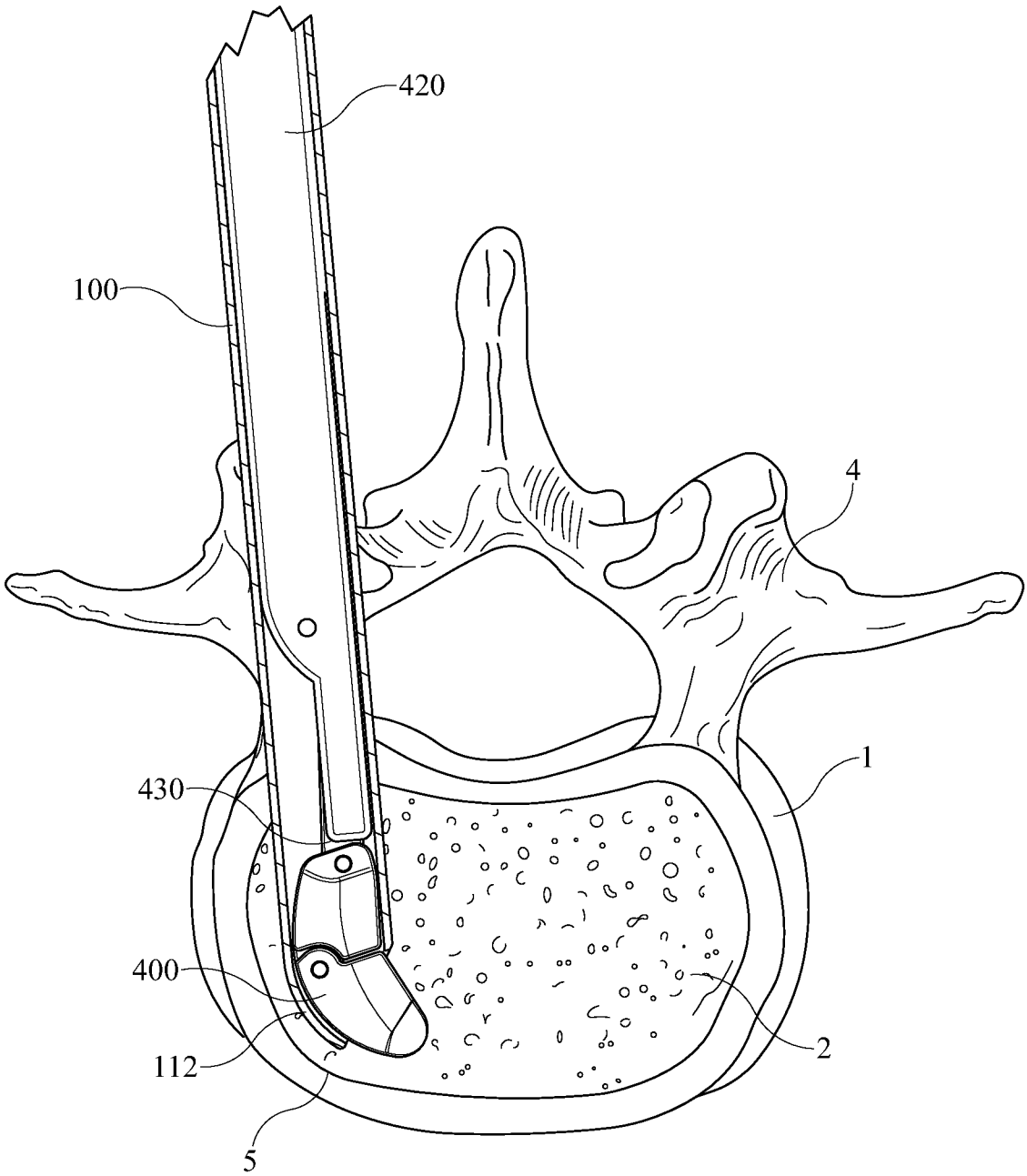


FIG. 40

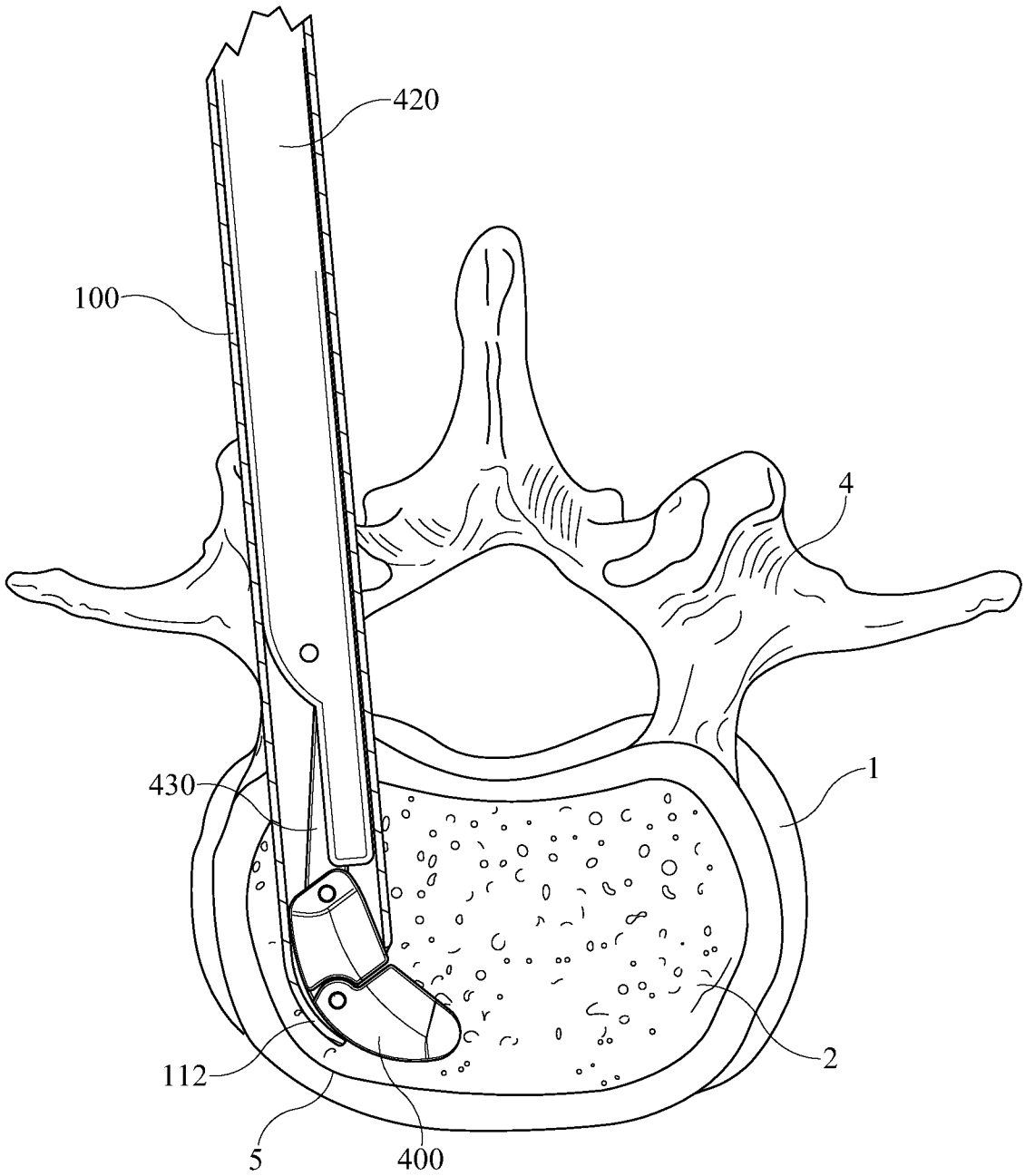


FIG. 41

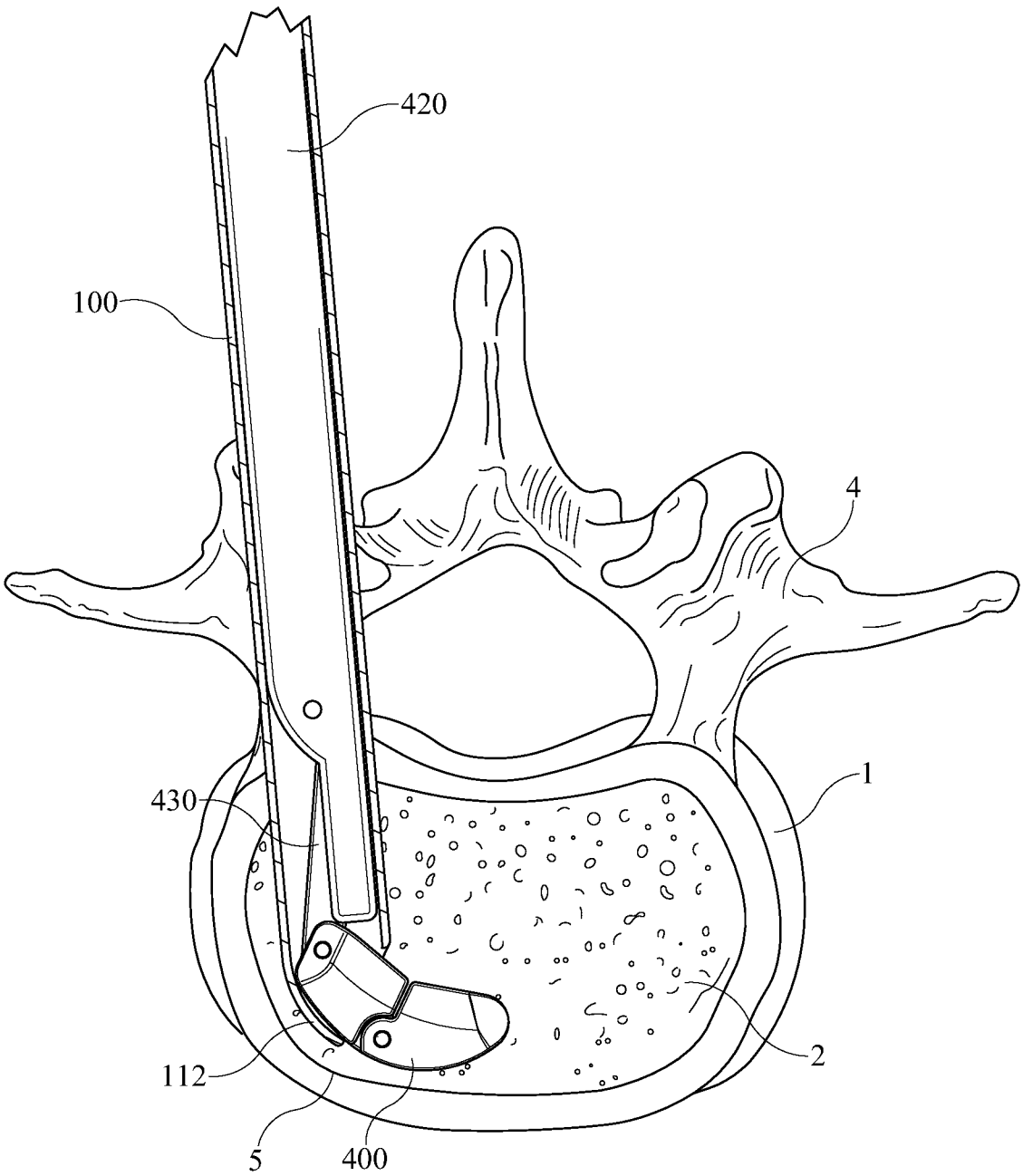


FIG. 42

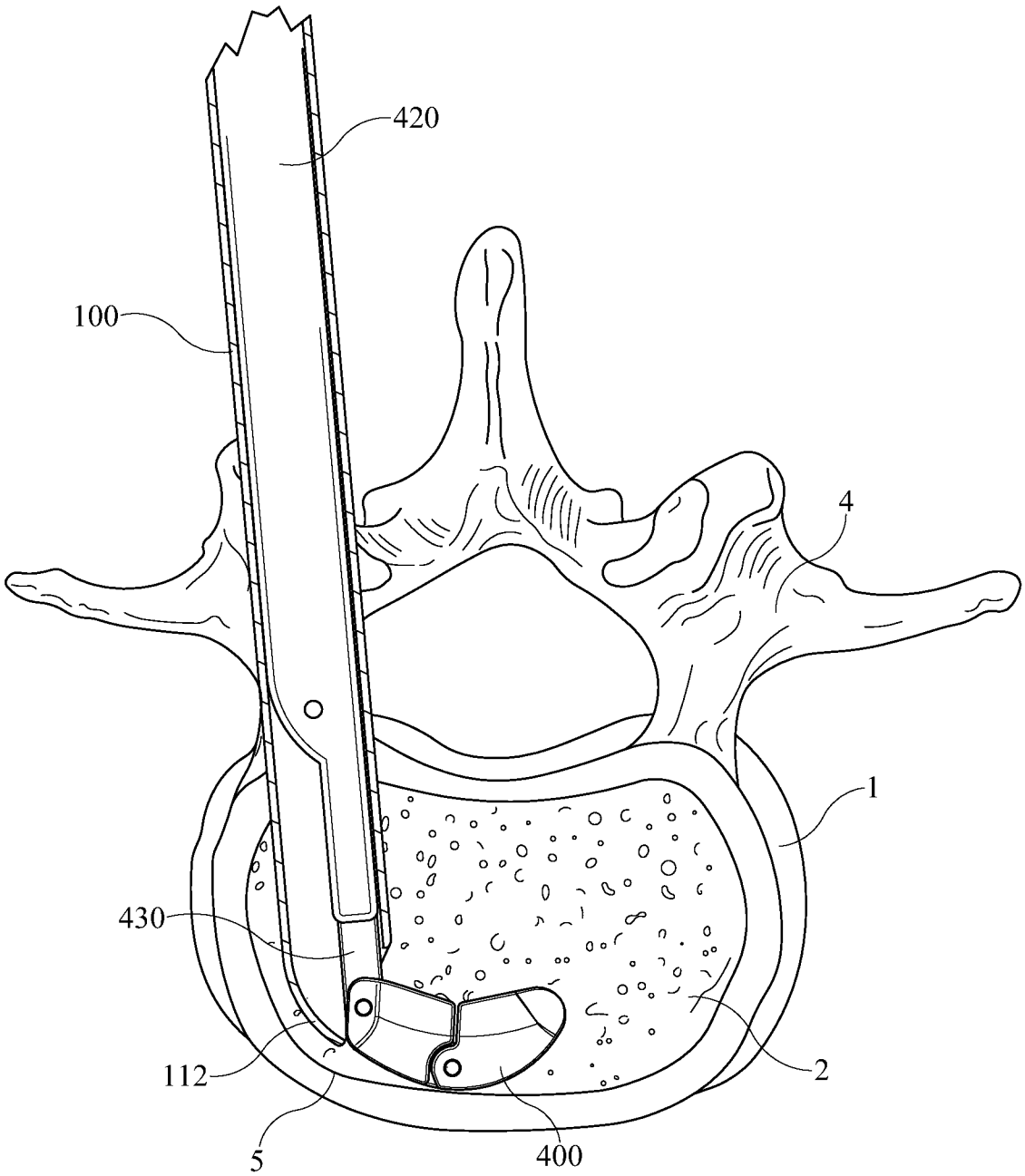


FIG. 43

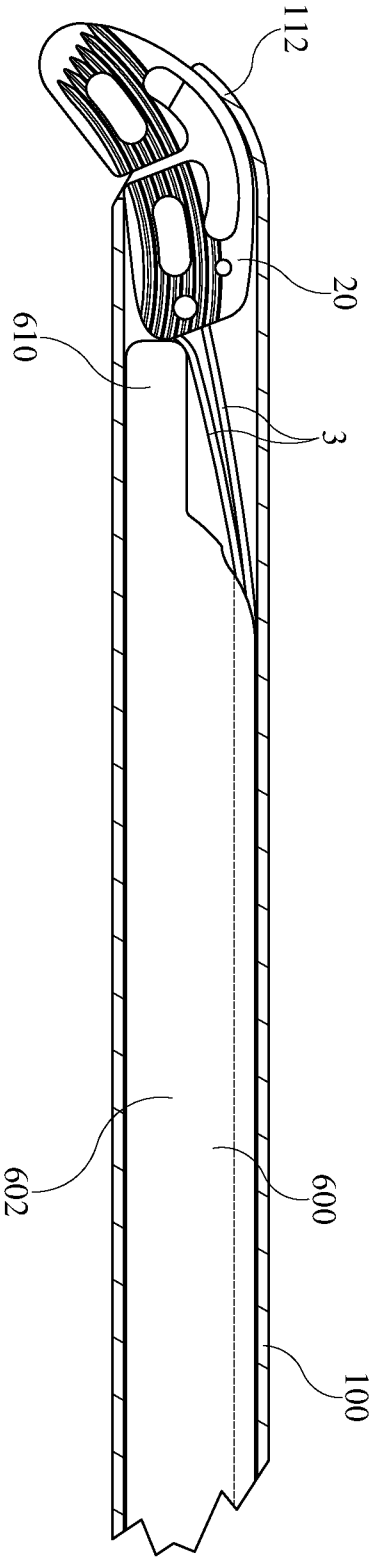


FIG. 44

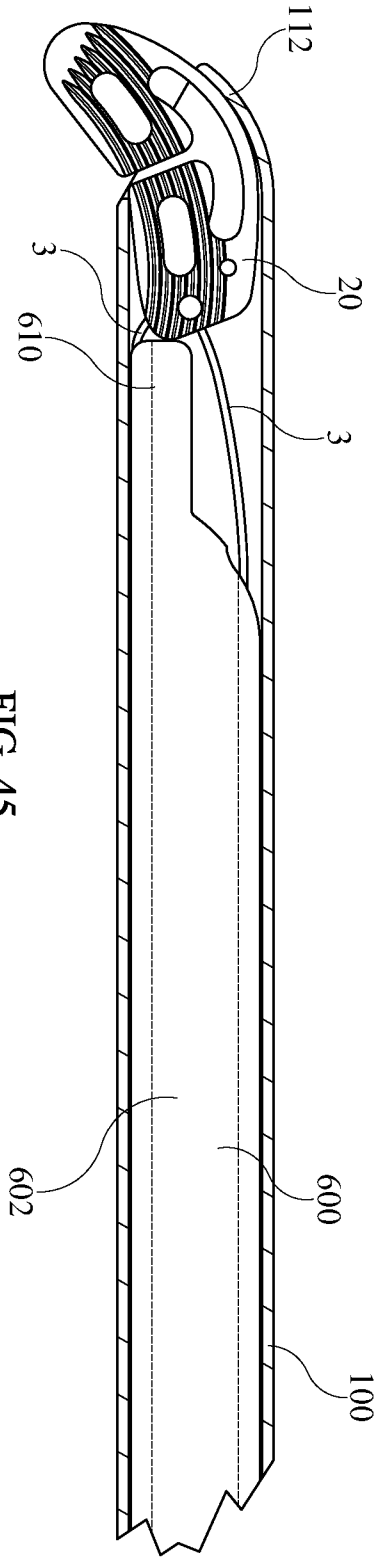


FIG. 45

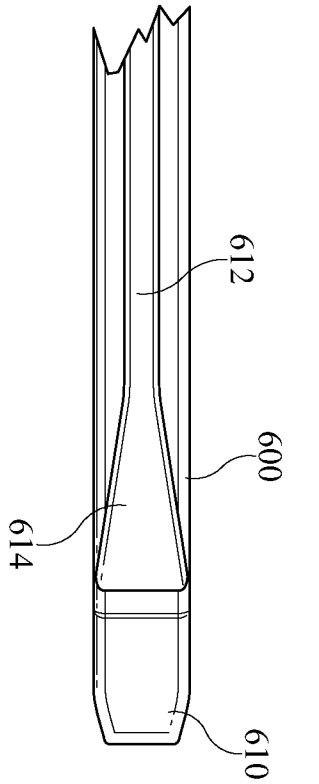


FIG. 46

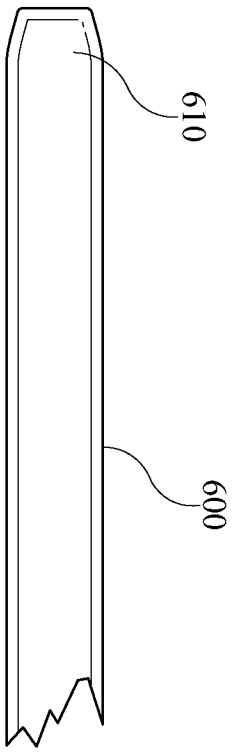


FIG. 47

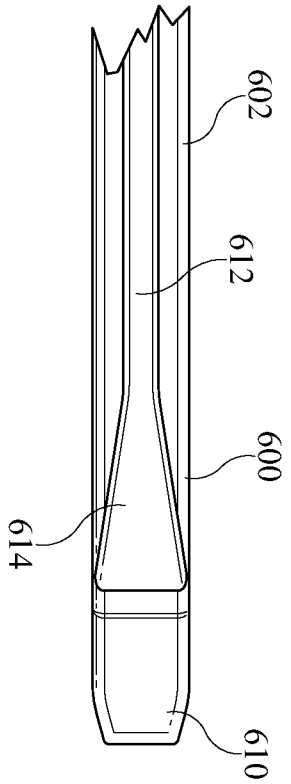


FIG. 48

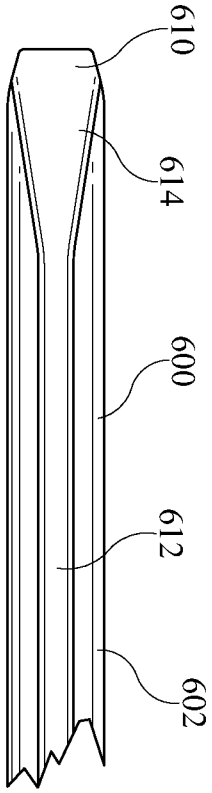


FIG. 49

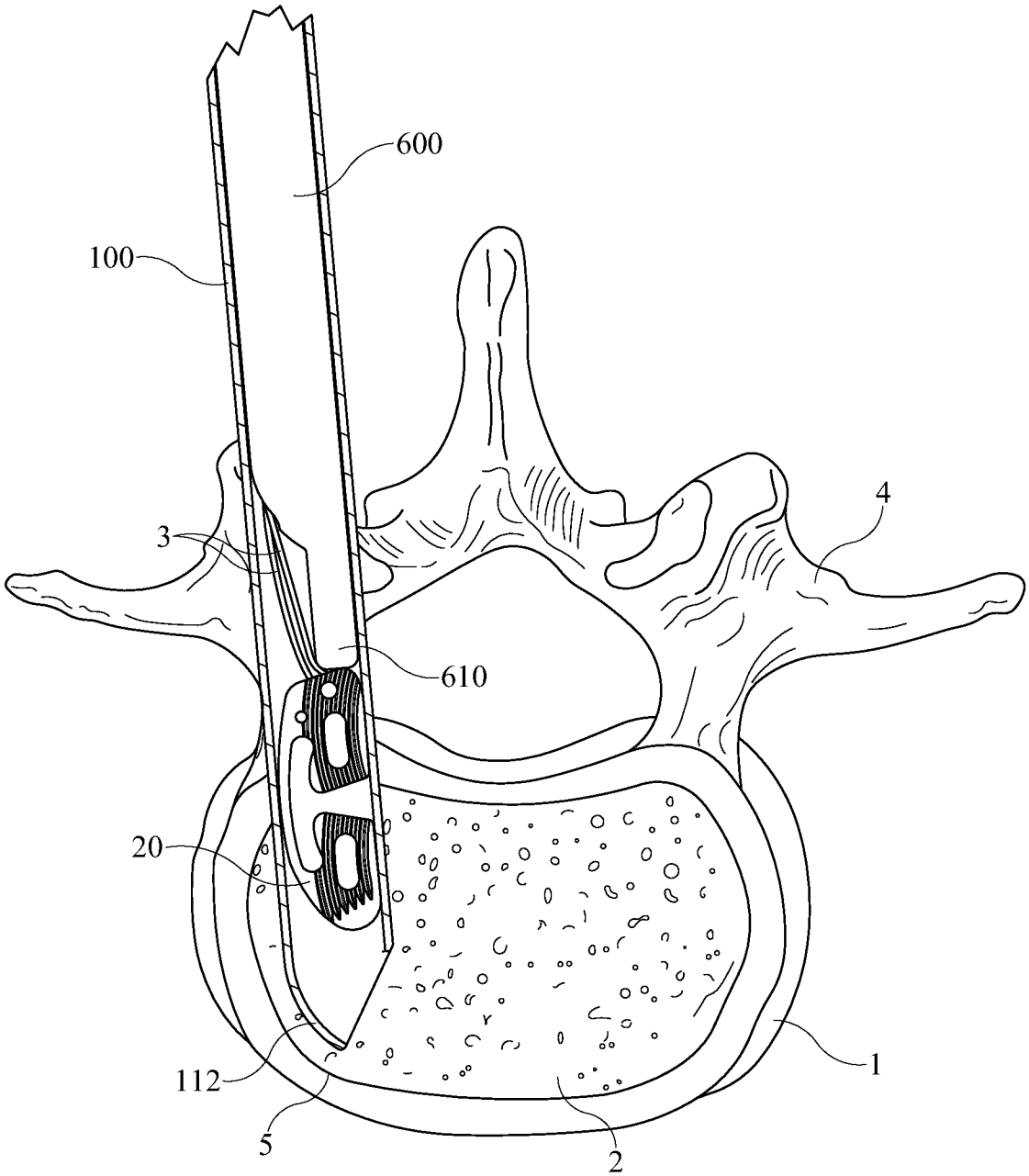


FIG. 50

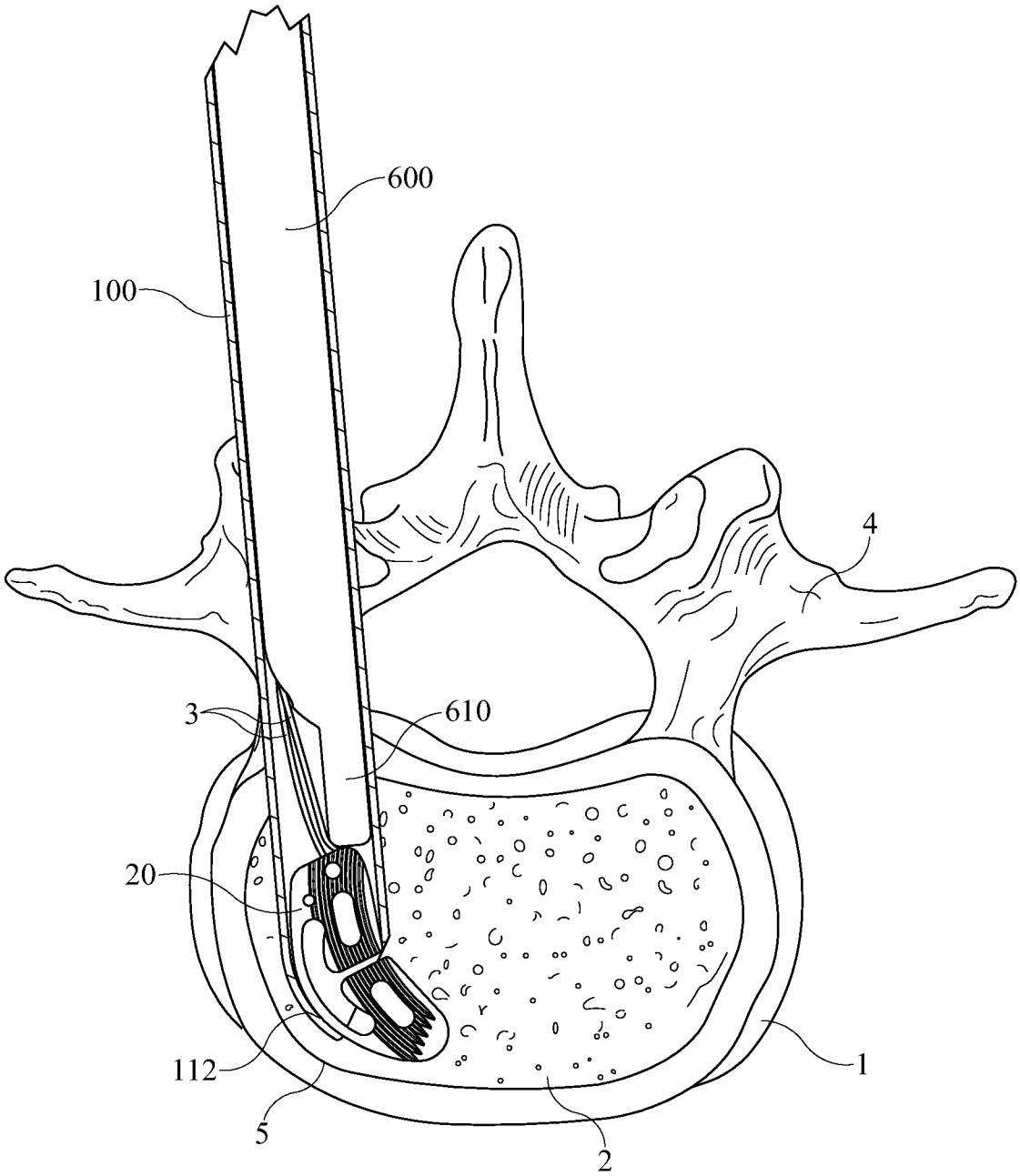


FIG. 51

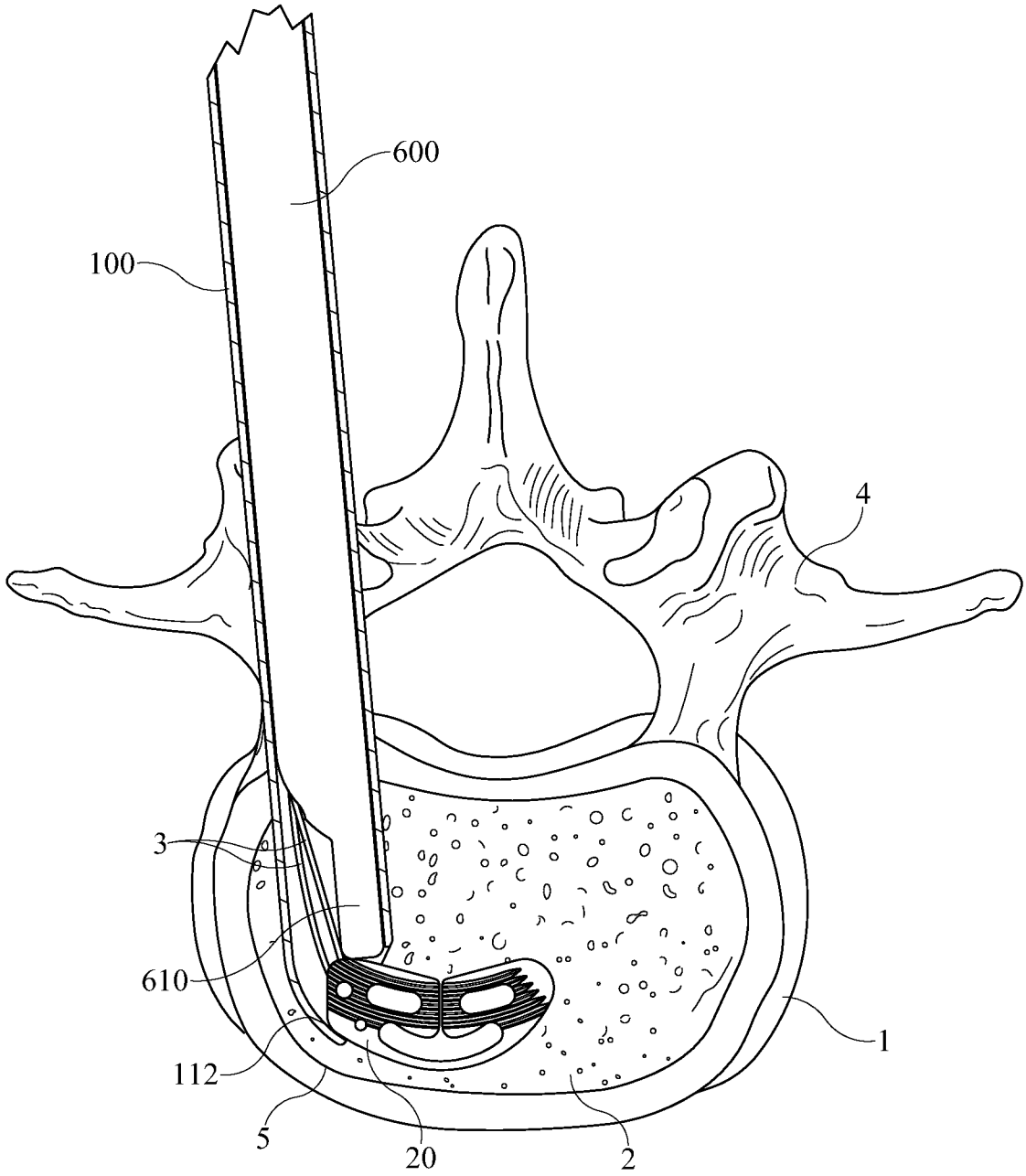


FIG. 52

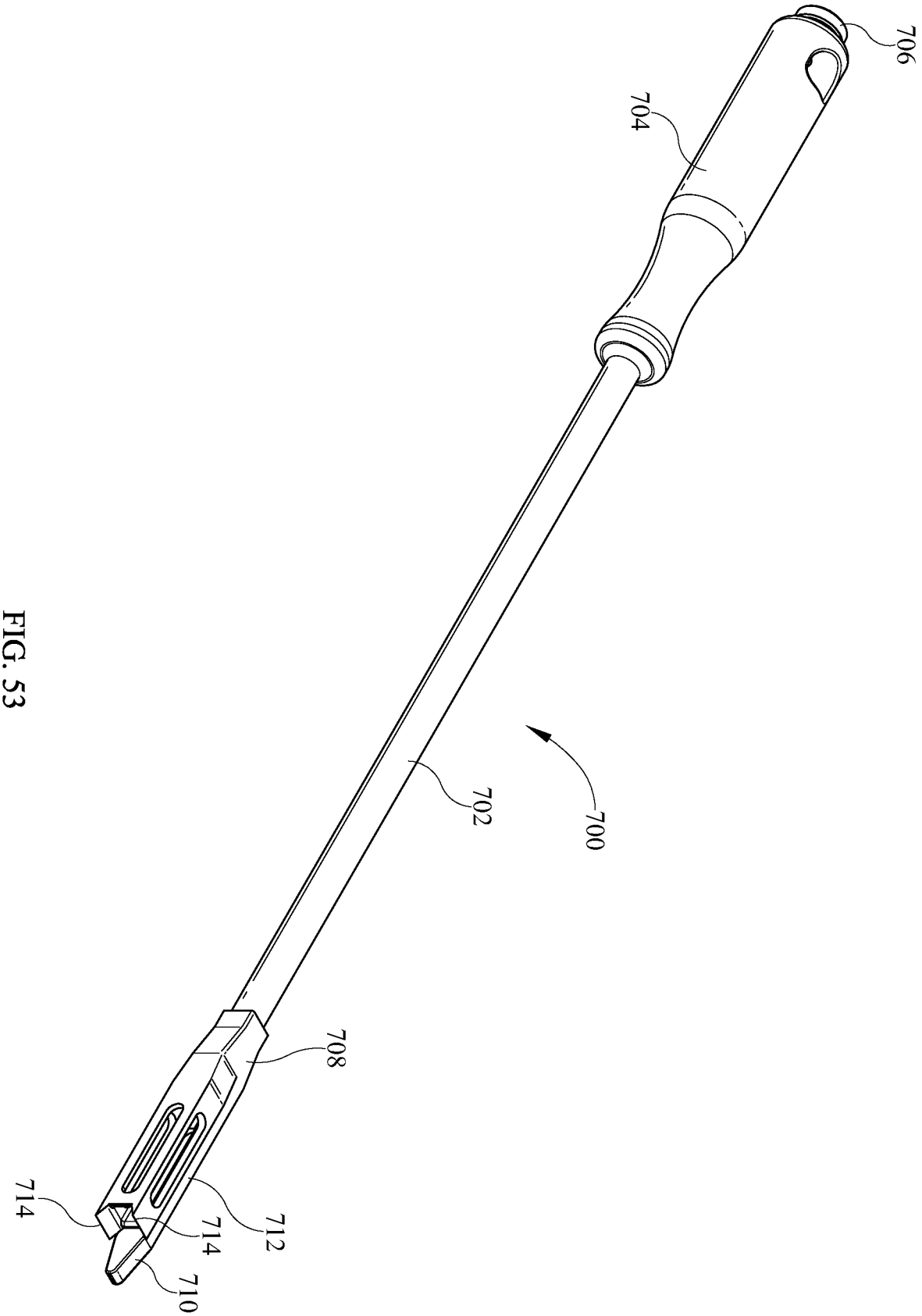


FIG. 53

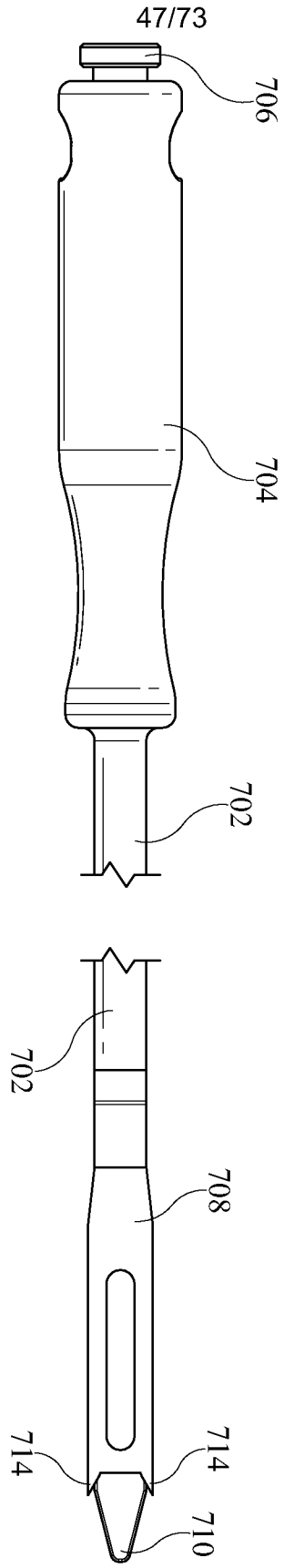


FIG. 54

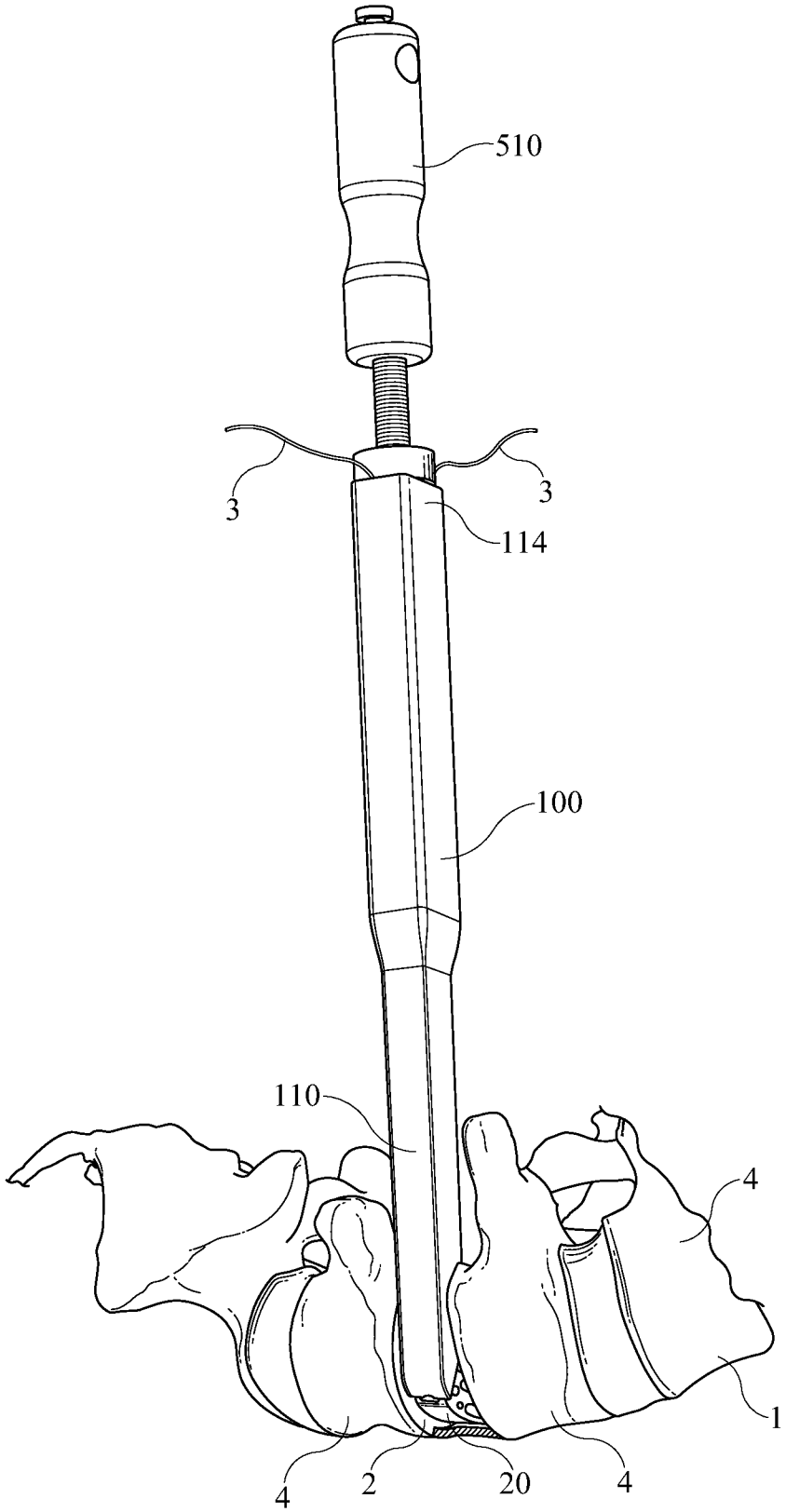


FIG. 55

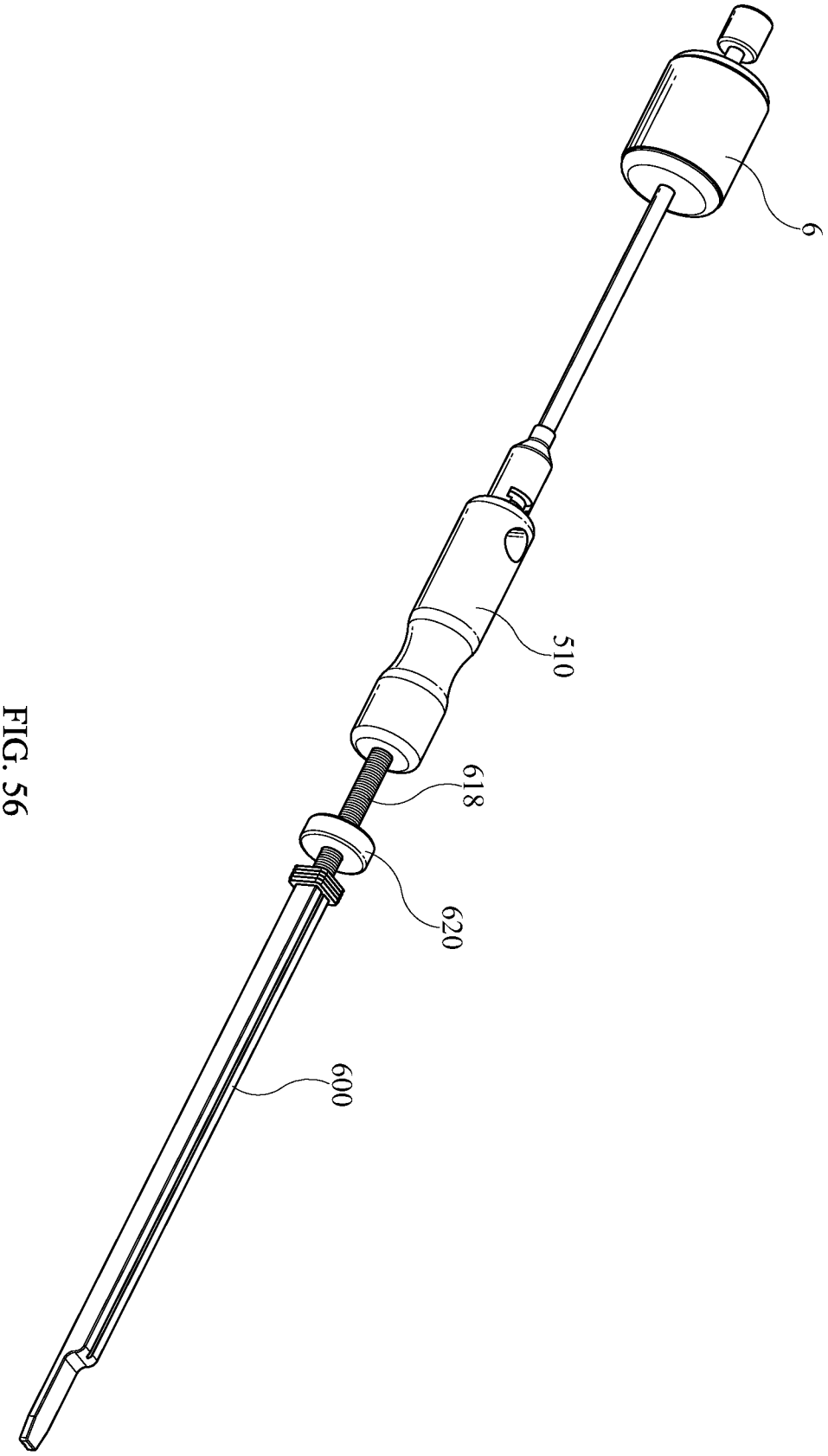


FIG. 56

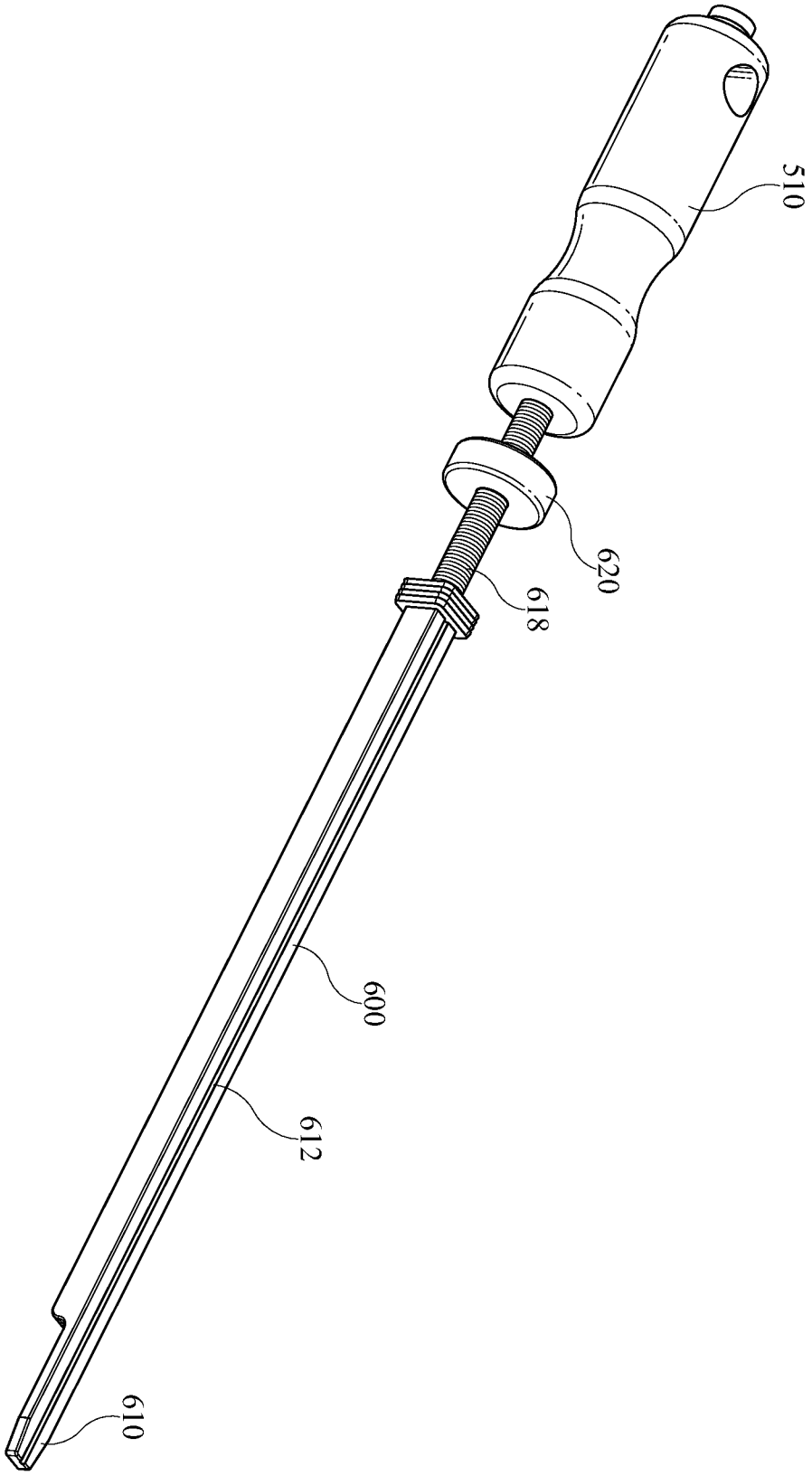


FIG. 57

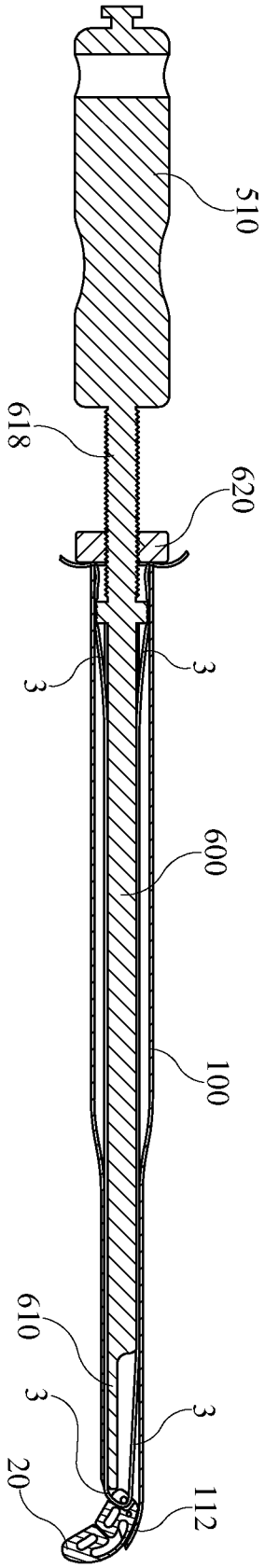


FIG. 58

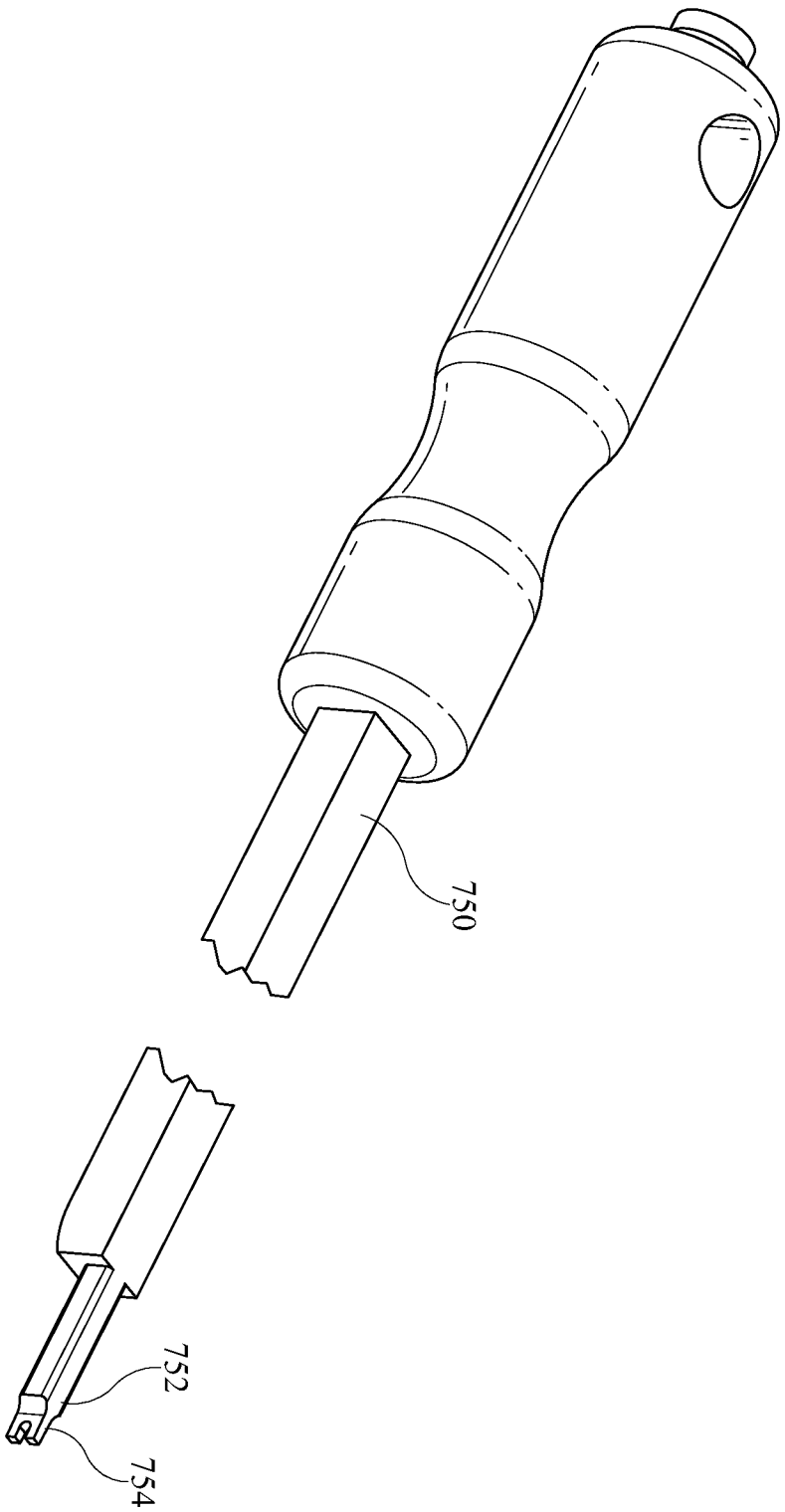


FIG. 59

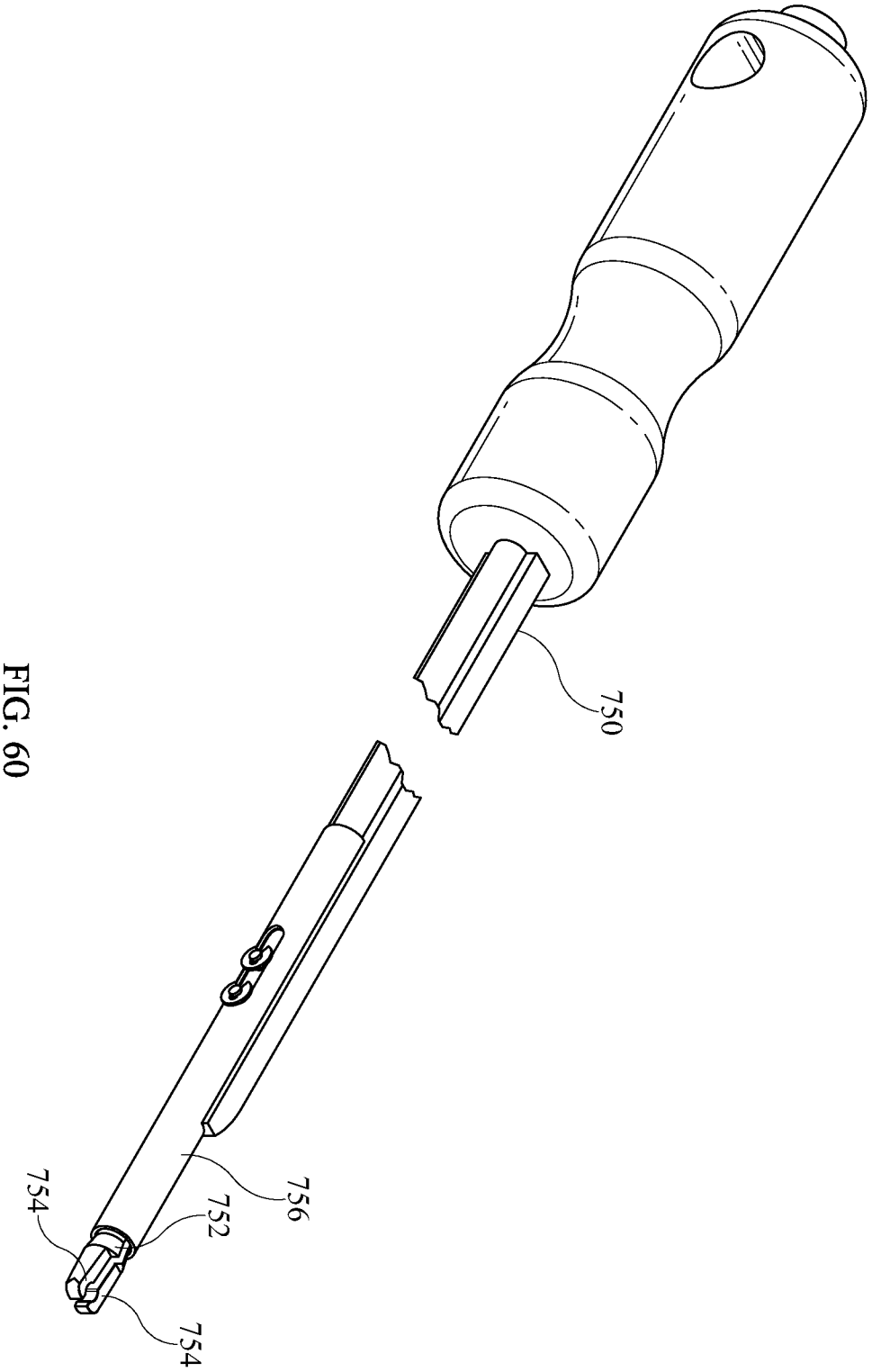


FIG. 60

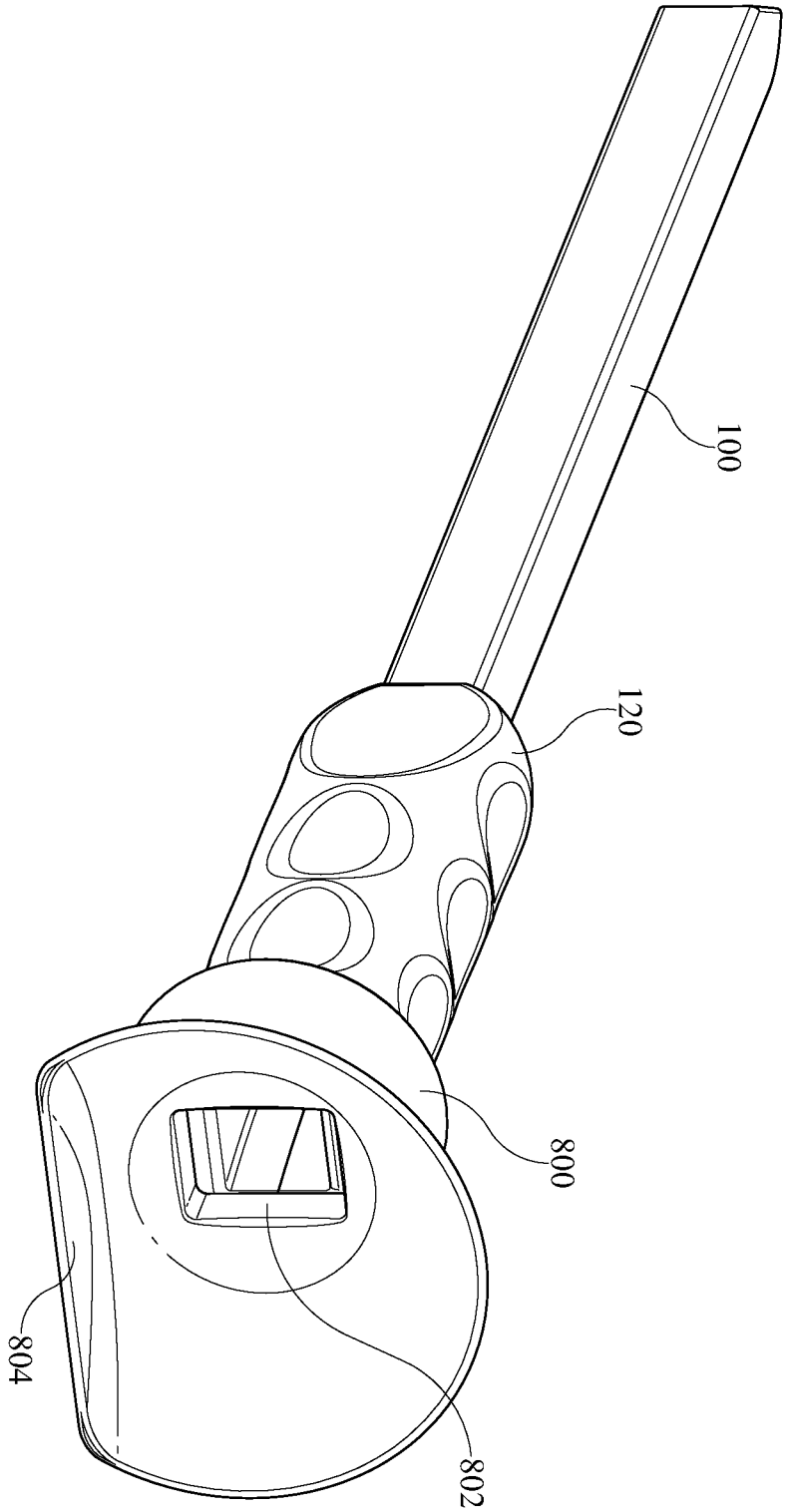


FIG. 61

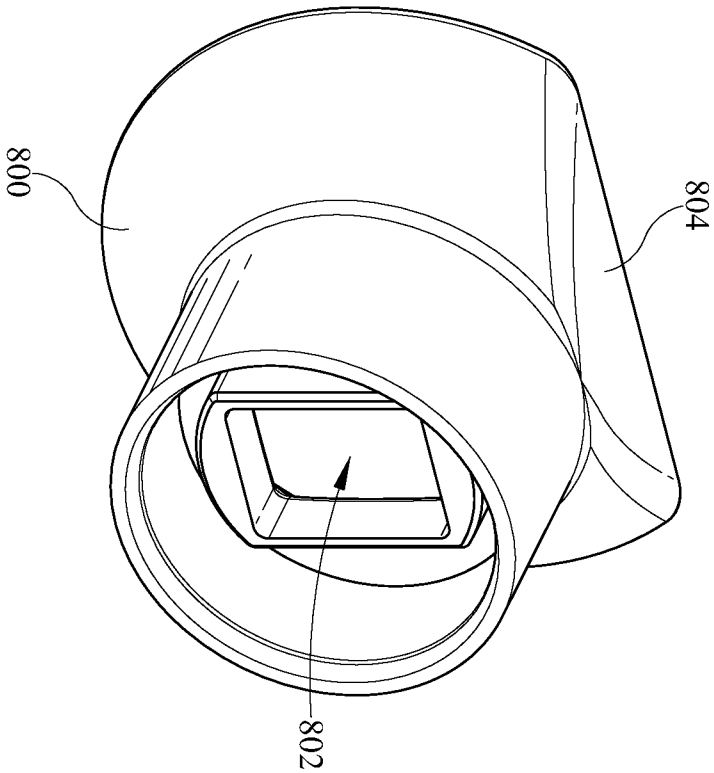


FIG. 62

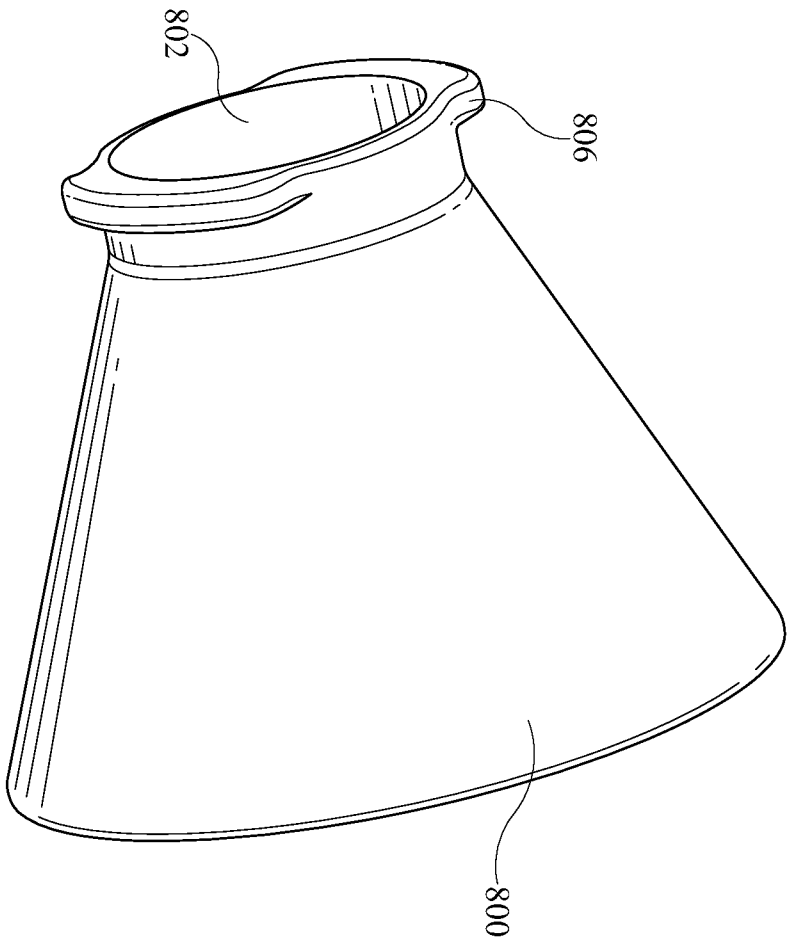


FIG. 63

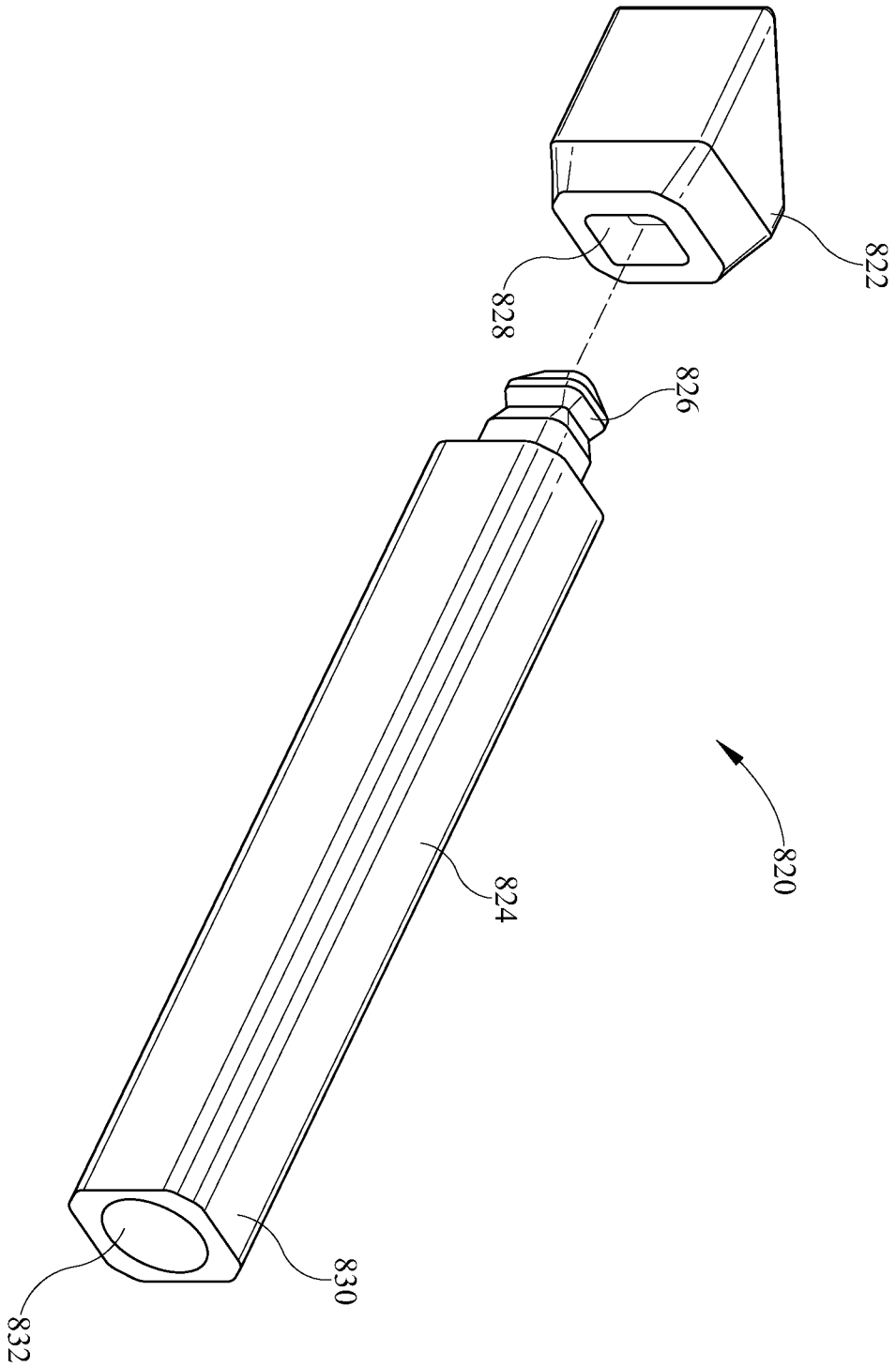


FIG. 64

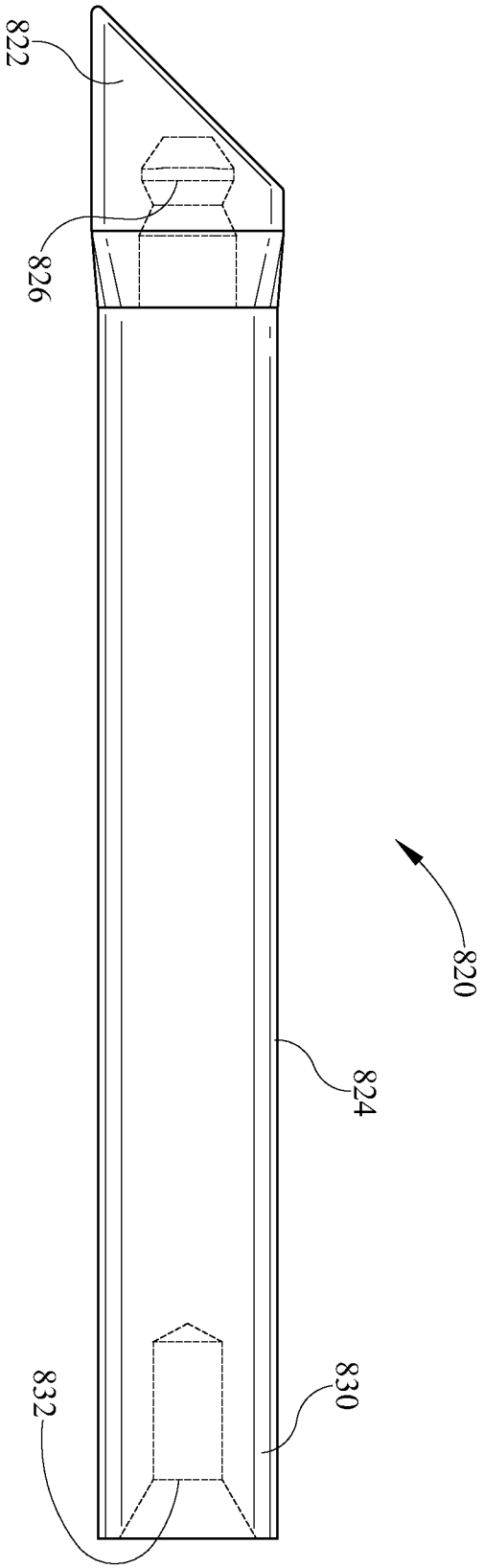


FIG. 65

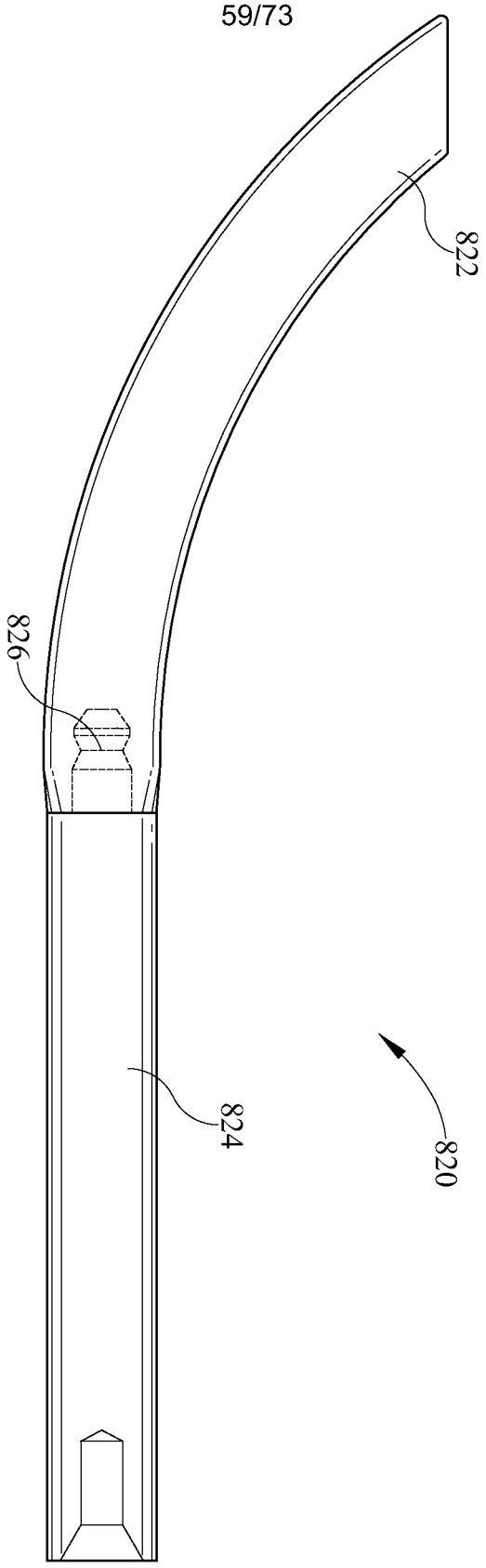


FIG. 66

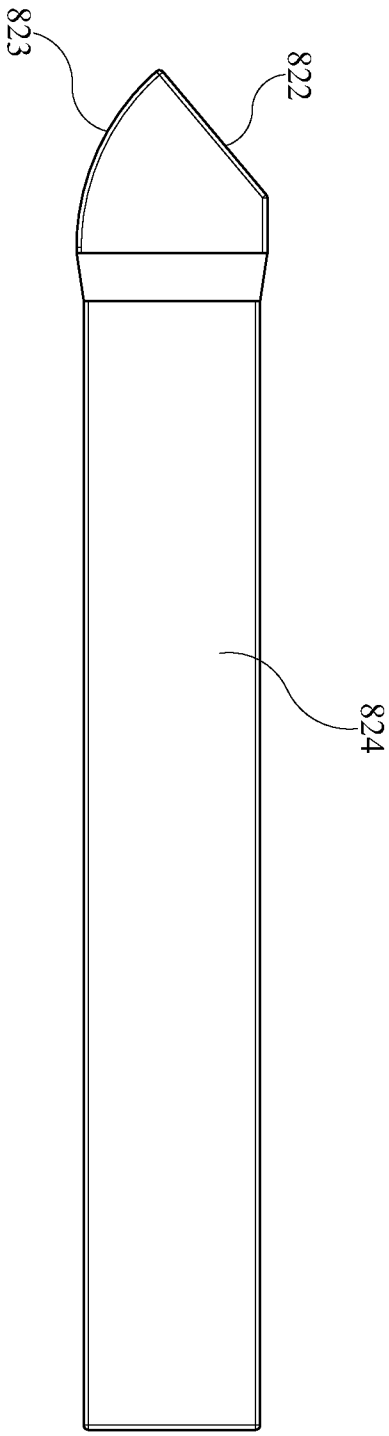


FIG. 67

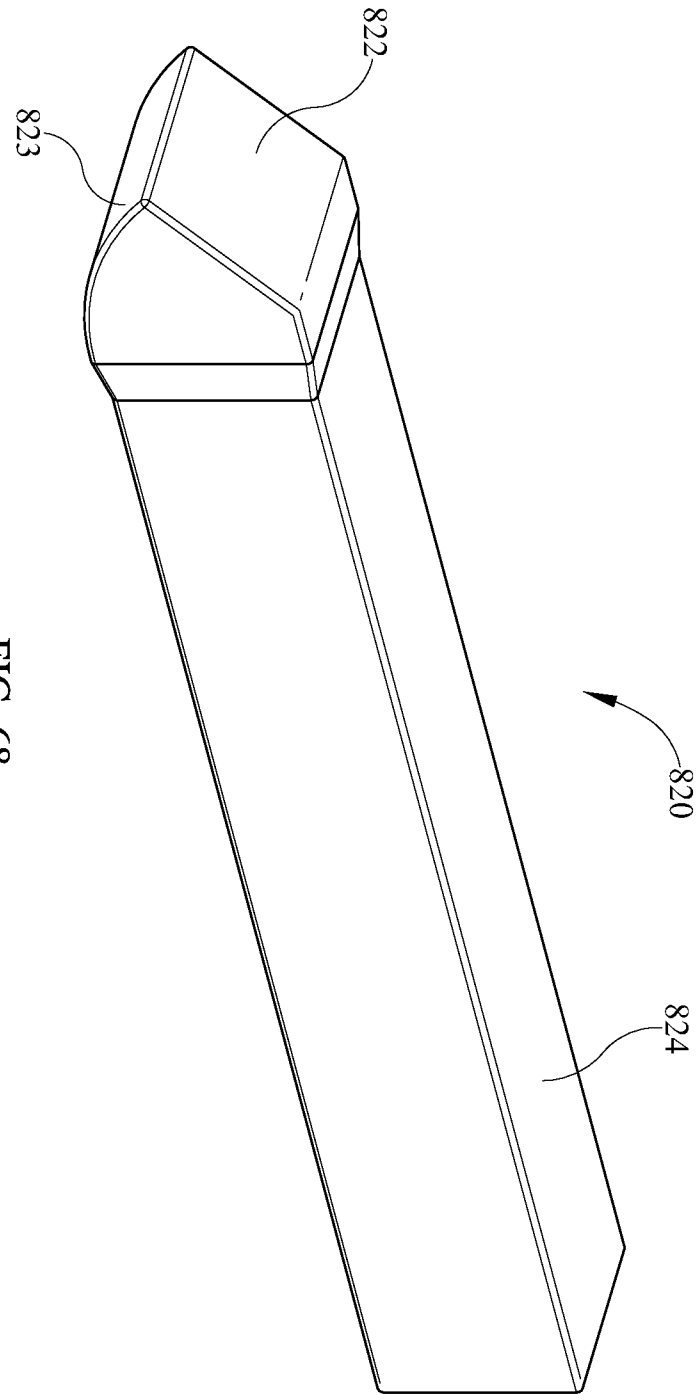


FIG. 68

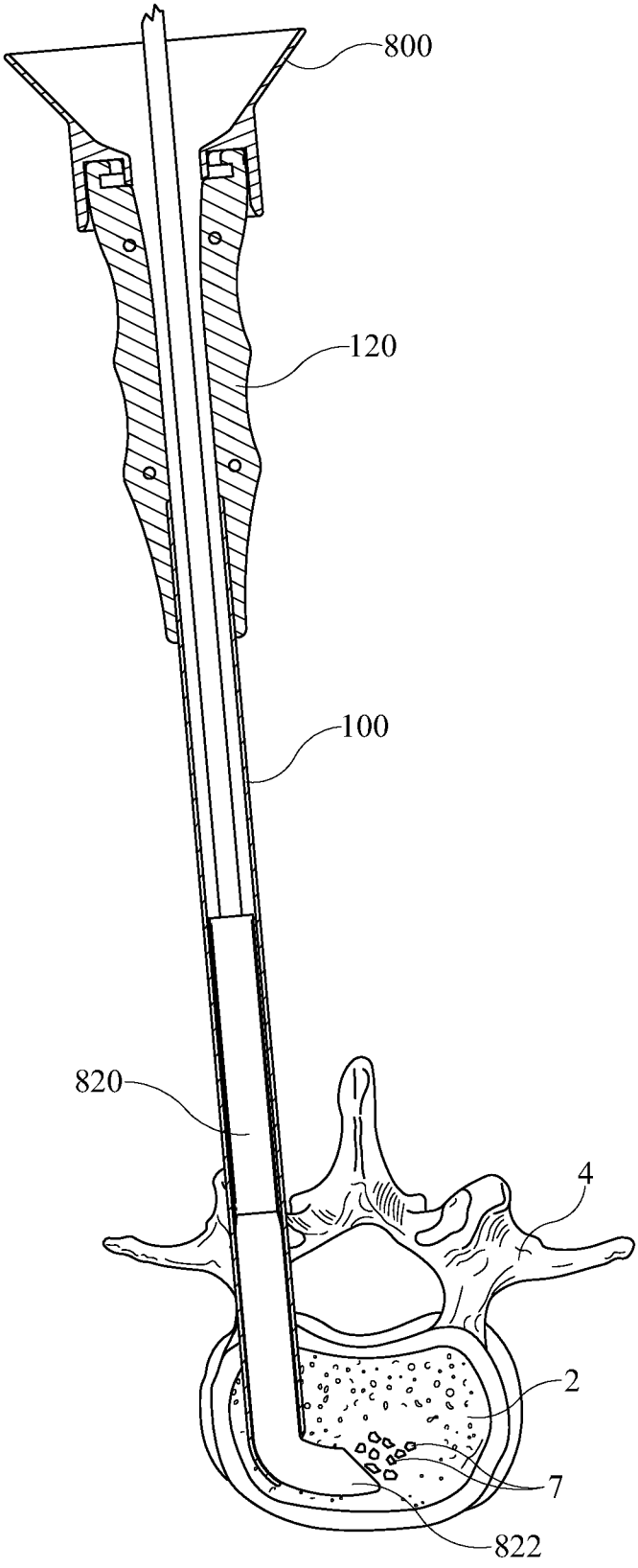


FIG. 69

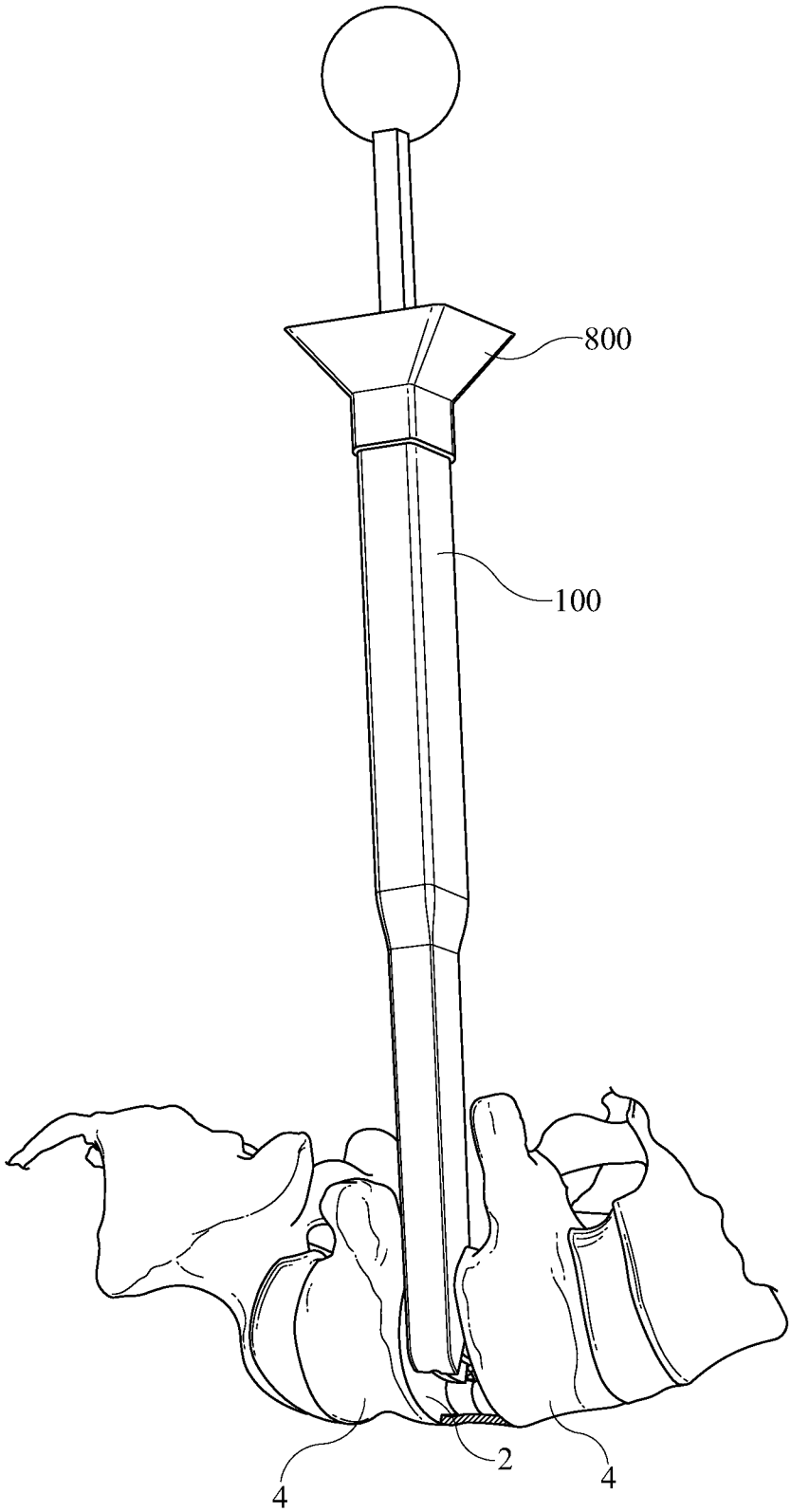


FIG. 70

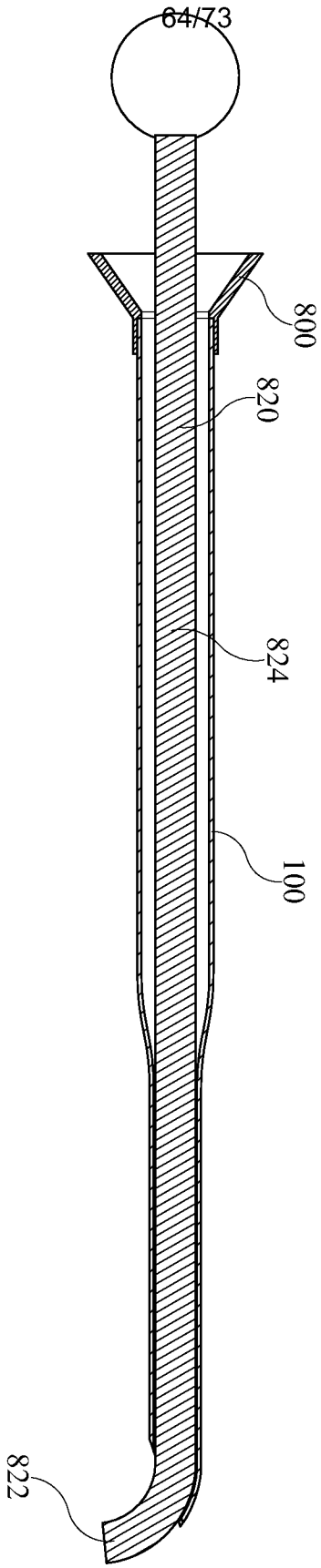


FIG. 71

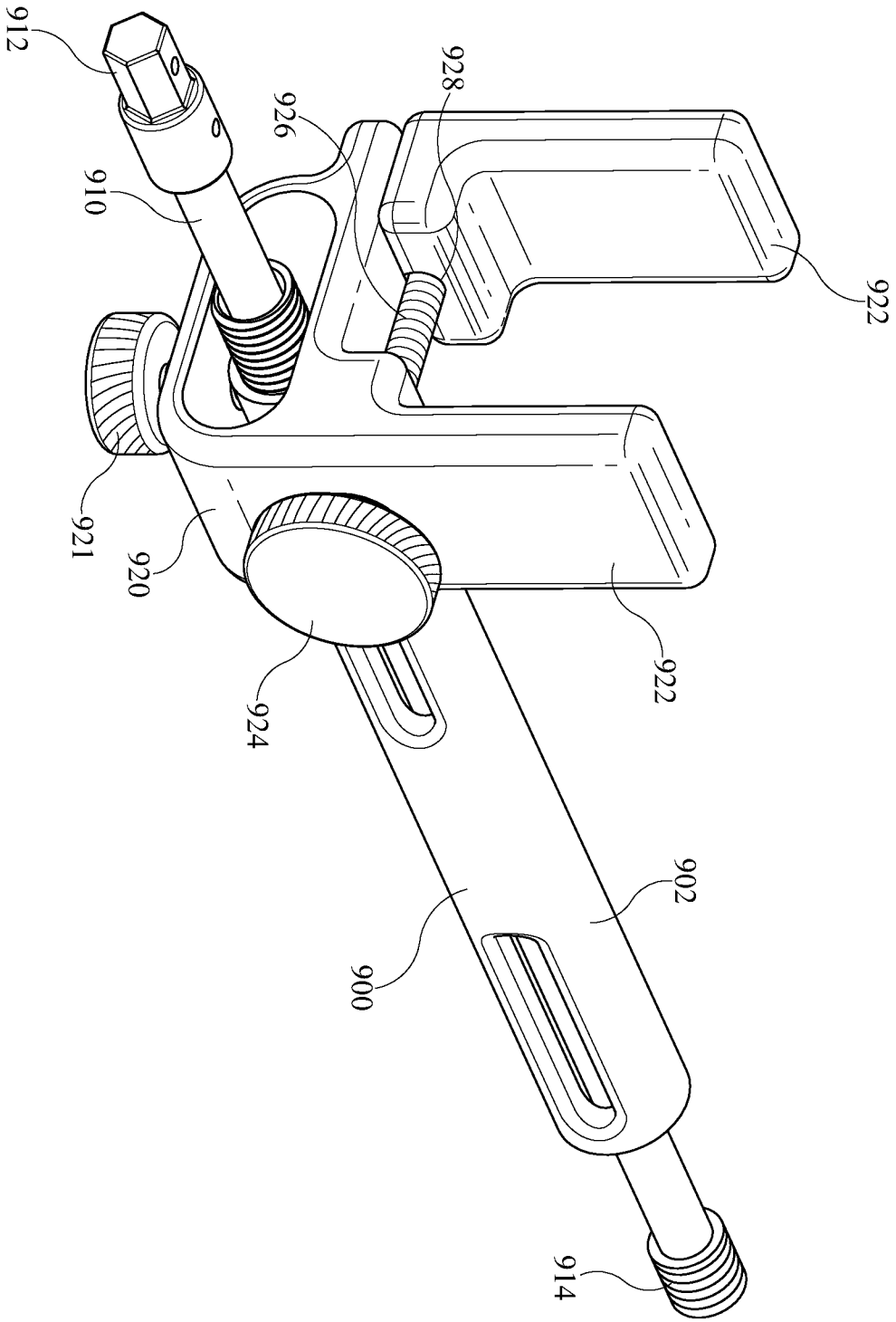


FIG. 72

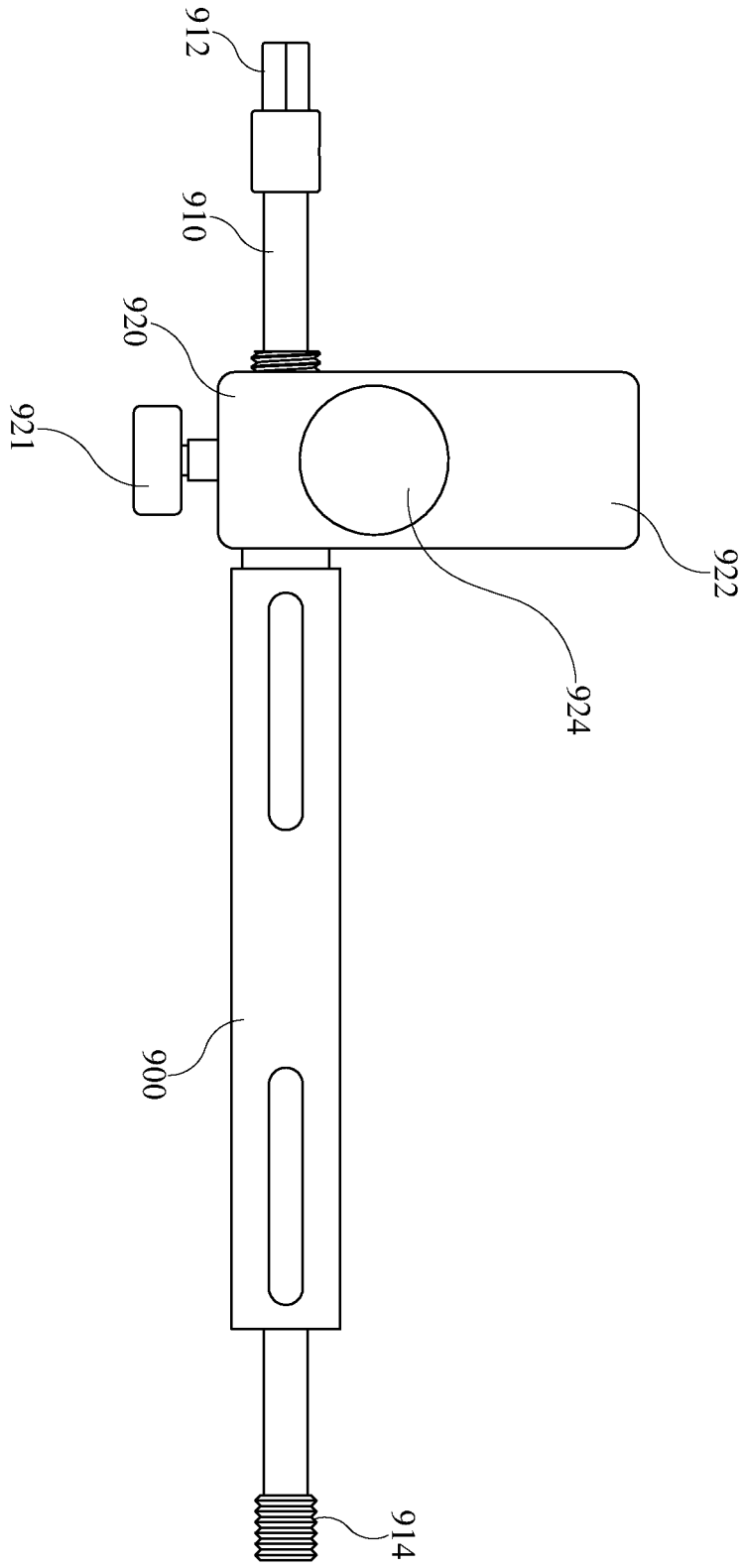


FIG. 73

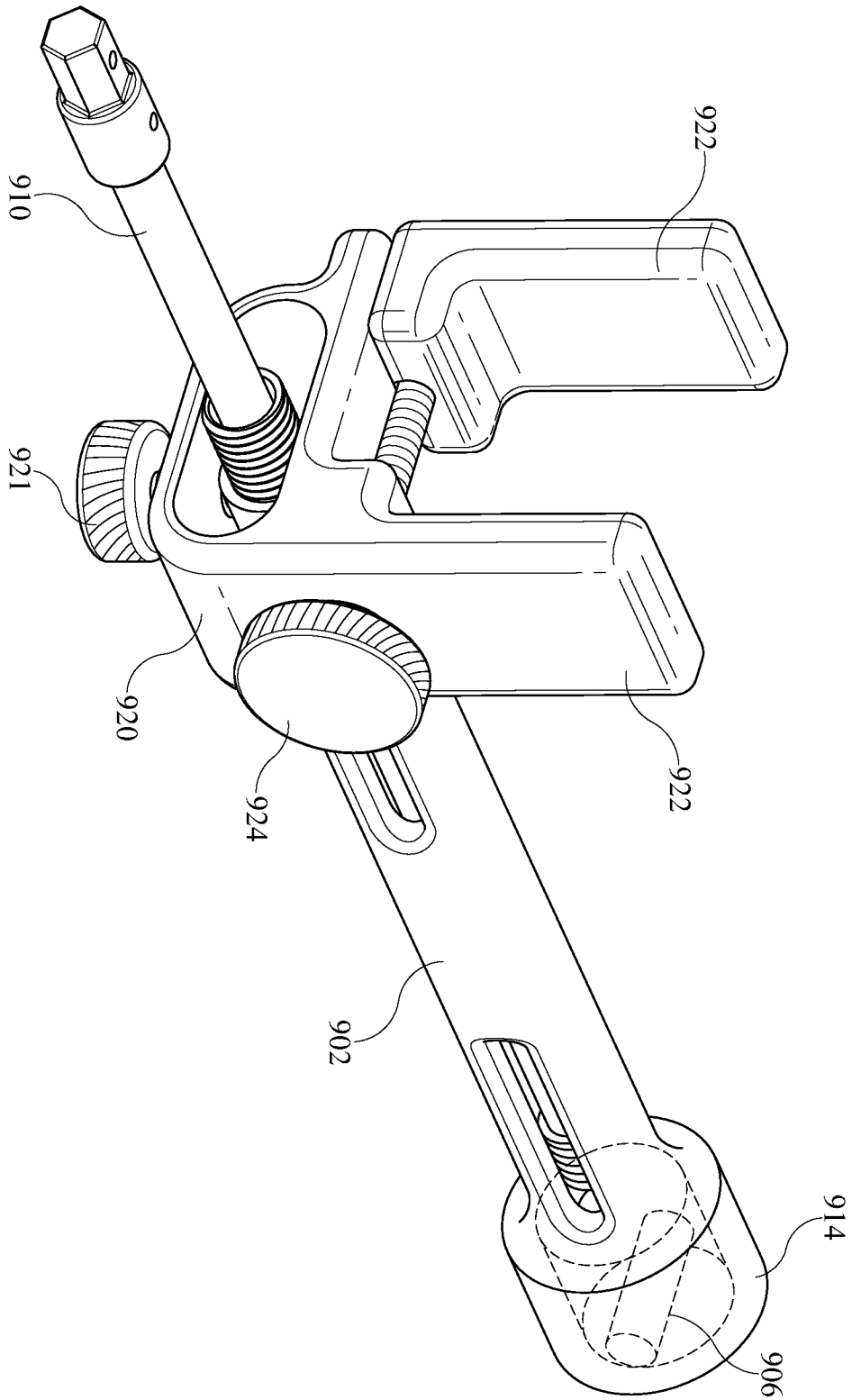


FIG. 74

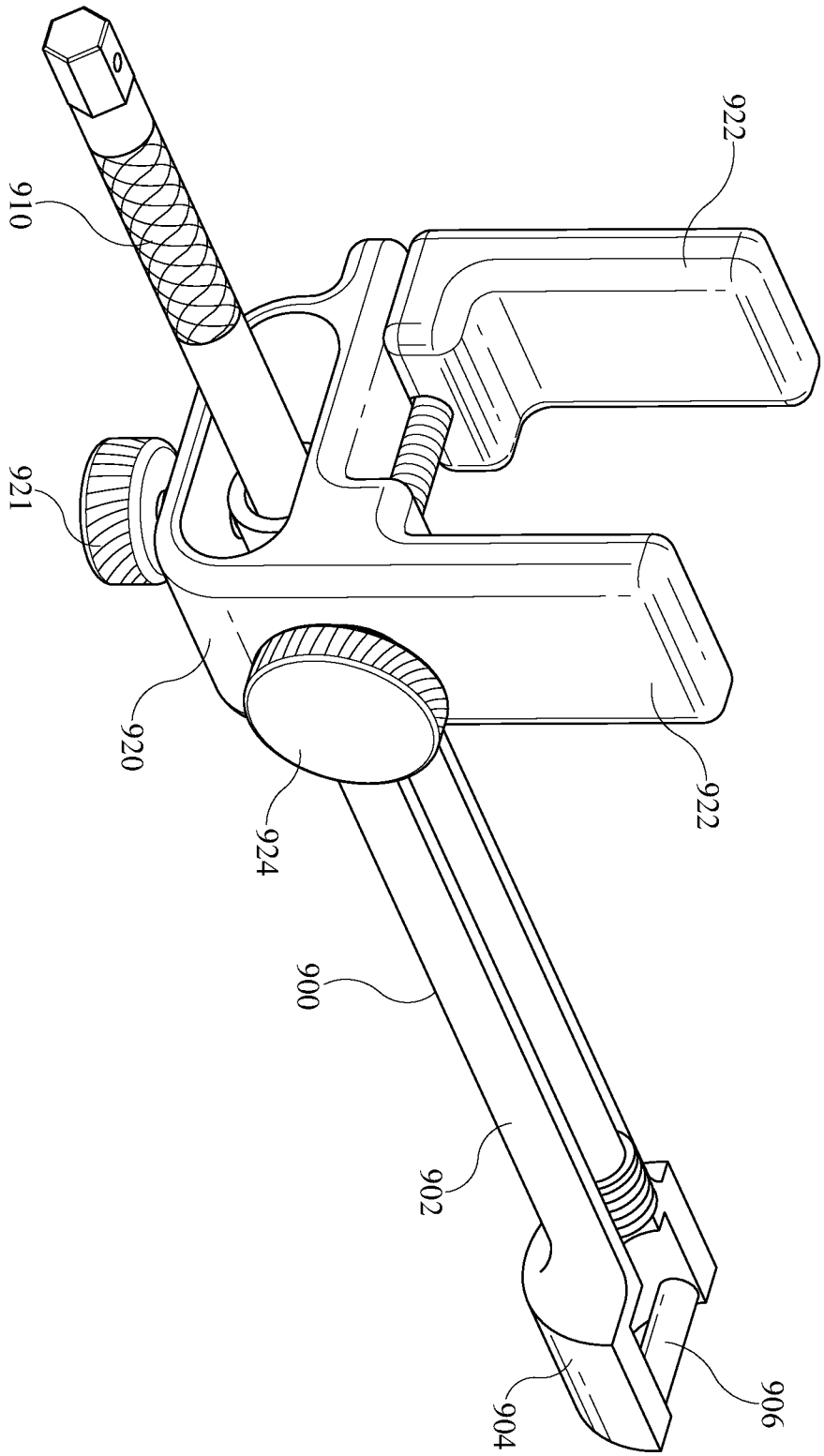


FIG. 75

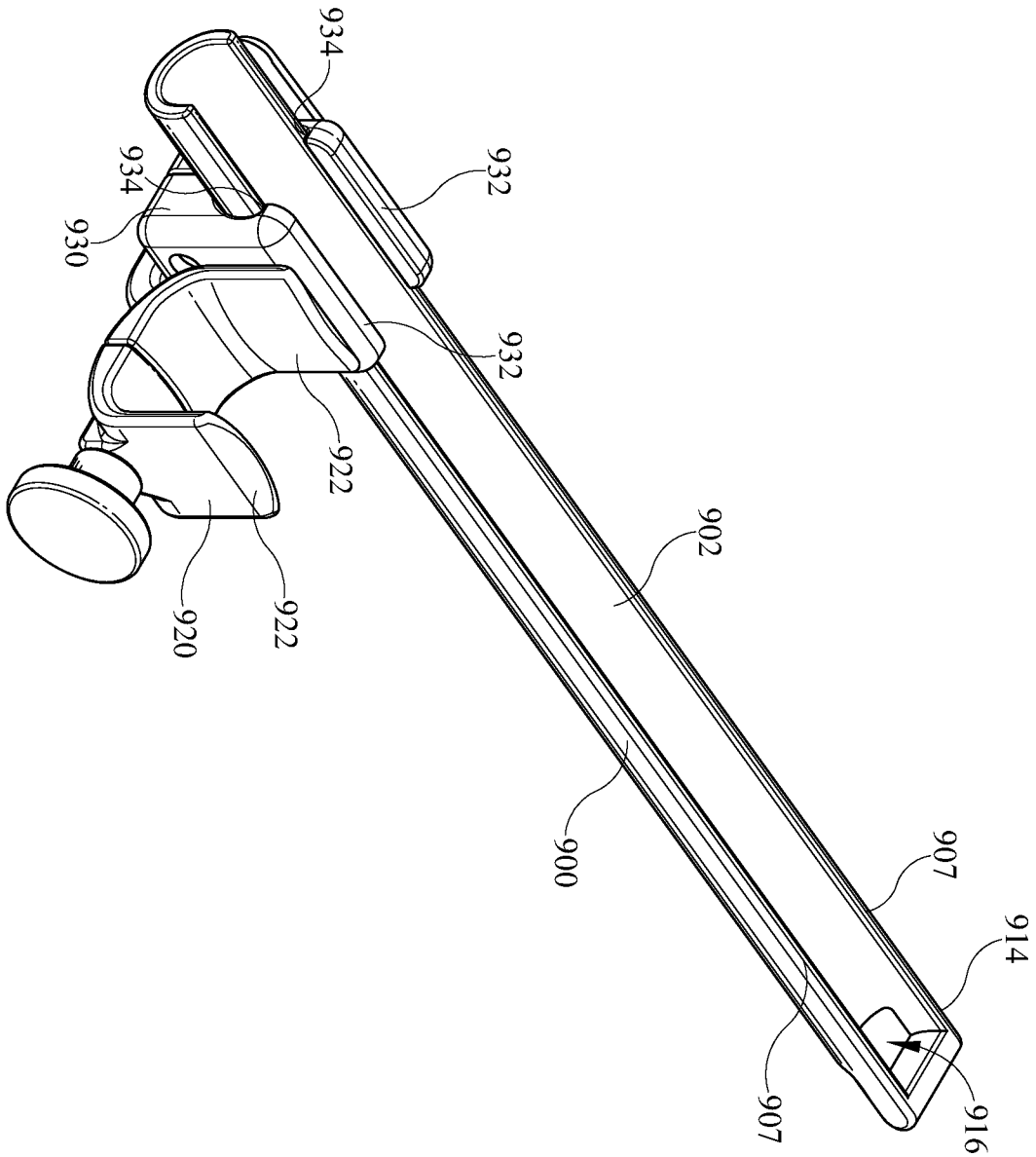


FIG. 76

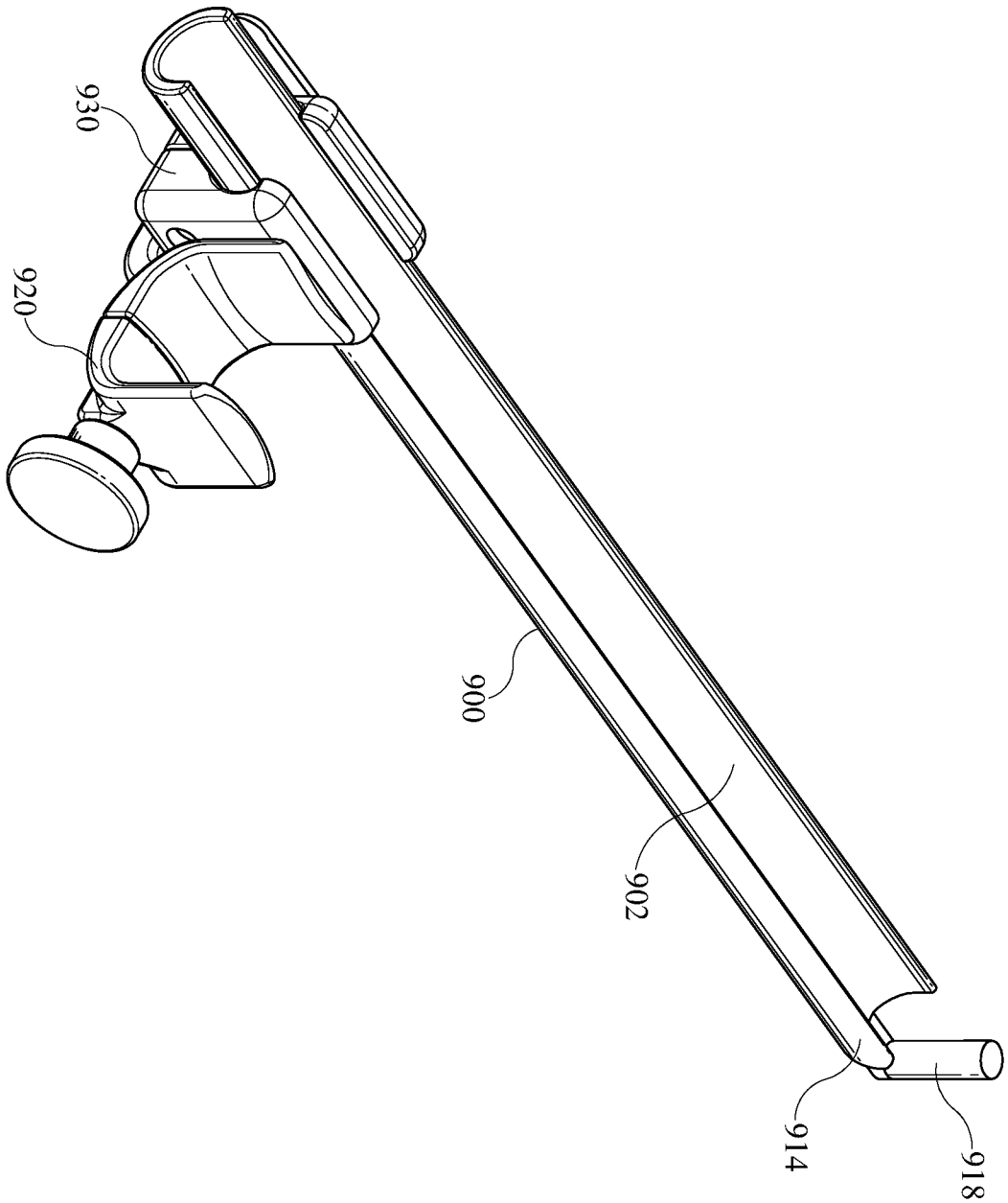


FIG. 77

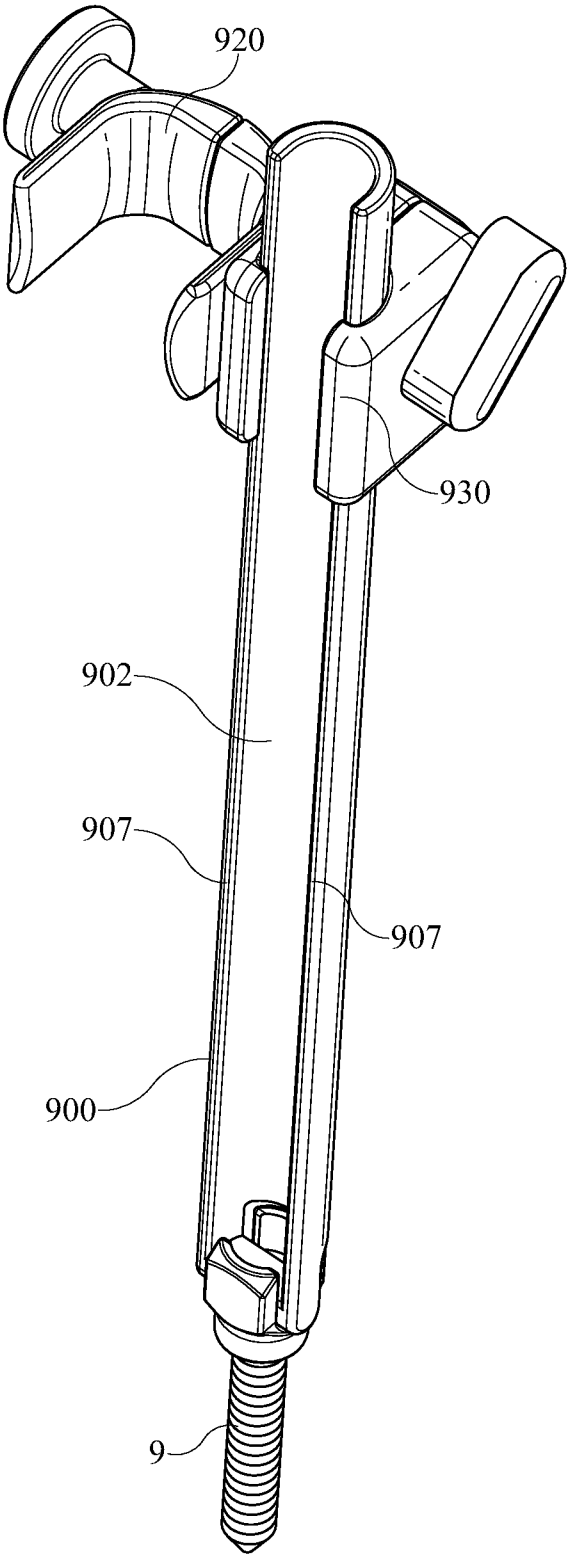


FIG. 78

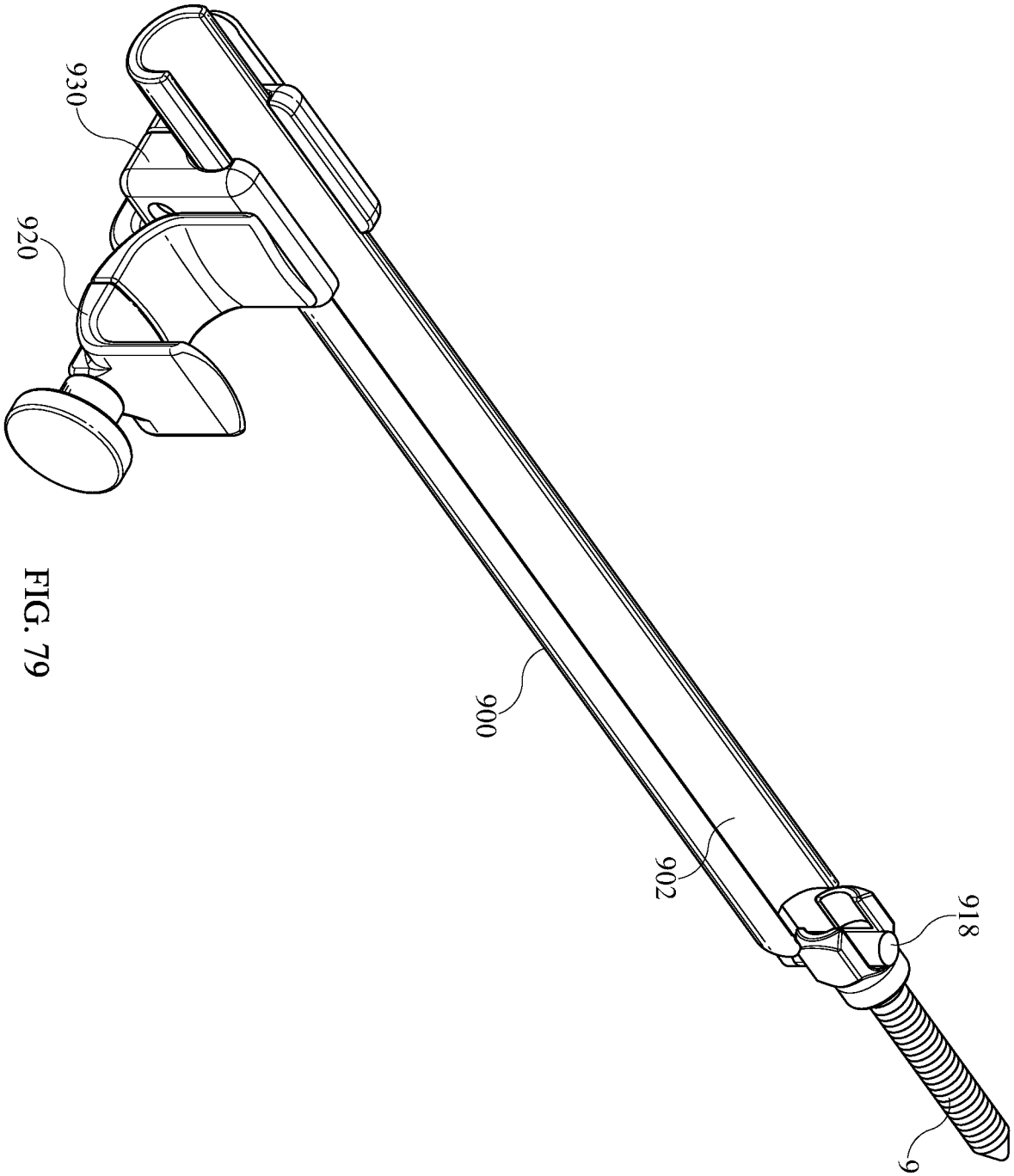


FIG. 79

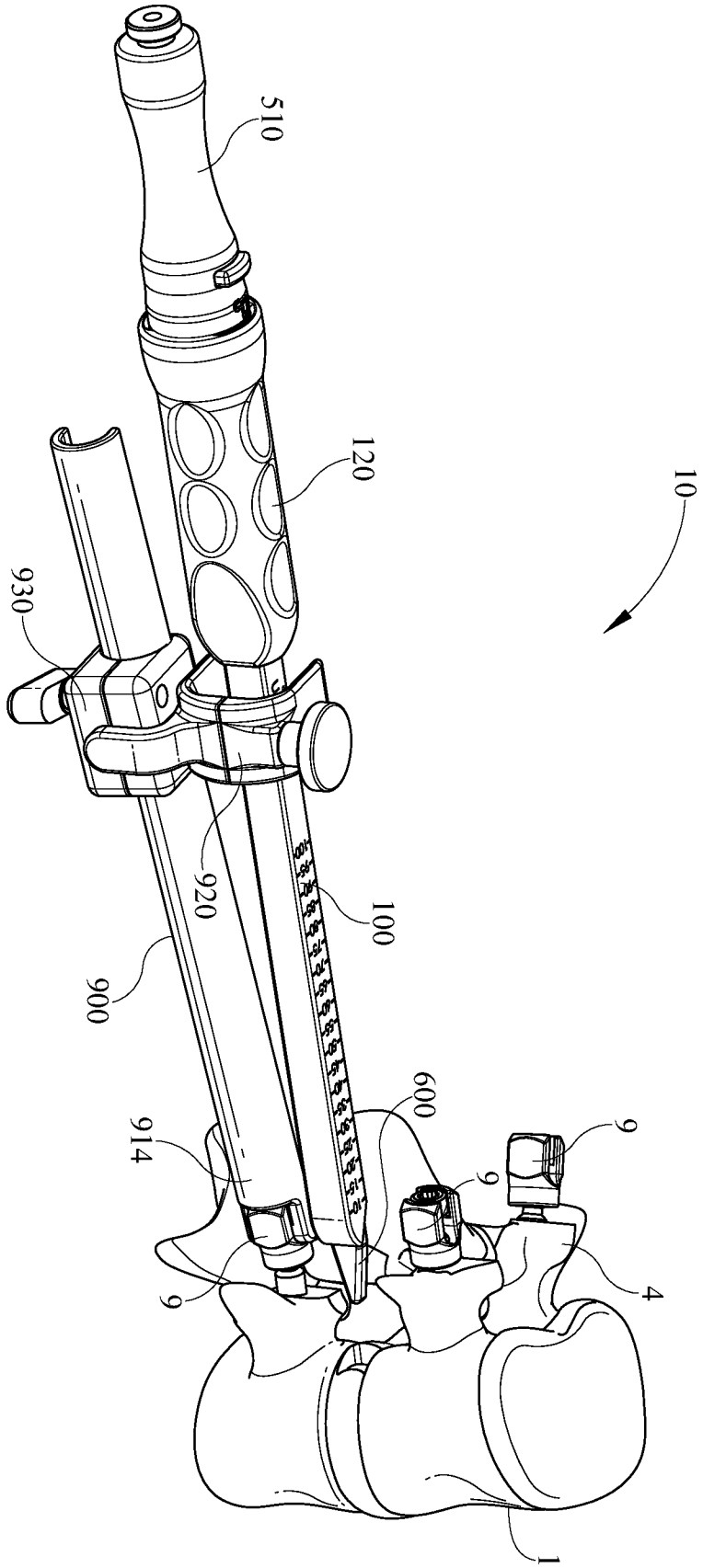


FIG. 80

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/041543

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/44 A61F2/46 A61B17/02
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61B B61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/077288 A1 (DEPUY SPINE INC) 25 August 2005 (2005-08-25) page 2 - page 15, line 20; claims page 19, line 23 - page 20, line 10; figures 3-11,36,37	1-31
X	WO 2007/124352 A2 (MEDITECH ADVISORS LLC) 1 November 2007 (2007-11-01) page 5, paragraph 3 - page 11; claims; figures	1-31
A	US 2009/030423 A1 (PUNO ROLANDO) 29 January 2009 (2009-01-29) paragraphs [0052] - [0080]; claims; figures 1-5b,10-15,19a-19c	1-31

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 November 2010	06/12/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kühne, H

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/041543

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 900 814 A1 (RAZIAN HASSAN) 16 November 2007 (2007-11-16) page 4, line 4 - page 9, line 31; claims; figures	1-31
A	FR 2 729 557 A1 (STRYKER CORP) 26 July 1996 (1996-07-26) page 7, line 14 - page 14, line 32; claims; figures	1-31
A	US 2004/093083 A1 (BRANCH CHARLES L ET AL) 13 May 2004 (2004-05-13) paragraphs [0110] - [0187]; claims; figures	1-31
A	WO 00/42898 A2 (MICHELSON GARY K) 27 July 2000 (2000-07-27) page 15, line 17 - page 33, line 25; claims; figures	1-31
A	US 2003/032962 A1 (MCGAHAN THOMAS V ET AL) 13 February 2003 (2003-02-13) paragraphs [0082] - [0129]; claims; figures	1-31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/041543

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. [X] Claims Nos.: 32-35
because they relate to subject matter not required to be searched by this Authority, namely:

No International Preliminary Examining Authority shall be required to search an international application on an international application if, and to the extent to which, its subject matter are methods for treatment of the human or animal body by surgery (Rule 39.1(iv) PCT).

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/041543

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005077288 A1	25-08-2005	AT 481035 T	15-10-2010
		AU 2005212352 A1	25-08-2005
		CA 2555876 A1	25-08-2005
		EP 1713408 A1	25-10-2006
		JP 2007521886 T	09-08-2007
		US 2007276406 A1	29-11-2007
WO 2007124352 A2	01-11-2007	EP 2012674 A2	14-01-2009
		JP 2009534130 T	24-09-2009
		US 2007270873 A1	22-11-2007
		US 2010023013 A1	28-01-2010
US 2009030423 A1	29-01-2009	AU 2008282493 A1	05-02-2009
		CA 2694734 A1	05-02-2009
		EP 2182894 A2	12-05-2010
		EP 2208481 A2	21-07-2010
		WO 2009018119 A2	05-02-2009
FR 2900814 A1	16-11-2007	NONE	
FR 2729557 A1	26-07-1996	AU 4625696 A	14-08-1996
		WO 9622747 A1	01-08-1996
US 2004093083 A1	13-05-2004	US 2010063554 A1	11-03-2010
WO 0042898 A2	27-07-2000	AT 464847 T	15-05-2010
		AU 773603 B2	27-05-2004
		AU 2628400 A	07-08-2000
		CA 2359943 A1	27-07-2000
		EP 1217961 A2	03-07-2002
		ES 2343162 T3	26-07-2010
		US 6224607 B1	01-05-2001
		US 2001010002 A1	26-07-2001
		US 2001010001 A1	26-07-2001
US 2003032962 A1	13-02-2003	US 2006241626 A1	26-10-2006
		US 2006195109 A1	31-08-2006