



(51) International Patent Classification:
A61B 17/70 (2006.01)

(21) International Application Number:
PCT/US2022/043033

(22) International Filing Date:
09 September 2022 (09.09.2022)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
17/470,694 09 September 2021 (09.09.2021) US

(72) Inventor; and

(71) Applicant: **BOEHM, JR., Frank H.** [US/US]; 155 Oxford Road, New Hartford, New York 13413 (US).

(74) Agent: **BLANK, Christopher** et al.; 11 Schoen Place, 2nd Floor, Suite 3, Pittsford, New York 14534 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA,

NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) Title: NON-INTRUSIVE BONE ANCHOR FOR USE ON VERTEBRAL LAMINAR PROCESSES

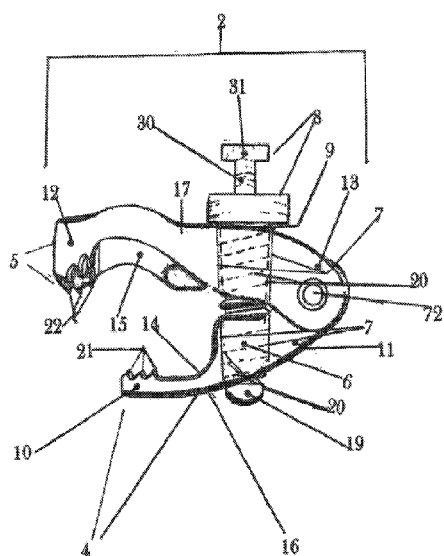


Figure 5

(57) Abstract: A non-intrusive bone anchor for attachment to vertebral lamina processes with a main body which has a lower fixed jaw; a connecting portion to said lower fixed jaw, a bore hole providing basis for an axis from one side of said connecting portion to the other, and a threaded two ring clamp where each ring has an inner threaded surface with a threaded axis; An externally threaded shaft with a first and second end, where said first end has an internal torquing indent and a portion adjacent thereto for a locking mechanism to engage the outer portion of the clamping ring and said first end has a fixation protuberance. An upper jaw that cooperates with said externally threaded shaft and engages bone between said upper jaw and said lower fixed jaw forming a diagonal across a clamped bone body; and an inter-anchor connector comprising an axis with a first connector end and a second connector end where said first connector end has a rod portion and said second end has a tulip rod fixer portion.

NON-INTRUSIVE BONE ANCHOR FOR USE ON VERTEBRAL LAMINAR PROCESSES

BACKGROUND OF THE INVENTION

[0001] The point in history when ancient physicians first recognized the cervical spine as a site of significant human pathology has been lost in the mists of time. The Smith Papyrus demonstrates that Egyptian physicians during the period of the Middle Kingdom were aware of pathology of the neck, and there is evidence to suggest that this document may have been copied from works of physicians from even earlier civilizations.

[0002] Today, cervical spine pain and related symptoms are among the most common reasons for patients to visit health care providers, as well as one of the most common sites for elective surgery upon the spinal column. Further- more, these are very frequently the major complaints following motor vehicle accidents and other domestic I civilian trauma and is probably the leading cause of litigation in that scenario. Cervical spine pain is a common complaint associated with Workers' Compensation injuries, leading to billions of dollars in medical care, disability benefits, and lost productivity. It cannot be overlooked, either, that such injuries plague military personnel and in particular pilots that operate supersonic aircraft; in this scenario, it has been often commented that for such pilots, it is "only a matter of time" until they experience CS-6 degeneration. Clearly, this is a very major problem in the United States, as well as most technologically advanced countries going forward into the New Millennium.

[0003] This contention is also supported by the fact that there are over 50,000 anterior cervical fusions performed every year in the United States alone. Primary posterior procedures may add up to 25,000 additional cases. Moreover, millions of patients suffer with chronic neck pain. This great prevalence has also spawned a vast number of alternative therapies to speak to this large patient population.

[0004] There are many theories as to the genesis of chronic neck I spine pain, but one of the more well-established hypotheses is that such "axial" pain represents an element of abnormal motion between two or more vertebrae, the so-called syndrome of "micro-instability." Furthermore, it is speaking to this issue of "micro-instability" that theoretically serves as the primary indication for spinal fusion; if one believes that the symptoms are the result of excessive motion then, obviously, successful fusion of the segment and hence eliminating all movement should resolve the issues. Unfortunately, for reasons that are not yet fully elucidated, this does not always resolve to be true.

[0005] In order to better understand the relationship between spinal biodynamics and axial pain, scientist and physicians studying the spine have developed a paradigm referred to as the "motion segment." This refers to a unit comprised of any two adjacent vertebrae, along with the technique of passing wires through holes drilled in the target spinous processes, and supplementing this with bone graft from the iliac crest. This technique was further modified by Whitehill, Benzel, and others.

[0006] Bohlman introduced a technique by which not only were the spinous processes wired, but elongated bone grafts from the iliac crest were wired to the lateral masses. Facet fixation was first introduced by Callahan in 1977, proposing that holes be drilled through the facets and wires passed into them ultimately stabilizing the construct. This was largely utilized in the lumbar spine, although some cases of cervical facet fusion were reported.

[0007] Cahill, in 1983, introduced a variation of Callahan's teachings which actually combined earlier techniques with facet wiring. He passed wires around the spinous process of the caudal vertebra of the target motion segment, pursuant of the classic technique as described by Hadra. The other ends of these wires were passed through holes drilled through the lateral masses, as described by Callahan.

[0008] In his landmark work starting in the 1950's, Harrington proposed a system of hooks which were passed under the edges of the laminae and then connected to long rods. This system was primarily introduced to correct scoliotic curvatures, but was responsible for the introduction of sublaminar hooks, which are now commonly used in a variety of systems used in all segments of the spine, including the cervical spine. The inventive process disclosed herein utilizes a sublaminar component similar to the hook method taught by Harrington.

[0009] Another method for posterior stabilization was introduced by surgeons at the University of Halifax in the mid 1980's, teaching that a pair of curved metal plates could be passed around the superior edges of the laminae of the cranial vertebra of a target motion segment, with a pair of "mirror image" curved plates being disposed around the inferior edges of the laminae of the caudal vertebra. The trailing ends of these plates are configured to be secured to each other by screws, which also provided adequate compression of the plates against the bone. Although this technique, when reduced to practice, enjoyed a brief period of popularity, they are rarely if ever used at this point, and are essentially of historic interest only.

[0010] Lateral mass screws were introduced by Roy-Camille in the early 1980's, and have ostensibly become, in one form or the other, the posterior cervical stabilization method of choice in 2015. Various systems have been introduced which allow for occipitocervical stabilization, cervicothoracic stabilization, and even occipitocervico-thoracic systems. This surgery requires an extensive exposure and cannot be performed using a minimally invasive technique; such MIS techniques have become increasingly desirable in today's healthcare environment for many reasons, particularly the reduced complications, shorter periods of hospitalization, and reduced need for postoperative pain management. Furthermore, there is a need for extremely precise location of the screws in order for them to be accurate, effective, as well as to minimize the

chances of significant injury to the nerve roots or vertebral artery. The latter is a rare but extremely serious complication and has been known to result in vertebral artery dissection, stroke and even infarct of the spinal cord.

[0011] Accordingly, and for all the foregoing reasons, a substantial need exists for a device which can stabilize the cervical spine utilizing a nonintrusive manner to the cervical one procedure, and without violating the cortical bone or causing substantial injury to the periosteum. This is important, as many recent studies have demonstrated that injury of the bone, or annulus fibrosis can accelerate the degenerative process. Such a device would, by inference and implication, have to be fully reversible not only in terms of implantation, but also terms of having no substantial impact upon the anatomy and function of the target motion segment. This device, as provided herein, would be unique, useful, novel and non-obvious and is as securely fixed to the spine as prior art apparatus and screws.

BRIEF DESCRIPTION OF THE INVENTION

[0012] The invention relates to the general field of spinal surgery, and specifically to a device and method for use by which a unique, useful, novel, and non-obvious stabilizing clamp is secured bilaterally to the posterior bony surfaces of at least two adjacent cervical vertebrae, and once positioned, connecting elements are secured to the cranial and caudal clamps bilaterally, thus eliminating any motion of the target motion segment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] So that the manner in which the features of the invention can be understood, a detailed description of the invention may be had by reference to certain embodiments, some of which are illustrated in the accompanying drawings. It is to be noted, however, that the drawings illustrate only certain embodiments of this invention and are therefore not to be considered limiting of its scope, for the scope of the invention encompasses other equally effective embodiments. The

drawings are not necessarily to scale; emphasis generally being placed upon illustrating the features of certain embodiments of the invention. In the drawings, like numerals are used to indicate like parts throughout the various views. Thus, for further understanding of the invention, reference can be made to the following detailed description, read in connection with the drawings, in which:

[0014] FIG. 1 shows an anterior view of the osseous cervical spine.

[0015] FIG. 2 is a right lateral view of the osseous cervical spine.

[0016] FIG. 3 show a posterior view of the osseous cervical vertebra.

[0017] FIG. 4 reveals a transaxial (top) view of a typical cervical vertebra.

[0018] FIG. 5 is a lateral view of an isolated laminar anchor.

[0019] FIG. 6 demonstrates a cut-away/hemisected view of the spine with the laminar anchor in place on the left C5 lamina

[0020] FIG. 7 is a lateral view of the preferred embodiment of the CMIS in which the rod-like connecting element couples a cranial laminar anchor to a caudal anchor.

[0021] FIG. 8 is a three quarters perspective view of a spinal laminar bone anchor embodiment with a J-shaped sublaminar jaw, a neck, an upper body and a rotating axially hinged dorsal jaw.

[0022] FIG. 9 is a three quarters view of the bone anchor of FIG. 8 showing the axially hinged dorsal jaw, and the rotatable U-shaped tulip fitting with the threaded interior.

[0023] FIG. 10 is another three quarters side view of the bone anchor of FIG. 8 illustrating the locking mechanism for the dorsal jaw and the U-shaped tulip.

[0024] FIG. 11 is the front view of the bone anchor of FIG. 8.

[0025] FIG. 12 is the rear view of the bone anchor of FIG. 8 and illustrates the rear of the body of the J-shaped jaw body and the neck that is configured to cooperate with a bone anchor placement tool.

[0026] FIG. 13 is a three quarters view from above of the bone anchor of FIG. 8 illustrating the inner threaded portion of the U-shaped rod holding tulip and the inner

[0027] FIG. 14 is a top view of the bone anchor of FIG. 8 showing a guide on the bottom of the J-shaped jaw that engages with the rod placement tool.

[0028] FIG. 15 is the bottom view of the bone anchor shown in FIG. 8

[0029] FIG. 16 is a side view of the embodiments of FIGS. 8 and 13 showing a short neck portion.

[0030] FIGS. 17 A–H show various forms of a vertebral anchor that operate by encircling the vertebral process.

[0031] FIG. 18A shows a retractor for placing vertebral anchors.

[0032] FIG. 18B shows a retractor with a handle for preparing a lamina for placing vertebral anchors.

[0033] FIG. 19 is an elevational view of the implantation instrument.

[0034] FIG. 20 shows an exploded view of the implantation instrument.

[0035] FIG. 21 illustrates the cranial laminar anchor being implanted.

[0036] FIG. 22 A/B demonstrate the caudal laminar anchor being implanted, and the connecting element being secured to the cranial anchor.

[0037] FIG. 23 is a posterior view showing the preferred embodiment of the CMIS linking two adjacent laminar anchors and stabilizing a target motion segment.

[0038] FIG. 24 reveals a two-level the construct spanning three vertebrae, shown in a posterior view.

[0039] FIG. 25 shows an alternative embodiment of the connecting element that couples to each of the anchors, thus stabilizing the system.

[0040] FIG. 26 is another alternative embodiment of the coupling of the connecting element to the laminar anchors.

[0041] FIG. 27 illustrates an elevational perspective of an alternative embodiment of the laminar anchor which has been provided with a cradle which houses the connecting element that couples one laminar anchor to another.

[0042] FIG. 28 demonstrates the connecting element of the laminar anchors which have been provided with the cradle embodiment.

[0043] FIG. 29 studies a construct in which the laminar anchors are coupled to each other in the alternative embodiment in FIGS. 27-28.

[0044] FIGS. 30A/B/C are views showing embodiments in which cradles have been provided to the anchors, coupled by a rod.

[0045] FIG. 31 is an alternative embodiment of the connecting element and how it is coupled to the anchor.

[0046] FIGS. 32A-D depict various elevated, exploded views of the alternative system seen in FIG. 31.

[0047] FIG. 33 portrays the coupling of two laminar anchors in the alternative embodiment in FIG. 31.

[0048] FIG. 34 shows a multilevel construct of the alternative embodiment in FIG. 31.

[0049] FIG. 35 depicts a multilevel construct of the alternative embodiment in FIG. 31 utilizing a rod connecting element.

[0050] FIG. 36A illustrates an elevational view of an embodiment in which the base of the connecting element is secured within a cup and is then rotated into position to couple with an adjacent anchor; FIG. 36B demonstrates a multilevel embodiment of the alternative configuration provided in FIG. 36A.

[0051] FIG. 37 is a lateral view of a variation of the embodiment examined in FIGS. 36A and B.

[0052] FIG. 38 reveals a lateral view of an alternative embodiment portraying extensions arising from the anchors and coupled by a unique coupling element.

[0053] FIG. 39A displays lateral view of an anchor utilized in a multilevel embodiment of the variation shown in FIG. 38; FIG. 39B demonstrates an assembled multilevel construct of the same.

[0054] FIG. 40 is a lateral view of another alternative embodiment which is provided with threaded extensions arising from the anchors and a connecting element which is configured to couple with these extensions.

[0055] FIG. 41 shows a lateral view of the alternative embodiment in FIG. 40 coupling multiple laminar anchors.

[0056] FIG. 42 illustrates a lateral view of a further variation of the embodiment examined in FIG. 40.

[0057] FIG. 43 is a lateral view of an even further variation of an embodiment utilizing threaded extensions to couple the construct.

[0058] FIGS.44 A and B reveal a lateral view of an alternative embodiment with a very low profile.

[0059] FIG. 45 illustrates an embodiment of the bone anchor on a cervical lamina. This illustrates the operation where the anchor is applied to a cervical lamina from the superior position and demonstrates that a levering effect is asserted to that main body of the bone anchor through the transverse extension in application. This effect is even greater when the bone anchor is applied to the inferior orientation.

SUMMARY OF THE INVENTION

[0060] This written description uses examples to disclose the invention, including the best mode and also to enable any person skilled in the art to practice the invention, including making and using any devices or systems and performing any incorporated methods. The patentable scope of the invention is currently defined by the description of the invention and will be further defined by claims.

[0061] The principal object of the invention is to provide a unique, useful, novel and nonobvious device and method for use by which the device stabilizes the posterior aspect of a target cervical spinal motion segment, immobilizing the segment. This device shall hereinafter be known as the Cervical Minimally Invasive System (CMIS), as it is designed to be implanted using a minimally invasive surgical technique.

[0062] In the preferred embodiment, the CMIS shall be fabricated from surgical grade titanium. Alternatively, this CMIS can be fabricated from surgical grade stainless steel, or of alloys of any metal, including but not limited to cobalt, nickel, chromium, molybdenum, or of other materials including Nitinol, carbon fiber, polyesters or polyamides, ceramic, PEEK, organic materials such as bone, or any other material known to or proven to be acceptable to the art.

[0063] The preferred embodiment is comprised of anchors which are sequentially secured to the lateral laminae of one or more cervical target motion segments; connecting elements then couple these anchors to each other, stabilizing the construct and eliminating any micromotion. In the preferred embodiment and all alternative embodiments, these constructs would typically be secured bilaterally. Additionally, in all embodiments, the craniocaudal dimensions of the target motion segments can be adjusted by applying distraction or compression along the connecting elements.

[0064] In the preferred embodiment, these laminar anchors secure to the inferior or caudal aspect of the lateral lamina. As reviewed in the "Detailed Description of the Drawings" section below, these laminar anchors are composed of a sublaminar jaw and a dorsal jaw. The sublaminar jaw is provided with a thin plate-like leading end, which is designed to be insinuated beneath a target lamina, dorsal to the ligamentum flavum, and occupying minimal space so as to not threaten the spinal cord or other intra-canalicular neurologic structures. The dorsal jaw is brought against the posterior aspect of the target lamina. These jaws are irreversibly coupled to an axle which is positioned at the trailing end of the anchor, orthogonal to the long axis of the anchor; as an indirect result of this coupling to the axle, the jaws are effectively coupled to each other. This axle is part of the actuator that draws the jaws towards each other thus securing to the lamina. Similarly, if removal is desired, the jaws can be released, and the anchor removed from the bone.

[0065] These jaws are substantially hemi-ovoid in configuration, as viewed from the side; furthermore, the leading end of each jaw may be provided with a limited array of small, non-biting teeth which are configured to not penetrate the cortical bone, but merely provide increased friction against the target bony surface. Once the jaws are in position, a securing screw contained within the articulating mechanism at the trailing end of the anchor is tightened. This serves as the actuator compelling the two jaws towards each other. The anchors are then coupled to each

other with a connecting element. In the preferred embodiment, the securing screw which causes the jaws to be drawn together is provided with a leading end, which passes through the anterior jaw, a shaft that bridges both jaws, and a trailing end which is actuated by the surgeon. The trailing most end is provided with a vertical extension which is then continuous with a horizontal bar.

[0066] In the preferred embodiment, the connecting element is a rod-like embodiment in which the leading end is provided with a flattened area which in turn has a central elongated aperture. The leading end is continuous with a central shaft-like portion, which, in turn, is continuous with a trailing end which is provided with a saddle that is secured to the dorsal jaw. In the preferred and other embodiments, the leading end of the connecting element is disposed over this horizontal bar on the trailing end of the screw of the cranial anchor. The configuration of the connecting element, principally the elongated configuration of the central aperture at the leading end of the connecting element allows for either distraction or compression of the target motion segment.

[0067] A new embodiment comprises a design of a main body with a dorsal jaw, a plate like jaw with multiple teeth, a neck, and a first clamp with a threaded opening to accommodate a threaded actuator, and a second slotted opening orthogonal to the plane of the jaws. The slotted orthogonal allows for a slotted rod to be affixed that holds a U-shaped tulip with internal threading and a threaded fastener for holding a connecting rod that allows fixation of the movement of vertebrae.

DETAILED DESCRIPTION OF THE DRAWINGS

[0068] In the preferred embodiment, the CMIS shall be fabricated from surgical grade titanium. Alternatively, this CMIS can be fabricated from surgical grade stainless steel, or of alloys of any metal, including but not limited to cobalt, nickel, chromium, molybdenum, or of other materials including Nitinol, carbon fiber, polyesters or

polyamides, ceramic, PEEK, organic materials such as bone, or any other material known to or proven to be acceptable to the art. An embodiment is comprised of anchors which are sequentially secured to the lateral laminae of one or more cervical target motion segments; connecting elements then couple these anchors to each other, stabilizing the construct and eliminating any micromotion. In the preferred embodiment and all alternative embodiments, these constructs would typically be secured bilaterally. Additionally, in all embodiments, the craniocaudal dimensions of the target motion segments can be adjusted by applying distraction or compression along the connecting elements.

[0069] In the preferred embodiment, these laminar anchors secure to the inferior or caudal aspect of the lateral lamina. As reviewed in the "Detailed Description of the Drawings" section below, these laminar anchors are composed of a sublaminar jaw and a dorsal jaw. The sublaminar jaw is provided with a thin plate-like leading end, which is designed to be insinuated beneath a target lamina, dorsal to the ligamentum flavum, and occupying minimal space so as to not threaten the spinal cord or other intra-canalicular neurologic structures. The dorsal jaw is brought against the posterior aspect of the target lamina. These jaws are irreversibly coupled to an axle which is positioned at the trailing end of the anchor, orthogonal to the long axis of the anchor; as an indirect result of this coupling to the axle, the jaws are effectively coupled to each other. This axle is part of the is achieved by any number of the connecting elements illuminated in the foregoing disclosure.

[0070] The novel anchor allows for fixation to a laminar process of a vertebrae across the lamina from the back to the front without penetration of the bone of the lamina. This allows the bone anchor of the invention to be set and reset without damage to the bone which this then allows the system to be reconfigured both during the initial surgical process and thereafter.

[0071] A combination of the embodiments disclosed above can be considered. For instance, one configuration would be a connecting element which is provided

with an aperture at one end and an open-ended embodiment at the other. Such an embodiment disposes the securing screw of one anchor through the aperture, which is then locked; the open-ended configuration is positioned under the trailing end of the screw of the adjacent anchor prior to complete tightening of the screws.

[0072] It is, of course, understood that combinations of those various embodiments presented herein are conceivable and likely to be envisioned I anticipated by those skilled in the art. All such embodiments and variations, and derivations therefrom are all included within the spirit and scope of the invention.

[0073] The invention will be best understood if the reader is provided with a fundamental understanding of the pertinent osseous anatomy, and the relationships of various landmarks of the osseous anatomy to key soft tissue structures of the spine. These images are representations of the bony cervical spine, as the object of the invention is to secure to the target vertebra. This, however, recognizes that critical neural and soft tissue structures have not been included in these drawings and that despite their exclusion, these structures must be accounted for within the process of implantation of the invention. Although these soft tissue structures (with the exception of the intervertebral discs) are not illustrated herein, the images will, nevertheless, sufficiently demonstrate the relationships of critical soft tissues such as the spinal cord and nerves to the bony anatomy. When relevant, these structures will be referred to by name in these initial images.

[0074] The landmarks demonstrated on these images are crucial in implanting the CMIS. It is important to recognize that the cervical spine is the most common site for anatomic anomalies within the spinal column. Such anomalies must be identified and taken into account when surgery using the CMIS is planned. It is imperative to recognize that in certain instances such anomalies, once identified, could represent a relative I absolute contraindication to the use of the CMIS. Also, these images do not include musculotendinous, vascular, or neurologic structures,

all of which could be critical in terms of the indications or contraindications of the use of this device.

[0075] Therefore, turning to the anterior view of the osseous cervical spine 99 in FIG. 1, the seven bones, or vertebrae, named/numbered by convention as C1-C7 can be seen. For the illustrative purposes of this application, these will bear the numbers 100-106 corresponding to C1 100-C7 106. The unique anatomy of the C1-C2 100-101 complex can be, in part, appreciated in this view, and in association with the other views can be more completely understood. It is noted that unlike the other cervical vertebrae, C1 does not have an expanded anterior vertebral body. Moreover, an extension from the C2 vertebra, the Odontoid Process 107 (also known as the Dens), can be seen extending above the top of the anterior arch 166 of C1 100. The mechanism created by this unusual anatomic arrangement is best understood in the lateral and posterior views and is more completely elucidated in FIGS. 2 and 3 below. In addition, one also notes the bilateral transverse processes of C1 167, which provided with the foramina transversaria of C1 170, through which the vertebral artery is transmitted. The course of this important vascular structure is again best seen in FIG.3. The transverse processes 167 are then continuous with the superior facets 168, which are better seen in the posterior view I FIG. 3 below, and which articulate with the Condyles of the Occipital bone to create the Craniocervical junction (not demonstrated). This view demonstrates other features of the cervical spine, including the bilateral lateral masses of C1 114 through C7 120, and the bilateral transverse processes of C2 141, C3 142, C4 143, C5 144, C6 145 and C7 146. These transverse processes are provided with grooves which are best seen in the transaxial view in FIG. 4, these grooves configured to transmit the nerve roots exiting the central nervous system and being directed to the upper extremities. Another prominent feature which is best seen in this perspective are the anterior aspects of the intervertebral disc joints, with C2-3 (there is no C1-C2 disc joint) being enumerated as 149 and the C6-C7 space being enumerated as 153. The disc joints are obviously soft tissues structures but are included in these views because of the visual

continuity they provide, and because these structures are critically important as these are a major site of degenerative disease.

[0076] FIG. 2 is a right lateral view of the skeletonized cervical spine demonstrating additional features of the anatomy. It is to be recalled that this image is only demonstrating the right sided structures in the instances where bilaterality is present. In particular, one notes the curvature of the spine; this illustration shows an idealized curve, referred to as cervical lordosis, in which the cervical spine arches anteriorly between C1 and C7 with the point of maximum eccentricity at C4-5. Loss of this normal curvature, or, even worse, reversal of the curvature with the spine bending posteriorly—a condition known as "kyphosis," are components of pathologies that commonly affect the spine, and surgeons often will attempt to restore this curvature and in that way restore the "balance," of the cervical spine. Also seen well in this view is the expanded anterior vertebral body, which is present in all but the first cervical vertebra C1 100. This vertebra is more poetically known as the Atlas honoring the protagonist of the Greek Myth who holds up the world; in an analogous fashion, C1 holds up the "globe" of the head. In the embryonic stage, the C1 vertebral body is separated from the remainder of its bony ring and migrates caudally to join the top of C2 101 to become the Odontoid Process 107. The C2 101 is also, and actually more commonly known as the Axis, or the point around which the Atlas, and its "passenger," the head, pivot; the Odontoid Process 107 principally constitutes that bony pivot point. This provides the healthy individual with the rotational ability of the head on the neck. The vertebral bodies 108-113 can be seen, as well as the spinous process 128-134. It is further noted that at each level, the facet joints 135-140 represent the posterior articulation of the vertebrae with each other; it should be recognized that the superior facets of C1 168 articulate with the occipital condyles, thus contributing to the occipital-cervical junction, also referred to widely as the craniocervical junction (not illustrated.) It is further understood that the inferior aspect of the C7 106 contributes to the cervicothoracic junction (also not

illustrated). Additionally, the transverse processes 141-146 are seen projecting anterolaterally at C2-C7. In discussing FIG. 1 above, it has been mentioned that these transverse processes transmit the cervical nerve roots from the spinal cord, which is found in the central canal created by the anatomic arrangement of the vertebrae.

[0077] Further details are seen in FIG. 3, which is a posterior view of the osseous cervical spine 99. This Figure is important to note, as the pertinent anatomy for implantation of the CMIS is noted on this image. The first cervical vertebra, C1100 and the second cervical vertebra C2101, as illustrated above, are unique in their anatomic configuration. This has already been viewed from an anterior as well as a lateral perspective and discussed thereto, and the uniquely situated anatomy can be further appreciated from this perspective. However, in this image, one can appreciate more completely the relationship of the Odontoid Process 107 to the posterior aspect of the anterior arch 166 of C1 100. Furthermore, one can better appreciate the configuration of the bilateral superior facet joints 168 of C1 100, and the position of the foramina transversaria 170 within the transverse processes 167. Of C1. The vertebral arteries, critical to the circulation which irrigates the brainstem and cerebellum, pass through these foramina. Upon doing so, the arteries are directed posteriorly and then pass through a groove 171 along the superior edge of the C1 lamina 121 bilaterally before passing through the dura and onto their critical intracranial functions. The large spinous process 129 and laminae 122 of C2 are important landmarks for determining issues such as placement of incisions during cervical surgery. The remainder of the cervical vertebrae C3-C7 102-106 are largely similar in morphology in this view, including the spinous processes 130-134, laminae 123-127, the lateral masses 114-120, and the bilateral facet joints 135-140. One recognizes that the laminae 123-127 continue from the base of the spinous processes 130-134, at which point the laminae 123-127 are quite steep in the A-P dimension, but become more horizontal in their lateral aspects, just prior to continuing laterally and transitioning into the lateral masses 114-120.

At the transition point, it is noted, that the lateral masses 114-120 overhang each other (referred to as "shingling," refer to FIGS. 14- 16) which would make it most difficult to insert the laminar anchor. Therefore, in implanting the CMIS, the transition points of the laminae 123-127, such as the bilateral lateral C4 124 and C5 125 laminae are ideal for attachment of the CMIS 1.

[0078] FIG. 4, a transaxial view of a "typical" cervical vertebra (this would be very similar from C3 to C6), as viewed from the top perspective, allows the reader to further appreciate the relevant bony morphology as well its relationship to critical soft tissue structures. The C5 vertebra 104 is illustrated in FIG. 4, but the landmarks described are understood to reflect the anatomy of any of the C3-C6 vertebrae, and with little modification, C7 as well. Again, for orientation purposes, the patient's front is at the top of the page, and the back is at the bottom. The patient's right side would be located on the viewer's right side. The expanded vertebral body 111 can be recognized conceptually as the anterior stabilizing component. On the lateral aspects of the vertebral body 111 are seen the uncinate processes 158, which serve to strengthen the articulation with the vertebra located superiorly to this one. Still further lateral are found the transverse processes 154, which on this view can be noted to be more complex than one might anticipate based on the other views. The neural foramina, as denoted by the bilateral open arrows, are canals which transmit the cervical nerve roots. These arise from the [all important] spinal cord and proceed anterolaterally from the central canal 156 along the groove in the transverse processes 154 to exit into the soft tissues adjacent to the spine, ultimately contributing to the brachial plexus. Also noted is the Foramen Transversarium 159, which transmits the Vertebral artery. The positions of the Vertebral Artery and the nerve roots, in particular, subject a patient to significant risk with placement of lateral mass screws. The pedicle 157, which is in reality a component of the transverse process complex, serves to connect the anterior structures to the posterior arch, thus creating the central canal 156. The posterior arch is comprised of the lateral masses 118 which create the superior

and inferior facet joints for the vertebra being examined. Additionally, the laminae 125 and the midline spinous process 132 complete the posterior arch. The central canal 156 contains the spinal cord 175 (not shown in this view), responsible for the transmission of all information to and from the brain, and whose integrity is mandatory for loco- motion and many essential functions, is the most critical structure which must be considered with the implantation of any surgical instrumentation into this area of the spine. Additionally, injuries to the vertebral artery or nerve roots must also be avoided as they carry with them substantial deleterious consequences. This view is particularly helpful in showing that the laminae 125 arise from the base of the spinous process 132, and initially assume a rather steep angle in the A-P plane as they move laterally. They then become more horizontal as they continue laterally to become the lateral masses 118. The ideal place for implantation of the laminar anchor is at the transition point, as this is lateral from the spinal cord 175. Such positioning is slightly medial to the lateral masses, where shingling would exclude the possibility of implantation. This ideal position is just slightly less than halfway between the midline and the lateral most edge of the spine, as seen in the posterior view.

[0079] This review isn't merely an academic exercise. Rather, it permits one to more completely understand the main and other objectives of the invention and view the invention and its objectives in the proper perspective. Having completed the review, the anatomic terms defined therein will be utilized for the balance of the disclosure.

DETAILED DESCRIPTION OF THE DRAWINGS DEMONSTRATING THE INVENTION

[0080] The invention is best understood by studying the following detailed descriptions in conjunction with the context of the accompanying images, wherein like reference numbers refer to like structures, in accordance with common practice. Also, in accordance with common practice, the structures illustrated are

not necessarily drawn to scale, nor can inferences of scale be developed with respect to such drawings. The embodiments presented and illustrations herein are general representations of the invention and are not nor can they be construed to be restrictive.

[0081] Therefore, in turning attention to FIG. 5, which demonstrates a lateral perspective of the preferred embodiment of the Laminar anchor 2, which consists of a minimum of two primary components: an anterior or sublaminar jaw component 4 and a posterior or dorsal jaw component 5. Each jaw is provided with a free end 10, 12, which, in the preferred embodiment, are positioned at the superior I cranial end of the anchor 2; additionally, the two jaws are coupled at the articulating ends 11, 13 located at the inferior I caudal aspect of the anchor 2. This coupling is accomplished in part by the complementary geometry of the articulating ends, which allows the articulating ends 11, 13 to mate with each other. Furthermore, an articulating axle 18 secures this irreversible coupling of two jaws 4, 5. Each jaw is further characterized by a side which is brought against the surface of the lamina, namely the laminar side 14, 15 of the sublaminar jaw 4, and dorsal laminar jaw 5. In addition, the free side of the sublaminar jaw 4 faces the spinal canal proper and therefore is known as the canalicular side 16, while the dorsal laminar jaw 5 is provided with the muscular side 17. Small teeth 21,22 are provided to the laminar sides 14, 15 along their free ends 10, 12. These teeth have blunted, rounded leading ends specifically designed to not penetrate the surface of the bone, but rather are designed to simply increase the surface area and create friction, thus providing greater hold. A tightening screw 6 serves as the actuator to secure the jaws 4, 5 to a target lamina. In the preferred embodiment, the screw 6 is disposed from the muscular side 17 of the articulating end 13 of the posterior jaw 5, transmitting through tract 7 in the articulating ends 11, 13 of the jaws 4, 5, through the coupling of the two jaws 4, 5 and into the articulating end 11 of the anterior jaw 4. The leading most end 19 of the screw can be seen along the canalicular side of the sublaminar jaw 4. The head 8 of this screw 6 is positioned within a threaded groove

9 at the dorsal aspect of the tract 7, with threading 20 of course being present throughout the tract 7. Another feature noted at the head, or trailing end 8 of the screw 6 is a monolithic dorsal extension 30 from the most posterior aspect of the screw. This dorsal extension 30 then terminates in a bar, known as the locking bar 31, which is continuous and monolithic with the dorsal extension 30. These structures serve to lock the connecting element 3 in place.

[0082] The anchor 2 is secured to the target lamina as shown in FIG. 6, a hemisected, non-midline sagittal view. The anterior 4 (stippled) and posterior 5 (striped) jaws are secured against an exemplary target lamina 125 of the C5 vertebra. It is critical to recognize that the thin dimensions of the anterior jaw 4, in combination with its somewhat angled position relative to the orientation of the lamina 125, infinitely reduces the chances of any incursion into the spinal canal 156 by the sublaminar jaw 4. This is further reduced by the technique utilized, and one can see that the spinal cord 175 [the most critical structure in this area under consideration], should not be intruded upon or disturbed in any manner. Upon placement of the anchor against the lamina, the screw 6 is tightened, compelling the jaws 4, 5 towards each other, securing the anchor 2 onto the lamina 125. This provides the system with the required strength of attachment. Again, it is noted that the teeth 21, 22 on jaws 4, 5 are just brought against the surfaces of the bone, but are not penetrating the cortical bone per se. Also noted anteriorly is the vertebral body 111 of C5 104 vertebra. It is recognized that in addition to the preferred embodiments described herein, other, similar embodiments will be obvious, especially to those skilled in the art. Such embodiments would include embodiments in which the anchor 2 would be secured to the superior rather than the inferior aspect of any lamina, which would then change the configuration of the jaw components 4, 5. All such embodiments would, of course, be within the spirit and scope of this application.

[0083] An elevational perspective of the connecting element 3 which couples the anchors is seen in FIG. 7. Here it can be seen that in the preferred embodiment, this element 3 is monolithic and comprised of a cranial end 74, a shaft-like central portion 76, and a trailing end 77. The element 3 is coupled with the posterior jaw of the caudal anchor through a locking mechanism in the trailing end 77. This is accomplished by providing a housing mechanism 78 which is continuous and monolithic with the trailing most end of the connecting element 3. This mechanism 78, and in turn the connecting element itself, can be brought against the muscular aspect of the dorsal jaw. Furthermore, this mechanism 78 gives rise to and is monolithic with a clamping arm 81 which extends anteriorly and has an internal surface 82 configured to oppose the side of the dorsal jaw. A movable component 79 is provided with a horizontal component 85 that is slidably coupled with the housing mechanism 78, specifically by passing through a substantially rectangular aperture 84 which is then continuous with a chamber 87 which has been provided to the dorsalmost aspect of the housing mechanism 78. This horizontal component 85 is then continuous and monolithic with a clamping arm 83, again with an internal surface 86 configured to be brought against the anchor which extends anteriorly along the opposite side of the dorsal jaw from the fixed clamp 81. These two clamping arms 81, 83 are displaced towards each other, and the dorsal jaw is secured between them, coupling the connecting element 3 to the anchor. On the dorsalmost aspect of the housing mechanism 78 is a tract 89 that accepts a securing screw, 88, which will lock the connecting element 3 onto the desired position on the jaw 5 of the anchor 2. This would be determined by the distance between the cranial and caudal anchors and coupling the connecting element 3 to the cranial anchor. This is accomplished by the configuration of the leading end 74, which demonstrates a unique area which is flattened, in the preferred embodiment is substantially rectangular but can be of any configuration and is provided with an aperture 75. The coupling is accomplished by disposing the aperture 75 over the locking bar 31 and rotating the screw; hence, the leading end

74 of the connecting element 3 will be secured simultaneously while the jaws 4, 5 are secured to the lamina.

[0084] In an optional variation, this connecting element can be divided into two halves throughout its length, so as to be configured to function as an actuator which can expand or contract the dimensions of the aperture at the leading end of this connecting element. Alternatively, in any of the embodiments, the connecting element may also be constructed of a cranial and caudal segment coupled by a separate element which can modulate the craniocaudal length of the connecting element, thus accounting for variances in this dimension.

[0085] Figure 8 shows a three quarters perspective view from above an embodiment bone anchor 811 of the cervical spinal fixation system of the present invention. The bone anchor has a main body 812 that has a lower sub-laminar jaw 813. The sub-laminar jaw has a leading end 814 that extends to a shoulder 815. The leading end has a wedge-shaped chin 816 and a plurality of teeth 817 that extend across or transverse the sub-laminar jaw and form friction zone for creating friction with a spinal lamina. The main body continues past the shoulder and rises to a neck 818 that connects to an upper body 819 with a first clamp ring 820 and a facing clamp ring 821 where the first clamp ring rests above the teeth of the sub-laminar jaw. The second clamp ring 821 sets above the first clamp ring and both are connected by upper jaw extensions 822, 823 and to the upper body. The first ring clamps has a threaded interior bore portion, 824 whereas the second ring clamp has an unthreaded bore 825 that aligns with the threaded bore of the first ring clamp. The two ring clamp bores may align with or slightly to the front of the sub-laminar jaw's chin.

[0086] The upper body further has a transverse bore 826 which has at least one ridge 827 on its interior surface that can hold a transverse sliding extension 828. The transverse sliding extension 829 extends beyond one side of the main body to allow fixturing of a connecting rod between at least two of said bone anchors disposed on adjacent cervical vertebrae lamina.

[0087] Figure 9 shows three quarters view of the bone anchor from a below view. The first and second clamps rings 820, 821 shown in Figure 9 have a threaded activation bolt 830 with an upper end 831 and a lower end 832. The upper end has an internal driving fixture in the form of a multitooth driver insert 832. The lower end of the threaded activation bolt has a hinged rotatable dorsal jaw with at least one 833 tooth 833 that has a textured lower tooth face 834.

[0088] Figure 9 shows that the transverse sliding extension extends transversely from the plane of the main body holding the jaws and has affixed on the end a U-shaped tulip fixture 835. The U-shaped tulip fixture has an interior slot with curved sides 836, 837 that are threaded on either side of the U-shaped bore indent 838.

[0089] The bone anchor has a tightening clamp for fixing the activation of the dorsal jaw tooth and tightening the transverse extension rod into a fixed position and angle of extension from the bone anchor body.

[0090] The design of the bone anchor is driven by the need to anchor to the lamina of a vertebrae. Since, lamina vary in thickness across the spine it is anticipated that the distance between the two jaws of the design will need to vary as well. Figure 10 shows three variations 840, 841 and 842 with varying neck lengths dimensioned to fit in this case different cervical lamina.

[0091] The dimension between the top surface of the sub-laminar jaw and the bottom of the dorsal tooth should be in the range of 4 to 11 mm for cervical lamina.

[0092] Figure 11 shows a three-quarters view of the bone anchor. The transverse extension with a u-shaped tulip fixture that can fixture a connecting rod in the cradle of the U-shaped tulip bore by screwing in a barrel tightener with a threaded exterior that complements the tulip threading. The barrel tightener as it is screwed into the U-shaped tulip applies pressure to a rod and drives it into the bottom of the U-shaped opening. The barrel tightener has an opening on the top that engages with a torque tool tip and rotates the barrel tightener so that it can be tightened or opened.

[0093] The dorsal tooth actuator has a hinged connection 838 to the dorsal jaw and as it is rotated through the driver indent in the top of the actuator, the dorsal jaw can be tightened or loosened. When the dorsal jaw is properly in contact with the lamina, and sufficient pressure is applied across the lamina between the sublaminar jaw and the dorsal jaw, a setting nut 839 can be tightened to secure the bone anchor grip on the lamina bone, and to set the transverse extension in place.

[0094] The main body of the clamp provides ridges and indentation that can be used to cooperate with a placement tool that allows placement of the sublaminar jaw under the lamina and then slight torquing of the sublaminar jaw against the sublaminar portion of said lamina while the dorsal jaw is activated to grip the lamina prior to fixation of the transverse extension into position.

[0095] Figure 12 shows the front level view of an embodiment of the bone anchor. This illustrates the threaded actuator traversing through the threaded ring clamp and the upper unthreaded ring clamp, and the upper tightener bolt that will draw the ring clamps together and fix the transverse extension in place.

[0096] Figure 13 shows the back level view of an embodiment of the bone anchor. And illustrates the ridge 840 and indentations 841, 842 that cooperates with a placement and fixation tool.

[0097] Figure 14 shows the bone anchor from above and illustrates the threaded actuator driver socket on the upper portion of the threaded actuator. It also shows the threaded interior portion of the U-shaped rod bearer and the collet between the threaded interior surfaces.

[0098] Figure 15 shows the bottom view of the bone anchor illustrating how the dorsal jaw tooth projects forward from the sublaminar jaw.

[0099] Figure 16 illustrates a system with multiple bone anchors connected with rods to fixate a portion of a movement sector of a cervical spine.

[00100] So the present invention is a nonintrusive bone clamp for stabilizing cervical vertebrae comprising: a J-shaped sublaminar jaw with a first leading end and a second anterior end, a neck portion and an upper body portion wherein said sublaminar first leading end has a relatively thin plate portion; A dorsal jaw; and means for pivotally coupling said sublaminar jaw and said dorsal jaw; and means for securing screw that connects to said sublaminar jaw and said dorsal jaw where the sublaminar jaw can be substantially hemi-ovoid in configuration and said dorsal jaw is substantially hemi-ovoid in configuration.

[00101] The non-intrusive bone clamp of claim 3 wherein said sublaminar jaw has an interior surface and an exterior surface and where said interior surface has a plurality of teeth disposed thereon and where the interior surface is configured to complement the surface of a first target cervical lamina by having said dorsal jaw has an interior surface and an exterior surface and where said interior surface has a plurality of teeth disposed thereon and where the interior surface is configured to complement the surface of a first target cervical lamina.

[00102] The present invention is also a noninvasive system for stabilizing cervical vertebrae comprising: A first non-invasive bone clamp with a sublaminar jaw with a first leading end and a second anterior end wherein said sublaminar first leading end has a relatively thin plate portion; a dorsal jaw; and means for pivotally coupling said sublaminar jaw and said dorsal jaw; and means for a securing screw that connects to said sublaminar jaw and said dorsal jaw; a second non-invasive bone clamp; and a connecting element which connects said first bone clamp to said second bone clamp. The non-invasive system for stabilizing cervical vertebrae of claim 6 where said sublaminar jaws of said first and second bone clamp are substantially hemi-ovoid in configuration. The non-invasive bone clamp of claim 3 wherein said sublaminar jaw has an interior surface and an exterior surface and where said interior surface has a plurality of teeth disposed thereon and where the interior surface is configured to complement the surface of a first target cervical

lamina. The interior surface has a plurality of teeth disposed thereon and where the interior surface is configured to complement the surface a first target cervical lamina.

[00103] Another embodiment of the invention is a bone anchor for attachment to vertebral processes comprising: a main body which has a lower fixed jaw ; a connecting portion to said lower fixed jaw, a bore hole providing basis for an axis from one side of said connecting portion to the other, and a threaded two ring clamp where each ring has an inner threaded surface with a threaded axis; A n externally threaded shaft with a first and second end, where said first end has an internal torquing indent and a portion adjacent thereto for a locking mechanism to engage the outer portion of the clamping ring and said first end has a fixation protuberance; An upper jaw that cooperates with said externally threaded shaft and engages bone between said upper jaw and said lower fixed jaw forming a diagonal across a clamped bone body; An inter-anchor connector comprising an axis with a first connector end and a second connector end where said first connector end has a rod portion and said second end has a tulip rod fixer portion.

[00104] The anchor of may also have an upper dorsal jaw is in the form of a disk with a first side and a second side and said second disk side has a texture to engage a bony surface and said second disk side has a central ball socket and a means to allow insertion of a ball formed as the protuberance on said externally threaded shaft.

[00105] In another embodiment, the anchor where the ball socket and ball form a pivoting connection between the dorsal jaw and a threaded activator. The internal torquing indent of said threaded shaft can be attachably linked to a torque shaft.

[00106] The anchor of claim 4 wherein said main body has two side profiles wherein said first side profile and said second side profile have profiles that can be held by a constricting tool to allow placement of said anchor above and below a bone body.

[00107] Th relative lengths of the sublaminar jaw and the dorsal jaw are critical to the effectiveness of the bone anchor to nonintrusive hold the bone and be as effective as

the state art bone screws. By have unequal lengths from the neck portion of the main bone anchor body. The body has a plurality of teeth located at a position that is farther from said connection portion of said main body than the upper jaw attached to said externally threaded shaft. The depth of the distance from the back of the jaw to the lower jaw, and the length from the back of the jaw to the upper jaw is not equal. For instance, the bone anchor of lower jaw portion may have at least three teeth arranged orthogonally from a plane formed by a main plane of the main body.

[00108] A further embodiment of the bone anchor comprising a main body with a fixed j shaped lower jaw with a plurality of teeth, a connecting body portion joining said lower jaw and a locking mechanism extension forward of said connecting body portion. A hinged upper jaw attached to said connecting body portion, a threaded activator and clamp.

[00109] In a variation the fixed lower jaw attached to a connecting body and an upper threaded jaw extension, and upper jaw disposed upon a threaded jaw tightener disposed in the threaded portion of said upper threaded jaw extension.

[00110] The dorsal jaw extends in front of the sublaminar jaw, and when the transverse extension is fixed to a rod, the grip between the sublaminar jaw and the dorsal jaw is brought under a pivot action that further secures the grip between the two jaws. Although the jaws can be arranged so that the sub-laminar jaw is longer than the dorsal jaw. The effective variable is that there is the possibility that there is some leverage created by the connector between the connection means that links the separate bone anchors when disposed on a vertebrae.

[00111] The embodiment of FIG. 1 illustrates the axis of the threaded activator connecting the round dorsal jaw with the single tooth forms an axis that is not at 90 degrees with the sublaminar jaw. In the drawing it this axis is less than 90 degrees relative to the neck of the bone anchor, and the axis extends slightly in front of the teeth placed on the surface of the sub-laminar jaw.

[00112] The dorsal jaw extends in front of the sublaminar jaw, and when the transverse extension is fixed to a rod, the grip between the sublaminar jaw and the dorsal jaw is brought under a lever action that further secures the grip between the two jaws.

[00113] The dorsal jaw extends in front of the sublaminar jaw, and when the transverse extension is fixed to a rod, the grip between the sublaminar jaw and the dorsal jaw is brought under a pivot action that further secures the grip between the two jaws.

[00114] The A system fixes at least two cervical lamina in their movement relative to one another comprising a first non-intrusive lamina anchor and a second non-intrusive lamina anchor, where each of said non-intrusive lamina anchor have a bone anchor for attachment to vertebral processes with a main body which has a lower fixed jaw; a connecting portion to said lower fixed jaw a hole providing basis for an axis from one side of said connecting portion to the other, and a threaded two ring clamp where each ring has an inner threaded surface with a threaded axis.

[00115] An externally threaded shaft with a first and second end, where said first end has an internal torquing indent and a portion adjacent thereto for a locking mechanism to engage the outer portion of the clamping ring and said first end has a fixation protuberance; an upper jaw that cooperates with said externally threaded shaft and engages bone between said upper jaw and said lower fixed jaw forming a diagonal across a clamped bone body.; An inter-anchor connector comprising an axis with a first connector end and a second connector end where said first connector end has a rod portion and said second end has a tulip rod fixer portion and said upper jaw is in the form of a disk with a first side and a second side and said second disk side has a texture to engage a bony surface and said second disk side has a central ball socket and a means to allow insertion of a ball formed as the protuberance on said externally threaded shaft.

[00116] FIG. 16 illustrates the system in place on a cervical vertebra. This particular embodiment of the invention is a system fixating a two segment section of movement and employs six bone anchors 844, 845, 846, 847, 848, and 849, placed on lamina of

three vertebrae. One bone anchor is placed on each lamina of the vertebrae and has the transverse rod fixturing hardware disposed on the outwardly from the spine. In this system embodiment each side of the fixture connects to a single rod 850. In sum, the system employs six bone anchors and two connecting rods.

[00117] A significant advantage with the use of this system is that each of the bone anchors is placed separately. Each bone anchor placement can be adjusted to allow and which can be re-adjusted in position, both the actual anchor placement and the placement of the rod holder extension since the transverse extension can be adjusted in offset and angle.

[00118] FIG. 45 illustrates an embodiment of the bone anchor on a cervical lamina. This illustrates the operation where the anchor is applied to a cervical lamina from the superior position and demonstrates that a levering effect is asserted to that main body of the bone anchor through the transverse extension in application. This effect is even greater when the bone anchor is applied to the inferior orientation.

[00119] The system is placed in the following steps. 1. A bone anchor mounted on a placement tool that includes a gripping section that is either activated, or is friction fitted to the bone anchor through indents and/or ridges is provided. 2. The bone anchor tool is lowered so the leading edge of the sublaminar jaw is beneath the target lamina, the lamina is slid beneath the lamina by moving the bone placement tool, with the bone anchor forward until the desired position is reached, 3. The threaded jaw activator is turned until the dorsal jaw contacts the upper surface of the target lamina site and torqued to 8-to-12-foot pounds. The activator driver may be included in the bone anchor placement tool. Step 3 is reversible but each of the desired bone anchors are placed and the transverse extension with the U- shaped tulip collets are arranged in position. 5. is placement of the connecting rod, which is either preformed, straight or curved. Placement of the rods followed by further adjustment of the tulip extenders and then tightening of the ring bolt tightener.

[00120] Each of the steps in the process can be re-done to allow for further adjustment allowing the fixation to be adjusted during the process to affect a specific spinal fixation result.

[00121] In the preferred and most alternative embodiments disclosed herein, this unique, useful, novel, and nonobvious system for stabilizing the cervical spine is secured to the target motion segment by implanting bilateral laminar anchors and coupling these with a connecting element. To achieve these ends, a device known hereinafter as the implantation instrument 44 undertakes multiple functions, including directing the anchor into the ideal position against the lamina, tightening the securing screw, and coupling the connecting element to the anchor. This instrument is disclosed in FIG. 19, a posterior elevational view of the instrument 44, and FIG. 20, an elevational, exploded view. Although FIG. 19 reveals that this instrument 44 is provided with an overall leading end 45, central shaft 46 and trailing end 47, further scrutiny demonstrates that this is a complex instrument 44 provided with a central trocar 48, an inner cannula 49 and an external cannula 50. This external cannula 50 also has a leading end 52, a central shaft 53, and a trailing end 54, with the leading end 52 provided with two additional features critical to achieving the goals of the invention: firstly, a cutaway 51 through which the connecting element is disposed in order to couple with the anchor being implanted; secondly, medial 55 and lateral 56 grasping arms are present to achieve the primary task of the instrument 44, that is to stabilize the laminar anchor during implantation. To this end, the laminar anchor can be "pressure fit," between them, and held in place during implantation. In FIG. 19, it is noted that the interior surface of the medial grasping arm 55 is contoured to accommodate the posterior jaw of the laminar anchor. When the screw of the anchor is tightened, driving the jaws of the anchor towards one another, the overall profile of the anchor is reduced thus relaxing the pressure fit. Once the anchor is securely attached to the target lamina, the instrument 44 is removed leaving the anchor in its desired position. In the preferred embodiment, the grasping arms 55, 56 are configured to hold the anchor at a bias (as demonstrated in FIGS. 19 and 20) consistent with the angle of the lamina, thus making implantation

more efficient. Other, more mechanically complex embodiments to hold the anchor in place can be contrived and anticipated by those knowledgeable in the art; all such embodiments would be within the spirit and scope of this invention.

[00122] The anchor is attached to the lamina by tightening the securing screw, which compels the jaws towards each other, grasping the lamina between them. In the preferred embodiment, this is accomplished by tightening the horizontal bar at the trailing most end of the screw; it can also be accomplished by providing the perimeter of the trailing end of the screw with a configuration such as a hexagonal profile on top view which can be rotated by a wrench. Obviously, combinations of these techniques can also be envisioned. This function of the implantation instrument 44 is accomplished by the central trocar 48 pictured in FIG. 20, an exploded view of the implantation instrument 44, which shows the central trocar 48 is provided with a leading end 66 configured to engage the horizontal bar, a shaft 67, and a trailing end/handle 68. The leading end 66 is disposed through a central channel 43 of the inner cannula 49, as indicated by the small, closed arrow, positioning the leading end 66 to engage the horizontal bar. Once the anchor is positioned against the lamina, the trailing end 68 of the trocar 48 is actuated, turning the leading end 66 tightening the screw. This will cause the jaws to move towards each other and create a secure grasp on the target lamina A sequence of thresholds within the instrument will create a first and second sound; with the first audible sound, the horizontal bar will be oriented in a generally craniocaudal direction, and ideally positioned for engaging the leading end of the connecting element. With engagement of that leading end, the horizontal bar is rotated another approximately 90°, and a second audible indicator is heard assuring the system is locked. Indicating the position of the horizontal bar can also be achieved by external markers on the cannula. In fact, those knowledgeable in the art can anticipate other and different systems for accomplishing this goal; all such embodiments are incorporated within the spirit and scope of this invention.

[00123] The implantation instrument 44 also captures the leading end of the connecting element and secures it to the trailing end of the securing screw. This is achieved by the inner cannula 49, which is also provided with a leading end 69, a shaft component 70, and a trailing end 71, also seen in FIG. 20. This cannula 49 is positioned within the outer cannula 50 in the assembled instrument 44, as indicated by the larger open arrow, with the leading end 69 dorsal to the cutaway 51 of the external cannula 50. This leading end 69 is configured to capture the flattened leading end of the connecting element and reposition it so that the horizontal bar can be disposed through the aperture in the leading end, that bar then rotated to cinch the connecting element into place, as will be demonstrated in FIG. 22.

[00124] FIG. 21 is a lateral elevational view of the left side of a posterior cervical motion segment demonstrating the implantation instrument 44 positioning a cranial laminar anchor 2. The anchor 2 is reversibly coupled with a slight anterior bias to the grasping arms 55, 56 of the leading end 45, aligning the anchor favorably with the bias of the target lamina, being introduced along its caudal aspect. The sub-laminar jaw 4 is insinuated beneath the lamina, in preparation for securing the jaws 4, 5 in place in the fashion described above in paragraph 152. The trailing end 68 of the central trocar 48 will be used to actuate the securing of the screw which locks the anchor 2 in position.

[00125] The caudal anchor 2a is then secured to the caudal lamina CDL LAM in the same fashion. The connecting element 3 (shown as an interrupted line outline) then couples the two anchors 2, 2a to form a right sided CMIS 1 construct, as shown in a posterior view in FIG. 22A. Upon passing the caudal anchor 2a into position, the securing screw 6a was tightened and the implantation instrument was removed. At that point, the housing mechanism 78 of the connecting element 3, which is slidably connected to the dorsal jaw Sa of the caudal anchor 2a, can be translated in a craniocaudal direction so as to accommodate passing the leading end 74 of the connecting element 3 through the cutaway 51 of the external cannula 50 of the implantation instrument 44 which has implanted the cranial anchor 2. Once the leading

end 74 is in ideal position, the surgeon may adjust the craniocaudal dimension by compression or distraction; then the securing screw 88 of the housing mechanism 78 of the connecting element 3 is locked, securing the connecting element 3 in position.

[00126] The next and final step necessary is to secure the connecting element 3 in position. This is illustrated in FIG. 22B, which is an enlarged view of the CMIS 1 shown in FIG. 22A; the enlargement permits a better illustration of the mechanism by which the leading end 74 of the connecting element 3 is captured and secured to the cranial anchor 2. In the preferred embodiment, the connecting element 3 is slidably coupled to the posterior jaw Sa of the caudal anchor 2a. This is accomplished, in the preferred embodiment, by providing a housing mechanism 78 which is a clamping mechanism actuated by the movable element 79 of this housing mechanism, which together form two clamping arms which are passed around the dorsal jaw Sa. Once the leading end 74 of the connecting element has been slid into the desired position, a securing screw 88 is tightened maintaining the position of the connecting element 3. The leading end 74 of the connecting element, which has been provided with an aperture 75 (shown in an outline of interrupted lines and solid circles) has been passed through the cutaway 51 of the implantation instrument 44 and is now positioned so that the aperture 75 can be disposed over the trailing end 8 of the securing screw 6 within the anchor. The inner cannula 49 within the instrument 44 can then be actuated by manually pushing its trailing end 71, which causes its bifurcated leading end 69 to push the leading end 74 anteriorly, disposing the aperture 75 over the horizontal bar 31 at the trailing end 8 of the screw 6; at that point, the trailing end 68 of the central trocar is actuated. I manually rotated, causing the leading end 66 of the trocar 48 to engage the horizontal bar 31 which is consequently rotated until the bar locks the leading end 74 of the connecting element 3 into position. Please note that the connecting element 3 is shown as an interrupted line outline to elucidate other structures contributing to the locking mechanism of the cranial anchor. Furthermore, the leading end of the dorsal jaw 5 of the cranial anchor is shown as a double interrupted line, distinguishing it from the other structures. Implantation is then considered complete. It should be appreciated that with

modifications contingent upon the specific embodiments, the implantation technique described in this, and the several previous drawings represents essentially the technique which would be utilized in all of the subsequent embodiments which have been disclosed and are illustrated in the drawings below.

[00127] FIG. 23 is a posterior view showing the preferred embodiment of a right sided CMIS 1 linking two adjacent laminar anchors and stabilizing a target motion segment. The patient is in the prone position. The retractor 230 illustrated in Paragraphs 142-149 maintains exposure, with the top of the page representing the top of the surgical field, and the patient's right side on the right side of the page. The dorsal jaw 5 of the cranial anchor 2 is at the top of the CMIS 1, with the cranial rim of the cranial lamina CR LAM seen above the superior edge of the jaw 5. In this preferred embodiment, the cranial anchor 2 does not require an associated connecting element. The horizontal bar 31 at the trailing end of the screw can be seen in a transverse position, with the edges of the bar capturing the leading end 74 of the connecting element 3, which extends caudally to couple with the caudal anchor 2a at the trailing end 77 of the connecting element 3. Again, the dorsal jaw 5a of that anchor 2a is seen, along with the horizontal bar 31 at the trailing end of the securing screw 6, which locked the anchor 2a to the caudal edge of the caudal lamina CDL LAM. The sublaminar jaws 4, 4a have been passed anterior to the respective laminae.

[00128] A multilevel construct is also anticipated. FIG. 24 reveals another level laminar anchor 2b has been implanted onto the caudal vertebra of the original construct, shown again in a posterior view. The construct 1 is most easily extended by adding to the caudal end. When doing so, the connecting element 3a of the additional anchor 2b is coupled with the most caudal anchor 2a within the existing construct. Again it is noted that at each level, the aperture 75, 75a in the leading ends 74, 74a of the connecting elements 3, 3a are disposed over the horizontal bars 31, 31a at the trailing end of the securing screws at each level (6b is the only screw that can be seen in this projection); specifically, the configurations of the apertures 75, 75a are such that the horizontal bars

31, 31a can be disposed through the long axes of their apertures, but when the screws are rotated so that the horizontal bars 31, 31a are oriented orthogonal to the long axis of the apertures 75, 75a, the ends of the horizontal bars 31, 31a will overhang the sides of the leading ends 74, 74a of the connecting elements 3, 3a.

[00129] FIG. 25 shows an alternative embodiment of the connecting element 23, specifically the trailing end thereof. It is recalled that in the preferred embodiment, this trailing end is a clamp-like configuration that couples with the dorsal jaw of the caudal anchor of a construct; the leading end of the preferred embodiment is a flattened segment with a central aperture. In this alternative embodiment, the connecting element 23 is provided with "mirror image," terminal segments 41, 42, each of which is configured to be flattened segments provided with apertures (not seen in this view), identical to the leading end in the preferred embodiment. Once the anchors 2, 2a are secured, the connecting element 23 is positioned so that the horizontal bars 31, 31a are disposed through the apertures and rotated, locking the construct against the dorsal jaws 5, 5a. When a lordotic curve is provided to the connecting element, such as in the image herein, the trailing end 5a of the securing screw 6a may be modified as illustrated to accommodate the trailing end 42 of the element 23.

[00130] The alternative connecting element 23 disclosed in FIG. 25 can be utilized with an alternative embodiment of the trailing ends of the securing screws 6, 6a, as demonstrated in a lateral view in FIG. 26. As such, these screws 6, 6a do not have the vertical extensions or horizontal bars seen in the preferred embodiment; rather, they terminate in a classical "screw head," embodiment 24. In this embodiment, the screws have been passed through both apertures in the terminal ends 41, 42 of the connecting element 23 prior to implantation—often referred to as "pre-loaded"—which mandates that the anchors 2, 2a must be implanted as a unit. Furthermore, it is readily apparent that those skilled in the art could anticipate another modification, in which the heads of the screws would be modified thus permitting the trailing ends of the connecting element to be disposed over the trailing ends of the screws, or other embodiments and relationships

between the trailing ends of the screws and the connecting element. All such modifications can be anticipated herein, are in keeping with the Spirit and Scope of the Invention, and of course would be included within this application.

[00131] FIG. 27 is an elevational view illustrating an alternative embodiment of the laminar anchor [2z in FIG. 28] in which a sphere 32 arises from the dorsal surface 17z of the cranial aspect 12z of the dorsal jaw this sphere 32 is irreversibly and rotatably coupled with a cradle 18, which in turn houses a connecting element (seen in FIG. 28) that couples this anchor 2z to the more cranial anchor. A hemi- sphere could also be anticipated in such an embodiment. This cradle 18 is a monolithic structure with a leading end 35 that encases the sphere 32, an articulation that confers upon the cradle 18 polyaxial movement, as indicated by the open arrows. Such movement permits reconciliation of slight changes in alignment of the anchors resulting from subtle anatomic variations after attachment to the adjacent laminae.

[00132] The cradle 18 is provided with a central channel 37 which has a base 26, a lateral wall 27 and a medial wall 28. This channel 37 houses an alternative embodiment of the connecting element 25, which is positioned for deployment within the cradle 18 at the time of implantation. One notes that the dorsalmost aspect of the cradle 18 is coupled with a screwcap 29. The interior surfaces 33, 34 of the dorsal- most aspects of the channel 37 are provided with threading (partially shown in relief); the leading end 36 of the screw- cap 29 is also threaded, and with satisfactory positioning of the connecting element 25, the screwcap 29 is deployed, securing the connecting element 25 in position.

[00133] It is again recognized that variations of these embodiments which maintain the spirit and scope of the invention can be envisioned. Such embodiments might include placing the threading disclosed above on the outside or exterior surfaces of the cradle rather than on the interior surfaces, which is then deployed by the use of a nut. In another embodiment, the walls of the cradle would be continuous with each other at the dorsalmost aspect of the cradle thus providing greater security to a central locking screw which would be disposed through this monolithic aspect of the cradle.

[00134] As viewed from the lateral perspective in FIG. 28, the connecting element 25 is contained within the cradle 18 at the time of the implantation. This element 25 may either be straight or [preferably] is provided with a slight lordotic curve, as demonstrated. Although this Figure demonstrates a lateral perspective, the connecting element 25 is rotated to demonstrate its unique configuration. One notes the components of the connecting element 25 including a leading end 39 which is substantially identical with that of the preferred embodiment disclosed in FIGS. 7, 8 above inasmuch that the current embodiment is also characterized by a flattened configuration which is ideally rectangular, but of course may be of any geometric configuration. This is, in turn, provided with a central aperture 40, which again is ideally a recapitulation of the same shape as the leading end 39 itself, but may be of any configuration. The aperture 40 is a critical component of the locking mechanism which secures the laminar anchors to each other, just as described in the preferred embodiment. In the ideal embodiment, the cross-section of the connecting element 25 is expected to be round so that it may easily disposed through the cradle 18, but any other geometric configuration is within the spirit and scope of the invention. Upon securing the caudal laminar anchor 2z to its target lamina, the connecting element 25 is advanced from its original position until its leading end 39 is secured to the anchor 2 at the superior level. The trailing end 37 of the connecting element 25 is slightly enlarged to serve as a stop on advancing the connecting element 25 inadvertently out of the cradle 18. Also seen in this image is the anterior jaw 4z, the coupling axle 72z, the securing screw 6z, and the teeth 21z, 22z of the anterior 4z and posterior 5z jaws, and the central portion 38 of the connecting element 25.

[00135] FIG. 29 further illustrates the alternative embodiment disclosed in FIGS. 27-28. In this lateral elevational perspective, one notes the connecting element 25 has been advanced cranially until the leading end 39 is in a position such that its aperture 40 is disposed over the horizontal bar 31 of the trailing end of the securing screw; that horizontal bar 31 is then rotated 90°, locking the leading end 39 of the connecting element 25 against trailing end of the screw. The connecting element 25 is then secured

caudally by tightening the securing cap 29 into the cradle 18, securing the trailing end 37 of the connecting element 25 in position. The cradle 18 can be seen as a component of the dorsal jaw 5z of the caudal anchor 2z, which has been secured against the caudal lamina. It can therefore be noted that the embodiment disclosed in FIGS. 27-29 would stabilize a target motion segment in a unique, useful, novel, and nonobvious fashion.

[00136] Another alternative embodiment is seen in FIGS. 30A/B; in FIG. 30A, one notes a lateral view showing anchors 330, 330a similar to those disclosed in the preferred embodiment inasmuch that they each are provided with a sublaminar jaw 331, 331a and a dorsal jaw 332, 332a which are secured against the laminae by actuating securing screws 333, 333a. Differentiating these anchors, however, are the tulips 334, 334a arising from the dorsal jaws 332, 332a and designed to accommodate a connecting rod 340 which stabilizes the construct. In FIG. 30A, one sees, in relief, images of the connecting rod 340 locked within the tulips 334, 334a by the locking screws 343, 343a. Certain aspects of the tulip 334 are more clearly demonstrated in FIG. 30B, which shows the dorsal jaw 332 giving rise to a pedestal 341 I sphere 339 complex. The leading end 338 of the tulip 334 is irreversibly coupled to the sphere 339, conferring polyaxial movement upon the tulip 334-as demonstrated by the curved arrows. This allows the embodiment to accommodate the varying geometry of the cervical spine FIG. 30B also demonstrates that the medial 335 [335a] and lateral 336 [336a] walls in turn create a channel 337 [337a] designed to accommodate the connecting rod 340. After securing the anchors 330, 330a to the laminae, the rod 340 is inserted into the channels 337 [337a]. The interiors of these channels 337 [337a] are provided with threading 347 [347a] which is configured to be complementary to the threading on the leading ends 344 [344a] of the locking screws 343 [343a]; these leading ends 344 [344a] are disposed through the trailing ends 345 [345a] of the tulips 334 [334a] and secured into position by a screwdriver securing the rod in place, thus stabilizing the construct. This stabilizes a target motion segment in a unique, useful, novel, and nonobvious manner.

[00137] A multilevel iteration of this embodiment is achieved with the use of an additional anchor 330b, and is illustrated in FIG. 30C. A longer rod 340, of course, would be utilized and passed into the channel 337b of the tulip 334b associated with the additional anchor 330b and secured in place, stabilizing the construct. Although a two-level construct is shown herein, using the same principles and iterations, a construct of any number of levels between C2 and the thoracic spine can be conceived. Variations of these embodiments can, of course, be envisioned and anticipated by those familiar with the art; all such variations are, of course, within the spirit and scope of the invention.

[00138] Another alternative embodiment of the CMIS which stabilizes a target motion segment in a unique, useful, novel and nonobvious manner is portrayed in a lateral view in FIG. 31. In this variation, an anchor 350 is again provided with a sublaminar jaw 351, as well as a dorsal jaw 352, which are irreversibly coupled by a pivoting axle 353, and compelled towards each other by a securing screw 354 capturing the lamina. Additionally, it is noted that the trailing end 355 of the securing screw 354 is threaded, which allows it to accept a coupling with the anchor secured to the more caudal level. In addition, a housing mechanism 356 can be seen secured to the dorsal jaw 352 by means of a locking screw 357, which together with a locking nut 358 controls a coupling apparatus (not seen in this view) component of the housing mechanism 356. This apparatus slidably couples with the trailing end 362 of a connecting element 361, rendering this element positionable in multiple planes, which again accommodates the CMIS to anatomic variations.

[00139] The complexity of the embodiment disclosed in FIG. 31 is appreciated in FIGS. 32 A-D, which depict elevational, exploded views of the components of the anchor 350 (32 A/B/C) as well entire embodiment. In FIG. 32A, the sublaminar jaw 351 and securing screw 354 are portrayed, with the sublaminar jaw 351 provided with a dorsal extension 366 which is configured to articulate with the dorsal jaw, as illustrated in FIGS. 32 B and D. An aperture 377 in the dorsal extension 366 receives an articulating axle to couple with the dorsal jaw 352, again seen in FIGS. 32 B and D.

This coupling confers the anteroposterior axis of movement upon the jaws 351, 352, which is actuated by the securing screw 354, the leading end 379 of which is disposed initially through the dorsal jaw, and then through the aperture 368 in the sublamina jaw 351. Other features of the screw 354 include the trailing end 355 and a hexagonal portion 381 of the shaft which is configured to couple with the leading end of the connecting element arising from the anchor caudal to the subject illustrated herein. Also seen in this image are the small teeth 389 on the sublamina jaw 351.

[00140] FIG. 32 B illustrates the dorsal jaw 352 coupling with the locking screw 357 which then couples the dorsal jaw 352 to the housing mechanism (FIG. 32 C). The leading end 385 of the dorsal jaw 352 is provided with a channel 371 through which a locking screw 357 is disposed; a retention pin 373 is passed through an aperture 372 at leading end 385, passing across the channel 371, as well as aperture 386 at the caudal aspect, this pin 373 maintains the locking screw 357 in position. The caudal end 376 of the dorsal jaw 352 is provided with a notch 378, through which the securing screw is positioned, as seen in 32 D. The axle 353 which couples the sublamina jaw 351 with the dorsal jaw 352 is disposed through aperture 360 in the caudal end 376 of the dorsal jaw 352, and after passing through the dorsal extension of the sublamina jaw (FIG. 32 D), this axle 353 is then secured into an aperture 380, which maintains the coupling of the jaws 351, 352.

[00141] The housing mechanism 356 and the connecting element 361 are portrayed in FIG. 32 C. Features of the housing mechanism 356 include a central channel 370 through which the locking screw is disposed (see FIG. 32D), with a threaded leading end 369 of a locking nut 358 securing the nut 358 to the dorsal aspect of the channel 370, with a channel 382 within the nut 358 that will receive the locking screw. A retention pin 367 will be passed through caudal and cranial apertures 387, 388 in the housing mechanism 356, to secure the locking screw during assembly. The connecting element 361 is coupled to the housing mechanism 356 which is provided with a coupling apparatus 375 that is actuated to optimally position the element 361. This is achieved

by tightening the securing nut 358 against the leading end of the locking screw, which causes the coupling apparatus 375 to narrow channel 383 into which the trailing end 362 and at least part of the shaft 363 of the connecting element 361 have been disposed and are repositionable prior to narrowing the channel 383. Once narrowed, the connecting element 361 is locked into position, with the leading end 364 of the element 361 coupling to the more cranial anchor of the construct, with the trailing end of the screw of the cranial anchor disposed through and interfacing with internal threading within channel 384 of the securing nut 365. Upon successful positioning, the securing nut 365 is tightened, thus stabilizing the target motion segment.

[00142] The assembly of the components illustrated in FIGS. 32A-C into the completed embodiment of anchor 350 is demonstrated in FIG. 32D. The coupling of the jaws 351, 352 is accomplished by inserting the dorsal extension 366 of the sublamina jaw 351 into the notch 378 of the dorsal jaw 352, as indicated by the arched interrupted line. Also indicated is the axle 353 passing through the aperture 360 in the dorsal jaw 352, and [presumably] passing through the channel 377 in the dorsal extension 366 once this is in position, and finally the leading end of the axle 353 is secured into aperture 380 again in the dorsal jaw, thus completing the coupling. In at least one embodiment, the axle 353 secures into aperture 380 with a "pressure fit." The securing screw 354 is disposed through the notch 378 in the dorsal jaw 352 and ultimately into the aperture 368 in the sublamina jaw 351, as indicated by the interrupted line highlighted by the downward directed arrows. This arrangement positions the screw 354 such that upon actuating the screw 354, the jaws 351, 352 are compelled towards each other, which, as previously disclosed, secures the anchor to the lamina. The locking screw 357 passes through the channel 371 of the dorsal jaw 352 and into the channel 370 of the housing mechanism 356, as indicated by the interrupted line highlighted with the upward directed arrows. A retention pin 373 passed through aperture 372 in the dorsal jaw 352 maintains the screw 357 in position. The leading end 359 of this screw 357 is disposed through the channel 370 of the housing mechanism 375, and into the channel 382 of the locking nut 358, locking the dorsal jaw 352 to the housing mechanism 375. A retention

pin 367 is used to maintain the screw 357 under tension. As previously disclosed, with tightening nut 358, the connecting element 361 is secured. Prior to securing this in place, the craniocaudal dimension may be adjusted by compression or distraction of the construct, and once this is accomplished and in satisfactory position, the locking nut 358 of the housing mechanism 356 is secured thus capturing the connecting element in the desired position.

[00143] A complete construct of the embodiment disclosed in FIGS. 31, 32 A-D is portrayed secured to the cervical spine in FIG. 33, a right-sided posterior oblique view of the C3 through C7 spinal segment. This demonstrates a construct 390 with right-sided anchors 350, 350a secured to the CS and C6 laminae, with a connecting element 361a stabilizing that motion segment. When reduced to practice, the connecting element 361 associated with the more cranial anchor 350 would not be incorporated into the final construct, as it could interfere with the movements of the lamina above the construct—in this example, the C4 right sided lamina. Also, the final iteration would configure the caudal anchor 350a so that it would not have a caudal overhang that interferes with the lamina caudal to the construct. This image is illustrative only, and it would be anticipated that in clinical practice, constructs would likely be implanted bilaterally.

[00144] A multilevel construct of the alternative embodiment in FIG. 31 can be anticipated, and a lateral view of such a construct in the isolated state is shown in FIG. 34. Each successive anchor 350, 350a, 350b, 350c, 350d are coupled to the more cranial anchor by the connecting elements 361, a-d in the same manner as seen in the single-segment embodiment.

[00145] FIG. 35 depicts a lateral view of an isolated, multilevel construct of the alternative embodiment of the anchor 350 presented in FIG. 31; however, this configuration utilizes a single rod connecting element 391 connected to the anchors 350, 350a-d and hence stabilize the construct. Variations of these embodiments can, of course, be envisioned and anticipated by those familiar with the art; all such variations are, of course, within the spirit and scope of the invention.

[00146] In another embodiment 400, anchors 401, 401a are again comprised of sublaminae jaws 402, 402a, dorsal jaws 403, 403a these pairs of anchors coupled by axles 411, 411a and actuated by securing screws 404, 404a disposed through the caudal aspects of the pairs of jaws 402, 403 and 402a, 403a and compelling the jaws towards each other hence securing the anchors 401, 401a to the laminae in a manner substantially equivalent to the previous embodiments herein disclosed. Also, as in some previous embodiments, the relationships of the screws 404, 404a within the anchors are such that a series of audible clicks are appreciated as the screws 404, 404a are brought into various positions. As illustrated in FIG. 36 A, an elevational view of this embodiment, the distinguishing feature of this embodiment is the connecting element 405, which in this alternative embodiment is comprised of a leading end, 406, a central portion 407, and a trailing end 408; the deployment of this connecting element 405 provides a device 400 which stabilizes a target motion segment in a unique, useful, novel and non-obvious fashion. The leading end 406 of the connecting element 405 is substantially flattened and expanded, and elliptical or rectangular in configuration. It is provided with a central aperture 409 and is substantially similar in configuration to the preferred embodiment of the connecting elements disclosed in FIGS. 7, 8, 22A, 22B, 23, as well as those seen in the alternative embodiments disclosed in FIGS. 25 ... 29. In this embodiment, after securing the cranial anchor 401 to the target lamina by actuating the securing screw 404, the first audible click indicates that the anchor is nearly completely secured, with the horizontal bar 413 provided to the trailing end 412 of the screw 404 is in ideal position (oriented along the craniocaudal axis) to accept the aperture 409 on the leading end 406 of the connecting element 405, which would be anticipated to be associated with the more caudal anchor 401a. A central feature of this embodiment is the trailing end 408 of the connecting element 405, which is a spherical configuration that is irreversibly anchored within a cupped socket 415a which arises from the muscular surface 416a of the dorsal jaw 403a. This configuration confers polyaxial movement upon the connecting element 405. A defect 417a in perimeter of the cupped socket 415 supports this coupling over a range of angles, accommodating slight variations in anatomy and

placement. The connecting element is then deployed by pursuing the course demarcated by the arching, interrupted line, passing the aperture 409 over the horizontal bar 413 of the securing screw 404. The final craniocaudal dimension can be achieved as a function of the configuration of the aperture 409, which is greater in that dimension. This permits the surgeon to apply compression/distraction achieving the optimal craniocaudal position, at which point the horizontal bar 413 is then rotated into final position. At that point, one or more securing screws 418 within the perimeter of the socket 415 are actuated to prevent rotation, achieving final locking and stabilization of the construct. It is also noted that the dorsal jaw 403 of the cranial anchor 401 is modified such that it is not provided with a socket as there is (obviously) no need for a [more] cranial connecting element. In a variant of this embodiment not illustrated herein, a socket is provided without a connecting element. Furthermore, these cupped sockets are designed such that the leading ends of the connecting elements can be inserted into the cups, having been provided with a configuration that permits the leading ends to be "snapped into" position if a cranialward extension is required in the future.

[00147] An isolated multilevel embodiment in which the connecting elements are rotated into position in this fashion is portrayed in FIG. 36 B. Again, the cranialmost anchor 401 is not provided with a connecting element mechanism. Otherwise, in the successive caudal direction, anchors 401a, 401b, and 401c are coupled to the more cranial anchors as the result of the deployment of connecting elements 405, 405a and 405b being locked by the horizontal bars 413, 413a and 413b. Again, within the perimeters of each of the sockets 415a, 415b, 415c are one or more screws 418 that upon actuation prevent spherical rotation. Variations of these embodiments can, of course, be envisioned and anticipated by those familiar with the art; all such variations are, of course, within the spirit and scope of the invention.

[00148] A variation of this embodiment 520 is examined in the lateral perspective in FIG. 37. As demonstrated, there are again cranial and caudal anchors 521, 521a which are actuated by screws 522, 522a to secure against target laminae. However, unlike

embodiments disclosed hitherto, this is uniquely characterized inasmuch as there is no distinct connecting element coupling these anchors 521, 521a to stabilize the construct. Rather, each anchor is provided with an elongated, monolithic hemi-connector 525, 525a comprised of an elongated leading end 527, 527a and a spherical trailing end 526, 526a which is seated within a cuffed socket 523, 523a. This arrangement confers polyaxial movement upon the hemi-connector 525. After positioning the anchors 521, 521a, the hemi-connectors are repositioned such that the leading most ends 528, 528a approximate each other, hence creating a "modular" connecting element. A coupling element 529 then completes the construct using either threading provided to the element 529 as well as the leading most ends 528, 528a, or "cold weld," "pressure fit," or any other method known and acceptable to the art. As a final step, screws 524, 524a are tightened against the spheres 525, 525a, preventing rotation [0174] A multi jointed embodiment can be envisioned, with a lateral view of such an embodiment 420 demonstrated in FIG. 38. Here it is noted that the anchors 421, 421a are again provided with sublaminar jaws 422, 422a, dorsal jaws 423, 423a, coupled by axles 424, 424a and actuated by securing screws 425, 425a, being secured against the laminae in the same manner as all anchors previously disclosed in this application. The distinguishing feature which confers upon this a unique, useful, novel, and nonobvious method for stabilizing a target motion segment is the manner by which a connecting complex 430 arising from the cranial anchor 421 is coupled to a connecting complex 430a arising from the caudal anchor 421a, each being "mirror images," of the other and directed towards each other, and coupled by a central stabilizing joint 427, hence stabilizing the construct 420.

[00149] Each connecting complex 430, 430a is comprised of a vertical segment 431, 431a and a horizontal segment 432, 432a. Projections 433, 433a (superimposed interrupted lines) arise from the dorsal surfaces 426, 426a of the dorsal jaws 423, 423a and fit into chambers 434, 434a within the vertical segments 431, 431a. These junctions are modulated by threaded positioning connectors 435, 435a which interface with threading on the external surfaces of the projections 433, 433a and the vertical segments 431, 431a. These couplings provide the surgeon with the ability to adjust the vertical

height of the construct as well as mediolateral rotation, accommodating anatomic variations. The horizontal segments 432, 432a are then coupled with the central stabilizing joint 427. In this illustration, the leading end 436 of the cranial horizontal segment is tapered and passed into a chamber in the leading end 436a of the caudal horizontal extension 432a; the central stabilizing joint 427 is substantially cylindrical, with a threaded central channel 428 (indicated by the diagonally oriented series of shaded circles), again configured to enmesh with threading on the horizontal segments 432, 432a. The central stabilizing joint 427 can be independently introduced or can be slidably coupled to one of the horizontal segments and repositioned. In another embodiment, the central stabilizing joint 427 is long enough to couple with the leading ends of both horizontal segments. Regardless of the embodiment, the central stabilizing joint 427 can satisfy the surgeon's requirements in the craniocaudal dimension, i.e., distraction I compression and the construct 420 is complete. Any other means of coupling, including cold welding, pressure fit, the use of a securing screw, and so forth are all within the spirit and scope of the invention. The orthogonal relationship of the vertical and horizontal segments is not an absolute; any angular relationship or any other configuration, including a single arched configuration, is within the spirit and scope of this application.

[00150] FIGS. 39A/B reviews a multilevel embodiment of the embodiment displayed in FIG. 38. It is noted that this embodiment provides for an intermediate anchor 440, illustrated in FIG. 39A, which shows that there is a cranial extension 441 and a caudal extension 442. These are each provided with a vertical segment 443, 444 and a horizontal segment 445, 446; the vertical extensions are provided with chambers 447, 448 which accept dorsal projections 449, 450 arising from the dorsal jaw 458, these junctions governed by positioning connectors 451, 452. The horizontal segments 445, 446 are the points of coupling to adjacent anchors, and are provided with unique components to achieve this. Again, the configurations can vary; in this image, it is noted that the cranial horizontal segment 445 is provided with a chamber 454, wherein the caudal horizontal segment 446 is provided with an extension 455 designed to be

disposed into such a chamber; however, these could be reversed, or both segments could be provided with extensions. Also noted is the central stabilizing joint 427, which is in this illustration slidably and irreversibly coupled to the cranial horizontal segment 445. A flange 453 is provided to the leading most end of the horizontal segment 445, preventing the joint 427 from slipping off the end. One can envision the mating of this segment with a complimentary segment, with the joint 427 then being slidably repositioned prior to locking the construct. As shown in FIG. 39B, these anchors 440, 440a couple with each other, as well as the cranial anchor 421 and the caudal anchor 421a using the cranial 430, 441 and caudal 430a, 442 extensions as well as the central stabilizing joints 427, 427a, 427b in the same manner as disclosed above. A construct extending over any number of motion segments can be anticipated.

[00151] In FIG. 40, an embodiment 460 is seen which is similar in some features to that disclosed in FIGS. 38 and 39. This lateral projection shows identical cranial 461 and caudal 461a anchors coupled to a central positioner 463, which is comprised of a cranial element 464 and a caudal element 465. These are comprised of vertical segments 468, 469 and horizontal segments 466, 467, the latter which are slidably coupled by the leading end of one segment (in this case 466) positionably inserted within a chamber of the other, slightly larger leading end. With precise craniocaudal positioning, a locking nut 470 secures the construct 460 in place, again creating a modular connecting element 463. The vertical segments 468, 469 have leading ends 472, 473 which are disposed into vertical couplers 474, 475 (these components of vertical segments denoted by stippling); the couplers are rotatable threaded cylinders 471, 471a configured to enmesh with threading on dorsal projections 462, 462a on the anchors 461, 461a. This configuration of the vertical segments and dorsal projections control the vertical dimension (anatomically, the anteroposterior dimension); additionally, the vertical segments can be rotated along the mediolateral axis, all of which accommodates variations in anatomy. Once the final position is achieved by the surgeon, the central positioner 463 is locked by securing the horizontal locking screw 470 and vertical locking screws 476, 477, thus stabilizing the construct 460 in a unique, useful, novel, and nonobvious fashion.

[00152] FIG. 41 illustrates a lateral projection of a multi-level construct 460a of the construct depicted in FIG. 40. Again provided is a series of identical anchors 461, 461(a-z); moreover, the embodiment 460a has an expanded central positioner 480 wherein the cranial element 485 and the caudal element 486 of this positioner 480 are coupled with a substantially "T-Shaped," intermediate element 481 provided with a horizontally-oriented segment 482 with a central channel 483 which accepts the leading ends of the horizontal segments 487, 488 of the cranial 485 and caudal 486 elements, these being locked in place by securing screws 489, 490. A vertical component 484 of the intermediate element 481 is solid and monolithic and is directed into the vertical coupler 476 (the vertical segment within the coupler is denoted by stippling) of the intermediate anchor 461a. Once this is secured by the locking screw 494a, then the horizontal segments 487, 488 are secured after slidably positioning them so that the vertical segments 492, 493 can be disposed into the vertical couplers (stippled within the couplers) 474, 475 of the cranial 461 and caudal 461b anchors, locking them with locking screws 494, 494a, 494b, thus completing the construct 460a. It is noted that the horizontal segments 487, 488 are provided with a lordotic curve, which is probably necessary in a multilevel construct. In larger constructs, it is anticipated that an accessory connecting rod that would be positioned between two intermediate elements 481, 481a-z. Presumably, the construct can include as many intermediate anchors and elements as needed, denoted by the letters.

[00153] A further variation of an embodiment 500 in which threaded dorsal projections arise from the anchors is portrayed in FIG. 42, wherein a lateral view shows substantially standard anchors 501, 501a in which threaded projections 503, 503a extend from the dorsalmost aspect of the securing screw 502, 502a. The unique, useful, novel, and nonobvious configuration of a modular connecting element 504 discloses a rod-like element comprised of a cranial 510 and caudal 511 components, with these components slidably coupled such that the free edge 512 of one component (in this example the cranial component 510) is disposed within an expanded central chamber 513 provided to the other component 511, slidably adjusting the craniocaudal dimensions. The com-

ponents are then locked by the securing screw 514. Each component 510, 511 of the connecting element 504 is provided with a cradle 515, 516 within which spherical couplers 505, 506 are irreversibly retained, providing the couplers with a substantial range of motion. These couplers 505, 506 are provided with threaded chambers 507, 508 (outlined by interrupted lines) which are disposed over the free ends 509, 509a, as indicated by arrows, with the spheres 505, 506 being rotated by a specialized instrument (not shown) until the construct is in place. Securing screws 517, 517a then lock the entire construct 500 in place. One can envision securing nuts being used in addition to, or in lieu of these screws. Multilevel embodiments can of course be anticipated and are within the spirit and scope of the invention.

[00154] An even more radical variation of this concept is conceived and shown in FIG. 43, a lateral view of a construct 530 in which the modified anchors 531, 531a do not include securing screws. Instead, the anchors 531, 531a are stabilized against the laminae by a purpose-specific modified implant instrument (not shown) while the unique, useful, novel, and nonobvious design of a modular connecting element 534 stabilizes the construct 530. The connecting element 534 is provided with cranial 535 and caudal 536 extensions, each provided with a coupling end 543, 544 which in turn is provided with a cradle 537, 538 which houses an articulating sphere 539, 540. Securing screws 541, 542 are continuous and monolithic with said spheres 539, 540; this configuration confers upon the spheres 539, 540, and hence the screws 541, 542 a significant range of motion. The screws 541, 542 are disposed through tracts 532, 532a within the anchors 531, 531a; this action simultaneously locks the anchors 531, 531a and stabilizes the construct 530. The construct 530 can also be adjusted along the craniocaudal axis. This adjustability results from coupling of the free ends 547, 548 of the extensions 535, 536, wherein the free end of one extension (in this case the caudal extension) is provided with an expanded free end within which a chamber 549 is present which accommodates an expansion 550 at the free end 547 of the cranial extension 535; this expansion assists in locking the extensions. The ends 547, 548 can be slidably repositioned with respect to each other, and hence the craniocaudal adjustability. Once

the desired position is achieved, a locking screw 551 secures the connecting element 534 in place.

[00155] FIG. 44A depicts a lateral view, the best perspective to appreciate the unique feature of an alternative embodiment 560 which is characterized by the lowest anterior-posterior profile of any of the embodiments disclosed in this specification. This is accomplished by disclosing a complex connecting element 562 to uniquely couple with the cranialmost 571 and caudal most 572 aspects of the anchors 561, 561a, said element 562 being best understood by scrutinizing the enlargement in FIG. 44B. This demonstrates that the connecting element 562 is provided with a trailing end 563 and a leading end 567. The trailing end 563 is monolithic but has two aspects, a spherical base 565 which is continuous with a connecting extension 564. The connecting extension 564 itself is provided with a receiving chamber within the free end 566 which accepts and slidably couples than adjustment rod 568 of the leading end 567 of the connecting element 562, adjusting for the craniocaudal dimension, and then locked by the middle securing screw 574. The spherical base 565 is irreversibly retained within a socket 570 that is a component of the cranialmost aspect 571 of the caudal anchor 561a, as seen in both FIGS. 44A and B. This configuration confers a polyaxial range of movement upon the connecting element 562 to accommodate anatomic variations. Once the desired orientation of the connecting element 562 is accomplished, the caudal securing screw 575 is deployed. The leading most aspect 569 of the leading end 567 of the connecting element demonstrates an enlargement, which is then disposed into housing chamber 576, and locked with the cranial securing screw 573. While in this portrayal, the spherical end 565 is coupled to the caudal anchor 561a, certainly an embodiment representing a reversal of the configuration can be anticipated and is within the spirit and scope of the invention.

[00156] One can continue to envision still other embodiments. In FIG. 45, an alternative embodiment 580 shows one laminar anchor 581 secured to the cranial aspect of the lamina of the cranial vertebra of the target motion segment, which is diametrically

contrasted to the typical fashion disclosed in this specification. This anchor 581 is then coupled by a rod-like connecting element 583 to a laminar anchor 582 which is secured to the lamina of the caudal vertebra in the standard fashion disclosed in all embodiments above. Each of these anchors 581, 582 are provided with cradles 584, 585, similar to those disclosed FIGS. 30 A-C and disclosed in paragraphs 166, 167. Such as the cradles in those embodiments, the cradles 584, 585 herein are provided with central channels 586, 587, as demonstrated by lines. The bases of these channels 586, 587 are configured to accommodate the connecting element 583; furthermore, the walls of these channels 586, 587 are provided with threading to interface with threading provided to the external surfaces of the securing bolts 588, 589. These bolts 588, 589 are outlined in interrupted lines within the cradles 584, 585, with their trailing ends at the tops of the cradles 584, 585. To complete the construct, the connecting element 583 is positioned within the channels and locked with the securing nuts 588, 589, stabilizing the construct 580.

Figure 45 illustrates an embodiment of the bone anchor on a cervical lamina. This illustrates the operation where the anchor is applied to a cervical lamina from the superior position and demonstrates that a levering effect is asserted to that main body of the bone anchor through the transverse extension in application. This effect is even greater when the bone anchor is applied to the inferior orientation.

What is claimed is:

1. A non-intrusive bone anchor for attachment to vertebral laminar processes comprising:
 - a. A main body which has a lower fixed jaw; a connecting portion to said lower fixed jaw, a bore hole providing basis for an axis from one side of said connecting portion to the other, and a threaded two ring clamp where each ring has an inner threaded surface with a threaded axis;
 - b. An externally threaded shaft with a first and second end, where said first end has an internal torquing indent and a portion adjacent thereto for a locking mechanism to engage the outer portion of the clamping ring and said first end has a fixation protuberance.
 - c. An upper jaw that cooperates with said externally threaded shaft and engages bone between said upper jaw and said lower fixed jaw forming a diagonal across a clamped bone body;
 - d. An inter-anchor connector comprising an axis with a first connector end and a second connector end where said first connector end has a rod portion and said second end has a tulip rod fixer portion.
2. The anchor of Claim 1 wherein said upper jaw is in the form of a disk with a first side and a second side and said second disk side has a texture to engage a bony surface and said second disk side has a central ball socket and a means to allow insertion of a ball formed as the protuberance on said externally threaded shaft.
3. The anchor of Claim 2 wherein said ball socket and ball form a pivoting connection.
4. The anchor of Claim 1 wherein the internal torquing indent of said threaded shaft can be attachably linked to a torque shaft.

5. The anchor of Claim 4 wherein said main body has two side profiles wherein said first side profile and said second side profile have profiles that can be held by a constricting tool to allow placement of said anchor above and below a bone body.
6. The anchor of Claim 1 wherein the lower jaw of said main body has a plurality of teeth located at a position that is farther from said connection portion of said main body than the upper jaw attached to said externally threaded shaft.
7. The anchor of Claim 6 wherein the depth of the distance from the back of the jaw to the lower jaw, and the length from the back of the jaw to the upper jaw is not equal.
8. The bone anchor of Claim 1 wherein said lower jaw portion has at least three teeth arranged orthogonally from a plane formed by a main plane of the main body.
9. A bone anchor comprising a main body with a fixed j shaped lower jaw with a plurality of teeth, a connecting body portion joining said lower jaw and a locking mechanism extension forward of said connecting body portion, a hinged upper jaw attached to said connecting body portion, a threaded activator and clamp.
10. A bone anchor for attachment to vertebral processes comprising:
 - a. A main body which has a lower fixed jaw; a connecting portion to said lower fixed jaw a hole providing basis for an axis from one side of said connecting portion to the other, and a threaded two ring clamp where each ring has an inner threaded surface with a threaded axis;
 - b. A n externally threaded shaft with a first and second end, where said first end has an internal torquing indent and a portion adjacent thereto for a

- locking mechanism to engage the outer portion of the clamping ring and said first end has a fixation protuberance;
- c. An upper jaw that cooperates with said externally threaded shaft and engages bone between said upper jaw and said lower fized jaw forming a diagonal across a clamped bone body;
 - d. An inter-anchor connector comprising an axis with a first connector end and a second connector end where said first connector end has a rod portion and said second end has a tulip rod fixer portion.
11. The anchor of Claim 11 wherein said upper jaw is in the form of a disk with a first side and a second side and said second disk side has a texture to engage a bony surface and said second disk side has a central ball socket and a means to allow insertion of a ball formed as the protuberance on said externally threaded shaft.
12. The anchor of Claim 12 wherein said ball socket and ball form a flexible connection.
13. The anchor of Claim 13 wherein the internal torquing indent of said threaded shaft can be attachably lined to a torque shaft.
14. The anchor of Claim 14 wherein said main body has two side profiles wherein said first side profile and said second side profile have profiles that can be held by a constricting tool to allow placement of said anchor above and below a bone body.
15. A bone anchor as illustrated in FIG. 9 of the specification.

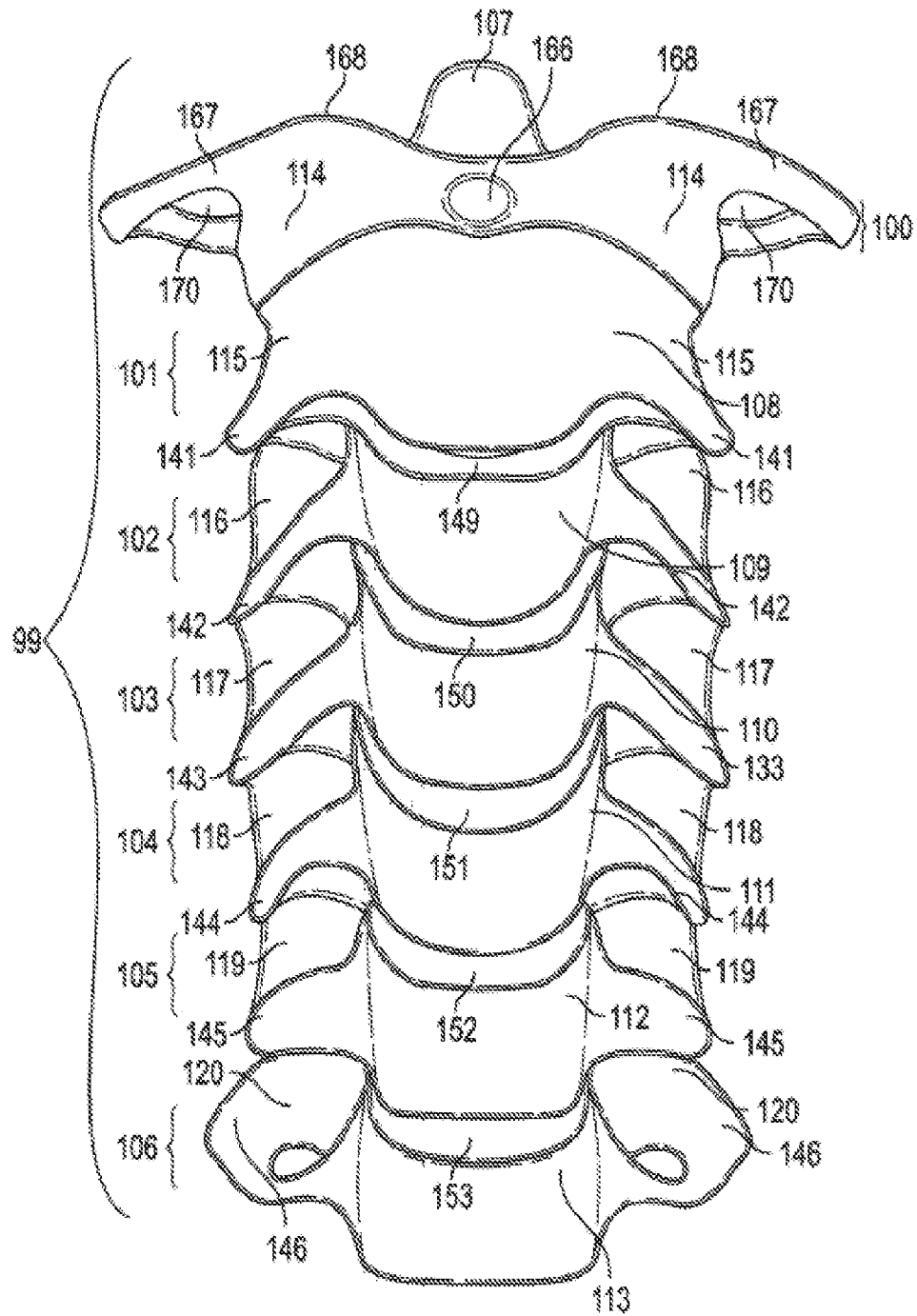


FIG. 1

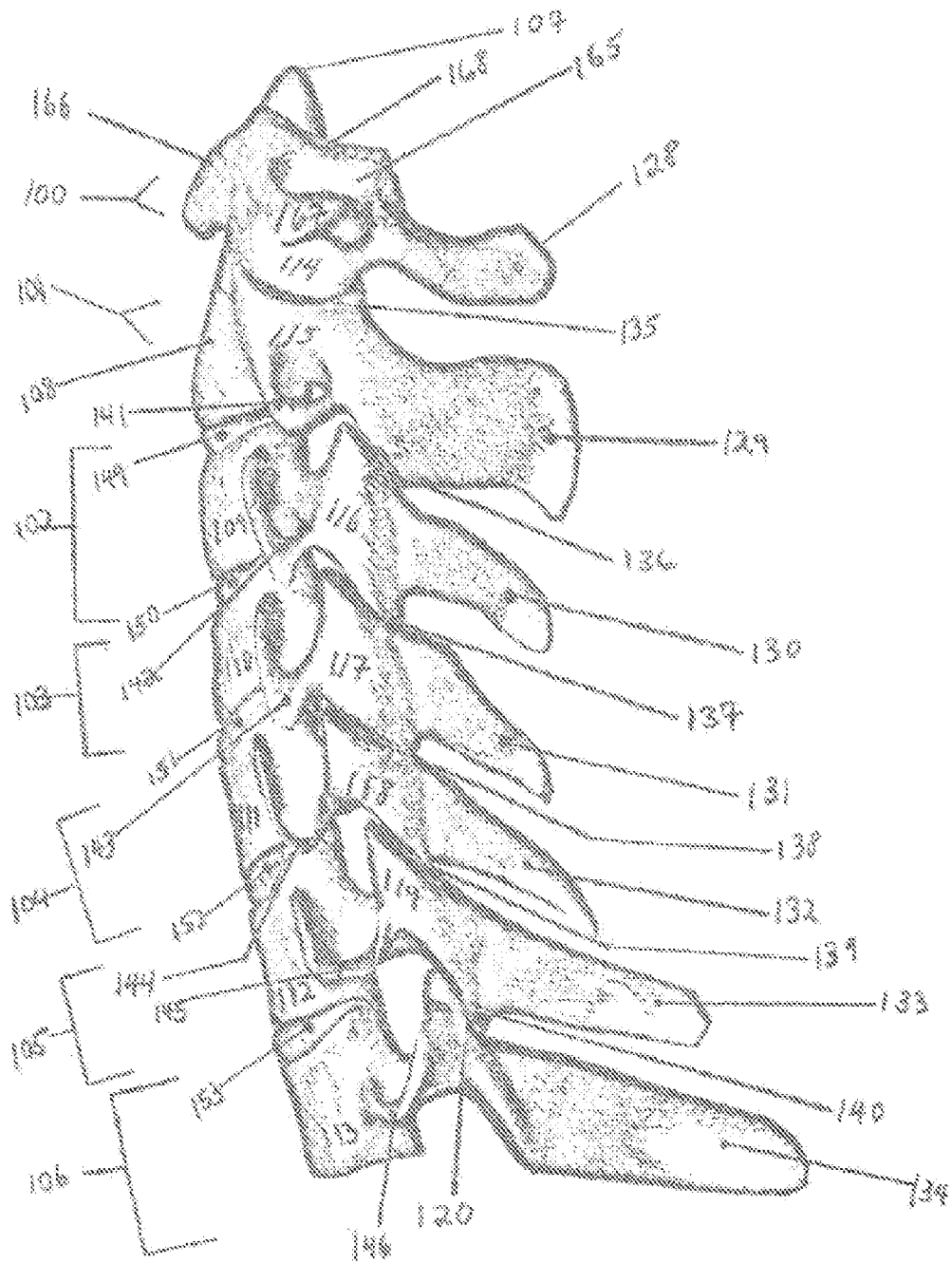
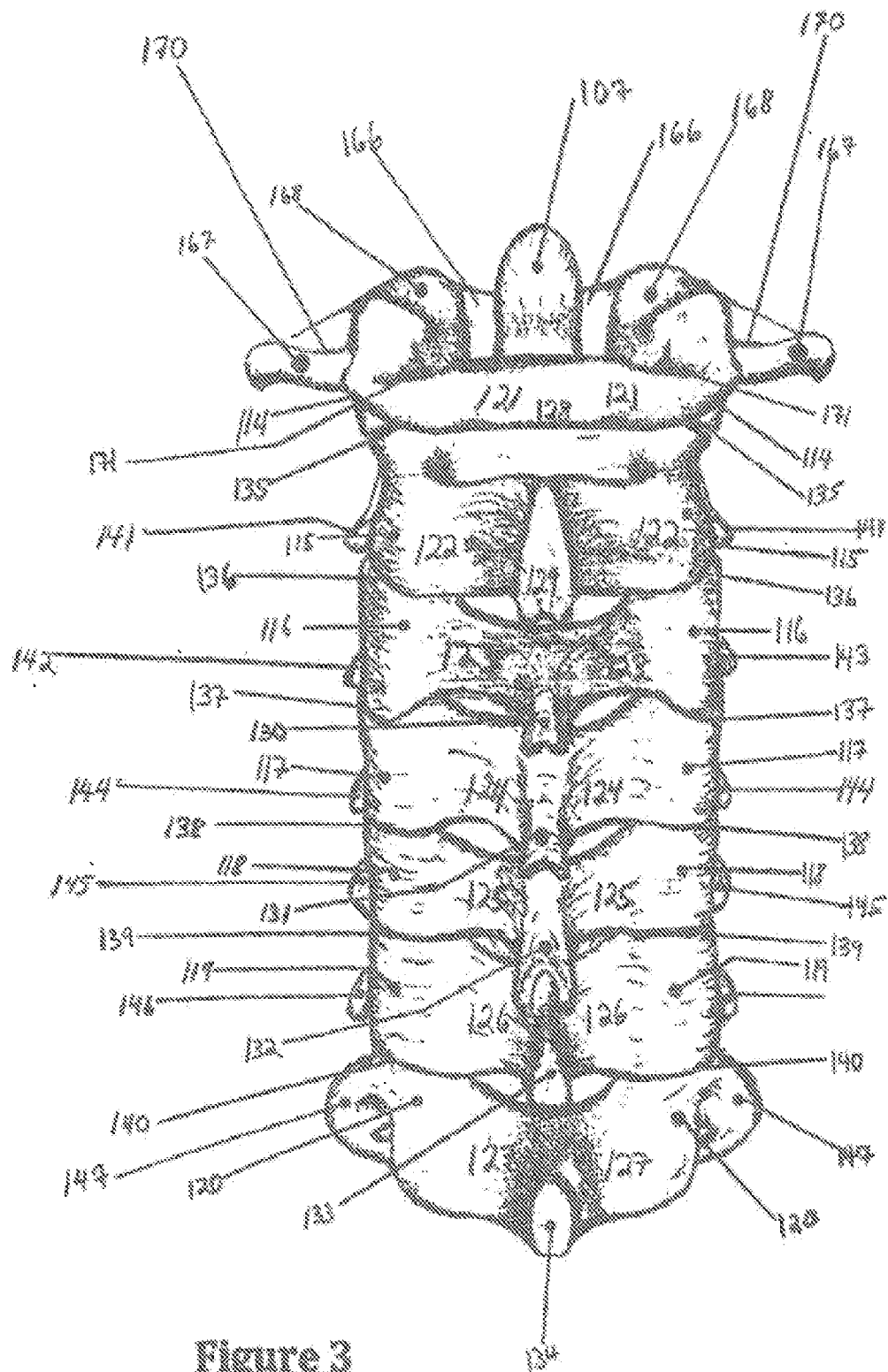


Figure 2



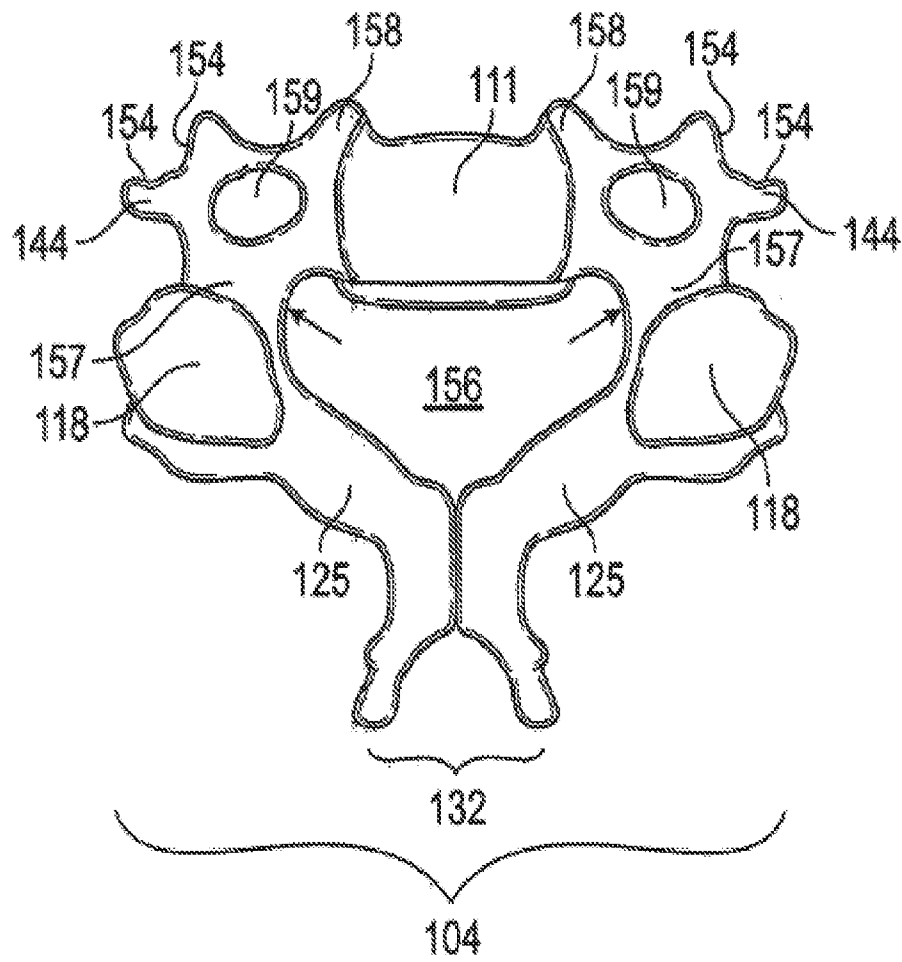


FIG. 4

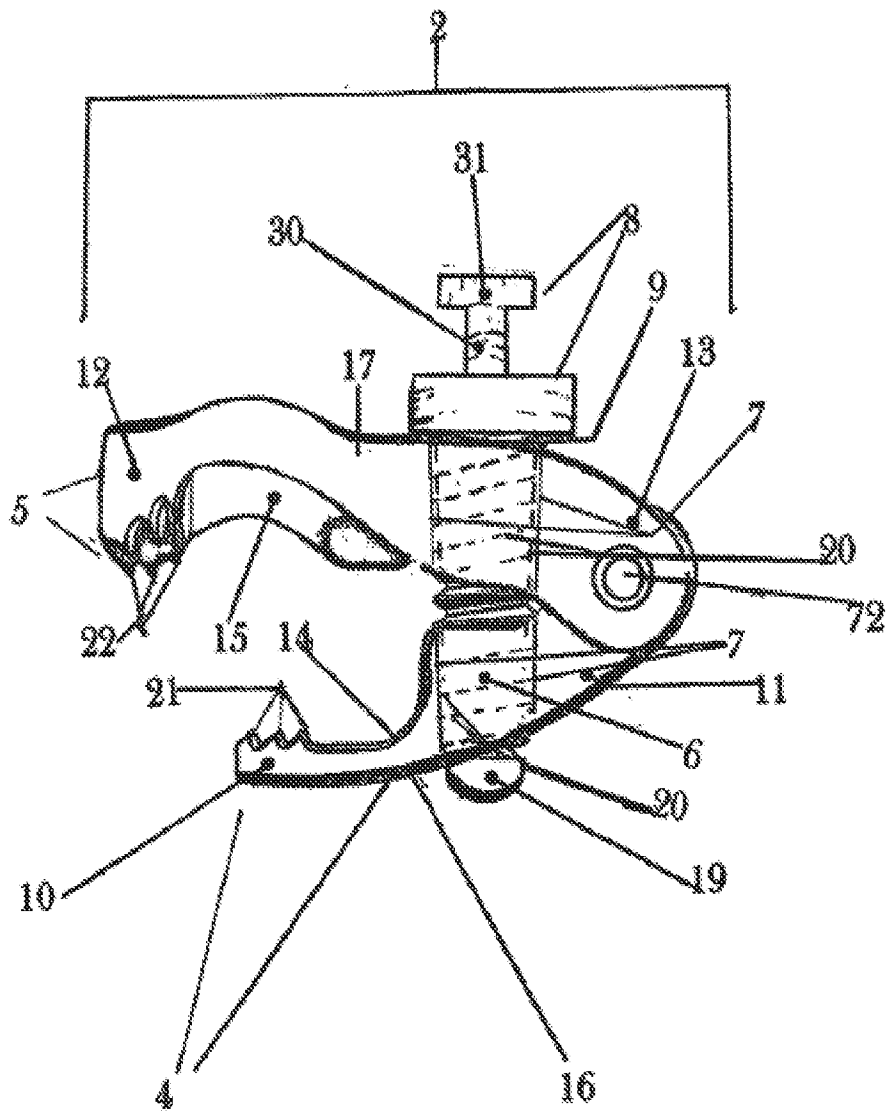


Figure 5

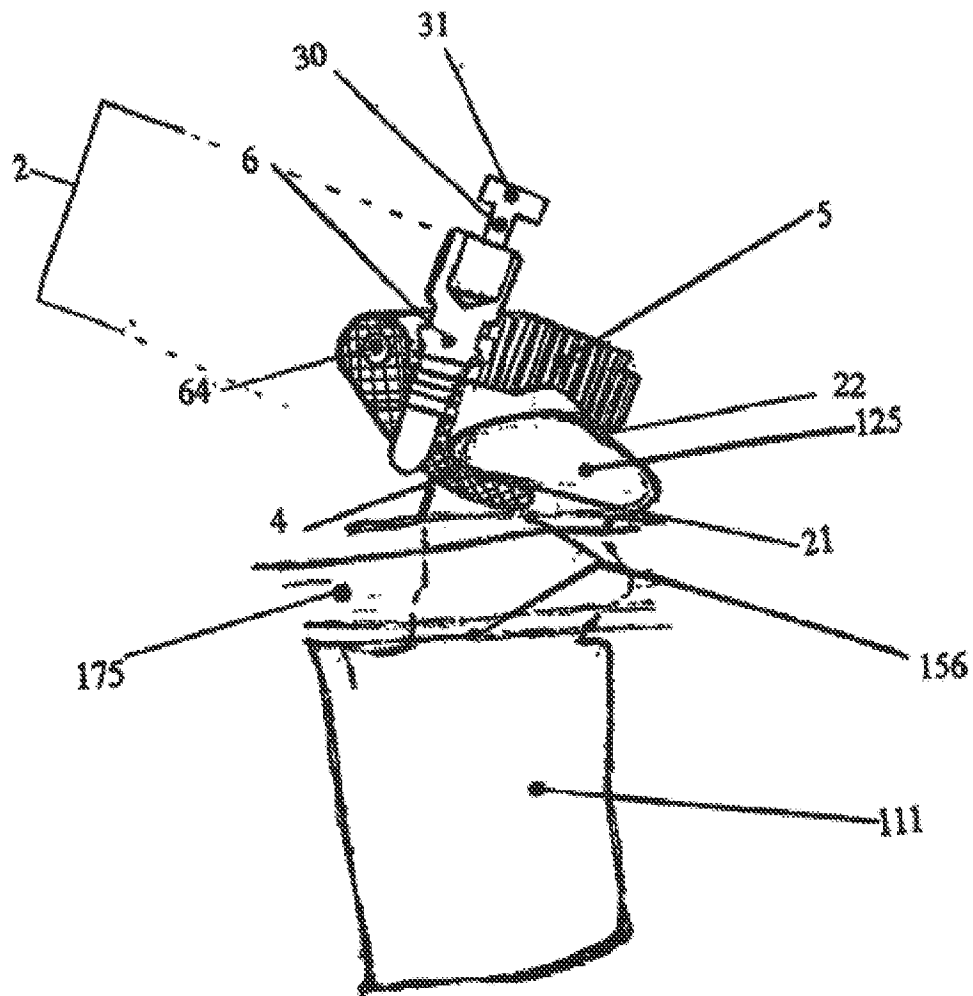


Figure 6

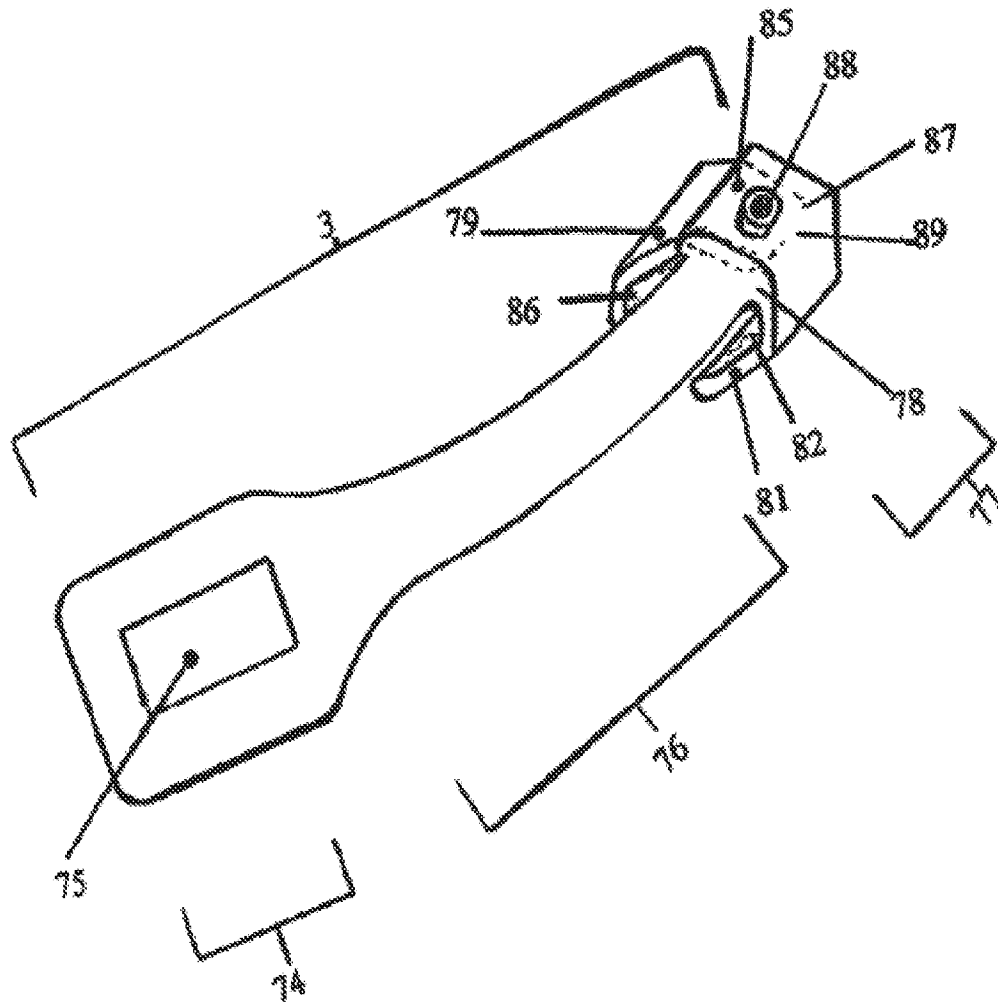


Figure 7

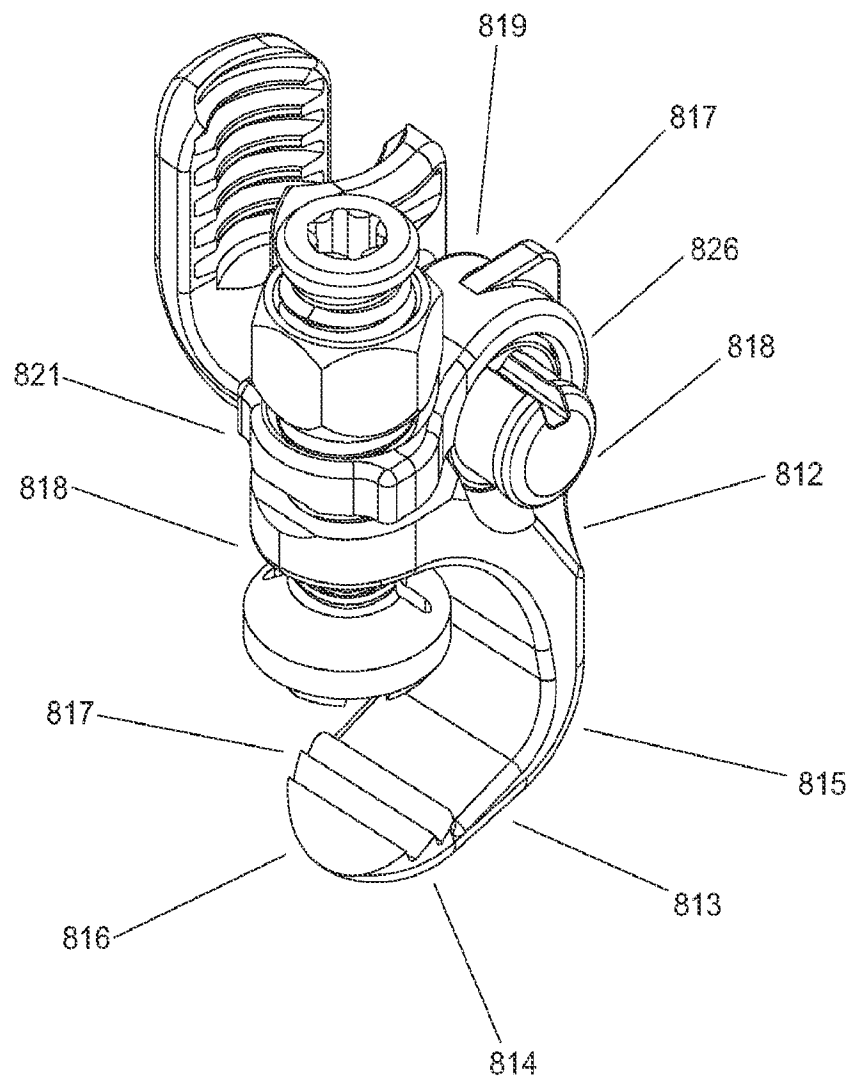


FIG. 8

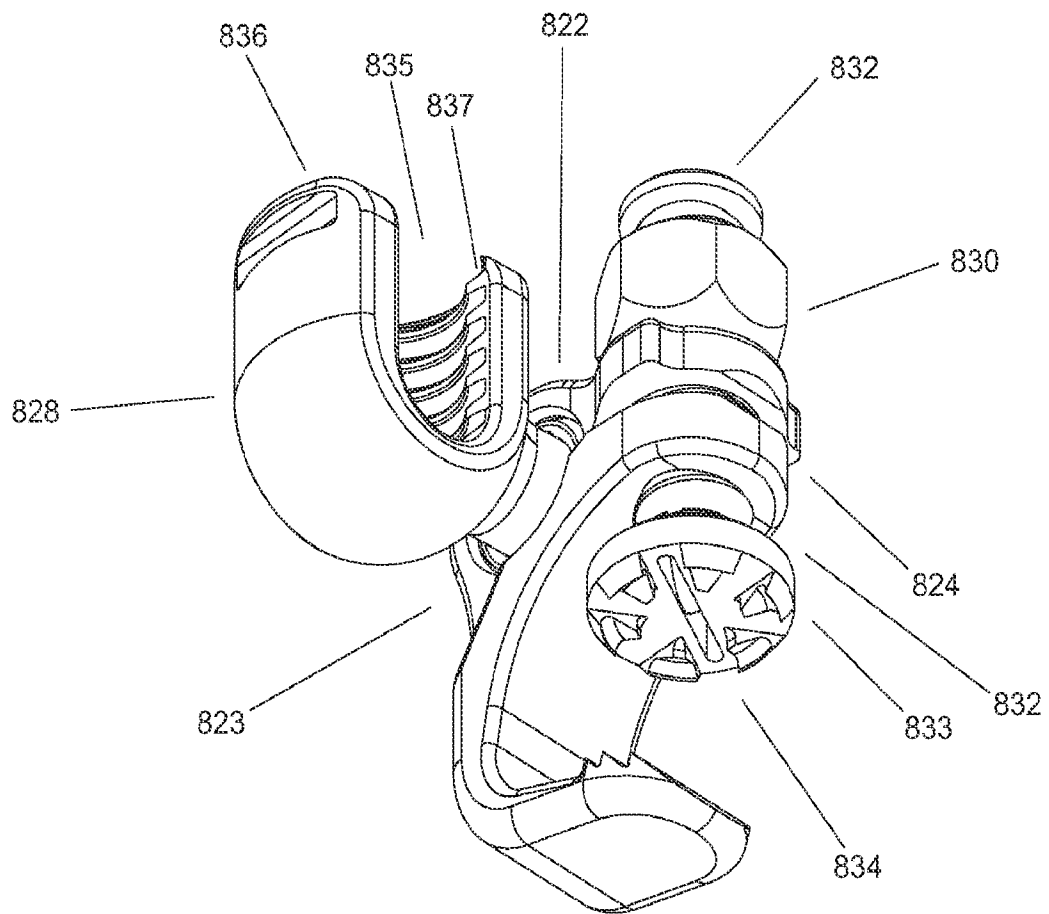


FIG. 9

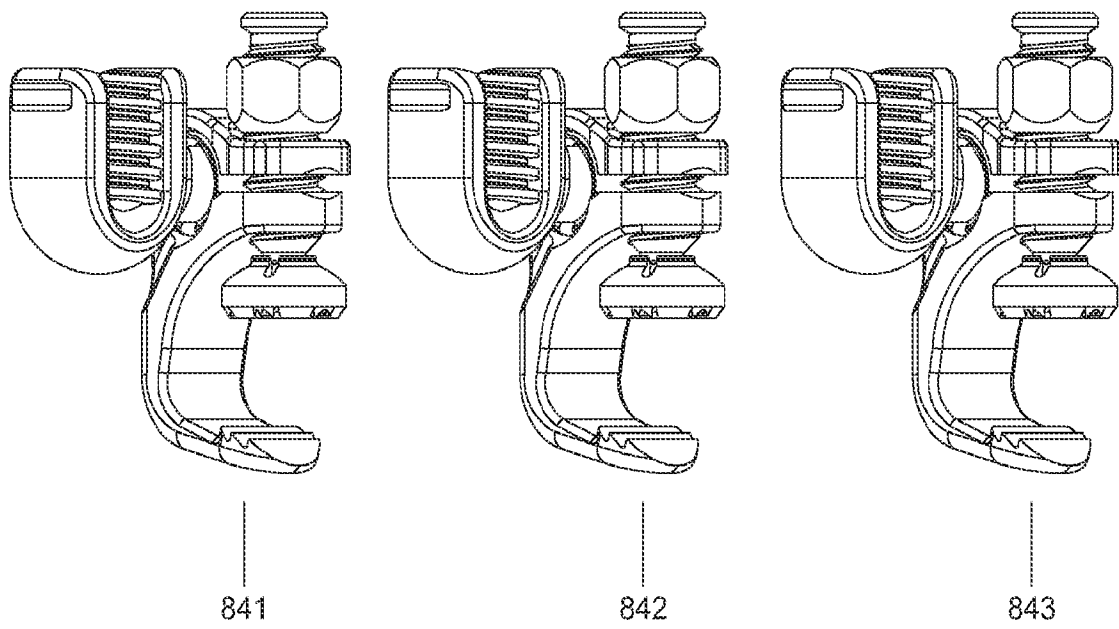


FIG. 10

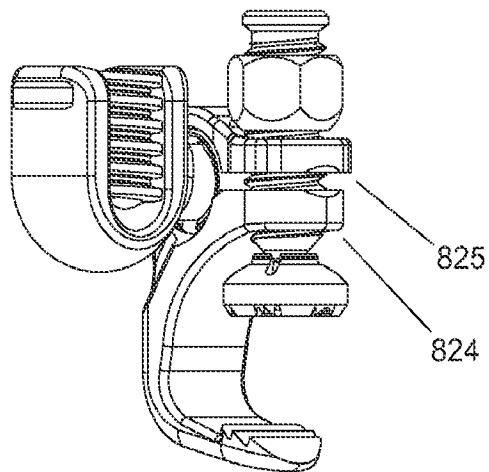


FIG. 11

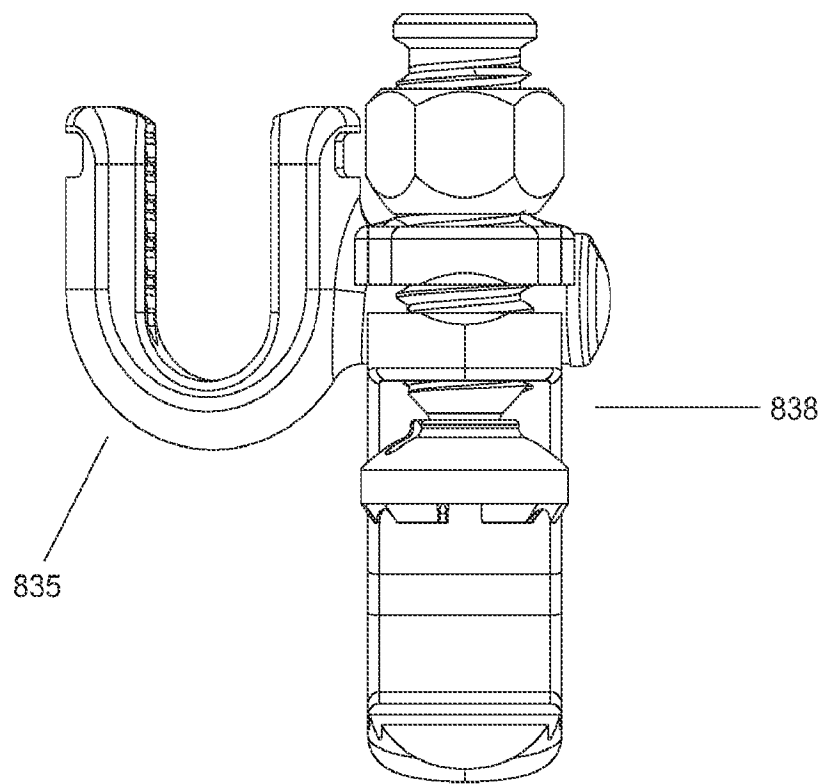


FIG. 12

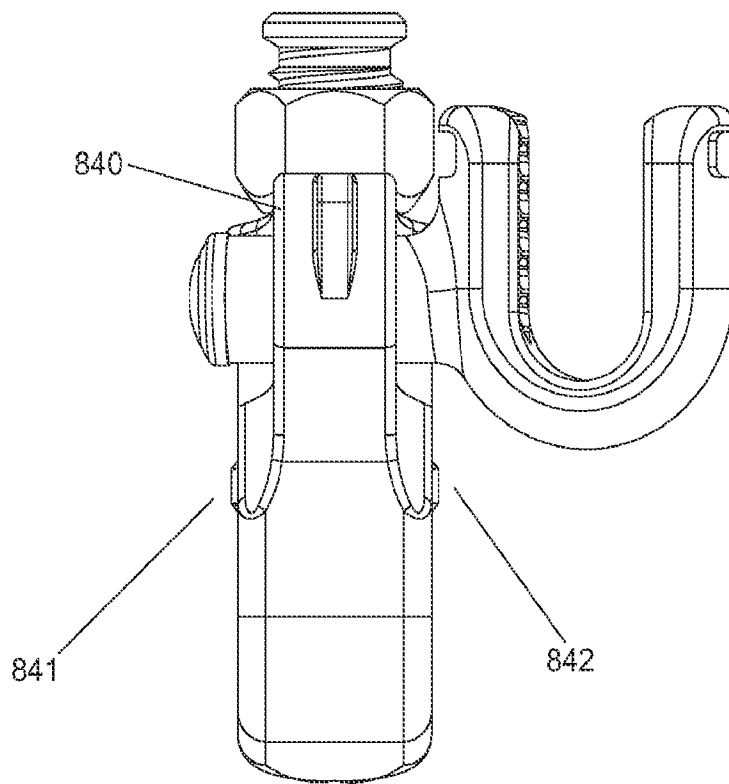


FIG. 13

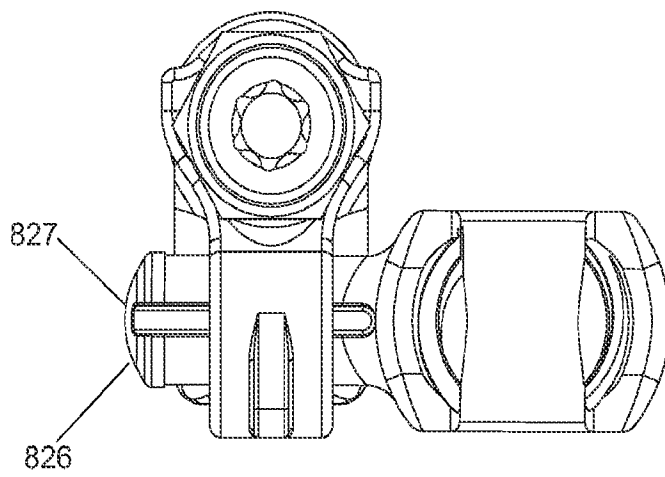


FIG. 14

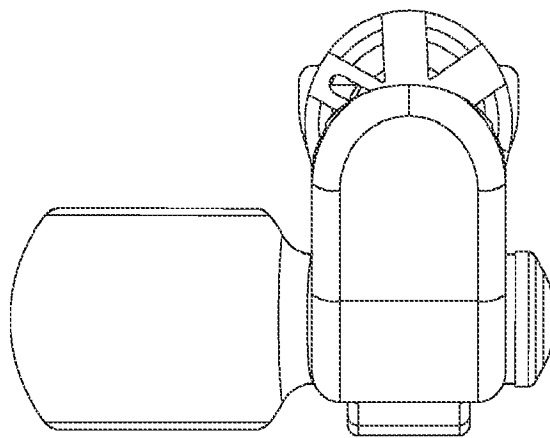


FIG. 15

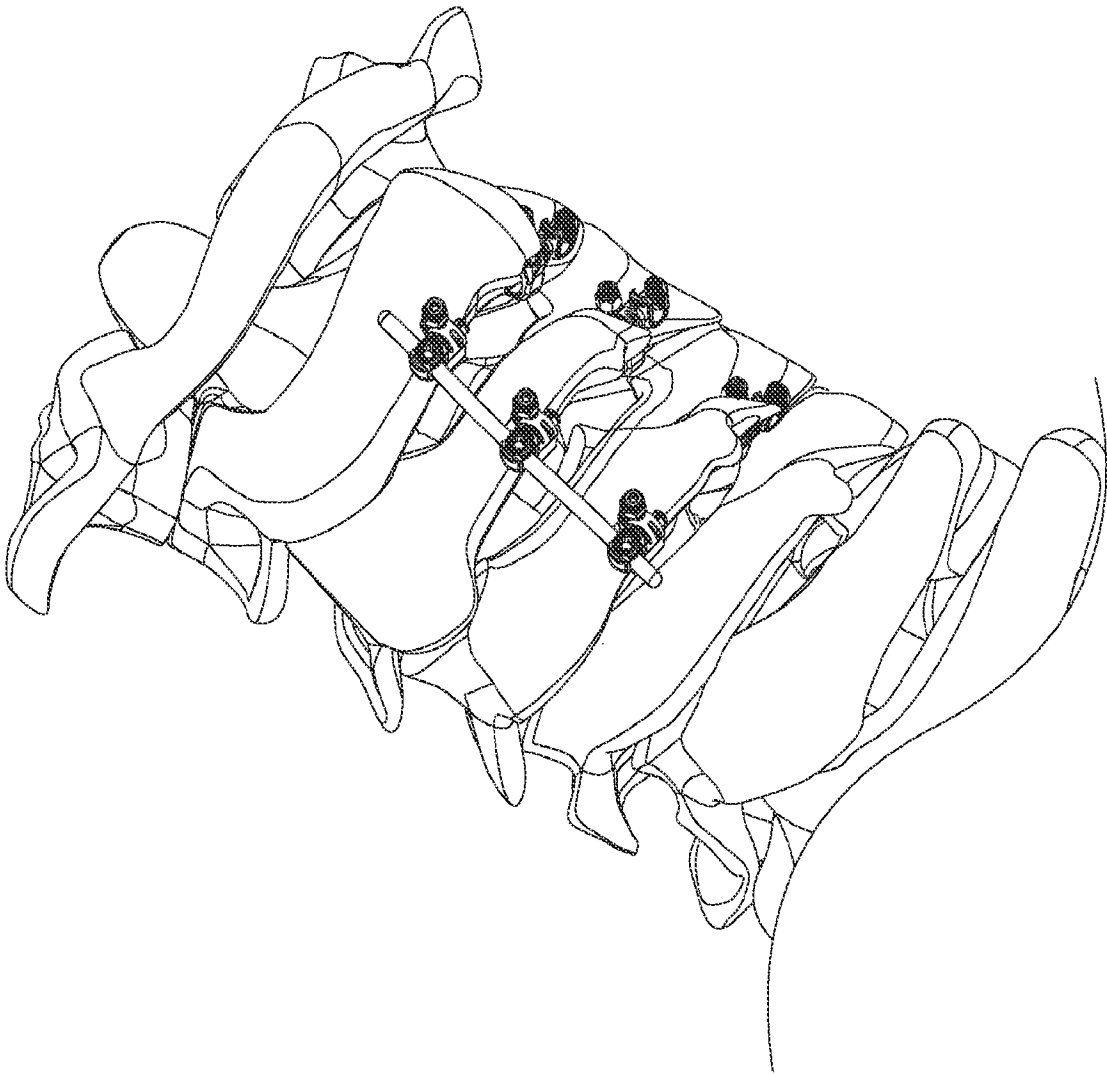


FIG. 16

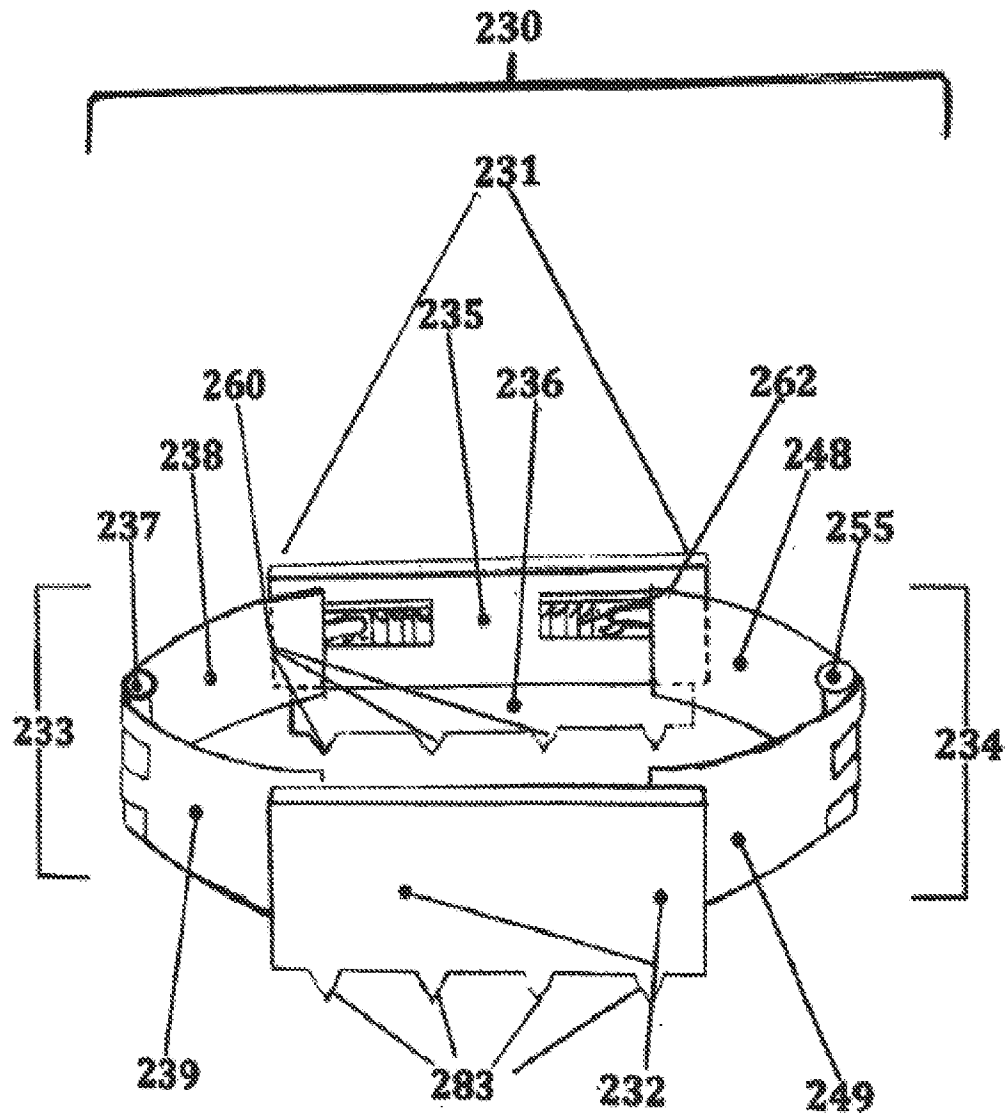


Figure 17 A

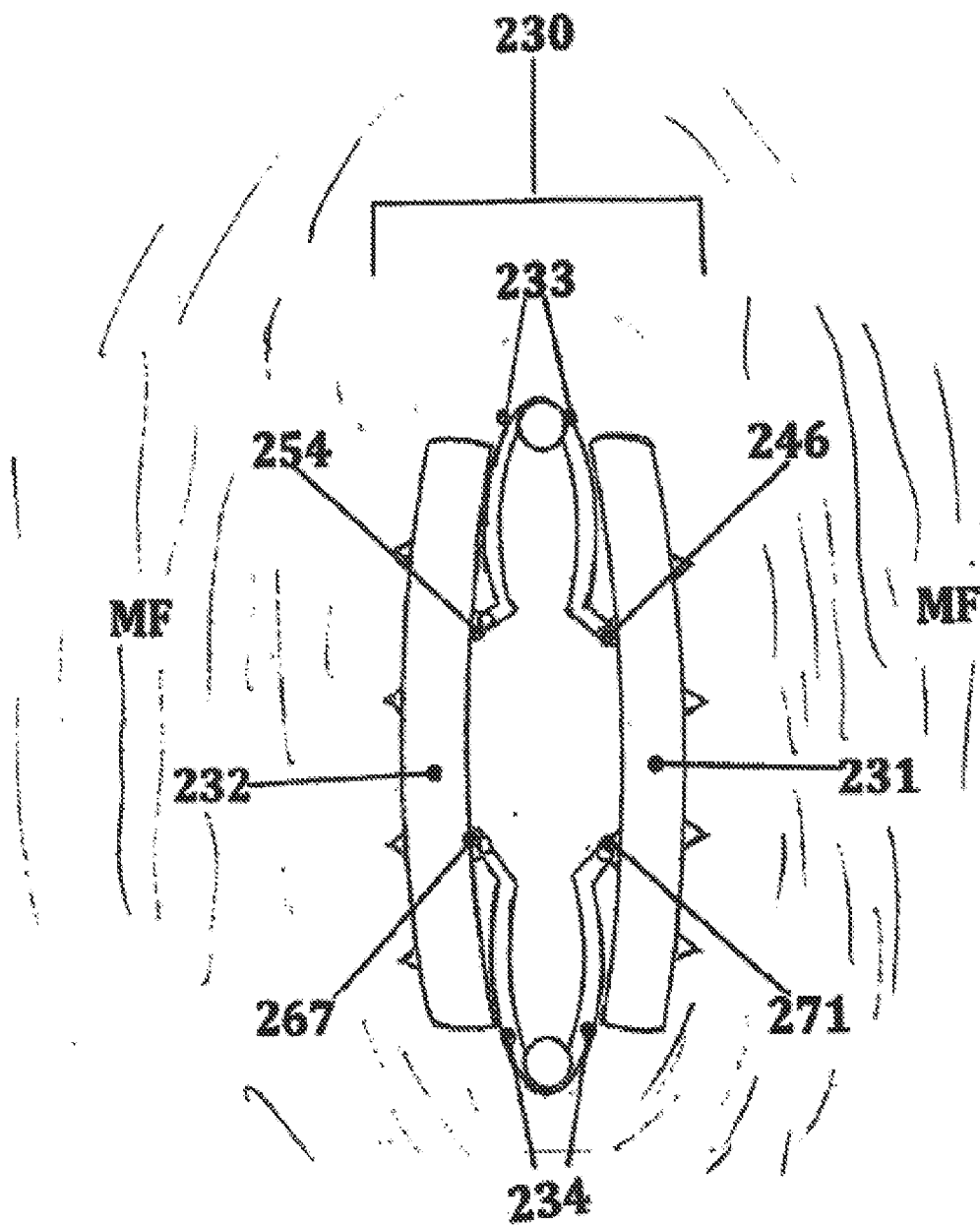


Figure 17 B

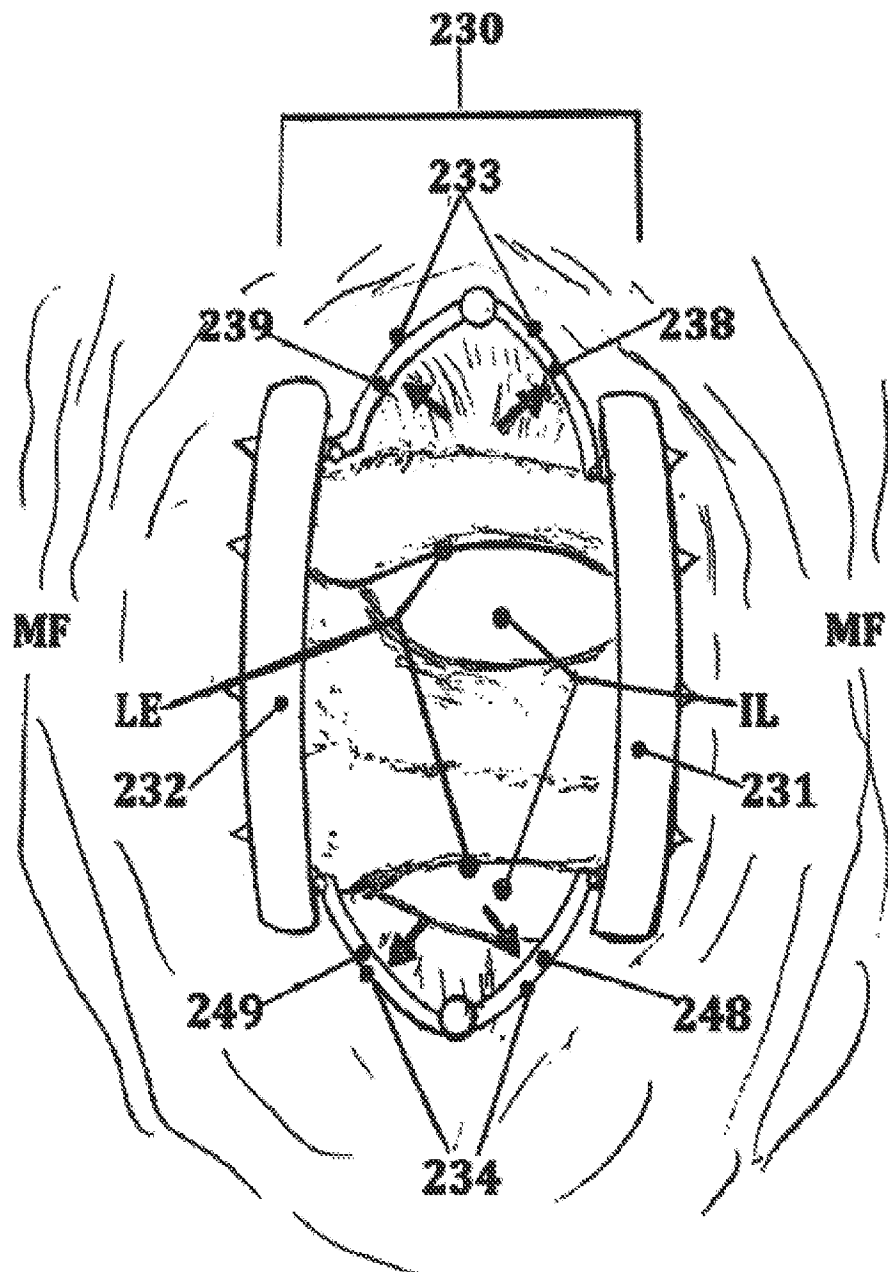


Figure 17 C

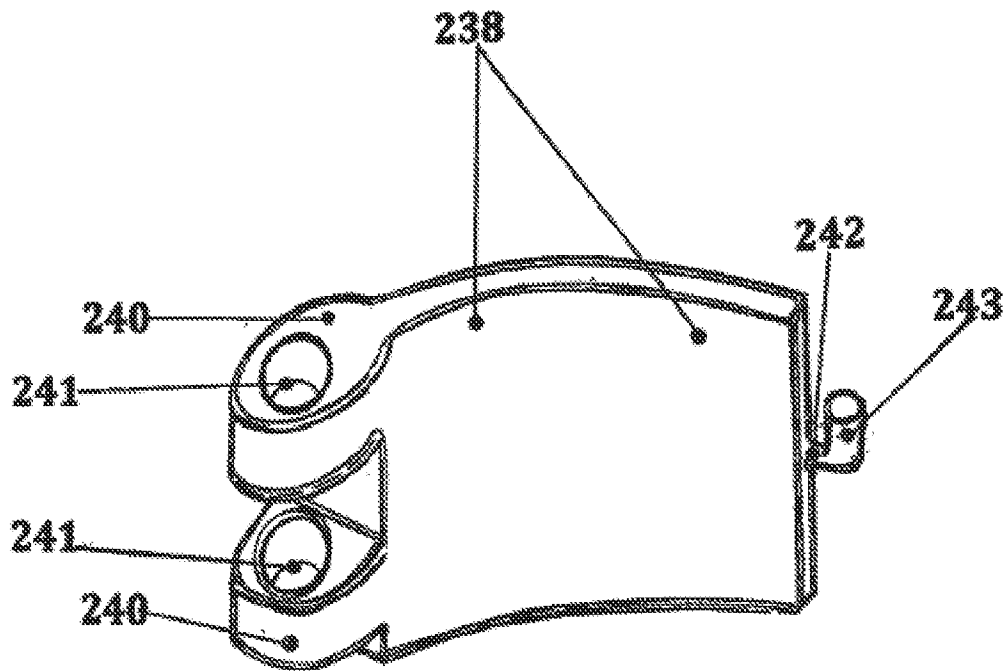
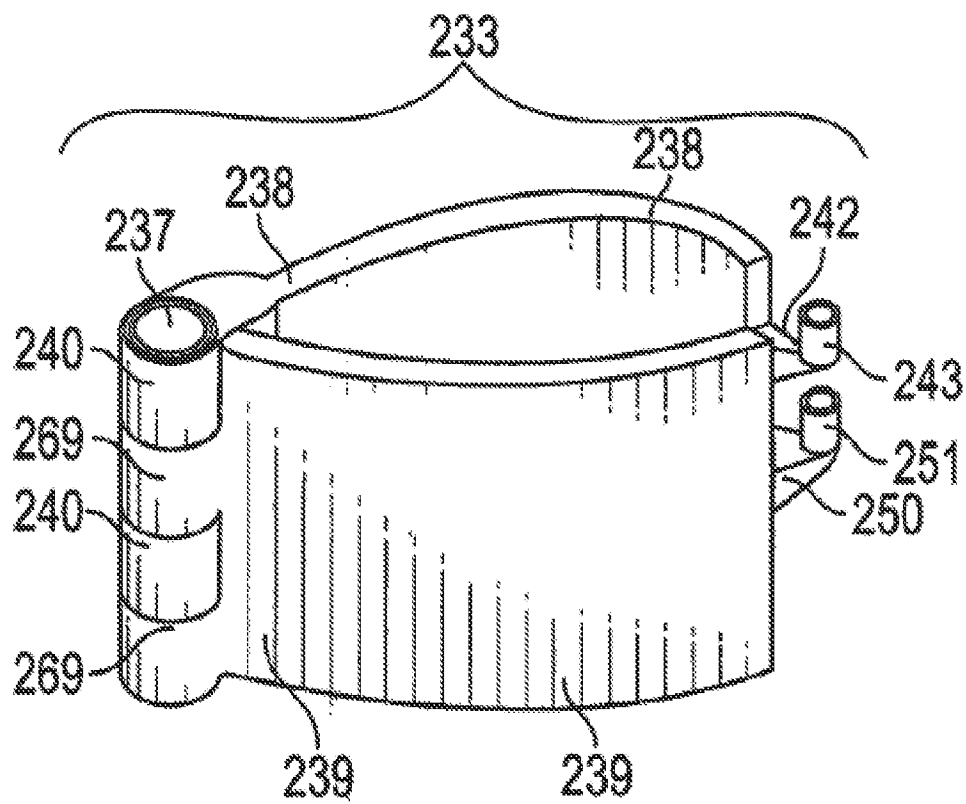


Figure 17 D

**FIG. 17E**

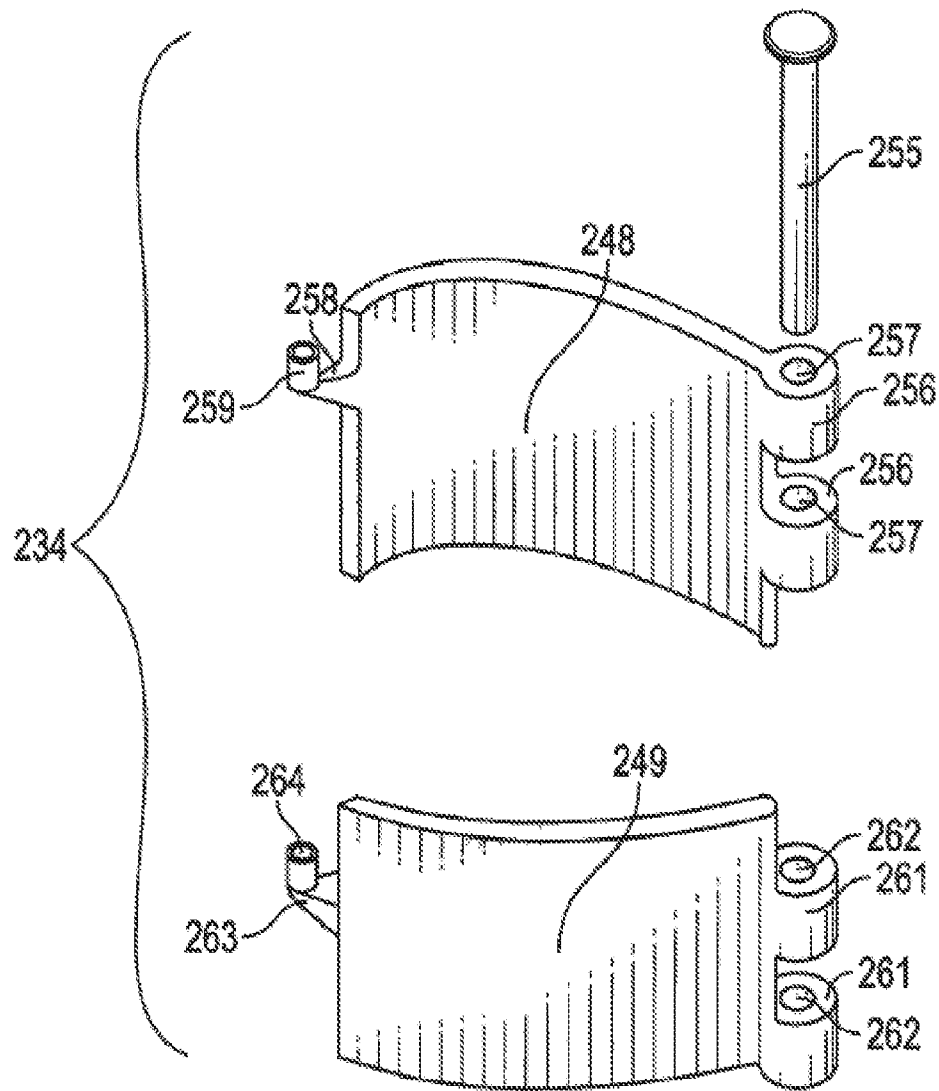


FIG. 17F

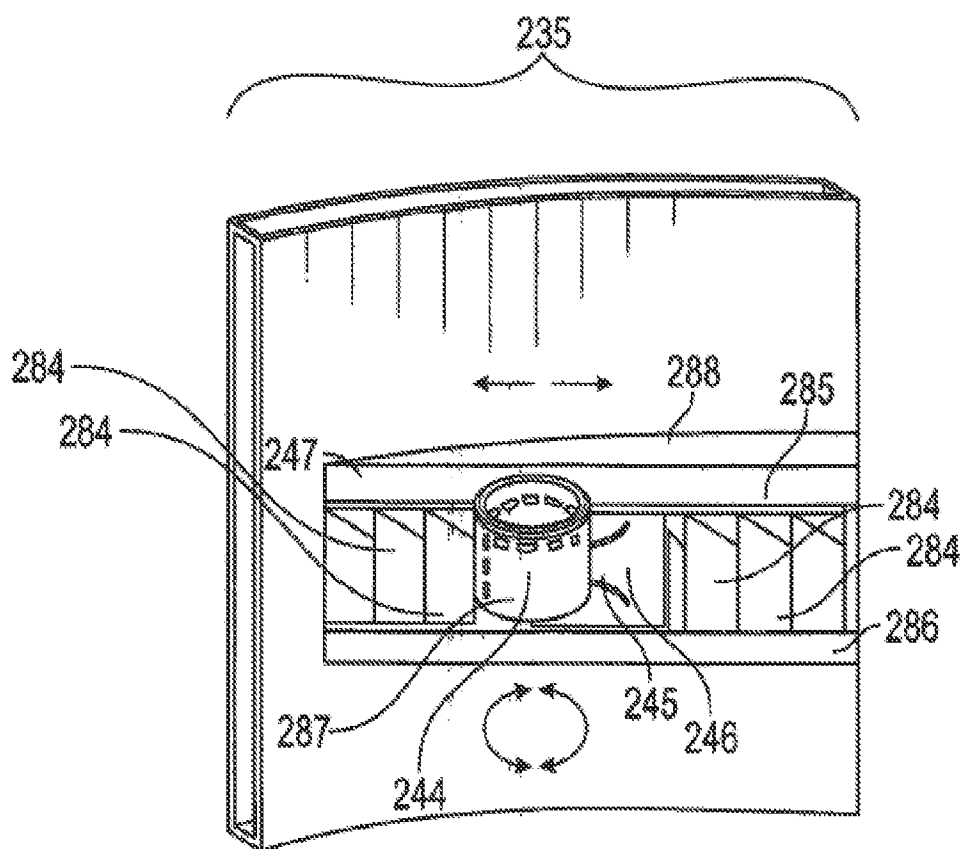
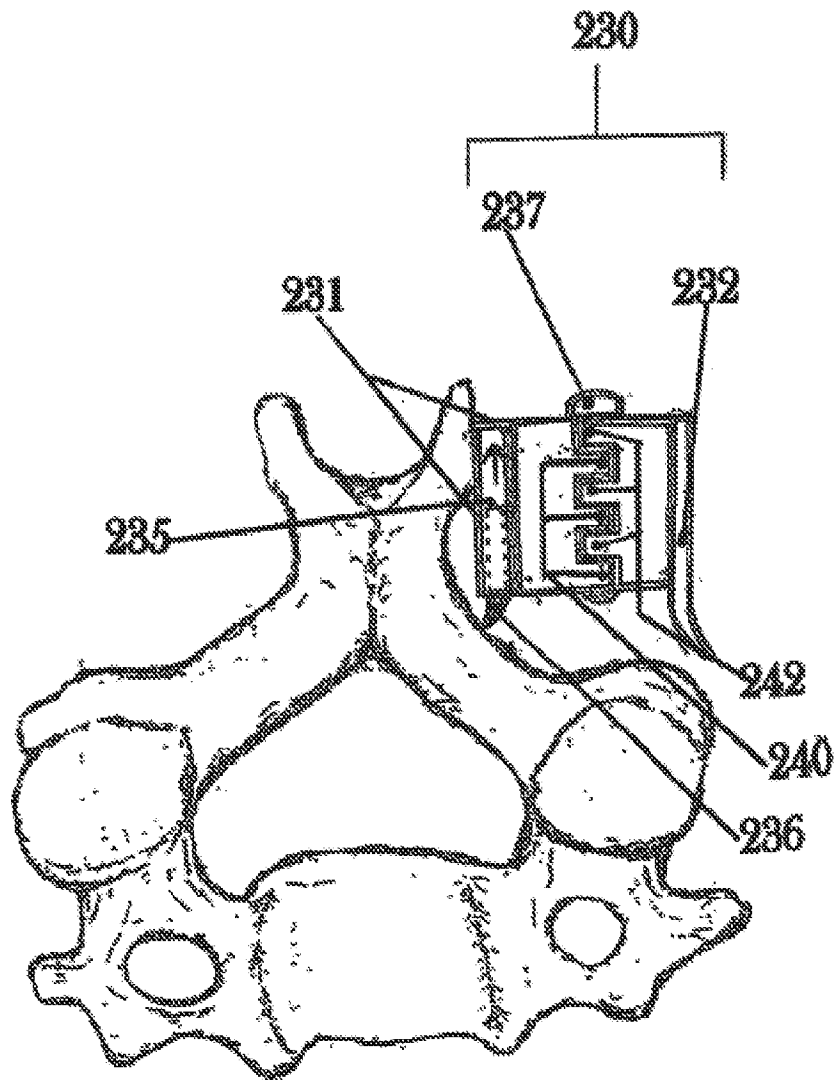


FIG. 17G



C5 Vertebra

Figure 17 H

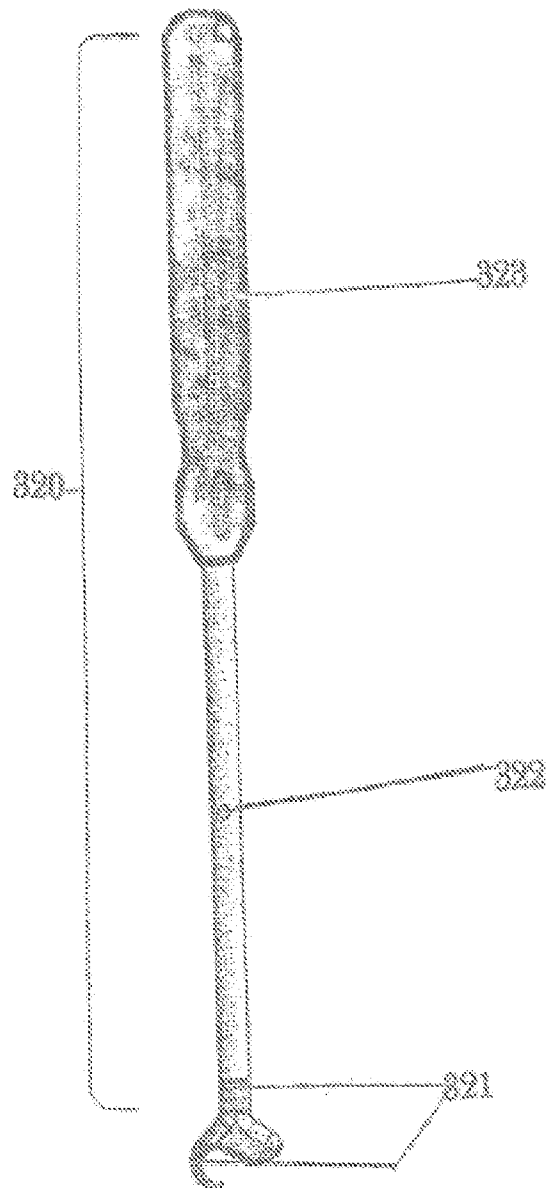


Figure 18 A

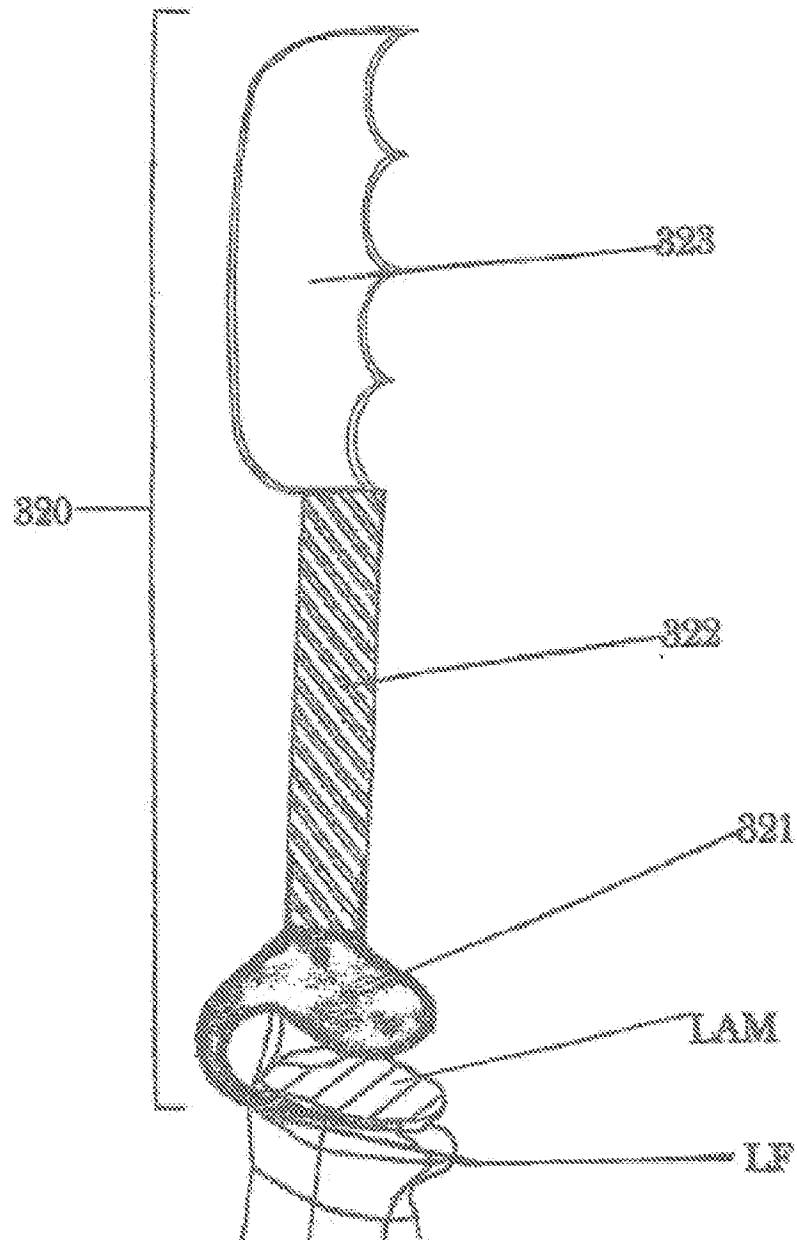


Figure 18 B

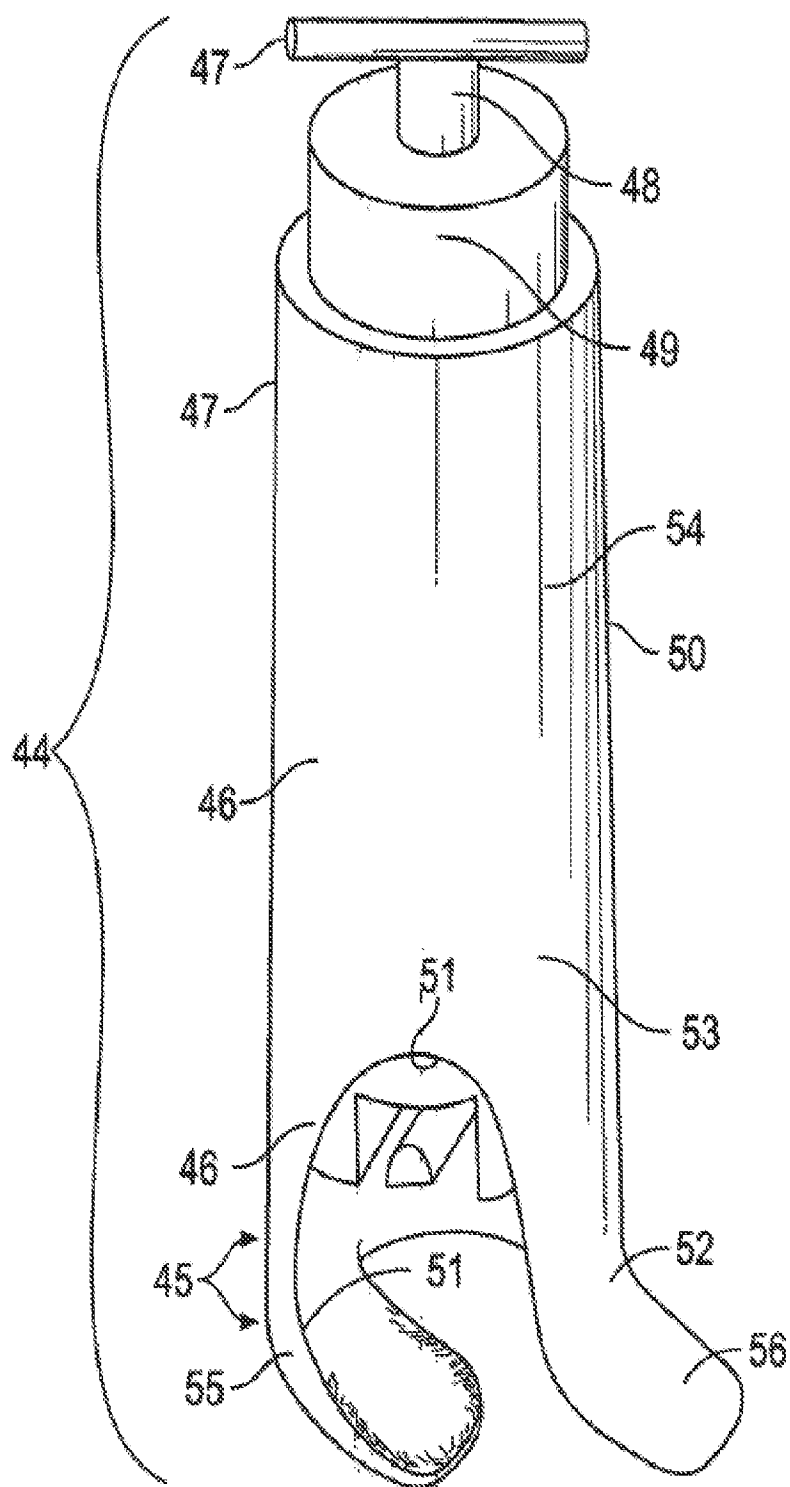


FIG. 19

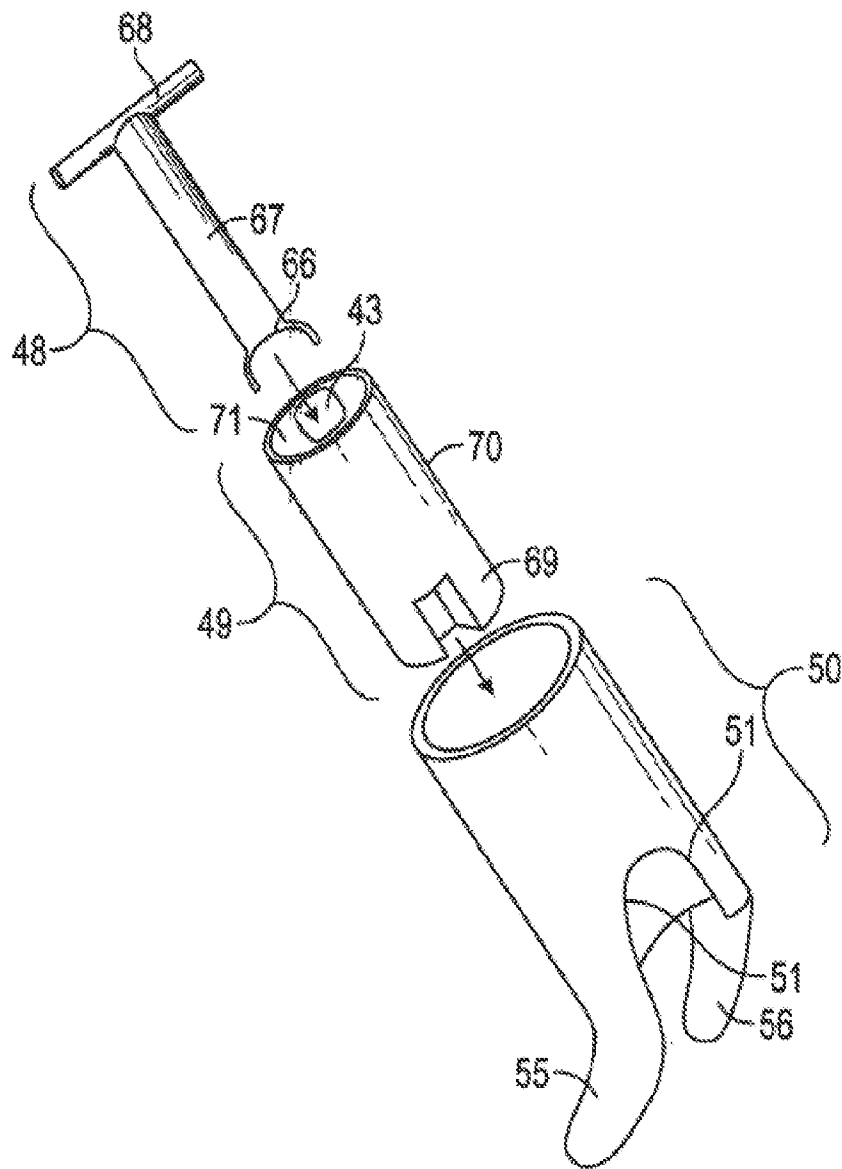


FIG. 20

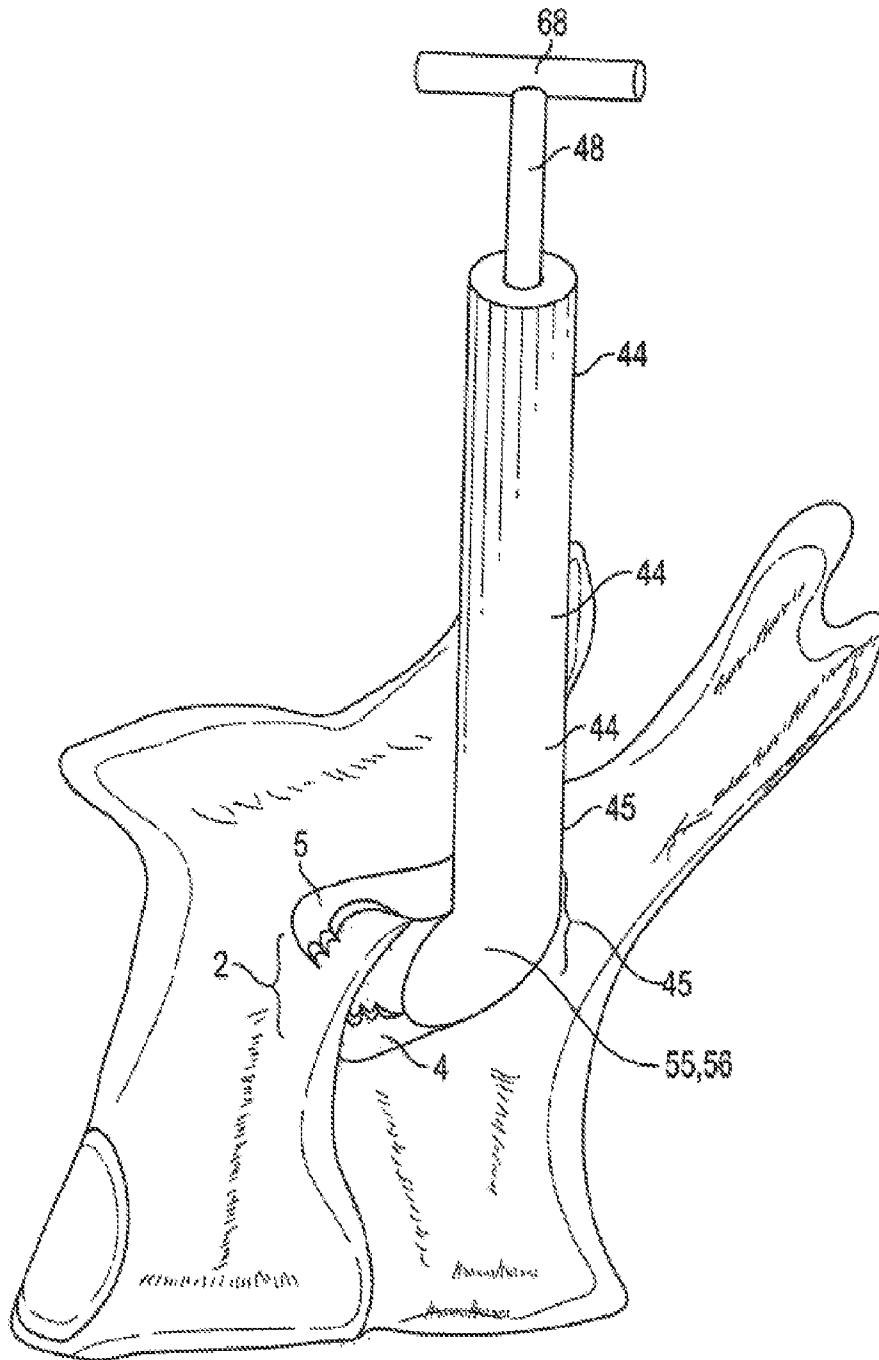


FIG. 21

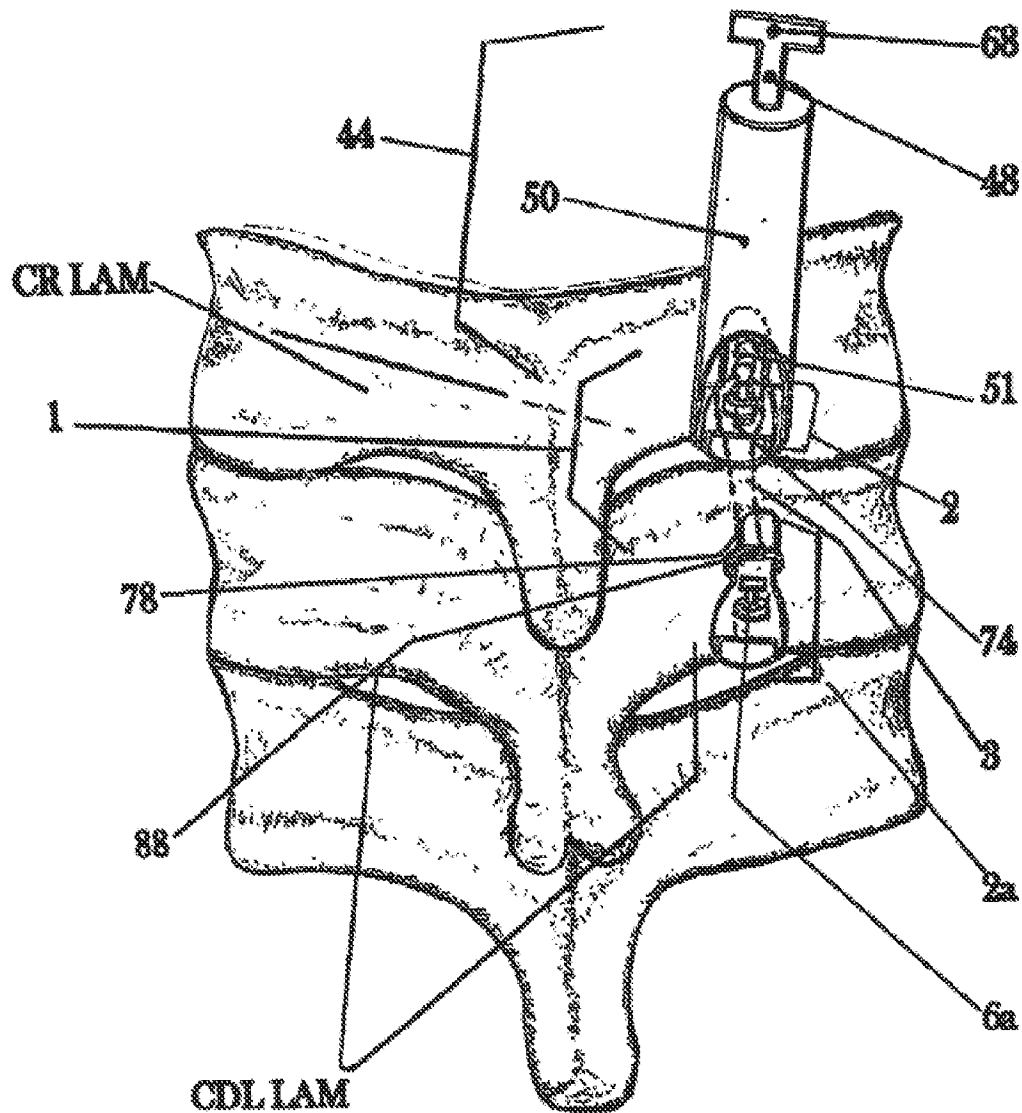


FIGURE 22 A

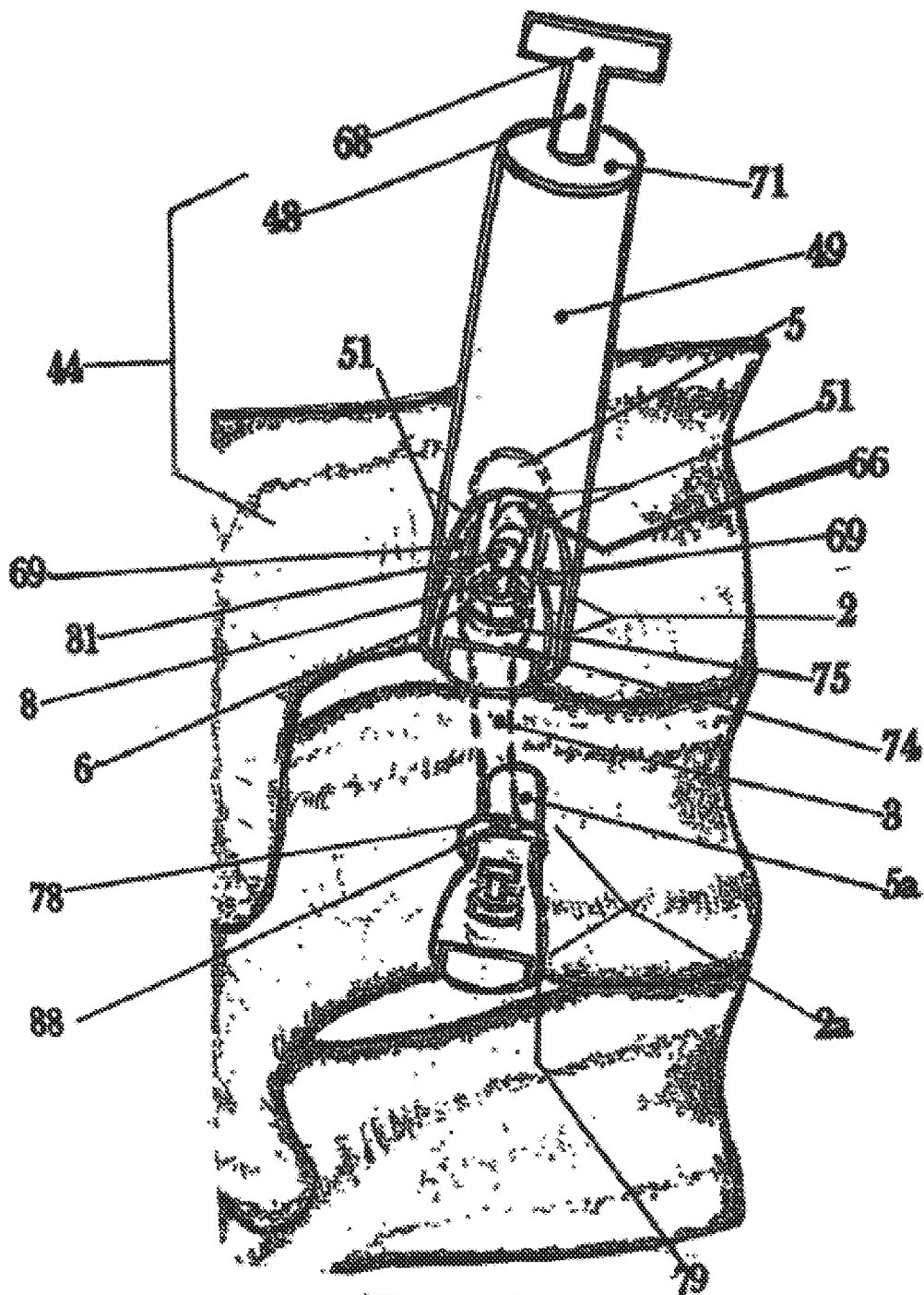


Figure 22 B

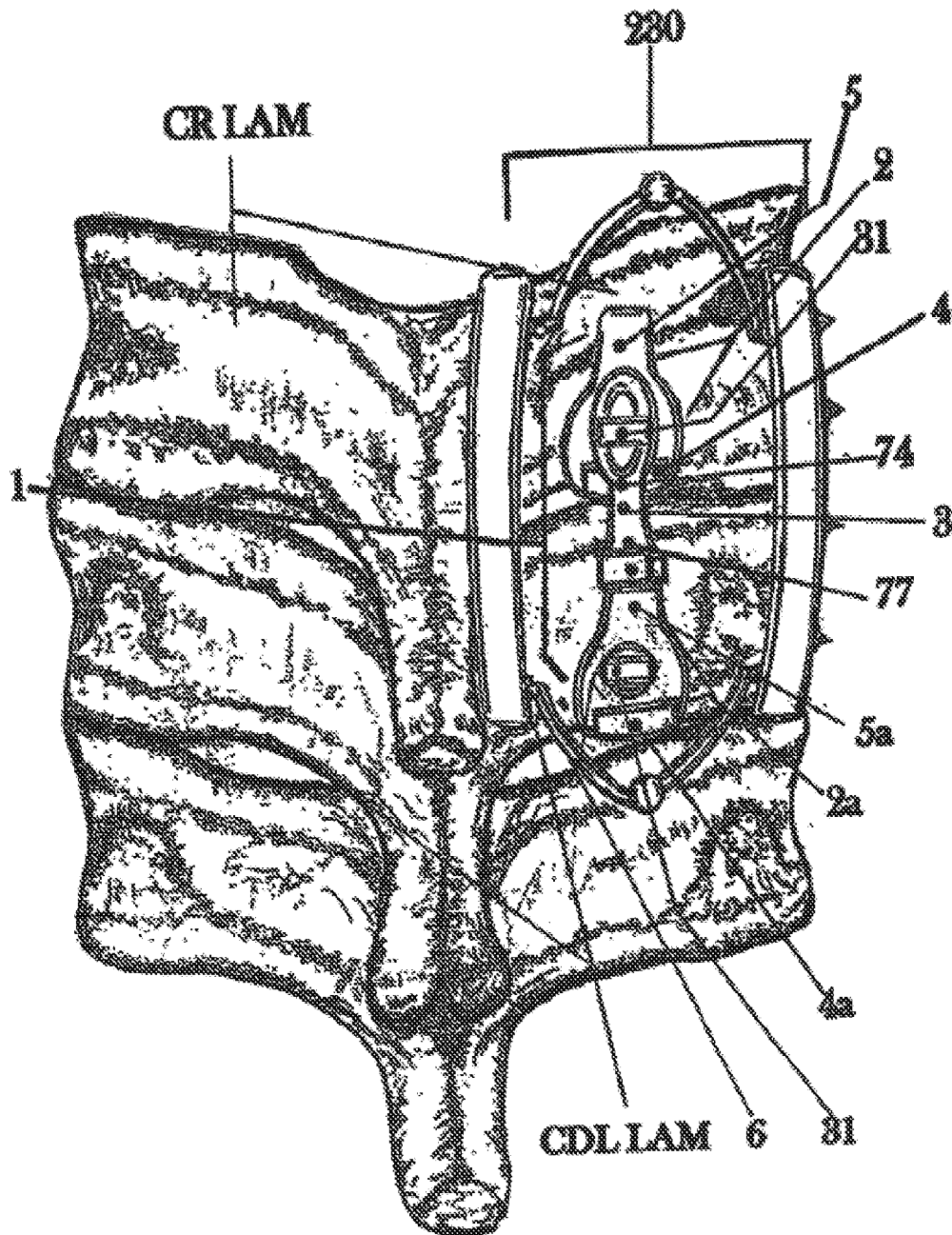


Figure 23

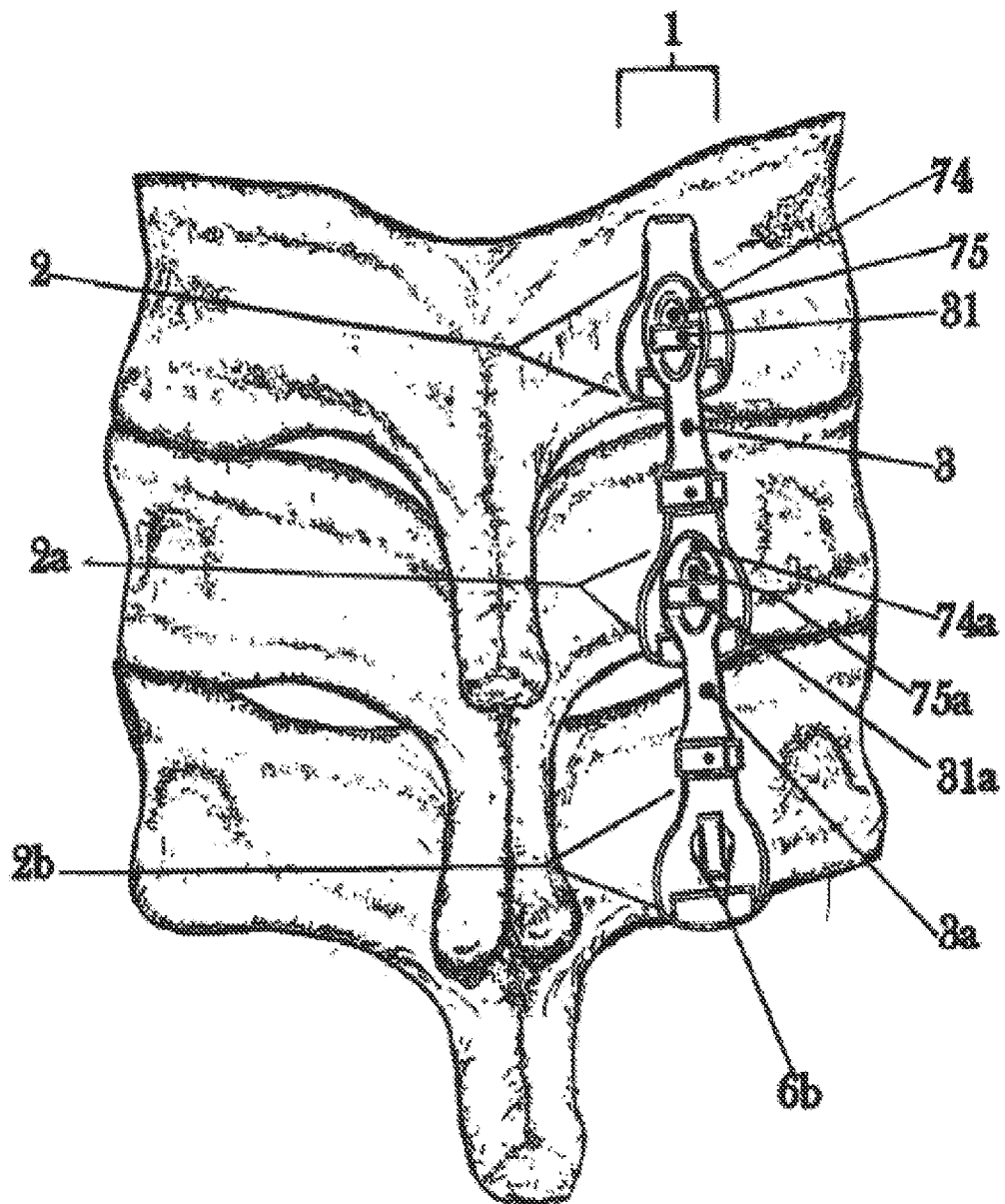


Figure 24

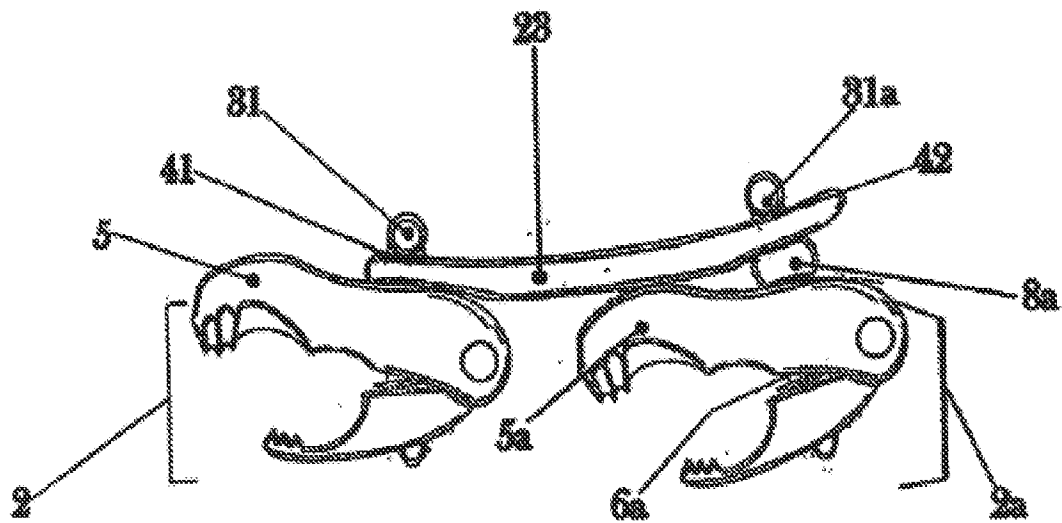


Figure 25

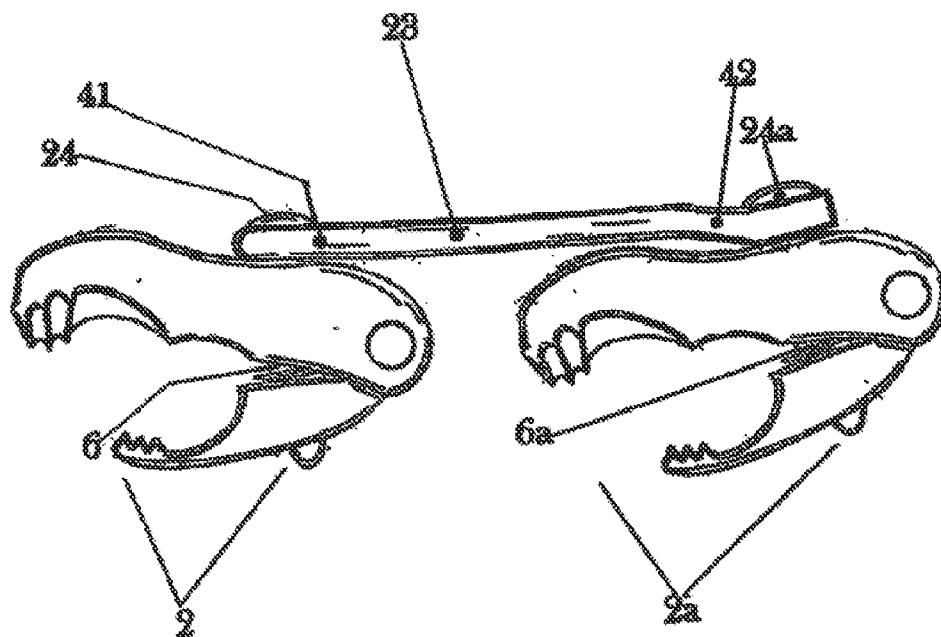


Figure 26

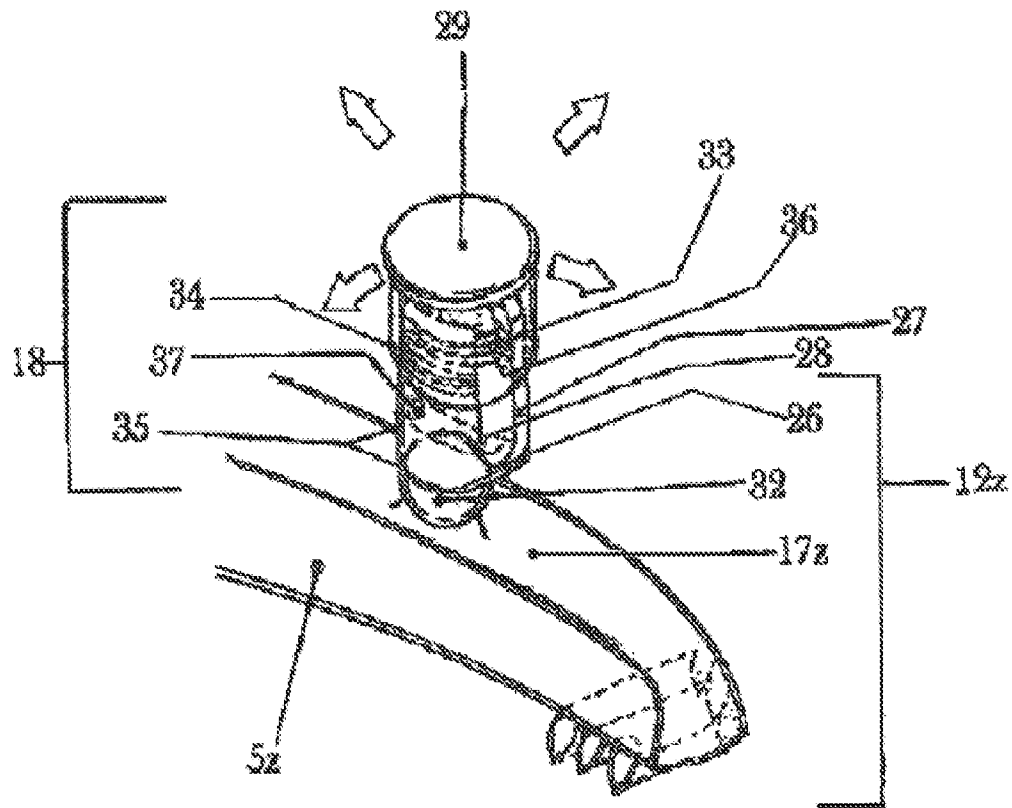


Figure 27

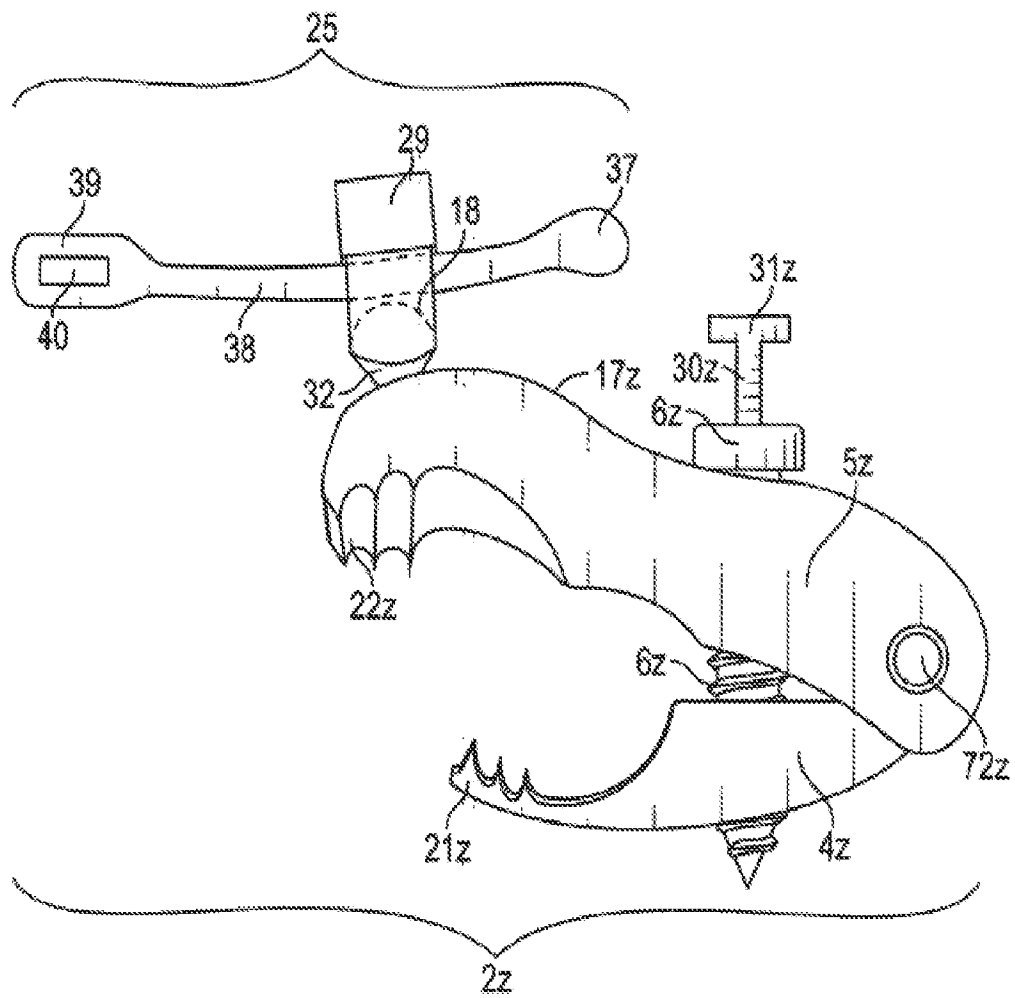


FIG. 28

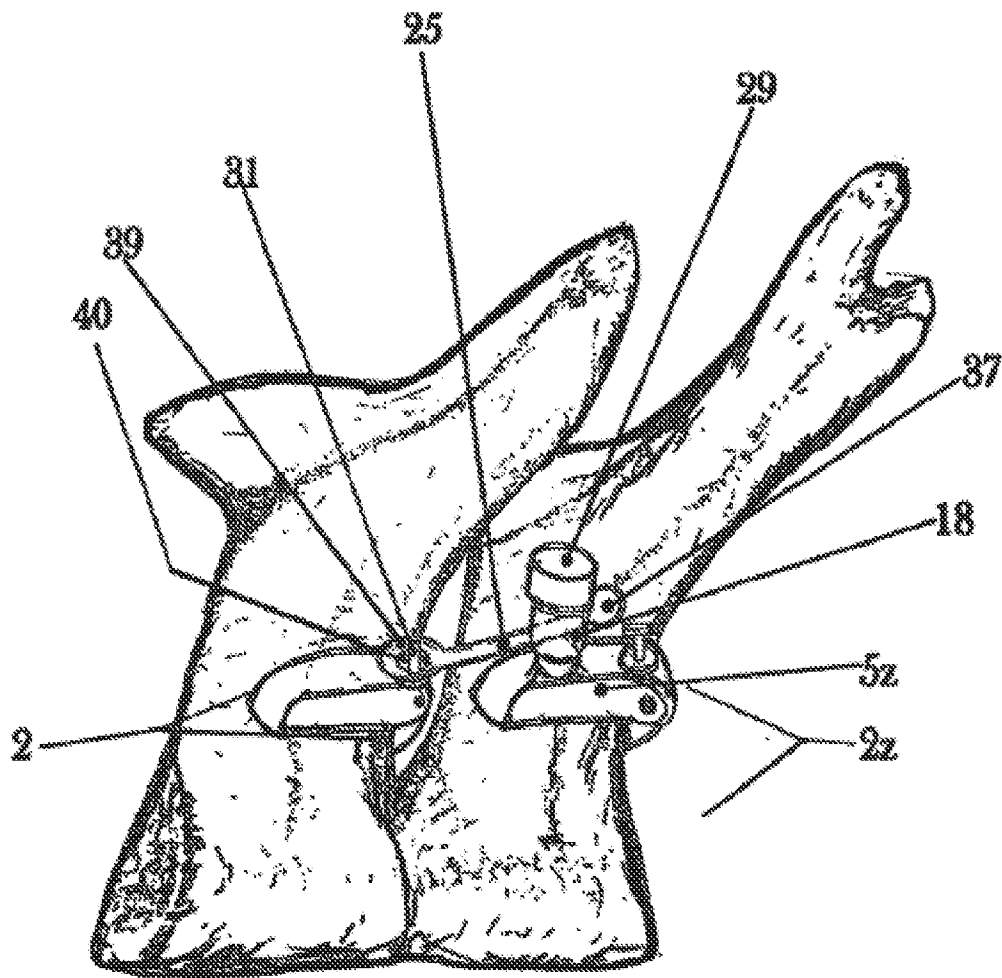


Figure 29

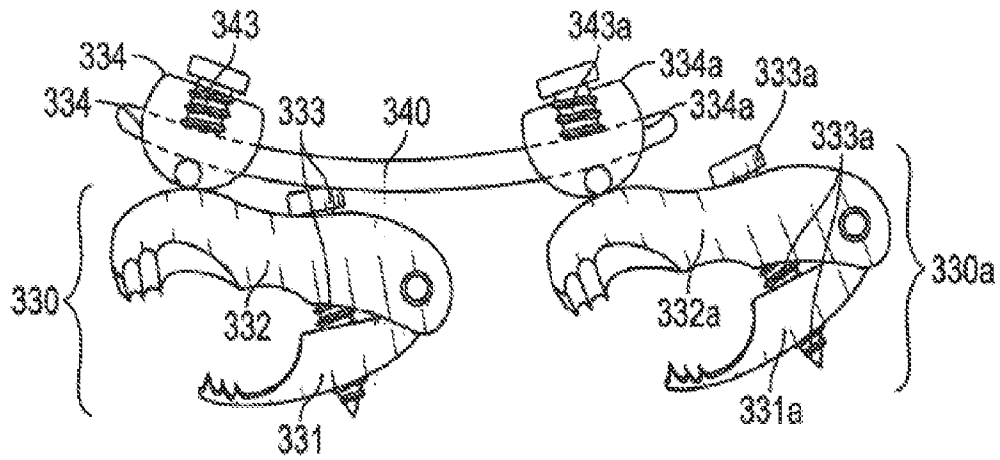


FIG. 30A

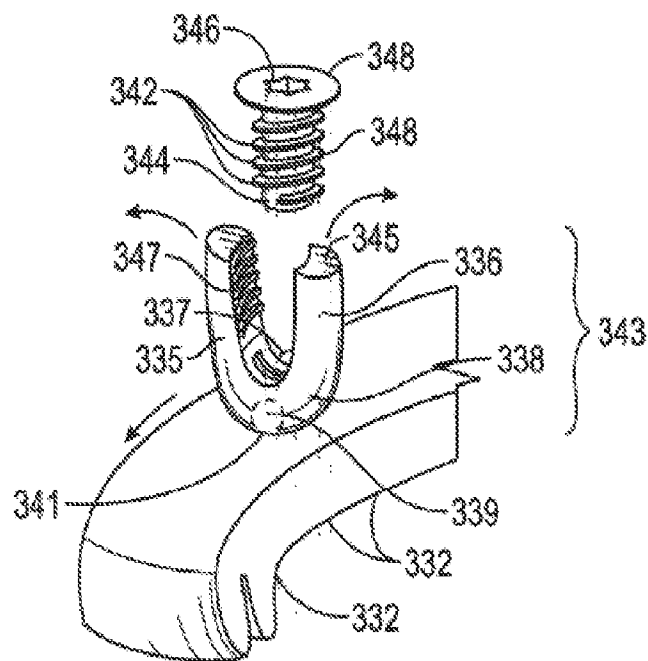


FIG. 30B

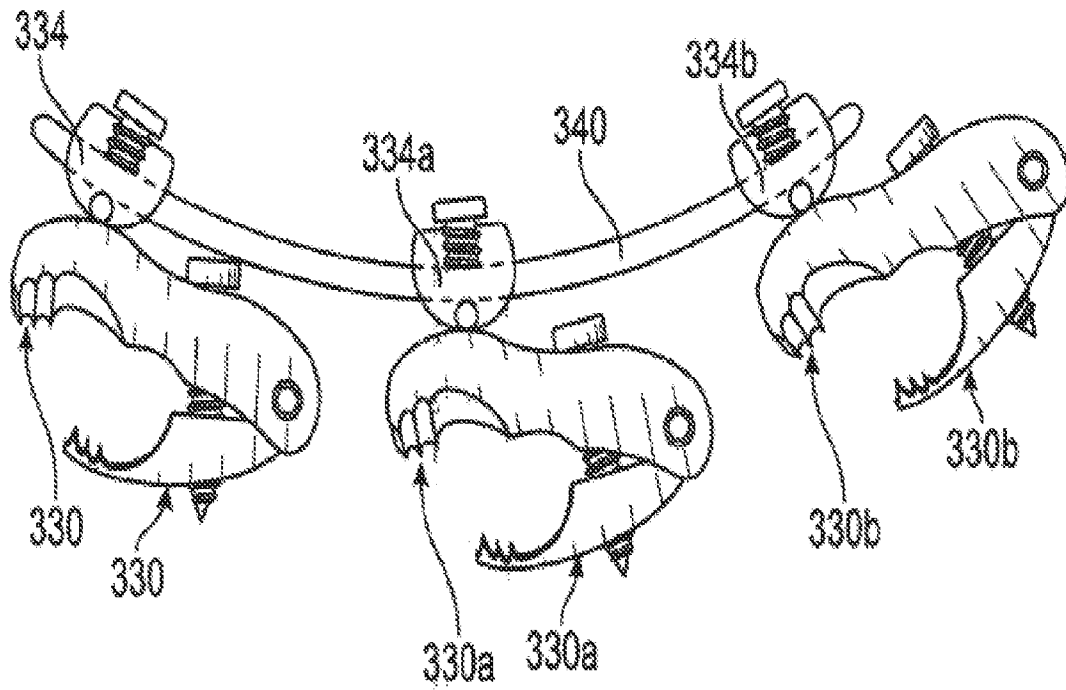


FIG. 30C

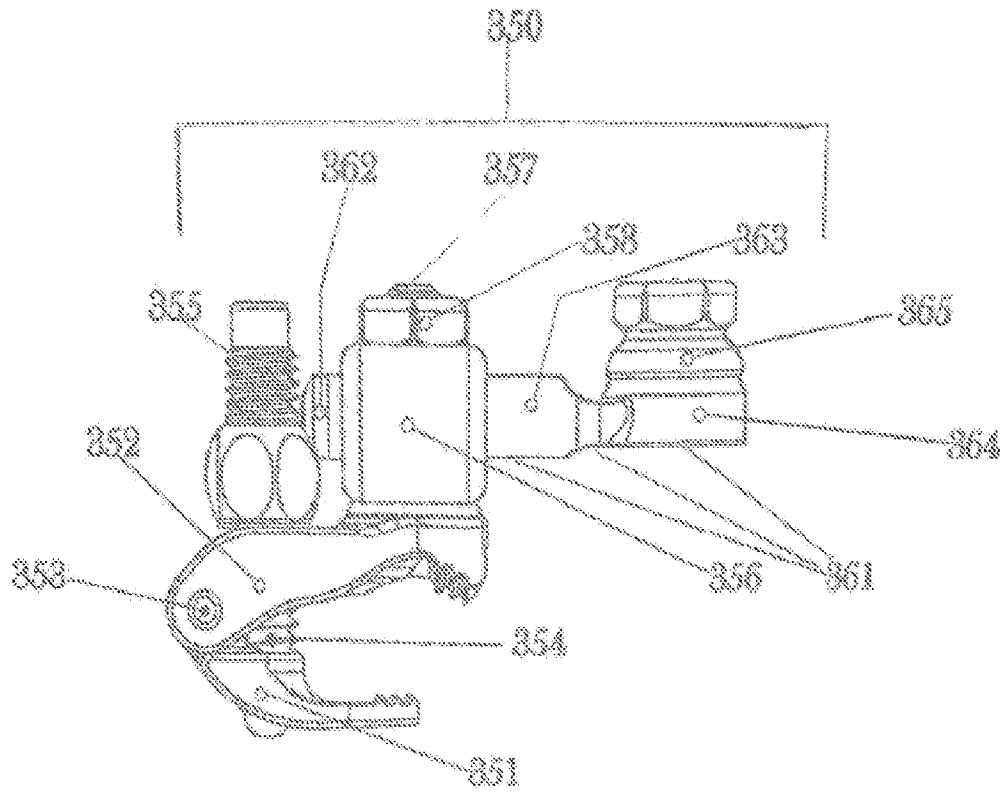


Figure 31

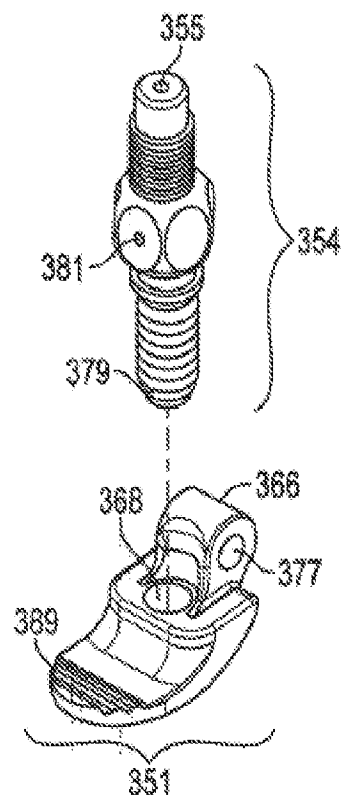


FIG. 32A

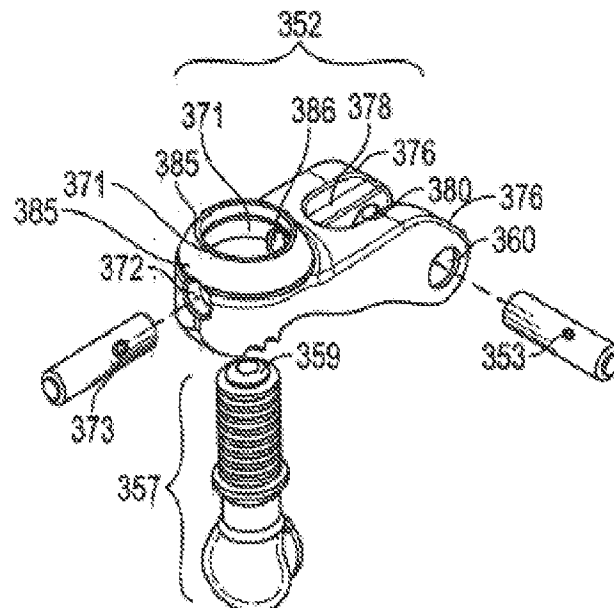


FIG. 32B

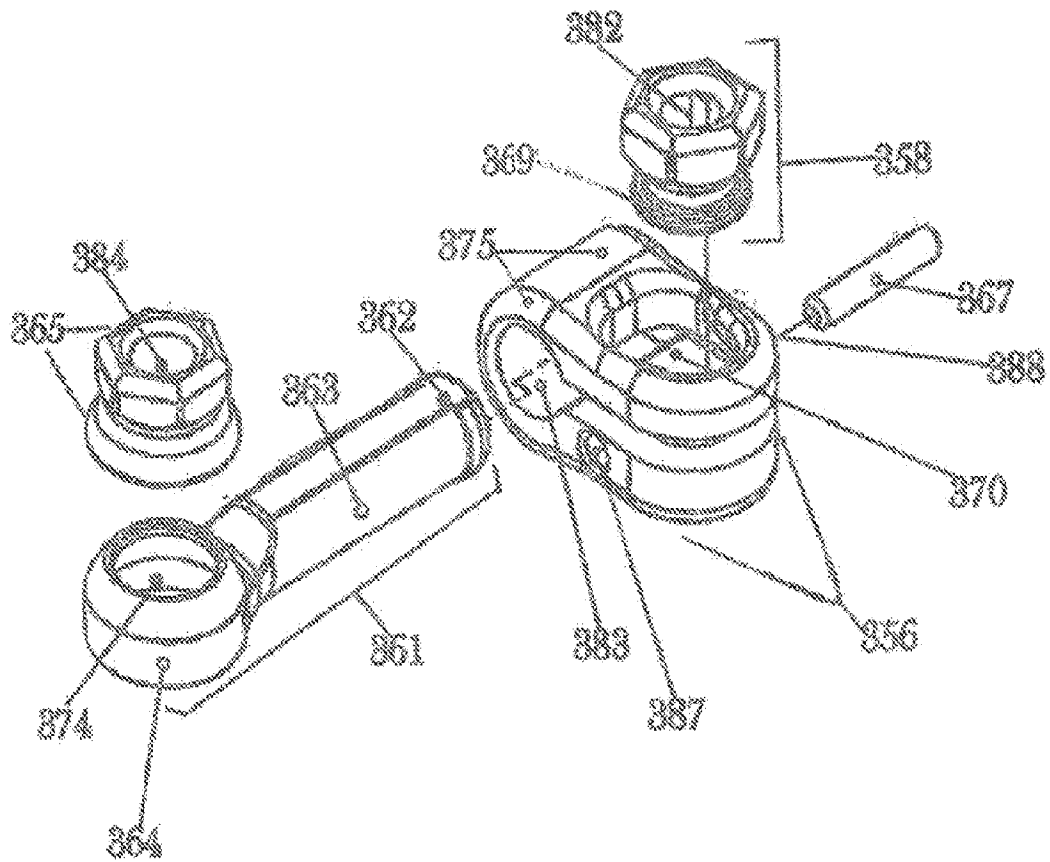


Figure 32 C

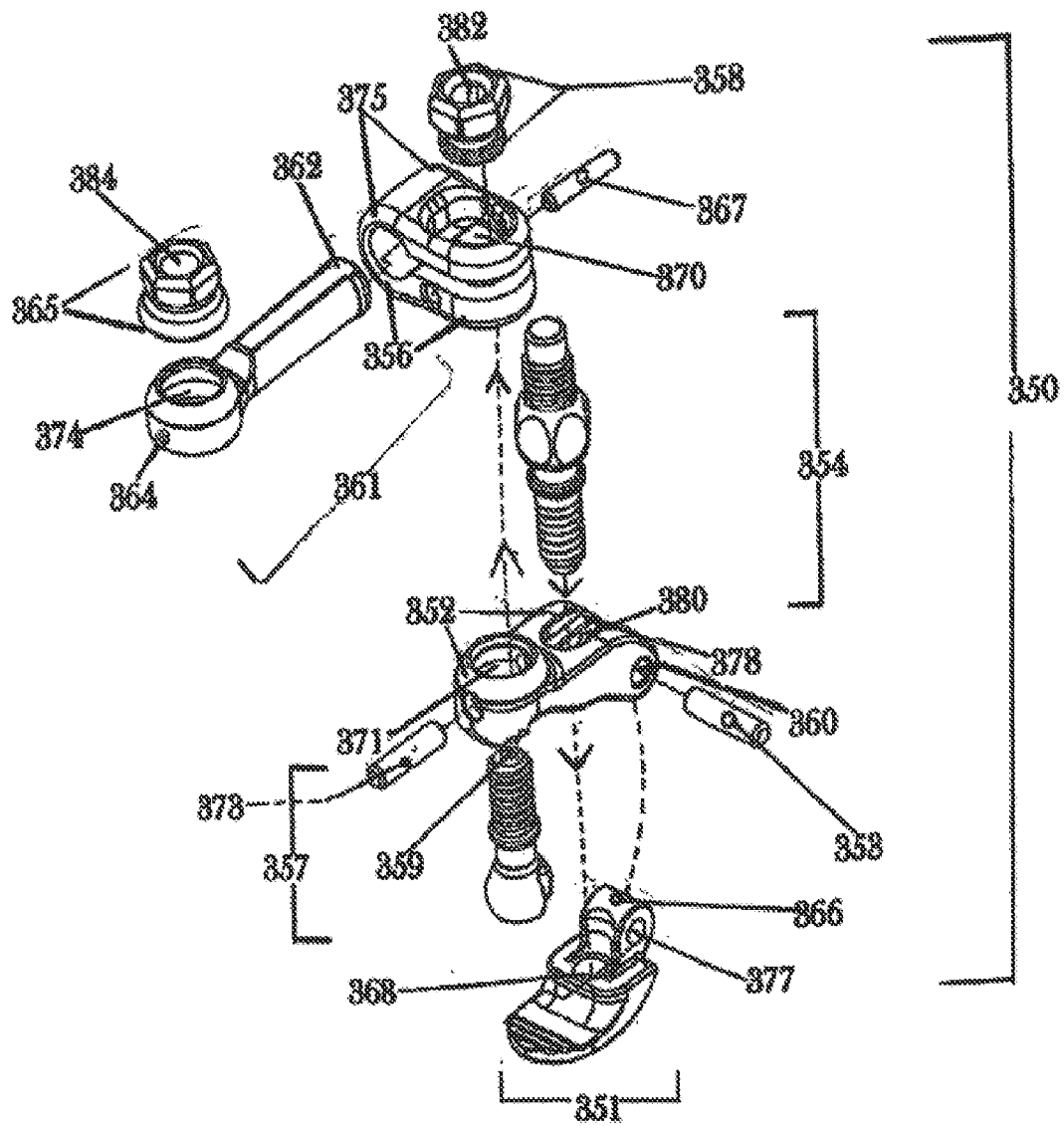


Figure 32 D

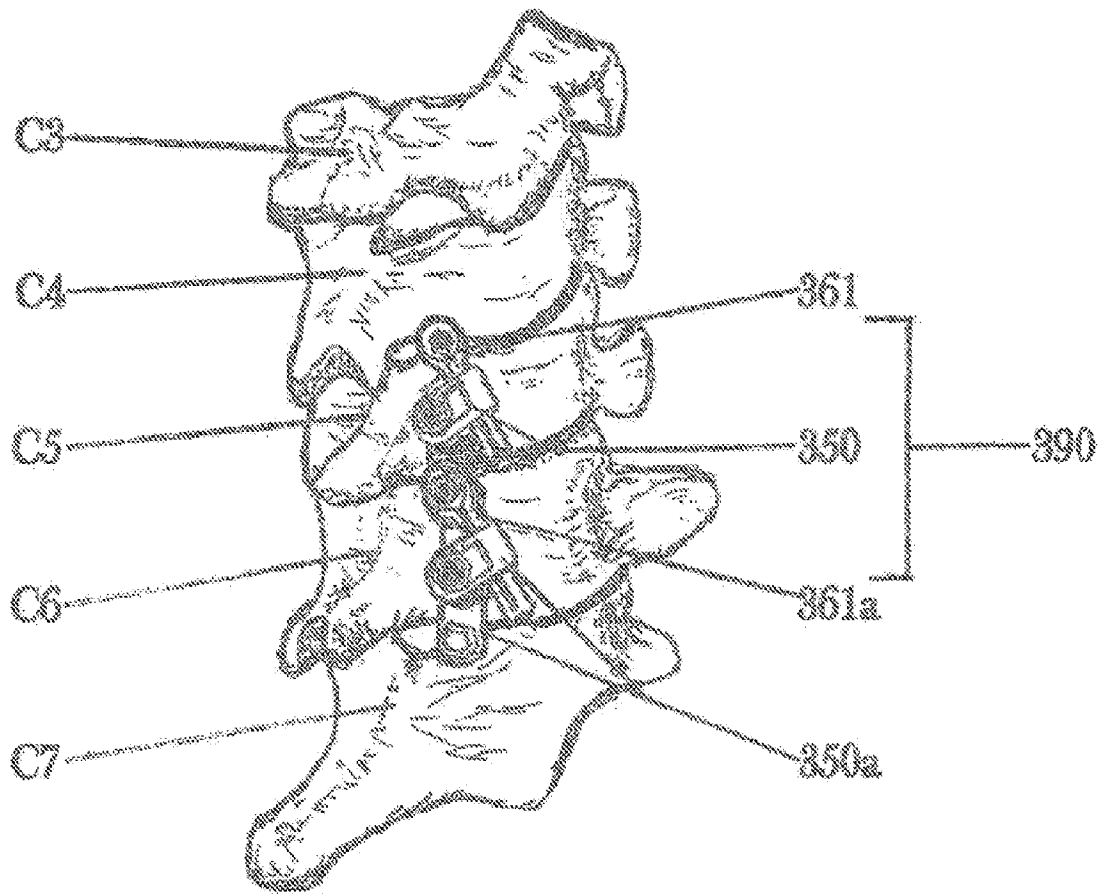


Figure 38

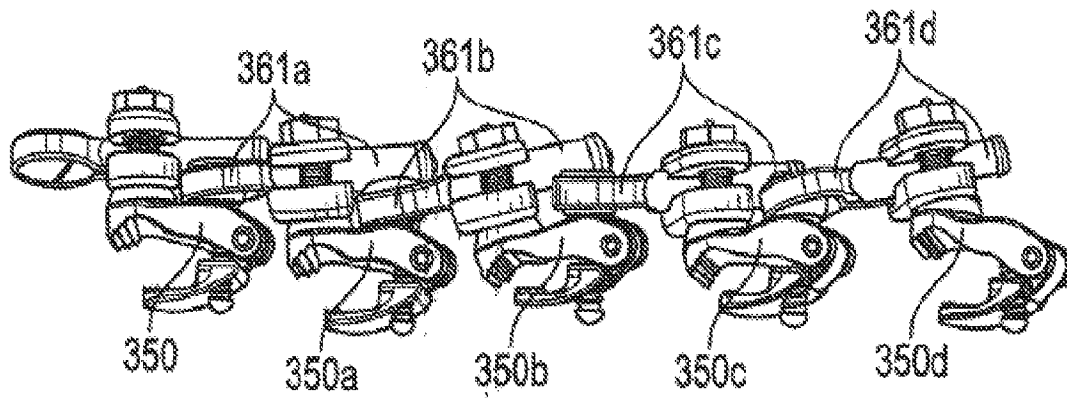


FIG. 34

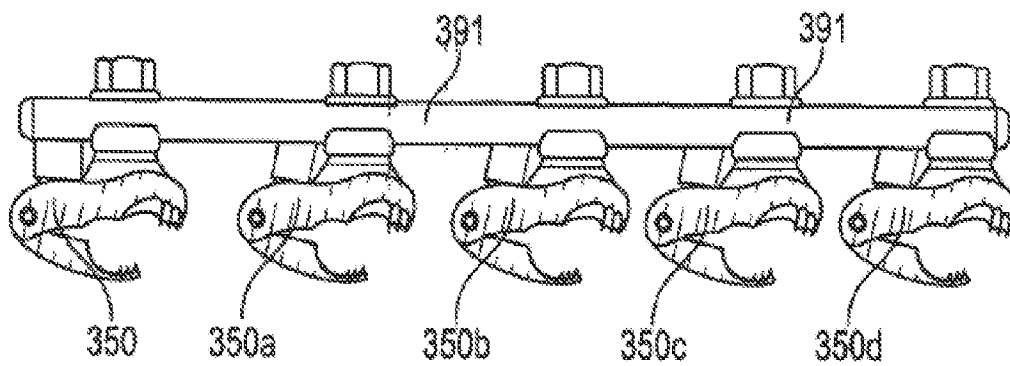


FIG. 35

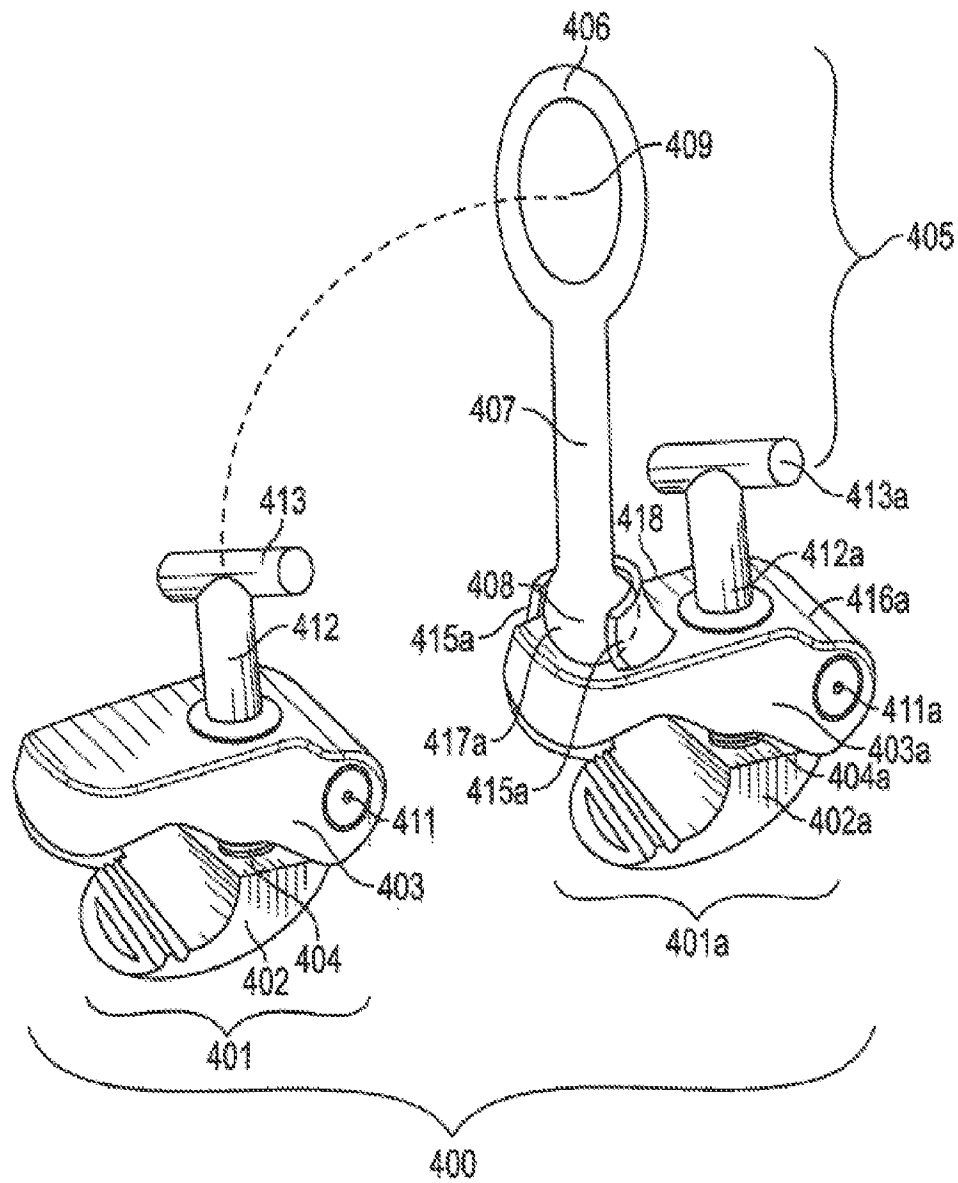


FIG. 36A

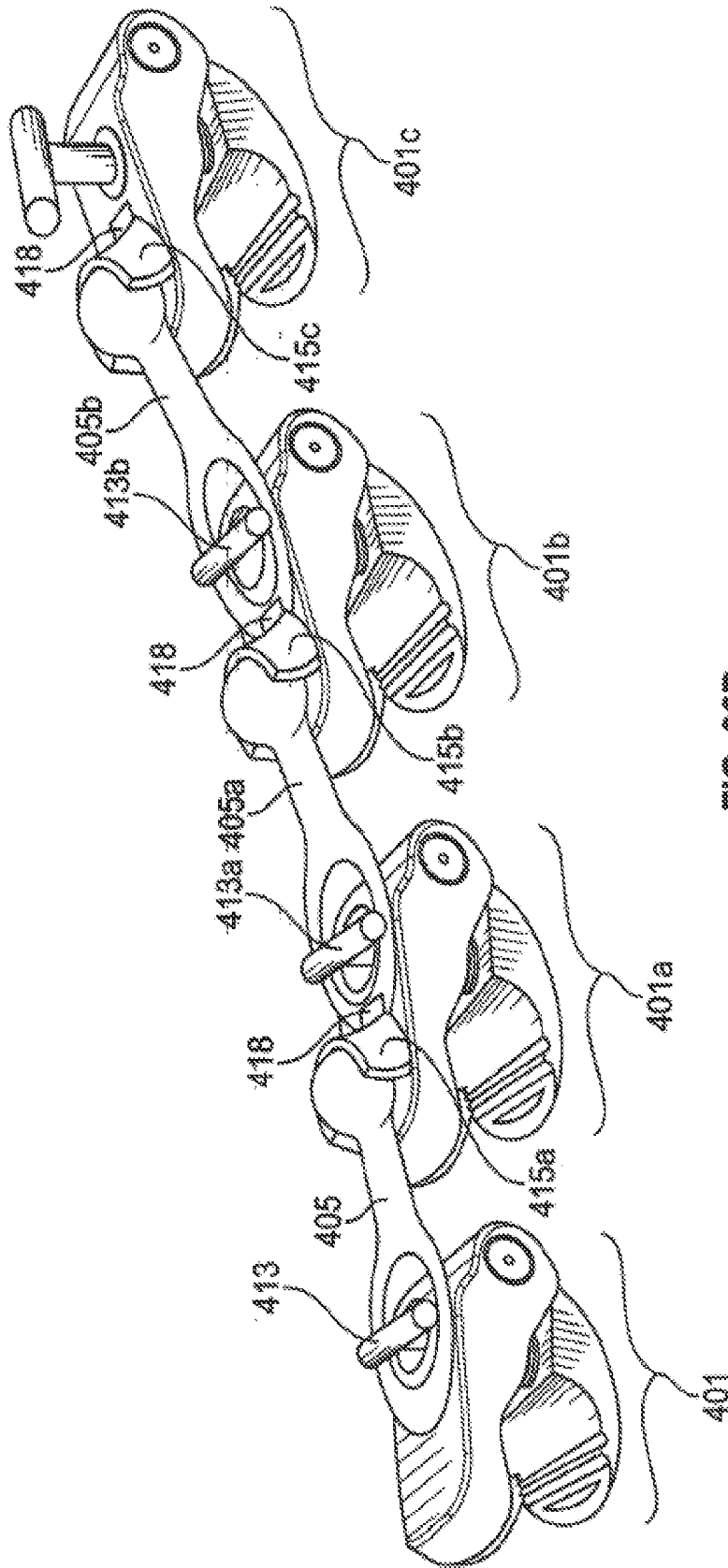


FIG. 36B

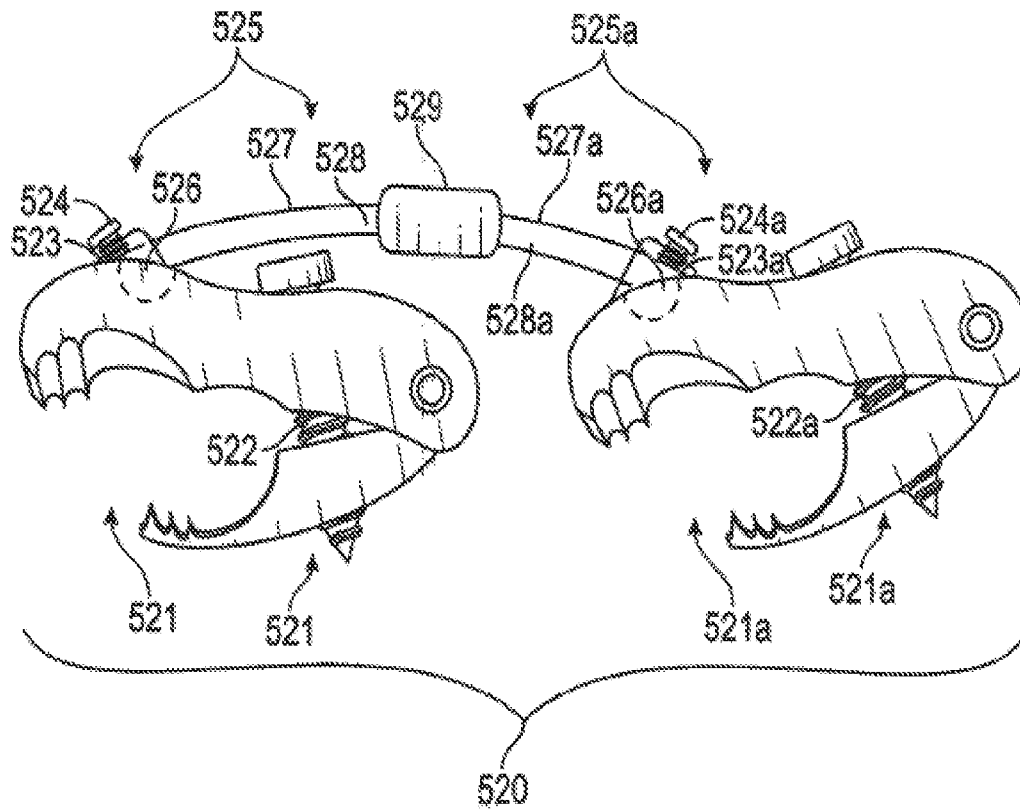


FIG. 37

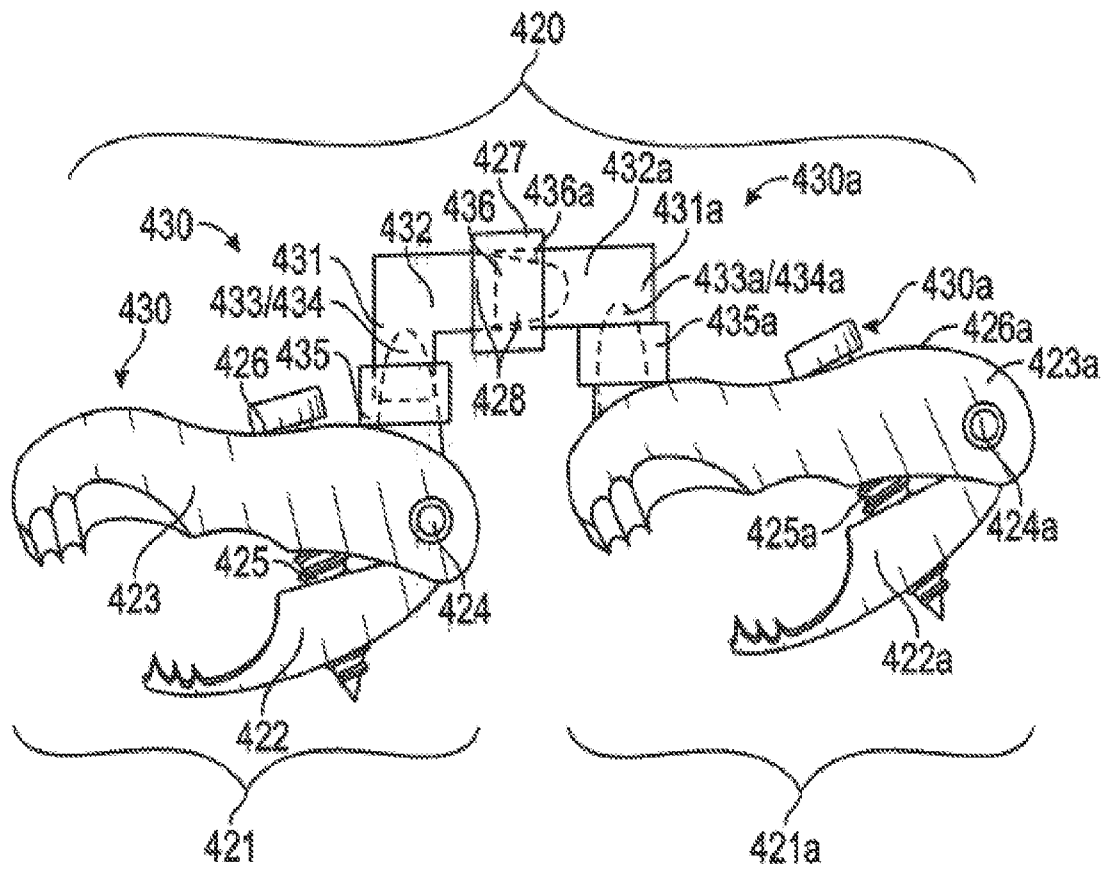


FIG. 38

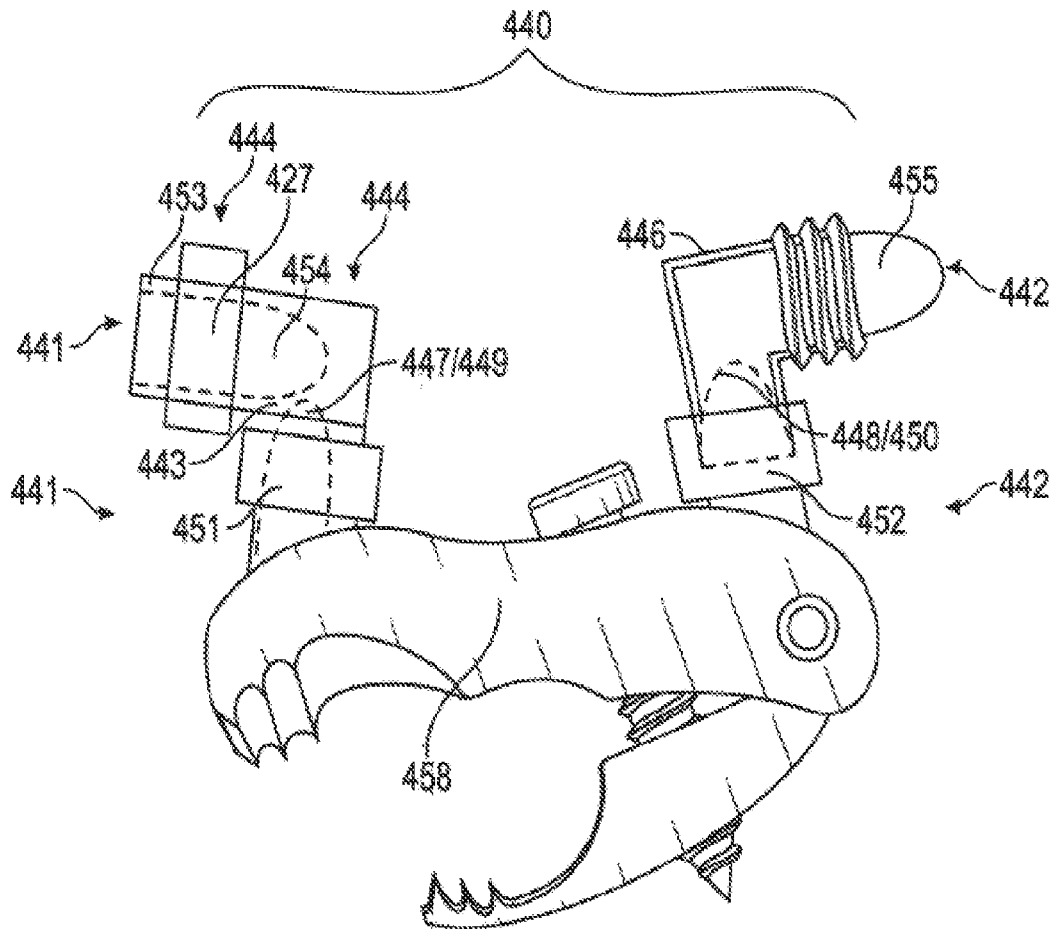


FIG. 39A

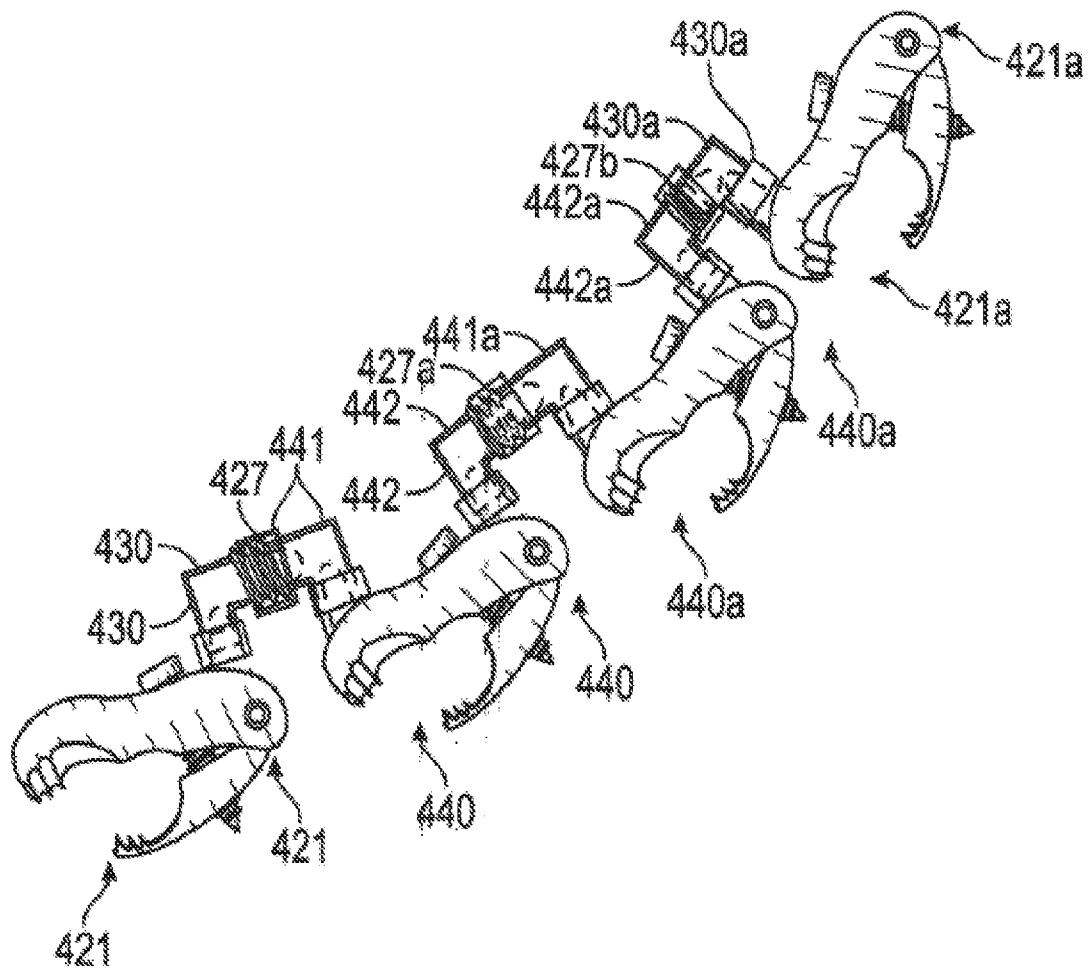


FIG. 39B

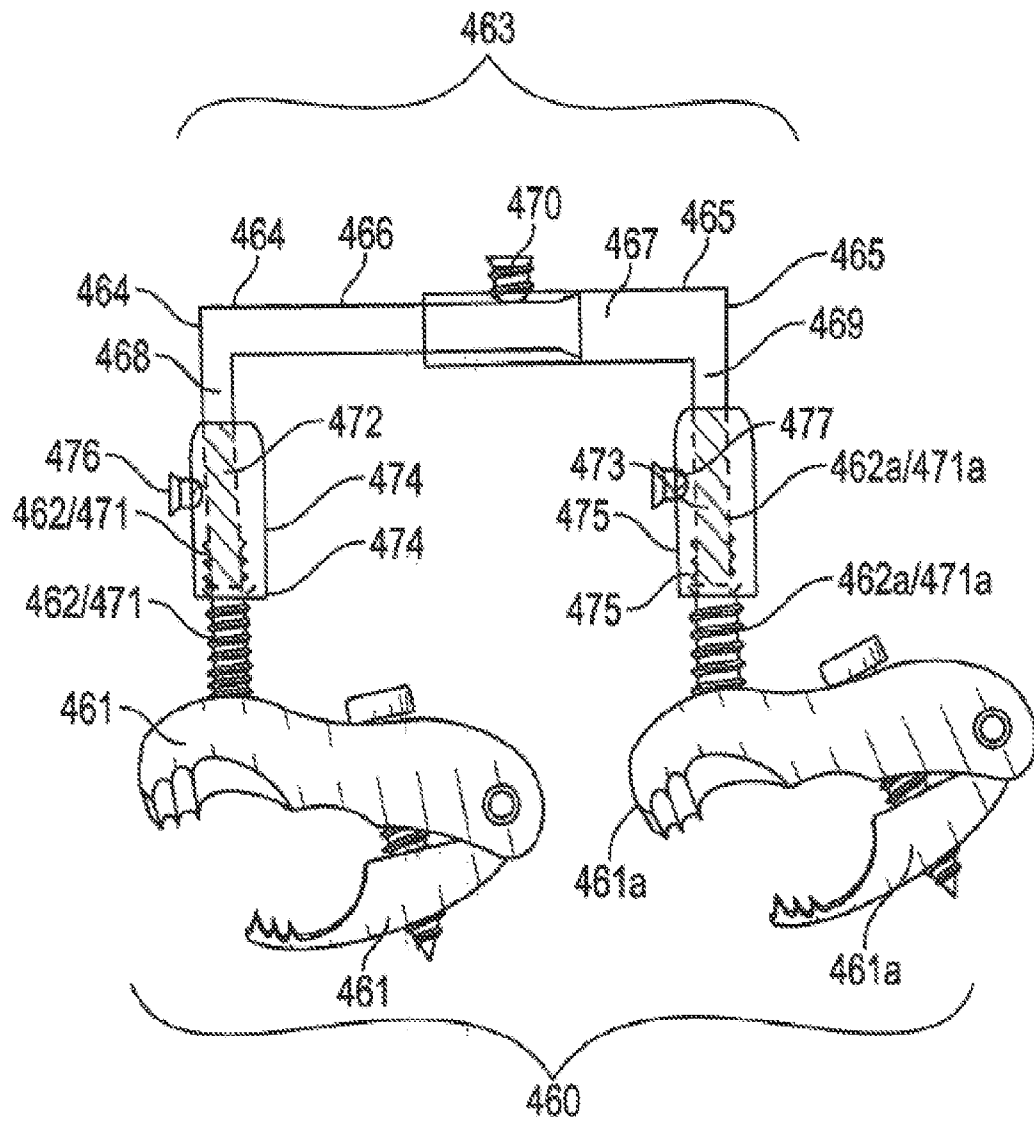


FIG. 40

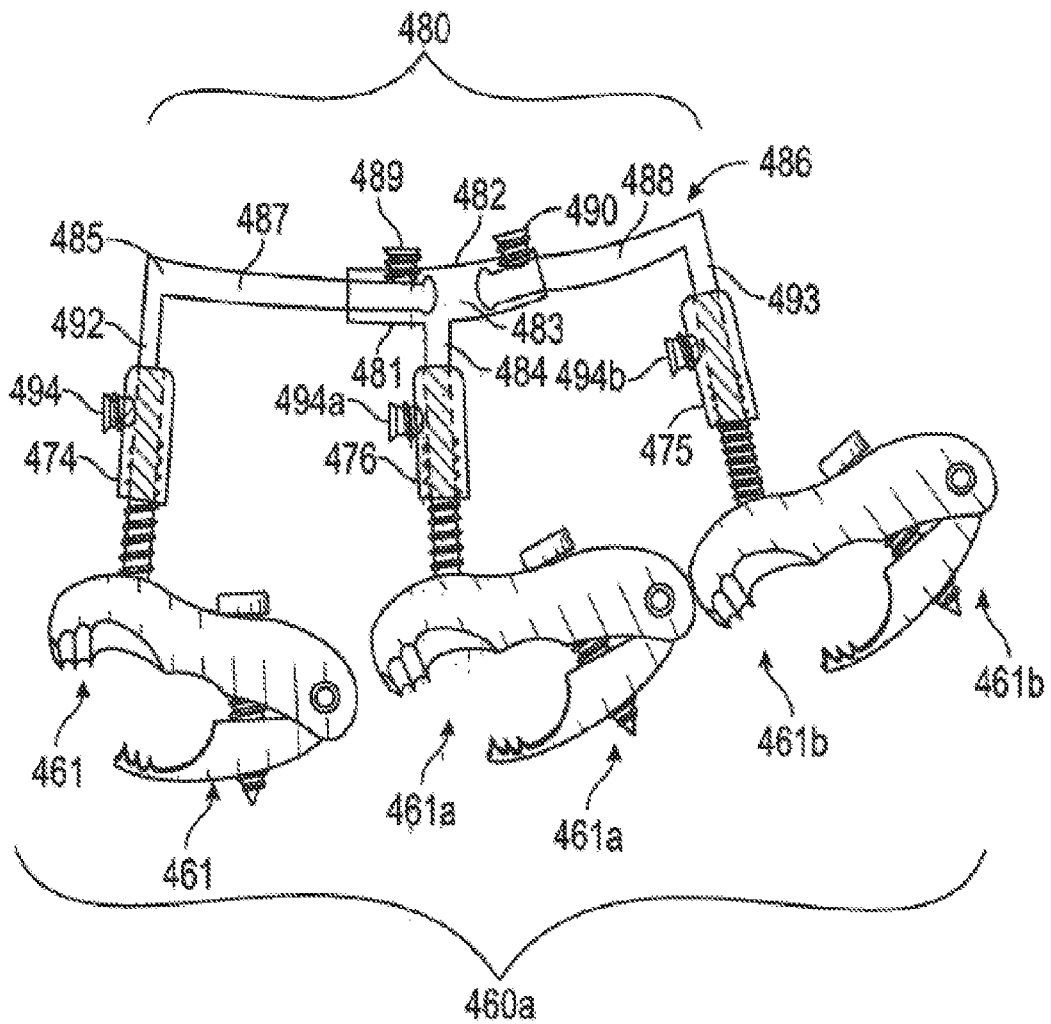


FIG. 41

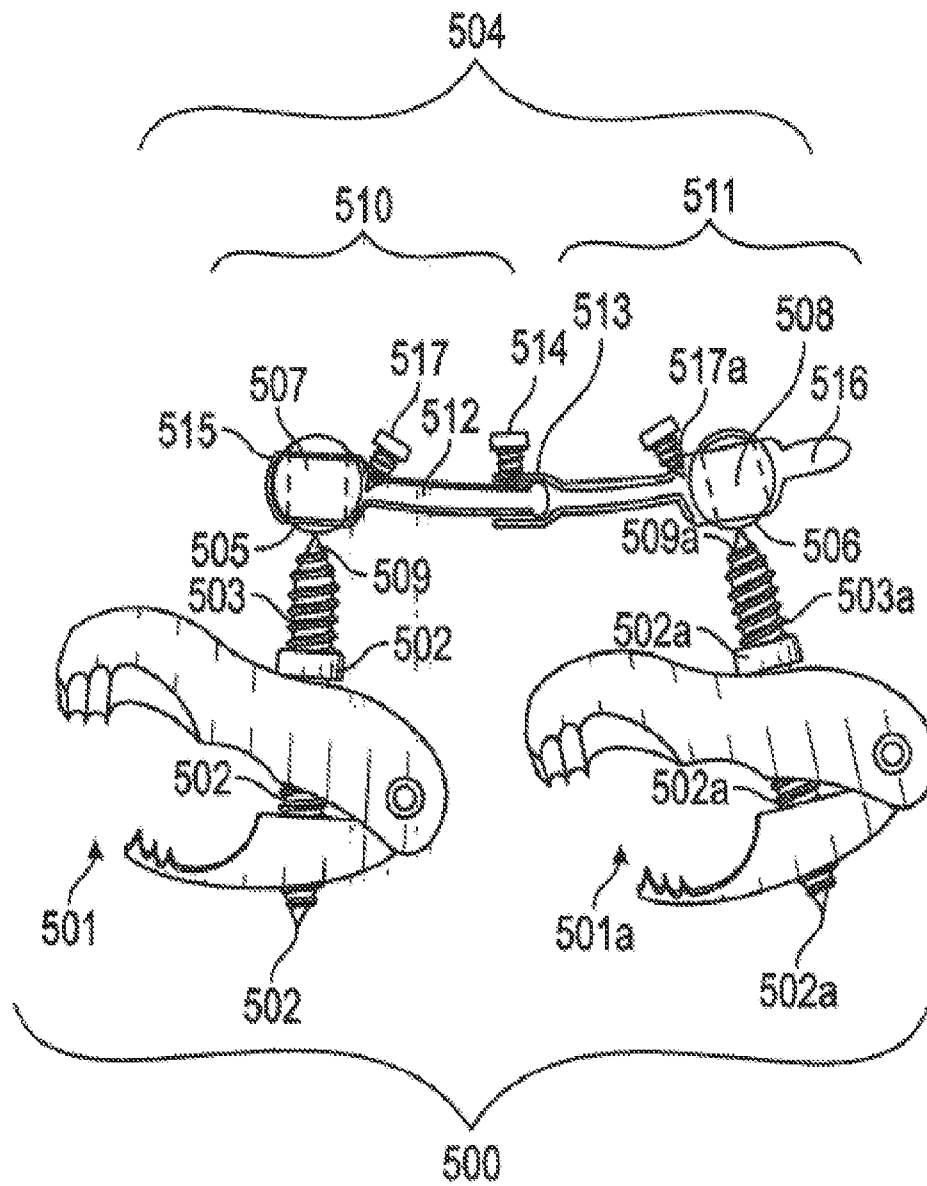


FIG. 42

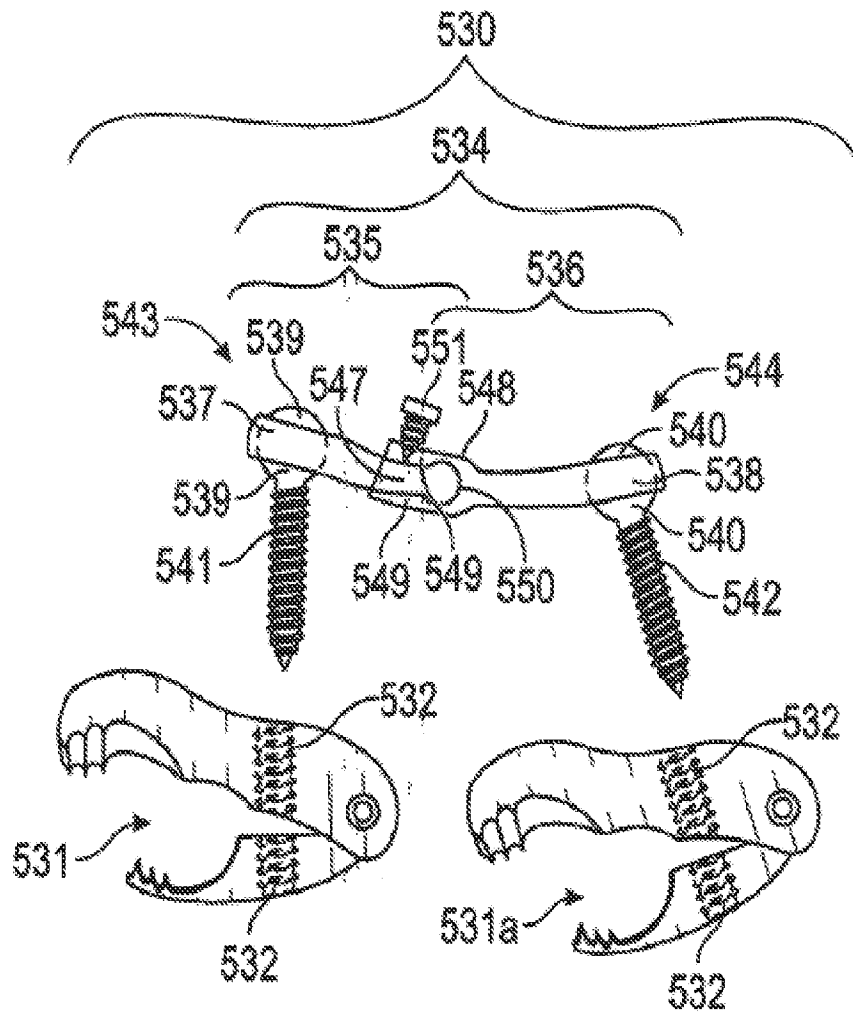


FIG. 43

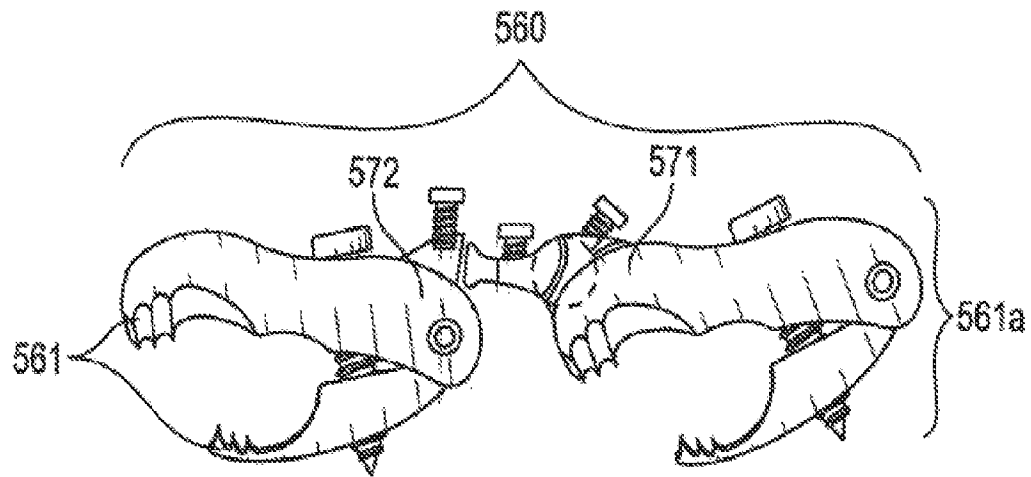


FIG. 44A

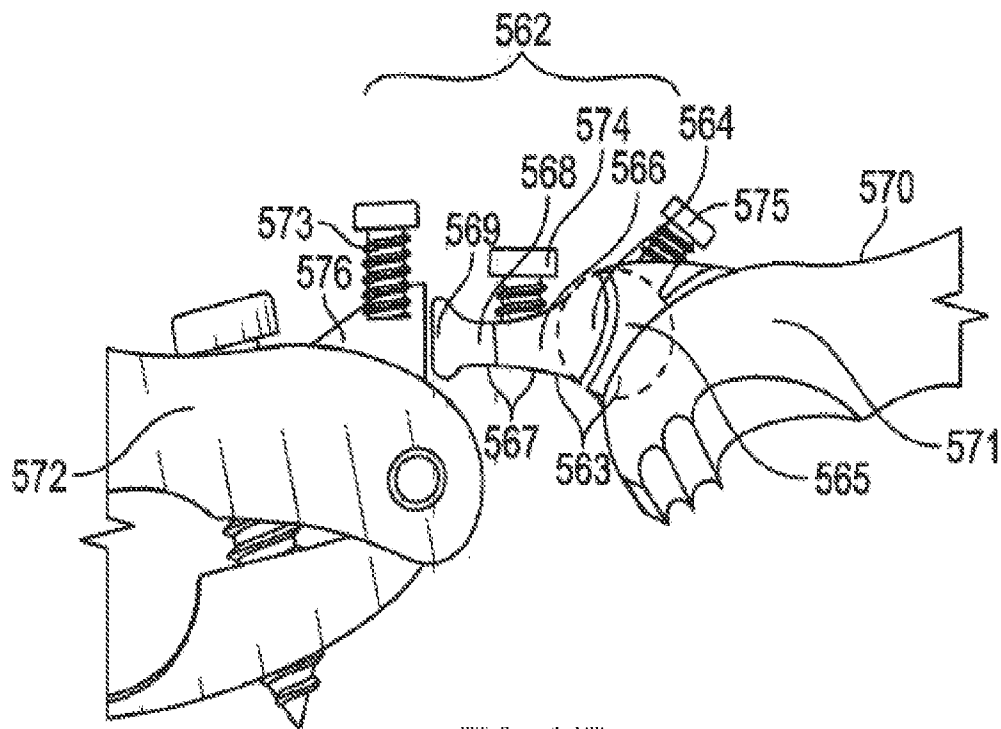


FIG. 44B

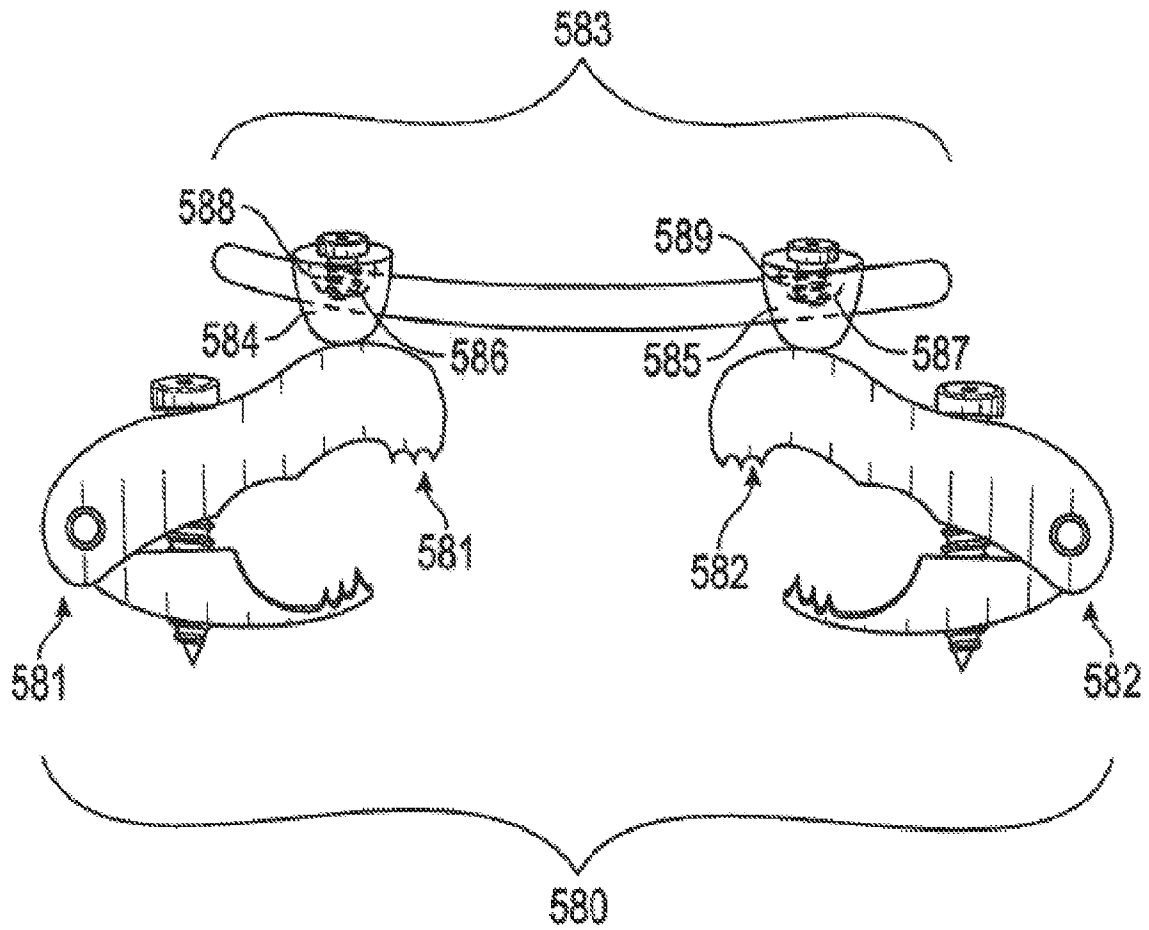


FIG. 45