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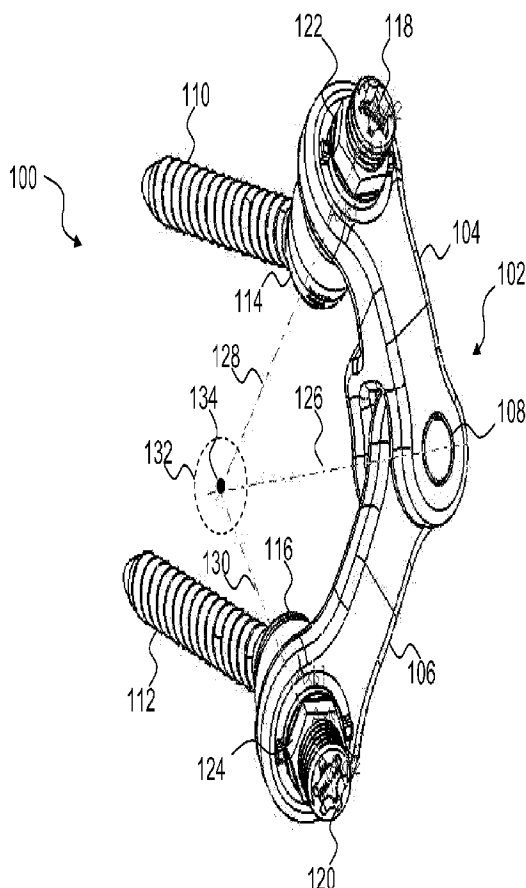
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[Continued on next page]

(54) Title: DYNAMIC MOTION SPINAL STABILIZATION SYSTEM



(57) Abstract: Provided is a system and medical implant for coupling two vertebrae, the implant characterized by a dynamic member (102) having two ends, wherein the dynamic member generally constrains relative movement of the first end with respect to the second end to a three-dimensional curved surface, the first end comprising a means for coupling to a first alignment member (118), the second end comprising a means for coupling to a second alignment member (120) such that the second end can rotate with respect to the longitudinal axis of the second alignment member. The first and second alignment members may be coupled to first and second bone anchoring means (110, 112) at the first and second ends respectively, and the first and second ends may be able to rotate with respect to the longitudinal axes (128, 130) of the first and second alignment members respectively.



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- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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DYNAMIC MOTION SPINAL STABILIZATION SYSTEM

CLAIM OF PRIORITY

[0001] This application claims priority from U.S. Provisional Patent Application Serial No. 60/786,898, filed on March 29, 2006, and U.S. Provisional Patent Application Serial No. 60/793,829, filed on April 21, 2006, both of which are incorporated by reference herein in their entirety.

FIELD OF THE INVENTION

[0002] This disclosure relates to skeletal stabilization and, more particularly, to systems and method for stabilization of human spines and, even more particularly, to dynamic stabilization techniques.

BACKGROUND

[0003] The human spine is a complex structure designed to achieve a myriad of tasks, many of them of a complex kinematic nature. The spinal vertebrae allow the spine to flex in three axes of movement relative to the portion of the spine in motion. These axes include the horizontal (bending either forward/anterior or aft/posterior), roll (bending to either left or right side) and vertical (twisting of the shoulders relative to the pelvis).

[0004] In flexing about the horizontal axis into flexion (bending forward or anterior) and extension (bending backward or posterior), vertebrae of the spine must rotate about the horizontal axis to various degrees of rotation. The sum of all such movement about the horizontal axis of produces the overall flexion or extension of the spine. For example, the vertebrae that make up the lumbar region of the human spine move through roughly an arc of 15° relative to its adjacent or neighboring vertebrae. Vertebrae of other regions of the human spine (e.g., the thoracic and cervical regions) have different ranges of movement. Thus, if one were to view the posterior edge of a healthy vertebrae, one would observe that the edge moves through an arc of some degree (e.g., of about 15° in flexion and about 5° in extension if in the lumbar region)

centered about a center of rotation. During such rotation, the anterior (front) edges of neighboring vertebrae move closer together, while the posterior edges move farther apart, compressing the anterior of the spine. Similarly, during extension, the posterior edges of neighboring vertebrae move closer together while the anterior edges move farther apart thereby compressing the posterior of the spine. During flexion and extension the vertebrae move in horizontal relationship to each other providing up to 2-3mm of translation.

[0005] In a normal spine, the vertebrae also permit right and left lateral bending. Accordingly, right lateral bending indicates the ability of the spine to bend over to the right by compressing the right portions of the spine and reducing the spacing between the right edges of associated vertebrae. Similarly, left lateral bending indicates the ability of the spine to bend over to the left by compressing the left portions of the spine and reducing the spacing between the left edges of associated vertebrae. The side of the spine opposite that portion compressed is expanded, increasing the spacing between the edges of vertebrae comprising that portion of the spine. For example, the vertebrae that make up the lumbar region of the human spine rotate about an axis of roll, moving through an arc of around 10° relative to its neighbor vertebrae throughout right and left lateral bending.

[0006] Rotational movement about a vertical axis relative is also natural in the healthy spine. For example, rotational movement can be described as the clockwise or counter-clockwise twisting rotation of the vertebrae during a golf swing.

[0007] In a healthy spine the inter-vertebral spacing between neighboring vertebrae is maintained by a compressible and somewhat elastic disc. The disc serves to allow the spine to move about the various axes of rotation and through the various arcs and movements required for normal mobility. The elasticity of the disc maintains spacing between the vertebrae during flexion and lateral bending of the spine thereby allowing room or clearance for compression of neighboring vertebrae. In addition, the disc allows relative rotation about the vertical axis of neighboring vertebrae allowing twisting of the shoulders relative to the hips and pelvis. A healthy disc further maintains clearance between neighboring vertebrae thereby enabling nerves from the spinal chord to extend out of the spine between neighboring vertebrae without being squeezed or

impinged by the vertebrae.

[0008] In situations where a disc is not functioning properly, the inter-vertebral disc tends to compress thereby reducing inter-vertebral spacing and exerting pressure on nerves extending from the spinal cord. Various other types of nerve problems may be experienced in the spine, such as exiting nerve root compression in the neural foramen, passing nerve root compression, and enervated annulus (where nerves grow into a cracked/compromised annulus, causing pain every time the disc/annulus is compressed), as examples. Many medical procedures have been devised to alleviate such nerve compression and the pain that results from nerve pressure. Many of these procedures revolve around attempts to prevent the vertebrae from moving too close to each in order to maintain space for the nerves to exit without being impinged upon by movements of the spine.

[0009] In one such procedure, screws are embedded in adjacent vertebrae pedicles and rigid rods or plates are then secured between the screws. In such a situation, the pedicle screws press against the rigid spacer which serves to distract the degenerated disc space thereby maintaining adequate separation between the neighboring vertebrae to prevent the vertebrae from compressing the nerves. Although the foregoing procedure prevents nerve pressure due to extension of the spine, when the patient then tries to bend forward (putting the spine in flexion), the posterior portions of at least two vertebrae are effectively held together. Furthermore, the lateral bending or rotational movement between the affected vertebrae is significantly reduced, due to the rigid connection of the spacers. Overall movement of the spine is reduced as more vertebrae are distracted by such rigid spacers. This type of spacer not only limits the patient's movements, but also places additional stress on other portions of the spine, such as adjacent vertebrae without spacers, often leading to further complications at a later date.

[0010] In other procedures, dynamic fixation devices are used. However, conventional dynamic fixation devices do not facilitate lateral bending and rotational movement with respect to the fixated discs. This can cause further pressure on the neighboring discs during these types of movements, which over time may cause additional problems in the neighboring discs.

[0011] Accordingly, dynamic systems which approximate and enable a fuller range of motion while providing stabilization of a spine are needed.

SUMMARY

[0012] In one embodiment, there is A medical implant for coupling two vertebrae of a spine, the implant characterized by a dynamic member having a first end and a second end, wherein the dynamic member generally constrains relative movement of the first end with respect to the second end to a three dimensional curved surface, the first end comprising a means for coupling to a first alignment member, such that the first end can rotate with respect to the longitudinal axis of the first alignment member, the second end comprising a means for coupling to a second alignment member such that the second end can rotate with respect to the longitudinal axis of the second alignment member.

[0013] The medical implant can be further characterized in that the dynamic member comprises a first link member, a second link member, and a means for rotationally coupling the first link member to the second link member.

[0014] The medical implant can be further characterized in that the means for rotationally coupling includes a pin joint.

[0015] The medical implant can be further characterized in that the longitudinal axes of the first alignment member, the second alignment member and the pin joint intersect about a center of rotation.

[0016] The medical implant can be further characterized in that the dynamic member comprises a first link member that is slidingly coupled to a second link member.

[0017] The medical implant can be further characterized in that the link members are non linear members.

[0018] The medical implant can be further characterized in that the means for coupling includes an aperture formed within the respective ends.

[0019] The medical implant can be further characterized in that the aperture is rotationally coupled to a bushing which is adapted to be mated to the aperture.

[0020] The medical implant can be further characterized in that the bushing is adapted to threadingly engage one of the alignment members.

[0021] The medical implant can be further characterized in that the alignment members include a means to engage a bone engagement member.

[0022] Additionally, there is also disclosed a medical system for coupling two vertebrae of a spine, the system characterized by a first bone anchoring means, a second bone anchoring means, a first alignment means coupled to the first bone anchoring means, a second alignment means coupled to the second bone anchoring means such that the longitudinal axes of the first and second alignment means can be aligned to intersect at a center of rotation, a dynamic member having a first end and a second end which allows for relative movement between the first end and second end, wherein the first end includes a means for coupling to the first alignment means, such that the first end can rotate with respect to the longitudinal axis of the first alignment means, and the second end includes a means for coupling to a second alignment member such that the second end can rotate with respect to the longitudinal axis of the second alignment means.

[0023] The medical system can be further characterized in that the dynamic member restricts the relative movement to a three dimensional curved surface.

[0024] The medical system can be further characterized in that the dynamic member comprises a first link member, a second link member, and a means for rotationally coupling the first link member to the second link member.

[0025] The medical system can be further characterized in that the means for rotationally coupling includes a pin joint.

[0026] The medical system can be further characterized in that the longitudinal axes of the first alignment member, the second alignment member and the pin joint intersect about a center of rotation.

[0027] The medical system can be further characterized in that the dynamic member comprises a first link member that is slidingly coupled to a second link member.

[0028] The medical system can be further characterized in that the link members are non linear members.

[0029] The medical system can be further characterized in that the means for coupling includes an aperture formed within the respective ends.

[0030] The medical system can be further characterized in that the aperture is

rotationally coupled to a bushing which is adapted to be mated to the aperture.

[0031] The medical system can be further characterized in that the bushing is adapted to threadingly engage one of the alignment members.

[0032] The medical system can be further characterized in that the alignment members include a means to engage a bone engagement member.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] For a more complete understanding of the present invention and the advantages thereof, reference is now made to the following Detailed Description taken in conjunction with the accompanying drawings, in which:

[0034] Fig. 1 is a perspective view of an embodiment of a dynamic stabilization system;

[0035] Fig. 2 is a perspective view of one embodiment of a dynamic stabilization device that may be used in the dynamic stabilization system of Fig. 1;

[0036] Fig. 3 is a view of the dynamic stabilization device illustrated in Fig. 2 in an extended position;

[0037] Fig. 4 is a cross-sectional view of the dynamic stabilization device of Fig. 3.

[0038] Fig. 5 is a perspective view of one embodiment of a member of the dynamic stabilization device of Fig. 2.

[0039] Fig. 6 is a perspective view of one embodiment of a member of the dynamic stabilization device of Fig. 2.

[0040] Fig. 7 is a side view of one embodiment of the dynamic stabilization device of Fig. 2.

[0041] Fig. 8 is a side view of one embodiment of the dynamic stabilization system of Fig. 1.

[0042] Fig. 9 is an enlarged view of a portion of the dynamic stabilization system of Fig. 8.

[0043] Fig. 10 is a cross-sectional view of the portion of the dynamic stabilization system of Fig. 9.

[0044] Fig. 11A is a sagittal perspective view of the dynamic stabilization system

illustrated in Fig. 1 in a neutral position;

[0045] Fig. 11B is a sagittal perspective view of the dynamic stabilization system illustrated in Fig. 1 in a flexion position;

[0046] Fig. 12A is a posterior perspective view of the dynamic stabilization system illustrated in Fig. 1 in a neutral position;

[0047] Fig. 12B is a posterior perspective view of the dynamic stabilization system illustrated in Fig. 1 in a flexion position;

[0048] Fig. 12C is a posterior perspective view of the dynamic stabilization system illustrated in Fig. 1 in a rotation position;

[0049] Fig. 12D is a posterior perspective view of the dynamic stabilization system illustrated in Fig. 1 in a lateral bending position;

[0050] Fig. 12E is a posterior perspective view of the dynamic stabilization system illustrated in Fig. 1 in an extension position;

[0051] Fig. 13 is a side view of another embodiment of a dynamic stabilization system;

[0052] Fig. 14A is a perspective view of one embodiment of a dynamic stabilization device that may be used in the dynamic stabilization system of Fig. 13;

[0053] Fig. 14B is a side view of the dynamic stabilization device of Fig. 14A;

[0054] Fig. 15 is a perspective view of one embodiment of a member of the dynamic stabilization device of Fig. 14A;

[0055] Fig. 16 is a perspective view of one embodiment of a member of the dynamic stabilization device of Fig. 14A;

[0056] Fig. 17A is a side view of the dynamic stabilization system of Fig. 13 in a neutral position;

[0057] Fig. 17B is a side view of the dynamic stabilization system of Fig. 13 in an extension position;

[0058] Fig. 17C is a side view of the dynamic stabilization system of Fig. 13 in a flexion position

[0059] Fig. 18A is a posterior perspective view of the dynamic stabilization system of Fig. 13 in a neutral position;

[0060] Fig. 18B is a posterior perspective view of the dynamic stabilization

system of Fig. 13 in an extension position;

[0061] Fig. 18C is a posterior perspective view of the dynamic stabilization system of Fig. 13 in a flexion position;

[0062] Fig. 18D is a posterior perspective view of the dynamic stabilization system of Fig. 13 in a lateral bending position;

[0063] Fig. 18E is a posterior perspective view of the dynamic stabilization system of Fig. 13 in a rotation extension position;

[0064] Fig. 18F is a posterior perspective view of the dynamic stabilization system of Fig. 13 in a rotation flexion position;

[0065] Fig. 19 is a posterior perspective view of an alternative embodiment of a dynamic stabilization system in a neutral position;

[0066] Fig. 20 is a posterior perspective view of another embodiment of a dynamic stabilization system in a neutral position; and

[0067] Fig. 21 is a perspective view of one possible component which may be used with some embodiments of the dynamic stabilization system shown of Figs. 13-10.

[0068] Fig. 22 is a flowchart of one embodiment of a method for using a dynamic stabilization system.

DETAILED DESCRIPTION

[0069] It is to be understood that the following disclosure provides many different embodiments, or examples, for implementing different features of the disclosure. Specific examples of components and arrangements are described below to simplify the present disclosure. These are, of course, merely examples and are not intended to be limiting. In addition, the present disclosure may repeat reference numerals and/or letters in the various examples. This repetition is for the purpose of simplicity and clarity and does not in itself dictate a relationship between the various embodiments and/or configurations discussed.

[0070] Certain aspects of the present disclosure provide dynamic stabilization systems, dynamic stabilization devices, and/or methods for maintaining spacing

between consecutive neighboring vertebrae and stabilizing a spine, while allowing movement of the vertebrae relative to each other in at least two and preferably three axes of rotation. The neighboring vertebrae may be immediately next to each other or spaced from each other by one or more intervening vertebrae.

[0071] It is sometimes difficult to match a dynamic stabilization system with a particular patient's anatomical structure while ensuring that a minimum range of motion is available for the dynamic implant due to factors such as the variability of pedicle to pedicle distance in the lumbar spine. Generally, it may be desirable to have a dynamic stabilization system implanted at a neutral position that allows for a minimum available range of motion, while having the system aligned with a center of rotation that is placed, for example, at the 60-70% A-P marker of a vertebral body.

[0072] For instance, if a sliding dynamic stabilization system has to be extended to reach amply spaced pedicles, the system may not have sufficient engagement left for flexion (i.e., the system may reach the end of the sliding motion before full flexion is achieved). In order to have a predictable and consistent range of motion, it may be desirable to have the relative starting engagement always be the same (e.g., neutral). This may also be desirable to ensure that dampening forces are consistent at both extremes of relative motion.

[0073] One possible solution to address the fit of a dynamic stabilization system to variations in anatomy is to design multiple sizes. For example, such dynamic stabilization systems may have a fixed relative starting engagement so the full range of motion would be available. However, the location of the center of rotation might need to be shifted forward or backwards in the A-P direction to fit the dynamic stabilization system (in its neutral engagement) in the anatomy. A sensitivity study has shown that a small change in pedicle to pedicle distance (e.g., one mm) may shift the center of rotation from the 65% A-P mark to the 70% A-P mark (i.e., a 5% change). A further change of pedicle to pedicle distance by another one millimeter may place the center of rotation at the 75% A-P mark, which may not be acceptable. As such, multiple sizes with overlapping ranges would have to be designed to accommodate all anatomy variations, align the center of rotation to the 60-70% A-P mark, and enable co-alignment of a dynamic stabilization system pair (i.e., left and right sides).

[0074] Accordingly, the following disclosure describes dynamic stabilization systems, devices, and methods for dynamic stabilization which may provide for adjustable distraction of the inter-vertebral space while still allowing a patient a substantial range of motion in two and/or three dimensions. Such a dynamic stabilization system may allow the vertebrae to which it is attached to move through a natural arc that may resemble an imaginary three dimensional surface such as a sphere or an ellipsoid. Accordingly, such a system may aid in permitting a substantial range of motion in flexion, extension, rotation, anterior-posterior translation and/or other desired types of natural spinal motion.

[0075] Referring to Fig. 1, one embodiment of a spine stabilization system 100 is illustrated. The spine stabilization system 100 may include a dynamic stabilization device 102 that includes two members 104 and 106 coupled by a pin 108. The pin 108 may enable the two members 104 and 106 to move with respect to one another, as will be described later in greater detail.

[0076] Each member 104 and 106 may be secured to a portion of a spine (not shown), such as a pedicle, by a fastening element such as a bone anchor (e.g., a pedicle screw) 110 and 112, respectively. Each bone anchor 110 and 112 may include or be attached to a polyaxial head, 114 and 116, respectively. The member 104 may be coupled to the polyaxial head 114 of its respective bone anchor 110 using, for example, a bearing post 118 (e.g., a set screw) and a locking nut 122. Similarly, the member 106 may be coupled to the polyaxial head 116 of its respective bone anchor 112 using, for example, a bearing post 120 (e.g., a set screw) and a locking nut 124.

[0077] As illustrated, the pin 108 may be aligned with a first axis 126. The bearing posts 118 and 120 may be aligned with a second axis 128 and a third axis 130, respectively. The axes 126, 128, and 130 may intersect an area 132 (e.g., an area of rotation). In some embodiments, the axes 126, 128, and 130 may intersect at a point 134 (e.g., a center of rotation) within the area 132. The point 134 may be stationary or may move within the area 132 in conjunction with movement of the vertebrae (not shown) to which the spinal stabilization device 102 is coupled. It is understood that the area 132 and the point 134 are for purposes of illustration only and are not limited to the shapes or sizes shown. For example, while the area 132 is shown as a sphere, the

area may be an ellipsoid or other shape. Furthermore, while the axes 126, 128, and 130 are shown intersecting each other at the point 134, it is understood that they may not actually intersect one another, but may instead pass within a certain distance of each other. Furthermore, the point 134 need not be a stationary point, but may follow a path on or through the area 132. For example, the point 134 may move along a surface of the area 132 such that the area 132 provides a shell, and movement of the point 134 is constrained by the device 102 to an outer surface of the shell. For purposes of convenience, the term center of rotation may be used herein to refer to a specific point and/or a three dimensional surface.

[0078] Referring to Fig. 2, one embodiment of the dynamic stabilization device 102 is illustrated. As stated with respect to Fig. 1, the dynamic stabilization device 102 may include two members 104 and 106 that are coupled via the pin 108. In the present example, the member 104 may include a joint end 202 and a fastening end 204, and the member 106 may include a joint end 206 and a fastening end 208. The joint end 202 of the member 104 may include one or more apertures 210 and the fastening end 204 of the member 104 may include an aperture 212. Similarly, the joint end 206 of the member 106 may include an aperture 214 (shown in Fig. 6) and the fastening end 208 of the member 106 may include an aperture 216. The pin 108 may couple the members 104 and 106 via insertion into the apertures 210 and 214, respectively. The bearing posts 118 and 120 (Fig. 1) be inserted into apertures 212 and 216, respectively, to couple members 104 and 106 to pedicles or other bone (not shown).

[0079] In the present embodiment, one or more of the apertures 210, 212, 214, and 216 may contain a bushing or other insertion member. For example, as illustrated, the aperture 212 may include a bushing 218 and the aperture 216 may include a bushing 220. The bushings 218 and 220 may aid in securing the dynamic stabilization device 102 to the bearing posts 118 and 120 (Fig. 1). One or both of the bushings 218 and 220 may be internally threaded to engage the respective bearing posts 118 and 120. In some embodiments, an external surface of the bushings 218 and 220 may be relatively smooth to facilitate rotation of the respective members 104 and 106 around the bushings.

[0080] As illustrated, the apertures 210 and 214 may be aligned with the first axis

126. The apertures 212 and 216 may be aligned with the second axis 128 and third axis 130, respectively. It is understood that, as the apertures 210, 212, 214, and 216 may be aligned with their respective axes, the pin 108 and bearing posts 118 and 120 may be aligned with the axes due to their insertion into the respective apertures. Alternatively, the pin 108 and bearing posts 118 and 120 may be aligned with their respective axes, and their alignment may result in the alignment of their respective apertures.

[0081] Referring to Fig. 3, the spinal stabilization device 102 of Fig. 2 is illustrated in a fully extended or lengthened position (e.g., during flexion). In the present embodiment, apertures 210, 212, and 216 are aligned with axes 126, 128, and 130, respectively, when in the fully extended position. Accordingly, the axes 126, 128, and 130 may intersect the point 134 and/or move along a surface provided by the area of rotation 132 as previously described.

[0082] With additional reference to Fig. 4, a cross-sectional view of one embodiment of the spinal stabilization device 102 of Fig. 3 is illustrated. As described previously, the members 104 and 106 may be coupled by the pin 108. As illustrated, the bushings 218 and 220 are positioned within the apertures 212 and 216, respectively. In the present example, a bushing cap 402 may abut the bushing 218 and a bushing cap 404 may abut the bushing 220. Also shown are a bushing 406 in the aperture 214 and an abutting bushing cap 408. In contrast to the illustrated bushings 218 and 220, the bushing 406 may have a smooth bore (e.g., rather than threaded) to facilitate rotation with the pin 108.

[0083] The pin 108 may couple the members 104 and 106 via insertion into the apertures 210 and 214, respectively. The bearing posts 118 and 120 may couple the members 104 and 106 to pedicles or other bone (not shown) via apertures 212 and 216, respectively.

[0084] Referring to Fig. 5, one embodiment of the member 104 of Fig. 1 is illustrated in greater detail. As described previously, the member 104 may include one or more apertures 210 at the joint end 202 and an aperture 212 at the fastening end 204. In the present example, the member 104 provides a "Y" shape or yoke formed by branches 506 and 508. The branches 506 and 508 may be spaced apart to provide

clearance for the end 206 of the member 106. As illustrated, a medial portion of the member 104 (e.g., the portion forming the bottom of the yoke) may be thicker than the fastening end 204 and the branches 506 and 508 forming the joint end 202.

[0085] In the present example, an upper surface 502 and a lower surface 504 of the member 104 may be curved to align the apertures 210 and 212 with axes 126 and 128 (Fig. 2), respectively, in order to accommodate the natural movement of the spine. It is understood that the curve may be defined differently depending on such factors as the length of the member 104, the location of the apertures 210 and/or 212, and the desired center of rotation for the dynamic stabilization device 102.

[0086] The inner walls 510 of the aperture 210 may be relatively smooth to facilitate rotation of the member 104 with respect to the pin 108. In some embodiments, a bushing (Fig. 4) may be provided to enhance the rotation of the pin 108 within the aperture 210. The inner walls 512 of the aperture 212 may contain ridges, grooves, threads, or other means for engaging the bushing 218 (Fig. 2). The member 104 may also include one or more beveled or otherwise shaped surfaces 514.

[0087] Referring to Fig. 6, one embodiment of the member 106 of Fig. 1 is illustrated in greater detail. As described previously, the member 106 may include an aperture 214 at the joint end 206 and an aperture 216 at the fastening end 208. In the present example, the joint end 206 may be sized to fit within a yoke (Fig. 5) of the member 104.

[0088] In the present example, an upper surface 602 and a lower surface 604 of the member 102 may be curved to align the apertures 214 and 216 with axes 126 and 130 (Fig. 2), respectively, in order to accommodate the natural movement of the spine. It is understood that the curve may be defined differently depending on such factors as the length of the member 106, the location of the apertures 214 and/or 216, and the desired center of rotation for the dynamic stabilization device 102.

[0089] The inner walls 606 of the aperture 214 may be relatively smooth to facilitate rotation of the member 106 with respect to the pin 108. In some embodiments, a bushing (Fig. 4) may be provided to enhance the rotation of the pin 108 within the aperture 214. The inner walls 608 of the aperture 216 may contain ridges, grooves, threads, or other means for engaging the bushing 220 (Fig. 2). The member 106 may

also include one or more beveled or otherwise shaped surfaces 610.

[0090] Referring to Fig. 7, a side view of one embodiment of the dynamic stabilization device 102 of Fig. 2 is illustrated. As described previously, the members 104 and 106 may be designed and arranged to align with axes 126, 128, and 130.

[0091] Referring to Fig. 8, a side view of the dynamic stabilization system 100 of Fig. 1 is illustrated. As described previously, the pin 108 may be aligned with the axis 126, and the bearing posts 118 and 120 may be aligned with axes 128 and 130, respectively. In the present example, the use of polyaxial heads 114 and 116 enables the spinal stabilization device 102 to be oriented to the area 132 even though bone anchors 110 and 112 may be oriented along other axes. This flexibility enables a surgeon to insert the bone anchors 110 and 112 as desired while maintaining the movement of the spinal stabilization device 102 with respect to the area 132 and/or point 134.

[0092] With additional reference to Figs. 9 and 10, an enlarged view of a portion of the spinal stabilization device 102 of Fig. 8 is illustrated in side perspective and cross-sectional views, respectively. As shown, the bearing post 118 may extend through the aperture 212 and into the polyaxial head 114. The bushing 218 and bushing cap 402 may be retained in the aperture 212. The locking cap 122 may be used to secure the member 104 to the bearing post 118 at a particular position, enabling a vertical height of the member 104 relative to the polyaxial head 114 to be adjusted. In the present example, a distal portion of the bearing post 118 may be tightened against the bone anchor 110 within the polyaxial head to lock the bone anchor into a desired position with respect to the polyaxial head 114. Prior to the tightening of the bearing post 118, the bone anchor 110 may move relatively freely within the polyaxial head 114. Accordingly, the dynamic stabilization device 102 may be positioned and then the bearing post 118 may be tightened to lock the position of the dynamic stabilization device relative to the polyaxial head 114 and bone anchor 110.

[0093] Referring to Figs. 11A and 11B, there are shown sagittal views illustrating a range of motion and center of rotation between two neighboring vertebrae 1100 and 1102 linked by the spine stabilization system 100 of Fig. 1. Fig. 11A illustrates the spine stabilization system 100 when the two adjacent vertebrae 1100 and 1102 are in a

neutral position. Fig. 11B illustrates the spine stabilization system 100 when the two adjacent vertebrae 1100 and 1102 are undergoing flexion (e.g., when the patient is bending forward). As illustrated in Figs. 11A and 11B, the spine stabilization system 100 maintains alignment with the area 132 (e.g., with a center of rotation or with an area of rotation) regardless of the position of the two vertebrae 1100 and 1102.

[0094] Referring to Figs. 12A - 12E, there are shown posterior views illustrating a range of motion and center of rotation between two neighboring vertebrae 1200 and 1202 linked by spine stabilization systems 100a and 100b. Although not described in detail herein, the spine stabilization system 100a may include members 104a and 106a (which may be similar or identical to the members 104 and 106 of Fig. 1) and the spine stabilization system 100b may include members 104b and 106b (which may be similar or identical to the members 104 and 106 of Fig. 1). Fig. 12A illustrates the spine stabilization systems 100a and 100b when the two adjacent vertebrae 1200 and 1202 are in a neutral position. Fig. 12B illustrates the spine stabilization systems 100a and 100b when the two adjacent vertebrae 1200 and 1202 are undergoing flexion (e.g., when the patient is bending forward). Fig. 12C illustrates the spine stabilization systems 100a and 100b when the two adjacent vertebrae 1200 and 1202 are undergoing rotation (e.g., when the patient is turning to the right or left). Fig. 12D illustrates the spine stabilization systems 100a and 100b when the two adjacent vertebrae 1200 and 1202 are in a lateral bending position (e.g., when the patient is bending towards the right or left). Fig. 12E illustrates the spine stabilization systems 100a and 100b when the two adjacent vertebrae 1200 and 1202 are undergoing extension (e.g., when the patient is bending backward). As illustrated in Figs. 12A-12E, the spine stabilization systems 100a and 100b maintain alignment with the area 132 (e.g., with a center of rotation or with an area of rotation) regardless of the position of the two vertebrae 1200 and 1202.

[0095] Referring to Fig. 13, in another embodiment, a spine stabilization system 1300 is illustrated. In the illustrated embodiment, the spine stabilization system 1300 includes a plurality of bone anchors 1302a and 1302b which may be secured into a patient's vertebrae or other bone structures. The bone anchors 1302a and 1302b may be pedicle screws or other suitable bone anchoring devices known to those skilled in the

art. A dynamic stabilization device 1304 is coupled between the bone anchors 1302a and 1302b. The dynamic stabilization device 1304 may be coupled to the bone anchors by threaded fastener systems 1306a and 1306b, which may enable adjustment of the dynamic stabilization device 1304 relative to the bone anchors 1302a and 1302b. In certain embodiments, the dynamic stabilization device 1304 may be adjusted so that relative movement between the exterior ends of the dynamic stabilization device follow the surface of a sphere or other three dimensional shape (e.g., an ellipsoid) having a center of rotation that approximates the spine's natural center of rotation.

[0096] For example, portions of the threaded fastener systems 1306a and 1306b may be aligned with axes 1322 and 1324, respectively. The axes 1322 and 1324 may intersect an area 1326 (e.g., an area of rotation). In some embodiments, the axes 1322 and 1324 may intersect at a point 1328 (e.g., a center of rotation) within the area 1326. The point 1328 may be stationary or may move within the area 1326 in conjunction with movement of the vertebrae (not shown) to which the spinal stabilization device 1304 is coupled. It is understood that the area 1326 and the point 1328 are for purposes of illustration only and are not limited to the shapes or sizes shown. For example, while the area 1326 is shown as a sphere, the area may be an ellipsoid or other shape. Furthermore, while the axes 1322 and 1324 are shown intersecting each other at the point 1328, it is understood that they may not actually intersect one another, but may instead pass within a certain distance of each other. Furthermore, the point 1328 need not be a stationary point, but may follow a path on or through the area 1326. For example, the point 1328 may move along a surface of the area 1326 such that the area 1326 provides a shell, and movement of the point 1328 is constrained by the device 1304 to an outer surface of the shell. For purposes of convenience, the term center of rotation may be used herein to refer to a specific point and/or a three dimensional surface.

[0097] The threaded fastener systems 1306a and 1306b may include bearing posts (e.g., set screws) 1308a and 1308b received into polyaxial heads 1310a and 1310b that may be coupled to the proximal ends of the bone anchors 1302a and 1302b, respectively. The fastener systems 1306a and 1306b may further include fasteners 1312a and 1312b for securing the dynamic stabilization device 1304 to the bearing

posts 1308a and 1308b. The fasteners 1312a and 1312b may be locking caps, nuts, or other similar threaded fasteners known to those skilled in the art. In some embodiments, the dynamic stabilization device 1304 may rotate around one or both of the bearing posts 1308a and 1308b, while in other embodiments the dynamic stabilization device may be immovably fastened to the bearing posts.

[0098] The dynamic stabilization device 1304 may include a male member 1314 and a female member 1316 each having an exterior and interior end. The male member 1314 and female member 1316 may be coupled together at their interior ends to allow for a sliding relative rotation about an axis of roll and a horizontal axis within a defined range of movement. The range of movement may be designed to permit a desired amount of lateral bending and twisting of upper and lower vertebrae relative to each other while maintaining a desired separation between the vertebrae. In certain embodiments, the male member 1314 and female member 1316 may be coupled by a curved shaft 1318 of the male member 1314 that is received into a channel of an extension 1320 of the female member 1316. In some embodiments, the curved shaft 1318 may be sized to slideably move and/or rotate within the channel of the extension 1320 about both a horizontal and vertical axis.

[0099] With additional reference to Fig. 14A, one embodiment of the dynamic stabilization device 1304 is illustrated. In the present example, the male member 1314 may include an aperture 1400 configured to receive the bearing post 1308a of the threaded fastener system 1306a (Fig. 13). A threaded bushing 1402, which may be similar or identical to the threaded bushing discussed with respect to previous embodiments, may be positioned within the aperture 1400. The bushing 1402 may be secured in the aperture 1400 using a bushing cap (not shown) that is secured (e.g., welded) to the bushing. In some embodiments, an external surface of the bushing 1402 may be relatively smooth to facilitate rotation of the male member 1314 around the bushing. The bearing post 1308a may be secured to the bushing 1402 by the fastener 1312a.

[00100] The female member 1316 may include an aperture 1404 configured to receive the bearing post 1308b of the threaded fastener system 1306b (Fig. 13). A threaded bushing 1406, which may be similar or identical to the threaded bushing

discussed with respect to previous embodiments, may be positioned within the aperture 1404. The bushing 1406 may be secured in the aperture 1404 using a bushing cap (not shown) that is secured (e.g., welded) to the bushing. In some embodiments, an external surface of the bushing 1406 may be relatively smooth to facilitate rotation of the female member 1316 around the bushing. The bearing post 1308b may be secured to the bushing 1406 by the fastener 1312b.

[00101] Referring to Fig. 14B, a side view of the dynamic stabilization device 1304 of Fig. 14A illustrates the male-female coupling relationship between the male member 1314 and female member 1316. As described previously, the extension 1320 of the female member 1316 may include a channel for receiving the curved shaft 1318 of the male member 1314 therein. For example, the curved shaft 1318 may have a curved surface for slideably engaging one or more interior curved surfaces of the channel of the extension 1320. This slideable engagement of the respective curved surfaces may allow the male member 1314 and female member 1316 to move relative to one another while maintaining their alignment with the area of rotation 1326 and/or center point 1328. This may maintain the alignment of the dynamic stabilization device 1304 with the spine's natural center of rotation, and may enable a more natural movement between the upper and lower vertebrae to occur while maintaining a degree of separation.

[00102] In other embodiments, the curved shaft 1318 and extension 1320 may include horizontal curved surfaces that allow a slideable movement horizontally with respect to the center of rotation. If the radii of the vertical and horizontal curves of respective surfaces have a substantially similar or identical center of rotation, the male member 1314 may move in a spherical manner with respect to the female member 1316. In other words, the movement of the male member 1314 and the female member 1316 may follow a path that is constrained to a spherical surface (e.g., the area of rotation 1326). It is understood that other curves may be used for the male member 1314 and/or the female member 1316 to create a non-spherical (e.g., ellipsoidal) path of movement.

[00103] Referring to Fig. 15, a perspective view of one embodiment of the female member 1316 of Fig. 13 is illustrated. In the present example, a channel 1500 in the

extension 1320 is illustrated. As described previously, the channel 1500 may be configured to receive the extension 1318 of the male member 1314. The channel 1500 may be curved or straight, and may have any desired cross-sectional characteristics. For example, the illustrated channel 1500 is substantially square in cross-section, but it is understood that the channel may have a cross-section that is circular, rectangular, or any other desired shape. A flange 1502 may be formed around the extension 1320 to engage or abut a complementary flange of the male member 1314.

[00104] Referring to Fig. 16, a perspective view of one embodiment of the male member 1314 of Fig. 13 is illustrated. As described previously, the curved shaft 1318 may be configured to enter the channel 1500 (Fig. 15) of the female member 1316. While the shaft 1318 is curved in the present example, it is understood that the shaft may be straight in some embodiments and may have any desired cross-sectional characteristics. For example, the illustrated curved shaft 1318 is substantially square in cross-section, but it is understood that the shaft may have a cross-section that is circular, rectangular, or any other desired shape. In some embodiments, a distal portion of the curved shaft 1318 may include a sloped surface 1600. Such a surface 1600 may, for example, aid movement of the curved shaft 1318 within the channel 1500. A flange 1602 may be formed around the curved shaft 1318 to engage or abut a complementary flange of the female member 1316.

[00105] Referring to Figs. 17A-17C, in one embodiment, side views illustrate the stabilization system 1300 of Fig. 13 coupled to an upper vertebra 1700 and a lower vertebra 1702. Figs. 17A-17C also illustrate an exemplary range of motion and the center point 1328 relative to the upper and lower vertebrae 1700 and 1702 around which the spine stabilization system 1300 may rotate. Fig. 17A illustrates the spine stabilization system 1300 when the two adjacent vertebrae 1700 and 1702 are in a neutral position. Fig. 17B illustrates the spine stabilization system 1300 when the two adjacent vertebrae 1700 and 1702 are in a full extension position (e.g., when the patient is bending backward). Fig. 17C illustrates the spine stabilization system 1300 when the two adjacent vertebrae 1700 and 1702 are in a flexion position (e.g., when the patient is bending forward).

[00106] Referring to Figs. 18A-18F, in one embodiment, posterior views illustrate

two spine stabilization systems 1300a and 1300b coupled to an upper vertebra 1800 and a lower vertebra 1802. Fig. 18A illustrates the spine stabilization systems 1300a and 1300b when the two adjacent vertebrae 1800 and 1802 are in a neutral position. Fig. 18B illustrates the spine stabilization systems 1300a and 1300b when the two adjacent vertebrae 1800 and 1802 are in an extension position (e.g., when the patient is bending backward). Fig. 18C illustrates the spine stabilization systems 1300a and 1300b when the two adjacent vertebrae 1800 and 1802 are in a flexion position (e.g., when the patient is bending forward). Fig. 18D illustrates the spine stabilization systems 1300a and 1300b when the two adjacent vertebrae 1800 and 1802 are in a lateral bending position (e.g., when the patient is bending towards the right or left). Fig. 18E illustrates the spine stabilization systems 1300a and 1300b when the two adjacent vertebrae 1800 and 1802 are in a lateral rotational extension position (e.g., when the patient is turning and bending backward). Fig. 18F illustrates the spine stabilization systems 1300a and 1300b when the two adjacent vertebrae 1800 and 1802 are in a lateral rotational flexion position (e.g., when the patient is turning and bending forward).

[00107] Referring to Fig. 19, in another embodiment, a posterior view is illustrated of the spine stabilization systems 1300a and 1300b when two adjacent vertebrae 1900 and 1902 are in a neutral position. In this example, the spine stabilization systems 1300a and 1300b incorporate control members 1904a and 1904b for controlling relative movement between the male members 1314a and 1314b and the respective female members 1316a and 1316b. In some embodiments, the control members 1904a and 1904b may be helical springs. The springs may provide an increasing resistance when the exterior ends of the male members 1314a and 1314b and the female members 1316a and 1316b slide closer together, such as in full extension. In some embodiments, the control members 1904a and 1904b may be coupled to both the male members 1314a and 1314b and the female members 1316a and 1316b. In such an embodiment, the control members 1904a and 1904b may also offer increasing resistance as the distance between the exterior ends of the male members 1314a and 1314b and the female members 1316a and 1316b increases, such as in full flexion.

[00108] Referring to Fig. 20, in another embodiment, a posterior view illustrates two neighboring vertebrae 2000 and 2002 coupled to spine stabilization systems 1300a

and 1300b. In this example, spine stabilization systems 1300a and 1300b incorporate control members 2004a and 2004b for controlling relative movement between the respective male members 1314a and 1314b and the female members 1316a and 1316b. In this embodiment, the control members 2004a and 2004b may be elastomeric sleeves. The control members 2004a and 2004b may provide an increasing resistance when the exterior ends of the male members 1314a and 1314b and the female members 1316a and 1316b slide closer together, such as in full extension. In some embodiments, the control members 2004a and 2004b may be coupled to both the male members 1314a and 1314b and the female members 1316a and 1316b. In such an embodiment, the control members 2004a and 2004b may also offer increasing resistance as the distance between the exterior ends of the male members 1314a and 1314b and the female members 1316a and 1316b increases, such as in full flexion. Furthermore, the sleeves may prevent surrounding flesh and tissue from intruding into the components of the respectively spine stabilization system.

[00109] Referring to Fig. 21, in yet another embodiment, a sleeve 2100 is illustrated that may be used with embodiments of the spine stabilization systems discussed above. In this embodiment, the sleeve 2100 may comprise a helical shape for use in conjunction with a spring member (not shown). In such embodiments, the spring may offer resistance or control the respective movement and the sleeve may prevent surrounding tissue from intruding into the spine stabilization system. In yet other embodiments, the sleeve may be made from a surgical mesh.

[00110] Referring to Fig. 22, in another embodiment, a method 2200 may be used to insert a dynamic stabilization system, such as the dynamic stabilization system 100 of Fig. 1 or 1300 of Fig. 13. In step 2202, a center of rotation may be identified between first and second vertebrae. In step 2204, a first member of a dynamic stabilization device may be coupled to a first polyaxial head and, in step 2206, a second member of the dynamic stabilization device may be coupled to a second polyaxial head. In steps 2208 and 2210, respectively, an axis of each of the first and second polyaxial heads may be oriented with the center of rotation. In step 2212, the first and second members may be secured relative to the first and second polyaxial heads, respectively, to maintain the orientation of the first and second axes with the center of rotation.

[00111] In another embodiment, a dynamic stabilization device may be inserted. As illustrated in previous embodiment, the dynamic stabilization device may be designed to be coupled to bone anchors inserted into neighboring vertebrae. For example, the dynamic stabilization device may include a bottom member and a top member that may be coupled together at the proximal ends thereof to allow relative rotation at least about both an axis of roll and a horizontal axis within a range of movement, the range of movement allowing lateral bending and twisting of the upper and lower vertebrae relative to each other while maintaining separation between the vertebrae. The distal end of the bottom member may be coupled to a lower bone anchor and the distal end of the upper member may be coupled to an upper bone anchor. The upper and lower links member be coupled to the bone anchors via a threaded fastener and bushings. The threaded fastener may comprise a bearing post secured by a locking cap or other similar threaded fasteners and locking mechanisms known to those skilled in the art. Both the upper and lower member may be vertically adjusted along the threaded fastener during adjustment of the dynamic stabilization device and thereafter locked down into a substantially permanent position once the device is aligned with the spine's natural center of rotation.

[00112] Once the bone anchors and dynamic stabilization device have been implanted and before the implant procedure is completed, the device may be aligned with the spine natural center of rotation. This may be accomplished by several methods, including but not limited to using an aligning cross-connector, using a removable alignment tool that is coupled to the bone anchors, using a removable alignment tool coupled to the dynamic stabilization device between the bone anchors, or various other alignment methods known to those skilled in the art. Generally, the alignment tool may be coupled to the dynamic stabilization device and then an alignment rod may be attached thereto. The alignment rod may be rotated to adjust various components of the dynamic stabilization device such that the components of the dynamic stabilization device align with the spine's natural center of rotation. Alternatively, an alignment tool coupled to the bone anchors may be used to align the bone anchors before any other components of the dynamic stabilization device are implanted.

[00113] Although only a few exemplary embodiments of this disclosure have been described in details above, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this disclosure. Also, features illustrated and discussed above with respect to some embodiments can be combined with features illustrated and discussed above with respect to other embodiments. Accordingly, all such modifications are intended to be included within the scope of this disclosure.

WHAT IS CLAIMED IS:

1. A medical implant for coupling two vertebrae of a spine, the implant characterized by:

a dynamic member having a first end and a second end, wherein the dynamic member generally constrains relative movement of the first end with respect to the second end to a three dimensional curved surface,

the first end comprising a means for coupling to a first alignment member, such that the first end can rotate with respect to the longitudinal axis of the first alignment member,

the second end comprising a means for coupling to a second alignment member such that the second end can rotate with respect to the longitudinal axis of the second alignment member.

2. The medical implant according to claim 1 characterized in that the dynamic member comprises a first link member, a second link member, and a means for rotationally coupling the first link member to the second link member.

3. The medical implant according to claim 2 characterized in that the means for rotationally coupling includes a pin joint.

4. The medical implant according to claim 3 characterized in that the longitudinal axes of the first alignment member, the second alignment member and the pin joint intersect about a center of rotation.

5. The medical implant of claim 1 characterized in that the dynamic member comprises a first link member that is slidingly coupled to a second link member.

6. The medical implant according to claims 2 through 5 characterized in that the link members are non linear members.

7. The medical implant according to claims 1 through 6 characterized in that the means for coupling includes an aperture formed within the respective ends.

8. The medical implant according to claim 7 characterized in that the aperture is rotationally coupled to a bushing which is adapted to be mated to the aperture.

9. The medical implant according to claim 8 characterized in that the bushing is adapted to threadingly engage one of the alignment members.

10. The medical implant according to claim 9 characterized in that the alignment members include a means to engage a bone engagement member.

11. A medical system for coupling two vertebrae of a spine, the system characterized by:

a first bone anchoring means,

a second bone anchoring means,

a first alignment means coupled to the first bone anchoring means,

a second alignment means coupled to the second bone anchoring means such that the longitudinal axes of the first and second alignment means can be aligned to intersect at a center of rotation,

a dynamic member having a first end and a second end which allows for relative movement between the first end and second end, wherein the first end includes

a means for coupling to the first alignment means, such that the first end can rotate with respect to the longitudinal axis of the first alignment means, and the second end includes a means for coupling to a second alignment member such that the second end can rotate with respect to the longitudinal axis of the second alignment means.

12. A medical system according to claim 11 characterized in that the dynamic member restricts the relative movement to a three dimensional curved surface.

13. The medical system according to claim 11 characterized in that the dynamic member comprises a first link member, a second link member, and a means for rotationally coupling the first link member to the second link member.

14. The medical system according to claim 13 characterized in that the means for rotationally coupling includes a pin joint.

15. The medical system according to claim 14 characterized in that the longitudinal axes of the first alignment member, the second alignment member and the pin joint intersect about a center of rotation.

16. The medical system according to claims 11 and 12 characterized in that the dynamic member comprises a first link member that is slidingly coupled to a second link member.

17. The medical system according to claims 13 through 16 characterized in that the link members are non linear members.

18. The medical system according to claim 11 through 17 characterized in that the means for coupling includes an aperture formed within the respective ends.

19. The medical system according to claim 18 characterized in that the aperture is rotationally coupled to a bushing which is adapted to be mated to the

aperture.

20. The medical system according to claim 19 characterized in that the bushing is adapted to threadingly engage one of the alignment members.

21. The medical system according to claim 20 characterized in that the alignment members include a means to engage a bone engagement member.

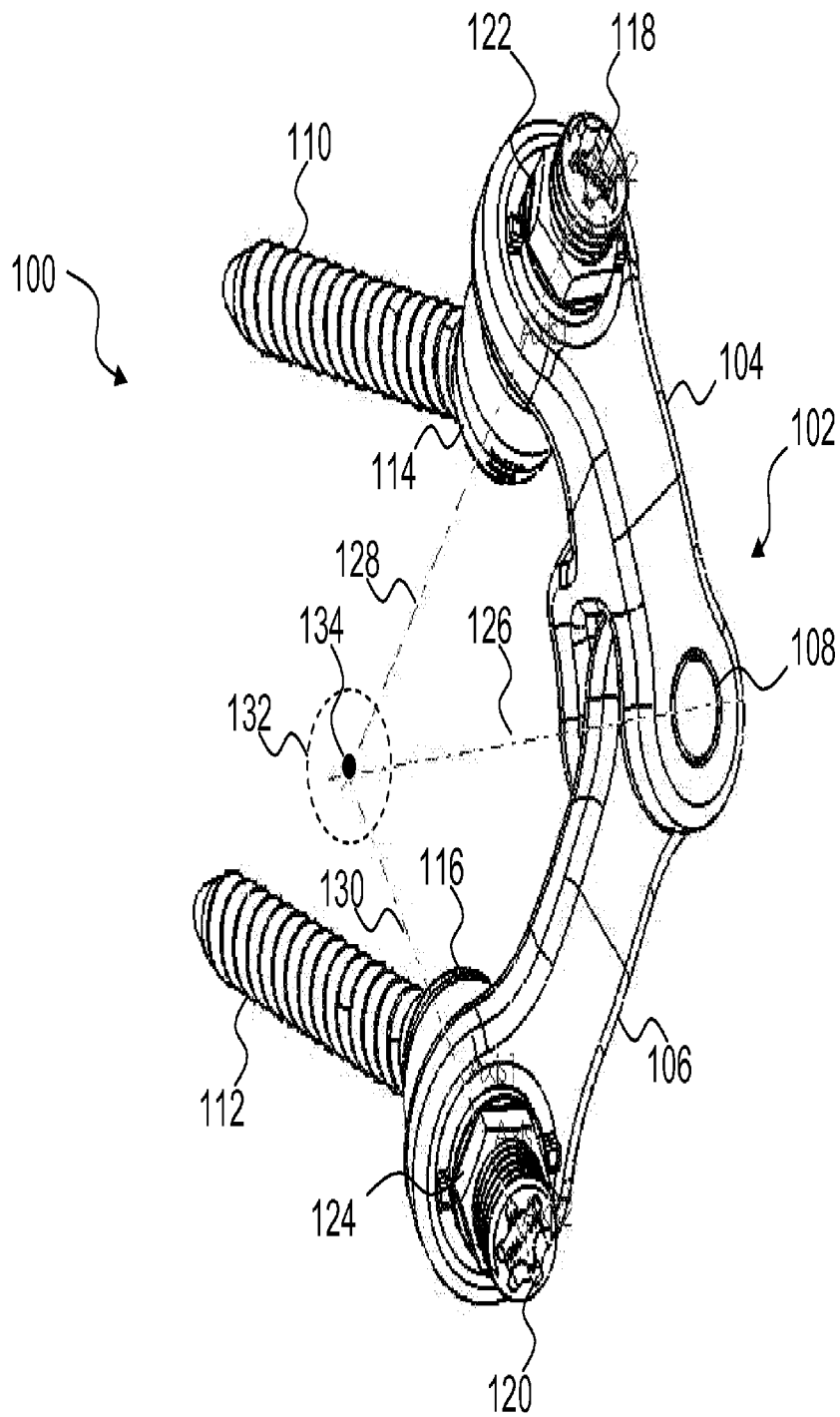


Fig. 1

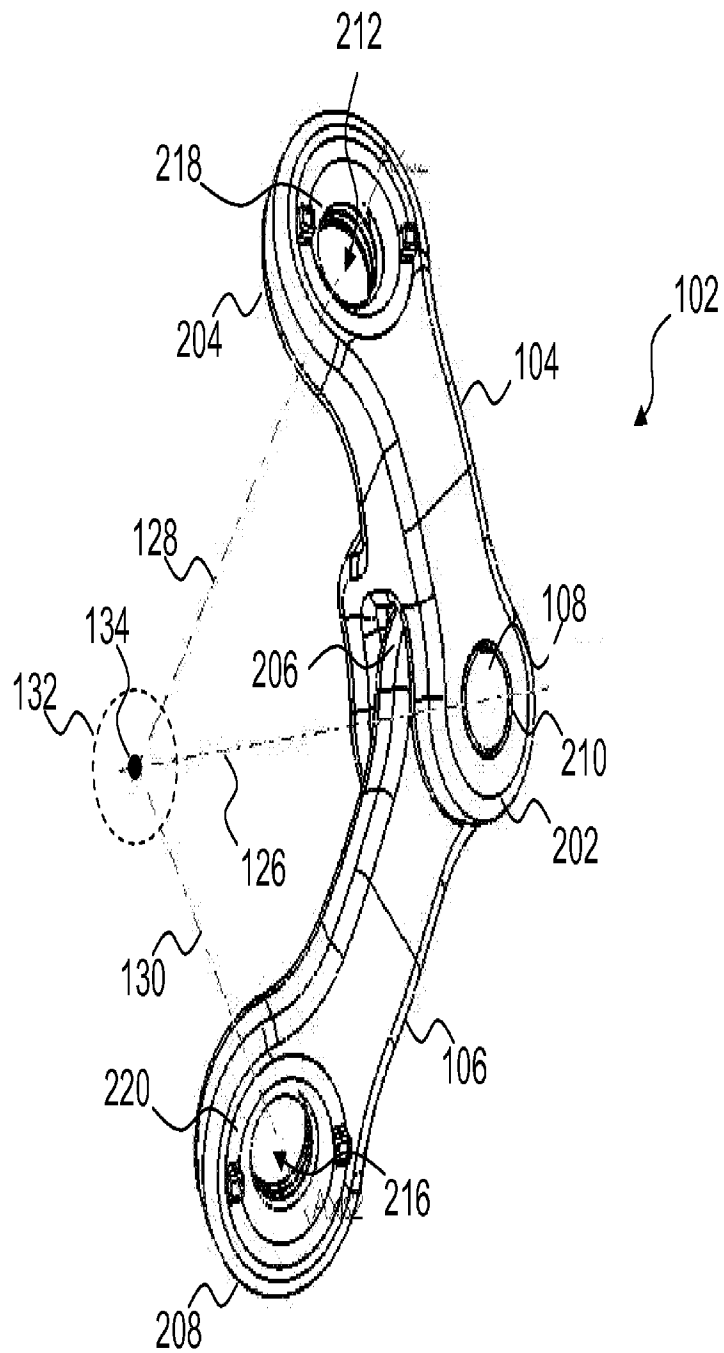


Fig. 2

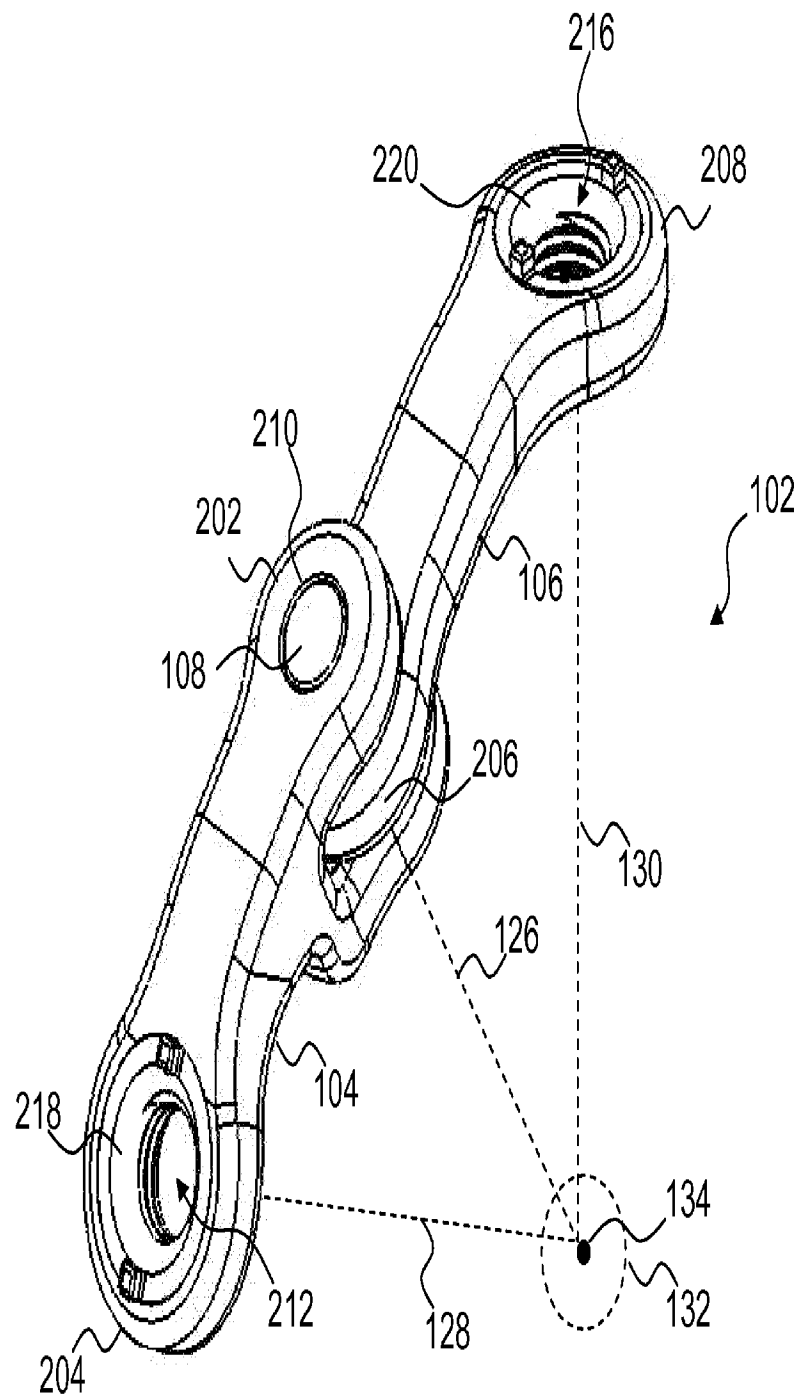


Fig. 3

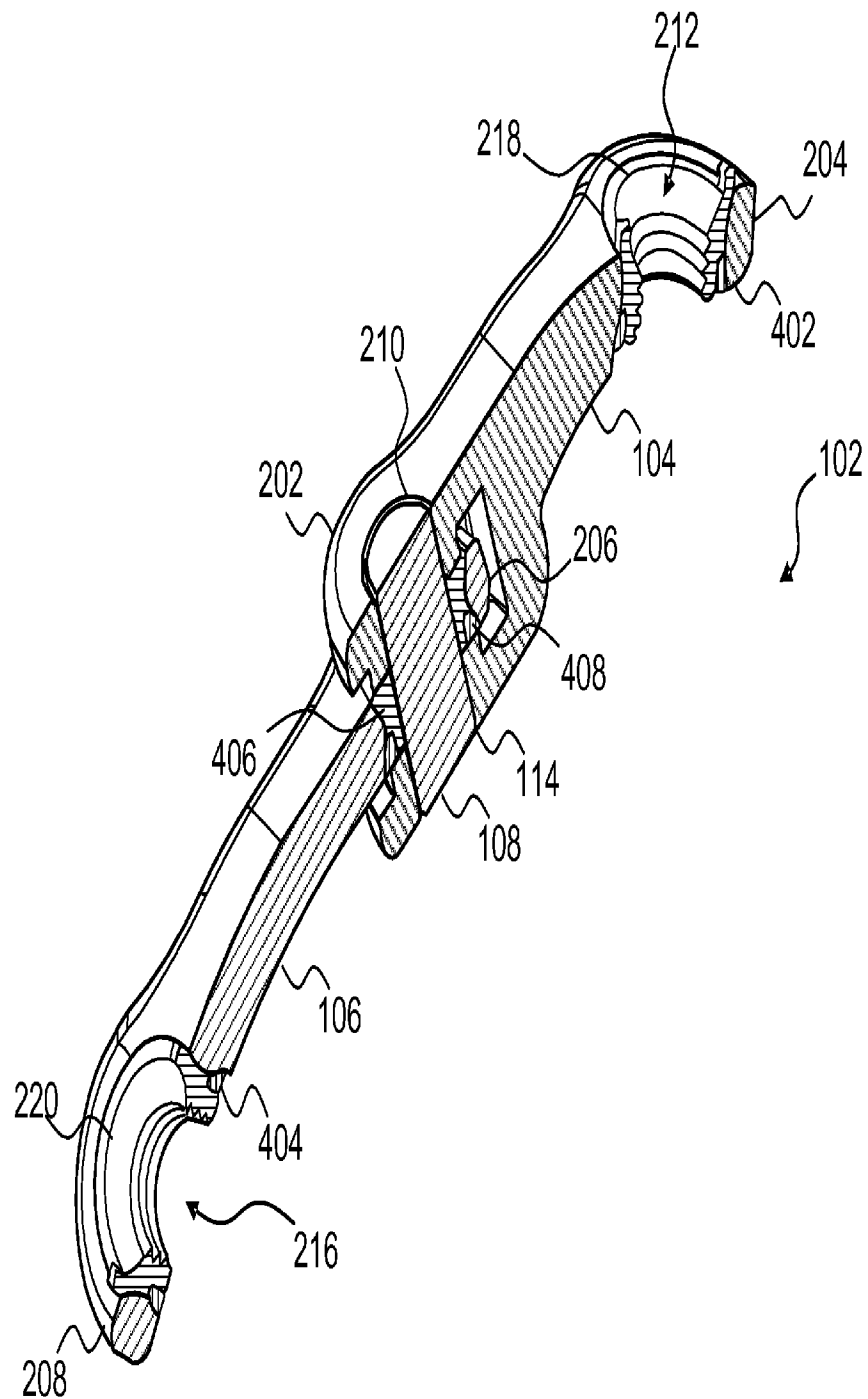


Fig. 4

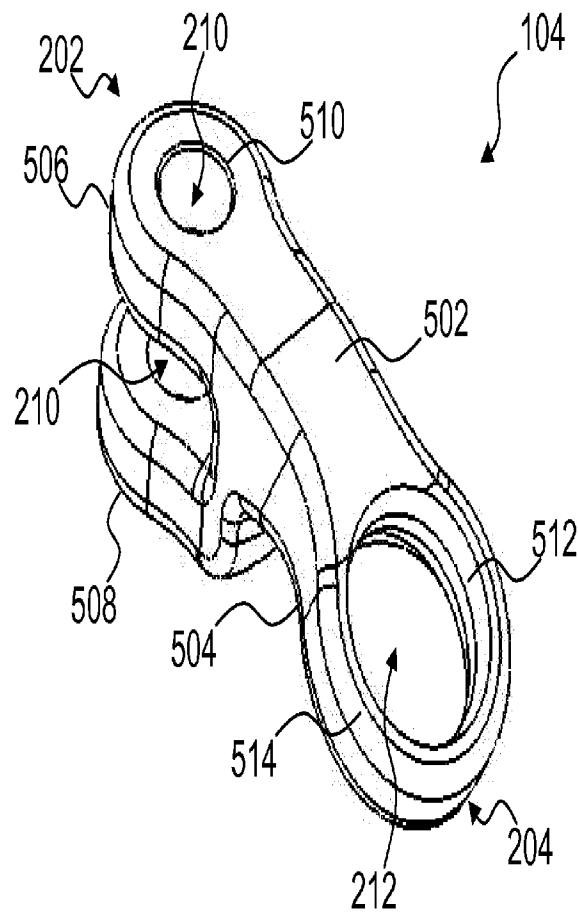


Fig. 5

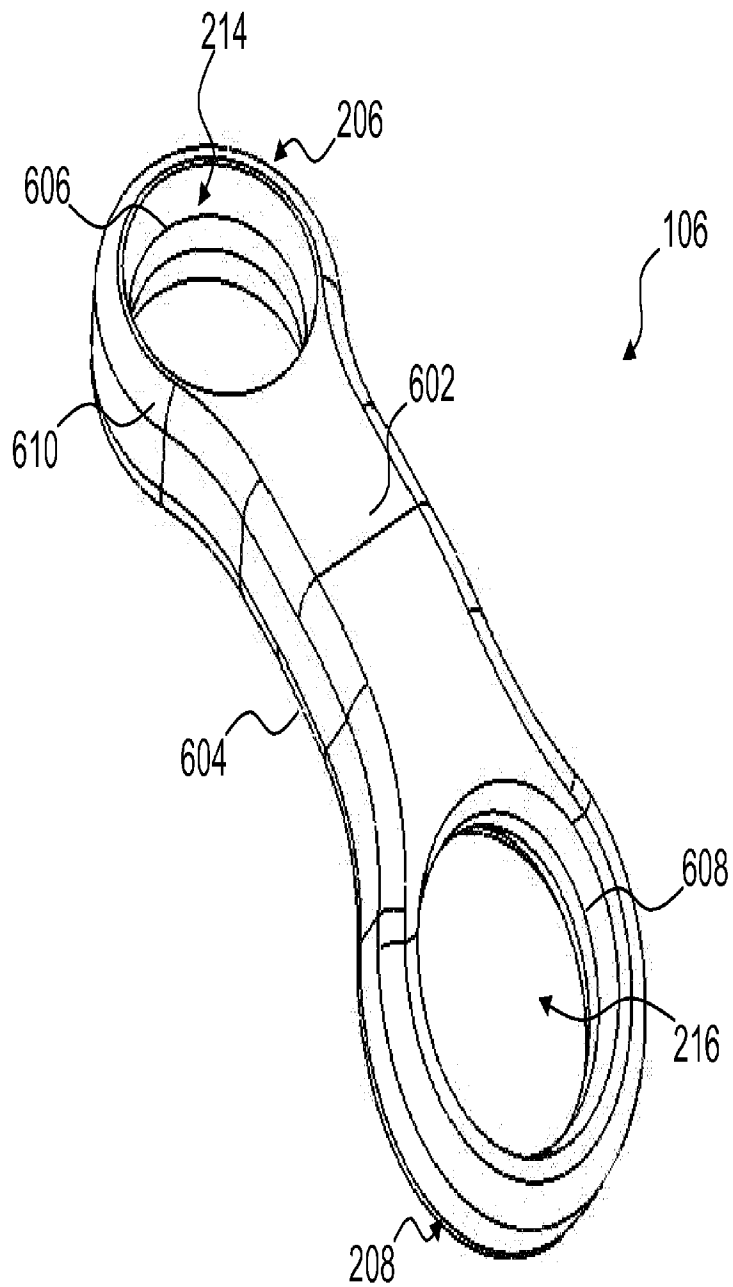


Fig. 6

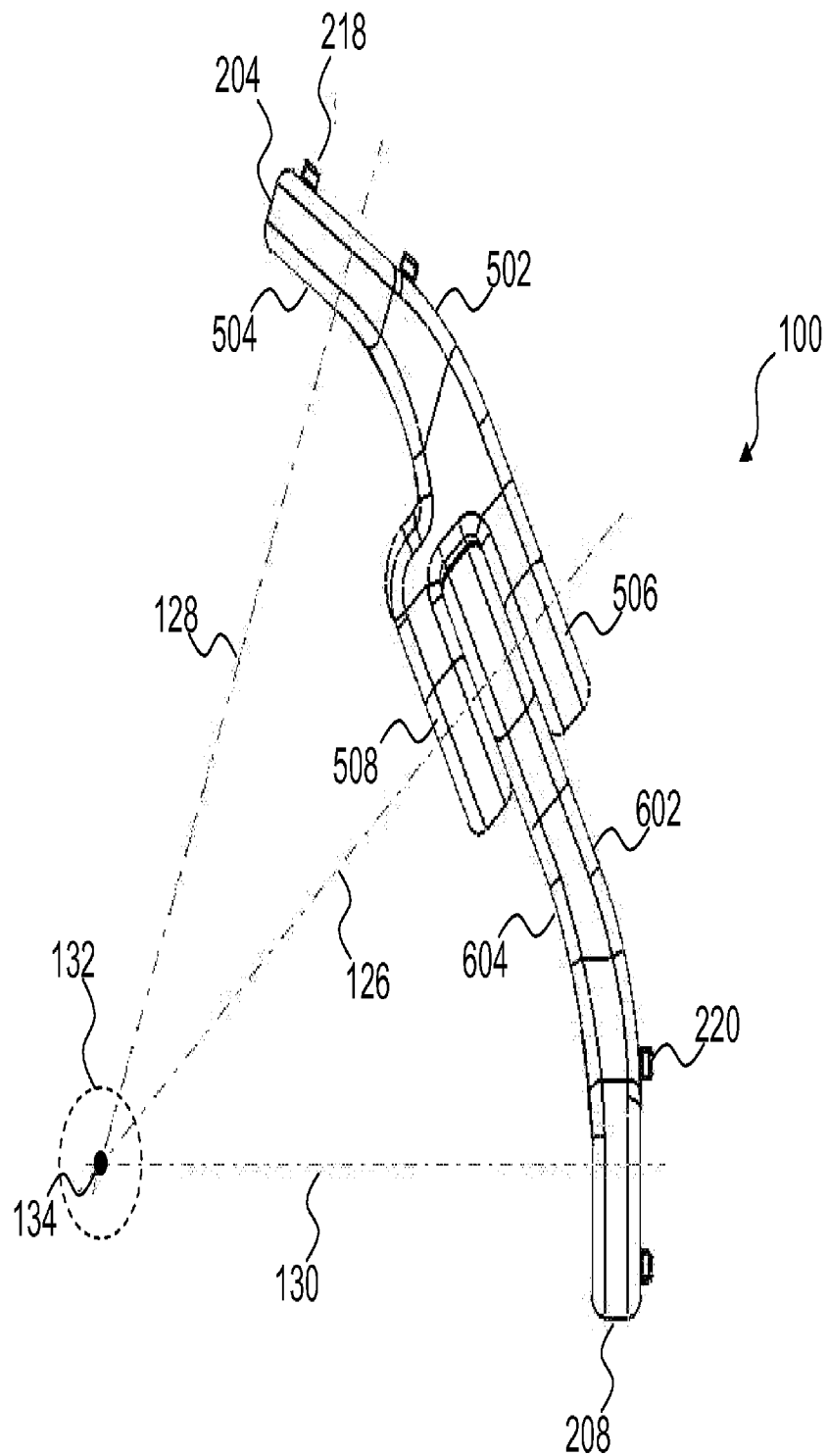


Fig. 7

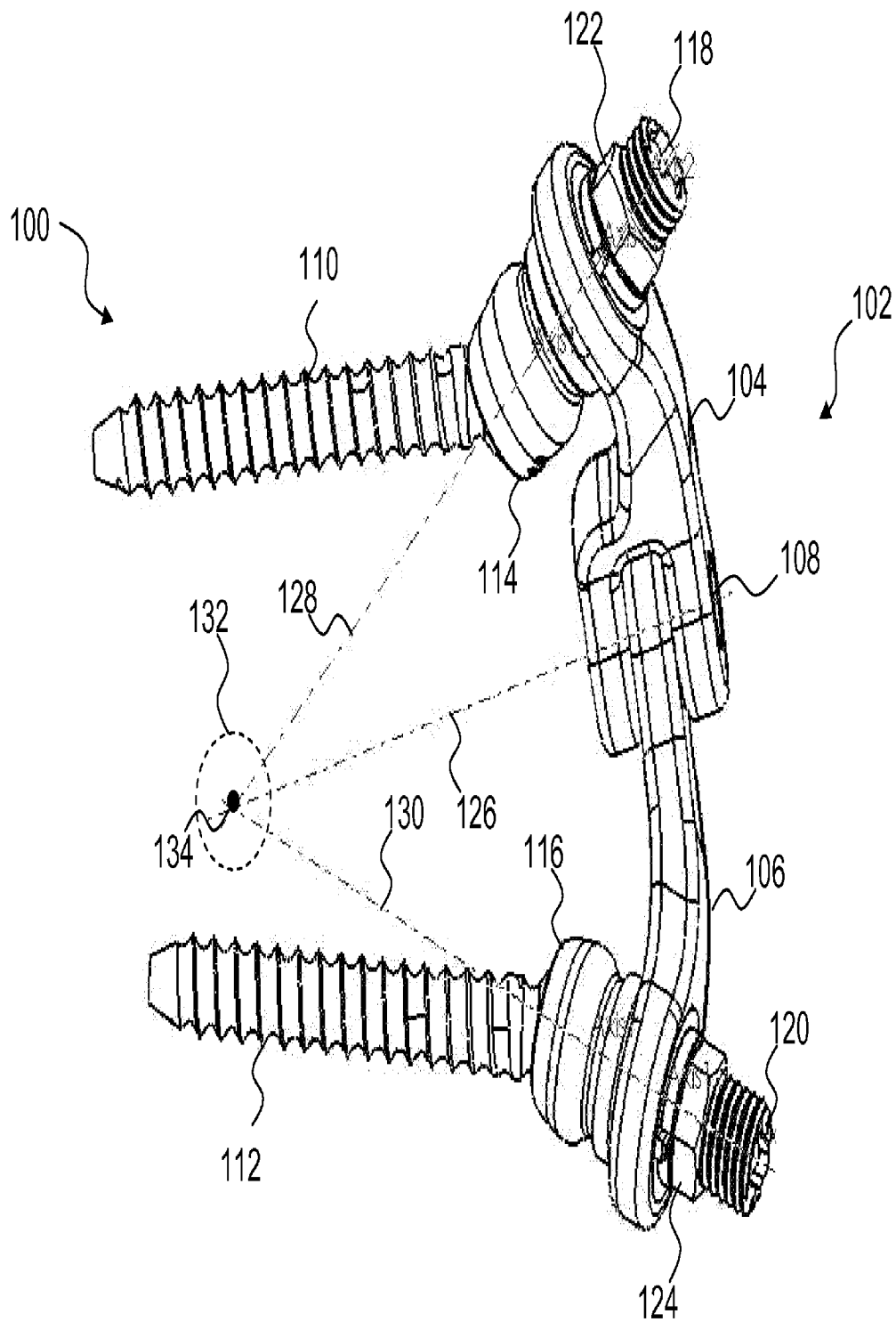


Fig. 8

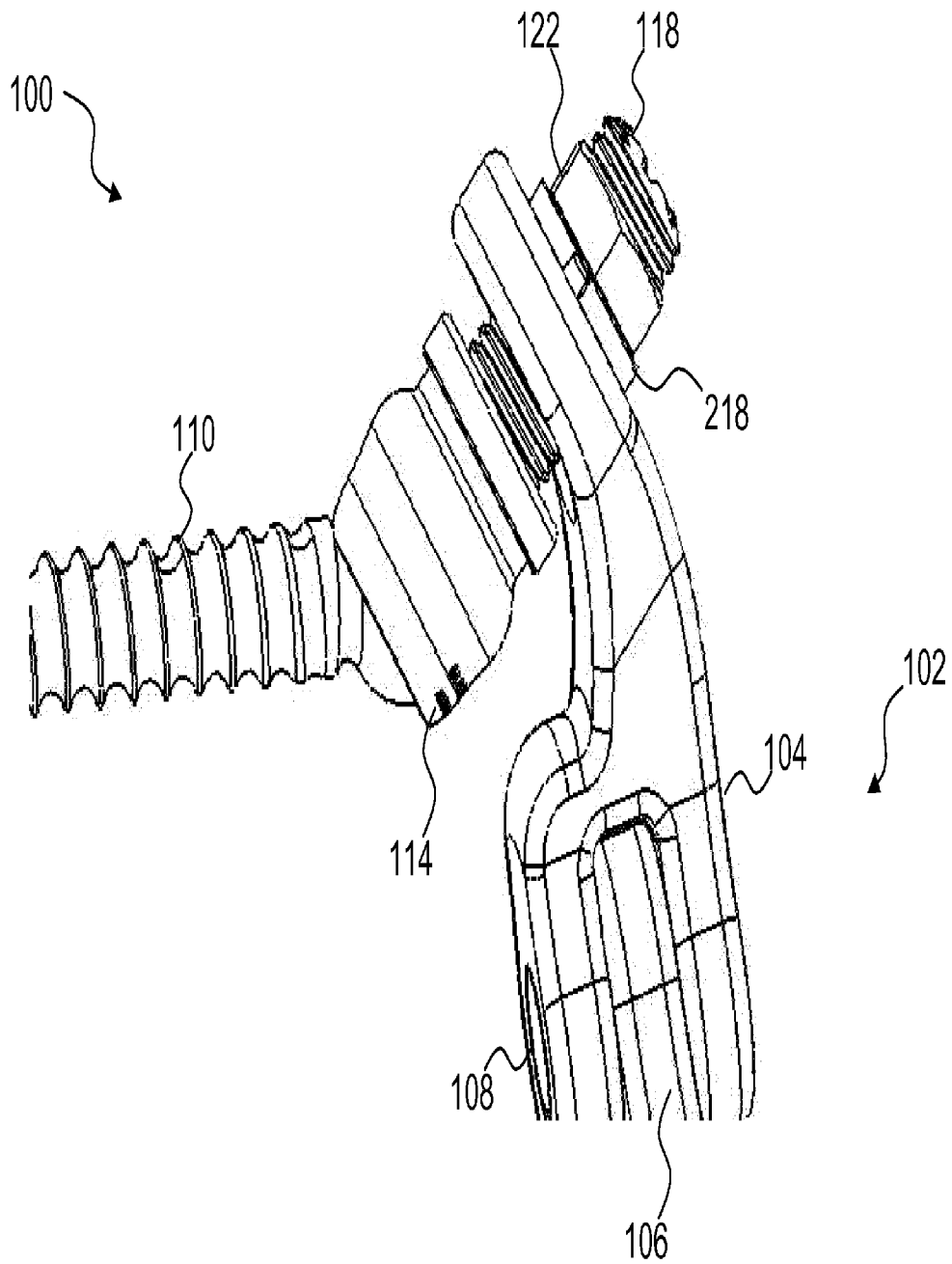


Fig. 9

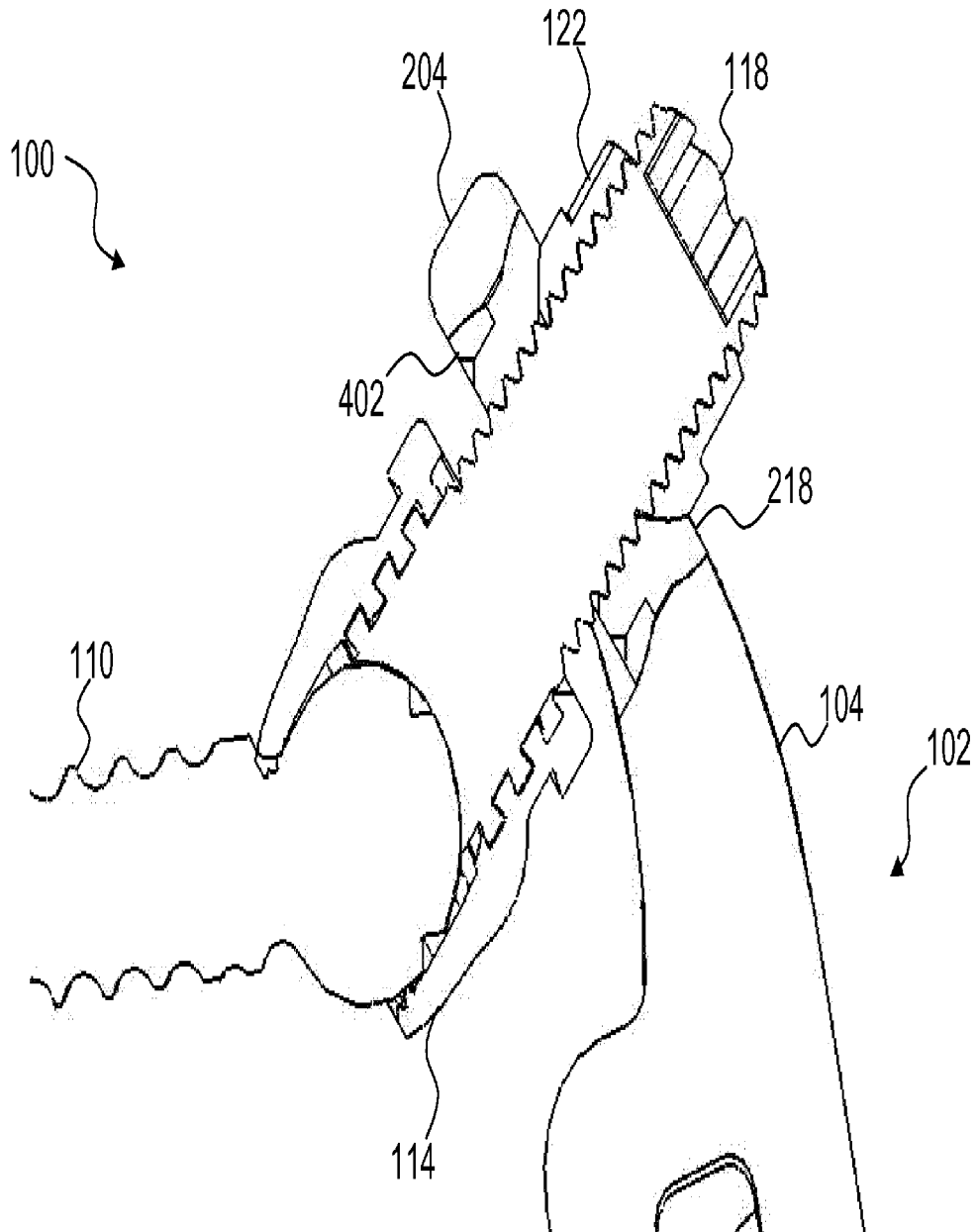


Fig. 10

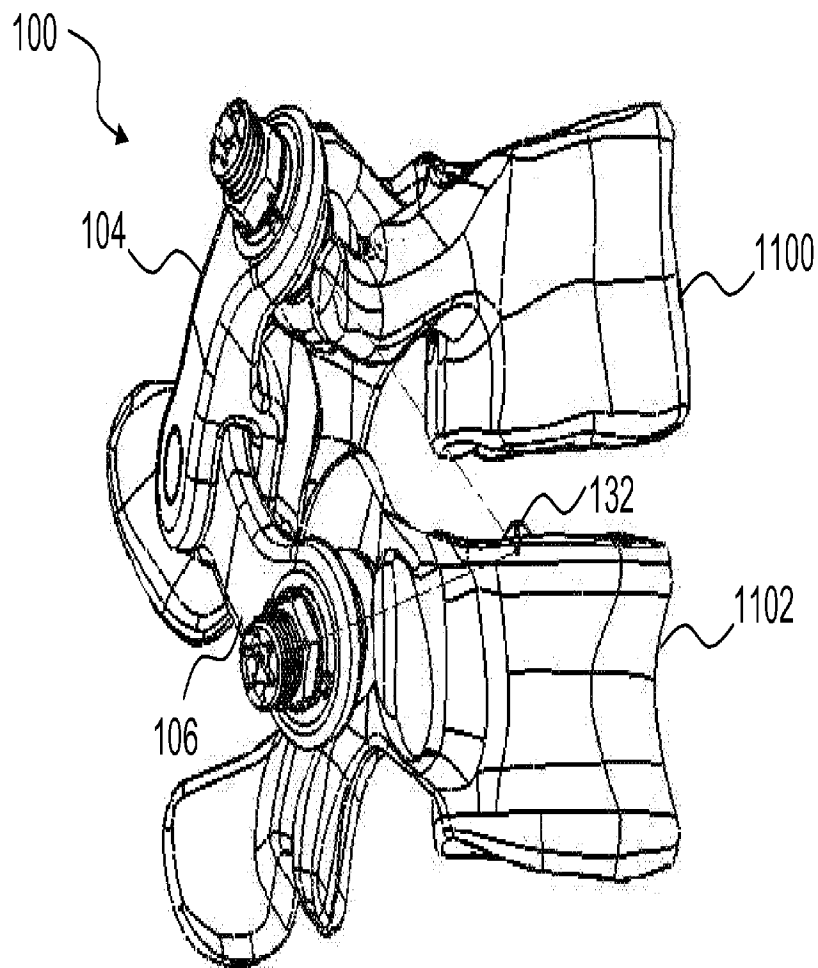


Fig. 11A

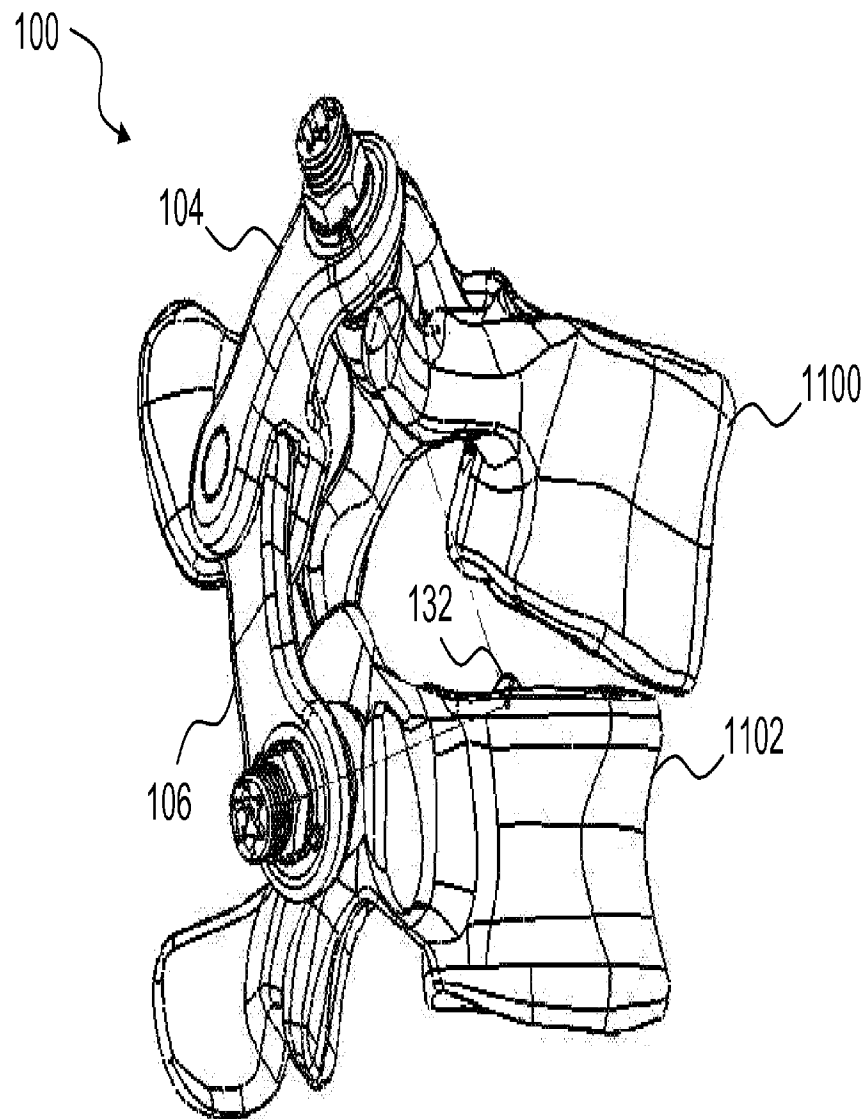
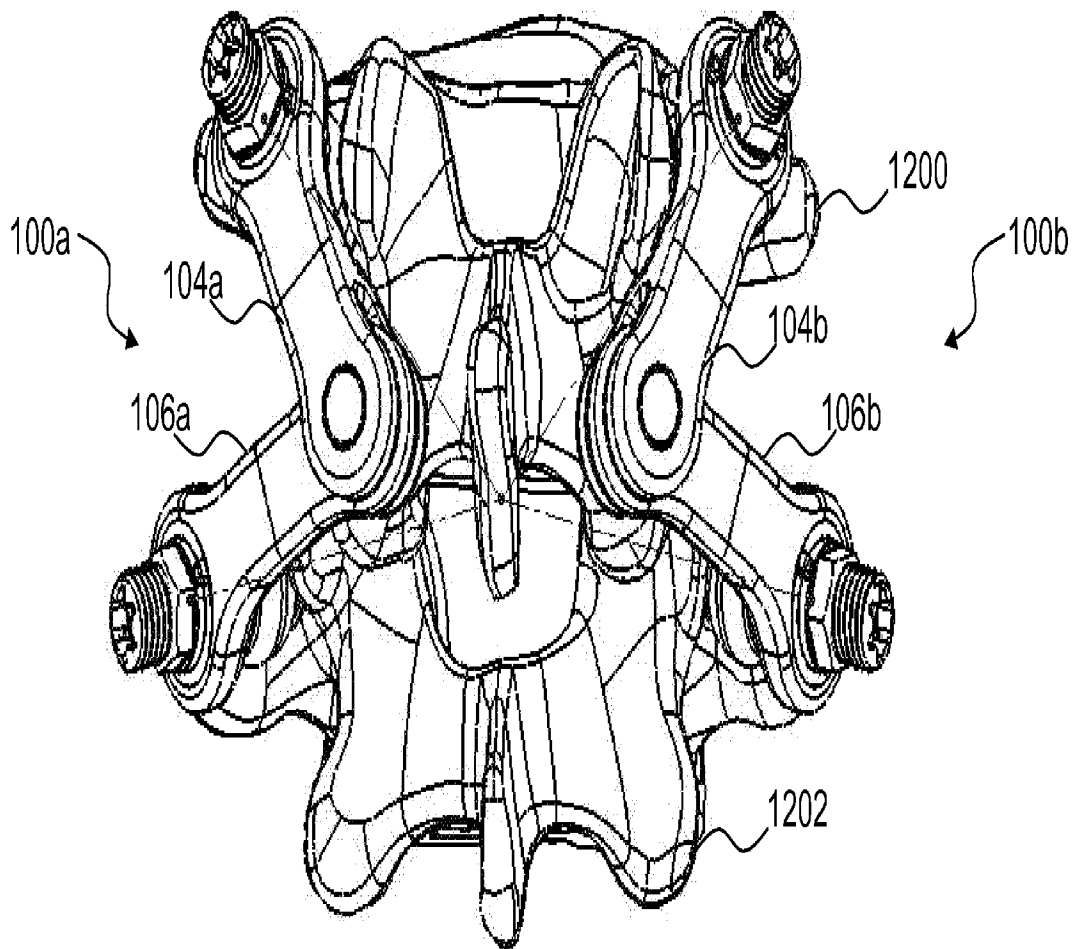
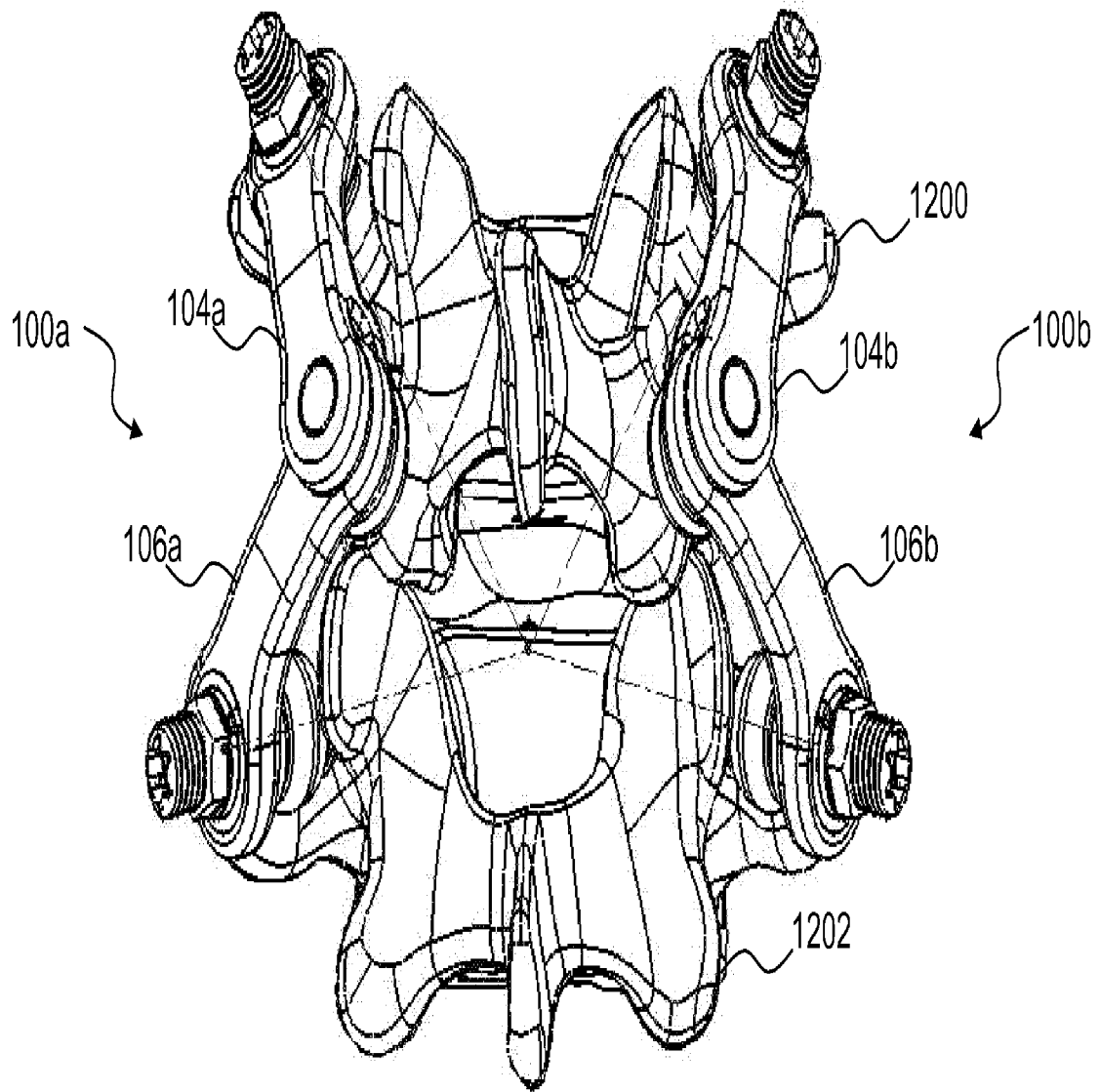


Fig. 11B



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Fig. 12A



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Fig. 12B

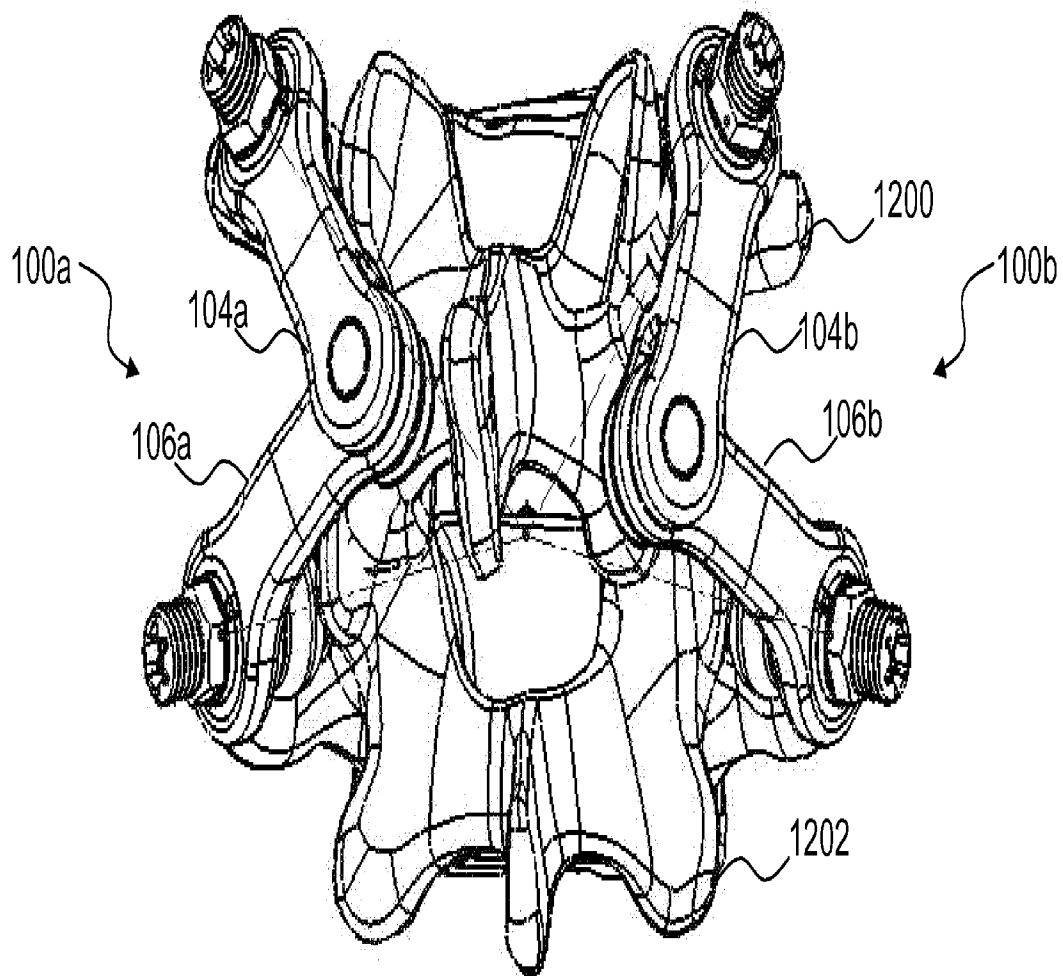


Fig. 12C

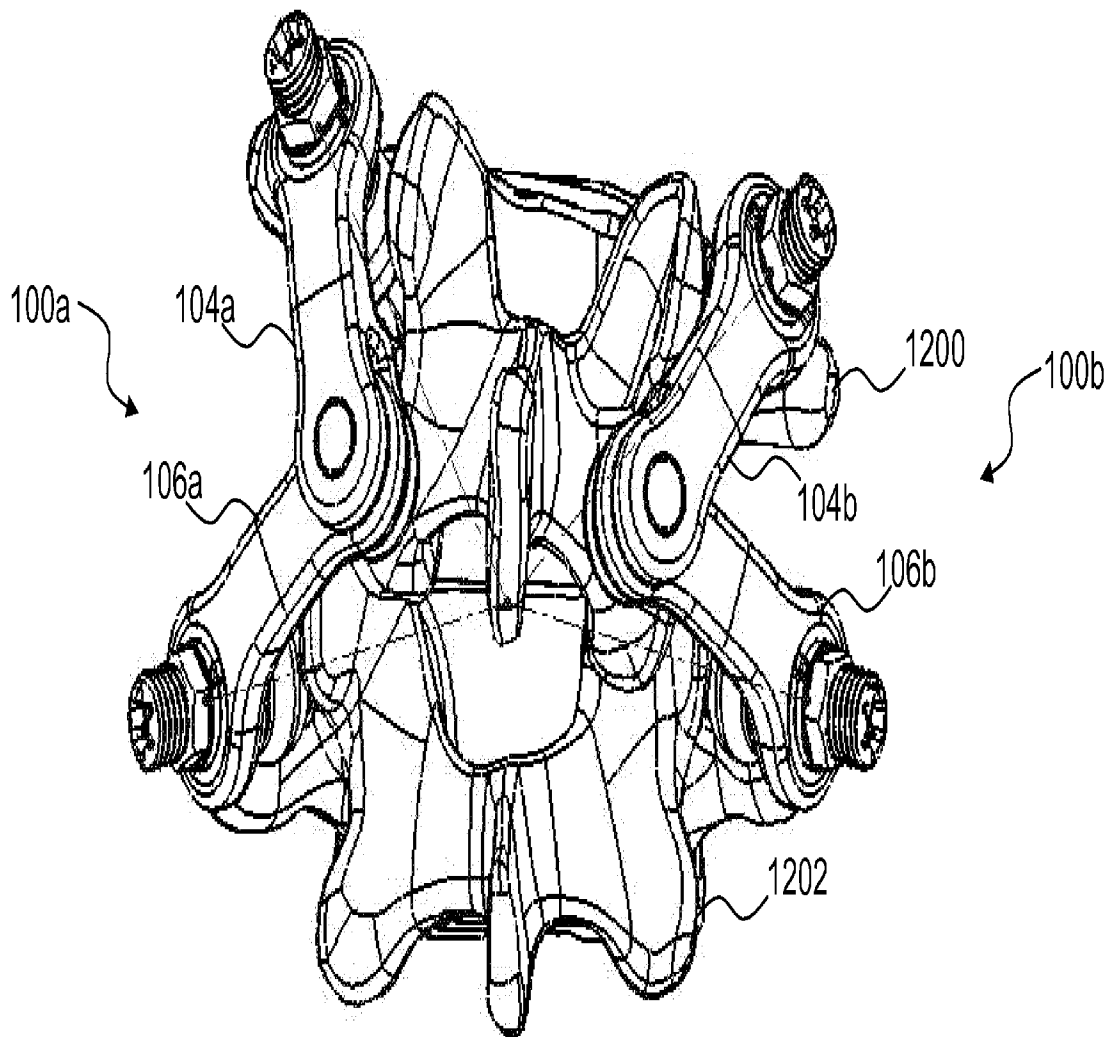


Fig. 12D

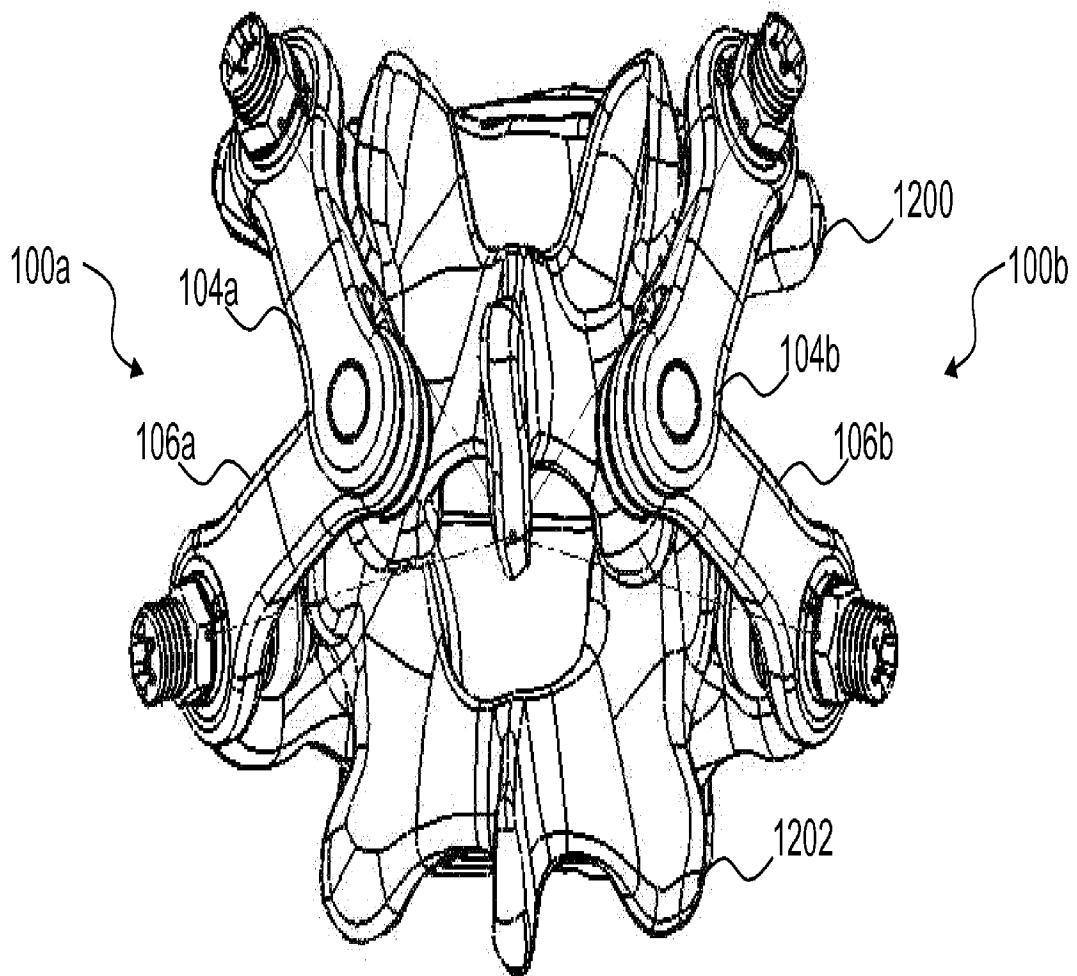
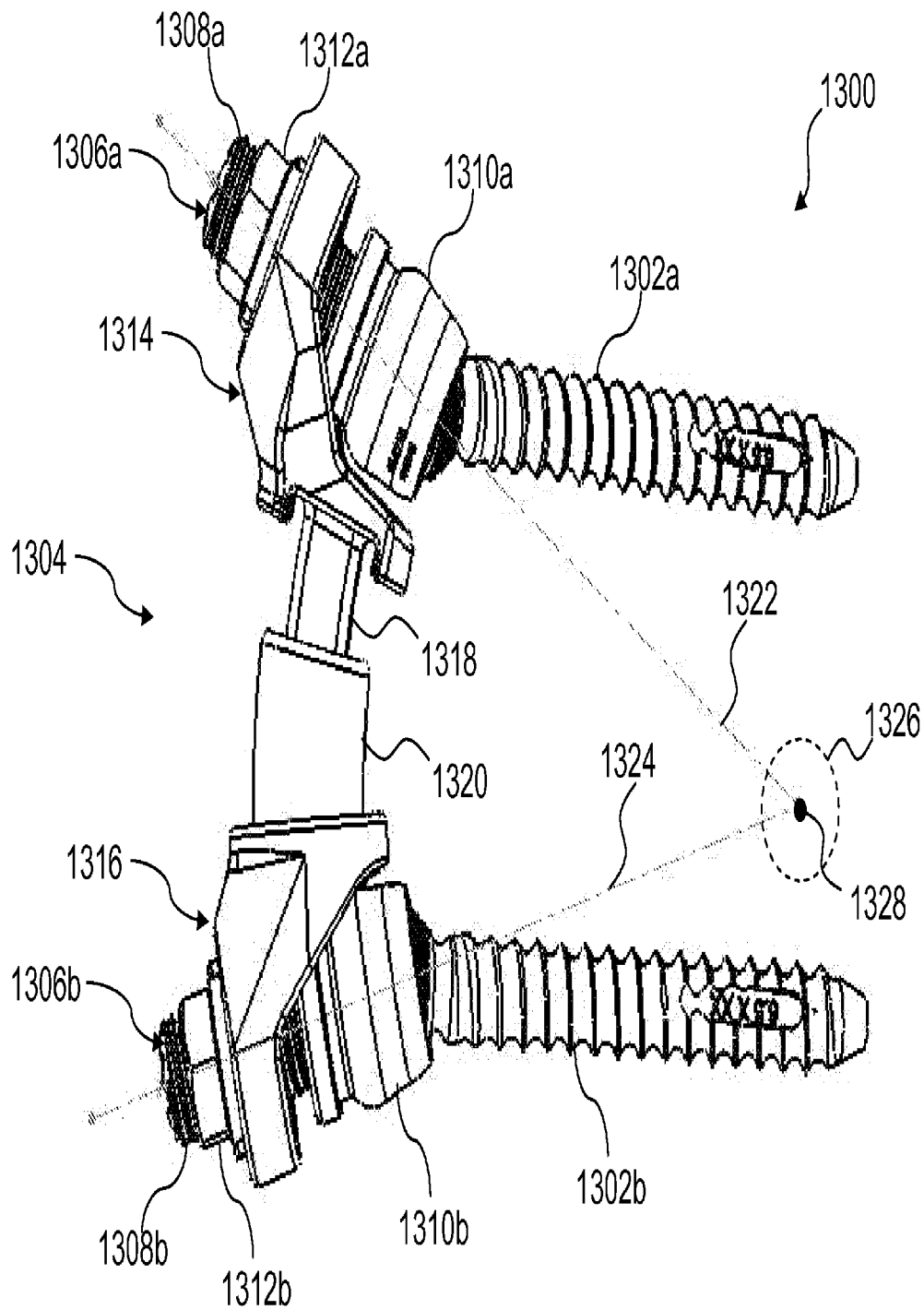


Fig. 12E

**Fig. 13**

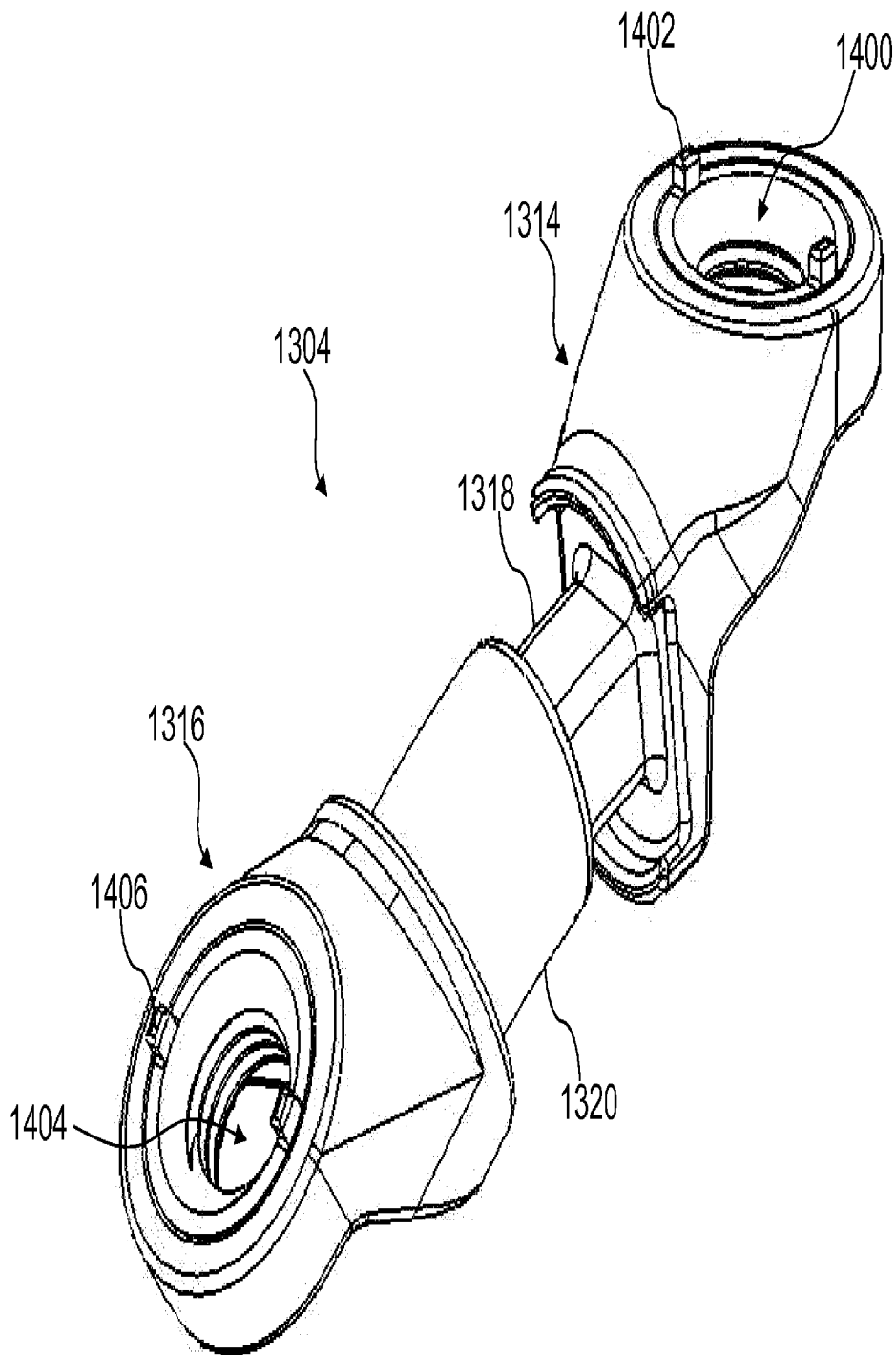
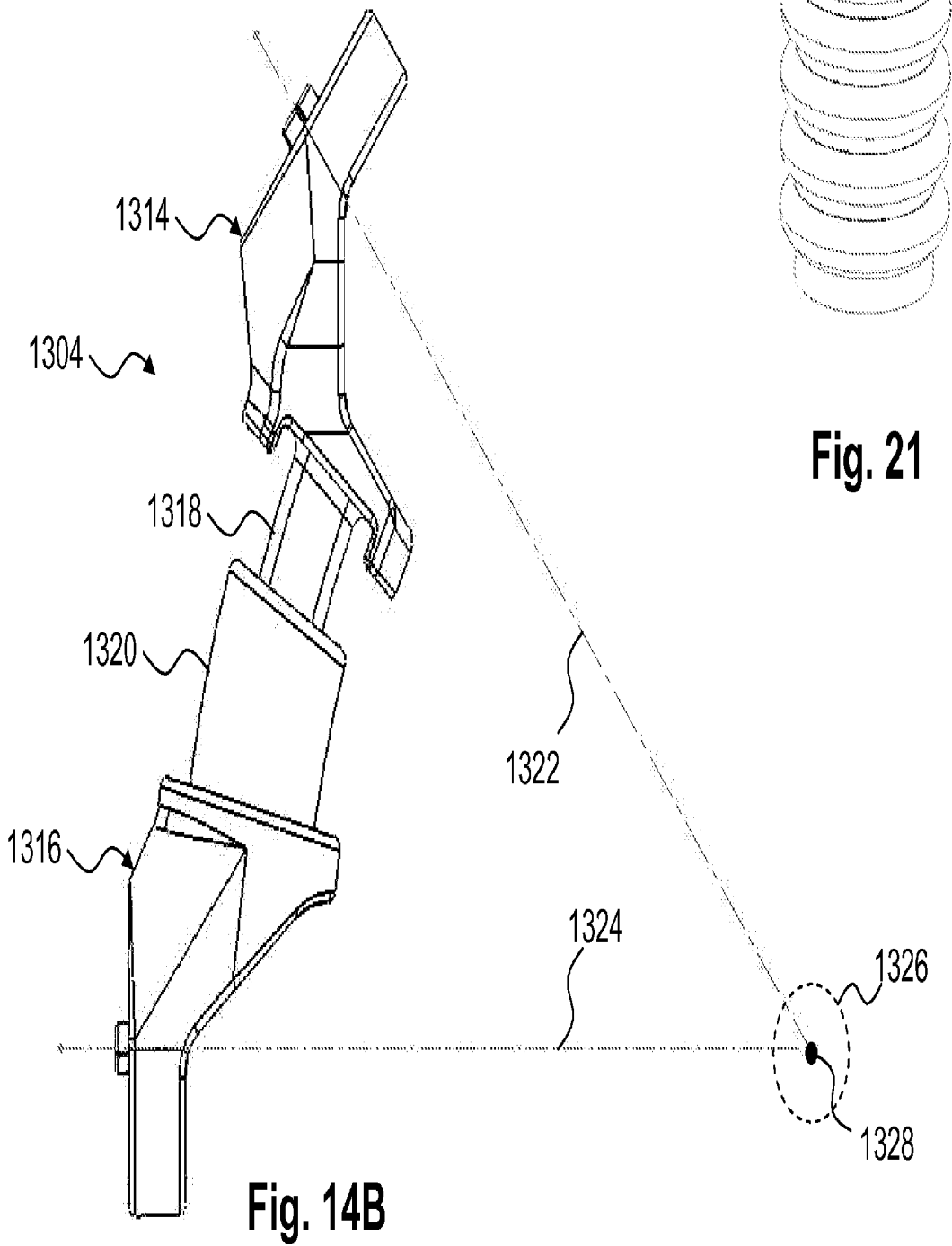


Fig. 14A



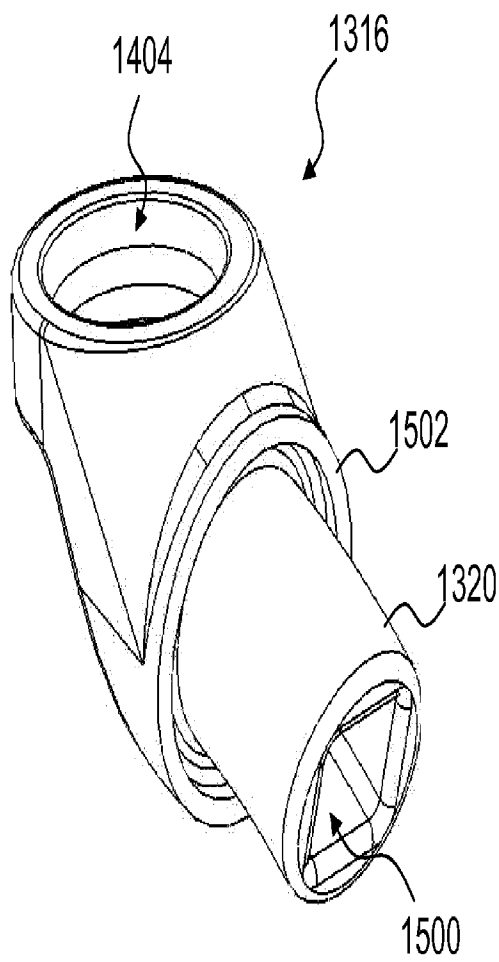


Fig. 15

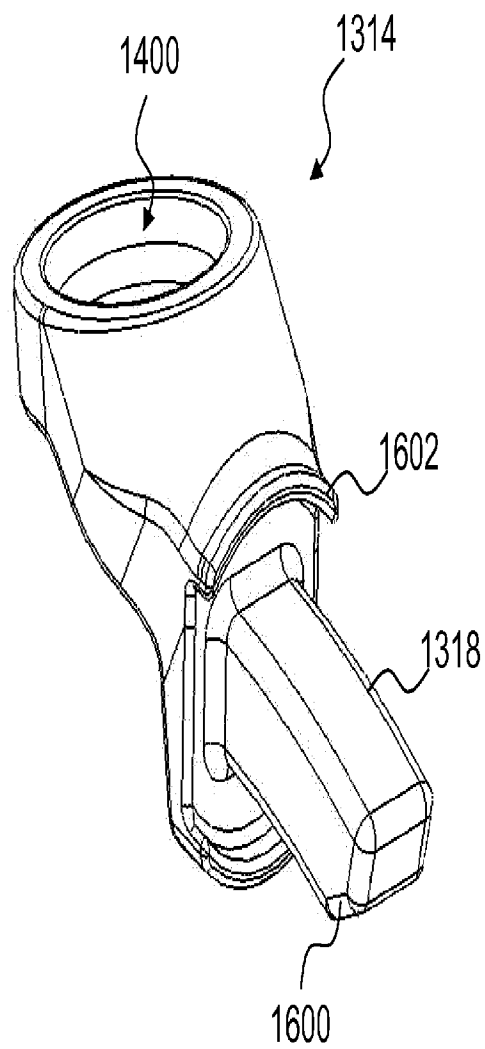
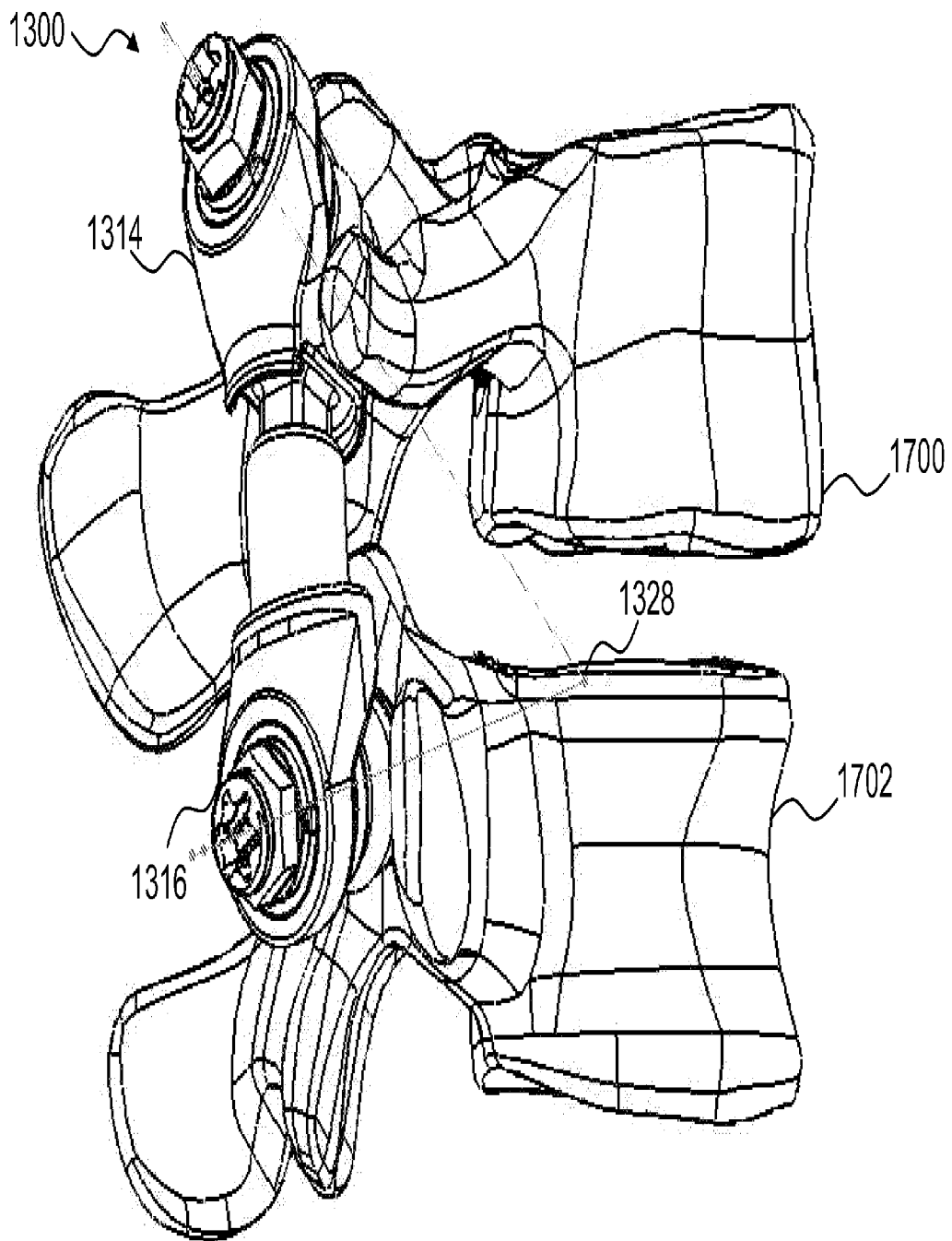


Fig. 16



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Fig. 17A

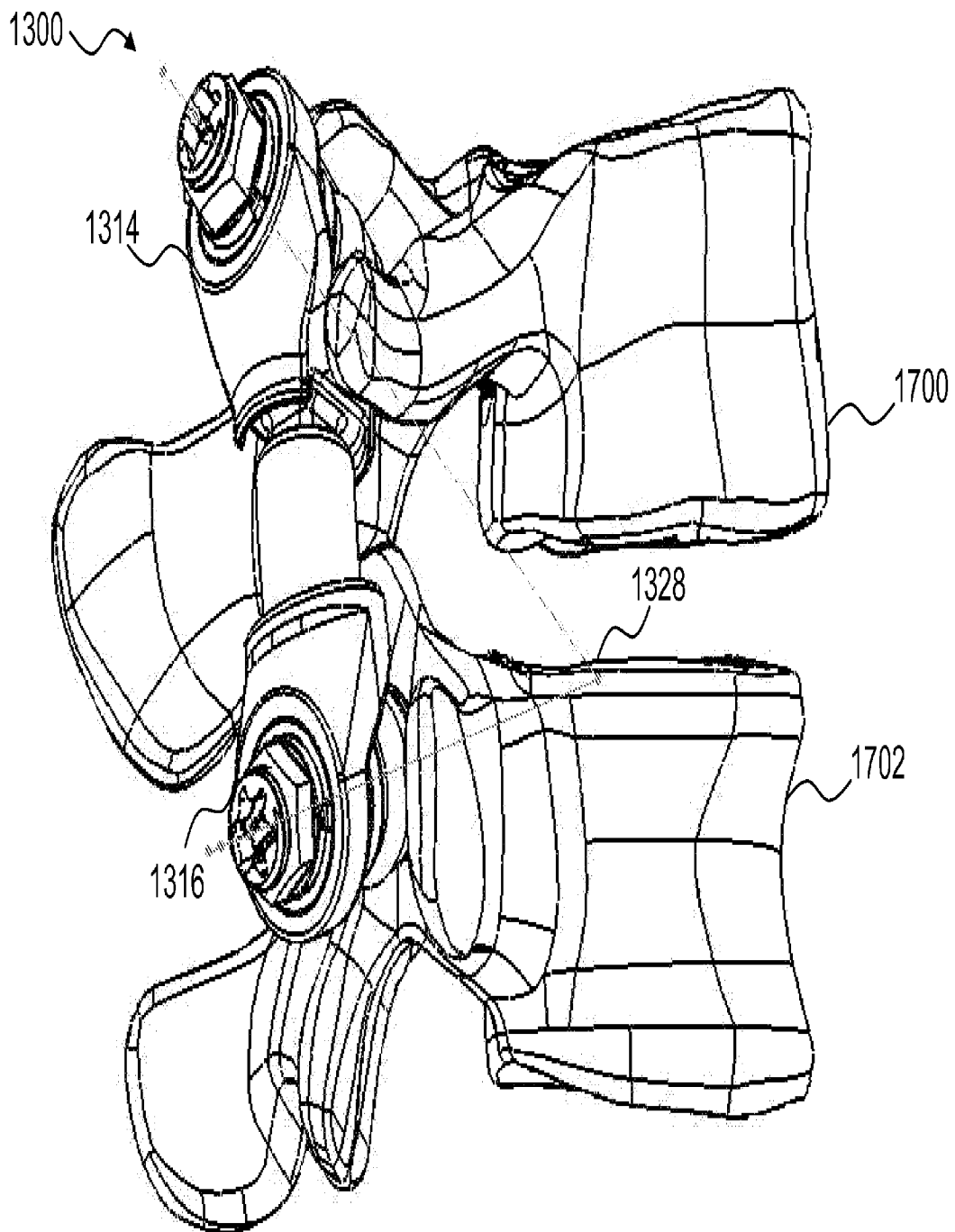


Fig. 17B

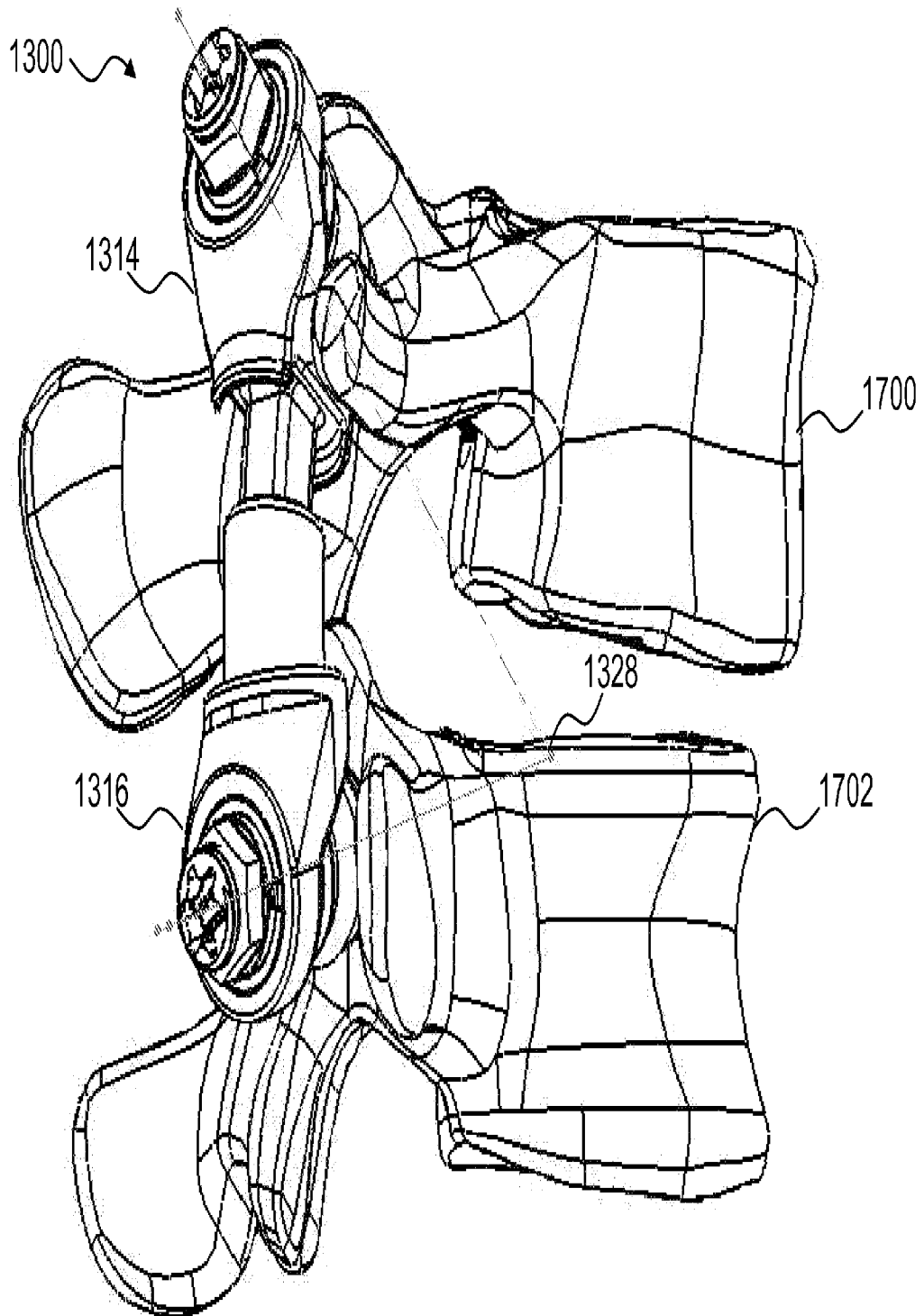


Fig. 17C

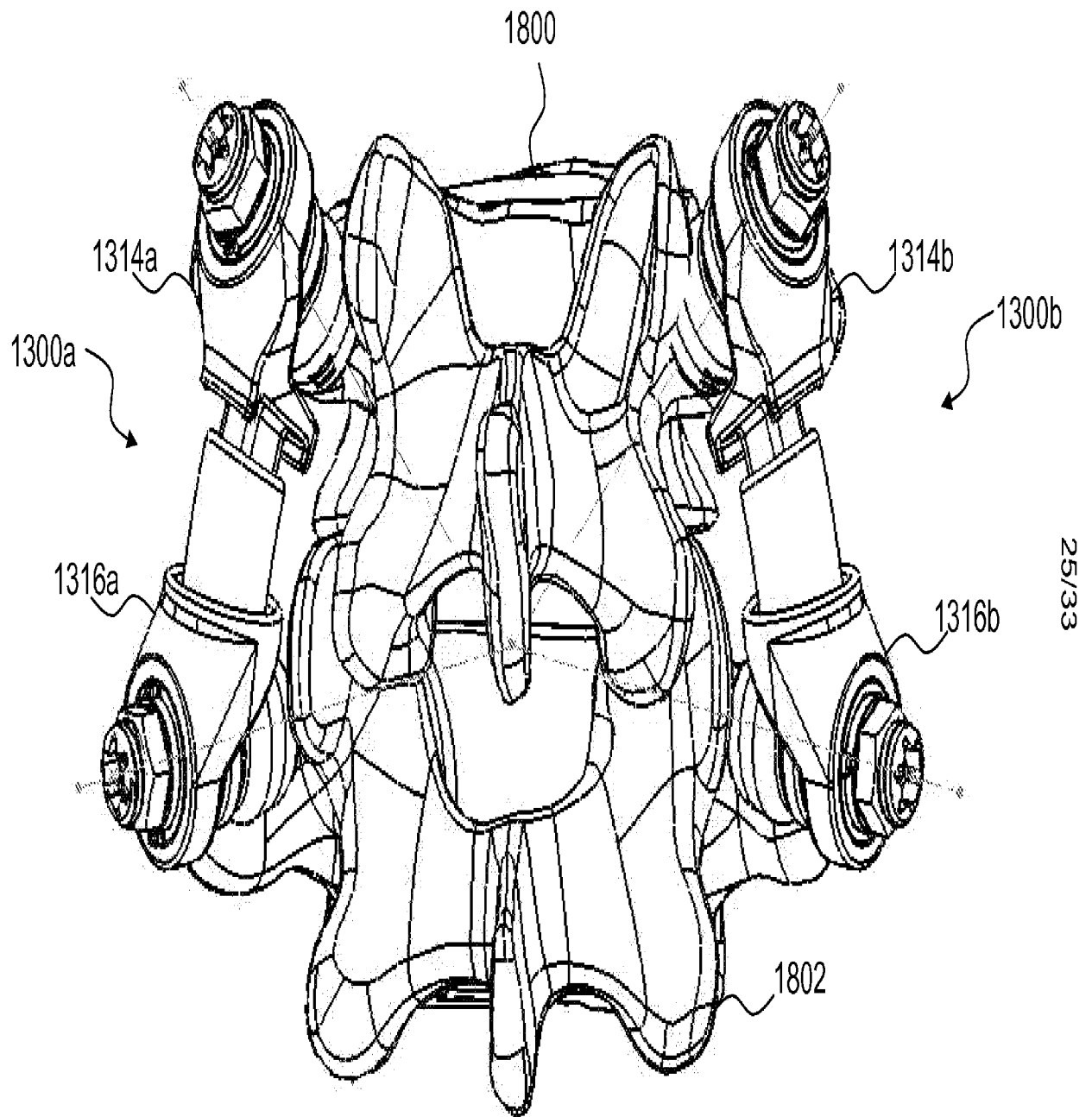


Fig. 18A

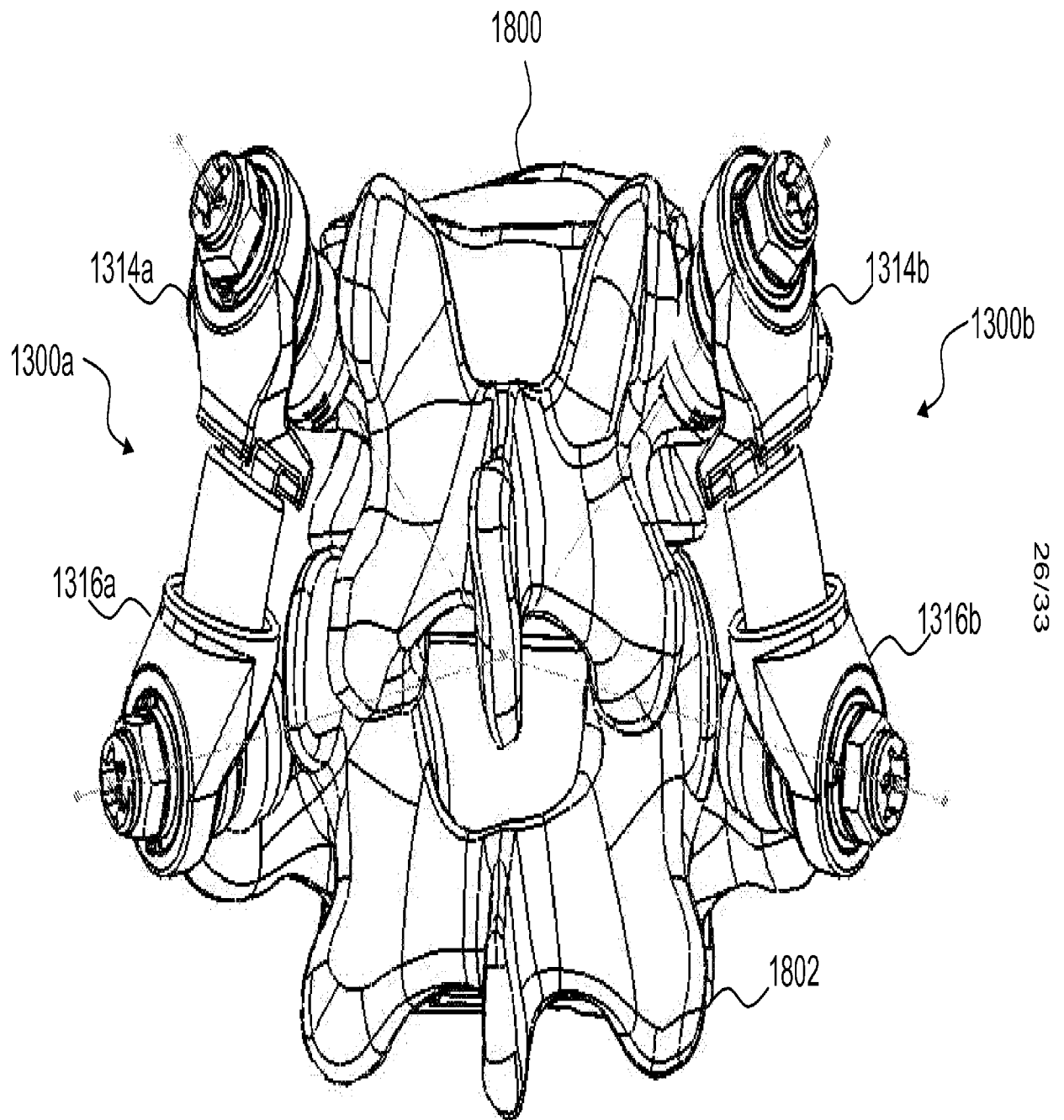
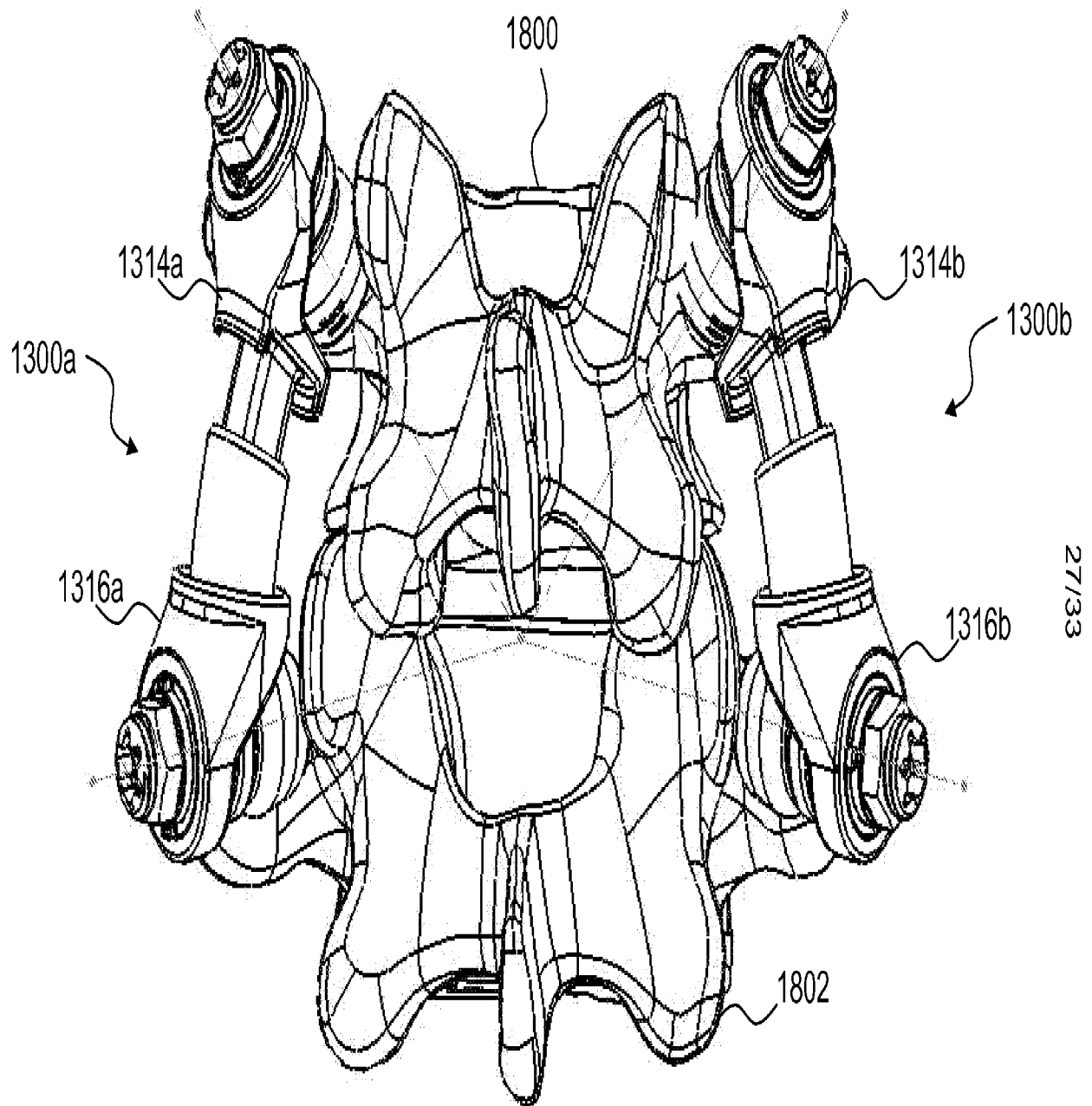


Fig. 18B



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Fig. 18C

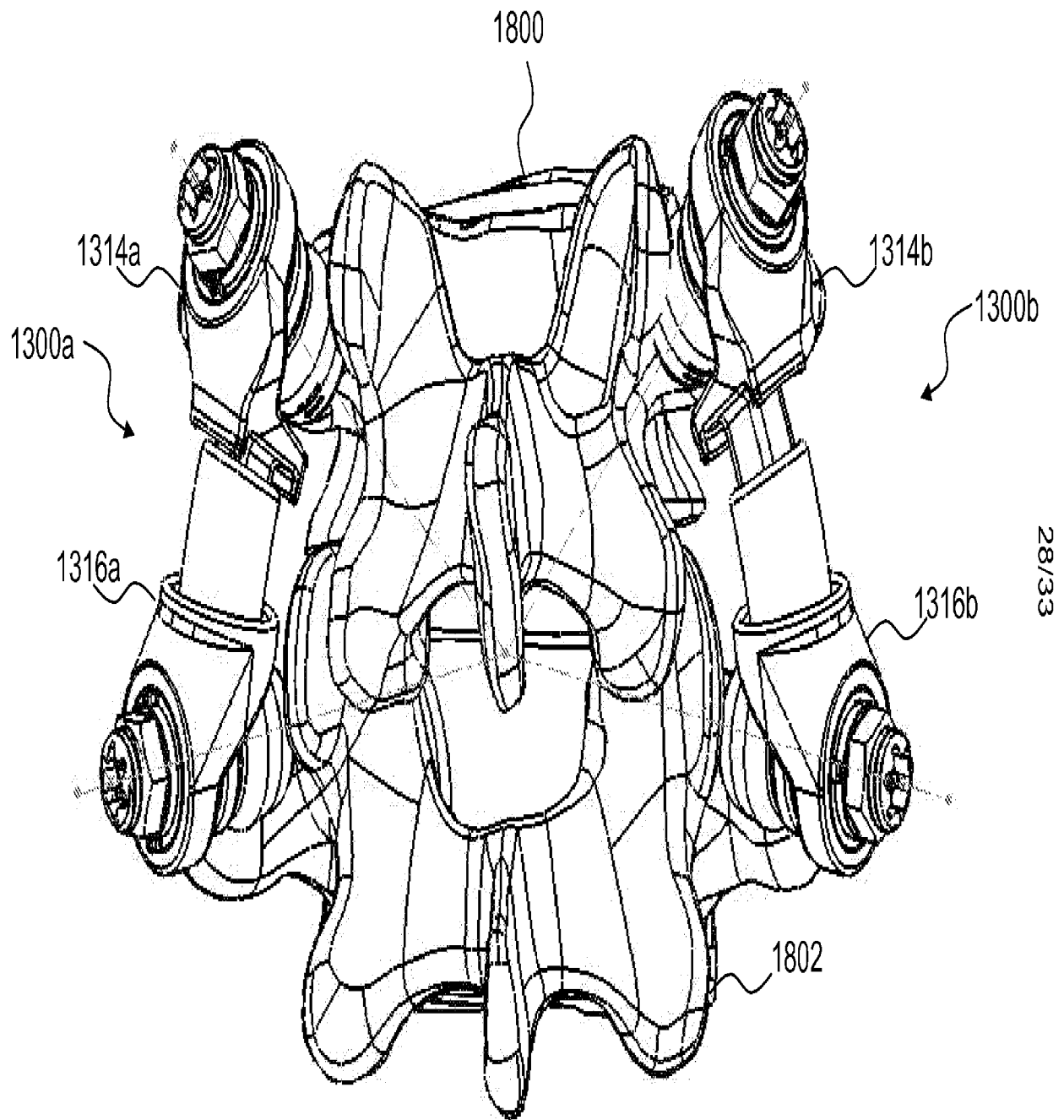
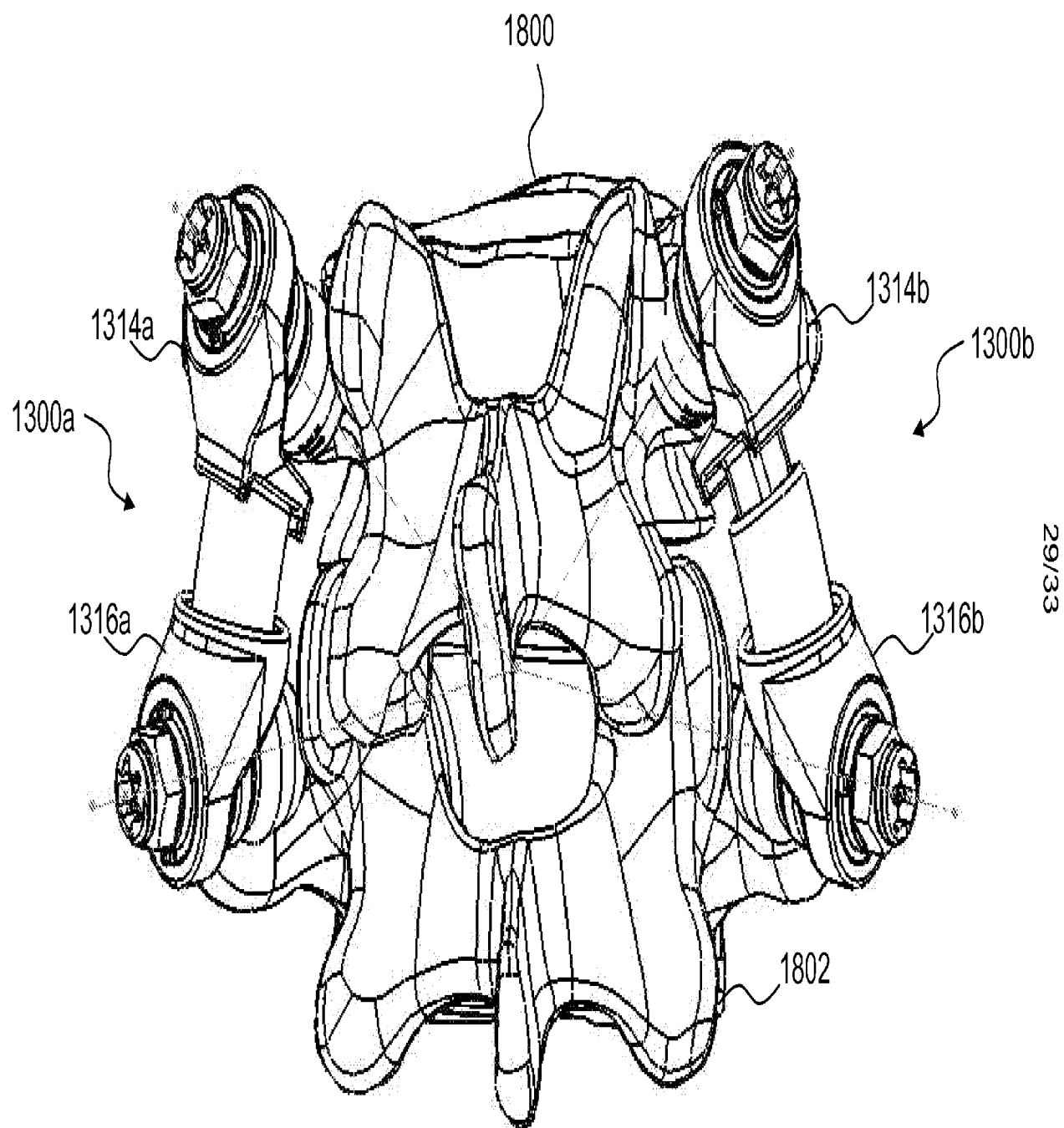
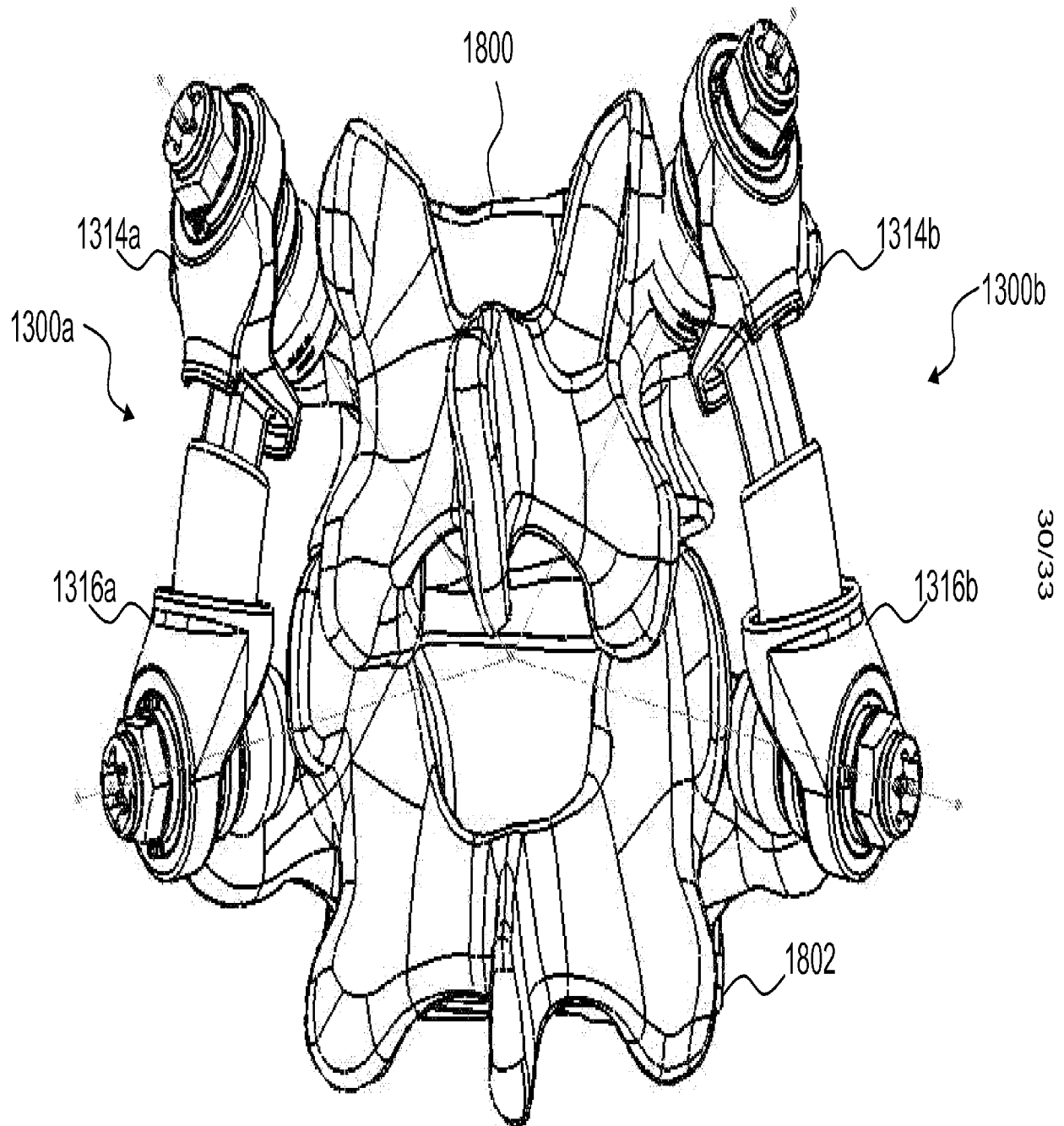


Fig. 18D



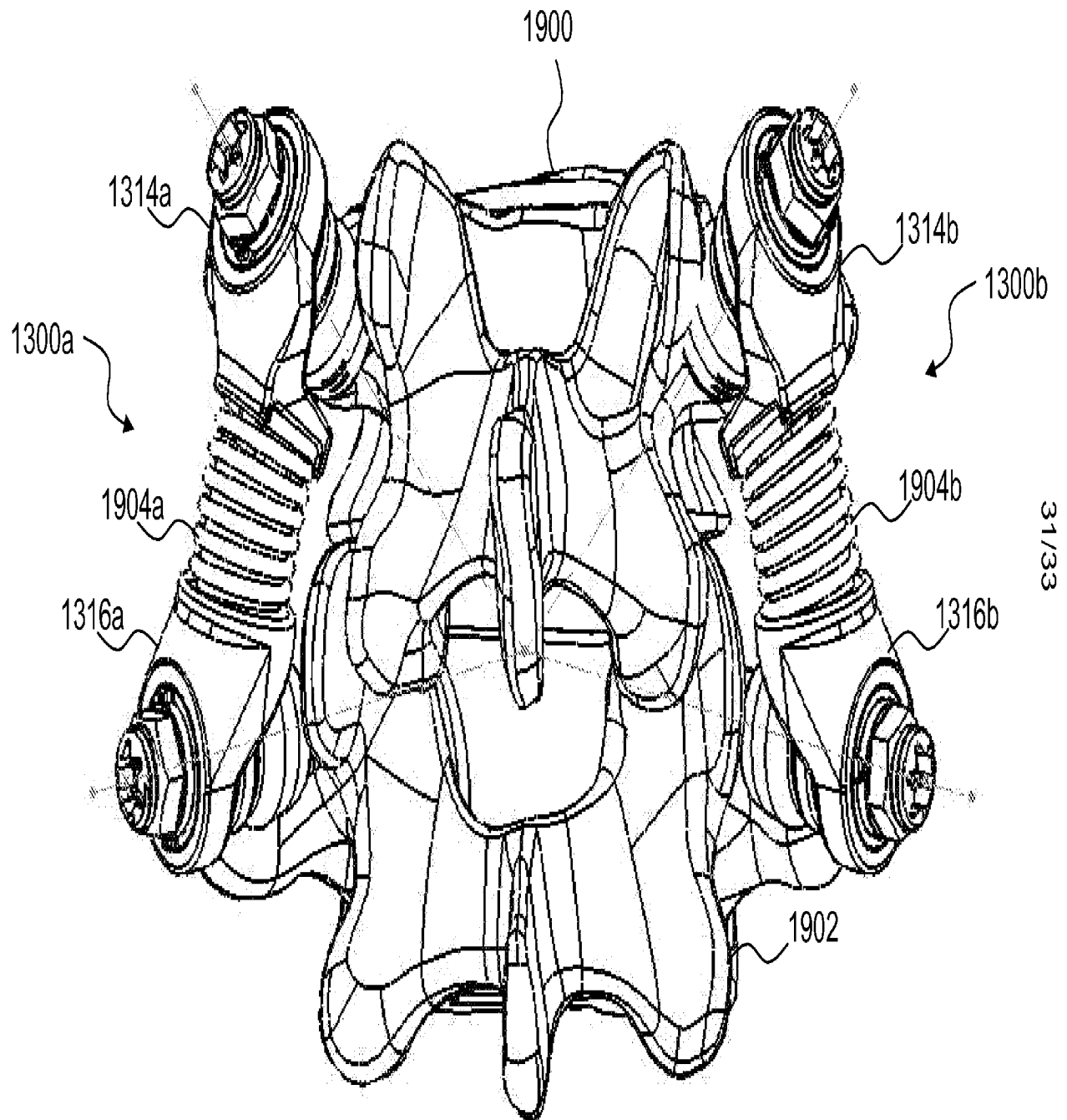
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Fig. 18E



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Fig. 18F



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Fig. 19

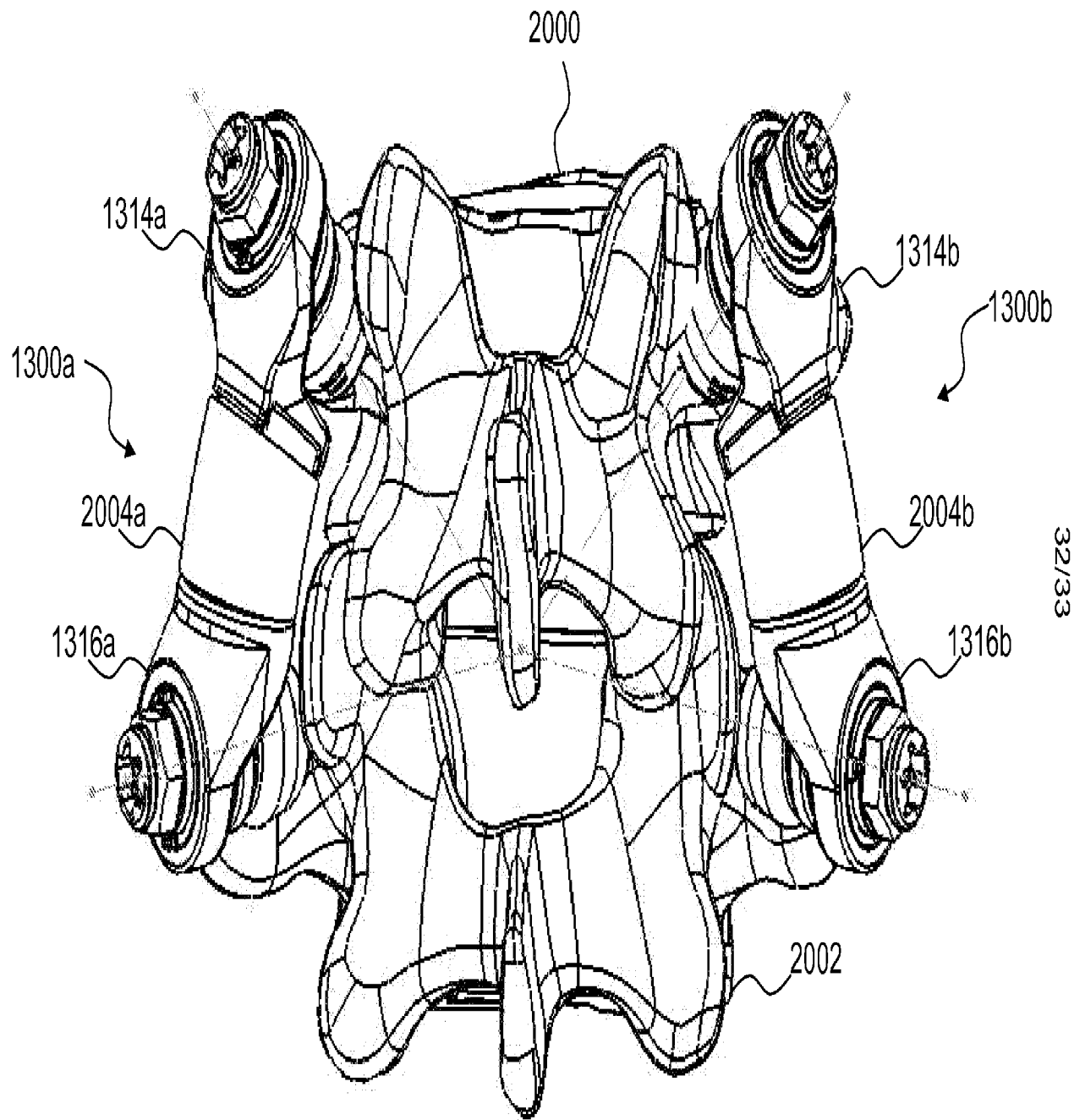
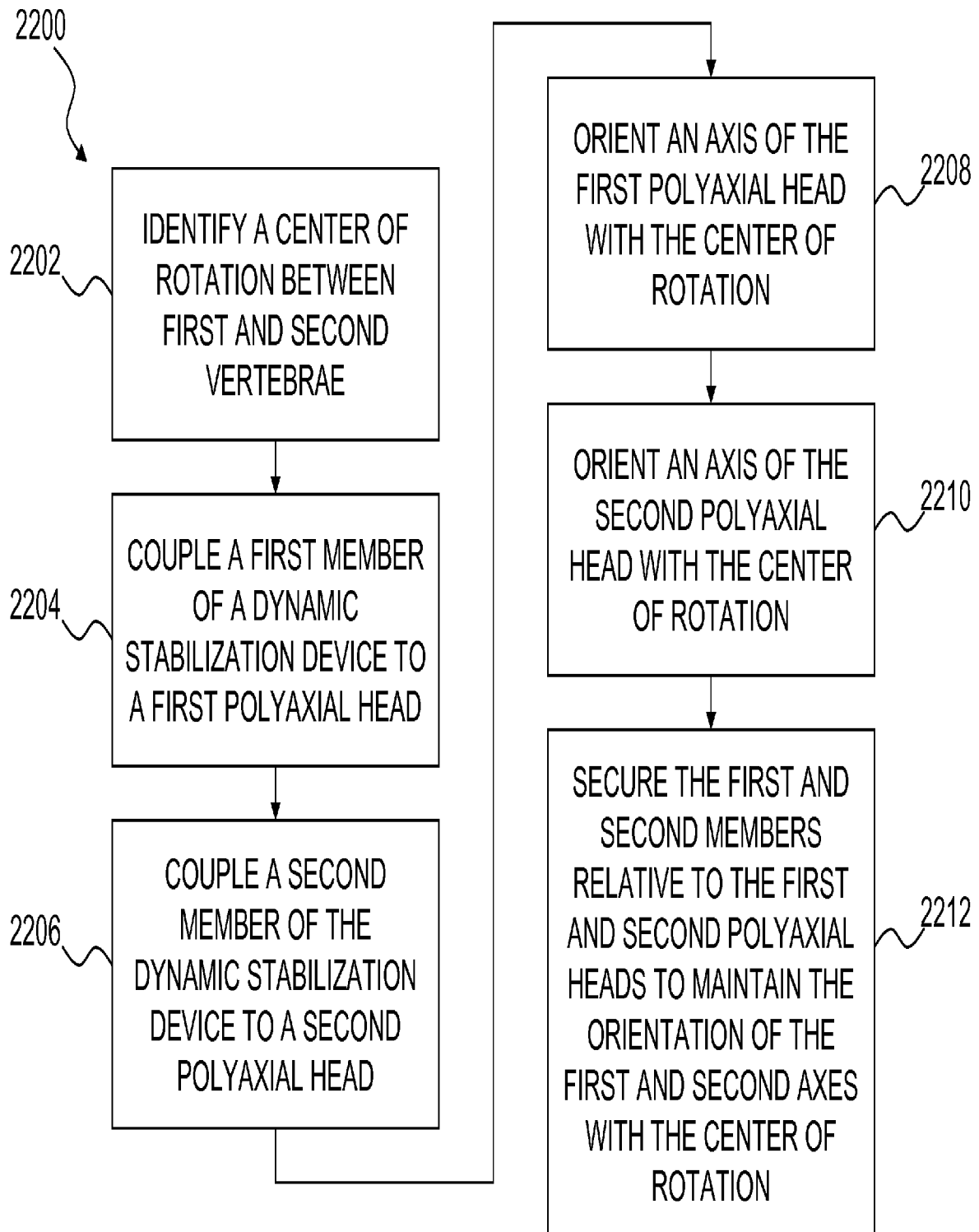


Fig. 20

**Fig. 22**

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/065525

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/020530 A (INNOVATIVE SPINAL TECHNOLOGIES) 23 February 2006 (2006-02-23) page 12, line 21 - line 27 page 13, line 6 - line 17 page 14, line 4 - line 9 page 14, line 14 - line 18 page 16, line 14 - line 29 page 17, line 4 - line 6 page 17, line 26 - page 18, line 5 page 18, line 21 - line 24 figures 2A-G, 3A-I	1-8, 11-19
X	EP 1 072 228 A (SOCIÉTÉ ÉTUDES ET DEVELOPPEMENTS) 31 January 2001 (2001-01-31) figure 1 ----- -/--	1, 2, 6, 7, 11-13, 17, 18

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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* & * document member of the same patent family

Date of the actual completion of the international search

14 August 2007

Date of mailing of the international search report

22/08/2007

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/065525

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/216005 A1 (HOWLAND R.S.) 29 September 2005 (2005-09-29) figures 1-3 -----	11, 13, 14, 18, 19
X	US 2005/267470 A1 (MCBRIDE D.Q.) 1 December 2005 (2005-12-01) abstract; figures 1-5 -----	11
A	US 2005/085813 A1 (SPITLER J.) 21 April 2005 (2005-04-21) -----	5, 6

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/065525

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2006020530	A	23-02-2006	AU 2005274013 A1	23-02-2006
			CA 2574277 A1	23-02-2006
			EP 1776053 A2	25-04-2007
			US 2006247637 A1	02-11-2006
EP 1072228	A	31-01-2001	FR 2796828 A1	02-02-2001
			US 6626904 B1	30-09-2003
US 2005216005	A1	29-09-2005	WO 2006017253 A2	16-02-2006
US 2005267470	A1	01-12-2005	NONE	
US 2005085813	A1	21-04-2005	CA 2543069 A1	12-05-2005
			EP 1682022 A1	26-07-2006
			WO 2005041799 A1	12-05-2005