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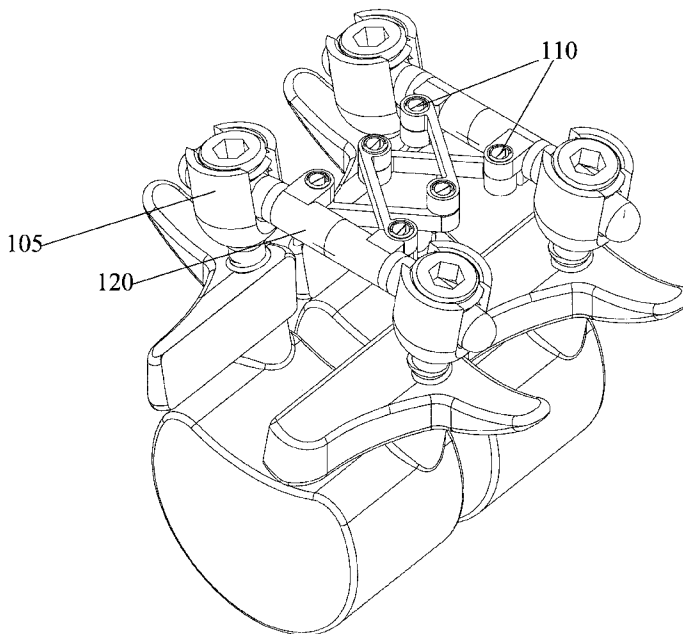
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(57) Abstract: In a spinal implant device, a frictionless pivot member is used to inter-connect multiple links and produce a scissor jack-like device with minimal frictional wear characteristics. The device is attached to at least two vertebrae, wherein a first device segment is attached to a first vertebra and at least one additional device segment is attached to at least one additional vertebra. The implanted device functions to control and dampen the movement between the attached vertebral bodies.



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DYNAMIC SPINAL STABILIZATION SYSTEMS AND METHODS OF USE

REFERENCE TO PRIORITY DOCUMENT

This application claims priority of co-pending U.S. Provisional Patent Application Serial No. 60/874,195, filed December 11, 2006. Priority of the
5 aforementioned filing date is hereby claimed and the disclosures of the Provisional Patent Application is hereby incorporated by reference in its entirety.

BACKGROUND

The present disclosure relates to methods and devices that permit
10 dynamic stabilization of the bony elements of the skeleton. The devices permit adjustment and maintenance of the spatial relationship(s) between neighboring bones. Depending on the specifics of the design, the motion between skeletal segments may be limited or enhanced in one or more planes.

15 Spinal degeneration is an unavoidable consequence of aging. The disability produced by the aging spine has emerged as a major health problem in the industrialized world. Alterations in the anatomical alignment and physiologic motion that normally exists between adjacent spinal vertebrae can cause significant pain, deformity, weakness, and catastrophic
20 neurological dysfunction. The traditional surgical treatment of spinal disease is decompression of the neural elements and complete immobilization of the involved bony spinal segments. Over time, an extensive array of surgical techniques and implantable devices has been formulated to accomplish this goal.

25 The growing experience with spinal fusion has shed light on the long-term consequences of vertebral immobilization. It is now accepted that fusion of a specific spinal level will increase the load on, and the rate of degeneration of, the spinal segments immediately above and below the fused level. As the number of spinal fusion operations have increased, so have the number of
30 patients who require extension of their fusion to the adjacent, degenerating levels. The second procedure necessitates re-dissection through the prior,

scarred operative field and carries significantly greater risk than the initial procedure while providing a reduced probability of pain relief. Further, extension of the fusion will increase the load on the motion segments that now lie at either end of the fusion construct and will accelerate the rate of
5 degeneration at those levels. Thus, spinal fusion begets additional fusion surgery.

In view of the proceeding, there is a growing recognition that segmental spinal fusion and complete immobilization is an inadequate solution to abnormal spinal motion and vertebral mal-alignment. Correction of the
10 abnormal movement and preservation of spinal mobility is a more intuitive and rational treatment plan.

The vast experience gained in the implantation of mobile prostheses in the hip, knee, shoulder, ankle, digits and other joints of the extremities has shown that the wear debris produced by the bearing surfaces and the
15 loosening that occur at the bone-device interface are major causes of implant failure. The latter is at least partially caused by the former, since it's been shown that the particulate debris from the bearing surfaces promote bone re-absorption at the bone-device interface and significantly accelerates device loosening. In the long term, the degradation products of the implant materials
20 may also produce negative biological effects at distant tissues within the implant recipient.

While ceramic and polymer implant components produce wear debris, these degradation products are usually deposited as insoluble particles around the implant thereby limiting the extent of potential toxicity. In contrast,
25 metallic degradation products may be present as particulate and corrosion debris as well as free metals ions, composite complexes, inorganic metal salts/oxides, colloidal organo-metallic complexes and other molecules that may be transported to distant body sites. In fact, studies have revealed chronic elevations in serum and urine cobalt and chromium level after
30 prosthetic joint replacement. Given the known toxicity of titanium, cobalt, chromium, nickel, vanadium, molybdenum and other metals used in the manufacture of orthopedic implants, the tissue distribution and biologic activity

of their degradation products is of considerable concern. Host toxicity may be produced directly by the reactive metallic moieties as well as by their alterations of the immune system, metabolic function, and their potential ability to cause cancer. These issues are thoroughly discussed in the text

5 "Implant Wear in Total Joint replacement" edited by Thomas Wright and Stuart Goodman and published by the American Academy of Orthopedic Surgeons in 2000. The text is hereby incorporated by reference in its entirety.

Unlike joints in the extremities, proper function of the spinal joints (i.e., inter-vertebral disc and facet joints) returns the attached bones to the neutral

10 position after the force producing the motion has dissipated. That is, a force applied to the hip, knee or other joints of the extremities produces movement in the joint and a change in the position of the attached bones. After the force has dissipated, the bones remain in the new position until a second force is applied to them. In contrast, the visco-elastic properties of the spinal disc and

15 facet joint capsule dampen the force of movement and return the vertebral bones to a neutral position after the force acting upon them has dissipated.

Prosthetic joint implants that attempt to imitate native spinal motion have usually employed springs, polyurethane, rubber and the like to recreate the visco-elastic properties of the spinal joints. When subjected to the millions

20 of cycles of repetitive loading that is required of a spinal joint prosthesis, all implants to date have been plagued by excessive wear and degeneration secondary to the fairly modest wear characteristics of these elastic elements. Thus, in addition to the wear debris generated by the bearing surface(s), the elastic materials used to dampen spinal motion will produce a second source

25 of degradation products. Given the number of joints in the spine and the extensive potential application of replacement technology in these joints, it is critical that the wear debris from the implanted prosthesis be minimized.

30

SUMMARY

The preceding discussion illustrates a continued need in the art for the development of mobile prostheses with a reduced wear profile. This development would maximize the functional life of the prostheses and minimize the production of toxic degradation products.

5 In a first embodiment, a frictionless pivot member is used to inter-connect multiple links and produce a scissor jack-like device with minimal frictional wear characteristics. The device is attached to at least two vertebrae, wherein a first device segment is attached to a first vertebra and at least one additional device segment is attached to at least one additional
10 vertebra. The implanted device functions to control and dampen the movement between the attached vertebral bodies. Multiple methods of device attachment are shown.

In a second embodiment, the frictionless pivot member is used to manufacture an orthopedic device capable of at least partially replacing the
15 function of a natural inter-vertebral disc. In a third embodiment, the frictionless pivot member is used to construct a connector that is used to inter-connect at least two bone screws that are connected to at least two vertebral bones. The inter-connector will function to control and dampen the movement between the attached vertebral bodies.

20 In other embodiments, devices are constructed out of malleable slats that are attached to the vertebral bodies in unique configurations. The devices control and dampen vertebral movement in one or more planes of motion. In a final embodiment, a device with a pyramidal articulation is used to interconnect the vertebral bodies. The device is adapted to resist motion
25 and dampen the movement between the attached vertebral bodies.

In one aspect, there is disclosed an implant adapted to dynamically stabilize two or more vertebral bodies, comprising: a first attachment member adapted to attach onto a first vertebral body; at least one second attachment member adapted to attach onto at least one additional vertebral body; at least
30 one linkage member coupled to the attachment members; and at least one pivotable bearing mechanism that connects the linkage members and the

attachment members, wherein: A) the pivotable bearing mechanism contains at least two rotatable members that pivot around a common central axis but do not directly contact one another; and B) the pivotable bearing mechanism contains at least one malleable member that connects the rotatable members and reversibly returns the bearing mechanism to a neutral position after the dissipation of a force acting upon it.

Other features and advantages will be apparent from the following description of various embodiments, which illustrate, by way of example, the principles of the disclosed devices and methods.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows perspective views of an exemplary embodiment of a dynamic orthopedic implant.

Figure 2 shows various views of the orthopedic implant attached to the vertebral bones.

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Figure 3A shows an assembled view of a portion of the implant.

Figure 3B shows an exploded view of a portion of the implant.

Figure 4 shows a perspective view of an embodiment of an articulation member.

Figure 5 shows the articulation member in partial cross section.

20

Figure 6 shows another embodiment of an articulating member.

Figure 7A shows an embodiment of an articulating rod.

Figure 7B shows the rod of Figure 7A in cross-section.

Figure 8 shows another embodiment of an articulating rod.

Figures 9-14B show additional embodiments of orthopedic implants.

25

Figures 15A and 15B show modular attachment members.

Figure 16 shows a perspective view of an interspinous device that is configured for placement between the spinous processes of two adjacent vertebral bones.

Figure 17 shows an exploded view of the device of Figure 16.

Figure 18 shows a cross-sectional view of the device implanted on the vertebral bones.

Figures 19-21 show another embodiment of an interspinous device.

5 Figures 22-26 show another embodiment of an interspinous device.

Figure 27 shows another embodiment of a vertebral implant.

Figure 28 shows the device of Figure 27 in an exploded state.

Figures 29A and 29B show the device in cross-section.

Figure 30A shows the vertebral bodies in partial flexion.

10 Figure 30B shows the vertebral bodies in full flexion.

Figure 31 shows another embodiment of a flex member.

Figure 32A shows the vertebral bodies in partial flexion.

Figure 32B shows the vertebral bodies in full flexion.

15 Figures 33 and 34 illustrate perspective and cross-sectional views of another embodiment of an interspinous device.

Figure 35 illustrates a coronal section through an embodiment of a mobile implant device.

Figures 36A-36B show another embodiment of an implant device.

20 Figures 37-40B illustrate multiple embodiments of mobile devices that are placed within the disc space between two vertebral bodies and used to at least partially replace and/or augment the function of the native disc.

Figure 41 illustrates a perspective view of the a dynamic rod.

Figure 42 shows the dynamic rod in an exploded state.

Figure 43 shows an exemplary bone screw assembly.

25 Figure 44 shows cross-sectional views of the dynamic rod.

Figure 45 shows a flexible pivot of the dynamic rod.

Figures 46-49 show a dynamic rod assembly that includes two rod members that are movably attached to one another via a dynamic pyramidal connector.

DETAILED DESCRIPTION

5 Figure 1 shows perspective views of an exemplary embodiment of a dynamic orthopedic implant. The implant can be anchored across multiple levels of vertebral bones via one or more anchor devices, such as bone screw assemblies 105 that anchor into the vertebral bones. The configuration of the bone screw assemblies 105 can vary. In an embodiment, the bone screw
10 assemblies are polyaxial bone screw assemblies each having a housing that can be locked to a bone screw. It should be appreciated that other types of bone screw assemblies can be used. Figure 2 shows various views of the orthopedic implant attached to the vertebral bones. For clarity of illustration, the vertebral bones are represented schematically and those skilled in the art
15 will appreciate that actual vertebral bones may include anatomical details not shown in Figure 1.

With reference to Figures 1, 2, and 3 the implant includes a connecting mechanism 107 (Figure 3A) that employs one or more articulating members
20 110 that provide an articulating connection between two or more rods 120 over multiple vertebral levels. The rods 120 are adapted to extend across the vertebral midline when the implant is positioned on the spine. Opposite ends of the rods 120 are attached to respective anchor devices 105. The articulating members 110 and the rods 120 are adapted to rotate around a central axis in response to the application of a rotational load. The connecting
25 mechanism 107 can be fixedly attached to one or both of the rods 120 such that the entire device is a unitary device. Alternately, the connecting mechanism 107 can modularly attach to one or both of the rods 120, as described more fully below. Moreover, the rods 120 can be articulating or can be solid rods of fixed size and shape, as described more fully below.

30 Figure 3A shows an assembled view of the implant while Figure 3B shows an exploded view of the implant. The connecting mechanism 107 includes the articulating members 110 that are interconnected via elongate

link members 305. The link members 305 can move relative to one another as a result of articulation of the articulating members 110. In this regard, the articulating members 305 are adapted to provide frictionless or near frictionless movement about an axis of rotation, such as the axis of rotation A show in Figure 3A. The axis of rotation extends through a central, longitudinal axis of the articulation member. In the embodiment shown in Figures 3A and 3B, the rods 120 are elongated sleeves that are adapted to receive an elongated rod therein. It should be appreciated that the rods 120 can be solid rods, sleeves, articulating rods, etc. In addition, the rods 120 can be replaced with another implant device other than a rod.

Figure 4 shows a perspective view of an embodiment of an articulation member 110. Figure 5 shows the articulation member 110 in partial cross section. With reference to Figures 4 and 5, each of the articulating members 110 is formed of a plurality of sections 410 and 420. The articulating member 110 permits the attached link members 305 (Figure 3A) to rotate about the longitudinal axis of the articulating member. In one embodiment, the rotational range is +30 to -30 degrees, although it should be appreciated that the rang can vary. The articulating member 110 is a flexure based bearing, utilizing internal flexible slats 1110 contained within a cylindrical housing, to provide precise rotation with low hysteresis and no frictional losses. The bearing is stiction-free, requires no lubrication, and is self-returning. The articulating member can resist rotational movement away from a neutral state and the extent of resistance to rotation is directly related to the extent of rotation. The extent of resistance to rotation can be a pre-determined property of the device. In one embodiment, the articulation member is has high radial stiffness, high axial stiffness and is frictionless (hence, no particle wear debris). An exemplary articulating member of the type shown in Figures 4 and 5 is distributed by Riverhawk Company of New York under the name FREE FLEX PIVOT. Figure 6 shows another embodiment of an articulating member 110. The embodiment of Figure 6 comprises several sections formed of a plurality of internal, interconnected structures that are adapted to move and/or deform relative to one another.

As mentioned, the rod 120 can be a solid device of fixed shape or it can be an articulating device adapted to change shape in response to loads. Figure 7A shows an embodiment of an articulating rod 120 formed of interconnected rod sections including an articulating member 705 that is
5 constructed in a manner similar to the articulating member 110. The articulating member 705 permits the rod sections to rotate about the axes of the central articulating member 705. Figure 7B shows a cross-sectional view of the articulating member 705, which comprises several sections formed of a plurality of internal slats that are adapted to deform in response to the
10 rotational movement of central member 705 relative to ends 706. Figure 8 illustrates an alternative embodiment of an articulating rod. The rod contains three solid segments that contain end recesses adapted to accept an articulation member 110. In the assembled state, a first articulation member 110 provides rotational movement between the first and second rod segments
15 and a second articulation member 110 provides rotational movement between the second and third rod segments.

The implant can use various configurations of the connecting mechanism 107. The connecting mechanism can employ various quantities of articulating members 110 that are linked to one another via link members
20 305 arranged in various structural and geometric configurations. Figure 9 shows an embodiment that includes several articulating members 110 that are linked together in series via several link members 305. The articulating members 110 are arranged in an undulating pattern between a pair of rods 120. Figure 10 shows another embodiment of an implant. In this
25 embodiment, one of the rods 120 is directly connected to two articulating members 110 while the opposite rod 120 has a direct connection to a single articulating member 110. A pair of in-between articulating members 110 are linked by link members 305 that cross over one another.

Figure 11 shows another embodiment of an implant wherein four
30 articulating members 110 are interlinked by link members 305 arranged in a cross-wise fashion. The articulating members 110a and 110b are slidably positioned in slots to permit sliding translation of the articulating members

110a and 110b within the slots and relative to the rod 120a. The implants can have several connecting mechanisms 107 that each extend across one or more vertebral levels. For example, Figures 12 and 13 shows an implant with two connecting mechanisms 107 that each extend across a vertebral level.

5 The geometric arrangement of the linking arms and the articulating members can be the same between different levels or it can vary between levels.

In certain circumstances, it may be desirable to provide one or more rods 120 that extend parallel to the vertebral midline. Figure 14A shows an embodiment of an implant with rods 120 that are parallel to the vertebral
10 midline along opposite sides of the vertebral midline. The implant also includes a cross-member 1405 that extends across the vertebral midline and connects at opposite ends to the rods 120.

As mentioned, an embodiment of the connecting mechanism 107 is adapted to modularly attach to a rod 120 or to another device. This permits
15 multiple connecting mechanisms to be removably attached to one another over several vertebral levels. For example, the embodiment of Figure 10 has at least one modular attachment member 1005 that removably attaches to a rod 120 or to another type of device. The modular attachment member 1005 can be configured to removably attach to a rod or another type of device using
20 various mechanisms. Figures 15A and 15B show top and side views of an embodiment of the attachment member 1005. The attachment member 1005 has a receiving cavity 1505 that is sized and shaped to removably receive a rod 120. It should be appreciated that the attachment member 1005 can have various types of structures that are adapted to removably receive or mate with
25 a rod or other device.

Spinous Process Devices

Figures 16-26 show various flexible pivoting interspinous devices that can be attached onto the spinous processes and/or lamina of neighboring vertebral bones. Figure 16 shows a perspective view of an interspinous
30 device that is configured for placement between the spinous processes of two adjacent vertebral bones. Figure 17 shows an exploded view of the device of

Figure 16. Figure 18 shows a cross-sectional view of the device implanted on the vertebral bones. The device includes an articulating central region 1605 that is sized and shaped to fit between the spinous processes of the two adjacent vertebral bodies. The device further includes a pair of attachment regions 1610 each adapted to attach and anchor onto the spinous process of a vertebral body. The central region 1605 can have a variety of shapes and sizes for placement between the spinous processes. The attachment regions 1610 can also have various sizes and shapes for attachment to the spinous processes.

The attachment regions are attached to a pair of threaded screws 1615 (threads not shown) that are attached the spinous processes. As shown in Figure 18, the screws 1615 have shank regions that extend into the spinous processes. It should be appreciated that means other than screws can be used to attach the attachment regions to the spinous processes. The central region 1605 of the device limits the extent of vertebral extension at the implanted level. The malleable nature of the device resists vertebral extension and rotation. The device also resists anterior or posterior displacement of one vertebral level relative to the other. While the illustrated embodiment will permit anterior flexion alone, additional members 110 may be added in the desired plane to produce additional rotational planes.

With reference to the exploded view of Figure 17, the central region 1605 includes a pair of arms 1705 that are movably attached to articulation locations or articulation points 1710. The articulation points 1710 provide means of movement of the arms 1705 about the articulation points. The articulation points 1710 can be conventional pins that serve as hinges, or the articulation points can be articulation members of the type shown in Figures 5-6. The articulation points 1710 are cylindrically shaped and rotatably positioned in openings 1712 in the attachment regions 1610 and in the arms 1705 to provide rotational movement therebetween. The arms 1705 are attached to a housing 1720 having an opening that receives a flexible pivot member 1725 that has a construction similar to or the same as the articulation members shown in Figures 5-6. The pivot member 1725 serves as a central

flexible pivot between the spinous processes. When implanted as shown in Figures 16 and 18, the device allows vertebral movement in certain planes while limiting vertebral motion.

5 Figures 19-21 show another embodiment of an interspinous device that is configured for placement between the spinous processes of two adjacent vertebral bones. Figure 19 shows a perspective view of the device mounted on vertebral bones while Figure 20 shows a lateral view of the device mounted on vertebral bones. Figure 21 shows cross-sectional views of the device. As in the previous embodiment, the device includes an articulating
10 central region 1605 that is sized and shaped to fit between the spinous processes of the two adjacent vertebral bodies. The device further includes a pair of attachment regions 1610 each adapted to attach and anchor onto the spinous process of a vertebral body. In this regard, the attachment regions 1610 are sized and shaped to at least partially encircle the spinous processes
15 in an anterior-posterior direction. The attachment regions 1610 are contoured to provide a relatively smooth fit when placed on the spinous processes.

The central region 1605 can have a variety of shapes and sizes for placement between the spinous processes. The central region 1605 includes an articulating member 1620 positioned between the spinous processes. The
20 articulating member 1620 can have a structure as shown in Figures 5-6. The articulating member is configured to provide a point of articulation between the vertebral bones. It should be appreciated that additional points or locations of articulation can be provided, such as in the previously-described embodiment. The central region 1605 further includes a pair of plate
25 members 1625 that abut the spinous processes in the implanted device.

Figures 22-25 show various views of another embodiment of an interspinous device that is configured for placement between the spinous processes of two adjacent vertebral bones. The device includes an articulating central region 1605 that is sized and shaped to fit between the
30 spinous processes of the two adjacent vertebral bodies. The device further includes a pair of attachment regions 1610 each adapted to attach and anchor onto the spinous process of a vertebral body. In this regard, the attachment

regions 1610 are sized and shaped to be positioned along the sides of the spinous processes. The attachment regions 1610 can have a clamp-like or "u"-shaped configuration that is positioned over the sides of the spinous processes.

5 Figure 26 is a cross-sectional view that illustrates how attachment screws attach the device to the spinous processes. A pair of bone screws 1615 extend through the attachment regions 1610 and into the spinous processes. The screws engage the interior aspect of the spinous processes at an angle to the long axis of the spinous processes. The screws follow a
10 trajectory that preferably aims the screw tips towards the vertebral midline M. An additional screw 1607 (Figures 23, 25) can be inserted into the anterior-superior lip of the spinous processes.

 With reference still to Figures 22-25, the device has at least one, and preferably three, points or locations of articulation. The articulation is
15 provided by one or more flexible pivot members 2205 located in the central region 1605. The pivot members can have a construction as shown in Figures 5-6.

 There are now described and illustrated additional embodiments that use flexible plank members 200 to produce mobile devices with minimal
20 frictional contact. Figure 27 shows a first embodiment of such a device. As in the previous embodiments, the device includes an articulating central region that is sized and shaped to fit between the spinous processes of the two adjacent vertebral bodies. The device further includes a pair of attachment regions each adapted to attach and anchor onto the spinous process of a
25 vertebral body. The central region uses flexible plank members comprised of elongate, planar elements that can flex. The device has a cross member that attaches at opposite end to bone screw assemblies. The device can attach to the spinous processes using screws. While illustrated as attaching onto the spinous process using screws positioned along the long axis of the spinous
30 process, the device may be alternatively attached to the bone using any of the previously illustrated fixation methods or any other applicable method that is

known in the art. Figure 28 shows the device of Figure 27 in an exploded state. Figures 29A and 29B show the device in cross-section.

The device includes attachment members 210, 220, and 230 that fit between the spinous processes. The attachment members are interconnected by the flexible plank members 200. A first member 210 is affixed onto one vertebra while a second member 220 is attached onto a second vertebra. A member 230 is placed within the space between the spinous processes at a distance from each of members 210 and 220 and attached to the former by two side flexible plank members 200 and to the latter by a central flexible plank member 200. The configuration of flexible plank members and attachment members permit particular movements and limit other types of movement. It should be appreciated that the quantity and shape of the flexible plank members can vary.

In specific, significant movement of the vertebra towards each other is prevented by the interaction of members 210 and 220. That is, vertebral extension is limited by the collision of member 210 and 220 with one another. Alternatively, member 230 may be enlarged and sized to limit vertebral extension by directly maintaining the distance between the spinous processes of the two vertebrae. The members are sized and shaped to provide a level of movement therebetween. The movement of the vertebra away from one another is permitted but reversibly opposed by the action of flexible members 200. The anterior translation of upper vertebra relative to the lower vertebra is prevented by the interaction of member 210 and 220. Lateral flexion of the vertebral bodies is permitted to a limited degree. Vertebral rotation is limited by the shape of the flexible members 200 since rotation requires flexure of members 200 towards one of the long sides of each plank member. Rotation is also opposed by the collision of the medial surface of each of the laterally-placed members 200 and the lateral surfaces of medially-placed member 220. The foregoing is illustrated in cross-section in Figure 30A where the vertebral bodies are in partial flexion and in Figure 30B where the vertebral bodies are in full flexion. Note that the amount of rotation does not vary with the extent of flexion.

Figure 31 shows another embodiment of the flex member 220. This embodiment has a "V"-shaped configuration with a thickness defined by side walls 2205. Along at least a portion of the member 220, the side walls 2205 are non-parallel. For example, this embodiment has side walls 2205 that
5 converge towards one another while the side walls 2205 of member 220 of the previous embodiment are parallel and non-convergent. With this modification, the present embodiment recreates physiologic spinal motion by allowing the extent of vertebral rotation to increase with progressive vertebral flexion. This is illustrated in cross-section in Figure 32A where the vertebral
10 bodies are in partial flexion and in Figure 32B where the vertebral bodies are in full flexion. Note that the distances between the medial edge of each of members 200 and lateral side walls 2205 of member 220 increase with flexion and permit a greater range of vertebral rotation.

Figures 33 and 34 illustrate perspective and cross-sectional views of
15 another embodiment of an interspinous device. Like the prior two embodiments, attachment members 210, 220, and 230 are inter-connected by flexible plank members 200 that extend between the attachment members. A member 210 is affixed onto one vertebra while member 220 is attached onto a second vertebra. Unlike the prior embodiments, the device is attached to the
20 vertebral bone using bone screws or similar fasteners that attach onto the pedicle portion of the vertebrae. A bone screw also attaches to the spinal process. The member 230 is placed at a distance from each of members 210 and 220 and attached to the former by two side flexible plank members 200 and to the latter by a central flexible plank member 200. The device is
25 functionally similar to the prior two embodiments.

There are now described multiple embodiments of mobile devices that are placed within the disc space between two vertebral bodies and used to at least partially replace and/or augment the function of the native disc. Each of these embodiments uses one or more of the flexible pivot members
30 (articulation members) such as the type shown in Figures 5 and 6. Figure 35 illustrates a coronal section through embodiment of such a mobile device. The device contains a top surface 440, a bottom surface 442, cylindrical

members 444 and 446, link members 448 and 450 as well as multiple flexible pivot members of the type shown in Figures 5 and 6. The cylindrical members 444 and 446 slidably reside within cylindrical channels in the upper surface of member 442. The articulations between the cylindrical members and cylindrical channels permit extension and anterior flexion of the implanted device and the attached vertebral bodies. In addition, the actions of the flexible pivot members 110 permit relative vertical movement of surfaces 440 and 442 and impart a shock-absorbing quality to the device. Finally, movement in the coronal plane recreates the lateral flexion movement of the natural disc but rotation is effectively prevented.

Figure 36A is another embodiment that is similar to the previous embodiment. This embodiment is structured such that it is effectively one half of the previous embodiment. The device is particularly useful in the correction of vertebral coronal plane mal-alignment (i.e., scoliosis). Figure 36B shows a mal-aligned vertebral segment and Figures 36C shows the segment with the device of 36A implanted. The device is adapted to re-align the mal-aligned vertebral segment when positioned between the vertebral bodies. As in the previous embodiments, the top and bottom surfaces can move relative to one another in response to loads. Further, device attachments onto the sides of the vertebral bones provide additional points of fixation.

Figures 37-40 illustrate multiple embodiments of mobile devices that are placed within the disc space between two vertebral bodies and used to at least partially replace and/or augment the function of the native disc. Each device embodiment uses one or more flexible plank members with a central mobile surface assembly 330 positioned therebetween. The assembly 330 is adapted to articulate in response to loads to provide relative movement between the flexible plank members. Figure 37 shows a perspective view of one embodiment while Figure 38 illustrates additional views of the embodiment. Figure 39 shows an exploded view of the central mobile surface assembly 330. An upper segment 310, middle segment 320 and lower segment 325 are interconnected by flexible plank members 315 as shown and collectively make up the upper one-half of assembly 330. The flexible plank

members 315 are spaced from one another to provide space for relative movement and articulation of the plank members 315. The lower one-half of the assembly is similarly configured but the moving members are situated perpendicular to the upper one-half of the assembly. Figures 40A and 40B
5 show alternative mobile assembly embodiments.

Figures 41 to 55 show a dynamic rod. The rod is adapted to be linked at opposite ends to bone screw assemblies which attach to vertebral bones. The rod is dynamic in that it can change shape in response to loads. The device is preferably attached to bone using a screw assembly such as shown
10 in the example of Figure 43. Figure 41 illustrates a perspective view of the device while Figure 42 shows the device in an exploded state. The opposed ends of the device each have a head that couples to the bone screw assembly.

Figure 44 shows cross-sectional views of the device. In use, each end
15 500 is paced within a receiving porting of a bone screw assembly (such as shown in Figure 43). After the devices are placed into the desired position, the locking screw of the screw assembly is tightened thereby locking both spherical segments 505 of ends 500 relative to the remainder of the screw assembly. Each end segment 505 is rigidly affixed to the end segments 507
20 of flexible pivot 509 (Figure 45). The middle segment 511 of pivot member 509 is rigidly affixed to the middle segment 515 (Figure 45). The configuration allows the movement of middle segment 515 relative to immobilized end segments 505 based on the action of flexible pivot 509. Each of rectangular rod 520 can move relative to one another in the direction of the long axis of
25 the rods.

In another embodiment, Figures 46-49 show a dynamic rod assembly that includes two rod members 4610 that are movably attached to one another via a dynamic pyramidal connector. The connector is formed of two pieces 4615 and 4620 that can slidably move relative to one another in a
30 male-female relationship. Figure 47 shows the device with the pieces 4615 and 4620 separated from one another. The piece 4620 is formed of a plurality of interconnected plank members that can flex relative to one another so as to

change the shape of the piece 4620. The piece 4620 fits into a cavity within the piece 4615, as shown in the cross-sectional views of Figures 48 and 49. When positioned in the cavity, the planks of piece 4620 expand outward such that the piece 4620 is retained within the cavity. Movement of the male
5 member relative to the female member is at least partially resisted by the action of the plank members.

The disclosed devices or any of their components can be made of any biologically adaptable or compatible materials. Materials considered acceptable for biological implantation are well known and include, but are not
10 limited to, stainless steel, titanium, tantalum, shape memory alloys, combination metallic alloys, various plastics, resins, ceramics, biologically absorbable materials and the like. Any components may be also coated/made with osteo-conductive (such as demineralized bone matrix, hydroxyapatite, and the like) and/or osteo-inductive (such as Transforming
15 Growth Factor "TGF- β ," Platelet-Derived Growth Factor "PDGF," Bone-Morphogenic Protein "BMP," and the like) bio-active materials that promote bone formation. Further, any surface may be made with a porous ingrowth surface (such as titanium wire mesh, plasma-sprayed titanium, tantalum, porous CoCr, and the like), provided with a bioactive coating, made using
20 tantalum, and/or helical rosette carbon nanotubes (or other carbon nanotube-based coating) in order to promote bone in-growth or establish a mineralized connection between the bone and the implant, and reduce the likelihood of implant loosening. Lastly, the system or any of its components can also be entirely or partially made of a shape memory material or other deformable
25 material.

Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated that other versions, embodiments, methods of use, and combinations thereof are also possible. Therefore the spirit and scope of the appended claims should
30 not be limited to the description of the embodiments contained herein.

CLAIMS

WHAT IS CLAIMED IS:

1. An implant adapted to dynamically stabilize two or more vertebral bodies, comprising:
 - 5 a first attachment member adapted to attach onto a first vertebral body;
 - at least one second attachment member adapted to attach onto at least one additional vertebral body;
 - at least one linkage member coupled to the attachment members; and
 - at least one pivotable bearing mechanism that connects the linkage
 - 10 members and the attachment members, wherein:
 - A) the pivotable bearing mechanism contains at least two rotatable members that pivot around a common central axis but do not directly contact one another;
 - B) the pivotable bearing mechanism contains at least one malleable
 - 15 member that connects the rotatable members and reversibly returns the bearing mechanism to a neutral position after the dissipation of a force acting upon it.
2. An implant as in claim 1, wherein at least one of the first and
- 20 second attachment members is a rod.
3. An implant as in claim 1, wherein the linkage member removably attaches to the attachment members.

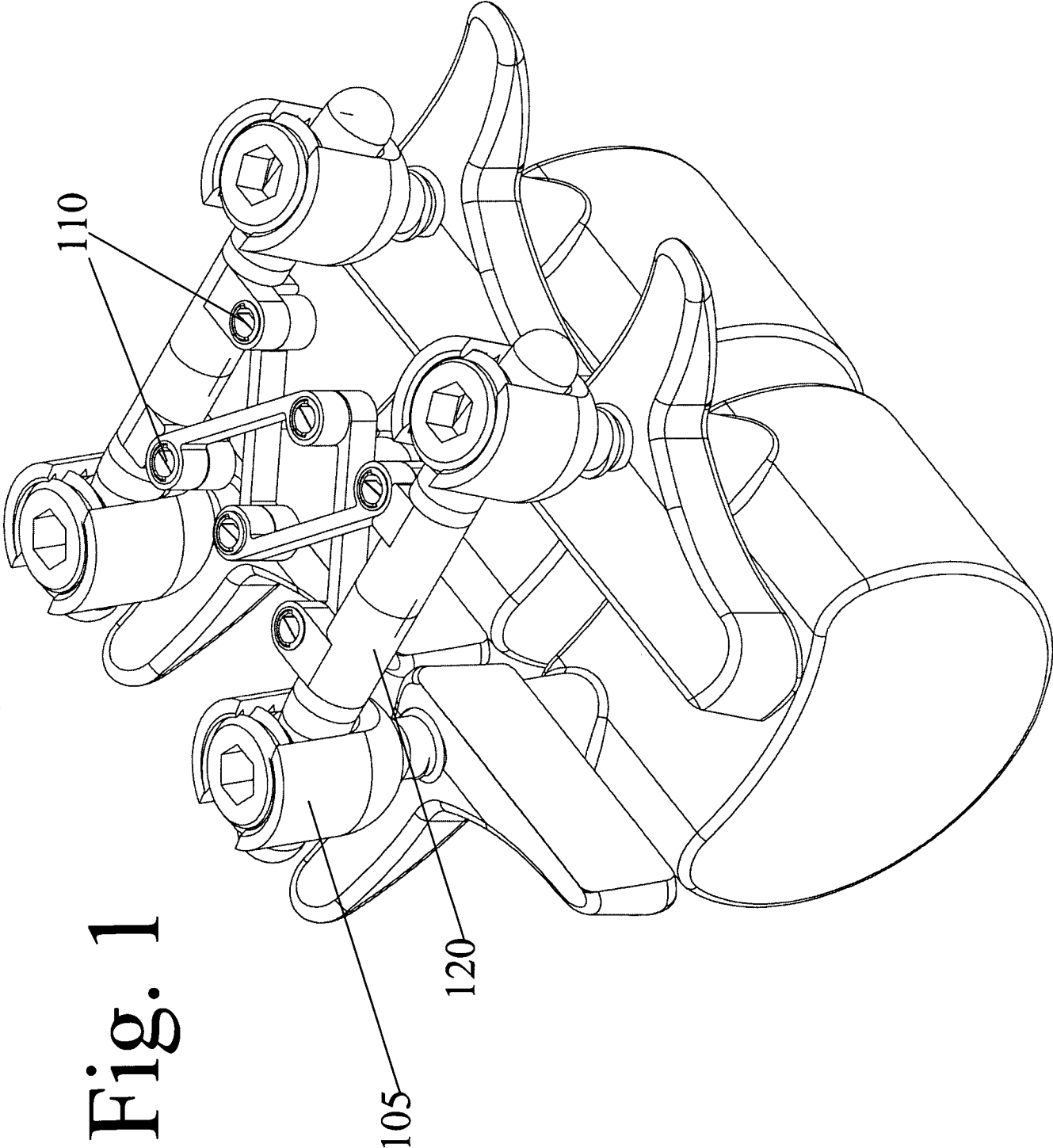
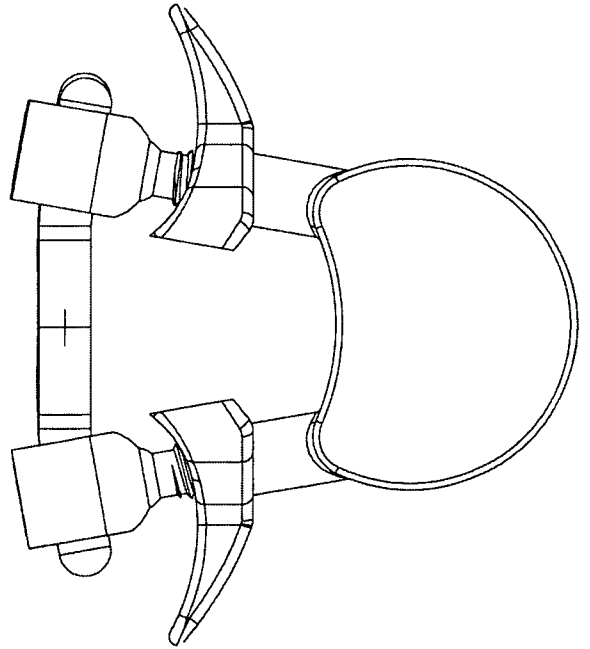
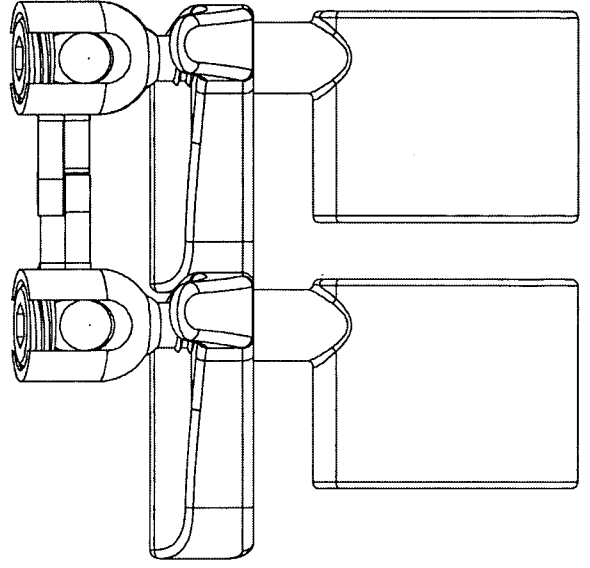
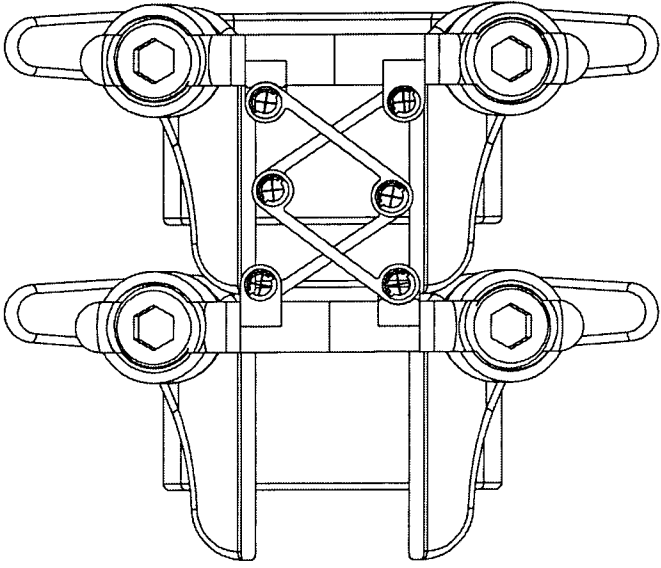


Fig. 1

Fig. 2



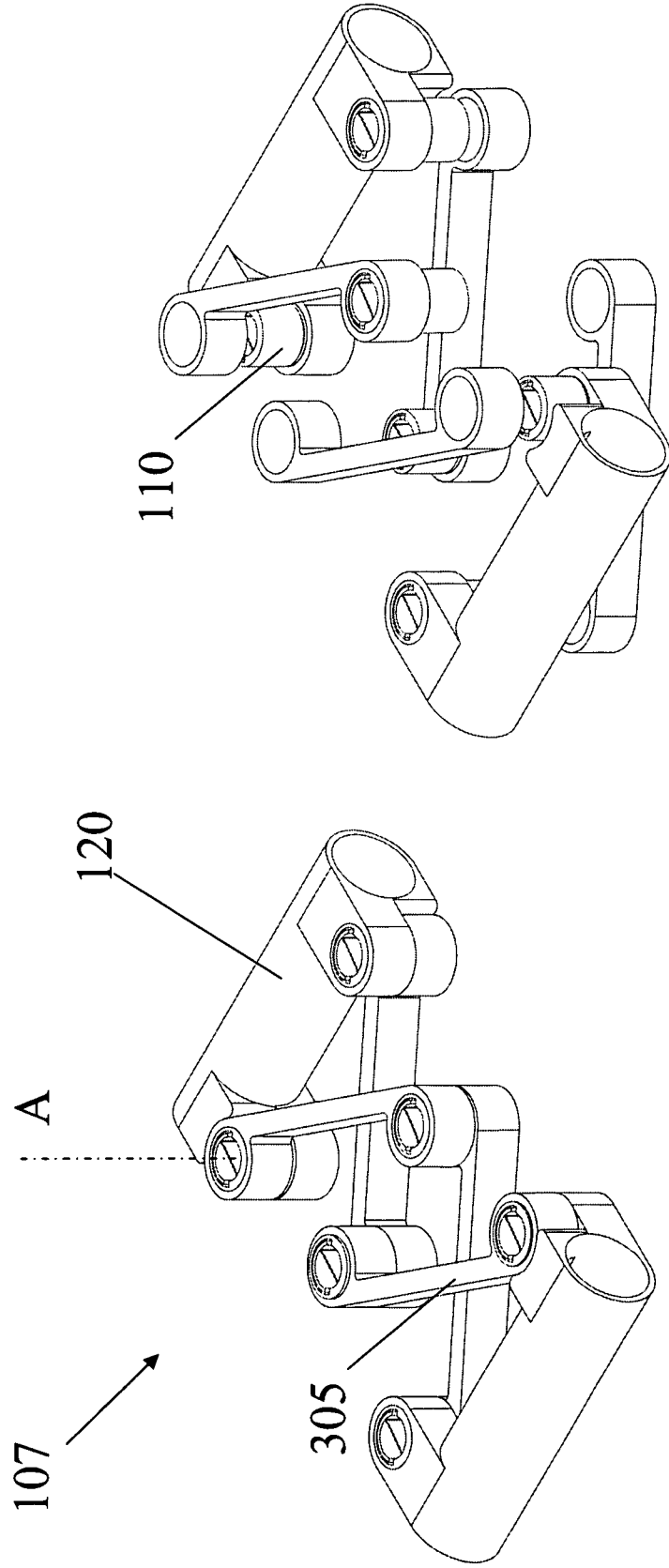


Fig. 3A

Fig. 3B

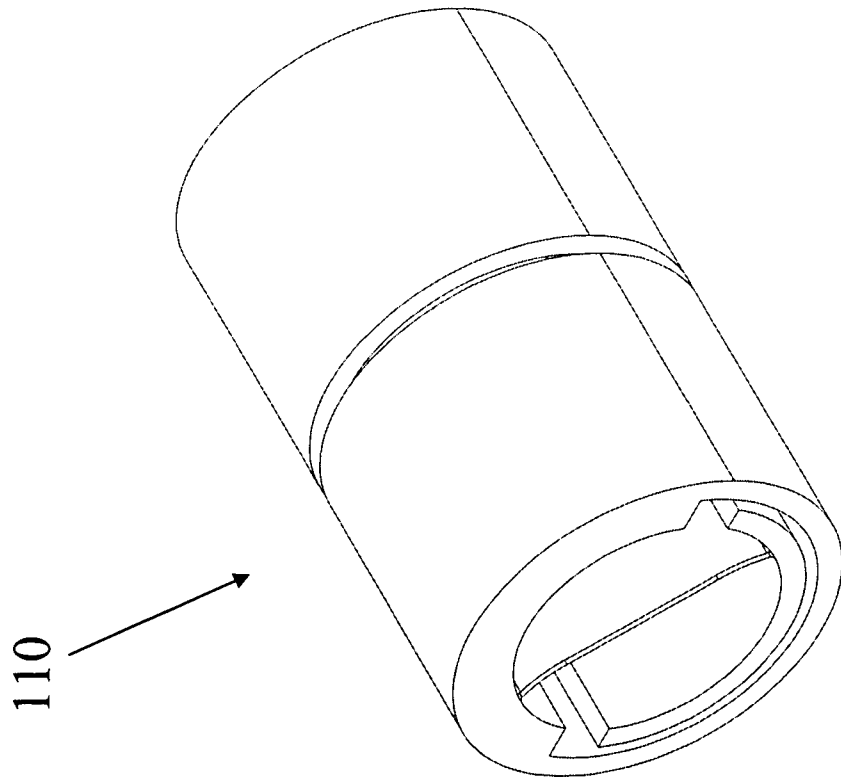


Fig. 4

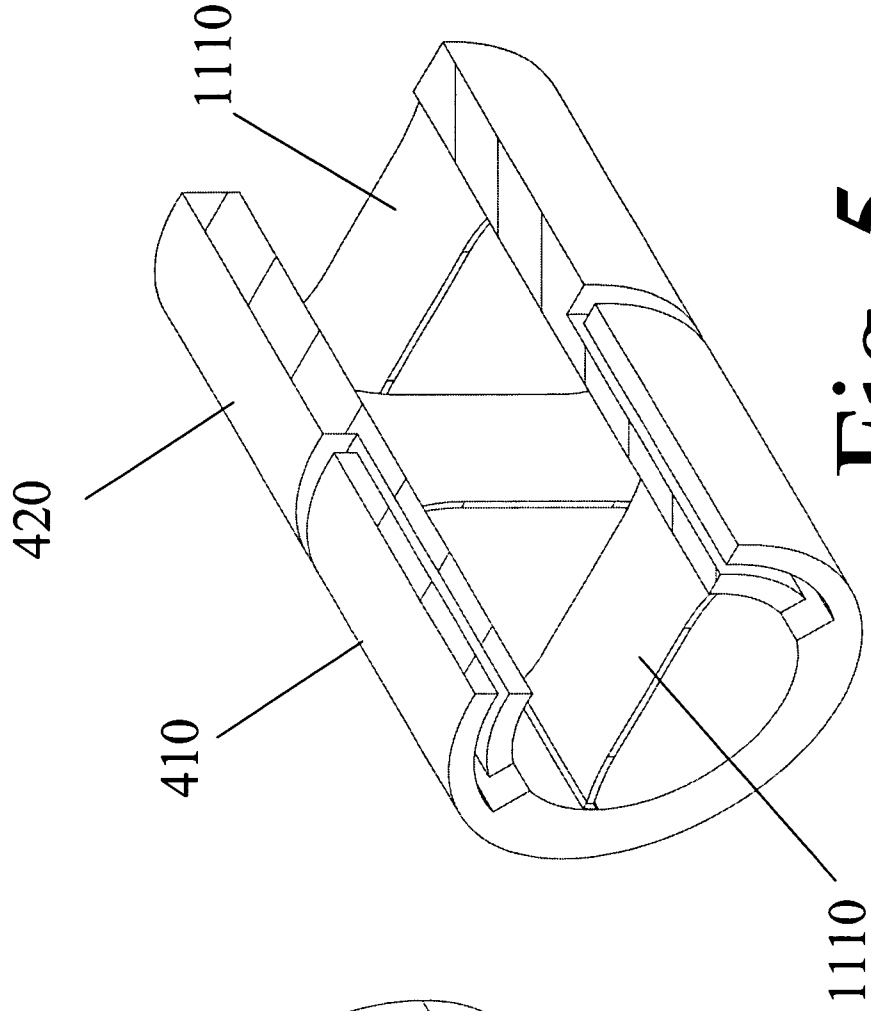


Fig. 5

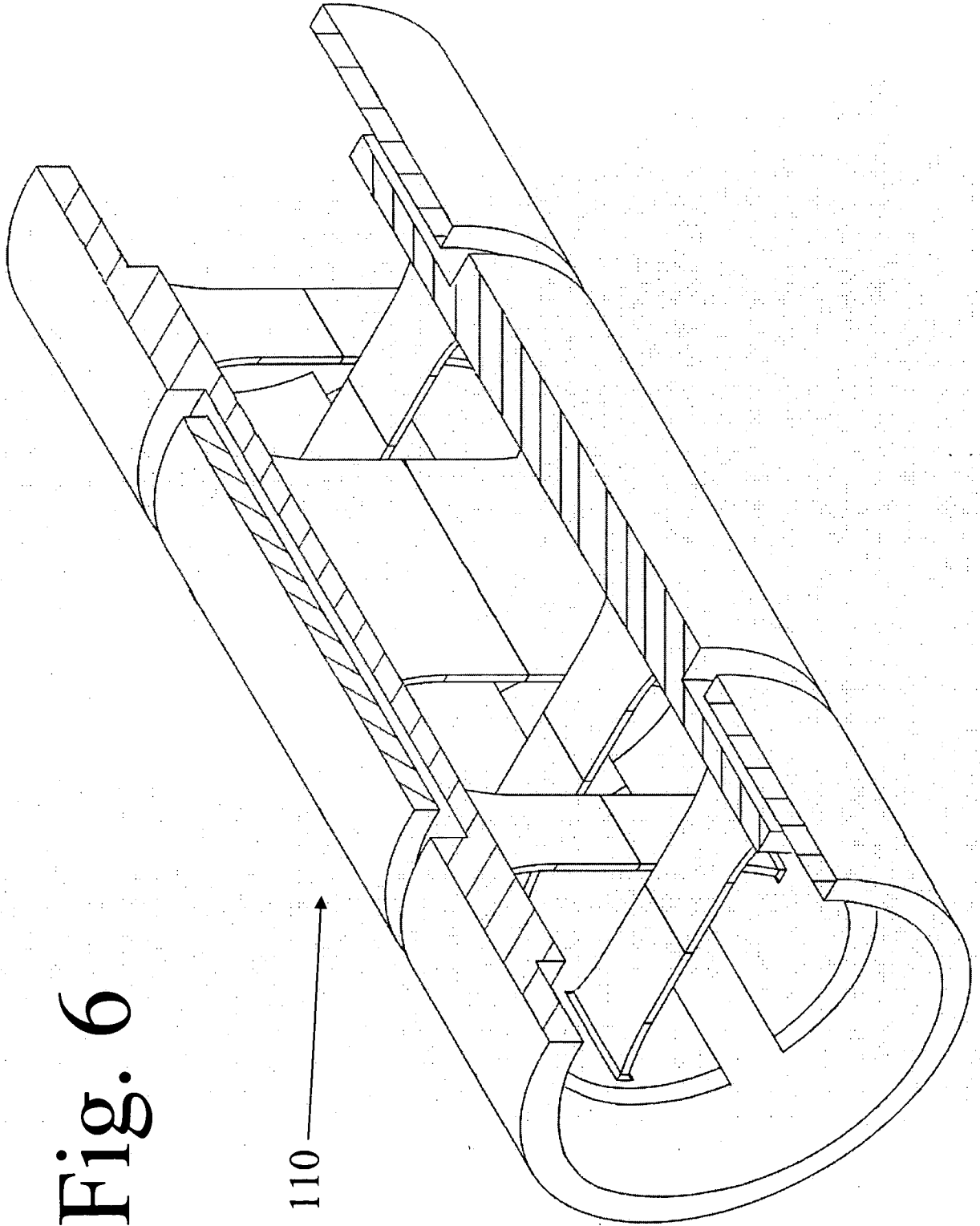


Fig. 6

Fig. 7B

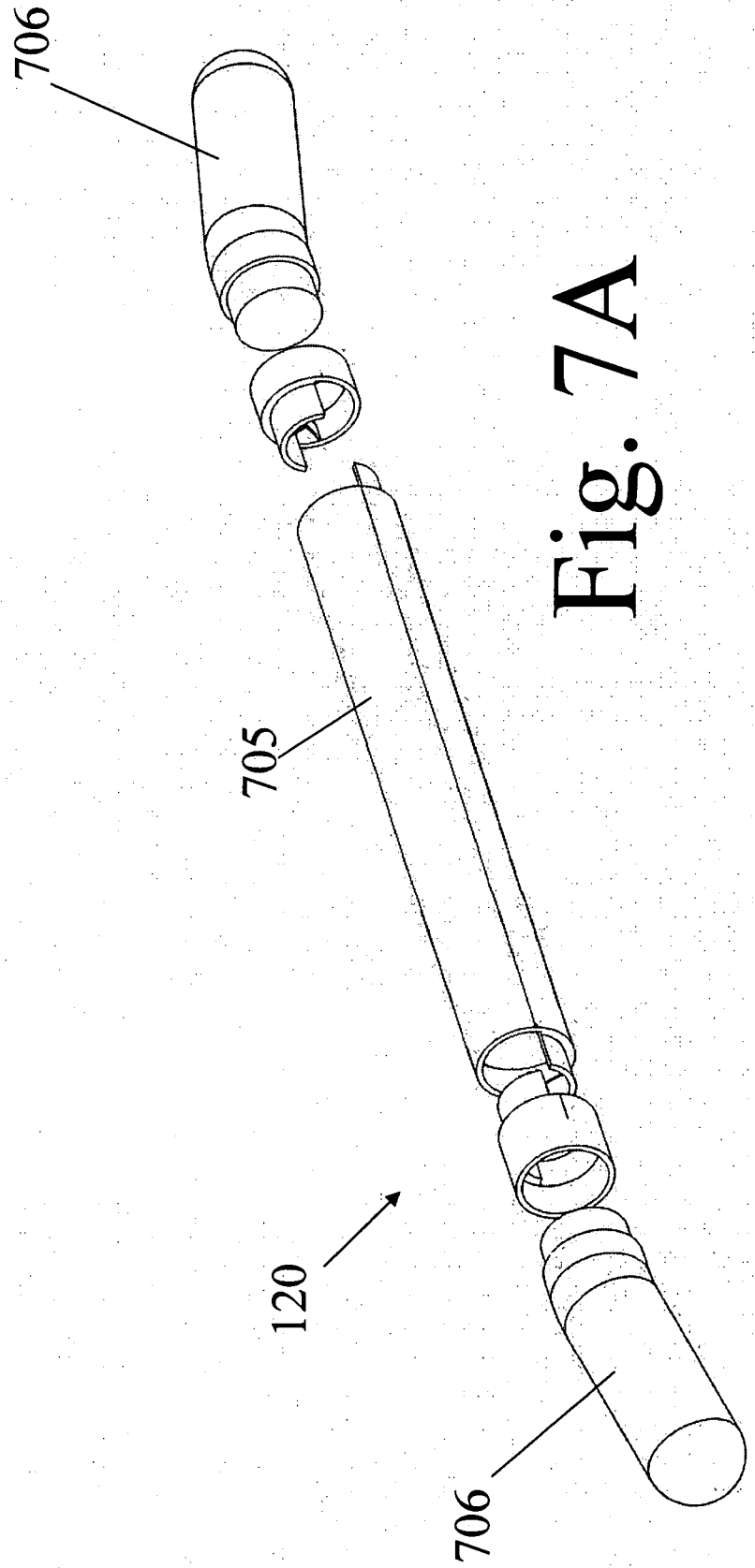
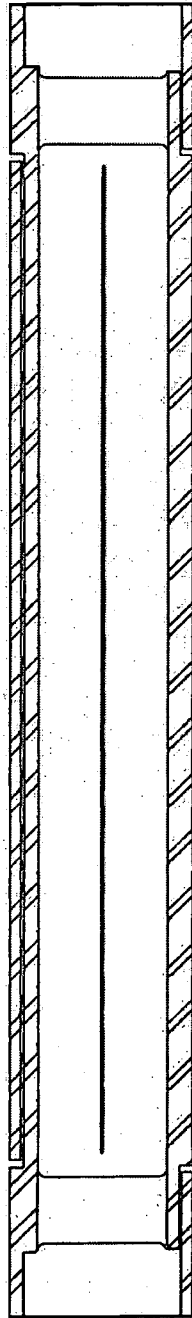


Fig. 7A

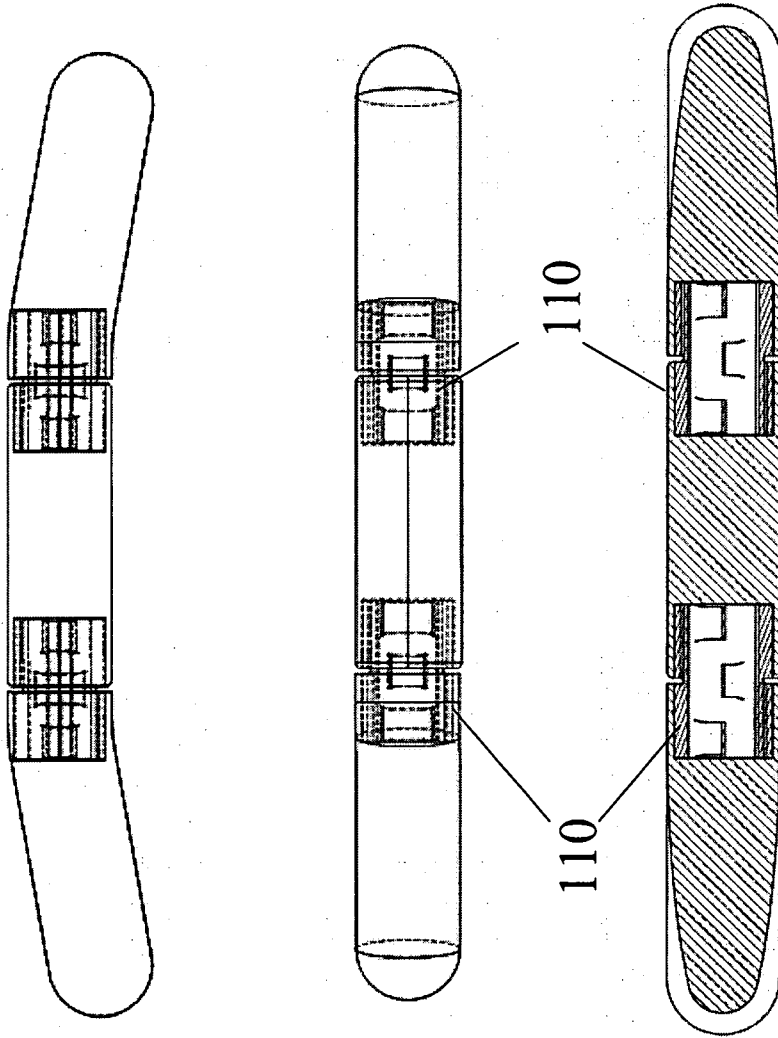


Fig. 8

Fig. 10

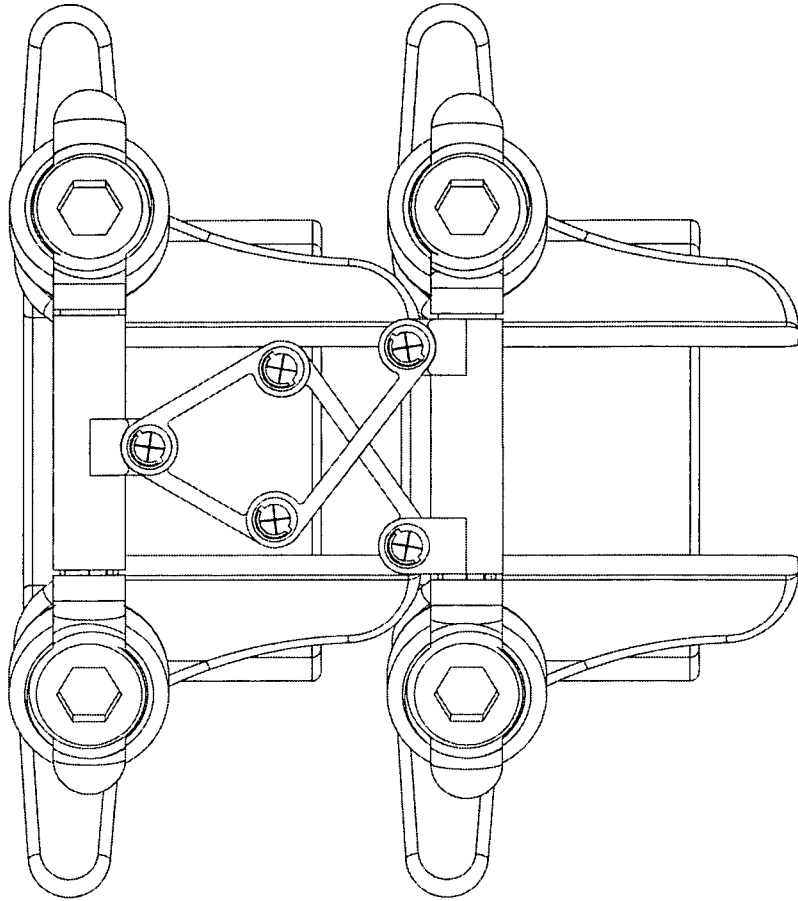


Fig. 9

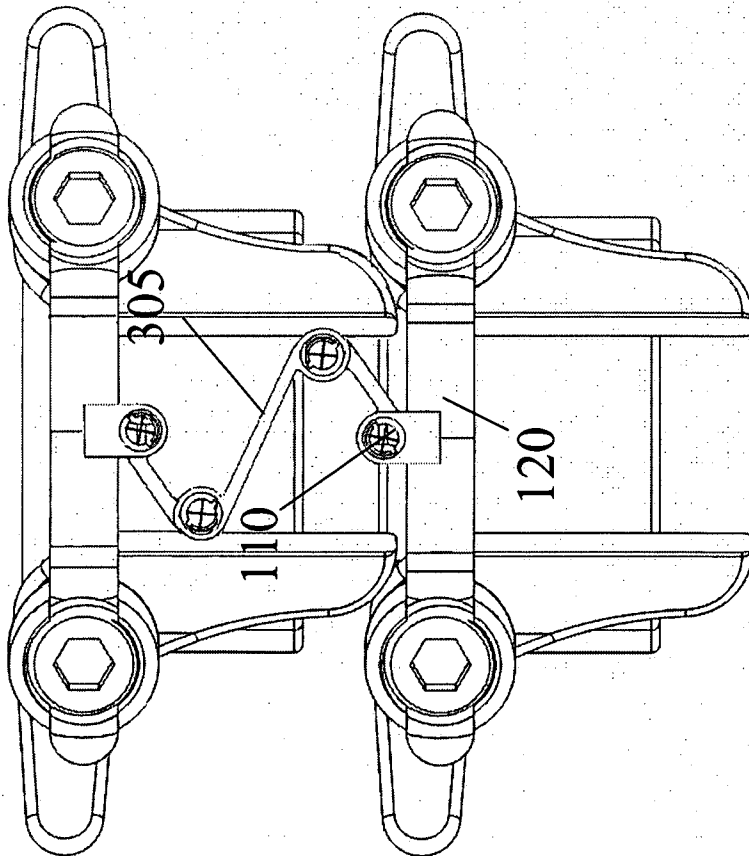


Fig. 12

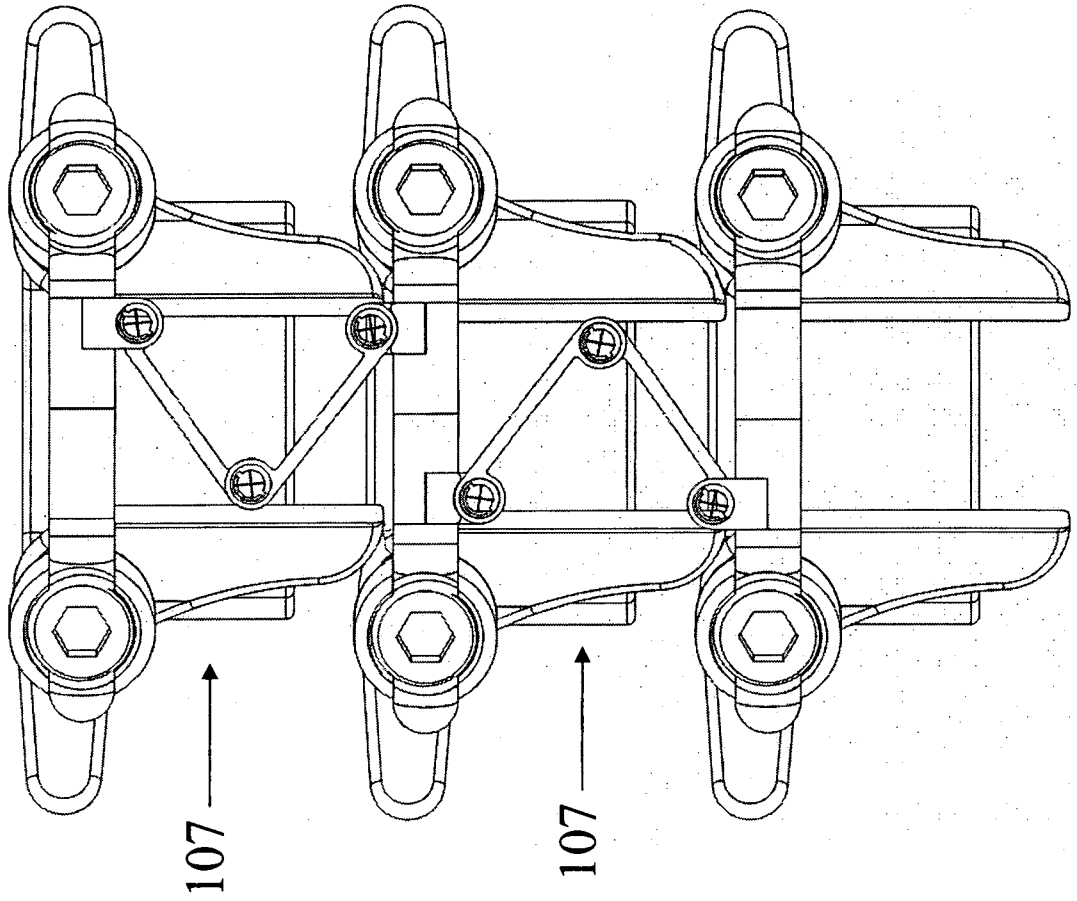
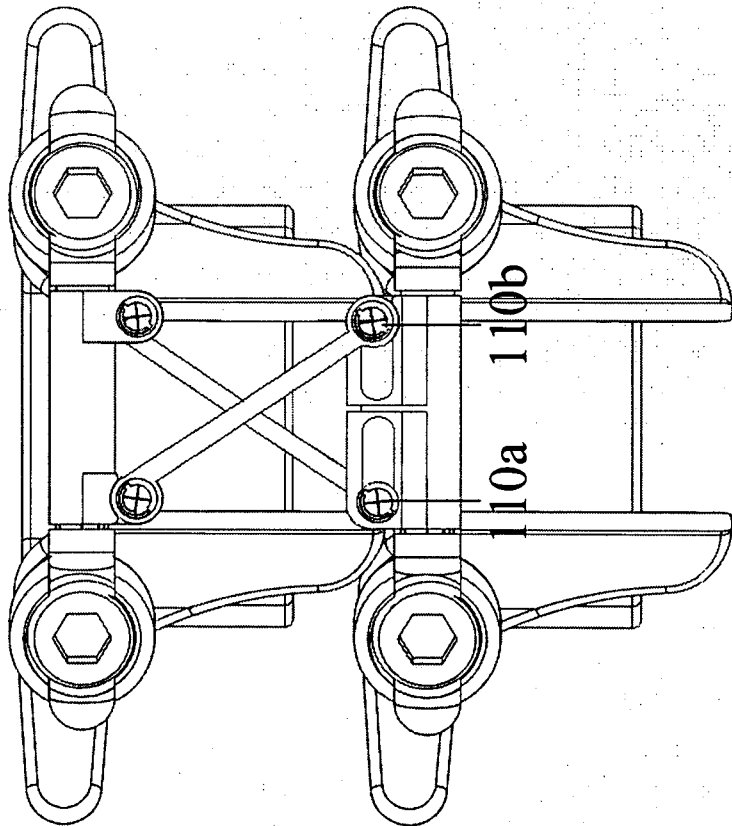


Fig. 11



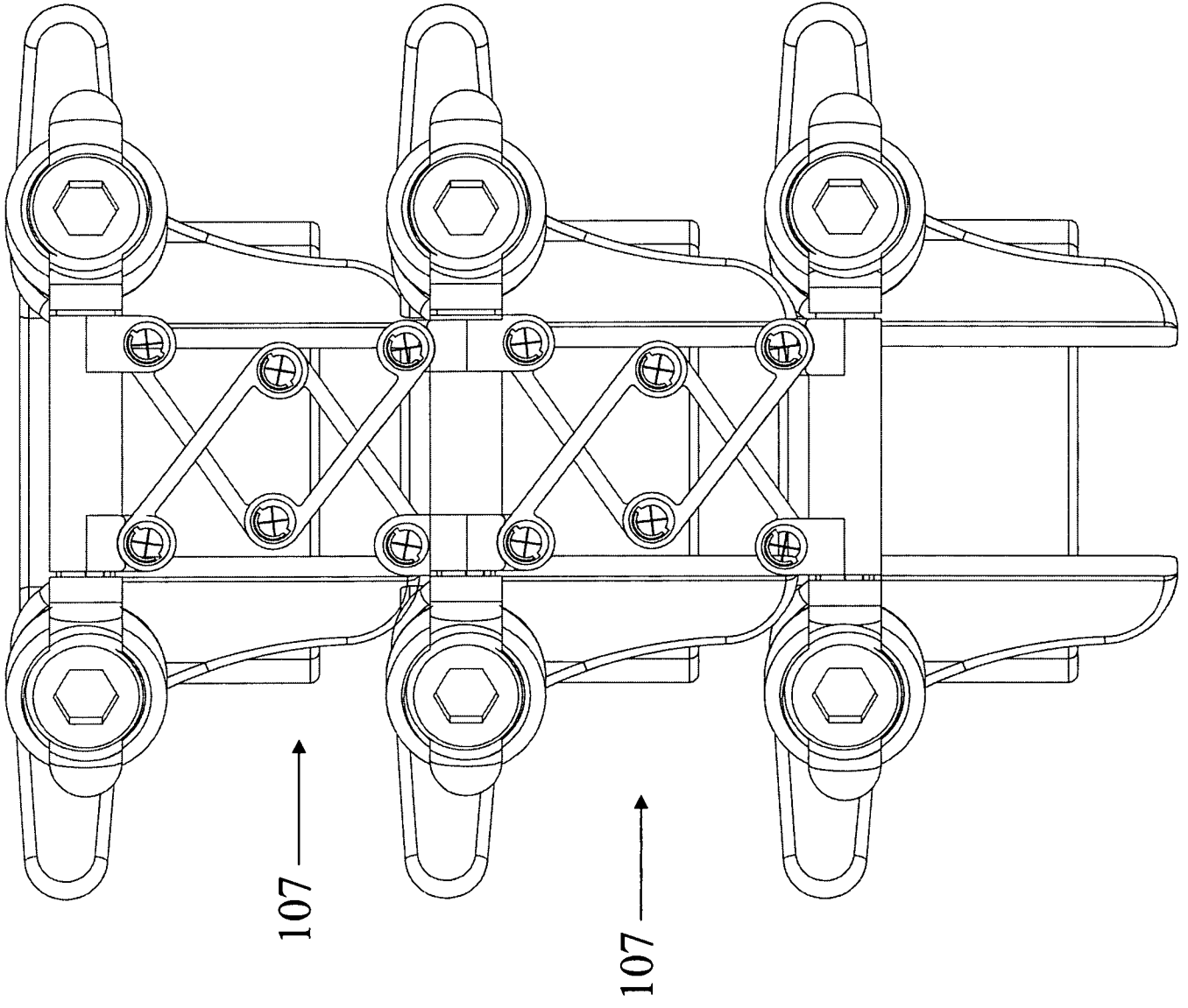


Fig. 13

Fig. 14A

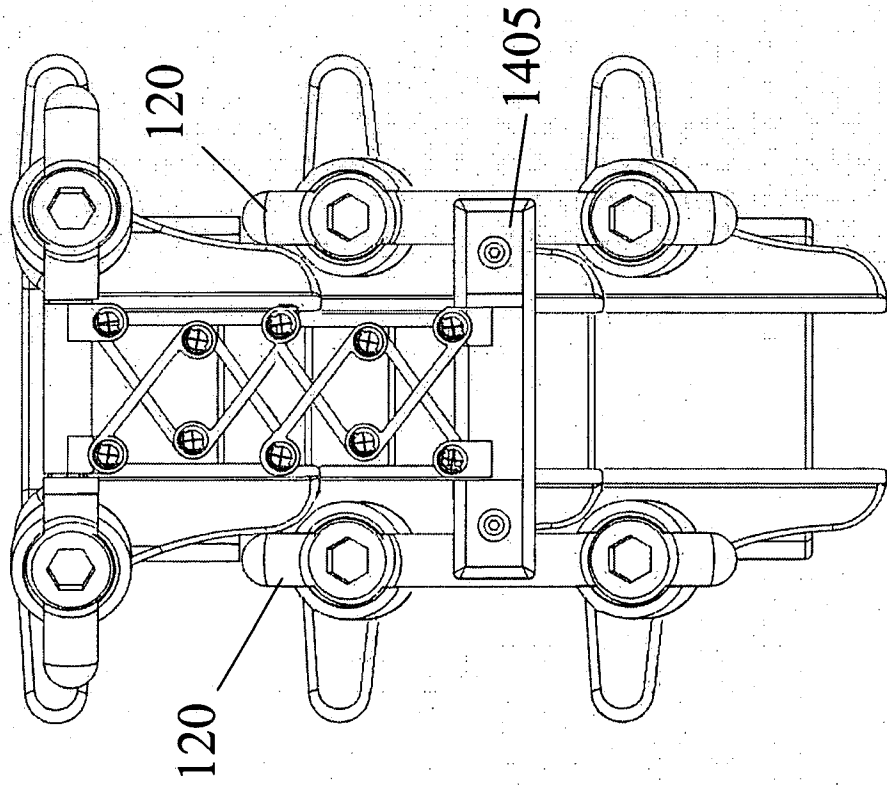
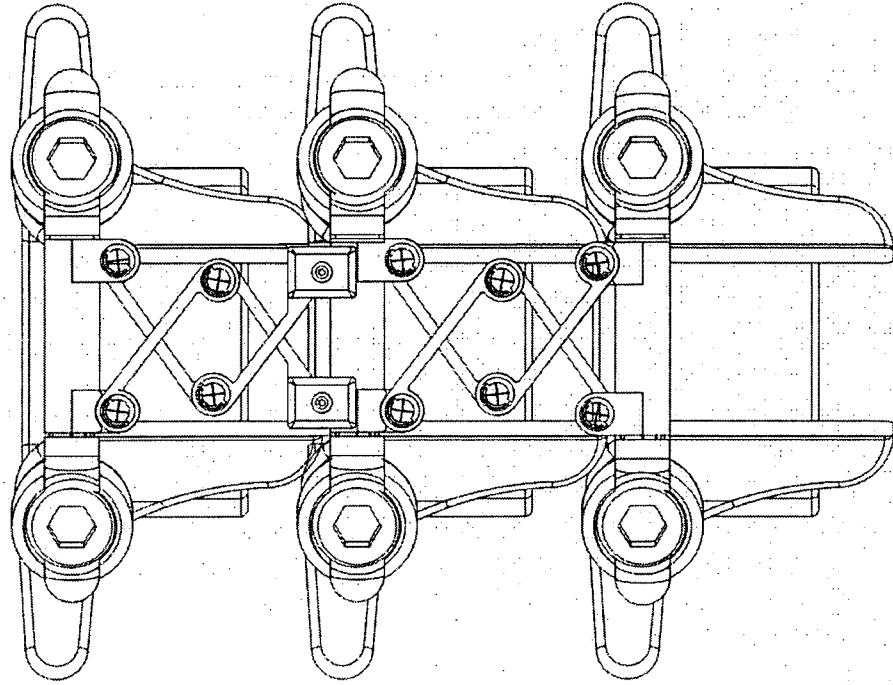


Fig. 14B



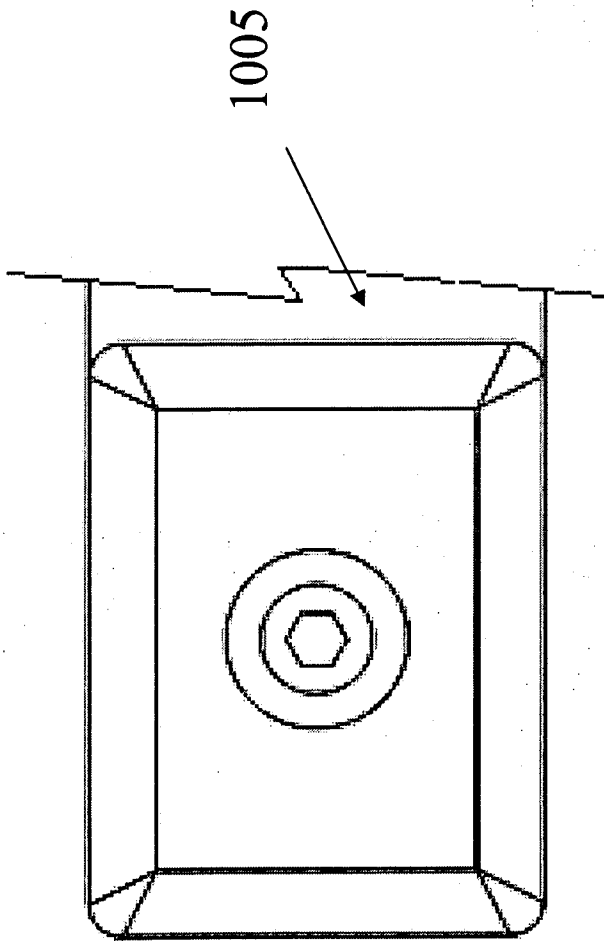


Fig. 15A

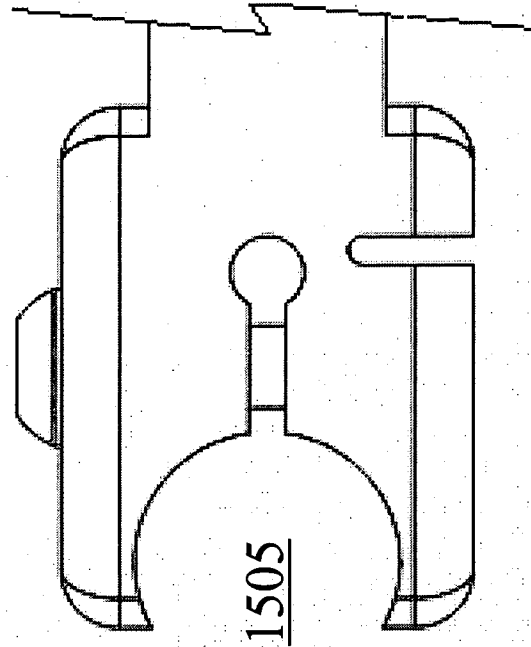


Fig. 15B

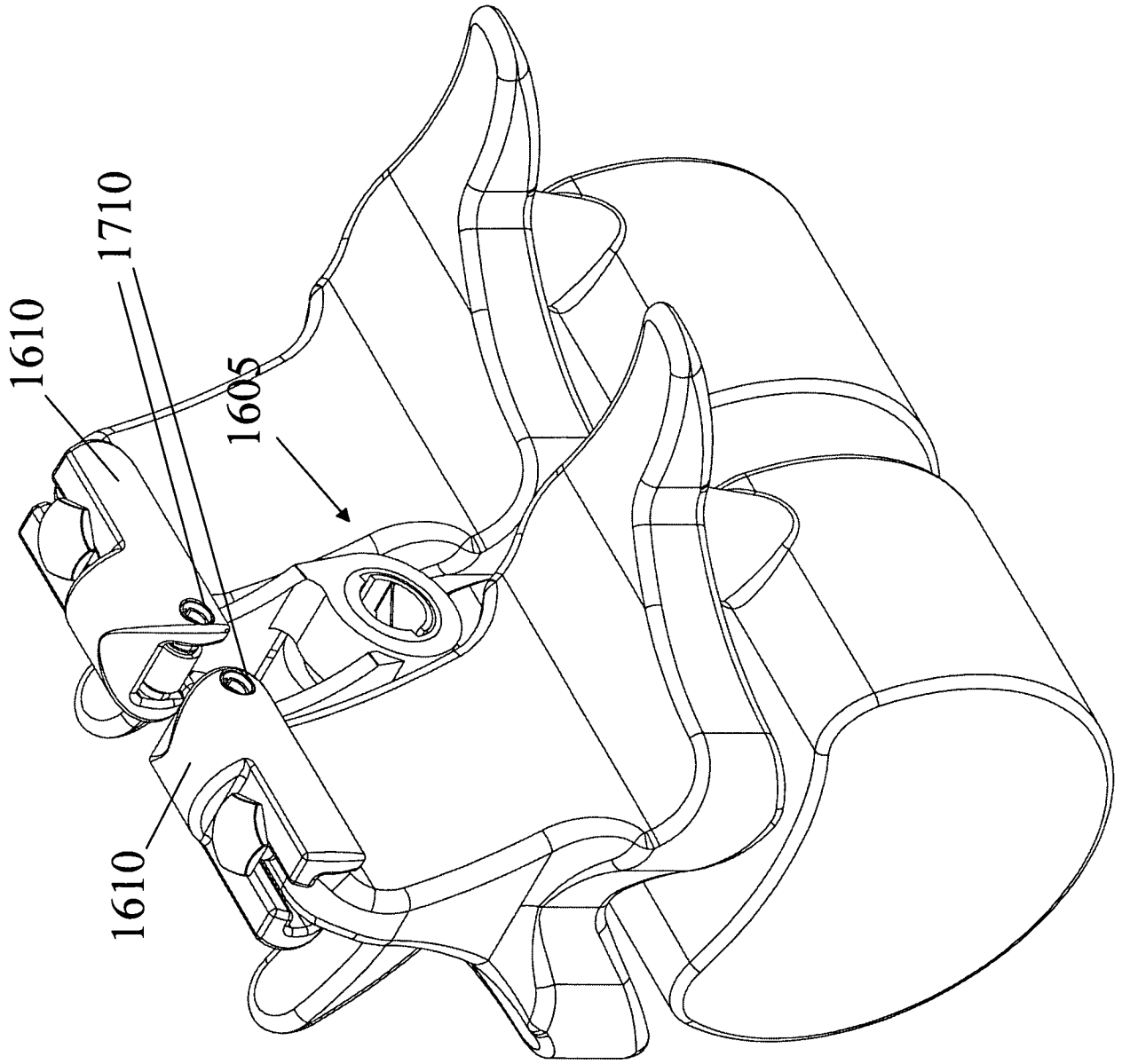


Fig. 16

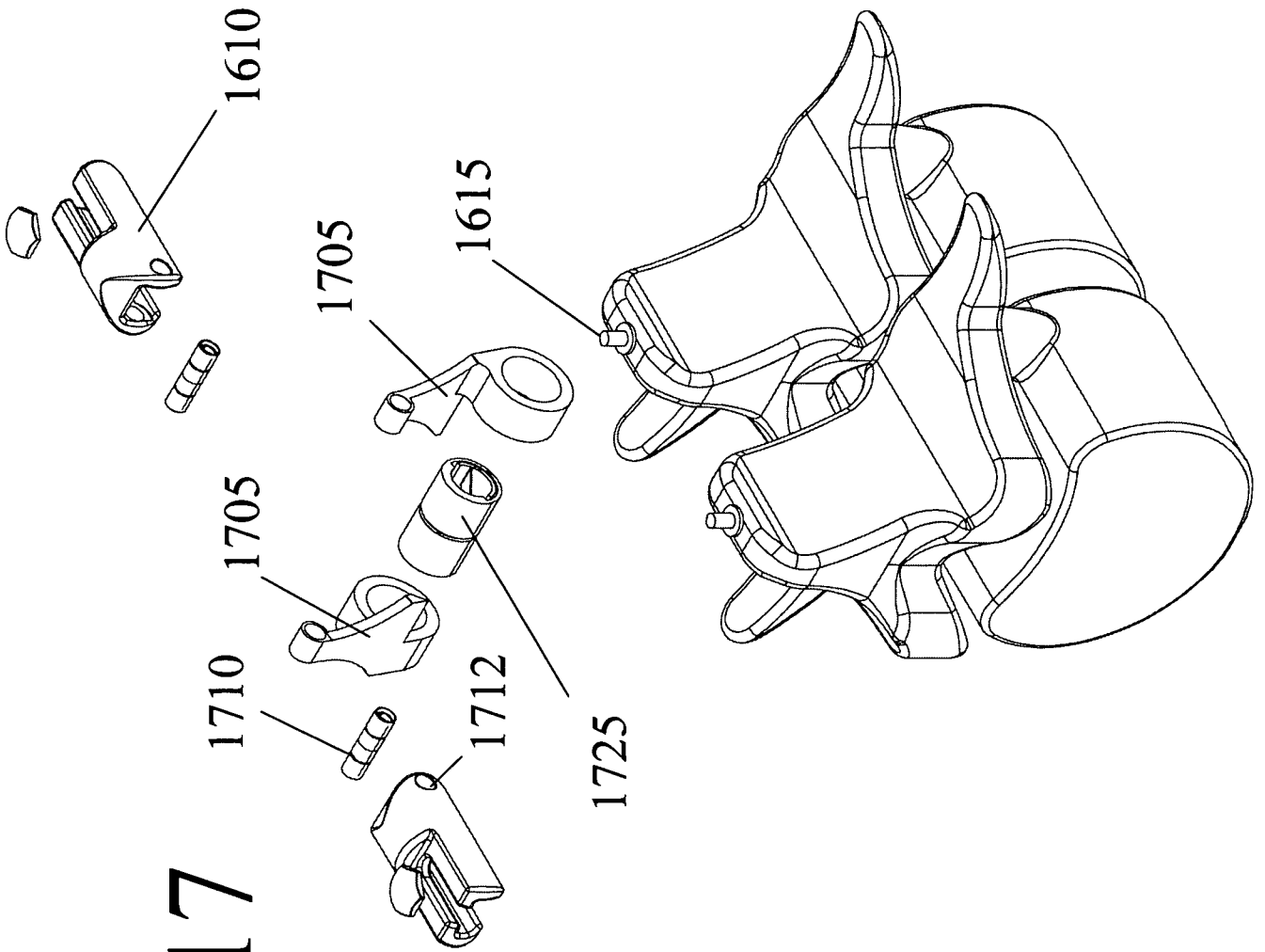


Fig. 17

Fig. 18

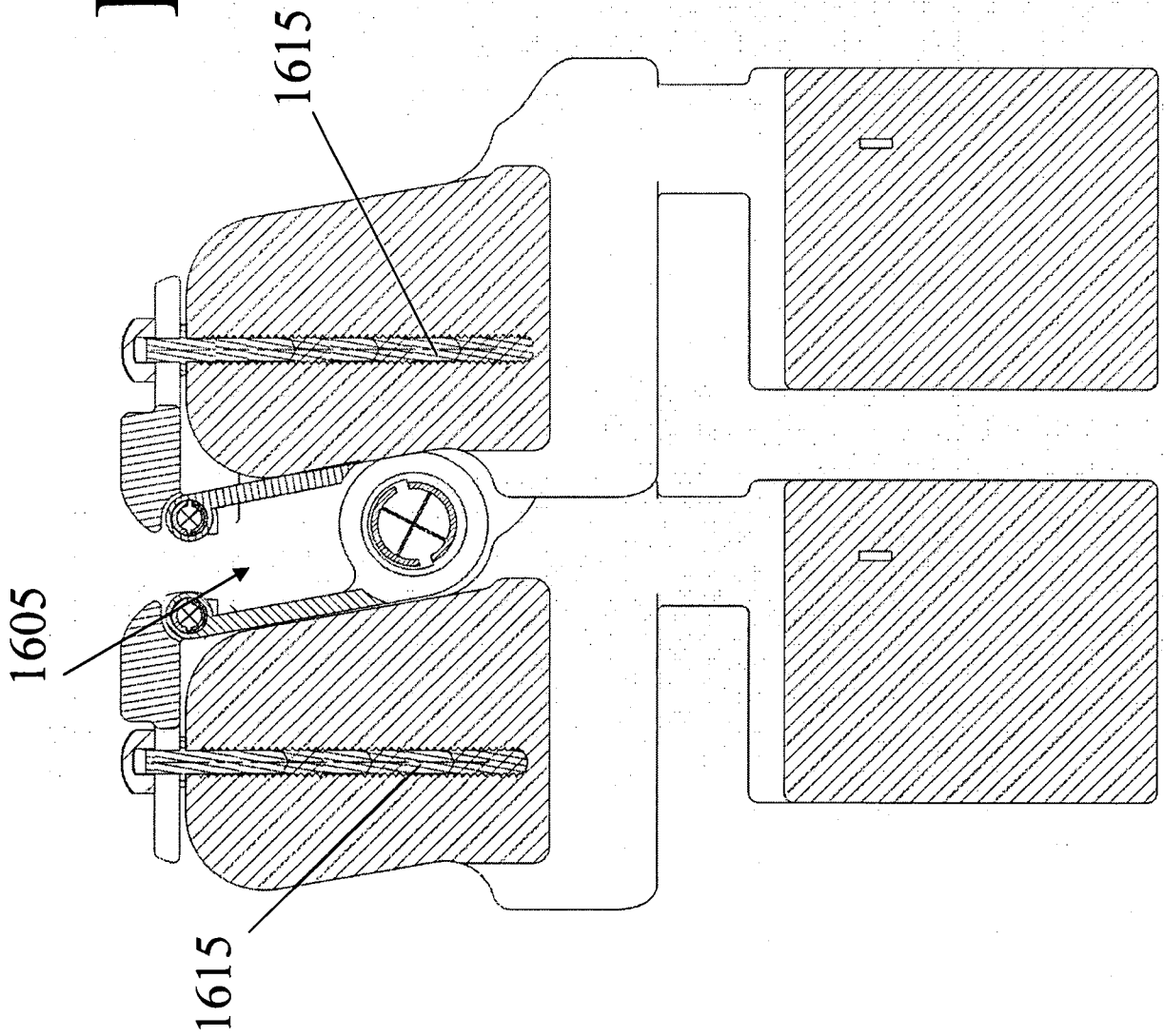


Fig. 19

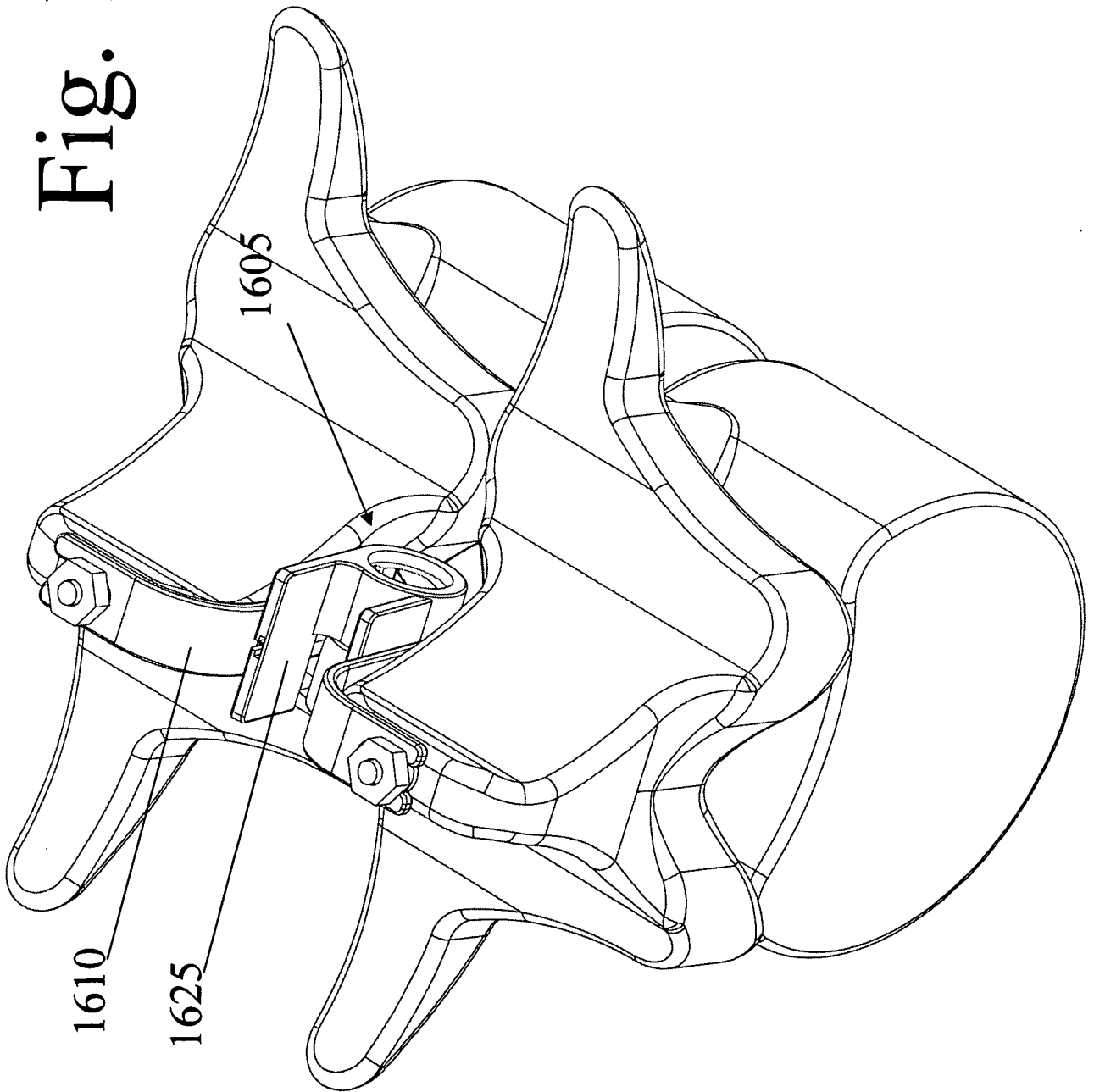


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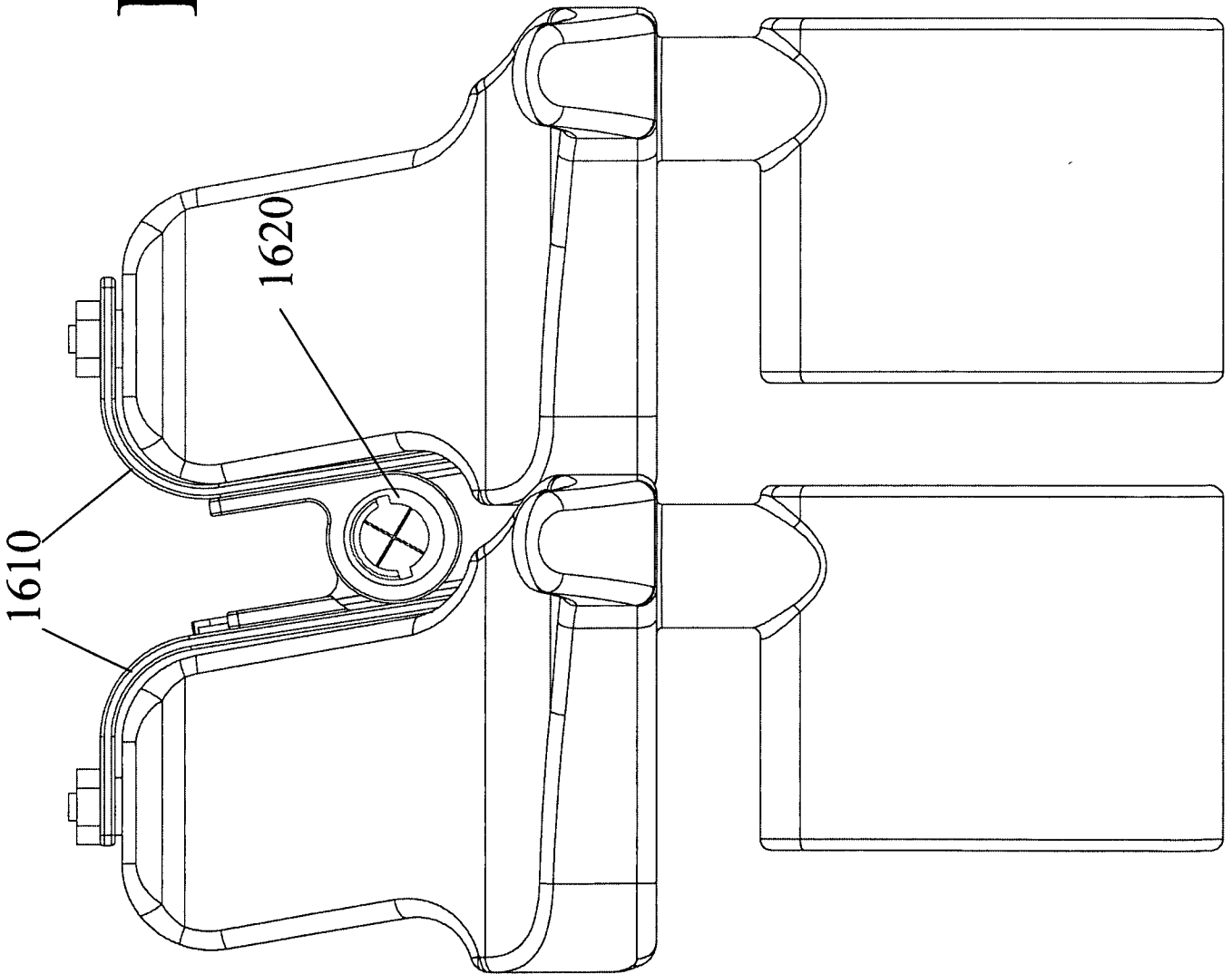
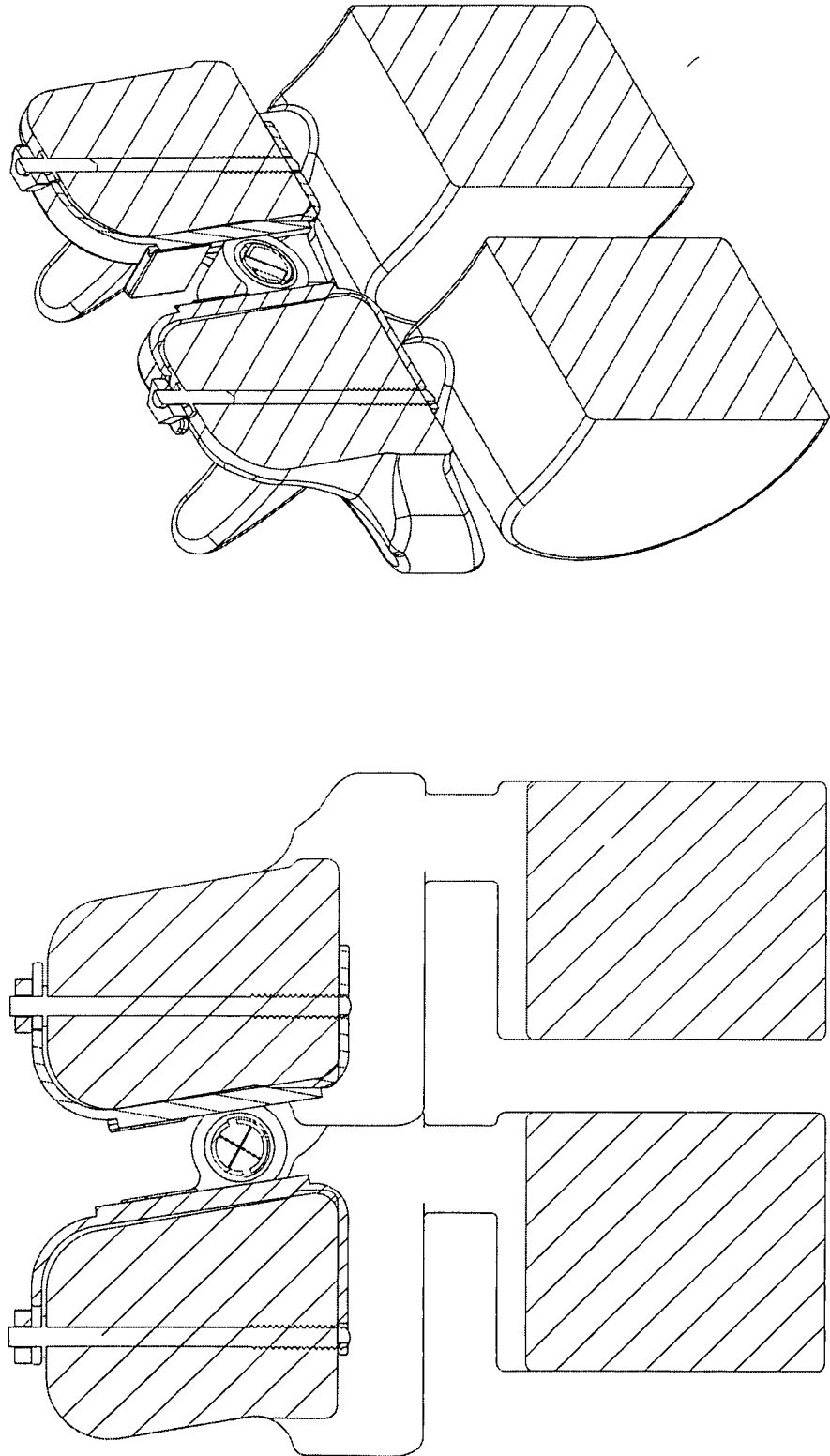


Fig. 21



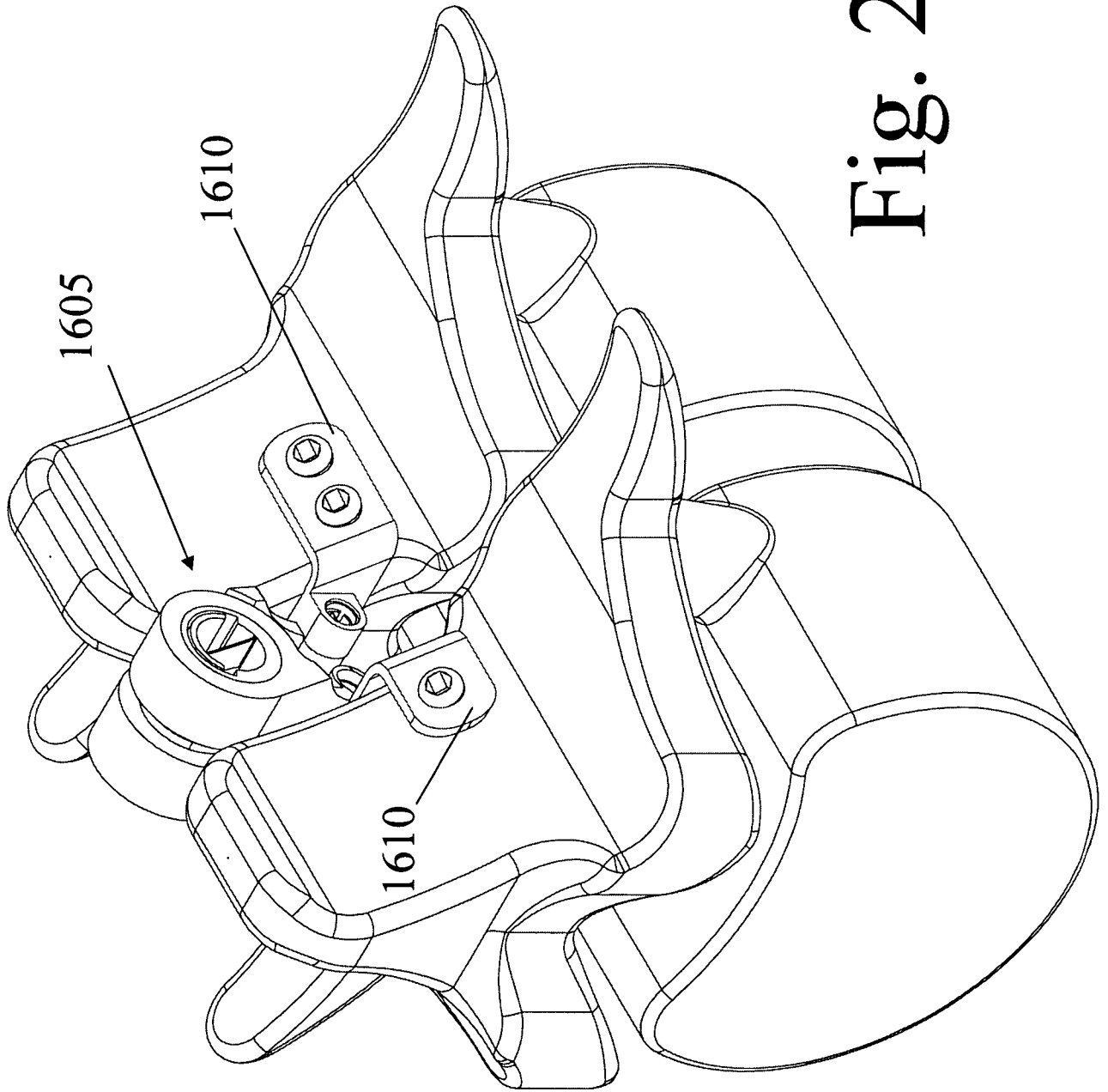
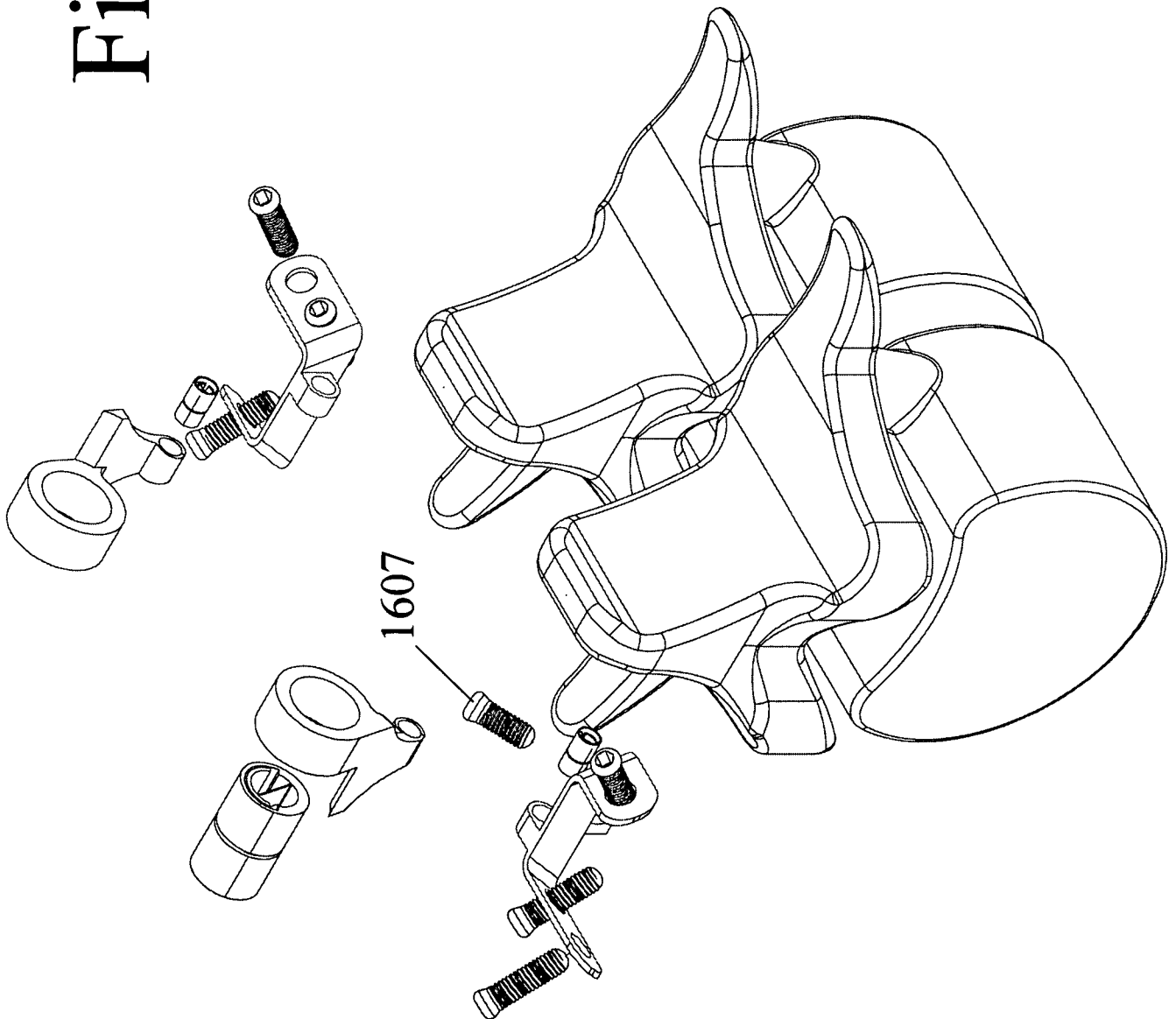


Fig. 22

Fig. 23



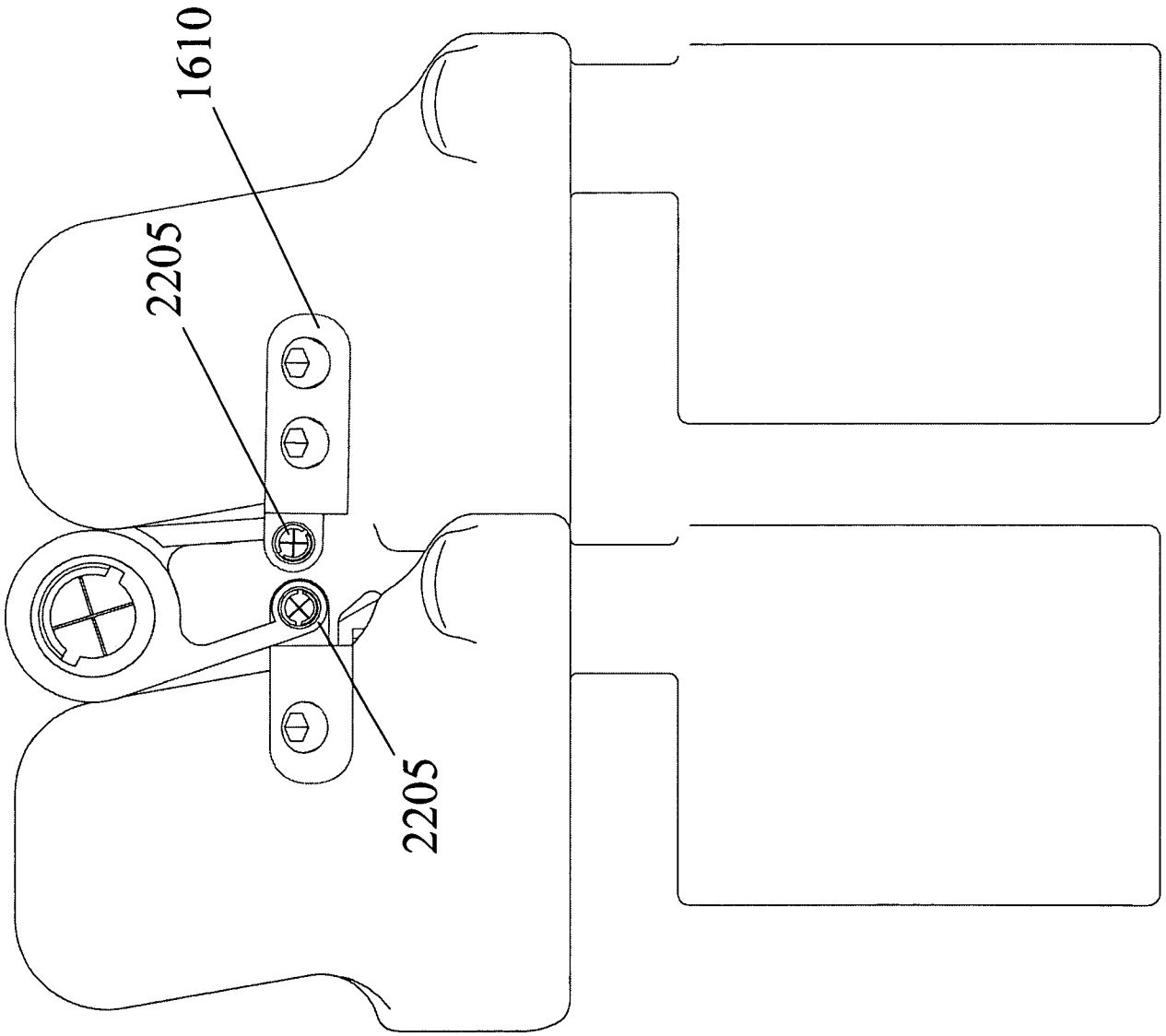


Fig. 24

Fig. 25

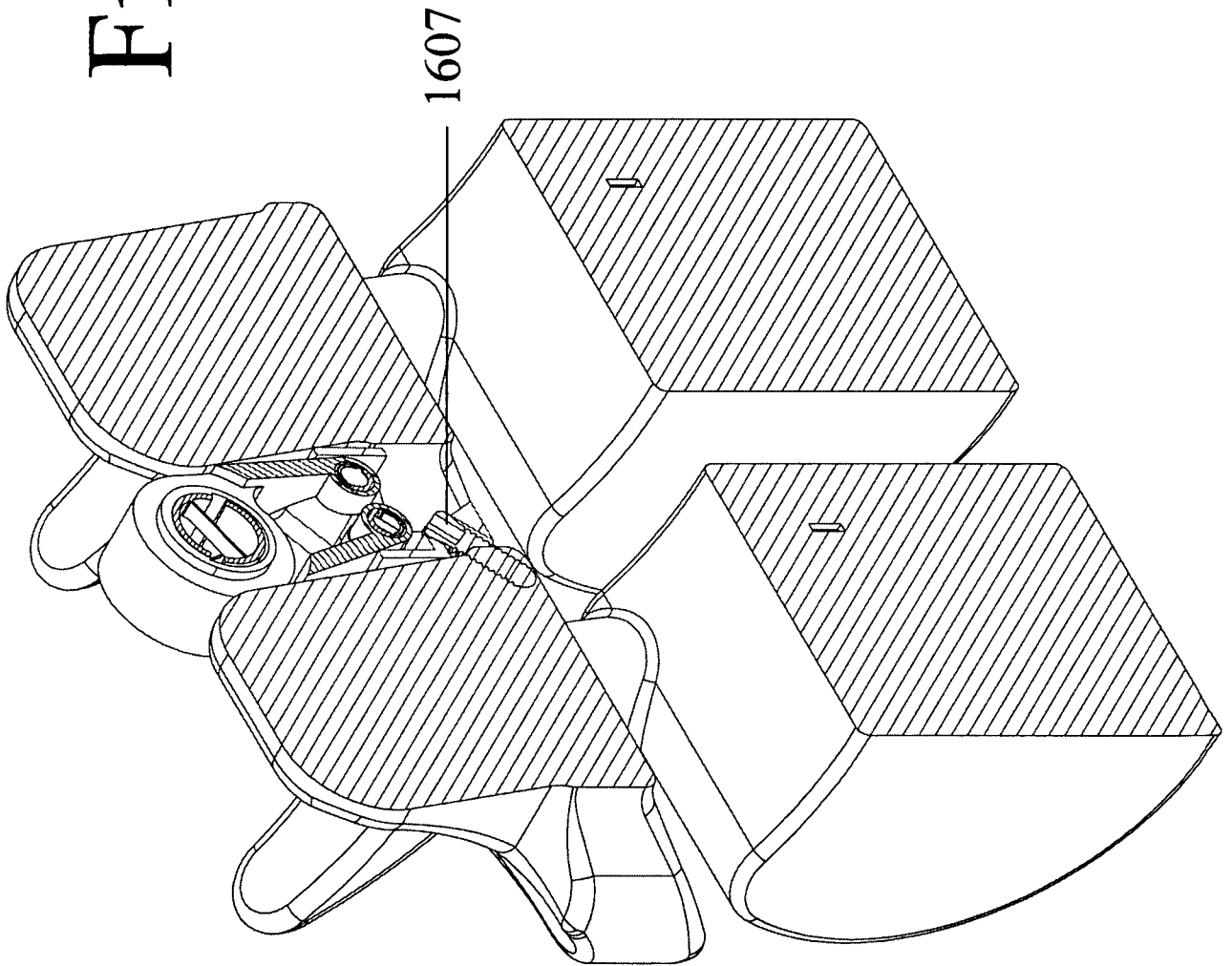
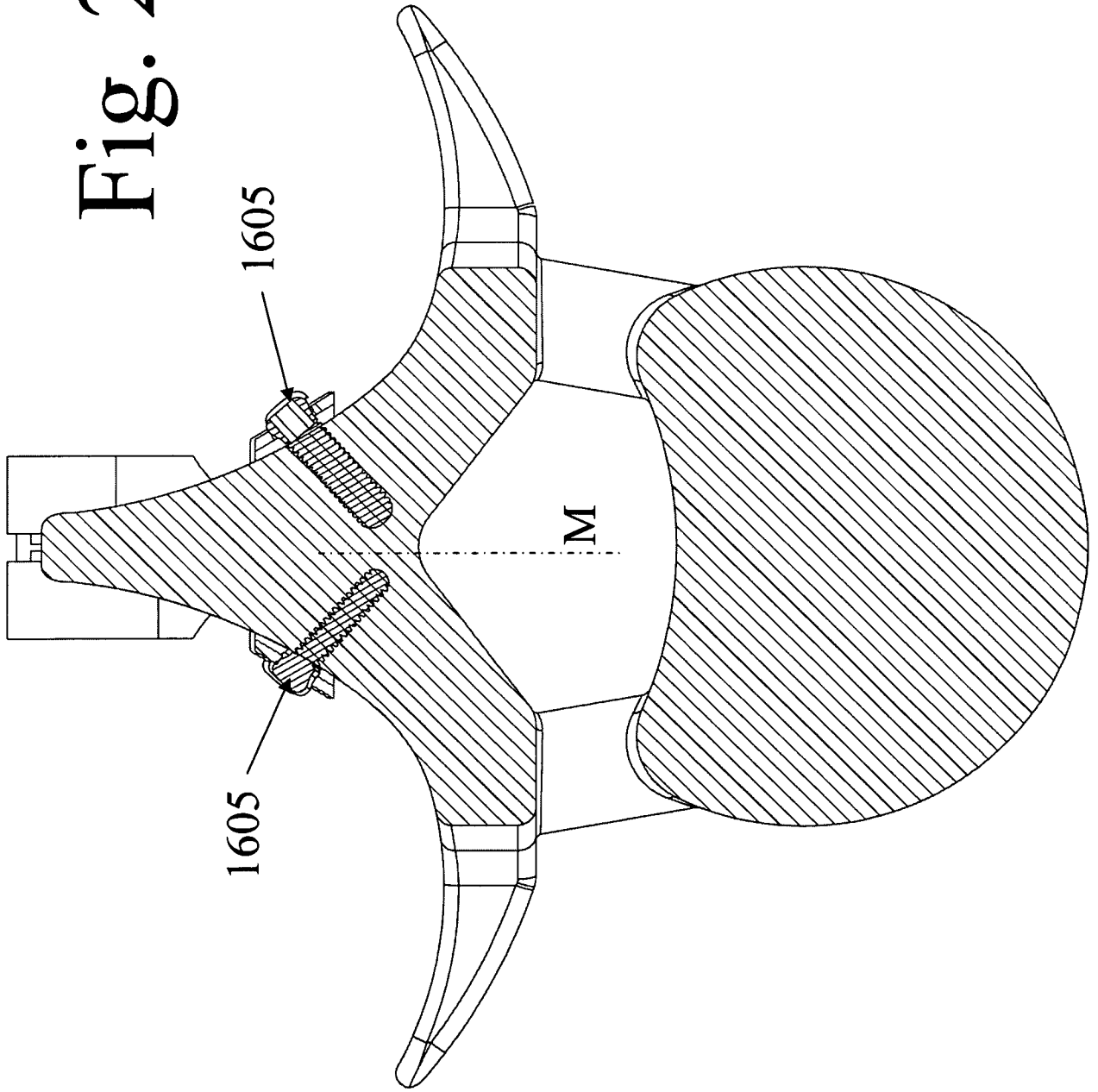


Fig. 26



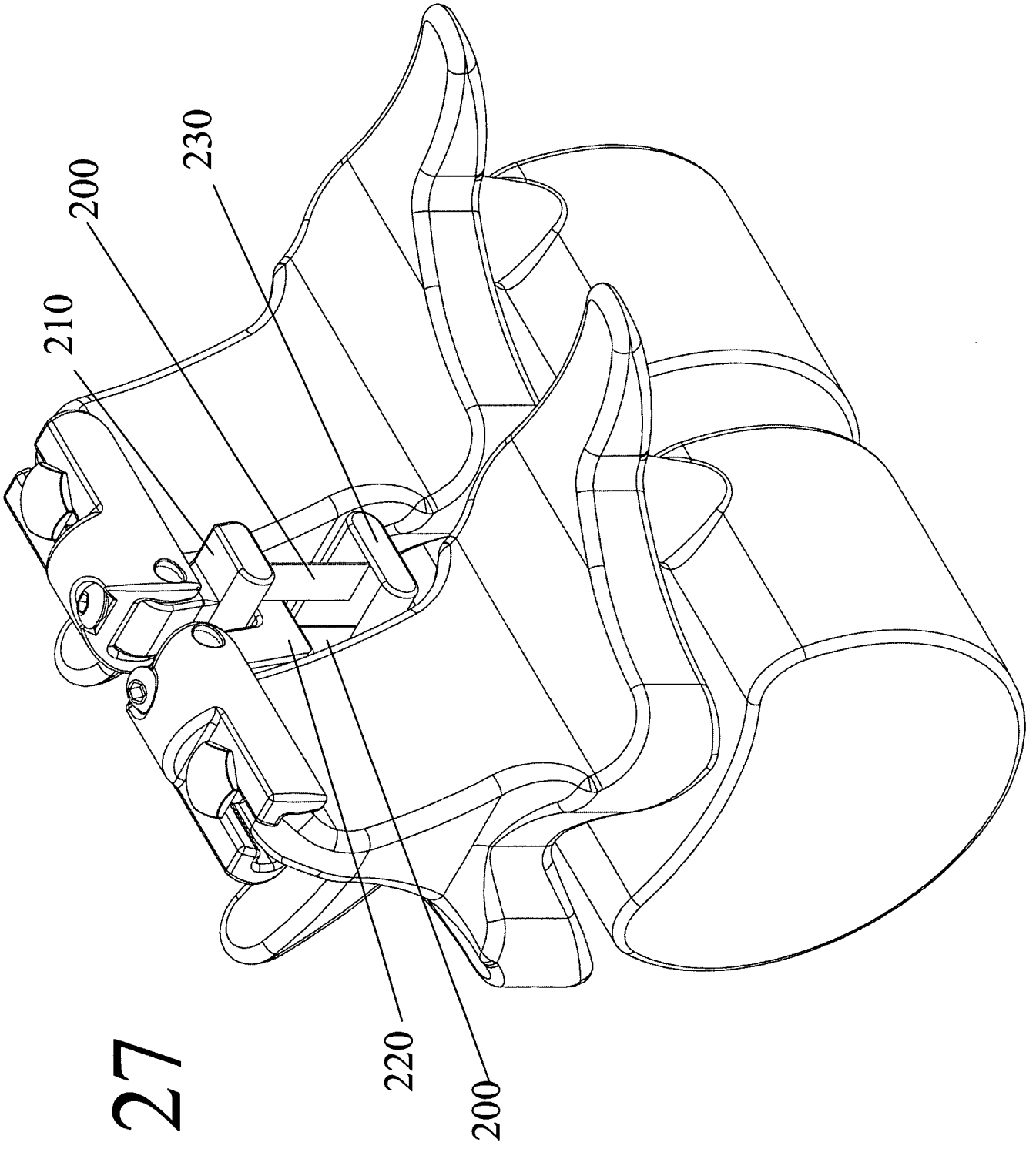


Fig. 27

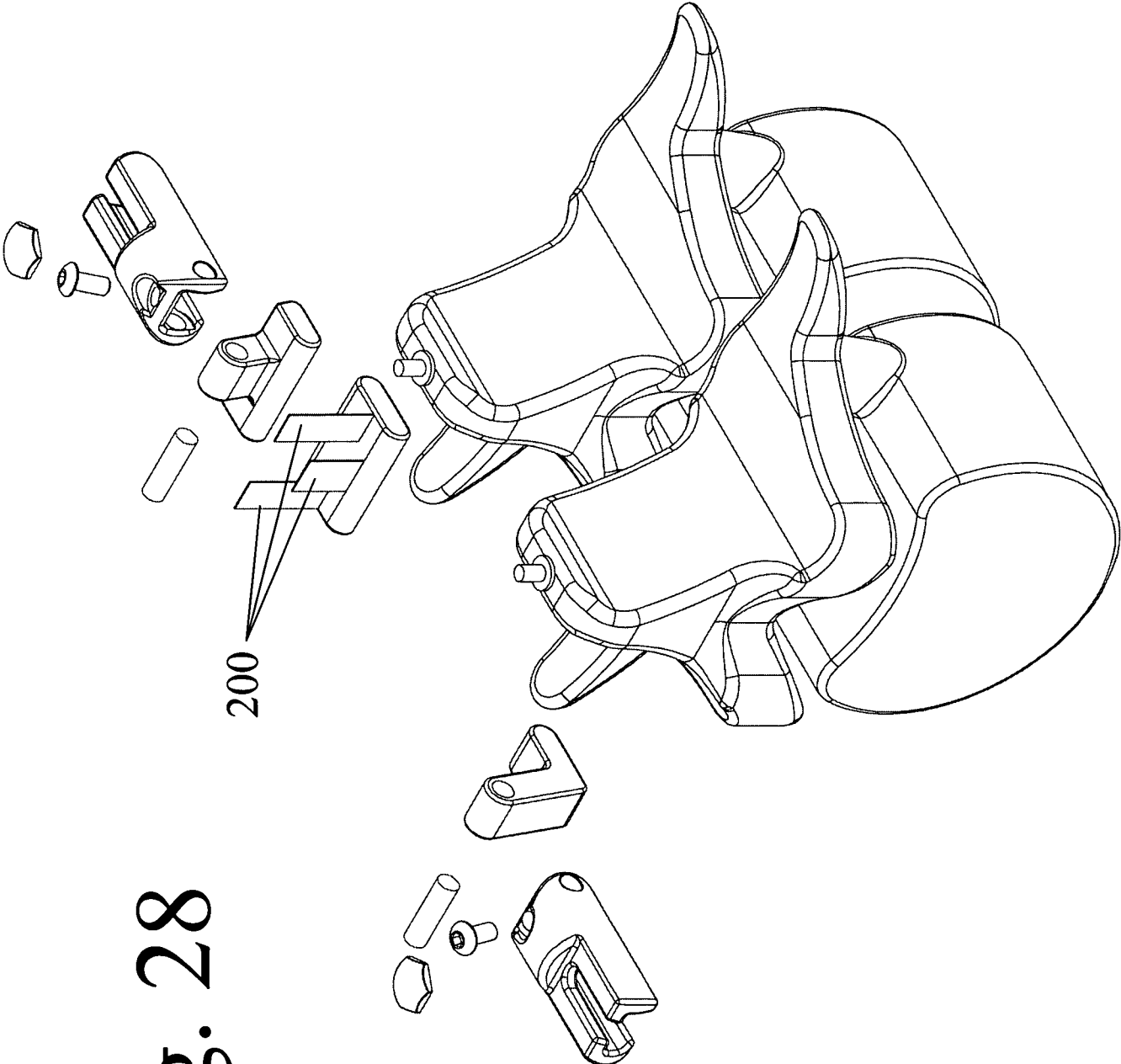


Fig. 28

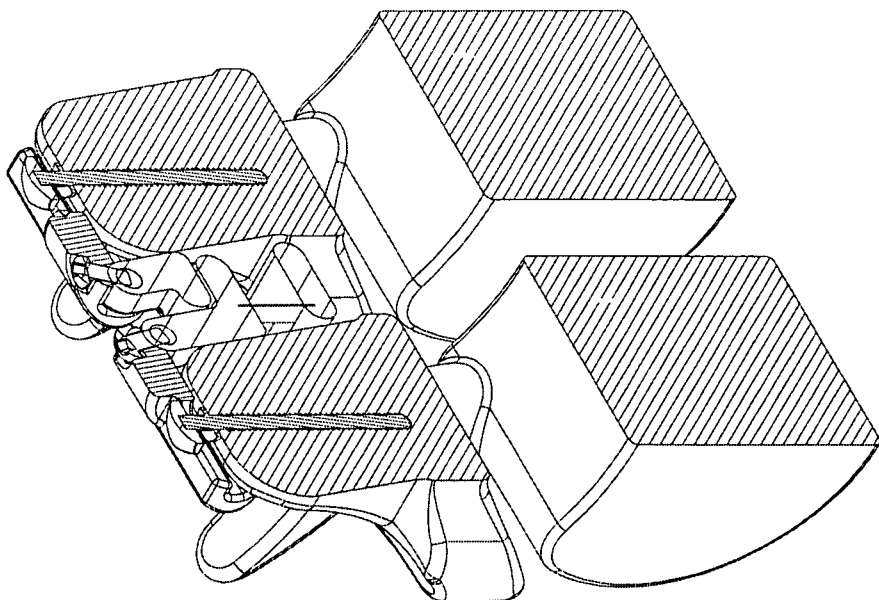


Fig. 29B

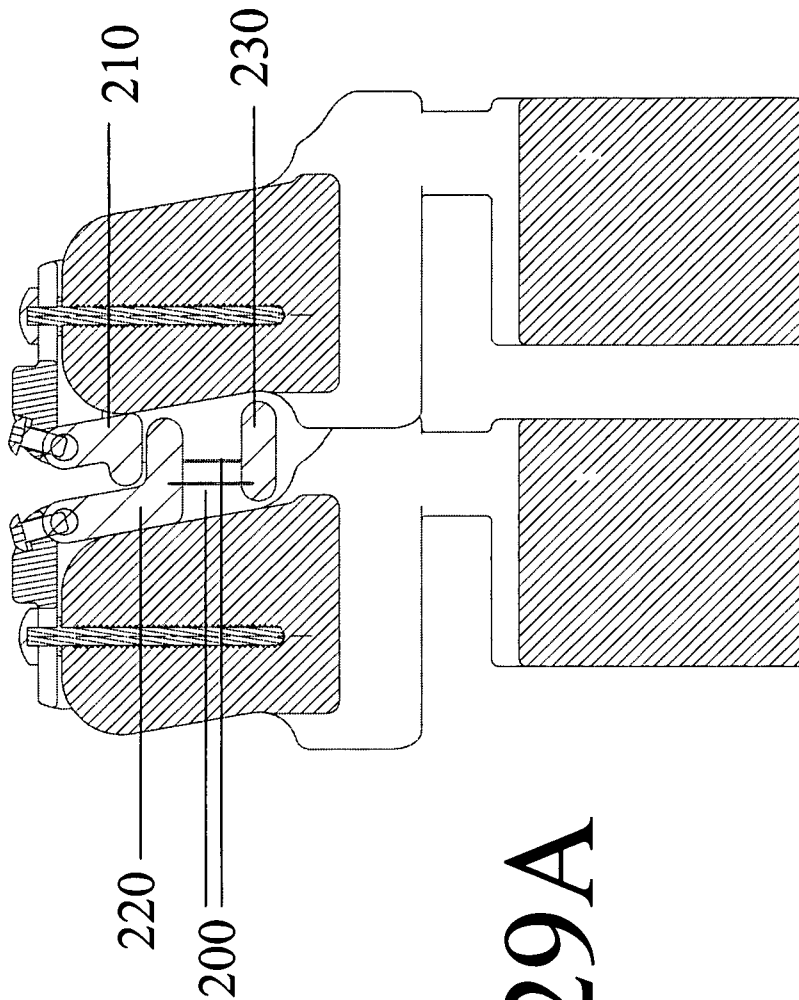


Fig. 29A

Fig. 30A

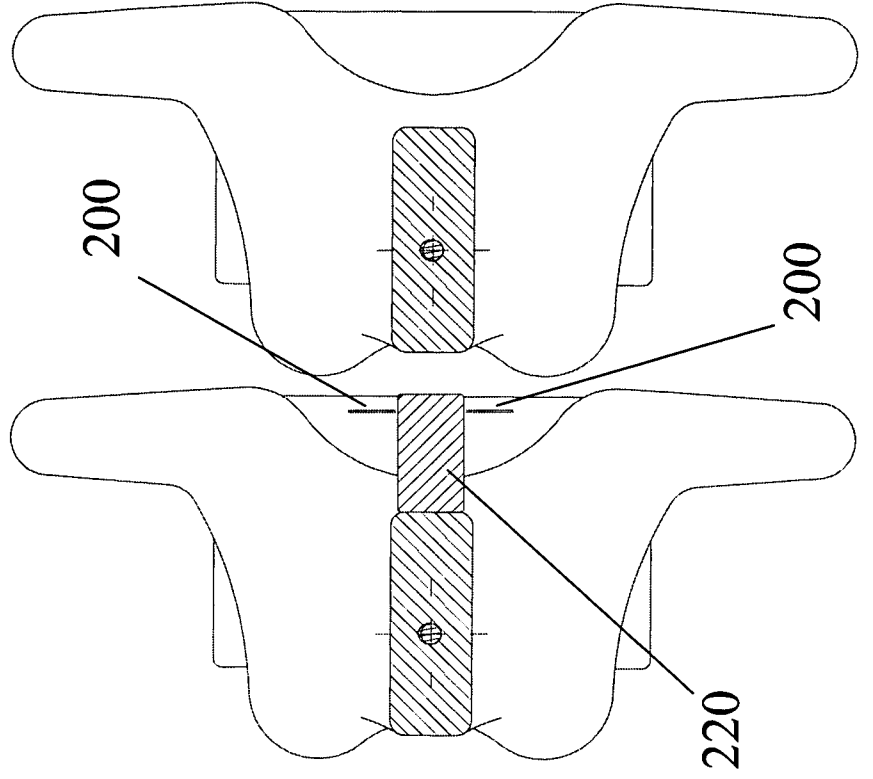
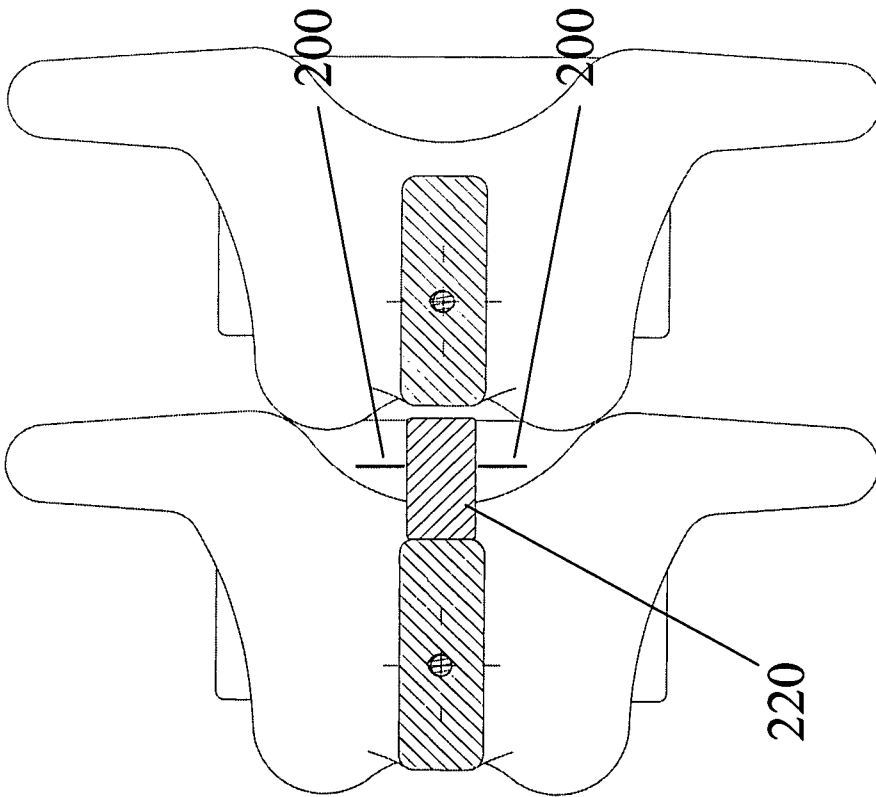


Fig. 30B

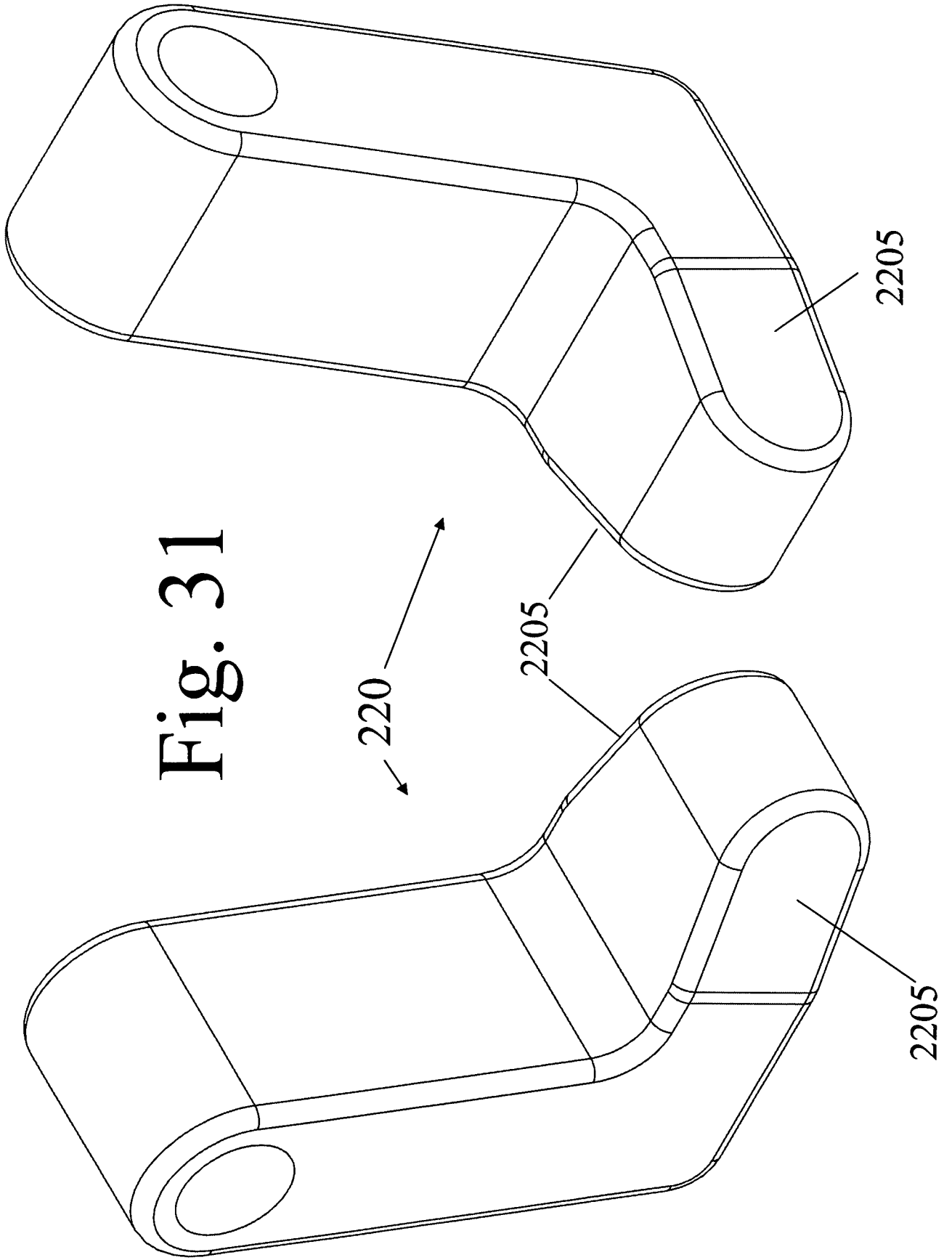


Fig. 32A

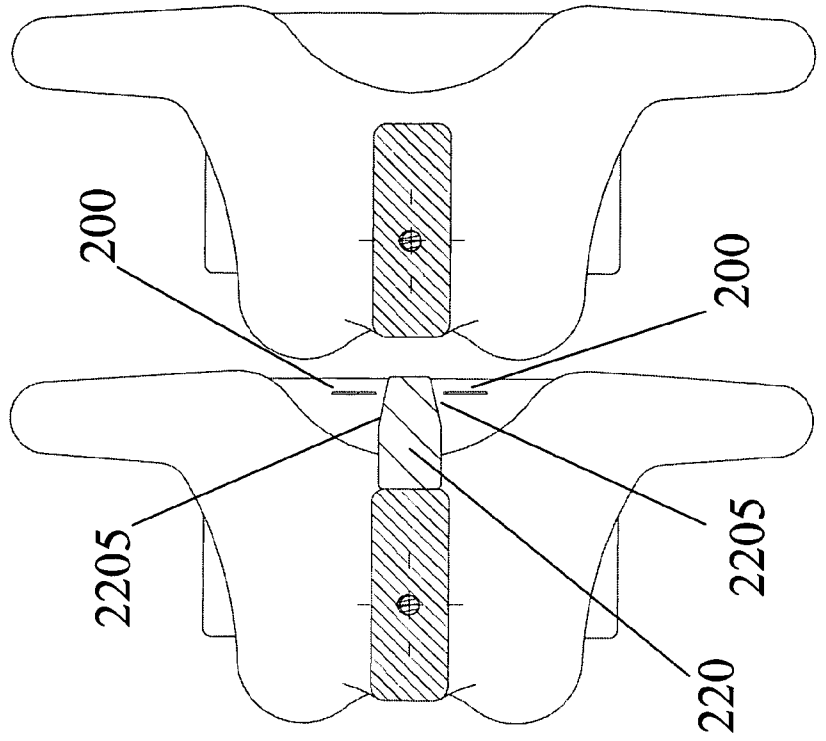
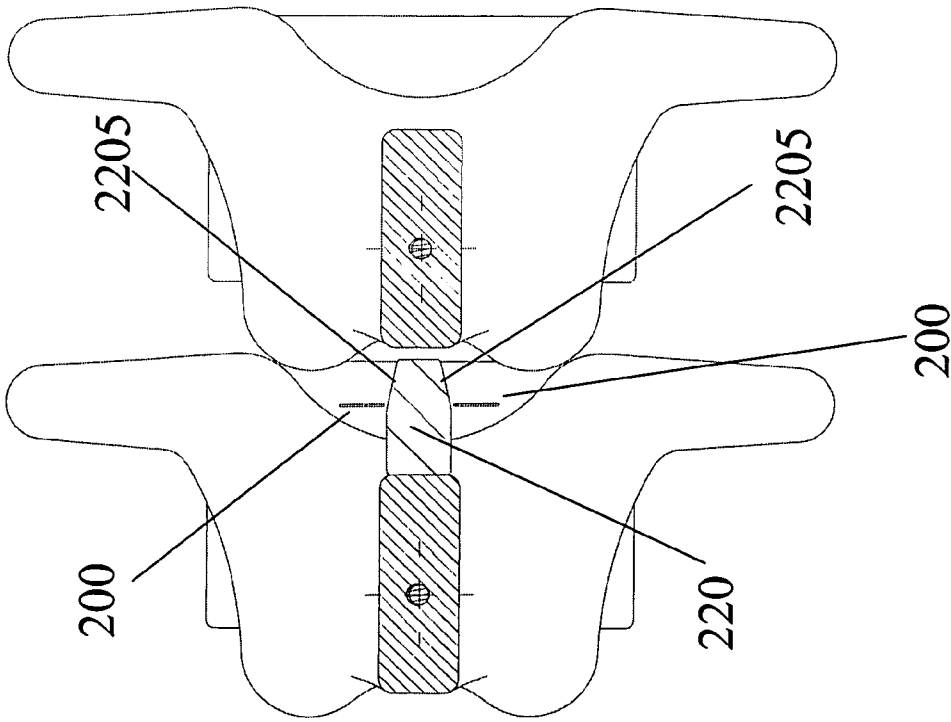


Fig. 32B

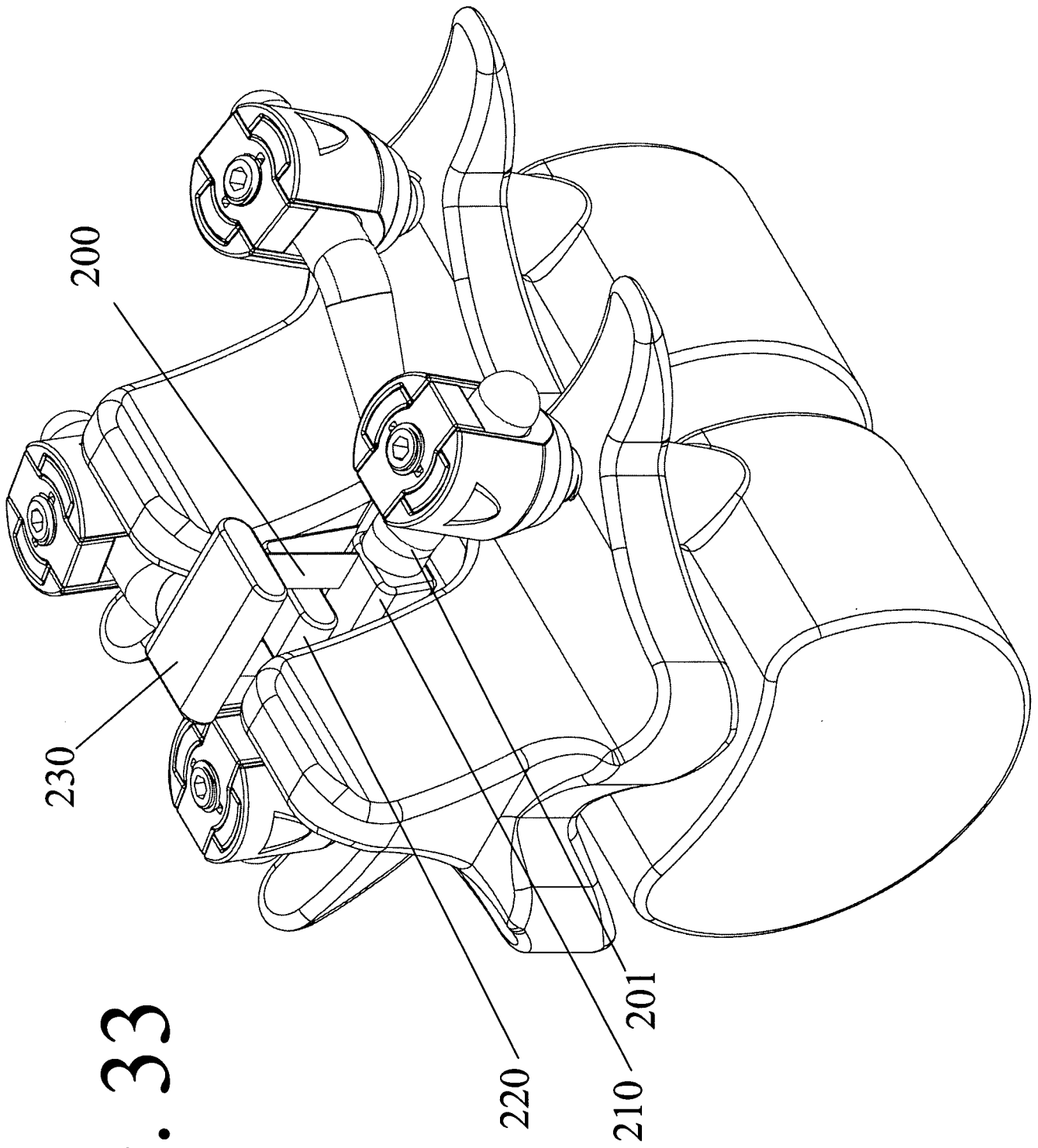


Fig. 33

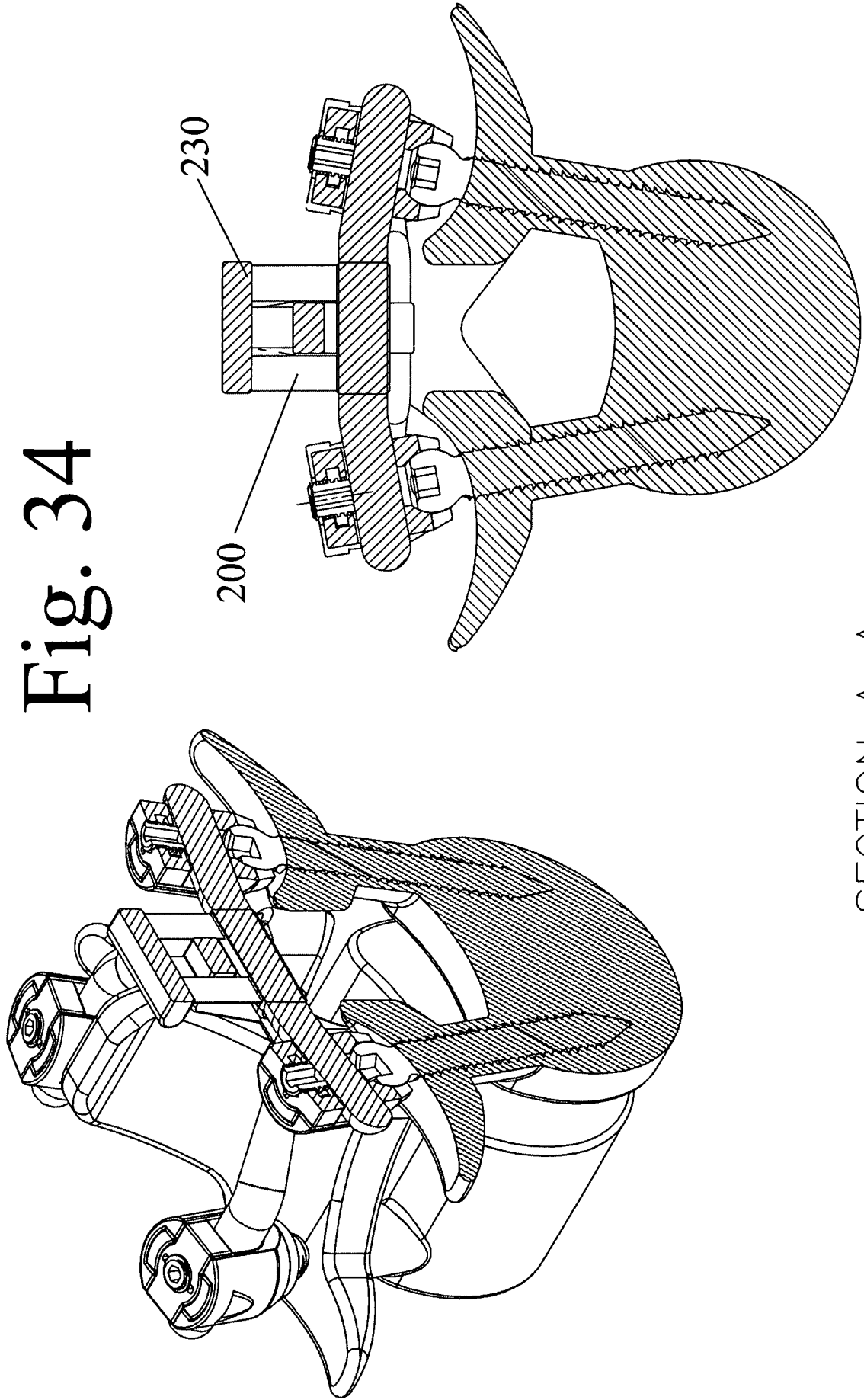
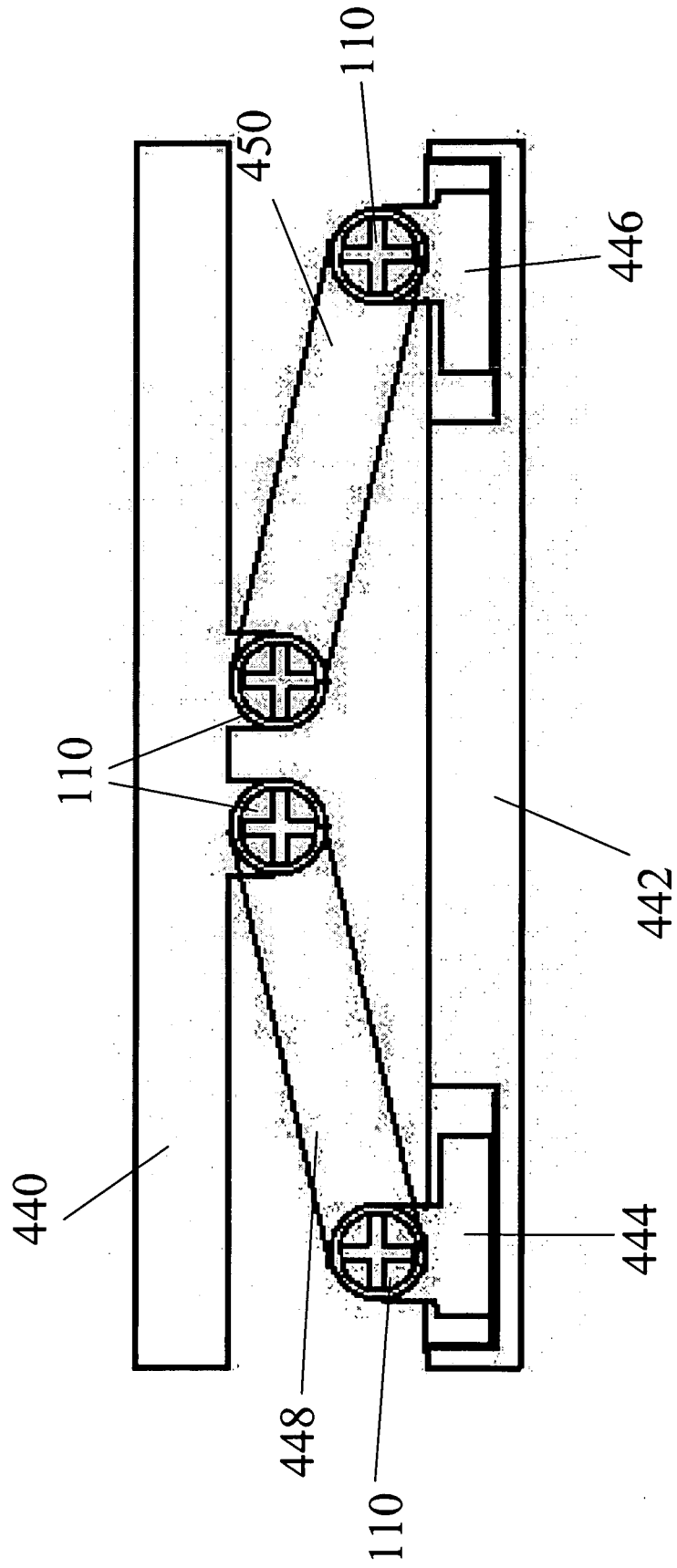


Fig. 34

SECTION A-A

Fig. 35



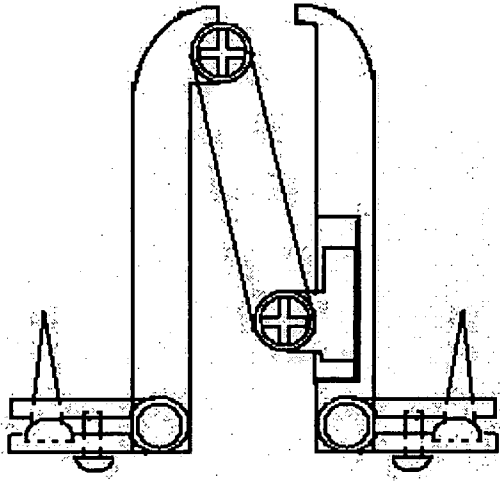


Fig. 36A

Fig. 36C

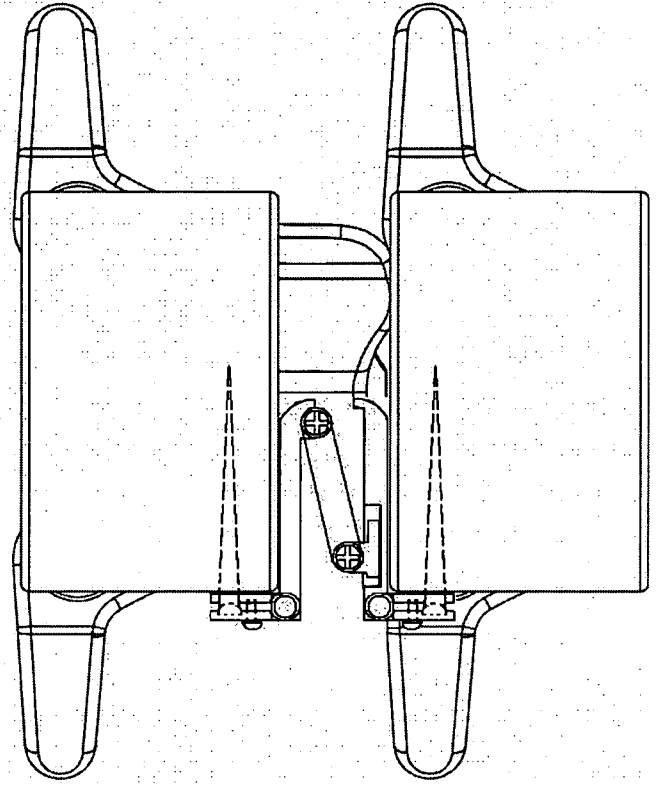


Fig. 36B

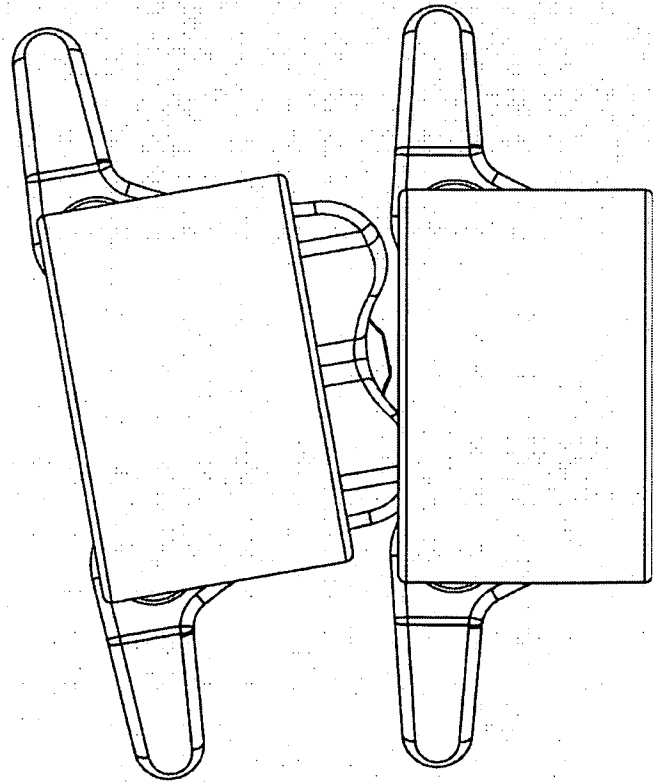
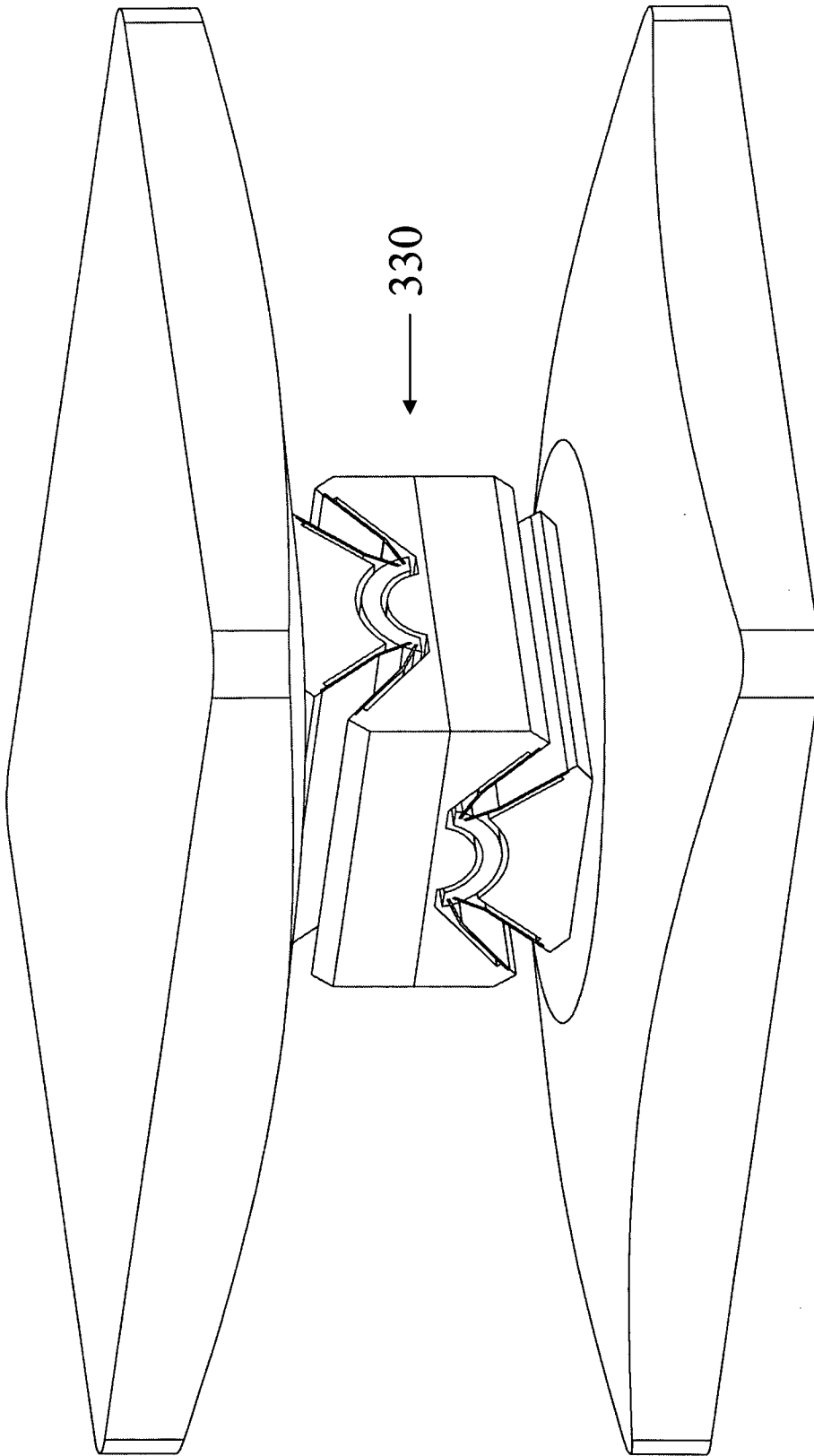


Fig. 37



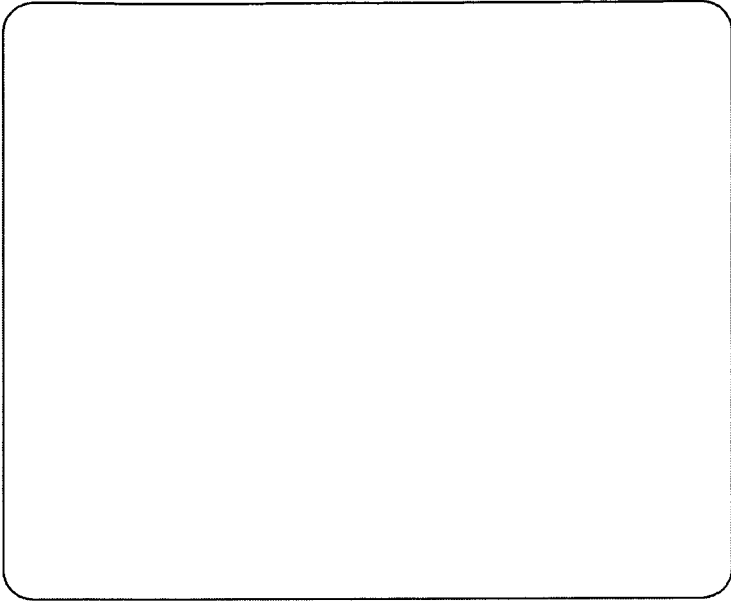
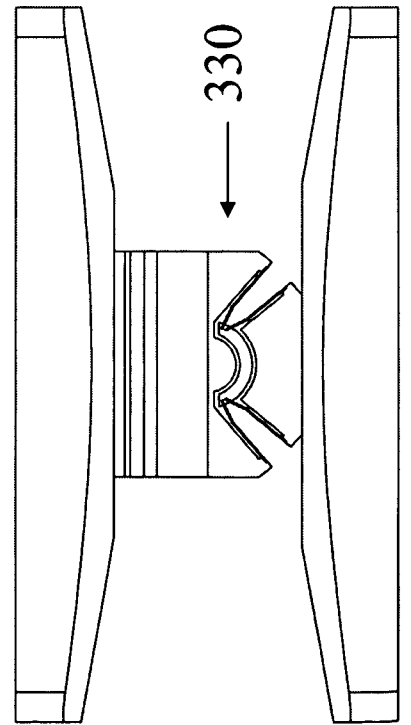
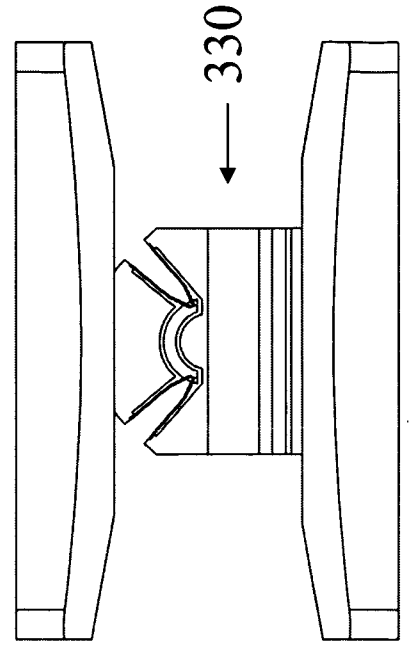


Fig. 38



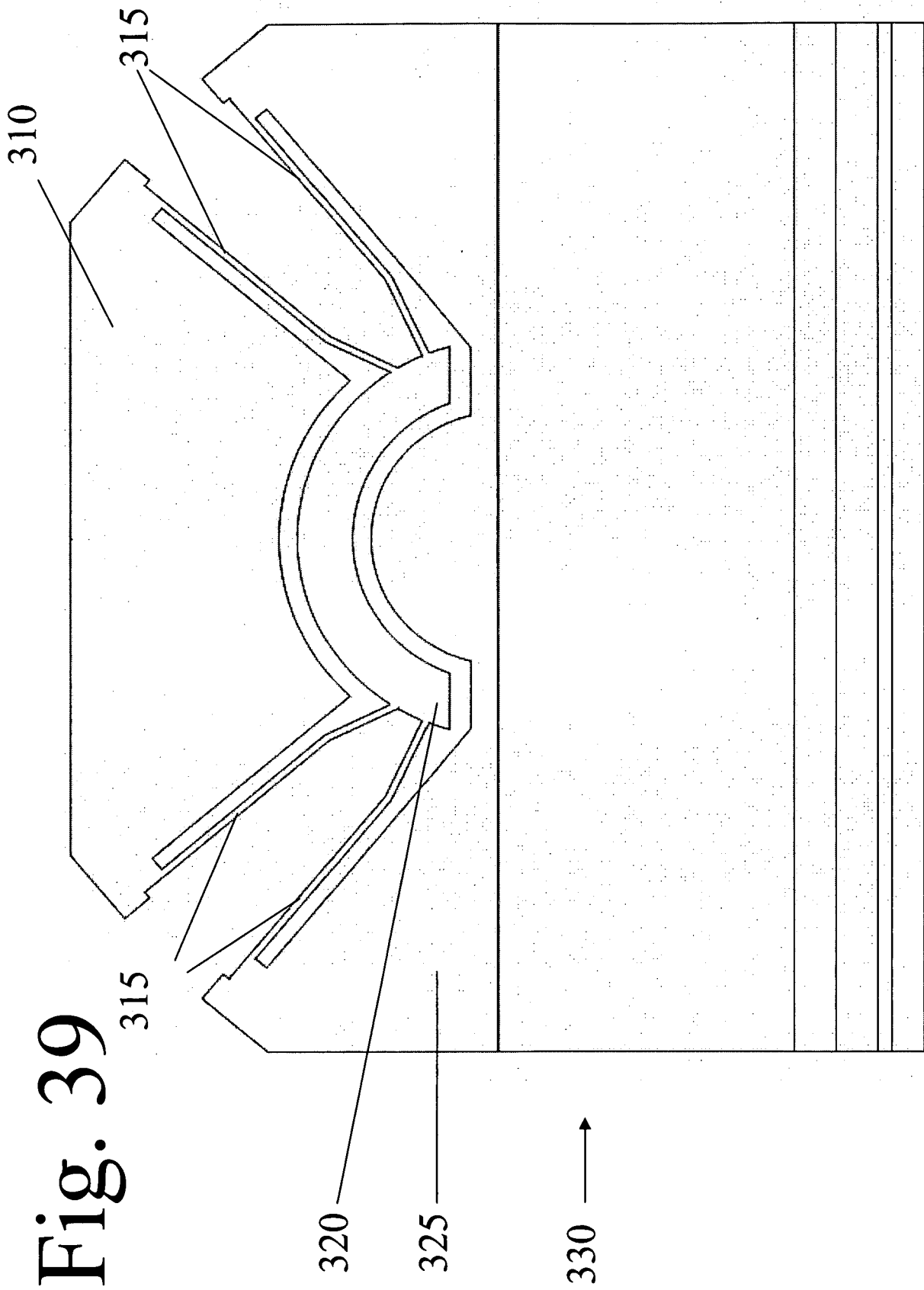


Fig. 40A

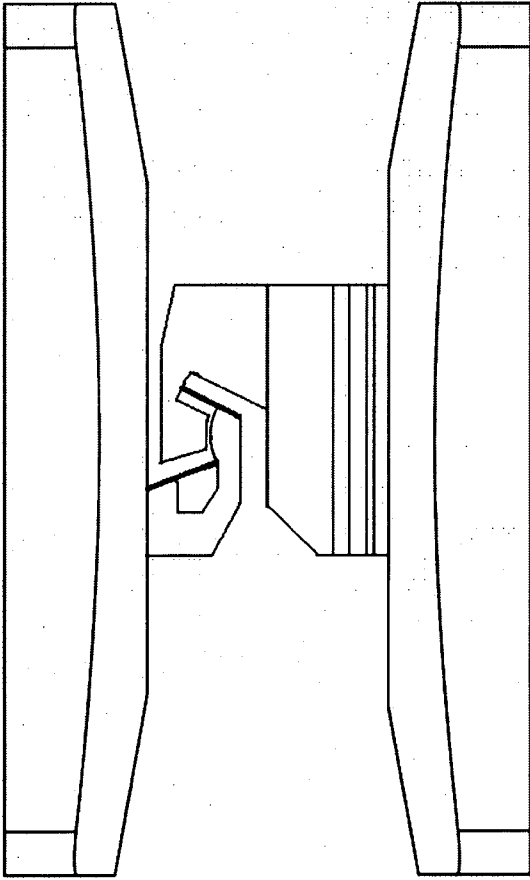
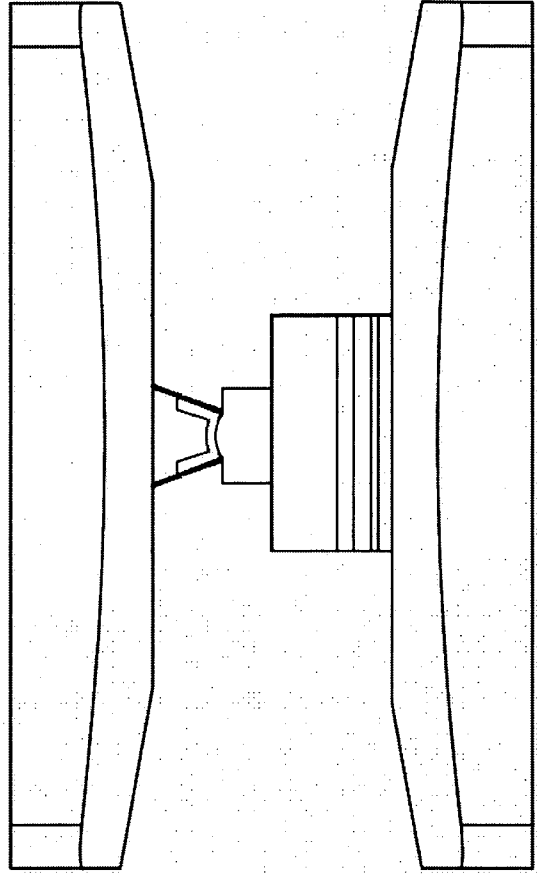


Fig. 40B



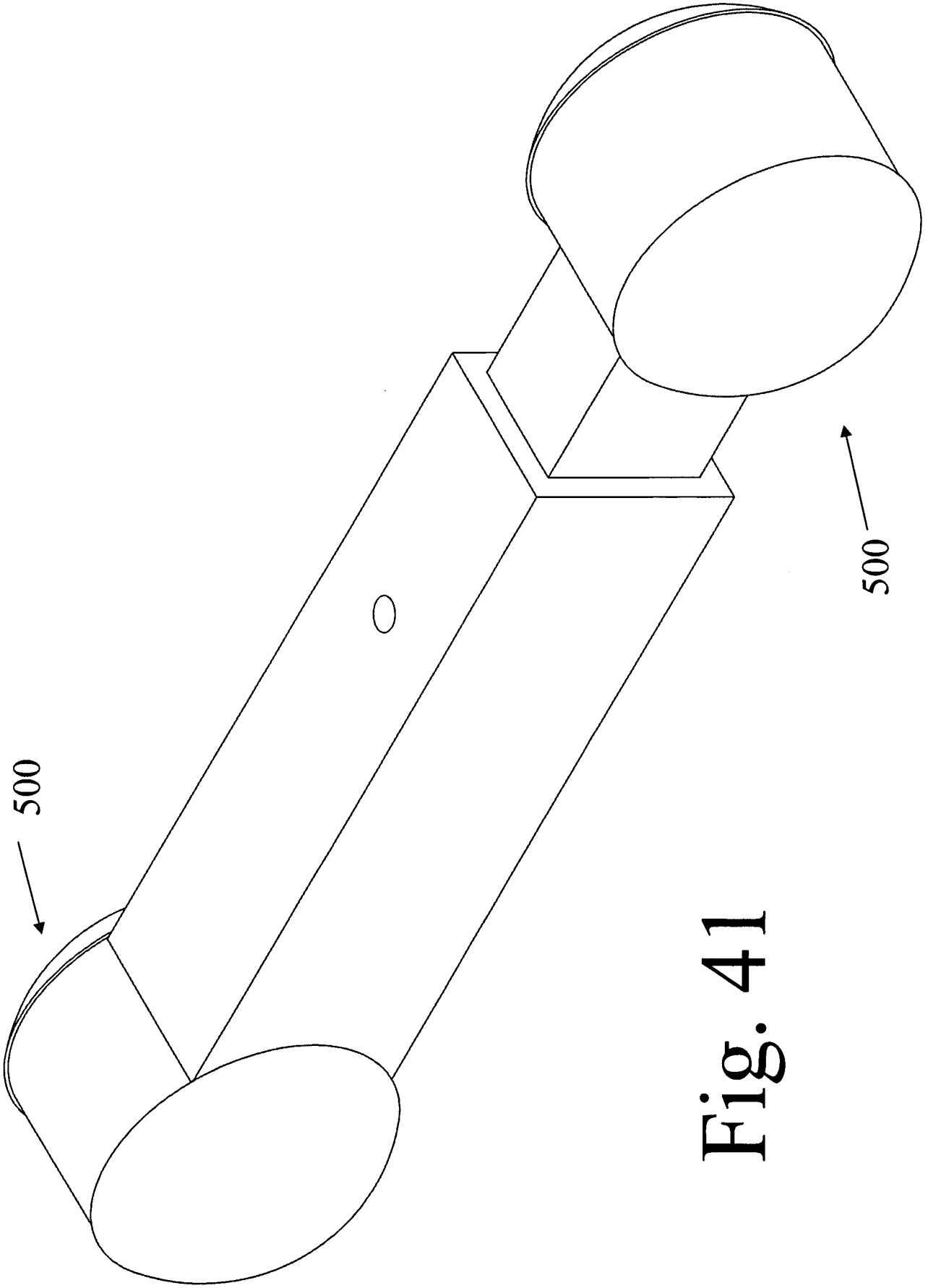


Fig. 41

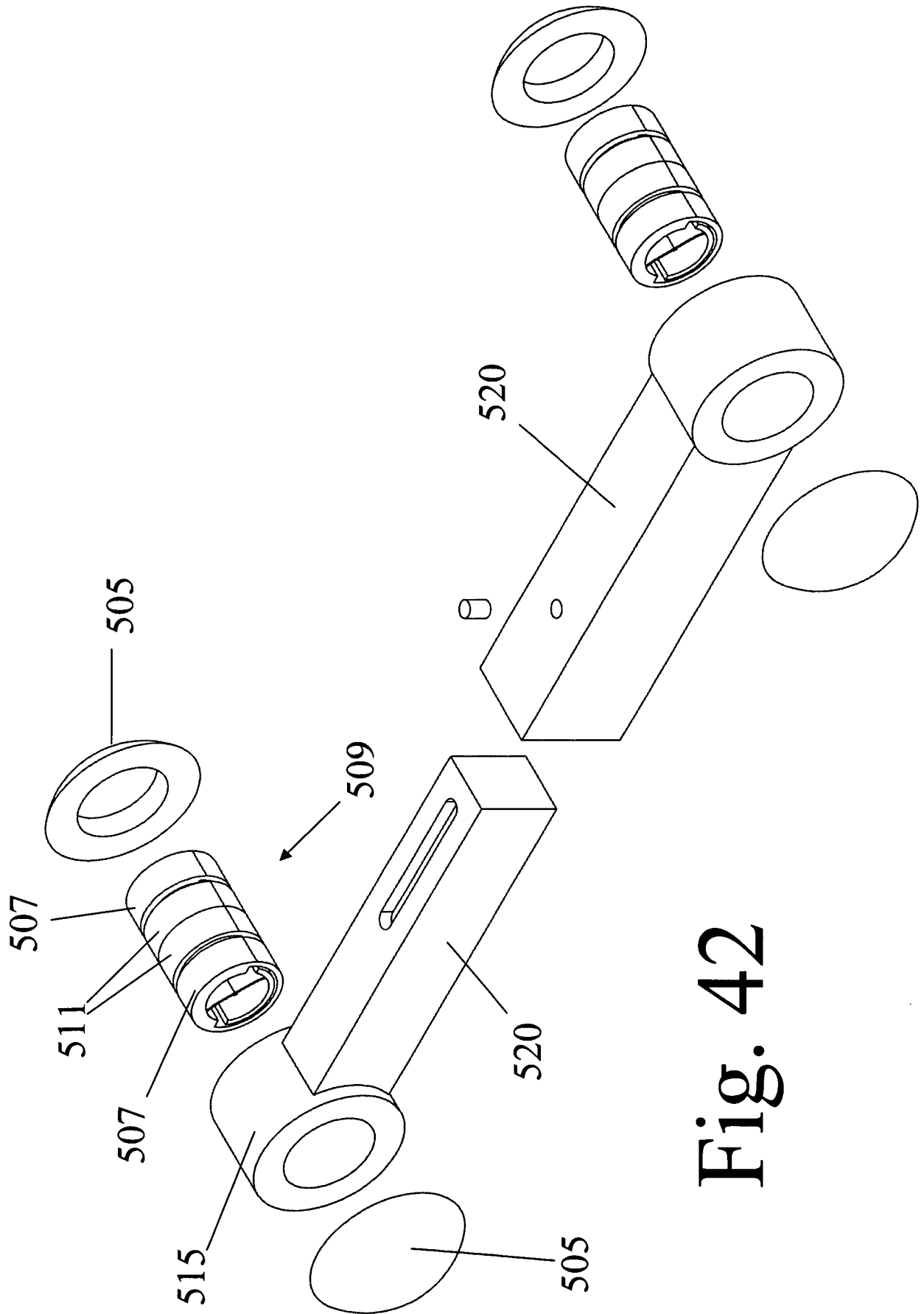
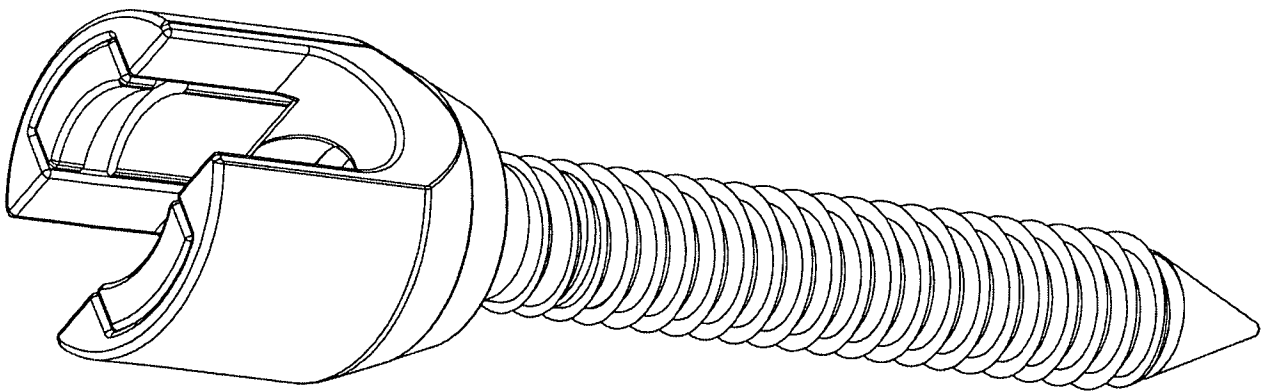
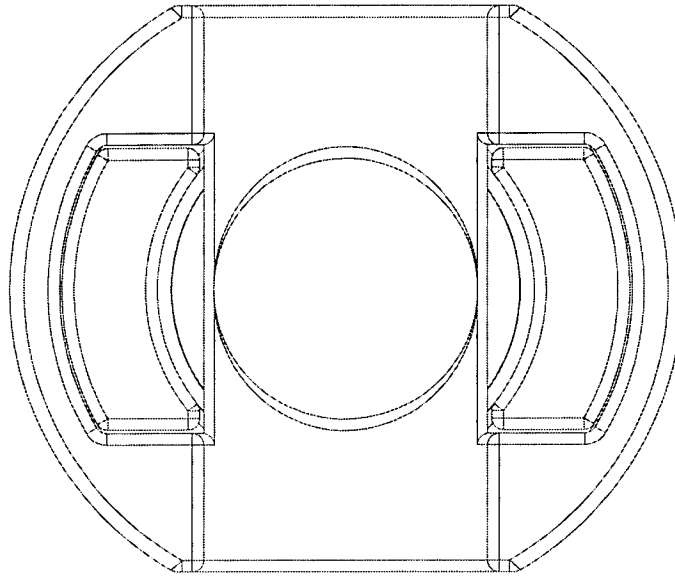


Fig. 42

Fig. 43



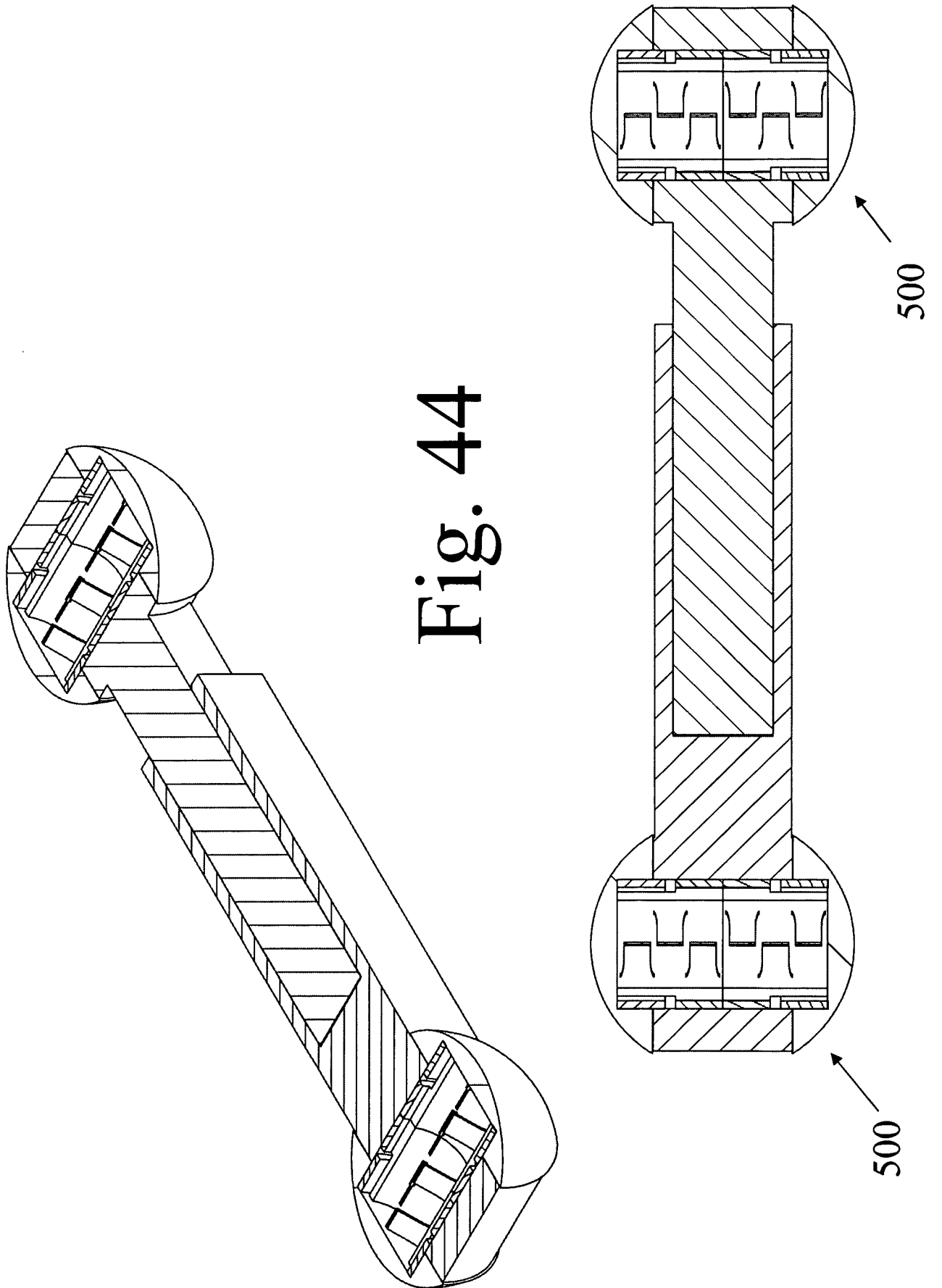


Fig. 44

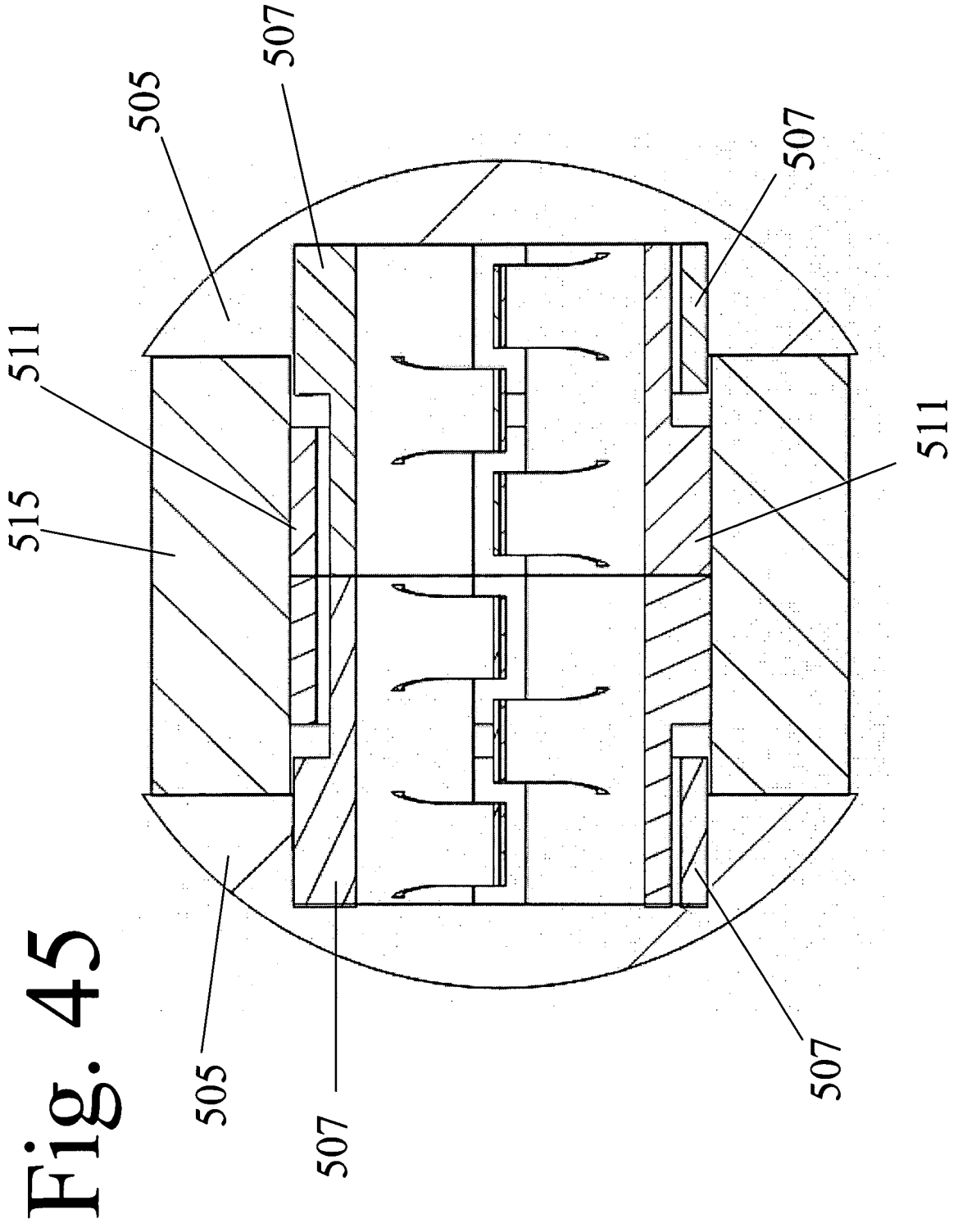


Fig. 45

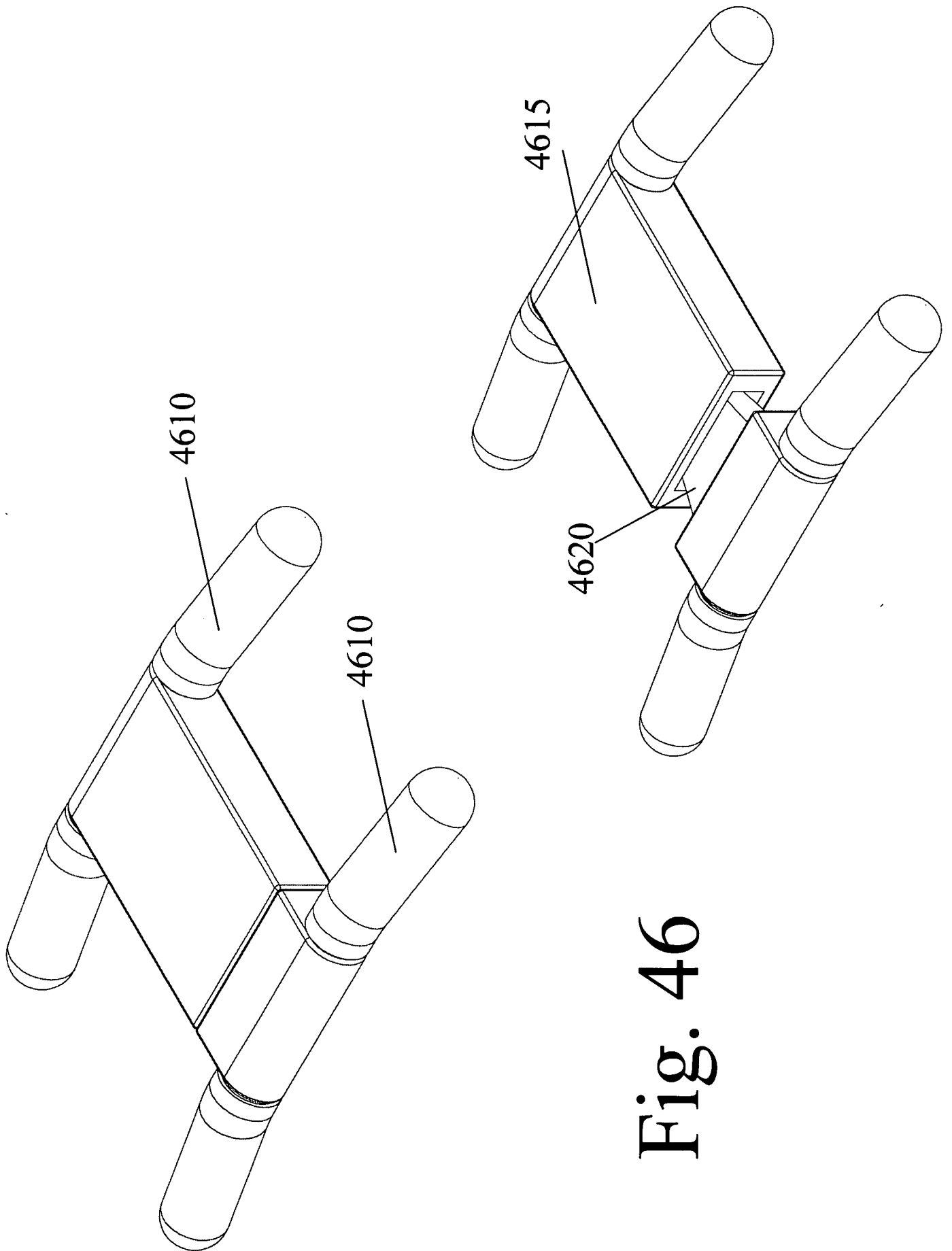


Fig. 46

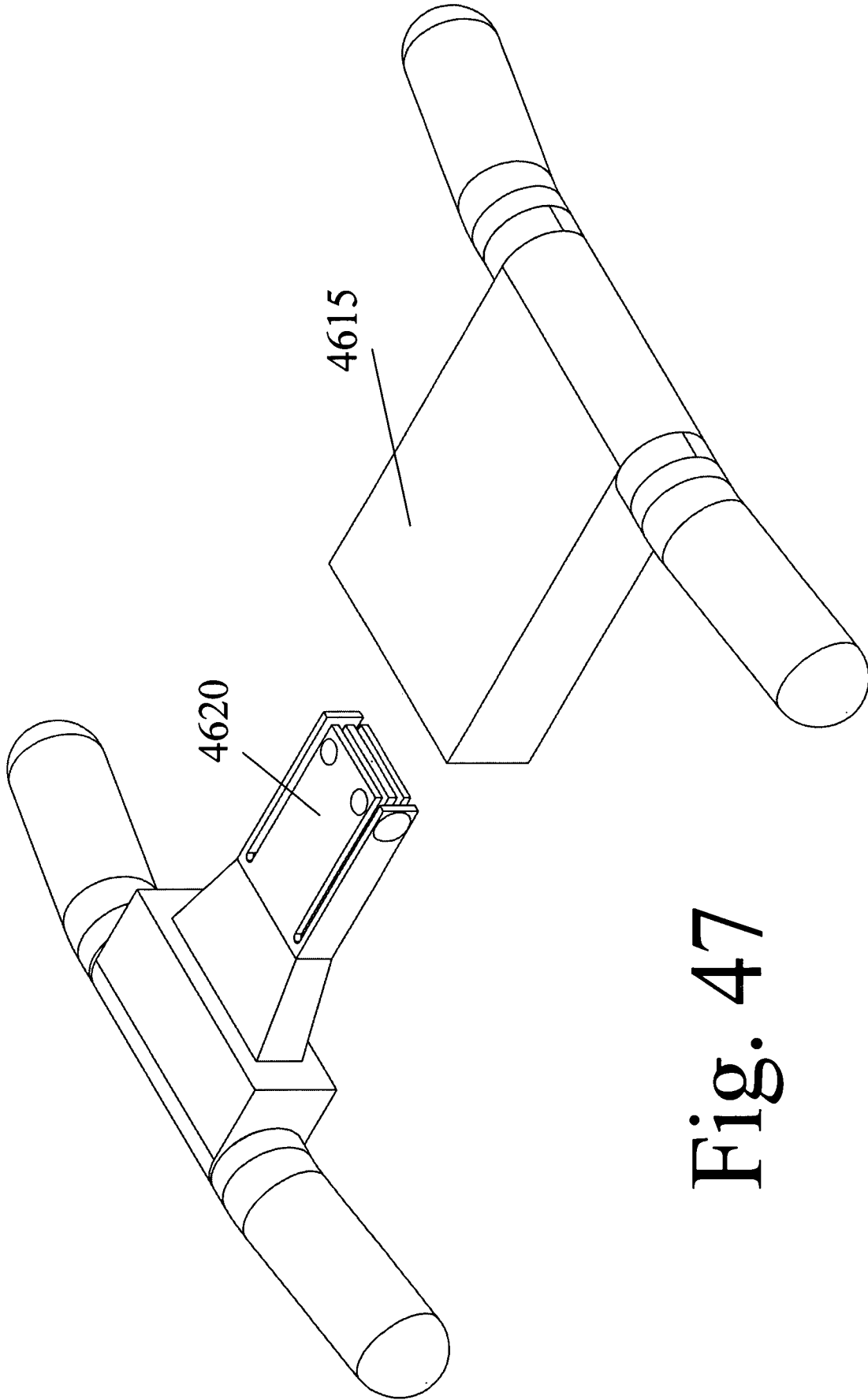


Fig. 47

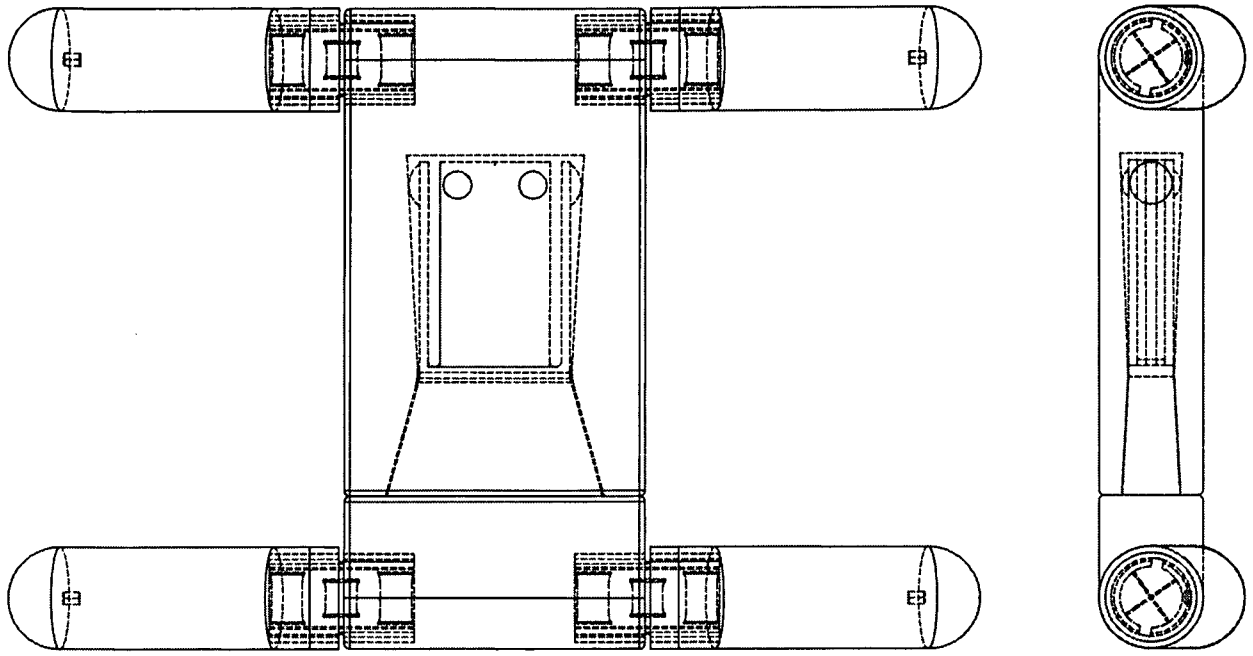
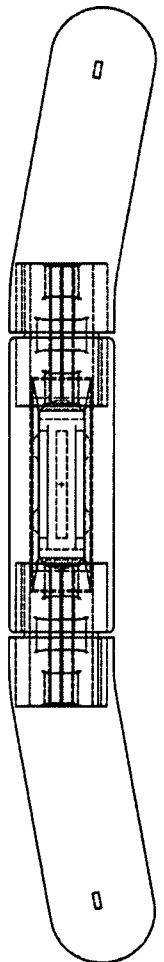


Fig. 48



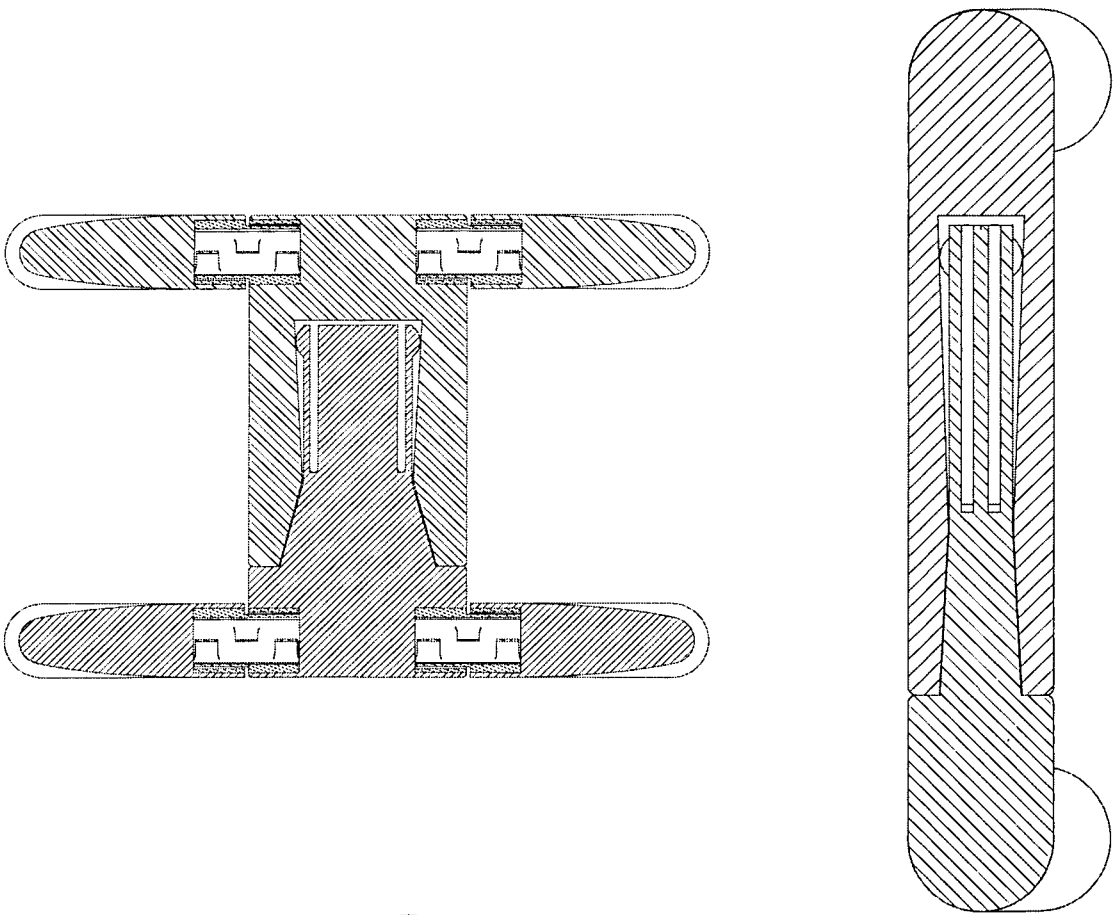


Fig. 49